FEATURE ARTICLE

Association Between Change in A1C and Use of Professional Continuous Glucose Monitoring in Adults With Type 2 Diabetes on Noninsulin Therapies: A Real-World Evidence Study

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This retrospective analysis examined the association between change in A1C and professional continuous glucose monitoring (p-CGM) use in patients with type 2 diabetes and poor glycemic control who were not using insulin. Data from 15,481 eligible patients (p-CGM users *n* = 707 and p-CGM nonusers *n* = 14,774) showed a greater decrease in A1C from baseline to the end of follow-up for p-CGM users, and differences favored p-CGM users regardless of whether they started insulin therapy during the follow-up period. These findings suggest that people with type 2 diabetes who have poor glycemic control using multiple noninsulin therapies may benefit from p-CGM, which can reduce A1C over a 6-month period compared with usual care.

Current treatment guidelines for diabetes suggest a glycemic target of A1C <7% for most people with diabetes (1) and the use of metformin as a first-line therapy with lifestyle changes for those with type 2 diabetes (2). Yet, a significant percentage of people with type 2 diabetes do not achieve their glycemic goals (3–5), which can lead to the development and progression of diabetes complications (6–11). Most people usually require a second-line therapy within a couple of years after treatment initiation. Additionally, there is often resistance among physicians to start patients on insulin therapy (5,12–15). When insulin is introduced, there is often poor patient adherence, which ultimately affects glycemic control (3,16–18).

Currently, once people with type 2 diabetes start insulin therapy, the most common method of glucose monitoring is self-monitoring of blood glucose (SMBG) using a blood glucose meter and test strips. Glucose monitoring is considered an important component of effective diabetes management for people taking insulin and is encouraged to prevent hypoglycemia and hyperglycemia (19). Some people on intensive insulin therapy, defined as multiple daily injections of insulin or the use of an insulin pump, may need to check their blood glucose levels 6–10 times per day. SMBG frequency was found to be correlated with lower A1C for people with type 1 diabetes (20,21).

For people with noninsulin-treated type 2 diabetes, SMBG has been shown to be less helpful for reaching glycemic goals unless the data are being used to make lifestyle changes or manage medications through active, shared decision-making between patients and health care providers (HCPs) (19,22–25). For example, in a meta-analysis by Mannucci et al. (24), the use of structured SMBG regimens with clearly defined timing and frequency of glucose measurements resulted in improved glycemic control compared with unstructured SMBG or no SMBG. The largest improvement in A1C was found for structured SMBG when the data were also used to adjust diabetes medications. However, patients and physicians often do not actively leverage the glucose data from SMBG. Other limitations to using SMBG are that it only provides a static point-in-time glucose value, it requires frequent painful fingersticks, and insurance coverage for test strips is limited for most people who do not take insulin (26).

Continuous glucose monitoring (CGM) systems may be a useful tool to help improve glycemic control prior to starting insulin therapy. People with diabetes, HCPs, and health care team members have started using CGM

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technology to achieve better glycemic outcomes (27–29). The two currently available type of personal CGM systems (i.e., CGM systems owned by individual patients) are real-time and intermittently scanned CGM systems. However, there are cost and access limitations for CGM for people with type 2 diabetes who are not treated with intensive insulin therapy. Presently, CGM is recommended and covered by insurance plans for people with type 1 diabetes and for those with type 2 diabetes who require intensive insulin therapy. However, noninsulin-treated patients with type 2 diabetes may not have insurance coverage for personal CGM use, and there are no established treatment guidelines for personal CGM use in this population (30).

In addition to personal CGM, professional CGM (p-CGM) systems are devices owned by clinics and provided by HCPs to patients for short-term use (usually a period of 3–10 days) to continuously collect glycemic data. p-CGM sensors transmit data to a receiver, which is often blinded to the patient, and the data are then assessed by the HCP. Hence, p-CGM is often referred to as masked or retrospective CGM (31,32). Newer real-time p-CGM devices can be used in blinded or unblinded modes (33,34). HCPs use p-CGM as a tool for identifying glycemic patterns to make informed decisions about patients' treatment regimens and lifestyle modifications (29). In addition, use of p-CGM is beneficial in setting appropriate individualized targets for time in range (TIR; the percentage of time spent with glucose of 70–180 mg/dL), as well as identifying nocturnal glucose patterns (33). p-CGM may also be applicable for people who have reservations about committing to long-term personal CGM use, allowing them to try wearing a CGM sensor before purchasing a system and for those who do not have adequate insurance coverage for personal CGM but may still benefit from the period collection of CGM data (34).

