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ORIGINAL ARTICLE

Effectiveness of Continuous Glucose Monitoring in Older Adults with Type 2 Diabetes Treated with Basal Insulin

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Abstract

Objective: To evaluate the effectiveness and safety of real-time continuous glucose monitoring (CGM) in adults 65 years old and older with type 2 diabetes (T2D) using basal without bolus insulin.

Research Design and Methods: Using data from the MOBILE randomized trial comparing CGM versus blood glucose meter (BGM) monitoring for T2D treated with basal insulin, the treatment effect in participants ≥65 years (range: 65–79 years, $N=42$) was compared with the treatment effect in participants <65 years (range: 33–64 years, $N=133$).

Results: For participants ≥65 years old, mean change in hemoglobin A1c (HbA1c) was −1.08% in the CGM group and −0.38% in the BGM group (adjusted mean difference = −0.65% [95% confidence interval (CI) −1.49 to 0.19]). In contrast, the adjusted mean difference in HbA1c between treatment groups was −0.35% [95% CI −0.77 to 0.07] in the <65 years age group. For time in range 70–180 mg/dL (TIR), mean adjusted treatment group difference was 19% (95% CI 4 to 35, $P=0.01$) in ≥65 years old participants and 12% (95% CI 4 to 19, $P=0.003$) in those <65 years old. Comparable treatment group differences favoring the CGM group were observed in both the ≥65 and <65 years age groups for mean glucose and less time >180, 250, and 300 mg/dL. Hypoglycemia was low in both groups with little difference between treatment groups in both age groups.

Conclusions: In this study of adults with T2D treated with basal insulin without bolus insulin, participants ≥65 years old using CGM had a greater increase in TIR and a reduction in hyperglycemia than those using BGM and the benefit appeared to be at least as great as that observed in younger adults.

Keywords: Continuous glucose monitoring, Older adults, Type 2 diabetes.

Introduction

Type 2 diabetes (T2D) affects nearly 21 million people, or 8.6% of the population, in the United States.[1] The prevalence of T2D in adults ages 65 years and older in the United States is roughly 19.6%, higher than any other age group.[1] In those with T2D, older age and worse glycemic control increase the risk of developing microvascular and macrovascular diabetes complications and a higher rate of morbidity and mortality.[2]

Many people with T2D treated with insulin struggle to maintain adequate glucose levels, with only 62% achieving a hemoglobin A1c (HbA1c) <8.0% and 31% achieving an HbA1c less than the recommended target of 7.0%.[3] Continuous glucose monitoring (CGM) allows individuals to see their glucose trends in real time by providing glucose measurements every 5 min, leading to more informed decisions regarding diabetes management.

Previous studies have shown that CGM improves glycemic outcomes in older adults with type 1 diabetes[4] and T2D using multiple daily injections (MDIs),[5,6] and a recent trial demonstrated the effectiveness of CGM therapy in adults with T2D using basal insulin.[7] However, information on the effectiveness of CGM in older adults not using MDIs or insulin pumps in a T2D cohort is lacking. Accordingly, some payers, such as the Centers for Medicare & Medicaid Services (CMS) restrict coverage for people with T2D to those using MDIs or insulin pumps.

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The MOBILE study was an 8-month randomized clinical trial comparing the use of CGM with the use of blood glucose meter (BGM) monitoring in adults with T2D treated with basal insulin without prandial or bolus insulin.[7] In this analyses, data collected from the MOBILE study were used to examine the effectiveness of CGM in improving glycemic status in adults aged 65 years or older and separately in adults <65 years. The safety and psychosocial impacts of CGM use within these age groups were also evaluated.

Methods

The MOBILE trial was a multicenter randomized open-label parallel-group trial conducted at 15 centers in the United States. Details of the protocol and methods have been previously published[7,8]; relevant aspects of the protocol are summarized hereunder. The protocol and informed consent form were approved by a central institutional review board for 14 centers and a local board for one center (trial registration NCT03566693).

Study participants and trial design

Potential participants with T2D using basal insulin without bolus insulin were recruited from primary care practices and could not be receiving care from an endocrinologist. Major inclusion and exclusion criteria have been summarized previously.[7] Enrolled participants had an age range of 33 to 79 years and an HbA1c range of 7.8% to 11.4% at screening. After enrollment, participants wore a blinded CGM for up to 10 days before randomization and participants must have provided at least 168 h (7 days) of CGM data to be eligible. Blood was drawn before randomization to measure HbA1c.

