Glycemic Control and Microvascular Complications among Type 2 Diabetes at Primary Care Units

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Objective: *To determine the status of disease control and to compare the prevalence of microvascular complications among type-2 diabetes in a primary care setting.*
Material and Method: *The authors performed a cross-sectional study of 287 diabetic patients from 13 primary care units in urban areas of Thailand. The status of diabetic control was dominantly defined by HbA_{1C} (A1C), blood pressure (BP). Screening programs for microvascular complications included retinopathy and nephropathy. Retinopathy used a seven-field stereoscopic retinal photography while nephropathy was defined by a random urine albumin-to-creatinine ratio.*
Results: *The A1C of 41.3% of the patients was lower than 7% however, 80% of them used only low doses of anti-diabetic drugs. The prevalence of microalbuminuria was 28.7% and macroalbuminuria was 5.7%, whereas diabetic retinopathy was 15.1%. In multivariate analyses, nephropathy was significantly related to duration of diabetes $\geq$ 4 years (odds ratio 1.5, 95% CI 1.2-1.8, $p < 0.001$) and A1C $\geq$ 8% (odds ratio 2.2, 95% CI 1.3-3.8, $p < 0.05$), while retinopathy was related to duration of diabetes $\geq$ 4 years (odds ratio 9.5, 95% CI 1.17-77.8, $p < 0.05$).*
Conclusion: *The present study shows that primary care units provides patients with well-controlled diabetes. Nonetheless, those type 2 diabetes patients have significantly higher rates of microvascular complications, despite shorter diabetes duration and lower A1C. Type 2 diabetic patients in primary care unit should be screened for complications and efforts should be done to reach optimal glycemic level, especially for individuals with diabetes $\geq$ 4 years.*

Keywords: *Blood glucose, Diabetes complications, Diabetes mellitus, type 2, Mass screening, Primary health care*

J Med Assoc Thai 2009; 92 (8): 1094-101
Full text. e-Journal: *http://www.mat.or.th/journal*

The Thailand Health Care Reform policy of 2001 changed the diabetes care system in hospitals in public sectors[1]. The principal mission of this policy is to decrease overcrowding in large-scale hospital. This is done by getting patients to visit their doctor at a neighboring primary care unit (PCU) instead of the general hospital. This policy expects patients to get much more time to be followed by their family physician. In general, diabetes care focuses on controlling blood glucose and screening diabetes-related vascular diseases-such as nephropathy, neuropathy, cardiovascular disease, and peripheral arterial disease[2,3]. The American Diabetes Association (ADA) recommends screening for those complications in all type 2 diabetic patients[2]. However, microvascular diseases are undiagnosed in up to 50% of diabetic patients. This may be because they are usually asymptomatic in their early phase. Besides, it is the fact that most hospitals have limitation in complication-screening medical equipment, which

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requires a huge and long-term investment from the government.

A degree of hyperglycemia is sufficient to develop pathological changes in various organs such as kidney and vessel damages[4-7]. Numerous studies clearly demonstrate that those microvascular complications can be prevented or delayed[2,3,8,9]. The UK Prospective Diabetes Study (UKPDS) confirmed a 25% reduction in the risk of microvascular disease in patients who have been treated[10]. Many studies show that those complications can be found even after a patient is firstly diagnosed, which consequently bring adverse morbidity and mortality[11,12]. Thailand Diabetes Registry Project demonstrates microvascular complications occur at the rate of 24.2 to 50.3% in diabetic retinopathy (DR) and 45.7 to 62.9% in diabetic neuropathy (DN)[3,14].

Nearly a decade after The Thailand Health Care Reform policy has been implemented, the authors can assume that a diabetes care strategy for PCUs in Samutsakhon province or elsewhere mainly focuses on glycemic control. Therefore, screening and intervention programs should proceed to rate and plan for further management in those preventable complications[15,16]. Nowadays, various studies demonstrate a prevalence of complications in patients who attend at secondary, tertiary, or super-tertiary hospital. On the other hand, there is only one study in a primary care setting in Thailand indicating DN and metabolic risk factors. The authors did not study other complications such as Diabetic retinopathy[17]. Therefore, the objectives of this project is to determine the status of disease control and the rate of micro-vascular complications including DN and DR among type 2 diabetes patients attending Diabetes/Hyper-tension Clinic at Primary Care Units, Samutsakhon province, Thailand.

