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What is the best cut-off point for screening gestational diabetes in Turkish women?

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Aim: To find an optimal threshold level with higher sensitivity and specificity for screening of gestational diabetes mellitus (GDM) in Turkish pregnant women.

Materials and methods: This was a retrospective study. Screening for GDM was performed in all pregnant women between 24 and 28 weeks of gestation using the 1 h 50 g glucose challenge test (GCT) with a subsequent 3 h 100 g oral glucose tolerance test (OGTT) for confirmation if screened positive. The glucose values obtained were analyzed by both the Carpenter and Coustan (C&C criteria) and National Diabetes Data Group (NDDG) criteria.

Results: There were 808 women meeting the study inclusion criteria. There were 66 (8.1%) women diagnosed with GDM using the C&C criteria and 45 (5.7%) using the NDDG criteria. The best cut-off point for GCT was 132 mg/dL for detecting GDM. No diabetes was found below the glucose level of 130 mg/dL.

Conclusion: GCT is suitable for screening of Turkish women, but place of residence as well as race must be taken into consideration to establish the best cut-off level of GCT, since ethnic and environmental factors may contribute to the occurrence of GDM.

Key words: Gestational diabetes, glucose challenge test, glucose tolerance test, cut-off

Türk kadınlarında gestasyonel diyabetin taranmasında en uygun kesme noktası nedir?

Amaç: Gebe Türk kadınlarında gestasyonel diyabetin (GDM) taranmasında en yüksek sensitivite ve spesifisiteye sahip olan optimal kesme noktasını bulmaktır.

Yöntem ve gereç: Bu çalışma retrospektif olarak yapılmıştır. Tüm gebe kadınlara 24-28 haftalar arasında 1 saatlik 50 gr glukoz deneme testi (GCT), bu testin pozitifliği durumunda da 3 saatlik 100 gr oral glukoz tolerans testi (OGTT) yapıldı. Elde edilen glukoz değerleri hem Carpenter ve Coustan (C&C) hem de National Diabetes Data Group (NDDG) kriterlerine göre incelendi.

Bulgular: Çalışma kriterlerine uyan 808 kadın çalışmaya alındı. C&C kriterlerine göre 66 (% 8,1) kadına GDM tanısı konulurken, NDDG kriterlerine göre 45 (% 5,7) kadın bu tanıyı aldı. GDM tesbitinde en uygun kesme noktası GCT için 132 mg/dL olarak tesbit edildi. GCT sonucu 130 mg/dL altında olan hiçbir hastada GDM izlenmedi.

Sonuç: GCT Türk kadınlarının taranması için uygun bir testtir. Ancak yerleşim yeri ve ırk faktörü de GCT için kesme noktasının belirlenmesinde dikkate alınmalıdır. Çünkü etnik ve çevresel faktörlerin gestasyonel diyabet gelişimine katkısı olabilir.

Anahtar sözcükler: Gestasyonel diyabet, glukoz yükleme testi, glukoz tolerans testi, kesme noktası

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Introduction

Gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance with onset or first recognition during pregnancy (1,2). It affects 1.2% to 14.3% of the pregnant population (1,2). Prevalence rates of GDM varies widely by ethnicity (3,4); Asians have the highest reported prevalence rates (4,5). Considering GDM consequences of increased perinatal and maternal morbidity and mortality, in addition to long-term complications, its accurate identification and treatment is very important (6,7).

The American College of Obstetricians and Gynecologists (ACOG) and the American Diabetes Association (ADA) have both recommended that all pregnant women should be screened for GDM (8,9). While the optimal method of screening remains controversial, the 50 g 1 h glucose challenge test (GCT) is performed most commonly in the world. This is often followed by a 100 g 3 h oral glucose tolerance test (OGTT) for confirmation, if screened positive.

The threshold for a positive GCT necessitating further diagnostic testing remains controversial (8-10). In the previous studies, authors recommended the use of a GCT cut-off level of 130-140 mg/dL for screening of GDM between 24 and 28 weeks of gestation (11,12). However, in later studies, most of the cut-off values were different from those in the previous reports (13,14). These findings may have been due to the differences in race and nutrition of the population.

Both the ADA and ACOG have stated that a glucose threshold value of ≥140 mg/dL identifies 80% of women with GDM, and the diagnostic accuracy is further increased to 90% using a cut-off of 130 mg/dL. No definitive screening threshold was adopted by the ACOG, who stated that "either threshold is acceptable" (1,2).

