

Thailand Diabetes Registry (TDR) Project: Clinical Status and Long Term Vascular Complications in Diabetic Patients

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Objective: The primary objectives of the Diabetes Registry project were to identify the characteristics of Thai diabetic patients in tertiary care medical centers and to determine the extent of long term diabetic complications. The secondary objective aimed at building up and strengthening clinical research network among Thai experts in diabetes mellitus and collection of baseline data for future follow-up study.

Material and Method: A cross-sectional, multi-center, hospital-based diabetes registry was carried out from diabetes clinics of 11 tertiary centers. Demographic data, clinical status of diabetes and its complications were collected and analyzed for the prevalence of complications and risk factors.

Results: Nine-thousand-four-hundred-and-nineteen patients were registered for the project and 94.6% were type 2 diabetes. Mean SD of age was 59.4 13.5 and duration of diabetes was and 10 7.6 years. Only 38.2% of the subjects achieved glycemic control of FPG under 130 mg/dl in only 30.7% had an HbA1c of less than 7%. The overall prevalence of dyslipidemia found in this population was 73.3%, hypertension was 63.3% and obesity (BMI > 25 kg/m²) was 52.6%. Diabetic nephropathy was the most common complication accounting for 43.9% followed by retinopathy 30.7%, IHD 8.1% and cerebrovascular disease 4.4%

Conclusion: The prevalence of dyslipidemia and hypertension were high in this population, which may be associated with the high prevalence of diabetic complications. The unsatisfactory control of metabolic status may be due to aging and long duration of diabetic patients in this registry.

Keywords: Diabetes Registry, Thailand, Microvascular, Macrovascular complication, Dyslipidemia, Hypertension

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Diabetes Mellitus is epidemic worldwide owing to the increasing number of aging population and globalization. The WHO predicted a doubling number of diabetic patients in the next twenty years especially in developing countries in Asia⁽¹⁾. Increased calorie intake and sedentary lifestyle are prerequisites to abdominal obesity underpin the development of diabetes mellitus⁽²⁾.

Thailand is inevitably moving towards the burden of such a public health problem. According to the cross country survey in the InterAsia study, the prevalence of type 2 diabetes in Thailand was 9.8 percent, which was doubling the number forecast by the WHO⁽³⁾. Hyperglycemia obviously causes diabetic retinopathy and nephropathy, the microvascular complications that are the leading causes of blindness and chronic renal failure.

In addition to hyperglycemia itself, diabetic patients also bring other components of the so called metabolic syndrome, i.e., hypertension, dyslipidemia, abdominal obesity and the consequent cardiovascular diseases⁽⁴⁾. Both microvascular and macrovascular complications are the burden of the disease not only in terms of individual health and well-being but also in having an impact on the economic status of their families and the country.

Unfortunately, the authors do not have their own data regarding the extent and impact of the disease in Thai population, which is essential for making a decision and budget allocation of the policy makers. In resource limited countries, appropriate allocation is very important. Inappropriate budget allocations have a huge impact on nearly all sectors of people.

The Clinical Research Cooperation Network (CRCN) supported by the Health System Research Institute (HSRI), initiates the multicenter cooperation of experts in diabetology to carry out a study to get the true picture of diabetes mellitus in Thailand. This cooperation aimed at capacity building to undertake a multicenter clinical study and strengthening research networks among medical institutions, as well as developing invaluable information on the status of diabetes mellitus in Thailand. The Diabetes Registry Project under the Thailand Endocrinology Society, supported by the CRCN and funded by HSRI, was established in 2003 to accomplish the afore-mentioned missions.

Objectives

The primary objectives of the Diabetes Registry project were to identify the characteristics of Thai diabetic patients in tertiary care medical centers

and to determine the extent of long term diabetic complications, which are expected to differ from other countries. The secondary aim of this project was to build up and strengthen a clinical research network in Thailand, especially experts who are interested in research into diabetes mellitus. Finally, the primary data collected in the registry will be baseline information for upcoming research into various aspects of diabetes in Thailand.

