original article

Gestational diabetes in Saudi women identified by the International Association of Diabetes and Pregnancy Study Group versus the former American Diabetes Association criteria: a prospective cohort study

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BACKGROUND AND OBJECTIVES: Use of the criteria of the International Association of Diabetes and Pregnancy Study Group (IADPSG) identifies additional cases of gestational diabetes mellitus (GDM) that have a lesser degree of hyperglycemia. The objective of this study was to compare the clinical characteristics and the pregnancy outcomes of GDM cases identified by IADPSG versus those identified by the former American Diabetes Association (ADA) criteria.

DESIGN AND SETTING: Prospective cohort study of Saudi women conducted at the Maternity and Children Hospital, Madinah, Saudi Arabia from October 2011 to August 2012.

PATIENTS AND METHODS: Consecutive pregnant women treated in the antenatal service performed oral glucose tolerance tests between 24 to 28 weeks of gestation. GDM was diagnosed according to IADPSG and the former ADA criteria. The women were divided into three groups by GDM diagnosed by both criteria, additional GDM identified by the IADPSG criteria, and cases with normal glucose tolerance (NGT). Clinical characteristics and pregnancy outcomes were compared.

RESULTS: Of 277 women who underwent OGTT, 47 (16.9%) were diagnosed by the former ADA criteria and 115 (41.5%) by the IADPSG criteria. The IADPSG criteria identified all women with GDM by the former ADA criteria and an additional 68 cases. The additional GDM cases had the same clinical characteristics as cases diagnosed by both criteria except for lower blood pressure and less frequent glycosuria. On the other hand, they were older, heavier and had a higher frequency of past GDM and history of recurrent abortions than the NGT group. In addition, they had significantly more cesarean deliveries, neonatal hypoglycemia, and a lower Apgar score than the NGT group.

LIMITATIONS: Relatively small numbers of subjects, which could limit the power of statistical findings.

CONCLUSIONS: The IADPSG criteria increased GDM frequency. The additional GDM cases identified by IADPSG have the same clinical characteristics and adverse pregnancy outcomes as cases with GDM identified by the older criteria.

In March 2010, the International Association of Diabetes and Pregnancy Study Groups (IADPSG) proposed new criteria for the diagnosis of gestational diabetes mellitus (GDM), aiming to standardize the criteria worldwide.[1] These recommendations are based on the results of the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study, which showed a continuous linear association between maternal glycemia and adverse fetal outcomes.[2] The prevalence of GDM increased after adoption of the IADPSG criteria.[3-12] This increase in prevalence was mainly due to a single abnormal value in the oral glucose tolerance test (OGTT) that is required to diagnose GDM. The cutoff values for fasting, 1- and 2-h glucose are slightly

lower than in most of the other criteria. For this reason, there is still controversy on the adoption of IADPSG worldwide. In January 2011, the American Diabetes Association (ADA) endorsed the IADPSG recommendations.[13] Recently, the Endocrine Society and the WHO endorsed the IADPSG recommendations.[14, 15] However, the American College of Obstetricians and Gynecologists[16] and the National Institutes of Health[17] have not endorsed the IADPSG recommendations and still recommend the traditional "two-step approach" of screening with a 1-h 50-g glucose load test followed by a 3-h 100-g OGTT for those with a positive screening. In the 2014 Standards of Care, ADA readdressed the NIH consensus along with the IADPSG guidelines because there were insufficient data to strongly demonstrate the superiority of one strategy over the other.[18]

The prevalence of GDM in Saudi women was previously reported as 12.5%.[19,20] Recently, Al-Rubeaan et al[21] reported a higher prevalence of GDM among Saudi women (36.6%) by applying partial IADPSG criteria for screening for GDM with fasting glucose levels only, without performing OGTT.[21]

There are contradictions between the studies on the impact of the IADPSG recommendations on pregnancy outcome.[10,11,22] In some studies, GDM identified by IADPSG criteria have the same adverse pregnancy outcomes as GDM identified by the older criteria both of which differ from non-GDM cases.[10,22] However, another study did not find differences.[11] We performed this study to compare the IADPSG criteria with the former ADA criteria before adopting the IADPSG recommendations. We intended to compare the frequency, clinical characteristics and pregnancy outcomes identified by each criterion among Saudi women.

