ONLINE FIRST

ORIGINAL ARTICLE

Frequency of Diabetic Macular Edema (DME) in Diabetic Patients and Comparison of Various Systemic Parameters that Increase its Risk between with and without Diabetic Macular EDEMA

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doi: 10.22442/jlumhs.2026.01411

ABSTRACT

OBJECTIVE: To determine the frequency of DME in diabetic patients presenting for ophthalmology assessment and to compare systemic parameters that contribute to the development of DME between patients with DME versus those without DME.

METHODOLOGY: This cross-sectional study was conducted at the Sindh Institute of Ophthalmology and Visual Sciences in Hyderabad, Pakistan, from January to June 2024. A total of 118 diabetic patients were assessed for the presence of DME by using optical coherence tomography. Patients with and without DME were assessed for various systemic parameters. Among these, quantitative systemic parameters were compared among patients using the Mann-Whitney U test, while qualitative systemic parameters were compared using the chi-square test.

RESULTS: Median age was 35.50 (9.00) years. There were 82 (69.50%) male and 36 (30.50%) female patients. Median BMI was 30.15 (6.02) kg/m2. Median duration of diabetes was 5.00 (2.00) years. DME was found in 34 (28.80%) patients. Upon comparison of systemic parameters, it was found that there was a significant difference between patients with and without DME in low-density lipoprotein levels ($p = 0.005$), glomerular filtration rate ($p = 0.024$), and the frequency of co-existing hypertension ($p < 0.001$).

CONCLUSION: In this study, DME was found in nearly one-third of patients, underscoring its significant burden in the local diabetic population. It was also observed that elevated LDL, reduced GFR, and co-existing hypertension were significantly associated with DME, while other systemic parameters showed non-significant difference, including.

KEYWORDS: Diabetes Mellitus, Macular Edema, Optical Coherence, Tomography.

INTRODUCTION

Diabetes mellitus (DM) leads to oedema of the macula, a condition known as diabetic macular oedema (DME), which is amongst the leading causes of visual impairment worldwide[1,2]. Uncontrolled DM leads to upregulation of vascular endothelial growth factor (VEGF), which increases vascular permeability and the breakdown of the blood-retinal barrier, thereby causing fluid build-up in the macula, i.e., DME, which is detected on optical coherence tomography (OCT)[3,4]. Globally, the prevalence of DME has been reported at 4.07% among the diabetic population[5]. In Pakistan, the exact prevalence of this condition is unknown. Still, according to a study with a large sample size in Pakistan, it was reported that among DM patients, DME prevalence was 30.5%. [6] Contrarily, in one study conducted on DM patients of Romania, it was observed that DME prevalence was only 15.3%. [7]

When it comes to systemic parameters comparison between DM patients with and without DME, it has been observed that various factors may not have any difference, including body mass index (BMI), smoking, history of hypertension, glycosylated haemoglobin and total cholesterol levels, while for some other variables, there could be a significant difference between these patients, including use of anti-hyperlipidaemic medication and glomerular filtration rate[8].

DME is a vision-threatening condition that has the potential to cause permanent blindness. When previous trends are analyzed, there is a significant disparity in reported DME prevalence (ranging from 5.47% global prevalence to 30.5%), and there is limited recent data on comparisons of various systemic parameters between patients with and without DME in the current local demographic. For this purpose, it is essential to determine the burden of this ocular condition in the diabetic population of the local community whilst focusing on various systemic parameters associated with this serious diabetic complication. For this purpose, the present study is being conducted of determine the frequency of DME in diabetic patients presenting for ophthalmology assessment and to compare systemic parameters that contribute to DME development between patients with DME and those without DME. Results from this study would help identify patients with DME, along with the assessment of various parameters that can potentially increase the likelihood of its development.

METHODOLOGY

This cross-sectional study was conducted at the Sindh Institute of Ophthalmology and Visual Sciences, Hyderabad, from January to June 2024, following approval of the research proposal by CPSP (Ref. #: CPSP/REU/OPL-2022-169-2538; dated 10/01/2024). A sample size of 118 was calculated using the WHO sample size calculator, with a 95% confidence interval, an absolute precision of 6.5%, and an anticipated DME frequency of 15.3% (8). The sample selection process used a non-probability, consecutive sampling technique. Before inclusion, it was ensured that all patients provided written informed consent, using a predesigned pro forma.

