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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Research Article

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Abstract

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

Methodology: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. Fasting blood glucose (FPG) and HbA1c were tested and a 75 g oral glucose tolerance test (OGTT) with 1-hour blood glucose (1hPG) and 2-hour blood glucose (2hPG) was performed during the first trimester of pregnancy. The women were seen at 24-28 weeks to follow-up for GDM. We calculated the receiver operating characteristic (ROC) and the area under the ROC curve (AUC) to determine the predictive values for early pregnancy FPG, 1hPG, 2hPG, and HbA1c for GDM in high-risk pregnant women.

Results:The prevalence of pregestational diabetes mellitus among pregnant women at high risk of diabetes was 5.6%, and GDM was 24.7%. The AUCs for the predictive value of FPG, 1hPG, 2hPG, and HbA1c in high-risk pregnant women were 0.64, 0.76, 0.71, and 0.67, respectively. The AUC for 1hPG prediction of GDM in high-risk pregnant women is greater than FPG, 2hPG, and HbA1c. All differences were statistically significant.

Conclusion:FPG, 1hPG, 2hPG, and HbA1c measured in the first trimester pregnancy of high-risk women are significant predictors of GDM. 1hPG was the most significant predictive value for GDM in high-risk pregnant women.

Objective

Gestational diabetes mellitus (GDM) is the most common complication in pregnancy. GDM increases the risk of complications, such as preeclampsia, cesarean section, fetal overgrowth, shoulder dystocia, neonatal hypoglycemia, and neonatal admission to intensive care (1,2). This complication also increases the risk of obesity and abnormal glucose metabolism in 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 in China (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 (9-10). However, there are still controversies about the screening standards and methods for GDM in early pregnancy. There are few relevant studies in China (11-13). This study collected fasting blood glucose levels (FPG) and glycated hemoglobin (HbA1C) from pregnant women at high risk of diabetes in early pregnancy. We also performed an oral glucose tolerance test and collected plasma glucose at 1 hour (1hPG) and 2 hours (2hPG). Our aim was to identify a single blood glucose test that could GDM in high-risk pregnant women.

Research Design And Methods

Study Population

We selected consecutive pregnant women with high risk factors 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 old, and any of the high-risk factors for diabetes. High risk factors(6,14-18) included age ≥ 35 years old, obesity (body mass index [BMI] ≥ 28 kg/m²), first-degree relatives with hypertension, first-degree relatives with diabetes, history of hypertension, history of a large baby, history of GDM, hypothyroidism, polycystic ovarian syndrome, history of spontaneous abortion, or previous complicated pregnancies and births (e.g., preterm delivery occurred after 28 weeks of gestation, stillbirth, fetal demise, malformed fetus, unexplained neonatal death). Finally, the women needed to be willing in the study and provide informed consent.

Our exclusion criteria included a history of type 1 or type 2 diabetes, no continuous obstetrics, 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 provided written informed consent. A total of 1311 subjects were tested with a 75 g OGTT and HbA1c in the first trimester. Seventy-three cases with PGDM were excluded, 36 patients were lost to follow-up, and 1202 cases of pregnant women were followed up to the mid-term GDM screening results. The sample population was separated by GDM screening results into 297 people in the GDM group and 905 people in the non-GDM group.

Research Methods And Laboratory Examination

All participants filled out the high risk factor questionnaire. The questionnaire includes general information about pregnant women (e.g. age, height, weight, gestational age, number of pregnancies, number of childbirths) and high risk factors. All subjects were tested with a 75 g OGTT and HbA1c at 6-14 weeks of pregnancy. The participants were instructed to fast for no less than 8 hours before taking 75 g OGTT. They also had a regular diet for three consecutive days before the test, which included eating no less than 150 g carbohydrates per day. The subjects did not smoke, drink tea and coffee, smoke, and did not do vigorous exercise. During the examination, 300 mL of liquid containing 75 g glucose was taken orally within 5 minutes, and blood samples were taken before and 1 and 2 hours after taking sugar. Hours of venous blood (calculated from the start of drinking glucose water), glycosylated hemoglobin, and fasting blood glucose are drawn together. We used the glucose oxidase method from the Beckman kit for the Beckman AU5821. The glycosylated hemoglobin uses high pressure liquid chromatography with a BIO-RAD, and the kit of original BIO-RAD reagents. 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. The women were followed at 24-28 weeks of pregnancy to assess the presence of GDM.

Diagnostic Criteria

According to the standard guidelines (6), Category “One”: GDM diagnostic criteria (any of the following: FPG ≥ 5.1 mmol/L, 1hPG ≥ 10.0 mmol/L, 2hPG ≥ 8.5 mmol/L at 24-28 weeks of pregnancy. Category “Two”: PGDM diagnostic criteria (any of the following): FPG ≥ 7.0 mmol/L, 2hPG ≥ 11.1 mmol/L, accompanied by typical hyperglycemia symptoms or hyperglycemic crisis, and random blood glucose ≥ 11.1 mmol/L.

