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Carpenter-Coustan Compared With National Diabetes Data Group Criteria for Diagnosing Gestational Diabetes

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Abstract

Objective—Use of Carpenter-Coustan compared to National Diabetes Data Group (NDDG) criteria increases the number of women diagnosed with GDM by 30-50%, but whether treatment of this milder GDM reduces adverse outcomes is unknown. We explored the effects of the diagnostic criteria used on the benefits of GDM treatment.

Methods—This was a secondary analysis of a randomized trial for treatment of mild GDM diagnosed using Carpenter-Coustan criteria. We evaluated the effect of treatment within two mutually exclusive diagnostic groups: 1) women who met the stricter NDDG as well as Carpenter-Coustan criteria (NDDG) and 2) those diagnosed by Carpenter-Coustan but not meeting NDDG criteria (Carpenter-Coustan only). Maternal outcomes examined were pregnancy-induced hypertension, shoulder dystocia, maternal weight gain, and cesarean delivery. Neonatal outcomes were large for gestational age, macrosomia (>4000 g), fat mass, small for gestational age, and a composite outcome of perinatal death, birth injury, hypoglycemia, hyperbilirubinemia, and hyperinsulinemia. Analysis of variance or the Breslow Day test, as appropriate, was used to test for the interaction between diagnostic criteria and GDM treatment on the outcomes of interest.

Results—Of 958 patients, 560 (58.5%) met NDDG criteria and 398 (41.5%) met Carpenter-Coustan only. Compared to untreated women, the direction of treatment effect did not differ by diagnostic criteria used and was consistent with the original trial. The p-value for interaction between diagnostic criteria and treatment status was not significant for any outcome.

Conclusion—The overall beneficial treatment effect on PIH, shoulder dystocia, cesarean delivery, and macrosomia was seen in patients diagnosed by the higher NDDG and by the lower thresholds of the Carpenter-Coustan criteria.

Introduction

Perinatal outcomes are linked to maternal glycemia in a continuous fashion; no distinct threshold exists above which the risk of adverse outcomes dramatically increases as compared to below.(1-3) As a result, the diagnostic criteria for diagnosing gestational diabetes mellitus (GDM) are intensely debated. For example, positive cutoffs for the 3-hour glucose tolerance test may be the Carpenter-Coustan criteria or the more stringent National Diabetes Data Group (NDDG) criteria (Table 1). Although both the American College of Obstetricians and Gynecologists and an NIH consensus statement endorse two-step GDM screening with a 1-hour glucose challenge test followed by a fasting 3-hour glucose tolerance test, neither institute endorses specific criteria (Carpenter-Coustan or NDDG) for GDM diagnosis.(4, 5)

One reason that no diagnostic criteria are recommended over the other is the lack of data comparing the two. Several prior retrospective studies have demonstrated that women meeting the Carpenter-Coustan criteria for GDM had worse perinatal outcomes (increased odds of operative delivery, shoulder dystocia, LGA, macrosomia, or preeclampsia) compared to women not diagnosed with gestational diabetes.(6-9) In these studies, the Carpenter-Coustan group was not treated for GDM; therefore, none can demonstrate that treatment at the Carpenter-Coustan level is effective at reducing these outcomes. However, compared to NDDG criteria, use of the less strict Carpenter-Coustan criteria would increase the number of women diagnosed with GDM by 30-50%.(10, 11)

We therefore explored the effects of the diagnostic criteria used for GDM diagnosis on the benefits of GDM treatment.

Materials and Methods

This was a secondary analysis of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network randomized clinical trial for the treatment of mild GDM.(12). In the primary study, women between 24 weeks 0 days and 30 weeks 6 days gestation with a 1-hour glucose challenge test between 135 and 200 mg/dL underwent a 3-hour glucose tolerance test. Women were excluded if they had pre-existing diabetes, prior GDM, history of stillbirth, multifetal gestation, asthma, chronic hypertension, fetal anomaly, or were taking corticosteroids. Mild GDM was defined by a fasting glucose less than 95 mg/dL and at least two glucose values exceeding the Carpenter-Coustan thresholds. Women meeting criteria for mild GDM were randomized to usual care or treatment for GDM, which included nutritional counseling, diet therapy, and insulin if needed. The study was approved by the institutional review boards of all participating clinical centers, and all enrolled women gave written informed consent. Details of the protocol are available elsewhere, a brief description of management of gestational diabetes follows.(12)

Patients randomized to the treatment group received dietary counseling according to the 2008 position statement of the American Diabetes Association within one week of enrollment. Women in the treatment group were instructed to take blood sugars fasting and

2-hours post-prandial with goals of <95 mg/dL fasting and <120 mg/dL post-prandial. Insulin therapy was reserved for patients with ≥50% of fasting or post-prandial levels elevated. In the control group, treatment was initiated at the discretion of the patient's provider for random blood glucose ≥160 mg/dL or fasting ≥95 mg/dL.

