INNOVAZIONE TECNOLOGICA
E SOSTENIBILITÀ NELLA GESTIONE
DEL DIABETE MELLITO

7-8 NOVEMBRE 2025

DOSSOBUONO DI VILLAFRANCA (VR)
Hotel Veronesi La Torre

I sistemi Automatizzati per l'Infusione di Insulina: una Tecnologia per Tutti

NO

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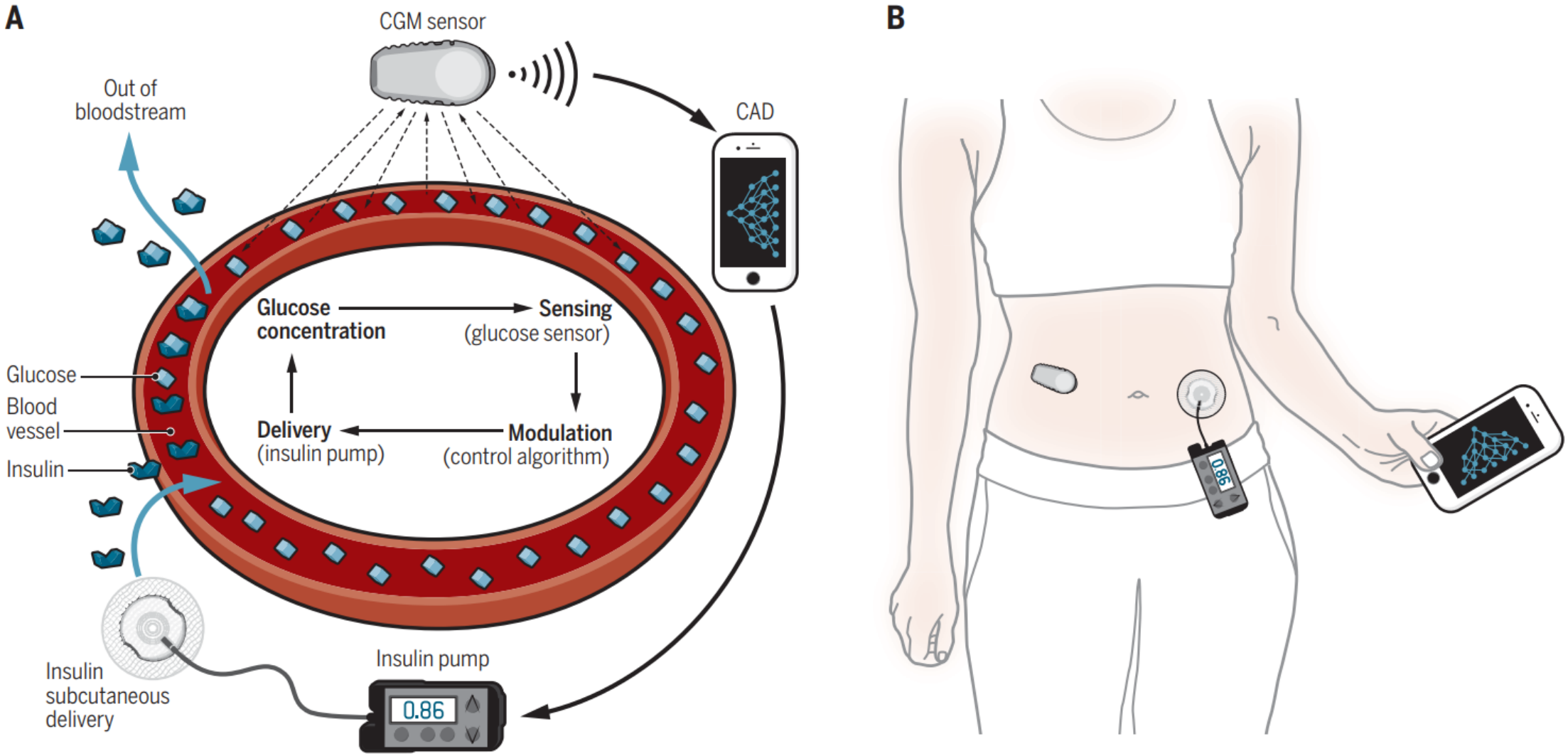
Direttore Prof. Francesco Giorgino

Il Dr Sergio Di Molfetta dichiara di aver ricevuto negli ultimi due anni compensi o finanziamenti dalle seguenti Aziende Farmaceutiche e/o Diagnostiche:

- Ascensia Diabetes Care
- Menarini Diagnostics
- Movi SpA
- Roche Diabetes Care Italy
- Sanofi
- Theras Lifetech Srl

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, ecc...)

