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Can Glycosylated Hemoglobin and Fasting Blood Sugar Replace Glucose Challenge Test in Screening for Gestational Diabetes?

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Abstract

Objectives: The present study aimed to compare the diagnostic values of glycosylated hemoglobin (HbA1c) and fasting blood sugar (FBS) using the glucose challenge test (GCT) in screening for gestational diabetes.

Materials and Methods: A total of 618 women at 24-28 weeks of pregnancy were selected, and their FBS and HbA1c were measured using the GCT. The obtained results were compared in terms of sensitivity, specificity, as well as positive and negative predictive values using the ROC curve.

Results: At the cut-off point of 1.4, sensitivity was 69.74% and specificity was 69.05 for the FBS test; at the cut-off point of 6.6, sensitivity was 90.79% and specificity was 80.95% for the HbA1c test; the area under the ROC curve was 0.925 with a 95% confidence interval (0.979, 0.872).

Conclusion: The diagnostic values of the HbA1c test and GCT were favorable in screening for gestational diabetes; the HbA1c test also showed a high diagnostic value in women with positive OGCT and GCT results.

Keywords: Diabetes, Pregnancy, Glucose challenge test, Glycosylated hemoglobin

Introduction

Gestational diabetes refers to any degree of glucose intolerance that begins or is first diagnosed during pregnancy (1). Various factors play a role in the incidence of gestational diabetes, including the method of diagnosis, ethnicity, as well as body composition and age at the onset of menstruation (2-4). Maternal age, overweight or obesity, ethnicity, family history of diabetes, and history of gestational diabetes mellitus (GDM) are some of the suggested risk factors for GDM. Studies have shown that in gestational diabetes, lipid peroxidation products may be increased and the activity of antioxidant enzymes may be reduced, which may have side effects on maternal and fetal health. Like type 2 diabetes, glycemic levels in patients with GDM are associated with lipid peroxide concentrations (5). The prevalence of gestational diabetes has recently increased in the world as well as in Iran (6-8). This common metabolic disorder of pregnancy is associated with many maternal and fetal complications (9,10). Gestational diabetes is often asymptomatic, and its early screening, diagnosis, and treatment are therefore imperative (11). An ideal screening test should identify as many patients at risk as possible and separate patients (i.e., those beyond the cut-off point) from healthy people (12). Some of the screening test for gestational diabetes include mass screening, which is applied to all pregnant women at 24-28 weeks of pregnancy (13), the fasting blood sugar (FBS) test, the glucose challenge test (GCT), and the glycosylated hemoglobin (HbA1c) test. The FBS test is easily-performed, well-tolerated, cheap, reliable, and repeatable (12), but it is not perfect since partial fasting or fasting for at least eight hours may not be easy for many pregnant women (14). GCT has been used over the years as a suitable screening test for gestational diabetes. Nevertheless, it is limited by relative complication, the administration of a specific glucose load, time-consuming procedure, and non-repeatability (15). The HbA1c test has been proposed as a diagnostic tool for diabetes. This test has advantage over other tests because it is convenient and fasting-free, and shows less daily variation (9). The oral glucose tolerance test (OGTT) is the standard diagnostic tool for gestational diabetes. The oral 100-g GTT and plasma glucose measurement are performed in fasting stage one, two, and three hours after the administration of 100 g of oral glucose (16). In a meta-analysis study, Tang et al reported that, at the cut-off point of 6.5%, the HbA1c

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Key Messages

- The diagnostic values of the HbA1c test and GCT were favorable in screening for gestational diabetes; the HbA1c test also showed a high diagnostic value in women with positive OGCT and GCT results.
- Gestational diabetes refers to any degree of glucose intolerance that begins or is first diagnosed during pregnancy.

test had 62% sensitivity and 96% specificity (17). In a study by Li et al, the HbA1c test showed sensitivity of 62% and specificity of 63% at the cut-off point of 5.3%; and the FBS test showed a sensitivity of 66% and a specificity of 63% at the cut-off point of 4.3 mmol/L (18). Despite reporting different cut-off points for the HbA1c test, according to Rajput and Jain, most studies have found that HbA1c levels greater than 5.95% can be used for diagnosing gestational diabetes with a high specificity (9).

