Risk Factor-Based Selective Screening Program for Gestational Diabetes Mellitus in Siriraj Hospital : Result from Clinical Practice Guideline

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Abstract

A clinical practice guideline for the screening and diagnosis of gestational diabetes mellitus (GDM) is currently implemented at Siriraj Hospital. During the year 2000, a total of 9325 pregnant women were screened for clinical risk factors during their first antenatal visits, and 3770 had at least 1 risk. After the 50 g glucose challenge test and 100 g oral glucose tolerance test, GDM was diagnosed in 235 women. The incidence of GDM was 6.2 per cent (95% CI 5.5-7.1) among high-risk pregnant women, and 2.5 per cent (95% CI 2.2-2.9) of all pregnant women. Significant risk factors identified from the present study were family history of DM (adjusted OR 1.86, 95% CI 1.38-2.51), age $\geq$ 30 years (adjusted OR 2.41, 95% CI 1.72-3.39), history of unexplained intrauterine fetal death (adjusted OR 4.30, 95% CI 2.04-9.04), and obesity (adjusted OR 2.83, 95% CI 1.88-4.25). The risk of developing GDM also increased when more than 1 clinical risk factor was identified. The results support the value of this screening program for GDM. Every obstetrician should be aware of the need to screen for GDM in every pregnant woman and a similar program should also be introduced to other settings.

Key word : Gestational Diabetes, Risk Factor, Selective Screening

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Gestational diabetes mellitus (GDM) is defined as carbohydrate intolerance of variable severity with onset or first recognition during pregnancy (1). The definition applies whether insulin or only diet modification is used for treatment and whether or not the condition persists after pregnancy. It does not exclude the possibility that unrecognized glucose intolerance may have antedated or begun concomitantly with pregnancy. Pregnant mothers often have or develop hypertension, and the fetus may suffer from various morbidities. Important causes of fetal morbidity include macrosomia which sometimes causes difficulties in delivery resulting in asphyxia or injury; respiratory distress syndrome which is more frequent and severe than would be expected from the degree of prematurity; polycythemia that sometimes causes thrombosis; hyperbilirubinemia and hypoglycemia. The infant of an insulin-dependent diabetic mother is at increased risk of perinatal death, neonatal problems and major congenital malformations.

The prevalence of GDM varies between studies, depending on the population being studied and the diagnostic technique employed. Reported prevalence ranges from 1-14 per cent of all pregnancies (2-4). Criteria for the diagnosis of GDM also vary among institutions, and there is still some debate on who should be screened, whether screening should be selective or universal, or how screening should be performed. Criteria for diagnosis and periodic screening change, and various expert committees have issued slightly different consensus statements. The most commonly cited criteria form three groups with somewhat overlapping membership, namely the American Diabetes Association (ADA), the International Workshop-Conference on Gestational Diabetes Mellitus, and the National Diabetes Data Group (NDDG). However, there is no agreement on the most appropriate diagnostic criteria for GDM, nor even the most appropriate selection of women to be screened for. Before 1998, the American Diabetes Association recommended universal screening for all pregnant women. The American Colleges of Obstetricians and Gynecologists (ACOG) recommended screening all pregnant women over 30 years of age as well as women with any risk factor.

Not until recently did Siriraj Hospital develop its own clinical practice guideline for screening and diagnosis of GDM. Previously, the prevalence of GDM in our institution was only 1.4 per cent(5), which was unusually low compared to many other reports. The authors use a selective screening process, based on history and clinical risk factors for GDM. A 50-g glucose challenge test (GCT) is used as a screening method and 100-g oral glucose tolerance test (OGTT) is used as a confirmatory test.

The objectives of this study were to determine the incidence of GDM among pregnant women attending the antenatal care clinic at Siriraj Hospital, using the current practice guideline, and to determine the significance of the clinical risk factors currently used for GDM screening.

MATERIAL AND METHOD

Between January and December 2000, all pregnant women who attended the antenatal clinic at Siriraj Hospital were assessed for clinical risks for GDM at their first visit. The clinical risk factors for GDM are shown in Table 1.

Pregnant women with at least 1 clinical risk were screened for GDM as soon as possible. The screening test consisted of a 50 g oral glucose load followed by a plasma glucose determination 1 hour later (50 g GCT). The patients need not be in a fasting state before the glucose load. A value of $\geq$ 140 mg/dL 1 hour after the 50 g glucose load indicates the need for a full diagnostic 100 g OGTT, performed in the

Table 1. Clinical risk factor for GDM in Siriraj Hospital.

