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PREVALENCE OF DIABETIC RETINOPATHY IN TYPE II DIABETES IN RELATION TO RISK FACTORS: A HOSPITAL BASED STUDY

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ABSTRACT BODY: BACKGROUND: The prevalence of type 2 diabetes is known to be very high in the Indian subcontinent. Indian patients demonstrate certain distinct features i.e., onset at a younger age, a strong genetic predisposition and less common obesity. It is estimated that 79.4 million people in India will have Diabetes by the year 2030. The rapid increase in the number of persons with Diabetes is expected to lead to an increase in the number of persons with ocular complications of diabetes. Few studies have reported the magnitude and distribution of diabetic retinopathy (DR) in India. Diabetes mellitus (DM) is a major cause of avoidable blindness in both the developing and the developed countries. Patients with diabetic retinopathy (DR) are 25 times more likely to become blind than non-diabetics. Studies of various complications in Indian diabetics is therefore of great interest and very few studies are available on the prevalence of diabetic retinopathy from India. This study aims to estimate the prevalence of Diabetic Retinopathy in type 2 diabetes and the possible risk factors associated with DR. **OBJECTIVES:** To estimate the prevalence of Diabetic Retinopathy (DR) and the possible risk factors associated with DR **METHODS:** Source of Data The materials for the present study will be drawn from patients attending the out-patient department of Ophthalmology at Chigateri General Hospital and Bapuji Hospital attached to J.J.M Medical College, Davangere from November 2010 to September 2012. **Method of collection of Data (including sampling procedures if any):** A minimum of 100 cases with Type 2 Diabetes in CG hospital and Bapuji Hospital, Davangere will be selected for the study. A careful and detailed history will be taken regarding the duration and symptoms of the disease. Thorough systemic examination will be done. Investigations like routine blood, urine examination, FBS/PLBS and Lipid Profile will be done. This will be followed by a detailed Eye examination including: Examination of adnexae and extraocular structures i.e. the examination of face, orbits, eyebrows, eyelids, palpebral fissure, extraocular movements and lacrimal sac. Examination of anterior segment by slit lamp biomicroscopy Examination of the posterior segment by ophthalmoscopy (direct and indirect) and +90D biomicroscopy. Fundus Photography followed by Fluorescein Angiography (if required) will be undertaken for positive cases. Recording of visual acuity and intraocular pressure (applanation) will be done. **RESULTS:** A total of 1711 patients (M: 941, F: 770) were screened and 223 type 2 diabetic patients were enrolled in the study (137 males (61.4%) 86 females (38.6%). The Mean age was 55.92 + 10.027 (Males: 56.12 + 10.218 years and females: 55.73 + 9.836 years). Mean duration of Diabetes was 6.83 + 5.694. Prevalence of Type 2 Diabetes among the study population was 13.03 %. (17.03% for males and 11.16% for females). The Prevalence of Diabetic Retinopathy among type 2 diabetic was 30.49% (68 out of 223 patients). Male preponderance was present among DR patients (40 cases were males (58.8%) while 28 cases (41.2%) were females). Out of 68 Diabetic retinopathy patients, 55 patients (80.89%) had Non Proliferative Diabetic Retinopathy (NPDR) while 13 patients (19.11%) had Proliferative Diabetic Retinopathy (PDR). Diabetic Maculopathy was seen in 6 patients (8.82%).

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Duration of Diabetes and Diastolic Blood pressure showed a positive association with retinopathy with Regression Co-efficient 0.323 and 0.094 respectively. These results were statistically significant $P=0.0001$ and $P=0.002$ respectively. Our study showed a higher prevalence of Diabetic retinopathy in patients on Insulin and a combination of Insulin and Oral hypoglycemic Agents (OHA) (42.85% and 64.28% respectively) in comparison to patients on OHA's alone or on no medication Random Blood sugar among patients having diabetic retinopathy was 209.44 ± 86.326 mg/dL, and was significantly higher than patients not having retinopathy 153.25 ± 62.143 mg/dL ($P=0.001$). There was no statistical significance between family history and Diabetic retinopathy in our study ($P=0.722$).

