

Evaluation of Risk Factors in the Severity of Diabetic Retinopathy

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ABSTRACT:

INTRODUCTION: Diabetes mellitus is one of the world's fastest-growing chronic diseases. According to WHO, it is estimated that 123.5 million are likely to have diabetes by the year 2040 in India (1). It is a heterogeneous group of metabolic diseases characterized by hyperglycemia due to insulin resistance or insulin secretion defects(2). Ophthalmic complications of diabetes include corneal abnormalities, pupillary abnormalities, iris neovascularization, glaucoma, cataracts, and retinopathy. Diabetic retinopathy, a vision-threatening disorder, remains the commonest complication(4). The prevalence of DR is expected to increase along with the increasing rate of diabetes. The risk factors for diabetic retinopathy are modifiable (blood glucose, blood pressure, serum lipids, obesity, anaemia, alcohol, and smoking), non-modifiable (duration, age, sex), and other independent factors like the type of Diabetes mellitus, family history of DR (5). The present aim of the study is to evaluate the multiple risk factors associated with the development and severity of Diabetic retinopathy.

AIM: To evaluate the multiple risk factors associated with the development and severity of Diabetic retinopathy

STUDY DESIGN: a hospital-based cross-sectional study.

METHODS: 139 patients included in the study were subjected to a detailed ocular examination which included Detailed ocular and medical history, Best-corrected visual acuity, Anterior segment examination, Posterior segment evaluation using a direct ophthalmoscope and 90D lens and Fundus photography. Systemic investigations included Blood pressure, Fasting blood sugar, postprandial blood sugar, HbA1c, Hemoglobin, Calculation of BMI. The Results obtained were subjected to statistical analysis.

RESULTS: The results showed that the progression of diabetic retinopathy is dependent on various risk factors like duration of diabetes, glycemic control, hypertension were having significant associations with diabetic retinopathy.

CONCLUSION: The present study showed that the progression of diabetic retinopathy is dependent on various risk factors like duration of diabetes, glycemic control, hypertension.

KEYWORDS: Diabetic retinopathy, Duration of Diabetes, HbA1C, Blood pressure.

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I. INTRODUCTION

Diabetes mellitus is one of the world's fastest-growing chronic diseases. According to WHO, it is estimated that 123.5 million are likely to have diabetes by the year 2040 in India(1). It is a heterogeneous group of metabolic diseases characterized by hyperglycemia due to insulin resistance or insulin secretion defects(2). Ophthalmic complications of diabetes include corneal abnormalities, pupillary abnormalities, iris neovascularization, glaucoma, cataracts, and retinopathy. Diabetic retinopathy, a vision-threatening disorder, remains the commonest complication(3). The risk factors for diabetic retinopathy are modifiable (blood glucose, blood pressure, serum lipids, obesity, anaemia, alcohol, and smoking), non-modifiable (duration, age, sex), and other independent factors like the type of Diabetes mellitus, family history of DR (4). Duration of Diabetes is one of the most important determining factors for the occurrence and progression of diabetic retinopathy (5). Hyperglycaemia is considered to play an important role in the pathogenesis of retinal microvascular damage. Retinal ischemia caused by diabetic retinopathy is aggravated by hypertension. Clinical evaluation of these determinants helps in awareness of what variables are significant to be controlled to prevent DR and its progression to blindness. Identifying risk factors and their control is as important as timely detection of diabetic retinopathy. This article evaluates the role of major risk factors in Diabetic retinopathy.

II. MATERIAL AND METHODS

STUDY DESIGN: a hospital-based cross-sectional study.

STUDY DURATION:

One year from the date of institutional scientific and ethics committee approval (Dec 2019 to Nov 2020)

STUDY SOURCE: The outpatient department of Ophthalmology, Sri Venkateshwara Medical College and SVRR Government General Hospital, Tirupati.

SAMPLE SIZE:

139 patients fulfilling the inclusion and exclusion criteria attending the outpatient department of ophthalmology, SVRRGH, Tirupati.

