Journal of Experimental and Clinical Medicine
https://dergipark.org.tr/omujecm

Research Article

J Exp Clin Med
2023; 40(3): 550-555
doi: 10.52142/omujecm.40.3.21

The efficiency of the first trimester 50 grams glucose tolerance test for detection of the gestational diabetes and the outcome of the pregnancy

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Received: 29.04.2023 • **Accepted/Published Online:** 23.08.2023 • **Final Version:** 30.09.2023

Abstract

We aimed to evaluate the effectiveness of the first trimester's 50 g glucose loading as a screening test for gestational diabetes mellitus and to find a cut-off value for 50 g OGCT in the first trimester. This study was conducted on pregnant women at low risk for diabetes mellitus. A 50-g glucose load was done in the first trimester, and then pregnant women were followed up. A 100-gram diagnostic test for gestational diabetes mellitus was administered to all participants at 24–28 weeks of gestation. The sensitivity, specificity, and false-positive rate of the 50 g glucose challenge test were determined. A total of 454 pregnant women were assessed in this study. 34 women (7.5%) were diagnosed with gestational diabetes. 420 women have constituted the non-diabetic group. In patients with gestational diabetes, age, weight, polyhydramnios, and macrosomia rates were significantly higher than in the non-diabetic group. The discriminative power of the 50 g glucose test in the first trimester was found to be significant (p = 0.001) in gestational diabetic patients. The area under the ROC curve was 0.927. The best cut-off value was 143 mg/dl. In this value, the sensitivity and false-positive rate were 85% and 11%, respectively. A 50-g glucose challenge test done in the first trimester may contribute to the reduction of maternal and perinatal risks and prevent long-term consequences such as obesity, type 2 diabetes mellitus, and lipid profile disorders with early glycemic control and lifestyle changes.

Keywords: diabetic complications, first trimester pregnancy, gestational diabetes mellitus, 50 g glucose loading test

1. Introduction

Diabetes mellitus (DM) is a metabolic disease characterized by hyperglycemia arising from inadequate insulin excretion or reduced biologic effectiveness of insulin due to various etiologic causes (1). The American Diabetes Association (ADA) describes GDM as diabetes mellitus diagnosed in the second or third trimester of pregnancy that is not clearly either type 1 or type 2 diabetes because GDM is usually diagnosed after 20 weeks of gestation and disappears either immediately or within 6 weeks after delivery. Pregnancies complicated with GDM require close monitoring to minimize maternal and neonatal morbidity, as maternal hyperglycemia increases the risk of preeclampsia, polyhydramnios, macrosomia, shoulder dystocia, and neonatal respiratory distress syndrome (RDS) (2).

There are two different approaches to identifying individuals with a high probability of having diabetes mellitus. Pregnant women with risk factors should be tested for overt diabetes mellitus at the first prenatal visit (3).

Universal screening for gestational diabetes is performed at 24 to 28 weeks of gestation. The American Diabetes Association (ADA) and American College of Obstetricians and Gynecologists (ACOG) recommend routine oral glucose tolerance tests (OGTT) with 50 grams of glucose between 24 and 28 weeks of gestation and with 100 grams of glucose for pregnant women whose plasma glucose is above 140 mg/dl in the first test, or they recommend directly applying oral glucose tolerance tests with 100 grams of glucose (4,5). Alternatively, a diagnostic test can be administered to all individuals, which is a one-step process.

The two-step approach is the most widely used approach for identifying pregnant women with gestational diabetes in the United Kingdom.

While there are no proven benefits to screening or testing for diabetes in early pregnancy, early diagnosis and treatment of maternal hyperglycemia may reduce fetal and maternal morbidity (6, 7). In the literature, there are quite a few reports investigating the association between 50-g glucose challenge test results and GDM in the first trimester (8–11).

In this study, we aimed to bring the old, safe, trendy, and most importantly, patient-friendly 50-gram OGCT and GDM screening to the first trimester. Especially the fact that 50 g of

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OGCT was easier to tolerate by the patient was one of the reasons for choosing this test. For these reasons, the 50-g OGCT test, which is usually applied between 24-28 weeks in GDM screening, could not be taken to an earlier period, for example, 11–14 weeks when aneuploidy screening was performed.

