Original research article

Clinical Profile of Diabetic Retinopathy in Tertiary Care Centre

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Abstract

Introduction: India is emerging as diabetic capital of world as 2nd most affected country in the world. Common microvascular complications are neuropathy, nephropathy and retinopathy. It is most common cause of preventable blindness all over the world. Hence has been included in VISION 2020. Global prevalence of DR was found to be 22.27%. In India the incidence and prevalence of diabetes and thereby DR is increasing exponentially in urban as well as rural population and involves population from all socioeconomic strata. The present study was undertaken to study the clinical profile of DR in known diabetics. It aimed to know the various factors affecting progression and pathogenesis of DR, to grade the DR, to know the complications and visual morbidity due to DR in our institution.

Methods: The present Prospective Observational study was conducted in the department of ophthalmology in a tertiary care hospital and medical college. Conducted amongst 102 walk in and referred, known (Diagnosed) Diabetic patients coming to Ophthalmic OPD during Jan. 2020 to June 2021.

Results: In present study majority 86.2% patients having DR were Type 2 diabetics. The male population was found to be 61.76% and the female constitute about 38.23%. Mean age was 58+13.76 years. Mean duration of Diabetes was 9.31+5.44, ranging from 1 to 25 years. 70.57% had poor control and 29.41% had very good control of sugars. Hypertension was found in 46 (45.09%) study participants. Among the 102 Diabetic patients, fasting lipid profile showed that 32.5% had higher cholesterol levels. 43.13% of the study population were on Oral Hypoglycemic Agents followed by 20% of them on insulin with 37.25% of the study population on both drugs. 64.8% patients (66) patients were affected with equal grades of DR bilaterally. 88% were diagnosed with NPDR whereas the remaining 12% were found to have PDR. PDR was diagnosed in 7.84% patients unilaterally and 3.9% patients bilaterally.

Conclusion: Untreated diabetes can worsen the case hence to avoid further complication it is very necessary to incorporate regular eye check-up among the Diabetic cases along with proper diabetic treatment. Regular retinal check-up should be included in standard treatment protocols (STP) of diabetes. Early diagnosis and treatment can further limit the disability.

Keywords: diabetes, neuropathy, nephropathy and retinopathy, Diabetic Retinopathy, microvascular complication

Introduction

"Diabetes Is The Silent Killer Which Kills By Part Of Our Life". The International Diabetes Federation (IDF) estimated the global population with diabetes mellitus (DM) to be 463 million in 2019 and 700 million in 2045.[1] India is emerging as diabetic capital of world as 2nd most affected country in the world with one in six people in the world with diabetes is from India**.[2]**

Common microvascular complications are neuropathy, nephropathy and retinopathy. Diabetes affects ocular health by frequent change is refractive error, Hastened cataract maturation, Glaucoma, Dry eyes, Ocular Nerve palsies and Diabetic retinopathy are manifestations due to diabetes Diabetic retinopathy is important microvascular complication of diabetes. It is most common cause of preventable blindness all over the world. Hence has been included in VISION 2020. Global prevalence of DR was found to be 22.27%.[1]

In India the incidence and prevalence of diabetes and thereby DR is increasing exponentially in urban as well as rural population and involves population from all socioeconomic strata. DR is still diagnosed incidentally in significant number of cases in ophthalmic OPD. There are no recent studies on the prevalence of diabetic retinopathy in different parts of India. This makes it difficult to identify where diabetic retinopathy screening and treatment programmes are most needed. Duration of diabetes, type of diabetes and glycemic control are important factors. The presentation and profile of each patient differs depending on stage of DR. Patients presenting with advanced disease have poor visual prognosis, hence early detection of DR can potentially improve the visual outcome.

Considering the above facts, the study was undertaken to study the clinical profile of DR in known diabetics. It aimed to know the various factors affecting progression and pathogenesis of DR, to grade the DR, to know the complications and visual morbidity due to DR in our institution.

MATERIAL AND METHODS:

The present Prospective Observational study was conducted in the department of ophthalmology in a tertiary care hospital and medical college. Conducted amongst 102 walk in and referred, known (Diagnosed) Diabetic patients coming to Ophthalmic OPD during Jan. 2020 to June 2021.

S**tatistical analysis**: Data analysis performed using SPSS (Statistical Package for Social Sciences) version 23:00. Qualitative data variables expressed by using frequency and percentage (%). Quantitative data variables expressed by using mean and SD.

