



ORIGINAL ARTICLE

## CGM, Pregnancy, and Remote Monitoring

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### Abstract

The glycemic goals of pregnancy are very narrow to reduce excess risks for numerous maternal and fetal complications. Continuous glucose monitors (CGMs) may help women achieve glucose goals and reduce hypoglycemia. CGM use has been found to be safe and effective in pregnancies associated with diabetes. CGM use can accurately identify glycemic patterns among women with and without diabetes in pregnancy. The data on the effects of CGM use on maternal and fetal outcomes are conflicting. Using CGMs in conjunction with continuous subcutaneous insulin infusion therapy in pregnancies complicated by diabetes may improve outcomes. There are limitations of CGM use that affect patients in and outside of pregnancy, as well as specific barriers that only affect pregnant women. Of importance, CGM use does not replace standard clinical care, but may be used as an adjunctive tool in pregnancy. CGM remote monitoring in pregnancy is an understudied field. In this study, we review the studies on CGM use in pregnancy.

**Keywords:** Continuous glucose monitoring, Pregnancy, Remote monitoring, Gestational diabetes, Preexisting diabetes.

### Introduction

PREGNANCIES ASSOCIATED WITH diabetes have high maternal and fetal risks, especially if metabolic control is suboptimal. These risks include fetal loss, congenital anomalies, abnormal fetal size (large-for-gestational age [LGA]; small-for-gestational age; macrosomia), preeclampsia/eclampsia, cesarean section, neonatal hypoglycemia, and neonatal hyperbilirubinemia, among others.<sup>1-4</sup> Therefore, the American Diabetes Association (ADA) recommends tight glycemic control throughout gestation<sup>5</sup> (Table 1). One tool that may help achieve optimal glycemic control in pregnancy is the continuous glucose monitor (CGM). CGM use improves hemoglobin A1C (A1C) levels in nonpregnant adults and children without increased hypoglycemia.<sup>6-8</sup> The ADA recommends CGM use in pregnancy for some high-risk women, such as those with hypoglycemia unawareness.<sup>2</sup> This review aims to (1) highlight studies on CGM use in pregnancy regarding safety, glycemic parameters, and maternal and fetal outcomes and (2) discuss remote monitoring methods of sensor glucose data and limitations of the technology.

### Methods

We conducted a PubMed electronic search using keywords “CGM,” “pregnancy,” then “remote monitoring.” When

data on specific platforms were absent, we conducted a secondary search, for example, for “carelink,” “glooko,” “diasend,” and “Tidepool.” We further defined searches when appropriate, for example, “dexcom” and “remote” together. We searched bibliographies of studies identified through the Medline (PubMed) inquiry for additional studies and we re-examined relevant articles previously known to the authors for appropriateness of inclusion. Studies were included that examined CGM effects on outcomes (glucose control, maternal, and fetal) in pregnancy. Articles were excluded if they did not present primary data, did not utilize a CGM system, or did not include pregnant women with diabetes.

### Safety and Accuracy of CGMs in Pregnancy

CGM use has been successful, safe, and accurate in detecting glucose levels in pregnancies with diabetes.<sup>9-12</sup> Chen et al. investigated CGM use in 57 women with gestational diabetes mellitus (GDM) between 24 and 36 weeks of gestation comparing 3-day CGM data with 6–8 daily self-monitoring of blood glucose (SMBG) measurements. CGM values strongly correlated with SMBG measurements. CGMs better detected high postprandial glucose levels and nocturnal hypoglycemia than SMBG testing.<sup>9</sup> In a study with eight women (type 1 diabetes [T1D] and GDM) on multiple daily

TABLE 1. AMERICAN DIABETES ASSOCIATION TARGET OF GLYCEMIC GOALS FOR PREGNANT WOMEN WITH DIABETES<sup>5</sup>

Variable	Glycemic targets		
	Gestational diabetes <sup>a</sup>	Preexisting diabetes <sup>a</sup>	Diabetes with significant hypoglycemia
Glycated Hemoglobin A1C	<6%	<6%	
Fasting glucose	≤95 mg/dL (5.3 mmol/L)	60–99 mg/dL (3.3–5.4 mmol/L)	<105 mg/dL (5.8 mmol/L)
Postprandial glucose	1-h: ≤140 mg/dL (7.8 mmol/L) 2-h: ≤120 mg/dL (6.7 mmol/L)	100–129 mg/dL (5.4–7.1 mmol/L)	1 h: <155 mg/dL (8.6 mmol/L) 2-h: <130 mg/dL (7.2 mmol/L)

