

EVALUATION OF A BREAKFAST AS SCREENING TEST FOR THE DETECTION OF GESTATIONAL DIABETES

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Abstract- A standard breakfast was evaluated as a screening test (BT) for gestational diabetes in a case-control study. Blood sugar (BS) was measured 1 hour after a breakfast that had 50gr simple sugar and was designed based on women preferences. In the same women glucose challenge test (GCT, 50gr 1hour glucose screening test) was performed one week later in randomized sequential. Cutoff values for both tests was ≥ 130 mg/dl. For both or one positive test GTT (100gr-oral glucose tolerance test) was performed. Sensitivity and specificity; optimal cutoff and concordance of both tests with GTT were calculated by X^2 , receiver operating characteristic (ROC) curve and kappa test. 41 women (29.3%) had positive GCT and 28 women (20%) had positive BT. 12 women (8.57%) had positive GTT. For BT and GCT, a sensitivity of 83.3% and 91.7% and specificity of 85.9% and 76.6% with cutoff level ≥ 130 mg/dl at 60 minute were found respectively. Optimal cutoff for BT and GCT were 130 mg/dl and 135 mg/dl respectively. Concordance of GTT with GCT and BT was 0.429 and 0.432, respectively. Standard breakfast can be used as an alternative method for assessing carbohydrate intolerance in pregnancy with same physiological response, better compliance and low cost.

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Acta Medica Iranica, 46(1): 43-46; 2008

Key words: Breakfast test, Gestational diabetes mellitus (GDM), Screening, GTT

INTRODUCTION

Gestational diabetes mellitus (GDM) is a risk factor for the mother and fetus. The risk increases proportionally to the maternal blood sugar concentration along a glycemic continuum (1-4).

Various screening and diagnostic tests are used. None of them offers the combination of qualities to be expected from a test: simplicity of use, reproducibility, specificity and sensitivity, but each of them provides a basis on which recommendations can be established.

It is recommended that screening for gestational diabetes should be performed between 24 and 28 weeks in those women not known to have glucose intolerance earlier in pregnancy. This evaluation is usually done in two steps. A 50gr oral glucose challenge test is followed by a diagnostic 100gr oral glucose tolerance test if results exceed a predetermined plasma glucose concentration (usually ≥ 130 or ≥ 140 mg/dl).(5)

Plasma glucose level is measured 1 hour after a 50gr glucose load without regard to the time of day or time of last meal. A value of 140 mg/dl (7.8 mmol/L) and 130 mg/dl (7.2 mmol/L) or higher identifies 80 percent and 90 percent of all women with gestational diabetes respectively. When the cutoff value of ≥ 130 mg/dl is used 20 to 25 percent of women have positive results compared with 14 to 18 percent when the 140 mg/dl or greater cutoff value is used (5).

Received: 19 Jun. 2006, Revised: 20 Aug. 2006, Accepted: 27 Aug. 2006

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This study was designed to evaluate the sensitivity, specificity, cutoff values and concordance of a standard breakfast test in comparison with 50gr oral glucose challenge test for screening GDM.

MATERIALS AND METHODS

In prenatal clinic of Shariati hospital GDM is screened by 1hr 50gr GCT universally.

A sample size of 138 cases was determined on the basis of an ability to have a 90% sensitivity for screening test. The gravidas who came for prenatal care and were willing signed informed consent form before randomization as a volunteer. Then they were randomly assigned to one of the 2 groups by computer generated selection with the use of consecutively numbered sealed envelopes. In the first group breakfast test was performed and 1 hr 50gr GCT one week later. In the second group the 1hr 50gr GCT was performed first and breakfast test one week later. In the women low risk for gestational diabetes the tests were performed between 24-28 weeks of gestation and in women high risk for gestational diabetes these tests were performed in the first prenatal visit. High risk patients included: > 25 years old, BMI > 27, multiple pregnancy, history of (macrosomia, unexplained still birth, preeclampsia, elevated blood pressure, neonatal hypoglycemia and prolonged neonatal icterus, fetal anomaly) and corticosteroid use. Exclusion criteria included pregestational and gestational diabetes. If any pregnant woman could not tolerate the glucose load or the designed breakfast was excluded from the study. In GCT, blood sugar was measured one hour after 50gr oral glucose and performed without regard to time and content of previous meal in the Shariati hospital laboratory. Breakfast test (BT) was performed one hour after a breakfast designed based on women's preferences. This breakfast had 50gr simple sugar and was designed by the diet department. A disposable tea-spoon was given to every pregnant woman and they were instructed to have either 10 tea-spoon of sugar with tea or 5 teaspoon of sugar with tea and 5 teaspoon of jam liquid through their breakfast. The blood sugar was measured one hour after a 50 gr glucose load (GCT)

or the designed breakfast in Shariati hospital laboratory. A positive screen was defined as a 1- hour postload value of at least 130 mg/dl of venous plasma, according to Carpenter and Coustan. For patients with a positive screen, a 100gr glucose load was administered after an overnight fast. Positive value was based on Carpenter and Coustan: Fasting BS \geq 95 mg/dl, 1st hour \geq 180 mg/dl, 2nd hour \geq 155 mg/dl, and 3rd hour \geq 140 mg/dl. Women were considered to have gestational diabetes if there were at least two abnormal values. Sensitivity and specificity for BT and GCT was calculated based on gold standard 100gr GTT. Optimal threshold of cutoff value for GCT and BT was determined using receiver operating characteristic (ROC) curve analysis. Concordance of BT and GCT was calculated through kappa test. Statistical analysis was done using the X^2 and Fisher exact tests where appropriate and $p < 0.05$ was considered statistically significant. The protocol was approved by the research committee of the medical school.

