A 4-Year Prospective Study on Long-Term Complications of Type 2 Diabetic Patients: The Thai DMS Diabetes Complications (DD.Comp.) Project

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Objective: *To assess the clinical course of long-term diabetic complications; diabetic retinopathy, nephropathy, and foot problems in Thai patients with type 2 diabetes.*
Material and Method: *Patients with type 2 diabetes were followed for four years between March 2006 and September 2010. Seven hospitals in all levels of care under the Ministry of Public Health Thailand were included in the present study. A physical examination and a diabetic complications assessment were performed each year during the study period, by physician specialists in the related areas.*
Results: *Among 1,120 patients who participated in the present study, 705 (62.95%) patients completed the 4-year follow-up time. There were 88 (7.86%) patients reported deaths during the present study period. The mean age was 59.14±10.12 years. The average duration of diabetes was 7.30±6.14 years. Approximately 57.32% of patients had a family history of diabetes. The average plasma glucose level and HbA1C were 153 to 160 mg/dl and 8.25 to 8.75%. Moreover, less than one-fourth of patients had HbA1C below 7%. The prevalence for diabetic retinopathy and nephropathy were approximately 23.7% and 38.3%. In addition, more than 15% of patients had diabetic foot problems, loss of protective sensation and pedal pulse deficit. Finally, the incidence rates were 80.1 per 1,000 person-years (95% CI 69.7, 91.8) for diabetic retinopathy, and 91.1 per 1,000 person-years (95% CI 78.8, 105.1) for diabetic nephropathy.*
Conclusion: *Problems regarding poor diabetes control exist in Thai diabetes patients. It results in high prevalence and incidence of diabetic complications. As such, it is crucial to establish the country's diabetes management plan as well as evaluate the long-term complications in diabetic patients annually, in order for patients to receive the benefits of early treatment and prevent further complications.*

Keywords: *Diabetes, Microvascular complication, Retinopathy, Nephropathy, Thailand*

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Diabetes is one of the global health concerns of chronic diseases. According to the World Health Organization (WHO)[1], the preponderance of diabetes patients lives in low- and middle-income countries. In Thailand, the data from the fourth National Health Examination Survey (NHES IV) in 2009 has shown that the prevalence of diabetes was 7.5%[2]. Among those who were diagnosed with diabetes, 35.4% had no previous knowledge of their health status[2]. Moreover, only 28.5% of patients who received treatment were able to control their blood glucose level[2]. Patients who are unable to control their blood glucose level are much more likely to develop the complications that affect both morbidity and mortality. Thus, it is necessary to carefully evaluate and monitor the disease and its complications.

Diabetic complications studies have been conducted in Thailand, however, those studies were mostly carried out in tertiary care settings[3-6]. In addition, the research designs were cross-sectional studies that lack information provided on incident cases, natural course of diabetes, and its complications.

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As such, the Institute of Medical Research and Technology Assessment (IMRTA), under the Department of Medical Services (DMS), Ministry of Public Health (MOPH) developed the Thai DMS Diabetes Complications (DD.Comp.) project to further study diabetes in different hospital settings. The project included three sub-projects that aimed to assess the clinical course of diabetic microvascular complications in Thai patients with type 2 diabetes involving eyes, kidney, and feet, respectively.

Material and Method

Study design and setting

A multicenter, prospective, descriptive study was conducted between March 2006 and September 2010. Participants were recruited from diabetic clinics in seven hospitals, four hospitals were located in Bangkok under the Department of Medical Services (DMS), Ministry of Public Health (MOPH), one general hospital, and two community hospitals in Pathum Thani province. These represent the different range of Thai health care institutions, primary, secondary, and tertiary hospitals.

The present study included three sub-projects, 1) examination of retinal complication, 2) evaluation of kidney complication, and 3) assessment of foot complication. These were approved by the Ethical Review Committee for Research in Human Subjects Ministry of Public Health (MOPH), Thailand.