PATIENTS AND METHODS

Consecutive pregnant women treated in the antenatal service at the Maternity and Children Hospital in Medina, Saudi Arabia, from October 2011 to August 2012 were recruited for this prospective cohort study. Women were eligible if they were of Saudi nationality, with a singleton pregnancy, planned to give birth at the study hospital, and were able to give written consent to participate. The exclusion criteria included pre-existing diabetes, non-Saudi nationality, unwillingness to deliver at the study hospital, multiple pregnancies, and chronic diseases and drugs that might affect pregnancy outcomes. The study was approved by the ethical committees of King Abdulaziz City for Science and Technology, Riyadh, Saudi Arabia, and the Maternity and Children Hospital, Medina, Saudi Arabia. All of the participants provided written informed consent.

Demographic data were obtained from all participants at the first antenatal visit. Each participant was assessed for risk factors for GDM including age, parity, family history of diabetes, and history of GDM, macrosomic infant (birth weight ≥4000 g), stillbirth, and unexplained neonatal death. Anthropometric measurements, including weight, height and body mass index (BMI) and blood pressure were taken and urine analysis was performed on all participants.

All participants performed a 75-g OGTT for 2 hours between 24-28 weeks of gestation. Gestational diabetes was diagnosed according to the IADPSG and the former ADA criteria, respectively. The cut-off values in the IADPSG criteria include fasting plasma glucose (FPG) ≥92 mg/dL (5.1 mmol/L), 1-h postprandial glucose (PPG) ≥180 mg/dL (10 mmol/L) or 2-h PPG ≥153 mg/dL (8.5 mmol/L) with a single abnormal value needed for GDM diagnosis. The cut-off values in the former ADA criteria included: FPG ≥95 mg/dL (5.3 mmol/L), 1-h PPG ≥180 mg/dL (10 mmol/L) or 2-h PPG ≥155 mg/dL (8.6 mmol/L) with at least two abnormal values needed for diagnosis.[23] All women diagnosed with GDM by any criteria were treated by diet and exercise. Insulin was added if the glycemic targets were not achieved. The glycemic targets were as follow: FG ≤90 mg/dL (5.0 mmol/L), 1-h post-meal: ≤140 mg/dL (7.8 mmol/L) or 2-h post-meal: ≤120 mg/dL (6.7 mmol/L).[23] All of the women were followed up until delivery by obstetricians. Additionally, a specialist team, consisting of an internal medicine physician, a diabetic educator, and a dietician, followed up the GDM patients.

After delivery, the medical records of all of the mothers and neonates were checked for pregnancy and neonatal outcomes. The fetal variables collected were weight, Apgar score at 5 min (>7 considered acceptable), congenital malformations, shoulder dystocia, fetal distress, hypoglycemia, hyperbilirubinemia, stillbirths, and admission to the neonatal intensive care unit and neonatal death. Macrosomia was defined as a birth weight of 4000 g or more. Neonatal hypoglycemia was defined as blood glucose levels below 2.2 mmol/L (40 mg/dL). For the detection of hypoglycemia, blood glucose monitoring was done to the newborns of GDM mothers and to those with macrosomia at half an hour after delivery, every 2 hours for 2 readings and then every 3 hours before the following 3 feedings.

Maternal outcomes were noted for polyhydramnios (diagnosed clinically or by ultrasound if the amniotic fluid index exceeded 24 cm or a single deepest pocket of fluid of at least 8 cm), preterm delivery (defined as <37 weeks of gestation), premature rupture of membranes

(PROM), type of delivery, induction of labor, lacerations, admission to the intensive care unit, and days of hospitalization.

The women were divided into three groups: GDM diagnosed by both criteria (group 1), additional GDM identified by the IADPSG criteria only (group 2), and normal by both criteria (group 3). Comparisons between the three groups were made in terms of clinical and metabolic characteristics and pregnancy outcomes. Measurements of serum glucose were performed by the glucose oxidase method. Measurements of HbA1C were performed at the time of entry into the study, by standardized HPLC. We included all women who attended the clinical and had an OGTT during the period between October 2011 and August 2012.

Statistical analyses were performed using SPSS software (v 16.0; SPSS Inc, Chicago, IL). Data are expressed as mean (standard deviation, SD), median (minimum and maximum), or percentages. Groups were compared using ANOVA followed by a post-hoc analysis (for continuous data), and the χ^2-test (for frequency data), otherwise the Mann-Whitney U test was used for comparison of medians. A divided χ^2 analysis was used when the null hypothesis was rejected to explore which category contributed to the difference. Whether the distributions of continuous variables were normal or not was determined by the Shapiro–Wilk test. A *P* value of <.05 (two-tailed) was considered significant.

