Dall'automonitoraggio ai sensori: le nuove metriche glicemiche nel monitoraggio in continuo della glicemia

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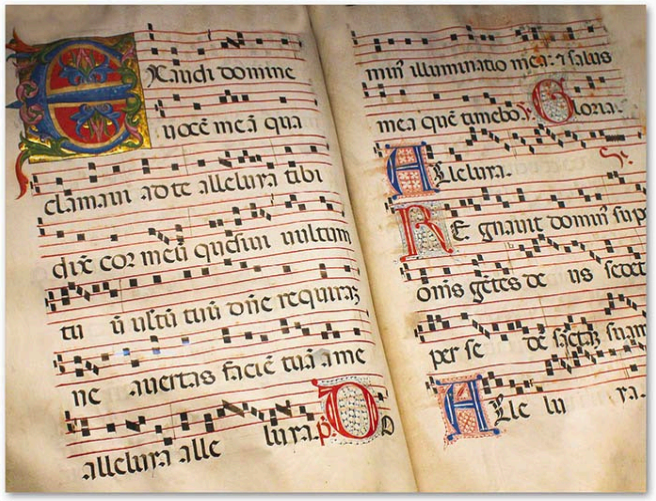
Disclosure

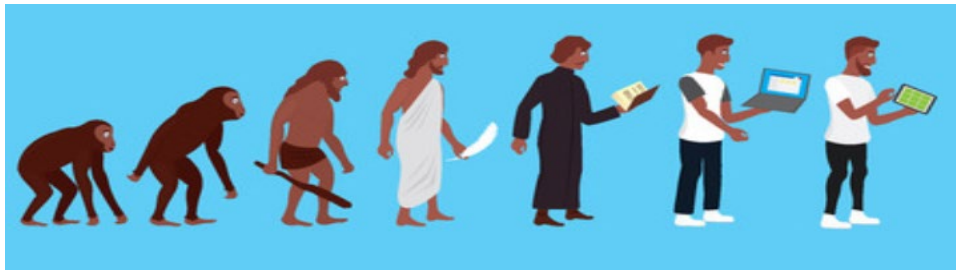
Dichiaro di aver avuto i seguenti rapporti anche di finanziamento con soggetti portatori di interessi commerciali in campo sanitario:

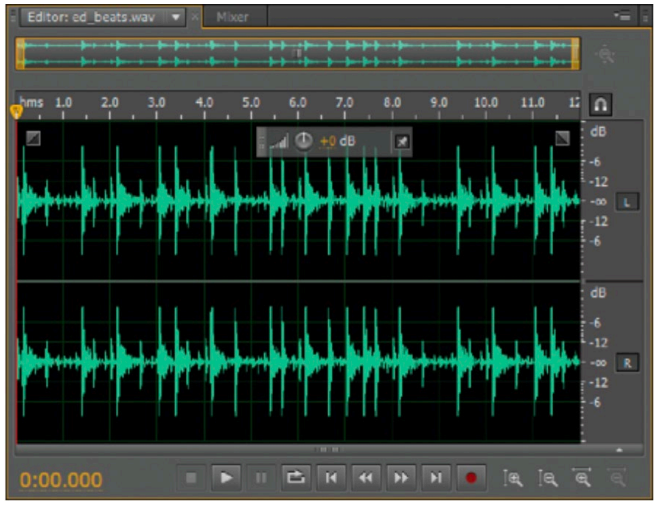
- Novo Nordisk
- Astrazeneca
- Menarini
- Boeringher
- Guidotti

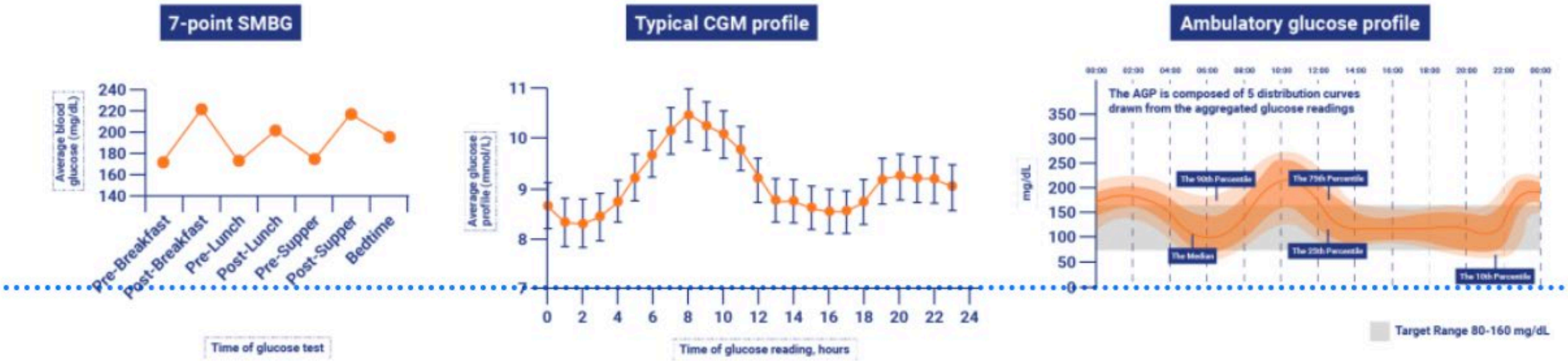
Dichiaro altresì il mio impegno ad astenermi, nell'ambito dell'evento, dal nominare, in qualsivoglia modo o forma,
aziende farmaceutiche e/o denominazione commerciale e di non fare pubblicità di qualsiasi tipo relativamente a
specifici prodotti di interesse sanitario (farmaci, strumenti, dispositivi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

Evoluzione delle metriche









Interpretare i dati raccolti e agire in modo appropriato: Obiettivi per le metriche FGM/CGM

International Consensus on Use of Continuous Glucose Monitoring

Diabetes Care 2017;40:1631–1640 | https://doi.org/10.2337/dc17-1600

Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range

https://doi.org/10.2337/dci19-0028

- Le 10 metriche più utili nella pratica clinica
- I target TIR, TAR, TBR per le diverse popolazioni (T1D, T2D, anziani/ad alto rischio, gravidanza)
- un rapporto standardizzato che includa le metriche e gli obiettivi TIR chiave e un profilo del glucosio ambulatoriale di 14 giorni (AGP), e sia parte integrante del processo decisionale clinico

Interpretare i dati e agire in modo appropriato: Obiettivi per le metriche FGM/CGM

International Consensus on Use of Continuous Glucose Monitoring

Diabetes Care 2017;40:1631–1640 | https://doi.org/10.2337/dc17-1600

Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range

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Table 2—Standardized CGM metrics for clinical care: 2019

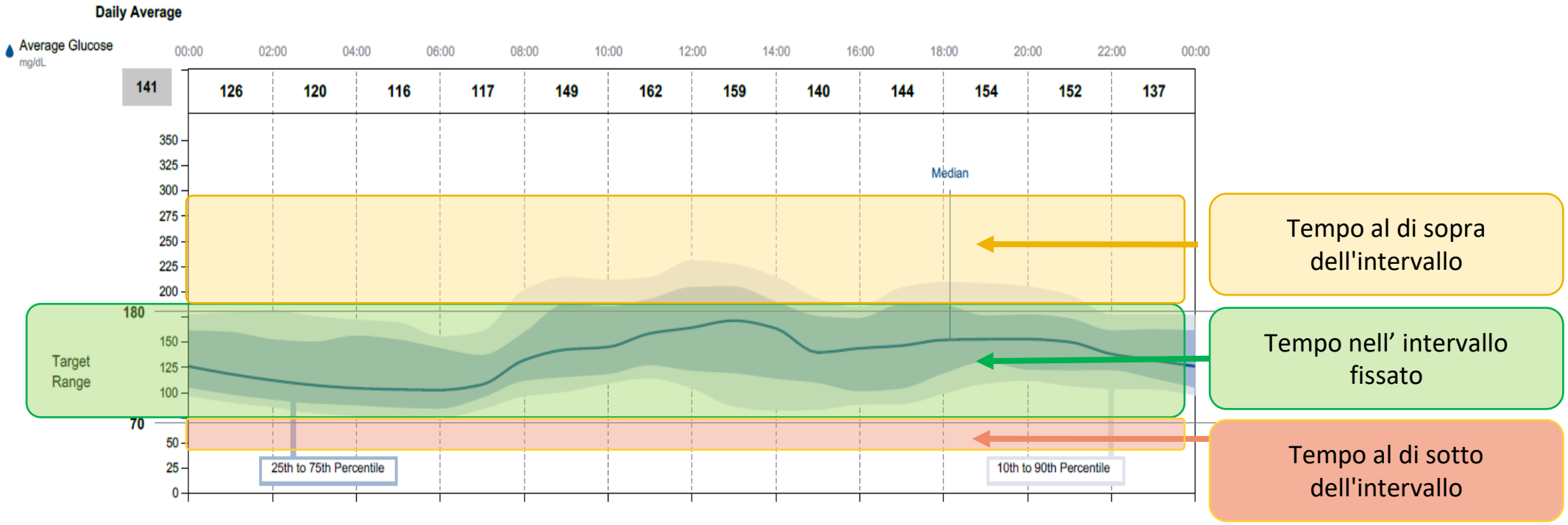
1. Number of days CGM worn (recommend 14 days) (42,43)	
2. Percentage of time CGM is active (recommend 70% of data from 14 days) (41,42)	
3. Mean glucose	
4. Glucose management indicator (GMI) (75)	
5. Glycemic variability (%CV) target ≤36% (90)*	
6. Time above range (TAR): % of readings and time >250 mg/dL (>13.9 mmol/L)	Level 2
7. Time above range (TAR): % of readings and time 181–250 mg/dL (10.1–13.9 mmol/L)	Level 1
8. Time in range (TIR): % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L)	In range
9. Time below range (TBR): % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L)	Level 1
10. Time below range (TBR): % of readings and time <54 mg/dL (<3.0 mmol/L)	Level 2
Use of Ambulatory Glucose Profile (AGP) for CGM report	

CV, coefficient of variation. *Some studies suggest that lower %CV targets (<33%) provide additional protection against hypoglycemia for those receiving insulin or sulfonylureas (45,90,91).

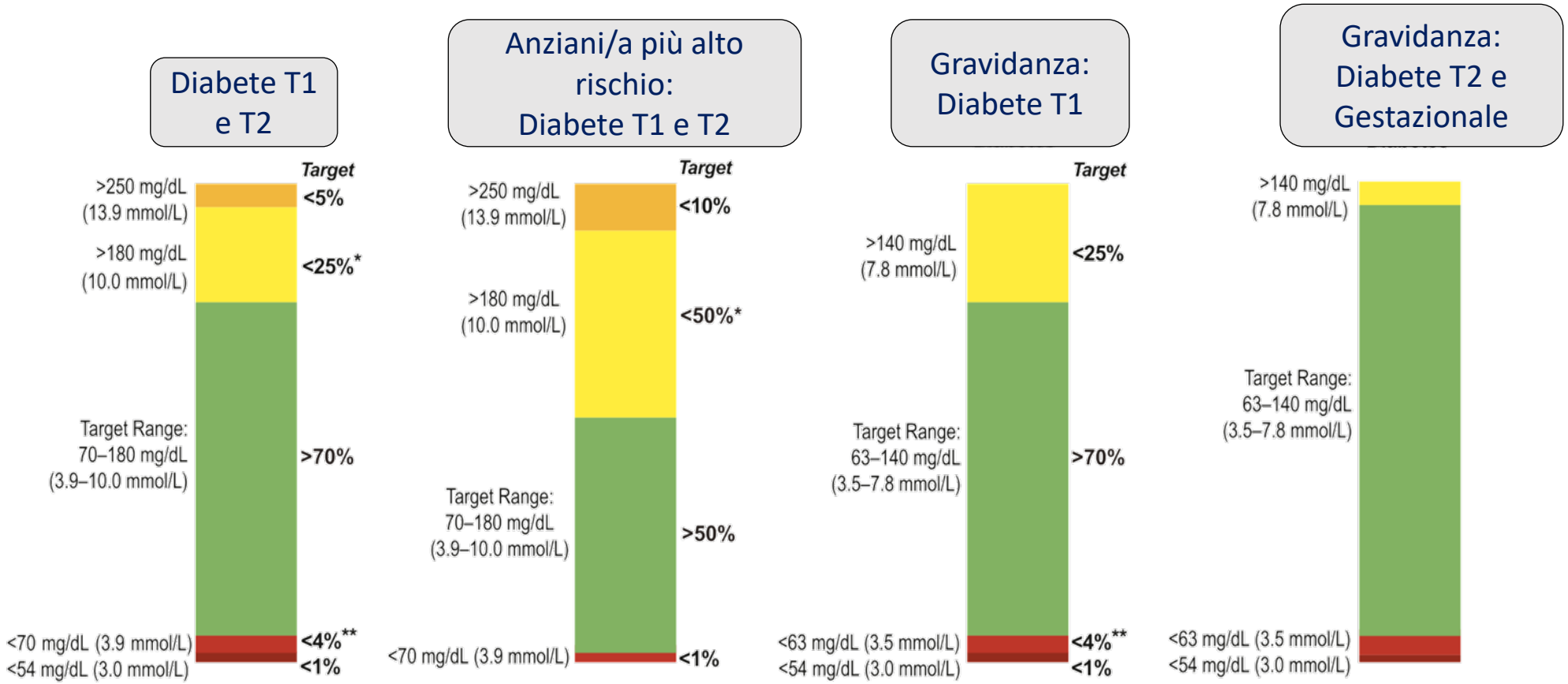
Time in Range: cos'è?