Closed-Loop Insulin Delivery



CGM, continuous glucose monitor; CAD, control algorithm device

Boughton CK et al. Sci Transl Med. 2019 Mar 20;11(484):eaaw4949

Efficacy and Safety of AID Systems in People with Type 1 Diabetes

Meta-Analysis; 65 Randomized Controlled Trials, n = 3,623

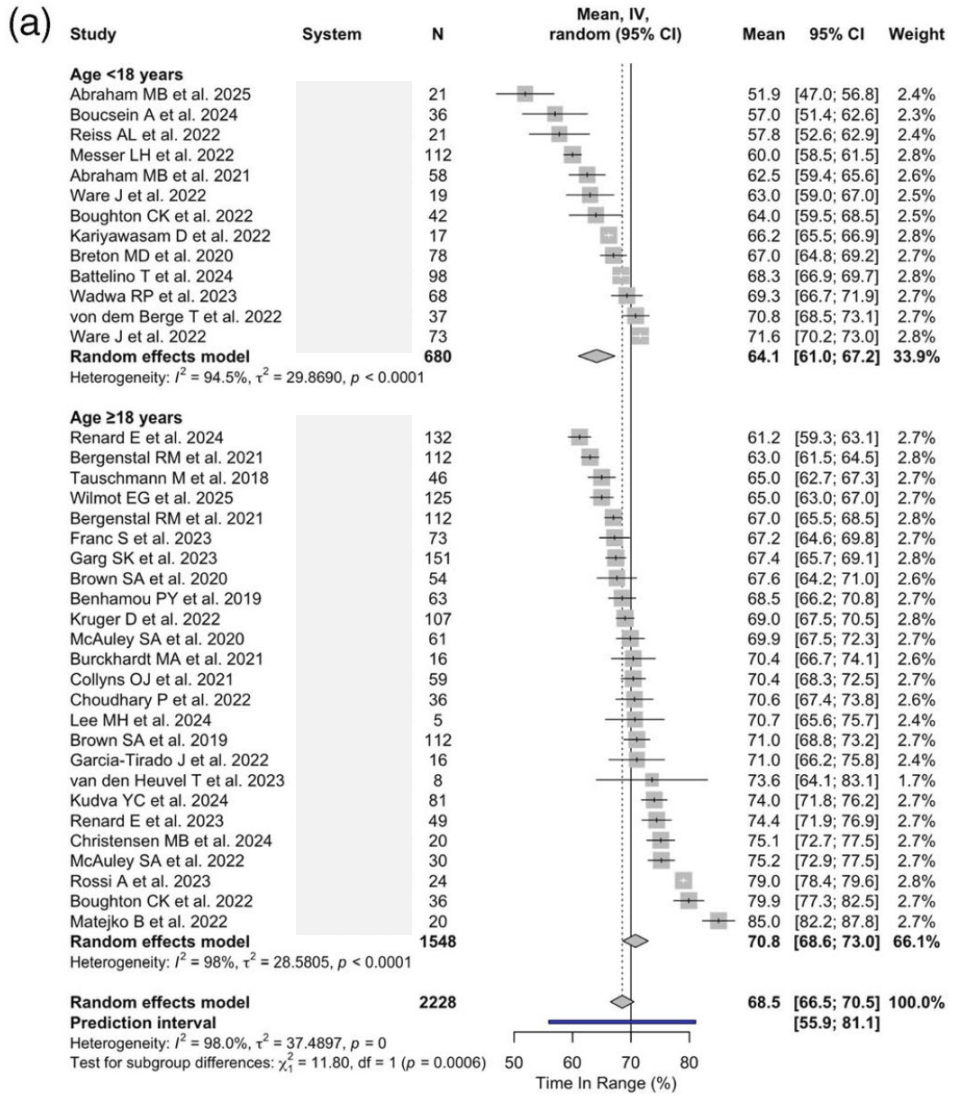
Outcome	No. of comparisons	No. of patients		Mean difference or relative risk (95% CI)	*P* value	I^2, %
		Intervention	Control			
Time in range	62	2,292	2,008	11.74 (9.37 to 14.12)	<0.001	94.6
Time below range	60	2,242	1,958	−1.20 (−1.62 to −0.79)	<0.001	91.7
Time above range	54	1,979	1,684	−10.17 (−13.18 to −7.16)	<0.001	96.0
Coefficient of variation, %	41	1,682	1,402	−1.31 (−2.16 to −0.47)	0.002	83.1
HbA1c, %	25	1,453	1,171	−0.36 (−0.44 to −0.28)	<0.001	28.0
Glycemia risk index	6	139	139	−3.74 (−6.34 to −1.14)	0.005	99.3
Insulin dose	44	1,538	1,376	0.03 (−0.08 to 0.15)	0.577	57.2
Severe hypoglycemia	21	1,134	977	0.92 (0.65 to 1.31)	0.661	18.7
Diabetic ketoacidosis	9	554	445	1.15 (0.47 to 2.80)	0.766	0.0

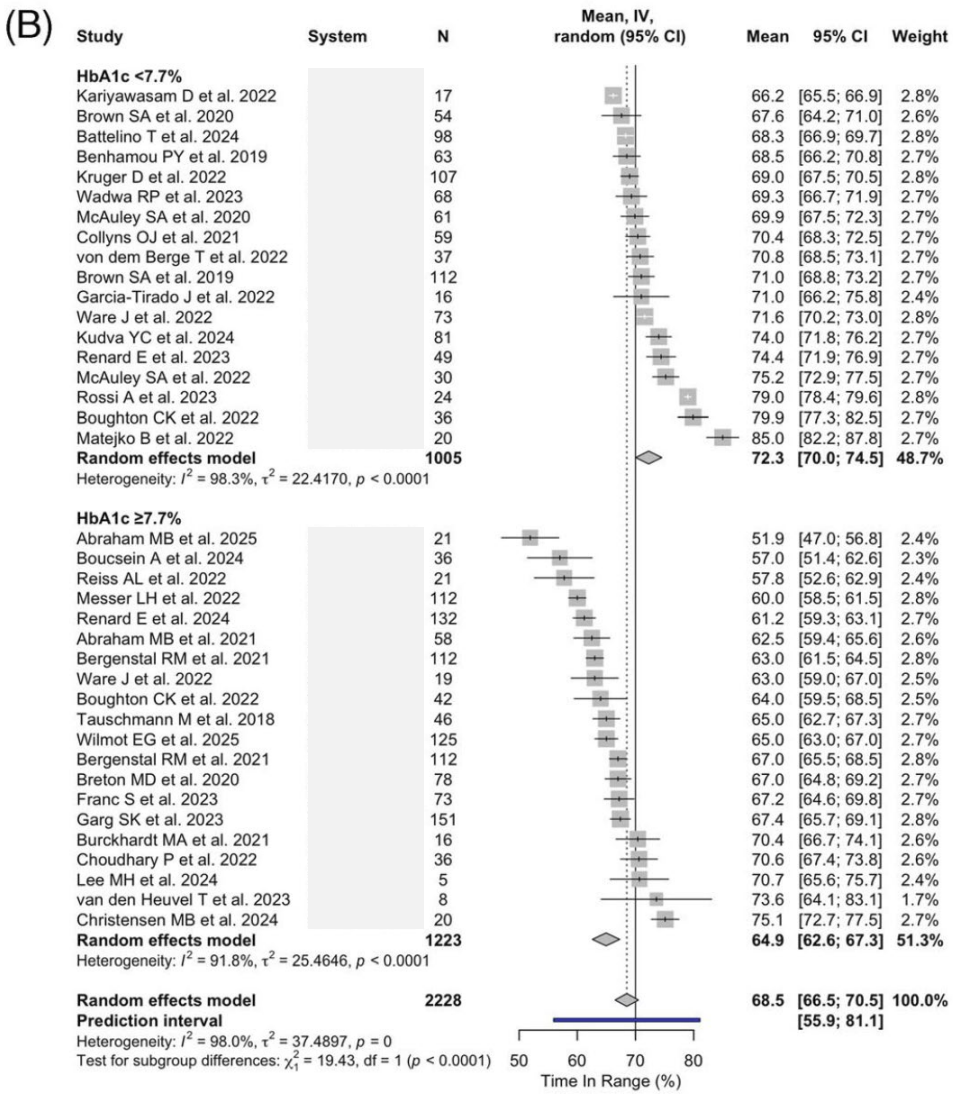
AID, automated insulin delivery; CI, confidence interval; HbA1c, glycosylated hemoglobin

Fan W et al. Diabetes Metab J. 2025 Mar;49(2):235-251

Effect of Different HCL Systems on TIR in People with Type 1 Diabetes

Meta-Analysis; 37 Randomized Controlled Trials, n = 2,228





HCL, hybrid closed-loop; TIR, time in range

Di Molfetta S, Di Gioia L et al. Diabetes Obes Metab. 2025 Sep 29

Insulin Pumps and AID Systems - Recommendations

7.26 AID systems should be the preferred insulin delivery method to improve glycemic outcomes and reduce hypoglycemia and disparities in youth and adults with type 1 diabetes **A** and other types of insulin-deficient diabetes **E** who are capable of using the device (either by themselves or with a caregiver). Choice of an AID system should be made based on the individual's circumstances, preferences, and needs. **A**

