

Survival Rates and Mortality Risk Factors of Thai Patients with Type 2 Diabetes Mellitus

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Background: Type 2 diabetes mellitus (T2DM) is a common public health problem due to both its micro- and macro-vascular chronic complications. Data on survival rates and mortality risk factors of T2DM in Thailand need to be investigated and updated.

Objective: To assess the survival rate and mortality risk factors in T2DM patients.

Material and Method: This study is a part of the Thai DMS Diabetes Complications project which is a prospective observational 4-year study of Thai T2DM patients. All patients were recruited from out-patient departments of seven public hospitals and received standard treatment from their doctors. Their clinical and laboratory status were evaluated annually over 4 years, with particular emphasis on diabetic nephropathy, retinopathy and neuropathy. Outcomes at the end of the four-year study were expressed as survival or death, and causes of mortality were identified.

Results: 1,097 from 1,120 stable T2DM patients were enrolled. After 4 years of follow-up, 80 patients (7.3%) had died. Causes of death were: cardiovascular disease (20 cases, 25.0%); infection (20 cases, 25.0%); malignancy (10 cases, 12.5%); end-stage renal disease (4 cases, 5.0%); and other causes (26 cases, 32.5%). Survival rates at 1, 2, 3, and 4 years were 98.9, 97.5, 96.2 and 92.7% respectively. Hazard ratios (95% CI) of all-cause mortality were being over 60 years old 1.84 (1.15-2.94) and having diabetic nephropathy 1.75 (1.12-2.75). Survival rates from cardiovascular mortality at 1, 2, 3, and 4 years were 99.2, 98.4, 97.4 and 94.5% respectively. Hazard ratios (95% CI) of cardiovascular mortality were: female gender 1.75 (1.05-2.94); diabetic nephropathy 1.72 (1.03-2.88); and diabetic retinopathy 1.74 (1.02-2.94).

Conclusion: The survival rate of Thai patients with T2DM over the 4 years was 92.7%. Being over 60 years old and having diabetic nephropathy were associated with all-cause mortality. Female gender, diabetic nephropathy and diabetic retinopathy were associated with cardiovascular mortality.

Keywords: Diabetes mellitus, Survival rate, Mortality risk factor

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The numbers of patients with type 2 diabetes mellitus (T2DM) have been increasing rapidly over the last ten years. A previous study projected that the global prevalence of diabetes mellitus would rise from 2.8% in 2003 to 4.8% in 2030⁽¹⁾. This disease is the most serious global public health problem because many patients with T2DM progress to cardiovascular disease and other chronic complications leading to permanent disability and death^(2,3). Patients with T2DM face a high risk of morbidity and mortality due to micro- and macrovascular complications. Microvascular

complications affect various major organs as seen in diabetic retinopathy, nephropathy and neuropathy while macrovascular complications may affect large vessels of the heart and brain. The prevalence of diabetic retinopathy, cardiac disease, stroke, peripheral neuropathy and end-stage renal disease have been found to be 15 to 48%^(4,5), 11 to 25%^(6,7), 20 to 40%⁽⁸⁾, 25 to 60%⁽⁹⁾ and 40 to 50%^(10,11), and diabetic patients have higher mortality rates than the general population⁽¹²⁾. Atherosclerosis causing cardiovascular complications has been identified as the most common cause of death in T2DM^(13,14). Studies from western countries have shown that the mortality risk factors were hypertension, dyslipidemia, poor glycaemic control and smoking^(15,16). The United Kingdom Prospective Diabetes Study (UKPDS)⁽¹⁷⁾ found the risk factors were coronary heart disease, dyslipidemia, hemoglobin A1C,

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systolic blood pressure, and smoking. Other studies have suggested that diabetic nephropathy⁽¹⁸⁾ and retinopathy^(19,20) may be mortality risk factors in diabetic patients. There is still a lack of a longitudinal study on survival and mortality risk factors of T2DM in Thailand. This prospective observational study aims to evaluate survival rates and identify risk factors related to all-cause and cardiovascular mortality in T2DM patients who have been followed-up clinically and biochemically for four years.

