

Blood Glucose Patterns in Type 2 Diabetic Patients with Optimal Fasting Plasma Glucose but High HbA_{1c}

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Background: Achieving fasting plasma glucose (FPG) target may not reflect hemoglobin A_{1c} (HbA_{1c}) target achievement.

Objective: Illustrate the blood glucose patterns contributing to HbA_{1c} > 7% in patients whose FPG was < 130 mg/dl and correlation between HbA_{1c} and plasma glucose at various times. The contribution of caloric intake, carbohydrate consumption and glycemic index of food to plasma glucose were determined.

Material and Method: Patients with type 2 diabetes, attended out-patient clinics at Siriraj Hospital, who had FPG of < 130 mg/dl but HbA_{1c} level of > 7% were invited to participate in this 4-week study. They were treated with single or combined oral hypoglycemic agents except for alpha glucosidase inhibitors and glinide. Each patient performed self monitoring of capillary plasma glucose (CPG) before and 2 hours after each meal and before retiring to bed on the most convenient day in the first and fourth weeks and monitored two CPG before breakfast and before dinner weekly. Daily food intake was recorded in the logbooks.

Results: The observed patterns of CPG in 60 cases were postprandial hyperglycemia with FPG of < 130 mg/dl in 21.7%, a high pre-meal and post-meal CPG with FPG of < 130 mg/dl in 36.7% and elevated all fasting, pre-meal and post-meal CPG in 41.7% of the patients. The correlation coefficients between HbA_{1c} at the end of the present study and CPG were 0.345, 0.40 and 0.337 at pre-breakfast, pre-lunch and pre-dinner, respectively ($p = 0.01$). The correlation coefficients between HbA_{1c} and 2 hours CPG post-lunch, post-dinner and bed time were 0.402, 0.412 and 0.472, respectively ($p = 0.01$). The correlation between CPG and caloric intake, carbohydrate consumption or glycemic index of food were not observed.

Conclusion: Elevated blood glucose at all times was the commonest finding in type 2 diabetic patients whose FPG < 130 mg/dl but HbA_{1c} level > 7%. A sole measurement of FPG should not be used to assure optimal glycemic control. Significant correlations between HbA_{1c} and pre- or post-meal CPG indicated that frequent monitoring of pre- and post-meal could be used in assessing overall glycemic control.

Keywords: Fasting plasma glucose, Hemoglobin A_{1c}, Postprandial hyperglycemia, Self monitoring of blood glucose

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Diabetes mellitus is a major health problem worldwide⁽¹⁾. UKPDS demonstrated that each 1% reduction in hemoglobin A_{1c} (HbA_{1c}) was associated with the reduction of 21% in any end point related to diabetes, 21% in deaths related to diabetes, 14% in myocardial infarction and 37% in microvascular complications⁽²⁾. HbA_{1c} level is the main target of glycemic control in all guidelines for diabetes

management⁽³⁻⁶⁾. Therefore, it is important to achieve HbA_{1c} goal to reduce morbidity and mortality related to diabetes. Thai guideline for management of diabetes mellitus suggests a fasting plasma glucose (FPG) goal of < 130 mg/dl and HbA_{1c} goal of < 7%⁽⁶⁾. In practice, a significant numbers of type 2 diabetic patients with unacceptable high HbA_{1c} level despite that the FPG levels were persistently < 130 mg/dl. A previous study suggested that postprandial hyperglycemia, particularly 2-hour postprandial plasma glucose concentrations was associated with high HbA_{1c} level in type 2 diabetic patients whose FPG levels were near-normal (<140 mg/dl)⁽⁷⁾. From a theoretical standpoint, three possibilities can explain the discrepancy between

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FPG and HbA_{1c}. First, there is an excessive postprandial glycaemic excursion among these patients resulting in an increase in mean plasma glucose and HbA_{1c} level. Second possibility is that plasma glucose levels are high at all times of the day except for the fasting period because the rising of plasma glucose following the first meal and persists throughout the day until the next fasting. Third, it is possible that poor glycaemic control occurs at all times except for short period before fasting blood glucose is measured. The present study was undertaken to find the cause of high HbA_{1c} levels in type 2 diabetic patients who have FPG < 130 mg/dl and to determine the correlation between HbA_{1c} and self-monitored capillary plasma glucose (CPG) at various times. Dietary effects on CPG were also evaluated.

