Should the SOGC Guidelines on Screening for Gestational Diabetes Mellitus Be Changed Once Again?

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In 2002, the Society of Obstetricians and Gynaecologists of Canada (SOGC) issued new guidelines on screening for gestational diabetes mellitus (GDM),[1] in effect overturning its 1992 guidelines. The issue of screening, however, remains controversial and recent evidence leads us to suggest that the guidelines may need to be reassessed again.

Traditional risk factors for GDM include a family history of diabetes, gestational glycosuria, macrosomia, and polyhydramnios. Screening on the basis of risk factors, however, fails to diagnose 50% of women with GDM.[2] Thus, the 1992 SOGC guidelines recommended universal screening for GDM.[3] In that same year, the Canadian Task Force on Periodic Health Examination determined that there was no evidence to justify screening of women at low risk for GDM.[4]

Other published guidelines suggested different screening strategies, some eliminating routine screening for "very low risk" women, despite the fact that this would still lead to screening 90% of pregnant women.[5–7] Still others, such as Naylor at al.,[8] suggested a scoring system based on clinical characteristics.

Disagreement also extends to the methods used for screening. In North America, the basis of screening is usually a glucose challenge test (GCT) in which a 50 g oral glucose load is followed by a single assay of plasma glucose one hour later. A positive test (for which the cut-off value also varies) is followed by a glucose tolerance test (GTT), in which a 100 g oral glucose load is followed by four plasma glucose determinations performed at hourly intervals. Gestational diabetes mellitus is diagnosed when two glucose values are abnormal. In contrast, European practitioners usually follow the World Heath Organization (WHO) guidelines, which recommend use of the 75 g oral GTT.[9]

There are also different recommended thresholds for the diagnosis of GDM; for example, the cut-off levels recommended by the American National Diabetes Data Group (NDDG)[10] are higher than those of Carpenter and Coustan.[11] Schwartz et al. applied these less stringent criteria to a retrospective cohort of 8857 women and found that this led to a 54% increase in the incidence of GDM but had a negligible effect on perinatal outcome.[12]

The Toronto Tri-Hospital GDM Project was the largest prospective outcome-based study (N = 3637) to examine the North American approach to screening,[8,13] i.e., using both the GCT and GTT on all patients. The frequency of GDM in the Tri-Hospital study was 3.8%; about 25% of women with GDM had a negative GCT. The frequency of a positive GCT was 15%, and the result was affected by food intake prior to the test.[14] The study showed that progressively increasing levels of carbohydrate intolerance were associated with macrosomia, preeclampsia, and Caesarean section (CS). In addition, labelling women with a diagnosis of GDM resulted in the CS rate almost doubling without a striking improvement in outcome.[15]

The soon to be released results of the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study,[16] a large multinational study using a methodology similar to that of the Tri-Hospital study, will provide outcome-based information on the use of the 75 g oral glucose load for screening for GDM.

The current SOGC guidelines, published in 2002 in this journal,[1] contain three sets of recommendations:

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1. *Screening*: The frequency of adverse GDM-related outcomes, other than macrosomia, is very low, requiring very large studies to show that screening and management alter these outcomes. Furthermore, screening for GDM is not an entirely benevolent procedure, as a diagnosis of GDM may increase a woman's risk of undergoing CS and may adversely affect a woman's perception of her health.[17,18] In the absence of data from large randomized controlled trials, the guidelines allowed either a policy of routine screening or a policy of non-screening for GDM.
2. *Testing*: The guidelines recommended testing in two separate groups:

a. Women with significant risk factors for GDM (e.g., a history of GDM, a previous unexplained stillbirth, or a first-degree relative with diabetes) could be tested early in pregnancy to detect pre-gestational diabetes. Women with negative tests are still at higher risk for GDM and should not be precluded from screening for GDM later in pregnancy.

b. Women found to have GDM should be tested for glucose intolerance at 6 to 12 weeks after delivery.

3. *The need for a large randomized controlled trial (RCT)*: The guidelines strongly recommended that a large RCT be conducted to determine the effect of screening for, diagnosing, and managing GDM on outcomes for both mother and baby to determine if routine screening for GDM is indicated.

The results of such a large multicentre RCT were recently published by Crowther et al.[19] This study randomly assigned 1000 women with GDM at 24 to 34 weeks' gestation to receive dietary advice, blood glucose monitoring, and insulin therapy as needed (the intervention group) or to receive routine care (the control group). The primary outcome was a composite of serious perinatal complications (perinatal mortality, shoulder dystocia, bone fracture, and nerve palsy), admission to the neonatal nursery, and jaundice requiring phototherapy. Maternal outcomes included induction of labour, CS, maternal anxiety, depression, and health status.

The study showed that the rate of serious perinatal complications, taken as an aggregate, was significantly lower among the infants of the intervention group (1%) than among the infants of the routine-care group (4%). However, more infants of women in the intervention group were admitted to the neonatal nursery (71% vs. 61%; $P = 0.01$).

Although women in the intervention group had a higher rate of induction of labour than the women in the routine-care group (39% vs. 29%; $P < 0.001$), the rates of CS were similar (31% and 32%, respectively). Three months after delivery, the intervention group had better mood and quality of life and lower rates of depression. The authors concluded that treatment of gestational diabetes reduces serious perinatal morbidity and may also improve women's health-related quality of life.

There are, however, several issues related to the design and conduct of this study that should be examined before making recommendations for widespread changes in practice.

Applicability of Results

The study of Crowther et al. was conducted in 18 units over 10 years. Assuming a GDM rate of 4%, and assuming that each of these units had only 2000 births annually, only 7% of the patients with GDM were recruited. Such a low recruitment rate has the potential to create bias towards selection of patients with mild or severe GDM, limiting general applicability. The following results suggest that the selection bias was in favour of women at higher risk for GDM and, thus a worse variant of the disease:

a. The admission rate to the neonatal nursery was extremely high (61–71%).

b. The rate of previous perinatal death in both groups (2–3%) was relatively high compared with the South Australian perinatal mortality rate of 0.77% during the years 1991–2000.[20]

c. The rate of CS in both groups (31% in the intervention group; 32% in the routine care group) was higher than the overall Australian CS rate, which increased from 19.0% in 1993 to 27.0% in 2002,[21] although this may reflect underlying pathology and not selection bias.

Blinding of the Patients

Most patients (94%) were recruited after an abnormal screening test, and this lack of blinding to the results of the GCT could lead to patients making changes in their diet or to modifications in ante- and intrapartum care. If this was the case, elimination of this possible bias would have increased the difference in primary outcomes between the two groups.

Inclusion of Twin Pregnancies

Crowther et al. did not provide any data on the association of poor pregnancy outcome with twinning. Because twin gestations experience a much higher frequency of perinatal morbidity than singletons,[22] cases of complicated twin gestation could have altered the results independent of GDM.

Primary Outcome

As the frequency of each adverse perinatal outcome is extremely low, the study used a composite of outcomes to achieve clinical significance. Shoulder dystocia (SD) could