<sup>a</sup>Aim for targets if achievable without significant hypoglycemia.

injections (MDIs), CGM use between 24 and 32 weeks of gestation was associated with effective treatment adjustments as undetected hyperglycemia, nocturnal hypoglycemia, and mean daily glucose levels were all reduced.<sup>10</sup> Results were consistent in both women with T1D and GDM. Kerksen and colleagues found that CGM values were comparable with SMBG values (93.8% of data were in the clinically acceptable zone of the Clarke error grid analysis, EGA) among 15 pregnant women with T1D. CGM use in pregnancy was well tolerated.<sup>11</sup>

A study with 12 women with T1D at high risk for severe hypoglycemia used CGMs from 10 to 20 weeks of gestation. Severe hypoglycemia incidence was decreased from pre- to post-CGM initiation. CGM use may have reduced severe hypoglycemic events later in pregnancy.<sup>12</sup> Buhling et al. measured rates and duration of hyperglycemia with CGMs or SMBG in nonpregnant and pregnant women (no diabetes, impaired glucose tolerance, or GDM). CGMs identified more episodes of sustained hyperglycemia in GDM compared with SMBG alone. CGMs better differentiated between groups compared with SMBG alone.<sup>13</sup> More recent studies have not reported significant concerns regarding safety or accuracy of CGM therapy. Thus, in pregnancies associated with diabetes, CGMs with SMBG may be superior to SMBG testing alone.

### CGM Pattern Recognition in Pregnancy

Numerous studies compared CGM glycemic patterns among women with abnormal glucose metabolism in pregnancy with those of women without diabetes in and outside of pregnancy. In 41 pregnant women with T1D, CGM wear for 3 days detected periods of hyperglycemia and hypoglycemia that were missed with SMBG and providers often changed treatment based on CGM profiles.<sup>14</sup> A study in women with T1D, diet-controlled GDM, and insulin-controlled GDM wearing a CGM for 3 days found that within 240 min after a meal, time to peak postprandial glucose level was similar between groups (82–93 min), but varied between individuals. About half the subjects did not reach preprandial glucose levels 3 h after meal consumption.<sup>15</sup> Other studies corroborated the within-day glucose variation seen with CGM technology that may be missed if relying on SMBG or A1C alone.<sup>16–18</sup>

One study examined postprandial glucose excursions with CGM and SMBG values for 3 days in pregnant women with normal glucose tolerance (NGT,  $n=36$ ) and with GDM or T1D ( $n=17$ ). Time to peak postprandial glucose was similar between groups ( $82 \pm 18$  min for NGT and  $74 \pm 23$  min for

DM). CGM values were slightly higher among women with diabetes, significantly so at 120 and 135 min postprandially. Differences in 60 to 150 min postprandial glucose levels were significantly associated with mode of delivery, infant birth weight percentile, and/or diabetes-associated complications.<sup>19</sup> A study looking at CGM profiles for 3–7 days in 17 pregnant women with diabetes compared profiles with women without diabetes (1 of 2 was pregnant). Women treated with insulin (GDM or overt DM) had more postprandial hyperglycemia and glycemic variability (measured by standard deviation, SD, and mean amplitude of glycemic excursions, MAGE).<sup>20</sup>

Mazze et al. compared CGM profiles for  $\geq 3$  days in the third trimester in 82 women with GDM, pre-existing DM, and NGT with 21 nonpregnant women with NGT. Women without diabetes had narrow glucose profiles in pregnancy. There was a 20% difference in diurnal glucose patterns between pregnant and nonpregnant women. Glucose variability was highest with pregestational diabetes compared with GDM.<sup>21</sup> In one study, 50 women with GDM, T1D, and NGT wore CGMs for 2 days each trimester. Multiple indicators of glucose variability were higher, worse, and correlated more strongly with each other for women with T1D.<sup>22</sup>

