

SGLT2

INIBITORI
e progressione
della **malattia renale**
nel **diabete tipo 2**



VIDEOCONFERENZA
25 novembre 2020

Epidemiologia della Malattia Renale Cronica nel Diabete

Dr. Marco Dauriz
MD PhD



Department of Medicine
Division of Endocrinology & Metabolism
University of Verona Hospital Trust
Verona, Italy

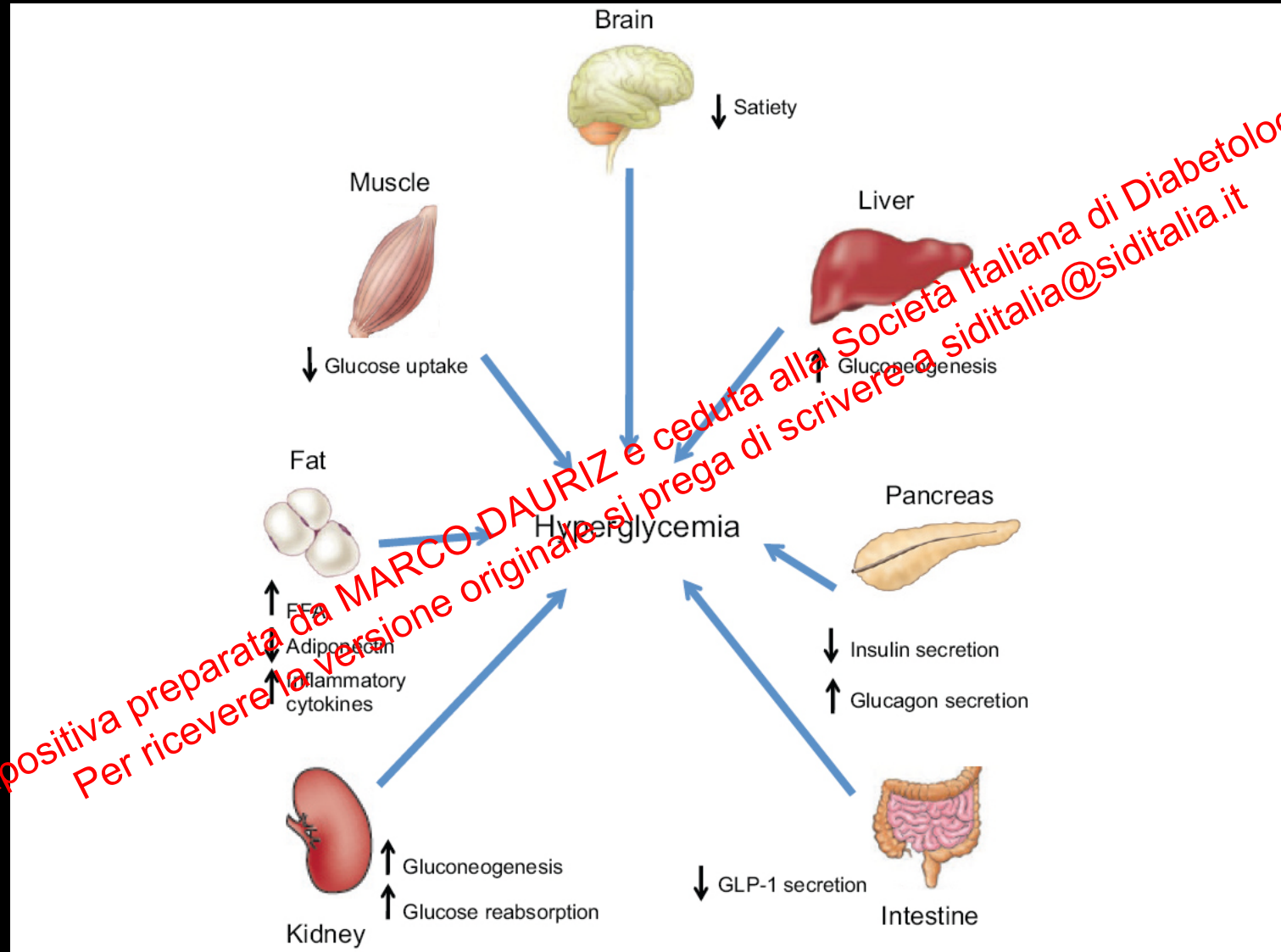
Department of Internal Medicine
Section of Endocrinology & Diabetes
General Hospital of Bolzano
Bolzano, Italy

PRESENTER FINANCIAL DISCLOSURE

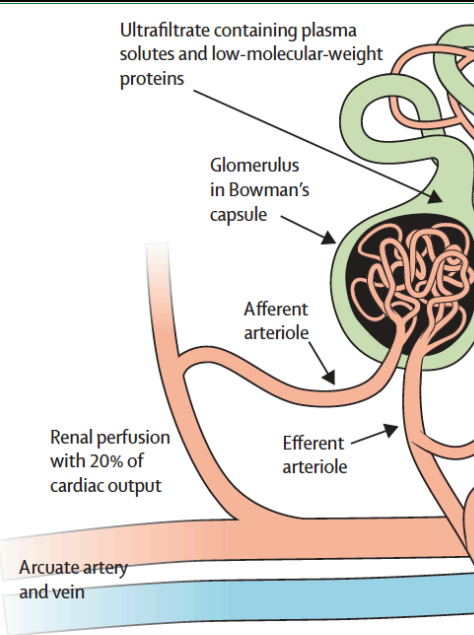
Over the past 2 calendar years, dr. M. Dauriz occasionally served as consultant for
NOVONORDISK, NOVARTIS, SANOFI, ELI LILLY/BOEHRINGER

Diapositiva preparata da MARCO DAURIZ e ceduta alla Societa Italiana di Diabetologia.
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Multi-organ & Tissue Physiology of Type 2 Diabetes



Form follows function - L. Sullivan, 1896



CKD DEFINITION & CLASSIFICATION

- CKD is defined as either the presence of kidney damage or GFR less than 60 mL/min/1.73 m² for three or more months
- CKD is classified based on cause, GFR category, and albuminuria category

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Primary & Systemic Causes of CKD

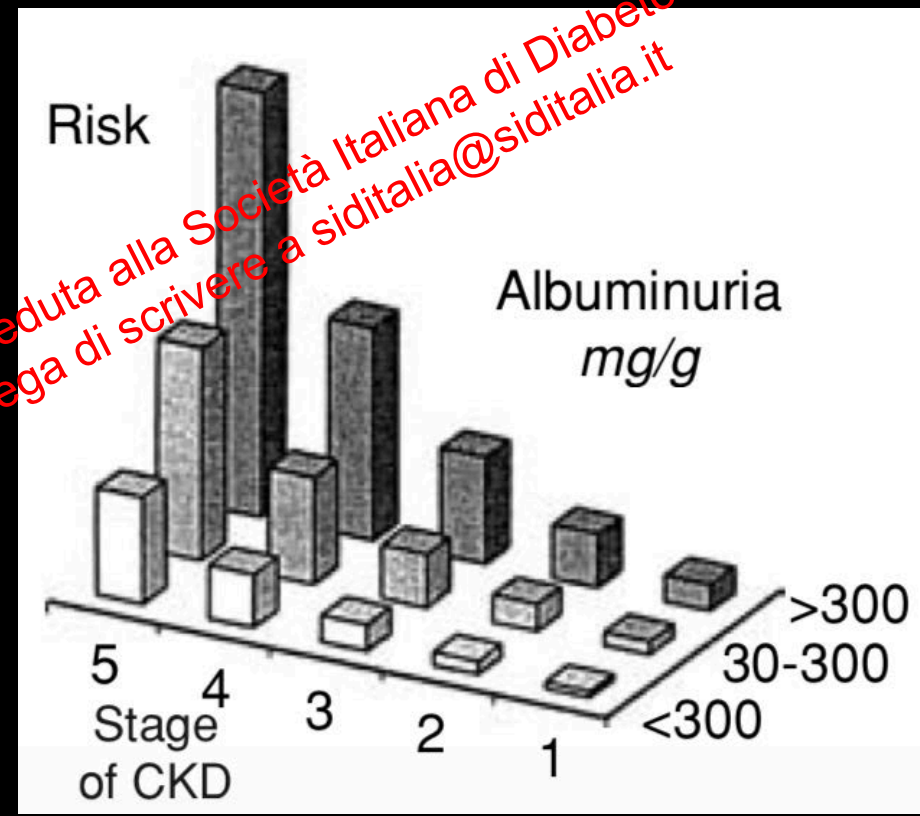
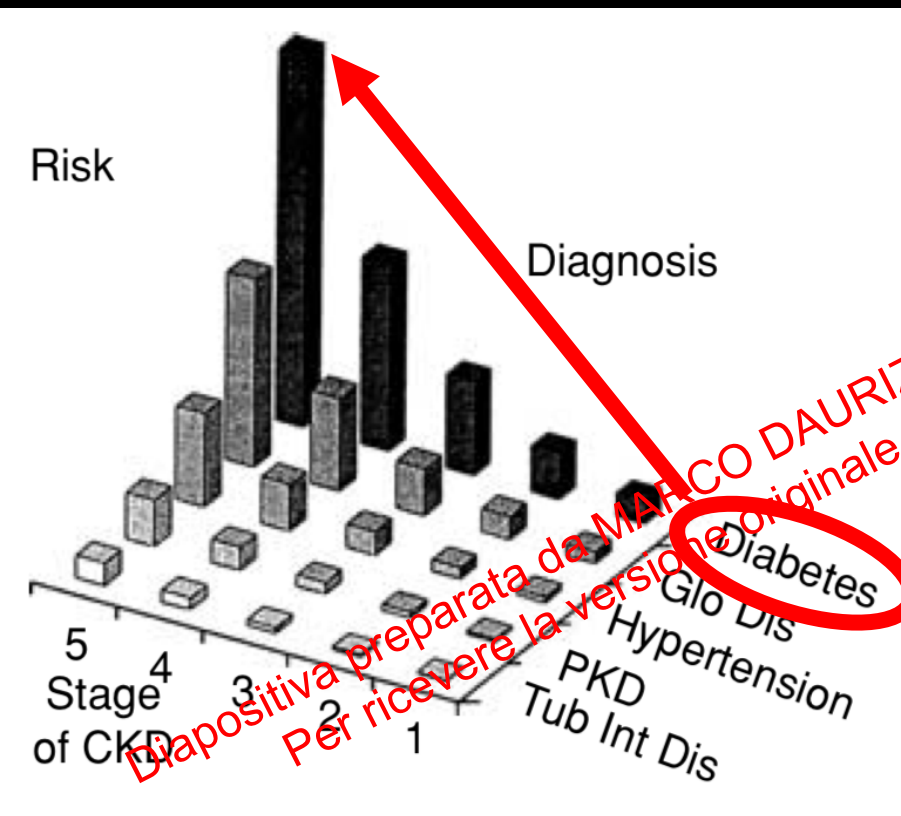
	Examples of primary kidney diseases	Examples of systemic diseases affecting the kidney
Glomerular diseases	Diffuse, focal or crescentic proliferative glomerulonephritis; focal and segmental glomerulosclerosis, membranous nephropathy, and minimal change disease	Obesity, metabolic syndrome and diabetes, systemic autoimmune diseases, systemic infections, drugs, complement diseases, and neoplasias and haemopoietic diseases
Vascular diseases	ANCA-associated renal limited vasculitis and fibromuscular dysplasia	Hypertension, atherosclerosis, ischaemia, cholesterol emboli, systemic vasculitis, thrombotic microangiopathy, and systemic sclerosis
Tubulointerstitial diseases	Urinary-tract infections, stones, and obstruction	Systemic infections, sarcoidosis, drugs, urate, environmental toxins (eg, lead, aristolochic acid), and neoplasia (myeloma)
Cystic and other congenital diseases	Renal dysplasia, medullary cystic disease, and polycystopathies	Autosomal-dominant polycystic kidney disease, Alport syndrome, and Fabry disease