Tempo nell' intervallo fissato

E' la percentuale del tempo trascorso nel target glicemico: 70-180 mg/dl



Obiettivi TIR per differenti popolazioni di persone con il diabete



¤ For age <25 yr., if the A1C goal is 7.5%, then set TIR target to approximately 60%. (See *Clinical Applications of Time in Ranges* section in the text for additional information regarding target goal setting in pediatric management.)

† Percentages of time in ranges are based on limited evidence. More research is needed.

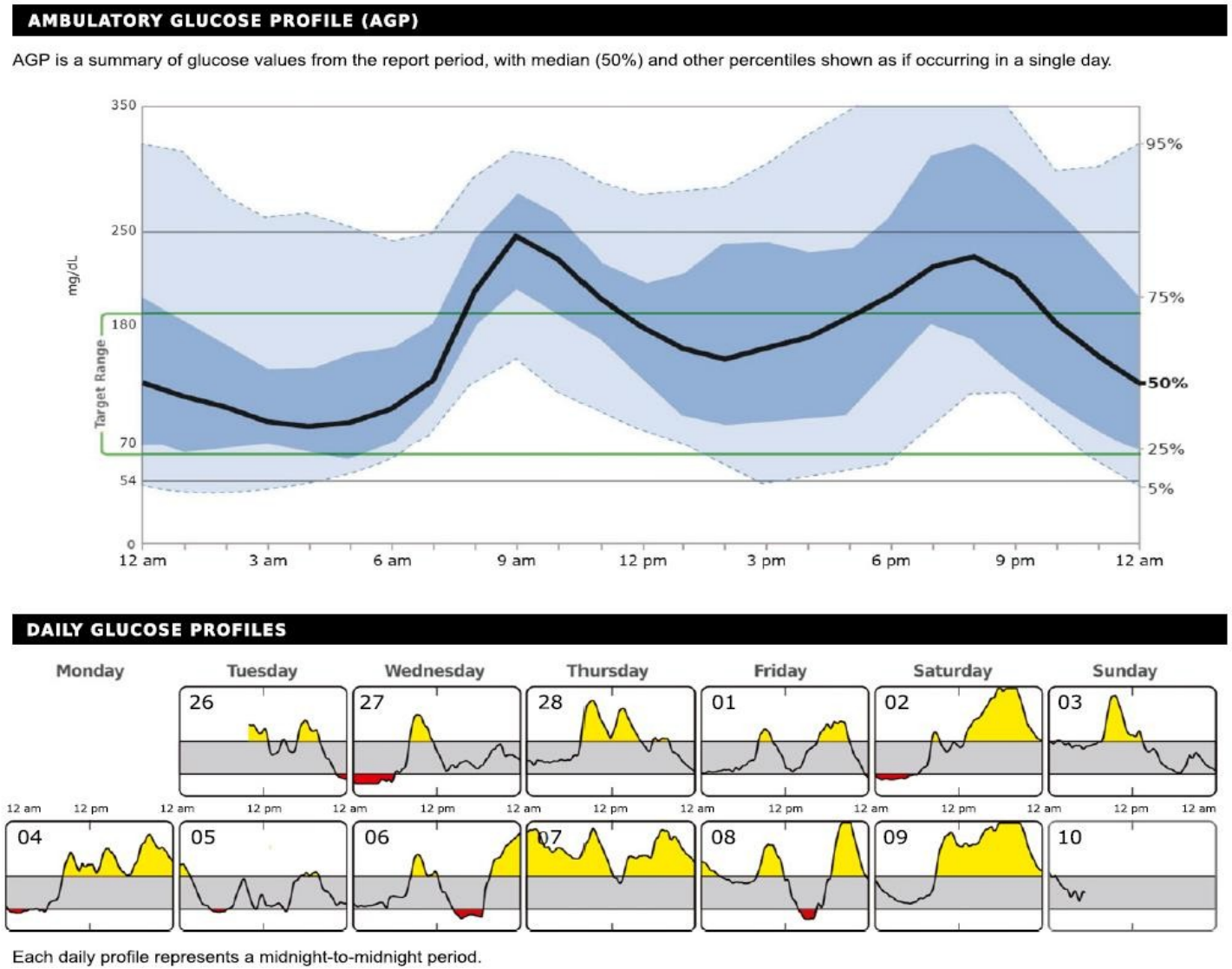
§ Percentages of time in ranges have not been included because there is very limited evidence in this area. More research is needed. Please see *Pregnancy* section in text for more considerations on targets for these groups.

* Includes percentage of values >250 mg/dL (13.9 mmol/L).

** Includes percentage of values <54 mg/dL (3.0 mmol/L).

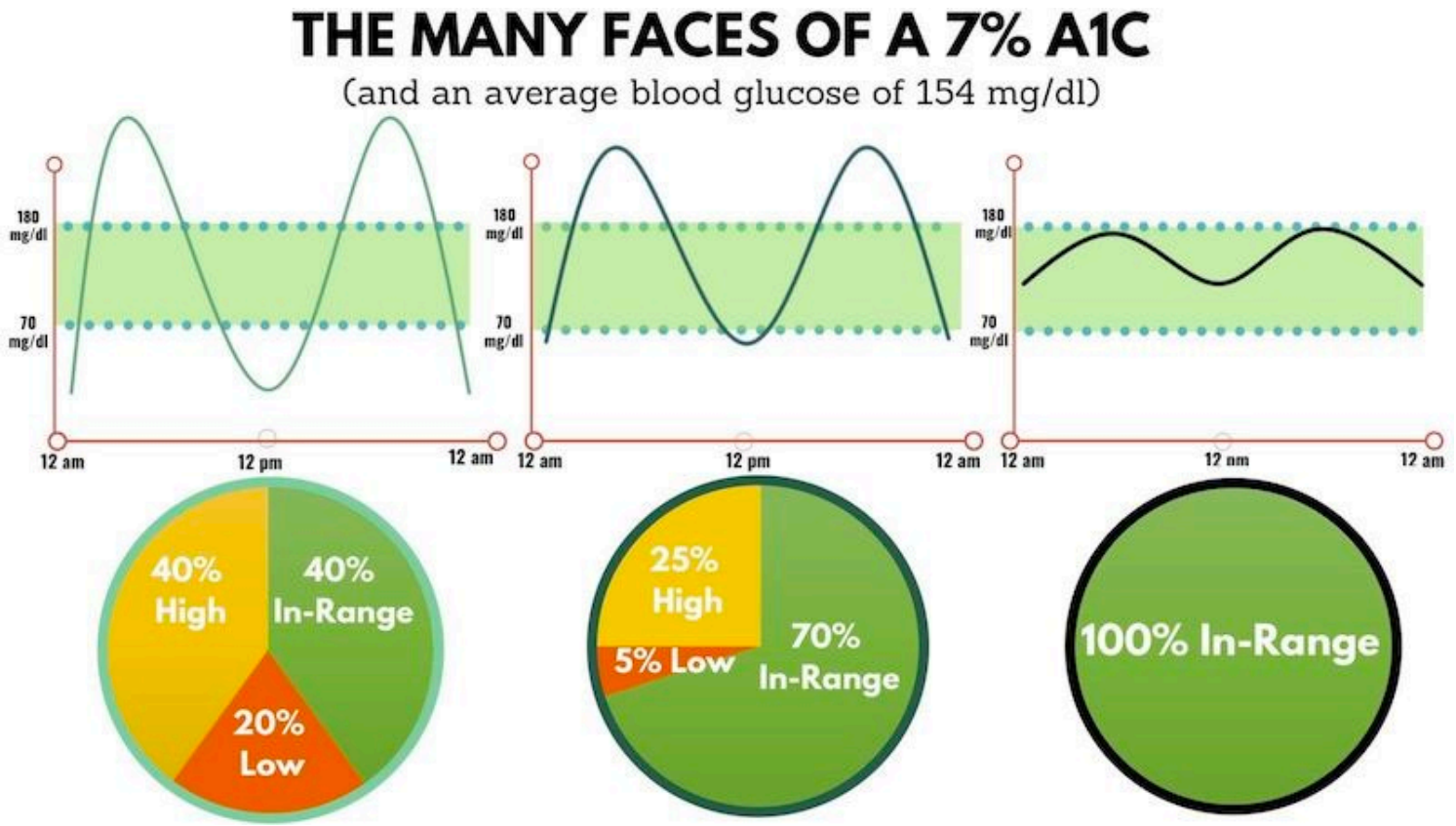
BattelinoT et al. Diabetes Care 2019: 1593-1603

Il profilo glicemico ambulatoriale (AGP) e profili glicemici giornalieri



HbA1c e Time In Range

HbA1c test score	MEAN BLOOD GLUCOSE mg/dL	mmol/L	
14.0	380	21.1	action suggested
13.0	350	19.3	
12.0	315	17.4	
11.0	280	15.6	
10.0	250	13.7	
9.0	215	11.9	
8.0	180	10.0	good
7.0	150	8.2	
6.0	115	6.3	excellent
5.0	80	4.7	
4.0	50	2.6	



Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials

Roy W. Beck,[1] Richard M. Bergenstal,[2] Tonya D. Riddlesworth,[1] Craig Kollman,[1] Zhaomian Li,[1] Adam S. Brown,[3] and Kelly L. Close[4]

Diabetes Care 2019;42:400–405 | https://doi.org/10.2337/dc18-1444

OBJECTIVE

This study evaluated the association of time in range (TIR) of 70–180 mg/dL (3.9–10 mmol/L) with the development or progression of retinopathy and development of microalbuminuria using the Diabetes Control and Complications Trial (DCCT) data set in order to validate the use of TIR as an outcome measure for clinical trials.

