# Continuous Glucose Monitoring in Pregnancy: New Frontiers in Clinical Applications and Research

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## Abstract

Current treatment of diabetes in pregnancy relies on intermittent self-monitoring of blood glucoses using finger sticks to monitor capillary blood glucoses. Continuous glucose monitoring (CGM) systems are an emerging technology that allow frequent glucose measurements (every 5 min) and the ability to monitor glucose trends in real time. Although these devices are currently expensive and mildly invasive to use, there is huge potential for their use in both the research and clinical realms. From a research perspective, there is the potential to better understand glucose metabolism in pregnancy, both in patients with and without diabetes. For the treating clinician, CGM has the potential to improve detection of hyperglycemic excursions as well as asymptomatic hypoglycemia and the data to improve management of glucose levels in diabetes patients. In this article, we review current literature examining use of CGM in both research and clinical applications.

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## Background

Diabetes complicates up to 14% of all pregnancies in the United States,<sup>1</sup> and this incidence is increasing.<sup>2</sup> Traditionally, diabetes in pregnancy has been categorized as pregestational diabetes [including type 1 and type 2 diabetes mellitus (T1DM, T2DM)] and gestational diabetes (GDM, defined as diabetes diagnosed for the first time during pregnancy). Of note, a significant subset of patients with presumed GDM may actually have preexisting diabetes that was not previously diagnosed.

Complications of diabetes during pregnancy have been well described. With poor glucose control early in pregnancy, there is a higher risk of congenital malformations. Poor glucose control later in pregnancy is associated with a higher risk of macrosomia and associated complications such as birth injury and need for operative delivery. In addition, there is an increased risk of fetal demise as well as neonatal complications such as hypoglycemia, hypocalcemia, hyperbilirubinemia, polycythemia, and respiratory distress syndrome. Exposure to a diabetes environment *in utero* also affects fetal metabolic programming and can increase risk of long-term health issues into childhood and adulthood, such as cardiovascular disease, diabetes, and obesity.<sup>3</sup>

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Abbreviations: (AUC) area under the curve, (CGM) continuous glucose monitoring, (CSII) continuous subcutaneous insulin infusion, (GDM) gestational diabetes mellitus, (HbA1c) hemoglobin A1c, (MAD) mean absolute difference, (MARD) mean absolute relative difference, (SMBG) self-monitoring of blood glucose, (T1DM) type 1 diabetes mellitus, (T2DM) type 2 diabetes mellitus

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Controversy surrounds the criteria used for screening and diagnosis of GDM. While current screening thresholds use an arbitrary cutoff for diagnosis of GDM, it is becoming clear that there is a spectrum of glucose intolerance in pregnancy—increasing levels of glucose intolerance correlate directly to increasing rates of pregnancy and neonatal complications,<sup>4</sup> and increasing levels of episodic hyperglycemia correlate with increasing fetal overgrowth.<sup>5</sup>

It remains unclear at which threshold treatment is costeffective and beneficial,<sup>6</sup> although some studies have demonstrated benefits to treatment of "mild gestational diabetes."<sup>7,8</sup> On the other hand, treatment of more severe diabetes in pregnancy is warranted for reduction of maternal and fetal complications.<sup>9,10</sup>

Although it is unclear exactly which levels of glycemia should be targeted for treatment, potential complications of hyperglycemia have been well described. Therefore, monitoring of diabetes in pregnancy is an important first step in learning more about optimal glycemic control, as well as optimizing pregnancy outcomes. Current monitoring of diabetes in pregnancy consists of intermittent self-monitoring of blood glucose (SMBG), which yields capillary glucose measurements. A new technology of continuous glucose monitoring (CGM) has been developed that has the potential to revolutionize management of both pregnant and nonpregnant diabetes patients. Continuous glucose monitoring can be used clinically in two ways. The first is as a retrospective diagnostic tool, where the patient is blinded to the readings; the medical provider later reviews the data and can make treatment changes at that time. The second is as a real-time diagnostic tool, where patients or their providers can follow glucose data and adjust treatment in real time.

