ORIGINAL ARTICLE

Comparative analysis of current diagnostic criteria for gestational diabetes mellitus

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Summary

Background: To compare current guidelines for diagnosis of gestational diabetes mellitus (GDM) and to identify the ones that are the most relevant for application among pregnant Bulgarian population.

Methods: A total of 800 pregnant women at high risk for GDM underwent 75 g oral glucose tolerance test between 24 and 28 weeks of gestation as antenatal screening. The results were interpreted and classified according to the guidelines of the International Association of Diabetes and Pregnancy Study Groups (IADPSG), American Diabetes Association (ADA), Australasian Diabetes in Pregnancy Society, Canadian Diabetes Association, European Association for the Study of Diabetes, New Zealand Society for the study of Diabetes and World Health Organization.

Results: The application of different diagnostic criteria resulted in prevalences of GDM between 10.8% and 31.6%. Using any two sets of criteria, women who were classified differently varied between 0.1% and 21.1% ($P < 0.001$).The IADPSG criteria were the most inclusive criteria and resulted in the highest prevalence of GDM. There was a significant difference in the major metabolic parameters between GDM and control groups, regardless of which of the diagnostic criteria applied. GDM diagnosed according to all criteria resulted in increased proportion of delivery by caesarean section (CS). However, only ADA and IADPSG criteria identified both increased macrosomia (odds ratio, 2.36; 2.29) and CS rate.

Conclusion: The need for GDM screening is indisputable. In our view, the new IADPSG guidelines offer a unique opportunity for a unified national and global approach to GDM.

Keywords: gestational diabetes mellitus, diagnostic criteria, prevalence

INTRODUCTION

Gestational diabetes mellitus (GDM) provokes scientific and medicosocial interest because of the high risk of maternal, fetal and neonatal complications. The reported prevalence of GDM varies between 3% and >10% depending on the diagnostic criteria employed and population studied.[1] The condition is recognized as carbohydrate intolerance of varying severity with onset or first recognition during pregnancy, irrespective of whether insulin is needed for treatment and whether the condition persists after pregnancy (International Diabetes Federation).

The diagnostic criteria for GDM were established for the first time more than 45 years ago[2] and, with some modifications, could be applied today. These criteria were mainly designed to identify women who were at high risk for developing type 2 diabetes later in life. Recent studies show that women with a history of GDM have a 3.5 times greater risk of developing postpartum diabetes mellitus (DM) than the general population.[3] The incidence of type 2 DM in early postpartum is reported as 10–15%. A prospective follow-up study on Korean women with GDM showed that approximately 40% of women with previous GDM were expected to develop DM within five years of postpartum.[3] The Diabetes Prevention Program demonstrated that women with a history of GDM had a 71% increased risk of developing type 2 DM, as compared with women without such a history.[4] Diagnosing GDM is also important as the condition is related to predictable adverse perinatal outcomes.[2,5] The main risks for the fetus and the newborn are related to fetal macrosomia, shoulder dystocia, birth trauma, increased risk for hypoglycaemia, hypocalcaemia, hyperbilirubinaemia, respiratory distress syndrome and polycythaemia. Later in life, the prevalence of overweight and DM is the main concern.[6–8] These risks can be reduced and controlled by early diagnosis of GDM, appropriate diet and/or insulin therapy, and continuing maternal and fetal follow-up.[6–8]

The International Association of Diabetes and Pregnancy Study Groups (IADPSG) has recently published a consensus based on the Hyperglycemia and Adverse Pregnancy Outcomes study (HAPO) findings.[9] Even though this new consensus is based on expert opinions, it should serve as the basis for internationally endorsed criteria for the diagnosis and

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classification of DM in pregnancy.[9] Furthermore, in January 2011, the American Diabetes Federation reviewed the screening consensus for GDM and has accepted the new IADPSG criteria.[10] However, in our study we have used the previous American Diabetes Association (ADA) criteria, because of our Clinical Center Statement and because the study took place before the IADPSG criteria were endorsed. The World Health Organization (WHO) is also expected to endorse IADPSG shortly (December 2011, IDF meeting) and soon all other major DM/obstetric organizations (e.g. ACOG, Canadian Diabetes Association [CDA], NICE, European Association for the Study of Diabetes [EASD]) should follow suit.

