Effects of Implementing International Association of Diabetes and Pregnancy Study Groups Gestational Diabetes Screening on Pregnancy Outcomes at a Small Community Teaching Hospital

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■ **IN BRIEF** Traditional methods of screening for and diagnosing gestational diabetes mellitus (GDM) have been challenged, leading to the development of new screening guidelines by the International Association of Diabetes and Pregnancy Study Groups (IADPSG). This study is a retrospective comparison of pregnancy outcomes based on the Carpenter and Coustan (CC) and IADPSG screening guidelines. It demonstrates that adoption of IADPSG guidelines increased the rate of GDM diagnosis and resulted in more women with diet-controlled GDM. However, a decrease in adverse pregnancy outcomes was not noted. Interestingly, women diagnosed by IADPSG criteria who had diet-controlled GDM had less maternal weight gain than those screened with the CC criteria who did not have GDM but did have an elevated 1-hour oral glucose tolerance test result.

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Gestational diabetes mellitus (GDM) has long been recognized as a risk factor for adverse maternal and neonatal outcomes, including preeclampsia, cesarean section, traumatic delivery, fetal macrosomia, neonatal hypoglycemia, hyperbilirubinemia, and fetal/neonatal death (1). In the United States, GDM screening is recommended after 24 weeks' gestation (2). The criteria for GDM diagnosis endorsed by the American College of Obstetricians and Gynecologists (ACOG) were developed and validated based on the predictive value for future diabetes mellitus in the mother (3). The protocol, developed by Carpenter and Coustan (CC), consists of an initial 1-hour, 50-g screening oral glucose tolerance test (OGTT) with a follow-up diagnostic 3-hour OGTT if the initial screening ≥135 mg/dL (Table 1). Although it is well known that GDM is a risk factor for subsequent maternal diabetes, GDM treatment has also demonstrated a reduction in serious perinatal morbidity and potential improvement in the woman's health-related quality of life (4).

In recent years, the traditional two-step CC method for GDM screening and diagnosis has been challenged by the results of the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) trial (5). HAPO provided data demonstrating that mild elevations in perinatal blood glucose levels, specifically those less than the CC GDM screening cutoff values, result in increased rates of adverse maternal and neonatal outcomes (5). In 2010, the International Association of Diabetes and Pregnancy Study Groups (IADPSG) published new diagnostic guidelines based on the HAPO outcomes (Table 1), with the intention of further minimizing adverse maternal and fetal outcomes associated with GDM (6). Because of a lack of consistent and objective evidence, as well as the limited number of retrospective and prospective studies supporting the new guidelines, ACOG has continued to endorse the

TABLE 1. Diagnosis of GDM Using CC and IADPSG Criteria

	CC (assuming a prior nonfasting, 50-g OGTT ≥135 mg/dL)	IADPSG
	100-g OGTT Serum Glucose Level (mg/dL)	75-g OGTT Serum Glucose Level (mg/dL)
Fasting	≥95	≥92
1 hour	≥180	≥180
2 hours	≥155	≥153
3 hours	≥140	
Criteria for diagnosis	Two or more	At least one

TABLE 2. Variables Examined During Data Collection

- Age
- Gravidity/parity
- Gestational age at delivery
- Screening/diagnostic glucose values
- Maternal tobacco use (past and current)
- Planned mode of delivery
- Actual mode of delivery
- Mechanism of labor (spontaneous or induced)
- GDM (managed with diet or medication)
- Preeclampsia
- Episiotomy or laceration
- Infant weight
- Infant height
- Infant head circumference
- Neonatal hyperbilirubinemia (need for phototherapy)
- Neonatal hypoglycemia (glucose ≤46 mg/dL)
- Shoulder dystocia
- Birth trauma

CC criteria. Thus, individual obstetricians have been reluctant to adopt the IADPSG guidelines in clinical practice (1).

In 2013, however, the World Health Organization updated its recommendations for diagnosis of GDM and overt diabetes during pregnancy to support IADPSG recommendations (7). Subsequently, the National Institutes of Health held a consensus development conference, which recommended continuation of the current two-step CC process until further evidence is available demonstrating improved pregnancy outcomes with the single-step IADPSG process (8). In light of this consensus statement, the American Diabetes Association amended its recommendations to support the use of either the one-step or the two-step process (9). Clearly, there is a lack of consensus in the international community regarding the diagnosis of GDM, and thus, further research is needed to evaluate differing diagnostic strategies.

