Continuous Glucose Monitoring Initiation at Hospital Discharge: A Feasibility Pilot Sutdy

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A Introduction & Background

Diabetes is a very common comorbidity in hospitalized patients. Patients with diabetes are highly likely to be hospitalized, with insulin use increasing this likelihood (1). It is estimated that up to 38% of patients in the hospital have diabetes or hyperglycemia, and likely many more have pre diabetes (2). Diabetes is associated with worse hospital outcomes including increased risk for falls, infections and readmissions. The hospital stay represents an opportunity to intervene and optimize diabetes management. Patients at our hospital also have access to specialized services including endocrinologists and certified diabetes educators. However, diabetes is a complex disease and is common for patients to feel overwhelmed with the burden of therapy. Continuous glucose monitors (GCMs) are commercially FDA approved devices for single-patient use that can measure interstitial glucose every 5 minutes. They vary slightly in the number of wear days, display and need of calibrations. Studies have shown that CGM use improves diabetes control and decrease episodes of hypoglycemia (3-5). One barrier for the effectiveness is uptake, they are not prescribed enough by primary care providers, another significant barrier has been cost. The overall goal of this current study is to assess the feasibility of initiating CGM in patients with diabetes at discharge. This strategy has the potential to overcome delay in accessing the technology and control cost.

One study looked at the feasibility of use in older patients with diabetes and dementia in the outpatient setting. In this study, of 17 people consented and 12 completed the study. Patient and caregivers reported that the device was nonintrusive and responded positively about recommending the device (6). Another study in the outpatient setting found that a total of 22 participants (48.9%) completed the study using the minimum number of 3 FreeStyle Libre sensors with 11 of the participants requiring extra sensors due to a faulty or misplaced sensor (7). One study using a 4 month Telehealth outpatient model utilizing CGM, showed 92% (55/60) completed the 4-month intervention, and 78.2% (43/55) met the criteria of follow-up CGM sensor–wear periods >90 days from baseline. This study showed improved time in range and a decrease in A1C by 1.6% (8).

B Study Objectives

B1 Primary Aim

To determine the feasibility of initiating a continuous glucose monitoring in patients with diabetes at hospital discharge. We hypothesize that starting and continuing to use a CGM at this critical time is feasible. Feasibility is defined as at least 20% of patients with diabetes referred for diabetes education meet inclusion criteria to participate and 75% agree to

participate. From those who participate, at least 50% continue using the CGM at 3 months.

B2 Secondary Aims

1. To characterize the barriers to continuing CGM use after discharge. We will systematically characterize the reasons for discontinuations (issues with wearing device, use, costs, getting refills, etc.)

2. To assess the effect of CGM initiation at hospital discharge on diabetes outcomes: Time in range, health utilization (clinic visits, ED visits, hospitalization), self-efficacy.

C Study Design

C1 Overview or Design Summary

This study will be an interventional, single-arm, open-label, prospective design.

C2 Subject Selection and Withdrawal

One hundred eligible adult patients will be recruited to the study.

2.a Inclusion Criteria

1. 18 years of age or older
2. Have diabetes (type 1 diabetes mellitus, type 2 diabetes mellitus, cystic fibrosis related diabetes mellitus)
3. Hemoglobin A1c greater than or equal to 8.0% or history of hypoglycemia unawareness
4. Able and willing to sign informed consent form
5. Have a valid telephone number
6. Willing to purchase FreeStyle Libre 2 CGM sensors out of pocket after discharge from hospital

2.b. Exclusion Criteria

1. Unable to sign informed consent form
2. Have altered mental status
3. Unable to manage diabetes independently at home
4. Have utilized CGM in the past
5. Pregnancy
6. New steroid-induced hyperglycemia
7. Unwilling to participate in the study
8. Have kidney disease requiring hemodialysis
9. Taking high doses of vitamin C daily (greater than 500 mg every day)

2.c Subject Recruitment Plans and Consent Process

The study team will identify potential participants from patients referred to the diabetes service or diabetes education service. Once a participant is identified, one of the study team members will approach the patient in their private hospital room, review the study and provide them with a written informed consent form to review. The study team will follow up 1-2 days later or prior to discharge to determine if the patient is interested in participating. If the patient is interested, the study team will review the informed consent form with them, answer all study related questions and obtain written informed consent. If a patient is not interested in the study, the study team will not coerce them into participating; participation is completely voluntary.

