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Accuracy of Capillary Glucose Testing in Gestational Diabetes Screening

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ABSTRACT

Objectives: To assess the accuracy of capillary whole blood glucose compared to conventional venous plasma glucose testing for 50-g GCT in gestational diabetes mellitus (GDM) screening.

Materials and Methods: A total of 180 women at-risk for GDM were randomly selected and enrolled and a 50-g GCT was offered as a screening test. At 1 hour after glucose loading, a capillary glucose testing was performed by well-trained nurses using a Nova Biomedical StatStrip®. Within 5 minutes after capillary glucose test, venipuncture was then performed by certified technicians and venous blood was sent to a certified central laboratory to determine plasma glucose value. Results from POCT glucose testing were compared with venous plasma glucose (gold standard) to evaluate for its accuracy. Women with venous plasma glucose ≥ 140 mg/dL were offered 100-g OGTT for GDM diagnosis according to current guideline.

Results: Mean age was 33.1 years and 53.9% were nulliparous. Common GDM risks were age ≥ 30 years (87.8%), family history of DM (32.2%), and BMI ≥ 25 kg/m^2 (25%). Mean gestational age at screening was 14.4 weeks. Mean venous plasma glucose was 131.6 ± 34.9 mg/dL and mean POCT glucose was 149.3 ± 27.7 mg/dL. Mean difference was 17.7 ± 19.4 mg/dL, corresponding to 16.8 ± 18.3%. POCT results were significantly correlated with venous plasma glucose (correlation coefficient 0.832, $p < 0.001$). GDM was diagnosed in 16 women (8.9%). At 140 mg/dL cut off, abnormal GCT was found in 37% by venous plasma glucose and 61% by POCT glucose results. Using 140 mg/dL cut off, POCT glucose has 97.1% sensitivity and 73.9% accuracy. At 165 mg/dL cut off, POCT glucose has 98.2% specificity and 82.8% accuracy.

Conclusion: POCT capillary glucose testing could be considered as an alternative to conventional venous glucose testing for 50-g GCT for GDM screening using 140 and 165 mg/dL cut off values.

Keywords: gestational diabetes, 50-g glucose challenge test, venous plasma glucose, capillary glucose, accuracy.

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ความแม่นยำของการใช้การตรวจน้ำตาลจากปลายนิ้ว ในการตรวจคัดกรองภาวะเบาหวานขณะตั้งครรภ์

อริสา คงเจริญสุขยิ่ง, บุญเลิศ วิริยะภาค, ดิฐกานต์ บริบูรณ์หิรัญสาร

บทคัดย่อ

วัตถุประสงค์: *เพื่อศึกษาความแม่นยำของการใช้การตรวจน้ำตาลจากปลายนิ้ว ณ จุดดูแลผู้ป่วย ในการตรวจคัดกรองภาวะเบาหวานขณะตั้งครรภ์*

วัสดุและวิธีการ: *ทำการศึกษาโดยสุ่มเลือกสตรีตั้งครรภ์ที่มีความเสี่ยงต่อภาวะเบาหวานขณะตั้งครรภ์ จำนวน 180 ราย ที่ได้รับการตรวจคัดกรองด้วยวิธี 50-g glucose challenge test หลังจากกินน้ำตาล 1 ชั่วโมง ทำการเจาะเลือดจากปลายนิ้วและตรวจด้วยเครื่องตรวจน้ำตาลในเลือด ณ จุดดูแลผู้ป่วย (Nova Biomedical StatStrip®) โดยพยาบาลผู้ชำนาญ จากนั้นภายใน 5 นาที ทำการเจาะเลือดจากหลอดเลือดดำโดยเจ้าหน้าที่ห้องปฏิบัติการ และส่งตรวจโดยวิธีมาตรฐานที่ห้องปฏิบัติการกลาง เพื่อตรวจระดับน้ำตาล ทำการเปรียบเทียบผลน้ำตาลจากการตรวจทั้ง 2 วิธี โดยใช้ค่าน้ำตาลที่ได้จากการเจาะหลอดเลือดดำเป็นมาตรฐาน เพื่อประเมินความถูกต้องแม่นยำ สตรีตั้งครรภ์ที่ผลน้ำตาลจากการเจาะหลอดเลือดดำ ≥ 140 มก/ดล จะได้รับการตรวจวินิจฉัยต่อไปตามแนวทางการดูแลมาตรฐาน*

