Original Article

Prevalence and Associated Factors of Diabetic Retinopathy in Type 2 Diabetic Patients: A Hospital-Based Study

Parinya Srihatrai MD, FICO[1], Thanita Hlowchitsieng MD[1]

[1] Department of Ophthalmology, Suddhavej Hospital, Faculty of Medicine, Mahasarakham University, Maha Sarakham, Thailand

Background: Diabetes mellitus [DM] is one the most diseases in non-communicable diseases [NCDs] clinic at Suddhavej Hospital. Diabetic retinopathy [DR], the microvascular complication, is one of the leading causes of visual impairment in these patients.

Objective: To report the prevalence of DR and determine the associated factors of DR in type 2 diabetic patients at Suddhavej Hospital, Mahasarakham University.

Materials and Methods: The present report was a hospital-based study carried out between January and June 2017 at Suddhavej Hospital. Two hundred and twenty-two diabetic patients attending NCDs clinic were recruited. All patients were assessed for diabetic microvascular complications, they were given comprehensive eye examinations by two ophthalmologists, and their laboratory results were retrospectively reviewed. Patients were divided into two groups: no DR and DR. The Chi-squared test and logistic regression were used to identify associated factors.

Results: Of the 443 eyes examined (one eye with severe cataract was excluded), the prevalence of DR was 26.0% (n = 115), 22.8% (n = 101) for non-proliferative DR [NPDR], and 3.2% (n = 14) for proliferative DR [PDR]. Male gender, longer duration of diabetes, serum creatinine level, and serum glycated hemoglobin [HbA_{1c}] level were found to be risk factors for DR as determined by univariate analysis. Multivariate analysis, adjusted for age and gender, revealed two risk factors, serum creatinine level (odds ratio of 24.07, 95% CI 2.79 to 207.94, $p = 0.004$) and HbA_{1c} (odds ratio of 5.42, 95% CI 1.68 to 17.44, $p = 0.005$).

Conclusion: The prevalence of DR is comparable to nationwide statistics. Nephropathy by serum creatinine level and high level of HbA_{1c} showed significant negative influence on diabetic retinal microvascular complications.

Keywords: Diabetes mellitus, Diabetic retinopathy [DR], Prevalence, Risk factor

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The number of diabetes mellitus [DM] patients continues to rise, with a global prevalence of 422 million people reported in 2014[1]. In 2015, 4.0 million Thai people were diabetic, with estimated 2.1 million were undiagnosed[2]. According to the recent Annual Epidemiological Surveillance Report, Maha Sarakham has a slightly higher proportion of diabetic patients, with a prevalence of 1,295 per 100,000[3]. According to Maha Sarakham Provincial Public Health Office, the Contracting Unit for Primary Care [CUP] area of Suddhavej Hospital currently includes 557 diabetic patients, 59% of which are aged over 60 years[4].

Diabetic retinopathy [DR] is the most common microvascular complication of longstanding uncontrolled DM and associated aggravating factors[5] such as high blood sugar level, high glycated hemoglobin [HbA_{1c}], high serum triglyceride [TG], and high systolic blood pressure. These result in destruction of the retinal vessels, leading to DR[5-15]. The prevalence of DR in Thailand was reported to be 31.4% in 2006 according to a diabetes registry project, this consisting of 22% non-proliferative DR [NPDR] and 9.4% proliferative DR [PDR][5]. This retinal microvascular complication can threaten vision through macular edema, macular ischemia, cataract, retinal detachment, and vitreous hemorrhage.

In the present study, the authors reported the prevalence of DR in patients attending a non-communicable diseases [NCDs] clinic. The data were analysed to determine the factors associated with DR in Maha Sarakham, the first report of its kind in this province.

Correspondence to:

Srihatrai P. Department of Ophthalmology, Suddhavej Hospital, Faculty of Medicine, Mahasarakham University, Maha Sarakham 44000, Thailand.
Phone: +66-86-5342777, **Fax**: +66-43-712991
Email: parinya@msu.ac.th

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Materials and Methods

Study design

The present report was a hospital-based study, carried out between January and June 2017 at the NCDs clinic in Suddhavej Hospital at Mahasarakham University. The study was approved by the Mahasarakham University Ethics Committee for Research Involving Human Subjects (EC ID 043/2017). All investigations were carried out in accordance to the tenets of the Declaration of Helsinki, and all participants signed informed consent. The study was also approved and registered with the Thai Clinical Trials Registry (TCTR; clinicaltrials.in.th; identification number: TCTR20170607002).

