Research Article



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The impact of expanding the screening interval for diabetic retinopathy in primary care centers

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Abstract

Objectives: This study aimed to estimate the prevalence of diabetic retinopathy (DR) and its determinant risk factors in people with diabetes attending primary care centers and to determine the impact of expanding the screening interval on the incidence and progression of (DR).

Methodology: This study was a cross-sectional chart review, that was conducted in three randomly selected primary care centers. A total of 250 diabetic patients had three consecutive annual screenings for DR from April 2014 to April 2017. At the initial visit, the ophthalmological findings were recorded. For three successive yearly screening , the screening results were assessed to estimate the changes that occurred in the prevalence, incidence, and progression of diabetic retinopathy in addition to the degree of association with the most predictable risk factors.

Results: The initial prevalence of DR was 15.2%. Over the three-consecutive annual screening, the DR prevalence increased to 19.6%, 22.4%, and 25.6%, respectively. Most cases (72%) of DR were of the mild non-proliferative diabetic retinopathy (NPDR) type. The annual incidence of DR was 4.4%, 2.8%, and 3.2%. The progression of DR occurred in 2 (0.08%) cases at the second screening interval and in 6 (2.4%) cases at the third screening interval. These changes were strongly associated with age, the duration of diabetes, HBA1C levels, hypertension, and insulin therapy (P-value 0.005). However, changes in the incidence and progression of DR over the three intervals were statistically non-significant (P-value 0.086).

Conclusion: DR, a serious microvascular complication of diabetes mellitus, is an asymptomatic disease with a slow onset and gradual progression. DR requires regular screening for early detection. The screening interval can be extended up to every three years in the very low-risk groups without threatening vision.

Background

Diabetes mellitus is one of the most prevalent diseases worldwide [1]. The Kingdom of Saudi Arabia has a high prevalence of diabetes mellitus at 23.7% [2], and this rate is expected to rise to 44.1% in 2022 [3]. DM is a well-known cause of microvascular and macrovascular complications. Diabetic patients often develop eye diseases as a complication. However, the most common and potentially sightthreatening of these complications is diabetic retinopathy (DR) [4]. The onset and progression of diabetic retinopathy is slow and gradual, advancing from mild non-proliferative diabetic retinopathy (NPDR), indicated by the presence of at least one microaneurysm, to moderate NPDR, indicated by the presence of hemorrhages, microaneurysms, and hard exudates. The severe form is characterized by hemorrhages and microaneurysms in four quadrants, with venous beading in at least two quadrants and intraretinal microvascular abnormalities in at least one quadrant. Proliferative diabetic retinopathy (PDR) is characterized by neovascularization, preretinal hemorrhages, hemorrhage into the vitreous, traction retinal detachments or macular edema (ME) [5]. Diabetic retinopathy is considered a frequent and leading cause of blindness, especially among the most productive age group between 20 and 60 years of age, with approximate estimates for the prevalence of retinopathy and vision-threatening retinopathy at 40.3% and 8.2%, respectively (6). Of the 37 million blind people reported worldwide in the year 2002, diabetic retinopathy was responsible for 1.8 million (4.8%) cases [6]. Diabetic retinopathy is considered the leading cause of blindness in the Kingdom of Saudi Arabia as well [7]. There is a wide discrepancy among the reported prevalences of DR. The overall global prevalence of DR among patients with type 2 diabetes is 27.23%, while the prevalence of DR among different ethnic groups varies widely from 20.8% among Asians to 46.7% among Caucasians [8]. Moreover, the data collected from the Saudi National Diabetes Registry indicates that the overall prevalence of diabetic retinopathy is 19.7% (9). The risk factors are mainly related to age, the duration of diabetes and glycemic control; other factors, such as obesity, dyslipidemia and nephropathy, were variably associated [9,10]. In Saudi Arabia, nephropathy, neuropathy, insulin use, poor glycemic control, hypertension and male gender significantly increased the risk for diabetic retinopathy, while smoking, hyperlipidemia and obesity significantly were associated with reduced risk for diabetic retinopathy among Saudi type 2 diabetics [9]. Regular screening is the best method for the early detection of diabetic retinopathy and is strongly recommended since early detection has

