Screening for Gestational Diabetes Mellitus: Recommendations And Rationale: United States Preventive Services Task Force

United States Preventive Services Task Force

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Abstract

This statement summarizes the current U.S. Preventive Services Task Force (USPSTF) recommendations on screening for gestational diabetes and the supporting scientific evidence, and it updates the 1996 recommendations contained in the Guide to Clinical Preventive Services, second edition.[1] Explanations of the ratings and of the strength of overall evidence are given in Appendix A and in Appendix B, respectively. The complete information on which this statement is based, including evidence tables and references, is available in the summary of the evidence, "Screening for Gestational Diabetes: A Summary of the Evidence for the U.S. Preventive Services Task Force"[2] and in the Systematic Evidence Review[3] on this topic, which can be obtained through the USPSTF web site (http://www.preventiveservices.ahrq.gov). The summary of the evidence and the recommendation statement are also available in print through the AHRQ Publications Clearinghouse (call 1-800-358-9295 or e-mail ahrqpubs@ahrq.gov).

Figure 3

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Figure 2

US Department of Health and Human Services

SUMMARY OF RECOMMENDATION

The U.S. Preventive Services Task Force (USPSTF) concludes that the evidence is insufficient to recommend for or against routine screening for gestational diabetes.

I RECOMMENDATION.

The USPSTF found fair to good evidence that screening combined with diet and insulin therapy can reduce the rate of fetal macrosomia in women with gestational diabetes mellitus (GDM). The USPSTF found insufficient evidence, however, that screening for GDM substantially reduces important adverse health outcomes for mothers or their infants (for example, cesarean delivery, birth injury, or

neonatal morbidity or mortality). Screening produces frequent false-positive results, and the diagnosis of GDM may be associated with other harms, such as negatively affecting a woman's perception of her health, but data are limited. Therefore, the USPSTF could not determine the balance of benefits and harms of screening for GDM.

CLINICAL CONSIDERATIONS

- Better quality evidence is needed to determine whether the benefits of screening for GDM outweigh the harms. Until such evidence is available, clinicians might reasonably choose either not to screen at all or to screen only women at increased risk for GDM.
- Patient characteristics most strongly associated with increased risk for GDM include maternal obesity (usually defined as a body mass index [BMI] of 25 or more), older age (usually defined as older than 25 years), family or personal history of diabetes, or a history of GDM in a prior pregnancy. Expert groups have also identified certain ethnic groups as being at increased risk for GDM (such as Hispanic, African American, American Indian, and South or East Asian). Using all the above criteria, however, would identify 90% of all pregnant women as being at increased risk for GDM.
- The optimal approach to screening and diagnosis is uncertain. Expert panels in the United States recommend a 50-g 1-hour glucose challenge test (GCT) at 24 to 28 weeks' gestation, followed by a 100-g 3-hour oral glucose tolerance test (OGTT) for women who screen positive on the GCT. Different screening and diagnostic strategies recommended by the World Health Organization (WHO) are commonly used outside of North America. The American Diabetes Association (ADA) and the WHO have published specific criteria for diagnosis, but the USPSTF could not determine the relative benefits of any specific approach.4,5

SCIENTIFIC EVIDENCE

EPIDEMIOLOGY AND CLINICAL CONSEQUENCES

Gestational diabetes mellitus is defined as glucose intolerance with onset or first detection during pregnancy.[6,7] GDM occurs in 2% to 5% of all pregnancies, or approximately 135,000 cases annually in the United States.[6] Major risk factors for developing GDM include increasing maternal age, family history of diabetes, history of GDM in a prior pregnancy, and increased pregravid BMI.[8] The prevalence of GDM varies in direct proportion to the prevalence of type-2 diabetes in a given population or ethnic group.[6] GDM is more common among African American, Hispanic, and American Indian women and less common among Asian women. Variations in screening practices and in other risk factors make it difficult to quantify the independent contribution of race and ethnicity to developing GDM. Prevalence of GDM in women with defined low-risk factors, such as being of white ethnic origin, being younger than 25 years, and having a BMI of less than 25 kg/m2, ranges from 1.4% to 2.8%.[9,10,11,12,13,14] The prevalence of GDM in women with defined high-risk factors, such as being older than 25 years, being obese, or having a family history of diabetes, ranges from 3.3% to 6.1%.[11]

