

# Glycated Haemoglobin and Diabetic Retinopathy in Type 2 Diabetic Patients in HRH Princess Maha Chakri Sirindhorn Medical Center

Peerapat Tangjai MD\*,  
Preerati Chingchana MD\*, Rutchaporn Taweerutchana MD\*

\* Division of Endocrinology and Metabolism, Faculty of Medicine, Srinakharinwirot University, Nakhon Nayok, Thailand

**Objective:** Diabetic retinopathy (DR) is an important cause of blindness in type 2 diabetic patients. When it occurs, it affects the patient's quality of life including their physical activity, emotion, mentality, and social interactions. Therefore, the objectives of this research were to study the relationship between glycaemic control and DR and the relationship between DR and other factors. We also aim to find the optimal cut-off point to screen diabetic retinopathy using glycated haemoglobin (HbA<sub>1c</sub>) levels.

**Material and Method:** We performed a case-control study. One hundred patients were divided into two groups (50 patients for DR group and 50 patients for non-DR group). Their HbA<sub>1c</sub>, weight, height, blood pressure, and lipid profiles were retrospectively reviewed by Electronic Medical Record (EMR). The data was analysed using both Chi-square test and logistic regression with two-tailed hypothesis.

**Results:** The research revealed that uncontrolled glycaemic in type 2 diabetic patients was significantly related to DR (Adjusted odds ratio 8.89, 95% CI = 2.3-18.00, p-value <0.001). In addition, it occurred more commonly in males (Adjusted odds ratio 6.41, 95% CI = 3.02-26.25, p-value <0.001). A cut-off level of HbA<sub>1c</sub> for screening DR is 7.25% (sensitivity 84%, specificity 66%, positive predictive value = 71.2%, negative predictive value = 80.5%).

**Conclusion:** HbA<sub>1c</sub> level and male gender are strongly related to DR (p<0.001) and the optimal cut-off level for DR screening is 7.25% in type 2 diabetic patients that were treated in HRH Princess Maha Chakri Sirindhorn Medical Center.

**Keywords:** Glycaemic control, Microvascular complication, Diabetic retinopathy, HbA<sub>1c</sub>, Hypertension, Dyslipidemia

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Recently, the number of patients diagnosed with diabetes has greatly increased<sup>(1)</sup> to the extent that it has become problematic for medical professionals to provide comprehensive care for all patients in need. Diabetes is a disease that cannot be entirely cured. Diabetic patients require people to care for them, medications, treatments, and many other high cost expenses. This disease can also bring about undesirable complications that can cause disabilities or even death<sup>(2)</sup>. One of the most crucial and most common of these complications is diabetic retinopathy.

Diabetic retinopathy (DR) is a very significant factor that causes patients to lose their vision. Information from a survey shows that the number of

DR patients has reached 65,000 in the United States; of which 28.5 percent are people age 40 and above<sup>(1)</sup>. Being affected DR depends on factors such as how long the patients have been afflicted with diabetes, glycated haemoglobin (HbA<sub>1c</sub>) present in the blood, hypertension, and dyslipidemia. DR greatly affects the quality of life of these patients<sup>(2,3)</sup>, decreases their ability to enjoy life by preventing them from doing their daily activities with ease, and is disease costly to treat.

Considering all the facts mentioned before, it is crucial to take notice of this disease and prevent its complications. Thus, this study was conducted to investigate the relationships between HbA<sub>1c</sub> level and other factors that may cause DR such as hypertension, dyslipidemia, gender, age, and body mass index (BMI) of the type 2 diabetic patients in HRH Princess Maha Chakri Sirindhorn Medical Center. Additionally, this research attempts to determine the optimal cut-off point for screening patients who have a tendency to develop DR complications. The data for this research was obtained through HRH Princess Maha Chakri

## Correspondence to:

Taweerutchana R, Division of Endocrinology and Metabolism, Faculty of Medicine, Srinakharinwirot University, HRH Princess Maha Chakri Sirindhorn Medical Center, Rangsit-Nakhon Nayok Road, Ongkharak, Nakhon Nayok 26120, Thailand.  
Phone: +66-37-395085 ext. 11001-3  
E-mail: [bbbell@gmail.com](mailto:bbbell@gmail.com)

Sirindhorn Medical Center electronic medical record (EMR).

