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Prevalence of retinopathy in newly diagnosed type 2 diabetes mellitus patients and its association with microalbuminuria and HbA1c: A cross sectional study from Rajasthan

Praveena T[1], Ashok Kumar[2,*], and Arya RK[3]

[1]Department of Ophthalmology, JLN Medical College, Ajmer, Rajasthan-305001, India
[2]Department of Community Medicine, JLN Medical College, Ajmer, Rajasthan-305001, India
[3]Department of General Medicine, All India Institute of Medical Sciences, Jodhpur, Rajasthan 342005, India

Abstract

Background: Diabetes mellitus is a major public health problem with multiple medical complications. Microvascular complications of diabetes including diabetic retinopathy, depend on the duration and severity of hyperglycemia. There is a paucity of data about the relationship among diabetic retinopathy, microalbuminuria and HbA1c in newly diagnosed type 2 diabetes mellitus (T2DM) patients. The study was conducted on the prevalence of diabetic retinopathy and its association with microalbuminuria and HbA1c among newly diagnosed T2DM patients.

Material and method: It was a hospital-based, cross-sectional study conducted at a tertiary care hospital in Rajasthan. After obtaining written informed consent, data were collected from 150 newly diagnosed T2DM patients. Data were analysed using SPSS 20.0. Categorical variables were presented as proportion and continuous variables were presented as mean (SD). Chi square test and one way ANOVA tests were used for bivariate analysis.

Results: The mean (SD) age of patients was 50.43 (12.73) years. About 52.7% (n=79) patients were male. About 30% (n=45) of newly diagnosed T2DM patients had microalbuminuria. Thirty patients (20%) had diabetic retinopathy (DR). About 8% (n=12) participants had mild DR, 10.7% (n=16) had moderate to severe DR and 1.3 (n=2) % had proliferative DR. Microalbuminuria was found significantly associated with HbA1c (P<0.01). Diabetic retinopathy and its severity were also found significantly associated with HbA1c (P<0.01).

Conclusion: In newly diagnosed T2DM patients, HbA1c and microalbuminuria are associated with the presence of retinopathy. If follow up studies support these results, periodic ophthalmologic monitoring may be beneficial for those newly diagnosed with T2DM.

Keywords: retinopathy; diabetes; microalbuminuria; HbA1c

Introduction

Diabetes mellitus (DM) has long been recognized as a major public health problem with far-reaching consequences, not only for its adverse health impact on individuals but also for its economic burden on the health care system [1, 2].

People with diabetes are vulnerable to multiple medical complications. These complications involve both macrovascular disease (heart disease, stroke) and microvascular disease [2]. The major microvascular complications are diabetic retinopathy, nephropathy,

***Corresponding author:** Dr. Ashok Kumar, Senior Demonstrator, Department of Community Medicine, JLN Medical College, Ajmer, Rajasthan-305001, India. Email: ashuchaniya@gmail.com

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and neuropathy [3]. Diabetic retinopathy is the most common microvascular complication of diabetes [4, 5]. The risk of developing diabetic retinopathy or other microvascular complications of diabetes depends on the duration and severity of hyperglycemia. Diabetic retinopathy may begin to develop as early as 7 years before the diagnosis of diabetes in patients with type 2 diabetes [5]. Advanced glycation end products (including glycosylated haemoglobin, HbA1c) are known to produce micro-vascular complications in diabetic retinopathy [6-8]. Higher amounts of HbA1c in diabetic patients, indicating poorer control of blood glucose levels, have been associated with diabetic complications like; cardiovascular disease, nephropathy, and retinopathy [6, 7].

The concordance of microalbuminuria and diabetic retinopathy is well studied in type 2 diabetes; however, for newly diagnosed type 2 diabetes mellitus (T2DM), there is a paucity of data. The current study aimed to find out the prevalence of diabetic retinopathy and its association with microalbuminuria and HbA1c among newly diagnosed T2DM patients.

