MACROANGIOPATIA DIABETICA

L'iter diagnostico e strategie di rivascolarizzazione nel diabetico ad alto rischio CV

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NESSUN CONFLITTO DI INTERESSE DA DICHIARARE

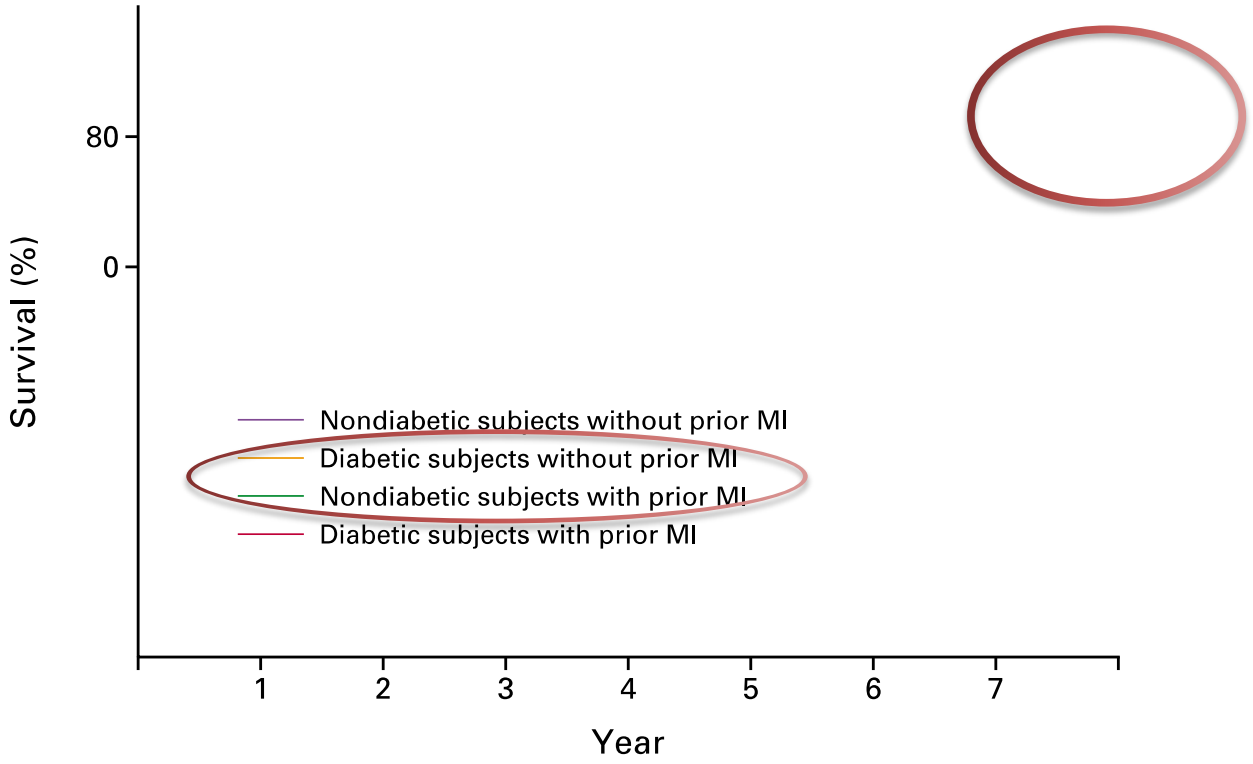
1) CHI DEVO SOTTOPORRE A SCREENING DIAGNOSTICO PER

CARDIOPATIA ISCHEMICA

2) COME E SE DEVO RIVASCOLARIZZARE IL MIO PAZIENTE

DIABETICO CON ATEROSCLEROSI ED ISCHEMIA CORONARICA

MORTALITY FROM CORONARY HEART DISEASE IN SUBJECTS WITH TYPE 2 DIABETES AND IN NONDIABETIC SUBJECTS WITH AND WITHOUT PRIOR MYOCARDIAL INFARCTION



…….. diabetic patients without previous myocardial infarction have ***as high a risk of myocardial infarction as nondiabetic patients with previous myocardial infarction****. These data provide a rationale for treating cardiovascular risk factors in diabetic patients as aggressively as in nondiabetic patients with prior myocardial infarction.*

Haffner SM, N Engl J Med 1998;339:229-34

Standard italiani per la cura del diabete mellito 2016

RACCOMANDAZIONI

Screening

E' consigliabile che lo screening di base sia effettuato annualmente in tutte le persone con diabete a partire dalla diagnosi della malattia.

(Livello della prova III, Forza della raccomandazione B)

Tutte le persone con diabete, indipendentemente dal livello di rischio, devono eseguire annualmente di base:

- esame dei polsi periferici e ricerca di soffi vascolari;
- ECG basale;
- determinazione dell'indice di Winsor (se normale può essere rivalutato a distanza di 3-5 anni; se <0,9 deve essere eseguito un ecodoppler degli arti inferiori).

(Livello della prova III, Forza della raccomandazione B)

1) CHI DEVO SOTTOPORRE A SCREENING DIAGNOSTICO PER

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DIABETICO CON ATEROSCLEROSI ED ISCHEMIA CORONARICA

Summary of the characteristics of the most important methods for diagnosing CAD in DM 2 patients

Diagnostic method	Technique	Contrast	Cost	Sens.	Spec.	Complications	Advantages	Disadvantages
Conventional angiography	Invasive	Yes	High	High	High	AMI, arrhythmias, bleeding, infections, stroke	Gold standard	Invasive
Ergometric test	Noninvasive	No	Low	Low	Low	Rare: arrhythmias, AMI	Low cost	Inconclusive results
Myocardial scintigraphy	Noninvasive	Yes	High	High	High	Rare	Physical stress or pharmacological	Functional test < sens I specif MSTC
Stress echocardiography	Noninvasive	No	Low	High	High	Rare: arrhythmias	Low cost	Difficulties: obese achieve submax HR
Carotid Doppler ultrasonography	Noninvasive	No	Low	Low	Low	No	Low cost fast	Indirect method No standard
Calcium Score	Noninvasive	Yes	High	Low	Low	Rare	Noninvasive	Indirect method does not show percentage obstruction
Intravascular ultrasound (IVUS)	Invasive	No	High	High	High	AMI, arrhythmias, bleeding, infections, stroke	Gold standard characterize plates	Invasive
Angiotomography coronary (MSTC)	Noninvasive	Yes	High	High	High	nephrotoxicity	Sens/Specif slightly lower of angiography	Not applicable in obesity and arrhythmias; cost

ArchEndocrinol Metab. 2016;60(2):143-51

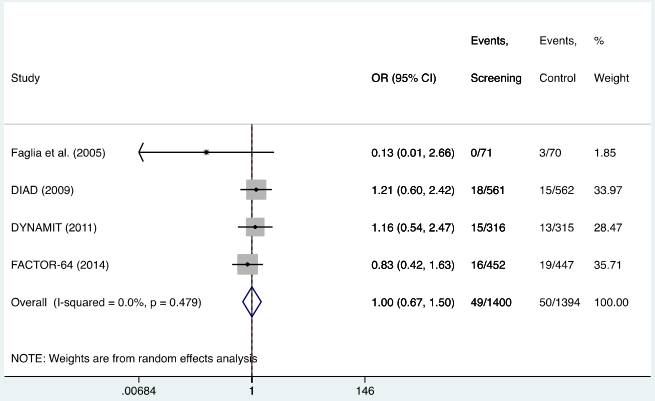
Bauters and Lemesle *BMC Cardiovascular Disorders* (2016) 16:90
DOI 10.1186/s12872-016-0256-9

