

First-Trimester Glycated Hemoglobin (HbA1c) and Maternal Characteristics in the Prediction of Gestational Diabetes Mellitus (GDM): A Prospective Cohort Study

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Objective: To assess the predictive performance of first-trimester HbA1c, both as an individual marker and in combination with clinical risk factors, for subsequent development of GDM.

Methods: A prospective cohort study was conducted at a single tertiary center in Thailand. Singleton pregnant women between 10 and 14 weeks of gestation were consecutively recruited. Women with pregestational diabetes mellitus were excluded. Baseline clinical characteristics were systematically recorded, and blood samples were obtained for HbA1c measurement. GDM was diagnosed at 24–28 weeks of gestation using the standard two-step approach, 100-g OGTT with NDDG thresholds. The predictive performance of HbA1c alone and in combination with clinical risk factors was evaluated using ROC curve analysis.

Results: Among 302 participants, 98 (32.5%) were diagnosed with GDM. Women who developed GDM were of more advanced maternal age and had higher pre-pregnancy BMI and body weight. They also more frequently reported a family history of diabetes mellitus and dyslipidemia. First-trimester HbA1c levels were significantly elevated in the GDM group. HbA1c alone demonstrated modest discriminatory performance (AUC=0.675). Incorporation of HbA1c into a multivariable model with maternal age and BMI improved predictive accuracy (AUC=0.726). At an probability cutoff 0.245, the combined model achieved a sensitivity of 80.6% and a specificity of 51.0%.

Conclusion: First-trimester HbA1c levels are significantly elevated among women who subsequently develop GDM. Although HbA1c alone provides modest discriminatory capacity, integrating HbA1c with maternal age and pre-pregnancy BMI substantially enhances predictive performance. These findings support the application of this straightforward combined model for early pregnancy risk stratification.

Keywords: gestational diabetes mellitus, glycated hemoglobin, HbA1c, prediction

Introduction

Gestational diabetes mellitus (GDM), defined as glucose intolerance first recognized during pregnancy,¹ represents one of the most prevalent obstetric complications. GDM is associated with a spectrum of adverse maternal and perinatal outcomes, including fetal macrosomia, fetal distress, preterm birth, preeclampsia, and an increased long-term risk of type 2 diabetes mellitus and metabolic disorders in both the mother and offspring. Accordingly, early identification and timely intervention are critical to optimizing pregnancy outcomes. Although universal or risk-based screening and diagnosis are conventionally based on an oral glucose tolerance test (OGTT) performed at 24–28 weeks' gestation,² increasing emphasis has been placed on earlier risk stratification to enable closer surveillance and facilitate prompt diagnosis and treatment.³ In this context, numerous studies have explored first-trimester risk assessment strategies to identify women at high risk for GDM who may benefit from targeted screening at 24–28 weeks of gestation, which



remains the standard approach in routine clinical practice in many settings. However, the predictive performance of existing models based solely on maternal clinical characteristics remains suboptimal, highlighting the need for more accurate and reliable predictive markers.

Glycated hemoglobin (HbA1c) has emerged as a potential biomarker for the early prediction of GDM. As an indicator of mean glycemic exposure over the preceding 2–3 months, HbA1c offers several practical advantages, including the absence of a fasting requirement, high sample stability, and widespread availability in routine clinical practice.⁴ Although an HbA1c threshold $\geq 6.5\%$ is diagnostic of overt diabetes mellitus, the clinical utility of lower first-trimester cutoffs for predicting subsequent GDM remains controversial.^{5–7} This uncertainty is partly attributable to physiological alterations in red blood cell turnover during pregnancy, which may influence HbA1c levels. Nevertheless, accumulating evidence indicates that women who subsequently develop GDM demonstrate significantly higher HbA1c levels as early as 8–13 weeks of gestation compared with those who maintain normal glucose tolerance. Reported predictive performance, however, has varied considerably across studies. Such heterogeneity may reflect differences in gestational age at testing, study design, and population characteristics, particularly ethnicity, which substantially influences GDM prevalence and metabolic expression. For instance, the prevalence of GDM in the Thai population has been reported to be as high as 33%,⁸ markedly exceeding the 8–10% observed in Caucasian populations.¹ Moreover, relatively few studies have evaluated the predictive performance of first-trimester HbA1c in combination with maternal clinical characteristics.⁹ Some investigations have included women assessed before 10 weeks of gestation, a period during which physiological insulin resistance is not yet pronounced, potentially limiting predictive sensitivity. We therefore hypothesized that HbA1c measured at 10–14 weeks of gestation could provide a clinically useful approach for stratifying women into high- and low-risk groups for development of GDM. The objective of this study was to develop the predictive performance of first-trimester HbA1c, both as an independent biomarker and in combination with clinical risk factors, for the prediction of GDM later in pregnancy.

