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Utilizing Continuous Glucose Monitoring for Early Detection of Gestational Diabetes Mellitus and Pregnancy Outcomes in an Asian Population

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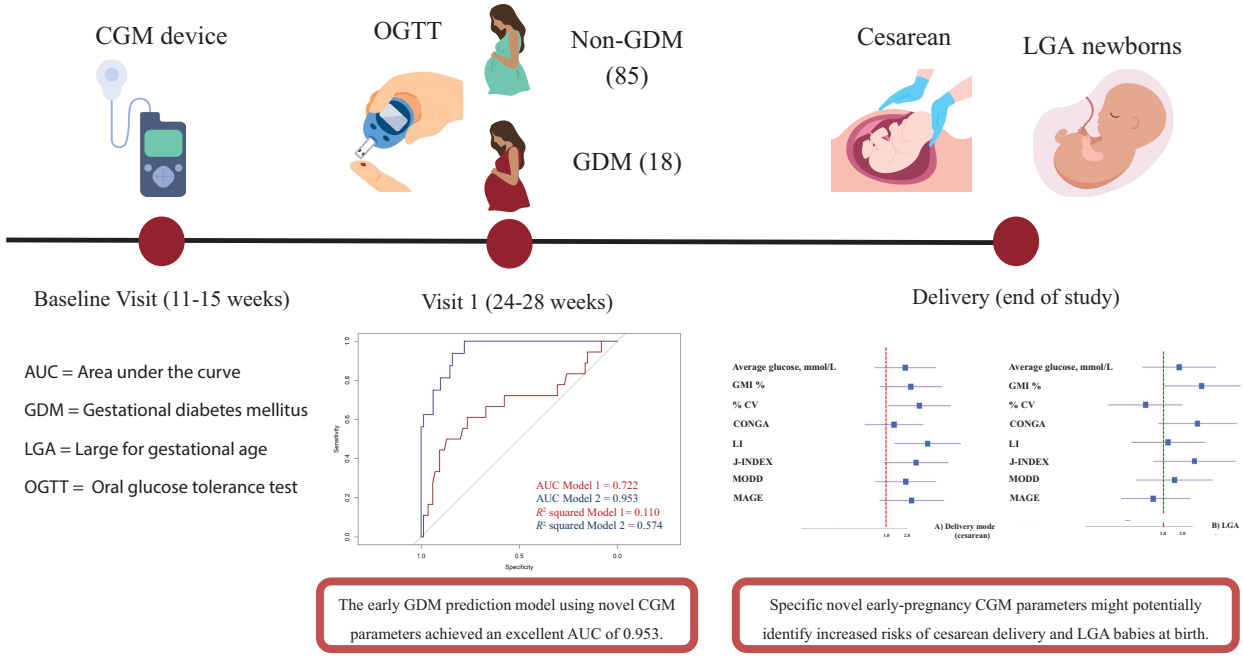

ARTICLE HIGHLIGHTS

- **Why did we undertake this study?**
  To assess the value of continuous glucose monitoring (CGM) as an alternative to the oral glucose tolerance test in defining gestational diabetes mellitus.

- **What is the specific question we wanted to answer?**
  Can CGM detect gestational diabetes mellitus and adverse pregnancy outcomes in the first trimester?

- **What did we find?**
  The CGM prediction model (percent glucose variability, continuous overlapping net glycemic action, glucose management index percent, mean amplitude of glycemic excursions) demonstrated superior sensitivity, specificity, area under the curve, and R^2 compared with the traditional risk model (maternal age, ethnicity, baseline BMI, and systolic blood pressure). Novel CGM parameters could also potentially predict primary cesarean and large-for-gestational age babies.

- **What are the implications of our findings?**
  CGM has potential clinical utility in predicting gestational diabetes mellitus and adverse pregnancy outcomes in the first trimester, particularly in the Asian individuals with overweight or obesity.

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BRIEF REPORT

OBJECTIVE

We explored the potential value of continuous glucose monitoring (CGM) in early pregnancy in predicting gestational diabetes mellitus (GDM) and pregnancy outcomes.

RESEARCH DESIGN AND METHODS

The study recruited 103 multiethnic Asian pregnant women with overweight or obesity from a hospital-based, prospective cohort. All of them had worn blinded CGM devices in early pregnancy and underwent the universal GDM screening at 24–28 gestation weeks. Models were selected based on early pregnancy risk factors and CGM-derived parameters to compare their respective predictive values for GDM and pregnancy outcomes.