INCLUSION CRITERIA: All patients of diabetic retinopathy who have given written and informed consent

EXCLUSION CRITERIA:

- 1) Patients with hazymedia which can interfere with a detailed examination of the fundus.
- 2) Type 1 Diabetes Mellitus
- 3) Gestational Diabetes Mellitus

METHODS: Ethical and scientific committee approval was obtained for conducting the study. Total 139 patients were included in this study as per the inclusion criteria. An informed, written consent was taken from all the patients.

All the subjects underwent a complete ophthalmic evaluation which included Detailed ocular and medical history, Best-corrected visual acuity, Anterior segment examination using slit-lamp biomicroscopy (CARL ZEISS MEDITECH AG 07740 Jena, Germany), Posterior segment evaluation using a direct ophthalmoscope and 90D lens. (Diabetic retinopathy was graded as per ETDRS classification) & Fundus photography.

Systemic investigations included Blood pressure, Fasting blood sugar, Postprandial blood sugar & HbA1c.

- The blood pressure of each subject was measured in the 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; patients were considered as hypertensive if the systolic BP was ≥ 140 mmHg or diastolic BP was ≥ 90 mmHg or if the patient was on anti-hypertensive treatment.
- Glycaemic control was graded according to HbA1c levels. Values less than 7% were considered as good control of diabetes. Levels between 7.1 to 8.5% - fair control and levels beyond 8.5% were considered poor control.

STATISTICAL ANALYSIS:

Results and data were analyzed using SPSS 22 Version, and statistical significance was expressed by p-value.

III. RESULTS

A total of 139 subjects with diabetic retinopathy were included in the present.

TABLE: 1 Age Distribution

Age group (in years)	Frequency	Percentage
31-40	7	5.0
41-50	38	27.3
51-60	48	34.6
61-70	39	28.1
≥ 71	7	5.0
Total	139	100.0

Most of the subjects were in the age group of 51-60 years (34.5%), followed by 61-70 (28.1%) years and 41-50 (27.3%) years. The mean age of subjects was $55.3 \pm$ year

TABLE: 2 Gender Distribution

Gender	Frequency	Percentage
Male	76	54.7
Female	63	45.3
Total	139	100.0

Among the 139 subjects, males were 76 (54.7%), and the rest were females (45.3%) and Male: Female ratio was 1.2:1

TABLE: 3Severityof diabeticrotinopathy

Diagnosis	Frequency	Percentage
Mild NPDR	28	20.1
ModerateNPDR	28	20.1
SevereNPDR	33	23.8
VerysevereNPDR	37	26.6
PDR	13	9.4
Total	139	100.0

Outof139subjects,28(20.1%)hadMildNPDR,28(20.1%)hadmoderateNPDR,33(23.8%) hadsevereNPDR,37(26.6%)hadverySevereNPDR,and13(9.4%)subject.

TABLE: 4Duration of diabetes mellitus

DurationofDM(inyears)	Frequency	Percentage
0-5	40	28.8
6-10	47	33.8
11-15	26	18.7
16-20	22	15.8
>21	4	2.9
Total	139	100.0

Out of 139 subjects, 47(33.8%) had a duration of diabetes for 6-10 years, followed by 0-5 years in 40(28.8%) subjects, 11-15 years in 26(18.7%) subjects, 16-20 years in 22(15.8%) subjects. Four subjects (2.9%) had a duration of DM \geq 21 years.

TABLE: 5 HbA1C levels

HbA1cLevels	Frequency	Percentage
<7%(Goodcontrol)	53	38.1
7.1-8.5%(Faircontrol)	53	38.1
>8.5%(Poorcontrol)	33	23.8
Total	139	100.0

Outof139subjects,53(38.1%)hadHba1clevelsls than7%,53(38.1%)hadHba1clevelsintherangeof7.1-8.5%and33(23.8%)hadHba1cgreaterthan8.5%.

