Original Article

Prevalence of Chronic Microvascular Complications and Diabetic Foot Problems in Patients with Diabetes Mellitus at Siriraj Hospital

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Background: The chronic disease diabetes mellitus [DM] and its associated complications substantially increase morbidity and mortality, resulting in major burdens on healthcare systems. Early detection and prevention of DM-related complications have proven to be cost-saving and cost-effective.

Objective: 1) To determine the prevalence of each microvascular complication in patients with DM at Siriraj Hospital and 2) To determine the factors associated with each microvascular complication.

Materials and Methods: In this cross-sectional observational study, the authors recruited patients with type 1 and type 2 DM who attended the diabetes clinic at Siriraj Hospital between January 1, 2012 and December 31, 2013 by searching the hospital database. Subjects who had been treated at the clinic for less than 12 months were excluded. Data was collected from the medical records for the 12 months preceding each patient's last visit.

Results: The study included 430 patients. The majority were female; tended to be aged 60 years or older; had a long duration of type 2 DM (more than 10 years); were either pre-obese (BMI 23.0 kg/m^2 or more but less than 24.9 kg/m^2) or obese (BMI of 25.0 kg/m^2 or more); and had the co-morbidities of hypertension [HT] and dyslipidemia. The mean fasting plasma glucose [FPG] and HbA1C were 147 mg/dl and 7.93%, respectively. The prevalence of diabetic nephropathy [DN], diabetic retinopathy [DR], and diabetic foot were 38.8% (95% CI 33.7 to 44), 40.4% (95% CI 35.7 to 45.3), and 39.1% (95% CI 34.4 to 43.9), respectively. The factors associated with DN were insulin use, HbA1C greater than 7%, HT, DR, and diabetic foot. Those associated with DR were insulin use, HbA1C greater than 7%, HT, an old cerebrovascular accident [CVA], DM duration longer than five years, DN and diabetic foot. The factors associated with diabetic foot were insulin use, HbA1C greater than 7%, duration of DM of longer than five years, smoking, type of DM (type 2 DM), coronary artery disease [CAD], DN and DR.

Conclusion: The prevalence of DN, DR, and diabetic foot were 38.8%, 40.4%, and 39.1%, respectively. Diabetic microvascular complications are common and are associated with poor glycemic control (HbA1C greater than 7%), insulin use, a long duration of diabetes, HT, and the presence of other microvascular complications.

Keywords: Microvascular complications, Diabetes mellitus

J Med Assoc Thai 2018; 101 (10): 1349-55
Website: http://www.jmatonline.com

Diabetes mellitus [DM] is a chronic disease that imposes major burdens on healthcare systems. The number of people with DM is increasing in most countries, including Thailand. The prevalence of patients with DM in Thailand is projected to increase from 6.42% in 2013 to 9.0% in 2035[(1)]. This will inevitably lead to an increase in the prevalence of DM-related complications, which cause substantial morbidity and mortality, and result in higher health-care expenditure, especially by individuals with poor glycemic control. A combination of early DM detection, the following of standard treatment recommendations, and the prevention of the associated complications have proven to be cost-saving and highly cost-effective[(2)].

Chronic diabetic complications are classified as either macrovascular or microvascular complications. The microvascular complications are composed of diabetic nephropathy [DN], diabetic retinopathy [DR], and diabetic foot. In a previous study, the prevalence of DN, DR, and diabetic foot among patients with DM at Siriraj Hospital were 37%, 31%, and 40%, respectively[(3)]. However, in that study, less than one-third of the subjects were screened for microvascular

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How to cite this article: Laotaveerungrueng N, Wanthong S, Wannachalee T, Lertwattanarak R. Prevalence of chronic microvascular complications and diabetic foot problems in patients with diabetes mellitus at Siriraj Hospital. J Med Assoc Thai 2018;101:1349-55.

complications; therefore, the true prevalence of complications may not have been ascertained.

The objectives of the present study were to determine 1) the prevalence of each microvascular complication in patients with DM at the diabetes clinic of Siriraj Hospital during the years 2012 to 2013, and 2) the factors associated with each microvascular complication.

Materials and Methods

Patients

The authors recruited subjects with type 1 and type 2 DM who were treated at the diabetes clinic, Siriraj Hospital, between January 1, 2012 and December 31, 2013 by searching the hospital database using ICD-10 codes E10x and E11x. Patients who attended the clinic for less than 12 months were excluded because a duration of one year was necessary for the screening of all of the diabetic microvascular complications, DN, DR, and diabetic foot. The present study was approved by the Institutional Review Board of the Faculty of Medicine, Siriraj Hospital, Mahidol University.

