Use of oral glucose tolerance testing and HbA1c at 6–14 gestational weeks to predict gestational diabetes mellitus in high-risk women

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Abstract

Purpose To study the prediction of gestational diabetes mellitus (GDM) in high-risk pregnant women by testing fasting blood glucose, 1-h (1hPG) and 2-h plasma glucose (2hPG) after an oral glucose tolerance test, and glycated hemoglobin (HbA1c) in early pregnancy (6–14 weeks).

Methods We recruited 1311 pregnant women at high risk for diabetes from the Obstetrics Clinic of Daxing District People’s Hospital between June 2017 and December 2019. The tests performed during the first trimester included fasting blood glucose (FPG), HbA1c, and 75-g oral glucose tolerance test (OGTT) with 1hPG and 2hPG. Seventy-three pregnant women diagnosed with pregestational diabetes mellitus (PGDM) early in pregnancy and 36 who were missed in the second trimester were excluded. A total of 1202 women were followed up until 24–28 weeks for GDM. The receiver operating characteristic (ROC) and area under the ROC curve (AUC) were calculated to determine the predictive values of FPG, 1hPG, 2hPG, and HbA1c for GDM in early pregnancy in high-risk pregnant women.

Results The AUC for 1hPG for the prediction of GDM in high-risk pregnant women was greater than those for FPG, 2hPG, and HbA1c. All differences were significant. The AUCs for the predictive values of FPG, 1hPG, 2hPG, and HbA1c in high-risk pregnant women were 0.63, 0.76, 0.71, and 0.67, respectively. The prevalence of PGDM among pregnant women at high risk of diabetes was 5.6%.

Conclusion First-trimester levels of FPG, 1hPG, 2hPG, and HbA1c in high-risk women are significant predictors of GDM, with 1hPG having the most significant predictive value.

Keywords First-trimester pregnancy · Gestational diabetes mellitus (GDM) · High-risk pregnant women · Glucose tolerance test (OGTT) · ROC curve

Introduction

Gestational diabetes mellitus (GDM) is the most common complication in pregnancy. GDM increases the risk of other complications, such as preeclampsia, cesarean section, fetal overgrowth, shoulder dystocia, neonatal hypoglycemia, and neonatal admission to intensive care [1, 2]. It also increases the risk of obesity and abnormal glucose metabolism in the offspring [3–5]. Currently, GDM is diagnosed at 24–28 weeks of gestation according to the diagnostic criteria recommended by the International Gestational Diabetes Research Group [6]. However, some pregnant women have high blood sugar in the early stages of pregnancy due to a missed diagnosis of pregestational diabetes mellitus (PGDM), which has a high prevalence in China [7, 8]. Early screening for GDM is recommended for pregnant women with risk factors to improve pregnancy outcomes [9–14].
However, there are still controversies about the screening standards and methods for GDM in early pregnancy. Hence, this study aimed to identify a single blood glucose test among HbA1c, fasting blood glucose (FPG), and 1-h(1hPG) and 2-h plasma glucose (2hPG) after an oral glucose tolerance test that could predict the occurrence of GDM in high-risk pregnant women.

### Research design and methods

#### Study population

We selected consecutive pregnant women with high risk for diabetes from the Department of Obstetrics and Gynecology of Daxing District People’s Hospital from June 2017 to December 2019. Our inclusion criteria were women who were at 6–14 weeks of gestation, age greater than 18 years, and presence of one or more risk factors included in the study. Risk factors [6, 15–19] included age ≥ 35 years, obesity (body mass index [BMI] ≥ 28 kg/m²), first-degree relatives with hypertension or diabetes, history of hypertension, History of macrosomia, history of GDM, hypothyroidism, polycystic ovarian syndrome, history of spontaneous abortion, or previous adverse pregnancies and births (includes preterm delivery occurring after 28 weeks of gestation, stillbirth, fetal demise, malformed fetus, unexplained neonatal death). Finally, the women should be willing to participate in the study and provide informed consent.

Our exclusion criteria included a history of type 1 or type 2 diabetes, no continuous obstetric examination and delivery in this hospital, or twin pregnancy. The Ethics Committee approved the project at Beijing Daxing District People’s Hospital (Lot Number: 2017–2–1–0828), and all participants signed the informed consent form. The sample population was separated by GDM screening results into 297 people in the GDM group and 905 in the non-GDM group. The specific steps for the inclusion and grouping of the study subjects are shown in Fig. 1.

