Simple Meal Bolusing on Automated Insulin Delivery

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Outline

- Challenges with meal boluses

- Evidence for simple meal boluses

- Implementing a simple meal bolus strategy

Exploring the Burden of Mealtime Insulin Dosing in Adults and Children With Type 1 Diabetes

Wendy Lane,[1] Emma Lambert,[2] Jesso George,[3] Naveen Rathor,[3] and Nandu Thalange[4]

- Online survey, 2019-2020 of adults with T1D (n=1401), parents of kids with T1D (n=350), and physicians (n=960)

- International (U.S., Canada, UK, Japan, Spain, France)

- 94-96% of people/parents believed accurate mealtime dosing was important

- 35% of adults/47% parents felt very confident in estimating insulin needed for a meal – 16% of physicians felt patients were very confident
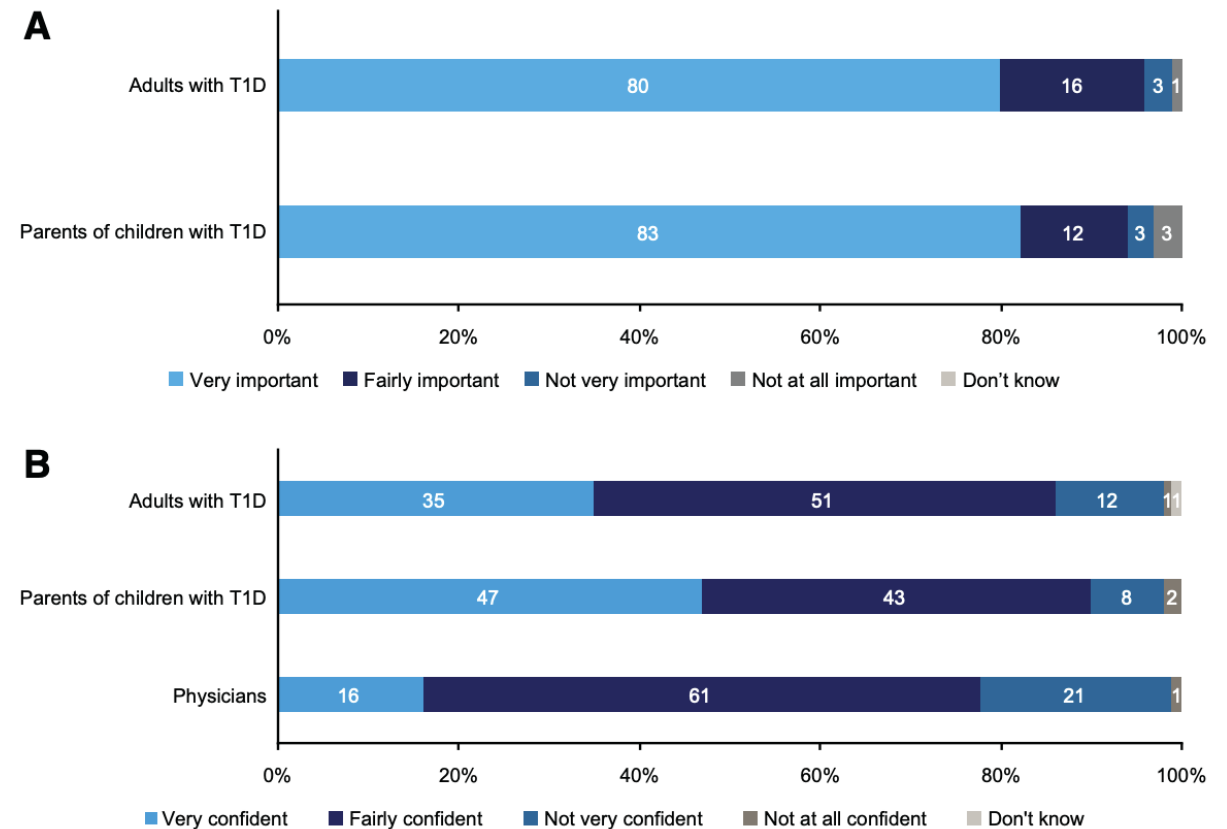

FIGURE 1 Attitudes toward mealtime insulin dosing. A) Importance of taking mealtime insulin accurately, as reported by adults and parents of children with type 1 diabetes. B) Confidence in estimating the amount of mealtime insulin accurately, as reported by adults with type 1 diabetes, parents of children with type 1 diabetes, and physicians assessing their patients with type 1 diabetes. Corresponding survey questions (A1 and A2 on the patient/parent survey and A1 on the physician survey) are included in the Supplementary Materials. T1D, type 1 diabetes.

Exploring the Burden of Mealtime Insulin Dosing in Adults and Children With Type 1 Diabetes

