Capillary Blood Glucose Screening (Accu-Chek Advantage) for Gestational Diabetes

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Objective: *To determine optimal threshold of capillary blood glucose screening (Accu-Chek Advantage) for gestational diabetes*
Study design: *A cross-sectional analytical study.*
Material and Method: *Capillary and venous blood of pregnant women who attended the antenatal clinic at Trang Regional Hospital between August 2007 and May 2008 were collected for glucose testing (by approach of American Diabetes Association's Fourth International Workshop-Conference on Gestational Diabetes) at one hour after taking 50 gm glucose. The glucose values of Accu-Check Advantage were compared with the standard venous plasma glucose. The receiver operator characteristic (ROC) curve was created to determine the optimal threshold of the capillary blood test screening for gestational diabetes.*
Results: *A total of 816 pregnant women were enrolled in the present study. Their capillary blood glucose values and plasma glucose values were checked with the Accu-Chek Advantage and the central laboratory chemistry analyzer, respectively. The good correlation between capillary blood glucose and plasma glucose values was found (correlation coefficient = 0.80, 95% CI 0.77-0.82). There was a significant difference in the average values of capillary blood and plasma blood (134.1 vs. 122.7 mg/dl, respectively). When the data were analyzed by ROC curve, the optimal level of capillary blood by Accu-Chek Advantage for performing a 100 gm oral glucose tolerance test was 140 mg/dl (reference plasma glucose level of at least140 mg/dl). The sensitivity, specificity, likelihood ratio for a positive test result and likelihood ratio for a negative test result were 93.8%, 83.6%, 5.71 and 0.07, respectively. The potential advantages of capillary blood glucose screening are simple to use, cheap and convenient.*
Conclusion: *Accu-Chek Advantage is suitable for screening gestational diabetes using the optimal threshold capillary glucose level of 140 mg/dl*

Keywords: *Blood glucose, Diabetes, gestational, Mass screening*

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Diabetes is a common medical complication of pregnancy. The prevalence may range from 1 to 14 percent of all pregnancies in the US[1]. In southern part of Thailand, the prevalence of diabetes during pregnancy at Songklanagarind Hospital is 1.3%[2]. The prevalence varies with criteria and population studied. Diabetic women can be separated into those detected before pregnancy (pre-gestational or overt) and those diagnosed during pregnancy (gestational diabetes)[3]. Gestational diabetes represents nearly 90% of all pregnancies complicated by diabetes[1]. Clinical recognition of gestational diabetes is important because management and assessment (including medical nutrition therapy, insulin when necessary, and antepartum fetal surveillance) can reduce the gestational diabetes-associated perinatal morbidity and mortality[4]. Moreover, pregnant women complicated by this disease are prone to have diabetes in the future, approximately 50% of cases within 20 years[5].

Gestational diabetes is defined as any degree of glucose intolerance with onset or first recognition during pregnancy[6]. Universal screening was changed to selective screening at the Fourth International Workshop-Conference on Gestational Diabetes[7]. In

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the present recommendation, 50 gm oral glucose challenge test is performed and plasma glucose level is measured 1 hour after that glucose load without regard to the time of day or time of last meal.

Currently, a glucometer is used worldwide for self-glucose monitoring because of comfortable use and yielding a quick result. The accuracy of these equipments for the assay of capillary glucose specimens has been well justified. Recently, many researches supported the accuracy of the glucometer[8-12]. In the previous researches, they studied the optimal cutoff point of the glucometer for screening gestational diabetes using gold standard of plasma glucose of 135 mg/dl[8-9]. Recently, American Diabetes Association's Fourth International Workshop-Conference on Gestational Diabetes recommended the cutoff point of plasma glucose was 140 mg/dl for screening gestational diabetes[6]. The optimal cutoff value is important for any screening test. It varies with population. Therefore, the author aimed to determine the optimal threshold of glucometer (Accu-Chek Advantage) for screening gestational diabetes.

