Microinfusore: limiti e vantaggi

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CONGRESSO REGIONALE CALABRIA SID-AMD 2024

T-HOTEL LAMEZIA TERME – 15 e 16 NOVEMBRE 2024

Disclosure

- Concetta Irace dichiara di aver ricevuto negli ultimi due anni compensi o finanziamenti dalle seguenti Aziende Farmaceutiche e/o Diagnostiche:

- Abbott
- Ascensia Diabetes Care Holdings AG
- Lilly Boehringer
- Medtronic
- Novo Nordisk
- Roche Diabetes Care Italia
- Sanofi

- *Dichiara altresì il proprio impegno ad astenersi, nell'ambito dell'evento, dal nominare, in qualsivoglia modo o forma, aziende farmaceutiche e/o denominazione commerciale e di non fare pubblicità di qualsiasi tipo relativamente a specifici prodotti di interesse sanitario (farmaci, strumenti, dispositivi medico-chirurgici, etc.)*

Table 1 AID systems terminology

Sensor-augmented pump (SAP)	Insulin pump with use of a CGM either on a separate device or displayed directly on the pump. These systems allow for viewing of the sensor data, but insulin delivery is not altered on the basis of sensor glucose values
Low glucose suspend (LGS) or predictive low glucose suspend (PLGS)	Insulin pump system that suspends insulin delivery for actual hypoglycaemia due to sensor glucose value (LGS) or for predicted hypoglycaemia (PLGS)
Hybrid AID (also known as hybrid closed loop)	Insulin pump system that automatically increases or decreases basal insulin delivery in response to sensor glucose values; user still needs to dose prandial insulin manually. Advanced hybrid AID systems are also available now. These next-generation systems not only adjust basal insulin delivery but also have the capacity to deliver automatic correction boluses. However, they still require the person with diabetes to dose prandial insulin
Full AID	AID system that automatically adjusts all insulin delivery, including prandial insulin
DIY AID (also known as Loop, OPEN APS, Android APS)	'Do-it-yourself' AID system using a commercially available CGM system and insulin pump, plus an open-source algorithm; currently not approved by regulatory agencies
Artificial pancreas (AP)	This term was used often in the past as a synonym for AID, but the AP does not take into account the exocrine functions of the pancreas
Bihormonal (bionic pancreas)	AID systems that incorporate two hormones (insulin and glucagon); insulin and pramlintide are also being studied

Diabetologia (2023) 66:3–22

The use of AID systems **does not mean that diabetes is 'cured'**; instead, when integrated into care, AID systems hold promise to **relieve some of the daily burdens** of diabetes care by adjusting basal insulin delivery and providing automatic correction doses

Diabetes/Metabolism Research and Reviews

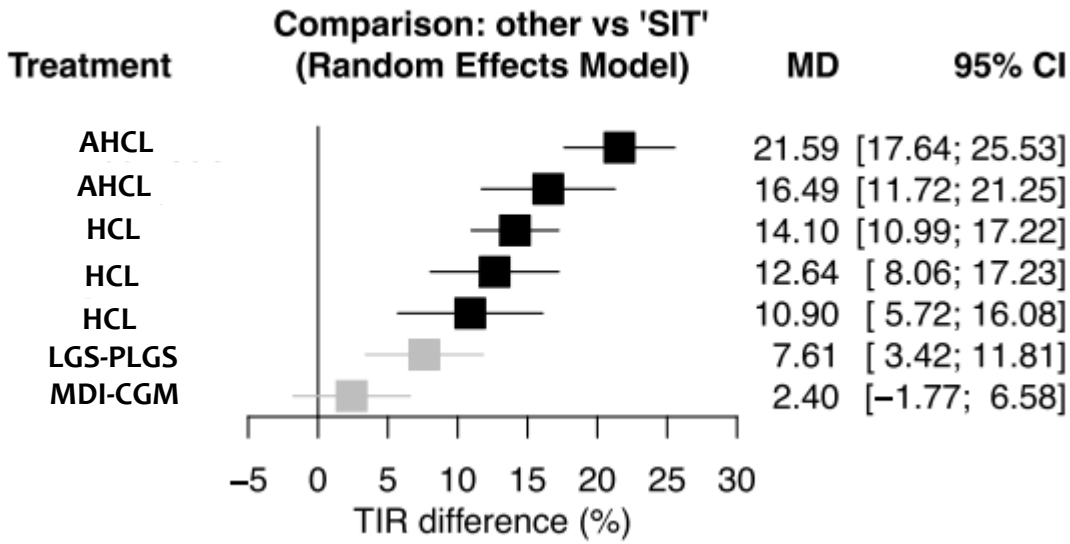
WILEY

REVIEW ARTICLE OPEN ACCESS

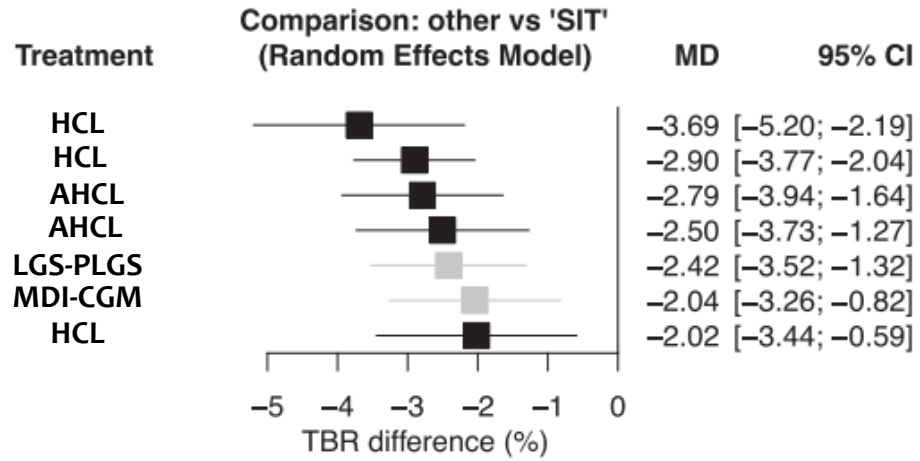
Efficacy and Safety of Different Hybrid Closed Loop Systems for Automated Insulin Delivery in People With Type 1 Diabetes: A Systematic Review and Network Meta-Analysis

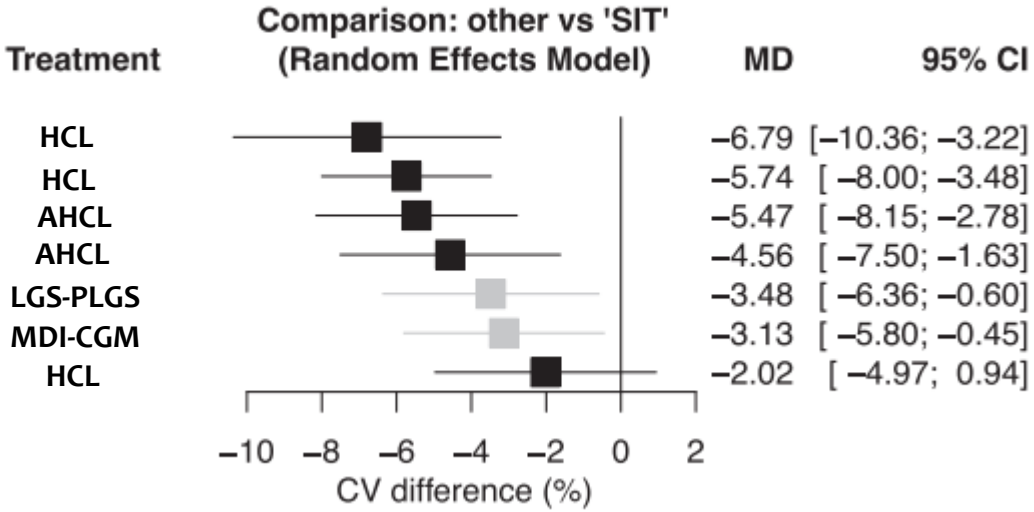
Sergio Di Molfetta[1] | Ludovico Di Gioia[1] | Irene Caruso[1] | Angelo Cignarelli[1] | Suetonia C. Green[2] | Patrizia Natale[3,4,5] | Giovanni F. M. Strippoli[3,4] | Gian Pio Sorice[1] | Sebastio Perrini[1] | Annalisa Natalicchio[1] | Luigi Laviola[1] | Francesco Giorgino[1]

Network meta-analysis results for Time In Range (TIR) compared with subcutaneous insulin therapy without CGM (SIT)