CONCLUSIONS: Diabetic retinopathy is a major health problem in patients with type 2 Diabetes. Given the large number of diabetic subjects in India, even with the lower prevalence rates the actually number of patients with DR would be large. Risk factors such as Age, Duration of Diabetes, Hypertension, Hyperglycemia, Hyperlipidemia etc. should be taken into account for regular check-ups and early detection of diabetic retinopathy Duration of Diabetes proved to be the single most important association of Diabetic Retinopathy in our study ($P=0.0001$) followed by Diastolic Blood Pressure ($P=0.002$). Although high associations were observed in our study, Age and Systolic Blood Pressure were not significant risk factors for Diabetic Retinopathy. Mean Random Blood Sugar (RBS) levels among retinopathy patients was significantly higher than that of non-retinopathy patients ($P=0.0001$).

KEYWORDS: Prevalence; Diabetic Retinopathy (DR); Type 2 diabetes; Risk factors.

INTRODUCTION: Diabetes Mellitus currently affects more than 171 million people worldwide and will affect an estimated 366 million by 2030, with the most rapid growth in low and middle-income countries among populations of working age. By 2030, it is estimated that the number of people with diabetes more than 64 years of age will be more than 82 million in developing countries and more than 48 million in developed countries. The prevalence of diabetes for all age groups worldwide is estimated to be 2.8% in 2000 and will rise to 4.4% in 2030. Even if the prevalence of obesity remains stable until 2030, which seems unlikely, it is anticipated that the number of people with diabetes will more than double as a consequence of population aging and urbanization.¹

By 2030, India will be the country with the maximum number of diabetics in the world. India now has 40.9 million people with diabetes and the projected estimate for the year 2030 is 80 million.² An improvement in economic standards with consequent adoption of more sedentary lifestyle has contributed to this epidemic, especially of Type 2 Diabetes. There is marked difference in the prevalence of diabetes between urban and rural areas of India. The prevalence of diabetes in urban India was 12.1% in 2002 as compared to rural India which had prevalence of 6.4%.³ Diabetic retinopathy is among the most common ophthalmic complication of diabetes mellitus.

WHO has estimated that diabetic retinopathy is responsible for about 4.8% of the 37 million cases of blindness throughout the world.⁴ The incidence of blindness is 25 times higher in people with diabetes than in general population.⁵ The estimates of the prevalence of diabetic retinopathy in India suggest that there are more than 5.6 million people with diabetic retinopathy with more than 0.3 million suffering from proliferative retinopathy.⁶

Diabetic retinopathy develops in nearly all persons with Type I diabetes and in more than 77% of those with Type 2 diabetes who survive over 20 years with the disease.⁷ There is evidence

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that retinopathy begins to develop at least 7 -12 years before the clinical diagnosis of Type 2 diabetes.⁸

OBJECTIVES:

- To estimate the prevalence of Diabetic Retinopathy (DR) among type 2 diabetics.
- To observe associated risk factors for Diabetic Retinopathy.

METHODOLOGY: A Prospective study to Estimate the prevalence of Diabetic Retinopathy in Type 2 Diabetes in relation to risk factors was conducted in the outpatient department of Ophthalmology at Chigateri General Hospital and Bapuji Hospital attached to J.J.M. Medical College, Davangere from November 2010 to September 2012. Out of 1711 patients attending the OPD, 223 cases with Type 2 Diabetes in C.G hospital and Bapuji Hospital, Davangere were enrolled in the study by universal sampling.

They all satisfied the predefined Inclusion criterion. A careful and detailed history regarding Duration, Type and Treatment of Diabetes, Family History and associated systemic diseases such as Hypertension, Nephropathy, Neuropathy and Non-healing was taken. Data was collected on the basis of a predefined semistructured proforma. The project was approved by the institutional ethics committee.

