Original Article

PERSONAL REAL-TIME CONTINUOUS GLUCOSE MONITORING IN PATIENTS 65 YEARS AND OLDER

Nicholas B. Argento, MD[1]; Katherine Nakamura, PhD[2]

ABSTRACT

Objective: Little information is available on personal real-time continuous glucose monitoring (PCGM) in patients ≥65 years old. We report on PCGM use in insulin-requiring patients ≥65 years old in a community endocrine practice.

Methods: Patients ≥65 or older who had been prescribed PCGM were identified by retrospective review. Glycated hemoglobin (A1C) values from the year prior and subsequent to PCGM prescription, the most recent A1C value, continued PCGM usage, percentage reporting severe hypoglycemia (SH), and rate of SH were examined.

Results: Thirty-eight patients were identified: 31 with type 1 diabetes, 21 females, mean age 70 years (range 65-78), and a mean diabetes duration of 31 years. Overall, 28 were on insulin pump therapy, 29 were using PCGM regularly, and 25 had both pre- and post-PCGM use A1C results. Regular PCGM use was associated with a decrease in mean (SD) A1C: 7.6 (0.9)% to 7.1 (0.9)%, (P<.0001) that was maintained until the most recent A1C value (7.2 [0.8]%, P = .0145, average 37 months), with fewer reporting SH (from 79% to 31%, P = .0002), and a lower rate of SH (0.37 to 0.12 per year, P = .0007). The group of 9 patients who did not continue PCGM (mean use 3 months) was too small to allow meaningful statistical evaluation. Lack of insurance coverage was the most common reason given for not using/continuing PCGM. Those continuing PCGM were more likely to have insurance coverage for PCGM (86%) than those not continuing PCGM (25%).

Conclusions: Patients ≥65 with insulin-requiring diabetes achieve improved glycemic control with regular PCGM use. The presence of PCGM insurance coverage favored continued PCGM use. **(Endocr Pract. 2014;20: 1297-1302)**

Abbreviations:
A1C = hemoglobin A1C; **PCGM** = personal real-time continuous glucose monitoring; **SH** = severe hypoglycemia; **T1D** = type 1 diabetes

INTRODUCTION

Regular use of continuous glucose monitoring (CGM) has been shown to improve blood glucose control in individuals with insulin-requiring diabetes (1-5). While some studies have included patients ≥65 years old, to our knowledge, results with personal real-time CGM (PCGM) in this group have not been reported separately. We report results of PCGM use in patients age ≥65 years in a community setting.

METHODS

This study was a retrospective electronic health record review from an adult endocrinology practice. An Institutional Review Board wavier was obtained. Subjects were identified by reviewing lists of patients for whom PCGM had been prescribed. Any patient who had been prescribed a CGM device and was ≥65 years as of June 15, 2013 was included. Patients' medical records were abstracted for demographic information, A1C data for the year prior to and subsequent to PCGM prescription/initiation, the most recent A1C value, whether the patient was still using PCGM regularly, reports of severe

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From the [1]Maryland Endocrine, PA; Columbia, Maryland and [2]Dexcom, Inc, San Diego, California.
Address correspondence to Dr. Nicholas B. Argento, 10710 Charter Drive Suite 410, Columbia, MD 21044. E-mail: silver_river@msn.com
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hypoglycemia (SH) for the 5 years prior to PCGM prescription/initiation and the period afterward, and whether CGM was covered by insurance.

Hypoglycemia was considered severe if the patient required third-party assistance and was counted as present if there was at least 1 recorded episode. Individual reports of SH were counted as single episodes when a specific reference was made in the record. If there was a reference to SH "episodes" or the term "several" was used, events for that period were counted as 2 events; when the terms like "multiple," "frequent," "many," or "numerous" were used, then they were counted as 3 episodes. If the patient had stopped or never used PCGM, the record was reviewed to see if a reason was given. If the patient had started on a PCGM that they used briefly or not at all, and later PCGM was represcribed and used regularly, the date of the second prescription was used as the start of PCGM.

All A1C values were from laboratory assays. Nearly all of the A1C determinations were performed using either the Tosoh G7 high pressure liquid chromatography system (Tosoh, Tokyo, Japan) or the Roche Cobas Tina-quant immunoassay system (Roche, Basel, Switzerland), each of which report valid results in the presence of common hemoglobin variants (6,7) and precision coefficients of variation <2% at high or low A1C values (8,9).