ผลการศึกษา: *สตรีตั้งครรภ์มีอายุเฉลี่ย 33.1 ปี เป็นครรภ์แรก 53.9 เปอร์เซ็นต์ ตวามเสี่ยงต่อภาวะเบาหวานระหว่างตั้งครรภ์ที่พบบ่อย ได้แก่ อายุ ≥ 30 ปี (ร้อยละ 87.8), ประวัติเบาหวานในครอบครัว (ร้อยละ 32.2), และค่าดัชนีมวลกาย ≥ 25 กก/ม^2 (ร้อยละ 25) อายุครรภ์เฉลี่ยที่ทำการตรวจคัดกรอง คือ 14.4 สัปดาห์ ค่าเฉลี่ยของระดับน้ำตาลจากการเจาะหลอดเลือดดำเท่ากับ 131.6 ± 34.9 มก./ดล. และค่าเฉลี่ยของระดับน้ำตาลจากการเจาะเลือดปลายนิ้ว เท่ากับ 149.3 ± 27.7 มก./ดล. ค่าเฉลี่ยความแตกต่างเท่ากับ 17.7 ± 19.4 มก./ดล. หรือร้อยละ 16.8 ± 18.3 ผลการตรวจจากการเจาะเลือดปลายนิ้ว สัมพันธ์กับผลการตรวจจากหลอดเลือดดำอย่างมีนัยสำคัญทางสถิติ (correlation coefficient 0.832, $p < 0.001$) ตรวจพบภาวะเบาหวานระหว่างตั้งครรภ์ 16 ราย ร้อยละ 8.9 ตรวจพบความผิดปกติของค่า GCT ที่จุดตัด 140 มก./ดล. 37 เปอร์เซ็นต์ จากการเจาะหลอดเลือดดำ และร้อยละ 61 จากการเจาะเลือดปลายนิ้ว พบว่าการใช้ค่าจุดตัดที่ 140 มก./ดล. การเจาะเลือดปลายนิ้วมีค่าความไว ร้อยละ 97.1 และมีค่าความแม่นยำร้อยละ 73.9 และที่ค่าจุดตัดที่ 165 มก./ดล. การเจาะเลือดปลายนิ้วมีค่าความจำเพาะร้อยละ 98.2 และมีค่าความแม่นยำร้อยละ 82.8*

สรุป: *การตรวจคัดกรองภาวะเบาหวานระหว่างตั้งครรภ์ด้วยเครื่องตรวจน้ำตาลจากปลายนิ้ว ณ จุดดูแลผู้ป่วย เป็นทางเลือกที่ดีในการตรวจแทนการเจาะเลือดจากหลอดเลือดดำ โดยมีค่าจุดตัดในการตรวจคัดกรองที่เหมาะสมคือ 140 และ 165 มก./ดล.*

คำสำคัญ: *ภาวะเบาหวานระหว่างตั้งครรภ์, 50-g glucose challenge test, ระดับน้ำตาลจากปลายนิ้ว, ระดับน้ำตาลจากหลอดเลือดดำ, ความแม่นยำ*

Introduction

Gestational diabetes mellitus (GDM), a condition in which carbohydrate intolerance develops during pregnancy, is one of the most common medical complications of pregnancy[1-3]. GDM is associated with a higher incidence of maternal morbidity including cesarean deliveries, shoulder dystocia, birth trauma, hypertensive disorders of pregnancy, and subsequent development of Type-2 DM. Perinatal and neonatal morbidities also increase, including macrosomia, birth injury, hypoglycemia, polycythemia, hyperbilirubinemia, and increased risks for obesity and diabetes later in life[1-3].

Although no global consensus has yet been established for GDM screening and diagnostic strategy, a 2-step approach is currently recommended by the American College of Obstetricians and Gynecologists (ACOG) and the American Diabetes Association (ADA)[1, 2]. A 50-g glucose challenge test (GCT) is used as a screening test, and individuals meeting or exceeding the screening threshold then undergo a 100-g oral glucose tolerance test (OGTT) for GDM diagnosis. Screening is generally performed at 24-28 weeks of gestation, but early screening is suggested in high-risk women. Repeat screening is recommended at 24-28 weeks of gestation if the result of early testing is negative.

