CGM nel Tipo 2:
Stato dell'arte e prospettive future

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Al cuore del diabete Roma 6-7 marzo 2026

Disclosures

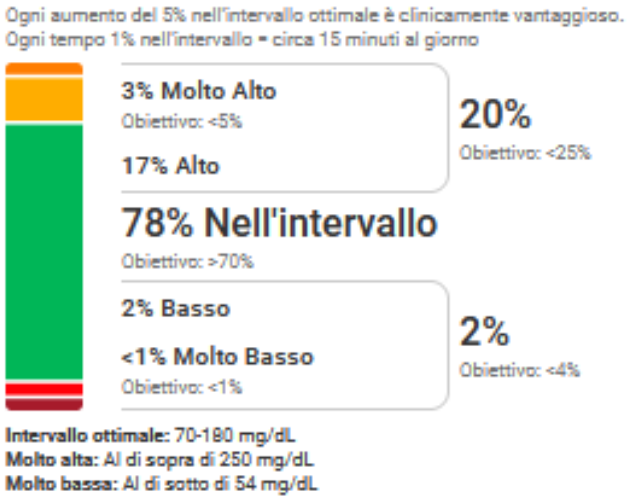
- Concetta Irace dichiara di aver ricevuto negli ultimi due anni compensi o finanziamenti dalle seguenti Aziende Farmaceutiche e/o Diagnostiche:

- Abbott
- Dexcom Italia
- Medtronic
- Novo Nordisk
- Roche Diabetes Care Italia
- Sanofi
- Theras

- *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.)*

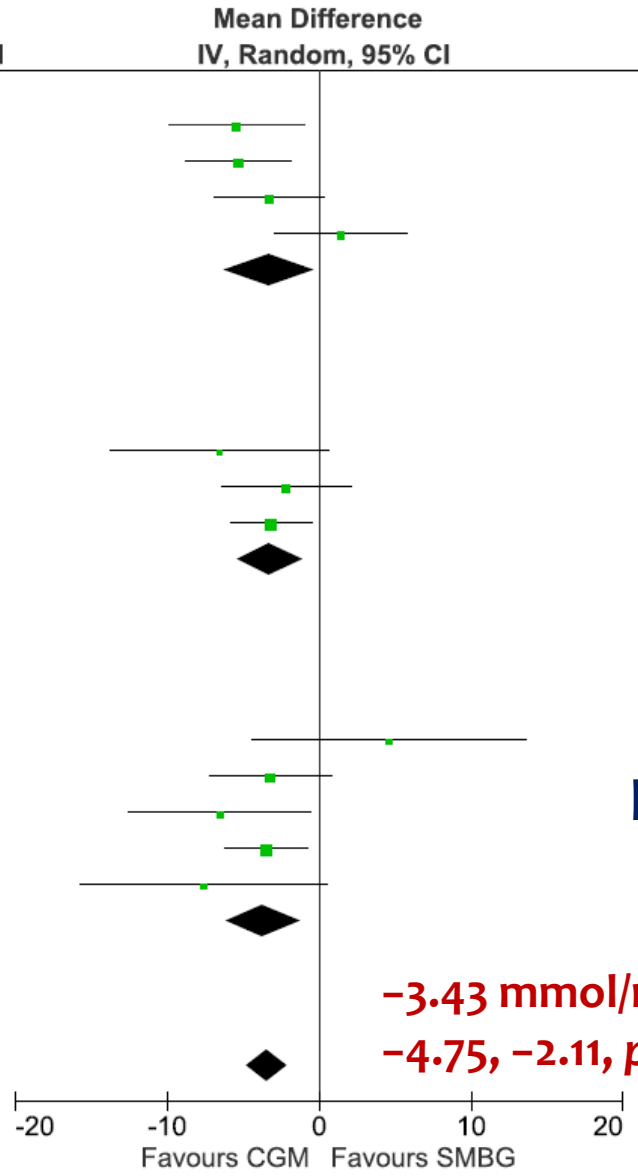
Stato dell’arte e prospettive future

CGM e Diabete di tipo 2 - MA



T2D - CGM e controllo glicemico: **HbA1c**

Study or Subgroup	CGM Mean	CGM SD	CGM Total	SMBG Mean	SMBG SD	SMBG Total	Weight	Mean Difference IV, Random, 95% CI
1.2.1 Insulin yes								
Martens (2021) [28]	-12	16.4	116	-6.56	13.1	59	7.5%	-5.44 [-9.92, -0.96]
Yaron (2019) [25]	-8.96	9.18	53	-3.61	8.52	48	11.6%	-5.35 [-8.80, -1.90]
Beck (2017) [22]	-8.74	10.1	77	-5.46	12.5	75	10.7%	-3.28 [-6.90, 0.34]
Haak (2017) [23]	-3.06	14.2	149	-4.48	16.4	75	7.9%	1.42 [-2.94, 5.78]
Subtotal (95% CI)			**395**			**257**	**37.6%**	**-3.27 [-6.22, -0.31]**
Heterogeneity: Tau² = 5.01; Chi² = 6.73, df = 3 (P = 0.08); I² = 55%								
Test for overall effect: Z = 2.17 (P = 0.03)								
1.2.2 Insulin no								
Moon (2023) [32]	-6.56	7.65	15	0	12	15	3.2%	-6.56 [-13.76, 0.64]
Price (2021) [29]	-5.46	9.84	44	-3.28	7.65	23	8.1%	-2.18 [-6.45, 2.09]
Wada (2020) [24]	-5.03	5.14	48	-1.86	7.76	45	16.8%	-3.17 [-5.86, -0.48]
Subtotal (95% CI)			**107**			**83**	**28.1%**	**-3.22 [-5.39, -1.05]**
Heterogeneity: Tau² = 0.00; Chi² = 1.06, df = 2 (P = 0.59); I² = 0%								
Test for overall effect: Z = 2.91 (P = 0.004)								
1.2.3 Insulin or other glucose lowering medication								
Ajjan (2023) [21]	-5.36	21.3	55	-9.95	26.5	55	2.1%	4.59 [-4.40, 13.58]
Bergenstal (2022) [26]	-12.2	12	59	-8.96	9.84	55	9.0%	-3.24 [-7.26, 0.78]
Vigersky (2012) [30]	-8.74	16.4	50	-2.19	14.2	50	4.4%	-6.55 [-12.56, -0.54]
Cosson (2009) [27]	-6.89	3.72	11	-3.39	3.17	14	16.3%	-3.50 [-6.25, -0.75]
Yoo (2008) [31]	-12	17.1	29	-4.37	14.2	28	2.5%	-7.63 [-15.78, 0.52]
Subtotal (95% CI)			**204**			**202**	**34.3%**	**-3.65 [-6.14, -1.15]**
Heterogeneity: Tau² = 1.79; Chi² = 5.09, df = 4 (P = 0.28); I² = 21%								
Test for overall effect: Z = 2.87 (P = 0.004)								
Total (95% CI)			**706**			**542**	**100.0%**	**-3.43 [-4.75, -2.11]**
Heterogeneity: Tau² = 0.80; Chi² = 12.95, df = 11 (P = 0.30); I² = 15%								
Test for overall effect: Z = 5.11 (P < 0.00001)								
Test for subgroup differences: Chi² = 0.07, df = 2 (P = 0.97), I² = 0%								