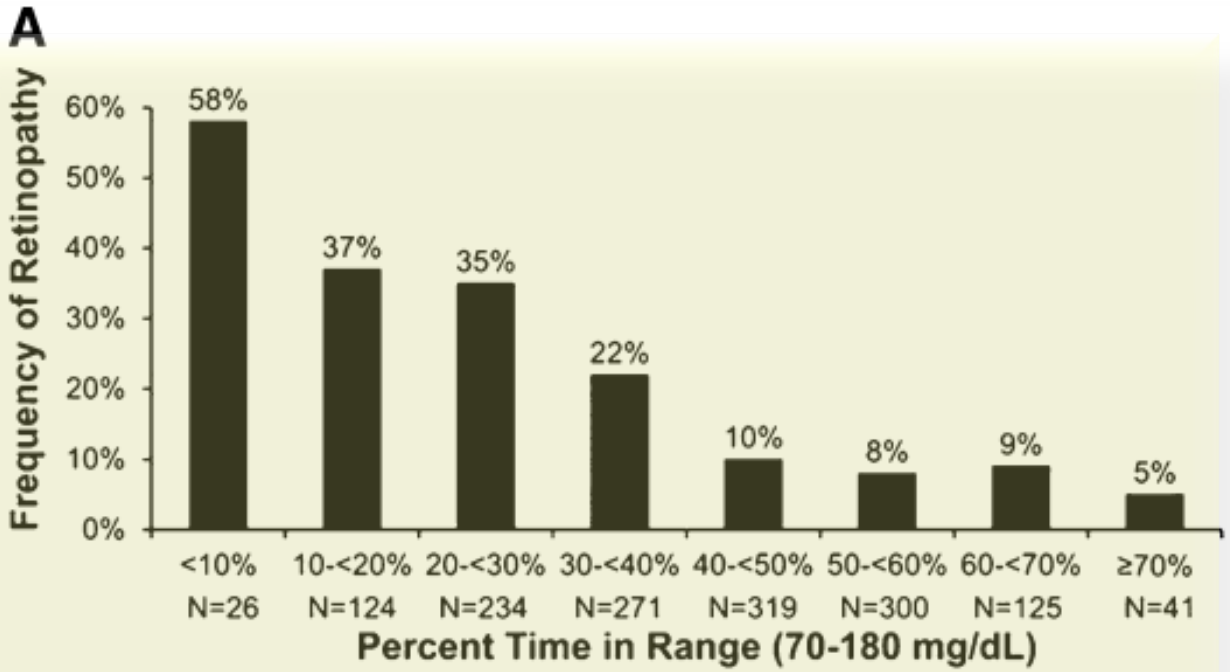
RESEARCH DESIGN AND METHODS

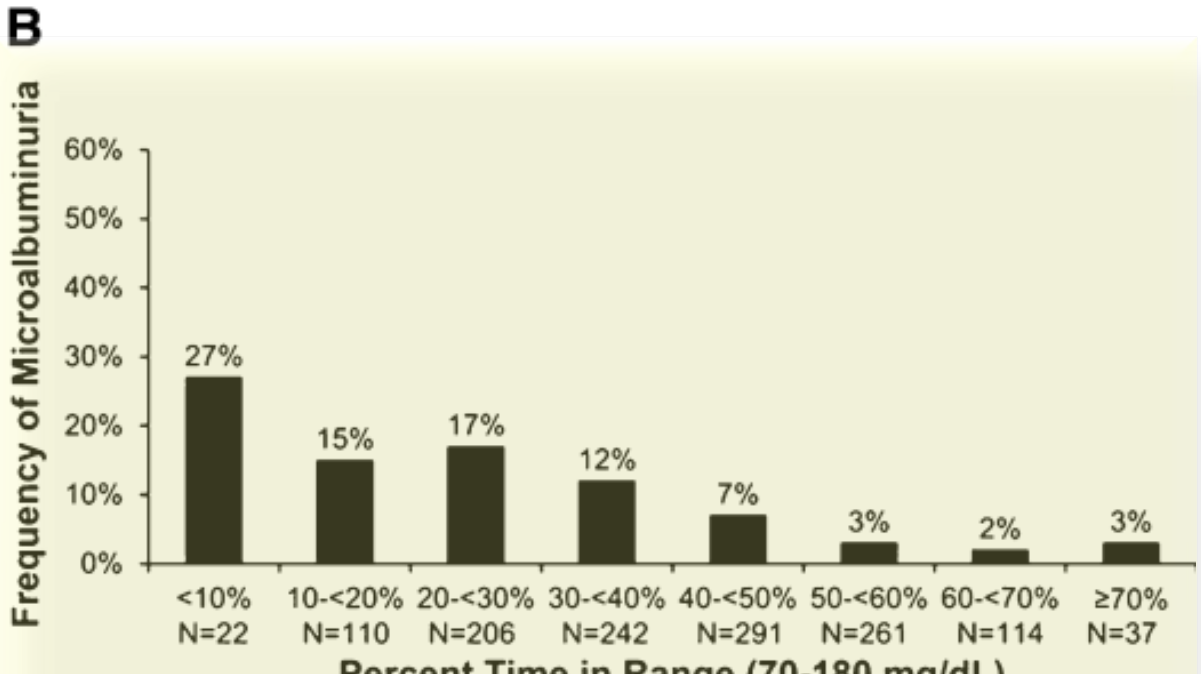
In the DCCT, blood glucose concentrations were measured at a central laboratory from seven fingerstick samples (seven-point testing: pre- and 90-min postmeals and at bedtime) collected during 1 day every 3 months. Retinopathy progression was assessed every 6 months and urinary microalbuminuria development every 12 months. Proportional hazards models were used to assess the association of TIR and other glycemic metrics, computed from the seven-point fingerstick data, with the rate of development of microvascular complications.

Il rischio di complicanze microvascolari è inversamente correlato al TIR

↓ 10% del TIR = ↑ 64% dell'HR per retinopatia

↓ 10% del TIR = ↑ 40% dell'HR per m.albuminuria





Diabetes Care 2019 Mar; 42(3): 400-405

TIR e rischio di complicanze

The Association of Time in Range and Diabetic Complications: The Evidence Is Strong

Roy W. Beck, MD, PhD

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 25, Number 6, 2023

DOI: 10.1089/dia.2023.0141

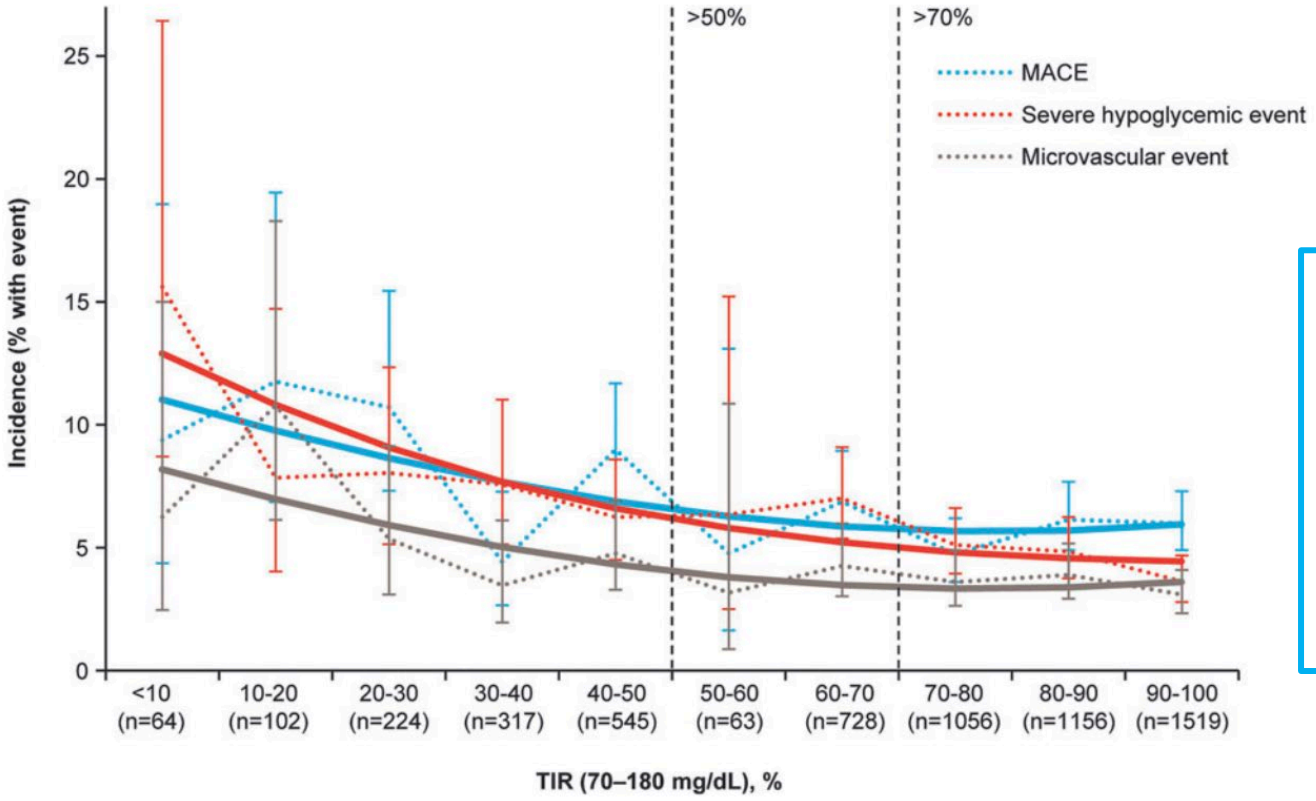
TABLE 1. STUDIES EVALUATING THE RELATIONSHIP BETWEEN CONTINUOUS GLUCOSE MONITORING-MEASURED TIME IN RANGE AND CHRONIC DIABETIC COMPLICATIONS

Study	*Study design*	*Cohort (N) [country]*	*Outcome*	*Findings*
Lu et al.[10]	Cross-sectional	T2D (3262) [China]	Retinopathy	Association between lower TIR and presence of retinopathy, particularly for severe retinopathy
Ranjan et al.[11]	Longitudinal	T1D (26) [Denmark]	Nephropathy	Increased TIR associated with improved urinary albumin excretion during 1-year follow-up
Yoo et al.[12]	Cross-sectional	T2D (866) [Korea]	Nephropathy	Higher prevalence of albuminuria when TIR <70%
Mayeda et al.[13]	Cross-sectional	T2D (105) [United States]	Peripheral neuropathy	Higher prevalence of peripheral neuropathy when TIR <70%
Lu et al.[14]	Cross-sectional	T2D (2215) [China]	Carotid intima-media thickness	Each 10% increase in TIR associated with a 6.4% lower risk of abnormal carotid intima-media thickness
Guo et al.[15]	Cross-sectional	T2D (349) [China]	Cardiovascular autonomic neuropathy	Lower TIR associated with increased prevalence of cardiovascular autonomic neuropathy
Kim et al.[16]	Cross-sectional	T2D (84) [Korea]	Cardiovascular autonomic neuropathy	Lower TIR associated with increased prevalence of cardiovascular autonomic neuropathy, with odds ratio of presence of CAN = 0.88 per 10% increase in TIR
El Malahi et al.[17]	Cross-sectional	T1D (515) [Belgium]	Microvascular/ macrovascular disease	Lower TIR associated with higher prevalence of retinopathy, nephropathy, neuropathy, and cardiovascular disease
Lu et al.[18]	Longitudinal	T2D (6225) [China]	Mortality	Lower TIR, particularly TIR <50%, associated with increased all-cause mortality and cardiovascular mortality

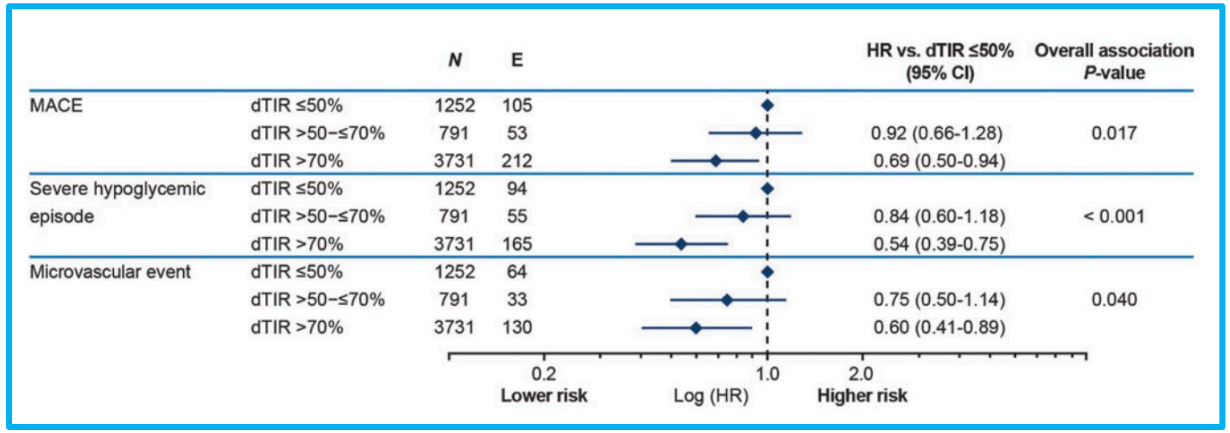
CAN, cardiovascular autonomic neuropathy; T2D, type 2 diabetes; TIR, time in range.

