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Predictive Factors of the Adherence to Real-Time Continuous Glucose Monitoring Sensors: A Prospective Observational Study (PARCS STUDY)

Takashi Murata, MD, PhD[1], Akio Kuroda, MD, PhD[2], Munehide Matsuhisa, MD, PhD[2], Masao Toyoda, MD, PhD[3], Moritsugu Kimura, MD, PhD[3], Yushi Hirota, MD, PhD[4], Ken Kato, MD, PhD[5], Hideaki Sawaki, MD, PhD[6,7], Atsuhito Tone, MD, PhD[8,9], Satoshi Kawashima, MD, PhD[10], Akira Okada, MD[11], Tomokazu Watanabe, MD[1], Shinsuke Nirengi, PhD[12], Akiko Suganuma, ABS[12], and Naoki Sakane, MD, PhD[12]

Abstract

Background: Information about factors related to better adherence to continuous glucose monitoring (CGM) sensor adherence is quite limited.

Materials and Methods: Forty-six participants with type 1 diabetes using continuous subcutaneous insulin infusion (CSII) without CGM were recruited. The participants' characteristics and diabetes-related quality of life (QOL) were evaluated at baseline and one year after starting to use CGM. Participants wearing the sensor for ≥60% of the time were considered as adherent.

Results: The mean age of the 46 participants was 44.1 ± 15.0 years old and the mean glycohemoglobin (HbA1c) was 7.7 ± 1.0%; 60.9% of the participants were classified as adherent. The duration of using CSII was longer in the adherent group, and the degree of diabetic retinopathy was significantly different. There were no significant differences in age, frequency of self-monitoring of blood glucose, or Hypoglycemia Fear Survey (HFS-B for behavior, HFS-W for worry) score at baseline between the adherent and nonadherent groups. The Problem Areas in Diabetes (PAID) score at baseline was significantly higher and the total CSII-QOL score at baseline was significantly lower in the adherent group. The usage of dual-wave bolus was significantly increased in the adherent group (34.6%-61.5%, $P = .016$), but not in the nonadherent group (33.3%-33.3%, $P > .999$). The HbA1c level showed a significant improvement in the adherent group (7.8%-7.3%, $P < .001$), but not in the nonadherent group (7.5%-7.2%, $P = .102$).

Conclusions: Higher adherence to CGM sensors may be associated with a heavier emotional burden of diabetes and a worse QOL in relation to CSII at baseline.

Keywords
adherence, CGM, CSII, HFS, PAID, QOL

Introduction

Type 1 diabetes (T1D) is a chronic condition that requires insulin therapy, leading to the potential adverse effect of hypoglycemia. Self-monitoring of blood glucose (SMBG) has been the standard method of glucose monitoring since the Diabetes Control and Complication Trial.[1] Indeed, the frequency of SMBG is negatively correlated with glycohemoglobin (HbA1c) in T1D patients.[2] Continuous glucose monitoring (CGM) was developed to overcome the lack of continuous information in SMBG.[3] Previous studies, including the Juvenile Diabetes Research Foundation (JDRF) and STAR-3 studies, demonstrated a relationship between HbA1c improvement and better CGM sensor adherence.[4-8] However, information about the factors related to the better adherence to CGM sensors is quite limited. For example, in the JDRF study, adherence to CGM sensors was associated with age ≥25 years and more frequent self-reported blood glucose meter measurements per day; other factors were unclear.[7] In this study, improvement in quality of life (QOL)

in relation to fear of hypoglycemia was observed.[8] As self-management behavior may be generally affected by psychosocial factors, we hypothesized that QOL related to factors such as fear of hypoglycemia and the psychological burden of diabetes, income, or need to drive might be associated with a higher frequency of CGM sensor usage.

To investigate factors related to better adherence to CGM sensors, we performed a prospective observational study of participants with T1D who were using continuous subcutaneous insulin infusion (CSII) and who started real-time CGM for the first time.

