Controllo glicemico nel paziente ad alto rischio cardiovascolare

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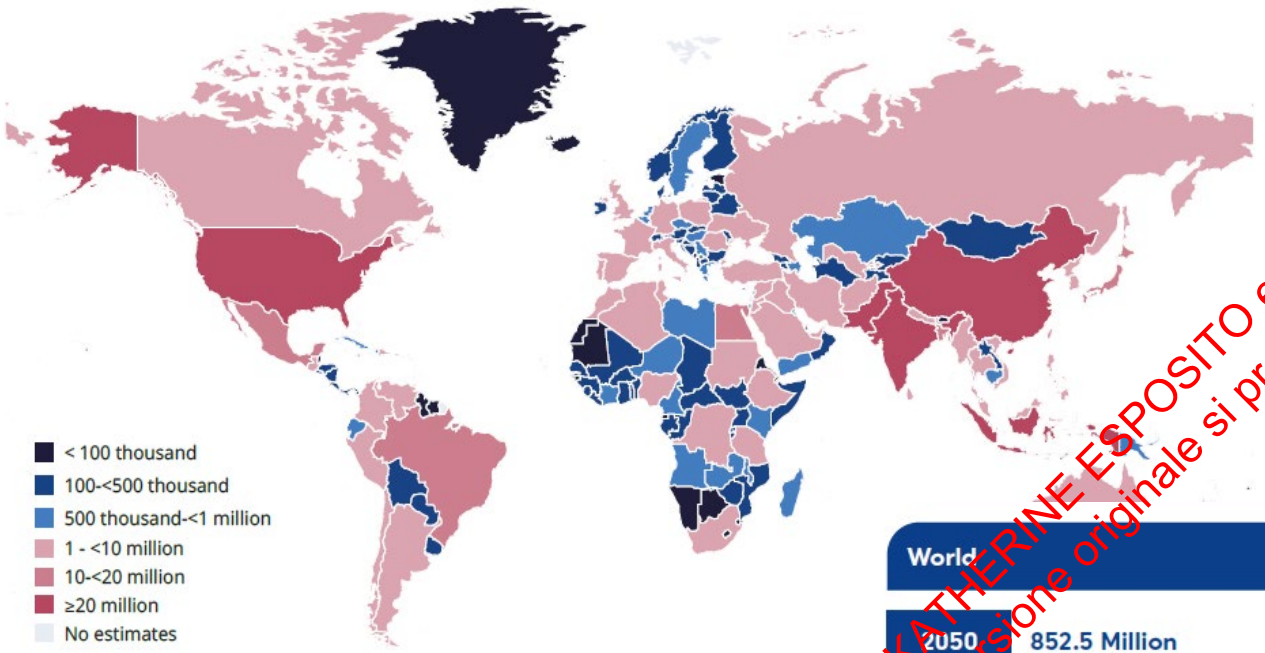
IDF Diabetes Atlas

11th edition | 2025

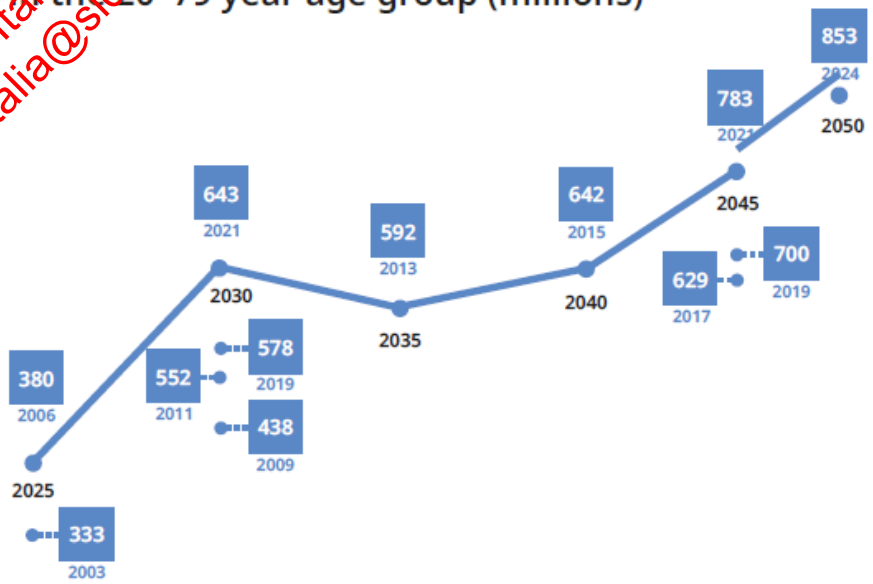
International Diabetes Federation

75 YEARS 1950–2025

Map 3.1 Estimated number of adults (20–79 years) with diabetes by country, 2024.



Projections of the global prevalence of diabetes in the 20–79 year age group (millions)



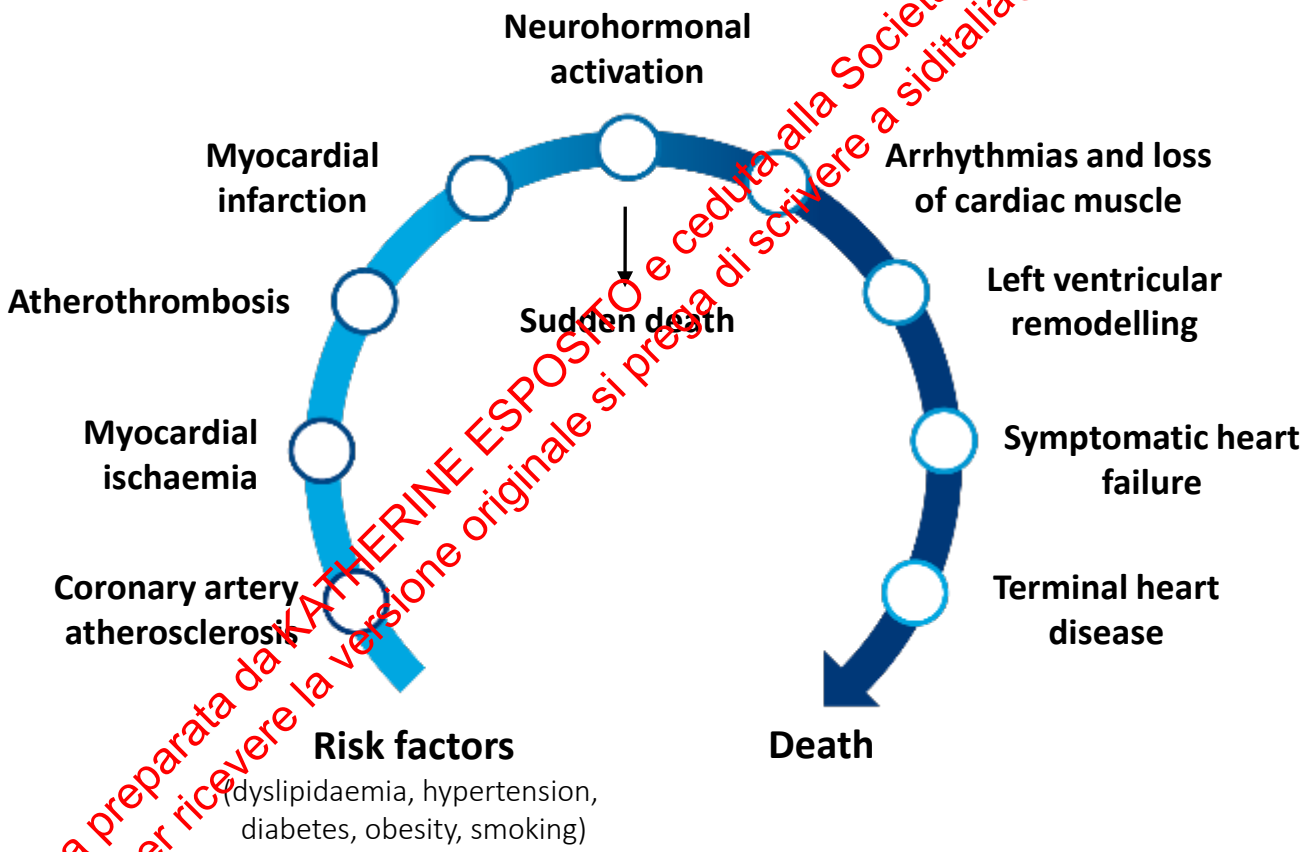
World

2050	852.5 Million	45% increase
2024	588.7 Million	

Europe (EUR)

2050	72.4 Million	10% increase
2024	65.6 Million	

Continuum Cardiovascolare nei pazienti con diabete mellito tipo 2



ATEROSCLEROSI

SCOMPENSO CARDIACO

FATTORI PROATEROGENI

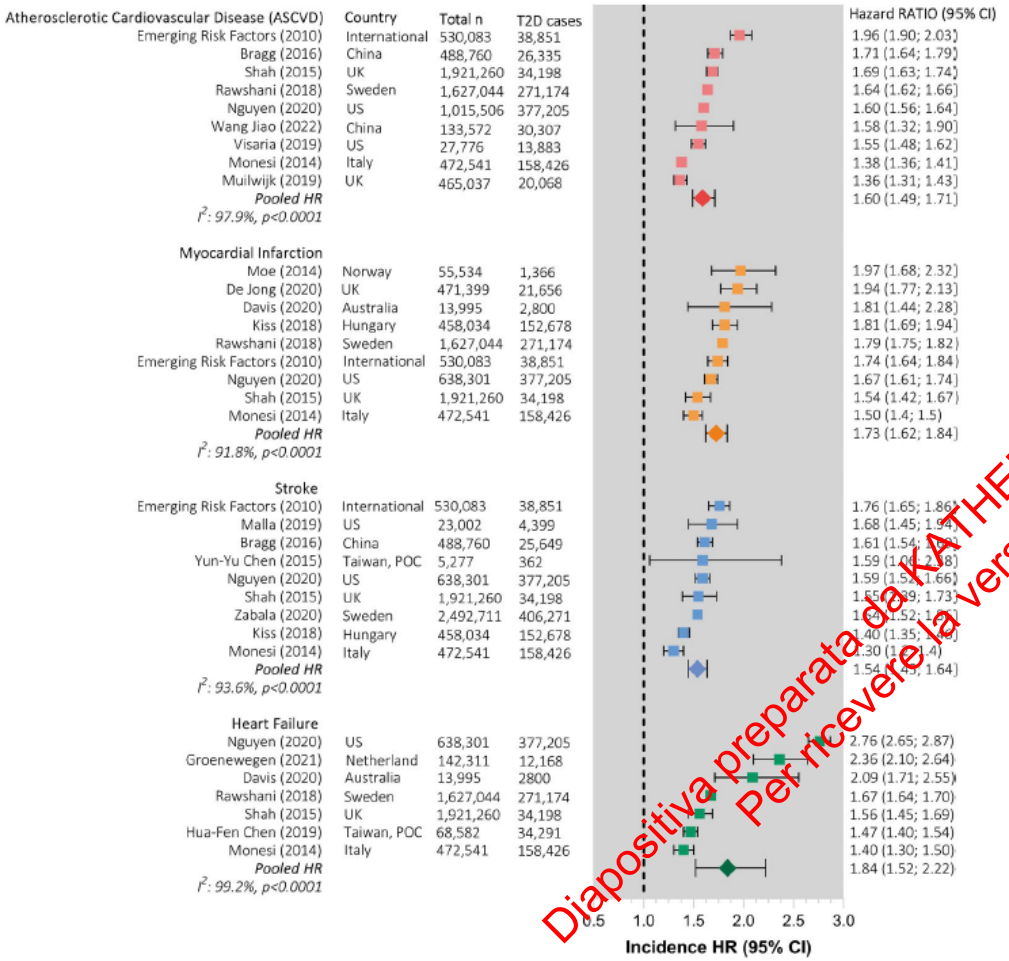
Dzau VJ et al. Circulation 2006

IDF Diabetes Atlas

11th edition | 2025

International Diabetes Federation — 75 YEARS 1950–2025

Meta-analysis of the incidence risk of atherosclerotic cardiovascular disease, stroke, myocardial infarction, and heart failure in people with type 2 diabetes versus those without diabetes.

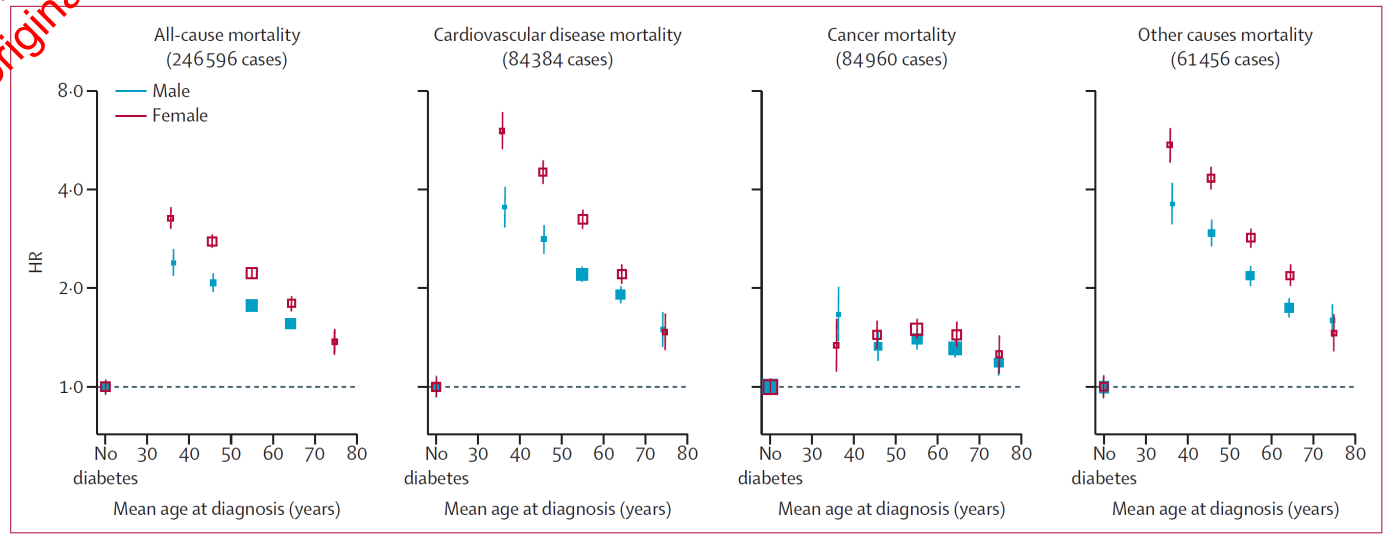


Findings from these studies indicate that, compared to those without diabetes, people with T2D face:

- 60% higher risk of developing any form of CVD
- 54% higher risk of stroke
- 73% higher risk of myocardial infarction (heart attack)
- 84% higher risk of heart failure

Linear dose–response association between earlier age at diagnosis and higher risk of all-cause mortality and cardiovascular disease mortality compared with participants without diabetes.

Life expectancy associated with different ages at diagnosis of type 2 diabetes in high-income countries: 23 million person-years of observation

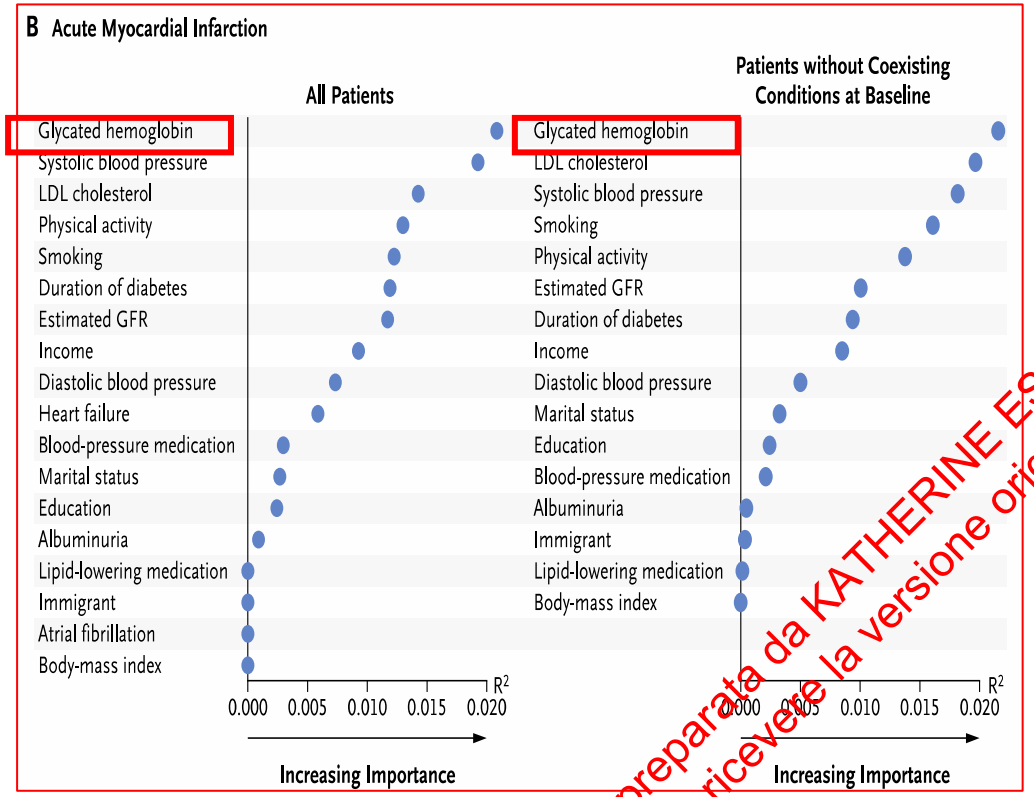


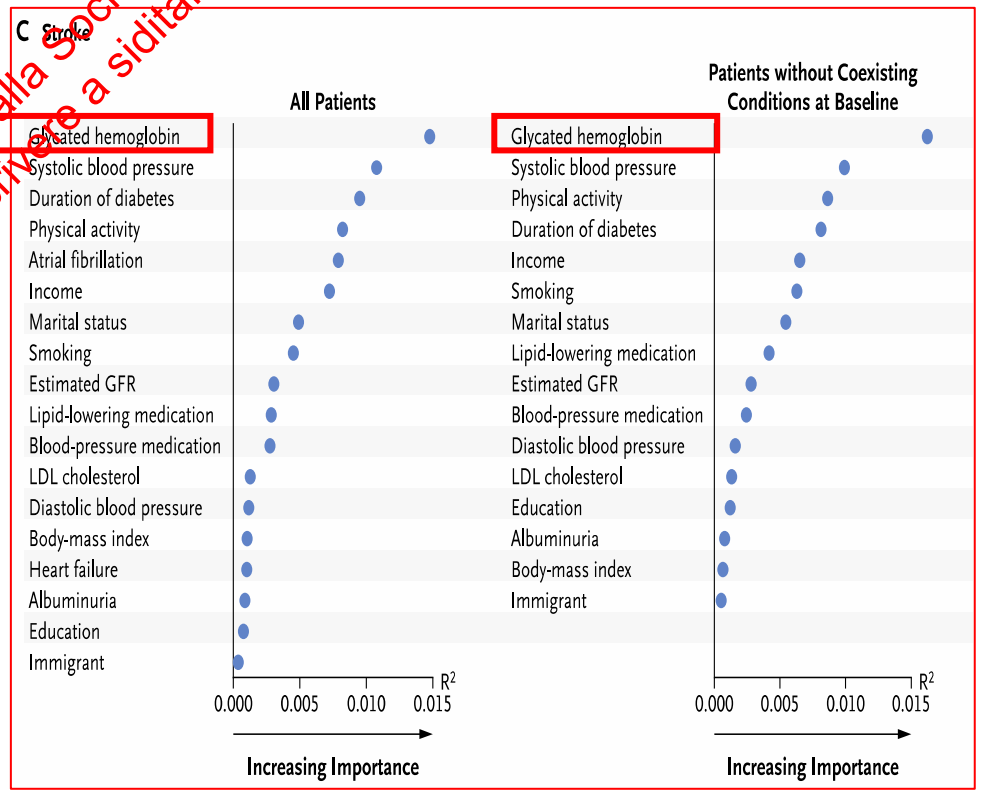
Lancet Diabetes Endocrinol 2023; 11: 731–42

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Risk Factors, Mortality, and Cardiovascular Outcomes in Patients with Type 2 Diabetes

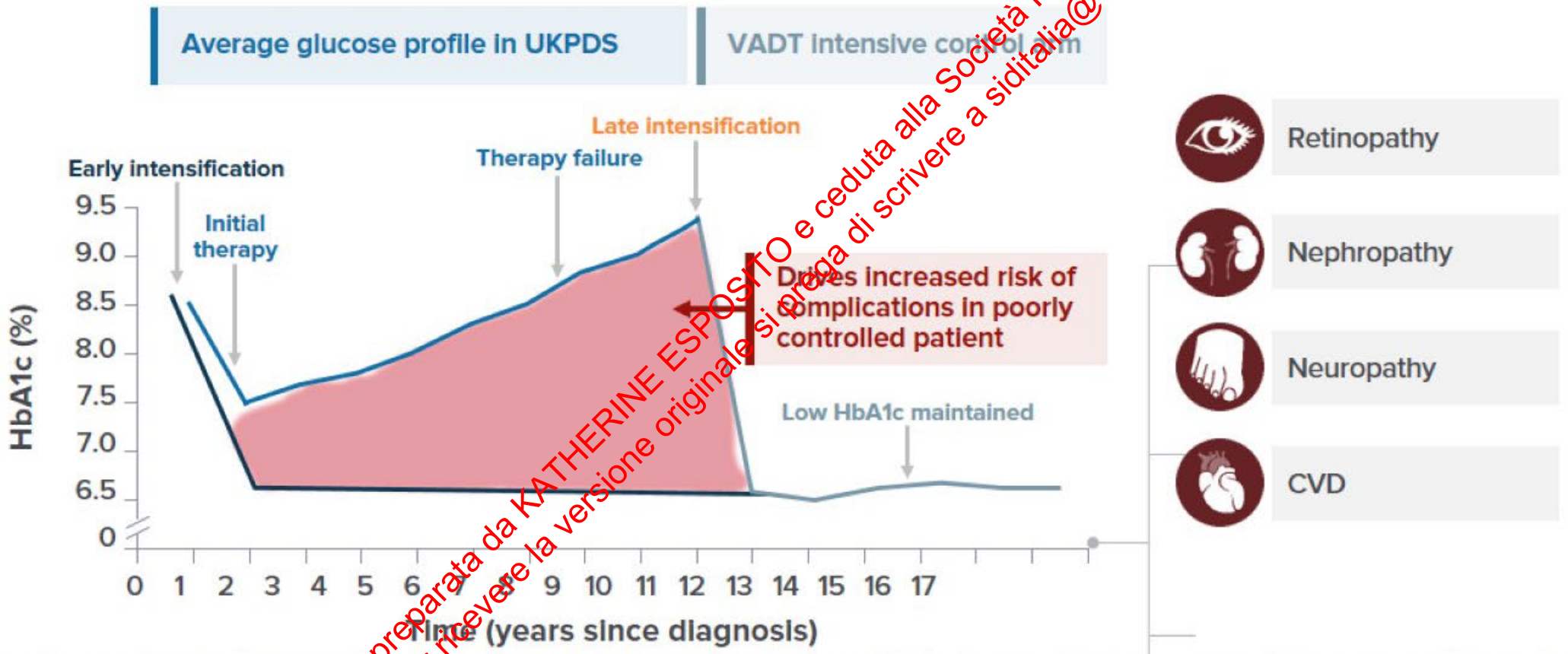




N Engl J Med 2018 Aug 16;379(7):633-644.

