

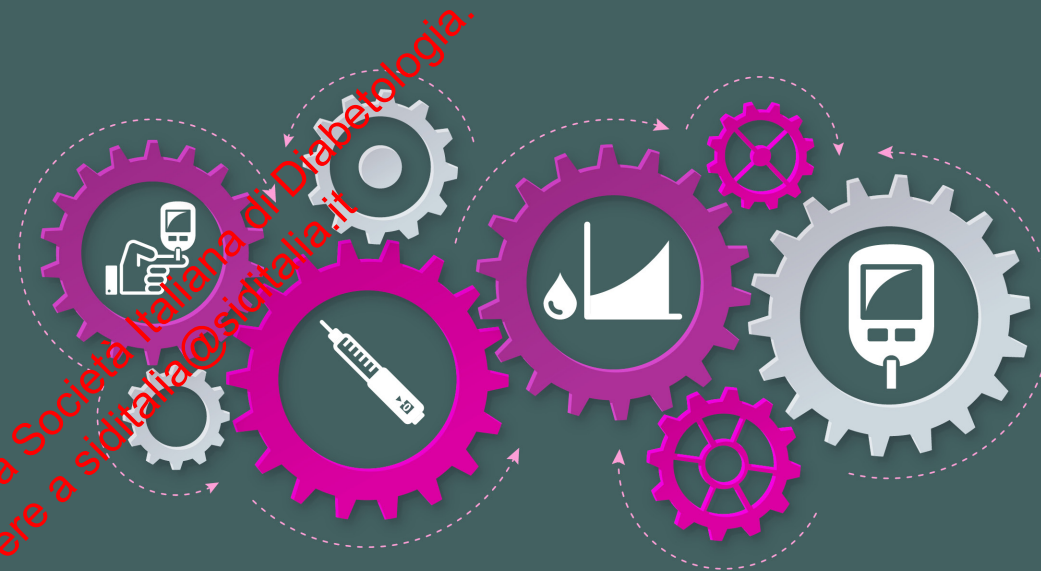


MONITORAGGIO GLICEMICO NEL DIABETE DI TIPO 2:

EVIDENZE, INNOVAZIONE
E PROSPETTIVE CLINICHE

11 NOVEMBRE 2025

MILANO Starhotels E.o.ho.



Controllo glicemico nel paziente ad alto rischio

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Diapositiva preparata da GIANLUCA PERSEGHIN e ceduta alla Società Italiana di Diabetologia.
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Conflict of Interest

last 3 years

Speaker in Scientific Events

AstraZeneca

Bayer

Boheringer Ingelheim

Daiichi Sankyo

Echosens

Lilly

Menarini Diag

Merck

Novartis

Novo Nordisk

Pfizer

PikDare

Roche Diag

Sanofi

Servier

Scientific AB

Amgen

Bruno Farmaceutici

EG

Lilly

Merck

Novartis

Novo Nordisk

Pfizer

PikDare

Sanofi



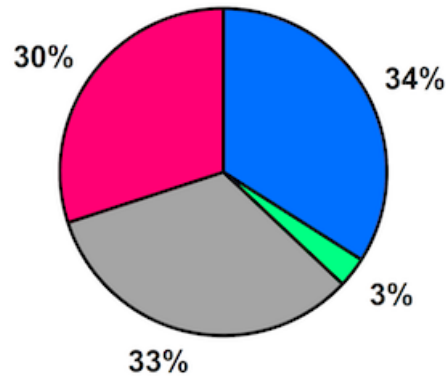
Centralità del DMT2 e del controllo glicemico (HbA1c) nel rischio di eventi CVD maggiori

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Mortality in Lombardy 2010-2019

