## **ORIGINAL ARTICLE**



# **Association of scan frequency with CGM‑derived metrics and infuential factors in adults with type 1 diabetes mellitus**

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### **Abstract**

**Introduction** This study aimed to investigate the association between scan frequency and intermittently scanned continuous glucose monitoring (isCGM) metrics and to clarify the factors afecting scan frequency in adults with type 1 diabetes mellitus (T1D).

**Methods** We enrolled adults with T1D who used FreeStyle® Libre. Scan and self-monitoring of blood glucose (SMBG) frequency and CGM metrics from the past 90-day glucose data were collected. The receiver operating characteristic curve was plotted to obtain the optimal cutoff values of scan frequency for the target values of time in range (TIR), time above range (TAR), and time below range (TBR).

**Results** The study was conducted on 211 adults with T1D (mean age,  $50.9 \pm 15.2$  years; male,  $40.8\%$ ; diabetes duration, 16.4 $\pm$ 11.9 years; duration of CGM use, 2.1 $\pm$ 1.0 years; and mean HbA1c, 7.6 $\pm$ 0.9%). The average scan frequency was  $10.5 \pm 3.3$  scan/day. Scan frequency was positively correlated with TIR and negatively correlated with TAR, although it was not signifcantly correlated with TBR. Scan frequency was positively correlated with the hypoglycemia fear survey-behavior score, while it was negatively correlated with some glycemic variability metrics. Adult patients with T1D and good exercise habits had a higher scan frequency than those without exercise habits. The AUC for >70% of the TIR was 0.653, with an optimal cutoff of 11 scan/day.

**Conclusions** In real-world conditions, frequent scans were linked to improved CGM metrics, including increased TIR, reduced TAR, and some glycemic variability metrics. Exercise habits and hypoglycemia fear-related behavior might afect scan frequency. Our fndings could help healthcare professionals use isCGM to support adults with T1D. Clinical Trial Registry No. UMIN000039376.

**Keywords** Blood glucose monitoring frequency · Flash glucose monitoring · Type 1 diabetes · Real-world data

# **Introduction**

Type 1 diabetes mellitus (T1D) is a chronic autoimmune disease characterized by the destruction of pancreatic beta cells [\[1](#page-6-0), [2\]](#page-6-1). For patients with T1D, continuous glucose monitoring (CGM) is a cost-efective adjunct to T1D management and has the potential to improve glycemic outcomes and quality of life  $[3-5]$  $[3-5]$ . Glycated hemoglobin (HbA1c) is a fundamental metric for monitoring blood glucose levels over several months and serves as an index of average glucose measurement. Despite being relatively inexpensive and simple to measure, it only provides an approximate estimate of glucose control and does not account for glycemic variability or hypoglycemic episodes. To overcome these limitations, CGM technology has been developed to aid clinicians and individuals with diabetes in managing their condition [[6\]](#page-6-4). For most patients with T1D, a time in range (TIR; 70–180 mg/dL, or 3.9–10 mmol/L) target of more than 70% is recommended, with each incremental increase of 5% toward this target being clinically meaningful [[7](#page-6-5)[–9](#page-6-6)]. Randomized controlled trials (RCTs) using FreeStyle® Libre™ (Abbott Diabetes Care, Alameda, CA) have the beneft of factory calibration and reduced glucose variability in both

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continuous subcutaneous insulin infusion and multiple daily injection users [[10\]](#page-6-7).

In real-world settings, studies using anonymized reader data from intermittently scanned continuous glucose monitoring (isCGM) users indicate that a higher scanning frequency is associated with a lower HbA1c and a higher TIR in Saudi Arabia [[11\]](#page-6-8), Netherlands [[12](#page-6-9)], Israel [[13\]](#page-6-10), Spain [\[14\]](#page-6-11), Brazil [\[15\]](#page-6-12), Poland [[16\]](#page-6-13), and Europe [\[17](#page-6-14)]. Because of the anonymous nature of the database used for these studies, detailed information concerning the characteristics of FreeStyle Libre users is lacking. Previous studies examining the relationship between the number of scans and TIR have relied on the internet-uploaded data to categorize scan frequency into 10 or 20 equal-sized groups, ultimately revealing a positive correlation between increased scanning and improved TIR. However, there exists no consensus on the optimal scanning frequency, and the impact of patient attributes, such as pathology, lifestyle, and type, remains largely unexplored.

