

Review

Comparing efficacy in glycaemic control and pregnancy outcomes between continuous glucose monitoring and self-monitoring of blood glucose in pregnancies complicated by gestational diabetes mellitus: a systematic review and meta-analysis

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ABSTRACT

Continuous glucose monitoring (CGM) may offer advantages over self-monitored blood glucose (SMBG) in gestational diabetes mellitus (GDM)-complicated pregnancies, but evidence remains inconsistent. We conducted a systematic review and meta-analysis of randomised controlled trials and observational studies published between January 1980 and April 2026 in PubMed, Embase, Scopus, Cochrane Library, and Web of Science, comparing CGM with SMBG in GDM pregnancies. The review was preregistered with PROSPERO (CRD420251084931). Primary outcomes were glycaemic control measures; secondary outcomes included maternal and neonatal events. Risk of bias was assessed using the Jadad scale and Newcastle-Ottawa Scale. Pooled risk ratios (RRs) or mean differences (MDs) with 95% confidence intervals (CIs) were calculated. Twenty-one studies involving 5,650 pregnant women were included, with low-to-moderate bias risks. Compared with SMBG, CGM significantly lower mean blood glucose (MD -0.24 mmol/L; 95% CI: -0.41 , -0.06), coefficient-of-variation (-0.78% ; -1.50 , -0.06), mean amplitude of glycaemic excursions (-0.22 mmol/L; -0.43 , -0.02), and time-above-range > 7.8 mmol/L (-2.19% , -3.78 , -0.60). CGM was also associated with an 21% increase in medication use and an 8–35% reduction in adverse maternal and neonatal outcomes, including caesarean delivery, macrosomia, neonatal hypoglycaemia, and hyperbilirubinemia. These findings suggest CGM improves glycaemic control in GDM and reduces maternal and neonatal complications.

1. Introduction

Gestational diabetes mellitus (GDM) is defined as hyperglycaemia first detected in pregnancy that does not meet the criteria for overt diabetes. [1] It is one of the most common metabolic complications of pregnancy, with a global prevalence between 7% and 14%. [1] Notably, its prevalence is higher in Asia, exceeding 20% in some countries. [1]

GDM is associated with hypertensive disorders, caesarean delivery, macrosomia, neonatal hypoglycaemia, and long-term risks of metabolic disease in both mother and offspring. [2] These complications are closely linked to maternal glycaemic control, which remains the cornerstone of GDM management. [3].

Traditionally, glycaemic monitoring in GDM relies on self-monitoring of blood glucose (SMBG) via multiple daily finger pricks.

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While considered standard care, SMBG provides only intermittent data and depends heavily on patient compliance and technique. [4] In addition, barriers to SMBG include pain, inconvenience, stigma, and psychological distress, which reduce adherence. [4]

Continuous glucose monitoring (CGM) has emerged as a novel technology that provides near real-time glucose data via a subcutaneous sensor, capturing glucose trends and excursions throughout the day and night. [5] By offering a more comprehensive glycaemic profile, CGM has previously been shown to enable early detection of dysglycaemia, improved therapeutic adjustments, and reduced glycaemic variability in pregnancies affected by type 1 diabetes. [6,7] However, its role in the management of GDM, particularly its effectiveness in improving both glycaemic control and clinical outcomes, remains less consolidated.

Given the increasing adoption of CGM in clinical practice, a comprehensive synthesis of evidence in comparing the clinical efficacy of CGM in reference to traditional SMBG in pregnancies complicated by GDM is warranted. Recent systematic reviews and *meta*-analyses have limitations: one included only five studies and assessed a substantially narrower range of outcomes, [8] while another pooled GDM and pre-gestational diabetes populations, reducing its applicability to GDM-specific clinical decisions. [9] Additionally, both studies focused exclusively on randomized controlled trials (RCTs), without conducting longitudinal studies, which offered a broader scope and richer insights compared to RCTs.

Considering these gaps, an updated and more comprehensive evaluation is needed. This systematic review and *meta*-analysis addresses these limitations, applying a rigorous and comprehensive methodological approach, and aimed to summarize and further compare the improvements of glycaemic control (e.g., mean glucose level) and key maternal (e.g., caesarean delivery) and neonatal outcomes (e.g., macrosomia) among women with GDM, who either used CGM or SMBG for antenatal care. We hypothesized that CGM, through its superior glucose monitoring capabilities and easy-to-use feature among users could significantly improve clinical outcomes compared to SMBG in this population.

2. Methods

2.1. Search strategy

This systematic review and *meta*-analysis was designed and performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement for the standard protocols. [10] This review was registered in PROSPERO International Prospective Register of Systematic Reviews (<https://www.crd.york.ac.uk/prospero/>) with registration No. CRD420251084931. Ethical approval was not required for this study, as the study was not directly involving human subjects, animals or private identifiable data.

References for this systematic review were identified through searches of five main databases (i.e., PubMed, Embase, Scopus, Cochrane Library and Web of Science) for articles published in English between January 1, 1980, and April 30, 2026. A combination of Medical Subject Headings (MeSH) keywords and free-text keywords were used for database searching: (i) “continuous glucose monitoring” or “real time glucose monitoring” or “ambulatory monitoring” or “CGM”; (ii) “blood glucose monitoring” and “continuous”; (iii) “gestational diabetes” or “pregnancy-induced diabetes”. We then performed the search by combining (i) or (ii) and (iii). The search strategy for each database is available in the [Supplementary Table 1](#).

2.2. Eligibility criteria

Randomised controlled trials (RCTs) and observational studies (prospective and retrospective cohort) that enrolled pregnant women diagnosed with GDM according to recognized diagnostic criteria were eligible for inclusion. Studies were excluded if they involved women

with pre-existing type 1 or type 2 diabetes, were not written in English, were non-human studies, or were published as reviews, case reports, or conference abstracts without full data. Studies had to report a direct comparison between CGM and SMBG used during pregnancy for glucose management and report at least one relevant glycaemic, maternal, or neonatal outcome.

2.3. Exposure Assessments—CGM versus SMBG

In our systematic review, the primary exposure of interest was the method of glucose monitoring, either CGM or SMBG, used for management in pregnant women diagnosed with GDM. CGM devices continuously measured interstitial glucose level, capturing real-time or blinded data throughout the day. Commonly used devices included Abbott FreeStyle Libre Pro, Medtronic, and Dexcom G-series, applied to the upper arm. SMBG involved capillary blood sampling via finger-prick, typically using a 7-point profile (pre- and post-meals, and bedtime), with glucometers such as Accu-Chek, Freestyle Optium Neo, OneTouch, or Contour. Participants were trained in proper sampling techniques, and both monitoring methods were used according to the protocols of the individual studies.

