Section: Opthalmology

Original Research Article

FUNDUS CHANGES IN TYPE 2 DIABETIC PATIENTS

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Received *: 15/03/2026*
Received in revised form *: 10/04/2026*
Accepted *: 26/04/2026*

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DOI: 10.70034/ijmedph.2026.3.799

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2026; 16 (3); 5172-5181

ABSTRACT

Background: The aim is to know the prevalence of diabetic retinopathy in relation to age, sex, duration of diabetes, glycemic control and to study fundus changes in type 2 diabetic patients.

Materials and Methods: This is a prospective non interventional case series. A total number of 500 cases are included in the study conducted during the period from December 2014 to June 2016.All patients with diabetes who attended the outpatient department of ophthalmology at Maharajah's institute of medical sciences, Vizianagaram, are included in the study and from whom the data collected was categorized into age, sex and then analyzed. Examination of anterior segment was done followed by posterior segment examination after dilating the pupil to look for any changes in the retina suggestive of diabetic retinopathy.

Results: In the present study, the prevalence of diabetic retinopathy in type 2 diabetes is nearly 40%. Diabetic retinopathy is more common in males than females with male: female ratio being 1.2:1. Non proliferative diabetic retinopathy was more common than proliferative diabetic retinopathy. Mild non proliferative diabetic retinopathy was seen in most patients with diabetic retinopathy. Diabetic macular edema is most commonly associated with very severe non proliferative diabetic retinopathy and proliferative diabetic retinopathy. Prevalence of diabetic retinopathy increases with the duration of diabetes with highest incidence after 10 years duration of diabetes. Severity of retinopathy also increases with the duration of diabetes; there was increased incidence of severe, very severe non proliferative diabetic retinopathy and proliferative diabetic retinopathy with diabetes greater than 10 years of duration.

Conclusion: The present study concluded that, good glycemic control should indeed have a beneficial effect on the micro vascular complications like cardiovascular complications, nephropathy, neuropathy and including retinopathy.

Keywords: Diabetic retinopathy, Glycemic control, Vascular complications, Posterior segment.

INTRODUCTION

Diabetic retinopathy (DR) is one of the main complications in patients with diabetes and has been one of the leading causes of visual loss. Diabetes mellitus may be defined as primary disorder of carbohydrate metabolism, secondarily involving the protein and fat metabolism characterized by hyperglycemia and glycosuria. It is a predictable but not a preventable disease. The increased longevity of diabetic patient as a result of modern treatment has made it as a major cause of serious eye diseases. Its gravest ocular manifestation, diabetic retinopathy is the most frequent and may be the earliest demonstrable evidence of complication of diabetes. Usually, a diabetic patient seeks the advice of ophthalmologist only when the ocular condition is in the advance stage. It is therefore, essential to examine the fundus and anterior segment of eye of

every diabetic patient periodically at regular intervals to detect early cases by diabetic clinics.

Chronic hyperglycemia and its associated nonenzymatic glycation play an important role in the development of microangiopathy. There are a series of risk factors related to the development and progression of DR such as duration of DM, poor glycemic control, and oxidative stress.[1] However, these factors alone do not explain the occurrence of retinopathy. It may be absent in some patients with poor glycaemic control even over a long period of time, while others may develop retinopathy in a relatively short period despite good glycaemic control. This raises the possibility of a genetic predisposition.

Blindness due to diabetes mellitus could have a variety of reasons including an increased prevalence of cataract, glaucoma and retinopathy. Two significant forms of sight-threatening retinopathy are proliferative diabetic retinopathy and diabetic maculopathy.

Present study was done to know to the prevalence of diabetic retinopathy in relation to age,sex,duration of diabetes,glycemic control and to study fundus changes in type 2 diabetic patients.

Aims and Objectives

1. To study fundus changes in type 2 diabetic patients.
2. To study prevalence of non proliferative diabetic retinopathy (NPDR) and proliferative diabetic retinopathy (PDR) in type 2 diabetic patients.
3. To study changes in the fundus in relation to duration of diabetes.

MATERIALS AND METHODS

All patients with diabetes who attended the outpatient department of ophthalmology at Maharajah's institute of medical sciences,Vizianagaram,are included in the study and from whom the data collected was categorized into age,sex and then analyzed. Detailed history was taken regarding duration of disease, glycemic control and ocular symptoms.Examination of anterior segment was done followed by posterior segment examination after dilating the pupil to look for any changes in the retina suggestive of diabetic retinopathy.

Study Design: This is a prospective non interventional case series.

Study Period: From December 2014 to June 2016.

Sample Size: A total number of 500 cases are included in the study

Source of data: The study is conducted on patients with diabetes who attended the department of ophthalmology at Maharajah's institute of medical sciences, Vizianagaram.