Assessment

All clinical data were captured from the medical records for the 12 months preceding each patient's last visit. The baseline characteristics of all subjects were recorded. They comprised age, sex, height in centimeters, weight in kilograms, history of smoking and alcohol consumption, current DM treatment, family history of DM, type and duration of DM, underlying diseases such as hypertension [HT], dyslipidemia, coronary artery disease [CAD], and old cerebrovascular accident [CVA].

The most recent fasting plasma glucose [FPG] and HbA1C level of the patients were assessed and divided into three groups, well-controlled (HbA1C less than 7%), fairly-controlled (HbA1C 7% to 8.9%), and poorly-controlled (HbA1C 9% or more). The HbA1C tests were performed at our hospital using methods certified by the National Glycohemoglobin Standardization Program and standardized to the Diabetes Control and Complications Trial reference assay.

All diabetic microvascular complications were assessed according to the American Diabetes Association [ADA] Standards of Medical Care in Diabetes 2014[4]. DR was assessed by a comprehensive eye examination performed by an ophthalmologist, and was divided into five groups, normal, mild non-proliferative DR [NPDR], moderate NPDR, severe NPDR, and proliferative DR [PDR]. DN was screened by measuring the albumin-to-creatinine ratio of a random spot urine sample and divided into three groups, normal (less than 30 mg/g Cr), microalbuminuria (30 to 299 mg/g Cr) and macroalbuminuria (300 mg/g Cr or more).

Diabetic foot was screened by medical history and clinical examination by an endocrinologist or a fellow of the Division of Endocrinology and Metabolism, Department of Internal Medicine. Subjects were identified as having diabetic foot if any one of the following were present such as prior foot or toe amputations, foot deformities, characteristic skin changes, dorsalis pedis or posterior tibial artery pulse deficits, or an abnormal 10-gm monofilament test.

Statistical analysis

The present study was a cross-sectional observational study. Descriptive data were expressed as mean ± SD for continuous variables, and as frequency and percentage for categorical variables. The primary outcomes were analyzed as frequency and percentage. As for the secondary outcomes, univariate comparisons were analyzed using Chi-squared testing for qualitative data, and the independent t-test for quantitative data. Multivariate regression was used to assess the associated risk factors of each microvascular complication, with odds ratio [OR] testing and a 95% confidence interval [CI]. A p-value less than 0.05 was considered statistically significant for each analysis. The sample size was calculated from the prevalence of diabetic complications in Sriwijitkamol et al study[3] by using the proportion of one group formula; a minimum of 374 patients were required to provide a power of at least 85%.

Results

The study included 430 patients. Almost two-thirds were female (62.3%), and the mean age of the study cohort was 62.0±13.0 years. The mean duration of DM was 14.5±9.5 years, with most patients having type 2 DM (96%). The patients' clinical and biochemical characteristics are summarized in Table 1.

The mean FPG and HbA1C were 147±50 mg/dl and 7.93±1.5%, respectively; only 27.7% of the subjects had an HbA1C lower than 7%, as shown in Figure 1. About half of the patients received two anti-diabetic agents. The number of anti-diabetic agents used by each patient are shown in Figure 2, and the most commonly used regimens are listed in Table 2.

The number of patients screened for DN, DR, and

diabetic foot were 356 (82.80%), 423 (98.40%), and 425 (98.80%), respectively. The prevalence of DN, DR, and diabetic foot were 38.8%, 40.4%, and 39.1%, respectively, as shown at Table 3. Among the patients with diabetic foot, the prevalence of the patients with prior foot or toe amputations, foot deformities, dorsalis pedis or posterior tibial artery pulse deficits, or an abnormal 10-gm monofilament test were 4.47%, 16.24%, 12.94%, and 17.65%, respectively.