2.d. Risks and Benefits

Participants may or may not benefit from participating in the study. Benefits of participating in the study may include the following:

1. Improved understanding of diabetes
2. Improved ability to manage diabetes
3. Discover glucose patterns previously unaware of.

Potential risks of participating in the study include the following:

1. Improperly treated diabetes risks may include: hypoglycemia, hyperglycemia, or ketoacidosis.
2. CGM sensor insertion risks may include: feeling like insulin injection; tenderness at the sensor site.
3. Pain, redness, swelling, minor infection and minor bleeding at the sensor insertion site.
4. Redness may occur where the device adhesive pads are placed.
5. Allergic reaction to one of more parts of the sensor.
6. Skin may blister or peal at the site of the sensor.
7. Sensor or insertion needle may break.
8. Fingerstick testing risks may include: finger feel sore, tender or may bleed.
9. Questionnaire risks may include: some questions may cause the participant to feel uncomfortable.

2.e. Early Withdrawal of Subjects

Participants may be withdrawn if certain situations arise:

1. Participant does not follow study instructions
2. Change in participant's medical condition (i.e., pregnancy, worsening clinical condition)
3. The study team of government agencies stop the study
4. In the opinion of the study team, there is no value in participant continuing the study.

5. If new information becomes available or harmful unexpected reactions are experienced by participants in the study.

C3 Study Device

3.a Description

FreeStyle Libre 2 Continuous Glucose Monitoring System manufactured by Abbott

D Study Procedures

D1 Screening for Eligibility

The study team will identify potential participants from patients referred to the diabetes service or diabetes education service. Once a potential patient has been identified, one of the study team members will review the inclusion/exclusion criteria to determine if the patient is eligible to participate.

D2 Schedule of Measurements

VISIT/PHONE CALL (estimated time) [window]	WHAT WILL HAPPEN?
Screening Visit (~45 minutes)	Review consent form and obtain consent Complete questionnaire, obtain diabetes history
Day of Discharge (~1 hour)	Complete FreeStyle Libre 2 CGM education Attach FreeStyle Libre 2 CGM sensor to your arm
Within 1-3 weeks from discharge Phone Call (~30 minutes)	Questions regarding use of FreeStyle Libre 2 CGM Current diabetes regimen Adverse Events Reminder to take FreeStyle Libre 2 CGM sensor prescription to pharmacy to be filled
1 & 3 Month Phone Call (~45 minutes) [+/- 5 days]	Questions regarding use of FreeStyle Libre 2 CGM Current diabetes regimen Complete questionnaire Adverse Events
6 Month Phone Call (~15 minutes) [+/- 10 days]	Questions regarding use of FreeStyle Libre 2 CGM Barriers to FreeStyle Libre 2 CGM use

D3 Visit 1a: During Hospital Stay

Study team member will meet with participant, review informed consent form and obtain written consent. Study team member will obtain the following information from patient or medical record after consent is obtained:

1. Most recent A1c

2. Heigth/Weight; calculate body mass index (BMI)
3. Year of diagnosis with diabetes
4. Type of diabetes
5. Has patient been admitted to the hospital or emergency department in the past 3 months for a diabetes related problem
6. Home diabetes regimen
7. Hospital diabetes regimen
8. Hospital discharge treatment regimen
9. Participant's reason/goal for using FreeStyle Libre 2 CGM
10. Does participant have frequent hypoglycemia or hypoglycemia unawareness
11. Complete "Diabetes Self-Management Questionnaire"

D4 Visit 1b: Day of Hospital Discharge:

On the day of participant's discharge from the hospital, one of the diabetes educators will complete the following with the participant:

1. Teach participant how to set up the FreeStyle Libre 2 CGM
2. Teach participant how to attache the FreeStyle Libre 2 CGM sensor to the upper arm
3. Teach participant how to measure blood glucose with FreeStyle Libre 2 CGM reader or personal smart phone
4. Assist participant download the free FreeStyle Libre 2 app from the app store on smart phone
5. Teach participant how to trouble shoot the FreeStyle Libre 2 CGM system
6. Provide participant with a handout for FreeStyle Libre 2 CGM system

The study physicians or nurse practitioners will provide the participant with a written prescription for three months of the FreeStyle Libre 2 CGM sensors to be filled by participant at their local pharmacy.

