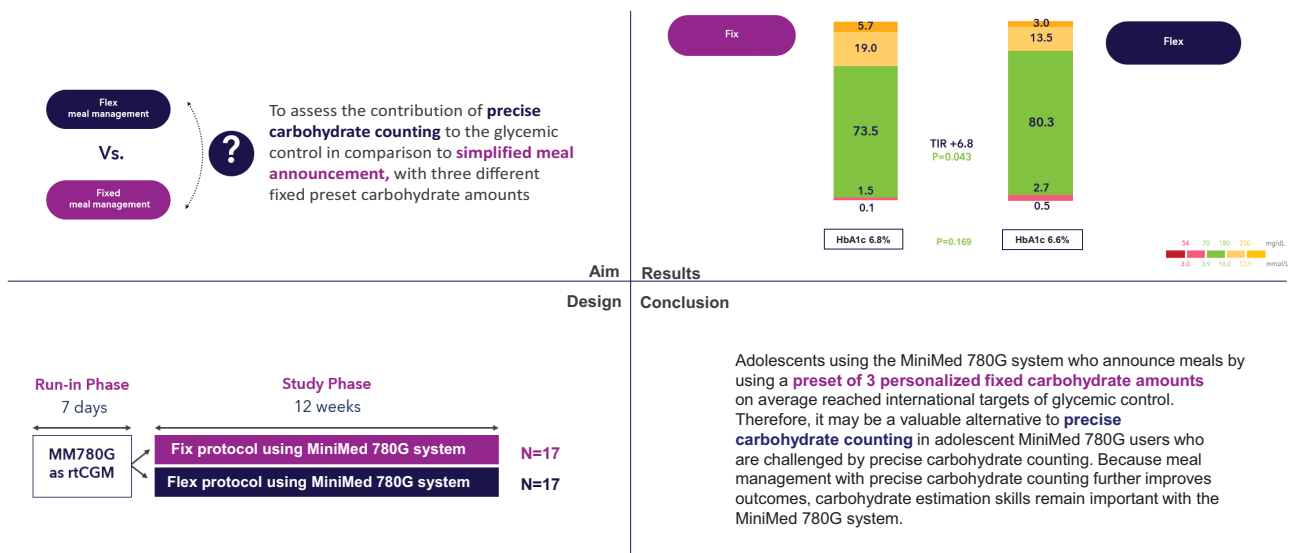# Simplified Meal Announcement Versus Precise Carbohydrate Counting in Adolescents With Type 1 Diabetes Using the MiniMed 780G Advanced Hybrid Closed Loop System: A Randomized Controlled Trial Comparing Glucose Control

Goran Petrovski, Judith Campbell, Maheen Pasha, Emma Day, Khalid Hussain, Amel Khalifa, and Tim van den Heuvel

Aim

Flex meal management Vs. Fixed meal management

To assess the contribution of **precise carbohydrate counting** to the glycemic control in comparison to **simplified meal announcement,** with three different fixed preset carbohydrate amounts

Results

Fix: 5.7 / 19.0 / 73.5 / 1.5 / 0.1 — HbA1c 6.8%
Flex: 3.0 / 13.5 / 80.3 / 2.7 / 0.5 — HbA1c 6.6%
TIR +6.8 P=0.043
P=0.169
54 70 180 250 mg/dL
3.0 3.9 10.0 13.9 mmol/L

Design

Run-in Phase — 7 days
Study Phase — 12 weeks

MM780G as rtCGM

Fix protocol using MiniMed 780G system — N=17
Flex protocol using MiniMed 780G system — N=17

Conclusion

Adolescents using the MiniMed 780G system who announce meals by using a **preset of 3 personalized fixed carbohydrate amounts** on average reached international targets of glycemic control. Therefore, it may be a valuable alternative to **precise carbohydrate counting** in adolescent MiniMed 780G users who are challenged by precise carbohydrate counting. Because meal management with precise carbohydrate counting further improves outcomes, carbohydrate estimation skills remain important with the MiniMed 780G system.

ARTICLE HIGHLIGHTS

- Adolescents using the MiniMed 780G system that announces meals by using a preset of three personalized fixed carbohydrate amounts on average reached international targets of glycemic control.
- This method may be a valuable alternative to precise carbohydrate counting in adolescent MiniMed 780G users who are challenged by precise carbohydrate counting.
- Meal management with precise carbohydrate counting further improves outcomes, and carbohydrate estimation skills remain important with the MiniMed 780G system.

