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Original Article

A Study on Prevalence, Severity, And Risk Factors of Diabetic Retinopathy (DR) And Diabetic Macular Edema (DME) In Patients with Type 2 Diabetes Mellitus (T2DM)

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ABSTRACT

Purpose: To determine the prevalence, severity, and risk factors of diabetic retinopathy (DR) and diabetic macular edema (DME) in patients with type 2 diabetes mellitus (T2DM).
Methods: A prospective observational study including 40 patients with T2DM. Ophthalmic evaluation included visual acuity, slit-lamp examination, dilated fundus examination, and fundus photography. DR was graded using ETDRS criteria. DME was assessed clinically and/or by OCT. Systemic variables (duration of diabetes, HbA1c, hypertension, dyslipidemia) were recorded. Associations were tested using Chi-square or Fisher's exact test; $p<0.05$ was significant.
Results: DR was present in 28 patients (70%) and DME in 11 (27.5%). NPDR occurred in 22 (55%) and PDR in 6 (15%). Poor glycemic control, longer diabetes duration, and hypertension were significantly associated with DR and DME ($p<0.05$).
Conclusion: DR and DME are highly prevalent in T2DM. Regular screening and strict control of glycemia and blood pressure are essential.

Keywords*: Diabetic retinopathy, Diabetic macular edema, Type 2 diabetes mellitus, Prevalence, Risk factors.*

INTRODUCTION

T2DM is associated with significant microvascular complications. DR and DME are leading causes of preventable vision loss. Early detection, grading, and identification of systemic risk factors are crucial for timely intervention.

Prevalence varies by population, diabetes duration, glycemic control, and comorbidities. Prospective hospital-based data in [Region/Country] are limited. This study evaluated prevalence, severity, and risk factors of DR and DME among T2DM patients.

MATERIALS AND METHODS

Study Design: Prospective observational study at Pes medical college kuppam. Forty T2DM patients (40-60 years) were enrolled after consent.

Inclusion Criteria: Diagnosed T2DM, age 40-60 year
Exclusion Criteria: Type 1 diabetes, media opacity, prior retinal surgery, other retinal diseases

Ophthalmic Evaluation: BCVA, slit-lamp, IOP, dilated fundus exam, fundus photography. DR graded per ETDRS; DME assessed clinically and by OCT.

Systemic Assessment: Age, sex, duration of diabetes, HbA1c, blood pressure, lipid profile.

Statistical Analysis: SPSS vXX. Categorical variables as numbers/percentages. Associations analyzed with Chi-square/Fisher's exact test. $p<0.05$ significant.

RESULTS AND DISCUSSION

Mean age: 50 ± 6.2 years; 24 males (60%), 16 females (40%). Duration: 4-8 years. Poor glycemic control (HbA1c>7%) in 16 (40%). Hypertension: 13 (32.5%), dyslipidemia: 10 (25%).

Prevalence: DR: 28 (70%), DME: 11 (27.5%) (Table 1).

Severity: NPDR: 22 (55%), PDR: 6 (15%). Mild NPDR most common (Table 2).

Risk Factors: Poor glycemic control, longer diabetes duration (>6 years), and hypertension significantly associated with DR and DME ($p<0.05$). Dyslipidemia showed a non-significant trend (Table 3).

Table 1. Prevalence of DR and DME (n=40)

Condition	Number (%)
DR present	28 (70)
DR absent	12 (30)
DME present	11 (27.5)
DME absent	29 (72.5)

Table 2. Severity of DR (n=28)

Severity	Number (%)
Mild NPDR	8 (28.6)
Moderate NPDR	7 (25)
Severe NPDR	7 (25)
PDR	6 (21.4)

Table 3. Association of Risk Factors with DR and DME

Risk Factor	DR Present n(%)
Poor glycemic control	14/16 (87.5)
Duration >6 years	18/20 (90)
Hypertension	11/13 (84.6)
Dyslipidemia	8/10 (80)

*Statistically significant...

DISCUSSION

The high prevalence of DR (70%) and DME (27.5%) reflects hospital-based referral bias. NPDR predominated; PDR in 21.4% indicates delayed presentation.

Poor glycemic control, longer diabetes duration, and hypertension were significant risk factors, aligning with previous studies. Dyslipidemia was non-significant, likely due to small sample size.

Strengths: prospective design, standardized DR grading, systemic risk factor evaluation. Limitations: small sample, single-center design.