Study population

Participants were enrolled in the present study, if they had type 2 diabetes and gave the written informed consent to participate in the present study. The number of participants was calculated and proportionate to the hospital sizes. The diabetes patients were diagnosed based on the American Diabetes Association (ADA) classification and diagnostic criteria[7]. The exclusion criteria for sub-project 1, which involved diabetic retinopathy, were those who were pregnant, had eye conditions that interfere with retina examination, had retinopathy from other causes, or did not cooperate to collect urine samples. The exclusion criteria for sub-project 2, diabetic nephropathy study, were those who were pregnant, had cancer history, used steroids, had chronic heart failure [the New York Heart Association (NYHA) Functional Classification III and IV], had a fever or urinary tract infection, in a menstrual period, had exercised within the previous one hour, had serum creatinine changed more than 20% compared to the first test, had white or red blood cell in urine more than 5 cell/LPF, or did not cooperate to collect a urine sample. The exclusion criteria for sub-project 3, foot complications study, were those who were pregnant, had foot or leg ulcers from other causes, or did not cooperate to collect a urine sample.

Study measurement

A medical history, physical examination and laboratory tests were gathered at the beginning of the present study for baseline information, and the same procedure was repeated every year for four times. The medical history and physical examination were obtained by trained nurse practitioners. Participants' blood pressures were measured, according to the protocol of the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC7)[8]. Laboratory tests, including urine and blood samples were examined by medical technologist at the ISO 9001:2008 certified central laboratory. Urine test included urinalysis, urine dipstick for microalbuminuria, spot urine for albumin/creatinine, and spot urine for protein/creatinine. Blood tests included the test for blood urea nitrogen (BUN), creatinine, fasting blood sugar, HbA1C, complete blood count (CBC), cholesterol, triglyceride, HDL-cholesterol, LDL-cholesterol, protein, and albumin. Research staff recorded all the data in "case report forms", created by physicians.

Diabetic retinopathy was diagnosed annually by retina specialists using indirect ophthalmoscope and the Proposed International Clinical Diabetic Retinopathy Disease Severity scales 2003 for severity grading[9]. Accordingly, patients were classified into five grades, no diabetic retinopathy (DR), mild non-proliferative diabetic retinopathy (NPDR), moderate NPDR, severe NPDR, and proliferative diabetic retinopathy (PDR).

Diabetic nephropathy screening was performed each year using the urine albumin test for three consecutive months. The diagnosis of diabetic nephropathy was established by the nephrologist, based on the presence of microalbumin in at least two of the three morning urine samples[10].

Finally, the risk of amputation in diabetic patients, loss of protective sensation and pedal pulse deficit, was evaluated annually by general surgeons. Protective sensation was assessed by using Semmes-Weinstein 5.07/10 gram monofilament. The positive monofilament test was defined by patient's inability to sense the pressure point at least one of seven sites of

each foot, except the heel area. Pedal pulse deficit was defined as the absence or diminished Dorsalis Pedis and/or Posterior Tibial artery pulses[11].

Quality control

Research quality assurance and control, were conducted to ensure the reliability and validity of the study. Patients from all centers were assessed by the single team of physicians and nurses. All research staff was trained, regarding the International Conference on Harmonization-Good Clinical Practice (ICH-GCP) protocol[12] and standard operating procedures (SOP) of the study. They then monitored the activities and quality of the study according to the SOP. External evaluators from Universities or Other Medical Associations annually assessed the quality of the present study based on ICH-GCP protocol and SOP. Finally, the calibration of all blood pressure measurement, weight measurement, and body temperature measurement was done by the Medical Engineering Division, Department of Health Service Support, MOPH Thailand.

