



**Selezione del paziente e comunicazione
efficace: i vantaggi dell'Hybrid Closed Loop verso la terapia MDI**

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La sottoscritta Elena Succurro

ai sensi dell'art. 76, comma 4 dell'Accordo Stato-Regioni del 2 febbraio 2017 e del paragrafo 4.5. del Manuale nazionale di accreditamento per l'erogazione di eventi ECM

dichiara che

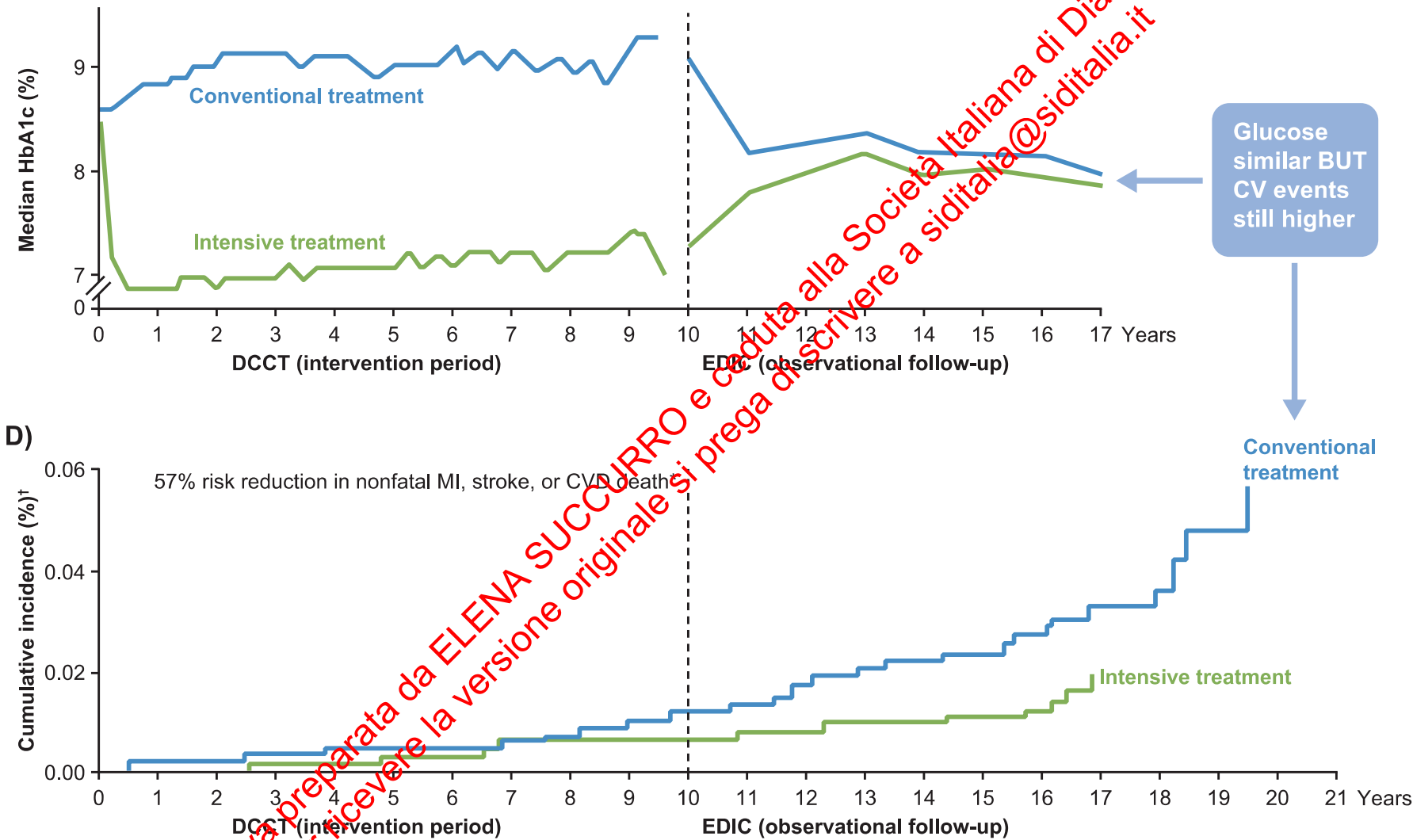
negli ultimi due anni ha avuto i seguenti rapporti con soggetti portatori di interessi commerciali in ambito sanitario

Novo Nordisk, Abbott Srl (*per eventi e advisory board*)

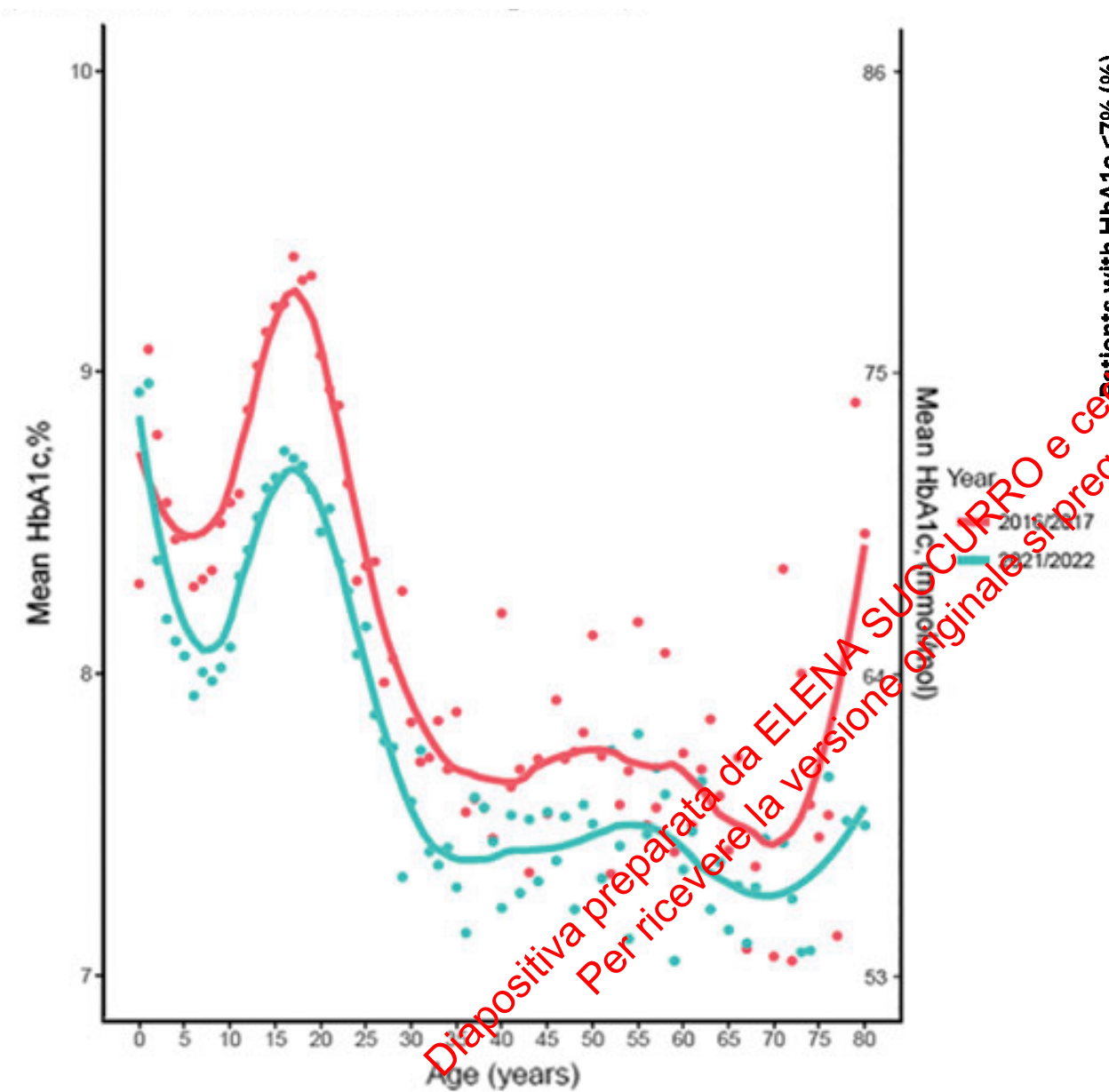
Dichiara altresì il proprio impegno ad astenersi, nell'ambito dell'evento, dal nominare, in qualsivoglia modo o forma, aziende farmaceutiche e/o di denominazione commerciale e di non fare pubblicità di qualsiasi tipo relativamente a specifici prodotti di interesse sanitario (farmaci, strumenti, dispositivi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

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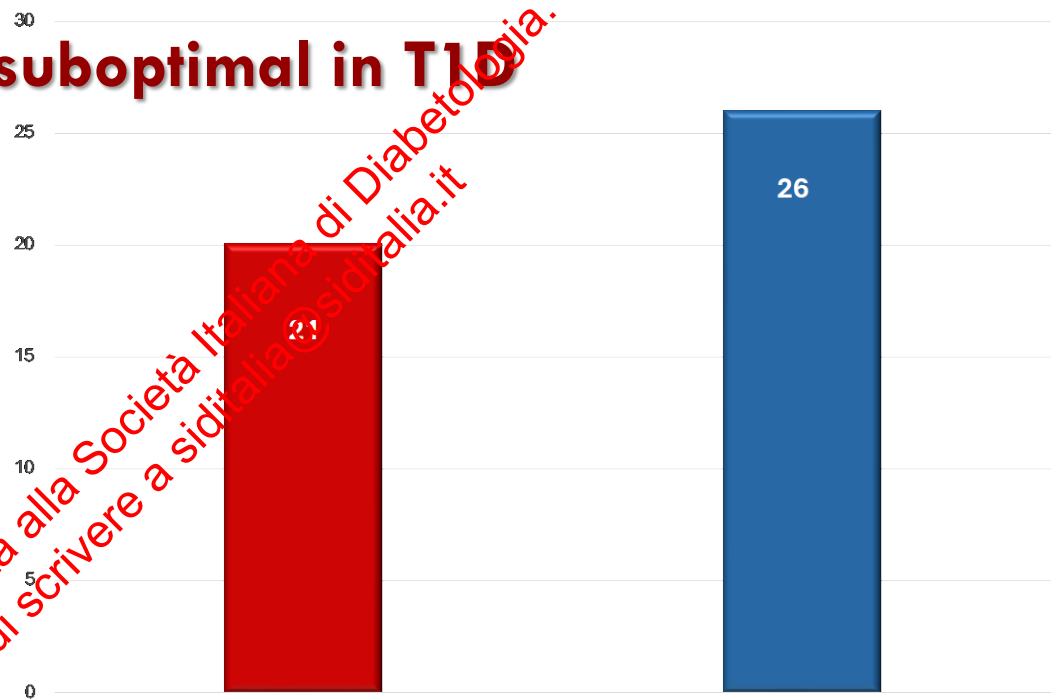
Benefits of early treatment of diabetes to reduce CVD risk. Legacy effect



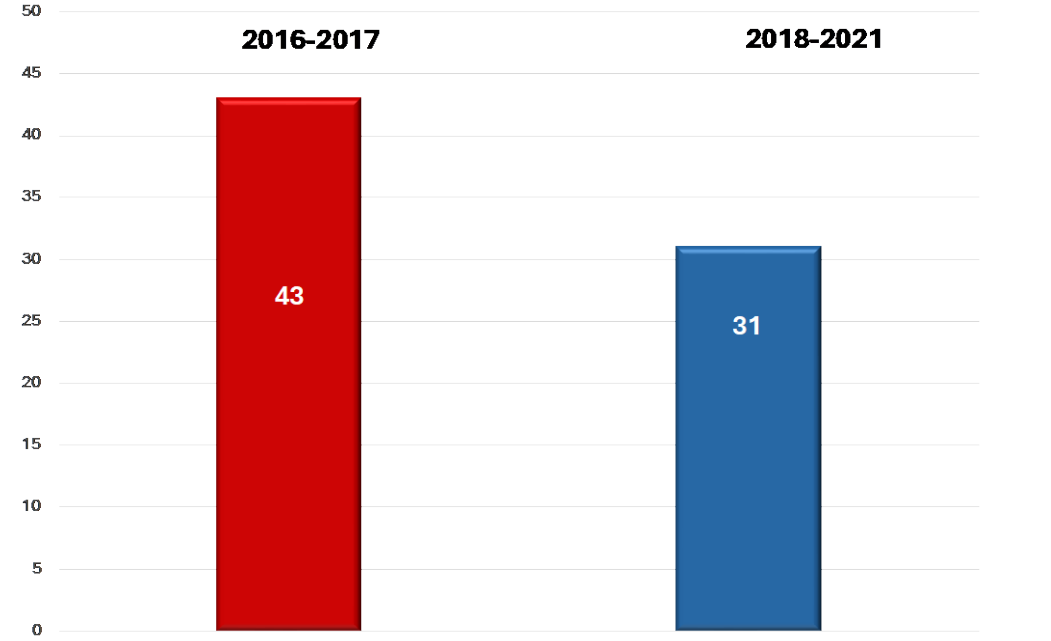
Glycaemic control remains suboptimal in T1D



Patients with HbA1c <7% (%)



