Dietary interventions in closed loop systems - Changing clinical nutrition approaches

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Disclosures

- Nothing to disclose

Evidence based vs. Experience based

- Advanced hybrid closed loop systems (AHCL) adopted into clinical care:
  - Insulin pump + real-time CGM + algorithm
  - Automated basal – up or down
  - Autocorrection insulin boluses

- Topics diet and AHCL systems:
  - Carbohydrate counting
  - Alcohol
  - Weight control/BMI

Research: diet and AHCL systems

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]

https://doi.org/10.2337/dc22-1692

Body mass index, basal insulin and glycemic control in children with type 1 diabetes treated with the advanced hybrid closed loop system remain stable – 1-year prospective, observational, two-center study

Sebastian Seget[1], Przemysława Jarosz-Chobot[1], Agnieszka Ochab[2], Joanna Polanska[3], Ewa Rusak[1], Paulina Witoszek[4] and Agata Chobot[2]*

A Randomized Crossover Trial to Compare Automated Insulin Delivery (the Artificial Pancreas) With Carbohydrate Counting or Simplified Qualitative Meal-Size Estimation in Type 1 Diabetes

Ahmad Haidar, Laurent Legault, Marie Raffray, Nikita Gouchie-Provencher, Adnan Jafar, Marie Devaux, Milad Ghanbari, and Rémi Rabasa-Lhoret

Diabetes Care 2023;46(7):1–7 | https://doi.org/10.2337/dc22-2297

Research: Educational and Psychological Aspects

The impact of using a closed-loop system on food choices and eating practices among people with Type 1 diabetes: a qualitative study involving adults, teenagers and parents

J. Lawton[1], M. Blackburn[1], D. Rankin[1], J. Allen[2,3], F. Campbell[4], L. Leelarathna[5], M. Tauschmann[2,3], H. Thabit[5], M. E. Wilinska[2,3] and R. Hovorka[2,3] on behalf of the APCam11 Consortium

Unannounced Meal Challenges Using an Advanced Hybrid Closed Loop System (AHCL)

Dr. Roy Shalit, Dr. Noga Minsky, Ms. Maya Laron-Hirsh, Dr. Ohad Cohen, Dr. Natalie Kurtz, Dr. Anirban Roy, Dr. Benyamin Grosman, Mr. andrea benedetti, and Prof. Amir Tirosh

Carbohydrate Tolerance Threshold for Unannounced Snacks in Children and Adolescents With Type 1 Diabetes Using an Advanced Hybrid Closed-Loop System

Gianluca Tornese,[1] Claudia Carletti,[1] Manuela Giangreco,[1] Daniela Nisticò,[2] Elena Faleschini,[1] and Egidio Barbi[1,2]

Diabetes Care 2022;45:1486–1488 | https://doi.org/10.2337/dc21-2643

Dietary determinants of postprandial blood glucose control in adults with type 1 diabetes on a hybrid closed-loop system

Claudia Vetrani[1] · Ilaria Calabrese[1] · Luisa Cavagnuolo[1] · Daniela Pacella[2] · Elsa Napolano[1] · Silvia Di Rienzo[1] · Gabriele Riccardi[1] · Angela A. Rivellese[1] · Giovanni Annuzzi[1] · Lutgarda Bozzetto[1]

Carbohydrate counting

Can we eliminate carbohydrate counting in AHCL systems?

Is carbohydrate counting the gold standard for mealtime bolusing?

- Carbohydrates + timing bolus influencing postprandial glycemic control

- Review (Kawamura 2007): Carbohydrate counting effective method and can improve glycemic outcomes and increase flexibility in food choices

- The Global TEENs Study (Anderson et al. 2017): Carbohydrate counting is related to better diabetes-specific health related quality of life and optimal glycemic outcomes

Kawamura. *Pediatr Diabetes* 2007;8(6):57-62
Anderson et al. *Diabetes Care*. 2017;40(8):1002-9

What is the best method to count carbohydrates?

- 1 gram counting or in increments of 10-15 grams?
- Children with T1D and caregivers can estimate carbohydrate content of meals with reasonable accuracy (Smart et al. 2010)
- 10 g variation in the estimate of 60 g carbohydrates is covered by intensive insulin therapy (Smart et al. 2009)

Can children with Type 1 diabetes and their caregivers estimate the carbohydrate content of meals and snacks?

C. E. Smart*†, K. Ross‡, J. A. Edge‡, B. R. King*, P. McElduff§ and C. E. Collins†

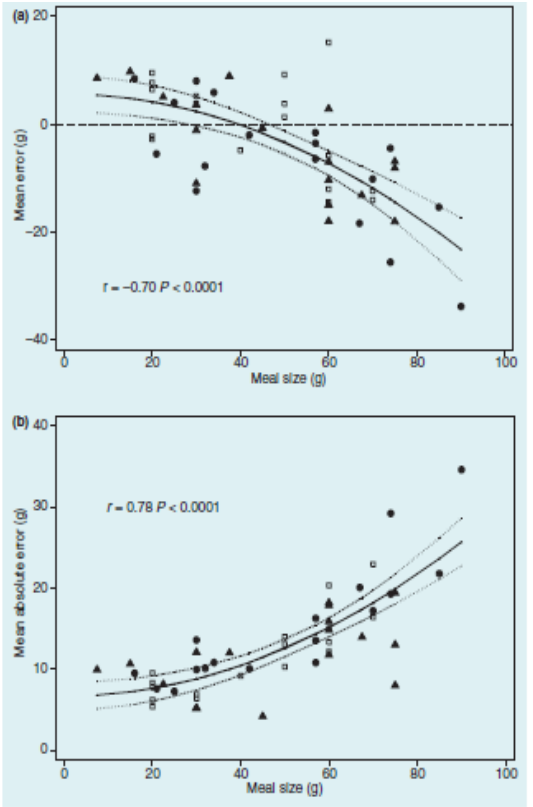


FIGURE 1 The relationships between mean gram error (a) and mean absolute gram error (b) by meal size and carbohydrate estimation method in 102 children and adolescents with type 1 diabetes on intensive insulin therapy and 110 primary caregivers who estimated 17 standard meals and snacks. There was no relationship between error and method of carbohydrate counting (• Gram increments □ 10 gram Portions (▲) 15 gram exchanges) ($p>0.05$).
(a) There was a strong negative correlation with mean gram error and total meal carbohydrate content ($r=-0.70$, $p<0.0001$), such that snacks were overestimated and main meals were underestimated.
- Predicted value, - - - Upper and Lower 95% CI.
(b) The mean absolute gram error increased with meals of larger carbohydrate quantity ($r=0.78$, $p<0.0001$).
- Predicted value, - - - Upper and Lower 95% CI.

