



Evaluation of Early Screening for Diabetes Mellitus in Pregnancy with Hemoglobin A1c

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Abstract

Early diabetes screening is recommended for high-risk pregnant women risk via a 1-hour glucose challenge test (1-hour GCT). Hemoglobin A1c (HbA1c) can be obtained with initial obstetric laboratories. We sought to examine the relationship between HbA1c and 1-hour GCT for early diabetes screening in pregnancy.

This is a retrospective cohort study of 204 high-risk pregnant women who underwent early HbA1c and 1-hour GCT. Simple logistic regression analysis was performed to predict abnormal 1-hour GCT and diagnosis of diabetes using HbA1c.

A total of 158 (77.5%), 44 (21.5%), and 2 (1%) women had HbA1c of less than 5.7, 5.7 to 6.4, and 6.5% or higher, respectively. Seven of 158 (4.4%) women with HbA1c less than 5.7% and 8 of 44 (18.2%) with HbA1c of 5.7 to 6.4% had a diagnosis of diabetes. A positive correlation between early HbA1c and 1-hour GCT was detected. Logistic regression showed HbA1c significantly predicted the risk of diabetes but was not a good predictor of abnormal 1-hour GCT. HbA1c of 5.5% or less had a 97% or higher negative predictive value for early diabetes in pregnancy.

There is a positive correlation between HbA1c and 1-hour GCT for the early screening of diabetes in pregnancy. Women with early HbA1c \leq 5.5% could forego further testing in early pregnancy.

Keywords

- ▶ diabetes
- ▶ pregnancy
- ▶ screening
- ▶ glucose challenge test
- ▶ hemoglobin A1c

Maternal diabetes mellitus has been of rising concern in the last four decades because of its increasing incidence and association with both maternal and fetal complications.^{1–3} Diabetes varies with population and complicates approximately 6 to 9% of pregnancies, with 90% of diagnosed cases being gestational diabetes.^{4,5} The American College of Obste-

tricians and Gynecologists (ACOG) recommends early screening in high-risk women (**Table 1**).⁶ In the United States, this screening is commonly performed using the 1-hour glucose challenge test (1-hour GCT), which consists of ingesting a 50-g glucose solution and measuring the venous glucose level an hour later.⁶ In the United States, an

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Table 1 Screening strategy for detecting diabetes in early pregnancy (pregestational or early gestational)

Consider testing in all women who are overweight or obese (i.e., have a body mass index $> 25 \text{ kg/m}^2$ or $> 23 \text{ kg/m}^2$ in Asian Americans) and have one or more of the following additional risk factors:
• Physical inactivity
• First-degree relative with diabetes
• High-risk race or ethnicity (e.g., African American, Latino, Native American, Asian American, Pacific Islander)
• Have previously given birth to an infant weighing 4,000 g (~9 lbs) or more
• Previous gestational diabetes mellitus
• Hypertension (140/90 mm Hg or on therapy for hypertension)
• High-density lipoprotein cholesterol level less than 35 mg/dL (0.90 mmol/L)
• A triglyceride level greater than 250 mg/dL (2.82 mmol/L)
• Women with polycystic ovarian syndrome
• A1C greater than or equal to 5.7%, impaired glucose tolerance, or impaired fasting glucose on previous testing ^a
• Other clinical conditions associated with insulin resistance (e.g., prepregnancy body mass index greater than 40 kg/m^2 , acanthosis nigricans)
• History of cardiovascular disease

^aDefined by the American Diabetes Association as fasting plasma glucose (FPG) of 100 to 125 mg/dL and impaired glucose tolerance (IGT) defined as 2-hour plasma glucose of 140 to 200 mg/dL after ingestion of 75 g of oral glucose load or a combination of the two based on a 2-hour oral glucose tolerance test.

elevated 1-hour GCT is followed by a 100-g 3-hour glucose tolerance test (3-hour GTT) to diagnose diabetes in pregnancy.⁶

In view of the high prevalence of overweight and obesity in the U.S. population, using the ACOG high-risk criteria suggests that a substantial number of pregnant women would require an early screening for diabetes in pregnancy. Implementing this strategy would increase the cost of testing and incidence of nausea and vomiting that often accompany the ingestion of the glucose solution. Looking at a potential alternative strategy could be of benefit.