Materials and Methods

This prospective cohort study was conducted at the antenatal care clinic of Chiang Mai University Hospital, a tertiary referral center, between February and December 2025. The study protocol was approved by the Institutional Review Board, Faculty of Medicine, Chiang Mai University (Research Ethics Committee Panel 5; study code OBG-2567-0726). All eligible women were invited to participate and provided written informed consent prior to enrollment after receiving comprehensive information regarding the study objectives and procedures.

Participants were consecutively recruited from the antenatal clinic. The inclusion criteria were as follows: (1) singleton pregnancy confirmed by first-trimester ultrasonography; (2) maternal age 20–45 years; (3) gestational age between 10 and 14 weeks, determined by a reliable last menstrual period consistent with first-trimester crown-rump length measurement; and (4) willingness to comply with all study procedures, including blood sampling, standard two-step GDM screening, and scheduled follow-up assessments.

Exclusion criteria comprised: (1) pre-existing diabetes mellitus diagnosed prior to pregnancy; (2) HbA1c $\geq 6.5\%$ at enrollment; (3) current use of medications known to influence glucose metabolism; and (4) loss to follow-up or failure to complete the 24–28-week GDM screening protocol.

At the enrollment visit, trained research personnel conducted standardized interviews using structured case report forms to obtain detailed demographic, obstetric, and medical history data. Collected variables included maternal age, pre-pregnancy weight and body mass index (BMI), and parity. Information regarding a first-degree family history of diabetes mellitus (DM) and history of GDM was also documented. Additionally, underlying medical disorders, including chronic hypertension and dyslipidemia, were recorded.

Laboratory Analysis

Venous blood samples for HbA1c measurement were collected from all participants at 10–14 weeks of gestation. HbA1c concentrations were determined quantitatively using the Tina-quant[®] Hemoglobin A1cDx Gen.3 assay on a Cobas c 503 analyzer. This test employs a Turbidimetric Inhibition Immunoassay (TINIA) applied to hemolyzed whole blood. The assay is standardized according to the International Federation of Clinical Chemistry (IFCC) and is transferable to the

National Glycated Hemoglobin Standard Program (NGSP) units. HbA1c values were expressed as percentage (%) according to NGSP standards using the conversion equation: $\text{NGSP \%} = 0.915 \times \text{IFCC (mmol/mol)} \pm 2.15$.^{10,11}

