Have pregnancy outcomes improved with the introduction of the International Association of Diabetes and Pregnancy Study Groups criteria in Japan?

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Keywords

Gestational diabetes mellitus, International Association of Diabetes and Pregnancy Study Groups criteria, Pregnancy outcome

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ABSTRACT

Aims/Introduction: This study aimed to investigate the effects of the introduction of the International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria for diagnosing gestational diabetes mellitus (GDM) on maternal and neonatal outcomes in Japan.

Materials and Methods: This was a retrospective study carried out at a tertiary center in Japan. Previously in Japan, GDM was diagnosed if two or more of the following Japan Society of Obstetrics and Gynecology (JSOG) criteria were met: fasting plasma glucose \geq 100 mg/dL, 1-h value \geq 180 mg/dL or 2-h value \geq 150 mg/dL on the 75-g oral glucose tolerance. Since 2010, GDM has been diagnosed if one or more of the following IADPSG criteria are met: fasting plasma glucose \geq 92 mg/dL, 1-h value \geq 180 mg/dL or 2-h value \geq 153 mg/dL on the 75-g oral glucose tolerance. We compared the pregnancy outcomes of all pregnant women with singleton pregnancies after 22 weeks' gestation at our hospital before (JSOG period) and after (IADPSG period) the IADPSG criteria were adopted. **Results:** There were 3,912 women in the JSOG period and 4,772 in the IADPSG period GDM prevalence increased from 2.9% in the JSOG period to 13% in the IADPSG period (P < 0.001). No significant differences between the groups were found in rates of macrosomia, or large for gestational age, and no significant differences were found in birthweight. The neonatal hypoglycemia rate and neonatal intensive care unit admission rate

were significantly lower in the IADPSG period (adjusted odds ratio 0.51 and 0.78, respectively).

Conclusions: Introduction of the IADPSG criteria for diagnosing GDM increased GDM diagnosis frequency fourfold, but reduced neonatal intensive care unit admission and neonatal hypoglycemia rates significantly.

INTRODUCTION

The aims of diagnosis and treatment of gestational diabetes mellitus (GDM) are to reduce the occurrence of hyperinsulinemia-related adverse events that affect the mother and/or infant at delivery, including macrosomia, infants who are large for gestational age (LGA), shoulder dystocia, neonatal hypoglycemia, respiratory distress syndrome and cesarean delivery^{1,2}. Previous studies have reported that screening for and treatment

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of GDM improves pregnancy outcomes³; however, GDM diagnostic criteria are inconsistent across countries^{4–6}, and it is hoped that an internationally uniform GDM screening system can be established^{7,8}.

In 2008, the Hyperglycemia and Adverse Pregnancy Outcome Study, an international, multicenter study, was carried out to establish international GDM diagnostic criteria⁹, and on the basis of the results, the International Association of Diabetes and Pregnancy Study Group (IADPSG) made the following proposal in 2010.

Screening for GDM must be carried out by means of a 75-g oral glucose tolerance test (75-g OGTT) during 24–28 weeks of gestation. This test involves measuring blood glucose immediately before, and 1 and 2 h after glucose load, and a diagnosis of GDM is made if at least one of these measurements is at least 92, 180 and 153 mg/dL, respectively¹⁰.

The GDM diagnostic criteria used previously in Japan were set by the Japan Society of Obstetrics and Gynecology (JSOG). They stated that the 75-g OGTT be carried out throughout pregnancy, with measurement immediately before and 1 and 2 h after glucose load. For a diagnosis of GDM, at least two of these measurements had to be at least 100, 180 and 150 mg/ dL, respectively. However, in 2010, the criteria were changed to be in line with the IADPSG guidelines such that the 75-g OGTT was to be carried out throughout pregnancy, with measurements immediately before, and 1 and 2 h after glucose load, with at least one of these measurements being at least 92, 180 and 153 mg/dL, respectively¹¹.

These changes in the diagnostic criteria in Japan resulted in a two- to fourfold increased prevalence of GDM during pregnancy^{12,13}, along with an associated increase in medical costs and burden on pregnant women. No previous study has investigated these effects on pregnant women after the introduction of the IADPSG criteria in Japan.

The present study investigated the effects of the changes to the GDM diagnostic criteria on all pregnant women, and aimed to verify whether introducing the IADPSG criteria in Japan was appropriate.

