Original Research

Gestational Diabetes Screening

The International Association of the Diabetes and Pregnancy Study Groups Compared With Carpenter-Coustan Screening

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OBJECTIVE: To evaluate whether one-step gestational diabetes screening recommended by The International Association of the Diabetes and Pregnancy Study Groups (IADPSG) is associated with better maternal, perinatal, or neonatal outcomes than the two-step Carpenter-Coustan screening.

METHODS: In this before–after retrospective cohort study conducted between July 1, 2010, and December 31, 2013, we compared Carpenter-Coustan and IADPSG screening in patients with singleton pregnancies. All patients diagnosed with gestational diabetes received intensive teaching, home glucose monitoring, and medications as indicated. The primary outcome was the rate of large-for-gestational-age neonates. Secondary outcome measures were macrosomia (greater than 4,000 g), primary cesarean delivery, neonatal intensive care unit admission, preterm delivery, preeclampsia, and hyperbilirubinemia. We determined that a sample size of 2,782 per group was sufficient to detect a 2% difference in the primary outcome between groups with 80% power assuming a 10% incidence in the before group. The groups were compared using Fisher exact test for proportions and a χ^2 test for odds ratios.

RESULTS: In the before (Carpenter-Coustan) group, 513 (17%) of the 2,972 patients were diagnosed with gestational diabetes, and in the after (IADPSG) group, 847 (27%) of the 3,094 patients were so diagnosed ($P<.001$). There was no significant difference in rates of large for gestational age, 10% and 9%, respectively ($P=.25$). The IADPSG group had a significantly higher primary cesarean delivery rate—16% compared with 20% ($P<.001$), but there were no significant differences in any other pregnancy outcomes.

CONCLUSION: Although one-step screening was associated with more patients being treated for gestational diabetes, it was not associated with a decrease in large-for-gestational-age or macrosomic neonates but was associated with an increased rate of primary cesarean delivery. Our results did not support the IADPSG-recommended screening protocol.

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See related editorial on page 3.

Gestational diabetes has been associated with preterm delivery, preeclampsia, macrosomia (birth weight greater than 4,000 g), increased risk of cesarean delivery for arrest disorders, shoulder dystocia, neonatal hyperbilirubinemia, and respiratory distress syndrome[1–5] as well as the later development of noninsulin-dependent diabetes mellitus.[6] Some studies show an association between fetal exposure to uncontrolled maternal blood glucose and subsequent neonatal and childhood obesity.[7,8]

Much controversy exists about how to identify gestational diabetes and whether the benefits of intervention justify the expense, the anxiety, and the possible risks associated with this diagnosis. For many years, health care providers in the United States have screened for gestational diabetes using a two-step test early in gestation in those patients deemed to be at high risk and a second test at 24–28 weeks of gestation to average-risk patients.[9] Values were considered abnormal if they exceeded those recommended by either the Carpenter and Coustan[10] and Fourth International Workshop-Conference Criteria[11] or the values designated by the National Diabetes Data

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Group.[12] The American College of Obstetricians and Gynecologists continues to recommend this two-step approach.

Based on observational studies that specifically evaluated maternal, perinatal, and neonatal outcomes, The International Association of the Diabetes and Pregnancy Study Groups (IADPSG) and the World Health Organization recommended new criteria for the diagnosis of gestational diabetes.[13] They recommend that a hemoglobin A_{1C} (Hb A_{1c}), a random plasma glucose, or a fasting plasma glucose test be performed at the first prenatal visit to identify undiagnosed pregestational diabetics and that a one-step 2-hour glucose tolerate test with a 75-g glucose load be performed at 24–28 weeks of gestation for those not identified as having pregestational diabetes.

In this study we sought to address whether changing from the traditional two-step Carpenter-Coustan screening recommended by the American College of Obstetricians and Gynecologists to the one-step test recommended by The International Association of Diabetes and Pregnancy Study Groups would be associated with meaningful improvements in maternal, perinatal, or neonatal outcomes.

