
OBSTETRICS

Additional Proportion and Adverse Pregnancy Outcomes of Gestational Diabetes Mellitus with Carpenter-Coustan Criteria but not with National Diabetes Data Group Criteria

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ABSTRACT

Objective: This study was to estimate the additional proportion of GDM detected by the Carpenter-Coustan (CC) criteria only, over the National Diabetes Data Group (NDDG) criteria, and the increased adverse pregnancy outcomes in this group.

Materials and Methods: This was a cross sectional study. By using retrospective data from the prenatal care unit of Lampang Regional Hospital, women were classified into 3 groups, based on oral glucose tolerance tests (OGTT). They were GDM by the NDDG criteria, GDM by the CC criteria only, and non-GDM by both criteria. The risks of adverse pregnancy outcomes were analyzed by a binary regression.

Results: There were 1,053 pregnancies with OGTT results. Among these, 33.3% was defined GDM by the NDDG criteria. More 13.2% were defined by the CC criteria only. Women in the CC-GDM group had higher risks to deliver neonates $\geq 3,500$ grams (RR = 2.33), and higher premature rupture of membranes (RR = 3.01).

Conclusions: The CC criteria increased more women to be diagnosed as GDM. Women detected as GDM by the CC criteria but not the NDDG criteria, had higher risks of neonates $\geq 3,500$ grams and premature rupture of membranes.

Keywords: pregnancy outcomes, gestational diabetes mellitus, Carpenter-Coustan criteria, National Diabetes Data Group Criteria, glucose tolerance test, obstetric complications

Introduction

Gestational diabetes mellitus (GDM) complicates pregnancy approximately 2-9% worldwide⁽¹⁾. The prevalence varies among ethnic groups but correlates strongly to the prevalence of type 2 diabetes in the population⁽¹⁾. Although GDM has been recognized as

high-risk pregnancy, which can cause multiple adverse pregnancy outcomes⁽²⁾. There is still no consensus on a standard protocol or criteria of diagnosis using oral glucose tolerance test (OGTT)⁽²⁾.

Until now, there are 4 sets of criteria that are commonly used to diagnose GDM. They are National

Diabetes Data Group (NDDG), Carpenter and Coustan (CC), World Health Organization (WHO) and the newly criteria proposed by International Association of Diabetes and Pregnancy Study Group (IADPSG). The former 2 are based on 100 grams (gm) glucose load while the others are based on 75 gm oral glucose. In Thailand, most hospitals use either NDDG or CC criteria⁽³⁻⁸⁾.

The NDDG criteria, proposed in 1979, uses plasma glucose cut off values at 105, 190, 165, 145 mg/dl for fasting, 1 hour, 2 hour and 3 hour after glucose load. GDM will be diagnosed if a woman has 2 or more plasma glucose higher than the cutoff values⁽⁹⁾. CC criteria was proposed later, in 1982, using the diagnostic threshold at 95, 180, 155, 140 mg/dl⁽¹⁰⁾. There were studies showed that by using CC criteria, which is more sensitive, the prevalence of GDM was increased by 31.8–59.3%⁽¹¹⁻¹⁷⁾. Nevertheless, there is still no strong evidence that this sensitive threshold would improve pregnancy outcomes.

There are studies that tried to retrospectively explore pregnancy outcomes of the untreated GDM women with CC criteria. They found that, these women had increased risk of preeclampsia, cesarean delivery, operative vaginal delivery, large infants and shoulder dystocia^(11,14,17). However, there are reports stating that these risks were not difference from non-GDM women^(16,17). NDDG criteria has also been known for its too high threshold. And there is one report even called it cumbersome criteria⁽¹⁸⁾. This encouraged obstetricians to consider using other more sensitive criteria like CC or WHO criteria to be able to detect more GDM.

In Lampang Hospital, before 2010, all the obstetricians used NDDG criteria to diagnosed GDM. They all changed to CC after that. The first objective of this study was to estimate the additional proportion of GDM when CC criteria was used for the diagnosis. This study used the data from the year 2006 to 2009. Thus, it would be ideal to also evaluate pregnancy outcomes of GDM women only by CC criteria, since they were managed as non-GDM women in that period. The

second objective of this study was to prove any increased risk of adverse pregnancy outcomes that related to GDM women diagnosed only by CC criteria.