Participants were randomly assigned to the CGM or BGM groups in a 2:1 ratio. The CGM group was provided with a G6 continuous glucose monitor (Dexcom, Inc., San Diego, CA). Participants in the BGM group were provided a Bluetooth-enabled BGM (OneTouch Verio Flex; LifeScan, Inc., Malvern, PA) and were asked to perform BGM fasting and postprandial testing one to three times daily. CGM and BGM data were remotely interpreted at months 2, 4, and 6 by clinicians at the research sites, discussed with participants, and shared with primary care providers who managed the participants' diabetes and therapeutics.

Participants in the CGM group wore the device continuously up through 8 months, whereas participants in the BGM group wore a blinded CGM during the 10 days after the 3-month visit and 10 days leading up to the 8-month visit. To get a comparable sample in the CGM group, data collected in the 10 days after month 3 and 10 days before month 8 were used to compute CGM outcomes. CGM metrics were calculated by pooling data from the 3- to 8-month CGM wear periods. HbA1c was collected at randomization, month 3, and month 8 and measured at a central laboratory. Changes in antihyperglycemic medications were made by the primary care provider.

Statistical methods

Participants were divided into two subgroups based on age at enrollment: ≥65 and <65 years. Outcomes for this study included HbA1c, time in range 70–180 mg/dL (TIR), mean glucose, glucose coefficient of variation, time >180, 250, and 300 mg/dL, time <70 and 54 mg/dL, change in insulin administration, adding or stopping diabetes medication, adding prandial insulin, and experiencing hyperglycemic events defined as at least 90 min with CGM >300 mg/dL in a 120-minute window. A prolonged hyperglycemic event was defined as a CGM-derived hyperglycemic event lasting 8 h or longer. Outcomes were compared between the treatment arm within each age group, and interactions between treatment and age group were tested.

Continuous outcomes were compared between treatment groups using longitudinal mixed effects linear models adjusting for the baseline value and clinical site as a random effect. A point estimate for the mean difference, 95% confidence interval (CI), and *P*-value are reported from each model. Binary outcomes were compared using repeated measures logistic regression models adjusting for the baseline value as a fixed effect and clinical site as a random effect. A risk difference, 95% CI, and *P*-value are reported for each binary outcome.

Risk differences were estimated as in Kleinman and Norton[9] and CIs were estimated using a bootstrap. For continuous outcomes, interactions were tested by adding a treatment by age group interaction term to the model. For binary outcomes, interactions on the risk differences were tested using a Q' test, which cannot adjust for baseline value or clinical site.[10] Quality of life and safety outcomes are reported descriptively with no formal statistical comparisons between groups.

All *P*-values and CIs reported are two sided. For this post hoc analysis, no adjustments were made for multiple comparisons and results are considered exploratory. Analyses were conducted using SAS version 9.4 (SAS Institute, Cary, NC).

Results

Demographic and clinical characteristics for the ≥65 years age group ($N = 42$) and the <65 years age group ($N = 133$) are given in Table 1. There was a higher proportion of participants of white race in the ≥65 years group. CGM use was high in both age groups, with both groups using CGM an average of 5.5 days per week.

Glycemic outcomes

Mean absolute reduction in HbA1c was −1.08% in the CGM group for both age cohorts, whereas the mean reduction in the BGM group was −0.38% and −0.73% in the ≥65 and <65 years age groups, respectively. Within the ≥65 years age group, the adjusted mean difference in HbA1c was −0.65% (95% CI −1.49 to 0.19), whereas in the <65 years age group, the adjusted mean treatment group difference in HbA1c was −0.35% (95% CI −0.77 to 0.07) (Table 2 and Fig. 1). Change in HbA1c showed treatment group differences that were largely consistent across age with little or no correlation with age (Fig. 2).

In the ≥65 years old participants, change in TIR from baseline was 16% ± 24% in the CGM group versus −5% ± 22% in the BGM group (adjusted difference = 19%, 95% CI 4 to 35, $P = 0.01$), whereas in the <65 years old participants, TIR change from baseline was 17% ± 29% versus 8% ± 26%, respectively (adjusted difference = 12%, 95% CI 4 to 19, $P = 0.003$; Table 2 and Fig. 1). Comparable treatment group differences favoring the CGM group were observed in both the ≥65 and <65 years age groups for mean glucose and less time >180, 250, and 300 mg/dL.

