The Thai DMS Diabetes Complications (DD.Comp.) Project: Prevalence and Risk Factors of Diabetic Retinopathy in Thai Patients with Type 2 Diabetes Mellitus

Amporn Jongsareejit MD*,
Somkiat Potisat MD**, Udom Krairittichai MD***,
Charnvate Sattaputh MD****, Woranut Arunratanachote MS**

** Prasat Neurological Institute, Department of Medical Services, MOPH, Bangkok, Thailand*
*** Institute of Medical Research and Technology Assessment, Department of Medical Services, MOPH, Bangkok, Thailand*
**** Rajavithi Hospital, Department of Medical Services, MOPH, College of Medicine, Rangsit University, Bangkok, Thailand*
***** Lerdsin Hospital, Department of Medical Services, MOPH, Bangkok, Thailand*

Objective: *To determine the prevalence of diabetic retinopathy (DR) among patients with type 2 diabetes mellitus (T2DM) in Thailand and their associated risk factors.*
Material and Method: *A cross-sectional, multi-sites, hospital-based study was carried out between June and December 2006. Diabetic patients from the outpatient department of seven public hospitals (3 tertiary, 2 secondary and 2 community hospital) in Thailand were performed by retinal specialist.*
Results: *One thousand seven of 1,120 diabetic patients received retinal examination using indirect ophthalmoscope. Patients were divided into two groups (absent and present DR). Most patients in both groups were female (72.7 and 68.0%). The prevalence of DR was 24.0% (n = 242), mild NPDR 9.4% (n = 95), moderate NPDR 10.5% (n = 106), severe NPDR 1.3% (n = 13), and proliferative (PDR) 2.8% (n = 28). Age at onset, duration of DM, systolic blood pressure, body mass index (BMI), fasting plasma glucose (FPG), HbA1c, Triglyceride (TG), alcohol consumption, foot ulcer, and proteinuria were recorded. Metformin and insulin taking were statistically, significantly different among these groups. There is more prevalent NPDR and PDR in insulin-taking than non-insulin-taking groups. The grading of diabetic retinopathy is associated with the duration of diabetes. In multivariate regression analysis, associated risk factors of DR patients were the duration of DM, HbA1c levels, and proteinuria.*
Conclusion: *Diabetic retinopathy was present in about one fourth of type 2 diabetic patients in this study. Associated risk factors of DR were the duration of DM, HbA1c levels, and proteinuria. Regular screening for DR especially in T2DM with associated risk factor should be done for early treatment.*

Keywords: *Diabetic retinopathy, Type 2 diabetes mellitus, HbA1c, Diabetic nephropathy*

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The World Health Organization has reported that diabetes mellitus (DM) is a chronic disease and its complications impose economic consequences on individuals, families, health systems, and countries. The prevalence of diabetes in all age-groups worldwide was estimated to be 2.8% in 2000 (171 million people) and projected to be 4.4% in 2030 (366 million people)[1]. The excess global mortality attributable to diabetes in the year 2000 was estimated to be 2.9 million deaths, equivalent to 5.2% of all deaths (1 million deaths in developed countries and 1.9 million deaths in developing countries)[2]. The diabetes epidemic is accelerating in the developing world with an increasing proportion of affected people in younger age groups, which increases the burden of chronic diabetic complications worldwide. Microvascular complications of diabetes mellitus, especially diabetic retinopathy (DR) are the leading cause of blindness, respectively, in many populations both developed and developing countries[3,4]. Type 2 diabetes may be present for several years before diagnosis, by which time many patients have already developed complications[5]. Most diabetic patients will lose chance to early detect microvascular complications (diabetic nephropathy and retinopathy) and treatment

Correspondence to:
Jongsareejit A, Department of Ophthalmology, Prasat Neurological Institute, Bangkok 10400, Thailand.
Phone: 081-376-3219
E-mail: ampornj@gmail.com

even though they are in early stage. Since most such people are asymptomatic at diagnosis, active cases detection would be required to identify them[4,6]. The prevalence and risk factors of DR among patients with types 2 diabetes mellitus (T2DM) in Thailand have been studied[7,8] but all studies were collected in tertiary care hospitals. The purpose of this study was to assess the prevalence of DR in patients with T2DM and to determine their associated risk factors in all levels of care under the Ministry of Public Health Thailand.

