Thailand Diabetes Registry Project: Prevalence of Diabetic Retinopathy and Associated Factors in Type 2 Diabetes Mellitus

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Objective: To determine the prevalence of and factors associated with Diabetic Retinopathy (DR) in type 2 diabetes in Thailand.

Material and Method: A cross-sectional, multicenter, hospital-based study was carried out between April and December 2003. Diabetic patients in diabetic clinics of 11 tertiary centers in Thailand were registered. Retinal examination of the participants was performed by ophthalmologists.

Results: 7,119 of 9,419 (75.6%) diabetic patients received retinal examination using direct ophthalmoscopy after full dilatation of pupils. 6,707 cases were type 2 diabetic patients. The prevalence of DR was 31.4% (N = 2105) which consisted of Non-Proliferative DR (NPDR) 22% (N = 1475), Proliferative DR (PDR) 9.4% (N = 630). Patients with DR were significantly older, had longer duration of diabetes, and higher Fasting Plasma Glucose (FPG), HbA1c, serum LDL, serum Tri Glyceride (TG) and systolic Blood Pressure (BP) levels than those without DR. Nephropathy (which consisted of positive microalbuminuria, proteinuria or renal insufficiency). The patients with DR presented in a significantly higher number of than those without DR. A. The factors associated with DR (adjusted Odds Ratio (OR) [95% CI]) were 1) duration of diabetes 1.4 [1.04-1.82] for duration of 5-9.9 years, 1.9 [1.47-2.58] for duration of 10-14.9 years, 2.9 [2.11-3.95] for duration of 15-19.9 years, 3.5 [2.58-4.79] for duration of ≥ 20 years when compared with duration of diabetes of less than 5 years, 2) latest HbA1c > 7% (1.5 [1.24-1.88]) when compared with HbA1c ≤ 7%, 3) systolic BP > 140 mmHg (1.4 [1.18-1.71]) when compared with systolic BP ≤ 140 mmHg, 4) nephropathy status i.e. positive microalbuminuria (1.5 [1.21-1.93]), positive proteinuria (1.9 [1.45-2.35]) and renal insufficiency (3.3 [2.29-4.70]) when compared with no nephropathy.

Conclusion: Diabetic retinopathy was present in about one third of type 2 diabetic patients in Thailand. The authors found the factors associated with DR were duration of diabetes, latest HbA1c level, systolic BP and diabetic nephropathy. Regular screening for DR and more aggressive management of associated factors should be done to reduce the prevalence of DR.

Keywords: Type2 diabetes, Diabetic retinopathy, Thailand, HbA1c, Hypertension, Diabetic nephropathy

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Diabetic Retinopathy (DR) is a sight-threatening, chronic microvascular complication that eventually afflicts most patients with Diabetes Mellitus (DM) despite the availability of various modalities of treatment. Up to 21% of patients with type 2 diabetes have retinopathy at the time of first diagnosis and more than 60% of those with type 2 diabetes have some degree of retinopathy twenty years after diagnosis(3). Although diabetic retinopathy does not cause obvious visual symptoms in the earlier stages, it threatens the sight of the patient once Proliferative Diabetic Retinopathy (PDR) or macular edema develops. According to the global update of available data on visual impairment in the year 2002(3), DR is a major global cause of total blindness. Its prevalence was estimated to be as high as 4.8 percent of the total of blindness. Furthermore, it is the leading cause of new-onset blindness among American adults aged 20-74 years(7) with an estimated 24,000 people losing vision each year as a consequence.

Epidemiologic studies and clinical trials have provided information on the incidence and prevalence of retinopathy and on the associated risk factors of retinopathy. Many important risk factors are identified to be related with progression of DR such as longer duration of diabetes, higher levels of glycosylated hemoglobin, higher blood pressure, and presence of proteinuria(1,4,5). Data on other factors including body mass index, male sex, serum lipids, and smoking have demonstrated varying results(1,4,6).

