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Original Article

EPIDEMIOLOGY OF DIABETIC RETINOPATHY IN PATIENTS WITH TYPE 2 DIABETES MELLITUS IN MIDDLE DELTA, EGYPT - A SINGLE CENTER BASED RETROSPECTIVE STUDY

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Abstract

Purpose: *The objective of this study was to investigate the prevalence of DR and to determine its risk factors in patients with T2DM in Middle Delta, Egypt.* ***Methods:*** *This retrospective study was conducted at Tanta Ophthalmic Hospital on patients with T2DM during the period from January 2019 to August 2022. The medical records of 1267 patients with T2DM were reviewed.* ***Results:****. It was found that 907 patients (71.6%) were females, the mean age was 57 years and 958 patients (75.6%) were non-occupied. Risk factors included un-controlled blood glucose in 748 patients (59%), hypertension in 712 patients (56.2%), hyperlipidemia in 329 patients (26%), obesity and ischemic heart disease in 188 patients (14.8%), 164 patients (12.9%) were smokers, and 57 patients (4.5%) had diabetic nephropathy. The mean duration since the diagnosis of DM was 13.45±7.64 years and the mean HbA1C was 8.31±2.02%. This study found that the prevalence of DR was 52.6% and it was categorized into mild non-proliferative diabetic retinopathy (NPDR) in 216 patients (17%), moderate NPDR in 170 patients (13.4%), severe NPDR in 100 patients (7.9%) and proliferative diabetic retinopathy in 181 patients (14.3%). and the prevalence of DME was 30.5%. The duration of DM, the serum level of HbA1C, age, and non-occupation correlated positively with an increasing prevalence of DR.* ***Conclusion:*** *The prevalence of DR in the Middle Delta district was 52.6% and DME was 30.5%. The duration of DM, serum level of HbA1C, age, and non-occupation correlated positively with the increasing prevalence of DR.*

Keywords: *Diabetic retinopathy, Type 2 DM, Prevalence*

1. Introduction

In 2019, the International Diabetes Federation (IDF) listed Egypt among the world top 10 countries in the number of patients with type 2 diabetes mellitus (T2DM). According to IDF, it is expected that the number of patients with T2DM in Egypt will increase from 8.9 million in 2019 to 11.9 million in 2030 [1]. Diabetic retinopathy (DR) is a sight-threatening, microvascular complication of diabetes mellitus (DM) and considered as a leading cause of blindness worldwide for those aged from 25 to 75 years old [2,3]. After 15 years of diabetes, approximately 2% of patients will develop blindness, while about 10% will develop severe visual handicap [4]. Blindness from DR is largely avoidable, but, it requires a greater awar-

eness of the need for early detection and early treatment [5,6]. The most relevant risk factors for the development and progression of DR are the duration of the disease, poor glycemic control and the presence of hypertension. Other determinants for DR include dyslipidemia, a higher body mass index (BMI), age, gender, socioeconomic status and smoking [7, 8]. Several studies have shown that timely laser treatment and intravitreal anti-vascular endothelial growth factor therapy can reduce severe vision loss from DR by 90% [9-12]. Since early DR is usually asymptomatic, then, the only avenue for patients to present in a timely fashion is through screening [13]. Robust data on incidence and progression of DR are necessary for development of screening programs [14]. In Egypt, the prevalence of DR in different studies varies from 20.5% [15] to 42% [16]. This makes it important to gather more information using different population samples, locations and time points [15]. To the best of our knowledge, neither similar studies were conducted nor were national screening programs established to investigate the prevalence and risk factors of DR and sight-threatening complications among diabetic patients in Middle Delta, Egypt. Middle Delta region constitutes one of the largest districts in Egypt (approximately 39 million populations). The objective of this study was to investigate the prevalence of DR and to determine its risk factors in patients with T2DM in Middle Delta, Egypt.

2. Patients and Methods

2.1. *Study design, population and setting*

It is a retrospective study and it was conducted on patients with Type 2 DM (T2DM) who attended "The clinic for screening and early management of complications of diabetes on the eye" in Tanta Ophthalmic Hospital during the period from January 2019 to August 2022. Our hospital is the largest and oldest ophthalmic hospital in Gharbia Governorate affiliated to the Ministry of Health and Population (MOHP), Egypt. *Inclusion criteria:* patients with T2DM. *Exclusion criteria*, include: ***)** Patients who did not attend for more than 2 screening appointments, ***)** Patients with media opacity interfering with examination, ***)** Pregnant females, and ***)** Files of dead patients.

