PREVALENCE OF DIABETIC RETINOPATHY IN TYPE-2 DIABETES MELLITUS PATIENTS IN TRIPURA

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ABSTRACT: OBJECTIVE: To study the prevalence of diabetic retinopathy and its relationship with the various risks factors in type 2 diabetes mellitus patients. **PATIENTS AND METHODS**: One hundred type 2 diabetes mellitus patients attending the departments of Medicine and Ophthalmology of TMC &Dr. BRAM Teaching Hospital comprised the material of this study. Detailed history, clinical examination and thorough ophthalmological examination including fundus photography of all the diabetic patients under study were done. The glycaemic control was evaluated for all the subjects by estimation of blood glucose and HbA1c, presence of microalbuminuria and lipid profiles. **RESULTS:** There were 61 (61%) females and 39 (39%) males in the study of which 42 (42%) patients, 15(35.7%) males and 27(64.3%) females had diabetic retinopathy. Among 42 retinopathy patients NPDR, PDR and ADR were 15(35.7%), 17 (40.48%) and 10 (23.81%) respectively. Duration of diabetes was found the most significant contributory factor in the causation of DR (Chi-square – 43.66; $p<0.01$& F- 78.037, $p=0.00$). Other factors which were significantly associated with diabetic retinopathy are age ($p=0.00$), glycaemic control as assessed by HbA1c ($p=0.00$), blood glucose- fasting ($p=0.00$) & postprandial ($p=0.00$) and MAU ($p=0.00$). Factors like blood pressure- Systolic ($p=0.655$) & diastolic ($p=0.964$), hypercholesterolemia ($p=0.140$), and BMI ($p=0.513$) did not show any significant correlation.
KEY WORDS: Diabetic retinopathy, type 2 diabetes mellitus

INTRODUCTION: Diabetic retinopathy (DR) is a sight threatening, chronic microvascular complication of diabetes mellitus that eventually afflicts most patients with DM despite the availability of various modalities of treatment. Upto two percent of type-2 diabetes have retinopathy at the time of first diagnosis and more than 60% of them have some degree of retinopathy by twenty years of diagnosis.[1]

DR is a major global cause of total blindness according to the global update of available data on visual impairment in the year 2002.[2] Its prevalence was estimated to be as high as 4.8% of the total of blindness. It is the leading cause of new-onset blindness among American adults aged 20-74 years[3] with an estimated 24, 000 people losing vision each year as a consequence. The risk factors identified to be related to the progression of DR are duration of DM, glycemic control, blood pressure and microalbuminuria. Data on other factors including BMI, male sex, serum lipids and smoking have demonstrated varying results.[4] We aim to study the prevalence of DR in Tripura and its correlation with age, obesity, glycemic control, hypertension and dyslipidemia as there is no data regarding the DR in Tripura so far.

PATIENTS AND METHODS: This study was carried out in Tripura Medical College and Dr. BRAM Teaching Hospital in the departments of Medicine and Ophthalmology for a period of one year with effect from 1st June 2010 to 31st May 2011. One hundred patients of type 2 diabetes patients were

selected randomly for this study. Patients with chronic renal failure, chronic liver disease, COPD, carcinoma, critical illness (sepsis, hyperosmolar coma) were excluded from the study. The diagnosis of type 2 diabetes was done according to the criteria laid down by American Diabetic Association (1997).

A detailed clinical history was taken using a structured questionnaire. Data regarding the age, sex, religion, occupation, address, h/o smoking, alcoholism, dietary habit, diabetes, hypertension with duration and treatment were obtained and recorded. A complete clinical examination was done including the height and weight on light cloths of the subjects. All the diabetes patients were referred to ophthalmology department for evaluation of diabetic retinopathy by ophthalmological examination. The following examinations for themwere performed, a) Ocular examination in diffuse light b) Slit lamp examination c) Direct ophthalmoscopy, d) Indirect ophthalmoscopy and e)+ 90 diopter lens examination. Fundus photography was done by FF 450 plus fundus camera with digital imaging system. The retinopathy of the patients was graded as a) non-proliferative diabetic retinopathy (NPDR), b) proliferative diabetic retinopathy (PDR) and c) advanced proliferative diabetic retinopathy associated either with or without macular edema (ADR).