2. Materials and Method

This study was conducted prospectively on pregnant women who were admitted to our antenatal clinic for the first-trimester aneuploidy screen. It was planned to perform screening at 11–14 weeks of gestation to rule out early pregnancy losses, standardize the study group, and exclude patients with aneuploidy risk and the possibility of pregnancy termination. The time period for the study was two years. The Scientific Research Project Support Unit of Karadeniz Technical University supported this study (project number 2010.114.002). The local ethics committee reviewed and approved the study protocol. Informed consent was obtained from volunteers.

Calculation of sample size: $n = z^2pq / d^2$ (n = the number of individuals to be sampled, p = frequency of occurrence / probability of the event to be examined (0.5), q = frequency of absence of the event to be examined / probability of not happening (1-p = 0.5), z = theoretical value (1.96 for 95% confidence interval) found from the z table at a certain confidence level, d = standard error of the rate to be determined in the study (0.05 for 95% confidence interval)). $N = 1.96^2 \times 0.5 \times 0.5 / 0.05^2 = 384$ According to this calculation, 384 pregnant women will constitute the sample of the study. In order to prevent possible data loss, 10–20% more pregnant women will be sampled, and the study was planned with a total of 463 pregnant women.

Inclusion criteria: It was determined that pregnant women between the ages of 18 and 40 had a BMI of 30 kg/m2. Exclusion criteria: pregnant women with a history of pregestational or gestational diabetes, older maternal age, previously infant weight, members with a high prevalence of type 2 DM, medical conditions associated with the development of DM, hypothyroidism, hyperthyroidism, hyperprolactinemia, hereditary thrombophilia, polycystic ovary syndrome, multiple pregnancies, IVF (in vitro fertilization) pregnancy, recurrent fetal losses, steroid use, and diabetes mellitus in the first-degree relatives were not included in the study.

A 50-g oral glucose load was given after measuring the fasting plasma glucose level, and another blood sample was obtained to measure the 1st hour glucose level. The Gluc3 Cobas Integra Cobs C system was used for glucose measurement. Pregnant women with fasting glucose >125 mg/dl or 1st hour glucose >199 mg/dl were accepted as having pregestational diabetes mellitus and excluded from the study. Pregnant women were followed up. A 100-gram, three-hour oral glucose challenge test was performed for a diagnostic test at 24-28 weeks of gestation when two glucose values were elevated. We used thresholds for defining elevated values, which have been proposed by Carpenter and Coustan (12). After 50 g of GCT was performed in the first trimester, 100 g of OGTT was performed on the same pregnant woman at 24–28 gestational weeks. After this stage, the patients were divided into two groups: GDM and non-GDM. Maternal and fetal complications were investigated in all cases. Preeclampsia, premature rupture of membranes, preterm delivery, macrosomia (newborn weight > 4000 g), vacuum or forceps delivery, postpartum hemorrhage, intensive care unit needs for the newborn, fetal hypoglycemia, and hypocalcemia were monitored and recorded.

2.1. Statistical Analysis

SPSS 21.0 (IBM, USA) was used for statistical analysis. The Kolmogorov-Smirnov test was used to check the normality assumption. The student t-test was used in order to compare variables. Continuous data was given as mean ± standard deviation; ordinal and nominal data were given as medians or modes. The area under the receiver operating characteristic curve was used to determine the discriminative power of the first trimester's 50 g OGCT in the prediction of gestational diabetes. All p values were two-tailed, and statistical significance was set at $p<0.05$.

3. Results

Pregestational diabetes mellitus was detected in nine pregnant women at the time of the first trimester screen, and they were excluded from the study. Therefore, a total of 454 pregnant women were used in the final analysis. Clinical characteristics of the patients are shown in Table 1.