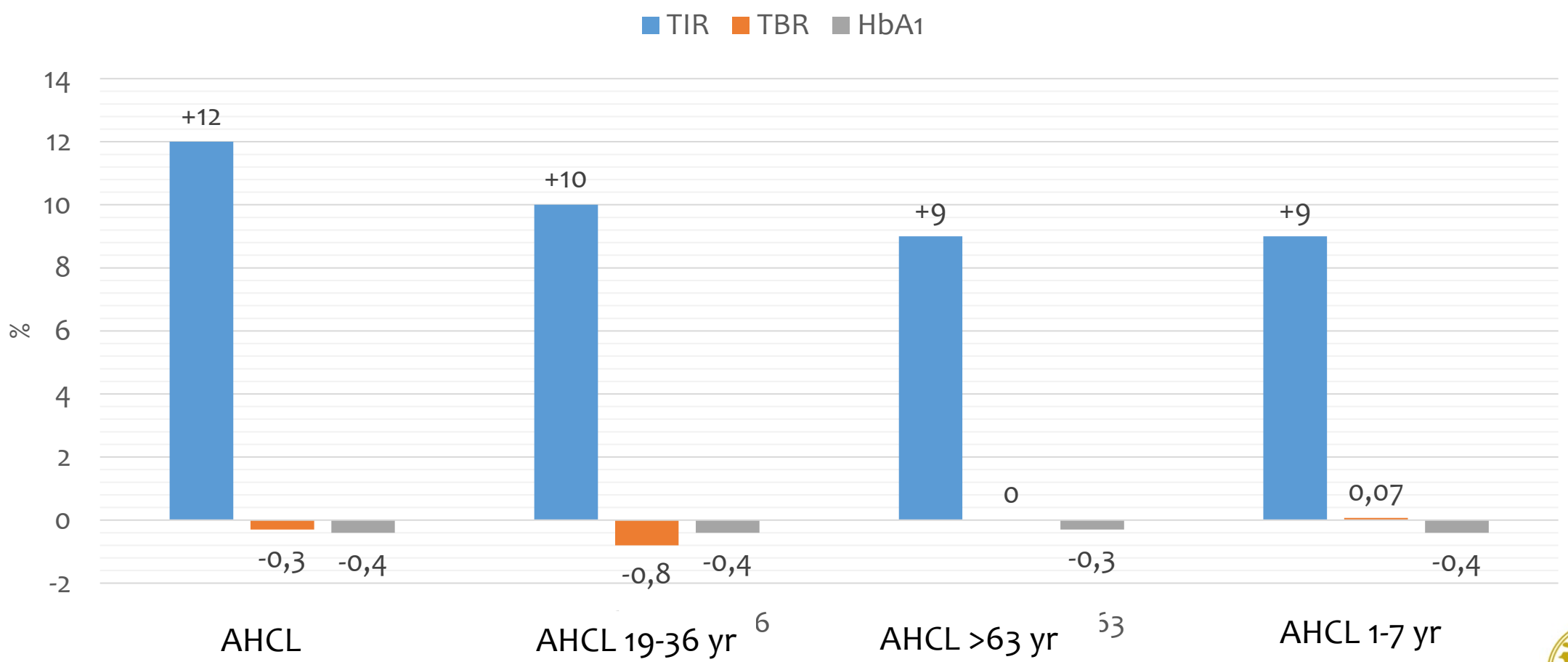
Network meta-analysis results for Time Below Range (TBR) and Coeffcient of Variation compared with subcutaneous insulin therapy without CGM (SIT)





Diabetes/Metabolism Research and Reviews, 2024; 40:e3842

Key real world trials



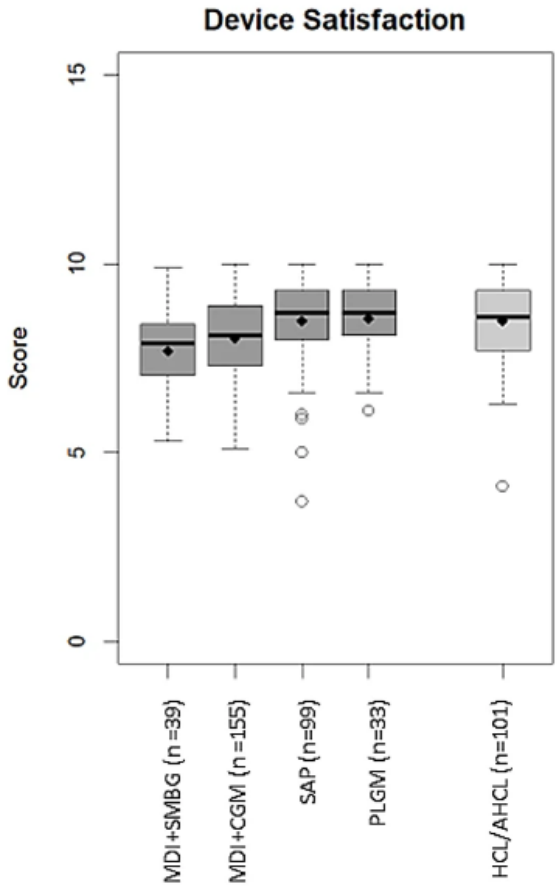
Acta Diabetologica
https://doi.org/10.1007/s00592-024-02381-3

ORIGINAL ARTICLE

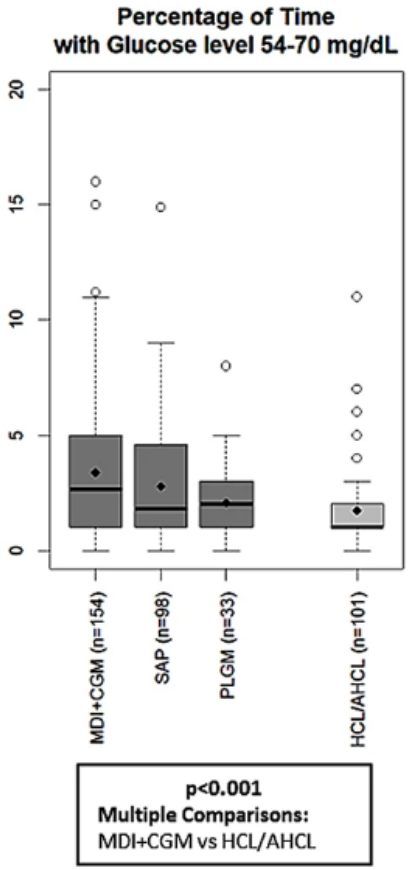
Glucose metrics and device satisfaction in adults with type 1 diabetes using different treatment modalities: a multicenter, real-world observational study

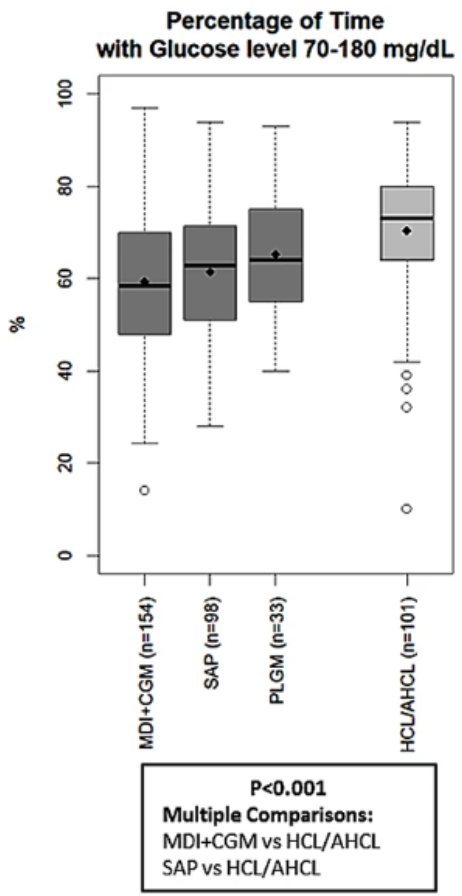
S. Di Molfetta[1] · A. Rossi[2,3] · R. Gesuita[4] · A. Faragalli[4] · A. Cutruzzolà[5] · C. Irace[6] · N. Minuto[7] · D. Pitocco[8] · F. Cardella[9] · C. Arnaldi[10] · A. Frongia[11] · E. Mozzillo[12] · B. Predieri[13] · P. Fiorina[14,15,16,17] · F. Giorgino[1] · V. Cherubini[18]

