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Investigation of 50 g Oral Glucose Challenge Test Efficacy in Pregnant with and Without Risk Factors in Gestational Diabetes Screening

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Abstract

Aim: Who should be screened for gestational diabetes mellitus (GDM) is still a matter of debate. This study was to investigate the results of administering the 50 g oral glucose loading test to pregnant women with risk factors for GDM instead of all pregnant.

Methods: In this retrospective study, pregnant women were divided into two groups according to whether they had at least one of these risk factors. Eighty-four pregnant women had no risk factor for gestational diabetes, while 120 of the 204 pregnant women had at least one risk factor. The 50 and 100 g oral glucose challenge test (OGCT) results were recorded. The prevalence of GDM and predictive values of OGCT were statistically analyzed.

Results: The positive predictive value of 50 g OGCT was 20% for pregnant women without risk factors and 48.39% for pregnant women with at least one risk factor. The difference between these two groups was statistically significant.

Conclusion: The positive predictive value of 50 g of OGCT in pregnant women without risk factors was 20%, whereas that in pregnant women with at least one of the risk factors was 48.39%, a statistically significant difference. According to our study, if a selective population is screened, 2.38% of pregnant women without risk factors will not be diagnosed. Therefore, we emphasize the importance of universal screening.

Keywords: Pregnancy, diabetes, 50 g glucose challenge test, risk factor, efficiency

Introduction

Gestational diabetes mellitus (GDM) is defined as carbohydrate intolerance at different levels that is first detected during pregnancy and is a common endocorinologic disorder in pregnancy (1,2). The established risk factors for GDM are: being over 35 years, body mass index >27 kg/m^2, history of macrosomic babies in previous pregnancies, poor obstetric history (recurrent pregnancy loss, unexplained intrauterine death, history of pre-eclampsia, birth of babies with unexplained anomalies), ethnicity (more in blacks), history of diabetes in first-degree relatives, and history of GDM in a previous pregnancy (3). Despite more than three decades of research, there is no consensus on the screening and diagnosis of GDM. Sensitivity, specificity, reproducibility, non-physiologicity for pregnant women, and cost-benefit calculation of glucose tolerance tests used for screening have always been a matter of debate, and no consensus has been reached on this issue (4-7). We hypothesized that GDM screening would only be sufficient for pregnant women with risk factors.

The American Diabetes Association (ADA) and the International Association of Diabetes and Pregnancy Working Groups have recommended one-step screening, whereas the American College of Obstetricians and Gynecologists (ACOG) has adopted the Carpenter-Coustan

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screening approach of 2-step screening (6). The one-step test is the 75 g oral glucose tolerance test (OGTT). Another method includes a 2-stage approach consisting of a 50 g oral glucose challenge test (OGCT) and a 100 g OGTT. The one-hour 50 g glucose test is frequently used for screening purposes worldwide, and its success in detecting GDM ranges between 60% and 89% (8). More pregnant women are diagnosed with diabetes with single-stage 75 g OGTT, and the fasting period of pregnant women must be sufficient for this test to be performed. The 50 g OGCT, which can be performed at any patient visit, is often sufficient to terminate screening and prevent unnecessary reuterin of patients. Specialized professional societies generally accept these two methods. In 20% of patients undergoing a one-step test, a three-hour second-step test on an empty stomach is required (9). However, perinatal outcomes were similar between the two tests (8). There are different opinions on whether 50 g OGCT should be performed in all pregnant women or in pregnant women with risk factors for GDM. There are organizations that support screening only pregnant women with risk factors, as well as those that recommend screening all pregnant women (7).