RESULTS

Eighteen GDM cases were ascertained. CGM-derived novel parameters demonstrated greater performance (e.g., area under the curve: 0.953 vs. 0.722) for predicting incident GDM compared with the model using traditional risks. Such novel CGM-derived parameters significantly differentiated primary cesarean and large-for-gestational age babies.

CONCLUSIONS

Our data suggest CGM's potential clinical utility in the first trimester for predicting GDM and adverse pregnancy outcomes, particularly in individuals with overweight or obesity.

Diabetes in pregnancy is on an alarming rise, with approximately one in six live births affected by hyperglycemia, of which 84% are diagnosed as gestational diabetes mellitus (GDM) (1). Although the oral glucose tolerance test (OGTT) has been the mainstay for diagnosing GDM for decades, its validity as the gold standard test has come into question in recent years, due to a lack of universally standardized OGTT procedural methods and diagnostic thresholds (2) and early fetal hyperinsulinemia preceding GDM universal screening (3). In the past few years, continuous glucose monitoring (CGM) has extended its clinical application from managing diabetes in general to encompassing monitoring diabetes during pregnancy. However,

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evidence using CGM for early prediction of GDM remains limited, particularly in the context of the Asian population. Therefore, we aimed to investigate the early GDM prediction potential of CGM in the first trimester in a prospective cohort among multiethnic Asian pregnant women with overweight or obesity in Singapore.

RESEARCH DESIGN AND METHODS

Study Design

Participants were recruited from an ongoing hospital-based, prospective cohort, Studying the Heterogeneity of Gestational Diabetes Mellitus: Cardio-Metabolic Alteration and Treatment Response in a Multi-Ethnic Population in Singapore (GDM-CARE) beginning in October 2022. We recruited Chinese, Malay, or Indian women with a singleton pregnancy who were overweight (BMI 23 kg/m^2–24.9 kg/m^2) or obese (BMI $\geq$25.0 kg/m^2), aged 21–45 years, planning for delivery in National University Hospital, willing to wear CGM devices for at least 7 days at each research visit, and without preexisting type 1 diabetes or type 2 diabetes as well as chronic preexisting conditions such as cancer or kidney dysfunction. All participants were recruited during early pregnancy (11–13 weeks of gestation), and then followed up subsequently at middle pregnancy (24–28 weeks of gestation) and late pregnancy (34–36 weeks of gestation). The study was conducted according to the guidelines under the Declaration of Helsinki and approved by the National Healthcare Group (NHG) Domain Specific Review Boards (DSRB; Singapore, Singapore; 2021/01076). At the point of analysis, we screened 1,217 pregnant women and enrolled 221 eligible participants, 103 of which had successfully delivered with all required study examinations performed.

Exposure—CGM Parameters

All participants were administered a FreeStyle Libre Pro CGM device (Abbott Diabetes Care, Wiesbaden, Germany) on the upper left arm, according to the standard protocol (4). The sensors were factory calibrated and did not require further calibration during the research application. Each CGM device was valid for 14 days, and all glucose data were automatically captured every 15 min and stored. All glycemic profile data were blinded to both participants and research coordinators during the 14 days of wearing and were later deidentified and uploaded onto a secure, cloud-based diabetes management system (LibreView). In addition to the original glycemic parameters generated from LibreView, the glycemic reports in Microsoft Excel format were further imported into EasyGV software to assess glycemic variability parameters. All CGM-derived parameters are shown in details in Supplementary Table 1 (5).

Primary Outcome—Diagnosis of GDM

Current guidelines by International Association of the Diabetes and Pregnancy Study Groups (IADPSG) recommend universal screening for GDM among pregnant women during 15–30 weeks of gestation using a 2-h 75-g 3-point OGTT (6). These guidelines define GDM based on any abnormal reading of fasting glucose concentration at $\geq$5.1 mmol/L, 1-h glucose concentration at $\geq$10 mmol/L, and/or 2-h glucose concentration at $\geq$8.5 mmol/L (6).