RESEARCH ARTICLE Open Access

-Faglia et al. Study
-DIAD study
-DYNAMIT study
-FACTOR-64 study
-DADDY-D study

monocentrici

multicentrici

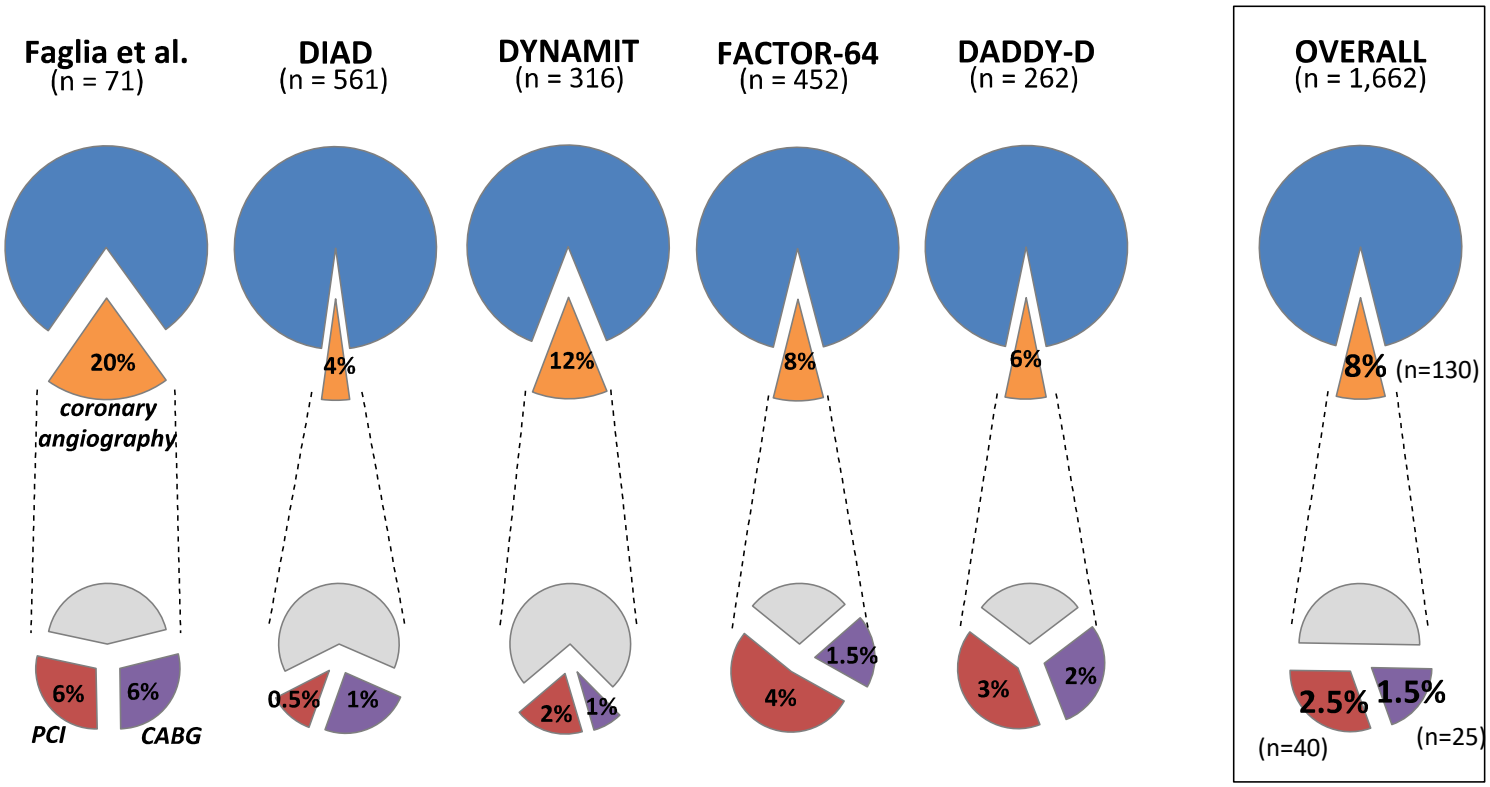


Bauters and Lemesle *BMC Cardiovascular Disorders* (2016) 16:90
DOI 10.1186/s12872-016-0256-9

RESEARCH ARTICLE Open Access

normal screening

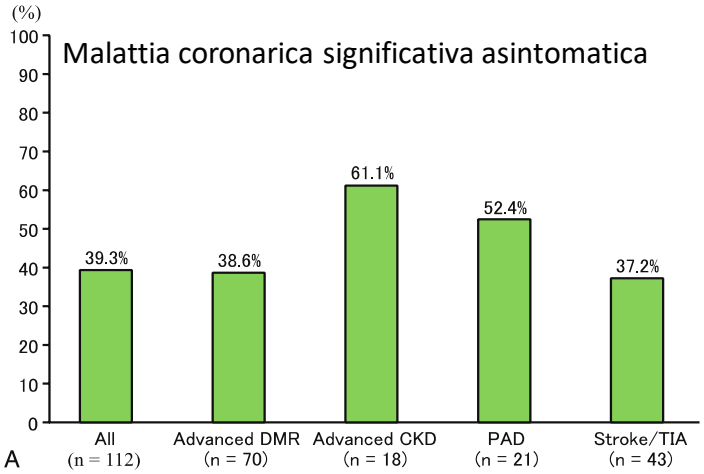
abnormal screening

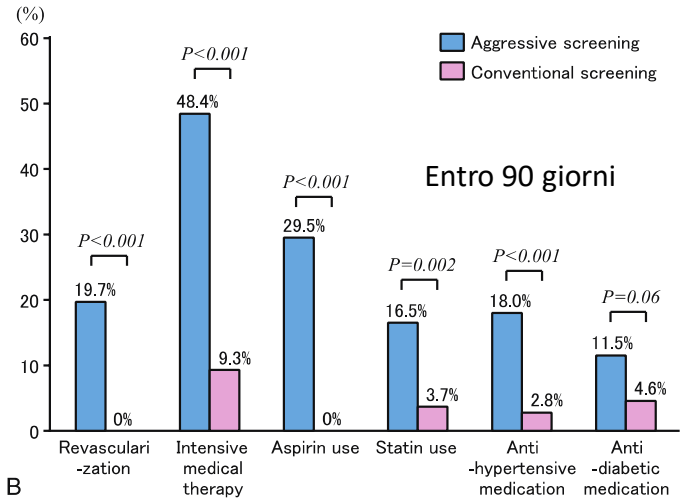


No evidence for a benefit of screening diabetic patients for the presence of asymptomatic CAD.
The proportion of patients who undergo myocardial revascularization as a consequence of screening was low.

