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

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OBJECTIVE

The use of the new International Association of the Diabetes and Pregnancy Study Groups criteria (IADPSGC) for the diagnosis of gestational diabetes mellitus (GDM) results in an increased prevalence of GDM. Whether their introduction improves pregnancy outcomes has yet to be established. We sought to evaluate the cost-effectiveness of one-step IADPSGC for screening and diagnosis of GDM compared with traditional two-step Carpenter-Coustan (CC) criteria.

RESEARCH DESIGN AND METHODS

GDM risk factors and pregnancy and newborn outcomes were prospectively assessed in 1,750 pregnant women from April 2011 to March 2012 using CC and in 1,526 pregnant women from April 2012 to March 2013 using IADPSGC between 24 and 28 weeks of gestation. Both groups received the same treatment and follow-up regimes.

RESULTS

The use of IADPSGC resulted in an important increase in GDM rate (35.5% vs. 10.6%) and an improvement in pregnancy outcomes, with a decrease in the rate of gestational hypertension (4.1 to 3.5%: −14.6%, $P < 0.021$), prematurity (6.4 to 5.7%: −10.9%, $P < 0.039$), cesarean section (25.4 to 19.7%: −23.9%, $P < 0.002$), small for gestational age (7.7 to 7.1%: −6.5%, $P < 0.042$), large for gestational age (4.6 to 3.7%: −20%, $P < 0.004$), Apgar 1-min score <7 (3.8 to 3.5%: −9%, $P < 0.015$), and admission to neonatal intensive care unit (8.2 to 6.2%: −24.4%, $P < 0.001$). Estimated cost savings was of €14,358.06 per 100 women evaluated using IADPSGC versus the group diagnosed using CC.

CONCLUSIONS

The application of the new IADPSGC was associated with a 3.5-fold increase in GDM prevalence in our study population, as well as significant improvements in pregnancy outcomes, and was cost-effective. Our results support their adoption.

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Gestational diabetes mellitus (GDM) is an important public health problem. Its prevalence is increasing as obesity, sedentary lifestyle, and older age at pregnancy become more common (1–4). GDM is associated with adverse outcomes in the mother, the gestation, and the newborn. The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study has recently established a relationship between maternal hyperglycemia and adverse outcomes (5), and a one-step approach to establishing the diagnosis of GDM using a 75-g 2-h oral glucose tolerance test (OGTT) has been proposed (6). The new criteria have been adopted by several societies, including the American Diabetes Association and the Endocrine Society (3,7). However, the consequences of the use of these new criteria, as regards pregnancy outcomes and costs, have yet to be determined (2–4,8,9). The American College of Obstetricians and Gynecologists has recently recommended that the prior two-step approach for the diagnosis of GDM be maintained, since the use of the new criteria would increase its prevalence (10–13), and evidence regarding the benefits of the new criteria is lacking (9).

The St. Carlos Hospital serves a geographically predetermined community in Madrid, Spain. GDM screening is universal, as recently recommended in Europe (14), and is centralized in the hospital laboratory. All pregnant women are followed by an obstetrician, and all women with GDM are seen and followed up in the Diabetes and Gestation Unit by an endocrinologist, obstetrician, and pediatrician as needed. Starting on the 1st of April of 2012, our unit and laboratory substituted the previous two-step protocol with the new International Association of the Diabetes and Pregnancy Study Groups criteria (IADPSGC) without modifying management protocols. Our protocols are based on self-monitoring of blood glucose (with targets of fasting glycemia <90 mg/dL [5.0 mmol/L], and postprandial glycemia <120 mg/dL [7.2 mmol/L] with initiation of insulin treatment when >50% of fasting or preprandial values are >95 mg/dL [5.3 mmol/L] or/and postprandial values are >140 mg/dL [7.8 mmol/L]), together with obstetric and pediatric monitoring as previously reported (14,15) and recommended by the Endocrine Society (7). The maintenance of treatment protocols by our unit, with modification solely of diagnostic criteria, permits the evaluation of the impact of the new criteria when comparing women studied previously with those screened from April 2012 on.

The aim of this study was to assess possible changes in pregnancy outcomes after the introduction of the new IADPSGC and to perform a cost-effectiveness analysis of their application.

