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Gestational Diabetes Screen One or Two-step Approach?

Gestasyonel Diyabet Taraması: Tek Adımlı Yaklaşım mı? İki Adımlı Yaklaşım mı?

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ABSTRACT

Objective: We aimed to compare the prevalence of gestational diabetes mellitus (GDM) according to one and two-step approaches in pregnant women and contribute to the national literature by determining which approach would be more beneficial for such women.

Methods: Our study included patients aged 15-45 years who were admitted to our hospital during their 24th-28th gestational weeks of pregnancies between January 2012 and December 2021. Participants were classified into five groups according to age: <25, 25-29, 30-34, 35-39, and more than 40 years. The prevalence of GDM in each group was separately calculated according to the results of the tests.

Results: Overall, 22,743 patients were included in the study. Of these, 2217 patients underwent a one-step 75-gram oral glucose tolerance test (OGTT). One hundred six patients could not tolerate the test, and the prevalence of GDM was 29.7% in 2111 patients who completed the test. Conversely, 20,526 patients underwent 50-gram OGTT, and the glucose level of 5761 (28%) patients was ≥140 mg/dL. A 3-hour 100-gram OGTT was performed for 2870 patients whose test results were positive. When the results of 2807 patients who completed the test were evaluated, the prevalence of GDM was found to be 3.1%.

Conclusion: The one-step approach significantly increases the prevalence of GDM compared with the two-step approach, and in the two-step approach, the diagnostic test can be skipped because the patients do not regularly undergo follow-up examinations. The results suggest that the one-step approach is more appropriate in societies that do not regularly attend follow-up visits.

Keywords: Gestational diabetes mellitus, oral glucose tolerance test, screening

ÖZ

Amaç: Kliniğimize başvuran gebelerde gestasyonel diabetes mellitus (GDM) prevalansını bir ve iki aşamalı yaklaşımlara göre karşılaştırmayı ve bu kadınlar için hangi yaklaşımın daha faydalı olacağını belirleyerek ulusal literatüre katkıda bulunmayı amaçladık.

Yöntem: Çalışmamıza Ocak 2012-Aralık 2021 tarihleri arasında hastanemize 24.-28. gebelik haftalarında başvuran 15-45 yaş arası gebeler dahil edildi. Katılımcılar yaşlarına göre <25, 25-29, 30-34, 35-39 ve >40 yaş olmak üzere beş gruba ayrıldı. Her gruptaki GDM prevalansı, bir ve iki aşamalı tarama testlerinin sonuçlarına göre ayrı ayrı hesaplandı.

Bulgular: Çalışmamıza 15-45 yaş arası 22.743 hasta dahil edildi. Bunlardan 2217 hastaya tek aşamalı 75 gram oral glukoz tolerans testi uygulandı. Yüz altı hasta testi tolere edemedi, testi tamamlayan 2111 hastada GDM prevalansı %29,7 olarak bulundu. Buna karşılık 20.526 hastaya 50 gram glukoz tarama testi uygulandı ve 5761 (%28) hastanın glukoz düzeyi ≥140 mg/dL idi. Test sonucu pozitif olan 2870 hastaya 3 saatlik 100 gram oral glukoz tolerans testi uygulandı. Testi tamamlayan 2807 hastanın sonuçları değerlendirildiğinde GDM prevalansı %3,1 olarak bulundu.

Sonuç: Tek aşamalı yaklaşım, iki aşamalı yaklaşıma göre GDM prevalansını anlamlı olarak artırmakta ve iki aşamalı yaklaşımda hastalar düzenli olarak kontrol muayenelerine uymadıkları için tanısal test atlanabilmektedir. Sonuçlar, düzenli olarak takip muayenelerine katılmayan toplumlarda tek adımlı yaklaşımın daha uygun olduğunu göstermektedir.

Anahtar Kelimeler: Gestasyonel diabetes mellitus, oral glukoz tolerans testi, tarama

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INTRODUCTION

Gestational diabetes mellitus (GDM) is defined as diabetes diagnosed in the second or third trimester of pregnancy, excluding overt diabetes diagnosed before pregnancy or at the latest in early pregnancy.[1] It is one of the most common complications of pregnancy and affects 6-25% of pregnant women based on the widely used diagnostic criteria.[2,3] The prevalence of GDM is increasing worldwide; if left untreated, it causes many serious complications that affect both mother and child, and the complications specifically include stillbirth and neonatal death.[3] Shortly after birth, blood glucose levels return to normal in children; however, women with GDM and their children are at an increased risk of developing type 2 diabetes later in their lives.[4] Data from randomized controlled trials in 24-28 week pregnant women indicated that GDM treatment reduced the incidence of complications, particularly macrosomia and preeclampsia.[5,6]