MATERIALS AND METHODS

In November 2011, our hospital and affiliated clinics switched from the two-step Carpenter-Coustan screening approach to the one-step approach recommended by the IADPSG. We performed a before–after retrospective cohort study that compared patients before and after the change. We extracted demographic and obstetric data from the electronic medical record and verified it by selective chart review.

The sample consists of singleton pregnancies managed from the first trimester within the Kaiser Permanente Baldwin Park Medical Center and its affiliated clinics between July 1, 2010, and December 31, 2013. Mothers who were classified as diabetic before pregnancy were excluded. To keep the before and after groups statistically independent, patients were excluded if they had more than one pregnancy in the study period.

For the primary outcome of large birth weight for gestational age and sex (LGA), we determined that a sample size of 5,564 (2,782 per group) would allow the detection of an absolute rate difference of 2% between groups assuming a rate of 10% in the before group with 80% power at the 0.05 (two-tailed) significance level.

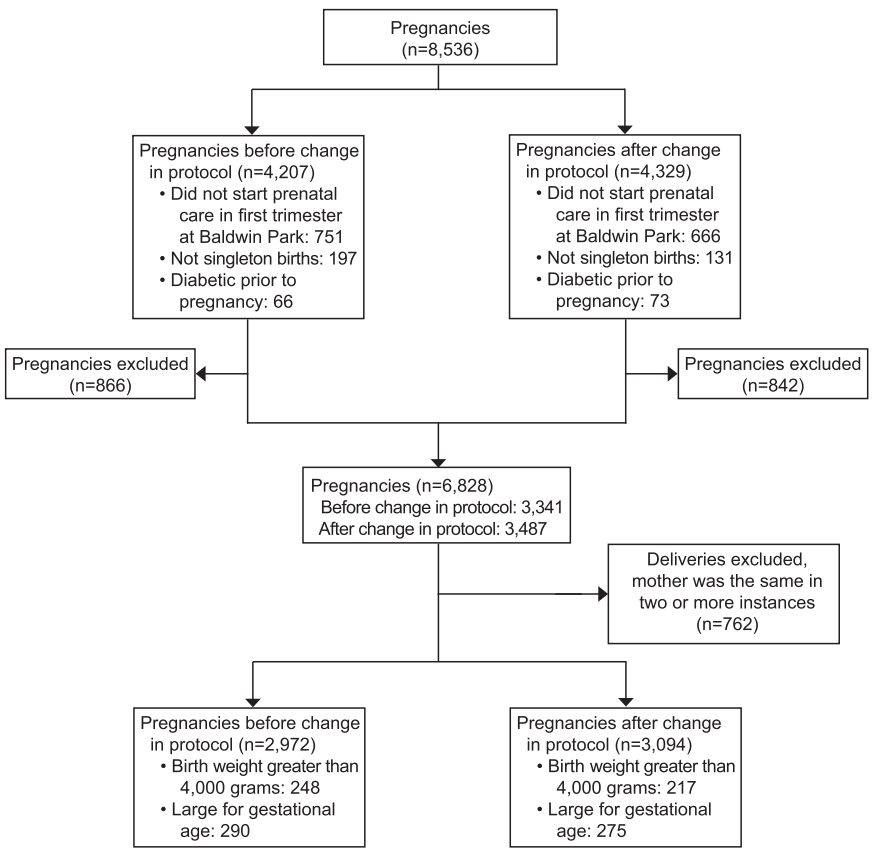

Fig. 1. Cohort selection criteria for before and after groups.

Feldman. Carpenter-Coustan Criteria vs IADPSG Criteria. Obstet Gynecol 2016.