Materials and Methods

This study was an open-label, single-arm, multicenter observational study conducted at nine institutes in Japan (National Hospital Organization Kyoto Medical Center, Tokushima University, Tokai University School of Medicine, Kobe University Graduate School of Medicine, National Hospital Organization Osaka National Hospital, Arisawa General Hospital, Okayama University Hospital, Kanda Naika Clinic, and Okada Clinic). Forty-six T1D participants using insulin pumps without CGM were recruited between February 2015 and January 2017. The participants were followed up for one year after switching to the MiniMed 620G (Medtronic, Inc., Northridge, USA) sensor-augmented pump (SAP). The study was approved by the Ethical Committee of NHO Kyoto Medical Center (14-088) and was registered in the UMIN Clinical Trials Registry (UMIN-CTR: UMIN000016588). Written informed consent was obtained from all participants prior to their participation in the study.

Study Population and Survey

The inclusion and exclusion criteria are described in Table 1. Information regarding the following baseline characteristics was collected: age, sex, duration of diabetes, duration of CSII use, model of insulin pump used prior to the study, diabetic retinopathy (none, background retinopathy, pre-proliferative retinopathy, proliferative retinopathy, or post-photocoagulation), diabetic nephropathy (none, microalbuminuria, macroalbuminuria, renal failure, or end-stage renal disease), HbA1c, body mass index (BMI), blood pressure (systolic, SBP and diastolic, DBP), total daily insulin dose (TDD), total daily basal insulin dose (TBD), frequency of SMBG, coverage by social security, employment (full-time employment, part-time employment, student, homemaker, pensioner, or unemployed), possession of driver's license, driving mileage, and annual income. HbA1c was measured at each medical institute satisfying the standards determined by JDS.[9] Severe adverse events (SAEs) were determined as death or hospitalization due to either severe hypoglycemia or diabetic ketoacidosis. Severe hypoglycemia was determined as hypoglycemia for which treatment required assistance.[1] Multiple episodes of adverse events (AEs) in the same participant were counted as one incidence.

Table 1. Inclusion and Exclusion Criteria.

Inclusion criteria
Age ≥15 y
T1D
Use of an insulin pump for ≥1 y
Participants willing to use SAP
Participants who regularly visit or were hospitalized at the medical institute participating in this study
Exclusion criteria
Previous usage of real-time CGM or SAP
Pregnancy or undergoing preconception care
Age <15 y
Participants not suitable to participate in this study for other reasons

Abbreviations: CGM, continuous glucose monitoring; SAP, sensor-augmented pump; T1D, type 1 diabetes.
A diagnosis of T1D was made according to the criteria of the Japan Diabetes Society (JDS).[10]

Psychometric Evaluation

To assess the QOL, the Hypoglycemia Fear Survey (HFS; HFS-B for behavior, HFS-W for worry) was used to evaluate the fear of hypoglycemia, Problem Areas in Diabetes (PAID;

[1]Diabetes Center, National Hospital Organization Kyoto Medical Center, Kyoto, Japan
[2]Diabetes Therapeutics and Research Center, Institute of Advanced Medical Sciences, Tokushima University, Tokushima, Japan
[3]Division of Nephrology, Endocrinology and Metabolism, Department of Internal Medicine, Tokai University School of Medicine, Isehara, Japan
[4]Division of Diabetes and Endocrinology, Department of Internal Medicine, Kobe University Graduate School of Medicine, Kobe, Japan
[5]Diabetes Center, National Hospital Organization Osaka National Hospital, Osaka, Japan
[6]Diabetes Center, Arisawa General Hospital, Hirakata, Japan
[7]Sawaki Internal Medicine and Diabetes Clinic, Takatsuki, Japan
[8]Diabetes Center, Okayama University Hospital, Okayama, Japan
[9]Department of Internal Medicine, Okayama Saiseikai General Hospital, Okayama, Japan
[10]Kanda Naika Clinic, Osaka, Japan
[11]Okada Clinic, Fukuoka, Japan
[12]Division of Preventive Medicine, Clinical Research Institute, National Hospital Organization Kyoto Medical Center, Kyoto, Japan

Corresponding Author:
Takashi Murata, MD, PhD, Diabetes Center, National Hospital Organization Kyoto Medical Center, 1-1 Fukakusamukaihata-cho, Fushimi-ku, Kyoto 612-8555, Japan.
Email: murata-tky@umin.net

