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Effects of switching from MiniMed™ 640G to 770G on continuous glucose monitoring metrics and DTR-QOL scores: An observational study of Japanese people with type 1 diabetes mellitus

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ABSTRACT

Aims/Introduction: We evaluated the effect of the MiniMed™ 770G, an insulin pump using hybrid closed-loop technology, on blood glucose management and quality of life in Japanese people with type 1 diabetes.

Materials and Methods: This was a 52-week, prospective, observational study. Fifty Japanese people with type 1 diabetes switched from the MiniMed™ 640G to 770G, and we analyzed the continuous glucose monitoring data of 24 subjects who used auto mode throughout the study. We also analyzed the scores of the Diabetes Therapy-Related Quality of Life questionnaire completed by 26 auto-mode users before and after the treatment change.

Results: The baseline time in range 70–180 mg/dL was 67.3 (54.8–78.4)%, with a significant improvement beginning 8 weeks after the switch and lasting until 52 weeks. The baseline time below range <70 mg/dL was 1.9 (0.6–3.6)%, with a significant increase at week 8; however, the mean value was less than 4% throughout the study period. On the other hand, the number of blood glucose measurements significantly increased. While there was no significant difference in the overall change in the total Diabetes Therapy-Related Quality of Life score, there was a significant decrease in the treatment satisfaction score.

Conclusions: Use of the MiniMed™ 770G improved continuous glucose monitoring metrics. However, treatment satisfaction decreased, probably due to the increased frequency of blood glucose monitoring necessary to maintain auto mode.

INTRODUCTION

Type 1 diabetes (T1D) is a disease caused by the destruction of insulin-producing beta cells in the pancreas[1]. In many cases, insulin secretion is severely impaired, resulting in frequent, unexpected episodes of hyperglycemia and hypoglycemia[2]. This makes strict glycemic control difficult, and thus pump therapy plays an important role. Currently, automated insulin delivery (AID) system is regarded to a useful tool to prevent hyperglycemia and hypoglycemia.

The MiniMed™ 770G, AID system that uses hybrid closed-loop (HCL) technology, was launched in January 2022 in Japan. When the HCL auto mode with the closed-loop algorithm is selected, the 770G automatically adjusts the basal insulin dose based on both sensor glucose levels and past insulin infusion history[3,4]. The target blood glucose level is 120 mg/dL, but it can be temporarily increased to 150 mg/dL[4]. However, to remain in auto mode, the Guardian 3 sensor of the

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MiniMed™ 770G requires a minimum of two daily calibrations by finger prick. The MiniMed™ 670G and 770G are nearly identical, but the 770G can connect to a mobile app that allows users to view glucose data and set up automatic cloud uploads[4]. Thus far, many studies have investigated the use of the 670G and 770G in patients in Western countries[5–12], but only a few have evaluated their clinical application in Japanese patients, and the duration of the analysis was short in each case[13–15]. Thus, this study evaluated the effects of the MiniMed™ 770G in Japanese people with T1D who used the system for a longer period.

MATERIALS AND METHODS

Study design

This was a prospective, observational study of people with T1D who switched from the MiniMed™ 640G (Medtronic Diabetes, Northridge, CA, USA) to the MiniMed™ 770G (Medtronic Diabetes) with auto mode. All subjects were seen at the outpatient clinic of Juntendo University Hospital from April 2022 to April 2023. The inclusion criteria were as follows: (1) age 20 years or older at the time of consent; (2) any gender; and (3) provision of written informed consent after receiving a full explanation of study participation. Subjects were excluded if they were judged by the principal investigator to be unsuitable for participation.

Patients were educated on the appropriate use of the 770G for more than 30 min by trained physicians or nurses in the outpatient clinic. Insulin pump data were collected in the outpatient clinic after being uploaded by each patient's device, and only continuous glucose monitoring (CGM) data available for at least 70% of 14 days[16,17] around on week 0, 8, 16, 24 and 52 after the switch to the 770G with auto mode were analyzed. Routine blood tests, including HbA1c levels, were also performed during these regular outpatient visits.

