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Additional Gestational Diabetes Screening in Subsequent Antenatal Care Laboratory Tests at Chonburi Hospital

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ABSTRACT

Objective: To evaluate the results of additional gestational diabetes (GDM) screening in subsequent antenatal care (ANC) laboratory tests at Chonburi Hospital.

Material and Method: A prospective descriptive study was conducted at the Antenatal Care Unit, Department of Obstetrics and Gynecology, Chonburi Hospital, Thailand. From October 1, 2008 to December 31, 2009. Glucose challenge tests (50-g GCT) simultaneously with subsequent laboratory tests were performed onpregnant women. All positive subjects based on the 50-g GCT were further evaluated by a diagnostic 100 grams oral glucose tolerance test (100-g OGTT). Data including demographic information, clinical risk factors for GDM, 50-g GCT ($\geq$ 140 mg/dL) and 100-g OGTT results were collectedand was analyzed using descriptive statistics.

Results: During the study period, 1,282 pregnant women were enrolled. Mean gestational age was 30.3 weeks. Most of them did not have clinical risk (979 cases, 76.4%). Rate of abnormal 50-g GCT in subsequent tests was 25.12% (322 cases). Of these, 262 cases received 100-g OGTT and 55(21%) of them had GDM. The estimated rate of GDM cases in the non-risk group was 5%. In clinical risk factor groups, the estimated rate of GDM cases in the non-prior test and prior negative tests was 7.4% and 3.9%, respectively. The approximate prevalence of GDM in our populations was 5.1%.

Conclusion: Performing the 50-g GCT simultaneously with subsequent ANC laboratory tests appeared to be feasible and helpful to detect GDM in pregnant women.

Keywords: gestational diabetes, screening test, glucose challenge test

Introduction

Diabetes mellitus (DM) is one of the most common medical complications during pregnancy. Gestational diabetes (GDM) is defined as carbohydrate intolerance of different intensities with onset or first recognition during pregnancy[1,2]. The world wide prevalence ranges from 2-12% depended upon population characteristics and diagnostic criteria[3]. In Thailand, the reported incidence of GDM ranges from 2.02 to 20.17% of the population[4-7]. GDM is associated with maternal and fetal morbidities[8]. The important perinatal concern is excessive fetal growth[9]. Other neonatal morbidities that can potentially and frequently occur are hypoglycemia, hyperbilirubinemia,

hypocalcemia, erythremia, and poor feeding[9]. Adverse maternal effects include an increased frequency of hypertension and cesarean delivery[1]. Moreover, GDM uncovers a pre-existing metabolic abnormality that may precede the development of overt diabetes mellitus[10]. Successful screening program could lead to accurate diagnosis and treatment, which could improve the prognosis and prevent morbidity and mortality of these pregnant women and their newborn infants.

The Fourth International Workshop-Conference on Gestational Diabetes Mellitus in 1997 has recommended selective screening based on risk assessment, similar to Chonburi Hospital[2,11]. However, ethnic groups with relatively high rates of carbohydrate intolerance during pregnancy, such as Asian population, were not included in the guideline. Selectively screening in Asian pregnant women may under-detect gestational diabetes. However,screening all pregnant women at 24-28 weeks of gestation may not be cost-effective, particularly in the low resource areas. According to Williams Obstetrics, subsequent antenatal care (ANC) laboratory tests should be repeated at 28 to 32 weeks for Hematocrit determination, syphilis (VDRL) and Human Immunodeficiency Virus (HIV) serology, which is similar to the public health service in Thailand[1]. Screening GDM at the same time may be cost–effective and convenient.

We studied GDM screening simultaneously with subsequent laboratory tests in all pregnant women. Clinical risk women who were negligently missed or poorly complied from initial GDM screening would be screened at this time. Likewise, any pregnant woman with clinical risk factors would be offered a repeated test if initial test was normal.

The objective of this study was to evaluate the results of additional gestational diabetes screening in subsequent ANC laboratory tests. The information from thisstudy may be useful to improve the clinical practice guideline for GDM screening.

Materials and Methods

This prospective descriptive study was conducted at the Department of Obstetrics and Gynecology, Chonburi Hospital, Thailand. The study enrolled pregnant women who attended ANC unit at Chonburi Hospital from October 1, 2008 to December 31, 2009. This study consisted of 1,282 pregnant women who were screened for GDM simultaneously with subsequent ANC laboratory tests at approximately 28 to 32 weeks of gestation. Women diagnosed with overt diabetes or GDM were excluded from the study. This study has been reviewed and approved by the Hospital Ethical Committee on Human Rights related to Research involving Human Subjects.

