- **I sistemi automatizzati per l'infusione di insulina: una tecnologia per tutti:**

- **SI: Carlo Negri**
- **Endocrinologia, Diabetologia e Malattie del Metabolismo**

AOUI Verona

Il dottor Carlo Negri dichiara di NON aver ricevuto negli ultimi due anni compensi o finanziamenti da Aziende Farmaceutiche e/o Diagnostiche

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.).

Centres

SI

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DI MOLFETTA

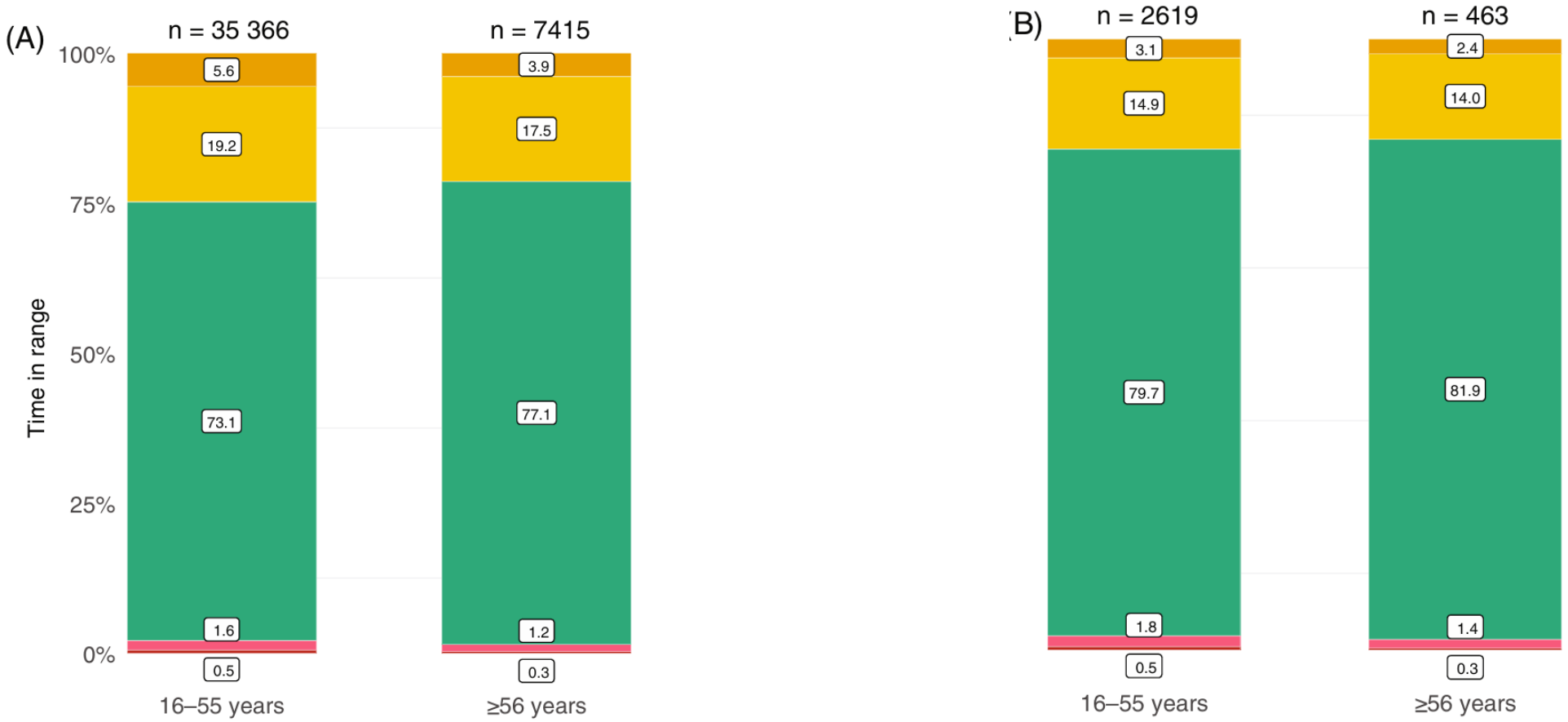
M------ ---G system performance in older users with type 1diabetes: Real-world evidence and the case for stricter glycaemic targets

Retrospective, observational study, real-world, multi-country data were analysed to evaluate the performance of the M ------- G system for a range of continuous glucose monitoring (CGM) related metrics.

The comparison was between older users, here defined as aged ≥56 years, and younger users, aged 16–55 years, with type 1 diabetes.

DiabetesObesMetab.2025;27:2242–2250.

M------ ---G system performance in older users with type 1diabetes: Real-world evidence and the case for stricter glycaemic targets



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M------ ---G system performance in older users with type 1diabetes: Real-world evidence and the case for stricter glycaemic targets

	Users aged 16–55 years	Users aged ≥56 years
Achievement cohort: all		
Users, *n*	35 366	7415
Sensor wear, %	88.3 ± 14.0	94.1 ± 7.6
Time in AHCL, %	88.9 ± 16.6	94.3 ± 11.8
Mean SG, mg/dL	150.9 ± 17.0	146.9 ± 14.2
GMI, %	6.9 ± 0.4	6.8 ± 0.3
Users with GMI <7%, %	62.9	72.9
Users with TIR >70%, %	66.0	79.2
Achievement cohort: recommended optimal settings		
Users, *n*	2619	463
Time in AHCL, %	93.2 ± 11.7	96.5 ± 7.6
Mean SG, mg/dL	140.2 ± 11.7	139.1 ± 11.3
GMI, %	6.7 ± 0.3	6.6 ± 0.3
Users with GMI <7%, %	88.6	91.8
Users with TIR >70%, %	89.5	93.7

DiabetesObesMetab.2025;27:2242–2250.