TIR e rischio di complicanze

Increased Derived Time in Range Is Associated with Reduced Risk of Major Adverse Cardiovascular Events, Severe Hypoglycemia, and Microvascular Events in Type 2 Diabetes: A Post Hoc Analysis of DEVOTE



il dTIR basato sui dati del profilo SMBG a 8 punti era significativamente associato negativamente al tempo al primo MACE, episodio ipoglicemico grave o evento microvascolare



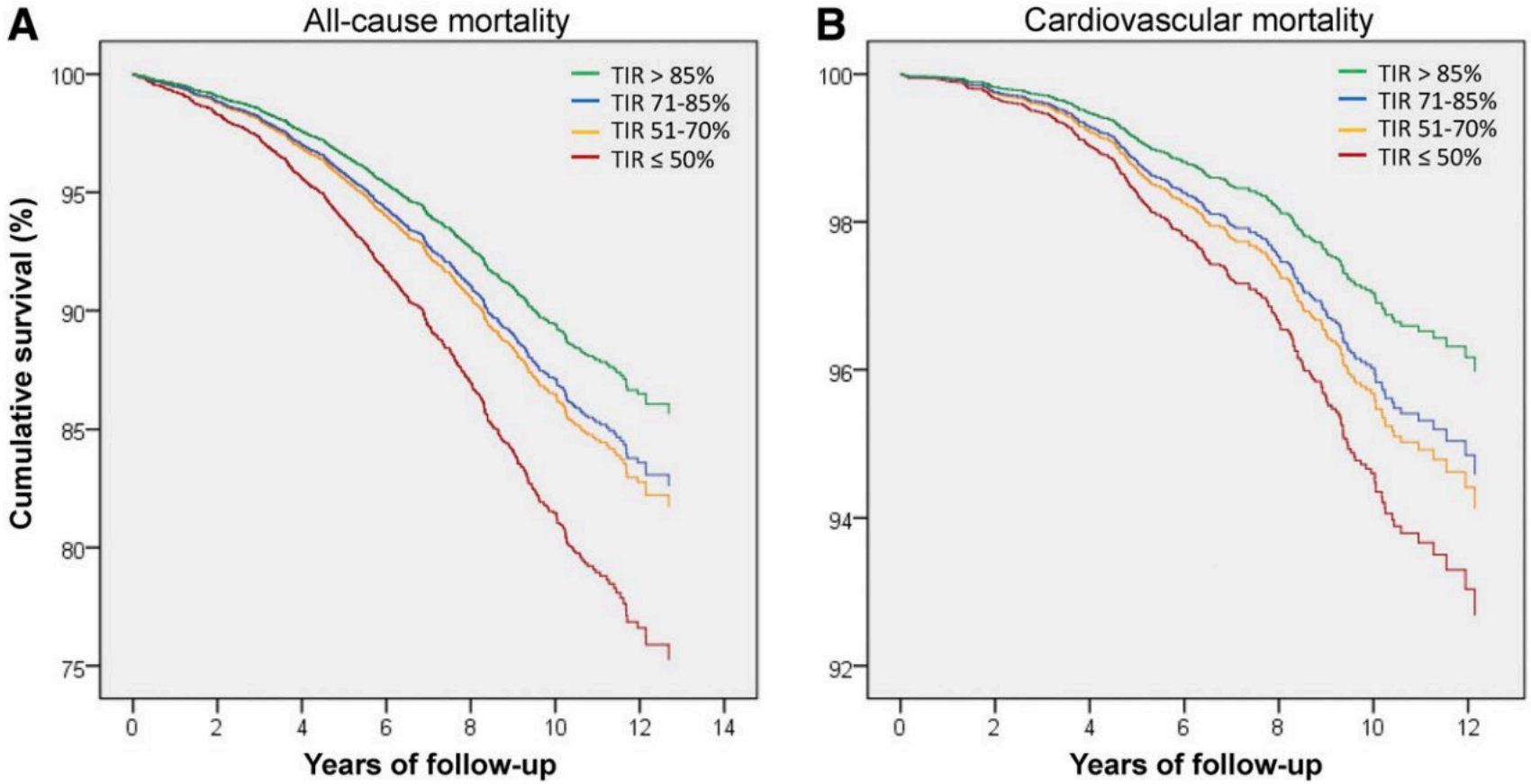
Bergenstal R. M. Et al. DIABETES TECHNOLOGY & THERAPEUTICS Vol 25, N 6, 2023

TIR e rischio di complicanze

Time in Range in Relation to All-Cause and Cardiovascular Mortality in Patients With Type 2 Diabetes: A Prospective Cohort Study

Jingyi Lu,[1] Chunfang Wang,[2] Yun Shen,[1] Lei Chen,[2] Lei Zhang,[1] Jinghao Cai,[1] Wei Lu,[1] Wei Zhu,[1] Gang Hu,[3] Tian Xia,[2] and Jian Zhou[1]

Diabetes Care 2021;44:549–555 | https://doi.org/10.2337/dc20-1862



Continuous glucose monitoring and metrics for clinical trials: an international consensus statement

	Measures	Aim
Percentage of sensor data obtained	The proportion of possible obtained readings by the CGM device; provides a measure of confidence in the all data-derived metrics	≥70% of data during the collection period
Frequency of scanning (eg, scans per day)	For FreeStyle Libre and FreeStyle Libre 2 systems, the sensor should be scanned periodically with a reader or the smartphone app; the frequency of scanning is associated with changes in glucose metrics[64]	Frequency of minimum once every 8 h to ensure no gaps in data
Time in ranges		
Time in range	Measures the percentage of time spent in consensus target glucose range 70–180 mg/dL (3·9–10·0 mmol/L); during pregnancy, this	>70% of time per day (ie, 16 h 48 min) in type 1 and type 2 diabetes; >50% of time per day (12 h) in
Time in tight range		
Time below range (low glucose or Level 1 hypoglycaemia)		
Time below range (very low glucose or Level 2 hypoglycaemia)	significant and requiring immediate attention	
Time above range (>180 mg/dL [>10·0 mmol/L])	Measures the percentage of time spent with >180 mg/dL (>10·0 mmol/L), including readings >250 mg/dL (>13·9 mmol/L)	<25% of time per day (6 h) in type 1 and type 2 diabetes; <10% of time per day (2 h 24 min) in people older than 60 years or patients at high risk
Time above range (high glucose or Level 1 hyperglycaemia)	Measures the percentage of time spent with glucose 181–250 mg/dL (10·1–13·9 mmol/L)	No international consensus recommendations
Time above range (very high glucose or Level 2 hyperglycaemia)	Measures the percentage of time spent with glucose >250 mg/dL (>13·9 mmol/L)	<5% of time per day (1 h 12 min) in type 1 and type 2 diabetes
Mean sensor glucose		
Glycemia Risk Index	graphically on a Glycaemia Risk Index grid	
Coefficient of variation	A measure of dynamic glucose variability expressed as percentage coefficient of variation and calculated as 100 × (SD divided by mean glucose); coefficient of variation is correlated with time below range	≤36% of glucose variability in type 1 diabetes
SD of mean glucose	The SD of mean glucose values is a measure of dynamic glucose variability; SD is strongly correlated with mean glucose	No international consensus recommendations

Each of these measures of glucose control can be derived and reported by CGM devices. They are all endorsed by international consensus guidance on the use of CGM devices in the management of diabetes.[4–6]

Table 2: Objective measures of glycaemic control derived from CGM devices

Time in tight range

Glycemia Risk Index

	Units and quantity
Core endpoints	
Time in range 70–180 mg/dL (3·9–10·0 mmol/L)	Percentage of time in range; amount of time (hours and minutes)
Time below range <70 mg/dL (<3·9 mmol/L), including readings of <54 mg/dL (<3·9 mmol/L)	Percentage of time below range; amount of time (hours and minutes)
Time below range <54 mg/dL (<3·0 mmol/L)	Percentage of time below range; amount of time (hours and minutes)
Time above range >180 mg/dL (>10·0 mmol/L), including readings of >250 mg/dL (<13·9 mmol/L)	Percentage of time above range; amount of time (hours and minutes)
Time above range >250 mg/dL (>13·9 mmol/L)	Percentage of time above range; amount of time (hours and minutes)
Coefficient of variation	Percentage coefficient of variation intraday (ie, within 24 h) and interday (ie, over multiple days)
SD of mean glucose	SD
Mean sensor glucose	mg/dL (mmol/L)
Secondary endpoints (continuous outcomes)	
Time in tight range 70–140 mg/dL (3·9–7·8 mmol/L)	Percentage of time in tight range; amount of time (hours and minutes)
Change in Glucose Management Indicator	Absolute mean change in mmol/mol or percentage
Extended hypoglycaemic event rate <70 mg/dL (<3·9 mmol/L)	Number of events with sensor glucose <70 mg/dL (<3·9 mmol/L) lasting at least 120 min; event ends when glucose returns to ≥70 mg/dL (≥3·9 mmol/L) for ≥15 min
Extended hyperglycaemic event rate >250 mg/dL (>13·9 mmol/L)	Number of events with sensor glucose >250 mg/dL (>13·9 mmol/L) lasting at least 120 min; event ends when glucose returns to ≤180 mg/dL (≤10·0 mmol/L) for ≥15 min
Secondary endpoints (binary outcomes)	
Proportion of participants with time in range 70–180 mg/dL (3·9–10·0 mmol/L) for >70% of each day	Percentage of participants
Proportion of participants with time in range 70–180 mg/dL (3·9–10·0 mmol/L) with ≥5% points improvement from baseline	Percentage of participants
Proportion of participants with time in range 70–180 mg/dL (3·9–10·0 mmol/L) with ≥10% points improvement from baseline	Percentage of participants
Proportion of participants with time below range <70 mg/dL (<3·9 mmol/L) for <4% of each day	Percentage of participants
Proportion of participants with time below range <54 mg/dL (<3·0 mmol/L) for <1% of each day	Percentage of participants
Proportion of participants with time above range >180 mg/dL (>10·0 mmol/L) for <25% of each day	Percentage of participants
Proportion of participants with time above range <250 mg/dL (>13·9 mmol/L) for <5% of each day	Percentage of participants
Composite endpoints	
Proportion with improvement in HbA1c >0·5% points without an in increase in TBR <54 mg/dL (<3·0 mmol/L) of >0·5%	Percentage of participants
Proportion of participants with >10% points improvement in percentage of time in range 70–180 mg/dL (3·0–10·0 mmol/L) without an increase in time below range <54 mg/dL (<3·0 mmol/L) of >0·5%	Percentage of participants
Proportion of participants with mean glucose <154 mg/dL (<8·6 mmol/L) and <1% time below range <54 mg/dL (<3·0 mmol/)	Percentage of participants
Proportion of participants with >70% time in range 70–180 mg/dL (3·0–10·0 mmol/L) and <4% time below range <70 mg/dL (<3·9 mmol/)	Percentage of participants
Proportion of participants with >70% time in range 70–180 mg/dL (3·0–10·0 mmol/L) and <1% time below range <54 mg/dL (<3·0 mmol/)	Percentage of participants

Table 3: Recommended CGM-derived endpoints for clinical trials

Battelino T et al, Lancet Diabetes Endocrinol. 2023 Jan; 11(1):42-57

GRI (Glycemia Risk Index)

Metrica composita che descrive la percentuale di tempo in ipo-iperglicemia in un tracciato del monitoraggio glicemico in continuo

// GLYCEMIA RISK INDEX CALCULATOR

DOWNLOAD EXCEL FILE FOR MULTIPLE TRACINGS

To calculate the Glycemia Risk Index for CGMs, please enter into the boxes below the percent of time spent in the VLow, Low, VHigh, and High ranges.

