Can we really diagnose diabetes during pregnancy?

Abstract

Objective: To identify the accuracy of diagnosing postpartum diabetes and glucose intolerance using antepartum glycosylated hemoglobin (HbA₁c) and fasting glucose values.

Study Design: A retrospective Hawaiian cohort of women with gestational diabetes during 2004–2011 were evaluated. Antepartum HbA₁c and postpartum 75-g glucose tolerance tests were obtained.

Results: An antepartum HbA₁c value of ≥6.5% had a 45.7% sensitivity, a 96% specificity and a 40% positive predictive value (PPV) for predicting postpartum diabetes. An antepartum HbA₁c value of ≥6.5% had a 6.6% sensitivity, a 94.2% specificity and a 27% PPV for predicting postpartum impaired glucose tolerance. An antepartum HbA₁c value of ≥6.5% had a 10.3% sensitivity, a 95.7% specificity and a 33.3% PPV for predicting postpartum impaired fasting glucoses.

Conclusion: We could not demonstrate a clinically useful PPV for diagnosing postpartum diabetes or glucose intolerance using an antepartum elevated HbA₁c value of ≥6.5% or a fasting glucose level of ≥90 mg/dL.

Keywords: Diabetes; diagnosis; HbA₁c; pregnancy.

Introduction

Recently, recommendations made by the International Association of Diabetes and Pregnancy Study Group (IADPSG) have allowed for the diagnosis of women with “overt diabetes” during pregnancy. The term overt diabetes is described by the IADPSG as “women with likely pre-pregnancy diabetes” and is defined as “any degree of glucose intolerance with onset or first recognition during pregnancy” [1–3]. Previously, pre-pregnancy diabetes could not formally be diagnosed until the postpartum period, once the insulin resistance of pregnancy had returned to baseline. Therefore postpartum diabetes was used as a surrogate diagnosis for pre-gestational diabetes. The new recommendations state that overt diabetes can now be diagnosed during pregnancy with a HbA₁c value of ≥6.5% or a random glucose value of >200 at the first prenatal visit [2]. The timing of the first prenatal visit, however, is not defined in the new recommendations [2].

Prior research shows that women with gestational diabetes are at increased risk for developing type II diabetes later in life [4–8]. Some women diagnosed with overt diabetes in the postpartum period entered the pregnancy with pre-gestational diabetes but were not diagnosed with hyperglycemia until they were enrolled in prenatal care. Identifying women with diabetes earlier (at entry into prenatal care) is the focus of the IADPSG and clinicians treating diabetic women.

Confounders complicate the diagnosis of overt and/or pre-gestational diabetes during pregnancy. Red cell mass turns over more rapidly, and therefore glycosylated hemoglobin represents approximately only the previous 6 weeks (vs. 12 weeks) of glycemic control. The increase in insulin resistance brought on by pregnancy (particularly in women with polycystic ovary syndrome) occurs almost immediately after conception, with a maximal effect approximately at 28 weeks [9–11].

Hawaii has one of the highest rates of hyperglycemia in pregnancy [12, 13]. Kapiolani Medical Center for Women and Children (Honolulu) maintains a database of the patients enrolled in the “Sweeter Choice” diabetes
management program. For more than 10 years, the Sweeter Choice program has been counseling women with pre-gestational and gestational diabetes (GDM) in Honolulu. Recently, the 10,000th patient was enrolled in the program. Pregnant women diagnosed prior to pregnancy with pre-gestational diabetes and women diagnosed with GDM enter the program until delivery. GDM is diagnosed if a 1-h 50-g glucose challenge test (GCT) equals or exceeds 200 mg/dL or two of four values are abnormal on a 3-h 100-g glucose tolerance test (GTT) based on the previously published Carpenter and Coustan criteria [14]. The database includes laboratory, clinical descriptors and pregnancy outcome data. As part of the program, women are asked to complete a postpartum 2-h 75-g oral glucose tolerance tests (OGTTs) with a fasting blood glucose (FBG) test. Our objectives were to identify the accuracy of diagnosing pre-gestational diabetes and glucose intolerance during pregnancy using ante partum glycosylated hemoglobin (HbA1c) and fasting glucose values during pregnancy.