2.4. Outcome Assessments—glycaemic control and maternal and neonatal outcomes

Glycaemic control outcomes included mean blood glucose, time in range (TIR) (3.5–7.8 mmol/L), time above range (TAR) (>7.8 mmol/L), time below range (TBR) (<3.5 mmol/L), and measures of variability such as the coefficient of variation (CV%), mean amplitude of glycaemic excursions (MAGE) and mean of daily differences (MODD). [11,12] Additional outcomes included hypoglycaemic events, HbA1c, fasting and postprandial glucose, medication (insulin and/or metformin) initiation, and patient adherence to CGM or SMBG.

Maternal outcomes included the requirement for insulin therapy; gestational weight gain (GWG), calculated as the difference between maternal weight at the end of the pregnancy and the pre-pregnancy weight; [12] induction of labour; mode of delivery (i.e., caesarean section, vaginal delivery); and pregnancy complications, such as hypertensive disorders during pregnancy (HDP) like gestational hypertension and pre-eclampsia.

Neonatal outcomes assessed included gestational age at birth; pre-term birth (defined as delivery before 37 completed weeks of gestation); [13] premature ruptures of membranes (PROM); Apgar scores at 5 min; birthweight. Small-for-gestational-age (SGA), defined as a birthweight below the 10th percentile for gestational age, based on Fenton 2013 growth chart, [14] standard Chinese population growth and development tables, [12] the International Society of Ultrasound in Obstetrics and Gynaecology practice guidelines, [15] and INTERGROWTH-21st chart, [16] with some applying GROW customised centile calculators. [17,18] Large-for-gestational-age (LGA), defined as a birthweight above the 90th percentile according to the same references, [12,14,16] including Voigt's percentiles [19] and the birthweight assessment algorithm of the foetal medicine foundation in London. [15] Macrosomia, defined as a mean birth weight greater than > 4000 g, regardless of gestational age. [12] A composite neonatal outcome was also evaluated, comprising any of the following occurring within 24 h of birth: neonatal hypoglycaemia (defined as a blood glucose level range from below 2–2.6 mmol/L), [12,14,15,17,18,20–24] hyperbilirubinemia (requiring phototherapy post-birth or a bilirubin level of $\geq 220 \mu\text{mol/L}$), [12,13] neonatal respiratory distress syndrome (RDS), defined as the need for supplemental oxygen in the neonatal nursery beyond 4 h after birth), [17] and admission to the neonatal intensive care unit (NICU). [12,13]

2.5. Data extraction & quality assessment

To ensure completeness, we also screened the reference lists of all

included studies. Grey literature and unpublished data were not included, and study authors were not contacted. Only published, peer-reviewed full-text articles were included. Data extraction focused on study-level summary estimates, not individual participant data.

Two investigators (S.Y. and E.T.-T.B.) independently screened the titles and abstracts of retrieved articles, followed by full-text screening of potentially eligible studies. Discrepancies in study selection were resolved by a third investigator (L.-J.L.). For each study, data were extracted on study characteristics (first author, year of publication, country), study design, participant demographics (sample size, mean age, pre-pregnancy BMI, gestational age at enrolment, ethnicity), diagnostic criteria for GDM, intervention and comparator details, reported outcomes related to glycaemic control, as well as maternal and neonatal health outcomes.

To assess methodological quality, we applied the Jadad scale for RCTs, which assigns a maximum of 5 points based on randomization, blinding, and reporting of withdrawals or dropouts. [25,26] Studies scoring 3 or more were considered high quality. [25,26] For observational studies, we used the Newcastle-Ottawa Scale (NOS), which assesses risk of bias across three domains: selection of study groups, comparability, and outcome/exposure ascertainment. [25,27,28] Studies were classified as low risk of bias (7–9 points), high risk of bias (4–6 points), or very high risk of bias (0–3 points). [25,27,28].

2.6. Statistical analysis

For outcomes assessed in continuous scale, mean differences (MDs) with 95% confidence intervals (CIs) were pooled using a random-effects model fitted with restricted maximum likelihood (REML) estimation and inverse-variance weighting. [29,30] For outcomes assessed in binary scale, risk ratio (RR) and 95% CI was pooled using random-effects meta-analysis (inverse-variance method). [29,30] When continuous outcomes were reported both as endpoint analyses adjusted for baseline values and as pre/post measurements, only the endpoint-adjusted results were

used to maintain consistency across studies.

Statistical heterogeneity was assessed using Cochran's Q-test [19] and quantified using the I^2 and τ^2 statistics, with 95% CIs derived from the Q-profile method. [31,32] Heterogeneity was interpreted as low (0–25%), moderate (26–50%), substantial (51–75%), or high (>75%). [32,33] Forest plots were used to visualize effect estimates. Publication bias was assessed visually using funnel plots, Egger's regression test, [34] and Begg's rank correlation test. [35].

Stratification analyses were then performed to explore potential sources of heterogeneity and examine the robustness of the findings. Subgroup analyses compared the effectiveness of CGM versus SMBG across different factors, including study race/ethnicity (Asian vs. non-Asian/mixed), study design (RCTs vs. observational studies), sample size (≥ 100 vs. < 100 participants) and GDM diagnosis (clear guidelines vs. self-reported without guidelines mentioned). All p-values were two-sided, with statistical significance set at $p < 0.05$. All analyses were conducted using R version 4.4.1.

3. Results

3.1. Study characteristics

Of 2,100 records identified through database searches, 1,941 were excluded at title screening and 113 at abstract screening. We assessed 46 full-text articles and excluded 28 for the following reasons: population did not meet GDM-specific eligibility criteria ($n = 6$); no direct CGM vs SMBG comparison ($n = 7$); no eligible outcome reported ($n = 4$); duplicate publication or overlapping cohort ($n = 13$). Five additional studies were identified from reference lists. In total, 21 studies were included: 14 RCTs and 7 observational studies (6 prospective, 1 retrospective) (Fig. 1).

