Continuous Glucose Monitoring During and After Surgery

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Objectives

During surgery high blood glucose levels, termed hyperglycemia, are commonly encountered due to the physiological stress. Hyperglycemia has been associated with complications such as surgical site infections, adverse cardiovascular and pulmonary events. Optimal glucose control targeted at preventing hyperglycemia has been shown to reduce the risk of complications. However, performing optimal glycemic management during and after surgery is a significant challenge because varying effects of surgical stress and anesthesia interventions produce rapid changes in glucose levels. The current method of manually measuring blood glucose every hour or less is grossly inadequate to track changes in glucose levels. Continuous Glucose Monitors (CGMs) have the ability to automatically measure blood glucose levels in near continuous fashion. Integrating CGMs as part of a glycemic control protocol can lead to better management of glucose levels with fewer hyperglycemia episodes and lower glucose level variability resulting in better post-surgical outcomes. The feasibility of using a CGM system during and after surgery for glycemic control has not been well studied. Furthermore, prior studies used older generation devices that were limited by longer required time for calibration and interactions with commonly used medications. We propose a study that aims to evaluate viability of using a current generation CGM in surgery patients.

Dexcom Gen 6 CGM and data loggers will be used for the proposed study. Dexcom Gen 6 CGM is FDA approved for non-hospital use. Enhancements over previous model, Dexcom Gen 4, include better accuracy of glucose measurement, better protection against measurement interference from acetaminophen, fewer calibration requirements and longer wear time. Dexcom Gen 6 uses the same sensing mechanism as Gen 4 with the measurements made non-invasively through a subcutaneous sensor (under the skin). For our proposed study we will be using the CGM monitor “Off-label” in a hospital setting in surgery patients. For this study the CGM will be used as a secondary monitor not intended for patient care. In the operating room and during the patient’s hospitalization, clinical providers will continue to use the existing manual glucose measurements (Point of care glucose meters or laboratory measurements) for clinical care. The measurements recorded by the Dexcom Gen 6 CGM will be blinded (not displayed) so that providers are not able use the measured values to inform treatment decisions.

The primary goal of this study is to evaluate the feasibility of a Continuous Glucose Monitor (CGM) in measuring blood glucose levels and trends in surgery patients. The secondary goal is to observe and analyze trends in perioperative blood glucose levels to understand the dynamic effects of surgical stress and anesthetic agents on blood glucose levels. This information will allow development of better intraoperative glucose management strategies and protocols. A third goal is to describe and compare blinded CGM (data not available to clinician) measures of blood glucose (percentage of time with hyperglycemia, maximum and minimum, amplitude of glycemic excursion) to usual care finger sticks and blood draws in the preoperative, perioperative and postoperative periods.

The specific aims of the study are outlined below:

1) Compare glucose measurements made by a next generation, investigational Continuous Glucose Monitor (Dexcom Gen 6 CGM) against usual care, during the preoperative, perioperative and postoperative periods.

2) Describe measures of blood glucose variability, including percentage of time with hyperglycemia, maximum and minimum glucose levles, amplitude of glycemic excursion.

Study Design

Prospective, single center, evaluation study of a continuous glucose monitor in adult patients undergoing elective surgery.

Background

Multiple studies have shown the benefit of optimal blood glucose management during and after surgery. Optimal glucose control avoiding high glucose level (called hyperglycemia) and very low glucose level (called hypoglycemia) have been associated with reduction in complications such as infection, adverse cardiac, pulmonary and renal events. However, optimal glucose management requires frequent monitoring of glucose levels and titration of insulin doses for the diabetic population. This places a significant burden on anesthesiologists and nursing staff in a busy and critical environment of operating room and post-surgery recovery areas. A continuous glucose monitor (CGM) can automatically and frequently monitor glucose levels and obviates the need for frequent manual measurement of glucose levels by providers during and after surgery. A CGM can facilitate closer monitoring of glucose levels, better glucose management and possibly better patient outcomes.

Current CGMs that are marketed have not been evaluated in surgery patients. This study aims to evaluate one such CGM (Dexcom G6) in surgery patients.

Study Procedures

a. Study design

The study will be conducted in a single phase on adult surgical patients with and without diabetes at the University of Washington Medical Center. However, after the first 4 patients with diabetes are enrolled, a safety evaluation will be performed. The study will be continued only if the CGM is determined to be safe and able to make glucose measurements that are comparable to those made by the standard point of care (POC) glucose meter.

The safety evaluation was performed and completed in December 2018. The conclusion was the study is safe to continue.

b. Sequence and timing of study procedures

The following procedures will take place for this study for all subjects enrolled:

1. **CGM placement:** The Dexcom Gen 6 Professional GCM sensor will be placed on the subject's upper arm 2-4 hours prior to surgery. The sensor placement will preferably occur in a private room. Placement of the sensor will take around 1 minute. It is placed subcutaneously under the skin, on the forearm and will be placed by a trained member of the research team.
   - The CGM monitor will be configured to not display the glucose measurements and trends (blinded mode; data not available to subject or clinician).
   - Lastly, the CGM clock will be synchronized to the hospital computer clock.

<u>During surgery</u>

2. **Primary CGM Data Measurements:** The CGM monitor will travel with the patient to the operating room. The CGM will keep a log of the continuous glucose measurements every 5 minutes for retrospective download and review. The CGM data measurements add no time to the patient's surgery.

**The institutional protocol for glucose management will be followed using the POC and lab glucose measurements as reference. The study will not interfere with the clinical protocol, and no one will be able to see or use the blinded CGM values for clinical care.

<u>After surgery (PACU/ICU/Wards)</u>

3. **Primary CGM Data Measurements:** After surgery, the CGM will continue to collect continuous measurements. The study team will recalibrate the CGM at specified intervals during its postoperative use. The CGM will remain on the subject and collect glucose readings for up to 10 days after surgery or until the patient is discharged from the hospital whichever occurs earlier.

4. **Secondary EMR data:** The study team will retrospectively abstract pertinent clinical data, including usual care glucose measurements.

5. ** The institutional protocol for glucose management will be continued after surgery in the PACU, surgical ICU or surgical wards. The study will not interfere with the clinical protocol, and the clinical providers will still be unable to see or use the blinded CGM values for clinical care.

6. **CGM monitor disconnect & cleaning:** The CGM sensor and monitor will be removed at the end of the study period by either the research coordinator or the bedside nurse. All three parts of the CGM device will be disposed of appropriately. Additionally, the CGM measurements will be downloaded from the monitor to a computer file using a software program provided by Dexcom Inc.