There is no scientific consensus on which method is better for GDM screening and diagnosis. O'Sullivan and Mahan[7] established the initial diagnostic criteria for GDM in the 1960s. In the 1980s, these criteria were revised by Carpenter and Coustan,[8] and they recommended a two-step screening test comprising a 50-g glucose tolerance test (GCT) and a 3-hour 100-g oral glucose tolerance test (OGTT) for positive cases. In 1980, a 2-hour 75-g OGTT was recommended by the World Health Organization for the screening of GDM. However, the American Diabetes Association (ADA) and many other organizations continued to use the 3-hour 100-g OGTT recommended by the National Diabetes Data Group (NDDG) as a diagnostic criterion, claiming that the studies on the 2-hour 75-g OGTT for pregnant women were insufficient. In 2010, the International Association of the Diabetes and Pregnancy Study Groups (IADPSG) aimed to combine screening and diagnostic guidelines by recommending a 2-hour 75-g OGTT as a universal diagnostic criterion.[9] Finally, professional organizations accepted two alternatives: one-step 2-hour 75-g OGTT recommended by IADPSG and two-step Carpenter-Coustan approach recommended by the American College of Obstetricians and Gynecologists (ACOG).[3,10]

An advantage of the one-step approach is that screening and diagnosis can be performed in a single step. However, the application of the IADPSG criteria increases the number of pregnant women diagnosed and treated with GDM.[11] A review of GDM screening published in 2019 evaluated 16 different guidelines that were adopted worldwide, and there was no consensus on the use of one- or two-step screening.[12]

To the best of our knowledge, there is no multicenter study on this subject in our country; hence, the national prevalence of GDM remains unknown. Therefore, in this study, we aimed to compare the prevalence of GDM in pregnant women attending our clinic in terms of one- and two-step approaches and to contribute to the national literature by identifying which approach would be more beneficial for such women.

METHODS

This study was retrospective to design. Permissions for conducting the study were obtained from Kahramanmaraş Sütçü İmam University Faculty of Medicine Clinical Research Ethics Committee (number: 05, date: 23.03.2022). The study was conducted in accordance with the principles of the Helsinki Declaration. The patient data were obtained from the hospital's patient information system. The study included patients who visited the Kahramanmaraş Gynecology and Obstetrics outpatient clinics between January 1, 2012 and December 31, 2021 for their routine pregnancy-related follow-up examination during the 24th-28th weeks of pregnancy, without any systemic disease, who were aged between 15 and 45 years, and who underwent one- or two-step GDM screening. Those who were previously diagnosed with diabetes mellitus and those who had endocrine diseases, such as Cushing's disease, Addison's disease, pituitary insufficiency, and acromegaly, were excluded from the study.

The IADPSG criteria were used to establish a diagnosis using the one-step approach.[9] Normal values based on the GDM criteria were as follows: fasting <92 mg/dL (5.1 mmol/L); 60 min <180 mg/dL (10.0 mmol/L); and 120 min <153 mg/dL (8.5 mmol/L). If one or more of these values were equal or higher than the defined criteria, the test was considered positive. In the two-step approach, pregnant women with a 50-g glucose load test result of ≥140 mg/dL were considered positive, and the results of these patients who underwent a 100-g OGTT were evaluated. Notably, the Carpenter and Coustan criteria were used to evaluate 100-g OGTT results[8]. Normal values based on the Carpenter and Coustan criteria were as follows: fasting <95 mg/dL (5.3 mmol/L); 60 min <180 mg/dL (10 mmol/L); 120 min <155 mg/dL (8.6 mmol/L); and 180 min <140 mg/dL (7.8 mmol/L). If one or more of these values were equal or higher than the defined criteria, the test was considered positive.

The included pregnant women were classified into the following five groups according to age: <25 years, 25-29 years, 30-34 years, 35-39 years, and more than 40 years, and the prevalence of GDM in each group was separately calculated according to the results of one- and two-step screening tests.

Statistical Analysis

Regarding the evaluation of the findings of the study, IBM Statistical Package for Social Sciences 22.0 (IBM, White Plains, New York, USA) program was used for statistical analysis. The Student's t-test was used to compare normally distributed quantitative variables, whereas the Mann-Whitney U test was used to compare non-normally distributed quantitative variables. Moreover, categorical variables were evaluated using the chi-square or Fisher's exact tests. The obtained results were evaluated at the 95% confidence interval, and a p-value of <0.05 was considered statistically significant.