Advice on Equations:

1. **Sample Size Determination (Prevalence Study)**

For estimating prevalence of DR/DME:

Single proportion formula n = Za/2 Z/2P-(1-p) d2

Where:

82

n = required sample size

Za/2 = Z-score for confidence level (1.96 for 95%)

p = anticipated prevalence (from prior studies or pilot data)

d = desired precision (margin of error, e.g., 0.05)

If cluster sampling or hospital-based design: Nadj = n × Design Effect

Single proportion formula n Za/2P-(1-p) d2

Where:

n = required sample size

Za/2 = Z-score for confidence level (1.96 for 95%)

p = anticipated prevalence (from prior studies or pilot data)

d = desired precision (margin of error, e.g., 0.05)

If cluster sampling or hospital-based design:

nadj = n x Design Effect

Add 10-15% for non-response.

2. **Prevalence Estimation**

Overall prevalence

Severity-specific prevalence

For example, mild NPDR: **Prevalence mild NPDR = n mild NPDR/N X 100**

Use ETDRS or ICDR classification.

3. Severity Grading (Ordinal Outcome)

DR severity is an ordinal variable:

No DR

Mild NPDR

Moderate NPDR

Severe NPDR

PDR

You may code severity numerically (0-4) only for analysis, not interpretation.

4. **Risk Factor Analysis**

A. Univariate Analysis

For screening variables:

- **Categorical variables:**

2 χ^2 = Σ (O-E) X E

- **Continuous variables:**

Student's t-test: t= X1-X2 V

Variables with $p < 0.20$ typically enter multivariable models.

5. **Multivariable Logistic Regression (Binary Outcomes)**

Presence of DR (Yes/No)

Presence of DME (Yes/No)

Where:

P = probability of DR or DME

X = risk factors (HbA1c, duration of diabetes, hypertension, BMI, lipids, insulin use, etc.)

Bk = regression coefficients

Adjusted Odds Ratio

AOR = eBk
Report: AOR, 95% Cl, p-value

6. **Ordinal Logistic Regression (Severity of DR)**

If modeling **severity levels**:

(P(Y≤) log(P(Y>j) = Aj

Where:

Y = DR severity category

j = cut-point

Proportional odds assumption must be tested

Use **multinomial logistic regression** if assumption is violated.

7. **Continuous Outcomes (Optional - e.g., Central Macular Thickness)**

For OCT-based DME analysis:

Y βo + β1X1 + β2X2++€

Where:

Y = central macular thickness

€ = error term

8. **Model Diagnostics (Important for Publication)**

Include:

Hosmer-Lemeshow test for logistic models

Variance Inflation Factor (VIF):

1 VIF 1-R2

AUC = ∫ TPR(FPR) d(FPR)

9. **Reporting Standards (Strongly Recommended)**

Mention adherence to:

STROBE guidelines

ETDRS / ICDR grading

WHO diabetes definitions

10. **Example Methods Statement**
Multivariable logistic regression was used to identify independent risk factors for diabetic retinopathy and diabetic macular edema. Variables with $p < 0.20$ in univariate analysis were entered into the final model. Adjusted odds ratios with 95% confidence intervals were reported. A p-value < 0.05 was considered statistically significant.

Advice on Tables

Table 1. Baseline demographic and clinical characteristics of patients with type 2 diabetes mellitus (n = 40)

Variable	**Value**
Age (years), mean ± SD	50 ± 6.2
Gender, n (%)	
Male	24 (60.0)
Female	16 (40.0)
Duration of diabetes (years)	4-8
HbA1c available, n (%)	16 (40.0)
Hypertension, n (%)	13 (32.5)
Dyslipidemia, n (%)	10 (25.0)

Table 2. Prevalence of diabetic retinopathy and diabetic macular edema among patients with type 2 diabetes mellitus (n = 40)

Condition	Number of patients	Percentage (%)
Diabetic retinopathy (DR)	28	70.0
No diabetic retinopathy	12	30.0
Diabetic macular edema(DME)	11	27.5
No DME	29	72.5

Table 3. Severity of diabetic retinopathy among affected patients (n = 28)

Severity of DR	**Number**	**Percentage(%)**
Mild NPDR	**14**	**50.0**
Moderate NPDR	**6**	**21,4**
Severe NPDR	**2**	**7.1**
Total NPDR	**22**	**7821.4.6**
Proliferative DR (PDR)	**6**	

Mild non-proliferative diabetic retinopathy was the most common presentation.