Il controllo glicemico precoce riduce il rischio di complicanze

Failure to intensify treatment and reach HbA1c target in a timely manner increases the risk of long-term complications related to sustained hyperglycemia[a,b]

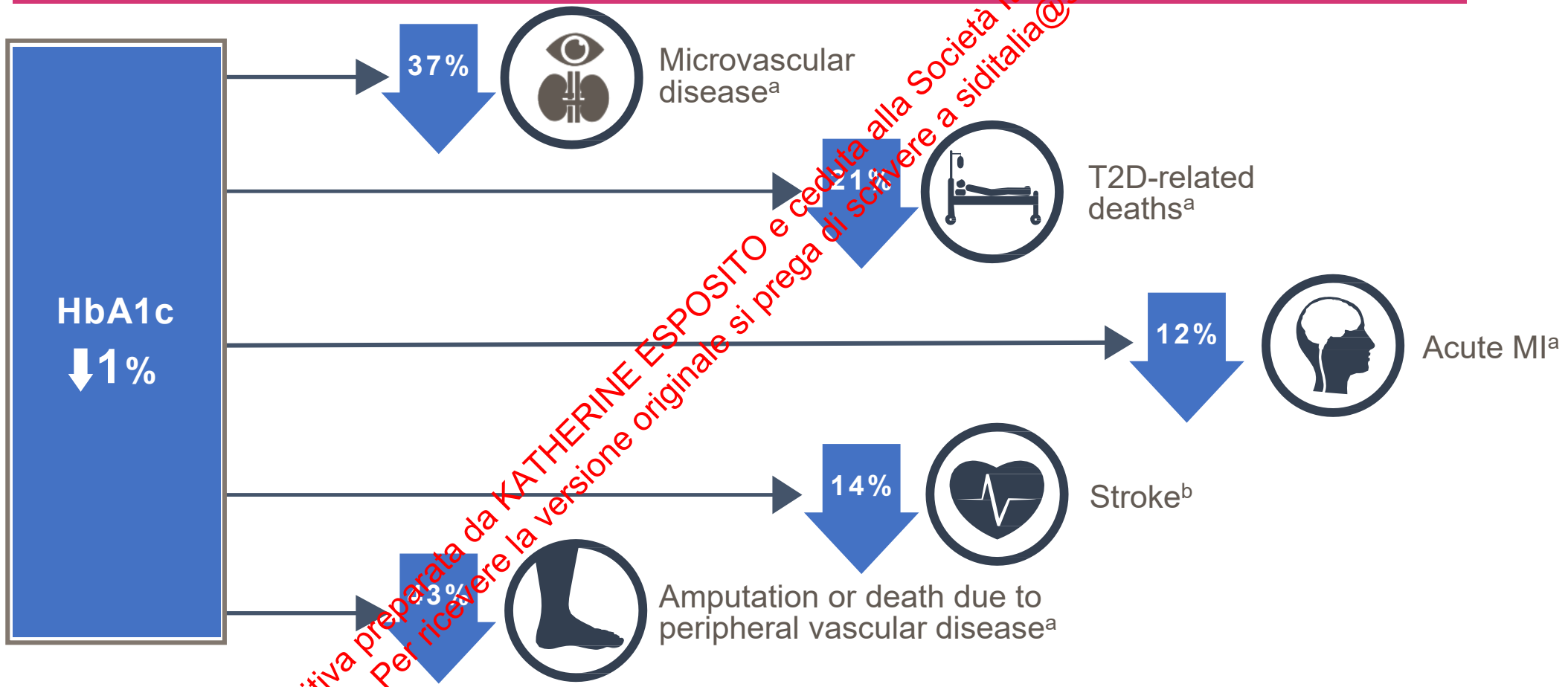


Hypothetical representation of the natural history of the patients with diabetes who were recruited in the VADT.[b] The upper blue line represents the time course of HbA1c estimated based on the average glucose profile described in the UKPDS. The green line represents the time course of HbA1c in the VADT. The lower gray line represents the ideal time course of glycemic control. CVD, cardiovascular disease; HbA1c, glycated hemoglobin; UKPDS, United Kingdom Prospective Diabetes Study; VADT, Veterans Affairs Diabetes Trial.

a. Okemah J, et al. Adv Ther. 2018;35:1735-1745; b. Del Prato S. Diabetologia. 2009;52:1219-1226.

UKPDS: Un controllo glicemico intensivo precoce riduce il rischio a lungo termine di complicanze croniche nel diabete di tipo 2

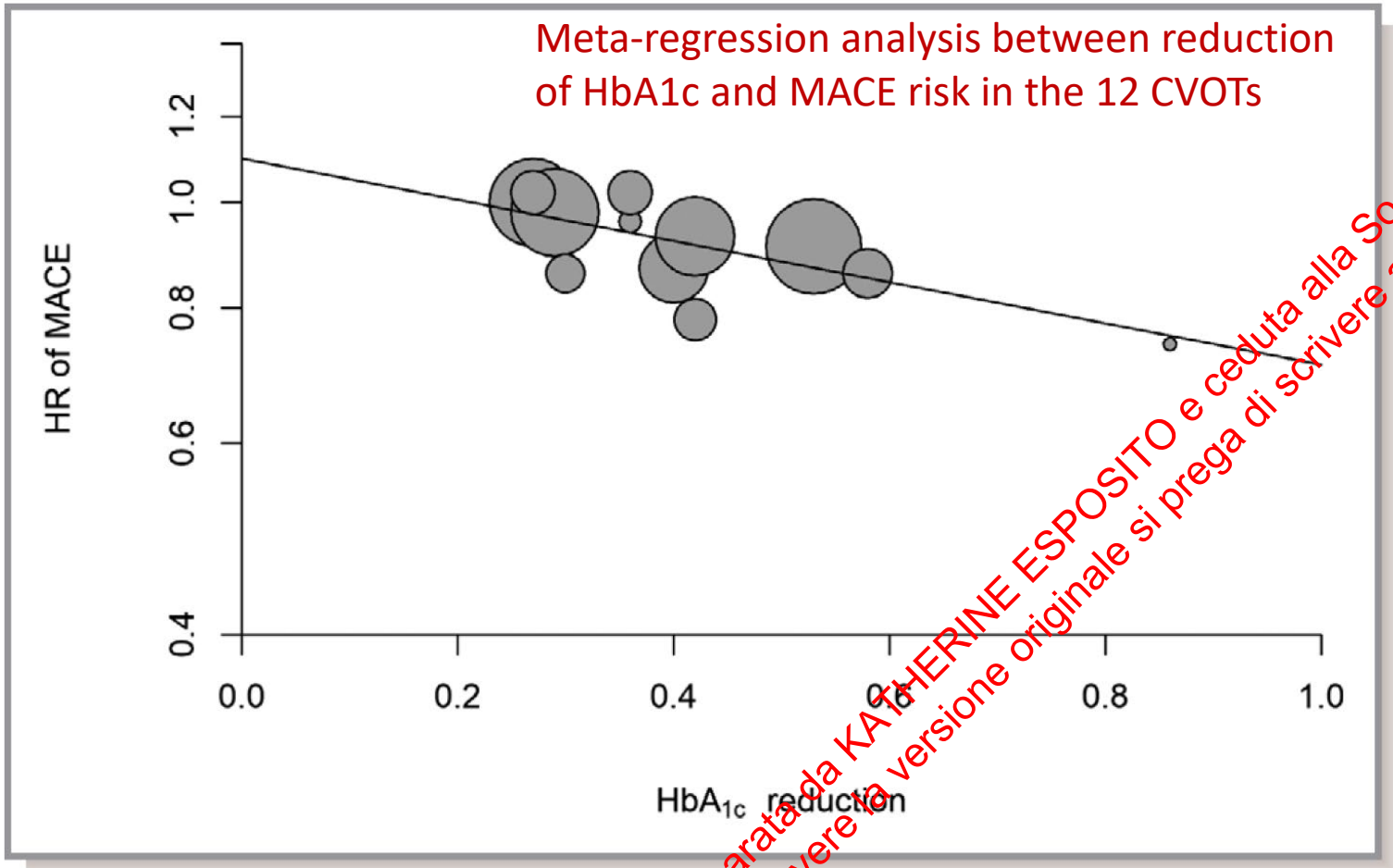
Estrapolazione epidemiologica che mostra il beneficio di una riduzione dell'1% dell'HbA1c



[a]p=.035; [b]p<.0001.

Stratton IM et al. BMJ. 2000;321(7258):405-412.

Greatest HbA1c reduction: lowest HR of MACE in CVOTs



Glycemic Control, Preexisting Cardiovascular Disease, and Risk of Major Cardiovascular Events in Patients with Type 2 Diabetes Mellitus: Systematic Review With Meta-Analysis of Cardiovascular Outcome Trials and Intensive Glucose Control Trials

Dario Giugliano, MD; Maria Ida Maiorino, MD, PhD; Giuseppe Bellastella, MD; Paolo Chiodini, MSc; Katherine Esposito, MD, PhD

J Am Heart Assoc. 2019;8(12):e012356

Association between reductions of HbA1C and risk of MACE
$P = .002$

If all CVOTs had reduced HbA1c by 0.9%, MACE reduction would have been 33%

*CVOTs with DPP-4 inhibitors: SAVOR-TIMI 53 (saxagliptin), EXAMINE (alogliptin), TECOS (sitagliptin), CARMELINA (linagliptin); SGLT-2 inhibitors: EMPA-REG OUTCOME (empagliflozin), CANVAS (canagliflozin), DECLARE (dapagliflozin); GLP-1 RAs: ELIXA (lixisenatide), LEADER (liraglutide), SUSTAIN-6 (subcutaneous semaglutide), EXSCEL (once-weekly exenatide), HARMONY OUTCOMES (albiglutide).

CVOT, cardiovascular outcomes trial; HbA1c, glycated haemoglobin; MACE, major adverse cardiovascular event.

Quale target glicemico perseguire?

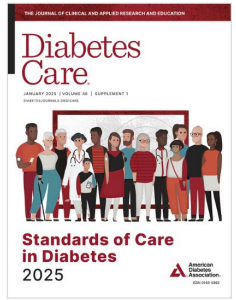
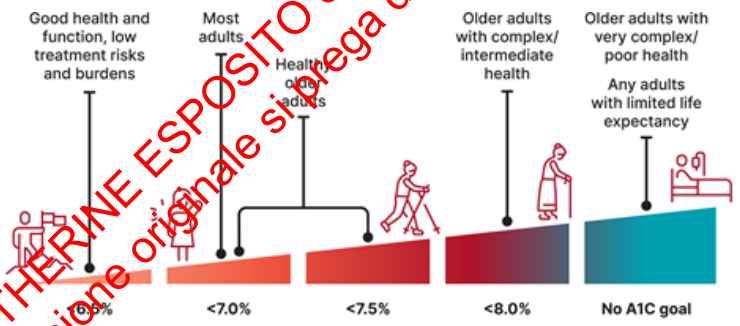


Table 6.3—Summary of glycemic goals for many nonpregnant adults with diabetes

A1C	<7.0% (<53 mmol/mol)*†
Preprandial capillary plasma glucose	80–130 mg/dL* (4.4–7.2 mmol/L)
Peak postprandial capillary plasma glucose‡	<180 mg/dL* (<10.0 mmol/L)



Modifying Factors

Favor more stringent goal	Favor less stringent goal
Short diabetes duration	Long diabetes duration
Low hypoglycemia risk	High hypoglycemia risk
Low treatment risks and burdens	High treatment risks and burdens
Pharmacotherapy with cardiovascular, kidney, weight, or other benefits	Pharmacotherapy without nonglycemic benefits
No cardiovascular complications	Established cardiovascular complications
Few or minor comorbidities	Severe, life-limiting comorbidities

Diabetes Care December 2024, Vol.48, S128-S145

Quale target glicemico perseguire?

SISTEMA NAZIONALE LINEE GUIDA DELL'ISTITUTO SUPERIORE DI SANITÀ

1. Obiettivi terapeutici

1.1 Si raccomanda un target di HbA1c tra 49 mmol/mol (6.6%) e 58 mmol/mol (7.5%) in pazienti con diabete di tipo 2 trattati con farmaci associati ad ipoglicemia.

1.2.1. Si raccomanda un target di HbA1c inferiore 53 mmol/mol (7%) in pazienti con diabete di tipo 2 trattati con farmaci non associati ad ipoglicemia.

1.2.2. Si suggerisce un target di HbA1c inferiore o uguale a 48 mmol/mol (6.5%) in pazienti con diabete di tipo 2 trattati con farmaci non associati ad ipoglicemia.

Linea Guida della Società Italiana di Diabetologia (SID) e dell'Associazione dei Medici Diabetologi (AMD)

La terapia del diabete mellito di tipo 2

Roma, 26 luglio 2021

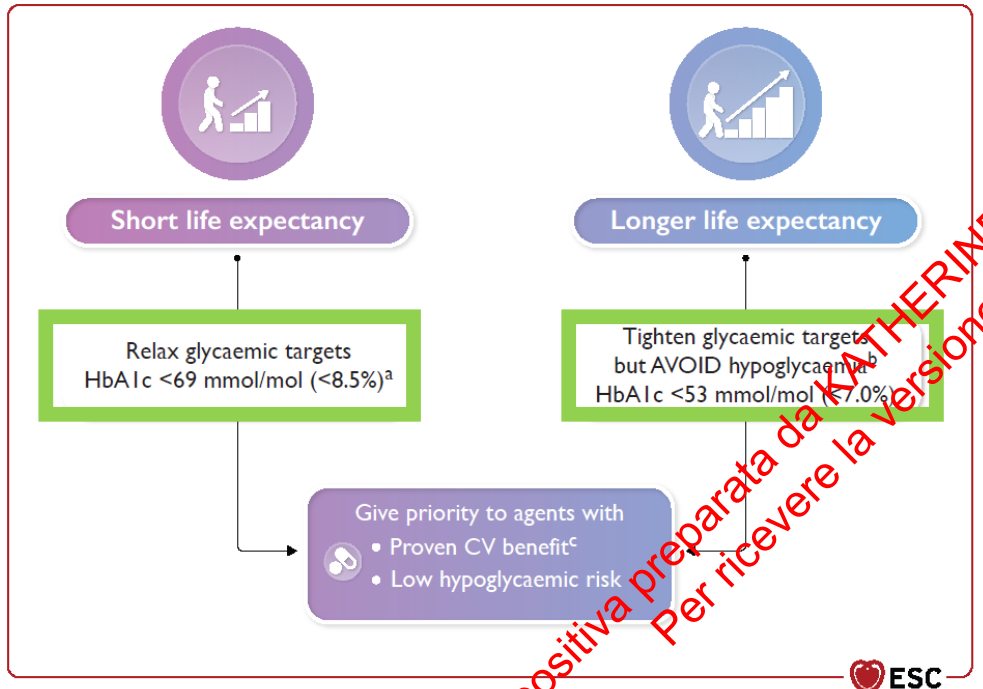
Aggiornamento 23 febbraio 2023

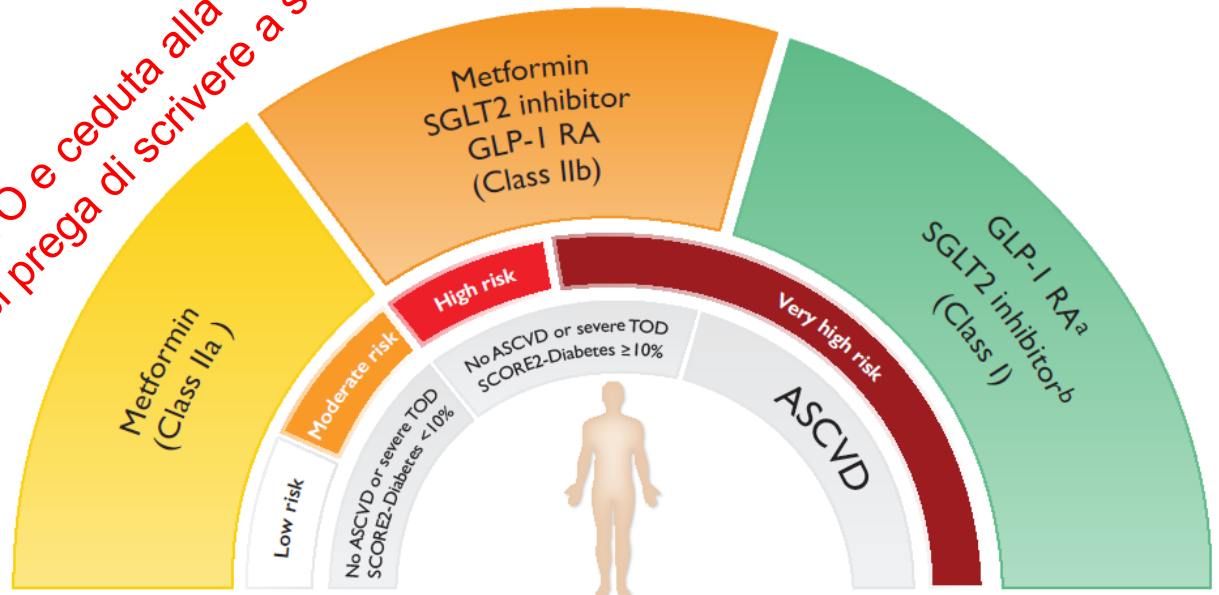
ESC European Society of Cardiology
European Heart Journal (2023) **44**, 4043–4140
https://doi.org/10.1093/eurheartj/ehad192

2023 ESC Guidelines for the management of cardiovascular disease in patients with diabetes

Recommendation Table 7 — Recommendations for glycaemic targets in patients with diabetes

Recommendations	Class[a]	Level[b]
It is recommended to apply tight glycaemic control (HbA1c <7%) to reduce microvascular complications.[126–128,133]	I	A
It is recommended to avoid hypoglycaemia, particularly in patients with CVD.[134–137,147]	I	B
It is recommended to individualize HbA1c targets according to comorbidities, diabetes duration, and life expectancy.[134,137]	I	C
Tight glycaemic control should be considered for reducing CAD in the long term, preferably using agents with proven CV benefit.[c,129–132]	IIa	B