Materials and Methods

It was a cross sectional study. Data were collected retrospectively from hospital electronic database of Lampang Regional Hospital. Data of pregnant women who had oral glucose tolerance test (OGTT) done from 1st October 2006 to 30th September 2009 were retrieved. Data were OGTT results, demographic, obstetric and pregnancy outcomes of both mother and child. This research had been endorsed by Ethics Committee of Lampang Regional Hospital.

In Lampang Regional Hospital risk factors used for GDM screening were maternal age 30 years old or more, family history of type 2 diabetes in the first degree relatives, glucosuria, BMI 25 kg/m² or more, hypertension, history of GDM in previous gestation, history of DFIU (dead fetus in utero), fetal anomaly and macrosomia (birth weight 4,000 gm or more).

Pregnant women with one or more risk factors and no previous history of diabetes were screened with glucose challenge test (GCT) using 50 gm glucose per oral and plasma glucose measurement after 1 hour. The positive result was defined as plasma glucose ≥ 140 mg/dl. Then, OGTT was done with 100 gm glucose ingestion. All the plasma glucose value were measured with glucose oxidase method by using venous blood. The hospital laboratory calibrated the machine daily according to standard protocol for quality control.

For the diagnosis of GDM in the study period, all obstetricians used NDDG criteria. The cutoff values of plasma glucose at fasting period, 1, 2 and 3 hour were 105, 190, 165, and 145 accordingly. The women with at least 2 out of 4 abnormal plasma glucose were classified as GDM by NDDG criteria. These women actually were GDM cases by both NDDG and CC criteria and were treated during pregnancy. The treatment consisted of diet control and insulin if diet control only

couldn't achieve goal of fasting plasma glucose of 105 mg/dl and 2 hour post pandrial of 120 mg/dl.

All the above OGTT results were again interpreted by an obstetrician for this study using CC criteria. The cutoff values of plasma glucose at fasting period, 1, 2 and 3 hour by CC criteria were 95, 180, 155 and 140 mg/dl, accordingly^(1,19). The women with at least 2 out of 4 abnormal plasma glucose were classified as GDM by CC criteria. These women were practically not known by their caregivers at that time as having GDM. They were managed as non-GDM cases.

In the analysis, the proportions of GDM by both NDDG and CC criteria were calculated. The demographic, obstetric and perinatal factors were compared among women with non-GDM, GDM by CC criteria only (GDM-CC) and GDM by NDDG criteria (GDM-NDDG). Women with multifetal pregnancy and congenital anomalies were excluded from the analysis. Data were analyzed in a retrospective cohort approach using standard statistical software. Fisher's exact probability test and student t-test were used for

univariate analysis. After that, another univariate analysis was done to compare GDM-CC group with non-GDM. This was to show the real increased risk of being GDM by CC criteria. Then those statistically significant variables were brought to multivariate analysis. A binary regression was used to quantify the effect of GDM-CC over non-GDM in pregnancy outcomes, adjusting for significantly different baseline characteristics.

Results

Within these 3 years period, there were 1,053 pregnancy cases that had OGTT results. All cases delivered in Lampang Regional Hospital and could be retrieved for important variables. Table 1 shows the proportion of GDM diagnosed by CC and NDDG criteria. By using NDDG criteria to diagnose GDM, 33.3% were diagnosed as GDM. By changing the criteria to CC criteria 13.2% more were diagnosed but had not been managed as GDM. This lowering of the diagnostic threshold increased 39.6% cases of GDM.

Table 1. Results of oral glucose tolerance test by GDM classifications.

GDM Classifications	Proportion (N = 1,053)	
	N	%
No GDM by both criteria	563	53.5
GDM by CC criteria only	139	13.2
GDM by CC criteria	490	46.5
GDM by NDDG criteria	351	33.3

Table 2 shows all demographic and obstetric data when comparing among 3 groups of cases. They were the groups of non-GDM, GDM-CC and GDM-NDDG. Univariate analysis showed that GDM-NDDG group had significantly more women with elderly pregnancy. Though mean maternal age of these 3 groups was comparable, it was statistically different. These 3 groups contained comparable proportion of nulliparous women. Nevertheless, GDM-CC group had more women with history of preterm birth though it was

marginally statistical significant. GDM-NDDG group also contained more private cases. These 3 groups had comparable amount of women with medical complications diagnosed before pregnancy. Top 3 most common medical complications in this study were anemia 7.7%, thyrotoxicosis 0.8% and heart disease 0.4%. From the univariate analysis done to compare only GDM-CC with non-GDM group, it showed that history of preterm birth was the only significant factor.