All women who consented to be in the study were evaluated for presence of risk factors for GDM. Patients were considered to be risk-factor positive if any of the following factors was present: maternal age $\geq$ 35 years (at the time of expected date of confinement), family history of diabetes in a first-degree relative, chronic hypertension (HT) or pregnancy induced hypertension (PIH), obesity (prepregnancy body mass index > 27 kilogram/meter^2), glucosuria (urine sugar >1+ on the screening day), polyhydramnios (amniotic fluid index > 25 centimeters), previous PIH, previous GDM, previous fetal macrosomia (birth weight $\geq$ 4,000 grams), previous unexplained fetal death, congenital abnormality in a previous pregnancy and neonatal hypoglycemia in a previous pregnancy.

According to the guideline used in this institution, a two-step approach was used to screen and diagnose GDM[11]. A 50-g glucose challenge test (50-g GCT) is followed by a diagnostic 100-g oral glucose tolerance test (100-g OGTT) if initial results exceed a predetermined plasma glucose concentration[1]. In this study, all pregnant women were screened for GDM during the subsequent ANC laboratory tests at approximately 28-32 weeks. A 50-g GCT was used for GDM screening. The test was performed by loading 50 grams of glucose orally, followed by determination of plasma glucose level at one hour later. A part of venous blood was collected for subsequent laboratory tests and promptly analyzed on glucometer (Accu-Chek® Advantage). The 50-g GCT level $\geq$ 140 mg/dL was considered abnormal and these women underwent a formal 100-g OGTT on the following day. After overnight fasting for at least eight hours, 100 grams of glucose was loaded orally, followed by plasma glucose levels determination at baseline

and hourly for three hours. Based on the National Diabetic Data Group, diagnosis of GDM was made when any two of four plasma glucose levels met or exceeded the value of 105, 190, 165, and 145 mg/dL at baseline, one, two and three hours respectively[12]. Pregnant women with GDM were counseled and treated individually according to the treatment guideline[1,11].

Baseline characteristics, obstetric data, and clinical risk profiles were extracted from antenatal records. Each pregnant woman with clinical risks would be classified whether she was had initial GDM screening. The date of birth, prepregnancy weight, family history and obstetric history was given by each woman. Body mass index (BMI) was calculated as the prepregnancy weight (in kilograms) divided by the square of the height (in meters). Glucosuria was detected by urine strip on the day of the screening. The gestational age was estimated by last menstrual period, confirmed or corrected by ultrasonography.

Descriptive statistics were used to describe patients' baseline characteristics, using mean, standard deviation, number and percentage. The sample size was calculated using pilot study (formula, $n = Z^2 P(1-P) /d^2$)[13]. The maximum permissible error (d) was less than 5% (0.05) and Z value was 1.96. The calculated sample size was 312 cases. Data were analyzed by a statistical package (MedCalc for Windows).

Primary outcome measures were the results of additional gestational diabetes screening in subsequent ANC laboratory tests in all pregnant women. The prevalence of GDM in pregnant women with clinical risks after normal initial test results and that negligently missed the initial GDM screening was estimated.

Results

Of the 1,282 pregnant women who were screened by 50-g GCT at the time of subsequent antenatal care laboratory tests, 25.1% (322 cases) were abnormal. Their baseline characteristics are shown in Table 1. Mean maternal age was 25.7 years and mean gestational age at screening day was 30.3 weeks. The mean maternal BMI was 23.7 kg/m^2. The majority of the women (42.1%) were nulliparous.

The results of gestational diabetes screening in the participants were shown in figure 1. Most of the women had no clinical risk (979 cases, 76.4%). The remaining 303 women (23.6%) had one or more clinical risk factors. Table 2 shows the clinical risk profiles of the pregnant women in the present study. The most common clinical risk factor was family history of DM (131 of 303 cases, 43.2%). Polyhydramnios and previous history of congenital fetal anomaly or preeclampsia or neonatal hypoglycemia are not identified in the participants.