Until now, there has been (1) neither population-based nor high-risk group study of the prevalence of GDM in Bulgaria; (2) no single diagnostic method accepted or recommended by national scientific bodies to be applied for the diagnosis of GDM; (3) different interpretation of the results from oral glucose tolerance test (OGTT) in major clinical centres in Bulgaria; (4) little information available regarding the proper approach to women with GDM including the need for therapy, maternal and fetal follow-up, evaluation of the risk for future development of DM.

This study was carried out to evaluate the differences in GDM prevalence and its implications when different diagnostic criteria of seven well-accepted expert international panels were applied. Furthermore, it will be used as the basis for initiation of a national screening programme for GDM in Bulgaria.

MATERIALS AND METHODS

Materials

A prospective cohort study among women at high risk for GDM was performed as a part of the screening programme for GDM in Bulgaria. The study was conducted at the Clinical Center of Endocrinology, Medical University Sofia and was approved by the institutional ethics committee. Between June 2009 and January 2011, 800 women were recruited for the purpose of the study. They were referred by obstetricians from antenatal clinics at any gestational age, mainly during second trimester when fetal scans were performed, because of the presence of one or more inclusion criteria.

The main *inclusion criteria* were relatives with DM, overweight/obesity before pregnancy, history of reproductive failure/pregnancy loss, GDM in previous pregnancy followed by normoglycaemia after delivery, polycystic ovarian syndrome, delivery of fetus with weight >4000 g, ultrasound parameters for macrosomia, multiparity, and maternal age >30 years.

Exclusion criteria were pregestational DM, previously diagnosed DM type 1 or 2, drug treatment with steroids, antipsychotics or other drugs interfering with glucose metabolism.

Assessment of pregnant women for risk factors was made by an endocrinologist and women were referred afterwards for further laboratory testing. Informed consent was obtained from each subject.

Methods

Clinical data

Detailed information was obtained from all women, regarding the main risk factors for GDM (see inclusion and exclusion criteria below). Anthropometric measurements of weight and height were needed to calculate the body mass index (BMI) = weight (kg)/height (m^2). BMI was calculated based on preconceptional weight (prepregnancy BMI) and measurements on the day when OGTT was performed (pregnancy BMI). Women were categorized according to their BMI as normal (BMI, 18.5–24.9 kg/m^2), overweight (BMI, 25–29.9 kg/m^2) and obese (BMI, 30–34.9 kg/m^2). Blood pressure was measured at the same appointment as BMI and mean arterial pressure (MAP) were calculated (MAP = [systolic blood pressure + diastolic blood pressure]/2).

Laboratory measurements

All participants underwent standard diagnostic 75 g OGTT after 10–12 hours of fasting with venous glucose sampling at 0, 60 and 120 minutes. The test was performed between 24 and 28 weeks of gestation (97%) and occasionally in other gestational weeks if clinically warranted (3%). Plasma glucose levels were measured by enzymatic hexokinase method (Roche Diagnostics), HbA1c by a turbidimetric method and insulin by radio immunoactive method. These measurements were run from the first blood sampling after 10–12 hours of overnight fasting when OGTT was performed. Homeostatic Model Assessment for insulin resistance index (HOMA-IR) was calculated = fasting glucose (mmol/L) × fasting insulin (μU/L)/22.5.

Diagnostic criteria

The diagnosis of GDM was based on the criteria of seven international expert panels (Table 1), including the International Association of Diabetes Pregnancy Study Group (International),[9] American Diabetes Association (American),[11] Australasian Diabetes in Pregnancy Society (Australasian),[12] the Canadian Diabetes Association (Canadian),[13] the European Association for the Study of Diabetes (European),[14] the New Zealand Society for the study of Diabetes (New Zealand)[12] and WHO.[15] As the old ADA diagnostic criteria were in use in our clinical centre at the time of the study, only women diagnosed according to them received medical counselling and treatment with diet/exercise and drug treatment. The women who did not have GDM, according to the ADA criteria, were considered as controls.