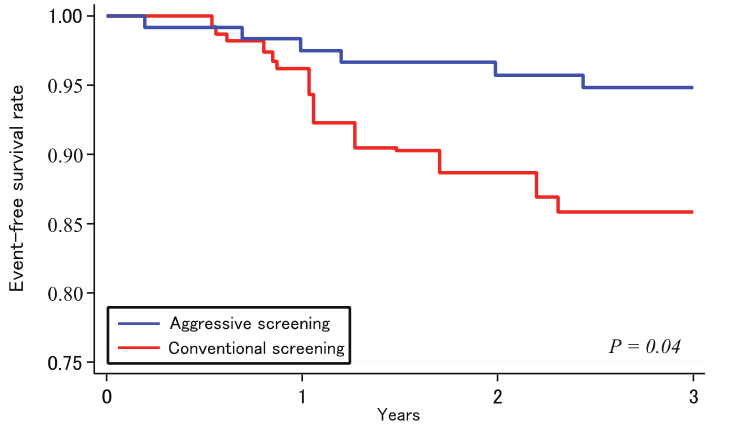
Medicine®

Beneficial effects through aggressive coronary screening for type 2 diabetes patients with advanced vascular complications





Morte cardiovascolare ed eventi cardiovascolari maggiori



Aggressive screening (No.at risk)	122	116	106	100
Conventional screening (No.at risk)	108	102	93	86

Aggressive coronary screening for T2D patients with advanced vascular complications can reveal several cases of having asymptomatically significant CAD that put patients at an elevated risk of severe coronary events

Medicine (2016) 95:33(e4307)

Lo screening indiscriminato per l'eventuale presenza di cardiopatia ischemica (IC) silente in pazienti asintomatici non è raccomandato, poiché non migliora gli outcome se tutti i fattori di rischio cardiovascolare sono trattati al meglio.
(Livello della prova II, Forza della raccomandazione B)

Lo screening per l'eventuale presenza di cardiopatia ischemica (IC) silente deve essere effettuato solo in pazienti con elevata probabilità pretest di IC silente e con ragionevole aspettativa e qualità di vita, in particolare se potenzialmente eleggibili per una eventuale rivascolarizzazione.
(Livello della prova VI, Forza della raccomandazione B)

L'identificazione dei pazienti diabetici con elevata probabilità di IC silente in atto può essere fatta sulla base di alterazioni elettrocardiografiche a riposo suggestive di ischemia (blocco di branca sinistro, alterazioni della ripolarizzazione ventricolare suggestive per ischemia miocardica, presenza di onda Q o di alterazioni del tratto S-T) e/o della copresenza dei fattori di rischio e delle condizioni cliniche evidenziate nella Tabella 22.
(Livello della prova VI, Forza della raccomandazione B)

La ricerca della cardiopatia ischemica asintomatica va effettuata dopo una attenta anamnesi ed esame obiettivo che ricerchi la presenza di sintomi (anche equivalenti coronarici come la dispnea da sforzo, affaticabilità, dolore toracico) o segni di cardiopatia.
(Livello della prova VI, Forza della raccomandazione B)

PAZIENTI AD ALTO RISCHIO DI CARDIOPATIA ISCHEMICA SILENTE

Standard italiani
per la cura del diabete mellito
2016

Macroangiopatia non coronarico avanzata/molto avanzata

Sintomatica

- Precedenti eventi aterotrombotici
- Interventi di rivascolarizzazione

Non sintomatica

- Arteriopatia periferica con ABI <0,9
- Stenosi carotidea asintomatica >50%
- Aneurisma aortico

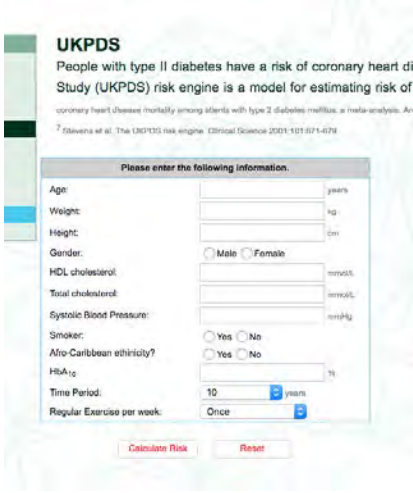
Score di rischio coronarico (UKPDS) >30% a 10 anni

Score di rischio coronarico (UKPDS) >20% a 10 anni + almeno uno dei seguenti:

- Placche ateromasiche determinanti stenosi ≥20%
- GFR <30 ml/min per 1,73 m^2
- Neuropatia autonomica cardiaca
- Disfunzione erettile
- Familiarità di 1° grado positiva per cardiopatia ischemica in giovane età (<55 anni maschi; <65 anni femmine)

Score di rischio coronarico (UKPDS) >20% a 10 anni + almeno due dei seguenti:

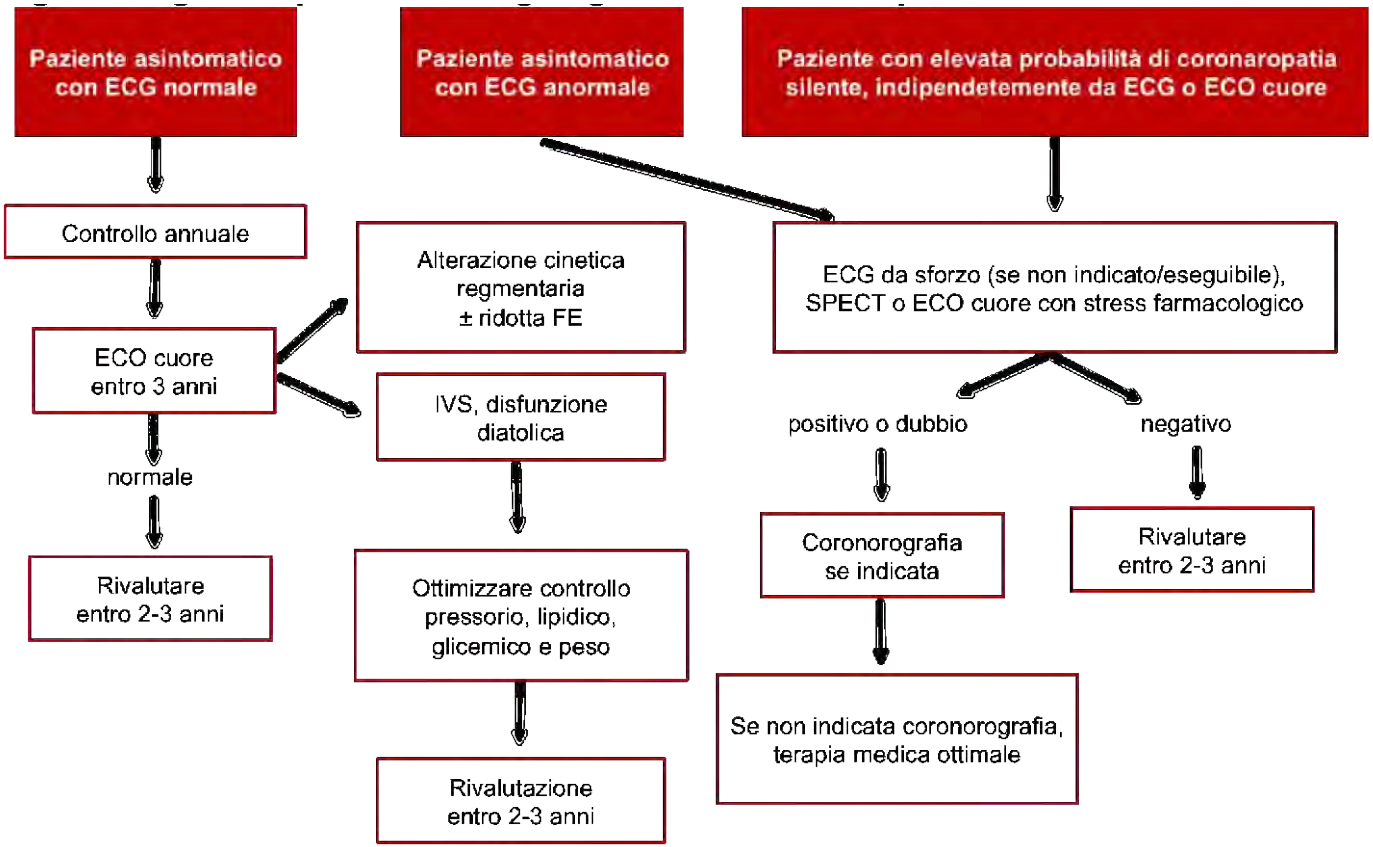
- GFR <30 ml/min per 1,73 m^2
- Micro- o macroalbuminuria
- Retinopatia laser-trattata/proliferante