Selection of cases

Inclusion criteria

1. All patients with type 2 diabetes mellitus including newly diagnosed cases
2. Type 2 diabetic patients with hypertension

Exclusion Criteria

1. Gestational diabetes mellitus
2. Steroid induced diabetes
3. Patients with co-morbidities like vasculopathies,bleeding disorders and trauma.

Ethical Issues

1. Informed consent was obtained.
2. Confidentiality of the individual's information was maintained

Methods of Clinical Examination

A detailed history was obtained with emphasis on duration of diabetes, glycemic status of patient and details regarding treatment of diabetes.(oral hypoglycemic drugs or insulin).

Ocular examination includes

1. Visual acuity, recorded by using snellen's charts for each eye separately.
2. Colour vision by using ishihara's charts.
3. Anterior segment of the eye is examined using slit lamp.
4. Intraocular pressure was recorded by using Non contact tonometer.
5. If the intra ocular pressures are normal pupil was dilated with 10%Phenylephrine and 1% Tropicamide eye drops.
6. After dilatation posterior segment examination was done using +78D or +90D lens to rule out any changes in the retina suggestive of diabetic retinopathy. Depending upon the changes in retina they were broadly classified into non proliferative diabetic retinopathy (NPDR) and proliferative diabetic retinopathy (PDR) according to Early treatment diabetic retinopathy study (ETDRS) classification. Non proliferative diabetic retinopathy was further classified into mild, moderate, severe and very severe NPDR with or without diabetic macular edema and proliferative diabetic retinopathy into early or high risk PDR.
7. Fundus picture was obtained using Topcon TRC-NW8F fundus camera. Other tests like Random blood sugar and glycated haemoglobin HbA1c were performed to know the glycemic status of the patient.

Early treatment diabetic retinopathy study (ETDRS) Classification:[2]

Non proliferative diabetic retinopathy

Proliferative diabetic retinopathy

Non proliferative diabetic retinopathy (NPDR)- It is characterized by micro-aneurysms, retinal haemorrhages, hard exudates, cotton wool spots,vascular changes like venous tortuosity, dilatation and beading.

MILD NPDR:

- At least one microaneurysm
- Definition not met for moderate nonproliferative retinopathy, severe nonproliferative retinopathy, early proliferative retinopathy, or high-risk proliferative retinopathy.

Moderate NPDR

- Hemorrhages and/or microaneurysms ≥ standard photograph 2A*; and/or soft exudates, venous beading, or intraretinal microvascular abnormalities definitely present
- Definition not met for severe non proliferative retinopathy, early proliferative retinopathy, or high-risk proliferative retinopathy.

Severe NPDR

- More than 20 intraretinal haemorrhages in each of the 4 quadrants.
- Definite venous beading in atleast 2 quadrants
- Prominent IRMA in atleast 1 quadrant
- No signs of proliferative retinopathy

Very severe NPDR

- Any two or more of severe NPDR
- Definition not met for early proliferative retinopathy, or high-risk proliferative retinopathy.

Proliferative diabetic retinopathy (PDR) – Composed of Neovascularisation on the Disc (NVD) or Elsewhere (NVE), and/or Preretinal or Vitreous haemorrhage, and/or Fibrous tissue proliferation.

Early PDR

- New vessels
- Definition not met for High risk PDR.

High-risk PDR

- NVD (1/3 – 1/2 disc area)
- NVD and preretinal or vitreous haemorrhage
- NVE ≥ 1/2 disc area and vitreous or preretinal haemorrhage

Advanced diabetic eye disease (not included in ETDRS classification)

Serious vision threatening complications of diabetic retinopathy occur in patients who have not had laser therapy or in whom laser photocoagulation has been unsuccessful or inadequate.They are

- Retrohyaloid or intragelhemorrhage
- Tractional retinal detachment
- Tractional retinoschisis
- Rubeosis iridis

Clinically significant macular oedema (CSME)–

It is defined as any of the following:

- Retinal thickening located at or within 500 microns from the centre of the foveal avascular zone (FAZ).
- Hard exudates with retinal thickening 500 microns at or within from the centre of FAZ
- Retinal thickening 1 disc diameter (DD) or larger in size located within 1DD of the FAZ.

RESULTS

Table 1: Showing sex distribution

Sex	Number	Percentage
Males	284	56.8%
Females	216	43.2%

Table 2: Age group prevalance

Age group	Males	Females	Total
30-39	10(2%)	12(2.4%)	22(4.4%)
40-49	43(8.6%)	54(10.8%)	97(19.4%)
50-59	88(17.6%)	78(15.6%)	166(33.2%)
60-69	110(22%)	60(12%)	170(34%)
70 and above	33(6.6%)	12(2.4%)	45(9%)

In our study majority of them presented in the seventh decade(34%) followed by sixth decade(33.2%).