20 items) was used to evaluate the emotional burden of diabetes, the Euro-QOL 5 dimensions 3-level version (EQ-5D-3L) utility score was used to measure the functional health status, and CSII-QOL (convenience factor, social restriction factor, and psychological problems factor) was used to evaluate the QOL in relation to CSII.[11-14] A higher HFS score indicates worse fear of hypoglycemia, a higher PAID score indicates a heavier emotional burden of diabetes, a lower EQ-5D-3L score indicates a poorer functional health status, and a lower CSII-QOL score indicates worse CSII-related QOL. All of the psychometric evaluations were conducted in Japanese. The Japanese versions of PAID[15] and EQ-5D-3L were linguistically validated, and the validated CSII-QOL was originally developed in Japanese. However, the Japanese version of HFS (B&W) is not back-translated despite it having been widely used for more than a decade.[16]

Statistical Analyses

CGM data were downloaded to PCs for the analysis. Sensor adherence was calculated as the time using the sensor per week using CareLink Pro Therapy Management Software Ver. 4.0C (Medtronic, Inc., Northridge, USA). Based on the observation in the STAR-3 study, participants wearing the sensor for ≥60% were considered adherent[5]. The adjusted mean change in body weight and HbA1c at year 1 was obtained using the last observation carried forward. Missing data in the QOL survey were omitted. For continuous variables, the Student's *t*-test was used to compare the mean values of the two study arms. For categorical variables, the X^2-test or Fisher's exact test was used to compare proportions. Pearson's correlation efficient was calculated to assess correlation. Spearman's correlation efficient was calculated to assess correlation with ranking. *P* values of $<.05$ were considered to indicate statistical significance. Data are expressed as the mean (standard deviation) or percentage. All statistical analyses were conducted using SPSS for Windows Ver. 23.0 (IBM, Armonk, NY, USA) or EZR.[17]

Results

Forty-six participants were recruited, and 45 completed the study. One participant withdrew six months after the start of the study.

The baseline characteristics of the participants are described in Table 2. Twenty-eight participants (60.9%) were classified into the adherent group and 18 (39.1%) were classified into the nonadherent group. The overall time wearing the sensor was 61.9 ± 26.8%. In the adherent group, the time wearing the sensor was significantly longer in comparison to the nonadherent group (80.1 ± 10.8% vs 33.5 ± 18.1%, $P < .001$).

The duration of using CSII use was longer in the adherent group, and the degree of diabetic retinopathy was significantly different in the adherent group (Table 2). The ratio of post-photocoagulation diabetic retinopathy in the adherent and nonadherent groups was not significantly different (13.0% vs 0.0%, $P = .068$). After one year, there was a significant increase of BMI in the overall study population and in the adherent group (Table 3). There was also a significant improvement in HbA1c in the overall study population and in the adherent group, but not in the nonadherent group. There was a significant increase of TDD in the overall study population and in the nonadherent group.

There was no significant difference in HFS (total HFS score, HFS-B score, and HFS-W score) at baseline between the adherent and nonadherent groups (Table 4). There was a significant improvement in the HFS-W score after one year in the overall study population. In the adherent group, the PAID score at baseline was significantly higher in comparison to the nonadherent group. There was no significant change in the PAID score after one year. There was a significant worsening in the EQ-5D-3L utility score after one year in the nonadherent group.

Each item of the PAID self-reported questionnaire was compared between the adherent and nonadherent groups, and the scores for items "7. Not knowing if your mood or feelings are related to your diabetes?", "11. Feeling constantly concerned about food and eating?", "13. Feelings of guilt or anxiety when you get off track with your diabetes management?", "19. Coping with complications of diabetes?", and "20. Feeling "burned out" by the constant effort needed to manage diabetes?" were significantly higher in the adherent group (Supplemental Table S1). Answers of severe distress (PAID scores 3 and 4) for items "7" and "13" were significantly frequent in the adherent group (Supplemental Table S2). There was no significant correlation between the duration of using CSII and the PAID score ($r = –0.004$, $P = .981$). The degree of diabetic retinopathy was not correlated with the PAID score (Supplemental Table S3).

In the adherent group, the total CSII-QOL score at baseline and the score for psychological problems at baseline were significantly lower in comparison to the nonadherent group (Table 5). After one year, the score for convenience significantly improved in comparison to that at baseline in the overall study population, and in the adherent and nonadherent groups.