http://integrate.ccretherapeutics.org.au/Calculator/UkPds.aspx

Standard italiani
per la cura del diabete mellito
2016

ALGORITMO PER LO SCREENING DIAGNOSTICO DELLA CARDIOPATIA ISCHEMICA



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CRITERI PER LA DEFINIZIONE DEL RISCHIO DEL PAZIENTE IN BASE AI TEST CARDIOLOGICI

Pazienti a rischio elevato (mortalità annua >3%)

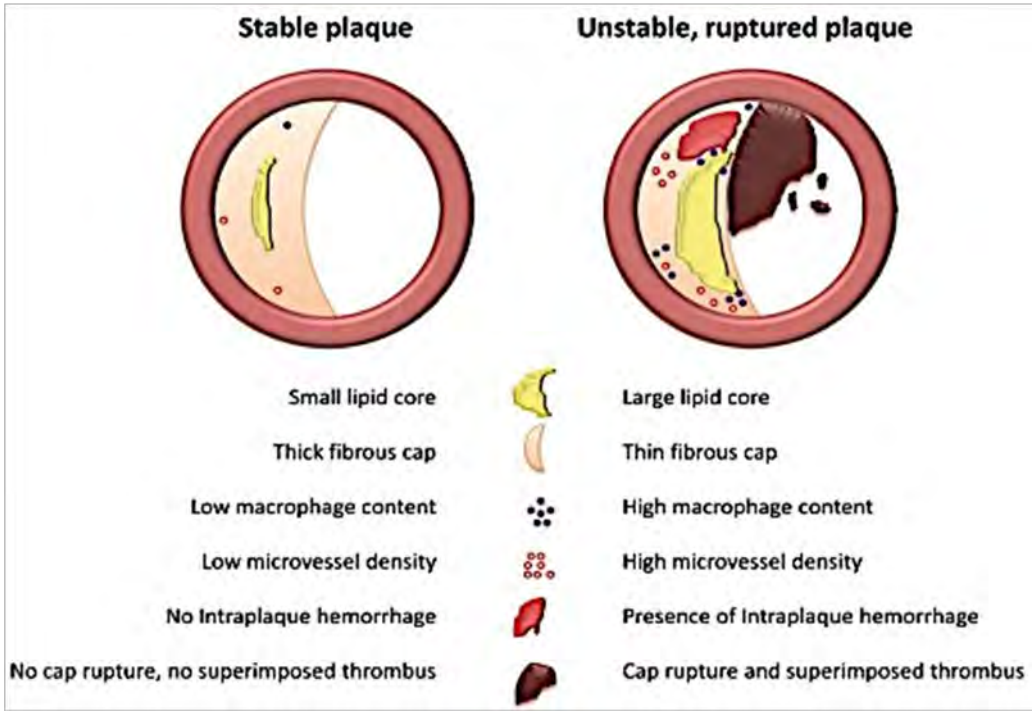
1. Frazione di eiezione a riposo del ventricolo sinistro <35%.
2. Test da sforzo ad alto rischio (score di Duke ≤ -11).
3. Importante disfunzione ventricolare sinistra in corso di esercizio (FE <35%).
4. Difetti di perfusione ampi, soprattutto se anteriori, allo stress test.
5. Difetti di perfusione multipli di dimensioni medie.
6. Difetti di perfusione estesi che non si modificano in corso di stress test, con dilatazione del ventricolo sinistro o captazione polmonare del tallio-201.
7. Difetti di perfusione di entità media in corso di stress test, con dilatazione del ventricolo sinistro o captazione polmonare del tallio-201.
8. Alterazioni della cinetica in più di due segmenti in corso di eco-stress a basse dosi di dobutamina (≤10 mg/kg/min) o con frequenza cardiaca <120 b/m.
9. Evidenza di ischemia estesa all'eco-stress.

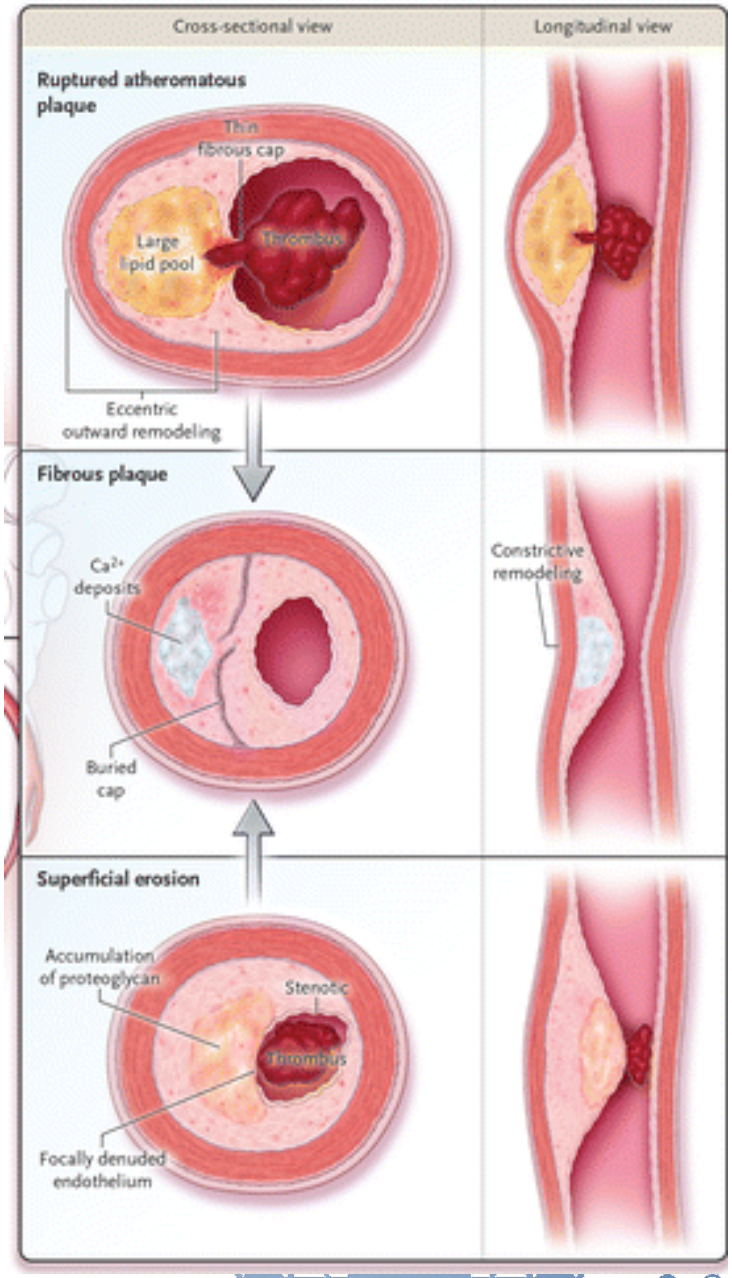
European Heart Journal (2013) 34, 2949–3003
doi:10.1093/eurheart/eht296