Table 1. Clinical and Demographic Characteristics Overall and by Age

	Overall		*Age ≥65 years*		*Age <65 years*	
	≥65 years (N = 42)	*<65 years (N = 133)*	*CGM (N = 27)*	*BGM (N = 15)*	*CGM (N = 89)*	*BGM (N = 44)*
Age, years (mean ± SD)	69 ± 4	53 ± 7	68 ± 3	70 ± 4	53 ± 7	55 ± 7
Gender—Female	19 (45%)	69 (52%)	14 (52%)	5 (33%)	47 (53%)	22 (50%)
Race or ethnicity group[a]						
White non-Hispanic	30 (71%)	53 (40%)	17 (63%)	13 (87%)	33 (37%)	20 (45%)
Black non-Hispanic	3 (7%)	29 (22%)	3 (11%)	0 (0%)	21 (24%)	8 (18%)
Hispanic or Latino	5 (12%)	44 (33%)	4 (15%)	1 (7%)	31 (35%)	13 (30%)
Asian	3 (7%)	5 (4%)	2 (7%)	1 (7%)	2 (2%)	3 (7%)
American Indian/Alaskan Native	1 (2%)	0 (0%)	1 (4%)	0 (0%)	0 (0%)	0 (0%)
More than one race	0 (0%)	2 (2%)	0 (0%)	0 (0%)	2 (2%)	0 (0%)
Highest education level						
Less than high school diploma	6 (14%)	30 (23%)	5 (19%)	1 (7%)	21 (24%)	9 (20%)
High school	12 (29%)	48 (36%)	6 (22%)	6 (40%)	33 (37%)	15 (34%)
Bachelor's degree	15 (36%)	44 (33%)	9 (33%)	6 (40%)	26 (29%)	18 (41%)
Advanced degree	8 (19%)	11 (8%)	6 (22%)	2 (13%)	9 (10%)	2 (5%)
Did not provide	1 (2%)	0 (0%)	1 (4%)	0 (0%)	0 (0%)	0 (0%)
Insurance coverage[b]						
Private	6 (14%)	67 (50%)	5 (19%)	1 (7%)	46 (52%)	21 (48%)
Medicare	35 (83%)	33 (25%)	21 (78%)	14 (93%)	21 (24%)	12 (27%)
Medicaid	1 (2%)	16 (12%)	1 (4%)	0 (0%)	10 (11%)	6 (14%)
Other government insurance	0 (0%)	12 (9%)	0 (0%)	0 (0%)	9 (10%)	3 (7%)
None	0 (0%)	5 (4%)	0 (0%)	0 (0%)	3 (3%)	2 (5%)
Diabetes duration, mean ± SD years	16 ± 10	13 ± 9	16 ± 9	17 ± 13	13 ± 9	14 ± 8
Self-reported BGM monitoring						
≤1 check per day	23 (55%)	61 (46%)	16 (59%)	7 (47%)	45 (51%)	16 (36%)
≥2 checks per day	19 (45%)	72 (54%)	11 (41%)	8 (53%)	44 (49%)	28 (64%)
Median (q1, q3)	1 (1, 2)	2 (1, 2)	1 (1, 2)	2 (1, 2)	1 (1, 2)	2 (1, 2)
Number of noninsulin glucose lowering medications						
None	3 (7%)	13 (10%)	2 (7%)	1 (7%)	9 (10%)	4 (9%)
1	15 (36%)	47 (35%)	10 (37%)	5 (33%)	32 (36%)	15 (34%)
2	20 (48%)	64 (48%)	13 (48%)	7 (47%)	43 (48%)	21 (48%)
3	3 (7%)	8 (6%)	1 (4%)	2 (13%)	5 (6%)	3 (7%)
≥4	1 (2%)	1 (<1%)	1 (4%)	0 (0%)	0 (0%)	1 (2%)
HbA1c level at randomization						
Mean ± SD%	9.0 ± 1.0	9.1 ± 0.9	9.1 ± 1.0	8.8 ± 0.8	9.2 ± 1.0	9.1 ± 0.9
<8.5%	15 (36%)	33 (25%)	9 (33%)	6 (40%)	22 (25%)	11 (26%)
8.5% to <10.0%	19 (45%)	71 (54%)	12 (44%)	7 (47%)	46 (52%)	25 (58%)
≥10.0%	8 (19%)	27 (21%)	6 (22%)	2 (13%)	20 (23%)	7 (16%)
Body mass index, mean ± SD kg/m^2	33.6 ± 5.6	33.9 ± 6.9	34.3 ± 6.1	32.4 ± 4.3	33.7 ± 6.9	34.5 ± 6.8
Basal insulin, mean ± SD U/kg per day	0.49 ± 0.23	0.48 ± 0.28	0.54 ± 0.22	0.40 ± 0.23	0.45 ± 0.26	0.53 ± 0.32
Non-HDL cholesterol[c], mean ± SD mg/dL	–03 ± 34	128 ± 47	103 ± 34	102 ± 35	128 ± 50	127 ± 43
C-peptide[c], mean ± SD ng/mL	2.8 ± 2.0	3.2 ± 2.6	2.8 ± 2.1	2.8 ± 1.8	3.0 ± 2.3	3.6 ± 3.3
Subjective Numeracy Scale[d], mean ± SD	3.9 ± 1.0	4.0 ± 1.0	3.9 ± 1.1	4.1 ± 0.7	4.1 ± 1.0	3.8 ± 1.2