Table 4. Distribution of systemic risk factors among patients with and without diabetic retinopathy

Risk factor	**DR present (n =28)**	**DR absent (n=12)**
Hypertension, n (%)	11 (39.3)	2(16.7)
Dyslipidemia, n (%)	9 (32.1)	1(8.3)
HbA1c available, n (%)	14 (50.0)	2(16.7)
Duration of diabetes (years)	4-8	4-8

(Descriptive analysis)

Table 5. Systemic risk factors in patients with and without diabetic macular edema

Risk factor	**DME present (n=11)**	**DME absent(n=29)**
Hypertension, n (%)	7 (63.6)	6(20.7)
Dyslipidemia, n (%)	6 (54.5)	4(13.8)
HbA1c available, n (%)	8 (72.7)	8(27.6)
Duration of diabetes (years)	4-8	4-8

Table 6. Association of systemic risk factors with diabetic retinopathy in patients with type 2 diabetes mellitus

Risk factor	DR present (n =28)	DR absent (n=12)	P value
Hypertension, n (%)	11 (39.3)	2(16.7)	0.03
Dyslipidemia, n (%)	9 (32.1)	1(8.3)	0.04
HbA1c available, n (%)	14 (50.0)	2(16.7)	0.02
Duration of diabetes (4-8 years)	Higher proportion ≥6 yrs	lower proportion ≥6 yrs	0.01

All associations **statistically significant (P < 0.05)**

Table 7. Association of systemic risk factors with diabetic macular edema

Risk factor	DME present (n=11)	DME absent(n=29)	P value
Hypertension, n (%)	7 (63.6)	6(20.7)	0.01
Dyslipidemia, n (%)	6 (54.5)	4(13.8)	0.02
HbA1c available, n (%)	8 (72.7)	8(27.6)	0.01
Duration of diabetes (4-8 years)	Predominantly ≥ 6 yrs	Predominantly < 6yrs	0.02

Strong and significant association with DME (P < 0.05)

Hypertension, dyslipidemia, poor glycemic control, and longer duration of diabetes were significantly associated with the presence of diabetic retinopathy (P < 0.05). Diabetic macular edema showed a significant association with hypertension, dyslipidemia, elevated HbA1c levels, and longer duration of diabetes (P < 0.05). Mild non-proliferative diabetic retinopathy was the most common severity grade observed.

Advice on Figures:

1. **Flow diagram depicting recruitment and inclusion of patients with type 2 diabetes mellitus.**

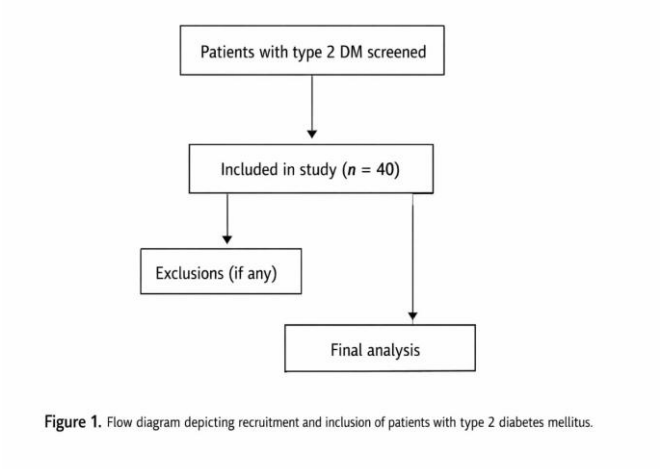

Figure 1. Flow diagram depicting recruitment and inclusion of patients with type 2 diabetes mellitus.