Material and Method

Population and sampling

Eleven tertiary care medical institutes participated in the present project, all of which have diabetic clinics in their hospitals. Inclusion criteria of the subject were any diabetic patients who were expected to contact the clinic for the consecutive year. The diagnosis of diabetes mellitus was made according to the American Diabetes Association (ADA) criteria 1997⁽⁵⁾, i.e. fasting plasma glucose being ≥ 126 mg/dl more than 2 times or plasma glucose after 2 hours being ≥ 200 mg/dl. The authors excluded only the subjects who were unable to communicate or give medical information to the investigators. The sample size was calculated based on ability of the study to detect a significant number of diabetic retinopathy, microvascular complications directly related to the natural history of diabetes mellitus. A previous study in 2,060 patients with type 2 diabetes reported that the prevalence of diabetic retinopathy was 32%. The authors expected 1% error (e) to detect diabetic retinopathy with a 95% confident interval for the sample size calculation using the following formula:

$$n = \frac{Z_{\alpha/2}^2 P(1-P)}{e^2}$$

The sample size was at least 8,360 subjects. Purposive sampling methods were employed to recruit those who met the criteria and the numbers of subjects enrolled from each site, based on the capability of each institute as shown in Table 1.

A cross-sectional, multi-center, hospital-based diabetes registry was carried out from April 2003 to December 2003 and 9,419 diabetic patients registered.

Type of diabetes was categorized in the present study as: (1) type 1 diabetes (T1DM) if they required insulin for glycemic control and prevention of diabetic ketoacidosis; (2) type 2 diabetes (T2DM) for subjects who used oral antidiabetic agents and had no history of diabetic ketoacidosis; (3) specific type of

Table 1. Numbers of subjects from the 11 participating medical centers

Institute	Number of subject
1 Rajavithi Hospital	1412
2 Chulalongkorn Hospital	1110
3 Maharaj Nakhon Ratchasima Hospital	1066
4 Vajira Hospital	997
5 Theptarin General Hospital	964
6 Phramongkutklao Hospital	956
7 Ramathibodi Hospital	843
8 Maharaj Nakorn Chiang Mai Hospital	675
9 Siriraj Hospital	621
10 Songklanakarindh Hospital	525
11 Khon Kaen University Hospital	250
Total	9419

diabetes such as maturity onset diabetes in the young (MODY); and (4) uncertain type.

Medical history and socioeconomic status were gathered and interviewed by research nurses. Physical examination including body weight, height, dorsalis pedis and/or posterior tibialis pulse, foot ulcer and amputation were done by endocrinologists on the date of registry. Blood pressure was measured twice, at least 1 minute apart, by automated blood pressure machine (Omron T4). Mean values of both systolic and diastolic blood pressure were used to define blood pressure levels. Hypertension was defined by mean blood pressure levels equal to or more than 140/90 mmHg or the use of antihypertensive agents. Eyes examinations were done by ophthalmologists within the past 12 months or within the next 3 months after registry. The diagnoses of cardiovascular diseases were based on clinical diagnosis documented in medical records. The details of diabetic complications were described in specific articles in this journal. The recent use of antidiabetic agents and other medications related to diabetes such as antihypertensive agents, lipid lowering agents and antiplatelets were retrieved from the medical records.

Laboratory results reported in the registry were collected from routine examinations of the institutes' clinical care which had been tested with the past 6 months or in the following 3 months after registration. The most recent results of fasting plasma glucose, HbA1c level, and lipid profile were recorded in the case record form. Dyslipidemia was defined as having serum cholesterol more than 200 mg/dl, triglycerides more than 150 mg/dl, HDL-cholesterol less than 40 mg/dl or recent use of lipid lowering agents. Nephropathy

was defined when the patient had at least one of the following; positive microalbuminuria within one year that was confirmed by elevated urine microalbumin levels in at least two of the three collections; positive proteinuria that was defined as a positive urine dipstick test at least 1+ level; renal insufficiency defined when serum creatinine level was equal or more than 2 mg/dl. Patients without nephropathy were defined when they had negative urine microalbumin.

The present study was approved by the ethics committee of each participating hospital. Signed informed consent was obtained from all participants.

Data collection

A data collection form was developed according to the primary objective of the present study. Training of researchers and research assistants was done during a pilot data collection period and case record form was standardized. Site visits by internal and external auditors were done regularly to assure quality of the data and the process. Data from all participant institutes was sent to the project center for double entry into the data base server and data cleaning was done by a research coordinator and a consultant statistician.