Materials and methods

A waiver was obtained for this research from the Hawaii Pacific Health IRB (study number 2011-072). The study design was a retrospective cohort and included data gathered from January 1, 1994, to June 30, 2011. For the purposes of this study, GDM in our database was defined as participants with either a prenatal 50-g GCT (a value of >200 was considered diagnostic of GDM) or a 3-h 100-g GTT with two of four abnormal values. All enrollees with GDM who had completed a postpartum OGTT and/or fasting glucose were included in the analyses. Women with known pre-gestational diabetes were excluded from the analyses. Participants were instructed to obtain an OGTT at 6–8 weeks postpartum. A commercial laboratory performed all the glucose tests. The following values were abstracted from the database: prenatal HbA1c, 1-h GCT, 3-h GTT, maternal body mass index (BMI), birth weight, gestational age at birth, cesarean delivery, postpartum fasting and OGTT values. Not all women with postpartum 2-h OGTT values also had prenatal FBG or HbA1c values available for review (Tables 1 and 2). HbA1c tests were performed prior to medication initiation, but at various times during the pregnancy, depending on the gestational age at enrollment.

For the purposes of this study, the presumptive diagnosis of diabetes was made if the 2-h value on the OGTT was ≥200 mg/dL or the FBG level was >126 mg/dL. The diagnosis of glucose intolerance was made if the 2-h value demonstrated impaired glucose tolerance (IGT) (glucose level 140–199 mg/dL) or the FBG demonstrated impaired fasting glucose (IFG) (glucose level 100–125 mg/dL).

Statistical methods

Sensitivity, specificity, positive predictive values (PPVs) and negative predictive values (NPVs) were calculated, along with Youden’s index, Cohen’s κ and diagnostic accuracy relating to both diabetes objectives were to identify the accuracy of diagnosing pre-gestational diabetes and glucose intolerance during pregnancy using ante partum glycosylated hemoglobin (HbA1c) and fasting glucose values during pregnancy.

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Table 2 Predicting abnormal postpartum fasting glucose (FBG) testing, with P-values and 95% confidence intervals in parentheses.