Wendy Lane,[1] Emma Lambert,[2] Jesso George,[3] Naveen Rathor,[3] and Nandu Thalange[4]
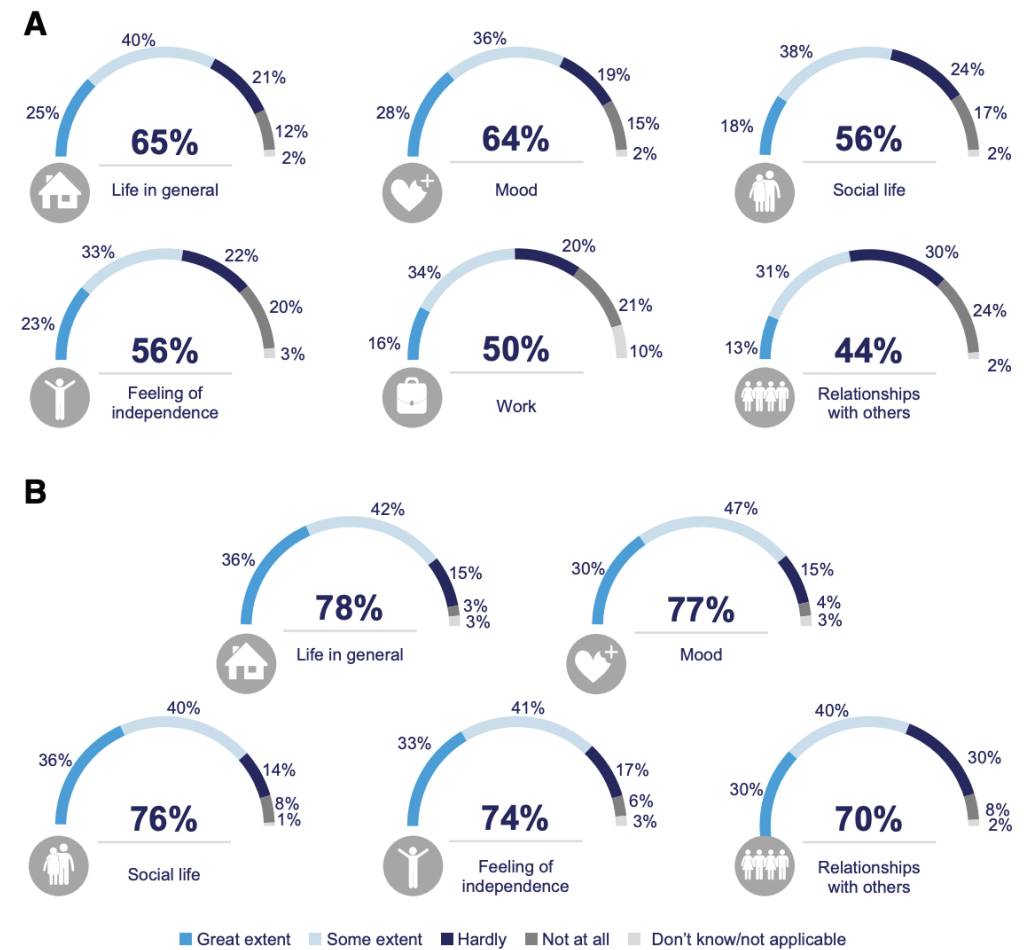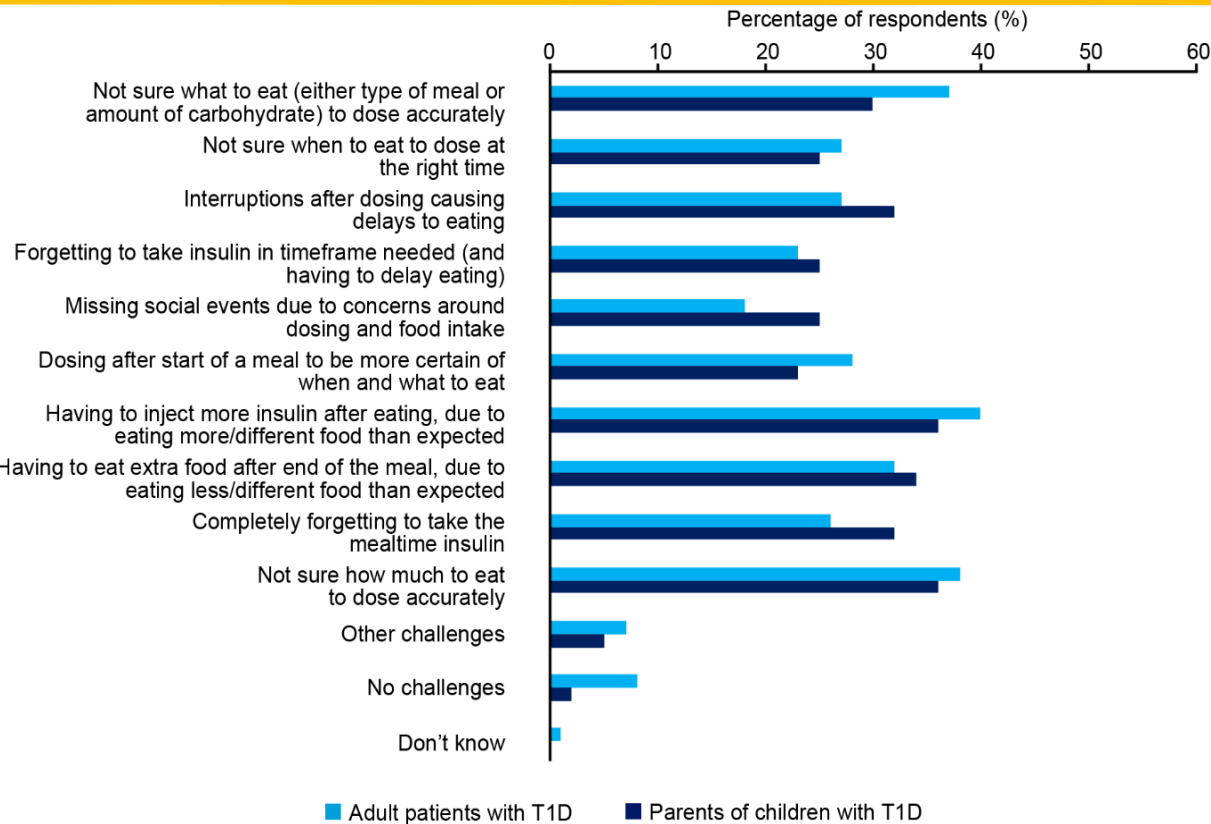
FIGURE 3 The extent of negative impact of premeal insulin dosing on day-to-day life in adults with type 1 diabetes (*A*) and parents of children with type 1 diabetes (*B*). The corresponding survey question (A14 on the patient/parent survey) is included in the Supplementary Materials.

82% of adults/93% of parents felt that having to administer insulin 15–20 minutes before their meals negatively affected their (or their child's) lifestyle greatly or to some extent

19% (n = 264) of surveyed adults and 44% (n = 153) of parents chose not to eat out at least once a week because they were unsure about how much bolus insulin might be needed for the meal

Self-reported insulin pump prescribing practices in pediatric type 1 diabetes

Meghan E. Fredette ✉, Mark R. Zonfrillo, Sangshin Park, Jose Bernardo Quintos, Philip A. Gruppuso, Lisa Swartz Topor

- Survey of Pediatric Endocrine Society members that prescribe pumps (n=192)