Smart et al. *Diabetic Med*. 2010;27(3):348-53
Smart et al. *Diabetic Med*. 2009;26:279-85

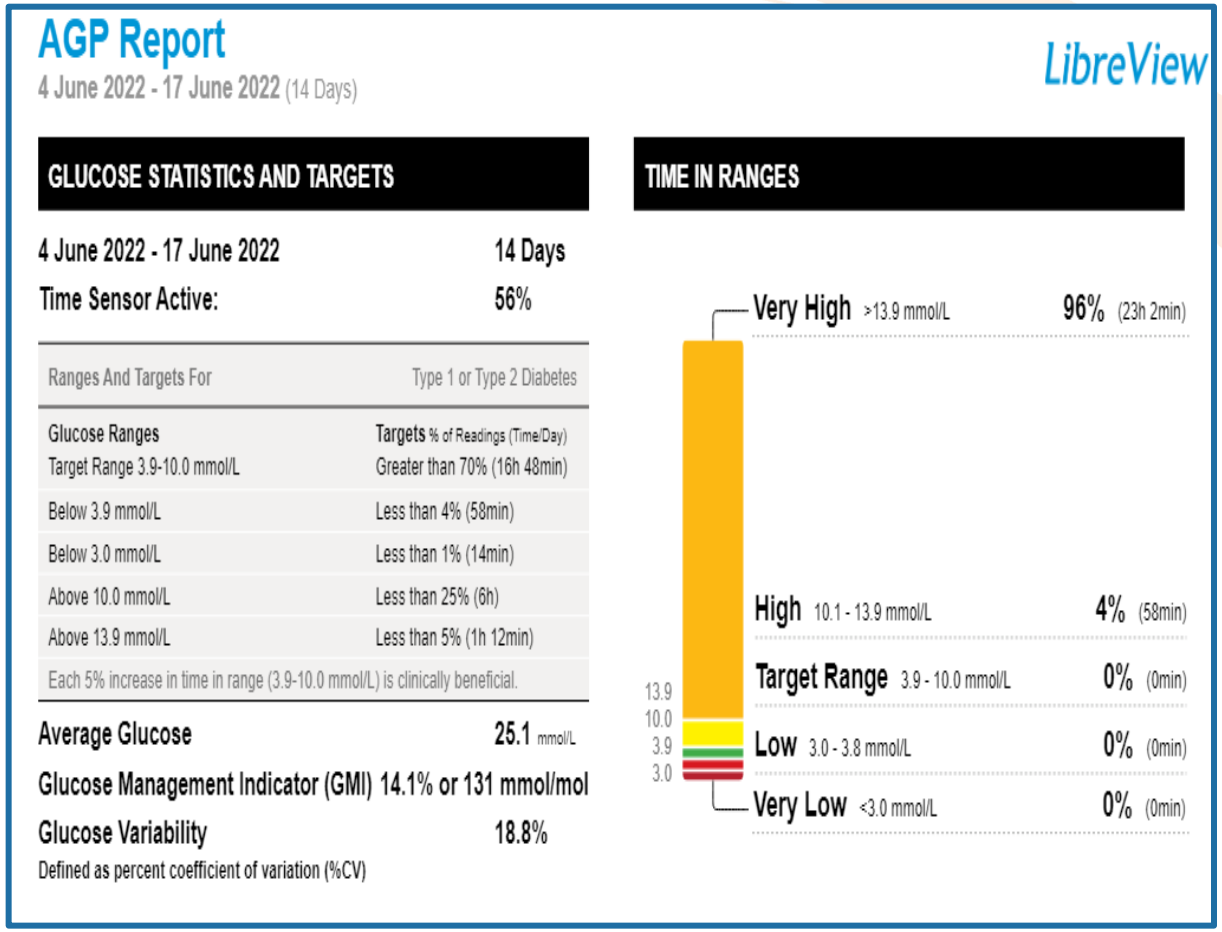
Carbohydrate counting in AHCL systems

- AHCL systems:
  - are safe
  - can improve glycemic control
  - reduced the risk of hypo- and hyperglycemia
  - reduced self-care burdens

- However, the user needs to count and enter carbohydrates (pre-meal bolus!) in the system for postprandial glycemic control

- But is precise carbohydrate counting in AHCL systems necessary for optimal glycemic control?

Case: Not able/willing to count carbohydrates



AGP Report

4 June 2022 - 17 June 2022 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

4 June 2022 - 17 June 2022	14 Days
Time Sensor Active:	56%

Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	Targets % of Readings (Time/Day)
Target Range 3.9-10.0 mmol/L	Greater than 70% (16h 48min)
Below 3.9 mmol/L	Less than 4% (58min)
Below 3.0 mmol/L	Less than 1% (14min)
Above 10.0 mmol/L	Less than 25% (6h)
Above 13.9 mmol/L	Less than 5% (1h 12min)
Each 5% increase in time in range (3.9-10.0 mmol/L) is clinically beneficial.	