While a higher threshold gives better specificity and lowers the likelihood of a false-positive test result, the disadvantage is that a number of women who may have gestational diabetes will remain undiagnosed and untreated. In contrast, a lower threshold yields a higher sensitivity, but more women will undergo unnecessary diagnostic testing, which can be expensive, time-consuming, and leads to unnecessary intervention. In this study we tried to find an optimal threshold level with higher sensitivity and specificity for screening of GDM in Turkish pregnant women.

Materials and methods

This retrospective study of diagnostic accuracy was conducted between January 2008 and December 2009 in Fatih University, Faculty of Medicine, Ankara. Women screened for GDM and who had given birth at Fatih University were enrolled in the study. All relevant data including demographic information, and GCT and OGTT results were collected for further analysis. Patients with potential diabetic pregnancy and any systemic disease were excluded from the study. Criteria for potential diabetic pregnancy were one or more of the following: previous history of GDM, including familial history; previous fetal weight > 4000 g, previous infants with congenital anomalies; previous unexplained fetal loss; hypertension; glucosuria by urine strip; and previous history of diabetic complications, polyhydramnios, multi-fetal pregnancies, and delivery prior to 24 completed weeks of gestation.

Screening for GDM was performed in all pregnant women between 24 and 28 weeks of gestation using the 1 h 50 g GCT in accordance with protocols recommended by the ADA and the ACOG with a subsequent 3 h 100 g OGTT for confirmation if screened positive. A positive result was defined as plasma glucose of 125 mg/dL or greater. The threshold was taken as 125 mg/dL in order not to miss GDM cases that can be seen with the lower GCT results. The glucose values obtained were analyzed by both the Carpenter and Coustan (C&C criteria) and National Diabetes Data Group (NDDG) criteria for the diagnosis of GDM and IGT (15,16).

An abnormal 3 h OGTT is defined as 2 or more plasma glucose values that meet or exceed the standards of C&C criteria (fasting ≥ 95, l h ≥ 180, 2 h ≥ 155, and 3 h ≥ 140 mg/dL) and the NDDG (fasting ≥ 105, 1 h ≥ 190, 2 h ≥ 165, and 3h ≥ 145 mg/dL). Fasting plasma glucose (FPG) ≥ 140 mg/dL was considered as showing diabetes and GCT was omitted. Plasma glucose ≥ 200 mg/dL after GCT were also accepted as showing diabetes and 3 h OGTT was

not performed. Treatment was based on the diagnosis made according to the C&C criteria. Plasma glucose was determined from a peripheral venous sample by the hexokinase method (COBAS Integra 800, Roche, Germany).

Firstly patients with GDM and IGT were seen by a dietician and received a dietary evaluation and diet therapy to achieve normoglycemia. Diet therapy continued if fasting blood sugar (FBS) < 105 mg/dL, and 2 h postprandial < 140 mg/dL, with home blood sugar monitoring continued once daily. In women with glucose values > 200 mg/dL on initial OGTT and those who recorded FBS > 105 and 2 h postprandial glucose > 140 for at least 2-3 values while on a dietary regimen, insulin therapy was commenced.

The statistical analyses were carried out using SPSS 15.0. Following the entering of patient data into the computer, all the necessary diagnostic checks and corrections were performed. Normal distribution of measurement values as a convenience was examined graphically and with the Shapiro-Wilk test. In presenting descriptive statistics, numbers and percentages were used for categorical variables, and median (interquartile range [IQR]) and mean ± SD values were used for the data. The groups, which were formed according to level of glucose intolerance, were compared to each other by Kruskal Wallis test and Bonferroni corrected Mann Whitney test. Spearman correlation analysis was used for evaluation of the relationship between demographic variables and GCT results. Chi-square and Fisher's exact test were used for comparison of categorical variables. Receiver–operating characteristics (ROC) curve analysis was performed to find the optimal cut-off point. Sensitivity; specificity; the area under the curve (AUC), which reflects the probability of correctly identifying patients; positive predictive value (PPV); and negative predictive value (NPV) were calculated. Two-tailed $P < 0.05$ was considered statistically significant.