Two recent studies investigated the use of p-CGM for type 2 diabetes management regardless of insulin therapy regimen (32,35). A quality improvement project in a team-based primary care setting evaluated care models using 2 weeks of blinded p-CGM, followed by an HCP visit that included shared decision-making regarding lifestyle and medication modifications (35). The use of p-CGM resulted in improved glycemic management (average change in A1C of −0.6%), which was attributed to lifestyle counseling and medication intensification, while the number of medications remained stable. Additionally, retrospective analysis of U.S. health care claims and laboratory data of patients with type 2 diabetes showed that use of p-CGM was associated with improved A1C and decreased growth in total health care spending 1 year after the use of p-CGM compared with 1 year before p-CGM (32).

For people with type 2 diabetes who do not use insulin, a recent pilot study assessed the episodic use of unblinded real-time p-CGM (10 days/month for 3 months) in patients who had previously failed to achieve glycemic goals while on multiple noninsulin therapies. Although 34.1% of patients reached an A1C <7.5% at 12 weeks, overall change in A1C did not differ statistically between groups. A clinically meaningful 10% increase in average TIR within the first week of use suggested that patients were able to make lifestyle changes based on real-time p-CGM data (36).

Although these previous studies of p-CGM have shown some evidence of improved glycemic control in people with type 2 diabetes, the aims of this study were to further examine the real-world potential value of p-CGM for individuals with type 2 diabetes who have poor glycemic control while using two or more noninsulin antidiabetic therapies and to understand medication modifications after p-CGM use.

Research Design and Methods

Study Design

This was a retrospective, observational, database study using de-identified administrative health claims and linked laboratory data from Optum's Clinformatics Data Mart (CDM) database. The CDM is statistically de-identified under the expert determination method consistent with the Health Insurance Portability and Accountability Act and managed according to Optum customer data use agreements in compliance with Code of Federal Regulations title 45, section 164.514(b) (1)13 (37). CDM administrative claims submitted for payment by HCPs and pharmacies are verified, adjudicated, and de-identified prior to inclusion. These data, including patient-level enrollment information, are derived from claims submitted for all medical and pharmacy health care services with information related to health care costs and resource utilization.

Study Population

The population included adult patients ≥30 years of age who had type 2 diabetes identified using *International Classification of Diseases*, 9th/10th Revisions (ICD-9/ICD-10), were enrolled in commercial or Medicare Advantage health plans, and had no prior personal CGM or p-CGM use. Patients with poor glycemic control, defined as an A1C value between 7.8 and 10.5%, and using two or more

noninsulin therapies were included in the cohort. p-CGM users were identified using Current Procedural Terminology (CPT) codes 95250 and 95251 between 1 January 2018 and 31 October 2020 (the study identification period). Patients without claims for use of p-CGM who had a pharmacy claim for an oral antidiabetic drug (OAD) during the study identification period were selected as the control cohort (nonusers of p-CGM). An index date was set as the earliest observed claim for p-CGM or an OAD.

Included patients were continuously enrolled in a health plan from at least 6 months pre-index (baseline) to at least 6 months post-index date (follow-up) and had no claims for a CGM device (personal or professional) during the baseline period.

Type 2 diabetes diagnoses were confirmed by patients having one or more inpatient hospital or emergency department medical claims or at least two ambulatory medical claims at least 30 days apart with an ICD-9 or ICD-10 diagnosis code for diabetes in any position on the claim during the baseline period. Additionally, patients were required to be using at least two noninsulin medications and not taking insulin (basal or bolus) in the baseline period. Finally, patients were required to have one or more laboratory A1C test results with values between 7.8 and 10.5% during the baseline period (including the index date) and at least one A1C laboratory test value during the follow-up period.

Outcome Measures

The primary outcome measure was change in A1C determined from the average of available A1C values during the baseline and follow-up periods. Change in A1C was computed as the average A1C follow-up value minus the average A1C baseline value, with negative values indicating improvement in A1C. Secondary outcomes were change in the number of medications by class, insulin use in follow-up period, and change in A1C for patients starting insulin and not starting insulin during the follow-up period.