RESULTS

The mean (SD) age of the 277 women included in the study was 30.8 (6.2) years, weight 70.3 (1.5) kg, and BMI 29.5 (6.3). Multiparity, previous GDM and family history of DM were present in 56.5%, 13.8% and 59.1%, respectively (**Table 1**). The number of women diagnosed with GDM using the former ADA criteria was 47 (16.9%) and by the IADPSG criteria 115 (41.5%). The IADPSG criteria identified all women with GDM by the former ADA criteria and categorized an additional 68 cases of GDM. Thus, there were 47 women in the group identified by both criteria; 68 women in the group identified only by the IADPSG criteria; and 162 women in the normal glucose tolerance (NGT) group (NGT by both criteria). Most (89.7%) of the additional cases of GDM identified by the IADPSG criteria as a result of a single abnormal glucose value during the OGTT.

The additional GDM group identified by the IADPSG criteria had the same clinical and metabolic characteristics as the GDM group identified by both criteria except for lower systolic blood pressure (*P*=.001), lower diastolic blood pressure (*P*=.02), and less frequent glycosuria (*P*=.01). The clinical and metabolic characteristics of the additional GDM group identified by the IADPSG criteria differed from the NGT group in age, weight, previous diagnosis of GDM, history of recurrent abortions, and glucose levels during OGTT and HbA1c (**Table 1**).

The maternal and neonatal outcomes

The maternal and neonatal outcomes are presented in **Table 2**. The women identified by the IADPSG criteria alone had the same perinatal outcomes as the GDM group identified by both criteria and differed significantly, in some outcomes, from the NGT group. The women identified by the IADPSG criteria had significantly more frequent cesarean deliveries (*P*=.040) than the NGT group. Neonatal hypoglycemia was observed exclusively in women in both GDM groups compared with the NGT group; (*P*=.001) and (*P*=.002), respectively. In addition, an Apgar score <7 at 5 minutes was significantly more frequent in the additional IADPSG-GDM group than in the NGT group (*P*=.024). The remaining perinatal outcomes were not significantly different between the three groups, except for induction of labor, which was significantly more frequent in the GDM identified by both criteria (group 1) than in the NGT women (*P*=.049).

DISCUSSION

This is the first study that has prospectively compared clinical characteristics and pregnancy outcomes of treated GDM cases as identified by the IADPSG criteria versus those identified by the former ADA criteria. Studies from Italy,[10] Canada,[11] and Belgium,[22] compared clinical characteristics and pregnancy outcomes in additional cases of GDM identified by the IADPSG criteria that were considered normal by the former criteria. However, all of these studies were retrospective and therefore the reclassified GDM group had not been treated. In addition, the Italian and the Belgian studies used 100-g OGTT instead of the 75 g as recommended by the IADPSG, and therefore the new GDM group in the latter two studies might include women without GDM by the IADPSG criteria if a 75-g OGTT had been used.

In the current study, the frequency of GDM among Saudi women was 41.5% by the IADPSG criteria and 16.9% by the former ADA criteria, indicating a 2.44-fold (144.6%) increase in the GDM frequency when applying the IADPSG criteria. This is consistent with the findings from recent studies, which showed significant increases in the GDM prevalence worldwide, by 1.24 to three-fold (*P*=.001), when applying the IADPSG criteria[3-10,12] (**Table 3**). The combined

Table 1. Clinical and metabolic characteristics of the 277 pregnant women who underwent OGTT and were classified according to the IADPSG and the former ADA criteria.

Variable	GDM identified by both criteria (group 1) (N= 47)	Additional GDM identified by IADPSG only (group 2) (N= 68)	Normal gucose tolerance* (group 3) (N= 162)	*P* value (group 1 vs. group 2)	*P* value (group 2 vs. group 3)	*P* value (group 1 vs. group 3)
Age (years)	34.1	31.9	29.3	.116	.004	.001
Weight (kg)	76.3	74.7	66.6	.844	.001	.001
Height (cm)	154.2	154.5	154.4	.809	.686	.988
BMI	32.3	31.3	28.0	.810	.001	.001
Systolic BP	124.9	115.3	115.7	.001	.961	.001
Diastolic BP	69.8	66.1	65.1	.02	.479	.003
Hx of GDM (%)	26.1	19.7	7.7	.492	.018	.001
Multiparity (%)	63.8	67.7	49.4	.450	.035	.083
Hx of recurrent abortions (%)	15.2	23.5	7.9	.422	.003	.290
Hx of stillbirth (%)	9.1	7.6	3.3	.99	.178	.120
Hx of neonatal death (%)	4.5	1.5	4.4	.563	.442	.001
Hx of preterm deliveries (%)	13	9	5	.543	.198	.062
Hx of delivering big baby (%)	8.8	8.7	8.8	.99	.99	1.000
Hx of malformed child (%)	8.7	6	3.1	.714	.455	.115
Hx of previous cesarean section (%)	45.6	44.8	28.2	.951	.077	.064
Hx of gestational hypertension (%)	10.6	7.5	4.4	.738	.344	.149
Hx of preeclampsia (%)	8.8	4.5	2.5	.444	.424	.080
Family hx of diabetes (%)	76.6	63.6	55.0	.142	.241	.011
Presence of glycosuria (%)	18.4	2.1	6.3	.01	.437	.027
Fasting glucose pre OGTT*	5.2	5.0	4.3	.002	.000	.000
1-h glucose post OGTT*	11.22	8.58	7.13	.001	.001	.001
2-h glucose post OGTT*	10.05	7.95	6.13	.001	.001	.001
HbA1c at diagnosis#	40 (5.8)	39 (5.7)	34 (5.3)	.001	.001	.001