Inclusion criteria: Following patients were included all walk in and all referred diagnosed type 1 and type 2 diabetic patients coming to ophthalmic OPD, all patients with diabetes and Hypertension.

Exclusion criteria: Following patients were excluded with opaque media- dense cataract, corneal opacities, serious complications due to Diabetes- Diabetic Ketoacidosis, Severe Hypertensive Retinopathy changes in fundus, not willing to participate in study, Patients lost to follow up.

History: Detailed clinical, personal, family history, laboratory investigation were done, detailed notes on diabetes like Onset, Age at the time of diagnosis of Diabetes, Duration of Diabetes, Time (Year) of diagnosis of diabetes, Duration since diagnosis, Medication history, Insulin, Oral Hypoglycaemic drugs, Combined treatment, Compliance to the treatment, Glycemic control.
Ocular Complaints were also noted in details.

Examination:

I. General systemic and systemic examination was carried out to rule out major complications due to diabetes and if present patients were excluded.

II. Ocular examination

a) Visual Acuity: Assessment of visual acuity was done on illuminated Snellen's chart at 6m distance, was tested both aided and unaided, for distance, near vision assessed with Times New Roman chart, For patients <6/60 vision, counting fingers method was followed and then perception of light and projection of rays were checked, Refraction by retinoscopy, Amslers grid assessment for macular involvement.

b) Intraocular Pressure: IOP was recorded on applanation tonometer after topical anesthesia with Paracaine.

c) Slit Lamp Examination: Pre dilatation slit lamp examination was done with due attention towards Conjunctiva: for dry eyes, tear film status, Cornea: diabetic keratopathy, persistent epithelial defect, AC- depth assessment, Iris- colour pattern, neovascularization, Pupil- size, shape, reaction to light, All patients were dilated with Tropicamide + Phenylephrine eye drops

after consent, for dilated fundus examination and Post dilatation, slit lamp examination was done to examine, Lens- grade of cataract, Anterior vitreous.

D) Slit Lamp Bio microscopy: Dilated fundus examination was done on slit lamp with +90D lens. Following points were examined in detail- Optic disc: (size, shape, margins, CDR), Hemorrhages, Neovascularization over disc, Blood Vessels: (Venous beading, looping,A:V ratio, Micro aneurysms, IRMA), Macula: Thickening- Hard exudates, Peripheral fundus: (Cotton wool spots, hemorrhages- Dot & Blot, microaneurysms, hard exudates, IRMSs, Neovascularization)

E) Indirect Ophthalmoscopy: Dilated fundus examination was also carried out with Indirect Ophthalmoscope with +20D lens in supine and sitting positions taking into consideration all above points.

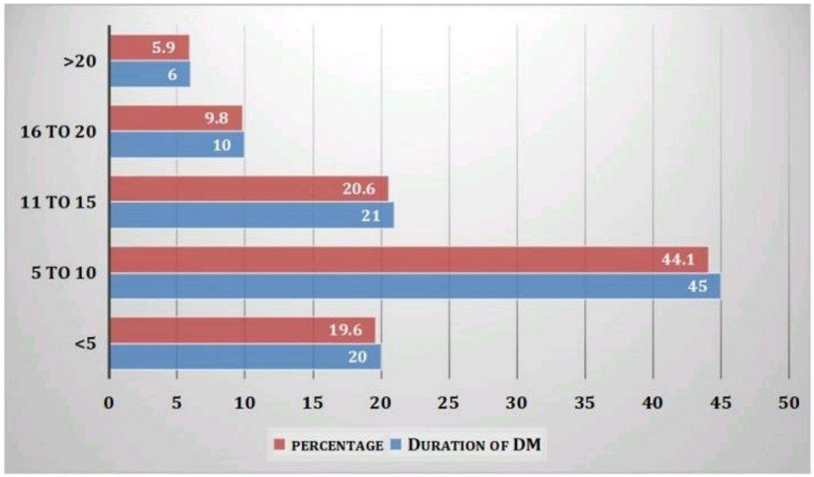
Results:

The present study was undertaken to study the clinical profile of DR in known diabetics. It aimed to know the various factors affecting progression and pathogenesis of DR, to grade the DR, to know the complications and visual morbidity due to DR in our institution.