Participants

The studied population consisted of diabetic patients from the NCDs clinic at Suddhavej Hospital. Patients were considered eligible if diagnosed as diabetes according to the American Diabetes Association [ADA] criteria by internists. In total, 557 diabetic patients were registered with Suddhavej Hospital CUP, of whom 222 patients (39.9%) enrolled in the DR screening project described. Patients were excluded if they refused to enroll, if an ocular media opacity obscured fundus detected on evaluation, or if their use of mydriatic drugs were contraindicated.

Data collection

Both eyes of all participants were evaluated for distance visual acuity [VA] using a Snellen VA chart at 6 meters in a well-lit room. Intraocular pressure was measured using an automatic non-contact tonometer, while an autorefractor and keratometer were used to measure ocular refraction. After that, an anterior eye segment examination was conducted using a slit-lamp biomicroscope in which the ophthalmologist assessed anterior chamber depth, neovascularization of the iris, and pupillary response to light prior to pupillary dilatation. We instilled tetracaine hydrochloride 0.5% and tropicamide 1% in all cases for pupillary dilatation, and phenylephrine hydrochloride 10% in some indicated cases. After full pupillary dilatation, the type of cataract was graded. Retinal examination was performed by ophthalmologists via slit-lamp fundoscopy using a 90-dioptre/superfield/digital wide field fundoscopy lens or by indirect ophthalmoscopy with 20-dioptre lens.

All data were recorded using the case record form divided into the following three categories: 1) patient background data (i.e., date of birth, gender, occupation, serum lipid profile, serum creatinine level, urine protein, systolic and diastolic blood pressure, weight/height, and underlying diseases); 2) diabetes history (i.e., type of diabetes, diabetic duration, last DR screening period, antidiabetic and other medications, DM complications, fasting plasma glucose level, and HbA_{1c} level); 3) ocular status (i.e., best possible corrected distance VA, eye surgery history, known co-morbid ocular conditions, lens status, cataract grading, and result of fundus examination). The severity of DR was classified according to the International Clinical Diabetic Retinopathy Disease Severity Scale[16].

Data analysis and statistics

Distance VA level results were divided into 4 categories following the 4 visual stratifications proposed by Brown et al in 2002[17]. Snellen VA was converted to logarithm of minimum angle of resolution equivalent units [LogMAR], Log (reciprocal of Snellen VA) ± (0.02 × additional letters). The presence and degree of DR was graded using the International Clinical Diabetic Retinopathy Disease Severity Scale. Clinically significant macular edema [CSME] was identified as described in the Early Treatment of Diabetic Retinopathy Study [ETDRS][18].

The prevalence of DR was reported by eye laterality (left or right), it was reported for all eyes and, in cases of bilateral DR, the laterality of the worse eye was noted. In cases where fundi could not be evaluated, those eyes were excluded from the study.

The worse eye in each patient of type 2 diabetes was selected, or randomly selected if DR grade was the same in both eyes, to evaluate the effect of possible risk factors. Results were expressed as mean ± standard deviation or median and range. Categorical variables were compared using Chi-squared test or Fisher's exact test. Continuous variables were compared using the t-test or Mann-Whitney U-test. Factors associated with DR status were determined by logistic regression analysis. The results were expressed as odds ratio [OR], 95% confidence interval [CI], and *p*-value. After a number of univariate association factors had been determined, forward stepwise selection was carried out to determine the appropriate multivariate model. All analyses were performed using the R program version 3.4.0 (R Foundation). A *p*-value of less than 0.05 was considered statistically significant.

Results

Patient demographics

Two hundred and twenty-two (39.9%) of the 557

diabetic patients were included for analysis. Only 3 (1.4%) of 222 patients had type 1 diabetes (aged 17.5 to 26.5 years). Retinopathy status (presence or absence of DR) was compared between the different groups.