Hemoglobin A1c (HbA1c) is a blood test that evaluates a patient's prior 2- to 3-month glycemic status. Our department implemented a new protocol in August 2018 for early diabetes screening in pregnancy in which HbA1c was added to the routine prenatal laboratory panel drawn at the first prenatal visit. We hypothesized that HbA1c results are highly correlated with 1-hour GCT in women who meet the ACOG criteria for early diabetes screening. The aim of our study was to determine an HbA1c value above which most or all women would test positive on the 1-hour GCT, forego the early screening test, and otherwise have the diagnostic 3-hour GTT.

Materials and Methods

This was a retrospective cohort study of all pregnant women at 20 weeks or less seen at our ambulatory clinics between August 2018 and December 2019 in Washington, DC. Med-Star Institutional Review Board approved this study (IRB number 2018-229). Women who were 18 years or older and without diabetes who presented for initiation of prenatal care prior to 20 weeks were included. We excluded women with diabetes and those who did not have HbA1c or 1-hour GCT done prior to 20 weeks' gestation.

Our departmental protocol was as follows:

- (1) All women received HbA1c at their first prenatal visit along with their prenatal panel.
- (2) Women who met the ACOG criteria for eligibility for early screening for diabetes⁶ underwent the 50-g 1-hour GCT at the first or second obstetric visit.
- (3) Women with elevated 1-hour GCT ($\geq 135 \text{ mg/dL}$) underwent a confirmatory 3-hour GTT at a later visit.

Our primary outcome was the diagnosis of diabetes mellitus in early pregnancy (pregestational or early gestational) using the Carpenter and Coustan definitions as confirmed by a 3-hour GTT.⁶

Definitions

A 1-hour GCT is a screening test with 50-g oral glucose intake followed by measurement of serum glucose 1 hour after ingestion.

A 3-hour GTT is a diagnostic test for diabetes in pregnancy using 100-g oral glucose solution, with serum glucose measurements at zero (fasting), 1, 2, and 3 hours subsequently. An abnormal 3-hour GTT is defined as two or more abnormal values on Carpenter and Coustan scale ($> 95 \text{ mg/dL}$ fasting, $> 180 \text{ mg/dL}$ at 1 hour, $> 155 \text{ mg/dL}$ at 2 hours, and $> 140 \text{ mg/dL}$ at 3 hours).

Interpretation of Hemoglobin A1c and 1-hour Glucose Challenge Test (► Fig. 1)

At less than 20 weeks' gestation, HbA1c 6.5% or more was diagnostic of diabetes in pregnancy as defined by the American Diabetes Association⁷ and endorsed by the International Association of the Diabetes and Pregnancy Study Groups in early pregnancy.⁸ We considered the diagnosis of pregestational diabetes (or type II diabetes) when HbA1c result was at

less than 14 weeks' gestation and gestational diabetes when HbA1c result was at 14 weeks' gestation or more. All women with HbA1c 6.5% or more did not have 1-hour GCT unless it was done on the same day of the HbA1c draw and they did not have a 3-hour GTT.

Women with HbA1c less than 6.5% underwent the 1-hour GCT if they met the ACOG criteria for early screening (► **Table 1**). If they were not candidates for early screening, the 1-hour GCT was administered at 24 to 28 weeks' gestation per standard of care.⁹

If the 1-hour GCT was less than 135 mg/dL, the early screening test was considered negative; the 1-hour GCT was then repeated at 24 to 28 weeks per standard of care.⁹

If the 1-hour GCT was 200 mg/dL or more, the patient was diagnosed with diabetes (pregestational diabetes [or type II diabetes] at less than 14 weeks and gestational diabetes at 14 weeks' or more).