All the tests are analyzed from venous plasma glucose, based on glucose oxidase–peroxidase method, as a standard for interpretation of the results. However, there are some drawbacks to be considered including the need of venipuncture, cost, and long results turnaround time. Point-of-care-test (POCT) for capillary glucose, using a certified glucose meter, has been extensively used in diabetes management for many decades. However, their use has not been advocated for GDM screening and diagnosis due to possible errors in measurement. As the reliability of glucose meter has been improved, several studies have evaluated the use of portable meters in screening for GDM. The use of various glucose meters for GDM screening with acceptable accuracy and reliability have been reported[4-8]. The use of POCT glucose for GDM screening has been reported to be cost-effective that standard laboratory studies can be avoided in 90% of patients[9]. A recent study reported that the use of POCT glucose has considerable potential for GDM screening and diagnosis using adjusted cutoff, particularly in healthcare settings with limited resources[5, 10-13].

In Siriraj Hospital, GDM screening by 50-g GCT is used and the results are analyzed by standard laboratory technic. As the hospital is a university-based tertiary care hospital, the results turnaround time can take up to 1 to 2 hours. As a consequence, many women are frequently informed about the results in their next visit. This also cause a delay in further OGTT for GDM diagnosis as well as initiation of treatment. Since 2008, POCT for capillary glucose, using certified glucose meter, has been used widely for improving patient care in Siriraj Hospital. However, its use in GDM screening is still not endorsed.

Due to some drawbacks and limitations of standard technic for GDM screening, POCT could be a potential alternative for 50-g GCT. Besides cost savings, the immediate results obtained by POCT measurement would allow for prompt identification of abnormal screening results and prompt scheduling for further evaluation of glucose intolerance during the pregnancy. However, data on the use of POCT for GDM screening is still limited in Thailand. Previously, there was only one study in southern Thailand and the results showed good correlation between capillary and venous plasma glucose and at 140 mg/dL cut-off, glucose meter has a sensitivity and specificity of 93.8% and 83.6% for detecting abnormal screening test[14]. However, the device for capillary glucose measurement has now been improved to meet the stricter International Organization for Standardization (ISO) standard and population and screening strategy are also differ between settings that the results might not be applied to our population.

Therefore, the objectives of this study were to

assess the accuracy of the POCT of capillary whole blood glucose compared to conventional venous plasma glucose testing for 50-g GCT in GDM screening and to determine appropriate cutoff values for POCT results to be applied for clinical use.

Materials and Methods

After approval of Siriraj Institutional Review Board, a prospective study was conducted at antenatal clinic of Department of Obstetrics and Gynecology, Faculty of Medicine Siriraj Hospital. During July and December 2016, a total of 180 pregnant women who were at risk for gestational diabetes were enrolled. Women with pre-gestational diabetes and those who did not agree to participate were excluded.

According to the institutional clinical practice guideline at our center[15], GDM screening and diagnosis is offered to all at-risk women. Risk factors for GDM include age ≥ 30 years, pre-pregnancy body mass index (BMI) ≥ 25 kg/m^2, family history of diabetes, presence of hypertension, previous GDM, and history of fetal macrosomia, stillbirth, or fetal anomaly. A 50-g GCT with a cut-off value of ≥ 140 mg/dL is used for GDM screening. For patients who meet or exceed the cut-off value of 140 mg/dL, a 100-g OGTT is used to diagnose the GDM using the criteria of Carpenter and Coustan. These procedures are offered during the patient's first visit, and they are then repeated at 24-28 weeks of gestation if the first screening result was normal. All GDM women receive dietary therapy, and insulin treatment is added as needed.

Pregnant women at any gestational age who were indicated for 50-g GCT were randomly selected to enroll in this study. After informed consent, all participants were offered GDM screening with 50-g GCT. At 1 hour after glucose load, venous and capillary blood were collected to determine glucose level. Capillary blood glucose determination was performed by well-trained nurses by POCT using StatStrip® glucose meter, which is a certified glucose meter currently used at Siriraj Hospital. The test principle used is electrochemical biosensor technology using glucose oxidase. The strip uses the enzyme glucose oxidase to produce an electrical current that will stimulate a chemical reaction. This reaction is measured by the device and displayed as a bloodglucose result. The glucose meter was calibrated and validated following the manufacturer's guidelines. Within 5 minutes after capillary glucose measurement, the patients were sent for venipuncture by certified hospital technicians to determine venous plasma glucose levels. Venous plasma glucose was measured by the glucose oxidase–peroxidase method autoanalyzer from the ISO-certified central laboratory. Interpretation of the results and further GDM diagnosis and management were provided according to the results of venous plasma glucose level as appropriate.