There were 123 (55.4%) male and 99 (44.6%) female participants. A higher proportion of males was observed in the DR group. The mean (SD) ages of all participants was 61.6 (10.1) years; 62.0 (10.0) years and 60.7 (10.3) years in patients without DR and patients with DR, respectively. The baseline characteristics differed significantly between groups were gender, occupation, dyslipidemia, LDL cholesterol level, proteinuria, and serum creatinine level. Other clinical data included for analysis were age, body mass index [BMI], systolic and diastolic blood pressure, current smoking, occupation, other underlying diseases, and other laboratory results as shown in Table 1.

Diabetes history

The duration of diabetes in participants with DR was significantly longer than those without DR (p = 0.012). The median time, since last eye screening, was 5 months in the group without DR and 12 months in the group with DR. A high level of fasting plasma glucose (p<0.001) and HbA_{1c} (p = 0.035) were found in the DR group. Oral hypoglycemic agents [OHAs] provided between groups were significantly different. In addition to retinal microvascular complications, peripheral neuropathy (diagnosed by podologist) and

Table 1. Clinical characteristics of diabetic patients according to retinopathy status

Characteristics	No DR (n = 158)	DR (n = 64)	*p*-value
Gender, n (%)			0.011
Male	79 (50.00)	44 (68.75)	
Female	79 (50.00)	20 (31.25)	
Age (years), n (%)			0.143
Less than 61	62 (39.24)	29 (45.31)	
61 to 64	30 (18.99)	17 (26.56)	
More than 64	66 (41.77)	18 (28.13)	
Mean ± SD	61.98±10.03	60.68±10.25	0.385
BMI (kg/m^2), n (%)			0.129
Less than 18.5	3 (1.90)	2 (3.13)	
18.5 to 22.9	33 (20.89)	11 (17.19)	
23.0 to 24.9	26 (16.46)	18 (28.13)	
25.0 to 29.9	60 (37.97)	26 (40.63)	
More than 29.9	36 (22.78)	7 (10.94)	
Mean ± SD	26.70±4.79	25.69±3.92	0.134
SBP (mmHg), mean ± SD	135.58±16.26	139.25±18.92	0.148
DBP (mmHg), mean ± SD	75.86±9.59	74.92±11.62	0.536
Current smoking, n (%)	12 (7.59)	6 (9.38)	0.660
Occupation, n (%)			0.046
Unemployed	48 (30.38)	8 (12.50)	
Governor	72 (45.57)	36 (56.25)	
Business owner	19 (12.03)	9 (14.06)	
Employee	12 (7.59)	5 (7.81)	
Others	7 (4.43)	6 (9.38)	
Underlying diseases, n (%)			
Hypertension	104 (65.82)	38 (59.38)	0.365
Dyslipidemia	97 (61.39)	27 (42.19)	0.011
History of CVA	2 (1.27)	0 (0.00)	1.000
History of CVD	3 (1.90)	2 (3.13)	0.628
Laboratory profile			
TG (mg/dL), median (range)	141 (50, 619)	138.5 (39, 340)	0.625
TC (mg/dL), mean ± SD	181.02±41.10	193.09±84.88	0.173
LDL (mg/dL), mean ± SD	116.64±36.19	103.31±33.39	0.016
HDL (mg/dL), mean ± SD	46.22±11.07	43.82±10.51	0.164
Proteinuria, n (%)	65 (48.87)	34 (62.96)	0.080
Serum Cr (mg/dL), median (range)	0.87 (0.42, 3.59)	0.93 (0.42, 8.78)	0.020

DR = diabetic retinopathy; BMI = body mass index; SBP = systolic blood pressure; DBP = diastolic blood pressure; CVA = cerebrovascular accident; CVD = cardiovascular disease; TG = triglyceride; TC = total cholesterol; LDL = low-density lipoprotein cholesterol; HDL = high-density lipoprotein cholesterol; Cr = creatinine; Others = student, priest, aviator, and farmer

nephropathy (diagnosed by serum creatinine level) were detected (Table 2).

