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CLINICAL ARTICLE

Q1 Prevalence of gestational diabetes mellitus according to IADPSG and NICE criteria

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ABSTRACT

Objective: To investigate the impact of the International Association of Diabetic Pregnancy Study Group (IADPSG) diagnostic criteria on the prevalence of gestational diabetes mellitus (GDM) and overt diabetes as compared with the UK National Institute for Health and Care Excellence (NICE) criteria, and to evaluate the prevalence of maternal and perinatal outcomes among pregnant women with fasting plasma glucose (FPG) levels of 5.1–5.5 mmol/L. **Methods:** A retrospective study was undertaken of data for women who underwent a 2-hour 75-g oral glucose tolerance test at 24–32 weeks of a singleton pregnancy at a center in Croatia between January 2012 and December 2014. **Results:** Among 4646 included women, 1074 (23.1%) had GDM according to IADPSG criteria, 826 (17.8%) would be diagnosed according to NICE criteria, and 50 (1.1%) had overt diabetes. FPG levels were 5.1–5.5 mmol/L for 409 (8.8%) women. Compared with a control group (n = 3391), these women had higher odds of large-for-gestational-age newborns (odds ratio 3.7, 95% CI 2.0–4.6) and cesarean delivery (odds ratio 1.8, 95% CI 1.3–2.3). **Conclusion:** Women with FPG levels of 5.1–5.5 mmol/L have an increased risk of adverse maternal and perinatal outcome, although they would not be diagnosed with GDM according to NICE criteria.

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1. Introduction

When hyperglycemia occurs in pregnancy, the rate of complications such as pre-eclampsia, polyhydramnios, fetal macrosomia, birth trauma, cesarean delivery, and perinatal mortality is increased [1–4]. Neonatal metabolic complications such as hypoglycemia, hyperbilirubinemia, hypocalcaemia, polycythemia, and respiratory distress syndrome also occur at an elevated frequency [5]. The newborn is also at risk of obesity and diabetes in the long term [6–8].

For the purpose of setting accurate diagnostic criteria and allowing classification of hyperglycemia in pregnancy (HIP), the international Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study was undertaken [1]. The International Association of Diabetic Pregnancy Study Group (IADPSG) used the results of this study to recommend new criteria and classifications of gestational diabetes mellitus (GDM) [9]. According to the IADPSG criteria, at least one maternal plasma glucose concentration should be equal to or above the upper limit—set at 5.1 mmol/L for fasting measurements, 10 mmol/L for

1-hour measurements, and 8.5 mmol/L for 2-hour measurements—for GDM to be diagnosed. The IADPSG criteria for overt diabetes in pregnancy are a fasting plasma glucose (FPG) concentration of at least 7 mmol/L or random plasma glucose concentration of at least 11.1 mmol/L, although if the random measurement is initially used, the diagnosis of overt diabetes should be confirmed by FPG (≥ 7 mmol/L) and/or hemoglobin A_{1c} ($\geq 6.5\%$ [48 mmol/mol]) levels [9].

WHO [10] and the American Diabetes Association (ADA) [11] have adopted the IADPSG criteria for GDM and diabetes in pregnancy, and currently a large number of countries worldwide use these criteria. However, the UK National Institute for Health and Care Excellence (NICE) proposed alternative criteria for the diagnosis of GDM in 2015 [12]: either a FPG concentration of 5.6 mmol/L or above, or a 2-hour plasma glucose concentration of at least 7.8 mmol/L.

The aim of the present study was to assess the impact of the IADPSG diagnostic criteria on the prevalence of GDM and overt diabetes as compared with that of the NICE criteria. Other aims were to evaluate the prevalence of obesity, cesarean delivery, and hypertensive disorders in a cohort of pregnant women, and perinatal outcomes among women with a FPG of 5.1–5.5 mmol/L. We hypothesized that FPG of at least 5.1–5.5 mmol/L had a potentially negative effect on perinatal outcome, even though these FPG values would not indicate GDM according to the NICE criteria.