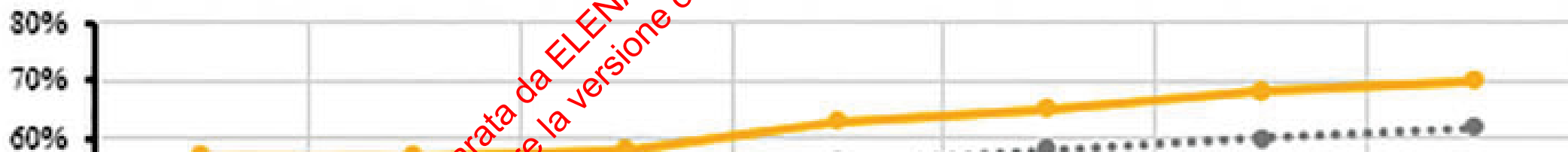
Patients with HbA1c >9 % (%)



Patients Longitudinal Trends in Technology Use in People with Type 1 Diabetes

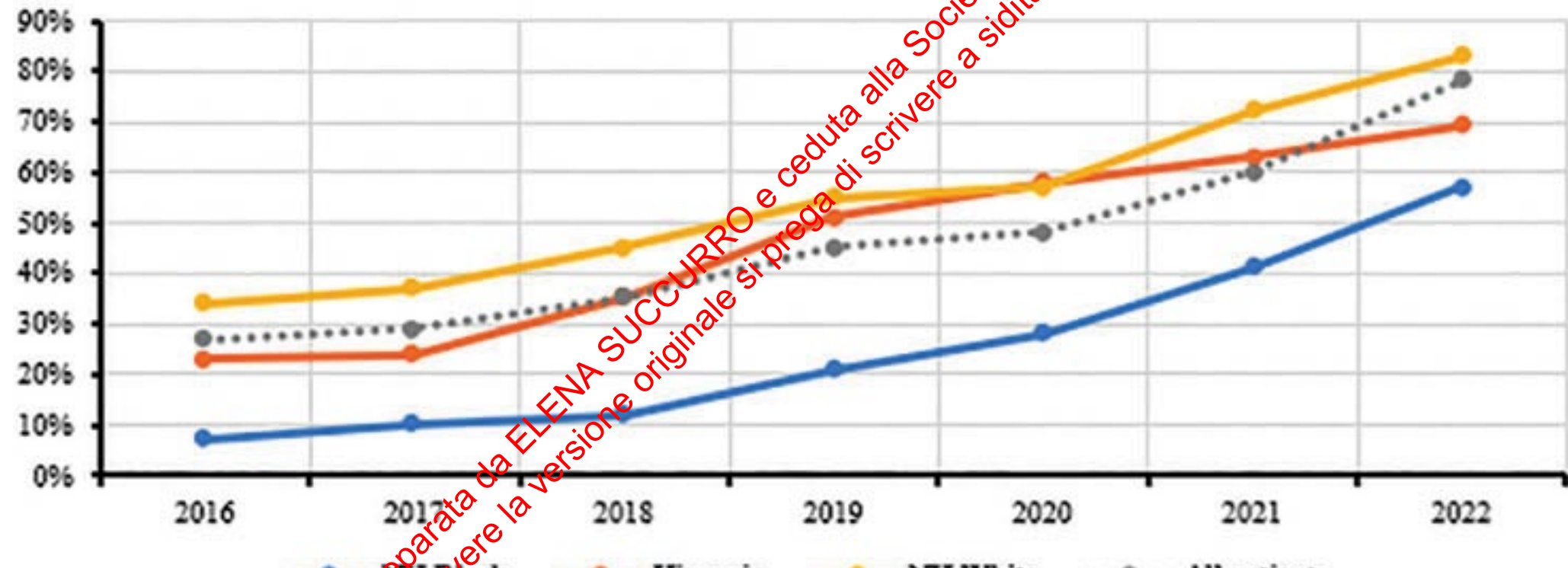


B Trends in Pump Use



Patients Longitudinal Trends in AHCL Use in People with Type 1 Diabetes

A Trends in CGM Use



7. Diabetes Technology: Standards of Care in Diabetes—2025

Diabetes Care 2025;48(Suppl. 1):S146–S166 | <https://doi.org/10.2337/dc25-S007>

Insulin Pumps and Automated Insulin Delivery 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**

American Diabetes Association
Professional Practice Committee*

Consensus Recommendations for the Use of Automated Insulin Delivery Technologies in Clinical Practice

- Strongly consider recommending AID systems to all people with T1D to improve glycemic control
 - School-aged children (7–14 years) (2, 3, 5, 20, 46, 63–67) **A**
 - Adolescents/Adults (3, 6, 68) **A**
- Consider recommending to:
 - Older adults (above 65 years) (2, 29, 68, 69) **B**
 - Preschool children (<7 years) (31, 32, 56, 57, 70–73) **B**
 - People with moderate/severe hypoglycemia and hypoglycemia unawareness (74–77) **C**
 - Pregnancy complicated with T1D (58, 60, 78–81) **C**
 - People with comorbidities: chronic renal failure and gastroparesis (82–84) **C**
- Consider recommending appropriate AID systems to people with other types of diabetes treated with intensive insulin therapy (multiple daily injections or pump therapy):
 - People with type 2 diabetes (60, 61) **C**
 - People after pancreatectomy **E**
 - People with cystic fibrosis–related diabetes (85, 86) **C**
- Use of AID under supervision should be allowed in hospital settings if not contraindicated by clinical status or treatment needs **E**

La terapia del diabete mellito di tipo 1

1.6 In soggetti con diabete mellito di tipo 1 è preferibile l'utilizzo di sistemi ad ansa chiusa costituiti da microinfusore e sensore con automatismo oppure sistemi senza automatismo?

In soggetti con diabete mellito di tipo 1 si raccomanda l'utilizzo di sistemi ad ansa chiusa costituiti da microinfusore e sensore con automatismo rispetto all'uso di sistemi senza automatismo.

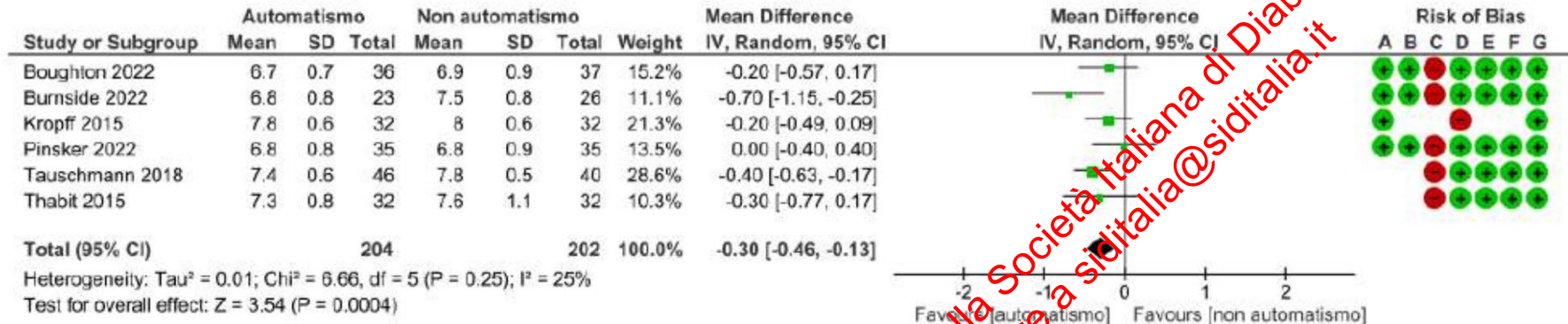
Raccomandazione forte a favore dell'intervento

Motivazione della raccomandazione

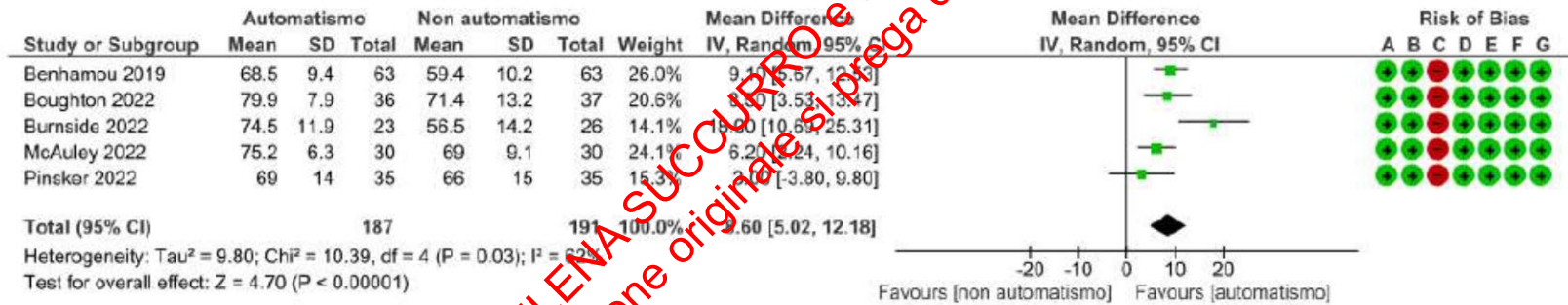
Qualità delle prove: alta.

Diversi trials clinici randomizzati hanno evidenziato vantaggi sui livelli di emoglobina glicata, sul Time In Range e sulla variabilità glicemica quando i soggetti partecipanti utilizzavano sistemi ad ansa chiusa costituiti da microinfusore e sensore con automatismo rispetto all'uso di sistemi senza automatismo. L'utilizzo di sistemi costituiti da microinfusore e sensore con automatismo è risultato essere costo-efficace.