If the 1-hour GCT was 135 mg/dL or more, the screening test was considered positive and a diagnostic 100-g 3-hour GTT was performed.⁶

If the 3-hour GTT test was positive by the above criteria, the patient was diagnosed with diabetes (pregestational diabetes [or type II diabetes] at less than 14 weeks' and gestational diabetes at 14 weeks' or more). If the test was negative, another 3-hour GTT was performed at 24 to 28 weeks per standard of care.⁶

If a patient had completed both HbA1c and 1-hour GCT, had an abnormal 1-hour GCT but did not complete her 3-hour GTT, she received the diagnosis of diabetes based on a 72-hour log of fingerstick glucose tests showing more than 50% elevated fasting values (>95 mg/dL) and/or elevated 2-hour postprandial values (>120 mg/dL). Rarely,

the diagnosis was made presumptively based on the patient's clinical risk (► **Fig. 1**).

The electronic medical record (EMR-Cerner) was used to extract data. Two of the study authors extracted data by chart review and data collected were saved in Redcap. Cross-checking of data collected was done by the extracting authors to ensure accuracy. We examined maternal demographics including age, gravidity, parity, body mass index (kg/m²) at the first prenatal visit, race/ethnicity, marital status, medical, obstetric, and family history to detect the ACOG criteria for early screening of diabetes in pregnancy, HbA1c, early 1-hour GCT, the 3-hour GTT, and the gestational age at which HbA1c and 1-hour GCT were collected. Women who did not get both HbA1c and 1-hour GCT completed before 20 weeks of gestation were excluded.

Statistical Analysis

Descriptive statistics were calculated for all study variables. Logistic regression analysis was performed to predict abnormal 1-hour GCT (≥ 135) and diagnosis of diabetes, respectively, using the level of HbA1c. Receiver operating characteristic (ROC) curve was then developed from each regression model, and the area under ROC curve (AUC) was estimated to evaluate the predictive performance. Youden's J statistic was utilized to obtain the optimal HbA1c value with corresponding sensitivity and specificity for detecting an abnormal 1-hour GCT and a diagnosis of early diabetes. We further investigated the association between HbA1c and early 1-hour GCT results as two continuous variables by calculating a Pearson correlation coefficient. In our analysis, we also aimed to find an HbA1c value above which all women tested positive for 1-hour GCT as well as an HbA1c value