Material and methods

This hospital-based cross-sectional study was conducted from November 2020 to December 2021 in a tertiary care hospital in Rajasthan. Newly diagnosed T2DM patients were included in this study. Exclusion criteria were patients with acute or chronic renal failure, having dense cataract or corneal opacities, having coexisting ocular disorders likely to mask the findings of diabetic retinopathy, and diabetes with prior hypertension. The Ethics approval was obtained from the Institutional Review Board of the author's institution. Written informed consent was taken from each participant.

Sample size: The sample size was calculated using a 16.5% prevalence of diabetic retinopathy in newly diagnosed T2DM patients in the available literature [9]. Estimated sample size was 147 with 6% absolute error and 95% confidence level, which was rounded off to 150. (Epi info™ 7.2.5.0).

Sampling technique: Patients were enrolled from OPD. Consecutive sampling technique was adopted for data collection. DM was defined as a fasting plasma glucose of more than or equal to 126 mg/dl or a 2-hour plasma glucose level after a glucose tolerance test of more than or equal to 200 mg/dl or random plasma glucose of more than or equal to 200 mg/dl in the presence of symptoms of hyperglycemia i.e., polyuria, polydipsia, polyphagia and unexplained weight loss [10].

Data collection

Data were collected using an interviewer-administered, semi-structured, pre-tested questionnaire. It consisted of sociodemographic detail, plasma glucose measurements, urinary albumin estimation and fundus examination. Patients were categorized into three categories based on their HbA1c values. These were- good control (HbA1c <6.5%), fair control (HbA1c 6.5-7.9%), poor control (HbA1c ≥8.0%) (10).

Urinary albumin level was measured with the Esbach test. Microalbuminuria was defined as albumin excretion of 30-299 mg/24 hours [11]. Severity of DR was clinically graded using Early Treatment Diabetic Retinopathy Study scales by a trained ophthalmologist. Diabetic retinopathy was recorded in four categories viz.- mild, moderate, severe and proliferative diabetic retinopathy [12].

Data management

Data were entered into a computer-based spreadsheet and cleaned. Data were analysed using SPSS 20.0. Categorical variables such as gender, microalbuminuria, diabetic retinopathy etc. were presented as proportion. Continuous variables such as age, HbA1c etc. were presented as mean (SD). Bivariate analysis was done with Chi-square test. P value <0.05 was considered significant.

Results

One hundred sixty-seven newly diagnosed T2DM patients were approached for the study. Seven refused to give consent, and 10 patients couldn't give complete information related to the study (Response rate= 89.8%). Data were analysed from 150 patients. The mean (SD) age of patients was 50.43 (12.73) years. About 52.7% (n=79) patients were male. The mean (BMI) of the patients was 25.43 (4.97) Kg/m^2. About 55.3% (n=83) patients had normal BMI. About 4.7% (n=7) had BMI <18.5 Kg/m^2, 22% (n=33) had BMI from 25.01 to 30.0 Kg/m^2, and 18% (n=27) had BMI >30 Kg/m^2 (Table 1).

About 30% patients had good glycaemic control (HbA1c <6.5%), 38% had fair control (HbA1c 6.5- 7.9%), and 32% had poor control (HbA1c ≥8.0%). About 30% (n=45) of newly diagnosed T2DM patients had microalbuminuria. Thirty patients (20%) had diabetic retinopathy. Microalbuminuria was found significantly associated with HbA1c (P<0.01). The presence of DR was also found significantly associated with HbA1c (P<0.01) (Table 2 & Figure 1).

Table 1: Distribution of participants according to age, gender and BMI (n=150).

	Number (n)	*Per cent (%)*
Age (Years)		
<30	9	6.0
31- 50	68	45.33
51-70	70	46.67
>70	3	2.0
Mean (SD)	50.43 (12.73)	
Gender		
Male	79	52.7
Female	71	47.3
BMI (Kg/m2)		
<18.5	7	4.7
18.5- 25	83	55.3
25.01- 30	33	22.0
>30	27	18.0
Mean (SD)	25.43 (4.97)	