INSULIN

NO INSULIN

INSULIN+GLM

−3.43 mmol/mol = −0.31% (95% CI −4.75, −2.11, *p*<0.00001)

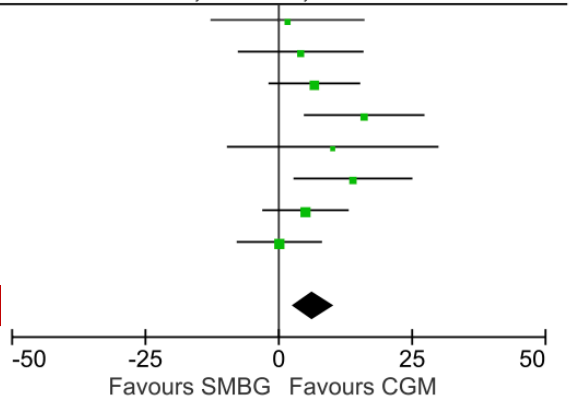
Jancev M et al. Diabetologia. 2024; 67:798–810

T2D - CGM e controllo glicemico: a) **TIR** b) **TBR**

a

Study or Subgroup	CGM Mean	CGM SD	CGM Total	SMBG Mean	SMBG SD	SMBG Total	Weight	Mean Difference IV, Random, 95% CI
Ajjan (2023) [21]	8.73	38.57	54	7.1	36.57	50	6.9%	1.63 [-12.81, 16.07]
Moon (2023) [32]	3.1	17.9	15	-1	14.9	15	10.0%	4.10 [-7.69, 15.89]
Bergenstal (2022) [26]	18.21	23.3	59	11.55	23.5	55	17.7%	6.66 [-1.94, 15.26]
Martens (2021) [28]	19	36.07	116	3	36.07	59	10.8%	16.00 [4.70, 27.30]
Price (2021) [29]	-3.2	35.36	42	-13.3	37.15	19	3.7%	10.10 [-9.73, 29.93]
Wada (2020) [24]	18.2	23.89	41	4.3	25.4	35	11.1%	13.90 [2.75, 25.05]
Beck (2017) [22]	4	24.83	78	-1	26.25	75	19.6%	5.00 [-3.10, 13.10]
Haak (2017) [23]	-1.2	26.82	149	-1.3	29.77	75	20.1%	0.10 [-7.90, 8.10]
Total (95% CI)			**554**			**383**	**100.0%**	**6.36 [2.48, 10.24]**

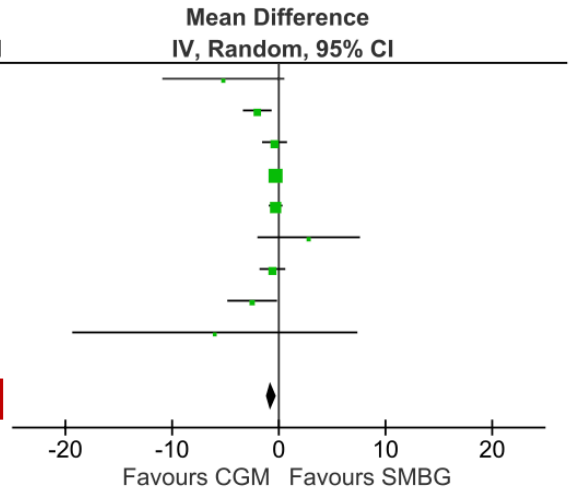
Heterogeneity: Tau² = 2.90; Chi² = 7.70, df = 7 (P = 0.36); I² = 9%
Test for overall effect: Z = 3.21 (P = 0.001)



b

Study or Subgroup	CGM Mean	CGM SD	CGM Total	SMBG Mean	SMBG SD	SMBG Total	Weight	Mean Difference IV, Random, 95% CI
Ajjan (2023) [21]	-3.91	11.92	54	1.29	17.15	50	0.9%	-5.20 [-10.92, 0.52]
Bergenstal (2022) [26]	-0.8	4.4	59	1.22	2.8	55	11.2%	-2.02 [-3.36, -0.68]
Moon (2023) [32]	-0.4	2.3	15	0	0.2	15	13.4%	-0.40 [-1.57, 0.77]
Martens (2021) [28]	-0.1	0.64	116	0.2	1	59	32.0%	-0.30 [-0.58, -0.02]
Price (2021) [29]	-0.3	1.62	42	0	0.92	19	23.6%	-0.30 [-0.94, 0.34]
Wada (2020) [24]	1.2	4.9	41	-1.6	13.78	35	1.2%	2.80 [-2.01, 7.61]
Beck (2017) [22]	-0.9	3.9	78	-0.3	3.72	75	12.8%	-0.60 [-1.81, 0.61]
Haak (2017) [23]	-2.9	8.17	149	-0.4	8.5	75	4.7%	-2.50 [-4.83, -0.17]
Cosson (2009) [27]	-4	15.52	7	2	12.04	12	0.2%	-6.00 [-19.36, 7.36]
Total (95% CI)			**561**			**395**	**100.0%**	**-0.66 [-1.21, -0.12]**

Heterogeneity: Tau² = 0.22; Chi² = 14.47, df = 8 (P = 0.07); I² = 45%
Test for overall effect: Z = 2.39 (P = 0.02)



Jancev M et al. Diabetologia. 2024; 67:798–810

Intervento in soggetti con T2D

Use the sensor glucose data for self-management, including **insulin dose titration**

Simple **dietary advice** to enhance consumption of healthy food with the low glycaemic index

General instruction about how to use CGM

Increase in total **exercise time**

Irace et al.Diabetes/Metabolism Research and Reviews, 2025; 41:e70059 https://doi.org/10.1002/dmrr.70059

Does Continuous Glucose Monitoring Use Prompt Greater **Engagement** in Self-Management? A Randomized Controlled Trial Focusing on Adults With Type 2 Diabetes