Table 1. The characteristics of the study population

	GDM Group (n=34)	Non-GDM Group (n=420)	p
Age (year)	33.38±5.29	28.84±5.34	
Gravida	3 (1-6)	2 (1-8)	0.558
Parity	1 (0-4)	2 (0-6)	0.442
Weight (kg)	72.81±8.08	62.87±6.5	**0.046**
Gestational age at delivery (day)	259	267	0.436
Neonatal birth weight (g)	3381.76±857.54	3220.5±555.21	0.582
APGAR 5	9	9	0.834
Mode of delivery			
Cesarean delivery (%)	58,8	47,4	**0.035**
Vaginal delivery%)	41,2	52,6	**0.033**

Data is presented as frequency and percentages or mean ± SD, n: number, g: gram, min-max. GDM: Gestational Diabetes Mellitus.

GDM was diagnosed in 34 (7.5%) cases. The mean serum glucose level at 1st hour following a 50 g glucose load was found to 169.5±28.95 mg/dl in 34 cases diagnosed with GDM. This value was obtained as 113.52±24.19 mg/dl for non-diabetic cases. The results demonstrated that the 1st hour serum glucose level following 50 g OGCT in the first-trimester was statistically significant in GDM cases (p<0.001). Maternal plasma glucose levels at the 1st hour following a 50 g glucose load at the first trimester and fasting, and 1st, 2nd, and 3rd hour glucose levels following 100 g OGCT at 24-28th weeks of gestation were presented in Table 2.

Table 2. The comparison of the mean glucose level measured at the first and second trimester

Serum Glucose (mg/dl)	GDM Group (n=34)	Non-GDM Group (n=420)	95% Confidence intervals	P
11-14 weeks 1.h-50g	169.5±28.95	113.52±24.19	-64.6 to-47.4	**0.001**
24-28 weeks fasting-100g	108.32±22.75	88.82±11.22	-23.9 to-15.1	**0.001**
24-28 weeks 1.h-100g	188.41±30.97	124.04±23.07	-72.7 to-56.1	**0.001**
24-28 weeks 2.h-100g	186.85±32.59	121.34±17.43	-72.2 to-58.9	**0.001**
24-28 weeks 3.h-100g	166.12±37.27	115.76±19.54	-57.8 to-42.9	**0.001**

Data are shown as mean ± Std

The mean age and the mean weight of the pregnant women were significantly higher in patients with GDM. Preeclampsia developed in 5 (1.1%) cases, and polyhydramnios was detected in 10 (2.2%) cases. Preterm birth occurred in a total of 48 (10.6%) cases. In a total of 28 (6.2%) cases, early rupture of the membranes complicated pregnancy. Macrosomia was detected in 23 (5.1%) cases. Of them, 9 (26.5%) were in the GDM group, and 14 (3.3%) were in the group without GDM. Shoulder dystocia developed in only one case without GDM. No woman required a vacuum or forceps delivery. In the GDM group, the rate of polyhydramnios, macrosomia, and neonatal metabolic complications was significantly higher despite treatment (Table 3).

Table 3. Maternal and neonatal morbidities of the study population

	GDM Group (n=34)	Non-GDM Group (n=420)	P
Preeclampsia, n (%)	0	5(%1)	0.435
Polyhidramnios, n (%)	6 (%17.6)	4(%1)	**0.001**
Preterm birth, n (%)	5 (%14.7)	43(%10.2)	0.546
Preterm rupture of membranes, n (%)	3 (%8.8)	25 (%6)	0.472
Postpartum hemorrhage, n (%)	1(%2.9)	6 (%1.4)	0.364
Macrosomia, n (%)	9 (%26.5)	14(%3.3)	**0.001**
Shoulder dystocia, n (%)	0	1(%0.2)	0.351
Respiratory distress syndrome, n (%)	2 (%5.9)	9(%2.1)	0.443
Neonatal metabolic complications, n (%)	3 (%8.8)	0	**0.001**
NICU admission, n (%)	6 (%17.6)	28 (%11.9)	0.523

Data are shown as percentage. n:number

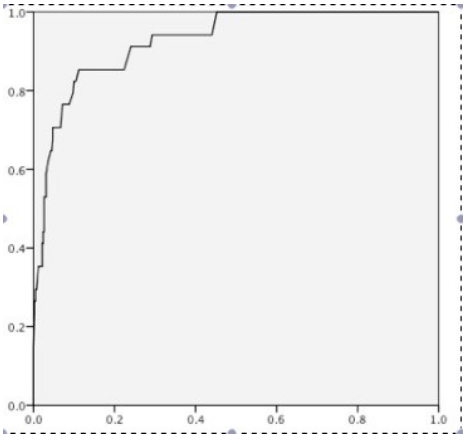

Fig. 1. Receiver operating characteristic curves for the first trimester 50 g glucose challenge test.