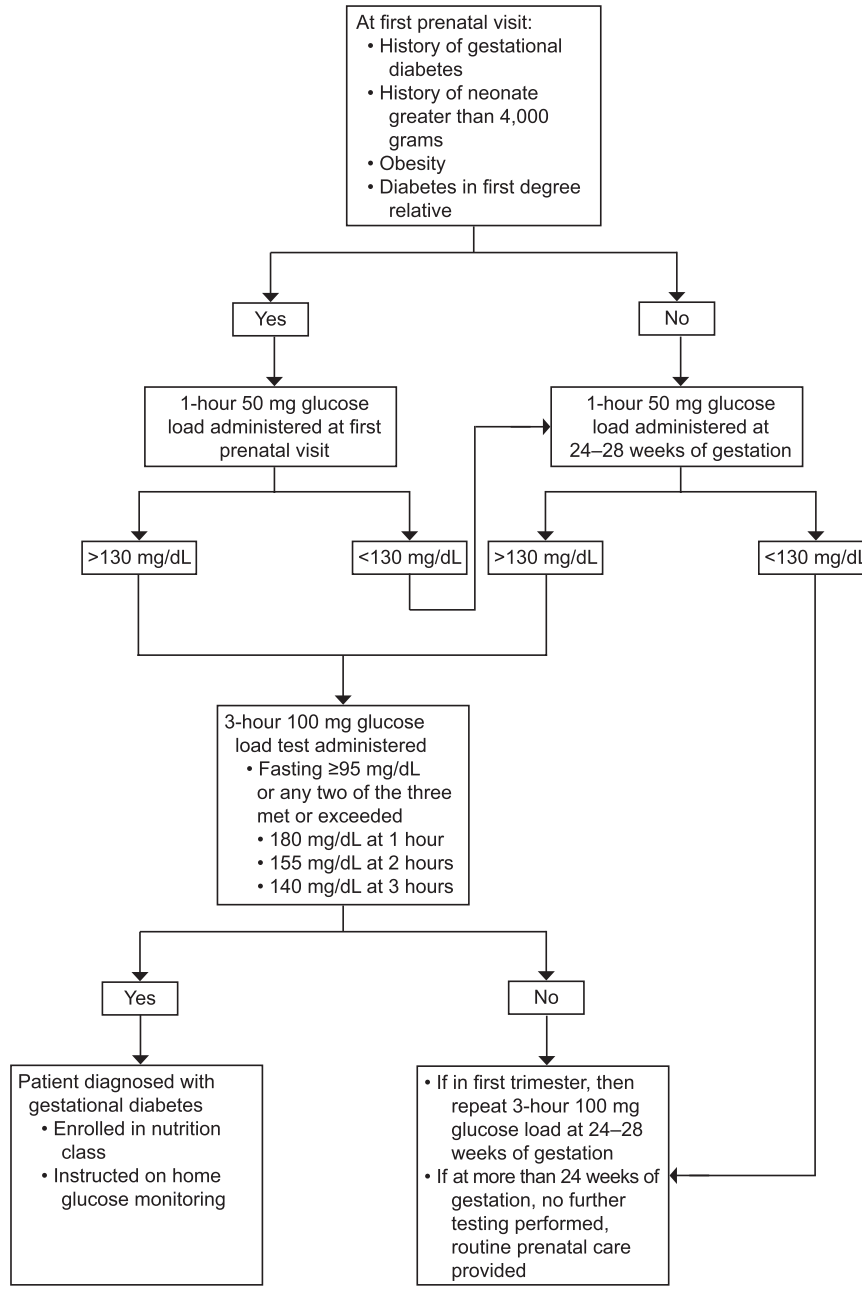

Fig. 2. The protocol for glucose screening in pregnancy before the change.

Feldman. Carpenter-Coustan Criteria vs IADPSG Criteria. Obstet Gynecol 2016.

Figures 1 and 2, respectively, illustrate the screening protocols used in the before and after groups. Patients with Hb A_{1c} levels of 6.5% or higher were considered to have overt diabetes. Because they had not been diagnosed with diabetes before the pregnancy, they were included in our treatment group and for statistical purposes were also categorized as having gestational diabetes. These patients were not excluded because our before group likely also had some patients with undiagnosed overt prepregnancy diabetes. Patients with Hb A_{1c} levels between 5.7 and 6.4 were diagnosed with prediabetes and were treated in a similar manner as those having gestational diabetes. For statistical purposes, they were also included with those having gestational diabetes.