Simplified Meal Announcement Versus Precise Carbohydrate Counting in Adolescents With Type 1 Diabetes Using the MiniMed 780G Advanced Hybrid Closed Loop System: A Randomized Controlled Trial Comparing Glucose Control

Goran Petrovski,[1] Judith Campbell,[1] Maheen Pasha,[1] Emma Day,[1] Khalid Hussain,[1] Amel Khalifa,[1] and Tim van den Heuvel[2]

OBJECTIVE

We aimed to compare glucose control in adolescents with type 1 diabetes (T1D) using the MiniMed 780G system who used simplified meal announcement with those who used precise carbohydrate counting.

RESEARCH DESIGN AND METHODS

This randomized controlled trial included 34 participants (age 12–18 years) with T1D who were on multiple daily injections or insulin pump and were scheduled to start using the MiniMed 780G system at Sidra Medicine in Qatar. After a 7-day run-in period, participants were randomly assigned to the fix group (simplified meal announcement by preset of three personalized fixed carbohydrate amounts) or the flex group (precise carbohydrate counting) and followed for 12 weeks. Between-group difference in time in range (TIR) was the primary end point. Secondary end points included HbA$_{1c}$ and other glycometrics.

RESULTS

During the 12-week study phase, TIR was 73.5 ± 6.7% in the fix and 80.3 ± 7.4% in the flex group, with a between-group difference of 6.8% in favor of flex (P = 0.043). Time >250 mg/dL was better in the flex group (P = 0.012), whereas HbA$_{1c}$ (P = 0.168), time below range (P = 0.283), and time between 180 and 250 mg/dL (P = 0.114) did not differ.

CONCLUSIONS

Adolescents using the MiniMed 780G system with a preset of three personalized fixed carbohydrate amounts can reach international targets of glycemic control. Therefore, it may be a valuable alternative to precise carbohydrate counting in users who are challenged by precise carbohydrate counting. Because carbohydrate counting further improves outcomes, these skills remain important for MiniMed 780G users.

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Carbohydrate counting is an essential component of diabetes management in both adults and children and together with an intensive insulin plan and increased blood glucose monitoring, is associated with lower HbA$_{1c}$ (1,2). Recent meta-analyses concluded that carbohydrate counting is an effective method in reducing HbA$_{1c}$, recommended carbohydrate counting over alternate advice, and encouraged patients with type 1 diabetes (T1D) to count carbohydrates (3,4). However, carbohydrate counting is perceived as one of the most burdensome tasks in T1D and is frequently done inconsistently and with poor accuracy (5).

Hybrid closed loop (HCL) systems have substantially changed T1D management and have been shown to improve glycemic outcomes across a broad age range of patients, including adolescents (6,7). The MiniMed 780G system is an advanced HCL system, and besides controlling basal insulin, it includes autocorrection boluses. The MiniMed 780G system has been shown to safely achieve internationally recommended glycemic targets in most adolescents and adults with T1D (8,9). The MiniMed 780G system, as are other current HCL systems, is not yet fully automated and still requires patients to enter carbohydrates for meal announcement.

In previous publications from our center (10) and others (11), the use of the MiniMed 780G system with precise carbohydrate counting resulted in improvement of HbA$_{1c}$ and time in range (TIR). However, not all adolescents are able to or willing to perform carbohydrate counting, and data on the effect of simplified meal announcement on glycemic control in users of the MiniMed 780G system are lacking. In this study, we aimed to compare glucose control in adolescents using the MiniMed 780G system with simplified meal announcement with those who used precise carbohydrate counting.

RESEARCH DESIGN AND METHODS

Study Design and Participants
This prospective, open-label, randomized controlled trial was performed at Sidra Medicine in Qatar. Participants were 12–18 years old, had a clinical diagnosis of T1D for at least 12 months, were on multiple daily injection (MDI) or insulin pump therapy, and were scheduled to start using the MiniMed 780G system

with Guardian 4 calibration-free sensor. Patients who had significant diabetes complications and/or a severe episode of diabetic ketoacidosis or hypoglycemia in the past 6 months were excluded. Participants were randomly assigned to either using a preset of three personalized fixed carbohydrate amounts (fix group) or precise carbohydrate counting (flex group) and followed for 12 weeks, and glycemic control was compared. Figure 1 depicts a high-level overview of the study design.

The study was approved by the institutional review board at Sidra Medicine and the national ethics committee of the Ministry of Public Health in Qatar. All participants and their guardians signed a written informed consent/assent before the start of study-related procedures.

Procedures
Participants were consecutively recruited at regular clinic visits. After obtaining consent/assent, the trial started with a 7-day run-in period to train participants on using the MiniMed 780G system. During this run-in period, participants used the MiniMed 780G system for real-time continuous glucose monitoring (CGM) without any insulin delivery by the MiniMed 780G pump (participants on MDI therapy remained on manual injections, and participants already on insulin pump therapy continued to use their previous model for insulin injections), and these

CGM data were used for baseline glycemic metrics. Also, carbohydrate counting skills were assessed during this period by a 7-day food and insulin diary, and participants in whom the announced carbohydrate amount deviated from the actual amount by >20% were excluded from randomization (n = 3).