- 76% require minimum # BG checks

- 25% require meeting A1c goal

- 80% felt ability to demonstrate carbohydrate counting was important
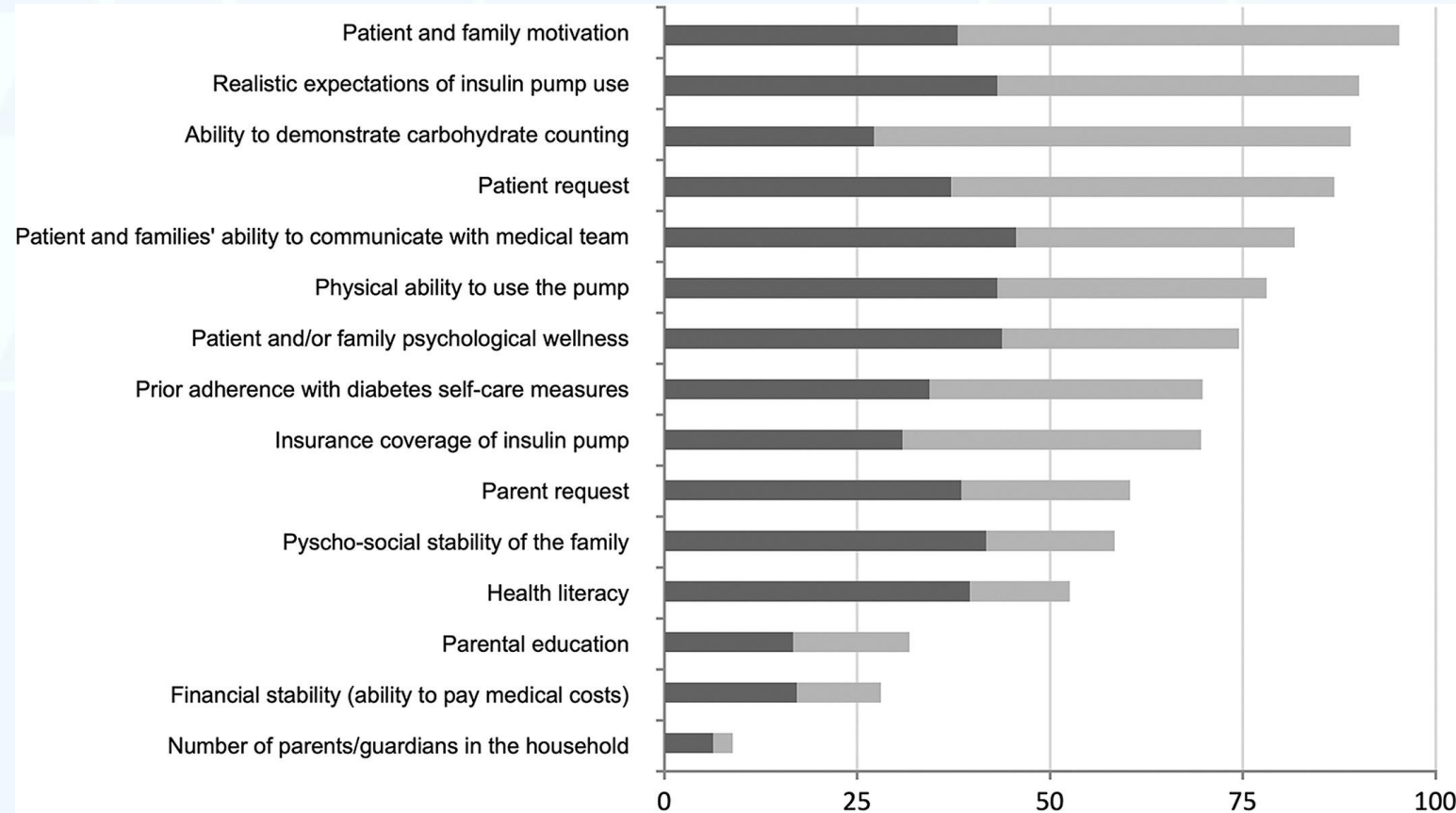
- Cross sectional study of 12-18 year olds (n=48)
- 23% able to demonstrate accurate carbohydrate estimation (within 10 g) for common meals

Randomized Nutrition Education Intervention to Improve Carbohydrate Counting in Adolescents with Type 1 Diabetes Study: Is More Intensive Education Needed?

Gail Spiegel MS, RD 👤 ✉, Andrey Bortsov MD, PhD, Franziska K. Bishop MS, Darcy Owen MS, RD, Georgeanna J. Klingensmith MD, Elizabeth J. Mayer-Davis PhD, RD, David M. Maahs MD, PhD

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- 12-18 year olds screened for carbohydrate counting accuracy
- 34/101 (33.7%) could identify carb counts within 10 g in 4 out of 6 meals

Is carbohydrate counting necessary on AID?

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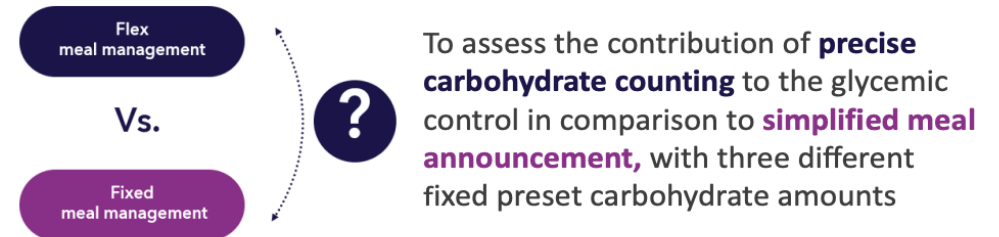Barbara Davis Center
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Simplified Meal Announcement Versus Precise Carbohydrate Counting in Adolescents With Type 1 Diabetes Using the MiniMed 780G Advanced Hybrid Closed Loop System: A Randomized Controlled Trial Comparing Glucose Control

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

Petrovski et al.

- 34 participants ages 12-18 in Qatar
- Minimed 780G users
- RCT of 3 personalized fixed carb amounts (fix) versus precise carb counting (flex)
- Fix – 3 preset carb options RD chose based on food diary
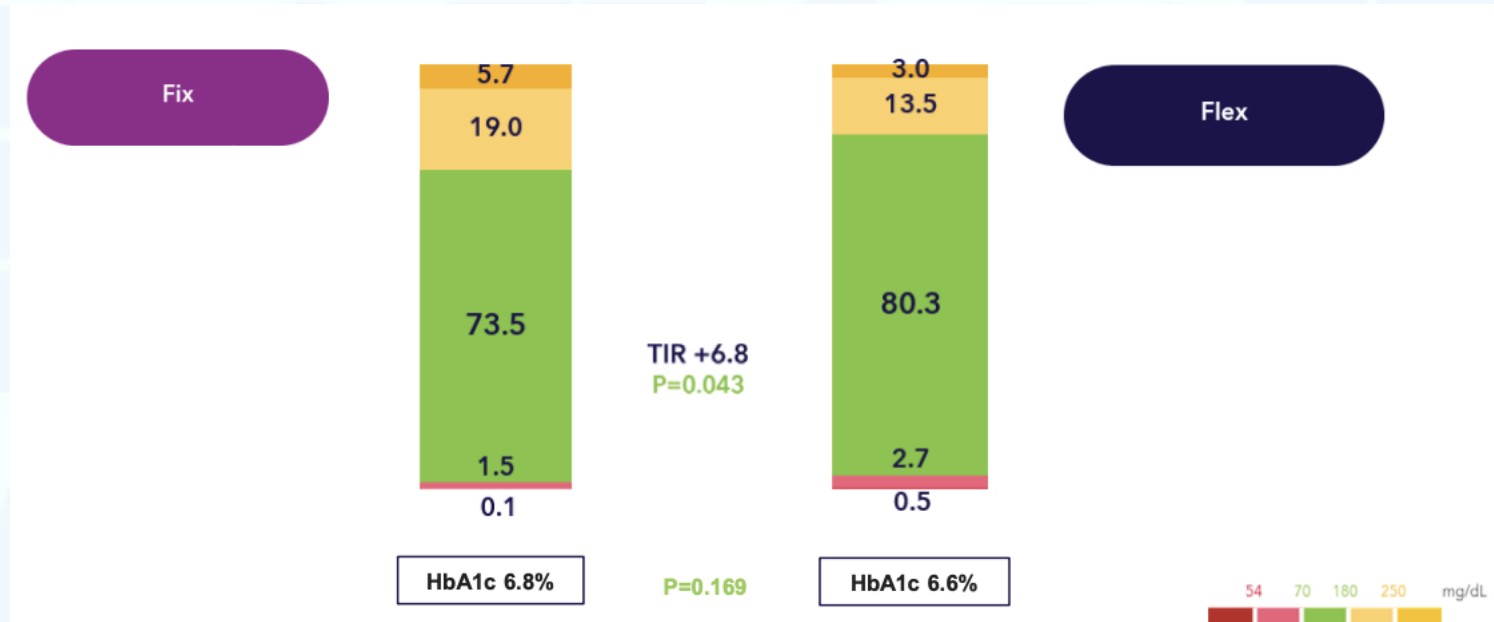 - Small 20 g (94%), regular 60 g (53%), and large 90 g (47%)

Petrovski et al.