Results

There were 808 women meeting the study inclusion criteria and available for analysis. The characteristics of the patients in this study were as follows [expressed as the median (IQR)]: maternal age was 28 (7) years, gravida 2 (2), parity 1 (2), BMI 26 (5), birth weight 3300 (300) g, GCT 157.50 (26). Demographic characteristics according to GCT results are shown in Table 1. Maternal characteristics associated with higher GCT categories included age ≥ 35 and multiparity ($P < 0.001$, $P = 0.002$).

There were 66 (8.1%) women diagnosed with GDM using the ADA criteria and 45 (5.7%) using the NDDG criteria during the study period. No diabetes was found below the glucose level of 130 mg/dL. If 132 mg/dL was taken as the cut-off point only 2 women with GDM were seen below this level.

Of the 12 women with GDM, 4 needed insulin treatment. The GCT results of all patients requiring insulin treatment were over 200 mg/dL. Table 2

Table 1. Demographic characteristics and GCT results of groups (median (IQR)).

	Normal GCT	FP-GCT	IGT	GDM	P value
Age (year)	28.0 (7.0)	28.5 (7.0)	29.0 (7.0)	28.5 (9.0)	0.612
Gravidity (n)	2.0 (2.0)	2.0 (2.0)	2.0 (3.0)	2.0 (2.0)	0.858
Parity (n)	1.0 (1.0)	1.0 (2.0)	1.0 (2.0)	1.0 (2.0)	0.893
G. age (week)	26.0 (3.0)	26.0 (3.0)	27.0 (3.0)	27.0 (3.0)	0.269
BMI	26.0 (5.0)	25.0 (4.0)	26.0 (5.0)	26.0 (4.0)	0.624
GCT	112.0 (72.0)	143.5 (22.0)	160.0 (21.0)	175.0 (48.0)	<0.001*
Birth weight (g)	3200.0 (400.0)	3200.0 (400.0)	3200.0 (650.0)	3400.0 (350.0)	0.001¶

* difference between control versus other 3 groups, between FP-GCT versus IGT and GDM
¶ difference between GDM versus other 3 groups.

Table 2. Sensitivity and specificity of various cutoff values of GCT.

Cut-off (mg/dL)	GDM according to C&C		GDM according to NDDG		Sensitivity	Specificity	PPV	NPV
	n	%	n	%	(%)	(%)	(%)	(%)
130	66	100,0	45	100,0	100,0	68,5	21,3	100
132	64	97,0	45	100,0	97,4	70,5	22,6	99,6
140	58	87,9	43	95,6	84,8	77,8	25,0	98,6
150	48	72,7	36	80,0	72,7	86,0	30,4	97,2
160	39	59,1	30	66,7	57,6	91,9	37,1	96,2
170	28	42,4	20	44,4	42,4	95,1	43,8	94,9
180	22	33,3	14	31,1	33,3	97,3	52,4	94,3

PPV: Positive predictive value
NPV: Negative predictive value

shows the sensitivity and specificity of various cut-off values of GCT. The probability of GDM in patients with different GCT results is shown in Table 3. The ROC curve identified the GCT result above 132 mg/dL as useful for detecting GDM (Figure). At this cut-off value, the sensitivity, specificity, PPV, and NPV of GCT were 97.0%, 70.5%, 22.6%, and 99.6%, respectively [AUC = 0.903 (95% CI: 0.877-0.930; P < 0.001)]. If 132 was taken as cut-off point to detect IGT together with GDM, sensitivity and specificity would be 99.1% and 74.0%, respectively (AUC = 0.921, 95% CI: 0.901-0.941; P < 0.001) (Figure).

Table 3. The probability of GDM in patients with different GCT results.

Cut-off value (mg/dL)	GDM (C&C)		GDM (NDDG)	
	n	(%)	n	(%)
130	66	(21.3)	45	(14.5)
132	64	(22.6)	45	(15.9)
140	58	(25.0)	43	(18.5)
150	48	(30.4)	36	(22.8)
160	39	(37.1)	30	(28.6)
170	28	(43.8)	20	(31.3)
180	22	(52.4)	14	(33.3)

