Evaluation of the gestational diabetes mellitus diagnostic criteria recommended by the international association of diabetes and pregnancy study group for long-term maternal postpartum outcomes in mainland China

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Abstract
The gestational diabetes mellitus (GDM) diagnostic criteria recommended by the International Association of Diabetes and Pregnancy Study Group (IADPSG) were established based on the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study and have been the most commonly used criteria for determining GDM worldwide. Although individuals from mainland China were not included in the HAPO study, the IADPSG criteria have been used in China since 2011. However, the appropriateness of the criteria for evaluating maternal postpartum outcomes in mainland China are unknown. We conducted this study to determine whether the IADPSG criteria are appropriate for Chinese patients for evaluating long-term maternal postpartum outcomes.

Eighty-four patients who were diagnosed with hyperglycemia during pregnancy and had delivery in Peking University First Hospital from February 2007 to December 2009 were enrolled in the study. For patients in Group A, GDM was diagnosed using both the National Diabetes Data Group (NDDG) criteria and the IADPSG criteria, while patients in Group B, gestational impaired glucose tolerance (GIGT) was diagnosed using the NDDG criteria while GDM was diagnosed based on the IADPSG criteria. Anthropometric data, glucose metabolism, lipid profiles, β-cell function, and insulin resistance index were evaluated and compared to baseline after 5–6-year postpartum period.

Patients in group A had significantly higher oral glucose tolerance test (OGTT) fasting, 2-hour and 3-hour plasma glucose levels compared to patients in group B at 24 to 28 weeks of gestation \( (P<.05) \). No significant differences were observed between the groups for anthropometric data, postpartum abnormal glucose metabolism (50.91% vs 44.83%, \( P=.596 \)), type 2 diabetes mellitus (T2DM) (16.36% vs 3.45%, \( P=.167 \)), lipid profiles, β-cell function (homeostasis model assessment β-cell function index (HOMA-β) 1.04 vs 0.99, \( P=.935 \)) and insulin resistance (homeostasis model assessment insulin resistance index (HOMA-IR) 2.01 vs 1.69, \( P=.583 \)).

Patients diagnosed with GDM using either the NDDG or IADPSG criteria had abnormal glucose levels and lipid metabolism after delivery. Patients with mild hyperglycemia had similar postpartum β-cell functional impairment and insulin resistance to those with moderate hyperglycemia during pregnancy. Hence, with respect to maternal long-term postpartum outcomes, the IADPSG diagnostic criteria for GDM could be appropriate for patients in mainland China.

Abbreviations: 2-h PG = 2-hour plasma glucose, ACOG = American College of Obstetricians and Gynecologists, ADA = American Diabetes Association, BMI = body mass index, FPG = fasting plasma glucose, GDM = gestational diabetes mellitus, GIGT = gestational impaired glucose tolerance, HAPO = Hyperglycemia and Adverse Pregnancy Outcome Follow-up Study, IADPSG = International Association of Diabetes and Pregnancy Study Group, IDF = International Diabetes Federation, ISI = insulin sensitivity index, LDL-C = low-density lipoprotein cholesterol, NDDG = National Diabetes Data Group, NGT = normal glucose tolerance, NIH = National Institutes of Health, OGTT = oral glucose tolerance test, T2DM = type 2 diabetes mellitus, TCHO = total cholesterol, TG = triglyceride, WHO = World Health Organization, WHR = waist hip ratio.

Keywords: gestational diabetes mellitus, IADPSG diagnostic criteria, long-term postpartum outcomes
1. Introduction