In our current study, we utilized receiver operating characteristic (ROC) curves and area under curve (AUC) to determine the optimal scan frequency, a novel approach that has not been previously reported. Therefore, this study aimed to determine the optimal scan frequency for the target achievement defned as TIR more than 70% and to clarify the infuential factors afecting scan frequency in adults with T1D.

# **Methods**

### **Study design**

The "FGM-Japan Study" was a cross-sectional investigation that aimed to assess the practical application of intermittently scanned CGM (isCGM) in a real-world setting. The primary endpoint was the target achievement defned as TIR more than 70%.

### **Participants**

Patients were recruited from a collaboration center between February 2020 and April 2021. The inclusion criteria were as follows: T1D, duration of isCGM use for  $\geq$  3 months,  $age \geq 20$  years, and regular attendance at the collaborating center. The exclusion criteria were non-insulin therapy, antidementia drug use, and inappropriate cases judged by the research director or coordinators.

#### **Clinical characteristics**

The self-reported number of severe hypoglycemia (SH) episodes in the preceding year, defned as "a hypoglycemic episode that you were unable to treat yourself," was collected. The self-reported number of hypoglycemic episodes in the preceding month was recorded. Impaired awareness of hypoglycemia was determined using the Gold method. Data on clinical characteristics, HbA1c, liver enzymes (i.e., aspartate aminotransferase, alanine transaminase, and gamma-glutamyl transferase), and lipid profles were collected from medical records. Diabetes distress and fear of hypoglycemia were assessed by the Problem Areas in Diabetes (PAID) survey and Hypoglycemia Fear Survey (HFS-B, for behavior, and HFS-W, for worry), respectively.

#### **Lifestyle factors**

Self-administered standardized questionnaires were used to extract data on lifestyle behaviors (current smoking, regular exercise, dietary habits, drinking habits, and sleeping habits) from the specifc health check and guidance system. Exercise habits included three items: 1) regular exercise ( $\geq$  2 times/week of exercise for  $\geq$  4 metabolic equivalents [METs]/h); 2) active physical activity ( $\geq$  23 METs-h/week); and 3) walking pace (rapid or not rapid), an indicator of physical ftness. Excessive drinking was defned based on answers to the questions on drinking habits, i.e., both "occasionally or every day" and " $\geq$  180 mL of sake (equivalent to  $\geq$  20 g of alcohol)." The classification of lifestyle behaviors as "healthy" or "unhealthy" was based on adherence to a healthy diet and active exercise habits for the former, and on an unhealthy diet and behavior (i.e., late-night dinner consumption, current smoking, and excessive alcohol intake) for the latter [\[18,](#page-6-15) [19](#page-6-16)].

#### **Continuous glucose monitoring derived metrics**

CGM metrics, including the average daily risk range (ADRR), average glucose, glucose management indicator, high blood glucose index (HBGI), low blood glucose index (LBGI), mean amplitude of glycemic excursion (MAGE), mean of daily diference for inter-day variation, standard deviation (SD), time in range (TIR) 70–180 mg/ dL, time below range (TBR) < 70 mg/dL or < 54 mg/dL, percent coefficient of variation (%CV), and time above range (TAR) > 180 mg/dL or > 250 mg/dL  $[20-23]$  $[20-23]$  $[20-23]$ , were collected during the last 90 days using the FreeStyle Libre system (Abbott Diabetes Care Inc., Alameda, CA, USA). CGM metrics were calculated for adequate isCGM data ( $\geq$  70%). Stable glucose levels were defined as a CV < 36%, and unstable glucose levels were defned as  $CV \geq 36\%$  according to the International Consensus on Use of CGM [[22\]](#page-6-19).