GDM has been linked to increased maternal perinatal morbidity (resulting from an increase in cesarean deliveries and forceps or vacuum extraction, as well as third- and fourth-degree lacerations), principally through its association with fetal macrosomia.[15,16,17,18,19,20,21,22]

Macrosomia is associated with an increased risk for neonatal adverse effects, such as brachial plexus injuries (most of which are temporary) and clavicular fracture.[17,21,23,24] Data on the overall impact of GDM screening and treatment on these outcomes is limited because most babies with macrosomia are born to mothers without GDM,[15,25,26,27,28,29] and most cases of injuries related to shoulder dystocia occur in pregnancies with infants of normal birthweight. The relationship between GDM and adverse outcomes is further confounded by the fact that maternal obesity is an independent risk factor for many of the same outcomes.[16,30,31] The tendency of clinicians to manage differently women who bear the diagnosis of GDM from those who do not may contribute to the observed increase in risk for cesarean delivery in women with GDM.[4]

ACCURACY AND RELIABILITY OF SCREENING TESTS

Defining the performance characteristics of screening strategies for GDM is complicated by the lack of a universally accepted “gold standard” for a diagnosis of GDM. Different diagnostic tests are used in North America

and in Europe.[4,32,33] Diagnostic criteria in the United States are based on a 100-g 3-h OGTT, but these criteria were originally developed for their ability to identify mothers at risk for developing diabetes, not those whose newborns were at risk for macrosomia or other complications. Expert groups have proposed different criteria for diagnosis based on the 3-h OGTT; although all the diagnostic criteria predict risk for macrosomia, evidence is weak to support any particular diagnostic standard for GDM. More liberal criteria increase the number of women diagnosed with GDM by more than 50% but may not reduce the prevalence of fetal macrosomia.[32]

Screening for GDM in North America is based on a 50-g 1-h GCT, usually performed during the 24th to 28th week of gestation. Two thresholds for an abnormal screen have been proposed by different experts: a venous plasma glucose cutoff of 130 mg/dL identifies more than 90% of all women with a positive 100-g 3-h OGTT; a higher cutoff of 140 mg/dL detects 80% of women with an abnormal OGTT but reduces the number of false positives, [34]which are common for the GCT. Fewer than 1 in 5 women with a positive GCT will meet criteria for GDM on a full OGTT.[35] The reliability of the GCT is questionable for one-third of women with GDM; in one study, screening performed on 2 successive days produced different results.[14] Data to support specific timing for screening also are sparse. Women who develop GDM early in pregnancy are at higher risk for neonatal hypoglycemia and other GDM-related outcomes than are those who develop GDM later in pregnancy.[36] Screening earlier in pregnancy detects fewer women with GDM, but identifies those at highest risk and allows for earlier intervention. Screening for GDM later in pregnancy detects a larger number of women with GDM, many of whom are at lower risk, but who would be treated for a shorter time.

EFFECTIVENESS OF EARLY DETECTION

No properly conducted randomized controlled trial (RCT) has examined the benefit of universal or selective screening for GDM compared with no screening. The only RCT that attempted to evaluate the effects of universal versus selective screening had important methodologic and analytic flaws. The differences in the timing of screening and the treatments in the study groups make it difficult to draw any conclusions about the benefits of screening.[36] A retrospective analysis that found similar rates of macrosomia in screened and unscreened populations cannot rule out an effect of screening, because screened women may have been at higher risk for GDM than unscreened women, and the study may not have been large enough to detect a benefit.[37] One well-conducted prospective cohort study suggests that screening and diagnosis can reduce macrosomia but that other health outcomes were not affected.[38] A proposed benefit of screening is that the diagnosis of GDM may lead to interventions to reduce the risk for mothers of developing diabetes later. The USPSTF found no evidence to determine whether diagnosis leads to important lifestyle changes for such women; many of the proposed interventions (eg, weight loss and exercise) could be recommended for these women on other grounds, independent of their risk for developing diabetes.