Gestational diabetes mellitus (GDM) is the occurrence of hyperglycemia that manifests during pregnancy in patients who have not been previously diagnosed with diabetes. However, no international consistent GDM diagnostic criteria have been established for long time. The National Diabetes Data Group (NDDG) criteria have been used across China prior to the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study being published. Due to severe gastrointestinal complications occurring in pregnant women with a 100-g glucose load, the majority of hospitals in China have used the 75-g oral glucose tolerance test (OGTT). However, the diagnostic cut-off values are still based on the NDDG 100-g OGTT criteria. After the HAPO study was published, new criteria were established in accordance with the International Association of Diabetes and Pregancy Study Group (IADPSG) guidelines for GDM. Since then, the IADPSG criteria have been gradually adopted by many countries and institutions. The American Diabetes Association (ADA) adopted the criteria in 2011, followed by World Health Organization (WHO) in 2013. The cut-off values in the IADPSG criteria are lower, with GDM being diagnosed in patients with only one threshold being met or exceeded. Hence, the incidence of GDM increased significantly under the new guidelines. In the HAPO study, GDM incidence was as high as 17.8%. The International Diabetes Federation (IDF) estimated that in 2019, 1 in 6 live births was affected by hyperglycemia in pregnancy, 84% of which was GDM. However, due to the lack of cost-effective analysis of the IADPSG criteria, several countries and institutions, with the majority being in North America, refused to accept these guidelines. The National Institutes of Health (NIH) accepts the Carpenter-Coustan criteria, while the American College of Obstetricians and Gynecologists (ACOG) accepts the NDDG criteria. The ADA guidelines recommend that GDM diagnosis could be accomplished using the one-step 75-g OGTT or “two-step” approach with a 50-g (non-fasting) screening, followed by a 100-g or 75-g OGTT for patients with positive results at screening. Even though patients in mainland China were not included in the HAPO study, the IADPSG criteria were implemented in China in December 2011. However, whether the IADPSG criteria are appropriate for patients in mainland China has not been evaluated. This study compared the different criteria in the same patient groups and observed that for patients who were diagnosed as mildly hyperglycemic using the new criteria were at risks for perinatal complications and their conditions worsened significantly without proper management, and perinatal outcomes improved with timely education and treatment. This suggests that the IADPSG criteria were appropriate for patients in China with respect to perinatal outcomes. The Hyperglycemia and Adverse Pregnancy Outcome Follow-up Study (HAPO FUS) observed that compared to normal glucose tolerance (NGT), women diagnosed with GDM based on the IADPSG criteria had a higher risk of long-term postpartum glucose metabolic disorders. Because HAPO and HAPO FUS did not include patients from mainland China, the long-term postpartum outcomes using the IADPSG criteria remains to be evaluated for this population. This study evaluated the feasibility of implementing the IADPSG GDM diagnostic criteria for long-term maternal postpartum prognosis in mainland China. We compared glucose and lipid metabolism, β-cell function and insulin resistance levels 5- to 6-year postpartum in patients who were diagnosed with GDM using both the NDDG and IADPSG criterion and in patients who were diagnosed with gestational impaired glucose intolerance (GIGT) using the NDDG criteria but with GDM using the IADPSG criteria.

2. Methods

2.1. Study population

Eighty-four women who were diagnosed with hyperglycemia using the NDDG criteria during pregnancy and delivered at the Peking University First Hospital from February 2007 to December 2009 were included in this study. The mean age of the study participants was 32.1 years.

2.2. Grouping methods

Eighty-four women were assigned to 1 of 2 groups based on their gestational glucose levels (evaluated between 24 and 28 weeks of pregnancy). Patients in group A met both the NDDG and IADPSG diagnostic criteria for GDM, while those in group B were categorized as GIGT using the NDDG criteria and GDM using the IADPSG criteria.

2.3. Study methods

All study participants were followed up at 5- to 6-year postpartum based on the original demographic data collected. Data on follow-up included maternal age, pre-gestational weight, pre-gestational body mass index (BMI), neonatal birth weight, and BMI at 5- to 6-year postpartum, waist circumference, hip circumference, waist-to-hip ratio, family history of diabetes, and perinatal outcomes. A 75-g OGTT was performed after an 8-hour overnight fasting, during which their fasting and 2-hour plasma glucose, insulin levels, and fasting lipid profiles were measured. Homeostasis model assessment insulin resistance index (HOMA-IR), Homeostasis model assessment β-cell function index (HOMA-β), and insulin sensitivity index (ISI) were also calculated. Plasma glucose was measured using the glucose oxidase method, and lipid profiles were measured using the enzymatic colorimetric and chemical method performed on a Hitachi 7600 Automatic Biochemical Analyzer (Kyoto, Japan). The chemiluminescence method was used to measure insulin levels using the Roche COBAS 6000 automatic electrochemiluminescence immunoassay analyzer (Kyoto, Japan). Demographic data, perinatal outcomes, glucose and lipid metabolism, β-cell function, and insulin resistance of the 2 groups 5- to 6-year postpartum were then compared.