CGMs have been utilized in special situations in pregnancy, such as pregnancy after Roux-en-Y gastric bypass,<sup>23</sup> obese pregnancies,<sup>24</sup> masked (asymptomatic) hypoglycemia in insulin-treated GDM,<sup>25</sup> and exercise with T1D.<sup>26</sup> Three of the abovementioned studies showed more or similar rates of hypoglycemia among pregnancies with NGT compared with other groups.<sup>21,22,25</sup> Therefore, CGMs have elucidated glucose variability and glycemic patterns in pregnancies with and without diabetes and shown that women with T1D and insulin-requiring GDM have more glycemic variability compared with those with diet-controlled GDM.<sup>15,20,21</sup>

### Randomized Controlled Trials of CGM Use in Pregnancy

Some randomized controlled trials (RCTs) have examined CGM use in pregnancy (Table 2). In one study, only 31% (5/16) of CGM users who met criteria for antihyperglycemic medication would have been identified with SMBG values alone.<sup>27</sup> Murphy et al. randomized women with T1D and type 2 diabetes (T2D) to standard care or intermittent CGM use between 8 and 32 weeks of gestation. CGMs were worn for a week every 4–6 weeks with data reviewed after each session. A1C was significantly lower in the CGM users between 32 and 36 weeks of gestation.<sup>28</sup> At 36 weeks of gestation, despite a mean A1C under 6%, time spent with sensor glucose levels

TABLE 2. RANDOMIZED CONTROLLED TRIALS OF CONTINUOUS GLUCOSE MONITOR USE IN PREGNANCIES ASSOCIATED WITH DIABETES

Study	Country	Diabetes	CGM system	No. of subjects per group	Intervention	Glucose outcomes	Significant differences in maternal and fetal outcomes between groups
RCT of CGM use Kestila et al. <sup>27</sup>	Finland	GDM	CGMS <sup>®</sup> Medtronic MiniMed	CGM: n = 36 SMBG: n = 37	Blinded CGM for 48 h after diagnosis <sup>a</sup>	Indication to start antihyperglycemic treatment: 44% (16/36) CGM group, 8% (3/37) SMBG group	None
Murphy et al. <sup>28,29</sup>	United Kingdom	T1D (n = 46), T2D (n = 25)	CGMS Gold Medtronic MiniMed	CGM: n = 38 SMBG: n = 33	Blinded CGM for ≤7 days every 4–6 weeks <sup>a</sup>	Similar mean A1C every 4 weeks between 8 and 28 weeks, but significantly lower in CGM group at 32 and 36 weeks (P = 0.0007)	Lower rate of macrosomia (P = 0.05), mean birth weight standard deviation score (P = 0.05), and median birth weight centile (P = 0.02) in CGM users
Secher et al. <sup>30,31</sup>	Denmark	T1D (n = 123), T2D (n = 31)	Guardian rtCGM Medtronic MiniMed (Sof-Sensor)	CGM: n = 76 SMBG: n = 75	rtCGM for 3–6 days at 8, 12, 21, 27, and 33 weeks <sup>31</sup> and labor and delivery <sup>30</sup>	No differences in A1C, median SMBG value, or SMBG values in the target range	None, <sup>31</sup> although in subanalysis, neonatal hypoglycemia more common with maternal hyperglycemia (>126 mg/dL) for 8 h before delivery (P = 0.02) <sup>30</sup>
Feig et al. (CONCEPTT Trial) <sup>32,b</sup>	Canada, United Kingdom, Spain, Italy, USA, Ireland	T1D (n = 110) pre-pregnant, n = 214 pregnant)	Medtronic MiniMed Guardian <sup>®</sup> , Paradigm <sup>®</sup> Veo <sup>™</sup> , or 640G system	CGM: n = 162 SMBG: n = 162	rtCGM daily	Primary outcomes: (1) Prepregnant group: change in A1C (baseline to 24 weeks or conception) (2) Pregnant group: change in A1C (baseline to 34 weeks of gestation) Secondary outcomes: (1) CGM time in target over time (2) A1C over time	Outcomes pending

(continued)

TABLE 2. (CONTINUED)

