ORIGINAL ARTICLE

Random Plasma Glucose for Prediction of Gestational Diabetes Mellitus

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Objective: To establish the random plasma glucose (RPG) threshold for predicting gestational diabetes mellitus (GDM) in pregnant individuals with a gestational age of less than 24 weeks.

Materials and Methods: A prospective cohort study was conducted at Rajavithi Hospital between September 2022 and August 2023. Pregnant women with gestational ages below 24 weeks were recruited during their initial antenatal visit, and RPG and hemoglobin A1c (HbA1c) levels were measured. Participants with pregestational diabetes mellitus were excluded. All participants underwent screening for GDM using a 50-g glucose challenge test (GCT) followed by diagnosis via a 100-g oral glucose tolerance test (OGTT). Test accuracy was assessed using the area under the receiver operating characteristic curve (aROC).

Results: Eight hundred three pregnant women were analyzed, with a GDM prevalence of 8.5%. An RPG threshold of 88.5 mg/dL or greater demonstrated the highest clinical relevance, with a sensitivity of 45.6% and a specificity of 82.5% (AUC 0.64, 95% CI 0.56 to 0.72). A "combined GDM predictive score" was developed using multivariate logistic regression analysis, incorporating RPG, HbA1c, age, glucosuria, and body mass index (BMI). This composite score yielded a sensitivity of 60.3% and a specificity of 85.3% (AUC 0.79, 95% CI 0.72 to 0.85). Furthermore, the specificity of the "combined GDM predictive score" in a non-high-risk subgroup was notably high at 92.4% (AUC 0.73).

Conclusion: Although RPG alone was not found to be a good predictor of GDM, the "combined GDM predictive score" is a useful tool for ruling out GDM in non-high-risk pregnant women before 24 weeks of gestation.

Keywords: Random plasma glucose; Gestational diabetes mellitus; Prediction; Predictive score; HbA1c; Glucosuria; BMI

Received 9 September 2024 | Revised 4 February 2025 | Accepted 7 February 2025

J Med Assoc Thai 2025;108(3):191-6

Website: http://www.jmatonline.com

Gestational diabetes mellitus (GDM) represents an abnormal metabolic condition characterized by elevated blood sugar levels during pregnancy. This condition poses significant risks for both maternal and fetal health, including complications such as pre-eclampsia, a heightened likelihood of cesarean section, birth injuries, shoulder dystocia, macrosomia with high birth weight, and neonatal hypoglycemia[1,2]. The Hyperglycemia and Adverse Perinatal Outcomes (HAPO), Jensen et al. studies showed that pregnant women with mild glucose intolerance also had significant adverse outcomes such as shoulder dystocia, spontaneous preterm delivery, macrosomia, and elevated cord-blood serum c-peptide[3,4]. In 2021, a study at Rajavithi Hospital in Bangkok, Thailand reported a prevalence rate of approximately 6.5% for GDM. These findings underscore the significance of early detection and effective management of GDM to mitigate the associated maternal and fetal complications.

There is currently no consensus about GDM screening. The National Institute for Health and Care Excellence (NICE) recommends risk-based screening to identify GDM[5]. The American Diabetes Association (ADA) and the U.S. Preventive Services Task Force (USPSTF) recommend universal screening for GDM at 24 to 28 weeks of gestation[6,7]. The American Congress of Obstetricians and Gynecologists (ACOG) also recommends universal screening and early pregnancy screening for undiagnosed type 2 diabetes mellitus or early GDM at the initial prenatal care in overweight or obese women with additional diabetic risk factors[8]. However, there is still no consensus on the best test for early GDM screening.

There is also a debate about the method for

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How to cite this article:

Metheetrairut S, Gleebkaew C. Random Plasma Glucose for Prediction of Gestational Diabetes Mellitus. J Med Assoc Thai 2025;108:191-6.
DOI: 10.35755/jmedassocthai.2025.3.191-196-01449

screening and diagnosing diabetes mellitus in pregnancy, including the two-step approach using the 50-g glucose challenge test (GCT) followed by the 100-g oral glucose tolerance test (OGTT), or the one-step approach using the 75-g OGTT[9,10]. Both the glucose challenge test and the glucose tolerance test have limitations. To obtain a reliable value, pregnant women must be given a glucose bolus, and blood must be drawn at precise intervals, moreover, women find such tests unpleasant. In addition, universal screening for GDM in all pregnant women at 24 to 28 weeks of gestation may not be feasible in resource-limited countries.