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the best chance of preventing retinal complications and blindness [5,7,11,12]. In the primary care setting, patients should be referred by a healthcare professional to an ophthalmologist or an optometrist who should perform a comprehensive eye examination including a dilated fundoscopy. Such an eye exam should be conducted annually and at regular intervals thereafter as recommended by the eye care professional [13]. Retinal photography can enhance the efficiency of screening and reduce costs [14]. With the rapid increase in the prevalence of diabetes, the burden and cost of annual screening are rising with no evidence of significant rewards in delaying the onset of DR, especially in newly diagnosed diabetics with controlled risk factors [15]. In diabetic patients with no retinopathy, there is reported evidence that biennial screening is cost-effective [14]. Screened patients who had no or non-proliferative retinopathy were found to have a very low risk of eventual blindness from diabetes [16].

In this study, we aimed to estimate the prevalence of diabetic retinopathy and its risk factors in the primary care setting and to measure the frequency of referral to an ophthalmologist for screening and the impact of expanding the DR screening interval among diabetic patients attending primary care centers.

Methods

This study was a cross-sectional chart review study using patient medical records. Three governmental primary health care centers were randomly selected from twelve centers equipped with well-established diabetic care units located in the city of Jeddah, Saudi Arabia. The total number of registered diabetics was 896 from April 2014 to April 2017. Medical records were reviewed, and only the complete medical records containing all the variables to be studied were included in this study. These variables included the following: the sociodemographic data [age, gender, height, weight, body mass index (BMI), smoking status]; systolic and diastolic blood pressure measurements obtained by the unit nurse for each visit or noted as a hypertensive patient undergoing treatment; type, onset and duration of DM; presence or absence of microvascular complications, such as retinopathy, neuropathy or nephropathy; presence or absence of macrovascular complications, such as stroke and cardiovascular disease (CVD); type of treatments prescribed (oral hypoglycemic, insulin combined with oral hypoglycemic or insulin alone); the frequency of ophthalmological referral; the results of the screening at the initial visit performed by ophthalmologists at the General Eye Hospital in Jeddah; the results of three consecutive screenings at regular one-, two- and three-year follow-up visits in the primary care center; and the measurement of hemoglobin A1c (HBA1C) and low-density lipoprotein (LDL) levels and the glomerular filtration rate (GFR). The level of HbA1C was measured using the method certified by the NGSP and standardized per the Diabetes Control and Complications Trial (DCCT) assay. The HBA1C level was categorized into three groups (less than 7, 7.1-10 and greater than 10). A value of less than 7 was considered controlled. The LDL level was used a marker for dyslipidemia, and a value greater than 100 mmol/l was considered high. The GFR was calculated using the National Kidney Foundation method of calculation, and a GFR less than 60 was considered to indicate nephropathy. The data were categorized as the dependent variable, which was diabetic retinopathy of any grade, and independent variables (age, sex, the duration of diabetes, BMI, HBA1C and LDL levels and the GFR). The screening intervals were categorized into four groups: the initial visit findings, and the findings after the first, second, and third annual screening intervals. The incidence of DR of any grade and the percentage of progression occurring over the three years were determined. This study was ethically approved by the Directorate of Health Affairs, the Research and Studies Department, the Scientific and Biomedical committee, Jeddah, Saudi Arabia (ethical approval number H-02-J-002).

Statistical analysis

Statistical analysis was conducted using the Statistical Package for Social Sciences (SPSS) version 20.0 software (IBM Corp., Armonk, NY). A chi-square test (v2) was used for categorical variables, while the t-test was used for continuous variables. A P value of <0.05 was used as the level of significance. Independent-samples t-tests were used to evaluate the changes that occurred during the three screening intervals. Multinomial logistic regression analyses were performed to determine the most significant risk factors associated with the changes in DR. Adjusted ORs, 95% confidence intervals (CIs) and a P-value of <0.05 as the level of significance were used to assess the risk factors most closely related to changes in the incidence and progression of DR during the three years.