OPHTHALMIC EXAMINATION:

A Detailed Eye Examination Included:

- Examination of adnexae and extraocular structures i.e the examination of face, orbits, eyebrows, eyelids, palpebral fissure, extraocular.
- Movements and lacrimal sac.
- Recording of Best corrected visual acuity (BCVA) and intraocular pressure (applanation) was done.
- Examination of anterior segment by slit lamp biomicroscopy.

A Detailed fundus examination was done by indirect ophthalmoscopy and +90D biomicroscopy. Non-proliferative Diabetic Retinopathy (NPDR) was diagnosed by the presence of Microaneurysms, Dot Blot hemorrhages, hard exudates or cotton wool spots. Proliferative Diabetic Retinopathy (PDR) was defined as the presence of abnormal new vessels on the disc or elsewhere. Retinopathy was classified according to the Diabetic Retinopathy Study (DRS) and Early treatment Diabetic Retinopathy Study (ETDRS).^{9,10} Due to limited resources and large number of patients, retinal photography followed by Fluorescein Angiography (if required) was done only in patients with evidence of retinopathy.

Systemic Examination and Investigations: A thorough systemic examination was done. Investigations like Routine blood investigations, Urine examination, Fasting plasma glucose and 2hr post prandial glucose, (Lipid Profile and HbA1c whenever possible) was advised and undertaken. Diagnosis of Diabetes was made in each case when Fasting Plasma Glucose (FPG) >126 mg/dL (7.0 mmol/L) or 2hr Post Prandial Glucose >200mg/dL (11.1 mmol/L) after a 75g glucose load¹¹ or any patient with a history of Diabetes on Treatment. Hypertension was defined as the presence of Systolic

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Blood Pressure >120 mmHg or a diastolic Blood pressure >80 mm Hg¹² or on Antihypertensive Treatment at the time of examination Urine protein estimation was done either in a 24hr sample of urine or the expected protein estimation by estimation of protein to creatinine ratio in a random sample. Presence of urinary infection was excluded before testing for proteinuria.

STATISTICAL ANALYSIS: Once data was collected and tabulated using MS Office Excel, the tabulated data was then analyzed on SPSS version 16.0 in 2 parts:

1. Descriptive Analysis: Percentages, Proportions, Mean and Standard Deviations
2. Inferential Analysis: unpaired T-tests, chi-square and binary logistic regression.

Prevalence of retinopathy in sub groups was compared by chi square test Contribution of risk factors such as age, duration of diabetes, Systolic Blood pressure, diastolic blood pressure to prevalence of Diabetic retinopathy was calculated by multiple logistic regression analysis and Odds Ratio.

EXCLUSION CRITERIA:

- Patients who are non-compliant.
- Patients who are under 40 years of age.
- Pregnant and Lactating women.
- Immunocompromised patients.
- Patient with renal insufficiency and Cardiovascular Diseases.

RESULTS: Out of 1711 patients (Males: 804; Females: 684) screened for Type 2 Diabetes, 223 patients had type 2 diabetes consisting of 137 Males and 86 Females. Prevalence Of Type 2 Diabetes among the study population was 13.03 %. (17.03% For males and 11.16% for females). Out of the total 223 cases of Diabetes Mellitus, majority of the cases (36.32%) were in the age group 40-50 years followed by 30.94% in the age group of 51-60 years, 23.76% in age group of 61-70 years and 8.96% in the age group of >70 years. Mean age of our study participants was 55.92 + 10.027 (SD). Mean age among males was 56.12 + 10.218 years and among females was 55.73 + 9.836 years. Out of the total 223 cases, 137 cases were males (61.4%) while 86 cases (38.6%) were females, showing male preponderance. Prevalence of Diabetic Retinopathy in our study population was 30.49%. Prevalence of DR was 29.19% among males and 32.55% among females.