#### Research methods and laboratory examination

This study collected indicators of FPG, 1hPG, 2hPG and HbA1c from pregnant women at high risk of diabetes in early pregnancy. First, all participants filled out the high-risk factor questionnaire. The questionnaire includes general information about pregnant women (e.g., age, height, weight, gestational age, gravidity, parity) and high-risk factors. All subjects were tested with a 75 g oral glucose tolerance test (OGTT) and HbA1c at 6–14 weeks of pregnancy. The participants were instructed to fast for no less than 8 h before taking the 75 g OGTT. They also had a regular diet for 3 consecutive days before the test, which included eating no less than 150 g of carbohydrates per day. The subjects did not smoke, drink tea, coffee, and do vigorous exercise. During the examination, 300 mL of liquid containing 75 g...
of glucose was administered orally within 5 min, and blood samples were taken prior to and 1 and 2 h after ingesting the glucose solution. Venous blood was collected for calculating the duration (calculated from the start of drinking glucose solution), HbA1c, and FPG. We used the glucose oxidase method from the Beckman kit for the Beckman AU5821. HbA1c measurement was performed using high-pressure liquid chromatography with a BIO-RAD and the original BIO-RAD reagents kit. The results of diabetes screening in early pregnancy (6–14 weeks) were collected. If the early pregnancy blood glucose level reached the PGDM standard, the participant was excluded. Women with undiagnosed PGDM were followed at 24–28 weeks of gestation to assess the presence of GDM.

### Diagnostic criteria

The standard guidelines are as follows [6]: GDM diagnostic criteria: FPG ≥ 5.1 mmol/L or 1hPG ≥ 10.0 mmol/L or 2hPG ≥ 8.5 mmol/L at 24–28 weeks of pregnancy. PGDM diagnostic criteria: FPG ≥ 7.0 mmol/L or 2hPG ≥ 11.1 mmol/L or accompanied by typical hyperglycemia symptoms and random blood glucose ≥ 11.1 mmol/L.

### Statistical analysis

SPSS 17.0 software was used for the statistical analysis of data. Measurement data conforming to normal distribution are represented by mean ± standard deviation (SD). We compared the groups using the t-test. Measurement data that did not conform to a normal distribution by M (P25, P75) were analyzed with a non-parametric rank-sum test (Z test). Discrete data are expressed as rate and the χ² test was used for the comparisons. We considered P<0.05 as statistically significant. We used MedCalc 18.2.1 software to calculate the area under the receiver operating characteristic curve (ROC). The DeLong method was used to measure the area under the ROC curve (AUC) of FPG, 1hPG, 2hPG, and HbA1c in early pregnancy, and the AUC was compared. The calibration test level was P<0.0083. We took the largest YouDen index as the best cut-off value and recorded the sensitivity and specificity at this value.

### Results

The study included 1311 subjects. We found that 73 subjects met the diagnostic criteria for PGDM in the first-trimester pregnancy, with a PGDM prevalence of 5.6% (Fig. 1). Descriptive characteristics of the study population at baseline are presented in Table 1. The mean age of women and pre-pregnancy BMI were 31 ± 4 years and 24.26 ± 4.34 kg/m², respectively. Women with GDM were older, had a higher pre-pregnancy BMI, had a history of GDM, and had a history of the polycystic ovarian syndrome than women without GDM.

The four glucose measures (FPG, 1hPG, 2hPG, and HbA1c) across the two groups of high-risk pregnant women in early pregnancy were significantly higher (P<0.05) in the GDM group than in the non-GDM group.