These studies involved 5,650 pregnant women aged 18–45 (CGM: $n = 1,724$; SMBG: $n = 3,997$), enrolled between 18- and 36-weeks' gestation. Participants' characteristics were generally comparable

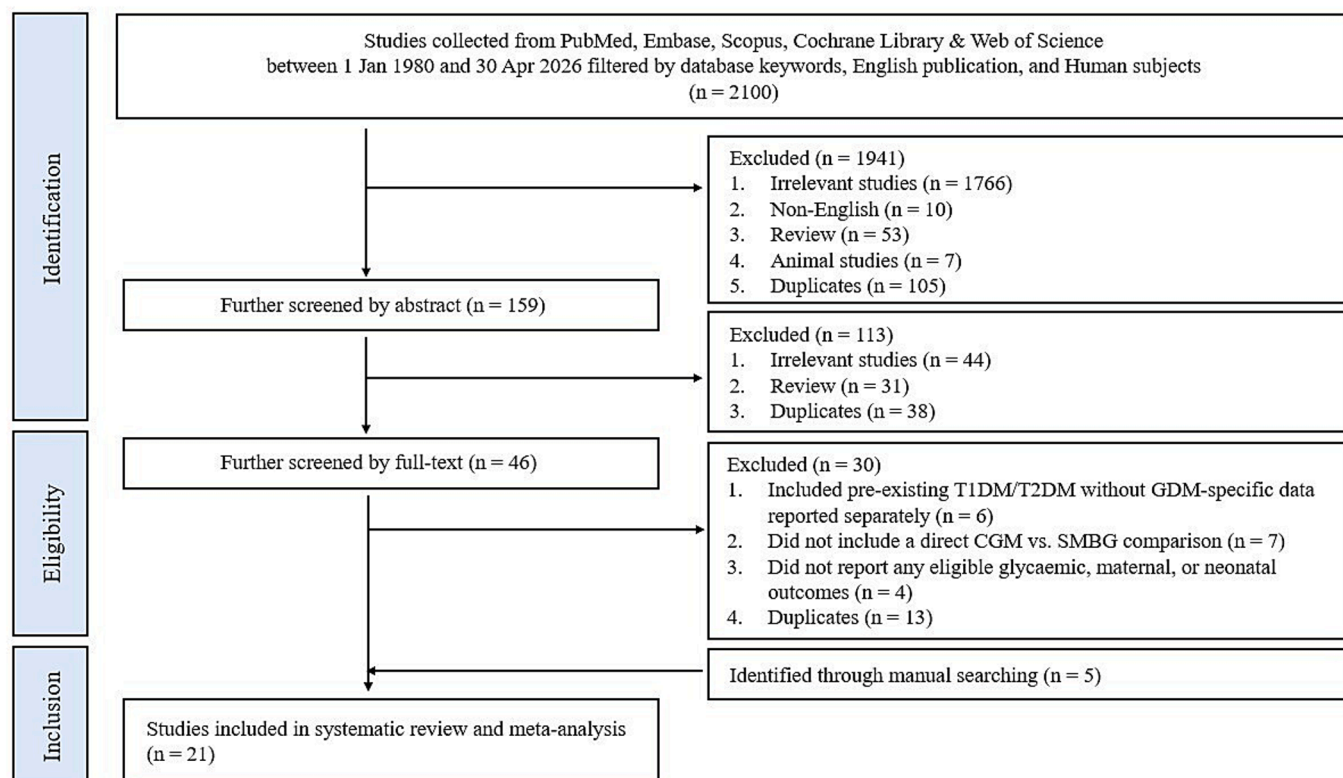


Fig. 1. Study selection process for systematic reviews and meta-analysis. Adapted from the PRISMA flow diagram.

across studies regarding maternal age, body mass index (BMI), and gestational age. More than half of the studies were conducted in Asia (China[11,12,17,22,36], India[37], Malaysia[14], UAE[38] and Saudi Arabia[20]), followed by US[23,24,39–41] and European countries (Poland[16,42], Finland[43], Netherlands[21], Austria, [18] Germany [18,19], and Switzerland[15,18]) (Supplementary Table 2). All studies used similar criteria for GDM diagnosis, primarily the International Association of Diabetes and Pregnancy Study Groups (IADPSG) [44], the 2013 World Health Organization (WHO) [45], or the American Diabetes Association (ADA) criteria, [46] except one study using the 2018 American College of Obstetricians and Gynaecologists (ACOG) [47] guidelines, and another applied local Malaysian guidelines. [14] As for GDM management, most RCTs adopted ADA-recommended glycaemic targets[48] (fasting glucose ≤ 5.2 – 5.5 mmol/L; 1-h postprandial ≤ 7.8 mmol/L; 2-h postprandial ≤ 6.7 – 7.2 mmol/L) [12,18,20] or ACOG-recommended targets[47] (fasting ≤ 5.0 mmol/L; 1-h postprandial < 7.8 mmol/L; 2-h postprandial ≤ 6.7 mmol/L). [23,24] One RCT applied the Malaysian national guidelines (fasting 3.5–5.0 mmol/L; pre-meal 4.0–5.8 mmol/L; 1-h postprandial < 7.9 mmol/L; 2-h postprandial 4.0–6.7 mmol/L), [14] and another followed local protocols and national guidelines used in the Netherlands (fasting 3.5–5.3 mmol/L; 1-h postprandial ≤ 7.8 mmol/L; 2-h postprandial ≤ 6.7 mmol/L). [21] Among observational studies, only one applied the 2011 German S3 guideline, [19] and another used the Diabetes Poland guideline. [42] The remaining RCTs and observational studies did not report any specific guideline for GDM management targets, with glycaemic values ranging from 3.5–5.5 mmol/L for fasting; pre-prandial ≤ 7.8 mmol/L; 1-h-postprandial ≤ 6.7 – 8.0 mmol/L; and 2-h-postprandial 3.3–6.7 mmol/L. [11,15–17,22,37,39,41,43] Three additional studies[36,38,40] did not report any of the GDM management targets (Supplementary Table 2). The CGM devices used were primarily Freestyle Libre Pro [49] ($n = 8$) [16,22,36–40,42] and Medtronic iPro2[50] ($n = 7$) [11,12,14,17,20,21,43], with five studies[15,18,23,24,41] using Dexcom G6[51] and one study[19] not explicitly reporting the CGM brand. Across studies, eight[11,12,14,17,21,37,38,43] used blinded CGM, seven[16,19,22,36,39,40,42] used intermittently-scanned CGM, and six [15,18,20,23,24,41] used real-time CGM, for 3–14 days, while control groups implementing standard SMBG 4–7 times daily. Quality assessment indicated low bias risk: 11 of 14 RCTs scored ≥ 3 on Jadad scale; 6 of 7 observational studies scored ≥ 7 on the Newcastle-Ottawa scale (Supplementary Table 3 and Supplementary Table 4).