Material and Method

The Thai DMS Diabetes Complications (DD.Comp.) the project is at all levels of care hospital-based study in central region of Thailand. This multi-sites study was approved by the Ethics Review Committee for Research in Human Subjects, Ministry of Public Health. All volunteer subjects had given written informed consent. One thousand one hundred twenty type 2 diabetic patients (diagnosed by using the American Diabetic Association criteria)[9] were recruited from seven public hospitals, including the Rajavithi Hospital, Lerdsin Hospital, Nopparatrajathanee Hospital, Mettaphacharak (Watraikhing) Hospital, Pathumthani Hospital, Lardlumkaew Hospital, and Nongsau Hospital between June and December 2006. All the subjects' personal data, complete physical examinations were obtained. Height, weight, and blood pressure were measured using standard procedures. The mean of two separate blood pressure results was taken as the final blood pressure recording. Two fasting blood and three random spot urine samples from all patients were collected over three consecutive months.

Fasting blood sugar, HbA1c and serum creatinine were determined by hexokinase enzymatic, immunoturbidimetric (DCCT/NGSP) assay and the Jaffe method (rate-blanked and compensated) using a COBASUNTEGRA400® analyzer (Roche Diagnostics, Indianapolis, IN, US). The quantity of urinary albumin concentration was determined by immunoturbidimetric assay urine creatinine concentration by the Jaffe method (rate-blanked and compensated) using a COBASUNTEGRA400® analyzer.

The duration of diabetes was that time period between the age at diagnosis and the age at the time of examination. The mean systolic blood pressure (SBP) is the average of the two SBP determinations and the mean diastolic blood pressure (DBP) is the average of the two DBP determinations.

Ocular perfusion pressure (PP) was defined as fellows)[10]:

$$PP = [DBP + 1/3 (SBP - DBP)] - IOP$$

Visual acuity (VA), intraocular pressure (IOP) and fundus examination with indirect ophthalmoscope were completely performed. Mydriatic ophthalmoscopy through dilated pupils was performed and the subjects were diagnosed retinopathy by a board-certified ophthalmologist who had subspecialty training in retina with experience in diabetic retinopathy grading. Diabetic retinopathy was classified into five grades, i.e., no DR, mild non-proliferative diabetic retinopathy (NPDR), moderate NPDR, severe NPDR, proliferative diabetic retinopathy (PDR) and diabetic macular edema (DME), classified by International clinical diabetic retinopathy and diabetic macular edema disease severity scales[11].

The critical statistic for this research was the determination factor shown as mean ± standard deviation. Univariate comparisons of the independent variables of continuous and categorical dependent variables were made using unpaired Student's t-test and Pearson Chi-square test respectively. Multivariate regression was used to assess the associated risk factors of DR with odds ratio and 95% confidence interval (95% CI). The p-value of less than 0.05 was considered as statistically significant. Analysis was made with the software program SPSS for Windows version 17.0 (SPSS Inc., Chicago, Illinois, USA).

Results

One thousand one hundred twenty patients enrolled in the present study. Among these, 1,007 patients who had retinal examination were included for the analysis. There were 721 females and 286 males. The patient characteristics and univariate analysis of factors associated with diabetic retinopathy (DR) patients were shown in Table 1. Patients were divided into two groups (No DR and present DR). Most patients in both groups were female (72.7 and 68.0%). Age at onset, duration of DM, systolic blood pressure, body mass index (BMI), fasting plasma glucose (FPG), HbA1c, triglyceride (TG), alcohol consumption, foot ulcer, and proteinuria were statistically significant ($p<0.05$) among these groups. Both groups of patients were similar in term of gender, age, diastolic blood pressure, waist, total cholesterol, LDL-C levels, HDL-C levels, ocular perfusion pressure, and smoking status. Medications used among diabetic patients were shown in Table 2. Metformin and insulin taking were statistically significant among these groups. There were

44 patients who took insulin and 200 who did not take insulin (Table 3). These were significant differences for duration of diabetes in both groups.