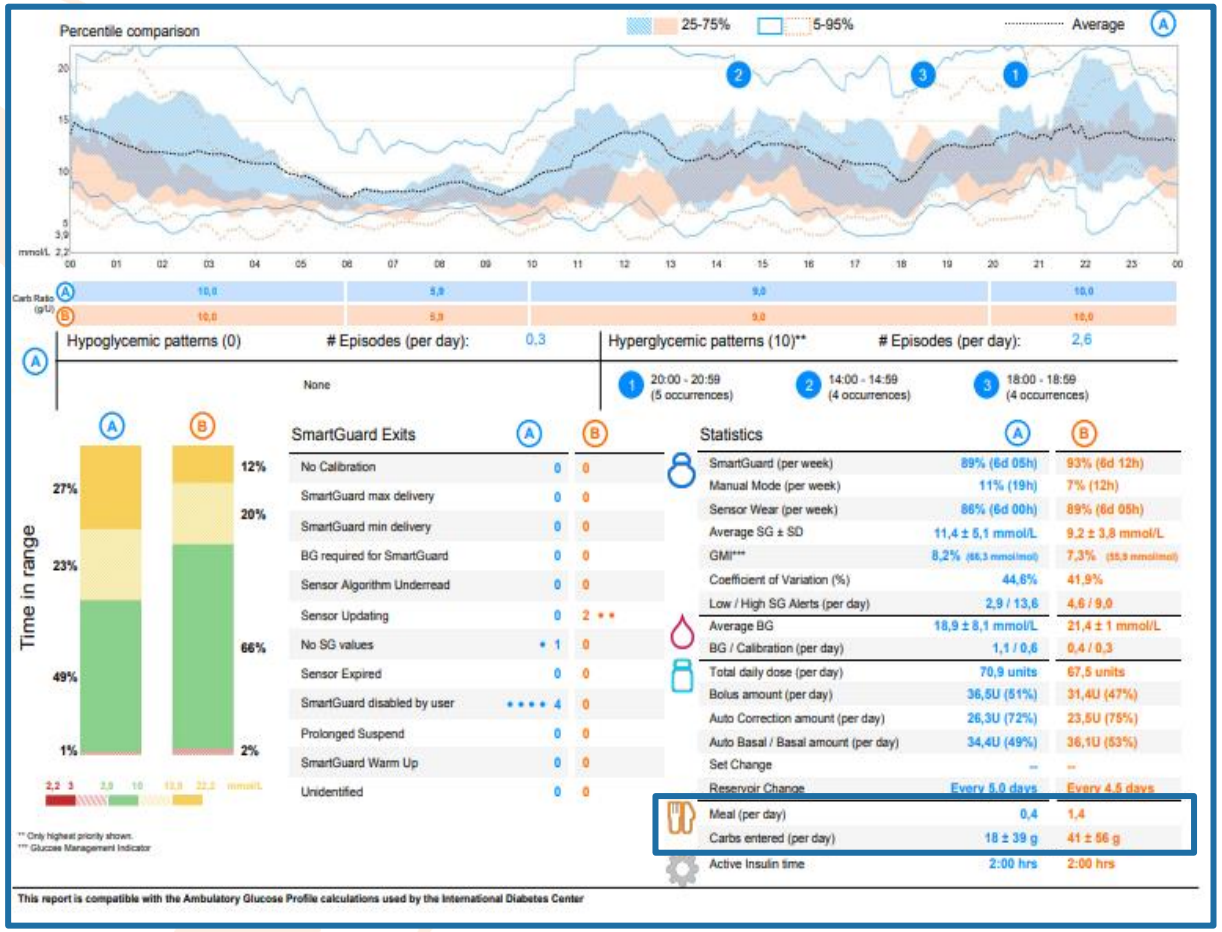
Average Glucose	25.1 mmol/L
Glucose Management Indicator (GMI)	14.1% or 131 mmol/mol
Glucose Variability	18.8%

Defined as percent coefficient of variation (%CV)

TIME IN RANGES

13.9
10.0
3.9
3.0

Very High	>13.9 mmol/L	96% (23h 2min)
High	10.1 - 13.9 mmol/L	4% (58min)
Target Range	3.9 - 10.0 mmol/L	0% (0min)
Low	3.0 - 3.8 mmol/L	0% (0min)
Very Low	<3.0 mmol/L	0% (0min)



Percentile comparison — 25-75% — 5-95% — Average

Hypoglycemic patterns (0) — # Episodes (per day): 0,3

None

Hyperglycemic patterns (10)** — # Episodes (per day): 2,6

1 20:00 - 20:59 (5 occurrences)
2 14:00 - 14:59 (4 occurrences)
3 18:00 - 18:59 (4 occurrences)

Time in range

	A	B
	27%	12%
	23%	20%
	49%	66%
	1%	2%

SmartGuard Exits

	A	B
No Calibration	0	0
SmartGuard max delivery	0	0
SmartGuard min delivery	0	0
BG required for SmartGuard	0	0
Sensor Algorithm Underread	0	0
Sensor Updating	0	2 **
No SG values	* 1	0
Sensor Expired	0	0
SmartGuard disabled by user	**** 4	0
Prolonged Suspend	0	0
SmartGuard Warm Up	0	0
Unidentified	0	0

** Only highest priority shown.
*** Glucose Management Indicator

Statistics

	A	B
SmartGuard (per week)	89% (6d 05h)	93% (6d 12h)
Manual Mode (per week)	11% (19h)	7% (12h)
Sensor Wear (per week)	86% (6d 00h)	89% (6d 05h)
Average SG ± SD	11,4 ± 5,1 mmol/L	9,2 ± 3,8 mmol/L
GMI***	8,2% (66,3 mmol/mol)	7,3% (55,9 mmol/mol)
Coefficient of Variation (%)	44,6%	41,9%
Low / High SG Alerts (per day)	2,9 / 13,6	4,6 / 9,0
Average BG	18,9 ± 8,1 mmol/L	21,4 ± 1 mmol/L
BG / Calibration (per day)	1,1 / 0,6	0,4 / 0,3
Total daily dose (per day)	70,9 units	67,5 units
Bolus amount (per day)	36,5U (51%)	31,4U (47%)
Auto Correction amount (per day)	26,3U (72%)	23,5U (75%)
Auto Basal / Basal amount (per day)	34,4U (49%)	36,1U (53%)
Set Change	--	--
Reservoir Change	Every 5.0 days	Every 4.5 days
Meal (per day)	0,4	1,4
Carbs entered (per day)	18 ± 39 g	41 ± 56 g
Active Insulin time	2:00 hrs	2:00 hrs

This report is compatible with the Ambulatory Glucose Profile calculations used by the International Diabetes Center

- Girl 20-y, T1D for 10 y, HbA1c 11-14%
- Since 2022 Medtronic MiniMed 780G, TIR around 50%, TBR 1%

- HbA1c before start Smartguard 11-14%
- HbA1c one year after start Smartguard 8.9%

Unannounced meal challenges using an AHCL system
(Shalit et al.)

- Single-arm study (14 adults) comparing the performance of the Medtronic Minimed 780G algorithm with and without meal announcement

- Study design:
  - 5 days supervised environment: outcomes not announcing meals (≤80 g of carbohydrates) were assessed
  - 90 day at home unannounced phase
  - 90 day at home announced phase

- Primary outcome: TIR between 3.9-10 mmol/l

Shalit et al. *Diabetes Technol Therp.* 2023; doi: 10.1089/dia.2023.0139

TIR: 90 days at home unannounced vs. announced meals

ALL MEALS	Unannounced period	Announced period	P-value
TIR (%)	67.5±12.5	77.7±9.5	<0.001
TBR (%)	1.6±1	2.8±1.8	<0.001
Auto corrections (%)	28.5±9	16.7±7	<0.001

MEALS 61-80 g carbs	Unannounced period	Announced period	P-value
TAR >10 mmol/l (%)	51.7±22.4	25.9±25.3	<0.01
TAR >13.9 mmol/l (%)	14.5±15.8	5.8±15.8	<0.01

MEALS 20 g carbs	Unannounced period	Announced period	P-value
TIR	70.8±24.4	70.3±26.5	>0.05
TAR >10 mmol/l (%)	27.6±25.1	27.1±26.3	>0.05

Shalit et al. *Diabetes Technol Therp.* 2023; doi: 10.1089/dia.2023.0139

AHCL system is optimized for use with meal announcement

- Not announcing meals up to 80 g of carbohydrates in this study did not result in serious adverse events (severe hypoglycemia or DKA)
- But, not announcing meals up to 80 g of carbohydrates led to less TIR
- Limitation of the study: meals containing no more than 80 g of carbohydrates

Shalit et al. *Diabetes Technol Therp.* 2023; doi: 10.1089/dia.2023.0139

Simplified meal management vs. precise carb counting

(Petrovski et al.)