Table 3: showing patients with and without retinopathy changes

Parameter	No of patients	Percentage
Without diabetic retinopathy	301	60.20%
With diabetic retinopathy	199	39.80%

In our study only 199(39.80%) out of 500 diabetic patients showed retinopathic changes.

Table 4: showing retinopathy changes

Parameter	Total no of eyes
MILD NPDR	151(39.2%)
MODERATE NPDR	108(28.1%)
SEVERE NPDR	71(18.4%)
VERY SEVERE NPDR	18(4.7%)
PDR	37(9.6%)

Among 199(398eyes) patients with retinopathy changes, mild NPDR was most common (39.2%), seen in 151 eyes followed by moderate NPDR (28.1%). Severe NPDR was seen in 71 eyes (18.4%) and very severe NPDR was seen in 18 eyes (4.7%). proliferative diabetic retinopathy was seen in 37 eyes(9.6%) and the rest 13 eyes were normal.

Table 5: showing patients with diabetic macular edema and clinically significant macular edema

Parameter	Total no of eyes	Percentage

Diabetic macular edema	52	13.5%
Clinically significant macular edema	27	7%

Out of 385 eyes with retinopathic changes only 52 eyes (13.5%) showed diabetic macular edema. Among these 52 eyes with macular edema, 27(7%) were clinically significant macular edema.

Out of 151 eyes with mild NPDR only 2 eyes (1.3%) had diabetic macular edema. Among 108 eyes with moderate NPDR 12 eyes(11.2%) had diabetic macular edema.In case of severe NPDR, 15 eyes (21.1%) had diabetic macular edema. Very severe NPDR was associated with diabetic macular edema in 14 eyes (77.7%). Nearly one fourth of patients 9 eyes (24.3%) with proliferative diabetic retinopathy had macular edema.

Table 6: showing retinopathy changes with duration of diabetes.

Duration of diabetes	Total no of patients	Patients with diabetic retinopathy
< 1 year	71	11(15.4%)
1- 5 years	263	81(30.7%)
6- 10 years	109	62(56.8%)
11- 15 years	32	27(84.3%)
> 15 years	25	18(72%)

It is clearly seen that number of patients with Retinopathy changes increase with the duration of diabetes. Out of 71 patients with duration of diabetes less than one year only 11 patients (15.4%) showed retinopathy changes. Highest prevalence of diabetic patients with retinopathy were seen with 11 to 15 years duration of diabetes.

With increasing in duration of diabetes, there is increased prevalence of diabetic retinopathy P value was calculated by using chi-square test (0.0006) which was highly significant.

Table 7: showing duration with various retinopathy changes

Duration of diabetes	Mild NPDR	ModeratenPDR	SeverenPDR	Very severe NPDR	Early PDR	HighriskPDR	Total
< 1 YEAR	20	-	-	-	-	-	20
1-5YEARS	70	45	24	7	6	-	152
6-10 YRS	47	40	10	8	18	-	123
11-15 YRS	8	6	32	2	1	5	54
>15YEARS	6	17	5	1	5	2	36
Total	151	108	71	18	30	7	385

In our study among 71 patients (142 eyes) with less than one year duration of diabetes only mild NPDR was found in 20 eyes(14.1%).There are no changes of severe diabetic retinopathy. The prevalence of diabetic retinopathy started to raise proportional to the duration of the disease such that those with upto 5 years duration. Among 263 patients(526 eyes),152 eyes(28.9%) had diabetic retinopathy,of which 37eyes (7.1%) had severe,very severe or early and high risk proliferative diabetic retinopathy.These figures have further increased in patients having diabetes for 6 to 10 years.123 eyes(56.4%) among 218 eyes showed evidence of diabetic retinopathy,of which 36 eyes (16.5%) had severe to very severe or proliferative diabetic retinopathy. Among 64 eyes with 11 to 15 years of duration of diabetes 54 eyes (84.4%) had retinopathy changes, of which 40 eyes(62.5%) had severe to very severe or proliferative diabetic retinopathy.25 patients(50 eyes) with duration of greater than 15 years of diabetes 36 eyes(72%) had retinopathy, among them 7 eyes(14%) had proliferative diabetic retinopathy.

Table 8: showing retinopathy changes in relation to glycemic status.

Glycemic status	Total no of patients	No of patients with diabetic retinopathy	Percentage
Controlled	166	53	31.9%
Uncontrolled	334	146	43.7%

In our study out of 500 patients 166 had good blood glucose control, of which 53(31,9%) patients had retinopathy whereas among 334 with no blood glucose control 146 (43.7%) had retinopathy.

Table 9: showing uncontrolled glycemic status with retinopathy

Duration	Total no of patients with uncontrolled diabetes	Patients with diabetic retinopathy
Less than 1 year	53	9(16.9%)
1-5 years	158	54(34.1%)
6-10 years	75	46(61.3%)
11-15 years	25	20(80%)
Greater than 15 years	23	17(73.9%)

With increasing duration and uncontrolled glycemic status, there is increased incidence of retinopathy.