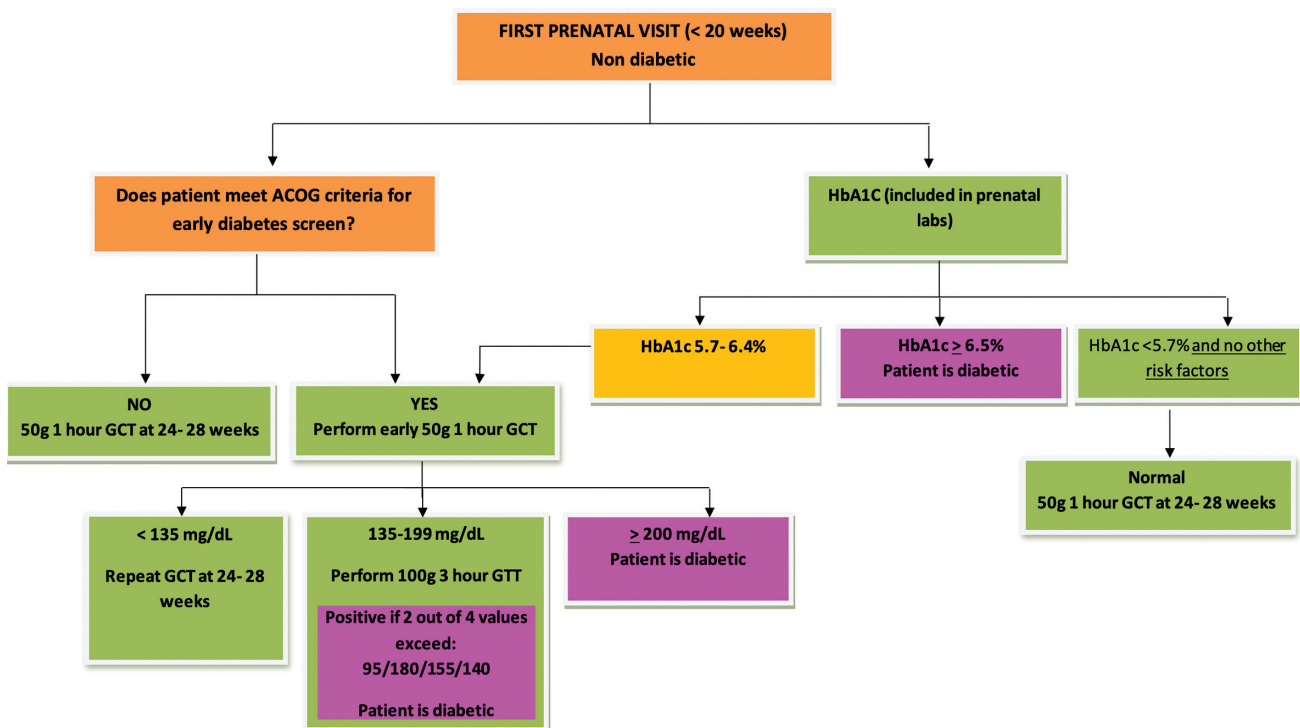


Fig. 1 Screening and management diagram. ACOG, American College of Obstetricians and Gynecologists; GCT, 50-g glucose challenge test; GTT, 100-g glucose tolerance test; HbA1c, hemoglobin A1c.

below which all 1-hour GCTs were negative. We used the Student's *t*-distribution for testing the Pearson correlation coefficient, whereas Mann–Whitney U test was applied for testing whether AUC is significantly different from 0.5. All statistical analyses were performed using the SAS 9.4 software.

Sample Size Calculation

Assuming a 10% prevalence of gestational diabetes based on the historical data, a sample size of 180 had 80% power to detect a difference of 0.2 between the area under the ROC curve (AUC) under the null hypothesis of 0.5 and that under the alternative hypothesis of 0.7 using a two-sided z-test at a significance level of 0.05.

Results

A total of 204 women were identified between August 2018 and December 2019 who had both 1-hour GCT and HbA1c done before 20 weeks of gestation. Maternal demographic and clinical characteristics are presented in **Table 2**. In our study population, HbA1c was drawn at a median of 8.86 weeks' gestation.

Of these 204 women, 17 (8.3%) women were diagnosed with diabetes (pregestational or early gestational). Two out of 17 (11.7%) were diagnosed with diabetes based on an HbA1c value of 36.5% and a 1-hour GCT 200 mg/dL or more and 9 (53%) women were diagnosed with diabetes based on an abnormal 3-hour GTT. An additional 6 (35.3%) women who had abnormal 1-hour GCT did not complete their 3-hour GTT, 3 of whom were diagnosed with diabetes based on their glucose logs, and 3 were presumptively diagnosed based on their high-risk profile. A total of 187 (91.7%) women had negative screening for diabetes (1-hour GCT < 135; **Fig. 2**).

The prevalence of diabetes in our study population was 8.3%. The number needed to screen for a diagnosis of diabetes in early pregnancy was 12 (204/17).

Table 2 Maternal characteristics of study patients

Characteristic	N = 204
Age (y)	30.67 (± 5.67)
Body mass index	36.24 (± 7.66)
Gestational age (wk) at HbA1c draw	10.06 (± 3.80)
Gestational age (wk) at 1-h GCT draw	13.89 (± 3.53)
Gravidity	2 (1–5)
Parity	1 (0–2)
Race ^a	
American Indian or Alaska	3 (1.49%)
Asian	9 (4.46%)
Black or African American	162 (80.20%)
Hispanic or Latino	10 (4.95%)
White	13 (6.44%)
Other	5 (2.48%)
Smoking ^a	6 (2.94%)
Alcohol ^a	20 (10.53%)
Previous GDM ^a	23 (11.44%)
HbA1c ≥ 5.7	46 (22.55%)

Abbreviations: GDM, gestational diabetes mellitus; HbA1c, hemoglobin A1c; 1-h GCT, 1-hour glucose challenge test.

