




## A hospital based cross sectional study on determining of prevalence and risk factors of eye disease among diabetes in a teaching tertiary care hospital in India

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### Abstract

**Background:** This study aimed to determine the prevalence of Diabetic Retinopathy and to find the associated risk factors of DR among known Type II DM patients.


**Materials and Methods:** A hospital-based cross-sectional and single center study was conducted among Type II DM patients with and without DR in the department of Endocrinology with a sample size of 150 with DM patients in 2018. Data were expressed as mean, standard deviation, proportions, Chi-Square, t-test test and Binary Logistic Regression analysis.

**Results:** Diabetic patients 150 were identified as Type II DM as per inclusion criteria with aged 30 years and above. Among 150 Diabetic patients, 39 (26%) patients had Diabetic Retinopathy and 111 (74%) patients were not having Diabetic Retinopathy. The association between groups (with and no DR) and duration of DM were very highly significant with p-value < 0.01. DR prevalence was higher in female when compared with male population.

**Conclusion:** From our study, we have concluded that the prevalence of DR was very high. DR was strongly associated with HbA<sub>1c</sub>, FBS, duration of DM, medication, duration of hypertension and smoking. Hence, there is a need for regular screening check-up with ophthalmologist to prevent diabetic retinopathy or to prolong or to escape from the vision loss.

**Keywords:** type II diabetic mellitus, diabetic retinopathy, prevalence, risk factors

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### Introduction

Diabetes mellitus (DM) is commonly called as diabetes, it is a chronic disease [1] and it is caused by the deficiency in the production of insulin by pancreas or by a deficit of the insulin produced in the human body. DM is a metabolic disorder in which there are high blood sugar levels over a long period in the human blood. DM causes morbidity and mortality about 180 million people worldwide [1, 2]. In some of the studies, the blindness from diabetes is almost entirely preventable with early diagnosis, controlling the risk factors and timely treatments with ophthalmologist [3, 4]. It is a public health problem both in developing and developed countries. The disease is classified into two according to the distinct groups of patients. They are type I diabetes and type II diabetes. Its prevalence is getting increased day by day due to variations have taken place in both demographic and epidemiology as a result of urbanization, industrialization, and globalization. Its prevalence is calculated to increase from 4% in 1995 to 5.4% by 2025. While considering diabetes prevalence, there is a 42% and 170% increase in both developed and developing countries. As per the new statistical result, there are approximately 33 million diabetic adults in India. India is becoming as diabetes mellitus patients' capital of the world within the year 2025 predicted by Wild et al [5].

Diabetic Retinopathy (DR) is a microvascular complication of diabetes mellitus [6]. DR causes complete blindness in both developing and developed countries. There is 25 times chance of getting blindness in diabetics than non-diabetics. Though Diabetes Mellitus causes many microvascular complications, retinopathy is considered to be the main morbidity as it threatens vision. DR is causing blindness in the world

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level and 70% people were affected those who were living in under developing income countries [7, 8]. Diabetic Retinopathy is a dreadful complication and every part of the eye will be affected. The factors responsible for the development of DR were duration of diabetes, poor glycemic control, age and gender, hypertension, nephropathy, genetics, serum lipids, anemia, puberty, socioeconomic status, pregnancy [4, 9, 10 and 11]. Duration of DM and glycemic control has a direct and indirect relationship between DR. Hypertension is also increasing the risk of DR in a Type II DM patients. The objectives of our present study were to determine the prevalence of Diabetic Retinopathy among known Type II DM patients and to find the associated risk factors of DR among known Type II DM patients.

