Evidence of Technology

YDEF 24.7.2025

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NHS Trust

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Disclosures

- KelCon GmbH: travel and accommodation fees for ATTD, Mar 2024.
- YDEF-Lilly scholarship to attend EASD, Sep 2024.
- EASD Robert Turner course,
  partially funded by Lilly, Apr 2025.

Learning outcomes

By the end of this session, attendants should be able to

1) Understand the research process behind the benefits of continuous glucose monitoring and pumps

2) Present a study in a PICO format

3) Recall 1 study per device

Abbreviations

PICO: Population, Intervention, Comparator, Outcome	IAH: Impaired awareness of hypoglycaemia
RCT: Randomised Controlled Trial	SH: Severe hypoglycaemia
RWE: Real world evidence	CBG: Capillary blood glucose
CGM: Continuous glucose monitoring	PROMs: Patient-reported outcome measures
isCGM: intermittently scanned CGM	T1D: Type 1 Diabetes
rtCGM: real-time CGM	PwT1D: person with T1D
HCL: Hybrid Closed Loop	PwD: person with Diabetes
TAR: Time above range	MDI: Multiple Daily Injections
TIR: Time in range	DDSc: Diabetes Distress Scale
TBR: Time below range	CSII: Continuous s/c insulin infusion

Contents

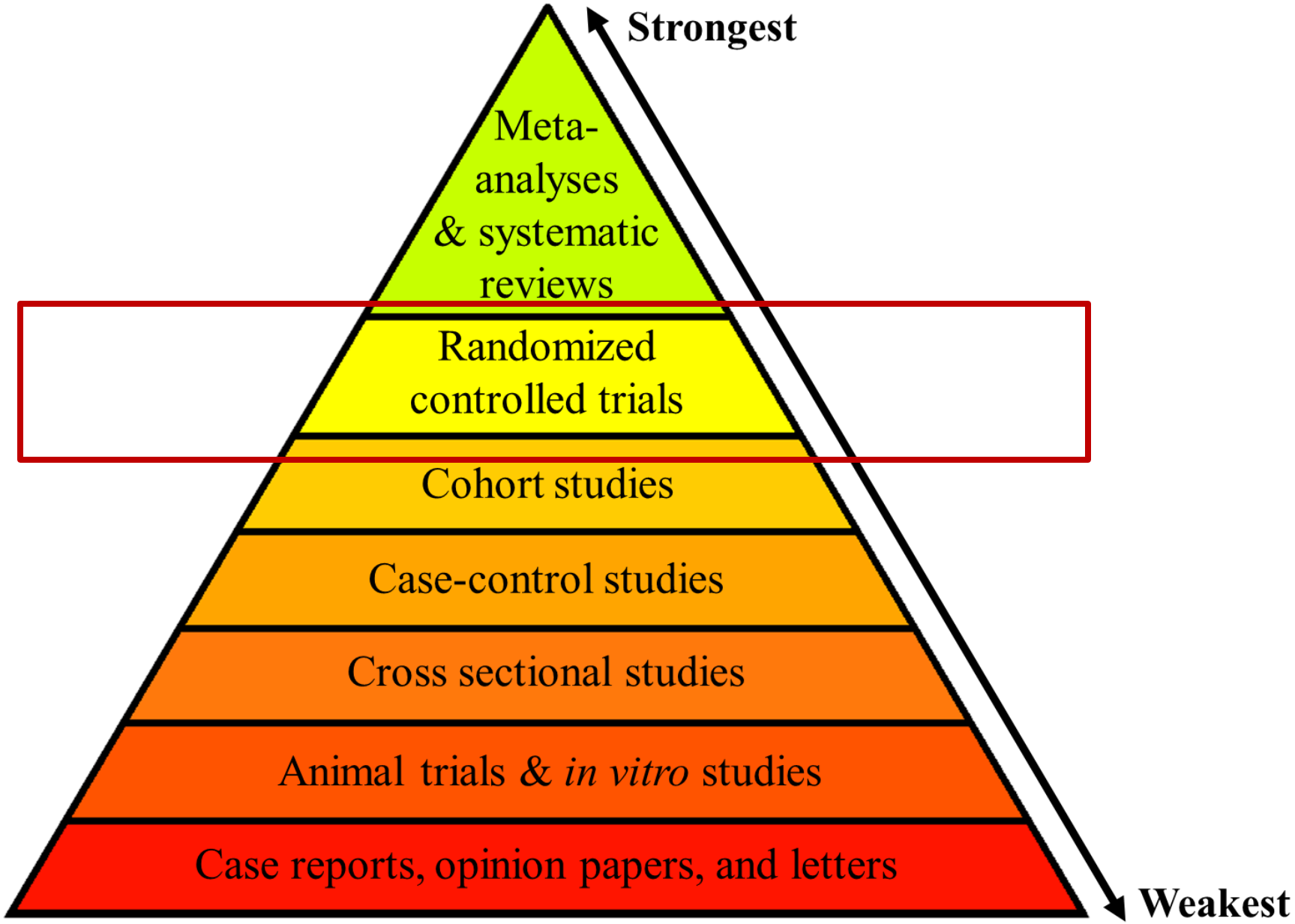
1) Research: the process

2) CGM:
   a) Minimed
   b) FSL
   c) FSL2
   d) Dexcom

3) HCL:
   a) T slim
   b) OP5
   c) Medtronic 780g
   d) CamAPS

Contents

Hierarchy of Scientific Evidence



thelogicofscience.com

RCTs vs RWE

RCTs	RWE
Prospective	Usually retrospective (observational)
Controlled conditions (experiment)	Real-world setting
Strict inclusion criteria: ‘select few’	Diverse participant population
Causal relationships	effectiveness, safety, usage
Low bias: however, trial effect!	Confounding factors
Expensive	Costs are lower
Time consuming: delay in adjustments to interventions due to study design requirements	Time is not a factor
“Can this work?”	“Does this actually work?”

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Minimed and TIR: InCONTROL 2015 (RCT)

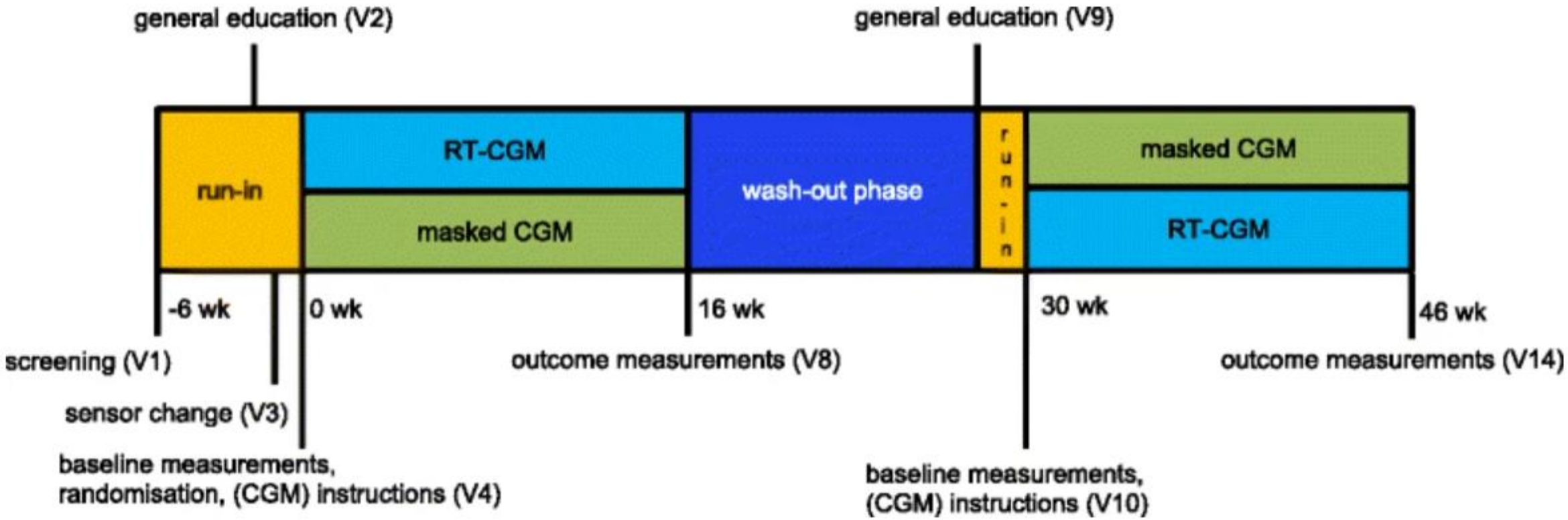
ARTICLES · Volume 4, Issue 11, P893-902, November 2016 Download Full Issue

Continuous glucose monitoring for patients with type 1 diabetes and impaired awareness of hypoglycaemia (IN CONTROL): a randomised, open-label, crossover trial

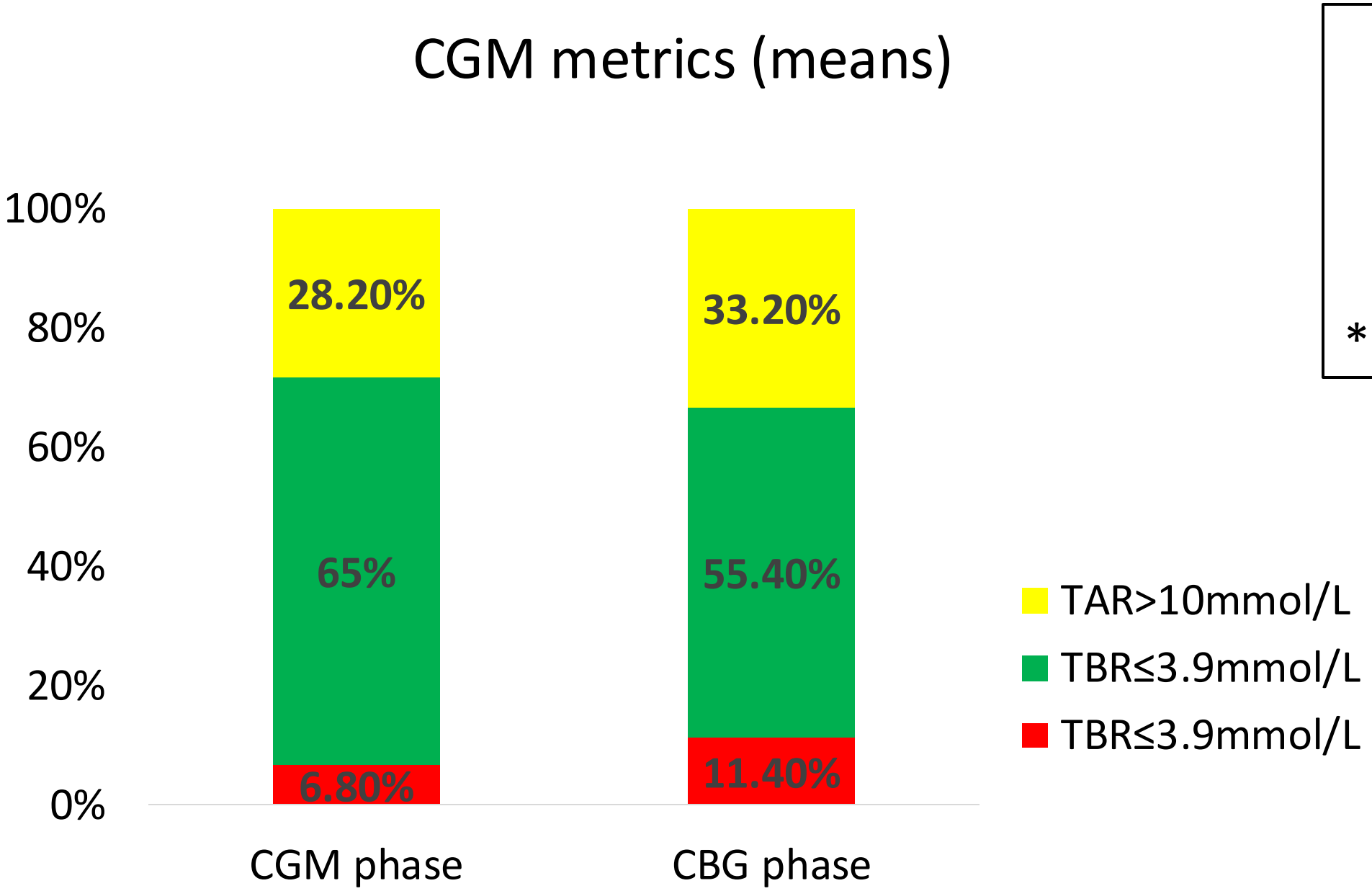
Dr Cornelis A J van Beers, MD [a] · Prof J Hans DeVries, MD [c] · Susanne J Kleijer, MD [a] · Mark M Smits, MD [a] · Petronella H Geelhoed-Duijvestijn, MD [e] · Prof Mark H H Kramer, MD [a] · Prof Michaela Diamant, MD [a,†] · Prof Frank J Snoek, PhD [b,d] · Erik H Serné, MD [a] Show less

P	PwT1D and IAH (Gold≥4), aged 18-75 yrs. HbA1c 7.5%-10.0% (58-86 mmol/mol), MDI
I	CGM (MiniMed Paradigm® Veo™ System)
C	CBG
O	*Primary*: TIR *Key secondary*: TBR, TAR, HbA1c, PROMs

InCONTROL: study design



Minimed usage increased TIR and reduced **TBR** and reduced TAR.



CGM vs CBG*

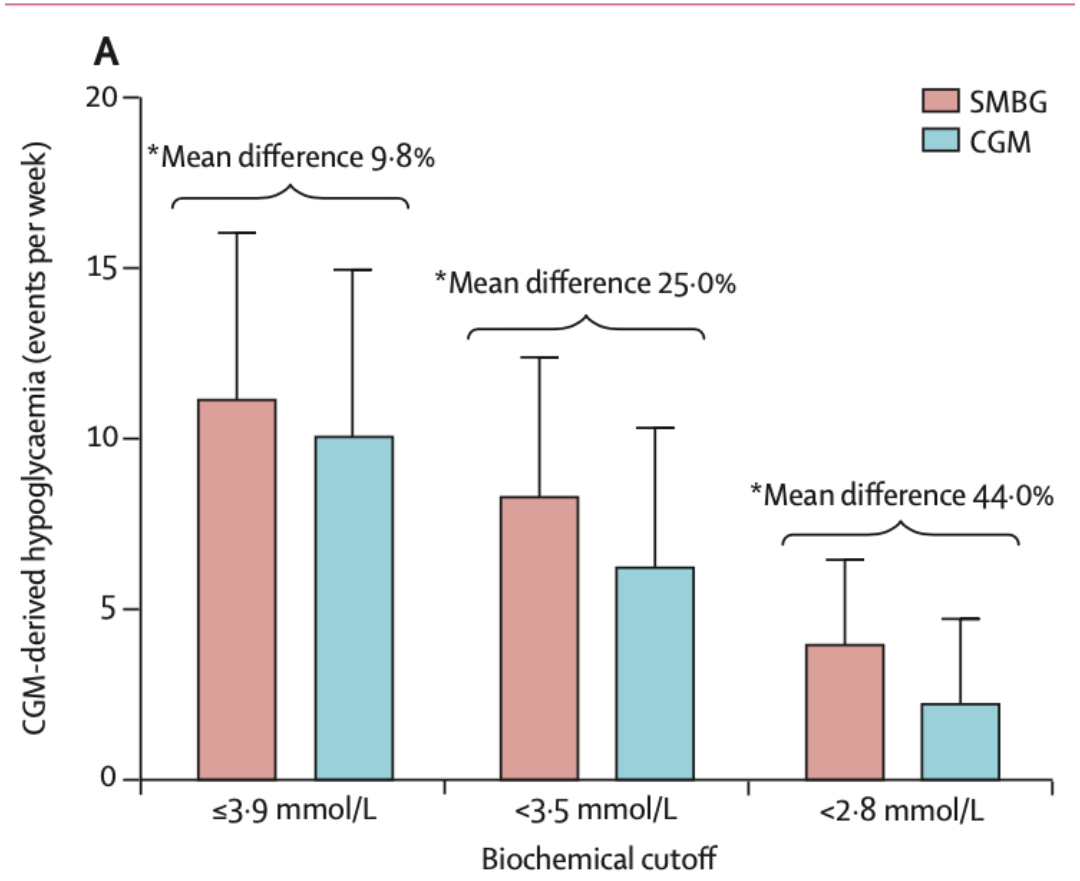
TIR: +9.6%

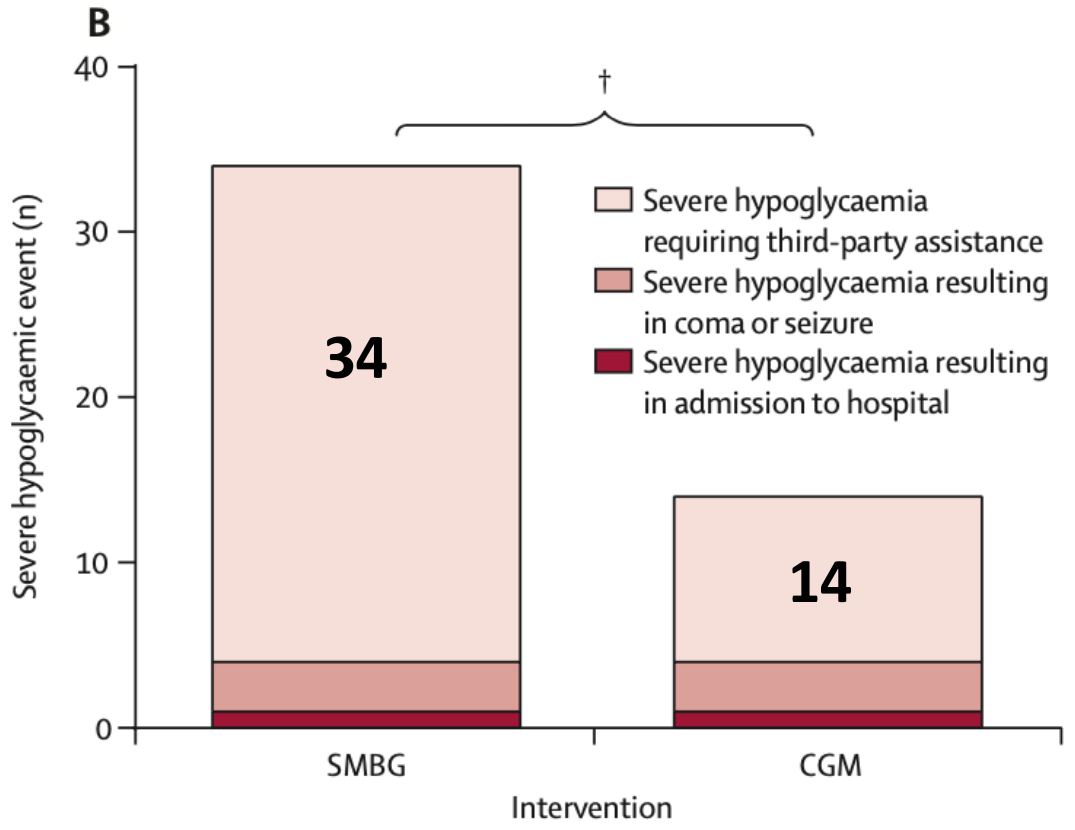
TAR: - 5%

TBR: -4.7%

* $p < 0.001$ for all

Minimed usage reduced **TBR** at three different cutpoints.
The number of SH episodes was lower during the CGM phase.





