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The Impact of Real-Time Continuous Glucose Monitoring in Patients 65 Years and Older

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Abstract

Background: Older adults with type 1 diabetes (T1D) or insulin-using type 2 diabetes (iT2D) are at high risk for severe hypoglycemic episodes. Real-time continuous glucose monitoring (RT-CGM) in this population may reduce this risk, but when patients switch to Medicare at age 65, RT-CGM is no longer a covered benefit. We developed a survey to examine health and quality of life (QOL) benefits of RT-CGM in seniors (age ≥ 65).

Methods: Two groups of seniors with T1D or iT2D—current RT-CGM users (n = 210) and RT-CGM "hopefuls" (patients who wanted but could not obtain RT-CGM due to lack of insurance coverage; n = 75)—completed an online survey. The survey examined history of hypoglycemic experiences as well as current quality of life (QOL), including generic and diabetes-specific measures.

Results: Current users reported fewer moderate ($P < .01$) and fewer severe hypoglycemic episodes ($P < .01$) over the past 6 months than "hopefuls" and greater reductions over time in hypoglycemic events requiring the assistance of another, ER visits, and paramedic visits to the home (in all cases, $P < .01$). Regarding QOL, current users reported significantly better well-being ($P < .001$), less hypoglycemic fear ($P < .05$), and less diabetes distress ($P < .05$) than "hopefuls."

Conclusions: These data suggest that RT-CGM use in seniors is associated with reductions in episodes of severe hypoglycemia and improved QOL, suggesting that restrictive access to RT-CGM in the Medicare age population may have deleterious health, economic, and QOL consequences.

Keywords
continuous glucose monitoring, Medicare, hypoglycemia, quality of life

Real-time continuous glucose monitoring (RT-CGM) is an expanding technology for use in the treatment of individuals with type 1 diabetes (T1D) and, to a lesser extent, those with insulin-using type 2 diabetes (iT2D). In both cases, reaching and maintaining a target A1C level can be challenging, in part because of the associated risk of hypoglycemia—both mild and severe.[1] Results from a large, randomized controlled trial showed that RT-CGM in T1D adults was associated with a significant reduction in A1C (mean = 0.5%) without an increase in hypoglycemia.[2] Recent survey data suggest that RT-CGM use is associated with key quality of life benefits, with most patients reporting that they feel more in control of their diabetes and safer from severe hypoglycemia.[3] The 2016 American Diabetes Association (ADA) Standards of Care as well as the recent American Association of Clinical Endocrinologists (AACE) CGM Consensus Conference recommends the use of RT-CGM in T1D individuals who are appropriate candidates.[4,5]

Older adults with T1D have higher rates of hypoglycemia, more hypoglycemic unawareness, and more glycemic variability than younger adults with T1D.[6,7] When older adults with T1D live alone—which is not uncommon with aging, often due to the loss of a spouse, friends and/or financial difficulties—the dangers due to severe hypoglycemia may rise

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even higher.[8] Indeed, among seniors with diabetes, recent studies have documented that hospitalizations for hypoglycemia exceed those for hyperglycemia and are linked to elevated mortality risk.[9] Early evidence suggests that RT-CGM use in this population may reduce the frequency of severe hypoglycemic episodes and improve overall glycemic control,[10] but—quite unfortunately—when many patients with T1D switch to Medicare at age 65, RT-CGM is no longer a covered benefit. This means that those individuals at the highest risk for hypoglycemia lose the security of having a device that can alert them to incipient and/or actual hypoglycemia. Indeed, the ADA warns against this, stating "individuals who have been successfully using RT-CGM should have continued access after they turn 65 years of age."

To further investigate this issue, we surveyed 2 groups of seniors (age ≥ 65) with diabetes who had sought to obtain an RT-CGM device, 1 group who had been successful in gaining access and were currently using RT-CGM (current RT-CGM users) and 1 group who had been unsuccessful (typically due to lack of insurance coverage, to be referred to henceforth as "RT-CGM hopefuls"). We hypothesized that RT-CGM use would be associated with fewer hypoglycemia-related difficulties as well as better quality of life (QOL).