The care of patients with gestational diabetes did not change over the time course of the study. Patients attended a nutrition class and began home glucose monitoring with a fasting and three postprandial tests. The patients were seen in the office every 1–4 weeks at the discretion of their health care provider.

Typically, if more than one third of the fasting results was greater than 95 mg/dL or one third of the postprandial tests greater than 130 mg/dL at 1 hour or 120 mg/dL at 2 hours, the patients were started on either insulin or glyburide at the discretion of their health care provider. During this study metformin was used only in isolated cases. Patients who were prescribed any medication were monitored with twice-weekly fetal nonstress tests and amniotic fluid index measurement from 34 to 36 weeks of gestation to delivery. Patients who required medication were induced at 39 weeks of gestation if they had not gone into labor spontaneously. Patients who did not require medication were induced by 42 weeks of gestation.

We described the characteristics of the before and after groups using means with standard deviations or medians with interquartile regions for continuous variables. For discrete variables, we used percentages and counts. *P* values were obtained using Fisher test for proportions and Wilcoxon for continuous variables.

The primary study outcome was LGA, defined as a birth weight greater than the 90th percentile for gestational age and sex. The odds ratio between the two groups was computed, and an unadjusted comparison of the before and after groups was done using a χ^2 test. We used a logistic regression model to compare the two groups adjusting for certain covariates.

Secondary outcomes included neonatal intensive care unit admission, preterm delivery (before 37 weeks of gestation), preeclampsia, and hyperbilirubinemia (which was inferred if phototherapy was used). A secondary analysis was performed to evaluate the association of body mass index (BMI, calculated as weight (kg)/[height (m)]^2) with the primary and secondary outcome measures. Body mass index was treated as a continuous variable. We used a logistic regression model to adjust for certain covariates.

This study was approved by the Kaiser Permanente Southern California institutional review board.

RESULTS

After exclusions, the final sample included 6,066 pregnancies (2,972 before protocol change and 3,094 after protocol change; Fig. 3; Table 1). The average maternal age of the two groups was 30 years. The median BMI at the first prenatal care visit for both groups was not significantly different. There was a greater proportion of patients with gestational diabetes mellitus in the after group (27% compared with 17%, $P<.001$) and more patients being diagnosed with prediabetes (15% compared with 4%, $P<.001$). There was no significant difference in rates of LGA, 10% in the before group and 9% in the after, respectively ($P=.25$). No significant difference was noted in the median number of perinatal encounters or in the proportion of patients who underwent labor induction. Although no significant difference existed in the number of patients being treated with metformin, a greater number was treated with insulin and glyburide in the after group. There was no significant difference in prenatal weight at the first prenatal care visit between the two groups ($P=.67$).

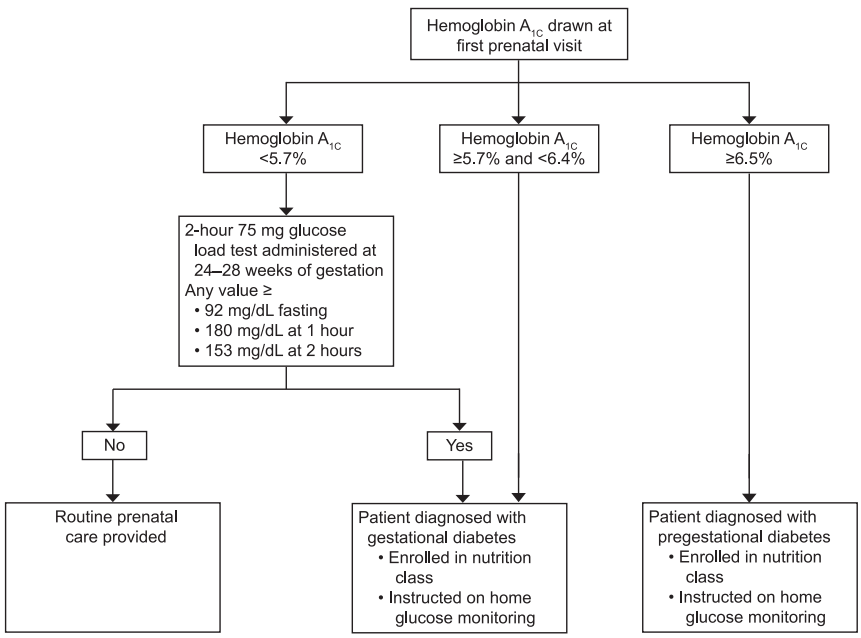

Fig. 3. The protocol for glucose screening in pregnancy after the change.