Secondary Outcomes—Adverse Pregnancy Outcomes

Maternal outcomes included delivery mode (including primary cesarean section, secondary cesarean section, or vaginal birth) and pregnancy complications, such as hypertensive disorders, during pregnancy (7). Fetal and neonatal outcomes included gestational age (GA) at delivery, preterm birth ($<$37 weeks), birth weight, small-for-GA (8), large-for-GA (LGA) (8), and Apgar scores ($<$7 vs. $\geq$7) at 1 min and 5 min.

Covariates

During recruitment, trained research coordinators conducted in-person interviews and measured the participant's weight, height, and blood pressure at the study clinic. Covariates collected via questionnaires at study entry included sociodemographic factors, health history, menstrual characteristics, and lifestyle behaviors.

Statistical Analysis

Student *t* test, Mann-Whitney *U* test, χ^2 test, and Fisher exact test were applied to assess observed differences in maternal characteristics, pregnancy outcomes, and CGM parameters at early pregnancy between GDM and non-GDM participants. For our primary aim, we chose the most parsimonious model as an early prediction model for GDM based on forward stepwise regression model selection regarding two sets of variables, namely conventional risk factors collected in our cohort and novel parameters derived from CGM glycemic profile. To compare the performance of the early GDM prediction model using traditional variables (model 1) and novel CGM-derived parameters (model 2) collected between 11 and 15 weeks of gestation, we performed the receiver operating characteristic curve to calculate the area under the curve (AUC) value for GDM diagnosed by IADPSG criteria. For our secondary aim, we investigated the associations between the centiles of each CGM parameter and all available pregnancy outcomes. Modified Poisson regression was applied to assess the associations between CGM novel parameters, GDM diagnosis (yes vs. no), and pregnancy adverse outcomes, both in the unadjusted and adjusted models, with variables identified in model 1.

We performed multiple imputations (n = 50) for all analyses to address the issue of missingness in our cohort using Rubin rules (9). All analyses were performed using R 4.2.1 software (R Studio, Boston, MA). The effect sizes were reported as estimates (β), odds ratio (OR), or adjusted relative risk (aRR) with a 95% CI or *P* value. We defined significance as a two-tailed *P* value of 0.05.

RESULTS

The incidence rate of GDM in our pilot data was 17.5% (18 of 103). Maternal characteristics collected in this cohort at baseline—such as maternal age, BMI, systolic blood pressure (SBP), ethnicity, education, nulliparous, family history of diabetes, and history of GDM—did not seem to differ significantly between women with and without GDM diagnosis (Table 1). Most CGM parameters assessed between 11 and 15 weeks of gestation showed significantly greater values in mothers diagnosed with GDM than those without (Supplementary Table 2).

Using stepwise forward logistical regression model selection based on two separate pools of factors (maternal characteristics vs. CGM parameters), we identified the most parsimonious GDM prediction models. These are represented as model 1, comprising maternal age, ethnicity, BMI, and SBP at study entry, and model 2,

Table 1—Maternal characteristics at study entry and pregnancy outcomes at delivery in the GDM-CARE study, categorized by GDM diagnosis at 24–28 weeks of gestation

	All (N = 103)	GDM (n = 18)	Non-GDM (n = 85)	P value*
Maternal characteristics at study entry (11–13 weeks of gestation)				
Maternal age, mean (SD) years	30.8 (4.05)	31.8 (4.02)	30.6 (4.05)	0.29
Education				
College degree and above	52 (50.5)	9 (50.0)	43 (50.6)	0.99
Ethnicity				
Chinese	33 (32.0)	6 (33.3)	27 (31.8)	0.80
Indian	6 (5.8)	0 (0)	6 (7.1)	
Malay	63 (61.2)	12 (66.7)	51 (60.0)	
Others	1 (1.0)	0 (0)	1 (1.2)	
BMI, mean (SD) kg/m^2	27.6 (3.62)	28.6 (4.27)	27.3 (3.46)	0.24
SBP, mean (SD) mmHg	119 (10.7)	124 (13.6)	118 (9.74)	0.07
GA while wearing CGM, mean (SD) weeks	12.2 (1.43)	12.4 (1.85)	12.2 (1.33)	0.61
Days of data available, mean (SD)	12.7 (3.32)	12.8 (4.14)	12.7 (3.15)	0.95
Nulliparous	45 (43.7)	6 (33.3)	39 (45.9)	0.45
Past history of GDM	3 (2.9)	1 (5.6)	2 (2.4)	0.86
Family history of diabetes	24 (23.1)	6 (33.3)	18 (20.9)	0.46
Pregnancy outcomes at delivery				
GA at delivery, mean (SD) weeks	38.4 (1.51)	37.9 (2.03)	38.5 (1.37)	0.22
Preterm (<37 weeks)	5 (4.9)	2 (11.1)	3 (3.5)	0.45
Delivery mode				
Cesarean	27 (26.2)	5 (27.8)	22 (25.9)	0.99
Primary cesarean	16 (15.5)	3 (16.7)	13 (15.7)	0.99
Birth weight, mean (SD) g	3,130 (432)	3,100 (464)	3,140 (428)	0.78
Small for gestational age	4 (3.9)	0 (0)	4 (4.7)	0.99
Large for gestational age	12 (11.7)	2 (11.1)	10 (11.8)	0.99
Hypertensive disorders during pregnancy	8 (7.8)	2 (11.1)	6 (7.1)	0.63
APGAR scores 1 min <7	2 (1.9)	1 (5.6)	1 (1.2)	0.32
APGAR scores 5 min <7	0 (0)	0 (0)	0 (0)	0.99