Three hundred and forty-seven patients (80.1%) were screened for all three complications. The prevalence of DN, DR, and diabetic foot were 38.9%, 40.1%, and 35.7%, respectively, which were consistent with our primary outcome. One hundred eleven patients (31.99%) had one complication, which was DN (9.22%), DR (11.53%), and diabetic foot (11.24%). One hundred nine patients (31.4%) had two complications, which were DN and DR (11.8%), DN and diabetic foot (7.8%), and DR and diabetic foot

Table 1. Patients' clinical and biochemical characteristics (n = 430)

Clinical and biochemical characteristics	n (%) or mean ± SD
Sex: female	268 (62.3)
Age (years)	62.0±13.0
Duration of DM (years)	14.5±9.5
Type 2 DM	413 (96.0)
Family history of DM	284 (66.0)
History of smoking	90 (20.9)
Underlying diseases	
Hypertension	349 (81.2)
Dyslipidemia	352 (81.9)
Coronary heart disease	40 (9.3)
Old cerebrovascular accident	12 (2.8)
Body mass index (kg/m^2)*	26.0±4.7
Waist circumference (cm)**	91.7±12.5
Hip circumference (cm)**	101.1±16.7
Waist:hip ratio**	0.93±0.1
FPG (mg/dl)	147±50.0
HbA1C (%)	7.93±1.5
Insulin use	199 (46.3)

DM = diabetes mellitus; FPG = fasting plasma glucose; HbA1C = hemoglobin A1C

* 96% of patients were screened for body mass index [BMI], ** 92% of patients were screened for waist:hip ratio

Table 2. Antidiabetic regimens used by the patients

No. of drug(s)	Most common regimens	n (%)
1	Insulin	61 (57.6)
	Metformin	30 (28.3)
	Sulfonylurea	13 (12.3)
	Other	2 (1.8)
2	Metformin + SU	90 (50.9)
	Metformin + Insulin	38 (21.5)
	Metformin + DPP-4i	10 (5.6)
	Other	39 (22.0)
3	Metformin + SU + Insulin	43 (40.2)
	Metformin + SU + TZD	32 (29.9)
	Metformin + SU + DPP-4i	7 (6.5)
	Other	25 (23.4)
4	Metformin + SU + Alpha + Insulin	7 (22.6)
	Metformin + SU + Alpha + TZD	5 (16.1)
	Other	19 (61.3)
5	Metformin + SU + TZD + DPP-4i + Insulin	2 (33.3)
	Metformin + SU + TZD + Alpha + DPP-4i	2 (33.3)
	Other	2 (33.3)

SU = sulfonylurea; DPP-4i = dipeptidyl peptidase-4 inhibitors; TZD = thiazolidinedione; Alpha = alpha-glucosidase inhibitor

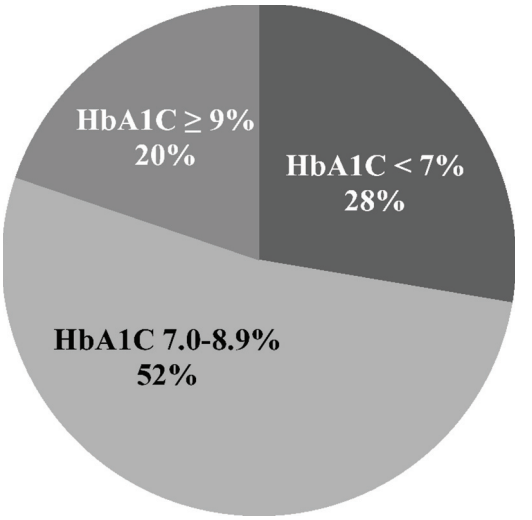

Figure 1. Glycemic status of the patients classified by HbA1C levels.

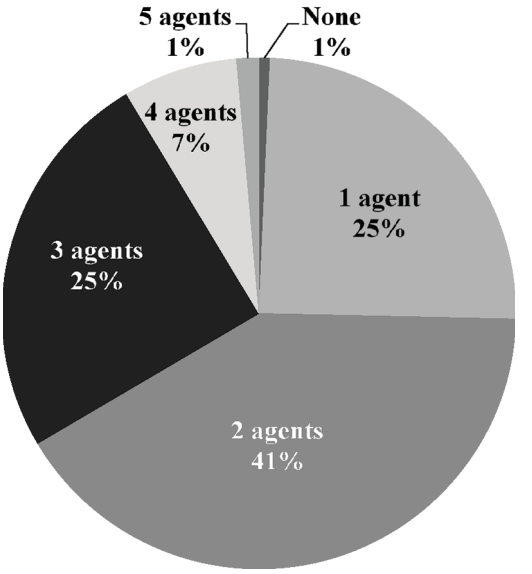

Figure 2. Number of antidiabetic agents used by the patients.