Participants were randomly assigned to either the fix group or the flex group. A permuted block randomization scheme was used. Block size was fixed at 6. Neither the investigators nor the participants and parents were masked to the treatment allocation.

After randomization, all participants were initiated on the MiniMed 780G system per Sidra Medicine's validated protocol for sensor-augmented pump (SAP) initiation (12). In brief, participants started using the MiniMed 780G system in open loop for 3 days (SAP period) for the MiniMed 780G algorithm to establish personalized parameters required for system initiation. The MiniMed 780G system was then initiated for all, and the participants used the meal management approach of their allocated group.

Participants in the fix group could choose among a preset of three fixed carbohydrate amounts for each meal announcement. These fixed amounts were personalized based on the 7-day diary; the carbohydrate amounts for a regular meal was set at 40–70 g, for a large meal at 60–90 g, and
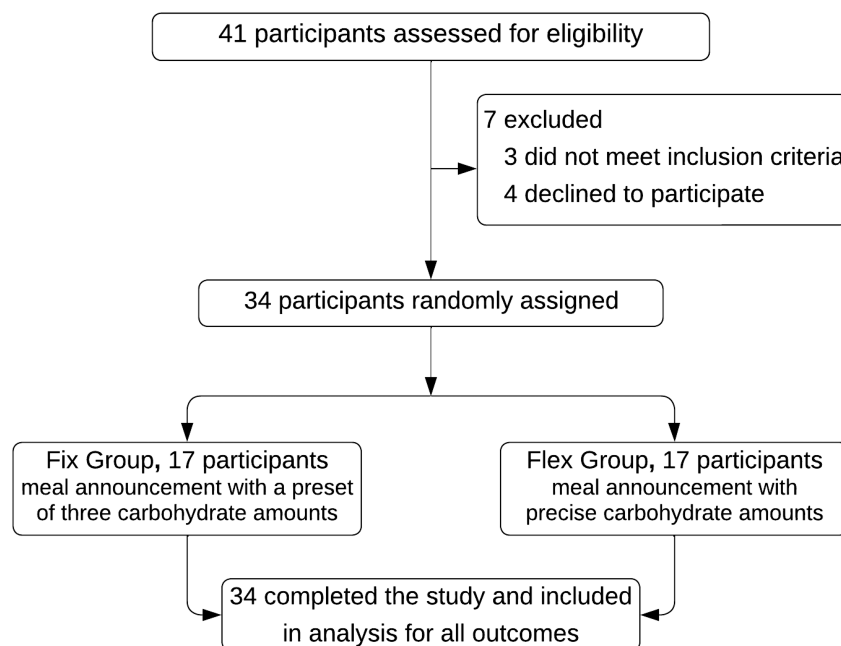

Figure 1—Study design and enrollment scheme.

for a snack at 15–20 g. Fixed amounts for meals were rounded to tens and for snacks, to fives. During individual consultations, a registered dietitian instructed the participants in the fix group to choose the appropriate personalized preset (i.e., the regular meal preset for a regular-sized meal regardless of food type, the large meal preset for eating more than a regular-sized meal, the snack preset for any snack regardless of the amount of carbohydrates). Participants in the flex group were instructed to use precise carbohydrate counting with increments of 1 g. No restriction in dietary intake or daily activities were advised during the study for both groups. Supplementary Table 1 shows the settings at MiniMed 780G system initiation, as well as the methods for calculating the fixed carbohydrate amounts.

Onsite follow-up visits were scheduled 2 and 12 weeks after initiating the MiniMed 780G system, and phone visits were scheduled after weeks 1, 4, and 8. Meal announcement as well as the insulin-to-carbohydrate ratio (ICR) were reassessed after weeks 1 and 2 and adjusted per clinical judgment (if needed) in both groups. Adherence to the correct meal announcement strategy was reviewed (and corrected if needed) at every visit in both groups. Clinical and technical support was available during the study. Standard local hypoglycemia and hyperglycemia treatment guidelines were followed.

Funds to cover devices were secured through medical insurance, self-funding, and donations made by the Qatar Diabetes Association for participants who could not afford the device. There were no rejections because of funding constraints.