Between 24 and 28 weeks of gestation, all participants underwent standard two-step screening for GDM. Initially, a 50-g oral glucose challenge test was performed irrespective of fasting status. A 1-hour plasma glucose level <140 mg/dL was considered normal, whereas a value ≥ 140 mg/dL prompted a diagnostic 100-g oral glucose tolerance test (OGTT) within one week. The OGTT, involving measuring plasma glucose levels at fasting and at 1, 2, and 3 hours after glucose ingestion. The corresponding diagnostic thresholds were ≥ 105 mg/dL (fasting), ≥ 190 mg/dL (1 hour), ≥ 165 mg/dL (2 hours), and ≥ 145 mg/dL (3 hours), following the National Diabetic Data Group criteria. GDM was diagnosed when at least two values met or exceeded these cut-off levels. If only one value was abnormal, the 100-g OGTT was repeated one month later using the same diagnostic criteria. Based on these results, participants were categorized into either the GDM or non-GDM group. Additional screening beyond 28 weeks of gestation was undertaken when clinically indicated, such as in cases of persistent glucosuria on dipstick testing or excessive gestational weight gain relative to pre-pregnancy BMI. Screening and diagnostic decisions were made by attending physicians in the antenatal clinic. Women diagnosed with GDM at any time during pregnancy were assigned to the GDM group. All participants were subsequently followed longitudinally by the research team.

To adequately address the primary outcome, this study required a minimum sample size of 47 cases in the affected group and 118 cases in the unaffected group to detect an AUC of 0.64, compared to an AUC of 0.50 under the null hypothesis, using a one-sided test with 80% power at a 95% confidence level, assuming an affected-to-unaffected case ratio of 30:70.

Statistical analyses were conducted using the Statistical Package for the Social Sciences (SPSS), version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were presented as mean \pm standard deviation (SD) or median with interquartile range (IQR), as appropriate according to data distribution. Comparisons of baseline characteristics between the GDM and non-GDM groups were performed using the Student's *t*-test or Mann–Whitney *U*-test for continuous variables, as appropriate, and the chi-square test for categorical variables. The discriminatory ability of individual risk factors and the combined model was assessed using binary logistic regression and the area under the receiver operating characteristic curve (AUC). For the development of a novel predictive model for GDM, HbA1c and relevant clinical risk factors were initially entered into a multivariable logistic regression model, and multicollinearity was assessed using variance inflation factor diagnostics. Backward elimination, guided by the principle of parsimony, was subsequently applied to derive the most concise model by sequentially removing the variable with the highest *p*-value at each step, provided that model performance was not adversely affected. Model performance was compared using paired-sample receiver operating characteristic (ROC) curve analysis based on the method of DeLong et al, together with log-likelihood evaluation. Internal validation was performed using bootstrap resampling with 500 replications, and calibration plots were constructed to assess agreement between predicted probabilities and observed outcomes. Diagnostic performance was further evaluated by calculating sensitivity, specificity, positive predictive value, and negative predictive value, using the probability cut-off based on fixed sensitivity of 80%. A two-sided *p*-value < 0.05 was considered statistically significant.

Results

During the study period, 324 women attended the antenatal care clinic and were initially enrolled, as illustrated in Figure 1. Of these, 302 met the inclusion criteria and were included in the final analysis. Ninety-eight participants (32.5%) were diagnosed with GDM at 24–28 weeks of gestation. Baseline characteristics differed significantly between women who developed GDM and those who did not (Table 1). In particular, pre-pregnancy weight and pre-pregnancy BMI were significantly higher in the GDM group. Maternal age was also significantly greater among women who developed GDM ($p < 0.001$). Additionally, a family history of DM and dyslipidemia were more frequently observed in the GDM group.

First-trimester HbA1c levels were significantly higher in women who subsequently developed GDM compared with those who did not, as presented in Table 1. The mean of HbA1c level in the GDM group was $5.38 \pm 0.40\%$, compared with $5.12 \pm 0.33\%$ in the non-GDM group, as presented in Figure 2.