Pregnancy outcome

Until June 2011, the pregnancy outcome was available for 546 (68.2%) of 800 cases included in this study, whereas the remaining had incomplete data. The following pregnancy outcome

Table 1 **Various diagnostic criteria and GDM prevalence, according to them**

Criteria	Abnormal values for diagnosis	Fasting glucose (mmol/L)	1 hour after loading (mmol/L)	2 hours after loading (mmol/L)	% (*n*) diagnosed with GDM
IADPSG	≥1	5.1	10	8.5	31.6 (253)
ADA	≥2	5.3	10	8.6	13.5 (108)
WHO	≥1	7		7.8	17.1 (137)
EASD	≥1	6		9	10.8 (86)
CDA	≥2	5.3	10.6	8.9	10.9 (87)
ADIPS	≥1	5.5		8	21.2 (170)
NZSSD	≥1	5.5		9	16.2 (130)

ADA=American Diabetes Association, ADIPS=Australasian Diabetes in Pregnancy Society, CDA=Canadian Diabetes Association, EASD=European Association for the Study of Diabetes, GDM=gestational diabetes mellitus, IADPSG=International Association of Diabetes Pregnancy Study Group, NZSSD=New Zealand Society for the Study of Diabetes, WHO=World Health Organization

data were analysed: proportion of CS deliveries, sonographically assessed fetal head/abdominal circumference ratio (HC/AC), the prevalence of macrosomia (birth weight $\geq$4000 g) and the ponderal index of the newborn. The ponderal index was calculated as fetal weight (grams) $\times$ 100/(fetal length (centimetres). These endpoints were used to assess the ability of the various criteria to predict macrosomia and CS. Comparisons were made, between women with and without (control group) GDM, as defined by each of the seven individual criteria.

Statistical analysis

Retrospective analysis of our prospective cohort was performed, following the new IADPSG guidelines endorsed in March 2010. Statistical analysis of the data was performed using SPSS 16.0 for Windows (SPSS, Chicago, IL, USA). The distribution of continuous variables was tested for normality by the Shapiro–Wilk test. The level of agreement in GDM diagnoses between the seven sets of criteria was evaluated by pairwise comparisons using the kappa-statistic (κ). The resultant coefficient gives values between 0 and 1.[16] The closer the value to 1, the better the agreement is. According to the values of κ, the association is graded as poor ($\kappa = 0$–0.19), fair ($\kappa = 0.2$–0.39), moderate (κ 0.4–0.59), good ($\kappa = 0.6$–0.79) and very good ($\kappa = 0.8$–1.0). Cross-tabulations were used to identify the number of women classified differently applying any two sets of criteria for GDM diagnosis; this difference in diagnosis was tested by McNemar's test. Odds ratio was used to compare the risk for macrosomia and CS. Statistical significance was accepted at a level of $P < 0.05$.

Descriptive statistics were performed using frequencies, percentages and frequency tables for qualitative variables and mean, standard error for quantitative variables.

Quantitative variables between groups were compared by univariate analysis and Student's unpaired *t*-test (variables were normally distributed). Comparison within the group was performed by Student's paired *t*-test. Comparisons between frequencies were assessed by χ^2 analysis.

The percentage of OGTT performed other than 24–28 weeks of gestation did not bias the results.

RESULTS

Prevalence of GDM

The prevalences of GDM when different diagnostic criteria were applied are shown in Table 1. The IADPSG criteria were the most inclusive, identifying 253 (31.6%) of the pregnant women as having GDM, followed by the Australasian Diabetes in Pregnancy Society, which identified 170 (21.2%) women as having GDM. The most restrictive were the EASD criteria, followed by CDA criteria with prevalence of women having GDM of 10.8% (86) and 10.9% (87), respectively.