Data are means or medians for continuous variables and percentages for categorical variables. The median was calculated for Fasting OGTT and HbA1c and the comparison was done by the Mann–Whitney U-test. NS: not significant; Hx: history;* by mmol/L, # by mmol/mol (%). GDM=gestational diabetes mellitus. OGTT=oral glucose tolerance test.

prevalence of GDM in the HAPO study based on the IADPSG criteria was 17.8%, but it varied substantially among different centers, with the lowest prevalence in Israel (9.3%), and the highest prevalence in the US (Bellflower, CA) (25.5%). This increment in the GDM prevalence increases the load on the health care system and may increase the likelihood of interventions. On the other hand, there are expected benefits to these pregnancies and the increase in cases identified might provide an opportunity to help more pregnant women avoid diabetes in the future. The additional cases of GDM identified by the IADPSG criteria mainly resulted from a single abnormal glucose value during OGTT (in 89.7% of patients), which was the case in the Italian[10] and Belgian[22] studies.

In the current study, the additional IADPSG-GDM group did have the same clinical characteristics and GDM risks as the GDM identified by both crite-

Table 2. Maternal and neonatal outcomes of the 277 pregnant women who underwent OGTT and were classified according to the IADPSG and the former ADA criteria.

Variable	GDM identified by both criteria (group 1) (N= 47)	Additional GDM identified by IADPSG only (group 2) (N=68)	NGT identified by both criteria (group 3) (N=162)	*P* value (group 1 vs. group 2)	*P* value (group 2 vs. group 3)	*P* value (group 1 vs. group 3)
Abortion (%)	0	0	1.8	NS	.552	.99
Polyhydramnios (%)	7.7	6.2	0	.99	.051	.058
Premature delivery	8.1	6.9	11.1	.864	.436	.765
PROM (%)	2.9	3.5	11.8	.99	.098	.197
Cesarean delivery	55.6	55.9	39.4	.99	.040	.090
Gestational week at delivery	38.2	38.1	38.3	.949	.155	.646
Induction of labor (%)	20	10.5	7.2	.230	0.562	.049
Laceration (%)	5.7	3.4	3.1	.752	.830	.774
Shoulder dystocia (%)	0	0	0.8	.99	.99	.99
ICU admission (%)	5.7	5.2	0.8	.99	.092	.118
Birthweight (g)	2862	2862	2994	.997	.135	.151
Apgar score <7 at 5 min	3.2	12	2.7	.99	.024	.612
Stillbirth (%)	0	0	3.1	NS	.579	.578
Neonatal death (%)	8.3	5.6	6	.701	.608	.701
Fetal malformation (%)	8.3	5.6	6	.680	1	.271
Neonatal hypoglycemia (%)	8.3	13.2	0	.734	.001	.002
Neonatal hyperbilirubinemia (%)	2.8	11.3	4.3	.234	.608	.99
Respiratory distress syndrome (%)	8.3	7.5	5.3	.99	.727	.370
Fetal injury (%)	0	0	0	NS	NS	NS
NICU admission (%)	22.2	20.8	16.2	.99	.520	.410

Macrosomia: 4 kg and above. Neonatal hypoglycemia defined as blood glucose below or equal to 40 mg/dL. PROM: premature rupture of membrane. NS: not significant.

ria, except for having lower blood pressure and less frequent glycosuria. On the contrary, in the Belgian[22] and the Italian studies,[10] the additional IADPSG-GDM groups were significantly younger compared with the GDM group diagnosed by the Carpenter and Coustan criteria. In addition, in the latter study, the pre-pregnancy BMI in this group was lower compared with the GDM group diagnosed by the older criteria.

In our study, the individuals in the additional IADPSG-GDM group were older and heavier and had a higher frequency of previous GDM and recurrent abortions than women with NGT. In a Canadian study, the authors reported higher rates of advanced maternal age, obesity, and previous GDM in women classified as GDM by the IADPSG criteria who did not fulfill the Canadian Diabetes Association criteria (CDA) for GDM or gestational glucose intolerance.[11] This finding is consistent with our results.