Table 1: Distribution of study participants on the basis of the duration of Diabetes Mellitus, N=102

Duration of Diabetes Mellitus (in years)	Frequency	Percentage
<5 years	20	19.6%
5-10	45	44.1%
11-15	21	20.6%
16-20	10	9.8%
>20	6	5.9%
Total	102	100%

Table no.1 shows that the maximum, 44.1% patients had duration of diabetes between ranges 5- 10 years. Only 5.9% patients were diabetics since > 20 years in our study. Mean duration of Diabetes was 9.31+5.44, ranging from 1 to 25 years.



Graph 1: Distribution of study participants on the basis of the duration of Diabetes Mellitus

Table 2: Distribution of patients based on Glycaemic control.

HbA1c levels	Frequency	Percentage
<6.5	30	29.41%
6.5-7.5	35	34.31%
7.6-8	14	13.72%
>8	23	22.54%
Total	102	100%

Table no.2 shows the distribution of diabetic control, as per our study 70.57% patients had poor control and 29.41% had very good control of sugars with the HbA1c less than 6.5.

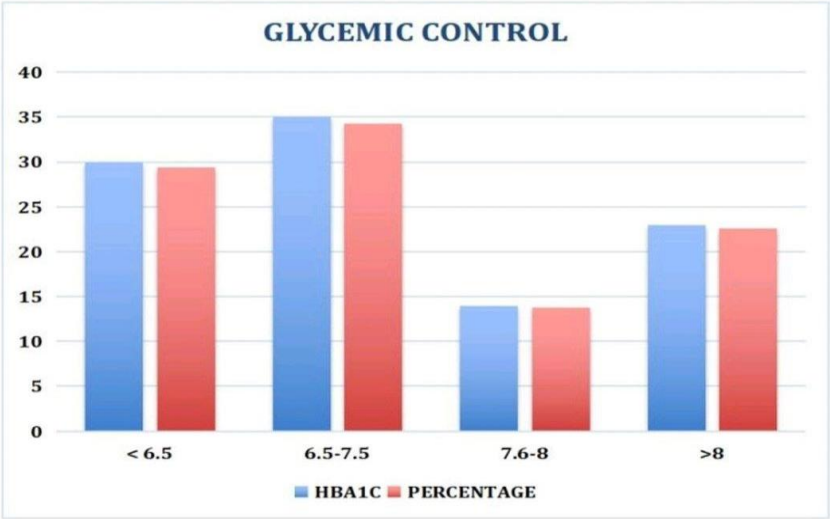


Chart 2: Distribution based on Glycaemic control

Table 3: Distribution of study participants on the basis of classification of DR, N=102

Grade	No. of Patients (102)		No. Of Eyes		Percentage of Eyes
	B/L	U/L	B/L	U/L	
Mild	34	08	68	16	41.1

Moderate	21	16	42	32	36.2
Severe	07	4	14	08	10.7
PDR	04	08	08	16	11.7
Total	66	36	132	72	100

Table no.3 shows that on assessing the classification of DR among the study population it was
found that 7.8% of the study population were found to have unilateral and 33.3% patients had bilateral Mild Diabetic retinopathy. Moderate DR was seen among 15.7% of the DM patients unilaterally and 20.5% patients bilaterally. Among the study population it was found that 3.8% had severe type of DR unilaterally and 6.9% patients bilaterally. PDR was diagnosed in 7.84%
patients unilaterally and 3.9% patients bilaterally.

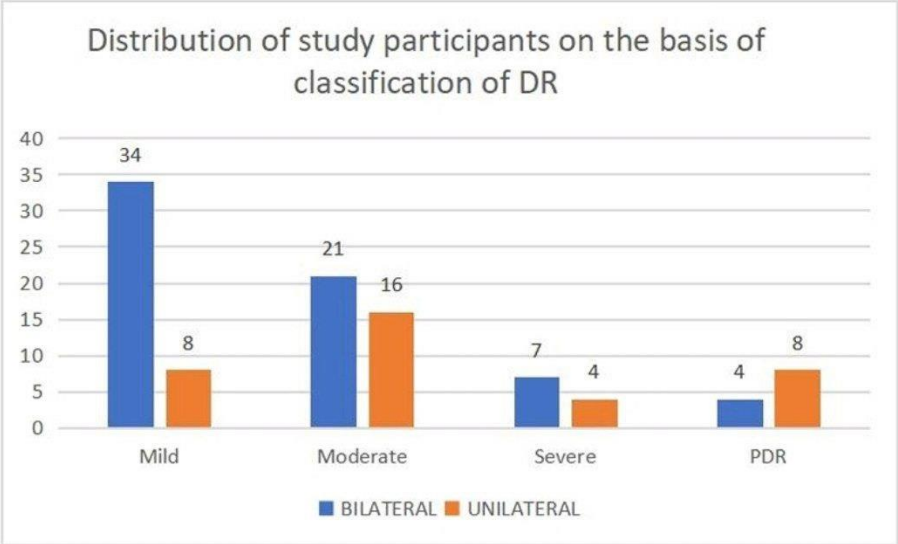


Chart 3: Distribution of study participants on the basis of classification of DR

Table 4: Distribution of study participants on the basis of presence of DME.