Material and Method

Patients

The present study recruited type 2 diabetic patients who were treated in the out-patient clinics at Siriraj Hospital. The duration for enrollment was from August 2007 to February 2008. The inclusion criteria were the patients who were more than 18 years old, had 2 consecutive FPG levels <130 mg/dl and HbA_{1c} level \geq 7% measured in 8-12 weeks apart, received sulfonylurea, metformin, thiazolidinediones as a single or combination therapy and had serum creatinine levels (Cr) \leq 2 mg/dl. The dosage of oral hypoglycemic drug was constant for 4-6 months before enrollment and during the present study. The exclusion criteria were the patients who received insulin, alpha-glucosidase inhibitors or glinide that directly affect postprandial glucose excursion, had any diseases interfering with the measurement of plasma glucose level by glucometer or HbA_{1c} level such as hemolytic anemia, and patients who received medications that affect plasma glucose level such as corticosteroids. The signed informed consents were obtained from all cases.

Data collection and intervention

Demographic data, diabetes history and current medications were recorded. All patients were asked to maintain on their previous meal patterns and activities. Each patient received a glucometer, glucose strips, equipment for self-monitoring of blood glucose (SMBG) and a logbook. The SMBG protocol consisted of all day monitoring and selected monitoring.

All day monitoring

Each patient selected the most convenient day to monitor CPG seven times per day during the

first and fourth week. Seven points time were before each meal (breakfast, lunch and dinner), 2 hours after each meal and before retiring to bed.

Selected monitoring

During the first to fourth weeks, the patients selected the convenient day to monitor CPG four points per week, two of which were before breakfast and the other two were before dinner. The pre-breakfast and pre-dinner could be on the same day or different day.

All patients were instructed to do a daily dietary record for 4 weeks. The patients recorded SMBG data and all meals in their logbooks. An assigned nutritionist gave instructions for dietary record and evaluated all the records. A weekly telephone visit to each patient was done to ensure the adherence to SMBG and dietary record.

At the end of 4 weeks, the patients visited the clinic and returned their logbooks. Fasting venous blood was obtained for determinations of FPG and HbA_{1c}.

Definition

The optimal pre-meal CPG level was < 130 mg/dl⁽³⁾. Postprandial hyperglycemia was defined as 2 hours post-meal CPG level of \geq 140 mg/dl⁽⁸⁾. The target glycaemic control was indicated by HbA_{1c} level of < 7%^(3,6). Postprandial hyperglycemic group was defined as the mean 2-hour post-meal CPG level \geq 140 mg/dl and more than a half of post-meal CPG measured points > 140 mg/dl. High each pre-meal CPG points were defined as mean pre-meal CPG \geq 130 mg/dl and more than half of the measured points were \geq 130 mg/dl. Caloric intake, carbohydrate portion and glycaemic index of food were calculated based on nutrient data of Thai foods and products⁽⁹⁾.

Statistical analysis

Continuous variables were presented as means \pm SD or median. Categorical variables were presented as numbers and percentages. Association between the two quantitative variables was assessed using scatter plot and Pearson's correlation. One-way ANOVA was employed to test the difference in normally distributed quantitative variables between the three groups whereas Kruskal-Wallis test was for non-normally distributed quantitative variables. Pearson's Chi-square test was applied to test the difference in qualitative variables between the three groups of subjects.

Results

Sixty four patients with type 2 diabetes who had FPG level of <130 mg/dl but having high HbA_{1c} level of ≥7% and met the inclusion and exclusion criteria were enrolled. The analysis included only data from 60 patients. The reasons for exclusion of four patients were two cases violated SMBG protocol (one took CPG at 1 hour postprandial, the other missed SMBG 50% of the times), one patient had unexplained good CPG at all times and one patient had CPG pattern not compatible with any groups.

There were three patterns of CPG in patients with high HbA_{1c} level but FPG <130 mg/dl (Table 1). The first was postprandial hyperglycemia found in 21.7% of the patients (Group 1). The second was good

FPG but elevated CPG at other time points observed in 36.7% of the patients (Group 2). The third showed elevation of CPG at all time points noted in 41.7% of the patients (Group 3). The characteristic of patients and detail of treatment in each group are shown in Table 2. There were significant differences in age of the patients and duration of diabetes in Group 3, which was lower compared to the other groups.