In our study, majority of the patients having Diabetic retinopathy (39.7%) were in the age group 61-70 years followed by patients >70 years (27.9%). Below the age of 60 years, less than 21% of patients had Diabetic retinopathy. In our study, 20 diabetic retinopathy patients (29.4%) had a positive family history of type 2 Diabetes where as 48 patients (70.6%) had a negative family history. There was no statistical significance between family history and diabetic retinopathy in our study ($P=0.722$). Diabetic retinopathy was seen in 95% of patients above 70 years of age followed by more than 50% in the age group 61-70 years of age. 20.28% of patients in the 51-60 age group and 9.87% of patients in the age group of 41-50 years had diabetic retinopathy. Our study shows that the prevalence of diabetic retinopathy increases with the age of the patient. In our study, Prevalence of diabetic Retinopathy was 83.87% and 99.99% with duration of Diabetes of 10-15 years and >15 years respectively. Our study shows that Prevalence of Diabetic retinopathy increases with duration

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of Diabetes. Mean duration of Diabetes in our study was 6.83 ± 5.694 years. Our study showed patients having systolic BP more than 140 mmHg had a prevalence of Diabetic Retinopathy of more than 60%.

Prevalence of Diabetic retinopathy increases with Increase in Systolic Blood Pressure. Our study showed that with an increase in Diastolic Blood pressure above 90 mmHg, the prevalence of Diabetic retinopathy was more than 70%. Patients with Diastolic BP of 91-100 and >100 mmHg had Prevalence of Diabetic Retinopathy of 78.94% and 87.50% respectively. The mean Systolic Blood pressure among males in our study was 126.35 ± 17.81 mmHg and the mean Systolic Blood pressure among females was 130.70 ± 18.96 mmHg.

The difference in mean Systolic Blood pressure among males and females, in our study, had no statistical Significance ($P=0.085$). In our study, the mean Diastolic Blood Pressure among males was 84.16 ± 9.974 mmHg and the mean Diastolic Blood Pressure among females was 83.72 ± 9.585 mmHg. There was no statistical significance ($P=0.745$) in the difference of mean Diastolic BP among males and females. In the study population of 223 patients, 14 patients (M: 7, F:7) had Nephropathy, 18 patients (M:12; F:6) had Neuropathy and 11 patients (M: 9; F: 2) had non-healing ulcers. Although our study showed males to have higher prevalence of systemic associations, there was no statistical significant association between sex of an individual and Nephropathy ($P=0.140$), Neuropathy ($P=0.634$) or Non-Healing Ulcers ($P=0.154$). Prevalence of NPDR was 80.89% and PDR was 19.11% in our study.

Among NPDR Patients, majority of the patients had Moderate NPDR (42.65%) followed by Mild NPDR (23.55%), severe (10.29%) and very severe NPDR (4.41%). Diabetic Maculopathy was seen in 6 patients (8.82%). Our study showed a higher prevalence of Diabetic retinopathy in patients on Insulin and a combination of Insulin and Oral hypoglycemic Agents (OHA) (42.85% and 64.28% respectively) in comparison to patients on Oral hypoglycemic agents alone or those patients controlled by only diet and exercise (24.21% and 10.25% respectively). In our study, Proteinuria was present in 20.58% of the patients with diabetic retinopathy and was associated with more severe forms of retinopathy (71.42% of patients had either severe or very severe NPDR or PDR) There was no statistical significance between Nephropathy and prevalence of Diabetic retinopathy in our study ($P=0.140$).

In our study, the mean Random Blood sugar among patients having diabetic retinopathy was 209.44 ± 86.326 mg/dL which was significantly higher than patients not having retinopathy 153.25 ± 62.143 mg/dL ($P=0.001$) The variables, which have an association with retinopathy, are listed in the table. Duration of Diabetes and Diastolic Blood pressure showed a positive association with retinopathy with Regression Co-efficient 0.323 and 0.094 respectively. These results were statistically significant $P=0.0001$ and $P=0.002$ respectively. In our study, the Odds of having Retinopathy is 1.052 with respect to Age, 1.381 with respect to Duration of disease and 1.099 with respect to Diastolic Blood Pressure. Duration of Diabetes proved to be the single most important association of Diabetic Retinopathy in our study ($P=0.0001$) In our Study, Age and Systolic Blood Pressure were not statistically significant risk factors of Diabetic Retinopathy.