The American Diabetes Association's 2012 Position Statement states that (1) high-quality (level A) evidence supports the use of CGM in adults (>25 years old) with type 1 diabetes for lowering glycated hemoglobin and (2) intermediate-quality (level C) evidence suggests it may also be helpful in children, teens, and young adults with type 1 diabetes.<sup>11</sup> No statement was made regarding use in pregnancy, as this is still a relatively new and developing area. For this review, a PubMed search for "continuous glucose monitor" *and* "pregnancy" was performed, and English-language articles published before January 1, 2012, were reviewed. We summarize some of the emerging literature on CGM in pregnant patients, including accuracy, research utility, and clinical utility, and conclude with our personal clinical experience and thoughts on potential future applications.

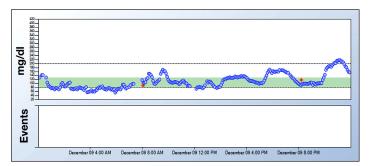
## **Continuous Glucose Monitoring Systems**

The CGM systems in clinical use in the United States include devices manufactured by Medtronic (Northridge, CA) and DexCom (San Diego, CA), which measure interstitial blood glucose. The Abbott device was taken off the U.S. market, although it remains in widespread use elsewhere. There is also a transcutaneous CGM device that utilizes a different technology (Glucoday; manufactured in Italy). Most studies have been performed using the interstitial CGM system. Unless otherwise specified, all studies reviewed here used interstitial CGM.

The Medtronic and DexCom CGM devices use a sensor that is implanted subcutaneously. Most sensors uses a glucose oxidase reaction to detect interstitial glucose levels every 10 s.<sup>12</sup> Measurements are then averaged over a 5 min period, and these data are transmitted to the receiver. Therefore, a glucose measurement is stored as a data point every 5 min, giving up to 288 data points in 1 day. (**Figure 1**) A finger stick glucose value is entered to calibrate the device two to four times a day, depending on the system. Each sensor lasts 3–7 days.<sup>12</sup> The devices cost approximately \$800–1000, and the portable receiver/monitor must be kept in close proximity to the implanted sensor.

## Accuracy of Continuous Glucose Monitors

Interstitial and blood glucoses correlate within 15–21% in nonpregnant T1DM patients.<sup>13</sup> Several studies using the devices in pregnant patients have shown them to be clinically valid in pregnancy as well, with similar margins of error as in nonpregnant patients. Mean absolute difference (MAD) and mean absolute relative difference (MARD) are two ways to describe the correlation between



**Figure 1.** An example of data obtained from a 24 h period of continuous monitoring. Red diamonds show the calibrating finger stick glucose value. Blue dots show the CGM data points.

interstitial and blood glucoses. Mean absolute difference is defined as the average of the absolute differences between the CGM (interstitial) measurement and the reference (blood) measurement. Mean absolute relative difference is an average of the absolute differences divided by the reference measurements, expressed as a percentage.<sup>13</sup>

A postmarketing study by Gross and Ter Veer<sup>14</sup> looked at data submitted from 138 female patients using the CGM system in routine clinical activity, of whom 9% were pregnant. In the entire population of patients, the correlation coefficient between CGM and finger sticks was 0.91, and MARD was 12.6%. Among the pregnant patients, MARD was 16.1%, which was considered to be clinically insignificant.

Yogev and colleagues<sup>15</sup> reported good accuracy in a pilot study of eight women with diabetes in pregnancy (six with T1DM and two with GDM). The absolute difference between finger stick and CGM measurements did not exceed 9.9 mg/dl in >82% of paired measurements.

