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Original Research Article

Assessment of HbA1c as a Predictor of Severity in Diabetic Macular Edema

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Abstract:

Background: Diabetic macular edema (DME) is a major vision-threatening complication of diabetes mellitus and is closely linked to chronic hyperglycemia. Hemoglobin A1c (HbA1c) reflects long-term glycemic control and may influence the severity of DME.

Aim: To evaluate the correlation between HbA1c levels and the severity of DME in patients with type II diabetes mellitus.

Methodology: This prospective hospital-based cross-sectional study included 90 patients with type II diabetes and DME attending the Department of Ophthalmology, Anugrah Narayan Magadh Medical College, Gaya ji, Bihar. Comprehensive ocular examination and HbA1c estimation were performed. Patients were categorized into good (<7%), moderate (7–8%), and poor (>8%) glycemic control groups. Severity of DME was graded clinically. Statistical analysis was done using SPSS version 27.

Results: Most patients had poor glycemic control (42.3%). Moderate (37.8%) and severe DME (33.3%) were common. Severe DME predominated in patients with HbA1c >8% (21/38), while mild DME was more frequent in those with HbA1c <7% (14/22), demonstrating a positive graded correlation.

Conclusion: Higher HbA1c levels are significantly associated with increased severity of DME, highlighting the importance of strict glycemic control.

Keywords: Diabetes mellitus, HbA1c, Diabetic macular edema, Glycemic control, Retinopathy.

Introduction

Diabetes mellitus is a chronic metabolic disorder which causes permanent high blood sugar levels through two types of insulin-related problems which include both faulty insulin secretion and impaired insulin function [1]. The global diabetes epidemic has steadily increased over the last 30 years to become one of the most critical public health problems which affects people throughout the world. The International Diabetes Federation estimates that hundreds of millions of individuals are currently living with diabetes, with projections indicating a continued rise in prevalence, particularly in low- and middle-income countries such as India [2]. Prolonged high blood sugar levels result in permanent harm which causes different organs to lose their ability to function correctly, especially affecting the eyes and kidneys and nerves and heart and blood vessels. Diabetic retinopathy (DR) stands as the most frequent microvascular complication of diabetes which endangers vision and serves as the main reason for blindness which doctors can prevent in working-age adults all over the world.

Diabetic macular edema (DME) serves as the primary visual impairment from diabetic retinopathy while it remains the most common reason diabetic patients experience vision loss [3]. The condition can develop at any point during diabetic retinopathy because it involves extracellular fluid buildup in the macula which results from heightened vascular permeability. Edema leads to structural and functional damage in the macula which serves as the center for vision and precise visual activities. The development of DME occurs through multiple complex mechanisms which result from sustained high blood sugar levels that create both chemical and blood flow changes in the body. The human body responds to extended periods of high blood sugar levels by activating multiple metabolic systems which include the polyol pathway and protein kinase C activation

and the creation of advanced glycation end-products (AGE) and oxidative stress pathways [4]. The processes result in damage to retinal capillary endothelial cells and pericytes which causes the blood-retinal barrier to break down and blood vessels to become more permeable leading to fluid buildup in the macular area.

The medical field acknowledges glycemic control as a crucial factor which determines how diabetic microvascular complications develop and progress through time.[5] The glycemic control test Hemoglobin A1c (HbA1c) measures average plasma glucose levels from the previous two to three months through its measurement of glycation in hemoglobin proteins.[6] The test serves as the primary method to measure extended diabetes control which medical professionals use for both diabetes diagnosis and treatment evaluation. The landmark Diabetes Control and Complications Trial (DCCT) and UK Prospective Diabetes Study (UKPDS) showed through their large clinical studies that higher HbA1c levels increase the likelihood of patients developing diabetic retinopathy and other microvascular complications. The research demonstrated that intensive glycemic control establishes a direct link between optimal HbA1c maintenance and reduced DR progression while demonstrating that the disease will develop at a lower rate.