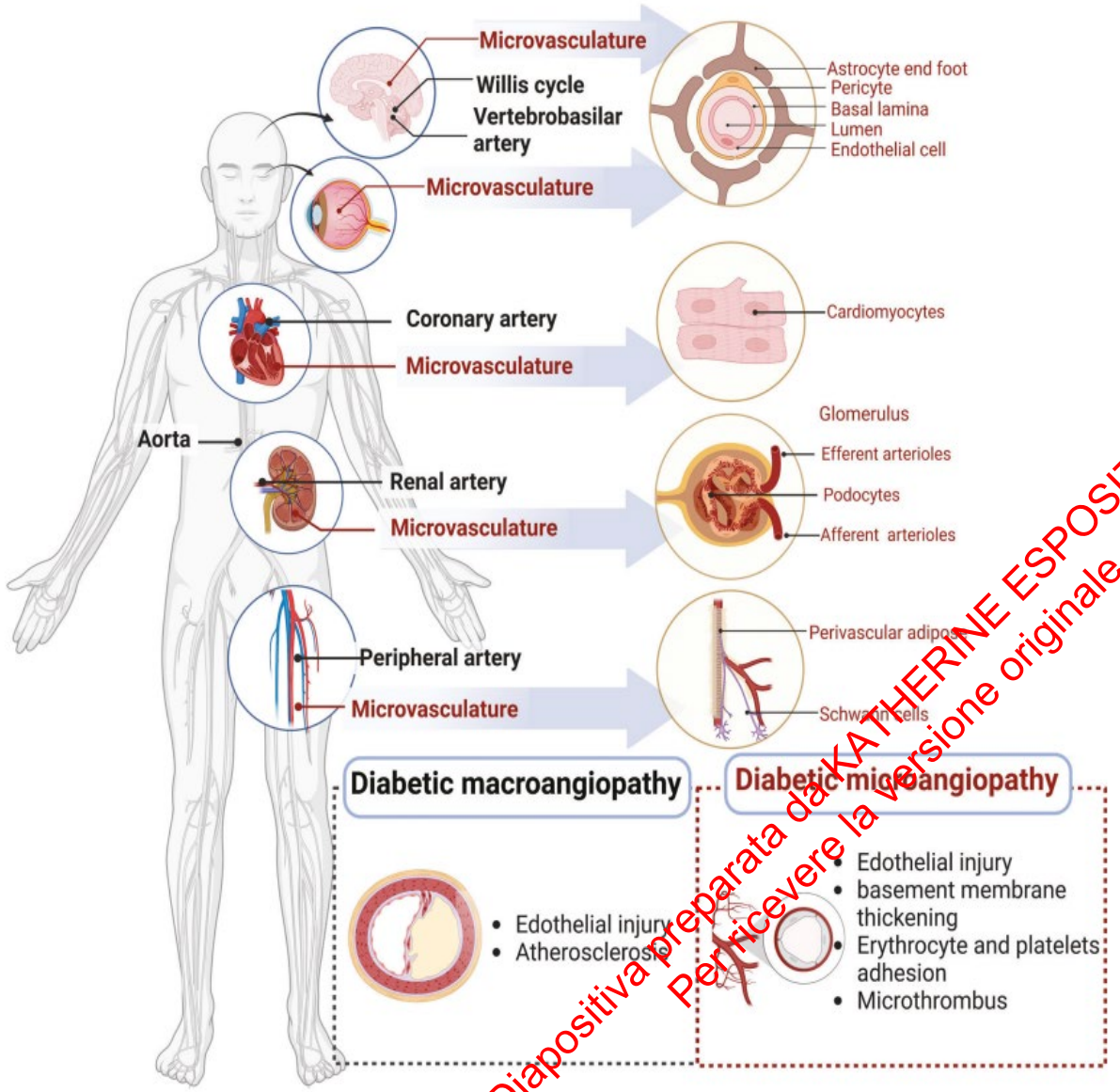


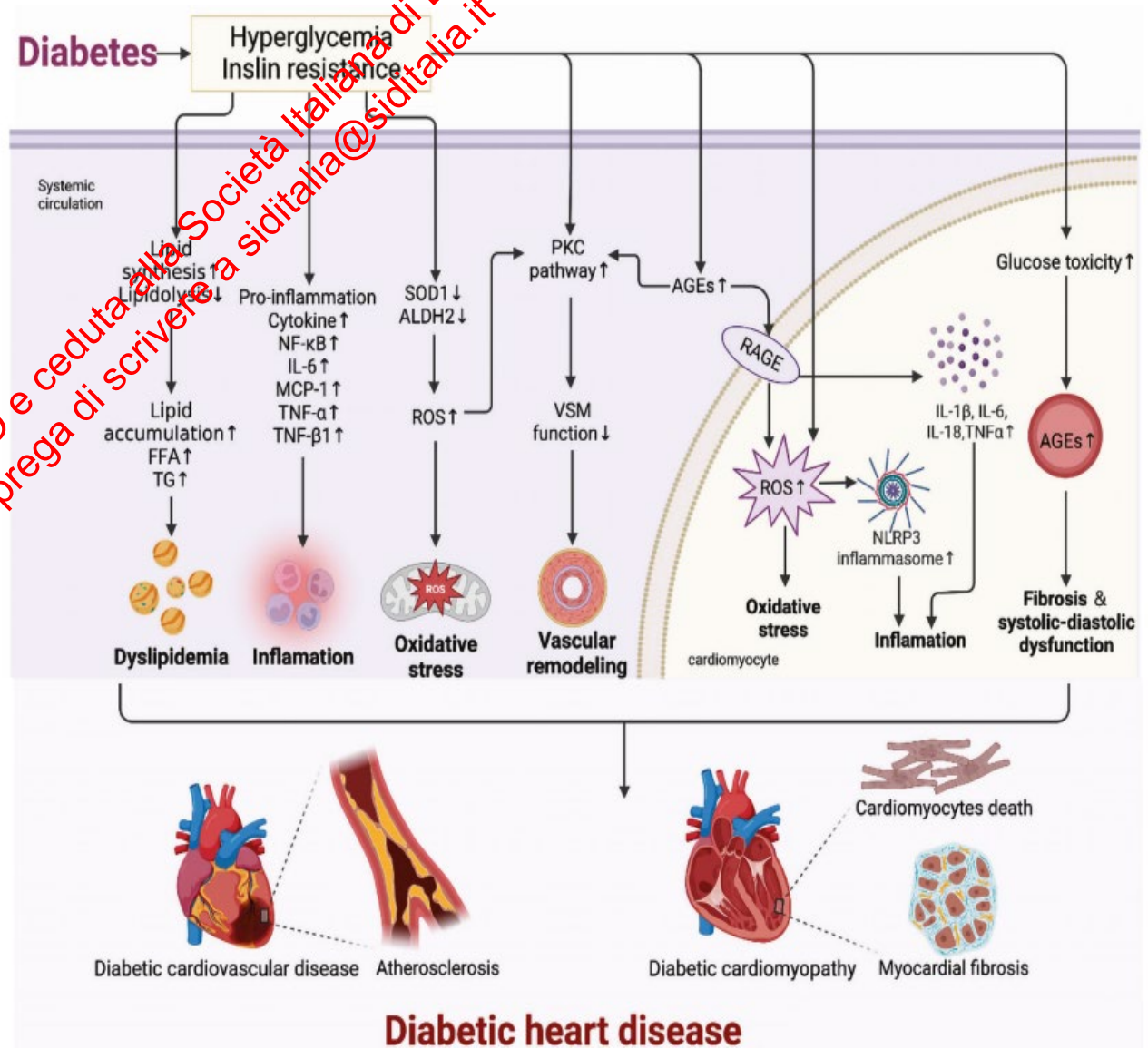
Risk assessment for patients with type 2 diabetes based on the presence of ASCVD/severe TOD and 10-year CVD risk estimation via SCORE2-Diabetes

ESC

Figure 4 Simple guide to glycaemic targets in patients with type 2 diabetes and cardiovascular disease. CV, cardiovascular; GLP-1 RA, glucagon-like peptide-1 receptor agonist; HbA1c, glycated haemoglobin, s.c., subcutaneous; SGLT2, sodium–glucose co-transporter-2. [a]Adjust target in the presence of hyperglycaemic symptoms (polyuria and polydipsia). [b]Hypoglycaemia is usually a concern only in those on a sulphonylurea and/or insulin. [c]SGLT2 inhibitors (empagliflozin, canagliflozin, dapagliflozin, sotagliflozin) or GLP-1 RAs (liraglutide, semaglutide s.c., dulaglutide, efpeglenatide).

IPERGLICEMIA



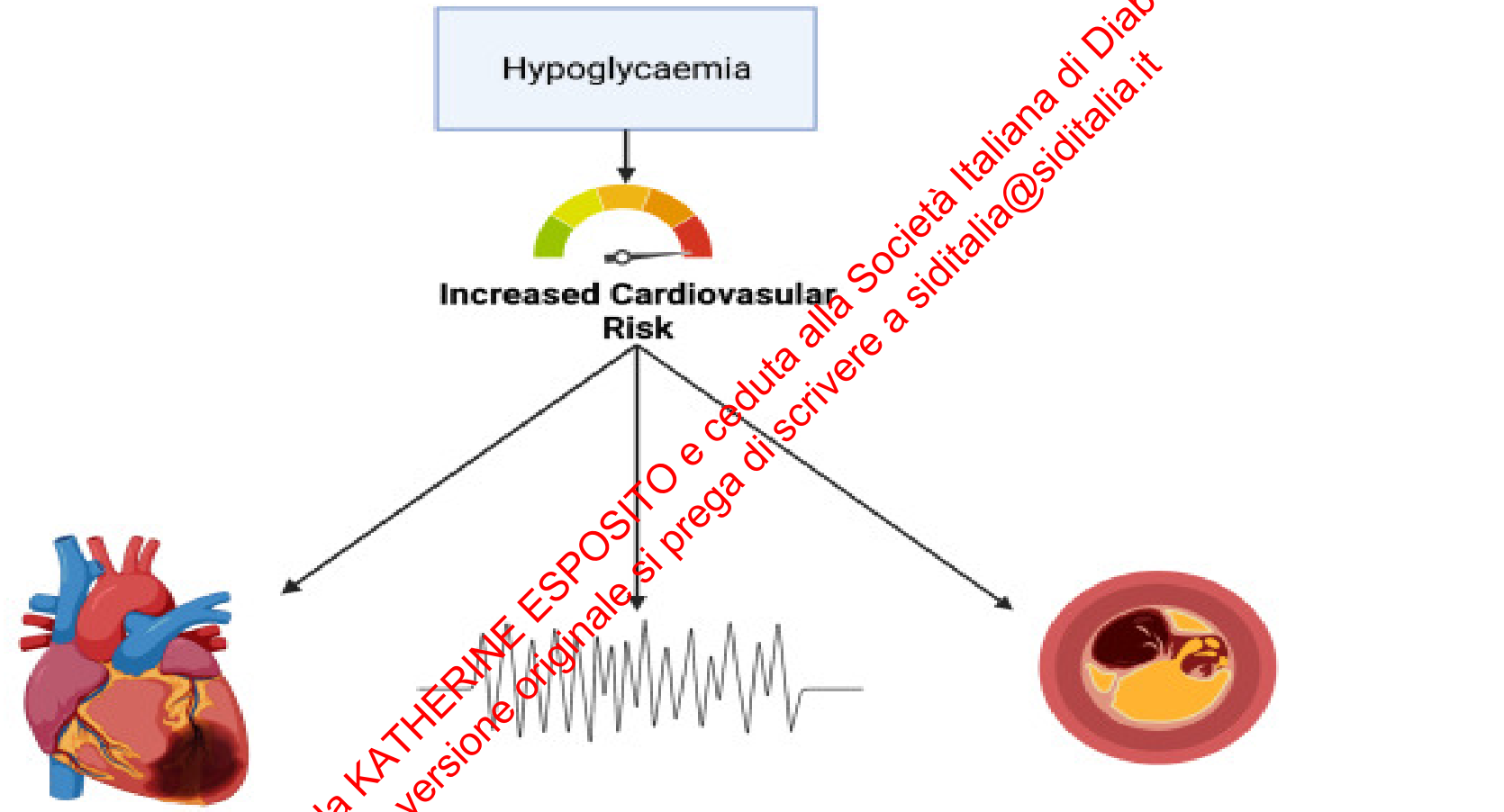


Signal Transduction and Targeted Therapy (2023) 8:152 ; https://doi.org/10.1038/s41392-023-01400-z

Study	Population	Design	Hypoglycaemia	CVD	All-cause mortality
DCCT/EDIC[9,10]	Patients with T1D aged 13–39 years ($N = 1441$)	Conventional treatment with 1–2 daily insulin injections *versus* intensive treatment with ⩾3 daily injections or insulin pump Mean follow up of 6.5 years	Threefold increase in severe hypoglycaemia in the intensive treatment group ($p < 0.001$)	No difference after the initial 6.5 years of follow-up. 57% reduction in in MACE ($p = 0.02$) after median follow up of 17 years	No difference between groups
UKPDS3[11,12]	Patients with newly diagnosed T2D ($N = 4209$)	Intensive treatment (metformin and SU/insulin) *versus* conventional therapy (primarily diet) Median follow up of 10 years	Two-fold increase in severe hypoglycaemia in the intensive treatment group ($p < 0.0001$)	No difference after the initial 10-years of follow up Significant reductions in both SU/insulin and metformin group after 10 years of post-trial follow up MI SU/insulin: RR 0.85 ($p = 0.01$) Metformin: RR 0.67 ($p = 0.005$) Stroke SU/insulin: RR 0.91 ($p = 0.6$) Metformin: RR 0.80 ($p = 0.35$)	No difference for insulin/SU group 36% reduction in the obese metformin group ($p = 0.01$) 13% ($p = 0.007$) and 17% ($p = 0.002$) reduction after 10 years of post-trial follow up
ACCORD[4]	Patients with T2D and established CVD (35%) or high CV risk ($N = 10,251$)	Intensive glycaemic control ($HbA_{1c} < 6.0\%$) *versus* standard therapy (HbA_{1c} 7.0–7.9%) All glucose-lowering therapies allowed. Discontinued after a mean follow up of 3.5 years	Percentage of patients experiencing at least one episode of severe hypoglycaemia 16.2 *versus* 5.1% ($p < 0.001$), respectively	MACE HR 0.90 ($p = 0.16$) CV mortality HR 1.35 ($p = 0.02$) Nonfatal MI HR 0.76 ($p = 0.004$) Nonfatal stroke HR 1.06 ($p = 0.74$) CV mortality remained significantly increased after a mean 7.7 years of follow up HR 1.20 ($p = 0.02$)	HR 1.22 ($p = 0.04$) All-cause mortality normalized after a mean of 7.7 years of follow up HR 1.01 ($p = 0.91$)
ADVANCE[13,14]	Patients with T2D and microvascular or macrovascular complication or ⩾1 risk factors ($N = 11,140$)	Intensive treatment ($HbA_{1c} < 6.5\%$) *versus* standard treatment. Median follow up of 5 years	Significant increase in severe hypoglycaemia in the intensive treatment group HR 1.86 ($p < 0.001$)	MACE HR 0.94 ($p = 0.37$) CV mortality HR 0.88 ($p = $ NS) Nonfatal MI HR 1.02 ($p = $ NS) Nonfatal stroke HR 0.98 ($p = $ NS) No effect observed after 5.4 years of post-trial follow up	HR 0.93 ($p = 0.28$) No effect observed after 5.4 years of post-trial follow up

Studio ACCORD: il controllo glicemico intensivo nei pazienti con diabete ha portato a un aumento significativo della mortalità totale, in particolare con un +35% di mortalità cardiovascolare rispetto alla terapia standard. Questo risultato ha determinato l'interruzione precoce dello studio. Entrambi i gruppi ricevevano insulina, sulfaniluree, metformina e tiazolidinedioni.

IPOGLICEMIA



Doi: 10.1016/B978-0-323-85732-1.00028-1
In book: Metabolic Syndrome January 2024

Lancet Diabetes Endocrinol 2019; 7: 385–96

Hypoglycaemia, cardiovascular disease, and mortality in diabetes: epidemiology, pathogenesis, and management

*The International Hypoglycaemia Study Group**

Associazione di severa ipoglicemia con il rischio di outcome clinico avverso o morte

	Severe hypoglycaemia (n=231)	No severe hypoglycaemia (n=10 909)	Hazard ratio (95% CI)
Major macrovascular events	33 (11·5%)	1114 (10·2%)	3·53 (2·41–5·17)
Major microvascular events	24 (10·4%)	1107 (10·1%)	2·19 (1·40–3·45)
Death from any cause	45 (19·5%)	986 (9·0%)	3·27 (2·29–4·65)
Cardiovascular disease	22 (9·5%)	520 (4·8%)	3·79 (2·36–6·08)
Non-cardiovascular disease	23 (10·0%)	466 (4·3%)	2·80 (1·64–4·79)

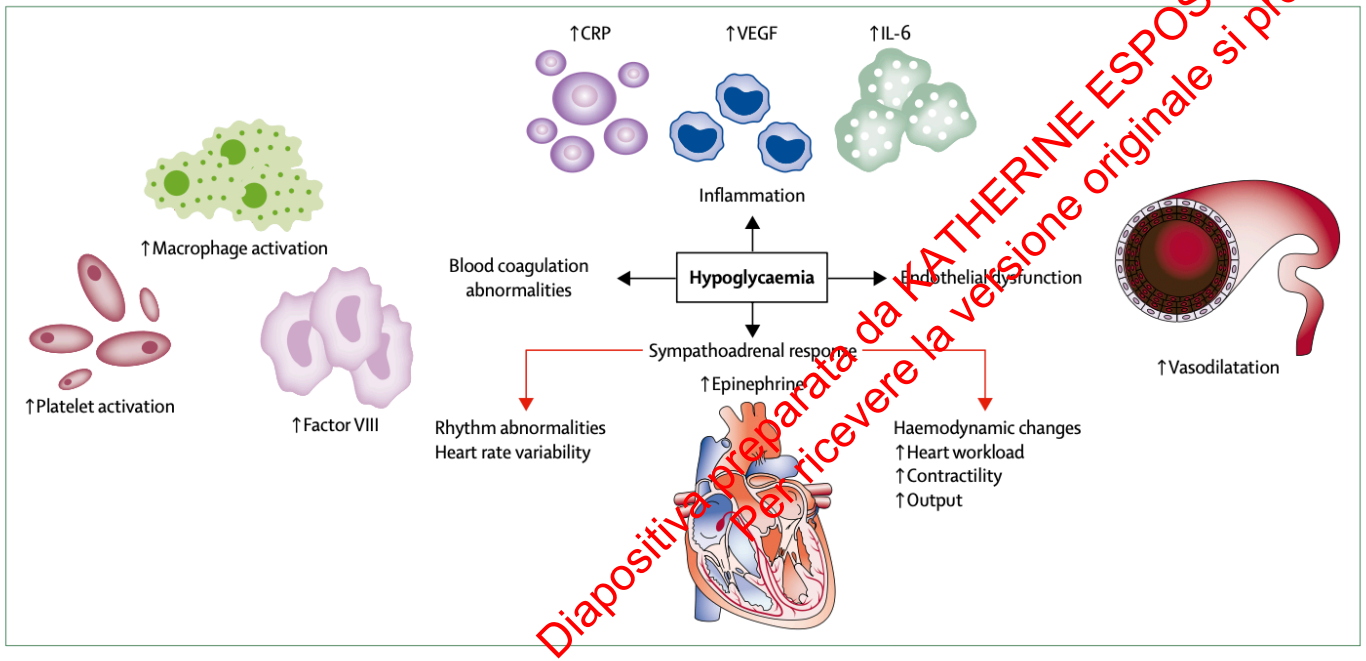


Figure 2: **Pathophysiological cardiovascular consequences of hypoglycaemia**

Ipoglicemia è un fattore di rischio cardiovascolare

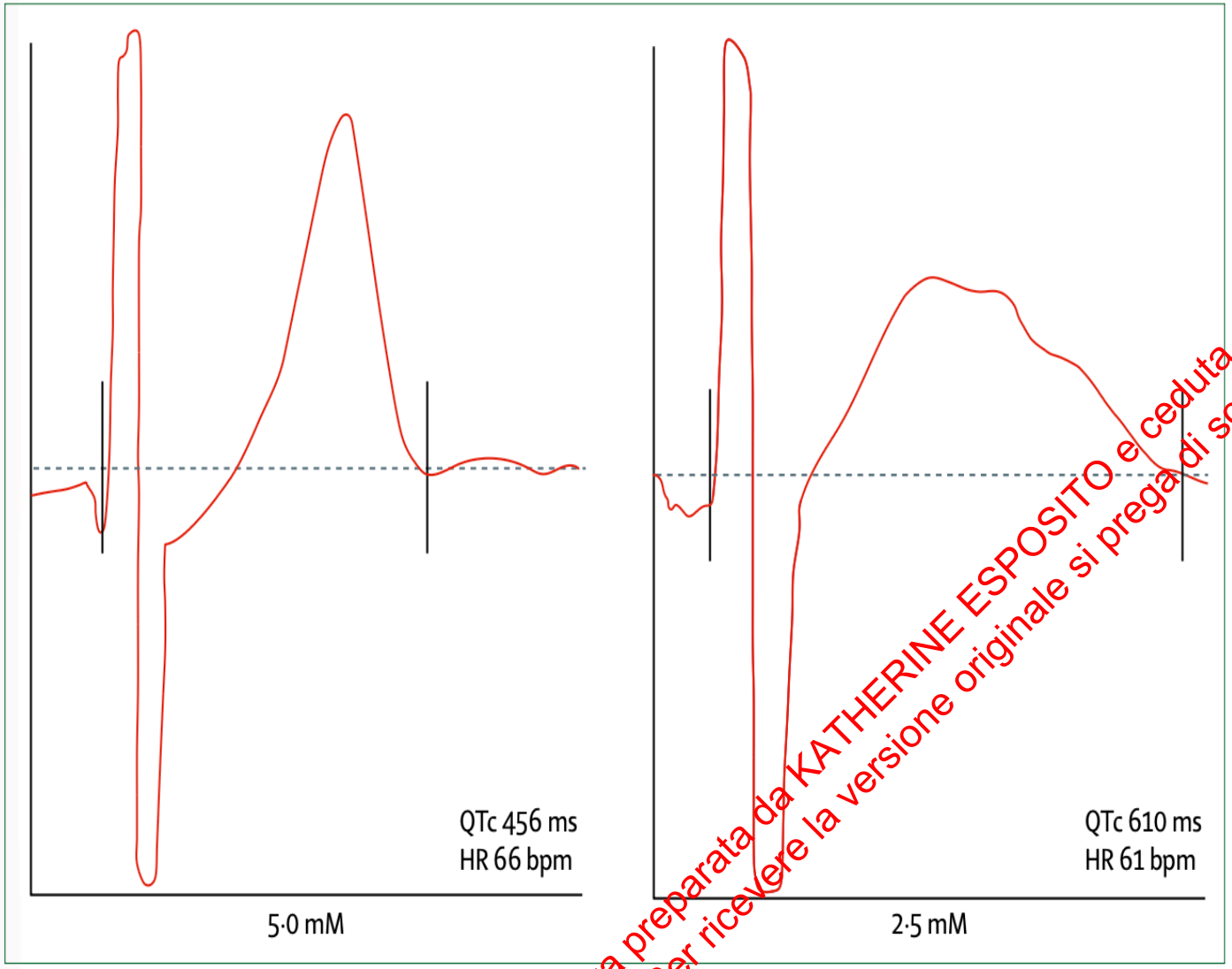
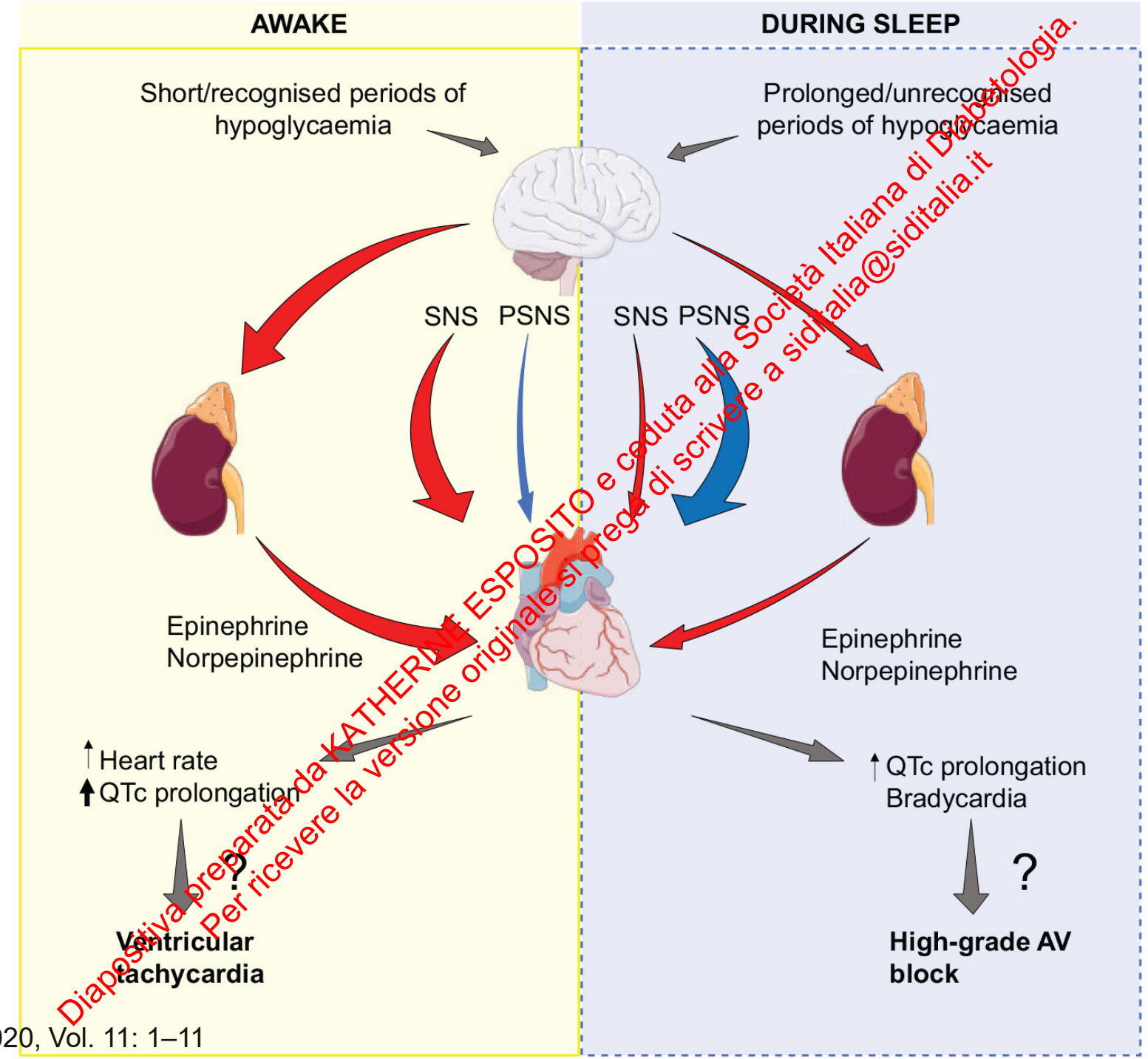


