OBSTETRICS

Software-guided insulin dosing improves intrapartum glycemic management in women with diabetes mellitus

Cheryl Dinglas, DO; Jolene Muscat, MD; Tracy Adams, MD; Virginia Peragallo-Dittko, RN; Anthony Vintzileos, MD; Hye J. Heo, MD

BACKGROUND: During labor, maintenance of maternal euglycemia is critical to decrease the risk of neonatal hypoglycemia and associated morbidities. When continuous intravenous insulin infusion is needed, standardized insulin dosing charts have been used for titration of insulin to maintain glucose in target range. The GlucoStabilizer software program (Indiana University Health Inc, Indianapolis, IN) is a software-guided insulin dosing system that calculates the dose of intravenous insulin that is needed based on metabolic parameters, target glucose concentration, and an individual's response to insulin. Although this tool has been validated and shown to reduce both hypoglycemia and errors in critical care settings, the utility of this software has not been examined in obstetrics.

OBJECTIVE: The purpose of this study was to determine whether the use of intravenous insulin dosing software in women with pregestational or gestational diabetes mellitus that requires intrapartum insulin infusion can improve the rate of glucose concentration in target range (70–100 mg/dL; 3.9–5.5 mmol/L) at the time delivery.

STUDY DESIGN: We performed a retrospective cohort study comparing laboring patients with diabetes mellitus that required insulin infusion who were dosed by standard insulin dosing chart vs the GlucoStabilizer software program from January 2012 to December 2017. The GlucoStabilizer software program, which was implemented in May 2016, replaced the standard intravenous insulin dosing chart. Inclusion criteria were women with pregestational or gestational diabetes mellitus who were treated with an intravenous insulin infusion intrapartum for at least 2 hours. Maternal characteristics, glucose values in labor, and neonatal outcomes were extracted from delivery and neonatal records. The primary outcome was the percentage of women who achieved the target glucose range (defined as a blood glucose between 70–100 mg/dL; 3.9–5.5 mmol/L) before delivery. Parametric and nonparametric statistics were used to compare both groups; a probability value of $<.05$ was considered statistically significant.

RESULTS: We identified 22 patients who were dosed by a standard insulin dosing chart and 11 patients who were dosed by the GlucoStabilizer software program during intrapartum management. The GlucoStabilizer software program was superior in achieving glucose values in target range at delivery (81.8% vs 9.1%; $P<.001$) compared with standard insulin dosing without increasing maternal hypoglycemia (0% vs 4.3%; $P=.99$). Patients whose insulin dosing was managed by the GlucoStabilizer software program also had lower mean capillary blood glucose values compared with the standard insulin infusion (102.9±5.9 mg/dL [5.7±0.33 mmol/L] vs 121.7±5.9 mg/dL [6.8±0.33 mmol/L]; $P=.02$). Before the initiation of the infusion, both groups demonstrated mean capillary blood glucose values outside of target range (122.6±8.8 mg/dL [6.7±0.49 mmol/L] for the GlucoStabilizer software program vs 131.9±10.1 mg/dL [7.3±0.56 mmol/L] for standard insulin treatment group; P=not significant). There were no significant differences in baseline maternal characteristics between the groups or neonatal outcomes.

CONCLUSION: This study is the first to demonstrate that the use of software-guided intravenous insulin dosing in obstetrics can improve intrapartum glycemic management without increasing hypoglycemia in women with both pregestational and gestational diabetes mellitus that is treated with an insulin infusion.

Key words: diabetes mellitus, glycemia, hyperglycemia, hypoglycemia, software-guided insulin dosing

The prevalence of diabetes mellitus during pregnancy has increased in recent years,[1] which has led to a large number of studies addressing preventive measures, antepartum interventions, and postpartum treatment of these patients.[2-5] However, studies that have addressed intrapartum glucose management are scarce. During labor and delivery, the goal is to maintain maternal glucose concentration in a target range to avoid both hypo- and hyperglycemic events. When necessary, blood glucose is managed with the use of a continuous intravenous insulin infusion that is dosed from a standard insulin dosing chart based on glucose values (Figure 1).[6]

The GlucoStabilizer software program (Indiana University Health Inc, Indianapolis, IN) is a software-guided insulin dosing system that has been cleared by the US Food and Drug Administration to calculate the dose of intravenous insulin that is needed to maintain capillary blood glucose concentration effectively in the target range while reducing hypoglycemia and reducing errors. An annual technology license includes service, support, and core system maintenance; 1-time costs are associated with installation, training, and interfacing. GlucoStabilizer is a trademark of Indiana University Health Inc, under license. The program calculates the insulin dose based on target glucose range and adjusts rates based on an individual's response to treatment, with the use of an insulin sensitivity factor.[7] In critical care

Cite this article as: Dinglas D, Muscat J, Adams T, et al. GlucoStabilizer software-guided insulin dosing improves intrapartum glycemic management in women with diabetes mellitus. Am J Obstet Gynecol 2018;●●●:●●●●.

