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Effect of new diagnostic criteria on detection and pregnancy outcomes of gestational diabetes mellitus: a retrospective study

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Introduction: To determine the effect of changes in the diagnostic criteria on the number of gestational diabetes mellitus (GDM) detected and on pregnancy and neonatal outcomes.
Methods: We retrospectively reviewed results of the 75g oral glucose tolerance test and pregnancy and neonatal outcomes of Chinese women with singleton pregnancies delivered at Tuen Mun Hospital between January and December 2016. Those with GDM was treated with lifestyle modification with or without insulin. Women with GDM detected by the old and new criteria were compared in terms of the numbers of GDM detected, maternal characteristics, pregnancy outcomes, and neonatal outcomes.
Results: Of 733 pregnant women, 211 (28.8%) and 190 (25.9%) were identified as having GDM based on the old or new criteria, respectively (p=0.01). Women with GDM based on the old or new criteria were comparable in terms of maternal characteristics, pregnancy outcomes, and neonatal outcomes. Among the 190 women with GDM based on the new criteria, 33 (17.4%) had normal fasting blood glucose and 2-hour glucose results but abnormal 1-hour glucose result. Compared with women without GDM, women with GDM detected by 1-hour glucose test alone had lower birthweight neonates (3.04 kg vs 3.22 kg, p=0.01), more neonates small for gestational age (3.7% vs 15.2%, p=0.01), with hypoglycaemia (15.2% vs 3.9%, p<0.001), and admission to neonatal intensive care unit (12.1% vs 1.3%, p<0.001).
Conclusions: The new criteria detected 2.9% fewer women with GDM. 17.4% of women with GDM who were associated with poor neonatal outcomes were detected exclusively by 1-hour glucose test. The new criteria can help identify high-risk women for fetal monitoring.

Keywords: Blood glucose; Diabetes, gestational; Pregnancy outcome

Introduction

Gestational diabetes mellitus (GDM) has significant health impact on mothers and children. Clear diagnostic criteria can help identify high-risk mothers for appropriate treatment with better use of the limited healthcare resources.

In the old diagnostic criteria for GDM, the cut-off value for GDM was fasting blood glucose (FBG) of ≥7.0 mmol/L and/or 2-hour glucose (2HG) of ≥7.8 mmol/L[1]. In 2013, the World Health Organization (WHO) adopted the new diagnostic criteria for GDM proposed by the International Association of Diabetes and Pregnancy Study Groups (IADPSG) in 2010[2,3]. The new criteria were based on the Hyperglycemia and Adverse Pregnancy Outcomes study[4], which prospectively examined 23316 women using the 75-g oral glucose tolerance test (OGTT). In the new criteria, GDM was defined as FBG ≥5.1 mmol/L, 1-hour glucose (1HG) test ≥10 mmol/L, and/or 2HG test ≥8.5 mmol/L. The cut-off values were devised from the blood glucose levels at which the risks of neonatal large for gestational age, primary Caesarean section, neonatal hypoglycaemia, and neonatal cord c-peptide >90th centile increased by a factor of 1.75[4]. Using the new criteria, the global prevalence of hyperglycaemia in pregnancy is estimated at 17%, with variations from 10% in North America to 25% in Southeast Asia[5]. The International Federation of Gynecology and Obstetrics recommended the WHO criteria for diagnosis of diabetes mellitus in pregnancy and the WHO and the IADPSG criteria for diagnosis of GDM.

Universal OGTT is not practised in Hong Kong; only women with one or more risk factors for GDM receive 75-g OGTT at 24 to 28 weeks of gestation. These risk factors are age ≥35 years at the expected date of conception, a pre-pregnancy body mass index (BMI) of ≥25 kg/m^2, having a first-degree relative with diabetes, having a previous neonate weighing ≥4 kg at birth, and having a history of GDM, intrauterine fetal death or polycystic

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ovary syndrome. OGTT is also recommended for women with signs suggestive of GDM such as fetal macrosomia or polyhydramnios.[6] In our department, pregnant women at high risk of developing diabetes mellitus in pregnancy are also offered OGTT at booking. These risk factors are BMI ≥30 kg/m^2, maternal age ≥40 years at the expected date of conception, and having co-morbidities of polycystic ovaries, coronary heart disease, chronic hypertension, or on long-term oral steroid.