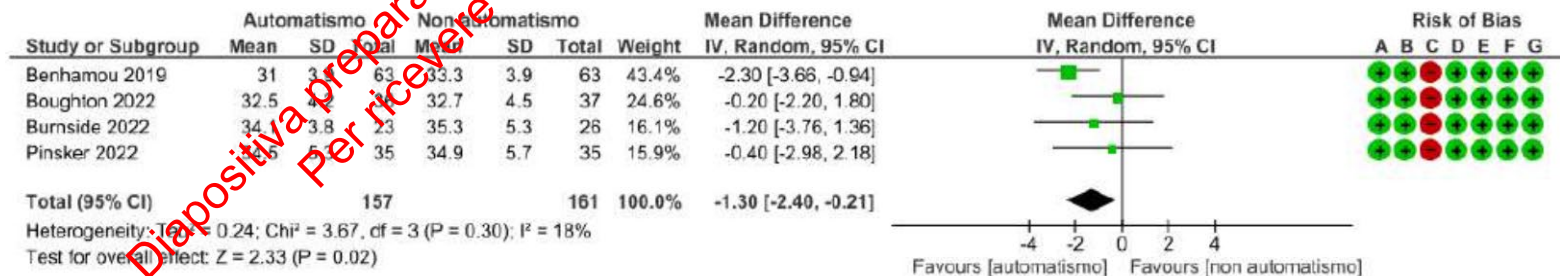
HbA1c



TIR



CV

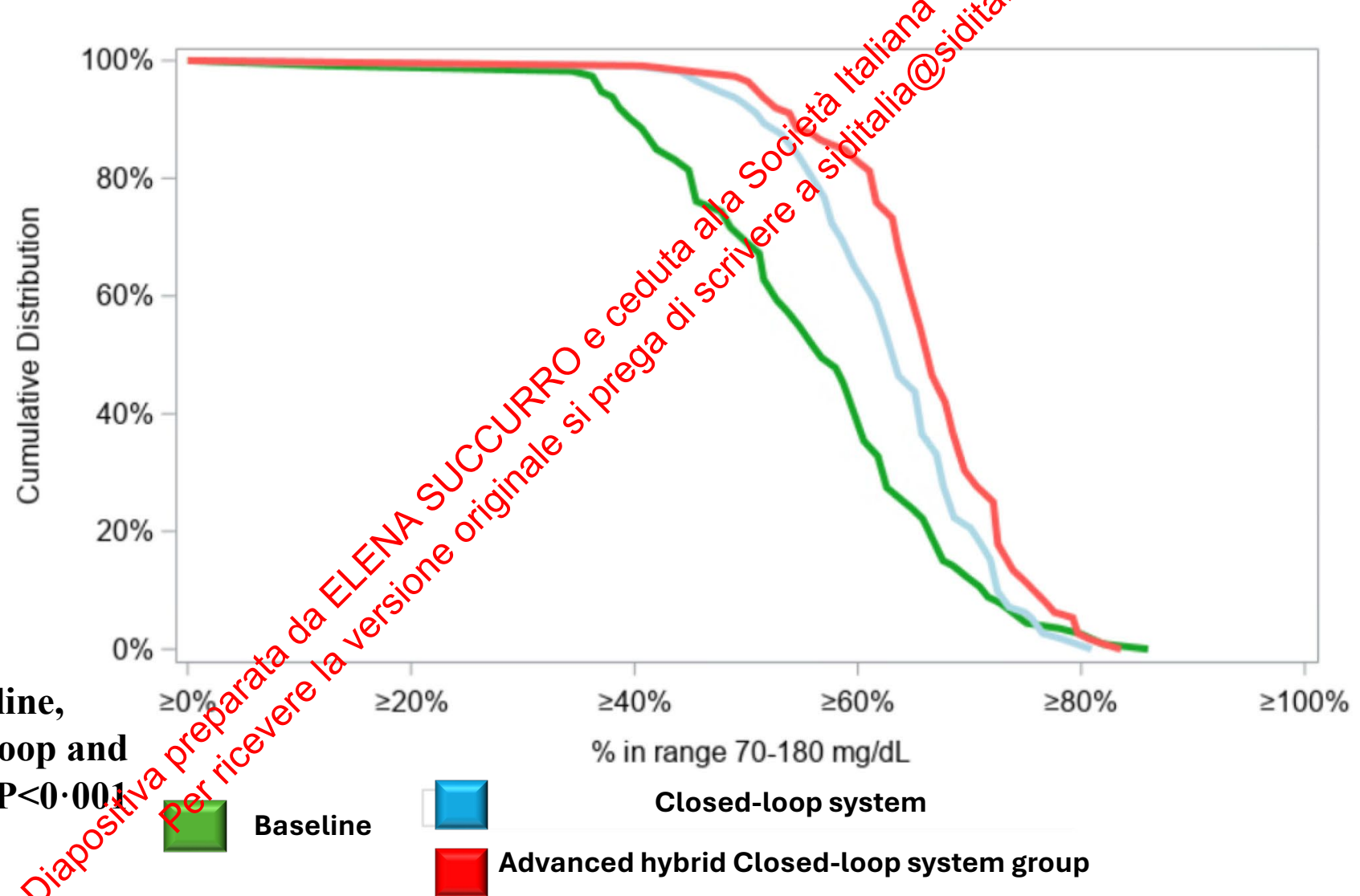


Improved TIR with ACHL than HCL system in young adults with T1D

FLAIR Study
Randomised
Crossover Trial

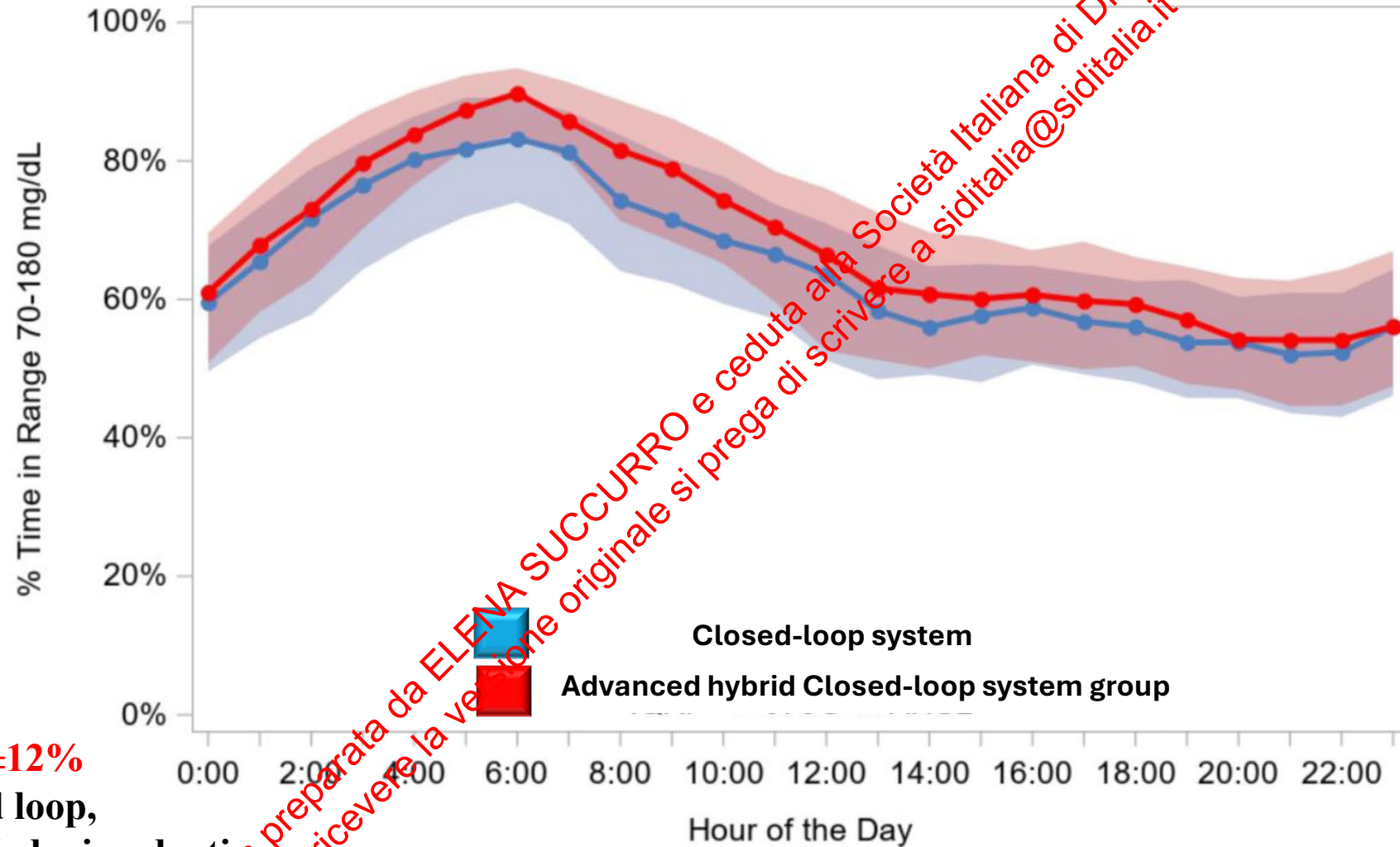
12 week period

TIR $57 \pm 12\%$ at baseline,
 $63 \pm 8\%$ with Closed loop and
 $67 \pm 8\%$ with AHCL $P < 0.001$



Improved TIR with ACHL than HCL system in young adults with T1D

FLAIR Study



TIR at baseline $56 \pm 12\%$
 $61 \pm 9\%$ with Closed loop,
 $64 \pm 9\%$ with AHCL during daytime

TIR $58 \pm 17\%$, $70 \pm 12\%$, and $74 \pm 11\%$, respectively overnight
 $P < 0.001$ comparing Closed loop versus AHCL

Bergenstal RM et al Lancet 2021

Improved glucose control with ACHL than PLGM in T1D

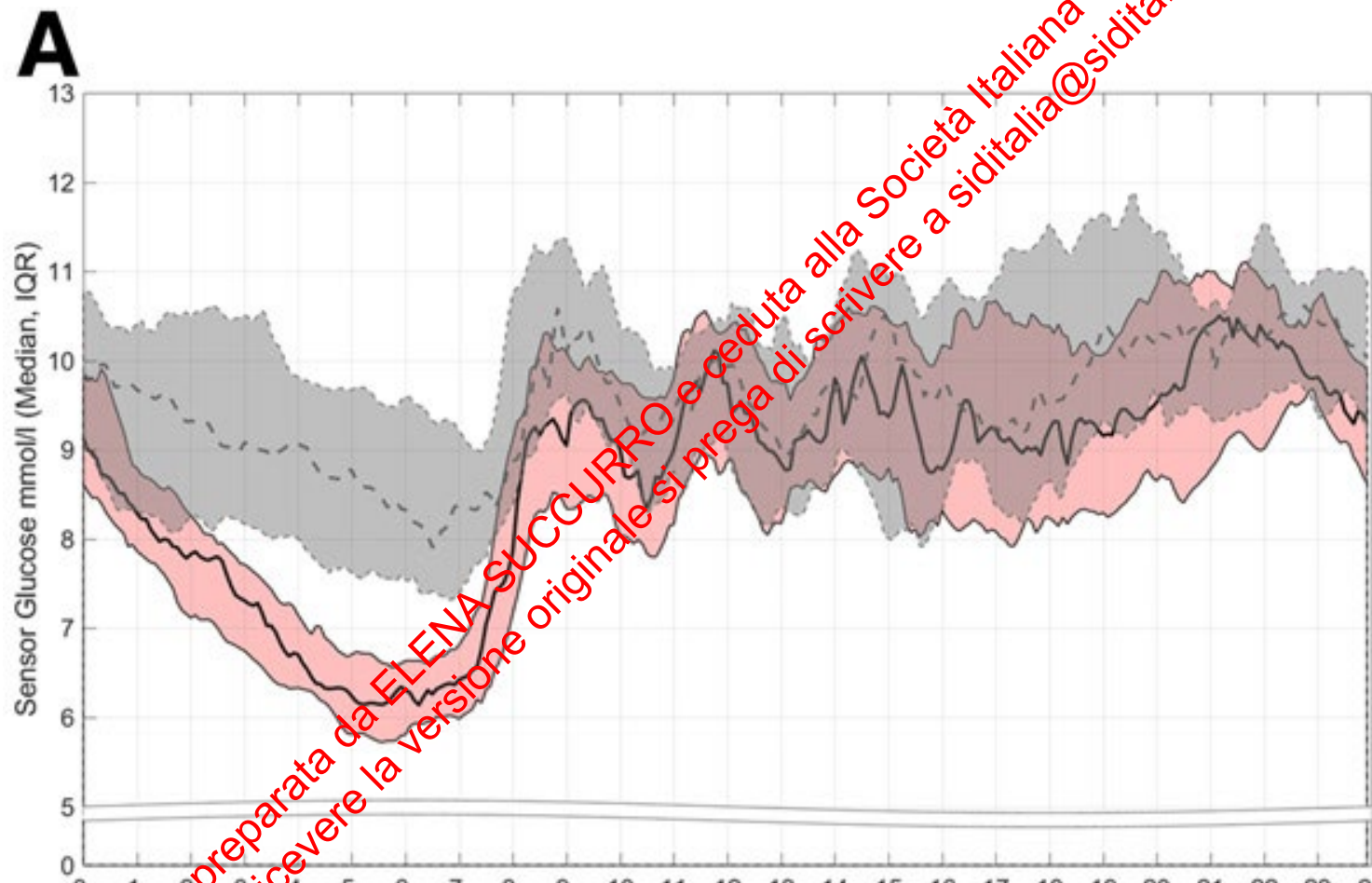
Category*	Run-in	PLGM	AHCL 5.6 mmol/L	AHCL total	Total		Children aged 7–13 years		Adolescents aged 14–21 years		Adults aged 22–80 years	
					% change	P	% change	P	% change	P	% change	P
					AHCL vs. PLGM	value§	AHCL vs. PLGM	value§	AHCL vs. PLGM	value§	AHCL vs. PLGM	value§
Subjects, n	59	59	52	59	59		19		14		26	
Average SG mmol/L overall	9.3 ± 0.9 (9.2)	9.5 ± 1.1 (9.4)	8.3 ± 0.7 (8.1)	8.5 ± 0.7 (8.4)	−0.6 ± 0.4 (−0.6)†	<0.001	−0.5 ± 0.4 (−0.6)†	<0.001	−0.7 ± 0.4 (−0.7)†	<0.001	−0.5 ± 0.5 (−0.5)†	<0.001
% CGM 3.9–10 mmol/L overall	59.0 ± 10.4 (60.8)	57.9 ± 11.7 (58.4)	72.0 ± 7.9 (71.9)	70.4 ± 8.1 (70.8)	12.5 ± 8.5 (11.2)†	<0.001	11.8 ± 7.4 (11.8)†	<0.001	14.4 ± 8.4 (12.3)†	<0.001	11.9 ± 9.5 (10.6)†	<0.001
% CGM 3.9–10 mmol/L day	58.2 ± 11.0 (57.9)	56.5 ± 12.2 (56.4)	68.7 ± 10.0 (69.5)	66.8 ± 9.9 (65.7)	10.4 ± 8.7 (9.0)†	<0.001	7.9 ± 7.1 (8.3)†	<0.001	14.1 ± 8.4 (13.6)†	<0.001	10.1 ± 9.4 (8.5)†	<0.001
% CGM 3.9–10 mmol/L night	61.2 ± 14.7 (63.5)	62.0 ± 15.0 (64.9)	81.9 ± 10.6 (82.3)	80.8 ± 10.4 (81.5)	18.8 ± 11.9 (19.3)†	<0.001	23.6 ± 11.3 (22.6)†	<0.001	15.1 ± 11.5 (11.6)†	<0.001	17.2 ± 14.0 (13.7)†	<0.001
% CGM >10 mmol/L overall	37.9 ± 10.6 (37.7)	39.6 ± 12.1 (39.2)	25.8 ± 8.2 (24.4)	27.5 ± 8.1 (27.7)	−12.1 ± 8.0 (−11.1)†	<0.001	−11.2 ± 8.0 (−12.6)†	<0.001	−14.0 ± 8.5 (−12.5)†	<0.001	−11.8 ± 10.0 (−9.5)†	<0.001
% CGM ≤3.0 mmol/L overall	0.5 ± 0.6 (0.3)	0.5 ± 0.5 (0.3)	0.4 ± 0.4 (0.3)	0.5 ± 0.5 (0.4)	−0.1 ± 0.4 (−0.1)†	0.025	−0.2 ± 0.5 (−0.1)†	0.0676	−0.1 ± 0.3 (−0.0)†	0.2441	−0.0 ± 0.2 (−0.1)†	0.5462
% CGM <3.9 mmol/L overall	3.1 ± 2.1 (2.7)	2.5 ± 1.6 (2.2)	2.2 ± 1.6 (1.9)	2.1 ± 1.4 (1.9)	−0.4 ± 1.3 (−0.4)†	0.0318	−0.7 ± 1.8 (−0.6)†	0.1216	−0.4 ± 1.1 (−0.4)†	0.1804	−0.1 ± 0.9 (−0.2)†	0.5184

*Results presented as mean ± SD (median). †SG % change is expressed as relative % reduction (% − %)/% comparing overall value in AHCL. ‡TIR differences are expressed as absolute difference (% − %). §Analyses using paired t test.

