Scholars Journal of Applied Medical Sciences
Abbreviated Key Title: Sch J App Med Sci
ISSN 2347-954X (Print) | ISSN 2320-6691 (Online)
Journal homepage: www.saspublishers.com

OPEN ACCESS

Ophthalmology

A Descriptive Clinical Study of Macular Edema in Patients of Diabetes Mellitus

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DOI: 10.36347/SJAMS.2019.v07i10.016 | **Received:** 07.10.2019 | **Accepted:** 14.10.2019 | **Published:** 30.10.2019

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Abstract **Original Research Article**

Background: The number of people with diabetes has risen from 108 million in 1980 to 422 million in 2014. Almost two-third of all Type 2 and almost all Type 1 diabetics are expected to develop diabetic retinopathy (DR) over a period of time. ***Objectives:*** to study clinical pattern of Diabetic macular edema in patients with diabetic retinopathy in Diabetes mellitus type 2 (NIDDM) patients. 2. To determine prevalence of different types of diabetic maculopathy as determined by FFA. ***Material and Methods:*** This descriptive study was conducted in Department of Ophthalmology of tertiary care teaching hospital in north Maharashtra, India after obtaining ethical committee clearance. Patients with type 2 diabetes mellitus who presented to outpatient department and inpatients referred from other departments were evaluated as per inclusion and exclusion criteria. Demographic, general and clinical details were obtained which special emphasis on diabetes profile, ocular examination and pupil examinations. ***Statistical analysis:*** Mean, standard deviation, percentages and proportions were used for descriptive statistics. ***Results:*** Total 60 patients were included in the study. All patients were between 45 and 85 years with 17 patients in 45-55 years and 26 patients in 56-65 years, 12 patients in 66-75 years and 5 in 76-85 years range. Out of 60 patients, 34 were males and 26 females. The mean age in males was 60.8 ± 8.3 years and the mean age in females was 59.4±7.6 years and the overall mean age was 60.3 ± 8.1 years. Among the 120 eyes of 60 patients studied, diabetic maculopathy was found in 92eyes. As assessed by FFA focal macular edema was found in 35 eyes (38%), diffuse macular edema including cystoid macular edema was found in 29 eyes (31.5%), Ischaemic maculopathy in 11 eyes (11.9 %) and mixed maculopathy in 17 eyes(18.6%). Out of 92 eyes with maculopathy, 34 eyes (36.6%) had severe NPDR, 24 eyes (25.4%) had very severe NPDR, 15 eyes (16.9%) had moderate NPDR, 10 eyes (11.3%) had low risk PDR and 9 eyes (9.9%) had high risk PDR. ***Conclusion:*** Diabetic maculopathy occurred commonly in type 2 diabetes patients within first 10 years of onset of disease. Visual acuity loss significantly correlated with type of maculopathy.

Keywords: Diabetes Mellitus, Macular Oedema, Clinial assessment.

INTRODUCTION

The number of people with diabetes has risen from 108 million in 1980 to 422 million in 2014. The global prevalence of diabetes among adults over 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014. Diabetes prevalence has been rising more rapidly in middle- and low-income countries. Diabetes is a major cause of blindness, kidney failure, heart attacks, stroke and lower limb amputation. In 2016, an estimated 1.6 million deaths were directly caused by diabetes. Another 2.2 million deaths were attributable to high blood glucose in 2012[1].

India is set to emerge as the diabetic capital of the world. According to the WHO, 31.7 million people were affected by diabetes mellitus (DM) in India in the year 2000. This figure is estimated to rise to 79.4 million by 2030, the largest number in any nation in the world. Almost two-third of all Type 2 and almost all Type 1 diabetics are expected to develop diabetic retinopathy (DR) over a period of time [2].

As the number of persons with diabetes increases, the development of microvascular complications like retinopathy, nephropathy and neuropathy also rises. These microvascular complications are linked to the duration of diabetes

mellitus, poor glycemic control and systolic hypertension [2]. The magnitude of damage caused by these microvascular complications of diabetes stresses the need for sensitive markers of screening for retinopathy and nephropathy. The sensitive marker for the detection of diabetic nephropathy is to estimate excretion of microalbumin in urine; and for the detection of diabetic retinopathy (DR), to have a fundus evaluation after pupillary dilatation [4, 5]. The common cause of visual impairment in diabetic retinopathy include macular edema, macular ischemia and complications due to proliferative retinopathy. Diabetic macular edema (DME) is the most common cause of visual impairment in patients with diabetes mellitus. The majority of diabetics have type 2 diabetes, wherin macular edema is commoner.