Outcomes and Analyses

The primary outcome was the between-group difference in TIR (70–180 mg/dL) in the 12-week study phase. Secondary outcomes were between-group differences in HbA_{1c}, other CGM-derived metrics for glycemic control (including time above range, time below range [TBR], mean sensor glucose, SD, and coefficient of variation [CV]), metrics for meal announcement and insulin use (including number of announced meals, announced grams of carbohydrates, the insulin total daily dose [TDD], and a breakdown of the delivered insulin in autobasal, autocorrection, and manual bolus), metrics for system settings (including ICR, use of

optimal settings, and sensor use), and safety. Safety end points included episodes of severe hypoglycemia (defined as a hypoglycemic event that requires medical assistance) and/or diabetic ketoacidosis (defined by a blood glucose >200 mg/dL, venous pH <7.3, or serum bicarbonate <15 mmol/L), and ketonemia (blood β-hydroxybutyrate ≥3 mmol/L or moderate or large ketonuria. An overview of the primary and secondary end points is shown in Tables 2 and 3.

As a secondary analysis, within-group changes in metrics for glycemic control were evaluated (separately for the fix and the flex group). This analysis was done for the entire 12-week study period and for the different study periods (i.e., run-in; SAP; automated insulin delivery in weeks 1, 2, 3–4, 5–8, and 9–12).

HbA_{1c} was collected by a point-of-care DCA Vantage Analyzer (Siemens Healthineers, Erlangen, Germany). Insulin and CGM data were collected from CareLink therapy management software.

Statistics

The study hypothesis was that the flex group is expected to show better glycemic control compared with the fix group. In addition, we wanted to learn whether the fix group still reaches international targets for glycemic control. On the basis of the hypothesis as well as an α of 0.05, a power of 80%, a TIR in the flex group of 78.9, an SD of 6%, and an effect size of 7% (13), we calculated that 32 participants would be required for

this study. To allow for dropouts, we planned to enroll 34.

All analyses were performed for the entire study population. Between-group differences were analyzed using paired Student t test or paired Wilcoxon test (in case of nonnormality). Within-group differences were analyzed using ANOVA. A two-sided α-level of 0.05 was used with no adjustment for multiplicity for secondary outcomes. Statistical analyses were performed using Statistica 12 (StatSoft, Tulsa, OK).

Data and Resource Availability

The data sets generated and/or analyzed during the current study are not publicly available due to institutional policies and regulations but are available from the corresponding author upon reasonable request.

RESULTS

Between November 2021 and February 2022, 34 participants were randomly assigned to either the fix group (n = 17) or the flex group (n = 17). All participants completed the 12-week follow-up and were included in the analyses. The enrollment scheme is shown in Fig. 1, and baseline characteristics are listed in Table 1.

Glycemic Control

Table 2 shows the glycemic control during the study. Mean ± SD TIR (70–180 mg/dL) in the fix group increased from 47.5 ± 18.3% at baseline to 73.5 ± 6.7% during the 12-week study phase ($P < 0.001$,

Table 1—Baseline characteristics

	Fix group	Flex group
Participants, n	17	17
Female, n (%)	9 (53)	10 (58)
Age, years	14.2 ± 1.5	13.9 ± 1.3
BMI, kg/m²	20.8 ± 3.2	21.4 ± 4.5
Duration of diabetes, years	5.3 ± 2.4	4.3 ± 1.7
HbA_{1c}		
%	8.0 ± 2.1	7.9 ± 1.5
mmol/mol	64 ± 26.2	63 ± 18.6
MDI therapy, n (%)	12 (71)	11 (65)
Pump therapy, n (%)	5 (29)	6 (35)
Meals per day	4.5 ± 1.3	4.1 ± 0.9
Carbohydrates, g/day	165 ± 72	169 ± 62

Data are mean ± SD, unless otherwise indicated.

Table 2—Glycemic control

	Fix group			Flex group			Group difference
	Baseline	Study	P	Baseline	Study	P	P
HbA$_{1c}$							
%	8.0 ± 2.1	6.8 ± 0.3	0.026	7.9 ± 1.5	6.6 ± 0.5	0.001	0.168
mmol/mol	64 ± 26.2	51 ± 3.3	0.026	63 ± 18.6	49 ± 5.5	0.001	0.168
Sensor glucose, mg/dL	174 ± 26	147 ± 23	0.002	168 ± 29	145 ± 18	0.005	0.804
CV, %	35.6 ± 8.1	34.1 ± 5.0	0.520	30.1 ± 4.4	30.8 ± 4.2	0.634	0.045
Sensor glucose values in range, %							
<54 mg/dL	0.2 ± 0.4	0.1 ± 0.3	1.000	0.8 ± 1.4	0.5 ± 0.3	0.275	0.167
54–70 mg/dL	1.4 ± 0.5	1.5 ± 1.5	0.605	2.0 ± 1.5	2.7 ± 1.7	0.718	0.283
70–180 mg/dL	47.5 ± 18.3	73.5 ± 6.7	0.001	49.1 ± 16.8	80.3 ± 7.4	0.001	0.043
180–250 mg/dL	22.6 ± 8.1	19.0 ± 5.2	0.122	26.8 ± 8.2	13.5 ± 5.9	0.001	0.114
>250 mg/dL	28.3 ± 15.9	5.7 ± 3.6	0.001	21.3 ± 11.8	3.0 ± 2.4	0.001	0.012
TDD, units/kg/day	1.0 ± 0.6	1.1 ± 0.4	0.517	1.0 ± 0.6	1.1 ± 0.5	0.601	0.984
Basal insulin, % of TDD	43.2 ± 6.7	34.2 ± 7.1	0.001	44.8 ± 5.9	32.6 ± 5.2	0.001	0.459
Weight, kg	52.2 ± 12.7	53.5 ± 11.2	0.753	51.3 ± 10.7	52.4 ± 9.6	0.754	0.765