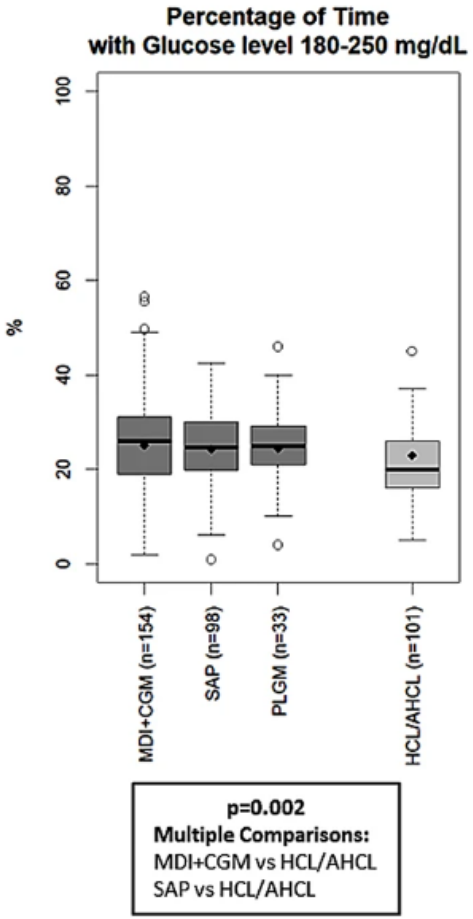
DIDS domains
F1. Device Satisfaction
1. Satisfaction
2. Trust
3. Helps me feel more in control of my diabetes
4. Helps me have good BG control
5. Easy to use
6. Is a hassle to use
7. Is too complicated

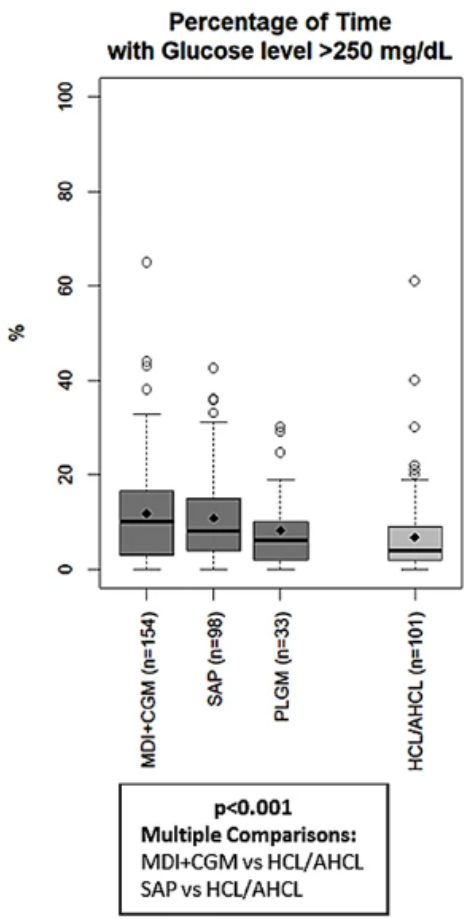


p<0.001
Multiple Comparisons:
MDI+SMBG vs HCL/AHCL
MDI+SMBG vs SAP
MDI+SMBG vs PLGM
MDI+CGM vs HCL/AHCL
MDI+CGM vs SAP


Percentage of Time
with Glucose level 54-70 mg/dL
0
5
10
15
20
MDI+CGM (n=154)
SAP (n=98)
PLGM (n=33)
HCL/AHCL (n=101)
p<0.001
Multiple Comparisons:
MDI+CGM vs HCL/AHCL


Percentage of Time
with Glucose level 70-180 mg/dL
%
0
20
40
60
80
100
MDI+CGM (n=154)
SAP (n=98)
PLGM (n=33)
HCL/AHCL (n=101)
P<0.001
Multiple Comparisons:
MDI+CGM vs HCL/AHCL
SAP vs HCL/AHCL


Percentage of Time
with Glucose level 180-250 mg/dL
%
0
20
40
60
80
100
MDI+CGM (n=154)
SAP (n=98)
PLGM (n=33)
HCL/AHCL (n=101)
p=0.002
Multiple Comparisons:
MDI+CGM vs HCL/AHCL
SAP vs HCL/AHCL


Percentage of Time
with Glucose level >250 mg/dL
%
0
20
40
60
80
100
MDI+CGM (n=154)
SAP (n=98)
PLGM (n=33)
HCL/AHCL (n=101)
p<0.001
Multiple Comparisons:
MDI+CGM vs HCL/AHCL
SAP vs HCL/AHCL

Diabetologia (2023) 66:3–22
https://doi.org/10.1007/s00125-022-05744-z

CONSENSUS REPORT

Automated insulin delivery: benefits, challenges, and recommendations. A Consensus Report of the Joint Diabetes Technology Working Group of the European Association for the Study of Diabetes and the American Diabetes Association

Jennifer L. Sherr[1] · Lutz Heinemann[2] · G. Alexander Fleming[3] · Richard M. Bergenstal[4] · Daniela Bruttomesso[5] · Hélène Hanaire[6] · Reinhard W. Holl[7,8] · John R. Petrie[9] · Anne L. Peters[10] · Mark Evans[11]

Limitations of AID systems

Physiological

1. Time lag in sensor glucose values as measured in ISF vs blood
2. Delayed absorption of insulin from subcutaneous depot; pharmacodynamic effects of applied insulin are different from physiological secreted insulin

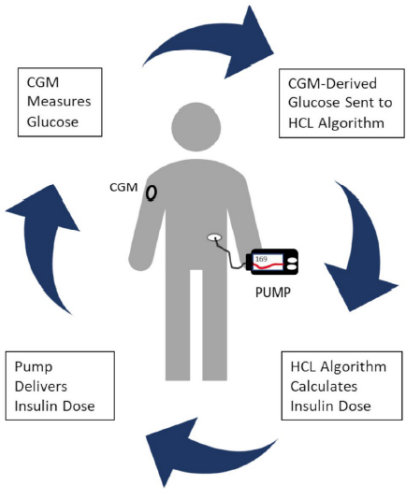
Technological

1. Suboptimal analytical accuracy of CGM systems in low glucose range
2. Compression of tissue around sensor insertion site leads to falsely detected hypoglycaemia
3. Missing sensor glucose data (e.g., due to transmission failures) and sensor warm-up time
4. Glucose sensor overreading and inadvertent overdelivery of insulin
5. Infusion set failures or pod failure
6. Outright pump failure due to software or hardware issues
7. Issues with data uploading, regular exchange of batteries, loss of communication between components of the AID system/cloud network
8. Server interruptions leading to inability to remotely track data
9. Cybersecurity/data protection/data privacy
10. Need for regular update of software/operating systems/apps
11. Impact of work or environmental conditions has to be considered (i.e., exposure to high or low temperatures, magnetic fields, or water)

Behavioural

1. Patient needs to bolus prandial insulin
2. Requirement of correction boluses
3. Problem-solving for hyperglycaemia (i.e., detect failed infusion sets, broken system components)
4. Avoidance of hyperglycaemia overcorrections and avoiding adding fake carbs, etc.
5. Overtreatment of hypoglycaemia
6. Limitations and challenges of exercise
7. Need for backup supplies

