

Flash CGM Associated With Event Reduction in Nonintensive Diabetes Therapy

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The increasing costs of avoidable hospitalizations and emergency department (ED) utilizations resulting from diabetes-related adverse events are creating an unsustainable economic burden on private and public health insurers.¹ In a recent study, the total cost of diagnosed diabetes in the United States in 2017 was estimated to be \$327 billion.² Data showed that approximately \$90.1 billion was spent on diabetes-related inpatient hospitalizations (\$69.7 billion), outpatient treatment (\$12.1 billion), ED utilization (\$8.0 billion), and ambulance services (\$32.0 million) during 2017 in the United States.²

Numerous study findings have shown that use of flash continuous glucose monitoring (CGM) is associated with improved glycemic control,^{3,7} reductions in hypoglycemia,^{3,5} fewer diabetes-related hospitalizations,^{3,5} decreased absenteeism,^{3,4} and improvements in treatment satisfaction^{3,8} in individuals with type 1 diabetes (T1D). Although similar benefits have been shown in individuals with type 2 diabetes (T2D) treated with intensive insulin therapy,^{4,9-11} the clinical utility of flash CGM in conjunction with basal or noninsulin treatment regimens has not been demonstrated.

The FreeStyle Libre 14-day flash glucose monitoring system (Abbott Diabetes Care) and the FreeStyle Libre 2 flash glucose monitoring system (Abbott Diabetes Care; FDA cleared on June 15, 2020) are the only flash CGM systems currently available in the United States. Unlike traditional blood glucose meters, which provide only a single “point-in-time” glucose value, flash CGM systems utilize a single-use, factory-calibrated sensor that continuously measures interstitial glucose levels. By scanning the sensor with a reader or smartphone, the user can view the current glucose value, the glucose pattern over the past 8 hours, and trend arrows that indicate the direction and velocity of changing glucose levels.

We assessed the effects of acquiring the flash CGM system on inpatient and emergency outpatient acute diabetes-related event (ADE) and all-cause inpatient hospitalization (ACH) rates in a large population of patients with T2D who received basal or noninsulin therapy.

ABSTRACT

OBJECTIVES: We evaluated the effects of acquiring a flash continuous glucose monitoring (CGM) system in the population with type 2 diabetes (T2D) treated with basal or noninsulin therapy.

STUDY DESIGN: This was a retrospective database analysis of the IBM MarketScan Commercial Claims and Medicare Supplemental databases that assessed rates of acute diabetes-related events (ADEs) and all-cause inpatient hospitalizations (ACHs) in a large population with T2D treated with basal insulin therapy or noninsulin medications. ADE and ACH rates 6 months prior to and 6 months post CGM acquisition were compared.

METHODS: Inclusion criteria for analysis were diagnosis of T2D; age 18 years or older; treatment with long-acting, neutral protamine Hagedorn, or premixed insulin or noninsulin therapy; naïve to CGM; and acquisition of their flash CGM system between October 2017 and March 2019. Patients served as their own controls. Event rates were compared using weighted Cox regression with Andersen-Gill extension for repeat events.

RESULTS: A cohort of 10,282 adults with T2D (mean [SD] age, 53.1 [9.6] years; 51.9% male) who met inclusion criteria were assessed. ADE rates decreased from 0.076 to 0.052 events per patient-year (HR, 0.68; 95% CI, 0.58-0.80; $P < .001$). ACH rates decreased from 0.177 to 0.151 events per patient-year (HR, 0.85; 95% CI, 0.77-0.94; $P = .002$).

CONCLUSIONS: Acquisition of the flash CGM system was associated with significant reductions in outpatient and inpatient ADEs and ACHs. These findings provide compelling evidence that use of flash CGM in patients with T2D treated with basal insulin therapy or noninsulin therapy improves clinical outcomes and potentially reduces costs.

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METHODS

Study Design

This retrospective cohort study utilized an analysis structure with prespecified outcomes to assess the effects of acquiring the flash CGM system within a large group of adults with T2D treated with basal insulin (defined as long-acting, neutral protamine Hagedorn, or premixed insulin) or noninsulin therapy—the overall cohort defined by the absence of intensive insulin therapy. Individuals treated with rapid- or short-acting insulin were excluded.