This study was approved by the Ethics Committee of the Peking University First Hospital. All subjects provided written informed consent forms.

2.3.1. Diagnostic criteria for abnormal gestational glucose metabolism

2.3.1.1. NDDG criteria. The 50-g glucose load test was performed at 24- to 28-week of gestation; if the 1-hour plasma glucose ≥7.8 mmol/L, a 3-hour 75-g OGTT was performed. The cut-off values for fasting, 1-hour, 2-hour, and 3-hour plasma glucose levels were 5.8, 10.6, 9.2 and 8.1 mmol/L, respectively. If a single threshold was met or exceeded, GIGT was diagnosed. If 2 or more thresholds were met or exceeded, GDM was diagnosed.

2.3.1.2. IADPSG criteria. The 75-g OGTT was performed at 24- to 28-week of gestation, with cut-off values for fasting, 1-hour
Table 1: Demographic profile of the 2 patient groups.

|                     | Group A (n=55) | Group B (n=29) | P     |
|---------------------|---------------|---------------|-------|
| Age (yr)            | 31.0±3.8      | 32.1±3.4      | .904  |
| Advanced maternal age | 16 (29.0%)    | 9 (31.03%)    | .853  |
| Family history of diabetes | 28 (50.91%)  | 12 (42.86%)  | .488  |
| Pre-gestational weight (kg) | 58.59±7.93   | 60.35±7.61   | .350  |
| Pre-gestational BMI (kg/m²) | 22.47±3.02   | 22.73±2.61   | .706  |
| Neonatal birth weight (g) | 3291±481      | 3411±537     | .300  |
| Waist-hip ratio     |               |               |       |

Advanced maternal age = maternal age ≥ 35 yr; BMI = body mass index; WHR = waist hip ratio.

2.3.2. Diagnostic criteria for abnormal glucose metabolism (5–6 years postpartum). The diagnostic criteria followed the 1999 WHO criteria:

1) Type 2 diabetes mellitus (T2DM): fasting plasma glucose (FPG) ≥ 7.0 (or) 2-hour plasma glucose (2-hour PG) ≥ 11.1 mmol/L;
2) Impaired fasting glucose: 6.1 ≤ FPG < 7.0 mmol/L and 2-hour plasma glucose (2-hour PG) < 7.8 mmol/L;
3) Impaired glucose tolerance: FPG ≥ 6.1 mmol/L and 7.8 ≤ 2-hour PG < 11.1 mmol/L.

2.3.3. Diagnostic criteria of abnormal lipid metabolism (5–6 years postpartum). Based on the Guidelines on Prevention and Management of Blood Lipid Abnormalities in Chinese Adults published in 2007, the criteria for lipid abnormalities were as follows:

1) hypertriglyceridemia: triglyceride (TG) concentration ≥ 1.7 mmol/L;
2) hypercholesterolemia: total cholesterol (TCHO) concentration ≥ 5.18 mmol/L;
3) low high-density lipoprotein cholesterol: high-density lipoprotein cholesterol (HDL-C) concentration < 1.04 mmol/L;
4) low high-density lipoprotein cholesterol: low-density lipoprotein cholesterol (LDL-C) concentration ≥ 3.37 mmol/L.

2.3.4. Formulas used for calculations.

1. BMI = weight (kg)/height (m²);
2. Waist hip ratio (WHR) = waist (cm)/hip (cm);
3. HOMA-IR = FPG (mmol/L) × fasting insulin (mIU/L)/22.5;
4. HOMA-β = 20 × fasting insulin (mIU/L)/(FPG (mmol/L) – 3.5)%;
5. ISI = 1/(FPG (mmol/L) × fasting insulin (mIU/L)).

2.4. Statistical analysis

Data was analyzed using the SPSS (version 16.0, USA). Measurement data fitting a normal distribution were expressed by mean ± standard deviation and analyzed using the t test. Other measurement data were described using median (25th–75th percentile) and analyzed using the Wilcoxon rank sum test. Categorical data, expressed by proportions (%), were analyzed using the χ² test or Fisher’s exact test. The threshold P value for statistical significance was set at P < .05.