Feldman. Carpenter-Coustan Criteria vs IADPSG Criteria. Obstet Gynecol 2016.

Table 1. Summary Statistics

Characteristics and Interventions	Protocol		*P*
	Before	After	
Total	2,972 (49)	3,094 (51)	
Maternal age (y)	30.3±5.6	30.2±5.7	.45
Ethnicity			.28
White	442 (15)	418 (14)	
Black	74 (2)	73 (2)	
Hispanic	1,799 (61)	1,871 (60)	
Asian Pacific Island	589 (20)	674 (22)	
Native American or Alaskan Native	5 (0)	7 (0)	
Other	59 (2)	46 (1)	
Unknown	4 (0)	5 (0)	
English speaker	2,737 (92)	2,872 (93)	.28
Parity			<.001
0	892 (31)	1,049 (40)	
1	1,068 (40)	973 (37)	
2 or more	753 (28)	601 (23)	
Prior cesarean delivery	432 (15)	438 (15)	.61
Induction of labor	538 (18)	585 (19)	.43
Hypertension	129 (4)	179 (6)	.012
GDM	513 (17)	847 (27)	<.001
Prediabetes	128 (4)	457 (15)	<.001
Treatment			
Insulin	134 (5)	121 (6)	.02
Glyburide	15 (1)	126 (4)	<.001
Metformin	28 (1)	25 (1)	.58
Perinatal encounter counts	15.0 (12.0–17.0)	15.0 (11.0–17.0)	.079
Prenatal BMI (kg/m^2)	26.1 (22.9–30.8)	26.1 (22.9–30.3)	.70
Prenatal weight (lb)*	150.0 (129.0–178.0)	149.0 (130.0–176.0)	.67
Predelivery weight (lb)†	175.6 (155.0–201.0)	174.0 (154.0–198.0)	.037
Postpartum weight (lb)‡	155.0 (136.0–180.2)	153.0 (134.6–177.0)	.037
Prenatal to postpartum change (lb)	4.54±12.50	2.91±12.43	<.001
Predelivery to postpartum change (lb)	−20.18±7.19	−20.14±7.19	.23

GDM, gestational diabetes mellitus; BMI, body mass index.
Data are n (%), mean±standard deviation, or median (interquartile range) unless otherwise specified.
P values obtained using Fisher test for proportions and Wilcoxon test for continuous variables.
* Weight at first prenatal care visit.
† Weight at last prenatal care visit before delivery.
‡ Weight at postpartum care visit.

Mothers in the before group had a higher median weight than those in the after group both at the last visit before delivery and at the postpartum checkup 4 weeks after the delivery. There was a significant difference between the before and after groups in weight change from the first prenatal care visit to the postpartum checkup. However, this change was too small to be clinically significant.

A significant difference in frequency of cesarean deliveries was noted between the before and after groups, even among patients not diagnosed with gestational diabetes (Table 2). However, there was no significant difference in the adjusted odds of cesarean deliveries resulting from arrest disorders between the two groups. Table 3 shows that the odds of having a primary cesarean delivery were significantly greater in the after group. However, no significant difference was noted in the odds of having LGA (greater than the 90th percentile for age and sex) between the before and after groups. In contrast, a statistically significant difference in LGA neonates, macrosomia, and primary cesarean delivery was noted between patients with different BMIs at the first prenatal visit (Table 4).