Data Sources

Patient data were obtained from the IBM MarketScan Commercial Claims and Medicare Supplemental databases, which capture paid and adjudicated billing claims from inpatient hospital stays, outpatient encounters, and pharmacy prescriptions for more than 30 million privately insured and Medicare supplemental patients throughout the United States. These nationally representative databases have been used to support publications in the field of diabetes research.^{12,13} The databases allow for longitudinal patient follow-up, but patients can be lost to follow-up for a variety of reasons, including switching employers, switching insurance, losing a job, or death. The data sets do not contain information on why a patient is no longer under observation.

Participants

The analysis included patients with a diagnosis of T2D, aged 18 years or older, naïve to CGM, and who acquired their flash CGM system during the period between October 2017 and March 2019. To select patients on basal insulin or noninsulin therapy, we excluded those with a purchase of short- or rapid-acting insulin in the 6 months prior to flash CGM acquisition. Patients without observed diabetes medications were included in the noninsulin therapy subgroup. Note that although the FreeStyle Libre 2 system is commercially available as of July 2020, it was not available during the observation period, which ended in September 2019. Patients were excluded if they did not have at least 6 months of database enrollment prior to the flash CGM system purchase or had gestational diabetes in the same time frame. Each patient served as their own control.

Procedures

International Classification of Diseases, Ninth Revision (ICD-9) and *Tenth Revision (ICD-10)* codes were used to identify patients with diagnosed T2D. In the rare case that the most recent claim had billing codes related to both T1D and T2D, the patient was not included. *ICD-9* and *ICD-10* codes were also used to identify prevalence of comorbidities within the study cohort.

TAKEAWAY POINTS

- ▶ Flash continuous glucose monitoring (CGM) use lowers glycated hemoglobin A_{1c} and reduces the incidence and severity of hypoglycemia in patients with type 2 diabetes (T2D) treated with intensive insulin regimens; however, CGM use with basal insulin or noninsulin therapy has not previously been studied.
- ▶ This retrospective cohort study utilized an analysis structure with prespecified outcomes to assess the effects of acquiring the flash CGM system within a large group of adults with T2D treated with basal insulin or noninsulin therapy.
- ▶ Significant reductions in acute diabetes-related events and all-cause hospitalizations were observed in a cohort of 10,282 adults with T2D treated with basal or noninsulin therapy who used flash CGM for 6 months.
- ▶ Use of flash CGM in patients with T2D treated with basal or noninsulin therapy improves clinical outcomes and potentially reduces health care resource utilization and associated costs.

Within the selected population, National Drug Code (NDC) data were used to identify patients who acquired a flash CGM system and to exclude patients who were treated with short- or rapid-acting insulin therapy within 6 months prior to system acquisition. Patients with evidence of prior CGM purchase, including sensor, transmitter, or receiver, were excluded. NDC sets compiled through medical expert review were also used to estimate noninsulin diabetes medication usage in the same time window.

Outcome Measures

The primary outcome measure was change in ADE rates during the 6 months following system acquisition compared with 6 months prior to use. Acute events included hypoglycemia, hypoglycemic coma, hyperglycemia, diabetic ketoacidosis (DKA), and hyperosmolarity. These were identified as either inpatient events, with the associated *ICD-10* code as the primary diagnosis code, or emergency outpatient events, which included ED services, urgent care, or ambulance services with the associated *ICD-10* code in any position. For each patient, medical billing codes associated with the same service or admit date were counted as a single event. The change in ACH rates was assessed as a secondary outcome. Event rates were calculated by dividing the number of observed events by the total observation time.

