Sensitivity and Specificity of Modified 100-G Oral Glucose Tolerance Tests for Diagnosis of Gestational Diabetes Mellitus

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Objective: *To study the sensitivity and specificity of the modified 100-g oral glucose tolerance test for diagnosis of gestational diabetes mellitus (GDM).*
Material and Method: *Medical records of pregnant women attending the antenatal clinic of King Chulalongkorn Memorial Hospital, Thailand, who underwent a 100-g oral glucose tolerance test (OGTT) during March 2004 to September 2009, were retrospectively reviewed. Three modified criteria were proposed for diagnosis of GDM. The screening efficacy of the modified criteria were assessed, using the National Diabetes Data Group (NDDG) criterion as gold standard.*
Results: *A total of 729 records were reviewed, 511 were included for analysis. Using the NDDG criterion as the gold standard, the modified II criterion has the highest sensitivity of 96.8%, and the highest accuracy of 90.8%. The modified II criterion can detect the same proportion of maternal and neonatal complications, compared to the NDDG criterion.*
Conclusion*: The modified II criterion, using the fasting plasma glucose and 2-hour plasma glucose measurements, showed high sensitivity and accuracy, with moderate specificity for diagnosis of GDM. Its potential use as an alternative to standard 100-g OGTT should be evaluated in the prospective study.*

Keywords: *Oral glucose tolerance test (OGTT), Gestational diabetes mellitus (GDM), National diabetes data group (NDDG)*

J Med Assoc Thai 2011; 94 (5): 540-4
Full text. e-Journal: *http://www.mat.or.th/journal*

Gestational diabetes mellitus (GDM) is defined as carbohydrate intolerance of variable severity with onset or first recognition during pregnancy[1]. The incidence of GDM is approximately 1-14%[2] and 0.89-2% in Thailand[3,4]. GDM is associated with increased maternal and fetal-neonatal complications, which include higher rates of pregnancy-induced hypertension, urinary tract infection, hydramnios, birth injury, rate of cesarean section due to cephalopelvic disproportion. Fetal complications include fetal macrosomia, shoulder dystocia, neonatal hypoglycemia, hyperbillirubinemia and respiratory distress syndrome.

Currently, the American College of Obstetricians and Gynecologists (ACOG) recommends the two-step approach for screening and diagnosis of GDM[5]. The 50-g glucose challenge test (GCT) is performed as an initial screening test, followed by 100-g oral glucose tolerance test (OGTT) as the diagnostic test[5]. The recent ACOG guidelines recommended the diagnostic criteria set forth by either the National Diabetes Data Group (NDDG) or the Carpenter and Coustan thresholds[6]. In King Chulalongkorn Memorial Hospital (KCMH), Thailand, the NDDG criterion was used as the "gold standard" for diagnosis of GDM.

A 100-g OGTT consists of 4 plasma glucose measurements, which requires a total duration of 3 hours to accomplish the procedure. Practically, the use of OGTT is limited by its time-consuming nature, numbers of venepuncture required, and a 6.3% incidence of reactive hypoglycemia during the test[7]. The attempts to simplify the procedure were reported with varying sensitivity and specificity[8-10].

The aim of the present study was to assess the screening efficacy of 3 modified criteria for diagnosis of GDM.

Material and Method

The medical records of pregnant women who attended the antenatal clinic, KCMH, during March

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2004 and September 2009 were retrospectively reviewed. Inclusion criteria were all cases undergoing 100-g OGTT at anytime during pregnancy. Exclusion criteria were cases of pregestational diabetes mellitus, cases not delivered at KCMH, and cases with incomplete medical record. The data collected were patient's demographic data, risk factors of GDM, route of delivery, and maternal/neonatal outcomes. Standard 100-g OGTT was used, GDM was diagnosed using the NDDG criterion.

Three modified criteria were proposed; modified I criterion used fasting glucose, and 1-hour glucose values; modified II criterion used fasting glucose and 2-hour glucose values; modified III criterion used fasting glucose, 1-hour and 2-hour values. Cut-offs for diagnosis of GDM were shown in Table 1.