At the end of the present study, HbA_{1c} level decreased in 60%, increased in 38.3% and stable in 1.7% of the patients. However, none of the changes reached statistical significance as shown in Table 3.

There was no correlation between daily caloric intake and HbA_{1c} levels as shown in Fig. 1. The correlation between CPG and caloric intake,

Table 1. Glycemic patterns by self monitoring of blood glucose

Pattern	Postprandial hyperglycemia	Optimal FPG but elevated CPG other times	Elevated CPG at all times
Pre-breakfast	Optimal	Optimal	High
Two hours post-breakfast	High	High	High
Pre-lunch	Optimal	High	High
Two hours post-lunch	High	High	High
Pre-dinner	Optimal	High	High
Two hours post-dinner	High	High	High
Bedtime	Optimal	High	High

Table 2. Characteristics of three groups of the patients according to glycemic patterns

Characteristics	Mean ± SD or median (min, max) or number			p-value
	Group 1 Postprandial hyperglycemia (n = 13)	Group 2 Good FPG but elevated CPG other times (n = 22)	Group 3 Elevated CPG at all times (n = 25)	
Age (years)	62.5 ± 7.5	67 ± 9.3	56.8 ± 12.3	0.006
Sex (% men)	61.5%	31.8%	36%	0.193
Duration of DM (years)	8 (3-20)	19.5 (1-30)	4 (2-30)	0.006
BMI (kg/m ²)	24.7 ± 2.5	24.9 ± 4.3	26.3 ± 4.3	0.358
Drug used				0.353
Metformin (MFM)	13	21	25	
Sulfonylurea (SU)	11	21	18	
Thiazolidinedione (TZD)	1	0	4	
Pattern of drug used				-
SU monotherapy	0	1	0	
MFM monotherapy	2	1	7	
Combined SU + MFM	10	20	14	
Combined SU + MFM + TZD	1	0	4	

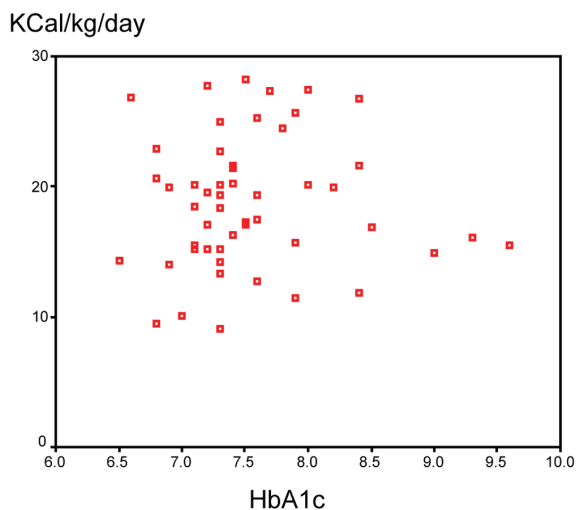


Fig. 1 Correlation between HbA_{1c} and daily caloric intake. Fifty three patients were in the analysis

carbohydrate count or glycemic index of food in each meal was not observed (Fig. 2). The correlations coefficients between CPG and calories, carbohydrate count and glycemic index were 0.054, 0.042 and 0.079, respectively. However, significant correlations ($p = 0.01$) were seen between HbA_{1c} level at the end of the present study and pre-breakfast 0.345, pre-lunch 0.400 and pre-dinner 0.337 (Table 4). The correlation coefficients between HbA_{1c} and 2 hours post-lunch, post-dinner and bedtime CPG were 0.402, 0.412 and 0.472, respectively and reached statistical significance ($p = 0.01$). The correlation between HbA_{1c} at entry and various points CPG were less pronounced (Table 4).

Discussion

The present study demonstrated three patterns of CPG in patients with type 2 DM who had acceptable FPG (< 130 mg/dl) but did not reach target HbA_{1c} level of < 7%. The most frequent pattern