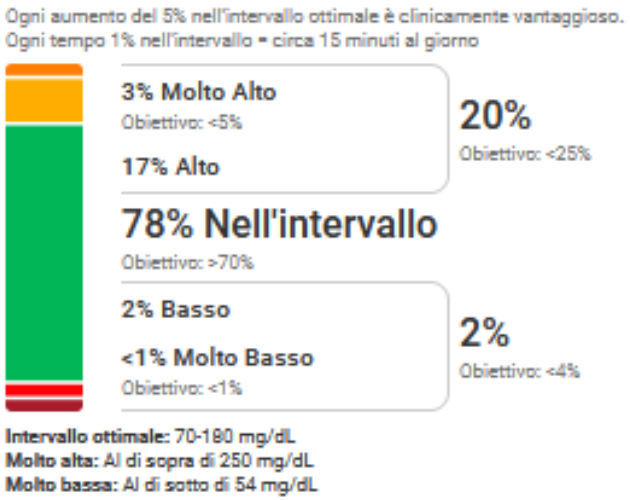
- **110** soggetti con **T2D;**
- HbA1c **>7,5%;**
- Terapia non insulinica o con insulina basale;
- RCT **rtCGM** vs **SMBG;**
- Follow-up **3 mesi;**
- Caratteristiche **socioeconomiche** paragonabili;
- Grado di **scolarizzazione** paragonabile;

CGM Mean difference HbA1c -0.65
SMBG Mean difference HbA1c -0.46

AREA	RISULTATI	ESEMPI
Capacità	↑ **Conoscenza** e **consapevolezza** su fattori che influenzano la glicemia	**Comprendere** impatto di alimentazione, esercizio e stress sui livelli di glucosio
Opportunità	↑ **Facilitazione** di interazioni e decisioni terapeutiche	**Dialogo più efficace** con operatori sanitari, personalizzazione terapia
Motivation	↑ **Aumento** della **motivazione** alla gestione autonoma del diabete	Mi ha aiutato a diventare **più ottimista** riguardo alla vita con il diabete

Polonsky WH, J Diabetes Sci Technol. 2025 Aug

Stato dell'arte e prospettive future

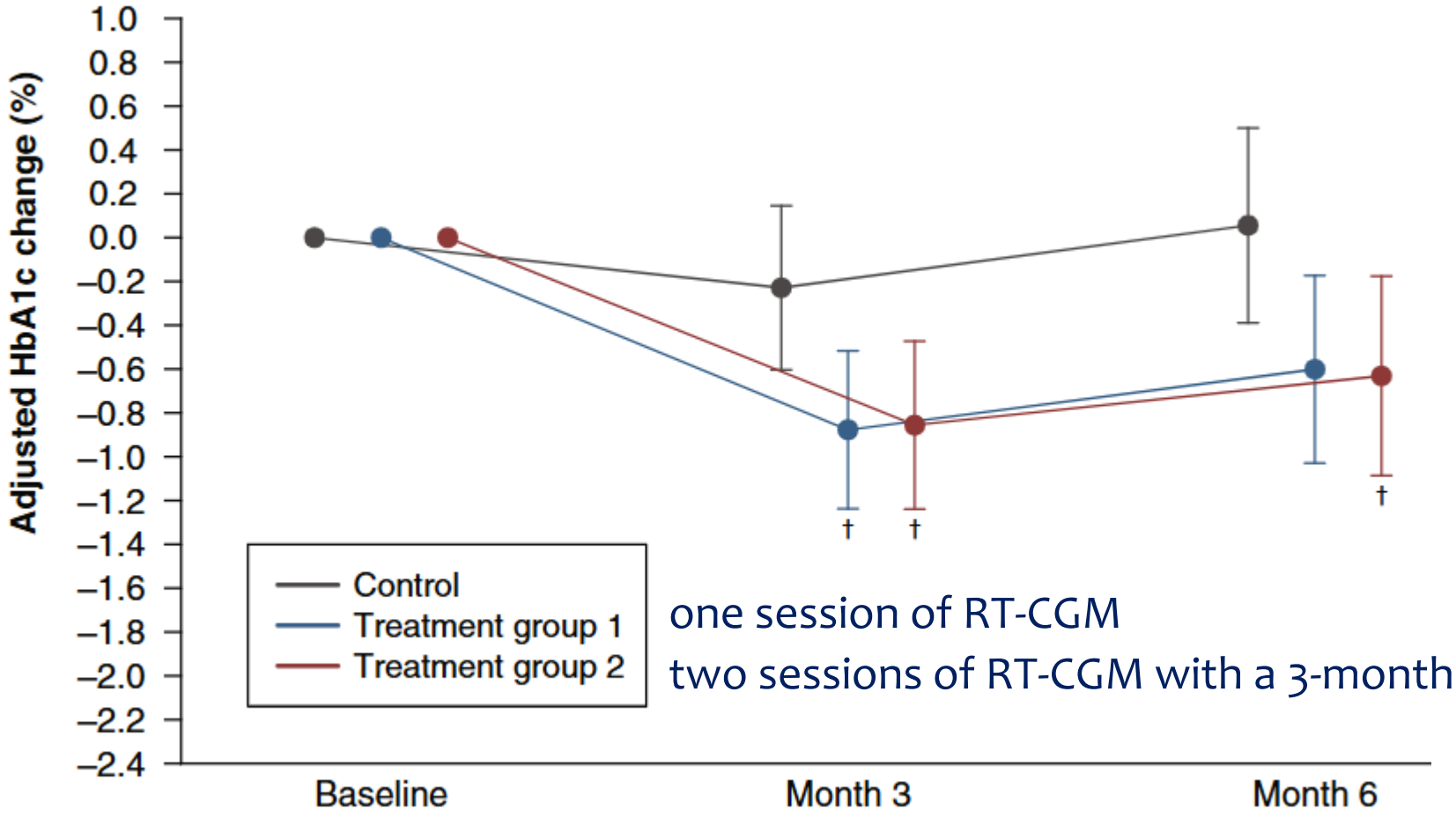


CGM e Diabete di tipo 2 - MA

CGM e uso non continuativo

Utilizzo non continuativo del CGM

RCT evaluating **48 non-insulin-treated** patients with T2D uncontrolled with OADs