Eyes	No. of Patients		Total	No. of Eyes		Total
	B/L	U/L		B/L	U/L	
Mild NPDR	1	3	4	2	3	5
Moderate NPDR	2	11	13	4	11	15
Severe NPDR	3	4	7	6	4	10
PDR	3	3	6	6	3	9
Total	9	21	30	18	21	39

Table no.4 shows the distribution of Diabetic Maculopathy in study participants. Total 29.41% patients had DME. In terms of eyes involved, 19.11% eyes had DME. 4 patients among mild NPDR, 13 patients among moderate NPDR, 7 patients among severe NPDR and 6 patients among PDR had DME.

Table 5: Distribution of study participants on the basis of visual acuity, N=102

Types of DR	Visual acuity
Mild NPDR	6/9-6/18

Moderate NPDR	6/18-6/60
Severe NPDR	6/60-2/60
PDR	3/60-PL

Table no.5 shows that on assessing the visual acuity, it was found that mild DR patients had the vision between 6/9 and 6/18. Patients with Moderate NPDR had vision ranging from 6/18 to 6/60 and severe NPDR had visual acuity from 6/60 to 2/60. The patients with PDR category had the vision ranging between 3/60 to No PL in the study population.

Discussion:

The present Prospective Observational study was conducted in the department of ophthalmology in a tertiary care hospital and medical college. Conducted amongst 102 walk in and referred, known (Diagnosed) Diabetic patients coming to Ophthalmic OPD during Jan. 2020 to June 2021.

In our study majority 86.2% patients having DR were Type 2 diabetics. As Type 2 diabetes is more prevalent, in patients with DR majority patients are type 2 diabetics.
In the present study, males are more affected than females 61.76% were males and 38.23% were females.

Vashist P et al study (2020) [3], out of 4522 KDs, the proportion of males and females was similar. Prevalence of DR in males was 17.0% (95% CI: 15.5– 18.5) and in females was 16.7% (95% CI: 15.5–18.0). Gadkari SS et al (2016) [4] study showed that the prevalence of DR was significantly higher in men than in women (21.3% vs. 14.6%; P < 0.0001).

González MV (1994)[5]Of the 1736 Types 2 diabetic subjects photographed, photographs could be graded in 1715 subjects. Stepwise ordinal logistic regression analysis revealed that male gender (P= 0.041) significantly associated with severity of DR. As we can see in most studies, the prevalence of DR was more in males as compared to females. Our study results are similar to previous studies except Vashist, Praveen et al study.

In the present study, the maximum patients 27% patients were in age group 61-70 years and the mean age in was 58+13.76 years, ranging from 34 to 87 years.

Vashist, Praveen et al (2020) [3] highest prevalence of DR was observed in the 60–69-years age group at 18.6% and a similar prevalence in age groups of70–79 years and >80 years age at 18.3% and 18.4%, respectively. An increased prevalence of DR with increasing age was seen in the present study this finding is similar to the findings of other epidemiologic studies by CURES Eye Study. [6]

In the present study, it was found that duration of DM was 11 to 15 years in 21 patients and in 10 patients, it was found that duration of DM was 16 to 20 years. Mean duration of Diabetes was 9.31+5.44, ranging from 1 to 25 years.
Raman Ret al (2009) [7] History-based variables that were significantly associated with increased risk of diabetic retinopathy included duration of diabetes (>15 years; OR, 6.43; 95% CI, 3.18-12.90); in their study stated that duration of diabetes is the strongest predictor for diabetic retinopathy. As duration increases prevalence of diabetic retinopathy also

increases. It was 8.9% in <5 years duration and 89.0% in 11- 15 years and 100% in cases with >15 years of diabetes.

