Original Article/นิพนธ์ต้นฉบับ

# Screening of Diabetes Mellitus in Pregnancy by Hemoglobin $A_{1c}$ and Fasting Plasma Glucose at Ramathibodi Hospital

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## Abstract

**Background:** Diabetes mellitus (DM) is an important complication during pregnancy. The International Diabetes Federation (IDF) recommended screening for pre-existing or overt DM and gestational diabetes (GDM) by hemoglobin $A_{1c}$ ($HbA_{1c}$) and fasting plasma glucose (FPG) at the first antenatal visit.

**Objective:** To study the incidence of DM in pregnancy by the new screening program, and its effects on perinatal outcomes in pregnant women who entered for antenatal visits at Ramathibodi Hospital.

**Methods:** The descriptive study analyzed results of screening DM by $HbA_{1c}$ and FPG among 421 pregnant women who came for antenatal visits during January 4, 2016, to March 31, 2016. Chi-square test, Fisher's exact test and logistic regression analysis were used to analyze the association between factors with significance level at $P < 0.05$.

**Results:** Among the 421 participants, 4 participants (0.95%) were diagnosed with pre-existing DM and 57 participants (13.54%) were diagnosed with GDM at first antenatal visit. In second screening at 24 - 28 weeks of gestational age another 62 participants (21.99%) among 282 participants were diagnosed GDM. Totally incidence of GDM in this study was 35.53%. Abortion rate (18.03%) was significantly higher among pregnant women with DM compared to normal women (2.01%). There was no significant association between DM in pregnancy and other outcomes of pregnancy.

**Conclusions:** This study showed that the incidence of pre-existing DM in pregnant women screened by HbA1c at the first antenatal visit was very low. DM in pregnancy was significantly associated with abortion, but not with other outcomes of pregnancy.

**Keywords:** Diabetes mellitus, Gestational diabetes, Pre-existing diabetes, Abortion, Outcomes of pregnancy

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## Introduction

Gestational diabetes mellitus (GDM) can cause complications for both maternal and fetus. Complications of GDM in mothers are increased maternal death, preeclampsia, diabetic nephropathy, diabetic retinopathy, diabetic neuropathy, diabetic ketoacidosis infections, pre-eclampsia, cesarean sections and development of Type 2 diabetes in subsequent years.[1] Complications of GDM in fetus are increased birth weight, birth trauma, respiratory distress syndrome (RDS), hypoglycemia, hyperbilirubinemia, polycythemia, hypocalcemia, major congenital anomalies and intrauterine deaths.[1]

The prevalence of GDM may range from 1% to 14% of pregnancies, depending on the population studied. GDM represents nearly 90% of all pregnancies complicated by diabetes. In the United State, GDM complicated about 4% of all pregnancies, approximately 135 000 cases annually.[2] In India, the prevalence of diabetes among pregnant women is estimated at 17.0%of women attending antenatal care in the first trimester.[3] In Thailand, that the prevalence of GDM was 15.7% by the World Health Organization (WHO) criteria.[4]

The criteria for diagnosing diabetes in pregnancy has evolved over time. The screening and diagnosis of GDM continues to be a contentious issue. Notwithstanding decades of research and several international workshops devoted to GDM, there is still no consensus among international bodies on a uniform global approach to screening and diagnosis of GDM.[5]

Recommendations from the American Diabetes Association's (ADA) Fourth International Workshop Conference on Gestational Diabetes Mellitus support the use of the Carpenter and Coustan diagnostic criteria as well as the alternative use of a diagnostic 50-gram screening test followed by 75-gram 2-hour oral glucose tolerance test (OGTT).[6] The International Association of Diabetes and Pregnancy Study Groups (IADPSG) has issued recommendations on the diagnosis and classification of hyperglycemia in pregnancy.[7] The recommendations stated that all pregnant women should undergo testing of fasting plasma glucose (FPG), hemoglobin $A_{1c}$ ($HbA_{1c}$), or random plasma glucose (RPG), based on the background frequency of abnormal glucose metabolism in the population and on local circumstances.

Ramathibodi Hospital adopted this recommendation and started screening DM in all pregnant women at the first antenatal visit by $HbA_{1c}$ and FPG since 2012. This study aimed to study the incidence of DM in pregnancy by the new screening program, and its effects on perinatal outcomes.