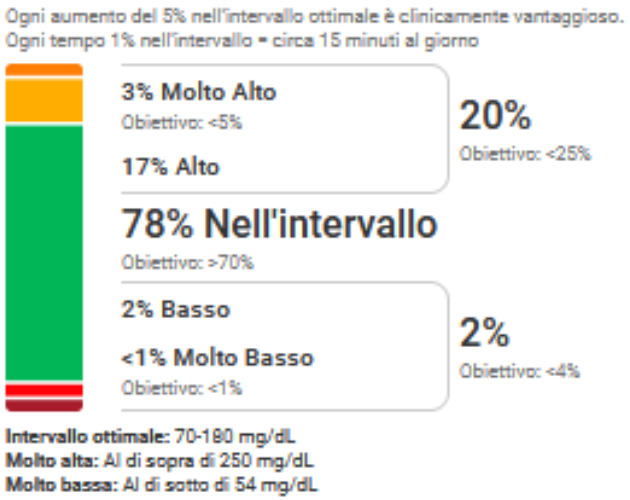


one session of RT-CGM

two sessions of RT-CGM with a 3-month interval

Moon SJ et al. Diabetes Obes Metab. 2023 Jan;25(1):110-120

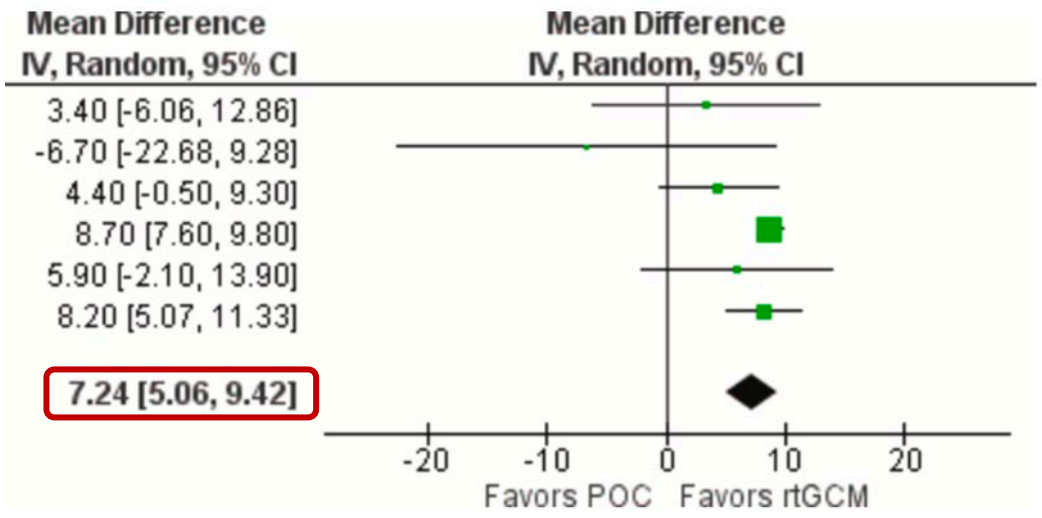
Stato dell'arte e prospettive future



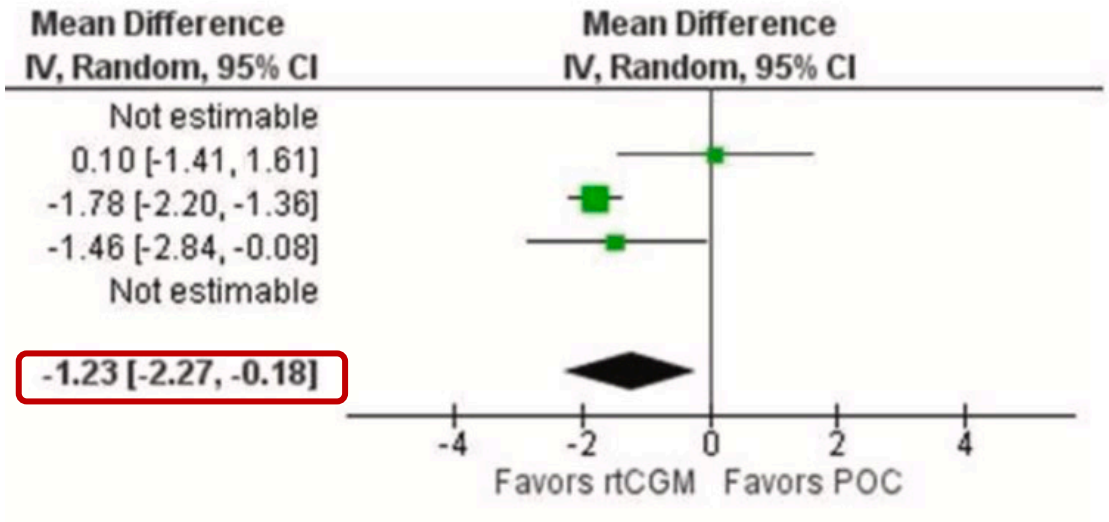
- CGM e Diabete di tipo 2 - MA
- CGM e uso non continuativo
- CGM in ospedale

Use of continuous glucose monitoring and point-of-care glucose testing in hospitalized patients with diabetes mellitus in **non-intensive** care unit settings: A systematic review and meta-analysis of randomized controlled trials