The sensitivity, specificity, false positive, false negative, positive predictive value, negative predictive value, and accuracy of each of the 3 modified criteria for diagnosis of GDM were analyzed; the NDDG criterion was used as the gold standard. Two by two table was used in statistical analysis. The Institutional Review Board approved the proposal before starting the present study.

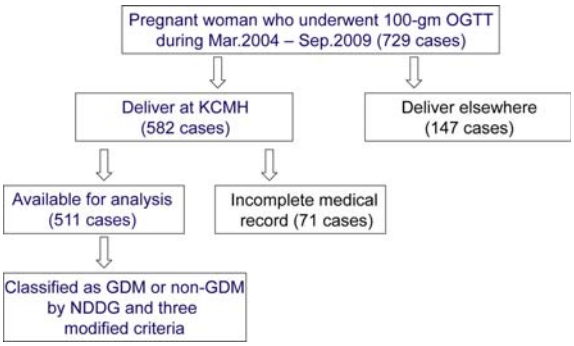

Fig. 1 Diagram shows the method of data collection

Results

A total of 729 medical records were included in the present study, 218 records were excluded; 147 cases were delivered elsewhere, and 71 cases had incomplete medical record (Fig. 1). Five-hundred and eleven records were available for analysis. Using the NDDG criterion, there were 308 cases of GDM, and 203 cases of non-GDM. The demographic characteristics of cases with GDM and non-GDM were presented in Table 2, there were no significant

Table 1. The NDDG criterion and three proposed modified criteria

Criteria	FPG	1-hour glucose	2-hour glucose	3-hour glucose	Diagnosis of GDM if there is/are
NDDG	105	190	165	145	$\geq$ 2 abnormal values
Modified I	105	190	Not used	Not used	$\geq$ 1 abnormal value
Modified II	105	Not used	165	Not used	$\geq$ 1 abnormal value
Modified III	105	190	165	Not used	$\geq$ 2 abnormal values

NDDG = national diabetes data group; FPG = fasting plasma; GDM = gestational diabetes mellitus

Table 2. Demographic characteristics in women with and without GDM using the NDDG criteria

Attribute	Women without GDM (n = 203)		Women with GDM (n = 308)	
	Range	Mean $\pm$ SD	Range	Mean $\pm$ SD
Age (yr)	17-44	32.6 $\pm$ 5.5	18-47	32.6 $\pm$ 5.3
Gravida (n)	1-7	2.2 $\pm$ 1.0	1-6	2.1 $\pm$ 1.1
Parity (n)	0-5	0.8 $\pm$ 0.8	0-5	0.7 $\pm$ 0.7
Prepregnancy BMI (kg/m^2)	16.8-35	23.5 $\pm$ 4.0	15.6-46.6	24.1 $\pm$ 4.6
Total weight gain (kg)	2-34	14.2 $\pm$ 4.8	1-37	12.9 $\pm$ 5.3
GA at diagnosis (week)	9-40	28.9 $\pm$ 6.6	9-40	25.5 $\pm$ 5.9
GA at delivery (week)	33-41	38.3 $\pm$ 1.3	31-41	37.9 $\pm$ 1.2

GDM = gestational diabetes mellitus; NDDG = national diabetes data group; GA = gestational age; SD = standard deviation

differences in demographic characteristics between the 2 groups.

Glucosuria, advanced maternal age, and family history of DM were the most common risk factors found in the present study (Table 3). Pregnant women with previous history of GDM had almost 90% risk of having GDM in current pregnancy, followed by 73% risk in obese mothers.

Screening efficacy of the 3 modified criteria were presented in Table 4. Modified II criterion yielded the highest sensitivity and accuracy, with high specificity. Overall, cesarean delivery was performed in 50.3% of cases, there was no significant difference in cesarean rate between GDM and non-GDM groups.