TABLE: 6Frequency of Hypertension

Hypertension	Frequency	Percentage
Present	81	58.3
Absent	58	41.7
Total	139	100.0

Outof139subjects,81(58.3%)hadhypertension.

TABLE: 7Diabetic retinopathy vs duration of diabetes (in years)

The severity of retinopathy vs Duration of DM(inyears)	0-5 N(%)	6-10 N(%)	11-15 N(%)	16-20 N(%)	\geq 21 N(%)	TotalN(%)	p-value*
Mild NPDR	23 (82.1)	4(14.3)	1(3.6)	0(0.0)	0(0.0)	28(100.0)	<0.001
Moderate NPDR	10 (35.7)	17(60.7)	1(3.6)	0(0.0)	0(0.0)	28(100.0)	
SevereNPDR	7 (21.2)	5(15.2)	15(45.5)	6(18.2)	0(0.0)	33(100.0)	
Very severeNPDR	0(0.0)	21(56.8)	7(18.9)	9(24.3)	0(0.0)	37(100.0)	
PDR	0(0.0)	0(0.0)	2(15.4)	7(53.8)	4(30.8)	13(100.0)	
Total	40 (28.8)	47(33.8)	26(18.7)	22(15.8)	4(2.9)	139(100.0)	

chi-square value=146.79;df=16.;Significant*

In the present study, the majority 23(82.1%) of subjects with Mild NPDR had aduration of diabetes for less than five years.

The most common duration of diabetes in Moderate NPDR was 6-10 year (60.7%), Severe NPDR was 11-15 years (45.5%), and in Very Severe NPDR was 6-10 years (56.8%). 30.8% of patients with PDR had a duration of greater than 21 years. As the severity of diabetic retinopathy increased, the duration of diabetes increased, and the difference in proportion was found to be statistically significant.

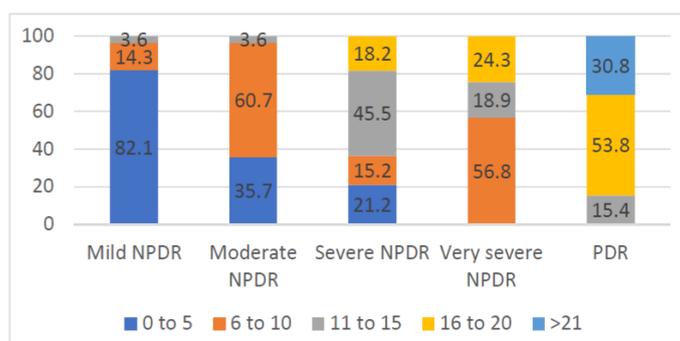


Chart 1: Diabetic retinopathy vs duration of Diabetes

TABLE: 8 Diabetic retinopathy vs HbA1c levels

Diagnosis vs HbA1c levels	<7%N(%)	7.1%-8.5%N(%)	>8.5%N(%)	TotalN(%)	p-value*
Mild NPDR	24(85.7)	4(14.3)	0(0.0)	28(100.0)	<0.001
Moderate NPDR	17(60.7)	8(28.6)	3(10.7)	28(100.0)	
Severe NPDR	4(12.1)	20(60.6)	9(27.3)	33(100.0)	
Very severe NPDR	7(18.9)	19(51.4)	11(29.7)	37(100.0)	
PDR	1(7.7)	2(15.4)	10(76.9)	13(100.0)	
Total	53(38.1)	53(38.1)	33(23.8)	139(100.0)	

chi-square value=70.514;df=8;Significant*

Among mild NPDR cases, 24(85.7%) had good Glycemic control and 4(14.3%) had fair control. In patients with moderate NPDR, 17(60.7%) had good Glycemic control, 8(28.6%) had fair control and 3(10.7%) had poor control of glycemia. 4(12.1%) subjects in severe NPDR had good glycemic control, 20(60.6%) had fair control and remaining 9(27.3%) had poor control. In very severe NPDR patients, majority (51.4%) had fair control of glycaemia. The majority of subjects with PDR 10(76.9%) had poor glycemic control.