Random plasma glucose (RPG) is a simpler, easy to perform, and less expensive screen for GDM. The present study was conducted to determine the optimal cut-off value of RPG for predicting GDM before 24 weeks' gestational age.

Materials and Methods

The present study was a prospective cohort study conducted between September 2022 and August 2023 at Rajavithi Hospital, Thailand. The study was approved by the Rajavithi Hospital Ethics Committee (No.115/2022), and all participants signed an informed consent. Pregnant women with gestational ages of less than 24 weeks, confirmed via ultrasound, and aged over 18 years at their initial antenatal visit were included.

The exclusion criteria comprised individuals diagnosed with pregestational diabetes mellitus, or overt DM, determined through a history of diabetic mellitus before pregnancy, RPG levels of 200 mg/dL or higher, or hemoglobin A1c (HbA1c) levels of 6.5% or greater. Additionally, pregnant women with severe medical conditions contraindicated for pregnancy, lethal fetal anomalies, inability to communicate in Thai, intake of medications affecting plasma glucose levels, and those who had not undergone screening for GDM at 24 to 28 weeks of gestation were excluded.

Maternal characteristics such as age, parity, pre-pregnancy body mass index (BMI), history of previous GDM, history of a first-degree relative with diabetic mellitus, previous macrosomia delivery with birth weight of 4,000 g or more, and glucosuria were recorded. Women with BMI of 25 kg/m² or more, glucosuria, a history of a first-degree relative with diabetic mellitus, previous GDM, or previous macrosomia delivery were considered at high-risk for GDM. Blood tests for RPG and HbA1c were collected along with routine prenatal laboratory tests at the first visit. The two-step approach to GDM testing was performed for all participants. The first screening with the administration of 50 g of oral glucose solution followed by a one-hour venous glucose evaluation was performed, and if their plasma glucose was 140 mg/dL or greater, they were scheduled for a 100 g, three-hour diagnostic OGTT within one week. Blood tests were performed by a fully automated "Alinity C" from Abbott company, of which Laboratory Quality Accreditation (LA) and the National Glycohemoglobin Standardization Program (NGSP) were approved the laboratory's quality control. GDM is diagnosed in women who have two or more abnormal values on the three-hour OGTT by the Carpenter-Coustan criteria, which is the fasting blood sugar of 95 mg/dL or more, one-hour plasma glucose of 180 mg/dL or more, two-hour plasma glucose of 155 mg/dL or more, and three-hour plasma glucose of 140 mg/dL or more[8]. The high-risk group was scheduled for the screening test at their first visit, and the test was repeated at 24 to 28 weeks of gestation if the initial test was normal, while the non-high-risk group was scheduled for the test between 24- and 28-weeks' gestational age.

The sample size was calculated from the following formula[11] using the variables from Meek et al.[12]

$$n = \frac{Z^2_{\alpha/2}\, P(1-P)}{d^2}$$

N was the sample size, P was the area under the ROC curve at 0.81, d was the acceptable tolerance of the p-value at 20%, which was 0.162, α was the standard statistical value corresponding to significance, and $Z_{\alpha/2}$ was 1.96

$$n = (1.96)^2 \times 0.81\,(1-0.81) / (0.162)^2 = 23 \text{ cases}$$

The prevalence of gestational diabetes mellitus at Rajavithi Hospital in 2021 differed between the non-high-risk group and the high-risk group, with rates of 4.2% and 7.3%, respectively. These figures served as the basis for calculating the sample size. Additionally, a dropout rate of 10% was factored into the calculation. Consequently, the sample size for the present study was determined to be 950 cases.