The existing research establishes a known link between HbA1c levels and diabetic retinopathy development, yet researchers continue to study how HbA1c levels relate to diabetic macular edema severity. Clinicians use fundoscopic examination to evaluate DME severity, but they need advanced imaging techniques, particularly optical coherence tomography (OCT), which delivers high-resolution retinal cross-sectional images and enables central macular thickness (CMT) measurement to achieve precise assessment of DME severity [7]. The biological mechanism supports the idea that elevated HbA1c levels, which indicate prolonged hyperglycemia, result in increased damage to the blood–retinal barrier and higher production of inflammatory substances like vascular endothelial growth factor (VEGF), which leads to worsened macular edema [8]. Clinical findings have shown varying results because the severity of DME depends on additional factors that include diabetes duration, blood pressure, lipid levels, renal function, and genetic predisposing factors.

The relationship between HbA1c levels and DME severity shows important value for clinical practice. If researchers find a strong positive correlation between HbA1c and ocular disease severity then HbA1c will function as both a body metabolic indicator and an eye disease severity prediction tool which helps doctors create personalized treatment plans for their patients. Patients with ongoing high HbA1c levels need to undergo more frequent eye tests because their condition requires early treatment to stop them from losing their vision. The research demonstrates how medical experts from multiple fields need to work together with endocrinologists and ophthalmologists and primary care physicians to deliver complete diabetes treatment.

Current therapeutic methods for DME treatment which use intravitreal anti-VEGF agents and corticosteroids and laser photocoagulation, focus primarily on treating the symptoms that occur in the eye. The treatment results will not reach their full potential until the patient achieves complete control over their blood sugar levels. The relationship between HbA1c levels and DME severity should be established because it will show whether patients who need ocular treatment will achieve better results through strict metabolic management".

Methodology

Study Design: This hospital-based observational cross-sectional study was conducted prospectively to evaluate the correlation between HbA1c levels and the severity of diabetic macular edema (DME) among patients with type II diabetes mellitus.

Study Area: The study was carried out in the Department of Ophthalmology, Anugrah Narayan Magadh Medical College, Gaya ji, Bihar, India.

Study Duration: The study was conducted over a period of 6 months from March 2025 to August 2025.

Study Participants: A total of 90 patients diagnosed with type II diabetes mellitus and diabetic macular edema attending the outpatient and inpatient services of the Department of Ophthalmology were included in the study after obtaining written informed consent.

Inclusion Criteria

- Patients aged 30 years and above diagnosed with type II diabetes mellitus.
- Patients diagnosed with diabetic macular edema on clinical and fundoscopic examination.
- Patients willing to provide written informed consent.
- Patients with documented HbA1c levels within the study period.

Exclusion Criteria

- Patients with type I diabetes mellitus.
- Patients with macular edema due to causes other than diabetes (e.g., retinal vein occlusion, uveitis).
- Patients with previous intraocular surgery (except uncomplicated cataract surgery within 6 months).
- Patients who had received prior intravitreal injections or laser photocoagulation for DME.

- Patients with significant media opacity interfering with fundus examination.
- Patients with systemic conditions affecting HbA1c interpretation (e.g., hemoglobinopathies, severe anemia).

Sample Size: The total sample size for the study was 90 patients fulfilling the inclusion criteria during the study period.

Procedure: written informed consent from the participants, detailed demographic data and medical history were recorded in a predesigned proforma. A comprehensive ocular examination was performed for all patients. Best corrected visual acuity (BCVA) was assessed using the Snellen chart for distance vision. Intraocular pressure was measured using Goldmann applanation tonometry. Slit lamp biomicroscopy was performed to evaluate the anterior segment.