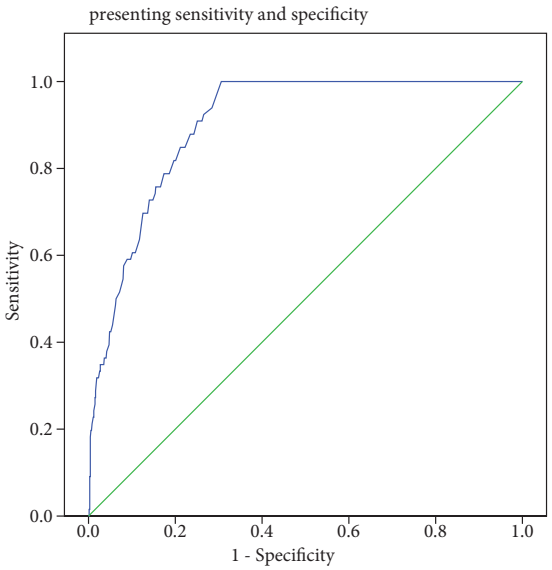

Figure. ROC curve presenting sensitivity and specificity.

Relation between GCT results and demographic variables were examined by Spearman correlation analysis. A weak positive correlation was found between GCT and maternal age, gravida, parity, and birth weight. There was a positive correlation between GCT value and 100 g OGTT 0, 1, and 2 h glucose levels. The relationship between OGTT results and demographic variables was also examined. A positive but weak correlation was found between 0, 1, and 2 h glucose levels and maternal age and BMI. Results of the correlation analysis are shown in Table 4.

Table 4. Correlation analysis between GCT results and demographic variables.

		50 g GCT	Age	Gravida	Parity	Birth weight	BMI	Gender	Delivery route	100 g 0	100 g 1	100 g 2	100 g 3
50 g GCT	Rho		0.196(**)	0.161(**)	0.130(**)	0.101(*)	0.074	0.036	0.057	0.156(*)	0.150(*)	0.185(**)	0.117
	P value		<0.001	<0.001	<0.001	0.025	0.100	0.428	0.205	0.019	0.024	0.005	0.077
Age	Rho	0.196(**)		0.540(**)	0.540(**)	0.020	0.197(**)	0.008	−0.013	0.092	0.203(**)	0.223(**)	0.134(*)
	P value	<0.001		<0.001	<0.001	0.663	<0.001	0.865	0.778	0.168	0.002	0.001	0.043
Gravida	Rho	0.161(**)	0.540(**)		0.876(**)	0.046	0.184(**)	0.009	−0.105(*)	−0.075	−0.004	−0.012	−0.051
	P value	<0.001	<0.001		<0.001	0.310	<0.001	0.833	0.020	0.279	0.958	0.857	0.462
Parity	Rho	0.130(**)	0.540(**)	0.876(**)		0.062	0.209(**)	0.054	−0.130(**)	−0.055	0.083	0.007	−0.039
	P value	<0.001	<0.001	<0.001		0.172	<0.001	0.231	0.004	0.430	0.232	0.914	0.573
Birth weight	Rho	0.101(*)	0.020	0.046	0.062		0.159(**)	−0.032	0.034	−0.079	0.106	0.052	−0.070
	P value	0.025	0.663	0.310	0.172		<0.001	0.483	0.448	0.374	0.235	0.557	0.431
BMI	Rho	0.074	0.197(**)	0.184(**)	0.209(**)	0.159(**)		−0.040	0.008	−0.042	0.329(**)	0.215(*)	0.092
	P value	0.100	<0.001	<0.001	<0.001	<0.001		0.377	0.857	0.635	<0.001	0.013	0.298
Gender	Rho	−0.036	0.008	0.009	0.054	−0.032	−0.040		0.002	−0.066	0.012	−0.033	−0.077
	P value	0.428	0.865	0.833	0.231	0.483	0.377		0.965	0.458	0.889	0.711	0.385
Delivery route	Rho	0.057	−0.013	−0.105(*)	−0.130(**)	0.034	0.008	0.002		0.076	−0.094	−0.100	−0.140
	P value	0.205	0.778	0.020	0.004	0.448	0.857	0.965		0.387	0.286	0.258	0.111
100 g 0	Rho	0.156(*)	0.092	−0.075	−0.055	−0.079	−0.042	−0.066	0.076		0.311(**)	0.358(**)	0.310(**)
	P value	0.019	0.168	0.279	0.430	0.374	0.635	0.458	0.387		<0.001	<0.001	<0.001
100 g 1	Rho	0.150(*)	0.203(**)	−0.004	0.083	0.106	0.329(**)	0.012	−0.094	0.311(**)		0.635(**)	0.287(**)
	P value	0.024	0.002	0.958	0.232	0.235	<0.001	0.889	0.286	<0.001		<0.001	<0.001
100 g 2	Rho	0.185(**)	0.223(**)	−0.012	0.007	0.052	0.215(*)	−0.033	−0.100	0.358(**)	0.635(**)		0.515(**)
	P value	0.005	0.001	0.857	0.914	0.557	0.013	0.711	0.258	<.001	<0.001		<0.001
100 g 3	Rho	0.117	0.134(*)	−0.051	−0.039	−0.070	0.092	−0.077	−0.140	0.310(**)	0.287(**)	0.515(**)	
	P value	0.077	0.043	0.462	0.573	0.431	0.298	0.385	0.111	<0.001	<0.001	<0.001	