Material and Method

Subjects

The authors performed a cross-sectional clinic-based study of 287 type 2 diabetic patients between March and October 2007. All diabetic patients who were diagnosed as A1C $\geq$ 7%, used anti-diabetic drugs, or were previously diagnosed with diabetes were recruited from those who attended one of the 13 diabetic-hypertensive clinics at PCUs in urban areas of Thailand. At those clinics, patients were primarily taken care of by family physicians, nurse practitioners, or well-trained nurses. All of the subjects took only oral anti-diabetic medications. All clinics operated under a single standard that included guidelines of diabetic treatments (according to ADA's recommendation), kinds of anti-diabetic drugs, items of investigation, and systems for referral. In each of the 13 clinics, subjects were randomly selected from the diabetic patients who had visited at least two times in the past six months.

Methods

Subjects gave their informed consent to participate and the protocols were approved by Samutsakhon General Hospital Review Board. Subjects were asked to complete a questionnaire to document the presence of ischemic heart disease, hypertension, dyslipidemia, smoking, drinking habits, and family history of type 2 diabetes. Blood pressure, height, weight, and waist circumference from the last visit were measured according to the guidelines of the World Health Organization (WHO)[18]. Five milliliters of venous blood collected for measurement of A1C and was analyzed by using turbidimetric inhibition immunoassay (Dade, Newark, NJ, USA) in a Dimension RxL Clinical Chemistry Analyzer. Subjects were scheduled for retinal photographs taken by the same ophthalmologist at the hospital. This protocol included seven-field stereoscopic retinal photography with a Non-mydriatic Retinal Camera (TOPCON TRC-NW6S), and a spot urinalysis for assessment of creatinine and protein. Diabetic Retinopathy (DR) was defined as the presence of at least one microaneurysm, hemorrhage, or evidence of proliferative retinopathy[19-22]. DR was reported into three categories, normal, non-proliferative diabetic retinopathy (NPDR), and proliferative diabetic retinopathy (PDR). Techniques and standards for diagnosing retinopathy did not change over the period of the present study. The photographs were graded by the same ophthalmologist. Albuminuria was assessed by measurement of mean albumin excretion rate (AER) on three consecutive, timed, overnight urine collections. Diabetic neuropathy (DN) was divided into three groups: normal (an albumin-to-creatinine ratio; Ualb/Ucr < 30 g/mg), Microalbuminuria (MIA, Ualb/Ucr 30-299 mg/g), and macroalbuminuria (MAA, Ualb/Ucr > 299 mg/g)[23-26].

Other variables of interest

Height and weight were measured, and BMI was calculated as kilograms divided by the square of height in meters. BMI was categorized according to the classification system established by WHO's BMI for Asian people[27-29], thin (less than 18.5), normal

(18.5-22.9), overweight (23-24.9), and obese (> 24.9). According to ADA's guideline[2], hypertension for diabetes was defined as a systolic blood pressure of > 130 mmHg, a diastolic blood pressure of > 85 mmHg, or current use of antihypertensive medications[29]. Glycemic control was assessed by measurement of A1C. An AIC of less than 7% resulted in glycemic control goals recommendations[2].

All clinics used the same type of medications and included glibenclamide (5 mg), metformin (500 mg), hydrochlorothiazide (50 mg), enarapril (5 mg), atenolol (50 mg), simvastatin (20 mg), aspirin (81 mg), and gemfibrozil (600 mg). No patients received other new generations of anti-diabetic or hypertensive drugs like thiazolidenediones or long-acting calcium channel blockers.