We calculated the area under the curve as 0.927 in the ROC analysis. 50 g of OGCT in the first trimester could discriminate GDM cases at a significance level of p<0.001 (Fig. 1). We calculated the best threshold value as 143 mg/dl for GDM screening with 50 g OGCT in the first trimester. The sensitivity of this value was 85%, and the false positivity was 11%. The 95% confidence interval value was found to be 0.886–0.968.

4. Discussion

GDM is an important health issue, as approximately 90% of DM seen in pregnancy is GDM, and it could significantly influence perinatal morbidity. Gestational diabetes mellitus (GDM) is the most common complication of pregnancy (13). The HAPO (Hyperglycemia and Pregnancy Outcome) trial, conducted in 15 centers in 9 countries between 2000 and 2006,

detected that elevated plasma glucose and increased pregnancy risks are directly interrelated. Many centers in the UK screen pregnant women who have risk factors (14, 15).

In contrast to the two-step or single-step diagnosis and screening performed at 24-28 weeks, in this study, we targeted both early diagnosis and planned to screen the patients with 50 g OGCT in the first trimester. Identifying and treating GDM earlier can have multiple benefits for patients (16). One possible explanation for the improvement in the results found may be the early treatment interventions in our study. Early screening increased the primary composite outcome (emergency caesarean section, neonatal hypoglycemia, and macrosomia; 41.2% vs. 30.3%) in the study on early detection of GDM reported by Ryan et al. (17).

Nahum et al. (8) performed a study involving 124 pregnant women using 1-hour oral glucose screening tests in the first and third trimesters (26–32 weeks). They reported that third-trimester glucose screening may be unnecessary for patients with first-trimester glucose screening test values of 110 mg/dL or less. In contrast, they reported that there was a high positive predictive value for high repeat glucose screening test results in the early third trimester for pregnant women whose first-trimester glucose test results were 135 mg/dL or above.

In a systematic review, at or after 24 weeks of gestation, oral glucose challenge tests with 140- and 135-mg/dL cutoffs had sensitivities of 82% and 93%, respectively, and specificities of 82% and 79%, respectively, against Carpenter and Coustan criteria. The 140-mg/dL cutoff had a sensitivity of 85% and a specificity of 81% against the National Diabetes Group Data criteria. (18). These studies were mainly conducted after the 24th week of pregnancy. Our study focused on GDM screening in the first trimester. In our study, we calculated the best threshold value as 143 mg/dl for gestational DM screening with 50 g OGCT in the first trimester. The sensitivity of this value was 85%, and the false positivity was 11%.

In a cohort study conducted in Finland, 75 g of OGTT was performed in the first trimester and at the 24th gestational week. While the rate of GDM diagnosed in the first trimester was 14.6%, the rate of GDM diagnosis in the 24th gestational week was 10.6%. According to the results of the study, they recommended the determination of new diagnostic cut-off values for the first trimester. The difference between this study and our study is that it should perform a single-step diagnostic test. Our study is screening by performing the 50 g GCT part of the two-step test in the first trimester (19).

Yeral et al. (9) carried out a randomized study involving 736 pregnant women. They performed first-trimester fasting blood glucose tests and two-stage 50-gram and 75-gram OGCT tests at 24-28 weeks. They reported the area under the ROC curves as 0.623, 0.708, and 0.792, respectively. They reported that 75 g of OGCT can be preferred for the GDM screening in the first trimester (9). In our study, we calculated the area under the curve as 0.927 in the ROC analysis.

In a randomized controlled study by Harper et al. (11) with obese women, it was found that performing early GDM screening did not decrease the incidence of primary results (56.9% in the early screen versus 50.8% in the routine screen). In obese women, primary outcomes may not be affected, but early glycemic control may improve primary outcomes in low-risk groups (11). We conducted our study not only on obese people but also on low-risk groups.

