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Evaluation of systemic risk factors in diabetic retinopathy among patients with type 2 Diabetes Mellitus in a hospital in North India- An analytical study.

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Abstract:

Objective: The objective of this study was to identify the incidence and risk factors for DR in diabetic patients undergoing treatment at Territory Hospital North India.

Methodology: A hospital-based cross-sectional study that used a random sampling methodology comprised 350 T2DM patients. Semi-structured questionnaires, document inspections, and physical examinations were used to collect the data. We used logistic regression and receiver operating characteristic curve analyses to determine the relationships between sociodemographic and physiological risk factors and the severity of DR.

Results: The mean age was 50.05 8.6 years among the 320 participants in this study, all of whom had T2DM, and DR was found in 134 patients (38.2%). Age (odds ratio [OR] = 1.184), body mass index (OR = 2.067), systolic and diastolic blood pressure, fasting blood glucose, 2 hours after breakfast sugar test, haemoglobin A1c, total cholesterol, triglycerides, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, serum creatinine, systolic blood pressure, 2 hours after breakfast sugar test, 2 hours after breakfast sugar were the major risk factors ($p<0.05$).

Conclusion: The identification of DR risk factors in T2DM patients is clinically significant since it demonstrates how DM self-management might mitigate DR effects.

Introduction:

The term "diabetes mellitus" (DM) refers to a group of chronic metabolic illnesses that are all characterised by elevated blood glucose levels as a result of either reduced insulin production or resistance to insulin, or both, in the

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body [1]. Diabetes mellitus, which affects 451 million people worldwide, is present in 8.7% of Indians [2].The number of diabetic patients is expected to rise in the coming years due to the rapid sociodemographic and economic development [3].Chronically high blood sugar levels result in both macro and microvascular problems as well as extensive vascular damage. The medical term for the long-term microvascular consequences of diabetes on the eye is diabetic retinopathy (DR). In the absence of early discovery and treatment, DR will progress from its minor aberrations to its later stages. The complications of diabetic retinopathy, macular edoema, tractional retinal detachment, and neovascular glaucoma ultimately result in a substantial visual impairment [4] .Estimates show that DR affects 27.0% of diabetics worldwide [5].The World Health Organisation (WHO) claims that DR is to blame for 37 million incidences of blindness worldwide [6]. When there is visual loss brought on by the disease, diabetes comorbidities, such as a decreased quality of life and blindness, are more challenging to manage [7].The risk factors that were most frequently associated with the development of DR in diabetic patients included longer duration of diabetes [8–14], high fasting blood sugar levels [7–13, 15, 16], hypertension [17,18], obesity [19, 20], being on insulin treatment alone [21–23], diabetes in a family [8, 16], diabetes in a family member [8, 16], and low socioeconomic status [24, 25]. By using effective early screening, controlling hypertension, and routine follow-up in a diabetic eye clinic, the risk of DR to vision can be decreased. Among the available treatments for diabetic retinopathy are timely laser therapy, steroid intraocular injections, anti-vascular endothelial growth factor medications, and intraocular surgery [26, 27]. The epidemiology and risk factors of DR have been adequately defined in affluent nations, and a few studies have also been made in less developed nations. However, there are little studies on the incidence of DR and its risk factors in India. The objective of this study was to identify the incidence and risk factors for DR in diabetic patients undergoing treatment at Territory Hospital North India.

Methodology:

The objective of this hospital-based cross-sectional study is to identify the prevalence of and risk factors for DR in people with T2DM.The study's population consisted of patients with T2DM, with or without DR, who received treatment at a hospital in India. The patients received a written description of the trial as well as an informed consent form. The interviewer read the information on the informed consent form aloud if the patient was illiterate or had vision problems. The study also included individuals with gestational diabetes mellitus, hypertensive retinopathy, which mimics fundus features with DR, and patients with vision problems brought on by mature cataracts and hazy media were excluded. In order to perform an indirect ophthalmoscope and slit lamp examination, patients with serious diseases and those who couldn't sit still were disqualified.For this study, information was collected from 320 diabetes individuals. Random sampling was the method used to select the samples. Semi-structured questionnaires were used to collect the data. This poll contained both closed-ended and open-ended questions. All study participants had their eyes carefully examined using dilated fundoscopy on the day of data collection, and an ophthalmologist performed a test to determine the existence of DR using direct ophthalmoscopy. The information was gathered using a questionnaire that had already been prepared and evaluated. Before the research began, each participant provided written informed permission along with a thorough medical history, blood pressure readings, and other information. The Snellen chart was used to evaluate visual acuity. Direct ophthalmoscopy was utilised by a single examiner to identify DR in diabetic patients after dilation of the pupils in both eyes with 1% tropicamide eye drops. The International Classification of Diabetic Retinopathy divided retinal disease into two categories: NPDR and PDR [28]. Using multimodal imaging techniques, such as colour fundus photos (CFPs) and fluorescence fundus angiography for every month of the year, or priority based on severity, each patient's diagnosis and categorization were determined. The recorded data sheets were used to gather clinical information for each patient, including age, gender, hypertension, dyslipidemia, and body mass index (BMI). The following measurements were made: lipid profiles (total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglycerides),

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haemoglobin A1c (HbA1c), fasting blood glucose (FBG), 2-hour after breakfast sugar test (2-h ABF), serum creatinine (SCr), and hypertension. Each patient provided both written and verbal informed consent prior to the assessment.

Statistical Analysis:

Data input and analysis were performed using IBM SPSS, version 25.0. In this study, descriptive statistical analysis was used to calculate the mean and standard deviation from quantitative data. Relationships between DR and physiological characteristics were discovered using a logistic regression model and a Chi-square test with a p-value. The severity of DR was divided into three groups using the International Classification of Diabetic Retinopathy and Diabetic Macular Edoema [29] (Mild, Moderate, and Severe NPDR).

Results:

The current trial comprised 350 T2DM patients with a 100% response rate. The responders had an average age of 50.05 + 8.584. Among 350 patients, 250 (71.4%%) were male and 100 (28.5%) were females. We divided the patients into two groups based on whether they had DR or not. Total of 134 (38.2%) patients had DR, while 216 (61.7%%) did not.With regard to age, 5.4% of patients in the study were between the ages of 30 and 39, followed by 28.5% of patients between the ages of 40 and 49, 36% of patients between the ages of 50 and 59, 24.8% of patients between the ages of 60 and 69, and 5.1% of patients between the ages of 70 and 79. The study's participants were 230 (65.7%) Hindu patients, 90 (25.7%) Muslims, and 30 (8.5%) Christians. Total of 31.4% of those with DR had a family history of eye disease, compared to 68.5% who did not. In contrast, 31.4% of individuals with DR and 68.5% of those without DR both had a history of eye disease in their families. DR and a family history of eye disease had a statistically significant correlation (p = 0.002). The therapy of DR relies heavily on exercise and proper drug administration (regular medication habits). The results of comparing patients with and without DR indicated risk factors that were closely related to the development of DR. (Table 1) Patients with DR used insulin therapy 69.1% of the time, 24.5% took pills, and 6.4% used both tablets and insulin to control their blood sugar.

Table 1: Socio-demographic characteristics

Variables	Diabetic Retinopathy		Total (N %)	p- value
	No (N %)	Yes (N %)		
Age				0.085
70 to 79	11 (61.1%)	7 (38.8%)	18 (5.1%)	
60 to 69	63 (72.4%)	24 (27.5%)	87 (24.8%)	
50 to 59	88 (69.8%)	38 (30.1%)	126 (36%)	
40 to 49	55 (55%)	45 (45%)	100 (28.5%)	
30 to 39	19 (100%)	0 (0%)	19 (5.4%)	
Gender				0.41
Male	148 (59.2%)	102 (40.8%)	250 (71.4%)	