ANCA=antineutrophil cytoplasmic antibody.

Lancet 2013; 382: 158–69

RISK* STRATIFICATION in CKD

*CKD progression, morbidity and mortality



Risk Factors for CKD Progression, Morbidity and Mortality

Outcome	Importance for different outcomes		
	CKD stage	Type of kidney disease (diagnosis) ^a	Proteinuria
Concurrent complications ^b	+++	+	+

Footnotes:

- b) Concurrent complications include hypertension, anemia, malnutrition, bone disease, neuropathy, and decreased quality of life.

KDIGO 2012

Risk for CKD progression, morbidity and mortality by GFR and Albuminuria Categories

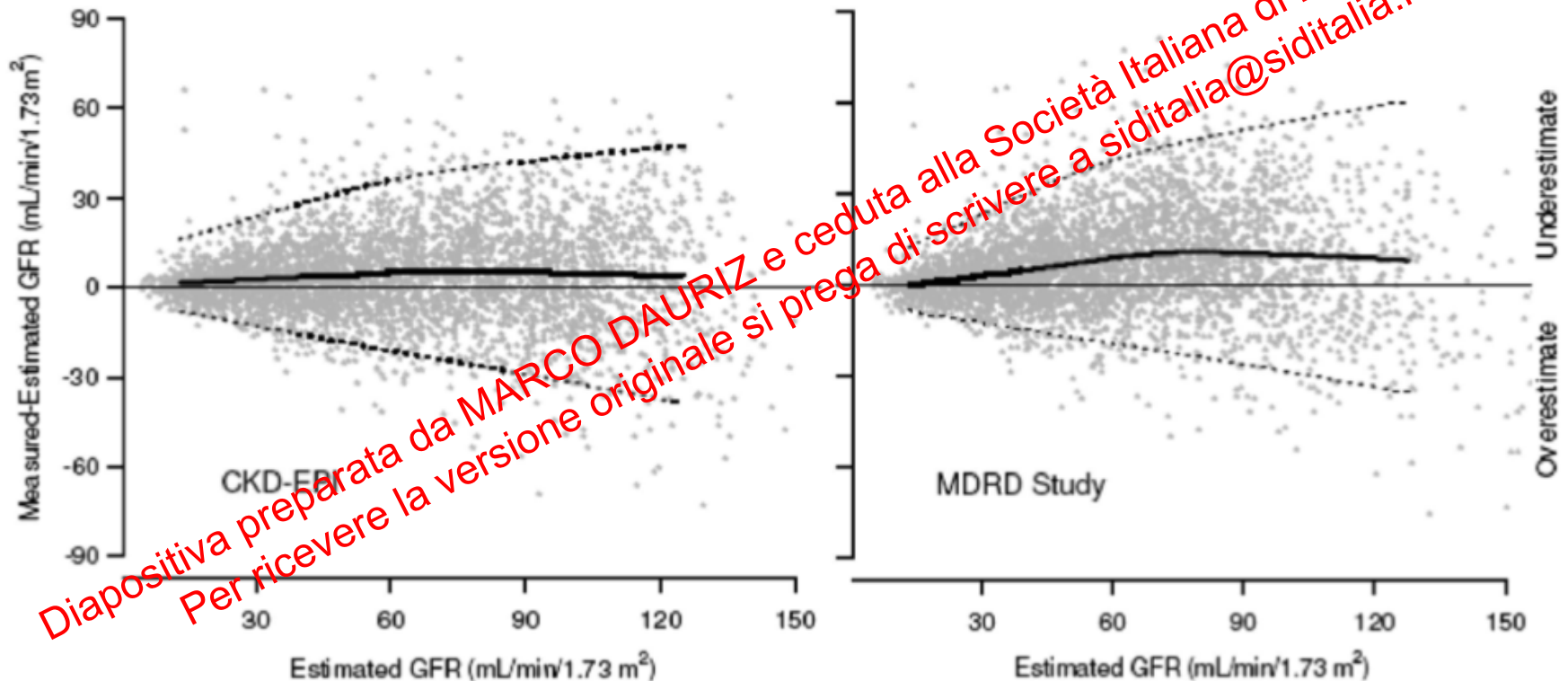


GFR categories (ml/min/1.73 m ²) Description and range	Persistent albuminuria categories Description and range			Description and range		
	G1	G2	G3a	G3b	G4	G5
	Normal or high ≥90	Mildly decreased 60-89	Mildly to moderately decreased 45-59	Moderately to severely decreased 30-44	Severely decreased 15-29	Kidney failure <15
	Normal or high <30 mg/g <3 mg/mmol	Mildly increased 30-300 mg/g 3-30 mg/mmol	Moderately increased >300 mg/g >30 mg/mmol	Severely increased		

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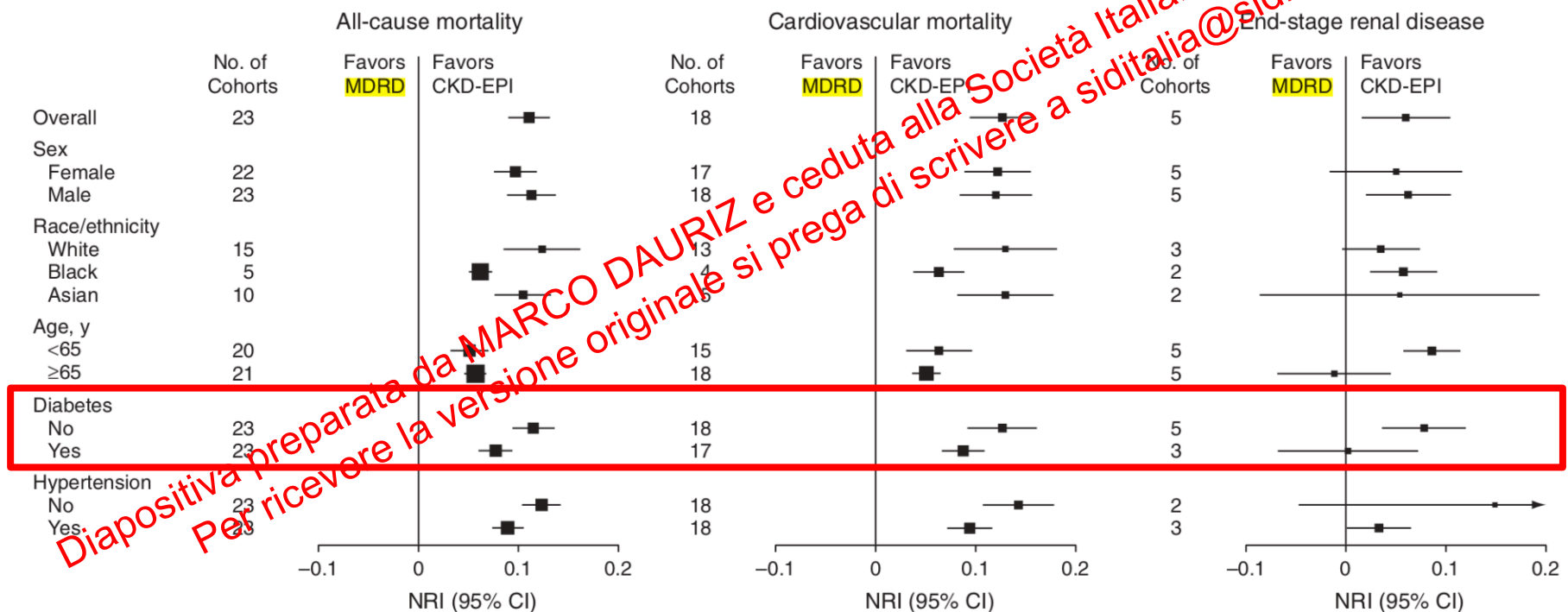
QUICK TOOLS