In this study, we anticipated a good prevention and minimization risk of DR in diabetic patients which resulted in better quality of life, reducing costs of treatment and great achievement of patient care.

### Material and Method

This research was conducted using a case control study on type 2 diabetic patients in HRH Princess Maha Chakri Sirindhorn Medical Center. The criteria of this research are limited to patients between the age of 45-65 with Thai nationality who have been diagnosed with diabetes for five or more years, still receive treatment and care from the HRH Princess Maha Chakri Sirindhorn Medical Center outpatient department, have been diagnosed with or without a DR complication by an ophthalmologist using slit lamp, were not pregnant, and have never received erythropoietin hormones. The patients were then divided into two groups: a group of diabetic patients who have been diagnosed with a DR complication and a group without DR complications. The samples were chosen from patients using a simple random sampling method. The number of patients in each group of the sample was calculated using two separate statistical formulas. One was by setting the prevalence of type 2 diabetic patients with DR without glycaemic control to 0.78. The other was by setting the prevalence of type 2 diabetic patients with retinopathy and glycaemic control to 0.22, according to Thanya et al<sup>(4)</sup>. Type I error of this research was at 5%, calculated into  $Z\alpha/2 = 1.96$  and type II error of this research was at 20% (power = 80%), calculated into  $Z\beta = 0.842$ . The calculated sample size at least 10 patients. However, in this study we collect data from 100 patients (50 patients per group) to achieve the best statistical analysis.

The level of HbA<sub>1c</sub> in DR patients was collected using the average data over a period of one year prior to diagnosis of DR. For non-DR patients, the level of HbA<sub>1c</sub> was collected using the average data over a period of one year before the most recent eye examination. Moreover, information on potential risk factors such as hypertension, dyslipidemia, gender, age, and BMI were collected using data from the participants and EMR from the HRH Princess Maha Chakri Sirindhorn Medical Center.

The data was categorized into different types for interaction testing. An analysis also took place to see if there was any relationship between hypertension,

dyslipidemia, gender, age, BMI and DR complication in type 2 diabetic patients by using bivariate statistical analysis with Chi-square test and multivariate analysis to control confounding variables. This was completed using two-tailed test with  $p \leq 0.05$ .

Definition for this research include:

1) HbA<sub>1c</sub> is haemoglobin that is measured the average plasma glucose concentration by turbidimetric inhibition immunoassay.

2) Diabetic retinopathy was diagnosed by an ophthalmologist using a slit lamp including diabetic macular oedema.

3) Controllable type 2 diabetes is considered when the patient has HbA<sub>1c</sub> level lower than 7%<sup>(5)</sup> during a period of one year before DR is identified.

4) Uncontrolled type 2 diabetes is considered when the patient has HbA<sub>1c</sub> equal to or higher than 7%<sup>(5)</sup> during a period of one year before DR is identified.

5) Hypertension is a condition when the diabetic patient developed blood pressure more than 140/90 mmHg or has been using any anti-hypertensive medications recently at least one year before DR is identified.

6) Dyslipidemia is when the patient's total cholesterol is higher than 200 mg/dl and/or LDL level is higher than 100 mg/dl and/or HDL level is lower than 40 mg/dl and/or triglyceride level is higher than 150 mg/dl<sup>(5)</sup>. That was diagnosis in during period of one year before examination of DR.

7) BMI according to Thai criterion: 18.50 to 22.99 kg/m<sup>2</sup> is considered normal, 23.00 to 24.99 kg/m<sup>2</sup> is considered overweight, and 25 kg/m<sup>2</sup> and above is considered obese.

### Results

The participants were categorized into a group of DR patients and a control group of non-DR patients, fifty patients of each group were selected from total 7,065 patients by random sampling method. Data on the patients' gender, BMI, blood pressure, HbA<sub>1c</sub> level and dyslipidemia were also collected and are displayed in Table 1.

Bivariate analysis shows that there is a relationship between diabetic retinopathy and other factors such as gender, high blood pressure, dyslipidemia, and glycated haemoglobin.

Using statistics to correlate factors and diabetic retinopathy, it was found that HbA<sub>1c</sub>  $\geq 7\%$  and male gender are risk factors in contracting DR in Table 2.

