Original Research Article

Prevalence of microalbuminuria in patients with type 2 diabetes mellitus having diabetic retinopathy in a tertiary care hospital in eastern India: A cross-sectional study

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ABSTRACT

Background: Diabetic retinopathy is a common microvascular complication of diabetes mellitus and one of the leading causes of acquired blindness. Microalbuminuria reflects a pathophysiological state of vascular dysfunction and organ damage. It is noticed that a rise in urinary albumin excretion is seen in the early phase of diabetic retinopathy. The concordance of microalbuminuria and diabetic retinopathy has been well reported in type 1 diabetes; however, for type 2 diabetes, there is a paucity of data.

Objective: To estimate the prevalence of microalbuminuria in diabetic retinopathy patients with type 2 diabetes attending the out-patient department (OPD) in a tertiary care center in eastern India and also to find out any association between microalbuminuria and severity of diabetic retinopathy.

Material and Methods: The study included 200 patients with type 2 diabetic patients having diabetic retinopathy. The study populations were selected by thorough clinical examination and as per inclusion–exclusion criteria. Estimation of urinary albumin and albumin creatinine ratio was done by using Konelab 20 Autoanalyzer machine by the immunoturbidimetry method. Diabetic retinopathy was classified as per the International Clinical Diabetic Retinopathy Severity Scales into mild, moderate, severe, very severe non-proliferative as well as proliferative diabetic retinopathy. Data were analyzed with ratio, rate, percentage, and statistical significance was considered if p<0.5.

Results: The prevalence of microalbuminuria was found in 36% (72 patients). The highest number of patients (88.24%) with microalbuminuria was found in severe NPDR. 93.06% of patients with microalbuminuria had clinically significant macular edema. A statistically significant correlation (p<0.001) was found between microalbuminuria and the degree of retinopathy in mild, moderate, and severe NPDR.

Conclusion: A significant correlation was found between urinary microalbumin and the severity of diabetic retinopathy.

1. Introduction

Diabetic retinopathy is a common microvascular complication of diabetes mellitus and one of the leading causes of acquired blindness.[1] Around 347 million people worldwide are diagnosed with diabetes as per an estimate by World Health Organization in 2014.[2] According to International Diabetic Federation report, India has 72.9 million diabetics which is almost 10.4% of population. Around 50% patients with type 1 diabetes and 30% with type 2 diabetes develop vision threatening retinal changes over time.[3] Duration of diabetes mellitus, hypertension,

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poor glycemic control have been identified as risk factors for microvascular complications. [4,5] Previous studies suggest that prevalence of any retinopathy in patients with diabetes is 35% while it is 7% for proliferative retinopathy. [6] Umerous studies have reported that microalbuminuria reflects a pathophysiological state of vascular dysfunction and organ damage. [7] Diabetes mellitus is one of the leading diseases in India which affects 10 to 15% of Indian population. [8,9] Diabetic retinopathy is present in almost all type 1 diabetes patients with nephropathy whereas, about 50 to 60% of type 2 diabetic patients with nephropathy have retinopathy. [10]

Diabetic retinopathy is a highly specific vascular complication and a sight threatening problem related to diabetes characterized by gradually progressive retinal microvascular alterations. Proportion of blindness cases attributable to DR was 2.6% in 2010. [11] Screening of patients with diabetes mellitus is important as early detection and treatment decrease the risk of vision loss. [12] In 2015, an estimated 2.6 million people were believed to be visually impaired due to diabetic retinopathy and the figure was expected to rise to 3.2 million by 2020. [13–16] Diabetic nephropathy occurs in as many as 30% of type I diabetes mellitus patients and 25% of type II diabetes mellitus patient. It is a dreaded disease with progressive and continuous deterioration in glomerular function. In the early phase of diabetic nephropathy, there is a rise in urinary excretion of albumin i.e. microalbuminuria (30-299mg/dl) which is detectable only by use of sensitive assay for urinary albumin. At this stage, urine is negative for macroalbumin and renal function is normal by standard clinical tests. The presence of microalbuminuria precedes the development of overt diabetic nephropathy by several years. The concordance of microalbuminuria and diabetic retinopathy has been well reported in type 1 diabetes; however, for type 2 diabetes, there is paucity of data.