Patients aged between 18 and 65 years, of either gender, who had diabetes (defined as having HbA1C% ≥ 6.5%) or were taking anti-diabetic medications for ≥ 12 months and were referred to the ophthalmology outdoor department by physicians for ophthalmology screening and assessment were included. Patients having ocular opacification (like dense cataract) that interfered with the reliability of optical coherence tomography (OCT) imaging, blind patients since birth, other retinopathic or maculopathic anomalies, congenital structural abnormality of the eye and those with a previous history of intervention for diabetic retinopathy were excluded.

Baseline characteristics, including age (in years), gender, and duration of diabetes, were documented after that OCT was performed to make a diagnosis of DME by the presence of retinal swelling, sub-retinal fluid and cystoid macular oedema on OCT in diabetic patients with central subfield thickness of ≥ 250µm. After this, patients with DME and those without DME were assessed for various systemic parameters including body mass index (BMI), glycosylated haemoglobin (HbA1C%), lipid profile [total cholesterol (TC), triglycerides (TG), high density lipids (HDL) and low density lipids (LDL)], co-existing hypertension, use of anti-hyperlipidaemic medication, smoking and glomerular filtration rate (GFR). GFR was measured by using the Modification of Diet in Renal Disease (MDRD) equation.

All collected data were entered and analyzed using SPSS version 30.0.0. Descriptive statistics were collected for qualitative and quantitative variables. Qualitative variables (gender, presence/absence of DME, co-existing hypertension, use of anti-hyperlipidaemic medication and smoking) were measured in terms of frequency and percentage. Quantitative variables (age, BMI, duration of diabetes, HbA1C%, TC, TG, LDL, HDL and GFR) were measured in median interquartile range (IQR) since all of these were found to be not distributed normally. Frequency of DME was stratified by age, gender, and duration of disease to account for effect modifiers. Post-stratification, the Chi-square test was used as the test of significance. To compare BMI, HbA1C%, lipid profile, and GFR between patients with and without DME, the Mann-Whitney U test was used. To compare co-existing hypertension, use of anti-hyperlipidaemic medication and smoking between patients with and without DME, the chi-square test was used. A p-value ≤ 0.05 was considered significant.

RESULTS

In this study, 118 patients were included. Median age was 35.50 (9.00) years. There were 82 (69.50%) male and 36 (30.50%) female patients. Median BMI was 30.15 (6.02) kg/m2. Median duration of diabetes was 5.00 (2.00) years. Patient demographics are given in **Table I**:

Table I: Patient demographics (n = 139)

Demographic variable	Median IQR; n (%)
Mean age	35.50 (9.00) years
Age group	
18-40 years	77 (65.30%)
41-65 years	41 (34.70%)
Gender	
Male	82 (69.50%)
Female	36 (30.50%)
Median BMI	30.15 (6.02) kg/m2
Mean duration of diabetes	5.00 (2.00) years
Duration of the diabetes group	
< 5 years	48 (40.70%)
≥ 5 years	70 (59.30%)

BMI = Body mass index

Among 118 patients, DME was found in 34 (28.80%), while 84 (71.20%) had none. Stratification DME frequency by confounding variables, including age, gender and duration of diabetes, is given in **Table II**:

Table II: Stratification of DME frequency by confounding variables (n = 118)

Age stratification			
	18-40 years (n = 77)	**41-65 years (n = 41)**	**p-value**
DME	22 (28.57%)	12 (29.27%)	0.937†
Gender stratification			
	Male (n = 82)	**Female (n = 36)**	**p-value**
DME	26 (31.71%)	8 (22.22%)	0.295†
Stratification by duration of diabetes			
	< 5 years (n = 48)	**≥ 5 years (n = 70)**	**p-value**
DME	17 (35.42%)	17 (24.89%)	0.190†

† = Chi-square test; DME = Diabetic macular oedema

Comparison of systemic parameters that have the potential to increase the risk of developing DME among patients with and without DME is given in **Table III**:

Table III: Comparison of systemic parameters of patients with and without DME (n = 118)

Parameter	DME (n = 34)	No DME (n = 84)	p-value
HbA1C%	10.40 (0.85)	10.20 (1.80)	0.466 *
TC (mg/dl)	216.50 (64.25)	191.00 (61.75)	0.058 *
TG (mg/dl)	221.50 (10.00)	222.00 (10.00)	0.560 *
LDL (mg/dl)	190.50 (49.50)	180.00 (47.75)	0.005 *
HDL (mg/dl)	38.50 (15.50)	41.00 (27.50)	0.166 *
GFR (ml/min/1.73m2)	78.00 (16.75)	92.00 (20.50)	0.024 *
Coexisting hypertension	23 (67.65%)	22 (26.19%)	< 0.001†
Use of anti-hyperlipidaemic medication	16 (47.06%)	31 (36.90%)	0.308†
Smoking	19 (55.88%)	32 (38.09%)	0.077†

** = Mann Whitney U-test; † = Chi-square test*

HbA1C% = Glycosylated haemoglobin, TC = Total cholesterol, TG = Triglycerides, LDL = Low density lipids, HDL = High density lipids, GFR = Glomerular filtration rate, DME = Diabetic macular oedema

DISCUSSION

Diabetes is a highly prevalent condition not only on a global scale but also in Pakistan, affecting a major proportion of the population. [9] This multi-system disease can lead to significant damage to the vision due to the ophthalmological complications, which can range from mild, asymptomatic and non-proliferative disease of the retina to a much more advanced condition like DME[9,10]. The effective management of this common morbidity is of utmost importance, since if this is not managed properly. The glycemic control stays poor for an extended period of time, which can lead to irreversible loss of the ability to see, resulting in significant deterioration of the general life quality of the ailing patients[11,12]. The present study thus focused on determining the frequency of this serious ophthalmologic complication of DM and on assessing differences in systemic parameters among patients with and without this complication of DM.

In the present study, the frequency of diabetic patients who were diagnosed with DME through OCT was 28.8%. This percentage represents that a significant proportion of patients who have diabetes can develop this vision-threatening condition, thereby exhibiting a high burden not only on the DME but also the high likelihood of encountering a high burden of patients who may develop irreversible blindness.

In comparison to this proportion, a study was conducted among patients with diabetes from Ethiopia. In their study, they found that the frequency of this retinal pathology in their study population was 25.8%.[13] This proportion of was comparable to the DME frequency of the present study.

Contrary to the present study's finding of a high frequency of DME, a large-scale meta-analysis examined the frequency of this complication by pooling data from 7 previously published studies. Upon detailed analysis, they reported that the global frequency of DME was only 5.47%, which was much lower than in the current study[14]. Similarly, one study was conducted in the Pakistani diabetic population. In this study, they found that the frequency of the same retinal pathology, which was the focus of the present study, was 13%, which was still lower than the DME frequency reported in the present study[15]. Although the exact reason behind this difference of the DME frequency in present and past studies could not be determined, there were multiple reasons hypothesized to have caused this difference. The primary reason for this difference in the DME frequency was considered to be differences in the sample sizes of the aforementioned study, which can directly influence the frequency percentage: if a sample size is large, even a relatively larger number can yield a lower frequency. In contrast, if a sample size is small, even a smaller patient number can yield a higher frequency. In addition, the demographics of the studied populations could also have contributed to the difference of DME frequency between the current and previously conducted studies.

Upon assessment of the distribution of DME across age groups, genders, and diabetes duration, it was observed that its frequency was not affected by any of these factors ($p > 0.05$). Most importantly, the gender distribution showed a non-significant difference ($p = 0.295$); however, the proportions indicated a slight male predominance. This male predominance was similar to a study in which it was observed that this pathology affected male patients much more than females. [16] Similarly, in general, it is considered that as the patient gets older, the chances of retinal diseases increase as the patient grows older[17,18]; however, in the present study, there was no difference in DME across the age groups ($p = 0.937$). One possible reason for this finding could be the higher number of patients of present study being in the younger age group. Similarly, as diabetes duration increases, the risk of retinal damage and DME increases, as per

previous literature; however, in the present study, this difference was not significant (p = 0.190)[19,20].