2013 ESC guidelines on the management of stable coronary artery disease

The Task Force on the management of stable coronary artery disease of the European Society of Cardiology

	Asymptomatic[a]		Symptomatic						
			Probability of significant disease[b]						
			Low (<15%)		Intermediate (15–85%)		High (>85%)		
	Class[c]	Level[d]	Class[c]	Level[d]	Class[c]	Level[d]	Class[c]	Level[d]	Ref[e]
Anatomical detection of CAD									
Invasive angiography	III	A	III	A	IIb	A	I	A	50–52,54
CT angiography[f,g]	III	B	III	C	IIa	A	III	B	57–62
Functional test									
Stress echo	III	A	III	A	I	A	III	A	63–65
Nuclear imaging	III	A	III	A	I	A	III	A	60,66–70
Stress MRI	III	B	III	C	I	A	III	B	71–75
PET perfusion	III	B	III	C	I	A	III	B	67,69,70,76,77
Combined or hybrid imaging test									
	III	C	III	C	IIa	B	III	B	78–83


Stable plaque
Unstable, ruptured plaque
Small lipid core
Large lipid core
Thick fibrous cap
Thin fibrous cap
Low macrophage content
High macrophage content
Low microvessel density
High microvessel density
No Intraplaque hemorrhage
Presence of Intraplaque hemorrhage
No cap rupture, no superimposed thrombus
Cap rupture and superimposed thrombus


Cross-sectional view
Longitudinal view
Ruptured atheromatous plaque
Thin fibrous cap
Large lipid pool
Thrombus
Eccentric outward remodeling
Fibrous plaque
Ca^{2+} deposits
Buried cap
Constrictive remodeling
Superficial erosion
Accumulation of proteoglycan
Stenotic
Thrombus
Focally denuded endothelium

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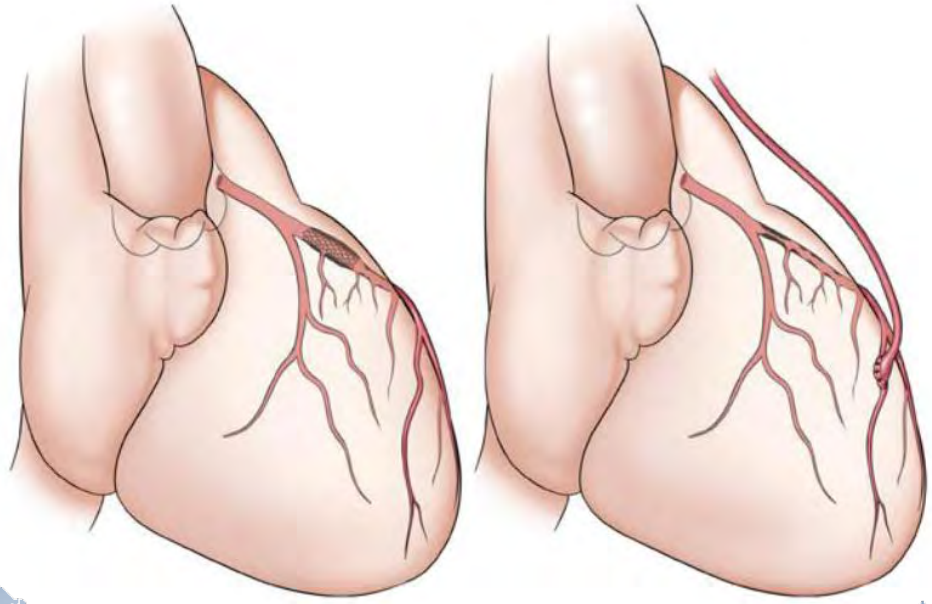
2) COME E SE DEVO RIVASCOLARIZZARE IL MIO PAZIENTE DIABETICO CON ATEROSCLEROSI ED ISCHEMIA CORONARICA