Automated insulin delivery systems in elderly patients with brittle type 2 diabetes

Brittle diabetes was defined as constant disruption of life by episodes of hypoglycemia or hyperglycemia

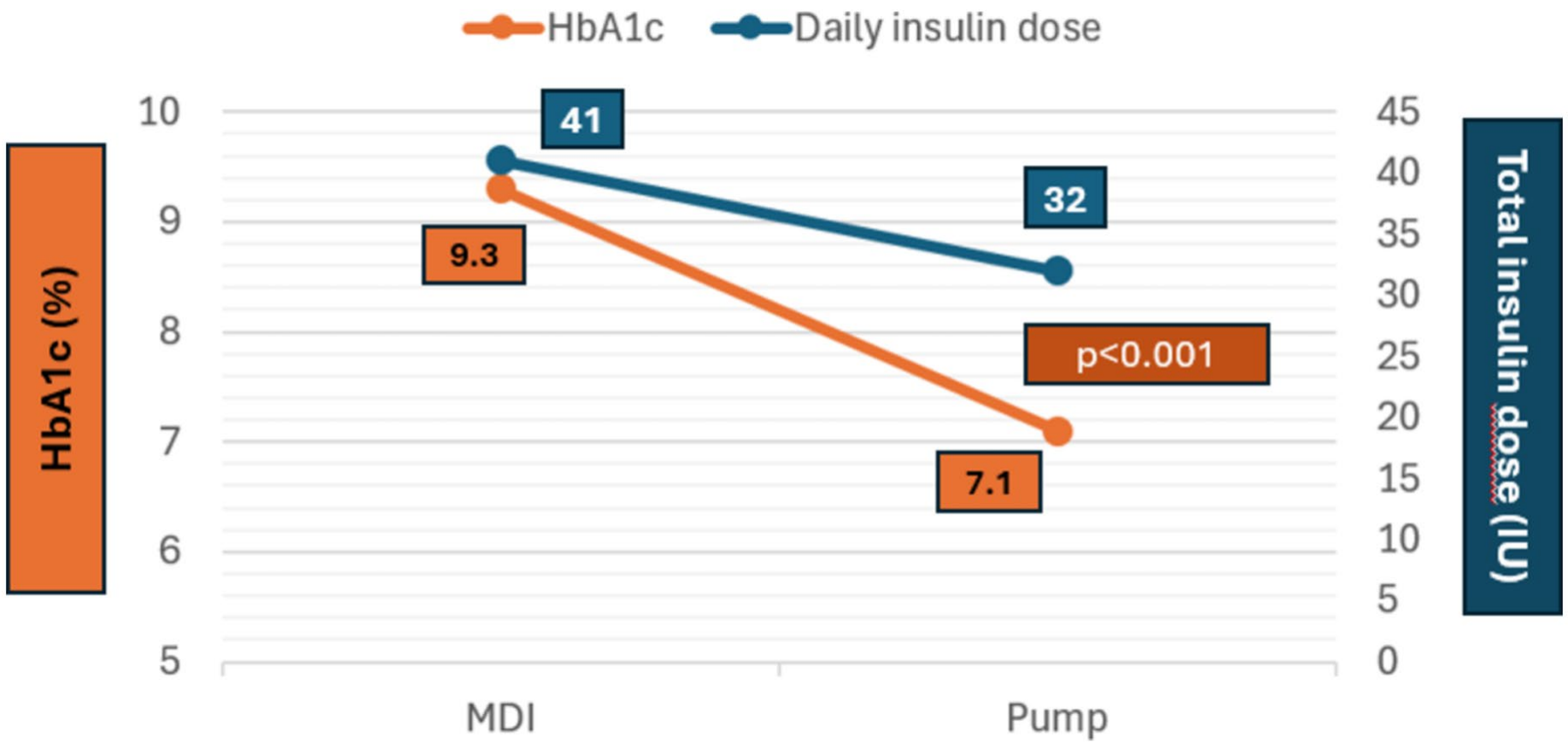
It was diagnosed based on clinical assessment after assessment of glycemic variation by self-reported glucose monitoring.

Automated insulin delivery systems in elderly patients with brittle type 2 diabetes

Table 1
Clinical parameters of the patients; BMI: body mass index.

Parameters	Mean (±SD) N = 34	Median (IQR) N = 34
Age (years)	69.3 ± 7.5	67.0 (63.0–75.5)
Diabetes duration (years)	17.7 ± 8.0	18 (13.0–22.0)
HbA1c (%)	9.4 ± 2.1	9.3 (7.6–11.0)
C-Peptide (ng/mL)	1.2 ± 1.1	0.8 (0.5–2.2)
Creatinine (mg/dL)	1.0 ± 0.4	0.9 (0.7–1.1)
Triglyceride (mg/dL)	126 ± 33	122 (110.0–154.0)
Total cholesterol(mg/dL)	188 ± 41	184 (150.0–216.0)
HDL cholesterol(mg/dL)	48 ± 10	44.0 (42.0–54.0)
LDL cholesterol (mg/dL)	112 ± 40	107.0 (82.0–141.0)
BMI (kg/m^2)	26.9 ± 5.6	26.0 (22.5–30.9)
Total insulin dose (IU)	41 ± 11	41.0 (32.0–53.0)

Automated insulin delivery systems in elderly patients with brittle type 2 diabetes



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Automated insulin delivery systems in elderly patients with brittle type 2 diabetes

The mean GLUCOSE range percent of the patients with AID systems were as follows;

TBR <54 mg/dL was 0.5 %,
TBR < 56–70 mg/dL was 1.3 %,
TIR 70–180 mg/dL was 64.8 %,
TAR >180 mg/dL was 26.7 %,
TAR >250 mg/dL was 6.7 %.

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Automated insulin delivery systems in elderly patients with brittle type 2 diabetes

Table 2
Progress of patients on chemotherapy and/or steroids.

Case Number	Gender	Age	Basal Hba1c (%)	Follow-up HbA1c (%)	Basal total insulin dose (IU)	Follow-up total insulin dose (IU)
1	F	60	11.20	9.20	35	27
2	M	77	9.60	11.43	32	37
3	F	71	6.30	5.90	28	23
4	F	79	7.80	6.50	34	35
5	F	87	7.30	7.30	62	30
6	M	79	12.40	6.30	29	23

F stands for female and M stands for male.

A Randomized Trial of Automated Insulin Delivery in Type 2 Diabetes

Trial patients were at least 18 years old and had had type 2 diabetes for at least 6 months, according to clinical history and available labora tory data. All the patients were receiving multiple daily injections of insulin with at least one injec tion containing rapid-acting insulin per day.

Concurrent treatment with noninsulin glucose-lowering medications or weight-reduction medications was permitted, provided the dose had been stable for the previous 3 months; during the trial, these medications were continued in both treatment groups.

From June 1, 2023, to June 21, 2024, a total of 319 patients were randomly assigned to the AID group (215 patients) or the control group (104 patients).

