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Original article

Prevalence of optical coherence tomography (OCT) detected diabetic macular edema in patients with diabetic retinopathy

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ABSTRACT:

Background*: Diabetic macular edema (DME) is the most common cause of decreased visual acuity in diabetic patients. Diabetic Macular edema is detected clinically only after its characteristic features which could damage the visual status of the patients. OCT (Optical coherence tomography) offers a non-invasive imaging technique that provides high-resolution cross-sectional images of the macula which can be helpful in early detection of Diabetic Macular Edema.*

Methods*: Hospital-based observational, descriptive, cross-sectional study, carried out from October 2016 to October 2018 in the Ophthalmology Department of Pravara Rural Hospital, a rural-based tertiary-level hospital. A total number of 130 cases with DRs fulfilling inclusion and exclusion criteria were included. The age and gender of the patient, duration of DM, medication for DM, stage of DR, and visual acuity were recorded and assessed for DME with the help of OCT.*

Results: *Out of 130 DR cases, the maximum number of cases was in the age group of 60- 70 years (50.77%). The prevalence of OCT-proven DME in cases with DR in the present study was 29.23%. 95.38% of cases had NPDR changes and 4.62% PDR changes. A higher (76.93%) number of DR cases were involved having a duration of DM up to 5 years. DR cases having a duration of DM up to 5 years had a prevalence of DME (57.90%). Early PDR changes had a maximum prevalence of DME (100%), followed by Severe (87.5%) and Very Severe NPDR (81.81%) respectively. The percentage of DR cases on Insulin was higher (66.66%) than cases not on Insulin (13.19%) showing a preponderance of cases on Insulin. Central macular thickness showed a significant increase in thickness with the progression of DR.*

Conclusion*: From the observations and results of the present study it is evident that the prevalence of OCT-proven DME is 29.23% in cases with DR. Prevalence of DME in PDR cases is more than with NPDR cases. Our study shows a higher percentage of DME with a duration of up to 5 years of DR.*

Keywords: *Optical Coherence Tomography, Diabetic Macular Edema, Diabetic Retinopathy.*

INTRODUCTION:

Diabetes mellitus (DM) refers to a group of common metabolic disorders that share the phenotype of hyperglycemia. It is caused by a complex interaction of genetics and environmental factors. It is the leading cause of end-stage renal disease, non-traumatic lower extremity amputations, and adult blindness. Chronic vascular complications of DM are divided as microvascular (retinopathy, nephropathy, neuropathy) and macrovascular (coronary artery disease, cerebrovascular disease).[1] Diabetic Retinopathy (DR) is a common microvascular complication of diabetes mellitus and a leading cause of visual disability and blindness. It is also the leading cause of legal blindness between the age group of 20-60 years.[2]

The incidence of diabetic retinopathy increases with the duration of the diabetes. DME is defined as retinal thickening at or within 1 disc diameter of the center of the macula or the presence of definite hard

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exudates.6 Diabetic macular edema increases with the duration of diabetes, and the prevalence is 5% within the first 5 years after diagnosis and 15% at 15 years.[3] Various types of diabetic maculopathies are Focal maculopathy, Diffuse maculopathy, and Ischemic maculopathy. The edema is caused primarily by a breakdown of inner blood-retinal barrier at the level of the retinal capillary endothelium, allowing leakage of fluid and plasma constituents into the surrounding retina. Multiple risk factors are found to be associated with the development and progression of diabetic maculopathy such as hyperglycemia, duration of DM, hypertension, hyperlipidemia, smoking, anemia, obesity, pregnancy, lifestyle, previous cataract surgery, and family history.[4] Among this poor glycemic control plays an important role.