We performed meta-analyses based on 21 papers across various outcomes published in the included studies, with summarized categories in 1) glycaemic profiles; 2) use of medication (e.g. metformin or insulin); 3) maternal outcomes; 4) neonatal outcomes. Miscellaneous outcomes such as user compliance, large amplitude of glycaemic excursions (LAGE), and cost of glucose monitoring, were also reported. Overall, CGM was associated with reduced LAGE, [11] high patient satisfaction, [24,36,37,40] but was generally more costly, [11] compared to SMBG. Although these benefits were reported, they could not be pooled for meta-analysis (Supplementary Table 2).

3.2. Meta-analysis on CGM versus SMBG in antenatal glycaemic profile

In our meta-analysis, CGM significantly improved glycaemic outcomes compared to SMBG, reducing mean blood glucose (MD -0.24 mmol/L, 95% CI -0.41 to -0.06) (Fig. 2A). The heterogeneity was high for this outcome ($I^2 = 83.8\%$; $p < 0.0001$). Egger's and Begg's tests (both $p > 0.05$) did not detect statistically significant publication bias, and the funnel plot (Supplementary Fig. 1) appeared slightly asymmetrical.

The use of CGM was also associated with a reduction in CV% (MD -0.78% (95% CI -1.50 to -0.06) (Fig. 2B); MAGE (MD -0.22 mmol/L, 95% CI -0.43 to -0.02) (Fig. 2C); and MODD (MD -0.19 mmol/L, 95% CI -0.25 to -0.14) (Fig. 2D), indicating improved glycaemic stability compared to SMBG, as well as TAR (MD -2.19% , 95% CI -3.78 to -0.60) (Fig. 2E). Heterogeneity from Cochrane's Q test was observed to be from

low to high (67.6% for CV%; 61.6% for MAGE; 0.0% for MODD; and 92.1% in TAR). Egger's and Begg's tests did not detect statistically significant publication bias for both outcomes (all Egger's and Begg's tests $p > 0.05$), with the funnel plot appeared asymmetrical (Supplementary Fig. 2).

Other glycaemic outcomes such as TIR, TBR, fasting blood glucose, post-prandial blood glucose, hypoglycaemia rate, and HbA1c, showed non-significant results (Supplementary Fig. 3–8). Funnel plot (Supplementary Fig. 9) and publication bias tests suggested no substantial bias, while heterogeneity across outcomes ranged from low to high.

3.3. Meta-analysis on CGM versus SMBG in GDM medication use

In our analysis, the likelihood of medication (insulin/metformin) initiation was higher among CGM users (RR 1.21, 95% CI 1.08 to 1.35) (Fig. 3), suggesting earlier detection of hyperglycaemia. Moderate heterogeneity was observed ($I^2 = 42.8\%$; $p = 0.0505$). The funnel plot (Supplementary Fig. 10) did not indicate substantial publication bias, supported by insignificant Egger's and Begg's tests.

3.4. Meta-analysis on CGM versus SMBG in maternal outcomes

Meta-analysis of the studies demonstrated that CGM significantly reduced the risk ratio of caesarean delivery (RR 0.92, 95% CI 0.86 to 0.98) (Fig. 4). The heterogeneity was also low across studies ($I^2 = 20.1\%$; $p = 0.2246$). Egger's and Begg's tests did not reach statistical significance, and the funnel plot (Supplementary Fig. 11) did not suggest marked asymmetry; nonetheless, publication bias cannot be definitively excluded.

Other maternal outcomes did not show statistically significant results, including GWG, vaginal delivery rate, induction of labour, miscarriage rate, hypertensive disorder rate, and pre-eclampsia rate, as detailed in Supplementary Fig. 12–18. Heterogeneity was generally low at 0% across maternal outcomes with a few outcomes (e.g. GWG and pre-eclampsia rate) showing substantial and high heterogeneity (53.9–77.7%). Egger's and Begg's tests did not detect statistically significant publication bias for these outcomes; small-study effects cannot, however, be excluded.

3.5. Meta-analysis on CGM versus SMBG in neonatal outcomes

CGM use was associated with a modest reduction neonatal birth weight, with a MD of -106.68 g (95% CI: -161.75 to -51.61) (Supplementary Fig. 19). The heterogeneity was moderate ($I^2 = 42.4\%$; $p = 0.0420$). Egger's and Begg's tests (both $p > 0.05$) did not reach statistical significance, though this does not confirm the absence of publication bias, and the funnel plots (Supplementary Fig. 20) appeared symmetrical.

In addition, CGM was linked with a lower risk of macrosomia (RR 0.71, 95% CI 0.51 to 0.99) (Fig. 5A), as well as LGA (RR 0.65, 95% CI 0.52 to 0.83) (Fig. 5B). The heterogeneity was respectively low and moderate for both outcomes ($I^2 = 9.9\%$; $p = 0.3525$ for LGA and $I^2 = 33.5\%$; $p = 0.1143$ for macrosomia). Egger's and Begg's tests did not detect statistically significant publication bias for both outcomes, with the funnel plot (Supplementary Figs. 21 and 22) appeared asymmetrical.

The use of CGM also corresponded with reduced risks of neonatal hypoglycaemia (RR 0.72, 95% CI 0.60 to 0.88) (Fig. 5C), neonatal hyperbilirubinemia (RR 0.79, 95% CI 0.65 to 0.96) (Fig. 5D) and NICU admission (RR 0.81, 95% CI 0.66 to 1.00) (Fig. 5E). Heterogeneity ranged from low to substantial across these outcomes, but Egger's and Begg's tests ($p > 0.05$) did not reach statistical significance and the corresponding funnel plots appeared symmetrical (Supplementary Fig. 23–25).

