Original Article
Yonsei Med J 2025 Jun;66(6):346-353
https://doi.org/10.3349/ymj.2024.0261
Yonsei Medical Journal
YMJ
pISSN: 0513-5796 · eISSN: 1976-2437

A Pilot Study Examining If the Additional Use of a Continuous Glucose Monitoring Is Helpful for Glucose Control in Older Adults

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Purpose: To investigate whether using a continuous glucose monitoring (CGM) for the second time (2nd_CGM) would be effective after using it for the first time (1st_CGM), depending on age.
Materials and Methods: This study included patients aged ≥40 years who were diagnosed with type 2 diabetes and had used a CGM at least twice between 2017 and 2021. Participants were divided into two groups based on their age: those aged <60 years and those aged ≥60 years. We assessed the glycemic control status of the 1st_CGM and 2nd_CGM, along with the glycemic variability.
Results: Overall, 15 patients were included in the study. The mean glucose level in users aged <60 years significantly decreased (p<0.001) owing to the CGM use, while it did not increase in those aged ≥60 years. In users aged ≥60 years, the 1st_CGM group showed a significant decrease in blood glucose levels over time (p<0.05), whereas the 2nd_CGM group only showed a non-significant decreasing trend. The time in range tended to increase in those aged <60 years but decreased in those aged ≥60 years. In those aged <60 years, the mean amplitude of glycemic excursions (p<0.001), standard deviation (p<0.05), and coefficient of variation (p<0.001) significantly decreased. In those aged ≥60 years, these parameters exhibited a non-significant decreasing trend.
Conclusion: Glycemic effect and variability improved as expected with 1st_CGM use. However, 2nd_CGM did not significantly improve glycemic effect or variability in users aged ≥60 years, contrary to expectations. To address this issue, further investigation is needed to understand why, compared to 1st_CGM, 2nd_CGM fails to achieve better glycemic control in individuals aged ≥60 years.

Key Words: Aged, diabetes mellitus, glycemic control

INTRODUCTION

The American Diabetes Association recommends the use of a continuous glucose monitoring (CGM) to control blood glucose levels in patients with diabetes.[1] CGM represents the most positive example of digital health intervention.[2] Digital health monitoring tools, including CGM, enable users to determine their blood glucose status autonomously,[3,4] resulting in lifestyle changes.[3] CGM use generates motivation to lower blood glucose levels and plays a positive role not only in blood glucose levels but also in glycemic variability.[4] Furthermore, the blood glucose level-lowering effect is strong only when a CGM is installed without adding any drugs.[5,6] Therefore, the utility of a CGM is expected to be extremely high.

Whether CGM will be properly used clinically, particularly by older adults, remains unclear[7] since the ability of the older adult population to use digital instruments is known to fall short of expectations in actual treatment situations.[8] With the release of various health-related digital devices linked to smartphones, health results based on the health-related data of us-

Received: August 29, 2024 **Revised:** November 28, 2024
Accepted: December 3, 2024 **Published online:** February 18, 2025
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•The authors have no potential conflicts of interest to disclose.

ers are being provided to them in different forms. However, owing to the multiple results expressed independently by various digital devices, users have become confused about the health results generated from the data,[7] which can affect them negatively. Furthermore, difficulty in using medical devices and applications can negatively affect users,[9] ultimately causing users to stop using these digital devices.

Considering these aspects, will the additional secondary use of CGM (2nd_CGM) improve blood glucose control in patients who have already learnt to understand their lifestyle habits through their first use of a CGM (1st_CGM)? Furthermore, questions persist about whether the blood glucose levels obtained from using the 1st_CGM can be continuously maintained without the installation of a 2nd_CGM. Thus, CGM engagement, particularly by older adults, is an important issue.[10] Therefore, in this study, we aimed to compare the differences in blood glucose control and glycemic variability between users of the 1st_CGM and 2nd_CGM implants, according to age, and analyze the blood glucose level-lowering effects and changes in glycemic variability based on the duration of device use.