Figure 4: **Abnormal cardiac repolarisation during experimental hypoglycaemia**

Misurazione tipica dell'intervallo QT che mostra un'onda T ben definita durante l'euglicemia (a sinistra), e durante ipoglicemia (destra), che evidenzia una ripolarizzazione prolungata e un'onda U prominente. Riprodotto da Marques et al.70, con autorizzazione di John Wiley & Sons. HR = frequenza cardiaca. QTc = QT corretto.

Lancet Diabetes Endocrinol 2019; 7: 385–96



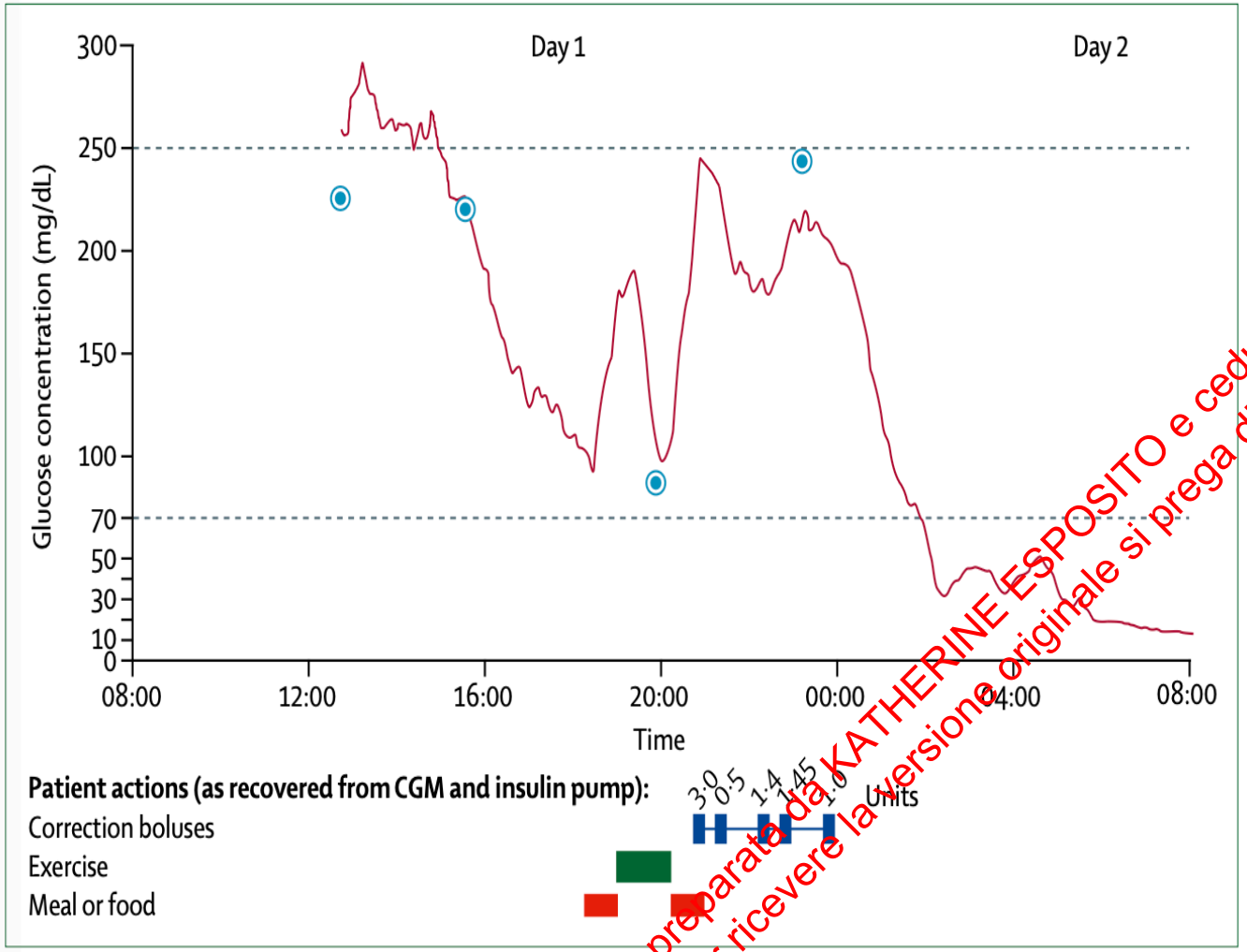


Figure 3: **Continuous glucose monitoring trace showing sudden death during hypoglycaemia**

Il grafico mostra le concentrazioni di glucosio registrate da un sistema CGM nella sera precedente e nella mattina del decesso di un paziente. Le calibrazioni misurate e inserite dal paziente sono rappresentate dai quattro cerchi. L'orario dei pasti, dell'attività fisica e dei boli correttivi di insulina è indicato dalle barre nella parte inferiore del grafico. Riprodotto da Tanenberg et al., con autorizzazione dell'American Association of Clinical Endocrinologists.

Lancet Diabetes Endocrinol 2019; 7: 385–96

Severe Hypoglycemia, Cardiac Structure and Function, and Risk of Cardiovascular Events Among Older Adults With Diabetes

Justin B. Echouffo-Tcheugui,[1] Natalie Daya,[2] Alexandra K. Lee,[3] Olive Tang,[2] Chiadi E. Ndumele,[4] B. Gwen Windham,[5] Amil M. Shah,[6] and Elizabeth Selvin[2]

Diabetes Care 2021;44:248–254 | https://doi.org/10.2337/dc20-0552

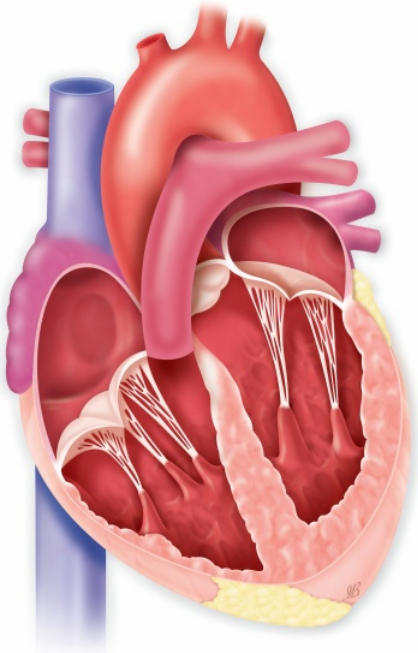
Table 2—Adjusted measures of association for severe hypoglycemia with indices of cardiac structure and function: ARIC visit 5 adults with diagnosed diabetes (2011–2013)

	β-Coefficient or odds ratio (95% CI)		
Indices of cardiac structure and function	Model 1	Model 2	Model 3
LV structure measures			
LVEDD, cm	0.17 (0.04, 0.30)	0.15 (0.02, 0.29)	0.10 (−0.03, 0.24)
Interventricular septum, cm	0.04 (−0.01, 0.08)	0.03 (−0.02, 0.07)	0.01 (−0.03, 0.06)
Mean wall thickness, cm	0.04 (−0.01, 0.08)	0.02 (−0.01, 0.06)	0.01 (−0.03, 0.05)
LV mass, g	21.03 (9.22, 32.84)	17.65 (5.63, 29.66)	10.94 (−1.19, 23.08)
Relative wall thickness	0.00 (−0.02, 0.02)	−0.00 (−0.03, 0.02)	−0.01 (−0.03, 0.02)
LVH*	0.99 (0.40, 2.47)	0.79 (0.31, 2.02)	0.73 (0.28, 1.91)
Ventricular systolic function			
LVEF, %	−3.66 (−5.54, −1.78)	−3.31 (−5.22, −1.39)	−2.93 (−4.86, −1.01)
LVEDV, mL	14.80 (8.77, 20.84)	12.76 (6.62, 18.90)	11.75 (5.49, 18.01)
LVESV, mL	12.02 (8.10, 15.93)	10.78 (6.79, 14.76)	9.79 (5.76, 13.83)
GLS, %	0.85 (0.13, 1.57)	0.77 (0.04, 1.50)	0.63 (−0.11, 1.36)
RVFAC	−0.03 (−0.05, −0.01)	−0.03 (−0.05, −0.01)	−0.03 (−0.05, −0.01)
PASP, mmHg	1.72 (−0.68, 4.12)	1.01 (−1.44, 3.46)	−0.03 (−2.54, 2.47)
LV diastolic function measures			
LA volume, mL	5.61 (0.69, 10.53)	4.83 (−0.18, 9.85)	2.98 (−2.08, 8.05)
E wave, cm/s	2.83 (−2.41, 8.07)	0.74 (−4.58, 6.06)	−0.85 (−6.30, 4.60)
E-to-A ratio	0.11 (0.03, 0.18)	0.10 (0.03, 0.18)	0.07 (−0.01, 0.15)
e′ septal, cm/s	−0.39 (−0.77, −0.01)	−0.30 (−0.68, 0.09)	−0.28 (−0.68, 0.12)
E/e′ septal	2.48 (1.13, 3.82)	1.82 (0.46, 3.18)	1.37 (−0.01, 2.75)

Model 1, adjustment for age, sex, and race/center; model 2, adjustment for variables in model 1 + diabetes duration; model 3, adjustment for variables in model 2 + prevalent CVD and hs-cTnT (categorized as ≤90th percentile and below). PASP, pulmonary artery systolic pressure. *Estimates are odds ratios for the presence vs. absence of LVH as the reference group (null value = 1).

- **Popolazione:** 2.193 anziani con diabete (studio ARIC, età media 76 anni).
- **Severe hypoglycemia (SH):**
- **SH associata a peggior funzione cardiaca (↓ FE, ↑ volumi ventricolari, ↑ markers diastolici).**
- **SH → rischio ↑ di CVD (IRR 2.19) e mortalità totale (HR 1.71).**

La storia di SH è un marker indipendente di disfunzione cardiaca e maggiore rischio cardiovascolare negli anziani con diabete.

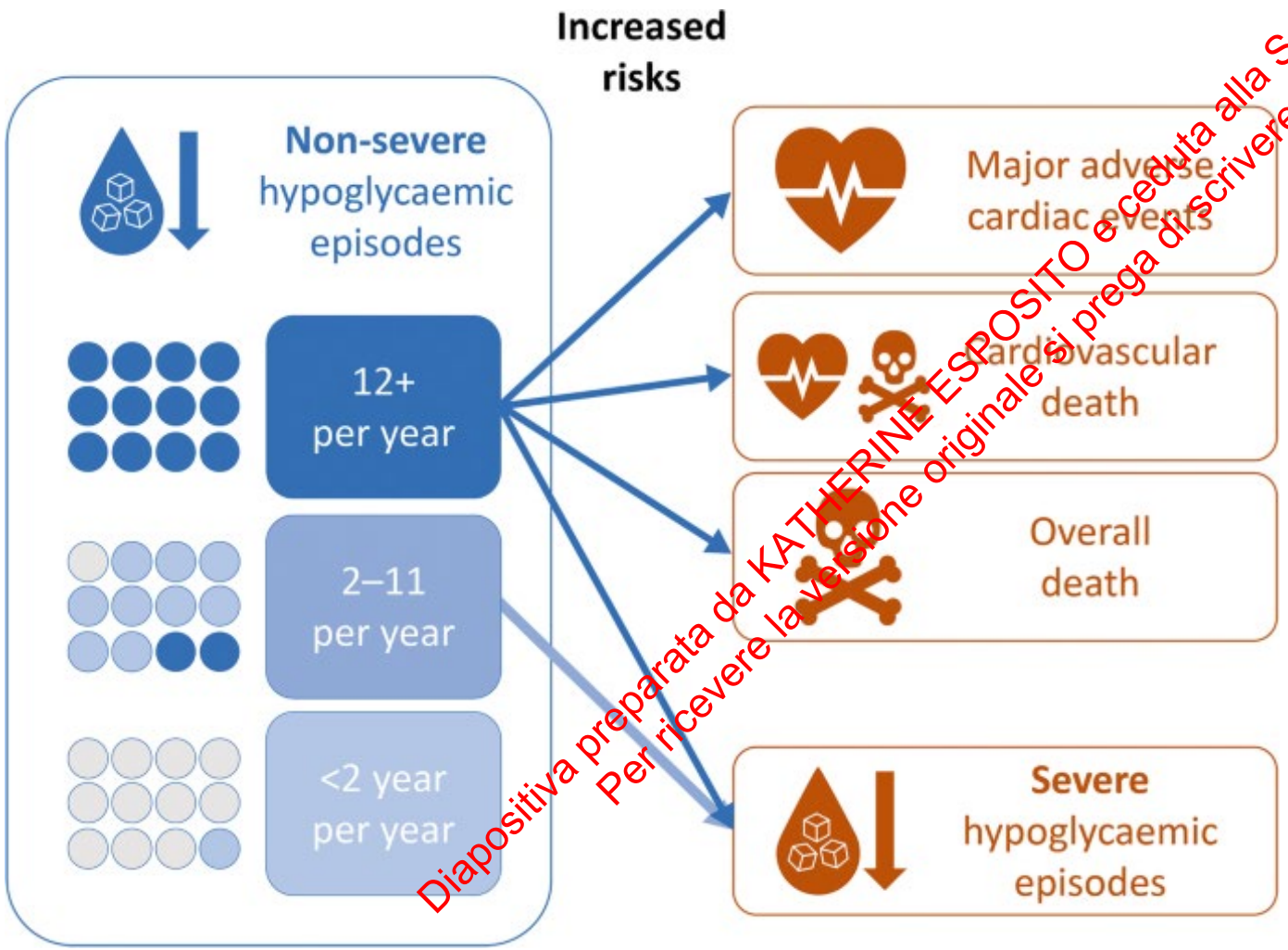


Diabetologia (2022) 65:55–64
https://doi.org/10.1007/s00125-021-05556-7

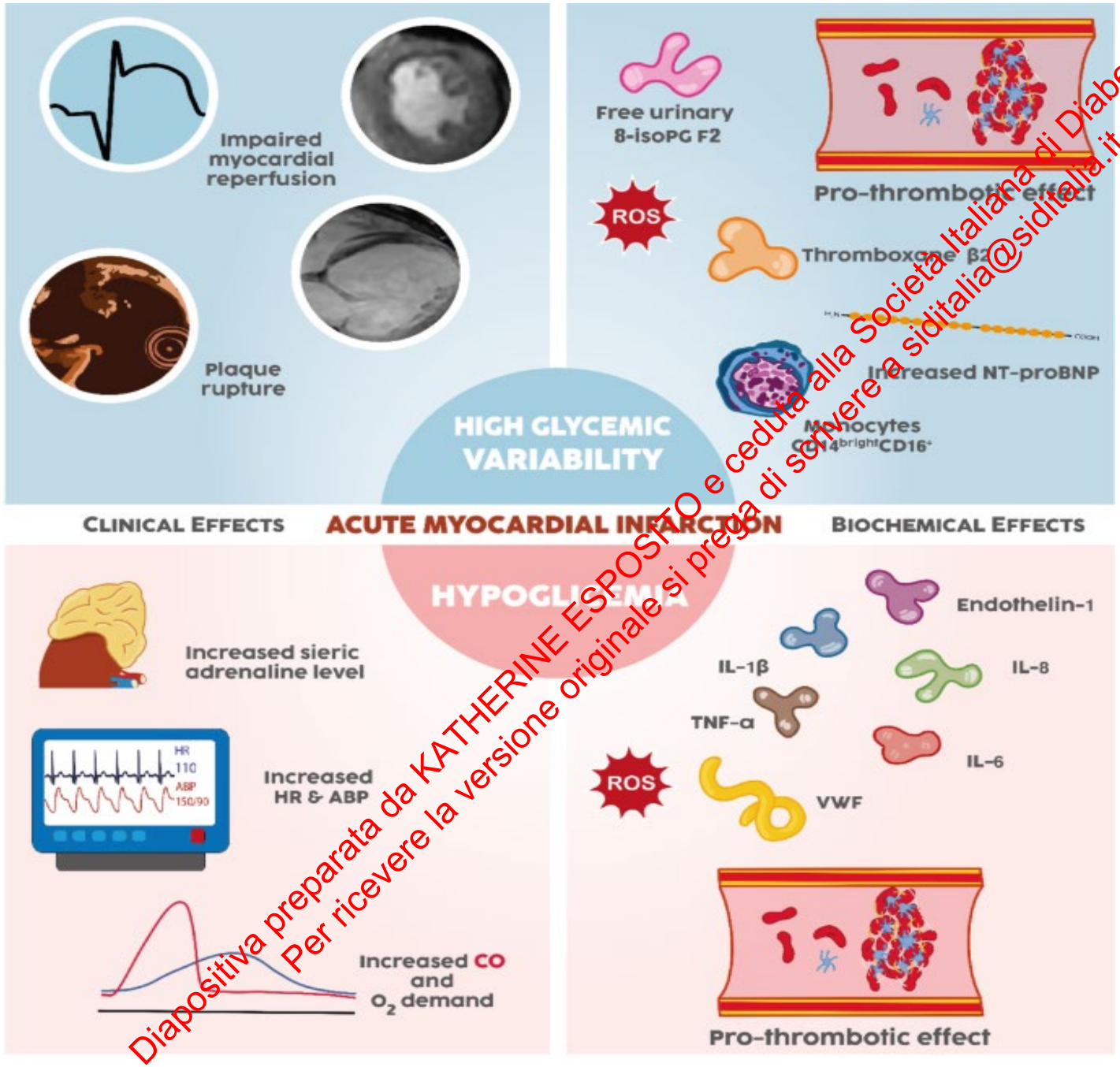
ARTICLE

A higher non-severe hypoglycaemia rate is associated with an increased risk of subsequent severe hypoglycaemia and major adverse cardiovascular events in individuals with type 2 diabetes in the LEADER study

Simon R. Heller[1] · Milan S. Geybels[2] · Ahmed Iqbal[1] · Lei Liu[2] · Lily Wagner[2] · Elaine Chow[1,3]



Esiste un'associazione tra gli episodi ipoglicemici non severi (NSHEs: 2–11 all'anno e ≥12 all'anno) e gli episodi ipoglicemici severi (HR non aggiustati 1,98 [IC 95% 1,43–2,75] e 5,01 [IC 95% 2,84–8,84], rispettivamente), associazione che rimaneva significativa anche dopo l'aggiustamento per le caratteristiche basali. Inoltre, mentre non è stata rilevata alcuna associazione tra 2–11 NSHEs/anno e outcome cardiovascolari avversi, un numero più elevato di NSHEs (≥12/anno) è risultato associato a un maggior rischio di MACE (HR 1,50 [IC 95% 1,01–2,23]), morte cardiovascolare (HR 2,08 [IC 95% 1,17–3,70]) e mortalità totale (HR 1,80 [IC 95% 1,11–2,92]).