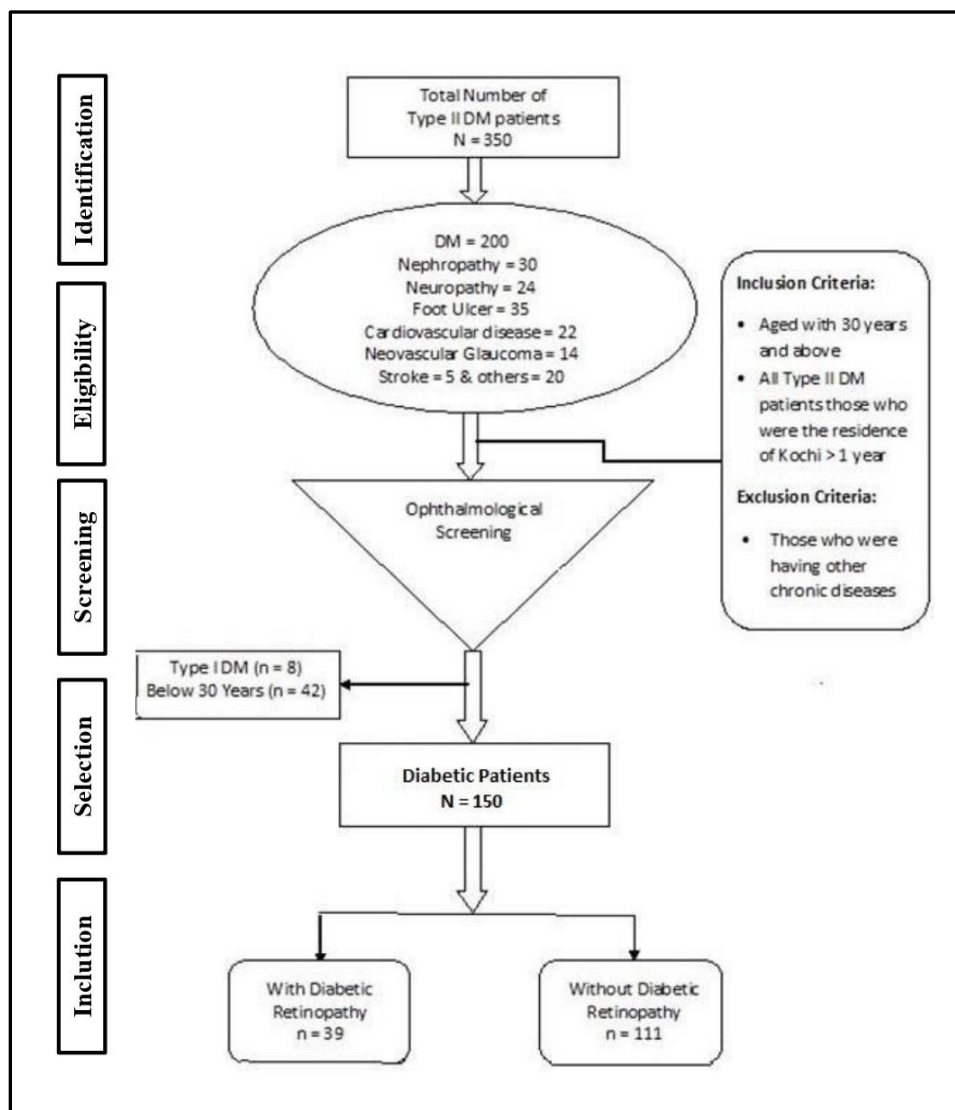
### Materials and Methods

We have done a hospital based cross-sectional study among known Type 2 DM patients on DR in the department of Endocrinology and retina center, Amrita Institute of Medical Sciences, Ponekkara, Kochi, Kerala

from 1<sup>st</sup> February to March 2<sup>nd</sup>, 2018 with a sample size of 150 known Type II DM patients with census sampling method.

**Selection of patients for the study:** Totally, 350 patients were screened in our study. In that, 200 were DM patients 150 were identified as Type II DM as per inclusion criteria. Patients those who were under diabetes came and under treatment for DM was consecutively selected by an ophthalmologist were included in our present study **Figure – 1**. DM Patients were screened, automated diagnosis and grading of DR by using Optical Coherence Tomography by a trained Ophthalmologist. Some of the patient’s data were collected from the hospital records and some data from the patients directly. An inclusion criterion of the patients with aged 30 years and above those who were having DM for at least one year and above and who are all the residence of Kochi area, Kerala, South India and with an exclusion criterion the patients those who were having chronic diseases and not willing to participate in our present study.

**Figure: 1** Distribution of basic and clinical characteristics among Type II Diabetes Mellitus patients



**Major divisions of Diabetic Retinopathy:** Normal human eye with clear retina and those who are affected by eye threatening disease DR in the Type II DM patients' eye is having black dots and hemorrhages. DR can be divided into two broader areas: (1). Non-proliferative Diabetic retinopathy (NPDR) and (2). Proliferative Diabetic retinopathy (PDR).