The prevalence and severity of DR was presented in Table 4. The prevalence of DR was 24.0%, mild NPDR 9.6%, moderate NPDR 10.5%, severe NPDR 1.3%, and PDR 2.8%. The distributions of retinopathy level are different in non-insulin-taking and insulin-taking groups. There is more prevalent NPDR and PDR in insulin-taking than non-insulin-taking groups. The distribution of retinopathy levels is different by duration of diabetes was shown in Table 5. When the duration increased the retinopathy level also increased.

In multivariate regression analysis, associated risk factors of DR were the duration of DM, HbA1c levels, and proteinuria (Table 6).

Discussion

The present study provides the DR prevalence and risk factors among patients with T2DM at all

Table 1. Characteristics of type 2 diabetes mellitus associated with retinopathy status (n = 1,007)

	No DR (n = 763)		DR (n = 244)		p-value
	Mean	SD	Mean	SD	
Gender: male/female, n (%)	208 (27.3)/555 (72.7)		78 (31.9)/166 (68.0)		0.156
Age (yr)	59.2	10.2	59.8	9.0	0.361
Age at onset (yr)	52.7	10.0	49.5	9.9	<0.001
Duration of diabetes (yr)	6.81	5.6	10.3	6.8	<0.001
Systolic BP (mmHg)	134.8	15.7	139.0	16.2	<0.001
Diastolic BP (mmHg)	74.1	9.4	73.6	8.8	0.396
BMI (kg/m^2)	27.3	4.7	26.5	4.1	0.014
Waist (cm)	91.3	11.9	91.8	11.0	0.593
FPG (mg/dl)	147.18	48.9	169.5	60.1	<0.001
HbA1c (%)	8.5	1.7	9.2	1.9	<0.001
Total cholesterol	205.5	42.9	211.4	49.3	0.095
HDL	53.2	13.5	51.8	11.6	0.119
LDL	135.2	38.3	139.8	45.5	0.161
TG	166.12	92.2	183.8	112.6	0.027
Ocular perfusion pressure	130.1	16.3	130.2	15.4	0.890
Smoking, n (%)					
No	671 (87.9)		212 (86.9)		0.669
Ever	36 (4.7)		15 (6.1)		
Current	56 (7.4)		17 (7.0)		
Alcohol, n (%)					
No	671 (87.9)		197 (80.7)		0.003
Ever	48 (6.3)		17 (7.0)		
Current	44 (5.8)		30 (12.3)		
Foot ulcer, n (%)					
No	727 (95.3)		222 (91.0)		0.012
Yes	36 (4.7)		22 (9.0)		
Proteinuria, n (%)					
Normal	502 (65.8)		111 (45.5)		<0.001
Micro	194 (25.4)		75 (30.7)		
Macro	57 (7.5)		58 (23.8)		
Unknown	10 (1.3)		-		

DR = diabetic retinopathy; BP = blood pressure; BMI = body mass index; FPG = fasting plasma glucose; HDL = high-density lipoprotein; LDL = low-density lipoprotein; TG = tri-glyceride