METHODS

This study was a retrospective, single-center study that used a database of the medical records of participants. The participants were pregnant women with singleton pregnancies at 22 weeks of gestation or later between 1 January 2005 and 31 December 2015, at Yokohama City University Medical Center's Perinatal Center for Maternity and Neonates, which is a Japanese tertiary healthcare center.

Patients with missing data and/or fetal congenital malformations were excluded from the study. Since the changes were made in the diagnostic criteria¹¹, we began diagnosing GDM based on the new criteria from 2010. We considered the period between 1 January and 31 December 2010, as the diagnostic criterion transition period. Therefore, we excluded women who gave birth during this period. The participants of this study were then assigned to one of two groups: the JSOG period, which consisted of 4,595 women with singleton pregnancies at 22 weeks of gestation before the GDM diagnostic criteria were changed (i.e., between 1 January 2005 and 31 December 2009), and the IADPSG criteria period, which consisted of 5,521 women with singleton pregnancies at 22 weeks of gestation or later after the GDM diagnostic criteria were changed (i.e., between 1 January 2011 and 31 December 2015). The frequencies of GDM-related diseases were compared in these two periods. This study was approved by the

ethics committee of the Yokohama City University Medical Center (B190600058).

In Japan, it is recommended that GDM screening be carried out with a two-step method during the first and second trimesters of pregnancy, with the second screening suggested at 24-28 weeks of gestation. Specifically, a random blood glucose test is recommended for first-trimester screening, and a 50-g glucose challenge test or random blood glucose test is recommended for screening at 24-28 weeks of gestation. Any women with measurements exceeding the cut-off level in either of these screenings were then screened for GDM with the 75-g OGTT¹¹. At our hospital, GDM screening with the 75-g OGTT is carried out during the first trimester for patients belonging to the GDM high-risk group, which means that these patients meet one or more of the following criteria: (i) casual blood glucose level of at least 95 mg/dL; (ii) obese, with a body mass index (BMI) of \geq 30 kg/m²; (iii) advanced maternal age, aged ≥35 years; (iv) one or more first- or second-degree relative with a history of GDM; (v) a history of macrosomia or large for gestational age in previous births; (vi) a history of delivery with shoulder dystocia; (vii) a history of perinatal infant death of unknown cause; (viii) a history of congenital anomalies of unknown cause; and (ix) a history of GDM.

Screening with the 50-g glucose challenge test is then carried out during 24–28 weeks of gestation for those patients not diagnosed with GDM in the first-trimester screening. If the 50-g glucose challenge test gives a result of \geq 140 mg/dL, the 75-g OGTT is carried out, and the decision about GDM diagnosis was made as follows.

GDM diagnoses were made according to the JSOG criteria between 1 January 2005 and 31 December 2009 (JSOG period). During this period, a diagnosis of GDM was made if at least two of three of the following threshold values on the 75-g OGTT were met: fasting plasma glucose, at least 100 mg/dL; 1-h value, at least 180 mg/dL; and 2-h value, at least 150 mg/dL.

GDM diagnoses were made according to the IADPSG criteria between 1 January 2011 and 31 December 2015. (IADPSG period) During this period, a diagnosis of GDM was made if one or more of the following criteria were met: fasting plasma glucose, at least 92 mg/dL; 1-h value, at least 180 mg/dL; and 2-h value, at least 153 mg/dL¹¹.

Therapeutic interventions after diagnosis of GDM were the same in both time periods. First, nutritional counseling and dietary therapy were provided, and then, if the target blood glucose levels (before meals, <100 mg/dL; 2 h after meals, <120 mg/dL) were not achieved, insulin therapy was initiated. Hemoglobin A1c and glycoalbumin were measured once per month and were controlled to target values of <5.8% and <15.8, respectively. Dietary therapy consisted of a caloric intake of ideal bodyweight × 30 kcal + 150 kcal until 28 weeks of gestation, ideal bodyweight × 30 kcal + 350 kcal during and after 28 weeks of gestation, or in the case of patients with a pre-pregnancy BMI of \geq 25 kg/m², ideal body weight × 30 kcal throughout pregnancy. For the patients in whom insulin

therapy was initiated, if the findings were favorable after 37 weeks 0 day of gestation, labor was induced. In any insulintreated case, labor was induced before 40 weeks 0 day of gestation.