The Medtronic CareLink Report, which we use in our daily practice, makes it very easy to obtain blood glucose summaries. However, values are displayed as integers; for example, a time below range (TBR) of 1% actually encompasses the range from 0.5 to 1.4%. Thus, the analysis results are influenced by the resulting fractional error, especially for small TBR values. Thus, in this study, the raw data were downloaded from the CareLink system in CSV format for data analysis. For raw data analysis, we used a package titled Cgmanalysis version 2.7.6, which was developed in the free programming language R version 4.3.1. When the cleandata function of Cgmanalysis was executed, a huge matrix file containing various pump parameters was reformatted into data containing only timestamps and glucose sensor information. From there, the 14 days to be analyzed could be extracted and the cgmvariables function could be executed to simultaneously obtain various CGM metrics such as the glucose monitoring indicator (GMI)[18,19], J-index, standard deviation (SD), mean of daily difference (MODD) of blood glucose levels, and mean amplitude of glycemic excursions (MAGE) (Table 1). The J-index is a measure of glycemic control quality that is determined based on the mean blood glucose level and its SD and is calculated as $0.001 \times (\text{mean} + \text{SD})$[20]. MODD is an index used to assess day-to-day glycemic variability and is calculated based on the absolute difference between the paired CGM values obtained on two successive days[20–22]. MAGE is an index of daily variability and is calculated as the mean of the differences between consecutive nadirs and peaks[20,21,23].

The Diabetes Therapy-Related Quality of Life (DTR-QOL) questionnaire is a validated diabetes-specific questionnaire developed to assess the impact of treatment on quality of life (Table 2). This questionnaire uses a 7-point Likert scale (1: strongly agree to 7: strongly disagree) and consists of 29 items divided into four domains: "Burden on social and daily activities"; "Anxiety and dissatisfaction with treatment"; "Hypoglycemia"; and "Satisfaction with treatment." "Burden on social activities and daily activities" domain pertains to the effects of diabetes on work and socializing; diet and appetite; time and effort; and pain and side effects. "Anxiety and dissatisfaction with treatment" domain covers the effects of treatment on weight, hyperglycemia, anxiety about complications, and psychological anxiety. "Hypoglycemia" domain includes difficulties with hypoglycemia and associated psychological anxiety, and "Satisfaction with treatment" domain includes questions on confidence, hope for the future, and satisfaction with glycemic control. Scores for each of the four domains are converted to a 0–100 point scale[24,25]. All auto-mode users were asked to complete the DTR-QOL questionnaire, and data from those who submitted their responses both before the pump change and at week 52 were analyzed.

The primary outcome comprised the changes in (1) time in range (TIR: percentage of readings with sensor glucose values between 70 and 180 mg/dL), (2) TBR (percentage of readings with sensor glucose values below 70 mg/dL), and (3) time above range (TAR: percentage of readings with sensor glucose values above 180 mg/dL) at around 8, 16, 24, and 52 weeks from the start of auto mode. Each due date had an allowance of 4 weeks before and after the date. Subanalyses examined TAR >250 mg/dL, TBR <54 mg/dL, TBR daytime (06:00–23:59), and TBR nighttime (00:00–05:59)[17]. The secondary outcome comprised the changes in scores of the DTR-QOL questionnaires for the subjects who continued in auto mode and for whom the questionnaires were collected at both weeks 0 and 52.

The protocol was approved by the Juntendo University institutional review board and was performed in accordance with the Declaration of Helsinki and current legal regulations in Japan (Juntendo University Ethics Committee approval No. E22-0009). After receiving a full explanation of the study, all subjects provided written informed consent regarding participation and study publication.

Statistical analysis

Data are expressed as the mean ± standard deviation for normally distributed data, and as medians (interquartile range) for

