Original Article

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Ophthalmology Section

Clinical Evaluation of Correlation Between Diabetic Retinopathy with Modifiable, Non-Modifiable and Other Independent Risk Factors in Tertiary Set-up in Central Rural India

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ABSTRACT

Introduction: Diabetes mellitus and its related ocular complication like diabetic retinopathy (DR) are showing increased prevalence in India, but the magnitude of presence and progression of DR in central rural population and its relation to certain variables requires further exploration.

Aim: To study the demographic profile on diabetic retinopathy and the association between different risk factors of diabetic retinopathy with its onset and severity.

Materials and Methods: A cross-sectional study was carried out on patients suffering from diabetes mellitus (n=100) admitted to AVBRH, Sawangi (Meghe) in a duration of 2 months from April to June 2014. Snellen's chart, slit lamp, and indirect ophthalmoscope were used for ocular examination of all patients. Comprehensive examination was used for risk factor assessment.

Statistical Analysis: All data was entered into the proforma. Chi-square test, Student's unpaired t-test and one way ANOVA using SPSS 17.0 and Graph Pad Prism 5.0. ($p<0.05$ was considered significant).

Results: The study showed that among all the diabetics (mean age 56.4+11.2 years), 68% were males and 97% type 2 diabetics. This study showed statistically significant association between serum triglyceride ($p=0.0003$), duration since diagnosis of diabetes mellitus ($p=0.0006$), serum total cholesterol ($p=0.0021$), FBG ($p=0.003$), serum HDL ($p=0.012$) and hypertension ($p=0.045$) with presence of diabetic retinopathy. The study also revealed that serum triglycerides ($p=0.001$), serum total cholesterol ($p=0.006$), BMI ($p=0.04$) and duration of diabetes ($p=0.04$) are the only factors which showed significant association with the severity of diabetic retinopathy.

Conclusion: Effective screening strategies for early detection of both diabetes and diabetic retinopathy should be formulated especially for the rural population which is not aware about the various complications of diabetes and their final outcomes. Diabetics should follow proper guidelines to prevent or delay progression of DR.

Keywords: Diabetes mellitus, Screening, Variables

INTRODUCTION

India, alone has been estimated to have 61.3 million people living with diabetes according to IDF. Diabetic retinopathy (DR), a major microvascular complication of diabetes, an increasing threat in India [1,2], is an important leading cause of visual impairment [3] world-wide because of formation of micro aneurysms (earliest sign), hard exudates, cotton wool spots, capillary changes, arteriovenous shunts, hemorrhages or abnormal vessels in the retina and neovascularisation [4].

Initially, diabetics suffering from retinopathy are usually asymptomatic but gradually they start experiencing various symptoms including floaters, distortion and blurred vision which further may progress to irreversible blindness. The prevalence of DR was reported to be 18% in studies carried out in South India, out of which almost all patients of IDDM and 75-80% of NIDDM were reported to suffer from DR, with further partial or complete blindness after 15-20 years of duration of diabetes [5, 6]. A "Madurai based" study done at tertiary level hospital revealed a prevalence of DR was 37% among newly detected diabetes patients. DR is seen in 3.5% of all and 18% of diabetic cases above 40 years of age [1]. Early detection, control and treatment of diabetes itself will help in reduction in cases of diabetic retinopathy and to delay progression of NPDR to PDR. The factors, which have a contribution in presence and progression of visual impairment, due to DR are modifiable (blood glucose, blood pressure, serum lipids, obesity, alcohol, and smoking), non-modifiable (duration, age, sex) [6,7] and other independent variables like type of diabetes mellitus, family history of DR. More focus should be towards modifiable risk factors. Long term protection is possible if blood glucose levels are controlled which reduces microvascular complications and progression of severity of DR [8]. Similarly, better blood pressure control in diabetic patients reduces progression of DR. Anti hypertensive medication with renin–angiotensin system blockade helps in prevention of occurrence of DR in type 1and of its progression in type 2 DM [8]. Lowering of blood lipids is beneficial to diabetic maculopathy because it results in less retinal vessel leakage and hard exudate formation.