<table>
<thead>
<tr>
<th>Prenatal GDM testing</th>
<th>PP FBG ≥ 126 g/dL (n=53)</th>
<th>PP FBG 100–125 g/dL</th>
<th>PP FBG &lt;100 g/dL (n=1446)</th>
<th>IFG Sensitivity (CI)</th>
<th>DM Sensitivity (CI)</th>
<th>IFG Specificity (CI)</th>
<th>DM Specificity (CI)</th>
<th>IFG PPV (CI)</th>
<th>DM PPV (CI)</th>
<th>IFG NPV (CI)</th>
<th>DM NPV (CI)</th>
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<tbody>
<tr>
<td>GCT</td>
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<tr>
<td>≥200</td>
<td>40</td>
<td>116</td>
<td>224</td>
<td>3.2 (2.9–3.5)</td>
<td>70.5 (62.6–78.8)</td>
<td>82.4 (74.2–89.0)</td>
<td>81.2 (79.3–83.2)</td>
<td>30.5 (25.5–35.6)</td>
<td>10.5 (7.8–14.0)</td>
<td>83.6 (81.6–85.4)</td>
<td>99.1 (98.5–99.5)</td>
</tr>
<tr>
<td>≥250</td>
<td>18</td>
<td>14</td>
<td>15</td>
<td>3.9 (2.3–6.6)</td>
<td>34.0 (22.7–47.4)</td>
<td>97.8 (97.6–98.0)</td>
<td>98.4 (97.7–99.4)</td>
<td>29.8 (18.7–42.2)</td>
<td>30.3 (25.8–35.6)</td>
<td>81.0 (79.1–82.7)</td>
<td>98.1 (97.1–98.6)</td>
</tr>
<tr>
<td>≥300</td>
<td>6</td>
<td>0</td>
<td>3</td>
<td>1.1 (0–1.1)</td>
<td>11.3 (5.3–22.6)</td>
<td>99.8 (98.9–99.7)</td>
<td>99.8 (99.5–99.9)</td>
<td>0 (0–29.9)</td>
<td>66.7 (35.4–97.9)</td>
<td>80.6 (78.3–81.9)</td>
<td>97.5 (96.6–98.1)</td>
</tr>
<tr>
<td>FBG</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
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<tr>
<td>≥90</td>
<td>28</td>
<td>225</td>
<td>506</td>
<td>72.4 (67.1–77.0)</td>
<td>93.3 (78.2–96.0)</td>
<td>63.9 (61.5–66.4)</td>
<td>58.5 (56.2–67.6)</td>
<td>29.6 (26.3–33.0)</td>
<td>3.7 (2.6–5.3)</td>
<td>91.7 (89.8–93.8)</td>
<td>99.8 (99.1–99.9)</td>
</tr>
<tr>
<td>≥126</td>
<td>23</td>
<td>292</td>
<td>1436</td>
<td>6.1 (3.9–9.3)</td>
<td>23.3 (11.8–40.9)</td>
<td>98.5 (97.9–99.0)</td>
<td>98.1 (97.3–98.6)</td>
<td>46.3 (32.1–66.1)</td>
<td>17.1 (8.5–31.3)</td>
<td>83.3 (81.5–85.0)</td>
<td>98.7 (98.0–99.7)</td>
</tr>
<tr>
<td>HbA1c ≥6.5% at 0–23 weeks</td>
<td>3</td>
<td>10</td>
<td>6</td>
<td>12.0 (8.6–16.6)</td>
<td>52.7 (37.5–67.1)</td>
<td>95.5 (94.1–96.5)</td>
<td>95.5 (94.2–96.5)</td>
<td>37.8 (28.1–48.6)</td>
<td>25.6 (17.4–36.0)</td>
<td>82.5 (80.4–84.5)</td>
<td>98.5 (97.7–99.1)</td>
</tr>
<tr>
<td>≥6.5% at &gt;24 weeks</td>
<td>27</td>
<td>21</td>
<td>15</td>
<td>18.5 (10.4–30.8)</td>
<td>37.5 (18.5–61.4)</td>
<td>94.0 (89.1–96.8)</td>
<td>93.1 (88.6–95.9)</td>
<td>52.6 (31.7–72.7)</td>
<td>31.6 (15.4–54.0)</td>
<td>76.3 (69.7–81.9)</td>
<td>94.6 (90.4–97.1)</td>
</tr>
<tr>
<td>≥6.5 %</td>
<td>21</td>
<td>31</td>
<td>30</td>
<td>10.3 (6.8–15.2)</td>
<td>62.5 (44.9–81.2)</td>
<td>95.7 (94.2–96.8)</td>
<td>95.8 (94.5–96.8)</td>
<td>33.3 (23.0–45.6)</td>
<td>23.8 (15.0–35.6)</td>
<td>83.5 (81.2–85.6)</td>
<td>99.3 (98.6–99.6)</td>
</tr>
</tbody>
</table>

PPV=Positive predictive values, NPV=negative predictive values, CI=95% confidence interval, IFG=impaired fasting glucose defined by postpartum FBG level of ≥126 mg/dL, DM=diabetes defined as postpartum FBG level of ≥126 mg/dL.