CKD-EPI vs. MDRD Study Equations



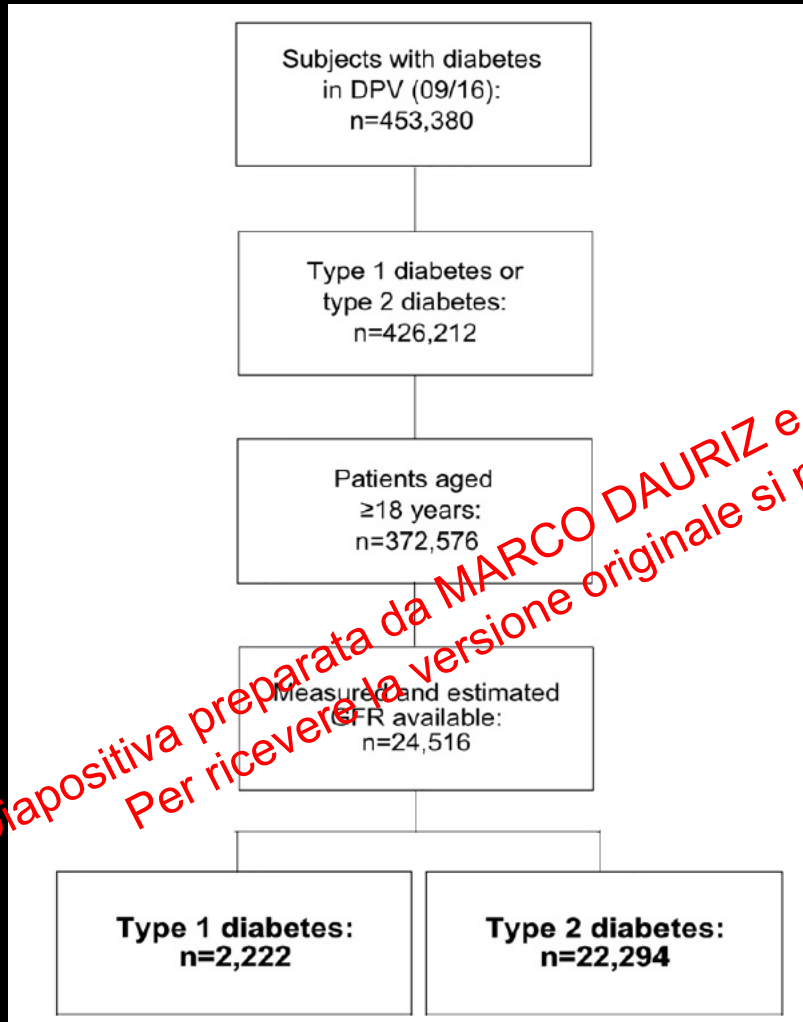
Meta-analysis of NRI on major survival outcomes in the general population

CKD-EPI vs. MDRD Study Equations



HOWEVER ...

CKD-EPI vs. MDRD Equations in the Diabetes-Patienten-Verlaufsdokumentation (DPV) Study



Accuracy (%) for each estimation method.

	MDRD	CKD-EPI
Entire study cohort	75.3	70.8
<i>Strata of GFR</i>		
GFR ≥90 ml/min/1.73 m ²	75.3	57.3
GFR 60–<90 ml/min/1.73 m ²	80.2	80.7
GFR 30–<60 ml/min/1.73 m ²	82.3	74.0
GFR 15–<30 ml/min/1.73 m ²	77.8	60.1
GFR <15 ml/min/1.73 m ²	71.0	49.8
<i>Age groups</i>		
18–<40 years	50.3	63.7
40–<60 years	68.7	72.8
60–<70 years	77.3	75.7
≥70 years	78.9	68.1
<i>Gender</i>		
Male	75.3	69.6
Female	75.3	71.2
<i>BMI groups</i>		
BMI < 25	72.6	66.0
25 ≤ BMI < 30	76.0	69.1
BMI ≥ 30	75.6	72.9
<i>Hypertension</i>		
Yes	74.8	68.9
No	76.4	73.8
<i>Microalbuminuria</i>		
Yes	70.8	62.6
No	74.8	71.4

CKD & DIABETES

Implications on Metabolic Control

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Accuracy and precision of A1c measurement declines with advanced CKD (G4-G5), particularly among patients treated by dialysis, in whom A1c measurements have low reliability

Novel subgroups of adult-onset diabetes and their association with outcomes: a data-driven cluster analysis of six variables

Emma Ahlqvist, Petter Storm, Annemari Käräjämäki*, Mats Martinell*, Mozhgan Dorkhan, Annelie Carlsson, Peter Vikman, Rashmi B Prasad, Dina Mansour Aly, Peter Almgren, Ylva Wessman, Nael Shaat, Peter Spégl, Hindrik Mulder, Eero Lindholm, Ole Melander, Ola Hansson, Ulf Malmqvist, Åke Lernmark, Kaj Lahti, Tom Forsén, Tiinamaija Tuomi, Anders H Rosengren, Leif Groop

Lancet Diabetes Endocrinol 2018

SARD=severe autoimmune diabetes

SIDD=severe insulin-deficient diabetes

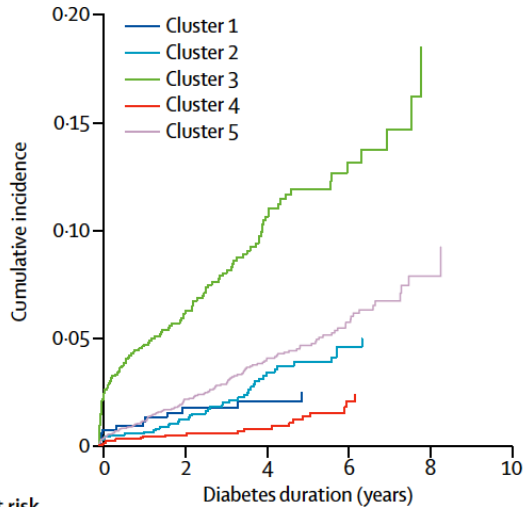
SIRD=severe insulin-resistant diabetes

MOD=mild obesity-related diabetes

MARD=mild age-related diabetes.

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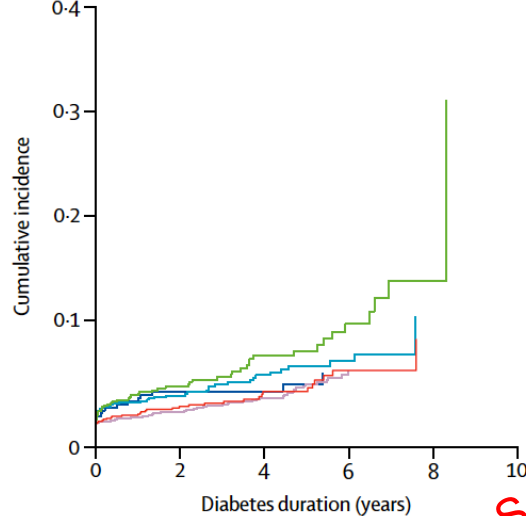
A Time to CKD >G3b



Number at risk

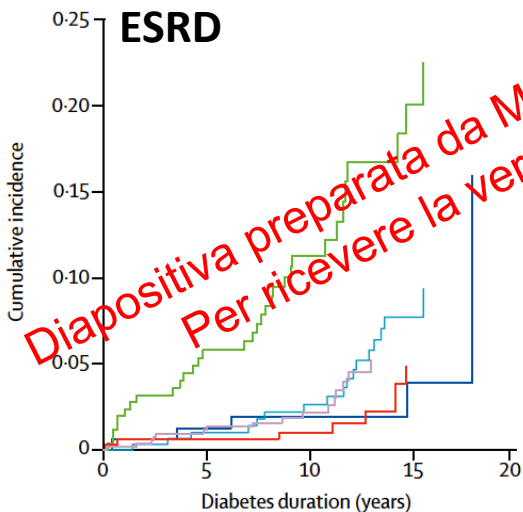
Cluster 1	496	362	220	82	11
Cluster 2	1325	912	511	180	17
Cluster 3	1061	669	337	105	13
Cluster 4	1607	1082	596	206	27
Cluster 5	2880	1968	1128	414	55

B Macroalbuminuria



333	213	117	39	5
388	513	266	81	
664	384	193	62	
922	546	268	77	
1665	1034	541	172	16

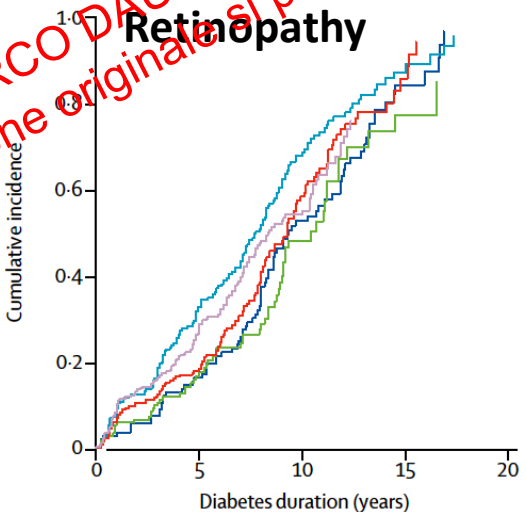
C ESRD



Number at risk

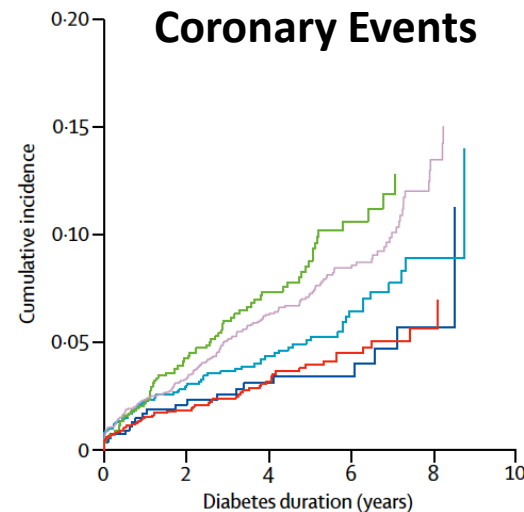
Cluster 1	158	123	70	22
Cluster 2	298	248	153	40
Cluster 3	239	166	81	21
Cluster 4	307	261	157	43
Cluster 5	514	381	184	42