Kerssen and associates<sup>16</sup> performed an accuracy assessment of CGM in 15 pregnant patients with T1DM. The Pearson correlation coefficient was 0.94 between finger sticks not used for correlating the CGM device and CGM readings. The MAD was 13 mg/dl. A total of 94% of the sensor values were in a clinically acceptable zone (85% had <20% deviation, and 8.4% had >20% deviation but did not lead to treatment changes). A total of 6.2% of readings were in error that led to a failure to detect and treat glucose levels.

In a separate study, Kerssen and associates<sup>17</sup> used two separate CGM devices simultaneously in five pregnant patients with T1DM. The correlation coefficient between simultaneously measured interstitial glucoses was 0.94 (p < .001), and 95% of data pairs had a difference <32 mg/dl.

Kovatchev and coauthors<sup>13</sup> performed hypoglycemic clamp studies to examine the accuracy of four different CGM devices (Medtronic Guardian, DexCom, Abbott Freestyle Navigator, and Glucoday). MARD between venous and CGM glucoses ranged from 10.3–21.2%. There was a concern regarding a transient loss of sensitivity during hypoglycemia, which, in some cases, may have been improved with later models of devices.<sup>18</sup>

Murphy and colleagues<sup>19</sup> examined accuracy of CGM to plasma glucose and found the MARD to be 13.3%

in 10 pregnant patients with T1DM. A total of 94.6% of CGM values were in a clinically acceptable zone (no overcorrection errors or unsafe glucose levels).

In summary, although studies in pregnant patients are limited by smaller numbers of patients, the accuracy of CGM, when compared with capillary (finger stick),<sup>14–16</sup> venous,<sup>13</sup> or plasma<sup>19</sup> glucoses is similar to that seen in nonpregnant patients.

## Gaining Knowledge through Continuous Glucose Monitors

The appeal of CGM for studying glucose metabolism in pregnancy is obvious. In a 24 h period, 288 data points are obtained, providing a nearly continuous profile of glucose levels over that time. Without CGM, this would require an onerous number of blood samples. Many investigators have used CGM to describe the basics of glucose profiles in pregnancy, which is crucial to further understanding of pregnancies both with and without diabetes.

#### Glucose Profiles in Normal Pregnancies

It is surprising that so little was known about the "normal" glucose profile prior to CGM. The following two studies focused solely on the nondiabetic pregnant population. In 2004, Yogev and associates<sup>20</sup> studied 57 nondiabetic pregnant women and reported the following: mean glucoses overall ( $84 \pm 18 \text{ mg/dl}$ ); fasting ( $75 \pm 12 \text{ mg/dl}$ ); at night ( $68 \pm 10 \text{ mg/dl}$ ); and 1, 2, and 3 h postprandial ( $105 \pm 12$ ,  $97 \pm 10$ ,  $84 \pm 14 \text{ mg/dl}$ , respectively). In addition, they found that the peak postprandial glucose level was  $110 \pm 16 \text{ mg/dl}$  and occurred at an average of  $70.5 \pm 13 \text{ min}$  following the start of the meal.

In 2008, Siegmund and coauthors<sup>21</sup> described glucose profiles longitudinally throughout pregnancy in 32 healthy Caucasian women without risk factors for GDM. Glucose profiles were obtained at 16, 22, 30, and 36 weeks' gestation, as well as 6 weeks postpartum. They found that fasting glucoses were significantly higher at 6 weeks postpartum than throughout pregnancy, although glucoses started to trend higher at 36 weeks. Two-hour postprandial glucoses tended to increase throughout pregnancy and then decreased significantly at 6 weeks postpartum. Maternal glucose values were measured in eight categories, including hyperglycemic time. While there was a significant correlation between fasting glucose and fetal abdominal circumference/ estimated fetal weight at 22 weeks, there was not a

correlation between birth weight and maternal glucose levels.

#### Glucose Profiles in Obese Pregnant Women

Harmon and colleagues<sup>22</sup> used CGM to compare glucose profiles in obese and normal-weight women, as well as examine the effect of a controlled diet on glucose profiles. Interestingly, a controlled diet did not make significant differences in most of the glucose parameters measured in both groups of patients. Obese patients did, however, have overall higher levels of glucose, including the 24 h area under the curve (AUC), daytime AUC, nocturnal AUC, mean glucose, and mean daytime glucose.