Hyperglycaemia was assessed by measuring HbA1c%. HbA1c <7% was considered as the optimal control. Hypertension was diagnosed if SBP and DBP were found to be> 140 and 90 mm of Hg or the patient was on medication for hypertension. Cut off value for hypercholesterolemia was kept at 150 mg%. BMI was calculated by the formula, weight in kg divided by height in cm squared. BMI <25 was considered as normal, above which the individual was considered as overweight. Urinary microalbuminuria was measured in the early morning first void urine sample by turbidometry method and <20mg/l was taken to be normal.

Statistical Analysis:The Statistical analysis was done using Statistical Package for Social Sciences (SPSS 16.0 version). Results were expressed as mean ± standard deviation. T-test (for gender differences), One- way Analysis of Variance (for retinopathy categories), Multinomial logistic regression has been used along with common graphical tools like Scatter Plot and Box-Plot whenever appropriate. A p-value <0.05 was taken as statistically significant.

RESULTS: The study comprised one hundred type 2 diabetic patients with 61(61%) females and39(39%) males whose mean age was 57.78±9.4 ranging from 41 years to 83 years and the mean duration of diabetes was 8.41± 5.30 years (Table 2).The average age of female patients were marginally higher with 58.02± 9.77 years compared to 57.41±8.91 of the male patients but the difference is not significant (p>0.05). The male patients had slightly longer duration of diabetes compared to the females (8.49 ± 5.29 vs. 8.36± 5.36 years, p=0.908) as seen in Table 3.Nine (9%) persons including a female were smokers and 5 persons (5%), including 1 female, admitted frequent consumption of alcohol. The mean BMI of the patients under study was 23.55 ± 2.84 and it is observed that the females had a higher BMI than the males although not statistically significant (23.68± 2.87 and 23.35± 2.81, p=0.571). Both systolic and diastolic blood pressures indicated higher average values for females than the males but the difference is not significant for both (p>0.05).

The males in the study had higher average blood glucose values both fasting (148.59± 42.52 vs. 145.11± 41.83, p= 0.689) and postprandial (240.85± 56.15 vs. 232.54 ± 65.40, p= 0.501). The male patients also had higher HbA1C (7.95 ± 1.11 vs. 7.78 ± 1.23, p=0.485) and MAU (42.95 ± 24.17

vs. 41.21 ± 26.04) compared to the female patients which were however statistically not significant (p> 0.05). Whereas female patients were found to have higher serum cholesterol levels (198.90 ± 34.66to 189.74 ± 34.73, p=0.202) shown in Table 2.

Age (Years)			41 to50	51 to 60	61 to 70	71 to 80	81 & above	Total
Non-Retinopathy	sex	F	18	16	1	0	0	35
		M	10	13	0	0	0	23
	Total		**28**	**29**	**1**	**0**	**0**	**58**
NPDR	sex	F	0	3	3	2	0	8
		M	0	2	3	2	0	7
	Total		**0**	**5**	**6**	**4**	**0**	**15**
PDR	sex	F	0	4	7	1	0	12
		M	0	1	4	0	0	5
	Total		**0**	**5**	**11**	**1**	**0**	**17**
ADR	sex	F	0	1	2	2	1	6
		M	0	0	3	1	0	4
	Total		**0**	**1**	**5**	**3**	**1**	**10**
Total	sex	F	18	24	13	5	1	61
		M	10	16	10	3	0	39
	Total		**28**	**40**	**23**	**8**	**1**	**100**

Table 1: Age and Gender Profile of the Samples according to their level of retinopathy (N=100)

Source: Primary Data

Parameters	Mean	T Score	Standard Deviation	95% CI of the Difference	
				Lower	Upper
Age	57.78	61.442***	9.40	55.91	59.65
Duration	8.41	15.853***	5.30	7.36	9.46
BMI	23.55	82.922***	2.84	22.49	23.61
BP sys	126.00	85.636***	14.71	123.08	128.92
BP dia	80.68	91.024***	8.86	78.92	82.44
Sugar F	146.47	34.941***	41.92	138.15	154.78
Sugar PP	235.78	38.153***	61.80	223.52	248.05
HBA1C	7.85	66.415***	1.18	7.61	8.08
MAU	41.89	16.613***	25.22	36.89	46.89
S Ch	195.33	56.132***	34.80	188.43	202.23

Table 2: Parameters of the patients with means, 'T' Values and Confidence Intervals (n=100)

Source: Computed; Notes- All 'T' significant at.01 percent levels (D.F- 99)