Table 1 | Glucose and clinical outcomes

	Baseline	8 weeks (*N* = 24)	*P*	16 weeks (*N* = 24)	*P*	24 weeks (*N* = 24)	*P*	52 weeks (*N* = 18)	*P*
TIR 70–180 mg/dL	67.3 (54.8–78.4)	73.4 (69.7–81.3)	**<0.01**	72.5 (69.6–78.6)	**0.014**	74.2 (66.2–80.9)	**0.024**	71.5 (64.1–81.0)	**0.016**
TAR >180 mg/dL	28.4 (18.3–43.1)	23.8 (17.5–26.4)	**<0.01**	23.9 (18.5–27.6)	**0.010**	22.0 (16.9–29.9)	**<0.01**	25.3 (15.8–34.7)	**<0.01**
TAR >250 mg/dL	6.4 (1.3–12.0)	3.5 (2.1–5.7)	**<0.01**	4.0 (2.3–6.7)	0.081	4.0 (1.8–7.0)	0.057	4.1 (1.5–8.3)	0.067
TBR <70 mg/dL	1.9 (0.6–3.6)	2.9 (1.8–4.9)	**0.027**	2.8 (1.1–4.0)	0.30	2.7 (1.7–4.9)	0.050	2.6 (1.5–4.8)	0.067
TBR <54 mg/dL	0.2 (0.0–0.7)	0.9 (0.3–1.3)	**<0.01**	0.5 (0.2–1.2)	**0.013**	0.4 (0.2–1.3)	0.055	0.5 (0.2–1.4)	0.098
TBR <70 mg/dL daytime (6:00–23:59)	1.5 (0.5–3.2)	2.8 (1.2–4.9)	**0.012**	2.6 (1.0–4.4)	0.071	3.1 (1.6–4.7)	**<0.01**	2.6 (1.2–4.3)	0.074
TBR <70 mg/dL nighttime (0:00–5:59)	2.5 (0.8–5.0)	2.2 (0.3–5.5)	0.84	2.4 (0.5–4.5)	0.92	1.6 (0.2–5.2)	0.55	2.8 (0.9–5.7)	0.38
TBR <54 mg/dL daytime (6:00–23:59)	0 (0–0.4)	0.6 (0.1–1.1)	**<0.01**	0.4 (0.1–1.0)	**<0.01**	0.4 (0.1–1.0)	**0.019**	0.4 (0.1–0.8)	0.074
TBR <54 mg/dL nighttime (0:00–5:59)	0 (0–0.9)	0.3 (0–1.4)	0.37	0 (0–1.1)	0.91	0 (0–1.1)	0.33	0.5 (0–2.7)	0.15
Mean glucose, mg/dL	158 ± 23	146 ± 12	**<0.01**	147 ± 12	**0.011**	148 ± 15	<0.01	149 ± 15	**<0.01**
SD	54.7 (40.6–59.6)	49.7 (43.0–56.2)	0.15	50.3 (45.8–56.4)	0.44	51.4 (44.4–57.0)	1.00	51.6 (43.8–58.6)	0.25
Glucose CV	33.4 ± 5.2	34.5 ± 5.3	0.14	34.8 ± 4.8	0.15	35.2 ± 4.8	0.081	34.5 ± 4.5	0.23
GMI, %	7.1 ± 0.5	6.8 ± 0.3	**<0.01**	6.8 ± 0.3	**0.018**	6.8 ± 0.4	**<0.01**	6.9 ± 0.3	**<0.01**
HbA1c, %	7.4 ± 0.7	7.2 ± 0.5	**0.025**	7.3 ± 0.5	0.11	7.4 ± 0.5	0.37	7.4 ± 0.6	0.14
Insulin TDD, units	40.8 ± 12.8	39.8 ± 12.7	0.35	40.6 ± 13.0	0.89	41.4 ± 16.5	0.73	42.2 ± 13.5	0.72
Insulin bolus, units	25.1 ± 10.2	24.3 ± 9.4	0.44	23.6 ± 8.5	**0.038**	25.1 ± 11.3	0.94	25.9 ± 8.8	0.49
Insulin basal, units	15.7 ± 4.9	15.5 ± 5.2	0.64	17.0 ± 6.5	0.12	16.3 ± 6.8	0.92	16.3 ± 6.7	0.27
CGM is active, %	89.1 ± 6.8	91.2 ± 6.7	0.13	91.3 ± 7.2	0.078	90.1 ± 7.4	0.24	91.1 ± 7.3	0.13
Auto mode, %	–	88.3 ± 8.1	–	85.5 ± 14.1	–	85 ± 13.5	–	86.9 ± 11.0	–
SMBG, times per day	4.3 ± 1.3	5.5 ± 1.5	**<0.01**	5.3 ± 1.3	**<0.01**	5.3 ± 1.1	**<0.01**	5.3 ± 1.5	**<0.01**
Active insulin time, h	3.75 (3.0–4.0)	3.5 (3.0–4.0)	0.30	3.5 (3.0–4.0)	0.17	3.5 (3.0–4.0)	0.056	3.5 (3.0–4.0)	0.13
MAGE	102.3 (80.8–120.7)	103.1 (80.7–115.4)	0.74	100.7 (88.7–116.8)	0.91	97.5 (82.9–114.5)	0.60	101.8 (86.3–117.2)	0.73
J-INDEX	43.7 (34.7–56.3)	39.4 (33.6–41.9)	**<0.01**	39.2 (35.8–44.4)	**0.029**	38.6 (33.2–44.6)	**0.017**	39.4 (32.2–49.3)	**0.014**
MODD	54.8 (44.2–62.4)	47.9 (42.4–54.0)	**<0.01**	48.2 (43.9–52.0)	**<0.01**	48.9 (44.3–53.5)	**<0.01**	48.2 (42.7–57.7)	**0.012**
LBGI	2.6 (2.1–3.6)	3.4 (2.4–3.8)	0.37	2.7 (2.0–3.7)	0.98	2.8 (2.2–3.6)	0.40	2.6 (2.0–3.9)	0.58