- RCT in 34 children and adolescents, 12-18 y, with T1D, using the MiniMed 780G, followed for 12 wks

- 2 groups:
  - Fixed group: regular meal 40-70 g, large meal 60-90 g, snack 15-20 g
  - Flex group: precise carbohydrate counting with increments of 1 g

- Primary outcome: Between-group difference in TIR

Petrovski et al. *Diabetes Care* 2023;46(3):544-50

TIR: fixed vs. flex group

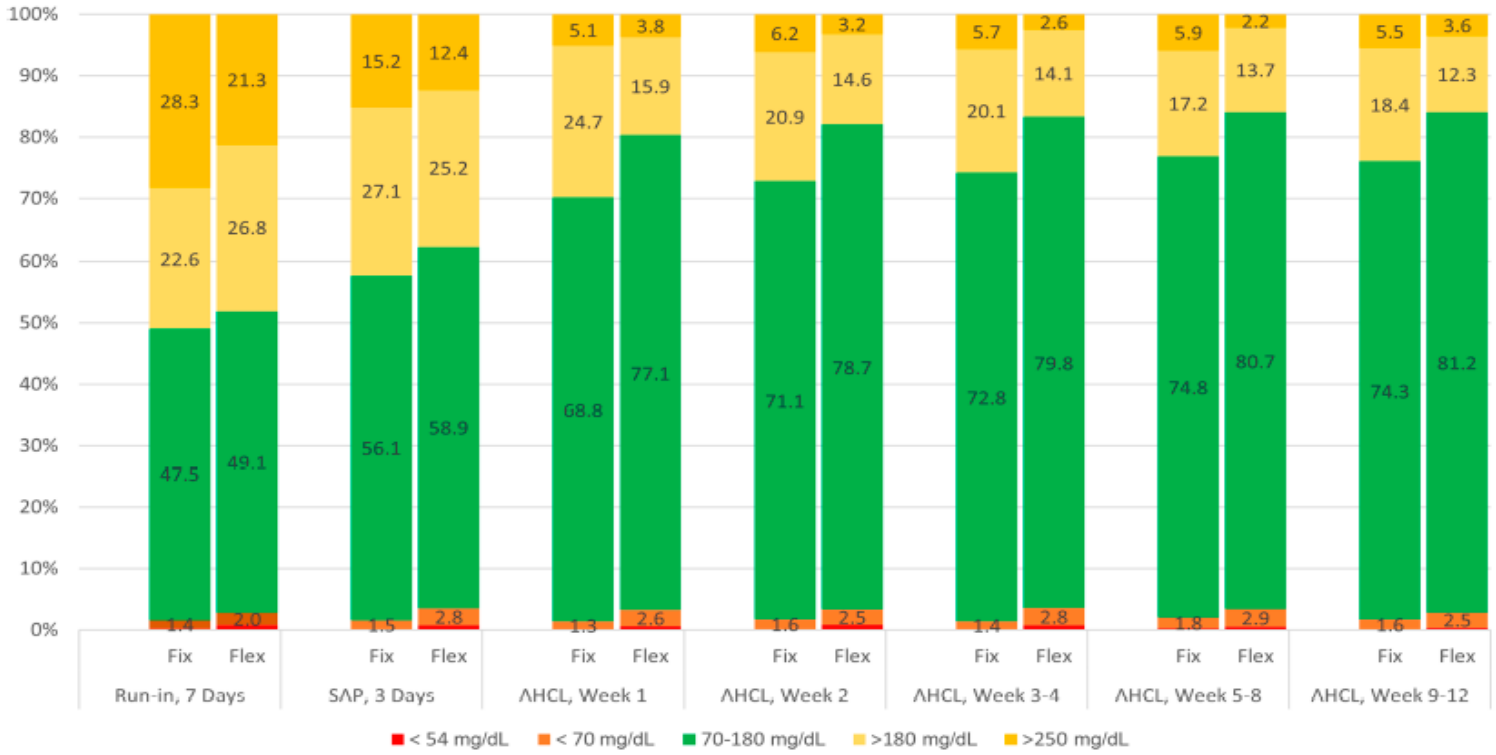


Figure 2—TIR during different study periods. Data are percentage of TIR during the interval. Glucose values <54 mg/dL are not shown on the graph. Baseline data were collected using the Guardian 4 sensor with the MiniMed 780G system for a 1-week period of training. AHCL, advanced hybrid closed loop.

- Significant TIR difference 6.8% in favor of the flex group
  The fixed group still reached international targets for glycemic control
- HbA1c and TBR did not differ between the 2 groups

Petrovski et al. *Diabetes Care* 2023;46(3):544-50

Autocorrection boluses twice higher in the fixed group

- Autocorrection boluses can partly correct for less accurate carbohydrate entries
  - Fixed group 17.9% autocorrection and 8.9% in flex group (p=0.003)
  - TBR did not differ between the 2 groups

- Experience clinical practice:

  Consequence: A more aggressive algorithm

  For example, exercise

Petrovski et al. *Diabetes Care* 2023;46(3):544-50

Carbohydrates are not the only factor which influence postprandial glycemic control

- Unannounced snacks up to 20 g of carbohydrates can avoid a difference in blood glucose < 2.8 mmol/l. Rise in blood glucose 2 h after the meal is mainly driven by complex carbohydrates and fats (Tornese et al. 2022)

- In HCL systems not only the amount of carbohydrates but the whole nutritional composition of the meal modulates blood glucose response (Vetrani et al. 2022)