Among all positive 50-g GCT women (n = 322), an OGTT was performed in 262 subjects because 60 women (18.6%) did not come back. Therefore, a total of 55 women were diagnosed with GDM, the overall prevalence was 4.5% (excluding drop out) in the entire cohort. After the screening, GDM was diagnosed in 43 women with no risk factor. There were 148 women (48% of 303 cases) who had either one or more risks and were not screened for GDM. Abnormal results were found in 57 of 148 cases (38.5%), and GDM was eventually diagnosed in 9 of 48 tested cases (18.8%). Of the 155 cases who had shown negative in initial screening yet presented some risk factor, abnormal results were found in 50 cases (32.2%). After that, only 26 cases received OGTT. GDM was diagnosed in three cases (11.5%) where they would have been missed if repeated screening test had not been done.

The number of expected GDM cases among women who were not tested by the OGTT was analyzed. The prevalence of observed GDM cases in the non-prior test of risk group was 18.8%. Assuming that women undergoing 100-g OGTT were represented for this group, we estimated that another two GDM women (9 x 18.8%) would have been identified if all women in the positive screening of risk group had been tested. Likewise, we estimated that another three GDM women (24 x 11.5%) would have been identified in the prior negative test of risk group. The expected prevalence, if all the pregnant women had been screened, would be 7.4% (11 of 148) for the non-prior tested group and 3.9% (6 of 155) for the prior negative tested group. We estimated that another six GDM women (27 x 22.9%) would have been identified if all

non-risk subjects had been tested. Thus, the estimated rate of GDM cases in the non-risk group was 5% (49 of 979). Overall, GDM was estimated in 66 women, resulted in an expected prevalence of 5.1% among the whole cohort.

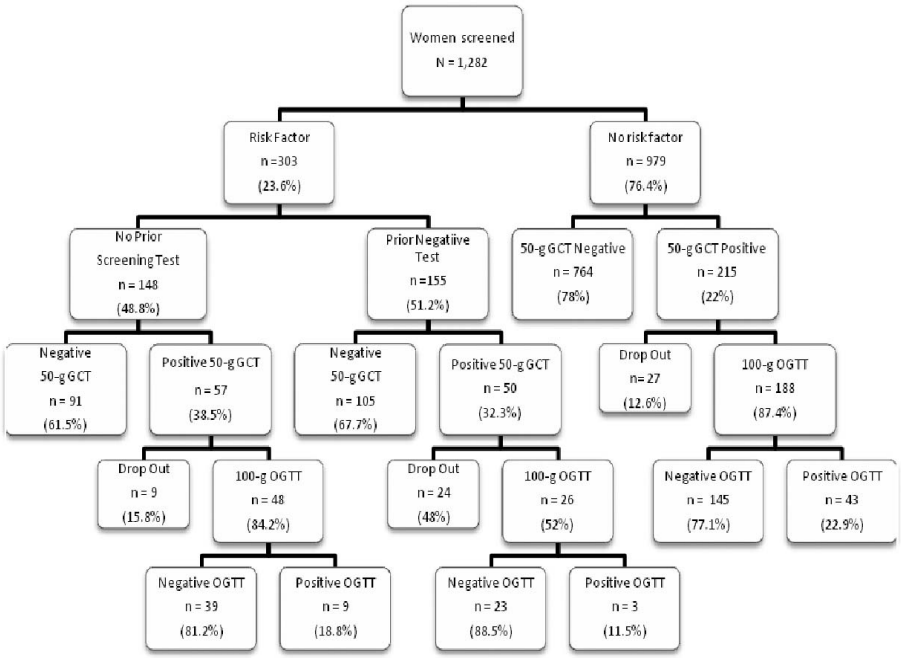

Fig. 1. Flow chart of gestational diabetes screening.

Table 1. Baseline characteristics of the pregnant women (N = 1,282)

Characteristics	Mean ± SD	Number (%)
Gestational age (days)	212 ± 18 (30.3 ± 2.5 weeks)	
Age (years)	25.7 ± 6.4	
Body mass index (kg/m^2)	23.7 ± 5.2	
Parity		
0		540 (42.1)
1		457 (35.6)
2		211 (16.4)
≥3		74 (5.8)

Table 2. Clinical risk factors for Gestational diabetes (N =303)

Clinical risk factors	Number (%)*		
	No prior test (n=148)	Prior negative test (n=155)	Total (n=303)
History of diabetes in a first-degree relative	64	67	131 (43.2)
Obesity (prepregnancy BMI ≥ 27 kg/m^2)	50	37	87 (28.7)
Glucosuria (urine sugar ≥1+) on screening day	20	50	70 (23.1)
Maternal age ≥ 35 years	26	36	62 (20.5)
Chronic HT or PIH in current pregnancy	7	4	11 (3.6)
Previous unexplained fetal death	3	0	3 (1)
Previous fetal macrosomia (birth weight ≥ 4000 g)	1	1	2 (0.7)
Previous GDM	1	0	1 (0.3)

*Women may have more than one clinical risk factor.