P value (0.00005) was calculated by using chi-square test by comparing total no of patients with

uncontrolled diabetes with patients who had retinopathy changes and without retinopathy with increased duration, which was found to be highly significant.

Table 10: showing controlled glycemic status with retinopathy

Duration	Total no of patients with controlled glycemic status	Patients with diabetic retinopathy
Less than one year	18	2(11.7%)
1-5 years	105	27(25.7%)
6-10 years	34	16(45.7%)
11-15 years	7	6(85.7%)
Greater than 15 years	2	1(50%)

Even with controlled glycemic status with increased duration there was increased incidence of retinopathy.

P value (0.00005) was calculated by using chi-square test by comparing total no of patients with controlled diabetes, with patients who had retinopathy changes and without retinopathy with increased duration, which was found to be highly significant.

Table 11: severity of retinopathy in relation to glycemic status.

Retinopathy	With glycemic control (99 eyes)	Without glycemic control (286 eyes)
Mild	54(54.5%)	97(33.9%)
Moderate	27(27.3%)	81(28.3%)
Severe	12(12.1%)	59(20.1%)
Very severe	2(2.0%)	16(5.6%)
Early pdr	4(4.0%)	26(9.1%)
High risk pdr	0	7(2.4%)

Among 166 patients(332 eyes) with good blood glucose control, only 99 eyes (29.8%) showed retinopathy changes.Outof these 99 eyes, half of them (54eyes)had mild NPDR. 27 eyes (27 .3%) had moderate NPDR,12 eyes(12.1%) had severe NPDR,and severe forms of retinopathy like very severe NPDR and PDR was seen in only 6% of cases.Whereasin patients who had poor blood glucose control mild NPDR was seen in one third of eyes (33.9%),moderate NPDR was seen in 81 eyes(28.3%),59 eyes(20.1%) had severeNPDR,very severe NPDR was seen in 16 eyes(5.6%) and PDR was seen in 33 eyes(11.5%). P value was calculated by comparing no of eyes in controlled and uncontrolled groups in each category of retinopathyit was 0.003 which is highly significant.

DISCUSSION

Age and Sex

In present study out of 500 cases 284(60.2%) were males and the rest 216(39.8%) were females with male: female ratio being1.3:1 showing a male predominance. [Table 1]

Out of 199 patients with retinopathy changes males were 122 and females were 77 with male: female ratio1.58:1. In our study it was observed that DR was found to be higher in men compared with women. Several studies also revealed that DR is more prevalent among men compared with women.

In the present study, 500 patients with type 2 diabetes were studied in different age groups which included a range from 30 to 90 years. Among them, 22 patients presented in their fourth decade.97 patients presented between 40-49 years,166 patients between 50-59 years with majority of them 170 patients presented in seventh decade(60-69).The rest 45 patients were above 70 years of age. [Table 2]

In our study the mean age of presentation in males was 62.3 years whereas in females it was 59.6 years. The mean age of diabetic patients with retinopathy were 61.1years and without retinopathy was 58.6 years.

Razia A Ahmed,[3]Shamsun N Khalil reported total of 401 randomly selected type 2 diabetic patients were included. Their ages ranged from 20 to 90 years, with a mean SD of 54.6 (12.3) years and a median of 54.0 years. The mean age of male and female diabetic patients were 54.93 years and 54.25 years. The mean age of onset for DM was 43.91 years with DR while it was 46.30 years for diabetics without retinopathy.

R Singh et al,[4] reported the mean age of diabetics with and without retinopathy was 52.8±11.5years and 49.3±8.5 years. The age of the patients was between 40 and 70 years for all the three groups. The mean age in diabetic patients with retinopathy was 58.56 ± 9.09 years, in diabetic patients without retinopathy 56.20 ± 9.89 years, and in controls 51.79 ± 10.12 years. In diabetic patients with retinopathy, the number of men were 36 and women were 14. Among the diabetic patients without retinopathy, the number of men were 39 and women were 11.

In study conducted by Lizette Mowatt,[5] there were 71 patients, 38 females and 33 males who were Type II Non-Insulin Dependent Diabetes Mellitus patients (NIDDM group). The mean age was 61.3 ± 1.3 years for the NIDDM group.

Prevalence of retinopathy in type 2 diabetic patients: Retinal involvement in diabetics is fairly common. Its incidence, in Indian series has varied from 7.3 to 40.0 percent and in the western series, from 4.8 to 45.3 percent. sometimes relatively higher (60.0%) incidence of retinopathy in patients is perhaps due to the hospital based study where a

natural selection is unavoidable, particularly in a referral centre.