Among the study parameters, the basal characteristics were maternal age, pre-pregnancy BMI, bodyweight change during pregnancy, and the rates of primiparity, GDM, pre-pregnancy diabetes and insulin therapy among patients with GDM. Pregnancy outcomes were gestational age (weeks), infant birthweight (g) and the rates of macrosomia, LGA, emergency cesarean delivery, operative vaginal delivery, small for gestational age (SGA), shoulder dystocia, neonatal intensive care unit (NICU) admission, neonatal jaundice requiring phototherapy, neonatal hypoglycemia and respiratory distress syndrome (%).

Pre-pregnancy BMI was calculated from self-reported height and pre-pregnancy bodyweight. The change in bodyweight during pregnancy was calculated by subtracting the pre-pregnancy bodyweight from bodyweight at delivery. Macrosomia was defined as birthweight >4,000 g. LGA was defined as infant birthweight at or above the 90th percentile; SGA was defined as birthweight below the 10th percentile for the respective gestational age, adjusted for parity and infant sex. Shoulder dystocia was defined clinically when manipulation was required to overcome difficulties with expulsion of the fetal shoulder after expulsion of the head, and measures of some sort had to be taken in response. The criterion for neonatal hypoglycemia was blood glucose <40 mg/dL. Respiratory distress syndrome was defined based on characteristic findings of the chest radiographic examination and oxygen requirements within 24 h after birth.

Data were presented as medians (ranges) and frequencies (percentages), and compared using the Mann–Whitney *U*-test and Fisher's exact test, respectively.

The level of statistical significance was set at P < 0.05. Data analyses were carried out with SPSS statistical software version 23 (IBM Corporation, Armonk, NY, USA). During the multi-variate analysis, a logistic regression analysis was carried out, and the 95% confidence intervals (CI) were obtained for the adjusted regression coefficient and adjusted odds ratio (aOR).

RESULTS

There were 3,912 deliveries in the JSOG criteria period and 4,772 in the IADPSG criteria period. Data for all participants are shown in Table 1. The number of participants with GDM increased from 112 (2.9%) in the JSOG criteria period to 620 (13%) in the IADPSG criteria period. This 4.5-fold increase was significant (P < 0.001). Additionally, the number of participants who required insulin therapy increased significantly (P = 0.003), from 20 (0.5%) to 53 (1.1%). Furthermore, maternal age was significantly greater, pre-pregnancy BMI was significantly greater in the IADPSG criteria period than in the JSOG criteria period. However, no significant differences between groups were found in rates of macrosomia, LGA and

SGA, and no significant differences were found in birthweight. The rates of neonatal hypoglycemia and NICU admission were significantly lower in the IADPSG period. The neonatal hypoglycemia rates were 0.8% in the JSOG criteria period and 0.4% in the IADPSG criteria period (aOR 0.51, 95% CI 0.29–0.88), and the NICU admission rates were 7.3% in the JSOG criteria period and 5.8% in the IADPSG criteria period (aOR 0.78, 95% CI 0.65–0.92).

Table 2 shows the data for pregnant women diagnosed with GDM in each period (112 in the JSOG criteria period and 620 in the IADPSG criteria period). No significant differences were found in the rates of macrosomia, shoulder dystocia, SGA or LGA. The NICU admission rate was significantly lower in the IADPSG criteria period (JSOG criteria period: 10.7%; IADPSG criteria period: 4.5%; aOR 0.30, 95% CI 0.21–0.92).

Data for participants with normal glucose tolerance according to the JSOG or IADPSG criteria are shown in Table 3. A total of 3,767 participants in the JSOG criteria period and 4,109 in the IADPSG criteria period had normal glucose tolerance. The NICU admission rate was significantly lower in the IADPSG criteria period than in the JSOG criteria period (5.9 vs 7.0%, [aOR 0.83, 95% CI 0.69–0.99]). The neonatal hypoglycemia rate was also significantly lower in the IADPSG criteria period (0.8% in the JSOG criteria period and 0.4% in the IADPSG criteria period; aOR 0.49, 95% CI 0.27–0.91).

DISCUSSION

The introduction of the IADPSG criteria resulted in a major (4.5-fold) increase in the rate of diagnosis of GDM. After the introduction of the IADPSG criteria in 2010, we found that during 2011–2015, there were no significant differences in macrosomia and LGA rates, whereas neonatal hypoglycemia and NICU admission rates were reduced significantly.