Study	Country	Diabetes	CGM system	No. of subjects per group	Intervention	Glucose outcomes	Significant differences in maternal and fetal outcomes between groups
Voormolen et al. (Glucose-MOMS trial) <sup>33,b</sup>	The Netherlands	T1D, T2D, insulin-requiring GDM (<30 weeks)	CGMS Medtronic MiniMed	CGM: n = 150 SMBG: n = 150	blinded CGM <sup>a</sup>	Secondary outcomes: (1) Hypoglycemia, symptomatic hypoglycemia, or severe hypoglycemia (2) A1C throughout pregnancy (3) Mean absolute glucose change per patient per hour and relative glucose variability	Outcomes pending
RCT of CGM use in women using CSII therapy							
Petrovski et al. <sup>43</sup>	Macedonia	T1D	Medtronic Mini-Link <sup>®</sup> sensor with Medtronic 722 or Veo pump	Constant CGM: n = 12 Intermittent CGM: n = 13	Constant: rtCGM 24 h/day; Intermittent: rtCGM every other week	Mean A1C significantly lower in the constant CGM group in the first trimester ( $P < 0.05$ ), but no difference initially or in other trimesters	More episodes of severe hypoglycemia and diabetic ketoacidosis in intermittent CGM group, no differences in other outcomes
Stewart et al. <sup>46</sup>	United Kingdom	T1D	Freestyle Navigator II (Abbott) with DANA Diabecare R Insulin Pump (SOOIL)	Closed-loop and SAPT: n = 16 (crossover randomization)	Overnight closed-loop insulin delivery for 4 weeks (intervention) versus SAPT (control)	Closed-loop therapy had (1) increased time within target glucose range (63–140 mg/dL), (2) reduced time with glucose >140 mg/dL, (3) reduced time with glucose >180 mg/dL, and (4) lower mean glucose levels overnight and with 24-h wear for all parameters compared with SAPT	14/16 women did continuation phase: • Preeclampsia: 5/16 women (1 with HELLP) • Cesarean section: 15/16 women • Preterm delivery: 7/16 women • LGA: 13/16 infants • Neonatal hypoglycemia: 14/16 infants <sup>c</sup>

<sup>a</sup>CGM data viewed after CGM wear sessions.

<sup>b</sup>Methods article.

<sup>c</sup>Eleven of 14 infants treated with intravenous dextrose in the neonatal intensive care unit and 3 treated with nasogastric or supplemental feeds.

A1C, glycated hemoglobin A1C; CGM, continuous glucose monitor; CSII, continuous subcutaneous insulin infusion; HELLP, hemolysis, elevated liver enzyme levels, and low platelet count; GDM, gestational diabetes mellitus; LGA, large-for-gestational age; RCT, randomized controlled trial; rtCGM, real-time continuous glucose monitor; SAPT, sensor-augmented pump therapy; SMBG, self-monitoring of blood glucose; T1D, type 1 diabetes; T2D, type 2 diabetes.

>140 mg/dL was  $\geq 8$  h/day in women with T1D and  $\sim 3$  h/day in women with T2D in each trimester.<sup>29</sup>

The Danish study of intermittent real-time CGM (rtCGM) found no differences in outcomes between groups; however, only 64% (49/76) in the rtCGM group followed the protocol.<sup>30,31</sup> Taken together, these studies suggest that adjunctive CGM use may help make decisions about therapy, but improvement of long-term glucose control and outcomes may require more than just intermittent use.

Two rtCGM RCTs published their methods, completed their studies, and have adequate power to address the effectiveness of CGM therapy in pregnancy. The CONCEPT trial randomized 324 women with T1D to standard care or SMBG with daily CGM use.<sup>32</sup> The GlucoMOMS trial randomized 300 women with diabetes (T1D or T2D before 16 weeks of gestation and GDM) to standard care or SMBG testing with masked CGM.<sup>33</sup> These RCTs (CONCEPT and GlucoMOMS) will give more definitive data on the efficacy of CGM therapy on maternal glucose control and maternal and fetal outcomes.

### CGM Use and Maternal and Fetal Outcomes

CGMs may affect outcomes of pregnancies complicated by diabetes (Table 3). Neonatal hypoglycemia is a frequent complication in infants of mothers with diabetes and can have lasting effects on children.<sup>34</sup> Two studies looked at effects of maternal glucose levels in insulin-treated women during labor and delivery (2 to 8 h before birth) and resultant neonatal hypoglycemia. Stenninger et al. found that multiple glycemic indices correlated positively with the need for neonatal intravenous glucose infusions.<sup>34</sup> In Secher's study (Table 2), 45% (27/60) of women in the CGM group were compared with 100% (59/59) in the control group. Among women in the CGM arm, 10 infants developed hypoglycemia compared with 27 in the non-CGM group (37% vs. 46%, respectively;  $P=0.45$ ).<sup>30</sup> They found that maternal hyperglycemia before delivery was correlated with neonatal hypoglycemia.