The usage of dual-wave bolus increased significantly in the adherent group but not in the nonadherent group (Supplemental Table S4).

No SAEs were observed in either groups. Episodes of severe hypoglycemia that did not result in hospitalization were observed in two participants in the adherent group (two episodes each). No episodes of diabetic ketoacidosis that did not result in hospitalization were observed. Contact dermatitis due to adhesive was observed in one participant each in the adherent and nonadherent groups. The incidence was 12.8 cases/100 person-years for total AEs, 8.5 cases/100

Table 2. The Baseline Characteristics of the Adherent and Nonadherent Groups.

Variables	Total ($n=46$)	Adherent ($n=28$)	Nonadherent ($n=18$)	*P* value
Age, y	44.1 (15.0)	45.8 (14.5)	41.5 (15.9)	.356
Female, %	73.9	67.9	83.3	.243
Diabetes duration, y	18.8 (13.6)	19.1 (11.7)	18.3 (16.5)	.849
CSII, y	3.7 (2.4)	4.3 (2.3)	2.7 (2.4)	.028*
Model of insulin pump				
Paradigm 712	2	2	0	.231
Paradigm 722	30	20	10	
MiniMed 620G	14	6	8	
Retinopathy				
None	30	15	15	.029*
Background retinopathy	9	7	2	
Pre-proliferative retinopathy	1	0	1	
Proliferative retinopathy	0	0	0	
Post-photocoagulation	6	6	0	
Nephropathy				
None	40	24	16	.354
Microalbuminuria	2	1	1	
Macroalbuminuria	3	3	0	
Renal failure	1	0	1	
ESRD	0	0	0	
HbA1c, %	7.7 (1.0)	7.8 (0.9)	7.5 (1.1)	.270
BMI, kg/m^2	22.7 (2.8)	22.7 (2.6)	22.8 (3.2)	.858
SBP, mmHg	118 (13)	117 (14)	120 (13)	.440
DBP, mmHg	72 (10)	71 (10)	73 (12)	.605
TDD, units/day	36.1 (13.8)	37.3 (12.8)	34.3 (15.4)	.483
TBD/TDD, %	33.8 (12.4)	34.8 (13.4)	32.2 (11.0)	.493
Frequency of SMBG, times/day	4.8 (1.8)	5.1 (1.9)	4.5 (1.5)	.299
Coverage by social security, %	8.7	7.1	11.1	.639
Status of employment				
Full-time employment	16	10	6	.791
Part-time employment	11	7	4	
Student	3	2	1	
Homemaker	9	6	3	
Pensioner	2	1	1	
Unemployed	4	1	3	
Possession of driving license				
Yes	38	23	15	$>$.999
No	7	4	3	
Driving mileage, km/y				
$\leq$3000	20	12	8	.648
3001-5000	10	5	5	
5001-10000	3	2	1	
10001-15000	2	0	2	
$\geq$15000	2	1	1	
Income (million yen/y), %				
$<$2	6	4	2	.743
2-6	27	15	12	
$\geq$6	10	7	3	
History of severe hypoglycemia within one year, %	13.3	11.5	16.7	.676
Frequency of self-reported hypoglycemia ($<$70 mg/dL) per month	7.0 (4.0, 13.5)	5.0 (4.0, 15.0)	8.5 (4.0, 10.0)	.860

Abbreviations: BMI, body mass index; CSII, continuous subcutaneous insulin infusion; DBP, diastolic blood pressure; ESRD, end-stage renal disease; HbA1c, glycated hemoglobin; SBP, systolic blood pressure; SD, standard deviation; SMBG, self-monitoring of blood glucose; TBD, total daily basal insulin dose; TDD, total daily insulin dose.

Data are presented as the number, percentage or mean (SD), median (25%, 75%), as indicated.

*$P<.05$.

Table 3. Change in Characteristics After One Year.