D5 Follow Up Telephone Calls

Within 1-3 Weeks after Discharge:

The study team will contact the participant by telephone to obtain the following information:

1. Is the participant still utilizing the FreeStyle Libre 2 CGM? If not, why was it stopped?
2. What barriers (such as discomfort, behavior modifications, lifestyle changes, diet changes) did the participant have with the FreeStyle Libre 2 CGM to limit use?
3. How satisfied with the FreeStyle Libre 2 CGM is the participant?
4. Has the participant been admitted to the hospital or been in the emergency department for a diabetes related problem since discharge?
5. Has the participant seen their outpatient diabetes provider since discharge?
6. What is the participant's current diabetes treatment regimen?

7. The study team will contact the participant to remind them to fill the prescription for a new FreeStyle Libre 2 CGM sensor with local pharmacy.

One Month after Discharge (+/- 5 days):

The study team will contact the participant by telephone to obtain the following information:

1. Is the participant still utilizing the FreeStyle Libre 2 CGM? If not, why was it stopped?
2. What is the average blood glucose for the past 30 days?
3. What barriers (such as discomfort, behavior modifications, lifestyle changes, diet changes) did the participant have with the FreeStyle Libre 2 CGM to limit use?
4. How satisfied with the FreeStyle Libre 2 CGM is the participant?
5. Has the participant been admitted to the hospital or been in the emergency department for a diabetes related problem since discharge?
6. Has the participant seen their outpatient diabetes provider since discharge?
7. What is the participant's current diabetes treatment regimen?
8. Administer the Diabetes Self-Management Questionnaire

Three Months after Discharge (+/- 5 days):

The study team will contact the participant by telephone to obtain the following information:

1. Is the participant still utilizing the FreeStyle Libre 2 CGM? If not, why was it stopped?
2. What is the average blood glucose for the past 30 days?
3. What barriers (such as discomfort, behavior modifications, lifestyle changes, diet changes) did the participant have with the FreeStyle Libre 2 CGM to limit use?
4. How satisfied with the FreeStyle Libre 2 CGM is the participant?
5. Has the participant been admitted to the hospital or been in the emergency department for a diabetes related problem since discharge?
6. Has the participant seen their outpatient diabetes provider since discharge?
7. What is the participant's current diabetes treatment regimen?
8. Administer the Diabetes Self-Management Questionnaire

Six Months after Discharge (+/- 10 days):

The study team will contact the participant by telephone to obtain the following information:

1. Is the participant still utilizing the FreeStyle Libre 2 CGM? If not, why was it stopped?

2. What barriers (such as discomfort, behavior modifications, lifestyle changes, diet changes) did the participant have with the FreeStyle Libre 2 CGM to limit use?

E Safety Monitoring

E1 Safety and Compliance Monitoring

The study team will meet every other week to review the status of the study, progress of recruitment, and adverse events. The study team will communicate directly with one another in between scheduled study team meetings if an unexpected adverse event occurs.

E2 Medical Monitoring

The study team will monitor patients throughout their participation in the study. Any adverse event or unexpected adverse event will be brought to the prinicipal investigator within 24 hours of study team notification of event.

F Statistical Plan

F1 Sample Size Determination and Power

One hundred patients will be recruited for the study with the anticipation that 50% will agree to participate in the study.

F2 Statistical Methods

Statistical methods will include descriptive statistics (means, SD, median, IQR) and pre-test/post-test ANOVA for the questionnaire.

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