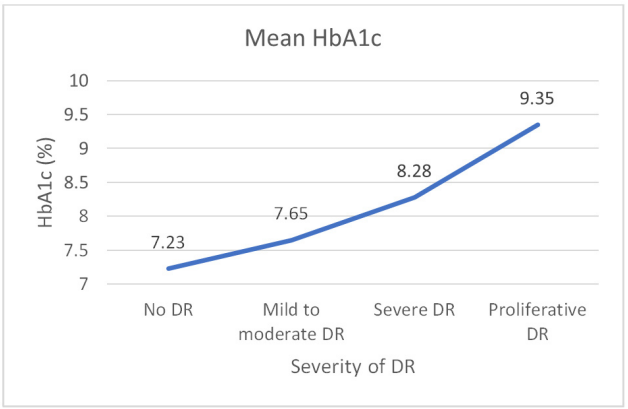

Figure 1: Association of mean HbA1c with severity of DR (n=150). One way ANOVA test, F statistics = 3.81, P= 0.011*. *Statistically significant.

About 8% (n=12) participants had mild DR, 10.7% (n=16) had moderate to severe DR and 1.3 (n=2) % had proliferative DR. Severity of DR was found significantly associated with HbA1c (P<0.01). Severity of DR was also found associated with presence of microalbuminuria (P<0.01) (Table 3).

Table 2: Association of HbA1c with microalbuminuria and diabetic retinopathy among newly diagnosed diabetic patients (n= 150).

		Total	*HbA1c*			*P value*
			Good (n= 45) N (%)	*Fair (n= 57) N (%)*	*Poor (n= 48) N (%)*	
Micro-albuminuria	Present	45	4 (8.9)	13 (22.8)	28 (58.3)	<0.01*
	Absent	105	41 (91.1)	44 (77.2)	20 (41.7)	
Diabetic retinopathy	Present	20	3 (6.7)	9 (15.8)	18 (37.5)	<0.01*
	Absent	130	42 (93.3)	48 (84.2)	30 (62.5)	

*Statistically significant

Table 4 shows association between diabetic retinopathy and microalbuminuria across the three HbA1c categories. DR was associated with microalbuminuria across the three categories. Among good glycaemic control patients, odds of having DR were 40 times higher among patients with microalbuminuria than patients without microalbuminuria (OR= 40.0, 95% CI= 2.45- 65.34). Among fair glycaemic control patients, odds of having DR were 11.71 times higher among patients with microalbuminuria than patients without microalbuminuria (OR= 11.71, 95% CI= 2.36- 58.08). Among poor glycaemic control patients, odds of having DR were 12 times higher among patients with microalbuminuria than patients without microalbuminuria (OR= 12.0, 95% CI= 2.32- 61.95).

Discussion

One hundred fifty newly diagnosed T2DM patients were included in the study. The mean (SD) age of the participants was 50.43 (12.73) years. In the present study, the prevalence of microalbuminuria among newly diagnosed T2DM patients was found 30%. Similar prevalence (32.9) was also reported in North India by Mir et al [13]; whereas, in Nigeria, it was reported higher i.e. prevalence rate of 50% [14]. The variation in the prevalence of microalbuminuria can be attributed to factors such as different methods of estimation of microalbuminuria, ethnic differences in the study populations, definitions of microalbuminuria, and adopted methods of urine collection, etc.

Table 3: Association of severity of diabetic retinopathy with HbA1c and microalbuminuria (n=150).

	Total	*No DR (n=120) N (%)*	*Mild (n=12) N (%)*	*Moderate to severe (n= 16) N (%)*	*Proliferative (n=2) N (%)*	*P value*
HbA1c						
Good (<6.5 %)	45	42 (93.3)	2 (4.4)	1 (2.2)	0 (0)	
Fair (6.5- 7.9 %)	57	48 (84.2)	3 (5.3)	6 (10.5)	0 (0)	<0.01*
Poor (≥8 %)	48	30 (62.5)	7 (14.6)	9 (18.8)	2 (4.2)	
Microalbuminuria						
Present	45	21 (46.7)	9 (20.0)	13 (28.9)	2 (4.4)	<0.01*
Absent	105	99 (94.3)	3 (2.9)	3 (2.9)	0 (0)	

*Statistically significant

Table 4: Association of diabetic retinopathy and microalbuminuria across the three HbA1c categories (n= 150).