In our study out of 500 patients with type 2 diabetes, only 199 (39.8%) had diabetic retinopathy changes and the rest 301(60.2%) patients had no retinopathy changes. So the prevalence of retinopathy in our study was nearly 40% which is comparable to other studies. [Table 3]

In a study conducted by, Mahdi Tazhib,[6] retinopathy prevalence in diabetic patients was 53.4%. In this study, 3535 patients were investigated, where 1887 cases (53.4%) had retinopathy.

Among 23 patients studied by, R Singh, JK Agrawal retinal changes were found in 16 (69.5%) patients. In the remaining 7(30.5%), the fundus was normal which was comparatively higher to small sample size.

A number of studies show marked differences in the prevalence of retinopathy in patients with type 2 diabetes. Of the estimated 10.2 million US adults 40 years and older known to have DM, the estimated crude prevalence rates for retinopathy were 40.3%, while an urban population-based study from India documented prevalence of diabetic retinopathy in diabetic subjects ranged from 17.6% to 26.8%.

Elhadd reported the prevalence of DR in persons with known diabetes was 17.8%, while in persons with newly detected diabetes (duration of diabetes <1 month) it was 10.2%. Persons with known diabetes had significantly higher prevalence of referable DR compared to newly detected diabetes [30.2% vs. 25.4%]. There is evidence that DR may be present even at the time of diagnosis of type 2 diabetes due to the insidious onset of this disease which estimates that on an average, the disease may set in up to 7 years before the initial diagnosis of diabetes.[7] The prevalence of DR among newly diagnosed diabetic subjects in this study was 10.2%, which is higher than the figure of 7.3%, reported earlier in a clinic-based population as well as in an earlier population based study from the same region (5.1%).

In our study out of 16 patients who were recently diagnosed to have diabetes(less than one month duration), 2 patients (12.5%) had retinopathy. The prevalence is almost similar to other studies.

In our study among199 patients retinopathy changes were seen only in 385 eyes. The rest 13 eyes showed no retinopathy. Among these 385 eyes with retinopathy Non proliferative diabetic retinopathy was seen in 348 eyes (90.5%)proliferative diabetic retinopathy was seen in 37 eyes (9.6%).

Among 348 eyes with Non proliferative diabetic retinopathy,Mild NPDR was most common(39.2%),seen in 151 eyes followed by moderate NPDR 108 eyes(28.1%),severe NPDR was seen in 71 eyes(18.44%) and very severe NPDR was seen in only in 18 eyes(4.6%). [Table 4]

Proliferative diabetic retinopathy was seen in 37 eyes (9.61%).out of 37 eyes with PDR 30(7.7%) had early PDR and the rest 7 eyes (1.8%) had high risk PDR.

In the present study out of 385 eyes with retinopathic changes only 52 eyes (13.5%) showed diabetic macular edema. [Table 5]

Out of 151 eyes with mild NPDR only 2 eyes (1.3%) had diabetic macular edema.Among 108 eyes with moderate NPDR 12 eyes(11.2%) had diabetic macular edema. In case of severe NPDR 15 eyes(21.1%) had diabetic macular edema. Very severe NPDR was associated with diabetic macular edema in 14 eyes(77.7%). Nearly one fourth of patients 9 eyes (24.3%) with proliferative diabetic retinopathy had macular edema.

It is clearly seen from our study that diabetic macular edema is more commonly associated with very severe non proliferative diabetic retinopathy and proliferative diabetic retinopathy which is consistent with other studies like Razia(108) who reported that maculopathy were found in only 7.2% of DR patients and maculopathy was associated significantly with the severe NPDR and PDR.

Out of these 52 with macular edema, 27 were clinically significant macular edema. It was seen in 2 eyes with moderate non proliferative diabetic retinopathy,8 eyes with severe and 10 eyes with very severe non proliferative diabetic retinopathy had clinically significant macular edema. It was seen in 7 eyes with proliferative diabetic retinopathy. Clinically significant macular edema was most commonly associated with very severe non proliferative diabetic retinopathy and proliferative diabetic retinopathy.

Our results were consistent with other studies,Agrawal, L.P et al,[8] in their study found that most of their patients had grade I and 11 retinopathy, Grade III retinopathy was seen in 1.5 per cent and none had grade 1V changes. Nearly sixteen percent of the patients had grade V changes.

In the study done by Razia AAhmed,[3]Shamsun N Khalil, MohammadAA Al-Qahtani

Mild NPDR was seen in 57.5% of the patients, moderate NPDR in 19.9% and severe NPDR in 11.0% while 11.6% of diabetic patients had PDR.