[a]Race/ethnicity is self-reported.
[b]Medicare includes nine in CGM group and two in control group who also had private insurance and two in CGM group and one in control group who also had Medicaid. Medicaid includes two in CGM group who also reported having private insurance.
[c]C-peptide and cholesterol were measured locally at each study center.
[d]Includes eight items, each on a 1–6 scale, evaluating ability to perform various mathematical tasks and preferences for the use of numerical versus prose information as an indicator of mathematical ability that may be useful for diabetes management. Each item is on a 1–6 scale. The score for a participant represents an average across the six items, with a higher score denoting a higher perceived mathematical ability.
BGM, blood glucose meter; CGM, continuous glucose monitoring; HbA1c, hemoglobin A1c; SD, standard deviation.

Changes in the CGM metrics had little or no correlation with age (Fig. 2 and Supplementary Fig. S1). The proportion of participants with an absolute increase of ≥15% TIR from baseline to 8 months was 59% in the CGM group and 14% in the BGM group for participants aged ≥65 years old (difference = 44%, 95% CI 16 to 67) and 51% versus 35% in the CGM and BGM groups, respectively (difference = 16%, 95% CI −10 to 39), for participants <65 years old (Table 2).

The proportion of participants with an absolute reduction of ≥1.0% HbA1c from baseline to 8 months, a relative reduction of ≥10% HbA1c from baseline to 8 months, and an