Note: Data are expressed as mean ± standard deviation, median (10th tile–90th tile) or number (%).

^aPatient characteristics were unavailable in some charts.

Our analysis showed a sensitivity of 11.76% for HbA1c to detect diabetes with a specificity of 100% (HbA1c ≥ 6.5% identified diabetes in 11.76% of women in our study). The 1-hour GCT had a sensitivity of 100% to detect diabetes with a specificity of 86.1%. The median HbA1c value for the women with normal 1-hour GCT (< 135) was 5.3% (10th %tile–90th %tile: 4.9–5.8) and the median HbA1c value

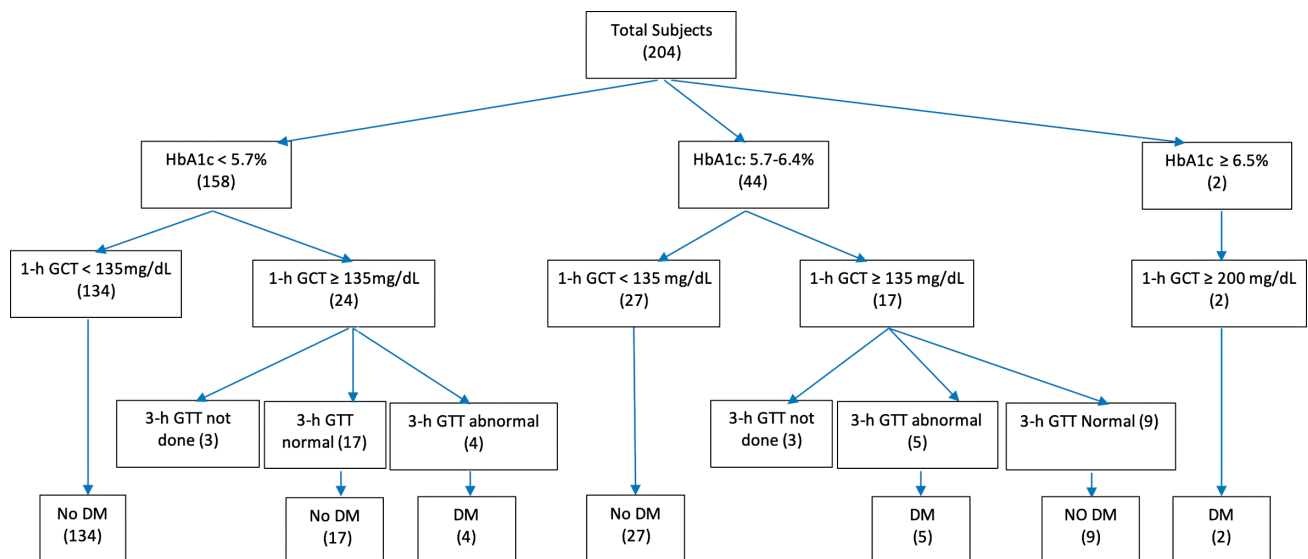


Fig. 2 Patient flowchart. Patient flow according to HbA1c, 1-hour GCT testing, and diabetes diagnosis. DM, diabetes mellitus; GCT, 50-g glucose challenge test; GTT, 100-g glucose tolerance test; HbA1c, hemoglobin A1c.

