ARTICLE

SHOULD MIDWIVES SCREEN FOR GESTATIONAL DIABETES MELLITUS (GDM)?

EST-CE QUE LES SAGES-FEMMES DEVRAIENT EFFECTUER DES TESTS DE DÉPISTAGE POUR LE DIABÈTE SUCRÉ GESTATIONNEL (DSG) ?

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ABSTRACT

Should we or shouldn't we engage in screening programmes for the detection and management of gestational diabetes mellitus? In this article, we review the Society of Obstetricians and Gynaecologists (SOGC) guidelines on screening for gestational diabetes mellitus and the evidence that led to these guidelines. We also reassess the recommendations in view of a recently published large randomized controlled trial.

KEY WORDS

gestational diabetes mellitus (GDM); screening; complications of pregnancy; glucose intolerance; macrosomia, mass screening

THIS ARTICLE HAS BEEN PEER-REVIEWED

RÉSUMÉ

Devrions-nous nous engager dans des programmes de dépistage pour le diagnostic et le traitement du diabète sucré gestationnel ? Dans cet article, nous examinons les lignes directrices de la Société des obstétriciens et gynécologues du Canada (SOGC) pour le dépistage du diabète sucré gestationnel ainsi que les données qui ont mené à ces lignes directrices. Nous allons aussi réévaluer les recommandations à la lumière d'un large essai contrôlé et randomisé (ECR) qui fut publié récemment.

MOTS CLÉS

diabète sucré gestationnel (DSG); dépistage; complications associées à la grossesse; intolérance au glucose; macrosomie foetale; dépistage de masse

CETARTICLE FUT RÉVISÉ PAR SES PAIRS

The short answer to the complex question of whether or not midwives should screen for gestational diabetes mellitus (GDM), is *maybe*! The Society of Obstetricians and Gynaecologists' (SOGC) guidelines of 2002, based on the available evidence at that time, both supported the option of screening all women, except those at very low risk for GDM, and the option of non-screening for GDM. These guidelines differed from other North American guidelines and expert panels that, based on the same data, recommended near universal screening for GDM2-4. However, two dedicated groups – the Canadian Task Force on the Periodic Health Examination⁵ and the U.S. Preventive Services Task Force⁶ – have stated that there is limited evidence to support universal screening of women for GDM. Therefore, midwives who do not screen routinely for GDM have three different guidelines and consensus statements to support their approach. However, this short answer is misleading, as the SOGC guidelines contain other recommendations that require an element of screening by history and baseline characteristics. Women identified as "low risk" by the criteria outlined in Table 1 need not be screened but, conversely, women labeled as "high risk" might benefit from testing early in pregnancy. There is no consensus regarding the definition of "high risk", but commonly quoted risk factors include marked obesity, a strong family history of type II diabetes, belonging to a highrisk ethnic group, persistent glycosuria, a personal history of GDM, macrosomia or unexplained fetal losses^{4;7}.

TABLE 1: Criteria for classification as "low-risk" for GDM

- Maternal age < 25
- Caucasian or member of other ethnic group with low prevalence of diabetes
- Pre-pregnant body mass index (BMI)= 27
- No previous history of GDM or glucose intolerance
- No family history of diabetes in first degree relative
- No history of GDM-associated adverse pregnancy outcomes

Adapted From: SOGC Clinical Practice Guidelines No. 121, November 2002 - Screening For Gestational Diabetes Mellitus¹.

The lat recommendation in the SOGC guidelines stated that a large randomized controlled trial (RCT) should be performed to enable an evidence-based approach to routine screening. Recently, the results of the first large RCT addressing this issue were published in the New England Journal of Medicine by Crowther et al. Although not designed specifically as a screening trial, the results of this study showed that diagnosis and management of GDM significantly reduces the incidence of severe adverse perinatal outcomes.⁸ This article will review briefly glucose intolerance in pregnancy, summarize the logic behind the SOGC 2002 guidelines on GDM and, finally, examine the results of Crowther et al's recent large RCT and its potential implications regarding current screening practices.

GDM is not a "normal" disease. The diagnosis is not symptom-based, as most women with GDM are completely asymptomatic. Furthermore, even in the presence of a strongly suggestive risk factor profile, only half the women with GDM would be detected.⁹ The diagnosis of GDM is, therefore, based on the results of a glucose tolerance test (GTT).