Table 2. Glycemic Outcomes by Age and Treatment Arm

	Age ≥65 years			*Age <65 years*		
	CGM N = *27*	*BGM* N = *15*	*Adjusted difference (95% CI) [P-value]*[a]	*CGM* N = *89*	*BGM* N = *44*	*Adjusted difference (95% CI) [P-value]*[a]
Baseline HbA1c (%)	9.1 ± 1.0	8.8 ± 0.8		9.2 ± 1.0	9.1 ± 0.9	
Baseline TIR 70–180 mg/dL	47% ± 22%	51% ± 20%		38% ± 26%	36% ± 26%	
HbA1c change from baseline to month 8	*N* = 25	*N* = 13		*N* = 79	*N* = 38	
HbA1c (%)	−1.08 ± 1.23	−0.38 ± 0.92	−0.65 (−1.49, 0.19) [0.13]	−1.08 ± 1.55	−0.73 ± 1.24	−0.35 (−0.77, 0.07) [0.10]
Decrease by ≥0.5%	18 (72%)	8 (62%)	22% (−6, 47) [0.13]	58 (73%)	25 (66%)	8% (−1, 20) [0.11]
Decrease by ≥1.0%	16 (64%)	3 (23%)	42% (16, 63) [0.003]	40 (51%)	17 (45%)	5% (−12, 23) [0.56]
Relative reduction ≥10%	18 (72%)	3 (23%)	49% (21, 71) [0.002]	48 (61%)	18 (47%)	13% (2, 25) [0.02]
Decrease by ≥0.5% or HbA1c <7.0% at month 8	18 (72%)	8 (62%)	22% (−6, 47) [0.13]	58 (72%)	25 (66%)	7% (−3, 19) [0.19]
CGM metrics change from baseline	*N* = 22	*N* = 14		*N* = 80	*N* = 40	
TIR 70–180 mg/dL	16% ± 24%	−5% ± 22%	19% (4, 35) [0.01]	17% ± 29%	8% ± 26%	12% (4, 19) [0.003]
Increase ≥5%	15 (68%)	5 (36%)	31% (0, 57) [0.05]	52 (65%)	20 (50%)	15% (−4, 33) [0.13]
Increase ≥10%	14 (64%)	3 (21%)	41% (16, 62) [0.002]	46 (58%)	17 (43%)	14% (−7, 35) [0.18]
Increase ≥15%	13 (59%)	2 (14%)	44% (16, 67) [0.003]	41 (51%)	14 (35%)	16% (−10, 39) [0.21]
T > 180 mg/dL	−16% ± 24%	4% ± 22%	−19% (−35, −4) [0.02]	−17% ± 29%	−9% ± 27%	−11% (−19, −3) [0.006]
T > 250 mg/dL[b]	−8% ± 14%	4% ± 14%	−12% (−21, −2) [0.02]	−13% ± 18%	−2% ± 16%	−11% (−16, −6) [<0.001]
T > 300 mg/dL[b]	−2% ± 9%	3% ± 8%	−6% (−11, 0) [0.04]	−7% ± 12%	1% ± 10%	−7% (−10, −4) [<0.001]
T < 70 mg/dL[b]	−0.06% ± 0.54%	0.21% ± 0.90%	−0.29% (−0.78, 0.20) [0.23]	−0.00% ± 0.44%	0.40% ± 0.95%	−0.47% (−0.74, −0.21) [<0.001]
T < 54 mg/dL[b]	0.02% ± 0.06%	0.03% ± 0.16%	−0.03% (−0.14, 0.08) [0.58]	0.02% ± 0.06%	0.14% ± 0.27%	−0.16% (−0.24, −0.08) [<0.001]
Mean glucose (mg/dL)	−21 ± 40	12 ± 39	−33 (−59, −7) [0.01]	−28 ± 49	−10 ± 53	−18 (−33, −4) [0.01]
Coefficient of variation (%)	−2% ± 5%	0% ± 6%	−3% (−5, 0) [0.06]	2% ± 6%	4% ± 8%	−2% (−4, −0) [0.05]
Insulin change from baseline	*N* = 23	*N* = 12		*N* = 74	*N* = 36	
Total daily insulin (units)	−0.03 ± 0.18	−0.02 ± 0.14	0.00 (−0.13, 0.13) [1.00]	0.04 ± 0.25	0.07 ± 0.23	−0.05 (−0.15, 0.04) [0.29]
Added prandial insulin	1 (4%)	1 (7%)	−5% (−33, 16) [0.64]	11 (12%)	8 (18%)	−6% (−24, 8) [0.45]
Medication changes	*N* = 27	*N* = 15		*N* = 89	*N* = 44	
Added ≥1 diabetes medication	7 (26%)	7 (47%)	−23% (−42, −1) [0.04]	30 (34%)	17 (39%)	−4% (−19, 11) [0.57]
Stopped ≥1 diabetes medication	5 (19%)	2 (13%)	6% (−8, 19) [0.42]	10 (11%)	8 (18%)	−7% (−20, 4) [0.21]
HbA1c at month 8	*N* = 25	*N* = 13		*N* = 80	*N* = 38	
<7.0%	9 (36%)	1 (8%)	29% (16, 42) [<0.001]	11 (14%)	4 (11%)	4% (−8, 16) [0.48]
<7.5%	11 (44%)	3 (23%)	23% (−10, 45) [0.12]	29 (36%)	9 (24%)	13% (−9, 32) [0.24]
<8.0%	16 (64%)	6 (46%)	22% (−3, 45) [0.09]	50 (63%)	14 (37%)	26% (11, 40) [<0.001]
TIR at month 8	*N* = 24	*N* = 14		*N* = 80	*N* = 40	
>70%	13 (54%)	3 (21%)	34% (6, 60) [0.02]	22 (28%)	6 (15%)	13% (2, 25) [0.02]
Hyperglycemic events at month 8[c]	*N* = 24	*N* = 14		*N* = 80	*N* = 40	
≥1 Hyperglycemic event >300 mg/dL	12 (50%)	12 (86%)	−35% (−59, −8) [0.02]	54 (68%)	32 (80%)	−13% (−24, −1) [0.03]
≥1 Prolonged hyperglycemic event	9 (38%)	7 (50%)	−19% (−35, −3) [0.02]	36 (45%)	24 (60%)	−15% (−28, −1) [0.03]

[a]For continuous outcomes, estimates, CIs, and *P*-values were calculated from a repeated measures mixed effects linear regression model adjusting for clinical site as a random effect. For binary outcomes the risk difference, CIs, and *P*-values were estimated from a logistic regression model adjusting for the baseline value as a fixed effect and clinical site as a random effect.

[b]Winsorized at the 10th and 90th percentile before reporting summary statistics.

[c]A hyperglycemic event >300 mg/dL is defined as spending a cumulative 90 min or more >300 mg/dL in a 120-min window. A prolonged hyperglycemic event is defined as an event lasting at least 8 h.

CI, confidence interval; TIR, Time in range.