RESEARCH DESIGN AND METHODS

Hospital Clínico San Carlos (St. Carlos Hospital) provides specialist health care to an estimated population of 440,342 people in Madrid, Spain. Universal screening is performed in all pregnant women in the General Hospital Laboratory. Prior to April of 2012, women were screened for GDM based on the two-step American Diabetes Association recommendations: at week 24–28 of gestation, women with no previous history of diabetes were assessed by means of the O'Sullivan test, after a 12-h fast, with no dietary restrictions on previous days. When plasma glucose levels 1 h after glucose load were ≥7.8 mmol/L (≥140 mg/dL), a further 100-g OGTT was performed, and new glucose levels were measured while fasting and 1, 2, and 3 h after intake. GDM was diagnosed according to Carpenter-Coustan (CC) criteria. In April of 2012, the new IADPSGC were adopted. Screening takes place at the same gestational age, a single 75-g 2-h OGTT is used, and IADPSGC are applied for diagnosis of GDM. Women with pregestational diabetes and/or with GDM diagnosed before week 24 of gestation were not assessed.

We designed this prospective study to analyze the changes in GDM risk factors and in gestation outcomes induced by moving to a new universal screening tool in two cohorts of women during 1 year. The study was approved by the ethics committee of Hospital Clínico San Carlos and was carried out according to the principles expressed in the Declaration of Helsinki.

Between April 2011 and March 2012, 1,750 pregnant women were screened between 24 and 28 weeks of gestation, according to two-step CC criteria, median age 32 years (interquartile range 28–36). Between April 2012 and March 2013, 1,526 pregnant women were screened using one-step IADPSGC (median age 32 years [interquartile range 28–36]). GDM women were followed according to local guidelines for GDM, with the same capillary blood glucose targets and use of lifestyle management in all cases. Women were advised to avoid or limit the intake of refined carbohydrates and sugary drinks including fruit juices, red meat (particularly processed meat), bakery, and pastries. At least three servings of skimmed milk dairy products per day, two servings of vegetables per day, and two servings of fresh fruit instead of juices per day were recommended. Nuts instead of processed meat snack, oily fish, and virgin olive oil were recommended daily. Whole-grain cereals and legumes instead of white cereals and potatoes were also recommended. A leisure-time physically active lifestyle including walking at least 15 min and climbing at least four floors of stairs four times a day >5 days per week was recommended. A semiquantitative questionnaire was used to evaluate lifestyle adherence to these recommendations and is displayed in Supplementary Table 1. The goal was to achieve a score >8. A six-point daily profile, with fasting and 1-h postprandial glycemias, was initially recommended. The goals were fasting and preprandial glucose <90 mg/dL (5 mmol/L) and 1-h postmeal glucose <120 mg/dL (6.6 mmol/L). Insulin therapy was initiated when >50% of fasting or preprandial values were >95 mg/dL (5.3 mmol/L) or 1-h postprandial levels were >140 mg/dL (7.8 mmol/L) (Supplementary Fig. 1). Women with normal glucose tolerance (NGT) were followed by the same obstetric team. All women were followed up until after delivery and discharge. Maternal age; ethnicity; family and personal history before actual gestation (family history of diabetes, hypertension, dyslipemia, or obesity, and metabolic syndrome was considered when more than two components of the metabolic syndrome were present in at least one first-degree family member); a personal history of hypertension, dyslipemia, obesity, thyroid disease, and other comorbidities; smoking status; and obstetric history (miscarriages, prior GDM, or other such as urine infection, hyperemesis, etc.) were considered. Women were considered to have no risk factors if they had not presented with complications in prior pregnancies. The number of pregnancies,

use of medication, pregestational (declared) and gestational (at 24–28 weeks of gestation) body weight, height, and BMI were assessed.

Data on maternal evolution, pregnancy-induced hypertension (defined as systolic blood pressure >140 mmHg and/or diastolic blood pressure >90 mmHg) and/or proteinuria, duration of gestation, delivery, and neonatal outcomes including weight, LGA (large for gestational age >90 percentile), SGA (small for gestational age <10 percentile), Apgar scores at 1 and 5 min, and admissions to the neonatal intensive care unit were collected.

Fetal growth was assessed by ultrasonography, usually performed three times during pregnancy, once each trimester. The first study determines gestational age compared with the start of amenorrhea. Ultrasonography estimation of fetal development for gestational age was recorded and included biparietal diameter, femur length, and abdominal circumference (AC). Intrauterine growth was considered normal when neither intrauterine growth retardation nor overgrowth (according to gestational age between the 90th percentile and the 10th percentile) was found.

