

Title:

Impact of more lenient A1C goals on hypoglycemic episodes in type 2 diabetic food insecure patients

Incentive Grant Category:

Residents and their Preceptors

Introduction:

The United States Department of Agriculture (USDA) defines food insecurity as a household level economic and social condition of limited or uncertain access to adequate food. Food insecurity can have a significant impact on patients with type 2 diabetes because patients are unable to easily access healthier food options.¹ In 2018, the USDA reported that 11.1% of American households were food insecure during some time of the year.¹ The incidence of food insecurity in diabetes can be up to 20%.² Patients living with diabetes and food insecurity have a higher chance of experiencing uncontrolled hyperglycemia and episodes of severe hypoglycemia, some leading to emergency visits and hospitalizations.³ The 2021 American Diabetes Association (ADA) Standards of Care guidelines recommend considering the risk of hypoglycemia when choosing medications and connecting patients with local resources to help reduce incidences of hypoglycemia. The guidelines also state that for diabetic patients living with food insecurity, the priority should be to reduce the increased risk for severe hypoglycemia and uncontrolled hyperglycemia. The recommended A1C goal per ADA is < 7%; however, a less stringent A1C goal (such as < 8%) may be more appropriate for certain patient populations. This less stringent goal may be beneficial in patients with a history of hypoglycemia, extensive comorbid conditions, and long-standing diabetics within whom reaching the goal is difficult to achieve despite self-management education, appropriate glucose monitoring, and effective doses of multiple glucose lowering agents.² The guidelines also address individualizing treatment based on social factors and recommends screening patients for food insecurity, as well as other social community barriers.²

For research purposes, the USDA published a food insecurity scale, known as the Household Food Security Survey. This 18-item survey is used to validate patients at a high risk for food insecurity. This scale has been shortened to a validated two-item survey for use as a screening tool in healthcare settings. If a patient answers “yes” to either one of the questions they are considered to be in a high risk food insecurity household.³

This research project attempted to evaluate if a more lenient A1C goal for type 2 diabetic patients with food insecurity could result in fewer incidences of hypoglycemia. Patients were identified at two of Inova Safety Clinics: Inova Cares Clinic for Community Bridging and Inova Juniper Program Prosperity which are both located in Fairfax, Virginia. Inova Cares Clinic for Community Bridging (ICCCB) offers support to patients discharged from an Inova hospital or emergency room who either do not have a medical home or cannot get an appointment with their primary care physician within 72 hours of discharge. The Inova Juniper Program serves as the

largest provider of HIV/AIDS care in Northern Virginia. Both clinics are designed to support medically vulnerable populations who require intense chronic care follow-up. The clinics staff includes any of the following health care professionals: hospitalists, nurse practitioners, nurses, case managers, and clinical pharmacists.

Objectives:

The objectives of this study were: 1) Identify type 2 diabetic patients at risk for food insecurity within Inova Safety Clinics, 2) identify type 2 diabetic patients with food insecurity and a history of multiple hypoglycemic episodes or severe hypoglycemia, and 3) determine if adjustment in A1C goals in type 2 diabetic food insecure patients will result in fewer episodes of hypoglycemia.

Methods:

The methods for this research project had to be adjusted due to staffing changes at the ICCCB during the study. Prior to the start of the study, all providers at the clinic were sent information concerning the study and verbally consented to participate.

As of March 2021, the clinical pharmacist resigned from the ICCCB clinic resulting in the clinic no longer having a clinical pharmacist. However, the Inova Juniper Program Prosperity site maintained a clinical pharmacist. To maintain consistency, both sites followed the same recruitment as outlined below.

Study population and Respondent Recruitment

A chart review was completed in Epic®, an electronic health record system, by the pharmacy resident each day to identify patients who were visiting the clinic for diabetic needs. A clinical message identifying eligible patients was sent to providers that included the patients' medical record number, time of visit, and food insecurity survey questions for the provider to ask in the upcoming appointment.

A similar process was used to identify hypoglycemic patients. Once a patient was identified as positive for food insecurity, a chart review was conducted to determine if they met hypoglycemic eligibility criteria: self-monitoring or plasma blood glucose < 70 mg/dL or a severe hypoglycemia episode, defined as severe cognitive impairment requiring external assistance for recovery,² in the last six months. If a patient was found to be food insecure and had a history of hypoglycemia, a clinical message was sent to the provider about potentially including the patient in the study.

Study Design:

Patients were screened for food insecurity during their appointment at either ICCCB or Inova Juniper Program in Fairfax, VA. Patients were screened utilizing the first two questions from the U.S Household Food Security survey (Table 1) to determine if they qualified as food

insecure. Patients were considered positive for food insecurity if they answered “sometimes true” or “often true” for either question.

Providers utilized the information provided regarding food insecurity status and hypoglycemia history to manage the patient’s diabetes therapy. Patients were given a more lenient A1C goal by increasing their current goal by 0.5% with a maximum goal of 8.5% for any given patient. Following this initial visit, chart reviews were completed for the remainder of the patients’ enrollment in the study. The chart review assessed for hospitalizations for hypoglycemia and documented blood glucose readings after seeing the provider.