<span id="page-2-0"></span>

Mean (SD, standard deviation) or %

*GA* glycated albumin, *CGM* continuous glucose monitoring, *TAR* time above range, *TIR* time in range, *TBR* time below range, *ADRR* average daily risk range, CV coefficient of variation, MAGE mean amplitude of glycemic excursion, *HBGI* high blood glucose index, *LBGI* low blood glucose index, *SD* standard deviation, *MODD* mean daily diference for inter-day variation, *PAID* problem areas in diabetes, *HFS-B* hypoglycemia fear survey-behavior, and *HFS-W* hypoglycemia fear survey-worry

#### **Statistical analysis**

Continuous variables were compared using Student's t-test or the Mann–Whitney *U* test. Correlations were assessed using Spearman's rank correlation coefficient or Pearson's correlation coefficient. Categorical variables were compared using the Fisher's exact test. The Youden index was used to determine the optimal cutoff value for the target value. Diagnostic accuracy using the area under the receiver operating characteristic (ROC) curve was defined as follows:  $< 0.5$ (test not useful),  $0.5-0.6$  (bad),  $0.6-0.7$  (sufficient),  $0.7-0.8$ (good), 0.8–0.9 (very good), and 0.9–1.0 (excellent) [[24](#page-6-20)]. To identify the indirect efect of scan frequency on glycemic variability (GV), we employed structural equation modeling (SEM) through the use of TAR or TBR. Statistical analysis was conducted using the R software program, version 4.1.2

<span id="page-2-1"></span>**Table 2** Scan frequency according to the interest variable category

| Variables                           | Yes  |             | No   |           | <i>p</i> value |
|-------------------------------------|------|-------------|------|-----------|----------------|
|                                     | %    | Mean $(SD)$ | %    | Mean (SD) |                |
| $\geq 60$ years                     | 29.0 | 10.4(3.2)   | 71.0 | 10.4(3.3) | 0.980          |
| Male sex                            | 40.8 | 10.4(3.6)   | 59.2 | 10.5(3.1) | 0.950          |
| $\geq$ 25 of BMI, kg/m <sup>2</sup> | 22.9 | 9.9(3.2)    | 77.1 | 10.6(3.3) | 0.205          |
| $\geq$ 7% of HbA1c                  | 76.3 | 10.2(3.1)   | 23.7 | 11.2(3.7) | 0.059          |
| Diabetic complica-<br>tions         |      |             |      |           |                |
| Retinopathy                         | 25.5 | 9.9(2.8)    | 74.5 | 10.6(3.4) | 0.217          |
| Nephropathy                         | 15.2 | 9.8(3.0)    | 84.8 | 10.6(3.4) | 0.224          |
| Peripheral neuropa-<br>thy          | 22.0 | 10.5(2.9)   | 78.0 | 10.4(3.4) | 0.894          |
| Coronary artery<br>disease          | 4.3  | 8.8(3.3)    | 95.7 | 10.5(3.3) | 0.128          |
| Cerebrovascular<br>disease          | 4.7  | 10.5(2.9)   | 95.3 | 10.4(3.3) | 0.937          |
| Peripheral arterial<br>disease      | 3.8  | 11.3(3.3)   | 96.2 | 9.6(3.5)  | 0.256          |
| <b>IAH</b>                          | 17.7 | 10.6(3.1)   | 82.3 | 10.4(3.4) | 0.729          |
| <b>SH</b>                           | 11.1 | 10.1(3.2)   | 88.9 | 10.4(3.3) | 0.664          |
| Diabetes treatment                  |      |             |      |           |                |
| CSII                                | 23.2 | 10.4(2.9)   | 76.8 | 10.5(3.4) | 0.864          |

% or mean (SD, standard deviation)

 $*1 p < 0.05$  (vs. no)

*BMI* body mass index, *IAH* impaired awareness of hypoglycemia, *SH* severe hypoglycemia, and *CSII* continuous subcutaneous insulin infusion

(the R Foundation for Statistical Computing, Vienna, Austria). Glycemic variability was calculated using the "*Gluvarpro*" and "*iglu*" R packages.

# **Results**

The study was conducted on 211 adults with T1D (mean age,  $50.9 \pm 15.2$  years; male, 40.8%; diabetes duration,  $16.4 \pm 11.9$  years; duration of CGM use,  $2.1 \pm 1.0$  years; mean TDD,  $34.0 \pm 15.4$ ; and mean HbA1c,  $7.6 \pm 0.9\%$ ) (Table [1\)](#page-2-0). The participants had 25.5% retinopathy, 22.0% neuropathy, and 15.2% nephropathy. The average scan frequency was  $10.5 \pm 3.3$  scan/day. This study did not include pregnant women.