Following clinical risk factors such as polyhydramnios, previous PIH, congenital abnormality and neonatal hypoglycemia in a previous pregnancy were not identified in all participants.

Discussion

GDM is a well established risk factor in pregnancy and there are clear benefits to identify and managepregnant women with GDM[1,9]. Screening for GDM is controversial[1]. In our institution, screening, diagnosis and management of pregnancy with diabetes were performed according to a clinical practice guideline developed in 2001 with subsequent periodic update in 2007 by the American Diabetes Association (ADA 2007) and the National Diabetes Data Group[2,9,11,12]. There is an important concern about the cutoff values. Although, the ADA has adopted the Carpenter-Coustan definitions for the upper limits of normal for OGTT values (95, 180, 155, 140 mg/dl, respectively) since 2000, the cutoff values for OGTT of 105, 190, 165, 145 mg/dl were used according to recommendation by the National Diabetes Data Group in, Chonburi Hospital and other institutions[2,5,9,11,12,14].

Universal screening is recommended for women in ethnic groups with relative high rates of carbohydrate intolerance during pregnancy and of diabetes later in life[9]. This would include Hispanic, African, Native American, South or East Asian, Pacific Islands, and Indigenous Australian ancestry women, particularly when they reside in Westernized countries or in an urban setting[2]. Few studies have been done locally to determine the prevalence of GDM in our local Asian population and to determine the feasibility of such a screening program. In Thailand, the rate of 2.02 to 20.17% was reported[4-7]. Jantarat W et al[6] reported that the prevalence of GDM in high-risk pregnant women in Bhumibol Adulyadej Hospital was 20.17%. In most western population, the low- and high-risk populations have a prevalence rate of 1.4-2.8% and 3.3-6.1%, respectively[15]. The prevalence of GDM in Asian women is higher than in the western population came as no surprise since Asian population in itself is considered a risk factor. However, this has not taken into consideration our universal Asian ethnicity, which in itself is considered a risk factor in the United States population. The 50-g GCT should be done for screening and detection of GDM in our population.

The recommendations of the Fifth International

Workshop (2007) for selective screening include age > 25 years as risk an indicator[9]. The mean age of women in our study were 25.7 years old, which means that an age criteria of 25 years alone would encompass a great number of the population. If age and ethnicity were added to the risk model, a large number of additional diagnostic tests would be needed with a very modest gain. In this study, we chose to employ all pregnant screening due to the difficulty involved in adhering to a selective screening protocol in a busy ANC clinic.

The mean time of screening in this study was 30.3 weeks which was quite late. The earlier schedule for the diagnostic of GDM could have led to an earlier diagnosis in women with historical risk factors, but it would not have facilitated the earlier diagnosis of those subjects with current risk factors who mostly present at third trimester (e.g. glucosuria, polyhydraminos, and preeclampsia in current pregnancy).

Because insulin resistance increases with gestational age because of hormones that act as anti-insulin effects (estrogen, progesterone, and human placental lactogen), these women were still at risk for developing GDM later in their pregnancies[1]. GDM with onset in mid-pregnancy or later pregnancy is not associated with an increased prevalence of congenital malformations. However, GDM diagnosed possibly represents preexisting type 2 diabetes[9]. Following this study, subsequent laboratory tests were repeated at approximately 28-32 weeks for hematocrit (Hct), syphilis serology (VDRL) and anti HIV, screening GDM at the same time may be cost–effective and convenient.

We used Accu-Chek®glucometer for 50-g GCT screening of gestational diabetes because of comfortable use and quick result. American Diabetes Association's Third International Workshop-Conference on Gestational diabetes did not recommend the use of glucometer for screening because of its low precision and accuracy[16]. However, the venous blood, not capillary blood was collected. If quality assurance of glucose meters had checked, Accu-Chek® glucometer may be acceptable. The cost of 50-g GCT at our institution, considering the direct costs of the laboratory kit is 65 baht, which is free for patient who has a medical insurance. While the no-screening strategy has no upfront screening costs, the initial cost savings is not sufficient to overcome the cost and disutility of potential obstetric complications[17]. The 50-g GCT is a simple, cheap and convenient test. It does not require a pregnant woman to be fasted and can be easily organized. Apart from the occasional nausea, it is simple.