As the severity of diabetic retinopathy increased, the proportion of patients with poor glycemic control increased and the difference in proportion was found to be statistically significant.

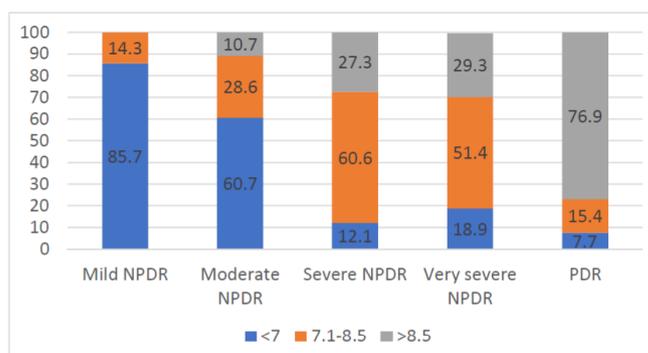


Chart 2: Diabetic retinopathy vs HbA1c levels

TABLE: 8 Diabetic retinopathy vs hypertension.

Severity of retinopathy vs hypertension	Present N(%)	Absent N(%)	Total N(%)	p-value*
Mild NPDR	12(42.9)	16(57.1)	28(100.0)	0.009
Moderate NPDR	15(53.6)	13(46.4)	28(100.0)	
Severe NPDR	15(45.5)	18(54.5)	33(100.0)	
Very severe NPDR	28(75.7)	9(24.3)	37(100.0)	
PDR	11(84.6)	2(15.4)	13(100.0)	
Total	81(58.3)	58(41.7)	139(100.0)	

Chi-square value=13.539;df=4;Significant*

Among the 139 subjects,81(58.3%) was found to have hypertension. Out of the mild NPDR cases,42.9% had hypertension.53.6% of moderate NPDR,45.5% of severe NPDR,75.5% of very severe NPDR and 84.6% of subjects with PDR had hypertension.

As the severity of retinopathy increased, the proportion of cases with hypertension increased, and the difference in proportion was statistically significant

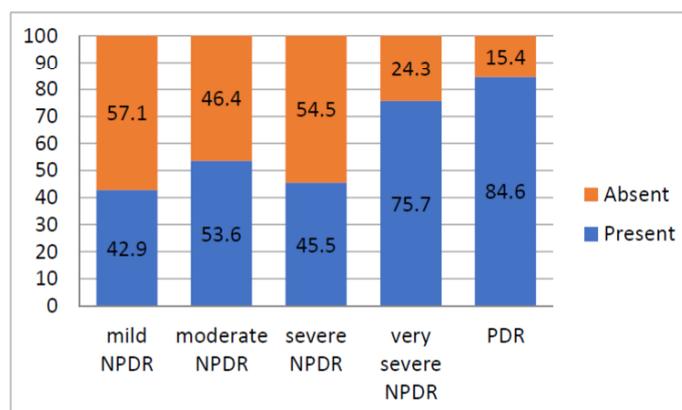


Chart3: Diabetic retinopathy vs hypertension

IV. DISCUSSION

Diabetes mellitus (DM) is a global epidemic. The ninth edition of diabetes Atlas by the International Diabetes Federation released in 2019 estimates the diabetic population will reach up to 700 million by the year 2045, the increase being disproportionately more in developing countries. This will result in a heavy burden on the healthcare system because of several DM-related complications. Studies from Southern India reported the range of prevalence from 12.2% to 18.03% in the population with known DM. The prevalence of DR among persons with diabetes ranged from 10% to 30.4%. Diabetic retinopathy is one of the potentially blinding conditions in middle age and elderly patients. Among the various factors that can influence the progression of diabetic retinopathy, the impact of duration of diabetes Mellitus, glycemic control, blood pressure were discussed in this study.

AGE DISTRIBUTION:

In the present study, the most common age group in the patients with diabetic retinopathy was 50-60 years (34.5%). The least common age group among the subjects was 31 to 40 years (5%) and >71 years (5%). The mean age group was 55.3 years which was similar to the studies in table 9.