Table 3. HbA_{1c} level before and at the end of study in each group

Mean HbA _{1c} before vs. after study	Group			p-value
	Postprandial hyperglycemia (n = 13)	Good FPG but elevated CPG other times (n = 22)	Elevated CPG at all times (n = 25)	
HbA _{1c} at entry (%) (min-max)	7.52 ± 0.37 (7.0-8.2)	7.70 ± 0.55 (7.1-9.2)	7.88 ± 0.83 (7.0-10.3)	0.274
HbA _{1c} at the end (%) (min-max)	7.35 ± 0.41 (6.8-8.1)	7.56 ± 0.59 (6.6-9.0)	7.68 ± 0.72 (6.5-9.6)	0.322
Decreased (n)	9	12	15	
HbA _{1c} level	7.68 → 7.31	7.77 → 7.39	8.25 → 7.73	0.295
Increased (n)	4	10	9	
HbA _{1c} level	7.18 → 7.45	7.61 → 7.76	7.34 → 7.63	0.916
No change (n)	0	0	1	
HbA _{1c} level	-	-	7.2 → 7.2	

Table 4. Correlation coefficients of HbA_{1c} and CPG of each meal

Meals	Correlation with HbA _{1c} at entry	Correlation with HbA _{1c} at the end	Number of meals used in calculation
Pre-breakfast	0.221*	0.345*	579
Two hours post-breakfast	0.097	0.202	137
Pre-lunch	0.253*	0.400*	115
Two hours post-lunch	0.213	0.402*	111
Pre-dinner	0.242*	0.337*	539
Two hours post-dinner	0.27*	0.412*	140
Bed time	0.215	0.472*	103

* p-value = 0.01

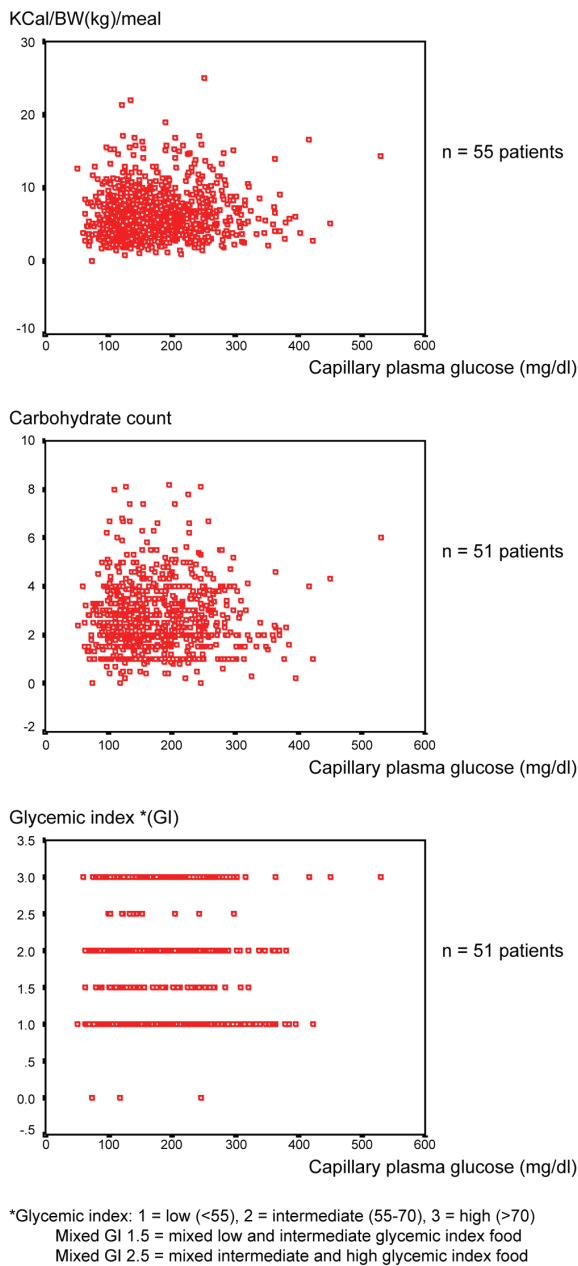


Fig. 2 Correlations between CPG vs calories, carbohydrate counting, glycemic patients index in each meal

observed was high CPG levels at all times in 41.7% of the patients followed by high pre-meal and post-meal CPG levels except for the pre-breakfast level of < 130 mg/dl in 36.7% of the patients. The sole high postprandial CPG levels were least found in 21.7% of the patients. Although the rate of formation of

HbA_{1c} is faster than its rate of disappearance⁽¹⁰⁾, the non-significant change of HbA_{1c} indicated that the patients continued their usual daily practice during 4 weeks of the present study.

