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A Prospective Observational Study on assessment of risk factor associated with diabetic retinopathy in patients diagnosed with type 2 Diabetes Mellitus in south Indian population

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ABSTRACT:

Objective: Diabetic Retinopathy (DR) appears to be the most common cause of blindness worldwide. The objective of the study was to assess the risk factors that would increase the onset or progression of the microvascular complication caused due to type 2 Diabetes Mellitus. **Methods:** A prospective observational study was conducted in a tertiary care hospital, Chennai. The enrolled patients based on their inclusion and exclusion criteria were followed and the information collected includes their demographic data and lab investigations such as, Hypertension, HbA1c, and Dyslipedimia. The data observed was analyzed with SPSS V20.0 to find significance among the risk factors of Diabetic Retinopathy. **Results:** Among the study population of 230, risk factor was analysed for occurrence of Diabetic Retinopathy, Female patient was more affected with Diabetic Retinopathy compared to male 112 and it showed the P - value of 0.001. Most of the people who have Diabetic Retinopathy fall under the age category of 40 to 60 years. The descriptive statistics for age showed the following results Mean ± SD (48.16±10.29) for patients without Diabetic Retinopathy and Mean ± SD (56.24±7.35) for patients with Diabetic Retinopathy. It showed a P-value of 0.004. A significant correlation was seen between the duration of Diabetes Mellitus and the occurrence of Diabetic Retinopathy, showing a P- value of 0.001. Presence of Hypertension also seemed to increase the occurrence of Diabetic Retinopathy, showing a highly significant P-value of 0.001. Presence of Hyperlipidemia had no correlation with the occurrence of Diabetic Retinopathy. A significant level of correlation was seen between the level of glycated haemoglobin and the occurrence of Diabetic Retinopathy showing a P- value of 0.001. **Conclusion:** Our study concluded that duration of diabetes, presence of hypertension, presence of dyslipedimia and high level of HbA1c has a significant relationship as a risk factor for the onset and progression of Diabetic Retinopathy (DR).

KEYWORDS: Risk Factors, Dyslipedimia, Hypertension, HbA1c, Diabetes, Retinopathy.

INTRODUCTION:

Diabetes mellitus can be termed as a metabolic disorder in which there is an increase in blood sugar level in the body,[1] which might lead to macro and microvascular complications. Serious complications such as stroke, heart disease, chronic kidney failure, foot ulcer and damage to the eye are caused when diabetes is left untreated.[2]
Diabetes is caused due to one the two reasons, that is either the pancreas does not produce enough insulin or the cells of the body does not respond properly to the insulin produced.[3] Long term elevation in the blood glucose level in the body leads to damage to the blood vessels, which is termed as angiopathy. In Diabetes Mellitus, the complications are classified into two, they are damage to small blood vessels (microvascular disease) ... e). Globally about 415 million people are affected by Diabetes Mellitus in 2 ... According to the international Diabetes foundation, India is considered to t ... he world. In India, about 62 million are affected by Diabetes Mellitus which ... average age of onset of Diabetes Mellitus in Indian population is 42.5 years. ... to Diabetes every year.[4]

Diabetic Retinopathy being one of the microvascular complication can be defines as diabetic eye disease of the retina caused due to diabetes mellitus, which can eventually lead to blindness.[5] Diabetic Retinopathy affects about 80 percent of the people who are diagnosed with Diabetes Mellitus for more than 20 years.[6] This rate of people affected with Diabetic Retinopathy can be reduced with proper treatment and monitoring.[7] The objective of this study was to assess the risk factors that would increase the onset or progression of the microvascular complication caused due to type 2 Diabetes Mellitus.

METHODS:

A prospective observational study was conducted in a Diabetes centre, Chennai, Tamil Nadu, India. Patients demographic and laboratory investigation was collected from case sheets for a period of 1 year. The study was conducted after getting an approval from Institutional Ethical Committee IEC (Ref: IEC/PHD/2015/2016/01). The inclusion criteria of the study was that, patients who are diagnosed with type 2 diabetes Mellitus above the age of 18 years and patients who are willing to

participate in the study were included in the study. The exclusion criteria of the study were that patients diagnosed with type 1 Diabetes Mellitus were excluded from the study. The enrolled patients were followed during the study period and the relevant study data, including demographic details which contains age, gender, grades of Diabetic Retinopathy and medical history were collected. After collecting all the relevant data's they were entered into SPSS V20.0 and analyzed. The statistics that were used in the study were descriptive statistics (mean, standard deviation) and simple paired t-test to find the significance among the possible risk factor for onset/progression of Diabetic Retinopathy.