Material and Method

A cross-sectional analytical study was conducted after approval of the ethics committee. Data were collected from pregnant women who came to the Antenatal Care Clinic, Trang Regional Hospital, between August 2007 and May 2008. Subjects were screened by recommended screening approach of American Diabetes Association's Fourth International Workshop-Conference on Gestational Diabetes Women with clinical characteristics consistent with a high risk of gestational diabetes (marked obesity, personal history of gestational diabetes, glycosuria, or a strong family history of diabetes) should undergo glucose testing as soon as feasible. If they were found not to have gestational diabetes at that initial screening, they should be retested between 24 and 28 weeks of gestation. Others should have testing undertaken at 24-28 weeks of gestation. No dietary plans were provided, and the check was made lacking regard to time of last meal. A total of 874 pregnant women were studies. For exactly 1 hour after taking 50 g glucose, the blood of their lateral side of fingertips (cleaned the 1st drop of blood and tested on the 2nd drop) were analyzed on glucometer (Accu-Chek Advantage) and then the blood of their same side of forearms were promptly collected and sent to the central laboratory analyzer (The VITROS 5.1 FS Chemistry System, Johnson and Johnson company). The correlation coefficient was calculated. ROC curve was performed to find out the optimal capillary blood glucose value for screening gestational diabetes.

Results

The age of the subjects ranged from 16 to 42 years with a mean age of 26.61 $\pm$ 6.08 years. More than half, 57.8% of cases were multiparity. The relationship between capillary blood glucose and central laboratory values are shown in Fig. 1. Measurements of the fingertips blood glucose level had a tendency to be higher than the venous plasma glucose level. The mean of 11.4 percents were the difference between capillary blood glucose and plasma blood glucose. The higher fingertips values were more likely to reflect the greater glucose concentration of capillary blood. (Correlation coefficient = 0.80, 95% CI 0.77-0.82). There was a significant difference in their average values of capillary and plasma blood (134.1 $\pm$ 33.7 vs. 122.7 $\pm$ 28.6 mg/dl, respectively).

The ROC curve was created by plotting sensitivities versus 1-specificities as shown in Fig. 2, with the value of area under the curve of 0.95. The sensitivity, specificity, likelihood ratio of a positive and negative tests were calculated for different cutoff values of capillary blood as shown in Table 1 to find out the proper cutoff value in the population. The results showed that value of 140 mg/dl represented the optimal threshold for screening gestational diabetes. Sensitivity, specificity, likelihood ratio for a positive and a negative test results were 93.8%, 83.6%, 5.71 and

Table 1. Sensitivity, specificity, likelihood ratio+ and likelihood ratio- of screening by capillary glucose

Capillary blood level (mg/dl)	Sensitivity (%)	Specificity (%)	Likelihood ratio+	Likelihood ratio-
$\geq$ 130	98.6	67.1	3.00	0.02
$\geq$ 135	97.2	76.3	4.10	0.04
$\geq$ 140	93.8	83.6	5.71	0.07
$\geq$ 145	88.2	90.4	9.13	0.13

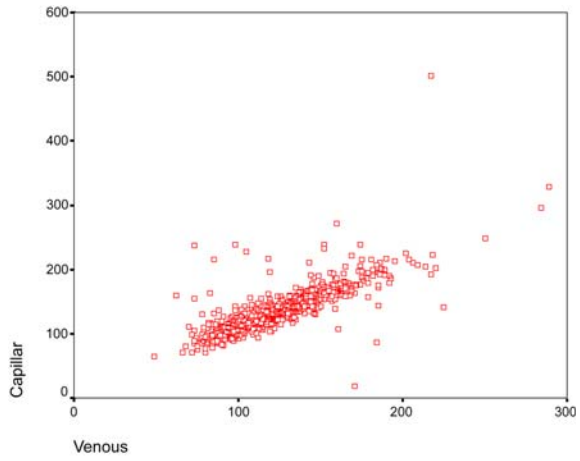

Fig. 1 Scatter plot of plasma and capillary glucose value at 1 hour after taking 50 gm glucose