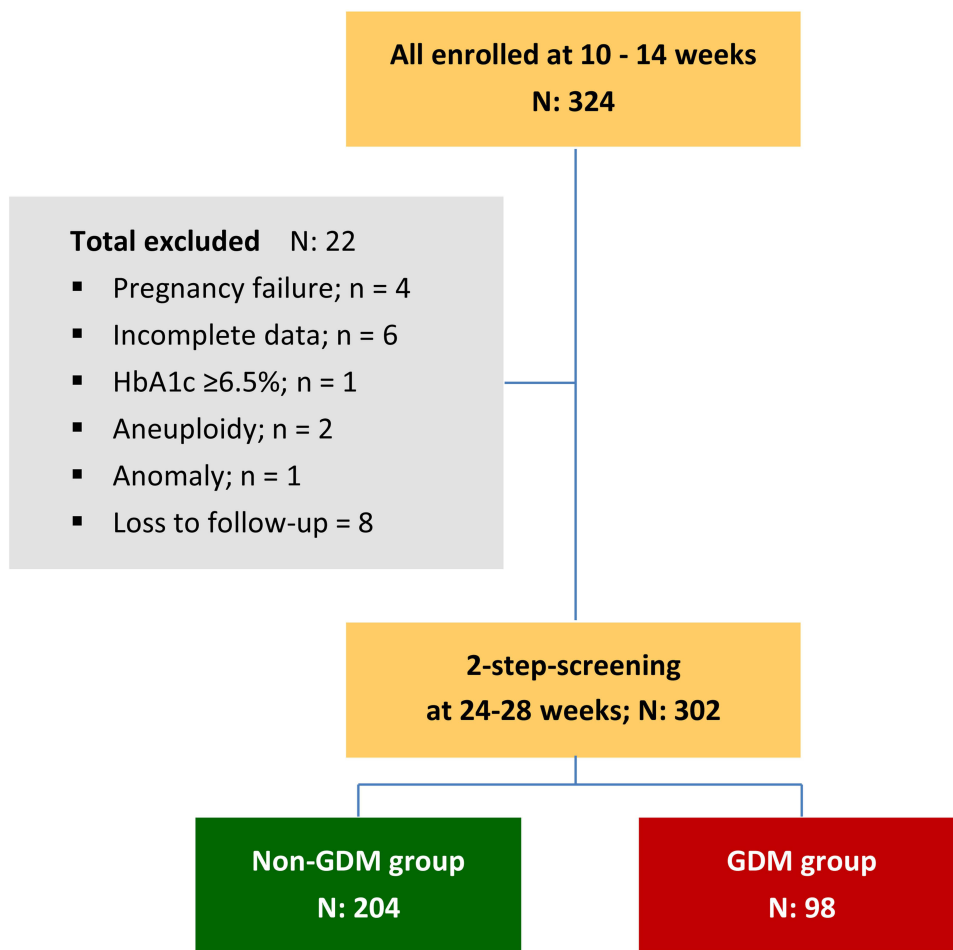


Figure 1 Flow chart of the study protocol. GDM: gestational diabetes mellitus.

Multivariate logistic regression analysis was performed to develop a predictive model for GDM, with initial inclusion of potential risk factors, including HbA1c level, maternal age, pre-pregnancy BMI, family history of diabetes mellitus, and a history of dyslipidemia. The most parsimonious model retained only HbA1c level, maternal age, and pre-pregnancy

Table 1 Characteristics of GDM and Non-GDM Group

Variables	Non-GDM; N: 204	GDM Group N: 98	P value
Age (year)	30.7±4.9	33.1±4.4	< 0.001
Pre-pregnancy BMI	23.0±4.3	24.9±4.9	< 0.001
Pre-pregnancy weight (kg)	57.7±12.5	61.9±13.4	0.007
Family history of DM	23 (11.3%)	23 (23.5%)	0.006
Chronic hypertension	2 (1.0%)	3 (3.1%)	0.185
Dyslipidemia	0 (0.0%)	4 (4.1%)	0.004
Parity			0.868
Nulliparous	129 (63.2%)	61 (62.9%)	
Parous	75 (36.8%)	37 (37.8%)	

(Continued)

Table 1 (Continued).

Variables	Non-GDM; N: 204	GDM Group N: 98	P value
Gestational age at recruitment	12.3±0.9	12.3±1.0	0.590
Gestational age at GDM screening	24.8±1.9	24.8±1.4	0.905
HbA1c level (%), mean±SD	5.12±0.33	5.38±0.40	< 0.001
HbA1c level (%), median (IQR)	5.16 (4.96–5.35)	5.36 (5.06–5.42)	< 0.001#

Note: # Mann–Whitney-U test.