For this analysis, two mutually exclusive groups were considered, 1) women with mild GDM meeting the NDDG criteria, 2) women with mild GDM meeting Carpenter-Coustan criteria but not NDDG criteria (Table 1). Within each of these two mutually exclusive exposure groups, women either received usual care or were treated for GDM, according to the randomization scheme used in the initial trial.

We selected outcomes from the primary study for which treatment of mild GDM was beneficial. In the primary study, treatment of mild GDM reduced the risk of pregnancy-induced hypertension (PIH, defined as a systolic blood pressure of 140 mm Hg or more or a diastolic blood pressure of 90 mm Hg or more on two occasions at least 4 hours apart or one elevated blood pressure treated with medication), cesarean delivery, shoulder dystocia, large for gestational age infants (LGA, defined as birth weight greater than the 90th percentile of a U.S. reference population),(13) and macrosomia (defined as birth weight greater than 4000 g). Treatment of mild GDM also reduced maternal gestational weight gain and neonatal fat mass. We therefore examined these outcomes in this secondary analysis. Although in the original study treatment did not demonstrate a reduction in the incidence of the primary outcome compared to usual care, we also compared the incidence of the original study's primary outcome between groups. The primary outcome of the original study was a composite of perinatal death, neonatal hypoglycemia (glucose <35mg/dL within 2 hours of birth), neonatal hyperbilirubinemia (serum bilirubin >95th percentile between 16-36 hours after birth), neonatal hyperinsulinemia (cord blood C-peptide>95th percentile), and birth trauma (brachial plexus palsy, clavicular fracture, humeral fracture, or skull fracture). Of note, no perinatal deaths occurred in the cohort. Additionally, we assessed the incidence of small for gestational age infants (SGA, defined as birth weight less than the 10th percentile of a U.S. reference population).(13) Trained study personnel collected antepartum, intrapartum, and postdelivery data for enrolled women and their newborns at the time of discharge from the hospital. All cases of hypertensive disorders and shoulder dystocia underwent masked central review by two reviewers to ensure accurate diagnosis. Baseline characteristics of those diagnosed by NDDG and those diagnosed by Carpenter-Coustan were compared using the chi-square test for categorical variables and the Wilcoxon rank sum test for continuous variables. The analysis of variance or the Breslow-Day test for homogeneity, as appropriate, was used to test for interaction between the diagnostic criteria used and GDM treatment on the outcomes of interest. We then calculated the number needed to treat to prevent each of the outcomes for the overall group, the NDDG group, and the Carpenter-Coustan group. No adjustments were made for multiple comparisons. Statistical analyses were conducted using SAS software (SAS Institute, Cary, NC).

Results

Of 958 women diagnosed with GDM in the primary study, 560 (58.5%) met NDDG criteria and 398 (41.5%) met Carpenter-Coustan criteria only. Baseline characteristics were similar

between groups except for alcohol use and expected differences in blood glucose values on both the 50-g screening and 100-g diagnostic tests (Table 2). Of these 958 women, 931 (97.2%) had outcomes data available and were included in further analysis.

Of 542 women meeting NDDG criteria with outcomes data available, 280 (51.7%) were randomized to treatment. Of 389 women with outcomes data meeting Carpenter-Coustan criteria alone, 196 (50.4%) were randomized to treatment. Maternal outcomes by diagnostic criteria and treatment status are shown in Table 3 (see Appendix 2, available online at http://links.lww.com/xxx). The direction of treatment effect is consistent with the original trial, regardless of diagnostic criteria. The p-value for interaction was not significant for any maternal outcomes, demonstrating that treatment benefit did not vary by the diagnostic criteria met.

Neonatal outcomes by diagnostic criteria and treatment status are summarized in Table 4 (see Appendix 3, available online at http://links.lww.com/xxx). Again, the direction of treatment effect was consistent with the original trial in both diagnostic criteria categories. The p-value for interaction was not significant for any neonatal outcomes, suggesting that those diagnosed by Carpenter-Coustan criteria benefit equally from treatment compared with those diagnosed by the stricter NDDG criteria.

The number needed to treat to prevent a single outcome of cesarean delivery, pregnancy-induced hypertension, shoulder dystocia, LGA, and macrosomia were calculated for all GDM, NDDG criteria, and Carpenter-Coustan criteria (Table 5). With the exception of shoulder dystocia, the numbers needed to treat are small (20 or less for the overall group) and are similar between NDDG and Carpenter-Coustan criteria. A number needed to treat was not calculated for the composite neonatal outcome, as this was not reduced by treatment in the original study.