Statistical analysis

Demographic data were expressed as mean \pm SD. Statistical analyses were performed using STATA version 8.0 (Stata Corporation, College Station TX, U.S.) Comparisons between groups were analyzed by unpaired t-test, Mann Whitney U. test, Chi-square test or Fisher's exact test, where appropriate. Prevalence of complications was described in percentage with 95%

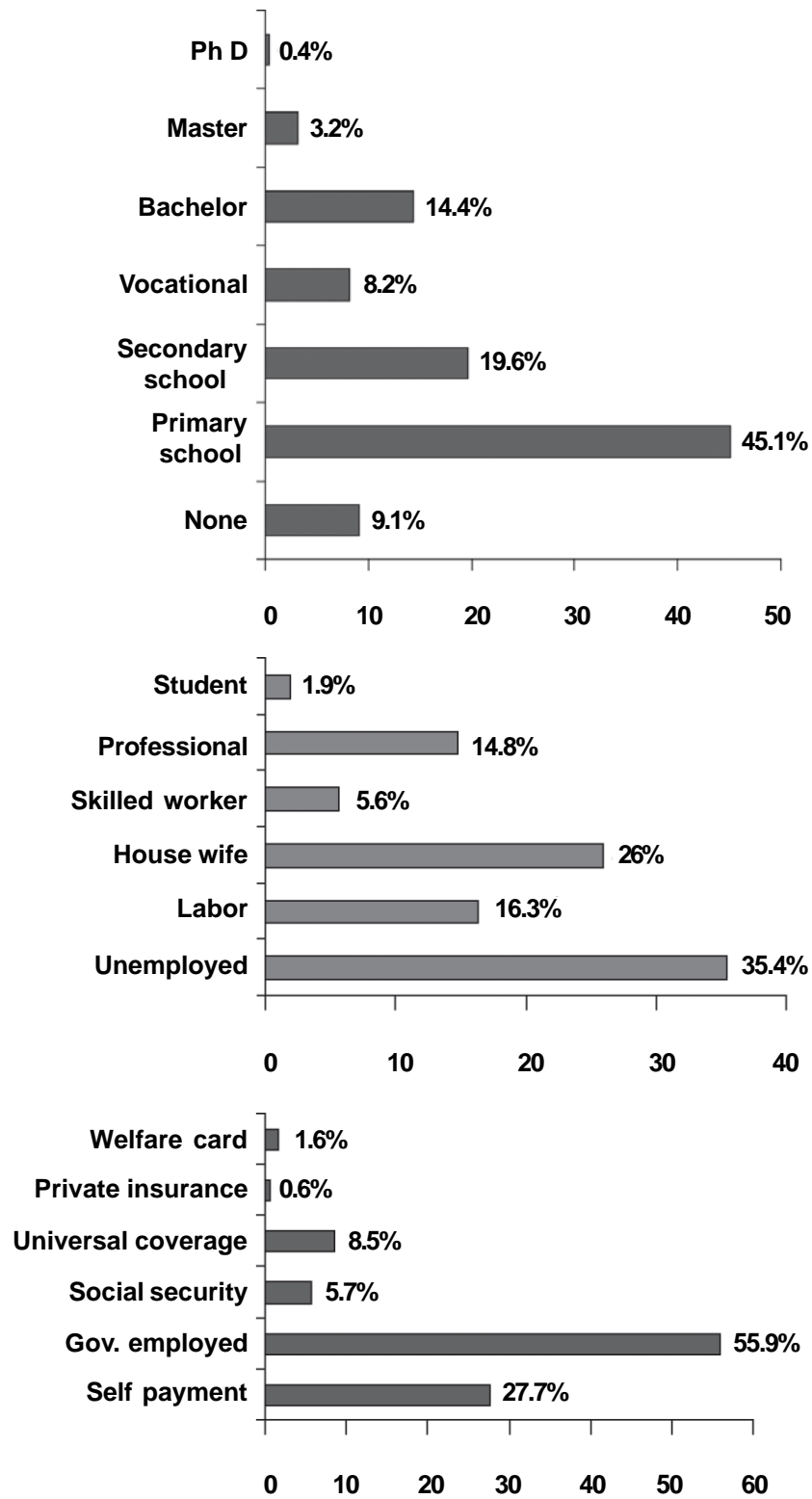


Fig. 1 Socioeconomic status of diabetic patients

confidence intervals (95% CI). Statistical significance was declared if p-value was less than 0.05.