In February 2011, a multi-physician obstetrics and gynecology group located in a small community hospital in southeastern Ohio adopted the IADPSG guidelines for GDM diagnosis. It was therefore necessary to use the information available to contribute to the understanding of GDM diagnosis under each of the two processes and explore the plausible associations with maternal and neonatal outcomes. The objective of this study was to describe the impact of implementing the IADPSG diagnostic guidelines in a rural Appalachian single practice during a 2-year time period. We hypothesized that the rate of diagnosis of GDM would increase under the IADPSG guidelines and that the adoption of IADPSG guidelines would decrease the incidence of adverse pregnancy outcomes in the practice's patients with GDM.

Research Design and Methods

This was a retrospective observational study. The University Office of Research Compliance approved the retrospective review, collection, and analysis of electronic medical record (EMR) information in compliance with the Health Insurance Portability and Accountability Act Privacy Rule (Code of Federal Regulations 45 Part 160 and Part 164 Subparts A and E). The study involved the review of medical charts of pregnant women to compare the outcomes data of those who were screened using the traditional two-step CC criteria to those screened with the one-step IADPSG criteria to determine possible differences in maternal and neonatal outcomes. The primary outcome measured was the rate of GDM diagnosed in each subgroup. Secondary outcomes included mode of delivery, gestational age at delivery, infant weight, neonatal hypoglycemia, neonatal hyperbilirubinemia, and maternal weight gain.

Maternal charts were accessed through the medical practice's billing system, and all deliveries between 1 February 2010 and 1 June 2012 were identified with the use of current procedural terminology codes for vaginal and cesarean deliveries. Choosing these dates captured a 12-month period during which patients were screened with the CC criteria, and the
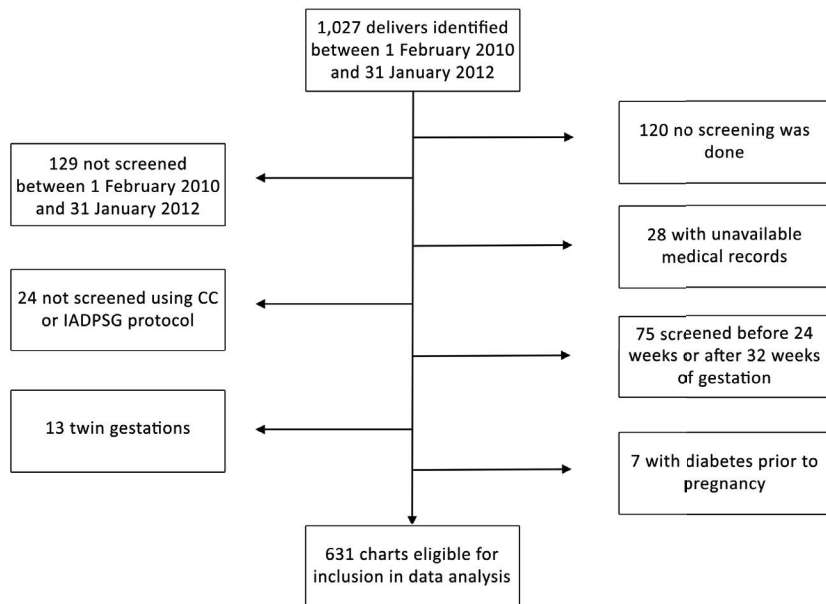
FIGURE 1. Schematic representation of the patient selection process.

subsequent 12-month period during which IADPSG guidelines were used for diagnosis. This timeline was chosen to collect two similar-sized sample groups in consecutive order.

Medical record numbers of delivering mothers and their infants were collected from the birth center logbooks and used to obtain medical records. Any patient whose GDM screening was not performed between the designated dates was excluded. Charts were also excluded if no screening test was found for the patient. Additional exclusion criteria included diabetes diagnosed before pregnancy, screening performed before 24 or after 32 weeks' gestation, multiple gestation, and a screening regimen inconsistent with either the CC or IADPSG criteria.