Total direct costs in this study were estimated as the cost per 100 women screened with each testing protocol. Estimation of economic cost (centralized purchase price for the social security system) included laboratory costs; bottles of 50 g (€4.1), 100 g (€5.3), and 75 g (€4.6) of glucose, respectively; duration of test (€31.4/h); insulin pharmaceutical expenditure (€24 for each pen of 300 UI including needles); the cost of SMBG strips (€0.23/strip, including the use of meter); provider visits to the gestational diabetes unit (endocrinologist, educational nurses, and obstetrician: €31.4/visit); and hospital/neonatal intensive care unit admissions.

To calculate hospital admission costs, we relied on Conjunto Mínimo Básico de Datos (16), a set of minimum basic data at discharge. Following this classification, each patient is assigned to a diagnosis-related group (DRG). DRGs classify patient hospitalizations by diagnosis and procedure on the assumption that similar costs are expended on patients by using similar resources (17). Each DRG has a relative weight that reflects the intensity of resources consumed, including length of hospital stay and treatment, and finally each DRG has a number and an economic value assigned. A more complex procedure (including complications and sources consumed) is assigned a greater economic cost. The following DRGs were considered: for deliveries, 371 (cesarean section, €3,494) and 372 (vaginal or instrumental delivery without complications, €2,381), and for the need for neonate admission to the neonatal intensive care unit, 619 (weight between 2,000 and 2,499 g with medical complications, including neonatal hypoglycemia, hypocalcemia, polycythemia, and/or the respiratory distress syndrome, €4,766), 620 (weight 2,000–2,499 g without complications, €1,176), 628 (weight >2,500 g with complications, including neonatal hypoglycemia, hypocalcemia, polycytemia, and/or the respiratory distress syndrome, €2,389), and 630 (weight >2,499 g and isolated neonatal hypoglycemia, €1,686).

Statistical Study

Statistical analyses were performed using SPSS 15.0. Continuous variables are expressed as median and interquartile range. Categorical data are expressed as number and percentage. The Shapiro-Wilk test was used to verify the normal distribution of data. Student *t* test and the ANOVA test were used when variables had a normal distribution and nonparametric Mann-Whitney and Kruskal-Wallis tests used to compare continuous variables between two independent groups if the variables did not present a normal distribution. Categorical variables were compared using the χ^2 test. A P value $<$ 0.05 was considered significant.

RESULTS

The prevalence of GDM by CC criteria was 10.6% (185 of 1,750) and by IADPSGC was 35.5% (542 of 1,526). Table 1 shows maternal characteristics of both cohorts. Both women cohorts were comparable, but there were fewer current or to-pregnancy smokers in IADPSGC cohort ($P < 0.039$). GDM women identified by both tools were older, more often were multiparous, and had a greater pregestational and gestational BMI and a higher-risk medical and obstetric medical history compared with NGT women. All of these factors were also more frequent in women with GDM identified prior to April of 2012 than in those diagnosed since.

Pregnancy outcomes, fetal development, and newborn outcomes are displayed in Tables 2 and 3. Following introduction of the new diagnostic criteria, there are reductions in the rate of gestational hypertension (4.1 to 3.5%; −14.6%, $P < 0.021$), prematurity (6.4 to 5.7%; −10.9%, $P < 0.039$), cesarean section (25.4 to 19.7%; −23.9%, $P < 0.002$), instrumental delivery (15.7 to 8.3%; −47.1%, $P < 0.002$), LGA (4.6 to 3.7%; −20%, $P < 0.004$), SGA (7.7 to 7.1; −6.5%, $P < 0.042$), and 1-min Apgar scores <7 (3.8 to 3.5%; −9%, $P < 0.015$). There is an increase in the rate of pregnancies with normal fetal development according to gestational age at the third trimester (86.9 to 88.6%; 2%, $P < 0.001$) and in the frequency of vaginal deliveries (58.3 to 72%; 23.5%, $P < 0.002$). Admissions to neonatal intensive care unit decrease from 8.2 to 6.2% (−24.4%, $P < 0.001$). The costs per 100 women evaluated associated with both screening strategies are summarized in Table 4. Despite an increase in costs related to provider visits, insulin, and SMBG strips, the use of the IADPSGC was accompanied by an estimated savings of €14,358.06 per 100 women evaluated compared with the use of the two-step CC criteria, principally due to a reduction in the rate of cesarean sections and neonatal intensive care unit admissions.