MATERIALS AND METHODS

This study used the CGM dataset from the Department of Geriatric Internal Medicine at Yonsei University Sinchon Severance Hospital (Seoul, South Korea), and was approved by the Clinical Research Ethics Committee of Yonsei University (IRB No. 4-2024-0551). The personal identification numbers of participants were excluded, and any information obtained through this study was stored in encrypted files with an anonymous password on an encrypted computer. Therefore, this study did not infringe on the privacy rights or welfare of the participants, and there was no possibility of physical or mental harm to them. Requirement for the acquisition of informed consent from the patients was waived. Confidentiality of personal information was guaranteed, and continuous monitoring was conducted to protect all data.

Study population and design

We included patients aged ≥40 years who were diagnosed with type 2 diabetes and used a CGM more than twice from 2017 to 2021, while excluding those who received oral hypoglycemic agents or insulin and those with type 1 diabetes. In addition, patients for whom the CGM installation period was <5 days or the 1st_CGM and 2nd_CGM had different device types were also excluded. First, the participants were divided into two groups: those aged <60 years and those aged ≥60 years. Age; estimated glomerular filtration rate (eGFR); and levels of glucose, HbA1c, blood urea nitrogen, and creatinine were then determined in each group before the CGM use. All patients received training on CGM installation. After installation, users were trained on how to check their blood glucose levels through the application. Finally, users were educated on precautions for using the CGM.

CGM

The CGM devices used were iPro2 (Medtronic Inc., Northridge, CA, USA), Guardian Connect (Medtronic Inc.), and FreeStyle Libre (Abbott, Chicago, IL, USA), which are currently available in Korea. After CGM installation, the time in range (TIR), time above range (TAR), and time below range (TBR) were calculated to determine the goal of blood glucose level management. Additionally, blood glucose level variability was evaluated by calculating the standard deviation (SD), coefficient of variation (CV), and mean amplitude of glycemic excursions (MAGE), which are the most commonly used indices for glycemic variability.

Statistical analysis

Values were presented as numbers (percentages) for categorical variables and means±SDs for continuous variables. This study was conducted using a normality assumption owing to the small sample size. For continuous variables, normality was assessed using the Shapiro–Wilk test. If normality was met, means and SDs were presented, and differences were tested using Student's t-test. If normality was not followed, medians and quartiles were presented, and the difference between the two groups was tested using the Wilcoxon rank-sum test. Categorical variables were presented as numbers (percentages), and *p*-values were calculated using the chi-square test, Fisher's exact test, or McNemar test. Data were analyzed using SAS software version 9.4 (SAS Institute, Cary, NC, USA).

RESULTS

Twenty-two patients were enrolled; however, six in the 1st_CGM or 2nd_CGM who had a device installed for 5 days and one whose 1st_CGM and 2nd_CGM were by different device models were excluded. Finally, 15 patients were included in the study (Table 1).

Baseline characteristics

Of the 15 patients, 8 (53.3%) were <60 years of age (average age: 51.4±7.0 years), while 7 (46.7%) were ≥60 years of age (average age: 72.6±8.8 years). The baseline HbA1c was 8.4±1.6% in those aged <60 years and 8.8±2.7% in those aged ≥60 years, with no significant difference between the two groups (p=0.689). The interval between the 1st_CGM and 2nd_CGM installations was 113.5±83.8 days, with no difference between the two groups (p=0.324). The eGFR for users aged ≥60 years was 72.4±10.7 mL/min/1.73 m^2, which was significantly lower than the eGFR of 83.3±6.7 mL/min/1.73 m^2 for users aged <60 years (p<0.05). However, no clinical differences were observed be-