Table 3. Prevalence of chronic microvascular complications and diabetic foot problems

Chronic microvascular complications (n = 430)	n (%) [95% CI]
Diabetic nephropathy (n = 356)	
No diabetic nephropathy	218 (61.2) [56.0 to 66.3]
Diabetic nephropathy	138 (38.8) [33.7 to 44.0]
• Microalbuminuria	92 (25.8) [21.4 to 30.7]
• Macroalbuminuria	46 (12.9) [9.6 to 16.9]
Diabetic retinopathy (n = 423)	
No diabetic retinopathy	252 (59.6) [54.7 to 64.3]
Diabetic retinopathy	171 (40.4) [35.7 to 45.3]
• NPDR	
- Mild NPDR	67 (15.8) [12.5 to 19.7]
- Moderate NPDR	70 (16.5) [13.1 to 20.4]
- Severe NPDR	6 (1.4) [0.5 to 3.1]
• PDR	28 (6.6) [4.4 to 9.4]
Diabetic foot (n = 425)	
No diabetic foot	259 (60.9) [56.1 to 65.6]
Diabetic foot	166 (39.1) [34.4 to 43.9]

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

(11.8%). Thirty-five patients (10.1%) had all three complications.

A univariate analysis revealed that the factors associated with DN were HT, insulin use, HbA1C greater than 7%, DR, and diabetic foot. The factors associated with DR were duration of diabetes, HT, old CVA, insulin use, HbA1C greater than 7%, DN, and diabetic foot. The factors associated with diabetic foot were smoking, duration of diabetes, type 2 DM, CAD, insulin use, HbA1C greater than 7%, DN, and DR (Table 4).

The results of a multivariate regression analysis indicated that the factors associated with DN were HT (OR 3.18), insulin use (OR 2.23), DR (OR 2.21), and diabetic foot (OR 1.79). Those associated with DR were duration of diabetes (OR 3.18), insulin use (OR 3.26), and DN (OR 2.46). The factors associated with diabetic foot were smoking (OR 1.88), CAD (OR 2.65), glycemic control (OR 1.88), and DN (OR 1.87), as presented at Table 5.

Discussion

The prevalence of DN in our study (40.4%) was similar to the rates that were found by two other studies in Thailand (37.2% and 42.9%)[5,6]. In addition, the present study found that the prevalence of microvascular complications among patients with type 1 and type 2 DM was almost the same as in a previous study at Siriraj Hospital[3], despite the advances in diabetic management with the advent of new antidiabetic agents. The reasons why the prevalence was not lower could be that 1) two-thirds of our subjects had an HbA1C greater than 7%, 2) our patients had a longer duration of DM than those in the previous study, and 3) a much greater proportion

Table 4. Univariate analysis of factors associated with each chronic microvascular complication

Factors	No DN (n = 218) n (%)	DN (n = 138) n (%)	*p*-value	No DR (n = 252) n (%)	DR (n = 171) n (%)	*p*-value	No diabetic foot (n = 259) n (%)	Diabetic foot (n = 166) n (%)	*p*-value
Gender (male)	87 (39.9)	50 (36.2)	0.487	100 (39.7)	59 (34.5)	0.280	99 (38.2)	63 (38.0)	0.955
History of smoking	43 (19.7)	33 (23.9)	0.347	51 (20.2)	36 (21.1)	0.258	44 (17.0)	46 (27.7)	0.009*
Duration of DM >5 years	173 (79.4)	117 (84.8)	0.199	189 (75.0)	158 (92.4)	0.000*	204 (78.8)	147 (88.6)	0.010*
Type 2 DM	208 (95.4)	134 (97.1)	0.425	240 (95.2)	166 (97.1)	0.345	245 (94.6)	164 (98.8)	0.043*
Family history of diabetes	152 (69.7)	91 (65.9)	0.455	166 (65.9)	115 (67.3)	0.768	177 (68.3)	103 (62.0)	0.182
Underlying diseases									
Hypertension	165 (75.7)	125 (90.6)	0.001*	195 (77.4)	148 (86.5)	0.019*	209 (80.7)	138 (83.1)	0.527
Dyslipidemia	174 (79.8)	116 (84.1)	0.316	199 (79.0)	147 (86.0)	0.067	212 (81.9)	138 (83.1)	0.736
Coronary heart disease	16 (7.3)	12 (8.7)	0.643	27 (10.7)	13 (7.6)	0.283	17 (6.6)	23 (13.9)	0.014*
Old CVA	4 (1.8)	5 (3.6)	0.317	3 (1.2)	8 (4.7)	0.040*	8 (3.1)	4 (2.4)	0.772
BMI ≥25 kg/m^2	106 (50.5)	75 (57.3)	0.223	122 (50.0)	93 (57.1)	0.162	123 (49.2)	91 (57.6)	0.098
HbA1C >7%	133 (61.0)	103 (74.6)	0.008*	156 (62.0)	132 (77.2)	0.001*	164 (63.3)	125 (75.3)	0.010*
Insulin use	79 (36.2)	81 (58.7)	0.000*	83 (32.9)	113 (66.1)	0.000*	102 (39.4)	93 (56.0)	0.001*
Diabetic nephropathy	-	-	-	59 (27.8)	76 (54.3)	0.000*	74 (33.0)	64 (50.4)	0.001*
Diabetic retinopathy	64 (29.4)	76 (55.1)	0.000*	-	-	-	92 (35.9)	78 (48.1)	0.014*
Diabetic foot	63 (28.9)	64 (46.4)	0.001*	84 (33.9)	78 (45.6)	0.014*	-	-	-

