Effects of a Bedtime Snack on Fasting Blood Sugar Levels in Patients with Gestational Diabetes

Protocol

Version 4

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1. Introduction

1.1. Study Abstract

Dietary changes are the first line management for patients with gestational diabetes. Multiple guidelines recommend a bedtime snack to improve fasting blood sugars. However, evidence for this intervention is conflicting, with some studies even showing an association between bedtime snacks and worse glycemic control.

This document describes a protocol of a randomized trial of a bedtime snack versus no bedtime snack in patients diagnosed with gestational diabetes.

1.2. Study Hypothesis:

In pregnant patients with gestational diabetes, a bedtime snack is associated with a decrease in fasting blood sugar levels.

1.3. Purpose of the Study Protocol

This protocol describes the background, design and organization of the randomized clinical trial. Institutional Review Board (IRB) approval will be obtained prior to beginning recruitment.

2. Background

2.1. Introduction

Diabetes affects up to 20% of pregnancies globally, of which around 90% are patients diagnosed with gestational diabetes[1]. The mainstay of diabetes management is dietary modification, and dietary education is therefore an integral component of patient management.

Despite dietary counseling and glucose monitoring, many patients struggle with elevated fasting blood glucose levels, which often lead to pharmacologic interventions. A recommendation that is often given, including by providers at EVMS OBGYN, to patients with diabetes in pregnancy is to have a bedtime snack consisting of protein and carbohydrates to help improve fasting blood sugars[2–4]. The proposed mechanism of this is thought to be multifactorial, and may include prevention of prolonged overnight fasting and onset of hepatic gluconeogenesis; and counteracting the "Somoygi effect", in which nocturnal hypoglycemia stimulates the release of hormones such as adrenaline, corticosteroids, growth hormone, and glucagon which cause a reflex hyperglycemia[2,4]. Providing a balanced bedtime snack may attenuate overnight hepatic glucose production by preventing prolonged fasting periods and insulin resistance–related glucose surges.

2.2. Rationale for Randomized Trial and Hypothesis

Evidence for whether a bedtime snack improves fasting blood sugar levels in conflicting, with some studies even showing an association between bedtime snacks and worse glycemic control[5–7].

This study proposes to include patients with a diagnosis of gestational diabetes to determine whether a bedtime snack may be beneficial in decreasing fasting blood sugars.

3. Study Design

3.1. Primary Research Question

This randomized trial will address the primary research question:

In patients with gestational diabetes, does taking a bedtime snack improve fasting blood sugar levels?

3.2. Secondary Research Questions

Secondary research questions that this study will address are whether a bedtime snack is associated with improvement in the following:

- Need for pharmacologic therapy (insulin or oral agents)
- Mean postprandial glucose levels
- Neonatal outcomes, including birth weight and a composite of adverse neonatal outcomes. We are collecting extensive neonatal outcomes data because improvement in blood sugar control is intended to prevent adverse neonatal outcomes. Collecting this data ensures that we can determine if the bedtime snack intervention is effective
- Composite of adverse maternal outcomes

3.3. Design Summary

This study is a non-blinded prospective randomized trial of pregnant patients with a singleton pregnancy between 24 weeks 0 days and 33 weeks 6 days gestation, who have gestational diabetes mellitus diagnosed using the Carpenter-Coustan criteria, which is the standard of care for diagnosis in the United States. Participants will be randomized to either:

- Mixed protein-carbohydrate bedtime snack;
- No bedtime snack.

3.4. Eligibility Criteria

3.4.1. Inclusion Criteria

- Patients older than 18 years of age;
- The patient is fluent in English, physically and mentally able to understand the

informed consent, and is willing to participate in this study;

- Diagnosis of gestational diabetes by the Carpenter-Coustan criteria;
- The patient is between 24 weeks 0 days and 33 weeks 6 days of gestation at the time of enrollment. Gestational age will be determined by last menstrual period, confirmed with a first trimester ultrasound, per the recommended guidelines by the American College of Obstetricians and Gynecologists.
- Patient has a singleton pregnancy

3.4.2. Exclusion Criteria

- Allergy to nuts;
- Unwilling or unable to perform blood glucose monitoring;
- Current use of anti-diabetic medication (such as metformin or insulin);
- Known or suspected fetal anomaly or aneuploidy;
- Prisoners;
- Planned delivery at an institution not linked to an EPIC electronic medical record.