The relationship between DR and HbA<sub>1c</sub> is

**Table 1.** Overall information of participants and analysis between diabetic retinopathy and other factors

Factors	Mean age (year)	Mean HbA <sub>1c</sub> (%)	Number	DR (n = 50)	Non-DR (n = 50)	p-value*
Glycated haemoglobin						
Controlled	54.9	6.5	36 (36%)	8 (16%)	28 (56%)	<0.001
Uncontrolled	54.2	8.8	64 (64%)	42 (84%)	22 (44%)	
Gender						
Male	55.1	8.2	42 (42%)	30 (60%)	12 (24%)	<0.001
Female	54.0	7.9	58 (58%)	20 (40%)	38 (76%)	
BMI						
Normal	54.8	8.1	20 (20%)	9 (18%)	11 (22%)	0.470
Overweight	55.2	8.1	24 (24%)	10 (20%)	14 (28%)	
Obese	54.0	8.0	56 (56%)	31 (62%)	25 (50%)	
Hypertension						
Yes	54.9	7.8	63 (63%)	38 (76%)	25 (50%)	0.037
No	53.7	8.5	37 (37%)	12 (24%)	25 (50%)	
Dyslipidemia						
Yes	54.3	7.8	77 (77%)	45 (90%)	32 (64%)	0.002
No	54.8	8.7	23 (23%)	5 (10%)	18 (36%)	

\* p-value based on Chi-square test, Mean age of DR patients are 55.5 years, non DR are 53.3 years, mean HbA<sub>1c</sub> are 8.06%

**Table 2.** The relationship between each factor and diabetic retinopathy using multiple logistic regression

Factors	Crude OR	95% CI	p-value	Adjusted OR*	95% CI	p-value
Glycated haemoglobin						
Controlled	1	-	-	1	-	-
Uncontrolled	6.68	2.61-17.10	<0.001	8.9	2.32-18.0	<0.001
Gender						
Female	1	-	-	1	-	-
Male	4.75	2.01-11.24	<0.00	6.41	3.02-26.25	<0.001
Hypertension						
No	1	-	-	1	-	-
Yes	3.16	1.35-7.43	0.008	2.22	0.77-6.36	0.14
Dyslipidemia						
No	1	-	-	1	-	-
Yes	5.06	1.70-15.05	0.004	2.10	0.56-8.26	0.28

\* Significant factors as glycated haemoglobin, gender, hypertension and dyslipidemia from univariate analysis were calculated as adjusted odds ratio (adjusted OR) in this multiple logistic regression model

shown as ROC curve (Fig. 1). We found that HbA<sub>1c</sub> cut-off point more than 7.25% carried the highest true predictive value (PPV 71.2%), sensitivity (81%), and specificity (66%). Regarding ADA 2015 the HbA<sub>1c</sub> level less than 7 is recommended to minimize risk of microvascular complications. At HbA<sub>1c</sub> level of 7% the sensitivity and specificity for retinopathy detection are 85% and 59%, respectively, and at HbA<sub>1c</sub> level of 6.5%, the sensitivity and specificity are 97% and 23%,

respectively (Table 3). Therefore, the lower the HbA<sub>1c</sub> cut-off point level, the higher the sensitivity of the test for early detection of DR.

## Discussion

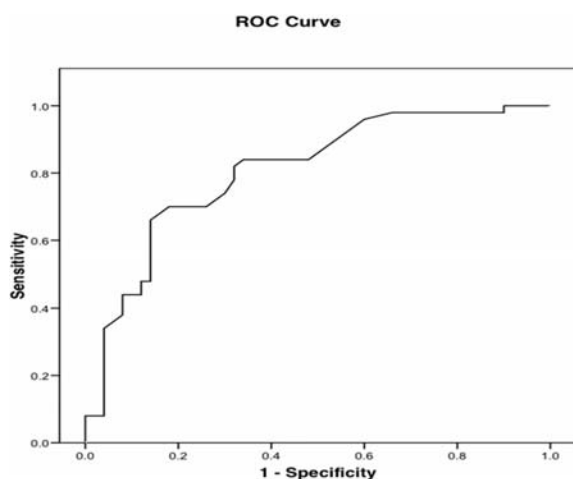
The results of this study indicate that type 2 diabetes patients who are not able to control their glycated haemoglobin levels according to the ADA 2015 guidelines<sup>(4)</sup> were at a higher risk of contracting

