nutrición clínica y Dietética Hospitalaria

Artículo Original

Nutr. clín. diet. hosp. 2017; 37(3):44-52
DOI: 10.12873/373neri

Impacto de los nuevos criterios diagnósticos para la Diabetes Gestacional. Ensayo clínico aleatorizado

The impact of the new diagnosis criteria for Gestational Diabetes. Randomized controlled trial

Fernández Pombo, Carmen Neri[1]; Luna Cano, María Reyes[1]; Blanco Dominguez, María Isabel[1]; Rempel, Claudete[2]; Moreschi, Claudete[2]

1 Servicio Gallego de Salud.
2 Centro Universitario UNIVATES.

Recibido: 5/enero/2017. Aceptado: 15/junio/2017.

ABSTRACT

Objective: To compare the prevalence of risk factors for Gestational Diabetes Mellitus (GDM), the prevalence of GDM and the pregnancy outcomes with the International Association of Diabetes and Pregnancy Study Groups (IADPSG) and the National Diabetes Data Group (NDDG).

Patients and methods: Randomized controlled and open study. The sample size analyzed was 197 pregnant women in the Intervention Group (IG) and 387 pregnant women in the Control Group (CG). Statistical analyses was made using SPSS.

Results: The prevalence of GDM increase using the IADPSG criteria comparing NDDG by 221.2% (36.3% vs. 11.3%). The maternal age are less in the IG-GDM than CG-GDM (32.6±5.4 vs. 34.7±4.6, P=0.028). The pre-gestational BMI are less in the CG-N and CG-GDM (24.8±4.3 vs. 26.3±4.9, P=0.020). The pregnant women CG-N gained significantly more weight during pregnancy than pregnant women in the IG-N (10.1 ± 4.4 vs 7.1 ± 3.1, p = 0.000). The results of the HbA1c trimester value shows that the HbA1c of the CG-GDM was significantly higher in second trimester than the IG-GDM (5.1 ± 0.3 vs 4.9 ± 0.2, p = 0.000).

Conclusions: The prevalence of GDM increases using the IADPSG criteria. The pregnant women diagnosed with IADPSG criteria had lower risk factors for GDM and some pregnant outcomes are better in the IG than the CG.

KEY WORDS

Pregnancy; Blood Glucose; Birth Weight; Parturition.

RESUMEN

Objetivo: Comparar la prevalencia de los factores de riesgo para la Diabetes Gestacional (DG), la prevalencia de la DG y los resultados de la gestación entre la International Association of Diabetes and Pregnancy Study Groups (IADPSG) y la National Diabetes Data Group (NDDG).

Pacientes y métodos: Ensayo clínico controlado, randomizado abierto y unicéntrico. La muestra a estudio analizada fue de 19 gestantes para el Grupo Intervención (GI) y de 387 para el Grupo Control (GC). Los análisis estadísticos se han realizado con el programa SPSS.

Resultados: La prevalencia de DG se incrementa en un 221% usando los criterios de la IADPSG en comparación con los del NDDG (36.3% vs. 11.3%). La edad materna fue menor en el GI-DG que en el GC-DG (32.6±5.4 vs. 34.7±4.6, P=0.028). El IMC pregestacional fue menor en el GC-N que en el GC-DG (24.8±4.3 vs. 26.3±4.9, P=0.020). Las embarazadas del GC-N ganaron más peso ponderal que las embarazadas del GI-N (10.1 ± 4.4 vs 7.1 ± 3.1, p = 0.000). Los resultados de la HbA1c mostró que la HbA1c del segundo trimestre fue mayor en el GC-DG frente al GI-DG (5.1 ± 0.3 vs 4.9 ± 0.2, p = 0.000).

Correspondencia:
Carmen Neri Fernández Pombo
carmennerifernandez@gmail.com

Conclusiones: La prevalencia de DG se ve incrementado tras la utilización de los criterios de la IADPSG. Las embarazadas diagnosticadas de DG con los criterios IADPSG tienen un perfil de riesgo menor para DG y algunos resultados obstétricos son mejores en el GI frente al GC.

PALABRAS CLAVE

Embarazo; Glucemia; Peso al nacer; Parto.

INTRODUCTION

The International Association of Diabetes and Pregnancy Study Groups (IADPSG) current proposal establishes a new terminology that tell apart Gestational Diabetes Mellitus (GDM), according to the previous definition, and overt Diabetes Mellitus (DM) (diabetes prior to pregnancy, undiagnosed until then)[1,2].

GDM is a major public health problem because of its high prevalence and the consequences for maternal and fetal health[3]. Therefore, the primary goals on every health care plan are identifying women with GDM and normalizing their glycemic profile, to prevent, or at least reduce, the complications[4–6].

The Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) multicentric international study has shown a correlation between the risk of adverse outcomes and levels of maternal fasting plasma glucose (FPG), 1-h, and 2-h after a 75-g oral glucose tolerance test (OGTT)[7]. It has also showed that the excess of fetal weight and the prevalence of pre-eclampsia are related to a high maternal Body Mass Index (BMI), regardless of the glucose levels. However, this study did not identify a cutoff point for a maternal glucose intolerance level above which the risk of an adverse outcome is higher.