The accuracy of the established cut-off level was assessed using sensitivity and specificity. All statistical analyses were conducted using IBM SPSS Statistics, version 22.0 (IBM Corp., Armonk, NY, USA). Baseline characteristics were presented as percentages. Continuous data with a normal distribution were summarized as mean and standard deviation (SD), while non-normally distributed data were reported as median, minimum, and maximum

Table 1. Baseline of all participant characteristics

Variables	n=950
Age (years); mean±SD	28.13±5.5
Parity; n (%)	
Nulliparity	427 (44.7)
Multiparity	523 (55.3)
Pre-pregnancy BMI (kg/m^2); median (range)	21.9 (13 to 47)
First-degree relatives with DM; n (%)	133 (13.9)
History of GDM; n (%)	2 (0.2)
Glucosuria; n (%)	20 (2.1)
Macrosomia; n (%)	7 (0.7)
Risk; n (%)	
Non-high	614 (64.6)
High	336 (35.4)

BMI=body mass index; DM=diabetes mellitus; GDM=gestational diabetes mellitus; SD=standard deviation

values. Comparisons of categorical data were performed using the chi-square test or Fisher's exact test, whereas continuous variables were evaluated using the Student's t-test for normally distributed data or the Mann-Whitney U test for non-normally distributed data. Correlation analysis was conducted using Pearson's correlation coefficient. Statistical significance was defined as a p-value of less than 0.05, with a 95% confidence level. The area under the curve (AUC) was calculated through receiver operating characteristic (ROC) analysis to identify an appropriate cut-off level for RPG in predicting GDM.

Results

Initially, the study enrolled 950 pregnant women, with 336 participants categorized as high-risk and 614 participants as non-high risk. However, 49 cases in the high-risk group and 98 cases in the non-high-risk group were excluded due to abortion, fetal anomalies, and a lack of GDM screening results. Consequently, the final analysis included 803 participants.

The demographic characteristics of the pregnant women in the present study are shown in Table 1. The mean maternal age was 28.18±5.5 years, and the median of pre-pregnancy BMI was 21.9 kg/m².

The diagnostic performance of RPG was analyzed by the ROC curve in Figure 1. The best threshold was 88.5 mg/dL with a sensitivity of 45.6% and a specificity of 82.5% (AUC 0.64).

The ability of HbA1c to predict GDM was also tested by the ROC curve in Figure 2. The most appropriate cut-off value was 5.1% with a sensitivity of 54.4% and a specificity of 78.6% (AUC 0.67).

Table 2 presents the results of univariate and

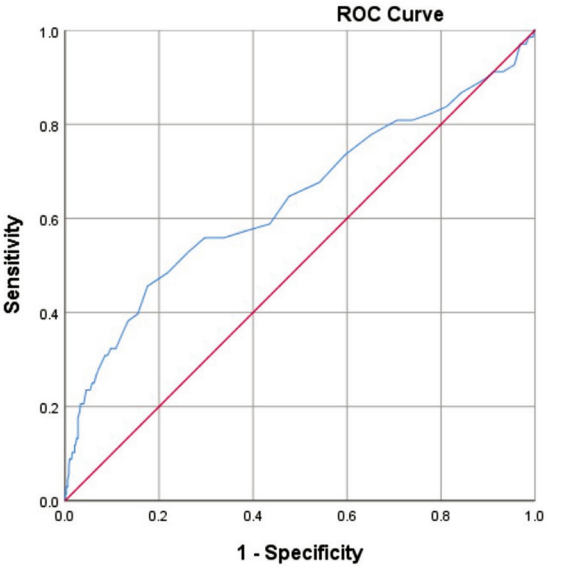

Figure 1. ROC curve of RPG to predict GDM.