## Methods

This study consecutively included 421 pregnant women who came for the first antenatal visit at Ramathibodi Hospital during January 4, 2016, to March 31, 2016. All pregnant women were included no matter of age, parity, personal history and other characteristics. They were screened for DM by blood test of $HbA_{1c}$ and FPG in the first trimester. The results of blood test were collected and pregnant women were classified as normal or abnormal (pre-existing DM or GDM). Their follow-up visits, treatments and outcomes of pregnancy which include type of delivery, preterm delivery newborn's birthweight, Apgar score, and newborn's admission into intensive care unit (ICU) were also collected form database in the computer of Ramathibodi Hospital. Those who lost to follow-up were contacted by phone to verify their outcomes of pregnancy.

Ethical approval for this study was obtained from the Ethics on Research Involving Human Subjects, Faculty of Medicine Ramathibodi Hospital, Mahidol University (No. MURA2017/222).

Thresholds for diagnosis of pre-existing DM during pregnancy were either FPG ≥ 7.0 mmol/L (126 mg/dL) or $HbA_{1c}$ level ≥ 6.5% or random plasma glucose ≥ 11.1 mmol/L (200 mg/dL). GDM was diagnosed if FPG was between 5.1 - 7.9 mmol/L (92 - 125 mg/dL). Otherwise women were diagnosed as normal. These normal pregnant women were screened for DM in pregnancy again at 24 to 28 weeks of gestation age by 75-gram 2-hour OGTT. A 75-gram 2-hour OGTT was performed after overnight fasting. GDM was

diagnosed if one or more values equals or exceeds thresholds of FPG (≥ 5.1 mmol/L, ≥ 92 mg/dL) or 1-hour plasma glucose (PG) level of 10.0 mmol/L (180 mg/dL), or 2-hour PG level of 8.5 mmol/L (153 mg/dL).[7]

The SPSS version 18 (PASW Statistics for Windows, Version 18.0. Chicago: SPSS Inc; 2009) was used for data analysis. Chi-square test, Fisher's exact test and logistic regression analysis were used for hypothesis testing with significance level at $P < 0.05$.

## Results

### Prevalence of DM in Pregnancy

Among 421 pregnant women, 4 cases (0.95%) of pre-existing DM were diagnosed by $HbA_{1c}$ at the first antenatal visit. None was diagnosed by FPG. Fifty-seven cases (13.54%) were diagnosed as GDM and 360 cases (85.51%) were normal (Figure 1).