CONCLUSIONS

This study indicates that the use of the new IADPSGC is associated with an improvement in pregnancy outcomes, presumably by permitting the treatment of a greater number of women at risk for pregnancy complications. The prevalence of gestational hypertension, prematurity, and cesarean sections and the number of LGA and SGA were reduced, and fewer newborns presented 1-min Apgar scores <7. Thus, the introduction of these criteria was cost-effective, in spite of a rise in the prevalence of GDM by a factor of 3.5, as was to be expected (10–14,18–20). Savings were primarily due to a reduction in cesarean sections, as well as to fewer neonate admissions to intensive care. Previous studies have found that women with one abnormal test value, considered as having mild GDM using the CC criteria, had outcomes similar to outcomes in

Table 1—Comparison of maternal population screening for GDM during 1-year period

	2-Step CC criteria (April 2011–March 2012)				IADPSGC (April 2012–March 2013)				
	All	GDM	NGT	*P*: GDM vs. NGT	All	GDM	NGT	*P*: GDM vs. NGT	*P*: CC cohort vs. IADPSGC cohort
N	1,750	185	1,565		1,526	542	984		
Age (years)	32 (28–36)	35 (32–38)	32 (28–35)	0.001	32 (28–36)	34 (30–37)	32 (28–35)	0.001	0.237
Ethnicity				0.016				0.05	0.895
Caucasian	1,085 (62.0)	131 (70.7)	954 (61)		945 (62.0)	350 (64.6)	595 (60.5)		
Hispanic	597 (34.1)	46 (25)	551 (35)		525 (34.4)	166 (30.6)	359 (36.5)		
African	39 (2.2)	6 (3.2)	33 (2.1)		21 (1.4)	8 (1.5)	13 (1.3)		
Asian	22 (1.3)	2 (1.1)	20 (1.3)		19 (1.2)	11 (2)	8 (0.8)		
Others	7 (0.4)	0	7 (0.6)		16 (1.1)	7 (1.4)	9 (0.9)		
Obstetric history				0.05				0.0001	0.144
No risk factors	1,175 (67.1)	115 (62.1)	1,060 (67.7)		1,059 (69.4)	341 (62.9)	718 (73)		
Miscarriage	426 (24.3)	42 (22.7)	384 (24.5)		364 (23.9)	142 (26.3)	222 (22.6)		
Prior GDM	43 (2.5)	9 (4.9)	34 (2.2)		31 (2.0)	23 (4.2)	8 (0.8)		
Others	106 (6.1)	19 (10.3)	87 (5.6)		72 (4.7)	36 (6.6)	36 (3.6)		
Personal history				0.002				0.001	0.154
No risk factors	1,506 (86.2)	144 (78.7)	1,362 (87.1)		1,342 (87.9)	449 (82.8)	893 (90.8)		
Overweight	82 (4.7)	17 (9.3)	65 (4.2)		68 (4.5)	46 (8.5)	22 (2.2)		
Others	160 (9.1)	24 (13)	136 (8.7)		116 (7.6)	47 (8.7)	69 (7)		
Family history				0.018				0.002	0.370
No risk factors	806 (46.1)	61 (33.0)	745 (47.6)		674 (44.2)	215 (39.7)	459 (46.6)		
DM	147 (8.4)	16 (8.7)	131 (8.4)		144 (9.4)	50 (9.2)	94 (9.6)		
MetS	797 (45.5)	109 (58.3)	688 (43.9)		708 (46.4)	277 (51.1)	431 (43.8)		
Smoker				0.175				0.978	0.039
CS	223 (12.7)	27 (14.6)	196 (12.5)		158 (10.4)	56 (10.3)	102 (10.4)		
TPS	246 (14.1)	26 (14.1)	220 (14.1)		207 (13.6)	73 (13.5)	134 (13.6)		
Parity				0.298				0.001	0.082
Primiparous	769 (43.9)	76 (38.3)	693 (44.3)		677 (44.7)	204 (37.6)	486 (49.4)		
2nd pregnancy	555 (31.7)	60 (32.4)	495 (31.6)		503 (33.8)	181 (33.4)	322 (32.7)		
>2 pregnancies	426 (24.3)	49 (26.5)	377 (24.1)		321 (21.5)	157 (29.0)	176 (17.9)		
Pregestational BMI (kg/m^2)	22.7 (20.8–25.4)	24.6 (22.5–28.7)	22.5 (20.6–25.1)	0.001	22.8 (20.8–25.5)	23.7 (21.4–27.0)	22.2 (20.4–24.6)	0.001	0.650
Gestational BMI (kg/m^2)	25.0 (23.0–27.7)	27.2 (24.5–30.1)	24.8 (22.9–27.6)	0.001	25.1 (23.0–27.7)	26.2 (23.9–29.5)	24.6 (22.8–26.8)	0.001	0.514
Weight gain at 24–28 weeks of gestation	6.0 (4.1–8.4)	5.9 (3.8–8.1)	6.0 (4.3–8.2)	0.132	6.0 (4.1–8.3)	6.0 (4.1–8.0)	6.0 (4.6–8.1)	0.017	0.300