Randomised Crossover Trial in AID-naïve T1D
participants (aged 7–80 years) compared
AHCL to (SAP 1 PLGM)

Improved glucose control with ACHL than PLGM in T1D

Randomised Crossover
Trial in A1D-naive T1D
participants (aged 7–80
years) compared ACHL to
(SAP 1 PLGM)



Diapositiva preparata da ELENA SUCCURRO e ceduta alla Società Italiana di Diabetologia.
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**The effectiveness of the AHCL system
depended on prior experience of CSII or
CGM technologies**

Naïve to technology

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Improved glucose control with Transition from MDI and SMBG to ACHL in T1D adults

Randomized Trial in patients in MDI + SMBG

Baseline characteristics

	Treatment arm (<i>n</i> = 20), Control arm (<i>n</i> = 17),		
	ACHL system	MDI + BGM	<i>P</i>
Sex, F (%)	8 (40.0)	8 (47.1)	0.920
Age (years)	39.8 ± 8.3	40.9 ± 7.8	0.671
Diabetes duration (years)	17.1 ± 12.2	17.6 ± 12.2	0.749
HbA _{1c} (%; mmol/mol)	7.05 ± 0.8; 54 ± 9	7.4 ± 1.2; 57 ± 13	0.349
BMI (kg/m ²)	24.5 ± 3.3	25.6 ± 2.64	0.280
Body weight (kg)	76.3 ± 14.7	77.7 ± 14.4	0.774
eGFR (mL/min)	112 ± 23	119 ± 24	0.341
Thyroid stimulating hormone (μU/mL)	1.51 ± 0.75	1.81 ± 0.73	0.241
AST (units/L)	26.4 ± 7.7	24.9 ± 4.7	0.720
Data are means ± SD or <i>n</i> (%). eGFR, estimated glomerular filtration rate; F, female.			

Improved glucose control with Transition from MDI and SMBG to ACHL in T1D adults

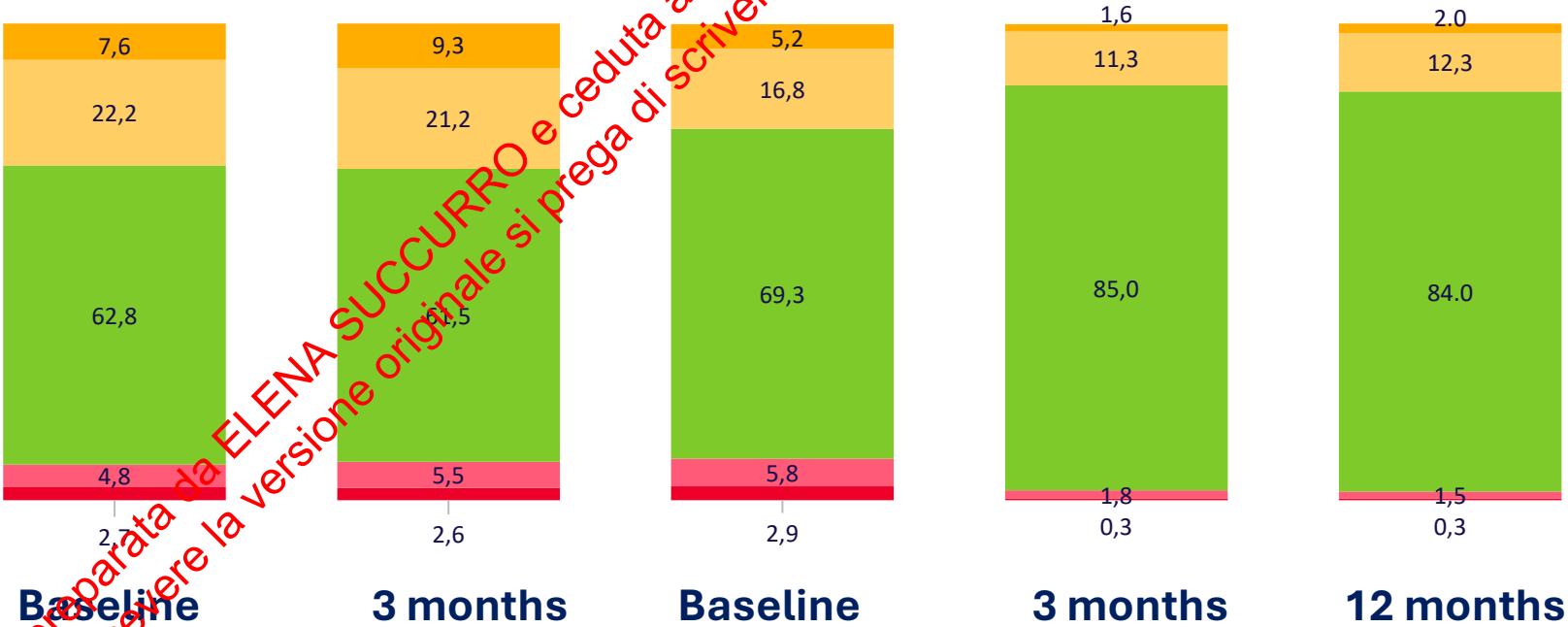
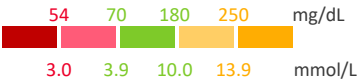
Randomized Trial in patients in MDI + SMBG

MDI + SMBG

ACHL



Time in Ranges, %



4.4%
TBR reduction

Improved glucose control with Transition from MDI and SMBG to ACHL in T1D adults

	Treatment arm (n = 20)		Control arm (n = 17)		Estimated difference	95% CI	P
	Baseline	ACHL system	Baseline	MDI + BGM	ACHL - MDI)†		
HbA _{1c} (%; mmol/mol)	7.05 ± 0.8; 54 ± 9	6.7 ± 0.4; 50 ± 5	7.4 ± 1.2; 57 ± 13	7.4 ± 0.8; 57 ± 9	−0.6	−0.9, −0.2	0.005
SG (mg/dL)	139.9 ± 21.2	133.2 ± 8.9	151.0 ± 23.6	153.1 ± 25.3	−15.4	−26.5, −4.2	0.008
GMI (%)	6.66 ± 0.51	6.50 ± 0.21	6.92 ± 0.55	6.97 ± 0.61	−0.4	−0.6, −0.1	0.008
CV of SG (%)	39.0 ± 7.1	30.6 ± 4.7	39.5 ± 4.7	40.7 ± 6.3	−9.4‡	−12.9, −5.6	<0.001
%SG <54 mg/dL	2.9 ± 3.8	0.3 ± 0.4	2.7 ± 4.9	2.6 ± 3.9	−0.9‡	−1.6, −0.3	0.010
%SG <70 mg/dL	8.7 ± 7.3	2.1 ± 1.7	7.5 ± 7.9	8.1 ± 7.1	−4.4‡	−7.4, −2.1	<0.001
%SG 70–180 mg/dL	69.3 ± 12.3	85.0 ± 6.3	62.8 ± 10.7	61.5 ± 11.2	21.5	15.7, 27.3	<0.001
%SG >180 mg/dL	22.0 ± 12.3	12.9 ± 5.8	29.8 ± 13.4	30.5 ± 14.2	−14.7	−21.4, −8.0	<0.001
%SG >250 mg/dL	5.2 ± 6.4	1.6 ± 1.6	7.6 ± 5.8	9.3 ± 8.3	−4.5‡	−11.0, −2.0	<0.001
Body weight (kg)	76.3 ± 14.7	75.6 ± 16.5	77.7 ± 14.4	77.8 ± 15.3	−2.9‡	−12.5, 8.1	0.637
BMI (kg/m ²)	24.5 ± 3.3	24.3 ± 3.9	25.6 ± 2.6	25.6 ± 2.9	−1.7‡	−3.9, 1.2	0.244

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Improved glucose control with Transition from MDI and SMBG to ACHL in T1D adults

Category	Treatment arm (n = 20)		Control arm (n = 17)		Estimated difference		
	Baseline	AHCL system	Baseline	MDI + BGM	AHCL -MDI	95% CI	P
Daytime (06:01–23:59 h)							
%SG <54 mg/dL	2.2 ± 3.0	0.3 ± 0.4	2.7 ± 4.8	2.3 ± 3.3	−1.8	−2.5, −1.0	<0.001
%SG <70 mg/dL [%]	7.2 ± 5.7	2.3 ± 1.9	7.4 ± 7.9	7.4 ± 6.3	−5.0	−7.0, −3.0	<0.001
%SG 70–180 mg/dL	69.0 ± 12.1	83.3 ± 6.9	62.7 ± 10.3	60.5 ± 11.1	20.5	14.8, 26.3	<0.001
%SG >180 mg/dL	23.8 ± 12.3	14.5 ± 6.5	29.8 ± 12.7	32.1 ± 14.1	−15.3	−22.0, −8.6	<0.001
%SG >250 mg/dL	5.3 ± 5.8	1.8 ± 1.6	7.9 ± 5.6	9.9 ± 8.3	−5.6‡	−10.5, −2.4	<0.001
Nighttime (00:00–06:00 h)							
%SG <54 mg/dL	5.0 ± 7.7	0.2 ± 0.4	2.9 ± 6.3	3.7 ± 5.6	−1.6‡	−2.7, −0.0	0.007
%SG <70 mg/dL	13.0 ± 14.7	1.7 ± 1.8	7.6 ± 8.8	10.5 ± 11.0	−7.0‡	−13.6, −0.3	0.025
%SG 70–180 mg/dL	70.1 ± 19.6	89.8 ± 7.1	63.3 ± 14.5	65.3 ± 16.4	26.2‡	33.5, 16.1	<0.001
%SG >180 mg/dL	17.0 ± 17.4	8.5 ± 7.1	29.1 ± 17.3	24.2 ± 19.2	−14.1‡	−23.9, −3.9	0.009
%SG >250 mg/dL	5.1 ± 10.9	0.8 ± 2.1	6.9 ± 8.1	7.1 ± 9.8	−1.8‡	−4.5, −0.0	0.013



90%
Mean TIR during the night

Improved QoL aspects with Transition from MDI and SMBG to ACHL in T1D adults

	Treatment arm (n = 20)		Control arm (n = 17)		Estimated difference	95% CI	P
	Baseline	AHCL system	Baseline	MDI + BGM			
Overall QoL Score	187.2 ± 32	202.5 ± 54.2	173.87 ± 46.24	173.6 ± 53.34	19.9	−17.7, 57.6	0.287
Feeling well	7.9 ± 3.2	9.8 ± 3.1	6.73 ± 3.31	7.87 ± 3.38	2.3	0.1, 4.6	0.042
Working	7.4 ± 2	10.4 ± 2.9	7.93 ± 4.15	7.33 ± 3.02	2.7	0.7, 4.6	0.010
Eating as I would like	4.9 ± 2.7	7.1 ± 3.8	3.87 ± 1.88	4.07 ± 2.62	3.1	0.8, 5.4	0.0110
Doing “normal” things	7.6 ± 2.9	9.9 ± 3.7	8.33 ± 3.66	8.21 ± 3.85	2.8	0.2, 5.4	0.0343

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Improved glucose control with ACHL than MDI + CGM in T1D

ADAPT
Randomized Trial in patients in MDI
and isCGM
Patients with HbA1c>8%

Primary endpoint between-group
difference in mean change in
HbA1c from baseline to 6
months.

Baseline characteristics

	Multiple daily injections of insulin plus isCGM group (n=41)	Advanced hybrid closed loop group (n=41)
Age, years		
Mean	39.7 (13.12)	41.5 (11.63)
Range	19–69	23–63
Sex		
Male, n (%)	25 (61%)	19 (46%)
Female, n (%)	16 (39%)	22 (54%)
Duration of type 1 diabetes, years	18.1 (9.97)	18.8 (11.42)
Weight, kg	78.4 (14.77)*	79.9 (15.09)
BMI, kg/m ²	25.8 (4.92)*	27.0 (4.37)
HbA _{1c} , %	9.07% (0.72)	9.00% (0.97)
HbA _{1c} , mmol/mol	75.7 (7.83)	74.9 (10.64)
isCGM scans, n per day	9.0 (5.23)*	8.8 (7.37)
Insulin total daily dose, units	53.3 (22.33)	54.3 (25.89)
Values are mean (SD) unless otherwise stated. HbA _{1c} =glycated haemoglobin. isCGM=intermittently scanned continuous glucose monitoring. *Data were missing for two participants.		

Choudhary P, et al. Lancet Diabetes Endocrinol. 2022.