Material and Method

The Thai DMS Diabetes Complications project was a prospective observational 4-year study of Thai T2DM patients conducted from March 2006 to September 2010⁽²¹⁾. The materials and methods were the same as those used in our previous study⁽²¹⁾. The study was approved by the ethics review committee for research in human subjects, Ministry of Public Health. As in our previous study, patients were recruited from the out-patient department of seven public hospitals: Rajavithi Hospital (Bangkok); Lerdsin Hospital (Bangkok); Nopparatrajathanee Hospital (Bangkok); Mettaphacharak Hospital (Nakhon Pathom); Pathumthani Hospital (Pathumthani); Lardlumpkaew Hospital (Pathumthani); and Nongsau Hospital (Pathumthani). This study is a sub-project of the Thai DMS Diabetes Complications project which aims to evaluate kidney complications from T2DM. The inclusion criteria were T2DM Thai patients diagnosed according to the American Diabetes Association's criteria⁽²²⁾, over 18 years of age, and stable clinical and laboratory status for at least 3 months. Exclusion criteria were: pregnancy; breast-feeding; acute systemic diseases; end-stage renal disease; other renal diseases; and incomplete test results for diabetic nephropathy, retinopathy or neuropathy within the first year of the study. Signed written informed consent was obtained from all participants.

All patients continued to receive standard treatment from their doctors without interference from the project, and their clinical and laboratory status were evaluated annually for 4 years. History review, complete physical examination and laboratory tests of these patients were evaluated every year. Blood pressure was taken as the mean of two consecutive readings in the sitting position after at least 15 min rest. Hypertension was diagnosed using the criteria of the seventh report of the Joint National Committee (JNC7)⁽²³⁾ as: systolic blood pressure 130 mm Hg or more; diastolic blood pressure 80 mm Hg or more; or being treated with any

anti-hypertensive drugs. Uncontrolled hypertension was defined as systolic blood pressure of 130 mmHg or more and/or diastolic blood pressure of 80 mmHg or more, whether or not patients were receiving anti-hypertensive treatment. Body mass index (BMI) was used as an indicator of being overweight according to the World Health Organization criteria⁽²⁴⁾. Diabetic nephropathy was evaluated and diagnosed by a nephrologist. Yearly random spot urine samples from 3 consecutive visits were tested for urine albumin/creatinine ratio (UACR) within one hour of collection, and diabetic nephropathy was diagnosed if 2 out of 3 UACR showed more than 30 mg/gm. Diabetic retinopathy was evaluated and diagnosed by an ophthalmologist. Diabetic neuropathy was evaluated and diagnosed by a surgeon if patients had deficit in proprioceptive sensation and pulse deficit in their feet.

Fasting blood sugar, hemoglobin A1c (HbA1c), lipid and serum creatinine were tested twice monthly for 3 consecutive months; their means were taken as the final laboratory result and were used in the report. Glomerular filtration rate (GFR) was estimated using serum creatinine levels according to the abbreviated Modification of Diet in Renal Disease formula⁽²⁵⁾. CKD staging was classified by the NKF-K/DOQI definition of CKD⁽²⁶⁾. End-stage renal disease was diagnosed when patients had GFR below 5 ml/min/body surface area 1.73 m² or were receiving renal replacement therapy. Fasting blood sugar, HbA1c and serum creatinine levels were tested by hexokinase enzymatic, immunoturbidimetric (DCCT/NGSP) assay and the Jaffe method (rate-blanked and compensated) using a COBAS INTEGRA 400[®] analyzer (Roche Diagnostics, Indianapolis, IN, US). Urine albumin was quantified by immunoturbidimetric assay and urine creatinine concentration by the Jaffe method (rate-blanked and compensated) using COBAS INTEGRA 400[®] analyzer.

At the end of the 4-year study, the outcomes were classified as either survival or death. Data on mortality were obtained from hospital records or patients' families, who were contacted directly. Death certificates were retrieved from government register records at the Department of Provincial Administration of Thailand. All deaths were classified as all-cause mortality. Deaths from cerebrovascular accident, myocardial infarction and sudden death were classified as cardiovascular deaths. Deaths without an established non-cardiovascular cause were assumed to be cardiovascular deaths.

Data were expressed as mean, standard

deviation and percentages. Two-tailed student's t-test and analysis of variance (ANOVA) were used to compare continuous variables between groups. Pearson's chi square or Fisher's exact test were used to compare categorical variables between groups. Survival from all-cause and cardiovascular mortality was evaluated by Kaplan-Meier test. Multivariate Cox regression analysis was used to determine the baseline variables predictive of all-cause and cardiovascular mortality. The baseline variables were those used in our previous study as mortality risk factors: gender; age; obesity; smoking status; uncontrolled hypertension; using angiotensin converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB); HbA1c; LDL-C and diabetic nephropathy. Results are described as hazard ratio with 95% confidence intervals, and a *p*-value of less than 0.05 was considered statistically significant. All statistical analyses were performed using SPSS 17.0 (SPSS Inc., Chicago, Illinois, USA).