	Total		Adherent		Nonadherent		
Variables	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*P* value
BMI							
Baseline	46	22.7 (2.8)	28	22.7 (2.6)	18	22.8 (3.2)	.858
1-y	46	23.2 (3.1)	28	23.3 (2.9)	18	23.0 (3.6)	.794
P value		.010*		.003*		.548	
SBP, mmHg							
Baseline	45	118.4 (13.5)	28	117.0 (13.7)	17	120.8 (13.2)	.440
1-y	45	117.8 (12.9)	28	114.6 (11.2)	17	123.1 (14.1)	.031
P value		.700		.195		.452	
DBP, mmHg							
Baseline	45	71.9 (10.1)	28	70.9 (9.5)	17	73.6 (11)	.605
1-y	45	71.5 (10.5)	28	70.4 (9.6)	17	73.4 (11.8)	.369
P value		.740		.716		.920	
HbA1c, %							
Baseline	46	7.7 (1.0)	28	7.8 (0.9)	18	7.5 (1.1)	.270
1-y	46	7.3 (0.7)	28	7.3 (0.7)	18	7.2 (0.7)	.571
P value		<.001*		.001*		.102	
TDD							
Baseline	46	36.1 (13.8)	28	37.3 (12.8)	18	34.3 (15.4)	.483
1-y	46	39.5 (14.2)	28	39.4 (13.4)	18	39.7 (15.7)	.932
P value		.023*		.28		.023*	
TBD/TDD, %							
Baseline	46	33.8 (0.1)	28	34.9 (0.1)	18	32.2 (0.1)	.493
1-y	46	32.9 (0.1)	28	33.2 (0.1)	18	32.5 (0.1)	.823
P value		.482		.265		.935	
Frequency of SMBG, times/day							
Baseline	46	4.8 (1.8)	46	5.1 (1.9)	46	4.5 (1.5)	.299
1-y	46	4.7 (1.5)	46	4.8 (1.5)	46	4.5 (1.7)	.544
P value		.464		.341		>.999	
Frequency of bolus							
Baseline	40	5.0 (1.8)	24	4.8 (1.9)	16	5.2 (1.7)	.515
1-y	40	5.3 (2.8)	24	5.2 (1.5)	16	5.5 (4.0)	.592
P value		.368		.268		.723	
Frequency of self-reported hypoglycemia (symptomatic or <70 mg/dL) per month							
Baseline	7.0	(4.0, 15.0)	6.0	(4.0, 15.0)	10.0	(4.0, 10.0)	.924
1-y	8.0	(5.0, 15.0)	10.0	(2.6, 15.0)	6.0	(5.0, 12.5)	.786
P value		.279		.476		.396	

Abbreviations: BMI, body mass index; DBP, diastolic blood pressure; HbA1c, glycated hemoglobin; SBP, systolic blood pressure; SD, standard deviation; SMBG, self-monitoring of blood glucose; TBD, total daily basal insulin dose; TDD, total daily insulin dose.
Data are presented as the number, percentage or mean (SD), median (25%, 75%), as indicated.
*$P < .05$.

person-years for AEs related to the study, 4.3 cases/100 person-years for severe hypoglycemia, and 4.2 cases/100 person-years for contact dermatitis due to adhesive. There were no statistically significant differences between the adherent and nonadherent groups in the incidence total AEs (17.8 vs 5.2 cases/100 person-years, $P = .217$), AEs related to the study (10.6 vs 5.2 cases/100 person-years, $P = .519$), severe hypoglycemia (7.2 vs 0.0 cases/100 person-years, $P = .256$), or contact dermatitis due to adhesive (3.5 vs 5.2 cases/100 person-years, $P = .789$).

Discussion

We performed a prospective observational study to investigate factors associated with adherence to CGM in T1D participants using insulin pumps. As there was a domestic issue that a standalone CGM device separate from an insulin pump was not commercially available in Japan when the current study was initiated, only patients who were already using a CSII were recruited. In addition, the incidence of T1D in East Asian populations is much lower than that in Caucasian

Table 4. HFS, PAID, and EQ-5D Utility Score.