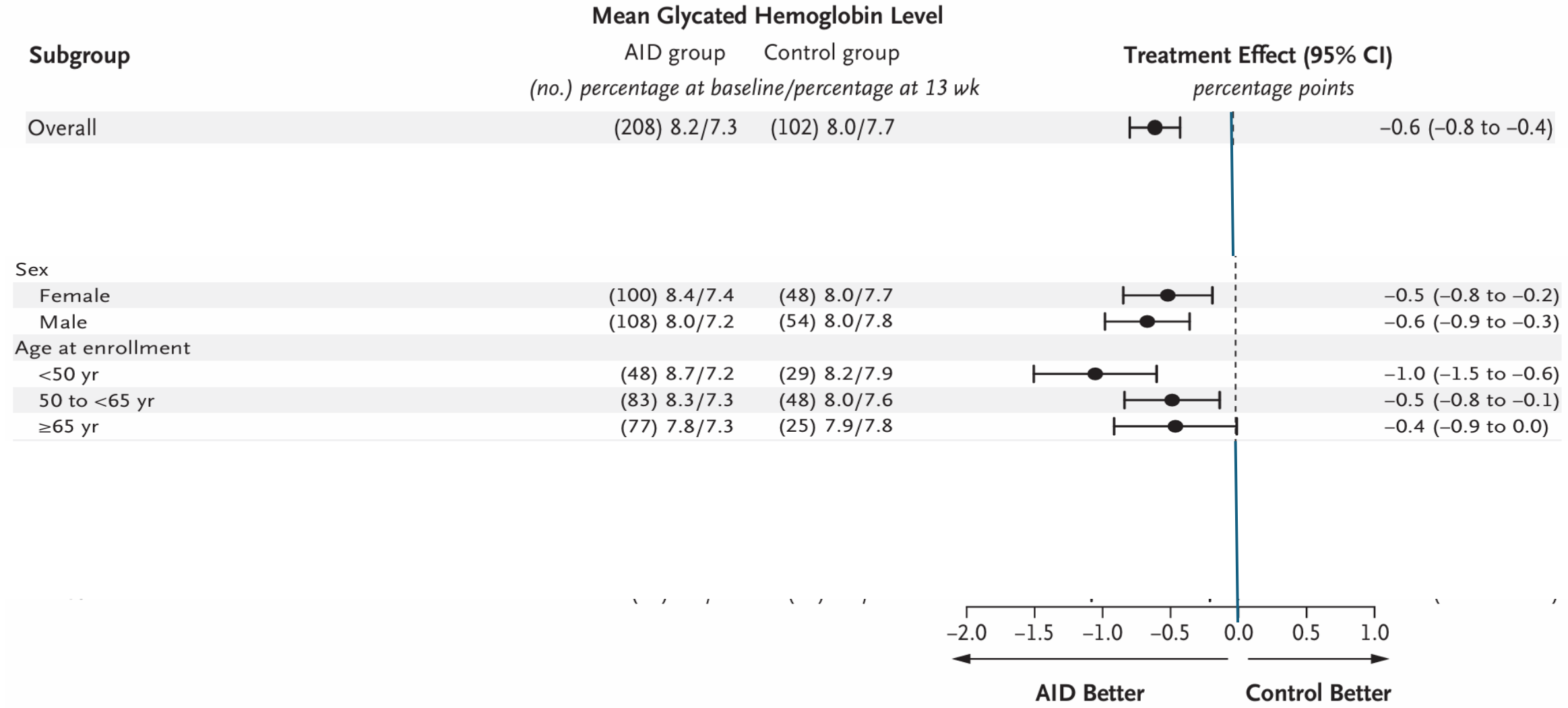
A Randomized Trial of Automated Insulin Delivery in Type 2 Diabetes

Characteristic	AID Group (N = 215)	Control Group (N = 104)
Age — yr		
Mean	59±12	57±12
Range	19–87	23–80
Female sex — no. (%)	105 (49)	49 (47)
Diabetes duration — yr		
Median (IQR)	18 (11–26)	18 (11–24)
Range	1–59	2–45
Body-mass index‡		
Median (IQR)	33 (29–40)	35 (29–40)
Range	19–56	20–57

A Randomized Trial of Automated Insulin Delivery in Type 2 Diabetes

Characteristic	AID Group (N = 215)	Control Group (N = 104)
Glycated hemoglobin level§		
Distribution — no. (%)		
<7.0%	28 (13)	15 (14)
7.0 to <8.0%	73 (34)	40 (38)
8.0 to <9.0%	66 (31)	24 (23)
≥9.0%	47 (22)	25 (24)
Mean value — %	8.2±1.4	8.1±1.2
Range in values — %	5.7–14.1	5.2–12.4
Noninsulin glucose-lowering medication — no. (%)¶		
Metformin	109 (51)	61 (59)
SGLT2 inhibitor	76 (35)	41 (39)
GLP-1 receptor agonist	87 (40)	54 (52)
SGLT2 inhibitor and GLP-1 receptor agonist	44 (20)	24 (23)
Other	9 (4)	10 (10)

