ORIGINAL

Sex differences in the impact of structured education together with isCGM in individuals with type 1 diabetes : post hoc analysis of the ISCHIA study

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Abstract : Background : The ISCHIA study demonstrated that intermittently scanned continuous glucose monitoring (isCGM) combined with structured education effectively reduced the time below range (TBR) in individuals with type 1 diabetes. Given that the influence of sex on CGM metrics has remained unclear, we performed a post hoc analysis of the ISCHIA study to evaluate the impact of isCGM together with structured education on TBR and other parameters in men and women separately. Methods : Data for 93 individuals who completed the ISCHIA study were analyzed. Baseline characteristics and intervention outcomes, including CGM indices and quality of life (QOL) scores, were stratified by sex for comparative analysis. Results : Age, body mass index, disease duration, and insulin dosage at baseline did not differ significantly between men and women. Intervention outcomes including TBR (9.9 ± 6.2% vs 10.3 ± 7.6% for men vs women, respectively), time in range (61.5 ± 11.2% vs 59.7 ± 10.9%), and time above range (28.6 ± 12.7% vs 30.0 ± 13.4%) as well as QOL scores also did not show any significant sex differences. Conclusion : The use of isCGM together with structured education was suggested to be effective in reducing TBR among individuals with type 1 diabetes regardless of sex. J. Med. Invest. 73 : 74-79, February, 2026

Keywords **:** *sex, hypoglycemia, intermittently scanned continuous glucose monitoring (isCGM), type 1 diabetes, time below range*

INTRODUCTION

Continuous glucose monitoring (CGM) has become widely adopted for and an essential tool in diabetes care (1). It is increasingly recommended for glycemic management, particularly in individuals with type 1 diabetes (T1D) (2). We previously showed in the ISCHIA study that intermittently scanned CGM (isCGM) combined with structured education with regard to the importance of scan frequency and the use of trend arrows effectively reduced the time below range (TBR) compared with self-monitoring of blood glucose (SMBG) in individuals with T1D (3). The identification of factors that influence the effectiveness of CGM is key to optimization of its use. Several studies have suggested that sex differences may influence treatment responses and outcomes in T1D. These include studies indicating sex differences in the daily insulin dose in individuals who achieved > 70% time in range (4) and meta-analyses showing a higher prevalence of heart failure in women (5). These findings suggest that sex differences in T1D may be related to treatment outcomes and prognosis. Whereas some studies have explored the impact of sex on glycemic management with CGM in T1D (6-8), the findings have been inconsistent. It has therefore remained unclear whether the effects of such interventions differ by sex. It is important to clarify whether treatment intervention effects differ by sex in order to optimize high-quality care for all individuals with T1D. We here conducted a post hoc analysis of the data obtained by the ISCHIA study to explore whether the effects of structured education in individuals with T1D using isCGM are influenced by sex.

MATERIALS AND METHODS

Study design

The protocol for the ISCHIA study was previously published (9). In brief, the ISCHIA study was a randomized, crossover trial performed with 104 individuals with T1D. During an 84-day intervention period, participants used isCGM after structured education, whereas during an 84-day control period they performed SMBG at least three times a day. Participants were instructed to perform frequent scanning of the isCGM sensor (at least 10 times a day) and to ingest sugar when hypoglycemia was

Received for publication July 22, 2025 ; accepted October 10, 2025.

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predicted on the basis of sensor glucose levels or trend arrows. The content of the structured education is publicly available (10). In the present study, we conducted a post hoc analysis of the dataset obtained during the ISCHIA study.

Setting

The ISCHIA study was conducted in the outpatient setting in Japan. Details on the locations and data collection were described previously (3).

Participants

The main inclusion criteria for the ISCHIA study were an age of 20 to 74 years, a diagnosis of T1D, administration of multiple daily injections of insulin, and a baseline hemoglobin A1c (HbA1c) level of < 8.5% (69 mmol/mol). The main exclusion criteria were hemodialysis, pregnancy, and the use of oral hypoglycemic agents to manage T1D within the past year (3, 9). Among the 104 participants, 93 completed the trial, with the CONSORT diagram having been presented previously (3).