Pupillary dilation was achieved using topical 2.5% phenylephrine and 0.5% tropicamide instilled at 10–15-minute intervals. Dilated fundus examination was conducted using indirect ophthalmoscopy with a 20D lens and slit lamp biomicroscopy with a +90D lens to assess the macular status. The severity of diabetic macular edema was graded based on clinical findings such as retinal thickening, presence of hard exudates, and involvement of the central macula.

For systemic evaluation, approximately 3 ml of venous blood was collected from each participant under aseptic precautions and sent to the central laboratory for estimation of HbA1c levels using standardized laboratory methods. Based on HbA1c levels, patients were categorized into three groups: good glycemic control (HbA1c <7%), moderate control (HbA1c 7–8%), and poor control (HbA1c >8%). All findings were systematically documented in a master chart to assess the relationship between glycemic control and the severity of diabetic macular edema.

Statistical Analysis: Data collected were entered into Microsoft Excel and subsequently analyzed using Statistical Package for the Social Sciences (SPSS) version 27.0. Descriptive statistics such as mean, standard deviation, frequency, and percentage were calculated for demographic and clinical variables. The correlation between HbA1c levels and severity of diabetic macular edema was assessed using Pearson's or Spearman's correlation coefficient as appropriate. The association between categorical variables was analyzed using the Chi-square test. A p-value of less than 0.05 was considered statistically significant".

Result

Table 1 shows the age distribution of the study participants (N = 90). The majority of participants belonged to the 51–60 years age group, comprising 28 individuals (31.10%), indicating that middle-aged to older adults formed the largest proportion of the study population. This was followed by the 41–50 years age group with 24 participants (26.70%). Participants aged more than 60 years accounted for 20 individuals (22.20%), while the 30–40 years age group had the lowest representation with 18 participants (20.00%). Overall, the data suggest that the study population was predominantly composed of individuals above 40 years of age, with a gradual increase in frequency from younger to middle age groups, followed by a slight decline in those above 60 years.

Table 1: Age Distribution of Study Participants (N = 90)

Age Group (Years)	Frequency (n)	Percentage (%)
30–40	18	20.00%
41–50	24	26.70%
51–60	28	31.10%
>60	20	22.20%
Total	**90**	**100%**

Table 2 shows the gender distribution of the 90 children included in the study. Out of the total sample, 52 participants (57.80%) were male, while 38 participants (42.20%) were female. This indicates a clear male predominance among the study population, with males constituting more than half of the total cases. The difference of 15.6% between male and female participants suggests that acute respiratory infections were observed more frequently in male children compared to female children in the present study sample. Overall, the table reflects an unequal gender distribution, with a higher proportion of male children affected.

Table 2: Gender Distribution (N = 90)

Gender	Frequency (n)	Percentage (%)
Male	52	57.80%
Female	38	42.20%
Total	**90**	**100%**

Table 3 shows the distribution of patients according to HbA1c levels among the total sample of 90 participants. The majority of patients, 38 (42.30%), had HbA1c levels greater than 8%, indicating poor glycemic control. This was followed by 30 patients (33.30%) who had HbA1c levels between 7–8%, reflecting moderate control. Only 22 patients (24.40%) achieved good glycemic control with HbA1c levels below 7%. Overall, the findings demonstrate that a substantial proportion of the study population had suboptimal glycemic control, with nearly three-fourths of the patients falling into the moderate to poor control categories, highlighting the need for improved diabetes management and monitoring strategies.

Table 3: Distribution of Patients According to HbA1c Levels (N = 90)		
HbA1c Category	**Frequency (n)**	**Percentage (%)**
<7% (Good Control)	22	24.40%
7–8% (Moderate Control)	30	33.30%
>8% (Poor Control)	38	42.30%
Total	**90**	**100%**

Table 4 shows the severity distribution of Diabetic Macular Edema (DME) among the 90 study participants. The majority of patients had moderate DME, accounting for 34 cases (37.80%), indicating that a considerable proportion of individuals presented at an intermediate stage of the disease. Severe DME was observed in 30 patients (33.30%), reflecting a substantial burden of advanced retinal involvement. Meanwhile, 26 patients (28.90%) were categorized as having mild DME. Overall, the findings suggest that more than two-thirds of the patients (71.10%) were in the moderate to severe stages, highlighting the need for timely screening and early intervention to prevent progression and vision-related complications among diabetic individuals.