** Correlation is significant at the 0.01 level. * Correlation is significant at the 0.05 level.

Discussion

There is a general consensus that the prevalence of GDM is increasing globally. The prevalence of GDM is reported to be 1.2% to 14.3% in the literature (1,2). Several studies have documented increasing trends in the prevalence from 2% in 1982 (17) and 7.62% in 1991 (18) to 16.55% in 2001 (19). A recent survey reported the prevalence of IGT in the age groups of 20-29 years and 30-39 years as 12.2% and 15.3%, respectively (20). The reasons for this increase and difference in prevalence rates in different populations are not known very well.

Ethnicity is one cause. The prevalence of GDM varies widely with ethnicity (3,4). Asians have the highest reported prevalence rates of GDM (4,5). On the other hand, environmental factors also may modify the condition. Asian immigrants in the United Kingdom, the United States, and Canada were investigated in previous studies on racial variations in the incidence of GDM (21-23). As a result, they found that environmental factors such as diet in Western countries may contribute to the high prevalence of GDM in Asian immigrants. Fujimoto et al. (24) have shown that environmental factors may play an important role in the development of type 2 diabetes since the prevalence of type 2 diabetes is about 2-fold higher in Japanese Americans than in native Japanese. Our own data show a prevalence of GDM of 8.1% if the diagnosis is based on the C&C criteria.

Numerous screening and diagnostic procedures such as glycosuria, random, and fasting plasma glucose to identify cases of GDM are employed worldwide (1,25), but there is no consensus as yet regarding the best screening method, with most centers using the ADA and the ACOG guidelines, which recommend screening with the 50 g GCT, followed by a 3 h 100 g OGTT in women who screen positive, while in the UK the 75 g load is favored, and this is also recommended by the WHO.

Finally, even after the diagnostic test is conducted, there is controversy regarding the diagnostic criteria. Because of perceived low sensitivities with the NDDG criteria, the ADA recommended that the C&C criteria should replace the NDDG. However, both are still in use, while in the UK the WHO recommended criteria following a 75 g OGTT are mostly used (26).

A cut-off value between 130 and 140 mg/dL is commonly used for performing the diagnostic OGTT in the clinical settings. To date, most studies that have examined the screening threshold of GCT have focused on the sensitivity and specificity of different GCT thresholds. Several authors evaluated the sensitivity and specificity to determine the cut-off value in different populations (27,28). In most studies, the authors recommended the use of GCT level at 130-140 mg/dL for GDM screening in potential diabetic pregnancy between 24 and 28 weeks of gestation (11,12). However, in some studies considerably lower or higher thresholds for GCT are advised. For example, while Vitoratos et al. (13) recommended 126 mg/dL as the optimal threshold, Punthumapol et al. (29) recommended 177 mg/dL and Tanir et al. (14) recommended 185 mg/dL. These findings may be due to the differences in race and nutrition of the populations. The sensitivity and specificity of these cut-off values were 50%-78.33% and 65.75%-86.79%, respectively. The PPVs were 26.72%-33.96%. Although the PPVs were low, the NPVs were high, i.e. 92.73%-94.82%, that meant low false negative. Low PPVs were not a problem, because GCT is a screening test and must be confirmed by OGTT for exact diagnosis of GDM.

Racial differences regarding the glucose screening test findings have been demonstrated. Nahum and Huffaker (30) suggested race-specific criteria for GCT because of the heterogeneity of glucose intolerance between ethnic groups. In the study by Eslamian and Ramezani (31), for GCT, a sensitivity of 91.7%, specificity of 83.6%, PPV of 34.4%, and NPV of 99.1% with a cut-off value of 135 mg/dL were found. In the study of Miyakoshi et al., based on receiver operating characteristic curve (ROC), they identified a GCT finding above 140 mg/dL as the cut-off value for detecting GDM, which showed a sensitivity and specificity of 96% and 76%, respectively (12).