Methods

An Internet-based survey was conducted by Harris Poll on behalf of Dexcom, Inc between July 2016 and November 2016 among adults with T1D and insulin-using T2D who either were currently using RT-CGM (current RT-CGM users) or had sought to obtain an RT-CGM device but found that their insurance would not cover it and they could not afford to purchase it on their own (RT-CGM hopefuls). All adults from the Dexcom, Inc central database who were initially identified as ≥ 65 years of age were contacted via email and invited to participate if they confirmed they were ≥ 65 years of age and had Medicare as their primary insurance or reported that they had no health insurance coverage. Harris Poll was responsible for contacting all potential participants and collecting and initial processing of all data. Qualified respondents who completed the survey received a $25 honorarium for their participation.

Measures

The survey consisted of 3 parts:

1. *Demographic* measures included age, gender, ethnicity (non-Hispanic white vs not non-Hispanic white), education (years), employment status, income level, type of diabetes, number of years since diagnosis, type of insulin delivery system, and frequency of blood glucose monitoring (self-monitoring of blood glucose).
2. *Hypoglycemia experience* included the frequency of low blood glucoses (<70 mg/dl) in the past month, with and without symptoms; over the past 6 months, the frequency of moderate hypoglycemic episodes (symptoms of confusion, disorientation, lethargy or being unable to treat oneself) and the number of a variety of events associated with severe hypoglycemia, including episodes requiring assistance from another person, hypoglycemia-related auto accidents, paramedic visits, ER visits, and hospitalizations. In addition, subjects estimated the frequency/number of these same events during the "retrospective baseline period," defined as the 6-month period before they first started RT-CGM (for the current RT-CGM users) or during the 6-month period before they first sought to acquire RT-CGM (for the RT-CGM hopefuls). Of note, because the hypoglycemia data were severely skewed, we calculated binary (yes/no) values for each of the hypoglycemia variables (ie, whether an event did or did not occur in the specified period of time).
3. *Psychosocial* measures included the World Health Organization–5 (WHO-5), a 5-item scale that assesses well-being;[11] the worry subscale of the Hypoglycemic Fear Survey (HFS-II);[12] and the Diabetes Distress Scale for Type 1 Diabetes (T1-DDS), which assesses worries and concerns specifically related to diabetes and its management and has been shown to be a good marker of diabetes-related emotional distress.[13] The T1-DDS includes 7 subscales: Powerlessness (a broad sense of feeling discouraged about diabetes), Hypoglycemia Distress (concerns about severe hypoglycemic events), Management Distress (disappointment with one's own self-care), Negative Social Perceptions (concerns about the possible negative judgments of others), Physician Distress (disappointment with current health care professionals), Friend/Family Distress (too much focus on diabetes amongst loved ones), and Eating Distress (concerns that one's eating is out of control).

Data Analysis

Chi-square and *t* tests, as appropriate, were conducted to test for differences in participant characteristics between current RT-CGM users and RT-CGM hopefuls. Linear and logistic regression models examined RT-CGM group differences on individual psychosocial measures and measures of hypoglycemia, first in univariate analyses without covariates, followed by models that adjusted for patient demographic factors (eg, age, gender, ethnicity, education, income, and type of diabetes). Change in hypoglycemia events was examined by comparing the past 6 month period to the 6-month period before starting or seeking to use RT-CGM. Changes in

Table 1. Sample Description by RT-CGM Group.