0002-9378/$36.00

https://doi.org/10.1016/j.ajog.2018.05.003

AJOG at a Glance

Why was this study conducted?

This study was conducted to validate the superiority of the GlucoStabilizer (Indiana University Health Inc, Indianapolis, IN) software–based insulin dosing program over standard insulin chart-based protocols in intrapartum glycemic treatment of women with diabetes mellitus that requires intravenous insulin infusion.

Key Findings

In women with diabetes mellitus that requires intrapartum insulin infusion, the use of the GlucoStabilizer software–guided insulin dosing program improves the rate of glucose concentration in target range (70–100 mg/dL; 3.9–5.5 mmol/L) at the time of delivery, without increasing hypoglycemic episodes.

What does this add to what is known?

This is the first study to demonstrate the utility of a software-guided insulin dosing program in intrapartum treatment of women with pregestational and gestational diabetes mellitus with the ability to individualize insulin dosing based on an individual's response to treatment.

settings, use of GlucoStabilizer software has been validated to be superior to standard paper protocols for insulin dosing in decreasing glucose variability, improving glycemia, and minimizing hypoglycemia.[7-10] Juneja et al[7] performed a retrospective study of 2398 patients who were admitted to the intensive care unit and who required an insulin infusion, assessing glycemic levels before and after implementation of the GlucoStabilizer software program. The percentage of measurements <110 mg/dL (6.1 mmol/L) in the intensive care units in the 3 months before introduction of the GlucoStabilizer program was 31.5%, compared with 51.5% in the 3 months after introduction of the software (P<.001).

With the established safety and efficacy of software-guided insulin infusion dosing in critical care settings, our institution implemented the use of the GlucoStabilizer software program for insulin infusion dosing in the intrapartum period in women who require an insulin infusion in labor. We performed a retrospective study comparing intrapartum glycemia in women who were treated after implementation of the GlucoStabilizer software program vs a standard intravenous insulin dosing chart before implementation at our institution.

FIGURE 1
Standard insulin infusion chart

Plasma/Capillary Glucose (mg/dL)	Infusion Rate (U/hr)
<80	Insulin off
80-100	0.5*
101-140	1.0
141-180	1.5
181-220	2.0*
>220	2.5*

*Intravenous bolus of 2-5 units when the rate increases

Reprinted from *Creasy & Resnick's maternal fetal medicine: Principles and practice, 7th Edition* (p 1020), by TR Moore, P Catalano, S Hauguel-DeMouzon, Philadelphia, PA: Saunders/Elselvier. 2014, with permission

The standard insulin infusion chart used in our institution before implementation of the software-guided insulin dosing system.

Dinglas et al. GlucoStabilizer insulin dosing and intrapartum glycemic management. Am J Obstet Gynecol 2018.

Materials and Methods

This was a retrospective cohort study that evaluated pregnant patients with diabetes mellitus who required an insulin infusion for glycemic management in the intrapartum period from January 2012 through December 2017. At New York University Winthrop Hospital, laboring patients who require an insulin infusion for intrapartum glycemic management had been treated by a standard paper intravenous insulin dosing chart (Figure 1)[6] until May 2016, at which time the GlucoStabilizer software program was implemented.

The GlucoStabilizer software-guided system is easy to operate, runs on a hospital's existing computer system and can be interfaced with a hospital information system for documentation. It is menu driven and provides alerts for nursing staff for when to draw the next point-of-care capillary blood glucose measurement and how to adjust the rate based on the patient's glucose value that has been entered into the system.[7,8] Figure 2 gives an example of a patient whose insulin was dosed with the GlucoStabilizer software program.

Using our electronic medical and pharmacy database, we identified a total of 39 patients with a diagnosis of pregestational or gestational diabetes mellitus that required intrapartum intravenous insulin infusion at the time of delivery during the study period. The intravenous insulin requirements for 23 patients were dosed with the use of standard insulin dosing charts, and 16 patients were dosed with the use of the GlucoStabilizer software program. We excluded patients who were treated with an intravenous insulin infusion for <2 hours because this could be insufficient time to demonstrate adjustments in