CHI RIVASCOLARIZZARE

COME RIVASCOLARIZZARE

QUANDO RIVASCOLARIZZARE

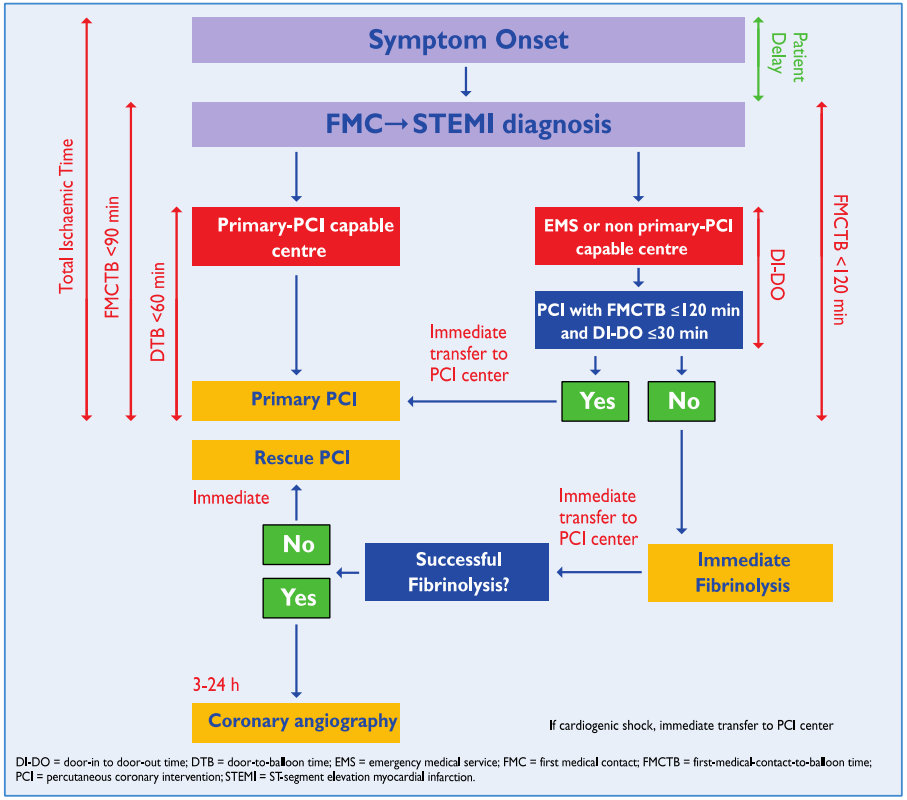
CHI RIVASCOLARIZZARE

COME RIVASCOLARIZZARE

QUANDO RIVASCOLARIZZARE

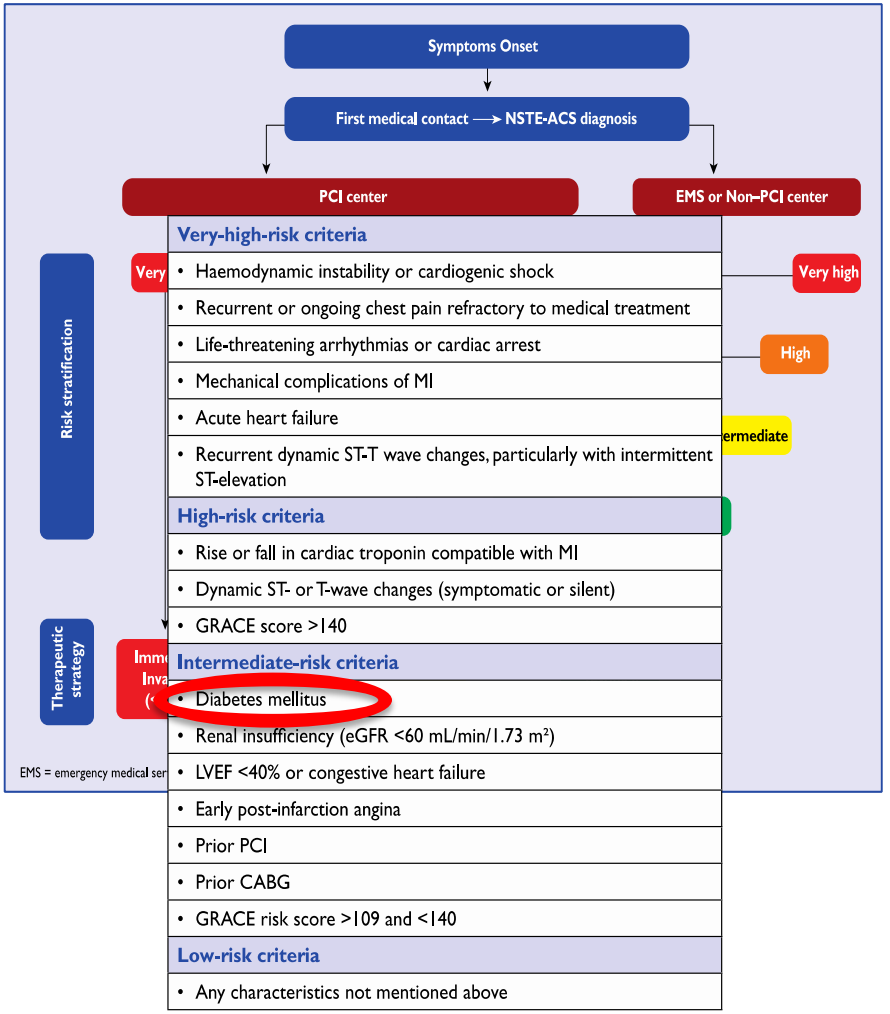
European Heart Journal (2014) 35, 2541–2619
doi:10.1093/eurheartj/ehu278

2014 ESC/EACTS Guidelines on myocardial revascularization

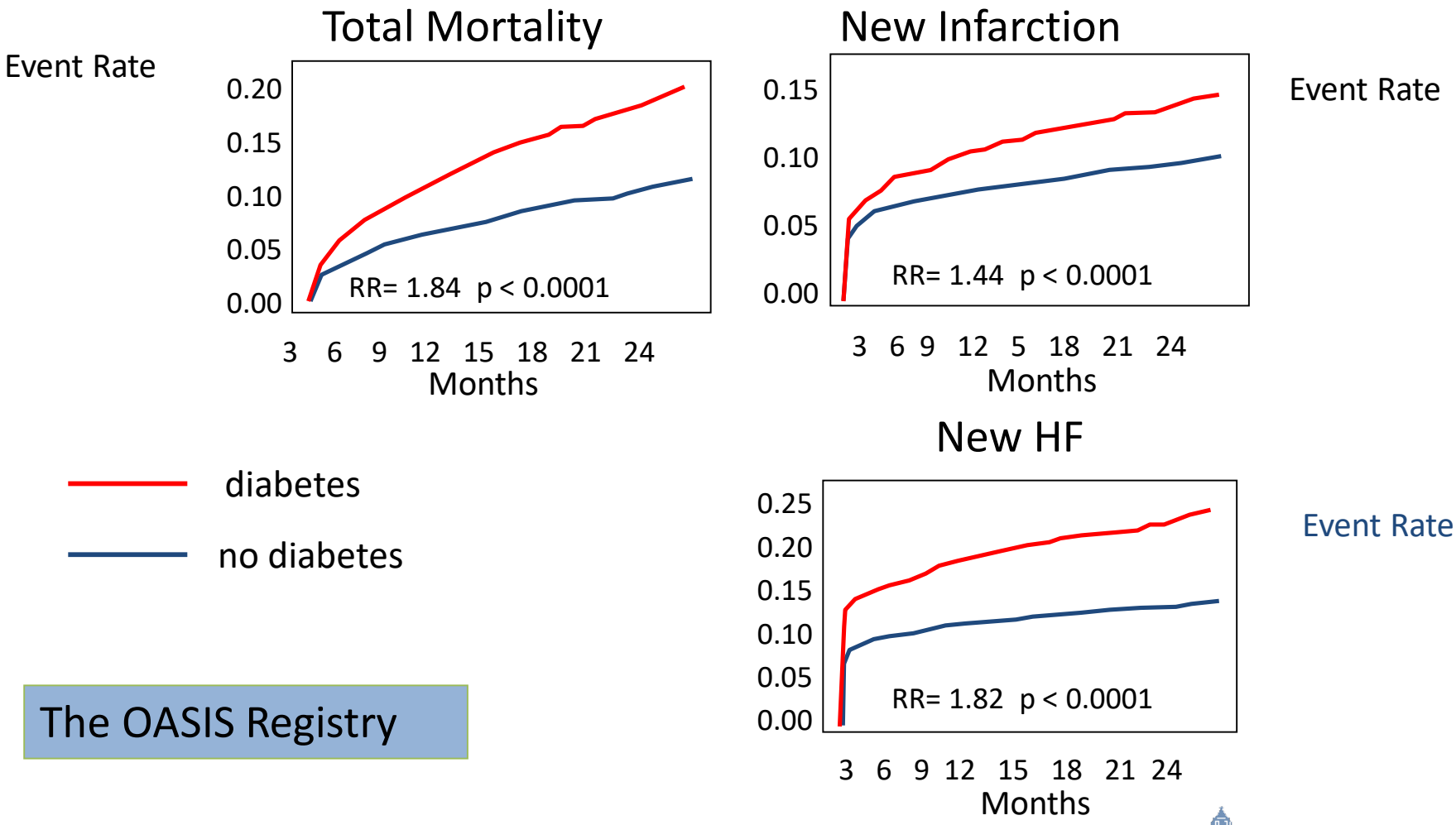


European Heart Journal (2016) 37, 267–315
doi:10.1093/eurheartj/ehv320

2015 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation



IMPATTO PROGNOSTICO IN DIABETICI CON ANGINA INSTABILE E Non-Q-MI



The OASIS Registry

Malmberg K et al. Circulation 2000; 102: 1014-1019

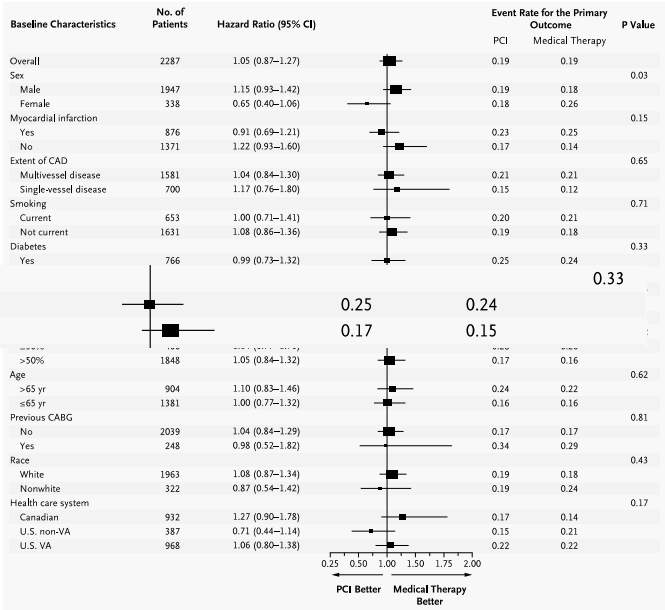
The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1812 APRIL 12, 2007 VOL. 356 NO. 15