Sample size calculation was based on estimated sensitivity and specificity of POCT glucose at 87.5% and 50% from a pilot study, respectively, and prevalence of abnormal GCT of 40%. At 95% significance level and 80% a sample size of at least 162 cases were required with 10% acceptable error.

Descriptive statistics were used to describe various baseline characteristics and 50-g GCT results, using number, percentage, mean, and standard deviation, as appropriate. Differences between POCT and venous plasma glucose were evaluated in both absolute and percentage differences. Pearson correlation coefficient was used to assess correlation between the 2 glucose results. Sensitivity, specificity, positive and negative predictive values (PPV and NPV), and accuracy of POCT glucose for determining abnormal 50-g GCT were estimated, using venous plasma glucose level as a gold standard. A p value of < 0.05 was considered statistical significance.

Results

A total of 180 pregnant women who were at risk for GDM were enrolled during August and November 2016. Table 1 shows baseline characteristics of the participants. Mean age was

33.1 ± 4.3 years, and majority of them were nulliparous (53.9%). Mean BMI 22.8 ± 4.3 kg/m^2 and 25% had BMI ≥ 25 kg/m^2. Common GDM risks were age ≥ 30 years (87.8%), family history of diabetes mellitus (32.2%), and overweight (23.9%).

Table 2 shows the characteristics of GDM screening and results. Mean gestational age at screening was 14.4 ± 8.9 week, mean venous plasma glucose was 131.6 ± 34.9 mg/dL and mean POCT glucose was 149.3 ± 27.7 mg/dL. Glucose level from POCT was higher than venous plasma with the mean of 17.7 ± 19.4 mg/dL, corresponding to 16.8 ± 18.3%. Abnormal GCT (≥ 140 mg/dL) from venous plasma glucose results were 37%, while it was 61% from POCT results. GDM was diagnosed in 16 cases (8.9%) and all had POCT glucose of ≥ 140 mg/dL. Among them, 1 had POCT glucose 140-164 mg/dL and 15 had POCT glucose ≥ 165 mg/dL.

Table 1. Baseline characteristics of the patients (N=180).

Characteristic	Mean ± SD
Age (years)	33.1 ± 4.3
BMI (kg/m^2)	22.8 ± 4.3
	N (%)
Nulliparous	97 (53.9)
BMI category	
Normal (BMI 18-24.9 kg/m^2)	114 (63.3)
Underweight (BMI <18 kg/m^2)	21 (11.7)
Overweight (BMI ≥ 25 kg/m^2)	45 (25)
Risk factors for GDM	
Age ≥ 30	158 (87.8%)
Family history of diabetes mellitus	58 (32.2%)
BMI ≥ 25 kg/m^2	45 (25%)
History of GDM	7 (3.9%)
Previous stillbirth	1 (0.6%)

Table 2. Capillary and venous plasma glucose results of 50-g GCT for GDM screening (N=180).

GDM screening results	Mean ± SD
GA at 50-g GCT (weeks)	14.4 ± 8.9
Venous plasma glucose (mg/dL)	131.6 ± 34.9
POCT glucose (mg/dL)	149.3 ± 27.7
Difference of glucose result (mg/dL)	17.7 ± 19.4
Percentage difference (%)	16.8 ± 18.3
	N (%)
Venous plasma glucose ≥ 140 mg/dL	68 (37%)
POCT glucose ≥ 140 mg/dL	111 (61%)