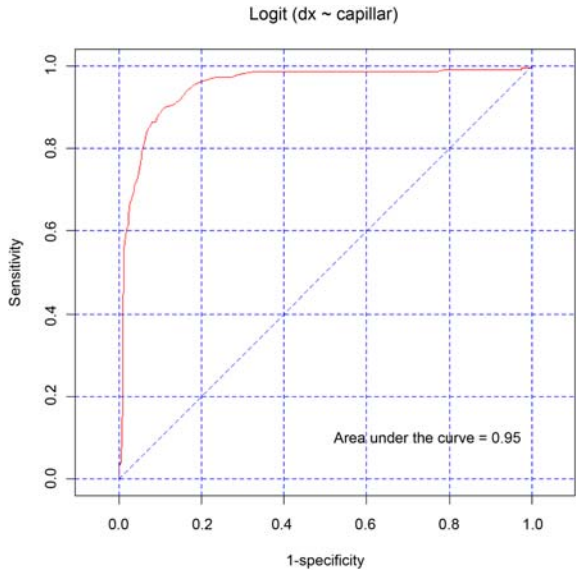

Fig. 2 Receiver operator characteristic curve referenced on 1-hour capillary data. The screening test positive if it correlates to a reference plasma glucose level of at least 140 mg/dl

0.07, respectively using the cutoff level of 140 mg/dl of the capillary blood by Accu-Chek Advantage.

Discussion

Blood glucometers are widely utilized in the clinical care of diabetes. American Diabetes Association's Third International Workshop-Conference on Gestational diabetes did not recommend the use of glucometer for screening because of their awful precision and its achievement on test accuracy[8]. Prior research by Carr et al[14] proved the effect of imprecision on the test function of available blood glucometer. The use of these older glucometers (Glucometer, Glucometer II, Glucoscan 3000, and Accu-Chek II) for screening of gestational diabetes would have a result in 45.2% of the screened population requiring the diagnostic 100 gm, 3-hour oral glucose tolerance test, comparing the diagnostic test when screened with the more precise laboratory standard technology. Carr et al[11] showed the adequate precision of newer models of glucometer as One Touch II and Hemo Cue.

Preliminary research of Accu-Chek, Landon et al[8] showed the good accuracy of this model for screening gestational diabetes. The sensitivity and specificity with the use of a meter value of 160 mg/dl were 93% and 96%, respectively, for detecting an abnormal screening test in venous plasma ($\geq$ 135 mg/dl). Weiner et al[15] evaluated the accuracy and cost effective of the Accu Chek III after 50 gm oral glucose challenge test and a 100 gm oral glucose tolerance test. They concluded that this model was feasible and cost effective for the diagnosis of gestational diabetes; however this model could have decreased sensitivity (83%) for detecting abnormal screening test plasma ($\geq$ 135 mg/dl in venous mg/dl). Cohen et al[16] evaluated the accuracy and precision of the five available blood glucometers and found that the precision of the last model of Accu-Chek (Accu-Chek Advantage) was accepted.

The data of accuracy of Accu-Chek Advantage for detecting an abnormal screening test in venous plasma ($\geq$ 140 mg/dl) according to American Diabetes Association's Fourth International Workshop-Conference on Gestational Diabetes were limited. Recently, Das et al[13] (n = 200) studied the one touch Accu-Chek I glucometer and used this recommendation. They found that the value of 140 mg/dl of capillary blood level was the optimal value for screening gestational diabetes because of the highest of the sensitivity and specificity (66.6% and 79.3%, respectively). The present study also showed the same optimal value of capillary blood level ($\geq$ 140 mg/dl) but with higher sensitivity and specificity (93.8% and 83.6% respectively), which could be explained by many factors. Quality assurance of glucose meters was one of the important factors. The other factors were the difference in ethnic groups and sample size.

The research showed the mean capillary blood glucose was 11.4% higher than mean venous plasma glucose after carbohydrate intake; similar to that found by Murphy et al[10], that is, 12%. Therefore, the clinician must be aware of implementing the glucometer for screening gestational diabetes

In conclusion, Accu-Chek Advantage can be used for screening gestational diabetes with a cutoff value of 140 mg/dl although the 11.4% higher capillary glucose level in the fed state was found because this point showed high sensitivity and specificity.