**Table 3.** Sensitivity and specificity of HbA<sub>1c</sub> cut-off point for prediction of DR

HbA <sub>1c</sub> cut-off point	Sensitivity	Specificity	PPV	NPV
7.25	84	66	71.2	80.5
7.00	85	59	68.0	79.3
6.50	97	23	56.5	90.0

AUC = 0.808, 95% CI = (0.72-0.89), *p*-value <0.001

PPV = Positive predictive value; NPV = Negative predictive value

**Fig. 1** The relationship between diabetic retinopathy and glycated haemoglobin.

diabetic retinopathy than those patients who could. This result is reinforced by the fact that the higher the plasma glucose, the more vulnerable the patients were of contracting diabetic retinopathy. Crawford et al<sup>(6)</sup> found that a high glycated haemoglobin level can cause a distortion in the shape and function of retinal capillaries decreasing their efficiency. Once this occurs the retinal tissue will lack oxygen causing it to release vascular endothelial growth factor (VEGF), resulting in angiogenesis around the retinal tissue. This theory is supported by many findings, including those of Adamis et al<sup>(7)</sup>, which showed that VEGF in the vitreous humour of diabetic retinopathic patients was significantly higher than that of the control group. This confirmed that there was an increase in VEGF. Moreover, a study by Wells et al<sup>(8)</sup> discussed the use of a treatment to resist VEGF by using VEGF-neutralizing antibodies to treat patients with macular oedema and patients with diabetic retinopathy. This treatment improved vision by 25-30% according to a visual acuity test<sup>(9-11)</sup>.

Additional studies support this research, Srisuda<sup>(12)</sup> in a case controlled study reported that the

higher glycated haemoglobin is related to a higher frequency of retinopathy. Another study compared a group of diabetic patients under intensive glycated haemoglobin therapy with a group with diabetic retinopathy. The UK Prospective Diabetes Study (UKPDS)<sup>(13)</sup> found that tight glycaemic control can decrease risk for any diabetic related end point (12% lower compared with conventional group) and most of risk reduction was due to a reduction in microvascular complication<sup>(13)</sup>. Excessive glycaemic control however may result in death due to cardiovascular disease according to a study by ACCORD study<sup>(14)</sup>.

As for factors related to diabetic retinopathy, statistical analyses in this study found that males had a significant higher tendency (6.41%) for contracting diabetic retinopathy than females. Chaurasia et al<sup>(15)</sup> explained that diabetic patients have higher levels of testosterone when compared to non-diabetics. Moreover, when considering levels of testosterone, it was found that diabetic patients with diabetic retinopathy had a significantly higher level of testosterone than diabetic patients without diabetic retinopathy.

Thus, it can be concluded that male patients are at a higher risk than female in contracting diabetic retinopathy. This finding agrees with a study by Klein et al<sup>(16)</sup>, which found that male gender is a factor that contributes to diabetic retinopathy. Currently, an insight study on the pathological physiology of sex hormones and their relationship with diabetic retinopathy has yet to be conducted. In addition, this study found that high blood pressure is not significantly related to diabetic retinopathy. The development of diabetic retinopathy is similar to other diabetic complications. Thus, it is essential that patients appropriately undergo glycaemic treatments and blood pressure tests. The National Cholesterol Education Program in 2012<sup>(17)</sup> has specified the appropriate index for blood pressure and other related factors to help to reduce side effects and complications of diabetes. Another study by Adler et al<sup>(18)</sup>, which referred to UKPDS, states that diabetes

and high blood pressure are contributing factors for causing microvascular complications<sup>(19)</sup>. In 2005, it was found that microvascular complications caused by high blood pressure and diabetes resulted from VEGF production becoming more active. This caused a build up of capillaries in various areas including the retina impairing vision. Currently, the appropriate high blood pressure control to help prevent diabetic retinopathy is still inconclusive. Nevertheless, the reason this study did not find a relationship between diabetic retinopathy and high blood pressure may be that the population sample was too small due to the wide confidence interval. Alternatively, the group of patients who could not control their blood pressure were under close watch and intensive care so they contracted diabetic retinopathy less often than the group of patients not under watch.