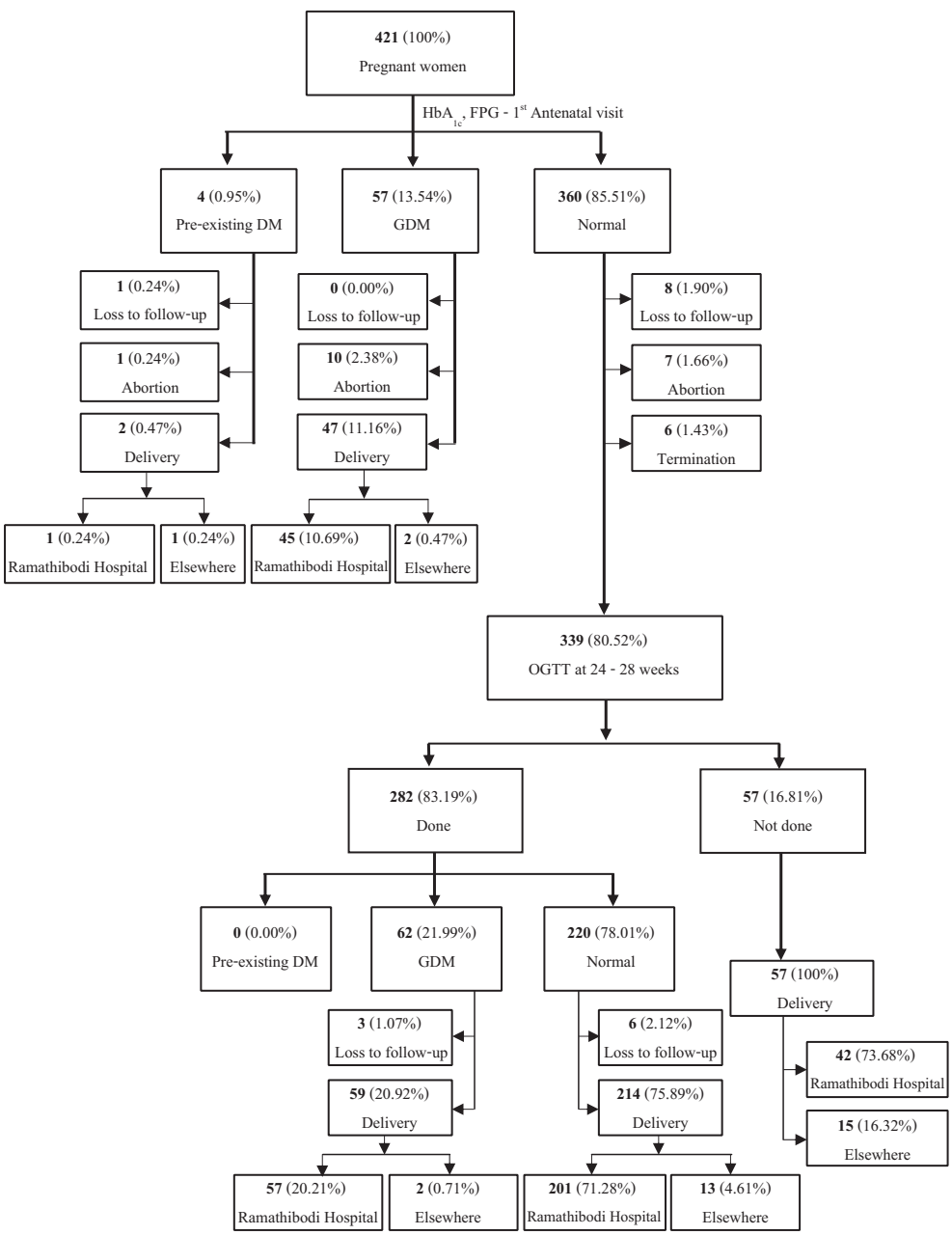


***Figure 1*** *Flow of Participants Through the Study*

HbA1c indicates hemoglobin A1c; GDM, gestational diabetes mellitus; OGTT, oral glucose tolerance test.

Among 339 pregnant women who had normal tests at the first visit were followed up. Only 282 pregnant women (83.19%) were screened again at 24 - 28 weeks of gestational age by 75-gram 2-hour OGTT. Fifty-seven pregnant women (16.81%) were not screened. Sixty-two cases (21.99%) of GDM were additionally diagnosed. Totally, incidence of GDM in this study was 35.53% (Figure 1).

## Management

All pregnant women who were diagnosed as DM in pregnancy were advised and educated about dietary control in classes of nutritional advice. Afterwards they had to monitor and record plasma glucose in their booklets more than once a day and brought the records for follow-up visits. None of DM pregnant women in this study received treatment of insulin or hypoglycemia agent.

## Outcomes of Pregnancy

### *Abortion*

Among 421 pregnant women who were screening for DM in pregnancy at the first antenatal visit, there were 18 cases (4.28%) of abortion. Abortion was significantly associated with DM in pregnancy ($HbA_{1c} \geq 6.5\%$ and/or FPG $\geq 92$ mg/dL) ($P < 0.01$) (Table 1).

### *Other Outcomes*

There was no significant association between DM in pregnancy and other outcomes of pregnancy which included type of delivery (non-operative vaginal delivery was found), preterm delivery, newborn's birth weight, Apgar score, and newborn's admission into intensive care unit (ICU) (Table 2). Regarding complication of pregnancy, no case of induction of labor or cesarean section due to preeclampsia or antepartum hemorrhage was found. Non-congenital malformation was reported among pregnant women in this study.

## Factors Associated With DM in Pregnancy

By univariate analysis, age, body weight and body mass index (BMI) were significantly associated with abnormal results of blood screening of DM in pregnancy. Pregnant women whose aged $\geq 25$ years old were significantly increased risk of DM in pregnancy (Table 3).

Pregnant women who had BMI $\geq 23$ kg/m$^2$ and weight $\geq 60$ kg were significantly increased risk of DM in pregnancy. Only 2 cases of past history of DM were found and confirmed pre-existing DM by blood test. Sixteen percent of women had family history of DM. Height, past history of DM, and family history of DM did not have any significant association with DM in pregnancy (Table 3).

When multiple logistic regression analysis was applied with forward stepwise procedure, only age group of $\geq 30$ years old was significantly associated with laboratory results of DM in pregnancy with adjusted OR 2.15 (95% CI: 1.37 - 3.39). The logistic regression equation could correctly predict the laboratory results at 64.14%.