Statistical Analysis

The analysis was structured with the patient as their own control. Rates for all primary and secondary measures were calculated in the 6-month windows pre- and post system purchase but are reported as events per patient-year. Rates were adjusted for variable follow-up after system purchase. Cumulative events figures are based on the Nelson-Aalen estimator. All HRs, 95% CIs, and *P* values are based on weighted Cox regression with Andersen-Gill extension for repeated events, adjusted for all comorbidities and insulin usage status as listed in [Table 1](#). Weighted Cox regression is used to account for nonproportionality of hazards, as tested via Schoenfeld residuals. All *P* values are reported without correction for multiple comparisons. RStudio version 1.0.153 with R version 3.4.0 (R Foundation for Statistical Computing) was used for statistical analysis.

TABLE 1. Patient Characteristics

Characteristic	Value
N	10,282
Follow-up in days, median (10%, 90% deciles)	171 (152, 182)
Age in years, mean (SD)	53.1 (9.6)
Aged 18-49 years	32.3%
Aged 50-64 years	62.5%
Aged ≥ 65 years	5.2%
Gender (male)	51.9%
Comorbidities	
Hypertension	80.6%
Obesity	55.6%
Pulmonary disease	24.5%
Depression	24.2%
Hypothyroid disease	21.5%
Anemia	19.2%
Liver disease	18.5%
MI or coronary artery disease	15.8%
Peripheral vascular disease	10.8%
Renal disease	9.6%
Heart failure	6.9%
Insulin usage status	
Insulin (basal/NPH/premixed)	38.7%
Noninsulin therapy	61.3%
Noninsulin diabetes medications	
Biguanide	71.2%
Sulfonylurea	30.4%
GLP1 agonist	30.3%
SGLT2 inhibitor	26.2%
DPP4 inhibitor	20.6%
TZD	7.4%
Meglitinides	1.6%
Alpha-glucosidase inhibitor	0.4%

DPP-4, dipeptidyl peptidase-4; GLP-1, glucagon-like peptide-1; MI, myocardial infarction; NPH, neutral protamine Hagedorn; SGLT2, sodium-glucose co-transporter 2; TZD, thiazolidinedione.

RESULTS

Patient Characteristics

We identified a cohort of 10,282 adult patients with T2D for assessment. The majority of patients were younger than 65 years, most had hypertension, and more than half were obese. Patient characteristics are presented in Table 1.

Outcomes

During the post-system acquisition period (171 days median follow-up), the rate of ADEs decreased from 0.076 to 0.052 events/patient-year (HR, 0.68; 95% CI, 0.58-0.80; $P < .001$) (Figure 1 [A]). The ACH rate decreased from 0.177 to 0.151 events/patient-year (HR, 0.85; 95%

CI, 0.77-0.94; $P = .002$) (Figure 1 [B]). The majority of ADEs were outpatient emergency events (Table 2). In addition, an examination of the unique patients affected by these events indicates that repeated events did not dominate. Less than 0.7% of patients experienced more than 1 ADE in a given pre- or postacquisition period.

Further analyses by gender, age, and insulin usage show a significant reduction in ADEs across all subgroups (Figure 2). Interaction terms with treatment were not significant for all 3 subgroups. Baseline rates of ADEs trended higher for patients younger than 50 years and insulin users.