After obtaining access to the medical records, the research team extracted data encompassing the delivery/birth admissions, maternal antepartum and postpartum admissions, and neonatal readmissions. Data were manually extracted from eligible charts. A list of all variables recorded is shown in Table 2.

The variables to be analyzed were defined using specific criteria. The discriminatory cutoff value for neonatal hypoglycemia was a glucose meter or laboratory serum glucose value of ≤46 mg/dL recorded at any time after delivery—the value at which the neonatal nursery protocol required intervention or follow-up monitoring. The need for phototherapy was used to classify neonatal hyperbilirubinemia. The presence of shoulder dystocia was determined by documentation in the physician or nursing delivery notes or the nursery notes. Birth trauma was documented if complications such as skull fracture, clavicle fracture, intracranial bleed, or intrapartum death had been recorded in the chart and encountered during data collection.

Data were de-identified, and calculations were performed to examine maternal weight gain, unplanned cesarean section, hypertensive disorder of pregnancy, and fetal macrosomia (≥4 kg birth weight). Statistical analysis consisted of both descriptive and inferential methods. Frequencies for categorical variables and summary statistics for continuous variables were generated. Independent sample t tests (or their nonparametric equivalents) were performed to compare the continuous variables for maternal and neonatal outcomes of the two screening regimens. Categorical variable outcomes

and the regimen comparisons were done using χ^2 tests of association or proportion, as appropriate. Statistical significance was set at $P \leq 0.05$.

A subset analysis was performed focusing on the women in the two-step CC group with a 1-hour glucose value ≥135 mg/dL and a normal 3-hour OGTT. This group was labeled with a diagnosis of mild hyperglycemia. They were further stratified based on their 3-hour OGTT results into two separate groups: those with one elevated value and those with all four normal values. The outcomes for these patients were then compared to the women with diet-controlled GDM diagnosed with the IADPSG criteria.

Results

A total of 1,027 deliveries were identified through an initial EMR search between 1 February 2010 and 1 June 2012. Of these, 631 deliveries met the inclusion criteria and were included in data analysis. Figure 1 depicts the patient selection process. There were 317 deliveries in the CC group and 314 in the IADPSG group. The prevalence of GDM was 7.9% in the CC group and 20.4% in the IADPSG group ($P <0.001$).

Table 3 further characterizes the demographics of the groups. The mean age of the mothers at delivery in each group were similar (27.5 years in the CC group and 27.4 years in the IADPSG group, $P = 0.477$). The mean gestational age at delivery was 39 weeks, 1 day, and 39 weeks, 0 days ,for the CC and IADPSG groups, respectively ($P = 0.643$). Maternal prepregnancy weights were also similar (154.18 vs. 154.99 lb in the CC and IADPSG groups, respectively, $P = 0.818$). Further statistical comparisons of descriptive variables confirmed that there were no differences between the two groups in terms of gravidity/parity, maternal weight gain, or tobacco use.

The proportion of women whose GDM was diet-controlled was 60% ($n =15/25$) in the CC group, com-

TABLE 3. Comparison of Descriptive Variables Between Screening Groups

	CC Group (*n* = 317)	IADPSG Group (*n* = 314)	*P*
Mean maternal age (years)	27.5	27.4	0.477
Mean gestational age at delivery (weeks)	39.1	39	0.643
Mean maternal prepregnancy weight (lb)	154.18	154.99	0.818
Mean maternal weight gain (lb)	32.43	32.95	0.691
Mean gravida	2.27	2.10	0.132
Parity: term	0.789	0.726	0.413
Parity: preterm	0.076	0.048	0.177
Parity: abortion	0.416	0.322	0.137
Previous smoker (%)	32.06	34.39	0.554
Current smoker (%)	24.44	21.66	0.449

TABLE 4. Comparison of Rate of GDM Between the Two Screening Regimens

	CC Group	IADPSG Group	*P*
Total GDM (% [*n*])	7.9 (25/317)	20.4 (64/314)	0.000
Diet-controlled GDM (% [*n*])	60 (15/25)	76.6 (49/64)	0.000
Medication-controlled GDM (% [*n*])	36 (9/25)	15.6 (10/64)	0.819
Untreated GDM (% [*n*])	4 (1/25)	7.8 (5/64)	—

pared to 76.6% (*n* = 49/64) in the IADPSG group (*P* <0.001). The number of women requiring medication to control their GDM was 36% (*n* = 9/25) in the CC group compared to 15.6% (*n* = 10/64) in the IADPSG group; this difference was not statistically significant (*P* = 0.819). Six patients with GDM did not receive treatment and were classified as untreated (Table 4).