The frequency of GDM diagnoses increased markedly with the change in the diagnostic criteria. The frequency of GDM diagnoses made using the IADPSG criteria has been reported to be higher in several countries. A recent multinational and retrospective study reported that, when assessed according to the IADPSG criteria, the frequency of GDM varied greatly (3.5–45.3%) depending on ethnicity and geographical location. In all regions, the frequency of GDM increased with the change in the diagnostic criteria, with the magnitude of the increase ranging from 1.03- to 3.78-fold¹⁴. In the present study, as in previous reports, the frequency of GDM diagnosis increased, and that increase was somewhat greater than that previously reported by any other study.

After introducing the IADPSG criteria, the frequency rates of neonatal hypoglycemia and NICU admission were reduced, but no significant changes in the rates of macrosomia or LGA were found. Additionally, comparisons within the normal glucose tolerance group (Table 3) showed that participants diagnosed with normal glucose tolerance based on the JSOG criteria had significantly higher rates of neonatal hypoglycemia and NICU admissions than participants diagnosed with normal glucose

	JSOG criteria group ($n = 3,912$)	IADPSG criteria group ($n = 4,772$)	P-value	Odds ratio	95% CI	Adjusted odds ratio [†] (95% Cl)
Maternal age (years)	32	33	<0.001			
Pre-pregnancy body mass index (kg/m ²)	20.4	20.5	0.025			
Height (am)	158	158	0.15			
Pre-pregnancy bodyweight (kg)	52	52	0.01			
Bodyweight at delivery (kg)	61.8	62.3	0.002			
Primipara	1,931 (49%)	2,468 (52%)	0.029			
GDM (including overt diabetes mellitus)	112 (2.9%)	620 (13%)	<0.001			
Insulin therapy in GDM patients	20 (0.5%)	53 (1.1%)	0.003			
Pre-pregnancy diabetes mellitus	33 (0.8%)	43 (0.9%)	0.82			
Weight gain during pregnancy (kg)	9.8	10	0.036			
Birthweight (g)	3,025	3,006	0.068			
Gestational weeks at delivery (weeks)	39.4	39.2	<0.001			
Macrosomia	38 (1.0%)	39 (0.8%)	0.49	0.84	0.54-1.32	0.91 (0.58–1.43)
Shoulder dystocia	46 (1.2%)	44 (0.9%)	0.29	0.76	0.50-1.16	0.81 (0.53–1.23)
Large for gestational age	412 (10.5%)	460 (9.6%)	0.17	0.91	0.79-1.045	0.88 (0.60–1.018)
Emergency cesarean delivery	278 (7.1%)	334 (7.0%)	0.87	0.98	0.83-1.16	0.94 (0.80–1.12)
Operative vaginal delivery	171 (4.4%)	205 (4.3%)	0.87	0.98	0.80-1.21	0.98 (0.79–1.22)
Small for gestational age	336 (8.6%)	432 (9.1%)	0.47	1.060	0.91-1.23	1.067 (0.92–1.24)
Admission to NICU	284 (7.3%)	277 (5.8%)	0.007	0.78	0.66-0.93	0.78 (0.65-0.92)
Neonatal hypoglycemia	33 (0.8%)	21 (0.4%)	0.019	0.52	0:30-0:90	0.51 (0.29-0.88)
Neonatal jaundice requiring phototherapy	179 (4.6%)	191 (4.0%)	0.20	0.87	0.71-1.071	0.85 (0.69–1.050)
Respiratory distress syndrome	3 (0.1%)	2 (0.003%)	0.66	0.55	0.091–3.27	0.50 (0.082–3.0050)
The criteria for phototherapy were as follows. If the birthweight was 2,000–2,499 g and the gestation at delivery was 37 weeks, the thresholds for blood bilitubin level were as follows: >10 mg/dL at day 1, >13 mg/dL at day 2 and >15 mg/dL at day 3. If the birthweight was 2,500 g and/or the gestation at delivery was 238 weeks, the thresholds of blood bilitubin level were as follows: >12 mg/dL at day 1, >15 mg/dL at day 2, and >18 mg/dL at day 3. [†] Adjusted odds ratio adjusted for maternal age, pre-pregnancy body mass index, primipara and gestational weeks at delivery. Cl, confidence interval; GDM, gestational diabetes melitus; IADPSG, the International Association of Diabetes and pregnancy Study Group; JSOG, the	vs. If the birthweight was 2,000–2,49 and >15 mg/dL at day 3. If the birt >15 mg/dL at day 2, and >18 mg/ lence interval; GDM, gestational dial	eight was 2,000–2,499 g and the gestation at delivery was 37 weeks, the thresholds for blood bilinubin level were as follows L at day 3. If the birthweight was 22,500 g and/or the gestation at delivery was 238 weeks, the thresholds of blood bilinubin day 2, and >18 mg/dL at day 3. [†] Adjusted odds ratio adjusted for maternal age, pre-pregnancy body mass index, primipara 50M, gestational diabetes mellitus; IADPSG, the International Association of Diabetes and pregnancy Study Group; JSOG, the	as 37 week estation at Ijusted for nal Associa	s, the thresho delivery was ≥ maternal age, tion of Diabet	lds for blood b 238 weeks, the pre-pregnancy tes and pregna	ilirubin level were as follows: thresholds of blood bilirubin body mass index, primipara ncy Study Group; JSOG, the