Abbreviations: GDM, gestational diabetes mellitus; BMI, body mass index; DM, diabetes mellitus; HbA1c, glycated hemoglobin; SD, standard deviation; IQR, interquartile range.

BMI, as presented in Table 2. This model yielded an area under the receiver operating characteristic (ROC) curve of 0.726 (95% CI: 0.665 to 0.787). The area under the curve of the model incorporating HbA1c was significantly greater than that of the model without HbA1c ($p = 0.035$). The areas under the ROC curves for individual risk factors and for the predictive model are presented in Table 3 and Figure 3.

Internal validation of the predictive model for subsequent development of GDM, assessed using bootstrap resampling with 500 repetitions, demonstrated good calibration (slope: 0.968, AUC: 0.718, optimism: 0.008), as illustrated by the calibration plot in Figure 4. Using a probability cut-off of 0.245, the predictive model demonstrated moderate discriminative performance, with a sensitivity of 80.6% and a specificity of 51.0%, as well as high negative predictive value of 84.6%, as shown in Table 4.

Discussion

Insights gained from this study are as follows: 1) First trimester HbA1c had modest performance in predicting GDM. 2) The combination of HbA1c levels and clinical characteristics could substantially improve the performance in predicting GDM.

First-trimester HbA1c levels were significantly higher among women who subsequently developed GDM compared with those who did not (5.38% vs. 5.12%, $p < 0.001$), consistent with findings from previous studies conducted in diverse populations.^{6,7,9,12,13} Comparable mean HbA1c values between GDM and non-GDM groups have been reported in Chinese (5.23% vs. 5.06%),⁷ Turkish (5.31% vs. 5.01%),¹³ Asian Indian (5.04% vs. 4.90%),⁶ and Swiss cohorts (5.26%

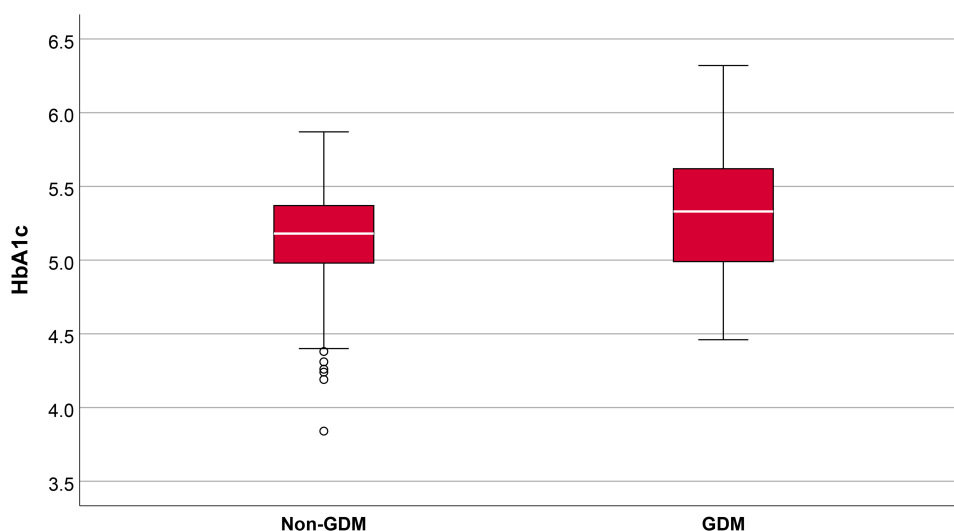


Figure 2 Boxplots for comparison of the levels of Hb A1c (%) between the two groups (GDM, gestational diabetes mellitus; HbA1c, glycated hemoglobin).