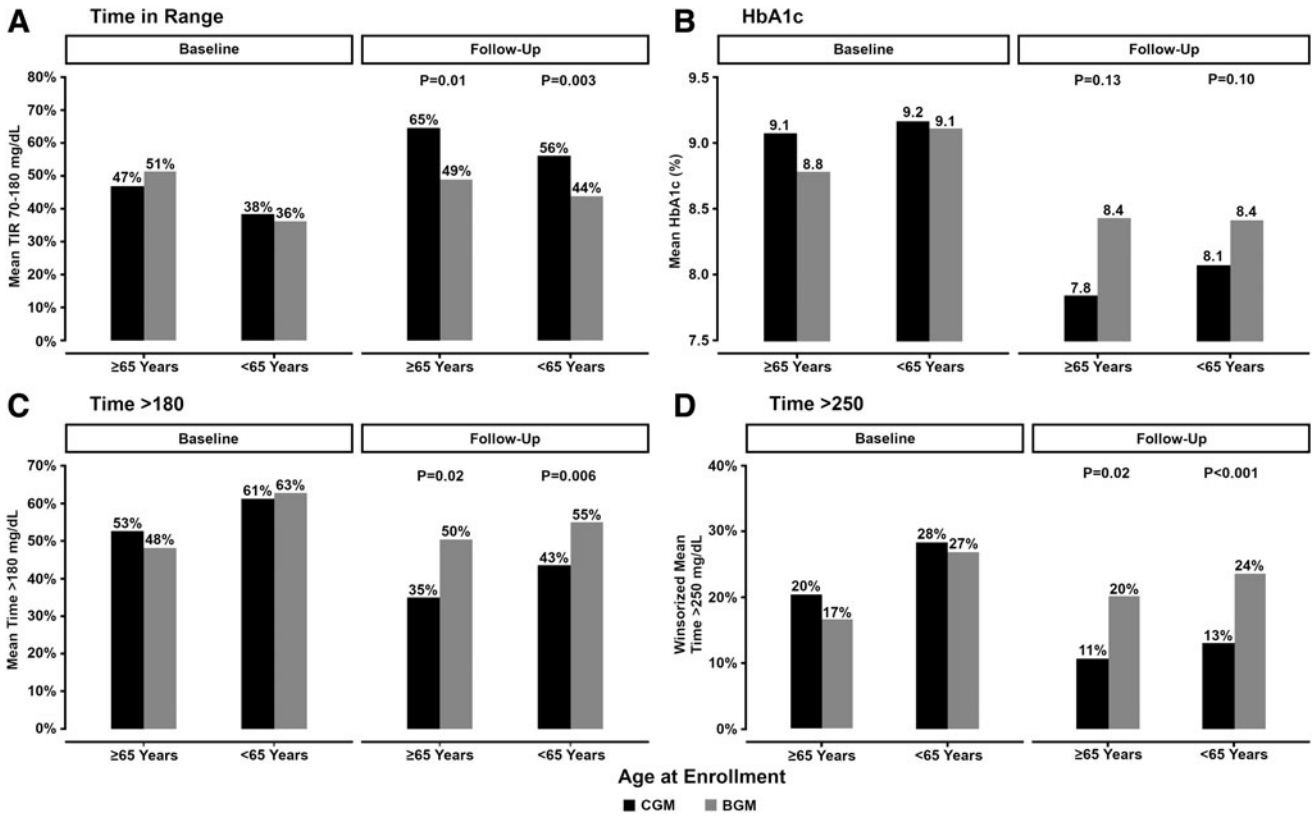

FIG. 1. **A:** Time in range 70–180 mg/dL. **B:** HbA1c. **C:** Time >180 mg/dL. **D:** Time >250 mg/dL. Glycemic outcomes by age and treatment arm at baseline and 8 months. Bar plots showing mean values at baseline and follow-up (month 3 and month 8 combined) by treatment group and age group. *P*-values for the mean difference between treatment groups within age groups are shown.

HbA1c <7.0% at 8 months were higher among CGM users in the ≥65 years group compared with CGM users in the <65 years group. In both age groups, a lower proportion of participants in the CGM group experienced a CGM-derived hyperglycemic event >300 mg/dL compared with the BGM group (Table 2). The amount of time spent in hypoglycemia was low in both age groups with little difference between treatment groups (Table 2). There were no significant interactions between age group and treatment for any outcomes.