The fact that different guidelines have different diagnostic approaches and threshold values leads to unfavorable results in terms of cost and efficiency worldwide. Different diagnostic approaches also lead to more or fewer diagnoses (10). However, the applicability of these diagnostic methods can be challenging for pregnant women. Although there is generally acceptance of the necessity of GDM screening worldwide, there is uncertainty about how such screening should be performed. Some organizations advocate GDM screening for all pregnant women, and others advocate GDM screening only for pregnant women with risk factors (10). If screening tests are performed in all pregnant women, problems such as a significant increase in cost and patient non-compliance may occur, whereas performing screening tests only in pregnant women with risk factors may cause concerns that some patients may be missed (1,10,11). Although National Institute for Health and Clinical Excellence (NICE), Australasian Diabetes in Pregnancy Society (ADIPS), and International Diabetes Federation support screening of selected populations with risk factors, international organizations such as ADA, WHO, and ACOG are more inclusive and advocate screening tests for the entire pregnant population (12,13).

The aim of this study was to investigate whether it would be sufficient to perform the 2-step test only in pregnant women with risk factors instead of all pregnant women.

Methods

Compliance with Ethical Standards

Informed consent for the use of hospital records was obtained from the patients. Institutional Review Board approval was obtained for this study (approval no.: 2010-88107).

Study Design

The data used in this study were obtained by retrospectively reviewing the records of 204 pregnant women approximately 24-28 weeks of gestation at gestation at Istanbul Sisli Hamidiye Etfal Health Practice and Research Center, Department of Obstetrics and Gynecology between January and April 2010. Patient information was accessed using files and patient records. Patient registration forms were examined, and characteristics such as age, height, and weight, body mass index, number of births, history of gestational diabetes in previous pregnancies, date of last menstrual period, personal and family history, medications used, history of macrosomic babies in previous pregnancies, history of preeclampsia, premature birth, abortion, and anomalous babies were questioned. Fetal weight and amniotic fluid index were also measured. Risk factors for gestational diabetes were included in the patient identification forms as follows (14,15).

1. Obesity (Body mass index >30 kg/m^2).
2. Anamnesis of gestational diabetes in previous pregnancies.
3. Type 2 diabetes in first-degree relatives.
4. History of macrosomic babies in previous pregnancies (>4000 kg).
5. Polyhydramnios in previous pregnancies (amniotic fluid >24 cm).
6. Polyhydramnios in the current pregnancy (amniotic fluid >24 cm).
7. Advanced-age pregnancy (>35).
8. Adverse obstetric anamnesis (preeclampsia, abortion, and preterm birth).
9. Presence of glucosuria.
10. Fetal size in the current pregnancy (>95th percentile).

Pregnant women were divided into two groups according to whether they had at least one of these risk factors. Eighty-four pregnant women had no risk factor for gestational diabetes, while 120 of the 204 pregnant women had at least one risk factor. Patients with type 1 or type 2 diabetes mellitus or carbohydrate intolerance at any level before pregnancy, those with multiple pregnancies, those with diagnosed endocrinopathy, renal and hepatic diseases, pregnant women under the age of 18 years, and those using drugs that may affect insulin secretion or sensitivity were excluded from the study. In addition, values ++ and above (approximately 5.6 mmol/L) were

considered indicative of glycosuria in pregnant women. Pregnant women were included and excluded in our study, and their numbers are presented in Figure 1.

Laboratory records of pregnant women were divided into groups, and screening test results were obtained. The ADA, ACOG, and the Fourth International Gestational Diabetes Study Group recommended a plasma glucose threshold value of 140 mg/dL. In our study, we accepted 140 mg/dL as the threshold value. The laboratory results of patients who underwent 50 and 100 g OGCT and OGTT were recorded.

Statistical Analysis

Statistical evaluation was performed using the SPSS 19.0 package. Categorical data were compared using the chi-square test. Logistic regression was used to analyze the relationship between binary results and the screening method applied according to the categorical variables of the pregnant woman. Positive predictive values of 50 g OGTT were calculated in pregnant women with and without risk factors. Descriptive statistics for numerical variables were presented as positive predictive values. $P<0.05$ was considered significant.

Results

The mean age of pregnant women was 25.5 years. Of the 204 pregnant women included in the study, 84 (41.18%) had none of the risk factors and 120 (58.82% of the cases) had at least one risk factor. Accordingly, obesity and a family history of DM ranked first among the risk factors (Table 1).