Parameters	Females		Males		't'	P value
	Mean	SD	Mean	SD		
AGE (Years)	58.02	9.77	57.41	8.91	-0.32	.750
DURATION (Years)	8.36	5.36	8.49	5.29	0.12	.908
BMI	23.68	2.87	23.35	2.81	-0.57	.571
BP SYS (mm Hg)	127.54	14.58	123.59	14.78	-1.31	.194
BP DYS (mm Hg)	81.67	9.16	79.13	8.26	-1.44	.154
GLUCOSE F (mg/dl)	145.11	41.83	148.59	42.52	0.40	.689
Glucose PP (mg/dl)	232.54	65.40	240.85	56.15	0.68	.501
HBA1C	7.78	1.23	7.95	1.11	0.70	.485
MAU (mg/l)	41.21	26.04	42.95	24.17	0.34	.735
S CH (mg/dl)	198.90	34.66	189.74	34.73	-1.29	.202

Table 3: Gender specific Mean & SD of Samples along with 'T' test (n=100, male=39; female= 61)

Source: Computed

Out of the 100 type 2 diabetics under study, 42(42%) patients had diabetic retinopathy comprising 15(15%) males and 27(27%) females (Table 1). The prevalence of diabetic retinopathy was highest among the age group 61 to 70 years (52.38%). It is observed that patients suffering from retinopathy were older in age (66.57± 6.45vs 51.41 ± 5.05. p < 0.01)compared to the non-retinopathy patients with ADR patients being the oldest (69.8 ± 7.61), however the mean age difference between the three retinopathy groups were not statistically significant(p> 0.05). Patients with retinopathy had longer duration of diabetes compared to the non-retinopathy population (13.52± 3.52 vs. 4.08 ± 2.60. p<0.01)) and among the retinopathy population, patients with ADR group had the longest duration of diabetes (16.01±5.06). In this study, age and duration of diabetes are strongly correlated with the prevalence of retinopathy (Fig 1).

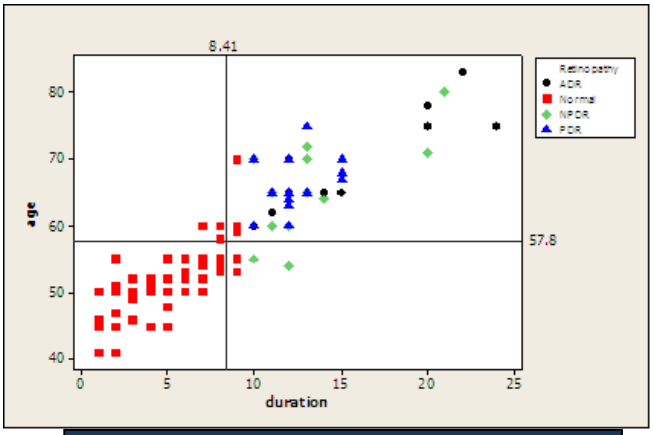

Fig. 1: Scatter Plot of Age and Duration

Source: Computed from Primary Data

BMI, Systolic BP and Diastolic BP did not vary significantly among the retinopathy and no-retinopathy patients ($p>0.05$), while all other parameters like age, duration, glucose (f), glucose (PP), HBA1c, MAU and serum cholesterol were significantly different ($p<0.05$) (Table 4). The mean BMI and systolic BP were found higher in the ADR group ($p>0.05$), while the mean diastolic BP was higher in the non-retinopathy group (80.97 ± 8.74 vs. 80.29 ± 9.12; $p >0.05$). It should be noted, here that, the differences in mean for these parameters were not statistically significant among the four categories. In the same way, statistically significant variation ($p>0.05$) was not observed for the serum cholesterol level (Table 5) where the PDR group had the highest mean (206.76±27.99), while the non-retinopathy group had the least average level (188.52± 38.95).

Parameters	No Retinopathy		Retinopathy		't'	P value
	Mean	SD	Mean	SD		
AGE (Years)	51.41	5.05	66.57	6.45	-12.68	0.00
DURATION (Years)	4.71	2.60	13.52	3.51	-13.75	0.00
BMI	23.26	2.94	23.96	2.67	-1.24	0.22
BP SYS (mm Hg)	124.8	13.9	127.6	15.7	-0.92	0.36
BP DYS (mm Hg)	80.97	8.74	80.29	9.12	0.37	0.71
GLUCOSE F (mg/dl)	130.8	35.0	168.1	41.4	-4.74	0.00
GLUCOSE PP (mg/dl)	210.5	55.3	270.6	53.1	-5.49	0.00
HBA1C	7.36	1.01	8.51	1.08	-5.41	0.00
MAU (mg/l)	25.7	15.3	64.3	18.1	-11.22	0.00
S CH (mg/dl)	188.5	38.9	204.7	25.7	-2.51	0.01

