Continuous Glucose Monitoring With Prandial Insulin Use Among Medicare Patients With Type 2 Diabetes Mellitus and Reductions in Diabetic Ketoacidosis Events

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Background

- Diabetic ketoacidosis (DKA) is a life-threatening complication of diabetes mellitus (DM)
- A recent study reported initiation of continuous glucose monitoring (CGM) in the French population with type 2 DM (T2DM) to be associated with a reduction in DKA events,[1] including among those aged ≥ 65 years and using intensive insulin therapy[2]
- In the USA, prior studies have found CGM initiation to be associated with reductions in hospitalization,[3,4] but data on the possible effects of CGM on DKA are limited
- This study examined the association between CGM use and changes in frequency of acute diabetes events (ADEs) in the Medicare population with T2DM who are using multiple daily injections of insulin (MDI)

Objective

- To determine whether CGM use is associated with a significant change in the rate of ADEs overall and DKA in particular

Methods

Study Design and data source

- This was an observational, retrospective cohort analysis using de-identified data from the Medicare fee-for-service claims database, which includes comprehensive medical and pharmacy claims for Medicare beneficiaries

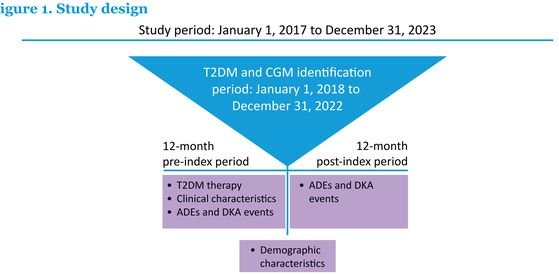
Study population

- The study population consisted of adult beneficiaries (aged ≥ 65 years) with a diagnosis of T2DM who were using MDI and who initiated CGM between January 1, 2018, and December 31, 2022 (**Figure 1**)
- Inclusion criteria were:
  - 1) An inpatient claim with a diagnosis code for T2DM (ICD-10-CM diagnosis codes E11.xx) or two outpatient claims with T2DM diagnosis codes at least 30 days apart
  - 2) ≥ 1 claim for CGM at any time following the first diagnosis of diabetes
- The earliest claim for CGM was set as the study index date, and continuous enrollment for at least 12 months before and after CGM initiation was required for inclusion
- People with T1D or gestational diabetes, end-stage renal disease, or age < 65 years were excluded

Variables and statistical analysis

- Demographic characteristics were captured at the index date
- Baseline clinical characteristics were based on diagnosis codes during the 12-month pre-index period
- The mean number of ADEs (defined as a composite outcome of hypoglycemia, hyperglycemia, hypoglycemic coma, DKA, and hyperosmolarity) and DKA events during the 12-month pre- and post-index periods were compared, as was the proportion of people who had at least one event
- Zero inflated negative binomial regression was used to evaluate changes in ADE and DKA event rates following CGM initiation
  - Covariates included Deyo-Charlson Comorbidity Index (DCI) score, depression, retinopathy, neuropathy, age, gender, race/ethnicity, index year, and Medicare/Medicaid dual eligibility

Figure 1. Study design



ADE, acute diabetes event; CGM, continuous glucose monitoring; DKA, diabetic ketoacidosis; T2DM, type 2 diabetes mellitus.

Results

Study population

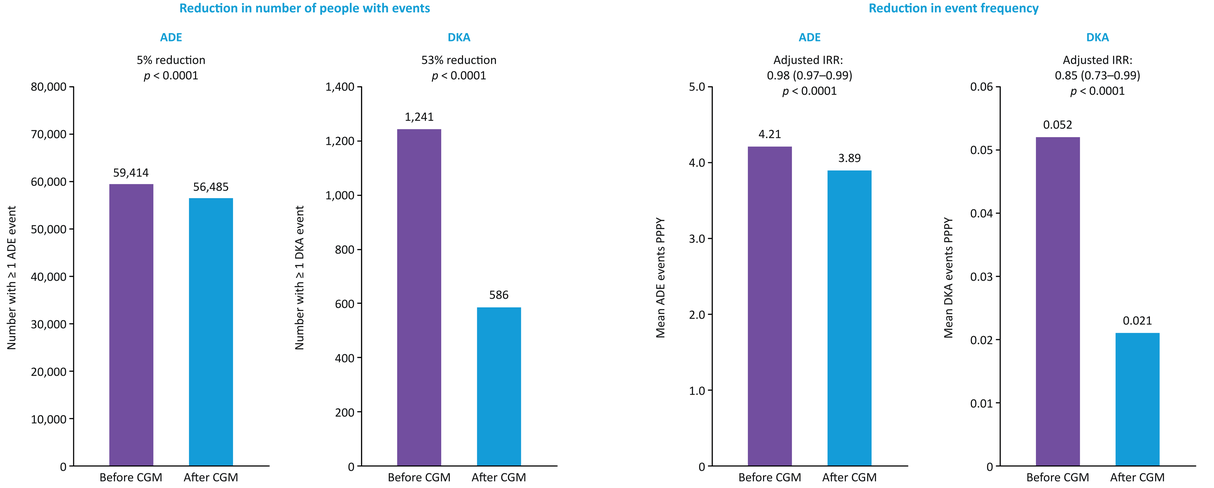
- Among 13,109,178 Medicare members with a diagnosis code for T2DM between January 1, 2018, and December 31, 2022, 78,813 met all of the inclusion criteria and were using MDI
- The mean age at the index date was 74.2 years (**Table 1**), with a spread across age groups (65–69, 27%; 70–74, 32%; 75–79, 22%; ≥ 80, 19%) and US regions
- A total of 52% of included people were female; 84% were White, 7% were Black, 2% were Asian, and 2% were Hispanic
- The mean DCI score was 5.6, indicating a high comorbidity burden
  - Multiple comorbidities were present at a high frequency, particularly hypertension (95%), lipid disorders (87%), obesity (52%), neuropathy (52%), coronary artery disease (44%), and renal disease (43%)