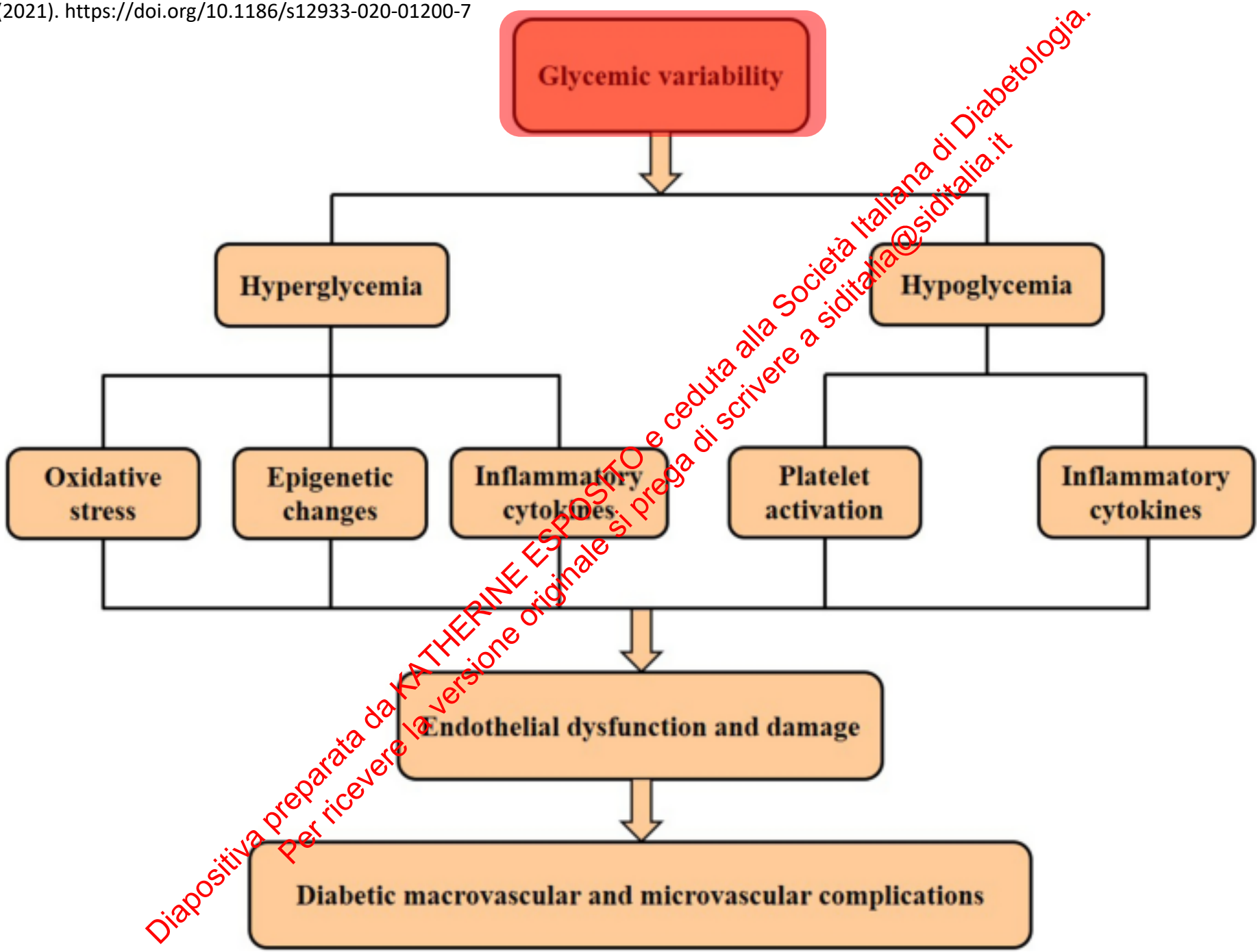


↑ Stress ossidativo
↑ Citochine infiammatorie
Disfunzione endoteliale
Alterazioni autonomiche
Vie pro-trombotiche

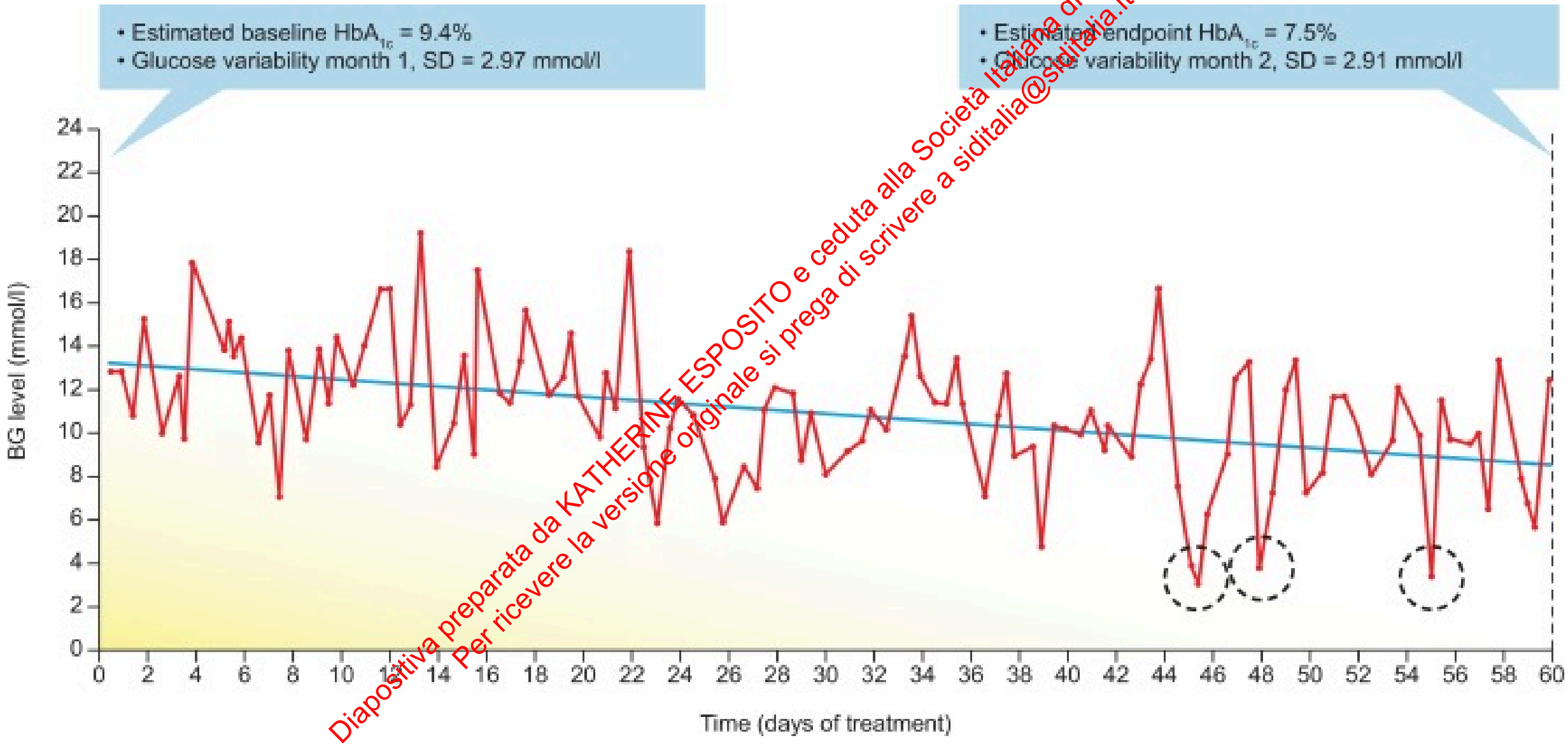
→ danno miocardico, instabilità di placca, compromissione omeostasi vascolare → ↑ rischio cardiovascolare

Cardiovascular Diabetology **volume 24**, Article number: 309 (2025)

Cardiovasc Diabetol 20, 9 (2021). https://doi.org/10.1186/s12933-020-01200-7



GLUCOSE VARIABILITY



Am J Med Sci. 2018 Dec;356(6):518-527.

Review
Type 1 Diabetes
Diabetes Metab J 2020;44:828-839
https://doi.org/10.4093/dmj.2020.0257
pISSN 2233-6079 · eISSN 2233-6087

dmj
DIABETES & METABOLISM JOURNAL
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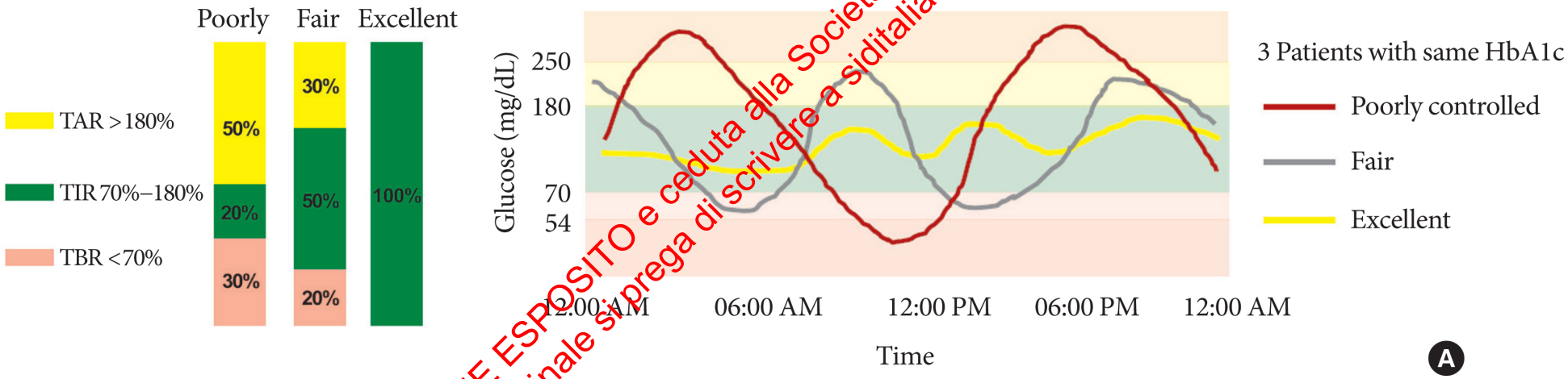
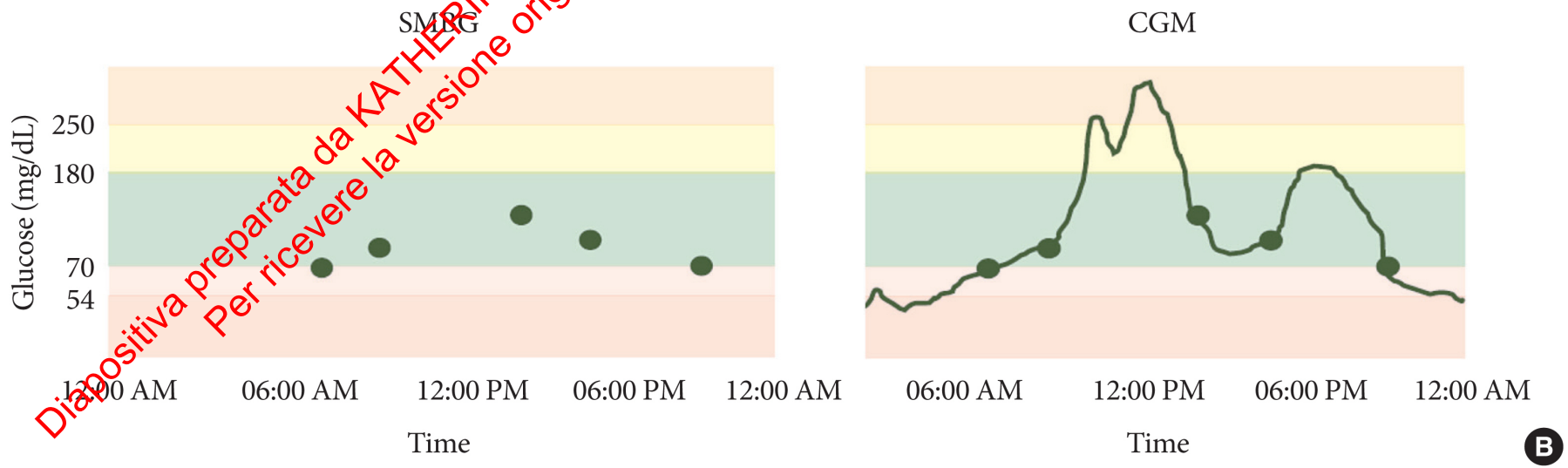
Time in Range from Continuous Glucose Monitoring: A Novel Metric for Glycemic Control

Jee Hee Yoo[1], Jae Hyeon Kim[2]





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)

Diabetes Care 2021;44:2589–2625 | https://doi.org/10.2337/dci21-0043

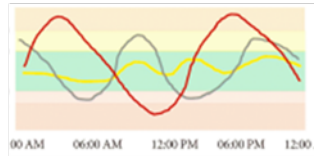
Table 1—Glycemic targets for most adults with type 1 diabetes

Variable	Target value
HbA_{1c}	<53 mmol/mol (<7.0%)
GMI	<53 mmol/mol (<7.0%)
Preprandial glucose	4.4–7.2 mmol/L (80–130 mg/dL)
1–2 h postprandial glucose[a]	<10.0 mmol/L (<180 mg/dL)
TIR	>70%
TBR	
Readings and time <3.9 mmol/L (<70 mg/dL; level 1 and level 2 hypoglycemia)[b]	<4%
Readings and time <3.0 mmol/L (<54 mg/dL; level 2 hypoglycemia)[b]	<1%
Time above range	
Readings and time >10.0 mmol/L (>180 mg/dL; level 1 and level 2 hyperglycemia)[c]	<25%
Readings and time >13.9 mmol/L (>250 mg/dL; level 2 hyperglycemia)[c]	<5%
Glycemic variability (%CV)[d]	≤36%

American Diabetes Association

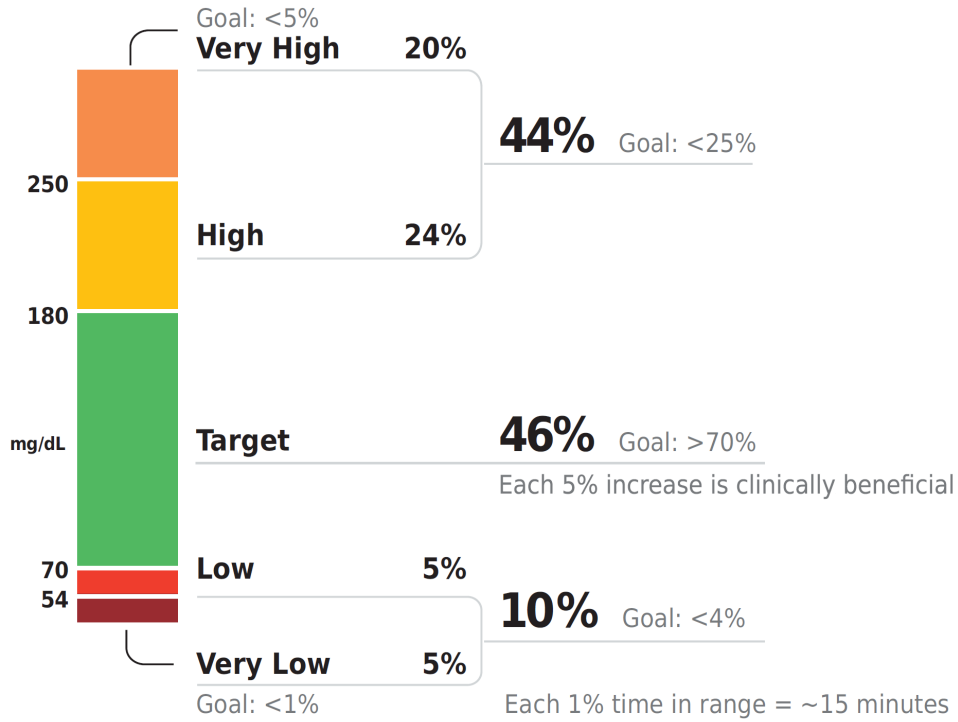
EASD
European Association for the Study of Diabetes

Glucose variability

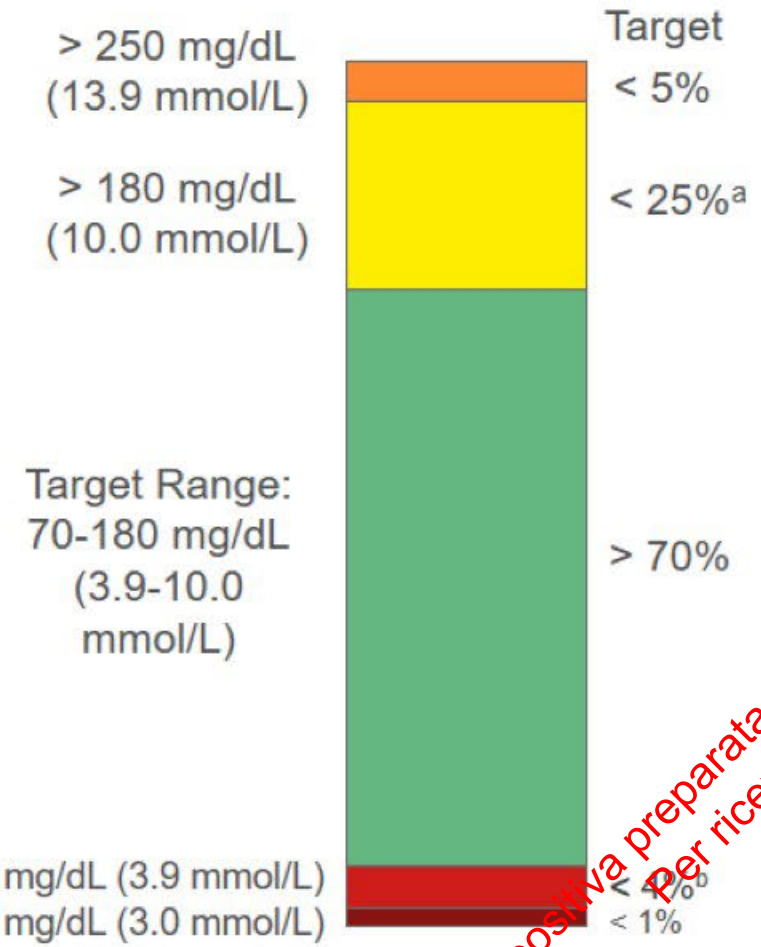


AGP Report: Continuous Glucose Monitoring

Time in Ranges Goals for Type 1 and Type 2 Diabetes



CGM-Based Targets for T1D[a] and T2D International Consensus



Aiming for this glucose target in most patients with diabetes

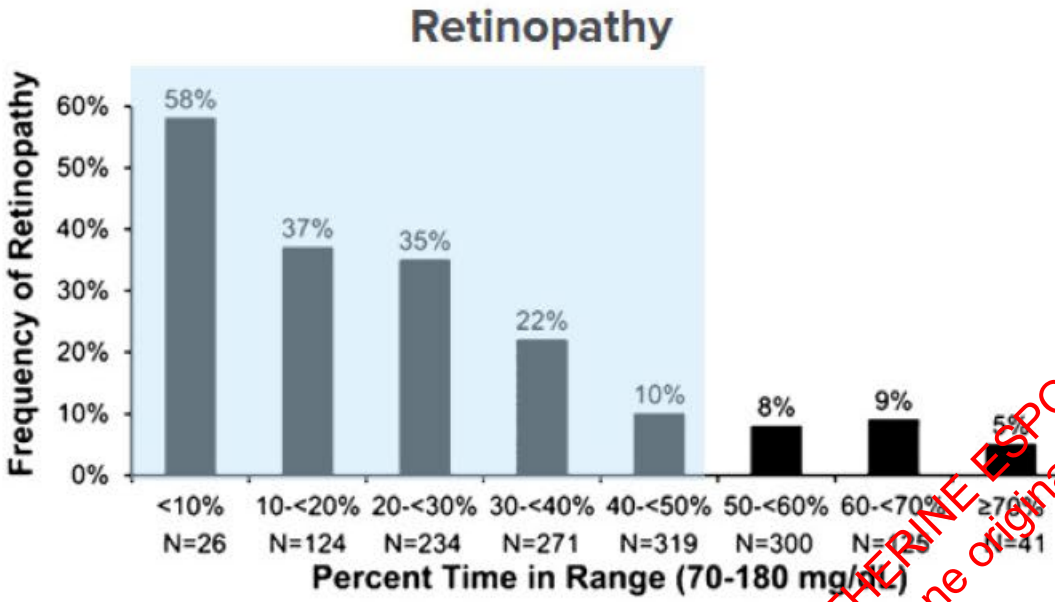
TAR
Time Above Range
Level 1 Hyperglycemia: 180-250 mg/dL
Level 2 Hyperglycemia: > 250 mg/dL

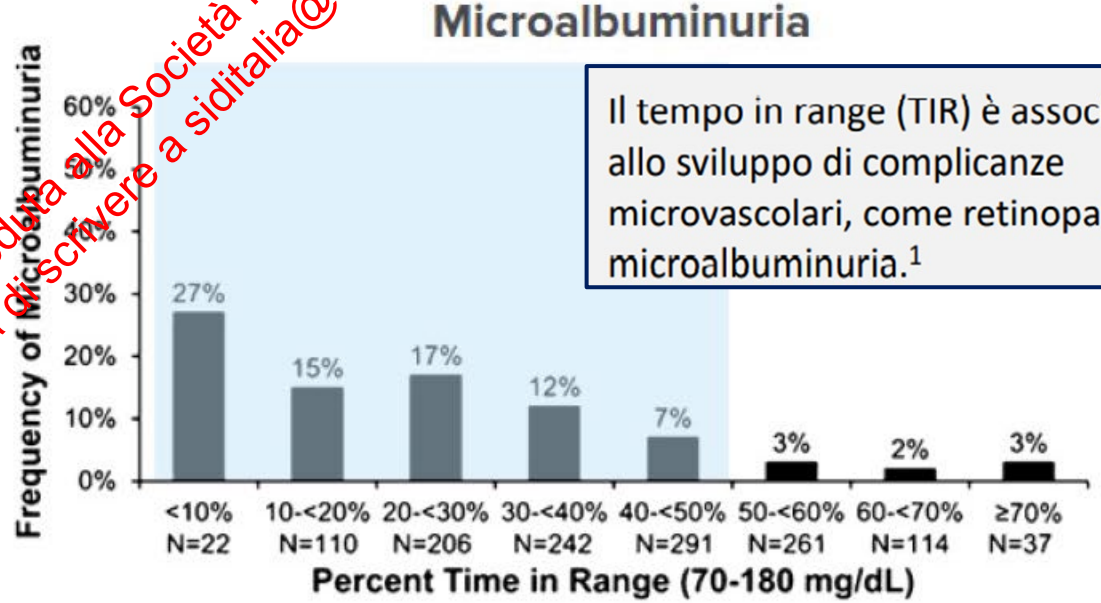
TIR
Time in Range 70-180 mg/dL

TBR
Time Below Range
Level 1 Hypoglycemia: 54-70 mg/dL
Level 2 Hypoglycemia: < 54 mg/dL

[a]For age <25 y, if the HbA1c goal is 7.5%, then set TIR target to approximately 60%; [b]Includes % of values >250 mg/dL (13.9 mmol/L).
T1D, type 1 diabetes; TAR, time above range; TBR, time below range; TIR, time in range.
Battelino T, et al. Diabetes Care. 2019;42:1593-1603.