Bold values indicate statistical significance at the $P < 0.05$ level.
Data are expressed as the mean ± standard deviation for normally distributed data and medians (interquartile range) for data with skewed distributions. CV, coefficient of variation; GMI, glucose monitoring indicator; LGBI, low blood glucose index; MAGE, mean amplitude of glycemic excursions; MODD, mean of daily difference of blood glucose; SD, standard deviation; TDD, total daily dose.

data with skewed distributions. Statistical analysis was performed using the JMP statistical software package, version 15.2.0 (SAS Institute, Cary, NC, USA), with the Mann–Whitney *U*-test and Wilcoxon signed rank test. A *P* value <0.05 denoted the presence of a statistically significant difference.

RESULTS

From April 2022 to April 2023, 81 patients switched from the MiniMed™ 640G to the 770G; of these, 50 were receiving AID system therapy while 31 were receiving only continuous subcutaneous insulin infusion therapy. The background characteristics of the 50 patients undergoing AID system therapy were as follows: mean age, 44 ± 13 years old; diabetes duration, 18 ± 9.4 years; and mean HbA1c level, 7.5 ± 0.8%. Of these 50 patients, 24 chose auto mode throughout the study period and had at least 70% of CGM data available for 2 weeks at each point up to week 24. The background characteristics of these 24 patients were as follows: mean age, 46 ± 15 years; diabetes duration, 17 ± 9.4 years; and mean HbA1c level, 7.4 ± 0.7%. Subsequently, prior to week 52, five patients stopped using auto mode and one patient discontinued AID system due to a diagnosis of pancreatic cancer. As a

Table 2 | Total and individual domain scores of the DTR-QOL (N = 26)