Data are mean ± SD. Study indicates 12 weeks of MiniMed 780G system use. CGM data at baseline were collected using the Guardian 4 sensor with the MiniMed 780G system for a 1-week period of training (no insulin delivery with pump).

95% CI 19.1–30.2), and in the flex group, TIR increased from 49.1 ± 16.8% to 80.3 ± 7.4% (P < 0.001, 95% CI 25.2–37.8), with a group difference of 6.8% (P = 0.043, 95% CI 4.1–9.2) during the study phase. HbA$_{1c}$ decreased from 8.0 ± 2.1% (64 ± 26.2 mmol/mol) at baseline to 6.8 ± 0.3% (51 ± 3.3 mmol/mol) at the end of the study in the fix group (P = 0.026, 95% CI −0.6 to −1.6) and from 7.9 ± 1.5% (63 ± 18.6 mmol/mol) to 6.6 ± 0.5% (49 ± 5.5 mmol/mol) in the flex group (P = 0.001, 95% CI −0.7 to −1.9), without a group difference (P = 0.168, 95% CI −0.1 to 0.4). Other CGM-derived metrics did not show a between-group difference except for time >250 mg/dL (P = 0.012, 95% CI −4.6 to −0.4) and CV (P = 0.045, 95% CI −6.5 to −0.1), which were better in the flex group than in the fix group.

In the fix group, 70% of participants reached an HbA$_{1c}$ of <7% at study end, 67% a TIR of >70%, and 82% a TBR of <4% vs. 75%, 72%, and 86% in the flex group, respectively. Fix group averages over the last 4 weeks were 74.3% for TIR, 6.8% for HbA$_{1c}$, and 1.7% for TBR (Fig. 2).

Table 3—Carbohydrate announcement, insulin, and system settings

	Fix group			Flex group			Group difference
	Weeks 1 and 2	Weeks 9–12	P	Weeks 1 and 2	Weeks 9–12	P	P
Meal announcement							
Meals per day	3.9 ± 1.9	3.7 ± 0.9	0.695	5.2 ± 2.7	5.1 ± 1.1	0.888	0.003
Carbohydrates, g/day	170 ± 84	165 ± 66	0.873	164 ± 82	178 ± 65	0.585	0.566
ICR, g	7.5 ± 2.2	5.8 ± 1.6	0.014	7.9 ± 2.5	6.0 ± 1.3	0.009	0.619
Insulin delivered, units/day							
Manual	22.6 ± 9.8	20.8 ± 9.1	0.528	23.0 ± 10.4	30.8 ± 9.4	0.034	0.003
Autocorrection	18.8 ± 14.2	17.9 ± 8.6	0.824	9.3 ± 8.6	8.9 ± 3.5	0.860	0.003
Autobasal	10.8 ± 10.4	22.1 ± 9.3	0.792	19 ± 7.5	20.4 ± 8.1	0.604	0.573
Total	52.2 ± 13.4	60.8 ± 10.2	0.043	51.3 ± 9.8	60.1 ± 8.8	0.009	0.813
Insulin delivered, %							
Manual	43	45		45	51		
Autocorrection	36	29		18	15		
Autobasal	21	26		37	34		
System use and setting							
Sensor wear, %	93.8 ± 9.6	95.8 ± 8.1	0.516	94.1 ± 10.5	94.5 ± 10.9	0.913	0.695
Advanced HCL usage, %	89.5 ± 6.9	92.1 ± 6.9	0.280	90.6 ± 8.5	93.2 ± 7.8	0.359	0.666
Advanced HCL exits*	0.7 ± 0.4	0.8 ± 0.5	0.524	0.7 ± 0.5	0.6 ± 0.4	0.523	0.207
SMBG per day	0.8 ± 0.6	0.4 ± 0.3	0.019	0.7 ± 0.5	0.3 ± 0.5	0.026	0.338
Set change, days	2.9 ± 0.7	2.8 ± 0.9	0.720	2.8 ± 1.1	2.9 ± 1.4	0.813	0.805
Reservoir change, days	2.4 ± 0.4	2.3 ± 0.6	0.571	2.2 ± 0.8	2.5 ± 0.9	0.312	0.451