In Turkey, Korucuoglu et al. (32) suggested that 50 g GCT as a diagnostic test is time-consuming, uncomfortable, and expensive and can be omitted up to a cut-off value of 147.5 mg/dL, especially for

those patients with no risk factors. On the other hand, a GCT value of 180 mg/dL or higher proves that a further diagnostic test is unnecessary as these patients are associated with unfavorable perinatal and fetal outcomes. They thought that this combined approach would improve maternal-fetal outcomes together with a decrease in unnecessary diagnostic tests.

Recently, the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study (33), which was a large-scale multinational epidemiologic study including 25,000 pregnant women, demonstrated that risk of adverse maternal, fetal, and neonatal outcomes continuously increased as a function of maternal glycemia at 24-28 weeks, even within ranges previously considered normal for pregnancy. These results have led to careful reconsideration of the diagnostic criteria for GDM and nowadays the International Association of Diabetes and Pregnancy Study Groups (IADPSG), an international consensus group with representatives from multiple obstetrical and diabetes organizations, including ADA, has recommended new diagnostic criteria for GDM (34). According to the statement of IADPSG, 75 g OGTT at 24-28 weeks of gestation was recommended with cut-off values of 5.1 mmol/L (≥92 mg/dL) for fasting plasma glucose (FPG), 10.0 mmol/L (≥180 mg/dL) for 1 h, and 8.5 mmol/L (≥153 mg/dL) for 2 h plasma glucose. Because only one abnormal value is sufficient to make the diagnosis, these new criteria will significantly increase the prevalence of GDM. In addition, there are few data regarding therapeutic interventions in women who will now be diagnosed with GDM based on only one blood glucose value above the specified cut-off points but fall in the normal category according to the older criterion that needs at least 2 abnormal values for diagnosis.

A few months ago, the 6th International Symposium on Diabetes and Pregnancy was held in Salzburg, Austria. It was stated in the symposium that the risk of adverse pregnancy outcomes in women with fasting plasma glucose (FPG) near to the cut-off value (FPG < 92) is not increased, indicating that the new criteria may lead to overdiagnosis. Similarly, there was a poor correlation between FPG and OGTT values. Therfore, it was stated that the new IADPSG criteria were "not evidence-based" and need modification (35,36). Additional well-designed clinical studies are needed to determine the optimal method and optimal threshold levels with higher sensitivity and specificity for screening of GDM.

In the present study, we used an ROC curve to find the best cut-off point. A cut-off value of 132 mg/dL yielded a sensitivity of 97.4% and a specificity of 70.5% for GDM. The proportion of gravidas exceeding 132 mg/dL was found to be 35% of all subjects, and 22.6% of women with a positive screening test were diagnosed with GDM.

An improvement of sensitivity from 84.8% for a threshold of 140 mg/dL to 97.4% for a threshold of 132 mg/dL has been demonstrated, with an increased screen positive rate and the performance of diagnostic OGTTs rising from 28.7% to 35.0%. Thus, if women with a GCT between 130 and 139 mg/dL remain at risk for due to hyperglycemia or undiagnosed GDM, then a threshold of 140 mg/dL may not adequately capture those at risk. Indeed, our study shows that women with a GCT between 130 and 139 mg/dL are at risk for GDM. Of note, the percentage of women in our cohort whose GCT values were 140 mg/dL or higher was 28.7%, and the percentage with plasma glucose of 132 mg/dL or higher was 35.0%, which were higher than those reported by Coustan et al. in 1998 (37). The reason for the higher rate may be ethnic and environmental differences and increased obesity in the Turkish population.

In conclusion, we recommend GCT as an international screening method. It is also suitable for Turkish women. The place of residence as well as race need be taken into consideration to establish the best cut-off level of GCT, since ethnic and environmental factors may contribute to the occurrence of GDM. Furthermore, with the C&C criteria, the highest sensitivity is achieved by using the glucose challenge test threshold of 130 mg/dL in the Turkish population. Because of the fact that failure to identify and treat GDM may result in an increase in perinatal and maternal morbidity and mortality, in addition to long-term complications, we think that a glucose challenge test threshold of 130 mg/dL should be considered a positive screening result.

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