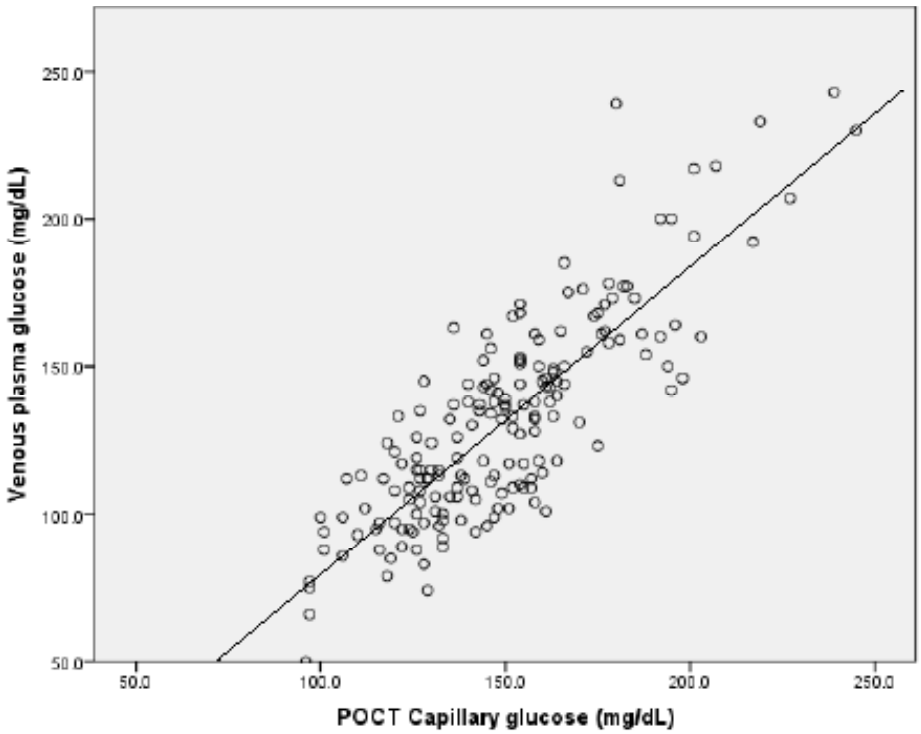

Fig. 1. Correlation between POCT and venous plasma glucose results (correlation coefficient 0.832, $p < 0.001$).

Table 3. Comparison between venous plasma and POCT glucose results of 50-g GCT.

		Venous plasma glucose		Total
		< 140 mg/dL	**≥ 140 mg/dL**	
POCT glucose	< 140 mg/dL	67	2*	69
	140 -164 mg/dL	43	27	70
	≥ 165 mg/dL	2	39	41
Total		**112**	**68**	**180**

* The 2 cases had normal 100-g OGTT results

Correlation between POCT and venous plasma glucose results are demonstrated in a scatter plot (Fig. 1). A significant correlation was observed between the 2 tests with Pearson correlation coefficient of 0.832, $p < 0.001$. Intraclass correlation coefficient was 0.811, $p < 0.001$.

Comparison between venous plasma and POCT glucose results of 50-g GCT is demonstrated in Table 3. Various cutoff values of capillary glucose results were evaluated that the lower cutoff should have high sensitivity and NPV that would miss only a few cases of abnormal GCT and the upper should have high specificity and PPV that would include only a few cases of normal GCT that need unnecessary OGTT. In addition, the proportion of pregnant women who still needed venipuncture for venous plasma glucose level were also considered. After such considerations, cutoff values of 140 and 165 mg/dL

was selected.

At 140 mg/dL cutoff for determining of abnormal GCT, POCT has sensitivity of 97.1% (95% CI 89.8-99.6), specificity of 59.8% (95% CI 50.1-69.0), PPV of 59.5% (95% CI 49.7-68.7), NPV of 97.1% (95% CI 89.8-99.6), and accuracy of 73.9% (95% CI 66.8-80.1). On the other hand, at 165 mg/dL cutoff, POCT has sensitivity of 57.4% (95% CI 44.8-69.3), specificity of 98.2% (95% CI 93.7-99.8), PPV of 95.1% (95% CI 83.5-99.4), NPV of 79.1% (95% CI 71.4-85.6), and accuracy of 82.8% (95% CI 76.5-88.0).

There were 2 cases who would have been missed for abnormal 50-g GCT (POCT < 140 mg/dL but venous plasma glucose ≥ 140 mg/dL) were further received 100-g OGTT and the results were normal. There were also another 2 cases that unnecessary 100-g OGTT would have been performed (POCT ≥ 165 mg/dL but venous plasma glucose < 140 mg/dL) if such cutoff values were used. It can be noted that, if POCT was used instead of venous plasma glucose with the cutoff at 140 and 165 mg/dL, 69 women (38.3%) could be assumed that they have normal GCT and 41 women (22.8%) will need 100-g OGTT to confirm diagnosis. Only 70 women (38.9%) would need confirmation with venous plasma glucose to determine GCT abnormalities.