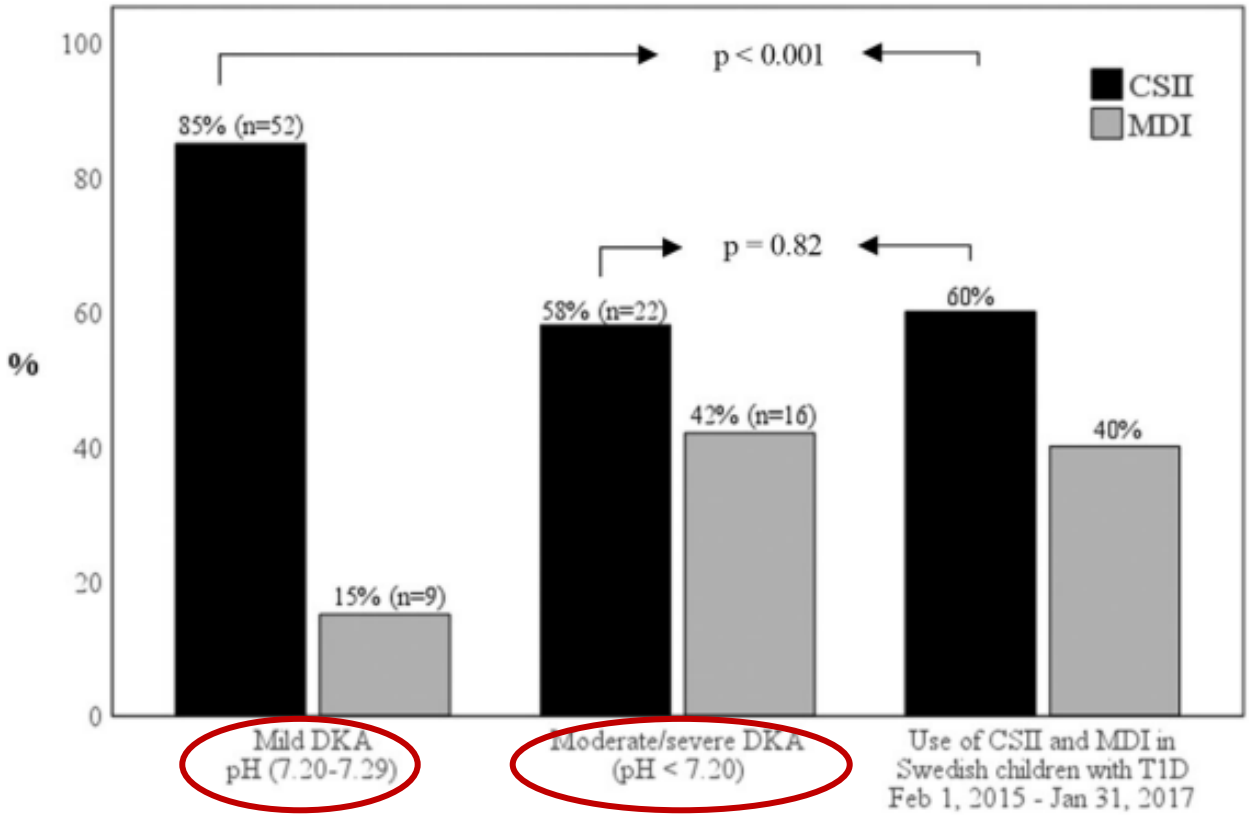
Hybrid Closed Loop Automation



Received: 9 March 2022 | Revised: 31 May 2022 | Accepted: 7 June 2022
DOI: 10.1111/pedi.13377

ISPAD WILEY

Insulin pump therapy is associated with higher rates of mild diabetic ketoacidosis compared to injection therapy: A 2-year Swedish national survey of children and adolescents with type 1 diabetes

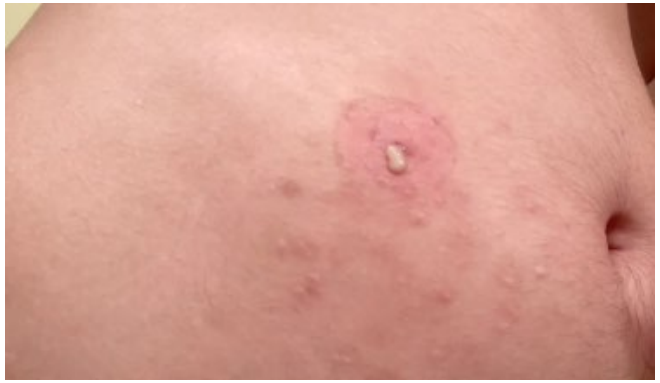


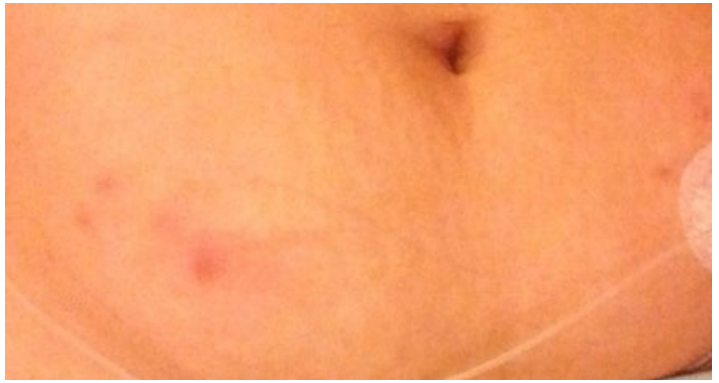
Journal of Diabetes Science and Technology
Volume 6, Issue 4, July 2012

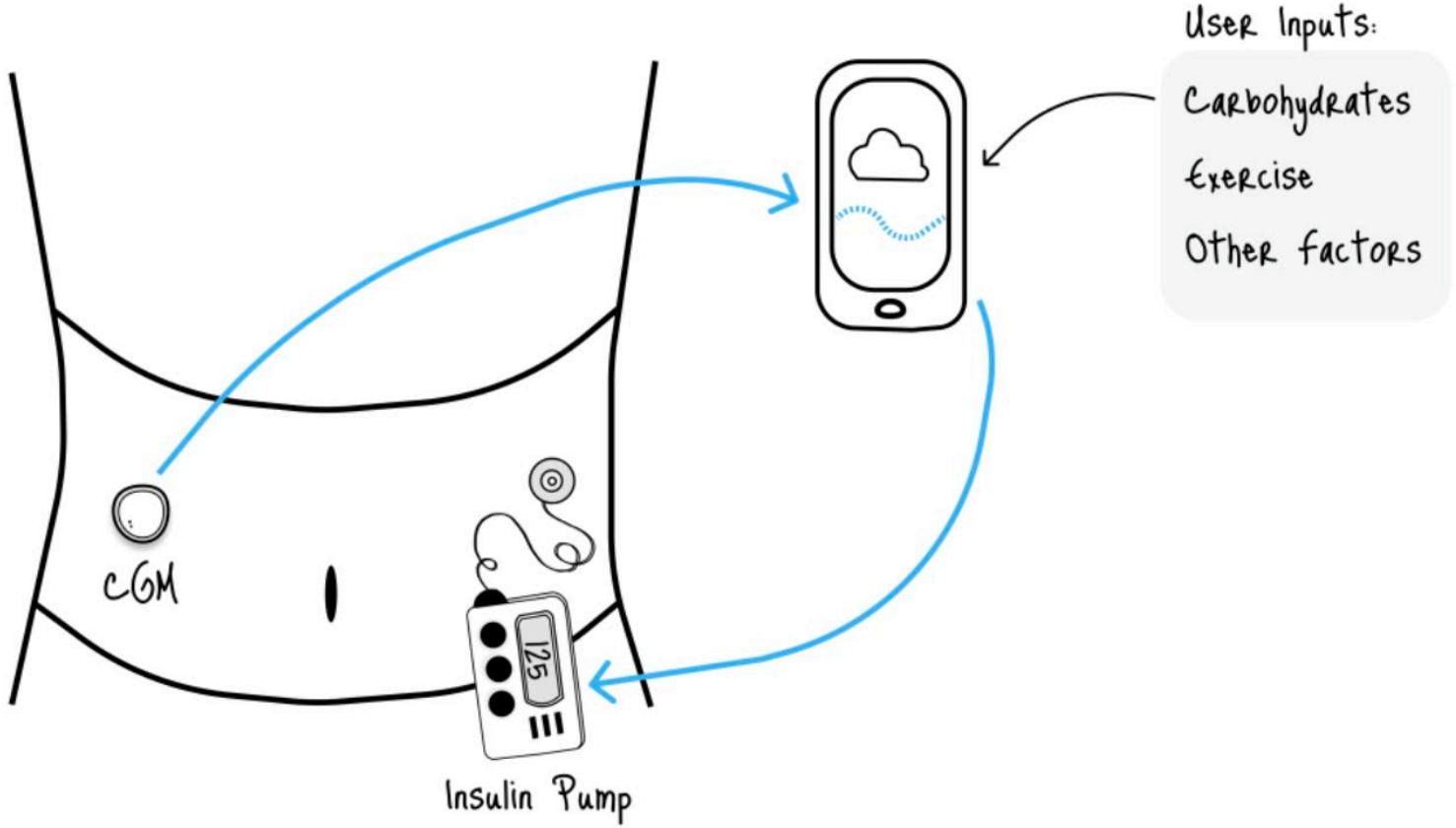
REVIEW ARTICLE

Insulin Infusion Set: The Achilles Heel of Continuous Subcutaneous Insulin Infusion

Lutz Heinemann, Ph.D.,[1] and Lars Krinelke, M.D., Ph.D.[2]