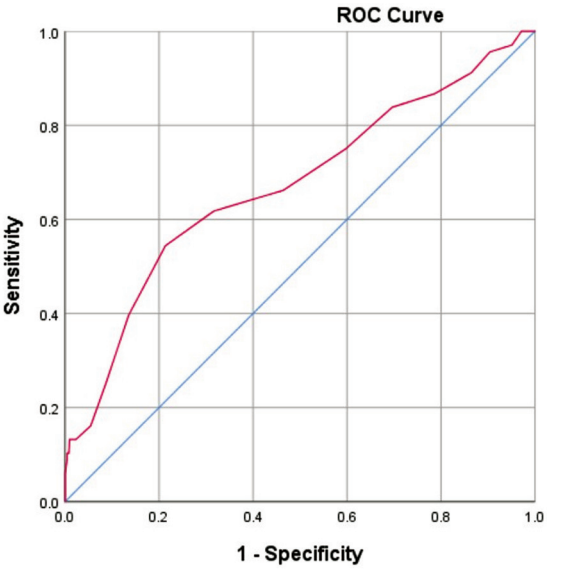

Figure 2. ROC curve of HbA1c to predict GDM.

multivariate logistic regression analyses of baseline characteristics, RPG, and HbA1c. Factors were found to be statistically significant, including age of 35 years or older, pre-pregnancy BMI of 25 kg/m² or greater, presence of glucosuria, RPG of 88.5 mg/dL or more, and HbA1c of 5.1% or more. Based on these significant factors, the "combined GDM predictive score" was developed, as shown in Table 3.

Figure 3 illustrates the diagnostic performance of the "combined GDM predictive score." At a score threshold of 3 or greater, the sensitivity was calculated

Table 2. Univariate and multivariate analysis

	Univariate			Multivariate		
	cOR	95% CI	p-value	aOR	95% CI	p-value
Age (<35 vs. ≥35 years)	15.96	5.42 to 47.04	<0.001	3.08	1.95 to 4.89	<0.001
BMI (<25 vs. ≥25 kg/m^2)	2.87	1.74 to 4.73	<0.001	1.95	1.10 to 3.46	0.023
1st-degree relative DM (no vs. yes)	1.59	0.85 to 2.95	0.147			
Previous GDM (no vs. yes)	10.62	0.66 to 17.71	0.096			
Glucosuria (no vs. yes)	21.51	6.99 to 66.19	<0.001	25.77	6.67 to 99.59	<0.001
Previous macrosomia (no vs. yes)	2.65	0.29 to 23.99	0.387			
RPG (<88.5 vs. ≥88.5 mg/dL)	3.76	2.26 to 6.25	<0.001	2.99	1.66 to 5.37	<0.001
HbA1c (<5.1% vs. ≥5.1%)	4.39	2.64 to 7.31	<0.001	2.54	1.42 to 4.53	0.002

BMI=body mass index; DM=diabetes mellitus; GDM=gestational diabetes mellitus; RPG=random plasma glucose; HbA1c=hemoglobin A1c; cOR=crude odds ratio; aOR=adjusted odds ratio; CI=confidence interval

Table 3. Combined GDM predictive score

Variable	Cut-off	Adjusted OR	Score
Age (years)	≥35	3.08	2
BMI (kg/m^2)	≥25	1.95	1
Glucosuria	Yes	25.77	13
RPG (mg/dL)	≥88.5	2.99	2
HbA1c (%)	≥5.1	2.54	1

BMI=body mass index; RPG=random plasma glucose; HbA1c=hemoglobin A1c; OR=odds ratio

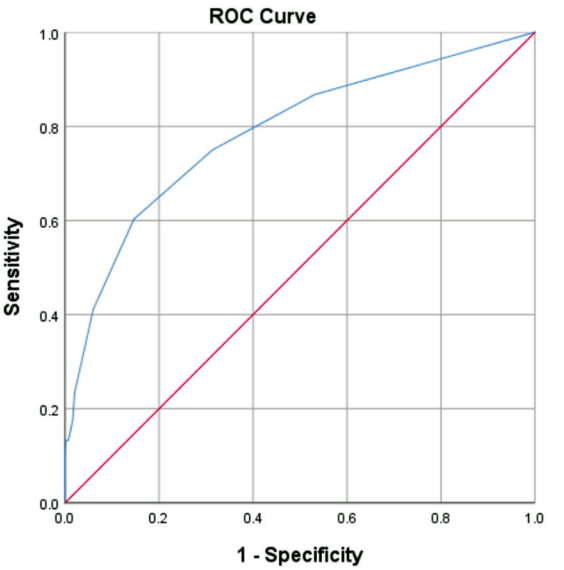

Figure 3. ROC curve of "combined GDM predictive score" to predict GDM.

to be 60.3%, and the specificity was 85.3% (AUC 0.79).