Glycemic variability has been investigated. One study used blinded 3-day CGM recordings with SMBG data at 26–28 weeks of gestation to measure maternal glucose excursions (24-h magnitude and duration of glucose excursions defined as glycemia index [GI]). GI correlated with fetal growth in all pregnancy populations, especially for  $GI > 130$ . The magnitude of glucose excursions was easier to quantify using CGM and would be underestimated by SMBG alone.<sup>35</sup> In a study with 340 GDM patients, the women in the CGM group had less glucose variability and better glycemic control. Women using CGM had significantly lower rates of preeclampsia and cesarean sections versus those using SMBG alone. Infants of mothers using CGM had significantly better outcomes compared with SMBG infants.<sup>36</sup>

Macrosomia has been examined in multiple studies. Dalfra et al. found that macrosomia was linked to maternal glycemic variability and hyperglycemia in diabetic pregnancies.<sup>37</sup> Infants born to mothers intermittently using CGMs had lower birth weights, decreased birth weight percentiles, and a lower risk of macrosomia (odds ratio 0.36, 95% confidence interval 0.13 to 0.98)<sup>28</sup> (Table 2).

LGA, defined as birth weight  $\geq 90$ th percentile for sex and gestational age, affects 50% of infants of mothers with diabetes, even with clinically well-controlled diabetes.<sup>38</sup> Law

et al. used CGMs in 117 pregnancies complicated by pre-existing diabetes to examine the impact of temporal glucose variations on fetal growth. Fifty-four infants (46%) developed LGA. Mean A1C levels were well controlled. There was no significant difference in maternal A1C levels between mothers with LGA infants versus those without. CGM data identified times of day that hyperglycemia impacted fetal growth more and trimester-specific diurnal glucose differences in women with LGA infants.<sup>38</sup> Overall, while CGM use with SMBG has been evaluated throughout pregnancies in numerous small studies, it remains unclear whether it improves pregnancy outcomes.

### Sensor-Augmented Pump Therapy in Pregnancy

Sensor-augmented pump therapy (SAPT), simultaneous use of continuous subcutaneous insulin infusion (CSII) therapy with rtCGM, improves glucose control and A1C over MDI alone or CSII use alone in nonpregnant populations.<sup>39–41</sup> Although studies are sparse, some have investigated SAPT use in pregnancies associated with diabetes (Table 2).

In one retrospective multicenter study, women with T1D using CSII therapy alone ( $n=47$ ) were compared with those who self-selected CSII therapy with rtCGM  $\geq 3$  times/month ( $n=18$ ) during pregnancy and delivery. Both groups had stable peripartum glycemic values, but mean capillary blood glucose levels were significantly lower in the rtCGM group throughout labor compared with CSII alone.<sup>42</sup> Petrovski et al. randomized 25 women with T1D using CSII therapy to constant or intermittent rtCGM use throughout gestation. A1C levels improved in both groups throughout pregnancy, but were significantly lower in early gestation in the constant CGM group.<sup>43</sup>

Finally, closed-loop insulin delivery employs feedback from rtCGM into mathematical algorithms inside insulin pumps to adjust insulin delivery to maintain euglycemia. Murphy et al. conducted three studies on hybrid closed-loop insulin delivery systems in pregnant women with T1D wherein women bolused for carbohydrates and insulin delivery was otherwise adjusted by the systems. The first study used CGMs for 24 h during early (12–16 weeks) and late gestation (28–32 weeks) in 10 women. Plasma glucose measurements every 15 min showed that time in the target range (63–140 mg/dL) overnight was 84% in early and 100% in late gestation (0% hypoglycemia at each time point), but in the postprandial period was reduced (dinner: 68%–77%; breakfast: 47%–59%).<sup>44</sup> Subsequently, 12 women were randomized to closed-loop or CSII therapy during daily activities and exercise for 24 h, then crossed over to the alternate therapy. Overall, time in the plasma glucose target range was 81% during both sessions, while time in hypoglycemia ( $\leq 45$  mg/dL) was lower with closed-loop therapy (0% closed loop vs. 0.3% CSII,  $P=0.04$ ). Nocturnal time in the CGM glucose target range was significantly higher in closed loop.<sup>45</sup> The Free-Style Navigator sensor used in these studies was found to have a MARD (mean absolute relative difference) of 11.4% and Clarke error grid analysis in clinically acceptable zones.<sup>44</sup> Closed-loop insulin delivery systems appear safe in pregnancy.<sup>44,45</sup>