Prevalence of diabetic retinopathy

One eye had to be excluded from analysis as a dense cataract obscured fundus evaluation. Of the remaining 443 eyes available for study, the prevalence of mild NPDR in the right eye, left eye, both eyes, and worse eye was calculated to be 5.0%, 5.4%, 5.2%, and 3.6%, respectively. The prevalence of moderate NPDR was 17.1%, 16.7%, 16.9%, and 21.2%, respectively. The prevalence of severe NPDR was 0.9%, 0.5%, 0.7%, and 0.9%, respectively. The prevalence of PDR was 3.2%, 3.2%, 3.2%, and 3.2%, respectively. CSME, diagnosed from retinal examination without optical coherence tomography [OCT] confirmation, was also reported (Table 3).

Concurrent ocular conditions

VA did not significantly differ between the group without DR and the group with DR. LogMAR was 0.14 for the group without DR, and 0.16 for the group with DR ($p = 0.117$). There were 407 (91.9%) phakic eyes with different types and grades of cataract. The proportion of pseudophakic eyes in the DR group was higher ($p = 0.037$). Also, all 17 (14.78%) of the eyes with CSME were in the DR group ($p<0.001$) (Table 4).

Factors associated with diabetic retinopathy

Next, each type 2 diabetic patient was categorized as whether having DR or not, according to the eye with higher degree of DR, and the two groups were analysed for possible associated factors. Five parameters were shown to be statistically significant as risk factors in univariate analysis when compared to the reference

Table 2. Diabetic conditions by diabetic retinopathy status

Characteristics	No DR (n = 158)	DR (n = 64)	*p*-value
Diabetic duration (years), n (%)			0.012
Less than 5	75 (47.47)	18 (28.13)	
5 to 10	41 (25.95)	15 (23.44)	
11 to 20	33 (20.89)	23 (35.94)	
More than 20	9 (5.70)	8 (12.50)	
Median time to last screening (months)	5 (2, 72)	12 (1, 108)	0.060
FPG (mg/dL), mean ± SD	142.54±39.93	166.81±53.78	<0.001
HbA_{1c} (%), mean ± SD	7.88±1.85	8.49±1.47	0.035
Types of diabetes, n (%)			1.000
Type 1 diabetes	2 (1.27)	1 (1.56)	
Type 2 diabetes	156 (98.73)	63 (98.44)	
Treatment, n (%)			
Lifestyle and diet control	2 (1.27)	1 (1.56)	1.000
OHA(s)	147 (93.04)	53 (82.81)	0.021
Insulin treatment	15 (9.49)	10 (15.63)	0.191
Statin therapy	101 (63.92)	41 (64.06)	0.984
OHA(s) and insulin	4 (2.53)	1 (1.56)	1.000
ASA prophylaxis	71 (44.94)	24 (37.50)	0.310
Other DM complications, n (%)			
Peripheral neuropathy	4 (2.82)	2 (4.44)	0.632
Nephropathy	16 (10.39)	13 (23.21)	0.023

FPG = fasting plasma glucose; HbA_{1c} = glycated hemoglobin; DM = diabetes mellitus; OHA = oral hypoglycemic agent; ASA = aspirin

Table 3. Prevalence of diabetic retinopathy

Characteristics	Right eyes (n = 222 eyes)	Left eyes (n = 221 eyes)	Both eyes (n = 443 eyes)	No. of patients (n = 222)
No DR, n (%)	164 (73.87)	164 (74.21)	328 (74.04)	158 (71.17)
DR, n (%)				
Mild NPDR	11 (4.95)	12 (5.43)	23 (5.19)	8 (3.60)
Moderate NPDR	38 (17.12)	37 (16.74)	75 (16.93)	47 (21.17)
Severe NPDR	2 (0.90)	1 (0.45)	3 (0.68)	2 (0.90)
PDR	7 (3.15)	7 (3.17)	14 (3.16)	7 (3.15)
CSME, n (%)	9 (4.05)	8 (3.64)	17 (3.85)	11 (4.95)

DR = diabetic retinopathy; NPDR = non-proliferative DR; PDR = proliferative DR; CSME = clinically significant macular edema