A study was done in Madras, south india where a cohort of 6792 of NIDDM were examined, which showed 2319(34.1%) of diabetic retinopathy, 2090(30.8%) being NPDR, 229(3.4%) being PDR and 435(6.4%) showed maculopathy.[9]

Agarwal et al conducted a study on 4067 patients out of which the prevalence rate of diabetic retinopathy was 1176(28.9%), 938 patients (79.8%) had NPDR, 172 patients (14.6%) had PDR and 68(5.8%) had maculopathy.[8]

A study done by Narendran et al in diabetic patients aged above 50 years of age in 5215 patients, which showed an overall prevalence rate of DR to be 26.2%, Out of which NPDR was seen in 94.1% cases.[10]

Bansal p et al conducted a study on 500 patients showed the prevalence of DR was seen to be 9.44%

when duration of diabetes detected was less than 5 years and was 76.47% in patients with diabetes of more than 20 to 25 years. The study also showed the prevalence of DR to be 32% and NPDR was 71.88% and 28.12% of PDR.[16]

Similarly, study conducted by Aggarwal et al,[8] showed that 79.8% patients had NPDR, 14.6% patients had PDR, and 5.8% patients had maculopathy. In study conducted by Javadi et al., 72.9% patients had NPDR, 27.1% patients had PDR, and 15.8% patients had CSME.

Another study conducted by Gunnlaugsdottir et al,[10] revealed that 92.75% patients had NPDR, 3.6% patients had PDR and 3.6% had CSME.

In the study done by UKPDS,[15]out of 142 diabetic retinopathy, 53.6% had mild non-proliferative diabetic retinopathy, 23.9% had moderate non-proliferative diabetic retinopathy, 2.8% had severe non-proliferative diabetic retinopathy, 7.8% had proliferative diabetic retinopathy, and 0.7% had high-risk proliferative diabetic retinopathy.)

	RAZIA et al	UKPDS	OUR STUDY
MILD NPDR	57.5%	53.6%	39.2%
MODERATE NPDR	19.9%	23.9%	28.1%
SEVERE NPDR	11.0%	2.8%	18.4%
VERY SEVERE NPDR	-	2.8%	4.7%
PDR	11.6%	8.5%	9.6%

Prevalance of retinopathy in relation to duration:

Retinopathy is one of the chronic and common disorders of diabetic and is the main cause of blindness in adult population. Many factors affect the development of diabetic retinopathy. In this study, in addition to determine retinopathy prevalence in diabetic patients, it's relation with duration of diabetes was also studied.

In the survey conducted by Askarishahiet al., significant association had been observed between duration of diabetes and blood sugar control method with retinopathy.[16] On the basis of the results declared by Rafati and their colleagues, significant association between retinopathy and sex, period of disease, and the blood sugar control method had been observed.[12]

In our study,it is clearly seen that number of patients with Retinopathy changes increases with the duration of diabetes. Out of 71 patients with duration of diabetes less than one year only 11 patients (15.4%) showed retinopathy changes. out of 263 patients with diabetes 1-5 year duration 81(51.5%) had retinopathy changes followed by 62 (56.8%)patients among 109 with 6-10 years of duration. Patients with Highest (84.3%)incidence of retinopathy changes were seen with 11 to 15 years duration of diabetes. Among 25 patients with diabetes greater than 15 years duration 18(72%) of them had diabetic retinopathy. [Table 6]

In our study with increasing in duration of diabetes, there is increased prevalence of diabetic retinopathy .p value was calculated by comparing total no of patients with diabetic retinopathy and without diabetic retinopathy in each duration. It (p value) was calculated using chi-square test (0.0006) which was highly significant. So in our study, there is significant association between duration of diabetes and diabetic retinopathy (P<0.0006).

Increased incidence of retinopathy with increase in duration of diabetes (type1 and type 2) was noted in studies conducted by Klein et al and Yanko et al.[9]

Agarwal et al study has shown the maximum prevalence of DR in patients of >15 years of diabetes to be 52.2%.[8] This study shows an increasing prevalence of DR with increasing duration of diabetes and 62% prevalence of DR with duration of DM of 16-20 years, but higher prevalence in 20-25years duration of DM and retinopathy was found to be maximum in patients with diabetes of more than 25 years.

The severity of the diabetic retinopathy was also found to have significant relationship with duration of diabetes. Agarwal et al,[8] reported that Fifty one percent of diabetics with less than ten years of duration of the disease, had grade I changes; while only 11.7 percent had grade I changes with diabetes of more than 10 years duration. The incidence of mixed variety of retinopathy was also significantly higher when the diabetes was of more than 10 years duration.