Results

A total of 1,120 stable T2DM patients from seven public hospitals were assessed as eligible but 23 were excluded due to incomplete data, and 1,097 were therefore enrolled. Table 1 shows characteristics and laboratory results of all patients. Most patients were female (71.0%), aged below 60 (53.1%), obese (66.7%), having family history of DM (56.1%), uncontrolled hypertension (62.7%), HbA1c above 7% (82.0%) with LDL-C above 100 mg/dl (80.8%), and 37.7% were hypertensive and on ACEI/ARB therapy. More patients with diabetic nephropathy were receiving ACEI/ARB than patients without it (42.8% vs. 35.2%, *p* = 0.028), and 5.3% were smokers. The prevalence rates of diabetic nephropathy, retinopathy and neuropathy were 38.4, 24.3 and 28.5% respectively.

At the end of 4 years, 80 of the patients (7.3%) had died. The causes of death were: cardiovascular disease (20 cases, 25.0%); infection (20 cases, 25.0%); malignancy (10 cases, 12.5%); end-stage renal disease (4 cases, 4.5%); and other causes (36 cases, 32.5%). The all-cause and cardiovascular mortality rates were 7.3% and 1.8% respectively. Fig. 1 shows the survival curve from all-cause mortality. Survival rates at 1, 2, 3, and 4 years were 98.9, 97.5, 96.2 and 92.7% respectively. Fig. 2 shows the survival curve from cardiovascular death. Survival rates at 1, 2, 3, and 4 years were 99.2, 98.4, 97.4 and 94.5% respectively.

Table 2 shows univariate and multivariate analysis for factors associated with all-cause mortality.

Table 1. Baseline characteristics and laboratory results of all 1,097 patients

Characteristic	Patients (n = 1,097)
Patient characteristic	
Female	779 (71.0)
Age (year)	52.9±10.0
Duration of DM (year)	7.3±6.1
Family history of DM	615 (56.1)
Smoking	58 (5.3)
Risk factors	
Hypertension	789 (71.9)
Uncontrolled hypertension	668 (60.9)
Using ACEI/ARB	414 (37.7)
Height (cm.)	156.0±7.5
Body weight (kg)	66.4±12.4
Body mass index (kg/m ²)	27.3±4.5
BP systolic (mmHg)	135.8±16.3
BP diastolic (mmHg)	74.3±9.4
Laboratory	
BUN (mg/dl)	84.9±26.3
GFR (ml/min/1.73m ²)	15.3±6.8
BUN (mg/dl)	0.9±0.4
Serum creatinine (mg/dl)	4.5±0.4
Serum albumin (mg/dl)	153.0±53.0
Fasting blood sugar (mg/dl)	8.7±1.8
HbA1c (%)	207.3±45.0
Serum cholesterol (mg/dl)	173.6±114.1
Serum triglyceride (mg/dl)	53.0±13.0
Serum HDL-C (mg/dl)	136.1±40.4
Serum LDL-C (mg/dl)	421 (38.4)
Complications	
Diabetic nephropathy	421 (38.4)
Diabetic retinopathy	267 (24.2)
Diabetic neuropathy	313 (28.5)

Values are presented as n (%) and mean ± SD

Univariate analysis showed that mortality risk factors were female gender, age over 60 year old, uncontrolled hypertension, using ACEI/ARB, diabetic nephropathy and diabetic retinopathy. Multivariate analysis revealed that the risk factors of age over 60 years and diabetic nephropathy were associated with all-cause mortality.

Table 3 shows univariate and multivariate analysis for factors associated with cardiovascular mortality. Univariate analysis showed that mortality risk factors were female, age over 60 years old, and diabetic nephropathy. Multivariate analysis, revealed that female gender, diabetic nephropathy and diabetic retinopathy were associated with cardiovascular mortality.