Table 1. Patient demographics at index data and pre-index comorbidities

Characteristic	
Age at index date, years	
Mean ± SD	74.2 ± 6.5
Median (IQR)	73.0 (9.0)
Age group at index date, n (%)	
Age 65–69 years	21,365 (27.1%)
Age 70–74 years	25,245 (32.0%)
Age 75–79 years	17,516 (22.2%)
Age ≥ 80 years	14,687 (18.6%)
Gender, n (%)	
Female	40,769 (51.7%)
Male	38,044 (48.3%)
Race, n (%)	
White	66,479 (84.4%)
Black or African American	5,380 (6.8%)
Asian American or Other Pacific Islander	1,777 (2.3%)
Hispanic or Latino	1,571 (2.0%)
Unknown/Other	3,606 (4.6%)
Census region, n (%)	
Northeast	13,208 (16.8%)
Midwest	22,911 (29.1%)
South	28,932 (36.7%)
West	13,756 (17.5%)
US territory	< 11[a]
Unknown	< 11[a]
Pre-index Deyo–Charlson Comorbidity Index score	
Mean ± SD	5.6 ± 2.9
Pre-index comorbidities of Interest, n (%)	
Hypertension	74,974 (95.1%)
Lipid disorder	68,450 (86.9%)
Obesity	41,364 (52.5%)
Neuropathy	40,636 (51.6%)
Coronary artery disease	34,940 (44.3%)
Renal disease	34,052 (43.2%)
Anemia	22,942 (29.1%)
Hypothyroid	22,935 (29.1%)
Peripheral vascular disease	22,743 (28.9%)
Chronic pulmonary disease	22,664 (28.8%)
Retinopathy	21,507 (27.3%)
Congestive heart failure	21,480 (27.3%)
Depression	18,729 (23.8%)
Cerebrovascular accident	17,176 (21.8%)

[a]Non-zero patient counts of N<11 will not be reported per CMS requirements.
CMS, Centers for Medicare & Medicaid Services; IQR, interquartile range; MDI, multiple daily injections of insulin; SD, standard deviation; T2DM, type 2 diabetes mellitus.

Figure 2. ADE and DKA events before and after CGM initiation



p values are from unadjusted analysis.
ADE, acute diabetes event; CGM, continuous glucose monitoring; DKA, diabetic ketoacidosis; IRR, incident rate ratio; PPPY, per person per year.

Acute diabetes events

- In the 12 months before the index date, 59,414 people with T2DM on MDI (75.4%) had at least one ADE, compared with 56,485 (71.7%) in the 12 months after initiating CGM (a reduction of 5%; $p < 0.0001$; **Figure 2**)
- People had a mean of 4.2 ADEs per year before initiating CGM, which was reduced to a mean of 3.9 events per year in the follow-up period ($p < 0.0001$)
- Binomial regression results showed a statistically significant reduction in ADEs after CGM initiation (adjusted incidence rate ratio, 0.98; 95% confidence interval, 0.97–0.99)

Diabetic ketoacidosis

- In the 12 months before initiating CGM, 1,241 people (1.6%) had one or more DKA events, compared with 586 (0.7%) during the post-index period (a reduction of 53%; $p < 0.0001$; **Figure 2**)
- The mean number of DKA events per person was 0.05 per year before initiating CGM, and 0.02 per year in the subsequent 12 months ($p < 0.0001$)
- In the binomial regression, the rate of DKA events was reduced by 15% after CGM initiation; this reduction was statistically significant (adjusted incidence rate ratio, 0.85; 95% confidence interval, 0.73–0.99)

Discussion

- Initiation of CGM by Medicare members aged 65 years and over who had T2DM managed with MDI was associated with statistically significant reductions in ADEs, and particularly in DKA events
- These data span the full continuum of care for a substantial portion of the older US population, addressing the evidence gap in the current literature
- Limitations include the exclusion of patients who die during the 12-month post-index period, which may exclude some high end-of-life resource utilization. In addition:
  - Administrative claims data are subject to data coding limitations and data entry error
  - Results may not be generalizable to patients without insurance or those with different health insurance
  - The study period included the coronavirus disease 2019 pandemic, which may have restricted access to care

Conclusion

- Incorporating CGM into diabetes management for older adults may lessen the incidence of acute events and reduce healthcare burden
- DKA events persist despite CGM use, indicating opportunities for further risk reduction in Medicare-insured older adults

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References

1. Roussel R *et al. Diabetes Care* 2021;44:1368–1376.
2. Guerci B *et al. Diabetes Technol Ther* 2023;25:384–394.
3. Garg SK *et al. Diabetes Obes Metab* 2024;26:5202–5210.
4. Hirsch IB *et al. J Manag Care Spec Pharm* 2024;30:S21–s29.

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