Table 2 Predictive Logistic Regression Parsimonious Model of First-Trimester Risk Factors for GDM

Risk Factors	Coefficient	Standard Error	z	P-value	95% CI
HbA1c level	1.823	0.414	4.400	< 0.001	1.010 to 2.635
Maternal age	0.097	0.030	3.290	0.001	0.039 to 0.155
Pre-pregnancy BMI	0.070	0.029	2.420	0.005	0.013 to 0.127
Constant	-15.085	2.406	-6.270	< 0.001	-19.800 to -10.369

Abbreviations: GDM, gestational diabetes mellitus; HbA1c, glycated hemoglobin; BMI, body mass index; CI, confidence interval.

Table 3 Areas Under the ROC Curves of Individual First-Trimester Risk Factors and the Predictive Model for Gestational Diabetes Mellitus

Risk Factors	Areas Under the ROC Curve	95% CI
Hb A1c	0.675	0.605 to 0.743
Maternal age	0.624	0.558 to 0.690
Pre-pregnancy BMI	0.617	0.550 to 0.685
Family history of DM	0.561	0.513 to 0.608
Dyslipidemia	0.500	0.500 to 0.500
The predictive model	0.726	0.665 to 0.787

Abbreviations: ROC, receiver operating characteristic; GDM, gestational diabetes mellitus; CI, confidence interval; HbA1c, glycated hemoglobin; BMI, body mass index; DM, diabetes mellitus.

vs. 5.10%).⁹ Despite the statistically significant difference observed, the discriminatory performance of HbA1c alone in our cohort was modest (AUC = 0.675). This performance was slightly superior to that reported in Asian Indian, Swiss, and Chinese populations (AUC range, 0.563–0.62),^{6,9,14} yet lower than the substantially higher accuracy described in Turkish and Iranian cohorts (AUC approximately 0.84).^{15,16} Such variability may be attributable to ethnic differences in baseline HbA1c distributions, as well as heterogeneity in diagnostic or inclusion criteria and study methodologies across populations. For example, some studies did not exclude cases with HbA1c levels greater than 6.5%,^{7,16} whereas others,¹⁵ including our study, applied this exclusion criterion. This may have narrowed the discriminatory range of HbA1c values and consequently contributed to the lower AUC observed.

Although HbA1c demonstrates statistical significance, it generally lacks adequate sensitivity to serve as a standalone screening or diagnostic test for GDM.^{7,14} While the application of higher HbA1c thresholds, such as values exceeding 5.9%, may improve specificity, sensitivity remains suboptimal, thereby increasing the likelihood of missed diagnoses when HbA1c is used in isolation.^{6,7} In contrast to most previous studies, our study evaluated HbA1c in combination with established clinical risk factors. This integrated approach significantly enhanced screening performance compared with HbA1c alone. From a practical standpoint, incorporating readily available clinical characteristics into risk assessment represents a pragmatic and cost-effective strategy, as these variables can be obtained without additional procedures, resources, or financial burden.

Notably, HbA1c appears to be more appropriately applied as a tool for early risk stratification rather than as a replacement for the OGTT.¹⁷ The proposed simplified model was able to identify approximately 80% of women who subsequently developed GDM within the Thai population. However, the false-positive rate was relatively high, which may increase the clinical workload associated with GDM screening, particularly in settings where universal screening is not routinely implemented. Importantly, elevated first-trimester HbA1c levels have been associated with adverse pregnancy outcomes, including fetal macrosomia, independent of a formal GDM diagnosis. This observation