Data are presented as n (%) unless indicated otherwise. AGPAR score, appearance, pulse, grimace, activity, and respiration; SMA, smaller than GA. *Student t test, χ^2 test, or Fisher exact test, whichever is applicable.

comprising %CV (glucose variability %), GMI% (glucose management index), CONGA (continuous overlapping net glycemic action), and MAGE (mean amplitude of glycemic excursions), all assessed at 11–15 weeks of gestation. Model 2 outperformed model 1 across various metrics, exhibiting higher sensitivity (1.000 vs. 0.812), specificity (0.780 vs. 0.667), and significantly enhanced the predictive value for GDM diagnosis from poor to excellent (AUC 0.953 vs. 0.722; R^2 0.574 vs. 0.110; $P < 0.001$) (Table 2 and Fig. 1).

After adjusting for model 1 variables, including maternal age, ethnicity, BMI, and SBP at baseline, CGM parameters assessed during early pregnancy showed significantly heightened risks of GDM development in the second trimester. For instance, as shown in Table 3, per SD increment in the aforementioned CGM parameters, assessed between 11 and 15 weeks of gestation, were associated with twofold risks in GDM diagnosis between 24 and 28 weeks of gestation (%CV: aRR 1.99, 95% CI 1.23, 3.22; MAGE: aRR 1.64, 95% CI 1.25, 2.15; GMI%: aRR 1.56, 95% CI 1.28, 1.91; and CONGA: aRR 1.47, 95% CI 1.17, 1.85, respectively). All of these associations remained significant

Table 2—Stepwise model selection for GDM prediction model

Models	Variables	Sensitivity	Specificity	PPV	NPV	AUC (95% CI)	R^2	P value
Model 1	Maternal age, ethnicity, BMI at baseline, SBP at baseline	0.812	0.667	0.429	0.92	0.722 (0.580, 0.865)	0.11	Ref
Model 2	% CV, CONGA, GMI%, MAGE	1.000	0.780	0.471	1.000	0.953 (0.911, 0.995)	0.574	*<0.001*

The P value is statistically significant ($P < 0.05$). NPV, negative predictive value; PPV, positive predictive value.