TIR ≤ 50% confers greater risk of complications in patients with T1D or T2D

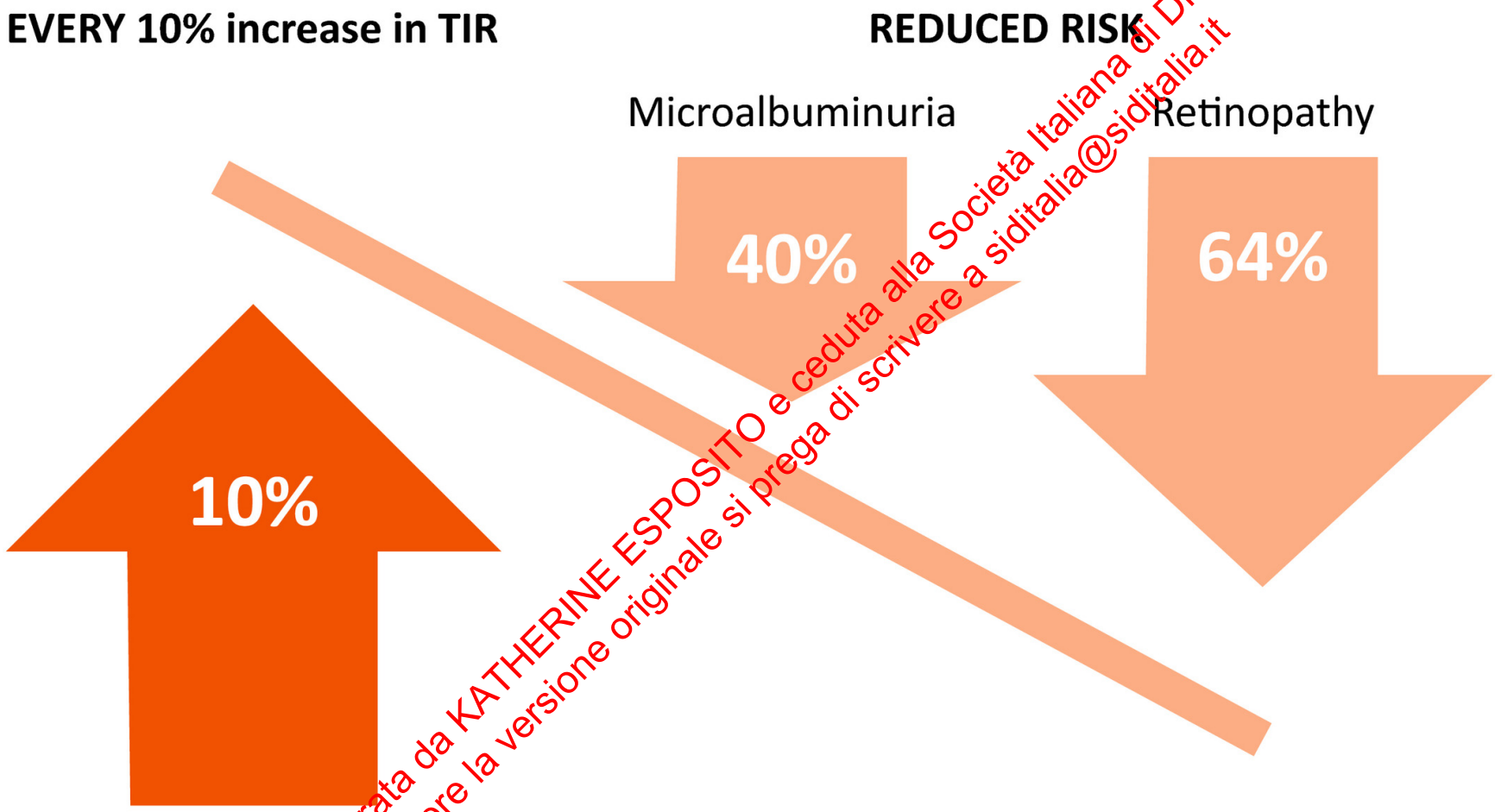




Il tempo in range (TIR) è associato allo sviluppo di complicanze microvascolari, come retinopatia e microalbuminuria.[1]

TIR	*N*	*N* (%) with outcome	Unadjusted HR (95% CI)*	Adjusted HR (95% CI)†	*N*	*N* (%) with outcome	Unadjusted HR (95% CI)*	Adjusted HR (95% CI)†
Overall								
≥50%	466	36 (8)	1.00	1.00	412	10 (2)	1.00	1.00
40 to <50%	319	32 (10)	1.54 (0.94–2.55)	1.61 (0.97–2.65)	291	20 (7)	2.44 (1.05–5.67)	2.40 (1.03–5.58)
30 to <40%	271	59 (22)	3.38 (2.22–5.15)	3.37 (2.20–5.15)	242	29 (12)	4.74 (2.16–10.40)	4.39 (2.01–9.58)
<30%	384	144 (38)	6.23 (4.25–9.13)	6.93 (4.69–10.24)	338	57 (17)	6.68 (3.35–13.29)	6.98 (3.49–13.96)

Beck RW, et al. Diabetes Care. 2019;42:400-405.



Adapted from: Beck RW et al. *Diabetes Care* 2018;42:400–405; Lu J et al. *Diabetes Care* 2018;41:2370–2376

Diabetic Medicine, Volume: 38, Issue: 1, First published: 19 October 2020,

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

Table 2—HRs for all-cause and cardiovascular mortality according to different levels of TIR

	TIR					
	>85%	71–85%	51–70%	≤50%	*P* for trend	TIR as a continuous variable (each 10% decrease)
All-cause mortality						
Number of participants	1,446	1,480	1,637	1,452		
Number of deaths	126	185	219	308		
Person-years	10,704.8	10,708.6	11,493.0	11,300.4		
Adjusted HRs (95% CIs)						
Model 1	1.00	1.26 (1.01–1.59)	1.39 (1.12–1.74)	1.98 (1.60–2.44)	<0.001	1.10 (1.07–1.13)
Model 2	1.00	1.23 (0.98–1.55)	1.30 (1.04–1.63)	1.83 (1.48–2.28)	<0.001	1.08 (1.05–1.12)
Cardiovascular mortality						
Number of deaths	37	64	81	105		
Adjusted HRs (95% CIs)						
Model 1	1.00	1.43 (0.95–2.14)	1.66 (1.12–2.45)	2.15 (1.47–3.13)	<0.001	1.08 (1.03–1.13)
Model 2	1.00	1.35 (0.90–2.00)	1.47 (0.99–2.19)	1.85 (1.25–2.72)	0.015	1.05 (1.00–1.11)

Model 1 adjusted for age and sex; model 2 adjusted for age, sex, smoking, diabetes duration, BMI, systolic blood pressure, triglycerides, HDL cholesterol, LDL cholesterol, history of cancer, history of CVD, and use of antihypertensive drugs, aspirin, and statins.

Obiettivo dello studio: Indagare l'associazione tra TIR e mortalità per tutte le cause e per causa cardiovascolare in soggetti con diabete di tipo 2.

Conclusioni: Questo studio prospettico ha dimostrato un'associazione inversa tra TIR e mortalità per tutte le cause e per causa cardiovascolare in soggetti con diabete tipo 2.

Commento: **Si dimostra la validità del TIR come marker surrogato di outcome avversi a lungo termine in soggetti con diabete di tipo 2**. Sono noti infatti i limiti dell'affidabilità dell'HbA1c in alcune condizioni (anemia, emoglobinopatie, gravidanza..). Inoltre, l'HbA1c non da informazioni in merito alla variabilità glicemica, all'ipo- ed iperglicemie. Il TIR risulta quindi complementare all'HbA1c nel fornirci informazioni sul controllo glicemico dell'individuo**>**

I principali indici di variabilità glicemica

TABLE 1 The main indices of glycaemic variability (GV).

Index	Units	Definition	Interpretation	Remarks
SD	mmol/L (mg/dL)	'Standard deviation' of mean glucose concentrations	Short-term within-day glucose variability	Dispersion of glucose data. Highly influenced by mean glucose (higher glucose = higher SD)
CoV	%	'Coefficient of variation' of mean glucose (% SD/mean glucose)	Short-term within-day glucose variability	Dispersion of glucose values corrected for mean glucose
IQR	mmol/L (mg/dL)	'Interquartile range' calculated from AGP at a given time point. It can be corrected for median glucose and presented as IQR/med (%)	Short-term within-day glucose variability	Measure of glucose variation at a given time point over several days
MAGE	mmol/L (mg/dL)	'Mean amplitude of glucose excursions' represents the difference between peaks and troughs of glucose fluctuations. Can also be corrected for mean glucose and presented as MAG/m (%)	Short-term within-day glucose variability	Capture mealtime glucose excursions. Calculations can be subjective and differ depending on whether ascending or descending glucose limbs are used for calculations
MAD	mmol/L (mg/dL)	'Mean absolute difference' of consecutive glucose values	Short-term within-day glucose variability	No real advantage over SD as an estimate of glycaemic variability
GVP	%	'Glycaemic variability percentage' is intended to capture both the amplitude and frequency of glucose oscillations	Short-term within-day glucose variability	A complex measure of amplitude and frequency of glucose oscillations, as well as aspects of distance travelled
MAG	mmol/L (mg/dL)	'Mean absolute glucose' change assesses glucose distribution at a given time point. Can be corrected for mean glucose and presented as MAG/m (%)	Short-term within-day glucose variability	Can differentiate between excursions of identical extent but of different duration
CONGA	mmol/L (mg/dL)	'Continuous overall net glycaemic action' integrates duration and degree of glucose excursions	Short-term within-day glucose variability	Requires complex calculations and measures amplitude and frequency of glucose oscillations
MODD	mmol/L (mg/dL)	'Mean of daily difference' assesses absolute difference between two values measured at the same daily time point	Short-term between-day glucose variability	Established measure of inter-day glycaemic variability
J-Index	Score	Calculated from mean and SD of all glucose values	Mean glucose and stability	Complex calculation, not widely used and additional value is uncertain
LBGI	Score	'Low blood glucose index' was originally designed to estimate hypoglycaemia risk from sparse capillary glucose readings	Risk of low glucose	While calculations can be complex, these measures aid in differentiating between variability above and below target range. Scope for above-target readings is significantly wider than for below-target readings, with associated implications for impact and risk
HBGI	Score	'High blood glucose index' was originally designed to estimate risk of hyperglycaemia from sparse capillary glucose readings	Risk of high glucose	
GFI	mmol/L (mg/dL)	'Glucose fluctuation index' compares differences in consecutive readings. Can be corrected for mean glucose and presented as glucose coefficient of fluctuation (GCF, %)	Short-term within-day glucose variability	The advantage over other GV metrics is unclear and is rarely used

Diabetes Obes Metab. 2024 Dec;26 Suppl 7(Suppl 7):3-16.

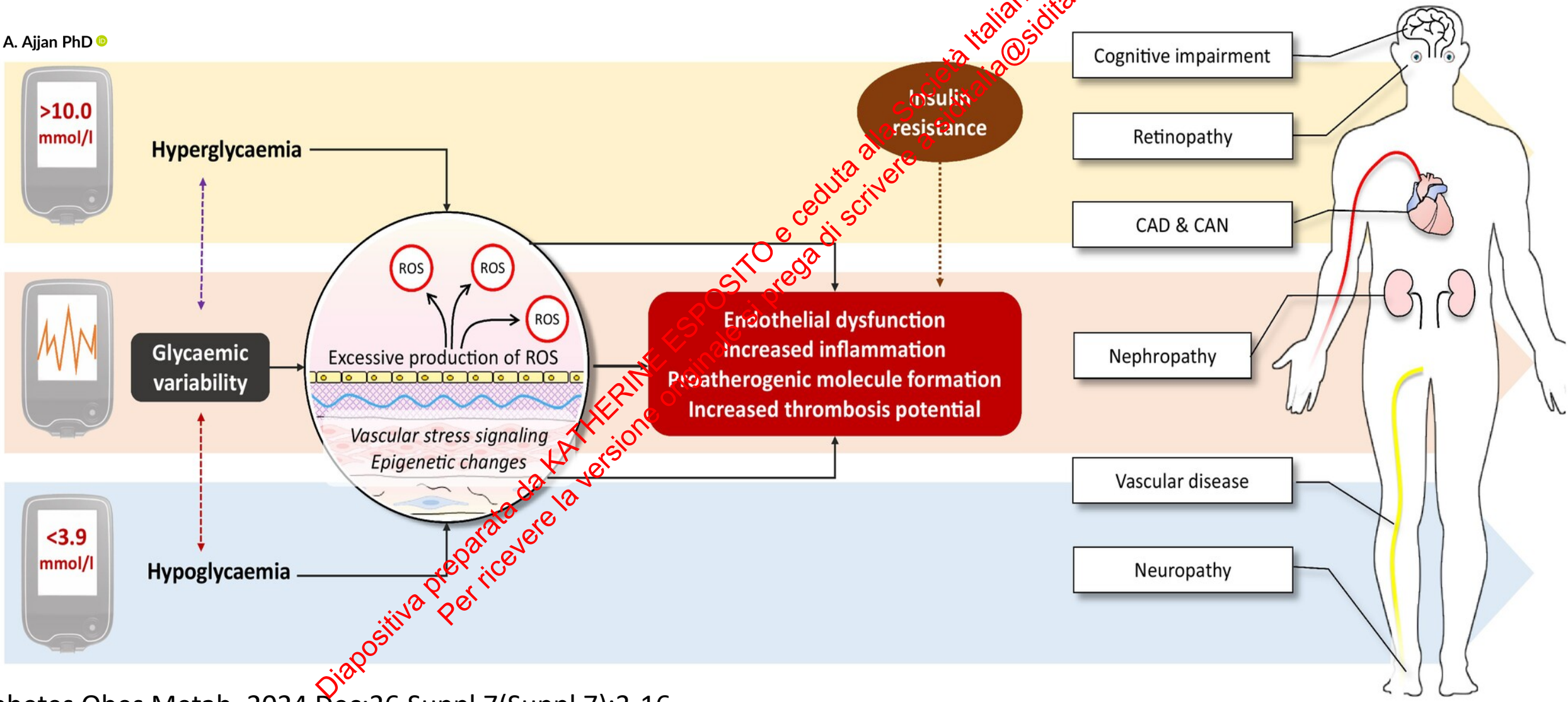
Received: 10 October 2024 | Revised: 14 November 2024 | Accepted: 17 November 2024
DOI: 10.1111/dom.16098

WILEY

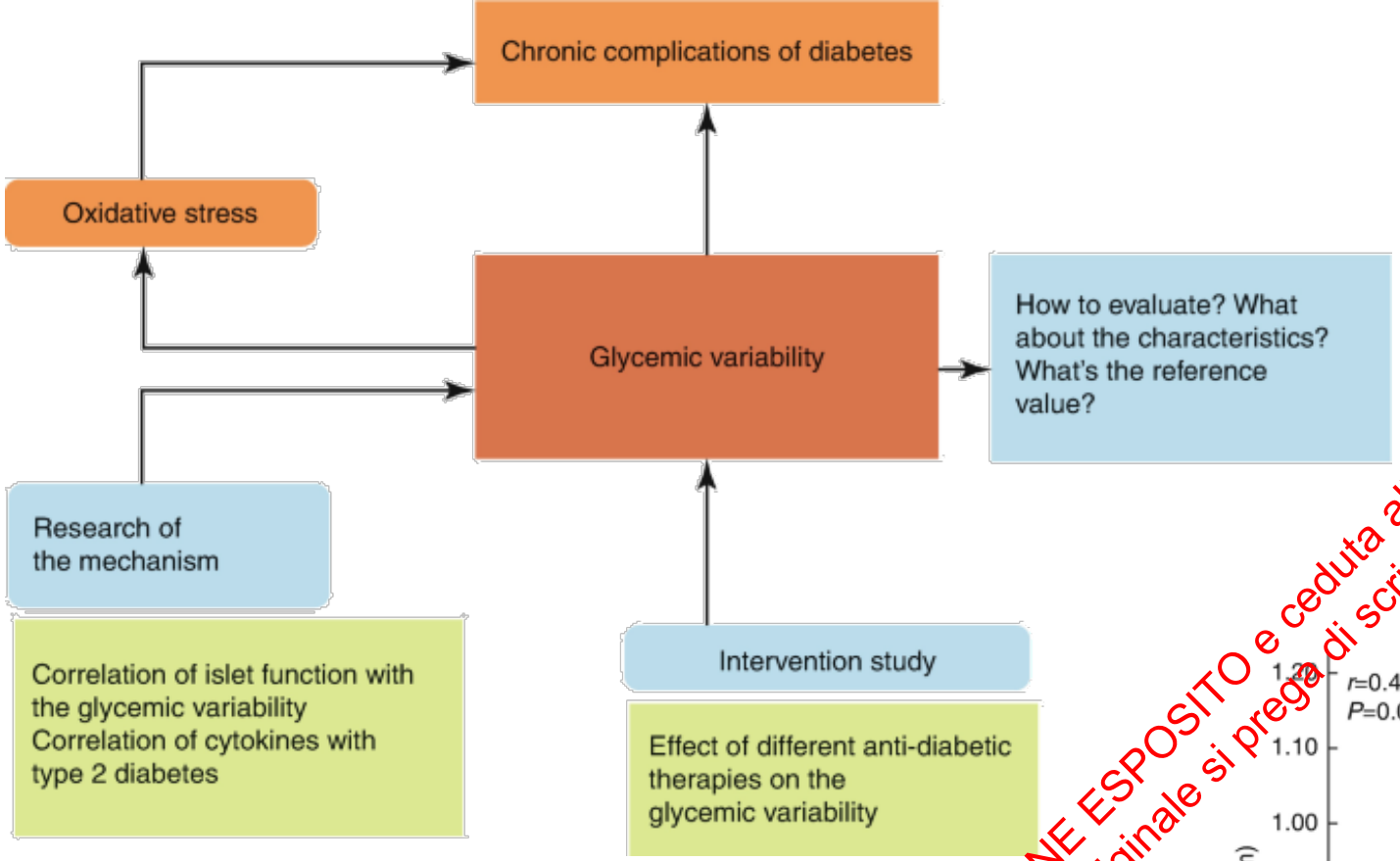
SPECIAL ISSUE ARTICLE

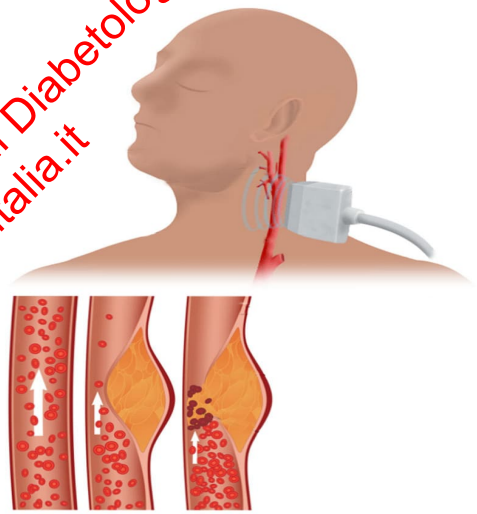
The clinical importance of measuring glycaemic variability: Utilising new metrics to optimise glycaemic control

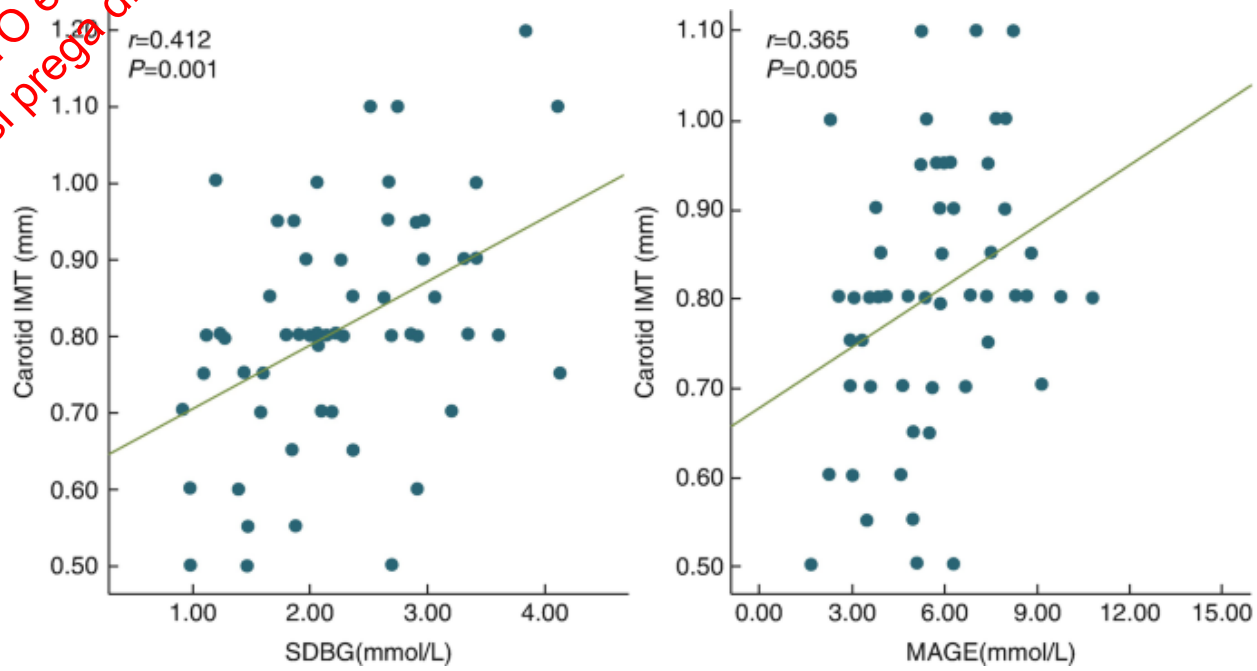
R. A. Ajjan PhD



Diabetes Obes Metab. 2024 Dec;26 Suppl 7(Suppl 7):3-16.