Glycaemic control	*MA*	*Number (n=150)*	*Diabetic retinopathy*		*OR (95% CI)*	*P value*
			Present (n= 30) N (%)	*Absent (n=120) N (%)*		
Good (<6.5 %)	Present	4	2 (50.0)	2 (50.0)	40.0 (2.45- 65.34)	<0.01
	Absent	41	1 (2.4)	40 (97.6)		
Fair (6.5- 7.9 %)	Present	13	6 (46.2)	7 (53.8)	11.71 (2.36- 58.08)	0.01
	Absent	44	3 (6.8)	41 (93.2)		
Poor (≥8 %)	Present	28	16 (57.1)	12 (42.9)	12.0 (2.32- 61.95)	0.01
	Absent	20	2 (10.0)	18 (90.0)		

In the current study, microalbuminuria was found associated with HbA1c. There was a steady increase in the prevalence of microalbuminuria with increasing HbA1c. Similar findings were also reported in North India by Mir et al [13]. United Kingdom Prospective Diabetes Study (UKPDS) study also showed that microvascular complications benefit from better control of blood glucose levels [15]. In a study on newly diagnosed T2DM patients in Nigeria, the authors also observed that an HbA1c value above 8% was associated with a higher incidence of microalbuminuria [16].

The prevalence of diabetic retinopathy was found as 20% in the current study. This was consistent with studies done in United Kingdom by Chowdhury et al [9] and Shah et al [17] where they found a 16.5% and 18% prevalence of DR, respectively. In India, Garg et al also found a similar prevalence i.e. 22.1% of diabetic retinopathy among T2DM patients living with diabetes for less than 10 years [18]. Whereas, Rani et al and Reddy et al observed a higher prevalence of diabetic retinopathy i.e. 31% and 36.5% respectively, in their studies conducted in India [19, 20]. In North India, Narang et al found 45% prevalence of diabetic retinopathy [21]. The risk of retinopathy in T2DM increases with the duration of diabetes. Only newly diagnosed T2DM patients were included in this study, which may be the reason for the comparatively lower prevalence of diabetic retinopathy in this study.

Diabetic retinopathy was found to be associated with HbA1c. It was found more among patients with higher HbA1c. A study from Central India also reported that patients having a good glycemic control had a lower prevalence of diabetic retinopathy as compared to those having poor control [18]. In the present study, eight per cent of participants had mild DR, 10.7% had moderate to severe DR and 1.3% had proliferative DR. Garg et al also made similar observations i.e. 14.4% of participants had mild DR, 15.3% had moderate to severe DR and 2.4 % had proliferative DR in patients with <10 years duration of T2DM in their study from Central India [18]. In different cross-sectional studies, the prevalence of different grades of retinopathy was found of similar order with a prevalence of lower grades of retinopathy being higher compared to higher grades or proliferative retinopathy [20-22].

In the current study, it was also found that diabetic retinopathy was associated with microalbuminuria. Garg et al, Manaviat et al and Boelter et al also reported a significant linear relationship between microalbuminuria

and the severity of diabetic retinopathy [18, 24, 25]. Few studies have identified that the renal changes seen in individuals with both microalbuminuria and retinopathy had a distinct pattern compared to those having microalbuminuria without retinopathy [26].

The current study provides a deep insight into the relationship among microalbuminuria, diabetic retinopathy and HbA1c level among newly diagnosed T2DM. It was observed that higher levels of HbA1c and the presence of microalbuminuria, are associated with the occurrence of diabetic retinopathy. These are also associated with the severity of diabetic retinopathy.

Limitations

It was a cross-sectional study, so association doesn't imply causation. The role of confounders was also not studied.

Conclusion

In newly diagnosed T2DM patients, HbA1c and microalbuminuria are associated with the presence of retinopathy. These findings imply that HbA1c and microalbuminuria may serve as predictors of the likelihood that proliferative retinopathy may occur. If follow up studies support these results, periodic ophthalmologic monitoring may be beneficial for newly diagnosed T2DM patients with high HbA1c and microalbuminuria.

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Conflict of interest

Authors declare no conflict of interest.

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