Table 4. Concurrent ocular conditions

Ocular conditions	No DR (n = 328 eyes)	DR (n = 115 eyes)	*p*-value
LogMAR visual acuity, median (range)	0.14 (0, 2)	0.16 (0, 1.40)	0.117
Visual acuity level, n (%)			0.043
Good reading vision (20/20 to 20/25)	163 (49.70)	44 (38.26)	
Legal driving vision (20/30 to 20/40)	128 (39.02)	48 (41.74)	
Moderate visual loss (20/50 to 20/100)	31 (9.45)	21 (18.26)	
Legal blindness (20/200 or worse)	6 (1.83)	2 (1.74)	
Lens status, n (%)			0.037
Phakia	307 (93.60)	100 (86.96)	
Pseudophakia	20 (6.10)	15 (13.04)	
Aphakia	1 (0.30)	0 (0.00)	
Presence of CSME, n (%)	0 (0.00)	17 (14.78)	<0.001

DR = diabetic retinopathy; CSME = clinically significant macular edema

strata assigned. Nephropathy by serum creatinine level was found to be a risk factor for DR with an OR (95% CI) of 29.22 (3.65 to 233.87). Having high level HbA_{1c} also increased the risk of retinopathy with an OR (95% CI) of 5.23 (1.77 to 15.47). Having diabetes for longer than 10 years or longer than 20 years were also risk factors with ORs (95% CI) of 2.70 (1.28 to 5.70) and 3.60 (1.22 to 10.65), respectively. Male gender increased the risk of retinopathy with an OR (95% CI) of 2.15 (1.16 to 3.98). By contrast, factors that decreased the risk of DR included high LDL cholesterol level, dyslipidemia and OHA(s) with ORs (95% CI) of 0.46 (0.25 to 0.85), 0.46 (0.25 to 0.83) and 0.32 (0.13 to 0.84), respectively (Table 5).

In multivariate analysis, adjusted by age and gender, serum creatinine level and HbA_{1c} both still showed a negative influence on retinopathy status with ORs (95% CI) of 24.07 (2.79 to 207.94) and 5.42 (1.68 to 17.44), respectively (Table 6).

Discussion

The prevalence of DR has been reported from different areas in Thailand. According to the national diabetes registry project, the largest series of DR studies in Thailand, the prevalence of DR was 31.4%, this consisting of 22% NPDR and 9.4% PDR[5]. In the northeast of Thailand, the prevalence of DR has been reported to vary from 17.1% to 25.1%[6,19]. We recruited 222 (39.9%) of the 557 diabetic patients in the present CUP area with the comparable to nationwide results.

The present study analysed the prevalence and associated factors of DR, after 6-month operation of the ophthalmology clinic in Suddhavej Hospital.

Table 5. Univariate analysis of diabetic retinopathy association in the worse eye

Factors	Crude OR	95% CI	*p*-value
Age range (years)			
Less than 61	1		
61 to 64	1.21	0.58 to 2.56	0.610
More than 64	0.58	0.29 to 1.16	0.126
Male gender	2.15	1.16 to 3.98	0.015
Diabetes duration (years)			
Less than 5	1		
5 to 10	1.48	0.68 to 3.25	0.324
10 to 20	2.70	1.28 to 5.70	0.009
More than 20	3.60	1.22 to 10.65	0.020
BMI			
18.5 to 22.9	1		
Less than 18.5	2.91	0.36 to 23.20	0.313
23.0 to 24.9	2.01	0.81 to 5.01	0.132
25.0 to 29.9	1.21	0.53 to 2.78	0.649
More than 29.9	0.57	0.20 to 1.63	0.292
Proteinuria	1.73	0.90 to 3.32	0.101
Current smoking	1.26	0.45 to 3.53	0.656
Pseudophakia or aphakia	2.43	0.94 to 6.31	0.067
Hypertension	0.76	0.42 to 1.39	0.374
Dyslipidemia	0.46	0.25 to 0.83	0.010
History of CVD	1.67	0.27 to 10.25	0.579
SBP 130 mmHg or more	1.25	0.66 to 2.37	0.494
DBP 80 mmHg or more	0.88	0.48 to 1.62	0.687
Lipid profile (md/dL)			
TG 150 or more	1.17	0.64 to 2.14	0.616
TC 200 or more	1.55	0.81 to 2.96	0.189
LDL 100 or more	0.46	0.25 to 0.85	0.014
HDL 40 (M), 50 (F) or less	1.14	0.61 to 2.12	0.690
Serum creatinine more than 2 mg/dL	29.22	3.65 to 233.87	0.001
Treatment			
OHA(s)	0.32	0.13 to 0.84	0.021
Insulin treatment	2.08	0.86 to 5.02	0.105
OHA(s) and insulin	0.61	0.07 to 5.59	0.664
Statin therapy	0.95	0.52 to 1.74	0.861
Aspirin prophylaxis	0.74	0.41 to 1.34	0.317
FPG 130 mg/dL or more	1.85	0.95 to 3.61	0.070
HbA_{1c} 7% or more	5.23	1.77 to 15.47	0.003