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Female	68 (68%)	32 (32%)	100 (28.5%)	
Religion				0.021
Hindu	154 (66.9%)	76 (33%)	230 (65.7%)	
Muslim	66 (73.3%)	24 (26.6%)	90 (25.7%)	
Chritians	8 (26.6%)	22 (73.3%)	30 (8.5%)	
Family history of diabetes mellitus				0.000
Yes	164 (66.9%)	81 (33%)	245 (70%)	
No	72 (68.5%)	33 (31.4%)	105 (30%)	
Family history of eye disease				0.0004
Yes	63 (57.2%)	47 (42.7%)	110 (31.4%)	
No	173 (72.0%)	67 (27.9%)	240 (68.5%)	
Family history of eye disease with diabetes mellitus				0.002
Yes	53 (53%)	47 (47%)	100 (28.5%)	
No	183 (73.2%)	67 ((26.8%)	250 (71.4%)	

Table 2: Risk factors of diabetes retinopathy

Risk factors	Mean ± SD	p-value
Age	50.05 ± 8.5	0.000
BMI (kg/m^2)	24.1 ± 1.9	0.000
Age at diagnosis	40.5 ± 4.27	0.000
Diastolic blood pressure (mmHg)	95.5 ± 16.7	0.000
Systolic blood pressure (mmHg)	144.7 ± 17.8	0.0000
Serum creatinine (mg/dl)	0.98 ± 0.2	0.000
Fasting blood glucose (mmol/L)	8.8 ± 1.2	0.0000
Hemoglobin A1c (%)	8.11 ± 1.35	0.000
2-h after breakfast sugar test (mmol/ L)	14 ± 1.7	0.000

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Triglycerides (mmol/L)	2.44 ± 0.8	0.000
Total cholestrol (mmol/L)	5.4 ± 1.09	0.000
High density lipoprotein cholestrol (mmol/L)	1.6 ± 0.5	0.000
Low density lipoprotein cholestrol (mmol/L)	3.9 ± 1.04	0.000
Diabetes mellitus duration	9.4 ± 5.8	0.000

Table 3: Logistic regression analysis of risk factors

Risk factors	Odd ratio (95% C.I)	p-value
Age	1.184 (1.13 to 1.23)	<0.001
BMI (kg/m^2)	2.06 (1.72 to 2.48)	<0.001
Age at diagnosis	1.35 (1.25 to 1.46)	<0.001
Diastolic blood pressure (mmHg)	1.224 (1.16 to 1.28)	<0.001
Systolic blood pressure (mmHg)	1.112 (1.08 to 1.14)	<0.001
Serum creatinine (mg/dl)	1.92 (1.73 to 2.051)	<0.001
Fasting blood glucose (mmol/L)	2.69 (2.06 to 3.51)	<0.001
Hemoglobin A1c (%)	18.7 (9.16 to 38.3)	<0.001
2-h after breakfast sugar test (mmol/ L)	2.39 (1.92 to 2.97)	<0.001
Triglycerides (mmol/L)	7.74 (4.57 to 13.1)	<0.001
Total cholestrol (mmol/L)	9.21 (4.49 to 18.90)	<0.001
High density lipoprotein cholestrol (mmol/L)	16.72 (8.3 to 33.7)	<0.001
Low density lipoprotein cholestrol (mmol/L)	5.48 (3.47 to 8.65)	<0.001
Duration of diabetes mellitus	1.17 (1.14 to 1.22)	<0.001

Table 2 presents descriptive statistical data on the association between physiological parameters based on continuous data and DR. We utilised analysis of variance on the DR data to establish statistical significance in this simulation.