Results

Eleven medical centers enrolled 9,419 diabetic patients in the present study and 65.9% were female. Age of the participants ranged from 1.6 to 96.4 years with 58.8% of them aged between 50 to 70 years and the mean age was 59.4 ± 13.5 years. Most of the subjects, 35.4% were unemployed, and 26.0% were housewives. Forty-five percent of the patients had primary school education and 18% had received a bachelor degree or higher. Most of the patients, 55.9%, were reimbursed for their medical expenses by the government as civil service welfare (Fig. 1).

The mean duration of diabetes was 10 ± 7.6 years and 38.9% had diabetes for more than 10 years as shown in Table 2. The majority (94.6%) of the patients was diagnosed as having T2DM, and the rest were T1DM 4.5%. Only 6 cases (0.1%) were MODY. Family history of diabetes in their first degree relatives was observed in 53.7% of the participants. Of those, 11.7% was in mothers only, 6% in fathers only and 2.4% in both fathers and mothers. There was a higher family history of diabetes in female than in male siblings, 9.4% and 5.1% respectively.

According to the ADA guideline of metabolic control for diabetic patients⁽⁵⁾, the mean fasting plasma glucose level was 153.6 ± 56.7 mg/dl and 38.2% of the subjects had Fasting Plasma Glucose (FPG) less than 130 mg/dl, while mean HbA1c was $8.2 \pm 1.9\%$ and 30.7% of the patients had HbA1c level of lower than 7% as

Table 2. Age group and duration of all subjects

Characteristic	Number (n = 9419)	Percent
Age group (years)		
< 10	53	0.6
11-20	135	1.4
21-30	135	1.4
31-40	455	4.8
41-50	1341	14.2
51-60	2566	27.3
61-70	2968	31.5
71-80	1525	16.2
> 80	241	2.5
Duration of diabetes (years)		
< 1	408	4.3
1-5	2619	27.8
6-10	2709	28.8
11-15	1676	17.8
16-20	1082	11.5
> 20	906	9.6
Unknown	19	0.2

shown in Fig. 2. For lipid profile, mean total cholesterol, triglycerides, LDL-C and HDL-C levels were 197 ± 43 , 151 ± 105 , 115 ± 36 , and 54 ± 15 mg/dl respectively. Achievement to the ADA guideline for cholesterol, triglycerides, LDL-C and HDL-C were 33.8, 37.2, 36.7 and 67.8% respectively. In the aspect of the Metabolic Syndrome, the overall prevalence of dyslipidemia was 73.3%, hypertension was 63.3%, and obesity (BMI > 25 kg/m²) was 52.6%.

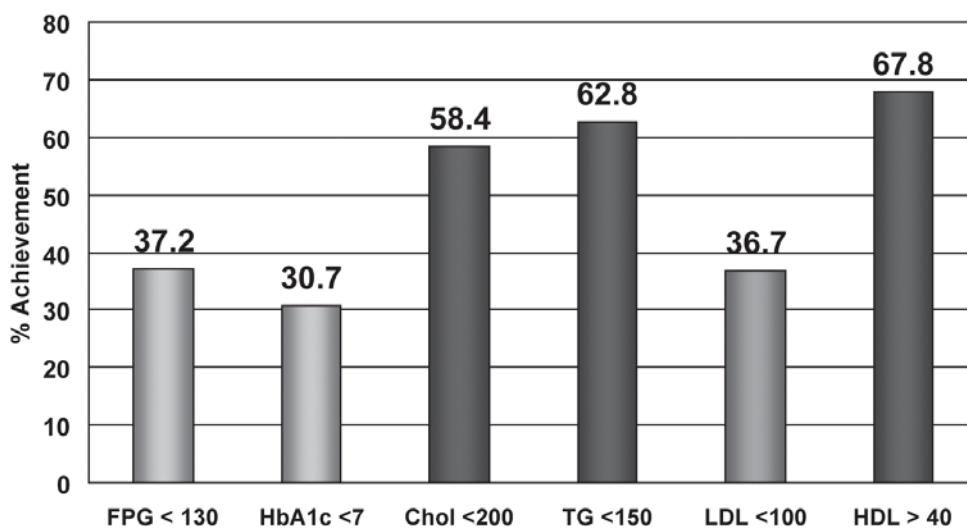


Fig. 2 Percent achievements of metabolic control according to the ADA guideline 2005