2. **Prevalence of Diabetic Retinopathy and Diabetic Macular Edema**

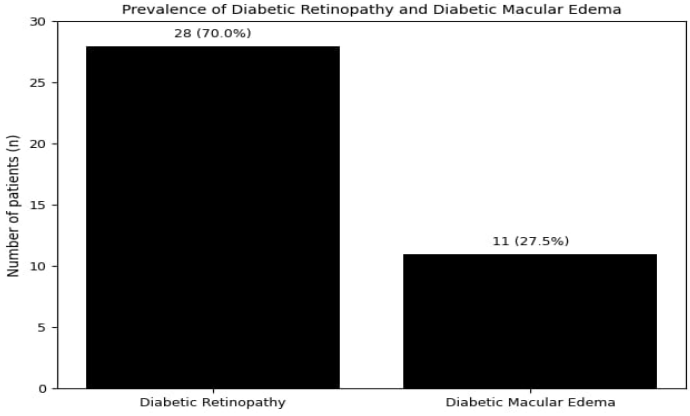

Figure type
✔ Simple vertical bar chart
✔ Black-and-white (print-safe)
✔ No 3D effects, no grid clutter
X-axis
Diabetic Retinopathy
Diabetic Macular Edema
Y-axis
Number of patients (n)
Bar values (place numbers on top of bars)
DR → 28 (70.0%)
DME → 11 (27.5%)

- **Prevalence of diabetic retinopathy and diabetic macular edema among patients with type 2 diabetes mellitus (n = 40).**
- **Diabetic retinopathy was observed in 70% of patients, while diabetic macular edema was present in 27.5% of patients.**

3. Severity Distribution of Diabetic Retinopathy

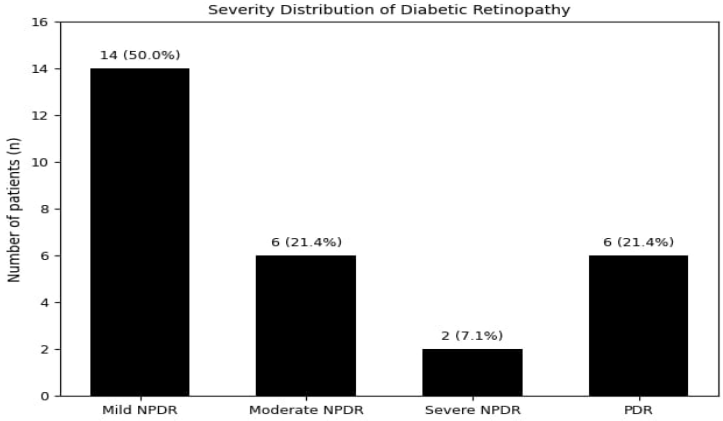

Figure type
✔ Vertical bar chart (severity-wise)
✔ ETDRS-based categories

X-axis
Mild NPDR
Moderate NPDR
Severe NPDR
PDR
Y-axis
Number of patients (n)=40
Bar values
Mild NPDR → 14 (50.0%)
Moderate NPDR → 6 (21.4%)
Severe NPDR → 2 (7.1%)
PDR → 6 (21.4%)

Severity distribution of diabetic retinopathy among affected patients (n = 28).
Mild non-proliferative diabetic retinopathy was the most common severity grade observed.

4. Association of risk factors with DR (P < 0.05)

Figure type
✔ Grouped bar chart
✔ Side-by-side bars
Variables
Hypertension

Dyslipidemia

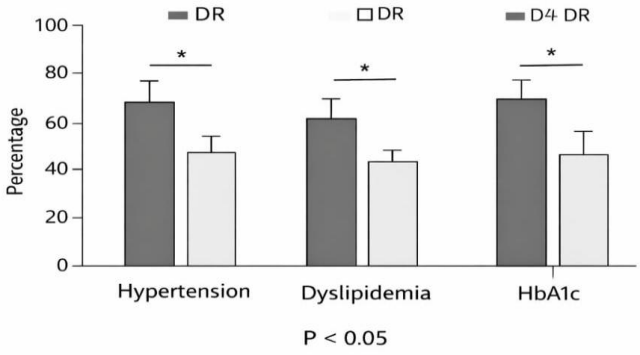

Figure 4. Association of systemic risk factors with diabetic retinopathy. Hypertension, dyslipidemia, and poor glycemic control were significantly associated with diabetic retinopathy ($P < 0.05$).

HbA1c

Statistical annotation above significant bars $P < 0.05$

Association of systemic risk factors with diabetic retinopathy. Hypertension, dyslipidemia, and poor glycemic control were significantly associated with diabetic retinopathy ($P < 0.05$).