After the HAPO study, the IADPSG has recommended a new strategy of detection and diagnosis of hyperglycemic disorders in pregnancy based on the perinatal outcomes, instead of on the risk of maternal future diabetes. So, the IADPSG consider the median glucose values for FPG, 1-h, and 2-h OGTT plasma glucose concentrations corresponding to an *Odds Ratio* (OR) of 1.75 to birth weight, cord C-peptide and percent body fat above the 90th percentile. It proposes a one-step diagnosis strategy, no need of a prior screening, and the diagnosis of overt DM during the first prenatal visit[2].

The new IADPSG diagnostic criteria has challenged most of the professionals who care these patients[8–11]. On one hand, the diagnosis strategy is simplified, it takes only one shorter diagnostic test that the pregnant woman tolerates better and it detects overt DM in the first prenatal visit. In addition, these criteria have been calculated for the first time to predict perinatal results. On the opposite side, we find the concern about the rise of the expected GDM prevalence (approximately 100% more), the potential of iatrogenesis in the patients receiving the intensive treatment used nowadays on GDM and the possible increase in the health care costs. The last concern was answer in the St. Carlos Diabetes Gestational Study[12], Spanish study publishes in September 2014, which after use the 75-g OGTT proposed by the IADPSG for diagnose the GDM, have found that the health care costs go down in Spain, being demonstrated that the change in criteria is clearly cost-effective.

The purpose of this study is to demonstrate the viability of the implementation of the new diagnostic criteria for GDM proposed by the IADPSG in our country, understood viability as the fulfillment of the following points: The management of clinical practice of GDM will not be altered with the acceptance of the IADPSG diagnosis criteria. The development of two different treatment strategies based on the presence of risk factors for GDM, the time of diagnosis and the test used to detect the GDM in pregnant women prevents any iatrogenic associated with overtreatment. The aims of this study were to evaluate the prevalence of GDM and overt DM to use IADPSG diagnostic criteria in the intervention group (IG) versus to use the NDDG diagnosis criteria in the control group (CG), to evaluate the importance of the risk factors for GDM in the diagnosis of GDM in the pregnant women of the IG and of the CG and to evaluate the impact of the diagnostic and the therapeutic strategy used in the IG and in the CG, in the results of the course of the pregnancy, in the birth outcomes and in the results of the 75-g OGTT postpartum.

PATIENTS AND METHODS

Study design

The study was designed as a randomized controlled and open intervention study was approved by the ethics committee at the Clinical Research Ethics Committee of Galicia (CEIC) (2012/214) and was registered as clinical trial in the Australian New Zealand Clinical Trials Registry (ACTRN12614000854639). The Study was conducted in accordance with the principles of the Declaration of Helsinki (version 2008) and the Medical Research Involving Human Subjects Act.

Study Site

The study was performed in the Coia's Speciality Medical Center, center responsible for the control of the pregnancy in all women registered in the performance area of the University Hospital Complex of Vigo (CHUVI), Spain. The Coia's Speciality Medical Center have five obstetrics medical consultations, one exclusive for high-risk pregnancy (pregnant women with diseases that endanger your life or that of the fetus and pregnancy with more than one fetus) and four for low-risk pregnancy. In this study was participated only the four low-risk obstetrics medical consultation was being the selection of study participants established at random one of these as an obstetric medical consultation for the participants of the IG, and the others three as an obstetric medical con-

sultation for the participants of the CG. This distribution was considered by all researchers as the most appropriate way to conduct the study.

The sample size

The sample size was calculated based on the results of the Spanish study Evaluación de las distintas Estrategias diagnósticas para Diabetes Gestacional[13] where it was reported that the prevalence of cesarean sections in the study sample was 17 to 39% in women with GDM and 16 to 26% in women with a negative screening for GDM.

In our study the prevalence of 39% cesarean section in women with GDM was assumed versus 26% in women with negative screening, which, based on a confidence level of 95%, a power of 90% and a ratio between groups of 1:2, a minimum sample size of 202 subjects in the IG and 404 subjects in the CG was obtained. Calculations realized using the Epidat 3.1 program.

Sample Szelection

The inclusion criteria for participate in the study was have maternal age ≥ 18 years old, a single-fetus pregnancy, have in the first prenatal obstetric consultation ≤ 12 age gestational, not presented some carbohydrate disorder that had been diagnosed before the pregnancy and signed consent to participate in the study. The exclusion criteria was not had all the inclusion criteria and participate in another research study. The data collected initiated in February 2013 and finished in Mai 2013. The final sample size were formed by a total of 223 pregnant women, in the IG, and 444 pregnant women, in the CG. All this pregnant women had the inclusion criteria. The analysis was done in March 2014.

Step of the RCT

The steps of the RCT were determined by the objectives established in it. The first step was evaluated the prevalence of GDM and overt DM to use IADPSG diagnostic criteria in the IG against to use the NDDG diagnosis criteria in the CG. The second step was evaluated the importance of the risk factors for GDM in the diagnosis of GDM between the pregnant women of the IG and the pregnant women of the CG. The third step was evaluated the impact of the criteria diagnostic and the therapeutic strategy used in the IG and in the CG in the results of the course of the pregnancy and in the birth outcomes. The four step was evaluated the results of the 75-g OGTT postpartum in relation with the criteria diagnostic and the therapeutic strategy used in the IG and in the CG.