TIR

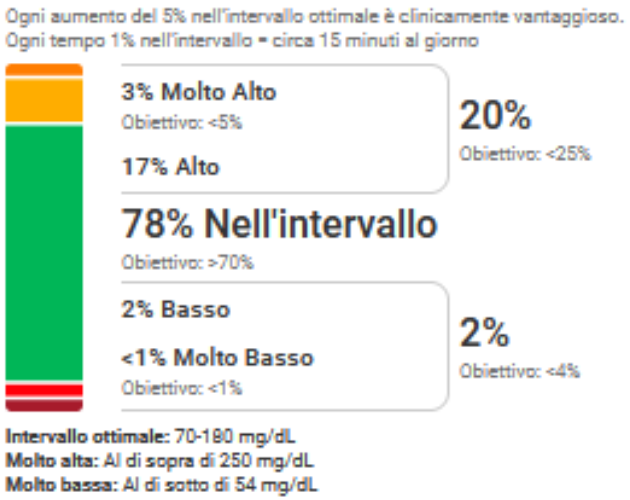


TBR



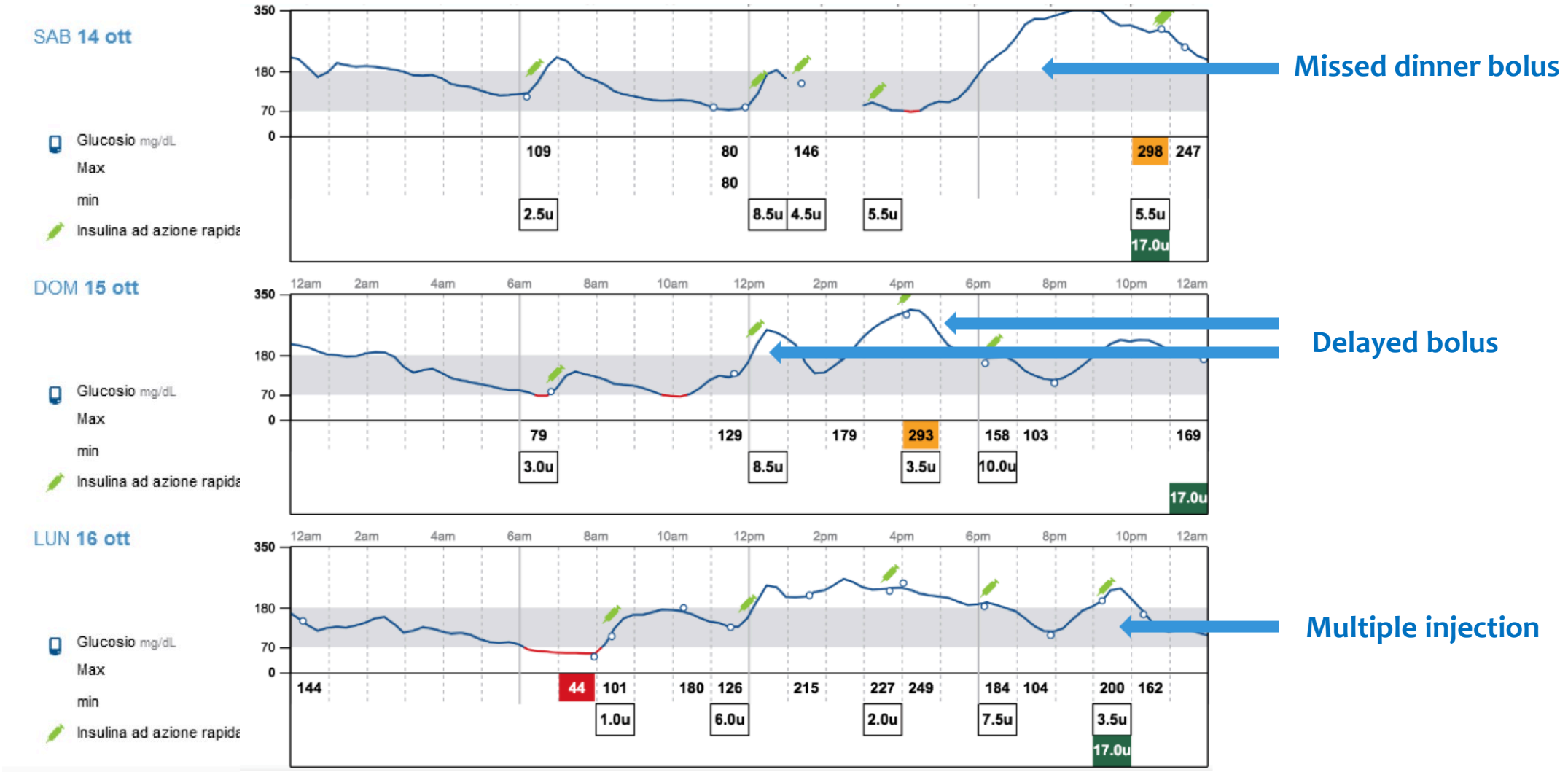
DRCP https://doi.org/10.1016/j.diabres.2024.111986

Stato dell’arte e prospettive future



- CGM e Diabete di tipo 2 - MA
- CGM e uso non continuativo
- CGM in ospedale
- CGM e connettività

Connected insulin pen



Association Between Treatment Adherence and Continuous Glucose Monitoring Outcomes in People With Diabetes Using Smart Insulin Pens in a Real-World Setting

METHODS

Retrospective real-world analysis of observational data[a] from **3,945** adults with diabetes[b] from **16 countries** (**Europe** and **Japan**) self-administering basal[c] and bolus[d] insulin using a smart insulin pen alongside CGM.[e]

Treatment adherence and **smart insulin pen engagement** were assessed over 14-day periods through **missed basal**[f] and **missed bolus**[g] insulin doses, and **frequency of data uploads**.[h]

RESULTS

Mean frequency (number) and estimated probability (%) of occurrence over a 14-day period

Missed basal insulin doses: 0.19
Missing ≥ 1 basal dose: 17.6% (95% CI: 16.5%, 18.7%)

Missed bolus insulin doses: 6.0
Missing ≥ 1 bolus dose: 99.1% (95% CI: 98.7%, 99.4%)

Over a 14-day period, one **missed basal** insulin dose or one **missed bolus** insulin dose was associated with:

- a significant decrease in the percentage of **TIR (3.9–10.0 mmol/L)** of **−2.8%** and **−1.7%**
- a significant increase in **GMI score** of **+0.2%** and **+0.1%**

Smart insulin pen engagement was positively associated with **glycemic outcomes**.

- Over a 14-day period, **1 day with at least one data upload** was associated with a significant increase (**+0.5%**) in percentage of **TIR (3.9–10.0 mmol/L)**.

These data highlight the challenges of adhering to basal-bolus insulin treatment in a real-world setting. **Missing two basal or four bolus insulin doses** over a 14-day period was associated with a **clinically relevant decrease of > 5%** in the percentage of **TIR (3.9–10.0 mmol/L)**.

[a]Data collection period: March 23, 2021–July 8, 2023. [b]Consented to sharing anonymous data. [c]Insulin degludec. [d]Insulin aspart or fast-acting insulin aspart. [e]Data from smart insulin pens and CGM devices were aggregated into 14-day periods. [f]A missed basal insulin dose was defined as a window of > 40 h between two consecutive doses. [g]A missed bolus insulin dose was defined as a meal with no bolus insulin injection within the window of 15 min before to 1 h after the start of a meal, with meals detected from the CGM signal. [h]The number of days with a data upload was used as a proxy for smart insulin pen engagement. CGM, continuous glucose monitoring; GMI, glucose management indicator; SD, standard deviation; TBR, time below range; TIR, time in range.

Diabetes Care 2024;47(6):995–1003 | https://doi.org/10.2337/dc23-2176

Glycaemic control after **connected** insulin **pen** initiation in people living with diabetes: Results from a **real-world setting**

TABLE 2 CGM parameters, glycaemic outcomes, bolus dosing information and proportions of individuals achieving clinically meaningful targets ($N = 86\,133$).

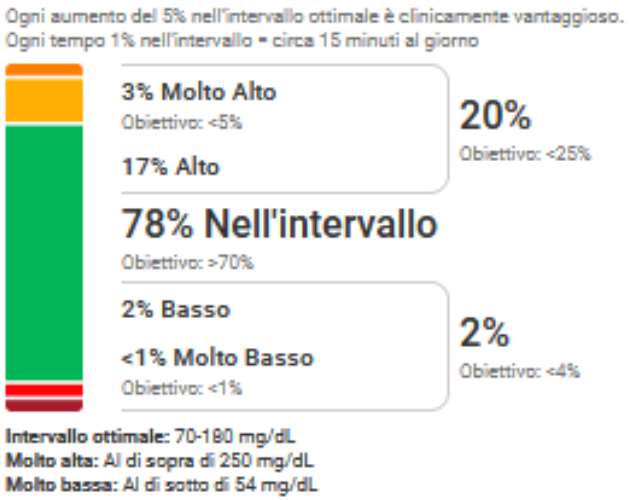
		Month 0	Month 3[a]	Change (95% CI)	Month 6[a]	Change (95% CI)	Month 12[a]	Change (95% CI)
TIR	%	52.4 (52.3, 52.6)	53.9 (53.7, 54.0)	1.5 (1.4, 1.6)	53.8 (53.6, 54.0)	1.4 (1.3, 1.5)	53.5 (53.3, 53.7)	1.1 (1.0, 1.2)
	Time	12 h 35 m	12 h 56 m	21.3 m (19.7 m, 22.8 m)	12 h 55 m	20.1 m (18.3 m, 21.8 m)	12 h 51 m	15.9 m (13.9 m, 18.0 m)

TABLE 3 Change of TIR and TBR by baseline TIR.