RESULTS

In total, 22,743 patients aged 15-45 years who visited the Obstetrics and Gynecology outpatient clinic between January 1, 2012 and December 31, 2021 for routine pregnancy-related follow-up examination at the 24th-28th week of pregnancy were included in the study.

Of the patients who participated in the study, 2217 underwent the one-step 2-hour 75-g OGTT; however, 106 patients could not complete the test. Based on the one-step 2-hour 75-g OGTT results evaluated according to the IADPSG criteria, the prevalence of GDM was found to be 29.7%. Moreover, the prevalence of GDM was found to increase with age, and the highest prevalence was 59% in patients aged more than 40 years (Table 1).

Overall, 20,526 patients underwent 50-g GCT, and the glucose level of 5761 (28%) patients was ≥140 mg/dL. A 3-hour 100-g OGTT was performed for 2870 patients with a positive test result; however, 63 patients could not complete the test. When the results of 2807 patients who completed the test were evaluated according to the Carpenter and Coustan criteria, the prevalence of GDM was found to be 3.1%. Moreover, the prevalence of GDM increased with age (Table 2). Percentages of GDM-positive patients compared to the one- and two-step approaches shown in Figure 1.

The mean age of pregnant women who underwent the one-step diagnostic test was 26.7 (±6.18) years, and the mean age of pregnant women who underwent the two-step screening and diagnostic test was 27.6 (±6.14) years. The difference between the mean ages of the two groups was not statistically significant (p=0.851).

DISCUSSION

Globally, there is no consensus on whether a one- or two-step approach is better for GDM screening and diagnosis. Although IADPSG and ADA recommend one-step 2-hour 75-g OGTT to prevent pregnancy-related complications due to the higher sensitivity, ACOG recommends a two-step approach.

In this study, we compared the two-step approach proposed by ACOG with the one-step approach proposed by IADPSG and ADA. In our study, the prevalence of GDM calculated using the one-step approach was approximately 10 times higher than that calculated using the two-step approach (29.7% vs. 3.1%). Depending on the method of screening test and the diagnostic criteria, the prevalence of GDM differs around the world.[13] In a study by Satodiya et al.[14] that compared the one- and two-step approaches, the prevalence was found to be 19.2% and 11.8% in the one- and two-step approaches, respectively. In a study comparing the one- and two-step approaches in Bulgaria, the prevalence of in one-step approach was three times higher than that of in two-step approach (31.6% in one-step; 10.8% in two-steps), whereas in a study conducted in the United Arab Emirates, the prevalence was five times higher in one-step approach (45.3% vs. 9.2%).[15,16] Although the USA commonly prefers the two-step approach, it has been observed that the one-step approach is preferred throughout the world. In our country, in a study by Sevket et al.,[17] the one- and two-step approaches were compared, and the prevalence of GDM was found to be 14.5% in the one-step approach, whereas the prevalence of GDM was 6% in the two-step approach. In a study conducted by Gürlek and İbrahim[18] in the province of Rize, the prevalence of GDM was found to be 27.9% with the one-step approach using the IADPSG criteria, whereas in another study conducted in the province of Kayseri, the prevalence of GDM was found to be 16% with the one-step approach using the same criteria.[19] There are two separate studies by Karcaaltincaba et al.[20] in which the prevalence was calculated using the one- and the two-step approaches. In a study of 21,531 pregnant women using the two-step approach conducted in 2009, the prevalence of GDM was 4.48% according to the Carpenter and Coustan criteria, whereas it was 3.17%

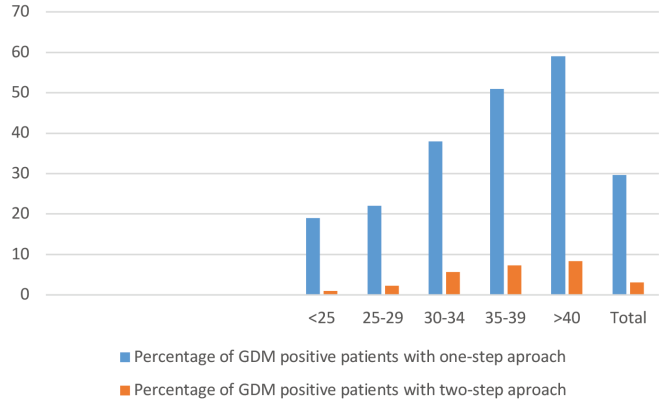

Figure 1. Comparison of the percentages of GDM positive patients compared to the one-step approach and the two-step approach