Optical Coherence Tomography (OCT) is a high-resolution non-contact imaging modality.[5] The ocular application of this technology provides quantitative measurements of the macular retinal thickness, peripapillary nerve fiber layer (NFL) thickness, and topographical measurements of the optic nerve head (ONH).[6] OCT of the retina is like doing a vertical biopsy section of the retina. Instead of a knife, light is used. Instead of viewing a stained section under a microscope, we are presented with a "false-color" view with micron-level resolution, with no physical contact with the eye.[7] The OCT software measures retinal thickness automatically while it is evaluating variations and deviations from the normal values. No previous studies had been conducted to find out the Prevalence of Optical Coherence Tomography (Oct) Detected Diabetic Macular Edema In Patients With Diabetic Retinopathy**,** hence the objective of our study was to investigate the prevalence of Diabetic Macular Edema (DME) in patients with Non-Proliferative Diabetic Retinopathy (NPDR) compared to those with Proliferative Diabetic Retinopathy (PDR). Additionally, it seeks to determine the percentage of DME among patients with Insulin Dependent Diabetes Mellitus (IDDM) versus Non-Insulin Dependent Diabetes Mellitus (NIDDM) who exhibit signs of diabetic retinopathy. Furthermore, the research will analyze the prevalence of DME based on the duration of Diabetes Mellitus (DM).

MATERIALS AND METHODS:

The study was designed as a hospital-based observational, descriptive, cross-sectional study conducted over a period of two years, from October 2016 to October 2018. It focused on a sample size of 130 cases of diabetic retinopathy, specifically within the Department of Ophthalmology at a tertiary care teaching hospital located in a rural area of Western Maharashtra. Data collection was performed using a structured proforma, followed by statistical analysis employing descriptive statistics such as mean, standard deviation (SD), and percentages. To assess the association between variables and groups, the Chi-Square test was applied, with a significance threshold set at $p < 0.05$. The analysis was conducted using SYSTAT version 12 software. Inclusion criteria encompassed diabetic patients presenting with signs of diabetic retinopathy at the hospital's outpatient department or admitted to the wards, provided they consented to participate. Conversely, patients were excluded if they exhibited hazy media due to corneal ulcers, dense cataracts, uveitis, vitreous opacities, or other conditions that could independently affect vision, including macular degeneration or non-diabetic macular edema. This methodology aims to elucidate the prevalence and risk factors associated with diabetic retinopathy in the studied population.

PROCEDURE:

Patients were selected based on established inclusion and exclusion criteria to ensure a representative sample for the study. A comprehensive medical history detailing the duration of diabetes and its treatment was meticulously recorded. During the ocular examination, visual acuity was assessed, followed by an anterior segment examination using diffuse light and a slit lamp to rule out any concurrent ocular diseases or septic foci. Fundus examination was conducted using +90 D and +78 D lenses to evaluate retinal health. Patients diagnosed with diabetic retinopathy (DR) underwent further assessment for Diabetic Macular Edema (DME) utilizing Optical Coherence Tomography (OCT). In alignment with the systematic review by Virgili G et al., a median central retinal thickness cutoff of 250 µm (with a range of 230 µm to 300 µm) was adopted for data extraction. Accordingly,

central retinal thickness measurements of 250±25 µm were classified as normal, while values exceeding this threshold were designated as indicative of DME. Importantly, patients incurred no additional costs for the OCT examination, ensuring accessibility to this critical diagnostic tool.

PROCEDURE FOR OCT:

Prior to the examination, the procedure was thoroughly explained to each patient to ensure their understanding and comfort. Following this discussion, **written consent** was obtained, affirming the patients' willingness to participate in the study. To facilitate a comprehensive assessment, the pupils were dilated using **dilating eye drops**, allowing for optimal visualization of the retina. Subsequently, **Optical Coherence Tomography (OCT)** was performed to accurately measure the **central macular thickness**. This systematic approach not only ensured ethical compliance but also enhanced the quality of the diagnostic evaluation, paving the way for reliable data collection regarding Diabetic Macular Edema (DME).

DATA ANALYSIS AND RESULT:

Out of a total of 130 DR cases, 75 cases (57.69%) were males and 55 cases (42.31%) were females showing male preponderance. In our study mean age was 59.79±12.02 years in males and 60.51±11.19 years in females, showing almost similar age groups in both genders. The OCT-proven Diabetic Macular Edema and Distribution of cases as per Stage of Diabetic Retinopathy are shown in Table No. 1 & 2. The Duration of Diabetes mellitus and Duration of Diabetes Mellitus-Diabetic Macular Edema can be observed via Tables 3 & 4. Tables No. 5A, B, and C show us the Stages of Diabetic Retinopathy, the Distribution of cases as per Stage of NPDR, and the Distribution of cases as per Stage of PDR respectively. The OCT-proven Diabetic Macular Edema and Stages of DiabeticRetinopathy and the Distribution of cases as per Insulin and Non-Insulin dependence are shown in Tables 6 & 7 respectively. Table no 8 shows us the OCT-proven Diabetic Macular Edema and Insulin, while Table No. 9 gives us the Central Macular Thickness and Stages of Diabetic Retinopathy.