#### Glucose Profiles in Pregnant Patients with Diabetes

In a subanalysis of their randomized clinical trial described later, Murphy and associates<sup>23</sup> examined glucose profiles longitudinally throughout gestation in 40 T1DM patients and 17 T2DM patients.<sup>24</sup> Interestingly, CGM revealed that, during early pregnancy, women with T1DM or T2DM spend, on average, only 50% of time with blood glucose levels in the euglycemic range (70–140 mg/dl). This proportion increases to only 66% by the end of pregnancy, despite intensive multidisciplinary support. Additionally, this study demonstrated that the duration of time spent in hypoglycemia (<70 mg/dl) did not lessen with progression of the pregnancy for both T1DM and T2DM patients. These longitudinal data afforded by CGM highlight the difficulty in reaching euglycemic targets, even in highly motivated women with T1DM.

#### Peak Postprandial Time

In SMBG values, most authorities advocate checking either 1 or 2 h postprandial glucose levels. Using CGM, some authors reported a mean time to postprandial glucose peak of 44-51 min.<sup>25,26</sup> Others found a longer time to peak glucose of 70-90 min.20,27,28 Interestingly, two studies completed by the same investigators (Buhling and coauthors<sup>25,28</sup>) showed this discrepancy in times to peak postprandial glucose (47-54 min in their firstpublished study,<sup>25</sup> and 74–82 min in the second<sup>28</sup>), despite seemingly similar methodologies. Aside from variation in diet or personal metabolism that is not accounted for in these studies, another possible explanation is that there is some amount of time spent at or close to the peak. For example, in the second study, glucose levels were close to peak by 60 min, so the difference between ~60 min postprandial and ~80 min postprandial may not be clinically significant. A summary of these findings is presented in **Table 1**. Buhling and coauthors<sup>28</sup> concluded that postprandial glucoses at 75-105 min

correlated with clinically significant differences in birth weight percentile and operative delivery.

#### Table 1. Time to Peak Postprandial Glucose Level using **CGM**<sup>*a*</sup> Time to peak Gestational Number of postprandial age in Study patients/ glucose in weeks, population reference minutes, mean range number ± standard (mean) deviation Not **8**<sup>25</sup> Nonpregnant 44 ± 26 applicable 24<sup>25</sup> (34.0) 47 ± 22 Pregnant, 3628 24-37 (32) 82 ± 18 no diabetes 5720 >20 (29.7) $70.5 \pm 13$ Pregnant, IGT 15<sup>25</sup> (31.0) $53 \pm 23$ Pregnant, diabetes 17<sup>28</sup> 24-37 (32) ± 23 unspecified 36 GDM<sup>26</sup> 22-34 51 17 A1-GDM<sup>25</sup> (31.0) $54 \pm 24$ Pregnant, GDM 26 A1-GDM<sup>27</sup> 26-36 (31.6) 82 ± 31 19 A2-GD<sup>M27</sup> 27-38 (32.0) $85~\pm~40$ 20<sup>27</sup> Pregnant, T1DM 19-36 (25.3) $93 \pm 40$ <sup>a</sup> IGT, impaired glucose tolerance; A1-GDM, GDM controlled with diet alone; A2-GDM, GDM requiring insulin treatment.

#### **Comparing Different Subsets of Glucose Tolerance**

Cypryk and colleagues<sup>29</sup> compared CGM profiles of seven diet-controlled GDM, five insulin-treated GDM, and seven non-diabetic pregnant women. No significant differences were seen in mean 24 h glucose, fasting glucose, postprandial glucose, mean nighttime glucose, AUC, total duration of hypoglycemia (<60 mg/dl), and total duration of glycemia >120 mg/dl, a testimony to good glucose control among the subjects.