This study was carried out with objectives

- To study clinical pattern of Diabetic macular edema in patients with diabetic retinopathy in Diabetes mellitus type 2 (NIDDM) patients.
- To determine prevalence of different types of diabetic maculopathy as determined by FFA.

METHODOLOGY

This descriptive study was conducted in Department of Ophthalmology of tertiary care teaching hospital in north Maharashtra, India after obtaining ethical committee clearance.

Source of Data

Patients who presented to our outpatient department and inpatients referred from other departments were evaluated as per inclusion and exclusion criteria and a total of 60 patients were selected for the study.

Inclusion Criteria

Patients who presented with following were included

- Patients reporting to ophthalmology OPD having age ≥ 45 yrs with Type II (NIDDM) diabetes mellitus
- Diabetic retinopathy with clinically significant macular edema.
- DME with any level of diabetic retinopathy.

Exclusion Criteria

- The following cases were excluded from the purview of the study.
- Opacities of the media affecting vision – corneal, lenticular and vitreous opacities.
- Complications of diabetic retinopathy like – vitreous haemorrhage, retinal
- Detachment and advanced diabetic eye disease.
- Cases with other macular diseases accounting for visual loss.
- Previous treatment for diabetic retinopathy – laser, IVTA.
- Contraindications for fluorescein angiography like known hypersensitivity and pregnancy.
- Patients with severe kidney disease or on renal dialysis

Sample size: This study included 60 patients with above mentioned criteria.with 120 eyes all having some form of CSME.

Procedure

- A case sheet is prepared noting the name, age, sex, address, occupation and income of the patients.
- Clinical history was recorded noting carefully –
- age of onset of diabetes
- duration of diabetes
- symptoms of diabetes and its complications
- history of treatment taken for diabetes
- history of ocular treatment taken if any
- history of hypertension etc.

Medical checkup of the patient done in detail

The patients were grouped as Type-II Non-Insulin dependent diabetes mellitus (NIDDM).

Subjects with type 2 diabetes were identified based on the American Diabete Association criteria.

Blood sugar level was monitored using glucometer and the patients were labelled as diabetic with-

- Fasting BSL more than 130mg/dl.
- Post prandial BSL more than 180 mg/dl.

The glucometer was calibrated every day and its reproducibility was assessed by measuring the blood glucose for the same patient six times and also with two machines

- An elaborate ocular examination was performed. Biomicroscopic examination of the anterior segment was performed to identify any abnormality. The visual acuity was recorded for both distance and near without and with correction. The IOP was recorded by Goldmann's Applanation Tonometer.
- The pupil was dilated using tropicamide and phenylephrine drops (phenylephrine avoided in patients who were hypertensive).
- A detailed fundus examination was done by direct, indirect ophthalmoscope and slit lamp biomicroscopy using 90D Volk lens.
- Retinal photographs were taken after pupillary dilatation (TOPCON fundus camera); all patients underwent 45°four-field stereoscopic digital photography. For those who showed evidence of any DR, additional 30° seven field stereo digital pairs were taken.

STATISTICAL ANALYSIS

Data was collected using a structured proforma on Excel software (Microsoft, Seattle, USA). Measurements were expressed as means and standard deviations for continuous variables and percentages for categorical variables and was analysed.

Ethical considerations

The study was conducted according to the Declaration of Helsinki; the protocol was reviewed and approved by the institutional ethics committee of the institute. A written informed consent was taken from all patients after explaining the procedure.

RESULTS

Total 60 patients were included in the study. All patients were between 45 and 85 years with 17 patients in 45-55 years and 26 patients in 56-65 years, 12 patients in 66-75 years and 5 in 76-85 years range. Out of 60 patients, 34 were males and 26 females. The mean age in males was 60.8 ± 8.3 years and the mean age in females was 59.4±7.6 years and the overall mean age was 60.3 ± 8.1 years.

Table-1: Duration of diabetes mellitus (n=60)

Duration of diabetic mellitus (in years)	No. of patients	Percentage
0-5	11	18.33%
6-10	20	33.33%
11-15	15	25.0%
16-20	10	16.66%
21-25	4	6.66%
Total	60	100%

In the study patients, the duration of diabetes mellitus ranged from 0-25 years. Among the 60 patients, 20 patients had diabetes mellitus since 6-10 years, 15 patients since 11-15 years, 10 patients since 16-20 years, 11 patients since less than 5 years and 4 patients from 20-25 years. Mean duration was 11.1 ± 6.1 years. Among the 60 patients, 42 patients (70%) were on oral hypoglycemic agents and 18 patients (30%) were on oral hypoglycemic agents and Insulin. Out of 60 patients of DME under study, 27 patients (45%) had unilateral DME whereas 33 patients (55%) had bilateral DME.