Gestational diabetes mellitus was detected in 32 of the 204 pregnant women included in the study, and its prevalence was calculated as 15.69%. The prevalence of GDM in pregnant women without risk factors was calculated to be 2.38%.

While the positive predictive value of 50 g OGTT was 20% in pregnant women without risk factors, it was 48.39% in pregnant women with at least one of the

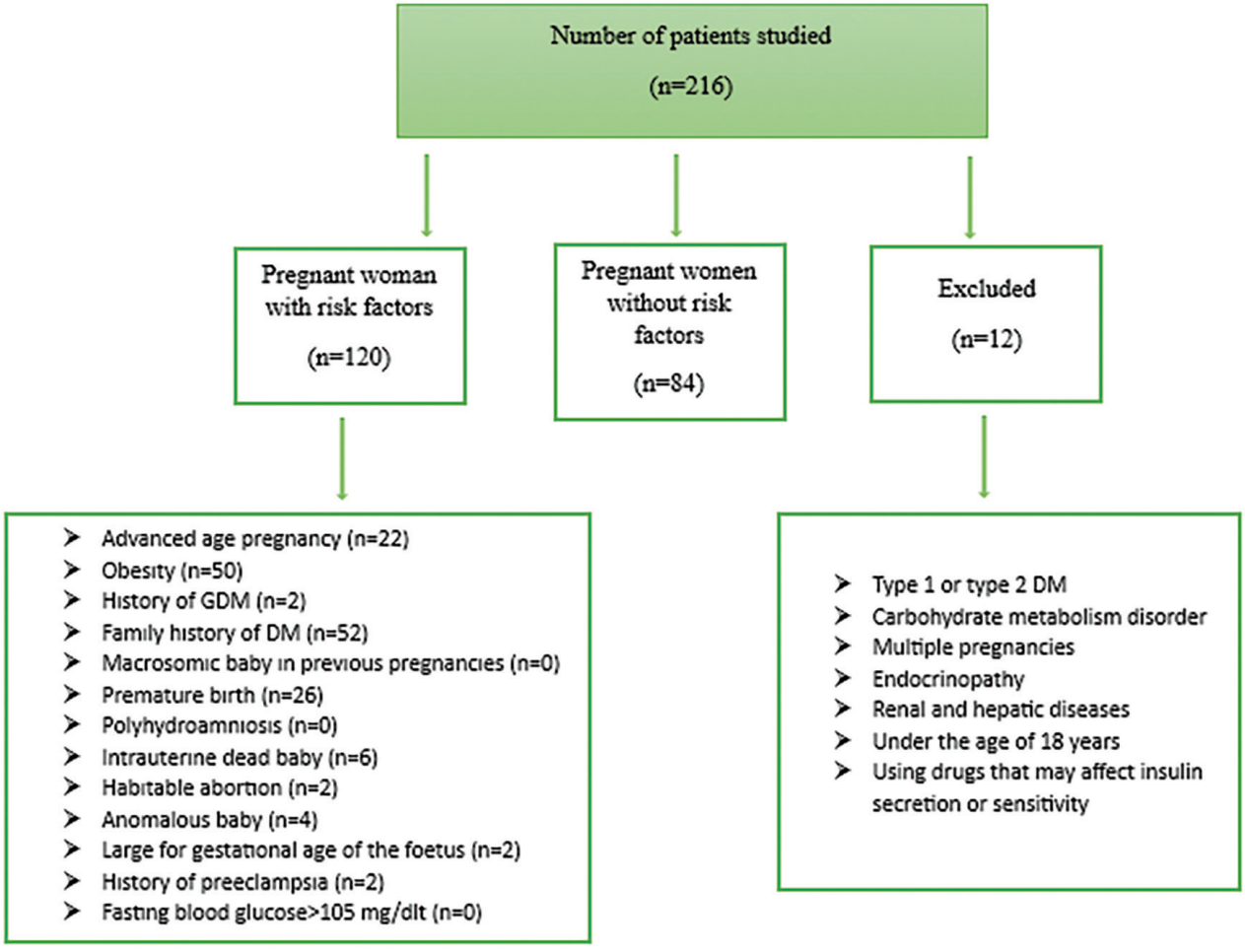

Figure 1. Consort flow diagram of the study

GDM: Gestational diabetes mellitus, DM: Diabetes mellitus

risk factors. The difference between these two groups was statistically significant ($p<0.05$). Although 94% of pregnant women diagnosed with GDM had at least one risk factor, the remaining 6% did not.

