



Research Article

Association of Diabetic Retinopathy Severity with Glycated Haemoglobin and Serum Triglycerides in Patients with Type 2 Diabetes Mellitus: A Cross-Sectional Observational Study from South India

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Abstract: Background: Diabetic Retinopathy (DR) is a major microvascular complication of Type 2 Diabetes Mellitus (T2DM), with poor glycaemic control and dyslipidaemia being important potentially modifiable risk factors. However, the association between serum triglycerides and the severity of DR remains inconsistent across populations. This study evaluated the association of glycated haemoglobin (HbA1c) and serum triglyceride levels with DR severity among patients with T2DM in a South Indian tertiary-care setting. **Methods:** A cross-sectional observational study was conducted at the Karnataka Institute of Endocrinology and Research, Bengaluru, India. Adults aged >18 years with confirmed T2DM were included. Patients with type 1 diabetes mellitus and retinal diseases other than diabetic retinopathy were excluded. All participants underwent ophthalmic examination and DR was graded according to the International Clinical Diabetic Retinopathy Severity Scale. HbA1c, serum triglycerides, HDL, LDL, total cholesterol, fasting and postprandial blood glucose, serum creatinine, blood urea, vitamin D and TSH were measured. Participants were categorised according to HbA1c and triglyceride levels. Associations between categorical variables were assessed. **Results:** A total of 344 patients with T2DM were included. Diabetic retinopathy was present in 105 (30.5%) participants, comprising mild NPDR in 52 (15.1%), moderate NPDR in 29 (8.4%), severe NPDR in 15 (4.4%) and PDR in 9 (2.6%). HbA1c showed a significant association with DR severity ($p < 0.001$); severe NPDR and PDR occurred only among participants with HbA1c >8.0%. The association between triglyceride category and DR was not statistically significant ($\chi^2 = 10.933$, $p = 0.206$), although the proportion without DR decreased across increasing triglyceride categories. Fasting and postprandial blood glucose, LDL cholesterol and total cholesterol differed significantly across DR severity groups. **Conclusion:** This study showed that poor glycaemic control was strongly associated with increasing severity of diabetic retinopathy. Serum triglyceride categories showed a non-significant trend towards greater DR frequency.

Keywords: Diabetic Retinopathy, Type 2 Diabetes Mellitus, HbA1c, Triglycerides, Dyslipidaemia

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INTRODUCTION

Diabetes has become one of the most pressing health problems of our time. The International Diabetes Federation estimated that about 537 million adults worldwide were living with the condition in 2021 [1]. India carries a heavy share of this burden and the ICMR-INDIAB study put the overall prevalence at 7.3% across 15 states [2].

Diabetic Retinopathy (DR) is one of the most feared complications of diabetes. A recent meta-analysis estimated its global prevalence among people with diabetes at 22.3%, with about 6.2% having vision-threatening disease [3]. In the Chennai Urban Rural Epidemiology Study, 17.6% of the diabetic population had retinopathy [4]. Because DR often causes no symptoms until damage is advanced, it remains a leading cause of preventable sight loss in working-age adults [3].

Which patients are most at risk of progression is a question we face. Duration of diabetes, poor glycaemic control and hyperlipidaemia are consistently reported as the main systemic risk factors [5]. The role of glycaemia is best supported, the Diabetes Control and Complications Trial and UKPDS 33 both showed that tighter glucose control lowers the risk of diabetic retinopathy. Glycated haemoglobin (HbA1c) is an established marker of long-term glycaemic control and is widely used in clinical practice to assess glycaemic exposure over the preceding two to three months [6,7].

Evidence regarding serum triglycerides and DR has also been inconsistent. An earlier meta-analysis of observational studies did not demonstrate a statistically significant difference in triglyceride concentrations between patients with and without DR. [8] In contrast, a more recent systematic review and meta-analysis restricted to patients with T2DM found that higher baseline triglyceride concentrations were associated with subsequent development of DR across 13 cohort studies involving 7459 participants [9]. These apparently differing findings highlight the importance of evaluating lipid abnormalities within specific populations and clinical settings rather than assuming a uniform association.

Therefore, the present hospital-based study was undertaken to evaluate the association of HbA1c and serum triglyceride levels with the severity of diabetic retinopathy among patients with T2DM in a South Indian population.