The last study was a crossover trial wherein 16 pregnant women were randomized to 4 weeks of closed-loop therapy or SAPT with a 2-week washout between sessions. Overnight

TABLE 3. CLINICAL TRIALS OF CONTINUOUS GLUCOSE MONITOR USE IN PREGNANCIES ASSOCIATED WITH DIABETES AND EFFECTS ON MATERNAL AND FETAL OUTCOMES

Study	Diabetes	CGM system	No. of subjects per group	Intervention	Glucose outcomes	CGM effects on maternal and fetal outcomes
Iafusco et al. <sup>74</sup>	T1D (n = 18)	CGMS Medtronic MiniMed (n=4) and Guardian <sup>®</sup> rtCGM Medtronic MiniMed (n = 14)	CGM: n = 18	rtCGM for 72h during betamethasone treatment and labor and delivery	Betamethasone treatment <sup>a</sup> : intravenous insulin adjustments based on CGM reduced glucose peaks <200 mg/dL Labor and delivery: mean glucose values of infants after birth 84 ± 16 mg/dL	<ul style="list-style-type: none"> <li>No infant respiratory distress syndrome or hypoglycemia for 72h after birth</li> </ul>
Stenninger et al. <sup>34</sup>	T1D (n = 17) T2D (n = 1) GDM (n = 2)	CGMS Medtronic MiniMed	CGM: n = 20	CGM during last 2 h of labor		<ul style="list-style-type: none"> <li>9/15 (60%) infants had neonatal hypoglycemia</li> <li>5/15 (33%) infants required intravenous glucose</li> <li>Area under the curve, mean glucose concentration, and cord plasma insulin levels positively correlated with intravenous glucose infusion in infants</li> </ul>
Taslimi et al. <sup>35</sup>	T1D (n = 3) T2D (n = 1) GDM (n = 1) NGT (n = 16)	Medtronic MiniMed Paradigm <sup>®</sup>	CGM: n = 21	Blinded CGM for 3 days 26–28 weeks of gestation	15 women (5 diabetes and 10 NGT) had CGM readings >130 mg/dL, 11 had SMBG >130 mg/dL	<ul style="list-style-type: none"> <li>Positive correlation between birth weight and glucose excursions &gt;130 mg/dL (P &lt; 0.03) in all groups</li> <li>No correlation between glucose excursions and vaginal or cesarean deliveries</li> </ul>
Dalfrà et al. <sup>37</sup>	T1D (n = 32) GDM (n = 31) NGT (n = 17)	GlucoDay <sup>®</sup> S system	CGM: n = 80	T1D: CGM for 2 days each trimester; GDM and NGT: CGM for 2 days in second and third trimesters	T1D: CGM for 2 days each trimester; GDM and NGT: CGM for 2 days in second and third trimesters	<ul style="list-style-type: none"> <li>MAGE significantly higher in T1D group during second and third trimester</li> <li>SD, interquartile range, CONGA highest in T1D group</li> <li>In second trimester, MAGE, SD, mean glucose higher in insulin-treated GDM vs. diet-controlled GDM</li> <li>A1C improved significantly in T1D group during pregnancy</li> </ul>

(continued)

TABLE 3. (CONTINUED)