Discussion

Screening for GDM has become a routine practice in prenatal follow-up because the problems it causes for mother and fetus can be prevented with appropriate treatment (16). With good glycemic control, malformation and perinatal mortality rates decrease. The aim in pregnant women with diabetes is to maintain the blood glucose profile at the optimum level and thus minimize poor perinatal outcomes. For this purpose, within the framework of the GDM screening program, a 1 h 50 g glucose tolerance test is recommended for all pregnant women between 24 and 28 weeks (17). One of the most controversial issues is whether the 50 g OGTT used in GDM screening should be performed in all pregnant women or in pregnant women with risk factors for developing gestational diabetes. Although screening for gestational diabetes is strongly recommended, there is no consensus among the WHO, ADA, ADIPS, NICE, and ACOG regarding screening recommendations for this disease (18). The ADA advocates the idea that performing this screening test in all pregnant women is unnecessary and costly, and there are studies supporting this (19-22). One such study, by Jiménez-Moleón et al. (23) in 2000, found GDM in 7 of 1138 pregnant women without risk factors.

The ADA does not recommend screening pregnant women with low-risk factors. In addition, it recommends screening pregnant women with high risk factors at the first visit and pregnant women with moderate risk factors at 24-28 weeks of gestation. NICE recommends screening only pregnant women with risk factors (13). In many countries around the world, GDM screening is routinely recommended to be performed between 24 and 28 weeks. In this case, all pregnant women were tested after glucose loading without differentiating between low-risk and high-risk GDM populations. We face many problems, such as negative feedback from patients, non-compliance of patients with the test, difficulties related to national economies such as cost-effectiveness, unnecessary additional tests due to different threshold values related to the tests, and low prevalence of GDM in pregnant women without risk factors. For these reasons, the idea of performing the test only in pregnant women with risk factors has emerged (24).

The risk factors for GDM identified in our review of the literature are as follows; Obesity (body mass index >30 kg/m^2), Anamnesis of gestational diabetes in previous pregnancies, type 2 diabetes in first-degree relatives, History of macrosomic babies in previous pregnancies (>4000 kg), Premature birth (births before 24-37 weeks of gestation), Polyhydramnios in previous pregnancies (amniotic fluid >24 cm), Polyhydramnios in the current pregnancy (amniotic fluid >24 cm), Intrauterine dead

Table 1. Distribution of risk factors in pregnant women

Risk factor	Number of patients	%
Advanced-age pregnancy	22	18.3
Obesity	50	41.7
History of GDM	2	1.7
Family history of diabetes mellitus	52	43.3
Macrosomic baby in previous pregnancies	0	0.0
Premature birth	26	21.7
Polyhydroamniosis	0	0.0
Intrauterine dead baby	6	5.0
Habitable abortion	2	1.7
Anomalous baby	4	3.3
Large for gestational age of the fetus:	2	1.7
History of preeclampsia:	2	1.7
Fasting blood glucose level >105 mg/dlt	14	11.7
Glucosuria	0	0.0

GDM: Gestational diabetes mellitus

Table 2. Diagnostic efficacy of the 50 g oral glucose challenge test (28)