GDM: Gestational diabetes mellitus

Table 1. Prevalence of gestational diabetes mellitus according to the International Association of the Diabetes and Pregnancy Study Groups criteria in terms of maternal age

Age	Total number of tests	Number of GDM positive patients	Percentage of GDM positive patients
<25	716	141	19%
25-29	575	125	22%
30-34	467	177	38%
35-39	276	140	51%
>40	77	46	59%
Total	2111	629	29.7%

GDM: Gestational diabetes mellitus

Table 2. Prevalence of gestational diabetes mellitus according to the Carpenter and Coustan criteria in terms of maternal age

Age	Total number of tests	Number of GCT positive patients (percent)	Number of patients who underwent 100-g OGTT	Number/percentage of GDM positive patients
<25	8415	1407 (17%)	707	90 (1%)
25-29	5424	1473 (27%)	729	129 (2.3%)
30-34	4053	1576 (39%)	789	233 (5.7%)
35-39	2121	1015 (48%)	457	155 (7.3%)
>40	513	290 (57%)	125	43 (8.3%)
Total	20526	5761 (28%)	2807	650 (3.1%)

GDM: Gestational diabetes mellitus, GCT: Glucose tolerance test, OGTT: Oral glucose tolerance test

according to the NDDG criteria; moreover, in a study of 1434 pregnant women evaluated according to the IADPSG criteria in 2017, the prevalence of GDM was found to be 11.1%.[21] In our prospective study, which was previously conducted with 182 pregnant women in Kahramanmaraş using the two-step approach, the prevalence of GDM was found to be 13.2%.[22]

Based on the relevant literature, it is evident that the prevalence of one-step approach is higher than that of two-step approach. However, a 10-fold difference in our study was beyond our expectations. The high prevalence in the results of the one-step 2-hour 75-g OGTT might have contributed to this difference; moreover, the fact that only 2870 of 5761 patients with a positive one-step 50-g screening test could proceed with a two-step 100-g OGTT might have led to this difference. The prevalence of GDM may be 2-3 times higher in the one-step test than in the two-step test due to a single positive value or lower thresholds.[23,24] In addition, given the role of ethnic and racial factors in the prevalence of GDM, the difference might have been caused by racial factors. [25] In the two-step approach, a screening test is initially performed using 50-g glucose; thereafter, a 3-hour 100-g OGTT is performed for those with positive results. To establish a diagnosis, patients must come to the hospital for a second visit. Based on the results of our study, almost 50% of those with positive initial test results did not undergo a diagnostic test using the two-step approach. This situation may reduce the prevalence of GDM and indicates that almost 50% of our patients did not attend their routine check-ups and follow-up visits. As expected in our study, the prevalence of GDM increased with maternal age in both the one- and two-step approaches.

Both approaches have some advantages and disadvantages. With the one-step approach, patients are required to fast for 12 h and the test takes 2 h; a single visit is sufficient and patients do not need to be hospitalized for the second time. However, the test is high sensitivity can result in more patients being diagnosed with GDM and requiring unnecessary treatment. It may also increase the rates of primary cesarean sections. Macrosomia is an important complication in patients with GDM, but it is not the only cause of macrosomia.[13] With the two-step approach, the screening test does not require the patient to fast in the first step, and the two-step approach has lower sensitivity and high specificity. Therefore, the false positive rate is low and unnecessary diabetes treatments are avoided; however, the fact that the patients have to be hospitalized for the second time is considered a disadvantage.

Study Limitations

Our study had some limitations. These include the retrospective nature of the study, the inability to assess perinatal outcomes because of the retrospective nature,

and the inability to fully evaluate demographic data such as body mass index, education level, delivery modes, number of pregnancies, and diabetes risk levels of the patients. Pregnant women who were found to be positive for 50 g-GCT in the two-step test but did not apply the 100-gram test significantly affected the prevalence of GDM diagnosed with the two-step OGTT, which is another limitation of our study.

CONCLUSION

The results indicated that the one-step approach significantly increases the prevalence of GDM compared with the two-step approach, and the diagnostic test can be skipped in the two-step approach because the patients attend their follow-ups regularly. Considering our target population, the one-step approach seems more appropriate than the two-step approach, although the false positive rate seems high. This is because there is no population that regularly attends follow-up visits. This study can help physicians determine the most appropriate screening strategy for their study population and their clinical approach.

Ethics

Ethics Committee Approval: The study was approved by the Kahramanmaraş Sütçü İmam University Faculty of Medicine of Local Ethics Committee (protocol no: 21, date: 23.03.2022).

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices - Concept - Design - Data Collection or Processing - Analysis or Interpretation - Literature Search - Writing: B.C., K.H.

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