Variables

Variables in the present study included socio-demographic data, medical history and medications, physical examination, laboratory data, diagnosis of diabetic retinopathy, diabetic nephropathy, and diabetic foot complications. All information was collected in the case record forms. After the completion of the data recording, each hospital sent a copy of patients' data record forms to the IMRTA for data analysis and management. Research project databases were developed based on the data collection program from "The Endocrine Society of Thailand". The double entry method was used to ensure the data accuracy.

Statistical analysis

Baseline characteristics of participants were calculated using mean with standard deviation for all normally distributed quantitative data, and median for non-normally distributed data In addition, the qualitative data was reported using frequency and percentage. The prevalence of diabetic complications, diabetic retinopathy, and diabetic nephropathy were expressed as a percentage, which was calculated by dividing the number of persons with diabetic complications by the number of total participants. The 95% confidence intervals (CIs) for prevalence were also calculated using the Wilson score method without continuity correction[13]. The incidence rates (IRs) of diabetic retinopathy and diabetic nephropathy per person-years of follow-up were calculated by dividing the number of new complication cases by the total number of total person-years at risk with 95% confidence interval.

Results

Participants

One thousand one hundred twenty patients enrolled in the present study. Among these, 705 (62.95%) completed the 4-year follow-up time. Approximately 10% of the participants were lost to follow-up each year, because they moved out of the area, they were dead, or their contact was lost. Table 1 presents the baseline characteristics of the present study population. There were 796 (71.07%) female and 324 (28.93%) male participants. The mean age was 59.14±10.12 years old. The majority of the participants (42.68%) had diabetes for less than five years. The age at diagnosis of diabetes among participants was 51.84±10.10 years old. The present study showed that there were 642 (57.32%) participants having a family history of diabetes. In addition, participants who had previous comorbid diseases, including hypertension, dyslipidemia, ischemic heart disease, and cerebrovascular disease, accounted for 720 (64.29%), 625 (55.8%), 58 (5.18%), and 35 (3.12%), respectively.

Diabetic control

The mean body mass index (BMI) was 27 kg/m^2. Approximately 65% of participants were obese (BMI >25 kg/m^2). Only 14 to 16% of participants had BMI in the normal range (18.5-22.9 kg/m^2). Some 80% of participants had high waist circumference, which was more than 90 cm in men and 80 cm in women.

Thirty-three to 37% of all participants had fasting plasma glucose level between 70 and 130 mg/dl and 15 and 23% had HbA1C less than 7%. Participants who could control their blood pressure, systolic blood pressure less than or equal to 130 mmHg and diastolic blood pressure less than or equal to 80 mmHg, accounted for 36 to 53%. About 17 to 33% of participants had LDL less than 100 mg/dl, 51 to 54% had triglyceride less than 150 mg/dl, 18 to 29% had total cholesterol between 130 and 170 mg/dl, and 59 to 63% had HDL more than 40 and 50 mg/dl in male and female respectively (Fig. 1). For overall performance, less than a half of participants achieving risk factors control both in 2006 and 2010.

Table 1. Baseline characteristics of the 1,120 study population

Characteristics	Data, n (%)
Age, year (mean ± SD)	59.14±10.12
Gender	
Male	324 (28.93)
Female	796 (71.07)
Occupation	
Housewife	547 (48.84)
Laborer	240 (21.43)
Skilled worker	50 (4.46)
Professional worker	81 (7.23)
Unemployment	202 (18.04)
Education	
No education	168 (15.00)
Primary school	599 (53.48)
Secondary school	192 (17.14)
Vocational education	66 (5.89)
Bachelor degree	92 (8.22)
> bachelor degree	3 (0.27)
Family history of diabetes	
Yes	642 (57.32)
No	387 (34.55)
Don't know	91 (8.13)
Duration of diabetes (years)	
<5.0	478 (42.68)
5.0-9.9	286 (25.54)
10.0-14.9	213 (19.02)
15.0-19.9	77 (6.87)
>20	66 (5.89)
Smoking	
Current	59 (5.27)
Never	980 (87.50)
Former	81 (7.23)
Comorbidity	
Hypertension	
Yes	720 (64.29)
No	400 (35.71)
Dyslipidemia	
Yes	625 (55.80)
No	495 (44.20)
Ischemic heart disease	
Yes	58 (5.18)
No	1,062 (94.82)
Cerebrovascular accident	
Yes	35 (3.12)
No	1,085 (96.88)