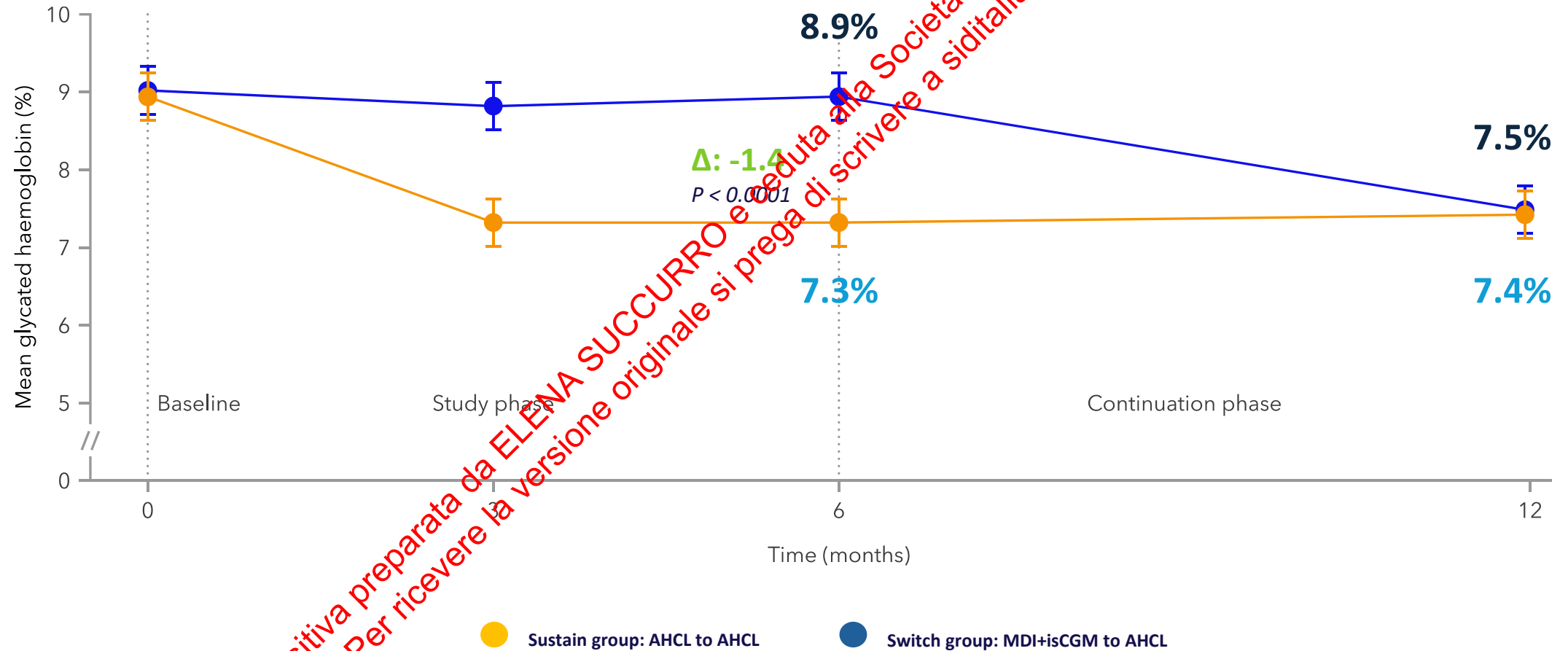
Edd SN, et al. Diabetes Obes Metab. 2023

Improved glucose control with ACHL than MDI + CGM in T1D

ADAPT

Randomized Trial in patients in MDI and isCGM

Patients with HbA1c > 8%



Choudhary P, et al. Lancet Diabetes Endocrinol. 2022.

Edd SN, et al. Diabetes Obes Metab. 2023

Improved glucose control with ACHL than MDI + CGM in T1D

ADAPT

Randomized Trial in patients in MDI and isCGM

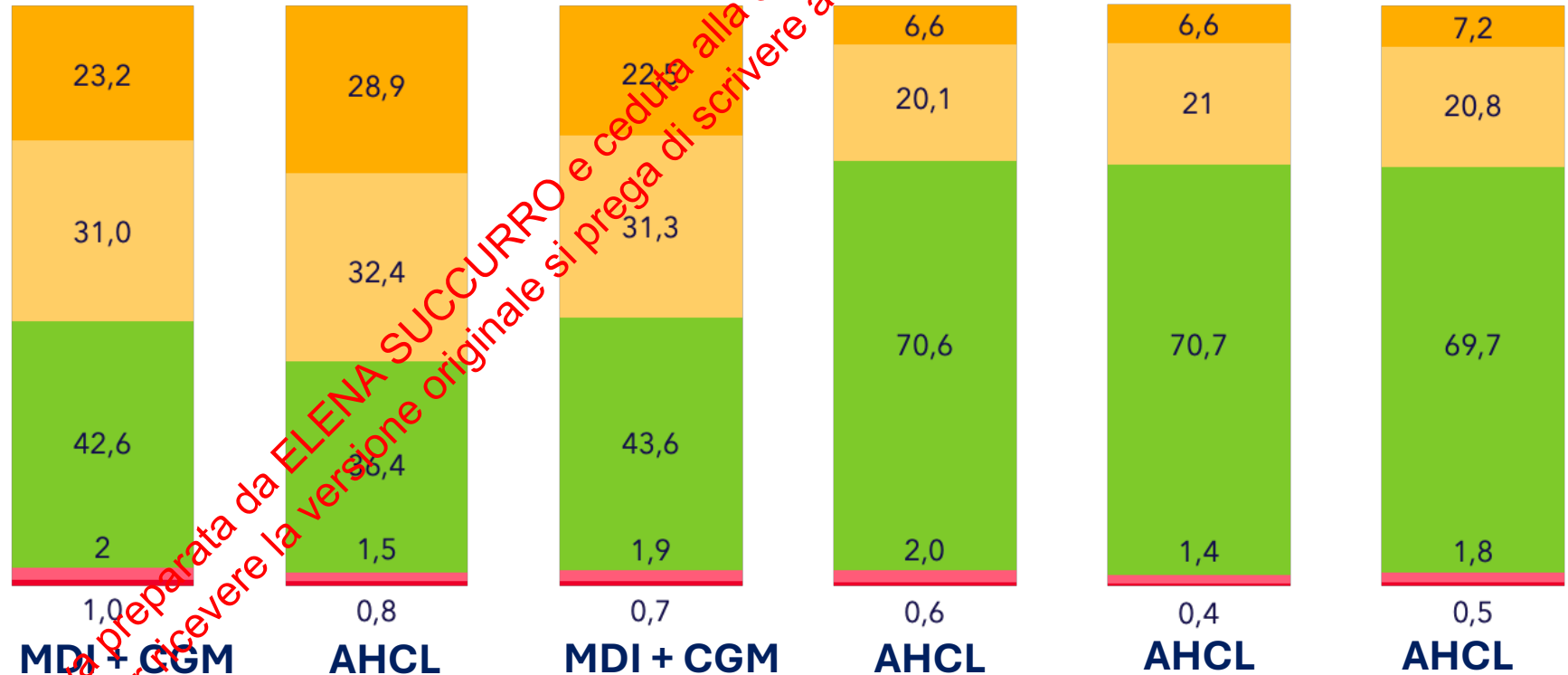
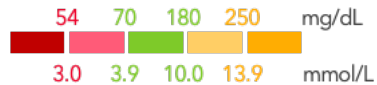
Patients with HbA1c>8%

Baseline

6 months

12 months

Time in Ranges, %



Choudhary P, et al. Lancet Diabetes Endocrinol. 2022.

Edd SN, et al. Diabetes Obes Metab. 2023

Improved Treatment satisfaction with ACHL than MDI + isCGM in T1D

	N	Multiple daily injections of insulin plus isCGM group	N	Advanced hybrid closed loop group	Model-based treatment effect
Change in DTSQs scores from baseline					
Treatment satisfaction score	39	0.2 (6.84)	35	6.1 (7.55)	6.2 (2.9 to 9.4; p=0.0003)
Perceived frequency of hyperglycaemia score	39	-0.3 (1.49)	35	-2.0 (1.69)	-1.8 (-2.5 to -1.0; p<0.0001)
Perceived frequency of hypoglycaemia score	39	0.2 (1.44)	35	-0.4 (1.80)	-0.5 (-1.2 to 0.3; p=0.22)
Change in DTSQc scores from baseline					
Treatment satisfaction score	38	3.7 (7.24)	35	13.7 (4.39)	9.8 (7.04 to 12.64; p<0.0001)
Perceived frequency of hyperglycaemia score	38	0.8 (1.42)	35	-1.1 (1.77)	-2.0 (-2.7 to -1.2; p<0.0001)
Perceived frequency of hypoglycaemia score	38	0.1 (1.27)	35	-0.5 (1.80)	-0.5 (-1.2 to 0.3; p=0.22)
Change in Hypoglycaemia Fear Survey scores from baseline					
Behaviour	39	-0.7 (7.52)	35	-4.8 (8.13)	-3.8 (-7.5 to -0.1; p=0.047)
Worry	39	-2.0 (8.58)	35	-5.4 (10.42)	-3.0 (-7.4 to 1.4; p=0.18)
Total score	39	-2.7 (13.08)	35	-10.2 (15.51)	-6.9 (-13.5 to -0.3; p=0.041)

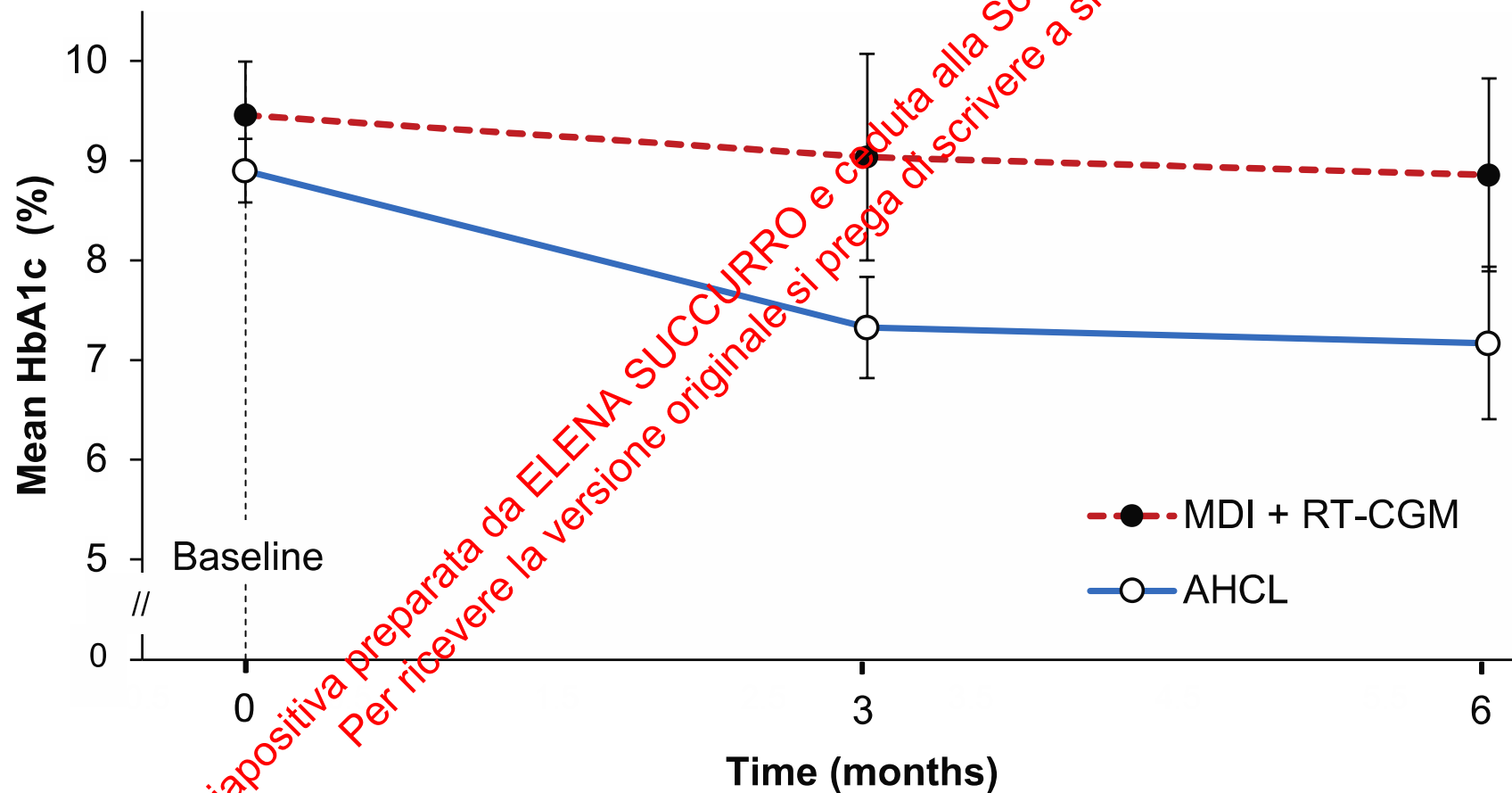
	N	Multiple daily injections of insulin plus isCGM group	N	Advanced hybrid closed loop group	Model-based treatment effect
Change in QoL scores from baseline*					
Treatment satisfaction score	25	-2.7 (13.57)	24	10.3 (16.35)	12.4 (3.9 to 21.0; p=0.0052)
Treatment impact score	24	0.1 (6.69)	24	4.4 (8.05)	4.0 (-0.2 to 8.3; p=0.062)
Social worry score	13	2.3 (10.64)	19	-0.3 (14.78)	-2.1 (-11.2 to 7.0; p=0.64)
Diabetes worry score	16	6.7 (12.99)	19	5.4 (15.41)	-1.7 (-11.3 to 7.8; p=0.72)
Total score	25	1.5 (10.08)	24	5.9 (10.60)	3.8 (-2.1 to 9.7; p=0.20)
General well-being score	24	-1.3 (11.96)	22	6.1 (16.96)	7.2 (-1.4 to 15.8; p=0.10)