In this study we found a significant correlation between duration of diabetes and severity of retinopathy. In our study among 71 patients (142 eyes) with less than one year duration of diabetes, only mild NPDR was found in 20 eyes (14.1%).There are no changes of severe diabetic retinopathy. The prevalence of diabetic retinopathy started to raise proportional to the duration of the disease such that those with up to 5 years duration. Among 263 patients (526 eyes), 152 eyes (28.9%) had diabetic retinopathy, of which 37eyes (7.1%) had severe, very severe or early and high risk proliferative diabetic retinopathy. These figures have further increased in patients having diabetes for 6 to 10 years.123 eyes(56.4%) among 218 eyes showed evidence of diabetic retinopathy, of which 36 eyes (16.5%) had severe to very severe or proliferative diabetic retinopathy. Among 64 eyes with 11 to 15 years of duration of diabetes 54 eyes (84.4%) had retinopathy changes, of which 40 eyes (62.5%) had severe to very severe or proliferative diabetic retinopathy.25 patients (50 eyes) with duration of greater than 15 years of diabetes 36 eyes (72%) had retinopathy, among them seven eyes(14%) had proliferative diabetic retinopathy. [Table 7]

In the present study highest prevalence of severe NPDR was seen in 11 to 15 years duration with PDR greater in 15 years duration. It is clearly seen that as the duration of the diabetes increases even the severity of retinopathy is increasing.

Whittington et al,[13] on the contrary failed to observe any difference in the incidence of retinopathy in cases with diabetes of even 30-40 years of duration. Urs,[14] has rather reported a decline in the incidence of diabetic retinopathy after 15 years of duration of the disease. These differences in the observations may be due to the type and the number of patients studied and the severity of the disease in them. It is quite likely that the genetic factors may also be responsible for the aetiology and the time of appearance of diabetic retinopathy.[14]

R Singh, et al,[4] reported that the duration of diabetes was less than 5 years in 56.5% and in the remaining it was more than 5 years. The diabetic state was mild (FBS (200 mg%) in 30.4% and severe (FBS - >200 mg%) in the remaining 69.6%. The frequency of retinopathy was found to have no correlation either with the duration or the severity of the disease.

Retinopathy in relation to glycemic status

Glycated hemoglobin levels are usually expressed as the percentage of total hemoglobin, either as the percentage of total glycated hemoglobin, or as the percentage of its largest fraction, hemoglobin A1c (usually abbreviated HbA1c; other, lesser, glycated fractions are HbA1a and HbA1b) period, the level of HbA1c is usually about two percentage points lower than that of total glycated hemoglobin. HbA1c levels in nondiabetic humans range between 4% and 6%, and the risk for development of the micro vascular complications of diabetes (retinopathy, nephropathy, and neuropathy) in controlled clinical trials has been shown to decrease steadily with decreasing HbA1c levels.

In our study out of 500 patients with diabetes. 166 had good blood glucose control, of which 53(31.9%) patients had diabetic retinopathy whereas among 334 with poor blood glucose control 146 (43.7%) had diabetic retinopathy. P value was calculated using chi-square test between patients who had diabetic retinopathy and who did not have diabetic retinopathy in comparison with controlled and uncontrolled glycemic status, and the p value (0.159) was not significant. There was no significant association between the prevalence of retinopathy and the control of diabetes. Subjects with poor glycemic control as indicated by a high glycosylated haemoglobin values had a similar prevalence of retinopathy when compared with those who have good control of their diabetes. [Table 8]

In our study more number of cases were reported with poor glycemic control but that is not statistically significant. It may be due to the fact that glycemic control only depicts the past 90 days control, may be because earlier control might not be good or diabetes may be of longer duration. Similarly, in cases having high HbA 1 C > 11.50, there was no DR. In these cases duration of diabetes could be short.

In contrast, the United Kingdom Prospective Diabetes Study (UKPDS),[15] found that good blood sugar control does reduce the risk of DR as well as does reduce the progression of retinopathy.[16] whereas, The Diabetes Control and Complications Trial (DCCT),[17] Diabetic Retinopathy Study (DRD), and Early Treatment of Diabetic Retinopathy Study (ETDRS)(also support that good glycogenic control is important in the early stage of the diabetes and helps in delaying the onset of retinopathy and halting the rate of progression. Hence, the preponderance of studies do indicate control of blood sugar level is a factor in preventing DR.

The CURES Eye Study,[18] also demonstrated a significant increase in the prevalence of DR with increasing glycated hemoglobin (HbA1c) levels.

In the present study with increasing duration and uncontrolled glycemic status, there is increased incidence of retinopathy. Out of 53 patients with uncontrolled diabetes with less than one year duration of diabetes only 9(16.9%) had diabetic retinopathy. With 1 to 5 years duration of diabetes, among 158 patients with uncontrolled diabetes 54(34.1%) of them had diabetic retinopathy 75 patients with 6 to 10 years duration of uncontrolled diabetes 46(61.3%) had diabetic retinopathy 25 patients with uncontrolled diabetes of duration 11 to 15 years, 20(80%) of them had diabetic retinopathy. Among 23 patients with uncontrolled diabetes greater than 15 years duration 17 (73.9%) showed diabetic retinopathy changes. [Table 9]

P value (0.00005) was calculated by using chi-square test by comparing total no of patients with uncontrolled diabetes with changes and without diabetic retinopathy with increased duration, which was found to be highly significant.