Statistical analysis

Demographic and baseline characteristics of all participants were represented with the mean ($\bar{x}$) ± Standard Error Mean (SEM). The authors used Mann-Whitney U test to compare mean of age, duration, BMI, waist, SBP, DBP, and A1C in the non-DR with the DR group and used Chi-squared test to compare the number of patients in the non-DR with the DR group. Individuals' mean A1C from all clinics was used to determine glycemic control. Clinical characteristics and complication rates were compared using t-tests for normal continuous data. Variables that were significantly associated with the outcome of DR and DN were then entered into the logistic regression model to determine odds ratio for independent predictors of DR and DN. The independent variables included age, duration of disease (< 4, ≥ 4 years), BMI, waist circumference, SBP DBP, and A1C. All statistical analyses were calculated with 95% confidence intervals, using SPSS for windows (version 11; Chicago, IL).

Results

Two hundred eighty seven diabetic patients, men (n = 79) and women (n = 208), participating in this project (as shown in Table 1) had a mean age of 59.2 ± 0.68 and 31.4% of them were aged 60-69 years. Mean A1C of these patients was 7.6 ± 0.1%, and mean of blood pressure was 134.3 ± 0.9 mmHg in SBP and 79.5 ± 0.48 mmHg in DBP. Additionally, 60.1% of the patients were prescribed a combination of anti-diabetic drugs, glibenclamide (GB) and metformin (Met). Approximately two-thirds of the patients with diabetes had hypertension however, 38.8% of patients did not take any antihypertensive drug (data was not shown). When measuring the glycemic control, the authors found that 41.3% of subjects had A1C below 7%, whereas 23.8% and 35.3% of them had A1C 7-8% and above 8%, respectively. Surprisingly, in patients with A1C below 7%, the authors observed 85% of them used only low dose anti-diabetic drugs, GB < 10 mg and/or Met < 1,000 mg, 11.0% used medium dose of anti-diabetic drugs, GB > 10 mg and/or Met > 1,000 mg, and only 3.7% of them used high doses of anti-diabetic drugs, GB = 20 mg and Met = 3,000 mg When analyzing complications according to the ADA's criteria, the authors found 28.7% of the subjects had micro-albuminuria and 5.7% had macroalbuminuria. Moreover, 85% of them were non-DR. On the other hand, the other

Table 1. Baseline clinical characteristics of 287 subjects (mean ± SE)

Characteritic	
Age (years)	59.2 ± 0.68
Duration (years)	5.5 ± 0.35
Family history risk (%)	
None	46.3
Stroke/CVD	2.0
Diabetes/hypertension	51.7
Smoking	10.8
Drinking	8.2
BMI (kg/m^2)	25.8 ± 0.24
Waist circumference (cm)	90.7 ± 0.68
SBP (mmHg)	134.3 ± 0.9
DBP (mmHg)	79.5 ± 0.48
Percentage of BP < 130/85 mm	41.5
HgA1C(%)	7.6 ± 0.1
Percentage of A1C < 7.0%	41.3
DM with HT (%)	41.6
Characterized by albuminuria*	
Normal (%)	65.6
Microalbuminuria (%)	28.7
Macroalbuminuria (%)	5.7
Characterized by diabetic retinopathy	
None (%)	85.0
NPDR (%)	11.6
PDR (%)	3.5
Characterized by disease	
Patient with no complication (%)	59.2
Both albuminuria and DR (%)	7.9

Data are n (%) and mean ± standard error, otherwise indicated
$\bar{x}$, mean; SE, standard error; SBP, systolic blood pressure; DBP, diastolic blood pressure; NPDR, non-proliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy
* According to the recommendation of ADA, 2009

15% were defined in DN and DR groups including about 8% with both DN and DR.