There were three categories of association (of five possible categories) as identified by κ statistic (Table 2). The 'very good' association (the best among all pairs) was found in two pairs of sets of criteria: the Canadian/American and the Australasian/New Zealand. 'Good' association was found among nine pairs. There was 'moderate' association among nine pairs too. There was no 'fair' association between any of the pairs.

The seven criteria resulted in 21 possible combination pairs and the difference in GDM diagnosis between any pair was significant ($P < 0.001$). The GDM diagnosis by the most statistically significant ($\kappa = 0.88$) and geographically associated criteria (American and Canadian) were significantly different ($P < 0.001$). The criteria of two other geographically related countries (Australia and New Zealand) were also significantly different.

The number of women classified differently between most of the combinations of any two criteria was significant ($P < 0.001$). The only exception was CDA/EASD combination, where they almost overlapped and the difference between them was only one case (0.1%, $P > 0.144$). For the other pairs, it varied from seven (0.9%) for the WHO/NZSSD combination to 167 women (21.1%) for the least-associated pair (EASD/IADPSG). The classification differently rate for nine pairs showing 'good' association varied from 1 (0.1%) woman to 83 (10.7%) women. The rate for the nine pairs showing 'moderate' association varied from 9 (0.9%) to 167 (21.1%) women.

The most and the least inclusive groups

The highest prevalence of GDM was found when the IADPSG criteria were applied, followed by the Australasian criteria. Despite the fact that the IADPSG criteria were the most inclusive, they still missed 13 cases, identified as having GDM according to the WHO criteria. Similarly, seven of 170 cases identified as having GDM according to the other more inclusive criteria (the Australasian) were classified as normal by the IADPSG criteria. Five women of 87 who were picked up by the very restrictive Canadian criteria were missed by the less restrictive Australasian criteria, even though the latter identified a quarter of all the women as having GDM.

Table 2 **Comparison of all diagnostic categories in pairs: number of women classified differently [*n* (%)] (below dark blocks) and in agreement [κ statistic] (above dark blocks)**

	IADPSG	ADA	WHO	EASD	CDA	ADIPS	NZSSD
IADPSG		0.5	0.49	0.41	0.42	0.67	0.59
ADA	145 (18.4)		0.58	0.69	0.88	0.65	0.73
WHO	116 (14.8)	29 (3.6)		0.59	0.5	0.77	0.56
EASD	167 (21.1)	22 (2.7)	51 (6.3)		0.74	0.62	0.77
CDA	166 (21)	21 (2.6)	50 (6.2)	1 (0.1)		0.56	0.69
ADIPS	83 (10.7)	62 (7.7)	33 (4.1)	84 (10.4)	83 (10.3)		0.84
NZSSD	123 (15.7)	22 (2.7)	7 (0.9)	44 (5.4)	43 (5.3)	40 (5)	

$\kappa = 0.20$–0.39, fair; 0.40–0.59, moderate; 0.60–0.79, good; 0.80–1.00, very good

ADA=American Diabetes Association, ADIPS=Australasian Diabetes in Pregnancy Society, CDA=Canadian Diabetes Association, EASD=European Association for the Study of Diabetes, GDM=gestational diabetes mellitus, IADPSG=International Association of Diabetes Pregnancy Study Group, NZSSD=New Zealand Society for the Study of Diabetes, WHO=World Health Organization

Maternal age and main metabolic parameters

The mean values for the main metabolic parameters are presented in Table 3. There were no significant differences in age between GDM and control groups when CDA, EASD and WHO criteria were used. All of the other parameters – mean arterial pressure, pregnancy and prepregnancy BMI, FBG, FPI, HOMA-IR index – and HBA1c showed differences between groups whichever criteria were applied. The mean gestational age at the time of the OGTT was 26.1 weeks (median, 26 weeks; SD 3.9; range, 8–38 weeks); the range showed wide variation. Many women were tested earlier than the scheduled 24–28 gestational weeks because of the presence of one or more risk factors for GDM, for instance GDM during a previous pregnancy.