**Table 1** Association Between DM Screening at the First Antenatal Visit and Abortion

| DM Screening | No. (%) | | *P* Value | OR (95% CI) |
|---|---|---|---|---|
| | Abortion | | | |
| | Yes | No | | |
| DM ($HbA_{1c} \geq 6.5\%$ and/or FPG $\geq 92$ mg/dL) | 11 (18.03) | 50 (81.97) | < 0.01* | 10.75 (3.98, 29.01) |
| Normal | 7 (2.01) | 342 (97.99) | | |
| Total | 18 (4.39) | 393 (95.61) | | |

Abbreviation: CI, confidence interval; DM, diabetes mellitus; FPG, fasting plasma glucose; $HbA_{1c}$, hemoglobin $A_{1c}$; OR, odds ratio.

* Fisher's exact test.

**Table 2** Association Between Outcomes of Pregnancy and DM in Pregnancy

| Outcome | No. (%) | | | OR (95% CI) |
|---|---|---|---|---|
| | DM in Pregnancy | | | |
| | Total (n = 322) | Yes (n = 108) | No (n = 224) | |
| Type of delivery | | | | |
| C/S | 157 (48.76) | 46 (29.30) | 111 (70.70) | 0.69 (0.43 - 1.10) |
| Vaginal (spontaneous) | 165 (51.24) | 62 (37.58) | 103 (62.42) | |
| Preterm delivery, wk | | | | |
| < 37 | 50 (15.53) | 21 (42.00) | 29 (58.00) | 1.54 (0.83 - 2.85) |
| ≥ 37 | 272 (84.47) | 87 (31.99) | 185 (68.01) | |
| Birth weight, g | | | | |
| < 3500 | 255 (79.19) | 79 (30.98) | 176 (69.02) | 1.70 (0.98 - 2.59) |
| ≥ 3500 | 67 (20.81) | 29 (43.28) | 38 (56.72) | |
| Apgar score, 5 min | | | | |
| < 7 | 2 (0.62) | 1 (50.00) | 1 (50.00) | 0.50 (0.03 - 8.11) |
| ≥ 7 | 320 (99.38) | 213 (66.56) | 107 (33.44) | |
| Newborn's admission into ICU | | | | |
| Yes | 3 (0.93) | 2 (66.67) | 1 (33.33) | 4.02 (0.36 - 44.82) |
| No | 319 (99.07) | 106 (33.23) | 213 (66.67) | |

Abbreviation: CI, confidence interval; C/S, cesarean section; DM, diabetes mellitus; ICU, intensive care units; OR, odds ratio.

**Table 3** Association Between Maternal Characteristics and Diagnosis of DM in Pregnancy by Univariate Analysis

| Maternal Characteristic | No. (%) | | | OR (95% CI) |
|---|---|---|---|---|
| | DM in Pregnancy | | | |
| | Total (n = 343) | Yes (n = 123) | No (n = 220) | |
| Age, y | | | | |
| < 25 | 73 (21.28) | 15 (20.55) | 58 (26.36) | 2.58 (1.39 - 4.78) |
| ≥ 25 | 270 (78.72) | 108 (40.00) | 162 (60.00) | |
| Weight, kg | | | | |
| < 60 | 247 (72.01) | 53 (32.39) | 167 (67.61) | 1.69 (1.05 - 2.74) |
| ≥ 60 | 96 (27.99) | 43 (44.79) | 53 (55.21) | |
| BMI, kg/m² | | | | |
| < 23 | 231 (67.35) | 73 (31.60) | 158 (68.40) | 1.75 (1.10 - 2.28) |
| ≥ 23 | 112 (32.65) | 50 (44.64) | 62 (55.36) | |
| Past history of DM (Type II) | | | | |
| No | 341 (99.42) | 121 (35.48) | 220 (64.52) | - |
| Yes | 2 (0.58) | 2 (100) | - | |
| 1st Degree family history of DM | | | | |
| No | 287 (83.67) | 100 (34.84) | 187 (65.16) | 1.30 (0.73 - 2.34) |
| Yes | 56 (16.33) | 23 (41.07) | 33 (58.93) | |

Abbreviation: BMI, body mass index; CI, confidence interval; DM, diabetes mellitus; OR, odds ratio; $X^2$.