Parameters examined

This post hoc analysis examined differences in CGM metrics and other parameters between men and women. The variables analyzed included age, body mass index (BMI), history of isCGM use, HbA1c level, insulin dose, history of smoking and alcohol consumption, time in range (TIR : 70–180 mg/dL [3.9–10.0 mmol/L]), time above range (TAR : > 180 mg/dL [> 10.0 mmol/L]), time below range (TBR : < 70 mg/dL [< 3.9 mmol/L]), mean sensor glucose values, glycated albumin level, the low blood glucose index (LGBI), frequency of SMBG, scan frequency, the Problem Areas in Diabetes Survey (PAID) score (11), and Hypoglycemia Fear Survey (HFS) scores (12) at baseline and after the intervention.

Data source

The dataset for the 93 adults who completed the ISCHIA study was used as the data source for the present study (3).

Bias

Given the nature of this post hoc analysis, the possibility of bias, including data dredging bias, could not be completely eliminated. Selection bias was minimized by use of the available data collected from all the participants who completed the trial.

Statistical analysis

Continuous and categorical variables are presented as means ± SD and percentages, respectively. Descriptive statistics were adopted to summarize the data, with comparisons conducted with the unpaired *t* test for continuous variables and Fisher's exact test for categorical variables. All statistical analyses were performed with R software (The R Foundation for Statistical Computing, Vienna, Austria). A *P* value of < 0.05 was considered statistically significant.

RESULTS

We analyzed baseline data that were previously reported for the ISCHIA study but are here stratified by sex (Table 1). The analysis included 44 men and 49 women, with the two groups showing no significant differences in age, BMI, disease duration, total daily insulin dose per body weight, or the percentage of basal insulin at baseline. However, fewer women than men were isCGM naïve (28.6% vs 65.9%, $P < 0.001$) or had diabetic

Table 1. Baseline clinical characteristics of the study participants.

Characteristic	Men ($n = 44$, 47.3%)	Women ($n = 49$, 52.7%)	*P* values
Age (years)	54.2 ± 14.0	48.8 ± 16.1	0.089
BMI (kg/m^2)	22.4 ± 3.0	22.9 ± 2.9	0.456
Diabetes duration (years)	20.1 ± 10.6	16.4 ± 9.3	0.077
isCGM naïve (%)	65.9	28.6	<0.001*
Diabetic complications (%)			
Retinopathy	25.6	20.8	0.626
Nephropathy	25.0	2.1	0.001*
Neuropathy	22.7	16.3	0.600
SMBG (%)			
90 times/month	20.5	22.4	>0.999
120 times/month	79.5	77.6	
HbA1c (%)	7.2 ± 0.6	7.4 ± 0.7	0.049*
Prescribed insulin			
TDD/BW (U/kg)	0.61 ± 0.23	0.60 ± 0.17	0.763
Basal insulin (%)	37.4 ± 13.6	32.6 ± 11.4	0.066
Lifestyle factors			
Alcohol drinking (days/week)	2.7 ± 2.7	1.4 ± 2.3	0.017*
Current smoker (%)	20.9	8.2	0.132

Values are mean ± SD or percentage. *$P < 0.05$ (unpaired *t* test or Fisher's exact test). BMI, body mass index ; isCGM, intermittently scanned continuous glucose monitoring ; SMBG, self-monitoring of blood glucose ; HbA1c, hemoglobin A1c ; TDD, total daily insulin dose ; BW, body weight.

nephropathy (2.1% vs 25.0%, $P = 0.001$), and women had higher HbA1c levels (7.4 ± 0.7% vs 7.2 ± 0.6%, $P = 0.049$) and a lower frequency of alcohol consumption (1.4 ± 2.3 vs 2.7 ± 2.7 days per week, $P = 0.017$).