Pregnancy outcomes of women with GDM were analyzed, and no statistically significant findings were noted for gestational hypertension, preeclampsia, any hypertensive disorders of pregnancy, neonatal hypoglycemia, neonatal hyperbilirubinemia, infant birth weight, macrosomia (≥4 kg), shoulder dystocia, or unplanned cesarean based on standard diagnostic methods. These same outcomes were analyzed in the patients without diabetes in both

study groups, and no statistically significant findings were observed.

A subset analysis of the women screened with the two-step CC regimen revealed that 34 women had a 1-hour glucose value equal to or greater than the screening cutoff (135 mg/dL) but did not meet diagnostic criteria for GDM on the 3-hour OGTT. The pregnancy outcomes for these 34 women were compared to the outcomes data for the 49 women who had diet-controlled diabetes diagnosed with IADPSG guidelines. Maternal weight gain was 24.8 lb in the IADPSG group compared to 33.4 lb in the subset of CC group women who failed the 1-hour OGTT (*P* = 0.03). There were no statistically significant differences in hypertensive disorders of pregnancy, neonatal hypoglycemia, unplanned cesarean section, infant weight, or gestational age in subset analysis.

Conclusion

Despite convincing arguments for the use of IADPSG guidelines to diagnose GDM, there have been few clinical data and a lack of consistent findings that demonstrate its association with improved pregnancy outcomes. Since the publication of the IADPSG guidelines, numerous retrospective, prospective, and cross-sectional studies have shown a significant increase in GDM diagnosis using IADPSG guidelines, which is consistent with the findings in this study (10–15). Our retrospective study demonstrated a 2.5-fold increase in the diagnosis of GDM with the implementation of IADPSG criteria, with no statistically significant differences in maternal or neonatal outcomes. This result has been similarly reported in two other studies (12,13).

Of pressing concern is the lack of consistency among studies validating or disproving the impacts of the new screening regimen on pregnancy outcomes. Examples in the literature address implementation of IADPSG, but published results compare entire cohorts of women screened with the CC criteria versus those screened with the IADPSG method rather than those who were diagnosed with GDM in each group (11,14).

In light of the ambiguous benefit and the significant increase in GDM diagnosis rates using the IADPSG regimen, some clinicians question whether there is any benefit from the diagnosis of GDM in this subset. However, data do support that women with mild GDM are at risk for adverse pregnancy outcomes (16). Similarly, it has been demonstrated that treatment of mild GDM with diet, self-monitoring of blood glucose, and insulin therapy if necessary lowers the risk of preeclampsia, shoulder dystocia, cesarean delivery, and fetal overgrowth compared to untreated counterparts (17). Additionally, those with normal glucose tolerance by the IADPSG criteria have been shown to have better perinatal outcomes and a decreased risk of polyhydramnios.

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Moreover, women with a positive CC screen but negative 3-hour results had a greater risk of preeclampsia than IADPSG-negative individuals (18).

It is likely that an increase in the GDM diagnosis rate will affect how physicians provide care. It is important to highlight that our study found an increase in women with diet-controlled GDM without increased rates of insulin use or further medical intervention (76.6 vs. 60%, P <0.001). This illustrates the value of providing patient education about proper nutritional habits and exercise plans to manage GDM and weight. It is assumed that this target group includes women who would not have been diagnosed with GDM under the CC criteria but were diagnosed using the IADPSG method. Remarkably, we found that women diagnosed by IADPSG criteria who had diet-controlled GDM had less maternal weight gain than those screened with the CC criteria who did not have GDM but did have an elevated 1-hour OGTT (24.8 vs. 33.4 lb, P = 0.03). The women without GDM who had an elevated 1-hour screen would likely have been diagnosed with GDM had they been in the IADPSG screening cohort. Outcomes of hypertensive disorders, unplanned cesarean, neonatal hypoglycemia, and birth weight demonstrated no statistically significant differences between the groups.