Results

A total of 250 medical records of those registered diabetic patients who were in primary care centers during the period from April 2014 to April 2017 were complete and fulfilled the inclusion criteria. There were 120 (48.0%) males and 130 (52.0%) females. The mean age \pm SD was 56 \pm 12 years (min 23-max 80 years). In the initial screening, there were 38 cases with retinopathy of any grade; these patients had a mean age ± SD of 61 ± 11 years (95% CI, 57.28-64.72%), while the mean age of those who had no retinopathy was 54 ± 10 years (95%) CI, 52.27-55.73%). This difference was statistically significant (P- value 0.001). There was an equal number of cases of DR among both genders, with 19 cases (50.0%) for each, while other eye diseases (cataract and refractive errors) were present in 40 (56.3%) females and 31 (43.7%) males. Normal eye exam results were observed for 141 diabetics, 71 (50.4%) females and 70 (49.6%) males. Chi-square statistical tests were performed to estimate the degree of association between DR and the independent variables. There was no significant association with gender (P-value 0.668), type of DM (P-value 0.080), obesity for either DM1 or DM2 (P-value 0.980), or smoking (P-value 0.992). While the duration of DM, HBA1C level, uncontrolled diabetes, hypertension, dyslipidemia, nephropathy, and insulin treatment were all significantly associated (P-value <0.005) (Table 1).

Initially, the prevalence of DR of any grade was 15.2% (95% CI 10.8-19.7%). The other eye diseases (refractive errors and cataract) were present in 71 cases with a prevalence of 28.4% (95% CI 22.8-34.2%). The total number of DR cases increased to 49 cases at the first annual screening interval, with a prevalence of 19.6% (95% CI 14-23.6%). At the second screening interval at two years, there were 56 cases of DR and the prevalence was 22.4% (95% CI 17.2-27.6%). A total of 64 cases were detected in the third screening interval after three years with a prevalence of 25.6% (95% CI 20.6-34.8%) (Table 2).

The frequency and percentage of the different grades and diagnoses at the three screening intervals were also determined (Table 3).

The main changes that occurred during the three annual screening intervals were as follows:

204 (81.6.4%) cases had no change from their primary initial diagnoses during the three screening intervals, while eleven cases (4.4%) had a new onset at the first annual screening interval, 7 (2.8%) cases had a new onset at the second interval, and 8 (3.2%) cases had a new onset at the third interval. While 2 cases (0.08%) progressed to the following grade of DR at the second screening interval, 6 cases

Variable	Normal	Diabetic retinopathy	Other eye disorders	P value
	No. (%)	No. (%)	No. (%)	i value
Sex				
Female	71 (50.4%)	19 (50.0%)	40 (56 3%)	
Male	70 (49.6%)	19 (50.078)	40 (30.376)	0.669
DM type		19 (50.0)	51 (45.7%)	0.008
DM1	13 (9.2%)	4 (10 50/)	1 (1 40/)	
DM2	128 (90.8%)	4 (10.5%)	1 (1.4%)	
Duration of DM		34 (89.5%)	70 (98.6%)	0.000
Less than 10 years	75 (53.2%)			0.080
10- 20 years	45 (31.9%)	3 (7.9%)	53 (74.6%)	
More than 20	21 (14 9%)	13 (34.2%)	17 (23.9%)	0.0005
BMI	21 (1 11570)	22 (57.9%)	1 (1.4%)	
Less than 30	73 (51.8%)			
Greater than 30	68 (48 2%)	20 (52.6%)	36 (50.7%)	
HBA1C	08 (48.270)	18 (47.4%)	35 (49.3%)	0.980
7 or less	54 (38 3%)			
7 01 1055	57 (40 49/)	1 (2.6%)	35 (49.3%)	
/.1-10 Creater than 10	37 (40.476) 20 (21 29/)	22 (57.9%)	30 (42.3%)	0.0005
Greater than 10	50 (21.5%)	15 (39.5%)	6 (8.5%)	
Control of DM	<i>(()</i> (<i>A</i> ()))			
Controlled	66 (46.8%)	5 (13.2%)	37 (52.1%)	
Uncontrolled	75 (53.2%)	33 (86.8%)	34 (47.9%)	0.0005
Hypertension:				
Yes	70 (49.6)	30 (78.9%)	19 (26.8%)	
No	71 (50.4%)	8 (21.1%)	52 (73 2%)	0.0005
Treatment :		0 (211170)	52((512)3)	010000
OHD	80 (56.7%)	4 (10.5%)	55 (77 5%)	
Insulin Only	14 (9.9%)	6 (15.8%)	1 (1 4%)	0.0005
Insulin +metformin	14 (9.9)	5 (12 2%)	6 (9 5%)	0.0005
Insulin +OHD	33 (23.4%)	3(13.270) 22(60,5%)	0 (8.576)	
Smoking :		23 (00.378)	9 (12.770)	
No	129 (91.5%)	25 (02 10/)	65 (01 59/)	
Yes	12 (8.5%)	33 (92.170)	03 (91.376)	0.002
Dyslipidemia:		3 (7.9%)	6 (8.5%)	0.992
No	84 (59.6%)	12 (21 (21)		0.002
Yes	57 (40.4%	12 (31.6%)	4/ (66.2%)	0.0005
Nephropathy:	, î	26 (68.4%)	24 (33.8%)	0.0005
No	131 (92.9%)	21 (55 284)	70 (00 (00)	
Yes	10 (7.1%)	21 (55.3%)	70 (98.6%)	
Total	141 (56.4%)	17 (44.7%)	1 (1.4%)	250 (100%)
		38 (15.2%)	71 (28.4%)	