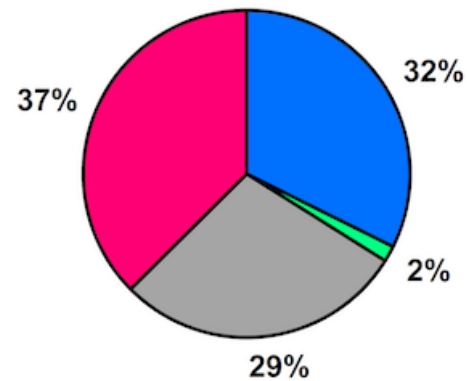
Individuals with diabetes

2010



■ Cardiovascular ■ Liver ■ Cancer ■ Other

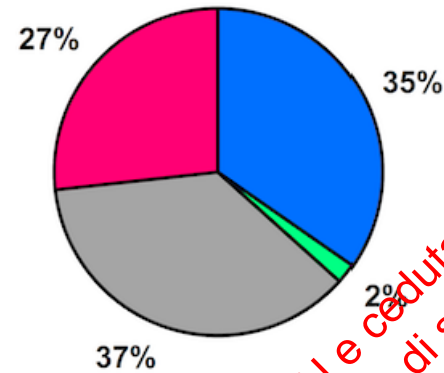
2019



■ Cardiovascular ■ Liver ■ Cancer ■ Other

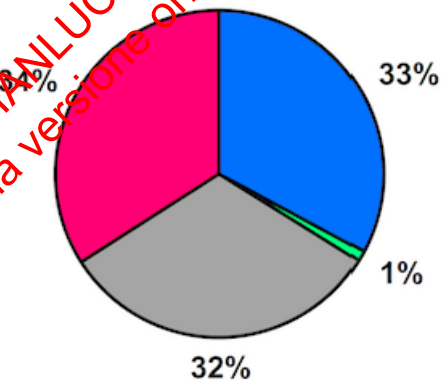
Individuals without diabetes

2010



■ Cardiovascular ■ Liver ■ Cancer ■ Other

2019

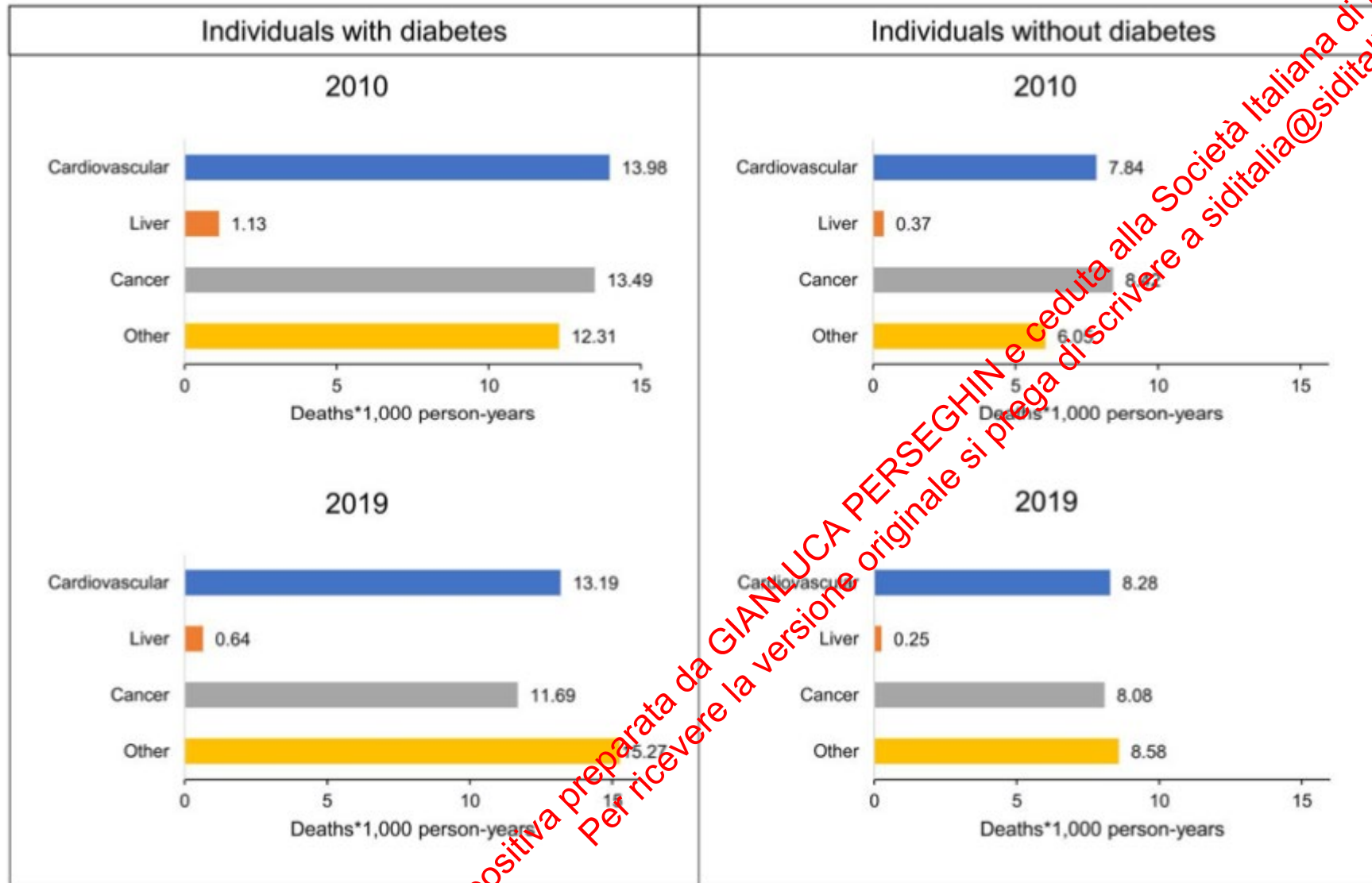


■ Cardiovascular ■ Liver ■ Cancer ■ Other

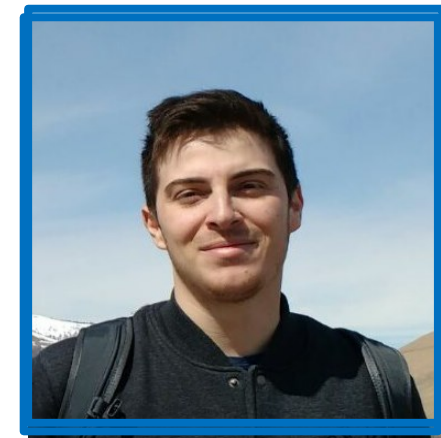
CVD still matters

Ciardullo S et al
J Clin Endocrinol Metab, 2024

In Lombardia



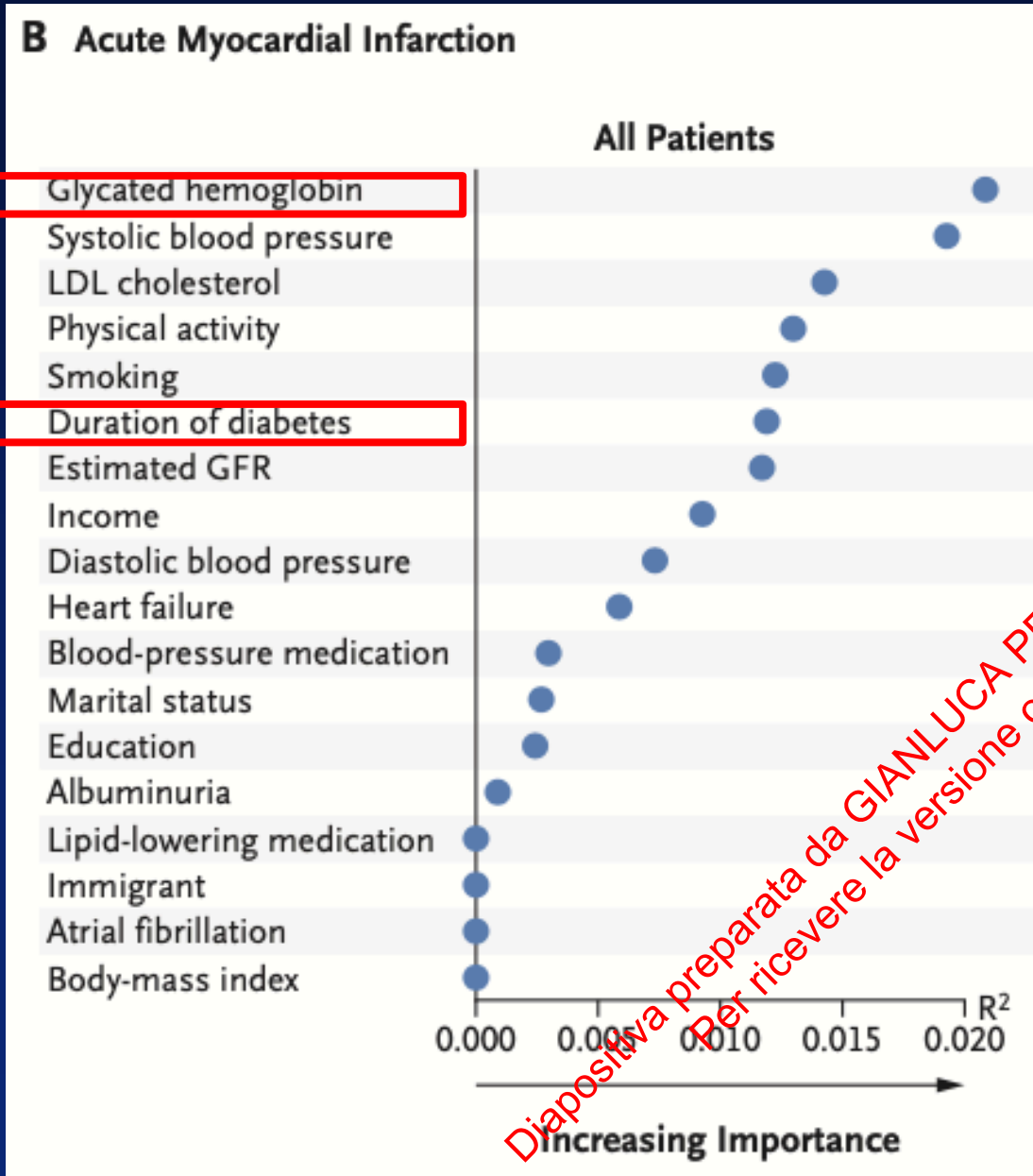
**CVD
still matters
!!!**



**Ciardullo S et al
J Clin Endocrinol Metab, 2024**

Figure 2. Absolute cause-specific mortality rates among individuals with and without diabetes at the beginning (2010) and at the end (2019) of the studied period.

Glycemic control counts!



Swedish National Diabetes Register
271,174 patients with T2DM vs. 1,355,870
matched controls on the basis of age, sex,
and county

Follow-up 5.7 years

175,345 deaths occurred

Risk factors:

- elevated HbA1c
- elevated LDL-chol
- albuminuria
- smoking cigarettes
- elevated blood pressure

Rawshani A et al N Engl J Med, 2018

Intensificazione terapeutica (HbA1c) riduce il rischio di eventi CVD

Diapositiva preparata da GIANLUCA PERSEGGIN e ceduta alla Società Italiana di Diabetologia.
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Effect of intensive control of glucose on cardiovascular outcomes and death in patients with diabetes mellitus: a meta-analysis of randomised controlled trials

Kausik K Ray, Sreenivasa Rao Kondapally Seshasai*, Shamellal Rajesuriya*, Rupa Sivakumaran*, Sarah Nethercott*, David Preiss, Sebat Ergou, Naveed Sattar

No effect on mortality

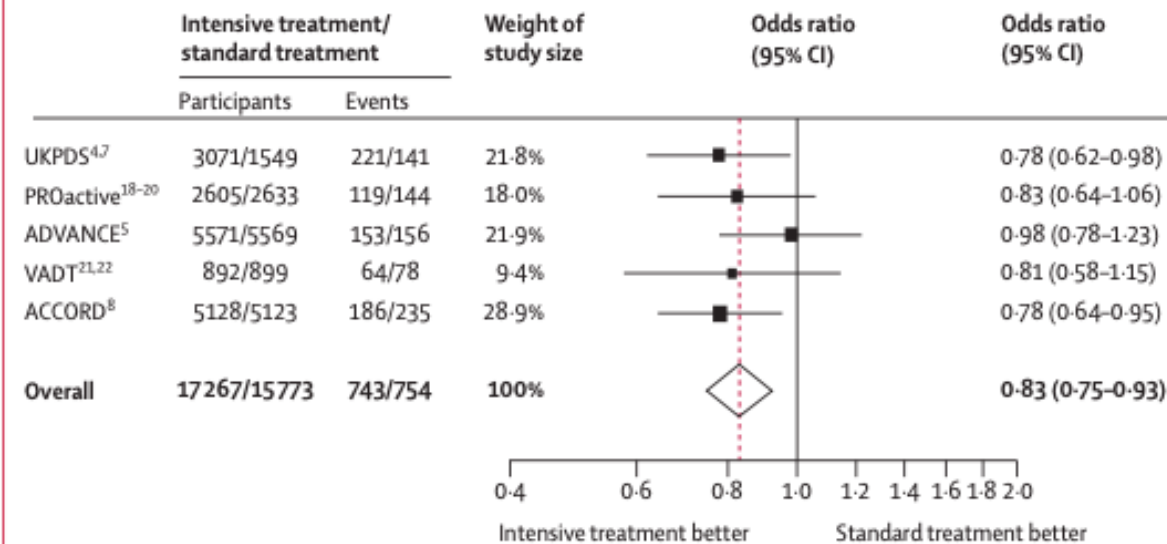


Figure 1: Probability of events of non-fatal myocardial infarction with intensive glucose-lowering versus standard treatment

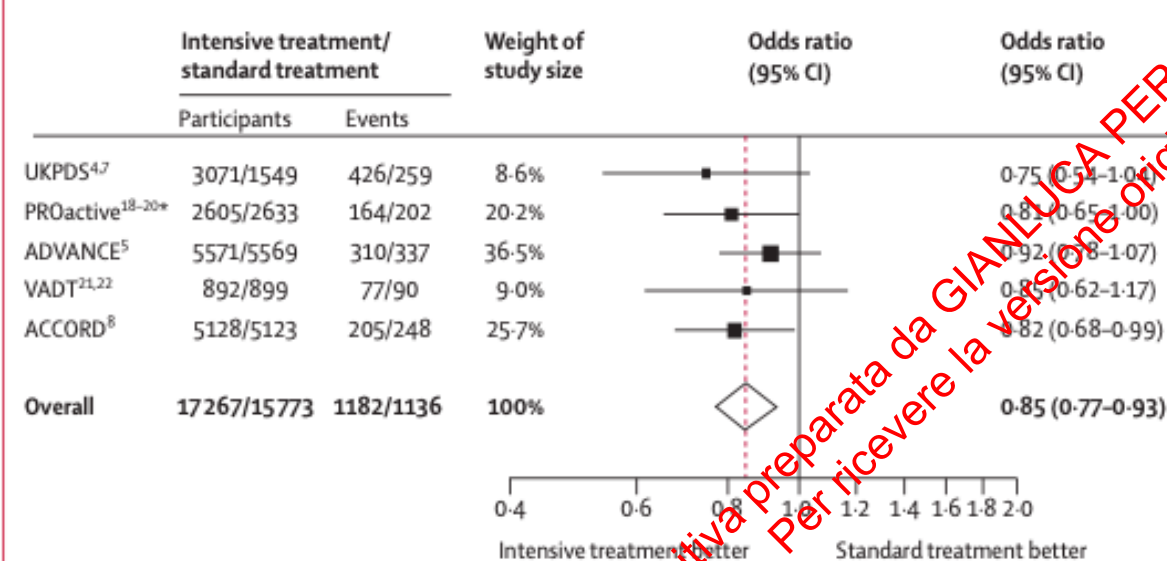


Figure 2: Probability of events of coronary heart disease with intensive glucose-lowering versus standard treatment

*Included non-fatal myocardial infarction and death from all-cardiac mortality.