		Baseline	52 weeks	P
Total score		65 (40.75–75.5)	55 (43.75–70.25)	0.079
Domain 1: Burden on social activities and daily activities		77 (53.5–87.25)	66 (57–79.75)	0.21
1	My current diabetes treatment interferes with my work and activities	4.5 (3–6)	3 (2.75–6)	0.49
2	My current diabetes treatment limits the scope of my activities	6 (3–6.25)	5.5 (3–6)	0.30
3	It is difficult to find places on time for my current diabetes treatment	5.5 (4–6.25)	5.5 (3–6)	0.29
4	My current diabetes treatment interferes with group activities and personal friendships	6 (3–6.25)	6 (3–6)	0.53
5	It is a burden getting up at a certain time every morning for my current diabetes treatment	6 (5–7)	6 (6–7)	0.33
6	With my current diabetes treatment, the restricted meal times are a burden	6 (5–7)	6 (5.75–6)	0.63
7	When I eat out, it is difficult to manage my current diabetes treatment	6 (4.75–6)	6 (3–6)	0.16
8	I feel like my current diabetes treatment takes away the enjoyment of eating	6 (4.75–7)	6 (5–6)	0.50
9	With my current diabetes treatment, it is hard to curb my appetite	6 (4.75–7)	6 (3.75–6.25)	**0.049**
10	The time and effort to manage my current diabetes treatment are a burden	3 (3–5.25)	3.5 (2–5.25)	0.88
11	I am constantly concerned about time to manage my current diabetes treatment	6 (3–6)	5 (3–6)	0.71
12	I have pain associated with my current diabetes treatment	6 (3–6)	4.5 (3–6)	0.14
13	Gastrointestinal symptoms (nausea, passing gas, diarrhea, abdominal pain) due to my current diabetes treatment are uncomfortable	6 (5–7)	7 (4–7)	0.91
Domain 2: Anxiety and dissatisfaction with treatment		50 (37.25–68)	46 (36.75–71)	0.20
14	I am bothered by weight gain with my current diabetes treatment	5.5 (4–7)	4 (3.75–7)	0.17
19	I have uncomfortable symptoms due to hyperglycemia (high blood glucose)	3 (3–4)	3 (2.75–5)	0.84
20	I am worried about high blood glucose	3 (3–5)	4 (3–6)	0.30
21	I am dissatisfied that my blood glucose is unstable (high and low)	3 (2–5)	3 (2–4.25)	0.37
22	I am worried that complications might get worse with my current diabetes treatment	3.5 (2–5)	4 (3–6)	0.30
23	I get anxious thinking about living while on my current diabetes treatment	4 (3–6)	3 (3–6)	0.34
24	I find it unbearable to think that even if I continue my current diabetes treatment, my diabetes may not be cured	4 (3–6)	3.5 (3–5.25)	**0.038**
25	I am concerned that if I continue my current diabetes treatment, its efficacy (effectiveness) may diminish	6 (4–6.25)	5 (4–6)	0.16
Domain 3: Hypoglycemia		38 (25–71)	38 (20–55)	0.17
15	I worry about low blood glucose due to my current diabetes treatment	4 (3–5.25)	3.5 (2–5)	0.46
16	I am scared because of low blood glucose	3.5 (2.75–6)	4 (2.75–6)	0.53
17	I am sometimes bothered by low blood glucose	3 (3–5.25)	3 (2–4)	0.29
18	Symptoms due to low blood glucose are uncomfortable	3 (2–5.25)	3 (1–3.25)	**0.018**
Domain 4: Satisfaction with treatment		65 (45–75)	50 (36.75–68)	**0.034**
26	Overall, I am satisfied with my current blood sugar control (glycemic control)	5 (3–5.25)	3.5 (2–5)	**0.020**
27	With my current diabetes treatment, I am confident that I can maintain good blood glucose control	4.5 (3.75–5.25)	4 (2.75–5)	**<0.01**
28	I am hopeful about the future with my current diabetes treatment	5 (4–6)	4 (4–5)	0.32
29	With regards to diabetes treatment, I am satisfied with current treatment methods	5 (4–6)	5 (4–6)	0.76

Bold values indicate statistical significance at the $P < 0.05$ level.
Data are expressed as medians (interquartile range) for data with skewed distributions.

result, 18 patients had the required amount of CGM data at week 52 (Figure 1).

At baseline, TIR 70–180 mg/dL, TAR >180 mg/dL, and TAR >250 mg/dL were 67.3 (54.8–78.4)%, 28.4 (18.3–43.1)% and 6.4 (1.3–12.0)% (data are expressed as medians [interquartile range]). At week 8, these values increased significantly ($P < 0.01$ for each comparison) to 73.4 (69.7–81.3)%, 23.8 (17.5–26.4)%, and 3.5 (2.1–5.7)%, respectively. The significant improvements in TIR 70–180 mg/dL and TAR >180 mg/dL lasted until the end of the study (Table 1, Figure 2).