% VLow (<54 mg/dL; <3.0 mmol/L)

% Low (54–<70 mg/dL; 3.0–< 3.9 mmol/L)

% VHigh (>250 mg/dL; > 13.9 mmol/L)

% High (>180–250 mg/dL; >10.0–13.9 mmol/L)

Hypoglycemia Component = VLow + (0.8 × Low)

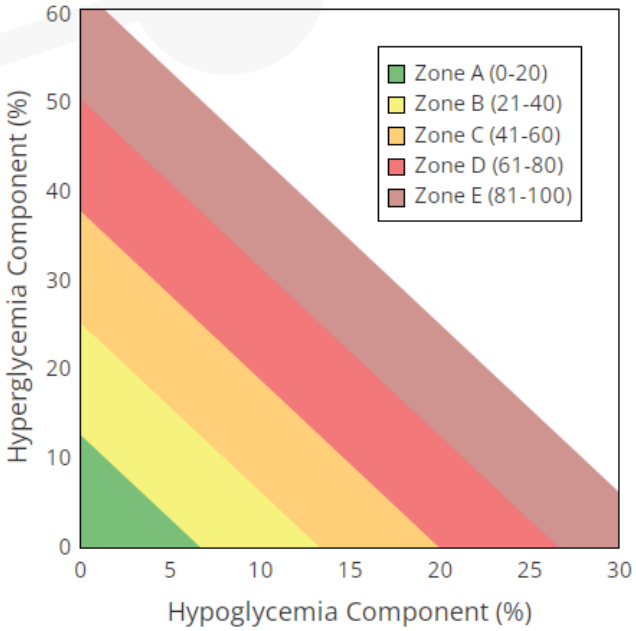
Hyperglycemia Component = VHigh + (0.5 × High)

GRI = (3.0 × HypoComponent) + (1.6 × HyperComponent)

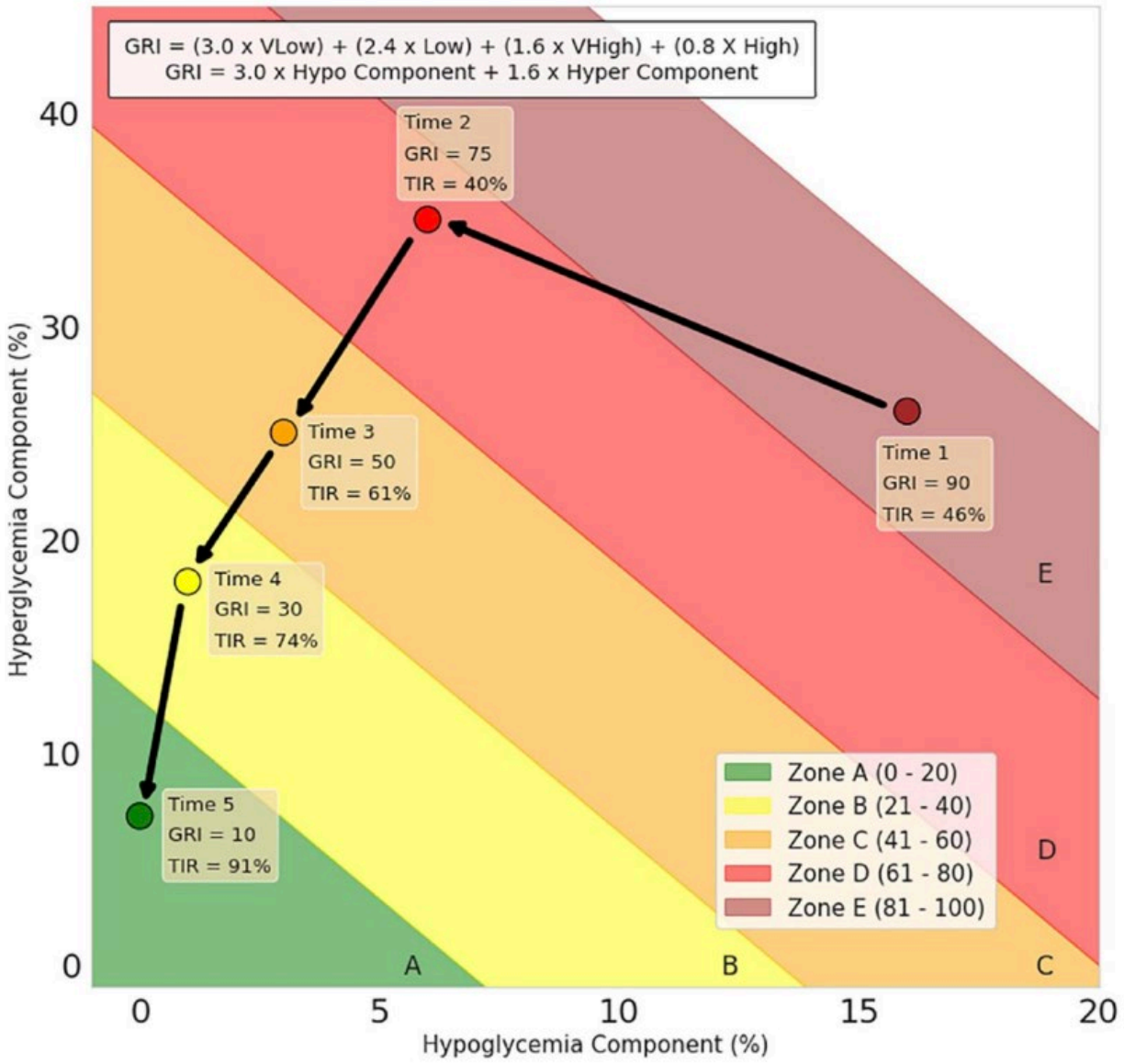
Equivalently,

GRI = (3.0 × VLow) + (2.4 × Low) + (1.6 × VHigh) + (0.8 × High)

GRI



GRI (Glycemia Risk Index)



A Glycemia Risk Index (GRI) of Hypoglycemia and Hyperglycemia for Continuous Glucose Monitoring Validated by Clinician Ratings

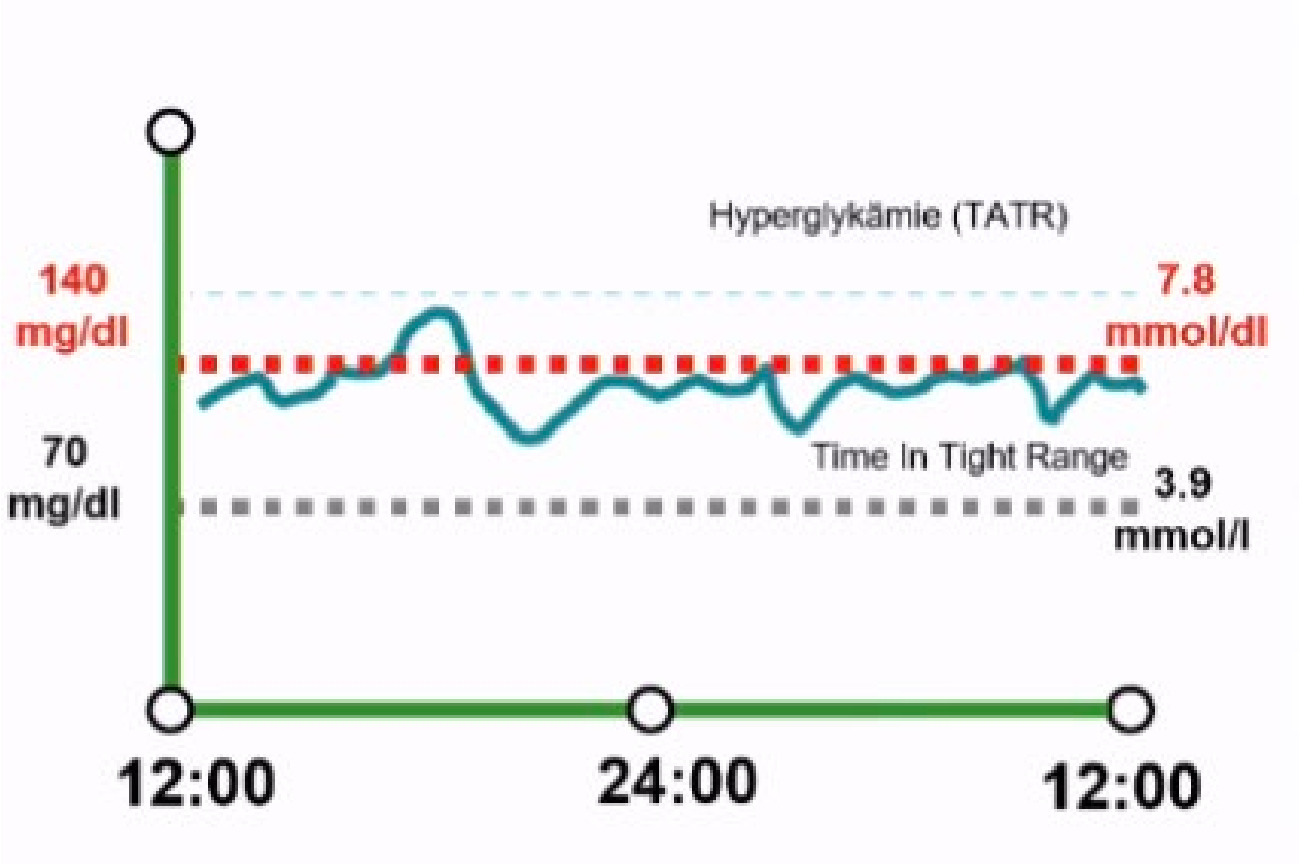
- Sensibile a ipo e iperglicemia
- Dà maggiore peso agli estremi
- Correla con il giudizio clinico meglio di TIR o TIR+ TBR

Klonoff D.C. et al, Journal of Diabetes Science and Technology 2022

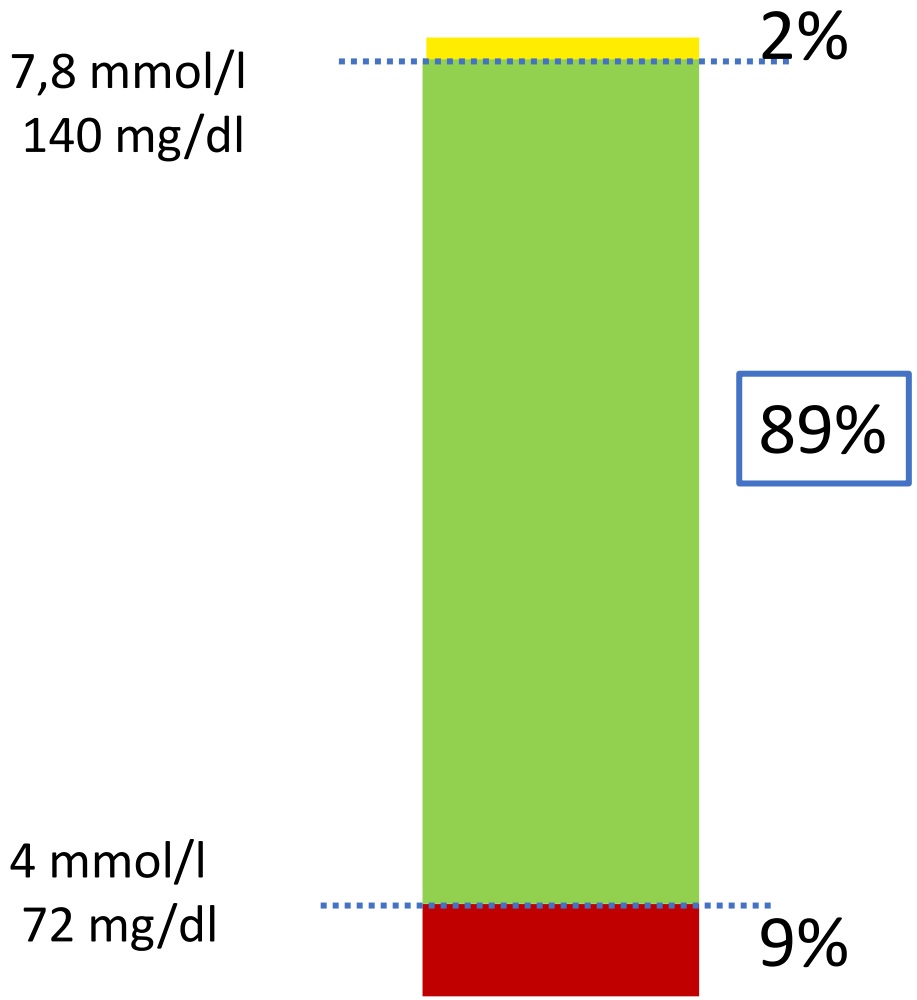
Time in Tight Range (TITR): cos’è?