Results

In total, 719 of 7041 women with GDM had postpartum OGTT 2-h glucose values available for review (Figure 1). A total of 1382 women had postpartum FBG values and glucose intolerance. Assessments were made both by gestational age grouping and overall. Receiver operator curves were calculated for the ability of prenatal HbA1c to predict a postpartum elevated FBG level of ≥126 mg/dL or a 2-h OGTT value of ≥200 mg/dL.

In total, 719 of 7041 women with GDM had postpartum OGTT 2-h glucose values available for review (Figure 1). A total of 1382 women had postpartum FBG available for review, and 648 women had both postpartum FBG and 2-h OGTT values available for review. Therefore a total of 20.7% of the population had some type of postpartum testing. Of these 648 women, 12 had both diabetic diagnostic levels for the FBG (≥126 mg/dL) and 2-h OGTT (≥200 mg/dL) values. The mean prenatal HbA1c for these women (11/12) was 7.2%.

HbA1c levels were elevated (≥6.5%) in 8.7% of antepartum enrollees (410/4691). Of these enrollees, 36.9% (150/407) values were obtained prior to 24 weeks. Women with normal 2-h values (<140 mg/dL) on the postpartum OGTT had lower average prenatal HbA1c values of 5.5% (95% confidence interval, CI 5.4–5.6). Women with IGT defined by postpartum OGTT values of 140–199 mg/dL had an average prenatal HbA1c value of 5.7% (CI 5.6–5.8), whereas women with 2-h OGTT values of ≥200 mg/dL had an average HbA1c value of 6.0% (CI 5.9–6.2). The mean prenatal HbA1c levels were elevated (≥6.5%) in 8.7% of antepartum enrollees (410/4691). Of these enrollees, 36.9% (150/407) values were obtained prior to 24 weeks. Women with normal 2-h values (<140 mg/dL) on the postpartum OGTT had lower average prenatal HbA1c values of 5.5% (95% confidence interval, CI 5.4–5.6). Women with IGT defined by postpartum OGTT values of 140–199 mg/dL had an average prenatal HbA1c value of 5.7% (CI 5.6–5.8), whereas women with 2-h OGTT values of ≥200 mg/dL had an average HbA1c value of 6.0% (CI 5.9–6.2).
When using only a single elevated 2-h OGTT value for the diagnosis of postpartum diabetes (≥200 mg/dL), only 16 of 40 women had an antepartum HbA1c value of ≥6.5%. Conversely, 16 women with a postpartum elevated 2-h OGTT (≥200 mg/dL) value had an antepartum HbA1c value of <6.5%. When using only a single elevated 2-h OGTT value for the diagnosis of postpartum IGT (140–199 mg/dL), only 13 of 165 women had an antepartum HbA1c value of ≥6.5%.

The patient characteristics are described in Table 3. Earlier gestational age at delivery, maternal BMI, birth weight of ≥4000 g, family history of diabetes and a weight gain of >50 lb were all statistically correlated with a prenatal HbA1c value of ≥6.5%. Of note, the risk of cesarean delivery was also correlated with a prenatal HbA1c value of ≥6.5% (31.4% vs. 54.0%, P<0.001) and correlated with a postpartum FBG level of ≥126 mg/dL (P<0.01) but not with a postpartum OGTT value of ≥200 mg/dL.

Sensitivities, specificities, PPVs and NPVs were calculated for the ability of different antenatal GCT, FBG and HbA1c values to predict a postpartum 2-h OGTT value of ≥200 mg/dL and to predict an impaired glucose tolerance with a 2-h OGTT value of 140–199 mg/dL (see Table 1 for details). Similar findings were found for predictive values of fasting glucose values at time of entry into care.

As shown in Table 2, similar calculations were performed to assess the ability to predict a postpartum IFG (defined by postpartum FBG of 100–125 mg/dL), diabetes mellitus (defined as postpartum FBG level of ≥126 mg/dL) and normal postpartum fasting glucose (defined as FBG level of <100 mg/dL).