RESULTS

A total of 141 pregnant women (same race) who met the inclusion criteria were included in the study analysis (Table 1). Three gravidas could not tolerate the 50gr load glucose in GCT and were excluded from the study. 41 women (29.30%) had positive GCT and 28 women (20.00%) had positive BT based on value of \geq 130 mg/dl.

12 women (8.57 %) had positive GTT and therefore prevalence of GDM in this study was 8.57%. For BT, a sensitivity of 83.3% and specificity of 85.9% with blood sugar \geq 130 mg/dl at 60 minute were found. For GCT sensitivity and specificity were 91.7% and 76.6% respectively with the same cutoff value (Table 2).

Table 1. Demographic and FBS data of the pregnant women (mean \pm SD)

Variables	
BMI	24.9 \pm 3.1
Age(yr)	27.5 \pm 4.6
Gravidity*	1
FBS(mg/dl)	52.0 \pm 9.8

(*median)

Table 2. Test characteristic for BT and GCT

Character	BT (%)	GCT (%)
Sensitivity	83.3	91.7
Specificity	85.9	76.6
Positive Predictive Value (PPV)	35.7	26.8
Negative Predictive Value (NPV)	98.2	99.0

Optimal threshold of cutoff value for both tests was calculated in receiver operating characteristic (ROC) curve. Optimal cutoff of 130 mg/dl and 135 mg/dl were found for BT and GCT respectively. A sensitivity and specificity of 91.7% and 83.6% were calculated respectively for GCT with this cutoff (Table 3). Concordance of GTT with GCT and BT was 0.429 and 0.432, respectively. Sensitivity and specificity of GCT and BT based on 95% confidence interval had not significant difference. BMI \geq 25 and positive history (as mentioned above in high risk group) were important risk factors for the development of gestational diabetes ($p=0.0001$).

Age > 25 yr was not an important risk factor for the development of gestational diabetes. ($P=0.764$).

DISCUSSION

The overall prevalence of gestational diabetes in this pregnant population was 8.75%. The prevalence is reported to be 1.23-19.8% in literature (4,6-16).

Three patients couldn't tolerate the 50gr load but all tolerated the BT test. (2% vs.0%, $p=0.2$) For BT a sensitivity of 83.3%, a specificity of 85.9%, PPV of 53.7% and NPV of a 98.2% with cutoff value of 130mg/dl were found. For GCT, a sensitivity of 91.7%, specificity of 83.6%, PPV of 34.4% and NPV of 99.1% with a cutoff value of 135 mg/dl were found. Caraveo - Enriquez et al reported a sensitivity of 90% and specificity of 100% with a glucose level ≥ 140 mg/dl (7.2 mmol/l) for a 719 Kcal breakfast (17). Miyakoshi et al based on receiver-operating characteristic curve (ROC) identified a GCT finding above 140mg/dl as the cut off value for detecting GDM, which showed a sensitivity and specificity of 96% and 76%, respectively (16).

Table 3. Cutoff value of BS for BT and GCT

BS (mg/dl)	Sensitivity %		Specificity %	
	BT	GCT	BT	GCT
120	91.7	91.7	74.2	64.8
125	91.7	91.7	81.2	70.3
130	83.3	91.7	85.9	76.6
135	66.7	91.7	86.7	83.6
140	58.3	75.0	89.8	86.7
145	41.7	75.0	93.0	89.8

In this study optimal threshold of cutoff value for BT and GCT based on receiver operating characteristic (ROC) curve were 130 mg/dl and 135 mg/dl, respectively. Yogeve et al reported a threshold of 130mg/dl as a screening threshold for GDM in Mexican- American Women (18).

Breakfast test with cutoff value of 130 mg/dl and GCT with cut off value of 135 mg/dl did not have significant difference in screening GDM.

Concordance of both tests with GTT were similar, 0.432 for BT and 0.429 for GCT. Caraveo-Enriquez et al found that concordance of GTT with GCT and BT (719 Kcal) was 0.53 and 0.92 respectively, both statistically significant (17). In this study age > 25 yr was not a significant risk factor for the (development) of gestational diabetes. ($P=0.764$) Probably because the mean age of this pregnant population was 27.5 \pm 4.6 years. Luyt and Erem C reported maternal age as the most important risk factor for GDM (14, 19). The study shows BMI ≥ 25 is an important risk factor for GDM. ($p=0.0001$) Erem and Lepercq reported a high association between BMI ≥ 25 and GDM. (11,14) Khine et al reported that BMI is an important risk factor for the development of GDM in adolescent gravidas (7).

Positive family history and high risk group (as mentioned above) were important risks factor for GDM ($p = 0.0001$). Lepercq also concluded that being high risk for diabetes is an important risk factor for GDM (11). Standard breakfast can be used as an alternative method for assessing carbohydrate intolerance in pregnancy with the same physiological response, better compliance and low cost.

Two potential biases in this study deserve mention. The patients studied represent a subset of

all women with glucose screening during pregnancy who delivered at our institution. Further in constructing the ROC curve we assumed that GTT results, had they been performed would have been normal in the 129 subjects with the glucose screen below 130 mg/dl. However although we can not exclude the possibility that these biases may have confounding effects on the results and conclusions, the magnitude of their impact given similar findings in other studies is questioned. Undiagnosed GDM is known to increase perinatal mortality and morbidity (6). In spite of two decades of study, the best method of screening GDM and the choice of optimum cutoff values for GDM remain controversial (6). The screening test is expected to offer a combination of qualities such as simplicity of use, reproducibility, specificity and sensitivity. The breakfast test (BT) is easy to use and has acceptable sensitivity and specificity. Standard breakfast can be used as an alternative method for assessing carbohydrate intolerance in pregnancy with the same physiological response, probably better compliance and low cost.

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