Statistical Analysis

Descriptive statistics, including percentages, means, and SDs, were calculated for patient characteristics and study outcomes and presented by patient cohort categories (i.e., p-CGM users and nonusers). Bivariate differences between the p-CGM user and nonuser groups were tested with independent sample *t* tests for continuous measures and χ^2 tests for categorical measures. Within-cohort comparisons of continuous measures were tested with paired *t* tests. The difference-in-differences (DiD) estimate was calculated as the difference in change in A1C values between the p-CGM user and nonuser cohorts. The DiD estimate indicates the magnitude and direction of change in outcome between the two groups. The association between p-CGM use and antidiabetic medication changes was tested using a logistic regression model. A χ^2 test was used to compare the difference in insulin use in the follow-up period between the two groups. For all analyses, statistical tests were two-tailed, with $P \leq 0.05$ considered statistically significant. Analyses were performed using Instant Health Data software (Panalgo, Boston, MA) and R, v. 3.2.1, software (R Foundation for Statistical Computing, Vienna, Austria).

Results

A total of 15,481 patients were identified during the study identification period, including 707 p-CGM users and 14,774 nonusers. Demographic characteristics were similar between cohorts as shown in Table 1. The majority in both groups were older (≥65 years of age), there were slightly more males, and most were Caucasian and predominantly covered by Medicare Advantage plans. Among patients using a p-CGM, an endocrinologist was the prescriber for 282 patients (39.9%), whereas for 275 patients (38.9%), the prescriber was a family or internal medicine physician or nurse practitioner. The remaining 21.2% of encounters at which p-CGM was prescribed were with some other type of HCP. Thus, ∼40% of patients received their p-CGM through primary care.

The p-CGM group reduced their A1C by a mean 0.83%, from 8.70 to 7.87%, while the nonusers had a reduction of 0.32%, from 8.56 to 8.23%. The DiD estimate was a −0.51% change in A1C and was statistically significant ($P < 0.0001$), as shown in Table 2.

As shown in Table 3, 140 p-CGM users (19.8%) started using insulin during the follow-up period, with most (112, or 15.8%) using basal insulin. About 10% of nonusers started insulin during the follow-up period. The A1C change among insulin users in the p-CGM group was −0.57%, from 8.90 to 8.34%, whereas the nonuser group had a slight increase in A1C of 0.13%, from 8.77 to 8.90%. The DiD estimate for change in A1C was −0.71% and statistically significant (Table 2). Similarly, for patients not starting insulin, we found a significant DiD change in A1C of −0.53% for nonusers of insulin during follow-up, reflecting a larger A1C decrease for p-CGM users compared with nonusers (Table 2).

Table 3 shows the diabetes medication use by cohorts during the baseline and follow-up periods. The most frequently

TABLE 1 Baseline Demographic Characteristics of the Study Cohort (*N* = 15,481)

Characteristic	p-CGM Users (*n* = 707)	Nonusers (*n* = 14,774)	*P*
Age, years	66.1 ± 10.8 (30–89)	66.7 ± 10.9 (30–89)	0.13
Age-group, years			0.63
30–44	30 (4.2)	541 (3.7)	
45–54	72 (10.2)	1,587 (10.7)	
55–64	157 (22.2)	3,064 (20.7)	
≥65	448 (63.4)	9,582 (64.9)	
Sex			0.24
Female	344 (48.7)	6,846 (46.3)	
Male	363 (51.3)	7,926 (53.7)	
Race/ethnicity			0.49
Asian	47 (7.0)	928 (6.6)	
Black	106 (15.8)	1,954 (13.8)	
Caucasian	337 (50.2)	7,367 (52.1)	
Hispanic	182 (27.1)	3,884 (27.5)	
Geographical region			<0.0001
Midwest	29 (4.1)	1,668 (11.3)	
Northeast	129 (18.3)	1,421 (9.6)	
South	426 (60.3)	7,886 (53.4)	
West	123 (17.4)	3,795 (25.7)	
Payer type			0.43
Commercial	200 (28.3)	3,971 (26.9)	
Medicare	507 (71.7)	10,803 (73.1)	
Charlson comorbidity index score	1.65 ± 1.6	1.42 ± 1.5	<0.0001
Blood glucose test strips claims at baseline	0.86 ± 1.3	0.77 ± 1.3	0.08

Data are mean ± SD (range), mean ± SD, or *n* (%).