### Table 1 Characteristics of high-risk women for gestational diabetes and comparison of GDM and non-GDM pregnant women

|                          | Total (n = 1202) | GDM (n = 297) | Non-GDM (n = 905) | Z/X²  | P value  |
|--------------------------|-----------------|--------------|------------------|------|---------|
| Age (Year)               | 31 ± 4          | 32 ± 4       | 30 ± 4           | −3.74 | <0.001* |
| BMI before pregnancy (kg/m²) | 24.26 ± 4.34 | 25.57 ± 4.52 | 23.83 ± 4.19 | −5.869 | <0.001* |
| Gestational weeks (week) | 12 (11, 13)     | 12 (11, 13)  | 12 (11, 13)     | −0.863 | 0.388   |
| Gravidity (time)         | 2 (1, 3)        | 2 (1, 3)     | 2 (1, 3)        | 1.189  | 0.235   |
| Parity (time)            | 2 (1, 2)        | 2 (1, 2)     | 2 (1, 2)        | 1.229  | 0.219   |
| History of GDM (%)       | 48 (3.99)       | 22 (7.41)    | 26 (2.87)       | 11.993 | 0.001*  |
| History of macrosomia (%)| 79 (6.57)       | 24 (8.08)    | 55 (6.08)       | 1.462  | 0.226   |
| Hypertension during pregnancy (%) | 13 (1.08) | 5 (1.68) | 8 (0.88) | 1.336 | 0.328 |
| Hypothyroidism (%)       | 171 (14.23)     | 35 (11.78)   | 136 (15.03)     | 0.181  | 1.927   |
| First-degree relatives have diabetes (%) | 239 (19.88) | 70 (23.56) | 169 (18.67) | 3.363 | 0.078  |
| First-degree relative have high blood pressure (%) | 411 (34.19) | 102 (34.34) | 309 (34.14) | 0.004 | 0.944 |
| Polycystic Ovary Syndrome (%) | 62 (5.16) | 24 (8.08) | 38 (4.20) | 6.888 | 0.015* |
| History of spontaneous abortion (%) | 77 (6.41) | 25 (8.41) | 52 (5.74) | 2.662 | 0.132 |
| Adverse birth history (%) | 25 (2.08) | 4 (1.35) | 21 (2.32) | 1.041 | 0.481  |

Adverse birth history includes preterm delivery occurred after 28 weeks of gestation, stillbirth, fetal demise, malformed fetus, unexplained neonatal death; P: GDM vs Non-GDM

BMI body mass index, GDM gestational diabetes mellitus

*Means P<0.05
(Table 2). The AUC of FPG, 1hPG, 2hPG, and HbA1c in early pregnancy predicting GDM in high-risk pregnant women was 0.63, 0.76, 0.71, and 0.67, respectively. The best FPG cut-off for the association with GDM was 4.86 mmol/L with a sensitivity of 48.44%, specificity of 75.58%, positive predictive value (PPV) of 39.45%, and negative predictive value (NPV) of 81.72%. The best cut-off point for 1hPG was 8.10 mmol/L, with a sensitivity of 80.62%, specificity of 60.04%, PPV of 39.77%, and NPV of 90.35%. The optimal node value for 2hPG was 7.40 mmol/L, with a sensitivity of 60.90%, specificity of 71.37%, PPV of 41.14%, and NPV of 84.78%. The best HbA1c cut-off for the association with GDM was 5.20%, with a sensitivity of 58.64%, specificity of 68.59%, PPV of 37.99%, and NPV of 83.47% (Fig. 2 and Table 3).

When the prediction sensitivity of all four indicators was 90%, the node value of FPG was 4.18 mmol/L with a specificity of 17.42%, PPV of 26.33%, and NPV of 84.08%. The cut-off value of 1hPG was 7.12 mmol/L, with a specificity of 36.85%, PPV of 29.90%, and NPV of 91.74%. The cut-off value for 2hPG was 5.83 mmol/L, with a specificity of 27.62%, PPV of 28.96%, and NPV of 89.29%. The

| Table 2 | Comparison of FPG, 1hPG, 2hPG and HbA1c levels in GDM group and non-GDM group (mmol/L) |
|---------|--------------------------------------------------------------------------------------------------|
|         | Total (n = 1202) | GDM (n = 297) | Non-GDM (n = 905) | Z    | P value |
| FPG     | 4.66 ± 0.49      | 4.85 ± 0.56   | 4.59 ± .45        | 7.44 | < 0.001 |
| 1hPG    | 8.18 ± 1.89      | 9.51 ± 1.73   | 7.74 ± 1.73       | 13.79| < 0.001 |
| 2hPG    | 7.06 ± 1.55      | 7.97 ± 1.63   | 6.76 ± 1.41       | 11.25| < 0.001 |
| HbA1c   | 5.15 ± 0.37      | 5.32 ± 0.39   | 5.10 ± 0.35       | 7.40 | < 0.001 |