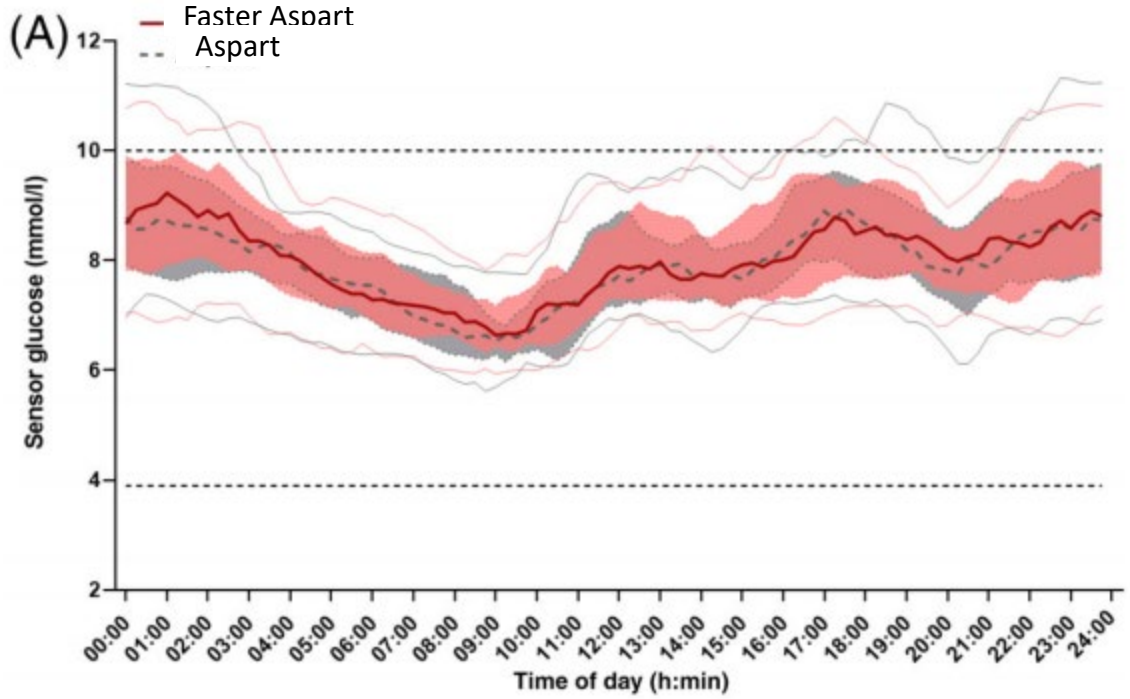
BUT WHAT IF IT WORKS

Received: 31 December 2020 | Revised: 11 February 2021 | Accepted: 16 February 2021
DOI: 10.1111/dom.14355

ORIGINAL ARTICLE

WILEY

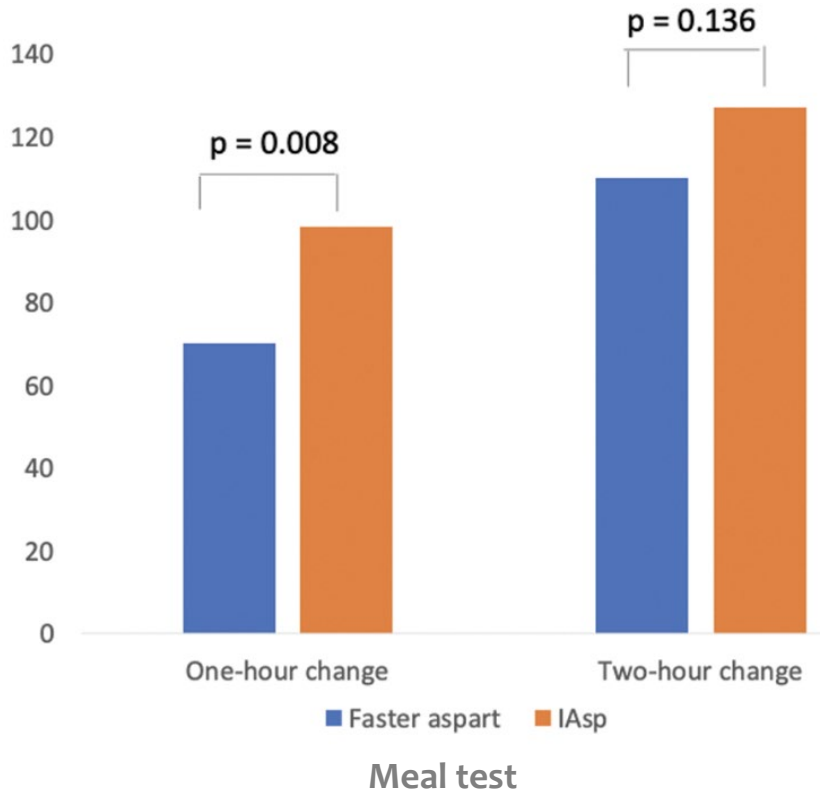
Hybrid closed-loop glucose control with faster insulin aspart compared with standard insulin aspart in adults with type 1 diabetes: A double-blind, multicentre, multinational, randomized, crossover study



Glucose control and insulin delivery over **8 weeks** of closed-loop with faster-acting insulin and closed-loop with standard insulin aspart;
* p=0.03

	Faster Aspart (N 25)	Standard insulin aspart (n = 25)
% of time with sensor glucose level		
3.9 to 10.0 mmol/L*	75 ± 8	75 ± 8
<3.9 mmol/L	2.4 (1.2, 3.2)	2.9 (1.7, 4.0)
<3.5 mmol/L	1.2 (0.5, 1.9)	1.7 (0.7, 2.3)
<3.0 mmol/L	0.4 (0.2, 0.7)	0.7 (0.2, 0.9) *

Fast Acting Insulin Aspart Compared with Insulin Aspart in the 670G Hybrid Closed Loop System in Type 1 Diabetes: An Open Label Crossover Study



Percentage of **time spent in range** with Faster Aspart relative to IAsp

	<70 mg/dL	70-180 mg/dL	>200 mg/dL
Percentage of time spent in range with FA relative to IAsp	-0.4% (p=0.029)	+1.81% (p=0.016)	-1.38% (p=0.016)

DIABETES TECHNOLOGY & THERAPEUTICS 23, 2021 DOI: 10.1089/dia.2020.0500

Strengths and Challenges of Closed-Loop Insulin Delivery During Exercise in People With Type 1 Diabetes: Potential Future Directions

Journal of Diabetes Science and Technology
2023, Vol. 17(4) 1077–1084

DOI: 10.1177/19322968221088327
journals.sagepub.com/home/dst
SAGE

Barbora Paldus, MBBS[1,2], Dale Morrison, PhD[1], Melissa Lee, MBBS[1,2], Dessi P. Zaharieva, PhD[3], Michael C. Riddell, PhD[4], and David N. O'Neal, MD[1,2]

Table 1. Strengths and Limitations of Current Commercially Available CL Systems During Exercise.

Strengths	Limitations
• Responsive to changes in glucose • Devices are portable • Improved time-in-range during exercise • Most systems are waterproof or water-resistant • Device performance is not significantly impacted by exercise	• Preplanning required due to slow onset and offset of subcutaneously delivered insulin • CGM and cannula site adhesive may be affected by sweat • Inability to automatically recognize exercise versus rest • CGM accuracy can be impacted with rapid changes in glucose during exercise

Abbreviations: CL, closed loop; CGM, continuous glucose monitoring.

A Randomized Crossover Trial Comparing Glucose Control During Moderate-Intensity, High-Intensity, and Resistance Exercise With Hybrid Closed-Loop Insulin Delivery While Profiling Potential Additional Signals in Adults With Type 1 Diabetes

Barbora Paldus,[1,2] Dale Morrison,[1] Dessi P. Zaharieva,[3] Melissa H. Lee,[1,2] Hannah Jones,[1,2] Varuni Obeyesekere,[2] Jean Lu,[1,2] Sara Vogrin,[1] André La Gerche,[4,5] Sybil A. McAuley,[1,2] Richard J. MacIsaac,[1,2] Alicia J. Jenkins,[1,6] Glenn M. Ward,[1] Peter Colman,[7] Carmel E.M. Smart,[8] Rowen Seckold,[8] Bruce R. King,[8] Michael C. Riddell,[3] and David N. O'Neal[1,2]