Diagnostic testing accuracy was best for an antenatal FBG level of >126 mg/dL at 96.3 and for an HbA1c value of >6.5% at 93.2. Cohen’s κ was best for an HbA1c value of >6.5% at 0.40.

Receiver operator curves were developed for the ability of antepartum HbA1c to predict postpartum hyperglycemia. Figure 2 shows a receiver operator curve for the diagnosis of postpartum 75-g 2-h hyperglycemia level of ≥200 mg/dL using antepartum HbA1c values. The area under the curve was 0.66 (95% CI 0.67–0.862). The calculated Youden’s index was an HbA1c value of >6.5%, which produces a sensitivity of 36.2% with a false-positive rate (FPR) of 77.1%. If an HbA1c value of ≥6.5% is used, then the sensitivity becomes 45.7% with a FPR of 4.0%. Figure 2 also shows a receiver operator curve for the diagnosis of postpartum FBG level of ≥126 mg/dL using antepartum HbA1c values. The area under the curve was 0.977 (95% CI 0.826–0.928). The calculated Youden’s index was an HbA1c value of >6.5%, which produces a sensitivity of 85% with a FPR of 31.3%. If an HbA1c value of ≥6.5% is used, then the sensitivity becomes 53.5% with a FPR of 4.6%.

Discussion

The data presented here do not support the use of antepartum HbA1c or fasting glucose to diagnose overt diabetes as defined by the IADPSG. Although the recommendation made by the IADPSG was supported by the American Diabetes Association (ADA) in December 2010, it is not supported by our data and would unnecessarily label women with the diagnosis of pre-gestational diabetes and/or glucose intolerance in our population.

Although women with elevated postpartum 75-g 2-h OGTT values tended to enter care with higher HbA1c, we could not demonstrate a clinically useful PPV for defining overt diabetes that persisted into the postpartum period using the cut-off of an antepartum HbA1c value of >6.5%. In our series, a prenatal HbA1c value of >6.5% had only a

Table 3  Characteristics of women with antepartum HbA1c, postpartum 2-h OGTT and postpartum fasting blood glucose (FBG).

<table>
<thead>
<tr>
<th>HbA1c &lt;6.5% [n]</th>
<th>HbA1c ≥6.5% [n]</th>
<th>Normal testing*</th>
<th>2-h 75-g OGTT ≥200 mg/dL [n]</th>
<th>FBG ≥126 mg/dL [n]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean), years (±SD)</td>
<td>31.7 (5.9) [4260]</td>
<td>31.7 (5.9) [397]</td>
<td>32.6 (5.5) [636]</td>
<td>32.9 (6.1) [39]</td>
</tr>
<tr>
<td>BMI, kg/m² (±SD)</td>
<td>27.4 (6.6) [3526]</td>
<td>32.8 (7.0)** [323]</td>
<td>26.6 (6.4) [634]</td>
<td>28.2 (6.6) [39]</td>
</tr>
<tr>
<td>Birth weight ≥4000 g, n (%)</td>
<td>7.9 (323) [4079]</td>
<td>23.0 (85)** [369]</td>
<td>8.2 (50) [608]</td>
<td>10.8 (4) [37]</td>
</tr>
<tr>
<td>Gestational age at birth, &lt;37 weeks, n (%)</td>
<td>8.9 (344) [3848]</td>
<td>19.8 (67)** [339]</td>
<td>7.8 (65) [577]</td>
<td>12.9 (4) [31]</td>
</tr>
<tr>
<td>Family history of diabetes, % (n)</td>
<td>60.2 (2108) [3503]</td>
<td>76.7 (250)** [326]</td>
<td>58.5 (372) [636]</td>
<td>64.1 (25) [39]</td>
</tr>
<tr>
<td>Weight gain in pregnancy ≥50 lb, % (n)</td>
<td>5.0 (197) [3973]</td>
<td>10.6 (36)** [341]</td>
<td>3.0 (18) [607]</td>
<td>5.4 (2) [37]</td>
</tr>
</tbody>
</table>

Statistical significance noted compares HbA1c of ≥6.5% vs. HbA1c of <6.5%, and 2-h 75-g OGTT of ≥200 mg/dL or FBG of ≥126 mg/dL vs. normal testing.