However, because of poor compliance we lost 60 cases (18.6%) of 50-g GCT positive women from 100-g OGTT diagnostic tests. Reasons for nonadherence included patient refusal, personal practices of some of the physicians, and dietary counseling and management after a positive initial 50-g GCT screening test result without verification by the 100-g OGTT. Therefore, the actual rate of abnormal test and GDM might be higher than the result suggests. To obtain expected prevalence, we calculated the expected number of GDM cases among those women who had not been diagnosed with 100-g OGTT, and then we added the observed cases plus the expected ones.

Most of our study population had no clinical risk factor (76.4%). Assuming that the rate of GDM expected in the random sample of no clinical risk women is applicable to the whole group of 979 women, then these 49 women could also have GDM (5%). Approximately one in 20 women with no clinical risk was found to have GDM. Thus, the incidence of GDM among Thai women with no risk factors is not low and cannot be ignored. These women would otherwise have been missed using historical/obstetric features alone as screening tests. Pregnant women with clinical risks may have been diagnosed with GDM early in their pregnancy and the risk for GDM for the rest of these women was not so great. Therefore, only 303 cases (23.6%) of women who had one or more clinical risks were enrolled. In the present study, we found 148 women with clinical risk did not receive the prior screening test (48.8% of 303 cases). This might be due to the negligence of the physicians themselves in missing clinical risk factors or the poor compliance of the pregnant women themselves for denial to test. Careful history reviewing plays an important role in identifying GDM risk factor for GDM screenings. Moreover, pregnant women with glucosuria on a screening day would not receive a prior screening

test. If these pregnant women were excluded, approximately 8.6% (11 of 128) of GDM would be missed. The results of the present study also showed that after initial normal test, GDM were found in 3 of 26 cases (32.2%), and the estimated of GDM was eventually diagnosed in 3.9% (6 of 155). It has been reported that a repeat test of glucose tolerance later in pregnancy enables diagnosis of GDM in women with negative test results earlier in pregnancy. These women might have some degree of diabetogenic effect but was not high enough to show up during initial tests. Even if small numbers was detected, the results showed the benefit for repeated screening even when initial tests were normal. Our study shows the screening strategy using 50-g GCT was able to detect an additional 5.1% of GDM in the population-based subjects. So, five in 100 pregnant women of GDM might be undetected if the screening tests with subsequent ANC laboratory tests were not done. This finding further emphasized the benefit for this screening strategy of GDM in our population.

There were some limitations to the present study. One limitation is our small sample size. However, results from larger samplemay not be different as our sample population is quite representative of the general pregnant population. The impact of GDM on obstetric complications and pregnancy outcomes were not evaluated. In the future, a larger scale of research should be conducted in a prospective manner to clarify the statistical difference in pregnancy complication and outcome. The importance of under detecting GDM should be assessed in the context of short- and long-term consequences for the mother and newborn, including the impact of GDM treatment on them. Further studies should be conducted to determine whether screening 50-g GCT simultaneously with subsequent ANC laboratory tests would improve maternal and neonatal outcomes in comparison with those who are not identified with GDM in their pregnancies. Moreover, further studies need to establish clearly whether the screening test is worthwhile, valid and cost-effective. Actual cost impact in the screening strategies is however, difficult to quantify as it does not only involves cost of tests and procedures, but also unnecessary interventions due to false positive results as well as the cost of therapy and its potential harms. The subject of GDM screening as a public health strategy calls for a deeper and more thorough analysis than this study. The choice of techniques does not only depend on the number of women screened or cases diagnosed; the effects of the disease on the mother and the newborn, the effectiveness of the treatment, and the cost-benefit relationship of the program should be assessed.

The non-participation rate of 18.6% in our study was high, especially in the prior negative tested group (48%). This mayreduce the prevalence of GDM. No information was collected about the women who declined to participate or was missed to detect risk factors. If all pregnant women could undergo the screening protocol, the true prevalence of GDM might be shown.

The aim of our study was not to take a firm position in favor of this systematic screening for GDM, but rather to simply assess the results of additional GDM screening simultaneously with subsequent ANC laboratory tests. This screening strategy may be a good measure to identify women with GDM at least in Thai population with a large percentage of women at medium/high risk for GDM, even if they had no other clinical risk factors. Moreover, the screening and subsequent ANC laboratory tests at the same time could be used to diagnose for GDM in women with clinical risk who were missed in risk factors detection and screened the prior negative tests.