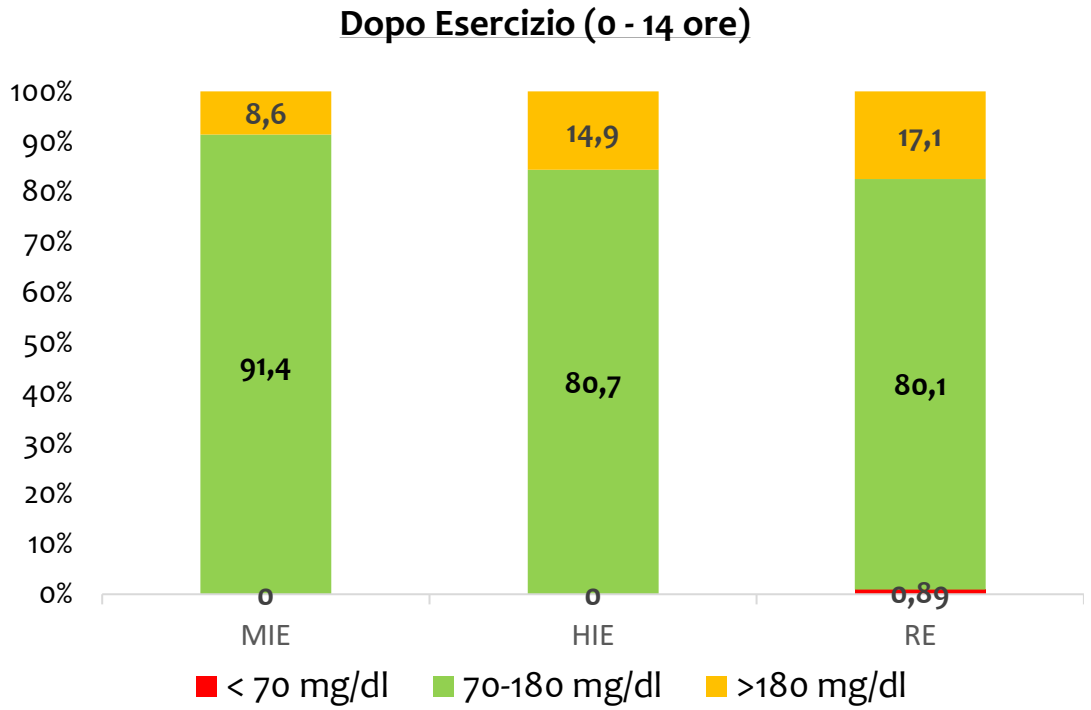
Diabetes Care 2022;45:194–203 | https://doi.org/10.2337/dc21-1593

MIE — 40 minuti di esercizio aerobico ad intensità moderata

HIE — 40 minuti di esercizio intervallato ad alta intensità

RE — 40 minuti di esercizio di forza

Pump setting: a temporary target set 2 h prior to and during exercise and 15 g carbohydrates if pre-exercise glucose was lower than 130 mg/dl.



DIABETES TECHNOLOGY & THERAPEUTICS
Volume 25, Number 7, 2023

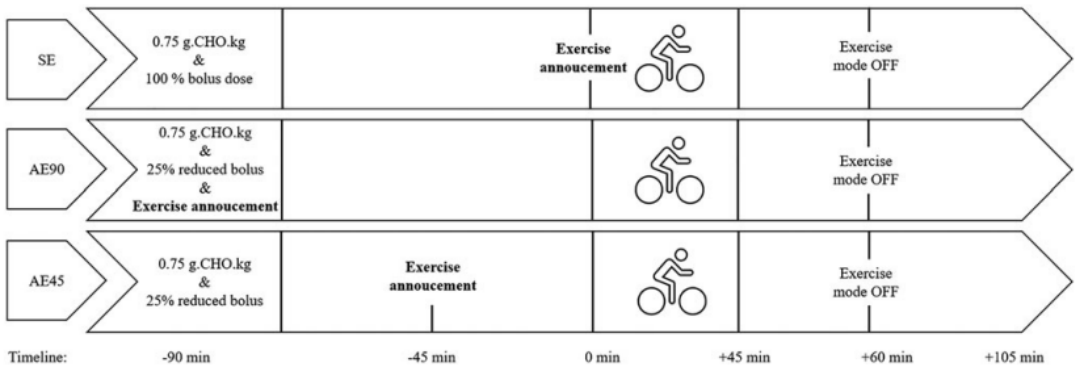
DOI: 10.1089/dia.2023.0009

ORIGINAL ARTICLE

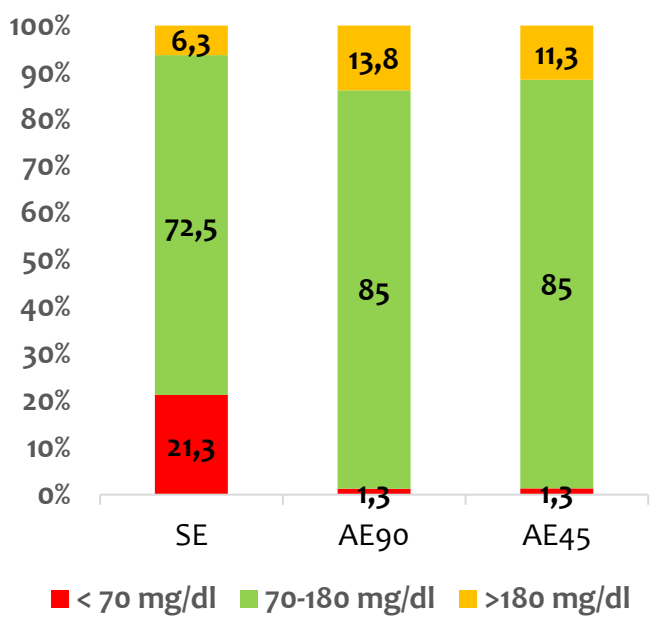
Automated Insulin Delivery Around Exercise in Adults with Type 1 Diabetes: A Pilot Randomized Controlled Study

Olivia M. McCarthy, PhD,[1,2] Merete B. Christensen, MD, PhD,[2] Kasper Birch Kristensen, MD, PhD,[2] Signe Schmidt, MD, PhD,[2] Ajenthen G. Ranjan, MD, PhD,[2,3] Stephen C. Bain, MD, PhD,[4] Richard M. Bracken, MD, PhD,[1] and Kirsten Nørgaard, MD[2,5]

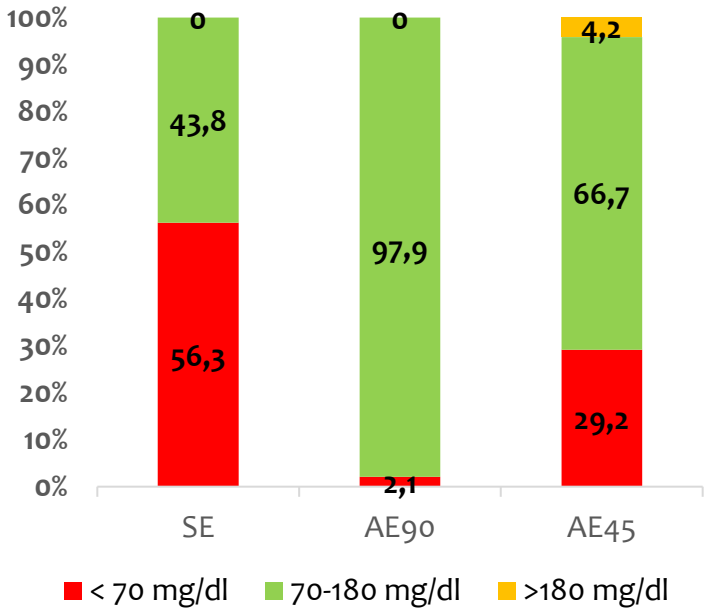
Study Design



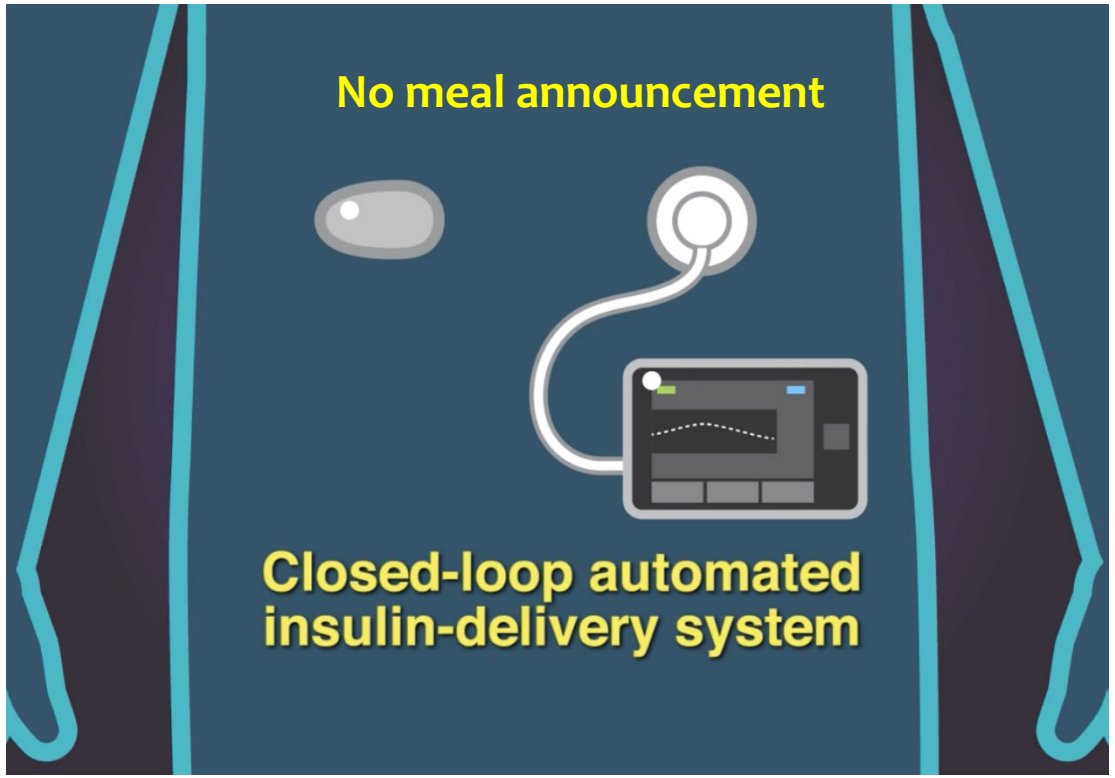
Durante Esercizio (0 - 45 min)