Taking into account the intolerance for glucose powder, especially during pregnancy, the need for developing an easier screening method for diabetes, the disparity of findings on the subject, as well as the lack of studies in this region to determine and compare the cut-off points of HbA1c and FBS using GCT at 24-28 weeks of pregnancy, the present study aimed to compare the diagnostic values of HbA1c and FBS in screening for gestational diabetes by using the GCT in order to facilitate the application of HbA1c test in screening for gestational diabetes when the results showed positive diagnostic values.

Materials and Methods

This descriptive-analytical study was conducted on pregnant women admitted to Ayatollah Rouhani Hospital in 2015-2016. Using the Daniel equation as well as taking into account the gestational diabetes prevalence of 8% and a confidence interval of 95%, the study sample size was estimated as 314 women but was raised to 400 for greater assurance; therefore, 400 subjects were selected through simple non-random sampling. The inclusion criteria were gestational age less than 20 weeks and an informed consent form signed by the participants. The exclusion criteria were a history or diagnosis of diabetes before pregnancy, the use of medications affecting glucose metabolism (i.e., glucocorticoids, thiazide diuretics, beta-blockers, and antipsychotic medications) and chronic liver, as well as glandular and connective tissue diseases. All participants were briefed on the study objectives, then were asked to sign informed written consent forms and complete the information questionnaire. Gestational age was determined in all the subjects based on a reliable last menstrual period or the first trimester ultrasound. The subjects' height and weight were also measured. All participants were screened for gestational diabetes. The screening test was required of those women who had one of the risk factors (e.g., prevalence of gestational diabetes, history of diabetes in first-degree relatives, history of gestational diabetes or neonatal macrosomia, weight before pregnancy, and glucose metabolism) in their first visit and at 24-28 weeks of pregnancy for the rest. If the risk factors were present and the results of the first test at 24-28 weeks of pregnancy were normal, then the test was repeated.

The FBS and HbA1c tests and GCT with the intake of 50 g of glucose in 250 cc of water were performed on a single day; one hour later, venous plasma glucose was measured using the blood samples taken at Rouhani Hospital Laboratory. FBS test was performed adopting enzymatic method with RA1000 auto analyzer at a concentration of 120 mg/dL as a diabetic indicator. A week later, the 100-g OGTT was performed on the subjects. This test was performed after a three-day preparation of the women and their intake of a normal carbohydrate diet with no restrictions; after a minimum of eight and a maximum of 14 hours of fasting, the FBS test was first performed, and BS was then controlled one, two, and three hours after the intake of 100 g of glucose. If two out of the four venous plasma glucose measurements were positive, then the gestational diabetes was suspected; if one of the measurements was positive, then impaired glucose tolerance (IGT) was suspected. The first measurement was taken at zero hours with the criterion ≥95 mg/dL, the second in the first hour with the criterion ≥180 mg/dL, the third in the second hour with the criterion ≥155 mg/dL, and the fourth in the third hour with the criterion ≥140 mg/dL based on the Carpenter-Coustan criteria. HbA1c was measured using high-performance liquid chromatography (HPLC) with 3 mL of the patient's non-clotted blood (fasting or otherwise) poured in vials designed for this test. All tests were carried out at Rouhani Hospital Laboratory, a Diazyme kit was used for performing the HbA1c test, and a bionic sugar kit was used for performing the GCT and GTT.

Statistical Analyses

SPSS 19.0 software was used in all statistical analyzes. Kolmogorov-Smirnov test was performed to determine the normality of the data. T-test was used to compare quantitative data differences between groups. Logistic regression was adopted to calculate the odds ratio. The sensitivity and specificity of the measurement methods were determined based on the ROC curve. The areas under the curves (AUC) were used to evaluate the diagnostic evaluation of each parameter. AUC greater than 0.9 was indicative of excellent diagnostic effectiveness, an AUC between 0.7 and 0.9 was suggestive of good diagnostic effectiveness, and an AUC between 0.5 and 0.7 was indicative of poor diagnostic effectiveness. Finally, an AUC of more than 0.5 markers was indicative of the lack diagnostic value. Chi-square tests were performed to compare percentages, and $P < 0.05$ was considered the significance level.