**Classifications of Diabetic Retinopathy:** Early Treatment Diabetic Retinopathy Study Research Group has classified NPDR into mild, moderate, severe and very severe and PDR into early PDR and high-risk PDR. Further classifications are as follows: (a). Mild Non-proliferative diabetic retinopathy; (b). Moderate Non-proliferative diabetic retinopathy; (c). Severe Non-proliferative diabetic retinopathy; (d). Very severe Non-proliferative diabetic retinopathy; (e). Early proliferative diabetic retinopathy; (f). High-risk PDR. If a patient hasn't treated in time is at high risk of severe then he will definitely get the visual loss the Diabetic Retinopathy Study Research Group (1981). In our study, we have divided DR stages as No DR, Mild DR, Moderate DR, Severe DR and PDR as per Diabetic Retinopathy PPP-Updated (2017). With the advancement of DR, the quality of life of patients diminishes, and the financial burden of society rises, both in the DR screening and treatment groups. DR has been found to be correlated with many other diabetes-related complications like nephropathy, peripheral neuropathy, low bone density, and cardiovascular events, all of which decreases the quality of life and cause a high rate of mortality in Early Treatment Diabetic Retinopathy Study Research Group (1991). Hence, it is recommended for early diagnosis and proper management by Wild et al (2004). Variables were included in the study, gender, age, educational Status, family history of DM, smoking habit, alcohol consumption, history of hypertension, medication, total cholesterol level, duration of hypertension, body mass index (BMI), duration of DM, fasting blood sugar (FBS), and hba<sub>1c</sub>. The data were collected by using a structured and tested questionnaire.

#### Data entry, its Management and Statistical Analysis:

The collected data were compiled by using Microsoft Excel 2010 (Office 365, Microsoft Ltd., USA) and analyzed by using Statistical Package for Social Sciences 20.0 version (SPSS Inc. Chicago, USA). The continuous data were mentioned as mean, standard deviation and categorical data were mentioned as frequency and proportions. In bivariate analysis, to compare the mean difference between continuous variables between groups by using independent samples t-test, to find the association between variables by using Chi-Square test and found the significant variables. In multivariate analysis, we have used binary logistic regression (BLR) analysis. The significant variables were obtained by bivariate analysis and p-value  $\leq 0.20$  were identified and included in the final BLR analysis with back ward elimination method and found the risk factors to develop DR among known Type II DM patients. The statistical significance was fixed at p-value less than 0.05.

#### Ethical approval and consent to participate:

This study was done with prior permission was obtained from Amrita Institute of Medical Sciences, Kochi before conducting this study. Ethical approval from the Institutional Ethical Committee of AIMS has been obtained and informed written consent was taken from all participants in the study.

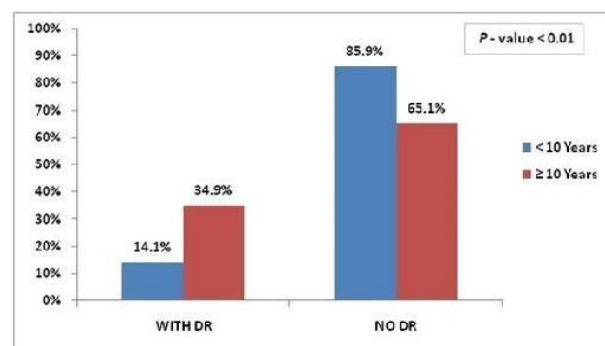
## Results

Totally 350 patients were screened by a trained ophthalmologist in our present study. Among 350 patients, 200 were Diabetic Mellitus only and 150 were various other diseases of Type II DM patients. Among 150 Type II DM patients, 85 (56.7%) were males and 65 (43.3%) were females. The mean age of the participants was found as  $58.15 \pm 10.46$  (Range: 31 to 87) years. Out 150 known Type II DM patients 39 (26.0%) were identified as DR and 111 (74.0%) weren't had DR. So, the overall prevalence of DR was found as 26% in the study population and other socio-economic variables were as shown in **Table – 1**.

Out of 123 normal total cholesterol patients, 87 (70.7%) patients weren't having DR (without DR) and 36 (29.3%) were having DR (with DR) and in 27 abnormal total cholesterol patients, 24 (88.9%) were without DR and 3 (11.1%) were with DR which was statistically merely significant with  $p=0.05$ . In medication, out of 93 tablet taking patients, 82 (88.2%) patients were not having DR and 11 (11.8%) were with DR and in 57 insulin taking patients, 29 (50.9%) were without DR and 28 (49.1%) were with DR and total cholesterol which were very highly significant with  $p<0.001$  except the variables like age, gender, body mass index (BMI), history of hypertension, fasting blood sugar (FBS), educational status, family history of DM, smoking habit, alcohol consumption, duration of hypertension, duration of DM, HbA<sub>1c</sub> which weren't significant with p-value  $> 0.05$ . 39 DR patients mean duration of DM was  $16.6 \pm 7.6$  years and mean duration for the without DR group was  $10.21 \pm 6.7$  years, which was very highly significant with  $p<0.01$ , 39 DR patients mean HbA<sub>1c</sub> was  $8.94 \pm 2.1\%$  and the mean HbA<sub>1c</sub> of 111 without DR group was  $7.97 \pm 1.8\%$ , which was highly significant with  $p<0.01$ , 35 DR patients mean FBS was  $160.25 \pm 55.8$  and the mean FBS of 100 without DR group was  $136.84 \pm 44.3$  which was significant with  $p<0.05$  and age wasn't significant with  $p>0.05$  as shown in **Table – 1**.