According to a consensus statement from the American Diabetes Association (ADA), targets included TBR <70 mg/dL under 4% of readings, and TBR <54 mg/dL under 1% of readings[16,17]. The baseline TBR <70 mg/dL and TBR <54 mg/dL were 1.9 (0.6–3.6)% and 0.2 (0.0–0.7)%, respectively. TBR <70 mg/dL and TBR <54 mg/dL at week 8 increased significantly to 2.9 (1.8–4.9)% ($P = 0.027$) and 0.9 (0.3–1.3)% ($P < 0.01$), although the mean values were within the target range. Subsequently, these values decreased at week 52–2.6 (1.5–4.8)% ($P = 0.067$) and 0.5 (0.2–1.4)% ($P = 0.098$), respectively (Table 1, Figure 2). Next, to investigate the timing of hypoglycemia, CGM data were examined separately during daytime (06:00–23:59) and nighttime (00:00–05:59), as defined in the ADA consensus statement[17]. Daytime TBR <70 mg/dL

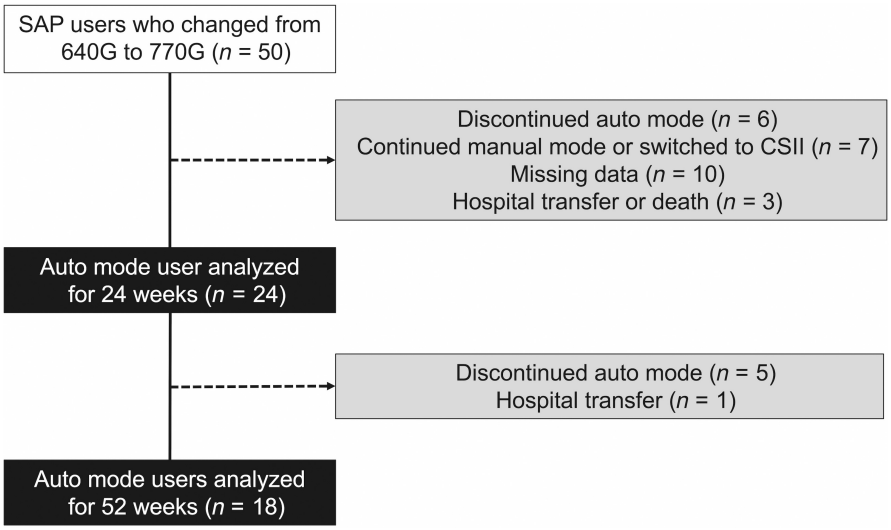

Figure 1 | Flowchart of the research participants. Insulin pump data were collected in the outpatient clinic, and only glucose profiles with data available for at least 70% of 14 days around on week 0, 8, 16, 24, and 52 after the switch to the 770G with auto mode were analyzed. Twenty-six auto-mode users completed the DTR-QOL questionnaires at weeks 0 and 52.

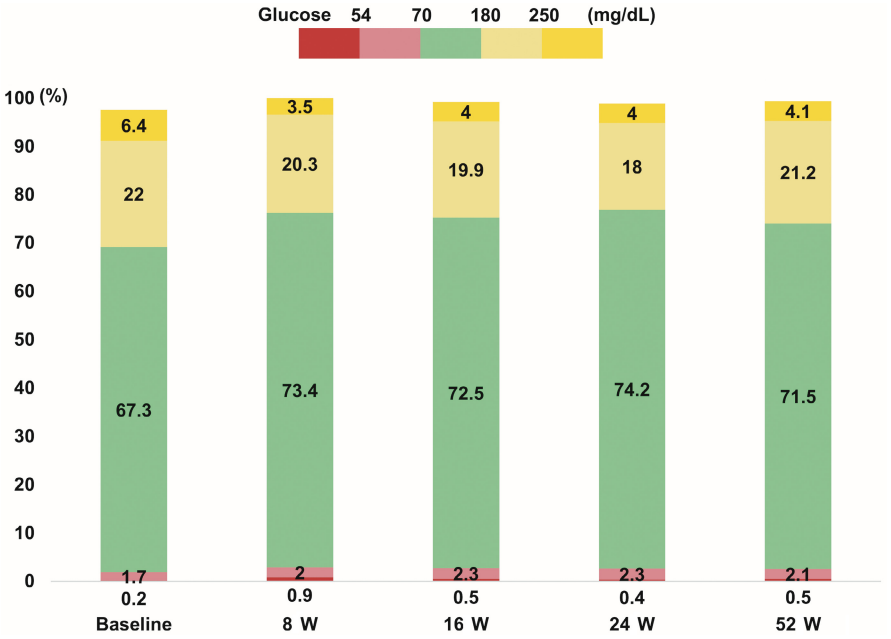

Figure 2 | Glycemic outcomes following continuous glucose monitoring. TIR 70–180 mg/dL, TAR >180 mg/dL, TAR >250 mg/dL, TBR <70 mg/dL, TBR <54 mg/dL are presented as the median. TAR >180 mg/dL includes percentages of values >250 mg/dL. TBR <70 mg/dL includes percentages of values <54 mg/dL.