Threshold	Screening	Criteria	Sensitivity	Specificity	LR+ (95% CI)	LR- (95% CI)
≥140	50 g OGCT	CC	85 (76-90)	86 (80-90)	5.9 (4.2-8.3)	0.18 (0.11-0.29)
≥140	50 g OGCT	ADA	88 (76-97)	84 (79-87)	6.0 (5.1-7.0)	0.16 (0.06-0.45)
≥140	50 g OGCT	NDDG	85 (73-92)	83 (78-87)	5.1 (3.9-6.6)	0.18 (0.10-0.34)
≥140	50 g OGCT	CDA	81 (58-95)	69 (59-79)	2.6 (1.8-3.8)	0.27 (0.11-0.67)
≥140	50 g OGCT	WHO	70 (43-85)	89 (73-94)	6.5 (5.1-8.3)	0.33 (0.22-0.52)
≥130	50 g OGCT	CC	99 (95-100)	77 (68-83)	4.2 (3.0-5.9)	0.02 0.003-0.08)
≥130	50 g OGCT	NDDG	88 (67-90)	66 (47-84)	2.7 (1.8-3.9)	0.14 (0.34-0.55)
≥220	-	CC	17 (12-24)	100 (99-100)	-	0.83 (0.78-0.89)

ADA: American Diabetes Association, CC: Carpenter Coustan, CDA: Canadian Diabetes Association, IADPSG: Association of the Diabetes and Pregnancy Study Groups, OGCT: Oral glucose challenge test, WHO: World Health Organization, LR+: Positive-likelihood ratio, LR: Negative-likelihood ratio, NDDG: National Diabetes Data Group, CI: Confidence interval

baby, Anamnesis of three or more abortions, History of an anomalous baby, Advanced age pregnancy (>35), Presence of glucosuria, Fetal size in the current pregnancy (>90 percentile), History of toxemia in previous pregnancies (3,21). The sensitivity, specificity, reproducibility, non-physiological, and cost-benefit calculations of glucose tolerance tests used for screening have always been a matter of debate, and no consensus has been reached on this issue (25).

The generally accepted view is that screening tests are expected to have a low false-negative rate. Typically, high specificity is expected in diagnostic tests. As with other screening tests, the aim of GDM screening is to ensure that false-negative and false-positive test results are close to 0. Although screening strategies with different options and cut-off values have been tried for this purpose, these objectives have not been achieved yet. Therefore, pregnant women who do not have GDM are often misdiagnosed with GDM, and some pregnant women are not diagnosed with GDM (10). The Table 2 shows the diagnostic yields of the 50 g OGCT test from different organizations (26).

In this study, we aimed to investigate whether it is sufficient to perform 50 g OGCTT alone in pregnant women with at least one risk factor for the development of GDM. However, performing OGTT on all pregnant women to detect GDM incurs significant costs. The difficulty in repeatability of the two-stage test, which is the most commonly used test in the world, side effects, such as nausea, vomiting, and feeling of weakness during the procedure, and the stress it causes in pregnant women until the second test, have mobilized researchers for alternative methods. Therefore, selective screening has attracted increasing attention in recent years (27-29). According to these views, if pregnant women with defined risk factors for GDM are screened instead of all pregnant women, screening costs can be significantly reduced, and unnecessary screening can be avoided because of the selective population (30).

In a study by Naylor et al. (29) (Toronto Trihospital Gestational Diabetes Project), 3131 pregnant women were categorized into low, intermediate, and high risk groups according to the presence of defined risk factors (age, pre-pregnancy body mass index, and ethnicity). In this manner, the low-risk group was not screened, whereas all patients in the intermediate- and high-risk groups underwent routine testing (31). Thus, 34.7% of pregnant women were protected from unnecessary testing and stress. It has been demonstrated that the incidence of GDM in pregnant women with no risk factors is 2%. This approach did not result in a significant decrease in the number of pregnant women diagnosed with GDM but protected a statistically significant number of pregnant women from unnecessary OGCT. In this study, we found that the prevalence of GDM among pregnant women without risk factors was 2%. Similar to Naylor et al. (29), when we excluded pregnant women with no risk factors, we found that approximately 41% of pregnant women did not need to undergo screening.

