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Commentary

CGM or BGM for Gestational Diabetes: Recent Evidence from Landmark Studies

Elizabeth Holt[1] MD FACE **and Mike Grady**[2*] MSc PhD

[1]LifeScan Global Corporation, 75 Valley Stream Parkway, Malvern, PA 19355 USA
[2]LifeScan Scotland Ltd, Beechwood Park North, Inverness, IV2 3ED

Corresponding author: Mike Grady PhD MSc, LifeScan Scotland Ltd, Beechwood Park North, Inverness, IV2 3ED

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A recent meta-analysis found a variable prevalence of gestational diabetes (GDM) in the US and Canada, averaging 6.9%. This was largely attributed to screening strategies, suggesting the true number may be higher (1). Research in the UK found that more than half of GDM cases are not diagnosed with current screening (2). The International Diabetes Federation estimates that 19.7% of live births in 2024 (23 million) were complicated by hyperglycemia, with 79% due to GDM (3). Given the prevalence and clinical impact of GDM, effective tools and strategies to support clinician-led and self-management of hyperglycemia are critical. Achieving glycemic targets is central in GDM. Until recently, glycemic management in GDM has been primarily by blood glucose monitoring (BGM), which remains the standard of care (4). Meanwhile, continuous glucose monitoring (CGM) has transformed the lives of people living with type 1 and type 2 diabetes. At present, however, there is uncertainty regarding the value of CGM for people with GDM. This has inspired three landmark randomized controlled trials (RCTs; DipGluMo, GRACE and CORDELIA) that compare the benefits and clinical outcomes of monitoring with real-time CGM vs BGM. In this commentary, we will compare the designs and clinical evidence from these studies and put this emerging data in context. We will first focus on DipGluMo, whose similar design to the other RCTs illustrates key underlying principles. DipGluMo (CGM in the management of gestational diabetes in Switzerland; NCT05037526) was an open-label, single-site RCT that investigated the effect of CGM vs BGM on perinatal outcomes (5,6). The study recruited 302 people with an A1c value < 6·5% (48 mmol/mol) diagnosed with GDM between weeks 24 and 28 of gestation. Subjects were randomised to use either the Dexcom G6 (G6) CGM (with the Dexcom Clarity app) or BGM. CGM subjects received training on sensor placement, understanding glucose readings, and how to react to readings by modifying diet and physical activity. Their data was uploaded via the app to enable clinicians to adjust therapy at routine visits. The CGM glucose target range was set at 3·5–7·8 mmol/L (63 to 140 mg/dL), and appropriate low and high glucose alerts and alarms were enabled. The BGM subjects were "instructed" on use of the mylife Unio Ypsomed BGM, although there is no detail on what this instruction entailed. This BGM has Bluetooth to connect to the mylife app, but use of the app was not required and was used by some of the participants only occasionally (7) Subjects were instructed to check blood glucose (BG) 6 times per day (before and 1 hour after meals) and record readings in a paper logbook. BGM subjects also wore a blinded G6 sensor at three timepoints to allow comparison to CGM users. The BGM targets were fasting readings < 5·3 mmol/L (63 mg/dL), pre-prandial readings < 5.4 mmol/L (97 mg/dL) and 1-hr postprandial readings < 8·0 mmol/L (144 mg/dL). All subjects (BGM and CGM) had office visits approximately every 2 weeks throughout the remainder of their pregnancies. A total of 299 subjects completed DipGluMo, 156 subjects using CGM and 143 using BGM. Baseline A1c was 5.1% in the CGM group and 5.04% in the BGM group. Results showed the primary composite outcome of adverse pregnancy and neonatal outcomes did not differ between CGM and BGM (odds ratio 1·02 [95% CI 0·63–1·66]). The number of large for gestational age (LGA) neonates was identical (10%) in the CGM and BGM groups, with no difference in neonatal hypoglycemia (6%). Obesity and previous gestational diabetes were independently associated with higher rates of neonatal complications. Surprisingly, the time in range (TIR) measured between weeks 34 and 36 of gestation was significantly higher using BGM (96.9%) than CGM (92·2%), although 43% of BGM users declined to wear a blinded CGM. Irrespective of monitoring device, these TIR levels far exceed those in the general population of people with type 1 or type 2 diabetes, a testament to the high levels of adherence in people with GDM. The authors describe a survey-based preference for CGM but acknowledge that this should be interpreted with caution since 43% of BGM users declined blinded CGM. The authors concluded that GDM outcomes were not improved by CGM but did propose that CGM could be offered to simplify diabetes management. Let us now examine GRACE (Glycemic control and pregnancy outcomes with real-time CGM in GDM, NCT03981328), a multinational open-label RCT with the primary outcome being proportion of LGA infants born to women using CGM vs BGM. The full study protocol for GRACE is published (8). GRACE mirrors DipGluMo with similar inclusion criteria, glucose monitoring devices and clinical endpoints. GRACE enrolled 375 women diagnosed with GDM who in keeping with DipGluMo, were randomized to use a G6 CGM (with Clarity app) or BGM. The BGM used in GRACE was the Contour Next One (Ascensia Diabetes Care) but the protocol does not specify whether the Contour diabetes app was used; instead, the protocol stipulated that BGMs be downloaded in-clinic. Virtually identical CGM- and BGM-based glucose targets were used in both studies. The DipGluMo protocol stipulated that BGM subjects perform 6 glucose checks per day (before and 1hour after meals), while subjects