- TIR: 73.5 ± 6.7% (fixed carbs) vs 80.3 ± 7.4% (flex), 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)

- HbA1c (P = 0.168), time below range (P = 0.283), and time between 180 and 250 mg/dL (P = 0.114) did not differ.

Twelve-Month Follow-up from a Randomized Controlled Trial of Simplified Meal Announcement Versus Precise Carbohydrate Counting in Adolescents with Type 1 Diabetes Using the MiniMed™ 780G Advanced Hybrid Closed-Loop System

Goran Petrovski, MD, PhD,[1] Judith Campbell, MN,[1] Maheen Pasha, BsC,[1] Khalid Hussain, MD, MPH,[1] Amel Khalifa, MD,[1] Fareeda Umer, BNurs,[1] Douha Almajaly, BNurs,[1] Manar Hamdar, BNurs,[1] Tim van den Heuvel, PhD,[2] and Shannon N. Edd, PhD[2]

- 12 month follow-up of prior RCT, outcomes recorded at 3, 6, 9, and 12 months

- At 12 months: TIR significantly lower in the fix versus flex group (72.9% vs. 80.1%, respectively; P = 0.001)

- No significant difference in HbA1c between the fix (6.8%) and flex groups (6.5%) at 12 months (P = 0.092)
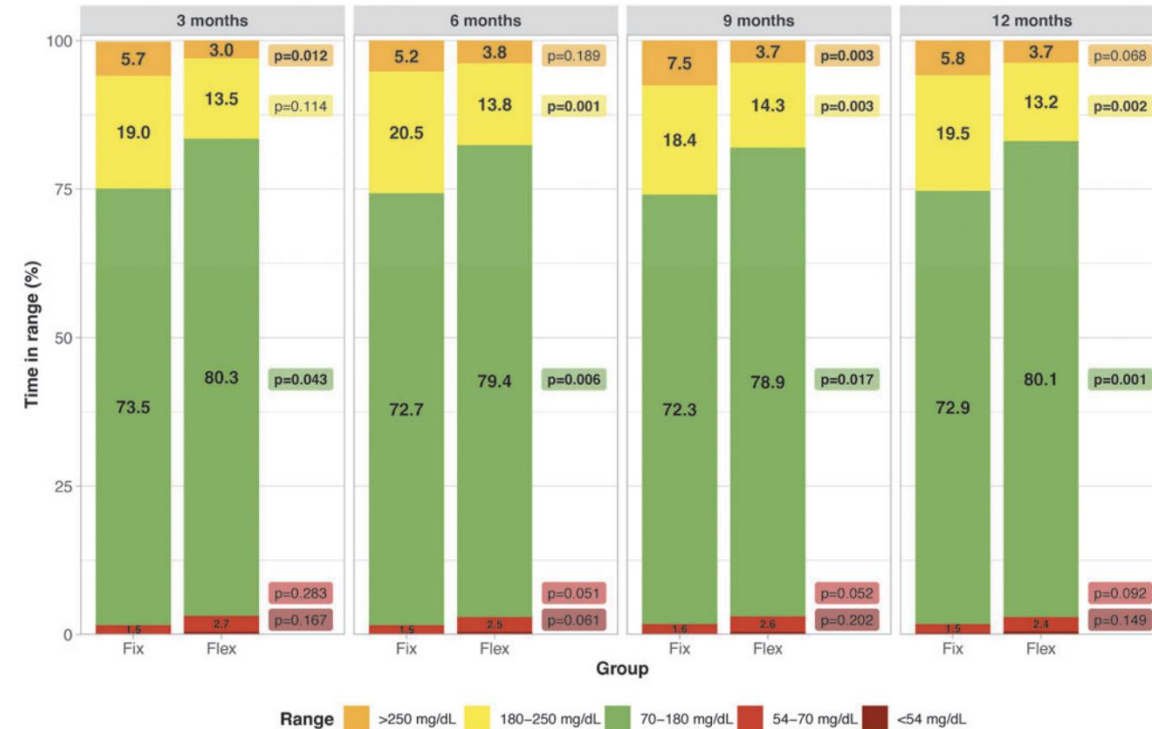

FIG. 1. Proportion of time in ranges over the four study periods. Values are shown as percentage of time spent in ranges during the interval. Time with glucose values <54 mg/dL are not shown on the graph and are as follows, fix versus flex: 0.1%±0.3% versus 0.5%±0.3%, P=0.167 at 3 months, 0.1%±0.4% versus 0.5%±0.7%, P=0.061% at 6 months, 0.2%±0.3% versus 0.5%±0.4%, P=0.202 at 9 months and 0.3%±0.4%, P=0.149 at 12 months.

6

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

- 30 adults on research devices (iPancreas)
- Carb counting vs 4 categories (<30 g (15), 30-60g (35), 60-90g (65), >90g (95))

Simplified meal announcement study (SMASH) using hybrid closed-loop insulin delivery in youth and young adults with type 1 diabetes: a randomised controlled two-centre crossover trial

Céline I. Laesser[1,2] · Camillo Piazza[3] · Nina Schorno[3] · Fabian Nick[3] · Lum Kastrati[3,4,5] · Thomas Zueger[3,6] · Katharine Barnard-Kelly[7,8] · Malgorzata E. Wilinska[9] · Christos T. Nakas[10,11] · Roman Hovorka[9] · David Herzig[3] · Daniel Konrad[1,2] · Lia Bally[3]

- 46 participants ages 12-20

- Mylife CamAPS FX system (YpsoPump, Dexcom G6)