Criteria for pregnant women needing selective screening for gestational diabetes
Family history of diabetes mellitus
Age $\geq$ 30 years
Previous history of macrosomia
Previous history of congenital fetal anomaly
Previous history of unexplained intrauterine fetal death (IUFD)
Previous history of gestational diabetes during previous pregnancy
Hypertension
Obesity * (body mass index $\geq$ 27 kg/m^2)(7)

* Obesity = pre-pregnancy weight (kg) divided by maternal height (m^2)

fasting state 1 week later. For the OGTT, the patient should fast at least 8 hours, but no more than 14 hours, before the test. In addition, her diet during the 3 previous days should have unrestricted carbohydrate intake. The patient is then administered 100 g of glucose orally, with a venous blood sample at baseline and hourly for 3 hours with continued fasting. Diagnosis of GDM requires any two of the four plasma glucose values obtained during the test to meet or exceed the value of 105, 190, 165, 145 mg/dL, respectively. These thresholds are based on the National Diabetes Data Group(6). All pregnant women diagnosed with GDM were admitted to a special ward for further investigation and treatment. If the pregnant women were found not to have GDM at initial screening, they were retested between 24-28 weeks and during 28-32 weeks of gestation.

Data on clinical risk factors for GDM, results of screening and diagnostic tests were collected from the antenatal care record forms. Analyses were performed using SPSS for Windows. Descriptive statistics were used to describe characteristics and risk factors of pregnant women. These included mean, standard deviation, number and percentage. The incidence of GDM among this risk-group was calculated. For each factor, the probability of GDM was compared between those with and without such risks. Relative risks and their 95 per cent confidence intervals were estimated. Multiple logistic regression analysis was then performed to determine the independent risk factor for developing GDM.

RESULTS

Between January and December 2000, a total of 9,325 pregnant women were interviewed for clinical risks of GDM during their first antenatal visit. Of these, 3,770 women had at least 1 clinical risk factor. After the screening and diagnostic tests, GDM were diagnosed in 235 pregnant women. Gestational age during diagnosis of GDM is shown in Table 2. Hence, the incidence of gestational diabetes was 6.2 per cent (95% CI 5.5-7.1) among high-risk pregnant women, and 2.5 per cent (95% CI 2.2-2.9) of all pregnant women. Table 3 demonstrates the prevalence of each risk factor in this group of women. The 2 most common risks identified were age of 30 years or more and a family history of DM (65.9% and 43.3% respectively). Most of the women had only 1 clinical risk (78.0%) and less than 1 per cent had 4 clinical risks or more, as shown in Table 4.

Table 2. Gestational age during diagnosis of GDM (n = 235).

GA diagnosis (weeks)	Mean ± SD (weeks)	Number	%
< 24	12.2 ± 4.0	156	66.4
24-28	25.5 ± 1.7	39	16.6
> 28	32.8 ± 15	40	17.0

Table 3. Prevalence of clinical risk factors.

Clinical risks	Number	%
Family history of DM	1,635	43.4
Age ≥ 30 years	2,486	65.9
History of macrosomia	110	2.9
History of congenital fetal anomaly	33	0.9
History of unexplained IUFD	56	1.5
History of GDM	29	0.8
Hypertension	123	3.3
Obesity	263	7.0

Table 4. Proportion of pregnant women with a different number of clinical risks.

Number of clinical risks	Number	%
1	2,941	78.0
2	727	19.3
3	79	2.1
≥ 4	23	0.6

Table 5 shows the probability of GDM for each clinical risk factor. Every risk factor increased the chance of developing GDM, more or less. All the risks seem to be relevant and justified. However, only age ≥ 30 years, history of unexplained IUFD, history of GDM, and obesity achieved statistical significance (p-value < 0.05). Concerning number of clinical risks, pregnant women who had more than 1 risk were significantly more likely to develop GDM compared to those with only 1 risk, as shown in Table 6. Moreover, the probability of GDM increased as the number of clinical risks increased.

Multiple logistic regression analysis was used to determine the independent risk factors for GDM. Every risk was entered into the model before stepwise selection of significant risks, and the results are shown in Table 7. Only family history of DM, age ≥

Table 5. Probability of GDM for each clinical risk factor.

Clinical Risks	Number of GDM	%	Relative risk (95% CI)
Family history of DM			
No	124	5.8	1.0
Yes	111	6.8	1.17 (0.91-1.50)
Age ≥ 30 years			
No	60	4.7	1.0
Yes	175	7.0	1.51 (1.13-2.00)*
History of macrosomia			
No	224	6.1	1.0
Yes	11	10	1.63 (0.92-2.90)
History of congenital fetal anomaly			
No	232	6.2	1.0
Yes	3	9.1	1.46 (0.49-4.34)
History of unexplained IUFD			
No	225	6.1	1.0
Yes	10	17.9	2.95 (1.66-5.24)*
History of GDM			
No	229	6.1	1.0
Yes	6	20.7	3.38 (1.64-6.97)*
Hypertension			
No	224	6.1	1.0
Yes	11	8.9	1.46 (0.82-2.60)
Obesity			
No	202	5.8	1.0
Yes	33	12.5	2.18 (1.54-3.18)*

* denotes statistical significance ($p < 0.05$)

30 years, history of unexplained IUFD, and obesity were independently associated with the development of GDM.