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FSL and glycaemic control, hypoglycaemia, diabetes-related distress, and hospital admissions: ABCD FSL audit 2020 (RWE)

EMERGING TECHNOLOGIES: DATA SYSTEMS AND DEVICES | JULY 15 2020

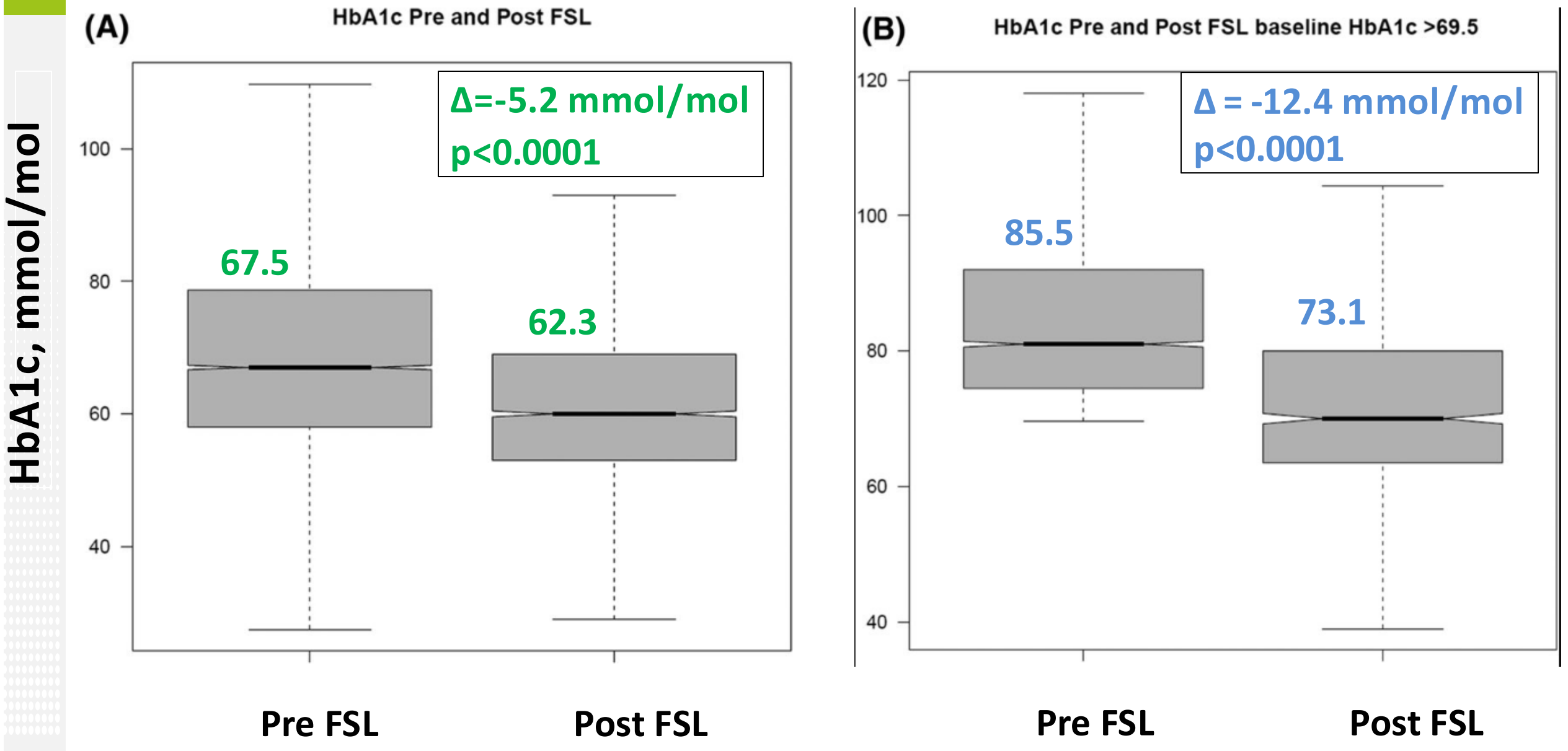
Effect of Flash Glucose Monitoring on Glycemic Control, Hypoglycemia, Diabetes-Related Distress, and Resource Utilization in the Association of British Clinical Diabetologists (ABCD) Nationwide Audit FREE

Harshal Deshmukh; Emma G. Wilmot; Robert Gregory; Dennis Barnes; Parth Narendran; Simon Saunders; Niall Furlong; Shafie Kamaruddin; Rumaisa Banatwalla; Roselle Herring; Anne Kilvert; Jane Patmore; Chris Walton; Robert E.J. Ryder; Thozhukat Sathyapalan

P	10,370 PwD (97% with T1D) on FSL
I	rtCGM (FSL)
C	CBG
O	*Primary*: glycaemic control, hypoglycaemia, diabetes-related distress, and resource utilisation **in the 12 months <u>before</u>** and **the 7.5 months <u>after</u>** initiation of CGM

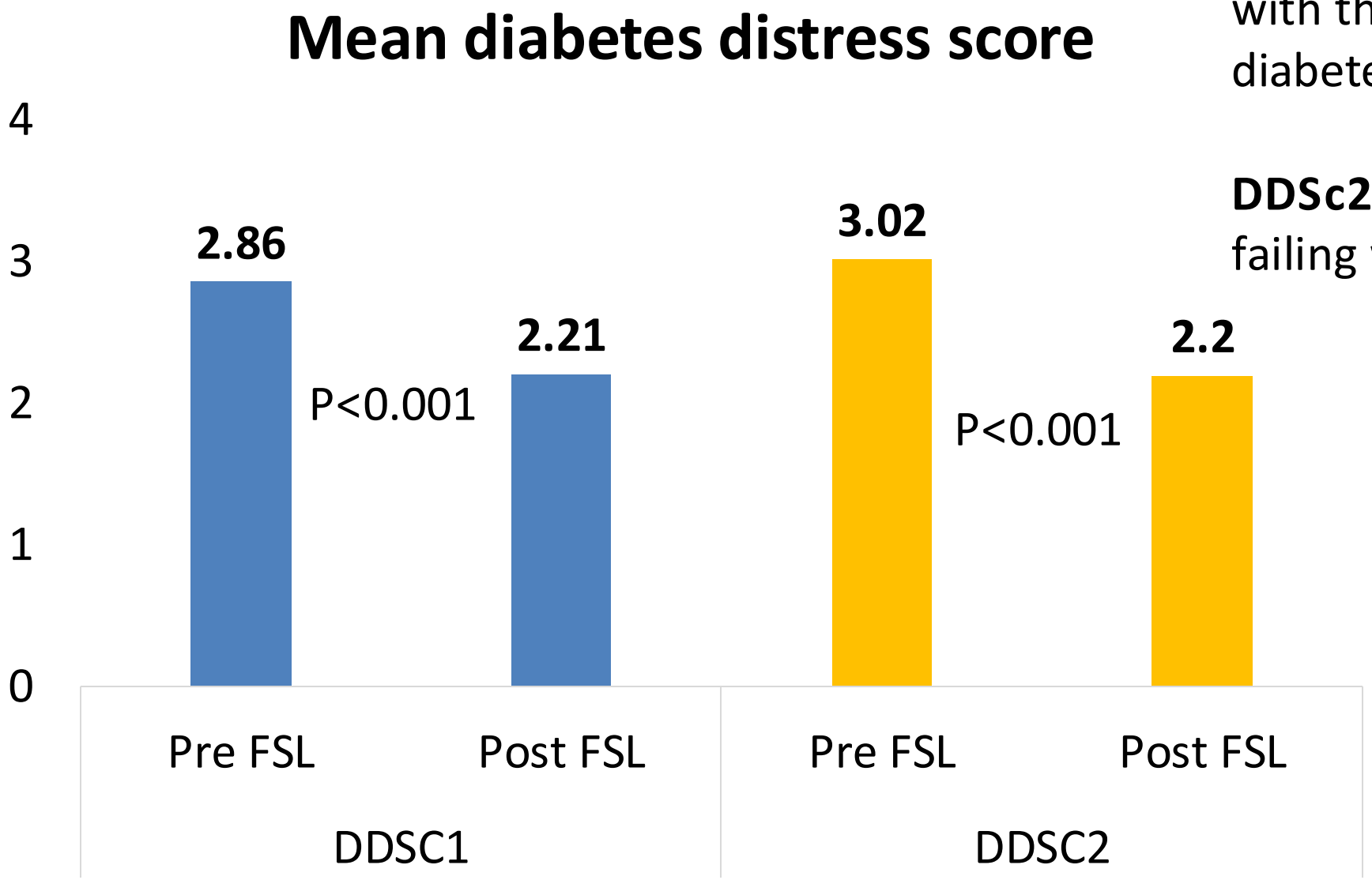
ABCD FSL audit and HbA1c

A1c decreased post-FSL start, with a larger decrease in A1c>69.5mmol/mol



ABCD FSL audit and DDS

Both scales showed reduction in diabetes distress

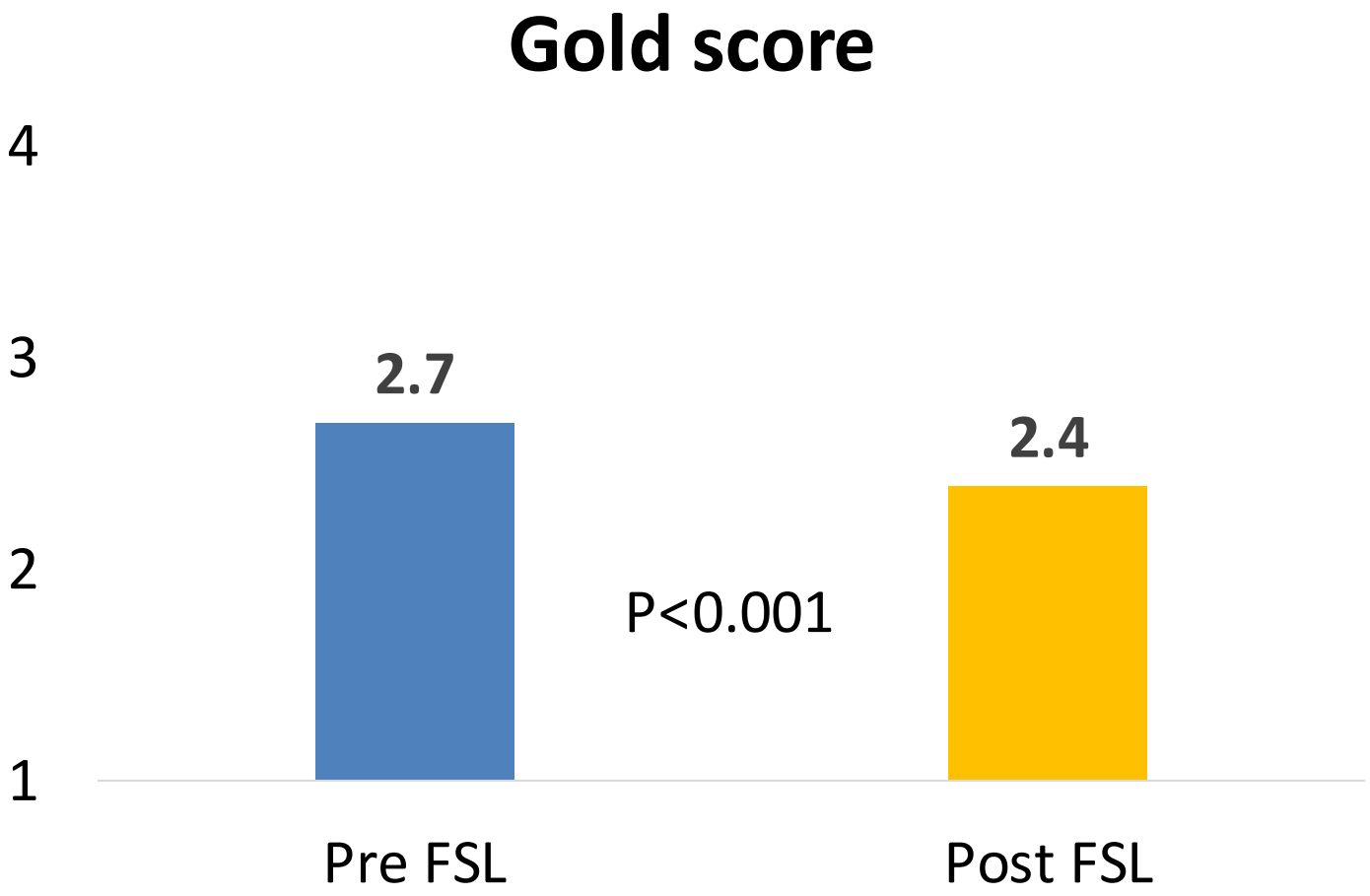


DDSc1: feeling overwhelmed with the demands of living with diabetes

DDSc2: feeling that I am often failing with my diabetes routine

ABCD FSL audit and IAH (Gold≥4)

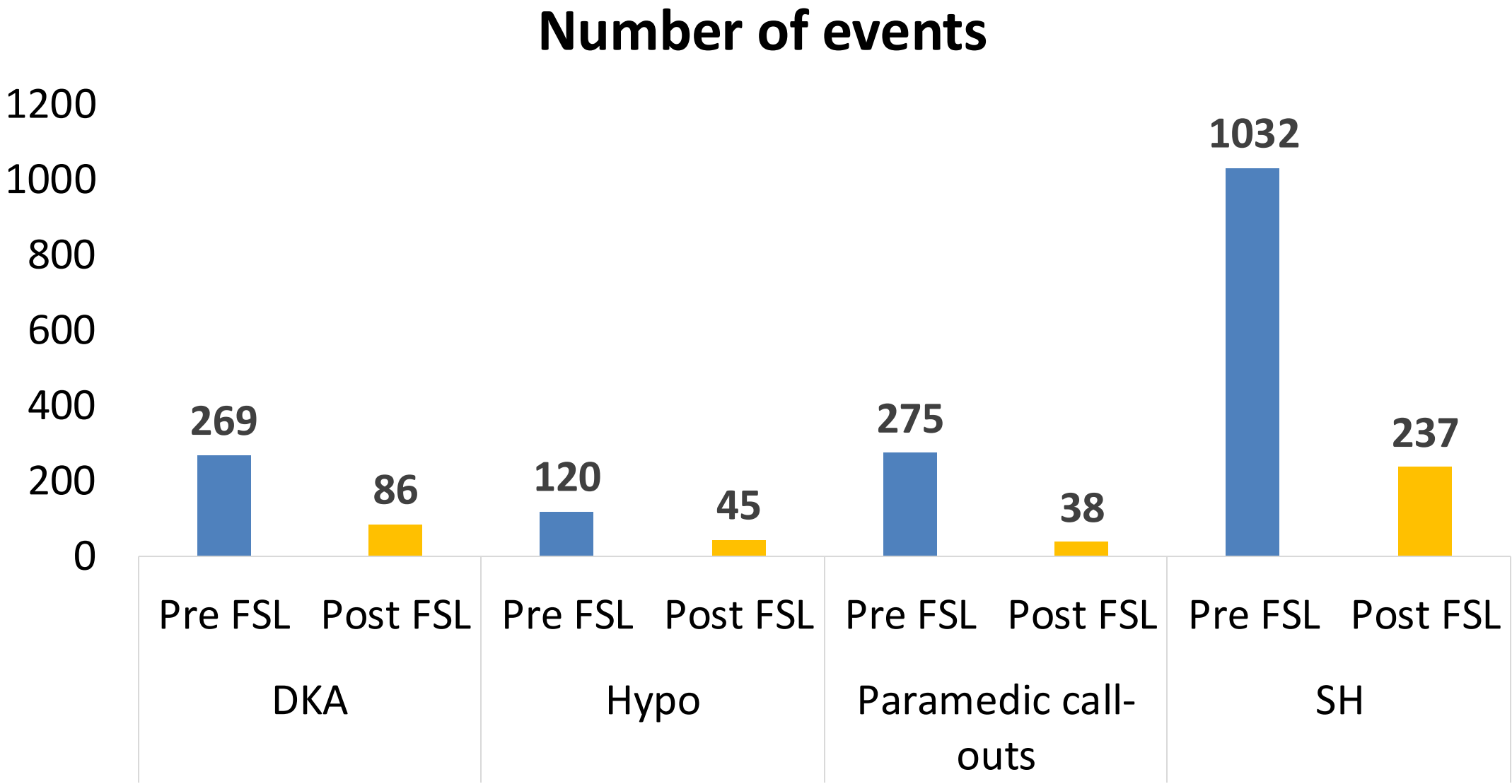
>50% regained hypoglycaemia awareness



- 53% of PwD and Gold≥4 reported Gold<4 at follow up
- 5% of PwD and Gold<4 reported Gold≥4 at follow up