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For this analysis, one group classified patients as having DR or not ('yes' or 'no') and the other group included physiological variables such as age, gender, BMI (kg/m2), SBP (mmHg), diastolic blood pressure (DBP; mmHg), FBG (mmol/L), 2 h after breakfast test sugar (2-h ABF; mmol/L), HbA1C (%), SCr (mg/dL), duration of diabetes mellitus, age of diagnosis, TC (mmol/L), TG (mmol/L), LDLC (mmol/L), and HDLC (mmol/L). The following risk factors were found to be statistically significantly related to DR: Age (), Body Mass Index (, 95% Confidence Interval 23.94-24.36), SBP (144.77 17.88, 95% Confidence Interval 142.80-146.7374, DBP (95.54 16.7, 95% Confidence Interval 93.7-97.37), FBG (8.8 1.3, 95% Confidence Interval 8.62-8.96), 2-h ABF (14.08 1.76, 95% Confidence Interval 13.9-14.3), All of these risk factors are quite worrying since they can increase the incidence of DR in people with T2DM.The relationships between the risk factors evaluated and DR among T2DM patients that were discovered using logistic regression analysis are shown in Table 3. Strong statistically significant correlations between the emergence of DR and the following independent variables were found by theanalyses: age (odds ratio [OR] = 1.184, 95% CI 1.135-1.234, $p < 0.001$), BMI (OR = 2.067, 95% CI 1.723-2.480, $p < 0.001$), SBP (OR = 1.112, 95% CI 1.085-1.085, $p < 0.001$), DBP (OR = 1.224, 95% CI 1.167-1.283, $p < 0.001$), FBG (OR = 2.694, 95% CI 2.067-3.511, $p < 0.001$), 2-h ABF (OR = 2.396, 95% CI 1.929-2.977, $p < 0.001$), HbA1c (OR = 18.759, 95% CI 9.168-38.381, $p < 0.001$), TC (OR = 9.213, 95% CI 4.490-18.905, $p < 0.001$), TG (OR = 7.749, 95% CI 4.574-13.129, $p < 0.001$),SCr (OR = 1.929, 95% CI 1.735-2.051), LDLC (OR = 5.485, 95% CI 3.475-8.655, p 0.001), HDLC (OR = 16.728, 95% CI 8.300-33.717), and DM duration (OR = 1.170, 95% CI 1.114-1.229, p 0.001). As a result, it was found that all risk factors with odds ratios more than 1 and a significance level of $p < 0.001$ were significantly connected to DR in patients with T2DM.It has been found that men experience DR much more frequently than women.Of the 350 participants in the study, 226 (64.5%) had T2DM without DR, and the other subjects had DR with or without clinically significant macular edoema (CSME). We initially looked at the right eye in the 134 patients with DR and discovered that 29 patients (8.2%) had mild NPDR, with 6 (4.4%) female patients and 23 (17.1%) male patients; 13 patients (3.7%) had mild NPDR with CSME, with 7 (5.2%) female patients and 6 (4.4%) male patients; 26 patients (7.4%) had moderate NPDR, with 9 (6.7%) female patients and 17 (12.6%) male patients; 14 patients (4%) had moderate NPDR with CSME, with 5 (3.7%) female patients and 9 (6.7%) male patients; and 6 patients (1.7%) had PDR, with 2 (1.7%) female patients and 4 (2.0%) male patients. Two patients (0.5%) had PDR with CSME, one (0.8%) was female and one (0.5%) was male. One patient (0.25%) had severe NPDR, and three patients (0.9%) had severe NPDR with CSME, two (1.7%) were female and one (0.5%) was male. When only the left eye was taken into account, we discovered that 29 patients (8.2) had mild NPDR, of which 9 (7.5%) were female and 20 (10%) were male; 13 patients (3.7%) had mild NPDR with CSME, of which 4 (3.3%) were female and 9 (4.5%) were male; 22 patients (6.2%), 8 (6.7%) of them were female and 14 (7%) were male, had moderate NPDR; 14 patients (4%) with moderate NPDR and CSME, 4 (3.3%) females, and 10 (5.0%) males; 9 patients (2.5%) with PDR, 4 (3.3%) females and 5 (2.5%) males, and 2 (0.5%) patients with PDR with CSME.