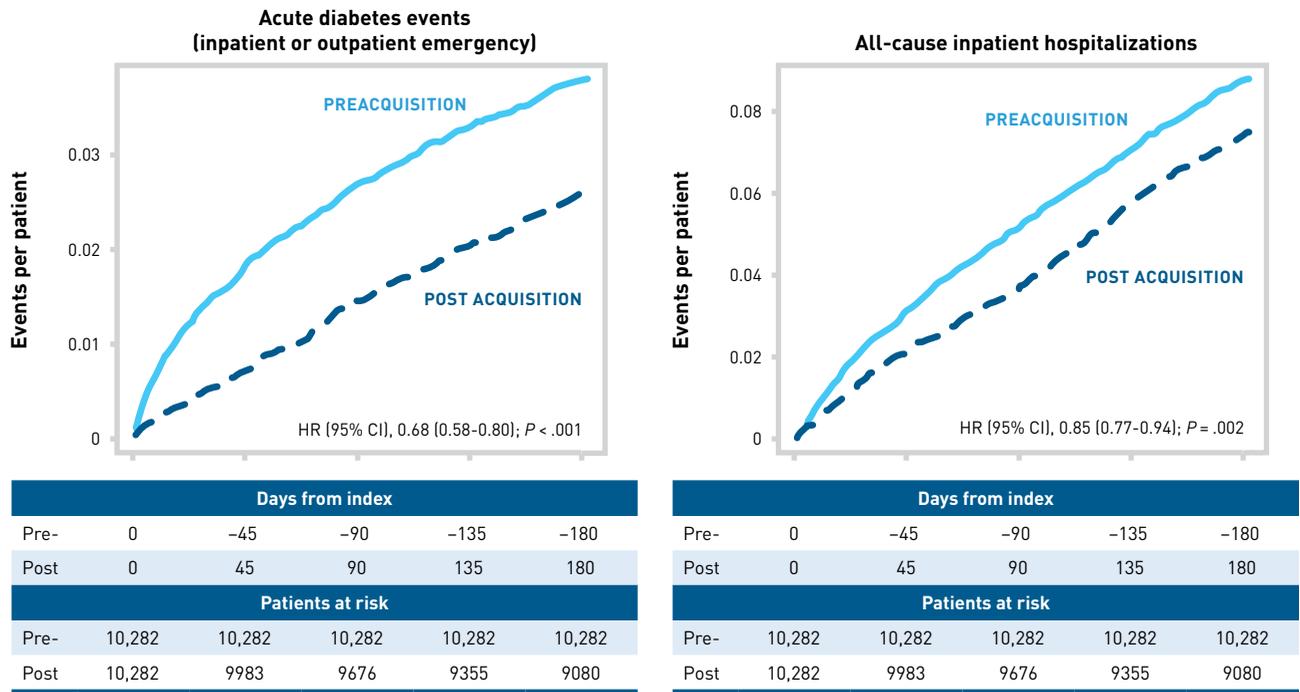
Causes of ACH

A further exploratory analysis of ACHs subdivided by major diagnostic category (MDC) is presented in descending order of frequency in Table 3. There are small decreases in the rates of circulatory system, nervous system, infectious disease, and kidney/urinary tract hospitalizations. The biggest drop is in the endocrine, nutritional, and metabolic system category (MDC 10), the one most closely associated with diabetes. Surgical procedures for obesity increased from less than 11 to 22 events.

DISCUSSION

To our knowledge, this is the first study to investigate the impact of acquiring flash CGM on ADEs and hospitalizations within a large population with T2D treated with nonintensive insulin therapy or noninsulin medications. Results from our analysis showed a significant association between acquisition of flash CGM and reductions in ADEs requiring emergency outpatient/inpatient hospital services and all-cause events requiring inpatient hospitalization. These results are particularly noteworthy given that patients treated with basal or noninsulin therapies tend to have lower rates of microvascular and macrovascular complications than patients treated with intensive insulin therapy.¹⁴

Reducing ADEs and hospitalizations is critical, as prevalence and costs of diabetes keep rising¹⁵ and health systems and payers are challenged to find ways to reduce incidence of diabetes-related hospitalizations. According to the CDC, approximately 460,000 ED visits for hyperglycemic crises (n = 224,000) and severe hypoglycemia (n = 235,000) were reported in 2016.¹⁶ The annual cost for hospitalizations and ED utilizations for hyperglycemic events in the United States now exceeds \$2.3 billion.¹⁷ The mean hospitalization cost for DKA increased from \$18,808 in 2003 to \$26,566 in 2014.¹⁸ A retrospective database study by Goyal et al reported that the total annual costs for hypoglycemia hospitalizations increased 33% from \$1.2 billion in 2001 to \$1.6 billion in 2011, with a mean cost of \$10,139 per admission.¹⁹ These costs are in addition to the increased costs associated with persistent suboptimal glucose control.²⁰⁻²² Although a cost offset analysis of our findings was not conducted, it is likely that the decreased rates of hyperglycemia- and hypoglycemia-related hospitalizations had a direct impact on reducing the direct costs of treatment and indirect costs associated with absenteeism.