Table 1. Baseline Characteristics of CGM Users

	Total (n=15)	<60 years old (n=8, 53.3%)	≥60 years old (n=7, 46.7%)	*p*-value
Male sex	10 (66.7)	6 (75.0)	4 (57.1)	0.608*
Age (yr)	61.3±13.3	51.4±7.0	72.6±8.8	<0.001†
40–49 years	3	3	0	
50–59 years	5	5	0	
60–69 years	3	0	3	
70–79 years	1	0	1	
≥80 years	3	0	3	
Insulin use	6	3 (37.5)	3 (42.9)	NS
CGM type				NS
iPro2	8	5	3	
Guardian Connect	5	2	3	
FreeStyle Libre	2	1	1	
HbA1c of pre 1st_CGM (%)	8.6±2.1	8.4±1.6	8.8±2.7	0.689†
HbA1c of pre 2nd_CGM (%)	7.8±1.9	7.9±2.1	7.7±1.8	0.825†
Interval between 1st and 2nd_CGM (days)	113.5±83.8	92.1±81.5	138.0±85.6	0.324
Fasting glucose (mg/dL)	219±70.8	188.7±38.8	245±84	0.161†
BUN (mg/dL)	18±4.5	17±5.1	19.2±3.7	0.563
Creatinine (mg/dL)	0.9±0.2	0.9±0.2	0.9±0.3	0.816†
eGFR (mL/min/1.73 m^2)	78.2±10.1	83.3±6.7	72.4±10.7	<0.05†

CGM, continuous glucose monitoring; 1st_CGM, first use of a CGM; 2nd_CGM, second use of a CGM; BUN, blood urea nitrogen; eGFR, estimate glomerular filtration rate.
Values are presented as number (percentage) for categorical variables and mean±SD for continuous variables.
p-values were calculated using the chi-square or Fisher's exact test* for categorical variables and t-test† or Wilcoxon rank-sum test for continuous variables.

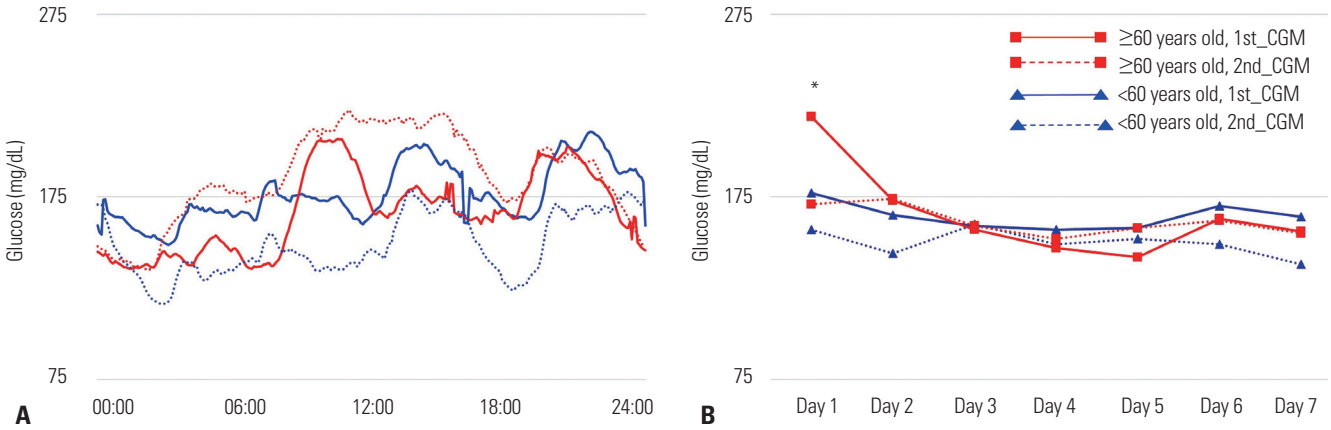

Fig. 1. Comparison of blood glucose patterns between the 1st_CGM and 2nd_CGM use according to age. (A) 24-hour blood glucose patterns and (B) daily glucose pattern. Red square solid line: 1st_CGM use in those aged ≥60 years; red square dotted line: 2nd_CGM use in those aged ≥60 years; blue triangle solid line: 1st_CGM use in those aged <60 years; blue triangle dotted line: 2nd_CGM use in those aged <60 years. *In users aged ≥60 years, the 1st_CGM use was associated with a significant decrease in blood glucose level over time (from 219 mg/dL to 156 mg/dL, $p<0.05$). CGM, continuous glucose monitoring.

tween the groups.