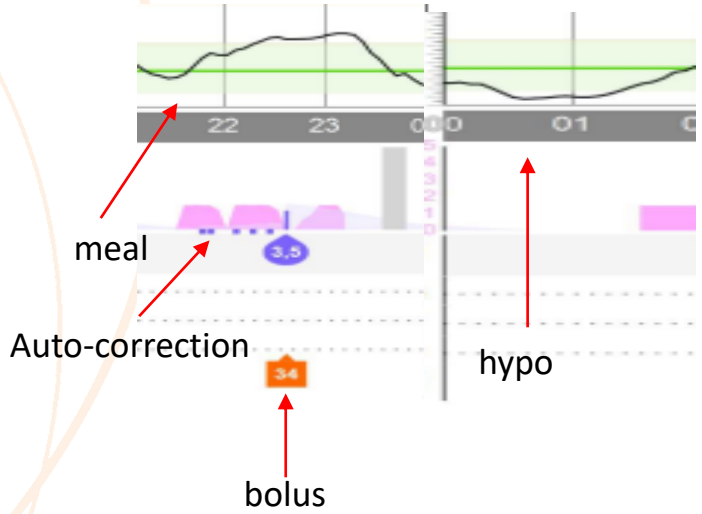
- In addition, also meal size should be considered when predicting postprandial blood glucose (Vetrani et al. 2022, Lehmann et al. 2020)

Tornese et al. *Diabetes Care* 2022 2;43:1486-88
Vetrani et al. *Diabetologia* 2022 65:79-87

Role of the dietitian

- Simplified meal management alternative approach
  Precise carbohydrate counting maybe not needed, but…
  - Carb counting skills are needed to determine meal portions:
    small, medium, large
  - Timing of bolus (premeal bolus)
  - Meal size/amount of carbohydrates
  - Meal composition
  - Education about healthy eating pattern

Example:
Delayed meal-time bolus



- High autocorrection boluses:
  Be aware of the consequences of an aggressive algorithm

Alcohol and AHCL systems

Alcohol and AHCL systems, not the best cocktail?

Alcohol and T1D

- Hypoglycemia: Interferes with the liver's efforts to release glucose and may result in delayed hypoglycemia 8-12 hrs after drinking

- Hyperglycemia: Due to alcoholic drinks high in sugar or additional snacks with carbs to prevent hypoglycemia

- Adolescents and young adults with T1D have similar rates of participation in alcohol drinking compared with their peers without T1D (Roberts et al. 2020, Sannegowda et al. 2023, Potter et al. 2018)
  - Young people with T1D have a high risk of alcohol-related hospital admissions, particularly at school age 14-17 y (Gartner et al. 2020)

Roberts et al. *Diabetes Res Clin Pract.* 2020 159:107980
Sannegowda et al. *Curr Diab Rep*. 2023;23:1-17
Potter et al . *Peadtr Child Health.* 2018;23:185-90
Gartner et al. *Pediatr Diabetes*. 2020;21:1333-42

Alcoholic beverages and carbohydrates

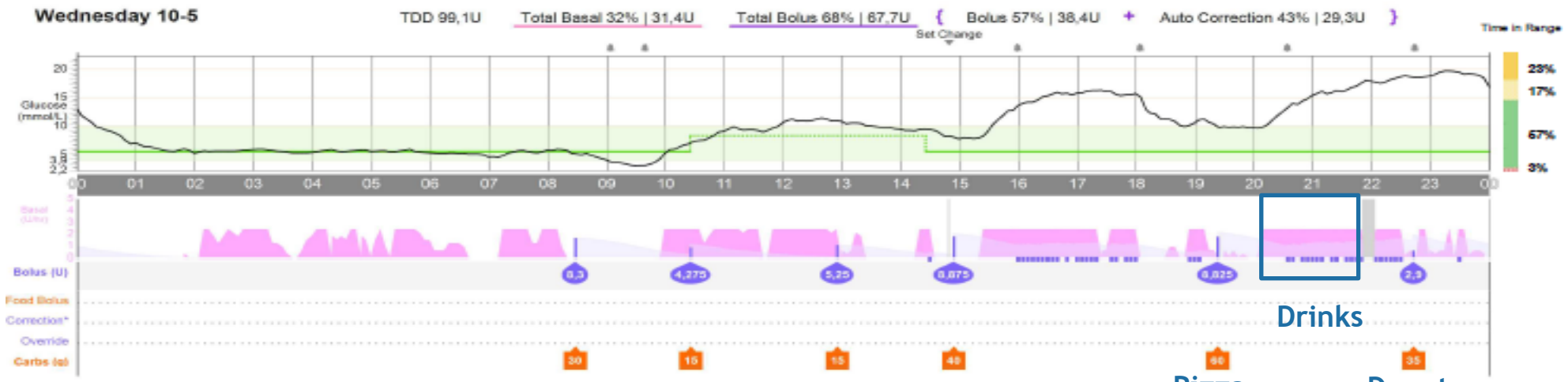
Alcohol drink	Amount (ml)	Carbohydrates (g)
Liqueur 15-25% (Blue Curacao,Pisang Ambon, Pina Colada, Safari, Passoa)	35 (one shot)	10
Liqueur >25% (Tia Maria, Amaretto, Sambuca)	35 (one shot)	10
Mixed drink glass (example rum + coke)	250 35 ml rum + 215 ml coke	22
Mixed drink bottle	275	27-30
Beer bottle	300	9
White wine dry White wine sweet	150 150	1 9