In various studies carried out in different parts of the world, DR was seen in all patients suffering from DM for >25 years, showed male preponderance and higher incidence in 50-60 years age group with relatively higher incidence in the referred cases as compared to the newly diagnosed cases of diabetes [9-12]. Higher blood pressure levels can cause rapid progression of DR [5,7,13,14]. Hard exudates in the macula, formed due to endothelial dysfunction as a result of reduced bioavailability of nitric oxide in those diabetics having hyperlipidemia, leads to blindness [7,15]. Lipid levels were higher in patients with DR compared to those without DR in a study carried out in Chennai [16]. NIDDM and IDDM are associated with BMI and smoking respectively whereas another study showed evidence of association between higher BMI levels with severity of DR, especially in IDDM patients [17]. This points to the inference that controlling BMI and cessation of smoking slow down the progression of retinopathy in these individuals [7,17,18].

There is paucity of data published regarding the prevalence of DR and associated risk factors of rural population in Maharashtra.

Clinical evaluation of these determinants helps in awareness of what variables are more significant to be controlled to prevent DR and its progression to blindness in central rural India.

AIM

To estimate the prevalence of DR among patients of diabetes in rural area of Wardha district and study the association between different risk factors and DR.

MATERIALS AND METHODS

A cross-sectional study was carried out in the Department of Ophthalmology on patients suffering from diabetes (n=100), selected by simple random sampling method, admitted to the Acharya Vinobha Bhave Rural Hospital, Sawangi (Meghe), Wardha, Maharashtra in a duration of 2 months from April to June 2014. Indian Ethical Committee approval was taken.

The prevalence of DR in India ranges from 18% to 44.4% in various studies carried out in the past [19, 20]. Considering the prevalence in central rural India (as the study methodology was similar to ours), based on the following assumptions: Prevalence of DR in general population is 44.4% with a precision of 10% and $p<0.05$ significant, the sample size was calculated to be 98.56 rounded up to 99, further considering it to be 100 samples, using the formula $4PQ/d^2$.

where: p (expected prevalence) = 0.44 and Q (1-p)=0.56 and d (precision) was considered 10%=0.10

Inclusion Criteria

(1) All new diagnosed (provisional) NIDDM and IDDM cases complaining of visual impairment.

(2) All known cases of NIDDM and IDDM (referred cases) complaining of visual impairment.

(3) All cases of diabetes showing no symptoms of visual impairment.

Exclusion Criteria

All patients of pediatric age group (below 18 years).

Sample Collection

The demographic information of each study subject including his/her name, age, sex, occupation, address was taken after obtaining his/her verbal informed consent.

Fasting blood glucose was estimated by performing glucose oxidase and peroxidase method. Then, history containing study variables like duration of diabetes, current insulin intake, alcohol intake, smoking status, and family history of diabetes was recorded. Blood pressure of each subject was measured in right arm, supine position. Two readings were taken half an hour apart and the average of two was taken as a final reading. In our study the patients were considered hypertensive as per JNC VII criteria in which the reported classification suggests that all patients having average blood pressure <120/80 mmHg are normotensive; systolic blood pressure (SBP) 120-139 mmHg or diastolic blood pressure (DBP) 80-89 mmHg are pre-hypertensive; SBP 140-159 mmHg or DBP 90-99 mmHg are stage 1 hypertensive; and SBP>160 mmHg or DBP>100 mmHg are stage 2 hypertensive. The hypertensive patients are further to be given appropriate medications.

Body weight was measured (to the nearest kilogram). Height was measured (to the nearest centimeter). BMI was calculated as weight in kilogram divided by height in meter square [weight (Kg) / Height $(m)^2$]. Based on the BMI individuals were classified as lean (BMI < 18.5), normal (BMI = 18.5 – 24.9), overweight (BMI = 25.0 – 29.9) and Obese (BMI > 30.0).

Visual acuity was measured by Snellen's chart. A slit lamp was used for anterior segment evaluation including the depth of anterior chamber. IOP measurement was performed by non-contact tonometry. Indirect ophthalmoscopy was done after complete pupillary dilatation by 1% tropicamide eye drops. Classification of retinopathy was based on the findings of the worst eye of each subject.