7.27 Insulin pump therapy, preferably with CGM, should be offered for diabetes management to youth and adults on MDI with type 2 diabetes who can use the device safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs. **A**

7.28 Individuals with diabetes who have been using CSII should have continued access across third-party payors. **E**

AID, automated insulin delivery; CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; MDI, multiple daily injections

Diabetes Care 1 January 2025; 48 (Supplement_1): S146–S166

EASD/ADA Considerations for Patient Selection for Current AID Systems

As previously described, there are many obvious advantages for using AID systems, but there are also some important limitations of the current and near-future AID systems. The following users are more likely to find greater and safer success with these systems:

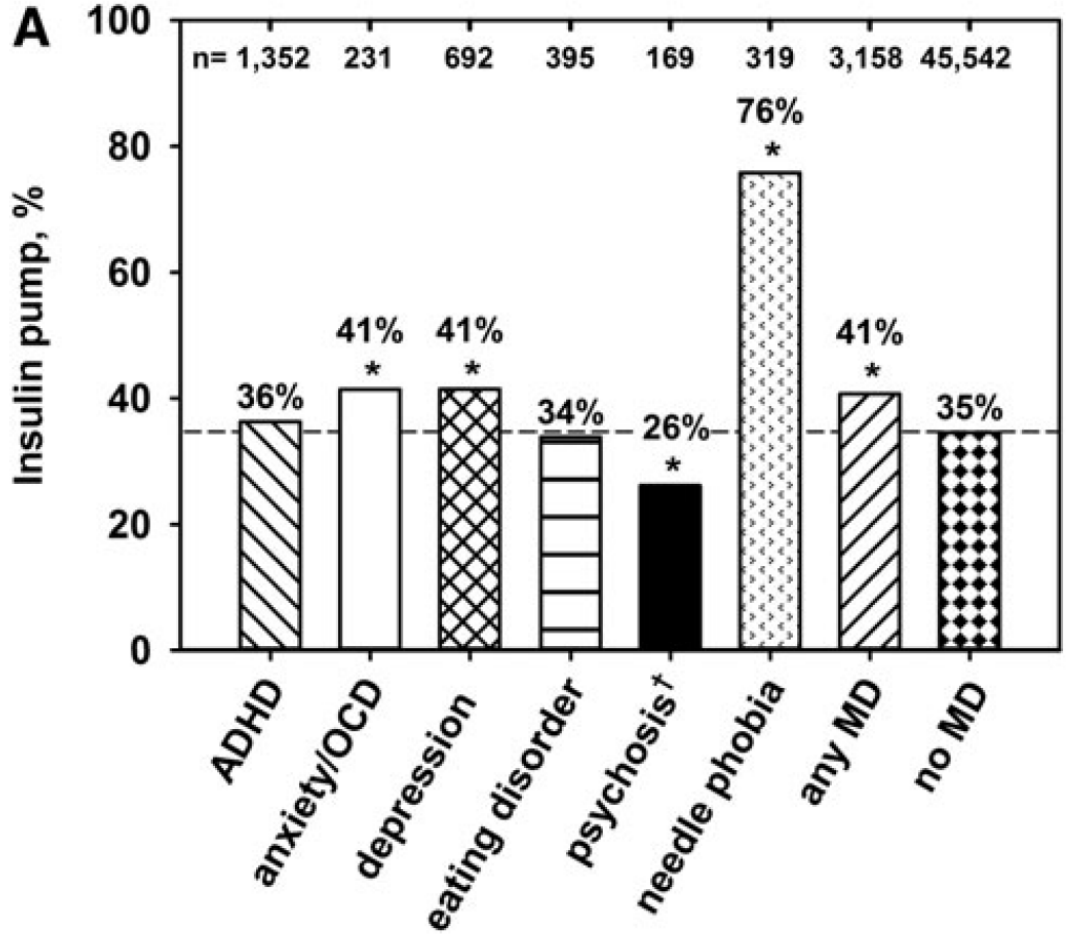
1. Those who are technically capable of using insulin pump therapy. For example, those who have been trained in the rigors of reservoir/set changes (needed with AID systems with use of conventional insulin pumps), have a basic understanding of carbohydrate counting and the glycaemic impact of fats and proteins (which is beneficial with current AID systems), comprehend the need to calibrate their sensor (if needed), and have the ability to troubleshoot. This includes understanding the limitations of all components of the AID system and knowing when to revert to manual insulin delivery and/or seek help.
2. Those with realistic a priori expectations of systems, which may help mitigate feelings of frustration given system limitations [68].
3. Those who are appropriately trained, as noted above, and properly supported. Ideally, they have a social environment supporting them and insurance coverage of AID systems. They also should have the ability to transmit their ongoing AID data to the healthcare professional team.
4. Those mentally and psychologically able to fulfil the requirements for successful AID implementation. People with diabetes and eating disorders or severe psychiatric comorbidities (e.g., severe depression, anxiety), and people who are not currently committed to change or are lacking desire to improve metabolic control, may not be suited to initiate AID.

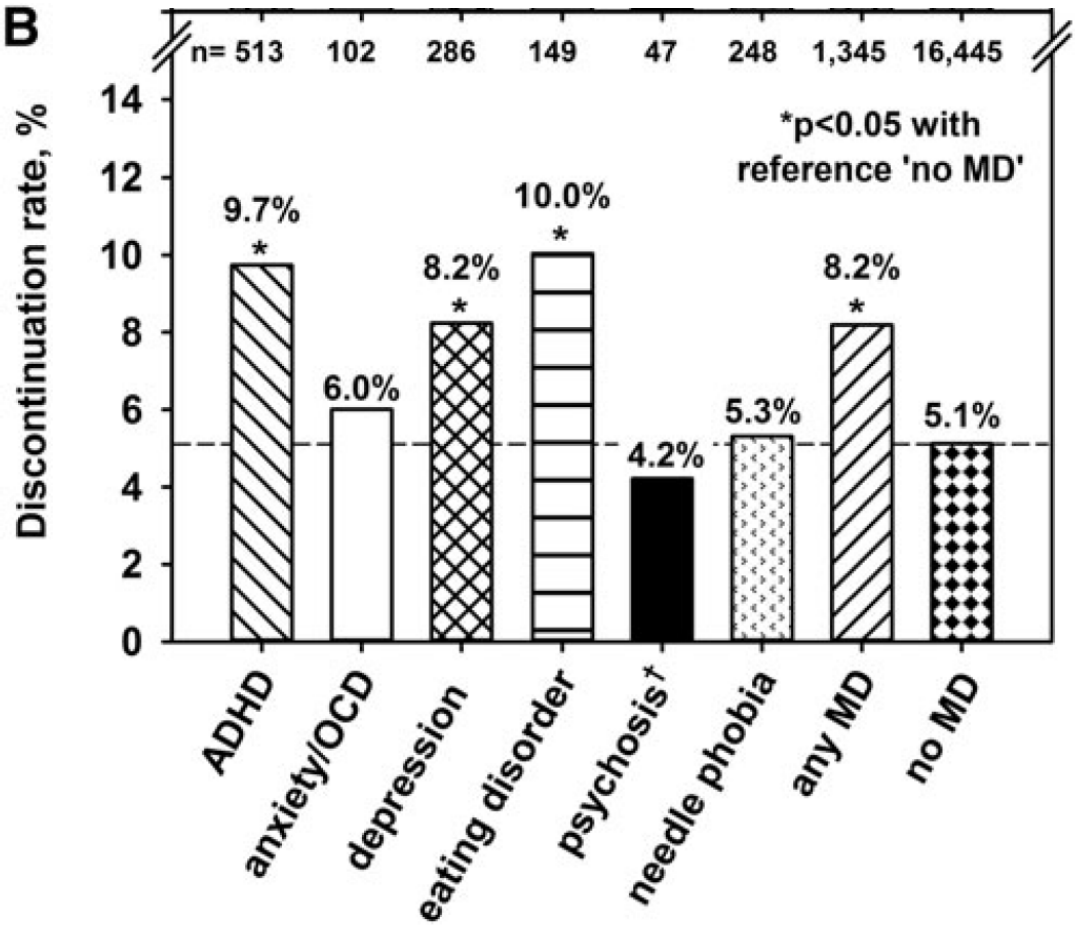
ADA, American Diabetes Association; AID, automated insulin delivery; EASD, European Association for the Study of Diabetes