Other neonatal outcomes, such as gestational age at delivery,

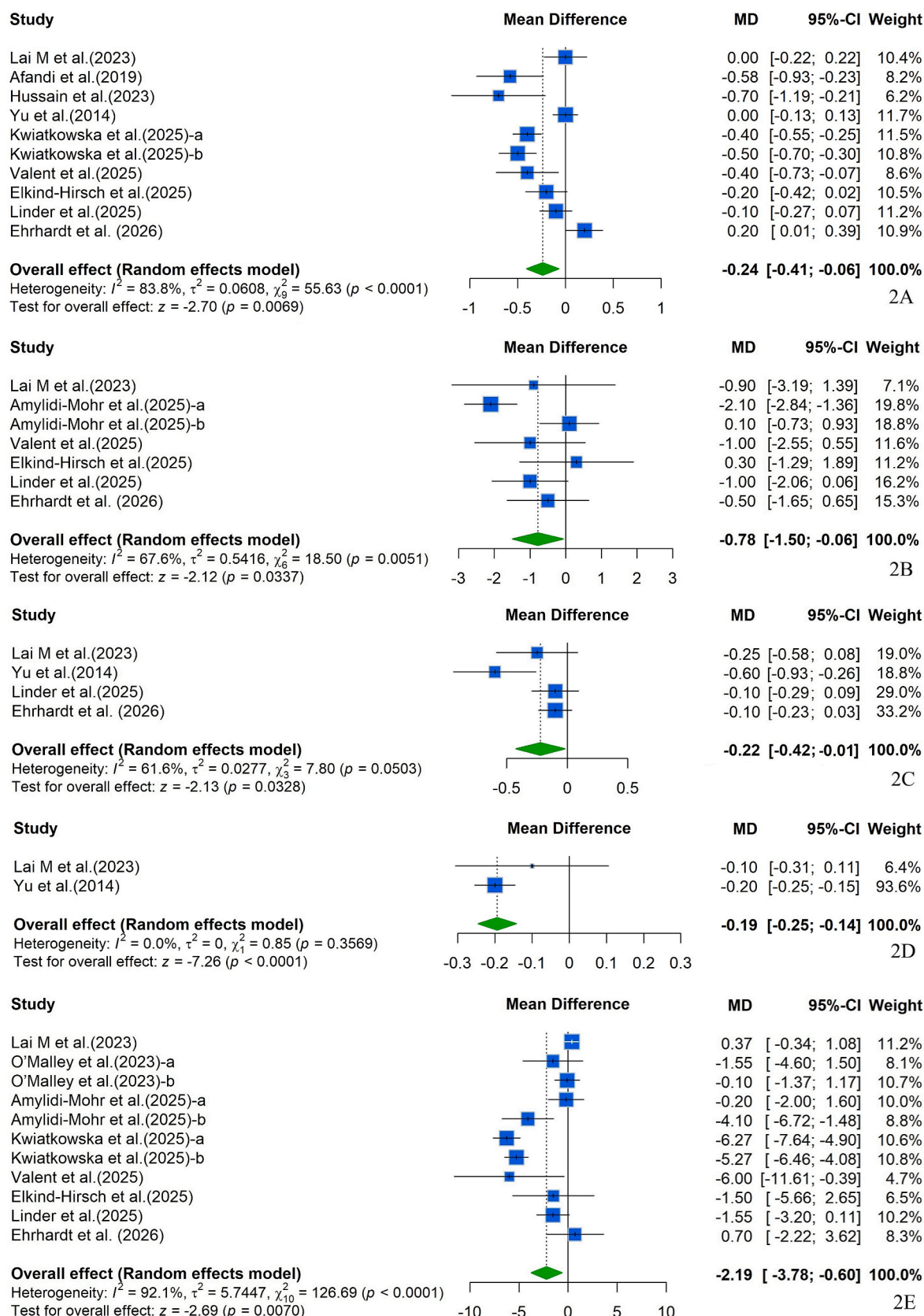


Fig. 2. Meta-analysis of glycaemic profiles comparing CGM and SMBG in women with GDM. Evidence of overall Mean Difference (MD) and 95% confidence interval (CI) for mean blood glucose (A), CV% (B), MAGE (C), MODD (D), and in TAR (E), using unadjusted random-effects model. Heterogeneity was presented in both I^2 (describing the percentage of variation across studies that is due to heterogeneity rather than chance) and τ^2 (reflecting the variance of the true effect sizes). Abbreviations: MD, mean difference; CI, confidence interval; %, percentage; GDM, gestational diabetes mellitus; CGM, continuous glucose monitoring; SMBG, self-monitoring of blood glucose; CV%, coefficient of variation; MAGE, mean amplitude of glycaemic excursions; TAR, time-above-range.

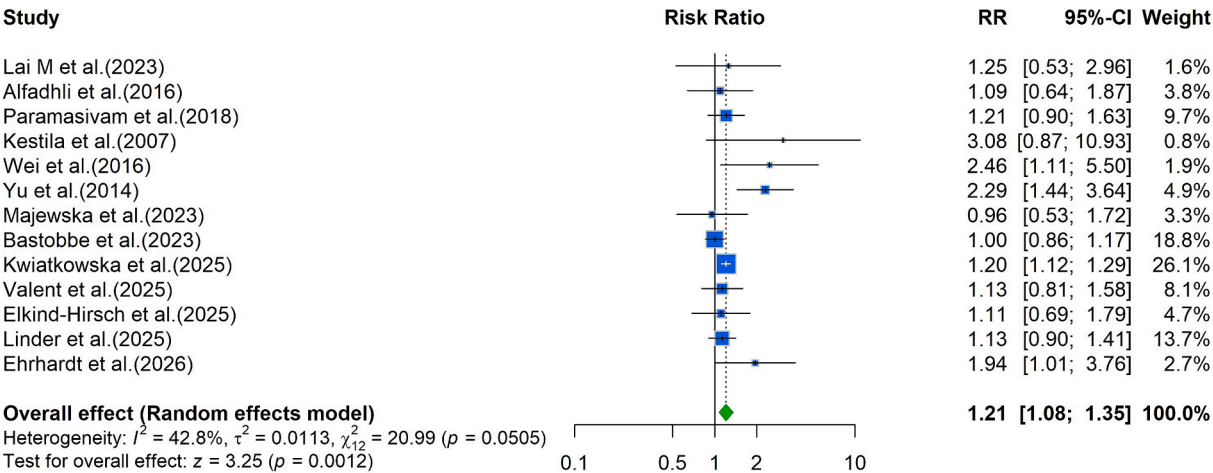


Fig. 3. Meta-analysis comparing medication use between CGM and SMBG in women with GDM. Evidence of overall Risk Ratio (RR) and 95% confidence interval (CI) for medication use, using unadjusted random-effects model. Heterogeneity was presented in both I^2 (describing the percentage of variation across studies that is due to heterogeneity rather than chance) and τ^2 (reflecting the variance of the true effect sizes). Abbreviations: RR, risk ratio; CI, confidence interval; %, percentage; GDM, gestational diabetes mellitus; CGM, continuous glucose monitoring; SMBG, self-monitoring of blood glucose.