RESULTS:

Table 1, Among the study population of 230 male and female patients were found to be 89 (38.7%) and 141(61.3%), 66(28.6%) of the subjects showed no sign of Diabetic Retinopathy, 61(26.5%) of the subjects showed signs of Diabetic Macular Edema, 86(37.3%) of the subjects showed signs of Non-Proliferative Diabetic Retinopathy and about 17(7.3%) subjects showed signs of Proliferative Diabetic Retinopathy.

Severity of Diabetic Retinopathy was characterized as follow,
Grade 0, No Retinopathy (Fundus WNL)
Grade 1, Diabetic Macular Edema
Grade 2, Non Proliferative Diabetic Retinopathy
Grade 3, Proliferative Diabetic Retinopathy

Table 2, Most of the patient who showed no signs of Diabetic Retinopathy, had diabetes less than 5 years (48.4%). Most of the patients showing signs of Diabetic Macular Edema had diabetes for more than 11 to 15 years (52.4%). Many of the patients participated in this study who showed signs of non-proliferative Diabetic Retinopathy had diabetes for duration of 6 to 10 years (80.2%) and also patients showing signs of Proliferative Diabetic Retinopathy had diabetes for more than 16 years (41.1%).

Table 1: Frequency categories of patients examined for the Occurrence of Diabetic Retinopathy

Fundus Findings	Male	Female	Frequency	Percentage
No Retinopathy (Fundus WNL)	37	29	66	28.6%
Diabetic Macular Edema	19	42	61	26.5%
Non Proliferative Diabetic Retinopathy	27	59	86	37.3%
Proliferative Diabetic Retinopathy	06	11	17	7.3%
Total	112	118	230	100%

WNL - Within Normal Limits

Table 2: Relationship between duration of diabetes and different types of Retinopathy

Duration	Grade of Retinopathy				Total f (%)
	Grade 0 f (%)	Grade 1 f (%)	Grade 2 f (%)	Grade 3 f (%)	
0-5 years	32(48.4)	12(19.6)	01(1.16)	0(0)	45(19.5)
6-10 years	12(18.1)	13(21.3)	69(80.2)	07(41.4)	101(43.9)
11-15 years	21(31.8)	32(52.4)	04(4.6)	03(17.6)	60(26)
≥16 years	01(1.51)	04(6.5)	12(13.9)	07(41.1)	24(10.4)
Total	66(100)	61(100)	86(100)	17(100)	230(100)

Grade 0 - No Retinopathy, Grade 1- Diabetic Macular Edema, Grade 2 -Non Proliferative Diabetic Retinopathy, Grade 3- Proliferative Diabetic Retinopathy

Table 3: Relationship between Hypertension and different types of Retinopathy

Status	Grade of Retinopathy				Total f (%)
	Grade 0 f (%)	Grade 1 f (%)	Grade 2 f (%)	Grade 3 f (%)	
Presence of HTN	24(36.3)	49(80.3)	57(66.2)	12(70.5)	142(61.7)
Absence of HTN	42(63.6)	12(19.6)	29(33.7)	05(29.4)	88(38.2)
Total	66(100)	61(100)	86(100)	17(100)	230(100)

HTN – Hypertension, Grade 0 - No Retinopathy, Grade 1- Diabetic Macular Edema, Grade 2 -Non Proliferative Diabetic Retinopathy, Grade 3- Proliferative Diabetic Retinopathy

Table 4: Relationship between Hyperlipidemia and different types of retino

Status	Grade of Retinopathy				
	Grade 0 f (%)	Grade 1 f (%)			
Presence of HLD	45(68.1)	24(39.3)	27(31.3)	5(29.4)	96(41.7)
Absence of HLD	21(31.8)	37(60.6)	59(68.6)	12(70.5)	134(58.2)
Total	66(100)	61(100)	86(100)	17(100)	230(100)

HLD – Hyperlipidemia, Grade 0 - No Retinopathy, Grade 1- Diabetic Macular Edema, Grade 2 -Non Proliferative Diabetic Retinopathy, Grade 3- Proliferative Diabetic Retinopathy