DISCUSSION

Although GDM has been studied extensively for more than 30 years, there is no consensus on specific screening strategies, criteria for screening, or even whether diagnosis and treatment have an effect on fetal outcome. A successful screening program could lead to early diagnosis and treatment, which could improve the prognosis and prevent morbidity and mortality of these pregnant women and their newborn infants. The clinical practice guideline for GDM screening and diagnosis was developed in our institute and implemented since January 2000.

Obviously, there is considerable controversy regarding the most appropriate way to screen and diagnose women with GDM. As in all tests that serve and diagnose disease, enhanced sensitivity usually results in lowered specificity. It is clear that random glucose measurements have both poor sensitivity and specificity, rendering them inadequate for assessing abnormal glucose tolerance in pregnancy[8]. Currently, there is no doubt that 50 g GCT should be used as a screening test for GDM[1]. Selective screening among women with identifiable risk factors for GDM is a reasonable approach to identifying the disease[9]. All pregnant women should have a thorough history taken to determine risk factors for GDM. On the contrary, some have recommended universal screening for GDM. They claimed that universal screening is superior to risk-based screening as it will detect more cases and facilitate early diagnosis[10]. However, to test every pregnant woman for GDM has a defined cost, which could be problematic in settings with limited resources. Although there are significant differences in the numbers of women diagnosed by various strategies, it is also important to realize that actual clinical differences in any given practice are not likely to be large.

For our practice guideline, the authors chose a selective screening strategy to identify pregnant women at risk, as shown in Table 1. In addition, those women are screened during their first visit at any gestational age. The authors can diagnose 156 cases

Table 6. Probability of GDM by number of clinical risk factors.

Number of clinical risks	Number of GDM	%	Relative risk (95% CI)
1	137	4.7	1.0
2	80	11.0	2.36 (1.82-3.08)*
3	13	16.3	3.49 (2.07-5.89)*
≥ 4	5	20.8	4.47 (2.02-9.92)*

* denotes statistical significance ($p < 0.05$)

Table 7. Independent clinical risk factors associated with GDM from multiple logistic regression analysis.

Clinical risk	Adjusted odds ratio (95% CI)	P-value
Family history of DM	1.86 (1.38-2.51)	< 0.001
Age ≥ 30 year	2.41 (1.72-3.39)	< 0.001
History of unexplained IUFD	4.30 (2.04-9.04)	< 0.001
Obesity	2.83 (1.88-4.25)	< 0.001

(66%) of GDM before 24 weeks of gestation, as shown in Table 2. It is much better to have earlier diagnosis. All of these criteria, chosen to reflect the risk of complications, were the synthesis of considerable thought and expertise and represented a consensus which would prove helpful to all clinicians. A 2-step procedure in the screening and diagnosis of GDM was used, starting with 50 g GCT for screening, followed by 100 g OGTT for the diagnosis. Advantages of the 2-step protocol include fewer blood tests for women with a negative 50 g GCT. Moreover, this protocol appears to be associated with lower direct implementation costs and less patient time expenditure than the 1-step scheme[11]. The 1-step protocol, using 75 g 2 hours OGTT (WHO criteria), is associated with slightly less travel time, but this is unlikely to offset the test time advantage of the 2-step protocol. Moreover, WHO criteria for GDM patients had significantly worse outcomes of pregnancy than the National Diabetes Data Group criteria[12].

The incidence of GDM in the present study was 6.2 per cent (95% CI 5.5-7.1) among high-risk pregnant women, and 2.5 per cent (95% CI 2.2-2.9) of all pregnant women, which is the same incidence as a previous report in Thailand (2.02% of pregnant women)[13]. The present study differed from previous reports in our institution (only 1.4%)[5]. Definitely, the incidence from the present study is more valid and reliable and should be closer to the true incidence in the population. Without this standardized strategy, a considerable number of GDM cases would have been missed.

In the present study, all the risks seem to be relevant and justified. The result showed that every risk factor increased the chance, of varying degree, for GDM. In addition, the number of risks was also related to the probability of GDM. It was found that those with more than 1 risk were significantly more likely to develop GDM, and the higher the number of risks, the higher the probability for GDM (Table 6). Multiple logistic regression analysis showed that only family history of DM, age ≥ 30 years, history of unexplained IUFD, and obesity were independently associated with the development of GDM (Table 7). Many believe that GDM and type 2 diabetes mellitus are nothing more than variations of the same general disease process. The evidence for this is based on similar epidemiologists, similar comorbid features, and a shared understood pathogenesis.