3. Results

3.1. Demographic data

There were no significant differences in maternal age (P=.904), the percentage of patients with advanced maternal age (P=.853) or family history of diabetes (P=.488), pre-gestational weight (P=.350), pre-gestational BMI (P=.706), neonatal birth weight (P=.300), percentage of patients with adverse perinatal outcomes (P=.150), maternal weight and BMI 5- to 6-year postpartum (P=.214, .537), waist circumference (P=.449), hip circumference (P=.264), and WHR (P=.540) between the 2 groups (Table 1).

3.2. Glucose metabolism, lipid metabolism, β-cell function, and insulin resistance

3.2.1. Glucose metabolism. Patients in group A had significantly higher levels of OGTT fasting, 2-hour and 3-hour plasma glucose compared to patients in group B at 24- to 28-week of gestation (P < .001, < .001, .009) (Table 2). However, there were no significant differences in the incidence of T2DM (P=.167), prediabetes (P=.537), or total abnormal glucose metabolism (P=.596) 5- to 6-year postpartum between the 2 groups (P > .05) (Tables 2 and 3). Using T2DM 5- to 6-year postpartum as end point, power calculation was performed, which turned out to be 0.573.

3.2.2. Lipid metabolism. No significant differences were found between the groups at 24- to 28-week of gestation or at 5- to 6-year postpartum follow-up for TG (P=.129, .951), TCHO (P=.587, .249), HDL-C (P=.670, .813), LDL-C (P=.657, .221), and the incidence of hypertriglyceridemia (P=.914, .781), hypercholesterolemia (P=.868, .129), low-high density lipoprotein cholesterol (P=.960, .698), and high-low density lipoprotein cholesterol (P=.731, .140) (Tables 2 and 3).

3.2.3. β-cell function and insulin resistance. There were no significant differences in fasting insulin levels (P=.774), OGTT 2-hour insulin (P=.582), HOMA-IR (P=.583), HOMA-β
cholesterol, OGTT

The suggestions included a results of the HAPO study, and suggested one-step screening recommended new guidelines for GDM diagnosis based on the criteria, the HAPO study[3], a global multicenter prospective to the need for an international consensus for GDM diagnostic than maternal and neonatal perinatal complications. Responding related to the subsequent risk of diabetes to the mother rather higher maternal glucose levels. [3] In 2010, the IADPSG investigated the incidence of adverse pregnancy outcomes, including cesarean sections, macrosomia, neonatal hypoglycemia and hyperinsulinemia, and determined that they correlated with higher maternal glucose levels.[13] In 2010, the IADPSG recommended new guidelines for GDM diagnosis based on the results of the HAPO study, and suggested one-step screening process in the diagnosis of GDM.[13] The suggestions included a 75-g OGTT during 24- to 28-week of gestation, with the following thresholds being met or exceeded for diagnosis: fasting: 5.1, 1-hour: 8.5 and 2-hour: 10.0 mmol/L.[3] However, GIGT was excluded from the new criteria.

The ADA 2011 guidelines adopted the IADPSG criteria.[6] The new diagnostic method was recommended in China on July 1, 2011 and implemented nationwide on December 1, 2011.[15] To date, the criteria have been adopted in most countries and regions worldwide. However, the diagnosis of GDM continues to be disputed, primarily because only 1 abnormal index is sufficient for diagnosis. The ADA recognized that the anticipated increase in the incidence of GDM would have a substantial impact on costs and medical infrastructure needs and have the potential to "medicalize" pregnancies previously categorized as normal.[16] Nevertheless, the ADA recommended these changes in the diagnostic criteria with the intent of optimizing gestational outcomes.[6] This was because the criteria were the only one based on pregnancy outcome rather than endpoints such as prediction of subsequent maternal diabetes. The expected benefits to the offspring were inferred from intervention trials that focused on women with lower levels of hyperglycemia compared to those identified using previous GDM diagnostic criteria.[6] In 2013, the NIH consensus panel[10] recommended a continuation of the "two-step" approach after reviewing the available data. The ACOG[11] updated its guidelines in 2013 and supported the "two-step" approach, a strategy commonly used in the U.S. Due to insufficient data demonstrating the superiority of one strategy over the other, the ADA 2014 guidelines stated that the GDM screening can be accomplished using either the "one-step" approach or the "two-step".[12]