Since 1 December 2014, our department has used the new diagnostic criteria for GDM. All women detected to have GDM are treated according to the Hong Kong College of Obstetricians and Gynaecologists guidelines on the management of GDM[6]. They are followed up and care for under the multidisciplinary team comprising obstetricians, endocrinologists, GDM specialty nurses, and dietitians. Lifestyle advice is given. The blood sugar profile at home is monitored and reviewed regularly. Ultrasonography is used to monitored fetal growth in the third trimester. Those with unsatisfactory glucose control are referred to endocrinologists for insulin treatment. Mode and time of delivery are advised depending on the glucose control and any antenatal and fetal complications. Women with well-controlled GDM can opt for a spontaneous onset of labour or induced labour by 40 weeks of gestation. Elective Caesarean section is offered to women with estimated fetal weight of ≥4 kg.

The effects of changes in cut-off values of FBG and 2HG on the detection rate of GDM and pregnancy outcomes have been reported[7,8]. However, studies of the additional 1HG test on the pregnancy outcomes are limited. This study aimed to determine the effect of changes in the diagnostic criteria on the number of GDM detected and on pregnancy and neonatal outcomes.

Methods

This study was approved by the New Territories West Cluster Clinical and Research Ethics Committee of Hospital Authority, Hong Kong (reference: NTWC/CREC/16047). We retrospectively reviewed OGTT results and pregnancy and neonatal outcomes of Chinese women with singleton pregnancies delivered at Tuen Mun Hospital between January and December 2016. The catchment area of the hospital has about 500,000 reproductive population according to the census in 2016[9]. Those with multiple pregnancies or non-Chinese ethnicity were excluded. For women with repeat OGTT when a new indication arose during pregnancy, their pregnancy outcomes were counted per woman to avoid repetition.

Women with GDM detected by the old and new criteria were compared in terms of the numbers of GDM detected, maternal characteristics, pregnancy outcomes, and neonatal outcomes. Maternal characteristics included age, smoking status, BMI and body weight at booking, education, parity, working status, conception by assisted reproductive technology. Pregnancy outcomes included pre-eclampsia, induction of labour, genital trauma, gestational age at delivery, and mode of delivery. Neonatal outcomes included prematurity, birthweight, stillbirth, Apgar score, hyperbilirubinemia requiring phototherapy, shoulder dystocia, neonatal hypoglycaemia (<1.7 mmol/L), and admission to neonatal intensive care unit.

Pre-eclampsia was defined as systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mmHg on at least two occasions at least 4 hours apart after 20 weeks of gestation in a previously normotensive patient together with the new onset of proteinuria or significant end organ dysfunction.[10] Genital trauma was defined as the third- or fourth-degree perineal tear, according to the Royal College of Obstetricians and Gynaecologists.[11] Gestational age was determined from the date of last menstrual period or by ultrasonography performed between 6 and 24 weeks of gestation. Prematurity was defined as delivery <37 weeks of gestation. Primary Caesarean section was defined as the first Caesarean section (excluding repeated Caesarean section for previous Caesarean section). Large for gestational age and small for gestational age were defined as birth weight above the 90th percentile and below the 10th percentile, respectively, according to the growth standards of newborns of ethnic Chinese origin in a prospective cross-sectional population study.[12] Stillbirth was defined as a baby delivered with no signs of life known to have died after 24 completed weeks of pregnancy, according to the MBRRACE-UK Perinatal Mortality Surveillance Report.[13] Clinical neonatal hypoglycaemia was considered present if there was a notation of neonatal hypoglycaemia in the medical record together with symptoms or treatment with a glucose infusion or a local laboratory report of a glucose level of ≤1.7 mmol/L in the first hour after birth.[14]

Statistical analysis was performed using SPSS (Windows version 22; IBM Corp, Armonk [NY], US). Continuous data were presented as median and interquartile range in case of skewed distribution. Categorical data were presented as numbers and percentages. Comparisons between groups were made using Student's *t* test or Mann-Whitney *U* test for continuous variables and Chi-squared test or Fisher's exact test for dichotomous outcomes. All p values were two-tailed. Statistical significance was set at $p<0.05$.