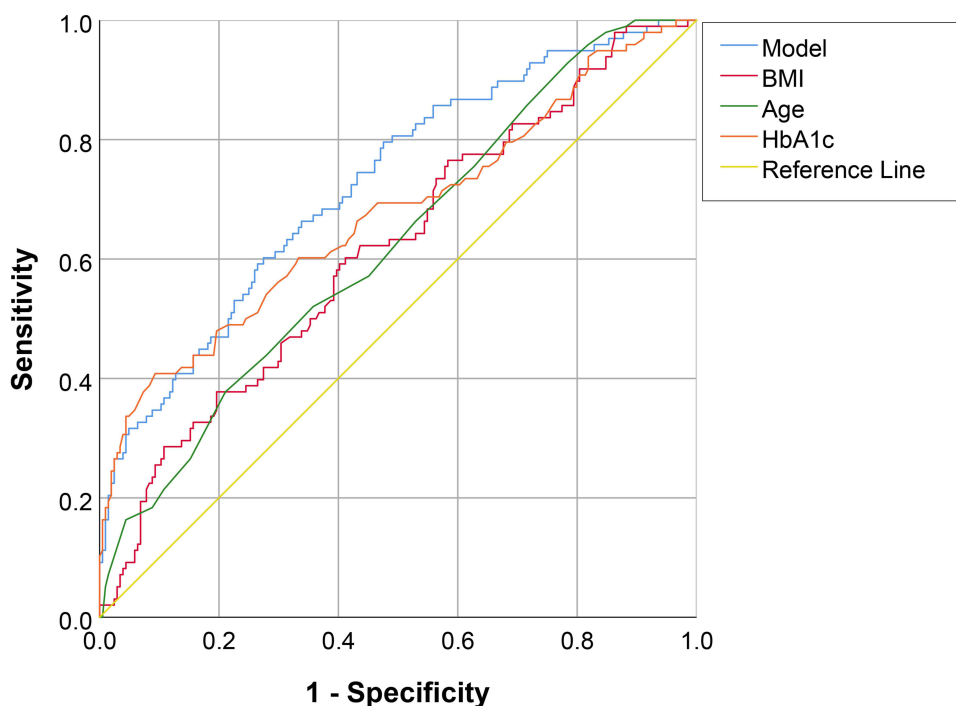


Figure 3 ROC curves for individual biomarkers and combined models in predicting GDM.
Abbreviations: ROC, receiver operating characteristic; GDM, gestational diabetes mellitus; BMI, body mass index; HbA1c, glycated hemoglobin.