Table 1. Association between socio-demographic characteristics and diabetic retinopathy and other eye disorders, P- value < 0.05= Significant association.

Table 2. The prevalence of diabetic retinopathy cases at each screening interval

Screening Interval	Normal	Diabetic retinopathy	Other eye disease	Total
Initial	141	38 (15.2%)	71 (28.4)	250
One year	126	49 (19.6%)	75 (30.0%)	250
Two years	116	56 (22.4%)	78 (31.2%)	250
Three years	103	64 (25.6%)	83 (33.2%)	250

Table 3. The frequency and percentage of the different diagnoses at the three screening intervals

	Initial finding	Screening Interval		
Diagnosis		One year	Two years	Three years
Normal	141 (56.4%)	126 (50.4%)	116 (46.4%)	103 (41.2%)
Mild NPDR	24 (9.6%)	35 (14%)	40 (16.0%)	42 (16.8%)
Moderate NPDR	10 (4.0%)	10 (4.0%)	12 (4.8%)	14 (5.6%)
Severe NPDR	0	0	0	2 (0.8 %)
Maculopathy	4 (1.6%)	4 (1.6%)	4 (1.6%)	6 (2.4%)
Cataract	3 (1.2%)	4 (1.6%)	7 (2. %)	12 (4.8%)
Refractive errors	68 (27.2%)	71 (28.4%)	71 (28.4%)	71 (28.4%)

(2.4%) progressed to another grade at the third screening interval. These changes over the three intervals were statistically non-significant (P-value 0.086).

A multinominal logistic regression with the calculation of the adjusted OR and 95% CI revealed a significant association of these changes with age >60 years, a duration of diabetes of >10 years, an HBA1C level >7.1, hypertension, and insulin therapy, and these factors were strong predictors of the incidence and progression of DR (Table 4).

Discussion

Diabetic retinopathy is one of the main microvascular complications of diabetes mellitus and can threaten the sight and progress to blindness [17,18] National and international studies that have been conducted to determine the prevalence of diabetic retinopathy have reported values that range from 15% in some studies to 36% in others [19-23]. Studies from Saudi Arabia's southern region reported a prevalence of 36.4%, which is much higher than the previously reported prevalence of

Variable	aOR	95% CI	P value
Duration of diabetes ≤ 10 years >10 years	2.37	1.25-4.94	0.001
Age ≤ 60 years > 60 years	0.56	0.21-0.90	0.002
HBA1C <8 >8	2.75	1.61-4.71	0.001
Hypertension Yes No	0.67	0.43-0.89	0.005
Insulin use -NO -Only or +OHG	2.04	1.67-4.56	0.002

Table 4. Logistic regression analysis for the risk factors that might be associated with the main changes. aOR: adjusted odds ratio.