Table 1. Maternal characteristics, pregnancy outcomes, and neonatal outcomes of women with gestational diabetes mellitus (GDM) detected by the old and the new criteria

Characteristics	Women with GDM detected by old criteria (fasting blood glucose ≥7.0 mmol/L and/or 2-hour glucose ≥7.8 mmol/L) [n=211]*	Women with GDM detected by new criteria (fasting blood glucose ≥5.1 mmol/L, 1-hour glucose ≥10.0 mmol/L, and/or 2-hour glucose ≥8.5 mmol/L) [n=190]*	p Value
Maternal characteristics			
Age, y	34 (30-37)	33 (29-36)	0.21
Pre-pregnancy body mass index, kg/m^2	24.4 (21.7-26.6)	24.4 (21.4-26.8)	0.90
<25	124 (58. 8)	113 (59.5)	0.96
25-29.9	69 (32.7)	61 (32.1)	0.90
≥30	18 (8.5)	16 (8.4)	0.97
Body weight at booking, kg	59.5 (53.6-67.2)	59.4 (53.6-65.9)	0.68
Education			0.98
Tertiary or above	50 (23.7)	47 (24.7)	
Secondary	155 (73.5)	139 (73.2)	
Primary	5 (2.4)	3 (1.6)	
No education	1 (0.5)	1 (0.5)	
Nulliparous	108 (51.2)	99 (52.1)	0.60
Smoking during pregnancy	9 (4.3)	12 (6.3)	0.59
Working mother	115 (54.5)	111 (58.4)	0.44
Assisted reproductive technology treatment	13 (6.2)	10 (5.3)	0.53
Pregnancy outcomes			
Pre-eclampsia	5 (2.4)	7 (3.7)	0.44
Induction of labour	83 (39.3)	84 (44.2)	0.60
Genital trauma	1 (0.5)	1 (0.5)	0.94
Gestational age at delivery, weeks	38 (38-39)	38 (37-39)	0.34
Mode of delivery			
Vaginal	99 (46.9)	94 (49.5)	0.64
Instrumental	20 (9.5)	20 (10.5)	0.74
Primary Caesarean section	40 (19.0)	35 (18.4)	0.81
Neonatal outcomes			
Prematurity	20 (9.5)	25 (13.2)	0.25
Birthweight, g	3250 (2950-3520)	3260 (2910-3480)	0.68
Small for gestational age	11 (5.2)	11 (5.8)	0.68
Large for gestational age	52 (24.6)	46 (24.2)	0.90
Stillbirth	3 (1.4)	4 (2.0)	0.61
Apgar score <7 at 5 minutes	1 (0.5)	1 (0.5)	0.99
Hypoglycaemia	12 (5.7)	14 (7.4)	0.50
Shoulder dystocia	1 (0.5)	1 (0.5)	0.94
Phototherapy	38 (18.0)	36 (18.9)	0.97
Admission to neonatal intensive care unit	5 (2.4)	8 (4.2)	0.31

* Data are presented as median (interquartile range) or No. (%) of cases

Table 2. Maternal characteristics, pregnancy outcomes, and neonatal outcomes of women with no gestational diabetes mellitus (GDM), women with GDM detected by 1-hour glucose (1HG) test only, and women with GDM detected by fasting blood glucose (FBG) test and/or 2-hour glucose (2HG) test, based on the new criteria