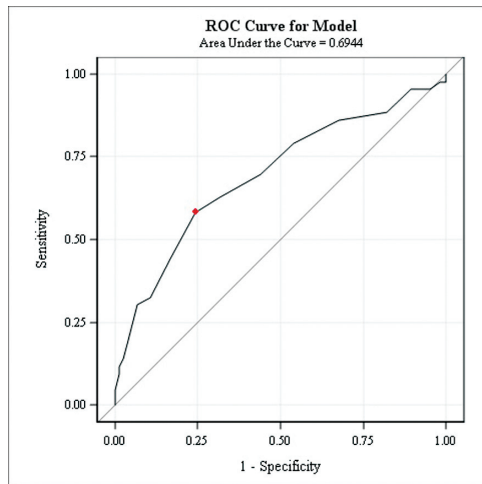


Fig. 3 ROC curve result for HbA1c and the 1-hour GCT. Optimal HbA1c cutoff point: 5.6 (red dot). AUC: 0.69 (95% CI: 0.60–0.79) $p < 0.0001$. Sensitivity: 0.58 and specificity: 0.76. AUC, area under the curve; CI, confidence interval; 1-hour GCT, 1-hour 50-g glucose challenge test; HbA1c, hemoglobin A1c; ROC, receiver operating characteristic.

for the women with abnormal 1-hour GCT was 5.6% (10th %tile–90th %tile: 5.0–6.2).

The ROC curves for predicting abnormal 1-hour GCT and diabetes using HbA1c are shown in ►Figs. 3 and 4, respectively. An HbA1c of 5.5% was found to provide optimal sensitivity and specificity for the diagnosis of diabetes in early pregnancy. The AUC was 0.82 (95% confidence interval [CI], 0.72–0.92), and HbA1c of 5.5% had a sensitivity of 88.24% for the diagnosis of diabetes (►Fig. 4). In ►Fig. 3, an HbA1c of 5.6% was found to provide optimal sensitivity and specificity for an abnormal 1-hour GCT. The AUC was 0.69 (95% CI, 0.60–0.79), and HbA1c of 5.6% had a sensitivity of 58% for an abnormal 1-hour GCT, indicating that an HbA1c alone likely cannot substitute for routine testing in all women. There was a significantly positive correlation detected

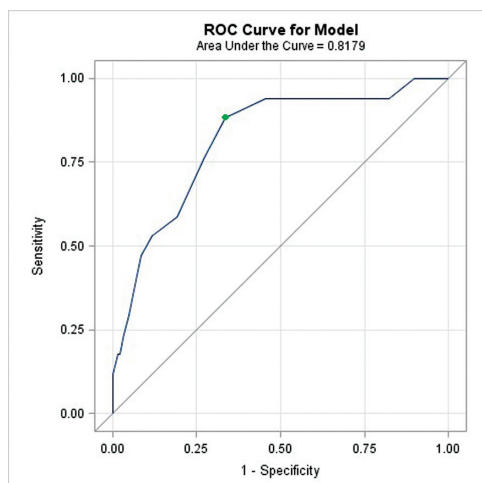


Fig. 4 ROC curve result for HbA1c and the diagnosis of diabetes. Optimal cutoff point: 5.5 (green dot). AUC: 0.82 (95% CI: 0.71–0.92) $p < 0.0001$. Sensitivity: 0.88 and specificity: 0.66. AUC, area under the curve; CI, confidence interval; HbA1c, hemoglobin A1c; ROC, receiver operating characteristic.

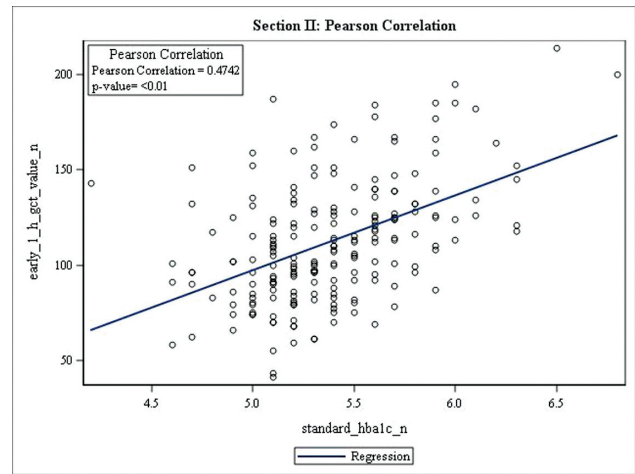


Fig. 5 Pearson correlation results: scatter plot of early 1-hour GCT and HbA1c with linear regression line. 1-hour GCT, 1-hour 50-g glucose challenge test; HbA1c, hemoglobin A1c.