Blood glucose patterns between the 1st_CGM and 2nd_CGM

Fig. 1A shows the changes during the utilization of the 1st_CGM and 2nd_CGM in users aged <60 years and ≥60 years, respectively. The mean glucose level in users aged <60 years significantly decreased from 162±43 mg/dL during the application of the 1st_CGM to 151±56 mg/dL during the use of the 2nd_CGM ($p<0.001$). The mean glucose level tended to increase in users aged ≥60 years (159±23 mg/dL during use of the 1st_CGM vs. 161±28 mg/dL during use of the 2nd_CGM, $p=0.578$); however, this was not significant (Fig. 1A and Table 2).

In patients aged <60 years, blood glucose levels tended to decrease over time when using the 1st_CGM (from 177 mg/dL to 164 mg/dL, $p=0.461$) and 2nd_CGM (from 155 mg/dL to 138 mg/dL, $p=0.844$) but the difference was not significant when compared with the values measured on day 1 (Fig. 1B). In patients aged ≥60 years, the 1st_CGM was associated with a significant decrease in blood glucose levels over time (from

https://doi.org/10.3349/ymj.2024.0261

219 mg/dL to 156 mg/dL, $p<0.05$), in contrast with the 2nd_CGM that only showed a decreasing trend in blood glucose levels (from 171 mg/dL to 155 mg/dL, $p=0.400$), which was not significant. The comparison of blood glucose levels by day over time indicated that the levels during the 2nd_CGM use tended to be lower than those during the 1st_CGM use in patients aged <60 years, whereas those during use of the 2nd_CGM tended to be higher starting from day 2 in patients aged ≥60 years.

Glycemic variability

In patients aged <60 years, MAGE (118±42 vs. 85±35, $p<0.001$), SD (32.4±12.1 vs. 28.2±14.9, $p<0.05$), and CV (0.20±0.05 vs. 0.18±0.06, $p<0.001$) significantly decreased (Table 3). However, in those aged ≥60 years, MAGE (108±39 vs. 103±40, $p=0.673$), SD (43.9±11.4 vs. 37.7±13.0, $p=0.296$), and CV (0.27±0.04 vs. 0.23±0.07, $p=0.228$) showed a decreasing trend that was not significant.

Regarding glycemic variability, irregular fluctuations were observed over time after CGM installation (Fig. 2), particularly on day 2, wherein MAGE, SD, and CV showed a tendency to

Table 2. Comparison of Ambulatory Glucose Profile According to Age

	Total			<60 years old			≥60 years old		
	1st_CGM	2nd_CGM	*p*-value	1st_CGM	2nd_CGM	*p*-value	1st_CGM	2nd_CGM	*p*-value
Number of measurements	1712±160	1621±245	0.121*	1735±185	1665±164	0.352	1687±135	1570±320	0.256*
Mean glucose (mg/dL)	161±34	155±44	0.405*	162±43	151±56	<0.001*	159±23	161±28	0.578
GMI (%)	7.2±0.9	6.9±1.1	0.405*	7.2±1.2	6.9±1.4	<0.001*	7.3±0.6	7.2±0.7	0.578
Very high (>250 mg/dL) (%)	9.1±12.9	9.5±14.7	0.358	8.5±16.2	10.9±18.6	0.578	9.8±8.9	7.9±9.6	0.578
TAR (>180 mg/dL) (%)	30±23	29±29	0.762	30.8±29.1	27.3±36.2	0.383	29.0±15.0	30.9±20.7	0.375
TIR (70–80 mg/dL) (%)	68.3±22	70.1±28.7	0.608*	67.7±28.0	72.2±36.0	0.195	69.1±14.7	67.7±19.9	0.775*
TBR (<70 mg/dL) (%)	1.7±2.7	0.9±1.5	0.275	1.5±3.4	0.5±0.7	0.625	1.9±1.8	1.4±2.0	0.438
Very low (<54 mg/dL) (%)	0.3±0.8	0.2±0.4	>0.999	0.4±1.0	0.1±0.3	0.750	0.2±0.3	0.2±0.5	>0.999