Data are median (Q1–Q3) or *n* (%). CS, current smoker; MetS, metabolic syndrome; TPS, to-pregnancy smoker.

Table 2—Pregnancy outcomes among women with and without GDM diagnosed by CC criteria or IADPSGC

	2-Step CC criteria (April 2011–March 2012)				IADPSGC (April 2012–March 2013)				
	All	GDM	NGT	*P*: GDM vs. NGT	All	GDM	NGT	*P*: GDM vs. NGT	*P*: CC cohort vs. IADPSGC cohort
N	1,750	185	1,565		1,526	542	984		
Gestational hypertension	72 (4.1)	9 (4.9)	63 (4.0)	0.047	53 (3.5)	31 (5.7)	22 (2.2)	0.009	0.021
Gestational age at delivery (weeks)	39 (38–40)	39 (38–40)	39 (38–40)	0.519	40 (38–40)	39 (38–40)	40 (39–40)	0.059	0.006
Prematurity (<37 weeks)	112 (6.4)	12 (6.5)	100 (6.4)	0.391	87 (5.7)	32 (5.9)	55 (5.6)	0.049	0.039
Insulin treated		39 (21.1)				108 (19.9)			
Bolus		33 (17.8)				35 (6.5)			
Basal		1 (0.5)				45 (8.3)			
Bolus basal		5 (2.7)				28 (5.2)			
Delivery				0.049				0.026	0.002
Vaginal	1,021 (58.3)	107 (57.9)	914 (58.4)		1,098 (72.0)	378 (69.7)	720 (73.2)		
Cesarean section	453 (25.9)	51 (27.6)	402 (25.7)		302 (19.7)	120 (22.1)	182 (18.5)		
Forceps	276 (15.7)	27 (14.5)	249 (15.9)		126 (8.3)	44 (8.2)	82 (8.3)		
Birth weight (g)	3,210 (2,928–3,515)	3,200 (2,878–3,481)	3,220 (2,935–3,535)	0.541	3,230 (2,910–3,515)	3,200 (2,875–3,525)	3,245 (2,913–3,508)	0.616	0.885
>4,500	25 (1.4)	6 (3.2)	19 (1.2)	0.150	14 (0.9)	11 (2.0)	3 (0.3)	0.277	0.277
4,000–4,499	46 (2.6)	2 (1.1)	44 (2.8)		42 (2.7)	15 (2.8)	27 (2.7)		
2,500–4,000	1,556 (88.9)	165 (89.2)	1,391 (88.9)		1,371 (89.8)	480 (88.6)	891 (90.6)		
<2,500	123 (7.1)	12 (6.5)	111 (7.1)		99 (6.5)	36 (6.6)	63 (6.4)		
LGA	81 (4.6)	9 (4.9)	72 (4.6)	0.913	57 (3.7)	26 (4.8)	31 (3.2)	0.041	0.004
SGA	134 (7.7)	15 (8.1)	119 (7.6)	0.834	109 (7.1)	39 (7.2)	70 (7.1)	0.938	0.042
Apgar score <7									
At 1 min	67 (3.8)	7 (3.8)	60 (3.8)	0.982	53 (3.5)	19 (3.5)	34 (3.5)	0.620	0.015
At 5 min	7 (0.4)	3 (1.6)	4 (0.3)	0.053	6 (0.4)	1 (0.2)	5 (0.5)	0.761	0.294
Admission to NICU	144 (8.17)	23 (12.4)	121 (7.7)	0.001	94 (6.16)	52 (9.6)	42 (4.3)	0.001	0.001
Isolated hypoglycemia	3 (0.17)	3 (1.6)	0	0.150	5 (0.33)	5 (0.9)	0	0.066	0.093
Weight 2,000–2,499 g and MC	55 (3.1)	6 (3.2)	49 (3.1)	0.839	32 (2.1)	14 (2.6)	18 (1.8)	0.031	0.021
Weight 2,000–2,499 g without MC	56 (3.2)	6 (3.2)	50 (3.2)	0.876	43 (2.82)	22 (4.1)	21 (2.1)	0.007	0.035
Weight >2,500 g with MC*	30 (1.7)	8 (4.3)	22 (1.4)	0.003	14 (0.92)	11 (2.0)	3 (0.3)	0.009	0.019