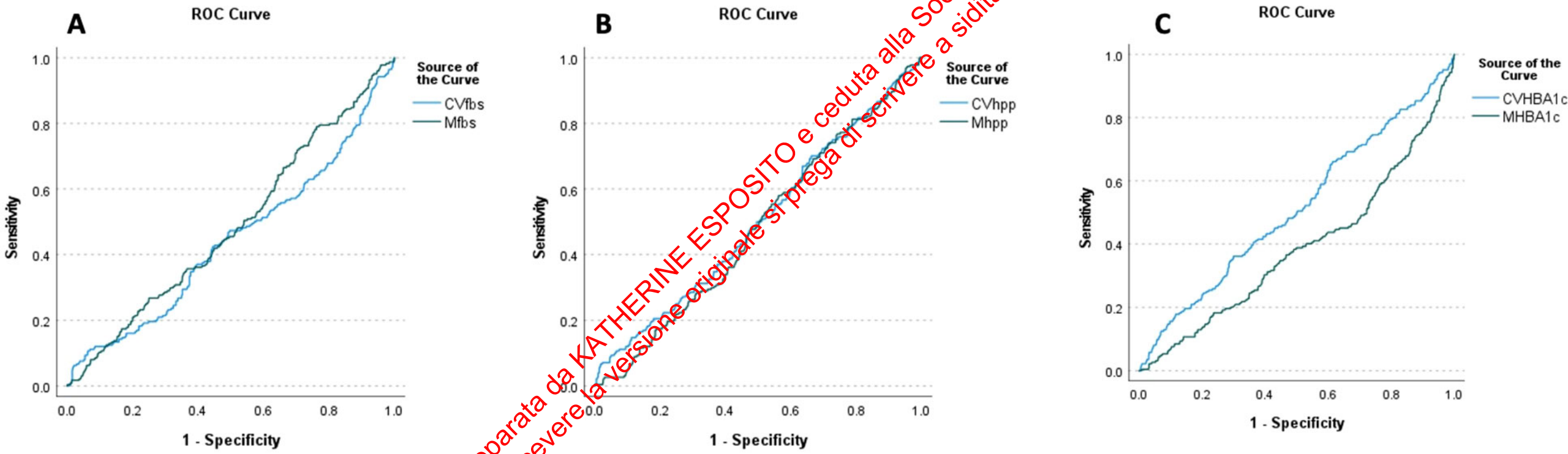


The correlation between glycemic variability and carotid IMT in 63 type 2 diabetes patients without atherosclerotic stenosis as determined by cranial/cervical magnetic resonance angiography

Zhou, J., Jia, W. (2018). Continuous Glucose Monitoring and Glycemic Variability. In: Jia, W. (eds) Continuous Glucose Monitoring. Springer, Singapore. https://doi.org/10.1007/978-981-10-7074-7_11

Glycemic profile variability as an independent predictor of diabetic retinopathy in patients with type 2 diabetes: a prospective cohort study

Studio su pazienti con **diabete di tipo 2**, seguiti per 10 anni.



Analisi della curva ROC della retinopatia basata sulla media e sul coefficiente di variazione degli indici glicemici: (A) HbA1c, (B) Glicemia a digiuno (FBS) e (C) glicemia 2 ore dopo pasto (2hpp) durante il periodo di follow-up. FBS (differenza AUC = −0,43, p = 0,146), 2hpp (differenza AUC = 0,493, p = 0,020) e HbA1c (differenza AUC = 1,27, p < 0,001).

Front Endocrinol (Lausanne). 2024 Nov 7:15:1383345.

Short-term glucose variability as a determinant of the healing rate of diabetic foot ulcer: A retrospective study

300 adults with DFU divided into 2 groups (low and high GV), according to the coefficient of variation (cut-off ≥36%).

Paola Caruso [a], Lorenzo Scappaticcio [b], Maurizio Gicchino [a], Filomena Castaldo [a], Mariluce Barrasso [a], Carla Carbone [a c], Mariangela Caputo [a], Maria Tomasuolo [b], Vanda Amoresano Paglionico [a b], Giuseppe Bellastella [a b], Maria Ida Maiorino [a b], Katherine Esposito [a b]

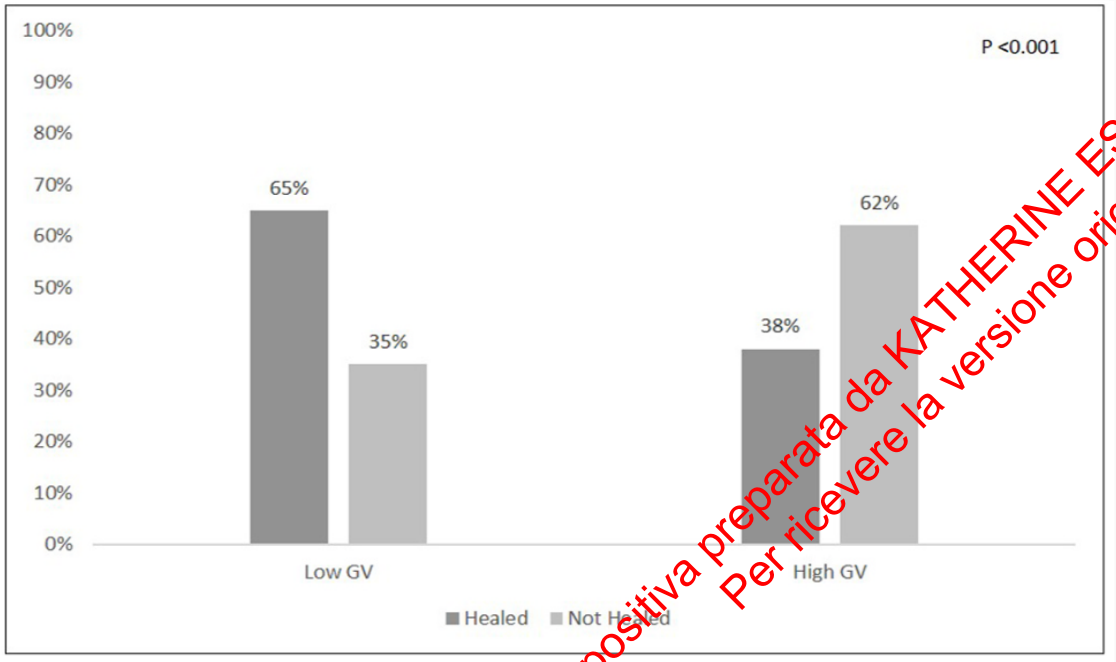


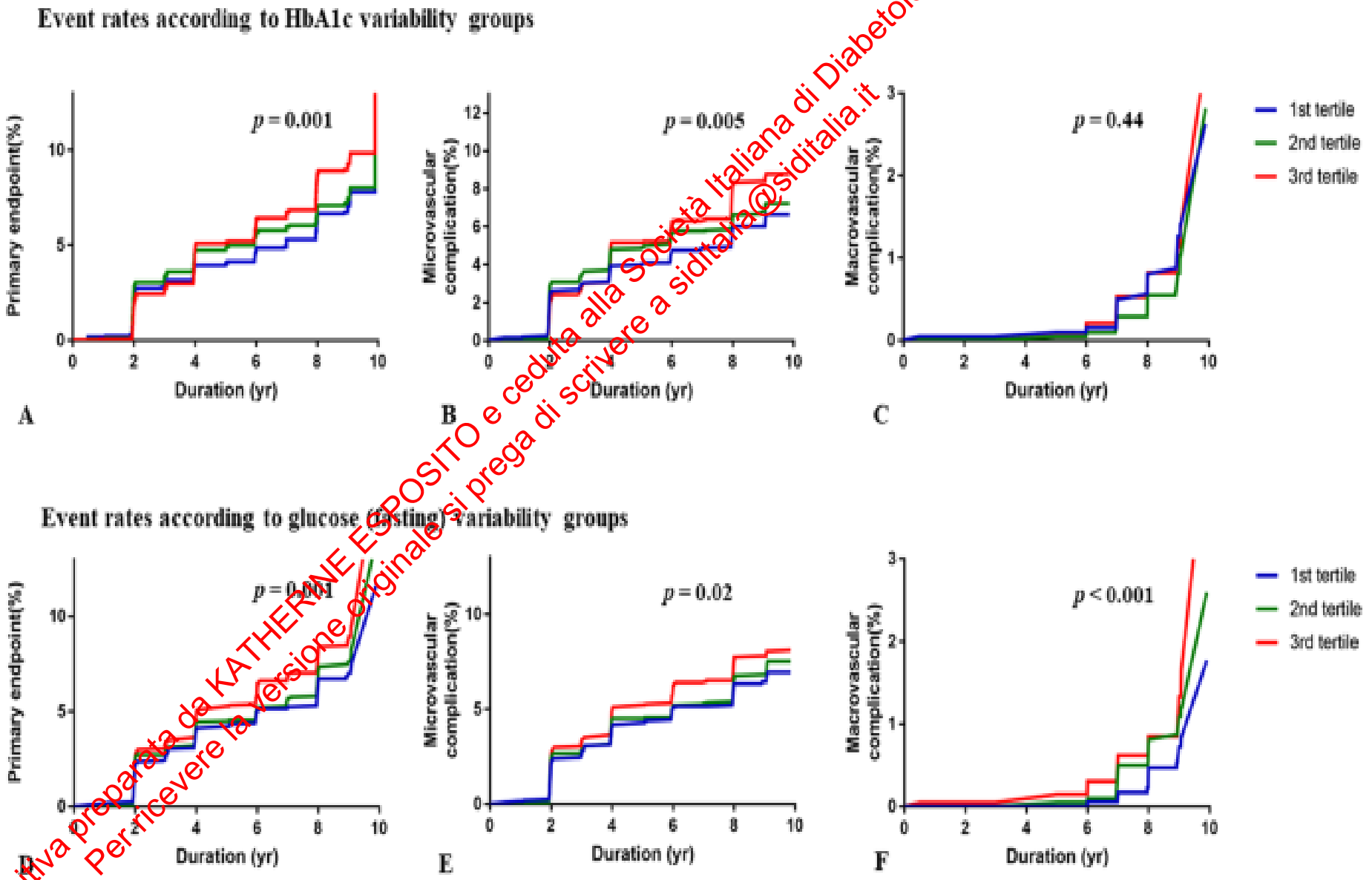
Fig. 1. Proportion of healed/not healed individuals with DFU in both groups with low and high glucose variability (GV).

Highlights

- Glucose variability (GV) is an emerging risk factors for chronic vascular diabetic complications.
- Adults affected by type 2 diabetes and diabetic foot ulcer (DFU) with high GV have a 3-fold risk of healing failure than those with low GV.
- GV indices as coefficient of variation (CV) and standard deviation (SD) are independent predictors of healing failure in adults with type 2 diabetes and DFU.
- GV should be a target of therapy in people with type 2 diabetes and DFU to improve their prognosis.

(KoGES – Ansung-Ansan Cohort)

- Popolazione: 6.462 adulti non diabetici (<65 anni), follow-up 10 anni
- Variabilità (CV) di: HbA1c, glicemia a digiuno (FBG), glicemia 2h postprandiale (PBG)
- Endpoint primario: eventi macro + microvascolari
- Risultati:
  - HbA1c-CV ↑: rischio indipendente di eventi microvascolari
  - FBG-CV ↑ e PBG-CV ↑: rischio di eventi macrovascolari
- Conclusione: maggiore variabilità glicemica = maggiore rischio vascolare anche in adulti non diabetici



Scientific Reports **volume 9**, Article number: 1374 (2019)

Effects of antidiabetes drugs on glycemic variability in patients with type 2 diabetes

Am J Med Sci. 2018 Dec;356(6):518-527.

Drug class Drug	Study design (duration)	Comparator	Results
Alpha glucosidase inhibitor			
Acarbose[a]	Double-blind, RCT (1 week)	Placebo[a]	Decrease in intra-day GV, especially postprandial variability with acarbose vs. placebo, but no significant change in inter-day GV[51]
DPP-4 inhibitor			
Saxagliptin[b]	RCT (1 year)	Acarbose[b]	Both saxagliptin and acarbose decreased GV to a similar extent. Greater reductions in A1C and FBG with saxagliptin vs. acarbose[52]
Sitagliptin[c]	Double-blind, RCT (4 weeks)	Glimepiride[c]	Both sitagliptin and glimepiride reduced A1C, however, significant reduction observed in the amplitude of GV (MAGE) with sitagliptin, but not with glimepiride. No difference in SD between treatment groups[53]
Vildagliptin[d]	OL, RCT (16 weeks)	Pioglitazone[d]	Both vildagliptin and pioglitazone significantly reduced A1C and mean plasma glucose, but reduction in GV was only seen with vildagliptin[54]
GLP-1 RA			
Liraglutide[e]	OL, RCT (6 months)	Insulin titration alone	Addition of liraglutide to intensive high-dose (basal-bolus) insulin therapy resulted in significantly greater reductions in A1C and GV vs. insulin therapy alone[48]
Sodium glucose co-transporter 2 inhibitor			
Dapagliflozin[f]	OL, RCT (20 weeks)[g]	Saxagliptin	Dapagliflozin was associated with a significant reduction in mean glucose levels and in indicators of hypoglycemia during Ramadan. However there were no significant differences between dapagliflozin and saxagliptin in GV pre-Ramadan and during Ramadan[55]
Rapid-acting basal insulin analogs			
Insulin aspart, glulisine or lispro	OL, RCT (26 weeks)	Exenatide	Reduced coefficient of variation with metformin + insulin glargine + exenatide compared with metformin + insulin glargine + RAI. Other GV indices showed nonsignificant trends toward improvement with exenatide[17]
Insulin lispro	*Post hoc* analyses of 3 studies	Insulin glargine alone	Premixed insulin glargine plus insulin lispro was associated with reduced glycemic variability in metformin treated patients compared with insulin glargine alone[60]
Long-acting basal insulin analogs			
Insulin detemir[h]	OL, RCT (52 weeks)	Insulin glargine[i]	Both insulins resulted in clinically important reductions in A1C, with no significant difference between insulin detemir and insulin glargine in within-subject variability for self-monitored FPG and premeal prandial glucose, or risk of hypoglycemia[56]
Insulin glargine	OL, RCT (2 years)	Standard care	Insulin glargine reduced PPG excursions. but did not increase risk of hypoglycemia, and was associated with similar SD and MAGE at 2 years compared with standard care[57]
Combination			
IDegLira[g]	*Post hoc* analysis of RCT (52 weeks)	Insulin degludec or liraglutide alone[g]	IDegLira treatment reduced glucose fluctuations and postprandial glucose excursions compared to insulin degludec[58]
iGlarLixi[i]	*Post hoc* analysis of RCT (30 weeks)	Insulin glargine alone[i]	iGlarLixi treatment (vs. insulininsulin glargine) significantly reduced GV compared to insulininsulin glargine[47]

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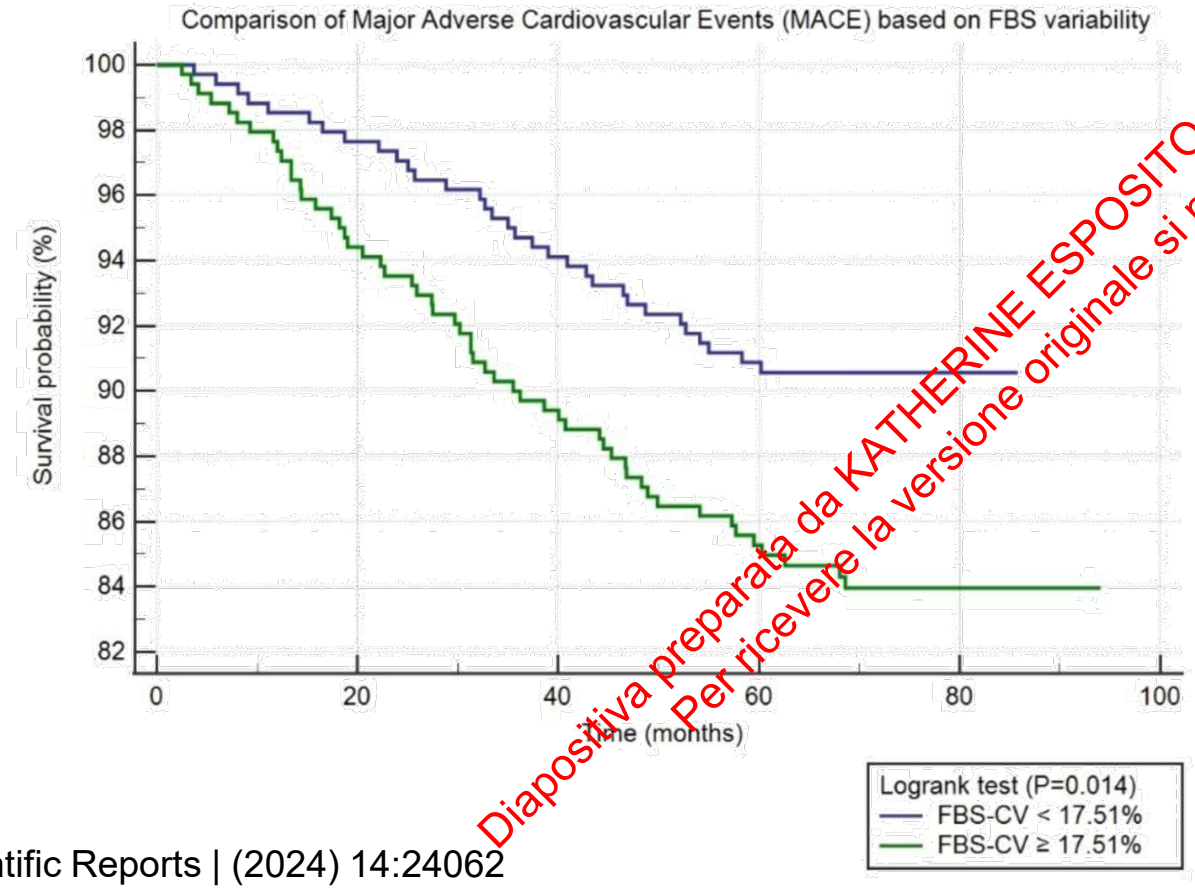
Clinical implications and pharmacological considerations of glycemic variability in patients with type 2 diabetes mellitus

Alanood A. Howsawi & Manal M. Alem



- Studio retrospettivo su **680 pazienti con diabete di tipo 2** (follow-up medio 78 mesi).
- La **variabilità glicemica a lungo termine (GV)**, in particolare **FBS-CV ≥17,5%**, predice eventi cardiovascolari maggiori (MACE) indipendentemente dal controllo glicemico (HR 1,589; p = 0,040).
- La GV **non predice le complicanze microvascolari**, che dipendono principalmente dalla durata del diabete e dal controllo glicemico (G-Hb/FBS).
- I pazienti trattati con **metformina o DPP-4 inibitori** avevano la GV più bassa rispetto a chi assumeva **insulina/sulfoniluree**, suggerendo un possibile ruolo dei farmaci nella protezione cardiovascolare.

Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy Dovepress
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Diabetes Metab Syndr Obes. 2020;13:777-784.
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ORIGINAL RESEARCH

Alterations in the Levels of Circulating and Endothelial Progenitor Cells Levels in Young Adults with Type 1 Diabetes: A 2-Year Follow-Up from the Observational METRO Study

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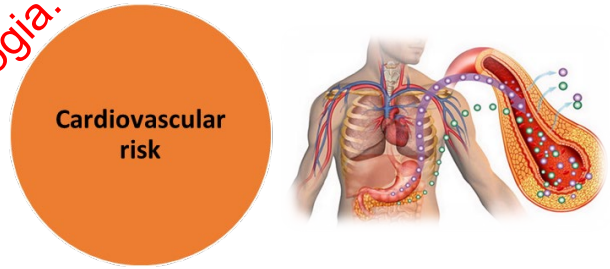
On Behalf of the METRO Study Group



204 type 1 diabetic patients
84 treated with insulin pump (CSII)
120 with multiple daily insulin injections (MDI) a 2-year follow-up.

Table 2 Main Outcome at 2 Years in the Overall Population

Parameters	All Patients (n=204)			
	Baseline	2 Years	Δ	P
Weight, kg	69.5 ± 10.7	70.1 ± 11.2	0.63 ± 1.4	0.056
BMI, kg/m^2	24.3 ± 3.1	24.4 ± 2.9	0.1 ± 1.8	0.384
Fasting glucose, mg/dL	208.6 ± 66.9	186.8 ± 71.4	−21.8 ± 89	<0.001
HbA1c, %	8.6 ± 1.1	8.2 ± 1.3	−0.3 ±	<0.001
Insulin dose, U/day	0.69 ± 0.21	0.56 ± 0.22	−0.13 ± 0.23	<0.001
MAGE, mmol/L	6.6 ± 2.1	6.1 ± 2.1	−0.5 ± 2.0	<0.001
CONGA, mmol/L	6.6 ± 1.7	6.3 ± 1.8	−0.2 ± 1.2	0.006
SD, mmol/L	3.5 ± 0.8	3.3 ± 0.8	−0.2 ± 0.7	<0.001
Lipids, mg/dL				
Total cholesterol	165.2 ± 28.1	163.5 ± 27.3	−2.1 ± 1.2	0.256
LDL-cholesterol	90.2 ± 23.5	88.3 ± 21.7	−1.8 ± 21.4	0.847
HDL-cholesterol	57.4 ± 12.9	56.7 ± 13.8	− 0.7 ± 12.3	0.691
Triglycerides	73.5 ± 21.4	76.8 ± 22.9	3.1 ± 21.8	0.481
Blood Pressure, mmHg				
SBP	120 (90–140)	120 (80–140)	0.3 ± 0.5	0.954
DBP	75 (60–90)	70 (60–90)	0.1 ± 0.6	0.723

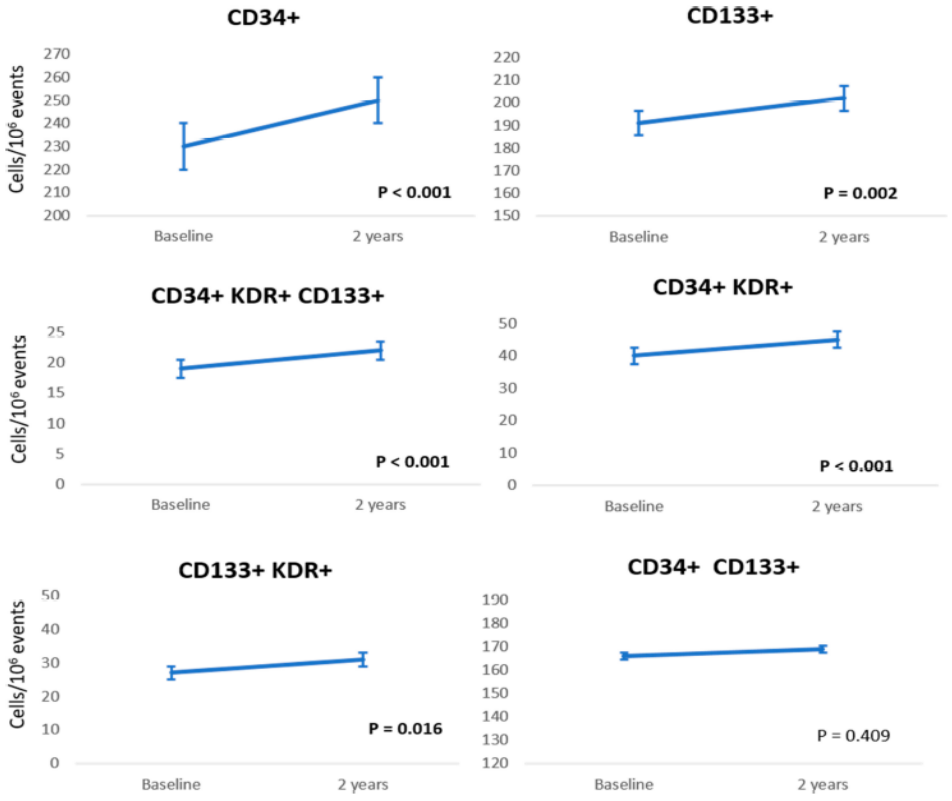
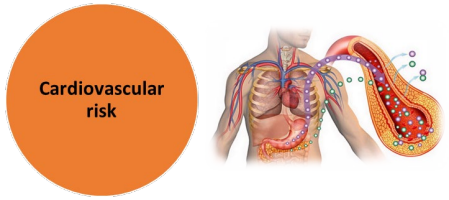


Figure 1 Change of circulating levels of six phenotypes of EPCs in the overall population over two year-follow-up.

EPCs IN TYPE 1 DIABETES

Diabetes Metab Syndr Obes. 2020;13:777-784.

EPCs Phenotypes	CSII (n = 84)		MDI (n = 120)	
CD34⁺				
Baseline	225 (155,324)	<0.001	247 (173,279)	0.046
2 years	256 (189,355)		251 (200,273)	
CD133⁺				
Baseline	178 (114,225)	0.005	214 (138,242)	0.094
2 years	199 (141,241)		217 (158,246)	
CD34⁺CD133⁺				
Baseline	150 (95,204)	0.516	178 (120,214)	0.632
2 years	149 (110,199)		177 (130,217)	
CD34⁺KDR⁺				
Baseline	42 (32,49)	<0.001	39 (29,44)	0.034
2 years	50 (40,84)		40 (30,49)	
CD133⁺KDR⁺				
Baseline	25 (23,35)	0.003	31 (23,38)	0.525
2 years	30 (22,50)		31 (22,38)	
CD34⁺KDR⁺CD133⁺				
Baseline	17 (14,24)	<0.001	20 (14,24)	0.286
2 years	25 (16,37)		20 (15,26)	



Parameter	Univariate Analysis		Multiple Regression Analysis	
ΔCD34⁺	r_{sp}	P	β-Coefficient	P
Δ Weight	0.100	0.365	0.098	0.459
Δ BMI	0.080	0.942	0.082	0.724
Δ Fasting glucose	0.044	0.685	0.039	0.287
Δ HbA1c	−0.145	0.063	−0.128	0.142
Δ MAGE	−0.387	<0.001	−0.322	0.020
Δ CONGA	−0.098	0.346	−0.041	0.836
Δ SD	−0.259	0.017	−0.152	0.078
ΔCD34⁺KDR⁺				
Δ Weight	−0.039	0.719	−0.033	0.542
Δ BMI	−0.114	0.303	−0.094	0.675
Δ Fasting glucose	−0.101	0.362	−0.087	0.763
Δ HbA1c	−0.112	0.075	−0.094	0.821
Δ MAGE	−0.355	0.019	−0.316	0.004
Δ CONGA	0.074	0.536	0.026	0.917
Δ SD	−0.272	0.025	−0.143	0.156
ΔCD34⁺KDR⁺CD133⁺				
Δ Weight	−0.005	0.615	−0.002	0.884
Δ BMI	−0.001	0.889	−0.009	0.742
Δ Fasting glucose	−0.072	0.497	−0.021	0.218
Δ HbA1c	−0.101	0.092	−0.091	0.194
Δ MAGE	−0.261	0.016	−0.188	0.176
Δ CONGA	−0.121	0.271	−0.083	0.564
Δ SD	−0.289	0.006	−0.092	0.692

META-ANALYSES

Effects of Continuous Glucose Monitoring on Metrics of Glycemic Control in Diabetes: A Systematic Review With Meta-analysis of Randomized Controlled Trials

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Diabetes Care 2020;43:1146–1156 | https://doi.org/10.2337/dc19-1459

Use of technologies

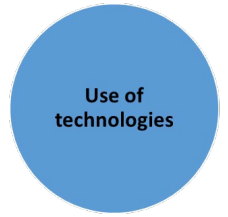
- We performed a meta-analysis of **15** randomized controlled trials (**RCTs**) comparing CGM with usual care for parameters of glycemic control in both **type 1** and **type 2** diabetes.

- We selected RCTs that assessed both changes in **HbA1c** and time in target range (**TIR**), together with time below range (**TBR**), time above range (**TAR**), and glucose variability expressed as coefficient of variation (**CV**).

Diabetes Care. 2020;43(5):1146–1156.

Table 2—Preplanned subgroup analysis

	Comparisons	Patients	Control subjects	Estimated WMD (95% CI)	*P*	I^2	*P* value of Q test
HbA_{1c}							
rtCGM	13	851	769	−0.23 (−0.36 to −0.10)	<0.001	92.2%	<0.001
iCGM	3	350	276	0.00 (−0.01 to 0.02)	0.861	0.0%	0.934
SAP	2	107	108	−0.16 (−0.67 to 0.35)	0.542	85.5%	0.009
Overall	18	1,308	1,153	−0.17 (−0.29 to −0.06)	0.003	96.2%	<0.001
TIR							
rtCGM	13	851	769	83.49 (52.68–114.30)	<0.001	66.5%	<0.001
iCGM	3	350	276	53.91 (28.54–79.27)	<0.001	0.0%	0.617
SAP	2	107	108	37.10 (0.74–73.45)	0.045	0.0%	0.799
Overall	18	1,308	1,153	70.74 (46.73–94.76)	<0.001	66.3%	<0.001
TBR level 1							
rtCGM	13	851	769	−15.82 (−25.70 to −5.95)	0.002	96.6%	<0.001
iCGM	3	350	276	−56.26 (−88.91 to −23.60)	0.001	93.7%	<0.001
SAP	2	107	108	−41.04 (−127.10 to 45.02)	0.350	88.1%	0.004
Overall	18	1,308	1,153	−27.16 (−42.08 to −12.25)	<0.001	98.9%	<0.001
TBR level 2							
rtCGM	8	524	450	−5.65 (−10.83 to −0.46)	0.033	74.3%	<0.001
iCGM	3	350	276	−26.23 (−49.07 to −3.40)	0.024	86.8%	0.001
SAP	1	76	77	−37.40 (−46.05 to −28.75)	<0.001	—	—
Overall	12	950	803	−13.58 (−20.63 to −6.53)	<0.001	91.7%	<0.001
TAR level 1							
rtCGM	12	788	716	−54.34 (−75.03 to −33.64)	<0.001	21.7%	0.230
iCGM	2	231	156	35.52 (−3.00 to 74.03)	0.071	0.0%	0.588
SAP	2	107	108	23.98 (−34.95 to 82.90)	0.425	26.3%	0.244
Overall	16	1,126	980	−30.26 (−58.15 to −2.38)	0.033	67.9%	<0.001
TAR level 2							
rtCGM	8	545	462	−44.79 (−74.97 to −14.61)	0.004	69.6%	0.002
iCGM	3	350	276	−16.16 (−30.57 to −1.74)	0.028	0.0%	0.562
SAP	1	76	77	−1.44 (−28.09 to 25.21)	0.916	—	—
Overall	12	971	815	−27.68 (−45.31 to −9.97)	0.004	63.9%	0.002
CV							
rtCGM	7	509	449	−2.56 (−5.28 to 0.17)	0.066	93.1%	<0.001
iCGM	3	350	276	−3.86 (−5.15 to −2.57)	<0.001	78.1%	0.010
SAP	—	—	—	—	—	—	—
Overall	10	859	725	−3.09 (−4.43 to −1.74)	<0.001	90.7%	<0.001



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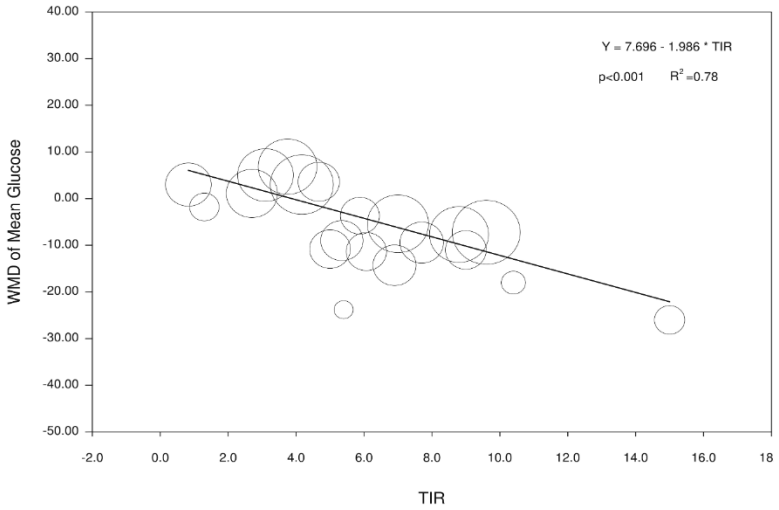
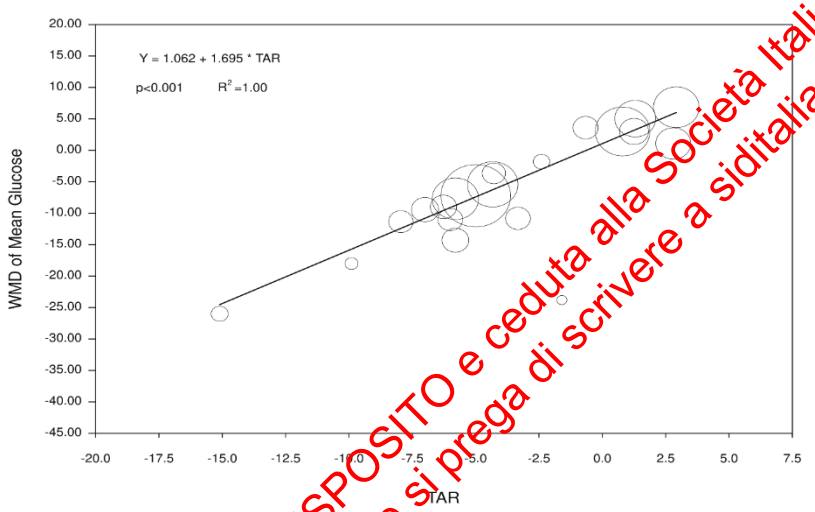
Endocrine
https://doi.org/10.1007/s12020-025-04405-6

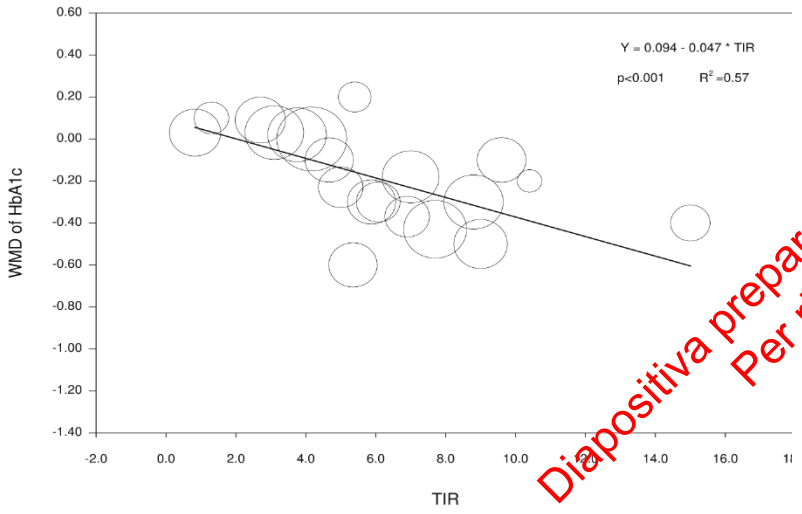
SYSTEMATIC REVIEW

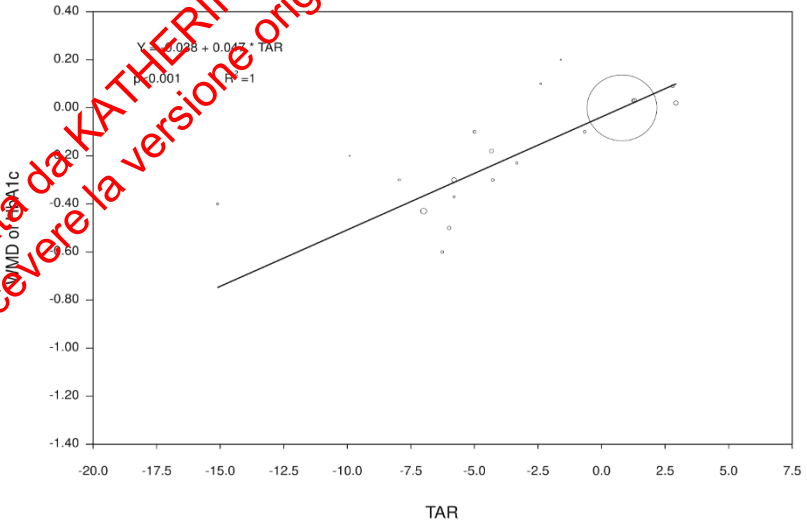
The therapeutic efficacy of continuous glucose monitoring in diabetes: an updated meta-analysis with meta-regression

Maria Ida Maiorino[1,2] · Nicole Di Martino[2] · Silvia Angelino[1,3] · Antonietta Maio[1] · Paola Caruso[2] · Michela Petrizzo[2] · Lorenzo Scappaticcio[1] · Miriam Longo[4] · Daniela Forestiere[1,3] · Chiara Porcellini[1,3] · Giuseppe Bellastella[1,2] · Dario Giugliano[1] · Katherine Esposito[1,2,3]









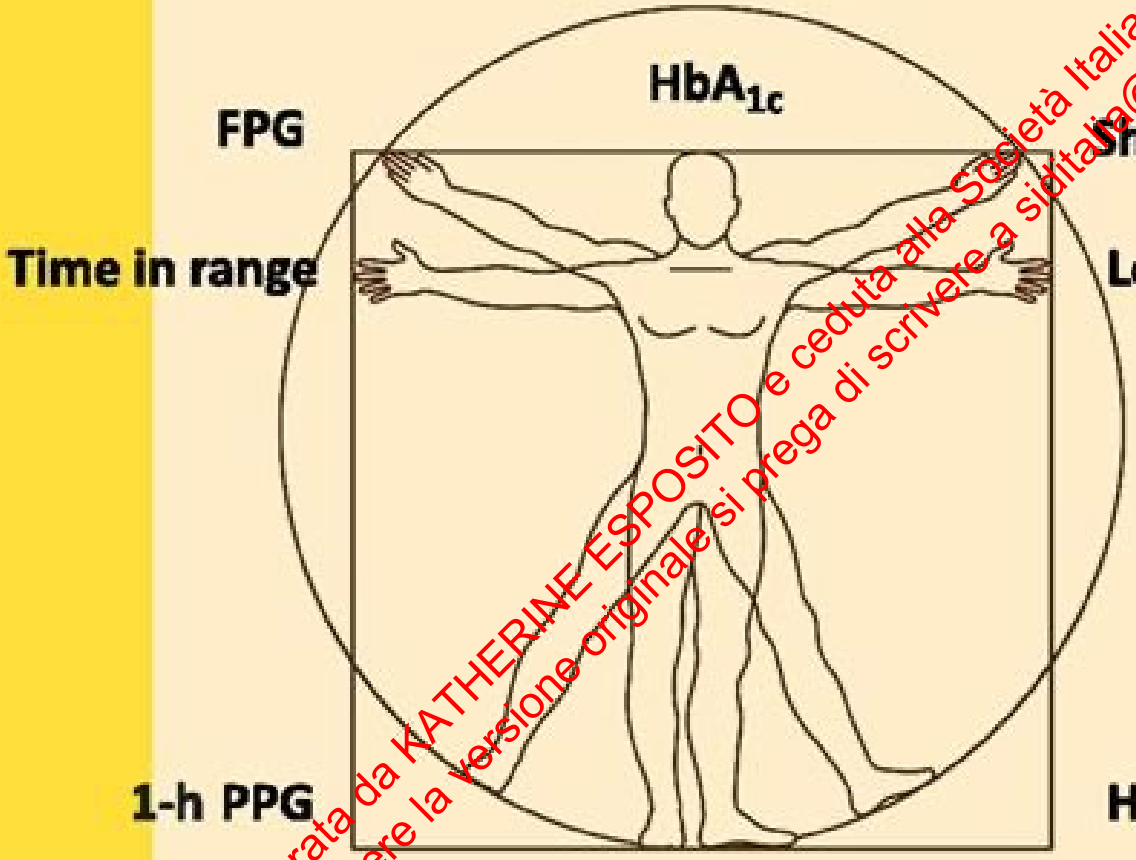
19 RCTs, 20 comparisons and 2949 patients

Variable	β Coefficient	P value	R^2 (%)
TIR	-1.98	0.000	78
TBR	-0.90	0.095	21
TAR	1.69	0.000	100

P: subjects with both type 1 and type 2 diabetes and pregnant women with diabetes.
I: CGM as either rtCGM, iCGM or SAP, compared with usual care (mainly self blood glucose monitoring).
C: age-matched subjects with type 1 or type 2 diabetes.
O: change in HbA1c, mean glucose and CGM-derived metrics (including TIR, TAR, TBR)

Variable	β Coefficient	P value	R^2 (%)
TIR	-0.046	0.000	57
TBR	-0.014	0.371	0
TAR	0.047	0.000	100

La gestione “perfetta” dell’iperglicemia oggi



Diabetes Care 2020;43(6):1169–1171