D Retinopathy



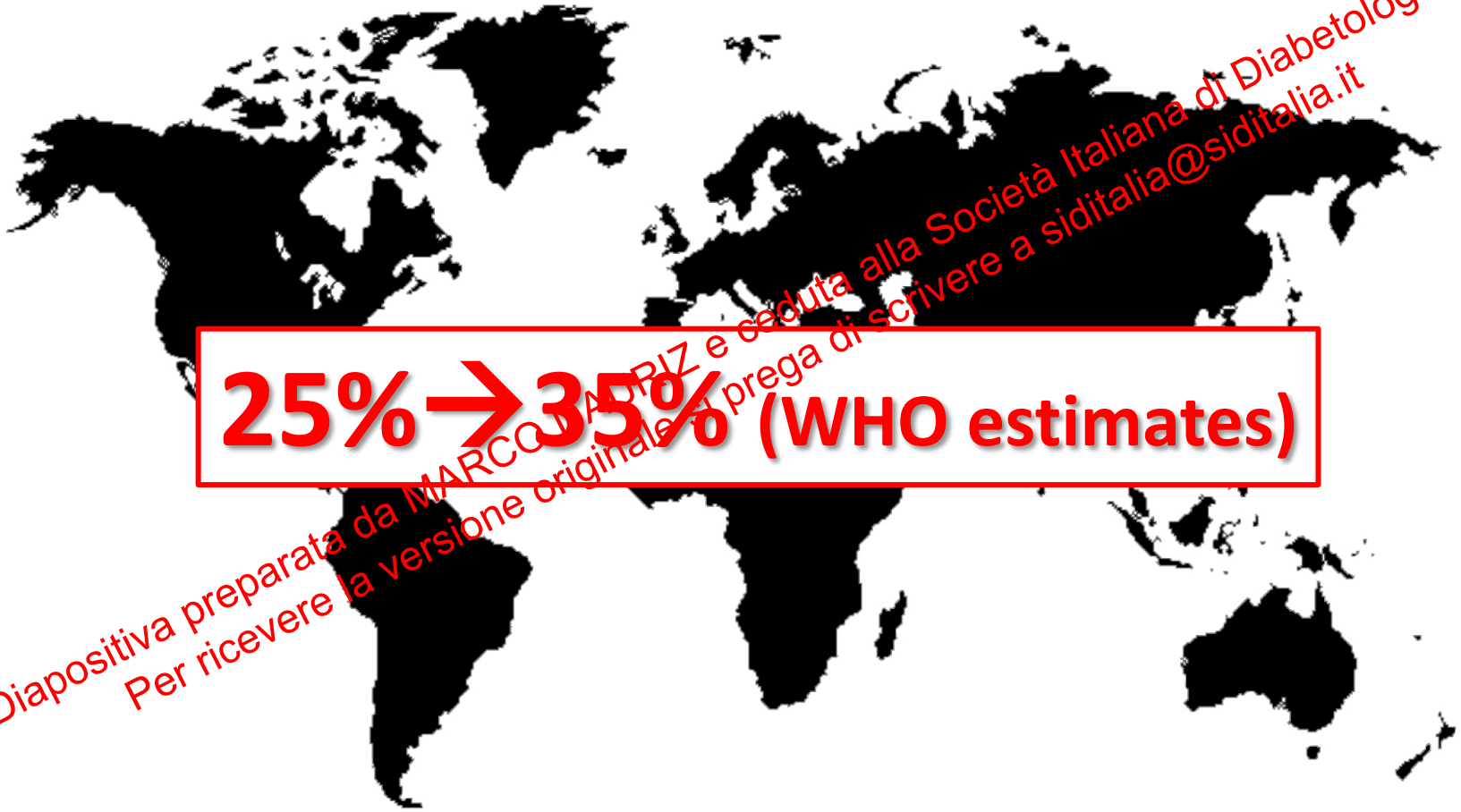
158	123	70	22
298	248	153	40
239	166	81	21
307	261	157	43
514	381	184	42

E Coronary Events



499	376	245	106	16
1325	936	557	215	32
996	658	349	118	20
1594	1115	647	252	43
26415	18450	1095	444	77

CKD PREVALENCE: A GLOBAL PERSPECTIVE



25% → 35% (WHO estimates)

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Estimated total number of adults (20-79 years) with diabetes in 2019