In another study, it was emphasized that 10% of GDM cases were missed as a result of not including the low-risk group in screening (30,31). In our study, we found that approximately 6% of GDM cases that should have been diagnosed would not have been diagnosed if pregnant women without risk factors for GDM were not screened (32,33). In a study by Weeks et al. (34), there was no statistically significant difference in the rates of macrosomia, cesarean delivery, and shoulder dystocia in pregnancy outcomes between groups with and without risk factors. In a study by Benjamin et al. (35) which included 341 pregnant women, the results of 50 and 100 g OGCTT along with fasting blood glucose levels and risk factors were comparatively analyzed. Sensitivity, positive and negative predictive values, positive and negative likelihood ratios, and false positive and false negative values were analyzed. As a result, fasting blood glucose levels together with risk factors were found to be superior to the 50 g glucose tolerance test due to its diagnostic efficacy, easy applicability, and low cost. In this study, we examined the positive predictive values of 50 g OGCT in pregnant women with and without risk factors for GDM and found that the difference was statistically significant. In this study, we found that the positive predictive value of 50 g OGCT increased to 60% in pregnant women with more than one risk factor. Similar to our study, de Sereday et al. (36) reported that a single-stage 100 g or 75 g loading test may be preferred for pregnant women with more than one risk factor. Although the fact that GDM incidence is below 5% in many populations suggests that screening is unnecessary, considering that it increases perinatal risks fourfold, this disease seems to be worth screening. We, like many expert professional organizations and health organizations, think that GDM screening should be performed (18). In our study, 204 pregnant women were admitted to our antenatal clinic, and all of them underwent a 50 g OGTT. Pregnant women with a 50 g OGTT >140 mg/dL underwent a 100 g OGTT. In our study, the prevalence of GDM was 15.69% among pregnant women. The prevalence of GDM in our clinic was found to be higher than that in many studies, which is due to the fact that our clinic is a tertiary health center. In our study, the prevalence of GDM was calculated as 2.38% in pregnant women without risk factors and 25% in pregnant women with at least one risk factor. In our study, as the number of risk factors increased, the prevalence of GDM also increased. In pregnant women with two

risk factors simultaneously, the positive predictive value of 50 g of OGTT increases to 60%, and the prevalence of GDM increases to 37.50%. Glucose loading without a 50 g glucose screening test in pregnant women with more than one risk factor may be a different method that should be investigated. According to the results of our study, the positive predictive value of 50 g OGTT was 20% in pregnant women without risk factors and 48.39% in pregnant women with at least one of the risk factors, and there was a statistically significant difference between them ($p<0.05$). In our study, 120 of the 204 pregnant women had at least one risk factor, and 84 did not have any risk factors. In 62 (51.6%) pregnant women with at least one risk factor, the blood glucose level was >140 mg/dL at the end of the 1st hour, and 30 (25%) of them were diagnosed with GDM. In 10 (11%) pregnant women without risk factors, the blood glucose level was >140 mg/dL at the end of the 1st hour, and 2 of them had GDM (25%). In this case, if only pregnant women with risk factors had been screened, 84 pregnant women would not have been screened, and 6.25% of the pregnant women who should have been diagnosed with GDM would not have been diagnosed. Carpenter and Coustan (37) reported in a selective study in which only pregnant women with risk factors were screened that 50% of pregnant women could not be screened, and in this case, 1/3 of pregnant women could not be diagnosed.

Study Limitations

There are various limitations to this study. This study was conducted retrospectively and has a small sample size. The study was conducted at a solitary center.

Conclusion

According to our study, if only pregnant women with risk factors are screened, 2.38% of pregnant women may not be diagnosed. Although selective screening, as opposed to universal screening, is an alternative for low-resource countries, the exclusion of pregnant women with risk factors is far from being generally accepted. However, although it is a controversial issue to perform GDM screening only in pregnant women with risk factors instead of all pregnant women, it may not be an erroneous approach to offer such an option according to our study.

Ethics

Ethics Committee Approval: Necessary permissions were obtained from the hospital management Institutional Review Board for this study (approval no.: 2010-88107).

Informed Consent: Informed consent for the use of hospital records was obtained from the patients.

Authorship Contributions

Surgical and Medical Practices: E.E., S.O., Concept: E.E., S.O., Design: E.E., S.O., Data Collection or Processing: E.E., Analysis or Interpretation: E.E., Literature Search: E.E., S.O., Writing: E.E.

Conflict of Interest: No conflicts of interest were declared by the authors.

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