Data are mean ± SD, unless otherwise indicated. SMBG, self-monitoring of blood glucose. *Advanced HCL exits per patient per week.
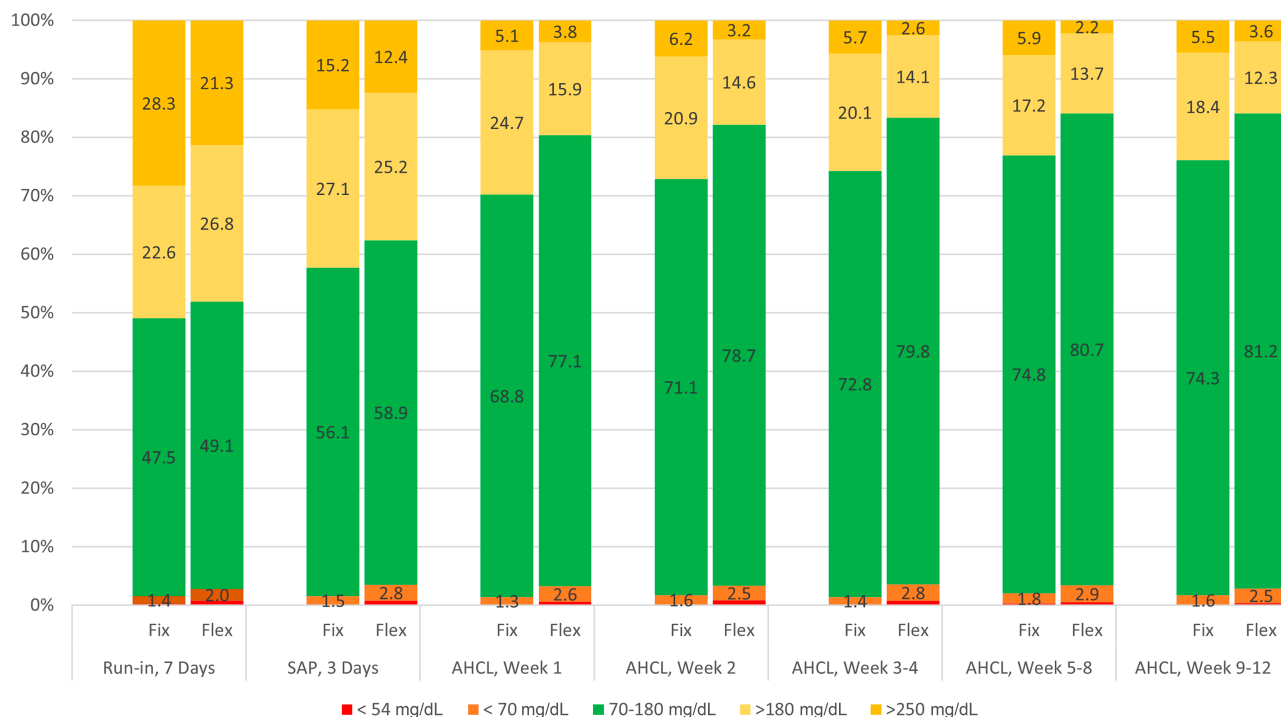
Figure 2—TIR during different study periods. Data are percentage of TIR during the interval. Glucose values <54 mg/dL are not shown on the graph. Baseline data were collected using the Guardian 4 sensor with the MiniMed 780G system for a 1-week period of training. AHCL, advanced hybrid closed loop.

Insulin Delivery and Carbohydrate Announcement

Table 3 shows insulin delivery and carbohydrate announcement during the study. The TDD increased by 0.1 unit/kg in both groups (fix group: 1.0 ± 0.6 to 1.1 ± 0.4 units/kg, P = 0.517, 95% CI −0.6 to 1.3; flex group: 1.0 ± 0.6 to 1.1 ± 0.5 units/kg, P = 0.601, 95% CI −0.7 to 1.4), with no group difference (P = 0.984, 95% CI −0.1 to 0.3) (Table 2). Basal insulin as a percentage of TDD decreased by 9.0% in the fix group (43.2 ± 6.7% to 34.2 ± 7.1%, P = 0.001, 95% CI −6.4 to −9.8) and 12.2% in the flex group (44.8 ± 5.9% to 32.6 ± 5.2%, P = 0.001, 95% CI −8.5 to −13.7), with no group difference (P = 0.459, 95% CI −2.7 to 5.9) (Table 2). At the end of the study, the amount of insulin delivered by autocorrection was almost twice as high in the fix group compared with the flex group (17.9 ± 8.6 vs. 8.9 ± 3.5 units/day, P = 0.003, 95% CI 4.1 to 10.9). The manual bolus amount was lower in the fix group than in the flex group (20.8 ± 9.1 vs. 30.8 ± 9.4 units/day, P = 0.003, 95% CI 3.8 to 12.7).