used medications in both cohorts were biguanides followed by sulfonylureas, glucagon-like peptide 1 (GLP-1) receptor agonists, and dipeptidyl peptidase 4 (DPP-4) inhibitors in the baseline and follow-up periods. Biguanide, sulfonylurea, and DPP-4 inhibitor use decreased slightly from baseline to follow-up in both groups, with odds ratios (ORs) showing that the p-CGM group was less likely to use these medications at follow-up, adjusting for baseline, compared with the nonuser group. GLP-1 receptor agonist, sodium–glucose cotransporter 2 (SGLT2) inhibitor, and meglitinide use increased in both groups, with ORs showing that the p-CGM group was more likely to use these medications at follow-up, adjusting for baseline, compared with the nonuser group. Overall, 447 patients (63.2%) had an additional p-CGM use during the 6-month follow-up period.

Discussion

The findings from this study suggest that there is a glycemic benefit of p-CGM use for adults with type 2 diabetes who are not on insulin therapy and are taking multiple OAD and/or noninsulin injectable medications with poor glycemic control. Use of p-CGM was associated with a clinically meaningful 0.51% reduction in A1C compared with the cohort of nonusers.

These findings align with other studies demonstrating a significant reduction in A1C values for p-CGM users with type 2 diabetes compared with control subjects (32,34,35). Previous studies have shown that p-CGM enables HCPs to make decisions such as adding insulin to patients' treatment regimens based on recorded sensor data, helping patients reach glycemic targets and promoting positive behavior change (35,36,38). Our findings suggest that p-CGM use is also a means to assess and monitor glycemia for noninsulin-treated patients and can be used as a tool for therapy modification.

Our analysis showed that ∼20% of patients initiated insulin therapy in the follow-up period after p-CGM use, which was more than the 10% who started insulin in the nonuser group, but this finding might be considered lower

TABLE 2 Baseline, Follow-Up, and Change in A1C for All Patients and Stratified by Insulin Initiation in Follow-Up Period

A1C, %	p-CGM Users			Nonusers			DiD		
	Baseline	Follow-Up	Difference*	Baseline	Follow-Up	Difference*	Estimate	95% CI	*P*
All patients (p-CGM users *n* = 707; nonusers *n* = 14,774)	8.70 ± 0.78	7.87 ± 1.15	−0.83	8.56 ± 0.77	8.23 ± 1.21	−0.32	−0.51	−0.62 to −0.40	<0.0001
Patients who started insulin during follow-up (p-CGM users *n* = 140; nonusers *n* = 1,450)	8.91 ± 0.80	8.34 ± 1.23	−0.57	8.77 ± 0.82	8.9 ± 1.34	0.13	−0.71	−0.98 to −0.44	<0.0001
Patients who did not start insulin during follow-up (p-CGM users *n* = 567; nonusers *n* = 13,324)	8.65 ± 0.76	7.75 ± 1.09	−0.9	8.53 ± 0.76	8.16 ± 1.17	−0.37	−0.53	−0.64 to −0.41	<0.0001

Baseline and follow-up A1C data are mean ± SD. *Difference is calculated as post-index value minus pre-index value.

than expected given that the cohort started with an average A1C >7.5% and may reflect HCP and/or patient inertia regarding initiating insulin therapy (12,14,15).

Even among patients who used p-CGM and did not start insulin therapy, there was significant improvement in A1C. This finding suggests that p-CGM can help with medication management and behavior change that might improve glycemic control and delay the need to start insulin therapy. The more granule daily patterns of glucose excursions that can be viewed through CGM, compared with average glycemic control reflected in A1C values, can help HCPs target diet and physical activity counseling to patients, which in turn could delay