Discussion

Patients with T2DM place a burden on the health care system. As life expectancy increases, so too do chronic diabetic micro and macrovascular complications. Ischaemic cardiovascular diseases, retinopathy, nephropathy and amputation of extremities reduce the diabetic patients' quality of life, causing permanent disability and high mortality. This prospective 4-year follow-up study assessed the survival rates and mortality risk factors of a cohort of 1,097 T2DM patients in seven public hospitals. The study was out-patient based in secondary and tertiary general hospitals in the central area of Thailand.

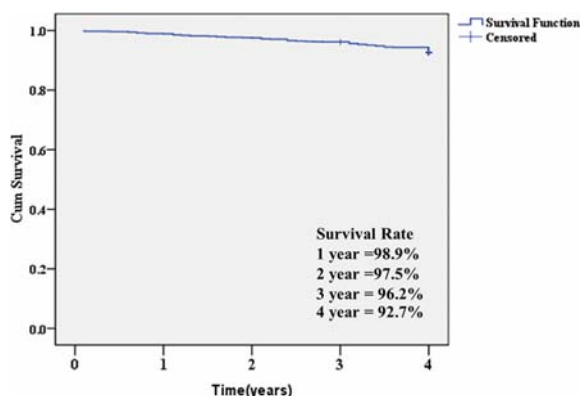


Fig. 1 Survival curve from all-cause mortality of these diabetic patients.

There were high prevalence rates of chronic microvascular and macrovascular complications in patients with T2DM. The incidence rates of chronic complications of T2DM including diabetic nephropathy, retinopathy and neuropathy in these patients were high at 38.4, 24.3 and 28.5% respectively, and this is in agreement with the findings of other studies^(27,28). These complications are associated with poor blood pressure and metabolic control⁽²⁹⁾. At the

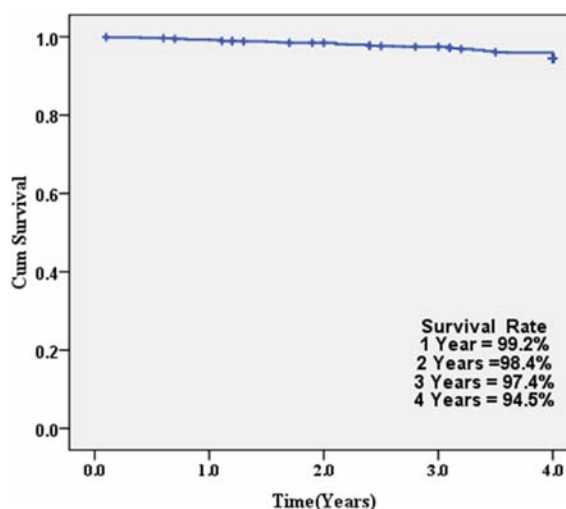


Fig. 2. Survival curve from cardiovascular death of these diabetic patients.

Table 2. Factors associated with the all-cause mortality of these patients

	HR (95% CI)	p-value
Univariate analysis		
Female	1.56 (1.01 to 2.44)	0.048*
Age >60 years	2.16 (1.37 to 3.43)	0.001*
Uncontrolled hypertension	2.26 (1.32 to 3.87)	0.003*
Using ACEI or ARB	1.61 (1.04 to 2.49)	0.034*
Smoking	1.13 (0.60 to 2.14)	0.705
HbA1c >7%	0.96 (0.55 to 1.68)	0.882
LDL-C >100 mg/dL	1.04 (0.59 to 1.82)	0.901
Diabetic nephropathy	2.03 (1.31 to 3.15)	0.002*
Diabetic retinopathy	2.09 (1.35 to 3.25)	0.001*
Multivariate analysis		
Female	1.39 (0.88 to 2.17)	0.156
Age >60 years	1.84 (1.15 to 2.94)	0.011*
BP >130/80	1.67 (0.96 to 2.90)	0.070
Using ACEI or ARB	1.31 (0.84 to 2.05)	0.232
Diabetic nephropathy	1.75 (1.12 to 2.75)	0.014*
Diabetic retinopathy	1.52 (0.96 to 2.42)	0.074