TABLE: 9 Mean age group of the study population

STUDY	MEAN AGE GROUP
Present study	55.3±
Anjali P. Shroete et al (6)	56.4±11.2 years
Anulekha Mary John et al (7)	59.9±12.18 years.
Balasubramanian Nadarajan et al (8)	56.69 years

PraveenaKKet.al(9)	56.7±11.2years
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In the Aravind Comprehensive Eye Study (ACES) conducted in a rural population in three districts of Tamil Nadu, the most common age group in patients with diabetic retinopathy was in the range of 60-69 years (10). The Singapore India Eye Study (SINDI), which was conducted on 2200 subjects ethnic Indians living in Singapore, also reported a mean age of 57.8 years (11). The Andhra Pradesh Eye Disease Study, which was carried out in 21 districts of India, reported a mean range of the urban residents as 46.7 ± 12.9 years; and for rural residents was 30 to 95 years 47.8±12.9 years (12).

GENDER DISTRIBUTION:

Out of 139 patients who participated in the study, 63 were females (45.3%), and 76 were males (54.7%).

TABLE: 10 Gender distribution among the study population.

STUDY	MALES	FEMALES
Present study	54.7%	45.3%
Anjali P Shorteet al.(6)	68%	32%
Abhishek Padha et al.(13)	74.5%	25.5%
Anulekha Mary John et al.(7)	62%	38%
Balasubramanian Nadarajan et al.(8)	43.8%	56.2%

There was male preponderance in the present study which was similar to a study done by Anjali P Shorteet al.(6) and Abhishek Padha et al.(13) also found similar results of a higher rate of diabetic retinopathy among the males. The study was done by Anulekha Mary John et al.(7) also found more prevalence of diabetic retinopathy among males. Female preponderance was observed in the study conducted by Balasubramanian Nadarajan et al.(8)

The Chennai Urban Rural Epidemiology Study in India and a hospital-based study in Oman found that DR was significantly higher in males than in female patients (14).

In contrary, a study which was conducted by MK Shrestha et al.(15) in Nepal showed a slightly higher prevalence in females (46.3%) than in males (42.6%).

INCIDENCE OF VARIOUS STAGES OF DIABETIC RETINOPATHY:

In the present study, 28 subjects (20.1%) presented with Mild NPDR, 28 subjects (20.1%) with moderate NPDR, 70 subjects (23.7%) with severe NPDR, 37 subjects (26.6%) with very severe NPDR and 13 subjects (9.4%) presented with PDR.

TABLE: 11 Incidence of various stages of diabetic retinopathy

STUDY	Mild NPDR	Moderate NPDR	Severe to Very Severe NPDR	PDR
Present study	20.1%	20.1%	50.3%	9.4%
Rishi Mehta (16)	51.31%	22.36%	17.1%	9.2%
Karma Loday Bhutia et al.(17)	51.7%	35.6%	4.6%	8%
Balasubramanian Nadarajan et al.(8)	44.4%	51.9%	3.7%	-

The present study had a more incidence of severe and very severe NPDR changes among the subjects. The studies conducted by Rishi Mehta et al., Karma Loday et al., (18) and Balasubramanian Nadarajan et al. (19) had more incidence of mild and moderate NPDR changes among patients.

DURATION OF DIABETICS:

The duration of diabetes is one of the strongest predictors for the development and progression of retinopathy. In the present study, 40 subjects (28.8%) had diabetes for a period of 0-5 years, 47 subjects (33.8%) in 6-10-year duration, 26 subjects (18.7%) in 11-15 years duration and 22 subjects (15.8%) in 16-20 years duration. Only four subjects (2.9%) had a duration of more than 21 years.