Data are median (quartile 1–quartile 3) or *n* (rate). MC, medical complication, including neonatal hypoglycemia, hypocalcemia, polycythemia, and/or the respiratory distress syndrome; NICU, neonatal intensive care unit.

those diagnosed with GDM (19–21), and intervention studies in this group of "mild GDM" have shown an improvement in adverse outcomes, including pregnancy-induced hypertension, cesarean section, and LGA (22–24). However, to our knowledge, the study we present is the first to demonstrate both health outcome and economic benefits in the use of the one-step IADPSGC.

We believe that the benefits observed by using the new criteria are related to the treatment of women with elevated fasting glucose levels and/or only one abnormal test value—patients previously considered normal with the two-step criteria. We found that 42% of the patients diagnosed as having GDM with the new criteria who would have previously been excluded presented fasting glucose levels between 92 and 95 mg/dL. These results are similar to those of other studies: between 28 and 55% (10,25). The HAPO findings (5) indicated that 55% of the newly diagnosed patients would present fasting blood glycemias superior to the threshold value for GDM, with 33% having glycemias over the 1-h and 12% over the 2-h cutoff value, respectively. We have found that this new group of GDM patients also presents an increase in risk factors for GDM compared with NGT women, although not to the extent of the group of GDM patients diagnosed prior to April of 2012. These results suggest that women at moderate to low risk of poor pregnancy outcomes are identified as having GDM after application of the IADPSGC.

Both groups of women—those diagnosed with GDM prior to April 2012 as well as those diagnosed from April of 2012 on—received the same treatment regimes. Nutritional treatment was effective in attaining glycemic targets in a similar proportion of women (80%) in both cases. However, the type of insulin treatment received varied when diet was insufficient. Insulin therapy was associated with diet in 39 (21%) of the GDM women identified by the older criteria and in 108 (20%) of cases if GDM was identified by IADPSGC. Bolus prandial insulin was prescribed in 33 (17.8%) and 35 (3.5%) women, respectively and basal insulin was started in 1 (0.5%) and 45 (8.3%) women and basal bolus in 5 (2.7%) and 28 (5.2%) women. Thus, the women newly identified as having GDM