Characteristics	Women with no GDM (FBG <5.1 mmol/L, 1HG <10.0 mmol/L, and/or 2HG <8.5 mmol/L) [n=543]	Women with GDM detected by 1HG (≥10.0 mmol/L) only (with normal FBG and 2HG) [n=33]	p Value	Women with GDM detected by FBG (≥5.1 mmol/L) and/ or 2HG (≥8.5 mmol/L) [n=157]	p Value
Maternal characteristics					
Treatment for GDM					<0.001
Diet	0	33 (100)		150 (95.5)	
Insulin	0	0		7 (4.5)	
Age, y	33 (30-36)	34 (29-36)	0.99	33 (29-36)	0.26
Pre-pregnancy body mass index, kg/m^2	22.4 (20.3-25.7)	24.0 (20.2-27.2)	0.21	23.8 (21.4-26.6)	0.06
<25	371 (68.3)	19 (57.6)	0.18	97 (61.8)	0.06
25-29.9	136 (25.0)	9 (27.3)	0.73	51 (32.5)	0.04
≥30	36 (6.6)	5 (15.2)	0.66	11 (7.0)	0.91
Body weight at booking, kg	57.4 (50.7-65.1)	59.1 (52.9-64.7)	0.45	59.4 (53.5-66.1)	0.53
Education			0.78		0.89
Tertiary or above	133 (24.5)	10 (30.3)		39 (24.8)	
Secondary	394 (72.6)	22 (66.7)		115 (73.2)	
Primary	13 (2.4)	1 (3.0)		2 (1.3)	
No education	3 (0.6)	0		1 (0.6)	
Nulliparous	247 (45.5)	18 (54.5)	0.62	83 (52.8)	0.21
Smoking during pregnancy	111 (20.4)	7 (21.2)	0.20	27 (17.2)	0.95
Working mother	301 (55.4)	21 (63.6)	0.23	92 (58.6)	0.41
Assisted reproductive technology treatment	30 (5.5)	1 (3.0)	0.53	10 (6.4)	0.18
Pregnancy outcomes					
Pre-eclampsia	20 (3.7)	3 (9.1)	0.13	4 (2.5)	0.62
Induction of labour	154 (28.4)	13 (39.4)	0.40	72 (45.9)	<0.001
Genital trauma	8 (1.5)	0	0.488	1 (0.6)	0.40
Gestational age at delivery, week	39 (38-39)	38 (37-40)	0.10	38 (37-39)	<0.001
Mode of delivery					
Vaginal	311 (57.3)	15 (45.5)	0.19	24 (15.3)	0.11
Instrumental	19 (3.5)	3 (9.1)	0.10	17 (10.8)	<0.001
Primary Caesarean section	90 (16.6)	10 (30.0)	0.74	29 (18.5)	0.74
Neonatal outcomes					
Prematurity	54 (9.9)	3 (9.1)	0.22	20 (12.7)	<0.001
Birthweight, g	3220 (2940-3500)	3040 (2570-3320)	0.01	3280 (2960-3520)	0.12
Small for gestational age	20 (3.7)	5 (15.2)	0.01	6 (3.8)	0.21
Large for gestational age	107 (19.7)	4 (12.1)	0.28	43 (27.4)	0.05
Stillbirth	2 (0.4)	0	0.73	3 (1.9)	0.81
Apgar score <7 at 5 minutes	2 (0.4)	0	0.40	1 (0.6)	0.81
Hypoglycaemia	21 (3.9)	5 (15.2)	<0.001	11 (7.0)	0.13
Shoulder dystocia	2 (0.4)	0	0.73	1 (0.6)	0.66
Phototherapy	90 (16.6)	4 (12.1)	0.49	32 (20.4)	0.11
Admission to neonatal intensive care unit	7 (1.3)	4 (12.1)[†]	<0.001	4 (2.5)	0.28

[*] Data are presented as median (interquartile range) or No. (%) of cases

[†] Two had meconium aspiration syndrome (one discharged on day 10 and another on day 14). Two others had prematurity. One was born at 26 weeks with respiratory distress syndrome and chronic lung disease requiring oxygen until the age of 6 months. Another was born at 30 weeks with respiratory distress syndrome, premature gut, and neonatal jaundice requiring phototherapy and was discharged after 2 months

Results

Of 733 pregnant women, 211 (28.8%) and 190 (25.9%) were detected to have GDM based on the old or new criteria, respectively (p=0.01). Women with GDM based on the old or new criteria were comparable in terms of maternal characteristics, pregnancy outcomes, and neonatal outcomes (Table 1).