Table 4: Mean & SD of Samples along with 'T' test with retinopathy as factor (n=100, retinopathy=42; Non-retinopathy= 58)

Source: Computed

The blood glucose levels for both fasting as well as postprandial were much higher in the retinopathy group compared to the non-retinopathy group which is statistically significant ($p<0.01$), while the average values of these two parameters within the three retinopathy classification did not vary much and the differences among ADR, PDR and NPDR were not statistically significant ($p>0.05$). The blood glucose levels never the less were observed highest among the ADR group for both categories (Fig 2) Similar is the situation for HBA1C and MAU. The non-retinopathy group has the lowest mean (HBA1C= 7.36±1.01; MAU= 25.69±15.27), which is significantly lower than the three retinopathy category ($p <0.01$). For these two parameters also, we observe the average to be highest for the ADR group. Fig 3 shows that the non-retinopathy patients generally have lower levels of HbA1c and MAU, while both increases as the intensity of the disease increases. The regression equation for the categories show that the non-retinopathy line lies much below the other three categories.

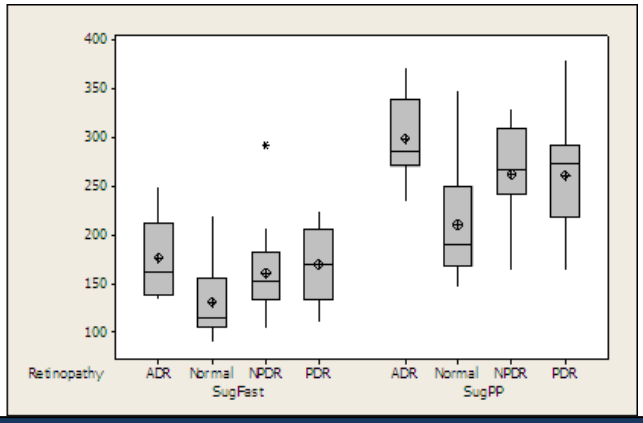

Fig. 2 Box Plot of Blood Sugar levels of Sample Groups

Source: Computed from Primary Data

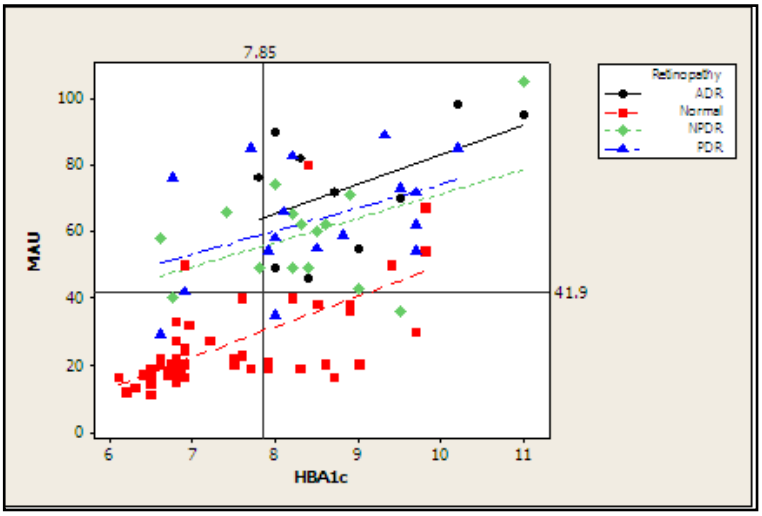

Fig. 3: Scatter Plot of HBA1C and MAU

Source: Computed from Primary Data

The table 5 supports our observations on the basis of the Table 4. The results of the Analysis of variance (test statistic, 'F') show significant variation ($p < 0.01$) among the four categories for age, duration, glucose (fasting), glucose (PP), HBA1C and MAU. A Sensitivity analysis was done incorporating the gender criterion as an added constraint for these variables and the new results (D.F: 7, 92) obtained corroborated the existing observation of significant differences even though the values of 'F' declined.

A multinomial logistic regression analysis undertaken with the four categories of retinopathy as dependent variable along with smoking, alcohol use, type of diet and gender as categorical variables while considering age, duration, blood pressure (systolic and diastolic), glucose (fasting and PP), HBA1C, MAU and serum cholesterol as co-variant. The model suggested a good fit, with Chi-square statistic (=164. 604) being highly significant and indicated that duration of the diabetes to be the most significant ($p < 0.001$) contributor for retinopathy.