Outcomes for the intervention period were also compared between the sexes (Table 2). There were no significant differences in TAR, TIR, or TBR between men and women. Similarly, mean sensor glucose levels, the LGBI, and glycated albumin levels did not differ between the sexes. Quality of life, as reflected by PAID, HFS-B, and HFS-W scores, was also similar for men and women. Although scan frequency did not differ significantly between men and women, the frequency of SMBG was significantly lower for women than for men (2.9 ± 1.5/day vs 3.5 ± 1.0/day, $P = 0.032$).

DISCUSSION

Our findings suggest that structured education, including encouragement to perform frequent scanning for isCGM and to use trend arrows, has sex-independent effects on CGM metrics. We thus found that TAR, TIR, and TBR did not differ significantly between men and women, nor did quality of life scores. At baseline, a higher proportion of men than women were isCGM naïve, whereas women had higher HbA1c levels. In previous meta-analysis, it has been reported that in individuals with T1D, the HbA1c reduction achieved by CGM was greater in groups with higher baseline HbA1c levels (13). In our study, given that CGM was combined with structured education, These findings imply that, when combined with structured education, CGM may confer benefits irrespective of sex, yielding comparable post-intervention outcomes despite higher baseline HbA1c in women. The prevalence of diabetic nephropathy was higher among men in our study. As far as we are aware, however, no previous study has evaluated the impact of diabetic nephropathy on CGM metrics, so the potential importance of this difference remains unclear. In addition, men reported a significantly higher frequency of alcohol consumption than did women. According to the National Health and Nutrition Survey conducted by the Ministry of Health, Labour, and Welfare of Japan, 14.1% of men and 9.5% of women consume alcohol in amounts that increase the risk of lifestyle-related diseases (14), suggesting that our present data are consistent with trends in the general population.

Data obtained for the intervention period showed that the frequency of SMBG was significantly higher in men. Few studies have examined the relationship between sex differences and SMBG frequency, and previous studies have reported inconsistent findings (15, 16). The reason why men performed SMBG more frequently in our study remains unclear ; however, unassessed factors such as behavioral differences related to sex or the influence of CGM use may have contributed. Previous studies have found a negative correlation between the frequency of SMBG and HbA1c levels in individuals with T1D (17, 18). However, we did not detect a sex difference in CGM metrics despite the significant difference in SMBG frequency. A plausible explanation is that, under CGM use, trend arrows and frequent scanning provide sufficient information, diminishing the incremental value of SMBG. Our study appears to be the first to provide data for SMBG frequency and CGM metrics during isCGM use in an intervention trial. Our findings suggest that SMBG frequency does not significantly affect CGM metrics under isCGM use. The frequency of scans did not differ between men and women during the intervention period. Previous studies have reported that men tend to scan less frequently and to show poorer adherence to isCGM compared with women (19), and that scan frequency is negatively correlated with TBR (20-22). The structured education provided in our study may have helped

Table 2. Outcomes for the intervention period.

Outcome	Men	Women	*P* values
TBR (<70 mg/dL)			
h	2.38 ± 1.49	2.47 ± 1.82	0.794
%	9.9 ± 6.2	10.3 ± 7.6	
TIR (70–180 mg/dL)			
h	14.76 ± 2.69	14.33 ± 2.62	0.448
%	61.5 ± 11.2	59.7 ± 10.9	
TAR (>180 mg/dL)			
h	6.86 ± 3.05	7.20 ± 3.22	0.613
%	28.6 ± 12.7	30.0 ± 13.4	
Mean glucose (mg/dL)	148.3 ± 23.2	150.3 ± 25.3	0.691
LBGI	2.4 ± 1.5	2.6 ± 2.1	0.580
SMBG frequency (/day)	3.5 ± 1.0	2.9 ± 1.5	0.032*
isCGM scanning frequency (/day)	12.6 ± 8.9	11.2 ± 4.2	0.300
PAID score	28.5 ± 16.8	34.8 ± 18.8	0.097
HFS-B score	16.7 ± 7.3	16.7 ± 5.5	0.999
HFS-W score	12.6 ± 9.8	13.7 ± 10.3	0.605
Glycated albumin	21.2 ± 3.2	22.4 ± 3.6	0.110