Table 1 | Maternal characteristics and pregnancy outcomes of all participants

Japan Society of Obstetrics and Gynecology; NICU, neonatal intensive care unit.

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	JSOG criteria group ($n = 112$)	IADPSG criteria group ($n = 620$)	<i>P</i> -value	Odds ratio	95% CI	Adjusted odds ratio [*] (95% Cl)
Maternal age (years)	34	35	0.034			
Pre-pregnancy body mass index (kg/m ²)	22.9	22.2	0.067			
Height (cm)	158	158.8	0.44			
Pre-pregnancy bodyweight (kg)	57	56	0.31			
Bodyweight at delivery (kg)	63.8	64.8	0.46			
Primipara	51 (45.5%)	349 (56.3%)	0.035			
GDM (including overt diabetes mellitus)	112 (100%)	620 (100%)				
Insulin therapy in GDM	20 (17.9%)	53 (8.6%)	0.003			
Pre-pregnancy diabetes mellitus	0	0				
Weight gain during pregnancy (kg)	6.3	8.2	<0.001			
Birthweight (g)	3,030	3,028	0.87			
Gestational weeks at delivery (weeks)	38.4	39	0000			
Macrosomia	2 (1.8%)	12 (1.9%)	0.92	1.086	0.24-4.92	1.071 (0.27–7.16)
Shoulder dystocia	2 (1.8%)	8 (1.3%)	0.68	0.72	0.15-3.43	0.61 (0.14-4.23)
Large for gestational age	23 (20.1%)	81 (13.1%)	0.037	0.58	0.35—0.97	0.65 (0.39–1.14)
Emergency cesarean delivery	10 (8.9%)	49 (7.9%)	0.71	0.88	0.43—1.78	0.98 (0.48–2.18)
Operative vaginal delivery	6 (5.4%)	24 (3.9%)	0.47	0.71	0.28-1.78	0.69 (0.28–1.96)
Small for gestational age	10 (8.9%)	48 (7.7%)	0.67	0.86	0.42—1.75	0.78 (0.39–1.69)
Admission to NICU	12 (10.7%)	28 (4.5%)	0.008	0.39	0.19-0.80	0.030 (0.21–0.92)
Neonatal hypoglycemia	1 (0.9%)	3 (0.5%)	0.59	0.54	0.056-5.24	1.0060 (0.11–23.00)
Neonatal jaundice requiring phototherapy	7 (6.3%)	23 (3.7%)	0.21	0.58	0.24-1.38	0.79 (0.34–2.092)
Respiratory distress syndrome	0	0				
The criteria for phototherapy were as follows. If the birthweight was 2,000–2,499 g and the gestation at delivery was 37 weeks, the thresholds of blood bilirubin level were as follows: >10 mg/dL at day 2 and> 15 mg/dL at day 3. If the birthweight was ≥2500 g and/or the gestational at delivery was ≥38 weeks, the thresholds of blood bilirubin level were as follows: >12 mg/dL at day 1, >15 mg/dL at day 2 and> 18 mg/dL at day 3. If the birthweight was ≥2500 g and/or the gestational at delivery was ≥38 weeks, the thresholds of blood bilirubin level were as follows: >12 mg/dL at day 1, >15 mg/dL at day 2 and> 18 mg/dL at day 3. [†] Adjusted odds ratio adjusted for maternal age, pre-pregnancy body mass index, primipara and gestational weeks at delivery. C, confidence interval; GDM, gestational diabetes mellitus; IADPSG, the International Association of Diabetes and pregnancy Study Group; JSOG, the	vs. If the birthweight was 2,000–2, and> 15 mg/dL at day 3. If the b >15 mg/dL at day 2 and> 18 mg lence interval; GDM, gestational di	eight was 2,000–2,499 g and the gestation at delivery was 37 weeks, the thresholds of blood bilitubin level were as follows: L at day 3. If the birthweight was 22,500 g and/or the gestational at delivery was 238 weeks, the thresholds of blood bilituk day 2 and> 18 mg/dL at day 3. ⁴ Adjusted odds ratio adjusted for maternal age, pre-pregnancy body mass index, primipara 5DM, gestational diabetes mellitus; IADPSG, the International Association of Diabetes and pregnancy Study Group; JSOG, the	vas 37 weel gestational a djusted for onal Associa	s, the thresho at delivery was maternal age, ttion of Diabet	lds of blood bi ≥38 weeks, th pre-pregnancy es and pregnaı	irubin level were as follows: e thresholds of blood bilirubin body mass index, primipara ncy Study Group; JSOG, the