The assessment of whether patients were regularly using the CGM system was determined from download review or statements in the medical record that they were using PCGM at least half of the time. Statistical analysis was performed with SAS version 9.2 or higher (SAS Institute Inc, Cary, NC). Continuous variables are reported as mean ± SD with range, and categorical variables are reported as number and frequency. Nonparametric paired tests were used to compare the difference of A1C. The χ^2 test was used to compare the difference in the number of SH episodes. Paired *t* tests were used to assess the statistical significance of the change of the rate of SH within subjects.

RESULTS

Thirty-eight patients ≥65 years old prescribed PCGM were identified; 29 were still regularly using PCGM, 2 were using professional CGM intermittently, and 7 had either never started PCGM (3 patients) or discontinued use of PCGM (5 patients: 3 using PCGM for ≤3 months, 1 using PCGM for ≤3 months then changing to intermittent professional CGM, and 1 using PCGM for 15 months). For the purpose of analysis, the patients using intermittent professional CGM were included in the group not using PCGM. The demographic description of the patients is shown in Table 1. Because of the small group size, glycemic data were not reported for the no PCGM group.

The average age of the entire group was 70 ± 3.6 years (range 65-78); 31 (82%) had type 1 diabetes (T1D). All patients were on intensive insulin regimens, and 28 (74%) were on insulin pump therapy. Compared to the no PCGM group, the PCGM group was younger with a longer duration of diabetes and more likely to have T1D. The PCGM

Table 1
Patient Demographics[a]

Characteristic	All Patients n = 38	PCGM n = 29	No PCGM n = 9
Age, years	69.7 ± 3.6 (65-78)	68.8 ± 3.5 (65-78)	72.7 ± 2.7 (65-78)
Sex	F 21/38 (55%)	F 17/29 (59%)	F 4/9 (44%)
Race	W 32/38 (84%) B 4/38 (11%) A 2/38 (5%)	W 24/29 (83%) B 3/29 (10%) A 2/29 (7%)	W 8/9 (89%) B 1/9 (11%) A 0/9 (0%)
Diabetes duration, years	31.2 ± 11.3 (7-60)	32.2 ± 11.7 (7-60)	28.0 ± 9.9 (16-43)
Diabetes type	T1D 31/38 (82%) T2D 7/38 (18%)	T1D 26/29 (90%) T2D 3/29 (10%)	T1D 5/9 (56%) T2D 4/9 (44%)
Insulin therapy	CSII 28/38 (74%) MDI 10/38 (26%)	CSII 21/29 (72%) MDI 8/29 (28%)	CSII 7/9 (78%) MDI 2/9 (22%)
PCGM duration, months	30.9 ± 20.9 (0-68)	36.8 ± 18.3 (4-68)	2.9 ± 4.8 (0-15)
Insurance PCGM coverage	Yes 28/37 (76%)[b] No 9/37 (24%)	Yes 25/29 (86%) No 4/29 (14%)	Yes 2/8 (25%)[b] No 6/8 (75%)

Abbreviations: A, Asian; B, black; F, female, CSII, continuous subcutaneous insulin infusion; MDI, multiple daily injections; PCGM, personal continuous glucose monitoring; T1D, type 1 diabetes; T2D, type 2 diabetes; W, white.
[a] Continuous variables are reported as mean ± standard deviation and range. Categorical variables are reported as number and percent.
[b] PCGM insurance coverage status was not available for 1 patient.

group was significantly more likely to have insurance coverage for PCGM (25/29, 86%) than those not on PCGM (2/8, 25%); information on PCGM coverage was not available for 1 non-PCGM patient. Cost was reported as a contributing reason for stopping or not starting PCGM in 6 of 7 patients for whom a reason was given. One non-PCGM patient was not thought to be able to handle the demands of PCGM.

Overall, 25 of 29 patients on PCGM had A1C values available for the year prior and subsequent to CGM prescription/initiation and the final A1C. In 4 PCGM patients, not all these values were available; these patients were excluded from the A1C analysis but not the hypoglycemia analysis. As shown in Figure 1, the PCGM group (n = 25) significantly (P<.0001) reduced their mean A1C from the year before to the year after PCGM use, and they maintained their reduced A1C until the most recent A1C (P = .0145), at an average duration of use of 37 ± 18.3 months. As shown in Figure 2, the percent of PCGM patients reporting SH declined from 79% to 31% (P = .0002, n = 29). There were a total of 52 SH episodes recorded in the PCGM group for the 5 years prior to PCGM initiation, and there were 12 SH episodes after initiating PCGM. It was noted that 5 of the SH episodes in the post-PCGM period occurred while the patient was not using PCGM. The yearly rate of SH (± SD) declined from 0.37 ± 0.38 to 0.12 ± 0.19 (P = .0007, n = 29) SH episodes per patient per year (Fig. 3).