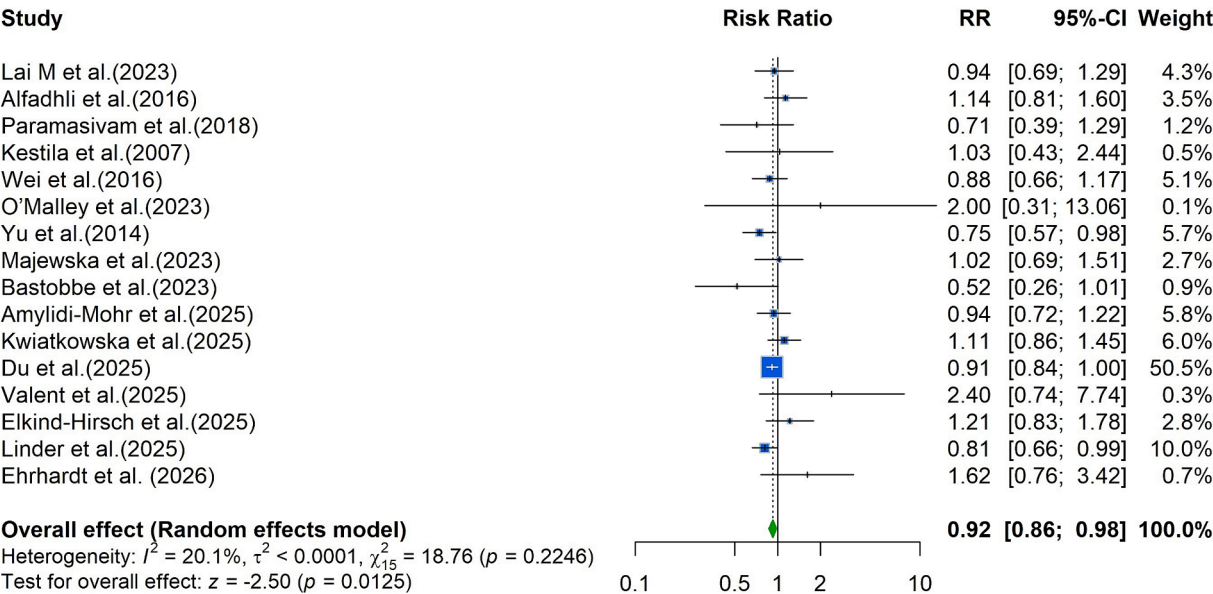


Fig. 4. Meta-analysis of maternal outcomes comparing caesarean delivery rates between CGM and SMBG in women with GDM. Evidence of overall Risk Ratio (RR) and 95% confidence interval (CI) for caesarean delivery, using unadjusted random-effects model. Heterogeneity was presented in both I^2 (describing the percentage of variation across studies that is due to heterogeneity rather than chance) and τ^2 (reflecting the variance of the true effect sizes). Abbreviations: RR, risk ratio; CI, confidence interval; %, percentage; GDM, gestational diabetes mellitus; CGM, continuous glucose monitoring; SMBG, self-monitoring of blood glucose.

preterm birth, Apgar at 5 min, SGA, RDS, and PROM, did not demonstrate statistically significant differences (Supplementary Fig. 26–31). Heterogeneity was generally low (0–18.5%) across neonatal outcomes (e.g. Apgar at 5 min, SGA, and PROM), although the remaining of the outcomes showing substantial heterogeneity (34.9–74.6%). Funnel plots (Supplementary Fig. 32–33), together with Egger's and Begg's tests, did not indicate significant publication bias.

3.6. Subgroup analyses

Subgroup analyses indicated that, compared with non-Asian studies, Asian studies showed greater reductions in GWG ($p = 0.0002$) and HbA1c ($p = 0.0194$) yet a less prominent decrease in mean glucose level ($p = 0.0088$) and MAGE ($p = 0.0785$) in mothers. In neonates, Asian studies also showed greater reductions in birthweight ($p < 0.0001$) and

macrosomia risk ($p = 0.0114$) in the CGM group). Observational studies showed significant reduction in mean blood glucose ($p = 0.0069$) and lower risks of preterm birth ($p = 0.0695$) and neonatal hyperbilirubinemia ($p = 0.0801$) with CGM, compared with RCTs. In addition, studies with sample sizes ≥ 100 yielded a lower risk of maternal hypoglycaemia in the CGM group than studies with sample < 100 ($p < 0.0001$) (Supplementary Fig. 34). No other subgroup differences were deemed plausibly significant (Supplementary Table 5).

4. Discussion

4.1. Main findings

In this systematic review and meta-analysis, we have compiled available evidence comparing CGM versus SMBG in pregnant women