increased from 1.5 (0.5–3.2)% at week 0 to 2.8 (1.2–4.9)% at week 8 (P = 0.012). Daytime TBR <54 mg/dL increased from 0 (0–0.4)% at week 0 to 0.6 (0.1–1.1)% at week 8 (<0.01). Significant increases in daytime TBR <54 mg/dL relative to week 0 were also observed at week 16 and 24, but not at week 52. On the other hand, nighttime TBR <70 mg/dL and nighttime TBR <54 mg/dL did not change significantly throughout 52 weeks (Table 1, Figure 2). Also, the low blood glucose index (LBGI) did not show significant changes at any point during the study period (Table 1).

HbA1c levels did not change significantly, but mean sensor glucose levels and GMI[18, 19] improved significantly throughout

the study period compared to baseline (Table 1). The J-index[20] and MODD[20, 21] improved significantly during the study period (Table 1). However, MAGE[20, 21] showed no significant differences.

Twenty-six auto-mode users completed the DTR-QOL questionnaire both at weeks 0 and 52 (Table 2). The total DTR-QOL score was not significantly different between week 0 (65 [40.75–75.5]) and week 52 (55 [43.75–70.25]). Regarding individual domains, on the other hand, there was a significant decrease only with regard to treatment satisfaction score when comparing week 0 (65 [45–75]) to week 52 (50 [36.75–68]) ($P = 0.034$). In particular, there were significant decreases for the following two items: question 26, "Overall, I am satisfied with my current blood sugar control (glycemic control)," and question 27, "With my current diabetes treatment, I am confident that I can maintain good blood glucose control."

During the observation period, there was no diabetic ketoacidosis or hypoglycemia requiring hospitalization, and no remarkable adverse events.

DISCUSSION

An international consensus statement was published regarding clinical targets and outcome measurements of CGM metrics that complement HbA1c for a wide range of people with diabetes[16, 17]. According to the statement, the recommendations for people with T1D are as follows: TIR over 70% of readings, TAR >180 mg/dL less than 25% of readings(including percentage of values >250 mg/dL), TBR <70 mg/dL less than 4% of readings (including percentage of values <54 mg/dL), TAR >250 mg/dL less than 5% of readings, and TBR <54 mg/dL less than 1% of readings[16, 17]. The median baseline TBR value in our study met the criteria, but the median baseline TIR and TAR did not. However, the median TIR improved immediately after using auto mode, exceeding 70% at week 8, and remained above 70% until week 52. Also, the median TAR fell below 25% by the first measurement at week 8. The median TAR at week 52 was slightly above the target, at 25.3%. Accordingly, auto mode of the 770G insulin pump was found to be useful in controlling hyperglycemia and maintaining a stable TIR for a year with people with T1D in Japan.

Although hypoglycemia levels met the consensus statement criteria from the beginning of the study, over the course of the subsequent year, the increase in hypoglycemia occurred predominantly soon after the pump change. Furthermore, TBR significantly increased during daytime, not nighttime. We do not know the exact reasons for these findings. However, to determine the cause of increased hypoglycemia, we analyzed all instances at week 24 with sensor glucose values <70 mg/dL, and found several representative patterns of hypoglycemia. The most common was that auto-mode basal rate was excessively high following a postprandial blood glucose spike (Figure S1). This pattern probably occurred because the carb-insulin ratio, the carbohydrate input amount, or the active insulin time was not set appropriately for the 770G algorithm. As shown in Figure S1, the active insulin time setting was too long and the basal insulin was not properly initiated against the postprandial blood glucose spike. Subsequently, the onset of the basal insulin infusion was too late, resulting in hypoglycemia. Another hypoglycemia pattern was that during the auto mode, basal insulin infusion sometimes did not stop despite the development of hypoglycemia (Figure S2). This could simply be due to pump timing discrepancies. The last pattern was that if an inappropriate amount of basal insulin was set in manual mode, hypoglycemia occurred when the auto mode was off (Figure S3). The MiniMed™ 640G has the predictive low glucose management (PLGM) or low-glucose suspend (LGS) functions that pause the pump to prevent hypoglycemia; with the 640G, 19 people set the PLGM, 4 people set the LGS and one did not use either. With the MiniMed™ 770G, these functions are only activated in manual mode. Strangely, however, even if these functions were originally switched on, they also have to be reset when the pump goes from auto mode to manual mode for some reasons, otherwise the pump does not stop before or on hypoglycemia, although the alerts are audible. During the last observation period of the 770G, nobody had reset the PLGM and LGS functions to be on. This leads to the hypoglycemia shown in Figure S3. In the MiniMed™780G, the PLGM/LGS functions have been improved so that they function naturally in manual mode without reset. These patterns may have been contributed to the increase in TBR. Hypoglycemia increased at about week 8 but improved afterwards. It is presumed that patients understood the characteristics of the 770G and gradually adapted to using it, for example by changing the insulin pump settings.