TITR: Tempo trascorso in normoglicemia

TATR (Time above Tight Range): tempo trascorso in disglicemia



Monitoraggio continuo del glucosio in bambini sani



CGM nella vita quotidiana di bambini sani di età 2 e 8 anni

15 bambini di età compresa tra 5,4 ± 1,6 anni hanno registrato una media di 1976 ± 15 profili

Il glucosio medio rilevato dal sensore era 5,3 ± 1,0 mmol/L (95 ± 18 mg/dL)

l'89% dei valori era compreso nell'intervallo 4-7,8 mmol/L (**72-140 mg/dL**)

il **9% dei valori** glicemici dal sensore era **<** 4,0 mmol/L (**72 mg/dL**)

il **2% dei valori** di glucosio del sensore erano **>**7,8 mmol/L (**140 mg/dL**)

Sundberg F , Forsander G.Continuous Glucose Monitoring in Healthy Children Aged 2–8 Years. Diabetes Technology & Therapeutics.Feb 2018.113-116.

CGM in persone non diabetiche

Table 2. Summary of Glucose Metrics Over a 24-h Period (n = 153)

	All Participants	Age Group				
		6 to <12 y	12 to <18 y	18 to <25 y	25 to <60 y	≥60 y
n	153	27	30	29	41	26
CGM use, h (mean ± SD) [range]	192 ± 31 [84–245]	180 ± 35 [84–233]	181 ± 28 [111–233]	192 ± 28 [92–223]	207 ± 25 [136–245]	195 ± 33 [124–236]
Overall glucose distribution and variability						
Mean, mg/dL (mean ± SD)	99 ± 7	99 ± 7	98 ± 6	98 ± 6	99 ± 6	104 ± 9
SD, mg/dL (mean ± SD)	17 ± 3	16 ± 3	15 ± 2	18 ± 3	16 ± 3	18 ± 5
CV, % (mean ± SD)	17 ± 3	16 ± 3	15 ± 2	18 ± 3	16 ± 3	17 ± 4
Percentage of glucose sensor values, median (IQR)						
>180 mg/dL	0.0 (0.0–0.2)	0.0 (0.0–0.1)	0.0 (0.0–0.0)	0.0 (0.0–0.4)	0.0 (0.0–0.2)	0.1 (0.0–0.5)
>160 mg/dL	0.3 (0.1–0.9)	0.2 (0.1–0.8)	0.2 (0.0–0.2)	0.4 (0.2–1.1)	0.4 (0.2–0.9)	0.6 (0.1–2.9)
>140 mg/dL	2.1 (0.9–3.9)	1.7 (0.8–2.9)	1.2 (0.3–2.0)	2.4 (1.3–4.4)	2.1 (1.1–3.1)	4.1 (1.3–8.6)
70–140 mg/dL	96 (93–98)	97 (94–97)	97 (95–98)	95 (91–97)	97 (94–98)	93 (89–96)
70–120 mg/dL	89 (82–92)	90 (83–92)	92 (86–93)	87 (82–90)	89 (86–91)	81 (71–86)
<70 mg/dL	1.1 (0.3–2.9)	1.1 (0.3–3.3)	1.7 (0.6–2.6)	1.3 (0.5–3.6)	1.0 (0.3–2.3)	1.4 (0.2–3.4)
<60 mg/dL	0.2 (0.0–0.6)	0.2 (0.0–0.3)	0.2 (0.0–0.8)	0.2 (0.0–0.7)	0.2 (0.0–0.4)	0.3 (0.0–0.7)
<54 mg/dL	0.0 (0.0–0.2)	0.0 (0.0–0.2)	0.0 (0.0–0.4)	0.1 (0.0–0.4)	0.0 (0.0–0.2)	0.1 (0.0–0.2)
Percentage of participants with ≥1 hypoglycemic event[a]	28	19	27	41	24	31
Duration of hypoglycemic events for participants with ≥1 hypoglycemic event (min)[a,b]						
n	70	9	10	23	17	11
Median (IQR)	58 (40–100)	60 (35–165)	53 (40–85)	50 (40–75)	65 (40–100)	80 (50–120)

TITR 70-140 mg/dl
96 (93-98)%

Viral N Shah et al Continuous Glucose Monitoring Profiles in Healthy Nondiabetic Participants: A Multicenter Prospective Study J Clin Endocrinol Metab, October 2019, 104(10):4356–4364

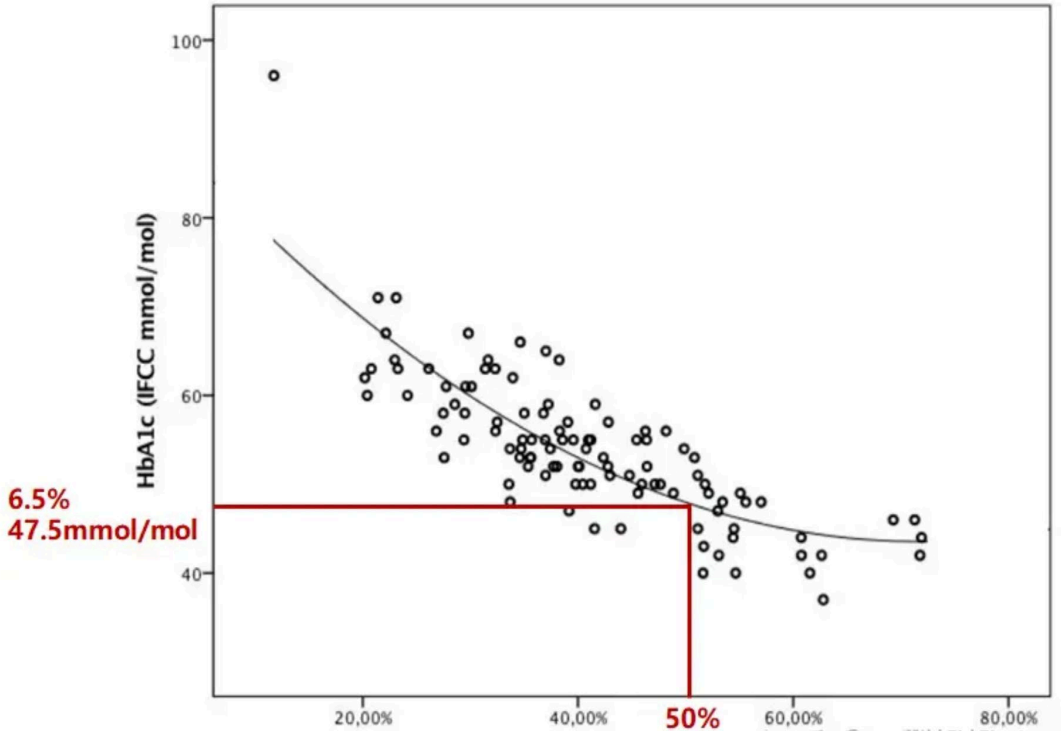
Relazione tra HbA1C e Time in Range nei pazienti con diabete

Table 5—Estimate of A1C for a given TIR level based on type 1 diabetes

Beck et al. (26) (n = 545 participants with type 1 diabetes)

TIR 70–180 mg/dL (3.9–10.0 mmol/L)	A1C, % (mmol/mol)	95% CI for predicted A1C values, %
20%	9.4 (79)	(8.0, 10.7)
30%	8.9 (74)	(7.6, 10.2)
40%	8.4 (68)	(7.1, 9.7)
50%	7.9 (63)	(6.6, 9.2)
60%	7.4 (57)	(6.1, 8.8)
70%	7.0 (53)	(5.6, 8.3)
80%	6.5 (48)	(5.2, 7.8)
90%	6.0 (42)	(4.7, 7.3)

Every 10% increase in TIR = ~0.5% (5.5 mmol/mol) A1C reduction



Time in target range 3,9-7,8 mmol/L

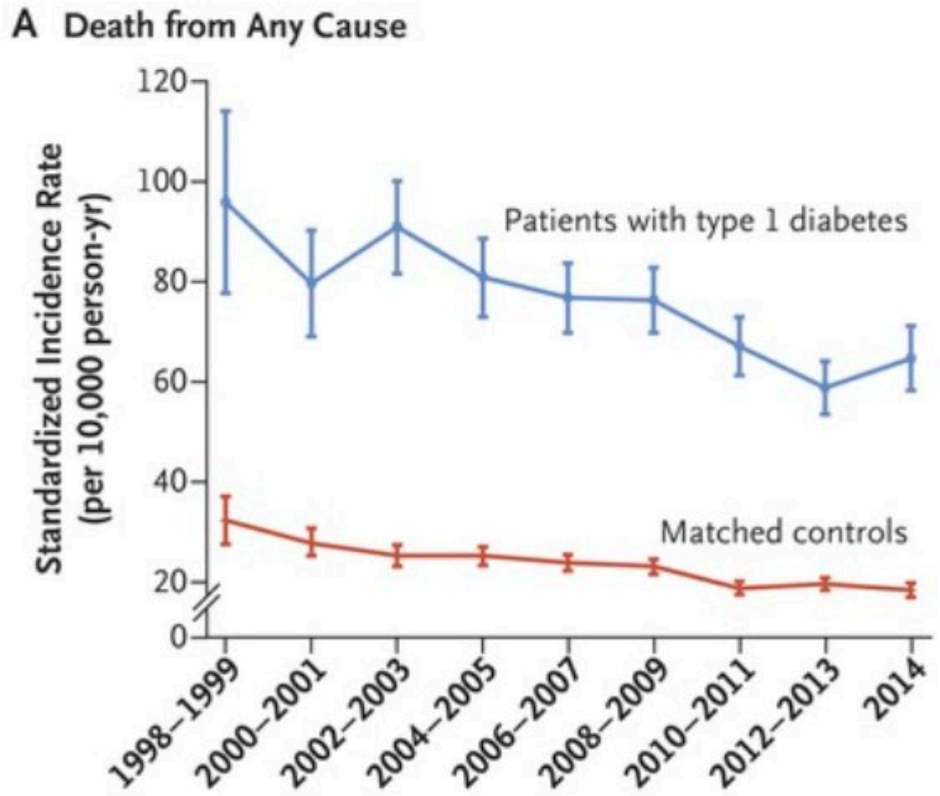
HbA1c di 6,5% corrisponde ad un TITR di circa il 50%

Battelino T et al Diabetes Care 2019
Petersson J et al Pediatr Diabetes 2019 May;20(3):339-344

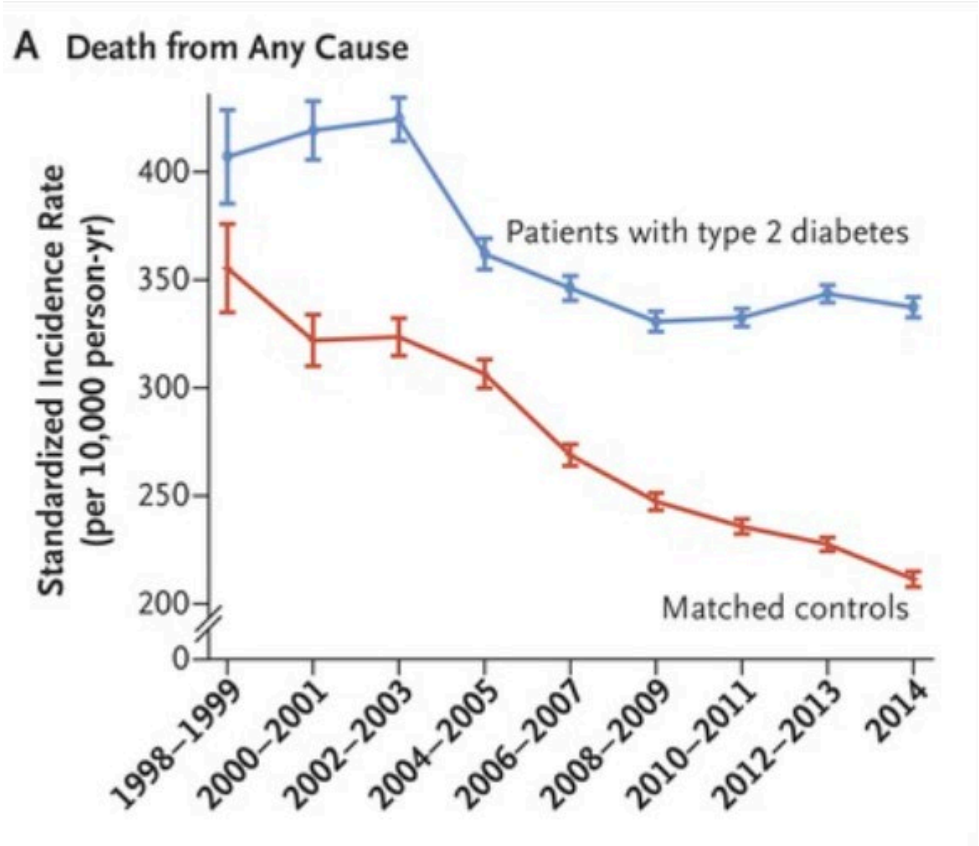
Time in Tight Range (TITR): perchè?