2.1.1. Data collection

The medical records of patients with T2DM who attended the screening clinic were reviewed and the following data were collected: **1)** *Demographic data:* age, gender, residence and occupation. **2)** *Patients' history including:* ***)** History of DM; duration of DM (starting from date of diagnosis of diabetes till the time of screening), treatment of DM (oral hypoglycaemic drugs or insulin). Diagnosis of DM was made by the history of medical treatment of diabetes or with haemoglobin A1C (HbA1C) ≥6.5%. ***)** Risk factors: body weight and body mass index (BMI), smoking (yes/no), hypertension (yes/no), dyslipidemia (yes/no), ischemic heart disease (yes/no), pregnancy (yes/no) and nephropathy (yes/no). **3)** *Ophthalmological examination:* ***)** Best corrected visual acuity on Snellen distance chart at 6 m, ***)** Anterior segment examination with slit-lamp biomicroscopy, ***)** Intraocular pressure measurements with Goldman applanation tonometery. ***)** Dilated fundus examination with slit-lamp biomicroscopy, +90 D Volk lens and indirect ophthalmoscopy. ***)** Grading of DR according to the International Clinical Disease Severity Scale for DR which does not require specialized examinations as Fundus Fluorescein Angiography (FFA) or Optical Coherence Tomography (OCT). It is based on clinical examination and applying

the Early Treatment Diabetic Retinopathy Study (ETDRS) 4:2:1 rule [17]. ***)** Macular edema evaluated according to ETDRS term of clinically significant macular edema (presence or absence). ***)** Investigations requested when indicated: FFA and OCT. ***)** The final diagnosis for each patient was based on the severest changes in both eyes.

2.1.2. Ethical issues

The study protocol was approved by the ethical committee of MOHP (No: 2-2022/7).

2.1.3. Statistical methods

Data were exported from E form for Coding and cleaning using Excel version (365) then exported for analysis on the statistical package of Social Science Software Program, version 23 (SPSS). Data were summarized using; mean, SD, Median and IQR for quantitative variables and number and percent for qualitative variable. Kolmogorov–Smirnov test was used to check data normality and data were non-normally distributed. Chi-square test was used to compare between qualitative variables. Fisher exact test was used when one expected cell or more are less than 5. Mann-Whitney U test was used for comparison of the quantitative data that were non-normally distributed variables. Med Calc program was used to check the discriminant power of HbA1C% using receiver operating characteristic (ROC) curve. P value equal to or less than 0.05 was considered of statistically significance.

3. Result

3.1. *Baseline demographic and clinical characteristics*

The current study included the medical records of 3000 patients with T2DM who attended at "The clinic for screening and early management of complications of diabetes on the eye", in Tanta Ophthalmic Hospital during the period from 2019 to 2022. According to our selection criteria, 1733 files were excluded due to missing data, missing follow-up which was largely affected by the social distancing of the COVID-19 pandemic, media opacity that interfere with examination and diagnosis, and death of the patients. The remaining 1267 files were included in the final analysis. Female patients were found to be 907 patients (71.6%) while male patients were 360 patients (28.4%), the mean (±SD) of age was 57.43 years (±9.51), and most of the patients 958 (75.6%) were non-occupied. Risk factors were relatively frequent among the studied population. Un-controlled blood glucose found in 748 patients (59%), 712 patients (56.2%) were hypertensive, 188 patients (14.8%) had obesity, 329 patients (26%) were hyperlipidemic, 188 patients (14.8%) with ischemic heart disease, 164 patients (12.9%) were smokers, and 57 patients (4.5%) had diabetic nephropathy. In addition, the mean duration since the diagnosis of diabetes mellitus was 13.45±7.64 years. The mean HbA1C was 8.31±2.02 %. The mean IOP was normal 14.18±4.14 mm Hg**.**

3.2. *Prevalence of DR and diabetic macular edema (DME) and their relations to risk factors and sociodemographic characteristics:*

Among the study population, DR was found in 667 patients (52.6%); which was categorized into: mild non-proliferative diabetic retinopathy (NPDR) found in 216 patients (17%), moderate NPDR in 170 patients (13.4%), severe NPDR in 100 patients (7.9%) and proliferative diabetic retinopathy (PDR) in 181 patients (14.3%). Moreover, DME was found in 380 out of all patients with DR (380/