Table 3—Ultrasonography of fetal growth and development

	2-Step CC criteria (April 2011–March 2012)				IADPSGC (April 2012–March 2013)					
	All	GDM	NGT	*P*: GDM vs. NGT	All	GDM	NGT	*P*: GDM vs. NGT	*P*: CC cohort vs. IADPSGC cohort
N	1,750	185	1,565		1,526	542	984		
GA at 2nd trimester	20 (19.5–20.4)	20 (19.6–20.4)	20 (19.5–20.3)	0.098	20.1 (19.6–20.4)	20.1 (19.6–20.4)	20.1 (19.6–20.4)	0.323	0.073
Biparietal diameter (cm)	4.7 (4.6–4.9)	4.8 (4.6–5.0)	4.7 (4.6–4.9)	0.294	4.8 (4.6–5.0)	4.8 (4.6–5.0)	4.8 (4.6–5.0)	0.708	0.428
AC (cm)	15.3 (14.8–15.9)	15.4 (14.7–16.1)	15.3 (14.8–15.9)	0.491	15.4 (14.8–16.0)	15.4 (14.8–16.0)	15.3 (14.8–16.0)	0.325	0.271
Femur length (cm)	3.2 (3.1–3.4)	3.3 (3.1–3.4)	3.2 (3.1–3.4)	0.346	3.2 (3.1–3.4)	3.2 (3.1–3.4)	3.2 (3.1–3.4)	0.331	0.098
NIG for GA	1,540 (88)	160 (85.6)	1,380 (88)	0.001	1,390 (91.1)	486 (89.7)	904 (92)	0.132	0.001
GA at 3rd trimester	32 (31.6–32.3)	32 (31.8–32.4)	32 (31.6–32.2)	0.095	32 (31.6–32.3)	32 (31.6–32.3)	32 (31.6–32.3)	0.687	0.351
Biparietal diameter (cm)	8.2 (8.0–8.4)	8.2 (8.0–8.5)	8.2 (8.0–8.4)	0.867	8.2 (8.0–8.4)	8.2 (8.0–8.5)	8.2 (8.0–8.4)	0.913	0.694
AC (cm)	28.2 (27.3–29.1)	28.4 (27.3–29.4)	28.2 (27.3–29.0)	0.316	28.2 (27.3–29.0)	28.2 (27.3–29.1)	28.1 (27.2–28.9)	0.109	0.560
Femur length (cm)	6.1 (6.0–6.3)	6.2 (6.0–6.3)	6.1 (5.9–6.2)	0.01	6.1 (6.0–6.3)	6.1 (6.0–6.3)	6.1 (6.0–6.2)	0.075	0.998
Weight estimation (g)	1,960 (1,836–2,100)	2,000 (1,850–2,157)	1,960 (1,830–2,100)	0.035	1,950 (1,825–2,081)	1,970 (1,832–2,100)	1,950 (1,821–2,065)	0.039	0.037
NIG for GA	1,522 (87)	157 (85)	1,365 (87)	0.001	1,352 (89)	470 (87)	882 (90)	0.090	0.001

Data are median (quartile 1–quartile 3) or *n* (%). GA, gestational age; NIG, normal intrauterine growth for GA.

Table 4—Estimation of cost after two-step or one-step screening for GDM per 100 women evaluated

	2-Step CC criteria		IADPSGC		
	N events per 100 women evaluated	Cost (€)	*N* events per 100 women evaluated	Cost (€)	Excess cost (IADPSGC − CC criteria)
Test (50 g/75 g/100 g)	100/0/48	664.4	0/100/0	460	−204.4
Laboratory visit (h)	244	7,671.36	200	6,288	−1,383.36
GDM SMBG strips					405.8
NITGDM no. (strips/pts)	8.4 (54)	104.3	28.4 (52)	339.7	
ITGDM no. (strips/pts)	2.2 (144)	72.9	7.1 (149)	243.3	
Total strips	770.4	177.2	2,534.7	583	
Insulin Bo/Ba/Bo-Ba	1.88/0.05/0.02	94	2.31/2.95/1.85	320	226
Provider visits by GDM					3,121.99
NITGDM no. (visits/pts)	8.4 (3.5)	925.07	28.4 (3.2)	2,860,48	
ITGDM no. (visits/pts)	2.2 (8.3)	574.62	7.1 (7.9)	1,761,2	
Total visit	47.7	1,499.69	147.1	4,621.68	
Delivery					−9,442.2
Vaginal	58.3	138,098	72	171,432	
Cesarean section	25.9	93,988.6	19.7	68,831.8	
Forceps/instrumental	15.7	37,381.7	8.3	19,762	
Total	100	269,468.3	100	260,026.1	
Admission NICU					−6,894.7
Isolated neonatal hypoglycemia	0.17	286.62	0.32	539.52	
Weight 2,000–2,499 g with other complications*	3.1	14,774.6	2.1	10,008.6	
Weight 2,000–2,499 g without complications	3.2	3,763.2	2.8	3,292.8	
Weight >2,500 g with complications*	1.7	4,061.3	0.9	2,150.1	
Total events	8.17	22,885.72	6.16	15,991.02	
Estimation of cost savings					−14,358.06

Ba, basal; Bo, bolus; Bo-Ba, bolus basal; ITGDM, insulin treated GDM; NICU, neonatal intensive care unit; NITGDM, non–insulin-treated GDM; pts, patients. *Including neonatal hypoglycemia, hypocalcemia, polycythemia, and/or the respiratory distress syndrome.

with IADPSGC required more basal insulin, and to a lesser extent more basal-bolus insulin, to achieve FPG levels <95 mg/dL and/or 1-h postprandial capillary glucose levels <140 mg/dL per guidelines. This shift in insulin regimes was to be expected, given the high percentage of patients with high fasting glycemic levels newly included when IADPSGC were applied.