Parameters	No Retinopathy (n=58)	NPDR (n=15)	PDR (n=17)	ADR (n=10)
AGE (Years)	51.41 [77.58]	65.87 [35.58]	65.29 [59.68]	69.8 [28.99]
DURATION (Years)	4.71 [13.77]	13.00 [15.28]	12.53 [31.8]	16.01 [10.01]
BMI	23.26 [60.29]	24.04 [39.76]	23.53 [31.15]	24.56 [31.98]
BP SYS (mm Hg)	122.66 [46.65]	127.33 [35.56]	125.88 [30.57]	131 [23.96]
BP DYS (mm Hg)	80.97 [70.55]	80.93 [52.30]	79.76 [28.74]	80.2 [26.84]
GLUCOSE F (mg/dl)	130.79 [28.47]	161.33 [13.73]	169.26 [17.91]	176.3 [13.40]
Glucose PP (mg/dl)	210.54 [28.98]	262.3 [20.43]	261.67 [18.97]	298.4 [20.49]
HBA1C	7.36 [55.62]	8.34 [30.08]	8.44 [31.24]	8.89 [26.74]
MAU (mg/l)	25.69 [12.81]	59.27 [13.52]	63.35 [14.7]	73.3 [12.44]
S CH (mg/dl)	188.52 [36.89]	204.87 [36.92]	206.76 [30.46]	201.1 [21.59]

Table 5: Parameters among the Non-Retinopathy and Retinopathy groups along with 'T' Values (n=100)

Notes- Figures in parentheses are the 'T' values and All 'T' significant at.01 percent levels

		Sum of Squares	Df	Mean Square	F	P value
age *	Between Groups	5736.228	3	1912.076	60.803	.000
	Within Groups	3018.932	96	31.447		
	Total	8755.160	99			
Duration *	Between Groups	1975.937	3	658.646	78.037	.000
	Within Groups	810.253	96	8.440		
	Total	2786.190	99			
Glucose F *	Between Groups	35299.618	3	11766.539	8.147	.000
	Within Groups	138658.009	96	1444.354		
	Total	173957.628	99			
Glucose PP *	Between Groups	98098.037	3	32699.346	11.211	.000
	Within Groups	280000.218	96	2916.669		
	Total	378098.254	99			
HBA1C *	Between Groups	34.274	3	11.425	10.557	.000

	Within Groups	103.889	96	1.082		
	Total	138.163	99			
MAU *	Between Groups	37448.461	3	12482.820	46.995	.000
	Within Groups	25499.329	96	265.618		
	Total	62947.790	99			
Ser. Ch	Between Groups	6611.935	3	2203.978	1.868	.140
	Within Groups	113270.175	96	1179.898		
	Total	119882.110	99			
BP Sys	Between Groups	356.626	3	118.875	0.541	.655
	Within Groups	21075.374	96	219.535		
	Total	21432.00	99			
BP Dia	Between Groups	22.237	3	7.412	0.092	.964
	Within Groups	7755.523	96	80.787		
	Total	7777.760	99			
BMI	Between Groups	18.739	3	6.246	0.772	.513
	Within Groups	776.933	96	8.093		
	Total	795.672	99			

Table 6: ANOVA

Source: Computed

DISCUSSION: In this study we have observed a relatively higher prevalence of retinopathy (42%) with female predominance (27% vs. 15%), which agrees with the findings of otherstudies.[2, 4-8] However a number of studies showed a lower prevalence of diabetic retinopathy.[1, 3, 9-15] Factors like unawareness of diabetes among the population, lack of facilities to check regularly retinopathy and other complications could have attributed to the higher prevalence of diabetic retinopathy in our study.

In our study, among the 3 categories of retinopathy PDR was found to be highest (17%), followed by NPDR (15%) and ADR (10%). This finding agrees with the findings of Lertkoonalak et al [12] who reported higher prevalence of PDR (95%) than NPDR (7.6%) in their study. Verna and his colleagues [16] also reported more of severe PDR (6.1%) compared to NPDR (4.4%) and they observed macular edema in (10.1%) of their patients of diabetic retinopathy. However other workers (Chethakul et al [4], Al Amer et al [2], Wover et al[5], and Mahar et al [16] observed NPDR more prevalent than PDR in their respective studies.