There are few population-based studies from eastern India regarding association of microalbuminuria with diabetic retinopathy in Type 2 Diabetes patients leading to paucity of data from eastern India.

Aims of this study were

1. To estimate the prevalence of microalbuminuria among patients with type 2 diabetes mellitus with diabetic retinopathy.
2. To find out association if any between microalbuminuria and severity of diabetic retinopathy.

2. Materials and Methods

It was an Institution based cross-sectional study conducted in out patient department of Ophthalmology Department, Calcutta National Medical College and Hospital, Kolkata over a period of 12 months (1st January2020 - 31st December 2020). Patients diagnosed with diabetic retinopathy in were chosen in study population. Sample size Included 200 patients, those who are diagnosed with diabetic retinopathy with or without micro albuminuria. Type 2 diabetic patients (diagnostic criteria for type 2 Diabetes mellitus taken as per American Diabetic Association: fasting blood glucose 126mg/dl or higher and/or 2 hour post prandial blood glucose test 200 mg/dl or higher and/or HBA1C 6.5% or higher) who are diagnosed with diabetic retinopathy aged >30years, whose refractive media were clear and fundus examination was possible and had no other organic eye disease were included in the study. Exclusion criteria included patients with acute complications of diabetes mellitus known case of and a history of non diabetic renal disease, urinary tract infection, symptoms or history of a heart disease, acute or severe chronic liver disease, pregnancy are excluded from the study and patients who did not give informed consent prior to the study.

Patients were categorized according to their degree of retinopathy. Urine for albumin estimation and albumin creatinine ratio were done using Konelab 20 Autoanalyzer machine by the method of immunoturbidimetry. American Society of Nephrology guidelines suggest measuring albuminuria in the first morning void, for urinary albumin concentration and the albumin to creatinine ratio (A:C). [17,18] As per American Diabetes Association, microalbuminuria is considered when A:C ratio 30-299(g/mg creatinine and/or urinary albumin is 30-299 mg in 24 hour collection. [19] Diabetic retinopathy severity classification as per the International Clinical Diabetic Retinopathy Severity Scales into 5 categories : No apparent retinopathy, Mild non proliferative diabetic retinopathy, Moderate non proliferative diabetic retinopathy, Severe non proliferative diabetic retinopathy, Proliferative diabetic retinopathy. [20]

Ophthalmologic examination included visual acuity by Snellen's chart, fundoscopy by slit lamp and +90D lenses and indirect ophthalmoscopy and intraocular pressure by Applanation Tonometry. Investigations included urine for albumin estimation in early morning spot urine sample (Konelab autoanalyzer using immunoturbidimetry method) Blood for HBA1C and PPBS, FBS, lipid profile. Cardiological check up by Electrocardiography (ECG) and Optical Coherence Tomography (OCT) and Fundus Fluorescein Angiography (FFA) if needed. Categorical variables are expressed as Number of patients and percentage of patients and compared across the groups using Pearson's Chi Square test for Independence of Attributes/ Fisher's Exact Test as appropriate. Continuous variables are expressed as Mean, Median and Standard Deviation and compared across the groups using Mann-Whitney U test.

The statistical software SPSS version 20 has been used for the analysis.

An alpha level of 5% has been taken, i.e. if any p value is less than 0.05 it has been considered as significant.