WORLD

2045	700 million
2030	578 million
2019	463 million

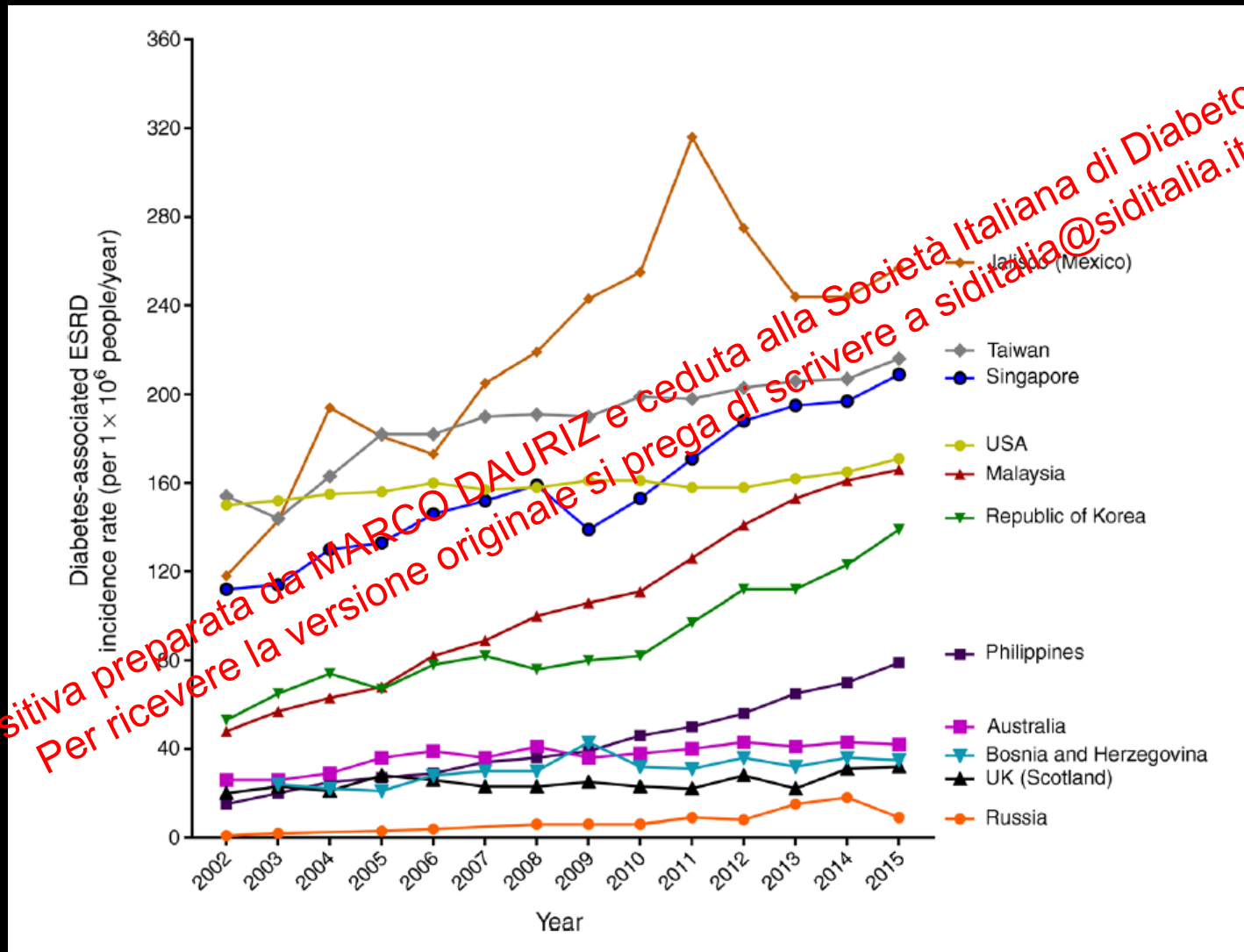
↑ 51%
increase



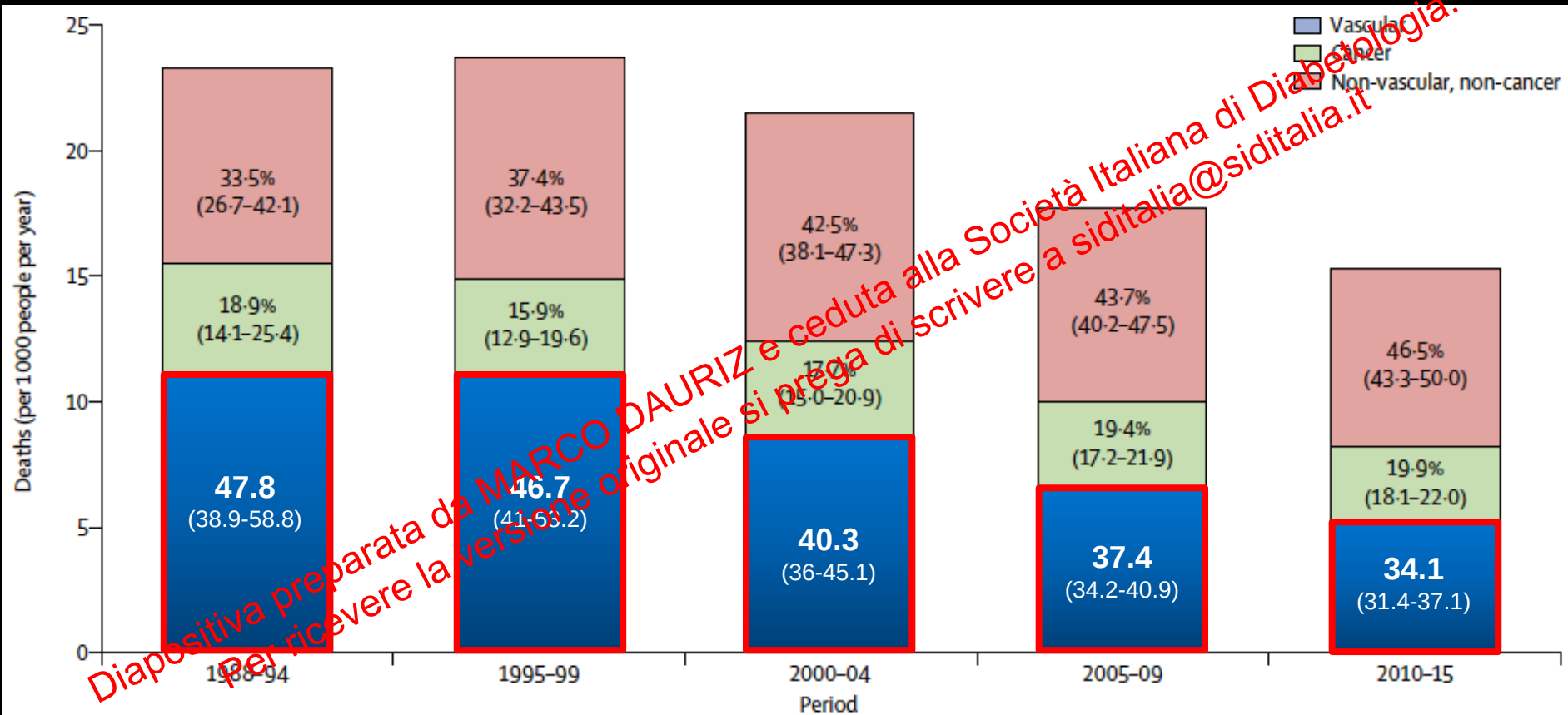
International
Diabetes
Federation

IDF Atlas 9th Ed. 2019

Incidence rate of ESRD (2002-2015)



All-cause mortality trends (1985-2015)



Lancet Diabetes Endocrinology 2018, 6(5):392-403



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CKD in VULNERABLE POPULATIONS (i)



Acute Coronary Syndrome

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The VASD OUTCOME Study

The Verona Acute Coronary Syndrome & Stroke in Diabetes Outcome Study

OBIETTIVO

Stimare la prevalenza di diabete mellito e verificarne l'associazione con sopravvivenza intra-ospedaliera, complicanze intra-ospedaliere e durata di degenza in un'ampia coorte di pazienti ricoverati in Unità di Terapia Intensiva Coronarica (UCIC)

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MATERIALI E METODI

SOGGETTI:

Tutti i pazienti con accesso primario presso l'UCIC dell'AOUI di Verona dal 1/01/2015 al 31/12/2016

($N_{tot} = 1,017$)

DATI:

- Dati demografici, clinici e antropometrici
- Fattori di rischio cardiovascolare in anamnesi
- Anamnesi farmacologica

DEFINIZIONE dei casi di DIABETE

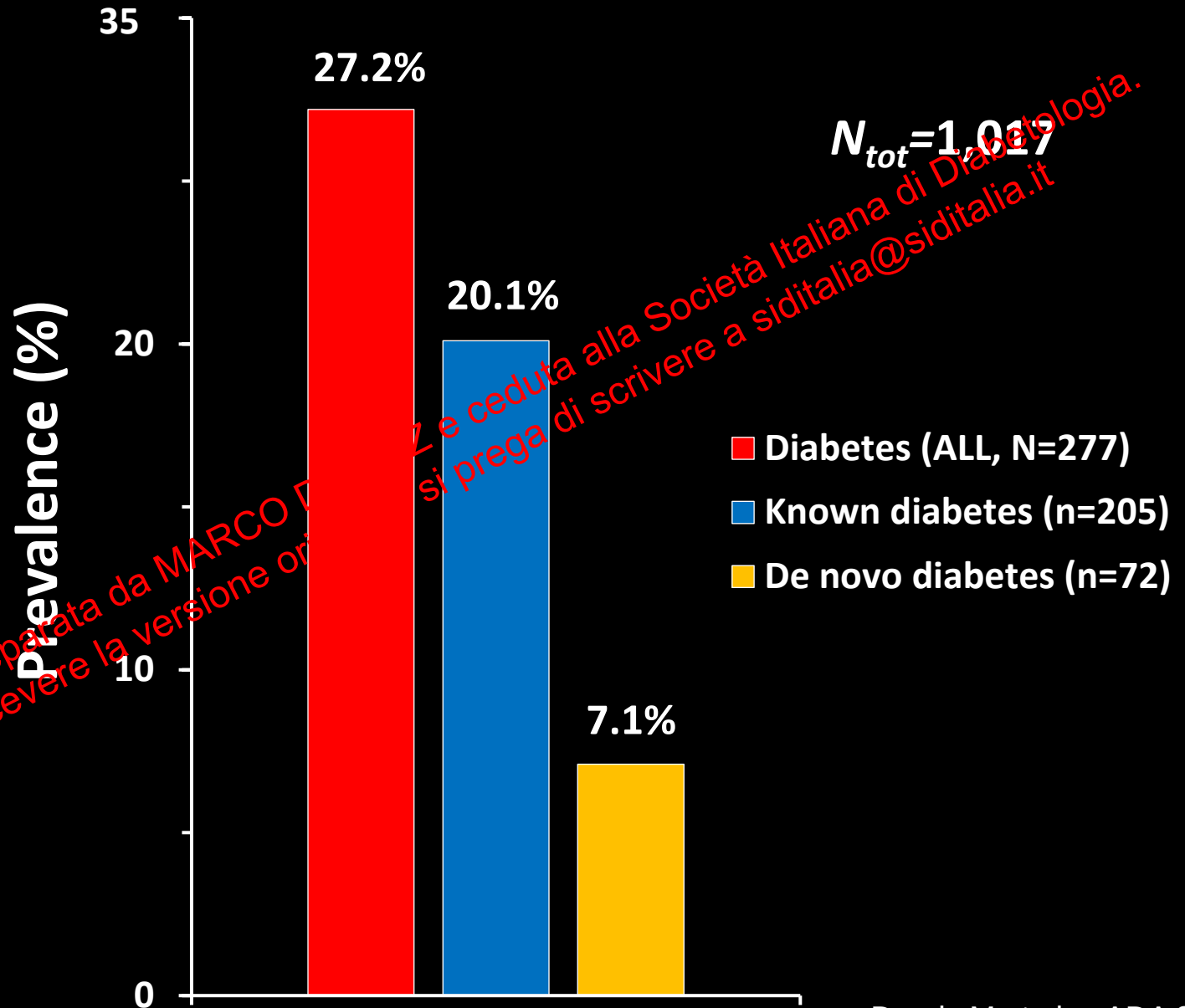
Diabete noto:

- Precedente diagnosi
- Terapia ipoglicemizzante all'ingresso

Diabete *de novo*:

- Terapia ipoglicemizzante alla dimissione
- Glicemia ≥ 200 mg/dL all'ingresso in UCIC

Prevalence of Diabetes in ICCU



Study Cohort ($N_{tot}=1,017$)