Subgroup	*n*	Month 0	Month 3[a]	Change (95% CI)	Month 6	Change (95% CI)	Month 12	Change (95% CI)
TIR (%)								
Any baseline TIR	40 770	54.4	55.0	0.6 (0.5, 0.8)	55.1	0.7 (0.6, 0.8)	54.8	0.4 (0.2, 0.6)
Baseline TIR <40%	9578	28.5	32.3	3.8 (3.5, 4.1)	33.0	4.5 (4.2, 4.9)	33.1	4.6 (4.2, 5.1)
Baseline TIR 40%–50%	7079	45.6	46.6	0.9 (0.6, 1.3)	47.0	1.4 (1.0, 1.7)	47.1	1.5 (1.1, 1.9)
Baseline TIR 50%–60%	8058	55.4	55.6	0.2 (−0.1, 0.5)	55.9	0.5 (0.2, 0.8)	55.6	0.3 (−0.1, 0.6)
Baseline TIR 60%–70%	7216	64.9	64.2	−0.6 (−0.9, −0.4)	64.1	−0.7 (−1.0, −0.4)	63.9	−0.9 (−1.3, −0.6)
Baseline TIR >70%	8839	80.1	78.6	−1.5 (−1.7, −1.3)	77.8	−2.3 (−2.5, −2.1)	76.9	−3.2 (−3.5, −3.0)

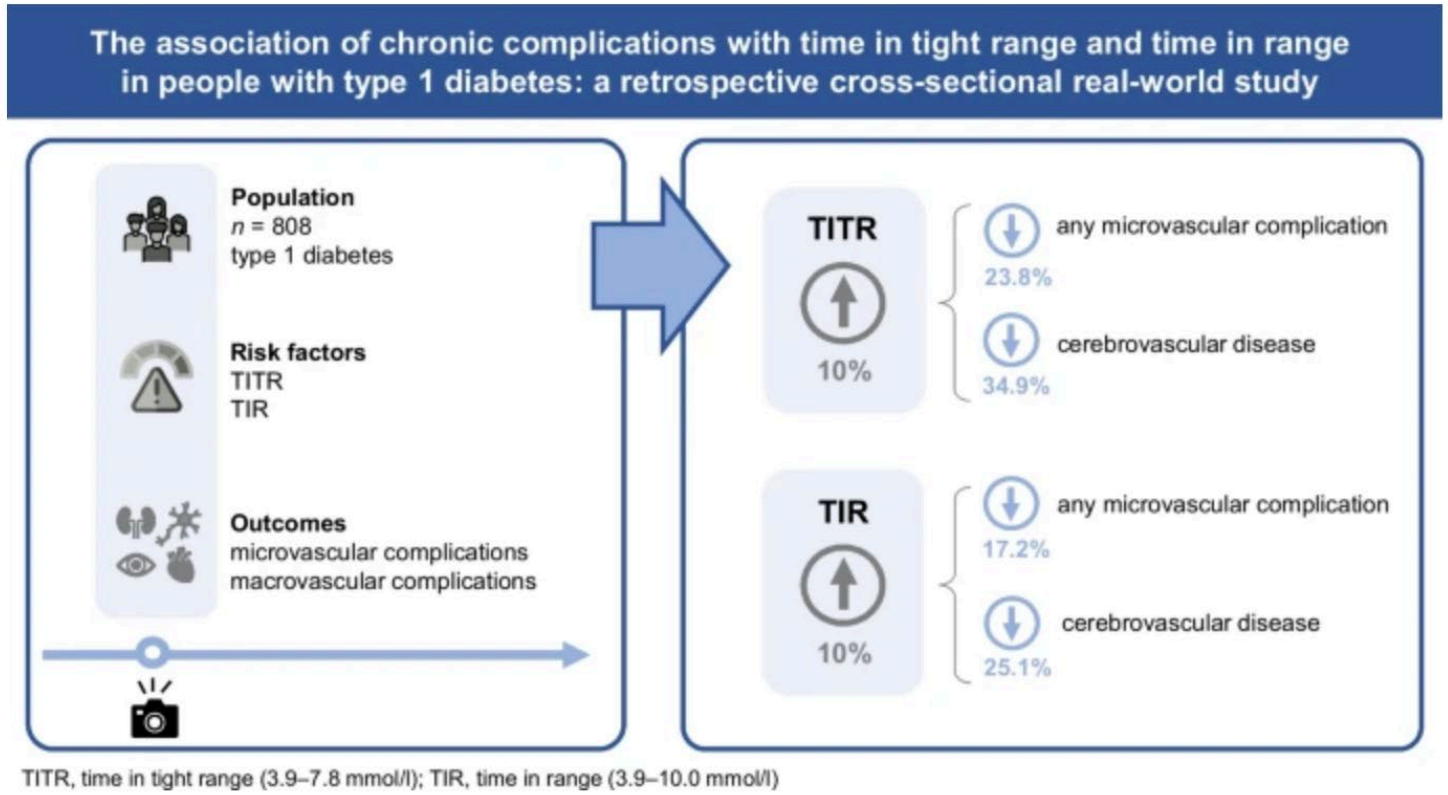
Diabetes Obes Metab. 2025;27:6507–6515

Stato dell'arte e prospettive future



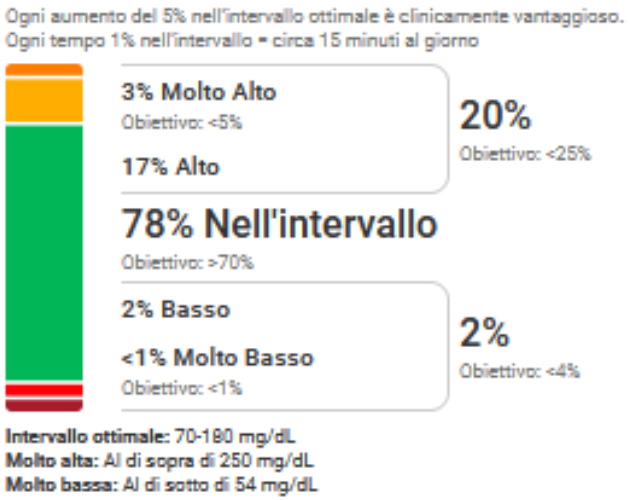
- CGM e Diabete di tipo 2 - MA
- CGM e uso non continuativo
- CGM in ospedale
- CGM e connettività
- CGM e complicanze