Maternal and neonatal complications are presented in Table 5 and Table 6, respectively. The most common maternal complication was pregnancy-induced hypertension (PIH) and gestational hypertension is the majority in this subgroup. No cases of diabetic ketoacidosis (DKA) and eclampsia was found in the present study. When comparing GDM cases diagnosed by the NDDG criterion with cases diagnosed by the modified II criterion, the equivalent percentage of these maternal complications can be identified.

Regarding neonatal outcomes, hyperbilirubinemia was the most common complication.

Table 3. The risk factors of GDM

Risk factors	Total (n)	NDDG criteria		PPV (%)
		Non GDM (%)	GDM (%)	
Glucosuria	261	47.8	53.2	62.8
Advanced maternal age	211	38.9	42.9	62.6
Family history of DM	161	29.1	33.1	63.3
Excessive weight gain	71	16.3	12.3	53.5
Obesity	53	6.9	12.7	73.6
Poor obstetric outcome	44	7.9	9.1	63.6
History of GDM	18	0.9	5.2	88.9

GDM = gestational diabetes mellitus; NDDG = national diabetes data group; PPV = positive predictive value

Table 4. Screening efficacy of various modified criteria using NDDG criterion as gold standard. and Accuracy of Modified 100-g OGTT for diagnosis of GDM

Modified criteria	SE (%)	SP (%)	FP (%)	FN (%)	PPV (%)	NPV (%)	Accuracy (%)
I	82.5	90.2	9.9	17.6	92.4	67	85.5
II	96.8	81.8	18.2	3.3	89	94.3	90.8
III	79.2	100	0	20.8	100	76	87.4
2-hr	95.8	82.3	17.8	4.2	88.5	92.8	90.4

SE = sensitivity; SP = specificity; FP = false positive; FN = false negative; PPV = positive predictive value; NPV = negative predictive value

Table 5. Maternal complications detected by NDDG criterion and various modified criteria

Complications	Total number	Percentage detected by various criteria			
		NDDG	Modified I	Modified II	Modified III
Pregnancy induced HT	35	54.2	42.8	60	37.1
Gestational HT	25	56	40	64	36
Mild preeclampsia	8	37.5	37.5	37.5	25
Severe preeclampsia	2	100	100	100	100
Urinary tract infection	13	61.5	53.8	61.5	53.8
Perineal tear	6	50	50	50	50
Hydramnios	3	66.7	33.3	66.7	33.3
Postpartum complications	9	66.7	77.7	66.7	66.7

GDM = gestational diabetes mellitus; NDDG = national diabetes data group

Table 6. Neonatal complications detected by NDDG criterion and various modified criteria

Complications	Total number	Percentage detected by various criteria			
		NDDG	Modified I	Modified II	Modified III
Hyperbilirubinemia	128	56.2	48.4	62.5	43.7
Fetal macrosomia	32	53.1	56.2	56.2	46.8
Hypoglycemia	26	76.9	61.5	76.9	61.5
Congenital anomalies	25	68	48	68	44
RDS	22	50	50	50	36.3
Stillbirth (%)	0	0	0	0	0

GDM = gestational diabetes mellitus; NDDG = national diabetes data group; RDS = respiratory distress syndrome

When comparing GDM cases diagnosed by the NDDG criterion with cases diagnosed by the modified II criterion, the same proportion of neonatal complications can be identified. No case of stillbirth was found in the present study.

Discussion

GDM is one of the most common medical complications during pregnancy, and is associated with increased risk of perinatal morbidity and mortality. Detection of GDM would lead to an appropriate treatment, resulting in an improvement of obstetric and neonatal outcomes. Appropriate modality for screening and diagnosis is important. Currently, the 100-g OGTT is globally used for diagnosis of GDM. Its main disadvantages are time-consuming nature of the test, laboratory cost, and number of venipunctures.

In the present study, the authors attempted to assess the screening efficacy of the simplified criteria which required fewer venous blood samples, and less time-consuming. The authors proposed 3 modified criteria based on previous report, which demonstrated that the 3-hour plasma glucose value gave the lowest yield for diagnosis of GDM[11-13].