## Discussion

There are still controversies in screening DM in pregnancy. Recently, the IADPSG recommended the protocol of screening DM in pregnancy by $HbA_{1c}$ and FPG at the first visit and by 75-gram 2-hour OGTT at 24 - 28 weeks. In this study, only 4 cases (0.95%) of pregnant women were diagnosed to have pre-existing DM only by measuring level of $HbA_{1c}$. Screening pre-existing DM at the first visit by FPG was not effective because fasting ≥ 126 mg/dL (7.0 mmol/L) level was inappropriate because FPG in pregnant state is lower than not pregnant state.[8]

In Australia, pre-existing DM was found in 0.5% of pregnant women by WHO and American Diabetes Association (ADA) classifications. From 1999 - 2008, the annual number of pregnant women with pre-existing diabetes in Australia almost doubled and the prevalence increased from 0.4% to 0.6%.[9] The study in Southern California, United States reported that an average of 1.3% of pregnant women were identified by $HbA_{1c}$ to have pre-existing DM. When age and race/ethnicity were adjusted, the prevalence was 0.81% in 1999 and increased to 1.82% in 2005 which was statistically significant ($P < 0.001$). Significant increases were observed in all age groups and all racial/ethnic groups.[10] In India, the prevalence of pre-existing DM among pregnant women was 3.8%.[11] In Thailand, the prevalence of pre-existing DM in pregnant women was not unavailable, because no study was done on screening at the first antenatal visit. In this study, only 0.95% of pregnant women were found to have pre-existing DM.

In 2010, IADPSG proposed new criteria of screening of GDM in pregnancy.[7] The recommendations stated that all pregnant women should undergo testing of FPG, $HbA_{1c}$, or RPG, based on the background frequency of abnormal glucose metabolism in the population and on local circumstances. The screening protocol of IADPSG results in higher prevalence of GDM. In the past (before 2014), the incidence of GDM was about 5% - 7% of pregnant women.[10, 12, 13] With these new criteria, the prevalence of GDM increased to be about 20% - 40%.[14]

The European Board and College of Obstetrics & Gynecology (EBCOG) in association with the European Association for the Study of Diabetes (EASD) suggested that due to lack of evidence on classifying GDM using FPG ≥ 92 mg/dL (5.1 mmol/L) in first trimester or first antenatal visit, the EBCOG stated that no clear recommendations can be made on diagnostic criteria for GDM in early pregnancy.[15]

The study of Galindo et al[16] found that DM in pregnancy was associated with abortion and congenital anomalies. Compared with pregnancies with a favorable outcome, a high $HbA_{1c}$ concentration in early pregnancy was observed in pregnancies with adverse perinatal outcome ($P = 0.001$).[16] Poor metabolic control around conception and in the early weeks of pregnancy may be the determining factor favoring abortion.[16, 17]

The study from Saudi Arabia showed that GDM was associated with increased risk for pre-eclampsia, preterm delivery, induction of labor, C/S delivery, macrosomia, stillbirth, preterm delivery and low Apgar scores at 5 minutes.[18, 19] In this study, none of the complications was found. The discrepancy may be due to different population with different degree of risk of DM in pregnancy, different screening methods and different in management. Education and dietary habit of pregnant women may play a role in incidence and outcomes of pregnancy in different population.[1] Negative association between DM and other outcomes of pregnancy may be the results of education, dietary advice and plasma glucose monitoring.

Different cut off points of age of pregnant women were found by univariate analysis to be associated with abnormal laboratory results. When logistic regression analysis was applied only factor of age ≥ 30 years old was significant associated with abnormal results of DM screening in pregnancy. Generally, age ≥ 25 years old was recommended as a cutoff point of screening DM in pregnancy in high income country where obesity and juvenile DM were more prevalent.[20]

Recent study by Bunak et al[21] who studied impact of maternal BMI and age on GDM diagnosed by IADPSG

criteria and found that BMI and age were also significant factors. In this study, association between BMI and DM in pregnancy were significant by univariate analysis but was excluded by logistic regression analysis.

The study of the National Institute for Health and Care Excellence (NICE) in 2015 based on reducing the average unit costs for selected adverse outcomes using health economic modelling which compared the cost effectiveness of NICE risk factors-based screening with universal screening. The analysis showed the incremental cost effectiveness ratios (ICER) in risk factor selected population compared to universal screening. The model did not support change to universal testing as recommended by IADPSG.[22]

Notwithstanding the scientific validity of any guideline, there are constraints of applying these criteria in low and middle-income countries (LMIC) such as Thailand, where resources are poor. In some remote rural areas, lack of access to a standardized laboratory and resources for performing the test are huge challenges that needs to be addressed. Often, lack or insufficiency of trained phlebotomists to collect venous blood samples, as required by most guidelines, pose a serious challenge in ensuring universal screening.[5]

## Conclusions

This study showed that the incidence of pre-existing DM in pregnant women screened by $HbA_{1c}$ at the first antenatal visit was 0.95% and the incidence of GDM was 35.53% by new program of DM screening. DM in pregnancy was significantly associated with abortion, but not with other outcomes of pregnancy. Factor of age ≥ 30 years old was significant associated with abnormal results of DM screening in pregnancy.