DN = diabetic nephropathy; DR = diabetic retinopathy; DM = diabetes mellitus; CVA = cerebrovascular accident; BMI = body mass index; HbA1C = hemoglobin A1C

* *p*-value <0.05 indicates statistical significance

Table 5. Multivariate regression analysis of factors associated with each chronic microvascular complication

Parameters	No DN (n = 218) n (%)	DN (n = 138) n (%)	Univariate analysis		Multivariate analysis	
			Odds ratio (95% CI)	*p*-value	Odds ratio (95% CI)	*p*-value
Hypertension	165 (75.7)	125 (90.6)	3.09 (1.61 to 5.91)	0.001	3.18 (1.59 to 6.33)	0.001
HbA1C >7%	133 (61.0)	103 (74.6)	1.88 (1.18 to 3.01)	0.008		
Insulin use	79 (36.2)	81 (58.7)	2.50 (1.62 to 3.87)	<0.001	2.23 (1.36 to 3.67)	0.001
Diabetic retinopathy	64 (29.4)	76 (55.1)	3.08 (1.97 to 4.82)	<0.001	2.21 (1.35 to 3.60)	0.002
Diabetic foot	63 (28.9)	64 (46.4)	2.06 (1.32 to 3.22)	0.001	1.79 (1.11 to 2.90)	0.018
	(n = 252)	(n = 171)				
Duration of DM >5 years	189 (75.0)	158 (92.4)	4.05 (2.15 to 7.63)	<0.001	3.18 (1.53 to 6.61)	0.002
Hypertension	195 (77.4)	148 (86.5)	1.88 (1.10 to 3.19)	0.019		
Old CVA	3 (1.2)	8 (4.7)	4.07 (1.07 to 15.58)	0.040		
HbA1C >7%	156 (62.0)	132 (77.2)	2.08 (1.34 to 3.23)	0.001		
Insulin use	83 (32.9)	113 (66.1)	3.97 (2.63 to 5.99)	<0.001	3.26 (2.02 to 5.25)	0.000
Diabetic nephropathy	59 (27.8)	76 (54.3)	3.08 (1.97 to 4.82)	<0.001	2.46 (1.52 to 3.98)	0.000
Diabetic foot	84 (33.9)	78 (45.6)	1.66 (1.10 to 2.47)	0.014		
	(n = 259)	(n = 166)				
Smoking	44 (17.0)	46 (27.7)	1.87 (1.17 to 3.00)	0.009	1.88 (1.08 to 3.25)	0.025
Duration of DM >5 years	204 (78.8)	147 (88.6)	2.09 (1.19 to 3.66)	0.010		
Type 2 DM	245 (94.6)	164 (98.8)	4.69 (1.05 to 20.89)	0.043		
Coronary heart disease	17 (6.6)	23 (13.9)	2.29 (1.18 to 4.43)	0.014	2.65 (1.18 to 5.94)	0.018
HbA1C >7%	164 (63.3)	125 (75.3)	1.77 (1.14 to 2.73)	0.010	1.88 (1.18 to 3.14)	0.017
Insulin use	102 (39.4)	93 (56.0)	1.96 (1.32 to 2.91)	0.001		
Diabetic nephropathy	74 (33.0)	64 (50.4)	2.06 (1.32 to 3.22)	0.001	1.87 (1.17 to 2.98)	0.008
Diabetic retinopathy	92 (35.9)	78 (48.1)	1.66 (1.11 to 2.47)	0.014		

DN = diabetic nephropathy; DM = diabetes mellitus; CVA = cerebrovascular accident; HbA1C = hemoglobin A1C

of the present study's subjects were screened for microvascular complications.