Sherr JL et al. Diabetologia. 2023 Jan;66(1):3-22

Use and Discontinuation of IP in T1D w/ or w/o Specific Comorbid MD

DPV Registry; n = 48,700, Median Age 15.6 [12.0–17.7] yrs, Median Duration of FU 4.1 [1.9–6.4] yrs





ADHD, attention-deficit hyperactivity disorder; FU, follow-up; IP, insulin pump; MD, mental disorder; OCD, obsessive compulsive disorder; T1D, type 1 diabetes

Prinz N et al. Diabetes Technol Ther. 2016 Jan;18(1):34-8

A retrospective real-world clinical audit of hybrid closed loop insulin therapy in people with type 1 diabetes and anxiety disorders

J.S. Croos[1], A.K. Shooshtarian[1], G. Gallen[2], B. Stotesbury[2], A. Ahuja[1], A. Shrestha[1], Y. Cheah[2], K. Lovie[2], M. Rosenthal[2], M. Calcia[2], K. Ismail[3,2], R. Tan[1,2], M. Stadler[1,2]

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Background and Aim

There is a significant prevalence of comorbid anxiety disorders in people with type 1 diabetes, ranging from 2.13% to 31.71% based off qualitative assessment (Benton et al. 2023). Hybrid closed-loop insulin therapy is known to improve glycaemic outcomes in the broader type 1 diabetes population, but limited data exist for individuals with co-morbid anxiety.

AIM: To evaluate the clinical outcomes and safety of hybrid closed-loop insulin therapy in those with type 1 diabetes and anxiety in a specialist tertiary setting integrating technological, psychiatric and psychological care

Study design and methods

- Single centre, retrospective, observational clinical cohort study (audit)
- EHR analysed to identify adults registered under diabetes service at KCH between 10/23 and 01/25 with a coded diagnosis of T1D and anxiety, concurrently using CGM
- Baseline demographics, psychiatric information and glycaemic data obtained from EHR and other clinical cloud data sources

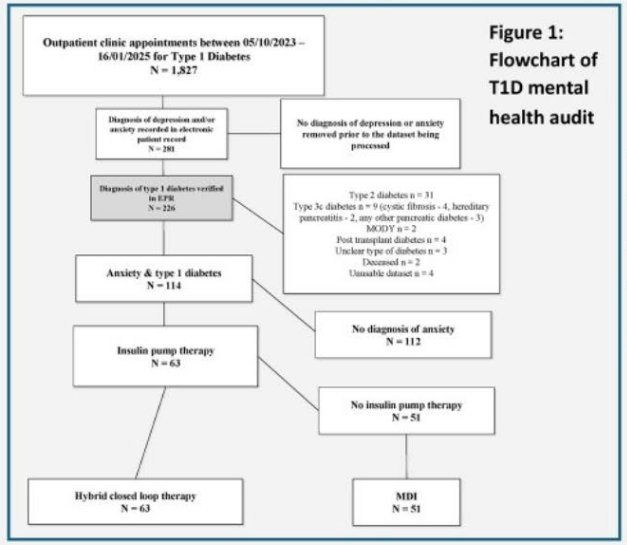


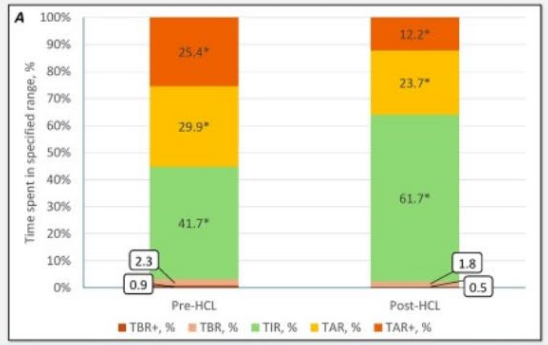
Figure 1: Flowchart of T1D mental health audit

Results

Baseline demographics: There were 114 people with T1D and a co-morbid anxiety disorder (27 men, 87 women; ethnicity 62.3% white, 6.1% black, 11% mixed, 5% other; age 37.3±13.6 years; BMI 27.4±6.5 kg/m^2; diabetes duration 23.2±12.7 years). Of these, 47 people had mixed anxiety/depression, and 19 had another additional psychiatric diagnosis. HCL was used by 63 people (9 males: 54 females; ethnicity 57.2% white, 4.8% black, 9.5% mixed, 3.2% other; age 37.1±13.0 years, BMI 28.1±4.9 kg/m^2, diabetes duration 24.0±12.7 years) and 51 were on multiple daily injections (MDI) (18 males:33 females; ethnicity 68.6% white, 7.8% black, 9.8% mixed, 5.9% other; age 37.5±14.4 years; BMI 26.5±7.9 kg/m^2; diabetes duration 22.5±12.7 years). Glycaemic and DDS2 outcomes are shown below.

Acute Complications: Diabetic ketoacidosis (DKA) episodes occurred in 1.6% of HCL users compared to 11.8% of MDI users, and severe hypoglycaemic episodes in 14.3% of HCL users compared to 13.7% of MDI users in the preceding 12 months. Sub-analysis by indices of multiple deprivation (IMD) in HCL users showed no significant difference.