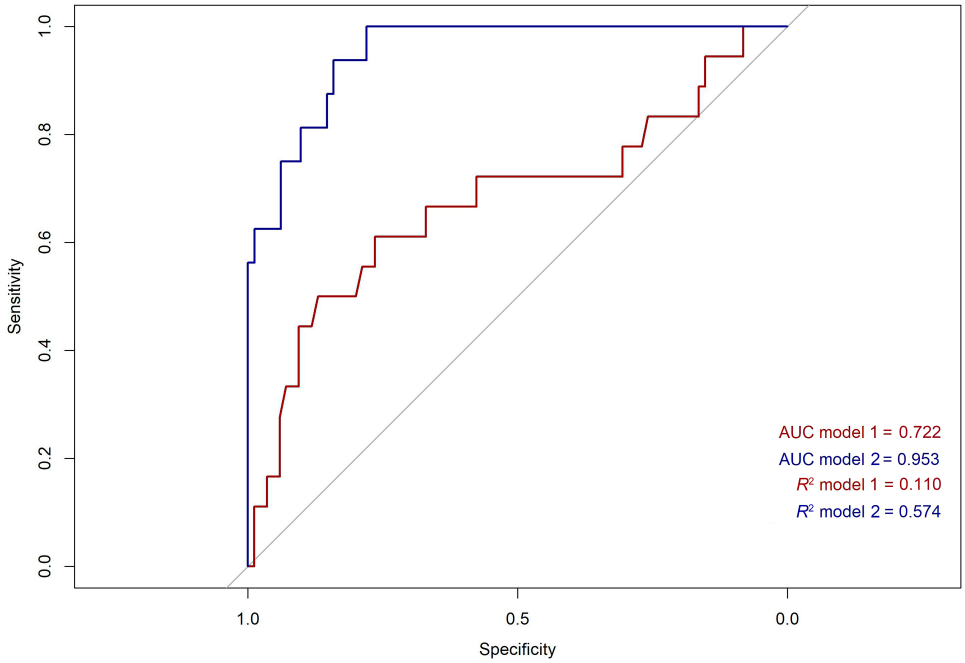

Figure 1—Receiver operating characteristic curve admissions of traditional risk factor model and novel CGM-derived parameters model on GDM early prediction. The red line represents traditional risk factor model (model 1) with R^2 = 0.110 and AUC = 0.722. The blue line represents novel CGM model (model 2) with R^2 = 0.574, AUC = 0.953.

after false-discovery rate correction (Table 3 and Supplementary Fig. 1).

After early trimester CGM parameters were categorized into centiles, our pilot data showed that the upper centiles of %CV (aRR 2.18; 95% CI 1.02, 4.62) and lability index (aRR 2.63; 95% CI 1.16, 5.97) were positively associated with a twofold increase in the risk of cesarean delivery (*n* = 27), and GMI% was further associated with a threefold increase in the risk (aRR 3.23; 95% CI 1.05, 9.95) of LGA (*n* = 12) at delivery (Supplementary Table 3 and Supplementary Fig. 2). In addition, the upper percentiles of %CV and lability index were found to be significantly associated with an approximately threefold increase in the risk of primary cesarean delivery (*n* = 16) (Supplementary Table 3). Our data did not show any significant association between CGM-derived metrics and other neonatal outcomes, such as GA, birth weight, and Apgar score (<7 vs. ≥7) (Supplementary Table 4), or IADPSG-defined GDM and any pregnancy outcomes (Supplementary Table 5).

CONCLUSIONS

In this ongoing prospective pregnancy cohort, our pilot data reported an incidence of 17.5% (18 of 103) in GDM among multiethnic Southeast Asian women with overweight or obesity, using IADPSG criteria. Compared with their counterparts, mothers with GDM exhibited a notably unique glycemic profile derived from the CGM device in early pregnancy, showing higher average glucose levels and various glycemic variability features. Through a stepwise forward regression model selection, the early GDM prediction model using novel CGM parameters significantly outperformed the traditional risk factors model, including maternal age, BMI, and SBP at baseline, achieving an excellent AUC of 0.953. Further analysis revealed that specific novel early-pregnancy CGM parameters might potentially identify increased risks of cesarean delivery and LGA babies at birth.

The CGM metrics observed in this population were comparable to those published in another tertiary hospital in Singapore (10), given the similarity in maternal characteristics such as maternal age and ethnicity. In our study, women with GDM showed a substantial difference in the values of a number of glycemic variability parameters assessed in early pregnancy, compared with the non-GDM participants. A combination of GMI% and glycemic variability parameters (i.e., MAGE, %CV, and CONGA), were highly predictive of GDM diagnosis in later gestation. Emerging evidence has shown that glycemic variability parameters, such as %CV and MAGE, could capture blood glucose oscillations that occur throughout the day, including hypoglycemic periods and postprandial increases, as well as blood glucose fluctuations that occur at the same time on different days (11). MAGE and %CV have been recognized as the gold standard metrics for assessing glycemic variability (12,13), acknowledged for their potential role in triggering biochemical, cellular, and molecular processes relevant to the pathogenesis of diabetes complications in patients with type 1 diabetes or type 2 diabetes (14). CONGA, similar to the MAGE, measures intraday variation but has the unique benefit of including minor fluctuations in blood glucose values in calculation, better reflecting the stability of glycemic control (15). Lastly, the GMI% has been suggested to reflect glycemic variability better than HbA_{1c} in the first trimester because it is not influenced by physiological changes such as alteration in red blood cell turnover and supplements taken during pregnancy (16).