DISCUSSION

We report that insulin-requiring patients ≥65 years old who use PCGM can derive clinically significant improvements in glycemic control, with a significant and durable improvement in A1C and reductions in both the percent reporting SH episodes and the frequency of SH per patient. The reduction in A1C was comparable to those reported in studies of younger patients (1-5). We demonstrated this in patients using PCGM in a real-world setting. To our knowledge, this is the largest report on PCGM use in this age group.

This retrospective study has some limitations. The A1C values were from more than 1 lab and assay system. However, this would not be expected to introduce a systematic bias. Although efforts are made to record SH episodes as part of routine follow-up, it is possible that the SH incidence was underreported, and the time on PCGM (37 months) was shorter than the 5-year pre PCGM comparison period. However, the rate of SH, which adjusts for time of exposure, was also significantly and meaningfully reduced in the PCGM group. It is noteworthy that 5 of the 12 post-PCGM SH events in this group occurred when the patient was not wearing the PCGM, indicating the importance of full-time PCGM use. The number needed to treat to prevent 1 SH per year was only 4.

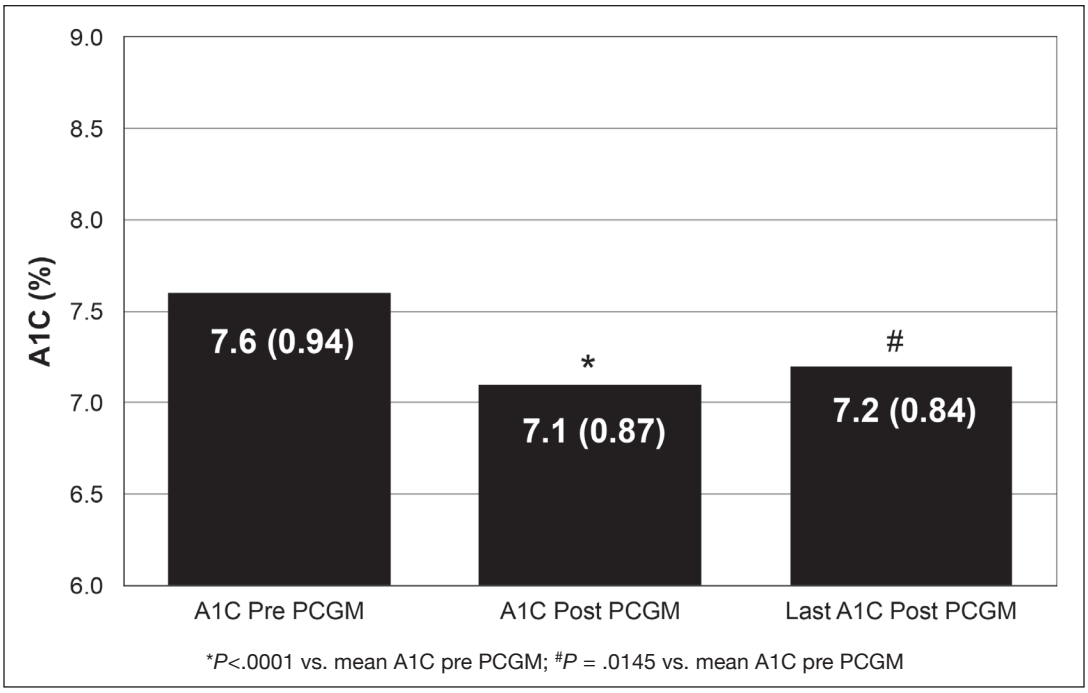

Fig. 1. A1C% with PCGM use. The mean (SD) A1C (%) for the year prior to the start of PCGM, the mean A1C for the year after, and the last A1C available are displayed for the group using PCGM (n = 25). The year pre- and post-PCGM data were not available for 4 PCGM patients, who were excluded. Nonparametric paired tests were used to compare the difference of A1C. *A1C* = glycated hemoglobin; *PCGM* = personal real-time continuous glucose monitoring.