levels of care hospital-based, multi-sites study in central region of Thailand. Patients were divided into two groups (absent and present DR). In DR group, age at onset, duration of DM, systolic blood pressure, FPG, HbA1c, triglyceride (TG), proteinuria, and insulin taking were statistically significant as others reported[4,7,8,12,13]. In the present study, there is more prevalent NPDR and PDR in insulin-taking than non-insulin-taking groups because of poorer control the blood/sugar level and long duration of treatment in insulin-taking group[4,7,8,12,13]. Same as other studies, insulin therapy does not protect against the development of DR[4,12]. The grading of diabetic retinopathy is associated with the duration of diabetes as other reports[4,7,8,12]. In this present study, multivariable analysis, the associated risk factors of DR were the duration of DM, HbA1c levels, and proteinuria. The significant risk factors with the Wisconsin epidemiologic study of diabetic retinopathy (WESDR)[4] were also duration of DM, HbA1c levels, and proteinuria. Moreover, the significant risk factors with TDR project[7] were duration of DM, HbA1c levels, proteinuria, and systolic BP. In the present study, the prevalence of DR was 24.0% and consisted of mild NPDR 9.4%, moderate NPDR 10.5%, severe NPDR 1.3%, and PDR 2.8%. The vision-threatening retinopathy (severe NPDR and PDR) was 4.1%. The prevalence rates of DR in present study were similar to that reported by Chandrubeksa Hospital (25.7%)[8], WESDR (21%)[4], and the Rotterdam study (26%)[14]. However, they were different from TDR Project (31.4%)[7] because the present study included patients from all levels of care hospitals, so the result was similar to the community based study[4,14] and community hospital (Chandrubeksa Hospital)[8]. There was no consistent association of blood pressure and DR in patients with T2DM[8,15,16]. This was different from the TDR Project[7]. Because the TDR Project was studied in the university (tertiary) hospitals, the patients' data are complicated with multi-organ diseases. The presence of proteinuria was

Table 2. Medications used among type 2 diabetic patients according to retinopathy status

	No DR (n = 763)	DR (n = 244)	p-value
Insulin, n (%)			
No use	709 (92.9)	200 (82.0)	<0.001
Use	54 (7.1)	44 (18.0)	
Sulfonylurea, n (%)			
No use	146 (19.1)	45 (18.4)	0.810
Use	617 (80.9)	199 (81.6)	
Glinide, n (%)			
No use	754 (98.8)	236 (96.7)	0.027
Use	9 (1.2)	8 (3.3)	
Metformin, n (%)			
No use	218 (28.6)	54 (22.1)	0.049
Use	545 (71.4)	190 (77.9)	
ARB/ACEI, n (%)			
No use	486 (63.7)	141 (57.8)	0.097
Use	277 (36.3)	103 (42.2)	

ARB/ACEI = angiotensin receptor blockers/angiotensin-converting enzyme inhibitor

Table 3. Comparison between insulin and non-insulin taking in presence retinopathy patients

	Non insulin (n = 200)		Insulin taking (n = 44)		p-value
	Mean	SD	Mean	SD	
Gender: male/female, n (%)	68 (34.0)/132 (66.0)		10 (22.7)/34 (77.3)		0.147
Age (yr)	59.9	9.0	59.5	9.0	0.792
Duration of diabetes (yr)	9.7	6.7	12.8	6.9	0.007
Systolic BP (mmHg)	138.99	15.1	139.2	20.7	0.930
Diastolic BP (mmHg)	73.9	8.6	71.8	9.2	0.133
BMI (kg/m^2)	26.3	4.1	27.3	4.2	0.179
FPG (mg/dl)	166.7	54.9	182.0	79.2	0.228
HbA1c (%)	9.08	1.8	9.9	2.7	0.051
Total cholesterol	211.2	49.0	212.3	50.9	0.888
HDL	52.3	11.9	49.6	9.9	0.163
LDL	139.1	44.9	142.8	48.8	0.629
TG	181.3	115.07	194.9	101.1	0.433

significantly associated with severity of DR[7,17-19]. It is that both organs are related to the generalized microvascular effect of DM. In this present study, the patients were classified by grading of DR by practical clinical criteria (International clinical diabetic retinopathy and diabetic macular edema disease severity scales) with retinal specialists. Nevertheless, the present study still was a hospital-based study (not

Table 4. Percent of diabetes patients with specified retinopathy level in worse eye by sex and insulin use