FIGURE 1. Changes in (A) ADE and (B) ACH*

ACH, all-cause inpatient hospitalization; ADE, acute diabetes-related event; CGM, continuous glucose monitoring.

*Figure shows reduction in ADEs and ACHs from the 6-month period pre-flash CGM acquisition (solid line, light blue) to the 6-month period post flash CGM acquisition (dashed line, dark blue). Cumulative event rate is based on a Nelson-Aalen estimator. Results of weighted Cox regression with Andersen-Gill extension are presented as HRs with 95% CIs and P values.

Our findings are consistent with results from a recent prospective, observational study involving patients with T1D and T2D treated with intensive and nonintensive insulin therapy.⁴ In the FLARE-NL4 nationwide registry survey, which included 1054 patients with T1D and 223 patients with T2D, investigators observed a significant 66% reduction in the percentage of diabetes-related hospital admissions, from 13.7% to 4.7% ($P < .05$), and a reduction in absenteeism, from 18.5% to 7.7% ($P < .05$), over 6 months.⁴

Our findings provide compelling evidence that supports expanding patient access to flash CGM within the broader population with T2D. Currently, many health plans and government payers provide CGM coverage only to patients with T1D and to patients with T2D treated with intensive insulin regimens (eg, multiple daily injections, insulin pumps). In light of the emerging evidence, health plans may begin to reconsider their eligibility criteria for patients with T2D treated with basal or noninsulin therapies. Another potential driver of expanded coverage for flash CGM is the increasing reliance on telemedicine and digital diabetes technologies as a result of the COVID-19 pandemic. All current CGM systems feature the ability to automatically transmit glucose data to clinicians via cloud-based software for interpretation and remote clinical visits.²³ This capability

TABLE 2. Number of Events Occurring Pre- and Post Acquisition of CGM

Event type	6 months preacquisition	6 months post acquisition
	No. of events (No. of affected)	No. of events (No. of affected)
All-cause inpatient hospitalizations	905 (688)	726 (558)
Overall ADEs*	391 (324)	252 (211)
Inpatient ADEs	68 (61)	20 (18)
Outpatient ADEs	324 (274)	234 (195)

ADE, acute diabetes-related event; CGM, continuous glucose monitoring.

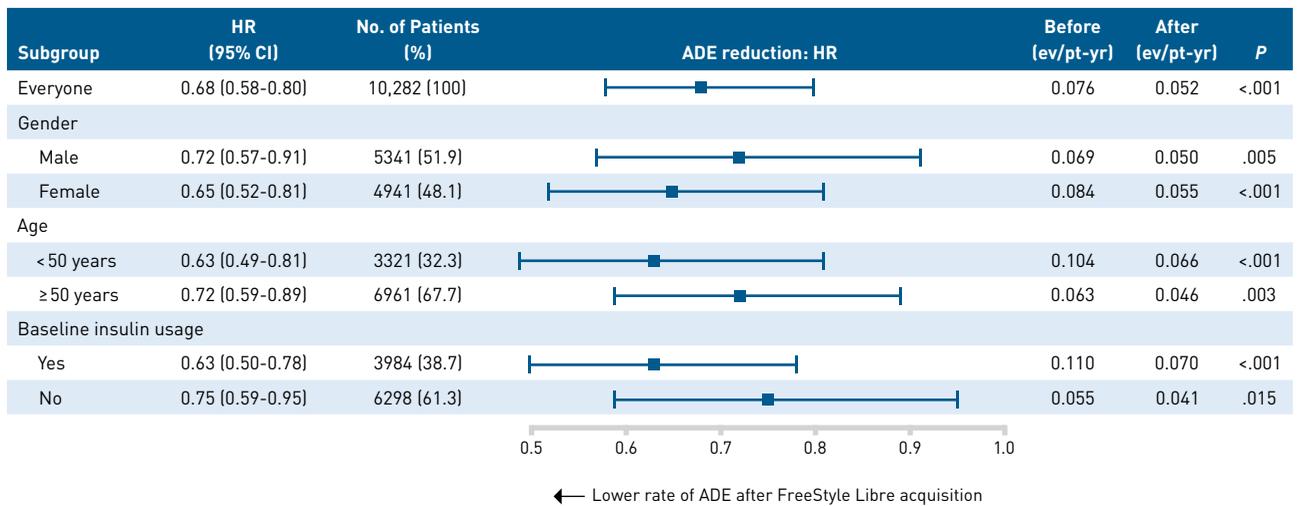
*In rare cases, when outpatient emergency service date overlaps with inpatient admission date, only 1 overall ADE is counted. Therefore, totals on this row will be slightly lower than the sum of the bottom 2 rows.