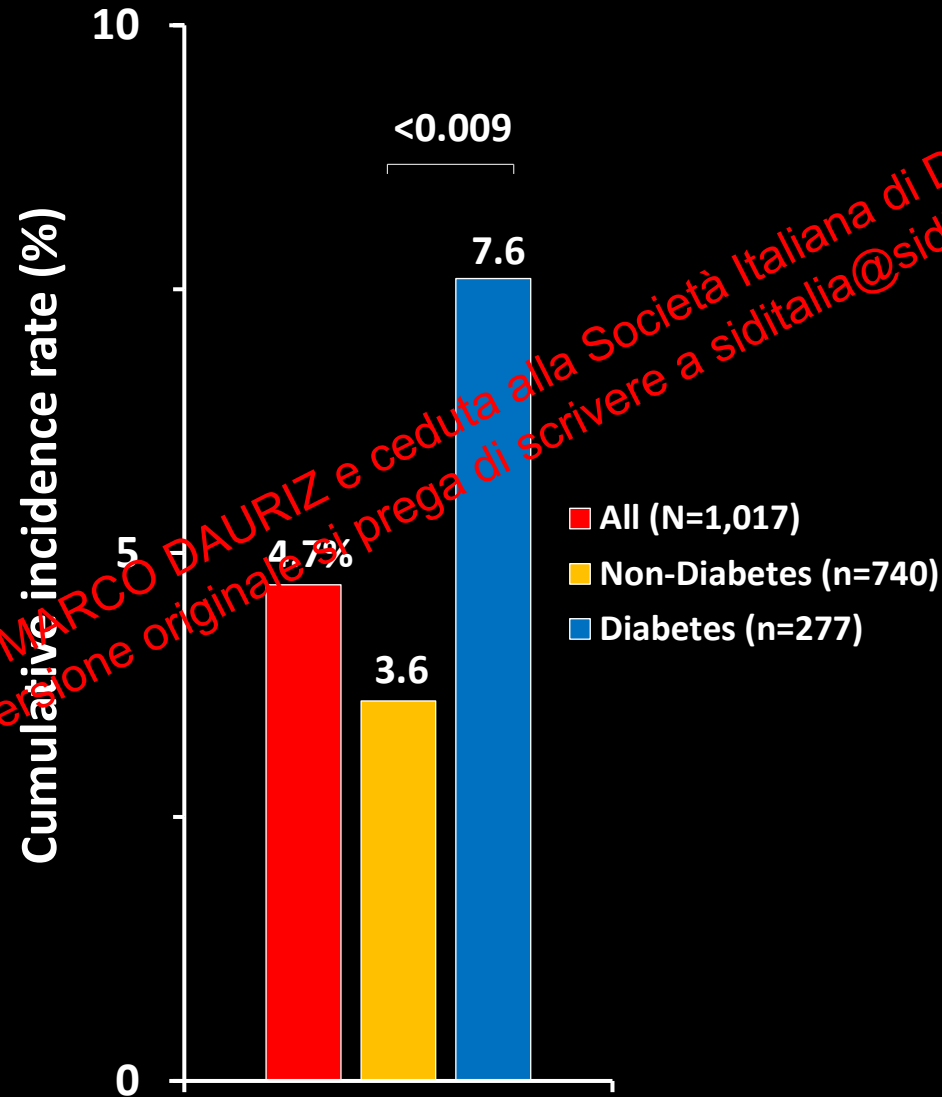
	Patients WITH diabetes ($N_{tot}=277$)	Patients WITHOUT diabetes ($N_{tot}=740$)	P-value
N , % males	181 (65.3%)	496 (67.0%)	0.654
Age , years	72.7 ± 11.6	66.7 ± 11.4	<0.001
BMI , Kg/m ²	27.6 ± 4.6	27.1 ± 4.6	<0.001
Systolic blood pressure , mmHg	141.6 ± 31.1	138.0 ± 31.1	0.11
Plasma glucose at ICCU admittance , mg/dL	220.0 ± 94.0	140.0 ± 60.0	<0.001
HbA_{1c} , mmol/mol	65.3 ± 21.1	54.0 ± 11.1	<0.001
Smoking , ever/never (%)	40.4%	51.2%	0.003
Total cholesterol , mg/dL	146 ± 44	168 ± 44	<0.001
LDL-C , mg/dL	74 ± 37	97 ± 38	<0.001
HDL-C , mg/dL	43 ± 13	46 ± 14	<0.001
Triglycerides , mg/dL	148 ± 132	121 ± 66	<0.001
Creatinine , mg/dL	1.62 ± 1.3	1.12 ± 0.82	<0.001
eGFR_{MDRD} <60 mL/min/1.73 m² , %	58.8%	30.5%	<0.001
Lipid-lowering meds , %	53.6%	26.1%	<0.001

Overall CKD prevalence
in subjects with ACS &
comorbid diabetes

58.8%

Data presented as median [IQR] or as percentage

In-hospital Mortality



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In-hospital Mortality

	Crude-OR (95% C.I.)	P-value
Diabetes status (yes vs. no)	2.17 (1.20-3.90)	0.01

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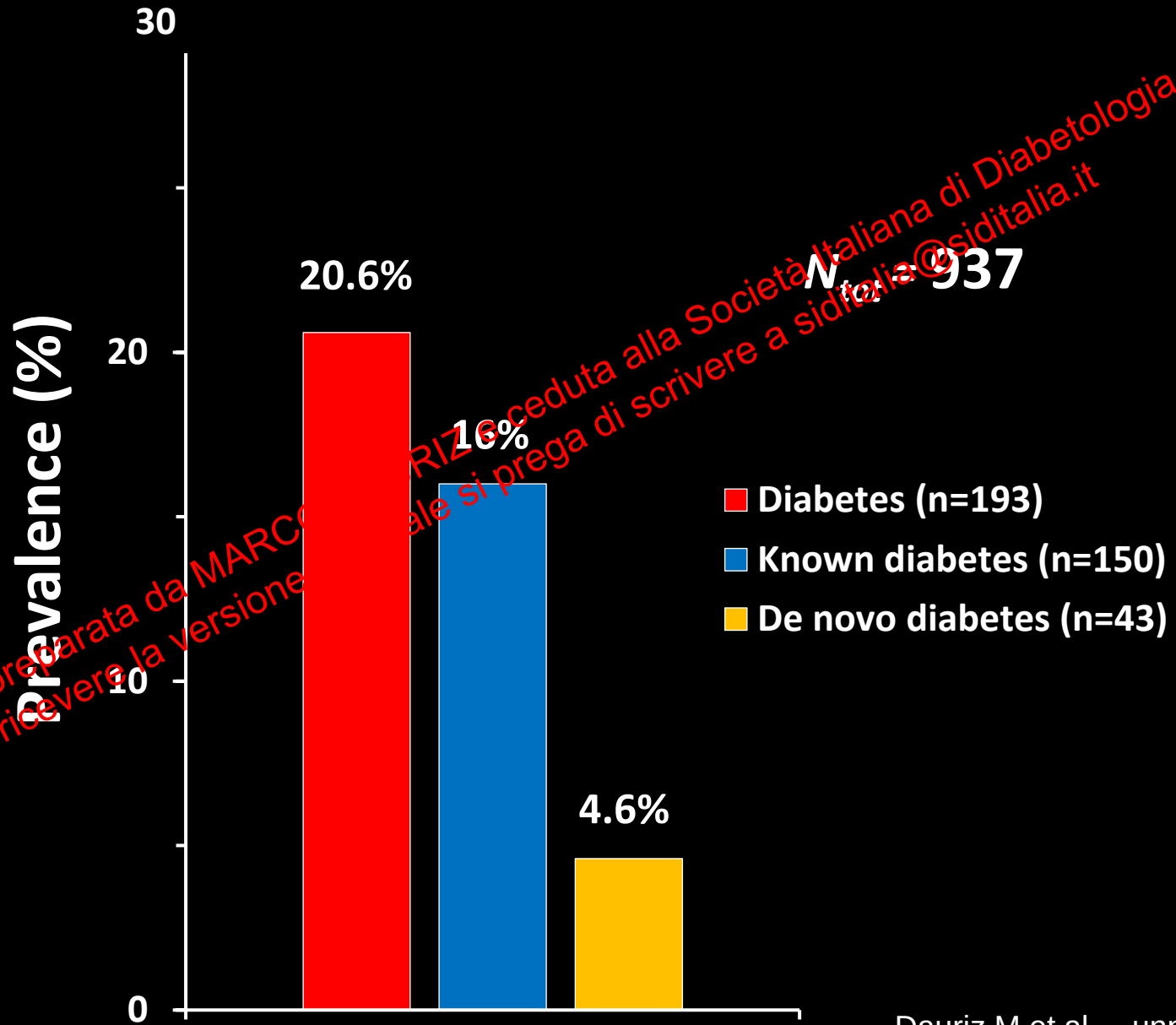
CKD

in VULNERABLE POPULATIONS (ii)

➤ Cerebrovascular Accidents

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Prevalence of Diabetes in Stroke Unit



Diapositiva preparata da MARCO RIZZARDI ceduta alla Società Italiana di Diabetologia.
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Study Cohort ($N_{tot}=937$)

	Patients WITH diabetes ($N_{tot}=193$)	Patients WITHOUT diabetes ($N_{tot}=744$)	P-value
Male, %	114 (59.1)	367 (49.3)	0.019
Age, years	75.5±10.1	73.1±1.2	0.03
BMI, Kg/m²	27.9±5.3	27.2±5.3	<0.001
Systolic blood pressure, mmHg	169±33	135±19	0.003
Hypertension on treatment, %	152 (78.8)	379 (51.1)	0.005
Plasma glucose at SU admittance, mg/dL	167.5±68.9	108.5±30.9	<0.001
HbA_{1c}, mmol/mol	63.9±22.5	52.5±11.5	<0.001
Smoking, ever/never (%)	28 (23.5)	129 (26.9)	0.487
Total cholesterol, mg/dL	159±46	175±41	<0.001
LDL-C, mg/dL	84±39	100±36	<0.001
HDL-C, mg/dL	46±15	52±15	<0.001
Triglycerides, mg/dL	140±66	113±51	<0.001
Uric acid, mg/dL	5.3±1.8	4.9±1.6	0.036
Creatinine, mg/dL	1.2±0.98	0.96±0.52	<0.001
eGFR_{MDRD} <60 mL/min/1.73 m², %	72 (37.7)	168 (23.0)	<0.001
Lipid-lowering medications, %	82 (44.1)	167 (23.2)	<0.001

Overall CKD prevalence
in subjects with CVA &
comorbid diabetes

37.7%

CKD in VULNERABLE POPULATIONS (iii)



Heart Failure

Diapositiva preparata da MARCO DAURIZ e ceduta alla Società Italiana di Diabetologia.
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Association Between Diabetes and 1-Year Adverse Clinical Outcomes in a Multinational Cohort of Ambulatory Patients With Chronic Heart Failure: Results From the ESC-HFA Heart Failure Long-Term Registry