Figure 4 shows the diagnostic performance of the "combined GDM predictive score" comparing between testing in the non-high-risk and the high-risk groups. The AUC was 0.73 and 0.79, respectively. In the non-high-risk group, the specificity rises to 92.4% with a sensitivity of 42.3%. In the high-risk group, the sensitivity was 60.3%, and the specificity was 85.3%, the same as when using this score alone.

Discussion

The prevalence of GDM in the present study was 8.5%, close to the value of 9.0% reported in Ghana[13] but higher than those found in Nigeria[14] and in Rajavithi Hospital in 2021. The NICE guidelines recommend that an RPG of 126 mg/dL or greater can be used as an indication for OGTT[5] while the ADA and ACOG recommended an RPG of 200 mg/dL or greater as the criterion for diagnosis of overt DM[6,8]. There is currently no consensus for the cut-off value of RPG to diagnose GDM. Faith et al. showed that the threshold of 90 mg/dL was the most effective value for screening GDM with a sensitivity of 70% but a low specificity of 38% (AUC 0.6). Although the accuracy of RPG was poor, it was higher than that of glucosuria and HbA1c[13]. Additionally, Meek et al. demonstrated that an RPG cut-off value 135 mg/dL or greater gave the best overall performance with a sensitivity of 69%, a specificity of 89%, and an AUC of 0.81[12]. However, around 30% of cases remained undiagnosed. Therefore, they tried decreasing the threshold to 85 mg/dL. It gave a higher sensitivity of 90% but with a lower specificity. A study by Adefisan et al. showed that the best threshold for screening GDM was an RPG of 97.2 mg/dL or greater, with a sensitivity of 45% and a specificity of 90% (AUC 0.72)(14). The study identified the optimal cut-off for RPG as 88.5 mg/dL, but this value varied significantly from previous research, and the sensitivity and specificity results were low (AUC 0.64). The lack of a universally agreed upon cut-off value for RPG in GDM screening leads to uncertainty

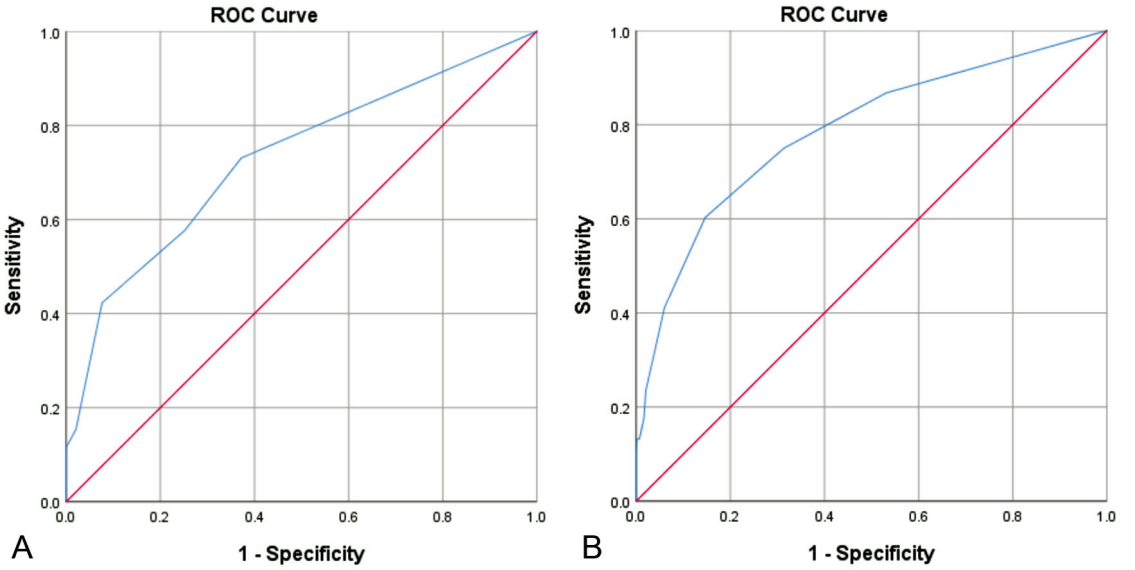

Figure 4. (A) ROC curve of the "combined GDM predictive score" to predict GDM in a non-high-risk group. (B) ROC curve of the "combined GDM predictive score" to predict GDM in a high-risk group.