There was no diference in scan frequency between age, sex, BMI, HbA1c, diabetic complications, and treatment categories (Table [2](#page-2-1)). Scan frequency was positively correlated with TIR and negatively correlated with TAR, although it was not signifcantly correlated with TBR. The scan frequency showed a negative correlation with ADRR, %CV, MAGE, HBGI, and SD. Scan frequency showed a positive correlation with hypoglycemia fear survey (HFS)-behaviors,

<span id="page-3-0"></span>**Table 3** Correlation of scan and SMBG frequency per day with interest variables



Mean (SD, standard deviation) or r (95% CI, confidence interval).  $* P < 0.05$ 

*SMBG* self-monitoring of blood glucose, *GA* glycated albumin, *CGM* continuous glucose monitoring, *TAR* time above range, *TIR* time in range, *TBR* time below range, *ADRR* average daily risk range, *CV* coefficient of variation, *MAGE* mean amplitude of glycemic excursion; *HBGI* high blood glucose index, *LBGI* low blood glucose index, *SD* standard deviation, *MODD* mean daily diference for inter-day variation, *PAID* problem areas in diabetes, *HFS-B* hypoglycemia fear survey-behavior, and *HFS-W* hypoglycemia fear survey-worry

but did not correlate significantly with the HFS-worry score. There was no signifcant association between selfmonitoring blood glucose (SMBG) frequency and any of the variables of interest, except for age (Table [3](#page-3-0)). There was no difference in scan frequency  $(10.3 \pm 3.2 \text{ vs. } 10.3 \pm 3.3,$ p=0.826) between isCGM-naïve user group (*n*=11, 5.2%) or non-naïve user group  $(n=200, 94.8\%)$ . There was no association between the duration of isCGM use and scan frequency (*r*=0.027 [95% CI -0.109, 0.163], *p*=0.696).

Adults with T1D and good exercise habits had a higher scan frequency than sedentary adults (Table [4\)](#page-4-0). There was no diference in the scan frequency between patients with healthy vs. unhealthy eating habits. The AUC for > 70% TIR was 0.653 with an optimal cutoff of 11 scan/day, although the AUC for  $< 25\%$  TAR or  $< 4\%$  TBR was not sufficient for diagnostic accuracy (Fig. [1\)](#page-5-0). For each additional scan per day, the mean GMI decreased 0.03% and TIR increased 0.83%. The SEM model revealed that scan frequency had an indirect infuence on GV in adults with T1D via TAR (with a standardized  $\beta$ -coefficient of -0.784, p < 0.001), but not TBR.

### **Discussion**

This is the frst study to examine the association between scan frequency and CGM metrics and to identify the optimal cutoff for achieving the glycemic target  $(>70\%$  of TIR) in Japanese adults with T1D. Furthermore, scan frequency was signifcantly associated with the HFS-B score, and exercise habits was associated with an increased the scan frequency.

The average scan frequency (10.5 scan/day) was relatively lower than that described in previous studies (12 in Israel [[13\]](#page-6-10), 13 in Spain [[14](#page-6-11)], 14 in Brazil [\[15](#page-6-12)], and 16.3 in Europe [[17\]](#page-6-14)). In 85 Japanese children and adolescents with T1D,

frequent scanning decreased hyperglycemia with increased TIR, but did not reduce TBR [\[25\]](#page-6-21). In 163 Denmark people with T1D, increased scanning frequency was associated with a higher TIR with no change in TBR [\[26\]](#page-6-22). These results were consistent with our own. In a study by Dunn et al., a scanning frequency of > 20 scans/day was associated with an estimated HbA1c level close to 7.0% [[17](#page-6-14)]. The study by Leelarathna et al. [\[27\]](#page-6-23) recommended scanning as much as possible, aiming>15 per day. The ISCHIA study advised frequent scanning ( $\geq 10$  times per day) [\[28](#page-7-0)]. Our ROC analysis showed that the optimal cutoff for achieving the glycemic target ( $>70\%$  of TIR) was 11 scans per day. SEM demonstrated the indirect correlation between scan frequency and GV. Therefore, in future investigations, a comprehensive examination with a large sample size will be necessary to validate both the direct and indirect efects of scan frequency on GV.