**Table 3** The optimal cut-off level, sensitivity and specificity of FPG, 1hPG, 2hPG and HbA1c for predicting GDM

|         | AUC | AUCof 95%CI | Optimal cut-off level | Sensitivity | Specificity | PPV   | NPV   |
|---------|-----|-------------|-----------------------|-------------|-------------|-------|-------|
| FPG     | 0.63| 0.59–0.66   | 4.86 mmol/L           | 48.44%      | 75.58%      | 39.45%| 81.72%|
| 1hPG    | 0.76| 0.73–0.79   | 8.10 mmol/L           | 80.62%      | 60.04%      | 39.77%| 90.35%|
| 2hPG    | 0.71| 0.68–0.74   | 7.40 mmol/L           | 60.90%      | 71.37%      | 41.14%| 84.78%|
| HbA1c   | 0.67| 0.64–0.70   | 5.20%                 | 58.64%      | 68.59%      | 37.99%| 83.47%|

**Fig. 2** ROC curves of FPG, 1hPG, 2hPG and HbA1c used in the diagnosis of GDM in high-risk pregnant women in early pregnancy

**Table 3** The optimal cut-off level, sensitivity and specificity of FPG, 1hPG, 2hPG and HbA1c for predicting GDM

- **AUC** area under receiver operating curve, **FPG** fasting blood glucose, **1hPG** 1 h plasma glucose, **2hPG** 2 h plasma glucose; **HbA1c** glycated hemoglobin, **PPV** positive predictive value, **NPV** negative predictive value
The node value of HbA1c was 4.78 mmol/L, with a specificity of 19.86%, PPV of 26.92% and NPV of 85.71% (Table 4).

The AUC of 1hPG for diagnosing GDM in early pregnancy was larger than the AUCs of FPG, 2hPG, HbA1c, and the differences were statistically significant ($P < 0.0083$) (Table 5).

### Discussion

We showed that the prevalence of PGDM in pregnant women at high risk of diabetes was 5.6%. Currently, most countries use 75 g OGTT to screen for GDM at 24–28 weeks of gestation. However, at this time, diagnosis and treatment are already in the second and third trimesters, and the effective intervention time for GDM is relatively short. Hyperglycemia, especially PGDM, in early pregnancy is harmful to mothers and children [20]. Early pregnancy cut-off of FPG and HbA1c could alert the physician of the possibility of previously undiagnosed diabetes [21]. Many studies have shown that abnormal blood glucose in early pregnancy can be reduced through lifestyle intervention [22–24] and by controlling the rate of weight gain [25], thereby reducing adverse pregnancy outcomes. Early recognition of and intervention for GDM are essential for mothers and children.

This study shows that the four glucose measures in early pregnancy have specific predictive effects on the occurrence of GDM in high-risk pregnant women. Among them, 1hPG has a better predictive effect on GDM in high-risk pregnant women. When the predictive sensitivity of all four indicators was 90%, the specificity of 1hPG remains the highest. Propranolol C [11] used the four-point blood glucose value of the glucose tolerance test, FPG, 1hPG, 2hPG, and 3-h blood glucose to predict mid-term and late GDM, which is consistent with our study. The Abdul-Ghani MA study [26] found that the blood glucose concentration of 1hPG correlated well with insulin resistance index and insulin secretion index, which are better than FPG and 2hPG. Type 2 diabetestes is characterized by defects in both insulin secretion and insulin action. Insulin resistance can be demonstrated long before overt diabetes is diagnosed, and 1hPG seems to be a good predictor.

Many researchers recommend FPG as a screening method for early diabetes, citing the advantages of being convenient, economical, and more easily accepted by patients [27–30]. However, the FPG gives varied results in different populations and its use as a screening test for GDM remains uncertain [31, 32]. Pregnant women with impaired postprandial glucose remain underdiagnosed using fasting glucose screening.

In this study, the AUC for the FPG was 0.63, and the best cut-off point was 4.86 mmol/L. A study found that the AUC for FPG was 0.63, and the best cut-off point was 4.5 mmol/L [33]. We found that the sensitivity and specificity of FPG for predicting GDM were not high. Our previous studies have shown that in early pregnancy, the prevalence of pre-pregnancy diabetes is 5.37% in high-risk women, of which 18.75% had only abnormal fasting blood glucose, 75% had only abnormal 2hPG, and 6.25% had both abnormal FPG and 2hPG [8]. This indicates that the missed diagnosis rate is relatively high if we only use FPG to predict GDM, suggesting that screening only with FPG in the first trimester will fail to detect abnormal blood glucose after meals and miss many patients with overt diabetes.