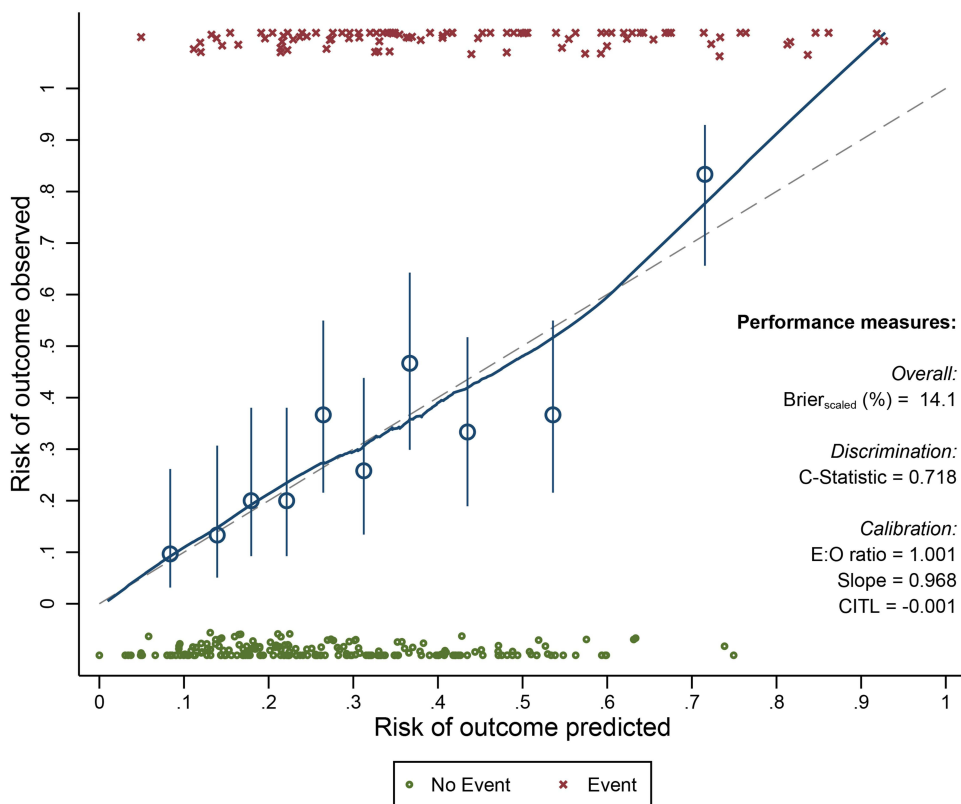


Figure 4 Calibration plot of the predictive model in predicting subsequent gestational diabetes mellitus.

Table 4 Diagnostic Performance of the Predictive Model to Predict the Development of GDM in Late Pregnancy (a Probability Cut-off of 0.245)

Diagnostic Indices	Percent	95% Confidence Interval
Prevalence	32.5%	27.2% to 38.0%
Sensitivity	80.6%	71.4% to 87.9%
Specificity	51.0%	43.9% to 58.0%
Positive predictive value	44.1%	36.7% to 51.7%
Negative predictive value	84.6%	76.9% to 90.4%

suggests that the clinical relevance of HbA1c may extend beyond the prediction of glucose intolerance alone, potentially reflecting broader metabolic risk during pregnancy.^{5,18,19}

In clinical practice, where HbA1c is routinely used to exclude overt diabetes mellitus at the first visit, this model may help raise clinicians' awareness and facilitate stratification of women into low- and high-risk groups for the subsequent development of GDM. However, for this purpose, HbA1c should be used in conjunction with clinical risk factors rather than used as a standalone predictor.

Research Implication

Although HbA1c may be useful for risk stratification in the first trimester, its predictive performance remains suboptimal. Therefore, additional biomarkers or clinical predictors that could enhance the diagnostic accuracy of HbA1c for early GDM screening warrant further investigation.

Strengths and Limitations

This study has several notable strengths. Its prospective design and consecutive recruitment strategy enhance methodological rigor and minimize selection bias. Additionally, the relatively adequate sample size and the homogeneity of the study population contribute to the internal validity and reliability of the findings, which was confirmed by the calibration plots. Nevertheless, certain limitations should be acknowledged. The sample size may have been insufficient to adequately evaluate less prevalent risk factors, such as dyslipidemia or a family history of DM, thereby limiting the statistical power to detect incremental benefits when incorporating these variables into the predictive model. Furthermore, the single-center design and exclusive inclusion of a Thai population may restrict the generalizability of the findings. Finally, other subtle conditions that may have confounded HbA1c levels, such as hemoglobinopathies and iron deficiency, were not evaluated in the present study.

Conclusions

First-trimester HbA1c levels are significantly elevated among women who subsequently develop GDM. Although HbA1c alone provides modest discriminatory capacity, integrating HbA1c with maternal age and pre-pregnancy BMI substantially enhances predictive performance. These findings support the application of this straightforward combined model for early pregnancy risk stratification, facilitating the identification of women at increased risk and enabling closer surveillance and timely intervention. Nonetheless, its predictive performance remains suboptimal. Therefore, further investigation into additional clinical predictors or novel biomarkers with stronger predictive capability is warranted to enhance the diagnostic accuracy of HbA1c for early screening of GDM.

Institutional Review Board Statement

The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by Research Ethics Committee 5, Faculty of Medicine, Chiang Mai University (Research Ethics Committee Panel 5; Research ID: OBG-2567-0726; date of approval: 06 January 2025).

Data Sharing Statement

The datasets analyzed during the current study are available from the corresponding author (TT) upon reasonable request.

Informed Consent Statement

Written informed consent was obtained from all participants.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare no conflicts of interest in this work.

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