Table 4: Severity of Diabetic Macular Edema (N = 90)		
Severity of DME	**Frequency (n)**	**Percentage (%)**
Mild	26	28.90%
Moderate	34	37.80%
Severe	30	33.30%
Total	**90**	**100%**

Table 5 shows the correlation between HbA1c levels and the severity of Diabetic Macular Edema (DME) among 90 patients. In the <7% HbA1c category (22 patients), the majority had mild DME (14 cases), followed by moderate (6 cases) and severe DME (2 cases), indicating better glycemic control was associated with milder disease. In the 7–8% category (30 patients), moderate DME was most common (15 cases), with 8 mild and 7 severe cases, suggesting a shift toward increased severity with rising HbA1c levels. In the >8% category (38 patients), severe DME predominated (21 cases), followed by moderate (13 cases) and mild (4 cases), demonstrating a strong association between poor glycemic control and increased severity of DME. Overall, the table indicates a clear positive correlation between higher HbA1c levels and greater severity of diabetic macular edema.

Table 5: Correlation Between HbA1c Levels and Severity of Diabetic Macular Edema (N = 90)				
HbA1c Category	**Mild DME**	**Moderate DME**	**Severe DME**	**Total**
<7%	14	6	2	22
7–8%	8	15	7	30
>8%	4	13	21	38
Total	**26**	**34**	**30**	**90**

Discussion

The worldwide health burden from diabetes mellitus maintains its status as a significant health problem because experts project an upcoming increase in its worldwide rate of occurrence (Wild et al., 2004) [9]. The two main microvascular complications that people suffer from are diabetic retinopathy and diabetic macular edema which both serve as the primary sources of visual impairment that affects working-age adults throughout the world (Yau et al., 2012) [10]. The researchers of this study conducted a specific examination of the relationship between HbA1c levels and DME severity because their results showed that insufficient glycemic management resulted in greater macular edema development".

The study found that most patients were in the 51 to 60 age group which made up 31.10 percent of the total sample while the 41 to 50 age group accounted for 26.70 percent and the average age matched findings from previous Indian and international

research. Singh et al. (2021) [11] reported similar age clustering which showed that most diabetic retinopathy patients fell between 51 and 65 years. Geany et al. (2022) [12] discovered that 51 to 60 age group represented the highest rate of occurrence. The research results show that DME develops as a result of prolonged type 2 diabetes which becomes medically important for people who are middle-aged and older. Yau et al. (2012) identified advancing age and extended diabetes duration as primary factors which increase the risk of developing sight-threatening retinopathy.

The current research found that male participants made up 57.80 percent of the study sample while female participants accounted for 42.20 percent of the study sample. Singh et al. (2021) found that 57.8 percent of their study participants were male, which matches the results obtained by Park et al. (2012) [13], who found that Korean males displayed higher prevalence rates. The studies showed different results because some studies found equal gender distribution or more women than men in the study samples, which indicated that gender differences in study results stemmed from social and cultural factors. The study results confirmed previous research findings, but different populations showed different patterns of gender distribution.

The study found that only 24.40% of patients achieved good glycemic control with their HbA1c results showing levels below 7% while 42.30% of patients exhibited poor control because their levels exceeded 8%. The distribution pattern matches the results of Singh et al. (2021) which showed that most patients with DR maintained HbA1c levels above 8%. The study by Cho et al. (2013) [14] showed a mean HbA1c value of 8.29 ± 1.71% with almost half the participants showing HbA1c levels above 8%. The evidence demonstrates that patients with retinal complications continue to experience problems with maintaining their blood sugar levels for extended periods of time.