1267, 30.5%). DR was significantly more frequent among non-occupied patients in respect to occupied patients ($p < 0.001$). The prevalence increased with increasing disease duration ($p < 0.001$), and HbA1C % ($p < 0.001$), tab. (1). Age was signify-cantly higher in DR patients compared with non-DR patients, and in NPDR compared with PDR ($p < 0.001$, $p < 0.01$ respective-ly). In addition, longer duration of diabetes and higher HbA1C% were significantly higher in DR compared with non-DR ($P < 0.001$) and in PDR compared with NPDR ($p = 0.001$, $p<0.001$ respectively)), tab. (2). The prevalence of non-occupation was significantly more frequent in patients with DME in comparison to those without ($p = 0.018$). Moreover, patients with DME had a significantly older age ($p <0.001$), longer duration of diabetes ($p = 0.006$) and higher level of HbA1C% ($P < 0.001$) in comparison to those without DME, tab. (3). The ROC curve showed poor dis-criminatory power of HBA1C level at cutoff point >7.7 between patient with/ without DR and those with/without DME, fig. (1).

Table 1: Prevalence of different categories of DR in relation to risk factors and socio-demographic characteristics (n=1267)

	No DR	Mild NPDR	Moderate NPDR	Severe NPDR	PDR	P value
Sex						
▪ ***Male***	151 (26.5)	65 (30.2)	53 (30.8)	23 (24.5)	68 (31.3)	0.485
▪ ***Female***	418 (73.5)	150 (69.8)	119 (69.2)	71 (75.5)	149 (68.7)	
Occupation						
▪ ***Non-occupied***	424 (74.5)	155 (72.1)	136 (79.1)	73 (77.7)	170 (78.3)	**<0.001**
▪ ***Industrial or agricultural***	18 (3.2)	10 (4.7)	8 (4.7)	3 (3.2)	12 (5.5)	
▪ ***Skilled worker***	32 (5.6)	16 (7.4)	10 (5.8)	3 (3.2)	12 (5.5)	
▪ ***Semi-professional***	55 (9.7)	27 (12.6)	12 (7)	11 (11.7)	18 (8.3)	
▪ ***Professional***	40 (7)	7 (3.3)	6 (3.5)	4 (4.3)	5 (2.3)	
Hyperlipidemia	152 (26.7)	52 (24.2)	41 (23.8)	18 (19.1)	66 (30.4)	0.246
Smoking	80 (14.1)	17 (7.9)	27 (15.7)	8 (8.5)	32 (14.7)	0.064
Obesity	170 (29.9)	62 (28.8)	48 (27.9)	28 (29.8)	77 (35.5)	0.479
IHD	79 (13.9)	26 (12.1)	34 (19.8)	20 (21.3)	29 (13.4)	0.076
Hypertension	309 (54.3)	112 (52.1)	103 (59.9)	54 (57.4)	134 (61.8)	0.197
HBA1C						
▪ ***<6.5***	154 (28.4)	35 (17.1)	21 (14.1)	6 (6.9)	15 (8.6)	**<0.001**
▪ ***>6.5***	389 (71.6)	170 (82.9)	128 (85.9)	81 (93.1)	159 (91.4)	

Values presented as n (%) or Median (IQR)

Table 2: DR in relation to risk factors (n=1267)

Variable	No DR	DR	P value	NPDR	PDR	P value	Mild / moderate NPDR	Severe NPDR	P value
Age	56 (49.5:62)	59 (53:65)	**<0.001**	60 (54:65)	57 (53:63)	**<0.01**	60 (54:65)	60 (53:64)	0.427
Duration of DM	9 (5:13)	16 (11:21)	**<0.001**	15 (11:20)	18 (13:22)	**0.001**	15 (11:20)	15.5 (11:21)	0.463
IOP	14 (12:16)	14 (12:16)	0.219	14 (12:16)	14 (12:16)	0.794	14 (12:16)	14 (12:16)	0.77
HbA1C%	7.4 (6.4:9)	8.4 (7.4:10)	**<0.001**	8.2 (7.1:9.9)	9 (8:10.2)	**<0.001**	8 (7:10)	8.4 (7.8:9.6)	0.184

Values presented as n (%) or Median (IQR)

Table 3: Prevalence of DME in relation to demographic and clinical characteristics (n=1267)