ABCD FSL audit and resource utilisation

The total number of PwD with ≥1 SH reduced from 357 to 104 at follow-up



FSL and HbA1c: RELIEF 2021 (RWE)

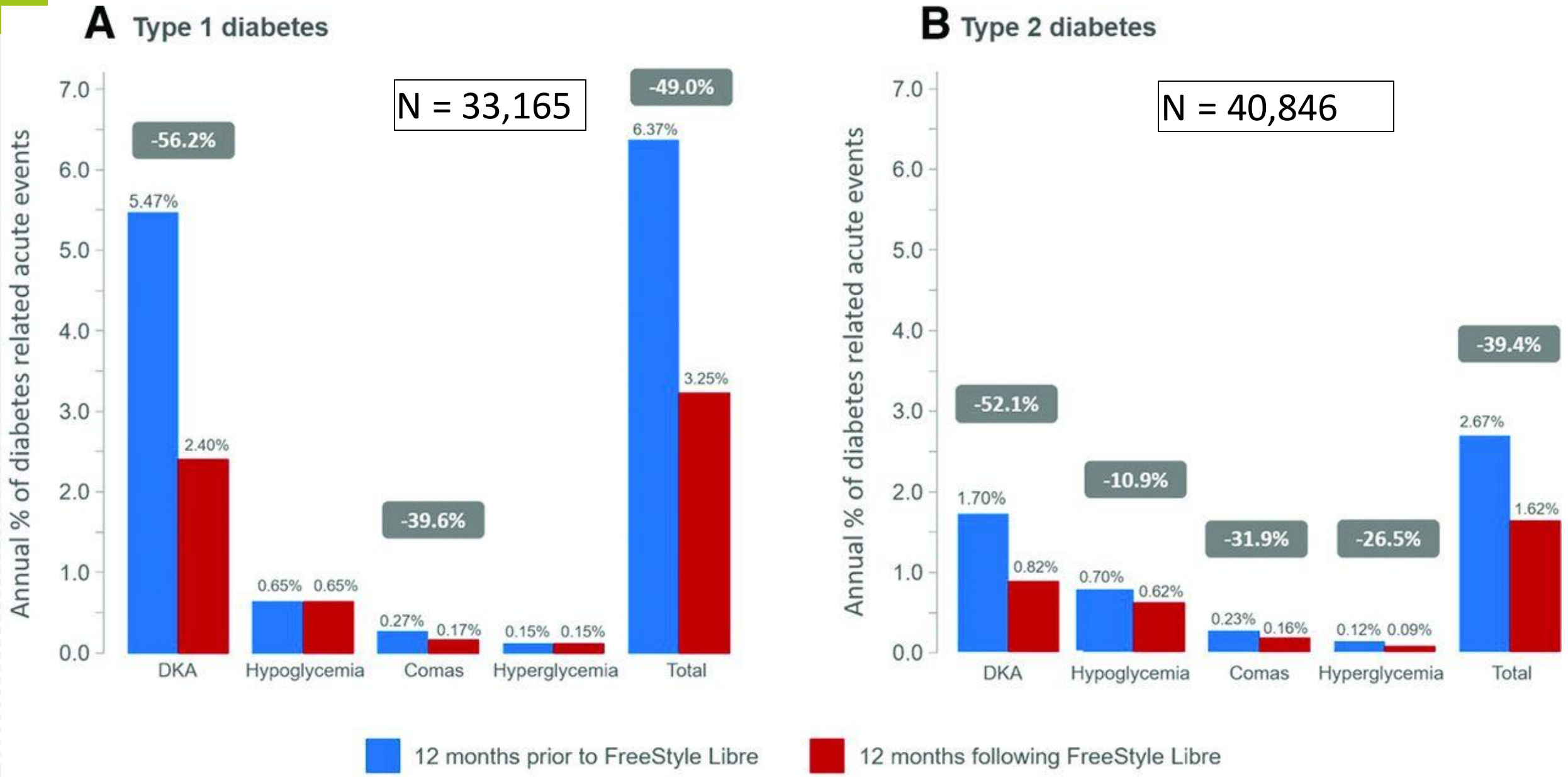
EMERGING TECHNOLOGIES: DATA SYSTEMS AND DEVICES | APRIL 20 2021

Important Drop in Rate of Acute Diabetes Complications in People With Type 1 or Type 2 Diabetes After Initiation of Flash Glucose Monitoring in France: The RELIEF Study FREE

Ronan Roussel; Jean-Pierre Riveline; Eric Vicaut; Gérard de Pouvourville; Bruno Detournay; Corinne Emery; Fleur Levrat-Guillen; Bruno Guerci

P	74011 PwD with hospitalisation due to acute diabetes-related complications
I	isCGM (FSL)
C	CBG
O	*Primary:* Risk of hospitalisation due to diabetes-related acute complications (DKA, hypoglycaemia, HHS, and hyperglycaemia) **in the 12 months <u>before</u>** and **the 12 months <u>after</u>** initiation of CGM

FSL reduced DKA and HHS admission rates in both T1D and T2D, and acute hypo-/hyperglycaemia in T2D 12 months before and after initiation.



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   c) Medtronic 780g
   d) CamAPS

FSL2 and HbA1c: FLASH-UK 2022 (RCT)

Intermittently Scanned Continuous Glucose Monitoring for Type 1 Diabetes

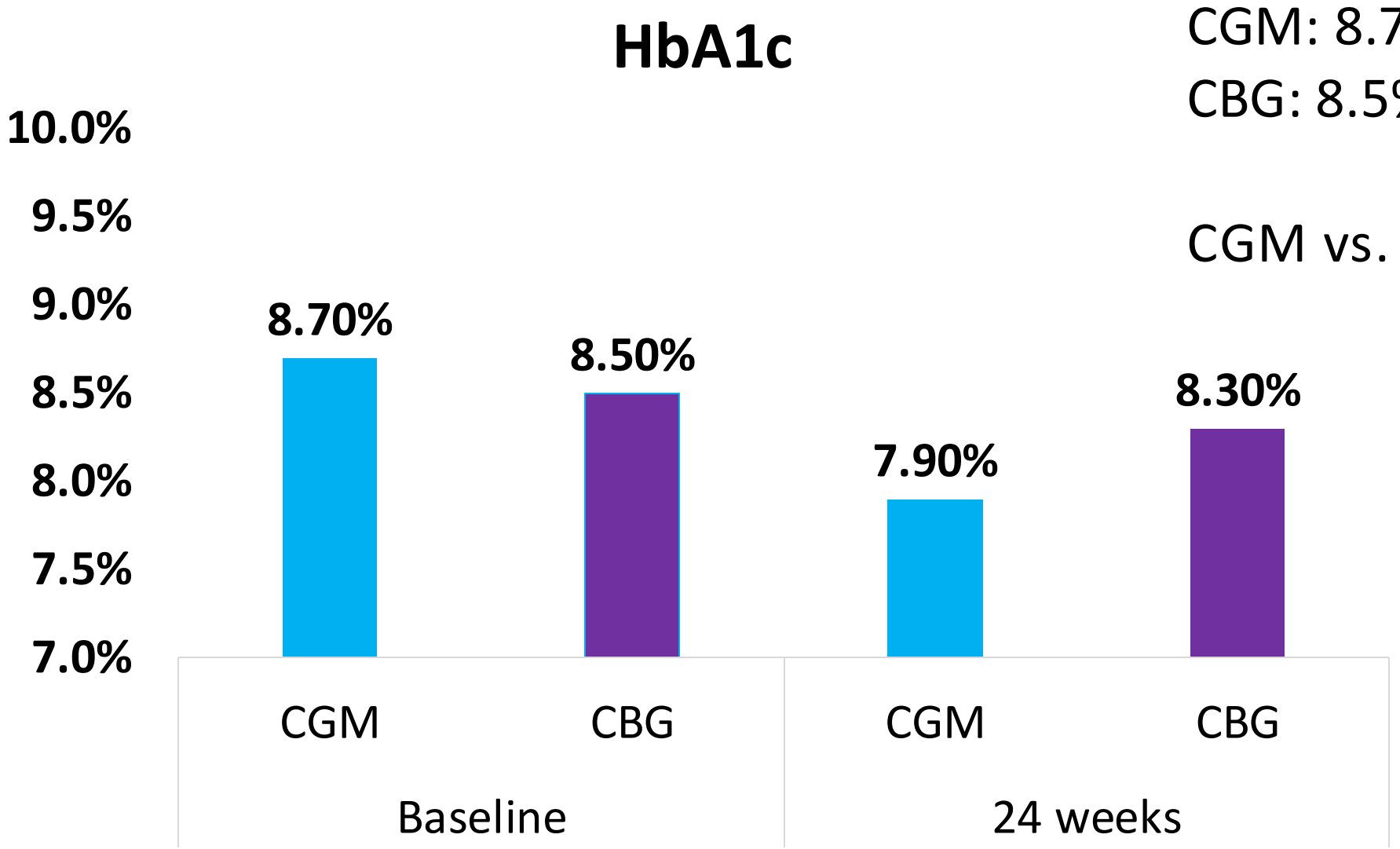
Authors: Lalantha Leelarathna, Ph.D. , Mark L. Evans, M.D., Sankalpa Neupane, Ph.D., Gerry Rayman, M.D., Sarah Lumley, M.R.C.G.P., Iain Cranston, F.R.C.P., Parth Narendran, Ph.D., Katharine Barnard-Kelly, Ph.D., Christopher J. Sutton, Ph.D., Rachel A. Elliott, Ph.D., Vicky P. Taxiarchi, Ph.D., Georgios Gkountouras, Ph.D., Matthew Burns, M.Sc., Womba Mubita, M.Sc., Naresh Kanumilli, M.R.C.G.P., Maisie Camm, B.Sc., Hood Thabit, Ph.D., and Emma G. Wilmot, Ph.D., for the FLASH-UK Trial Study Group* -11 Author Info & Affiliations

Published October 5, 2022 | N Engl J Med 2022;387:1477-1487 | DOI: 10.1056/NEJMoa2205650

VOL. 387 NO. 16 | Copyright © 2022

P	PwT1D, HbA1c 7.5-11.0% (58-97 mmol/mol), MDI or CSII
I	isCGM (FSL2)
C	CBG
O	*Primary*: HbA1c at 24 weeks *Key secondary*: sensor data, PROMs, safety

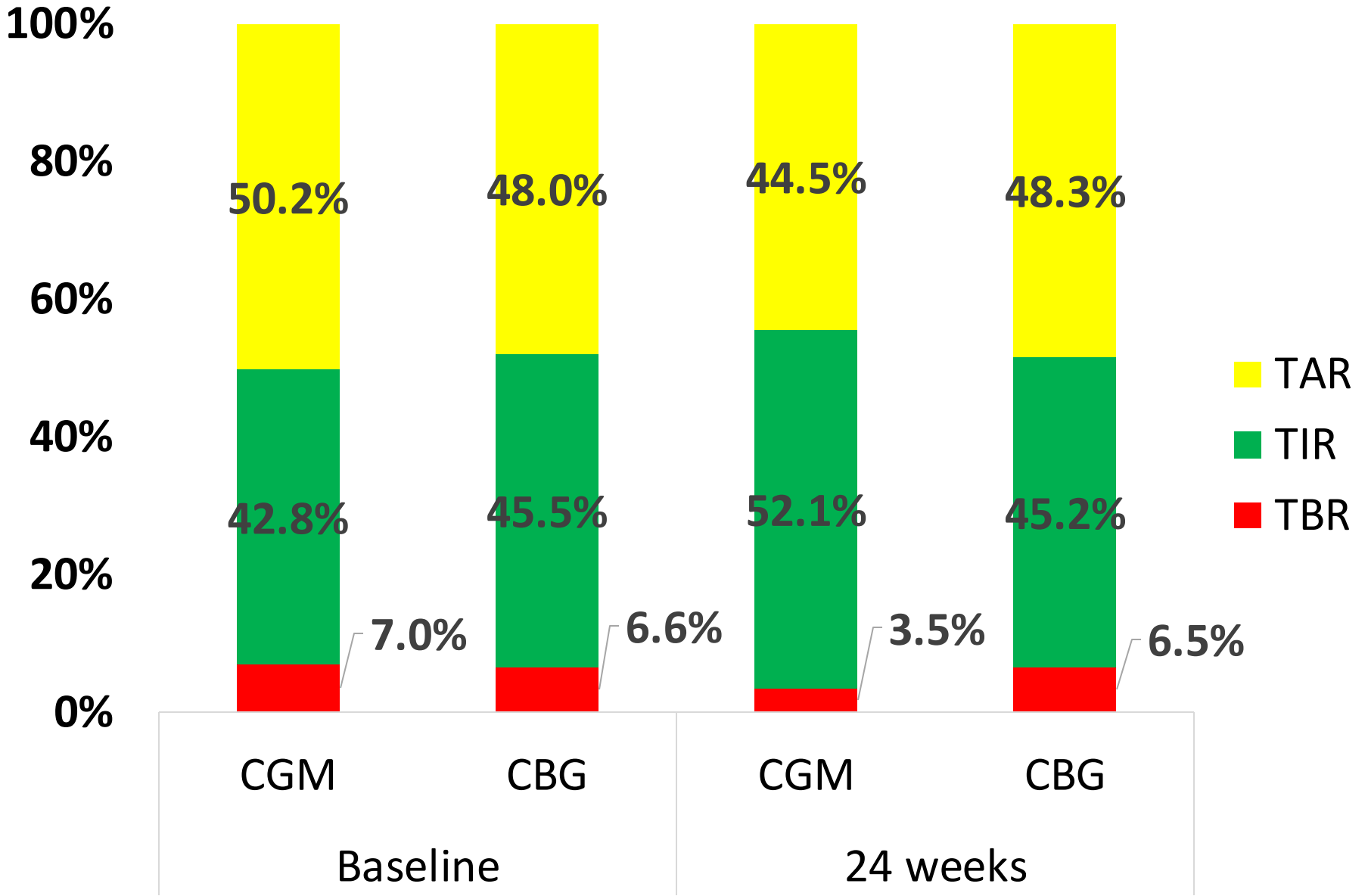
HbA1c improved in both groups.
HbA1c reduction was 0.5% greater in CGM (FSL2) vs. CBG



CGM: 8.7% -> 7.9%: 0.8%
CBG: 8.5% -> 8.3%: 0.2%

CGM vs. CBG: 0.5%, $p<0.001$

CGM (FSL2) usage increased TIR and reduced **TBR** and reduced TAR.