Study	Diabetes	CGM system	No. of subjects per group	Intervention	Glucose outcomes	CGM effects on maternal and fetal outcomes
Yu et al. <sup>36</sup>	GDM (n = 340)	CGMS Medtronic MiniMed	CGM: n = 150 SMBG: n = 190	CGM for 72 h every 2–4 weeks	SD, MAGE, and mean of daily differences value significantly lower in CGM group	<ul style="list-style-type: none"> <li>• Lower risk of preeclampsia and cesarean section rates in CGM group (<math>P &lt; 0.05</math>)</li> <li>• Lower infant birth weight, less hypoglycemia, less hyperbilirubinemia, and less RDS in CGM group (<math>P &lt; 0.05</math>)</li> <li>• More preterm births in non-CGM group (<math>P &lt; 0.05</math>)</li> <li>• No significant decelerations in cardiotocography tracing</li> <li>• Elevated maternal glucose linked to increased FHR (<math>R = 0.32</math>; <math>P &lt; 0.0001</math>) and higher chance of FHR accelerations</li> <li>• LGA associated with lower and less variable glucose levels in first trimester, higher and more variable glucose levels in other trimesters</li> </ul>
Cypryk et al. <sup>75</sup> (Murphy <sup>76</sup> )	T1D (n = 14)	iPro <sup>®</sup> 2 Medtronic	CGM + FHR monitor: n = 14	Blinded CGM and continuous cardiotocography <sup>b</sup> in the third trimester for $\geq 20$ h	Mean A1C $< 6\%$	
Law et al. <sup>38</sup>	T1D (n = 89) T2D (n = 28)	CGMS Gold Medtronic MiniMed and Guardian rCGM Medtronic MiniMed (Soft-Sensors)	CGM: n = 117	rtCGM daily	A1C similar between groups	

<sup>a</sup>Betamethasone treatment was used to prevent infant respiratory distress syndrome and during labor and delivery to reduce neonatal hypoglycemia.

<sup>b</sup>Cardiotocography measures fetal heart rate as an indicator of fetal well-being.

CONGA, continuous overlapping net glycemic action; FHR, fetal heart rate; MAGE, mean amplitude of glucose excursions; NGT, normal glucose tolerance; rtCGM, real-time continuous glucose monitor; SD, standard deviation.

and 24-h glucose targets were significantly better in closed-loop sessions with time in the target range (overnight: 74.7% closed-loop vs. 59.5% SAPT,  $P=0.002$ ; 24-h: 66.3% closed-loop vs. 56.8% SAPT,  $P<0.001$ ), hyperglycemic ranges, and mean glucose levels. After the crossover study, 14 women continued closed-loop therapy until delivery. The median glucose level 24 h before delivery was 110 mg/dL with 86.8% time in the target range.<sup>46</sup> Of note, in supplementary material, it is reported that there were numerous device deficiencies during this study for the CGM, CSII, tablet computer, and downloading of devices, but none of them led to severe adverse glycemic or clinical outcomes. Thus, SAPT and closed-loop insulin delivery systems need further evaluation to determine if they improve glucose control in pregnant women with diabetes.

### Caveats about CGM Use in Pregnancy

CGM is beneficial as an adjunctive glucose management tool in pregnancy, but has limitations. Many limitations are inherent to the technology and apply in and outside of pregnancy. Barriers to successful use of CGM include discomfort, sensor accuracy, pharmacologic interference with readings, cost, reimbursement issues, and lack of time and training for healthcare professionals.<sup>47-49</sup>

Participants in the T1D Exchange clinic registry reported a discontinuation rate of 41% within a year of CGM initiation from device discomfort or technical problems.<sup>49</sup> As the abdomen becomes more protuberant in pregnancy, comfortable sensor insertions may be challenging. Although other sites are considered off-label use, we and other practices have found that sensor insertions in the arm or flank are worth considering in the third trimester. Sensor accuracy can be a barrier despite recent improvements.<sup>47</sup> Pharmacologic agents, such as acetaminophen, aspirin, and vitamin C, can give falsely high or low sensor glucose readings.<sup>48</sup> This is problematic in pregnancy as acetaminophen is the most compatible analgesic given that nonsteroidal anti-inflammatory drugs are contraindicated. Additionally, aspirin is becoming a common gestational therapy because when started by 16 weeks, the risk of preeclampsia is reduced in pregnancies complicated by diabetes.<sup>50</sup> CGM accuracy during hypoglycemia is questionable,<sup>47</sup> which is concerning given the increased hypoglycemia risk associated with tight glycemic pregnancy targets.<sup>51,52</sup> Furthermore, CGM systems measure interstitial fluid glucose as a marker of blood glucose with a lag time. The lag (5–10 min) is greatest during times of rapidly changing plasma glucose levels and can affect calibrations and long-term accuracy of the CGM.<sup>53</sup> Another potential problem is the physiologic change in the interstitial fluid that accompanies pregnancy and may impact sensor accuracy, although one study found that this was not relevant for the sensor used.<sup>44</sup>