Data on the effects of diet therapy alone for treating GDM are limited. An overview of 4 RCTs found no significant benefits of diet, but the studies were small and had other limitations.[39] Randomized trials have shown that adding insulin to diet therapy, compared with diet therapy alone, can reduce the incidence of macrosomia, but they have not shown improvement in other important maternal or perinatal outcomes such as cesarean delivery rates, birth trauma, or perinatal mortality.[40,41,42] These trials are hampered by small size and lack of power for detecting small changes in more important health outcomes.

Even if screening and treatment are effective, the benefits of widespread screening as a means for preventing birth trauma due to macrosomia are likely to be small. Modeling done for the USPSTF, which assumed that treatment with insulin would reduce the risk of having an infant with macrosomia in mothers with GDM by 75%, calculated that nearly 7,000 women at high risk, and 9,000 women at average risk, would need to be screened to prevent 1 case of brachial plexus injury. Although serious, 80% of such injuries resolve within the first year.

POTENTIAL HARMS OF SCREENING AND TREATMENT

Data are insufficient to make conclusive statements about possible harms of screening for GDM. Screening generates frequent false-positive results requiring the inconvenience of further testing. One study raises the possibility that the diagnosis of GDM may influence provider decision-making and could increase cesarean delivery rates, despite measures taken to decrease the risk for fetal macrosomia.[31] This study evaluated the rates of cesarean delivery related to birth weight and GDM. In this study, women who were diagnosed and treated for GDM had substantially higher rates of

cesarean delivery (34%) than controls (20%) even though rates of macrosomia were comparable. In a second control group, in which clinicians were not informed that women had borderline GDM, rates of macrosomia were higher than rates among treated women, yet cesarean delivery rates were slightly lower (30%) and other birth outcomes (lacerations) were comparable.

The data are limited and mixed as to whether the diagnosis of GDM adversely affects women's perception of their health during pregnancy.[43,44,45,46] Limited data suggest that the diagnosis of GDM may have long-term effects on women's perception of their health.[45,47] Potential adverse effects of treatment strategies for GDM include increased maternal starvation ketosis resulting from aggressive glycemic-lowering therapy, and infants who are small for their gestational age. Even uncommon risks are potentially important since nearly 100 women need to be treated with insulin to prevent 1 case of brachial plexus injury due to macrosomia. However, the magnitude of these potential harms has not been evaluated and quantified.[48,49]

COST AND COST-EFFECTIVENESS

In the absence of adequate evidence to determine whether selective or universal screening is effective in improving important health outcomes, reliable estimates of cost-effectiveness of screening are not possible. The cost-effectiveness of screening depends greatly on the unproven assumption that screening will significantly lower rates of cesarean section and birth trauma. No studies include all relevant cost information related to screening for GDM, including the costs of screening and diagnostic tests, costs of various treatments, and the costs of complications. Reliable estimates of the costs of GDM for women who are not screened are not available.

RECOMMENDATIONS OF OTHERS

The American Diabetes Association (ADA) recommends screening all women at risk for GDM. The ADA considers women to be at risk for GDM unless they are younger than 25 years, have normal body weight, are not a member of a high-risk ethnic group, have no first-degree relatives with diabetes, and have no personal history of glucose intolerance or poor obstetrical outcome.[5] A 2001 Practice Bulletin of the American College of Obstetricians and Gynecologists (ACOG) recommends a similar risk-based approach, but notes that since only a small percentage of patients meet criteria for low risk, universal 50-g 1-h GCT screening may be a more practical approach.[6] The Canadian Task Force on Preventive Health Care concluded in 1991 that the available evidence did not support a recommendation for or against universal screening for GDM50

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*Member of the USPSTF at the time this recommendation was finalized.

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U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS AND RATINGS

The Task Force grades its recommendations according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):

A. The USPSTF strongly recommends that clinicians routinely provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.

B. The USPSTF recommends that clinicians routinely provide [this service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

C. The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

D. The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.

I. The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that the [service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.

U.S. PREVENTIVE SERVICES TASK FORCE STRENGTH OF OVERALL EVIDENCE

The USPSTF grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

Fair: Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

Poor: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information on important health outcomes.

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