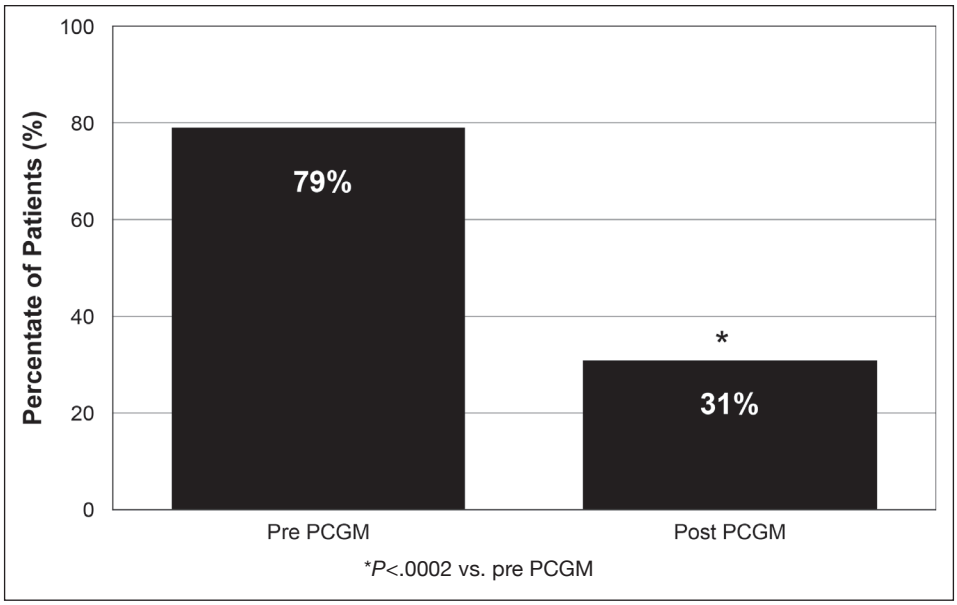

Fig. 2. SH before and after starting PCGM. The percent of patients who had at least 1 SH event recorded for the 5 years before the start of PCGM versus the percent of patients with a recorded SH event after the start of PCGM in the group using PCGM (n = 29). The duration of use was 37 ± 18.2 (4-68) months. The χ^2 test was used to compare the difference in the number of hypoglycemia episodes. *PCGM* = personal real-time continuous glucose monitor; *SH* = severe hypoglycemia.

Five of the patients who were regularly using PCGM had used PCGM briefly and then stopped but restarted at a later date, so it is possible the brief use period had affected their glycemic control, although this would presumably tend to improve what was considered their baseline level of control. The non-PCGM group was too small to allow meaningful statistical analysis. It is noteworthy that the reason most commonly given to stop or not start PCGM was lack of insurance coverage (6 out of 8). Another limitation in this retrospective observational study is the lack of a control group.

Insulin-requiring patients that have reached Medicare age tend to have a longer duration of diabetes and are thus more likely to have significant micro- and macrovascular complications and suffer from other comorbidities. Schütt et al reported that T1D patients over age 60, in addition to having higher rates of complications, had nearly twice the incidence of SH compared to younger T1D patients (10). The Type 1 Diabetes Exchange Clinic Registry reported that patients over 65 had a high yearly rate of SH (0.168), which was mostly accounted for by the long diabetes duration in many patients in that age group (11). Our PCGM group had an even higher baseline yearly SH rate (0.37), which was often the principle reason to recommend PCGM. SH can be particularly dangerous in older patients and is associated with increases in the risks of falls with injury, myocardial infarcts, arrhythmias, temporary or permanent cognitive impairment, and death (12). In another report, a history of SH was reported to increase the 5-year mortality in a group of older (mean age 60) diabetes clinic patients by 3.4 fold (13).

The American Diabetes Association suggests modifying glycemic goals in diabetic patients with a short life expectancy, a history of SH despite intervention, or a high burden of comorbidities (14). However, patients reaching Medicare age do not necessarily fall into any of these groups. Furthermore, patients with higher A1C levels continue to have a significant risk of SH (11), indicating that using higher A1C goals is not sufficient protection against SH. The Endocrine Society has endorsed the use of PCGM in adults who will use it on a nearly daily basis (15). Currently, the Center for Medicare and Medicaid Services does not generally cover PCGM, but intermittent professional CGM may be covered (16). In contrast, most private insurers will cover PCGM in at least some circumstances (17), and they sometimes provide coverage for PCGM in patients on Medicare. In our study, most Medicare age patients who continued to use PCGM had insurance coverage, either from a secondary insurance policy or because they were still working and had work-related primary insurance coverage, and most that did not have supplemental insurance cited cost as a factor. It should be stated that there are many patients in our practice who were not included in this report for whom PCGM was considered, discussed, or recommended, but no prescription process was initiated because the patient did not have insurance coverage for PCGM and indicated that they could not afford it on a self-pay basis.