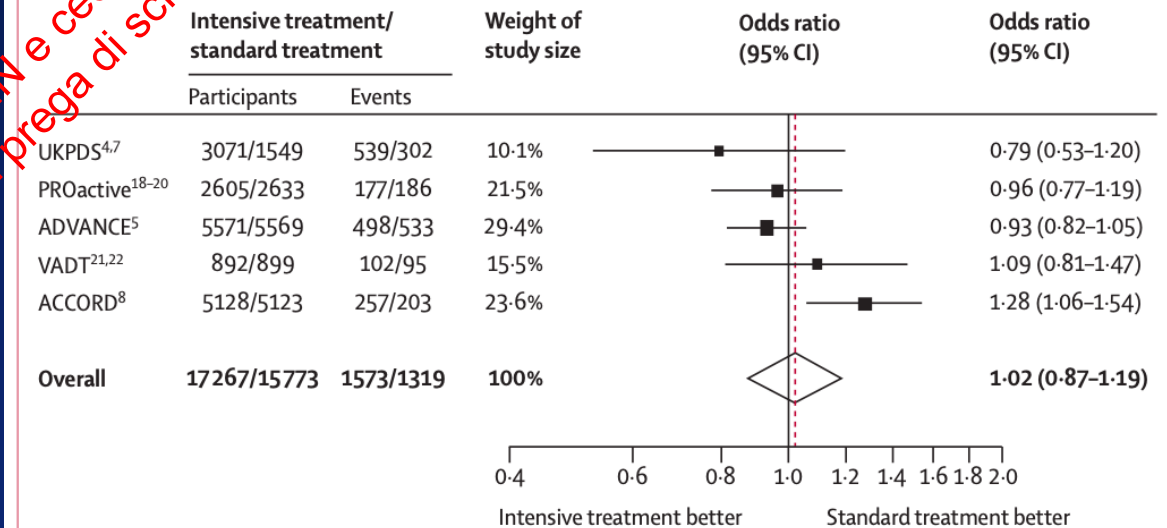


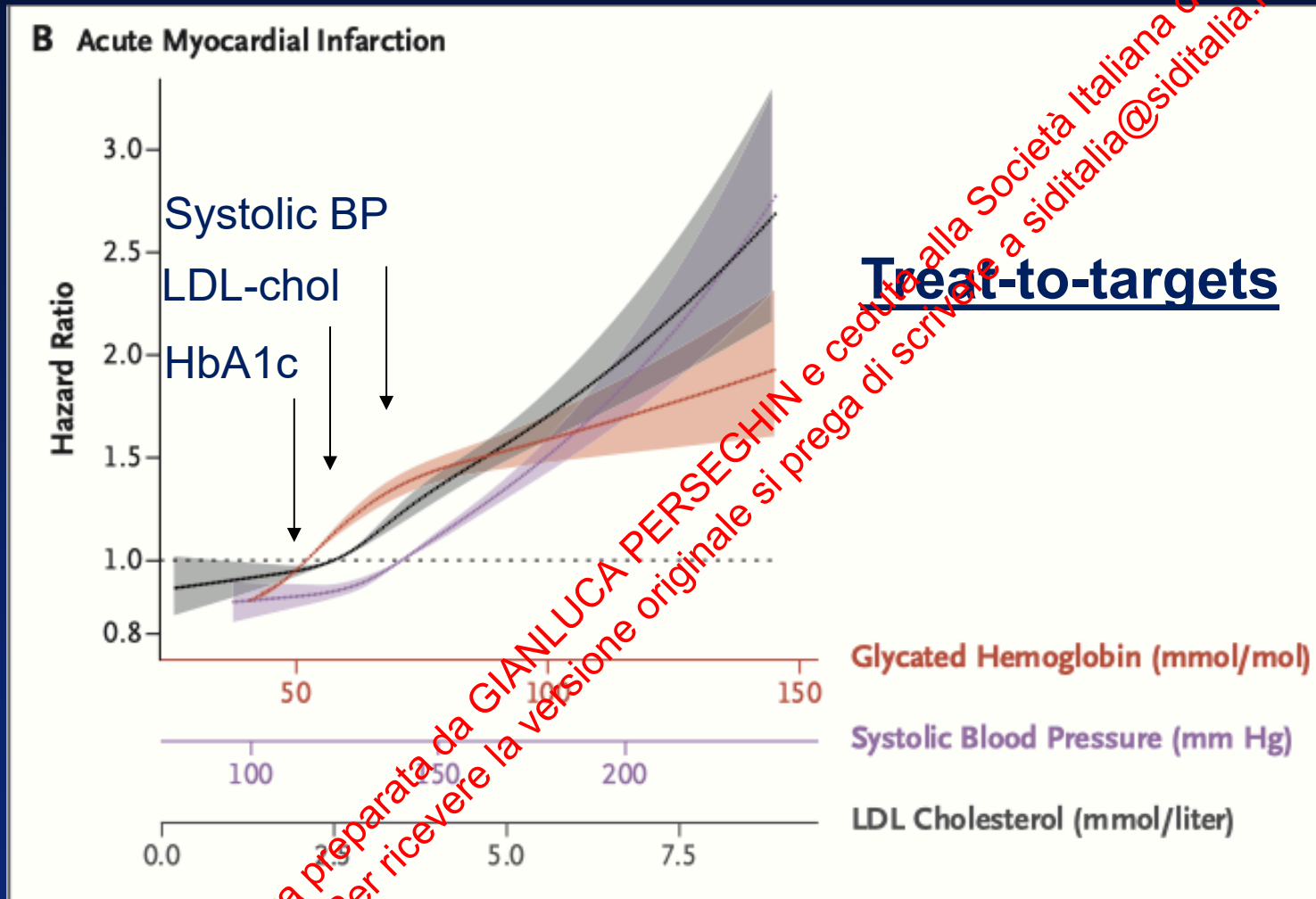
Figure 4: Probability of events of all-cause mortality with intensive glucose-lowering versus standard treatment

Ray KK et al Lancet, 2009

Personalizzazione degli obiettivi terapeutici

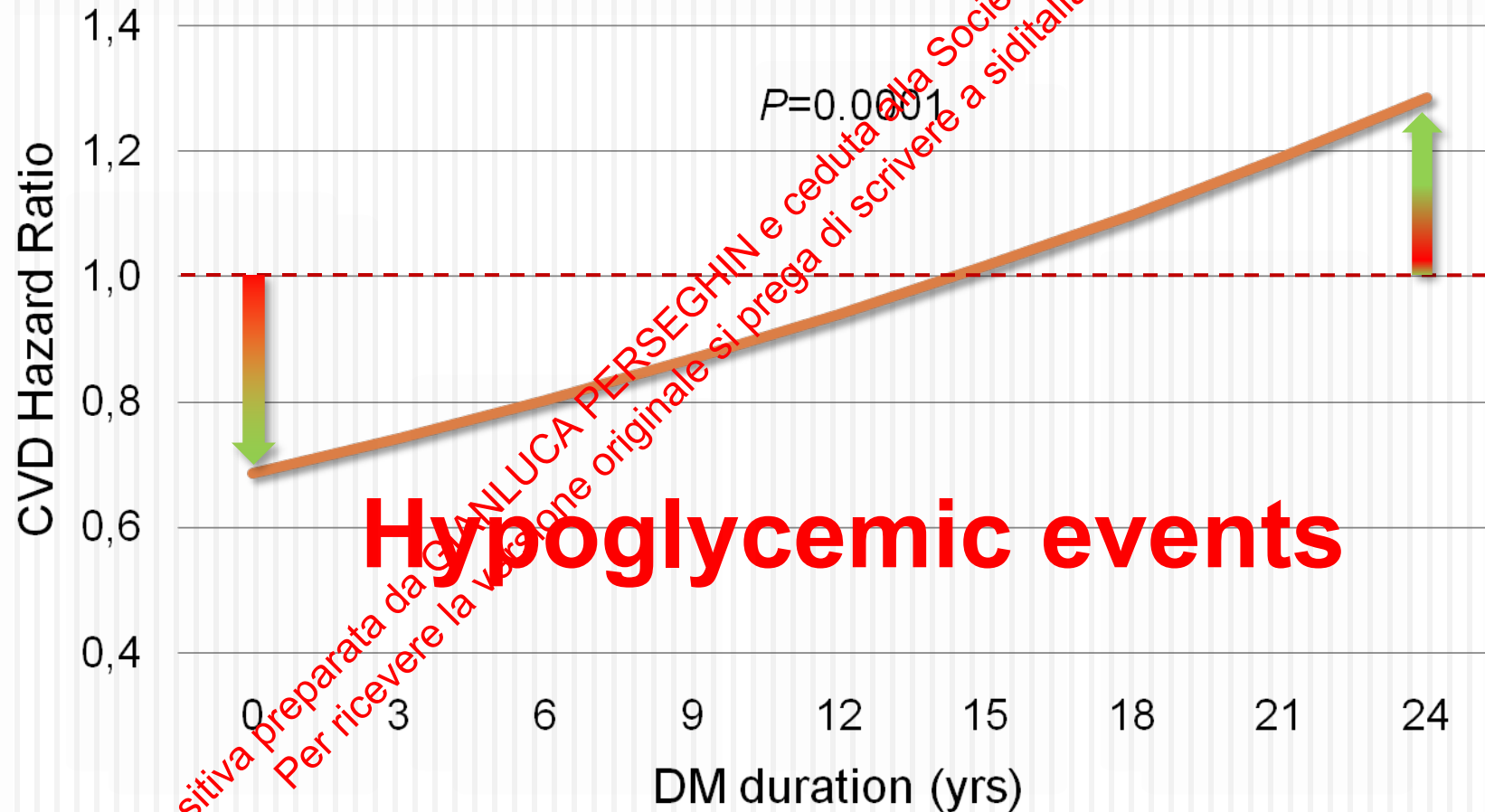
Diapositiva preparata da GIANLUCA PERSEGGIN e ceduta alla Società Italiana di Diabetologia.
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Obiettivi terapeutici: multiple RFs



Rawshani A et al N Engl J Med, 2018

Relationship of DM Duration and HR for CVD Events with Intensive Therapy



Hypoglycemic events

Diapositiva preparata da GIULIA PERSEGHIN e ceduta alla Società Italiana di Diabetologia.
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Rischio ipoglicemico nei pazienti ad alto rischio vascolare

Impatto dell'ipoglicemia su esiti cardiovascolari e mortalità

Diapositiva preparata da GIANLUCA PERCEGHIN e ceduta alla Società Italiana di Diabetologia.
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Evidence in the acute setting in patients with CVD event