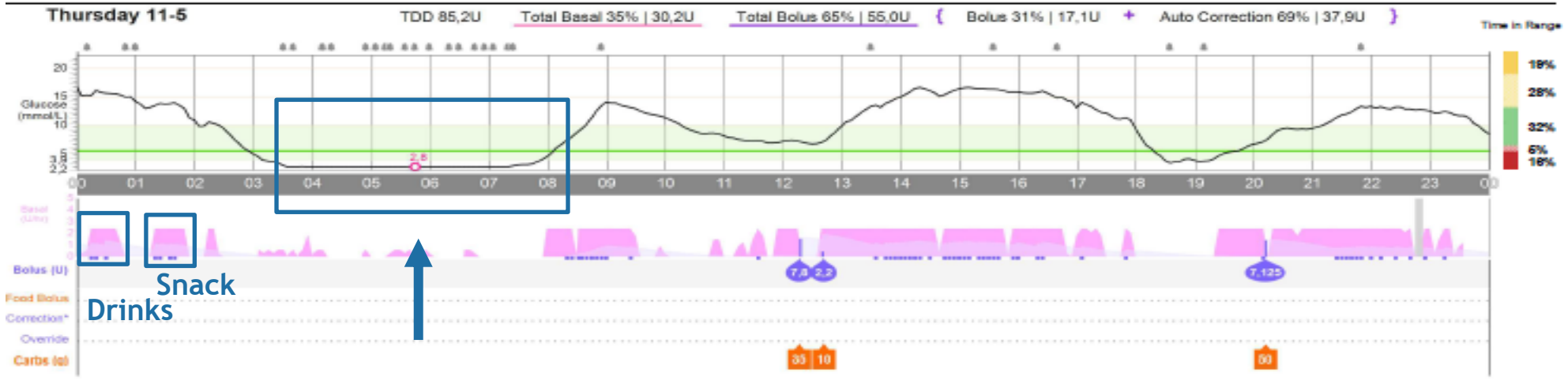
Case 1: Alcohol and AHCL

- Girl, 19 y
- MiniMed 780G (SG 7 months)
- Target 5.5

- HbA1c = 6.5%
- TIR = 66%
- TBR = 7%

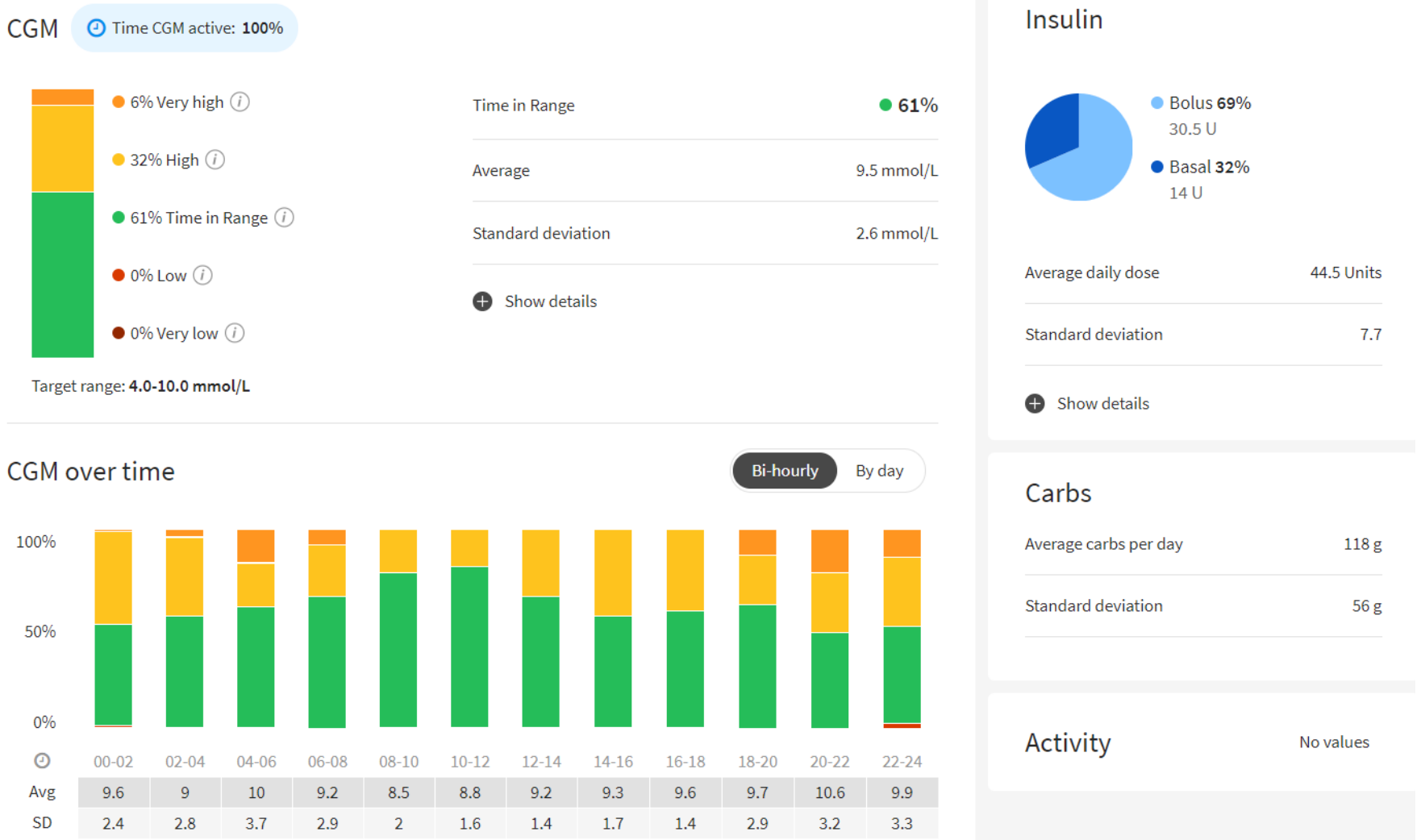
What happened?



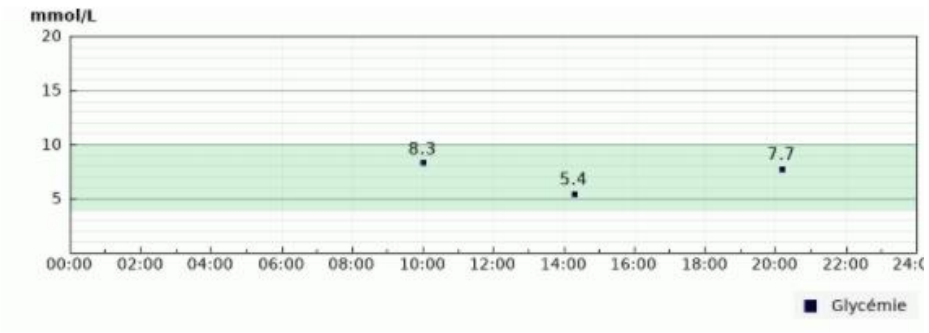


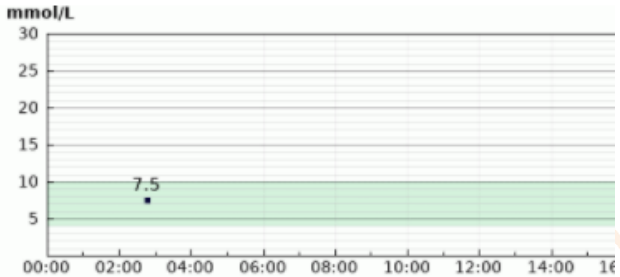
Case 2: Alcohol and AHCL

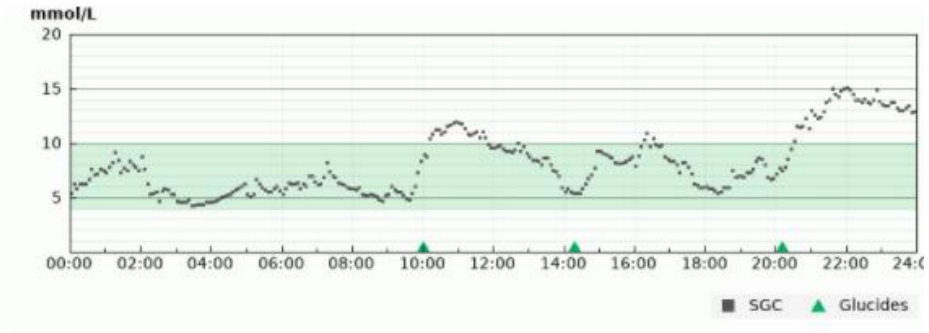
- Young adult
- Tandem, Control IQ
- HbA1c on MDI = 9%
- TIR after 6 d = 61%
- TBR = 0%