Biochemical studies including estimation of total serum cholesterol by CHOD/PAP method, high density lipoprotein by direct enzymatic method, serum TG by GPO/PAP method. Glycemic control is measured by HbA1C, but as HbA1C is not standardized in India and due to the unaffordable cost of the test, fasting blood glucose levels was used as an index for current glycemic control instead of HbA1C.

STATISTICAL ANALYSIS

All the data collected was compiled, edited classified as was entered into the proforma. The difference between DR and non DR was statistically analysed on the basis of all the independent variables with the retinopathy and was then compared with the previous data from the articles of various medical journals. Statistical analysis was done by using descriptive and inferential statistics using chi-square test, student's unpaired t test and one way ANOVA. The software used in the analysis were SPSS 17.0 and GraphPad Prism 5.0 and $p<0.05$ was considered as level of significance ($p<0.05$).

RESULTS

A total of 100 diabetic patients were evaluated. Mean age was 56.4±11.2 years. [Table/Fig-1] shows positive correlation between DR and increasing age but it was not statistically significant. [Table/Fig-1,2] show that retinopathy was prevalent in type 2 diabetes compared with those of type 1 (84% vs. 2% for NPDR; and 14% vs. 0% for PDR), majority fortunately being mild to moderate NPDR cases and a few diabetics unfortunately diagnosed to have PDR.

[Table/Fig-3,4] show that duration of DM, total serum cholesterol, serum triglycerides were significantly associated with both presence and severity of DR ($p<0.05$). There was significant association of presence of DR with HDL ($p=0.012$), hypertension ($p=0.045$), current insulin intake ($p=0.02$) and with FBG ($p=0.003$), while BMI showed significant association with severity of DR ($p=0.040$). Sex, alcohol, smoking, type of DM were not associated with DR at statistically significant levels.

Characteristics		n (%)
Age (Years)	20-30	1(1%)
	31-40	8(8%)
	41-50	24(24%)
	51-60	29(29%)
	>60	38(38%)
Sex distribution	Male	68(68%)
	Female	32(32%)
Type of diabetes	Type I	3(3%)
	Type II	97(97%)
Duration since diagnosis of diabetes	Newly diagnosed (<1month)	6(6%)
	Referred cases (known cases of diabetes)	94(94%)

[Table/Fig-1]: Characteristics of study participants

DISCUSSION

Recent studies have reported that the prevalence of DM in India has rapidly increased to become more than 61 million due to rapid transition economically, demographically and nutritionally along with changes in lifestyle in both rural and urban population. This in turn suggests that in a few more years most of these diabetics will show ocular complications (DR) leading to blindness which is a matter

of concern. The figures for NPDR were much higher than other studies which showed prevalence rates of 71.79% and 71.88% [11,19]. This could be due to the reason that participants with lesser duration of diagnosed diabetes were higher in comparison to the other studies. 14% prevalence of PDR in this study, much higher than 5.12% in Loni [19] may be due to poor diabetic control or due to late diagnosis of pre-existing diabetes, which are both very common in rural population of India, where the economic status is poor and there is lesser awareness about diabetes and its systemic complications.

Inclusion of both IDDM and NIDDM may explain the wide range of age of DR patients (32 to 85 years) similar to 2 other studies [11,20], unlike most other studies. The studies have shown that onset of DR may depend on the age of onset of diabetes indirectly, which is a reason for screening of all diabetics of this age group. 70% male prevalence of DR in this study, similar to studies carried out in Ahmednagar (64.10%) and Dhaka (58.9%) [12,19], could be because of higher social status of males over lesser prioritized females in rural India.

16.67% of newly diagnosed diabetics showed DR, which is higher than previous studies [5,6] which may be because of an underscore of early diagnosis of DM which in turn decreases chances of prevention of onset of DR, leaving prevention of progression of severity of DR as the only choice. With increase in duration of diabetes, the magnitude and prolonged exposure of hyperglycemia increase, if other risk factors are not prevented or controlled.