DISCUSSION

In our study cohort, the use of the one-step IADPSG protocol for gestational diabetes screening instead of the two-step approach using the Carpenter-Coustan criteria cutoffs was associated with an increase in the rate of gestational diabetes from 17% to 27%. However, the IADPSG approach was not associated with a lower rate of LGA neonates, macrosomia, neonatal

Table 2. Pregnancy Outcomes

Pregnancy Outcomes	Protocol		
	Before	After	*P*
Total	2,972 (49)	3,094 (51)	
LGA	290 (10)	275 (9)	.25
Macrosomia	248 (8)	217 (7)	.054
NICU admission	121 (4)	170 (5)	.01
Preterm birth	228 (8)	254 (8)	.45
Total cesarean deliveries	731 (26)	923 (30)	<.001
Primary cesarean delivery*	409 (16)	543 (20)	<.001
Cesarean delivery as a result of arrest disorder	221 (7)	286 (9)	.012
Preeclampsia	89 (3)	134 (4)	.006
Hyperbilirubinemia	265 (9)	315 (10)	.097
Shoulder dystocia	12 (0)	8 (0)	.37
Cesarean deliveries in patients without GDM†	594 (25)	625 (28)	.01
Cesarean deliveries in patients with GDM‡	137 (29)	298 (36)	.01
Fetal demise at greater than 20 wk of gestation	16 (0.5)	18 (0.6)	.86

LGA, large for gestational age; NICU, neonatal intensive care unit; GDM, gestational diabetes mellitus.
Data are n (%) unless otherwise specified.
P values obtained using Fisher test for proportions and Wilcoxon for continuous variables.
* Patients with prior cesarean deliveries not included. There were 2,540 patients before and 2,565 patients after the protocol change that did not have a prior cesarean delivery.
† There were 4,577 patients without GDM (2,375 before and 2,202 after).
‡ There were 1,298 patients without GDM (472 before and 826 after).

Table 3. Unadjusted and Adjusted Odds Ratios With the Before Group as the Referent Group

Pregnancy Outcomes, Before vs After	OR (95% CI)	Adjusted OR (95% CI)
LGA	0.9 (0.76–1.07)	0.84 (0.68–1.03)
Macrosomia	0.83 (0.69–1)	0.81 (0.65–1.01)
NICU admissions	1.37 (1.08–1.74)*	1.24 (0.94–1.65)
Preterm births	1.08 (0.89–1.3)	1.03 (0.82–1.3)
Total cesarean deliveries	1.27 (1.13–1.42)†	1.22 (1.06–1.4)*
Primary cesarean deliveries	1.3 (1.13–1.5)‡	1.2 (1.01–1.42)§
Cesarean deliveries as a result of arrest disorders	1.27 (1.06–1.52)	1.12 (0.9–1.39)
Preeclampsia	1.47 (1.12–1.93)*	1.73 (0.87–3.51)
Hyperbilirubinemia	1.16 (0.98–1.38)‖	1.13 (0.92–1.38)
Shoulder dystocia	0.64 (0.25–1.55)	0.69 (0.25–1.76)

OR, odds ratio; CI, confidence interval; LGA, large for gestational age; NICU, neonatal intensive care unit.
Adjusted odds ratios account for maternal age, race–ethnicity, parity, prenatal body mass index measured at first prenatal care visit, and hypertension status.
Significance codes:
* .01.
† .0001.
‡ .001.
§ .05.
‖ .1.

intensive care unit admissions, preterm births, preeclampsia, shoulder dystocia, or hyperbilirubinemia.

In contrast, a number of studies have noted that treating patients with glucose intolerance below the Carpenter-Coustan criteria can reduce the number of LGA fetuses. Bonomo et al and Bevier et al showed that treating women with an elevated 50-g glucose challenge test but a normal 100-g glucose tolerance test resulted in fewer LGA neonates.[14,15] Crowther et al[16] showed that treating women diagnosed with gestational diabetes by a 50- g oral glucose challenge test followed by a 75-g oral glucose tolerance test decreased serious perinatal complications. The IADPSG extrapolated from these studies that expanding the number of patients diagnosed with and treated for gestational diabetes would result in fewer LGA neonates. However, the current study does not support that hypothesis. The cutoffs chosen by the IADPSG, based on the results of the Hyperglycemia and Adverse Pregnancy Outcomes study,[17,18] may be too low and thus result in too many patients being treated as having gestational diabetes. Different cutoff values need to be evaluated and more attention needs to be focused on controlling prepregnancy BMI.