In this study, T1D adults with exercise habits had more frequent scanning. They might scan frequently because of worrying hypoglycemia during the exercise. But the accuracy of the isCGM diminished during the exercise and using isCGM to monitor glucose levels during exercise is not recommended [[29\]](#page-7-1). Moreover, the accuracy decreased when carbohydrate was consumed before exercise. Careful attention should be paid for the use of isCGM during the exercise. Adults with T1D can read a glucose trend arrow and a graph of glucose readings over the preceding 8 h

<span id="page-4-0"></span>**Table 4** Scan frequency according to the eating, exercise, and lifestyle categories [[30](#page-7-2)]. However, we did not check the degree of consideration trend arrow for T1D management. Recently, the use of isCGM with optional alarms for high and low blood glucose levels decreased HbA1c levels in 156 British adults with T1D [[27](#page-6-23)]. Now, Japanese adults with T1D did not use the isCGM system with optional alarms.

In this study, scan frequency was associated with HFS-B scores but not HFS-W scores. In 61 American youth with T1D, consistent CGM use was associated with treatment adherence and improved glycemic control without an increase in psychosocial distress [\[31\]](#page-7-3). Also, isCGM use with the structured education and regular support by healthcare professionals improved quality of life in British 52 children with T1D [\[32\]](#page-7-4). The use of isCGM produced a reduction in the frequency and severity of diabetic ketoacidosis (DKA) events in 47 Saudi Arabian T1D people with recurrent DKA [[33](#page-7-5)]. Further examination including a trend arrow, isCGM with optional alarms [\[34\]](#page-7-6), and longer follow-up are required to confrm these issues.

### **Limitation of the study**

The strengths of this study include real-world data and detailed information on the T1D treatment, lifestyle, and psychological factors. There were several limitations, including the cross-sectional design of this study



% or mean (SD, standard deviation)

\**p*<0.05



<span id="page-5-0"></span>Fig. 1 A series of ROC analysis demonstrating optimal cutoff values of scan frequency for achieving HbA1c and CGM-derived metrics target. ROC, receiver operating characteristic; CGM, continuous glucose monitoring; TBR, time below range; TIR, time in range; TAR,

time above range; GMI, glucose management indicator; CV, coefficient of variation, AUC, area under curve; and CI, confdential interval

precluding conclusions concerning causality, and the target population comprised only adult patients with T1D. Generalizability was limited by the target population, i.e., Japanese adults with T1D. COVID-19 lockdown may have affected scan frequency, but the participants were only followed for three months, making it difficult to analyze the impact. Systematic review indicated that glycemic values in people with T1D signifcantly improved during COVID-19 lockdown, which may be associated with positive changes in self-care and digital diabetes management [\[35\]](#page-7-7). Further examinations including COVID-19 lockdown periods are required to confrm these issues. In this study, we did not measure the frequency of insulin administration including correction bolus. In future, it will be necessary to investigate the relationship between the frequency of insulin administration, especially correction by insulin regimen, and various indicators.

# **Conclusions**

In real-world conditions, frequent scans are linked to improved CGM metrics, including increased TIR, reduced TAR, and glycemic variability indicators. Exercise habits and hypoglycemia fear-related behavior might afect scan frequency. This information will help diabetes health professionals support adults with T1D and isCGM.

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### **Declarations**

**Conflict of interest** YH received lecture fees from Eli Lilly, Sanof, Abbott, Terumo and Sumitomo Pharma, and research expenses and grants from Sumitomo Pharma. JM received lecture fees from Terumo. MT received lecture fees from Abbott, Terumo and Sumitomo Pharma, Novo Nordisk, and Boehringer Ingelheim and subsides or donations from Cocokara fne Healthcare Inc., LifeScan Japan, Roche DC Japan, and SUPER LIGHT WATER CO., LTD. AT receives lecture fees from Eli Lilly, Sanof, Abbott, and Terumo.TM received lecture fees from Eli Lilly. Other members declare no competing interests.

**Ethical Approval** This study conformed to the standards of the Declaration of Helsinki. The present study was approved by the Ethics Committee of the National Hospital Organization Kyoto Medical Center (No.19–072, approval date: January 20, 2020).

**Informed consent** Informed consent or substitute for it was obtained from all patients for being included in the study. Approval date of Registry and the Registration No. of the study/trial: Trial registration number: University hospital Medical Information Network (UMIN) Center: UMIN000039376).

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