Retinopathy level	Non insulin taking			Insulin taking			All		
	Male (n = 254)	Female (n = 655)	Total (n = 909)	Male (n = 32)	Female (n = 66)	Total (n = 98)	Male (n = 286)	Female (n = 721)	Total (n = 1,007)
No DR	186 (73.2)	523 (79.9)	709 (78.0)	22 (68.8)	32 (48.5)	54 (55.1)	208 (72.7)	555 (77.0)	763 (75.8)
Mild NPDR	27 (10.6)	53 (8.1)	80 (8.8)	4 (12.5)	13 (19.7)	17 (17.4)	31 (10.9)	66 (9.1)	97 (9.6)
Mod. NPDR	28 (11.0)	57 (8.7)	85 (9.4)	6 (18.7)	15 (22.7)	21 (21.4)	34 (11.9)	72 (10.0)	106 (10.5)
Severe NPDR	6 (2.4)	6 (0.9)	12 (1.3)	-	1 (1.5)	1 (1.0)	6 (2.1)	7 (1.0)	13 (1.3)
PDR	7 (2.8)	16 (2.4)	23 (2.5)	-	5 (7.6)	5 (5.1)	7 (2.4)	21 (2.9)	28 (2.8)

NPDR = non-proliferative diabetic retinopathy; PDR = proliferative diabetic retinopathy

Table 5. Percent of diabetes patients with specified retinopathy level in worse eye by sex and insulin use

Retinopathy level	Duration of diabetes (yrs)						p-value
	≤5 (n = 390)		5-15 (n = 509)		>15 (n = 108)		
	n	%	n	%	n	%	
No DR	334	85.6	371	72.9	60	55.6	<0.001
Mild NPDR	23	5.9	58	11.4	14	13.0	
Moderate NPDR	25	6.4	59	11.6	22	20.4	
Severe NPDR	3	0.8	8	1.6	2	1.8	
PDR	5	1.3	13	2.5	10	9.2	

Table 6. Multivariate analysis of adjusted factors associated with DR patients

	Crude OR	Adjusted OR	95% CI of adjusted OR	p-value
Gender: male/female, n (%)				
Female	1	1		
Male	1.15	1.08	0.74-1.59	0.673
Duration of diabetes (yr)				
≤5	1	1		
5.1-10.0	1.94	1.78	1.20-2.64	0.004
10.1-15.0	2.91	2.73	1.75-4.30	<0.001
>15	4.26	4.07	2.49-6.64	<0.001
BMI (kg/m^2)	0.96	0.97	0.93-1.00	0.055
HbA1c (%)	1.22	1.16	1.07-1.26	<0.001
Proteinuria				
No	1	1		
Microalbuminuria	1.82	1.73	1.21-2.47	0.003
Macroalbuminuria	4.56	4.05	2.55-6.44	<0.001
Insulin	3.27	1.54	0.95-2.50	0.077

Adjusted for sex, age, and duration of diabetes
OR = odds ratio; CI = confidence interval
* Significant at p<0.05

community-based); therefore, using this study for national policy would nee to be adjusted.

Conclusion

About 24.0% of T2DM patients have DR that related to age at onset, duration of DM, systolic blood pressure, body mass index (BMI), Fasting Plasma Glucose (FPG), HbA1c, Tri-glyceride (TG), Alcohol consumption, foot ulcer, proteinuria, and insulin taking. The grading of diabetic retinopathy is associated with the duration of diabetes. By multivariate regression analysis, the duration of DM, HbA1c level, and proteinuria were risk factors in this cross-sectional study but longitudinal studies are necessary to quantitate the strength of these risk factors. Therefore, regular screening for DR especially in T2DM with associated risk factors should be done for early treatment in patients with the vision-threatening retinopathy (severe NPDR and PDR).

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Potential conflicts of interest

None.