The total daily announced carbohydrates did not differ between the groups at study end (165 ± 66 vs. 178 ± 65 g in the fix and flex groups, respectively, P = 0.566, 95% CI −11 to 26), though the

individual meal carbohydrate quantity distribution did (Supplementary Fig. 1). In addition, participants in the fix group announced fewer meals per day compared with the flex group (3.7 ± 0.9 vs. 5.1 ± 1.1, P = 0.003, 95% CI 0.7–2.1).

Most of the of the participants in the fix group announced snacks by 20 g (94%), regular meal by 60 g (53%), and large meal by 90 g (47%) (Supplementary Table 2). There was no difference in the carbohydrate amounts that individuals announced for snack, regular meal, and large meal at the beginning versus the end of the study.

MiniMed 780G System Use and Settings

Table 3 shows system use at baseline and during the study. More than 90% of both groups wore the sensor and used the MiniMed 780G system during the study, but no group difference was observed (P = 0.695 [95% CI −5.4 to 8.1] and 0.666 [95% CI −6.1 to 4.2] between the fix and flex groups, respectively). The number of exits per patient per week did not differ between the groups and was 0.8 in the fix group and 0.6 in the flex group (P = 0.207, 95% CI −0.1 to 0.5). The number of finger pricks (i.e., self-monitoring of blood glucose) per day

significantly decreased from 0.8 ± 0.6 to 0.4 ± 0.3 (P = 0.019, 95% CI −0.3 to −0.5) in the fix group and from 0.7 ± 0.5 to 0.3 ± 0.5 (P = 0.026, 95% CI −0.2 to −0.7) in the flex group, without a between-group difference (P = 0.338, 95% CI −0.1 to 0.3). Infusion sets and reservoirs were changed approximately every 2–3 days.

In terms of optimal settings, 80% of participants initiated the MiniMed 780G system with an active insulin time of 2 h, which increased to 94% of participants at study end. A glucose target of 100 mg/dL was used in 94% of participants at MiniMed 780G system initiation and remained the target during the study.

Safety

No serious adverse events or episodes of severe hypoglycemia or hyperglycemia with ketosis were reported in both groups. Skin irritations related to sensor use occurred in two participants in the fix group and three participants in the flex group. Two participants from the fix group had mild respiratory tract infections. All reported adverse events were resolved without sequelae.

Temporal Trends Analysis

Figure 2 shows the TIR during the different study periods from baseline to using

the MiniMed 780G system. TIR increased from baseline to SAP by almost 9% in both groups. In the fix group, TIR reached >70% from the 2nd week and reached a plateau of >74% after ~5 weeks. In the flex group, TIR also plateaued at ~5 weeks and reached >80%. TBR <54 mg/dL remained <1% and TBR <70 mg/dL <3% in both groups during the study. Time above range decreased over time.

The ICR in the fix group was adjusted during the study phase from 10.8 g at baseline to 7.5 g at MiniMed 780G initiation ($P = 0.001$, 95% CI −2.5 to −4.0, adjustment made in 14 participants) with a further decrease to 5.8 g after 2 weeks of MiniMed 780G use ($P = 0.014$, 95% CI −0.8 to −2.4, 11 participants). In the flex group, adjustments were from 11.2 g at baseline to 7.9 g ($P = 0.001$, 95% CI −2.3 to −4.2, 12 participants) and then to 6.0 g ($P = 0.009$, 95% CI −1.1 to −2.5, 10 participants), respectively. All participants used one ICR over a 24-h period, and no further changes were made after the 2nd week of MiniMed 780G usage.

CONCLUSIONS

In this study, we investigated glycemic control in adolescents using the MiniMed 780G system with a relatively simple mode of meal announcement, including a preset of three different personalized fixed-carbohydrate amounts (fix group) compared with MiniMed 780G users who performed precise carbohydrate counting (flex group). The key finding of this study is that glycemic control as achieved in the flex group was superior to that achieved in the fix group. This finding is based on a significant 6.8% TIR difference in favor of the flex group during the study phase, as well as a significant −2.7% difference of time >250 mg/dL. The other metrics of glycemic control, such as HbA_{1c}, TBR, and time between 180 and 250 mg/dL, did not show any between-group differences, and there was no between-group difference in safety.