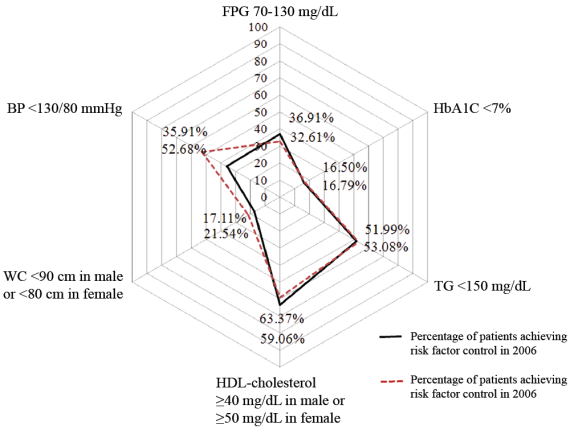

Fig. 1 The percentages of type 2 diabetic patients achieving risk factor control in 2006 and 2010.

Prevalence of diabetic complications, diabetic retinopathy, diabetic nephropathy, and diabetic foot complications

The prevalence of diabetic complications is shown in Table 2. During the study period, approximately 32 to 38% of all participants had at least one microvascular complication, 17 to 19% had two complications, and 4 to 6% had all three types of complications. Diabetic nephropathy is the most common complications, followed by diabetic retinopathy and diabetic foot problems.

About 73 to 76% of participants had no diabetic retinopathy, while 18 to 21% had diabetic retinopathy that affected both eyes, and 4 to 7% affected only one eye.

Participants who had normal albuminuria accounted for 61 to 64%. Approximately 25 to 28% of participants had Microalbuminuria, and 10 to 12% had macroalbuminuria.

Regarding diabetic foot problems (loss of protective sensation and pedal pulse deficit), participants who had normal protective sensation accounted for 76 to 84%, and those who have lost protective sensation were 16 to 24%. In addition, 92 to 98% of participants had normal pedal pulses, while 2 to 7% had pedal pulse deficits.

Incidence rates of diabetic complications, diabetic retinopathy and diabetic nephropathy

Of all 1,120 patients included in the present study, the number of participants who were free of diabetic retinopathy and diabetic nephropathy at the beginning of the study were 774 (75%) and 609 (54.38%). Among those, 186 (24.03%) and 168 (27.59%) had developed diabetic retinopathy and nephropathy within the four years of the follow-up period. Table 3 shows the incidence rate of diabetic complications.

Table 2. Prevalence of diabetic retinopathy, diabetic nephropathy, and foot problems at the beginning of study period

Complications	Total No.	Cases (% prevalence)	95% CI
Diabetic retinopathy	1,101	261 (23.71)	21.29, 26.31
Diabetic nephropathy	1,099	421 (38.31)	35.48, 41.22
Diabetic foot problems			
Loss of protective sensation	996	209 (20.98)	18.57, 23.62
Pedal pulse deficit	1,109	59 (5.32)	4.15, 6.80

Table 3. Incidence rate of diabetic retinopathy and diabetic nephropathy between March 2006 and September 2010

Diabetic complications	No. of new cases	No. of person-years	Incidence rate per 1,000 person-years (95% CI)
Diabetic retinopathy (n = 774)	186	2,323	80.1 (69.7, 91.8)
Diabetic nephropathy (n = 609)	168	1,844	91.1 (78.8, 105.1)

Discussion

Studies on diabetic complications in Thailand were mostly cross-sectional studies conducted in tertiary care settings[3-6]. The present study, the DD. Comp. project, was conducted in primary, secondary, and tertiary hospitals. A 4-year multicenter prospective study addressed the long-term diabetic complications in the Thai patients with type 2 diabetes.