Conclusion

The 50-g GCT performed simultaneously with subsequent ANC laboratory tests appeared to be feasible, simple, convenient, and easy to organize in the ANC outpatient setting for detecting more GDM that occurs late in pregnancy in our population.

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การตรวจคัดกรองโรคเบาหวานขณะตั้งครรภ์เพิ่มเติมในการเจาะเลือดฝากครรภ์ซ้ำที่โรงพยาบาลชลบุรี

วีณา ครุฑสวัสดิ์, ธีระ ศิวะดุลย์

วัตถุประสงค์ : เพื่อศึกษาผลของการตรวจคัดกรองโรคเบาหวานขณะตั้งครรภ์ในการเจาะเลือดฝากครรภ์ซ้ำที่โรงพยาบาลชลบุรี

วัสดุและวิธีการ : การศึกษาไปข้างหน้าเชิงพรรณนาจัดทำขึ้นที่หน่วยฝากครรภ์ กลุ่มงานสูตินรีเวชกรรม โรงพยาบาลชลบุรีประเทศไทย โดยมีกลุ่มตัวอย่างเป็นสตรีตั้งครรภ์ที่มาฝากครรภ์และได้รับการเจาะเลือดฝากครรภ์ครั้งที่ 2 ช่วงระหว่าง 1 ตุลาคม พ.ศ.2551 ถึง 31 ธันวาคม พ.ศ.2552 สตรีตั้งครรภ์ทั้งหมดได้รับการตรวจ 50 กรัม Glucose Challenge Tests (50-g GCT) พร้อมกับการเจาะเลือดฝากครรภ์ครั้งที่ 2 (Anti HIV, VDRL และ Hct) สตรีตั้งครรภ์ที่มีระดับน้ำตาล ≥ 140 มก./ดล. จะได้รับการตรวจต่อด้วยวิธี 100 กรัม oral glucose tolerance test (100-g OGTT) ทำการเก็บข้อมูลพื้นฐาน ได้แก่ ข้อมูลทางด้านประชากรศาสตร์ ปัจจัยเสี่ยงต่อโรคเบาหวานขณะตั้งครรภ์ ผลการตรวจ 50-g GCT และ100-g OGTT และนำข้อมูลที่ได้มาวิเคราะห์ทางสถิติ

ผลการศึกษา : ในการศึกษารวบรวมสตรีตั้งครรภ์จำนวน 1,282 คน โดยมีอายุครรภ์เฉลี่ย 30.3 สัปดาห์ สตรีตั้งครรภ์ส่วนใหญ่เป็นกลุ่มที่ไม่มีปัจจัยเสี่ยง 979 ราย (76.4%) อัตราการตรวจพบความผิดปกติของ 50-g GCT ในการตรวจคัดกรองโรคเบาหวานระหว่างตั้งครรภ์ในการเจาะเลือดฝากครรภ์ซ้ำเท่ากับ 25.1% (322 ราย) โดยในจำนวนนี้ 262 ราย ได้รับการตรวจต่อด้วยวิธี 100-g OGTT เพื่อวินิจฉัยโรคเบาหวานขณะตั้งครรภ์ ผลการตรวจพบสตรีตั้งครรภ์ 55 ราย (21%) เป็นโรคเบาหวานระหว่างตั้งครรภ์ ในกลุ่มสตรีตั้งครรภ์ที่มีปัจจัยเสี่ยง อัตราการวินิจฉัยโรคเบาหวานระหว่างตั้งครรภ์ในกลุ่มที่ไม่เคยตรวจคัดกรองมาก่อนและกลุ่มที่เคยตรวจคัดกรองแล้วผลปกติประมาณ 7.4% และ 3.9% ตามลำดับ ในกลุ่มสตรีตั้งครรภ์ที่ไม่มีปัจจัยเสี่ยง อัตราการวินิจฉัยประมาณ 5% อัตราการวินิจฉัยโรคเบาหวานระหว่างตั้งครรภ์ในกลุ่มประชากร คิดเป็น 5.1%

สรุป : การตรวจคัดกรองโรคเบาหวานระหว่างตั้งครรภ์พร้อมการเจาะเลือดฝากครรภ์ครั้งที่ 2 มีประโยชน์ในกลุ่มที่ไม่มีปัจจัยเสี่ยงและมีปัจจัยเสี่ยงต่อโรคเบาหวานระหว่างตั้งครรภ์ โดยสามารถวินิจฉัยโรคเบาหวานระหว่างตั้งครรภ์ได้เพิ่มขึ้น