- 3 months CC vs 3 months simple

- 3 day diet history: mean CHO intake per meal was rounded and classified as a medium meal size
  - snack: 25%, small meal 50%, large meal 150%
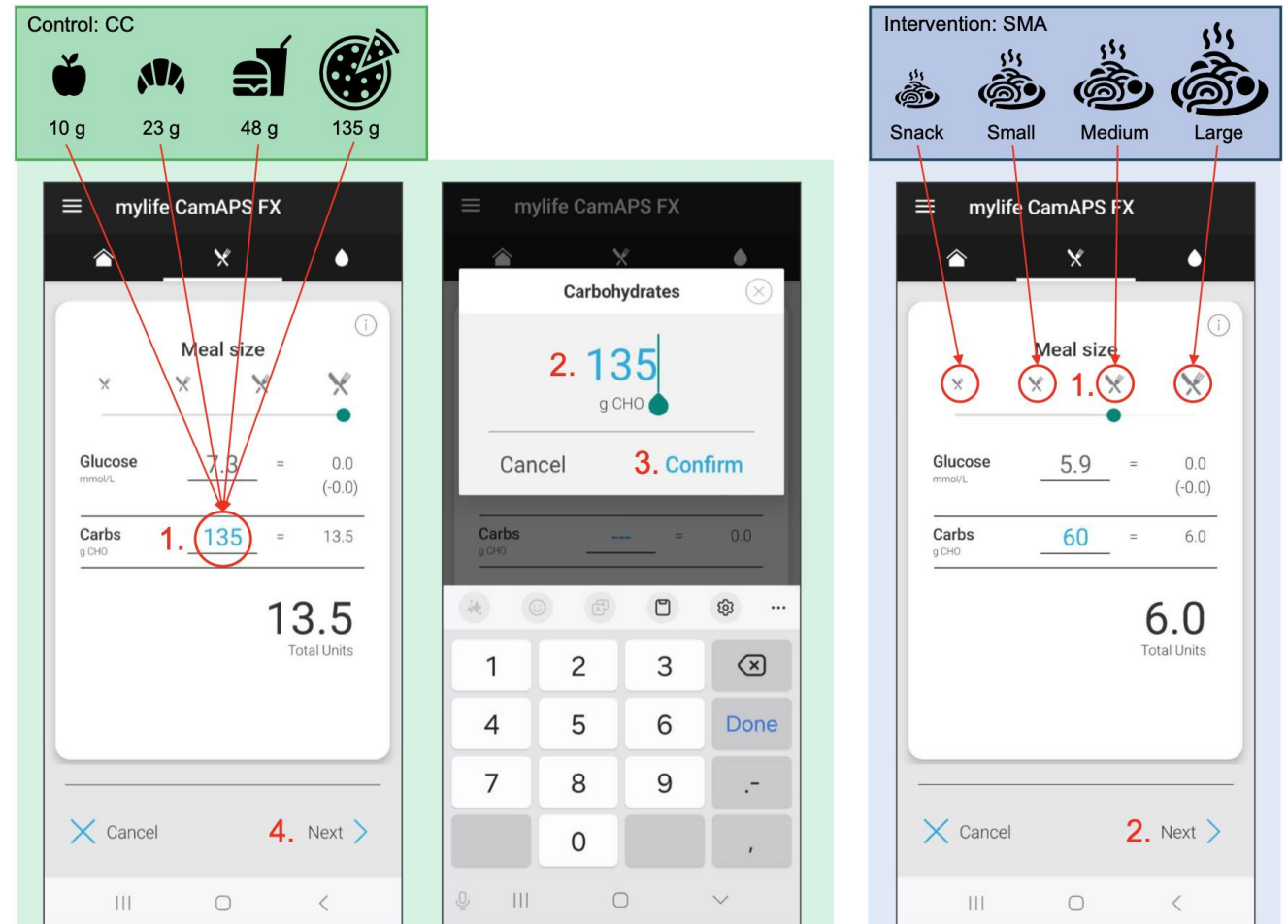
Results

Simplified meal announcement study (SMASH) using hybrid closed-loop insulin delivery in youth and young adults with type 1 diabetes: a randomised controlled two-centre crossover trial

Simplified Meal Management in Adults Using an Advanced Hybrid Closed-Loop System

Noga Minsky, MD,[1] Roy Shalit, MPH,[1] Andrea Benedetti, BME,[3] Maya Laron-Hirsh, BSc,[1] Ohad Cohen, MD, MBA,[1–3] Natalie Kurtz, DVM,[3] Anirban Roy, PhD,[3] Benyamin Grosman, PhD,[3] and Amir Tirosh, PhD[1,2]

- 14 adults with T1D on Medtronic 780G
- 13 weeks of carb counting
- 3-4 weeks of entering 1 preset amount (based on age and kg)
- 3-4 weeks of entering 1x, 2x, or 3x the preset amount
- 1 preset: TIR 75.4 % vs. Precise TIR 77.7%, P = 0.12
- Multiple preset: 80.5% vs Precise 77.7, p = 0.02

Simplified Meal Bolus Strategies with Control-IQ+ Automated Insulin Delivery Are Safe and Effective in Adults with Type 2 Diabetes

Carol J. Levy, MD,[1] Lauren Kanapka, PhD,[2] Sue A. Brown, MD,[3] Sheryl Marks, MD,[4] Tamara Spaic, MD, FRCPC, MSc,[5] Devin W. Steenkamp, MBChB,[6,7] Virginia S. Lu, MS,[8] Peter Zhao, MS,[8] John W. Lum, MS,[2] Roy W. Beck, MD, PhD,[2] and Jordan E. Pinsker, MD,[8] for the 2IQP Study Group*

- 201 adults with Type 2 diabetes on Control IQ+
- 13 week trial, main outcome change in A1c
- 2:1, AID vs pre-trial insulin delivery

TABLE 1. CLASSIFICATION OF MEAL BOLUS STRATEGIES USED IN THE TRIAL AMONG AID PARTICIPANTS

Classification	Number of participants	Criteria
Carbohydrate Counting	68	≥25% of user-initiated boluses included entered carbohydrates <60% of user-initiated boluses w/carbs were their top four entries
Preset Carbohydrate Amounts[a]	79	≥25% of user-initiated boluses included entered carbohydrates ≥60% of user-initiated boluses w/carbs were their top four entries
Fixed Insulin Doses[a]	27	<25% of user-initiated boluses included entered carbohydrates ≥60% of user-initiated boluses were their top four entries
Other Methods	27	<25% of user-initiated boluses included entered carbohydrates <60% of user-initiated boluses were their top four entries

[a]Also commonly referred to as simplified dosing or small/medium/large.

Results

- Similar, significant improvements in HbA1c from baseline
  - -0.9% for Carbohydrate Counting (P < 0.001)
  - -1.1% for Preset Carbohydrate Amounts (P < 0.001)
  - -0.8% for Fixed Insulin Doses (P < 0.001)
  - -0.9% for Other Methods (P = 0.003)

- Hypoglycemia rates were low at baseline and remained low for all bolus strategies.

- More participants opted to use a simplified bolus strategy in the second half of the study compared with the first half (63% vs. 52%).

SIMPLIFIED MEAL BOLUSES VERUS CARBOHYDRATE COUNTING IN ADOLESCENTS WITH HYBRID CLOSED LOOP SYSTEMS: A Randomized Crossover Trial

Alexandra Sawyer, Lindsey Towers, Samantha Lange, Amy Stein, Cari Berget, Gregory Forlenza[1]

[1]Barbara Davis Center for Diabetes, University of Colorado Anschutz Medical Campus, Aurora, CO, USA

AIMS

- **The objective of this study was to evaluate the effectiveness of a simple meal bolus strategy in achieving glycemic control while reducing mealtime burden**

- Aim 1: To evaluate the difference in glycemic control (including TIR, mean sensor glucose, SG coefficient of variation) in adolescents and young adults on HCL systems while using a simple meal bolus strategy and while using precise carbohydrate counting (4 weeks each).

- Aim 2: To evaluate the safety of using simple meal boluses.