CGM, continuous glucose monitoring; 1st_CGM, first use of a CGM; 2nd_CGM, second use of a CGM; TAR, time above range; TBR, time below range; TIR, time in range.
Values are presented as mean±SD for continuous variables.
p-values were calculated using the McNemar test for categorical variables and paired t-test* or Wilcoxon rank-sum test for continuous variables.

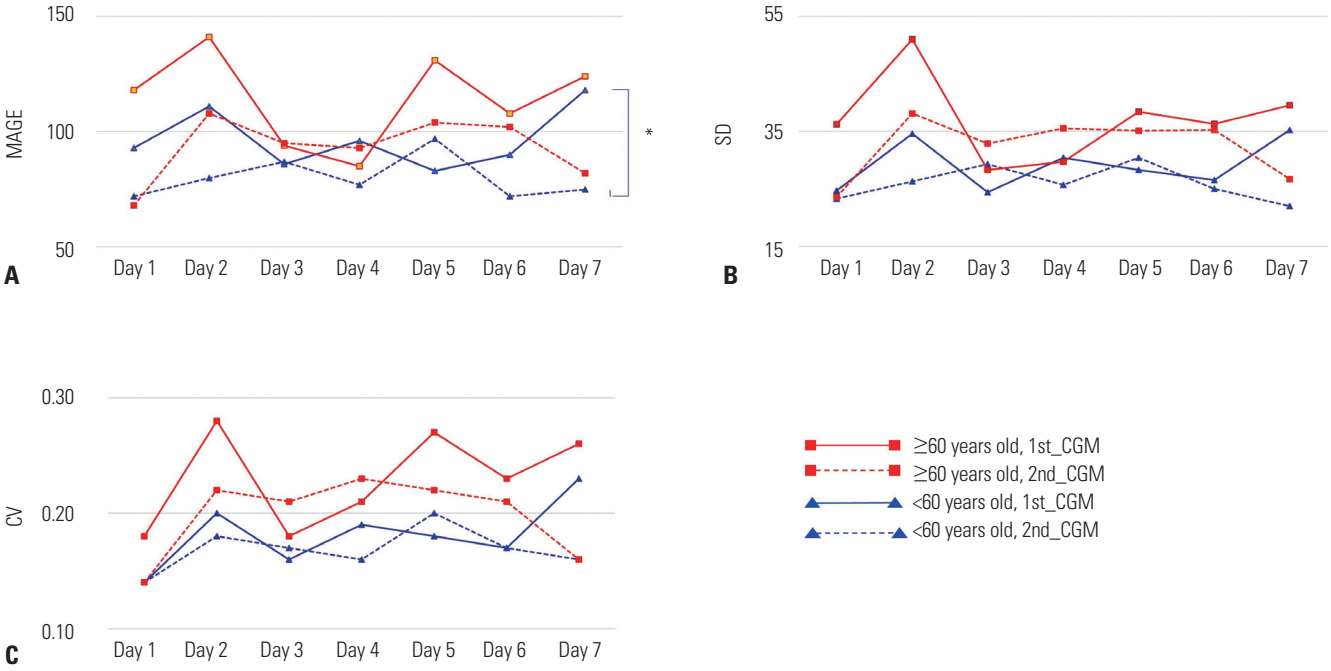

Fig. 2. Comparison of patterns in glycemic variability: (A) MAGE, (B) SD, and (C) CV. Red square solid line: 1st_CGM use in those aged ≥60 years; red square dotted line: 2nd_CGM use in those aged ≥60 years; blue triangle solid line: 1st_CGM use in those aged <60 years; blue triangle dotted line: 2nd_CGM use in those aged <60 years. *MAGE in users aged <60 years tended to be significantly lower during use of the 2nd_CGM than during use of the 1st_CGM (118 vs. 75, $p<0.05$). CGM, continuous glucose monitoring; CV, coefficient of variation; MAGE, mean amplitude of glycemic excursions; SD, standard deviation.