Discussion

The results of this study showed that glucose measurement by POCT using a glucose meter correlated well with the standard laboratory technic for 50-g GCT (correlation coefficient 0.832, p<0.001) and POCT results was approximately 17.7 mg/dL (16.8%) higher than venous plasma glucose. The results were similar to previous studies that reported good correlation of the results between the 2 technics with correlation coefficients between 0.8 to 0.93[11, 14, 16] and that the results from POCT were higher than venous plasma values[8, 11, 14].

Although the POCT capillary blood glucose determination was accurate and correlate well with standard laboratory technic, the direct substitution of plasma glucose values with capillary glucose values in screening for or diagnosing GDM is still not recommended[16]. However, it is recommended that specific cutoff values for each glucose meter be established for each facility[9]. For the use of POCT in GDM screening, various thresholds have been reported. A threshold of 163 mg/dL has also been reported from earlier study with sensitivity and specificity of 85.7% and 86.8%[17]. Another study reported that cutoff of POCT at 155 mg/dL may be more appropriate for GDM screening, considering the 10-15% higher capillary glucose level, with sensitivity and specificity of 81% and 74%[8]. A more recent study in Thailand reported that the threshold of 140 mg/dL yielded sensitivity and specificity of 93.8% and 83.6%[14].

The results of this study showed that, at 140 mg/dL cut-off, the use of POCT would almost double the abnormal screening results and the need for 100-g OGTT, i.e., from 37% by venous plasma glucose to 61% by POCT. Although the sensitivity was 97.1%, the specificity was only 59.8%, which correspond to 40.2% false positive rate. Therefore, another cut-off value at 165 mg/dL was evaluated and the results showed that specificity increased to 98.2%. The use of both cut-off values at 140 and 165 mg/dL would be more appropriate that they would give high sensitivity at 140 mg/dL to "rule out" and high specificity at 165 mg/dL to "rule in" women with abnormal 50-g GCT.

If POCT is used in clinical practice, based on the results of this study, 38.3% of the women can be reassured of normal test results (POCT < 140 mg/dL), and another 22.8% can be immediately scheduled for 100-g OGTT (POCT ≥ 165 mg/dL). Venipuncture for plasma glucose testing can also be avoided in these women. Only 38.9% will require standard venous plasma glucose testing to confirm the results. A previous study also reported that, by using POCT for GDM screening, as many as 90% of patients will not require laboratory studies[9]. This will result in significant cost savings and, in addition, the immediate results obtained by POCT will allow for prompt identification of an abnormal screen and prompt scheduling for further evaluation of glucose intolerance during the pregnancy. Some studies have suggested that the use of POCT

capillary glucose for GDM screening might be more appropriate in resource-constraint settings, such as where standard laboratory technic is not readily available or in a community-based practice[5, 12, 13].

Differences in the results between studies might partly be due to differences in GDM risks in each population, screening and diagnostic strategies and criteria used, and types of glucose meters used. However, all the results were in the same direction that POCT results were accurate and can be applied in clinical practice as a substitution for standard venous plasma glucose determination for GDM screening.

Some limitations of this study should be mentioned. Time lag between POCT and venipuncture for plasma glucose testing could possibly deviate the results. However, in this study, venipuctures were no later than 10 minutes after POCT that the delay should not seriously affect the results. Moreover, generalization of the results to other clinical settings might be limited due to differences in baseline GDM risks and screening and diagnostic strategies and criteria used. Different types of glucose meter for POCT might produce different results that the threshold to be used for GDM screening should be evaluated and applied in each setting. Technical errors from the use of glucose meter in this study should be minimal since the tests were performed by well-trained personnel who are familiar with the equipment.

Given many advantages of POCT for glucose determination, such as lower cost, simplicity, better patient acceptance, and immediate availability of the result, capillary blood glucose testing should be considered as a good alternative for GDM screening in routine clinical practice, especially in settings with limited resources.

Conclusion

Glucose measurement by POCT correlated well with the standard laboratory technic for 50-g GCT for GDM screening (correlation coefficient 0.832, $p < 0.001$). The POCT results was approximately 17.7 mg/dL (16.8%) higher than venous plasma glucose. The cut-off values at 140 and 165 mg/dL provided sensitivity of 97.1% and 98.2%, respectively. If POCT is used, venipuncture for plasma glucose can be avoided in approximately 60% of pregnant women.

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Potential conflicts of interest

The authors declare no conflict of interest.

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