Albeit not as good as the flex group, most participants in the fix group still reached international targets for glycemic control (14). In total, 70% of participants reached an HbA_{1c} of <7% at study end, 67% a TIR of >70%, and 82% a TBR of <4% (vs. 75%, 72%, and 86%, respectively, in the flex group). Also, group averages of HbA_{1c} (6.8%), TIR (74.3%), and TBR (1.6%) were well within targets. These

data indicate that meal announcement by using a preset of three personalized fixed-carbohydrate amounts is a valuable alternative to conventional carbohydrate counting.

The MiniMed 780G algorithm with its autocorrection boluses can partly correct for less accurate carbohydrate entries, which is demonstrated by the double amount of insulin delivered by autocorrection bolus in the fix group versus the flex group (17.9% vs. 8.9%, respectively, $P = 0.003$). The amount delivered autobasally was similar in both groups.

The simplified method for meal announcement as presented in this article may have some room for improvement in terms of both training and defining the personalized presets. First, the fix group announced significantly fewer meals compared with the flex group (3.7 vs. 5.1, respectively), and based on the baseline data, as well as Qatari eating habits, this seems an underrepresentation. Improved and recurrent training might lead to more meal announcements, less need for the MiniMed 780G system to autocorrect, and better glycemic control. Second, although the presets were personalized, the fix method only included three presets (regular meal, large meal, and snack). Further investigation is warranted of whether more than three presets with smaller increments provides better glycemic control without increasing burden. In addition, the high percentage of insulin that was delivered by autocorrection in the fix group may point to an underestimation of announced carbohydrates. Third, carbohydrate consumption may change when young people age, and a timely revision of the personalized presets may be included in the method.

One other meal announcement method has been described for the MiniMed 780G system so far. Unannounced snacks of up to 20 g of carbohydrates can avoid a difference in blood glucose of ≥50 mg/dL in pediatric MiniMed 780G users, and unannounced meals of up to 30 g of carbohydrates are safe (15). However, the MiniMed 780G system is not designed as a full closed loop system; thus, meal announcement is preferred. To our knowledge, other means of carbohydrate counting have not yet been studied in the MiniMed 780G system. Methods such as recommended by American Diabetes Association and International Society for Pediatric and Adolescent Diabetes guidelines, including

the use of 10-g portions and 15-g exchanges (16), may also provide safe glycemic control and reduce burden compared with precise carbohydrate counting.

A clear TIR improvement already presented 1 week after MiniMed 780G system initiation, and TIR reached a plateau after ~5 weeks both in the fix and the flex arms. This rapid and clear increase is in line with a previous study from our center (10) and is partly attributed to the modification of ICR in order to stabilize postmeal glucose levels. The end-of-study TIR of >81% in the flex group was relatively high compared with the MiniMed 780G pivotal study in adolescents (72.7%) (17) and compared with real-world data in users ≤15 years of age (73.9%) (13). However, >90% of participants in our study used the recommended optimal system settings (i.e., a glucose target of 100 mg/dL and active insulin time of 2 h). These settings are known to be predictors for a higher TIR and most probably are attributed to the high TIR (18).

This study has several limitations. First, the follow-up time of 12 weeks is relatively short. Albeit long enough to show changes in TIR and HbA_{1c}, the sustainability of results beyond the duration of this study cannot be confirmed. Second, generalizability was hampered by the fact that patients with limited carbohydrate counting skills were excluded from the study. Third, use of the DCA Vantage Analyzer for the HbA_{1c} analysis is not a laboratory test per se, and some have described the findings from these types of tests as inaccurate (19). On the other hand, the DCA Vantage Analyzer has been frequently used in daily diabetes care and diabetes research and meets NGSP performance criteria (20). Fourth, the study is limited by the window for calculating CGM data. Per Battelino et al. (14), a minimum of 10 days of CGM data is needed to accurately provide CGM metrics, and in our study, this was possible for some but not all studied periods. Finally, we did not adjust for multiplicity on secondary outcomes because of the small sample size.

The main strength of our study is the randomized controlled trial design, which led to two similar groups at baseline. Any difference in glycemic control at study end can therefore mainly be attributed to differences in meal announcement method.

In conclusion, adolescents using the MiniMed 780G system who announce meals through a preset of three personalized fixed-carbohydrate amounts on average reached international targets of glycemic control. Therefore, the preset announcements may be a valuable alternative to precise carbohydrate counting in adolescent MiniMed 780G users who are challenged by precise carbohydrate counting. Because meal management with precise carbohydrate counting further improves outcomes, carbohydrate estimation skills remain important with the MiniMed 780G system.

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