At present, evidence for screening for GDM is difficult to interpret and often conflicting. There is not an international consensus on definitions, and method for screening and neither screening nor diagnostic criteria for GDM are based on risks of adverse perinatal outcomes. For example, there is significant disagreement over whether to use the more conservative National Diabetes Data Group (NDDG) criteria[6] or the criteria suggested by Carpenter and Coustan[14] to interpret and classify the test results.

The latter criteria with a lower cutoff value can lead to a somewhat greater incidence of GDM diagnosis, without clear implications for improving perinatal outcomes(15).

SUMMARY

A clinical practice guideline for screening and diagnosis of GDM was developed and implemented in Siriraj Hospital since January 2000. Screening and diagnostic tests were performed selectively on 3770 at-risk pregnant women. The incidence of GDM was 6.2 per cent (95% CI 5.5-7.1) among high-risk pregnant women, and 2.5 per cent (95% CI 2.2-2.9) of all pregnant women. Every risk factor appeared to be reasonable and relevant. Significant risk factors identified from the present study were family history of DM, age ≥ 30 years, history of unexplained IUFD, and obesity. The risk of developing GDM also increased among women with more than 1 clinical risk factor. This confirms and emphasizes the usefulness of this guideline for the diagnosis of GDM. Similar risk factor-based screening programs should be encouraged and implemented in other settings as well. However, further extensive studies may be required to determine whether these screening and diagnostic procedures could, in addition, help in early diagnosis and improve maternal and perinatal outcomes.

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การตรวจคัดกรองเฉพาะกลุ่มที่มีปัจจัยเสี่ยง เพื่อค้นหาภาวะเบาหวานขณะตั้งครรภ์ในโรงพยาบาลศิริราช : ผลจากการใช้แนวทางการดำเนินการทางเวชปฏิบัติ

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ในปัจจุบันได้มีการนำแนวทางการดำเนินการทางเวชปฏิบัติเกี่ยวกับการตรวจคัดกรองและการวินิจฉัยภาวะเบาหวานขณะตั้งครรภ์มาใช้ในโรงพยาบาลศิริราช ได้ทำการสอบถามถึงปัจจัยเสี่ยงทางคลินิกต่อภาวะเบาหวานในสตรีตั้งครรภ์จำนวน 9,325 รายในปี พ.ศ. 2543 พบสตรีตั้งครรภ์จำนวน 3,770 ราย ที่มีปัจจัยเสี่ยงต่อภาวะดังกล่าวอย่างน้อย 1 ข้อ ได้ทำการตรวจคัดกรองและตรวจยืนยันภาวะเบาหวานขณะตั้งครรภ์โดย 50 g glucose challenge test และ 100 g oral glucose tolerance test สามารถให้การวินิจฉัยภาวะเบาหวานขณะตั้งครรภ์ทั้งหมด 235 ราย อุบัติการณ์การเกิดภาวะดังกล่าวคิดเป็นร้อยละ 6.2 (95% CI 5.5–7.1) ในสตรีตั้งครรภ์ที่มีปัจจัยเสี่ยง และร้อยละ 2.5 (95% CI 2.2–2.9) ในสตรีตั้งครรภ์ทั้งหมด การศึกษาครั้งนี้พบปัจจัยเสี่ยงที่มีความสำคัญต่อการเกิดภาวะเบาหวานขณะตั้งครรภ์ คือประวัติเบาหวานในครอบครัว (adjusted OR 1.86, 95% CI 1.38–2.51) อายุมากกว่าหรือเท่ากับ 30 ปี (adjusted OR 2.41, 95% CI 1.72–3.39) ประวัติการเสียชีวิตของทารกในครรภ์โดยไม่ทราบสาเหตุ (adjusted OR 4.30, 95% CI 2.04–9.04) และภาวะอ้วน (adjusted OR 2.83, 95% CI 1.88–4.25) สตรีตั้งครรภ์ที่มีปัจจัยเสี่ยงหลายข้อจะมีแนวโน้มในการเกิดภาวะเบาหวานเพิ่มมากขึ้น ผลการศึกษาครั้งนี้สนับสนุนความสำคัญของการตรวจคัดกรองภาวะเบาหวานขณะตั้งครรภ์ สูติแพทย์ทุกท่านควรตระหนักถึงความจำเป็นในการตรวจคัดกรองดังกล่าวในสตรีตั้งครรภ์ทุกราย และสมควรเผยแพร่แนวทางการดำเนินการดังกล่าวสู่สถานบริการอื่นต่อไป

คำสำคัญ : เบาหวานขณะตั้งครรภ์, ปัจจัยเสี่ยง, การตรวจคัดกรองเฉพาะกลุ่ม

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