Figure 2A and 2B: Paired CGM data comparing (A) pre-post HCL and (B) people on HCL vs. other insulin therapies, *p<0.05 statistically significant as per paired t-test / Mann-Whitney U test



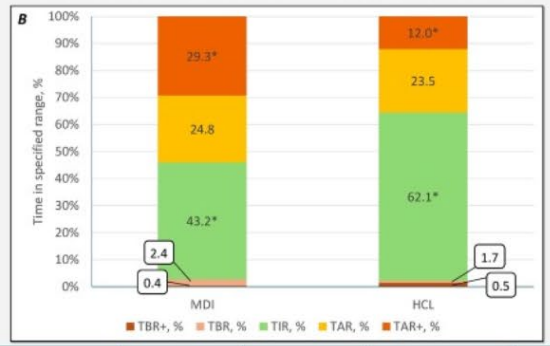


Table 1	Pre-HCL	Post-HCL	Paired change (n)	P value
HbA_{1c}, mmol/mol	70.0±17.8	61.8±14.6	**-8.6** [-5.11, -12.04] (51)	**<0.001**
%	8.6±1.6	7.8±1.3	**-0.8** [-0.5, -1.1] (51)	
DDS2, 6-point Likert	4.0 (3.0-5.0)	3.0 (1.5-4.5)	**-0.75** [-0.30, -1.42] (33)	**0.006**

Table 2	HCL	MDI	Mean difference [95% CI]	P value
HbA_{1c}, mmol/mol *	60.0 (52.0-67.0)	73.4 (56.5-86.8)	**-12.6** [-5.3, -19.9]	**0.001***
%	7.6 (6.9-8.3)	8.9 (7.3-10.1)	**-1.2** [-0.4, -1.7]	
DDS2, 6-point Likert #	3.1±1.5	3.4±1.5	-0.4 [0.4, -1.1]	0.336

Table 1/2: HbA_{1c} and DDS2 in 1) Pre vs Post HCL and 2) HCL vs MDI users - HbA_{1c}= glycated haemoglobin A1c; TIR= glucose time in range; DDS2 = Diabetes Distress Score 2; HCL = hybrid closed-loop, IQR = interquartile range, CI = confidence interval, MDI = multiple daily injections, SD = standard deviation. Significance

Conclusions

Use of HCL demonstrated a clear improvement in glycaemic parameters such as HbA_{1c} and TIR in people with T1D and comorbid anxiety disorders. Benefits are observed not only in people before and after therapeutic start, but compared with people on MDI or open loop insulin therapy. Deprivation indices appear to have no significant impact on HCL related outcomes in people with anxiety. Overall, these real-world data support the use of HCL in people with co-morbid anxiety disorder in a multidisciplinary care setting. Qualitative studies and clinical trials will be needed to provide further evidence of the impact of HCL on mental health and biomedical outcomes.

Time above range+ (TAR+): >13.9 mmol/L/>250mg/dL, %
Time above range (TAR): >10.0 mmol/L/>180mg/dL, %
Time in range (TIR): 3.9 – 10.0 mmol/L/70-180mg/dL, %
Time below range (TBR): <3.9 mmol/L./<70mg/dL, %
Time below range+ (TBR+): <3.0 mmol/L/<54mg/dL,%

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EASD European Association for the Study of Diabetes
61st Annual Meeting Vienna, Austria, 15-19th September 2025
ePID1868

Diabetes Technologies in People with T1DM and Disordered Eating

TABLE 2 Preliminary findings on diabetes technology use in people with T1DM and dysfunctional eating behaviours or eating disorders

		Eating disorders		
	Dysfunctional eating behaviours	**Anorexia nervosa**	**Bulimia nervosa**	**Binge-eating disorder**
CSII	• Heterogenous findings on the frequency of use • Potential benefit: less dysfunctional eating behaviours including insulin omission through greater flexibility[34,37,39]	• Lower frequency of use[11,12]	• Potential benefit: greater flexibility may improve uncontrollable hunger and bulimic symptoms[42] • Potential pitfall: facilitation of insulin dose manipulation[41]	• Potential benefit: storage data can reveal additional boluses[40]; CSII data may be used to support the assessment of binge-eating patterns
CGM	• Potential benefit: dysfunctional eating behaviours may be reflected in CGM data,[38,39,47] complementing the diagnostic process	-	-	-
AID	• Potential pitfall: greater flexibility may lead to disinhibited eating[48]	-	-	-

AID, automated insulin delivery; CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; T1DM, type 1 diabetes mellitus

Priesterroth L et al. Diabet Med. 2021 Jul;38(7):e14581

ATTD Recommendations for Initiating AID Use

- Make AID systems available to all people with T1D (2, 3, 7, 8).
- Initiation of AID can be done with in-clinic or digital/virtual training; further research is warranted on how to design, implement, and evaluate individual training programs, including required follow-up and long-term glycemic outcomes.
- Ensure that the PwD and their care partners can demonstrate proficiency in intensive insulin therapy knowledge and skills before initiating AID.
- Individualize training in AID based on each PwD's current therapy:
  - MDI + blood glucose monitoring
  - MDI + CGM
  - CSII + blood glucose monitoring
  - CSII + CGM (as nonintegrated and integrated components)
  - AID system
- Personalize training and follow-up based on the PwD/family, health care settings, etc.
- Consider starting people with T1D who are "*technology naïve*" on either an insulin pump or CGM before transitioning to AID. In some cases, the insulin pump and CGM can be initiated simultaneously.
- Advise people with T1D who are transitioning from prior insulin pump therapy to AID to use current pump settings if glycemic control is acceptable; however, pump parameters (basal rate, bolus settings) may need reassessment.
- Address insulin to carbohydrate ratios (ICRs), correction doses, basal rates, accounting for ratio of basal/TDD as well carbohydrate intake (eg, low carb diets).
- Individualize the approach to AID depending on the AID system, considering target glucose, active insulin time, etc.
- Provide fundamental guidance regarding hypoglycemia and hyperglycemia treatment with AID, exercise management, switching to open loop or MDI (for "pump vacation"), sick day management, etc (*see* "Clinical Recommendations for AID Use" section).
- Particular attention should be paid to use of adjunctive therapies (eg, SGLTs), and whether continuing such therapy is safe or feasible.
- The diabetes care team should discuss limitations and benefits for AID use:
  - Set realistic expectations for AID system user requirements: handling mealtime boluses/timing; handling CGM and pump use; handling exercise with pre-, during, and post- exercise adjustment as needed; manual insulin delivery during CGM warm-up, loss of connectivity, etc.
  - Review published data on the expected benefit on glycemic outcomes, improvement in overnight glucose control, restful sleep.
- Considerations should be made when initiating AID for people with long diabetes duration (especially those with eating disorders) and/or suboptimal control:
  - Potential transient worsening of retinopathy with need for ophthalmologic care prior to initiation of AID along with close follow-up with ophthalmology.
  - Potential temporary neuropathic pain, insulin edema, increase in microalbuminuria and other microvascular complications.