References

1. Engelgau MM, Herman WH, Smith PJ, German RR, Aubert RE. The epidemiology of diabetes and pregnancy in the U.S., 1988. Diabetes Care 1995; 18: 1029-33.
2. Prince of Songkla University. Annual statistical report 2005. Songkla, Thailand: Biostatistic Unit, Department of Obstetrics and Gynecology, Faculty of Medicine, Prince of Songkla University; 2005.
3. Cunningham FG, Leveno KJ, Bloom SL, Hauth JC, Gilstrap LC III, Wenstrom KD. Diabetes. Williams obstetrics. 22nd ed. New York: McGrall-Hill; 2005: 1169-87.
4. Langer O, Rodriguez DA, Xenakis EM, McFarland MB, Berkus MD, Arrendondo F. Intensified versus conventional management of gestational diabetes. Am J Obstet Gynecol 1994; 170: 1036-46.
5. O'Sullivan JB. Body weight and subsequent diabetes mellitus. JAMA 1982; 248: 949-52.
6. American Diabetic Association. Report of the expert committee on the diagnosis and classification of diabetes mellitus Diabetes Care 2003; 26 (Suppl 1): S5-20.
7. Metzger BE, Coustan DR. Summary and recommendations of the Fourth International Workshop-Conference on Gestational Diabetes Mellitus. The Organizing Committee. Diabetes Care 1998; 21 (Suppl 2): B161-7.
8. Landon MB, Cembrowski GS, Gabbe SG. Capillary blood glucose screening for gestational diabetes: a preliminary investigation. Am J Obstet Gynecol 1986; 155: 717-21.
9. Murphy NJ, Meyer BA, O'Kell RT, Hogard ME. Screening for gestational diabetes mellitus with a reflectance photometer: accuracy and precision of the single-operator model. Obstet Gynecol 1994; 83: 1038-42.
10. Carr SR, Slocum J, Tefft L, Haydon B, Carpenter M. Precision of office-based blood glucose meters in screening for gestational diabetes. Am J Obstet Gynecol 1995; 173: 1267-72.
11. Dillon AE, Menard MK, Rust P, Newman RB, VanDorsten JP. Glucometer analysis of one-hour glucose challenge samples. Am J Obstet Gynecol 1997; 177: 1120-3.
12. Das V, Jain V, Agarwal A, Pandey A, Pandey S, Agarwal CG. Glucometer screening of gestational diabetes. J Obstet Gynecol India 2006; 56: 499-501.
13. Metzger BE. Summary and recommendations of the Third International Workshop-Conference on Gestational Diabetes Mellitus. Diabetes 1991; 40 (Suppl 2): 197-201.
14. Carr S, Coustan DR, Martelly P, Brosco F, Rotondo L. Precision of reflectance meters in screening for gestational diabetes. Obstet Gynecol 1989; 73: 727-31.
15. Weiner CP, Faustich MW, Burns J, Fraser M, Whitaker L, Klugman M. Diagnosis of gestational diabetes by capillary blood samples and a portable reflectance meter: derivation of threshold values and prospective validation. Am J Obstet Gynecol 1987; 156: 1085-9.
16. Cohen M, Boyle E, Delaney C, Shaw J. A comparison of blood glucose meters in Australia. Diabetes Res Clin Pract 2006; 71: 113-8.