Loss of sample size

The criteria for loss of sample size determinate in this RCT was not complete the diagnosis strategy for GDM for not go through with pregnancy (abortion physiological or induced), not complete the care protocol established in the study groups (leaving the study or not performing the prescribed therapeutic activities) and not realized the 75-g OGTT postpartum. The pregnant women who had anyone of these criteria were excluded of this RCT, but the data registered in the last step was analyzed and included in this study.

Risk factors for GDM

Maternal age ≥ 30 years old, pre-gestational BMI ≥ 30 kg/m^2, chronic hypertension (HTN ≥ 140 / 90), DM in first-degree relatives, personal history of GDM, congenital malformations, macrosomia (birthweight ≥ 4000 g), caesarean section, perinatal mortality or pregnancy-related hypertension (gestational HTN ≥ 140/90 mmHg).

Intervention group. Diagnosis and therapeutic strategic

All of 223 pregnant women included in the IG were performed the IADPSG diagnosis criteria, being diagnoses with GDM in the first trimester the pregnant women with FPG ≥ 92 [5.1 mmol/L] but < 126 mg/dL [7.0 mmol/L]. The pregnant women with FPG < 92 mg/dL [5.1 mmol/L] was performed the 75-g OGTT at week 24-28 of gestation for reevaluate their glucose tolerance, being diagnoses with GDM the pregnant women who presented one or more of these values: FPG ≥ 92 mg/dL [5.1 mmol/L], after 1-hour ≥ 180 mg/dL [10 mmol/L] and/or after 2-hours ≥ 153 mg/dL [8.5 mmol/L].

For stablished the therapeutic strategy, in the IG was formed two groups, one with pregnant women diagnosed with GDM (IG-GDM) and another one with pregnant women without GDM (IG-N).

In the IG, the pregnancy women were followed with an intervention protocol (IG-IP) created in this study. The IG-IP includes the next activities: to check the capillary plasma glucose at home in six times a day (three preprandial and three postprandial), once a month; to go to the nursing consultation between the weeks: 20-22, 28-31, 35-37 and 39-40; to receive for the control of GDM only dietary advice during all the pregnancy. The pregnant women go to the Medical Specialist in Endocrinology if they have a wrong glycemic control (HbA1c in any trimester ≥ 5.3% or more than three values up about the next: preprandial capillary plasma glycemic ≥ 95 mg/dL [5.3 mmol/L] and/or 1h-postprandial ≥ 140 mg/dL [7.8 mmol/L]).

In the IG-N, the pregnant women have also an intervention protocol with the next activities: to go to the nursing consultation between the next weeks: 20-22, 28-31, 35-37 and 39-40 for receive dietary advice during all the pregnancy. In each nursing consultation, the pregnant women received dietary advice based in standards of good pregnant women's nutrition includes in the guidelines of the Spanish Group of Diabetes and Pregnancy (GEDE)[14].

Control group. Diagnosis and therapeutic strategic

All of 444 pregnant women included in the CG followed the NDDG diagnosis criteria being diagnosed with GDM the pregnant women were performed the 50g-OGTT at week 24-28 of gestation when 1h plasma glucose levels were ≥ 140 mg/dL [7.8 mmol/L] and after the 3-hours 100g-OGTT present also two or more values ≥ to the following: FPG 105 mg/dL [5.8 mmol/L]; after 1-hour 190 mg/dL [10.6 mmol/L], after 2-hours 165 mg/dL [9.2 mmol/L] and after 3-hours 145 mg/dL [8.1 mmol/L].

Overt DM was diagnosed when the results of FPG was ≥ 126 mg/dL [7.0 mmol/L] or the random PG was ≥ 200 mg/dL [11.1 mmol/L] in two different checks.

For established the therapeutic strategy, in the CG there were formed two groups, one with pregnant women diagnosed with GDM (CG-GDM) and other one with pregnant women without GDM (CG-N). The pregnant women in the CG-GDM were followed the standard care plan which includes the next activities: to check the capillary plasma glucose at home in six times a day (three preprandial and three postprandial) one out of three days; to go to the Medical Specialist in Endocrinology consultation at least between the weeks: 20-22, 28-31, 35-37 and 39-40; to receive for the control of GDM only dietary advice or with insulin.

Both groups. Partum

In the period of partum the nurses and/or the specialist in medicine were the responsible for ensuring, in the case of pregnant women with GDM, the maternal and newborn (NB) normoglycemia following therapeutic schemes developed by medical specialists in Endocrinology and Nutrition in the "Diabetes and Pregnancy Protocol" (84). In this period, they were recorded the following clinical data: type of delivery; cause of cesarean, being considered the disproportion pelvic fetal (DPF) and shoulder dystocia as directly related to the DMG causes; Birth Weight registered in grams (g) and also registered as percentile as small for gestational age (SGA) (percentile < 10), appropriate to gestational age (AGA) (percentile ≥ 10 ≤ 90) and large for gestational age (LGA) (percentile > 90) taking into account also the macrosomic (weight ≥ 4000 g); Apgar score ≤ 7 and NB complications such as hypocalcemia, hypoglycemia, polycythemia, birth trauma, neonatal mortality, cardiomyopathy, respiratory distress syndrome (RDS) and shoulder dystocia. All these data were collected from the notes taken by health personnel in IANUS.