### Table 2

| Glucose and lipid metabolism at 24 to 28 wk of gestation in the 2 patient groups. | Group A (n = 55) | Group B (n = 29) | P |
| --- | --- | --- | --- |
| OGTT FPG (mmol/L) | 5.39±0.61 | 4.98±0.40 | .001 |
| OGTT 1-h PG (mmol/L) | 11.68±1.69 | 10.47±1.13 | .003 |
| OGTT 2-h PG (mmol/L) | 10.05±1.22 | 8.34±1.53 | .001 |
| OGTT 3-h PG (mmol/L) | 7.68±1.94 | 6.50±1.65 | .009 |
| TG (mmol/L) | 2.61±1.38 | 3.18±1.75 | .129 |
| TCHO (mmol/L) | 5.62±0.95 | 5.76±1.14 | .587 |
| HDL-C (mmol/L) | 1.67±0.38 | 1.71±0.34 | .670 |
| LDL-C (mmol/L) | 2.97±0.75 | 2.88±0.91 | .657 |
| Hyperglycemia, n (%) | 43 (64.31%) | 20 (63.3%) | .914 |
| Hypercholesterolemia, n (%) | 33 (47.14%) | 16 (55.17%) | .670 |
| Low high-density lipoprotein cholesterol, n (%) | 2 (3.42%) | 1 (4.17%) | .900 |
| High low-density lipoprotein cholesterol, n (%) | 15 (29.41%) | 8 (33.33%) | .731 |

1-h PG = 1-h plasma glucose, 2-h PG = 2-h plasma glucose, 3-h PG = 3-h plasma glucose, FPG = fasting plasma glucose, HDL-C = high-density lipoprotein cholesterol, LDL-C = low-density lipoprotein cholesterol, GIGT = oral glucose tolerance test, TCHO = total cholesterol, TG = triglyceride.

(P = .935), and ISI (P = .583) ± 5- to 6-year postpartum follow-up between the groups, P > .05 (Table 4).

### Table 3

| Five- to six-year postpartum glucose and lipid metabolism data for the 2 patient groups. | Group A (n = 55) | Group B (n = 29) | P |
| --- | --- | --- | --- |
| T2DM, n (%) | 9 (16.36%) | 1 (3.45%) | .167 |
| Prediabetes, n (%) | 19 (34.55%) | 12 (41.38%) | .527 |
| DM or prediabetes, n (%) | 28 (50.91%) | 13 (44.83%) | .596 |
| NGT, n (%) | 27 (49.09%) | 16 (55.17%) | .596 |
| OGTT FPG, (mmol/L) | 5.37±0.79 | 5.20±0.48 | .241 |
| OGTT 2-h PG, (mmol/L) | 8.39±2.52 | 7.38±1.93 | .136 |
| TG, (mmol/L) | 1.28±1.21 | 1.30±0.84 | .951 |
| TCHO, (mmol/L) | 4.71±0.91 | 4.49±0.64 | .499 |
| HDL-C, (mmol/L) | 1.31±0.29 | 1.29±0.29 | .813 |
| LDL-C, (mmol/L) | 2.87±0.82 | 2.66±0.66 | .221 |
| Hyperglycemia, n (%) | 10 (18.18%) | 6 (20.69%) | .781 |
| Hypercholesterolemia, n (%) | 15 (27.27%) | 3 (10.34%) | .129 |
| Low high-density lipoprotein cholesterol, n (%) | 6 (10.91%) | 4 (13.79%) | .698 |
| High low-density lipoprotein cholesterol, n (%) | 13 (23.64%) | 3 (10.34%) | .140 |

2-h PG = 2-h plasma glucose, DM = diabetes mellitus, FPG = fasting plasma glucose, HDL-C = high-density lipoprotein cholesterol, LDL-C = low-density lipoprotein cholesterol, NGT = normal glucose tolerance, OGTT = oral glucose tolerance test, T2DM = type 2 diabetes mellitus, TCHO = total cholesterol, TG = triglyceride.