A Randomized Trial of Automated Insulin Delivery in Type 2 Diabetes



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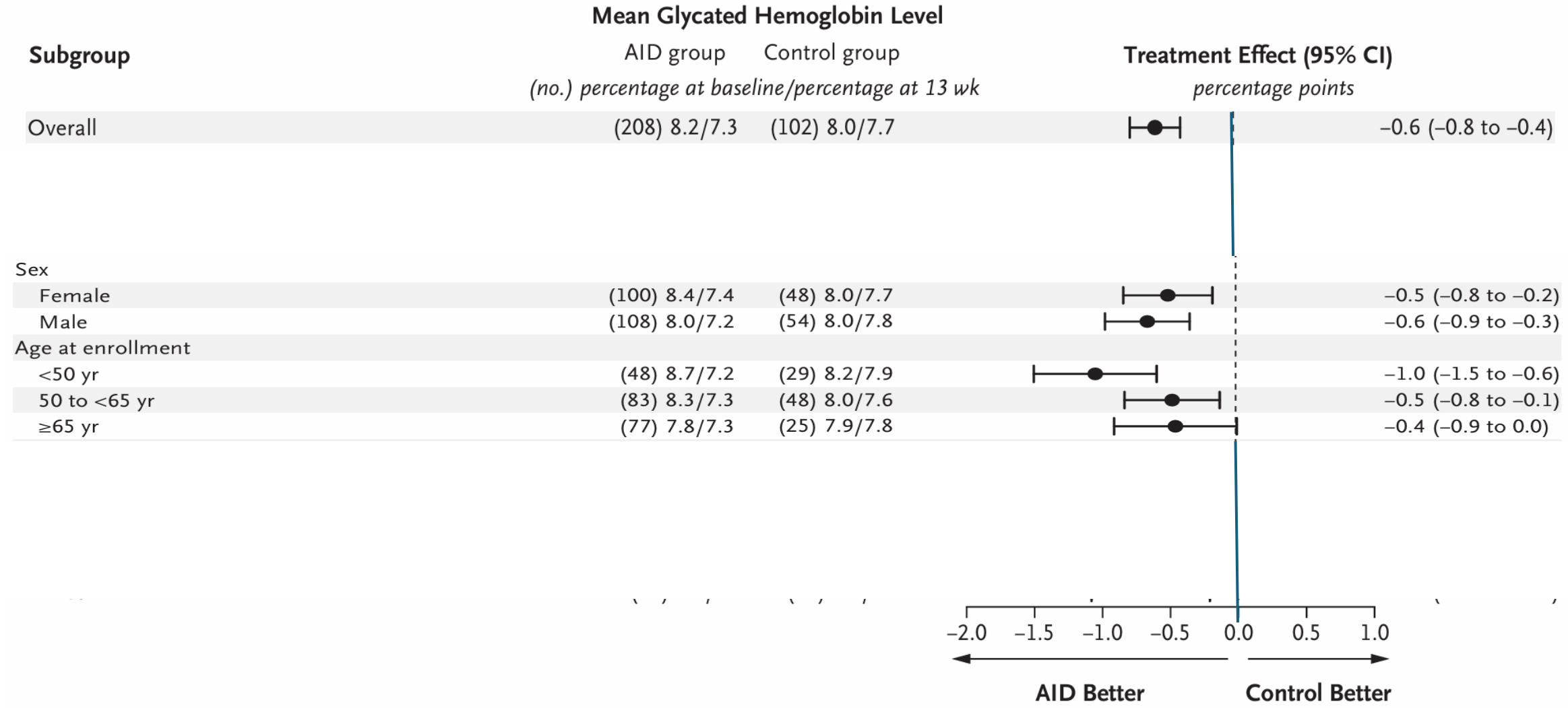