Results

Out of the 618 pregnant women, 207 ones were excluded as per the exclusion criteria and, therefore, 411 women willing to participate were included in this study. Screening methods are shown in Figures 1 and 2. Basic details of the participating women are shown in Table 1. Table 2 presents a comparison of some of the quantitative variables between the healthy women and those with gestational diabetes. Out of the 78 women with diabetes according to the standard test, 76 ones were also diagnosed with diabetes based on the GCT; out of the 118 women having diabetes based on the GCT, 76 ones were also diagnosed with diabetes based on the standard test. Given the kappa agreement coefficient of 0.709, these two tests have an almost acceptable consistency, and according to the chi-square test, the relationship between the two tests is significant ($P=0.0009$, OR = 263.28). The kappa agreement coefficient greater than 0.85 is indicative of the acceptable agreement between these two diabetes diagnostic tests. Therefore, the subsequent tests were only performed on 118 women diagnosed with diabetes in the GCT. Figure 2 shows the ROC curve for the standard glucose test regarding FBS in the participating pregnant women using the GCT. Out of the 76 women with diabetes according to the standard test, 51 ones were also diagnosed with diabetes using the FBS test with the cut-off point of 104; out of the 64 women diagnosed with diabetes based on the FBS with the cut-off point of 104, 51 ones also had diabetes according to the standard test. Given the Kappa agreement coefficient of 0.34, the consistency between these two tests is not acceptable, and the Chi-square test shows that the relationship between the two tests is significant ($P=0.009$, OR = 4.551). There is a poor agreement between the FBS test with the cut-off point of 104 and the standard test in women diagnosed with diabetes based on the GCT. Comparing the diagnostic accuracy of the HbA1c test with the cut-off point of 6.6 and the standard GTT in women with positive GCT showed that a positive family history of diabetes had the highest odds ratio (4.10), and gravity and weight before pregnancy had the lowest odds ratio (0.27 and 0.66, respectively) in comparison to other variables. Given the Kappa agreement coefficient of 0.704, there is an almost acceptable level of agreement between the two tests, and the chi-square test also shows a significant relationship between them ($P=0.009$). Table 3 presents a comparison of different ROC curves for the FBS and HbA1c.

Discussion

From early pregnancy, the placenta secretes a wide range of hormones that play major roles in metabolic changes during pregnancy. Placental growth hormone, placental lactogen, prolactin, and progesterone are the main metabolic hormones derived from placenta by modulating glucose metabolism (e.g., decreased glucose uptake, decreased insulin function, decreased insulin receptor, increased gluconeogenesis, etc) in skeletal muscle. Liver, pancreas and adipose tissue have regulatory effects on maternal blood glucose levels and are effective in advancing gestational diabetes. Given the intolerance for glucose powder, especially during pregnancy, there is a need to develop an easier screening method for diabetes (19). The result obtained in our study showed that the HbA1c test had a good diagnostic value for diagnosing the gestational diabetes, which was in agreement with the result obtained in some previous studies.

A study by Li et al reported that the HbA1c test was an accurate diagnostic test for gestational diabetes, and that the risk of diabetes was associated with age, obesity, history of IGT and glucosuric status. The given study

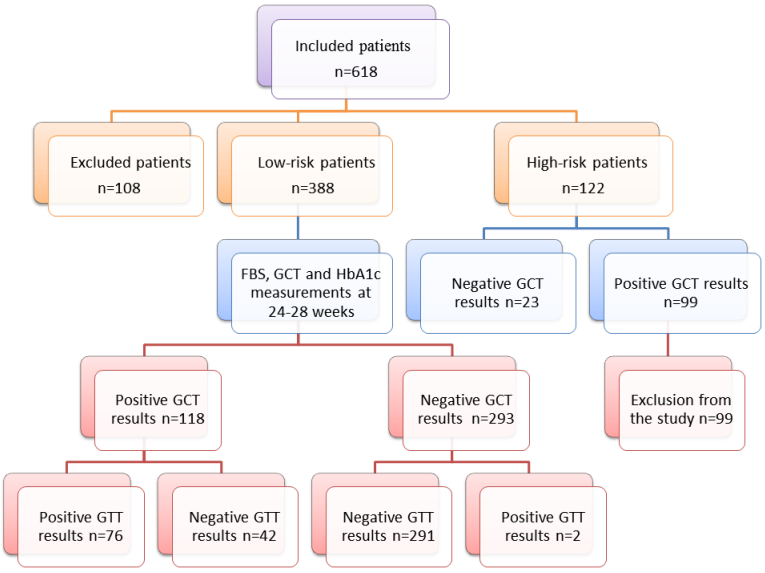

Figure 1. A Flowchart Showing the Screening Methods Used.