3. Results

The present study included 200 patients of type 2 diabetes mellitus with diabetic retinopathy. The study population was graded according to severity of diabetic retinopathy as per International Classification of Diabetic Retinopathy. The male to female ratio was found to be 1.25:1.62.5% of study population had more severe involvement of left eye. Study population constituted 30% mild NPDR, 41.5% moderate NPDR, 17% severe NPDR and 11.5% PDR.55% of the study population had clinically significant macular edema. 36% of the study population had microalbuminuria 9.72% of mild NPDR patients, 22.22% of moderate NPDR patients, 41.67% of severe NPDR patients and 26.39% of PDR patients had microalbuminuria. Statistically significant correlation was present between microalbuminuria and prevalence of mild, moderate and severe retinopathy.Statistically significant correlation was found between age, duration of diabetes, FBS, PPBS, HBA1C, LDL, total cholesterol, triglyceride with degree of diabetic retinopathy. Statistically significant correlation was found between risk factors like age, duration of diabetes, FBS, PPBS, HBA1C, TC, LDL, Hb with microalbuminuria. No statistically significant correlation was found between serum TG and HDL with microalbuminuria. Among the patients with microalbuminuria, 11.67% had mild NPDR, 19.28% had moderate NPDR, 88.24% had severe NPDR, 82.61% had PDR.93.06% of patients with microalbuminuria had clinically significant macular edema. Among patients with mild, moderate, severe NPDR, statistically significant correlation was found between degree of retinopathy and microalbuminuria. In our study there is almost similar prevalence of microalbuminuria in patients with severe NPDR and PDR with slight preponderance in severe NPDR category. 36% of the study population had microalbuminuria. Among patients with mild, moderate, severe NPDR, statistically significant correlation was found between degree of retinopathy and microalbuminuria. In our study, there is almost similar prevalence of microalbuminuria in patients with severe NPDR and PDR with slight preponderance in severe NPDR category. In our study, out of 200 cases, 60 (30%) cases had mild NPDR, 83 (41.5%) had moderate NPDR, 34 (17%) cases had severe NPDR, 23 (11.5%) cases had PDR. 93.06% of patients with microalbuminuria had clinically significant macular edema. In the current study there is almost similar prevalence of microalbuminuria in patients with severe NPDR and PDR with slight preponderance in severe NPDR category. The mean age of cases with mild, moderate, severe NPDR and PDR were 54.13±5.37, 57.10±6.77, 60.68±7.16 and 61.74±4.92yearsrespectively. There was statistically significant correlation between severity of diabetic retinopathy and age of patient(p<0.001). The mean duration of diabetes in cases with mild, moderate, severe NPDR and PDR were 8.07±2.55, 9.29 ± 3.56, 11.85 ±3.80 and 11.52 ± 2.64 years respectively. There was statistically significant correlation between severity of diabetic retinopathy and duration of diabetes of patient (p<0.001). The mean fasting blood sugar of cases with mild, moderate, severe NPDR and PDR were 91.92±13.20, 97.43 ± 15.08, 111.29 ±12.88 and 121.61 ± 10.72 mg/dl respectively. There was statistically significant correlation between severity of diabetic retinopathy and fasting blood sugar of patient(p<0.001). The mean post prandial blood sugar in cases with mild, moderate, severe NPDR and PDR were147 ±32.30, 150.24 ± 26.95, and 165.41± 31.92, 204.74 ±38.89mg/dl respectively. There was statistically significant correlation between severity of diabetic retinopathy and post prandial blood sugar of patient(p<0.001). The HBA1C of cases with mild, moderate, severe NPDR and PDR were 5.50±0.38%, 5.61±0.70, 6.31±1.25 and 7.16±2.02% respectively. There was statistically significant correlation between severity of diabetic retinopathy and HBA1C of patient (p<0.001). The mean systolic BP of cases with mild, moderate, severe NPDR and PDR were 118.25±14.6 ± 12.74, 139.56 ±10.05 and 138.35 ± 9.43 mmHg respectively. There was statistically significant correlation between severity of diabetic retinopathy and systolic BP of patients (p<0.001). The mean diastolic BP of cases with mild, moderate, sever NPDR and PDR were 72.40 ±8.49, 75.33±9.29, 80.94 ±7.80 and 82.70 ± 8.63 mmHg respectively. There was statistically significant correlation between severity of diabetic retinopathy and diastolic BP of patient (p<0.001).

