

การศึกษาเปรียบเทียบการตรวจวัดระดับกลูโคสด้วยวิธี biosensor และวิธีมิตรฐาน glucose oxidase

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Comparative study between glucose determination by capillary glucose biosensor and standard venous glucose oxidase test

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วัตถุประสงค์: เพื่อทำการศึกษาเปรียบเทียบการตรวจวัดระดับ

กลูโคสด้วยวิธี biosensor และวิธีมิตรฐาน glucose oxidase

รูปแบบการศึกษา: การศึกษาเปรียบเทียบวิธีการตรวจทางห้องปฏิบัติการ

ตัวอย่างที่ทำการศึกษา: ตัวอย่างเลือดจำนวน 100 ตัวอย่าง

วิธีการศึกษา: ได้ทำการเก็บตัวอย่างเลือดจำนวน 100 ตัวอย่าง เพื่อทำการทดสอบหาระดับกลูโคสด้วยวิธี glucose oxidase method และได้ทำการเก็บตัวอย่างเลือดจากเส้นเลือดฝอยจากในราย เดียวกันเพื่อทำการหาระดับกลูโคสด้วยวิธี biosensor (Boehringer Manheim) จากนั้นจึงทำการเปรียบเทียบผลการตรวจด้วยวิธีทั้งสอง

ผลการศึกษา: ผลการศึกษาเปรียบเทียบระหว่างวิธีทั้งสอง พบ ความสัมพันธ์ระหว่างวิธี glucose oxidase (X) และวิธี biosensor (Y) เป็นดังสมการเรียงเส้นกำลังสองน้อยที่สุด $Y = 1.006X - 1.358$ ($r = 0.998$) จากการศึกษาไม่พบความแตกต่างอย่างมีนัยสำคัญในการ ตรวจวัดระดับกลูโคสด้วยวิธีทั้งสอง ณ ระดับความเข้มข้นของ เลือดที่แตกต่างกัน

บทสรุป: การทดสอบหาระดับกลูโคสด้วยวิธี biosensor เป็นวิธี ใหม่ที่ให้ความสัมพันธ์ดีกับวิธี glucose oxidase จัดว่าเป็นวิธีที่มี ประสิทธิภาพ

คำสำคัญ: กลูโคส, การวัดระดับ

Objective: to compare between glucose determination by capillary glucose biosensor and standard venous glucose oxidase test

Study design: A laboratory method comparative study

Subjects: blood samples from 100 individual subjects.

Methods: For each subject, two methods for glucose determination were performed. The first method was the standard venous glucose oxidase test and the second was capillary glucose biosensor (Boehringer Manheim). Then comparison for both methods was performed.

Results: From the study, the comparison-of-methods plot of capillary glucose biosensor (Y) VS standard venous glucose oxidase (Y) gave the least square linear regression equation of $Y = 1.006 X - 1.358$ ($r = 0.998$)

Conclusion: The new glucose determination by capillary glucose biosensor gave good correlation to the standard method

Key Words: glucose determination

Diabetes Mellitus is a very important health problem in Thailand. Self-monitoring of blood glucose has proved to be a valuable tool in the outpatient care of diabetic patients¹. Several hand-held devices for capillary glucose

determinations by both patient and health care workers have been demonstrated²⁻⁴. Due to the point-of-care concepts in the present day, capillary blood glucose evaluation by glucose oxidase reagent strip is a new

technique even provides a rapid, inexpensive, sensitive and accurate measurement. But inaccuracies have occurred under specific conditions such as extreme low or high hematocrit⁵⁻⁶.

The oxygen-insensitive based on glucose dehydrogenase enzyme biosensors seem to be the new technology produced to solve this problem. This study was set in order to test the new capillary glucose biosensor comparing to the standard venous glucose determination.

Materials and method

This study was performed in Clinical Chemistry Unit, Laboratory Medicine Department, King Chulalongkorn Memorial Hospital. All 100 individual subjects were included in this study. Venipuncture was performed on each subject to collect venous blood specimen into 5 milliliters Sodium Fluoride tube (Beckton-Dickinson[®]) for venous glucose determination. Each subject was also got a finger stick to get capillary blood sample for new glucose biosensor (Boehringer Manheim) and manual hematocrit (Hct) determination by microhematocrit method at the same time.

1. New glucose biosensor

The new glucose biosensor (Boehringer Manheim) is based on glucose dehydrogenase and a coupled ferri/ferrocyanide pair that shuttles electrons to the electrodes where a reduced mediator is reconverted to an oxidized mediator. The reagent comprise of 0.9 per cent glucose dehydrogenase, 52.8 per cent potassium ferricyanide, 5.3 per cent stabilizer, 8.1 per cent non-reactive ingredients, and 32.9 per cent buffer. The current measured at the electrodes is directly proportional to the glucose level. A hand-held, digital, battery power meter, AdvantageTM, was altogether used.