The AUC of HbA1c in this study was 0.67, and the best cut-off point was 5.2%. Another study [34] indicated that

### Table 4

| Cut-off level | Sensitivity | Specificity | PPV | NPV |
|---------------|-------------|-------------|-----|-----|
| FPG 4.18 mmol/L | 90% | 17.42% | 26.33% | 84.08% |
| 1hPG 7.12 mmol/L | 90% | 36.85% | 29.90% | 91.74% |
| 2hPG 5.83 mmol/L | 90% | 27.62% | 28.96% | 89.29% |
| HbA1c 4.78 mmol/L | 90% | 19.86% | 26.92% | 85.71% |

**FPG** fasting blood glucose, **1hPG** 1 h plasma glucose, **2hPG** 2 h plasma glucose; **HbA1c** glycated hemoglobin, **PPV** positive predictive value, **NPV** negative predictive value.

### Table 5

| Difference | 1hPG – FPG | 1hPG – 2hPG | 1hPG – HbA1c | 2hPG – FPG | 2hPG – HbA1c | FPG – HbA1c |
|------------|------------|-------------|--------------|------------|--------------|-------------|
| Standard error | 0.027 | 0.028 | 0.028 | 0.029 | 0.029 | 0.029 |
| 95% CI | 0.077–0.183 | 0.033–0.143 | 0.025–0.137 | −0.018–0.097 | −0.0163–0.099 |
| Z statistics | 4.784 | 3.143 | 2.813 | 1.336 | 1.409 |
| $P$ value | $P < 0.001^*$ | $P = 0.002^*$ | $P = 0.005^*$ | $P = 0.182$ | $P = 0.159$ |

**FPG** fasting blood glucose, **1hPG** 1 h plasma glucose, **2hPG** 2 h plasma glucose; **HbA1c** glycated hemoglobin; **AUC** area under receiver operating curve; $P < 0.0083$ is statistically significant.

*Means $P < 0.0083$
the sensitivity and specificity of this indicator were 61% and 68% when the cut-off point of HbA1c was 5.1%. Xiaoping [35] found that the AUC for HbA1c was 0.729, and the best cut-off point was 5.05%, with the sensitivity and specificity being 71.8% and 66.7%, respectively, which are different from our study. This finding may be related to differences in the regions, testing equipment, and diagnostic criteria. HbA1c is the product of the combination of hemoglobin in the red blood cells and glucose. The accumulation of HbA1c reflects the average glucose level that cells are exposed to during their life cycle. It can be used to evaluate the effectiveness of treatment. This feature also makes HbA1c valuable for predicting GDM [36].

When the cut-off point for 1hPG was 8.10 mmol/L, the NPV is 90.35%. It is reasonable to conclude that repeated OGTT can be avoided in the second trimester when the 1hPG in the first trimester is less than 8.1 mmol/L. However, further testing is still recommended in medically and economically developed areas. Although all four indicators had some predictive value for GDM, the sensitivity and specificity of their optimal node values did not reach 90%. Therefore, using a single-time point blood glucose screening for GDM in early pregnancy is not recommended. However, blood glucose screening in the first trimester is significant for the early identification of PGDM and abnormal glucose tolerance, and performing a 1hPG blood glucose test during OGTT screening in the first trimester will not significantly increase patients' economic burden. Most pregnant women could tolerate the oral 75 g OGTT in this study, except a few who had serious early pregnancy reactions.

Limitations

Our study has several limitations. First, the study was a single-center study. Second, the participants were limited to high-risk pregnant women in our hospital’s obstetrics and gynecology department. The adaptability to low-risk pregnant women needs to be verified. Third, the study was a prospective study, out of ethics and patient benefits, we conducted dietary and exercise education for pregnant women with impaired glucose tolerance in early pregnancy.

Conclusions

In conclusion, FPG, 1hPG, 2hPG, and HbA1c in early pregnancy have some predictive value for the occurrence of GDM in high-risk pregnant women. 1hPG in early pregnancy has the highest predictive value for GDM in high-risk pregnant women. Therefore, multi-time OGTT is recommended for pregnant women who are at a high risk of diabetes in early pregnancy or before a planned pregnancy if possible. If medical conditions are limited or patient compliance is not high, 1hPG is recommended. However, further prospective multi-center studies are needed to determine the impact of early pregnancy glucose screening on pregnancy outcomes and offspring metabolism.

Author Contributions Professor MX carried out the research design and article revision. PX was responsible for the specific implementation of the experiment, data collection, statistical analysis and article writing. LM, GJ, and WY participated in the writing process. The data is interpreted by all authors who participated in the writing and revision of the manuscript.

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Declarations

Conflict of interest All authors have no conflict of interest.

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