Both groups. Postpartum

At 12 weeks after delivery, pregnant women with GDM were cited for a 75-g OGTT, in order to reclassify their metabolic state. According to the results of the 75-g OGTT, the women were classified into four groups according to present tolerance to carbohydrates (CH) (FPG < 100 mg/dL and glycemic after two hours < 140 mg/dL), impaired fasting glucose (IFG) (FPG ≥ 100 mg/dL [5.6 mmol/L] but < 126 mg/dL [7.0 mmol/L]), intolerance to CH (ICH) (glycemic after two hours ≥ 140 mg/mL [7.8 mmol/L] but < 200 mg/dL [11.1 mmol/L]) or DM (FPG ≥ 126 mg/dL [7.0 mmol/L]) or glycemic after two ≥ 200 mg/dL [11.1 mmol/L]).

Statistical methods

Statistical analyses was made using SPSS 22.0. Continuous variables were reported as median ± standard deviation (SD) and categorical variables were reported as number (n) and frequency (%). Student *t* test was used in continuous variables with normal distribution and Mann-Whitney and Kruskal-Wallis as a non-parametric test used to compare continuous variables with not normal distribution. *Pearson's chi-squared test* were used for comparing categorical variables. A *P* value < 0.05 was considered significant.

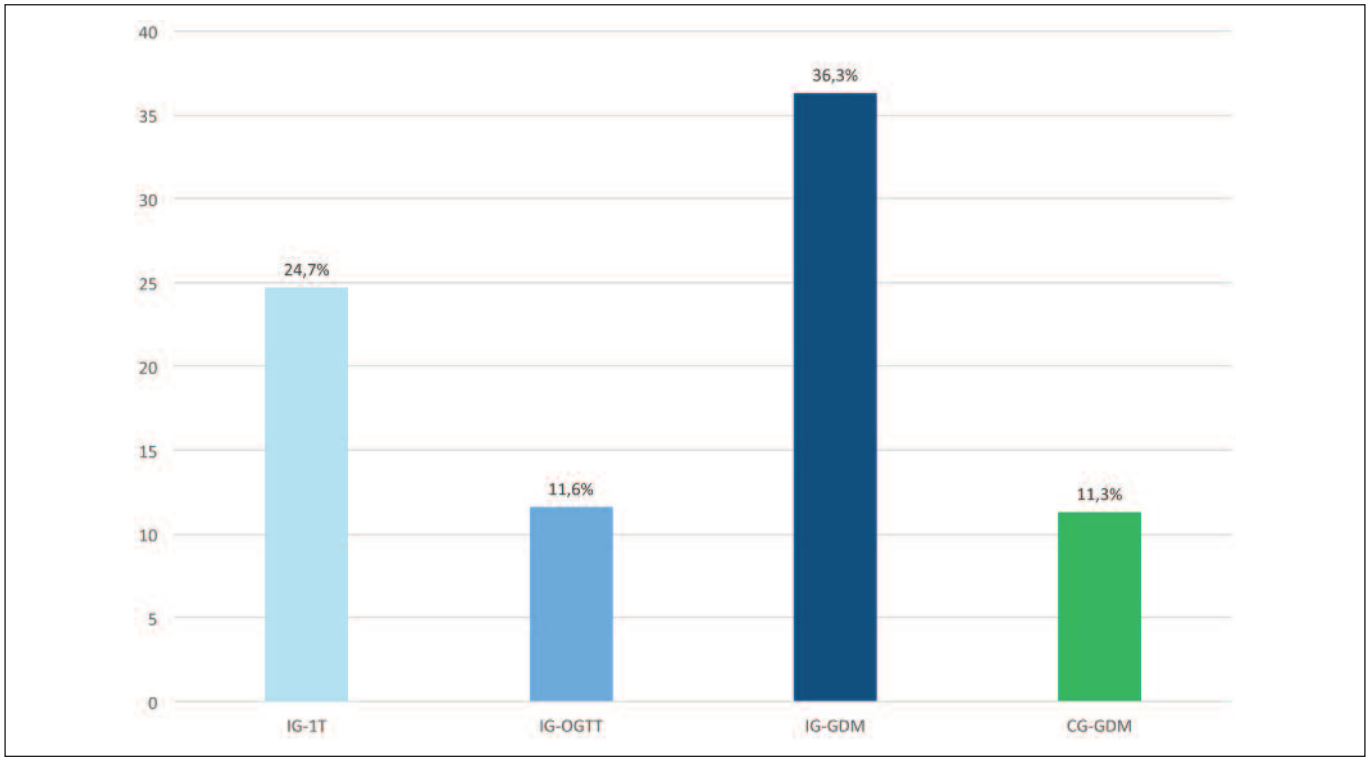
RESULTS

The percentage of pregnant women who did not finish the diagnostic strategy for GDM were 11.2% (n: 25) in the IG and 12.6% (n: 56) in the CG, so they were excluded from the study. The prevalence of overt DM was 0.4% (n: 1) in IG and 0.2% in CG (n: 1). Total prevalence of GDM was 36.3% (n: 81) in IG versus (vs.) 11.3 % (n: 50) in CG. In the IG, 24.7% (n: 55) of pregnant women were diagnosed by the first trimester FPG and the 11.6% (n: 26) was diagnosed by the 75-g OGTT (Figure 1).