Values are means ± SD. *$P < 0.05$ (unpaired *t* test). TBR, time below range ; TIR, time in range ; TAR, time above range ; LBGI, low blood glucose index ; PAID, Problem Areas in Diabetes Survey ; HFS-B, Hypoglycemia Fear Survey for Behavior ; HFS-W, Hypoglycemia Fear Survey for Worry.

men to maintain adherence to isCGM and to increase their scan frequency, resulting in no sex difference in TBR.

There are several limitations to the present study. First, as a post hoc analysis, it may have been influenced by data dredging bias. In addition, the sample size of the current study was calculated to test the primary endpoint, the TBR, and may not be optimal for this post hoc analysis. Second, the version of the FreeStyle Libre (isCGM) device used by the study participants differs from the one currently available. This newer version (FreeStyle Libre 2 ; Abbott Diabetes Care, Alameda, CA, USA), which is now available in Japan, allows continuous display of sensor glucose values and trend arrows on a smart device and has an alert function for hypoglycemia and hyperglycemia. However, its overall functionality remains essentially the same as the earlier version paired with a reader, despite the addition of an alarm. Third, given that our study recruited adults with T1D who had a baseline HbA1c level of < 8.5% (69 mmol/mol) and were treated with multiple daily injections of insulin, our findings may not apply to individuals with T1D in general. Further studies will be needed to determine whether they indeed apply to children and adolescents as well as to individuals using continuous subcutaneous insulin infusion.

CONCLUSION

The results of this post hoc analysis of the ISCHIA study suggest that most treatment outcomes of isCGM use combined with structured education do not differ between men and women.

ACKNOWLEDGMENTS

We thank Yuki Fushiki and Masayuki Domichi (National Hospital Organization [NHO] Kyoto Medical Center) for support in study management, as well as Keith W. Brocklehurst for English language editing.

AUTHOR CONTRIBUTIONS

TM chaired and designed the study as well as drafted and revised the manuscript. NS designed the study, conducted statistical analysis, and drafted and revised the manuscript. YH, KH, KK, AK, MM, JM, AT, and MT designed the study, acquired and interpreted data, and drafted and revised the manuscript. SS, AY, MU, SM, AI, NK, and AS acquired and interpreted data as well as drafted and revised the manuscript.

FUNDING

This work was supported by the Japan Agency for Medical Research and Development (grant nos. 18ek0210104h0001, 19ek0210104h0002, and 20ek0210104h0003) and the Japan IDDM Network, a nonprofit corporation.

DATA AVAILABILITY

The data availability statement for the ISCHIA study has been provided in detail previously (3).