In Thailand, there were previous studies on the prevalence and the associated risk factors of DR, but the results varied greatly because of the differences in classification of DR and the demography of patients studied(7-10). Therefore, the purpose of the present study was to determine the prevalence and the factors associated with DR in type 2 diabetic patients recruited in Thailand Diabetes Registry Project.

**Material and Method**

**Setting and Subjects**

Thailand Diabetes Registry Project was a cross-sectional hospital-based study carried out during April to December 2003. It was conducted in the diabetic clinics of eleven tertiary care centers comprising of seven university hospitals, three regional hospitals and one private hospital of Thailand. The subjects in the present registry were diabetic patients who were treated in these diabetic clinics and agreed to participate in this registry. The diagnosis of DM was made according to the American Diabetes Association (ADA) criteria 1997(13). The total number of subjects was 9,419, and their clinical characteristics have been presented in the previous section of this issue. Among 7,119 patients (75.6%) who had received the retinal examination, 6,707 patients had type 2 diabetes and were included for further analysis.

**Method and Measurements**

The registry data were obtained by interviewing, examining the patients and reviewing their medical records, and recorded in the case record form. Data included demographic characteristics, pertinent parts of physical examinations, laboratory results, use of medications including insulin, oral hypoglycemic agents, antihypertensive agents, lipid lowering agents and aspirin, and diabetic complications.

Results of eye examination reported within one year prior to registry day were recorded, including the results of retinal examination, visual acuity, and the presence of cataracts. The retinal examination was evaluated by the ophthalmologists from each center with direct ophthalmoscopy after full dilatation of pupils. In the present study, DR was classified into only the Non-Proliferative Diabetic Retinopathy (NPDR) and Proliferative Diabetic Retinopathy (PDR) categories. NPDR was defined if it was characterized by an increase in vascular permeability or vascular closure; such as microaneurysms, dot and blot hemorrhage, or exudates. PDR was defined if vasoproliferation of new vessels occurred on or within the retina including complications such as vitreous hemorrhage or pre-retinal hemorrhage. Level of retinopathy was based on the grading of the worst eye. Visual acuity was assessed by Snellen’s chart. Legal blindness was defined as visual acuity of less than 6/60 in the better eye with best possible correction. Cataract findings were defined as positive or negative results.

Nephropathy was defined when a patient had at least one of the following condition; positive microalbuminuria within one year, defined by elevated urine microalbumin levels in at least two of three urine collections; positive proteinuria, defined as a positive urine dipstick test at 1+ level or more in at least two of three urine collections; or renal insufficiency, defined when serum Creatinine (Cr) was equal to or greater than 2 mg/dl. Any patient with negative urine microalbuminuria was defined as having no nephropathy.

The authors defined smoking status into three categories as following: current smokers were those who had continued smoking until the day of the examination or who quit smoking less than one year prior to
the day of the examination, ex-smokers were those who had stopped smoking at least one year prior to the day of the examination, and non-smokers were those who had never smoked. The authors defined alcoholic drinking status into three categories as following: current drinkers were those who continued drinking until the day of the examination, abstinence were those who had abstained from alcohol for at least one year prior to the day of the examination, and non-alcoholic drinkers were those who had never drunk alcohol or had drunk less than twice a month.

Fasting Plasma Glucose (FPG), serum total cholesterol, HDL Cholesterol (HDL-C) and triglyceride levels were determined by enzymatic methods. LDL Cholesterol (LDL-C) was calculated using the Friedewald’s formula (LDL-C = total cholesterol – HDL-C – TG/5). Glycosylated hemoglobin (HbA1c), plasma Cr, and urine microalbumin levels were determined by the central laboratory of each hospital using standard methods with local quality control. Urine analysis was performed by morning urine specimen.

Blood pressure was measured over the right arm twice, 30 seconds apart, after resting for 5 minutes, by automated blood pressure machines (OMRON T4) from Omron Corporation, Japan. Hypertension was defined as systolic blood pressure \( \geq 140 \text{ mmHg} \) and/or diastolic blood pressure \( \geq 90 \text{ mmHg} \), or patients being treated with antihypertensive drugs. Height and weight were measured in light clothing and body mass index was calculated as weight (kg)/height (m)\(^2\). Information on alcohol consumption, cigarette smoking, medication and history of diabetes were obtained by interview.