Results from the present study have shown that the majority of participants were unable to control diabetes according to ADA's recommendation[14]. Approximately 80% of patients had HbA1C more than 7%. In addition, more than half of the patients were unable to control their blood pressure level or lipid profiles. These are consistent with previous studies. When comparing the results of the present study in 1998[4], the diabetes control has not yet been improved in Thai patients. These results reveal that problems still exist in Thai diabetes management. Accordingly, the numbers of diabetic complications were high.

In Thailand, several projects provided information on the epidemiology of diabetes and its complications in the Thai population. In 1994, the "Thai Multicenter Research Group on Diabetes Mellitus"[5] has shown that prevalence for diabetic retinopathy was 32.1%, diabetic nephropathy was 18.7% and 5.8% of patients had dorsalis pedis pulse deficit. The "Diabcare-Asia" study[4] in 1998 reported that there were 21% of patients with diabetic retinopathy, and 62% had diabetic nephropathy. Later, in 2003, the "Thailand Diabetes Registry (TDR)" project[3] was conducted. There were reported 30.7% diabetic retinopathy, and 43.9% diabetic nephropathy. The present study, the "DD.Comp." project achieved in 2006, has found that the highest prevalence of diabetic complications was diabetic nephropathy, which accounted for 38.3%, followed by diabetic retinopathy 23.7%, and foot problems; loss of protective sensation 21% and pedal pulse deficits 5.3%, respectively. This high prevalence of the diabetic complications was similar to the previous studies. However, they were lower than results from the TDR study. One of the reasons may be due to the present study settings. The TDR study was conducted in tertiary care hospitals, while the present study recruited patients in all levels of care. Some of the patients who went to tertiary centers were referred from the secondary or primary hospitals. They tend to be more complicated and required advanced medical treatment.

Data on incidence of diabetic complications in type 2 diabetes patients remains limited in Thailand. The present study has shown that the incidence rate of diabetic retinopathy was higher than diabetic nephropathy. In addition, the incidence rates compared to other countries; such as Japan[15,16], UK[17], or US[18,19], were higher for both diabetic retinopathy and diabetic nephropathy. One of the reasons can be due to the poor diabetic control in Thai populations.

Limitations to the present study regarding the generalizability of the findings need to be considered. In addition, the prevalence of the diabetic complications may be higher than that general population. Since the present study was conducted in hospital settings, those who come to hospitals often have severe illnesses. Consequently, the findings may not represent the overall picture of the prevalence of diabetic complications in Thailand. However, patients seeking medical care in the study's centers arrived from different locations, and not limited to the area of the hospital's sites. Furthermore, the authors employed all

levels of hospitals; primary, secondary and tertiary centers in the present study. The results of the present study delivered the important message that the burden on diabetic complications in Thailand exist and have not been improved over the past ten years.

Conclusion

The present study reveals the long-term diabetic complications problems that will soon become a major public health priority. Poor diabetes control reflects problems that exist in Thai diabetes management and care. Consequently, Thailand will face a burden from rising treatment costs on diabetes and its complications. Further studies on the factors associated with increased incidence of diabetic complications in the Thai population need to be evaluated, in order to design a proper diabetic management plan.

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Potential conflicts of interest

None.