CGM vs CBG*

TIR: +9%

TAR: - 6%

TBR: -3%

* $p < 0.05$ for all

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Dexcom G4 and HbA1c: DIAMOND 2017 (RCT)

Original Investigation FREE

Cite Permissions Metrics

JAMA
Published Online: January 24/31, 2017
2017;317;(4):371-378. doi:10.1001/jama.2016.19975

Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections

The DIAMOND Randomized Clinical Trial

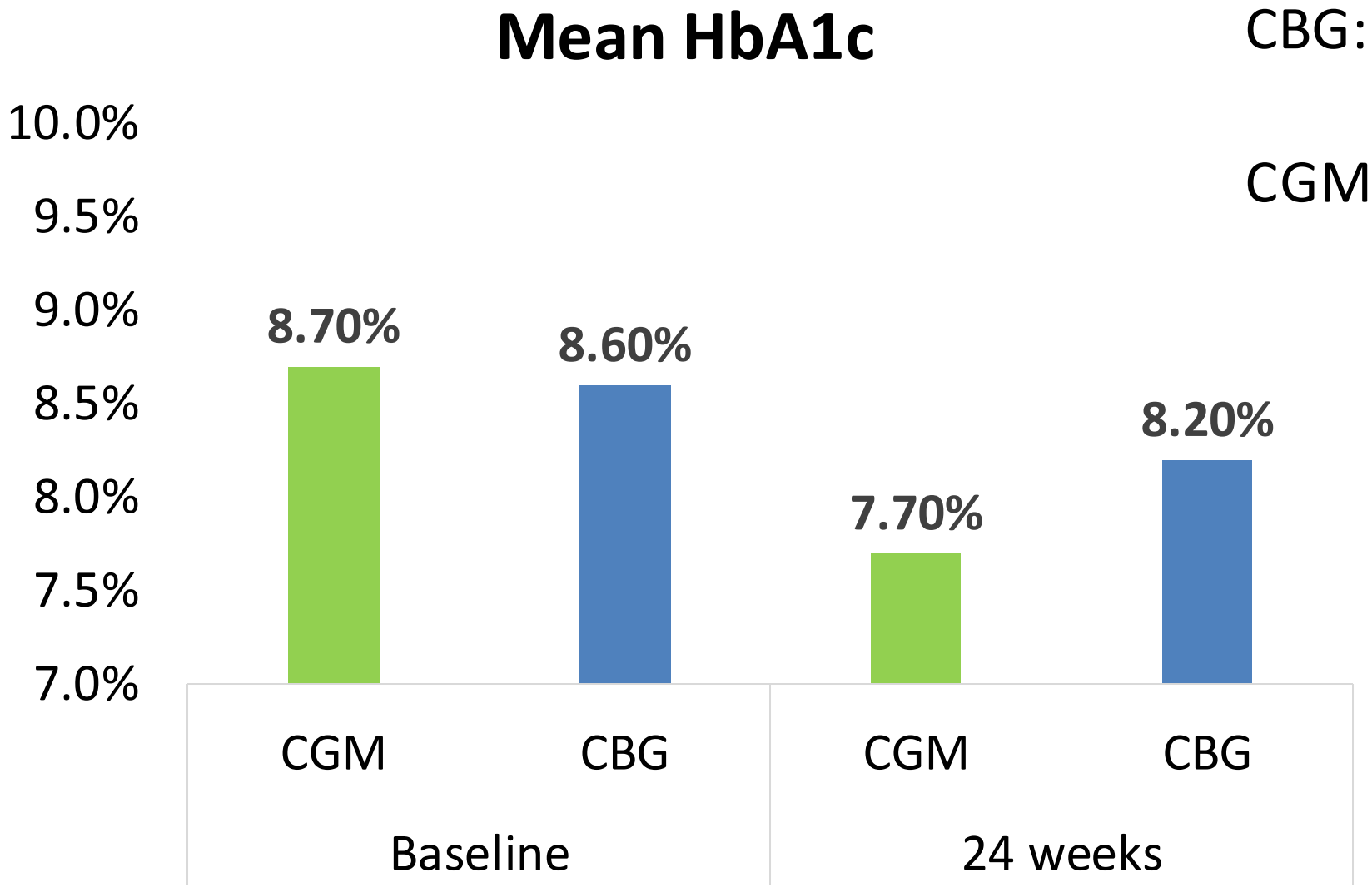
Roy W. Beck, MD, PhD[1]; Tonya Riddlesworth, PhD[1]; Katrina Ruedy, MSPH[1]; Andrew Ahmann, MD[2]; Richard Bergenstal, MD[3]; Stacie Haller, RD, LD, CDE[4]; Craig Kollman, PhD[1]; Davida Kruger, MSN, APN-BC[5]; Janet B. McGill, MD[6]; William Polonsky, PhD[7]; Elena Toschi, MD[8]; Howard Wolpert, MD[8]; David Price, MD [9]; for the DIAMOND Study Group

P	PwT1D, HbA1c 7.5%-10.0% (58-86 mmol/mol), MDI
I	CGM (Dexcom G4, needing calibration twice daily)
C	CBG
O	*Primary*: HbA1c at 24 weeks *Key secondary*: CGM metrics

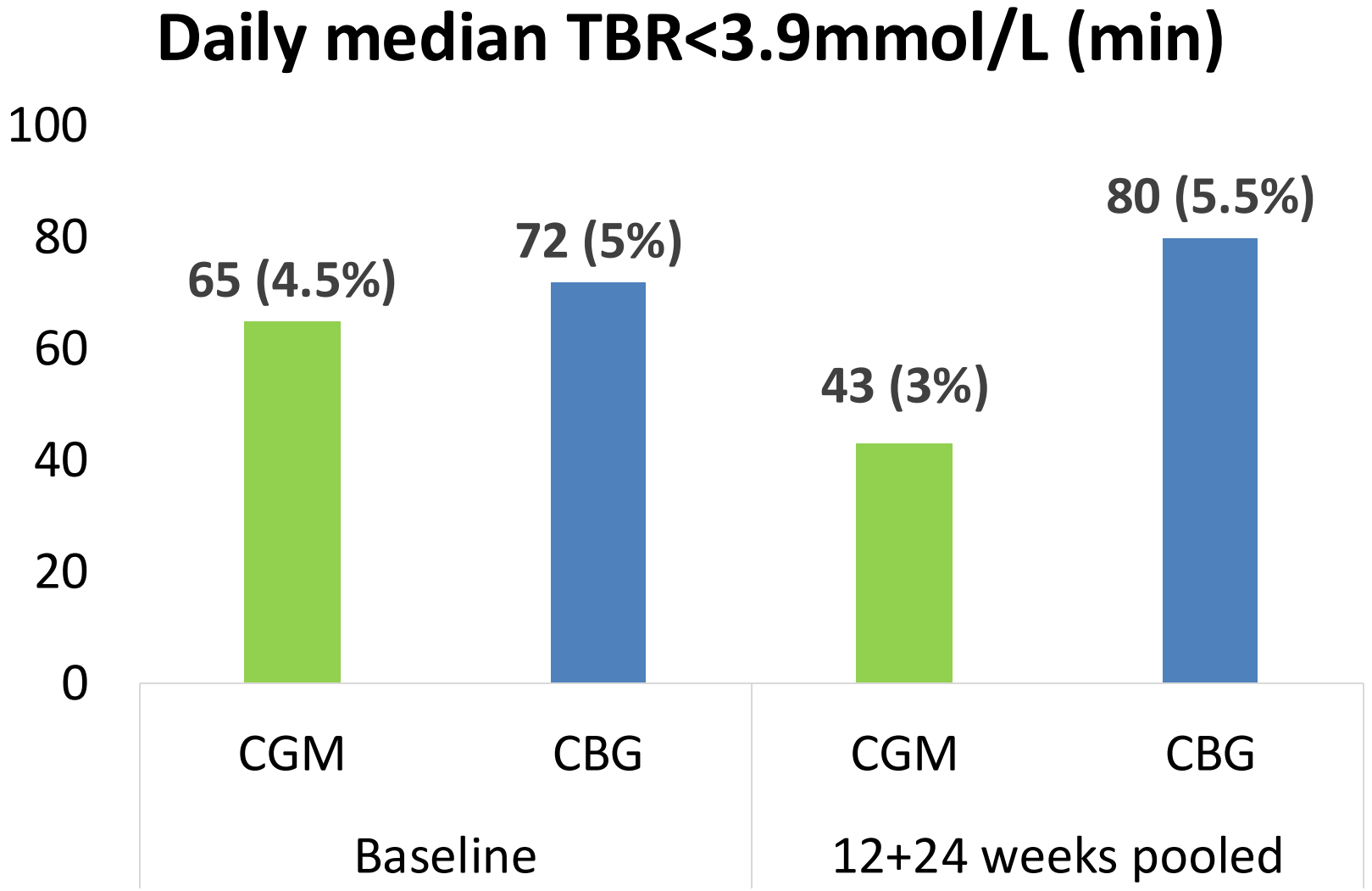
HbA1c improved in both groups.
HbA1c reduction was 0.6% greater in CGM (G4) vs. CBG

CGM: 8.7% -> 7.7%: 1.0%
CBG: 8.6% -> 8.2%: 0.4%

CGM vs. CBG: 0.6%, p<0.001



HbA1c reduction in CBG group led to higher **TBR**.
CGM (G4) usage improved HbA1c and reduced **TBR**.



CGM: 65min -> 43min:
22min
CBG: 72min -> 80min:
-8min

CGM vs. CBG: 30min, p<0.001

Dexcom G5 and HbA1c: HypoDE 2018 (RCT)

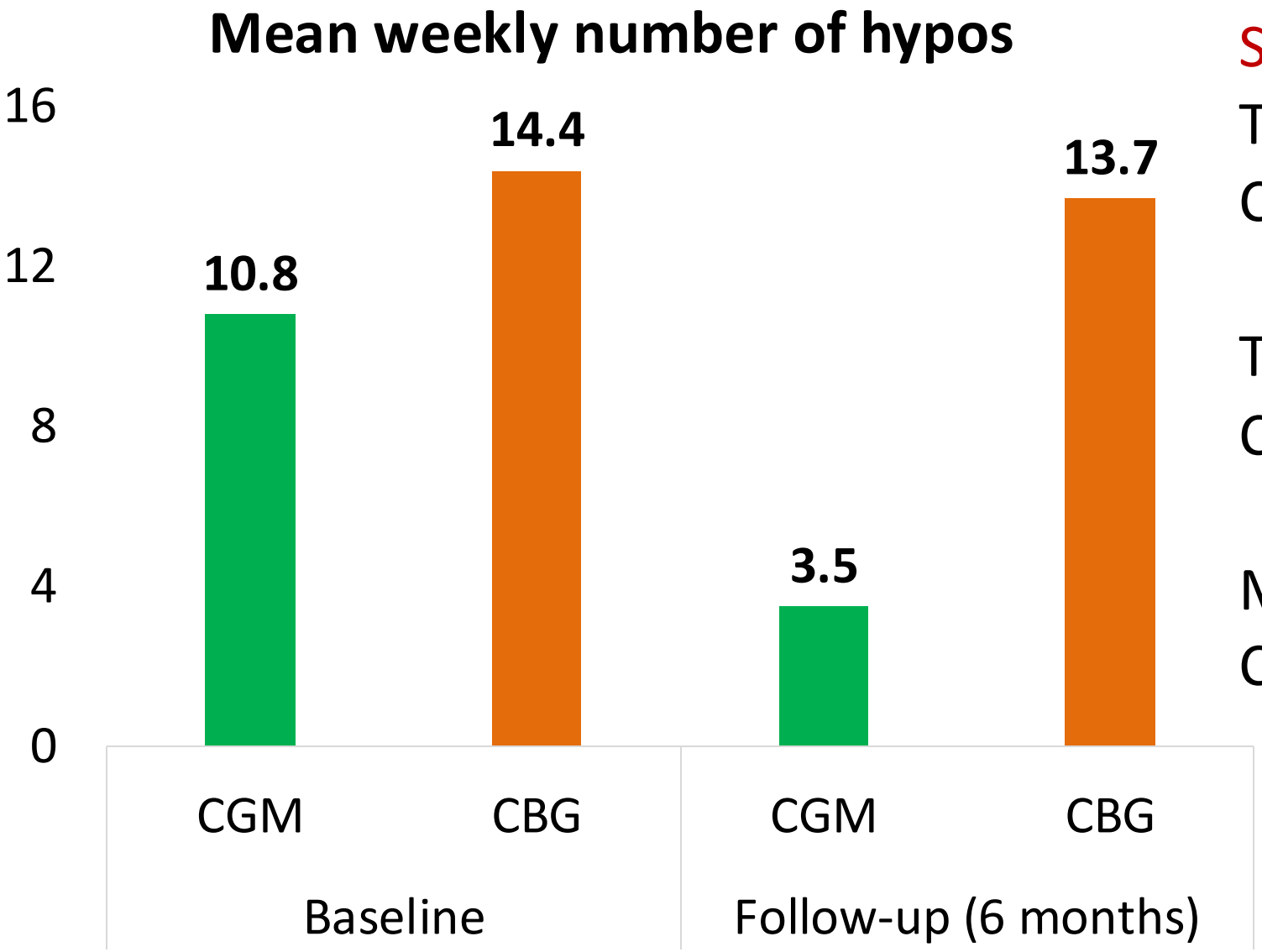
ARTICLES · Volume 391, Issue 10128, P1367-1377, April 07, 2018 Download Full Issue

Real-time continuous glucose monitoring in adults with type 1 diabetes and impaired hypoglycaemia awareness or severe hypoglycaemia treated with multiple daily insulin injections (HypoDE): a multicentre, randomised controlled trial

Prof Lutz Heinemann, PhD [a] · Guido Freckmann, MD [b] · Dominic Ehrmann, PhD [c,d] · Gabriele Faber-Heinemann, MA [a] · Stefania Guerra, PhD [e] · Delia Waldenmaier, MSc [b] · Prof Norbert Hermanns, PhD [c,d] Show less

P	PwT1D on MDI, with a PMHx of IAH or SH the year preceding the study
I	rtCGM (Dexcom G5)
C	CBG
O	Primary: baseline-adjusted number of hypoglycaemic events (glucose ≤3.0 mmol/L for ≥20 min) during the follow-up phase (6 months)

Primary: CGM (G5) usage reduced incidence of hypoglycaemia by 72% (p<0.001).



Secondary:

TBR<3.9mmol/L:

CGM vs. CBG: 6.4% vs 1.6%

TBR<3.0mmol/L:

CGM vs. CBG: 2.5% vs 0.3%

Median Duration <3.0mmol/L:

CGM vs. CBG: 3.8min vs 0.0min

Dexcom G6 vs FSL: ALERTT1 2021 (RCT)

ARTICLES · Volume 397, Issue 10291, P2275-2283, June 12, 2021

Download Full Issue

Comparing real-time and intermittently scanned continuous glucose monitoring in adults with type 1 diabetes (ALERTT1): a 6-month, prospective, multicentre, randomised controlled trial

Margaretha M Visser, MD [a] · Sara Charleer, PhD [a] · Steffen Fieuws, PhD [b] · Prof Christophe De Block, MD [c] · Robert Hilbrands, MD [d] · Liesbeth Van Huffel, MD [e] · Toon Maes, MD [f] · Gerd Vanhaverbeke, MD [g] · Eveline Dirinck, MD [c] · Nele Myngheer, MD [g] · Chris Vercammen, MD [f] · Frank Nobels, MD [e] · Prof Bart Keymeulen, MD [d] · Prof Chantal Mathieu, MD [a] · Pieter Gillard, MD [a,d] Show less

P	PwT1D, HbA1c 7.5-11.0% (58-97 mmol/mol), MDI or CSII
I	rtCGM with alert functionality (Dexcom G6)
C	isCGM without alert functionality (FSL)
O	*Primary*: Between-group difference in TIR at 6 months *Key secondary:* TBR, HFSII, HbA1c, Frequency of SH at 6 months

Study design and main outcomes

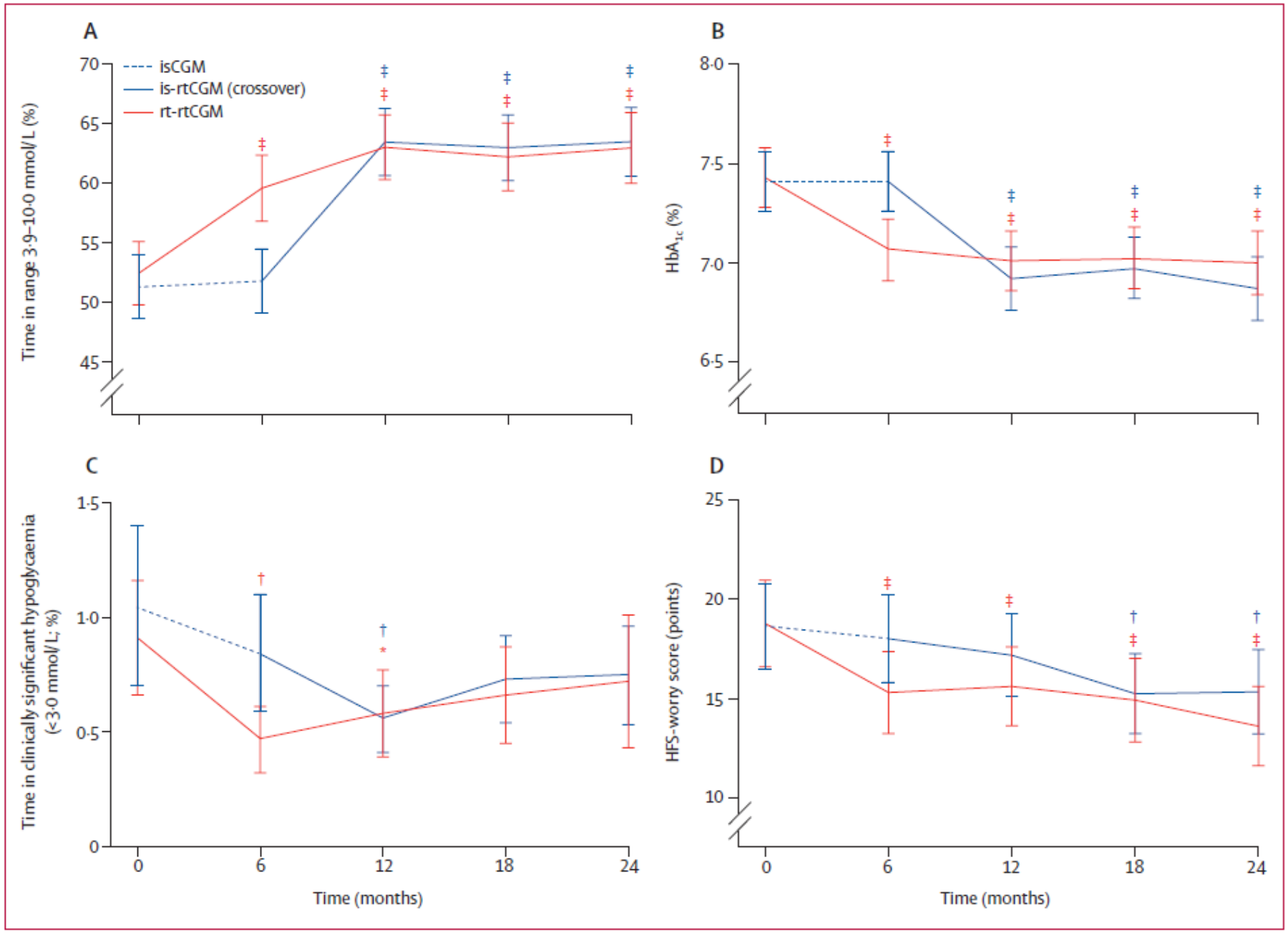
After 6 months:

a) HbA_{1c}:
   G6 vs. FSL: **7.1%** vs 7.4%; p<0.0001
b) TBR<3.0 mmol/L:
   G6 vs. FSL: **0.47%** vs 0.84%; p=0.007
c) HFSII – w subscale:
   G6 vs. FSL: **15.4** vs 18.0; p=0.007
d) Frequency of SH:
   G6 vs. FSL: **3** vs 13; p=0.008

More skin reactions with FSL.