Our study showed that the modified II criterion gave the highest sensitivity and accuracy, with high specificity. Interestingly, we also found a high sensitivity, specificity, and accuracy using a single value of 2-hour $\geq$ 165 mg/dL, similar to another study[9].

The modified II criterion could detect the equivalent percentage of maternal and fetal/neonatal complications associated with GDM, as compared to the NDDG criterion. This test is more convenient, less time-consuming, reduced laboratory costs, and required only 2 blood samples. It may be a useful alternative for the diagnosis of GDM. Due to the retrospective nature of the present study, however, a prospective study may be required to assess the true usefulness of this modified criterion.

Conclusion

The modified criterion using the fasting plasma glucose and 2-hour plasma glucose measurements for diagnosis of GDM showed high sensitivity (96.8%) and accuracy (90.8%), with high specificity (81.8%). This criterion can detect the same proportion of maternal and neonatal complications, as compared to the NDDG criterion. It is more convenient, and more practical than the standard 100-g OGTT.

Potential conflicts of interest

None.

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การศึกษาความไวและความจำเพาะของการตรวจ modified 100-g oral glucose tolerance test วิธีต่าง ๆ ในการวินิจฉัยภาวะเบาหวานขณะตั้งครรภ์

จารุณี หาญสาริกิจ, ศักนัน มะโนทัย

วัตถุประสงค์*: เพื่อศึกษาความไวและความจำเพาะของการตรวจ modified 100-g oral glucose tolerance test วิธีต่าง ๆ ในการวินิจฉัยภาวะเบาหวานขณะตั้งครรภ์*

วัสดุและวิธีการ*: เป็นการศึกษาย้อนหลังโดยเก็บรวบรวมข้อมูลจากเวชระเบียนของหญิงตั้งครรภ์ที่มาฝากครรภ์ในคลินิกฝากครรภ์ โรงพยาบาลจุฬาลงกรณ์ และได้รับการตรวจ 100-g oral glucose tolerance test (OGTT) ในช่วงระหว่างเดือน มีนาคม พ.ศ. 2547 ถึง เดือนกันยายน พ.ศ. 2552 ผู้นิพนธ์กำหนดเกณฑ์การวินิจฉัย 3 วิธี เพื่อใช้วินิจฉัยภาวะเบาหวานขณะตั้งครรภ์ เปรียบเทียบกับเกณฑ์ของ National Diabetes Data Group (NDDG) เป็นเกณฑ์มาตรฐาน*

ผลการศึกษา*: หญิงตั้งครรภ์จำนวน 729 ราย ได้รับการตรวจ 100-g OGTT โดยที่ 511 ราย สามารถนำมาวิเคราะห์ข้อมูลได้ เมื่อใช้เกณฑ์ของ NDDG เป็นมาตรฐาน การใช้ modified criteria วิธีที่ 2 มีความไวสูงที่สุด เท่ากับ 96.8% ความแม่นยำสูงที่สุดเท่ากับ 90.8% ในการวินิจฉัยภาวะเบาหวานขณะตั้งครรภ์ วิธีการนี้สามารถตรวจพบภาวะแทรกซ้อนในมารดาและทารกได้เท่ากับการวินิจฉัยโดยใช้เกณฑ์มาตรฐาน*

สรุป*: การใช้ค่าระดับน้ำตาลในเลือดก่อนอาหาร และหรือ ค่าระดับน้ำตาลในเลือดที่ 2 ชั่วโมง หลังรับประทานกลูโคส 100 กรัม เป็นวิธีที่มีความไว ความแม่นยำสูง และมีความจำเพาะปานกลาง ในการวินิจฉัยภาวะเบาหวานขณะตั้งครรภ์ ควรมีการศึกษาแบบไปข้างหน้าเพิ่มเติมก่อนนำวิธีการนี้มาใช้ในทางปฏิบัติ*