More than half a century ago, Pedersen (17) postulated that maternal hyperglycemia could influence fetal insulin release, leading to fetal hyperinsulinemia and diabetic fetopathy, including excess body fat deposition. This was confirmed

Table 3—Modified Poisson regression of CGM parameters and GDM, after adjusting for maternal age, ethnicity, BMI and systolic blood pressure at baseline

CGM parameters at 11–13 weeks of gestation per SD increase	aRRs (95% CI)	*P* value	FDR correction
Average glucose, mmol/L	1.53 (1.26, 1.85)	*<0.001*	*<0.001*
GMI, %	1.56 (1.28, 1.91)	*<0.001*	*<0.001*
CV, %	1.99 (1.23, 3.22)	*<0.01*	*<0.05*
Time above range (>7.8 mmol/L), %	1.18 (0.96, 1.45)	0.12	0.72
Time in range (3.5–7.8 mmol/L), %	1.10 (0.71,1.72)	0.66	0.99
Time below range (<3.5 mmol/L), %	0.79 (0.48, 1.29)	0.34	0.99
CONGA	1.47 (1.17, 1.85)	*<0.01*	*0.01*
Lability index	1.44 (1.16, 1.79)	*<0.01*	*0.01*
J-Index	1.44 (1.19, 1.73)	*<0.001*	*<0.01*
Low blood glucose index	0.71 (0.45, 1.13)	0.16	0.72
High blood glucose index	1.37 (1.15, 1.64)	*<0.001*	*<0.01*
Mean of daily differences	1.75 (1.27, 2.42)	*<0.001*	*<0.01*
MAGE	1.64 (1.25, 2.15)	*<0.001*	*<0.01*
M value	0.67 (0.40, 1.11)	0.12	0.72
Average daily risk range	1.46 (1.19, 1.80)	*<0.001*	*<0.01*
Mean absolute glucose change	2.04 (1.43, 2.90)	*<0.001*	*<0.01*
Glycemic risk assessment diabetes equation	1.18 (0.83, 1.68)	0.35	0.99

The italic *P* values are statistically significant ($P < 0.05$). FDR, false discovery rate.

later on by the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study that found strong correlations between the continuum of increasing levels of maternal glucose and cord serum C-peptide, a marker of insulin (18). Our study results suggested that the mean of glycemic values, together with glycemic variability, may also impact fetal growth and, consequently, size at birth (e.g., LGA). Additionally, our results also revealed a significant association between glycemic variability and cesarean delivery, especially primary cesarean delivery. This could be explained by the link between glycemic variability and cesarean-related risks such as polyhydramnios and excessive gestational weight gain (19). Research indicated that suboptimal glycemic control in pregnant individuals with diabetes could lead to polyhydramnios, as augmented amniotic fluid production ensued from increased osmotic diuresis (19), and increase the risk for primary cesarean delivery (20).

The prospective and longitudinal design allowed for the exploration of temporal relationships between novel CGM parameters in early pregnancy and subsequent GDM diagnosis and adverse outcomes. The comprehensive range of novel CGM parameters facilitated a detailed understanding and comparison of various markers of glycemic variability. However, our study also exhibited some limitations. First, the relatively modest sample size of 103 participants with 18 GDM cases may constrain the statistical power to detect more associations. For instance, the evaluation of overnight hyperglycemia and GDM was impeded by the limited sample size. Second, the generalizability of our findings is restricted, because the cohort comprised overweight and obese Asian women attending outpatient clinics within a subsidized medical setup.

Our results present distinctive evidence supporting the novel use of CGM-derived parameters in the first trimester for prediction of GDM and its associated complications at delivery. CGM could offer the potential to deepen our understanding of GDM pathophysiology in early pregnancy, especially the role of glycemic variability.

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Author Contributions. B.S.Y.L. collected data and wrote the first draft of the manuscript. Q.Y. performed the statistical analysis. M.C., D.S.L.G., S.-Y.C., Y.S.C., and C.Z. reviewed and edited the manuscript. All authors approved the final version of the manuscript. L.-J.L. conceptualized the study, collected data, assisted with the statistical analysis, acquired funding, and wrote, reviewed, and edited the manuscript. L.-J.L. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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