DISCUSSION: Diabetic retinopathy is an emerging public health problem with both medical and economic considerations involved. It is now considered as the commonest cause of new cases of legal blindness among the working age individuals both in developing and developed countries. This study presents the prevalence of retinopathy in a cohort of South Indian type 2 diabetic patients from the

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city of Davangere. This was a prospective study on all patients attending the Out patient department of Chigateri District Hospital and Bapuji Hospital attached to J.J.M Medical College Davangere, a tertiary level health care center.

SOCIO-DEMOGRAPHIC CHARACTERISTICS OF THE STUDY: A total of 1711 patients (M: 941, F: 770) were screened and 223 patients (M: 137, F: 86), having type 2 diabetes, were enrolled in the study. Prevalence Of Type 2 Diabetes among the study population was 13.03 %. (17.03% for males and 11.16% for females).

Age and Sex Distribution in Study Population: Out of the total study population of 223 cases, 137 cases were males (61.4%) while 86 cases (38.6%) were females. Among patients having diabetic retinopathy, 40 cases were males (58.8%) while 28 cases (41.2%) were females, showing male preponderance. The Mean age of our study was 55.92 + 10.027 (Males: 56.12 + 10.218 years and females: 55.73 + 9.836 years) which was similar to other studies. The Difference in the mean ages among males and females was not statistically significant ($P=0.778$). In the study population, 36.32% were in the age group of 40-50 years, 30.94% were in the age group of 51-60 years, 23.76% were in age group of 61-70 years and 8.96% were in the age group of >70 years. However, majority of the patients having Diabetic retinopathy (39.7%) were in the age group 61-70 years followed by patients >70 years (27.9%). Below the age of 60 years, less than 21% of patients had Diabetic retinopathy.

Prevalence of Diabetic Retinopathy: We observed different types of Retinopathy in 68 patients out of 223 i.e Prevalence of Diabetic Retinopathy in our study was 30.49% (29.19% among males and 32.55% among females). Our results are consistent with various other studies. Family History and Diabetic Retinopathy In our study, 20 diabetic retinopathy patients (29.4%) had a positive family history of type 2 Diabetes where as 48 patients (70.6%) had a negative family history. there was no statistical significance between family history and Diabetic retinopathy in our study ($P=0.722$).

RISK FACTOR ASSESSMENT OF THE STUDY: Age of Patient and Diabetic retinopathy In our Study, Diabetic retinopathy was seen in 9.87% in the 40-50 age group, 20.28% in the 51-60 age group, 50.94% in the 61-70 age group and 95% in the >70 age group (95%). Hence, there were higher number of retinopathy patients in age groups 61-70 years and >70 years as compared to lower age groups. The Odd 's ratio in our study of retinopathy with respect to age was 1.052 (95% CI 0.999-1.107). However, Age was not a statistically significant risk factor for the prevalence of Diabetic retinopathy in our study ($P=0.053$).

Duration of Diabetes and Diabetic Retinopathy: The mean duration of diabetes was 6.83 years + 5.69. In our study the duration of Diabetes was the strongest predictor for development and progression of Diabetic Retinopathy ($P=0.0001$). Our results show that 83.87% of patients having duration of diabetes more than 10 years had Diabetic Retinopathy whereas 99.99% of patients having duration of Diabetes more than 15 years had retinopathy in comparison to 7.07% of patients with duration of diabetes less than 5 years.

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Systolic and Diastolic Blood Pressure and Diabetic Retinopathy: In our study, Diastolic Blood Pressure showed a significant association with prevalence of diabetic retinopathy ($P=0.002$) whereas, although systolic blood pressure was associated with higher prevalence of diabetic retinopathy, it was not statistically significant ($P=0.605$). The mean Systolic Blood pressure among males in our study was 126.35 ± 17.81 mmHg and the mean Systolic Blood pressure among females was 130.70 ± 18.96 mmHg. This difference in mean Systolic Blood pressure among males and females, in our study, had no statistical significance ($P=0.085$). Similarly, there was no statistical significance ($P=0.745$) in the difference of mean Diastolic BP among males (84.16 ± 9.974 mmHg) and females (83.72 ± 9.585 mmHg).