GRADING OF DR(international AAO classification) [21]	n (%)
0(no DR)	50(50%)
1(mild NPDR)	21(21%)
2(Moderate NPDR)	18(18%)
3(Severe NPDR)	4(4%)
4(PDR)	7(7%)

[Table/Fig-2]: Distribution of diabetic patients according to severity of DR

33.33% vs. 45.2% type 1 and 43.30% vs. 54.8% of type 2 DM patients suffered from NPDR and PDR respectively in our study vs. one carried out in another developing nation [22]. Also 2% vs. 43.3% and 98% vs. 56.67% of DR patients suffered from type 1 and 2 respectively in our study vs. one carried out in another country [22].

Family history of diabetes mellitus could not be considered for correlation with DR due to unawareness among most patients about the strong link between family history of DM and its systemic complications. There was no association between type 1 and DR which may be explained by the insulin therapy and hypoglycemic drugs which probably must have prescribed at the time of diagnosis of DM with the aim of maximum protection so as to reduce the risk of such complications. There was no significant association found between current alcohol intake and DR. Other studies reported significant association between heavy alcohol consumption for long durations. This shows a limitation in our study being that only history of current alcohol intake was taken without proper data regarding duration and quantity of alcohol consumption. No significant association between smoking and DR was found in this study may be due to less prevalence of tobacco smoking in comparison to other forms in rural India.

This study showed an inverse association between the insulin intake and the presence of DR, similar to 2 other studies in India [2, 9], which may lead to a theory that control of blood glucose levels by insulin intake, delays ocular complications. Our study has shown statistically significant association between FBG and presence of DR (p=0.003). Similar to other study in South Asia [22] 8% DR cases, where FBG was <100mg/dl, may have resulted due to poor metabolic control earlier or because of longer duration of DM. 80% patients having FBG>150mg/dl, did not suffer from DR.

Risk factors		DR n (%)	No DR n(%)	p-value
Smoking	No	48(96%)	48(96%)	1.00 Not significant p>0.05
	Yes	2(4%)	2(4%)	
Alcohol	No	40(80%)	34(68%)	0.07 Not significant p>0.05
	Yes	10(20%)	16(32%)	
Duration since diagnosis of diabetes	Newly diagnosed (< 1 month)	1(2%)	5(10%)	0.0006 Significant p<0.05
	1 month to 5 years	19(38%)	26(52%)	
	5 to 10 year	19(38%)	8(16%)	
	10 to 15 years	7(14%)	4(8%)	
	More than 15 years	4(8%)	7(14%)	
BMI	Lean(<18.5)	4(8%)	5(10%)	0.50 Not significant p>0.05
	Normal (18.5-24.9)	22(44%)	26(52%)	
	Overweight (25-29.9)	22(44%)	18(36%)	
	Obese(>30)	2(4%)	1(2%)	
HTN	Yes	25(50%)	32(64%)	0.045 Significant p<0.05
	No	25(50%)	18(36%)	
FBG	<100mg/dl	4(8%)	2(4%)	0.003 Significant p<0.05
	100-150 mg/dl	17(34%)	8(16%)	
	>150mg/dl	29(58%)	40(80%)	
Current insulin intake	No	41(82%)	34(68%)	0.02 Significant p<0.05
	Yes	9(18%)	16(32%)	
Lipids; Mean (SD)	High-density lipoprotein	39.87 (7.22)	44.02 (10.67)	0.012 Significant p<0.05
	Triglyceride	166.16 (67.11)	106.98 (28.34)	0.0003 Significant p<0.05
	Total Cholesterol	196.36 (49.48)	168.92 (31.66)	0.0021 Significant p<0.05