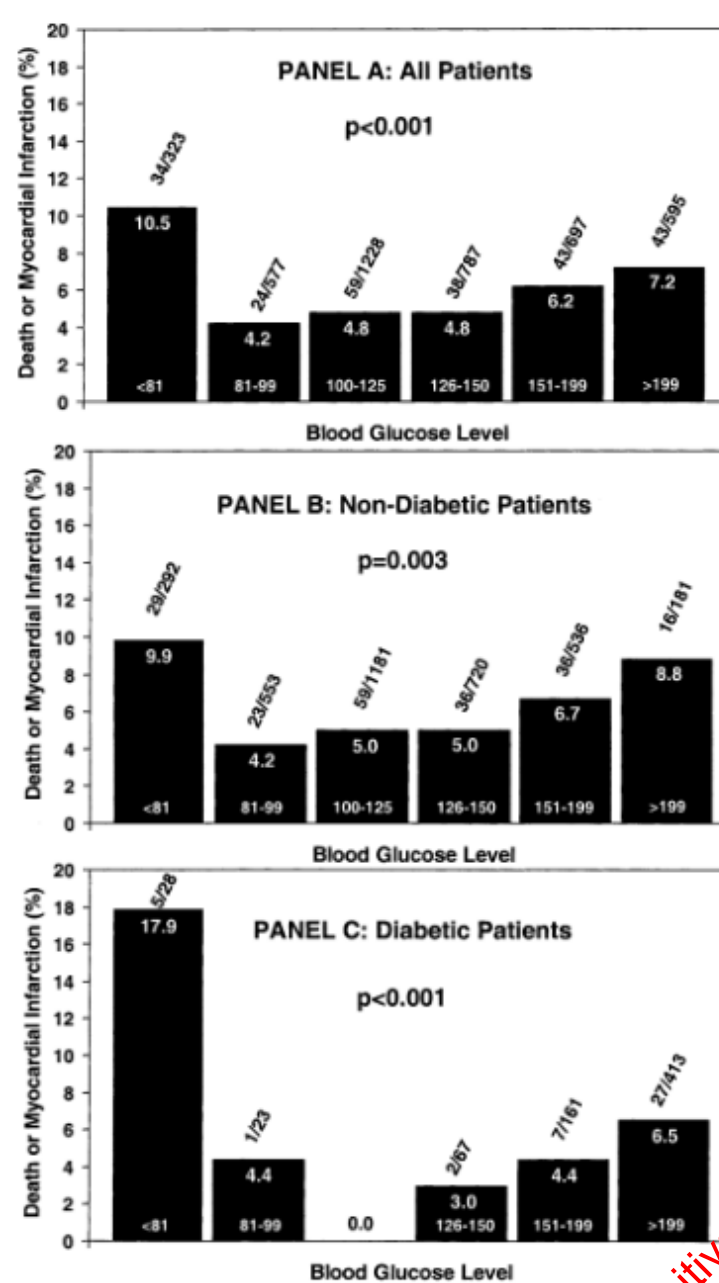
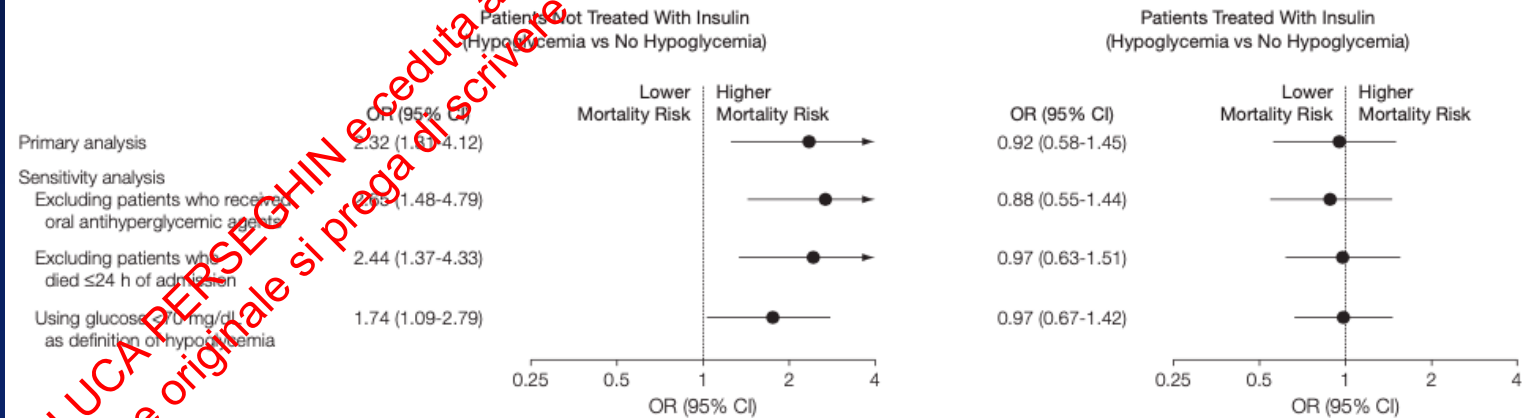


Figure 1. U-shaped association of admission blood glucose level with death or recurrent myocardial infarction at 30 days in the overall population (n = 4,227) (A), nondiabetic patients (n = 3,463) (B), and diabetic patients (n = 738) (C).

Figure. Association Between Hypoglycemia and Mortality After Multivariable Adjustment



OR indicates confidence interval; OR, odds ratio. To convert glucose to mmol/L, multiply by 0.0555.

Kosiborod M et al JAMA, 2015

Pinto DS et al J Am Coll Cardiol, 2005

Why?

Pathogenic mechanisms

1. blood coagulation abnormalities
2. inflammation
3. endothelial dysfunction
4. sympathetic nervous system activation

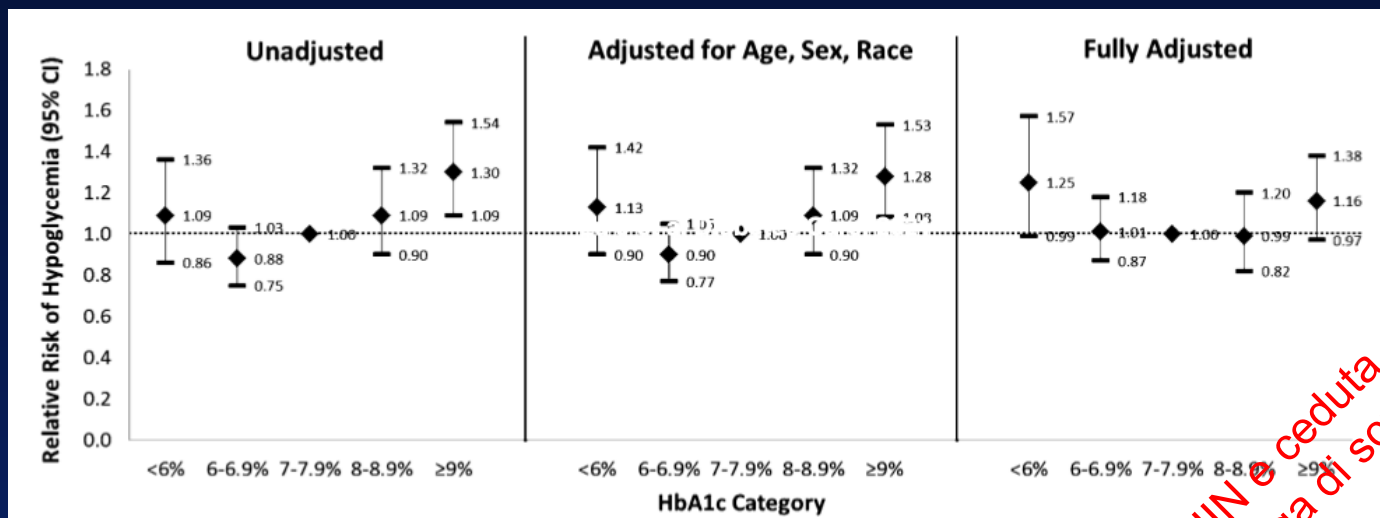
Evaluation of the individual risk profile

Table 3. Risk Factors for Severe Hypoglycemia

Hemoglobin A1c <6%
Hypoglycemic unawareness
Autonomic neuropathy
Cognitive impairment
Renal dysfunction
Insulin therapy
Sulfonylurea therapy
Previous episodes of severe hypoglycemia
Missed meals

Hide Hypo in T2DM

Lipska KJ et al Diabetes Care, 2013



..... in older T2DM

Unexpectedly high frequency of hypoglycemic episodes in older adults even with poor glycemic control.

This finding is critical in the debate over glycemic goals in older adults.

Current guidelines based on expert opinions suggest relaxing A1C goals to <8% for vulnerable elders to avoid hypoglycemia-related morbidity.

Here, 65% of patients with A1C >8% were found to have ≥1 hypoglycemic episode over a 3-day period.

Importantly, 12 of 26 patients with hypoglycemia were found to have at least one episode of severe hypoglycemia (glucose level below 50 mg/dl).

These results suggest that simply relaxing A1C goals may not be adequate to protect frail older adults against hypoglycemia.

Munshi MN et al Arch Intern Med, 2011

CGM

ruolo della variabilità glicemica (GV) e della metrica

Diapositiva preparata da GIANLUCA PERSEGHI e ceduta alla Società Italiana di Diabetologia.
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Effectiveness and Safety of the Intermittently Scanned Continuous Glucose Monitoring System FreeStyle Libre 2 in Patients with Type 2 Diabetes Treated with Basal Insulin or Oral Antidiabetic Drugs: An Observational, Retrospective Real-World Study

This was an observational, retrospective, real-world study enrolling patients with T2DM who were starting the use of isCGM.

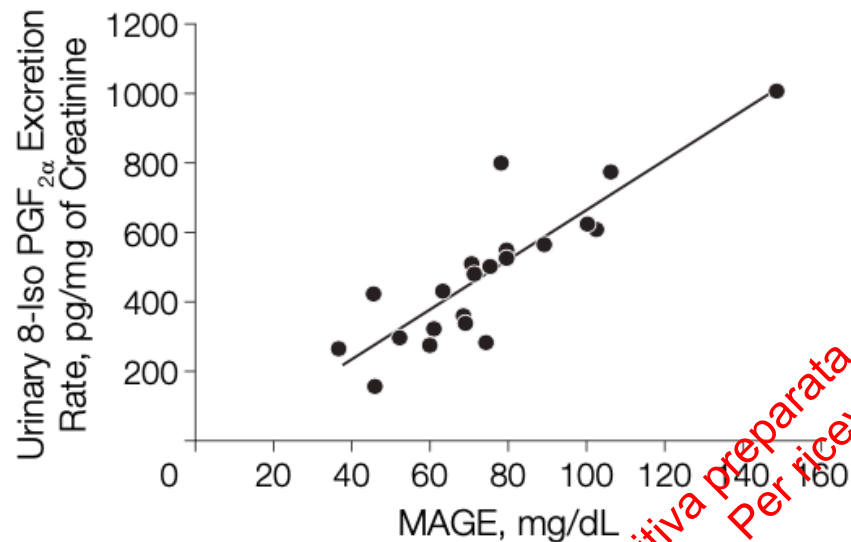


Conti M et al J Clin Med, 2024

Activation of Oxidative Stress by Acute Glucose Fluctuations Compared With Sustained Chronic Hyperglycemia in Patients With Type 2 Diabetes

GV is associated with oxidative stress

Figure 2. Linear Correlation Between 24-Hour Urinary Excretion Rates of 8-Iso Prostaglandin $F_{2\alpha}$ ($PGF_{2\alpha}$) and Mean Amplitude of Glycemic Excursions (MAGE)



$r=0.86$; $P<.001$.

Table 3. Independent Effects of Markers of Diabetic Control on Urinary 8-Iso $PGF_{2\alpha}$ Excretion Rates

	Standardized Regression Coefficient	t	P Value	Adjusted R^2 of the Model
Model 1			<.001	0.72
Mean glucose concentrations*	-0.012	-0.093	.93	
MAGE	0.830	6.551	<.001	
Fasting plasma insulin	0.128	1.020	.32	
Model 2			.007	0.41
Mean glucose concentrations*	-0.236	-1.128	.27	
AUCpp	0.700	3.405	.003	
Fasting plasma insulin	0.456	2.550	.02	

Abbreviations: AUCpp, postprandial incremental area under the curve; 8-iso $PGF_{2\alpha}$, 8-iso prostaglandin $F_{2\alpha}$ excretion rate; MAGE, mean amplitude of glycemic excursions.