The duration since diagnosis of DM was  $< 10$  years in 42.7%,  $\geq 10$  years in 34.9% and  $\geq 15$  years in 39.3%. The association between groups (with and without DR) and duration of DM were very highly significant with p-value  $< 0.01$  as shown in **Figure – 2**.

**Figure – 2 Association between duration of diabetic mellitus and with and without diabetic retinopathy**



**Table: 1 Distribution of basic and clinical characteristics among Type II Diabetes Mellitus patients**

Variables		No. of Patients	Diabetic Retinopathy		P – value <sup>§</sup>
			With DR	Without DR	
Gender	Male	85 (56.7)	20 (23.5)	65 (76.5)	0.430 <sup>#</sup>
	Female	65 (43.3)	19 (29.2)	46 (70.8)	
Age (in years)	Age (Mean ± SD)	58.15 ± 10.46 (Range: 31 – 87) years			
Age groups (in years)	≤ 50	34 (22.7)	60.38	9.06	0.122 <sup>#†</sup>
	> 50	116 (77.3)	57.37	10.84	
Educational Status	School	91 (60.7)	23 (25.3)	68 (74.7)	0.801 <sup>#</sup>
	College	59 (39.3)	16 (27.1)	43 (72.9)	
Family History of DM	Yes	47 (31.3)	9 (19.1)	38 (80.9)	0.196 <sup>#</sup>
	No	103 (68.7)	30 (29.1)	73 (70.9)	
Smoking Habit	Yes	136 (90.7)	33 (24.3)	103 (75.7)	0.131 <sup>#</sup>
	No	14 (9.3)	6 (42.9)	8 (57.1)	
Alcohol Consumption	Yes	127 (84.7)	32 (25.2)	95 (74.8)	0.598 <sup>#</sup>
	No	23 (15.3)	7 (30.4)	16 (69.6)	
History of hypertension	Yes	55 (36.7)	8 (14.5)	47 (85.5)	0.616 <sup>#</sup>
	No	95 (63.3)	31 (32.6)	64 (67.4)	
Medication	Tablet Users	93 (62.0)	11 (11.8)	82 (88.2)	0.0001 <sup>**</sup>
	Insulin Users	57 (16.0)	28 (49.1)	29 (50.9)	
Duration of DM	< 10 years	64 (42.7)	16.62	7.57	0.0001 <sup>***†</sup>
	≥ 10 years	86 (57.3)	10.21	6.65	
BMI Classifications	18.5 – 24.9 (Normal)	68 (45.3)	17 (24.6)	52 (75.4)	0.726 <sup>#</sup>
	25.0 – 29.9 (Over Weight)	82 (54.7)	22 (27.2)	59 (72.8)	
Total Cholesterol	Normal	123 (82.0)	36 (29.3)	87 (70.7)	0.056 <sup>*</sup>
	Abnormal	27 (18.0)	3 (11.1)	24 (88.9)	
HbA <sub>1</sub> C (in %)	≤ 6.5	30 (20.0)	8.94	2.12	0.007 <sup>***†</sup>
	> 6.5	120 (80.0)	7.97	1.83	
Fasting Blood Sugar ~	Normal	14 (10.4)	2 (14.3)	12 (85.7)	0.013 <sup>*</sup>
	Abnormal	121 (89.6)	33 (27.3)	88 (72.7)	

<sup>§</sup>Chi Square Test P – value; <sup>†</sup>t – test P – value; <sup>\*\*</sup>P – value < 0.01 Highly Significant; <sup>\*</sup>P – value < 0.05 Significant; <sup>#</sup>P – value > 0.05 Not Significant; ~Missing value occurred