Voigt M et al(2018) [8] examined prevalence and progression of retinopathy in dependence on diabetes duration in order to estimate the probability of progression.: 25.8% of the patients had retinopathy (20.2% non-proliferative, 4.7% proliferative, 0.7% were not classified, 0.1% blindness). The prevalence of retinopathy in dependence on diabetes duration was 1.1% at diagnosis, 6.6% after 0<5 years, 12% after 5<10 years, 24% after 10<15 years, 39.9% after 15<20 years, 52.7% after 20<25 years, 58.7% after 25<30 years and 63% after ≥30 years. Hence, Within the first 10 years of diabetes duration, the prevalence of retinopathy is low and the progression infrequent. Similar to previous studies, in our study prevalence of DR increases in patients after 5 years of duration of diabetes.

As per the present study 70.57% patients had poor control and 29.41% had very good control of sugars with the HbA1c less than 6.5. Poor control of diabetes mellitus showed a positive association with the presence of diabetic retinopathy. In the present study most of the subject in no and mild diabetic retinopathy had good glycemic control. Mean HbA1c was 7.07+0.85. ranging from 6.1 to 8.3.

In the Rema M et al study (2005) [6], a linear trend in the prevalence of retinopathy with increase in quartiles of HbAlc (trend Chi square: 51.6, P0.001) from 8.1 per cent (HbAlc level < 6.9 %) to 31.7 per cent. (HbAlc level >10.3%) was observed. HbA1C level is the earliest proven clinical predictor of the risk of diabetic retinopathy. These findings are comparable to these studies.

Pradeepa R et al (2008) [9] study Of the 1736 Types 2 diabetic subjects photographed, photographs could be graded in 1715 subjects. Stepwise ordinal logistic regression analysis revealed that glycated haemoglobin (HbA1c; P < 0.0001). The risk for developing DR was 7.7 times (95% confidence interval 4.71-12.48, P < 0.0001) for elevated postprandial plasma glucose levels compared with 4.2 times (95% confidence interval 2.78-6.34, P < 0.0001) for elevated fasting plasma glucose when the fourth quartile values were compared with the first quartile glucose values. As we can see in most of the studies severity and progression of DR is associated with poor glycemic control. Hence, majority of the patients with DR (70.57%) had poor glycemic control.

In our study, Hypertension was found in 46 (45.09%) study. The UKPDS (1998) [10] showed that the incidence of retinopathy was associated with systolic blood pressure, while in the WESDR(1985) [11], diastolic pressure was a significant predictor of progression of diabetic retinopathy to PDR over 14 years of follow up in patients type diabetes. In the Indian context, hypertension was not a significant confounding factor in the CURES Eye study (2005) [12], however uncontrolled hypertension did influence the progression of DR. Hypertension is also positively associated with diabetic maculopathy.

Among the 102 Diabetic patients, fasting lipid profile showed that 41.5% had no abnormality, 32.5% had higher cholesterol levels,7.5% had high Triglycerides and 18.5 had high LDL in blood. Rema M et al (2006) [13], CURES eye study (2019) [2]: The mean serum cholesterol (P = 0.024), serum triglycerides (P = 0.017) and non-high-density lipoprotein (HDL)-cholesterol (P = 0.025) concentrations were higher in subjects with DR compared with those without DR. The DCCT study evaluated the relationship between serum lipid levels and clinically significant macular edema (CSME), hard exudate, and other DR end points in 1441

patients with type 1 diabetes 103. The authors found that total to- HDL cholesterol ratio and LDL-C predicted development of CSME and hard exudate. Higher serum lipids were associated with increased risk of CSME and retinal hard exudate. Hence, findings in our study are consistent with previous studies.

Among the study population it was found that (66.66) 67% patients had family history of diabetes mellitus. In Salil S. Gadkari et al (2016) [4] study close to half 46.1% had no family history.

The study showed that 65.7% of the study population were on Oral Hypoglycemic Agents followed by 19.6% of them on insulin with 14.7% of the study population on both drugs.
Mohan R et al (2005) [6] showed that the prevalence of retinopathy was higher in those on insulin treatment in our study, which is perhaps explained by the fact that subjects with retinopathy may have been preferentially treated with insulin. Mohan R et al (2005) [6] of the 1364 subjects with self-reported diabetes, 1112 (81.5%) were taking oral hypoglycemic agents, 111 (8.1%) were on insulin, and 141 (10.3%) were on a dietary regimen. Of the subjects on insulin, 46.8% had DR compared with 20.0% in those using oral hypoglycemic agents ($P < 0.001$)