[Table/Fig-3]: Association of various risk factors with presence of DR

Risk factors		Diabetic retinopathy		No DR No (%)	p-value
		NPDR No (%)	PDR No (%)		
Smoking	No	41(82%)	7(14%)	48(86%)	0.13 Significant p>0.05
	Yes	2(4%)	0(0%)	2(4%)	
Alcohol	No	36(72%)	4(8%)	34(68%)	0.13 Not significant p>0.05
	Yes	7(14%)	3(6%)	16(32%)	
Duration since diagnosis of diabetes	Newly diagnosed (< 1 month)	1(2%)	0(0%)	5(10%)	0.040 Significant p<0.05
	1 month to 5 years	19(38%)	0(0%)	26(52%)	
	5 years to 10 year	15(30%)	4(8%)	8(16%)	
	10 to 15 years	5(10%)	2(4%)	4(8%)	
	More than 15 years	3(6%)	1(2%)	7(14%)	
BMI	lean(<18.5)	3(6%)	1(2%)	5(10%)	0.040 Significantp<0.05
	Normal(18.5-24.9)	18(36%)	4(8%)	26(52%)	
	Overweight (25-29.9)	20(40%)	2(4%)	18(36%)	
	Obese(>30)	2(4%)	0(0%)	1(2%)	
HTN	Yes	21(42%)	4(8%)	32(64%)	0.33 Not significant p>0.05
	No	22(44%)	3(6%)	18(36%)	
FBG	<100mg/dl	4(8%)	0(0%)	2(4%)	0.06 Not significant p>0.05
	100-150 mg/dl	16(32%)	1(2%)	8(16%)	
	>150mg/dl	23(46%)	6(12%)	40(80%)	
Current insulin intake	No	34(68%)	7(14%)	34(68%)	0.13 Not significant p>0.05
	Yes	9(18%)	0(0%)	16(32%)	
Lipids; Mean (SD)	HDL	39.69 (7.68)	41.00(3.36)	44.02 (10.67)	0.078 Not significant p>0.05
	TG	167.41 (71.01)	158.42 (37.30)	106.98 (28.34)	0.001 Significant p<0.05
	Total Cholesterol	197.25 (49.37)	190.85 (53.70)	168.92 (31.66)	0.006 Significant p<0.05

[Table/Fig-4]: Association of various risk factors with severity of DR

This could be due to shorter duration of DM among most of these patients or absence of other associated risk factors. Hypertension was significantly associated with presence of DR (p=0.45) similar to the study done by UKPDS [23]. There was no association found with progression of DR. 64% non- DR and 50% DR patients had hypertension. Anti-hypertensive therapy taken by earlier diagnosed hypertensive diabetics may have caused shift from recently uncontrolled to normal blood pressure levels, thus preventing or delaying effects on retinal capillary endothelial cells, which may explain why more hypertensive diabetic patients did not suffer from DR in comparison to those who did suffer. Another related possible mechanism by which hypertension may cause DR is through VEGF (vascular endothelial growth factor), but if the patient is on anti-VEGF for prevention of systemic complications, the chances of the diabetic hypertensive patient suffering from DR may reduce upto a certain extent. The mean serum total cholesterol, mean serum triglycerides, and mean HDL in any DR patients among the participants of our study versus the reports from the study done at Dhaka were196.36 mg/dl versus 272.33 mg/dl, 166.16 mg/dl versus 282.43 mg/dl, and 39.87 mg/dl versus 38.61 mg/dl [12]. In our study, HDL was only significantly associated with presence and not the severity of DR unlike triglycerides and total cholesterol which were related to both presence and severity of DR. This could be because of the low mean lipid levels of the participants in our study. Assessing these risk factors is important for early management to reduce the onset and progression of the ocular complications of diabetes [24].

LIMITATIONS

There are some limitations in this study. A majority of the participants selected were self-reported diabetics hospitalized for various systemic complications other than DR. Few of the patients in this study were detected to be diabetic only after being hospitalized for other diseases. This may have caused selection bias. Lack of fundus photography may be responsible for missing some early diabetic retinopathy cases and thus an underestimate of its prevalence. Due to the lack of standardization of measuring HbA1c in our country and relatively higher cost of this test, glycemic control over a longer duration, of the study participants could not be measured. Only current control could be measured which would in turn bring out a possibility of underscore of magnitude of diabetic patients with uncontrolled hyperglycemia and its association with presence and severity of DR.

CONCLUSION

The under estimated diabetic population includes mostly undetected population of rural settings, who are unaware of both the disease and the risk factors which may lead to systemic complications. With improved strategies of health care services, more diabetics will live for a longer duration, which in turn will lead to increased patients of diabetic retinopathy even if most of the risk factors are prevented or controlled. Thus screening of all high risk individuals for diabetes is required and then further should be made aware of methods to eliminate various risk factors and then receive complete ocular examination at regular intervals.

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