Table 2. Comparing demographic and obstetric factors.

Factor	Non-GDM	GDM-CC	GDM-NDDG	p-value comparing 3 groups	p-value Non-GDM vs GDM-CC
	N = 563	N = 139	N = 351		
	n (%)	n (%)	n (%)		
Maternal age*	30.4 (6.4)	31.4 (6.0)	32.5 (5.6)	0.019	0.250
Maternal age group				0.002	0.493
< 20 years old	32 (5.7)	6 (4.3)	5 (1.4)		
20 – 34 years old	368 (65.4)	86 (61.9)	212 (60.4)		
≥ 35 years old	163 (28.9)	47 (33.8)	134 (38.2)		
Nulliparous	234 (41.6)	48 (34.5)	128 (36.5)	0.162	0.147
History of preterm birth	5 (0.9)	5 (3.6)	7 (2.0)	0.062	0.030
Private case	203 (36.1)	59 (42.5)	159 (45.3)	0.018	0.171
Medical complications	66 (11.7)	18 (12.9)	30 (8.5)	0.365	0.728

* Mean (SD)

Outcomes of pregnancy both of mother and child are shown in Table 3. GDM-NDDG group had significantly higher rate of cesarean section comparing to the other two groups. It increased to more than half of the women delivered. Women in these 3 groups delivered neonates with comparable gestational age (GA). Proportions of fetal sex were also found to be comparable among these 3 groups. GDM-CC group had significantly higher proportion of large fetus that weighs $\geq 3,500$ gm. When comparing mean weight, GDM-CC group had higher mean weight than the other two groups.

Proportions of neonates with asphyxia (Apgar

score 0-7) in these 3 groups were comparable. There was only 1 case that had severe asphyxia (Apgar score = 3) in this study. And it was in the NDDG group. Nevertheless, it showed that CC group had significantly higher proportion of women with obstetric complications. Although percentage of women pre-eclampsia had tendency to be higher in GDM-CC and GDM-NDDG group, it was not statistically significance. When another univariate analysis was done to compare GDM-CC with non-GDM group, it showed birth weight group and premature rupture of membranes as significant factors.

Table 3. Comparing obstetric and perinatal outcomes.

Factor	Non-GDM	GDM-CC	GDM-NDDG	p-value	p-value
	N = 560	N = 139	N = 349	comparing	Non-GDM
	n (%)	n (%)	n (%)	3 groups	vs GDM-CC
Mode of delivery					
Normal delivery	270 (48.0)	58 (41.7)	122 (34.8)	0.002	0.347
Cesarean section	252 (44.8)	68 (48.9)	202 (57.5)		
Vacuum	41 (7.2)	13 (9.4)	24 (6.8)		
Forceps	-	-	1 (0.3)		
Breech assisting	-	-	1 (0.3)		
BBA	-	-	1 (0.3)		
Gestational age*	38.5 (1.6)	38.5 (1.6)	38.1 (1.7)	0.246	1.000
GA group					
< 37 weeks	41 (7.3)	11 (7.9)	41 (11.7)	0.241	0.956
37-41 weeks	514 (91.3)	126 (90.7)	305 (86.9)		
≥ 42 weeks	8 (1.4)	2 (1.4)	5 (1.4)		
Male fetus	275 (48.9)	61 (43.9)	184 (52.4)	0.222	0.299
Birth weight*	3,058.6 (511.4)	3,179.3 (530.7)	3,112.5 (589.7)	0.011	0.056
Birth weight group					
< 2,500 gm	63 (11.2)	10 (7.2)	44 (12.5)		
2,500 – 3,499 gm	407 (72.3)	91 (65.5)	226 (64.4)		
≥ 3,500 gm	93 (16.5)	38 (27.3)	81 (23.1)		
Apgar score 0-7					
at 1 minute	12 (2.1)	1 (0.7)	11 (3.1)	0.300	0.482
at 5 minute	2 (0.4)	0 (0)	5 (1.4)	0.159	1.000
at 10 minute	3 (0.5)	0 (0)	3 (0.9)	0.728	1.000
Obstetric complications					
Any complication	27 (4.8)	14 (10.1)	31 (8.8)	0.021	0.021
Pre-ecalmsia	8 (1.4)	4 (2.9)	11 (3.1)	0.171	0.268
Preterm labor	4 (0.7)	2 (1.4)	4 (1.1)	0.501	0.340
PROM	3 (0.5)	4 (2.9)	6 (1.7)	0.037	0.031
PPH	3 (0.5)	0 (0)	1 (0.3)	1.000	1.000
Shoulder dystocia	0 (0)	0 (0)	3 (0.9)	0.084	-