	Total sample (n = 285), n (%)	Current RT-CGM users (n = 210), n (%)	RT-CGM hopefuls (n = 75), n (%)	*P* value
Age, mean (SD)	70.7 (5.0)	70.4 (5.0)	71.4 (4.9)	.16
Gender (female)	137 (48.1)	99 (47.1)	38 (50.7)	.60
Education level				.03
Some high school or high school graduate	29 (10.2)	17 (8.1)	12 (16.0)	.49
Some college	61 (21.4)	39 (18.6)	22 (29.3)	.29
College graduate	51 (17.9)	38 (18.1)	13 (17.3)	
Some postgraduate work	36 (12.6)	27 (12.9)	9 (12.0)	
Postgraduate degree	108 (37.9)	89 (42.4)[a]	19 (25.3)[b]	
Ethnicity				.55
Non-Hispanic white	267 (95.7)	197 (95.6)	70 (95.9)	
African American	3 (1.1)	2 (1.0)	1 (1.4)	
Hispanic	2 (0.7)	1 (0.5)	1 (1.4)	
Asian or Pacific Islander	5 (1.8)	5 (2.4)	0 (0)	
Native American	2 (0.7)	1 (0.5)	1 (1.4)	
Employed (part- or full-time)	44 (15.4)	33 (15.7)	11 (14.7)	.83
Annual household income				<.001
Less than $50,000	73 (25.6)	41 (14.4)[a]	32 (42.7)[b]	
$50,000-$99,999	84 (29.5)	64 (30.5)	20 (26.7)	
$100,000-$149,999	40 (14.0)	37 (17.6)[a]	3 (4.0)[b]	
$150,000 or more	88 (30.9)	68 (32.4)	20 (26.7)	
Diabetes type				.01
Type 1	260 (91.2)	197 (93.8)	63 (84.0)	
Type 2	25 (8.8)	13 (6.2)	12 (16.0)	
Years since diagnosis, mean (SD)	36.1 (18.5)	35.7 (18.8)	37.3 (18.8)	.51
Insulin delivery system				.20
Pump	161 (56.5)	125 (59.5)	36 (48.0)	
MDI	119 (41.8)	82 (39.0)	37 (49.3)	
Pump and MDI	5 (1.8)	3 (1.4)	2 (2.7)	
Blood glucose monitoring (tests/day), mean (SD)	5.8 (2.8)	5.6 (2.6)	6.5 (2.9)	.008

reported unadjusted rates of hypoglycemia events were examined with McNemar analyses, followed by logistic regression analyses that controlled for patient demographic factors.

Results

Sample Demographics

A total of 609 patients began the survey, though 251 did not meet entry criteria and a further 62 did not complete the survey. Thus, 296 eligible participants completed the entire survey (48.6% of the total). Of that number, 210 were from current RT-CGM users, 75 from RT-CGM hopefuls and an additional 11 were from former RT-CGM users. This last group was too small for data analysis and was therefore excluded from further investigation.

As seen in Table 1, mean age was 70.7 (±5.0) years, mean diabetes duration was 36.1 years (±18.5), 48.1% were female and 56.5% were using CSII. The majority of respondents were non-Hispanic white (95.7%), had T1D (91.2%), and were not employed either full time or part time (84.6%). Compared to current RT-CGM users, RT-CGM hopefuls reported significantly lower incomes (42.7% vs 14.4% made < $50,000/year; $P < .001$) and less education (45.3% vs 26.7% had not completed college; $P < .05$). Of note, blood glucose monitoring was significantly more frequent among RT-CGM hopefuls than among current RT-CGM users (6.5 tests/day vs 5.6 tests/day; $P < .01$). Finally, the current RT-CGM user sample included fewer iT2D patients than the RT-CGM hopeful sample (6.2% vs 16.0%; $P = .01$).

Hypoglycemia

RT-CGM hopefuls were significantly more likely than current RT-CGM users to report ≥ 1 moderate hypoglycemic episode over the past 6 months (90.7% vs 78.1%; $P < .05$), ≥ 1 hypoglycemia-related ER visit over the past 6 months (18.7% vs 6.7%; $P = .003$) and ≥ 1 hypoglycemic event requiring the assistance of another person over the past 6 months (80.0% vs 57.6%; $P = .001$) (Table 2). Except for ER visits, these group differences remained significant ($P < .01$)

Table 2. Group Differences on Psychosocial and Hypoglycemia Variables, Current RT-CGM Users Compared to RT-CGM Hopefuls.