Mortalità nel diabete di tipo 1 e di tipo 2

Pazienti con diabete di tipo 1 e controlli abbinati



Pazienti con diabete di tipo 2 e controlli abbinati



Rawshani A et al Mortality and Cardiovascular Disease in Type 1 and Type 2 Diabetes NEJM April 13, 2017

Time in Tight Range (TITR): perchè?

Mortalità nel diabete di tipo 1

Variable	Hazard Ratio	
	Death from Any Cause	Death from Cardiovascular Disease
Time-updated mean glycated hemoglobin level — no. of events/total no.	7386/200,539	2326/200,539
Reference group (controls)	1.00	1.00
≤6.9%	2.36 (1.97–2.83)	2.92 (2.07–4.13)
7.0–7.8%	2.38 (2.02–2.80)	3.39 (2.49–4.61)
7.9–8.7%	3.11 (2.66–3.62)	4.44 (3.32–5.96)
8.8–9.6%	3.65 (3.11–4.30)	5.35 (3.94–7.26)
≥9.7%	8.51 (7.24–10.01)	10.46 (7.62–14.37)

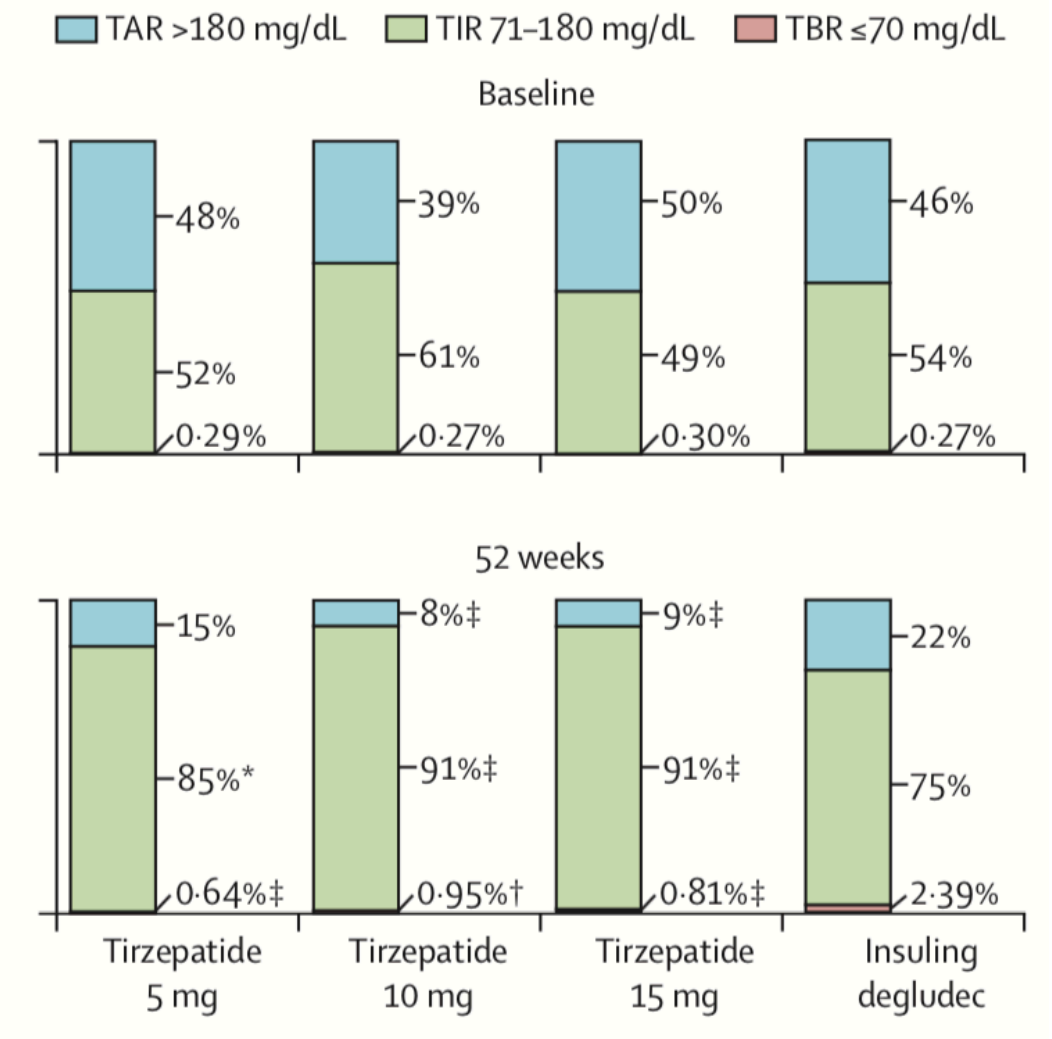
Lind M et al N Engl J Med 2014;371:1972-82

Time in range nel DM2: Studio clinico con tirzepatide

Efficacy of once-weekly tirzepatide versus once-daily insulin degludec on glycaemic control measured by continuous glucose monitoring in adults with type 2 diabetes (SURPASS-3 CGM): a substudy of the randomised, open-label, parallel-group, phase 3 SURPASS-3 trial

Tadej Battelino, Richard M Bergenstal, Angel Rodríguez, Laura Fernández Landó, Ross Bray, Zhentao Tong, Katelyn Brown

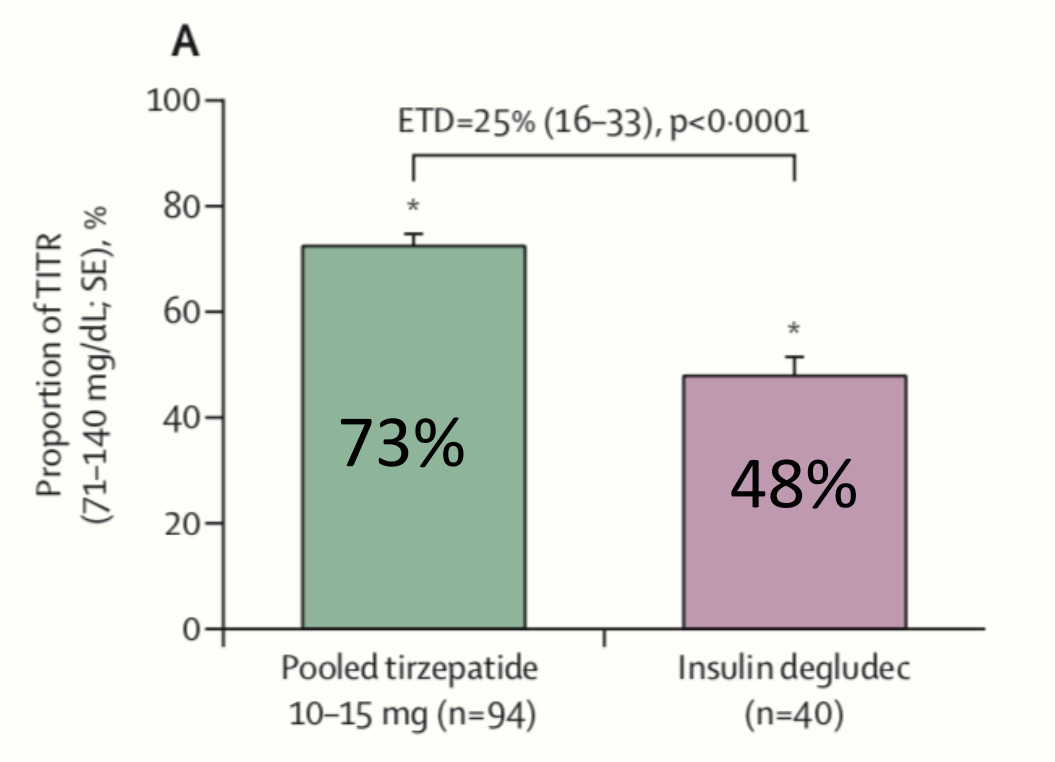
Percentuale di pazienti in TBR, TIR e TAR al basale e dopo 52 settimane di trattamento

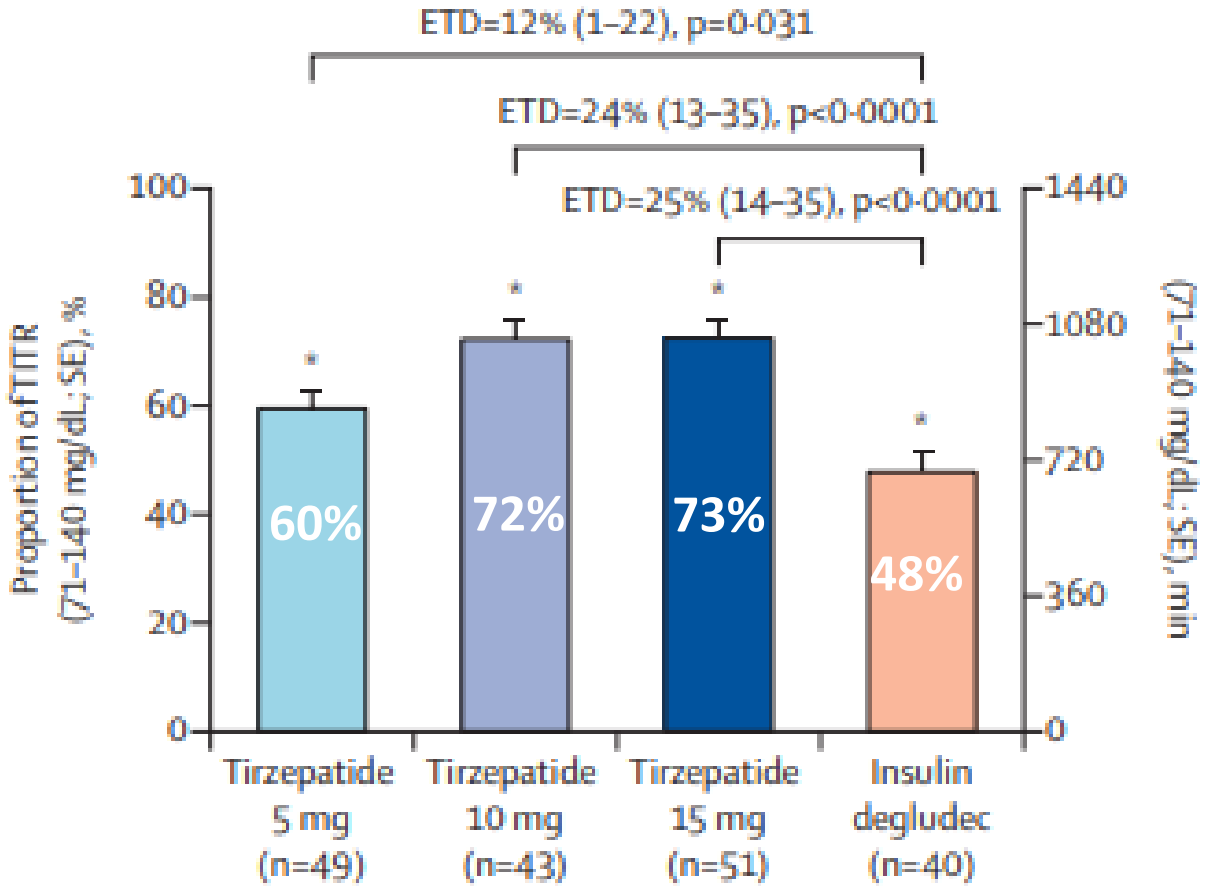


Battelino T et al . Lancet Diabetes Endocrinology Vol 10 June 2022

TITR nel DM2: Studio clinico con tirzepatide

Percentuale in TITR (70-140 mg/gl)