* Mean (SD) PROM = premature rupture of membranes, PPH = postpartum hemorrhage

Two outcome factors, birth weight group and premature rupture of membranes, were brought to binary regression analysis by having history of preterm birth as the controlled confounder. The result of this

multivariate analysis is shown in table 4. It showed that being GDM by only CC criteria had significantly more chance of having large neonates weighing ≥ 3,500 gm and more premature rupture of membranes.

Table 4. Results of multivariate analysis.

Outcome of pregnancy	Risk ratio	95% confidence interval
Large neonate weighing \geq 3,500 gm	2.33	1.25-4.33
Premature rupture of membranes	3.01	1.56-5.83

Discussion

This study showed that by lowering the diagnostic threshold of GDM to CC criteria, increased 39.6% cases of GDM. This concurs with many previous studies, which stated this figure from 31.8 – 59.3%^(11,17). This should, by now, alert obstetricians in the institutes which still use NDDG criteria that, they would miss nearly 40% of GDM cases undiagnosed.

The results of pregnancy outcomes also concur with many studies. Though this study did slightly different analysis than the others. But only by doing 2 univariate analyses, the true risk of GDM by CC criteria would be shown. From the first univariate analysis, comparing all 3 groups together, many input factors were significantly different. But when comparing GDM-CC group with non-GDM group, only 1 factor that was statistically significant was history of preterm birth. Then it was used as controlled confounders in multivariate analysis.

There were only 2 adverse pregnancy outcomes that had their risk significantly increased for being in GDM-CC group. They were large neonate weighing \geq 3,500 gm (RR 2.33, 95% CI 1.25-4.33) and premature rupture of membranes (RR 3.01, 95%CI 1.56-5.83). Other adverse pregnancy outcomes that had tendency to increase but was not statistically significant in GDM-CC group comparing to non-GDM group were cesarean section, operative vaginal delivery and pre-eclampsia. According to other studies, there were some other outcomes that had their risk significantly increased in GDM diagnosed by CC criteria only. They were e.g. preeclampsia, cesarean delivery, operative vaginal delivery, large infants and shoulder dystocia^(11,14,17). The different result of this study from others might be explained by 2 reasons. First, in this study non-GDM

group came from women with positive GCT but OGTT were normal by both CC and NDDG criteria. While other studies non-GDM group also included women with negative GCT result. Another explanation might be because of larger sample size of other studies. The more power of detection of other studies might have capability to detect the small effect size of some factors e.g. shoulder dystocia.

One interesting finding from this study was that the cesarean section rate was highest in GDM-NDDG group while mean birth weight and proportion of birth weight group \geq 3,500 grams was lower than the GDM-CC group. This may be from bias of the obstetrician to the women diagnosed as GDM. The study of Cheng YW also showed the same thing as our finding⁽¹⁴⁾.

As this study was a retrospective study that retrieved data from the electronic database, there might be some confounders that couldn't be controlled. Some variables such as indication for GDM screening and indication for cesarean section were not available in the database.

Ultimately, this paper has achieved its goals by producing 2 interesting results that can be used in daily practice. The first result should convince many hospitals both in Thailand and abroad to shift from using NDDG criteria to CC criteria to prevent missing many cases of GDM. This can be more compelling if the hospitals would also do their own cost-benefit analysis. Since more cases of GDM diagnosed mean more expenses on both the treatments and health care personnel.

The second result, though there were only 2 pregnancy outcomes proved in this study. It was more than enough in the view of preventive medicine.