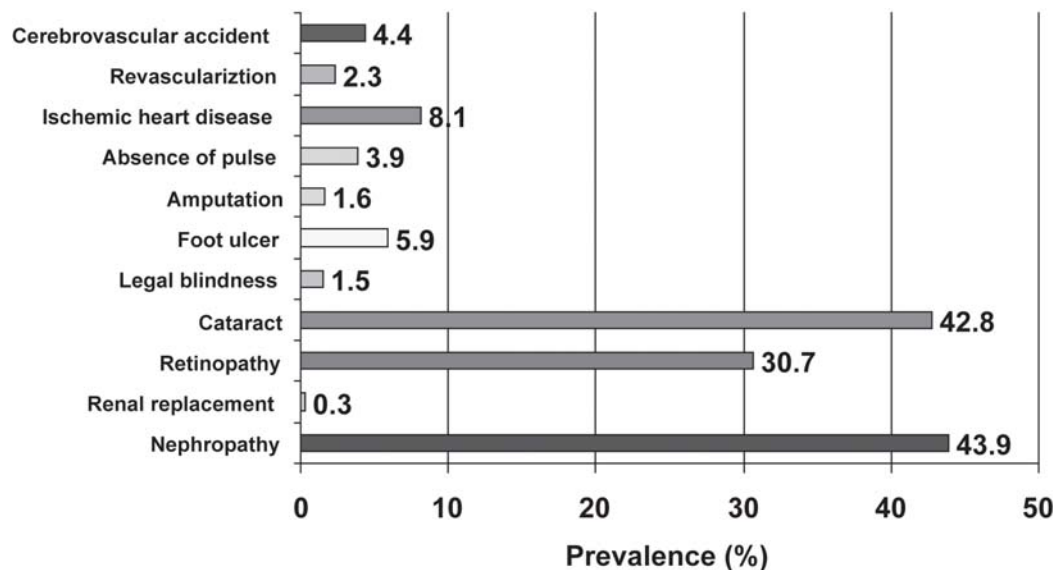


Fig. 3 Prevalence of long term diabetes complications

The most common diabetic complication was nephropathy at 43.8%, followed by diabetic retinopathy at 30.7%. In terms of macrovascular complications, the prevalence of ischemic heart disease was 8.1% followed by cerebrovascular disease at 4.4%. The prevalence of

amputation was only 1.6%, but if the authors took into account foot ulcer and absence of peripheral pulse as peripheral vascular disease this prevalence increased to 11.4% (Fig. 3). The prevalences of all complications were higher in type 2 diabetes than those in type 1 as

Table 3. Number (%) of diabetic complications in type 1 and type 2 diabetes

Complications	Type 1 DM (%)	Type 2 DM (%)	Total (%)
Nephropathy			
Total number	207 (100)	4874 (100)	5131 (100)
Microalbuminuria	31 (15.0)	879 (18.0)	915 (17.8)
Proteinuria	41 (19.7)	866 (17.8)	915 (17.8)
Serum creatinine > 2 mg/dl	20 (9.7)	402 (8.3)	423 (8.3)
No nephropathy	115 (55.6)	2727 (55.9)	2878 (56.1)
Retinopathy			
Total number	347 (100)	6707 (100)	7119 (100)
Non-proliferative	38 (10.9)	1474 (22.0)	1516 (21.3)
Proliferative	37 (10.6)	629 (9.4)	671 (9.4)
No retinopathy	272 (78.5)	4604 (68.6)	4932 (69.3)
Ischemic heart disease			
Total number	421 (100)	8851 (100)	9353 (100)
Definite	4 (0.9)	398 (4.5)	403 (4.3)
Possible	3 (0.7)	353 (4.0)	358 (3.8)
No ischemic heart disease	414 (98.4)	8100 (91.5)	8592 (91.9)
Cerebrovascular disease			
Total number	424 (100)	8993 (100)	9419 (100)
Ischemic stroke	6 (1.4)	320 (3.6)	326 (3.5)
Hemorrhagic stroke	0	39 (0.4)	39 (0.4)
Undefined cause	0	48 (0.5)	50 (0.5)
No cerebrovascular disease	418 (98.6)	8586 (95.5)	9004 (95.6)

shown in Table 3, with one exception. Diabetic nephropathy was found in equal percentage in both types of diabetes.