Discussion:

Diabetic retinopathy is the most typical cause of adult blindness in wealthy countries [1]. Nearly all people with type 1 diabetes mellitus (DM) and more than 60% of people with type 2 DM will have some degree of retinopathy after 20 years of diabetes [2].The current study was carried out to explore the risk factors of diabetic retinopathy among North Indians. We found that age, body mass index, diastolic blood pressure, systolic blood pressure, fasting blood glucose and after breakfast sugar test were the major risk factors along with total cholesterol, triglycerides, low-density lipoprotein cholesterol and high-density lipoprotein cholesterol. These results are consistent with international studies. Studies have shown varying results on the relationship between BMI and diabetic retinopathy. Obesity with a BMI of >30 kg/m2 was found to be the main risk factor for diabetic retinopathy in a study that primarily focused on individuals with type 1 DM, even after accounting for other risk variables including HbA1c and the use of

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cardioprotective medications [30]. In a different study, patients with retinopathy were more likely to be obese, and obesity was related with an increased frequency of retinopathy. However, this association did not hold after controlling for confounding variables including blood pressure [31]. But among retinopathy patients, higher BMI was found to be positively correlated with more severe retinopathy and retinal that threatens vision [32]. According to certain research, a high BMI is not linked to a higher risk of retinopathy [33,34]. However, some research even claim that there is a causal link between BMI and diabetic retinopathy. Those with diabetes who were underweight (BMI 20 kg/m2) had a higher incidence of retinopathy than those who were obese (RR=1.99; 95% CI, 1.21-3.26 vs. RR=1.27; 95% CI, 1.00-1.61) according to the Wisconsin Epidemiologic Study of Diabetic Retinopathy [35]. In fact, by the age of 10, retinopathy had already set in for all of the underweight research participants. This discovery encompassed the growth of retinopathy as well. In comparison to obese people, patients who were underweight had diabetes for a longer period of time and were more likely to be using insulin.Therefore, they suggested that the underweight people may have had worse overall glycaemic control and were consequently in a more "severe" phase of diabetes than their obese counterparts.40 This hypothesis backs up the findings of the DCCT study that rigorous glycemic control increases the likelihood of being overweight [36]. Despite the fact that this correlation was not statistically significant, Wong et al [37] found a link between a lower BMI and diabetic retinopathy.

Various associations between high cholesterol and diabetic retinopathy have been discovered in studies. The findings of Yau et al [38]found that higher total serum cholesterol was associated with a higher prevalence of diabetic macular oedema and vision-threatening diabetic retinopathy have not been confirmed by other investigations. Tomi et al [39] found no statistically significant difference in cholesterol levels among people with varied degrees of diabetic retinopathy. The Hoorn study did not discover a relationship between total cholesterol level and the prevalence of diabetic retinopathy [40, 41], despite the fact that higher blood lipid levels are associated with an increased prevalence of the hard exudates that characterise NPDR. This link between high serum lipid levels and hard exudates has been observed in other studies [42,43, 44].

It has been demonstrated time and time again that hypertension is closely related to the development of diabetic retinopathy. The LALES trial found that for every 20 mm Hg rise in blood pressure, the OR was 1.26 (P=0.002) [45]. According to the Hoorn study, people with hypertension had a more than twice as high risk of developing retinal after 10 years compared to diabetic patients with normal blood pressure [40]. In patients with diabetic retinopathy, Stratton et al [46] found that the incidence of developing new retinopathy increased from 17% to 32% (P <0.0001) when comparing the lowest tertile with the top third of mean blood pressure. Hypertension can cause morphological abnormalities in the retinal vasculature, such as hard exudates, cotton-wool patches, and retinal haemorrhages, that are comparable to those seen in mild-to-moderate NPDR [38].

Conclusion:

The prevalence of DR was 29.4% among the 350 T2DM patients in this study, which is a pretty high rate. The most important sociodemographic risk variables for the development of DR were smoking, education, monthly income, age at diagnosis, medication behaviours, medication type, regularity of physical activity, length of DM, and poor hypoglycemia control. Therefore, both socio-demographic and physiological factors affect the risk of DR in T2DM patients. The emergence of DR was also influenced by a number of social, nutritional, and lifestyle factors related to T2DM and its consequences in India.Numerous public health professionals believe that DM with DR is a serious issue for the Indian population from both a clinical and public health perspective. Patients with DM should have routine, cost-free DR testing to address this. Raising awareness of these issues and enhancing diabetes patients' and DRs' access to healthcare services are also essential.

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