The association of **chronic complications** with time in tight range and time in range in people with **type 1** diabetes: a retrospective cross-sectional real-world study



Diabetologia 2024 Aug;67(8):1527-1535

Stato dell’arte e prospettive future



- CGM e Diabete di tipo 2 - MA
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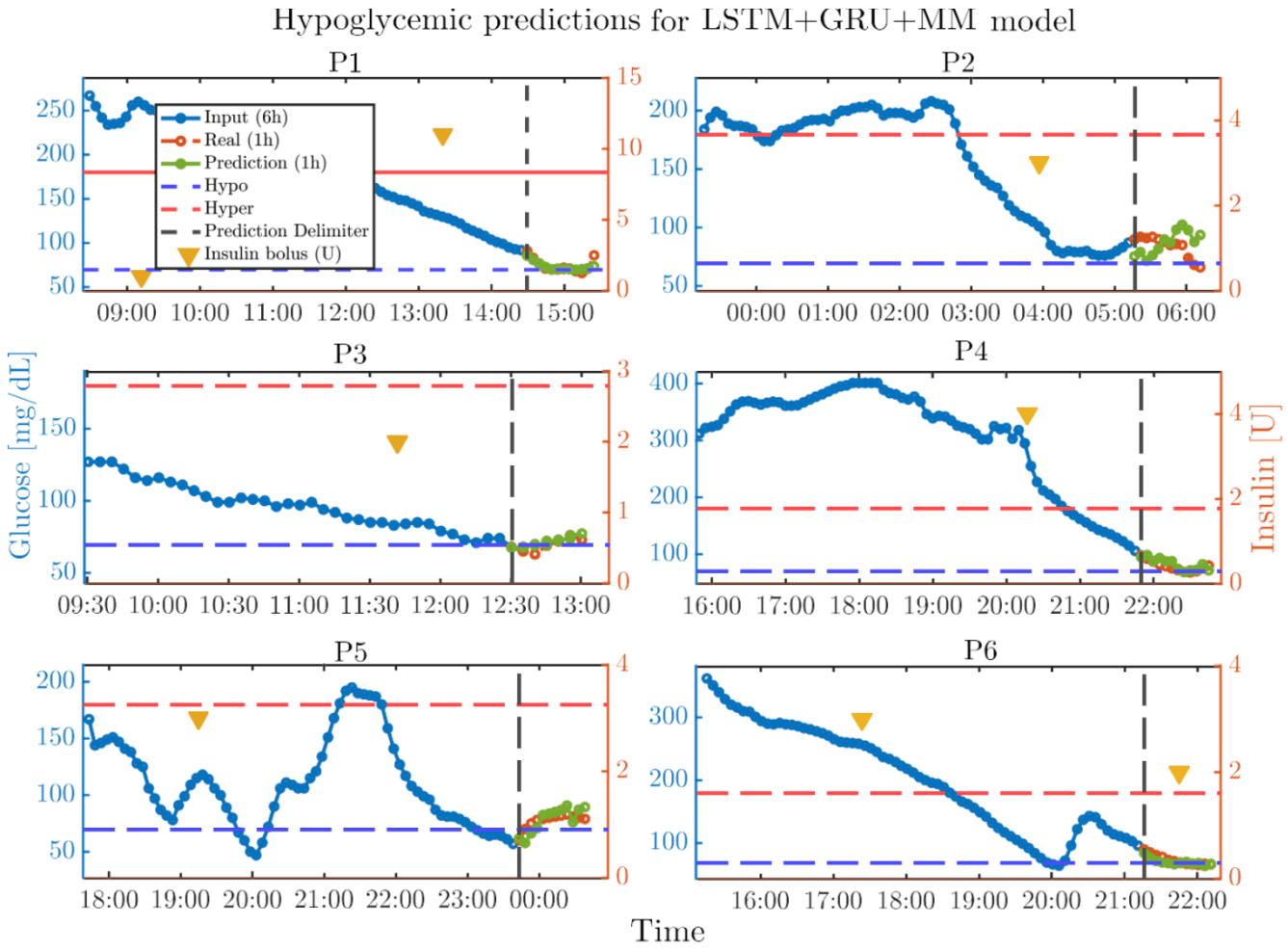
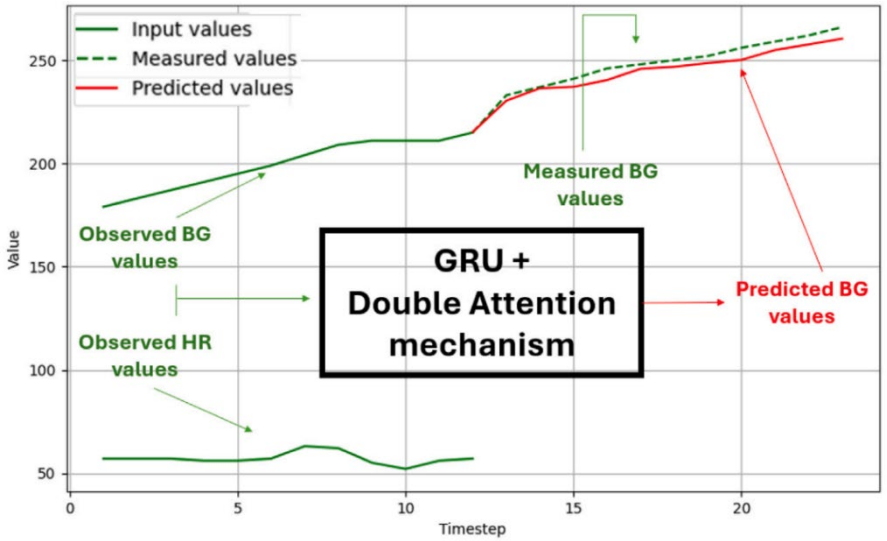
- CGM in ospedale
- CGM e connettività
- CGM e complicanze
- CGM e prospettive future

Hybrid Mechanistic-Data Driven model for **Hypoglycemia prediction** in patients treated with once-weekly basal insulin



Article Submitted
Nilde Fera et al. OP ATTD Barcellona 2026

Forecasting glucose values for patients with type 1 diabetes using heart rate data