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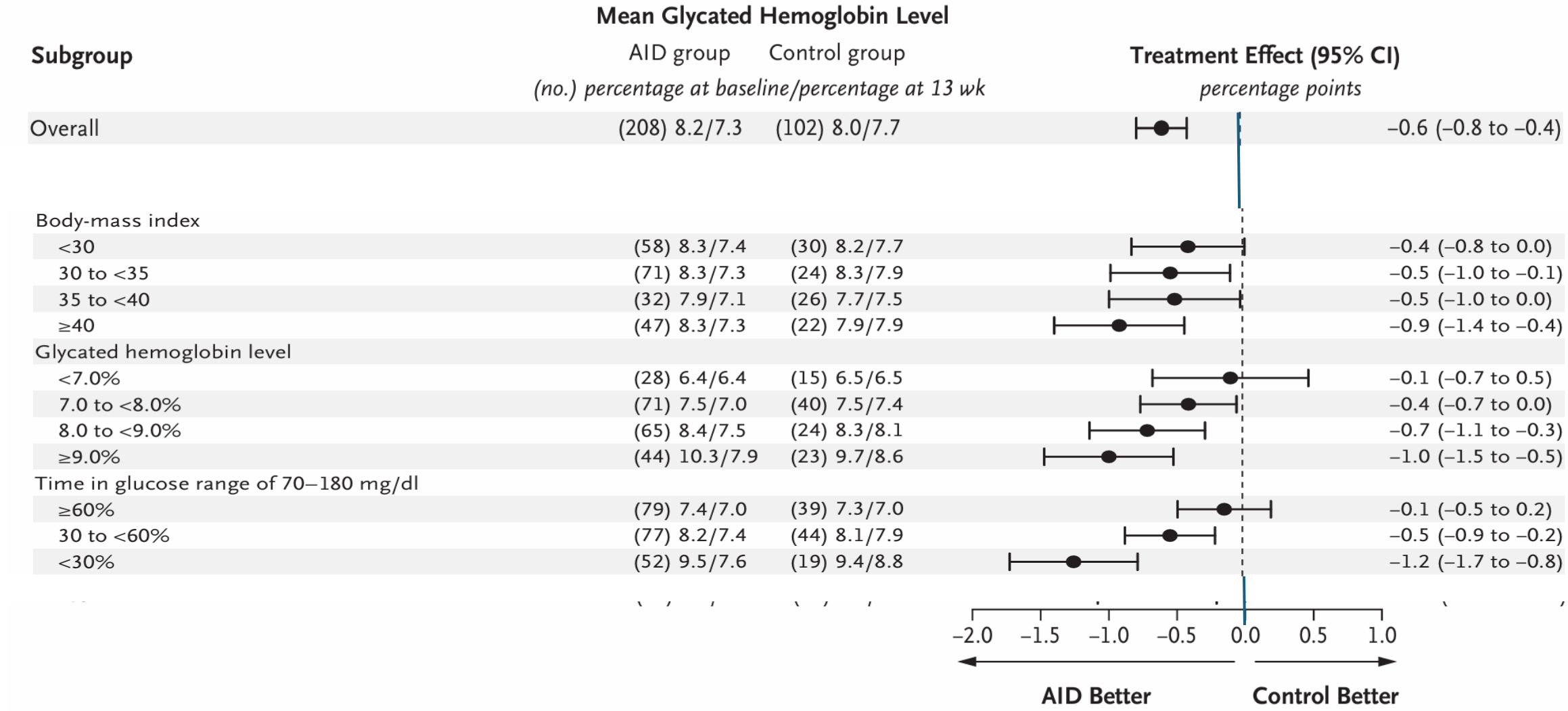
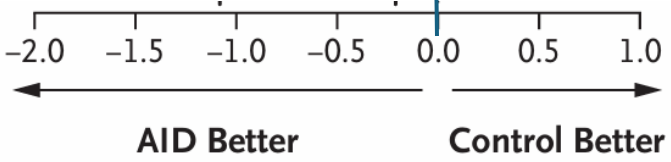
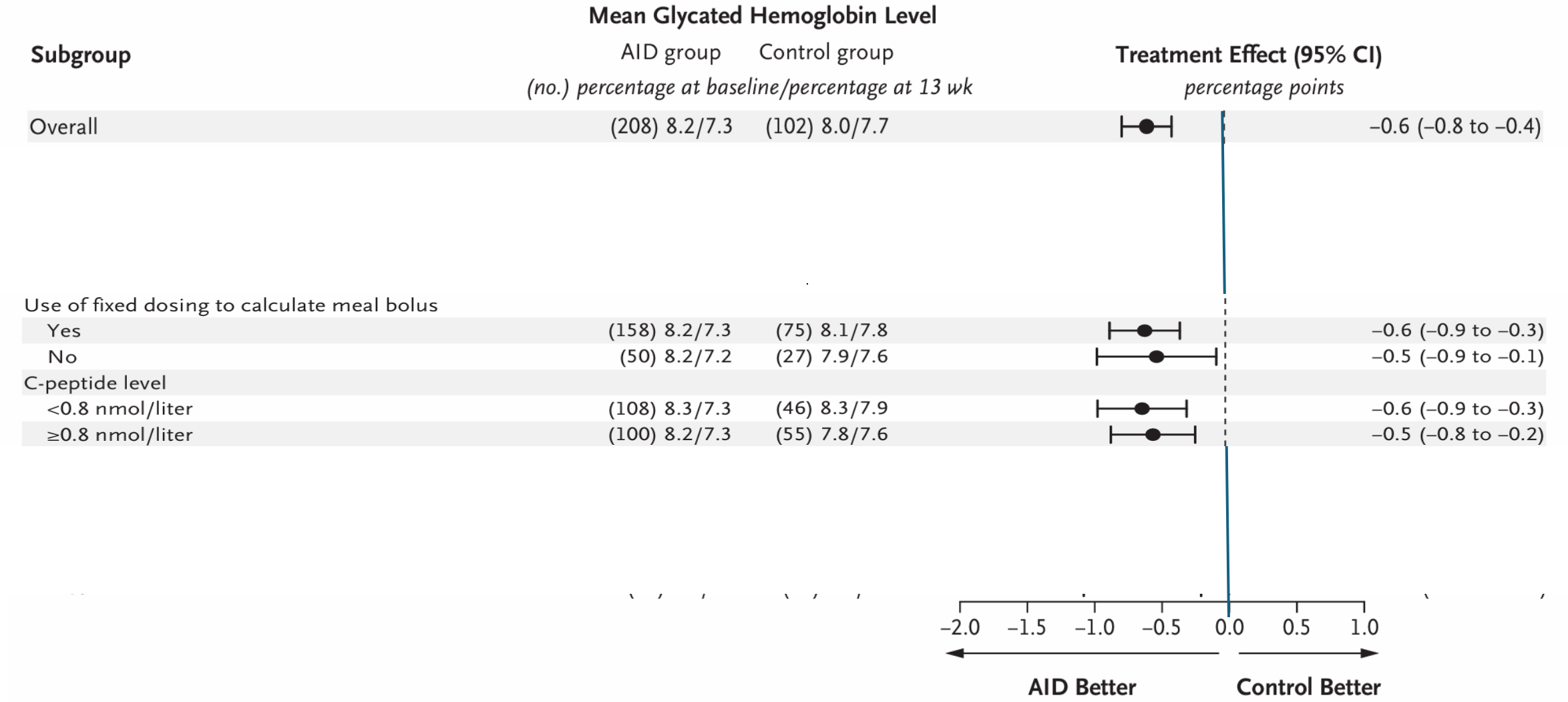