Table No.1: OCT proven Diabetic Macular Edema:

Diabetic Macular Edema	No. of cases	Percentage (%)
Present	38	29.23%
Absent	92	70.77%
Total	**130**	**100%**

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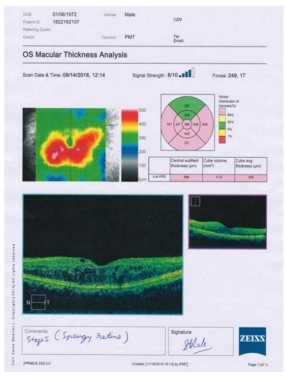

Figure no. 1: Spongy Retina

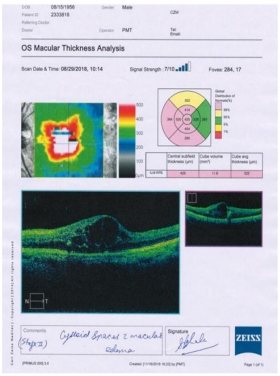

Figure no.2: CME

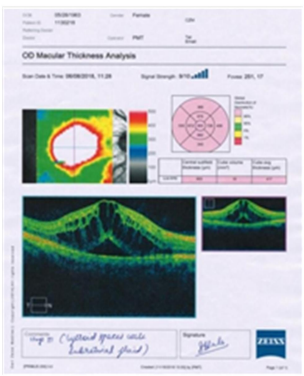

Figure no. 3: CME with SRF

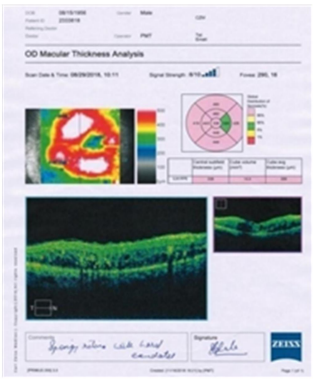

Figure no.4: Spongy retina with hard

Table no.2 Distribution of cases as per Stage of Diabetic Retinopathy:

Stage of Diabetic Retinopathy	No. of cases	Percentage
NPDR	124	95.38%
PDR	6	4.62%
Total	**130**	**100%**

Table No.3: Duration of Diabetes mellitus:

Duration	No. of cases	Percentage (%)
0 months- 5yrs	100	76.93%
5yrs – 10yrs	22	16.92%
>10yrs	8	6.15%
Total	**130**	**100%**
Mean ± SD	**5.26yrs.±2.14yrs**	

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Table No.4: Duration of Diabetes mellitus and Diabetic Macular Edema

Duration	Diabetic Macular Edema	
	Present	**Absent**
0 months- 5yrs	22(57.90%)	78(84.78%)
5yrs – 10yrs	9(23.68%)	13(14.13%)
>10yrs	7(18.42%)	1(1.09%)
Total	**38(29.23%)**	**92(70.77%)**
Mean ± SD	**6.77yrs.±3.89yrs**	**3.29yrs.±2.14yrs**

Table No. 5 A: Stages of Diabetic Retinopathy:

Stages	No. of cases	Percentage (%)
Mild NPDR	59	45.38%
Moderate NPDR	38	29.23%
Severe NPDR	16	12.31%
Very severe NPDR	11	8.46%
Early Proliferative Diabetic Retinopathy	6	4.61%
Late Proliferative Diabetic Retinopathy	0	0%
Total	**130**	**100%**

Table no. 5 B: Distribution of cases as per Stage of NPDR:

Stage of NPDR	No. of cases	Percentage
Mild NPDR	59	47.58%
Moderate NPDR	38	30.65%
Severe NPDR	16	12.90%

Very Severe NPDR	11	8.87%
Total	**124**	**100%**

Table no. 5 C: Distribution of cases as per Stage of PDR:

Stage of Diabetic Retinopathy	No. of cases	Percentage
Early PDR	6	100%
Late PDR	0	0%
Total	**6**	**100%**