Few studies have demonstrated that DR is related to dyslipidemia. Chew et al<sup>(20)</sup> found that the higher hypercholesterolemia becomes the greater the risk for developing DR up to a two times greater chance of forming a hard exudate. Also, The ACCORD Study Group and ACCORD Eye Study Group<sup>(21)</sup> showed that intensive control of glucose and lipid level could slow progression of DR. Additionally, patients undergoing intensive treatment had a lowered chance of 4 year progression to diabetic retinopathy from 10.2% to 6.5% compared to the control group<sup>(21)</sup>. The results of our study however indicated no relationship between dyslipidemia and DR.

The results of this study indicated that the BMI in patients does not significantly relate to diabetic retinopathy. This finding is not correlate with findings in other works. A study by Dirani et al<sup>(22)</sup> found that patients with higher BMI had a higher chance of contracting diabetic retinopathy (6.5 more times) compared to those with normal BMI. In addition, those with higher BMI had a higher tendency of experiencing worsening symptom. This result corresponded with a study by Katusic et al<sup>(23)</sup>, which found that not only does a high BMI worsen symptoms, it could also lead to higher blood pressure and higher glycated haemoglobin level. The reason for this deviation may be that the population sample was too small. In addition, the BMI cannot always be correlated with obesity, since the calculation of BMI is also influenced by gender, ethnicity, and illness. BMI gives neither an accurate indication of fat nor resistance to insulin in a patient. For example, a person with a high BMI may have a dense musculature.

The ROC curve demonstrate a relationship

between diabetic retinopathy and glycated haemoglobin. It indicates that merely one year of poorly controlled HbA<sub>1c</sub> significantly increased the risk of developing DR, particularly those patient whose HbA<sub>1c</sub> level >7.25%. Thus, HbA<sub>1c</sub> level should be strictly controlled in diabetic patients which is in agreement with the ADA 2015 recommendation for controlling of HbA<sub>1c</sub> under 7% to prevent microvascular complication. Furthermore, early screening for diabetic retinopathy should be performed in all diabetic patients to prevent the disease progression.

The limitations of this research include a discrepancy with other studies regarding the prevalence of diabetic retinopathy in patients with and without appropriate glycaemic treatment. It is possible that a small sample size was unable to show a connection between DR and other factors. It would be advisable to investigate correlations between other factors that were studied, as they could reveal a relationship to DR. In addition, there were some systematic errors that occurred in this study. Moreover, other potential limitations of this study include incomplete database collection.

Intensive glycaemic treatment in type 2 diabetic patients and gender are significantly correlated with diabetic retinopathy. The optimal cut-off point in screening patients for risk of diabetic retinopathy is when the level of glycated haemoglobin is at 7.25% in type 2 diabetic patients under the care of HRH Princess Maha Chakri Sirindhorn Medical Center.

Future studies on this matter should focus on calculating sample sizes based on other factors, and sample populations should be as large as possible to optimize the potential for discovering connection between diabetic retinopathy and unknown factors. It is also advisable to further this research by conducting a study with experimental randomized control trials of glycaemic treatment to reduce confounding variables.

## Conclusion

HbA<sub>1c</sub> level and male gender are significantly related to diabetic retinopathy and the optimal HbA<sub>1c</sub> level cut-off level for screening diabetic retinopathy is 7.25% in type 2 diabetic patients in HRH MSMC from this retrospective study. However, study larger number of sample size and randomized control trials study are recommended to identify the other potential risk factors associated with diabetic retinopathy.

## What is already known on this topic ?

According to Thailand Diabetes Registry



Project<sup>(4)</sup>: Prevalence of Diabetic Retinopathy and Associated Factors in Type 2 Diabetes Mellitus, high glycated haemoglobin level caused an increase in prevalence of diabetic nephropathy, duration of diabetes, systolic blood pressure, as well as diabetic nephropathy which is correlated to ADA 2015<sup>(5)</sup>.

#### What this study adds ?

This report exhibited significant impact of gender and glycated haemoglobin level on the prevalence of diabetic retinopathy. As the result preciously displayed on ROC curve, one year of poorly controlled HbA<sub>1c</sub> potentially increased risk of developing diabetic retinopathy, especially in those whose HbA<sub>1c</sub> level >7.25%. Thus, in accordance with ADA guideline 2015, strictly controlled of HbA<sub>1c</sub> level in diabetic patients should be emphasized. Moreover, early screening for diabetic retinopathy is recommended for all diabetic.