The relationship between postprandial hyperglycemia and HbA_{1c} was demonstrated but the definition of postprandial hyperglycemia had been a matter of debate^(11,12). American Diabetes Association accepted that measured two-hour postprandial glucose was reasonably practical in general⁽¹²⁾. Recently, International Diabetes Federation issued a guideline for management of post-meal glucose which two hour-postprandial glucose level is targeted at less than 140 mg/dl⁽⁸⁾. Therefore, two hour-postprandial glucose of 140 mg/dl or higher was applied to classify the postprandial hyperglycemia in the present study.

Although, the dietary record failed to demonstrate the correlation between CPG level and caloric intake, amount of carbohydrate consumed or glycemic index of food. The authors postulated that high CPG levels at all times in almost one-half of the presented patients were related to non-compliance to treatment most of the time but the patients changed their behaviors close to the time of scheduled clinic visit. The higher mean BMI of this patient group, although being not significant compared to the other groups could support this postulation. In a recent study, the adherence to dietary recommendations of patients with type 2 diabetes was not completely satisfactory⁽¹³⁾. Moreover, food record was shown to underestimate energy intake⁽¹⁴⁾. Another explanation might be that there was incomplete record of food in each meal by the patients with or without intention. One third of the presented patients had hyperglycemia throughout the day. This indicated that long time food deprivation is required to reach plasma glucose level of < 130 mg/dl. The sole postprandial hyperglycemia contributed to failure in achieving HbA_{1c} target was less frequent in this group of patients.

The contribution of meal-time related elevation of blood glucose to glycosylated hemoglobin was determined in one study⁽¹⁵⁾. The excursion of post-meal glucose contributed to glycosylation of hemoglobin more than the fasting plasma glucose in type 2 diabetic patients whose HbA_{1c} were less than 7.3%. On the contrary, in patients with HbA_{1c} level of 9.3% or higher, post-meal glucose appeared to be a weak contributor, while both fasting and post-meal glucose contributed almost equally in the patients with HbA_{1c} 7.3-9.2%. This information made the findings in the present study

expected since two third of the patients had HbA_{1c} level of 7.3-9.2%.

The findings of the present study could indirectly support the recommendation of SMBG for the patients who had acceptable FPG but HbA_{1c} of $\geq 7\%$. Identifying the blood glucose pattern in each patient can direct to an appropriate management for individual case. Empowerment on diet adherence and increased physical activity and/or a specific prescription of drug to control prandial hyperglycemia can be more individualized. SMBG had been shown to be an effective tool in improving glycemic control in patients with type 2 diabetes who are not using insulin^(16,17). Furthermore, SMBG was associated with decreased diabetes-related morbidity and all cause mortality in type 2 diabetes and possible associated with a healthier lifestyle and/or better disease management⁽¹⁸⁾.

The present study showed a significant correlation between HbA_{1c} and pre- or post- meal CPG. In previous report, HbA_{1c} level could translate to average blood glucose profile from multiple SMBG data⁽¹⁹⁾. This was recently confirmed by other research groups^(20,21). Therefore, frequent monitoring of pre- and/or post- meal CPG could substitute HbA_{1c} to assure optimal glycemic control in the circumstance that measurement of HbA_{1c} was not available or applicable.

The limitation of the present study was a small number of subjects and no estimation of daily activity. The completeness and reliability of dietary records were not verified. The authors concluded that food record did not provide any useful information. In the majority of patients whose FPG < 130 mg/dl in the present study, the uncontrolled day-time blood glucose contributed to high HbA_{1c} level. Postprandial hyperglycemia only was the least frequent cause. SMBG might be essential in modifying management to achieve the HbA_{1c} target. Monitoring of FPG only could not be used to reflect glycemic control. A significant correlation between HbA_{1c} and pre- or post- meal CPG indicated that frequent monitoring of pre- or post- meal CPG could assure overall optimal glycemic control.