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

**Statistical analysis**

Descriptive statistics were applied to the study data. Categories of studied variables were compared with Chi-square test and Fisher’s exact test. Differences in mean values of variables were compared through student t-tests and Mann-Whitney U tests with 0.05 levels of significance. The crude Odds Ratio (OR) was calculated to define each associated factor with DR. Then confounding factors were adjusted by multiple logistic regression to determine the associated factors with DR. Whenever two variables were very similar and had multicollinearity, only one of them would be included in the model. Statistical analyses were performed using STATA version 8.0 (STATA Corporation, College Station TX, US).

**Results**

Six thousand seven hundred and seven patients with type 2 diabetes who had retinal examination were included for the analysis. There were 4,434 females and 2,273 males and their age ranged from 11 to 96 years. The duration of diabetes varied from newly diagnosed to 46 years. The prevalence of DR was 31.4% (N = 2105) and consisted of NPDR 22.0% (N = 1475) and PDR 9.4% (N = 630). As shown in Fig. 1, the majority of the presented patients were between 50 to 69 years-old. Increase in prevalence of DR was associated with increased age from 30 to 69 year-old, and the preva-
lence of DR demonstrated a peak at an age of 60-69 years-old at 36.8%. Moreover, the prevalence of DR in patients with type 2 diabetes increased with increased duration of diabetes from less than 5 years to 15 years as shown in Fig. 2. The authors found that the prevalence of cataracts was 44.3%. The prevalence of diabetes-related legal blindness was 1.5% and that of non-diabetic related legal blindness was 1.2%.

The clinical characteristics of patients according to DR status were demonstrated in Table 1. When the authors compared the clinical characteristics between diabetic patients with and without DR, those with DR were significantly older at the time of the examination, had longer duration of diabetes, higher systolic blood pressure, higher FPG, higher glycosylated hemoglobin, higher serum Cr, higher total cholesterol, higher triglyceride and higher LDL-C levels. Moreover, the percentage of patients with nephropathy was significantly higher in those with DR than those without. Both groups of patients were similar in terms of gender, alcohol consumption, smoking status, BMI, mean diastolic blood pressure, and HDL-C levels.

The proportions of diabetic patients categorized by levels of metabolic and blood pressure control are demonstrated in Table 2. This was done using the cut-off points based on the recommendations for adults with diabetes from the ADA\(^{13}\). Patients with DR had higher frequencies of glycosylated hemoglobin levels of more than 7%, systolic blood pressure levels of more than 140 mmHg, serum Cr levels of more than 2 mg/dl.

By multiple logistic regression, factors associated with DR were duration of diabetes, HbA1C, systolic blood pressure and presence of diabetic nephropathy (Table 3). No association was found between the presence of retinopathy and the smoking status.

Medications used among diabetic patients are shown in Table 4. Patients with DR more frequently used insulin, antihypertensive agents, lipid lowering agents and aspirin than those without DR.

**Discussion**

The present study is a large multicenter study on diabetic retinopathy in tertiary care centers in Thailand. It demonstrated that the prevalence of retinopathy in outpatients with type 2 diabetes was 31.4% (NPDR 22.0% and PDR 9.4%). The prevalence of DR in the present study was similar to that reported by a previous multicenter hospital-based study, reported in 1994, by the Thai Multicenter Research Group on DM\(^{7}\). In that study, the prevalence of DR was 32.1% (background DR 25.5% and proliferative DR 6.6%). Prevalence of DR, especially PDR, in the present study was higher compared to those found in other community-based studies and some studies from university or provincial hospitals in Thailand\(^{8,9,14,15}\). This demonstrated that the prevalence of NPDR ranged from 12 to 21% and PDR ranged from 2 to 5%. This could be partly explained by referral bias to the tertiary care centers.
### Table 1. Clinical characteristics of type 2 diabetic patients according to retinopathy status: the Diabetic Registry Project 2003