ETHICS DECLARATIONS
CONFLICT OF INTEREST

No potential conflicts of interest were reported by the ISCHIA study group relevant to this article. Potential conflicts of interest for individual investigators were reviewed by the Certified Review Board in accordance with the Clinical Trials Act. The conflicts of interest of the writing group are as follows : YH has received lecture fees from Eli Lilly Japan K.K., Sanofi, Terumo Corp., Sumitomo Pharma Co., Ltd., Novo Nordisk Pharma Ltd., Abbott Japan LLC., Medtronic Japan Co., Ltd., Dexcom Inc., Mitsubishi Tanabe Pharma Co., Daiichi Sankyo Co., Teijin Pharma Ltd., Sanwa Kagaku Kenkyusho Co., Novartis Pharma K.K., Kyowa Kirin Co., Ltd., Roche Diagnostics K.K., Kowa Co., Ltd., Otsuka Pharmaceutical Co., Ltd., Nippon Boehringer Ingelheim Co., Ltd., LifeScan Japan K.K., Nipro Corp., Mochida Pharmaceutical Co., Ltd. ; research expenses (including for contracted research, joint research, and clinical trials) and grants from Sumitomo Pharma Co., Ltd., Kyowa Kirin Co., Ltd., Medtronic Japan Co., Ltd., and Nippon Boehringer Ingelheim Co., Ltd. ; and scholarship donations from Abbott Japan LLC. SM has received lecture fees from Abbott Japan Co. Ltd., Asahi Kasei Pharma Corp., Astellas Pharma Inc., AstraZeneca K.K., Bayer Yakuhin Co., Ltd., Daiichi Sankyo Co., Ltd, EA Pharma Co., Ltd., Eli Lilly Japan K.K., Kowa Company, Ltd., Kyowa Hakko Kirin Co. Ltd., Life Scan Japan Inc., Mitsubishi Tanabe Pharma Corporation, Mochida Pharmaceutical Co. Ltd., MSD K.K., Nippon Boehringer Ingelheim Co. Ltd., Novartis Pharma K.K., Novo Nordisk Pharma Ltd., Ono Pharmaceutical Co. Ltd., Roche Diagnostics K.K., Sanofi, Sanwa Kagaku Kenkyusho Co. Ltd., Sumitomo Pharma Co. Ltd., Taisho Pharmaceutical Co. Ltd., Teijin Pharma Ltd. AI has received lecture fees from Dexcom Inc., Abbott Japan LLC., Medtronic Japan Co., Ltd., Terumo Corp., Eli Lilly K.K., Sanofi, and Novo Nordisk Pharma Ltd. NK has received lecture fees from Novo Nordisk Pharma Ltd., Dexcom Inc., Sanofi, Abbott Japan LLC., Medtonic Japan Co., Ltd., LifeScan Japan LLC., and Terumo Corp. AK has received lecture fees from Astellas Pharma Inc., Abbott Japan LLC., Sanwa Kagaku Kenkyusho Co., Ltd., Sanofi, Kowa Company, Ltd., Terumo Corp., Eli Lilly K.K., Medtronic Japan Co., Ltd., Novo Nordisk Pharma Ltd., Nippon Boehringer Ingelheim Co., Ltd., Roche Diagnostics K.K., Nipro Corp., Dexcom Inc. MM has received consulting fees from Orizuru Therapeutics, Inc. as well as lecture fees from LifeScan Japan LLC., Abbott Japan LLC., Daiichi Sankyo Co., Ltd., Sanofi, Kowa Co., Ltd., Otsuka Pharmaceutical Factory, Inc., Sanwa Kagaku Kenkyusho Co., Ltd., Ono Pharmaceutical Co., Ltd., Novo Nordisk Pharma Ltd., Teijin Home Healthcare Ltd., Nippon Boehringer Ingelheim Co., Ltd., Sumitomo Pharma Co., Ltd., Mitsubishi Tanabe Pharma Co., Fujifilm Toyama Chemical Co., Ltd., Eli Lilly Japan K.K., Arkray Marketing, Inc., Terumo Corp., Kyowa Kirin Co., Ltd., Nippon Becton Dickinson Co., Ltd., Cosmic Corp., AstraZeneca K.K., Ajinomoto Co., Inc., Novo Nordisk Pharma Ltd., MSD Co., Ltd, Astellas Pharma Inc., Senju Pharmaceutical Co., Ltd., Kaken Pharmaceutical Co., Ltd., Welby, Inc., Teijin Pharma Ltd., Dexcom Inc., and Otsuka Pharmaceutical Co., Ltd. JM has received lecture fees from Novo Nordisk Pharma Ltd., LifeScan Japan K.K., Abbott Japan LLC., Kowa Co., Ltd., Arkray Marketing Co., Ltd., Sanofi, Eli Lilly Japan K.K., Medtronic Japan Co., Ltd., Nipro Corp., Sumitomo Pharma Co., Ltd., Astellas Pharma Inc., Dexcom Japan G.K. and Terumo Corp. as well as a research grant from Terumo Corp., Sanofi. ; serves as a member of Japanese Diabetes Society Academic Council, Japanese Society for Advanced Diabetes and Type 1 Diabetes Research Committee, Pediatric Insulin Therapy Research Committee, Tokyo Women's Medical University Academic Council, Research Committee on