Table-2: Laterality Wise Distribution of Diabetic Macular Edema (n=60)

Laterality	No. of Patients
Unilateral DME	27
Bilateral DME	33
Total	60

Among the 120 eyes of 60 patients studied, diabetic maculopathy was found in 92eyes. As assessed by FFA focal macular edema was found in 35 eyes (38%), diffuse macular edema including cystoid macular edema was found in 29 eyes (31.5%), Ischaemic maculopathy in 11 eyes (11.9 %) and mixed maculopathy in 17 eyes (18.6%).

Table-3: Distribution of types of diabetic maculopathy (n=92)

Type of maculopathy	No. of eyes	Percentage
Focal	35	38%
Diffuse	29	31.5%
Ischaemic	11	11.9 %
Mixed	17	18.6%
Total	92	100%

Out of 92 eyes with maculopathy, 34 eyes (36.6%) had severe NPDR, 24 eyes (25.4%) had very severe NPDR, 15 eyes (16.9%) had moderate NPDR, 10 eyes (11.3%) had low risk PDR and 9 eyes (9.9%) had high risk PDR.

Table-4: Distribution of severity of diabetic retinopathy (n=92)

Severity of retinopathy	No. of eyes	Percentage
Mild NPDR	-	-
Moderate NPDR	15	16.9%
Severe NPDR	34	36.6%
Very severe NPDR	24	25.4%
Low Risk PDR	10	11.3%
High Risk PDR	9	9.9%
Total	92	100%

Out of 92 eyes with maculopathy, 34 eyes (36.6%) had severe NPDR, 24 eyes (25.4%) had very severe NPDR, 15 eyes (16.9%) had moderate NPDR, 10 eyes (11.3%) had low risk PDR and 9 eyes (9.9%) had high risk PDR.

Table-5: Distribution of type of Diabetic Macular Edema depending on severity (n=60) (international clinical classification of diabetic retinopathy severity of diabetic macular edema)

Severity of Maculopathy	No. Of Patients	Percentage%
Mild	16	26.7%

Moderate	18	30%
Severe	26	43.3%
Total	60	100%

Among the 60 patients with CSME, 60 patients had macular edema in one or both the eyes. Among the 60 patients with macular edema, 16 patients (26.7%) had mild degree of macular edema whereas 18 patients (30%) had moderate and 26(43.3%) patients had severe type of macular edema.

DISCUSSION

In the present study all patients were between 45 and 85 years of age. The majority (43.3%) of them were between 56 and 65 years of age. Mean age in males was 60.8 ± 8.3 years and in females was 59.4±7.6 years. Overall mean age was 60.3 ± 8.1 years. In the study by Lawson *et al*. [6] the mean patient age was 58 years (range 29-73 years). In the study by Sander *et al*. [7] the mean age of patients was 57 years (range 28-71 years). The study by Golubovic A[8] included 86 patients with mean age of 61.8 years (range 49-73 years) in males and 62.8 years (range 51-74 years) in females.

In the present study all patients had type 2 diabetes mellitus. In the study by Shetty KJ *et al*.[9] 30 of 56 patients had Type 2 diabetes and majority were in 5th decade. In the study by Lawson PM *et al*.[6] of 94 patients with untreated diabetic maculopathy the patients were predominantly Type 2 diabetics.

In the present, gender distribution was with total of 34 males and 26 females. The study by Wani J *et al*.[10] was showing a slight predominance of females with an overall male:female ratio of 27:29. In the study of Golubovic Arsovska[8] a mild domination of females (55.8%) versus males (44.2%) was observed, but there was no statistical significant association with its presence.

In the present study, the duration of diabetes mellitus ranged from 0 year to 25 years with a mean duration of 11.1 ± 6.1 years. The study by Zhang *et al*. [10] showed that diabetic maculopathy often occurred within 10 years of diabetic duration and its severity and incidence increased year by year. In the study by Shetty KJ *et al*.[9] the duration of diabetes in patients with diabetic maculopathy ranged from 8-18 years in type 2 diabetes (mean 12.7 years) and 16-21 years in type 1 diabetes (mean 18.7 years).