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โครงการศึกษาผู้ป่วยที่มีผลแทรกซ้อนจากเบาหวานในคนไทย: ความชุกและปัจจัยเสี่ยงของโรคจอตาผิดปกติจากเบาหวานในผู้ป่วยเบาหวานชนิดที่ 2

อัมพร จงเสรีจิตต์, สมเกียรติ โพธิสัตย์, อุดม ไกรฤทธิชัย, ชาญเวช ศรัทราพุทธ, วรนุช อรุณณัตนโชติ

วัตถุประสค์: *เพื่อหาความชุกและปัจจัยเสี่ยงของโรคจอตาผิดปกติจากเบาหวาน ในผู้ป่วยเบาหวานชนิดที่สอง ประเทศไทย*
วัสดุและวิธีการ: *ศึกษาเชิงวิเคราะห์ ณ จุดเวลาใดเวลาหนึ่ง (cross-sectional analytic study) ในผู้ป่วยเบาหวานชนิดที่สอง จากคลินิกผู้ป่วยนอกของโรงพยาบาลรัฐ 7 แห่ง (โรงพยาบาลตติยภูมิ 3 แห่ง, โรงพยาบาลทุติยภูมิ 2 แห่ง และโรงพยาบาลชุมชน 2 แห่ง) โดยจักษุแพทย์ด้านจอประสาทตา ระหว่างเดือนมิถุนายน ถึง เดือนธันวาคม พ.ศ. 2541*
ผลการศึกษา: *จากผู้ป่วยที่เข้าโครงการทั้งหมด 1,120 ราย ได้คัดเลือกมาในการศึกษาครั้งนี้จำนวน 1,007 ราย ผู้ป่วยทั้งหมดได้รับการตรวจจอตาด้วยเครื่อง indirect ophthalmoscope โดยจักษุแพทย์เฉพาะทางด้านจอตา ผู้ป่วยแบ่งออกเป็น 2 กลุ่ม กลุ่มที่ไม่พบโรคจอตาผิดปกติจากเบาหวานและกลุ่มที่พบโรคจอตาผิดปกติจากเบาหวาน ความชุกของโรคเบาหวานขึ้นจอตา ร้อยละ 24.0 แบ่งเป็น mild NPDR ร้อยละ 9.4, moderate NPDR ร้อยละ 10.5, severe NPDR ร้อยละ 1.3, และ PDR ร้อยละ 2.8 พบว่า อายุที่เริ่มเป็นโรคเบาหวาน, ระยะเวลาที่เป็นโรคเบาหวาน, systolic blood pressure, body mass index (BMI), FPG, HbA1c, triglyceride (TG), การดื่มสุรา, ตรวจพบแผลที่เท้า, proteinuria และผู้ป่วยที่ได้รับยา metformin และ insulin มีความแตกต่างอย่างมีนัยสำคัญทางสถิติเมื่อเปรียบเทียบกับกลุ่มที่ไม่มีโรคเบาหวานขึ้นจอตา พบโรคจอตาผิดปกติจากเบาหวานในกลุ่มผู้ป่วยที่ได้รับ insulin มากกว่าผู้ป่วยที่ไม่ได้รับ insulin และเมื่อระยะเวลาที่เป็นโรคเบาหวานนานขึ้น ความรุนแรงของโรคจอตาผิดปกติจากเบาหวานจะมากขึ้นด้วย เมื่อคำนวณด้วย multivariate regression analysis ปัจจัยเสี่ยงของโรคจอตาผิดปกติจากเบาหวาน คือ ระยะเวลาที่เป็นโรคเบาหวาน, HbA1c levels, และ proteinuria*
สรุป: *ในการศึกษานี้ พบความชุกของโรคจอตาผิดปกติจากเบาหวานประมาณหนึ่งในสี่ของผู้ป่วยที่เป็นเบาหวาน ปัจจัยเสี่ยงของโรคจอตาผิดปกติจากเบาหวาน คือ ระยะเวลาที่เป็นโรคเบาหวาน, HbA1c levels, และ proteinuria การตรวจจอตาอย่างสม่ำเสมอ โดยเฉพาะในกลุ่มที่มีปัจจัยเสี่ยงเป็นสิ่งที่ควรกระทำ เพื่อสามารถให้การรักษาโรคจอตาผิดปกติจากเบาหวานโดยฉพาะในกลุ่ม severe NPDR and PDR ตั้งแต่ระยะเริ่มต้นได้*