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2. Materials and methods

A retrospective study was conducted using data for patients who visited the Department of Obstetrics and Gynecology, Clinical Hospital Center, Zagreb, Croatia, between January 1, 2012 and December 31, 2014. Inclusion criteria were spontaneous singleton pregnancy with a diagnostic 2-hour 75-g oral glucose tolerance test (OGTT) between 24 and 32 weeks of pregnancy. Exclusion criteria were pre-existing diabetes mellitus, pregnancy after in vitro fertilization, and multiple pregnancy. The research is part of a scientific project approved by Croatian Ministry of Science, Education and Technology (Number 108-1080401-0385) and was also approved by Ethics Committee of the Department of Obstetrics and Gynecology. Informed consent was not obtained from the patients as a result of the study's retrospective nature.

Data on pregnancy and the perinatal outcomes were collected from medical records and analyzed. Anthropomorphic and biological data, and obstetric and infant outcomes were recorded. Weight and height were obtained from prenatal record. Body mass index (BMI) was calculated by dividing pre-pregnancy weight in kilograms by the square of height in meters. Pre-pregnancy BMI was classified as normal (18.5–24.9), overweight (≥ 25), or obese (≥ 30) [13]. Gestational weight gain was calculated as the difference between pre-pregnancy and delivery weight. Length of pregnancy was calculated from last menstrual period and confirmed by first-trimester ultrasonography.

The OGTT was performed by administering 75 g anhydrous glucose dissolved in 250 mL water over 5 minutes after a minimum fast of 8 hours. Venous plasma glucose was measured at 0 and 1 hours, and after 2 hours using the hexokinase method. The diagnosis of GDM/overt diabetes was made according to the IADPSG adopted in Croatia. Patients diagnosed with GDM (with various degrees of HIP) and overt diabetes were instructed to follow a diabetic diet (calorie intake calculated using BMI, length of pregnancy, and ideal body weight).

Chronic hypertension was diagnosed if blood pressure exceeded 140/90 mm Hg (18.7/12.0 kPa) before pregnancy or in the first 20 weeks. Gestational hypertension was defined as the onset of hypertension after the 20th week of pregnancy in the absence of accompanying proteinuria. Pre-eclampsia was defined as systolic blood pressure of at least 140 mm Hg (18.7 kPa) and diastolic blood pressure of at least 90 mm Hg (12.0 kPa) after the 20th week of pregnancy in previously normotensive women with proteinuria (urinary protein excretion of 300 mg in the course of 24 hours).

Ponderal index was calculated as birth weight/(height³) \times 100. Large-for-gestational-age (LGA) neonates had a gestational-age-specific birth weight of higher than the 90th percentile for their sex [14]. Macrosomia was defined as a birth weight of 4000 g or more. Preterm delivery was defined as delivery before 37 weeks. Hyperbilirubinemia was defined in premature newborns as a serum bilirubin concentration of at least 170 μ mol/L, and in term newborns as concentration of at least 398 μ mol/L. Apgar scores were recorded at 1 and 5 minutes.

For the present study, the 2-hour OGTT results were used to create five groups of patients on the basis of IADPSG and NICE criteria (Table 1). Values were expressed as mean \pm SD. Statistical analysis was done using SPSS version 17 (SPSS Inc, Chicago, IL, USA). The χ^2 test was used for between-group comparisons; for independent samples, the *t* test was performed. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated to compare frequency of adverse pregnancy outcomes between groups. $P \leq 0.001$ was considered statistically significant and $P \leq 0.01$ was considered a trend.

3. Results

Among 4646 pregnant women included, 1074 (23.1%) had GDM according to IADPSG criteria (group 1). When NICE criteria were used, 826 (17.8%) women were deemed to have GDM (group 2). Another 409 (8.8%) women met the FPG criteria from IADPSG but not NICE (group 3) and 50 (1.1%) women had overt diabetes (group 4). The

Table 1

Criteria used to divide patients into the five study groups.