- Aim 3: To evaluate the feasibility, acceptability, and self-reported mealtime insulin bolus burden of using simple meal boluses in adolescents and young adults.

Methods

- Prospective randomized crossover trial in participants age 14-26 using AID systems
- Simple Meal Bolus Strategy
  - Participants instructed to enter 30, 60, or 90 g for small/medium/large meals
  - Carbohydrate ratios standardized to 450/TDD
- Precise Carbohydrate Counting
  - Provided basic re-education on carbohydrate counting
  - Instructed to enter exact carbohydrate counts
- We hypothesized TIR would not be inferior by more than 5% during the simple bolus period. Other measures of glycemic control compared using paired t-tests
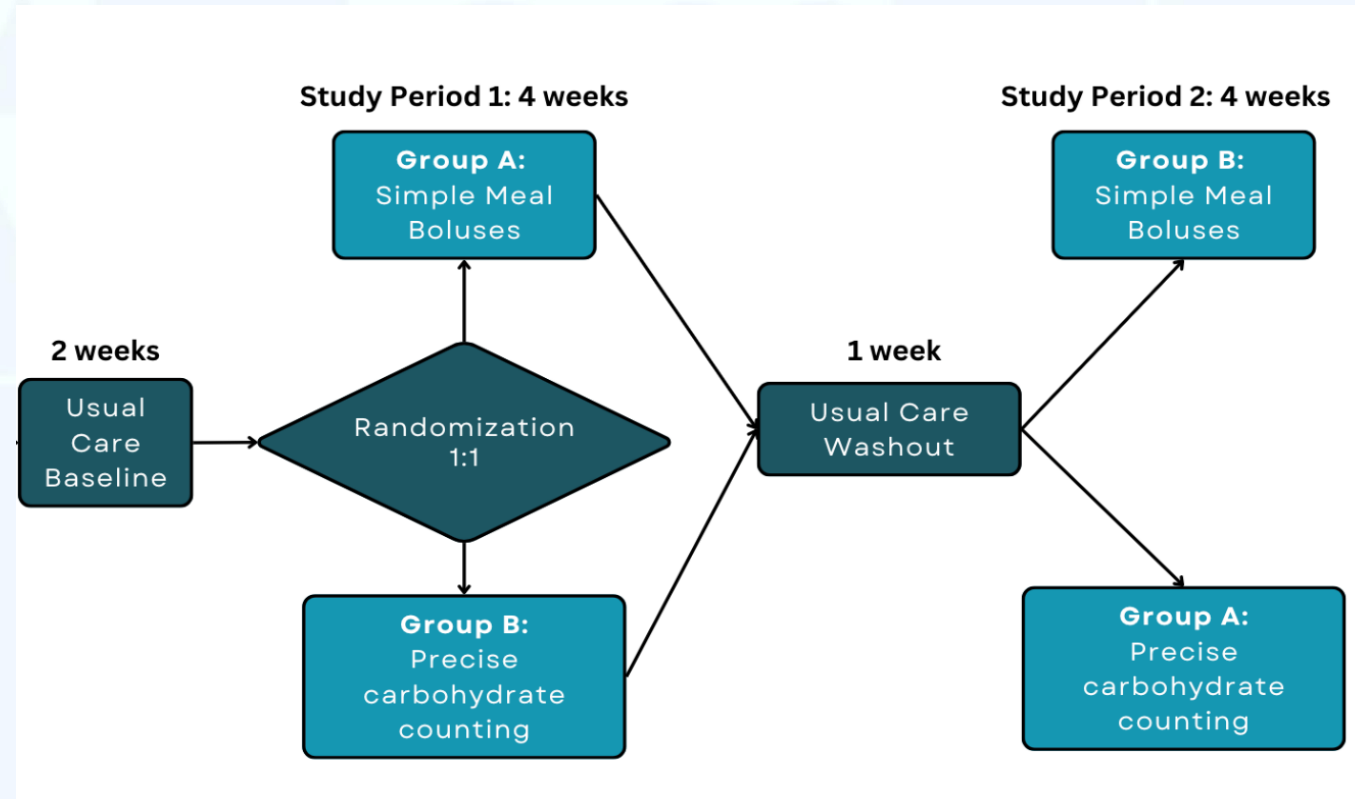
Results

- **31** participants
  - 17.4 yrs; 51.6% female; T1D$_{Dur.}$ 8.3 yrs
  - 67.7% Tandem, 19.4% OP5, 12.9% 780G
  - Baseline TIR 63.8%
- Baseline bolus habits
  - Baseline # boluses/day: 4.6
  - Educated guessing (90.3%), Entering similar values each meal (6.5%), or Using labels/resources to CC (3.23%)

Demographics	
N	31
Age (years ± SD)	17.4 ± 3.0 [14.0, 23.0]
Race/Ethnicity – n (%)	
Non-Hispanic White	28 (90.3%)
Hispanic	1 (3.2%)
Black or African American	1 (3.2%)
Asian	1 (3.2%)
Gender – n (%)	
Female	16 (51.6%)
Male	15 (48.4%)
Insurance – n (%)	
Public	5 (16.1%)
Private	24 (77.4%)
Other	2 (6.5%)
Diabetes duration (years ± SD)	8.3 ± 3.4 [2.4, 14.5]
AID system – n (%)	
Tandem Control IQ	21 (67.7%)
Omnipod 5	6 (19.4%)
Medtronic 780G	4 (12.9%)
Baseline TIR (mean % ± SD)	63.8 ± 10.4 [43.0, 89.0]
Baseline # of User Boluses/day (mean % ± SD)	4.6 ± 2.6 [1.0, 12.0]

Results

- TIR with simple meal boluses **was not inferior** to TIR with CC

- Simple TIR 64.2% vs CC TIR 66.0%, (difference -1.7%, 95% CI: -3.9, ∞, p = 0.008, indicating non-inferiority at a margin of Δ = 5)

- There were no differences in % time > 250 mg/dL (difference 1.2%, p = 0.3) and % time < 70 mg/dL (difference -0.02%, p = 0.9)