*Normal testing indicates a 2-h 75-g OGTT level of <200 mg/dL and a FBG level of <126 mg/dL. P<0.05. **P<0.001.
45.7% sensitivity with a 4% FPR in predicting a postpartum OGTT value of ≥200 mg/dL and only a 53.5% sensitivity with a 4.6% FPR in predicting a postpartum FBG value of >126 mg/dL.

Previous data demonstrated a 13.5% rate of abnormal postpartum glucose testing after GDM in Caucasian women [15, 16]. In this series of 855 women with GDM, 1.3% were diagnosed postpartum with diabetes, 2.5% with IFG and 7.5% with IGT [16]. Yet, in our study, if we were to use the diagnosis of an antepartum HbA1c value of >6.5% to diagnose diabetes, IFG and IGT, our rate with diabetes postpartum would be 8.7%, 38% with IFG and 33% with IGT.

Women with elevated antepartum HbA1c values at least may have glucose intolerance that would be classified as overt diabetes by the IADPSG, but even this supposition is not supported by our data. An antepartum HbA1c value of >6.5% predicted postpartum IGT only 27% of the time and predicted postpartum impaired fasting sugar (IFG) only 33% of the time.

Whether or not it is appropriate to use a 75-g 2-h OGTT value of ≥200 mg/dL and a FBG level of ≥126 mg/dL as surrogate markers for the diagnosis of diabetes in the postpartum or non-pregnant state is debated. This criterion has been set for by the American Diabetes Association and the World Health Organization [17, 18]. Certainly, if one uses a more stringent criterion for the diagnosis of diabetes, the sensitivity of an antepartum HbA1c would be improved. One could also argue that the WHO threshold for diagnosing overt diabetes of ≥200 mg/dL is too high and that it is more clinically relevant to set the bar lower.

This study is limited by the fact that women with OGTT values often had no other testing for diabetes other than that single value. Additionally, a relatively small portion (20.7%) of participants pursued postpartum testing, which could potentially introduce a selection bias and potentially underestimate the diagnosis of glucose intolerance. FBG tests were only additionally available in a small portion of patients. Other populations have reported a higher postpartum testing rate of 23–58% [19, 20]. Given that the time period over which this study was performed was very long, the emphasis on postpartum testing was likely not well established in the early part of the study period. Other limitations of our study included the inability to control for breastfeeding status, the lack of uniform gestational age at which the HbA1c tests were performed and the inability to accurately assign ethnicity. Evidence conflicts regarding whether ethnicity plays a role in the ability of an HbA1c or an FBG test to accurately reflect hyperglycemia [15, 21–24]. The role of ethnicity may have factored into our findings. Our local population in Hawaii has diverse mix ethnicity, with a high percentage of Asian, Polynesian, Micronesian and mixed ethnicities. In addition, the importance of obesity with GDM in the development of metabolic syndrome cannot be understated [7, 25, 26]. If obesity and ethnicity are factored into future diagnostic or predictive criteria, the specificity of an antepartum HbA1c may be improved upon.

A strength of our study is the large number of participants. However, with even larger numbers, perhaps a threshold value can be established for the diagnosis of overt or even type 2 diabetes at different time points during pregnancy.

In conclusion, at this time, it is premature to diagnose women with type 2 diabetes who present during pregnancy with elevated HbA1c values, especially those presenting at later gestational ages. In our population, women with an antepartum HbA1c value of ≥6.5% have only a 40% a risk of having type 2 diabetes. Future algorithms taking into account not only HbA1c but also BMI, ethnicity and gestational age may produce better predictive values for the diagnosis of postpartum glucose intolerance and diabetes during pregnancy.

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