MATERIALS AND METHODS

Study Design and Setting

A cross-sectional observational study was conducted at the Karnataka Institute of Endocrinology and Research, Bengaluru, India.

Study Population

We included all patients aged above 18 years with a confirmed diagnosis of type 2 diabetes mellitus. We excluded patients younger than 18 years, those with type 1 diabetes and those with any retinal disease other than diabetic retinopathy. A physician examined every patient to rule out other systemic disease.

Study Procedure

Every patient had a full eye examination. This covered a detailed history, best-corrected visual acuity, slit-lamp examination, indirect ophthalmoscopy and slit-lamp biomicroscopy with a +90D lens. Retinopathy was graded as mild NPDR, moderate NPDR, severe NPDR or Proliferative Diabetic Retinopathy (PDR), following the International Clinical Diabetic Retinopathy Severity Scale [10].

Laboratory investigations like HbA1c, triglycerides, HDL, Total Cholesterol, FBS, PPBS, Blood urea, Serum Creatine, Vitamin -D and TSH were measured. For analysis, patients were grouped by HbA1c into <6.5%, 6.5-8.0% and >8.0%. They were grouped by serum triglycerides into <150 mg/dL, 150-199 mg/dL and ≥200 mg/dL.

Sample Size Calculation

The required sample size was calculated using the single-proportion formula for a cross-sectional study:

$$n = \frac{Z_{\alpha/2}^2 p(1-p)}{d^2}$$

where, $Z_{\alpha/2} = 1.96$ for a 95% confidence level, p is the anticipated prevalence of diabetic retinopathy and d is the desired absolute precision. Based on the previously reported prevalence of diabetic retinopathy of 17.6% in the Chennai Urban Rural Epidemiology Study (CURES) Eye Study, [4] $p = 0.176$ and $1-p = 0.824$ were used. With an absolute precision of 5%, the minimum sample size was approximately 224 participants. A total of 344 eligible participants were ultimately included in the study.

Data Analysis

Data were analysed using appropriate descriptive and inferential statistical methods. Categorical variables were summarised as frequencies and percentages. Continuous variables were assessed for distribution and are presented as median with Interquartile Range (IQR), where appropriate. The Pearson chi-square test was used to assess associations between categorical variables, including the association of HbA1c and triglyceride categories with diabetic retinopathy severity. The Kruskal-Wallis test was used to compare biochemical parameters.

Ethical Considerations

The study was conducted after obtaining approval from the Institutional Ethics Committee and written informed consent was obtained from all participants before enrolment.

RESULTS

Demographic Characteristics of the Study Participants

A total of 344 patients with type 2 diabetes mellitus were included in the study. Men were slightly more numerous than women (55.8% Vs 44.2%). Most participants were middle-aged: 78.2% were between 41 and 70 years, the 51-60-year group was the largest (36.3%) and only 3.2% were aged 18-30 years. Nearly two-thirds were overweight (64.0%), about one-third had a normal BMI (34.3%) and underweight and obese patients accounted for 0.9% each. Retinopathy was present in 105 patients (30.5%): mild NPDR in 15.1%, moderate NPDR in 8.4%, severe NPDR in 4.4% and PDR in 2.6%. The remaining 239 patients (69.5%) had no DR. Glycaemic control was poor in almost half the cohort (HbA1c >8.0%, 49.4%), while 22.7% had HbA1c <6.5%. Triglycerides were ≤150 mg/dL in 59.6%, 151-199 mg/dL in 23.0% and ≥200 mg/dL in 17.4%. Depicted in Table 1.

Association between HbA1c and Diabetic Retinopathy

HbA1c showed a strong association with DR. In the group with HbA1c below 6.5%, 97.4% of patients had no DR. This fell to 80.2% in the 6.5-8.0% group and 50.6% in the group above 8.0%. Severe NPDR (8.8%) and PDR (5.3%) occurred only in patients with HbA1c above 8.0%. The association was statistically significant ($\chi^2 = 75.462$, $p < 0.001$) as depicted in Table 2.

Association between Triglyceride (TGL) and Diabetic Retinopathy

The proportion of patients without DR decreased as triglyceride levels rose: 73.7% for levels below 150 mg/dL, 64.6% for 150-199 mg/dL and 61.7% for levels above 200 mg/dL. Even so, the association between triglyceride category and DR was not statistically significant ($\chi^2 = 10.933$, $p = 0.206$) as shown in Table 3.