AID, automated insulin delivery; ATTD, Advanced Technologies & Treatments for Diabetes; CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; MDI, multiple daily injections; PwD, people with diabetes; T1D, type 1 diabetes; TDD, total daily dose

Phillip M et al. Endocr Rev. 2023 Mar 4;44(2):254-280

Impiego di CSII in Persone con Diabete Mellito

La terapia con CSII non dovrebbe essere impiegata se si verificano le seguenti condizioni:

Esistono controindicazioni assolute o relative all'uso della CSII, che sono legate al paziente stesso e/o alle condizioni ambientali e sociali in cui vive. Pochi studi esistono su questo aspetto, quindi le controindicazioni sono frutto di "consenso degli esperti" (38,39).

Controindicazioni assolute:

- mancata aderenza alla terapia e all'automonitoraggio
- rifiuto/non volontà di gestire in maniera autonoma la modulazione della terapia insulinica intensiva
- regolare esposizione a campi magnetici
- condizioni psichiatriche non controllate (come stati ansioso-depressivi gravi, psicosi, gravi disturbi del comportamento alimentare).

Controindicazioni relative:

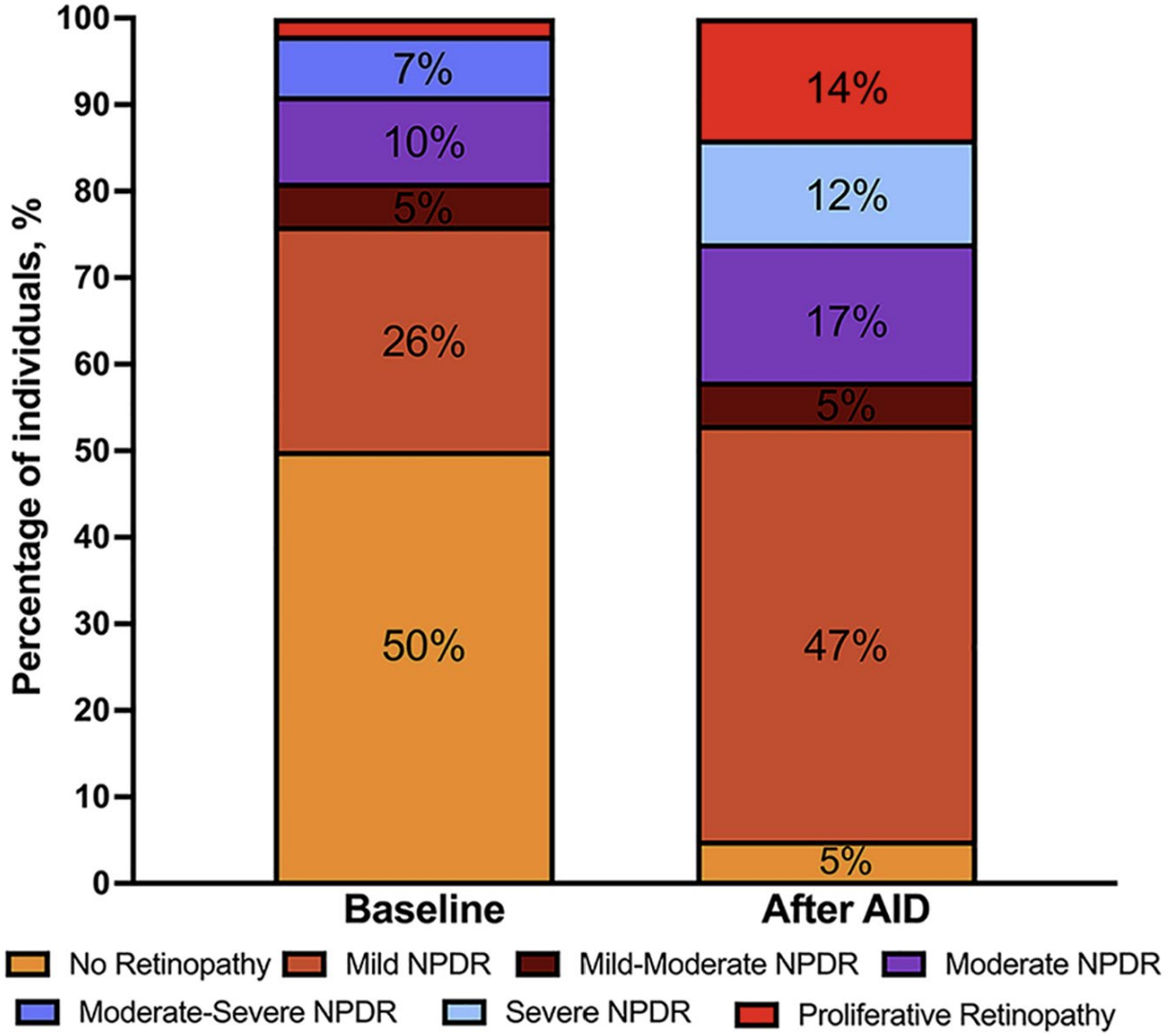
- retinopatia proliferante che richiede trattamento laser
- attività sportive o lavorative che potrebbero interferire con la funzionalità della pompa (es. sport di contatto con allenamenti giornalieri, ambienti lavorativi con temperature estreme)
- false aspettative sulla CSII (es. credere che la CSII permetta al paziente di deresponsabilizzarsi)

CSII, continuous subcutaneous insulin infusion

Gruppo di Studio Intersocietario AMD-SID-SIEDP "Tecnologia e Diabete", 2019

Progression of DR after Initiation of AID in Adults With Type 1 Diabetes

Retrospective Study, n = 152, Age 42±14 yrs, Diabetes Duration 26±13 yrs, Up to 2.7-year FU



DR, diabetes retinopathy; FU, follow-up, NDPR, nonproliferative diabetes retinopathy

Karakus KE et al. J Diabetes Sci Technol. 2025 Feb 14:19322968251318740

UK's ABCD-DTN Best Practice Guide for HCL Therapy

During the initial few weeks of HCL user onboarding, HCPs will need to provide intensive support in terms of education, training and ongoing evaluation. Our experience suggests that after this period, follow-up requirements tend to be reduced compared to pre-HCL care. Onboarding needs to be tailored to the individual and system requirements (e.g. face to face vs. remote, group vs. one-to-one). Careful consideration should be given to pwT1D who have had T1D for many years, those unfamiliar with technologies and those with a high HbA_{1c}. Rapid improvements in glycaemic management, particularly in those with pre-existing retinopathy and longstanding history of HbA_{1c} >86 mmol/mol, may potentially be associated with a transient worsening of retinopathy. In addition, in these individuals the potential risks of temporary neuropathic pain, insulin oedema or worsening albuminuria should be considered. For these people, we recommend starting with higher glucose targets and then gradually bringing them down over 3 months. This may involve a period of open-loop pump and CGM use and/or a higher target glucose level or range (e.g. staying in exercise activity or using temporary targets) may be appropriate. Depending on the status of pre-existing retinopathy, early follow-up may be recommended.