Discussion

Because this Diabetes Registry Project has been undertaken in a period of only 6 months, the authors could not recruit all diabetic patients from each center. However, 9,419 subjects are enough to study patients' characteristics and measure the burden of the complications in the presented diabetic patients. More female subjects were enrolled in the registry accounting for 69.5%. This is higher than the prevalence of Thai female diabetes in a previous report and in other Asian populations⁽⁶⁾.

Socioeconomic status to some extent may affect diabetic complications and mortality as described in a study done in the United Kingdom⁽⁷⁾. They found that the mortality rates in type 2 diabetes were higher for those who left school before 16 years of age compared to those who left school at or after 16 years of age (OR 2.86, CI 1.93-4.25). Subjects who were unemployed had a higher mortality rate than those employed (OR 2.88, CI 2.12-3.91). In the present study the authors found that 35% of the patients were unemployed and nearly half of them had only primary school or lower education. This finding would be taken into consideration not only for diabetes care, but also for standard of living.

The higher mean age of 59 years and longer duration, 10 years of diabetes contributed to a high prevalence of diabetic complications, especially microvascular complications that are directly related to duration of the disease^(8,9). It is well established that microvascular complications, diabetic retinopathy and nephropathy, are related to degree of glycemic control⁽¹⁰⁾. Even in this cross sectional data, 70% of the patients did not achieve the ADA guidelines of FPG and HbA1c. This leads to a huge number of diabetic nephropathy and retinopathy. Compared with the macrovascular complications, the higher prevalence of microvascular complications may be due to diagnosis criteria of the present study, but this is comparable to a previous report⁽¹⁰⁾. Microvascular complications were mostly diagnosed using screening tests such as urine microalbuminuria and retinal examination by ophthalmologists in asymptomatic stage while cardiovascular diseases were diagnosed only in full-blown subjects. Comparison regarding the prevalence of diabetic complications in Table 3 shows that diabetic nephropathy is higher in type 2 diabetic subjects

probably due to the other factors consisting of hypertension and dyslipidemia. These are related to the renal complications and are more aggregated in T2DM patients with increasing age.

The prevalence of ischemic stroke being 4 times higher than that of hemorrhagic stroke, is not different from another study in an Asian population⁽¹¹⁾. In addition, the authors found that the prevalence of stroke was 4.4%, which was lower than that of 10% in coronary heart diseases. This finding is the same as found in other Asian populations, but is different from that found in the European populations⁽¹²⁾. This may be due to a lower level of HDL-cholesterol in the Asian population. However, it may be due to selection bias of this present study that excluded patients who had a communication disability. Nonetheless, well-established risk factors are quite high such as dyslipidemia at 73% and hypertension at 63%. They may increase the incidence of diabetic complications in the future. A follow-up study for incident cases of this cohort will give more precise information.

Achievement of glycemic control and metabolic derangement is another important issue to mention in this present registry. The authors found that glycemic control achieved the target in only 30% of the patients, and LDL-C of being less than 100 mg/dl was achieved in only 38.1% of all patients regardless of any treatment strategies; all of those accounted for macrovascular diseases. This achievement is similar to the average achievement as studied by the DiabCare Asia that is in between 20 to 30%, according to the countries⁽¹³⁾. If the authors regard that annual screening for diabetic complications is an indicator for standard of care, 2300 out of 9419 cases (24.4%) did not undergo eye examinations by ophthalmologists in the past year. The inadequate eye examination is clearly due to a limited number of ophthalmologists as found in a study in Nakhonrajassima province showing that eye examinations could be done in only 23.5% of diabetic patients⁽¹⁴⁾. Screening for diabetic nephropathy may be more serious in this patient population since nearly a half of the patients in the present registry had not been tested for urinary microalbuminuria and the authors found that 41% of the screened subjects had diabetic nephropathy. The large number of unscreened cases is due to financial limitation.

The present study recruited nearly 10,000 diabetic patients. This is a large enough sample size to see the characteristics and burden of diabetic complications in the Thai population. Even though the present study was done in tertiary care medical centers, that

may be different from those in a primary care situation, the authors might be able to forecast the magnitude of the problem related to diabetes in Thailand.