Data collection:

The study received IRB approval from Inova Health Systems outside contractor, Western Institutional Review Board (WIRB). The initiation of the study was delayed due to the reorganization of the IRB approval process. Data collection included in this report was collected from April 2021 - May 2021.

Early in the study, providers would share the food insecurity results with the pharmacy resident. As the study progressed, the medical director and pharmacy resident worked to create a dot phrase in Epic®, “itsfoodinsecurity.” A dot phrase in Epic® is a saved template of text used to write notes during patient visits. This specific dot phrase included the two food insecurity questions which offered the providers an easy and consistent way to access the survey and document in the patients’ charts.

Data analysis:

Statistical analysis was performed by an outside statistician with de-identified data. All analyses were performed using SAS® with statistical significance assumed for $p \leq 0.05$, two-tailed. Group comparisons were established with Fisher’s Exact test or Wilcoxon Rank-sum test.

Results:

Sixteen patients were screened and a total of fifteen patients completed the abbreviated U.S. Household Food Security survey. Out of these fifteen patients, three met the criteria for documented history of hypoglycemia.

Nine of the fifteen patients (60%) surveyed were found to be positive for food insecurity. The average age for these patients in both groups were between 46 – 50 years old and the average most recent hemoglobin A1C documented was approximately 11%. There were slightly more males who tested positive for food insecurity and those with hispanic/latino ethnicity had the highest percentage of food insecure patients. A further breakdown of the specific characteristics of the food insecure patients is found in Table 2.

There were a total of three patients identified by chart review who had a documented history of hypoglycemia. Of those three patients, two tested for food insecurity and enrolled into

the study per the provider. The first patient was a 58 year old Caucasian male with a documented history of blood glucose < 70 mg/dL; the specific blood glucose value was not documented. Prior to the enrollment in the study, this patient had an A1C of 12.1 and his medications included insulin NPH 70/30 10 U twice daily and metformin 1,000 mg twice daily. At first, his medications were not adjusted because he had one documented episode of hypoglycemia. However, after reporting another episode of hypoglycemia at his follow up visit 2 weeks later, the insulin was discontinued and he was initiated on glipizide 2.5 mg daily with the intention of titrating up based on blood glucose readings. His A1C goal started as <7% and was adjusted to <7.5%. This patient has not had reported signs and symptoms of hypoglycemia or had a blood glucose reading < 70 mg/dL since the medication adjustments.

The second patient was a 63 year old Hispanic male with documented signs and symptoms of hypoglycemia: shakiness, dizziness, and polyphagia. He presented to his first appointment with these symptoms and they resolved within 15 minutes after receiving apple juice. The patient stated “he has no money for food right now” and reported eating mainly fruit and occasionally bread with meat. At the initial visit, he was taking metformin 1,000 mg twice daily, glipizide 10 mg twice daily and Bydureon (exenatide extended release) 0.2 mg weekly. The patient’s A1c goal was < 7% and subsequently was increased to < 7.5%. Since this patient was enrolled later in the study period, he has only had one follow up, in which he reported less frequent symptoms of hypoglycemia and his blood glucose log contains no blood glucose readings < 70 mg/dL . He has been provided resources to assist with his food insecurity.

Discussion:

The results from the food insecurity survey suggest that the Inova Safety Clinics provides care to patients facing issues with food insecurity. The last calculated percentage for food insecure patients in Virginia was 22.5%⁵ as of April 2020. The percentage of surveyed patients who were identified as having food insecurity was 60%, which is much higher than the state’s average. However, this number may be higher than the average because of our small sample size and our study specifically focused on clinics made to serve underrepresented populations. Additionally, these results are consistent with the current food insecurity numbers presented by Fairfax County which is where the clinic is located. According to the Fairfax County website, although it has an overall low food insecurity-rate, the county is home to the highest number of food insecure patients in the state (approximately 58,000 residents).⁶ This research project allowed the clinic to identify potential barriers to their patients' diabetes care and assess if food insecurity surveys should be continued long term to identify this vulnerable population.

We were only able to capture three patients with documented history of hypoglycemia during the course of this research project. Despite the history of hypoglycemia, the average hemoglobin A1C for patients who tested positive for food insecurity was around 11% (Table 2). As mentioned in the introduction, research has shown that patients with food insecurity are at an

increased risk of uncontrolled hyperglycemia or severe hypoglycemia, but there are no studies demonstrating if a patient is at a higher risk of one compared to the other. In our study, it appears more patients had severe hyperglycemia. This finding could be specific to our geographic location or patient population, or may suggest that food insecurity places patients at a higher risk of hyperglycemia compared to hypoglycemia. Further research with large sample sizes could give clinicians a better idea of how to properly manage patients with food insecurity.