LBGI, a measure of hypoglycemia, did not change between week 0 and week 52, with a median of 2.6 at both time points. Values below 2.5 are considered to be associated with low risk, those between 2.5 and 5 with medium risk, and those above 5 with high risk[26]. The LBGI values in this study suggest that our patients were not at high risk of hypoglycemia.

Fifty participants changed from the 640G to the 770G. Seven of them chose to use manual mode instead of auto mode from the beginning, while 10 had insufficient CGM data. Four were excluded due to transfer or death. Eleven participants stopped using auto mode during the study; discontinuation was considered to have occurred if there was less than 10% time in auto mode at any time point without returning to at least 10% or more time in auto mode at a later time point[27]. Of those who initially requested auto mode and stayed at our hospital, the 1-year dropout rate was 38%. In a study by Berget *et al.*[9], the percentage of time spent in auto mode decreased from 66% in the first month to 51% after 6 months. Lal *et al.*[10] observed a decline in this percentage from a mean of 74% in the first week of use to 50% by month 6 and 35% by month 12. The reasons for the high dropout rate with insulin pumps have been discussed. Time constraints, technical challenges, sensor alerts, sensor efficacy, sensor longevity, and skin irritation are some of the barriers to continued insulin pump use[28, 29], and these were also factors in our study. In

particular, the 770G system is known to require frequent blood glucose input and frequent alarms in order to maintain its auto-mode function. Self-monitoring of blood glucose (SMBG) increased significantly from 4.3 ± 1.3 times/day to 5.3 ± 1.5 times/day ($P < 0.01$), which may have been one of the reasons for auto-mode discontinuation. The dropout rate is expected to improve with the next-generation 780G system, as it will have no SMBG requirement.

Analysis of the DTR-QOL scores of 26 people who had used auto mode for 1 year and who submitted questionnaires before and at 52 weeks after the pump change showed that the total score tended to decline, but did not differ significantly before or after the switch (Table 2). However, a significant decline was observed in the domain related to treatment satisfaction. Within this domain, there was a significant decrease in two particular items: "Overall, I am satisfied with my current glycemic control," and "I am confident that I can maintain good glycemic control with my current diabetes treatment." The increased number of SMBG instances or alerts to maintain auto mode may have contributed to these findings.

Limitations of this study include the relatively small number of eligible patients and the high attrition rate, as just described, as well as the fact that diet and physical activity levels were not specifically reported.

CONCLUSION

This is the first report in Japan on the effects of 52 weeks of MiniMed™ 770G use, along with results of the DTR-QOL questionnaire. Auto mode of the 770G insulin pump was found to be useful in controlling hyperglycemia and maintaining stable TIR. However, a significant decline was observed in the domain related to treatment satisfaction. The next-generation 780G insulin pump will have auto basal and auto-correction bolus functions, which are expected to provide better glycemic control without the frequent need for SMBG. Nonetheless, it will remain essential to closely monitor blood glucose levels to ensure that unexpected episodes of hyperglycemia and hypoglycemia do not occur.

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AUTHOR CONTRIBUTIONS

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Figure S1 | Example 1 of hypoglycemia during auto mode.

Figure S2 | Example 2 of hypoglycemia during auto mode.

Figure S3 | Example 3 of hypoglycemia during auto mode.