More post insertion bleeding with G6.

Study design and main outcomes



CGM and long-term HbA1c outcomes: 2022 (RWE)

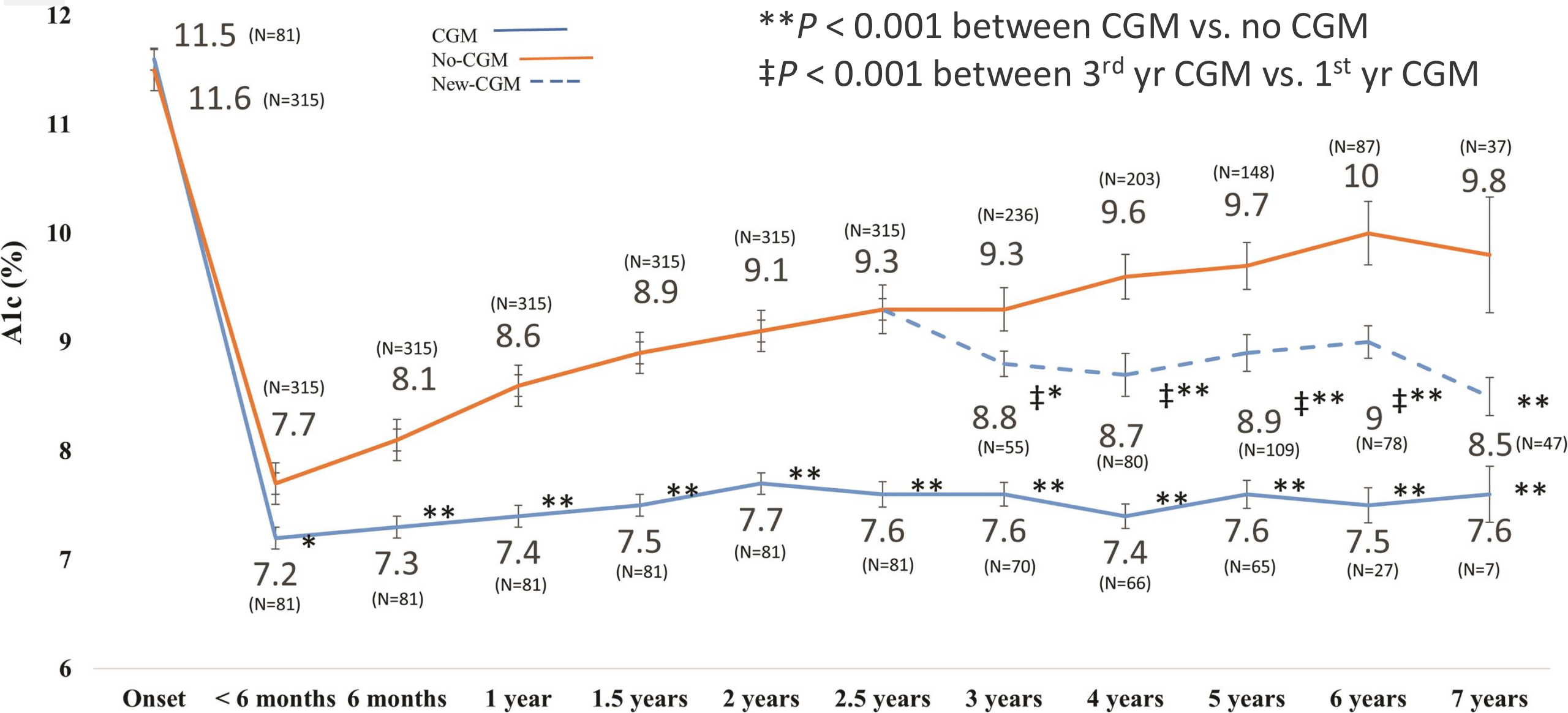
NOVEL COMMUNICATIONS IN DIABETES | JANUARY 12 2022

Continuous Glucose Monitoring Initiation Within First Year of Type 1 Diabetes Diagnosis Is Associated With Improved Glycemic Outcomes: 7-Year Follow-Up Study FREE

Anagha Champakanath; Halis Kaan Akturk; G. Todd Alonso; Janet K. Snell-Bergeon; Viral N. Shah

P	PwT1D between 1-35 yrs of age (pumps or MDI); 93% children
I	**a)** CGM 1st year of Dx; **b)** CGM 3rd year of Dx (Dexcom, Libre, Medtronic etc.)
C	No CGM
O	*Primary:* HbA1c throughout 7 years between 1st yr CGM vs. no CGM *Key secondary:* HbA1c throughout 7 years between 3rd yr CGM vs. no CGM

Sustained HbA1c reduction for 7 yrs post CGM start within 1st yr of Dx
HbA1c reduction regardless of CGM initiation timing



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T:slim (Control IQ) and TIR: A meta-analysis of 3 RCTs, 2023

Diabetes Technology & Therapeutics > Vol. 25, No. 5

Research Article | OPEN ACCESS | Published Online: 4 May 2023

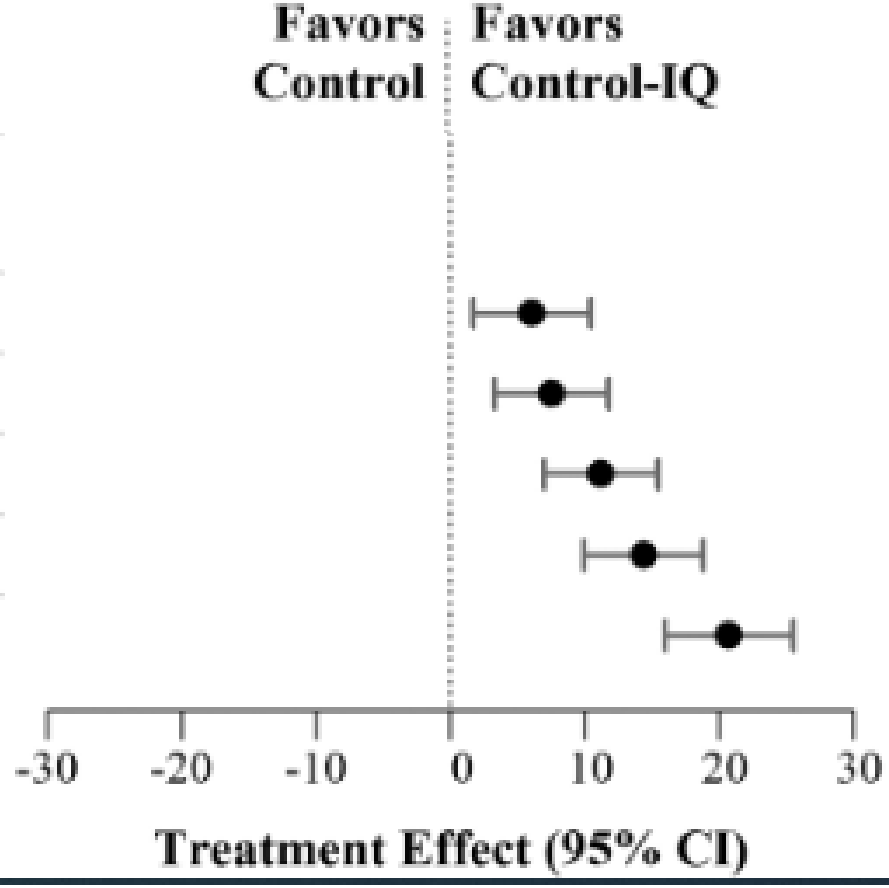
A Meta-Analysis of Randomized Trial Outcomes for the t:slim X2 Insulin Pump with Control-IQ Technology in Youth and Adults from Age 2 to 72

Authors: Roy W. Beck, Lauren G. Kanapka, Marc D. Breton, Sue A. Brown, R. Paul Wadwa, Bruce A. Buckingham, Craig Kollman, and Boris Kovatchev | AUTHORS INFO & AFFILIATIONS

P	PwT1D between 2-72 yrs of age from 3 RCTs: **DCLP3, DCLP5, PEDAP**
I	HCL (t:slim Control IQ algorithm)
C	MDI, CGM or CBG
O	*Primary:* between-group difference in TIR between baseline and end of each RCT *Key secondary:* CGM metrics, other CGM metrics, socio-economical parameters

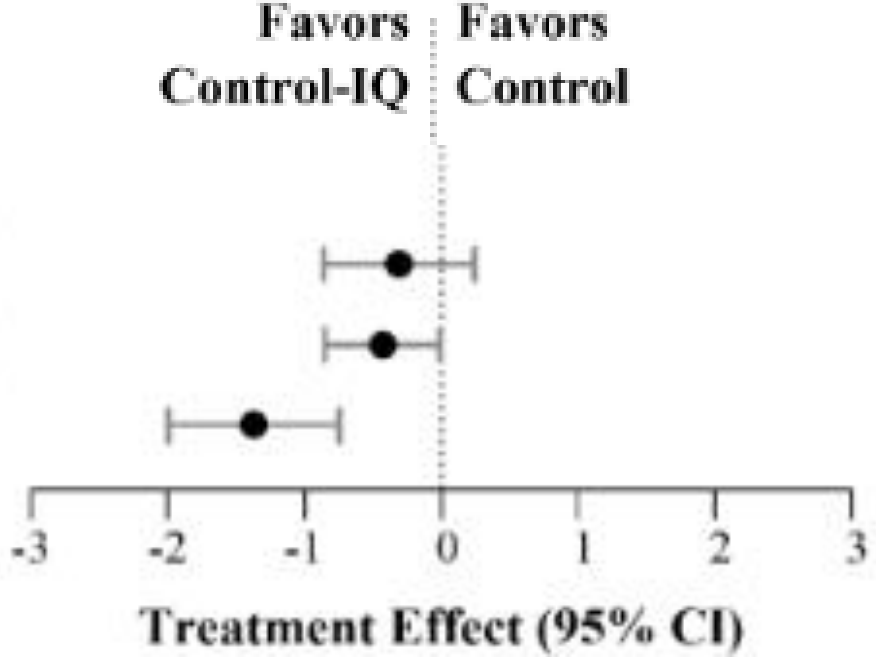
TIR was higher in the Control-IQ group than the Control group in all subgroups.

Group	N Baseline/Follow-up Control-IQ	Control	Treatment Effect (95% CI)	Interaction *P* value
Baseline Time in Range 70-180 mg/dL				<0.001
≥70%	67/67	21/21	6.0% (1.6%, 10.4%)	
60-<70%	49/49	25/25	7.5% (3.2%, 11.7%)	
50-<60%	50/50	27/26	11.1% (6.9%, 15.4%)	
40-<50%	50/50	19/19	14.3% (9.9%, 18.8%)	
<40%	38/38	20/20	20.7% (15.9%, 25.5%)	



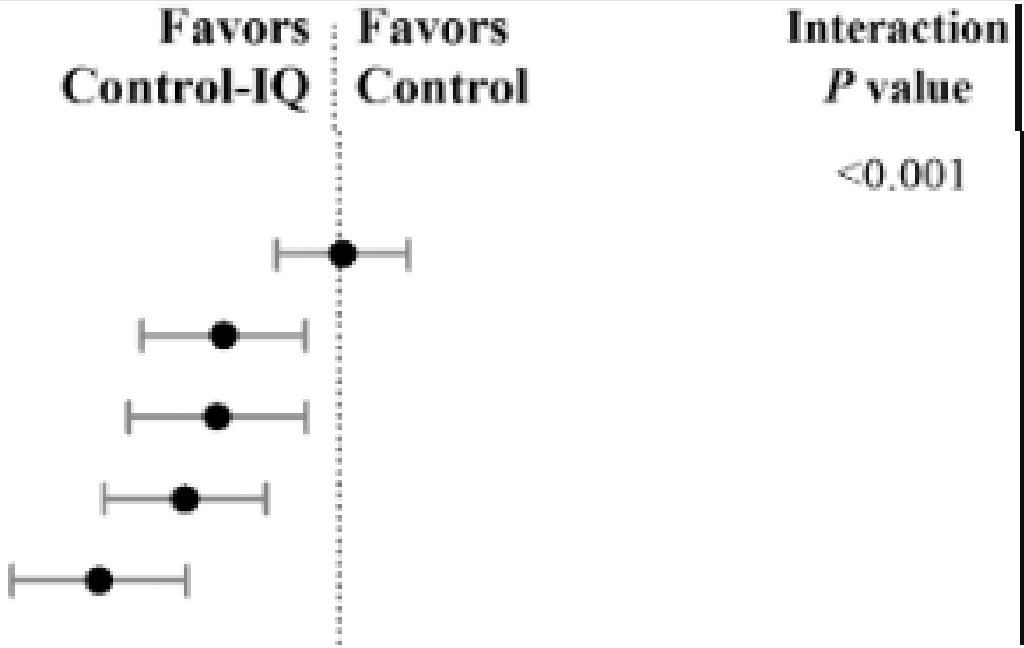
TBR was lower in the Control-IQ group than the Control group in all subgroups, with the most benefit seen in those spending 1%-4% of their time below range, and even more for those ≥4%.

Group	N Baseline/Follow-up Control-IQ	Control	Treatment Effect (95% CI)	Interaction *P* value
Baseline Time <70 mg/dL				<0.001
<1%	74/74	28/28	-0.3% (-0.9%, 0.2%)	
1-<4%	110/110	59/58	-0.4% (-0.9%, 0.0%)	
≥4%	70/70	25/25	-1.4% (-2.0%, -0.7%)	



HbA1c was lower in the Control-IQ group than the Control group in all subgroups except for baseline HbA1c<7.0%.

Group	N Baseline/Follow-up Control-IQ	Control	Treatment Effect (95% CI)	Interaction *P* value
Baseline HbA1c				<0.001
<7.0%	82/79	30/30	0.01 (-0.23, 0.26)	
7.0-<7.5%	47/46	20/20	-0.42 (-0.72, -0.12)	
7.5-<8.0%	46/46	18/18	-0.45 (-0.77, -0.12)	
8.0-<8.5%	35/34	26/24	-0.56 (-0.86, -0.26)	
≥8.5%	42/40	17/16	-0.88 (-1.20, -0.56)	



T:slim (Control IQ+G6): 2022 (RWE)

Diabetes Technology & Therapeutics > Vol. 24, No. 11

Research Article | OPEN ACCESS | | Published Online: 31 October 2022

Real-World Evidence Supporting Tandem Control-IQ Hybrid Closed-Loop Success in the Medicare and Medicaid Type 1 and Type 2 Diabetes Populations

Authors: Gregory P. Forlenza, Anders L. Carlson, Rodolfo J. Galindo, Davida F. Kruger, Carol J. Levy, Janet B. McGill, Guillermo Umpierrez, and Grazia Aleppo

AUTHORS INFO & AFFILIATIONS

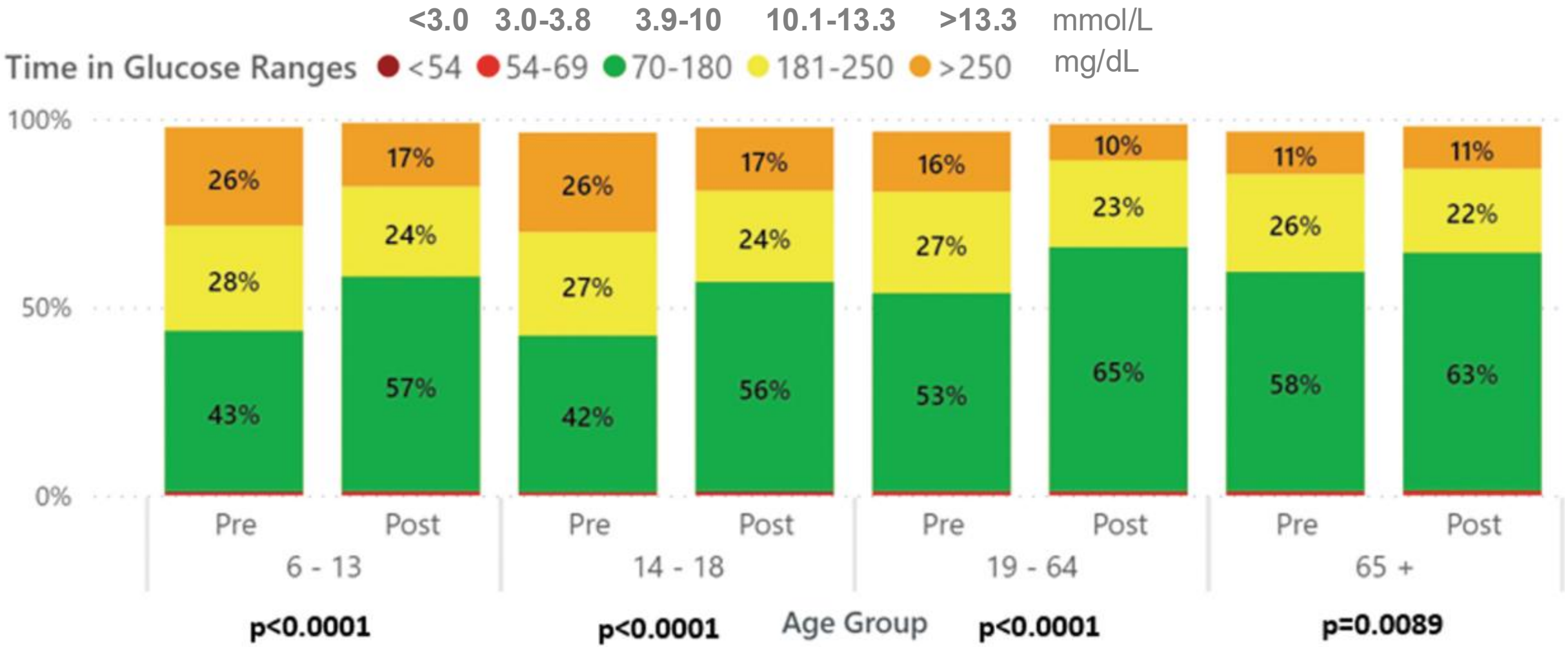
Publication: Diabetes Technology & Therapeutics • https://doi.org/10.1089/dia.2022.0206

P	5575 users (500 with T2D) from the US (Medicare and Medicaid) on Control IQ for at least 12 months (data collected from January 2020 till January 2022)
I	HCL (CIQ)
C	Baseline (before initiation of HCL)
O	*Primary:* TIR, TAR, TBR at 12 months of follow-up *Key secondary:* GMI at 12 months of follow-up

In adults, CIQ improved TIR, TAR, and **TBR<3.0mmol/L** without increasing TBR<3.9mmol/L.