We have used Binary Logistic Regression equation with backward conditional analysis to predict the influencing factor to develop the diabetic retinopathy among known Type II DM patients. From binary logistic regression, the above results were obtained and Hosmer-Lemeshow test was showed a goodness of fit with Chi-Square value was 2.891 and the corresponding p-value was 0.941 which wasn't statistically significant with p-value > 0.05. Therefore, from this we have concluded that the Chi-Square value wasn't significant and this was proved the model was a good fit. ie., the selected variables are perfectly fit to that binary logistic regression equation model approach. The history of hypertension wasn't significant in the bivariate analysis but included in the final BLR analysis. Finally, we have got in the backward elimination step-3, the variables HbA<sub>1</sub>C, FBS, smoking habit, intake of tablet/insulin, duration of DM and history of hypertension are significant with p-value <0.05 except age and total Cholesterol. The included variables and their odds ratio, significance and 95% Confidence Interval were as shown in **Table – 2**.

### Discussion

Diabetic Retinopathy (DR) is a common disease in Type II Diabetes Mellitus (DM) patients [12]. In some epidemiological studies on DR including both cross-sectional and cohort studies have conducted worldwide. Their intention was to explore the risk factors that were associated with the disease and on the prevention and management of this disease [20]. The greater risk factor for DR and progression

of DR is found to be older female patients with longer disease. The similar type results of risk factors for DR and DR progression were found in older female patients with longer disease in our present study also. In addition, having renal complications of diabetes, poor glycemic control, hypertension was also identified as the risk factors for DR. Among these identified factors, duration of DM, hyperglycemia, and hypertension were considered to be the most affecting risk factors for advancement vision loss. Nevertheless, DR and risk factors of DR hardly gained any attention and the concurrence with the eye screening is often poor was mentioned by Early Treatment Diabetic Retinopathy Study Research Group [4]. Abnormal glucose metabolism has led to an increase in the prevalence rate of DM as well as DR. In our study, the prevalence of DR in the study population was found as 26%. Raman et al [13] have revealed that the prevalence of DR among DM patients was 10.3%. However, Xu et al. [14] have found 24.7% as overall prevalence among Beijing population, China. Whereas, the prevalence of DR was 11.9% in another one study from Northeastern area of China by Hu et al. [15]. In another one study by Looker et al. [16] the prevalence of any DR at their first screening was found as 19.3%. Moreover, in some other studies the prevalence of DR was found by Pamu et al. [17] 41%, Giri et al. [18] 44.4%, Liu et al. [19] 34.1%, Ahmed et al. [20] 36.4%, Zhang et al. [21] 27.9%. Furthermore, the prevalence of DR in our study was higher than those documented in other studies 21.7% by Gadkari et al. [22] and 18% by Kim et al. [10].

**Table – 2 Distribution of prediction variables in the multivariate analysis equation, its significance, odds ratios and 95% Confidence Interval (N = 150)**

Prediction Variables in the equation	AOR	Significance	95% CI	
			Lower	Upper
Age	0.97	0.296 <sup>#</sup>	0.92	1.03
Smoking habit	15.39	0.002 <sup>**</sup>	2.66	89.18
Duration of Diabetes Mellitus	1.18	0.001 <sup>**</sup>	1.07	1.31
HbA <sub>1</sub> C	1.34	0.035 <sup>*</sup>	1.02	1.75
Fasting Blood Sugar	1.01	0.027 <sup>*</sup>	1.00	1.02
Medication	5.72	0.002 <sup>**</sup>	1.93	16.91
History of Hypertension	1.10	0.016 <sup>*</sup>	1.02	1.18
Total Cholesterol	5.86	0.065 <sup>#</sup>	0.90	38.41

**AOR – Adjusted Odds Ratio; 95% CI: 95% Confidence Interval; \*\*P – value < 0.01 Highly Statistically Significant; \*P – value < 0.05 Statistically Significant; #P – value > 0.05 Statistically Not Significant**