11.3% in the same region by Al-Khaldi, et al [24]. The last study using the Saudi National Diabetes Registry (SNDR) found that the overall prevalence of diabetic retinopathy of only 19.7% [9]. In most of these studies, the risk factors were related to age, the duration of diabetes mellitus and poor glycemic control, while other factors, such as gender, obesity, smoking, nephropathy, and neuropathy, had no clear associations with diabetic retinopathy [9,25-29]. In this study the initial prevalence of diabetic retinopathy was 15.2% (95% CI, 14.6-19.6%). There was a significant association between diabetic retinopathy and the age of the patient. There was no significant association with gender, in contrast to some studies which reported a predominance for males [28,30]. There was no significant association with the type of diabetes mellitus, although studies around the world found that the prevalence of diabetic retinopathy was higher in people with type 1 diabetes than in those with type 2 diabetes [8,31,32]. Regarding association of obesity with diabetic retinopathy, this study found no significant association, since the relative risk (RR) of BMI (less than 30/more than 30) was 0.615 (95% CI 0.334-1.130). Although a positive correlation of obesity with DR has been found in some studies [3,9,24,32-34], it was found to be protective in another studies [9)]. Controlling blood sugar is a protective factor [5,8,11,32,33,35], and this association was proven in this study. Glycemic level was controlled in only 2.6% of the DR cases, while 97.4% of the DR cases were uncontrolled and had HBA1C level >8.1 (P-value 0.005); the relative risk was 0.25 (95% CI 0.113-0.586). There was a strong association between insulin therapy and DR in this study. Similar findings have been reported in studies from China, Finland, Jordan and Saudi Arabia [9,23,24,28,36]. Hypertension has a strong association with DR (P-value 0.0001), and this was well documented in most of the other studies [24,32,33,37,38]. Like other studies, smoking was not associated with DR (P-value 0.992) [5,9,11,24,39]. The relationship between dyslipidemia and nephropathy has been proven in this study and other studies in Saudi Arabia and worldwide [8,21,25-28,40].

The screening program for diabetic retinopathy in primary care centers follows the Saudi National Diabetic Guideline for Primary Care, which recommends an annual referral to ophthalmologists or optometrist to perform a comprehensive ophthalmological examination for the early detection of DR, and the findings and recommendations of these professionals are sent back to the referring center.-Diabetic retinopathy has a delayed onset and a slow, gradual progression over many years and can even regress when the disease is in an early mild form [41-43]. Therefore, expanding the screening interval is permissible with no additional risks, especially in those with no retinopathy or with mild NPDR within the first 10 years of diabetes duration, since the prevalence of retinopathy during the first 10 years of a diabetes diagnosis has been found to be low, and progression in these cases was rare [43]. Furthermore, a study performed to determine the diabetic retinopathy screening interval based on the time from no retinopathy to laser therapy concluded that the screening interval for diabetic patients could be extended to two or three years. Patients with no retinopathy or who have a non-proliferative form have a very low risk of eventual blindness from diabetes [16].

In this study, it was found that the initial prevalence of diabetic retinopathy was 15.2%. Most of these cases had mild nonproliferative retinopathy. There was a low but definite annual incidence in these patients; however, progression was relatively infrequent and was associated with age, the duration of diabetes, hemoglobin A1c levels, hypertension, and insulin therapy.

In view of these findings, we concluded that regular screening for DR, and improving treatment for diabetics with new onset of retinopathy is of paramount importance to decrease the incidence and progression. Based on the findings from this study it is suggested that diabetic screening intervals could be increased to every 3 years in low risk patients.

Considering the increasing prevalence of diabetes mellitus that will overwhelm the diabetic care system, it would be more cost-effective to expand the screening interval for low risk groups. Applying a risk-based model of screening for DR can help in estimating the appropriate screening interval for DR [15]. Primary prevention is highly recommended to control the risk factors that will delay the onset and progression of diabetic retinopathy.

Limitations

Limitations of this study are the small sample size and the variation in the initial presentations and in the preregistration history of diabetes and its complications in the patients who were included in the study. This study was performed in the primary care setting, which is different from a hospital-based setting that may affect the outcome.

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