Upon comparison of systemic parameters, patients with DME had significantly higher LDL levels (p = 0.005), lower GFR (p = 0.024), and a higher frequency of co-existing hypertension (p < 0.001). In contrast, no significant difference was observed between these patients based on any other systemic parameters, including HbA1C% (p = 0.466), TC (p = 0.058), TG (p = 0.560), HDL (p = 0.166), use of anti-hyperlipidaemic medication (p = 0.308) and smoking (p = 0.077). In comparison, Shaikh et al. also compared various systemic parameters between patients with and without DME. It was found that, in terms of body mass index (p = 0.697), smoking (p = 0.267), history of hypertension (p = 0.138), glycosylated haemoglobin (p = 0.326), and total cholesterol levels (p = 0.272), there was no significant difference between these patients. In contrast, in terms of use of anti-hyperlipidaemic medication (p = 0.030) and glomerular filtration rate (p = 0.003) the difference was significant with lower frequency of use of anti-hyperlipidaemic drugs and lower GFR in patients with DME[8]. In coherence with the aforementioned findings, a study found that having higher levels of LDL increases the chances of developing eye complications in diabetic patients (p = 0.00)[21]. The reason for this association lies in the endothelial damage mediated by the presence of hyperlipidaemia. [21] Similarly, the finding that DME patients had significantly low GFR strengthens the findings of previous literature that show a strong correlation of declining GFR with worsening and progression of diabetic retinal disease (p < 0.001)[22]. Another important association in the present study was between the presence of DME and the co-existence of hypertension. In a review by Rasoulinejad, it was reported that hypertension can potentially increase the propensity to develop DME by 1.7 times[23]. This association is due to the ability of hypertension to exert its own detrimental effects on the retinal vasculature and thus synergizing the diabetic damage to the retina, thereby increasing the likelihood of developing DME[23,24].

The present study exhibits a large proportion of patients with diabetes who have DME, which signifies the importance of frequent screening of diabetic patients for this vision-threatening complication. In addition, this study provides useful insights into the systemic parameters that warrant close attention when providing regular follow-up care to these patients.

There were several limitations linked to the present study. The cross-sectional design did not permit causal inference. The limited sample size of 118 patients from a single centre in Hyderabad limits generalizability to larger populations, as demographics and access to healthcare vary across regions. Non-probability consecutive sampling can also lead of selection bias, as patients who visited the ophthalmology department may not be representative of the entire population of diabetic patients. Also, the use of OCT as a diagnostic tool without the support of other imaging techniques, like fluorescein angiography, may have resulted in a false detection of subtle cases or a false classification. Possible confounders (medication compliance, socioeconomic status, and control and duration of hypertension) that could have an impact on systemic parameters and ocular results were not considered in the study as well. Lastly, the young median age of participants (35.5 years) could be a biasing factor because older groups of diabetics tend to have more ocular complications.

CONCLUSION

In this study, DME was found in nearly one-third of patients, underscoring its significant burden in the local diabetic population. It was also observed that elevated LDL, reduced GFR, and co-existing hypertension were significantly associated with DME, while other systemic parameters showed non-significant difference, including. Importantly, patient demographics (age, gender, and diabetes duration) did not significantly influence DME frequency. These results emphasize the need for routine ophthalmic screening in patients with DM. By targeting modifiable systemic risk factors, clinicians may reduce the likelihood of vision-threatening complications. Overall, the study highlights the importance of integrated diabetes care to preserve visual outcomes.

Acknowledgements: All authors are thankful to the participant and the SIOVS technical and non-technical staff

Ethical permission: College of Physicians & Surgeons Pakistan, ERC approval letter No. 8167.
Conflict of interest: There is no conflict of interest between the authors.
Financial Disclosure / Grant Approval: No funding agency was involved in this research.
Data Sharing Statement: The corresponding author can provide the data proving the findings of this study on request. Privacy or ethical restrictions bound us from sharing the data publicly.

AUTHORS' CONTRIBUTION

Bushra: Data collection, statistical expertise
Talpur BR: Critical revision
Rameesha: Manuscript drafting
Fattah A: Manuscript drafting, assembly of data

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