3.5. Informed Consent Criteria

Patients will be approached at the time of one of their prenatal visits between 24 weeks 0 days and 33 weeks 6 days to determine study eligibility.

Written informed consent will be obtained before enrollment into the study. A copy of the consent form will be provided to the patient.

3.6. Randomization Method

Patients will be randomized to either taking or not taking a bedtime snack. Patients will be randomized in a 1:1 ratio using a computer-generated random sequence using REDCap.

4. Study Procedures

4.1. Screening for Eligibility and Consent

Patients will be identified by the study team through the EVMS Maternal-Fetal Medicine provider schedules. The study team will then approach eligible patients at the time of one of their prenatal visits with the MFM clinic between 24 weeks 0 days and 33 weeks 6 days to determine study eligibility. Patients may also be approached during telehealth visits.

If a patient agrees to participate, a member of the study team will engage in the process of

informed consent with the patient and the patient will sign the consent form. At telehealth visits, this will be done with econsent. For econsent, patients will be emailed a consent form and will discuss the study in a remote meeting with a member of the study team. If the patient agrees to participate, she will be asked to sign the consent form and either email or fax it back to the study team.

4.2. Randomization

Patients will be randomized to taking either taking or not taking a bedtime snack.

4.3. Baseline Procedures

The patient's eligibility information will be collected, including gestational age and estimated date of delivery, in addition to the following:

- Demographics: age, race, insurance status;
- Medical history: pre-pregnancy weight, current weight, height, current blood pressure, past medical history, diabetes history, history of diabetic ketoacidosis, last Hemoglobin A1c level;
- Social history: marital status, years of education, alcohol use, tobacco use, and other maternal drug use;
- Obstetrical history: previous miscarriages and terminations, history of preeclampsia or other obstetric complications in prior pregnancies.

Patients will be randomized to one of two arms:

1. No bedtime snack
2. A 15g carbohydrate/protein bedtime snack, such as:
    a. 1 Tbsp of peanut butter with 3 Triscuits
    b. 1 Tbsp almond butter with 1 Graham Cracker
    c. 3 Tbsp of Planters® Trail Mix

Patients with dietary restrictions or with allergies to these foods will not be enrolled in the study. Regardless of which group they are randomized to, patients will receive standard diabetic counseling, which is standard of care for all patients referred to our clinic. This counseling will be delivered by clinic providers. The primary outcome will be average fasting blood sugars for the first 7 days after starting the intervention, obtained via continuous glucose monitoring or finger stick testing. The intervention will continue for the remainder of the pregnancy. Patients are responsible for the cost of the snacks.

To monitor participant adherence, we will ask patients about their adherence at a follow-up visit 1 week after randomization. All patients who receive a diagnosis of gestational diabetes at our clinic receive a blood sugar logbook. At the time of the 1-week visit, we will review the logbook, including glycemic data about fasting and postprandial blood sugars, as well as the frequency

and timing of hyperglycemic and/or hypoglycemic episodes. The patients food diary will be reviewed in conjunction to determine dietary or medication changes that may be needed to improve glycemic control.

4.4. Patient Management and Follow Up

Patients will continue to receive standard prenatal care with their treating physician. Patients typically have their blood pressure and weight measured at all prenatal visits, and this information will be collected. We will also collect blood sugar levels for the remainder of the pregnancy, either via linked continuous glucose monitoring or by phone to review blood sugar levels. Additionally, we will collect the same data that was collected at the week-1 visit, including glycemic data about fasting and postprandial blood sugars, and frequency of hypoglycemic or hyperglycemic episodes. This will continue at in-clinic visits, which occur at least every two weeks, until delivery.