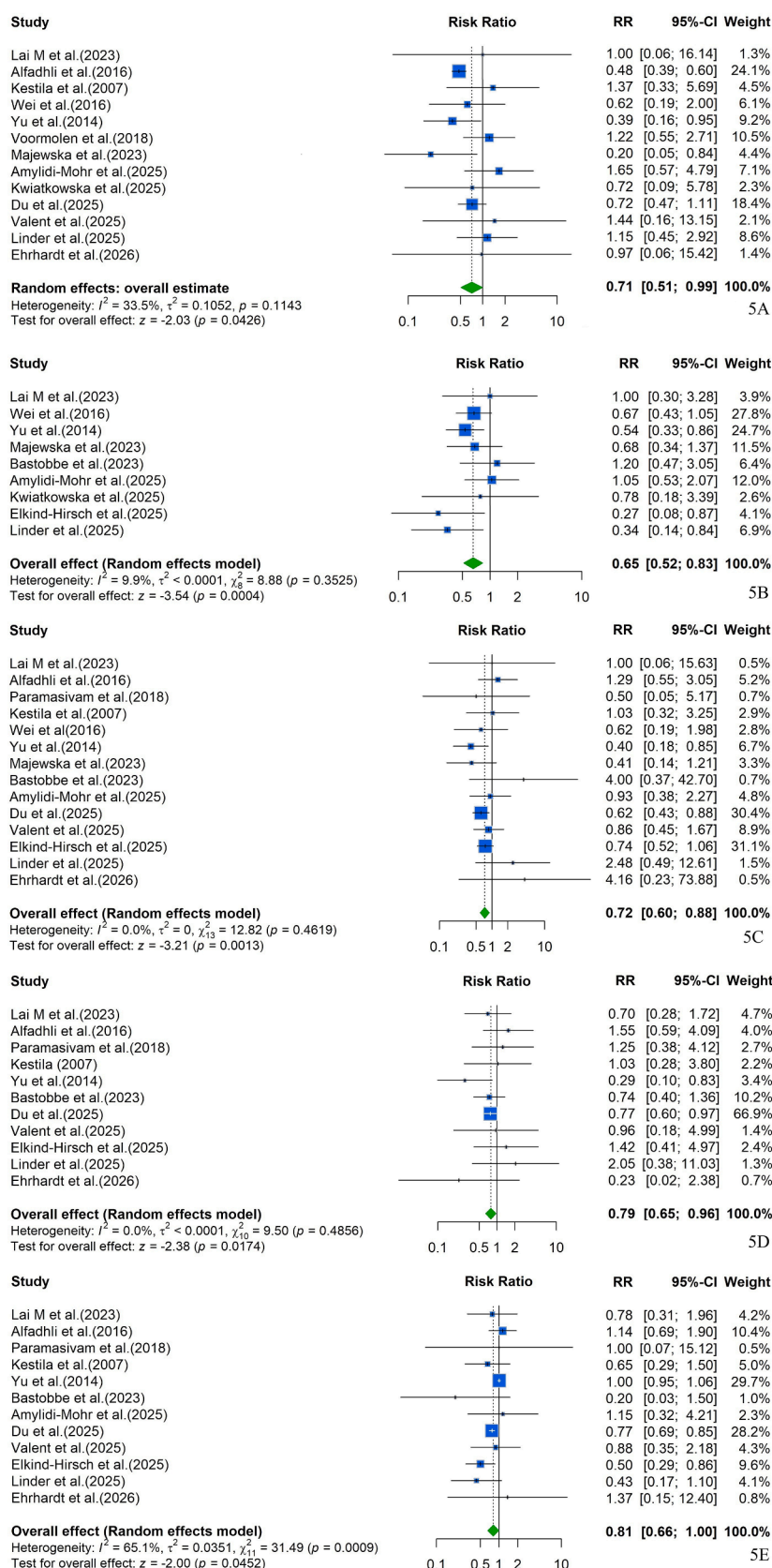


Fig. 5. Meta-analysis of neonatal outcomes comparing CGM and SMBG in women with GDM. Evidence of overall Risk Ratio (RR) and 95% confidence interval (CI) for macrosomia (A), LGA (B), neonatal hypoglycaemia (C), neonatal hyperbilirubinemia (D), and NICU admission (E), using unadjusted random-effects model. Heterogeneity was presented in both I^2 (describing the percentage of variation across studies that is due to heterogeneity rather than chance) and τ^2 (reflecting the variance of the true effect sizes). Abbreviations: RR, risk ratio; CI, confidence interval; %, percentage; GDM, gestational diabetes mellitus; CGM, continuous glucose monitoring; SMBG, self-monitoring of blood glucose; LGA, large-for-gestational-age; NICU, neonatal intensive care unit.

with GDM, covering patient experience, management, and maternal and neonatal outcomes. Our findings demonstrated that, beyond improving compliance, CGM increased the initiation of insulin or metformin by 21% and enhanced glycaemic control, with lower mean blood glucose, CV%, MAGE, MODD, and TAR. Additionally, CGM was associated with an 8–35% reduction in adverse maternal and neonatal outcomes such as caesarean delivery, macrosomia, LGA, neonatal hypoglycaemia, hyperbilirubinemia, and NICU admission, compared to SMBG.

4.2. In the context of current literature

Improved user compliance with CGM, as seen in pregnancies complicated by chronic diabetes, enables more responsive and personalized GDM management by providing continuous real-time glucose feedback, allowing prompt detection of excursions and timely adjustments to diet, activity, or medication. This could facilitate earlier initiation of insulin or metformin, leading to improved glycaemic stability, as reflected by lower MAGE, MODD, CV%, and mean blood glucose. [17] MAGE has been identified as an independent determinant of birth weight and customized birth weight centile, [17] whereby fluctuating glucose levels may exert deleterious effects by inducing oxidative stress and endothelial dysfunction, which are key mechanisms of pre-eclampsia pathogenesis. [52] Consequently, the reduced MAGE observed may contribute to the reduced risk of pre-eclampsia and other vascular complications. [17].

Consistently, our review found 8–35% lower risks of caesarean delivery, macrosomia, LGA infants, neonatal hypoglycaemia and hyperbilirubinemia with CGM, highlighting its role in preventing foetal overgrowth while maintaining optimal foetal development, and reducing maternal complications. Maternal hyperglycaemia is known to increase nutrient delivery to the foetus, leading to foetal hyperglycaemia, which stimulates maturation and hypertrophy of the foetal pancreas, [53] resulting in hypersecretion of insulin, as described by the Pedersen hypothesis. [54,55] Elevated foetal insulin acts as a potent growth hormone, promoting accelerated foetal growth. [55] These conditions contribute substantially to birth trauma, shoulder dystocia, and labour complications, thereby increasing the likelihood of caesarean delivery. [56] Kristensen *et al.* [57] further demonstrated that mean glucose levels and time spent in or outside target ranges (TAR/TIR/TBR) are critical predictors of LGA and other neonatal outcomes. Caesarean delivery may also increase the risk of neonatal hypoglycaemia, [58,59] partly because excessive maternal glucose infusion before or during the procedure could induce foetal hyperglycaemia and hyperinsulinemia, followed by reflex hypoglycaemia after birth. [60] Additionally, caesarean delivery bypasses the physiological hormonal and metabolic stress-induced catecholamine and steroid surges, predisposing infants to hypoglycaemia. [61,62] Emerging evidence has shown an interrelated pathophysiological mechanisms between neonatal hypoglycaemia and hyperbilirubinemia; He *et al.* [58] demonstrated that neonates with hypoglycaemia had a 1.81-fold higher incidence of hyperbilirubinemia. Persistent foetal hyperinsulinemia from maternal hyperglycaemia may precipitate postnatal hypoglycaemia, leading to metabolic stress, hypoxia, and impaired bilirubin clearance in the neonates, all of which ultimately could promote neonatal hyperbilirubinemia, [58] which may in turn lead to an increase in NICU admission. [63] Therefore, by maintaining maternal glucose levels such that time above range remains below 7.8 mmol/L and by reducing glycaemic variability, CGM could lower the risk of excessive foetal growth and its associated offspring complications, including foetal hyperinsulinemia, macrosomia, LGA, shoulder dystocia, neonatal hypoglycaemia, and hyperbilirubinemia, [64,65] thereby reducing the NICU occupancy rate. [66]

Although CGM has demonstrated benefits for key outcomes, there were no significant differences seen for hypertensive disorders during pregnancy, SGA, PROM, or RDS. This null finding is likely multifactorial. Statistical power was limited because few studies reported these outcomes, and their event rates were lower than for many other maternal or

neonatal complications, making true differences harder to detect. These events also have complex aetiologies only partially related to glycaemia, whereas maternal cardiovascular risk, infection, placental pathology, and incompetent clinical practice may be more influential. [67,68] Future studies are warranted to investigate the CGM impact on such outcomes.