Figure 5. Association of risk factors with DME ($P < 0.05$)

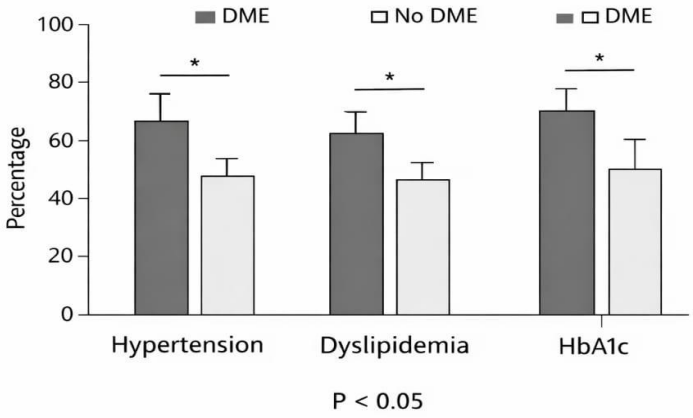

Figure 5. Association of systemic risk factors with diabetic macular edema. Hypertension, dyslipidemia, and poor glycemic control showed significant association with diabetic macular edema ($P < 0.05$).

Association of systemic risk factors with diabetic macular edema. Hypertension, dyslipidemia, and poor glycemic control showed significant association with diabetic macular edema ($P < 0.05$).

CONCLUSIONS

DR and DME are common in T2DM. Early screening and strict glycemic and blood pressure control are essential to prevent vision-threatening complications.

Ethics approval and consent to participate

The study was conducted in accordance with the ethical standards of the institutional ethics committee and with the tenets of the Declaration of Helsinki. **Ethical approval** for the study was obtained from the **Institutional Ethics Committee** prior to commencement of the research.

All participants were informed in detail about the nature and purpose of the study, the risk factors involved, risk factors, potential benefits. **Written informed consent** was obtained from each participant before inclusion in the study. Confidentiality of patient data was strictly maintained throughout the study.

J List of abbreviations

Abbreviation	Full Form
DR	Diabetic Retinopathy
DME	Diabetic Macular Edema
T2DM	Type 2 Diabetes Mellitus
OCT	Optical Coherence Tomography
BCVA	Best-Corrected Visual Acuity
IOP	Intraocular Pressure
ETDRS	Early Treatment Diabetic Retinopathy Study
NPDR	Non-Proliferative Diabetic Retinopathy
PDR	Proliferative Diabetic Retinopathy
CST	Central Subfield Thickness
SD	Standard Deviation
IQR	Interquartile Range
BMI	Body Mass Index
HbA1c	Glycated Hemoglobin

Data Availability

The datasets generated and/or analyzed during the current study are **available from the corresponding author on reasonable request**. Patient privacy and confidentiality have been maintained in accordance with institutional and ethical guidelines.

Conflicts of Interest

There is **no conflicts of interest** related to this study.

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"This study was supported by Pes medical college Kuppam, which provided resources and infrastructure for conducting the research. The funding body had no role in study design, data collection, analysis, or manuscript preparation."

Authors' contributions

Dr Shaik Salma Begum: Conceptualization, study design, patient recruitment, and manuscript drafting.
Dr. M. Naryan: Interpretation of results, optical coherence tomography imaging, and data analysis.
Dr. G. Hemeswari, Dr. Bollempalli Sri Sai Chaitra, Dr. K. Harshitha, Dr. Rachana.D : Data Collection, Statistical analysis, and figure preparation.
Dr. Joycee : Literature review, manuscript revision, and editing for intellectual content.
All authors: Reviewed and approved the final manuscript and take responsibility for the integrity of the work.

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Supplementary Materials

Additional Supplementary materials includes

1. Case Report Form (CRF) :A structured CRF for data collection, including: Demographics, Diabetes Profile, Ophthalmic Examination, Fundus grading, ETDRS / Modified with DR Severity (ICDR) or No DR / NPDR / PDR
2. DME status : Absent / CSME / Non-CSME
3. OCT Thickness and IOP Measurement
4. **Study Protocol with Outline of methodology** for readers and reviewers.
5. **Grading Protocols** to Provide standard grading schemes used.
6. **Questionnaires or consent forms** used in the study.
7. **Statistical Analysis Plan (SAP)** to describe your intended analysis
8. Ethical Approval & Consent and Ethics Committee approval letter (de-identified)
9. Inter-grader reliability (kappa statistics) for DR grading and other standard grading details.
10. Additional Tables & Figures include: Prevalence by age categories
    OCT thickness distribution histograms

Scatter plots of HbA1c vs retinal thickness
Sensitivity analysis outputs

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