Table 3. Comparison of Glycemic Variability According to Age

	Total			<60 years old			≥60 years old		
	1st_CGM	2nd_CGM	*p*-value	1st_CGM	2nd_CGM	*p*-value	1st_CGM	2nd_CGM	*p*-value
Number of measurements	1712±160	1621±245	0.121*	1735±185	1665±164	0.352	1687±135	1570±320	0.256*
MAGE	113±40	93±38	0.079*	118±42	85±35	<0.001*	108±39	103±40	0.673*
SD	37.8±12.8	32.6±14.4	0.080*	32.4±12.1	28.2±14.9	<0.05*	43.9±11.4	37.7±13.0	0.296*
CV	0.23±0.06	0.21±0.07	0.075*	0.20±0.05	0.18±0.06	<0.001*	0.27±0.04	0.23±0.07	0.228*

CGM, continuous glucose monitoring; CV, coefficient of variation; MAGE, mean amplitude of glycemic excursions; SD, standard deviation.
Values are presented as mean±SD for continuous variables.
p-values were calculated using the McNemar test for categorical variables and paired t-test* or Wilcoxon rank-sum test for continuous variables.

increase compared to the baseline values and increased again on days 4–5, exhibiting a tendency for large fluctuations. MAGE, SD, and CV were lower during the use of the 2nd_CGM than the 1st_CGM across all ages (Fig. 2 and Table 3). MAGE measured on day 7 (93 vs. 118, p=0.287 during use of the 1st_CGM in patients aged <60 years; 72 vs. 75, p=0.534 during use of the 2nd_CGM in those aged <60 years; 118 vs. 124, p=0.836 during use of the 1st_CGM in those aged ≥60 years; and 68 vs. 82, p=0.313 during use of the 2nd_CGM in those aged ≥60 years) did not show a decrease when compared to that measured on day 1. The results revealed similar patterns for SD and CV (Fig. 2B and C). However, based on the MAGE recorded on day 7, the last day of CGM use, the MAGE in those aged <60 years tended to be significantly lower during the use of the 2nd_CGM than the 1st_CGM (118 vs. 75, p<0.05).

DISCUSSION

It may be challenging to observe short-term effects in older adults owing to their difficulties in accessing new devices, such as the 1st_CGM.[8] However, in this study, the application of the 1st_CGM led to a decrease in mean blood glucose levels and glucose management indicators across all ages, with satisfactory TIR, TAR, and TBR values. Definitive conclusions cannot be drawn without a control group. Contrary to concerns, this study showed that even older users exhibited relatively good glucose status from using the 1st_CGM. Therefore, despite concerns about accessibility for older adults in the digital health field,[8] the CGM use indicated that those aged ≥65 years were relatively less affected by digital accessibility in this study. The changes in blood glucose increasing or decreasing trends (including TIR, TAR, and TBR) revealed via the ambulatory glucose profile—a summary result provided by each CGM company—are well-structured, making it easy for older users to understand.[11] We believe that this will be useful for digital accessibility among older adults. This is because, with the 1st_CGM use, users could learn to understand their blood glucose patterns and change their lifestyle habits, such as diet and exercise.[12]

However, in this study, unlike the 1st_CGM use, there was a noticeable age-related difference with the 2nd_CGM use. In those aged <60 years, the use of a 2nd_CGM revealed an increase in TIR and a decrease in TAR and TBR compared to those when using the 1st_CGM, raising expectations about the positive role of the 2nd_CGM. However, in users aged ≥60 years, contrary to expectations, TIR tended to decrease and TAR increased, indicating that the effect of the CGM reinstallation was not significant. Thus, older users may be more vulnerable than younger users. It is important to explore why the effect of 2nd_CGM is not significant in people aged ≥60 years. Identifying the underlying causes is essential for developing effective solutions.