has already been shown to be a viable option for delivering essential health care to patients during the COVID-19 pandemic²⁴ and will likely lead to use of telemedicine and cloud-based CGM data as a standard of diabetes care in the future.

Strengths and Limitations

A key strength of our analysis was the use of claims data from a large data set, which included 10,282 patients with T2D treated with basal

FIGURE 2. ADEs by Gender, Age, and Baseline Insulin Usage



ADE, acute diabetes-related event; ev, events; pt-yr, patient-years.

TABLE 3. Most Common Causes of All-Cause Hospitalization by Major Diagnostic Category Before and After Flash CGM Acquisition

Before flash CGM		After flash CGM	
Hospitalizations (events/100 pt-yr)	Major diagnostic category	Hospitalizations (events/100 pt-yr)	Major diagnostic category
3.4	Circulatory system	3.0	Circulatory system
2.3	Endocrine, nutritional, and metabolic systems	1.7	Endocrine, nutritional, and metabolic systems
1.9	Nervous system	1.7	Musculoskeletal system and connective tissue
1.8	Infectious and parasitic	1.5	Digestive system
1.5	Musculoskeletal system and connective tissue	1.4	Nervous system
1.3	Kidney and urinary tract	1.2	Infectious and parasitic
1.3	Digestive system	0.9	Kidney and urinary tract

CGM, continuous glucose monitoring; pt-yr, patient-years.

insulin and noninsulin therapy. Moreover, the data set provided reliable information about acquisition of the flash CGM system and details on patient treatment post flash CGM system acquisition. Importantly, use of ICD-10 codes allowed us to accurately quantify complications and utilization of health care resources (eg, ED visits, inpatient hospitalizations) without reliance on patient-reported data.

Our study had notable limitations. The observational design of our study precluded a matched control group for comparison. A randomized controlled study design would have allowed us to quantify differences in outcomes between flash CGM acquisition and continued use of traditional blood glucose monitoring or no monitoring. Nor did our study directly estimate the impact of clinical history on physician prescribing behavior. Another limitation was our inability to determine patients' use of their devices, including utilization of glucose data in their daily self-management. Additionally, the MarketScan data set provided no information regarding glycated

hemoglobin A_{1c} values, socioeconomic and educational characteristics, or education/training in diabetes self-management, all of which could have affected outcomes. Because the data are largely composed of information provided by employers, our findings may not be generalizable to older patients with diabetes (≥65 years), a population that is at higher risk for severe hypoglycemia.²⁵⁻²⁷ Our findings may also not be generalizable to Medicaid patients, as the characteristics of the employed population may be different from those of patients on Medicaid. The latter patients often develop diabetes earlier, tend to have more severe disease, and have less access to new technologies due to their socioeconomic status.²⁸

CONCLUSIONS

This study demonstrated an association between flash CGM acquisition and reduction in ADEs and ACHs in adults with T2D

not treated with short- or rapid-acting insulin. These data are important as payers try to cope with mounting costs related to care for patients with diabetes, especially direct costs for inpatient and outpatient treatment. Additional studies are needed to assess the frequency and persistence of flash CGM use within this population to determine its impact on longer-term clinical outcomes. Moreover, data from these studies may add to our understanding of the feasibility and clinical utility of flash CGM within the broader population with T2D and help guide clinicians in developing personalized treatment regimens that meet the individual needs of each patient. ■

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