Improved glucose control with ACHL than MDI + CGM in T1D

Substudy from ADAPT

Randomized Trial in patients in MDI and RT-CGM

Patients with HbA1c > 8%



Improved glucose control with ACHL than MDI + CGM in T1D

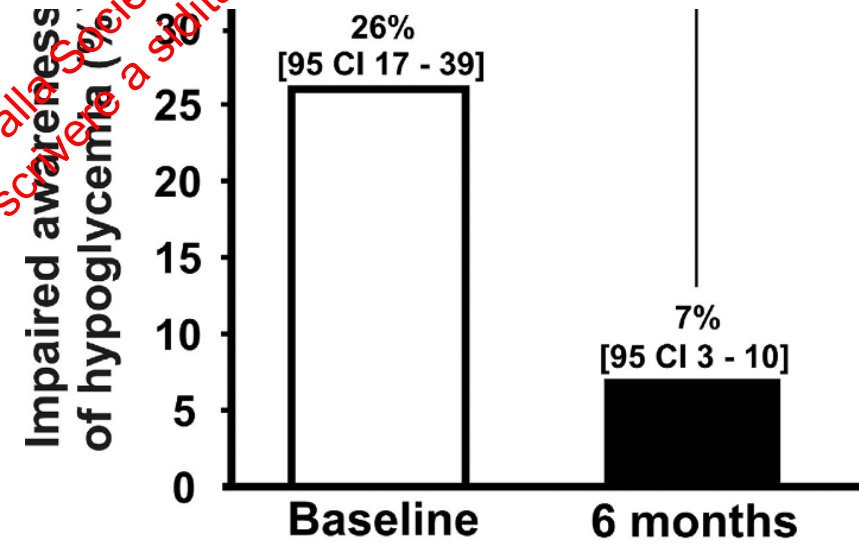
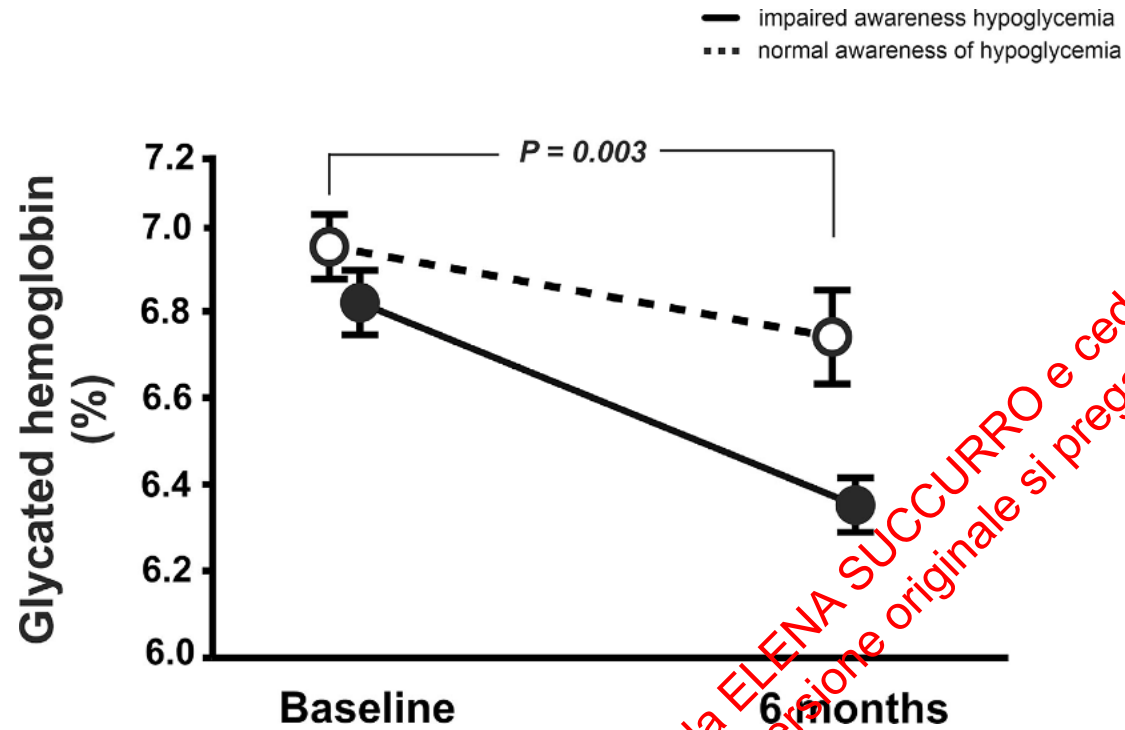
ADAPT Trial

	MDI+RT-CGM group				AHCL group				Model-based treatment effect
	Run-in		Study		Run-in		Study		
	N	Value	N	Value	N	Value	N	Value	
HbA1c, %	5	9.46 ± 0.6	5	8.9 ± 1.1	8	8.9 ± 0.5	7	7.2 ± 1.0	—
Change in HbA1c from baseline, percentage points	-	-	5	-0.6 ± 1.3	-	-	7	-1.7 ± 1.0	-1.1 (-2.2 to 0.0; P = .0508)
TIR, %									
>250 mg/dL (13.9 mmol/L) ^a	4	20.7 ± 6.1	5	21.6 ± 9.3	7	22.8 ± 14.7	8	6.3 ± 5.2	-16.0 (-26.0 to -6.2; P = .0051)
>180 mg/dL (>10.0 mmol/L) ^a	4	53.9 ± 9.9	5	50.9 ± 15.6	7	55.2 ± 15.8	8	24.0 ± 13.5	-28.5 (-45.3 to -11.6; P = .0043)
70-180 mg/dL (3.9-10.0 mmol/L) ^a	4	43.9 ± 9.6	5	46.4 ± 12.5	7	42.1 ± 15.3	8	73.6 ± 13.7	28.8 (12.3-45.3; P = .0035)
<70 mg/dL (3.9 mmol/L) ^b	4	2.2 ± 2.5	5	2.7 ± 3.1	7	2.7 ± 3.0	8	2.4 ± 2.0	-0.6 (-2.6 to 1.4; noninferiority met)
<54 mg/dL (3.0 mmol/L) ^c	4	0.3 ± 0.4	5	1.0 ± 1.6	7	0.9 ± 1.4	8	0.5 ± 0.7	-0.7 (-2.0 to 0.6; non-inferiority met)
Mean of SG, mg/dL	4	191.8 ± 14.6	5	191.1 ± 26.4	7	194.6 ± 25.8	8	147.3 ± 20.8	-46.9 (-73.8 to -20.0; P = .0034)
Standard deviation of SG, mg/dL	4	70.1 ± 5.3	5	68.9 ± 7.4	7	67.2 ± 8.2	8	52.6 ± 12.7	-16.2 (-31.1 to -1.2; P = .0372)
Users achieving HbA1c <7.0%, % (n/N) ^d	5	0.0 (0/5)	5	0.0 (0/5)	8	0.0 (0/8)	7	42.9 (3/7)	0.0 (0.0 to 3.18; P = .2045)
Users achieving GMI <7.0%, % (n/N) ^d	4	0.0 (0/4)	5	20.0 (1/5)	7	0.0 (0/7)	8	62.5 (5/8)	0.18 (0.0 to 3.0; P = .2657)
Users achieving TIR >70%, % (n/N) ^d	4	0.0 (0/4)	5	0.0 (0/5)	7	0.0 (0/7)	8	62.5 (5/8)	0.0 (0.0 to 1.31; P = .0754)
Users achieving TBR <4%, % (n/N) ^d	4	75.0 (3/4)	5	80.0 (4/5)	7	71.4 (5/7)	8	75.0 (6/8)	1.3 (0.0 to 98.0; P = .9999)

Switching to AHCL system improves hypoglycemia awareness and metabolic control in adults with T1D

Variable	Baseline (T0)		After 2 months (T2)		After 6 months (T6)		P
	IAH (n = 12)	Normal AH (n = 34)	IAH (n = 12)	Normal AH (n = 34)	IAH (n = 12)	Normal AH (n = 34)	
Continuous glucose monitoring metrics							
TBR < 54 mg/dL	0.3 ± 0.8	0.4 ± 0.9	0.2 ± 0.4	0.5 ± 1.1	0.3 ± 0.5	0.4 ± 0.7	NS
TBR < 70 mg/dL ^{a,b}	7 ± 10	6 ± 6	2 ± 2	3 ± 2	2 ± 1	3 ± 2	0.027
Total TBR < 70 mg/dL ^{a,b}	7 ± 10	6 ± 6	2 ± 2	4 ± 3	2 ± 2	3 ± 3	0.018
TIR 70 and 180 mg/dL ^{a,b}	70 ± 14	68 ± 15	86 ± 7	82 ± 14	85 ± 7	80 ± 7	<0.001
TAR > 180 mg/dL ^{a,b}	24 ± 15	24 ± 15	11 ± 5	18 ± 6	11 ± 6	15 ± 6	<0.001
TAR > 250 mg/dL	3 ± 4	2 ± 3	1 ± 2	3 ± 3	1 ± 2	2 ± 2	NS
Total TAR > 180 mg/dL ^{a,b}	27 ± 18	26 ± 14	12 ± 6	16 ± 8	12 ± 7	17 ± 7	<0.001
Other outcomes							
Mean sensor usage (%)	92 ± 7	84 ± 9	90 ± 11	87 ± 9	90 ± 6	81 ± 19	NS
GMI (%) ^{a,b}	6.7 ± 0.3	6.9 ± 0.5	6.5 ± 0.3	6.6 ± 0.3	6.4 ± 0.3	6.6 ± 0.3	0.003
Mean sensor glucose (mg/dL) ^{a,b}	147 ± 19	146 ± 18	132 ± 11	135 ± 12	130 ± 11	137 ± 12	0.001
CV of sensor glucose (%) ^{a,b}	38 ± 10	39 ± 11	30 ± 5	33 ± 5	30 ± 4	32 ± 4	0.007
SD of sensor glucose (mg/dL) ^{a,b}	47 ± 9	53 ± 13	40 ± 8	45 ± 9	39 ± 8	45 ± 8	0.001
Time in closed loop system (%)	–	–	91 ± 17	90 ± 13	97 ± 3	85 ± 25	NS
Daily carbohydrate amount (gr/d) ^d	–	–	108 ± 53	126 ± 37	152 ± 70	124 ± 43	0.007
Biochemical variables							
Fasting plasma glucose (mg/dL)	153 ± 53	124 ± 35	–	–	122 ± 44	132 ± 41	NS
eGFR (mL/min/1.73 m ²) ^b	80 ± 10	93 ± 14	–	–	91 ± 16	100 ± 22	0.011
UACR (mg/g)	9 ± 5	14 ± 18	–	–	8 ± 3	10 ± 11	NS
A _{1c} (%) ^{b,d}	6.9 ± 0.5	6.9 ± 0.5	–	–	6.4 ± 0.4	6.8 ± 0.6	0.003
Daily insulin dose and BMI							
Total daily insulin dose (U/Kg) ^c	0.52 ± 0.12	0.58 ± 0.16	0.53 ± 0.15	0.57 ± 0.17	0.60 ± 0.17	0.60 ± 0.19	0.028
Basal daily insulin (U/kg)*	0.25 ± 0.75	0.25 ± 0.89	0.21 ± 0.85	0.25 ± 0.92	0.23 ± 0.95	0.26 ± 0.95	NS
Bolus daily insulin (U/kg) ^b	0.27 ± 0.73	0.31 ± 0.10	0.31 ± 0.78	0.33 ± 0.99	0.37 ± 0.10	0.34 ± 0.12	0.002
Automatic correction bolus (U/kg) ^c	–	–	0.06 ± 0.04	0.07 ± 0.03	0.08 ± 0.05	0.09 ± 0.05	0.005
Mean BMI (kg/m ²)	27.1 ± 4.5	24.3 ± 3.5	27.2 ± 4.5	24.3 ± 3.5	27.6 ± 4.6	25.3 ± 4.1	NS

Switching to AHCL system improves hypoglycemia awareness and metabolic control in adults with T1D



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Higher levels of stress in adults with T1D than general population