Table No.6: OCT proven Diabetic Macular Edema and Stages of DiabeticRetinopathy:

Stages of Diabetic Retinopathy	No. of cases	DME Present	DME Absent
Mild NPDR	**59**	0(0%)	59(100%)
Moderate NPDR	**38**	9(23.68%)	29(73.32%)
Severe NPDR	**16**	14(87.5%)	2(12.5%)
Very severe NPDR	**11**	9(81.81%)	2(18.19%)
Early Proliferative Diabetic Retinopathy	**6**	6(100%)	0(0%)
Late Proliferative Diabetic Retinopathy	**0**	0%	0%
Total	**130**	**38(29.23%)**	**92(70.77%)**

Table No. 7: Distribution of cases as per Insulin and Non-Insulin dependence:

Types	No. of cases	Percentage (%)
Patients on Insulin	39	30%
Patients not on Insulin	91	70%
Total	**130**	**100**

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Table No.8: OCT-proven Diabetic Macular Edema and Insulin:

Insulin	Diabetic Macular Edema		
	No. of cases	Present	Absent
		No. (%)	No. (%)
Patients on Insulin	39	26 (66.66%)	13 (33.34%)
Patients not on Insulin	91	12 (13.19%)	79 (86.81%)
Total	**130**	**38**	**92**

Table No. 9: Central Macular Thickness and Stages of Diabetic Retinopathy:

Stages of Diabetic Retinopathy	No. of cases	Central Macular Thickness	
		Right Eye	Left Eye
		Mean ± SD	Mean ± SD
Mild NPDR	59	244.56±4.19	248.66±5.33
Moderate NPDR	9	263.55±21.79	266.79±25.69
Severe NPDR	14	309.0±30.98	317.81±30.27
Very Severe NPDR	9	310.27±36.33	314.72±36.88
Early Proliferative Diabetic Retinopathy	6	354.17±36.41	354.50±36.08
Late Proliferative Diabetic Retinopathy	0	-	

DISCUSSION:

India is becoming one of the diabetic capitals in the world. With this ever-growing diabetic population, the complications due to diabetes are also growing. Diabetes is a known cause of microvascular angiopathy which leads to end organ damage. One of the organs is the eye which it leads to diabetic retinopathy. Diabetic maculopathy is the most common cause of decreased visual acuity in patients with type II DM. Diffuse macular edema is caused by extensive capillary leakage and localized edema by focal leakage from microaneurysms.

The onset and progression of diabetic maculopathy depends on several predisposing risk factors such as duration of diabetes mellitus,

IDDM, and stage of DR. DME is detected clinically only after its characteristic features which could damage the visual status of the patients. However, it is possible to prevent this using OCT evaluation as DME can be detected early in various stages of DR.

In the present study, all patients were between 20 and 80 years of age. The majority (50.77%) of them were between 60 to 70 years of age. The mean age in males was 59.79±12.02 years and in females was 60.51±11.19 years. Overall mean age was 60.52±11.57years, showing almost similar age groups in both genders.

Davis et al studied the prevalence of DME in patients with DR selected at retina clinics and found mean age of 59 years which is similar to this study.[8] **Strom et al** studied DME in DR patients using OCT and stereo fundus photographs and also found a mean age of 53 years, with female to male ratio as 11:36 again showing male predominance.[9] In the current study mean age was 60.52±11.57years and showing an almost similar age group in both genders; it is similar to the study done by **Davis et al** which was 59 years but with male predominance. Whereas **Strom et al** found the mean age group as 53 years with male predominance which differed from this study.

In our study prevalence of OCT-proven DME in DR cases found was 29.23%. **Acan D et al** studied the prevalence of DME which was 15.3% out of 63 cases of DR, which is less than our study.[65]

We studied 130 DR cases in our study, out of which 124 cases (95.38%) were of NPDR and 6 cases (4.62%) were of PDR. **Acan D et al** found 28 cases (44.4%) of NPDR and 35 cases (55.5%) of PDR.[10] Observations in our study do not correlate with his study.

In our study mean duration of DM found was 5.26± 2.14 years. **Davis et al** found the mean duration of DM in cases having DR as 14 years which is more than the current study.[8] We studied the correlation of the duration of DM with OCT-proven DME and found that out of 130 cases of DR, a total of 38 cases (29.23%) had DME. Out of these 38 cases having DME, 22 cases (57.90%) had 5 years duration of DM; 9 cases (23.68%) had a duration up to 10 years and remaining 7cases (18.42%) had more than 10 years of duration.