	Total sample (n = 285)	Current CGM users (n = 210)	CGM hopefuls (n = 75)	Univariate model	Adjusted model
Mild/moderate hypoglycemic episodes (yes/no)					
Moderate episodes (≥1), past 6 months	232 (81.4%)	164 (78.1%)	68 (90.7%)	OR = 2.73*	OR = 4.67**
BG reading < 70, with symptoms (≥1), in past month	137 (56.8%)	99 (57.9%)	38 (54.3%)	OR = 0.86	OR = 1.37
BG reading < 70, no symptoms (≥1), in past month	147 (60.7%)	103 (59.9%)	44 (62.9%)	OR = 1.13	OR = 1.31
Severe hypoglycemia-related events (yes/no)					
Episode requiring assistance (≥1), past 6 months	181 (63.5%)	121 (57.6%)	60 (80.0%)	OR = 2.92**	OR = 3.51**
Paramedic visit (≥1), past 6 months	39 (13.7%)	25 (11.9%)	14 (18.7%)	OR = 1.70	OR = 1.41
ER visit (≥1), past 6 months	28 (9.8%)	14 (6.7%)	14 (18.7%)	OR = 3.21**	OR = 1.92
Auto accident (≥1), past 6 months	7 (2.5%)	5 (2.4%)	2 (2.7%)	OR = 1.12	OR = 0.89
Hospitalization (≥1), past 6 months	13 (4.6%)	7 (3.3%)	6 (8.0%)	OR = 2.52	OR = 2.55
Quality of life					
Well-being (WHO-5)	3.2 (1.0)	3.3 (1.0)	2.7 (1.2)	β = –.25***	β = –.24***
Hypoglycemia Worry (HFS)	28.2 (15.4)	27.1 (15.4)	31.5 (15.1)	β = .13*	β = .12
Diabetes Distress total (T1-DDS)	2.3 (0.7)	2.2 (0.7)	2.5 (0.7)	β = .20*	β = .12
T1-DDS subscales					
Powerlessness	3.1 (1.2)	2.9 (1.2)	3.5 (1.2)	β = .19**	β = .16*
Management	2.0 (0.9)	1.9 (0.9)	2.3 (1.0)	β = .19**	β = .10
Hypoglycemia	3.4 (1.4)	3.2 (1.4)	3.8 (1.3)	β = .19**	β = .17*
Negative social perceptions	1.6 (0.8)	1.5 (0.8)	1.6 (0.9)	β = .04	β = .06
Eating	2.3 (1.0)	2.2 (1.0)	2.5 (1.0)	β = .11	β = .03
Physician	1.4 (0.7)	1.3 (0.6)	1.5 (0.9)	β = .10	β = .03
Family/friends	2.0 (1.1)	1.9 (1.0)	2.2 (1.2)	β = .10	β = .05

Univariate linear and logistic regression models examined RT-CGM group differences in hypoglycemic events. Adjusted models also controlled for age, gender, ethnicity, education level, annual household income, and type of diabetes. Standardized betas are reported from linear models.
*$P < .05$. **$P < .01$. ***$P < .001$.

after adjusting for key covariates (age, gender, ethnicity, diabetes type, education level, and income).