การตรวจคัดกรองน้ำตาลกลูโคสในเลือดจากหลอดเลือดฝอยด้วยเครื่อง (Accu-Chek Advantage) สำหรับเบาหวานขณะตั้งครรภ์

ธนะรัตน์ ศรีเมฆารัตน์

วัตถุประสงค์: *เพื่อตรวจคัดกรองน้ำตาลกลูโคสในเลือดจากหลอดเลือดฝอยด้วยเครื่อง (Accu-Chek Advantage) สำหรับเบาหวานขณะตั้งครรภ์*

การออกแบบ: *การศึกษาวิเคราะห์แบบตัดขวาง*

วัสดุและวิธีการ: *ศึกษาจากหญิงตั้งครรภ์ที่มารับบริการที่คลินิกฝากครรภ์โรงพยาบาลตรัง ในช่วงเดือนสิงหาคม พ.ศ. 2550 - พฤษภาคม พ.ศ.2551 โดยใช้แนวทางการคัดกรองเบาหวานขณะตั้งครรภ์ของ American Diabetes Association's Fourth International Workshop-Conference โดยหญิงตั้งครรภ์ที่เข้าเกณฑ์จะได้รับการตรวจระดับน้ำตาลในเลือด หลังจากได้รับประทานน้ำตาลกลูโคส 50 กรัม ไปแล้ว 1 ชั่วโมง โดย 2 วิธีพร้อมกันคือ กลูโคมิเตอร์ Accu-Chek Advantage จากปลายนิ้วและจากหลอดเลือดดำด้วยวิธีมาตรฐาน นำผลที่ได้มาเปรียบเทียบกัน และวิเคราะห์หาค่าจุดตัดที่เหมาะสมโดยใช้ ROC curve*

ผลการศึกษา: *หญิงตั้งครรภ์ทั้งหมด 816 คนได้รับการตรวจระดับน้ำตาลในเลือดด้วยกลูโคมิเตอร์ Accu-Chek Advantage และนำผลที่ได้ไปเปรียบเทียบกับค่าระดับน้ำตาลในพลาสมาที่ตรวจด้วยวิธีมาตรฐานหลังจากได้รับประทานน้ำตาลกลูโคส 50 กรัมไปแล้ว 1 ชั่วโมง ระดับน้ำตาลทั้ง 2 ค่ามีความสัมพันธ์กัน (ค่าสัมประสิทธิ์สหสัมพันธ์เท่ากับ 0.80และร้อยละ 95 ของค่าความเชื่อมั่นอยู่ในช่วง 0.77-0.82) ค่าเฉลี่ยของระดับน้ำตาลที่ได้จากการตรวจทั้ง 2 วิธีมีความแตกต่างกัน (ค่าเฉลี่ยระดับน้ำตาลจากการตรวจเลือดด้วยกลูโคมิเตอร์ Accu-Chek Advantage เท่ากับ 134.1 มิลลิกรัมต่อเดซิลิตร และค่าเฉลี่ยระดับน้ำตาลในพลาสมาที่ตรวจด้วยวิธีมาตรฐานเท่ากับ 122.7 มิลลิกรัมต่อเดซิลิตร) และเมื่อใช้ ROC curve หาค่าระดับน้ำตาลที่ได้จากการตรวจด้วยกลูโคมิเตอร์ ที่เหมาะสมเพื่อใช้ในการวางแผนตรวจ 100 gm oral glucose tolerance test พบว่าค่าดังกล่าวคือมากกว่าหรือเท่ากับ 140 มิลลิกรัมต่อเดซิลิตร (หากใช้ค่าระดับน้ำตาลในพลาสมามากกว่าหรือเท่ากับ 140 มิลลิกรัมต่อเดซิลิตร เป็นตัวอ้างอิง) โดยมีค่าความไว, ค่าความจำเพาะ, likelihood ratio for a positive test result และ likelihood ratio for a negative test result เท่ากับร้อยละ 93.8, 83.6, 5.71 และ 0.07 ตามลำดับ ประโยชน์ที่เห็นได้ชัดจากการใช้กลูโคมิเตอร์เพื่อช่วยในการคัดกรองภาวะเบาหวานขณะตั้งครรภ์คือใช้ง่าย ราคาถูก และสะดวก*

สรุป: *Accu-Chek Advantage เหมาะสมในการใช้ตรวจคัดกรองเบาหวานขณะตั้งครรภ์ ค่าจุดตัดระดับน้ำตาลที่เหมาะสมคือมากกว่าหรือเท่ากับ 140 มิลลิกรัมต่อเดซิลิตร*