Table 5: Relationship between level of HbA$_1$C and different types of Retinopathy

Level of HbA$_1$C	Grade of Retinopathy				Total f (%)
	Grade 0 f (%)	Grade 1 f (%)	Grade 2 f (%)	Grade 3 f (%)	
> 6.5%	42(63.6)	0(0)	0(0)	0(0)	42(18.2)
6.5 – 7.5%	12(18.1)	01(1.6)	02(2.3)	0(0)	15(6.5)
7.5 – 8.5%	06(9)	09(14.7)	41(47.6)	03(17.6)	59(25.6)
8.5 – 9.5%	02(3)	32(52.4)	34(39.5)	06(35.2)	74(32.1)
< 9.5%	04(6)	19(31.3)	09(10.4)	08(47)	40(17.3)
Total	66(100)	61(100)	86(100)	17(100)	230(100)

Grade 0 - No Retinopathy, Grade 1- Diabetic Macular Edema, Grade 2 -Non Proliferative Diabetic Retinopathy, Grade 3- Proliferative Diabetic Retinopathy

Table 6: Risk factors associates with Diabetic Retinopathy in patients diagnosed with type II Diabetes Mellitus

Demographics	Without Diabetic Retinopathy (n=66)	With Diabetic Retinopathy (n=164)	P-Value
Sex (Male:Female)	37:29	52:112	0.001
Age (years)	48.16±10.29	56.24±7.35	0.004
Duration of diabetes (years)	6.06±4.74	11.06±4.35	0.001
Diagnosed Hypertension	24(36.36)	118(71.95)	0.001
Diagnosed Hyperlipidemia	45(68.18)	56(34.14)	0.001
HbA1c	6.75±1.51	9.16±0.96	0.001

Table 3, shows that most of the patients who had Diabetic Retinopathy also had Hypertension has a comorbidity (71.9%), which concludes that the onset/progression of Diabetic Retinopathy is directly proportional to the presence of Hypertension as a comorbidity.

Table 4, Hyperlipidemia has one of the co-morbidity of the patients having type 2 Diabetes Mellitus had no correlation with the onset/progression of Diabetic Retinopathy. About 65.8% of patients have Diabetic Retinopathy in the absence of Hyperlipidemia.

Table 5, shows that most of the patients had Grade 3 (Proliferative Diabetic Retinopathy) when their HbA1C levels were above 9.5% and also about 47.6% had grade 2 Diabetic Retinopathy when their HbA1C level were in-between 7.5 - 8.5%.

Table 6, shows that Female patients (n= 112) were more affected with Diabetic Retinopathy (DR) compared to male patients. In case of age, patients who were above the age of 55 years were more prone to Diabetic Retinopathy (DR). The duration of diabetes showed a significant relationship between the onset/progression of Diabetic Retinopathy (DR). Patients who were diabetic for a longer period of time had increased rate of Diabetic Retinopathy (DR). It showed a higher significance P-value of 0.001. Patients who had hypertension has a comorbidity had increased chance of Diabetic Retinopathy (DR). Statistics showed a higher significance P-value of 0.001. Patient who had increase in cholesterol level also had an increased probability of Diabetic Retinopathy (DR). Finally, higher the level of HbA1c, more than 9% they had higher probability of onset/progression of Diabetic Retinopathy (DR).

DISCUSSION:

Diabetic Retinopathy is considered to be the most severe microvascular complication in patients with type 2 Diabetes Mellitus, which turns out to be the leading cause of blindness in the age group of 20–74 years.[8] Our study also shows similar results most of the patients enrolled in our who have Diabetic Retinopathy falls under the age category of 40-60 years, In our study, most of the patients who had Diabetic Retinopathy were female, out of 164 patients who had Diabetic Retinopathy, 68% were female patients. Increase in the rate of Diabetic Retinopathy in type 2 Diabetes Mellitus patients imposes large economic burden to the health care system and society.[8] Our study shows that, significant association between duration of Diabetes Mellitus and onset/progression of Diabetic Retinopathy. Increase in duration of Diabetes Mellitus, have increased probability of progression of Diabetic Retinopathy. Patients who had Diabetes Mellitus for 0-5 years, about 8% had Diabetic Retinopathy. Patients having duration of diabetes for 6-10 years, about 54% had Diabetic Retinopathy. Patients having duration of diabetes for 11-15 years, about 24% had Diabetic Retinopathy. Patients having duration of diabetes for more than 16 years, about 14% had Diabetic Retinopathy. Most of the patients who had Diabetic Retinopathy fall under the group of 6-10 years of duration. Previous studies also showed similar results. A study conducted to find the association of duration of diabetes and occurrence of Diabetic Retinopathy showed the following results; about 76.7% of patients who suffered from diabetes for more than 20 years were diagnosed with Diabetic Retinopathy Aiello et al.[9] Another study suggests that people who are diabetic for more than 20 years have about 60% chance to have retinopathy independent of diabetic control.[10] The duration of Diabetes Mellitus is a meaningful predictor to assess the severity of Diabetic Retinopathy.[11] In another study, the following results were seen, 45.8% of patients diagnosed with Diabetes Mellitus more than 20 years exhibit proliferative Diabetic Retinopathy and also 88.9% of patient who have been _____ s are free of Diabetic Retinopathy.[12] Chronic hyperglycemia plays a m _____ tinopathy.[13] Krishnaiah et al suggested that high blood pressure have a sign _____ nd also as a modifiable risk factor.[14] Our study also proved similar results _____ tes Mellitus increases the probability of onset/progression of Diabetic Retinopathy. From the results obtained, out of 142 patients who had Hypertension, 118(83%) had Diabetic Retinopathy as well. High significance was seen with the p value of 0.001. Hypertension seems to be an important risk factor for the onset and progression of Diabetic Retinopathy.[15] The UK prospective diabetes study (UKPDS) shows that controlling blood pressure associated with reduction in onset as well as progression of Diabetic Retinopathy.[16]

HbA1c acts as a significant screening tool for diagnosis, management of Diabetes Mellitus and also in the onset/progression of Diabetic Retinopathy which is one of the major microvascular complications of Diabetes Mellitus.[17] HbA1c as a screening tool seems to be more effective compared to the blood glucose level, in defining the level of hyperglycemia which leads to the progression of Diabetic Retinopathy.[18,19] Previous studies have also shown a significant association between the level of HbA1c and severity of Diabetic Retinopathy through different grades.[20-22] Many previous studies also suggest that HbA1c as a modifiable risk factor.[23,24] Our study also showed similar results compared to previous studies as well, most the patients who had Diabetic Retinopathy had an HbA1c value above 8.5%.

Our study clarified that duration of diabetes, Hypertension and HbA1c are the most important predictor of Diabetic Retinopathy. Our study also suggests a significant association between increase in cholesterol level and occurrence of Diabetic Retinopathy. Based on the results obtained out of 96 patients who had Dyslipedimia, 56 (58%) had Diabetic Retinopathy. Fundus examination at the time of diagnosis of diabetes has been proven to be essential. Patients who are diabetic for a longer period of time has higher chance of progression of Diabetic Retinopathy but contradictory results were also seen in some studies. [25, 26]

CONCLUSION:

The significant morbidity and mortality of diabetes mellitus predominantly results from its complications, among which the vascular dysfunction leading to macular edema resembles the most important vision threatening complication. In our study, certain risk factors were found to be in association with the onset and progression of Diabetic Retinopathy such as, duration of diabetes mellitus, presence of hypertension, presence of hyperlipidemia, and also glycated haemoglobin level. Previous studies were also found to support similar results.

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CONFLICT OF INTEREST:

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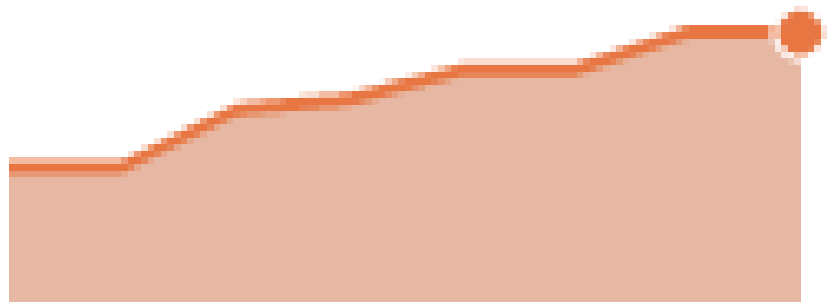# Research Journal of Pharmacy and Technology

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