A Randomized Trial of Automated Insulin Delivery in Type 2 Diabetes

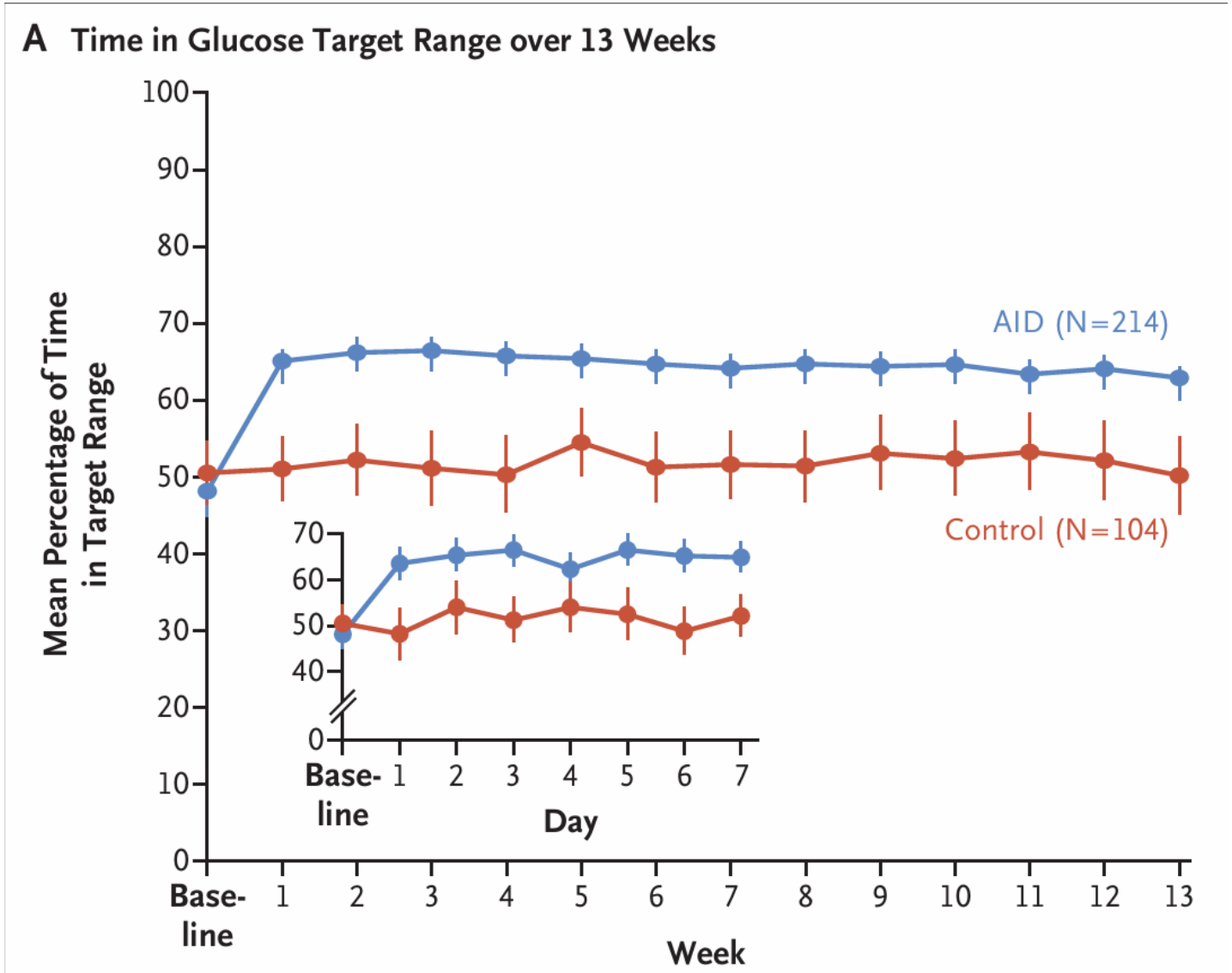
Subgroup	Mean Glycated Hemoglobin Level: AID group (no.) percentage at baseline/percentage at 13 wk	Mean Glycated Hemoglobin Level: Control group (no.) percentage at baseline/percentage at 13 wk	Treatment Effect (95% CI) percentage points
Overall	(208) 8.2/7.3	(102) 8.0/7.7	−0.6 (−0.8 to −0.4)
Use of noninsulin glucose-lowering medications			
None	(46) 8.7/7.3	(12) 8.7/8.4	−1.0 (−1.6 to −0.4)
Other, but no SGLT2i or GLP-1ra	(48) 8.3/7.3	(20) 8.3/8.0	−0.7 (−1.2 to −0.2)
GLP-1ra, but no SGLT2i	(42) 8.1/7.3	(29) 7.8/7.5	−0.3 (−0.7 to 0.1)
SGLT2i, but no GLP-1ra	(29) 8.2/7.5	(17) 7.8/7.6	−0.3 (−0.8 to 0.3)
Both GLP-1ra and SGLT2i	(43) 7.9/7.1	(24) 7.8/7.7	−0.6 (−1.1 to −0.2)
Total daily insulin intake			
<100 units/day	(125) 8.3/7.3	(57) 7.9/7.6	−0.5 (−0.8 to −0.2)
100 to <150 units/day	(55) 8.1/7.2	(27) 8.2/7.9	−0.6 (−1.1 to −0.2)
150 to <200 units/day	(14) 8.0/7.5	(12) 7.7/7.9	−0.7 (−1.4 to 0.0)
≥200 units/day	(14) 7.9/7.0	(6) 8.7/7.7	−0.1 (−1.0 to 0.8)
Duration of diabetes at enrollment			
<5 yr	(10) 8.5/7.3	(9) 8.3/8.0	−0.9 (−1.7 to −0.1)
5 to <10 yr	(29) 8.5/7.2	(10) 8.4/7.8	−0.7 (−1.3 to 0.0)
10 to <20 yr	(69) 8.2/7.3	(38) 8.1/7.9	−0.7 (−1.0 to −0.3)
≥20 yr	(100) 8.1/7.3	(45) 7.8/7.5	−0.4 (−0.7 to −0.1)