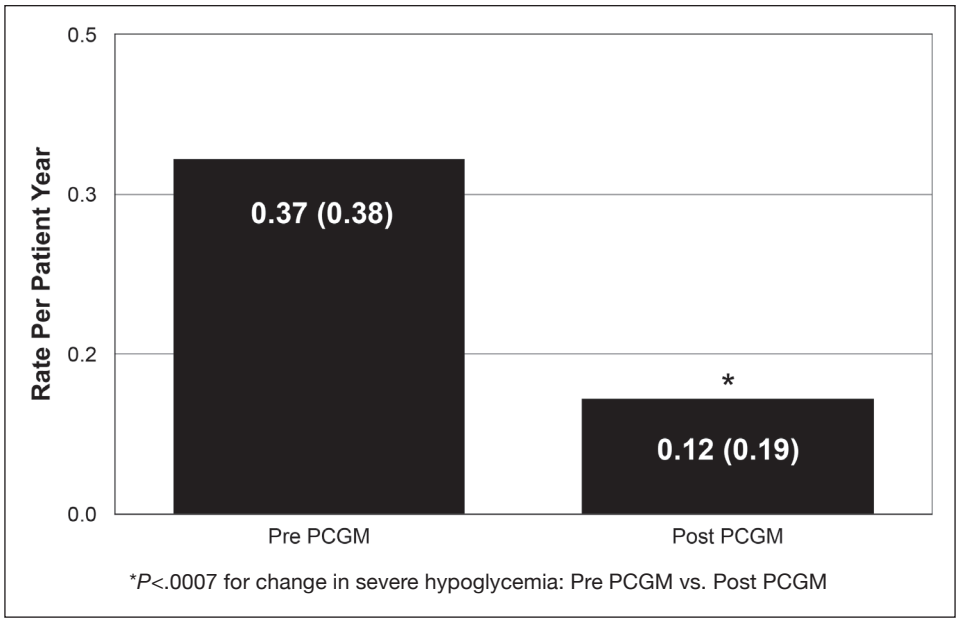

Fig. 3. Rate of SH, per patient per year, before and after starting PCGM. The mean (SD) rate of SH per patient per year in the 5 years before the start of PCGM and the period after, in the group who continued PCGM (n = 29). The duration of use was 37 ± 18.2 (4-68) months. Paired *t* tests were used to assess the statistical significance of the change of the rate of SH within subjects. *PCGM* = personal real-time continuous glucose monitor; *SH* = severe hypoglycemia.

CONCLUSION

Insulin-requiring patients ≥65 years old in our retrospective study from a community endocrine practice achieved a significant and durable improvement in glycemic control when using PCGM. The improvement in glycemic control was comparable to that reported in younger patients (1-5). The substantial reduction in SH may be of particular benefit in older patients. Lack of PCGM coverage by CMS was the most common reason cited to not start or to discontinue PCGM use.

DISCLOSURE

A portion of the data reported here was presented as an abstract and poster at the 13th Annual Diabetes Technology Meeting, Burlingame, California on October 31, 2013. No grant support was received for the study. Dexcom, Inc, (San Diego, CA) provided funding for IRB review fees and supported manuscript editorial assistance from Christopher G. Parkin (CGParkin Communications, Inc).

Dr. Nicholas B. Argento has received educational grants, done promotional programs, and consulted and serves on the clinical advisory board and speakers bureau for Dexcom; has participated in an advisory board for Medtronic Diabetes; serves on advisory boards and has done promotional programs for Eli Lilly; served on an advisory board and consulted for Becton, Dickinson and Company; served on advisory boards for Janssen and Roche (USA); and has served on speaker's bureaus for Novo Nordisk, Bristol-Myers Squib, AstraZeneca, Janssen, and Boehringer-Ingelheim. Dr. Katherine Nakamura is employed by Dexcom, Inc.

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