For the various criteria, the mean birth weight (grams), HC/AC ratio and the ponderal index for women with and without GDM are shown in Table 4. There was a significant difference in birth weight between the GDM and control groups only when IADPSG, ADA and CDA were used. Macrosomia (birth weight $\geq$4000 g) was present in 76 (9.5%) of the neonates. Three hundred and sixteen (57.9%) women delivered by CS and seven (1.3%) women had stillbirth. The odds ratios for having macrosomia and a CS for the seven criteria are shown in Table 5. 14% (20) of cases of macrosomia were missed in those women who were not classified as GDM by ADA before initiation of new IADPSG criteria.

The mean fetal HC/AC ratio between groups GDM compared with non-GDM (controls) did not show significant differences in any of the various criteria. Significant differences were found regarding the ponderal indices of the neonates when CDA and ADA criteria were used.

DISCUSSION

The world desperately needs implementation of international recommendations, which combine all of the present criteria, lower the adverse pregnancy outcome and reduce the incidence of DM later in life. There is still variability in the different presented criteria for the diagnoses of GDM. Up to now, there has only been one study, conducted in Bulgaria, and this showed a prevalence of GDM of 11.3%[17] On the basis of our results, prevalence varies from 10.8% to 31.6%. Even though our study was conducted on high-risk pregnancies, the prevalence of GDM is high. The IADPSG criteria were the most inclusive yielding the highest prevalence – 31.6%. This is 1.5- to 1.8-fold more than the other high-prevalence criteria – i.e. Australasian and American. They missed only 13 cases identified as GDM with the WHO criteria. These were women who were diagnosed on plasma glucose levels at 120 minutes, which were between 7.8 and 8.4 mmol/L. According to the current ADA criteria used, they did not require medical counselling or treatment. Furthermore, in our follow-up they have presented with normal fetal outcome. The percentage of women classified differently varies from 0.1% to 18.4%. These differences were present between any two criteria in any of the 21 possible combinations. Previous research, carried out to quantify the differences in GDM diagnosis with its potential implications among six well-known criteria, has shown similar results.[18] Most studies have compared two criteria[19] and inclusion of more increases the variability and the differences in GDM. Endorsing the new IADPSG criteria from major DM/obstetric organizations as has ADA and most probably WHO, ACOG, CDA, NICE, EASD, etc. will reduce variability concerning the diagnosis, treatment and further follow-up of the patients.

Table 3 **Mean values of the main important parameters in the group with GDM and the control group, according to the various criteria**