Among current users, the likelihood of severe hypoglycemic events in the past 6 months was significantly lower than in the 6-month period before beginning RT-CGM (the "retrospective baseline period"). As seen in Table 3, this includes drops in the incidence of events requiring the assistance of another, hypoglycemia-related hospitalizations, ER visits, paramedic visits to the home, and auto accidents. In contrast, among RT-CGM hopefuls, there were no significant differences in the occurrence of severe hypoglycemic events in the past 6 months versus the retrospective baseline period (the 6-month period before they first requested RT-CGM). Current RT-CGM users were significantly more likely than RT-CGM hopefuls to report reductions over the 2 time periods in events requiring the assistance of another, ER visits and paramedic visits to the home (in all cases, $P < .01$). These group differences remained significant after adjusting for key covariates (age, gender, ethnicity, diabetes type, education level and income). Of note, there were no significant group differences in reported hypoglycemic events during the retrospective baseline period, except for paramedic visits to the home (significantly more incidences among RT-CGM current users vs RT-CGM hopefuls, $P < .05$).

Quality of Life

RT-CGM hopefuls reported significantly poorer well-being ($P < .001$), greater hypoglycemic fear ($P < .05$), and more overall diabetes distress ($P < .05$) than current RT-CGM users (Table 2). Among the T1-DDS subscales, RT-CGM hopefuls reported significantly more hypoglycemic distress, more diabetes management distress, and more feelings of powerlessness than current RT-CGM users (in all cases, $P < .01$). After adjusting for key covariates, significant differences in well-being ($P < .001$), hypoglycemic distress ($P < .05$), and feelings of powerlessness ($P < .05$) remained.

Discussion

These findings suggest that RT-CGM may be of significant value among adults with diabetes ≥ 65 years. In contrast to those who had tried to obtain RT-CGM but could not do so due to inadequate insurance coverage (RT-CGM "hopefuls"), current RT-CGM users reported significantly fewer moderate and severe hypoglycemic episodes over the past 6 months as well as significantly better QOL (ie, greater well-being, less emotional distress concerning hypoglycemia and less distress regarding feelings of diabetes-related powerlessness). In addition, current RT-CGM users reported significantly greater

Table 3. Change Over Time in Hypoglycemic-Related Events for Current RT-CGM Users and Hopeful RT-CGM Users.

	Current RT-CGM user	RT-CGM hopeful	Univariate model	Adjusted model
Episode requiring assistance (yes/no)			OR = 4.35***	OR = 5.53***
During the 6 months before starting, or seeking, RT-CGM	154 (73.3%)	56 (74.7%)		
Last 6 months	121 (57.6%)	60 (80.0%)		
Pre-post difference	–15.7%***	+5.3%		
Paramedic visit (yes/no)			OR = 3.48**	OR = 3.39*
During the 6 months before starting, or seeking, RT-CGM	69 (32.9%)	16 (21.3%)		
Last 6 months	25 (11.9%)	14 (18.7%)		
Pre-post difference	–21.0%***	–2.6%		
ER visit (yes/no)			OR = 5.22***	OR = 3.49*
During the 6 months before starting, or seeking, RT-CGM	41 (19.5%)	11 (14.7%)		
Last 6 months	14 (6.7%)	14 (18.7%)		
Pre-post difference	–12.8%***	+4.0%		
Auto accident (yes/no)			OR = 1.54	OR = 3.72
During the 6 months before starting, or seeking, RT-CGM	14 (6.7%)	4 (5.3%)		
Last 6 months	5 (2.4%)	2 (2.7%)		
Pre-post difference	–4.3%**	–2.6%		
Hospitalization (yes/no)			OR = 2.91	OR = 4.32
During the 6 months before starting, or seeking, RT-CGM	18 (8.6%)	6 (8.0%)		
Last 6 months	7 (3.3%)	6 (8.0%)		
Pre-post difference	–5.3%*	0%		

McNemar analyses compared pre-post hypoglycemic events within each RT-CGM group. Univariate logistic regression models examined RT-CGM group differences on changes in hypoglycemic events. Adjusted logistic regression models also controlled for age, gender, ethnicity, education level, annual household income, and type of diabetes.
*$P < .05$. **$P < .01$. ***$P < .001$.