Subgroup analyses suggested differences by ethnicity. Compared with non-Asian populations, Asian participants had greater reductions in GWG and increases medication use despite smaller improvements in mean glucose and MAGE, possibly reflecting lower pre-pregnancy BMI and higher likelihood of meeting GWG guideline ranges, as well as ethnic differences in body composition and metabolism (e.g., higher visceral adiposity and relatively impaired β -cell function at lower BMI), [69,70] predominant insulin secretory defects limiting pharmacological efficacy, pharmacogenomic differences may further attenuate therapeutic response, and disproportionately high postprandial excursions driven by high-glycaemic-index diets and delayed first-phase insulin response [71] contributing to persistently elevated MAGE not adequately captured by conventional monitoring. Consistent with this, Asian populations also showed reductions in the risk of macrosomia and birth-weight, likely mediated more by GWG instead of glucose profile. However, GWG is more vulnerable to measurement and reporting bias than mean glucose, which may contribute to the apparent discrepancy and warrants further study. Observational studies showed larger improvements in mean glucose and lower risk of preterm birth and neonatal hyperbilirubinemia than RCTs, potentially due to larger samples, longer follow-up, and greater inclusion of women with clinical indications for CGM. However, observational designs are more prone to confounding and baseline differences in who receives CGM, whereas smaller RCTs may be underpowered and protocol-driven care may attenuate detectable differences. [72]

Strengths and limitations

This review's strength lies in its comprehensive synthesis of RCTs and observational studies, covering diverse glycaemic, maternal and neonatal outcomes, with rigorous methods including duplicate screening, independent data extraction, and bias assessment, which all enhanced validity. Nonetheless, this study has several limitations. First, the review included only publications sourced from five databases and was restricted to English-language articles, potentially introducing bias by excluding relevant studies published in other languages or outside these sources. Second, the included studies exhibited heterogeneity in study design, standardized protocols (e.g., growth chart, definition of GDM and neonatal outcomes), study duration, and sample sizes, with many being short-term or small-scale, thereby constraining the assessment of long-term maternal and neonatal outcomes. Third, the limited representation of Black and Hispanic populations restricts the generalizability of findings to more diverse populations. Fourth, most studies were underpowered for maternal and neonatal outcomes, which may account for null findings. Fifth, the potential influence of a Hawthorne effect in control groups cannot be overlooked, which may have impacted the reported results. Sixth, the pooled estimates reflect a heterogeneous mix of CGM modalities spanning different technological generations. As such, the true effect of contemporary real-time CGM on clinical outcomes may differ from the overall pooled estimate. These findings should be updated as more studies using real-time CGM become available for meta-analysis in the near future. Lastly, non-significant Egger's and Begg's tests throughout this review indicated that statistically significant publication bias was not detected; however, these tests have limited power with small numbers of studies, and the funnel plot asymmetry observed suggests that small-study effects or selective outcome reporting cannot be excluded.

4.4. Clinical relevance and implications

Given the elevated risk of adverse outcomes in GDM pregnancies, CGM may strengthen antenatal care by enabling earlier detection of hyperglycaemia and more responsive management. Across studies, CGM use was associated with improved glycaemic control and signals of better neonatal outcomes, supporting its role as a valuable adjunct in antenatal care, especially for higher-risk pregnancies or those requiring pharmacological therapy.

For a health systems perspective, although CGM is costlier than SMBG, wider use may be justified if it reduces complications and healthcare utilization and improves neonatal outcomes. On balance, these findings support consideration of CGM not as a replacement for SMBG in all cases, but as a targeted strategy for women at higher risk or poor glycaemic control, where the clinical and economic returns are likely greatest. In this context, subsidies or insurance coverage for high-risk GDM cases could improve equitable access and population-level cost-effectiveness. Importantly, while a recent consensus statement has been published, [73] routine CGM TIR targets for GDM are not yet firmly established with evidence or consistently incorporated into global practice. Large, pragmatic RCTs are therefore needed to move the field from consensus to evidence-based guidance by defining actionable CGM targets, clarifying who benefits most, and quantifying real-world clinical and economic impact, including effects on maternal well-being, adherence, and individualized care. Complementary individual participant data *meta*-analyses could further refine risk stratification and inform more precise, guideline-ready recommendations for CGM adoption and coverage.

5. Conclusions

In conclusion, CGM may offer advantages over SMBG in pregnancies complicated by GDM by improving glycaemic control and potentially reducing adverse maternal and neonatal outcomes. Real-time feedback can support clinical decision-making and improve adherence and satisfaction through more individualized management. Future large, high-quality pragmatic RCTs should evaluate cost-effectiveness, implementation in routine care, and longer-term maternal and child outcomes, alongside optimizing treatment strategies. Given limited power in existing studies, an individual participant data *meta*-analysis could clarify which subgroups benefit most and what CGM targets are most appropriate in GDM. Finally, policy support (e.g., subsidies or insurance coverage) will be important to improve access and enable broader adoption of CGM.

Authors' contributors

S.Y. and E.T.-T.B. conducted the literature screening and data extraction, and cross-verified each other's works. J.S., and L.-J.L. independently verified the extracted data. J.S. performed the statistical analyses, and L.-J.L. supervised the analyses. S.Y. and L.-J.L. interpreted the findings, drafted the manuscript, and revised the manuscript. E.T.-T.B. contributed to drafting the Introduction section. Q.Y., Q.Y.C., J.L., Y.H., Y.W., H.Q., M.C., K.B., and L.-J.L. critically reviewed the manuscript and approved the final version for submission. L.-J.L. is the guarantor and accepts full responsibility for the integrity of the work. L.-J.L. had full access to the data used in the study and made the final decision to submit for publication. The corresponding author confirms that more than one author directly accessed and verified the underlying data, and all listed authors meet authorship criteria with none omitted.

CRediT authorship contribution statement

Shirlyn Yang: Writing – review & editing, Writing – original draft, Visualization, Validation, Resources, Methodology, Data curation. **Emelia Tze-Ting Boon:** Writing – review & editing, Writing – original

draft, Validation, Resources. **Qian Yang:** Writing – review & editing. **Qing Yi Chen:** Writing – review & editing. **Jiayi Shen:** Writing – review & editing, Validation, Formal analysis, Data curation. **Jie Li:** Writing – review & editing. **Yali Hu:** Writing – review & editing. **Yufan Wang:** Writing – review & editing. **Hongbo Qi:** Writing – review & editing. **Mahesh Choolani:** Writing – review & editing. **Katrien Benhalima:** Writing – review & editing. **Ling-Jun Li:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Methodology, Data curation, Conceptualization.

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Data availability statement

No datasets were generated or analysed during the current study.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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