As with any medical device, CGMs can be cost-prohibitive. CGM coverage from payers has improved, but may still be expensive for patients. Diabetes in pregnancy requires frequent provider visits to obstetricians, endocrinologists, and other specialists. Adding costs to visit copays and prescriptions may not be feasible for some patients. Additional barriers are poor reimbursement and lack of training for healthcare professionals.<sup>47</sup>

CGM use in pregnancy is not a substitute for SMBG, but rather a supplemental means of capturing glucose levels and

trends.<sup>7</sup> SMBG measurements are often required for calibrations for CGM systems. Seven-point profiles and glucose log sheets are recommended for routine antenatal care in diabetic pregnancies.<sup>2</sup> In women on MDIs, CGM does not provide information on insulin doses or carbohydrates consumed such as is seen on glucose log sheets, making insulin adjustments challenging based on CGM data alone. CGM technology has improved drastically since its introduction.<sup>47</sup> As this continues, many barriers may recede, thus enhancing the utility of CGM therapy in pregnancy.

Finally, it is important to note that most of the studies included in this review have relatively small sample sizes. Thus, any conclusions that one can make, in particular regarding glycemic control and clinical outcomes, are limited. More and larger studies are warranted.

### Remote Monitoring in Pregnancy

An emerging area of study is how the use of remote monitoring of glucose data affects patient outcomes. Remote monitoring includes the ability to see glucose meter data, CGM data as trends or daily patterns, and insulin pump downloads. Regarding CGM remote monitoring, some companies have software specifically for their products, such as CareLink and CareLink Pro for Medtronic products,<sup>54-59</sup> and Studio, Share, and Clarity for Dexcom products.<sup>60,61</sup> Other programs can download multiple devices and view data in one system, such as Glooko,<sup>61-63</sup> Tidepool Blip,<sup>61,64</sup> and Diasend.<sup>61,65</sup> Software and online programs have been used in remote or retrospective monitoring of glucose data in non-pregnant populations.<sup>55-59,66-68</sup>

One CGM system was evaluated with concurrent remote monitoring at children's diabetes camps. On control nights of CGM use, subjects ( $n=57$ ) could hear hypoglycemia alarms, but on intervention nights, only medical personnel received alarms through remote monitoring. Subjects were evaluated under control and intervention conditions on alternating nights for each. The intervention significantly reduced the hypoglycemic events ( $<70$  mg/dL) lasting 1 h (7 intervention vs. 33 control,  $P=0.003$ ) and 2 h (0 intervention vs. 12 control,  $P=0.01$ ), reduced extreme hypoglycemic events ( $<50$  mg/dL) lasting  $>30$  min (0 intervention vs. 9 control,  $P=0.021$ ), and improved response rates to CGM hypoglycemia (100% intervention vs. 54% control arm).<sup>66</sup>

Some studies examined remote monitoring of glucose meter data by a provider who then adjusted treatment in pregnant women with GDM or T1D.<sup>69-72</sup> We presented data at the American Diabetes Association (ADA) Scientific Sessions of interim analyses of a study using CGM alone or with Share™ remote monitoring technology in pregnant women with T1D. Share allows followers (family and friends) to view sensor glucose trends and receive alerts. There was a trend for improved glucose control and reduced fear of hypoglycemia with CGM Share use.<sup>73</sup> More studies are needed to examine how remote monitoring affects glucose control and pregnancy outcomes.

### Conclusions

CGM use appears to be safe and effective in pregnancies complicated by diabetes. CGMs can help identify glycemic patterns in pregnancy, obtain and maintain glucose targets, and reduce hypoglycemia. CGM helps with treatment adjustments



in pregnancies associated with diabetes. It is unclear whether CGM use in pregnancy affects maternal and fetal outcomes. Using CSII in conjunction with rtCGM (SAPT) may improve outcomes in pregnancies associated with diabetes. CGM is not a substitute for standard clinical care, such as adhering to carbohydrate intake goals, collecting seven-point profiles, and filling in log sheets (MDI patients). Although more studies are needed, CGM use has promise as a therapy to improve outcomes in pregnancies associated with diabetes.

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