In our study, 11, 88% patients were diagnosed with NPDR whereas the remaining 12% were found to have PDR. Out of 102 patients, 90 patients had NPDR and 12 patients had PDR.
Cui Y et al (2019) [14] systematic search online search using PubMed, EMBASE, Web of Science, the Cochrane Library, and China WeiPu Library to identify eligible studies that reported the prevalence of DR, PDR and NPDR in Asian T2DM patients. . The prevalence of DR, PDR, and NPDR was 28%, 6%, and 27% in T2DM patients, respectively; while the prevalence of PDR and NPDR in DR patients was 17% and 83%, respectively. The prevalence of PDR in T2DM from India was higher than patients from other locations of Asia, and the same results were also observed in NPDR patients. Hence, findings are consistent with other studies.

On assessing the classification of DR among the study population it was found that 19.6% of the study population were found to had unilateral and 33.3% patients had bilateral Mild Diabetic retinopathy. Moderate DR was seen among 15.7% of the DM patients unilaterally and 20.5% patients bilaterally.

Cui Y et al (2019) [14] showed that the standardised prevalence of DR in participants with DM was 18.2%. There was a significant difference in the prevalence of different grades of DR. NPDR, moderate NPDR, severe NPDR and PDR) ($p<0.001$). The prevalence rates of NPDR and PDR were 16.9% and 0.9%, respectively. NPDR was more common among the patients with DR, which accounted for 94.8%. Results from our study are similar to these results.
In our study, total 29.41% patients had DME. In terms of eyes involved, 19.11% eyes had DME. 4 patients among mild NPDR, 13 patients among moderate NPDR, 7 patients among severe NPDR and 6 patients among PDR had DME.

Raman R et al (2009) [7] The incidences of DR, diabetic macular edema (DME), and sight threatening diabetic retinopathy (STDR) were 9.2%, 2.6%, and 5.0%, respectively. Incident DR, DME, and STDR were associated with higher systolic blood pressure (odds ratio, OR, 1.21, 2.11 and 1.72, respectively, for every 10-mmHg increase). Incident DR and DME were associated with increasing duration of diabetes (OR 2.29 and 4.77, respectively, for every 10-

year increase) and presence of anemia (OR 1.96 and 10.14, respectively). Incident DR was also associated with higher hemoglobin A1c (OR 1.16 for every 1% increase). Variables associated with 1-step progression were every 10 mg/dL increase in serum total cholesterol (OR 15.65) as a risk factor, and 10 mg/dL increase in serum triglyceride (OR 0.52) as a protective factor. Hence, as the severity of DR increases, DME prevalence increases which corresponds to deranged lipid levels and poor glycemic control in patients. So, these findings are consistent in our study.

In our study, on assessing the visual acuity, it was found that patients with moderate NPDR had vision ranging from 6/18 to 6/60 and severe NPDR had visual acuity from 6/60 to 2/60. The patients with PDR category had the vision ranging between 3/60 to No PL in the study population Hence, sight threatening DR was seen in 13% patients with PDR and 29.41% patients with DME.

In Vashist P et al study (2020) [3] found that out of 5986 persons with diabetes assessed, 214 were having STDR, a potentially blinding complication of diabetes. Prevalence of STDR, which included proliferative retinopathy (R4) and hard exudates within one-disc diopter of the center of fovea (M2), was 3.6% in the population with diabetes assessed for DR changes by dilated fundus examination. The prevalence of blindness among persons with diabetes was 2.1% and that of moderate severe visual impairment (MSVI) was 11.6%; the difference was not significant as compared to normal persons who had prevalence of blindness and MSVI as 2.0% and 12.0%, respectively.

Conclusion:

Every fourth person with DM was found to have DR, and among them majority have NPDR. Untreated diabetes can worsen the case hence to avoid further complication it is very necessary to incorporate regular eye check-up among the Diabetic cases along with proper diabetic treatment. Regular retinal check-up should be included in standard treatment protocols (STP) of diabetes. Early diagnosis and treatment can further limit the disability.

Abbreviations:

DCCT - Diabetes Control and Complications Trial
CURES- Chennai Urban Rural Epidemiology Study
DR – diabetic retinopathy
B/L- Bilateral
U/L- Unilateral
STDR – sight threatening diabetic retinopathy
CSME- clinically significant macular edema
IRMA – intraretinal microvascular abnormalities
NPDR- Non proliferative diabetic retinopathy
PDR- proliferative diabetic retinopathy

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