#### Maternal and Neonatal Outcomes

#### **Congenital Malformations**

Kerssen and associates<sup>30</sup> reported 3 cases of congenital anomalies among 53 pregnant patients with T1DM. First trimester CGM profiles in these 3 patients revealed hyperglycemic excursions that were not necessarily reflected in their hemoglobin A1c (HbA1c) measurements (which ranged from 6.0–7.8%). Although these HbA1c measurements were higher than that of nondiabetic pregnant controls (5.5–5.6%), they were not in a range that is considered at a high risk for congenital malformations. Therefore, they concluded that CGM was more sensitive in detecting hyperglycemia than HbA1c.

#### <u>Birth Weight</u>

In a prospective observational study with predetermined glucose cutoffs in a mixed population (16 nondiabetic, 3 T1DM, 1 T2DM, and 1 GDM), Taslimi and coauthors<sup>5</sup> found that AUC of hyperglycemia over 130 mg/dl correlated with infant birth weight centile. In this study, customized birth weight centiles were used that factored in maternal parity, ethnicity, and body mass index and fetal gender.

Dalfra and colleagues<sup>31</sup> conducted a study of 80 patients (17 nondiabetics, 32 T1DM, and 31 GDM). They correlated neonatal birth weight and ponderal index (a measure of leanness) not only to measures of hyperglycemia, but also to various indices of glucose variability. In pregnant T1DM patients, various measures of glucose variability and hyperglycemia throughout gestation correlated to ponderal index. In GDM patients, hyperglycemia and mean glycemia in the second trimester correlated to ponderal index. No significant correlations were seen in the control patients.

Kerssen and coauthors<sup>32</sup> examined 51 pregnant T1DM patients. A subset of these patients developed "early large for gestational age" fetuses (estimated fetal weight >90th percentile at <30 weeks); these patients had significantly higher median 24 h glucose values, especially in the second trimester. In a population of 32 healthy pregnant women, Siegmund and coworkers<sup>21</sup> found no correlation between birth weight and maternal glucose values.

#### **Operative** Delivery

One study examined correlation between glucose profiles and mode of delivery<sup>5</sup>; however, this was a small study and did not find a significant association. In addition, in two randomized trials, use of CGM did not alter rates of operative delivery in patients with GDM<sup>26</sup> or T1DM and T2DM.<sup>23</sup> Given that mode of delivery was not the primary outcome for these studies, it is likely that they were underpowered to detect a difference.

## Clinical Utility of Continuous Glucose Monitoring Systems

It seems intuitive that having more data available via CGM may change clinical management. To this end, McLachlan and colleagues<sup>33</sup> looked at 68 CGM tracings obtained at varying stages of pregnancy in 55 patients with diabetes, and found that, in 62% of cases, additional information was gained that altered clinical management. Continuous glucose monitoring was more helpful in T1DM (altered management in 89%) than in T2DM

(altered in 57%) or GDM (altered in 56%). In particular, CGM demonstrated postprandial hyperglycemia and overnight hypoglycemia and hyperglycemia that was either not evident or underestimated by finger stick monitoring. In addition, CGM was very acceptable to patients, with 77% saying that benefits outweighed inconveniences and 92% saying it was very easy or easy to use.

Yogev and associates<sup>34</sup> also examined if CGM altered management, this time in 34 pregnant T1DM patients. They found that, in 70% of cases, insulin regimen was changed following CGM, with the most common change being a decrease in long- or intermediate-acting insulin at night due to previously undetected hypoglycemia.