Optimal Medical Therapy with or without PCI for Stable Coronary Disease

William E. Boden, M.D., Robert A. O'Rourke, M.D., Koon K. Teo, M.B., B.Ch., Ph.D., Pamela M. Hartigan, Ph.D., David J. Maron, M.D., William J. Kostuk, M.D., Merril Knudtson, M.D., Marcin Dada, M.D., Paul Casperson, Ph.D., Crystal L. Harris, Pharm.D., Bernard R. Chaitman, M.D., Leslee Shaw, Ph.D., Gilbert Gosselin, M.D., Shah Nawaz, M.D., Lawrence M. Title, M.D., Gerald Gau, M.D., Alvin S. Blaustein, M.D., David C. Booth, M.D., Eric R. Bates, M.D., John A. Spertus, M.D., M.P.H., Daniel S. Berman, M.D., G.B. John Mancini, M.D., and William S. Weintraub, M.D., for the COURAGE Trial Research Group*

N=2287
CCS1-3
30% diabetici
Malattia coronarica multivasale con ischemia inducibile
FU 2,5 e 7 anni

Outcome	Number of Events		Hazard Ratio (95% CI)†	P Value†	Cumulative Rate at 4.6 Years	
	PCI Group	Medical-Therapy Group			PCI Group	Medical-Therapy Group
					%	
Death and nonfatal myocardial infarction‡	211	202	1.05 (0.87–1.27)	0.62	19.0	18.5
Death§	68	74				
Periprocedural myocardial infarction	35	9				
Spontaneous myocardial infarction	108	119				
Death, myocardial infarction, and stroke	222	213	1.05 (0.87–1.27)	0.62	20.0	19.5
Hospitalization for ACS	135	125	1.07 (0.84–1.37)	0.56	12.4	11.8
Death§	85	95	0.87 (0.65–1.16)	0.38	7.6	8.3
Cardiac	23	25				
Other	45	51				
Unknown	17	19				
Total nonfatal myocardial infarction	143	128	1.13 (0.89–1.43)	0.33	13.2	12.3
Periprocedural myocardial infarction	35	9				
Spontaneous myocardial infarction	108	119				
Death, myocardial infarction, and ACS	294	288	1.05 (0.90–1.24)	0.52	27.6	27.0
Stroke	22	14	1.56 (0.80–3.04)	0.19	2.1	1.8
Revascularization (PCI or CABG)¶	228	348	0.60 (0.51–0.71)	<0.001	21.1	32.6



European Heart Journal (2014) 35, 2541–2619
doi:10.1093/eurheartj/ehu278

2014 ESC/EACTS Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

INDICATIONS FOR REVASCULARIZATION IN PATIENTS WITH STABLE ANGINA OR SILENT ISCHAEMIA

Extent of CAD (anatomical and/or functional)		Class[b]	Level[c]	References
For prognosis	Left main disease with stenosis >50%[a]	I	A	108,134,135
	Any proximal LAD stenosis >50%[a]	I	A	94,108,135,136
	Two-vessel or three-vessel disease with stenosis > 50%[a] with impaired LV function (LVEF<40%)[a]	I	A	93,94,108,112, 121,135,137–142
	Large area of ischaemia (>10% LV)	I	B	54,91,97,99,143,144
	Single remaining patent coronary artery with stenosis >50%[a]	I	C	
For symptoms	Any coronary stenosis >50%[a] in the presence of limiting angina or angina equivalent, unresponsive to medical therapy	I	A	54,96,105,108, 118–120,145

CHI RIVASCOLARIZZARE

COME RIVASCOLARIZZARE

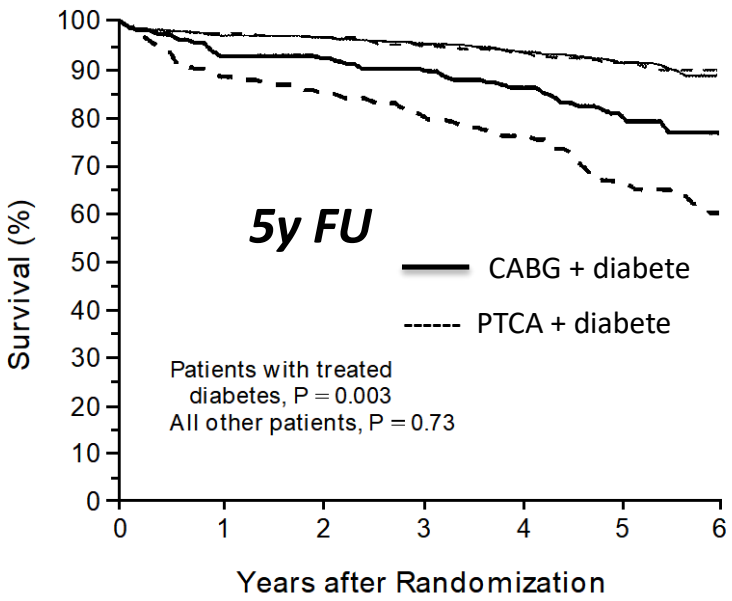
QUANDO RIVASCOLARIZZARE

The New England
Journal of Medicine

VOLUME 335 JULY 25, 1996 NUMBER 4

COMPARISON OF CORONARY BYPASS SURGERY WITH ANGIOPLASTY IN PATIENTS WITH MULTIVESSEL DISEASE

THE BYPASS ANGIOPLASTY REVASCULARIZATION INVESTIGATION (BARI) INVESTIGATORS*



PATIENTS WITH TREATED DIABETES			
CABG	180	161	93
PTCA	173	139	69
ALL OTHER PATIENTS			
CABG	734	696	449
PTCA	742	701	468