2. Standard venous glucose determination

Collected venous blood with fluoride preservation was centrifuged at 8,000 rpm for 5 minutes. Then the supernatant was analyzed using glucose oxidase standard method on a automated clinical chemistry analyzer, Hitachi 917.

Result from each determination was collected and then analyzed. Precision analysis for the new glucose biosensor was performed. Comparison between new capillary glucose biosensor and standard glucose determination was performed using linear regression analysis. At each level of hematocrit, comparison of glucose level determined by both method was also performed at significant level = 0.05.

Results

Data from glucose and hematocrit determination was presented in Table 1. Precision analysis of the new capillary

glucose biosensor at each glucose level was shown in Table 2. The least-squares equation from comparing capillary glucose biosensor (Y) to the venous glucose oxidase standard method (X) gave $Y = 1.006 X - 1.358$ ($r = 0.998$) (Figure 1). In evaluation, there was no significant difference in glucose levels measured by both methods at different hematocrit level (Table 3).

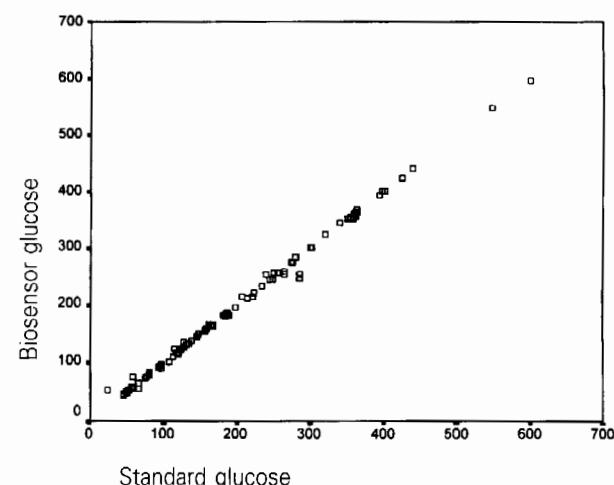


Figure 1. Comparison of new capillary biosensor glucose and venous standard glucose levels.

Discussion

Glucose determination plays very important role in taking care of diabetic patient. Because poor control of blood glucose level can result in many complications of diabetes mellitus such as retinopathy, nephropathy, cardiopathy and neuropathy⁷. Good control of blood glucose in the proper level is one factor in success in diabetic control. Therefore, continuous and intensive blood glucose determination in diabetic patient is necessary.

But it is impossible for the patient to get the daily venous glucose determination, therefore, capillary glucose determination is an useful tool for monitoring of diabetic patient. Furthermore, the capillary glucose determination can be used as a home self-monitoring system for the patient²⁻⁴.

Although many capillary glucose devices were introduced but they depended on the principle of glucose oxidase reagent strip, which some limitations were detected in cases with low or high hematocrit⁵⁻⁶. Therefore, inaccuracy can be expected in such case.

In this study, the new capillary glucose using glucose dehydrogenase-base electrochemical biosensor was tested. The result showed that it correlated well with the standard venous glucose determination method ($r = 0.998$). Furthermore, the results showed that the hematocrit of

Table 1. Data from glucose and hematocrit determination in this study.

Parameter	mean	SD	maximum	Minimum
Glucose				
- Biosensor glucose (mg/dL)	198.04	120.22	596	45
- Standard glucose (mg/dL)	197.83	121.11	600	45
Hematocrit (%)	40.94	9.21	68	28

Table 2. Precision analysis of the new glucose biosensor.

Within run precision	Mean (mg/dL)	SD (mg/dL)	CV (%)
Low glucose (n = 5)	64.86	1.02	1.58
Medium glucose (n = 5)	159.84	2.41	1.51
High glucose (n = 5)	419.30	5.79	1.38

Table 3. Blood glucose level at difference hematocrit level.

Hematocrit level	Biosensor glucose (mg/dL)	Standard glucose (mg/dL)
Low (Hct < 37, n = 41)	190.76 ± 112.77	190.08 ± 113.11
Medium (Hct = 37-51, n = 39)	208.00 ± 134.67	208.76 ± 136.10
High (Hct > 51, n = 20)	193.52 ± 109.20	192.38 ± 109.70

blood did not influence the new electrochemical biosensor. No significant difference was obtained comparing the biosensor to standard method at each hematocrit level. Therefore, the new glucose biosensor is a useful tool one in monitoring the blood glucose level.

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