	DME		P value
	Present	*Absent*	
Sex			0.741
▪ *Male*	98 (27.8)	262 (28.7)	
▪ *Female*	255 (72.2)	651 (71.3)	
Occupation			**0.018**
▪ *No work/housewife*	289 (81.9)	668 (73.2)	
▪ *Industrial or agricultural worker*	14 (4)	37 (4.1)	
▪ *Skilled worker*	13 (3.7)	60 (6.6)	
▪ *Semiprofessional*	25 (7.1)	98 (10.7)	
▪ *Professional*	12 (3.4)	50 (5.5)	
Hyperlipidemia			0.435
▪ *Yes*	86 (24.4)	242 (26.5)	
▪ *No*	267 (75.6)	671 (73.5)	
Smoking			0.633
▪ *Yes*	48 (13.6)	115 (12.6)	
▪ *No*	305 (86.4)	798 (87.4)	
Obesity			0.592
▪ *Yes*	111 (31.4)	273 (29.9)	
▪ *No*	242 (68.6)	640 (70.1)	

	DME		P value
	Present	*Absent*	
IHD			0.614
▪ *Yes*	55 (15.6)	132 (14.5)	
▪ *No*	298 (84.4)	781 (85.5)	
Hypertension			0.825
▪ *Yes*	200 (56.7)	511 (56)	
▪ *No*	153 (43.3)	402 (44)	
HbA1C			**<0.001**
▪ *<6.5*	30 (10.3)	201 (23.2)	
▪ *>6.5*	261 (89.7)	665 (76.8)	
Age	59 (54:64)	57 (51:64)	**0.006**
Duration of disease	17 (12:21)	11 (6:17)	**<0.001**
RT_IOP	14 (12:16)	14 (12:16)	0.936
LT_IOP	14 (12:16)	14 (12:16)	0.518
HbA1C%	8.6 (7.6:10)	7.9 (6.6:9.3)	**<0.001**

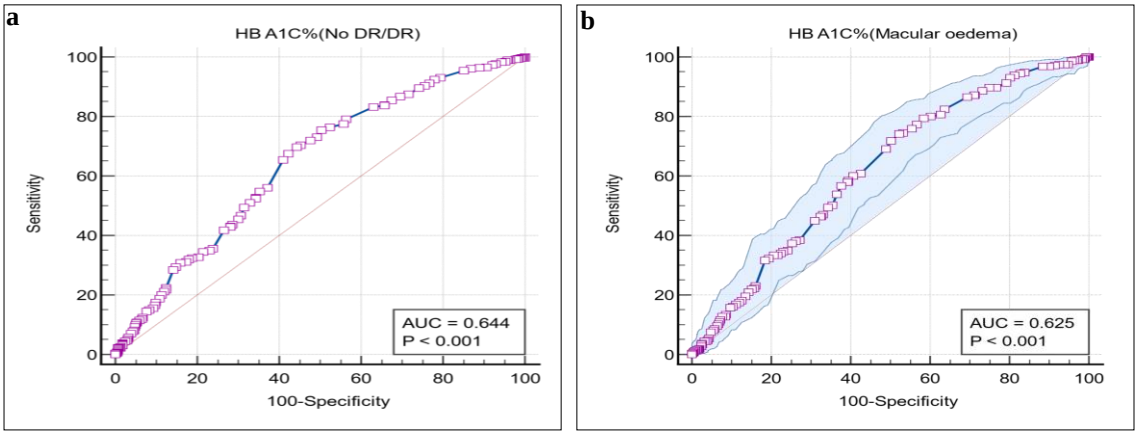

Figure 1: Discrimnatory power of HbA1C in patient with DR (A) and DME (B)

*The area under the ROC curve **(AUC)** results were considered excellent for AUC values between 0.9-1, good for AUC values between **0.8-0.9**, fair for AUC values between 0.7-0.8, poor for AUC values between 0.6-0.7 and failed for AUC values between 0.5-0.6. **PPV** positive predictive value, **NPV** negative predictive value.*