To confuse the issue further, there is no consensus regarding the test used and the threshold for abnormal glucose tolerance. The testing schema in North America was traditionally of a screening test followed by a diagnostic test. The screening test was a glucose challenge test (GCT) of 50 grams of glucose (nonfasting), followed by measurement of plasma glucose an hour later. Women whose one hour glucose level exceeded a threshold (usually 7.8 mmol/dL) were labeled as having a positive test and required a diagnostic test - usually the 100 gram oral glucose tolerance test (OGTT). The OGTT, performed in a fasting state, after three days of unrestricted diet (>150 gram carbohydrate intake), includes ingestion of 100 grams of glucose with four blood glucose determinations (prior to ingestion and every hour for three hours following ingestion).

Two abnormal glucose levels are required to diagnose GDM. However, there are some data suggesting that patients with only one abnormal value might be subject to some of the same risks as GDM patients.¹⁰ These patients are often labeled as having "glucose intolerance", although there is no such classification in the pregnant state. The alternative screening strategy is the method endorsed by the World Health Organization (WHO), and includes ingestion of a 75 gram glucose load. This may be done as a screening GCT (with only one glucose determination)¹⁰ or, more commonly, as a diagnostic GTT with a fasting glucose sample and either one or two glucose determinations after the glucose load (Table 2).

If the thresholds for these blood tests are reduced, the frequency of diagnosing GDM increases, without a

TABLE 2: Criteria for diagnosis of Gestational Diabetes Mellitus (GDM) withthe 75g oral glucose tolerance test (OGTT)

Organization	Fasting	1-h PG	2-h PG *	Diagnostic criteria for GDM	
WHO** ⁷³	e 7.0 mmol/L (126 mg/dL)	Not measured	e7.8 mmol/L (140 mg/dL)	One abnormal value	* PG: Post glucose ** WHO: World Health Organization # ADA: American Diabetes Association + IGT: Impaired glucose tolerance Adapted From: SOGC Clinical Practice Guidelines No. 121, November 2002 - Screening For Gestational Diabetes Mellitus'
Fourth International Workshop ⁷ /ADA# ⁷⁴	e 5.3 mmol/L (95 mg/dL)	e 10.0 mmol/L (180 mg/dL)	e 8.6 mmol/L (155 mg/dL)	Two or more abnormal values	
Clinical Practice Guidelines for the Management of Diabetes in Canada ⁴	e 5.3 mmol/L (95 mg/dL)	e 10.6 mmol/L (190 mg/dL)	e 8.9 mmol/L (160 mg/dL)	GDM : Two or more abnormal values IGT+: One abnormal value	

clear clinical benefit.¹¹ Most Canadian guidelines have adopted the higher thresholds of the National Diabetes Data Group (NDDG)¹², and not the lower ones advocated by Carpenter and Coustan¹³, thus ensuring a lower rate of diagnosis of GDM.

A large prospective outcome-based study on screening for GDM (the HAPO study) is about to be concluded.¹⁴ This study will provide, for the first time, outcome-based thresholds for the 75 gram OGTT.

Some investigators have questioned whether GDM represents a distinct clinical entity.¹⁵⁻¹⁷ The response to this can perhaps be found in the results of the largest prospective study to date on screening for GDM – the Toronto Tri-Hospital Gestational Diabetes Project.^{18,19} In this study, 3,637 women underwent a GCT, followed by a GTT. The frequency of GDM in the study was 3.8%. The frequency of abnormal GCT was about 15%. It is also interesting to note that 25% of women with GDM had a normal GCT.

The Toronto Tri-Hospital Gestational Diabetes Project has provided evidence that the relationship between glycemic response to a carbohydrate load and adverse perinatal outcomes is not dichotomous but, rather, responds along a glycemic continuum. As post load glucose level increased, there were more cases of preeclampsia, macrosomia and Caesarean deliveries. However, as the SOGC guidelines of 2002 clearly outlined, there is a difference between proving that a disease exists and determining that there is a benefit to universal screening. In the case of GDM, there are data showing that the combination of screening, diagnosing, and managing the disease have reduced perinatal mortality,^{20,21} but these findings have not been reproduced in more recent studies. This may be a result of the overall reduction in perinatal mortality in developed countries, or due to the fact that the studies were underpowered to identify a reduction in this rare outcome.^{18,22,23}