Glycemic variability is greater in older patients with diabetes than in younger patients. This pattern was more prominent in the present study. In those aged <60 years, MAGE, SD, and CV, which indicate glycemic variability, were significantly improved in the case of the 2nd_CGM compared to that of the 1st_CGM. Improving MAGE, SD, and CV is an important purpose of CGM, and in users aged <60 years, repeated CGM use clearly helps to improve blood glucose levels. However, in users aged ≥60 years, the 2nd_CGM was not associated with any significant improvement in glycemic variability. Glycemic variability measured using CGM is correlated with severe diabetic retinopathy, nephropathy, peripheral neuropathy, and hypoglycemic unawareness.[13-16] Finally, the importance of glycemic variability in measuring and controlling blood glucose level variability is highlighted.

Failure to maintain the effectiveness of CGM eventually leads to worsened blood glucose control. As mentioned above, the reason for the effectiveness of 2nd_CGM decreases in people over 60 years of age must be clearly considered, and a solution must be found. The first assumption is that repeated use of CGMs may reduce users' interest in them.[17] Focusing on the interest or sustainability of CGM by targeting users aged ≥60 years is crucial.[18] This is an issue related to "user persistence," which is emphasized in the digital health field,[18] meaning that user persistence decreases in older adults. The persistence of one's will to improve lifestyle habits for continuous blood glucose control is important; however, this indicates that CGM does not provide enough interest or medical value to maintain the persistence of that will.[7,18] The 2nd_CGM did not provide additional valuable information other than the analysis of their blood glucose patterns already provided via the 1st_

https://doi.org/10.3349/ymj.2024.0261

CGM. Although CGM is vital in health management, it is difficult to expect an effect if it is not used.

The basic concept of digital health devices, such as a CGM, begins with making users aware of their health patterns.[3] The key to user sustainability in the CGM use is the extent to which the user is willing to actively attempt health management based on their own patterns, that is, the degree to which motivation can be raised.[3,4] It is essential to determine for how long this increased motivation can be maintained. Accessibility to a CGM should also have a considerable impact. In the case of older individuals, user retention may be low, or the medical device itself may be the reason that it is difficult for older users to find it valuable,[8,18,19] but the price also plays a role.[20] Users must be able to find the value that suits them with limited data, and medical education in this regard is essential. It should be understood as the concept of so-called digital literacy.[21] Digital literacy refers to the ability to find, evaluate, and combine clear information while accessing various media platforms.[22] Even if a CGM is designed to be easy to use by older adults, it is difficult to increase user sustainability by simply providing the TIR, TBR, and TAR. Although this effect may be achieved with a single use of a CGM, it may be difficult to maintain the effect when it is used more than once. In addition to the CGM simply showing the trends in blood glucose changes, the 2nd_CGM should provide additional secondary analyses of blood glucose changes. If the 1st_CGM analyzes a user's condition, the 2nd_CGM must provide something new and valuable that the user is unaware of. For continued use beyond simple reports, such as the HIR, there must be new value creation through more data and information provided by the CGM. Therefore, it may be difficult for older individuals to acquire upgraded functions.[8,18,19]

CGM use is considered the most desirable practice in digital healthcare;[2] however, the extent to which it demonstrates positive blood glucose control effects in a variety of users in clinical practice must be impartially evaluated. The effect of changing lifestyle habits on chronic diseases depends on one's will, not on technology. CGM only helps determine the user's blood glucose levels. Each user must explore various ways to increase their digital literacy to improve the usability of the CGM and consider the targets and methods of education on digital literacy that differ for each user.[23] Detailed guidelines are required to select patients who may benefit from CGM.