After being diagnosed, a total of 5.4% (n: 12) pregnant women in the IG and of 2.7% (n: 12) in the CG were also excluded from the study for not finish the therapeutic intervention. The final size analyzed was 185 pregnant women in the IG: 71 in the IG-GDM and 114 in the IG-N and 375 pregnant women in the CG: 50 in the CG-GDM and 325 in the CG-N.

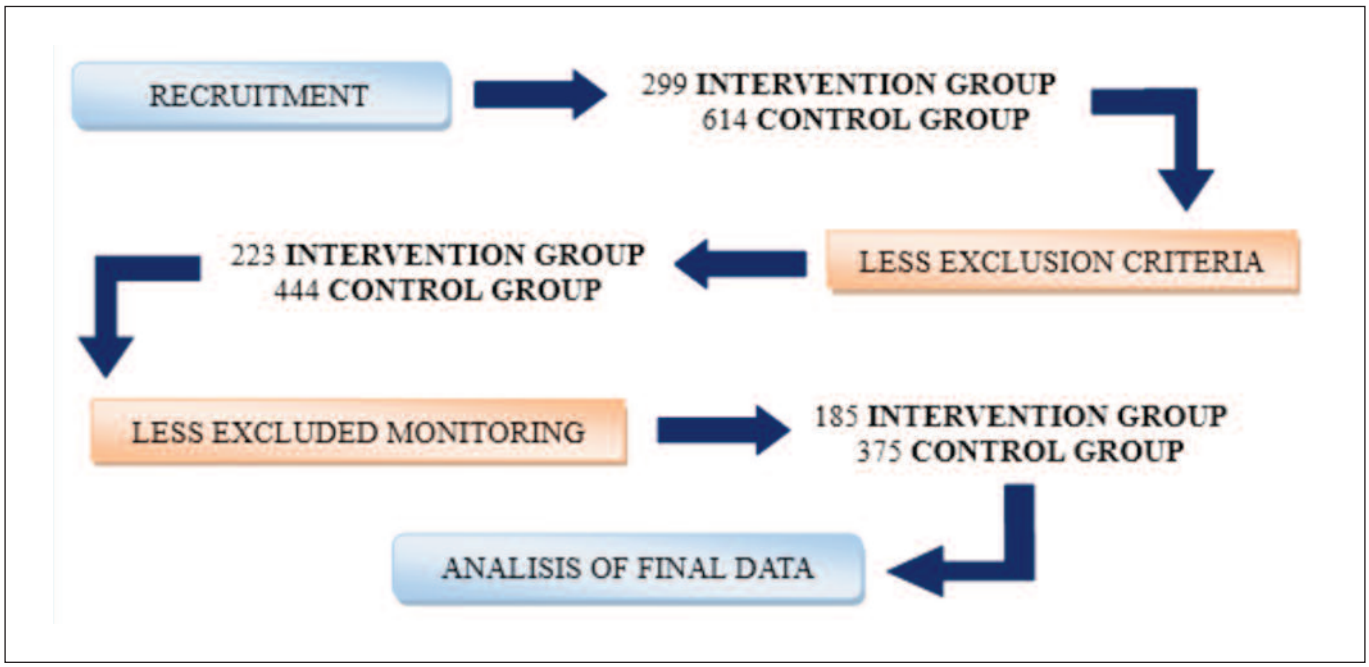
The table 1 shows the prevalence about the risk factors studied in the sub-groups of IG and the CG. There were found significant differences 182 between IG-GDM and CG-GDM for the age variable (32.5 years old ± 5.4 vs. 34.7 years old ± 4.6, $P = 0.028$). In the CG, were found significant differences between CG-N and CG-GDM groups for maternal age ≥ 30 years old (71.8% vs. 88.0%, $P = 0.015$) and pre-gestational BMI (24.8 kg/m^2 ± 4.3 vs. 26.3 kg/m^2 191 ± 4.9, $P = 0.020$). After studying the relation between these two variables, were found that the ≥ 30 years old pregnant women have 1.1 higher risk (95% CI 1.0 – 1.2) of developing GDM than younger women. Also, pregnant women with a pregestational BMI ≥ 26.3 kg/m^2 194 present a 3.1 higher risk (95% CI 1.3 – 7.5) of developing GDM that the women with a lower BMI. Were not found any case in the studied groups for chronic HTN and perinatal mortality (Figure 2).

Figure 1. Prevalence of Gestational Diabetes Mellitus in Intervention.



The table 1 shows the prevalence about the risk factors studied in the sub-groups of IG and the CG. There were found significant differences 182 between IG-GDM and CG-GDM for the age variable (32.5 years old ± 5.4 vs. 34.7 years old ± 4.6, *P* = 0.028). In the CG, were found significant differences between CG-N and CG-GDM groups for maternal age ≥ 30 years old (71.8% vs. 88.0%, *P* = 0.015) and pre-gestational BMI (24.8 kg/m^2 ± 4.3 vs. 26.3 kg/m^2 191 ± 4.9, *P* = 0.020). After studying the relation between these two variables, were found that the ≥ 30 years old pregnant women have 1.1 higher risk (95%

Figure 2. Algorithm of study participants.