Table 2 and 3 show the comparison of clinical characteristics and microvascular complications (DN and DR). In the logistic regression models, the factors independently related to DN included duration of diabetes, and A1C. Those with DN were prone to have longer duration of diabetes (≥ 4 years) and higher levels of A1C (≥ 8%). Each unit of A1C was associated with 1.49 times of having DN (95% CI 1.24-1.79). The mean difference of A1C between no DN and DN was also shown in Fig. 1. Patients with duration of diabetes ≥ 4 years were 2.2 times more liable to have DN (95% CI 1.33-3.80). No correlation between obesity indices and DN (either BMI or waist circumference) was demonstrated. Besides, DR was also relevant to

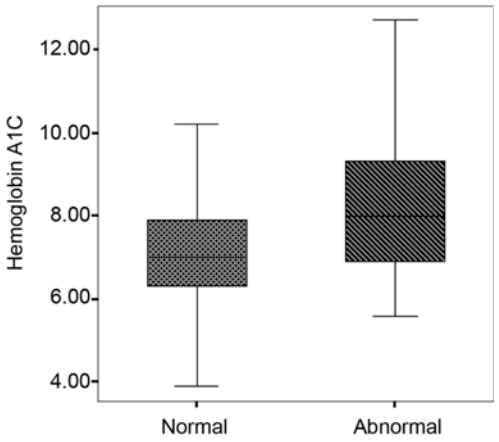

Fig.1 Difference of mean A1C between no DN and DN groups

Table 2. Variables associated with diabetic nephropathy (DN) by logistic regression

Parameters	DN		OR	95% CI	p-value
	No	Yes			
Age (years)	61.0 (33-85)	59.0 (27-86)	0.985	0.962-1.009	0.214
Duration of diabetes (years)					
< 4	104 (73.2)	38 (26.8)	1		
≥ 4	62 (54.9)	51 (45.1)	2.251	1.332-3.805	0.002*
BMI (kg./m^2)	25.5 (16.8-39.1)	25.0 (16.2-33.7)	0.955	0.894-1.019	0.164
Waist circumference (cm)	91.0 (60.0-125.0)	90.0 (60.0-115.0)	0.988	0.965-1.012	0.333
SBP (mmHg)	134.0 (100.0-182.0)	130.0 (105.0-200.0)	0.990	0.974-1.007	0.257
DBP (mmHg)	80.0 (50.0-100.0)	79.2 (60.0-110.0)	0.985	0.955-1.016	0.350
A1C (%)	7.0 (3.9-12.0)	8.0 (5.6-12.7)	1.489	1.236-1.794	<0.001*

OR, odds ratio; DN, diabetic nephropathy; A1C, hemoglobin A1C

Table 3. Variables associated with diabetic nephropathy (DR) by logistic regression

Parameters	DR		OR	95% CI	p-value
	No	Yes			
Age (years)	59.0 (34-80)	60.0 (45-68)	1.006	0.940-1.078	0.855
Duration of diabetes (years)					
< 4	42 (97.7)	1 (2.3)	1.000		
≥ 4	44 (81.5)	10 (18.5)	9.545	1.170-77.845	0.035*
BMI (kg./m^2)	25.5 (16.8-38.4)	25.4 (22.3-39.1)	1.033	0.881-1.212	0.688
Waist circumference (cm)	92.5 (67.0-118.0)	91.0 (82.0-125.0)	1.027	0.971-1.086	0.358
SBP (mmHg)	133.0 (100.0-174.0)	138.0 (120.0-156.5)	1.020	0.980-1.061	0.330
DBP (mmHg)	79.8 (66.0-100.0)	80.0 (70.0-93.3)	1.025	0.948-1.109	0.531
A1C (%)	7.4 (5.4-10.8)	7.3 (6.7-11.7)	1.117	0.728-1.713	0.612

OR, odds ratio; DR, diabetic retinopathy; A1C, hemoglobin A1C

duration of diabetes. Those with duration of diabetes ≥ 4 years were 9.5 times more likely to have DR (95% CI 1.17-77.85). Still, no significant relation between other clinical factors and these microvascular diseases was observed.