The difference in the prevalence rate is due to the fact in that many of the studies were population-based and due to the different screening techniques adopted. The mean age of the participants was a little bit high than a study was conducted in Pondicherry, South India by Vasudevan et. al. [11]. Furthermore, the similar type of results was mentioned in another one study on the prevalence of DR and its associated factors in a rural area of Tamil Nadu, South India was done by Nadarajan et. al. [23]. Whereas the mean age of the participants was found as very high  $69.2 \pm 8.5$  years in a study by Wang et al [24] in Guangzhou, China. DR prevalence is higher in the female when compared with male population. The similar type of results has been mentioned in a Chennai Urban Rural Epidemiology Study (CURES) Eye Study-I by Rema et al. [25]. In our study, we have found that the mean duration of DM was  $16.62 \pm 7.6$  years. In our present study, 34.9% of DM patients had DR for 10 years and above and 14.1% of DM patients had DR less than or equal to 10 years. The test was statistically highly significant with  $p$ -value  $< 0.01$  as shown in **Figure – 2**. Whereas one study from Karnataka by Nayak et al. [26] have mentioned the very high prevalence of DR as mentioned half percentage for more than 10 years and a similar percentage were having DM more than 5 years. Retinopathy increases with younger age at onset of diabetes and showed a significant association between DR and duration of diabetes, which is consistent with most of the previous studies Pamu et al. [17], Giri et al. [18], Liu et al. [19] and Ahmed et al. [20]. The risk factors like duration of DM, HbA<sub>1c</sub>, FBS, history of hypertension and medication also showed a higher significance with DR. However, we didn't find any significant association between DR and age, gender, education, family history of DM, total cholesterol and BMI. Similarly, a study by Liu et al. [19] also didn't find any association with gender but showed association with duration of the disease.

Out of the 150 known Type II DM patients, 85 were males and 55 were females. Among that 23.5% of the males and 29.2% of the females were affected by DR. The age group of the study ranged from 31–84 years. Majority of the patients in our study were aged above 50 years and DR was also found in the mean age of  $60.38 \pm 9.06$ . But the study by Pamu et al. [17] has shown a slight male preponderance in all age groups and the majority of DM patients in the age group of 41–50 years. Risk factors like BMI, hypertension, HbA<sub>1c</sub>, duration of DM and microalbuminuria were identified as statistically significant in their study. A similar type of results was found in our study that history of hypertension, HbA<sub>1c</sub>, and duration of DM were significant with  $p$ -value  $< 0.05$ . More than half of the study population was having hypertension and higher proportion of DR was seen among hypertensive patients (32.6%) than non-hypertensive patients (14.5%), which was significant with  $p$ -value  $< 0.05$ . Similar result was found in the study by Giri et al. [18] also.

In addition to that gender, age, duration of DM, history of addiction, family history of DM was also significant in their study. In bivariate analysis, the smoking habit wasn't significant with DR in our study. But smoking habit has been found as significant in the final multivariate analysis and it was found that the chance of getting DR in smokers was 15 times more than that of non-smokers. We have estimated the strongest predictors of DR through BLR analysis. Some of the variables which were not significant in bivariate analysis but significant in multivariate analysis and one variable were

eliminated. The strongest predictors were HbA<sub>1c</sub>, FBS, smoking habit, medication (intake of tablet/insulin), duration of DM, and history of hypertension was eliminated from the third step of BLR analysis. A similar study was conducted to estimate the strongest predictors by Ahmed et al. [20] and Pradeepa et al. [27].

In a study by Gadkari et al. [22] has resulted that the prevalence was found more in males, DM was happened after 5 years, DM patients was in above 40 years, insulin users and history of vascular accidents. But our study, the prevalence was more in males among females, DM more than 10 years, those aged above 50 years. We didn't take into an account of the history of vascular accidents. A Korean study by Kim et al. [10] has showed that the odds ratio of the DR increased with duration of DM, postprandial glucose levels, and HbA<sub>1c</sub> and in our study odds ratio was also increased with smoking habit, medication, and HbA<sub>1c</sub>. Kohner et al. [28] has mentioned in their study that the presence of retinopathy was the same percentage in both the male and female and fasting plasma glucose level was the risk factor for developing DR. We have also found the same type of results in our present study. So, the ophthalmologic examination is needed for all known Type II DM patients for the management and treatment of DR for every year from the diagnosis date of DM.

## Conclusion

From this present study, we have concluded that the prevalence of DR among Type II DM patients was high. There is a need of necessary and immediate steps/actions need to be taken to reduce the prevalence through the Government, medical institutions and other Non-Government organizations. Retinopathy is strongly associated with Hemoglobin A<sub>1c</sub>, fasting blood sugar, duration of DM, medication, duration of hypertension and smoking. So, there is a need of regular check-up for known Type II DM patients to prevent DR. Further studies are needed in this area and health education is necessary to create awareness among DM patients.

**Availability of data and materials:** Patients' data were confidential and preserved by the institution.

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**Conflict of Interest:** The authors are not having any kind of conflict of interest.

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