Systemic Associations and Diabetic Retinopathy: In our study population of 223 patients, 14 patients (M: 6, F:8) had Nephropathy, 18 patients (M:12; F:6) had Neuropathy and 11 patients (M: 9; F: 2) had non-healing ulcers. Although our study showed males to have higher prevalence of systemic associations, there was no statistical significant association between sex of an individual and Nephropathy ($P=0.140$), Neuropathy ($P=0.634$) or Non-Healing Ulcers ($P=0.154$). In our study, Proteinuria was present in 20.58% of the patients with diabetic retinopathy and was associated with more severe forms of retinopathy (71.42% of patients had either severe or very severe NPDR or PDR). Types of Diabetic Retinopathy Out of 68 Diabetic retinopathy patients, 55 patients (80.89%) had Non Proliferative Diabetic Retinopathy (NPDR) while 13 patients (19.11%) had Proliferative Diabetic Retinopathy (PDR). NPDR Patients consisted of 16 patients (23.55%) of Mild NPDR, 29 patients (42.65%) of Moderate NPDR, 7 patients (10.29%) of Severe NPDR and 3 patients (4.41%) of Very severe NPDR. Diabetic Maculopathy was seen in 6 patients (8.82%).

Treatment Modality and Diabetic Retinopathy: Our study showed a higher prevalence of Diabetic retinopathy in patients on Insulin and a combination of Insulin and Oral hypoglycemic Agents (OHA) (42.85% and 64.28% respectively) in comparison to patients on Oral hypoglycemic agents alone or those patients not on any medication (24.21% and 10.25% respectively) probably because of longer duration of diabetes or poor glycemic control prompting the use of Insulin/ Insulin combination with OHAs.

Blood Glucose levels and Diabetic Retinopathy: Our results showed that the mean Random Blood sugar among patients having diabetic retinopathy was 209.44 ± 86.326 mg/dL which was significantly higher than patients not having retinopathy 153.25 ± 62.143 mg/dL ($P=0.001$). This statistically significant finding in our study hints towards the protective effect of glycemic control on the development and progression of Diabetic Retinopathy.

LIMITATIONS OF STUDY:

1. Small Sample Size: A larger sample size would better reflect the Prevalence of Retinopathy and identify risk factors.
2. Referral Bias: Being a tertiary care hospital, prevalence rates of retinopathy may show referral bias.

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3. Fundus angiography was not done in all patients with Diabetic retinopathy due to monetary reasons. This would have lead to an underestimation of prevalence and severity of diabetic retinopathy.
4. HbA1c levels to evaluate glycemic control of patients were not included due to poor follow-up and monetary factors. Thus, glycemic control as an association to prevalence of Diabetic retinopathy could not be evaluated.
5. Other risk factors of Diabetic retinopathy such as hyperlipidemia, anemia, alcoholism, pregnancy and Obesity (BMI) were not evaluated in this study.

CONCLUSION: Diabetic retinopathy is a major health problem in patients with type 2 Diabetes. As new therapies for DR and its associated complications emerge, the need to collect and monitor new epidemiological data becomes increasingly important to be able to evaluate the impact and effectiveness of these therapies. Risk factors such as Age, Duration of Diabetes, Hypertension, Hyperglycemia, Hyperlipidemia etc. should be taken into account for regular check-ups and early detection of diabetic retinopathy. Given the large number of diabetic subjects in India, even with the lower prevalence rates the actually number of patients with DR would be large.

This underscores the need for routine retinal screening of diabetic individuals annually to detect DR and prevent visual impairment. In addition, optimized control of systemic considerations, which affect onset and/or progression of DR, through an intensive, multidisciplinary, healthcare team-based approach, can markedly reduce impairment of vision due to Diabetic Retinopathy.

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