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#### Potential conflicts of interest

None.

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ระดับน้ำตาลสะสมในเลือดกับภาวะเบาหวานขึ้นจอประสาทตาในผู้ป่วยเบาหวานชนิดที่ 2 ที่เข้ารับการรักษาในศูนย์การแพทย์สมเด็จพระเทพรัตนราชสุดาฯ สยามบรมราชกุมารี

พีรพัฒน์ ต่างใจ, ปรีดีรติ ชิงชนะ, รัชพร ทวีรุ่งชนะ

**วัตถุประสงค์:** เพื่อศึกษาความสัมพันธ์ระหว่างการควบคุมระดับน้ำตาลสะสมในเลือด รวมทั้งปัจจัยเสี่ยงอื่นๆ ต่อภาวะเบาหวานขึ้นจอประสาทตาในผู้ป่วยซึ่งเป็นสาเหตุสำคัญของตาบอด ส่งผลกระทบต่อการใช้ชีวิตของผู้ป่วยที่มารับบริการที่ศูนย์การแพทย์สมเด็จพระเทพรัตนราชสุดาฯ สยามบรมราชกุมารี และศึกษาเกณฑ์ที่เหมาะสมในการตรวจคัดกรองผู้ป่วยที่มีแนวโน้มเป็นภาวะเบาหวานขึ้นจอประสาทตา

**วัสดุและวิธีการ:** งานวิจัยในครั้งนี้ใช้รูปแบบ case-control ศึกษาในกลุ่มผู้ป่วยเบาหวานชนิดที่ 2 โดยแบ่งตัวอย่างเป็น 2 กลุ่ม คือ กลุ่มที่ได้รับการวินิจฉัยภาวะเบาหวานขึ้นจอประสาทตา และกลุ่มที่ไม่มีภาวะเบาหวานขึ้นจอประสาทตาอย่างละ 50 คน จากนั้นเก็บข้อมูลการควบคุมระดับน้ำตาลสะสมในเลือดย้อนหลัง 1 ปีก่อนการวินิจฉัย และเก็บข้อมูลปัจจัยเสี่ยงอื่นๆ โดยทำการวิเคราะห์ข้อมูลเชิงคุณภาพด้วย Chi-square test และวิเคราะห์สหสัมพันธ์ด้วย logistic regression ทดสอบสมมติฐานแบบสองทางด้วยค่า  $p \leq 0.05$

**ผลการศึกษา:** พบว่าการควบคุมระดับน้ำตาลสะสมในเลือดในผู้ป่วยโรคเบาหวานประเภทที่ 2 มีความสัมพันธ์กับการเกิดภาวะเบาหวานขึ้นจอประสาทตาอย่างมีนัยสำคัญทางสถิติ Adjusted odds ratio 8.89, 95% CI = 2.3-18.00,  $p$ -value <0.001 และพบความสัมพันธ์กับการเกิดภาวะเบาหวานขึ้นจอประสาทตาในผู้ป่วยโรคเบาหวานชนิดที่ 2 อย่างมีนัยสำคัญทางสถิติ Adjusted odds ratio 6.41, 95% CI = 3.02-26.25,  $p$ -value <0.001 การใช้ระดับน้ำตาลสะสมในเลือด 7.25% เป็นจุด Cut-off point ในการเกิดภาวะเบาหวานขึ้นจอประสาทตา sensitivity 84%, specification 66%, positive predictive value = 71.2%, negative predictive value = 80.5%

**สรุป:** การควบคุมระดับน้ำตาลสะสมในเลือดของผู้ป่วยโรคเบาหวานชนิดที่ 2 และเพศชายมีความสัมพันธ์กับการเกิดภาวะเบาหวานขึ้นจอประสาทตาอย่างมีนัยสำคัญทางสถิติ และเกณฑ์ที่เหมาะสมในการตรวจคัดกรองผู้ป่วยที่มีแนวโน้มเป็นภาวะเบาหวานขึ้นจอประสาทตา คือ ค่าระดับน้ำตาลสะสมในเลือดที่ 7.25% ในผู้ป่วยเบาหวานชนิดที่ 2 ที่เข้ารับการรักษาในศูนย์การแพทย์สมเด็จพระเทพรัตนราชสุดาฯ สยามบรมราชกุมารี

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