The additional IADPSG-GDM group in our study had the same pregnancy outcomes as women considered to have GDM by both criteria, and they differed significantly, in some outcomes, from the NGT group. This is in agreement with the Italian[10] and the Belgian[22] findings, but opposite to the results of the Canadian study,[11] which did not find significant differences in pregnancy outcomes between women with NGT and

Table 3. Prevalence of gestational diabetes mellitus in different countries by the IADPSG versus older criteria.

Country	Old criteria used	Prevalence of GDM by old criteria (%)	Prevalence of GDM by IADPSG (%)	Increment (fold)
Italy10	IWC	35.4	53.4	1.50
United Arab Emirates[3]	Former ADA[23]	12.9	37.7	2.92
Norway (Ethnic minorities)[4]	WHO	15	37*	2.46
Mexico[5]	Former ADA[23]	10.3	30.1	3
Australia[8]	ADIPS	20	25.6	1.28
Norway (Western European)[4]	WHO	11	24*	2.1
Japan[6]	JSOG	8.6	23.6	2.74
Italy[7]	Old Coustan & Carpenter	8.7	20	2.29
Australia[9]	ADIPS	9.6	13	1.35
Sri Lanka[12]	WHO	7.2	8.9	1.24

ADA; American Diabetes Association, WHO; World Health Organization, IWC; Fourth International Workshop Conference, ADIPS; Australia Diabetes in Pregnancy Society; JSOG; Japan Society for Obstetrics and Gynecology; *Used modified IADPSG.

women classified as GDM by the IADPSG criteria but considered normal by the CDA. The CDA defines a single abnormal glucose value in the OGTT as gestational glucose intolerance and treats this group of patients in the same way as patients with GDM. This could explain the findings of no differences in the pregnancy outcomes between the additional IADPSG-GDM group and women with NGT in the Canadian study.[11] Jensen et al found that pregnant women with mild glucose intolerance, but not classified as GDM, had worse perinatal outcomes, more cesarean sections, more spontaneous preterm deliveries and more macrosomia than women with NGT.[24] This is consistent with the worse perinatal outcomes among the women in the additional IADPSG-GDM group in our study. Furthermore, treatment of mild GDM has been shown to improve perinatal outcomes.[25,26]

However, we did not find statistically significant differences among the three groups in other clinically important outcomes such as stillbirth, neonatal death and absolute birth weight (too few observations were available to evaluate macrosomia). This could be attributed to effective treatment of GDM patients in the current study. The small sample size could be another factor explaining the lack of differences in these variables. The Belgian[22] and Italian studies[10] reported same findings of no differences in the birth weight and the rate of macrosomia between the three groups. However, when the latter study calculated the ponderal index for newborns, they found the reclassified GDM group by the IADPSG criteria had a higher newborn ponderal index than both the NGT and the treated GDM group.[10] The ponderal index of the newborn is the ratio of weight/length cubed, and may be a more accurate measurement of fetal overgrowth than birth weight; however, this value was not calculated in our study. A recent retrospective study from Japan found the number of infants with a birthweight ≥3600 g was significantly higher among women reclassified as GDM by the IADPSG criteria, but who were formerly classified as normal by the Japan Society of Obstetrics and Gynecology criteria than among women with normal glucose.[6] Of note, the latter two studies did not treat the additional IADPSG-GDM cases as we did, and this could explain the differences between their results and ours.

The strengths of our study include being prospective and population-based with an analysis of large amounts of data on maternal characteristics and pregnancy outcomes separately. Another important strength in the current study is that all women diagnosed with GDM were treated, unlike other studies, thus removing confounding by treatment. A limitation of the study is the relatively small numbers of subjects, which could limit the power of statistical findings.

In conclusion, the new criteria proposed by the IADPSG for diagnosing gestational diabetes identify more cases of GDM with a lesser degree of hyperglycemia than those identified by the former ADA criteria and hence increase the GDM frequency. The addition-

al GDM cases identified by the IADPSG have clinical and metabolic characteristics resembling those women who would have GDM according to the former ADA criteria. Those women have an increased risk for adverse pregnancy outcomes compared with women with NGT. Treatment and medical follow up are warranted in this group and further studies are needed to look at the efficacy of treating this category. Larger prospective studies are needed to confirm our results. Studies on the cost effectiveness of applying the IADPSG recommendations on the screening and diagnosis of GDM are also needed.

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Conflicts of interest

The author has no conflict of interest.

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