Questionnaire	General healthy population		Studied population of patients with T1DM ^a at baseline (N=37)		<i>P</i> value ^b
	People, n (%)	Mean (SD)	Patients, n (%)	Mean (SD)	
CISS^c					
Task-oriented score	151 (100)	56.95 (8.65)	34 (92) ^d	58.09 (10.33)	.581
Emotion-oriented score ^a	151 (100)	45.16 (9.94)	34 (92) ^d	36.94 (10.65)	<.001
Avoidance-oriented score	151 (100)	43.54 (8.64)	34 (92) ^d	40.78 (9.05)	.105
Distraction score ^a	151 (100)	19.11 (5.51)	34 (92) ^d	16.34 (4.40)	.002
Social diversion score	151 (100)	16.42 (3.62)	34 (92) ^d	16.44 (4.09)	.979
Brief-COPE^e					
Active coping ^a	590 (100)	1.57 (0.79)	37 (100)	2.22 (0.69)	.003
Planning ^a	590 (100)	1.89 (0.79)	37 (100)	2.30 (0.69)	.005
Positive reframing ^a	590 (100)	1.67 (0.77)	37 (100)	1.89 (0.54)	.020
Acceptance ^a	590 (100)	1.78 (0.77)	37 (100)	2.11 (0.63)	.002
Humor ^a	590 (100)	0.82 (0.78)	37 (100)	1.16 (0.67)	.003
Religion	590 (100)	0.85 (0.85)	37 (100)	0.87 (0.95)	.900
Use of emotional support	590 (100)	1.66 (0.91)	37 (100)	1.93 (0.78)	.043
Use of instrumental support	590 (100)	1.56 (0.93)	37 (100)	1.83 (0.8)	.049
Self-distraction	590 (100)	1.37 (0.84)	37 (100)	1.33 (0.61)	.925

Switching to AHCL system from MDI improves Psychological Parameters and Qol in adults with T1D

Category	Treatment arm		Control arm		Estimated difference (AHCL ^a – MDI ^b) ^c	95% CI	P value
	Baseline	MiniMed 780G AHCL	Baseline	MDI+SMBG ^d			
CISS^e	Coping Inventory for Stressful Situations (CISS)						
Task-oriented score	60.67 (7.59)	58.44 (11.24)	53.75 (13.53)	54.75 (13.59)	4.0 ^f	–10.6 to 2.0	.213
Task-oriented sten	6.44 (1.76)	6.11 (2.00)	5.33 (2.32)	5.53 (1.88)	1.0 ^f	–10.0 to 2.0	.237
Emotion-oriented score	37.33 (9.47)	32.78 (7.04)	36.5 (11.51)	37.12 (13.17)	–4.9	–10.4 to 0.6	.077
Emotion-oriented sten ^g	4.06 (1.83)	3.17 (1.29)	3.88 (2.09)	4.19 (2.59)	–1.1	–2.2 to 0.0	.043
Avoidance-oriented score	37.33 (9.47)	39.56 (5.96)	40.88 (10.89)	36.75 (10.02)	2.8	–2.1 to 7.8	.249
Avoidance-oriented sten	4.83 (1.92)	4.50 (1.34)	5.13 (2.26)	4.40 (1.84)	0.2	–0.7 to 1.2	.602
Distraction score	15.94 (4.17)	15.61 (4.65)	16.94 (4.80)	15.00 (4.65)	0.9	–1.8 to 3.7	.506
Distraction sten	4.28 (1.41)	4.28 (1.07)	4.75 (1.84)	4.00 (1.67)	0.4	–0.6 to 1.3	.468
Social diversion score	17.00 (3.30)	16.50 (3.70)	15.80 (4.90)	14.80 (4.50)	2.0 ^f	–1 to 4.0	.243
Social diversion sten	5.70 (1.50)	5.60 (1.60)	5.10 (2.30)	4.80 (2.10)	0.5	–0.7 to 1.6	.408
–Self-blame ^h	1.09 (0.88)	0.81 (0.68)	0.83 (0.67)	1.13 (0.85)	–0.5	–0.9 to –0.09	.020
STAIⁱ	State-Trait Anxiety Inventory (STAI):						
STAI X1 score ^g	38.00 (9.30)	34.50 (7.80)	35.00 (8.80)	38.70 (12.90)	–6.8	–11.8 to –1.8	.009
STAI X1 sten ^g	5.20 (2.20)	4.60 (2.00)	4.50 (2.30)	5.30 (3.00)	–1.4	–2.5 to –0.3	.013
STAI X2 score ^g	41.00 (8.50)	37.60 (8.40)	37.90 (9.50)	38.30 (9.70)	–3.5	–6.5 to –0.5	.022
STAI X2 sten	5.00 (2.50)	4.30 (2.70)	4.10 (2.30)	4.50 (2.20)	<0.001 ^f	–1 to 2.0	.589

Switching to AHCL system from MDI improves Psychological Parameters and QoL in adults with T1D

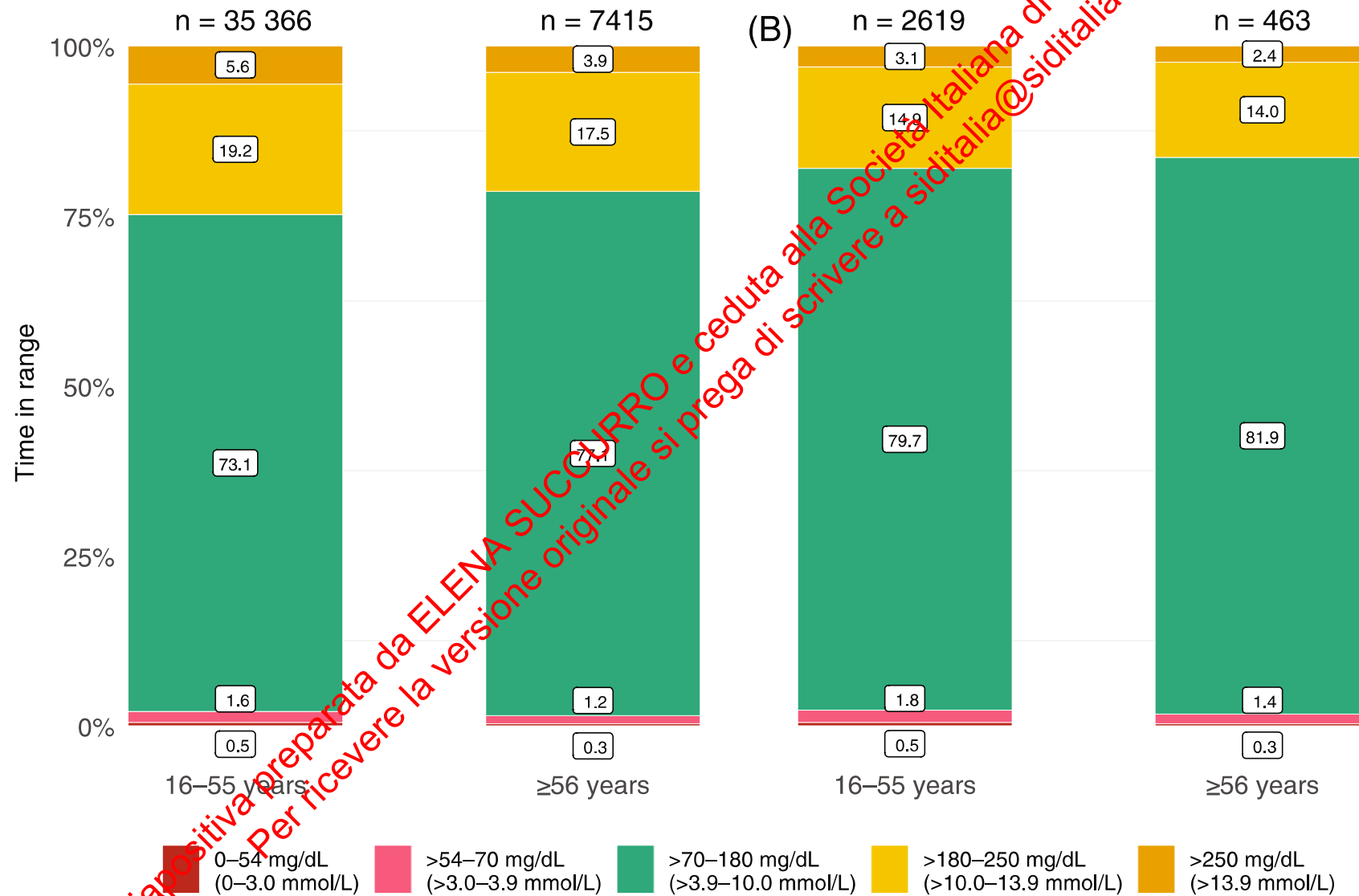
QoL-Q Diabetes^p

Global QoL ^q score	187.20 (32.00)	202.50 (54.20)	173.87 (46.24)	173.60 (53.34)	19.9	17.7 to 57.6	.287
QoL family relation- ships/friendships	9.90 (3.40)	10.00 (3.50)	8.27 (3.13)	10.20 (3.49)	<−0.001 ^f	−1.99 to 2.0	.604
QoL going out or social- izing	8.20 (2.70)	8.00 (2.80)	8.07 (3.43)	9.33 (2.97)	−1.02	−3.1 to 1.0	.311
QoL partner/spouse re- lationship	9.80 (3.00)	9.70 (4.00)	9.53 (3.34)	9.73 (4.10)	−0.1	−3.0 to 2.8	.943
QoL enjoying sexual activity	8.40 (2.30)	8.80 (3.10)	8.71 (2.43)	9.21 (3.21)	−0.32	−2.9 to 2.3	.797
QoL being physically active	80 (2.10)	8.80 (2.80)	7.47 (3.14)	8.36 (3.06)	0.71	−1.7 to 3.1	.544
QoL feeling well ^g	7.90 (3.20)	9.80 (3.10)	6.73 (3.31)	7.87 (3.38)	2.3	0.1 to 4.6	.042
QoL feeling in control of my body	7.90 (2.50)	8.70 (3.40)	7.50 (2.44)	8.93 (3.59)	<−0.001 ^f	−2.0 to 2.0	.801
QoL looking good	7.20 (2.20)	7.70 (2.50)	7.79 (2.78)	8.20 (3.38)	0.3	−1.6 to 2.3	.718
QoL having holidays	8.90 (3.50)	9.30 (3.40)	8.93 (3.01)	7.53 (2.59)	1.3	−0.9 to 3.5	.234
QoL working ^g	7.40 (2.00)	10.40 (2.90)	7.93 (4.15)	7.33 (3.02)	2.7	0.7 to 4.6	.010
QoL eating as I would like ^g	4.90 (2.70)	7.1 (3.3)	3.87 (1.88)	4.07 (2.62)	3.1	0.8 to 5.4	.011
QoL looking after or being useful to others	8.90 (2.20)	8.7 (1.9)	7.33 (2.47)	7.31 (3.30)	2.0 ^f	−4.5 to 4.0	.081
QoL pets/animals	5.70 (2.00)	8.80 (3.70)	7.09 (2.88)	6.44 (2.35)	2.1	−0.1 to 4.4	.065
QoL being independent	9.00 (3.20)	11.10 (3.10)	9.80 (2.93)	9.62 (3.73)	1.5	−0.7 to 3.8	.178
QoL being in control of my life	9.20 (3.20)	10.60 (3.50)	9.20 (3.21)	8.57 (4.26)	1.7	−1.0 to 4.5	.208
QoL being spontaneous	6.50 (2.70)	6.50 (2.70)	6.67 (3.62)	6.67 (3.62)	1 ^f	−2.0 to 4.0	.430
QoL doing a “normal”	7.60 (2.90)	9.90 (3.70)	8.33 (3.66)	8.21 (3.85)	2.8	0.2 to 5.4	.034