There are more recent data showing that screening and managing GDM reduces the frequency of macrosomia.²³ However, macrosomia, in itself, is only an associated factor linked to increased Caesarean section (CS) rates, and a surrogate marker for increased risk of shoulder dystocia and nerve palsy. In fact, there are some data showing that diagnosing and managing GDM could result in adverse effects. In one study, aggressive management of GDM resulted in an increased rate of intra-uterine growth restriction.²⁴ In the Toronto Tri-Hospital Gestational Diabetes Project, women diagnosed with GDM had a 50% increase in CS rate (from 20% to 30%), despite a decreased incidence of both preeclampsia and The probable explanation for this macrosomia. increase is a bias of both caregivers and patients who

were aware of the diagnosis of GDM and the risk of macrosomia, leading to a lower threshold for Caesarean delivery.²⁵

The conflicting evidence, little of which is based on the results of randomized controlled trials, prompted the authors of the SOGC guidelines of 2002 to conclude that there is no good evidence to mandate either the screening of all women for GDM or the abandonment of such screening. The guidelines emphasize the need for a large RCT designed to resolve this issue.¹

Included in the SOGC guidelines were other recommendations regarding testing. Women with significant risk factors (e.g. first degree relatives with GDM) are at risk of having asymptomatic diabetes prior to pregnancy and should be tested early in pregnancy. Even when these test results are normal, these women are at higher risk for developing GDM

TABLE 3: Criteria for Screening Tests⁴⁰

- The condition should be an important health problem
- The natural history of the condition should be understood
- There should be a recognizable latent or early symptomatic stage
- There should be a test that is easy to perform and interpret, acceptable, accurate, reliable, sensitive and specific
- There should be an accepted treatment recognized for the disease
- Treatment should be more effective if started early
- There should be a policy on who should be treated
- Diagnosis and treatment should be costeffective
- Case-finding should be a continuous process

Source: Wilson JMG, Jungner G. Principles and practice of screening for disease. 1968. Geneva, WHO. Public Health. Paper Number 34.³²

later in pregnancy thus in this setting, testing for GDM should be repeated at 24-28 weeks gestation.¹ Due to the increased risk of developing type II diabetes in women who have been diagnosed with GDM, the guidelines also call for testing of these women with a 75-gram GTT 6-12 weeks post partum.¹ In most cases, these tests will be negative and thus confirm the diagnosis of GDM, but in the minority they will identify a subset of women whose diabetes persists after pregnancy.

What are the theoretical benefits of a widespread screening program? The classic criteria for a mass-screening test can be found in Table 3. Screening for GDM has not been adequately proven to meet most of these criteria.²⁶ Screening must also meet the ethical criteria of beneficence and non-maleficence. The benefits traditionally associated with screening are both short and long-term. The short-term benefits include potential reduction of the incidence of macrosomia, shoulder dystocia and its associated nerve damage, Caesarean section for non-progressive labour and other neonatal complications, such as hypoglycemia and hyperbilirubenemia.

The possible long-term benefits affect both the mother and child. The risk of developing diabetes later in life in women with GDM is well known, with the magnitude of risk ranging from 20-50%, being lower in Caucasians and higher in Latinos, women of Mediterranean or East-Asian descent, Native Americans and the Canadian Aboriginal population.²⁷⁻³⁰ Identification of GDM in this population provides the caregiver with an opportunity to embark on relevant dietary and lifestyle modifications that may prove beneficial in delaying the onset of type II diabetes and its complications.³¹⁻³³

Several studies have shown that the offspring of women with GDM are at increased risk of childhood obesity and impaired glucose tolerance.³⁴⁻³⁶ It is unclear, however, whether diagnosis and therapy of GDM will reduce these risks through alteration of the intra-uterine environment. In fact, possible harm associated with mass screening for GDM includes the above-mentioned iatrogenic increase in Caesarean section rate, the impact on maternal anxiety and health perception,^{37,38} and the economic implications of

diverting precious health care resources.

It may be that the historical equipoise on the need to screen for GDM should be reassessed, based on the results of a recent RCT published by Crowther et al.⁸ This large multi-centre trial was designed to assess whether the treatment of gestational diabetes would reduce perinatal complications and to assess the effects of treatment on maternal outcome, mood, and quality of life. The study randomized 1,000 women at 24-34 weeks gestation with GDM to receive dietary advice, blood glucose monitoring, and insulin therapy as needed (the intervention group) or to routine care. In the routine care group, both the patients and caregivers were blinded to the diagnosis of GDM but not to the results of the GCT that was performed prior to randomization. GDM was diagnosed after a 75-gram OGTT if fasting plasma glucose was less than 7.8 mmol/l and the two-hour value was between 7.8 mmol/l and 11.0 mmol/l. Primary outcomes included serious perinatal complications (defined as death, shoulder dystocia, bone fracture, and nerve palsy), admission to the neonatal nursery, jaundice requiring phototherapy, induction of labour, Caesarean birth, and maternal anxiety, depression, and health status.