Exploratory Studies of New Pathophysiological Mechanisms in Type 1 Diabetes, Japanese Diabetes Society, and Research Committee on the Development of Appropriate Treatment Based on an Analysis of the Current Status of Type 1 Diabetes in Japan, Japanese Diabetes Society. AT has received lecture fees from Johnson & Johnson K.K., LifeScan Japan K.K., Medtronic Japan Co. Ltd., Eli Lilly Japan K.K., Sanofi, Kowa Pharmaceutical Co. Ltd., Mitsubishi Tanabe Pharma Co., Novo Nordisk Pharma Ltd., Sanwa Kagaku Kenkyusho Co. Ltd., Sumitomo Pharma Co. Ltd., Novartis Pharma K.K., Taisho Pharmaceutical Co. Ltd., Kyowa Hakko Kirin Co. Ltd., Abbott Japan LLC., Nippon Boehringer Ingelheim Co. Ltd., AstraZeneca K.K., Terumo Corp., H2 Co. Ltd., Otsuka Pharmaceutical Co. Ltd., Teijin Healthcare Ltd., Roche Diagnostics K.K., Arkray Marketing Inc., and Dexcom Japan G.K. MT has received lecture fees from Eli Lilly Japan K.K, Mitsubishi Tanabe Pharma Co., Kowa Co., Ltd., Terumo Corp., Sumitomo Pharma Co., Ltd., Novo Nordisk Pharma Ltd., Nippon Boehringer Ingelheim Co., Ltd., Daiichi Sankyo Co., Ltd., Kissei Pharmaceutical Co., Ltd., Sanwa Kagaku Kenkyusho Co., Ltd., AstraZeneca K.K., Dexcom Inc., and Abbott Japan LLC. ; research expenses (including for contracted research, joint research, and clinical trials) and a grant from Dexcom Inc. ; and scholarship donations from LifeScan Japan K.K. TM has received lecture fees from Dexcom Inc., Medtronic Japan Co., Ltd., and Abbott Japan LLC. as well as research grants from the Japan Agency for Medical Research and Development, the Japan IDDM Network, and Medtronic Japan Co., Ltd. AS has received lecture fees from Sanofi, Abbott Japan LLC., and serves as a director of Japan Diabetes Society. KK has received lecture fees from DM network, Novo Nordisk Pharma Ltd., Dexcom Japan G.K., Medtronic Japan Co., Ltd., Terumo Corp., H2 Co., Ltd., Abbott Japan LCC., Sumitomo Pharma Co., Ltd., Mitsubishi Tanabe Pharma Co., Sanwa Kagaku Kenkyusho Co., Kyowa Kirin Co., Ltd., Kowa Pharmaceutical Co., Ltd., Novartis Pharma K.K., Teijin Pharma Ltd., Nippon Boehringer Ingelheim Co., Ltd., and Kissei Pharmaceutical Co. SS, AY, MU, KH, and NS declare that they have no conflicts of interest.

INFORMED CONSENT

Informed consent or an appropriate substitute for it was obtained from all patients prior to their inclusion in the study. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and/or with the Helsinki Declaration of 1964 and later versions. The study protocol was approved by the Certified Review Board (NHO Osaka National Hospital) ; original approval (N2018002) was granted on 14 February 2019 (version 0.7), with the latest revision (version 1.6) being approved on 26 May 2020. Clinical trial registration : jRCT 1052180075 (approval date, 26 February 2019).

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