Table 1: Distribution of cases according to age group

Age Ingroup	Frequency	Percent
41-50	38	19.0
51-60	103	51.5
61-70	52	26.0
71-80	7	3.5
Total	200	100.0

Table 2: Distribution of cases according to gender

Sex	Frequency	Percent
Female	89	44.5
Male	111	55.5
Total	200	100.0

The mean total cholesterol of cases with mild, moderate, severe NPDR and PDR were 153.78±49.63, 155.04 ± 41.68, 211.24 ±78.06 and 214.13± 56.65 mg/dl respectively. There was statistically significant correlation between severity of diabetic retinopathy and total cholesterol of patient (p<0.001). The mean low density lipoprotein of cases with mild, moderate, severe NPDR and PDR were 116.00±31.98, 112.88 ± 32.20, 132.00 ±42.65 and 135.91 ± 31.66 mg/dl respectively. There was statistically significant correlation between severity of diabetic retinopathy and

Table 3: Distribution of different risk factors according to diabetic retinopathy severity status

	Fundus													
	Mildnpdr			**Moderatenpdr**			**Severenpdr**			**PDR**				
	Mean	Median	SD	Mean	Median	SD	Mean	Median	SD	Mean	Median	SD	pValue	Sig
AGE(Y)	54.13	54.50	5.37	57.10	56.00	6.77	60.68	60.50	7.16	61.74	62.00	4.92	<0.001	S
Duration	8.07	8.00	2.55	9.29	9.00	3.56	11.85	11.50	3.80	11.52	11.00	2.64	<0.001	S
SBP	118.25	112.00	14.69	125.89	120.00	12.74	139.56	142.00	10.05	138.35	140.00	9.43	<0.001	S
DBP	72.40	72.00	8.49	75.33	72.00	9.29	80.94	80.00	7.80	82.70	82.00	8.63	<0.001	S
FBS	91.92	89.00	13.20	97.43	96.00	15.08	111.29	112.50	12.88	121.61	126.00	10.72	<0.001	S
PPBS	147.57	149.00	32.30	150.24	147.00	26.95	165.41	168.00	31.92	204.74	211.00	38.89	<0.001	S
HBA1C	5.50	5.40	0.38	5.61	5.40	0.70	6.31	5.90	1.25	7.16	6.00	2.02	<0.001	S
TC	153.78	129.50	49.63	155.04	155.00	41.68	211.24	194.50	78.06	214.13	220.00	56.65	<0.001	S
LDL	116.00	112.00	31.98	112.88	110.00	32.20	132.00	127.50	42.65	135.91	133.00	31.66	0.004	S
HDL	46.25	46.00	11.40	47.20	44.00	18.62	40.38	39.50	10.45	41.87	41.00	9.58	0.025	S
TG	154.23	140.50	47.23	154.87	144.00	52.63	191.88	200.00	69.80	196.87	177.00	83.72	0.003	S
HB	12.50	12.40	1.37	12.37	12.70	1.57	11.11	10.95	1.82	10.68	10.20	1.51	<0.001	S
Urinema	27.16	20.90	21.77	37.21	20.80	44.83	67.37	58.00	43.08	60.87	40.00	48.88	<0.001	S
Urine ACR	28.27	20.45	22.01	40.46	20.80	50.25	85.49	61.50	67.79	61.96	37.80	46.19	<0.001	S

Table 4: Distribution of cases according to severity of diabetic retinopathy

Fundus	Frequency	Percent
Mildnpdr	60	30.0
Moderatenpdr	83	41.5
Severenpdr	34	17.0
PDR	23	11.5
Total	200	100.0

Table 5: Distribution of cases according to urine albumin excretio

Albuminuria	Frequency	Percent
Normoalbuminuria	128	64.0
Microalbuminuria	72	36.0
Total	200	100.0

Table 6: Distribution of cases according to severity of diabetic retinopathy and urine albumin

		Albuminuria		Total	P Value	Significance
		Normoalbuminuria	Microalbuminuria			
Fundus	Mild NPDR	53(41.41)	7(9.72)	60(30)		
	Moderate NPDR	67(52.34)	16(22.22)	83(41.5)	<0.001	Significant
	Severe NPDR	4(3.13)	30(41.67)	34(17)		
	PDR	4(3.13)	19(26.39)	23(11.5)		
Total		128(100)	72(100)	200(100)		

Table 7: Distribution of cases according to clinically significant macular edema and urine albumin