*Mean glucose concentrations were calculated over 24 hours.

GV is associated with CVD

Table 1 Studies assessing the impact of GV on cardiovascular outcomes in patients with T2D

Study	Patients, population	Follow-up (months)	GV measure, metrics	Outcomes	Results
ADVANCE Hirakawa <i>et al</i> ²¹	4399, T2D	24	FG and HbA1c visit-to-visit variation (CV)	Combined macrovascular and microvascular events and all-cause mortality	Increased HbA1c visit-to-visit variation was associated with increased risk of vascular events ($p=0.01$, HR 1.64, 1.05–2.55), macrovascular events ($p=0.02$), and mortality ($p=0.001$, HR 3.31, 1.57–6.98). FG visit-to-visit variation was associated with increased risk of CV events ($p<0.001$, HR 2.70, 1.65–4.42) and macrovascular ($p=0.005$) and microvascular ($p<0.001$) events.
DEVOTE 2 Zinman <i>et al</i> ⁴⁹	7586, T2D	24	SMBG (SD)	MACE, severe hypoglycemia	GV was associated with severe hypoglycemia: HR 4.11 (3.15–5.35); MACE: HR 1.36 (1.12–1.65); and all cause mortality: HR 1.58 (1.23–2.03).
Takahashi <i>et al</i> ⁵⁰	417, ACS	39	CGM (MAGE)	MACCE	MAGE was associated with increased MACCE (23.3% vs 11.6%, $p=0.002$) and was an independent predictor of poor prognosis ($p=0.045$, HR 1.84, 1.01–3.36).
Gerbaud <i>et al</i> ⁴²	327, ACS	16.9	SMBG (SD)	MACE	GV cut-off of >2.70 mmol/L was the strongest independent predictive factor of MACE: OR 2.21 (1.64–0.98), $p<0.001$.
VADT Zhou <i>et al</i> ⁵¹	1791, T2D	84	FG and HbA1c (CV, ARV)	MACCE	CV and ARV of FG were significantly associated with CVD: CV glucose: $p=0.003$, OR 1.162 (1.054–1.281); ARV glucose: $p=0.0006$, OR 1.168 (1.069–1.275).
HEART2D Siegel <i>et al</i> ⁵²	1115, AMI	42	SMBG (MAGE, MAG, SD)	MACCE	No association between GV and CVD. MAG $p=0.57$, MAGE $p=0.49$ and SD $p=0.52$.
DIGAMI 2 Mellbin <i>et al</i> ⁵³	578, AMI	12	BG (RMSE)	Mortality, stroke, reinfarction	No association between GV and complications. Composite endpoint: RMSE $p=0.28$, HR 1.09 (0.93–1.27), mortality $p=0.21$, HR 1.14 (0.93–1.38).

GV – chronic setting

GV was assessed during initial hospitalization for Acute Coronary Syndrome
MACE, including new-onset myocardial infarction, acute heart failure, and cardiac death
(follow-up 17 months)

Table 3—Multivariate logistical regression analysis of predictive factors for MACE

Variables	OR	95% CI	P value
Personal history of CAD	1.42	1.05–1.91	0.03
SS >34 (compared with SS ≤34)	1.88	1.26–2.82	0.002
LVEF <40% (compared with LVEF ≥40%)	1.71	1.14–2.54	0.009
GRACE score >140	1.07	0.77–1.49	0.69
Vasopressor/inotropic agents	1.73	0.87–3.44	0.12
GV (SD) >2.70 mmol/L	2.21	1.64–2.98	<0.001

P values in boldface type indicate numbers that are significant at the 95% confidence limit.

SS: Syntax Score

GRACE: Global Registry of Acute Coronary Events

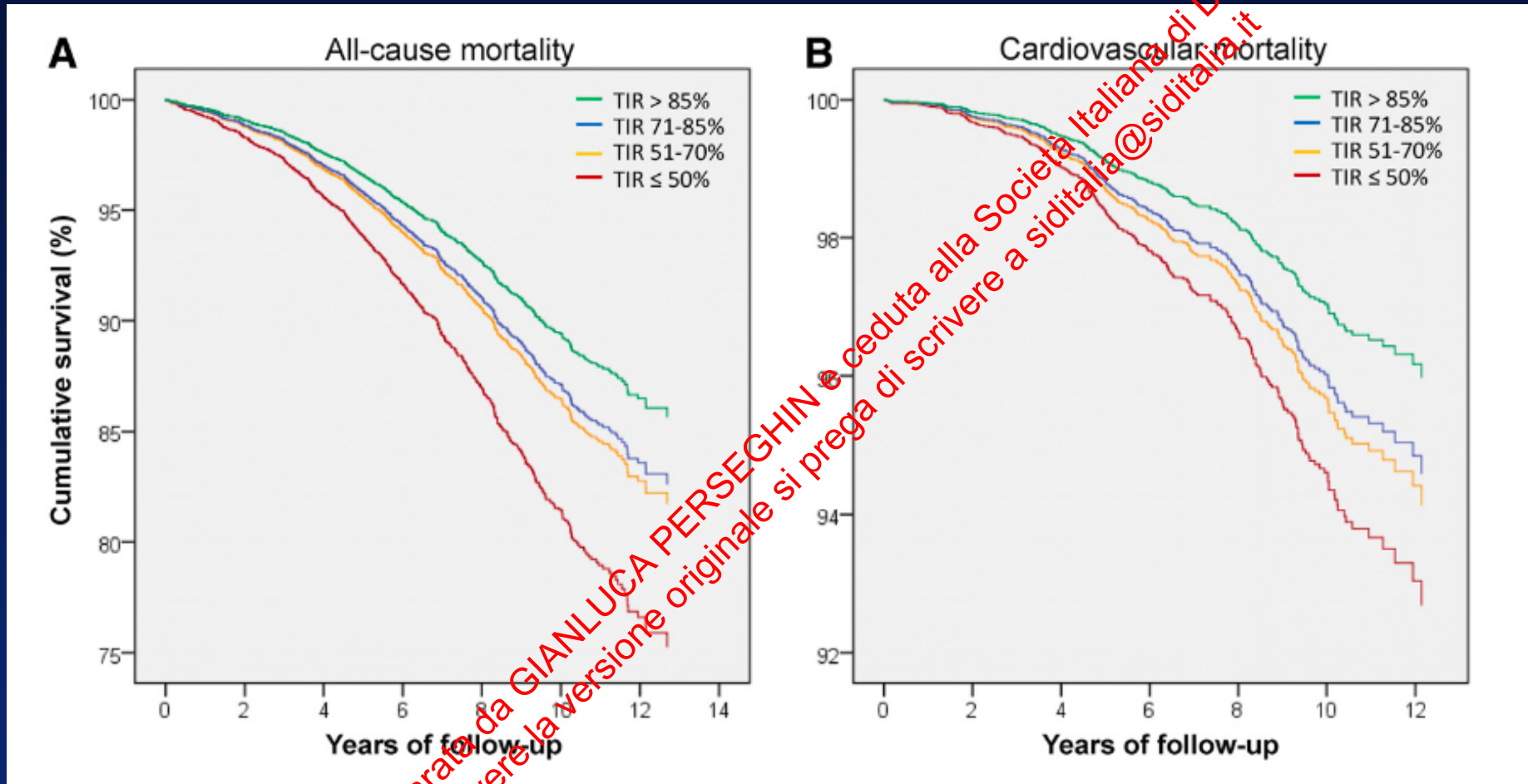
Gerbaud E et al Diabetes Care, 2019

85. Lu, J. et al. Association of time in range, as assessed by continuous glucose monitoring, with diabetic retinopathy in type 2 diabetes. *Diabetes Care* **41**, 2370–2376 (2018).
86. Yang, J. et al. Association of time in range, as assessed by continuous glucose monitoring, with painful diabetic polyneuropathy. *J. Diabetes Invest.* **12**, 828–836 (2021).
87. Li, F. et al. TIR generated by continuous glucose monitoring is associated with peripheral nerve function in type 2 diabetes. *Diabetes Res. Clin. Pract.* **166**, 108289 (2020).
88. van der Heide, F. C. T. et al. (Pre)diabetes, glycemia, and daily glucose variability are associated with retinal nerve fiber layer thickness in the Maastricht study. *Sci. Rep.* **12**, 17750 (2022).
89. Gad, H. et al. Continuous glucose monitoring reveals a novel association between duration and severity of hypoglycemia, and small nerve fiber injury in patients with diabetes. *Endocr. Connect.* **11**, e220352 (2022).
90. Lu, J. et al. Time in range is associated with carotid intima-media thickness in type 2 diabetes. *Diabetes Technol. Ther.* **22**, 72–78 (2020).
91. Zhou, H. et al. Time in range, assessed with continuous glucose monitoring, is associated with brachial-ankle pulse wave velocity in type 2 diabetes: a retrospective single-center analysis. *Front. Endocrinol.* **13**, 1014568 (2022).
92. Lu, J. et al. Time in range in relation to all-cause and cardiovascular mortality in patients with type 2 diabetes: a prospective cohort study. *Diabetes Care* **44**, 549–555 (2021).
93. Li, J. et al. Association of time in range levels with lower extremity arterial disease in patients with type 2 diabetes. *Diabetes Metab. Syndr. Clin. Res. Rev.* **14**, 2081–2085 (2020).
94. Xie, P. et al. Time in range in relation to amputation and all-cause mortality in hospitalised patients with diabetic foot ulcers. *Diabetes Metab. Res. Rev.* **38**, e3498 (2022).
95. Mayeda, L. et al. Glucose time in range and peripheral neuropathy in type 2 diabetes mellitus and chronic kidney disease. *BMJ Open Diabetes Res. Care* **8**, e000991 (2020).
96. Guo, Q.-Y. et al. Continuous glucose monitoring defined time-in-range is associated with sudomotor dysfunction in type 2 diabetes. *World J. Diabetes* **11**, 489–500 (2020).
97. Kim, M. Y. et al. The association between continuous glucose monitoring-derived metrics and cardiovascular autonomic neuropathy in outpatients with type 2 diabetes. *Diabetes Technol. Ther.* **23**, 434–442 (2021).
98. Guo, Q. et al. Time in range, as a novel metric of glycemic control, is reversely associated with presence of diabetic cardiovascular autonomic neuropathy independent of HbA1c in Chinese type 2 diabetes. *J. Diabetes Res.* **2020**, 5817074 (2020).
99. Yoo, J. H. et al. Association between continuous glucose monitoring-derived time in range, other core metrics, and albuminuria in type 2 diabetes. *Diabetes Technol. Ther.* **22**, 768–776 (2020).