About 80% of the patients with mild NPDR had diabetes for a period of less than five years. The most common duration of diabetes in patients with moderate NPDR (60.7%) was 6-10 years, and in severe NPDR was 11-15 years. Patients with very severe NPDR had diabetes for 6-10 years, followed by 16-20 years. 53.8% of patients in PDR had diabetes for 16-20 years, and 30.8% had diabetes for more than 21 years. As the severity of diabetic

retinopathy increased, the duration of diabetes increased, and the difference in proportion was found to be statistically significant. ($p < 0.001$)

TABLE: 12 Mean duration of diabetes (in years) with the severity of diabetic retinopathy.

STUDY	MILDNPDR	MODERATE NPDR	SEVERE-VERY SEVERE NPDR	PDR
PRESENT STUDY	4.00±2.47	6.89±2.28	11.42±4.58	19.2±4.00
Abhishek Padha et al. (10)	14.95±4.29	17.76±3.89	18.66±3.69	24.53±5.92
Kaur Pet et al. (20)	11.62±4.41	14.50±7.17	14.76±6.45	23.45±10.13
Shantha Sruthi. (21) Met. al	2.9±1	6.5±1.8	8.5±3.3	15.8±1.4

The results of the present study were comparable with Shantha Sruthi. Met. al. (21) study where the severity of diabetic retinopathy was significantly associated with duration of diabetes. Abhishek Padha et al. (68) with $p < 0.00001$ and Kaur Pet et al. (20) with $p < 0.001$ reported a similar significant association of severity of diabetic retinopathy with the duration of diabetes mellitus. The Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR) reported a higher prevalence of DR associated with a longer duration of diabetes (22). In persons with type 1 diabetes with less than 5 years of duration, the prevalence of retinopathy was about 10%, whereas it ranged from 25 to 40% in individuals with type 2 diabetes. In the CURES Eye study, 41.8% had DR after 15 years of diabetes, and the severity of DR proportionally increased with the duration of diabetes. The study also demonstrated that for every five-year increase in the duration of diabetes, the risk for DR increased by 1.89 times. (23) Indian studies have shown an increased prevalence of DR as the duration of diabetes increased (14, 22, 23) In a study conducted by Dandona et al. (24) in type 2 diabetes, 87.5% of patients with >15 years duration of diabetes had DR and only 18.9% showed DR changes with <15 years duration of diabetes.

GLYCAEMIC CONTROL:

There is strong evidence to suggest that the development and progression of DR is influenced by the level of hyperglycaemia.

TABLE: 12 GLYCAEMIC CONTROL

STUDY	Glycaemic control (HbA1c %)	Mild NPDR	Moderate NPDR	Severe NPDR	Very severe NPDR	PDR
Present study	<7	85.7%	60.7%	12.1%	18.9%	7.7%
	7.1-8.5	14.3%	28.6%	60.6%	51.4%	15.4%
	>8.5	0%	10.7%	27.3%	29.7%	76.9%
Dr Srinivas Phani Nakkella et al. (25)	6.5-8.5	93%	55%	13%	-	15%
	8.6-10.5	7%	32%	55%	-	54%
	10.6-12.5	0%	9%	27%	-	31%
	12.6-14.5	0%	4%	5%	-	0%

In the present study, as the severity of diabetic retinopathy increased, the proportion of patients with poor glycaemic control increased and the difference in proportion was found to be statistically significant. ($p < 0.001$). This was similar to the study done by Dr Srinivas Phani Nakkella et al., (25) which showed that the HbA1c levels increased with the severity of diabetic retinopathy. Poor glycaemic control led to the worsening of retinopathy.

Similar results were found in a study done by Pragati Garg et al. (26), in which the majority of patients with mild and moderate NPDR (34%) showed fair glycaemic control, whereas the majority of patients (28%) with severe and very severe NPDR had poor glycaemic control. PDR was found in a higher proportion of patients with poor control (36%) as compared to fair control (3.4%) and good control (0.4%) of HbA1c values. A significant association between severity of retinopathy and HbA1c values was found ($p < 0.001$)

Kahlon, Pathak, 2011 (27) Study showed intensive glycaemic control with HbA1c value <6.5% has significantly ($p < 0.003$) reduced the progression of retinopathy.