	Patients	IDPSG	ADA	WHO	CDA	EASD	ADIPS	NZZSD
Age	GDM	32.2 ± 5.2	32.4 ± 4.8	31.7 ± 4.8	32.4 ± 4.7	31.8 ± 4.6	31.9 ± 5.0	32.2 ± 4.8
	Controls	30.6 ± 4.4	30.9 ± 4.7	31.0 ± 4.7	30.9 ± 4.7	31.0 ± 4.7	30.9 ± 4.6	30.9 ± 4.7
	Significance (*P*)	0	0.01	0.2	0.02	0.2	0.05	0.02
MAP	GDM	94 ± 25	100 ± 19	92 ± 26	99 ± 19	95 ± 18	95 ± 24	97 ± 20
	Controls	86 ± 22	86 ± 23	87 ± 23	87 ± 24	87 ± 24	86 ± 22	87 ± 23
	Significance (*P*)	0	0	0	0	0	0	0
Pregnancy BMI	GDM	31.7 ± 6.6	33.5 ± 7.0	30.6 ± 6.5	33.3 ± 7.3	31.3 ± 7.1	31.7 ± 6.6	32.3 ± 7.0
	Controls	27 ± 5.4	27.9 ± 5.6	28.3 ± 6.0	28.1 ± 5.7	28.4 ± 5.9	27.9 ± 5.7	28.0 ± 5.7
	Significance (*P*)	0	0	0.01	0	0	0	0
Prepregnancy BMI	GDM	27.1 ± 7.4	28.7 ± 7.7	25.6 ± 7.4	28.3 ± 8.3	26.4 ± 7.8	26.9 ± 7.7	27.7 ± 7.8
	Controls	23.3 ± 4.9	23.9 ± 5.5	24.3 ± 5.8	24.1 ± 5.6	24.3 ± 5.8	23.9 ± 5.5	23.9 ± 5.5
	Significance (*P*)	0	0	0.02	0	0	0	0
Fasting blood glucose	GDM	5.5 ± 0.8	6.0 ± 0.9	5.5 ± 1.1	6.1 ± 0.9	6.1 ± 1.1	5.7 ± 0.9	6.0 ± 0.9
	Controls	4.5 ± 0.4	4.6 ± 0.5	4.6 ± 0.5	4.6 ± 0.5	4.6 ± 0.5	4.6 ± 0.4	4.6 ± 0.4
	Significance (*P*)	0	0	0	0	0	0	0
Fasting insulin	GDM	15.6 ± 8.7	18.3 ± 9.4	15.3 ± 9.4	19.0 ± 9.6	18.1 ± 9.7	16.0 ± 8.6	17.1 ± 8.6
	controls	9.4 ± 7.0	10.3 ± 7.3	10.6 ± 7.6	10.5 ± 7.4	10.6 ± 7.5	10.2 ± 7.5	10.3 ± 7.6
	Significance (*P*)	0	0	0	0	0	0	0
HOMA-IR index	GDM	3.8 ± 2.5	4.8 ± 2.9	3.7 ± 3.0	5.1 ± 3	4.8 ± 3.2	4.0 ± 2.7	4.5 ± 2.8
	controls	1.8 ± 1.4	2.0 ± 1.6	2.2 ± 1.7	2.1 ± 1.7	2.1 ± 1.7	2.0 ± 1.6	2.0 ± 1.6
	Significance (*P*)	0	0	0	0	0	0	0
HbA1c	GDM	5.8 ± 0.5	6.0 ± 0.6	5.9 ± 0.6	6.1 ± 0.6	6.1 ± 1.5	5.9 ± 0.6	6.0 ± 0.6
	controls	5.4 ± 0.4	5.5 ± 0.4	5.5 ± 0.4	5.5 ± 0.4	5.5 ± 0.4	5.5 ± 0.4	5.5 ± 0.4
	Significance (*P*)	0	0	0	0	0	0	0

HbA1c=glycated hemoglobin, HOMA-IR index=homeostatic model assessment index for insulin resistance, MAP=mean arterial pressure, Prepregnancy BMI=body mass index before pregnancy, Pregnancy BMI=body mass index at the time of the screening, ADA=American Diabetes Association, ADIPS=Australasian Diabetes in Pregnancy Society, CDA=Canadian Diabetes Association, EASD=European Association for the Study of Diabetes, GDM=gestational diabetes mellitus, IADPSG=International Association of Diabetes Pregnancy Study Group, NZSSD=New Zealand Society for the Study of Diabetes, WHO=World Health Organization

Table 4 **Mean values of the birth weight, HC/AC ratio and ponderal index in the GDM and control groups, according to various criteria**

Criteria	Type	Birth weight	*P*	HC/AC	*P*	Ponderal index	*P*
IADPSG	GDM	3345.4 ± 730.2	0.03*	1.08 ± 0.25	0.08	2.61 ± 0.31	0.17
	Controls	3215.9 ± 616.2		1.13 ± 0.37		2.57 ± 0.27	
ADA	GDM	3351.1 ± 849.1	0.04*	1.01 ± 0.34	0.55	2.65 ± 0.33	0.04*
	Controls	3244.0 ± 617.1		1.13 ± 0.33		2.57 ± 0.27	
WHO	GDM	3280.2 ± 811.4	0.27	1.07 ± 0.28	0.4	2.59 ± 0.33	0.25
	Controls	3251.6 ± 618.6		1.12 ± 0.35		2.58 ± 0.27	
CDA	GDM	3407.6 ± 798.5	0.03*	1.00 ± 0.33	0.05	2.67 ± 0.34	0.02*
	Controls	3237.9 ± 630.8		1.13 ± 0.33		2.57 ± 0.27	
EASD	GDM	3353.9 ± 835.3	0.1	1.07 ± 0.24	0.53	2.63 ± 0.24	0.24
	Controls	3243.3 ± 627.9		1.12 ± 0.34		2.58 ± 0.27	
ADIPS	GDM	3320.3 ± 762.9	0.25	1.08 ± 0.24	0.4	2.61 ± 0.31	0.25
	Controls	3239.5 ± 624.4		1.12 ± 0.35		2.57 ± 0.27	
NZSSD	GDM	3341.4 ± 782.0	0.08	1.09 ± 0.23	0.29	2.62 ± 0.32	0.29
	Controls	3238.6 ± 625.9		1.12 ± 0.35		2.58 ± 0.27	