TIR and complications

- Retinopathy
- Retinal nerve fiber layer
- Albuminuria
- Painful polyneuropathy
- Peripheral nerve function
- Small nerve fiber injury
- Cardiovascular Autonomic Neuropathy (CAN)
- IMT
- Brachial- ankle artery pulse wave velocity
- PAD & amputation
- Sudomotor dysfunction

TIR & CVD survival



6225 adult patients with T2DM from a single center in Shanghai, China. Median follow-up: 7 years

TIR at baseline stratified into 4 groups

Cox proportional hazards regression models were used

Lu J et al Diabetes Care, 2021

TAR₍₁₈₀₋₂₅₀₎ e MASLD in T1DM

262 adult individuals with established T1D undergoing vibration-controlled transient elastography (VCTE). All participants underwent CGM.

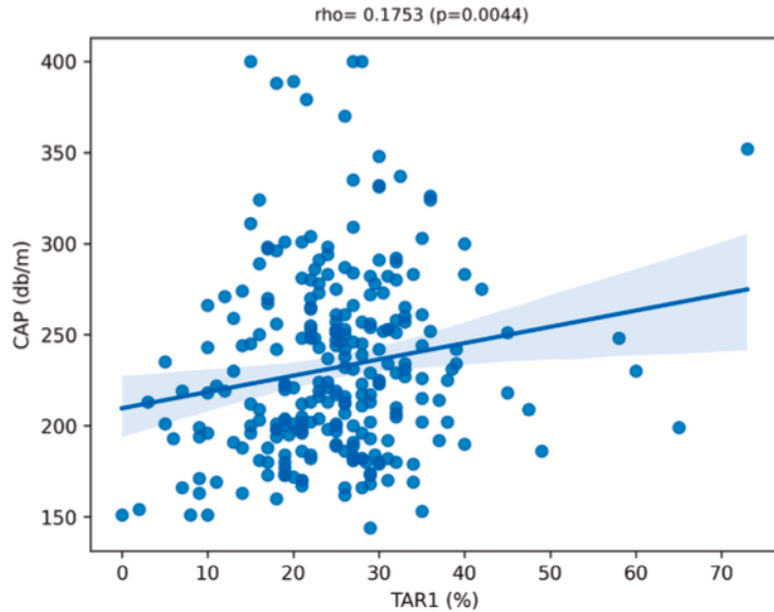


Fig. 1. Scatterplot showing the correlation between CAP (on the Y-axis) and TAR1 values (on the X-axis). Spearman's rho coefficient: 0.175, $p = 0.004$.

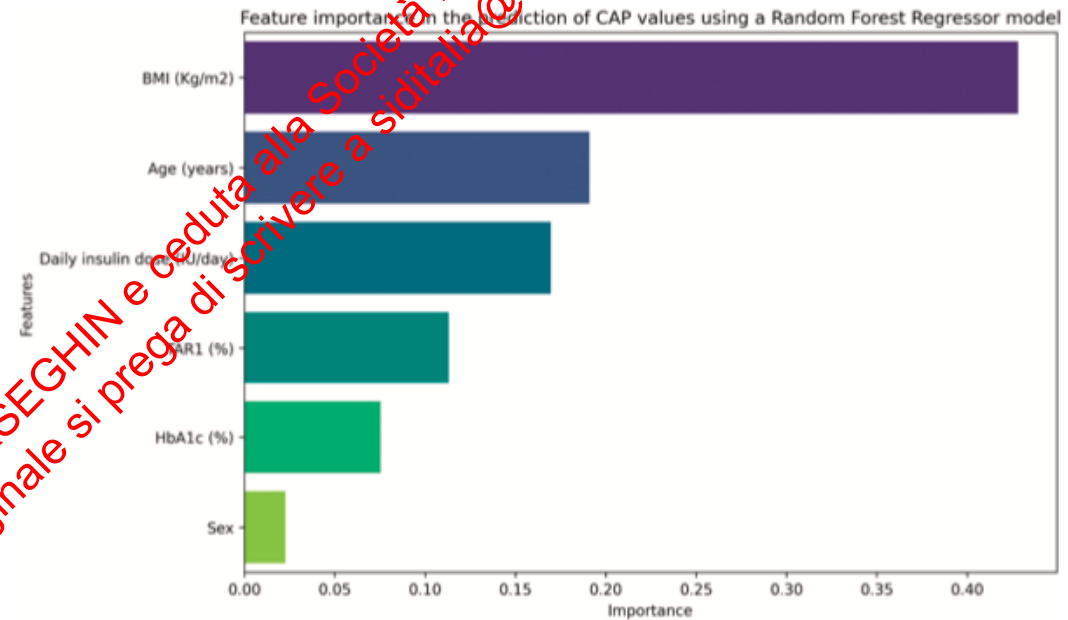


Fig. 2. Feature importance in the prediction of CAP using a Random Forest Regression model. The plot shows the relative contribution of each predictor to the performance of this model.

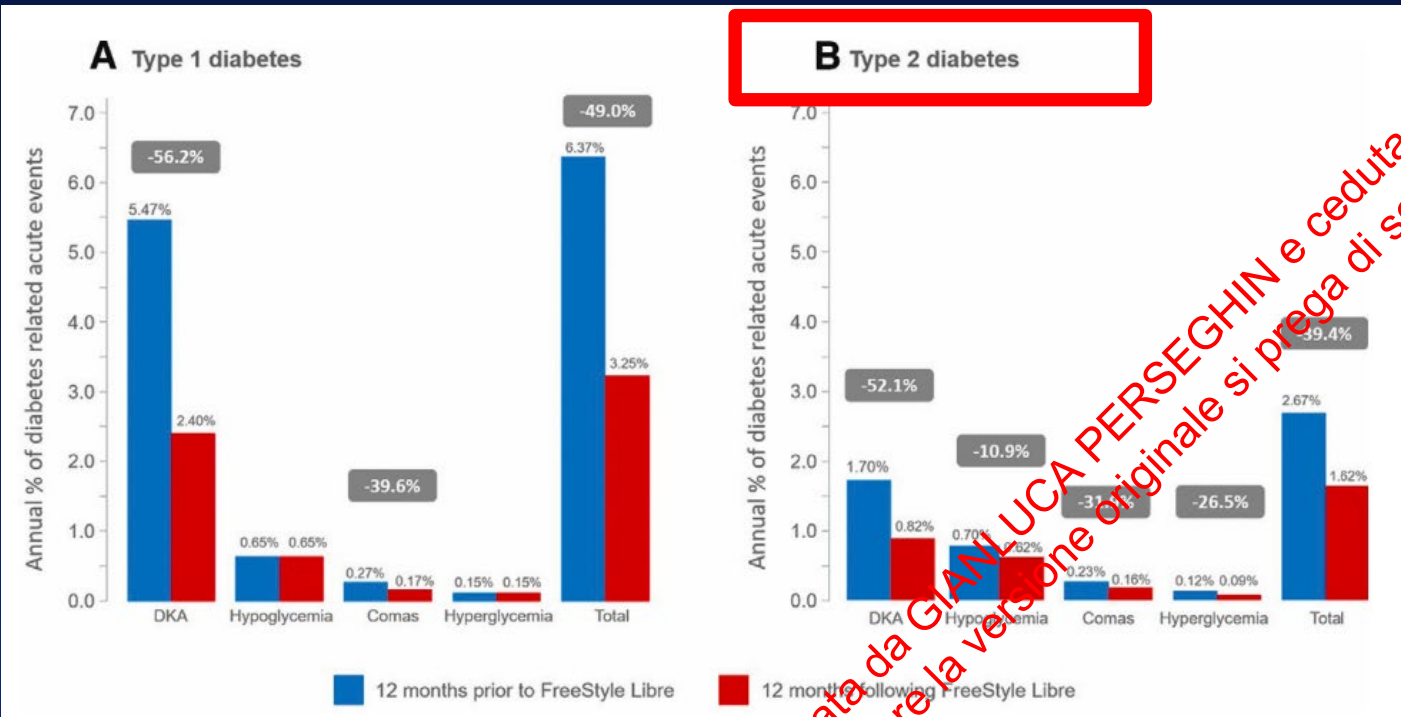
MASLD was defined as CAP ≥ 248 dB/m and the presence of at least one cardiometabolic risk factor. Significant liver fibrosis was defined as LSM ≥ 8 kPa.

Raggiungimento del target glicemico: tra efficacia e sicurezza

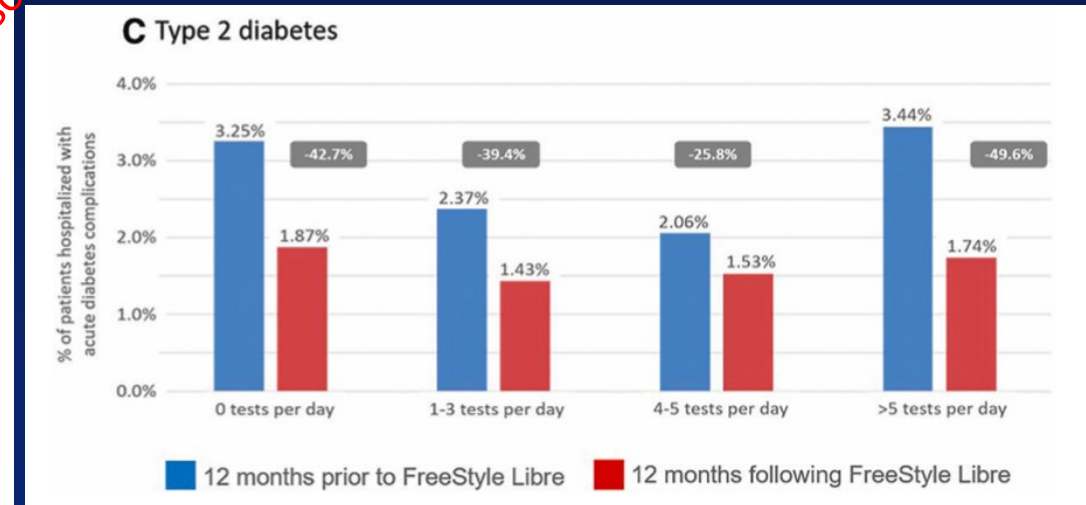
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Acute diabetes complications: RELIEF study