In the HAPO study, in the long-term results of GDM, the development of obesity in pregnant women with GDM was found to be much more significant than in pregnant women without GDM. (19.1% GDM (+) - 9.9% GDM (-)). If an early lifestyle change is made with an early diagnosis, the patient's compliance increases, and obesity can be reduced due to weight gain. Alyas et al. (17) proved that patients with GDM (+) had deterioration in blood lipid profiles, and this could lead to vascular damage. Early glycemic control would reduce these results.

Yalçın et al. (20) found the GDM incidence to be 6.6% in their study conducted at Ankara Zekai Tahir Burak Hospital in 1996. We obtained a higher GDM rate of 7.5% compared to the result of Yalçn et al. (20). We consider that the results of our study may reflect the GDM incidence in our region.

In our study, GDM (+) and GDM (-) pregnant women were compared in terms of fetal macrosomia, delivery type, preterm labor, preeclampsia, polyhydramnios, shoulder dystocia, RDS, neonatal hypoglycemia, and referral to neonatal intensive care. Fetal macrosomia, polyhydramnios, and neonatal hypoglycemia were seen more in the GDM (+) group, and this rate was statistically significant. These results were found to be similar to the current literature (20–26). There was no significant difference between the groups in terms of preterm labor, delivery type, shoulder dystocia, RDS, or referral to the NICU. These results may have been caused by the prevention of fetal macrosomia by strict glycemic control and good prenatal follow-up in our clinic.

While class B diabetics according to the White classification have similar risks as non-diabetics, hypertensive complications increase in patients in classes D, F, and R (14, 15). In this study, while preeclampsia was detected in 5 patients without GDM, it was not detected in patients with GDM. In addition, while the preeclampsia ratio is 1.1% among all patients, it was found to be 1.2% in patients without GDM, and the difference was not found to be significant. We considered that this resulted from the risk increasing by 60% due to the coexistence of GDM-related nephropathy and chronic hypertension, and we did not include pregnant women who had pre-gestational DM, previous GDM, or chronic hypertension in the study (22).

By performing 50 g of GCT in the first trimester, GDM complications that may occur up to the second trimester can be

prevented. In addition, with GDM screening in the first trimester, both aneuploidy and GDM screening will be performed in one visit, and glucose regulation will be started early since it has a high diagnostic reliability in the early period, and thus both maternal and fetal complication rates will decrease.

Limitations of our study: It was not randomized; patients with pregestational DM were excluded from the study; we did not treat those we thought to be GDM; and we waited 24–28 weeks for 100 g OGCT.

Strength: Contrary to the literature, we found that pulling the current cut-off value up rather than down reduced the sensitivity of the test and the rate of false positivity.

In conclusion, Making a 50-g glucose loading test together with the first-trimester combination test between 11 and 14 gestational weeks may contribute to making a diagnosis of GDM in the early weeks of gestation, planning the management of these cases, and reducing maternal and perinatal risks. During this period, if the 1st hour glucose threshold value is taken as 143 mg/dl, GDM cases can be detected with 11% false positivity and 85% sensitivity. These ratios are similar to the ratios of the 50-g loading test, which is routinely done between 24 and 28 gestational weeks. We believe that our study demonstrates the feasibility of early and one-step screening of GDM and can shed light on new research on this issue.

Conflict of interest

The authors declared no conflict of interest.

Funding

This study was supported The Scientific Research Project Support Unit of Karadeniz Technical University

Acknowledgments

This study was presented as an oral presentation at the 2018 congress of the Turkish German Gynecology Association. (27 April- 1 May 2018 XII. Turkish German Gynecology Congress, Cyprus)

The authors thank to The Scientific Research Project Support Unit of Karadeniz Technical University

Authors' contributions

Concept: K.B.E., T.A., Design: K.B.E., T.A., Data Collection or Processing: K.B.E., T.A., A.Ö., Analysis or Interpretation: K.B.E., T.A., Literature Search: K.B.E., T.A., Writing: K.B.E., T.A.

Ethical Statement

This study was approved by the clinical research ethics committee of the Karadeniz Technical University. Date: 01.05.2012, number: B301KTÜ0200000/489.

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