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Appendix

TDR Working Group:

The following persons participated in the Thailand Diabetic Registry:

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โครงการลงทะเบียนผู้ป่วยเบาหวานในประเทศไทย: ลักษณะทางคลินิกและความชุกของภาวะแทรกซ้อนระยะยาวทางระบบหลอดเลือด

เพชร รอดอารีย์, ฉัตรประอร งามอุโฆษ, ชัยชาญ ดีโรจนวงศ์, สมพงษ์ สุวรรณวัลย์กร, ธัญญา เขมฐาภกุล, สิริเนตร กฤติยาวงศ์, ยุพิน เบ็ญจสุรัตน์วงศ์, พงศ์อมร บุณนาค, ญัฐพงศ์ โฆษิตชนพันธ์, ญัฐเชษฐ์ เปล่งวิทยา, รัตนา ลีลาวัฒนา, ธงชัย ประภาณวัตร, สุภาวดี ลิขิตมาศกุล, สิริมา มงคลสัมฤทธิ์

วัตถุประสงค์: เพื่อศึกษาลักษณะและปัญหาเกี่ยวกับภาวะแทรกซ้อนของผู้ป่วยเบาหวานที่เข้ารับการรักษาในโรงพยาบาลตติยภูมิหลายสถาบันในประเทศไทย และเพื่อเป็นการสร้างเครือข่ายการวิจัยทางคลินิกและฐานข้อมูลผู้ป่วยเบาหวานเพื่อการวิจัยในอนาคต

วัสดุและวิธีการ: การศึกษานี้เป็นการลงทะเบียนผู้ป่วยเบาหวานที่มารับการรักษาที่คลินิกเบาหวานของโรงพยาบาลระดับตติยภูมิทั้งหมด 11 แห่ง มีการเก็บข้อมูลด้านประวัติ, การตรวจร่างกายและการตรวจเลือดเพื่อหาความชุกของโรคแทรกซ้อน การบรรลุเป้าหมายในการรักษาโรคเบาหวานและความผิดปกติที่พบร่วม

ผลการศึกษา: มีผู้ป่วยจำนวนทั้งสิ้น 9,419 ราย จากโรงเรียนแพทย์และสถาบันในระดับตติยภูมิ 11 สถาบัน ในช่วงปี พ.ศ. 2546 จากข้อมูลในภาคตัดขวางพบว่าผู้ป่วยร้อยละ 94.6 เป็นเบาหวานชนิดที่ 2 มีอายุเฉลี่ย 59.4 ± 13.3 ปี และเป็นเบาหวานมานานเฉลี่ย 10 ± 7.6 ปี ผู้ป่วยมากกว่าร้อยละ 50 ได้รับการศึกษาในระดับประถมหรือต่ำกว่า และส่วนใหญ่เป็นผู้ว่างงาน ผู้ป่วยสามารถควบคุมระดับน้ำตาลในเลือดได้ตามเป้าหมายร้อยละ 38.2 และระดับ HbA1c ถึงเป้าหมายร้อยละ 31.7 นอกจากนี้ยังพบว่า มีโรคความดันโลหิตสูงและไขมันผิดปกติในเลือดสูง ร้อยละ 63.3 และ 73.3 ตามลำดับ โรคแทรกซ้อนส่วนใหญ่ที่พบเป็นในระบบหลอดเลือดขนาดเล็กที่ตา ร้อยละ 30.7 ที่ไต ร้อยละ 43.9 และพบมีโรคแทรกซ้อนในหัวใจและสมองร้อยละ 8.1 และ 4.4 ตามลำดับ

สรุป: ผู้ป่วยในกลุ่มนี้มีอายุเฉลี่ยสูง และเป็นโรคเบาหวานมานาน ทำให้พบมีความผิดปกติอื่นร่วมด้วยมาก นอกจากนี้ยังพบว่าการควบคุมระดับน้ำตาลในเลือดและเมตาโบลิสมทำได้ไม่ดี จึงเกิดโรคแทรกซ้อนได้มาก โดยเฉพาะที่พบบากในโครงการนี้คือทางระบบหลอดเลือดเล็กที่ไตและที่จอประสาทตา