Diabetes-related acute events



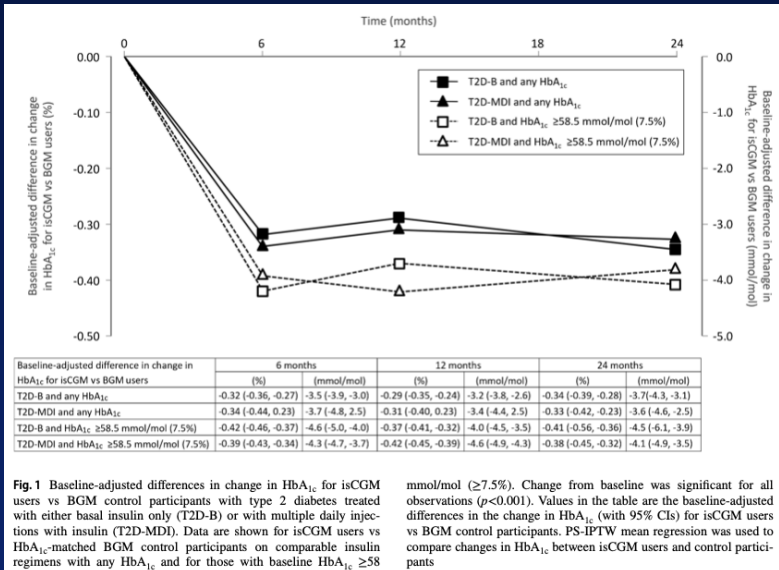
% of patients hospitalized



Hospitalizations for DKA, severe hypoglycemia, diabetes-related coma, and hyperglycemia 12 months before and after initiation FSL

Outcomes in isCGM in T2DM on insulin (in Sweden)

HbA1c



Retrospective comparative (isCGM vs BGM) cohort study

To assess the impact of initiating isCGM compared with BGM on longitudinal changes from baseline for adults in Sweden with T2DM in

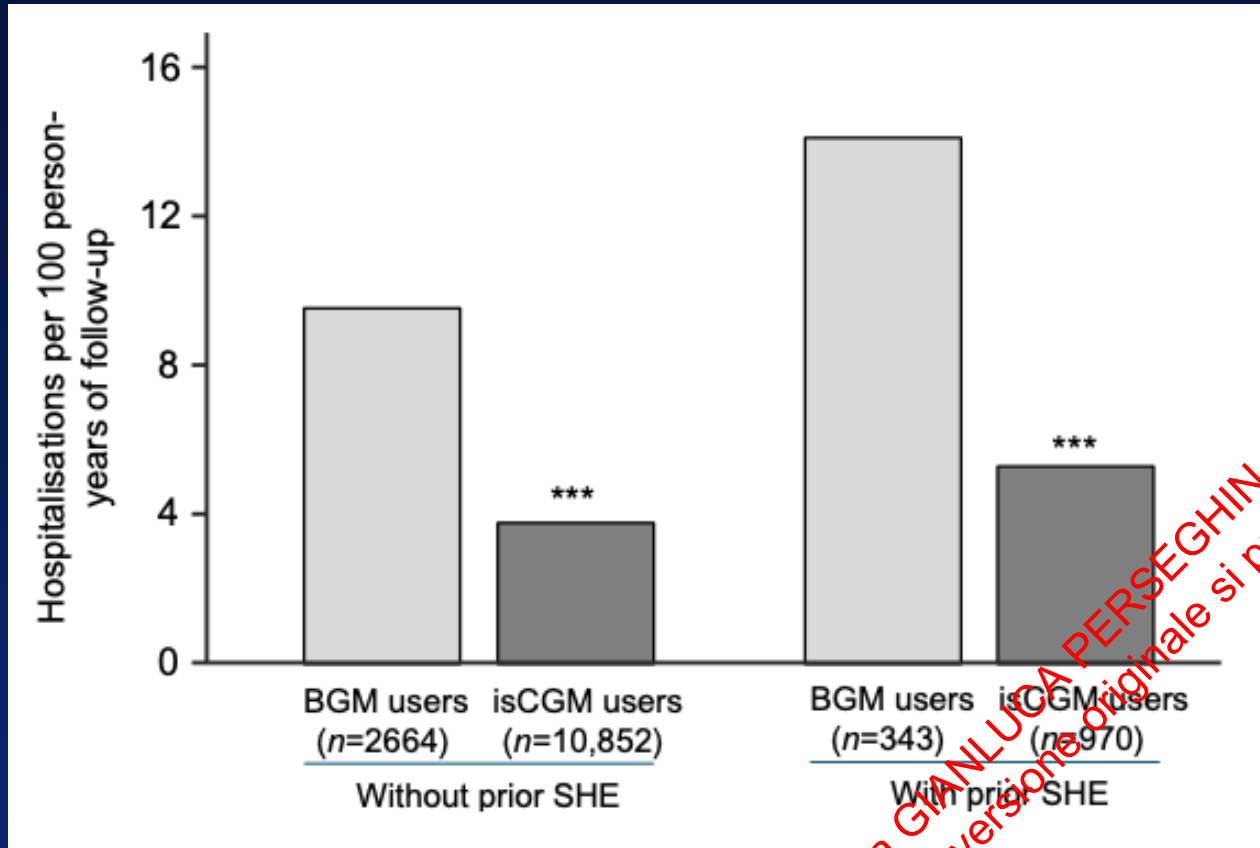
- HbA1c
- severe hypoglycaemia
- rates of hospital admission for known micro and macrovascular complications
- overall hospitalisation for any reason

Table 2 Hospital admissions for diabetes complications for isCGM users with type 2 diabetes vs BGM control participants (all participants)

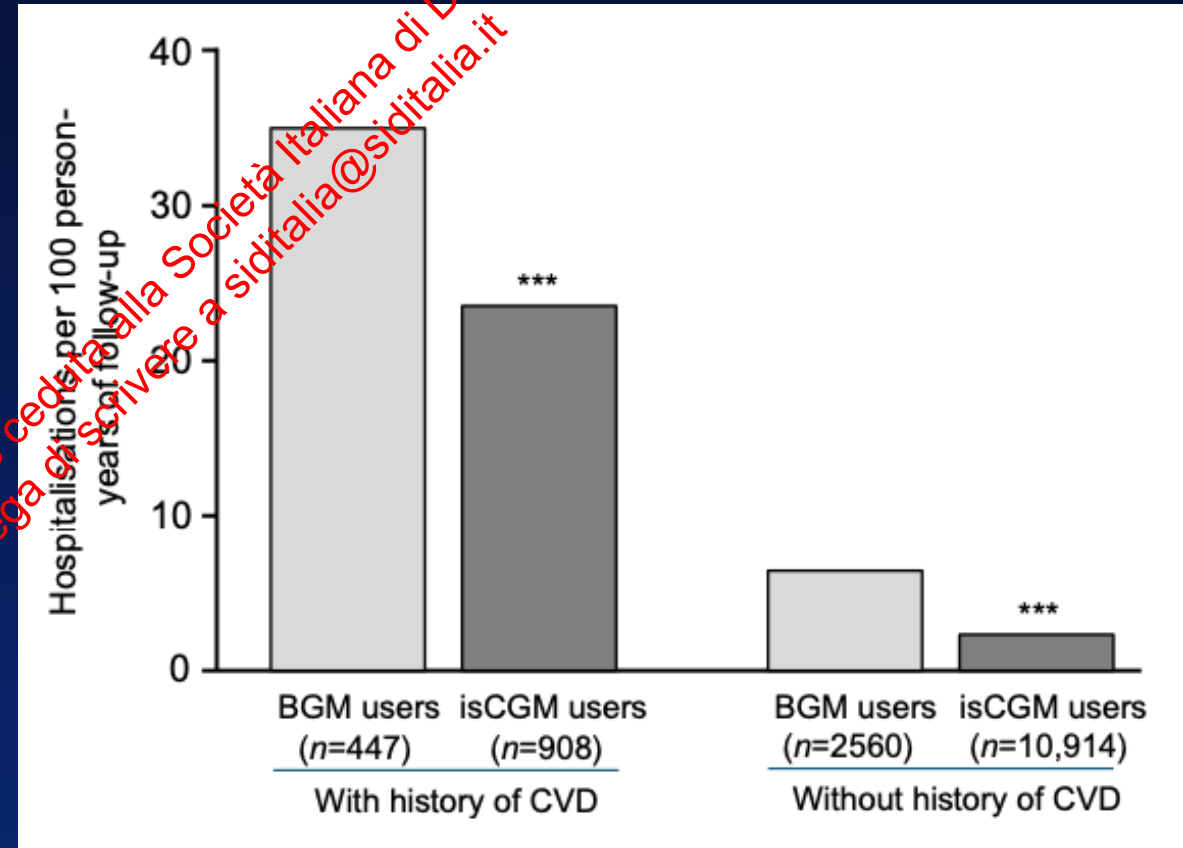
Primary diagnosis at hospital admission	No. of hospital admissions	Hospitalisation event rate per 100 person-years of follow-up (95% CI)		RR (95% CI)	p value
		isCGM (n=6800)	BGM (n=78,386)		
Hypoglycaemia	22	0.17 (0.10, 0.25)	0.33 (0.31, 0.35)	0.43 (0.27, 0.70)	0.001
Coma	1	0.01 (0.00, 0.04)	0.01 (0.00, 0.01)	Insufficient events	N/A
Acute myocardial infarction^a	219	1.65 (1.44, 1.89)	2.20 (2.15, 2.26)	0.67 (0.56, 0.82)	<0.001
Angina	181	1.37 (1.18, 1.58)	1.04 (1.00, 1.08)	1.27 (1.03, 1.57)	0.025
Ischaemic heart disease	68	0.51 (0.40, 0.65)	0.47 (0.45, 0.50)	1.08 (0.80, 1.44)	0.621
Stroke	14	1.31 (1.13, 1.53)	1.92 (1.87, 1.97)	0.56 (0.46, 0.69)	<0.001
Peripheral vascular disease	16	0.12 (0.07, 0.20)	0.12 (0.10, 0.13)	0.98 (0.49, 1.96)	0.961
Heart failure	434	3.28 (2.98, 3.60)	4.16 (4.09, 4.24)	0.63 (0.53, 0.76)	<0.001
Atrial fibrillation	167	1.26 (1.08, 1.47)	1.16 (1.12, 1.20)	1.00 (0.80, 1.25)	0.994
Kidney disease	485	3.66 (3.35, 4.01)	3.33 (3.26, 3.40)	0.89 (0.77, 1.04)	0.144
Retinopathy	14	0.11 (0.06, 0.18)	0.07 (0.06, 0.08)	1.55 (0.81, 2.98)	0.189
Neuropathy	2	0.02 (0.00, 0.05)	0.01 (0.00, 0.02)	1.05 (0.21, 5.38)	0.951
Foot ulcer	4	0.03 (0.00, 0.08)	0.04 (0.03, 0.05)	0.71 (0.24, 2.10)	0.533
Hospitalisation for any reason^b	7930	59.91 (58.59, 61.24)	65.34 (65.04, 65.64)	0.71 (0.67, 0.75)	<0.001

PS-IPTW negative binomial regression was used to calculate rates of hospital admission for diabetes-related events per 100 person-years of cumulative follow-up. RRs (95% CIs) are for admission to hospital for isCGM users compared with BGM control participants

Outcomes in isCGM in T1DM (in Sweden)



SHE: severe hypoglycemic event



History of CVD

Retrospective comparative
(isCGM vs. BGM) cohort study

Eeg-Olofsson K et al Diabetologia, 2025

Controllo glicemico nel paziente ad alto rischio

1. Ruolo centrale del controllo glicemico per la prevenzione di eventi cardiovascolari maggiori
2. Raggiungere gli obiettivi terapeutici, anche glicemici
3. Personalizzare gli obiettivi
 - Rischio ipoglicemico nei pazienti ad alto rischio vascolare
 - Impatto dell'ipoglicemia su esiti cardiovascolari e mortalità
 - Strategie che minimizzano il rischio ipoglicemico: monitoraggio attivo
4. Ruolo della variabilità glicemica e della metrica come fattori indipendenti di rischio per complicanze micro e macrovascolari
5. Il monitoraggio attivo: raggiungimento degli obiettivi glicemici con “efficienza” e sicurezza

Di Mario C on Behalf Expert Panel Group
Cardiovasc Diabetol, 2022





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Michela Vergani (UNIMIB)
Matteo Conti (UNIMIB)

Clinical Nutrition

Alice Oltolini
Alessia Bongo
Giulia Rossini

R.N.