The mean duration of DM found in this study was 6.77±3.89 years, by applying Chi-Square test there was a significant association with χ^2=20.553 and p=0.001 which was significant. **Aiello LP et al** studied DR and found that DME increases with the duration of DM and prevalence is 5% within the first 5 years after diagnosis and 15% at 15 years.[11] His study showed a higher prevalence of DME with increasing duration of DM; however, our study had a higher prevalence even with a duration up to 5 years of DR.

In our study, out of 130 DR cases, 59 cases (45.38%) had Mild NPDR changes, 38 cases (29.23%) of Moderate NPDR, 16 cases (12.31%) of Severe NPDR, 11 cases (8.46%) of Very Severe NPDR and 6 cases (4.61%) of Early PDR cases. **Acan D et al** studied 63 cases out of which 18 cases (28.6%) were having Mild-ModerateNPDR, 10 cases (15.9%) had Severe- Very Severe NPDR and 35 cases (55.5%) had PDR. This shows that he had more cases with PDR as compared to our study.[10]

Out of 130 cases, there were 59 Mild NPDR cases that did not show DME, 38 Moderate NPDR cases with 9 cases (23.68%) of DME, 16 Severe NPDR cases with 14 cases (87.5%) of DME, 11Very Severe NPDR cases with 9 cases (81.81%) of DME and 6 early PDR cases with 6 cases (100%) of DME. This shows that the occurrence of DME is consistent with the advancing stage of DR. By applying the Chi-Square test there is a significant association between DME and stages of DR with χ^2 =34.89, p=0.0001 which is significant. **Acan D et al** also studied the prevalence of OCT-proven DME and stage of DR and found that the prevalence of DME in Mild to Moderate NPDR was 28.6%, Severe to Very Severe NPDR was 15.9% and PDR was 55.5%.[10] In Mild-Moderate NPDR stages our findings are similar to that of **Acan D et al**; however, there is no similarity in the Severe-Very Severe NPDR group. In the case of PDR, the occurrence of DME is more in his and our study also. **Davis et al** in their large case series of DR and CSME found a higher prevalence of

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CSME in NPDR stages.[8]

Out of 130 DR cases, 39 cases (30%) were on Insulin and 91 cases (70%) were not on Insulin. Out of 39 DR cases on Insulin, 26 cases (66.66%) had OCT-proven DME,and out of 91 DR cases that were not on Insulin, 12 cases (13.19%) had OCT-proven DME.

This shows that prevalence of DME is higher in patients who were on insulin than of patients who were not on Insulin. We studied the correlation of central macular thickness and stage of diabetic retinopathy and found that, out of 59 Mild NPDR cases mean of central macular thickness was 244±4.19 in right eyes and 248±5.33 in left eyes, out of 9 Moderate NPDR cases it was 263.55±21.79 in right eyes and 266.79±25.69 in left eyes; out of 14 Severe NPDR cases it was 309.0±30.98 in right eyes and 317.81±30.27 in left eyes; out of 9 Very Severe NPDR cases it was 310.27±36.41 in right eyes and 314.72±36.88 in lefteyes; out of 6 Early PDR cases it was 354.17±36.41 in right eyes and 354.50±36.08 inleft eyes.

This shows that there is a significant increase in central macular thickness with the Severe NPDR stage onwards. Hence as the stage of DR progresses, there is an increase in macular thickness which may lead to visual loss due to DME. In a systematic review of **Virgili G et al**, the median central retinal thickness cutoff selected for data extraction was 250 µm (range 230 µm to 300 µm).[12] We followed the same guideline to define OCT proven DME and considered central retinal thickness 250±25 µm as normal, above these values we labelled it as DME.

CONCLUSION:

From the observations and results of the present study, it is evident that the prevalence of OCT-proven DME is 29.23% in cases with DR. Prevalence of DME in PDR cases is more than in NPDR cases. The percentage of OCT-proven DME in DR cases that were on Insulin (66.66%) is more than in cases not on Insulin (13.91%). Our study shows a higher percentage of DME with a duration of up to 5 years.

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