The two hypoglycemic patients who had interventions based on their positive food insecurity screening both had fewer episodes of reported hypoglycemia at later visits. This may suggest that increasing a patient's hemoglobin A1C goal may result in less episodes of hypoglycemia; however, a larger study would need to be conducted to come to this conclusion. Also, due to the short data collection period, we were not able to reassess the patients' hemoglobin A1C after 3 months. This follow up A1C would allow us to determine if a patient's diabetes was still relatively controlled despite having more lenient management.

This study had the following limitations. The biggest limitation was the absence of a clinical pharmacist at ICCCB during the course of this research. This made it difficult to recruit and manage the participants' diabetes. Although providers were messaged a daily list of patients to give the survey to, many times the providers would forget. The research team discussed giving paper surveys to patients prior to their visit; however, this idea was declined by the clinic staff. Another downside to not having a clinical pharmacist was any recommendations for adjustments had to be approved by the provider versus a clinical pharmacist making the adjustments based on a collaborative practice agreement. Additionally, the clinic's high no-show rate served as a limitation. There were several days that a large number of patients would be identified for potential inclusion in the study and only half of those patients came to their appointment. Lastly, another major limitation was the short duration of the study. Unfortunately due to delays in the IRB approval process, the originally planned six month study was condensed into a one and a half month study. This not only limited enrollment of patients, but also we were not able to see the full benefit of interventions made based on the study's protocol.

Conclusion:

Due to the small sample size of hypoglycemic patients, it is hard to make a conclusion about whether adjusting their A1C goal will result in fewer episodes of hypoglycemia. Further research should be conducted to see the full emphasis of adjusting A1C goals. However, food insecure patients were identified during this research project by utilizing the Household Food Security survey. This suggests that adding this survey to the ICCCB and Inova Juniper Program workflow could assist in identifying diabetic patients with food insecurity, regardless of if they're experiencing hypo- or hyperglycemia.

Evaluation Strategy:

This research project was reviewed by the Institutional Review Boards of INOVA Health Systems and the WIRB. The research progress was evaluated on a weekly basis by the post-graduate year two (PGY2) ambulatory care resident, two residency research preceptors, and the PGY2 ambulatory care residency director. Participants were enrolled based on their responses to the food insecurity survey.

Maya Edmond, PharmD - Resident and Primary Investigator

Qualifications: Dr. Edmond is a PGY2 Ambulatory Care resident with INOVA Health Care Systems. She completed a PGY1 Pharmacy residency at MedStar Union Memorial Hospital, where she completed an IRB-approved research project and presented her results in person and virtually to hospital pharmacists and staff as well as an additional conference.

Role: Dr. Edmond will serve as the primary investigator. She will be responsible for submitting IRB approval to both INOVA Health Systems and Shenandoah University. She is also responsible for executing the project, which includes but is not limited to, assuring the clinic and patients have needed tools/materials, collecting and interpreting data, and presenting research findings.

Erin N. Adams, PharmD, BCACP - Research Preceptor

Qualifications: Dr. Adams is an Associate Professor and Vice-Chair of the Department of Pharmacy Practice at Shenandoah University. In her role, she mentors and works with faculty in developing their teaching, clinical services and research and scholarship. She has completed a PGY-1 Residency focused in ambulatory care. She has also served as an ambulatory care clinical pharmacist at Fairfax Family Practice where she has provided care to patients for a variety of conditions, including diabetes. She has been active in training student pharmacists to be advocates for patients for affordable healthcare.

Role: Dr. Adams will commit 10% of her work week to assist the primary investigator. She will help address related questions and concerns from patients and providers. Dr. Adams will also assist w/ project decisions, analyzing results and dissemination of the results.

Dr. Caitlin Prather, PharmD, AAHIVP, TTS - Research Preceptor

Qualifications: Dr. Prather is a clinical pharmacist and preceptor to pharmacy residents and students in Inova Prosperity Clinic. One of her clinical focuses is managing diabetes in patients with HIV and educating patients on their disease, adjusting medications, and following up with outcomes.

Role: Dr. Prather will commit 10% of her work week to assist the primary investigator. She will help address related questions and concerns from patients and providers. Dr. Prather will also assist with project decisions, analyzing results, and dissemination of the results.

Dr. Jonathan Puhl, PharmD - PGY-2 Ambulatory Care Residency Director

Qualifications: Dr. Puhl is the Ambulatory Care Pharmacy Manager at INOVA Fairfax Hospital in Fairfax, VA. He also serves as the PGY2 Ambulatory Care Residency Program director.

Role: Dr. Puhl will oversee the execution of the project. He will help address related questions related to the administration behind this research project.

Dr. Whitney Zentgraf initially signed on as the clinical pharmacist at the Inova Cares Clinic for Community Bridging (formally known as the Inova Transitional Clinic) but left prior to initiating the study. She was removed from the study protocol and replaced by Dr. Prather.

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I would like to thank the American Pharmacists Association for providing our research team with grant funding through the Incentive Grant for residents. With this money, we were able to purchase Reli-on Premier Classic and Prime glucometers as well as accompanying test strips and lancets for patients at Inova Safety Clinics. Funding was also used to help compensate our outside statistician.

References:

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