In a separate study, Yogev and associates<sup>15</sup> examined eight pregnant patients with either T1DM or insulin-treated GDM. In all these patients, insulin regimen was adjusted on the basis of CGM data. When the same patients were reexamined with CGM 2–4 weeks after insulin regimen adjustments, they were found to have decreased total time of undetected hyperglycemia and decreased mean 3-day glucose by both SMBG and CGM.<sup>15</sup>

Taken together, these studies show that CGM provided information that altered clinical management in pregnant patients with diabetes, especially those with T1DM, but also in those with GDM.<sup>15,33,34</sup>

It is one thing to show that use of CGM alters clinical management and another to show that it alters clinical outcomes. Therefore, two prospective randomized clinical trials were performed to assess clinical outcomes in groups of pregnant patients with diabetes who were randomized to CGM versus standard care (intermittent SMBG). Kestila and coauthors<sup>26</sup> included 73 patients with GDM; 31% (11/36) of the CGM patients received antihyperglycemics on the basis of their monitoring, as compared with only 8% (3/37) of the SMBG group. There were no differences in other pregnancy outcomes such as macrosomia, prematurity, preeclampsia, and cesarean delivery; however, this study was not powered to detect differences in obstetrical outcomes.

In another prospective randomized clinical trial, Murphy and colleagues<sup>23</sup> included 71 pregnant patients with T1DM or T2DM and randomized them to CGM versus standard care. Those in the CGM group had 5–7 days of continuous monitoring at a time, every 4–6 weeks, from 8–32 weeks gestation. In the CGM group, differences in maternal HbA1c levels began to emerge at 28 weeks, becoming statistically significant after 32 weeks. The CGM group also had significant decreases in median birth weight centile and rate of macrosomia. Specifically, 35% of infants in the intervention arm were macrosomic, compared with 60% in the control arm, for an odds ratio of 0.36. A nonsignificant decrease was noted for rate of elective cesarean delivery among the CGM group compared with controls (6% versus 16%; p = .07). These results are in contrast to the study by Kestila and coauthors.<sup>26</sup>

To summarize, one randomized trial showed no differences in clinical outcomes when CGM was used in GDM patients,<sup>26</sup> whereas another randomized trial showed significant decreases in HbA1c, birth weight, and macrosomia,<sup>23</sup> as well as a trend toward decreased elective cesarean delivery rates. The second trial differed from the first in that the patients had more severe diabetes (T1DM and T2DM; not GDM) and that CGM was used serially throughout pregnancy, starting as early as 8 weeks of gestation.

### Continuous Glucose Monitoring in Conjunction with Insulin Pump

Continuous subcutaneous insulin infusion (CSII; also known as insulin pump) is sometimes used in management of T1DM patients. Continuous glucose monitoring is used in conjunction with CSII in two ways. The first is sensor-augmented pump therapy, in which CGM data guide manual changes to insulin delivery. The second is a closed-loop system, in which an automated closed-loop algorithm controls insulin delivery.

In *nonpregnant* patients with T1DM, use of CSII together with CGM has been shown to be useful. The STAR (Sensor-Augmented Pump Therapy for A1C Reduction) 3 Trial of nonpregnant patients compared the efficacy of multiple daily injections with use of CSII augmented with CGM. This trial demonstrated significant improvement in HbA1c reduction for all groups tested, without increasing hypoglycemia. The benefit appeared to have direct correlation with sensor use: among patients randomly assigned to CSII with CGM, those who used CGM <40% of the time had no improvement compared with multiple daily injections, and the HbA1c improvement was greatest for those who used the sensor >80% of the time.<sup>35</sup>

Several studies examined use of CGM specifically in *pregnant* T1DM patients who were using an insulin pump (CSII). In one randomized pilot study, pregnant T1DM patients who were using CSII preconceptionally were randomized to continuous CGM versus intermittent CGM.

In the intermittent CGM group, they used the sensor 1 week and then went without for 1 week, alternating throughout the pregnancy. The continuous CGM group seemed to have a larger improvement in HbA1c levels in the first trimester, but there were no significant differences in fetal outcomes, HbA1c levels, or mean blood glucoses throughout the remainder of the pregnancy.<sup>36</sup>

Murphy and coauthors<sup>19</sup> demonstrated feasibility and safety of using a closed-loop system with CGM and CSII in pregnant T1DM patients. Murphy and coauthors <sup>37</sup> then performed a randomized cross-over trial with 12 women, comparing CSII guided by conventional SMBG to CSII guided by CGM (closed-loop insulin delivery); the patients then switched treatment groups at a later gestational age. In this study, closed-loop insulin delivery was as effective as SMBG and resulted in a lesser extent and duration of hypoglycemia.