Association Demographic Variables with Diabetic Retinopathy

Women made up 44.2% of the cohort but 60.0% of severe NPDR and 66.7% of PDR cases, while men predominated in mild (69.2%) and moderate NPDR (69.0%). Regarding age, none of the 11 patients aged 18-30 years had DR and 4 of the 9 PDR cases (44.4%) were aged 71-85 years, a group that formed only 7.8% of the sample. Sex ($p = 0.042$) and age group ($p = 0.023$) were significantly associated with DR severity, whereas BMI category was not ($p = 0.934$) as shown in Table 4.

Table 1: Demographic characteristics of the Study Participants

Demographic variable	Frequency (n)	Percentage	p-value
Sex			
Female	152	44.2	p = 0.031
Male	192	55.8	
Total	344	100.0	
Age Group (years)			
18-30	11	3.2	p<0.001
31-40	37	10.8	
41-50	73	21.2	
51-60	125	36.3	
61-70	71	20.6	
71-85	27	7.8	
Total	344	100.0	
BMI Category			
Underweight	3	0.9	p<0.001
Normal	118	34.3	
Overweight	220	64.0	
Obese	3	0.9	
Total	344	100.0	
Diabetic Retinopathy (DR) Severity			
No DR	239	69.5	p<0.001
Mild NPDR	52	15.1	
Moderate NPDR	29	8.4	
Severe NPDR	15	4.4	
PDR	9	2.6	
Total	344	100.0	
HbA1c Category			
<6.5	78	22.7	p<0.001
6.5-8.0	96	27.9	
>8.0	170	49.4	
Total	344	100.0	
Triglyceride (TGL) Category (mg/dL)			
< = 150	205	59.6	p<0.001
151-199	79	23.0	
> = 200	60	17.4	
Total	344	100.0	

p-values are from the chi-square goodness-of-fit test. DR = Diabetic Retinopathy, NPDR = Non-Proliferative DR, PDR = Proliferative DR

Table 2: Association between HbA1c Category and Diagnosis of Diabetic Retinopathy

HbA1c Category	MILD NPDR	MOD NPDR	NO DR	PDR	SEVERE NPDR	Total	Chi-Square (χ^2)	p-value
<6.5	1 (1.28%)	1 (1.28%)	76 (97.44%)	0 (0.00%)	0 (0.00%)	78 (100.00%)	75.462	<0.001
6.5-8.0	17 (17.71%)	2 (2.08%)	77 (80.21%)	0 (0.00%)	0 (0.00%)	96 (100.00%)		
>8.0	34 (20.00%)	26 (15.29%)	86 (50.59%)	9 (5.29%)	15 (8.82%)	170 (100.00%)		
Total	52 (15.12%)	29 (8.43%)	239 (69.48%)	9 (2.62%)	15 (4.36%)	344 (100.00%)		

Table 3: Association between Triglyceride (TGL) Category and Diagnosis of Diabetic Retinopathy

TGL Category (mg/dL)	MILD NPDR	MOD NPDR	NO DR	PDR	SEVERE NPDR	Total	Chi-Square (χ^2)	p-value
<150 mg/dL	29 (14.15%)	15 (7.32%)	151 (73.66%)	5 (2.44%)	5 (2.44%)	205 (100.00%)	10.933	0.206
150-199	12 (15.19%)	7 (8.86%)	51 (64.56%)	4 (5.06%)	5 (6.33%)	79 (100.00%)		
>200	11 (18.33%)	7 (11.67%)	37 (61.67%)	0 (0.00%)	5 (8.33%)	60 (100.00%)		
Total	52 (15.12%)	29 (8.43%)	239 (69.48%)	9 (2.62%)	15 (4.36%)	344 (100.00%)		

Table 4: Association of other Demographic Variables with Diabetic Retinopathy Severity