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Potential conflicts of interest

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รูปแบบการเปลี่ยนแปลงระดับน้ำตาลในเลือดของผู้ป่วยเบาหวานชนิดที่ 2 ที่มีระดับกลูโคสในเลือดเมื่ออดอาหารข้ามคืนอยู่ในเกณฑ์ดี แต่มีระดับฮีโมโกลบิน เอ วัน ซี สูง

วรรณ จรรย์ศิริชัยยศ, วรรณ นิธิยานันท์, ปอแก้ว ทับแสง, สุทิน ศรีอักษรภาพ, สาธิต วรรณแสง

ภูมิหลัง: ผู้ป่วยที่ควบคุมระดับน้ำตาลในเลือดเมื่ออดอาหารข้ามคืน (fasting plasma glucose: FPG) ได้ดีค่าเฉลี่ยน้ำตาลสะสม (hemoglobin A_{1c}: HbA_{1c}) อาจไม่ได้ตามเป้าหมาย การศึกษานี้ต้องการแสดงรูปแบบการเปลี่ยนแปลงระดับน้ำตาลในเลือดของผู้ป่วยที่ FPG < 130 มก./ดล. แต่มี HbA_{1c} ≥ 7% และแสดงความสัมพันธ์ของ HbA_{1c} กับระดับน้ำตาลในเลือดในเวลาต่าง ๆ รวมถึง ศึกษาความสัมพันธ์ระหว่างระดับน้ำตาลในเลือดกับปริมาณแคลอรี, ปริมาณคาร์โบไฮเดรต, glycemic index ของอาหารที่รับประทาน

วัตถุประสงค์และวิธีการ: ผู้ป่วยเบาหวานชนิดที่ 2 ในแผนกผู้ป่วยนอกของโรงพยาบาลศิริราช ที่มี FPG < 130 มก./ดล. แต่ HbA_{1c} ≥ 7% ขณะรับประทานยาลดน้ำตาลขนาดคงที่ ≥ 1 ชนิด ยกเว้น α -glucosidase inhibitor และ glinide เข้าร่วมการศึกษาโดยไม่มีการเปลี่ยนแปลงของชนิดและปริมาณยา รวมถึงการออกกำลังกายและลักษณะอาหาร ผู้ป่วยบันทึกชนิดและปริมาณอาหารที่รับประทานทุกวัน ผู้ป่วยแต่ละรายเลือกว่าจะตรวจระดับน้ำตาลในเลือดจากปลายนิ้ว (capillary plasma glucose: CPG) 7 ครั้งต่อวันคือ ก่อนและหลังอาหาร 2 ชั่วโมง ทุกมื้อ และก่อนนอน และตรวจวัด CPG 2 ครั้งต่อวันคือ ก่อนอาหารเช้าและเย็น อีก 2 วันต่อสัปดาห์เป็นเวลา 4 สัปดาห์

ผลการศึกษา: รูปแบบ CPG ของผู้ป่วย 60 ราย พบเป็น CPG สูงเฉพาะหลังอาหารโดยที่ FPG และ CPG ก่อนมื้ออาหาร < 130 มก./ดล. (postprandial hyperglycemia) ร้อยละ 21.7, ร้อยละ 36.7 มี CPG สูงทุกเวลายกเว้นตอนเช้าที่ FPG < 130 มก./ดล., และร้อยละ 41.7 มี CPG สูงตลอดทั้งก่อนอาหารและหลังรับประทานอาหาร correlation coefficients ของ HbA_{1c} กับ CPG ก่อนอาหารเช้า กลางวัน เย็น คือ 0.345, 0.40, 0.337 (p = 0.01) ตามลำดับ, และ HbA_{1c} กับ CPG หลังอาหาร กลางวัน เย็น 2 ชั่วโมง และก่อนนอน คือ 0.402, 0.412, 0.472 (p = 0.01) ตามลำดับ การศึกษานี้ไม่พบความสัมพันธ์ระหว่าง CPG กับปริมาณแคลอรี ปริมาณคาร์โบไฮเดรต หรือ glycemic index ของอาหารที่รับประทาน

สรุป: ในผู้ป่วยเบาหวานชนิดที่ 2 ที่มี FPG < 130 มก./ดล. แต่ HbA_{1c} ≥ 7% ส่วนใหญ่มีระดับน้ำตาลในเลือดสูงทุกช่วงเวลา การติดตาม FPG เพียงอย่างเดียวไม่สามารถประเมินว่าการควบคุมระดับน้ำตาลอยู่ในเกณฑ์ที่เหมาะสม การพบความสัมพันธ์อย่างมีนัยสำคัญทางสถิติ ระหว่าง HbA_{1c} กับ CPG ก่อนและหลังอาหาร บ่งชี้ว่าการตรวจวัด CPG ก่อนและหลังอาหารบ่อยครั้ง สามารถใช้ประเมินภาพรวมของการควบคุมระดับน้ำตาลในเลือดได้