reductions over time than RT-CGM hopefuls in hypoglycemic events requiring the assistance of another, hypoglycemia-associated ER visits, and paramedic visits to the home. Note that all of these results remained significant after adjusting for critical demographic differences (eg, income and education level). While health care cost data were not available, these results suggest that current RT-CGM users may have had lower costs—at least over the prior 6 months, due to the relative absence of ER and paramedic visits—compared to RT-CGM hopefuls. In total, these data are consistent with recent patient-reported findings pointing to impressive glycemic and QOL benefits resulting from RT-CGM use in broader populations.[3]

It is noteworthy that severe hypoglycemic events, especially among the RT-CGM hopeful group, were far from rare—with 80% reporting at least 1 severe event in the past 6 months, 19% reporting at least 1 hypoglycemia-related ER visit and/or 1 paramedic visit, and 8% reporting at least 1 hypoglycemia-related hospitalization in that same time period. Indeed, this is in keeping with previous studies indicating that hospitalizations and ER visits for hypoglycemia among Medicare beneficiaries are, unfortunately, surprisingly common.[9,14] Given the potential vulnerability of this older population and the resulting costs associated with these events, it is unfortunate that RT-CGM is not at this time covered as a benefit under Medicare, thereby often making it all but unaffordable to those in the elderly population at lower or fixed income levels. Not surprisingly, the current study found that income level in the RT-CGM hopeful group was significantly lower than in the RT-CGM current users group. As an illustration, consider that those with incomes < $50,000/year comprised 42.7% of RT-CGM hopefuls versus only 14.4% of RT-CGM current users.

The potential value of RT-CGM in older adults is becoming more widely recognized,[10] especially given the growing understanding that reduced hypoglycemic awareness is a major contributor to the problems of severe hypoglycemia in this patient population.[6] Indeed, from the RT-CGM current users group, we informally surveyed a small number of their physicians (n = 26) and found that the vast majority agreed that RT-CGM had helped their patient to achieve better control of their diabetes (96.2%) and had led to an improvement in their patient's QOL (100%), while all agreed that Medicare should provide RT-CGM coverage in "appropriately needy patients over 65." Future studies will need to document these observations in a more prospective manner.

Major strengths of this study include the use of well-established psychometric instruments as well the inclusion of a relatively large sample of older adults who were interested in RT-CGM but were unable to obtain insurance coverage (the RT-CGM hopefuls); this is, as far as we can ascertain, the first investigation of this patient population. Several cautions, however, should be noted. The study was limited to cross-sectional data only, and relied on respondents' self-reports of their current and past experiences. In addition, there were key differences between the 2 groups, with the RT-CGM hopeful group reporting significantly lower income and fewer years of education and composing a larger percentage of iT2D patients than the RT-CGM current users group. Given the problems with insurance coverage, these differences are to be expected, but it remains as a notable issue—even though statistical adjustments were made—that the groups were not evenly matched. Finally, it is important to recognize that the overall sample was highly educated and mostly non-Hispanic white, as was seen in a previous study of Dexcom RT-CGM users,[3] but it is not known whether survey responders are truly representative of the larger population of elderly RT-CGM users.

In summary, these data suggest that RT-CGM use in seniors is associated with marked reductions in suffering from severe hypoglycemia and notable improvement in QOL. Thus, restrictive access to RT-CGM due to lack of Medicare coverage may have significant deleterious health, economic, and QOL consequences in this population. Further studies are needed to confirm these findings.

Abbreviations

AACE, American Association of Clinical Endocrinologists; ADA, American Diabetes Association; ER, emergency room; HFS, Hypoglycemic Fear Survey; iT2D, insulin-using type 2 diabetes; MDI, multiple daily injections; QOL, quality of life; RT-CGM, real-time continuous glucose monitoring; T1D, type 1 diabetes; T1-DDS, Diabetes Distress Scale for Type 1 Diabetes; WHO-5, World Health Organization–5.

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Declaration of Conflicting Interests

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