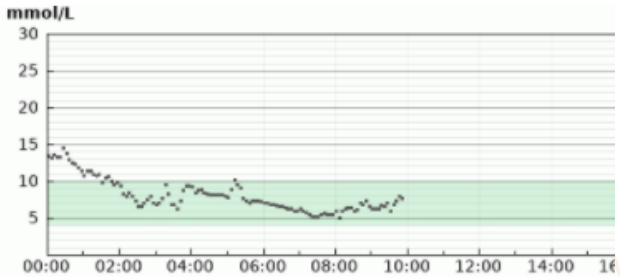


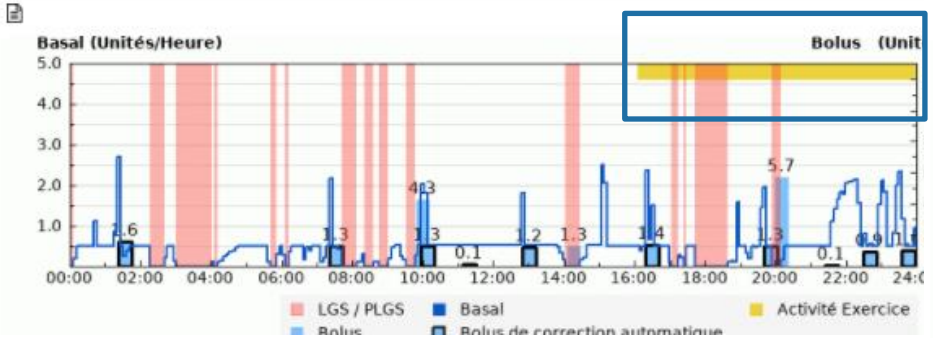
What happened?

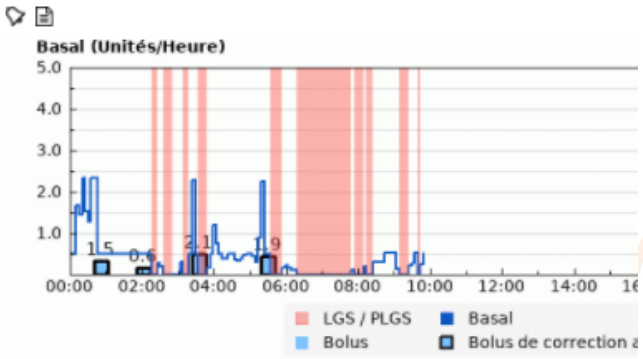












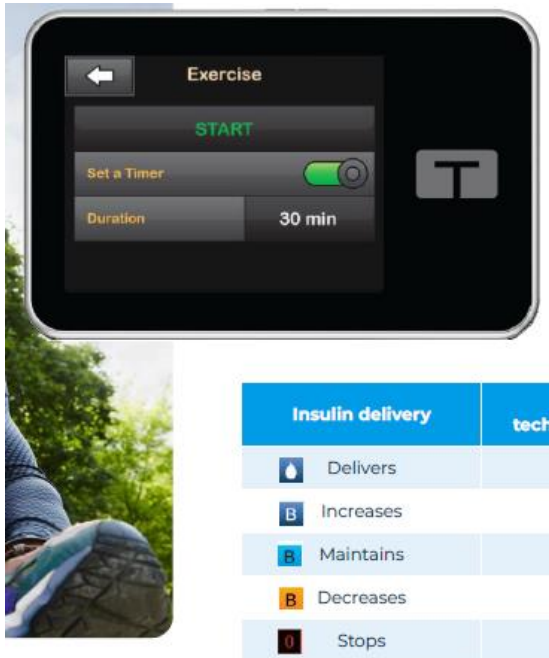
Basic tips and tricks

- AVOID ALCOHOL: minimum legal age (in the Netherlands ≥18 y)

- Avoid alcohol with added sugar (sweet wines, liqueurs)
- Avoid sweet mixers (regular soda, juice or margarita mix)
- Do not drink on an empty stomach, eat first
- Be aware of eating without bolusing
- Avoid binge drinking (>4 standard drinks)
- Drinking alcohol can be a risk factor among young people not following their usual self-care routine

Tips AHCL systems and alcohol

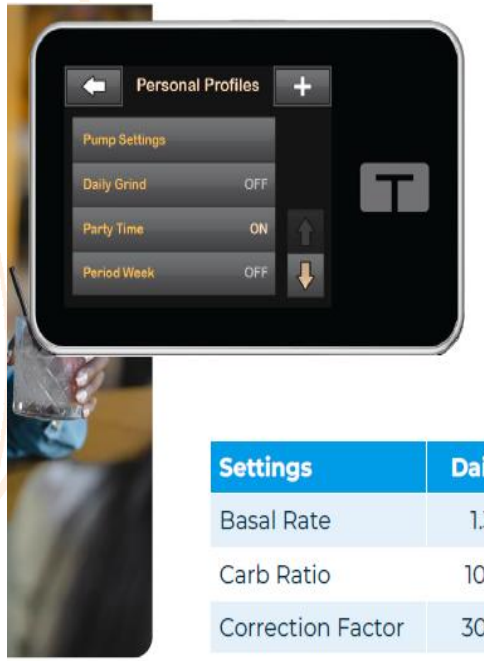
- Medtronic Minimed 780G: use temp target 8.3 before drinking and x hours after drinking (until you wake-up)



Exercise Activity

Insulin delivery	Control-IQ technology(mmol/L)	Exercise activity (mmol/L)
Delivers	10.0	10.0
Increases	8.9	8.9
Maintains	6.25 – 8.9	7.8-8.9
Decreases	6.25	7.8
Stops	3.9	4.4

- Tandem/Tslim: consider using exercise activity + personal profile



Personal Profiles

Settings	Daily Grind	Party Time
Basal Rate	1.3 units	0.9 units
Carb Ratio	10 grams	13 grams
Correction Factor	30 mg/dL	40 mg/dL

Weight control/BMI

What is the impact of an AHCL system on food choices and weight control?