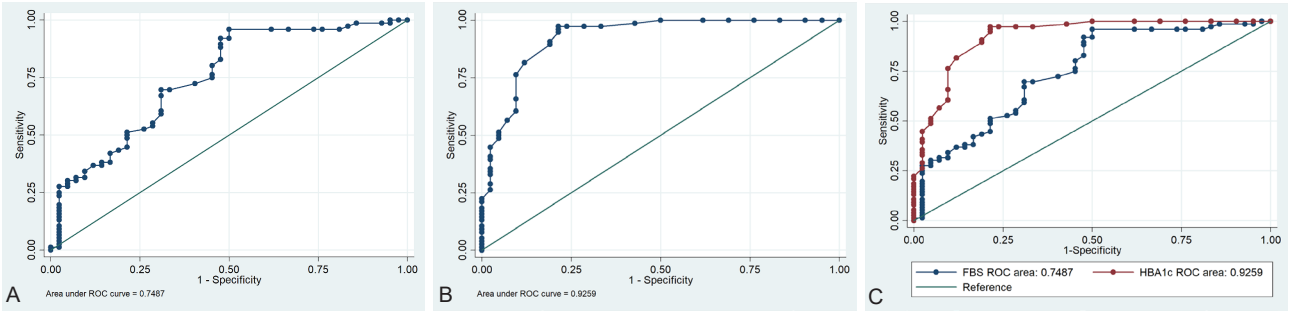

Figure 2. The ROC curve for the standard glucose test in terms of FBS (A), HbA1c (B), FBS and HbA1c (C) in the participating pregnant women with positive GCT results.

also found that the risk of gestational diabetes increased with age, history of diabetes in the family, pre-pregnancy weight, and weight at 20 weeks (18).

The cut-off point found in the study of Ye et al was lower than that obtained in the present study. These researchers argued that HbA1c failed to provide an ideal screening test for diabetes, and found that the area under the ROC curve was 0.66, which were not consistent with the present study findings. In both studies, 6.1% was taken as a cut-off point; however, sensitivity was 76% in the present study, while it was as low as 1% in the study by Ye et al. Similar to Renz and colleagues' study, the mean hemoglobin level was much lower in Ye and colleagues' study (~5) compared to that in the present study (~7%), which may

Table 1. The basic Details of the Participating Women

Variables	Diabetic Group	No diabetic Group	*P* Value
Age (y), Mean ± SD	30.07 ± 5.74	29.82±5.38	0.71
GA (wk), Mean ± SD	25.93 ± 8.89	27.75±8.55	0.32
Education, No. (%)			
<Diploma	15 (19.2)	84 (25.2)	0.56
Diploma	35 (44.9)	138 (41.4)	
Super-diploma	24 (30.8)	87 (26.1)	
BS	4 (5.1)	24 (7.2)	
BMI (kg/m^2), No. (%)			
<18.5	1 (1.3)	3 (0.9)	0.001
18.5-29.9	38 (48.7)	132 (40.2)	
25-30	23 (29.5)	169 (51.5)	
>30	16 (20.5)	24 (7.3)	
FBS (mg/mL), Mean ± SD	130.07±50/39	97.12±26.83	0.001
GCT (mg/mL), Mean ± SD	193.91±62.17	132.27±27.02	0.001
HbA1c, Mean ± SD	7.88±1.50	5.49±0.71	0.001

Table 2. A comparison of some of the quantitative variables in the participating women in the healthy and diabetic groups

Variables		GCT			OR (Diabetic/No Diabetic)	Kappa	*P* Value
		No	Yes	Total			
HBA1C Cut-off Point 6.6	No	34	8	42	36.125	0.704	0.0009
	Yes	8	68	76			
	Total	118	76	42			