Discussion

The overall beneficial effect of treating GDM did not vary by the diagnostic criteria used. Women benefited from treatment even at the lower thresholds of the Carpenter-Coustan criteria. Additionally, with the exception of shoulder dystocia, the numbers needed to treat to prevent one adverse outcome are small, even in the Carpenter-Coustan group. The NIH consensus panel stated that a single standard for screening and diagnosis of GDM should be adopted by the appropriate professional organizations.(5) However, in the most recent practice bulletin, ACOG refrained from favoring one set of diagnostic criteria over the other due to lack of comparative trials.(4)

Several cohorts have been used to investigate outcomes in GDM diagnosed by NDDG and Carpenter-Coustan criteria. Cheng et al demonstrated that untreated GDM diagnosed by Carpenter-Coustan had higher risks of operative delivery, cesarean delivery, macrosomia, and shoulder dystocia compared to glucose-tolerant women.(8) In a large prospective cohort in Spain, women with untreated GDM diagnosed by Carpenter-Coustan criteria had increased risks of PIH and LGA infants compared to glucose-tolerant women.(6) Berggren et al compared outcomes in women with untreated GDM diagnosed by Carpenter-Coustan to

those with treated GDM diagnosed by NDDG criteria; untreated GDM diagnosed by the less stringent criteria was associated with increased risks of PIH and similar risks of cesarean, operative delivery, macrosomia, and shoulder dystocia.(7) Landon et al demonstrated that the risk of LGA and hypertensive disorders increased with values on the glucose tolerance test below the Carpenter-Coustan levels (1-hour value on the glucose tolerance test of 165-179 mg/dL); however, only untreated women were included in this analysis.(3)

We identified one study in which women diagnosed with GDM by Carpenter-Coustan criteria alone were treated and compared to women with normal glucose tolerance.(10) In this study, women diagnosed and treated by the Carpenter-Coustan criteria alone had an increased risk of macrosomia compared to women with normal glucose tolerance. Unfortunately, only 16 women in this study met the definition of GDM by Carpenter-Coustan criteria but not NDDG criteria; consequently, no comparisons were made to women with GDM by NDDG criteria.

While these studies consistently demonstrate increased risks of adverse outcomes in GDM diagnosed by Carpenter-Coustan criteria, none of them had a sufficient cohort of women treated at this level of glycemia to demonstrate treatment benefit. Our cohort is unique in that we had both treated and untreated women meeting both sets of diagnostic criteria, providing evidence that even at the lower glycemic thresholds of the Carpenter-Coustan criteria women can benefit from treatment.

Stratifying the cohort into two sets of diagnostic criteria naturally limited the power to detect a difference in outcomes between treated and untreated women in each diagnostic group. Despite the smaller numbers when comparing treated versus untreated within each diagnostic criteria category, the direction of treatment effect remained consistent with the original trial and no interaction between diagnostic criteria used and treatment effect was detected, indicating that both groups benefit equally from treatment. In addition, the estimates of outcomes for the two groups are fairly similar with overlapping 95% confidence intervals (available in Supplementary Material), suggesting that the non-significant p-values for interaction are not due to a lack of statistical power but are rather an indication that treatment benefits those diagnosed by both sets of criteria, although lack of statistical power cannot be completely ruled out.

In sum, women diagnosed with mild GDM by the less stringent Carpenter-Coustan criteria and by the stricter National Diabetes Data Group criteria both benefit from nutritional counseling, dietary therapy, and insulin when indicated.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Diagnostic criteria for 3-hour glucose tolerance test.

Time of Testing	Carpenter-Coustan	National Diabetes Data Group
Fasting	95	105
1-Hour	180	190
2-Hour	155	165
3-Hour	140	145

At least 2 levels must be greater than or equal to the thresholds listed. All thresholds presented as mg/dL.

Table 2

Study population characteristics.