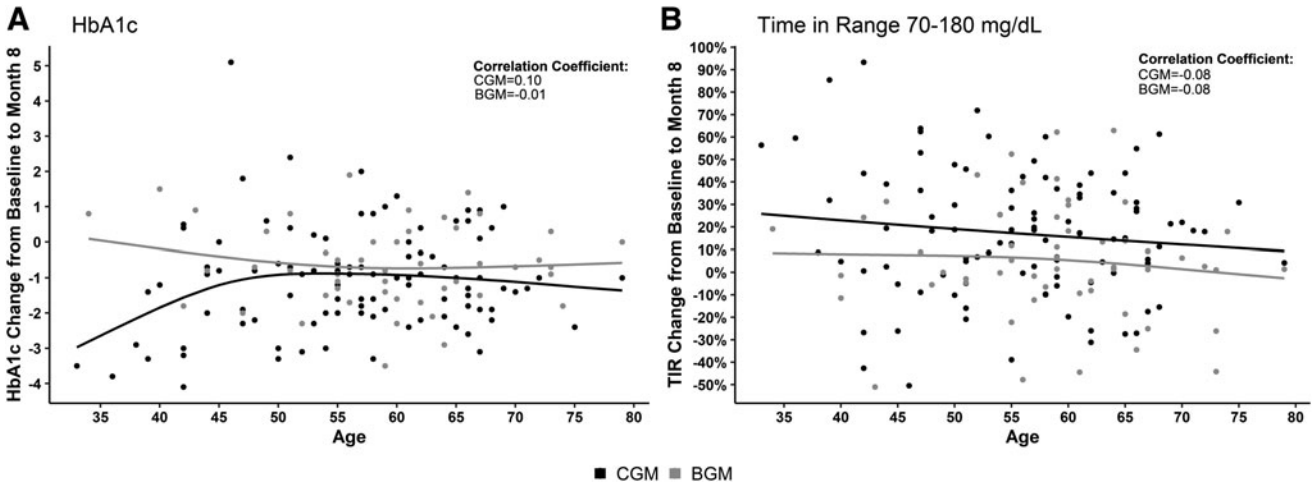

FIG. 2. Age by HbA1c (panel A) and TIR (panel B) change from baseline. Scatter plots showing smoothing spline curves for the relationship between age and change in HbA1c/TIR from baseline for each treatment arm. Treatment group differences were largely consistent across age except for HbA1c at younger age where the sample sizes are small and the mean baseline HbA1c is slightly higher. Spearman correlation coefficients are also reported. HbA1c, hemoglobin A1c; TIR, time in range.

Table 3. Quality of Life Improvement by Age

	Age ≥65 years		*Age <65 years*	
	CGM (N = 25)	*BGM (N = 13)*	*CGM (N = 83)*	*BGM (N = 42)*
Change from baseline				
Glucose monitoring satisfaction, mean score (range −4 to 4)	0.5 ± 0.7	0.2 ± 0.7	0.5 ± 0.7	0.2 ± 0.6
Openness mean score	0.9 ± 1.0	0.7 ± 1.0	0.7 ± 1.0	0.2 ± 1.0
Emotional burden mean score	−0.6 ± 1.4	−0.1 ± 1.5	−0.5 ± 1.1	−0.2 ± 1.4
Behavioral burden mean score	−0.5 ± 1.2	−0.1 ± 1.3	−0.7 ± 1.1	−0.5 ± 1.1
Trust mean score	−0.3 ± 0.9	−0.2 ± 0.9	−0.2 ± 0.7	−0.2 ± 0.8
CGM satisfaction at month 8				
Overall mean score (range 1 to 5)	4.0 ± 0.4	—	4.1 ± 0.5	—
Benefits subscale mean score	4.1 ± 0.5	—	4.2 ± 0.5	—
Hassles subscale mean score	2.0 ± 0.6	—	1.9 ± 0.6	—

Shaded rows in this table denote questionnaires that are reversed scored (lower number is better).

Insulin and diabetes medications

There were no significant differences in total daily insulin requirements between treatment groups in either age category (Table 2). Prandial insulin was added during follow-up in only 1 participant aged ≥65 years old in each treatment group (4% in CGM group vs. 7% in BGM group) and in 11 (12%) in the CGM group and 8 subjects (18%) in the BGM group for those <65 years old. Nearly double the percentage of participants in the ≥65 years old group using BGM added a new antihyperglycemic medicine relative to the CGM group (26% CGM vs. 47% BGM), whereas the percentage adding antihyperglycemic medication(s) was similar between treatment groups for those <65 years old (34% CGM vs. 39% BGM).

Quality of life

Descriptively, changes in quality-of-life measures appeared similar between treatment groups in both the ≥65 and <65 years age groups. For those ≥65 years, mean change in the diabetes distress scale score from baseline to 8 months was −0.3 and −0.4 in the CGM and BGM groups, and −0.4 and −0.3 in the CGM and BGM groups for those <65 years, respectively. Mean change in the hypoglycemia fear survey score was −0.1 and 0.0 in the CGM and BGM groups for those ≥65 years, and −0.2 and +0.2 in the CGM and BGM groups for those <65 years, respectively. The mean change from baseline to month 8 in overall glucose monitoring satisfaction score was 0.5 in the CGM group and 0.2 in the BGM group for both age groups (Table 3). Overall mean CGM satisfaction scores at month 8 was 4.0 out of 5 for ≥65 years age group and 4.1 out of 5 for <65 years age group.