Comparison of ROC levels for two variables FBS and HBA1C

Test	ROC AREA	Upper 95% CI	Lower 95% CI	*P* Value
FBS	0.748	0.841	0.653	0.0009
HBA1C	0.925	0.979	0.872	

Table 3. A comparison of some of the quantitative variables in the participating women in the healthy and diabetic groups

First Author	Year	%Specificity	Sensitivity%	Cut-off Point
Rajput (9)	2012	61.1	85.7	5.45
Li (18)	2014	63	62	5.3
Renz (20)	2015	100	7	6.5
Soumya (26)	2015	95	%46.7	6.1
Ye (27)	2016	31.8	88	4.8
This Study	2017	80.95	90.79	6.6

have explained their poor sensitivity and the disparity of the findings (20).

In the present study, an optimal cut-off point for FBS was approximately 104, at which sensitivity and specificity were 69.74% and 69.05% respectively, and the FBS test results were weaker than the HbA1c test results. Out of 76 women diagnosed with diabetes based on the standard test, 51 were also diagnosed with diabetes according to the FBS test with a cut-off point of 104; out of the 64 women diagnosed with diabetes based on the FBS test with the cut-off point of 104, 51 were also diagnosed with diabetes by the standard test.

In a study by Trujillo et al in Brazil, compared to our study, more favorable results were obtained. They argued that the FBS test was suitable for screening for gestational diabetes, which may have been attributed to the bias in their study, since 80% of the pregnant women undergoing the OGTT remained in the study but other patients withdraw from it and, therefore, no information was recorded about their FBS level. In our study, on the other hand, all eligible patients remained until the very end of the study (21).

Partial fasting and the difficulty of fasting for at least eight hours were reported by Agarwal as the disadvantages of the FBS test for many pregnant women. Many studies conducted in developing countries have shown that visiting healthcare centers while fasting is difficult for majority of women (14).

In the present study, 19% of the women had gestational diabetes, which was slightly higher than that found in studies by Odsæter et al in Norway (22) and Kashi et al in Sari (23). In a review study in Iran, Hossein-Nezhad et al discovered that one out of 20 Iranian pregnant women was afflicted with gestational diabetes (24). The inconsistency may have been due to the study population and setting. In the present study, almost 30% of the pregnant women had body mass index (BMI) >30 prior to pregnancy, which was consistent with the results from other studies conducted in this region (25); since obesity before pregnancy is a risk factor for gestational diabetes (10), the rate of gestational diabetes was higher in the present study compared to that in previous studies.

In the present study, the women with positive GCT results underwent two other tests (i.e., the FBS and HbA1c tests) and were assessed using the logistic regression analysis, which showed the FBS level to be less than 7; however, this was not the case for the HbA1c test. Moreover, the area under the ROC curve was greater for HbA1c than for FBS. The HbA1c test had a good diagnostic accuracy (i.e., it was more accurate than the FBS test) in women with positive GCT and GTT results.

Limitations and Recommendations

This study faced some limitations. First, the follow-up was not carried out until delivery; therefore, it was not possible to assess and report the complications in mother and neonate. Second, patients with overt diabetes were not investigated in this study.

It was recommended that the perinatal complications in neonates should be considered in future studies according to FBS, the importance of the age in gestational diabetes screening, and the importance of the body mass index in gestational diabetes screening.

Conclusions

It was confirmed that the HbA1c and GCT were accurate tests for diagnosing gestational diabetes, while the FBS test had poorer diagnostic accuracy than other two despite its favorable acceptability. It was also found that HbA1c had high importance in gestational diabetes screening, and that the HbA1c test produced more favorable results than the FBS test when dealing with the pregnant women with diabetes diagnosed by both the GCT and GTT.

Authors' Contribution

ZB was responsible for conceptualization and methodology, ZB designed the study and led the conduction of the research. FM took part in investigation and formal analysis of the results. SD and SHY contributed to validation and anlyses of the obtained results of the study. All authors contributed to writing-original draft preparation and review and editing. All authors approved the final manuscript and take responsibility for the integrity of the data.

Conflict of Interests

Authors declare that they have no conflict of interests.

Ethical Issues

The Ethics Committee of Babol University of Medical Sciences approved the study (Code: MUBABOL.REC.1394.62).

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