and limits the external validity of the study. Almost all participants underwent the plasma glucose test along with routine prenatal laboratory tests in the morning. The possibility that participants misunderstood the instructions regarding fasting before RPG testing could have influenced the RPG values, undermining the accuracy of the screening method. In previous studies[12-14], they used a one-step 75-g OGTT as the diagnostic test, in contrast to the present study, which used a two-step approach to diagnose GDM.

A previous study showed that combining the risk factors including age of 30 years or older and BMI of 30 kg/m² or greater, with RPG of 135 mg/dL or greater did not improve the overall accuracy compared with RPG alone, whereas combining age and BMI, RPG and age, or RPG and BMI could improve the sensitivity to 83% to 95% but reduce the overall AUC to 0.6 to 0.78[12]. Another study showed that risk factors such as previous macrosomia, a first-degree relative with diabetic mellitus, and obesity were significantly associated with GDM when analyzed by multiple regression analysis and that combining RPG with these risk factors improved the overall AUC[14]. However, the combination and cut-off values used were different from the combination with the best diagnostic performance as indicated by multivariate analysis in the present study, which combined the age of 35 years or older, BMI of 25 kg/m² or more, and glucosuria. Thus, the "combined GDM predictive score" was created to improve the specificity and AUC, especially in the non-high-risk group.

Both RPG and HbA1c, though tested as screening tools, showed suboptimal diagnostic accuracy, with low sensitivity and specificity values. The reliance on RPG with a sensitivity of 45.6% and specificity of 82.5%, and HbA1c with a sensitivity of 54.4% and specificity of 78.6%, indicate that these tests alone are not sufficiently reliable for early GDM detection. However, the "combined GDM predictive score" is useful, especially in non-high-risk groups, due to its high specificity. It would be useful in clinical practice if performing RPG as part of a routine prenatal laboratory test for non-high-risk pregnant women below 24 weeks of gestation. The results of the present study indicate that it is unlikely that those in this group would develop GDM if they had a "combined GDM predictive score" of less than 3, so universal screening is unnecessary in this group.

The strengths of the present study are that it provides a large sample size, which identifies the accuracy of RPG by using a two-step approach as a gold standard and develops a new score for predicting GDM. This score is easy to use, and the RPG and HbA1c can be performed during the antenatal care visit without special pretest preparation.

The limitations of the present study are that the test was not cost-effective, and more than 10% of the initial participants were lost in the final analysis. Therefore, the study excluded a considerable number of participants due to abortion, fetal anomalies, and a lack of GDM screening results, which may have introduced selection bias.

Conclusion

Although the RPG alone was not a good predictor of GDM, the "combined GDM predictive score" is a useful tool for excluding GDM in non-high-risk pregnant women before 24 weeks of gestation.

What is already known about this topic?

The one- and two-step approaches are widely used to screen for and diagnose GDM, but there are limitations, such as the effects of the last meal, cost, and unpleasantness experienced by pregnant women. The RPG test is simple and easy to perform, but there are currently no appropriate cut-off values for predicting GDM.

What does this study add?

The best threshold of RPG to predict GDM was 88.5 mg/dL, but the sensitivity and specificity were 45.6% and 82.5%, respectively. In addition, the "combined GDM predictive score" that is newly created in this study may be useful to exclude GDM, especially in non-high-risk pregnancies before the gestational age of 24 weeks.

Acknowledgment

The authors would like to thank Assistant Professor Dr. Suphet Tuipae and Assistant Professor Dr. Somboon Sornsukolrat, head and former head of the Department of Obstetrics and Gynecology, for permission to perform the present research, and Rajavithi Hospital for funding.

Conflicts of interest

The authors declare no conflict of interest.

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