	Total		Adherent		Nonadherent		
Variables	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*P* value
HFS (total)							
Baseline	43	34.3 (16.8)	26	37.5 (17.5)	17	29.4 (14.7)	.112
1-y	43	30.3 (13.7)	26	31.9 (14.2)	17	28.0 (12.9)	.218
P value		.057		.064		.584	
HFS-B							
Baseline	43	16.9 (6.6)	26	18.2 (6.2)	17	15.0 (6.8)	.101
1-y	43	16.9 (6.8)	26	16.9 (6.7)	17	16.8 (7.0)	.961
P value		.952		.192		.15	
HFS-W							
Baseline	43	17.3 (12.0)	26	19.3 (13.1)	17	14.4 (9.6)	.178
1-y	43	13.5 (8.9)	26	15.0 (9.5)	17	11.2 (7.6)	.165
P value		.024*		.093		.109	
PAID							
Baseline	44	34.7 (17.0)	27	38.1 (18.2)	17	29.4 (13.8)	.044*
1-y	44	33.5 (17.2)	27	36.0 (16.0)	17	29.5 (18.8)	.227
P value		.531		.387		.984	
EQ-5D-3L utility							
Baseline	43	0.897 (0.159)	26	0.876 (0.165)	17	0.928 (0.147)	.412
1-y	43	0.875 (0.159)	26	0.902 (0.157)	17	0.835 (0.158)	.184
P value		.339		.360		.007*	

Abbreviations: EQ-5D-3L, Euro-QOL 5 dimensions 3-level version; HFS, Hypoglycemia Fear Survey (HFS-B for behavior, HFS-W for worry); PAID, Problem Areas in Diabetes; SD, standard deviation.
Data are presented as the number or mean (SD).
*$P < .05$.

Table 5. CSII-QOL Score.

	Total		Adherent		Nonadherent		
Variables	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*P* value
Total score							
Baseline	44	60.1 (14.3)	27	57.0 (13.9)	17	65.1 (13.8)	.045*
1-y	44	63.4(16.4)	27	61.9 (16.9)	17	65.9 (15.8)	.428
P value		.090		.073		.763	
Convenience							
Baseline	44	16.3 (2.3)	27	16.5 (2.3)	17	15.9 (2.3)	.486
1-y	44	20.0 (3.6)	27	20.5 (3.2)	17	19.1 (4.1)	.223
P value		<.001*		<.001*		.003*	
Social restriction							
Baseline	44	25.0 (6.6)	27	23.6 (6.5)	17	27.2 (6.2)	.057
1-y	44	24.8 (7.3)	27	23.8 (7.9)	17	26.2 (6.3)	.291
P value		.786		.889		.422	
Psychological problems							
Baseline	44	18.8 (7.6)	27	16.8 (7.5)	17	22.1 (7.0)	.022*
1-y	44	18.7 (8.0)	27	17.6 (8.4)	17	20.6 (7.2)	.225
P value		.911		.613		.241	

Abbreviations: CSII, continuous subcutaneous insulin infusion; QOL, quality of life; SD, standard deviation.
Data are presented as the mean (SD) or number.
*$P < .05$.

populations[18]; thus, there was difficulty in recruiting participants. As a result, only 46 participants were recruited from nine institutes. The majority of participants in this study were female, which was consistent with the observation in a

previous study regarding the usage of CSII among T1D patients in Japan.[19] The reason why a longer duration of CSII use was associated with better adherence to CGM remains unclear. The reason why there was a significant difference in the degree of diabetic retinopathy between the two groups also remains unclear; however, it is possible that participants with advanced diabetic retinopathy might want to use CGM more constantly to prevent a further worsening of the complication. The reason why age was not associated with CGM adherence may be due to the higher age of the T1D participants in this study. The frequency of SMBG was positively associated with adherence to CGM in the JDRF study,[7] but not in this study. One of the largest differences between the JDRF study and the current study is that the participants in the JDRF study included both patients using multiple daily injections (MDI) and CSII; the present study only included participants using CSII.

The significant improvement of HbA1c in the overall study population (mean time wearing the sensor: 61.9%) and in the adherent group (mean time wearing the sensor: 80.1%), but not in the nonadherent group (mean time wearing the sensor: 33.5%) was consistent with previous studies.[4,5] The reason why there was a significant increase in the BMI in the overall study population and in the adherent group, but not in the nonadherent group, remains unclear. The reason why there was significant increase in the TDD in the overall study population and nonadherent group, but not in the adherent group, also remains unclear.