Moreover, the prevalence of DR in our study was similar to the mean reported in a further study conducted at the diabetes clinics of 11 tertiary centers in Thailand (31.4%)[7]. However, the prevalence in the current study was higher than that found by a study undertaken at seven Thai public hospitals (40.4% versus 24%, respectively)[8]. This could be because our study was performed at a tertiary center, and our diabetic patients had a longer mean duration of DM and more comorbidities than patients in the study at seven public hospitals[8].

Furthermore, the prevalence of diabetic foot in the present study (39.1%) was markedly higher than the incidences for the related conditions of diabetes, neuropathy (15%) and peripheral vascular disease (2%), found by another Thai study[9]. Unfortunately, the incidence of diabetic foot was not specifically reported by that study. The high level of diabetic foot found in the current study would be because the authors performed comprehensive foot examinations using additional parameters in accordance with ADA recommendations, namely, the history of foot ulcers and amputations, and the characteristics of skin changes.

In addition, the present study showed that at the diabetes clinic of Siriraj Hospital, which is serviced by endocrinologists and fellows, a much greater proportion of patients (80% to 98%) were screened for diabetic complications than reported for other clinics (17% to 57%) in a previous study[3]. Other physicians and general practitioners should be encouraged to follow the ADA recommendations or the Thai diabetes clinical practice guidelines for the screening of diabetic complications. These measures are very cost-effective and can reduce morbidity[4,10].

The factors associated with DN were HT and the presence of other microvascular complications. This was consistent with prior studies[5,6]. The authors also found that DN was associated with insulin treatment. This could be explained by the fact that most guidelines recommend against using metformin in subjects with moderate to severe renal insufficiency; insulin could be an alternative in these populations[4,10,11]. In contrast to one study[5], our study did not reveal an association

of DN with either HbA1C greater than 7% or the duration of DM. Since the diagnosis of DN in the current study was based on a single urine measurement, without concern for angiotensin-converting enzyme inhibitors [ACEI] or angiotensin II receptor blocker [ARBs] usage, the prevalence of DN might have been underestimated.

Similar to other studies, the factors associated with DR were duration of DM longer than five years and DN[7,8]. The current study found that patients with DR, of whom more than half also had DN, had greater use of insulin compared with subjects who did not have DR.

Regarding diabetic foot, our results were consistent with another study where the factors associated with diabetic foot were HbA1C greater than 7%, and DN[9]. Peripheral artery disease [PAD] has been shown to be an independent risk factor for diabetic foot ulcers and amputations[12]. Consistent with that, the present study found that the PAD risk factors[13], smoking, and CAD, were associated with diabetic foot, but not associated with either DN or DR.

The authors found that diabetic patients using insulin had a greater prevalence of microvascular complications. Thus, in hospitals with limited resources, this group of patients should be aggressively screened for chronic diabetic complications.

Conclusion

The prevalence of DN, DR, and diabetic foot were 38.8%, 40.4%, and 39.1%, respectively. Factors associated with those complications were poor glycemic control, a long duration of diabetes, the use of insulin, HT, and the presence of other microvascular complications. Early screening would be a cost-effective strategy to prevent morbidity in those patients. In addition, patients with one microvascular complication may also have other DM-associated complications.

What is already known on this topic?

The microvascular complications among diabetic patients at Siriraj Hospital were common despite the low rate of screened patients. Since 2012, the clinicians were encouraged to follow guidelines to screen microvascular complications in all diabetic patients.

What this study adds?

With increased rate of screening in diabetic patients, the prevalence of microvascular complications shows similar prevalence to previous study. Furthermore, this study shows the risk factors associated each microvascular complication.

Acknowledgement

The authors thank Miss Khemajira Karaketklang for her assistance with the statistical analyses.

Potential conflicts of interest

The authors declare no conflict of interest.

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