ABCD-DTN, Association of British Clinical Diabetologist's Diabetes Technology Network; HbA1c, glycated hemoglobin; HCL, hybrid closed-loop; HCPs, health care professionals; pwT1D, people with type 1 diabetes; T1D, type 1 diabetes; UK, United Kingdom

Griffin TP et al. Diabet Med. 2023 Jul;40(7):e15078

Automated Insulin Delivery for Inpatient Diabetes Management

Benefits

- Improved glycaemic outcomes (i.e. increased time spent within target range and reduced time above range; no increase in hypoglycaemia risk)
- Autonomous glucose control can be achieved and maintained with reduced staff workload

LOS, length of stay

Thabit H et al. Diabetologia. 2024 Oct;67(10):2114-2128

Summary of Clinical Studies Assessing Closed-Loop Use in Hospital

Study	Study design	No. of participants	Intervention	Control	Main outcome/finding	Other relevant findings
Fortmann [64]	RCT	110	RT-CGM	POC-BG with blinded CGM (for data collection only)	Control group vs. RT-CGM group, mean (SD) glucose:13.2 (2.5) vs 12.2 (2.4) mmol/l, p=0.0311	Control group vs RT-CGM group, % time in range (BG 3.9–10.0 mmol/l): 19.89 (3.34–40.09) vs 25.31 (11.78–42.97), p=0.1460; % time in range (BG 3.9–13.9 mmol/l): 63.95 (31.25–77.95) vs 72.83 (59.03–83.57), p=0.0404 No significant differences between groups in time spent in hypoglycaemia (BG <3.0 mmol/l and <3.0 mmol/l)
Thabit [76]	RCT	40	Fully closed-loop AID	Conventional s.c. insulin therapy	AID vs control, % time in range (BG 5.6–10.0 mmol/l): 59.8 ± 18.7% vs 38.1 ± 16.7%, p=0.0004	AID vs control, % time >10.0 mmol/l BG: 30.1 ± 20.4% vs 49.1 ± 24.1%, p=0.011 No differences between groups were observed in % time <5.6 and <3.5 mmol/l BG
Bally [77]	Multicentre RCT	136	Fully closed-loop AID	Conventional s.c. insulin therapy	AID vs control, % time in range (BG 5.6–10.0 mmol/l): 65.8 ± 16.8% vs 41.5 ± 16.9%, p<0.001	AID vs control, % time >10.0 mmol/l BG: 23.6 ± 16.6% vs 49.5 ± 22.8%, p<0.001 No difference between groups was observed in % time <3.0 mmol/l BG
Boughton [78]	Multicentre RCT	43	Fully closed-loop AID	Conventional s.c. insulin therapy	AID vs control, % time in range (BG 5.6–10.0 mmol/l): 68.4 ± 15.5% vs 36.4 ± 26.6%, p<0.0001	AID vs control, % time >10.0 mmol/l BG: 22.2 ± 15.7% vs 54.8 ± 29.7%, p<0.0001 No differences between groups were observed in % time <3.9 and <3.0 mmol/l BG
Davis [79]	Single-arm pilot study	22	Hybrid closed-loop AID	None	% time in range (BG 3.9–10.0 mmol/l): 68 ± 16% (in n=16)	% time <3.9 mmol/l BG: 0.17 ± 0.3%; % time <3.0 mmol/l BG: 0.06 ± 0.2%

AID, automated insulin delivery; BG, blood glucose; RCT, randomized controlled trial; s.c., subcutaneous; T1D, type 1 diabetes; T2D, type 2 diabetes

Thabit H et al. Diabetologia. 2024 Oct;67(10):2114-2128

Automated Insulin Delivery for Inpatient Diabetes Management

Benefits

- Improved glycaemic outcomes (i.e. increased time spent within target range and reduced time above range; no increase in hypoglycaemia risk)
- Autonomous glucose control can be achieved and maintained with reduced staff workload

Limitations

- Limited data on clinical and hospital LOS outcome
- Limited evidence on use outside research settings and cost-effectiveness

LOS, length of stay

Thabit H et al. Diabetologia. 2024 Oct;67(10):2114-2128

Contraindications to Insulin Pump Therapy in the Hospital

- Impaired level of consciousness or confusion
- Critical illness requiring intensive care/high dependency care
- Diabetic ketoacidosis or hyperosmolar hyperglycaemic state
- During MRI
- Psychiatric illness or suicidal ideation
- The individual is unable to use hands and/or physically manipulate pump due to medical condition
- The individual is unwilling to participate in diabetes self-management, or share pump management decisions with hospital clinical staff
- Lack of pump supplies or mechanical pump malfunction
- Lack of trained healthcare providers or available diabetes specialists to supervise pump therapy
- Medical team decision for health and safety of the individual

MRI, magnetic resonance imaging

Avari P et al. Diabet Med. 2025 Mar;42(3):e15452

Challenging Scenarios for Hybrid Closed-Loop Systems in the Hospital

- Rapid fluctuations in insulin requirements due to acute illness
- Use of glucocorticoids causing severe insulin resistance and hyperglycaemia
- Nausea and vomiting
- Parenteral or enteral nutrition through nasogastric/percutaneous endoscopic gastrostomy (PEG) feed

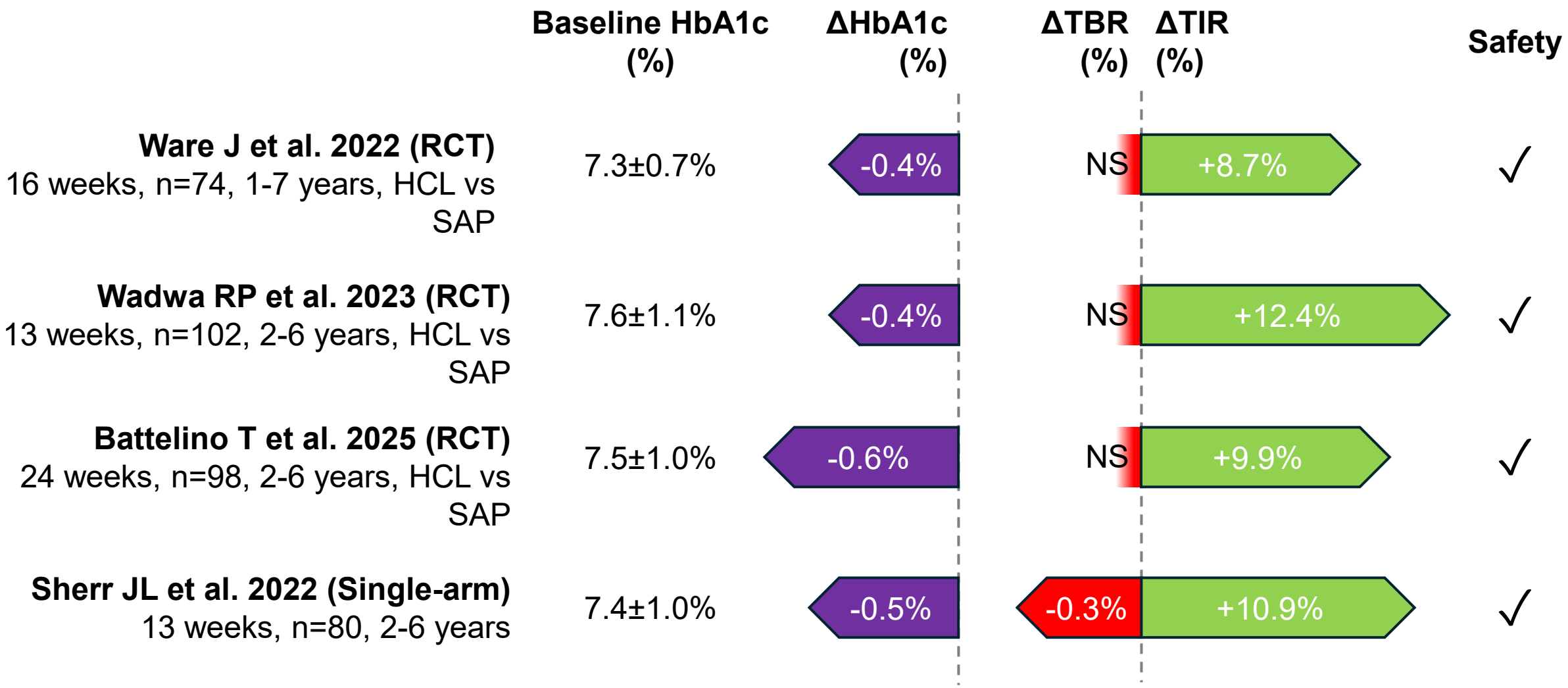
Avari P et al. Diabet Med. 2025 Mar;42(3):e15452