Group	Fasting plasma glucose, mmol/L	1-h plasma glucose, mmol/L	2-h plasma glucose, mmol/L	
1 (HIP according to IADPSG criteria)	≥ 5.1	≥ 10.0	≥ 8.5	t1.4
2 (HIP according to NICE criteria)	≥ 5.6	–	≥ 7.8	t1.5
3 (HIP according to IADPSG but not NICE criteria)	5.1–5.5	≤ 9.9	≤ 7.7	t1.6
4 (overt diabetes)	≥ 7.0	≥ 10	≥ 11.1	t1.8
5 (control group)	≤ 5.0	≤ 9.9	≤ 7.7	t1.9

Abbreviations: HIP, hyperglycemia in pregnancy; IADPSG, International Association of Diabetic Pregnancy Study Group; NICE, National Institute for Health and Care Excellence.

control group (group 5) contained 3391 (73.0%) women. Overall, 540 (11.6%) patients were in both groups 1 and 2.

Pregnant women diagnosed with HIP were significantly older, had higher body weight and BMI, and were more often multiparous, although they had significantly lower gestational weight gain compared with control group (Table 2). The proportions of women deemed obese were significantly higher in all HIP groups than in the control group ($P < 0.001$ for all) (Table 3). The highest prevalence of obesity was recorded for group 4 (Table 3).

Length of pregnancy at delivery was significantly lower in groups 2, 3, and 4 than in the control group ($P < 0.001$ for all) (Table 4). Additionally, the prevalence of LGA newborns was higher in all HIP groups ($P < 0.001$ for all) (Table 4). The odds of LGA or macrosomia were highest in group 3 (Table 4). Ponderal index was higher in groups 3 and 4 than in the control group ($P < 0.001$ for both) (Table 4). Apgar score at 1 minute was lower in groups 1 and 2 than in the control group ($P < 0.001$ for both) (Table 4).

A significantly higher frequency of chronic hypertension was recorded in groups 2 and 4 than in the control group ($P < 0.001$ for both) (Table 4). Gestational hypertension and pre-eclampsia were more common in groups 1 and 2 than in the control group ($P < 0.001$ for both) (Table 4). Cesarean delivery was more common in groups 1, 2, 3, and 4 than in the control group ($P < 0.001$ for all) (Table 4).

A total of 1255 pregnant women fulfilled both criteria for GDM (IADPSG and NICE). These women were divided into two groups: women with FPG of 5.0 mmol/L or less ($n = 422$) and those with FPG of at least 5.1 mmol/L ($n = 833$). The odds of LGA newborns and pre-term delivery were increased among pregnant women with FPG of at least 5.1 mmol/L (Table 5). Among the 50 pregnant women with overt diabetes, odds of LGA newborns were higher than among control women (OR 2.7, 95% CI 1.5–4.6). The odds of hyperbilirubinemia were higher among women with HIP than in the control group (Table 5). The number of congenital malformations was very small in all groups, with no between-group differences (data not shown).

4. Discussion

In the present study, the prevalence of GDM according to the NICE criteria was 17.8%, but was 23.1% according to IADPSG. Women diagnosed with GDM according to either set of criteria were at increased risk of adverse outcomes—e.g. LGA newborns and cesarean delivery—when compared with a control group. More than 400 women had an FPG concentration of 5.1–5.5 mmol/L and a 2-h OGTT concentration of less than 7.8 mmol/L, and therefore would not have been diagnosed with GDM if only NICE criteria had been applied. Nevertheless, these women were also at increased odds of adverse outcomes. Therefore, the detection of pregnant women with a FPG concentration of 5.1–5.5 mmol/L is important.

The importance of the IADPSG criteria [9] is evident when using FPG values to diagnose GDM: 18% of the pregnant women included in the present study would have been diagnosed with GDM on the basis of FPG alone. Even so, women with GDM who had an FPG concentration

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