### Table 4

| Five- to 6-year postpartum β cell function and insulin resistance data for the 2 patient groups. | Group A (n = 55) | Group B (n = 29) | P |
| --- | --- | --- | --- |
| FINS (μU/mL) | 8.84 (5.10–13.56) | 7.32 (5.46–10.60) | .774 |
| 2-h INS (μU/mL) | 70.97 (44.97–92.11) | 56.15 (35.46–106.14) | .582 |
| HOME-β | 2.01 (1.16–2.93) | 1.69 (1.24–2.56) | .583 |
| HOME-β | 1.04 (0.59–1.42) | 0.99 (0.69–1.32) | .935 |
| ISI | 0.0221 (0.0149–0.0382) | 0.0263 (0.0174–0.0360) | .583 |

2-h INS = oral glucose tolerance test 2 h, insulins, FINS = fasting insulin, HOME-β = homeostasis model assessment β-cell function index, HOME-β = homeostasis model assessment insulin resistance index, ISI = insulin sensitivity index.
The one-step IADPSG criteria are more convenient to perform compared to the previous criteria. However, with lower thresholds for plasma glucose levels, the diagnostic rate for GDM significantly increased.\[10\] This subsequently increased the number of patients requiring clinical intervention, which placed an even heavier burden on medical resources and patients.\[12\] Additionally, the lack of data from patients in mainland China in the HAPO study and the suitability of IADPSG criteria for use in China has garnered attention in recent years. Several studies conducted in China\[14–16\] have found that the use of the new criteria have increased GDM diagnostic rate. This has resulted in a significantly higher number of patients receiving prompt interventions to reduce the risk of perinatal complications and improve maternal and neonatal outcomes. These newly diagnosed patients had mild hyperglycemia, and most of them achieved good glycemic control with lifestyle interventions alone. Hence, managing these patients has considerably reduced the risk of perinatal complications cost-effectively.\[13\] This strongly suggests that the IADPSG criteria are appropriate for patients in China with respect to perinatal outcomes.

It is well known that there is a high risk of T2DM postpartum using the previous GDM criteria. Women with a history of GDM have a higher risk of T2DM over time and not solely within the 6- to 12-week postpartum time frame. HAPO FUS\[17,19\] demonstrated that 52.2% of mothers with IADPSG GDM experienced prediabetes at 5- to 6-year postpartum as compared to 20.1% of those without GDM. However, the lack of data from mainland Chinese women in the HAPO and HAPO FUS makes long-term prognosis of IADPSG GDM uncertain for this population.

Our study compared the 5- to 6-year postpartum data of patients meeting the GDM diagnosis using both the NDDG and IADPSG criterion, and patients diagnosed with GIGT using the NDDG criteria but with GDM using the IADPSG criteria. Our results demonstrated that patients who only met the IADPSG criteria had significantly lower gestational OGTT plasma glucose levels compared to patients meeting both criteria. However, there were no remarkable differences in glucose metabolism, lipid metabolism, \(\beta\)-cell function, and insulin resistance at 5- to 6-year postpartum between the 2 groups.

We believe that pregnant women with mild gestational hyperglycemia during pregnancy are also at a high risk of glucose or lipid abnormalities and insulin resistance after delivery. Without proper management, increased long-term incidence and mortality rate from cardiovascular diseases is possible. Hence, prompt interventions during gestation to reduce the risks of adverse perinatal outcomes as well as postpartum adverse outcomes are required. Additionally, patients should undergo regular postpartum follow-ups to monitor their glucose and lipid metabolism.\[20\] Early diagnosis, and timely treatment may reduce the long-term incidence and mortality from cardiovascular diseases.\[21\]

5. Conclusions

Patients diagnosed with GDM using either the NDDG or the IADPSG criteria manifest abnormal glucose and lipid metabolism after delivery. It was observed that patients with mild hyperglycemia had similar postpartum \(\beta\)-cell functional impairment and insulin resistance compared to patients with moderate hyperglycemia during pregnancy. With respect to long-term maternal postpartum outcomes, the IADPSG diagnostic criteria that recommend management and follow-up of GDM patients could be appropriate for the Chinese population.

The limitations of the current study include the small patient cohort and relatively short follow-up period, as well as patient selection from a single hospital. Future studies on this issue should include larger patient cohorts, longer follow-up periods, and multicenter studies to confirm or rule out our conclusions. The outcomes for the offspring were not addressed by this study, which also needs to be further explored.

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