All other obstetric care is at the discretion of the primary provider, including but not limited to: treatment of maternal medical comorbidities or obstetric complications, timing and frequency of antenatal ultrasound, maternal and fetal surveillance, and timing and mode of delivery.
The study team will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. Individuals engaged in the research will have no part in determining the viability of a neonate.

The bedtime snack intervention will continue for the duration of pregnancy.

4.5. Monitoring Patient Compliance

Patients will be asked about compliance at the time of the 1 week visit.

4.6. Procedures in the Third Trimester, on Labor and Delivery, and Postpartum

At delivery, study personnel will chart abstract maternal and infant delivery information and maternal and infant data will be collected until day of discharge or up to 30 days postpartum, whichever occurs first. The data for this study will be collected from the Sentara EPIC and VHS EPIC electronic medical record.

4.7. Adverse Event Reporting

Detailed information concerning adverse events will be collected and evaluated throughout the conduct of the protocol. Adverse events will be reported to the Institutional Review Board per policy.

4.8. Study Outcome Measures

4.8.1. Primary Outcome

The primary outcome is mean fasting blood sugars for the first 7 days after

randomization

4.8.2. Maternal and Neonatal Secondary Outcomes

Secondary outcomes collected will include the following. For a full list of collected outcomes, please see the attached data collection forms in Appendix 1.

- Hypertensive disorders of pregnancy
- Preterm birth < 34 weeks and <37 weeks, both spontaneous and indicated;
- Operative vaginal delivery and cesarean delivery;
- Estimated and quantitative blood loss;
- Blood transfusion;
- Maternal morbidity and adverse maternal outcomes, including endometritis / chorioamnionitis, wound infection, venous thromboembolism, massive transfusion and postpartum hemorrhage, ICU admission, and maternal death.
- Fetal antepartum, intrapartum, or neonatal death;
- Neonatal intubation, continuous positive airway pressure (CPAP) or high-flow nasal cannula (HFNC) for ventilation or cardiopulmonary resuscitation within first 72 hours;
- Neonatal hypoglycemia (glucose < 35 mg/dl) requiring IV glucose therapy;
- Neonatal birth weight;
- Neonatal encephalopathy as defined by the NICHD Neonatal Research Network criteria;
- Shoulder dystocia;
- Neonatal birth trauma (bone fractures, brachial plexus palsy, other neurologic injury, retinal hemorrhage, or facial nerve palsy);
- Neonatal intracranial hemorrhage (intraventricular hemorrhage, subgaleal hematoma, subdural hematoma, or subarachnoid hematoma)
- Neonatal hyperbilirubinemia requiring phototherapy or exchange transfusion
- NICU admission

5. Statistical Considerations

5.1. Data Relevant to the Primary Outcome

Prior data suggests that fasting blood sugar levels of 102.6 mg/dL in patients newly diagnosed with gestational diabetes[8].

5.2. Sample Size and Power

Assuming a standard deviation of 20 mg/dL and a 10% decrease in fasting blood sugar after taking a bedtime snack, a total of 120 patients will provide 80% power and an alpha of 0.05. Accounting for a 10% loss to follow up rate, a total of 134 mother-infant dyads will be enrolled in the trial.

5.3. Planned Analyses

Continuous variables will be analyzed using Student's t-test or Mann-Whitney-U test as appropriate. Categorical variables will be compared using Chi-squared or Fisher's exact tests as appropriate.

6. Data collection and security

Data collection will be done using REDCap database. Only individuals who are included as investigators or study personnel will be granted access to the database. The main REDCap database will NOT include any protected health information; patients will be identified by a unique Study ID. There will be a separate secure database at linking Study ID with the patient's MRN. User access will be granted by the PI only to IRB-approved site personnel. When study personnel/investigators are no longer part of the institution or study, the PI will be notified and their access to the database will be immediately discontinued.

References

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