Screening tests for gestational diabetes: a systematic review for the US Preventive Services Task Force


CRD summary
This review concluded that the oral glucose challenge test and fasting plasma glucose could identify women without gestational diabetes mellitus, and the challenge test was better at identifying women with the condition. Despite some data issues, such as low quality and a variety of reference standards, this review was well conducted and these conclusions are likely to be reliable.

Authors' objectives
To assess the accuracy of various screening tests, in detecting gestational diabetes mellitus, across a range of recommended diagnostic glucose thresholds.

Searching
Fifteen databases, including MEDLINE, EMBASE and The Cochrane Library, were searched for English-language studies, from 1995 to May 2012. Search terms were reported. Relevant proceedings of conferences held between 2009 and 2011 were searched. Trial registries and websites of relevant organisations were searched. Reference lists of relevant reviews and included studies were screened.

Study selection
Clinical trials and prospective cohort studies that compared any gestational diabetes mellitus screening test versus any reference standard (another screening or diagnostic test), in pregnant women with no known history of diabetes, were eligible for inclusion. The eligible studies had to report sufficient data for a 2x2 table to calculate sensitivity and specificity.

The included studies evaluated the 50g oral glucose challenge test, measurement of fasting plasma glucose or glycated haemoglobin, risk-factor screening, or other tests. The reference standards were the criteria developed by Carpenter and Coustan, the American Diabetes Association (endorsed from 2000 to 2010), the National Diabetes Data Group, or the World Health Organization (WHO). Most included studies tested for diabetes between 24 and 28 weeks of gestation; one study tested before 24 weeks of gestation. The mean age of participants was 29 years. About half of the studies were conducted in developing countries and used WHO criteria to diagnose gestational diabetes.

Two reviewers independently assessed studies for inclusion, with any disagreement resolved by consensus or by a third reviewer.

Assessment of study quality
The quality of studies was assessed using the QUADAS-2 checklist. Two reviewers independently assessed quality, with any disagreements resolved by consensus.

Data extraction
The data were extracted to construct 2x2 tables of true and false, positive and negative results. Sensitivity, specificity, and positive and negative likelihood ratios, with 95% confidence intervals, were calculated.

One reviewer extracted the data and a second reviewer checked their accuracy.

Methods of synthesis
The pooled estimates of sensitivity, specificity and positive and negative likelihood ratios, with 95% confidence intervals, were calculated, using the bivariate and hierarchical summary receiver operating characteristic curves, where more than three studies were clinically similar (included women at less than 24, or 24 or more weeks of gestation, and had similar thresholds and diagnostic criteria). The analyses were grouped by type of screening test and then further grouped by reference standard.
Sensitivity analyses were performed to assess the effects of partial verification bias, in 18% studies, on the analyses of the oral glucose challenge test, using Carpenter-Coustan criteria, and the fasting plasma glucose assessment with thresholds of 4.7 millimoles (mmol)/L or 85mg/dL and 5.3mmol/L or 95mg/dL.

Results of the review
Fifty-one prospective cohort studies were included in the review. The sample size ranged from 32 to 9,270 women (median 709). For patient selection, 47% of studies were judged as having a high or unclear risk of bias. For the reference standard, 80% of studies were judged as having a high or unclear risk of bias. For partial verification, 18% of studies were judged as having a high risk of bias.

Nine studies assessed the oral glucose challenge test, at a threshold of 7.8mmol/L (140mg/dL). The sensitivity was 85% (95% CI 76 to 90), the specificity was 86% (95% CI 80 to 90), the positive likelihood ratio was 5.9 (95% CI 4.2 to 8.3), and the negative likelihood ratio was 0.18 (95% CI 0.11 to 0.29).

Six studies assessed the oral glucose challenge test at a threshold of 7.2mmol/L (130mg/dL). The sensitivity was 99% (95% CI 95 to 100), the specificity was 77% (95% CI 68 to 83), the positive likelihood ratio was 4.2 (95% CI 3.0 to 5.9), and the negative likelihood ratio was 0.02 (95% CI 0.003 to 0.08).

Four studies assessed fasting plasma glucose at a threshold of 4.7mmol/L (85mg/dL), the sensitivity was 87% (95% CI 81 to 91), the specificity was 52% (95% CI 50 to 55), the positive likelihood ratio was 1.8 (95% CI 1.6 to 2.0), and the negative likelihood ratio was 0.25 (95% CI 0.16 to 0.38).

One study assessed glycated haemoglobin at a threshold of 5.0%. The sensitivity was 92% (95% CI 86 to 96), the specificity was 28% (95% CI 23 to 33), the positive likelihood ratio was 1.3 (95% CI 1.2 to 1.4), and the negative likelihood ratio was 0.28 (95% CI 0.15 to 0.50).

All the above results used the Carpenter-Coustan criteria as the reference standard. The results for other tests and standards were presented. No studies assessed the oral glucose challenge test compared with International Association of the Diabetes and Pregnancy Study Groups diagnostic criteria.

Sensitivity analysis showed that the performance of the oral glucose challenge test was not affected by the inclusion or exclusion of studies with partial verification bias.

Authors’ conclusions
The oral glucose challenge test and fasting plasma glucose, at a threshold of 4.7mmol/L (85mg/dL), at 24 weeks of gestation, could identify women without gestational diabetes mellitus. The oral glucose challenge test was better at identifying women who had the condition, but it was not validated against the International Association of the Diabetes and Pregnancy Study Groups diagnostic criteria.

CRD commentary
The review question was clear and was supported by appropriate inclusion criteria. Relevant databases were searched, and efforts were made to find published and unpublished studies, reducing the potential for publication bias. Only English-language studies were included, so some relevant studies may have been missed. Sufficient attempts were made to minimise error and bias, throughout the review.

The quality of the included studies was assessed using appropriate criteria, which indicated that many trials were at risk of bias. The effect of partial verification bias on the results was assessed in a sensitivity analysis. Appropriate methods were used to pool the results. The authors acknowledged some problems with the data identified, including the low quality of some studies, the variety of reference standards used, and the possibility that the results might not be generalisable to developed countries.

Despite these issues, the review was generally well conducted and the data were carefully analysed. The authors’ conclusions are likely to be reliable.

Implications of the review for practice and research
Practice: The authors stated that a practical option might be to offer women the choice of the oral glucose challenge test.
or the fasting plasma glucose test, since fasting glucose better predicted foetal overgrowth, which could be reduced by metabolic management during pregnancy.

**Research**: The authors stated that further studies were required to demonstrate the potential value of measuring glycated haemoglobin to identify overt diabetes in pregnancy.

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