Based on the new criteria, women with and without GDM were comparable in terms of maternal characteristics, except that more women with GDM detected by FBG and/or 2HG tests were in the BMI category of 25-29.9 kg/m^2 (32.5% vs 25.0%, p=0.04, Table 2).

Among the 190 women with GDM based on the new criteria, 33 (17.4%) had normal FBG and 2HG results but abnormal 1HG result. Compared with women without GDM, women with GDM detected by 1HG test alone had comparable pregnancy outcomes (pre-eclampsia, induction of labour, genital trauma, and primary Caesarean section) but poorer neonatal outcomes: lower birthweight (3.04 kg vs 3.22 kg, p=0.01), more neonates small for gestational age (3.7% vs 15.2%, p=0.01), with hypoglycaemia (15.2% vs 3.9%, p<0.001), and admission to neonatal intensive care unit (12.1% vs 1.3%, p<0.001).

Compared with women without GDM, women with GDM detected by FBG and/or 2HG test were more likely to require induction of labour (45.9% vs 28.4%, p<0.001) and instrumental delivery (10.8% vs 3.5%, p<0.001) and have more neonates born prematurely at <37 weeks of gestation (12.7% vs 9.9%, p<0.001) and large for gestational age (27.4% vs 19.7%, p=0.05).

Discussion

Based on the new diagnostic criteria, the number of GDM cases detected in our cohort reduced 2.9%. Nonetheless, most studies reported an increase in the number of GDM cases[15-20], although some studies reported similar or decreased in number of GDM cases.[21,22] This reduction reflected that most GDM cases detected in the Chinese population was by the 2HG test. Therefore, a decrease in the number of GDM cases detected was due to the loosening of the 2HG test. Although women with 2HG in the range of 7.8-8.4 mmol/L were classified as non-GDM by the new criteria and were untreated, there was no change in pregnancy outcomes between the old and new criteria. This is reassuring to adopt the new criteria.

The additional 1HG test requires extra healthcare resource, but it can pick up cases with poor neonatal outcomes. Based on the new criteria, 17.4% of women with GDM were detected exclusively by 1HG test with normal FBG and 2HG results. Neonatal outcomes of these women were poorer, including lower birthweight, more hypoglycaemia, and more admission to neonatal intensive care unit. The additional 1HG test helps identify high-risk women for fetal surveillance. If the 1HG test was not implemented (old criteria), these women would have been classified as non-GDM. The poorer neonatal outcomes would have been the result of no treatment. Further randomised controlled trials on the treatment effects on women with GDM detected by the 1HG test alone are warranted.

This study has some limitations. There is no universal screening for GDM in Hong Kong; only women with one or more risk factors for GDM or signs suggestive of GDM are tested. Therefore, the number of pregnancies affected by GDM represented only women at higher risk of GDM (rather than the general obstetric population). In addition, the sample size may be too small to show any statistical significance. However, more samples will be included to increase the power of the study. Further randomised controlled trials are warranted to assess the effect of treatment for women with abnormal 1HG test result only on pregnancy outcomes.

Conclusion

The new criteria detected 2.9% fewer women with GDM. 17.4% of women with GDM who were associated with poor neonatal outcomes were detected exclusively by 1HG test. The new criteria can help identify high-risk women for fetal monitoring. More extensive or territory-wide studies on the effect and cost-effectiveness analysis of the new diagnostic criteria are warranted.

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Declaration

The authors have no conflict of interest to disclose.

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