Discussion

Since 1997, ADA[13] recommends that every type-2 diabetic patient be checked for diabetic-related complications, like DR and DN as soon as possible because diabetes provides a long asymptomatic period. The present study is consonant with others that found that DN was closely related to the duration of diabetes and A1C[26-29]. That is, the longer the diabetes, the higher chance of having DN[12,30]. The study of UKPDS indicates diabetes with A1C less than 7% inclined to have lower rate of microvascular complications than those with 8% of A1C or more. Moreover, they found a 25% reduction in the risk of microvascular disease in patients who were treated (A1C < 7%) when compared with the control group (A1C 7.9%)[31]. Aekplakorn confirmed similar results, indicating that each percent of A1C was associated with 1.54 times of having MIA and 2.06 times of MAA. Patients with the duration of diabetes > 5 years were 1.31 times more likely to have MIA and 2.39 times to have MAA compared with those with a duration < 5 years[34].

In the present study, 40% of the patients reached a target of diabetic control as defined by ADA (A1C < 7%). Furthermore, in this group, the authors surprisingly found that 80% of them used only low doses of anti-diabetic drugs. This observation means that good diabetic control prevented the need to take large numbers of medications, and did refer to a quality of primary care unit management that motivated patients to have more self-control to maintain an optimum blood glucose level. Furthermore, some patients could sustain blood glucose even though the doctor reduced the diabetic medication. The authors called this method empowerment.

In addition, the UKPDS illustrates an A1C is strongly pertinent to microvascular complications more than macrovascular complications, which was expounded to be the result that the structures of micro vessels themselves are more susceptible to high blood glucose concentration than those of macro vessels[31,32]. However, the authors know from the fact that these microvascular diseases are preventable and treatable. DN treatment in many studies showed successful reduction in the progress of DN after introduction ACE-I or ARB in treatment protocol[2,12,33].

Based on present data, the authors found 28.7% and 5.7% of the patients had MIA and MAA, respectively. These rates were lower than the rates shown in the study of Microalbuminuria Prevalence Study (MAPS) that found 43.4% and 13.4% of the patients had MIA and MAA, and lower that those rates of Aekplakorn's study of 39.12% and 7.83% of patients with MIA and MAA, respectively[17]. However, all those studies, including the authors', still had a higher rate of those two complications when compared with the studies in Western countries that found only 17-21%[32]. The variation of the finding may be due to the disparity in duration of disease, communities, and treatment setting[17,34]. Moreover, 40% of these subjects achieved target of blood pressure control below 130/85 mmHg according to ADA's criteria[2]. This result is better than that in many studies, such as in MAPS[30,31]. The presented data also showed a correlation between DR and level of blood pressure, which was similar to the result of UKPDS 38[10]. It stated that lower blood pressure lowers microvascular complications by 12-13%. Those complications were detected in studied patients in the present study even though they had just been diagnosed with diabetes. This may be the result from two factors, first, diabetes provides a long period of unobservable symptoms therefore, most of these patients will not come for early treatment. Furthermore, the complication screening uses many specific medical equipment, available specialists, and practical referral systems thus, at a high cost. Second, the present public policy of diabetic management focuses on community-based action instead of hospital-based action to reduce overcrowding in large-scale hospitals and encourage those patients to receive diabetic service at primary care units in their community. This free-of-charge benefit results in more convenience, faster and easier for the patient. However, it will cause many patients not to be concerned about their diabetes diagnostic or mitigate personal self-care[8,9]. Still, owing to the limitation of some screening equipment at PCU, such as a stereoscopic retinal photography and some laboratory tests etc., every patient is scheduled to go to have those examinations at a hospital that is inconvenient for them and finally lose contact. Therefore, a low rate of screening leads to a high chance of suffering microvascular diseases.

Conclusion

The present study demonstrates that primary care units provide enough care to patients to control

diabetes well. Nonetheless, type 2 diabetic patients still have significantly higher rates of microvascular complications, despite shorter diabetes duration and lower A1C. The present study also indicates diabetes-related microvascular complications are related to duration of diabetes and poor glycemic control. The results shows that type 2 diabetic patients should be screened in primary care unit for complications and given the tools to reach optimal glycemic level.