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การศึกษาแบบไปข้างหน้า 4 ปี เรื่องภาวะแทรกซ้อนระยะยาวในผู้ป่วยเบาหวานชนิดที่ 2: โครงการภาวะแทรกซ้อนทางคลินิกในผู้ป่วยโรคเบาหวานชนิดที่ 2

สมเกียรติ โพธิสัตย์, อุดม ไกรฤทธิชัย, อัมพร จงเสรีจิตต์, ชาญเวช ศรัทธาพุทธ, วรนุตร อรุณรัตนโชติ

วัตถุประสงค์: *เพื่อศึกษาการดำเนินโรคทางคลินิกของภาวะแทรกซ้อนระยะยาวในผู้ป่วยเบาหวาน ได้แก่ โรคเบาหวานเข้าจอประสาทตา โรคไตจากเบาหวาน และปัญหาเท้าในผู้ป่วยเบาหวาน ชนิดที่ 2*

วัสดุและวิธีการ: *การศึกษานี้ ได้ติดตามผู้ป่วยเบาหวาน ชนิดที่ 2 เป็นระยะเวลา 4 ปีในช่วงเดือนมีนาคม พ.ศ. 2549 ถึง กันยายน พ.ศ. 2553 สถานที่ศึกษาเป็นโรงพยาบาลระดับต่าง ๆ ในสังกัดกระทรวงสาธารณสุข จำนวน 7 แห่ง ผู้ป่วยจะได้รับการตรวจร่างกายและประเมินภาวะแทรกซ้อนจากโรคเบาหวานทุกปีในระยะเวลาที่ศึกษา โดยแพทย์ผู้เชี่ยวชาญสาขานั้น ๆ*

ผลการศึกษา: *มีจำนวนผู้ป่วยที่เข้าร่วมการศึกษาทั้งหมด 1,120 ราย ในจำนวนนี้มีผู้ป่วยมาเข้าร่วมโครงการอย่างต่อเนื่องครบทั้ง 4 ปี จำนวน 705 ราย คิดเป็นร้อยละ 62.95 มีอายุเฉลี่ย 59.14±10.12 ปี ระยะเวลาที่ป่วยเป็นเบาหวานโดยเฉลี่ย 7.30±6.14 ปี และพบว่ามีประวัติครอบครัวร้อยละ 57.32 ระดับน้ำตาลในเลือด และระดับน้ำตาลสะสมในเลือด (HbA1C) โดยเฉลี่ยอยู่ระหว่าง 153-160 มก./ดล. และร้อยละ 8.25-8.75 ตามลำดับ นอกจากนี้ผู้ป่วยที่ระดับ HbA1C น้อยกว่าร้อยละ 7 มีน้อยกว่า 1 ใน 4 ความชุกของโรคเบาหวานเข้าจอประสาทตาและโรคไตในผู้ป่วยเบาหวานมีประมาณร้อยละ 23.7 และ 38.3 นอกจากนี้มากกว่าร้อยละ 15 ของผู้ป่วยมีปัญหาที่เท้า คือ สูญเสียประสาทความรู้สึกป้องกันอันตรายที่เท้าและมีภาวะแทรกซ้อนของหลอดเลือดที่เท้า อุบัติการณ์ของโรคเบาหวานเข้าจอประสาทตาเท่ากับ 80.1 ต่อประชากร 1,000 คนต่อปี (95% CI 69.7, 91.8) และอุบัติการณ์ของโรคไตในผู้ป่วยเบาหวานเท่ากับ 91.1 ต่อประชากร 1,000 คนต่อปี (95% CI 78.8, 105.1)*

สรุป: *ปัจจุบันผู้ป่วยเบาหวานยังคงมีปัญหาเรื่องการควบคุมเบาหวานให้อยู่ในเกณฑ์ที่เหมาะสม ผลที่ตามมาทำให้ความชุกและอุบัติการณ์ของภาวะแทรกซ้อนจากโรคเบาหวานสูงขึ้น ดังนั้นจึงเป็นเรื่องสำคัญในการจัดทำแผนการจัดการโรคเบาหวานระดับประเทศ รวมถึงการประเมินภาวะแทรกซ้อนในผู้ป่วยเบาหวานทุกปี เพื่อผู้ป่วยจะได้รับประโยชน์จากการรักษาในระยะแรกและป้องกันการเกิดภาวะแทรกซ้อนต่อไป*