Values are presented as Median(min-max), * = Significant at $p < 0.05$

Table 3. Factors associated with the CVD mortality of these patients

	HR (95% CI)	p-value
Univariate analysis		
Female	1.89 (1.14 to 3.13)	0.013*
Age >60 years	1.75 (1.05 to 2.94)	0.033*
Uncontrolled hypertension	1.68 (0.95 to 2.98)	0.075
Using ACEI or ARB	1.29 (0.78 to 2.16)	0.324
Smoking	1.09 (0.52 to 2.30)	0.817
HbA1c >7%	0.88 (0.47 to 1.66)	0.702
LDL-C >100 mg/dL	0.86 (0.47 to 1.60)	0.643
Diabetic nephropathy	1.90 (1.14 to 3.15)	0.013*
Diabetic retinopathy	1.98 (1.18 to 3.34)	0.010*
Multivariate analysis		
Female	1.75 (1.05 to 2.94)	0.031*
Age >60 years	1.61 (0.96 to 2.71)	0.071
Diabetic nephropathy	1.72 (1.03 to 2.88)	0.039*
Diabetic retinopathy	1.74 (1.02 to 2.94)	0.041*

Values are presented as median (min-max); * = significant at $p < 0.05$

start of this study, over 50% of patients had poor control of blood pressure, blood glucose and blood lipids. Hypertension and hyperglycemia are especially well-established factors associated with chronic DM complication and efforts should be directed at their improved control in order to reduce complications. Physicians could emphasize the links of obesity, hypertension and blood glucose control with high mortality and disabilities and encourage patients to modify their lifestyle, diet and exercise.

The all-cause mortality rate in our patients was 7.3%. The most common causes of death were cardiovascular disease and infection. Risk factors of being aged over 60 years old and having diabetic nephropathy were associated with all-cause mortality, and this is consistent with data from other studies⁽¹⁸⁾. During the 4 years of the study, 1.8% of our patients died from cardiovascular disease. Female sex, diabetic nephropathy and diabetic retinopathy were associated with cardiovascular mortality. Chronic complications, especially diabetic nephropathy and retinopathy, were associated with high morbidity and mortality rates, and this is in keeping with the findings of previous research⁽¹⁸⁻²⁰⁾. This study did not show any relationship between mortality and other metabolic risks (such as smoking, hypertension, hyperglycemia or dyslipidemia), but proper management of metabolic control and appropriate blood pressure should be performed because it may help to retard chronic complications and reduce mortality rates in the future.

Glycemic control has shown the benefit in reducing the risk of chronic complications of diabetes. Control of hypertension is a well-established method of slowing progression of diabetic nephropathy, although multiple antihypertensive drugs may be required to keep blood pressure on target. Antihypertensive drugs, especially ACEI/ARB, have been recommended as medication for patients with T2DM to control blood pressure and delay diabetic nephropathy⁽²⁶⁾. Only 37.3% of all patients in this study had good blood pressure control with 37.7% of them receiving ACEI/ARB. Physicians should regularly monitor blood pressure of T2DM patients and prescribe appropriate medication to help reduce morbidity and mortality.

Some limitations of this study need to be taken into consideration. Firstly, changes in diabetic treatments, modifications of life styles or risk factors during the 4-year study could not be controlled and may have interfered with the mortality rates. Secondly, diabetic patients often have silent coronary heart disease, and some of our patients may already have had ischemic heart disease which we were unable to detect clinically from history and physical examination alone. For this reason the actual incidence could well be higher than our reported findings.

Conclusion

The survival rate of Thai patients with T2DM in the 4-year period was 92.7%. Age over 60 years old and diabetic nephropathy were associated with the all-

cause mortality, while female gender, diabetic nephropathy and diabetic retinopathy were associated with cardiovascular mortality. Diabetic nephropathy may be a contributor to mortality in patients with T2DM. The treatment of AECI/ARB can retard the progression of chronic complications, especially diabetic nephropathy, and may reduce mortality.

What is already known of this topic?

T2DM constitutes one of the most serious global public health problems because many patients with T2DM progress to cardiovascular disease and other chronic complications, leading to permanent disability and death. Diabetic patients have higher mortality rates than the general population, and atherosclerosis causing cardiovascular complications was a common cause of death in these T2DM patients. The mortality risk factors identified in previous studies were hypertension, dyslipidemia, poor glycaemic control, smoking, diabetic nephropathy and retinopathy.

What this study adds?

Thai patients with T2DM had a high prevalence of chronic complications including diabetic nephropathy, retinopathy and neuropathy. The survival rates of all-cause and cardiovascular mortality of Thai patients with T2DM in the 4-year period were 92.7% and 94.5% respectively. Female gender, age over 60 years old, diabetic nephropathy and retinopathy may be mortality risk factors of these patients.