A Randomized Trial of Automated Insulin Delivery in Type 2 Diabetes

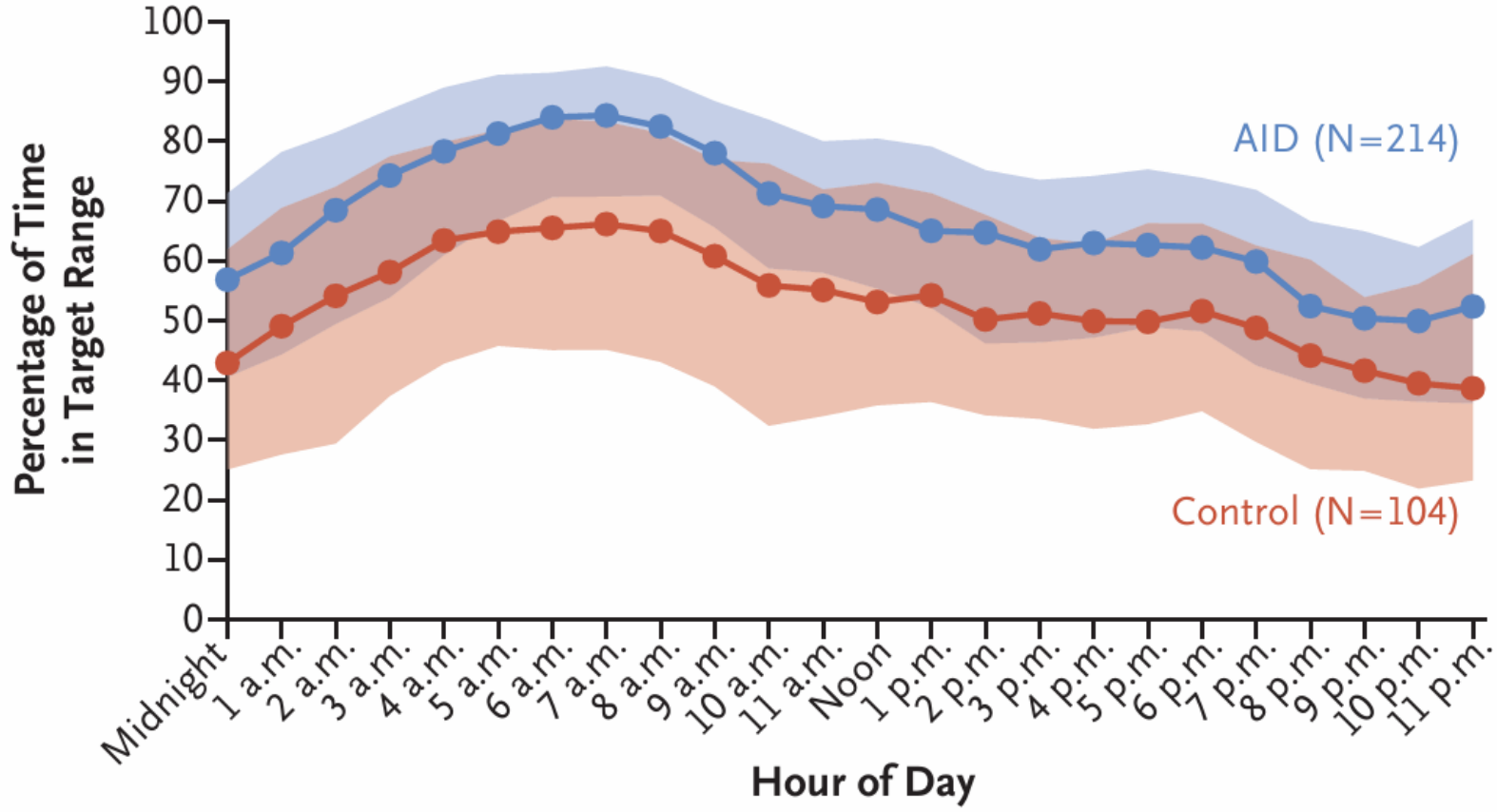


A Randomized Trial of Automated Insulin Delivery in Type 2 Diabetes



A Randomized Trial of Automated Insulin Delivery in Type 2 Diabetes

B **Time in Glucose Target Range According to Hour of Day over 13 Weeks**



A Randomized Trial of Automated Insulin Delivery in Type 2 Diabetes

Table 3. Safety Outcomes during the 13-Week Trial Period.

Adverse Event	AID Group (N = 215)		Control Group (N = 104)	
	no. of events	*no. of patients (%)*	*no. of events*	*no. of patients (%)*
Any adverse event*	106	64 (30)	26	19 (18)
Specific event				
Severe hypoglycemia	1	1		0
Diabetic ketoacidosis or hyperosmolar hyperglycemic syndrome		0		0
Other serious adverse event†	18	16 (7)	7	7 (7)
Other adverse event				
Hyperglycemia with or without ketosis				
Related to trial device	20	13 (6)		0
Not related to trial device	1	1 (<1)	2	2 (2)
Nonsevere hypoglycemia	10	9 (4)	2	2 (2)
Other reportable adverse event	56	37 (17)	15	14 (13)

Early use of hybrid closed-loop following total pancreaticoduodenectomy

Our four patients – three females aged 69 (patient 1), 74 (patient 3) and 64 years (patient 4) and one 62-year-old male (patient 2) – gave their consent to publish this report.

Their mean age ± standard deviation was 67.5 ± 5.2 years.

Patients 1 and 4 underwent TP for pancreatic adenocarcinoma, requiring adjuvant chemotherapy, patient 3 for a pancreatic localization of kidney carcinoma, and patient 2 for an intraductal papillary mucinous neoplasm.

They all experienced post-operative symptoms of delayed gastric emptying (DGE), with nausea, epigastric pain, and voluminous stomach visualized on computed tomography, leading to insufficient calorie intake and irregular carbohydrate consumption.

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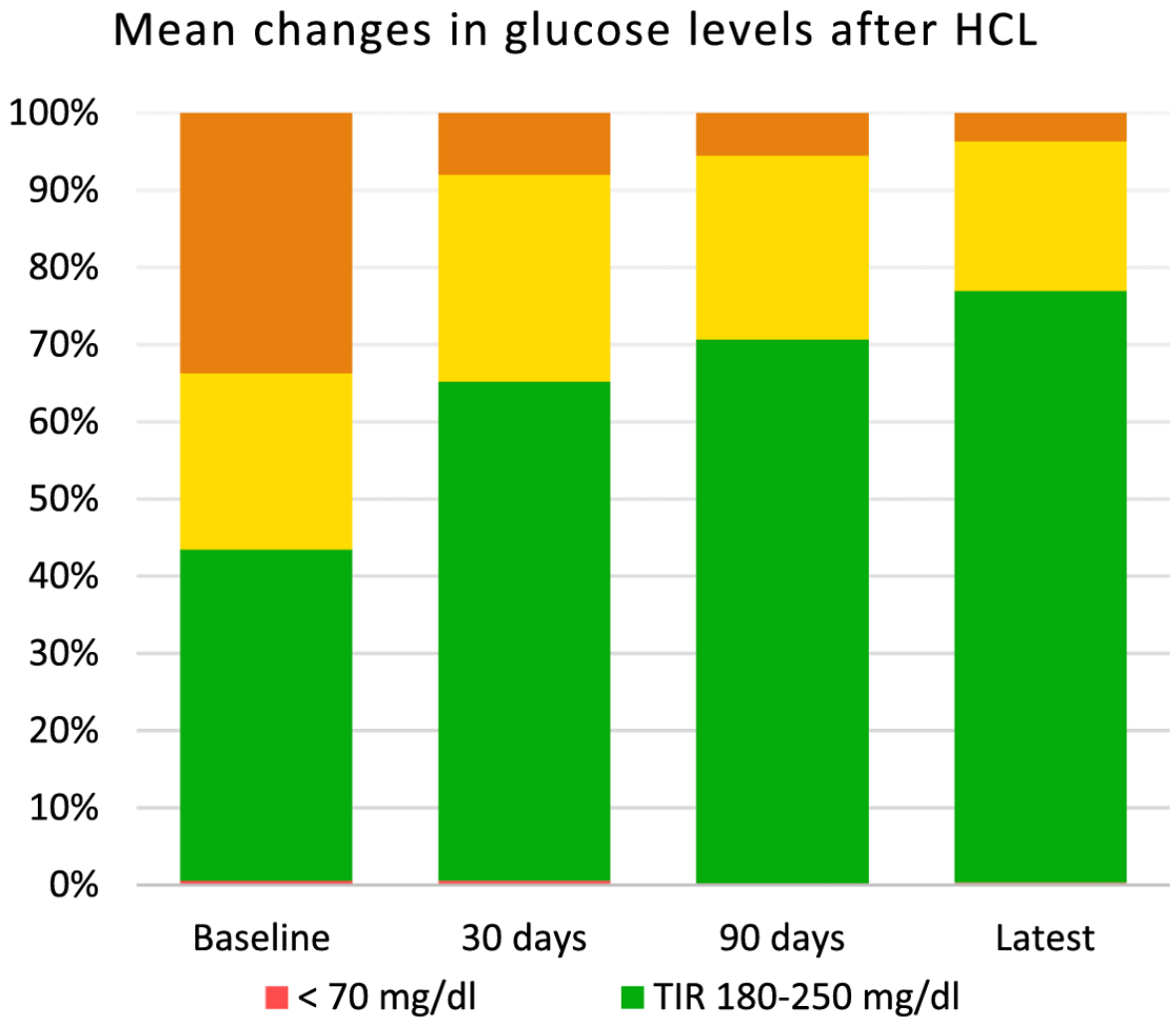
Early use of hybrid closed-loop following total pancreaticoduodenectomy