## **Our Clinical Experience**

Similar to the literature reviewed earlier, our experience on the Stanford Obstetrics service has been to employ CGM as an adjunct to SMBG for assessing patterns in glycemic management and for avoidance of nocturnal hypoglycemia. Patients with long-standing brittle T1DM, some with hypoglycemia unawareness, benefit from the anticipatory demonstration of developing hypoglycemia and utilize the alarm function to awaken and treat hypoglycemia before becoming severely symptomatic or impaired. Some patients, however, may not awaken, and in those who use CSII, CGM can be used to trigger a "low glucose suspend" feature, which turns off the basal insulin dose. This feature, while available in the United Kingdom, has not yet been approved for use in the United States, although there are completed and ongoing studies looking at its use in nonpregnant patients with diabetes.38

Detection of hypoglycemia by CGM is particularly important, as severe hypoglycemia is a significant maternal risk associated with intensive therapy of pregnant women with T1DM: in one study, 30% of patients experienced at least three episodes of hypoglycemia during a 2-week period between 10 and 17 weeks' gestation.<sup>39</sup> Two randomized controlled trials have demonstrated decrease in incidence and/or length of hypoglycemic episodes in nonpregnant patients with diabetes.<sup>40,41</sup>

Although the effect of maternal hypoglycemia upon the developing fetus is limited, animal studies suggest possible risk of fetal malformations, even with short durations of exposure to hypoglycemia.<sup>42,43</sup> While the teratogenic effects of hyperglycemia are widely known, the possibility that hypoglycemia may also be teratogenic is an important concept. In that case, using CGM to treat previously undetected overnight hypoglycemia could be an important way to improve fetal outcomes in patients with pregestational diabetes, especially T1DM.

Lastly, in patients with complex and highly variable SMBG glycemic profiles, CGM allows for more rapid and thoughtful assessment of control and insulin modifications in the busy clinic setting, particularly with regard to timing of meal-related glycemic excursions and utilization of meal-specific insulin administration profiles such as those afforded by CSII.

## Conclusion

Continuous glucose monitoring has a promising role in clarifying glucose metabolism in pregnancy, promoting optimized management, and improving outcomes for mother and infant. In a research setting, CGM may provide novel information to correlate glucose profiles with fetal growth, fetal development, and pregnancy complications, even in those patients who are currently considered to be "nondiabetic." In addition, use of CGM in this way may help define ideal screening criteria for GDM as well as clinically relevant goals for glucose control. By providing real-time data and trends in glucose levels, CGM can be used in a clinical setting to optimize counseling and management of diabetes patients.

At this time, clinical trials of CGM in pregnancy are limited. We reviewed many descriptive studies that either used CGM as a tool to describe glucose profiles in normal or DM pregnancies or to correlate these profiles with pregnancy outcomes. Only two randomized clinical trials have been published looking at CGM as an intervention to alter pregnancy outcomes. Both these trials used CGM retrospectively, so there remains a gap in published data using real-time CGM to alter pregnancy outcomes. Randomized clinical trials of real-time CGM are currently under analysis<sup>44</sup> or in planning.<sup>45</sup> Until we have evidence for clinical efficacy, the expense of CGM limits its adoption into routine clinical use. If CGM technology becomes more accessible and convenient, probable future uses may extend to nondiabetic pregnancies as well, elucidating hidden blood glucose excursions and examining their correlation to fetal overgrowth or other complications such as unplanned operative deliveries.

#### Disclosures:

Joyce F. Sung and M. Mark Taslimi are conducting an investigator-initiated trial sponsored by DexCom, San Diego, CA.

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