Characteristic	NDDG (n=560)	Carpenter-Coustan Only (n=398)	P-value
Age (yr)	29.3 ± 5.6	28.7 ± 5.7	0.19
Nulliparous	174 (31.1%)	132 (33.2%)	0.49
Race			0.48
African American	63 (11.3%)	47 (11.8%)	
Caucasian	135 (24.1%)	107 (26.9%)	
Hispanic	322 (57.5%)	224 (56.3%)	
Other	40 (7.1%)	20 (5.0%)	
Smoking	41 (7.3%)	28 (7.0%)	0.87
Alcohol use	13 (2.3%)	21 (5.3%)	0.01
BMI at entry (k/m2)	30.1 ± 5.1	30.2 ± 5.1	0.84
Gestational age at randomization (weeks)	28.8 ± 1.5	28.9 ± 1.5	0.16
50 gm screening value (mg/dl)	161.3 ± 15.9	156.7 ± 14.3	<0.001
3 hour OGTT values			
Fasting (mg/dl)	87.0 ± 5.5	85.7 ± 5.9	<0.001
1 hour (mg/dl)	198.6 ± 21.1	184.1 ± 16.9	<0.001
2 hour (mg/dl)	181.6 ± 20.4	162.0 ± 14.9	<0.001
3 hour (mg/dl)	142.2 ± 30.6	126.6 ± 27.3	<0.001

OGTT: Oral glucose tolerance test. NDDG: National Diabetes Data Group.

Data are mean ± standard deviation or as n (%), unless otherwise specified.

Table 3

Maternal Outcomes

Outcome	NDDG (n=542)		Carpenter Coustan Only (n=389)		P-value For Interaction
	Treated (n=280)	Usual Care (n=262)	Treated (n=196)	Usual Care (n=193)	
Pregnancy-Induced Hypertension	25 (8.9%)	35 (13.4%)	16 (8.2%)	27 (14.0%)	0.73
Shoulder dystocia	5 (1.8%)	15 (5.7%)	2 (1.0%)	3 (1.6%)	0.46
Maternal Weight Gain (kg) *	2.9 ± 3.1	4.9 ± 3.1	2.2 ± 3.8	5.0 ± 3.6	0.07
Cesarean Delivery	78 (27.9%)	79 (30.2%)	50 (25.5%)	75 (38.9%)	0.08
Glycemic Control					
Median Fasting	80 [76-86]	-	80 [76-86]	-	-
Median Post-Prandial Breakfast	94.5 [87.5-101]	-	95 [87-102]	-	-
Median Post-Prandial Lunch	100 [94-108]	-	100 [93.5-107]	-	-
Median Post-Prandial Dinner	106 [100-113]	-	105 [98.5-112.5]	-	-
Insulin Use **	23 (8.3%)	2 (0.76%)	14 (7.2%)	0	-

NDDG: National Diabetes Data Group.

Data are n (%) or mean ± standard deviation, unless otherwise specified.

- Cannot be reported as the usual care group did not measure fasting and post-prandial blood sugars. A p-value for the difference in insulin use was not calculated as the usual care group did not routinely follow blood glucose levels.

* Maternal weight gain reported for n=276 in NDDG treated, n=259 in NDDG untreated, n=194 in Carpenter-Coustan treated, n=191 in Carpenter-Coustan untreated

** Insulin use available for n=276 in NDDG, treated, n=262 in NDDG untreated, n=195 in Carpenter-Coustan treated, n=193 in Carpenter-Coustan untreated

Table 4

Neonatal Outcomes

Outcome	NDDG (n=542)		Carpenter Coustan Only (n=389)		P-value For Interaction
	Treated (n=281)	Usual Care (n=261)	Treated (n=196)	Usual Care (n=193)	
LGA	17 (6.1%)	41 (15.7%)	17 (8.7%)	25 (13.0%)	0.17
Neonatal fat mass (gm) *	420.4 ± 179.8	476.2 ± 219.7	426.6 ± 178.5	448.7 ± 225.3	0.24
Macrosomia	16 (5.7%)	41 (15.7%)	12 (6.1%)	24 (12.4%)	0.47
SGA	22 (7.8%)	17 (6.5%)	14 (7.1%)	12 (6.2%)	0.93
Composite Neonatal Outcome **	89 (32.7%)	104 (40.9%)	60 (31.9%)	59 (31.7%)	0.20

NDDG: National Diabetes Data Group. LGA: Large for gestational age. SGA: Small for gestational age.

* Neonatal fat mass available for n=248 in NDDG, treated, n=229 in NDDG untreated, n=194 in Carpenter-Coustan treated, n=191 in Carpenter-Coustan untreated

** Composite neonatal outcome: perinatal death, birth traum, hypoglycemia, hyperbilirubinemia, or hyperinsulinemia assessed in n=272 in NDDG treated, n=254 in NDDG untreated, n=188 in Carpenter-Coustan treated, n=186 in Carpenter-Coustan untreated

Data expressed as n (%) or mean ± standard deviation unless otherwise specified.

Table 5

Number Needed to Treat

Outcome	All GDM	NDDG	Carpenter Coustan Only
Cesarean Delivery	14	44	7
Gestational Hypertension/Preeclampsia	20	23	17
Shoulder Dystocia	40	25	187
LGA	14	10	23
Macrosomia	12	10	16