Our study has important limitations: patients are not randomized, and it is not a clinical trial, but screening is universal and centralized since 2002. We compared patients 1 year prior to and 1 year after the introduction of the new IADPSGC. However, we believe the findings to be valid, given that, with the exception of the diagnostic criteria, other variables are constant. The characteristics of both study cohorts were similar, as evaluated by age, parity, ethnicity, BMI, and personal medical and family GDM risk factors, and the screening was universal. Patients in both groups were attended in the same unit (since 2002), and their treatment protocols were identical (since 2006). Furthermore, results obtained in clinical trials are often different from what is observed in real-life clinical practice, given that in trials both the patients and health personnel are highly motivated, whereas our study has the advantage of registering the benefits of the introduction of the new diagnostic criteria in a setting of standard care. We therefore believe that the improvement in outcomes observed, and the accompanying savings, can in all probability be attributed to the modifications introduced in the diagnostic criteria of GDM.

The current study addresses some of the previously unanswered questions that have limited the extension of the use of the IADPSGC for the diagnosis of GDM. First of all, is the application of IADPSGC associated with a decrease in adverse outcomes compared with the use of CC criteria? Our study finds that this is indeed the case. Patients of similar characteristics treated with the same protocol presented a significant reduction in pregnancy-induced hypertension, cesarean deliveries, and instrumental deliveries, with a decrease in both LGA and SGA, and in newborns requiring admittance to a neonatal intensive care unit. Parameters involved in the risk of cesarean section such as age, parity, and ethnicity remained stable in both cohorts. The decreases in prematurity and LGA in patients screened with HAPO criteria, as well as gestational hypertension, may contribute to the reduction of cesarean section rate. Our feeling is that improvement in maternal and fetal health accompanying better care of women previously considered to be normal leads to a lower need for cesarean sections.

Second, does the application of IADPSGC result in the identification and treatment of women at a low risk for GDM who were previously considered to have mild GDM? Yes, this is indeed the case, as IADPSGC clearly increases the prevalence of GDM, and patients considered by CC to have normal or mild GDM are now included (mainly patients with fasting plasma glucose between 92 and 95 mg/dL).

However, changes in nutritional behavior in Spain and an increase in the prevalence of type 2 diabetes and the metabolic syndrome as recently reported (26–28) could also be contributing to an increase in the prevalence of GDM.

Third, could the use of the new criteria induce overtreatment? We have found that the introduction of IADPSGC did not modify the percentage of patients needing insulin therapy to achieve glycemic goals and was accompanied by a marked improvement in pregnancy outcomes. Furthermore, we observed a decrease in newborns <2,500 g and in SGA, as opposed to an increase (which could indicate overtreatment). Although these figures can be expected, since there were fewer smokers, our results suggest that the use of the new criteria did not induce overtreatment.

Fourth, could the use of IADPSGC increase health care costs by increasing the prevalence of GDM? On the contrary, we have found that costs go down, as pregnancy outcomes improve, the rate of cesarean sections decreases, and the number of neonate intensive care unit admissions is reduced. The savings in these two areas more than compensate initial increases in expenditures to cover more outpatient visits, SMBG strips, and insulin therapy. Using an estimation of costs applied in other studies in Spain (29,30), we found that €14,358.06 were saved for every 100 pregnant women evaluated, in spite of an increase in the prevalence of GDM of the order of 3.5. Therefore, the change in criteria is clearly cost-effective. One of the limitations of our study is the fact that it ends with hospital discharge and does not take into account postdischarge costs. However, in our protocol for follow-up of all women postpregnancy, a laboratory test with fasting glycemia is done 12 weeks after discharge, regardless of whether patients had GDM—with no cost difference. If we were to perform OGTT at this time in patients diagnosed as having GDM, the use of criteria would still be cost-effective, since the additional cost owing to use of these criteria would be of €1,678.27 (€2,392.7 vs. €714.44) per 100 screened women.

In conclusion, in the groups of women we studied, the use of IADPSGC substantially increased the number of cases of GDM diagnosed and treated and was accompanied by important health outcome benefits. Furthermore, improved outcomes resulted in significant economic savings. We believe that our findings support the widespread use of the IADPSGC for the diagnosis of GDM.

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