In this study, after CGM installation, blood glucose levels over time showed a tendency to decrease, irrespective of age; however, MAGE significantly increased and decreased depending on the day. MAGE during the use of the 2nd_CGM was clearly lower but showed significant fluctuations by date than during the use of the 1st_CGM. This phenomenon was consistent for SD and CV. Although the improvement and deterioration patterns were repeated from the date of CGM installation to the date of its removal, there was no overall significant difference. Blood glucose variability appeared to increase uniformly on the first day, suggesting a level of adaptation to the device's operation. The reason MAGE started to decrease from day 2 and then increased again from day 5 may be because willpower decreased after wearing the CGM. We believe that this may be due to a decline in user sustainability.[8,18,19] This pattern showed a similar tendency during the 2nd_CGM. Large-scale research in this area is required.

We need to explore the reason older users aged ≥60 years are less willing to maintain long-term CGM use. Given the difference in CGM usage abilities among users aged ≥60 years, efforts should be made to enhance the digital skills of this age group, which is vulnerable to digital technology, to maximize CGM effectiveness.[19] We should not expect healthcare issues to improve by simply installing digital healthcare devices. Medical staff should be most careful about the exaggeration that patients' digital healthcare will solve all healthcare problems in actual clinical fields.

This study had some limitations. First, this was a pilot study conducted among a small number of users. Second, the use of different CGMs may have influenced the study results, and caution should be exercised in generalizing the findings. Careful attention to data interpretation is required. Therefore, we cannot solely rely on this study to establish clinical significance. However, as excessive expectations for CGM have recently increased, concerns have emerged, and specific approaches to address these issues remain limited. As a pilot study, we believe that our research has sufficiently fulfilled its role by providing insights and suggesting directions for future large-scale clinical studies. Moreover, users' digital literacy is crucial for effectively utilizing CGMs, and this is influenced by the user's socioeconomic and educational background.[24] The lack of investigation into these factors was an additional limitation of this study. Long-term studies with larger sample sizes should be conducted, including detailed baseline characteristics of users such as education level and receptivity to CGM education, along with a detailed protocol that ensures consistent use of CGM equipment. Finally, CGM accuracy can decrease during the initial wear period, which was a trend observed in this study (Figs. 1B and 2). However, this did not significantly impact the overall research results.

In conclusion, as Korea has already become a super-aging society, a new approach to healthcare is needed since most patients with diabetes are older and may experience difficulties in using digital medical devices or apps.[25] If a CGM does not provide medical value to the users, they will no longer use it. If the CGM is not used, data are not generated; and if data are not generated, the device cannot provide valuable information—thereby creating a vicious cycle. Users will continue using the CGM only if it continuously provides valuable information, rather than simply reporting changes in blood glucose levels. To achieve this, we must understand the differences between older and younger adults. With continued CGM use, the research results will not be reliable, as they are limited

to only a portion of the younger generation who are familiar with CGM. Clinicians should contemplate the level of data literacy among older adults and explore solutions for improving it. Simply applying a CGM without a proper follow-up should not be expected to yield improvements. The target population, method, and duration of CGM should be realistically considered. In the future, greater attention should be paid to repeated CGM usage, and large-scale, long-term follow-up studies should be conducted.

DATA AVAILABILITY

The data that support the findings of this study are available from the corresponding author upon request.

ACKNOWLEDGEMENTS

This research was supported by the Bio & Medical Technology Development Program of the National Research Foundation (NRF) funded by the Korean government (MSIT) (No. NRF-2019M3E5D3073104). This research was also supported by the "National Institute of Health" research project (Project No. 2022ER110300).

This research was also supported by a grant from the Patient-Centered Clinical Research Coordinating Center (PACEN) funded by the Ministry of Health and Welfare, Republic of Korea (grant number: HC20C0086).

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