The average age of the sample respondent is 57.78 years and the average duration of diabetes is 8.41 years in our study which agrees with the studies conducted by Al Amer et al [2] who found mean age was 57.8 years and duration of DM 9.6years in their study and also by Al- Sammari et al[3] where mean age was 54.28 ± 8.7 years and duration of diabetes was (13.2 ± 5.8 years).

Age, duration of diabetes, blood glucose both fasting and postprandial, HbA1c and urinary microalbuminuria were found to be associated with diabetic retinopathy which are statistically significant and out of these, duration of diabetes was the most significant contributor for the retinopathy. The same observation was also seen in a number of studies conducted in different parts of the world.[2-4, 7, 10, 12-15, 17] The average duration of diabetes, was 8.41 years and that of different

categories of individual like non – retinopathy, NDPR, PDR and ADR was 4.71, 13.0, 12.53 and 16.01 years respectively. In a study Kleinet al [18] also mentioned that the prevalence of diabetic retinopathy varied from 17% to 97.5% in persons with diabetes for <5 years and >15 years or more years respectively.

In our study age also was found to be statistically significant factor in occurrence of diabetic retinopathy. Mean age of the individuals was 57.78 years. Non-retinopathy group had the average age only 51.41 years and different retinopathy groups NPDR, PDR, and ADR was 65.87, 65.29 and 69.8 years respectively. The maximum occurrence of the retinopathy was in the age group of 61.70 years (22%) and all the patients in groups of 71 to.80 years and 81 years and above had retinopathy of any categories. Chetthakul T et al [4], Klein R et al [18]&Maskari FA [13] also mentioned that increasing age is a risk factor in occurrence of diabetic retinopathy.

HbA1c which is considered the gold standard for the glycemic control of the diabetic patients found to be a very important risk factor for diabetic retinopathy as mentioned in different studies worldwide.[2, 3, 4, 7, 10, 13,14,15,17] HbA1c is found to be statistically significant risk factor for DR in our study also. HbA1c in non – retinopathy, NPDR, PDR, and ADR group were 7.36, 8.44, and 8.89 respectively. From this data it is quite evident that the higher HbA1c i.e. poor glycemic control the more the risk of diabetic retinopathy. Blood glucose level as measured by blood glucose (Fasting) and (PP) also found to be statistically significant in occurrence of DR. Mean blood glucose (F) & (pp) for the non – retinopathy group were 130.29 and 210.54 mg% respectively. Whereas blood glucose (F) &(PP) levels in NPDR, PDR, and ADR groups were higher, 161.33 & 262.3 mg%, 169.26 and 261.67 mg% and 176.3 & 298.4 mg% respectively. Chetthakulet al [4] also observed a statistically significant higher blood glucose level in DRin their study.

Urinary microalbuminuria (MAU) was also observed to be a statistically significant risk factor for diabetic retinopathy in our study which was also observedin a number of studies.[3, 5, 7, 12, 17] The mean value of MAU in non – retinopathy, NPDR, PDR and ADR are 25.69, 59.27, 63.35 and 73.3, makes it quite evident that more the MAU value more the severity of retinopathy.

Though systolic blood pressure (SBP) was found to be a significant risk factor in some of the studies [4,10,12,18] and diastolic blood pressure (DBP) and mean arterial pressure in the studies conducted by Beket al [10] and Park et al [15], our study failed to establish the relationship between the SBP, DBP or mean arterial pressure with diabetic retinopathy. It is most probably due to a better control of blood pressure as evidenced by the normal mean SBP and DBP in the individuals in our study. Mohanet al [14] also could not establish hypertension as a risk factor for DR in their study. Serum cholesterol could not be established as a risk factor in our study which is a similar finding in the study conducted by Jostet al [7], though Mohanet al [14] and Park CY [15] found hypercholesterolemia as a risk factor for DR.

In our study females are found to have retinopathy more in number, but failed to establish any statistical significance. Likewise smoking and alcohol intake also did not have any significant correlation with diabetic retinopathy. It may be due to a very few patients with smoking and alcohol intake in the study.

CONCLUSION: The prevalence of DR in diabetes mellitus patients of Tripura is relatively high. Also there is high prevalence of PDR and ADR. Age, duration of diabetes, blood glucose both fasting and postprandial, HbA1c and urinary microalbuminuria were found to be significantly associated with

diabetic retinopathy and duration of diabetes was the most significant contributor for the retinopathy.The cause of severe type of retinopathy may be attributed to poor glycemic control for a longer duration which may be due to lack of awareness among the diabetic patients in our place. It may be avoided by regular and periodical retinal check up in the part of the diabetic patients.

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