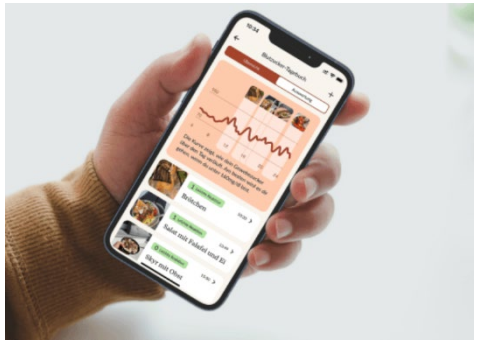


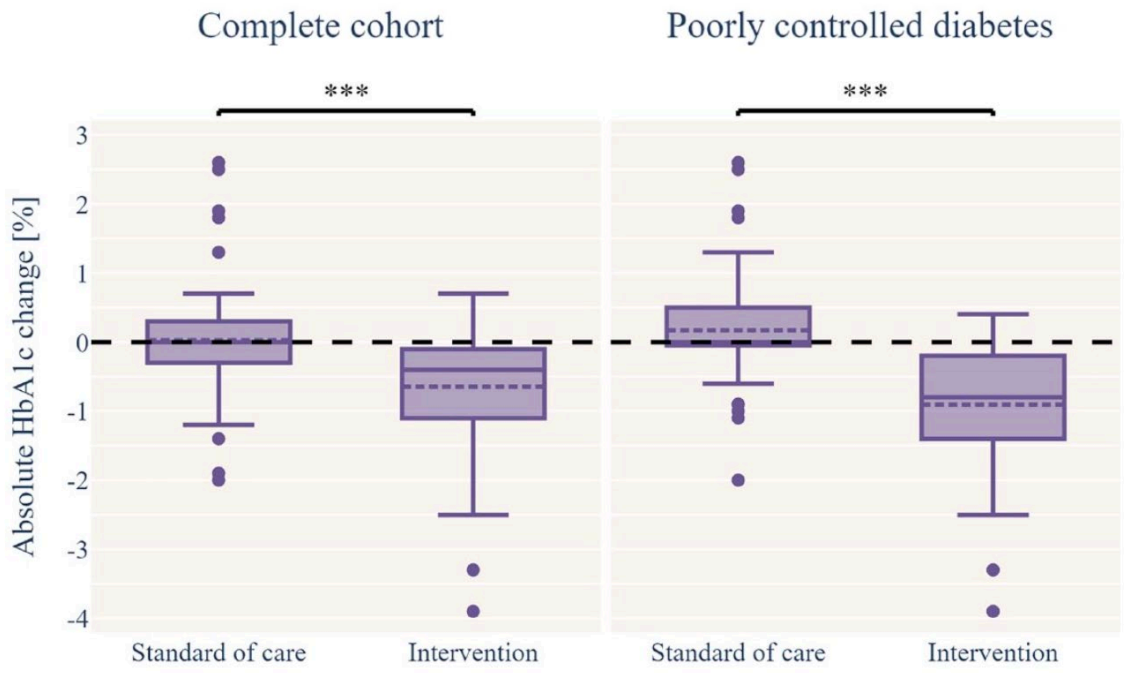
	5 min ahead			10 min ahead			15 min ahead			20 min ahead		
	Loss	RMSE	MAE	Loss	RMSE	MAE	Loss	RMSE	MAE	Loss	RMSE	MAE
LSTM	40.48	6.14	3.32	110.19	9.35	5.88	206.47	12.54	8.28	315.12	16.56	11.13
GRU	45.23	6.04	3.57	116.46	9.68	6.08	212.32	13.40	8.58	326.47	15.88	10.69
Gru+A	42.68	5.27	3.01	113.66	**9.16**	**5.55**	213.31	12.86	8.08	321.49	15.56	10.45
GRU+DA	40.39	**5.00**	**2.73**	111.63	9.38	6.10	209.10	**12.39**	**7.96**	312.24	**15.27**	**10.07**

Il modello include il valore del **glucosio** e della **frequenza cardiaca** misurata nei minuti precedenti ed utilizzata come input.
Il valore più basso di RMSE (radice quadrata della media dei quadrati degli errori) misurato in mg/dL, per ciascuna finestra di predizione temporale sono in bold.

Computer Methods and Programs in Biomedicine 257 (2024) 108438

Unlocking Potential: **Personalized Lifestyle** Therapy for Type 2 Diabetes Through a Predictive (AI) Algorithm-Driven Digital Therapeutic





-0.65 [-0.79, -0.50]

-0.91 [-1.10, -0.71]

- Personalized recommendation for low glycemic index diet;
- CGM meal responces;
- Suggestions for targeted meal comparisons to illustrate individual postprandial differences for similar meal types;
- Impementation of lifestyle modification;
- Personalized prediction of blood glucose responce to specific meal.

Proposed use of CGM throughout the **natural history** of T2DM

Group	At diagnosis and early disease	Management of stable disease	Long duration of disease[a]
All people with T2DM	Utilize CGM for 14 days after T2DM diagnosis Establish a baseline glucometric profile Provide education on the glycaemic response to diet and exercise in T2DM Decide on the initial treatment plan and therapy Evaluate the patient's early (14-day) response to T2DM treatment	Predict risk of microvascular complications Adjust therapy Manage glycaemic goals for time in range, time below range, time above range, glycaemic variability and glucose management indicator (CGM-defined HbA_{1c} correlate)	Facilitate T2DM therapy de-escalation in older and/or frail people with T2DM Prevent hypoglycaemia Reduce risk of cardiorenal complications (for example, chronic kidney disease) Reduce incidence and progression of microvascular disease Allow care workers to more effectively manage the care of people with T2DM
People with T2DM on: Multiple daily injections Basal insulin Premixed insulin Insulinotropic drugs[b]	**Continuous access to CGM for daily use** Prevent hypoglycaemia Manage hyperglycaemia Support self-management	Prevention of hypoglycaemia Manage hyperglycaemia Facilitate periods of therapy escalation or de-escalation Support self-management	
People with T2DM on non-insulin therapy[c]	**Intermittent use of CGM at least every 3 months, with HCP review** Reinforce education on glucose profiles, diet, physical activity and the effects of medication	Can be combined with a coincident HbA_{1c} test HCP can make decisions on whether to change therapy or not Predict changes in risk of microvascular complications People with T2DM can re-establish the behaviours of good self-management with support from CGM	

CGM, continuous glucose monitoring; HCP, health-care professional; T2DM, type 2 diabetes mellitus. [a]People with long-standing T2DM, with risk of consequent comorbid microvascular and macrovascular disease. [b]People with T2DM at increased risk of frequent hypoglycaemia confirmed during a CGM-led medical review. [c]Can include people on insulinotropic oral drugs with low risk of hypoglycaemia confirmed during a CGM-led medical review.

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Conclusioni

- Il CGM è **efficace** e **sicuro** nel diabete di tipo 2 indipendentemente dal tipo di trattamento;
- Il CGM è efficace e sicuro nel paziente con diabete ricoverato in **ospedale;**
- La **connessione** tra CGM e App dedicate contribuisce soprattutto a supportare l'autogestione e l'educazione del paziente;
- Studi osservazionali e retrospettivi hanno dimostrato il beneficio del CGM sullo sviluppo delle **complicanze;**
- L'accoppiamento di CGM e modelli di **machine learning** ha il potenziale per consentire una gestione individualizzata del diabete.