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Potential conflict of interest

None.

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อัตราการรอดชีวิตและปัจจัยเสี่ยงต่อการเสียชีวิตในผู้ป่วยคนไทยที่เป็นโรคเบาหวานชนิดที่ 2

อุดม ไกรฤทธิชัย, สมเกียรติ โพธิ์สัตย์

ภูมิหลัง: โรคเบาหวานชนิดที่ 2 เป็นโรคที่เกิดปัญหาสุขภาพได้บ่อยจากภาวะแทรกซ้อนของหลอดเลือดเล็กและใหญ่ ข้อมูลเกี่ยวกับอัตราการรอดชีวิตและปัจจัยเสี่ยงต่อการเสียชีวิตในผู้ป่วยคนไทยที่เป็นโรคเบาหวานชนิดที่ 2 ควรได้รับการศึกษา

วัตถุประสงค์: เพื่อศึกษาอัตราการรอดชีวิตและปัจจัยเสี่ยงต่อการเสียชีวิตในผู้ป่วยคนไทยที่เป็นโรคเบาหวานชนิดที่ 2

วัสดุและวิธีการ: จากการศึกษา Thai DMS Diabetes Complications project ที่ติดตามเป็นเวลาต่อเนื่อง 4 ปี ในผู้ป่วยโรคเบาหวานชนิดที่สองจำนวน 1,120 ราย จากคลินิกผู้ป่วยนอกของโรงพยาบาลรัฐบาล 7 แห่ง ผู้ป่วยทุกคนได้รับการรักษามาตรฐานจากแพทย์ของผู้ป่วย อาการทางคลินิกและผลตรวจทางห้องปฏิบัติการจะได้รับการประเมินทุกปี เพื่อประเมินภาวะแทรกซ้อนทางระบบไต ตาและประสาท เมื่อสิ้นสุดปีที่ 4 จะมีการประเมินอัตราการรอดชีวิต รวมทั้งสาเหตุของการเสียชีวิต

ผลการศึกษา: ผู้ป่วยจำนวน 1,097 ราย สามารถเข้าศึกษาได้ตามเกณฑ์พบว่าเสียชีวิต 80 ราย (7.3%) เมื่อสิ้นสุดปีที่ 4 พบว่าผู้ป่วยเสียชีวิต 80 ราย (7.3%) สาเหตุการเสียชีวิตเกิดจากโรคหัวใจ 20 ราย (25.0%), ติดเชื้อ 20 ราย (25.0%), มะเร็ง 10 ราย (12.5%), ไตวายระยะสุดท้าย 4 ราย (5.0%) และสาเหตุอื่นๆ 26 ราย (32.5%) อัตราการรอดชีวิตจากสาเหตุทั้งหมดใน 1, 2, 3, 4 ปี เท่ากับ 98.9, 97.5, 96.2 และ 92.7% ตามลำดับ Hazard ratios (95% CI) ของปัจจัยเสี่ยงต่อการเสียชีวิตทั้งหมด คือ อายุเกิน 60 ปี 1.84 (1.15-2.94) และโรคไตเรื้อรังจากเบาหวาน 1.75 (1.12 ถึง 2.75) ส่วนอัตราการรอดชีวิตจากโรคหัวใจใน 1, 2, 3, 4 ปี เท่ากับ 99.2, 98.4, 97.4 และ 94.5% ตามลำดับ Hazard ratios (95% CI) ของปัจจัยเสี่ยงต่อการเสียชีวิตจากโรคหัวใจ คือ เพศหญิง 1.75 (1.05 ถึง 2.94) โรคไตเรื้อรังจากเบาหวาน 1.72 (1.03 ถึง 2.88) และโรคเบาหวานขึ้นจอประสาทตา 1.74 (1.02 ถึง 2.94)

สรุป: อัตราการรอดชีวิตใน 4 ปี ของผู้ป่วยคนไทยที่เป็นโรคเบาหวานชนิดที่ 2 เท่ากับ 92.7% ปัจจัยเสี่ยงต่อการเสียชีวิต ทั้งหมด คือ อายุเกิน 60 ปี และโรคไตเรื้อรังจากเบาหวาน ส่วนปัจจัยเสี่ยงต่อการเสียชีวิตจากโรคหัวใจ คือ เพศหญิง, โรคไตเรื้อรังจากเบาหวาน และโรคเบาหวานขึ้นจอประสาทตา