DOI: 10.2337/dc16-2016

Marco Dauriz,¹ Giovanni Targher,¹ Cécile Laroche,² Pier Luigi Temporelli,³ Roberto Ferrari,⁴ Stephen Anker,⁵ Andrew Coats,^{6,7} Gerasimos Filippatos,⁸ Maria Crespo-Leiro,⁹ Alexandre Mebazaa,¹⁰ Massimo F. Piepoli,¹¹ Aldo P. Maggioni,^{2,12} and Luigi Tavazzi,^{4,13} for the ESC-HFA Heart Failure Long-Term Registry*



THE JOURNAL OF CLINICAL AND APPLIED RESEARCH AND EDUCATION

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Diabetes Care

WWW.DIABETES.ORG/DIABETESCARE

MAY 2017

Cost-effective Use of the 2014 U.S. Preventive Services Task Force (USPSTF) Recommendations for Intensive Behavioral Counseling Interventions for Adults With Cardiovascular Risk Factors

J. Li, A. S. Bardenheier, D.B. Rolka, W.E. Gregg, Y. Hong, C. C. Albright, and P. Zhang

Diurnal Differences in Risk of Cardiac Arrhythmias During Spontaneous Hypoglycemia in Young People With Type 1 Diabetes

P. Novodvorsky, A. Bernjak, E. Chou, A. Iqbal, L. Sellors, S. Williams, R.A. Fawcay, B. Parekh, R.M. Jacques, J.L.B. Marques, P.J. Sheridan, and S.R. Heller

Association Between Diabetes and 1-Year Adverse Clinical Outcomes in a Multinational Cohort of Ambulatory Patients With Chronic Heart Failure: Results From the ESC-HFA Heart Failure Long-Term Registry

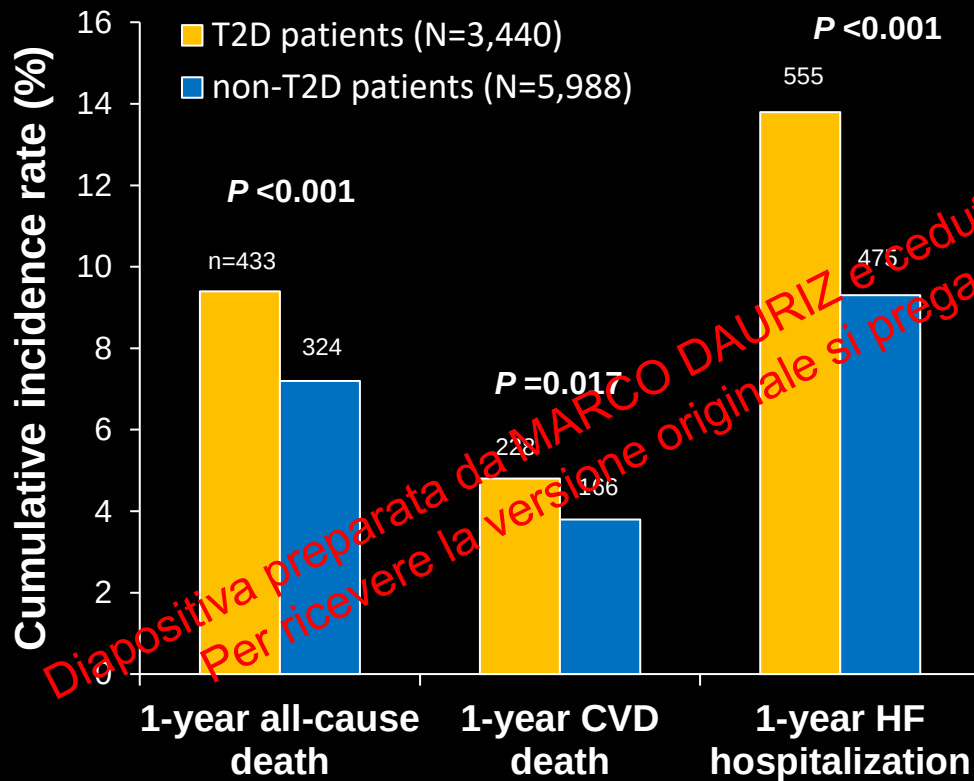
M. Dauriz, G. Targher, C. Laroche, P.L. Temporelli, R. Ferrari, S. Anker, A. Coats, G. Filippatos, M. Crespo-Leiro, A. Mebazaa, M.F. Piepoli, A.P. Maggioni, and L. Tavazzi, for the ESC-HFA Heart Failure Long-Term Registry

In Utero Exposure to Maternal Hyperglycemia Increases Childhood Cardiometabolic Risk in Offspring

W.H. Tam, R.C.W. Ma, R. Ozaki, A.M. Li, M.H.M. Chan, L.Y. Yuen, T.T.H. Lao, X. Yang, C.S. Ho, G.E. Tutino, and J.C.N. Chan

American Diabetes Association
ISSN 0149-5992

One-year incidence rates of long-term adverse outcomes in CHF outpatients from the EORP-HF Long-Term Registry.



Diabetes Prevalence

OVERALL: 36.5% (n= 3,440)

Known DM: 80.9%
(n= 2,782)

Previously unknown DM: 19.1%
(n =658)

Table 1—Baseline demographic, clinical and biochemical characteristics of outpatients with CHF, enrolled in the ESC-HFA Heart Failure Long-Term Registry, stratified by diabetes status

	N/N	Patients with diabetes (n = 3,440)	Patients without diabetes (n = 5,988)	P value
Male sex (%)	3,440/5,988	74.7	69.7	<0.001
Age (years)	3,440/5,988	67.1 ± 10.9	63.7 ± 14.4	<0.001
Caucasian Ethnicity (%)	3,300/5,654	95.3		
Creatinine (mg/dL)	3,202/5,335	1.2 (0.9–1.5)		
eGFR _{MDRD} (mL/min/1.73 m ²)	3,202/5,335	58.3 (42.1–75.7)		
eGFR _{MDRD} <60 mL/min/1.73 m ² (%)	3,202/5,335	52.4		
Hemoglobin (g/dL)	2,970/4,900	13.1 ± 1.6		
NT-proBNP (pg/dL)	1,194/1,970	1,324 (546–3,470)		
LVEF (%)	2,969/5,099	37.1 ± 13.1		
LVEF >45% (%)	2,969/5,099	22.6		
NYHA functional class (%)	3,433/5,970			
Class I		13.5	19.4	
Class II		57.6	56.1	
Class III		26.3	22.8	
Class IV		1.6	1.7	
HF etiology (%)	3,430/5,943			<0.001
Ischemic		53.4	36.8	
Dilatative		23.8	32.3	
Hypertensive		8.5	8.1	
Other		14.3	22.7	
Atrial fibrillation (%)	3,440/5,987	39.2	36.5	0.009
Implantable cardioverter defibrillator (%)	3,429/5,970	16.4	15.3	0.127
COPD (%)	3,435/5,974	16.6	12.6	<0.001
Previous stroke (%)	3,436/5,983	10.8	8.5	<0.001

Data are presented as the mean ± SD or median (interquartile range), unless otherwise indicated. ARB, angiotensin receptor blocker; N/N, number of patients with and without diabetes who had measurements available for each single variable at the study entry; NT-proBNP, N-terminal of the prohormone brain natriuretic peptide.

**Overall CKD prevalence
in subjects with CHF &
comorbid diabetes**

52.4%

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In-hospital and 1-year mortality associated with diabetes in patients with acute heart failure: results from the ESC-HFA Heart Failure Long-Term Registry

Giovanni Targher¹, Marco Dauriz¹, Cecile LeRoche², Pier Luigi Temporelli³, Mahmoud Hassanein⁴, Petar M. Seferovic⁵, Jaroslaw Drozd⁶, Roberto Ferrari⁷, Stephan Anker⁸, Andrew Coats⁹, Gerasimos Filippatos¹⁰, Maria G. Crespo-Leiro¹¹, Alexandre Mebazaa¹², Massimo F. Piepoli¹³, Aldo Pietro Maggioni^{2,14*}, and Luigi Tavazzi¹⁵ on behalf of the ESC-HFA HF Long-Term Registry investigators[†]

Diabetes Prevalence

OVERALL: 49.4% (n= 3,422)

Known DM: 80.5%
(n= 2,755)

Previously unknown DM: 19.5%
(n =667)

Table 1 Baseline characteristics of the whole cohort of patients with acute heart failure stratified by diabetes status