ADA=American Diabetes Association, ADIPS=Australasian Diabetes in Pregnancy Society, CDA=Canadian Diabetes Association, EASD=European Association for the Study of Diabetes, GDM=gestational diabetes mellitus, IADPSG=International Association of Diabetes Pregnancy Study Group, NZSSD=New Zealand Society for the Study of Diabetes, WHO=World Health Organization
*Significance

There are some major differences in the cut-off values of the plasma glucose between individual criteria. Up to now, the WHO has used the same cut-off values for the diagnosis of GDM and DM, even though there are reliable studies showing that the data from non-pregnant women and men cannot be applied during pregnancy.[20] The New Zealand criteria are more restrictive than the Australian, which will identify fewer cases, but will reduce the financial costs.[21] The Canadian criteria are similar to the American, but they will also identify fewer GDM patients. The cut-off value for the one and two hours plasma glucose are a bit higher, which makes them also more restrictive. The American criteria have the same cut-off values for the 75 g OGTT and 100 g OGTT. The OGTT could be performed in three hours, but because of compliance of the women it is not well tolerated.[21] The EASD criteria have not been very well studied. The HAPO study was designed to clarify the risks of adverse outcome associated with degrees of maternal glucose intolerance less severe than those with overt DM during pregnancy.[22] The reason for defending the current threshold for plasma glucose by the IADPSG criteria (based on HAPO data) was the strong linear associations of the risks found for >90th percentiles of birth weight, cord C-peptide and percent body fat with each of three measures of maternal glucose (fasting plasma glucose [FPG], 1- and 2-hour post-75 g load).[9] Furthermore, in our study group of 145 women who were missed by ADA and classified as GDM by IADPSG, we found high prevalence of macrosomia (14%). Some of these women did not benefit from medical counselling and treatment before initiation of the new criteria.

Owing to some limitations of OGTT, the usefulness of FPG and HbA1c has also been discussed. A recently published study aimed to determine the impact of the new IADPSG on the diagnosis of GDM compared with ADA and the FPG to predict GDM to decide whether to proceed with OGTT.[23] The IADPSG recommends that all pregnant women should undergo OGTT, but this will overload the laboratory. According to Agarwal *et al.*,[9] if you screen only the women with FPG between 4.4 and 5.1 mmol/L you will misclassify only 4.6% of GDM patients, which are under the threshold of 4.4, but are classified as GDM using ADA/IADPSG criteria. Meanwhile, the risk of adverse pregnancy outcomes was low at FPG under 4.4 mmol/L according to IADPSG. There is a big difference in cut-off values between the current WHO and IADPSG recommendations for FPG. If you follow the recommendations of Agarwal *et al.*[9] there is no need for OGTT if a woman presents with FPG ≥7 mmol/L. Furthermore, IADPSG stated that FBG ≥7 mmol/L should be considered not as GDM, but as overt DM in pregnancy. EASD stated that HbA1c should not be used as a diagnostic test. According to

Table 5 **Odds ratio for macrosomia and caesarean section rate by various criteria**