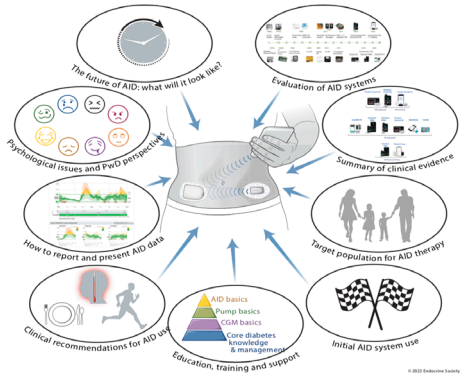


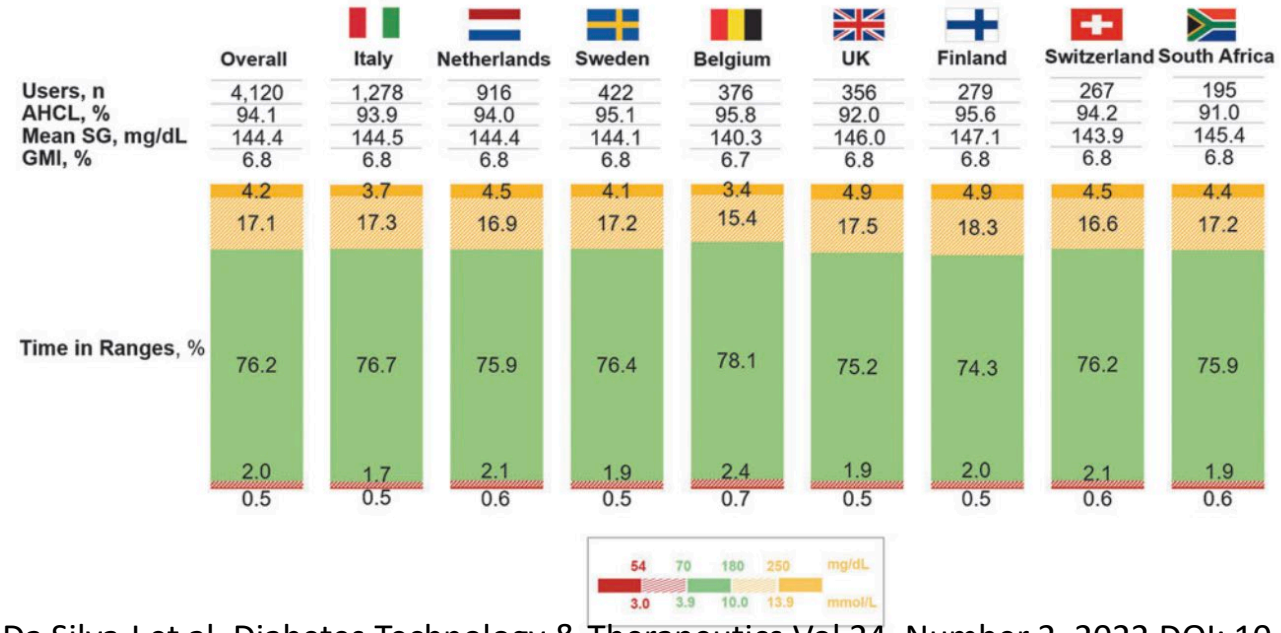


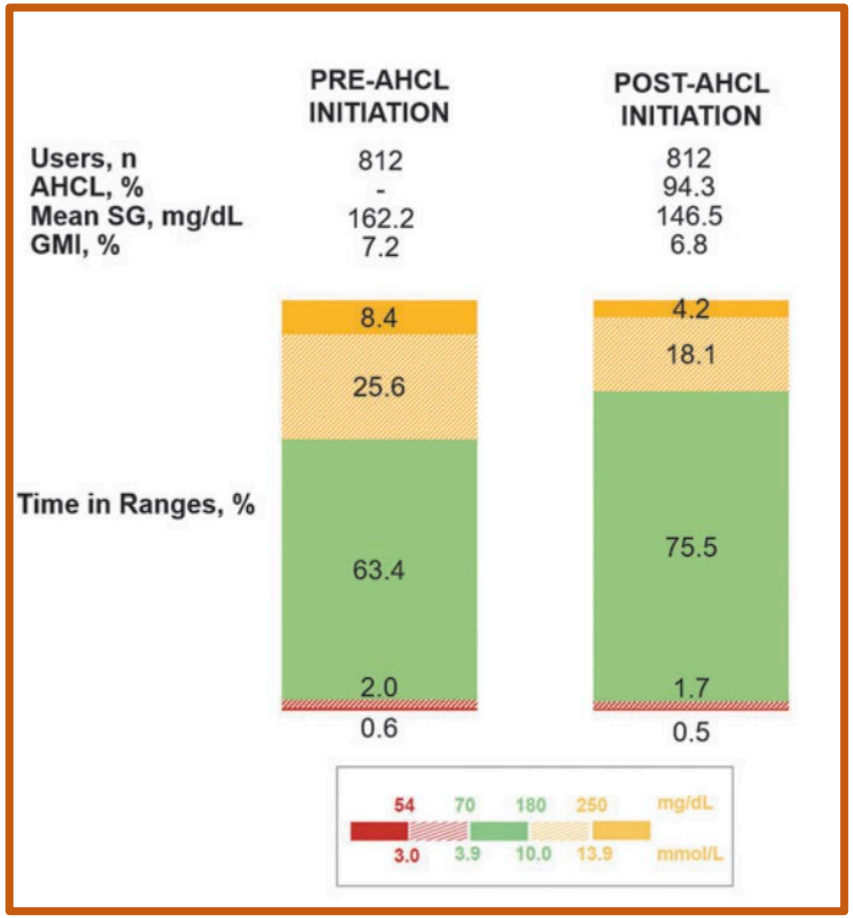
Battelino T et al . Lancet Diabetes Endocrinology Vol 10 June 2022

Time in Tight Range (TITR): come?

Time in range nel DM1: Performance after Advanced Hybrid Closed Loop





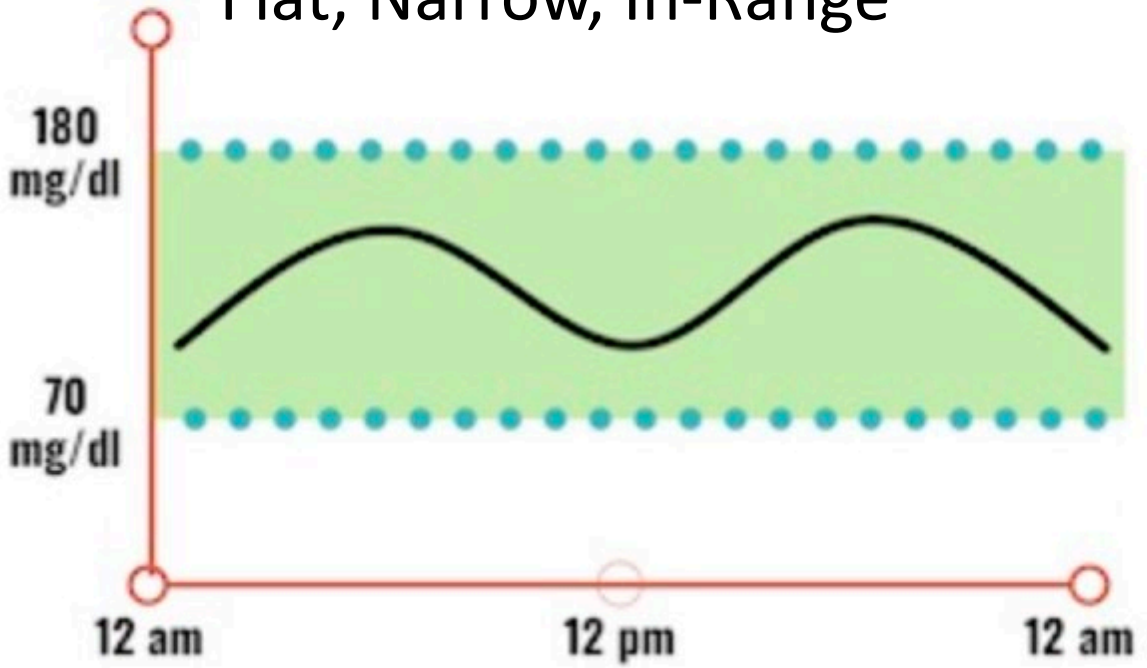


Da Silva J et al. Diabetes Technology & Therapeutics Vol 24, Number 2, 2022 DOI: 10.1089/dia.2021.0203

…quindi qual è il nostro obiettivo?

FNIR

Flat, Narrow, In-Range



CONSENSUS REPORT

The management of type 1 diabetes in adults. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)

Richard I. G. Holt[1,2] · J. Hans DeVries[3,4] · Amy Hess-Fischl[5] · Irl B. Hirsch[6] · M. Sue Kirkman[7] · Tomasz Klupa[8] · Barbara Ludwig[9] · Kirsten Nørgaard[10,11] · Jeremy Pettus[12] · Eric Renard[13,14] · Jay S. Skyler[15] · Frank J. Snoek[16] · Ruth S. Weinstock[17] · Anne L. Peters[18]

Section 3: Aims and goals of management of type 1 diabetes

The aim of diabetes care and management is to support people with type 1 diabetes to live a long and healthy life.

- Effectively delivering exogenous insulin to maintain glucose levels as close to the individual's target range as is safely possible to prevent the development and progression of diabetes complications while:
  - Minimising episodes of hypoglycaemia, of all levels, including Level 1 (<3.9 to ≥3.0 mmol/l [<70 to ≥54 mg/dl]) but, in particular, Level 2 (<3.0 mmol/l [<54 mg/dl]) and Level 3 (severe event characterised by altered mental and/or physical functioning that requires assistance from another person for recovery) hypoglycaemia, and preventing episodes of DKA, while treating these appropriately should they occur.
- Effectively managing cardiovascular risk factors.
- Providing approaches, treatments and devices that minimise the psychosocial burden of living with type 1 diabetes and, consequently, diabetes-related distress, while promoting psychological wellbeing.

Management strategies should adapt to new therapies and technologies as they become available, according to the wishes and desires of the person with diabetes.

Conclusioni 1

- Le differenti metriche del CGM sono uno strumento utile e potente per valutare e quantificare la qualità del controllo glicemico

- I livelli di TIR sono correlati con lo sviluppo di complicanze croniche del diabete

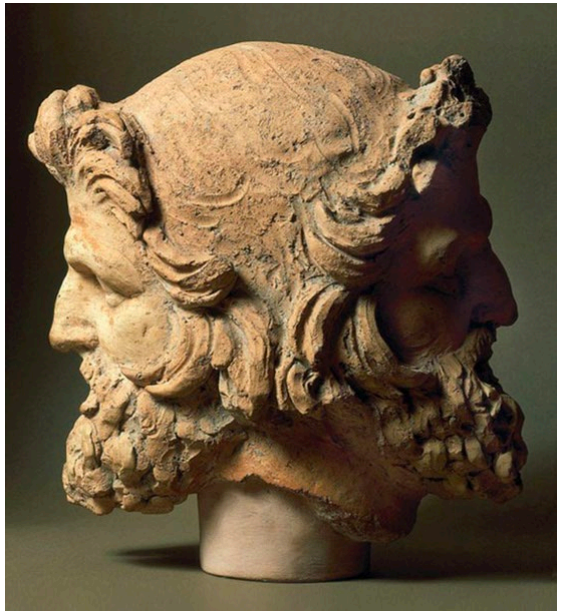
- Il TIR **può essere considerato un valido end point per i trials clinici in associazione all'emoglobina glicata.**

Conclusioni 2

- E’ importante non focalizzarsi solo sul TIR ma anche sulla qualità del controllo glicemico. Il **GRI** è una metrica composita che fornisce informazioni sul tempo trascorso in ipo e iperglicemia, e può essere utilizzata per determinare gli effetti glicemici dei trattamenti prescritti

- Il **TITR** (Time in Tight Range) 70-140 mg/dl è un obiettivo sfidante ma raggiungibile con i farmaci e le tecnologie oggi a disposizione. Perseguibile nell’ottica di ridurre le complicanze croniche del diabete e migliorare l’aspettativa di vita

Conclusioni 3



Metrica= da metriḱe (téchnē) '(arte) metrica', deriv. di metron 'misura, misura del verso

- Le metriche sono solo un mezzo per misurare la realtà
- la tecnologia è solo uno strumento per raggiungere l’obiettivo che è il benessere e la qualità di vita del paziente