Table 2 | Maternal characteristics and pregnancy outcomes in women with gestational diabetes mellitus

Japan Society of Obstetrics and Gynecology

	JSOG criteria group ($n = 3,767$)	IADPSG criteria group ($n = 4,109$)	<i>P</i> -value	Odds ratio	95% CI	Adjusted odds ratio (95% Cl) ⁺
Maternal age (years)	32	33	<0.001			
Pre-pregnancy body mass index (kg/m ²)	20.3	20.3	0.90			
Height (cm)	158	158	0.20			
Pre-pregnancy bodyweight (kg)	51.6	52	0.68			
Bodyweight at delivery (kg)	62	61.7	0.097			
Primipara	1,866 (50%)	2,099 (51%)	0.18			
GDM (including overt diabetes mellitus)	0	0				
Insulin therapy in GDM	0	0				
Pre-pregnancy diabetes mellitus	0	0				
Weight gain during pregnancy (kg)	9.9	10.3	<0.001			
Birthweight (g)	3,024	3,006	0.054			
Gestational weeks at delivery (weeks)	39.6	39.4	<0.001			
Macrosomia	36 (1.0%)	27 (0.7%)	0.16	0.69	0.42-1.13	0.76 (0.46–1.26)
Shoulder dystocia	42 (1.1%)	35 (0.9%)	0.25	0.76	0.49-1.20	0.82 (0.52–1.29)
Large for gestational age	378 (10%)	371 (9.0%)	0.13	0.89	0.77-1.035	0.89 (0.77–1.041)
Emergency cesarean delivery	263 (7.0%)	280 (6.8%)	0.79	0.97	0.82-1.16	0.94 (0.79–1.13)
Operative vaginal delivery	164 (4.4%)	178 (4.3%)	1.00	0.99	0.80-1.24	0.99 (0.79–1.24)
Small for gestational age	324 (8.6%)	380 (9.2%)	0.32	1.083	0.93-1.26	1.07 (0.92–1.25)
Admission to NICU	263 (7.0%)	244 (5.9%)	0.060	0.84	0.70-1.0071	0.83 (0.69-0.99)
Neonatal hypoglycemia	29 (0.8%)	16 (0.4%)	0.035	0.50	0.27-0.93	0.49 (0.27–0.91)
Neonatal jaundice requiring phototherapy	166 (4.4%)	164 (4.0%)	0.37	0.90	0.72-1.12	0.89 (0.71–1.11)
Respiratory distress syndrome	2 (0.05%)	3 (0.1%)	0.68	1.38	0.23-8.24	0.56 (0.092–3.36)
The criteria for phototherapy were as follows. If the birthweight was 2,000–2,499 g and the gestation at delivery was 37 weeks, the thresholds of blood bilirubin level were as follow: >10 mg/dL at day 1, >13 mg/dL at day 2 and> 15 mg/dL at day 3. If the birth weight was 22,500 g and/or the gestation at delivery was ≥38 weeks, the thresholds of blood bilirubin level were as follows: >12 mg/dL at day 1, >15 mg/dL at day 2 and> 18 mg/dL at day 3. [†] Adjusted odds ratio adjusted for maternal age, pre-pregnancy body mass index, primipara and gestational weeks at delivery. Cl, Confidence Interval; GDM, Gestational Diabetes Mellitus; IADPSG, the International Association of Diabetes and pregnancy Study Group; JSOG, the	As. If the birthweight was 2,000–2,45 and> 15 mg/dL at day 3. If the birt >15 mg/dL at day 2 and> 18 mg/ lence Interval; GDM, Gestational Dia	eight was 2,000–2,499 g and the gestation at delivery was 37 weeks, the thresholds of blood bilitubin level were as follow: L at day 3. If the birth weight was ≥2,500 g and/or the gestation at delivery was ≥38 weeks, the thresholds of blood bilitubi day 2 and> 18 mg/dL at day 3. [†] Adjusted odds ratio adjusted for maternal age, pre-pregnancy body mass index, primipara 5DM, Gestational Diabetes Mellitus; IADPSG, the International Association of Diabetes and pregnancy Study Group; JSOG, the	as 37 weel Jestation al justed for i nal Associ	s, the threshc : delivery was maternal age, ation of Diabe	blds of blood b ≥38 weeks, th pre-pregnancy	ilirubin level were as follow: e thresholds of blood bilirubin · body mass index, primipara ancy Study Group; JSOG, the