	Medicare T1D: 4243			Medicare T1D: 1332			T2D: 500		
	Pre-CIQ	Post-CIQ	*P*	Pre-CIQ	Post-CIQ	*P*	Pre-CIQ	Post-CIQ	*P*
GMI (%)	7.3	7.0	<0.0001	7.9	7.5	<0.0001	7.3	7.1	<0.0001
Mean SG (mg/dL)	166.8	154.3	<0.0001	191.9	175.2	<0.0001	166.8	158.4	<0.0001
TIR 70–180 mg/dL (%)	64	74	<0.0001	46	60	<0.0001	64	72	<0.0001
TBR 54–69 mg/dL (%)	0.74	0.74	0.327	0.74	0.75	0.518	0.26	0.28	0.719
TRR <54 mg/dL (%)	0.11	0.13	<0.0001	0.15	0.18	<0.0001	0.04	0.06	<0.0001
TAR 181–250 mg/dL (%)	26	20	<0.0001	27	24	<0.0001	27	22	<0.0001
TAR >250 mg/dL (%)	8	5	<0.0001	21	13	<0.0001	7	5	<0.0001

CIQ+G6


<3.0 3.0-3.8 3.9-10 10.1-13.3 >13.3 mmol/L
Time in Glucose Ranges <54 54-69 70-180 181-250 >250 mg/dL
100%
50%
0%
26%
28%
43%
17%
24%
57%
26%
27%
42%
17%
24%
56%
16%
27%
53%
10%
23%
65%
11%
26%
58%
11%
22%
63%
Pre
Post
6 - 13
14 - 18
19 - 64
65 +
p<0.0001
p<0.0001
Age Group
p<0.0001
p=0.0089

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   a) T slim
   b) **OP5**
   c) Medtronic 780g
   d) CamAPS

OP5+G6 and TIR in adults and older children: 2021 (RCT)

EMERGING TECHNOLOGIES: DATA SYSTEMS AND DEVICES | JULY 20 2021

Multicenter Trial of a Tubeless, On-Body Automated Insulin Delivery System With Customizable Glycemic Targets in Pediatric and Adult Participants With Type 1 Diabetes FREE

Sue A. Brown; Gregory P. Forlenza; Bruce W. Bode; Jordan E. Pinsker; Carol J. Levy; Amy B. Criego; David W. Hansen; Irl B. Hirsch; Anders L. Carlson; Richard M. Bergenstal; Jennifer L. Sherr; Sanjeev N. Mehta; Lori M. Laffel; Viral N. Shah; Anuj Bhargava; Ruth S. Weinstock; Sarah A. MacLeish; Daniel J. DeSalvo; Thomas C. Jones; Grazia Aleppo; Bruce A. Buckingham; Trang T. Ly; Omnipod 5 Research Group

P	112 children (age 6–13.9 years) and 129 adults (age 14–70 years), HbA1c <10%; single-arm, multicentre trial
I	HCL (OP5+Dexcom G6)
C	Standard therapy (MDI) for 14 days prior to HCL initiation
O	*Primary:* **Safety** (rates of SH, DKA) and **Glycaemic** (HbA1c, TIR) at 3 months from baseline *Key secondary:* TBR, TAR

In adults, OP5+G6 improved HbA1c, TIR, and **TBR** at two levels, both diurnal and nocturnal.
No documented episodes of SH or DKA.

ADULTS	Baseline	3 months	Difference	P value
	14-day usual care	OP5 + G6		
HbA1c (%)	7.16	6.78	-0.38	<0.001
TIR (%)	64.7	73.9	9.3	<0.001
TIR (%) 00:00 – 06:00	64.3	78.1	13.8	<0.001
TBR<3.9mmol/L (%)	2.89	1.32	-1.57	<0.001
TBR<3.0mmol/L (%)	0.62	0.23	-0.39	<0.001
TBR<3.9mmol/L (%) 12am – 6am	3.64	1.17	-2.46	<0.001
TBR<3.0mmol/L (%) 12am – 6am	0.95	0.24	-0.70	<0.001

OP5+FSL2: RADIANT 2025 (RCT)

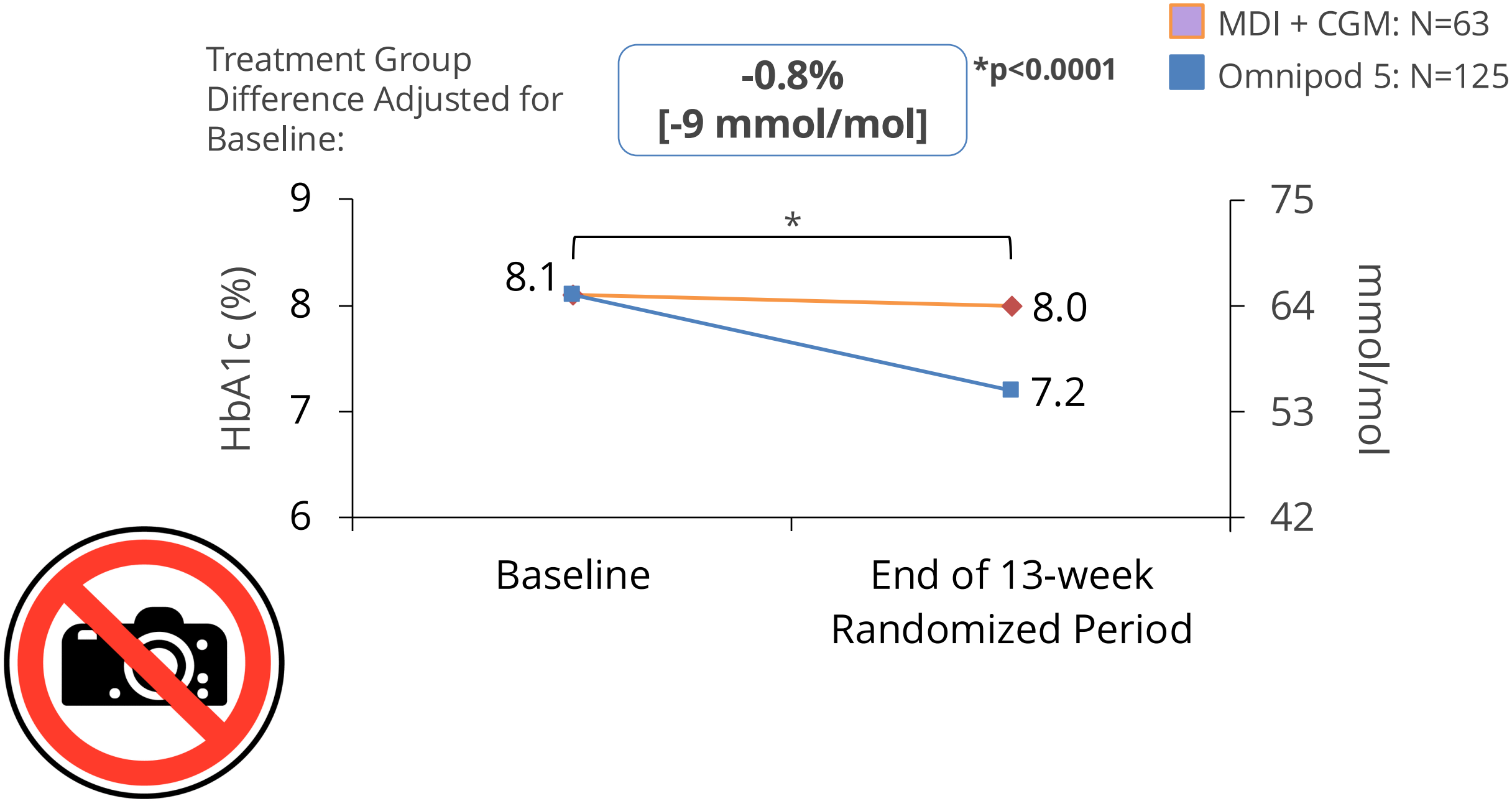
OR: NEW TECHNOLOGY—INSULIN DELIVERY SYSTEMS | JUNE 20 2025

314-OR: Improved Outcomes across Baseline Time-in-Range Levels with the Omnipod 5 AID System Compared with Multiple Daily Injections (MDI) in Type 1 Diabetes (T1D)—Analysis of the RADIANT Study FREE

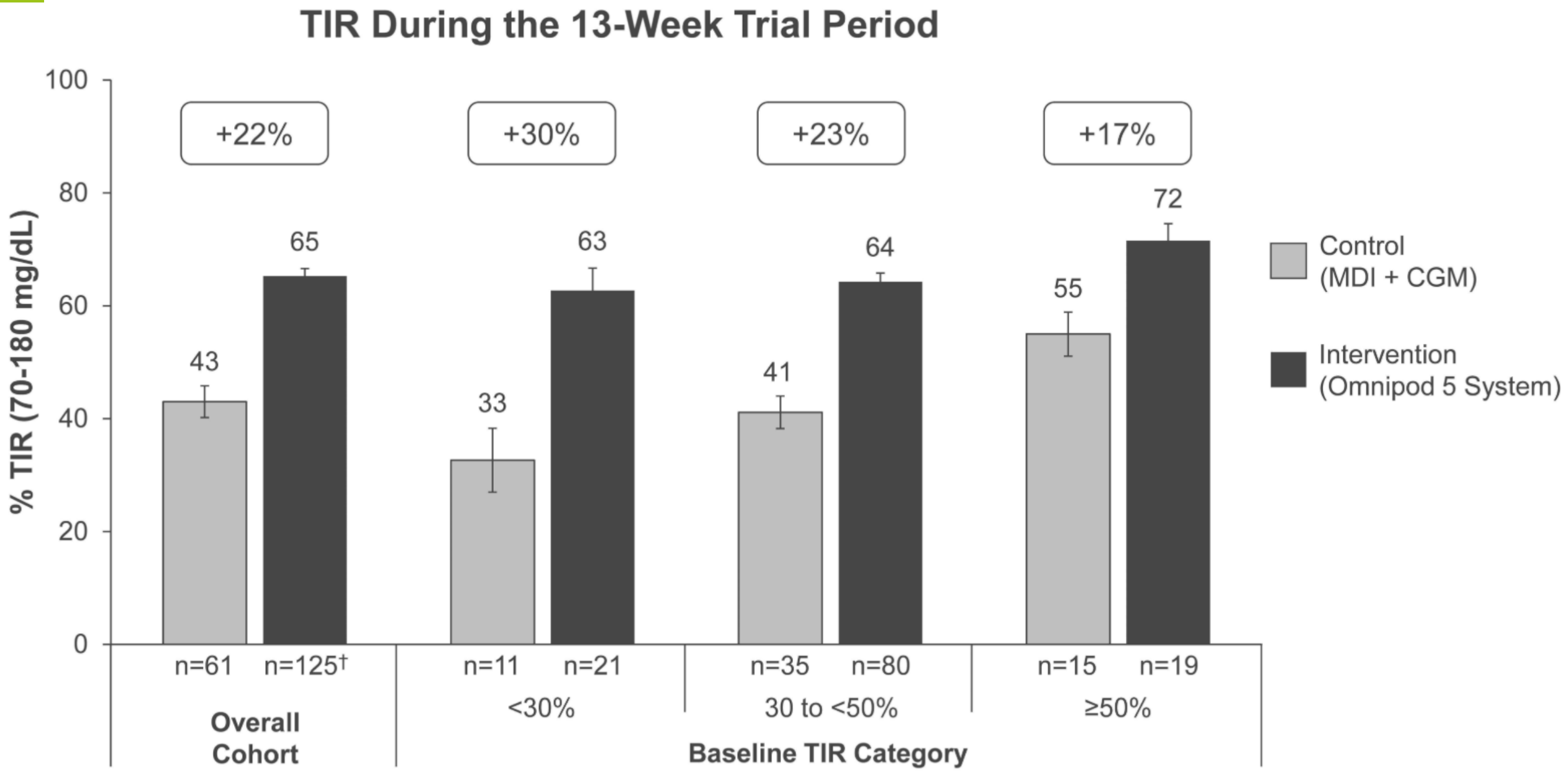
EMMA G. WILMOT; JACQUES BELTRAND; BRUNO GUERCI; AURÉLIE BEROT; HÉLÈNE HANAIRE; ELISE BISMUTH; PIETER GILLARD; MARIE-BÉATRICE SAADE; MICHAEL JOUBERT; RANDA SALET; PRATIK CHOUDHARY; RACHEL REYNAUD; LALANTHA LEELARATHNA; EMELINE RENARD; SANDRINE LABLANCHE; CECILE GOUILLARD DARNAUD; SZE M. NG; PHILIPPE A. LYSY; NIKOLAOS DASKAS; KEVIN PERGE; THOMAS S. CRABTREE; TRANG T. LY; MARC NICOLINO; RADIANT STUDY GROUP

P	Children and adults with T1D on MDI, HbA1c 7.5% - 11% (58-97 mmol/mol), multicentre multinational trial (UK, France, Belgium)
I	HCL (OP5+FSL2)
C	Standard therapy (MDI+FSL2) for 14 days prior to HCL initiation
O	*Primary:* HbA1c at 13 weeks *Key secondary:* TIR at 13 weeks

Adults: **HbA1c** was reduced by -0.8% at 13 weeks



Adults: TIR was improved by 22% in total



OP5+G6: 2024 (RWE)

Real-World Evidence of Omnipod® 5 Automated Insulin Delivery System Use in 69,902 People with Type 1 Diabetes

Authors: Gregory P. Forlenza, Daniel J. DeSalvo, Grazia Aleppo, Emma G. Wilmot, Cari Berget, Lauren M. Huyett, Irene Hadjiyianni, José J. Méndez, Lindsey R. Conroy, Trang T. Ly, and Jennifer L. Sherr | AUTHORS INFO & AFFILIATIONS

Publication: Diabetes Technology & Therapeutics • https://doi.org/10.1089/dia.2023.0578

P	69,902 users from 34 countries (children≥2 and adults) with T1D on 780g+Minimed sensor (data collected from August 2020 till August 2023)
I	HCL (OP5+g6)
C	TIR before initiation of HCL
O	*Primary:* TIR at 12 months *Key secondary:* TAR, TBR at 12 months

TIR with glucose target 6.1mmol/L: 67.7%

Glucose target ADULTS+CHILDREN	6.1mmol/L	6.7mmol/L	7.2/7.8/8.3 mmol/L
GMI (%)	7.2	7.5	7.9
TBR<3.0 mmol/L	0.35	0.28	0.25
TBR<3.9 mmol/L	1.62	1.26	1.07
TIR 3.9–10.0 mmol/L	67.7	60.6	52.5
TAR >10.0 mmol/L	30.6	38.2	46.5

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   c) **Medtronic 780g**
   d) CamAPS

Medtronic 780g+Minimed sensor: ADAPT 2022 (RCT)

ARTICLES · Volume 10, Issue 10, P720-731, October 2022 Download Full Issue

Advanced hybrid closed loop therapy versus conventional treatment in adults with type 1 diabetes (ADAPT): a randomised controlled study