<table>
<thead>
<tr>
<th>Parameters*</th>
<th>DR (N = 2105)</th>
<th>No DR (N = 4602)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female (%)</td>
<td>65.5</td>
<td>66.4</td>
<td>NS</td>
</tr>
<tr>
<td>Age (years)</td>
<td>62.2±10.4</td>
<td>60.3±11.7</td>
<td>&lt;0.001</td>
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<tr>
<td>Duration of DM (years)</td>
<td>14.0±8.2</td>
<td>9.4±7.0</td>
<td>&lt;0.001</td>
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<tr>
<td>Duration of DM (years) (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 5</td>
<td>12.4</td>
<td>29.3</td>
<td></td>
</tr>
<tr>
<td>5-9.9</td>
<td>21.3</td>
<td>30.7</td>
<td></td>
</tr>
<tr>
<td>10-14.9</td>
<td>24.8</td>
<td>21.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>15-19.9</td>
<td>19.2</td>
<td>10.1</td>
<td></td>
</tr>
<tr>
<td>≥ 20</td>
<td>22.4</td>
<td>8.2</td>
<td></td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>25.6±4.2</td>
<td>25.8±4.2</td>
<td>NS</td>
</tr>
<tr>
<td>Current smokers and ex-smokers (%)</td>
<td>20.8</td>
<td>19.7</td>
<td>NS</td>
</tr>
<tr>
<td>Current drinkers and abstinence (%)</td>
<td>18.7</td>
<td>18.9</td>
<td>NS</td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>148.2±23.3</td>
<td>141.2±21.3</td>
<td>&lt;0.001</td>
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<tr>
<td>Diastolic BP (mmHg)</td>
<td>78.7±11.4</td>
<td>78.9±11.0</td>
<td>NS</td>
</tr>
<tr>
<td>Fasting plasma glucose (mg/dl)</td>
<td>156.5±60.7</td>
<td>150.6±51.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hemoglobin A1c (%)</td>
<td>8.6±1.9</td>
<td>8.0±1.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Serum creatinine (mg/dl)</td>
<td>1.3±1.0</td>
<td>1.1±0.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total cholesterol (mg/dl)</td>
<td>198.0±47.1</td>
<td>194.6±39.8</td>
<td>0.004</td>
</tr>
<tr>
<td>Triglyceride (mg/dl)</td>
<td>155.5±125.1</td>
<td>148.9±92.6</td>
<td>0.033</td>
</tr>
<tr>
<td>LDL cholesterol (mg/dl)</td>
<td>114.9±37.6</td>
<td>113.0±33.7</td>
<td>0.043</td>
</tr>
<tr>
<td>HDL cholesterol (mg/dl)</td>
<td>52.9±14.6</td>
<td>53.5±14.5</td>
<td>NS</td>
</tr>
<tr>
<td>Nephropathy (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive microalbuminuria</td>
<td>33.2</td>
<td>32.6</td>
<td></td>
</tr>
<tr>
<td>Positive proteinuria</td>
<td>31.8</td>
<td>23.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>13.5</td>
<td>5.0</td>
<td></td>
</tr>
</tbody>
</table>