Diabetes & Metabolism 51 (2025) 101619

Early use of hybrid closed-loop following total pancreaticoduodenectomy

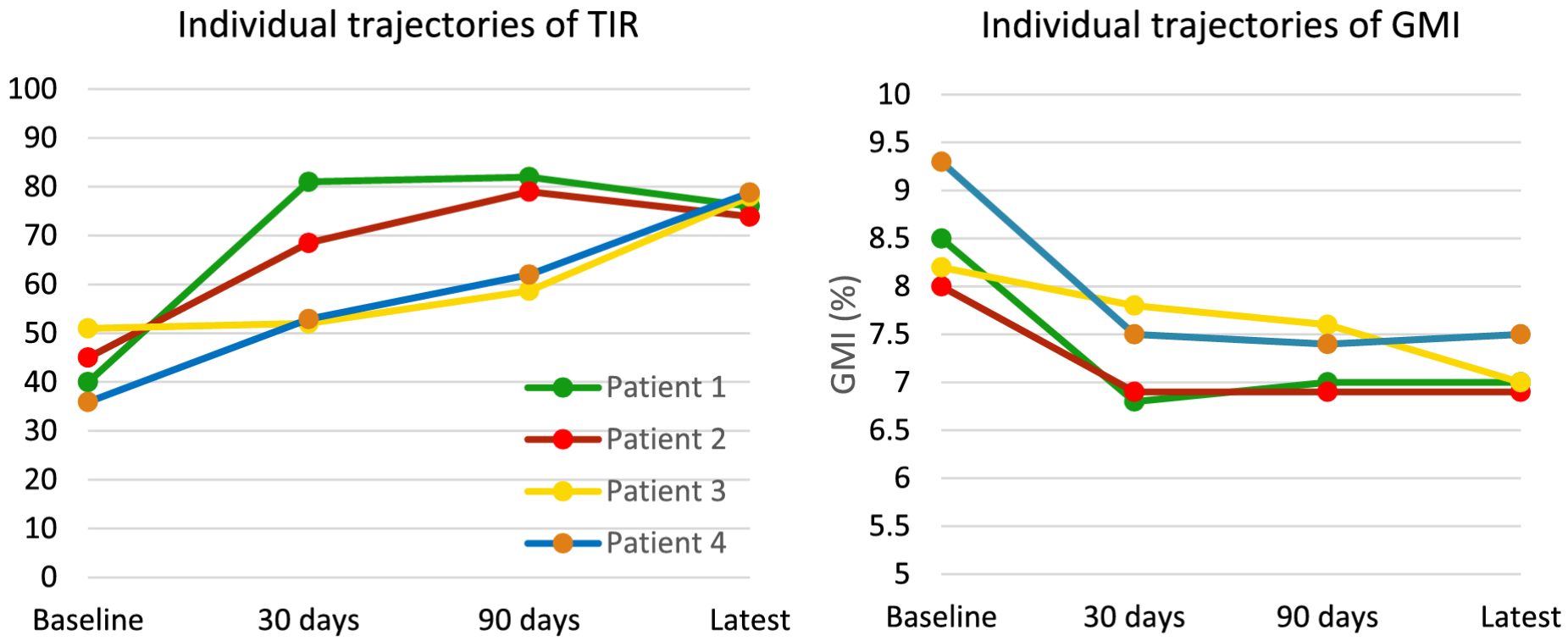


Fig. 1. Mean continuous glucose monitoring changes and individual trajectories for time-in-range (TIR) and glucose management indicator (GMI).

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DM1

ADA – American Diabetes Association (Standards of Care 2024–2025)

•Raccomanda l'uso di **CSII** e soprattutto dei sistemi **AID / ibridi in loop chiuso (HCL)** nei pazienti con diabete tipo 1 di qualsiasi età **quando possibile e se il paziente è motivato e formato**.

NICE – Regno Unito (Linee guida 2023–2024, NG17 e MTG65)

•Dal 2023 NICE **raccomanda l'uso di AID (closed loop)** per:

- Tutte le persone con DM1 > 18 anni con HbA1c ≥ 7,5% nonostante MDI/CSII + CGM,
  oppure
- Se presentano ipoglicemie problematiche

SID – Società Italiana di Diabetologia / AMD (Standard Italiani 2022–2024)

•I sistemi **CSII e HCL** sono indicati:

- In DM1, soprattutto in caso di scarso controllo con MDI, ipoglicemie frequenti o marcata variabilità glicemica.
- È esplicitato che i sistemi **HCL migliorano tempo in range, HbA1c e riducono ipoglicemie**.

•Raccomandato il matching con educazione terapeutica e team esperto.

DM2

ADA

•CSII può essere **considerata** in:
- Persone con DM2 in terapia insulinica complessa che non raggiungono target glicemici.

•I sistemi **AID/HCL nel DM2**: ADA dal 2024 introduce la possibilità **in casi selezionati**, soprattutto se già in terapia insulinica intensiva.

NICE

•Nel DM2 **non raccomanda l'uso routinario** di AID.
•La CSII può essere considerata solo in eccezioni (DM2 insulinizzato con grandi fabbisogni e scarsa risposta a MDI).

SID / AMD

•Uso di CSII nel DM2 **non escluso**, ma riservato a casi molto selezionati (insufficienza nel raggiungere il controllo glicemico nonostante terapia intensiva e buon addestramento).
•AID **non raccomandato di routine** nel DM2.

ALTRI TIPI DI DIABETE (es. LADA, diabete secondario)

•**ADA e SID**: la CSII/AID può essere **considerata caso-per-caso** (es. LADA in fase insulinica, diabete secondario con bisogno di insulinoterapia).

CONCLUSIONI

Gruppo	CSII (pompa)	AID/HCL (loop chiuso)
DM1	Fortemente raccomandata da SID/ADA/NICE	Fortemente raccomandata (ADA/NICE/SID)
DM2 insulinizzato	Possibile in casi selezionati	Solo in casi selezionati (ADA 2024), non routine (NICE/SID)
Altri tipi di diabete	Valutazione individuale	Possibile ma non standard

CONCLUSIONI

Gruppo		
DM1	Anche nei pazienti > 56 anni	Maggior TIR vs < 56 anni
DM2 insulinizzato	Evidenze positive in tutti i sottotipi di dm2	Attenzione agli eventi ipo/iperglicemici
Altri tipi di diabete	Evidenze positive in Dm post-pranceasectomia	Numero dei pazienti trattati ridotto