Bar chart. Values — Time in Range 70-180 mg/dL, %: Simple Meal Boluses 64.2, Precise Carbohydrate Counting 66. Time less than 70 mg/dL, %: Simple Meal Boluses 2, Precise Carbohydrate Counting 2. Time over 250 mg/dL, %: Simple Meal Boluses 11.7, Precise Carbohydrate Counting 10.6.
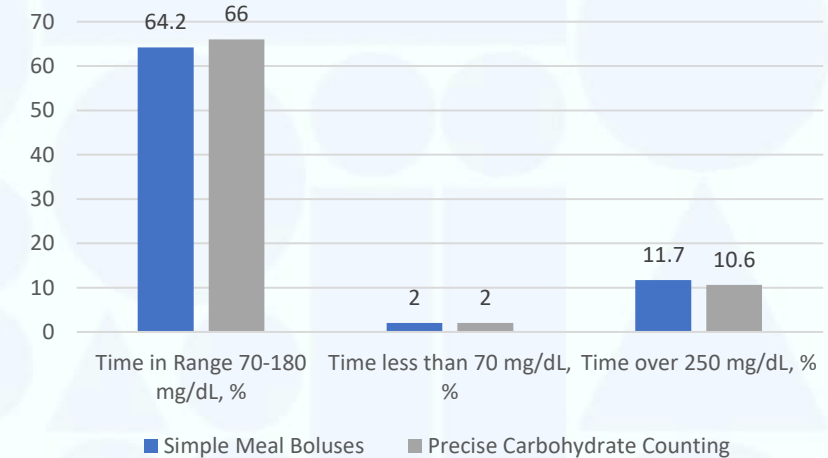
	Simple	CC	Difference	P-value
Mean SG, mg/dL	167.1	161.7	5.4	0.1
CV SG, %	39.2	38.3	0.7	0.2
Mean daily user boluses	4.5	5.1	-0.7	0.04
Mean TDD, units	68.6	69.3	-0.7	0.7
Average daily carbs, g	139.2	144.3	-5.0	0.7

Comparison of Survey Responses at Baseline and During the CC and Simple Meal Bolus Study Periods

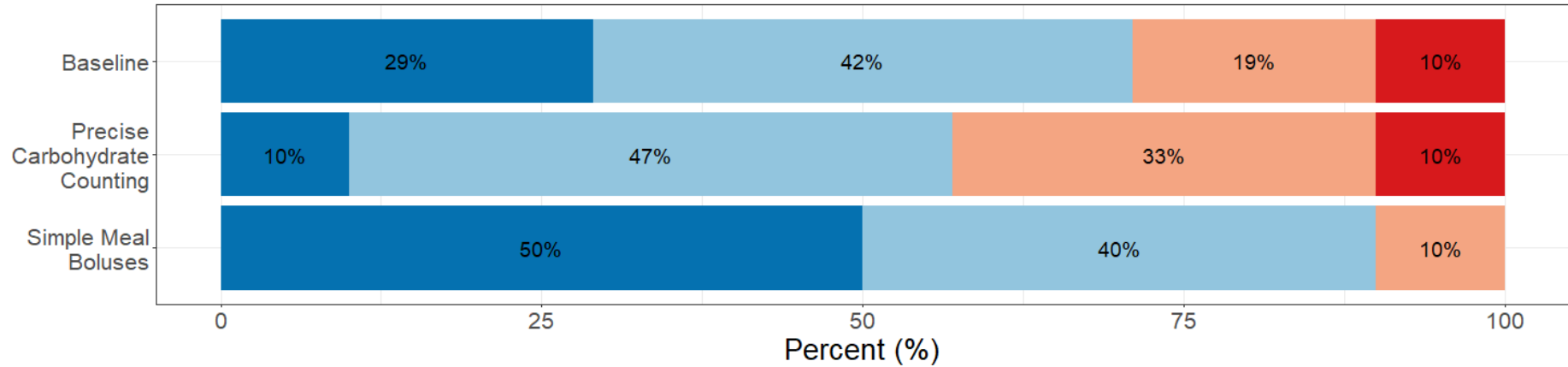| QUESTION	BASELINE	PRECISE CARBOHYDRATE COUNTING	SIMPLE MEAL BOLUS STRATEGY	P-VALUE**
How often did you need to eat extra food to avoid low blood sugar due to too much insulin at a meal	2.52 (0.93)	2.55 (0.93)	2.81 (1.01)	0.3310
How often did you need to take extra insulin because blood sugar was high after eating	3.43 (0.82)	3.67 (0.61)	3.70 (0.99)	0.1625
How often did you forget to give insulin before a meal	2.74 (1.03)	2.80 (0.96)	2.57 (0.90)	0.4169
How often are you worried about post-meal blood glucose	1.94 (0.51)	2.07 (0.52)	2.17 (0.79)	0.2319
How did this meal bolus strategy impact quality of life	-	2.90 (0.92)	2.50 (1.04)	0.1249
How burdensome did bolusing for meals feel	2.03 (0.89)	2.43 (0.82)	1.60 (0.67)	0.0007
How difficult was it to determine how much insulin to give at meals	1.58 (0.62)	1.83 (0.75)	1.63 (0.61)	0.3321

*Higher scores indicated worse outcomes (higher frequency, burden, worry, difficulty, or negative impact

** The p-value is based on a Friedman test (non-parametric RM ANOVA)

Results

How burdensome did bolusing for meals feel in day to day life?

	Never burdensome	Occasionally burdensome	Moderately burdensome	Very burdensome
Baseline	29%	42%	19%	10%
Precise Carbohydrate Counting	10%	47%	33%	10%
Simple Meal Boluses	50%	40%	10%	

Legend: Very burdensome · Moderately burdensome · Occasionally burdensome · Never burdensome

How did the meal bolus strategy impact your quality of life?

	Very negative impact	Moderately negative impact	No impact	Moderately positive impact	Very positive impact
Precise Carbohydrate Counting	3%	23%	36%	36%	3%
Simple Meal Boluses	3%	19%	10%	58%	10%

Legend: Very positive impact · Moderately positive impact · No impact · Moderately negative impact · Very negative impact
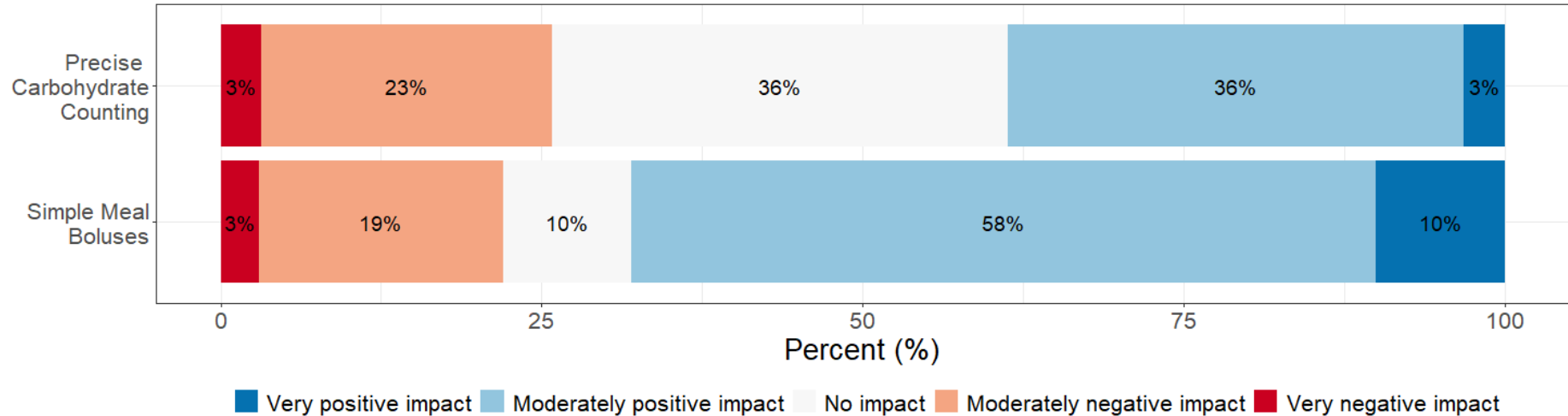
Results