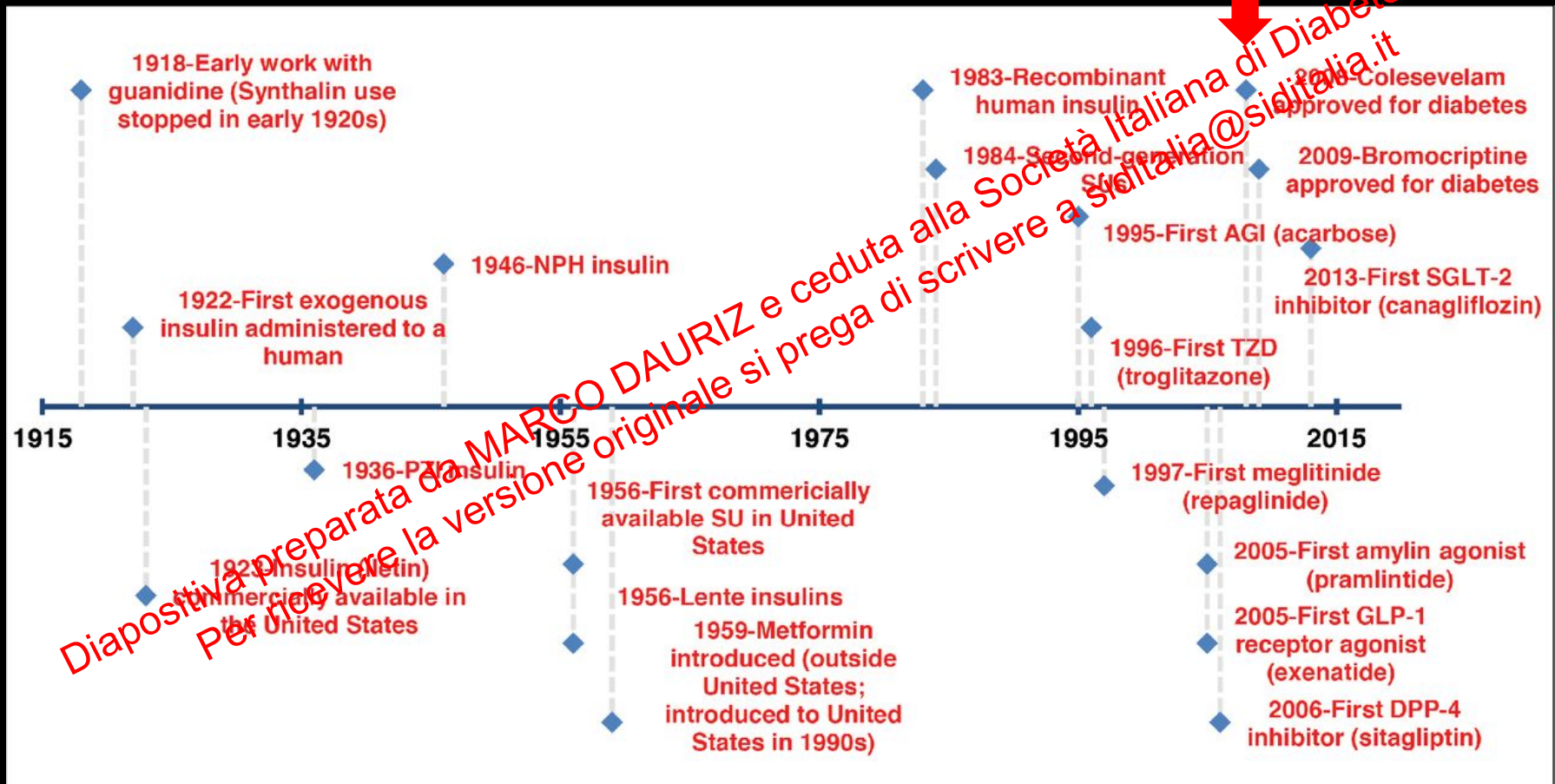
	Diabetic patients (n = 3422)	Non-diabetic patients (n = 3504)	P-value
Males	61.1%	64.8%	0.002
Age (years)	70.0 ± 11.4	68.0 ± 14.4	<0.001
Ethnic origin (Caucasian)	82.9%	82.2%	0.498
BMI (kg/m ²)	29.3 ± 5.4	27.7 ± 5.3	<0.001
Systolic BP (mmHg)	134.9 ± 29.6	130.1 ± 27.3	<0.001
Diastolic BP (mmHg)	79.2 ± 16.1	78.1 ± 15.4	0.003
Total cholesterol (mg/dL)	164.6 ± 54.6	164.7 ± 50.8	0.900
Heart rate (b.p.m.)	82.0 ± 20.6	80.5 ± 20.7	<0.001
Plasma glucose (mg/dL)	168.8 ± 75.3	96.2 ± 14.2	<0.001
Haemoglobin A _{1c}	7.4 ± 3.8		0.001
Hypertension	71.4%		0.001
Smoking status	15.7%		0.07
Diabetes medications ^a			
Insulin	52.5%		
Oral hypoglycaemic drugs only	47.5%		
Diet only	0.0%		
Cardiovascular medications			
Statins	47.3%		0.001
ACE inhibitors or ARBs	73.4%		0.02
Beta-blockers	62.8%	62.5%	0.809
Aldosterone antagonists	36.6%	41.4%	<0.001
Diuretics	70.0%	71.5%	0.055
Digitalis	20.0%	23.1%	0.005
Calcium channel blockers	20.7%	14.0%	<0.001
Antiplatelets or anticoagulants	78.8%	75.7%	0.004
Nitrates	30.6%	23.2%	<0.001
Amiodarone	10.0%	11.7%	0.037
LVEF _{max} (mL/min/1.73 m ²)	54.9 ± 25.2	62.6 ± 34.7	<0.001
eGFR _{MDRD} <60 mL/min/1.73 m ²	61.3%	50.0%	<0.001
Haemoglobin (g/dL)	12.4 ± 2.2	12.7 ± 2.2	<0.001
Sodium (mEq/L)	137.6 ± 5.4	138.3 ± 5.1	<0.001
NT-proBNP (pg/dL)	3900.0 (1674–9300)	3791.0 (1619–8878)	0.321
LVEF (%)	39.2 ± 14.2	39.2 ± 14.5	0.971
LVEF >45%	28.3%	31.2%	0.025
NYHA class III–IV	86.8%	83.0%	<0.001
HF aetiology (ischaemic)	63.7%	49.0%	<0.001
HF (de novo)	28.5%	30.2%	0.118
Atrial fibrillation	42.2%	45.0%	0.020
COPD	21.8%	16.8%	<0.001
Previous stroke	13.7%	10.6%	<0.001

**Overall CKD prevalence
in subjects with AHF &
comorbid diabetes**

61.3%

Diapositiva preparata da MARCO PAURIZ e ceduta alla Societa Italiana di Diabetologia.
per ricevere la versione originale si prega di scrivere a pauriz.m@uniroma1.it

The Golden Age of Diabetes Medications



Novel tools to win the competition are not sufficient...



Bobby Fisher vs. Boris Spassky - World Chess Championship, 1972

A comprehensive, recursive, multidisciplinary and pathophysiology-oriented approach is needed

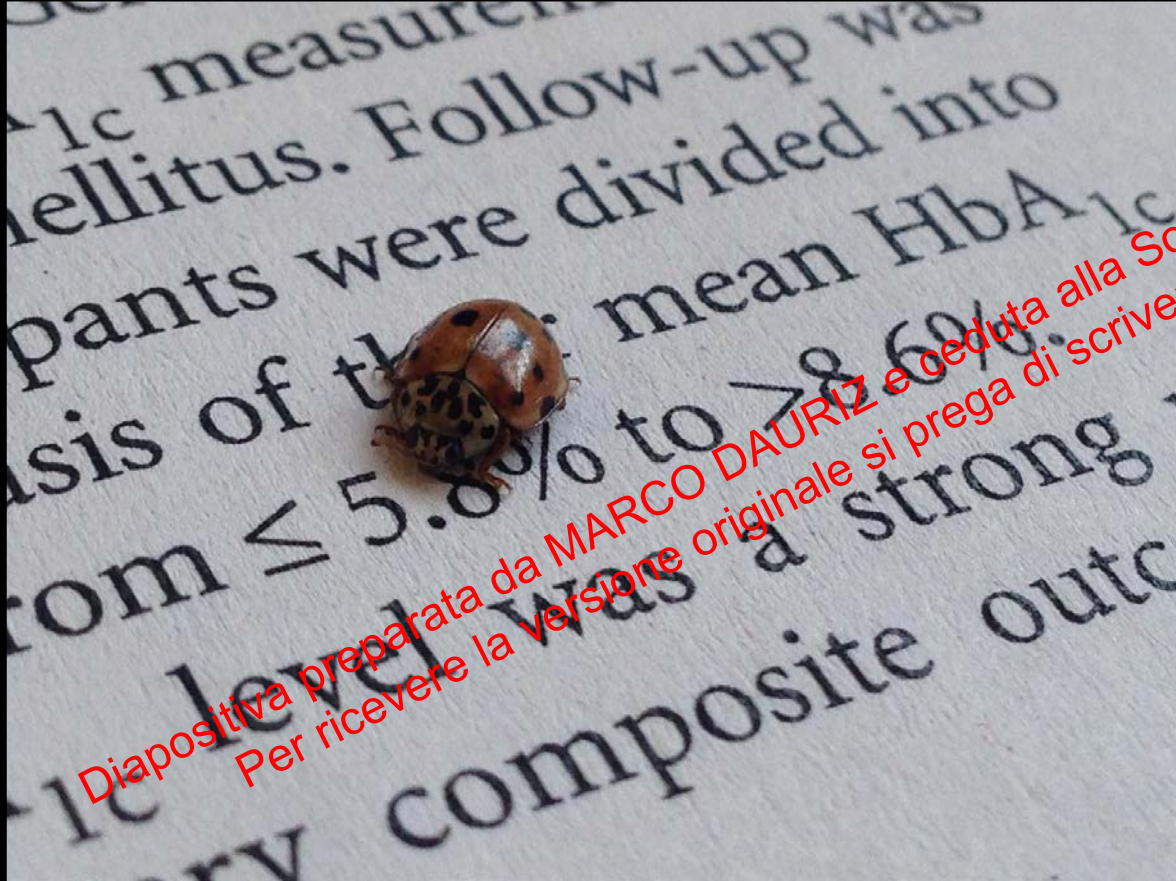


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The Zenon's Paradox

SUMMARY

- **Heterogeneity is hallmark of diabetes and its complications**
- **CKD is highly prevalent, though yet underscored, particularly in vulnerable populations**
- **CKD incidence is increasing worldwide, possibly due to increased life expectancy**
- **Awareness and rationale use of most modern medications could stop and possibly reverse the ticking clock of diabetes complications**



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THANK YOU!

SPARE SLIDES

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GLYCEMIC MONITORING AND TARGETS IN PATIENTS WITH DIABETES AND CKD

Recommendation 2.2.1. We recommend an individualized HbA1c target ranging from <6.5% to <8.0% in patients with diabetes and CKD not treated with dialysis (Figure 9) (1C).