whose readings remained at targets could decrease check frequency to 4 times daily, including a daily fasting check (7). In contrast, the GRACE protocol specified "BG monitoring as routinely used for patients with GDM, that is, at least 4 BG values daily including measurements in a fasting state as well as 1hour after starting each meal." It is noteworthy that GRACE did not offer a compatible diabetes app to BGM-using subjects and the BGM diabetes app was not often used in DipGluMo, despite apps being commonplace and helpful tools. Both studies relied instead on meter downloads or paper logbooks, which are often incomplete, unreliable and not conducive for pattern recognition. In contrast, the CGM-using subjects in both studies were fully trained on using the sensor and the app with its insights and features, including pre-programmed target ranges and alerts and alarms. A full publication for GRACE is not available as we write this commentary, but headline results were published in an abstract and presented at the 2025 European Association for the Study of Diabetes (EASD) congress (9). Additionally, key results were presented in a Dexcom-sponsored EASD symposium. In contrast to DipGluMo, where the proportion of LGA infants was 10% in both study arms, GRACE found the number of LGA infants was lower in women using CGM compared to BGM (3·5% vs 10·3%) and that newborn weight percentiles were lower in those using CGM. However, as pointed out by Dr. Helen Murphy at EASD, the rate of LGA infants in the general population is 10%, equal to the 10.3% rate found in GRACE. Dr. Murphy goes on to point out that "we shouldn't expect women with GDM to have smaller babies than they would if they didn't have diabetes" (10). The CGM group in GRACE showed improved time in pregnancy range (65-140 mg/dl) between weeks 36 and 38 of gestation. DipGluMo observed that time in pregnancy range (63 to 140 mg/dL) was actually higher in BGM than CGM users, albeit this was measured 2 weeks earlier in gestation than in GRACE. Subjects in DipGluMo were prescribed only insulin if they needed glucose-lowering medications, with 48% of subjects starting on insulin during the study, higher in the CGM group (55%) than in the BGM group (45%). In contrast, GRACE found no difference in the numbers of subjects requiring glucose-lowering medications, although rapid-acting insulin was more often prescribed to women using CGM (41% vs 30%), perhaps as a consequence of greater visibility of their daily glucose excursions. A peer-reviewed article describing full results from the GRACE study is expected shortly, and may further explain why the primary, and some secondary, outcomes were different than those in DipGluMo.

This renewed focus on GDM continues with a study entitled "Continuous glucose monitoring for women with gestational diabetes: a randomized controlled trial," CORDELIA (NCT06310356). CORDELIA is an ongoing, open-label, multicentre RCT in Belgium and Australia designed to assess the efficacy and cost-effectiveness of CGM vs BGM in women with GDM. In keeping with GRACE and DipGluMo, the study's primary outcome will focus on a composite adverse pregnancy outcome, including preterm delivery, LGA, neonatal hypoglycemia, and stillbirth or neonatal death. Furthermore, the study will assess which CGM glycemic goals to aim for in GDM. CORDELIA will randomize 386 women to use either the Libre 3 CGM (Abbott Diabetes Care) or a Bluetooth connected BGM (OneTouch Ultra Plus Reflect) in combination with the OneTouch Reveal mobile diabetes app. BGM subjects will wear a blinded CGM (Freestyle Libre Pro IQ) at least twice during their pregnancy. BGM subjects will be instructed to perform at least 4 glucose checks per day (fasting and 1 or 2 hour(s) after meals). This approach of combining a modern BGM that includes many on-meter insight features (e.g., customizable colored target range indicator and BG pattern recognition) with its compatible app will enable clinicians and subjects to easily track glucose trends, visualize insights and share progress. Use of this advanced BGM and app ecosystem will yield a control group using modern BGM technology for comparison to CGM. The study is expected to report out in 2027. CORDELIA reminds us that BGM remains the predominant monitoring technology used globally and that most modern BGMs can connect to a diabetes app to enhance diabetes management. Neither GRACE nor DipGluMo assessed the combination of BGM and a diabetes management app, perhaps unfairly handicapping the BGM group, and CORDELIA data is not yet available. To bridge this gap, let's review data from a real-world evidence (RWE) study that evaluated glycemic trends and achievement of guideline-recommended targets in women with GDM using the OneTouch Reveal diabetes app with connected OneTouch BGMs (11). In contrast to an RCT, an RWE approach enables a step-change in the scale and diversity of the study population. Using anonymized glucose and app analytics data from 26,382 women with GDM, we analysed their first 7-days using the BGM and app compared to the last 7-days prior to a 10-week timepoint. We found fasting readings in range (RIR, < 5.3 mmol/L; < 95 mg/dL) improved by +20.3 percentage points (%pts) and overall RIR (3.5 to 7.8 mmol/L; 63 to 140 mg/dL) improved by +8.3 %pts. As expected, people with GDM were highly motivated, averaging 17 sessions and 90 minutes per week on the app. In summary, the findings of two recent landmark RCTs do not align on whether perinatal outcomes are improved using CGM vs BGM. Both do, however, align on the fact that subjects preferred to use CGM for convenience and to negate fingersticks. In light of recent RWE data on BGM, it will be interesting to understand how BGM subjects in CORDELIA, using advanced BGM in combination with a diabetes app, perform in terms of perinatal outcomes to help clinicians make informed recommendations for people with GDM based on needs, personal circumstances, and cost-effectiveness.

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