Japan Society of Obstetrics and Gynecology.

tolerance based on the IADPSG criteria. This might have been because mild hyperglycemia below the threshold of JSOG criteria was not treated, and women would have been diagnosed with GDM if the IADPSG criteria had been used. Therefore, it appears that the introduction of the IADPSG criteria led to the positive effects of reducing neonatal hypoglycemia and NICU admission rates. It might be surmised that the reduced NICU admission rate was the result of reduced diabetes-related complications, such as neonatal hypoglycemia and neonatal jaundice requiring phototherapy. Numerous reports have been published regarding pregnancy outcomes in patients with GDM before and after the introduction of the IADPSG criteria; however, there have been few studies on the changes in GDM complications as a result of the introduction of the IADPSG criteria that included all pregnant women. In Spain, with the change from the Carpenter-Coustan criteria to IADPSG criteria, the rates of gestational hypertension, cesarean delivery, operative vaginal delivery, LGA, SGA and NICU admissions for all pregnant women decreased. Therefore, the economic burden decreased as a result of lower rates of NICU admissions and cesarean deliveries, which more than accounted for the increased burden of an increase in the prevalence of GDM¹⁵. Therefore, Duran et al.¹⁵ concluded that the introduction of the IADPSG criteria had positive health and economic effects. According to a study carried out in the USA¹⁶, introduction of the IADPSG criteria resulted in a reduced rate of LGA; however, considering the absence of other improvements in outcomes, it cannot be clearly stated whether the increase in GDM rates as a result of the introduction of the IADPSG criteria was cost-effective. Furthermore, in China, although pregnancy outcomes were favorable, because the LGA and macrosomia rates were reduced, the increased frequency of GDM diagnosis was associated with a major increase in the burden on medical personnel. Therefore, the introduction of the IADPSG criteria resulted in increased human and economic burdens¹⁷. In the present study, despite the fourfold increase in GDM diagnosis frequency after the introduction of the new diagnostic criteria, the LGA rate for all participants decreased only slightly, and not significantly; the only significant decreases were observed in the rates of neonatal hypoglycemia and NICU admission. Nevertheless, it remains uncertain whether the changes in pregnancy outcomes counterbalance the fourfold increase in the prevalence of GDM, which results in more pregnant women requiring therapeutic intervention. Therefore, this should be investigated further.

The present study had several limitations. First, it was a retrospective study at a single tertiary medical institution that handles a large number of high-risk patients. It is therefore probable that the rate of GDM was higher than in the general population of pregnant women. Second, the results of this study might not have been solely due to the changes in the GDM diagnostic criteria, but due to some other factors, such as changes over time. Third, the treatment of GDM has two aims: to improve the perinatal outcomes of the index pregnancy, and to improve the long-term health of both the mother and the offspring¹⁸, however, long-term effects were not investigated in the present study.