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Original Article/นิพนธ์ต้นฉบับ

# การคัดกรองภาวะเบาหวานในสตรีตั้งครรภ์โดยการตรวจวัดระดับฮีโมโกลบินเอวันซี และระดับน้ำตาลในพลาสมาหลังอดอาหาร ณ โรงพยาบาลรามาธิบดี

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## บทคัดย่อ

**บทนำ:** เบาหวานเป็นภาวะแทรกซ้อนที่สำคัญขณะตั้งครรภ์ สมาพันธ์เบาหวานนานาชาติแนะนำให้ตรวจคัดกรองภาวะเบาหวานในสตรีตั้งครรภ์โดยการเจาะเลือดตรวจวิเคราะห์ระดับฮีโมโกลบินเอวันซี (Hemoglobin $A_{1c}$, $HbA_{1c}$) และระดับน้ำตาลในพลาสมาหลังอดอาหาร (Fasting plasma glucose, FPG) ตั้งแต่มาฝากครรภ์ครั้งแรก

**วัตถุประสงค์:** เพื่อศึกษาอุบัติการณ์ของภาวะเบาหวานในสตรีตั้งครรภ์ที่ได้รับการตรวจคัดกรองภาวะเบาหวานแบบใหม่และผลการตั้งครรภ์ของสตรีที่มาฝากครรภ์ในโรงพยาบาลรามาธิบดี

**วิธีวิจัย:** การวิจัยเชิงพรรณนา เก็บข้อมูลจากกลุ่มตัวอย่างสตรีที่มาฝากครรภ์ครั้งแรกในโรงพยาบาลรามาธิบดี จำนวน 421 คน ระหว่างวันที่ 4 มกราคม ถึงวันที่ 31 มีนาคม พ.ศ. 2559 และได้รับการเจาะเลือดเพื่อตรวจวัดระดับฮีโมโกลบินเอวันซีและระดับน้ำตาลในพลาสมาหลังอดอาหาร จากนั้นวิเคราะห์ความสัมพันธ์ของตัวแปรโดยใช้สถิติ Chi-square test, Fisher's exact test และ Logistic regression analysis กำหนดค่านัยสำคัญทางสถิติที่ 0.05

**ผลการศึกษา:** จากการตรวจวินิจฉัยครั้งแรกในกลุ่มตัวอย่าง พบสตรีที่มีภาวะเบาหวานก่อนการตั้งครรภ์ จำนวน 4 คน คิดเป็นร้อยละ 0.95 และสตรีที่มีภาวะเบาหวานขณะตั้งครรภ์ จำนวน 57 คน คิดเป็นร้อยละ 13.54 และเมื่อทำการตรวจวินิจฉัยครั้งที่ 2 ในสตรีตั้งครรภ์ จำนวน 282 คน ที่มีอายุครรภ์ 24 - 28 สัปดาห์ พบสตรีที่มีภาวะเบาหวานขณะตั้งครรภ์ จำนวน 62 คน คิดเป็นร้อยละ 21.99 รวมทั้งสิ้นพบสตรีที่มีภาวะเบาหวานขณะตั้งครรภ์ร้อยละ 35.53 ภาวะเบาหวานขณะตั้งครรภ์มีความสัมพันธ์กับการแท้งบุตรอย่างมีนัยสำคัญ แต่ไม่มีความสัมพันธ์กับผลการตั้งครรภ์อื่นๆ

**สรุป:** การศึกษานี้แสดงให้เห็นว่า สตรีที่มีภาวะเบาหวานก่อนการตั้งครรภ์พบอุบัติการณ์น้อยมาก ซึ่งภาวะเบาหวานขณะตั้งครรภ์มีความสัมพันธ์กับการแท้งบุตร แต่ไม่มีความสัมพันธ์กับผลการตั้งครรภ์อื่นๆ

**คำสำคัญ:** เบาหวาน ภาวะเบาหวานในขณะตั้งครรภ์ ภาวะเบาหวานก่อนการตั้งครรภ์ การแท้งบุตร ผลการตั้งครรภ์

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