	Macrosomia			Caesarean section rate		
	Odds ratio	95% CI	*P*	Odds ratio	95% CI	*P*
IADPSG	2.29	0.734–6.255	0.02*	1.81	1.149–2.844	0.01*
CDA	1.67	0.432–6.480	0.43	3.24	1.563–6.697	0.001*
EASD	0.82	0.175–3.849	1	2.25	1.128–4.507	0.025*
ADA	2.36	0.766–7.255	0.01*	3.49	1.741–6.981	0.000*
NZSSD	1.58	0.531–4.673	0.37	2.26	1.260–4.055	0.006*
WHO	1.58	0.531–4.673	0.37	2.13	1.197–3.778	0.01*
ADIPS	1.39	0.508–3.815	0.58	2.13	1.250–3.637	0.005*

ADA=American Diabetes Association, ADIPS=Australasian Diabetes in Pregnancy Society, CDA=Canadian Diabetes Association, EASD=European Association for the Study of Diabetes, GDM=gestational diabetes mellitus, IADPSG=International Association of Diabetes Pregnancy Study Group, NZSSD=New Zealand Society for the Study of Diabetes, WHO=World Health Organization
*Significance

some investigators, despite all the progress in methodology, HbA1c remains a poor test to screen for GDM.[24]

Most of the various criteria showed significant differences between the groups of GDM and non-GDM women with regard to age, prepregnancy BMI and BMI at the time of the screening, FPG, fasting insulin, glycated haemoglobin. The HOMA index was further enhanced in GDM patients ($P < 0.001$). BMI at the time of the screening was compared between the groups with equivalent gestational week and not in the entire groups. These data suggest that the results are reliable and could be used as additional information. The Ponderal index is a frequently used measure of obesity at birth.[25] However, as BMI, the ponderal index accounts for only a fraction (15%) of the variance in adiposity in the neonate (Catalano *et al.*, 1992) and it did not show any significance between the groups in our cohort. Ultrasound is an essential tool in the management of pregnancies affected by maternal DM. Its use in each trimester may provide invaluable information about the developing fetus including gestational age and growth patterns, anatomical structure and function, assessment of fetal wellbeing and prediction of adverse outcomes.[26] However, in our study, we used HC/AC ratio and it did not show any differences between groups in any of the various criteria. Maybe further evaluation of more sonographic parameters is needed for better prenatal diagnosis and management. Both ADA and IADPSG criteria predicted an increased incidence of both macrosomia and the rate of CS even though all women with GDM received proper medical counselling about diet/exercise and medical treatment if needed. The prevalence of CS as a method of delivery in Bulgaria is high, following the world trends.[27] The increased CS rate cannot be explained by known and collected maternal or pregnancy characteristics, but it might be due to differences in clinical decision-making or maternal request. Future efforts to reduce the overall CS rate should be focused on reducing the primary CS rate.

Even though using the IADPSG criteria, the prevalence of GDM was the highest, this may lead to over-diagnosing. There are some advantages and disadvantages of these criteria. This may cause multiple antenatal visits with more laboratory tests, but it might be helpful in long-term prognoses for the reduction in the incidence of DM later in life. According to the prediction of Zimmer and Albetry (2001), the prevalence of type 2 DM will increase to 365 million people in 2030. This is mainly due to the contemporary way of life, the different exogenous factors and their combined role with the endogenous factors, which also determine the rising number of pregnant women with GDM and explain the heterogeneity of the disease.[28] 'Excessive' diagnosis might be most beneficial for women with mild hyperglycaemia.[29]

CONCLUSION

The IADPSG are the first criteria, designed to identify the largest proportion of women with GDM and thus to reduce the risk of adverse pregnancy outcome. However, the real benefits of diagnosing GDM are not only to reduce the adverse pregnancy outcome, but also to reduce the incidence of DM later in life. Type 2 DM often affects young people, including women of reproductive age. Hence, lifestyle intervention including diet, exercise and weight control, ideally before and very early during gestation, offers the potential for both short- and long-term benefits for the mother and her child. Clinical attention to GDM has suffered from the lack of standardized and clear guidelines. In our view, the new IADPSG guidelines should be introduced as a diagnostic tool in the national and global approach to GDM.

DECLARATIONS

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