In the study by Lawson *et al*. [6] 32 of 94 patients had maculopathy diagnosed at or within 2 years of the diagnosis of diabetes. In the study by Wani JS *et al*. [10] 62% in Group I (patients having NPDR) and 88% in Group II (patients having PDR) had a duration of diabetes ranging between 6 and 15 years. The average duration of diabetes was 10.3 years and 11.1 years in Groups I and II respectively. In both groups, patients with maculopathy had an average duration of diabetes, greater than seen in subjects without maculopathy.

In the present study of 60 patients 70% were on oral hypoglycemic agents and 30% on oral hypoglycemic agents + insulin. Sparrow *et al*.[11] found a slightly higher prevalence of maculopathy in patients without insulin treatment and the reduction of vision due to maculopathy was revealed in 10% of the population on insulin.

In the study by Wani S *et al*. [10] in Group I (patients with NPDR) 76.19% were controlled on various hypoglycemic agents and insulin respectively. There was significant difference statistically (p=0.01) among patients on oral hypoglycemic agents and on insulin.

Diabetic maculopathy was classified into 4 types depending on fluorescein angiography findings. Out of the 120 eyes of 60 patients, 92 eyes showed diabetic maculopathy. Out of the 92 eyes, focal macular edema (38%) and diffuse macular edema including cystoid macular edema (31.5%) were seen predominantly. Ischaemic maculopathy (11.9%) and mixed maculopathy (18.6%) with a combination of focal and diffuse or focal and ischaemic were seen in the rest of the eyes.

In the study by Jian Wanchen *et al*.[12] out of 211 eyes studied, 126 eyes had focal edema (59.7%), 60 eyes had diffuse edema (28.4%) and 5 eyes had ischaemic maculopathy (2.4%).

In comparison, in the study by Zi-qin MA *et al*.[13] out of 819 eyes studied, 311 eyes showed focal macular edema (38%), 434 eyes showed diffuse macular edema including cystoid macular edema (53%) and 25 eyes showed ischaemic maculopathy (3.1%). In study by Golubovic-Arsovska[8] mixed type of maculopathy was most frequently seen (56%).

In the study by Espiritu *et al*. [14] FA findings were macular staining (83.86%), macular ischaemia (10.76%) and preretinal membrane (5.38%). Microaneurysms (72.65%) was the most common lesion associated with macular staining, followed by capillary leakage (40.04%), cystoid macular edema (3.59%), perifoveal capillary dropout with microaneurysm (2.24%) and capillary with microaneurysm leakage (1.34%).

In the study conducted by us, the severity of diabetic retinopathy was graded based on ETDRS classification. The maculopathy was more frequently seen in NPDR (76%) than PDR (24%). In comparison,

the study by Klein R *et al*. [15] reported an incidence of 8% of macular edema among eyes with moderate to severe NPDR and 71% among eyes with PDR.

In the study by Gaudric *et al*.[16] the incidence of diabetic maculopathy was 6% among eyes with mild-moderate NPDR, 20-60% among eyes with severe and very severe NPDR and 70-74% among eyes with PDR. In the study by Wani J *et al*. [10] the incidence of maculopathy was more in eyes with PDR (70%) than is eyes with NPDR (42%). The higher prevalence of maculopathy in NPDR in the present study could have been due to nonrecognition of maculopathy in PDR due to retinal proliferation, vitreous haemorrhage, tractional bands and other complications obscuring the macular region.

CONCLUSION

Diabetic maculopathy occurred commonly in type 2 diabetes patients within first 10 years of onset of disease. Fluorescein angiography showed higher frequency of focal macular edema due to leakage from microaneurysms and diffuse macular edema due to leakage from retinal capillary bed and intraretinal microvascular abnormality. Visual acuity loss significantly correlated with type of maculopathy. Ischaemic maculopathy with enlarged foveal avascular zone and mixed maculopathy had poor visual prognosis. Visual acuity loss was more in diffuse edema as compared to focal edema. Normal vision was noted in patients with focal macular edema due to sparing of fovea. Diabetic maculopathy can occur even with normal vision. Preservation of sight is of great importance in maculopathy since improvement in vision is uncommon in spite of best treatment. This highlights the importance of detailed fundus examination by slit lamp biomicroscopy in all cases of diabetic retinopathy for early and prompt diagnosis. Further ancillary investigation by FA helps in delineating the type and extent of lesion and in assessing the severity and prognosis. FFA also serves as a guide in laser photocoagulation and for followup after treatment and for retreatment.

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