CI 1.0 – 1.2) of developing GDM than younger women. Also, pregnant women with a pregestational BMI ≥ 26.3 kg/m^2 194 present a 3.1 higher risk (95% CI 1.3 – 7.5) of developing GDM that the women with a lower BMI. Were not found any case in the studied groups for chronic HTN and perinatal mortality.

The table 2 shows the comparative analysis done between the respectively sub-groups of IG and the CG with the variables registered. The analysis had significant results for the weight gain during pregnancy and in the trimester value of HbA1c. The results of the weight gain during pregnancy shows that in the CG, the pregnant women in the CG-N gained significantly more weight during pregnancy than those of the CG-GDM (10.1 ± 4.4 vs 7.3 ± 6.6, p = 0.000). Comparing sub-groups of IG and CG was observed that preg-

Table 1. Risk factor's comparison for GDM among the groups. Vigo, Spain, 2013 – 2014.

	IADPSG CRITERIA			**NDDG CRITERIA**			
	IG-N	**IG-GDM**	***P***	**CG-N**	**CG-GDM**	***P***	***P***
N	**114**	**71**	**IG-N vs. IG-GDM**	**325**	**50**	**CG-N vs. CG-GDM**	**IG-GDM vs. CG-GDM**
Maternal age (years old)	31.9 ± 4.8	32.4 ± 5.4	0.513	32.5 ± 4.7	34.7 ± 4.6	0.002	0.012
Maternal age			0.551			0.004	0.084
< 30	37 (32.5)	19 (26.8)		91 (28.0)	6 (12.0)		
≥ 30 < 35	39 (34.2)	23 (32.4)		121 (37.2)	15 (30.0)		
≥ 35	38 (33.3)	29 (40.8)		113 (34.8)	29 (58.0)		
Pre-gestational BMI (kg/m^2)	24.2 ± 4.3	24.5 ± 4.2	0.646	24.8 ± 4.3	26.3 ± 4.9	0.021	0.032
Pre-gestational BMI			0.453			0.078	0.108
< 18.5	6 (5.3)	1 (1.4)		6 (1.8)	1 (2.0)		
≥ 18.5 < 25.0	64 (56.1)	43 (60.6)		192 (59.1)	20 (40.0)		
≥ 25.0 < 29.9	29 (25.4)	15 (21.1)		93 (28.6)	20 (40.0)		
≥ 30	15 (13.2)	12 (16.9)		34 (10.5)	9 (18.0)		
GDM	0	2 (2.8)	0.072	1 (0.3)	3 (6.0)	0.000 *	0.386
First-degree relative DM	12 (10.5)	11 (15.5)	0.319	26 (8.0)	4 (8.0)	1.000	0.218
Congenital malformation	1 (0.9)	2 (2.8)	0.630	4 (1.2)	1 (2.0)	0.556	0.802
Caesarean section	2 (1.8)	4 (5.6)	0.147	24 (7.4)	5 (10.0)	0.858	0.343
Macrosomia	3 (2.6)	2 (2.8)	0.940	4 (1.2)	1 (2.0)	0.659	0.776
Gestational HTN	0	0		2 (0.6)	1 (2.0)	0.306	0.231
Parity			0.560			0.415	0.354
Primiparous	66 (57.9)	38 (53.5)		182 (56.0)	31 (62.0)		
Multiparous	48 (42.1)	33 (46.5)		143 (44.0)	19 (38.0)		

* IADPSG: International Association of Diabetes and Pregnancy Study Group; NDDG: National Diabetes Data Group. IG-N: Intervention Group without Gestational Diabetes Mellitus; IG-GDM: Intervention Group with Gestational Diabetes Mellitus; CG-N: Control Group without Gestational Diabetes Mellitus; CG-GDM: Control Group with Gestational Diabetes Mellitus. BMI: Body Mass Index; GDM, Gestational Diabetes Mellitus; DM: Diabetes Mellitus; HTN: chronic hypertension. † Date are median ± SD or n (%). ‡ P value not be considered because the rate of less than 5 cells is greater than 25%.

Table 2. Pregnancy and control glycemic outcomes among women included in the IG (IADPSG criteria) and in the CG (NDDG criteria). Vigo, Spain, 2013 – 2014.