BMI = body mass index; CVD = cardiovascular disease; SBP = systolic blood pressure; DBP = diastolic blood pressure; TG = triglyceride; TC = total cholesterol; LDL = low-density lipoprotein cholesterol; HDL = high-density lipoprotein cholesterol; OHA = oral hypoglycemic agent; FPG = fasting plasma glucose; HbA_{1c} = glycated hemoglobin

Therefore, some of DR patients were diagnosed from another hospitals, and some patients with first diagnosis of diabetes were recruited for DR screening program in the authors' center. In consequence, median time to last eye screening may not relate to the presence or absence of DR in the present study.

Several risk factors have been identified for DR in previous studies. Reports from different areas of Thailand and other countries have established a longer

Table 6. Univariate analysis and multiple logistic regression of age and gender adjusted factors associated with diabetic retinopathy in the worse eye

DR associated factors	Univariate analysis			Multivariate analysis		
	OR	95% CI	*p*-value	Adjusted OR	95% CI	*p*-value
Serum Cr >2	29.22	3.65 to 233.87	0.001	24.07	2.79 to 207.94	0.004
HbA_{1c} ≥7	5.23	1.77 to 15.47	0.003	5.42	1.68 to 17.44	0.005

DR = diabetic retinopathy; Cr = creatinine; HbA_{1c} = glycated hemoglobin

duration of diabetes is associated with the development of DR[5,6,9,11-13,20]. HbA_{1c} has also been identified as a risk factor by many studies, albeit with different cutoff points[5,6,10,11,15]. With other variables, for example BMI[11,12,15], lipid profile[6,10,15], microalbuminuria[21], and gender[6,10,11], the consensus has not yet been reached as to whether these are risk factors. Some large studies from other countries suggest these factors may relate the severity of DR[8,14]. In the present study, multivariate analysis showed a high level of serum creatinine and HbA_{1c} were DR risk factors. A longer duration of diabetes and male gender were found to be risk factors for DR by univariate analysis. High LDL cholesterol level, dyslipidemia, and OHA(s) were, by contrast, protective factors against retinopathy in diabetic patients by univariate analysis.

The present study had two important limitations. Firstly, the authors did not recruit all of the diabetic patients in the CUP area or province, and this may have influenced the results. Secondly, laboratory results such as FPG, proteinuria, HbA_{1c} and lipid profile may have been affected by medications the participants were taking. A multicenter study in cooperation with community hospitals and Maha Sarakham Provincial Hospital would permit a more reliable determination of DR prevalence and identification of associated factors for this area.

Conclusion

In conclusion, the prevalence of DR in the present study was 26.0% which is comparable with other reports. Factors associated with DR severity were nephropathy by serum creatinine and high HbA_{1c} level.

What is already known on this topic?

The prevalence of DR had been reported from different area of Thailand with variable results: 1.1% to 11.36% for PDR, and 7.6% to 25.3% for NPDR. In Northeast region of Thailand, there were few studies reported the prevalence of DR, the only 1 study determined the associated factors of DR development. Although many DR associated factors had been well established, some of which had contradictory results, i.e., age, gender, body mass index, blood pressure level, serum lipid profiles, and the use of insulin treatment.

What this study adds?

After the initiation of ophthalmology service in Suddhavej Hospital. The authors recruited the participants in DR screening project. The prevalence in the present was reported according to the overall, laterality and by one worse eye per participant. The well-known, possible and other additional data were recruited for association analysis. The present study emphasized the nephropathy by serum creatinine level and high level of HbA_{1c} as the significant factors. On the contrary, serum low-density lipoprotein cholesterol [LDL] and dyslipidemia were found to be protective factors for DR progression in univariate analysis. These inconsistent results may require further study.

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Potential conflicts of interest

The authors declare no conflict of interest.

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