The study showed that the rate of serious perinatal complications, when taken as a composite outcome, was significantly lower among the infants of the intervention group than in the routine-care group (4%)vs. 1%; relative risk adjusted for maternal age, race or ethnic group, and parity, 0.33; 95 percent confidence interval, 0.14 - 0.75; P=0.01). However, more infants of women in the intervention group were admitted to the neonatal nursery (71% vs. 61 %; adjusted relative risk, 1.13; 95 percent confidence interval, 1.03 - 1.23; P=0.01) despite there being no difference in fiveminute Apgar scores, respiratory distress, jaundice, neonatal convulsions or severe hypoglycemia. Women in the intervention group had a higher rate of induction of labour than the women in the routinecare group (39% vs. 29 %; adjusted relative risk, 1.36; 95 percent confidence interval, 1.15 -1.62; P<0.001), although the rates of Caesarean delivery were similar (31 percent and 32 percent, respectively; adjusted relative risk, 0.97; 95 percent confidence interval, 0.81 -1.16; P=0.73).

At three months post partum, data on the women's mood and quality of life revealed lower rates of depression and improved health status in the intervention group. The conclusions of the authors were that treatment of gestational diabetes reduces serious perinatal morbidity and may also improve the woman's health-related quality of life.

This study has several limitations. It was conducted over a very long period, during which the definition of GDM was changed. The patients had a high previous perinatal death rate (2-3%), Caesarean section rate (31-32%) and admission rate to the nursery (61-71%), which may suggest a selection bias. The study included multiple gestations, whose higher perinatal mortality rate is usually unrelated to GDM. Although these factors might limit the applicability of the results to the general population, the randomization process should ensure that there would be no affect on the significance of the primary findings.

There are some concerns regarding the primary outcome. There were very few cases of perinatal death and at least one was definitely unrelated to GDM (congenital anomalies). Of the four cases of reported bone fracture and nerve palsy, only one was related to shoulder dystocia.

The most striking difference between the groups was the near doubling of the rate of shoulder dystocia in the routine care group. Using shoulder dystocia as part of the composite primary outcome is potentially problematic as its diagnosis is subjective, unless objective criteria such as head-body delivery interval are used.³⁹ Although the subjectivity of the diagnosis would apply to both groups there could potentially be a skewing of the tendency to label a difficult delivery as shoulder dystocia based on the neonatal outcome, knowledge of GDM status or concern of potential litigation. One might also question whether shoulder dystocia is in fact a "serious perinatal complication" or just a surrogate for the more clinically important outcome of permanent nerve palsy. Having said that, if one recalculates the significance of the outcomes after removing the cases of shoulder dystocia without nerve palsy and the perinatal death secondary to multiple congenital abnormalities, the difference between the two groups remains significant but the number needed to treat to prevent one adverse outcome increases from 34 to 65.

It must be emphasized that this trial was not designed to answer the question of whether screening for GDM is beneficial, but rather to assess whether treatment of gestational diabetes, after it has been diagnosed, leads to improved health outcomes. The ability to extrapolate from these findings and provide a recommendation for screening would likely be linked to the prevalence of GDM in the specified population. Calculating for the Canadian population, if we assume an incidence of GDM of $3.8\%^{18}$ and an incidence of excess severe perinatal outcomes of 3% as seen in this RCT, the number needed to screen to prevent one adverse outcome is 830. If we remove the cases of shoulder dystocia and unrelated perinatal mortality, the risk difference decreases to 1.5% and the number needed to screen increases to 1,723. One must also take into account the implications of the increase in labour inductions, neonatal nursery admissions, physician visits and perhaps Cesarean deliveries²⁵ that will result from identifying more cases of GDM.

Conclusion

Despite its flaws and limitations, the Crowther et al. study provides the best evidence to date supporting identification and treatment of GDM. Whether the results are applicable to all populations and constitute a reason to recommend mass screening for GDM remains to be determined.

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