* The parameter values are presented with mean ± SD and percentages

### Table 2. Metabolic and Blood pressure control in type 2 diabetic patients according to retinopathy status (N = 6707)

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Percentage of Patients with DR (N = 2105)</th>
<th>Percentage of Patients with No DR (N = 4602)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic BP &gt; 140 mmHg</td>
<td>59.5</td>
<td>46.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diastolic BP &gt; 90 mmHg</td>
<td>16.3</td>
<td>16.2</td>
<td>0.899</td>
</tr>
<tr>
<td>Fasting plasma glucose ≥ 130 mg/dl</td>
<td>66.9</td>
<td>67.3</td>
<td>0.740</td>
</tr>
<tr>
<td>Hemoglobin A1c &gt; 7 %</td>
<td>77.8</td>
<td>65.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Serum creatinine &gt; 2 mg/dl</td>
<td>8.8</td>
<td>3.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total cholesterol ≥ 200 mg/dl</td>
<td>43.5</td>
<td>41.9</td>
<td>0.233</td>
</tr>
<tr>
<td>Triglyceride &gt; 150 mg/dl</td>
<td>38.3</td>
<td>36.9</td>
<td>0.300</td>
</tr>
<tr>
<td>LDL cholesterol &gt; 100 mg/dl</td>
<td>62.9</td>
<td>62.4</td>
<td>0.697</td>
</tr>
<tr>
<td>HDL cholesterol &lt; 40 mg/dl (male)</td>
<td>33.9</td>
<td>32.2</td>
<td>0.197</td>
</tr>
<tr>
<td>&lt; 50 mg/dl (female)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Prevalence of retinopathy reported worldwide varied considerably, due to the difference in methodology and study populations. Most studies were population-based. The prevalence of DR and vision-threatening retinopathy among diabetic patients 40 years or older were 40.3% and 8.2% respectively as reported by the Eye Diseases Prevalence Research Group. Their crude prevalence of DR was higher than that from the
authors’ finding. The Australian Diabetes, Obesity and Lifestyle study (AusDiab study)\(^{17}\) reported the prevalence of DR and PDR of 21.9% and 2.1% in patients with type 2 diabetes, which is lower than ours figures. This may be explained partly by lower levels of glycosylated hemoglobin in their study population.

In agreement with earlier reports\(^{1,7-10,17}\), the present study demonstrated that the prevalence of DR increased with increasing duration of diabetes. Increase in DR prevalence was seen among diabetic patients from the WESDR\(^{11}\). This showed the rising of prevalence of any DR from 23% in people who had had diabetes for less than two years to 57.7% in people with the disease for more than 15 years. DR was found in 12.4% of our patients with duration of diabetes of less than 5 years, suggesting that detection and treatment of DR should not be neglected even in type 2 diabetic patients with relatively short duration.

The authors have also demonstrated that the occurrence of DR increased with increasing age, consistent with the results from the WESDR\(^{11}\). The present data showed an increasing DR prevalence with an increasing age from 30 to 69 year-old, peaking at 36.8% in the age group of 60 to 69 year-old. Nevertheless, the prevalence of DR decreased to 23.9% in diabetic patients whose ages were more than or equal to 70 years, which might be explained by an underestimation of DR in this age groups.

DM is a risk factor associated with acquired cataracts. Patients with diabetes are 2-4 times more likely to develop cataract than those without diabetes\(^{18}\). The prevalence of cataracts in the present study was 44.3%
nephropathy. The presence of microalbuminuria was the earliest clinical evidence in patients with diabetic retinopathy in previous studies(1,7,24). Microalbuminuria is consistent with a role in the development of diabetic nephropathy as evidenced by proteinuria or elevated serum creatinine levels. The present study was the presence of nephropathy. Renal disease, as evidenced by proteinuria or elevated serum creatinine level, was demonstrated to be a factor associated with diabetes. The prevalence of microalbuminuria was also significantly associated with the presence of retinopathy(25). Nevertheless, the relationship between diabetic nephropathy and DR is less predictable in type 2 diabetes than in type 1 diabetics. Type 2 diabetics with marked proteinuria and retinopathy are more likely to have diabetic nephropathy, whereas those without retinopathy have a higher incidence of nondiabetic glomerular disease.

The present study did not demonstrate the association between serum lipid levels and the occurrence of DR. The association between serum lipids and retinopathy was not consistent. However, two studies, the ETDRS and the WESDR(6,26) have demonstrated that cholesterol was a significant factor in determining the severity of retinal hard exudates, but not the severity of retinopathy in any group. Cigarette smoking was not demonstrated to be associated with retinopathy in the present study. This is in agreement with the results of WESDR(27) that also found no significant relationship between cigarette smoking and DR. Nevertheless, the failure to find an association between smoking and DR does not imply that people with diabetes who smoke should not stop. Cigarette smoking is a strong risk factor for other diabetic complications, especially cardiovascular disease.