		Albuminuria		Total	P Value	Significance
		Normoalbuminuria	Microalbuminuria			
CSME	No	85(66.41)	5(6.94)	90(45)		
	Yes	43(33.59)	67(93.06)	110(55)	<0.001	Significant
Total		128(100)	72(100)	200(100)		

Table 8: Association between microalbuminuria and severity of diabetes retinopathy

		Fundus				Total	P Value	Significance
		Mild NPDR	Moderate NPDR	Severe NPDR	PDR			
Albuminuria	Normoalbuminuria	53(88.33)	67(80.72)	4(11.76)	4(17.39)	128(64)	<0.001	Significant
	Microalbuminuria	7(11.67)	16(19.28)	30(88.24)	19(82.61)	72(36)		
Total		60(100)	83(100)	34(100)	23(100)	200(100)		

Table 9: Measures of central tendency two groups normoal abuminuria and microalbuminuria according to risk factors

	Albuminuria							
	Normoalbuminuria			Microalbuminuria				
	Mean	Median	Std.Deviation	Mean	Median	Std.Deviation	pValue	Significance
Age(Y)	55.62	55.00	5.97	60.43	60.00	7.06	<0.001	Significant
Logmarre	0.59	0.48	0.34	1.19	1.08	0.51	<0.001	Significant
Logmarle	0.50	0.48	0.31	1.08	1.08	0.41	<0.001	Significant
Duration	8.50	8.00	2.94	11.60	12.00	3.60	<0.001	Significant
SBP	123.73	120.00	14.54	133.81	139.00	13.42	<0.001	Significant
DBP	74.89	72.00	9.57	78.67	80.00	8.70	0.004	Significant
FBS	94.59	91.50	13.69	112.17	116.00	16.04	<0.001	Significant
PPBS	143.38	140.00	23.09	184.78	190.00	38.44	<0.001	Significant
HBA1C	5.66	5.50	0.86	6.26	5.70	1.39	0.012	Significant
TC	158.01	155.00	50.60	194.13	190.00	66.17	<0.001	Significant
LDL	115.56	112.00	32.02	127.10	123.00	38.82	0.034	Significant
HDL	45.41	44.00	15.70	44.68	44.00	12.92	0.681	NotSignificant
TG	158.72	145.00	52.07	178.39	167.00	72.65	0.108	NotSignificant
HB	12.68	12.70	1.21	10.78	10.20	1.72	<0.001	Significant
Urinema	21.00	20.00	5.09	79.45	61.00	51.86	<0.001	Significant
Urineacr	21.40	20.00	5.27	92.32	75.00	62.69	<0.001	Significant

low density lipoprotein of patient (p=0.004). The mean high density lipoprotein of cases with mild moderate, severe NPDR and PDR were 46.25±11.40, 47.20±18.62, 40.38±10.45 and 41.87±9.58 mg/dl respectively. There was statistically significant correlation between severity of diabetic retinopathy and high density lipoprotein of patient(p=0.025).

The mean triglyceride of cases with mild, moderate, severe NPDR and PDR were 154.23±47.23, 154.87±52.63, 191.88±69.80 and 196.87±83.72mg/dl respectively. There was statistically significant correlation between severity of diabetic retinopathy and triglyceride of patient(p=0.003). The mean hemoglobin of cases with mild, moderate, sever NPDR and PDR were 12.50 ±1.37, 12.37 ±1.57, 11.11 ±1.82 and 10.68 ± 1.51 g/dl respectively. There was statistically significant correlation between severity of diabetic retinopathy and haemoglobin of patient(p<0.001).

The mean microalbumin level of cases with mild, moderate, severe NPDR and PDR were 27.16±21.77, 37.21 ± 44.83, 67.37 ±43.08 and 60.87 ± 48.88 mg respectively. There was statistically significant correlation between severity of diabetic retinopathy and microalbumin level of patient(p<0.001).

The mean albumin creatinine ratio of cases with mild, moderate, severe NPDR and PDR were 28.27±22.01, 40.46 ± 50.25, 85.49 ±67.79 and 61.96 ± 46.19 mg/g respectively.