Statistical Analysis

SPSS 17.0 software was used for statistical analysis of data. Measurement data conforming to the normal distribution is represented by mean $\pm$ standard deviation (SD). We compared the group by t-test. Measurement data that does not conform to a normal distribution by M (P25, P75) were analyzed with non-parametric rank-sum test (Z test). Discrete data were expressed as a rate and the χ^2 test was used for the comparisons. We considered $P < 0.05$ 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 (YouDen) as the best cut-off value and recorded the sensitivity and specificity at this value.

Results

The study included 1311 subjects with a loss to follow-up rate of 2.9%. We found a prevalence of PGDM of 5.6%, and GDM of 24.7%, as shown in 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, a history of GDM, and a history of the polycystic ovarian syndrome than women without GDM.

Comparing the four glucose measures across the two groups of high-risk pregnant women in early pregnancy that all four measures, FPG, 1hPG, 2hPG, and HbA1c, were significantly higher than those of the non-GDM group. The difference was statistically significant ($P < 0.05$) (Table 2). The area under the curve of FPG, 1hPG, 2hPG, and HbA1c in early pregnancy predicting GDM of high-risk pregnant women is 0.63, 0.76, 0.71, and 0.67, respectively (Fig. 2 and Table 3). The AUC of 1hPG diagnosed GDM in early pregnancy was larger than the AUC of FPG, 2hPG, HbA1c, and the differences were statistically significant (Table 4).

Discussion

Our research concluded that the prevalence of PGDM in pregnant women at high risk of diabetes is 5.6% and these women should be managed as soon as possible after early recognition. At present, most countries use 75 g OGTT to screen for GDM at 24 to 28 weeks of gestation. However, at this time, diagnosis and treatment have reached the middle and late stages of pregnancy, and the effective intervention time for GDM is relatively short. Hyperglycemia, especially PGDM, in early pregnancy, is

harmful to mothers and children (19). Many studies have shown that abnormal blood glucose in early pregnancy can be reduced through lifestyle intervention (20-22) and controlling the rate of weight gain (23), and thereby reduce adverse pregnancy outcomes. Early recognition of GDM and early intervention is essential for mothers and children.

This study shows that FPG, 1hPG, 2hPG, and HbA1c 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. The best cut-off point for blood glucose prediction is 8.1 mmol/L and the sensitivity is 80.62%, and the specificity is 60.04%. Phaloprakarn (11) used the four-point blood glucose value of the glucose tolerance test, FBG, 1hPG, 2hPG, and 3-hour blood glucose, to predict mid-term and late GDM, which is consistent with our research results. The blood glucose concentration of 1hPG correlates with the insulin resistance index and the insulin secretion index, which is better than FPG and 2hPG (24). The blood glucose concentration also determines that it can be used as a good predictor. Performing a 1hPG blood glucose test during OGTT screening in the first trimester will not significantly increase patients' economic burden. Most pregnant women could have an oral 75 g OGTT test in this study, except for a few serious early pregnancy reactions.

Many researchers recommend early pregnancy FPG as a screening method for early diabetes, citing the advantages of being convenient, economical, strong operability, highly consistent, and more easily accepted by patients [25-28].

In this study, the AUC for the FPG is 0.63. The best cut-off point is 4.86 mmol/L, the sensitivity and the specificity are 48.44% and 75.58%, respectively. A study found that their AUC for FPG is 0.63, the best cut-off point is 4.5 mmol/L, the sensitivity and specificity are 64.29% and 56.46%, respectively (29). But we also found that the sensitivity and specificity of FPG predicating for GDM are not high. Our previous studies have shown that in early pregnancy, the prevalence of pre-pregnancy diabetes is 5.37% in high-risk women. In comparison, impaired fasting plasma only accounts for 18.75%, impaired glucose tolerance accounts for 75%, and increased FPG and 2hPG accounts for 6.25%. It indicates that the missed diagnosis rate is relatively high if we only use fasting blood glucose to predict GDM(8), suggesting that screening only with FPG in the first trimester fails to detect abnormal blood glucose after meals, but also misses many patients with overt diabetes.

The area under the curve of HbA1c in this study was 8.64%, the best cut-off point is 5.2%, the sensitivity and specificity are 58.64% and 68.59%, respectively. Another study (30) indicated that the sensitivity and the specificity are 61% and 68% when the cut-off point of HbA1c is 5.1%. Xiaoping (31) found that the AUC for the HbA1c is 0.729, the best cut-off point is 5.05%, and the sensitivity and specificity are 71.8%, 66.7%, respectively, which is different from our study. This finding may be related to 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 (32).