We found that a higher baseline PAID score was associated with better adherence to CGM usage. The baseline HFS score (total, behavior, and worry) and EQ-5D-3L utility score were not associated with adherence to CGM in this study. The reasons for these observations are not clear; however, it is possible that participants who felt a heavy burden of diabetes even after starting CSII may use CGM more frequently. It is also possible that participants with better adherence to CGM may include individuals who feel a heavier burden of diabetes. Indeed, there were significant differences between the adherent and nonadherent groups in scores for PAID items related to difficulty in coping with T1D.

The absence of improvement in the PAID score after one year of CGM is of interest, as it suggests that CGM did not significantly relieve the burden of diabetes in this study population. The current study might have failed to detect the change in the PAID score due to the small sample size, or the effect of real-time CGM on QOL could differ depending on the patient background or the modalities used to evaluate QOL. The DIAMOND study conducted in the United States, which exclusively recruited patients using MDI reported an improvement in Diabetes Distress Scale.[20] The RESCUE Trial conducted in Belgium, which exclusively recruited patients using CSII, reported an improvement in the Problem Area in Diabetes-short form and Short Form 36.[21] These studies did not analyze the association between diabetes-related QOL and CGM adherence.

In contrast, the HFS-W score significantly improved in the overall study population after one year. This observation was similar to the RESCUE Trial,[21] but differed from the JDRF study in which the HFS-B score improved after CGM usage[8] or from the DIAMOND and Hypo-DE studies in which there was no significant change in the HFS-W score.[20,22] The reason why there was a significant worsening in the EQ-5D-3L utility score after one year in the nonadherent group remains unclear. There was no significant difference in the EQ-5D Utility Index between the rt-CGM arm and control arm in Hypo-DE study.[22] One possibility is that there might be some confounding factors between the worsening of the EQ-5D-3L utility score and the nonadherence to CGM.

We also used the recently developed CSII-QOL score, which was created to assess the QOL specifically related to CSII.[14] Better adherence to CGM was associated with worse CSII-related QOL, especially with psychological problems, which suggests that participants who had unmet needs in the self-management of T1D, even after starting CSII, might have wanted to perform CGM more constantly.

The observation that the usage of dual-wave bolus increased significantly in the overall study population and in the adherent group, but not in the nonadherent group, may suggest an important role of CGM in the management of postprandial hyperglycemia. Watching daily glucose excursion through CGM might have motivated the participants to use dual-wave bolus to manage the prolonged postprandial hyperglycemia accompanying the consumption of fat and protein rich food.

The incidence of severe hypoglycemia (4.3 cases/100 person-years) in this study was low; however, this rate might not be accurate due to the relatively small study population.

Although not significantly different, the incidence of severe hypoglycemia in the adherent group tended to be higher than that in the nonadherent group. As real-time CGM is reported to be useful for reducing hypoglycemic events in T1D patients using MDI,[22] it is possible that patients with a higher risk of developing severe hypoglycemia might have wanted to use CGM more frequently, but the sample size and duration of the current study were not sufficient to compare the incidence of severe hypoglycemia in both groups. A future study with a larger population and longer duration will be necessary to address this issue, combined with a survey of the past history of severe hypoglycemia at baseline.

The present study was associated with some limitations. First, the study population was relatively small. Second, it employed an open-label, single-arm observational design. Third, only T1D participants using an insulin pump were included and those using MDI were excluded, as no real-time CGM separate from the insulin pump was available in Japan when this study was planned. Fourth, factors that might underlie poor adherence, such as dissatisfaction with sensor accuracy and pain, were not investigated in this study.

Conclusion

In this study, a heavier psychological burden of diabetes, as measured by the PAID score and a worse CSII-related QOL, as measured by the CSII-QOL score before the start of CGM, were associated with better adherence to CGM (≥60%) after its introduction in participants with T1D who were already using CSII. The PAID score was not improved after CGM, but worry in relation to hypoglycemia, as measured by the HFS-W score, improved after CGM. Our results suggest that the assessment of psychological status in T1D patients before starting CGM may predict adherence to CGM after its introduction.

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Declaration of Conflicting Interests

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ORCID iD

Takashi Murata https://orcid.org/0000-0001-8634-9657

Supplemental Material

Supplemental material for this article is available online.

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