Finally, the present study had some limitations due to its design. It was a cross-sectional study and it could demonstrate only the association between the risk factors and the occurrence of DR rather than identifying any causation. However, the present study has demonstrated many metabolic risk factors associated with the occurrence of DR. Early detection and intervention for DR in combination with aggressive glycemic and blood pressure control would reduce the prevalence of DR and, therefore, reduce the numbers of patients who develop vision-threatening retinopathy.

Conclusion

DR affects about one third of type 2 diabetic patients in diabetic clinics of tertiary centers in Thailand. The authors found cataracts in nearly half of the diabetic patients and the prevalence of DM related legal blindness was 1.5%. The prevalence of DR increased with the age of patients and the duration of diabetes. Factors associated with the occurrence of DR in type 2 diabetics were duration of diabetes, HbA1c, systolic blood pressure, and the presence of nephropathy that consisted of positive microalbuminuria, positive proteinuria or renal insufficiency. Regular screening for DR and more aggressive management of metabolic factors should be done to reduce the prevalence of DR.
Acknowledgements

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โครงการลงทะเบียนผู้ป่วยเบาหวานในประเทศไทย: ความชุกและปัจจัยที่สัมพันธ์กับเบาหวานในจอประสาทตาในผู้ป่วยเบาหวานชนิดที่สอง

ธัญญา เขยญกุล, ชัยชาญ ดีโรจนวงศ์, สมพงษ์ สุวรรณวลัยกร, ณัฐพงศ์ โฆษชุณหนันท์, ฉัตรประภานุพงษ์ งามอุโฆษ, เพชร รอดอารีย์, สิริเนตร กฤติยาวงศ์, ยุพิน เบ็ญจสุรัตน์วงศ์, สิริมา มงคลสัมฤทธิ์

วัตถุประสงค์: เพื่อศึกษาความชุกและปัจจัยที่สัมพันธ์กับเบาหวานในจอประสาทตาในประเทศไทย

วัสดุและวิธีการ: ทำการศึกษาแบบภาพตัดขวางแบบ hospital-based ในหลายสถาบัน ตั้งแต่ เมษายน พ.ศ. 2546 ถึง ธันวาคม พ.ศ. 2546 โดยทำการลงทะเบียนผู้ป่วยเบาหวานที่มารักษาในคลินิกเบาหวานของโรงพยาบาลตติยภูมิ 11 แห่ง และมีจักษุแพทย์เป็นผู้ตรวจจอประสาทตาของผู้ป่วยเบาหวาน

ผลการศึกษา: มีผู้ป่วย 9,419 รายที่ได้รับการลงทะเบียน ได้แก่ 7,119 รายได้รับการตรวจจอประสาทตาประกอบด้วยผู้ป่วยเบาหวานชนิดที่สอง 6,707 ราย พบความชุกของเบาหวานในจอประสาทตาของเบาหวานชนิดที่สองร้อยละ 31.4 ประกอบด้วย NPDR ร้อยละ 22 และ PDR ร้อยละ 9.4 พบว่าผู้ป่วยที่มีโรคของเบาหวานในจอประสาทตา มีอายุมากกว่า มีระยะเวลาเป็นเบาหวานมากกว่า มีระดับน้ำตาลในเลือดสูง, น้ำตาลสะสมสูง, ไขมันแอลดีแอลสูง, ไตรกลีเซอริดสูง, และการสูบบุหรี่ มีอายุมากกว่าเพิ่มความเสี่ยงให้ดีไซนัทีโอสูงกว่าผู้ป่วยที่ไม่มีโรคของเบาหวานในจอประสาทตาอย่างเห็นได้ การตรวจจอประสาทตาอย่างสม่ำเสมอ การควบคุมปัจจัยทางเมตาบอลิกอย่างเข้มงวด และการบริหารจัดการโรคความดันโลหิตสูง โรคไต อาจช่วยลดความเสี่ยงของโรคของเบาหวานในจอประสาทตาได้.