In a meta-analysis study, intensive glycaemic control reduced the risks of retinal photocoagulation or vitrectomy, macular oedema and progression of retinopathy (Zhang G et al., 2015) (28).

Thus, good glycemic control has proven to retard the progression of diabetic retinopathy in DM patients. In the CURES Eye Study (16), a linear trend in the prevalence of retinopathy with an increase in HbA1c levels was observed. For every 2 per cent elevation of HbA1c, the risk for DR increased by a factor of 1.710. In the UKPDS (29), the risk reduction in eye complications for every 1 per cent decrease in HbA1c was 19 per cent. Thus, it was observed that long term glycemic control plays an important role in delaying the onset and slowing down the progression of DR.

HYPERTENSION:

It has been hypothesized that increased blood pressure causes damage to the retinal capillary endothelial cells through the effects of increased blood flow.

In this study, hypertension was the most common systemic comorbidity found in 58.3% of the patients. The prevalence of hypertension in Diabetic retinopathy compared with other studies is given in the table.

TABLE: 13 Prevalence of hypertension in patients with diabetic retinopathy

STUDY	Percentage of patients with hypertension
Present study	58.3%
P.Kauretal.(25)	46.5%
Kamranet.al(30)	43%
AshokKumar etal.(31)	72%
AbhishekPadha(20)	68.54%
Anjali Pshorteet.al(10)	50%

The present study was comparable with P.Kauretal.(25) and Anjali Pshorteet.al.(10)

TABLE: 14 Severity of diabetic retinopathy with hypertension

	Present study	Rizkiet.al(82)
Mild	42.9%	0%
Moderate	53.6%	22.2%
Severe	45.5%	48.1%
Very severe	75.7%	-
PDR	84.6%	67.7%

As the severity of DR increased, the proportion of cases with hypertension also increased, and the difference in proportion was found to be statistically significant ($p=0.009$). This was comparable with the study conducted by Rizkiet.al.(27)

A study by MK Shrestha et al. (15) showed that hypertension and DR had a strong association ($p=0.00$). The development of diabetic retinopathy was twice more likely in hypertensive than non-hypertensive cases.

The UKPDS (29) showed that the incidence of retinopathy was associated with systolic blood pressure. In 1919 patients with type 2 diabetes retinal photographs taken at diagnosis and six years later showed a significant association of systolic hypertension with retinopathy incidence. Those with systolic blood pressure ≥ 140 mm Hg were 2.8 times (95% confidence interval) as likely to develop retinopathy than people with systolic blood pressure < 125 mm Hg.

In the

Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR), diastolic blood pressure was a significant predictor of progression of diabetic retinopathy to proliferative diabetic retinopathy over 14 years of follow up in patients with younger-onset (type 1) diabetes mellitus, independent of glycosylated hemoglobin and the presence of gross proteinuria. (22)

The Appropriate Blood Pressure Control in Diabetes (ABCD) Trial (28) compared the effects of intensive (diastolic blood pressure goal of 75 mm Hg) and moderate (diastolic blood pressure of 80–89 mm Hg) blood pressure control in 470 hypertensive subjects (baseline diastolic blood pressure of ≥ 90 mm Hg) with type 2 diabetes mellitus. Over a 5 year follow up period, intensive and moderate groups did not show any difference regarding the progression of diabetic retinopathy. The lack of efficacy of the trial compared to the UKPDS might be due to the shorter time period of the ABCD trial (5 years versus 9 years on average for

the UKPDS), lower average blood pressure control in the ABCD trial (144/82 mm Hg versus 154/87 mmHg in the UKPDS), and poorer glycemic control in the ABCD trial than the UKPDS.

In the Indian context, hypertension was not a significant confounding factor in the CURESE eye study, however, uncontrolled hypertension did influence the progression of DR. (14)

V. CONCLUSION

The progression of diabetic retinopathy is dependent on various risk factors, and this study showed that duration of diabetes, glycemic control, hypertension were having significant associations with diabetic retinopathy.

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