There was statistically significant correlation between severity of diabetic retinopathy and albumin creatinine ratio of patient(p<0.001).

In this study, out of 200 cases, 128(64%) of study population had urine albumin level within normal range and 72 (36%) had microalbuminuria. The correlation between severity of diabetes mellitus and microalbuminuria was statistically significant(p<0.001). There correlation between clinically significant macular edema and microalbuminuria was found to be statistically significant(p<0.001). 36% of the study population had microalbuminuria.

Among patients with mild, moderate, severe NPDR, statistically significant correlation was found between degree of retinopathy and microalbuminuria.

In the current study, there is almost similar prevalence of microalbuminuria in patients with severe NPDR and PDR with slight preponderance in severe NPDR category.

4. Discussion

The present study is a cross-sectional observational study conducted in a tertiary care institute. The study was done to estimate the prevalence of microalbuminuria among type 2 diabetes mellitus patients with retinopathy and to find correlation between different stages of diabetic retinopathy and urine microalbumin. The study

population constitutes 55.5% male patients and 44.5% female patients. In the present study, raised FBS, PPBS, HBA1C suggested poor glycaemic control. The mean values of FBS, PPBS and HBA1C were higher with increasing severity of DR showing statistically significant correlation (p<0.001). Mean values of FBS, PPBS and HBA1c were also significantly higher in patients with microalbuminuria. Urine microalbumin was found to have significant correlation with duration of diabetic retinopathy (P<0.001), FBS (P<0.001), PPBS (P<0.001), HbA1C (P = 0.012). Out of 200 cases of diabetic retinopathy, 30% had mild NPDR, 41.5% had moderate NPDR, 17% severe NPDR and 11.5% had PDR.36% of study population(72 patients) had microalbuminuria and 64% (128 patients) had urine albumin level within the normal range.Several studies conducted in past have yielded variable incidence rates of microalbuminuria depending on the study population chosen and methods involved. Parving et al. reported 22% incidence rate of microalbuminuria in type 2 diabetics[21] while Lunetta et al. reported an incidence of 15%.[22] Wisconsin epidemiologic study on diabetic retinopathy concluded that Microalbuminuria is associated significantly with the presence of retinopathy in persons with diabetes.[23]

Study conducted by Singh SK et al. found that patients with diabetic retinopathy had microalbuminuria test positive and level was significantly higher in patients with proliferative retinopathy than in patients with background retinopathy.[24] A Sankar Nethralaya diabetic retinopathy study found the prevalence of microalbuminuria in the study subjects to be 15.9%.[25] Manaviat et al. in their study found that the overall prevalence of retinopathy was 39.3% of which 5.4% were proliferative diabetic retinopathy (PDR) and concluded that microalbuminuria is associated with diabetic retinopathy in type II diabetic patients and is a reliable marker of retinopathy.[26] In our study there, is almost similar prevalence of patients with severe NPDR and PDR with microalbuminuria with slight preponderance in severe NPDR category.

Ryan Lee et al. in their study concluded that diabetic nephropathy is closely associated to diabetic retinopathy and macular edema as many of the pathologic processes affecting microvasculature in retinopathy are likely to be causative of nephropathy as well in diabetes.[27] Increased severity of diabetic retinopathy was associated with increasing severity of chronic kidney disease and decreased estimated glomerular filtration rate.[28] Longitudinal studies are required to confirm these findings and if established, the data can be utilized in type 2 diabetic individuals with microalbuminuria to benefit from regular ophthalmologic follow up.

5. Conclusion

36% of the study population had microalbuminuria. Among patients with mild, moderate, severe NPDR, statistically significant correlation was found between degree of retinopathy and microalbuminuria. In our study, there is almost similar prevalence of microalbuminuria in patients with severe NPDR and PDR with slight preponderance in severe NPDR category.

Our study was a hospital based cross-sectional study design with limited sample size. An analytical community based study with a larger sample size is recommended for external validity of the results. In this study there is a chance of information bias on duration of diabetes mellitus.

6. Source of Funding

7. Conflict of Interest

None.

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