Characteristic	Total (n = 344)	No DR (n = 239)	Mild NPDR (n = 52)	Moderate NPDR (n = 29)	Severe NPDR (n = 15)	PDR (n = 9)	Chi-square (χ^2)	p-value
Sex							9.88	0.042 *
Female	152 (44.2)	112 (46.9)	16 (30.8)	9 (31.0)	9 (60.0)	6 (66.7)		
Male	192 (55.8)	127 (53.1)	36 (69.2)	20 (69.0)	6 (40.0)	3 (33.3)		
Age group (years)							34.4	0.023 *
18-30	11 (3.2)	11 (4.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
31-40	37 (10.8)	28 (11.7)	3 (5.8)	3 (10.3)	3 (20.0)	0 (0.0)		
41-50	73 (21.2)	52 (21.8)	12 (23.1)	6 (20.7)	3 (20.0)	0 (0.0)		
51-60	125 (36.3)	83 (34.7)	21 (40.4)	15 (51.7)	4 (26.7)	2 (22.2)		
61-70	71 (20.6)	47 (19.7)	13 (25.0)	3 (10.3)	5 (33.3)	3 (33.3)		
71-85	27 (7.8)	18 (7.5)	3 (5.8)	2 (6.9)	0 (0.0)	4 (44.4)		
BMI category							5.61	0.934
Underweight	3 (0.9)	3 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Normal	118 (34.3)	84 (35.1)	17 (32.7)	12 (41.4)	3 (20.0)	2 (22.2)		
Overweight	220 (64.0)	149 (62.3)	35 (67.3)	17 (58.6)	12 (80.0)	7 (77.8)		
Obese	3 (0.9)	3 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		

P-values are from the Pearson chi-square test comparing the distribution across the five DR groups

Table 5: Comparison of Biochemical Parameters across Diabetic Retinopathy Severity Groups

Biochemical Parameter	No DR (n = 239) Median (IQR)	Mild DR (n = 52) Median (IQR)	Mod DR (n = 29) Median (IQR)	Sev DR (n = 15) Median (IQR)	PDR (n = 9) Median (IQR)	Kruskal-Wallis H	p-value
FBS (mg/dL)	125.00 (104.00-163.00)	166.00 (128.00-208.00)	170.00 (140.50-214.00)	205.00 (167.00-285.00)	227.00 (116.00-307.50)	44.560	<0.001
PPBS (mg/dL)	201.00 (146.00-278.00)	266.50 (204.25-324.50)	283.00 (241.00-343.00)	338.00 (289.00-395.00)	366.00 (229.50-472.00)	52.491	<0.001
HDL (mg/dL)	38.20 (32.90-44.90)	37.20 (33.00-43.85)	35.40 (32.40-43.85)	33.70 (31.00-35.00)	40.10 (32.15-45.50)	5.312	0.257
LDL (mg/dL)	110.00 (87.00-138.00)	87.50 (67.75-105.50)	125.00 (100.00-159.00)	124.00 (100.00-149.00)	104.00 (71.50-110.00)	24.325	<0.001
Blood urea (mg/dL)	24.00 (19.00-32.00)	24.00 (19.00-33.00)	26.00 (19.00-36.50)	35.00 (22.00-39.00)	30.00 (22.00-45.50)	5.856	0.210
Serum Creatine (mg/dL)	0.80 (0.70-0.90)	0.80 (0.70-1.00)	0.90 (0.80-1.10)	0.80 (0.70-1.00)	1.00 (0.70-1.20)	11.063	0.026
Vitamin -D (ng/mL)	12.77 (8.71-18.95)	10.88 (7.66-19.02)	9.15 (6.34-17.19)	9.06 (7.00-19.68)	8.81 (6.69-15.98)	6.530	0.163
TSH (μ U/mL)	2.26 (1.50-3.73)	3.26 (1.54-4.85)	2.50 (1.40-3.81)	2.55 (1.70-4.44)	3.24 (2.30-3.80)	4.829	0.305
Total Cholesterol	183 (152-210)	150 (130.50-190)	187 (170-215)	187 (172-219)	169 (127-189.5)	18.635	0.001

Kruskal-Wallis's test is used to find the p-value

Comparison of Biochemical Parameters and Diabetic Retinopathy

Glycaemic indices rose steadily with DR severity. Median FBS increased from 125 mg/dL (no DR) to 227 mg/dL (PDR; $H = 44.560$, $p < 0.001$) and median PPBS from 201 to 366 mg/dL ($H = 52.491$, $p < 0.001$). LDL cholesterol ($p < 0.001$) and total cholesterol ($p = 0.001$) also differed across groups, but not in a stepwise way: both were lowest in mild NPDR (LDL 87.5 mg/dL; total cholesterol 150 mg/dL) and higher in the moderate and severe groups. Serum creatinine differed marginally ($p = 0.026$), with medians of 0.8 to 1.0 mg/dL across groups. HDL cholesterol ($p = 0.257$), blood urea ($p = 0.210$), vitamin D ($p = 0.163$) and TSH ($p = 0.305$) showed no significant differences as shown in Table 5.