Dopo Esercizio (50 - 105 min)



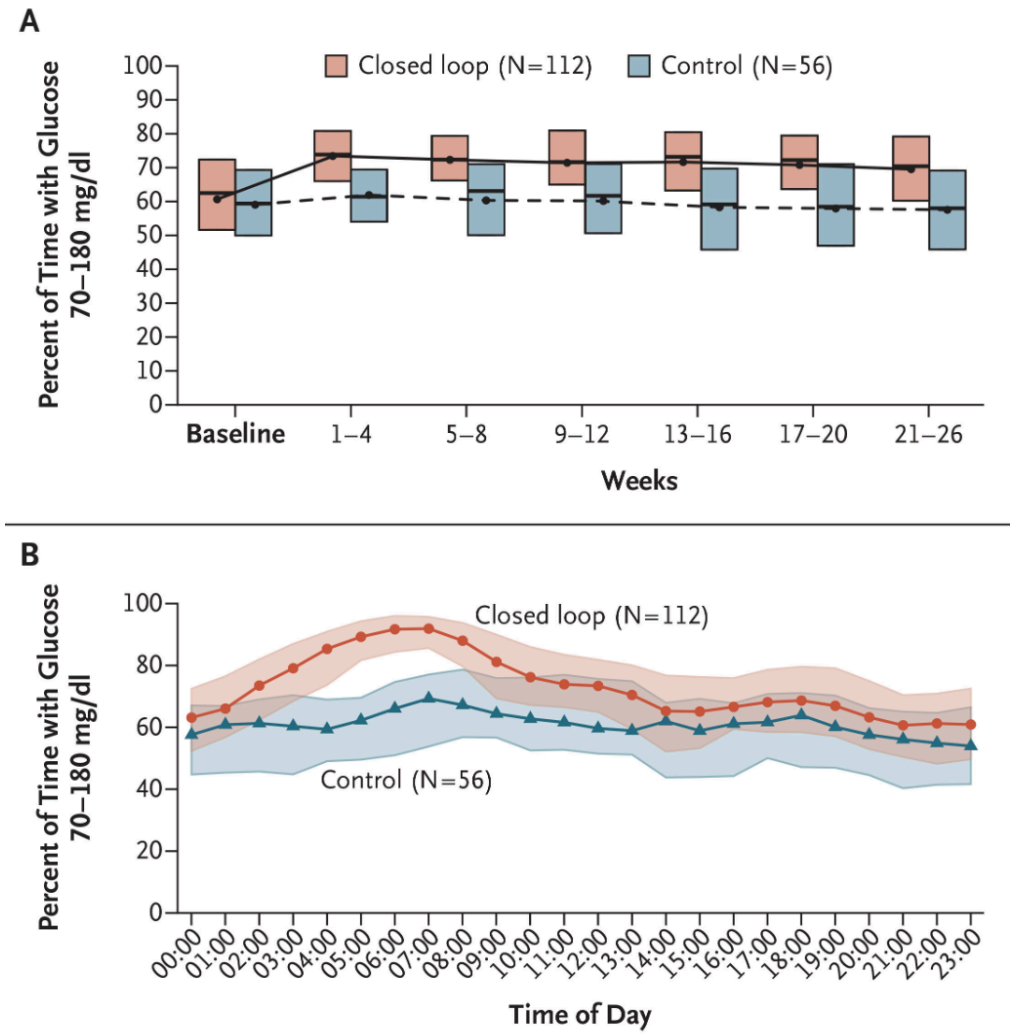
Toward Fully closed-loop



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 31, 2019 VOL. 381 NO. 18

Six-Month Randomized, Multicenter Trial of Closed-Loop Control in Type 1 Diabetes



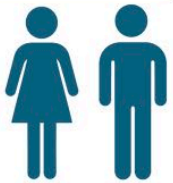
Fully Closed-Loop Glucose Control Compared With Insulin Pump Therapy With Continuous Glucose Monitoring in Adults With Type 1 Diabetes and Suboptimal Glycemic Control: A Single-Center, Randomized, Crossover Study

Charlotte K. Boughton, Sara Hartnell, Rama Lakshman, Munachiso Nwokolo, Malgorzata E. Wilinska, Julia Ware, Janet M. Allen, Mark L. Evans, and Roman Hovorka

Diabetes Care 2023;46(11):1916–1922 | https://doi.org/10.2337/dc23-0728

Participants

26 adults with type 1 diabetes and suboptimal glycemic control
- Baseline HbA_{1c} 9.2% (77 mmol/mol)

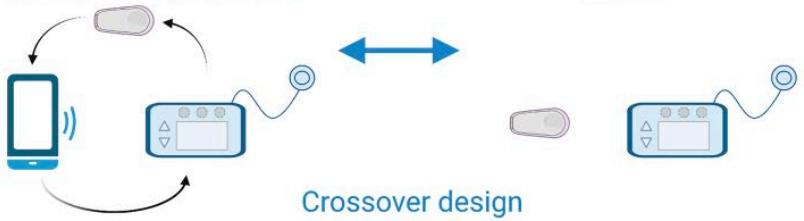


Intervention

Fully closed-loop insulin delivery for eight weeks

Control

Pump with CGM for eight weeks



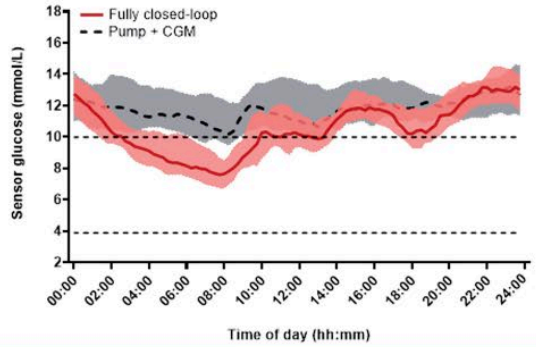
Crossover design

Primary Outcome

Proportion of time spent in target glucose range (3.9 to 10.0 mmol/L).

Results

- Time in target range was significantly higher during closed-loop than during pump with CGM (50.0±9.6% vs. 36.2±12.2%; P<0.001).
- Time with glucose <3.9mmol/L was similar between periods.
- No severe hypoglycemia or ketoacidosis occurred.



Conclusions

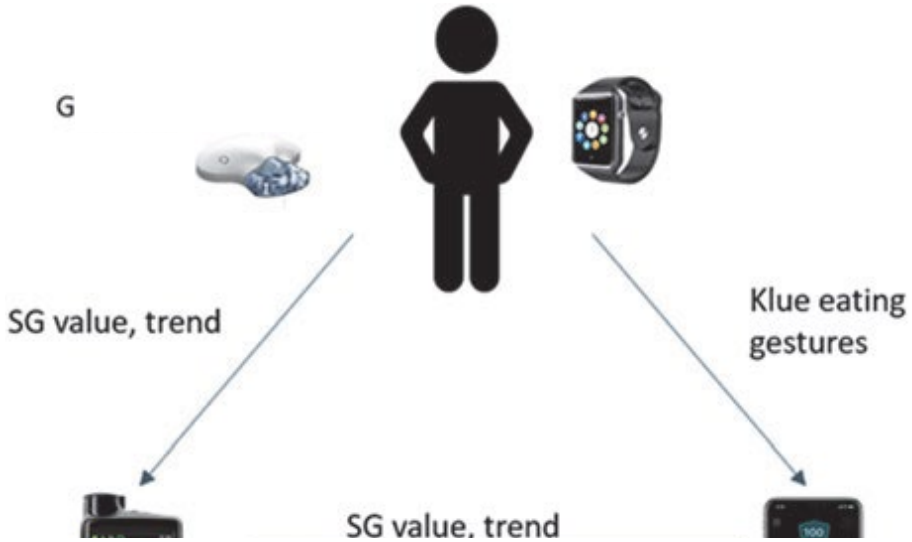
Fully closed-loop insulin delivery with CamAPS HX improved glucose control compared to insulin pump therapy with CGM in adults with type 1 diabetes and suboptimal glycemic control.