Paola Parmeggiani (Education)
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Diapositiva preparata da GIANLUCA PEREGO e ceduta alla Società Italiana di Diabetologia.
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GRADE Visual Evidence Chart

Outcome Type	Strength of Evidence	GRADE Icons
Microvascular	Moderate	★★★★☆
Macrovascular	Low–Moderate	★★☆☆☆

Effect Size

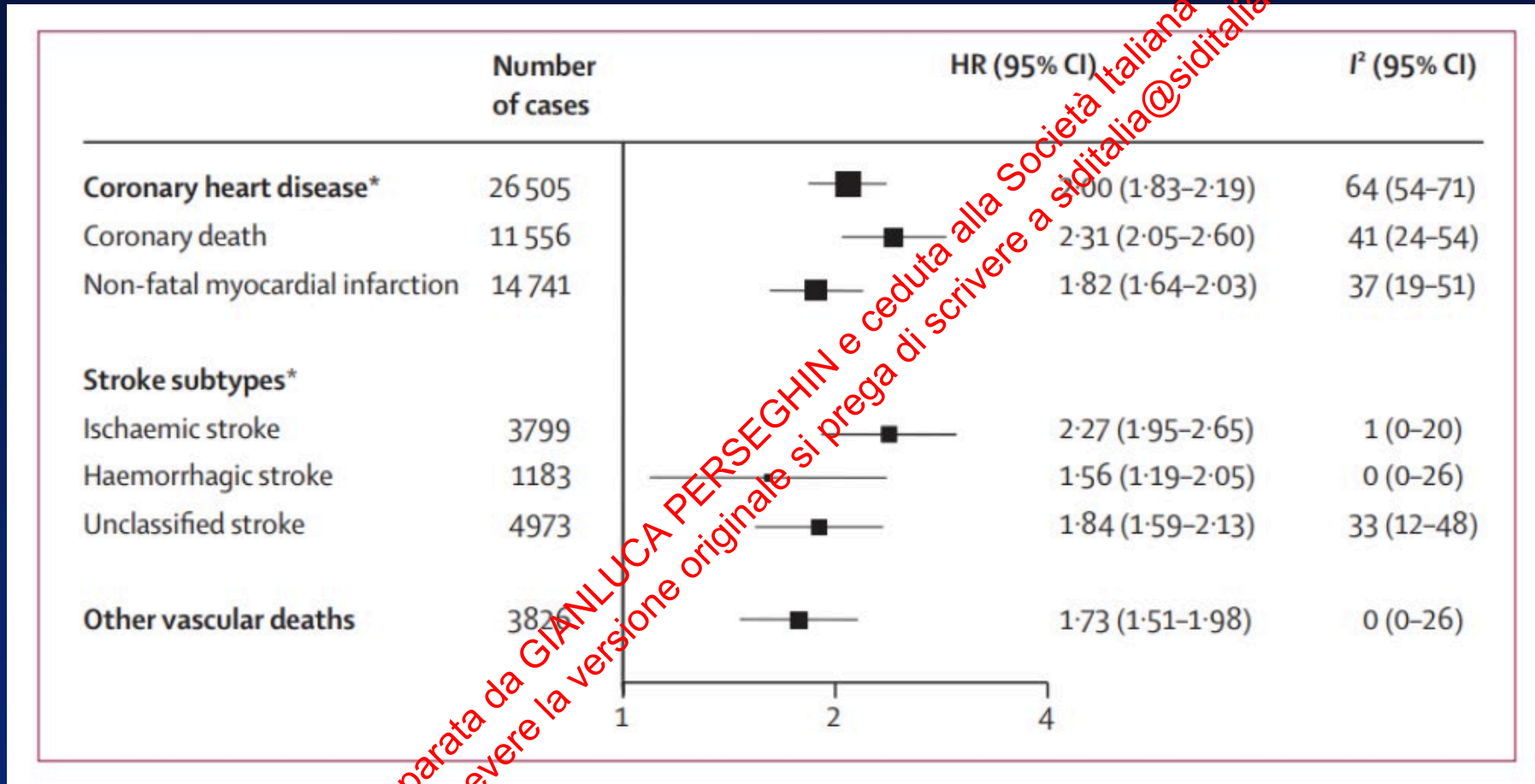
- Microvascular: ~40% lower risk of retinopathy progression per +10% TIR (cohort data)
- Macrovascular: ~30–70% fewer CVD-related admissions in registry analyses after isCGM

Evidence Summary: FreeStyle Libre & Vascular Outcomes (GRADE Framework)

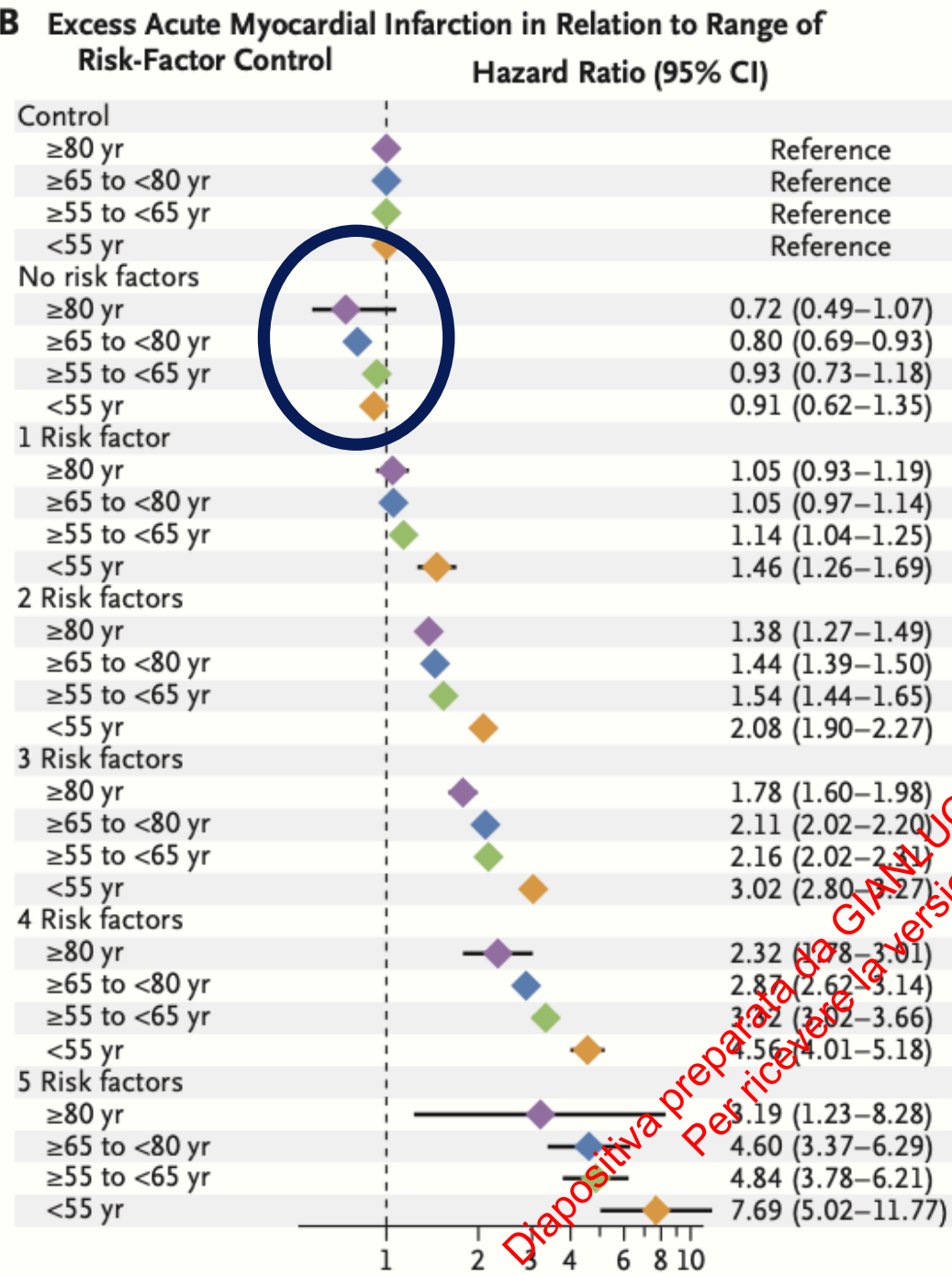
- Microvascular Outcomes (Retinopathy, Nephropathy, Neuropathy):
 - Evidence Quality: Moderate
 - Study Types: Cohort studies, registry data, emerging real world outcome data
 - Key Findings: Associations with improved TIR & reduced retinopathy progression
- Macrovascular Outcomes (Cardiovascular Events, Stroke):
 - Evidence Quality: Low to Moderate
 - Study Types: Real-world registry analyses, limited RCT data
 - Key Findings: Reduced hospitalizations for cardiovascular events; need prospective trials
- Overall GRADE Summary:
 - Strong rationale via glycaemic improvements
 - Associations encouraging, but causality not yet proven
 - Large outcome RCTs underway

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CVD in T2DM



Sarwar N et al for the Emerging Risk Factors Collaboration – Lancet, 2010



Treat-To-Targets

Key Message: “In conclusion, patients with T2DM who had five risk-factor variables within target ranges appeared to have little or no excess risks of death, myocardial infarction, and stroke as compared with the general population”