Which method of determining how much insulin to give at meals do you prefer?
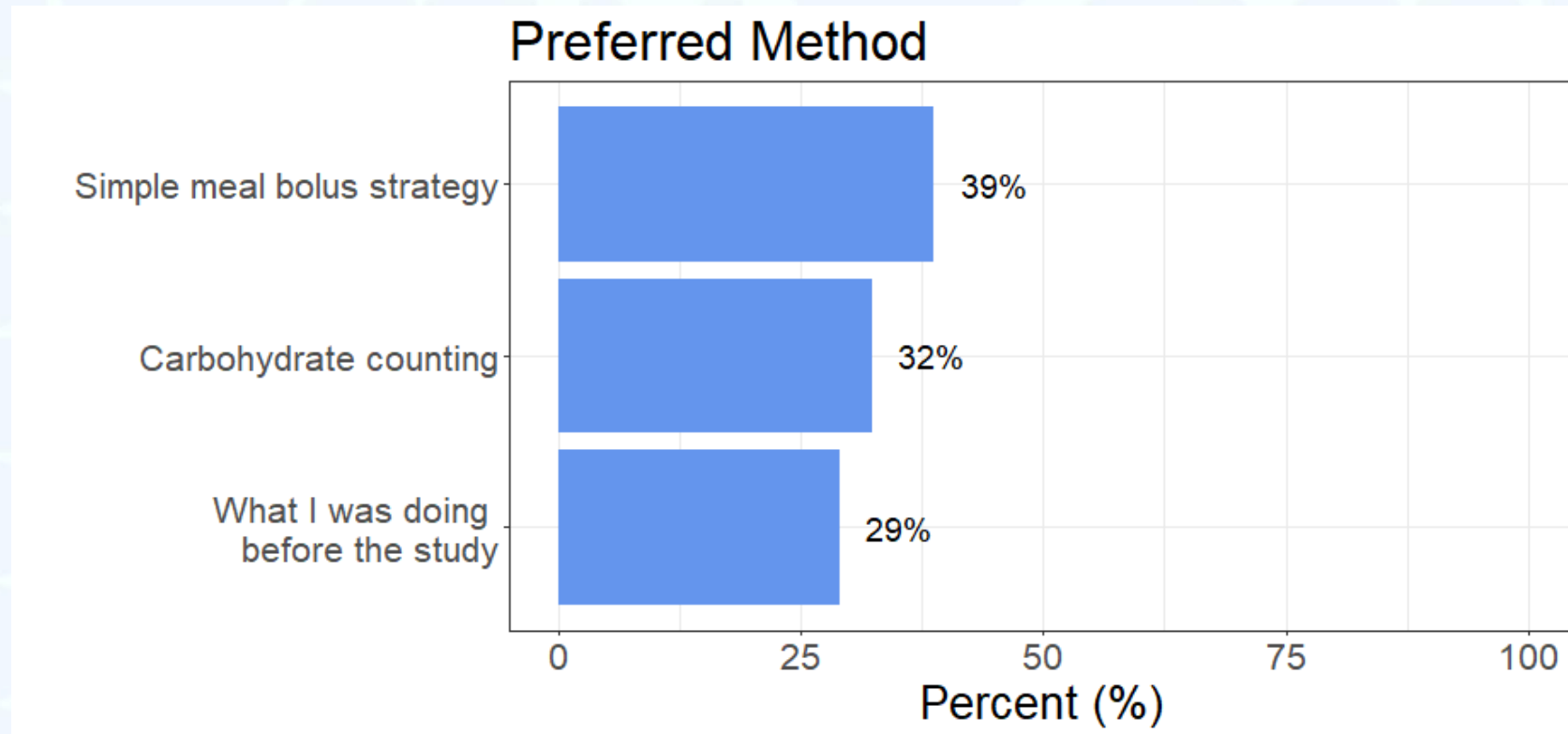
Conclusions

- Using a simple meal bolus strategy had a similar impact on glycemic control as precise carbohydrate counting

- Precise carbohydrate counting may be an unnecessary burden for T1D adolescents using AID, and requiring it could impact success with or access to these systems

Existing tools to implement simple meal boluses

Omnipod 5

Tap Custom Foods

Add Custom Food

Food Name

Enter a Name

0 / 32 Characters

Carbs (g)

0   g

Bolus

🍴 Carbs   CUSTOM FOODS

0   g

Meal Bolus: 0 U

🩸 Glucose   USE SENSOR

— —   mg/dL

Correction Bolus: 0 U

Total Bolus   CALCULATIONS

0   U

IOB of 1 U

CANCEL   CONFIRM

Custom Foods

Select custom food(s) to add

☑ Coffee   8 g

☑ Banana   24 g

☐ Pizza   98 g

Total: 32 g

2 items selected

CANCEL   ADD

Tandem Control IQ

- Could utilize quick bolus feature
- Tandem has PDF worksheets for different bolusing options, set carbs, set units etc
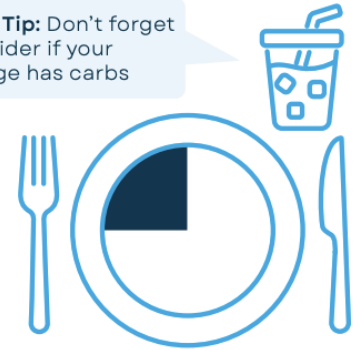
Know Your Carb Meal Sizes

Before you eat, look at the amount of carbs on your plate to decide your carb meal size (Small, Medium, Large, Extra Large). Use the My Carb Meal boxes below to enter one or two sample meals.

My Small Carb Meal

30 Grams OR _____ Grams

Helpful Tip: Don't forget to consider if your beverage has carbs
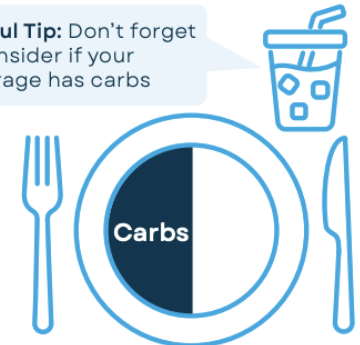
Know Your Carb Meal Sizes

My Medium Carb Meal

60 Grams OR _____ Grams

Helpful Tip: Don't forget to consider if your beverage has carbs

Carbs

My Large Carb Meal

90 Grams OR _____ Grams

Medtronic 780G

- Has preset bolus feature
- Breakfast, Lunch, Dinner, and Snack
- CANNOT be used in auto mode

Personalized

- Often used by our RD's

Mentors and Collaborators (alphabetical order)

Mentors & Collaborators:

Todd Alonso

Jen Barker

Cari Berget

Shanlee Davis

Gregory Forlenza

Megan Kelsey

Samantha Lange

Natalie Nokoff

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Grant Support

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