Our study found that 37.80% of patients showed moderate DME whereas 33.30% showed severe DME which resulted in over two-thirds of patients 71.10% showing moderate to severe disease. The late-stage presentation matches Chou et al. (2009) [15] findings which showed that higher HbA1c levels caused a notable link to clinically significant macular edema (CSME). Do et al. (2005) [16] found that patients with ongoing DME showed higher HbA1c levels at diagnosis than patients whose edema disappeared. The studies demonstrate that poor metabolic control leads to both the development and the ongoing severe state of macular edema.

The most significant finding of the present study was the graded relationship between HbA1c categories and DME severity. Among patients with HbA1c <7%, the majority (14 out of 22) had mild DME, and only 2 cases had severe DME. In contrast, in the >8% HbA1c group, severe DME predominated (21 out of 38 cases), while only 4 cases had mild disease. The intermediate 7–8% group showed a transitional pattern, with moderate DME being most common (15 cases). This clear shift from mild to severe DME with increasing HbA1c strongly indicates a dose-response relationship.

Other research studies which investigated retinopathy severity found similar trends which this study established as evidence. Singh et al. (2021) demonstrated a statistically significant association between higher HbA1c and more advanced stages of retinopathy ($p<0.05$). Cho et al. (2013) found an optimal HbA1c cutoff for diabetic retinopathy detection which showed that risk increased progressively beyond this threshold. Although their study addressed DR broadly rather than DME specifically the underlying pathophysiological mechanism (chronic hyperglycemia leading to capillary leakage and increased vascular permeability) remains common to both conditions.

Chou et al. (2009) showed that patients with HbA1c levels above 8.6% had more common cases of clinically significant macular edema, which matches our research showing that most severe DME cases occurred in the >8% category. Do et al. (2005) discovered that people with persistent DME showed higher HbA1c levels, and those with more advanced cases of the condition experienced bilateral involvement. The results of the present study match with the previous research findings because they show that ongoing glycemic control protects against disease progression.

Research indicates that although HbA1c functions as a strong predictor of DME severity diabetes duration together with hypertension and dyslipidemia create their own separate effects on DME progression (Park et al. 2012 Yau et al. 2012). The presence of multiple causes for DME development shows that HbA1c serves as the main factor in this situation. The major epidemiological studies still show that HbA1c remains one of the strongest risk factors which researchers can modify after they examine these factors.

The progressive increase in DME severity from HbA1c <7% to >8% shows the same pattern which Cho et al. (2013), Singh et al. (2021), Chou et al. (2009), and Do et al. (2005) observe. The evidence collectively supports the conclusion that chronic hyperglycemia, as reflected by elevated HbA1c, directly correlates with worsening macular pathology.

The fundamental method for stopping diabetic macular edema from starting and existing cases from getting worse requires strict glycemic control to be maintained as the primary method of treatment. The research provides additional validation to existing evidence because it shows a direct relationship

between different levels of HbA1c and their impact on performance. The identification of patients who have an HbA1c level exceeding 7% especially those who exceed 8% enables medical professionals to conduct urgent ophthalmic assessments which work to prevent serious vision issues.

Conclusion

The present study demonstrates a clear and positive correlation between HbA1c levels and the severity of diabetic macular edema among patients with type II diabetes mellitus. The majority of patients had moderate to poor glycemic control, and a progressive increase in DME severity was observed with rising HbA1c levels. Patients with HbA1c <7% predominantly exhibited mild DME, whereas those with HbA1c >8% showed a higher proportion of severe DME, indicating a dose–response relationship between chronic hyperglycemia and macular involvement. These findings emphasize that inadequate long-term glycemic control significantly contributes to worsening retinal pathology. Therefore, maintaining optimal HbA1c levels through strict metabolic control, regular monitoring, and interdisciplinary management is essential to prevent progression of DME and reduce the risk of vision-threatening complications in diabetic patients.

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