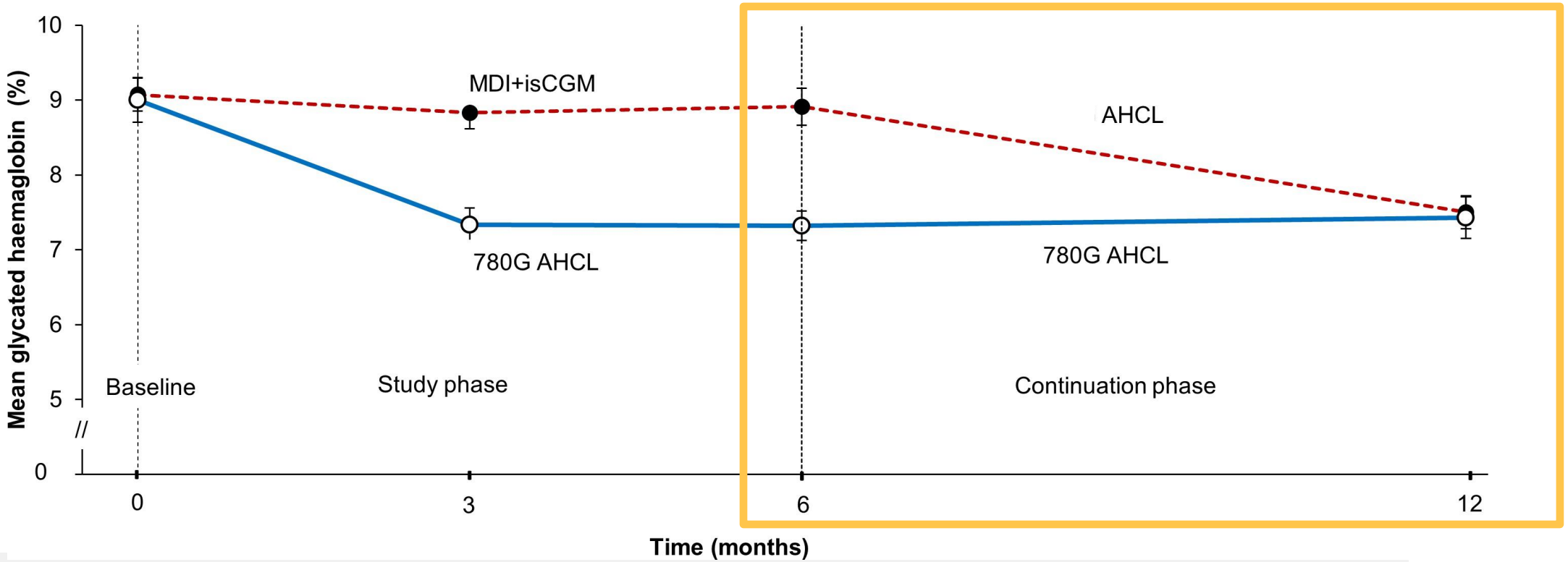
Prof Pratik Choudhary, MBBS [a,b] · Ralf Kolassa, MD [c] · Winfried Keuthage, MD [d] · Jens Kroeger, MD [e] · Prof Charles Thivolet, MD [f] · Prof Mark Evans, MD [g] · Roseline Ré, MS [h] · Simona de Portu, PharmD [h] · Linda Vorrink, MS [h] · John Shin, PhD [i] · Aklilu Habteab, PhD [j] · Javier Castañeda, MS [j] · Julien da Silva, MS [h] · Prof Ohad Cohen, MD [h] on behalf of the ADAPT study Group [†] Show less

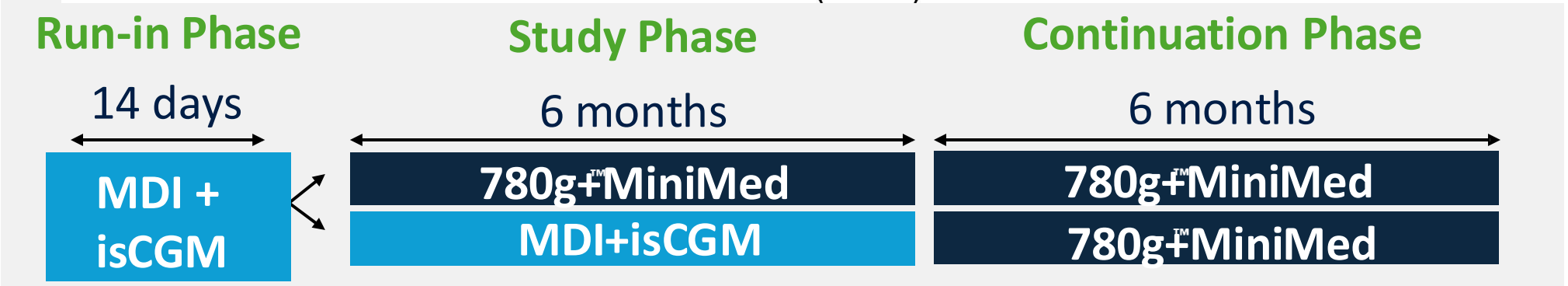
P	Adults aged ≥18 years, with T1D on MDI ≥2 years AND isCGM ≥ 3 months, HbA1c ≥8%. Multicentre trial
I	HCL (780g+Minimed sensor)
C	Standard therapy (MDI+isCGM) for 14 days prior to HCL initiation
O	*Primary:* **Glycaemic** (HbA1c, TIR) at 6 months from baseline *Secondary:* **Safety** (rates of SH, DKA), CGM metrics, PROMs

MDI+isCGM to HCL arm: 1.4% HbA1c reduction at 12 months (p<0.001)

Continued on HCL arm: No change in HbA1c at 12 months (non inferiority met)

Arm difference: At 12 months, no between-group difference (non inferiority met)





Medtronic 780g+Minimed sensor: 2024 (RWE)

Diabetes Technology & Therapeutics > Vol. 26, No. S3

Research Article | OPEN ACCESS | Published Online: 5 February 2024

Celebrating the Data from 100,000 Real-World Users of the MiniMed™ 780G System in Europe, Middle East, and Africa Collected Over 3 Years: From Data to Clinical Evidence

Authors: Pratik Choudhary, Arcelia Arrieta, Tim van den Heuvel, Javier Castañeda, Vittorino Smaniotto, and Ohad Cohen | AUTHORS INFO & AFFILIATIONS

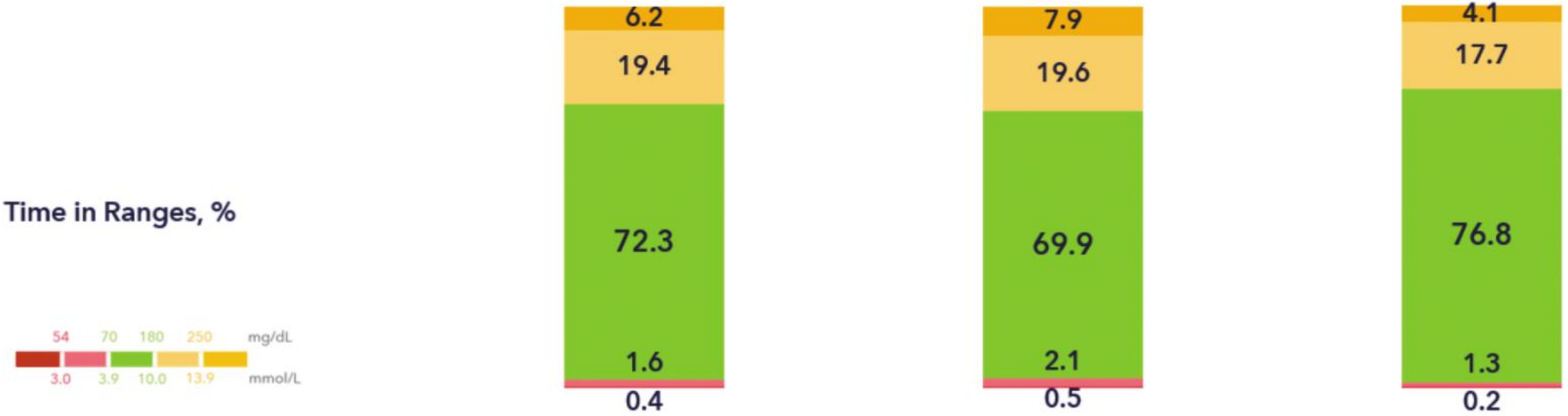
Publication: Diabetes Technology & Therapeutics • https://doi.org/10.1089/dia.2023.0433

P	101,629 users from 34 countries (children and adults) with T1D on 780g+Minimed sensor (data collected from August 2020 till August 2023)
I	HCL (780g+Minimed sensor)
C	TIR before initiation of HCL
O	*Primary:* TIR over 12 months *Key secondary:* TAR, TBR

TIR in total: 72.3%

	All users	≤15 years	>56 years
Users, *n*	101,629	22,541	13,202
Time in AHCL, %	90.1	90.9	94.5
Mean SG, *mg/dL (mmol/L)*	152.0 (8.4)	154.0 (8.6)	148.0 (8.2)
GMI, %	7.0	7.0	6.8

Time in Ranges, %

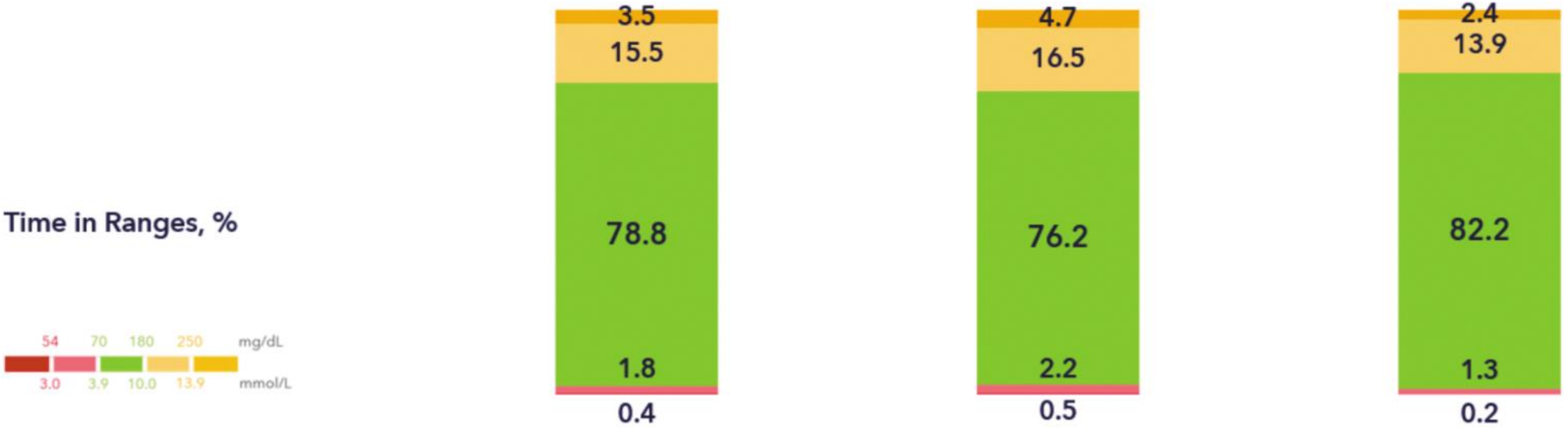


TIR with **optimal** settings: 78.8%

**optimal settings: ≥95% of time with glucose target of 5.5 mmol/L, and ≥95% of time with AIT of 2 h*

	All users	≤15 years	>56 years
Users, *n*	6,531	1,366	803
Time in AHCL, %	94.5	95.4	97.1
Mean SG, *mg/dL (mmol/L)*	142.0 (7.9)	144.0 (8.0)	139.0 (7.7)
GMI, %	6.7	6.7	6.6

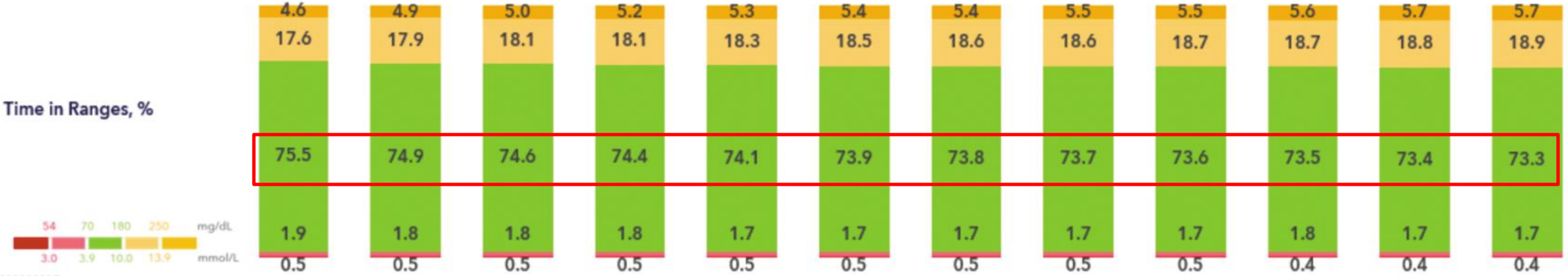
Time in Ranges, %



Sustained TIR reduction

	1st Month	2nd Month	3rd Month	4th Month	5th Month	6th Month	7th Month	8th Month	9th Month	10th Month	11th Month	12th Month
Users, *n*	32,028	32,028	32,028	32,028	32,028	32,028	32,028	32,028	32,028	32,028	32,028	32,028
Time in AHCL, %	94.1	93.6	93.4	93.2	93.2	93.1	93.2	93.2	93.2	93.2	93.2	93.3
Mean SG, *mg/dL*	146	147	148	148	149	149	149	149	150	150	150	150
GMI, %	6.8	6.8	6.8	6.9	6.9	6.9	6.9	6.9	6.9	6.9	6.9	6.9
Percentage of users achieving treatment goals, %												
GMI<7%	73.9	71.0	69.7	68.6	67.5	66.2	65.9	65.5	64.8	64.0	63.6	63.0
TIR>70%	74.3	71.9	70.7	69.6	68.4	67.4	67.1	66.8	66.4	65.9	65.3	65.1
TB70<4%	82.8	84.1	84.4	84.1	84.6	84.7	84.5	84.9	85.1	85.8	85.6	86.2
TB54<1%	86.1	86.6	86.7	86.5	86.5	86.9	86.9	87.2	87.4	87.8	88.0	88.3

Time in Ranges, %



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   c) Medtronic 780g
   d) **CamAPS**

CamAPS

DIABETIC Medicine

DIABETES UK
KNOW DIABETES. FIGHT DIABETES.

Review Article

Artificial Pancreas Project at Cambridge 2013

R. Hovorka

First published: 27 March 2015 | https://doi.org/10.1111/dme.12766 | Citations: 15

The 2013 Dorothy Hodgkin Lecture was delivered to the Annual Professional Conference of Diabetes UK, Manchester, 13–15 March 2013

Roman Hovorka

2011 - 2014	Night-only and free-living feasibility trials (children, young adults, pregnancy), over 7 days
2015 - 2016	Short day-and-night free-living trials (adults, adolescents), over 3-4 weeks
2017-2018	Longer day-and-night and young-children trials, over 2 years
2019 (CamAPS Fx)	Pregnancy, children (aged 1-7 yrs)

CamAPS+Dexcom G6: RWE 2023

Open access | Research article | First published online July 8, 2023

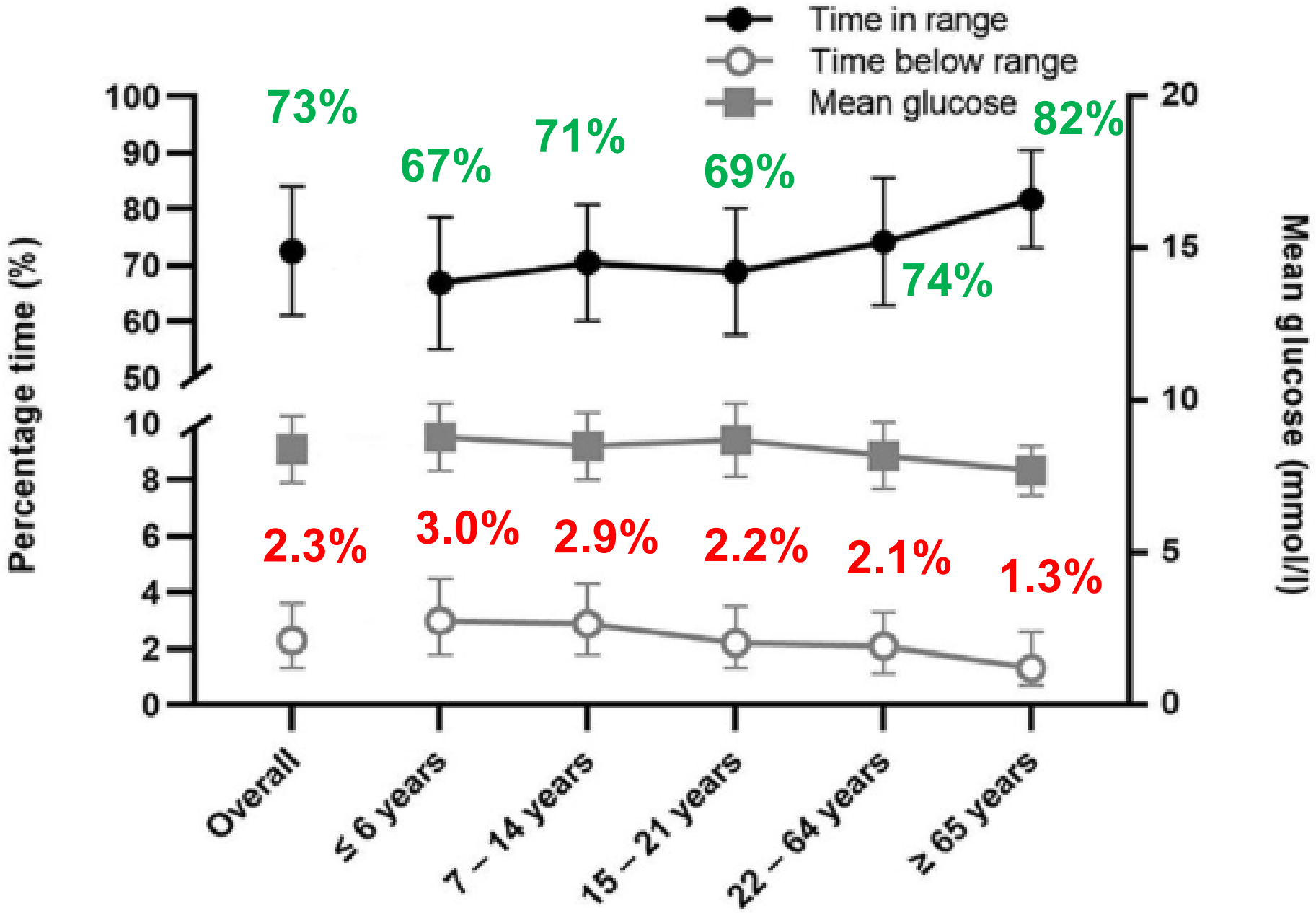
Real-World Evidence Analysis of a Hybrid Closed-Loop System