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, which may have a certain impact on the outcome of GDM. Multi-center large sample prospective randomized controlled studies are required to confirm our results.

In conclusion, FPG, 1hPG, 2hPG, and HbA1c in early pregnancy have some predictive effect on 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, it is recommended to perform OGTT multi-time blood glucose testing for pregnant women at high risk of diabetes in the early pregnancy when conditions permit. If conditions are limited or patient compliance is not high, perform OGTT 1-hour blood glucose testing as much as possible. In this way, we can detect pregnant women with high blood sugar as soon as possible, manage blood sugar early, and improve pregnancy outcomes.

Declarations

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Tables

Table 1. Characteristics of 1202 high-risk women for gestational diabetes mellitus who develop and did not develop gestational diabetes mellitus in pregnancy

	Total	GDM (n=297)	Non-GDM (n=905)	Z/X ²	P for trend
AgeYear	31±4	32±4	30±4	-3.740	<0.001*
BMI before pregnancykg/m ²	24.26±4.34	25.57±4.52	23.83±4.19	-5.869	<0.001*
Gestational weeksweek	121113	121113	121113	-0.863	0.388
Graviditytime	213	213	213	1.189	0.235
paritytime	212	212	212	1.229	0.219
History of GDM%	483.99	227.41	262.87	11.993	0.001*
Gigantic history%	796.57	248.08	556.08	1.462	0.226
Hypertension during pregnancy%	131.08	51.68	80.88	1.336	0.328
Hypothyroidism%	17114.23	3511.78	13615.03	0.181	1.927
First-degree relatives have diabetes %	23919.88	7023.56	16918.67	3.363	0.078
First-degree relative have high blood pressure%	41134.19	10234.34	30934.14	0.004	0.944
Polycystic Ovary Syndrome%	625.16	248.08	384.20	6.888	0.015*
History of spontaneous abortion %	776.41	258.41	525.74	2.662	0.132
Bad birth history%	252.08	41.35	212.32	1.041	0.481

BMI: body mass index, GDM: gestational diabetes; * means P<0.05

Table 2 Comparison of blood glucose at different times and HbA1c levels in OGTT between two groups of high-risk women in early pregnancy (mmol/L)

	Total (n=1202)	GDM (n=297)	Non-GDM (n=905)	Z	P for trend
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±.39	5.10±.35	7.40	<0.001

FPG: fasting blood glucose; 1hPG: OGTT 1 hour plasma glucose; 2hPG: OGTT 2 hour plasma glucose; HbA1c: glycosylated hemoglobin; OGTT, oral glucose tolerance test; GDM, gestational diabetes

Table 3. The AUC, Optimal cutoff level, the sensitivity and specificity of each of the three plasma glucose values and HbA1c of oral glucose tolerance test in early pregnancy

	AUC	AUC of 95%CI	Optimal cutoff level	sensitivity	specificity
FPG	0.63	0.59 - 0.66	4.86mmol/L	48.44%	75.58%
1hPG	0.76	0.73 - 0.79	8.10mmol/L	80.62%	60.04%
2hPG	0.71	0.68 - 0.74	7.40mmol/L	60.90%	71.37%
HbA1c	0.67	0.64 - 0.70	5.20%	58.64%	68.59%

AUC: Area under receiver operating curve; FPG: Fasting blood glucose; 1hPG: 1 hour plasma glucose; 2hPG: 2 hour plasma glucose; HbA1c: Glycated hemoglobin.

Table 4. Comparison of AUC in each of the three plasma glucose values and HbA1c of oral glucose tolerance test to predict GDM in early pregnancy

	1hPG~FPG	1hPG ~ 2hPG	1hPG ~ HbA1c	2hPG ~FPG	2hPG ~ HbA1c	FPG ~ HbA1c
Difference	0.130	0.049	0.088	0.081	0.039	0.042
Standard error	0.027	0.018	0.028	0.029	0.029	0.029
95% CI	0.077 - 0.183	0.013 - 0.084	0.033 - 0.143	0.025 - 0.137	-0.018 - 0.097	-0.0163 - 0.099
Z statistics	4.784	2.658	3.143	2.813	1.336	1.409
P for trend	P < 0.001*	P = 0.008*	P = 0.002*	P = 0.005*	P = 0.182	P = 0.159

FPG Fasting blood glucose FPG Fasting blood glucose 1hPG 1 hour plasma glucose 2hPG 2 hour plasma glucose HbA1c Glycated hemoglobin ROC Receiver operating characteristic curve P<0.0083 is statistically significant.

Figures

Figure 1

Flow chart of study inclusion criteria

Figure 2

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