Adverse events

There were two severe hypoglycemic events: one in the BGM group in the <65 years age group and one in the CGM group in the ≥65 years age group. One participant in the <65

Table 4. Adverse Events and Serious Adverse Events by Age

	Age ≥65 years		*Age <65 years*	
	CGM (N = 27)	*BGM (N = 15)*	*CGM (N = 89)*	*BGM (N = 44)*
Adverse events (including serious adverse events[a])				
No. of adverse events	14	2	31	14
Participants with one or more adverse events, *n* (%)	10 (37%)	2 (13%)	20 (22%)	10 (23%)
Serious adverse events[a] (excluding severe hypoglycemia and diabetic ketoacidosis events)				
No. of serious adverse events	3	2	11	5
Participants with one or more serious adverse events, *n* (%)	3 (11%)	2 (13%)	7 (8%)	3 (7%)
Severe hypoglycemic events				
No. of severe hypoglycemic events	1	0	0	1
Participants with one or more severe hypoglycemic events, *n* (%)	1 (4%)	0 (0%)	0 (0%)	1 (2%)
Diabetic ketoacidosis events				
No. of diabetic ketoacidosis events	0	0	1	0
Participants with one or more diabetic ketoacidosis events, *n* (%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)

[a]The following serious adverse events with hospitalization were reported:
≥65 years: CGM group: total knee replacement (2), arteriosclerotic heart disease (1). BGM group: chest pain (1), worsening hypertension (1).
<65 years: CGM group: hydronephrosis (1), COVID-19 (1), stroke (1), neurological disorder (1), infection (3), back surgery (1), intraspinal abscess (2), pneumonia (1). BGM group: osteomyelitis (1), kidney stones (1), catheter site pain (1), infection (1), shortness of breath (1).

years old in the CGM group had a diabetic ketoacidosis event. Other serious adverse events are listed in Table 4. There were no deaths.

Discussion

In this post hoc analysis of a randomized trial comparing CGM with BGM in adults with T2D using basal insulin without bolus insulin, improvement in key glycemic outcomes including TIR, and less time in hyperglycemia were observed with CGM compared with BGM in participants ≥65 years old, and was comparable with the treatment effect observed in younger participants. A comparable trend was observed for HbA1c reduction being greater with CGM than BGM. Compared with the BGM group, use of CGM yielded a 0.65% greater reduction in HbA1c for participants ≥65 years old and a 0.35% greater reduction in HbA1c for participants <65 years old.

Importantly, glycemic outcomes were improved using CGM while maintaining low frequency of hypoglycemia for both age groups. Although no age group by treatment interactions were significant, effect sizes were numerically larger in the ≥65 years group for key outcomes including HbA1c, TIR 70–180 mg/dL, and less time >180 mg/dL. A lack of statistical significance may be attributable to low statistical power for testing interactions. The ≥65-year-old group had a higher proportion of non-Hispanic white participants than the <65 years old group, but this did not affect the CGM–BGM comparisons.

The large treatment effect observed for the ≥65 years old age group is clinically relevant given the fact that this age group is at a higher risk of micro- and macrovascular complications related to poor glycemic control,[2,11] and since elderly patients face more challenges in finger stick self-glucose monitoring and insulin administration, due to vision, dexterity, cognitive impairment, and other comorbidities.[12] Current policy from CMS requires Medicare beneficiary being treated with three or more daily insulin injections or insulin pump to qualify for CGM coverage.[13]

Our study provides evidence that CGM therapy is effective in T2D using basal insulin without bolus insulin, and that elderly people with T2D on CGM therapy enjoy similar glycemic benefits as their younger counterparts. Therefore, there is need for a policy change to reflect the evidence and enable Medicare beneficiaries using basal without bolus insulin to have access to CGM.

The limitations of this analysis include a small sample size to test age group–treatment interactions. No adjustments for multiplicity were done and, therefore, the type 1 error rate may be inflated. The presumed lifestyle changes made by CGM users were also not defined and it is unknown how much of the benefit was related to dietary change, enhanced activity, or improved medication adherence.

In conclusion, the use of CGM is safe and beneficial for adults ≥65 years with T2D with poor glycemic control using basal-only insulin regimens. The glycemic improvements with CGM are at least as great in the elderly as observed in younger adults.

Authors' Contributions

S.B. and R.B. wrote the first draft and reviewed/edited the article. R.B. and P.C. conducted the statistical analyses. R.W.B. reviewed and edited the article. Dexcom had no approval authority for the article before submission, including no right to veto publication and no control on the decision regarding to which journal the article was submitted.

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Supplementary Material

Supplementary Figure S1

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