TABLE 3 Medication Use During Baseline and Follow-Up Periods

Drug Class*	p-CGM Users† (*n* = 707)		Nonusers† (*n* = 14,774)		OR	95% CI	*P*
	Baseline	Follow-Up	Baseline	Follow-Up			
Biguanide	486 (68.7)	452 (63.9)	10,631 (72.0)	10,383 (70.3)	0.68	0.54–0.86	0.0011
Sulfonylurea	410 (58.0)	351 (49.7)	9,335 (63.2)	9,401 (63.7)	0.39	0.31–0.49	<0.0001
DPP-4 inhibitor	144 (20.4)	124 (17.5)	3,017 (20.4)	3,163 (21.4)	0.61	0.46–0.80	0.0004
GLP-1 receptor agonist	187 (26.5)	249 (35.2)	1,792 (12.1)	2,113 (14.3)	3.30	2.59–4.21	<0.0001
SGLT2 inhibitor	162 (22.9)	191 (27.0)	2,002 (13.5)	2,362 (16.0)	1.62	1.26–2.09	0.0002
Thiazolidinedione	93 (13.2)	110 (15.6)	1,777 (12.0)	2,071 (14.0)	1.12	0.82–1.54	0.47
Meglitinide	36 (5.1)	53 (7.5)	282 (1.9)	320 (2.2)	4.23	2.66–6.73	<0.0001
α-Glucosidase inhibitor	7 (1.0)	6 (0.9)	137 (0.9)	156 (1.1)	0.54	0.16–1.83	0.32
Insulin							<0.0001
Total insulin‡	NA	140 (19.80)	NA	1,450 (9.81)			
Basal insulin§	NA	112 (15.84)	NA	1,219 (8.25)			
Bolus insulin§	NA	45 (6.36)	NA	289 (1.96)			
Mixed insulin§	NA	13 (1.84)	NA	148 (1)			

*Table reports medication at therapeutic drug class level. Example medications in each class include biguanide (metformin), sulfonylurea (glipizide), DPP-4 inhibitor (linagliptin), GLP-1 receptor agonist (exenatide), SGLT2 inhibitor (empagliflozin), thiazolidinedione (pioglitazone), meglitinide (repaglinide), and α-glucosidase inhibitor (acarbose). NA, not applicable. †Data are *n* (%). ‡Data are *n* (%) of total insulin users in the cohort. §Insulin users are in more than one group.

or prevent microvascular and macrovascular diabetes complications (8,10,38).

Associations were found between p-CGM use and changes in the use of noninsulin diabetes medications. The most prominent change was a 33% increase in the use of GLP-1 receptor agonists, which seems warranted given the cardiovascular risk-reduction benefits of this drug class and the cohort's baseline A1C and average age >65 years. There was also a 14% decrease in sulfonylurea use in the p-CGM group, which may have been precipitated by p-CGM detection of previously unknown time spent in the hypoglycemic range.

There are limitations to our study. The number of identified p-CGM users with A1C values was relatively small compared with the nonuser cohort. For this analysis, we included only patients who had A1C values in both the baseline and follow-up time periods. Although the cohorts were comparable with regard to demographic variables and baseline A1C, there was the chance of confounding by indication, through which patients using p-CGM could have been different from nonusers on unmeasured variables that prompted the use of p-CGM.

Although the database provided crucial information about participants' health status, comorbidities, medications, and use of p-CGM, it did not provide other information such as socioeconomic status or participation in diabetes health coaching programs. We also cannot determine from the data whether and to what extent HCPs and patients engaged in shared decision-making about diabetes and lifestyle management. Similarly, changes in physical activity or other positive behavioral changes and their impact on overall glycemic improvement could not be assessed. Without this information, it is not possible to fully understand how p-CGM may help individuals to improve their diabetes management.

p-CGM use is documented in health care claims with CPT codes 95250 and 95251; therefore, it was not possible to distinguish the specific p-CGM brands or products used. Three p-CGM systems were available in the United States during this study period: the Dexcom G4/G6 Pro, the FreeStyle Libre Pro, and the Medtronic iPro2. Differences among these brands may influence users' experience and adherence to wearing the devices (34).

A key strength of our analysis was its use of comprehensive, standardized health information contained within a large database. Access to the database allowed us to use quantitative data to verify participant eligibility and identify patients' treatment regimens during the baseline and follow-up periods. An additional study strength was that the resulting cohorts were ethnically diverse, with nearly half being non-Caucasian, which supports the generalizability of the findings beyond Caucasian individuals.

Conclusion

Although randomized controlled trials are considered the gold standard for demonstrating the effects of therapeutic interventions, results from retrospective, observational studies of large health data systems can inform clinicians and regulatory agencies about the real-world efficacy of treatment interventions. Our findings suggest that p-CGM use in adults on noninsulin therapies is associated with improved glycemic control and thus may be a tool HCPs can use to help patients reach their glycemic goals.

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DUALITY OF INTEREST

The authors are employees of Dexcom, Inc. No other potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

P.M.N. researched the data, conducted data analyses, and wrote the manuscript. K.L.H. and G.J.N. researched the data and reviewed and edited the manuscript. P.M.N. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

PRIOR PRESENTATION

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