4. Discussion

This study was conducted on patients with T2DM presented to the screening clinic of our hospital during the period from January 2019 to August 2022. During that period, 3000 patients' files were available; 1733 files were excluded for different reasons leaving 1267 for final analysis. Most of our patients; 907 (71.6%) were females, while males constituted only 360 patients (28.4%). This outcome can be explained by the higher prevalence of T2DM in females. In a population-based cross-sectional study conducted in Sohag governorate, Egypt in 2019, Al-Sawahli et al, found that the prevalence of DM was 20.9% (95% CI 19.3% to 22.5%) and the prevalence of DR in females (23.8%; 95% CI 21.4% to 26.3%) was significantly higher than in males (18.9%; 95% CI 17.1% to 20.7%) (p=0.0001) [18]. Moreover, some data suggest that female patients usually seek medical advice more frequently and earlier than male patients when they have any complaint [19]. The prevalence of DR in our study was (52.6%) which is greater than those reported in previous studies by Macky et al 2011, who reported a prevalence of DR in 20.6% of their patients [15] and Heman et al 1998, who had a 42% prevalence of DR [16]. We thought that the difference in prevalence of DR between our study and those authors can be attributed to the different study populations. Our study was conducted in middle Delta, which is a rural area with a low socioeconomic standard and low educational level of most of the population. Most of our patients were relu-

ctant to seek medical care of their diabetes and most of them had poor glycaemic control. Moreover, most patients were unaware about the complications of diabetes on the eye. The study of Mackey et al, on the other hand, was conducted in Cairo, which is an urban area with a higher educational and socioeconomic standards and easier access to health service. Moreover, the prevalence of undiagnosed, DM is more in urban areas than in ruler areas due to increased obesity and low physical activity [20] which interfere with reach to many patients for screening for DR. our study conducted on T2DM while Dr. Macky on type I and type II diabetes. Studies conducted in the Middle East to investigate the prevalence of DR found that a significant proportion of those patients (10.6–17.5%) had sight threatening DR and most of the included patients were examined and diagnosed late [21,22]. In our study, on the other hand, the prevalence of mild non-proliferative DR was 17% indicating that a significant fraction of our patient was picked up early in the course of their disease. It is to be noted that our study was conducted in a specialized ophthalmological hospital where the included patients were examined by retina consultants and the diagnosis was confirmed by OCT in cases of clinically significant macular edema. These 2 important differences between the current study and the reported other studies help explain the greater prevalence of DME among all patients with DR; 30.5% that may have been underdiagnosed in the other studies. The current study was launched five years after the establishment of the screening clinic, a time that is sufficient enough for diabetic patient to hear of and know about the clinic. Moreover, as the screening clinic is centered in a public hospital, it is quite easy for the target population to gain access to the services provided by the clinic. These factors also may explain the greeter prevalence of DR in the current study in comparison to other studies. In our study, we found that the duration of diabetes, the serum level of glycated haemoglobin, and the patients' occupation and the patients' age at the time of examination have correlated with the development of DR. The duration of T2DM was strongly associated with the prevalence of DR ($p < 0.001$); an outcome that agreed with that of Macky et al [15], who found that the prevalence of DR correlated positively with the duration of diabetes ($p < 0.001$). Other studies reported similar results [23-26] Regarding glycaemic control, HbA1C is considered a biomarker for monitoring glycemic control [27]. In the current study, we found significant association of high HbA1C level and the development of DR among T2DM patients ($p < 0.001$). This outcome agrees with that reported by Matthews et al [28]. In the current study, increasing age (median 59 years) in comparison to younger age (median age 56) is significantly associated with increasing prevalence of DR ($p < 0.001$). This outcome agrees with the outcome of the clinical study conducted in Iran that found the prevalence of DR increased with increasing the patients' age [29]. Interestingly, younger patients (median age 57 years) had a higher risk of developing PDR than patients of older age (median age 60 years); an outcome that agrees with that of Chen et al [30]. Non-occupied patients in our study had an increased prevalence of DR in comparison to occupied ones ($p<0.001$). Cardoza et al [31] reported that DR was more prevalent among clerks and homemakers. ($p= 0.004$). Since more than 70% of our study population was females and most of them were non-occupied house wives, we assume that this outcome is due to lack of knowledge about the complication of DM on the eye among those patients. The main limitation of our study is that it is a single center study targeting patients in a Middle delta. We suggest that similar studies to be conducted in other regions in our country.

5. Conclusion

With the increasing number of patients with T2DM in Egypt, we need to set screening programs for DR to prevent its progression to a sight-threatening disease. This study found that the prevalence of DR in middle Delta district was 52% and the prevalence of DME was 30.5%. The duration of DM, the serum level of HbA1C, age and non-occupation correlated positively with increasing prevalence of DR. Similar studies should be conducted in different regions in Egypt.

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