	IADPSG CRITERIA			**NDDG CRITERIA**			
	IG-N	**IG-GDM**	***P***	**CG-N**	**CG-GDM**	***P***	***P***
N	**114**	**71**	**IG-N vs. IG-GDM**	**325**	**50**	**CG-N vs. CG-GDM**	**IG-GDM vs. CG-GDM**
Weight gain (kg)	7.1 ± 3.1	7.2 ± 3.8	0.779	10.1 ± 4.4	7.3 ± 6.6	0.000	0.844
Birth Weight (g)	3317.5 ± 539.8	3266.3 ± 416.9	0.495	3285.2 ± 486.9	3188.0 ± 524.0	0.231	0.361
Birth Weight Percentile			0.121			0.376	0.411
NGA	90 (78.9)	64 (90.1)		272 (83.7)	40 (80.0)		
SGA	14 (12.3)	5 (7.0)		27 (8.3)	7 (14.0)		
LGA	10 (8.8)	2 (2.8)		26 (8.0)	3 (6.0)		
Newborn Gender			0.676			0.654	0.656
Female	63 (55.3)	37 (52.1)		145 (44.6)	24 (48.0)		
Male	51 (44.7)	34 (47.9)		180 (55.4)	26 (52.0)		
Prematurity (< 37 weeks)	3 (2.6)	1 (1.4)	0.578	19 (5.8)	1 (2.0)	0.260	0.802
Delivery			0.860			0.334	0.908
Vaginal	79 (69.3)	47 (66.2)		185 (56.9)	34 (68.0)		
Forceps	19 (16.7)	12 (16.9)		77 (23.7)	9 (18.0)		
Cesarean section	16 (14.0)	12 (16.9)		63 (19.4)	7 (14.0)		
Apgar score < 7						0.127	0.231
At 1 min	0	0		0	2 (4.0)		
At 5 min	0	0		0	0		
HbA1c		4.9 ± 0.2			5.1 ± 0.3		0.000
Treatment for the GDM							0.726
Dietary Advice		64 (90.1)			46 (92.0)		
Diet + Insulin		7 (9.9)			4 (8.0)		
75-g OGTT postpartum		N 52 (73.2)			N 34 (68.0)		0.111
Normal		48 (92.3)			29 (85.3)		
IFG		2 (3.8)			0		
IHC		2 (3.8)			5 (14.7)		

* IADPSG: International Association of Diabetes and Pregnancy Study Group; NDDG: National Diabetes Data Group. IG-N: Study Group without Gestational Diabetes Mellitus; IG-GDM: Study Group with Gestational Diabetes Mellitus; CG-N: Control Group without Gestational Diabetes Mellitus; CG-GDM: Control Group with Gestational Diabetes Mellitus. GDM, Gestational Diabetes Mellitus; NGA: Normal Gestational Age; SGA: Small Gestational Age; LGA: Large Gestational Age; HbA1c: Glycosylated Hemoglobin; OGTT: Oral Glucose Tolerance Test; IFG: Impaired Fasting Glucose; ICH: Intolerance Carbohydrates. † Date are median ± SD or n (%).

nant women CG-N gained significantly more weight during pregnancy than pregnant women in the IG-N (10.1 ± 4.4 vs 7.1 ± 3.1, p = 0.000). The analysis had significant results for the weight gain during pregnancy and in the quarterly value of HbA1c. The results of the HbA1c trimester value shows that the HbA1c of the CG-GDM was significantly higher in second trimester than the IG-GDM (5.1 ± 0.3 vs 4.9 ± 0.2, p = 0.000). There were no significant differences between the sub-groups of IG and the CG for the birth weight, delivery, Apgar score < 7, type of treatment for GDM and the results of the 75-g OGTT postpartum.

DISCUSSION

The prevalence of GDM after applying the complete IADPSG diagnosis criteria increased more than threefold compared to prevalence described in the group who used the NDDG diagnosis criteria (36.3% vs. 11.3%, increase 221.2%). Comparing the prevalence of GDM described in this study with that in other studies, we find that our prevalence increased more than doubled compared to the HAPO study[15] (36.3% vs. 16.1%, increase 124.1%), almost double compared to the Chinese study IADPSG Criteria for Diagnosing Gestational Diabetes Mellitus and Predicting Adverse Pregnancy Outcomes[16] (36.3% vs. 19.9%, increase 82.4%) and is slightly higher than the St. Carlos Gestational Diabetes Study[12] (36.3% vs. 35.5%, increase 2.3%).

However, these studies did not use the complete IADPSG diagnosis criteria, using for the diagnosis, the HAPO[15] and the St. Carlos Gestational Diabetes Study[12], only the 75-gr OGTT and the Chinese study[16] only the result of the FPG in the second trimester blood test.

The results of this study are a novel contribution to the literature, because are the only study published with the real prevalence of GDM using the complete IADPSG diagnosis criteria. Furthermore, this study shown that using the complete IADPSG criteria many pregnant don't need perform the 75-g OGTT, because they are diagnosed exclusively by the FPG in the first trimester, reducing the number of 75-g OGTT to realize and allowing that the treatment and the monitoring of pregnant women start in the first trimester. This finding also indicates that the costs published in the St. Carlos Gestational Diabetes Study would be further reduced[12].

The results of the intervention protocol showed that the intervention performed in the SG was beneficial for all subgroups in the SG, presenting, although not significantly, better pregnancy outcomes the IG-N with respect to CG-N. The results show that pregnant women in the IG-GDM (criteria IADPSG) have better pregnancy outcomes regarding pregnant women in the CG-GDM (criteria NDDG) and better tolerance to carbohydrates postpartum. The development of two different intervention protocol based on the presence of risk factors for GDM, the moment of diagnosis and the test used to detect the GDM, avoid any kind of iatrogenic associated with over-treatment in pregnant women diagnosed of GDM based on the IADPSG criteria. The increased prevalence of GDM after using the complete IADPSG diagnosis criteria can be accepted for not modify the routine clinical practice being treated pregnant women with GDM, by nurses trained in nutrition and diabetes, as well as medical specialists in Endocrinology.