Acknowledgement

The authors wish to thank our colleagues for their dedication to this study. We thank them for all the support offered from the committee at Samutsakhon General Hospital, National Health Security office. Last, we thank all diabetic patients who collaborated to this project.

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การควบคุมระดับน้ำตาล และภาวะแทรกซ้อนในผู้ป่วยเบาหวานที่มารับการรักษาที่ศูนย์สุขภาพชุมชน

กรภัทร มยุระสาคร, นวรัตน์ สมทิพย์, สุภัค แซ่โง้ว, ณหทัย จุลกะรัตน์, โมลี วนิชสุวรรณ

วัตถุประสงค์: *เพื่อประเมินผลการควบคุมโรค และเปรียบเทียบความชุกของภาวะแทรกซ้อนทางหลอดเลือดเล็กในผู้ป่วยเบาหวานชนิดที่สองที่มารับการรักษาที่ศูนย์สุขภาพชุมชน*

วัสดุ และวิธีการ: *ผู้นิพนธ์ใช้การศึกษาภาคตัดขวางในผู้ป่วยเบาหวาน 287 คน จากศูนย์สุขภาพชุมชน 13 แห่งในชุมชนเขตเมืองในประเทศไทย ผลการควบคุมโรคเบาหวานวัดได้จาก HbA_{1C} (A1C) และความดันโลหิต (BP) ส่วนการคัดกรองภาวะแทรกซ้อนทางหลอดเลือดเล็กนั้น ผู้นิพนธ์ได้ทำการประเมินภาวะ retinopathy ด้วยการใช้ retinal photography และประเมินภาวะ nephropathy โดยการประเมินอัตราส่วน albumin/creatinine จากการสุ่มตรวจปัสสาวะ*

ผลการศึกษา: *พบว่าผู้ป่วย 41.3% และ 41.5% มีระดับ A1C ต่ำกว่าร้อยละ 7 ในจำนวนนั้นประมาณร้อยละ 80 ใช้ยาเบาหวานในปริมาณน้อย นอกจากนี้ผู้นิพนธ์พบความชุกของการมี microalbumin เท่ากับ 28.7% และ macroalbumin ในปัสสาวะเท่ากับ 5.7% ในขณะที่พบภาวะ diabetic retinopathy ประมาณ 15.1% นอกจากนี้จากการตรวจสอบความสัมพันธ์ของตัวแปร พบว่าการเกิด nephropathy สัมพันธ์กับผู้ป่วยที่เป็นเบาหวาน $\geq$ 4 ปี (odds ratio 1.5, 95% CI 1.2–1.8, $p < 0.001$) และมีระดับ A1C $\geq$ 8% (odds ratio 2.2, 95% CI 1.3–3.8, $p < 0.05$) ในขณะที่ การเกิด retinopathy สัมพันธ์กับการเป็นเบาหวาน $\geq$ 4 ปี (odds ratio 9.5, 95% CI 1.17-77.8, $p < 0.05$)*

สรุป: *จากการศึกษาแสดงให้เห็นว่า ผู้ป่วยเบาหวานที่มารับการรักษาที่ศูนย์สุขภาพชุมชนส่วนใหญ่ควบคุมเบาหวานได้ดีแต่ก็ยังมีความชุกของโรคแทรกซ้อนทางหลอดเลือดเล็กในปริมาณที่สูง ถึงแม้ว่าผู้ป่วยจะเป็นโรคเบาหวานไม่นานและมีระดับ A1C ที่ต่ำ และผู้ป่วยเบาหวานชนิดที่สองที่มารักษาที่ศูนย์สุขภาพชุมชน จำเป็นต้องได้รับการตรวจคัดกรองภาวะแทรกซ้อนทางหลอดเลือดอย่างน้อย 1 ครั้ง และควรกระตุ้นให้ผู้ป่วยควบคุมระดับน้ำตาลให้ดีที่สุด โดยเฉพาะในผู้ป่วยที่เป็นเบาหวานมานานกว่า 4 ปี*