between HbA1c and early 1-h GCT with a Pearson correlation coefficient of 0.47, p -value less than 0.01 (►Fig. 5).

In our analysis, we also aimed to find an HbA1c value above which all women tested positive for 1-hour GCT as well as an HbA1c value below which all 1-hour GCTs were negative. ►Tables 3 and 4 provide the sensitivity and specificity values along with negative predictive value (NPV) and positive predictive value (PPV) for all HbA1c results by 0.1%.

With HbA1c values of less or equal to 5.5%, NPV predicting the diagnosis of diabetes ranged 97 to 100% with most of our women (140/204 = 68.6%) having an HbA1c in that range. The NPVs predicting an abnormal 1-hour GCT ranged 0 to 90%.

We were unable to identify the HbA1c value above which all early 1-hour GCTs would be abnormal. For example, with HbA1c values of 6% or more, PPVs predicting an abnormal 1-hour GCT ranged from 57 to 100%.

Discussion

In this cohort of women, we report our experience in evaluating the results of universal first visit HbA1c for the early screening of diabetes in pregnancy (pregestational or early gestational). Our main findings include:

- HbA1c of 5.5% or less is a strong predictor for the absence of diabetes early in the pregnancy. With an NPV of 97% or more for women with HbA1c of 5.5% or less we can safely rule out the diagnosis of diabetes in early pregnancy and 1-hour GCT can be deferred. The patient would then be able to have only one test at 24 to 28 weeks' gestation.
- HbA1c level itself is a weak predictor for having an abnormal 1-hour GCT, having a wide range of PPV and NPV. However, it could be a good predictor for the diagnosis of diabetes with a sensitivity of 88.24% at the optimal, predicting HbA1c value of 5.5% (►Table 4).
- There is no specific cutoff point for early HbA1c above which we could safely conclude that the majority of the women would have an abnormal 1-hour GCT. Therefore, we were not able to determine an HbA1c cutoff value

Table 3 Sensitivity and specificity values for predicting abnormal 1-hour glucose challenge test (≥ 135 mg/dL) by each level of hemoglobin A1c as cutoff

HbA1c cutoff	True+	True–	False+	False–	NPV (%)	PPV (%)	SEN (%)	SPE (%)
6.8	1	161	0	42	79	100	2	100
6.7	1	161	0	42	79	100	2	100
6.6	1	161	0	42	79	100	2	100
6.5	2	161	0	41	80	100	5	100
6.4	2	161	0	41	80	100	5	100
6.3	4	159	2	39	80	67	9	99
6.2	5	159	2	38	81	71	12	99
6.1	6	157	4	37	81	60	14	98
6.0	8	155	6	35	82	57	19	96
5.9	13	150	11	30	83	54	30	93
5.8	14	144	17	29	83	45	33	89
5.7	19	134	27	24	85	41	44	83
5.6	25	122	39	18	87	39	58	76
5.5	27	110	51	16	87	35	63	68
5.4	30	90	71	13	87	30	70	56
5.3	34	74	87	9	89	28	79	46
5.2	37	52	109	6	90	25	86	32
5.1	38	29	132	5	85	22	88	18
5.0	41	17	144	2	89	22	95	11
4.9	41	10	151	2	83	21	95	6
4.8	41	8	153	2	80	21	95	5
4.7	42	3	158	1	75	21	98	2
4.6	42	0	161	1	0	21	98	0

Abbreviations: 1-hour GCT, 1-hour glucose challenge test; HbA1c, hemoglobin A1c; NPV, negative predictive value; PPV, positive predictive value; SEN, sensitivity; SPE, specificity.