CONCLUSIONS

The results of this study, together with the study published in St. Carlos Gestational Diabetes Study, shows that the complete IADPSG diagnosis criteria are viable in Spain and respond to the dilemmas posed by the GEDE, to be shown that implantation produces no iatrogenia associated with treatment in the pregnant women, in their fetuses or in the newborn and that acceptance of these new criteria are cost-effective. The prevalence of GDM increases using the IADPSG criteria. The pregnant women diagnosed with IADPSG criteria had lower risk factors for GDM and some pregnant outcomes are better in the IG than the CG.

REFERENCES

1. Metzger BE, Coustan DR. Summary and Recommendations of the Fourth International Workshop-Conference on Gestational Diabetes. Diabetes. 1998; 21(suppl. 2): B161-B167. http://journal.diabetes.org/diabetescare/supplement298/B161.htm.

2. International Association of Diabetes and Pregnancy Study Groups Recommendations on the Diagnosis and Classification of Hyperglycemia in Pregnancy. Diabetes Care. 2010; 33:676-82. doi: 10.2337/dc09-1848.

3. Buchanan TA, Xiang AH. Gestational diabetes mellitus. Journal of Clinical Investigation. 2005;115(3):485-491. doi:10.1172/JCI200524531.

4. García-Patterson A, Erdozain L, Ginovart G, Adelantado JM, Cubero JM, Gallo G et al. In human gestational diabetes mellitus congenital malformations are related to pre-pregnancy body mass index and to severity of diabetes. Diabetologia. 2004 Mar;47(3):509-14. Epub 2004 Feb 10. http://www.ncbi.nlm.nih.gov/pubmed/14770278.

5. Martínez-Frías ML, Bermejo E, Rodríguez-Pinilla E, Prieto L, Frías JL. Epidemiological analysis of outcomes of pregnancy in gestational diabetic mothers. Am J Med Genet. 1998; 78: 140-145. doi: 10.1002/(SICI)1096-8628(19980630)78:2<140::AID-AJMG8>3.0.CO;2-S.

6. Riskin-Mashiah S, Younes G, Damti A, Auslender R. First-trimester fasting hyperglycemia and adverse pregnancy outcomes. Diabetes Care. 2009; 32:1639-1643. doi:10.2337/dc09-0688.

7. The HAPO Study Cooperative Research Group: Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study: associations with maternal body mass index. British J Ob Gyn. 2010;117:575-584. doi: 10.1111/j.1471-0528.2009.02486.x.

8. Horvath K, Koch K, Jeitler K, Matyas E, Bender R, Bastian H et al. Effects of treatment in women with gestational diabetes mellitus: systematic review and meta-analysis. BMJ. 2010; 340:c1398. doi: 10.1136/bmj.c1395.

9. Flack JR, Ross GP, Ho S, McElduff A. Recommended changes to diagnostic criteria for gestational diabetes: impact on work-load. Aust NZ J Obstet Gynecol. 2010; 50: 439-43. doi: 10.1111/j.1479-828X.2010.01218.x.

10. Ryan EA. Diagnosing gestational diabetes. Diabetes. 2011; 54: 480-6. doi: 10.1007/s00125-010-2005-4.

11. Corcoy R, Lumbreras B, Bartha JL, Ricart W, Grupo Español de Diabetes y Embarazo (GEDE). Nuevos criterios diagnósticos de diabetes mellitus gestacional a partir del estudio HAPO. ¿Son válidos en nuestro medio? Av Diabetol. 2010; 26: 139-42. Vol.26 N.3 Mayo-junio 2010. http://www.avancesendiabetologia.org/revista/buscador.asp?autores=Grupo%20Espa%F1ol%20de%20Diabetes%20y%20Embarazo%20(GEDE)&busca=1

12. Duran A, Sáenz S, Torrejón MJ, Bordiú E, Del Valle L, Galindo M, 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 Sep;37(9):2442-50. doi: 10.2337/dc14-0179.

13. Rodríguez I. Evaluación de las distintas estrategias diagnósticas para diabetes gestacional [Tesis doctoral]. Universidad de Santiago de Compostela; 2011. http://docplayer.es/5705796-Evaluacion-de-las-distintas-estrategias-diagnosticas-para-diabetes-gestacional.html

14. Grupo Español de Diabetes y Embarazo (GEDE): Sociedad Española de Diabetes (SED), Sociedad Española de Ginecología y Obstetricia (SEGO) y Asociación Española de Pediatría (Sección Neonatología). Guía asistencial de diabetes mellitus y embarazo. Av. Diabetol. 2006;22(1):73-87 Vol.22 N.1 enero-marzo 2006. http://www.avancesendiabetologia.org/revista/buscador.asp?autores=Grupo%20Espa%F1ol%20de%20Diabetes%20y%20Embarazo%20(GEDE)&busca=1

15. Metzger BE, Lowe LP, Dyer AR, Trimble ER, Chaovarindr U, Coustan Dr, et al. Hyperglycemia and adverse pregnancy outcomes. N Engl J Med. 2008;358 (19):1991-2002. doi: 10.1056/NEJMoa0707943.

16. Shang M, Lin L. IADPSG criteria for diagnosing gestational diabetes mellitus and predicting adverse pregnancy outcomes. J Perinatol. 2014 Feb;34(2):100-4. doi: 10.1038/jp.2013.143.