Interestingly, this study reaffirmed other studies that found a high correlation between BMI and proportion of LGA neonates.[8,19,20] Black et al followed women who were found to have IADPSG-defined gestational diabetes but who were not treated. They found that prepregnancy maternal obesity had a greater effect on the proportion of LGA neonates than did untreated gestational diabetes.[19] Di Benedetto et al[20] evaluated nondiabetic women and found that those who were obese and overweight had a significantly greater percentage of macrocosmic neonates than women who were not obese and not diabetic. Pettitt et al[1] in evaluating gestational diabetes in Pima Indians noted that maternal weight, maternal age, and third-trimester glucose values were so closely related that it was difficult to discern which had the greatest effect. These studies taken together with the current one suggest that a renewed focus on reducing prepregnancy overweight and obesity rates may result in a smaller proportion of LGA neonates.

A strength of this study is that the same physicians treated patients who came from the same community

Table 4. Unadjusted and Adjusted Odds Ratios for Events by Body Mass Index at First Prenatal Care Visit

Pregnancy Outcomes, Before vs After	OR (95% CI)	Adjusted OR (95% CI)
LGA	1.08 (1.06–1.09)*	1.07 (1.06–1.09)*
Macrosomia	1.07 (1.05–1.09)*	1.06 (1.04–1.08)*
NICU admissions	1.01 (0.99–1.03)	0.99 (0.97–1.02)
Preterm births	1.04 (1.02–1.05)*	1.02 (1–1.03)
Total cesarean deliveries	1.05 (1.03–1.06)*	1.04 (1.03–1.05)*
Primary cesarean deliveries[§]	1.03 (1.02–1.05)*	1.03 (1.02–1.05)[†]
Cesarean deliveries as a result of arrest disorders	1.02 (1.01–1.04)[‡]	1.03 (1.01–1.05)[‡]
Preeclampsia	1.07 (1.04–1.09)*	0.97 (0.93–1.01)
Hyperbilirubinemia	1.01 (0.99–1.03)	1.01 (0.99–1.03)
Shoulder dystocia	1.08 (1.02–1.15)[‡]	1.06 (0.99–1.13)*

OR, odds ratio; CI, confidence interval; LGA, large for gestational age; NICU, neonatal intensive care unit.

Adjusted odds ratios account for maternal age, race–ethnicity, parity, and hypertension status. Body mass index was treated as a continuous variable.

Significance codes:

* .0001.

† .001.

‡ .01.

§ Patients with prior cesarean deliveries not included. There were 2,540 patients before and 2,565 patients after the protocol change that did not have prior cesarean delivery.

using the same treatment for gestational diabetes for both the before and after time periods. However, this strength may limit the generalizability of the results. The population studied had a majority Hispanic and Pacific Islander and Asian ethnicity. For this population, the rate of gestational diabetes by either testing criteria is higher than what has been reported in other studies with more diverse populations.[21] Furthermore, as a retrospective analysis, this study has inherent limitations. Changes in practice patterns do occur over time as noted by the increase in cesarean deliveries even in patients who did not have gestational diabetes. However, the increase in total cesarean deliveries between the before and after groups was even greater. The difference between the increase that can be accounted for by changes in practice pattern and the total increase suggests that changing the testing criteria contributed to the increase in cesarean deliveries. This study grouped patients with prediabetes with those who developed gestational diabetes in the late second trimester. These two groups may be intrinsically different and may require a different treatment approach. A study evaluating the differences between these two groups and how they respond to treatment may result in a smaller proportion of LGA neonates and possibly even cesarean deliveries.

In summary, in this study, the IADPSG screening method for gestational diabetes was not associated with a reduction in LGA newborns or cesarean deliveries but was associated with a higher rate of gestational diabetes.

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