Note: The optimal cutoff is 5.6 based on Youden's J statistic.

above which we could recommend foregoing the 1-hour GCT and replace it with the diagnostic 3-hour GTT. This is consistent with other published studies where women with HbA1c at ranges of 5.7 to 6.4% had a significantly higher risk of progression to GDM.¹⁰

HbA1c at the first prenatal visit appears to be an important assessment tool for diabetes in pregnancy, especially in a population with high prevalence of risk factors.⁶ Abnormal values can prompt further evaluation and early identification of diabetes; normal values may allow high-risk women to forego early 1-hour GCT and undergo screening according to routine guidelines.

As more studies show HbA1c thresholds below which all 1-hour GCTs are normal, new guidelines might be considered for the purpose of avoiding a more burdensome test.

Strengths and Limitations

The strength of our study is that it permits the expansion of evidence that directly evaluates both the early 1-hour GCT and the early diagnosis of diabetes in pregnancy based on the

HbA1c values collected at the first prenatal visit, which promotes early treatment of diabetes. Other studies mainly focused on comparing HbA1c with 1-hour GCT at 24 to 28 weeks or compare HbA1c with the ability to rule in diabetes early in the pregnancy.¹¹

Our study is not without limitations. First, our study focused on a specific high-risk population with 80.2% African American patients in one large ambulatory clinic cluster; therefore, it may not be generalizable to different ethnic backgrounds. Future multicenter studies would be useful. A second limitation is the observational aspect of our study; thus, our data only suggests association. Third, we did not examine detailed information regarding neonatal outcomes within the different HbA1c groups. Lastly, in our study, no cost analysis was done to assess the cost-effectiveness of universal first visit HbA1c.

Conclusion

HbA1c at the first prenatal visit could be a helpful tool to determine the necessity of early 1-hour GCT testing in pregnancy. Women at high risk with an early HbA1c of

Table 4 Sensitivity and specificity values for predicting diabetes mellitus by each level of hemoglobin A1c as cutoff

HbA1c cutoff	True+	True–	False+	False–	NPV (%)	PPV (%)	SEN (%)	SPE (%)
6.8	1	187	0	16	92	100	6	100
6.7	1	187	0	16	92	100	6	100
6.6	1	187	0	16	92	100	6	100
6.5	2	187	0	15	93	100	12	100
6.4	2	187	0	15	93	100	12	100
6.3	3	184	3	14	93	50	18	98
6.2	3	183	4	14	93	43	18	98
6.1	4	181	6	13	93	40	24	97
6.0	5	178	9	12	94	36	29	95
5.9	8	171	16	9	95	33	47	91
5.8	9	165	22	8	95	29	53	88
5.7	10	151	36	7	96	22	59	81
5.6	13	136	51	4	97	20	76	73
5.5	15	124	63	2	98	19	88	66
5.4	16	102	85	1	99	16	94	55
5.3	16	82	105	1	99	13	94	44
5.2	16	57	130	1	98	11	94	30
5.1	16	33	154	1	97	9	94	18
5.0	17	19	168	0	100	9	100	10
4.9	17	12	175	0	100	9	100	6
4.8	17	10	177	0	100	9	100	5
4.7	17	4	183	0	100	9	100	2
4.6	17	1	186	0	100	8	100	1

Abbreviations: DM, diabetes mellitus; HbA1c, hemoglobin A1c; NPV, negative predictive value; PPV, positive predictive value; SEN, sensitivity; SPE, specificity.

Note: The optimal cutoff is 5.5 based on Youden's J statistic.

5.5% or less could potentially forego early diabetes screening and only undergo the routine 24 to 28 weeks' screening. Further research is needed to determine the HbA1c cutoff above which we could forego the 1-hour GCT and move on straight to the diagnostic 3-hour GTT.

Conflict of Interest

None declared.

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