Unhealthier eating pattern or better glycemic control?

- Hypothesis 1: The use of an AHCL system may result in an unhealthier eating pattern
  - Poor dietary quality has been widely described in young people living with T1D (Dłużniak-Gołaska et al. 2019)

- Hypothesis 2: The use of an AHCL system may result in better glycemic control with the consequence for weight gain

Dłużniak-Gołaska et al. *Diabetes Metab Syndr Obes.*2019 17;12:161-70

Unhealthier eating pattern?

- Lawton et al. 2019: The impact of a HCL system on people's food choices and dietary practices
  - N=24: interviews before start HCL system and 3 months after

- Preparing and/or eating similar meals, but feeling more normal and less burdened
- Increased snacking and portion sized and consumption of fatty foods
- HCL system could lead to deskilling and unhealthier eating patterns

> 'So I could pretty much just eat whatever I wanted . . . I felt like I didn't have to watch what I was eating . . . I could go a little bit more luxury, and I could have things that I wouldn't usually go for because I'd go: Oh, it's got loads of sugar in, that. Sod it. It tastes nice.' (participant 7)

> 'My portion size increased slightly, because like I say, I enjoy my food. I like cooking. I like eating . . . The first couple of weeks I was eating very carefully and doing everything as I should. And then I realized, I simply realized how good the closed-loop was, and went: Oh, slightly bigger portion sizes now.' (participant 9)

> 'I mean, yeah, the only other sort of thing is that there is this danger that you, if you were too used to closed-loop, then there's a chance that I would have unlearnt in a way, some of the, some of those skills, like accurately counting your carbohydrates.' (participant 14)

Lawton et al. *Diabetic Med.* 2019; 36(6):753-60

BMI in children with T1DM treated with AHCL (Seget et al.)

- Changes in weight of children and adolescents with T1D using the Medtronic Minimed 780G after 1 y of follow-up

- Prospective study, N=50
  age 5-16 y with T1D using the MiniMed 780G

- BMI and height collected after AHCL enrollment, 6 m and 1 y after

- BMI z-score was calculated using the individual's weight and height and the WHO references values

Seget et al. *Front Endocrinol.*2022 11;13:1036808

BMI z-scores did not change significantly neither after 6 nor after 12 months of follow-up

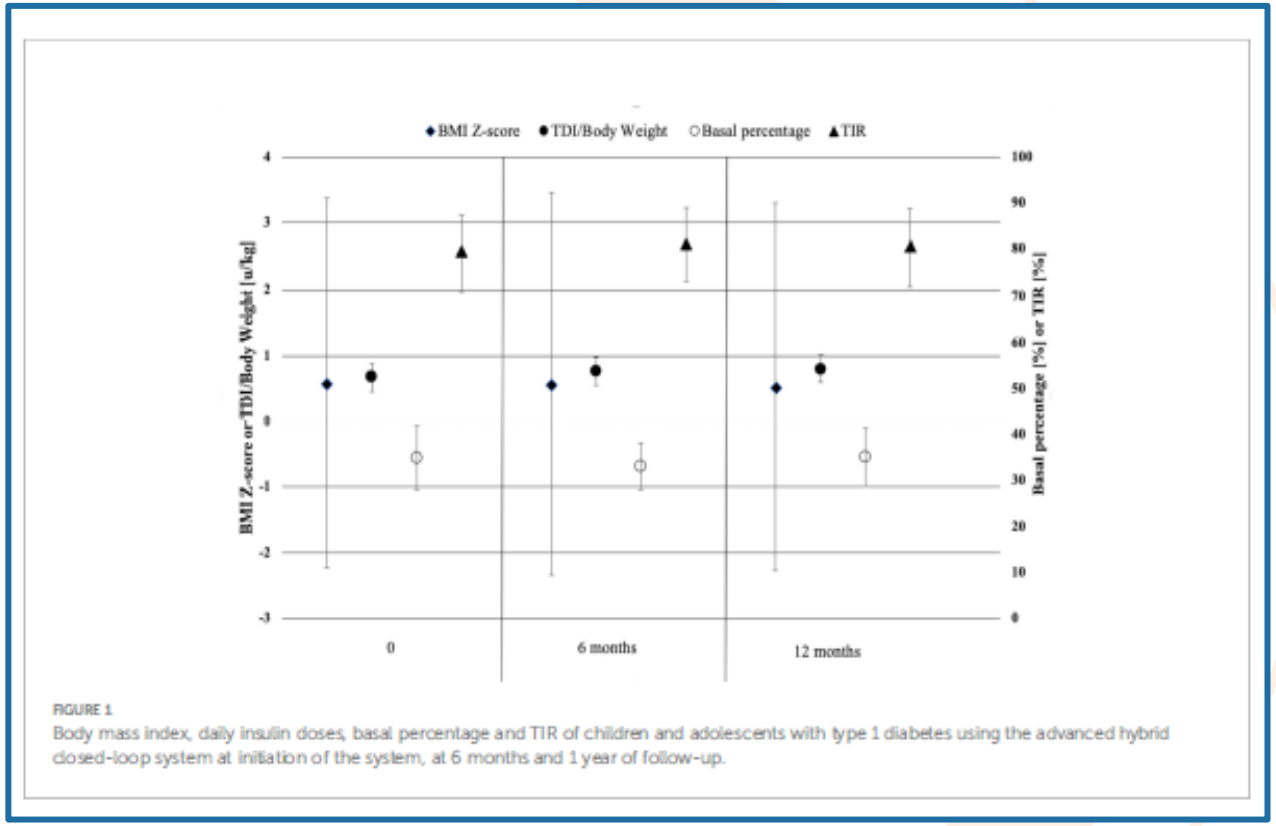


FIGURE 1
Body mass index, daily insulin doses, basal percentage and TIR of children and adolescents with type 1 diabetes using the advanced hybrid closed-loop system at initiation of the system, at 6 months and 1 year of follow-up.

- The cohort in this study had a good baseline glycemic control

Seget et al. *Front Endocrinol.*2022 11;13:1036808


THANK
YOU

Case 2: Alcohol and AHCL

- Girl, 22 y
- MiniMed 780G (SG one week)
- Target 6.7

- TIR = 73%
- TBR = 1%

What happened?