In conclusion, after the introduction of the IADPSG criteria to diagnose GDM, the rates of neonatal hypoglycemia and NICU admission decreased. However, the introduction of the IADPSG criteria resulted in a significant increase in the prevalence of GDM, and a fourfold increase in the number of pregnant women requiring therapeutic intervention. Further research is required to determine whether the effects are consistent with these changes and to evaluate the validity of these diagnostic criteria.

DISCLOSURE

The authors declare no conflict of interest.

REFERENCES

- 1. Crowther CA, Hiller JE, Moss JR, *et al.* Effect of treatment of gestational diabetes mellitus on pregnancy outcomes. *N Engl J Med* 2005; 352: 2477–2486.
- 2. Landon MB, Spong CY, Thom E, *et al*. A multicenter, randomized trial of treatment for mild gestational diabetes. *N Engl J Med* 2009; 361: 1339–1348.
- 3. Diagnostic criteria and classification of hyperglycaemia first detected in pregnancy: a World Health Organization guideline. *Diabetes Res Clin Pract* 2014; 103: 341–363.
- 4. Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Diabetes and pregnancy. *Can J Diabetes* 2013; 37: S168-S183.
- 5. Jarrett RJ. Gestational diabetes: a non-entity? *BMJ* 1993; 306: 37–38.
- 6. Waugh N, Pearson D, Royle P. Screening for hyperglycaemia in pregnancy: consensus and controversy. *Best Pract Res Clin Endocrinol Metab* 2010; 24: 553–571.
- 7. Caissutti C, Berghella V. Scientific evidence for different options for GDM screening and management: controversies and review of literature. *Biomed Res Int* 2017; 2017: 2746471.
- Benhalima K, Mathieu C, Damm P, *et al.* A proposal for the use of uniform diagnostic criteria for gestational diabetes in Europe: an opinion paper by the European Board & Obstetrics and Gynaecology (EBCOG). *Diabetologia* 2015; 58: 1422–1429.
- 9. HAPO Study Cooperative Research Group. Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study Cooperative Research Group. Hyperglycemia and adverse pregnancy outcomes. *N Engl J Med* 2008; 358: 1991–2002.
- 10. International Association of Diabetes and Pregnancy Study Groups Consensus Panel International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. *Diabetes Care* 2010; 33: 676–682.
- 11. Committee of the Japan Diabetes Society on diagnostic criteria of diabetes mellitus. Report of the committee on

the classification and diagnostic criteria of diabetes mellitus. *J Diabetes Investig* 2010; 1: 212–228.

- 12. Morikawa M, Yamada T, Yamada T, *et al.* Change in the number of patients after the adoption of IADPSG criteria for hyperglycemia during pregnancy in Japanese women. *Diabetes Res Clin Pract* 2010; 90: 339–342.
- 13. Nobumoto E, Masuyama H, Hiramatsu Y, *et al.* Effect of the diagnostic criteria for gestational diabetes mellitus among Japanese women. *Diabetol Int* 2015; 6: 226–231.
- 14. Brown FM, Wyckoff J. Application of one-step IADPSG versus two-step diagnostic criteria for gestational diabetes in the real world: Impact on health services, clinical care, and outcomes. *Curr Diab Rep* 2017; 17: 85.
- 15. Duran A, Saenz S, Torrejon MJ, *et al.* Introduction of IADPSG criteria for the screening and diagnosis of gestational diabetes mellitus results in improved pregnancy outcomes

at a lower cost in a large cohort of pregnant women: the St. Carlos Gestational Diabetes Study. *Diabetes Care* 2014; 37: 2442–2450.

- 16. Lee GT, Satyan MT, Grothusen JD, *et al*. A retrospective study comparing outcomes in a midwestern US population after introduction of IADPSG guidelines for gestational diabetes. *J Matern Fetal Neonatal Med* 2019; 32: 67–72.
- 17. Hung TH, Hseieh TT. The effects of implementing the International Association of Diabetes and Pregnancy Study Groups criteria for diagnosing gestational diabetes on maternal and neonatal outcomes. *PLoS ONE* 2015; 10: e0122261.
- Loew WL Jr, Scholtens DM, Kuang A, et al. Hyperglycemia and Adverse Pregnancy Outcome Follow-up Study (HAPO FUS): maternal gestational diabetes mellitus and childhood glucose metabolism. *Diabetes Care* 2019; 42: 372–380.