Although it is interesting to note that there were no differences in maternal weight gain with regard to women with GDM as a whole, the significantly lower weight gain observed in women with diet-controlled GDM in the IADPSG group may represent a stricter adherence to dietary guidelines provided through medical nutrition therapy. It is likely that women who control their GDM with diet demonstrate a combination of mild hyperglycemia and strict adherence to dietary recommendations. Further investigation into these differences in weight gain may prove beneficial because excessive

weight gain has been correlated with poor maternal and neonatal outcomes regardless of GDM diagnosis (19,20). It has been shown that the incidence of subsequent diabetes in those with a history of transient gestational glucose intolerance is significantly higher in overweight individuals (46.7%) compared to patients within normal weight parameters (25.6%) (21). Providing dietary and exercise counseling to those with mild GDM could decrease their risk for weight gain outside the expected norms and ultimately affect their subsequent risk for future diabetes.

These are the first published findings demonstrating that women diagnosed by IADPSG criteria with diet-controlled GDM have less maternal weight gain than women screening with the CC criteria who have an elevated 1-hour result but no diagnosis of GDM. Although initial screening for GDM was first developed to identify the risk of a subsequent diabetes diagnosis, it is also known that obesity positively correlates with an increased risk of diabetes. It is possible that diagnosis of GDM with the IADPSG criteria could reduce the overall diagnosis rate of diabetes. The education and dietary changes acquired during pregnancy that allow for decreased weight gain could represent a benefit of the new diagnostic regimen. More studies must be conducted, however, to validate the impact of IADPSG-identified, diet-controlled diabetes on maternal weight gain, particularly in women who would only be diagnosed under the IADPSG guidelines and not under the CC criteria.

Strengths and Limitations
Our study has multiple strengths, including population uniformity. All deliveries occurred at a single institution, and pregnancies were managed within a single obstetrics practice, both of which ensure that standards of management were consistent for mothers and infants.

Limitations of this study include the inherent relative weakness of a retrospective compared to a prospective study. It is important to note that prospective comparisons of IADPSG to traditional guidelines are sparse in the literature (22). Uniform documentation of outcomes and more specific definitions of outcomes would be possible in a well-developed prospective setting. Additionally, in our study, we defined hyperbilirubinemia as the need for phototherapy, but this did not take into account a subset of infants that required repeated laboratory tests and outpatient visits for bilirubin monitoring. Clinically and economically, inclusion of those patients would be informative and could be included by design with a prospective study. Additionally, infants in the newborn nursery at the study institution did not uniformly have glucose monitoring. They were subject to the standard protocol to selectively check blood glucose on infants at risk for hypoglycemia—namely, infants whose mothers were diagnosed with GDM, preterm infants, infants in the >90th percentile for gestational age at delivery, or infants demonstrating distress. Consequently, this lack of uniform screening could falsely lower the frequency of neonatal hypoglycemia found in the infants of mothers without GDM. A prospective study could ensure uniformity of glucose testing for all infants. A larger sample size, especially at the subgroup level, would have allowed for more robust analysis of subsets of women with GDM and hyperglycemia. For example, improvement in several obstetrical outcomes with implementation of IADPSG guidelines in a Spanish population with a sample size approximately five times larger than ours was recently reported (11).

In this study, adoption of the IADPSG recommendations increased the rate of GDM diagnosis without improving maternal or neonatal outcomes. The increased rate of diagnosis was limited to diet-controlled GDM.

IADPSG-identified women with GDM controlled by diet had significantly less maternal weight gain compared to those who only had an elevated 1-hour result in the CC criteria screening.

The IADPSG guidelines were proposed to prevent adverse pregnancy outcomes but were based solely on statistical models that have not been validated in real-world clinical practice. Studies such as this one continue to show that adopting of the IADPSG guidelines drastically increases the rate of GDM, specifically diet-controlled GDM, whereas the increase in diagnoses does not result in improved obstetrical outcomes. In light of this, caution should accompany the sole use of the IADPSG guidelines in GDM screening to improve obstetric outcomes.

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