Heba Alwan, MD, Malgorzata E. Wilinska, PhD, Yue Ruan, PhD, Julien Da Silva, MS, and Roman Hovorka, PhD

Volume 19, Issue 2 | https://doi.org/10.1177/19322968231185348

P	PwT1D aged ≥1 years, with T1D on MDI ≥2 years AND isCGM ≥ 3 months, HbA1c ≥8%. Multicentre trial
I	HCL (CamAPS+G6)
C	Standard therapy (MDI+isCGM) for 14 days prior to HCL initiation
O	*Primary:* CGM metrics between between May and December 2022 *Secondary:* **Safety** (rates of SH, DKA), CGM metrics, PROMs

CamAPS+Dexcom G6



CamAPS+Dexcom G6

TIR, night time (12am-6am) vs. day time:
77.8% vs. 70.8%

Mean TBR<3.9mmol/L, night time vs. day time:
1.7% vs. 2.5%

HCL ABCD audit: RWE 2025

Diabetes Technology & Therapeutics > Ahead of Print

Research Article | OPEN ACCESS | Published Online: 30 May 2025

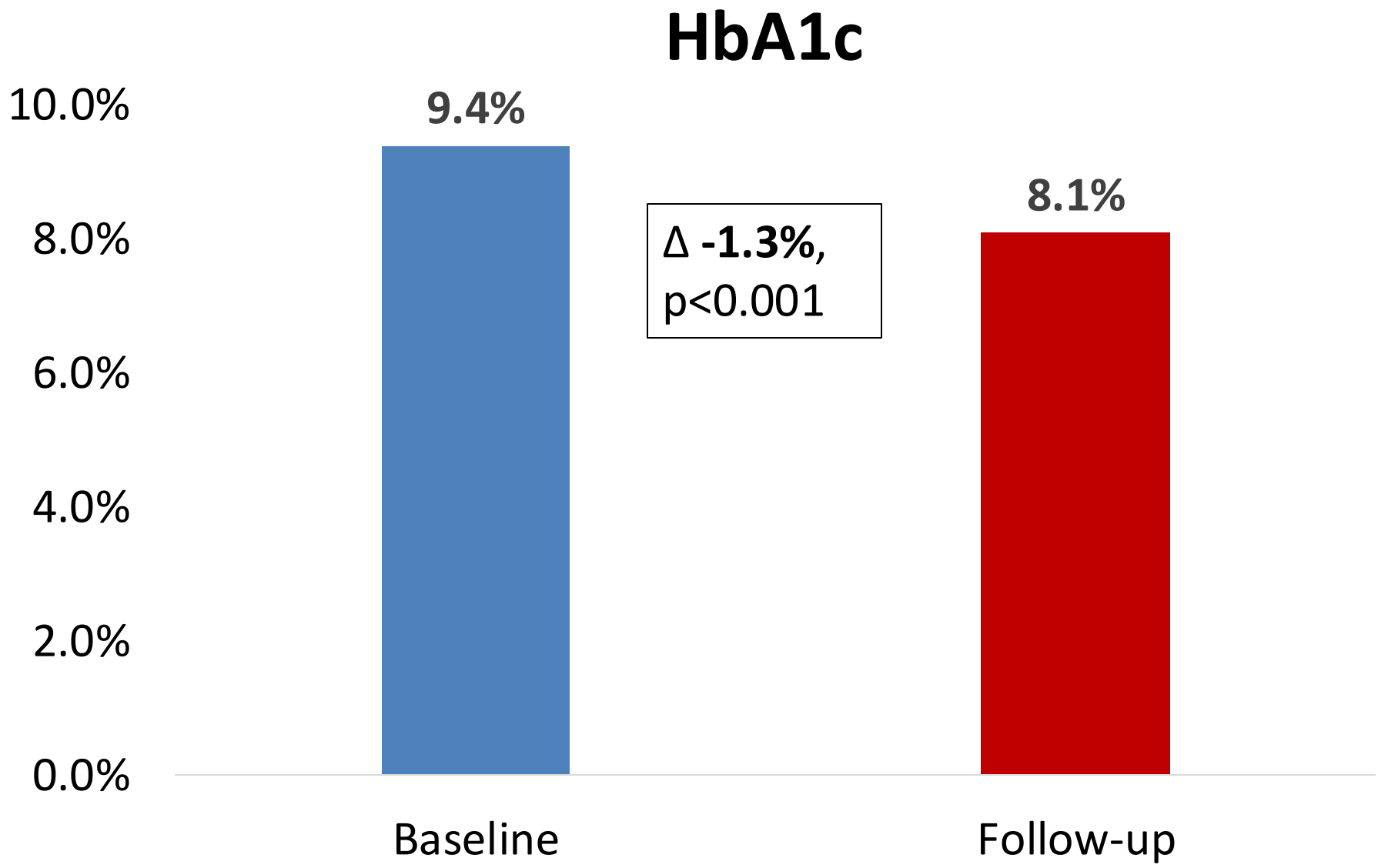
Hybrid Closed-Loop Therapy in Adults with Type 1 Diabetes in England: Long-Term Outcomes from a Real-World Observational Study

Authors: Alexandros L. Liarakos, Thomas S.J. Crabtree, Tomás P. Griffin, Sufyan Hussain, Geraldine Gallen, Jackie Elliott, Niall Furlong, Parth Narendran, Hood Thabit, Lalantha Leelarathna, Mark L. Evans, Christopher Philbey, Iain Cranston, Shafie Kamaruddin, Zin Zin Htike, Lynn Sawyer, Louise Curtis, Jesina Kirby, Isy Douek, Ali J. Chakera, Simon Saunders, Alex Bickerton, Zosanglura Bawlchhim, Clare Soar, Claire Wadham, Claire Williams, Mindy Levitt, Philip Weston, Partha Kar, Robert E.J. Ryder, Alistair Lumb, Pratik Choudhary, and Emma G. Wilmot SHOW FEWER | AUTHORS INFO & AFFILIATIONS

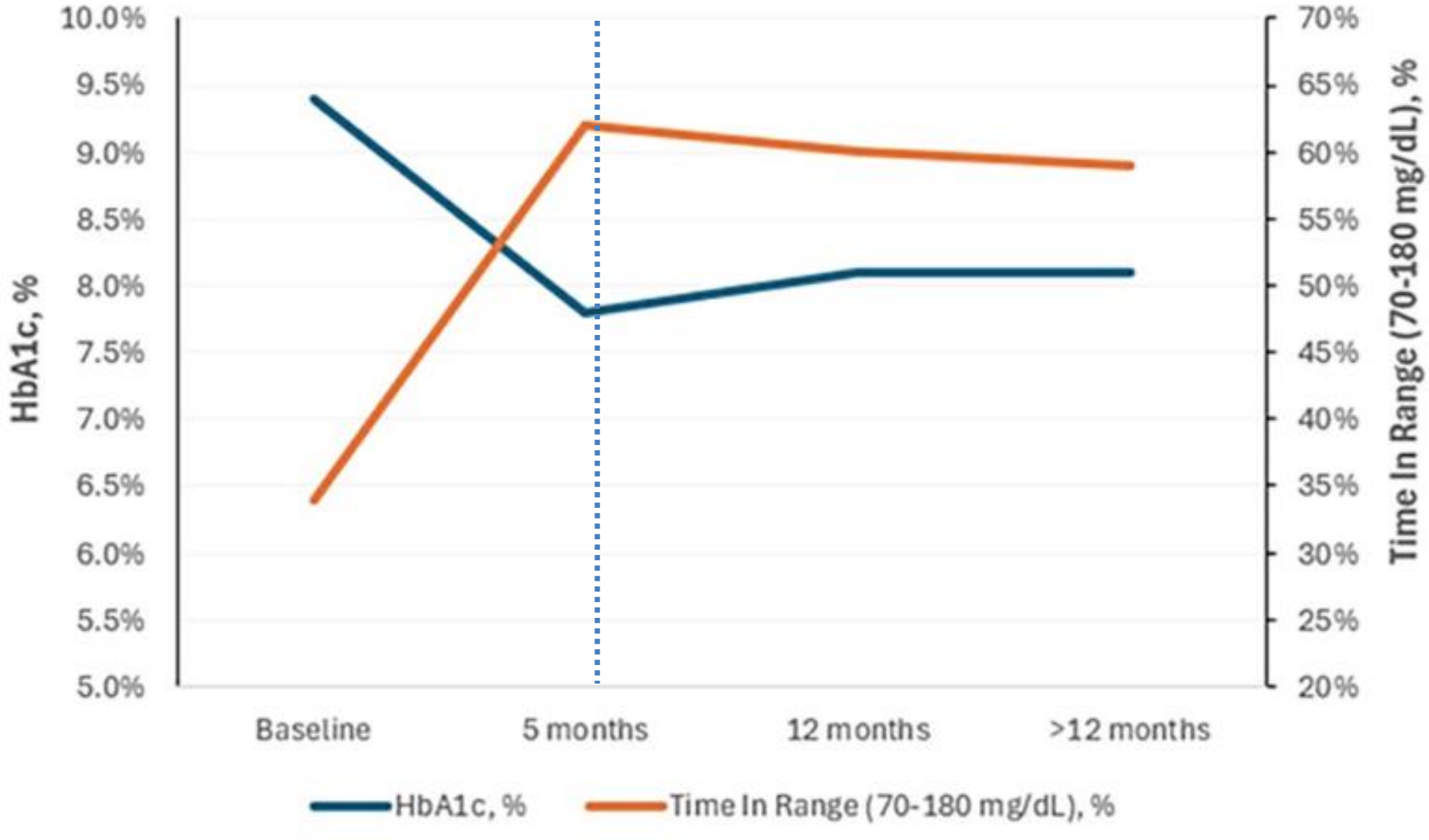
Publication: Diabetes Technology & Therapeutics • https://doi.org/10.1089/dia.2025.0165

P	PwT1D (adults) with HbA1c ≥8.5% (69 mmol/mol) on HCL between August and December 2021. 30 centres in the UK.
I	HCL (any system) at baseline
C	HCL (any system) at follow-up (between 6 and 38 months of follow-up), from March 2022 to October 2024
O	*Primary:* HbA1c *Secondary:* CGM metrics glucometrics, Gold score (hypoglycaemia awareness), diabetes distress score, acute event rates, user opinion of HCL

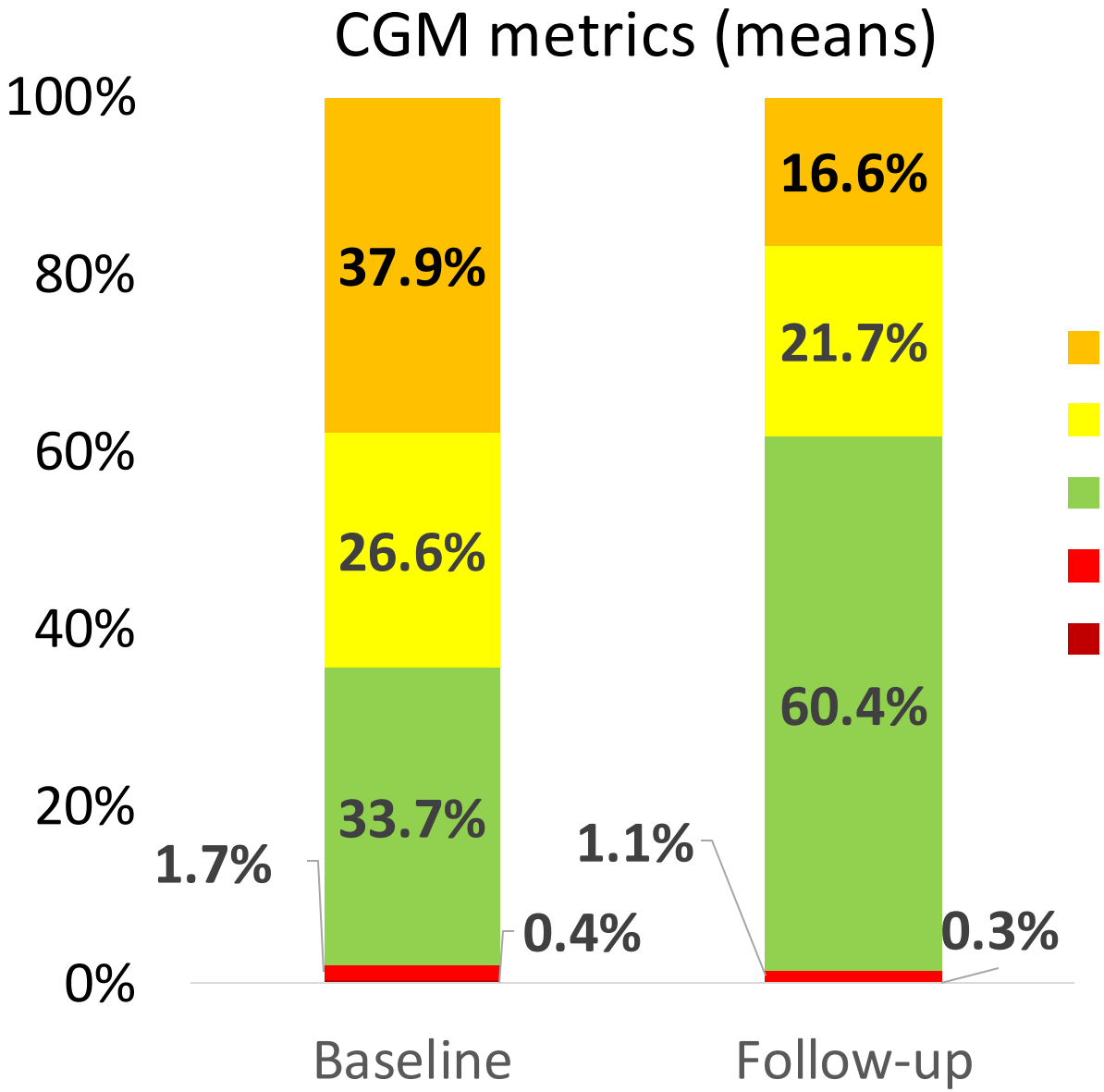
HCL usage reduced HbA1c by 1.3%.



HCL usage led to HbA1c decrease 5 months post initiation, which was sustained for the rest of the follow-up period.



HCL usage increased TIR, reduced TAR, and reduced **TBR<3.9mmol/L** without increasing **TBR<3.0mmol/L**.



Δ **-21.3%**, p<0.001
Δ **-4.9%**, p<0.001
Δ **+26%**, p<0.001
Δ **-0.6%**, p<0.001
Δ **-0.1%**, p=0.08

HCL ABCD audit

	Number	Baseline	12m	Change (95% CI)	P value
Diabetes distress scale score, mean ± SD	347	3.3 ± 1.2	2.2 ± 1.0	−1.1 (−1.3, −1.0)	<0.001
People with high diabetes distress (DDS2 score ≥3), % (*n*)	347	67.4 (234)	23.1 (80)	−44.3 (−154)	<0.001
Gold score, mean ± SD	349	2.2 ± 1.4	1.8 ± 1.2	−0.4 (−0.5, −0.2)	<0.001
People with IAH (Gold score ≥4), % (*n*)	349	16.6 (58)	9.2 (32)	−7.4 (−26)	<0.001

Unanswered question: HCL and IAH?

RCT: To use new technologies and educational courses to restore the awareness of hypoglycaemia in patients with type 1 diabetes.

CLEAR
Closed Loop and Education for hypoglycemia Awareness Restoration

P: People with T1D with impaired awareness of hypoglycaemia
HCL naïve and non-naive

I: Psychoeducational courses and HCL systems

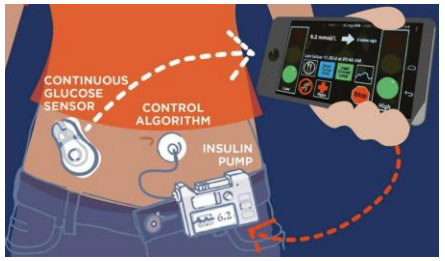
C: Standard care

O: Restoration of awareness determined by counterregulatory and symptom response to experimental hypoglycaemia (**clamp**).

My hypo compass

HARPdoc

VS



Acknowledgements

Image: Professor Pratik Choudhary

Prof Pratik Choudhary
Professor of Diabetes medicine
University of Leicester
YDEF ex Chair, currently committee member

Image: Dr. Alexandros Liarakos

Dr Alexandros Liarakos
Diabetes and Endocrinology Specialty Registrar ABCD Research Fellow
PhD student, University of Nottingham
YDEF committee member

Thank you for listening. Any questions?

Email: vk154@leicester.ac.uk