Because Thai and Asian women are small in size. In a case-control study about risk factors for cesarean section due to cephalo-pelvic disproportion from Lamphun hospital, mean birth weight in cesarean section group in their study was only 3,357.3 grams⁽²⁰⁾. Thus, having a fetus weighing $\geq 3,500$ gm would already threaten the pregnancy outcome. So, proper screening of GDM together with proper GDM management would ultimately prevent unnecessary adverse events during pregnancy.

Further research should be done regarding the appropriate criteria for each ethnic group. There was a paper comparing international criteria with national developed criteria⁽¹³⁾. Which interestingly produce even more sensitive diagnostic threshold, because it related with more adverse pregnancy outcomes. Newer researches should investigate some other neglected pregnancy outcomes like neonatal hypoglycemia or postpartum persistent of glucose intolerance⁽²¹⁾. Since, these factors might also be the results of different criteria approach.

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สัดส่วนที่เพิ่มขึ้นและผลลัพธ์การตั้งครรภ์ของเบาหวานจากการตั้งครรภ์ที่วินิจฉัยโดยเกณฑ์ของ Carpenter-Coustan แต่ไม่เข้าเกณฑ์ของ The National Diabetes Data Group

ดารินทร์ อริร่า, รายิน อริร่า, ชัยนันตร์ ปทุมานนท์

วัตถุประสงค์ : การศึกษาเพื่อหาสัดส่วนของการเป็นเบาหวานจากการตั้งครรภ์ที่วินิจฉัยได้เพิ่มโดยการใช้เกณฑ์ของ Carpenter-Coustan (CC) นอกเหนือจากการใช้เกณฑ์ของ The National Diabetes Data Group (NDDG) และหาผลลัพธ์ที่ไม่พึงประสงค์ของการตั้งครรภ์ของหญิงตั้งครรภ์กลุ่มนี้

วัสดุและวิธีการ: งานวิจัยนี้เป็นการศึกษาแบบ cross sectional เก็บข้อมูลย้อนหลังจากคลินิกฝากครรภ์ของโรงพยาบาลศูนย์ลำปาง หญิงตั้งครรภ์ถูกจัดออกเป็น 3 กลุ่ม ตามการแปลง oral glucose tolerance tests (OGTT) โดยแบ่งเป็นการวินิจฉัยเบาหวานจากเกณฑ์ของ NDDG, CC และเป็นเบาหวานจากทั้ง 2 เกณฑ์ จากนั้นรายงานสัดส่วนของการเป็นเบาหวานที่พิบากทั้ง 3 กลุ่ม และทำการวิเคราะห์หาความเสี่ยงต่อการเกิดผลลัพธ์ที่ไม่พึงประสงค์จากการตั้งครรภ์ โดยใช้สต็อกิต binary regression

ผลการศึกษา: มีหญิงตั้งครรภ์จำนวน 1,053 รายที่มีผล OGTT โดยในกลุ่มนี้ มีร้อยละ 33.3 ที่ถูกวินิจฉัยว่าเป็นเบาหวานตามนิยามของ NDDG อีกร้อยละ 13.2 ถูกวินิจฉัยว่าเป็นเบาหวานตามนิยามของ CC หญิงตั้งครรภ์ในกลุ่ม CC มีความเสี่ยงสูงที่จะคลอดทารกน้ำหนัก 3,500 กรัมหรือมากกว่า ($RR=2.33$) และมีความเสี่ยงของการเกิดภาวะน้ำนมก่อนการเจ็บครรภ์ลดมากขึ้น ($RR=3.01$)

สรุป: การใช้เกณฑ์ของ CC ทำให้มีหญิงตั้งครรภ์จำนวนมากขึ้นที่ถูกวินิจฉัยว่าเป็นเบาหวานจากการตั้งครรภ์ หญิงตั้งครรภ์ที่ถูกวินิจฉัยว่าเป็นเบาหวานจากการตั้งครรภ์โดยเกณฑ์ของ CC แต่ไม่ได้เป็นจากเกณฑ์ของ NDDG นี้ มีโอกาสเสี่ยงในการเกิดผลลัพธ์ที่ไม่พึงประสงค์จากการตั้งครรภ์มากขึ้น ได้แก่ การคลอดทารกน้ำหนัก 3,500 กรัมหรือมากกว่า และภาวะน้ำนมก่อนการเจ็บครรภ์ลด