Current CE Marking Indications for Hybrid Closed Loop Systems

					
Preschool children (<7 years)					
Pregnancy complicated with type 1 diabetes					
People with type 2 diabetes					

Di Molfetta S, 2025

Evidence for HCL Insulin Delivery in Very Young Children with T1D



HbA1c, glycated hemoglobin; HCL, hybrid closed-loop; RCT, randomized controlled trial; T1D, type 1 diabetes; TBR, time below range; TIR, time in range

Di Molfetta S, 2025

Current CE Marking Indications for Hybrid Closed Loop Systems

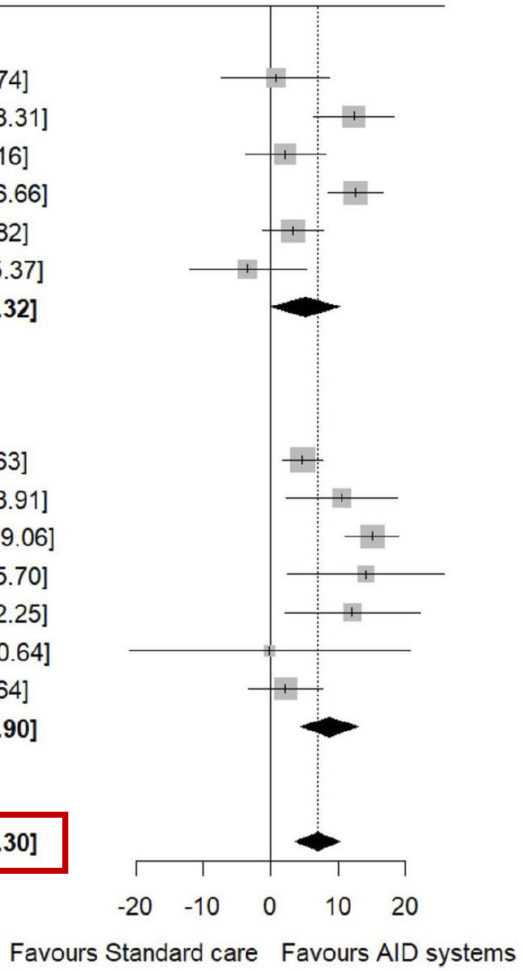
					
Preschool children (<7 years)	●	●	●	●	●
Pregnancy complicated with type 1 diabetes					
People with type 2 diabetes					

Di Molfetta S, 2025

Automated Insulin Delivery in Pregnant Women with Type 1 Diabetes

Meta-Analysis; 13 Studies (6 Randomized Controlled Trials), n = 450

Study or Subgroup	AID systems Total	Mean	SD	Standard care Total	Mean	SD	Mean Difference IV, Random, 95% CI
Randomized controlled trials							
Murphy 2011	12	77.25	8.86	12	76.50	11.00	0.75 [-7.24; 8.74]
Stewart 2016	17	70.50	8.86	17	58.15	8.86	12.35 [6.39; 18.31]
Stewart 2018	17	62.30	8.86	17	60.10	8.86	2.20 [-3.76; 8.16]
Lee 2023	61	68.20	10.50	63	55.60	12.50	12.60 [8.54; 16.66]
Benhalima 2024	46	66.50	10.00	49	63.20	12.40	3.30 [-1.22; 7.82]
Polsky 2024	12	60.10	11.08	12	63.46	10.73	-3.36 [-12.09; 5.37]
Total (95% CI)	**165**			**170**			**5.19 [0.06; 10.32]**
Heterogeneity: Tau^2 = 31.02; Chi^2 = 23.18, df = 5 (P = 0.0003); I^2 = 78.4%							
Observational studies							
Albert 2023	6	66.25	2.73	6	61.50	2.34	4.75 [1.87; 7.63]
Dodesini 2023	8	64.99	9.21	8	54.40	7.70	10.59 [2.27; 18.91]
Guibert 2023	13	60.33	3.78	13	45.25	6.27	15.08 [11.10; 19.06]
Levy 2023	10	78.60	9.20	10	64.50	16.30	14.10 [2.50; 25.70]
Fresa 2024	6	79.91	5.59	6	67.75	11.31	12.16 [2.07; 22.25]
Nandam 2024	6	67.90	15.70	2	68.10	12.00	-0.20 [-21.04; 20.64]
Quirós 2024	59	66.73	13.03	53	64.53	16.00	2.20 [-3.24; 7.64]
Total (95% CI)	**108**			**98**			**8.71 [4.51; 12.90]**
Heterogeneity: Tau^2 = 16.99; Chi^2 = 24.08, df = 6 (P = 0.0005); I^2 = 75.1%							
Total (95% CI)	**273**			**268**			**7.01 [3.72; 10.30]**
Heterogeneity: Tau^2 = 23.54; Chi^2 = 47.83, df = 12 (P < 0.0001); I^2 = 74.9%							
Test for subgroup differences: Chi^2 = 1.08, df = 1 (P = 0.2980)							



AID, automated insulin delivery; CI, confidence interval; SD, standard deviation

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Current CE Marking Indications for Hybrid Closed Loop Systems

					
Preschool children (<7 years)	●	●	●	●	●
Pregnancy complicated with type 1 diabetes	●	●	●	●	●
People with type 2 diabetes					

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Grazie