DISCUSSION

In this study of 344 adults with T2DM, 30.5% had retinopathy and 7.0% had severe NPDR or PDR. This is higher than the global estimates of 22.3 and 6.2% [3] and the 17.6% reported by Rema *et al.* [4] and below the overall prevalence reported by Yau *et al.* [11] as this study was conducted in tertiary endocrinology setting, which draws patients with longer-standing and less controlled disease, probably explains this. Nearly half of our patients had HbA1c above 8.0%. The main finding of this study was statistically significant, graded relationship between HbA1c and DR severity. With no statistically significant association for serum triglycerides and DR.

This study findings align with findings of other studies. The DCCT and UKPDS 33 studies showed that intensive glucose control lowers retinopathy risk [6,7] and UKPDS 50 identified HbA1c as a good predictor of both incidence and progression [12]. A study by Pradeepa *et al.* (CURES) in South India, found that duration of diabetes, HbA1c, male gender, macroalbuminuria and insulin therapy were independent risk factors for DR severity [13]. In the ACCORD Eye trial, intensive glycaemic control and combination lipid therapy with fenofibrate and simvastatin reduced retinopathy progression [14]. This study showed risk is more at high HbA1c in our data: Severe NPDR and PDR occurred only in patients above 8.0%. The rise in fasting and postprandial glucose across DR grades (Table 5) supports the same conclusion. Sustained hyperglycaemia damages the retinal microvasculature, HbA1c reflects only the preceding two to three months, while retinopathy reflects cumulative exposure and is also influenced by glycaemic variability, so HbA1c should be seen as a convenient marker and not a complete measure of risk [15,16].

This study showed DR frequency increased across triglyceride categories, but the overall association was not statistically significant. This is conflicting meta-analysis by Zhou *et al.* [8] which found no difference in triglycerides between patients with and without DR while in other study found that higher baseline triglycerides predicted incident of DR. [9] In a study by Rema *et al.* [17] reported that triglycerides remained significantly associated with DR after adjustment for HbA1c and BMI and a multinational case-control study by Sacks *et al.* [18] linked plasma triglycerides and HDL cholesterol retinopathy. Trials of fenofibrate also suggest that fenofibrate slows progression of DR [14,19].

In this study LDL and total cholesterol differed across groups but did not rise progressively with severity of DR; they were lowest in mild NPDR. Possible explanation for this is treatment effect: Patients already known to have retinopathy may have been started on statins, which would lower LDL and total cholesterol in the retinopathy groups. In contrast study by Rema *et al.* [17] and Chew *et al.* [20] showed that raised serum lipids linked with severity of DR.

In this study age and sex showed statistically significant but modest associations with DR. DR was absent in patients aged 18-30 and PDR frequent in those aged 71 and older, but the age pattern was not linear and age probably acts as a proxy for duration of diabetes, a well-established determinant of retinopathy [13,21]. In this study women were more effected with severe NPDR and PDR. This finding is inconsistent with CURES study which identified male sex as an independent risk factor [13].

Among the other biochemical markers accessed in this study, serum creatinine showed statistically significant association with DR grades, but the clinical significance is small. Retinopathy and diabetic kidney disease share microvascular mechanisms that can explain the possible reason for association in this study [15]. Vitamin D tended to be lower with increasing severity, but the difference was not significant. Whereas a meta-analysis by Luo *et al.* [22] found vitamin D deficiency associated with higher DR risk in T2DM. This study did not show association between TSH and DR, but a study by Yang *et al.* [23] concluded that subclinical hypothyroidism has been linked with sight-threatening DR.

Limitations

This study has some limitations. Its cross-sectional design shows association but not cause and effect and data from a single tertiary centre may not represent all patients with diabetes. We also did not analyse duration of diabetes, blood pressure, albuminuria, or the use of statins, fibrates and insulin, all of which could have influenced our findings.

CONCLUSION

DR severity was significantly and progressively associated with HbA1c and advanced DR occurred only at HbA1c above 8.0%. Triglyceride levels showed a non-significant upward trend which needs evaluation in larger studies. Our findings highlight the importance of keeping blood sugar well controlled from an early stage and of regular eye screening for all patients with type 2 diabetes.

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