Similarly in our study with controlled glycemic status and increased duration there was increased incidence of diabetic retinopathy. Out of 18 patients with controlled diabetes of less than one year duration only 2(11.7%) had diabetic retinopathy. Among 105 patients with 1-5 years duration of controlled glycemic status only 27 (25.7%) had diabetic retinopathy. With 6-10 years duration of 34 controlled diabetic patients 16(45.7%) had diabetic retinopathy. Among 7 patients with controlled diabetes for 11 to 15 years duration,6 (85.7%) had diabetic retinopathy changes.2 patients with controlled diabetes greater than 15 years duration one had (50%) diabeticretinopathy. [Table 10]

P value (0.00005) was calculated by using chi-square test by comparing total no of patients with controlled diabetes with patients retinopathy changes and without retinopathy with increased duration, which was found to be highly significant.

This shows that irrespective of the glycemic status of an individual there is an increased prevalence of retinopathy in both the groups with increased

duration of the disease but the rate of progression of the disease is fast in uncontrolled diabetics.

In our study, the results were analysed to know if there was any difference in the progression and severity of retinopathy between controlled and uncontrolled diabetics based on the glycemic status [Table 11] among 99 eyes of 53 patients with controlled glycemic status 54 eyes (54.5%) had mild NPDR 27 eyes(27.3%) had moderate NPDR 12(12.5%) eyes showed severe NPDR and 2 (2.2%) eyes had very severe NPDR early PDR was seen in 4 eyes (4%),whereas no eye exhibited high risk PDR. Among 286 eyes of uncontrolled glycemic status 97 (33.9%) eyes had mild NPDR 81 eyes(28.3%) had moderate NPDR ,severe NPDR was seen in 59 eyes(20.1%) and very severe NPDR was seen in 16 eyes (5.6%),early PDR was seen in 26 eyes(9.1%) and high risk among 7 eyes(2.4%).while the control group showed mild to moderate NPDR in 81.8%,severe to very severe NPDR in 14.%and early PDR in 4% only. In patients with uncontrolled glycemic status mild to moderate NPDR in 66.2%, moderate NPDR in 25% these values are stastically significant with the progression of the disease to severe forms including proliferative diabetic retinopathy. P value of 0.003 (highly significant) as per Chi-square test. This clearly shows that poor glycemic status has an adverse effect on the severity of retinopathy and it's progression.

This shows that although the prevalence of retinopathy in our study did not correlate with the glycemic status, the severity of retinopathy had a significant correlation with the glycemic status of an individual, as most of the patients with good glycemic control had milder forms of retinopathy when compared to patients with poor glycemic control, where severe forms of retinopathy were more common.

The UKPDS studied the impact of tight control versus conventional control on the micro vascular and macro vascular complications in Type 2 diabetes. After 6 years follow-up, the intensive treatment group had significantly lower rate of the two-step progression of DR and a 25% risk reduction in micro vascular end points, including the need for retinal laser photocoagulation. UKPDS showed that intensive blood glucose control, irrespective of the antidiabetic agents used, substantially decreased the risk of microvascular complications.[18]

Though in our study it was seen that glycemic control had no impact on prevalence of retinopathy. It is better to control the blood sugar levels as it is well known that hyperglycemia is one of the most important determinants of diabetic retinopathy and other micro vascular complications. Hence, good glycemic control should indeed have a beneficial effect on the micro vascular complications like cardiovascular complications, nephropathy, neuropathy and including retinopathy.

Limitations of the present study:

1. Study sample was small.
2. There was no follow up of cases in my study.
3. Treatment of diabetic retinopathy was not included in our study.
4. Investigations like Fluoresicin angiography and OCT were not performed, they might have picked very early disease and would have given better information about the status of retina including macula.

Recommendations: Continuation of the present study for a longer period is recommended so that there will be larger sample size with better follow up.

Further investigative modalities like FFA, OCT to be included.

CONCLUSION

The present study concluded that although prevalence of diabetic retinopathy also depends upon the glycemic status (blood glucose control), in our study there was no significant association between the prevalence of retinopathy and control of diabetes. Subjects with poor glycemic control as indicated by a high glycosylated haemoglobin values had a similar prevalence of retinopathy when compared with those who have good control of their diabetes. Severity of retinopathy also depends on glycemic status of the individual, it had a significant correlation with the glycemic status of an individual, as most of the patients with good glycemic control had milder forms of retinopathy when compared to patients with poor glycemic control, where severe forms of retinopathy were common. Hence a tight control of diabetes is advised since the chances of developing severe forms of retinopathy are less.

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