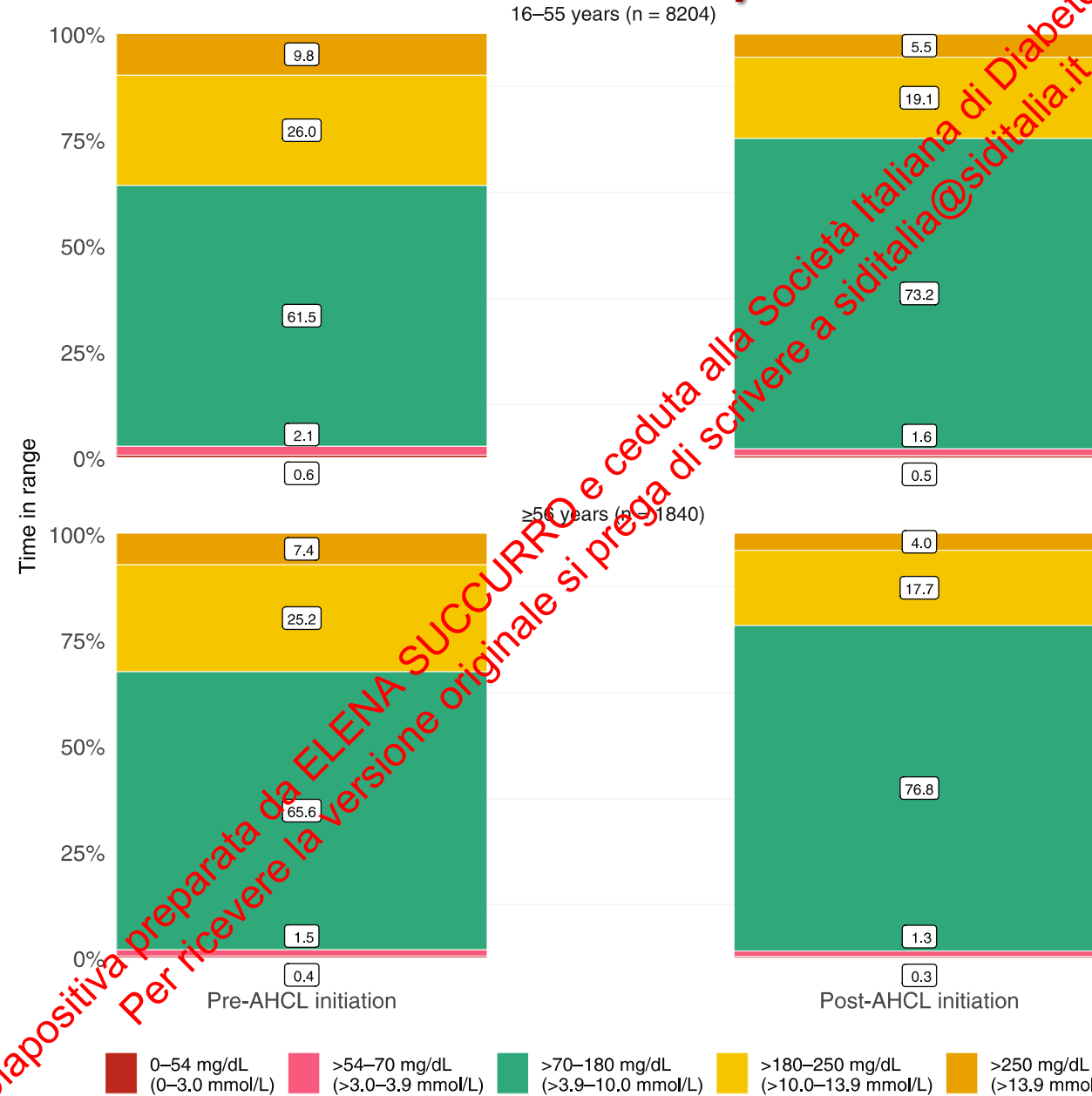
Switching to AHCL system from MDI improves Psychological Parameters and QoL in adults with T1D

Category	Beginning of the study		End of the study (12 months)		Cohen's d effect size	Absolute difference in mean scores	P value
	M	SD	M	SD			
STAI: State-Trait Anxiety Inventory.							
STAI X1 score	37.5	8.48	33.06	10.25	0.46	4.44	.08
STAI X1 sten	5.12	1.93	3.88	2.53	0.56		.04
STAI X2 score	40.44	8.87	36.56	10.27	0.60	3.88	.02
STAI X2 sten	4.83	2.62	3.83	2.87	0.60		.02
GSES: Generalized Self-Efficacy Scale							
GSES score	30.4	2.17	31.8	3.16	0.45	1.4	.03
GSES sten	6.9	0.88	7.1	0.99	0.32		.42
QoL-Q Diabetes							
Global QoL score	185.41	32.03	209.94	39.73	0.61	24.53	.02
QoL family relationships/friendships	9.65	3.24	10.94	2.3	0.35	1.29	.17
QoL going out or socializing	8.5	2.54	10.06	2.08	0.50	1.56	.65
QoL partner/spouse relationship	9.82	3.11	10.76	3.31	0.32	0.94	.20
QoL enjoying sexual activity	8.25	2.38	9.81	3.58	0.46	1.56	.08
QoL being physically active	7.88	2.15	11.06	3.63	0.71	3.72	.02
QoL feeling well ^g	7.1	3.14	10.94	2.95	0.73	2.93	<.01
QoL feeling in control of my body	7.71	2.39	9.88	3	0.72	2.17	<.01
QoL looking good	7.29	2.2	9.47	2.72	1.07	2.18	<.01
QoL having holidays	9.12	3.52	9.94	3.56	0.23	0.82	.36
QoL working ^g	7.29	1.99	9.76	2.56	1.12	2.47	<.01

Glycemic target in older and adults AHCL system users with T1D

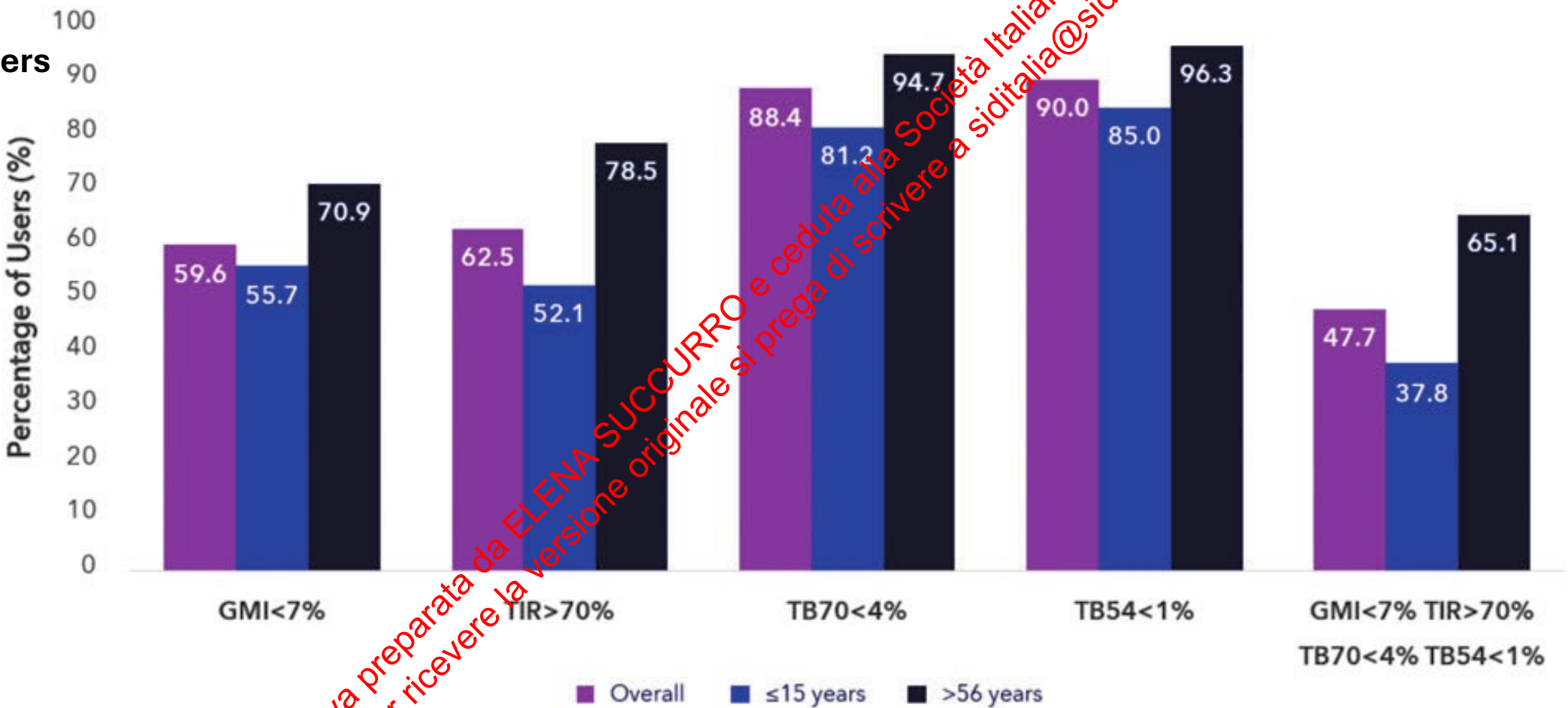


Improved TIR in older and adults AHCL system users with T1D

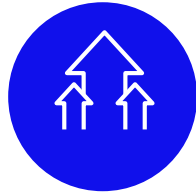


Percentage of real-world AHCL system users that reach international targets

101.629 users



Long-term cost-effectiveness of AHCL system



HbA1c reduction compared to MDI + isCGM



Better health outcomes

~3years

time complications-free



Potential cost savings

~32,000 €

2.27 QALYs

more gained vs MDI+isCGM

Compared with MDI + isCGM in people with T1D with suboptimal glycaemic control

Model: IQVIA Core Diabetes Model

Time horizon: 40 years

Clinical data source: ADAPT study2

Ozdemir Saltik AZ et al 2023; Choudhary P, et al. Lancet Diabetes Endocrinol. 2022; Choudhary P. et al. Diabet Med. 2019

Short-term economic benefits of AHCL system



Potential annual cost savings per patient
in Europe, over 5 years of therapy

~490 €

Saved on average in
avoided complications costs

~710 €

Saved on average in
avoided complications costs
& reduced absenteeism

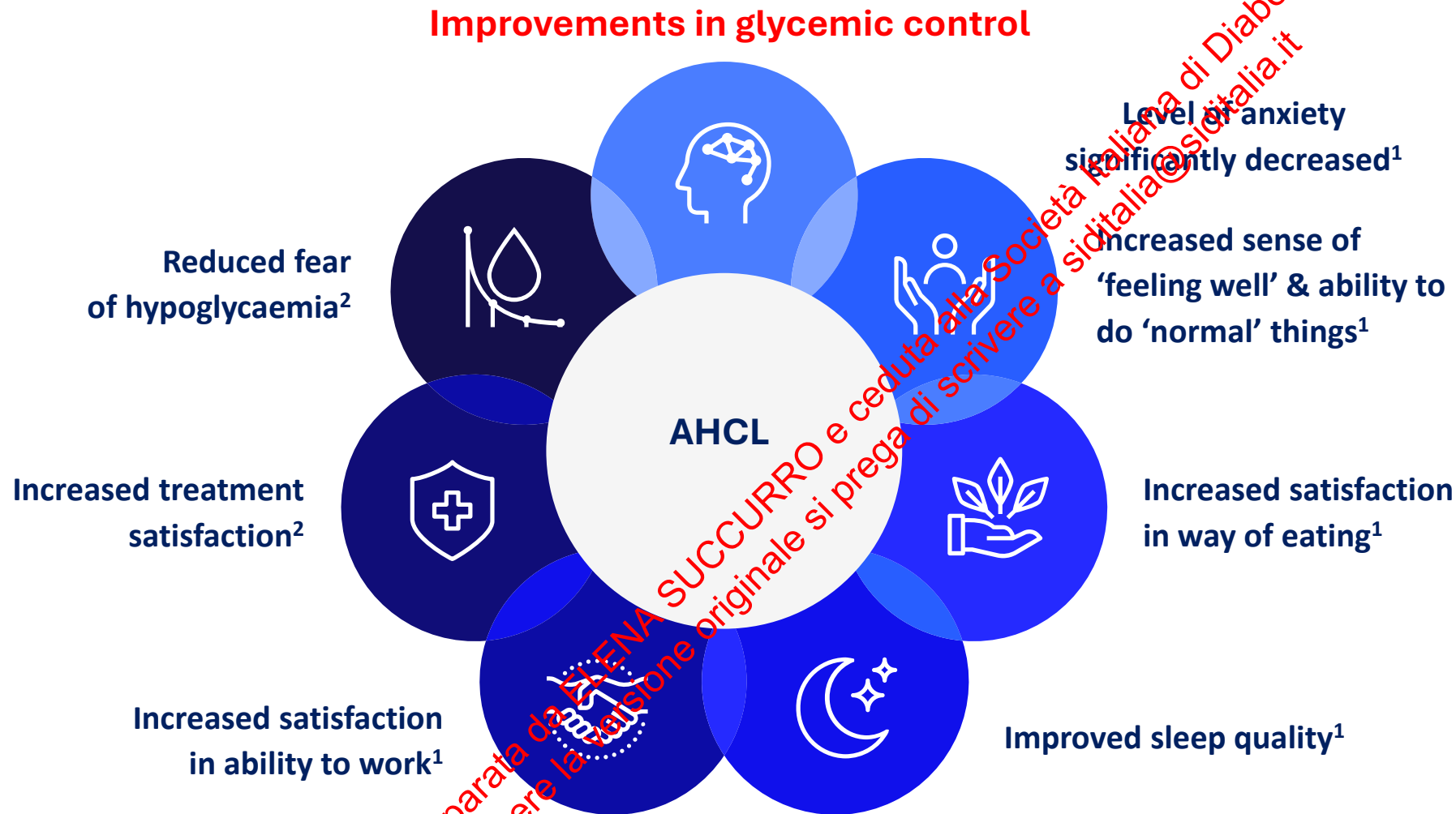
Compared with MDI + isCGM in people with T1D with
suboptimal glycaemic control

Ozdemir Saltik AZ et al 2023; Choudhary P, et al. Lancet
Diabetes Endocrinol. 2022; Choudhary P. et al. Diabet Med. 2019

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Table 7. Summary of recommendations: 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.



Given the associated improvements in glycemic control and quality of life measures, clinicians should strongly consider use of AID systems in PwD who would benefit from this technological option



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