An Automated Insulin Delivery System with Automatic Meal Bolus Based on a Hand-Gesturing Algorithm

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 26, Number 9, 2024

DOI: 10.1089/dia.2023.0529

Anirban Roy, PhD,[1] Benyamin Grosman, PhD,[1] Andrea Benedetti, MS,[1] Bahman Engheta, PhD,[1] Diana Miller, MS,[1] Maya Laron-Hirsh, RD,[2] Yael Cohen, MBA,[2] Roseline Ré, MSc,[3] Shannon N. Edd, PhD,[3] Robert Vigersky, MD,[1] Ohad Cohen, MD,[1,3] and Amir Tirosh, MD, PhD[2]



Nessuna differenza nel TAR o TBR
Nessun evento grave

	Home-stay	*Hotel-stay*	*Change*[a]	P
Overall day				
% Time in AHCL	99.2 (1.6)	99.7 (1.1)	0.5 (1.3)	0.1173
% <54 mg/dL	0.3 (0.3)	0.3 (0.3)	0 (0.4)	0.765
% <70 mg/dL	3.1 (1.9)	3.0 (2.5)	−0.1 (2.5)	0.9144
% 70–180 mg/dL	83.4 (7)	80.6 (6.7)	−2.8 (5.9)	0.08
% 70–140 mg/dL	62.7 (9.8)	57.9 (9.4)	−4.8 (10.3)	0.07
% >180 mg/dL	13.5 (6.8)	16.3 (7.4)	2.8 (6.8)	0.1046
% >250 mg/dL	1.7 (2.8)	2.5 (2.1)	0.8 (3.8)	0.4299
Mean of SG, mg/dL	131.2 (10.7)	136.2 (12.9)	5 (13)	0.1294
SD of SG, mg/dL	42.3 (9.1)	44.8 (6.8)	2.5 (9.9)	0.3141
CV of SG	32.2 (5.2)	33 (5)	0.9 (6.3)	0.5735
TDD, U/day	44.7 (15.8)	43.7 (15.2)	−1.3 (6.8)	0.4546
Daytime period (06:00–23:59)				
% <54 mg/dL	0.4 (0.5)	0.4 (0.4)	−0.1 (0.5)	0.6261
% <70 mg/dL	3.7 (2.7)	3.5 (2.8)	−0.1 (3)	0.8793
% 70–180 mg/dL	81.3 (7.3)	77.9 (7.2)	−3.4 (6.4)	**0.0471**
% >180 mg/dL	15.1 (7.3)	18.5 (7.5)	3.5 (7.9)	0.0869
% >250 mg/dL	1.9 (3.2)	3.1 (2.6)	1.4 (4.2)	0.194
Mean of SG, mg/dL	132.7(12.6)	138.4 (13)	5.7 (14.7)	0.1299
Nighttime period (00:00–05:59)				
% <54 mg/dL	0 (0)	0 (0.1)	0 (0.1)	0.3322
% <70 mg/dL	1.7 (2.6)	1.5 (2.4)	−0.2 (3)	0.8118
% 70–180 mg/dL	89.3 (9.8)	89.2 (11.1)	−0.1 (12.1)	0.9766
% >180 mg/dL	9 (9.7)	9.3 (11.6)	0.3 (11.8)	0.9272
% >250 mg/dL	1 (2.6)	0.5 (1.1)	−0.5 (3)	0.4789

Data are shown as mean (SD).
[a]Home-stay values deducted from Hotel-stay values. $N = 17$ participants for both.
AHCL, advanced hybrid closed-loop; CV, coefficient of variation; SG, sensor glucose.

Integrating metabolic expenditure information from wearable fitness sensors into an AI-augmented automated insulin delivery system: a randomised clinical trial

Peter G Jacobs, Navid Resalat, Wade Hilts, Gavin M Young, Joseph Leitschuh, Joseph Pinsonault, Joseph El Youssef, Deborah Branigan, Virginia Gabo, Jae Eom, Katrina Ramsey, Robert Dodier, Clara Mosquera-Lopez, Leah M Wilson, Jessica R Castle

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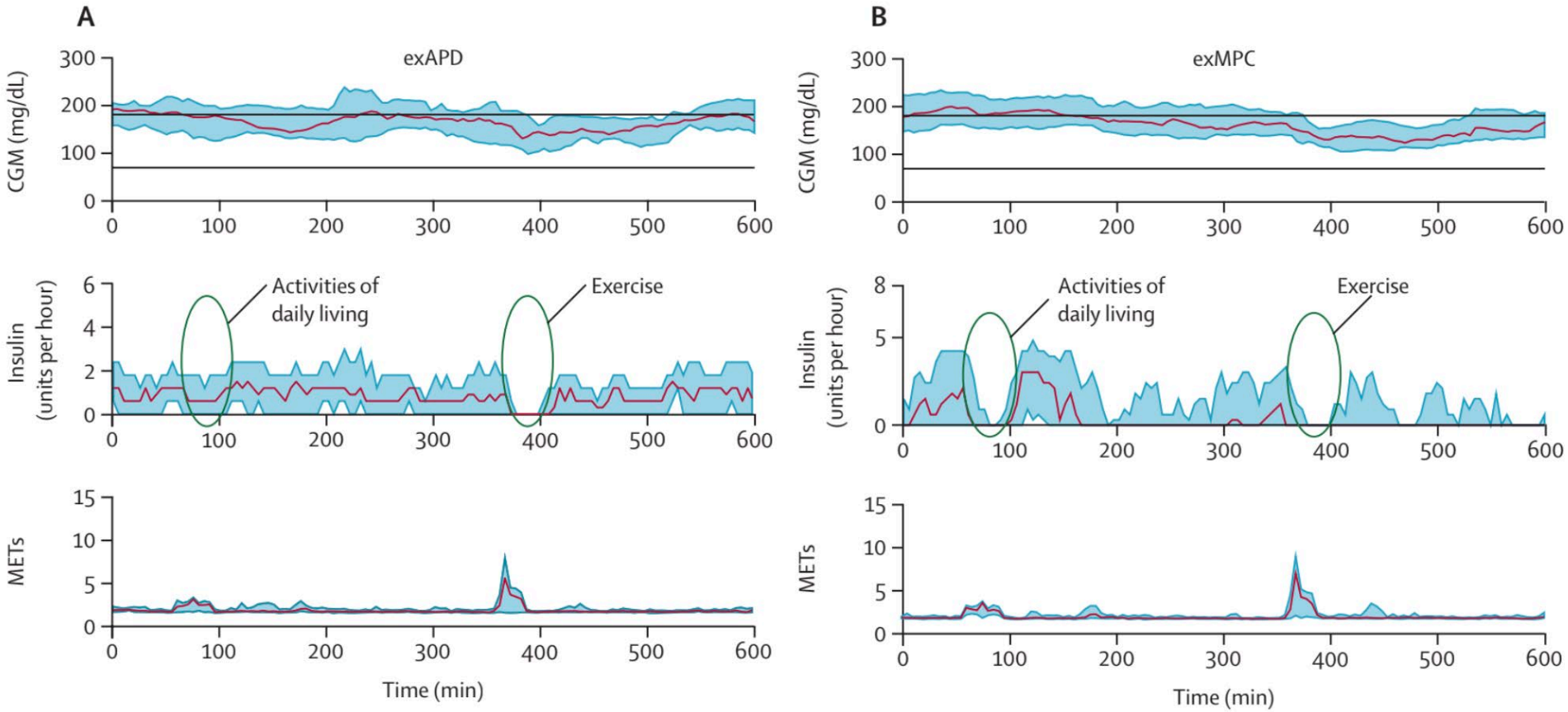

Conclusioni

- I sistemi automatici attualmente disponibili per l'erogazione dell'insulina **migliorano la metrica** del glucosio;
- I sistemi automatici per l'erogazione dell'insulina **migliorano la qualità di vita del paziente** in termini di accettazione della terapia;
- La gestione del **pasto e dell'esercizio fisico** rappresenta ancora una barriera nella terapia con microinfusore in assenza di una adeguata gestione del microinfusore;
- L'**AI** è promettente per l'implementazione dei benefici della automazione nell'ottica di una personalizzazione della terapia.