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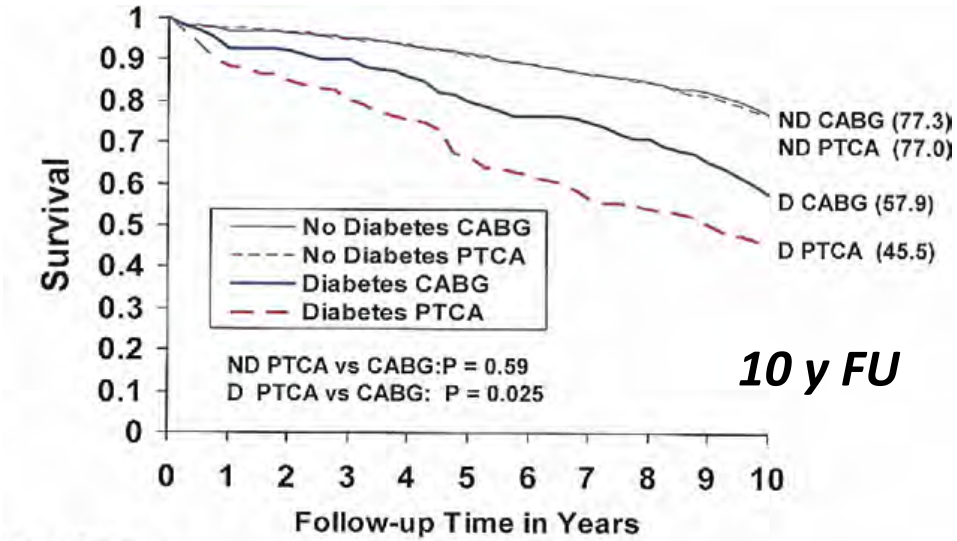
doi:10.1016/j.jacc.2006.11.048

CLINICAL RESEARCH Clinical Trial

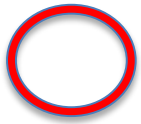
The Final 10-Year Follow-Up Results From the BARI Randomized Trial

The BARI Investigators*



No. of Patients					
ND CABG	734	698	669	613	473
ND PTCA	742	703	675	621	477
D CABG	180	161	143	124	80
D PTCA	173	139	115	93	63

BARI TRIAL



uting stent.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 20, 2012 VOL. 367 NO. 25

Strategies for Multivessel Revascularization in Patients with Diabetes

Michael E. Farkouh, M.D., Michael Domanski, M.D., Lynn A. Sleeper, Sc.D., Flora S. Siami, M.P.H., George Dangas, M.D., Ph.D., Michael Mack, M.D., May Yang, M.P.H., David J. Cohen, M.D., Yves Rosenberg, M.D., M.P.H., Scott D. Solomon, M.D., Akshay S. Desai, M.D., M.P.H., Bernard J. Gersh, M.B., Ch.B., D.Phil., Elizabeth A. Magnuson, Sc.D., Alexandra Lansky, M.D., Robin Boineau, M.D., Jesse Weinberger, M.D., Krishnan Ramanathan, M.B., Ch.B., J. Eduardo Sousa, M.D., Ph.D., Jamie Rankin, M.D., Balram Bhargava, M.D., John Buse, M.D., Whady Hueb, M.D., Ph.D., Craig R. Smith, M.D., Victoria Muratov, M.D., M.P.H., Sameer Bansilal, M.D., Spencer King III, M.D., Michel Bertrand, M.D., and Valentin Fuster, M.D., Ph.D., for the FREEDOM Trial Investigators*

n= 1900 diabetici

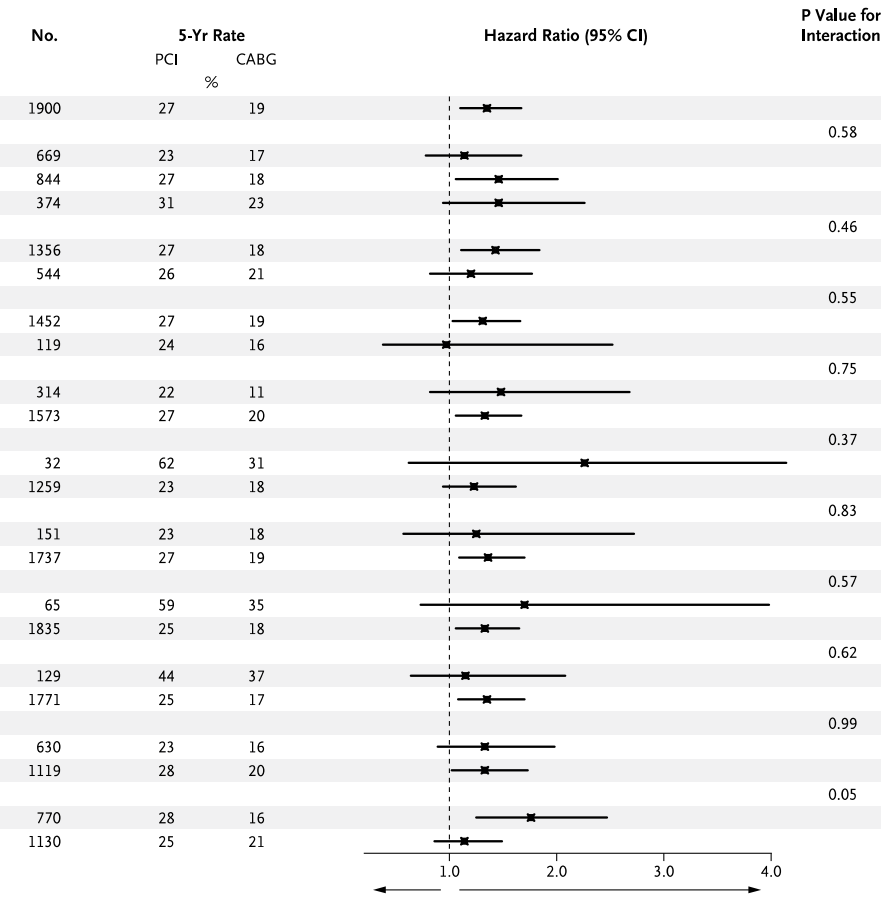
Malattia coronarica multivasale (SYNTAX score medio 26.2 ± 8%)

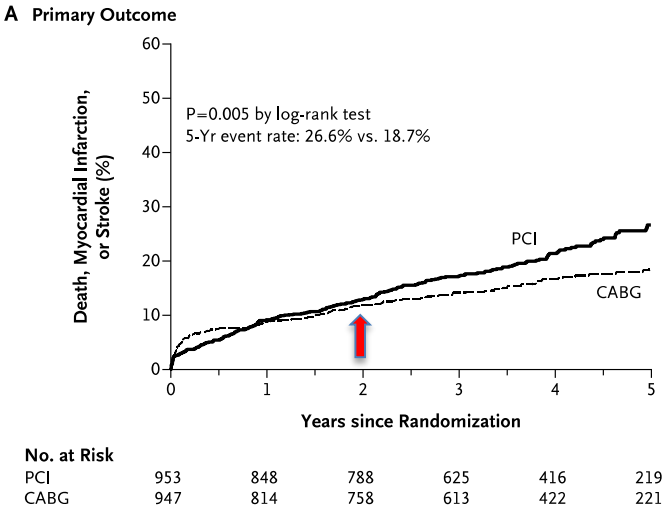
No malattia del tronco comune

Hb glicata media 7,8 ± 1,7%

GABG vs Stent medicati (SES/PES)

Outcome	2 Years after Randomization		5 Years after Randomization		Patients with Event		P Value*
	PCI	CABG	PCI	CABG	PCI	CABG	
	number (percent)				*number*		
Primary composite†	121 (13.0)	108 (11.9)	200 (26.6)	146 (18.7)	205	147	0.005‡
Death from any cause	62 (6.7)	57 (6.3)	114 (16.3)	83 (10.9)	118	86	0.049
Myocardial infarction	62 (6.7)	42 (4.7)	98 (13.9)	48 (6.0)	99	48	<0.001
Stroke	14 (1.5)	24 (2.7)	20 (2.4)	37 (5.2)	22	37	0.03§
Cardiovascular death	9 (0.9)	12 (1.3)	73 (10.9)	52 (6.8)	75	55	0.12

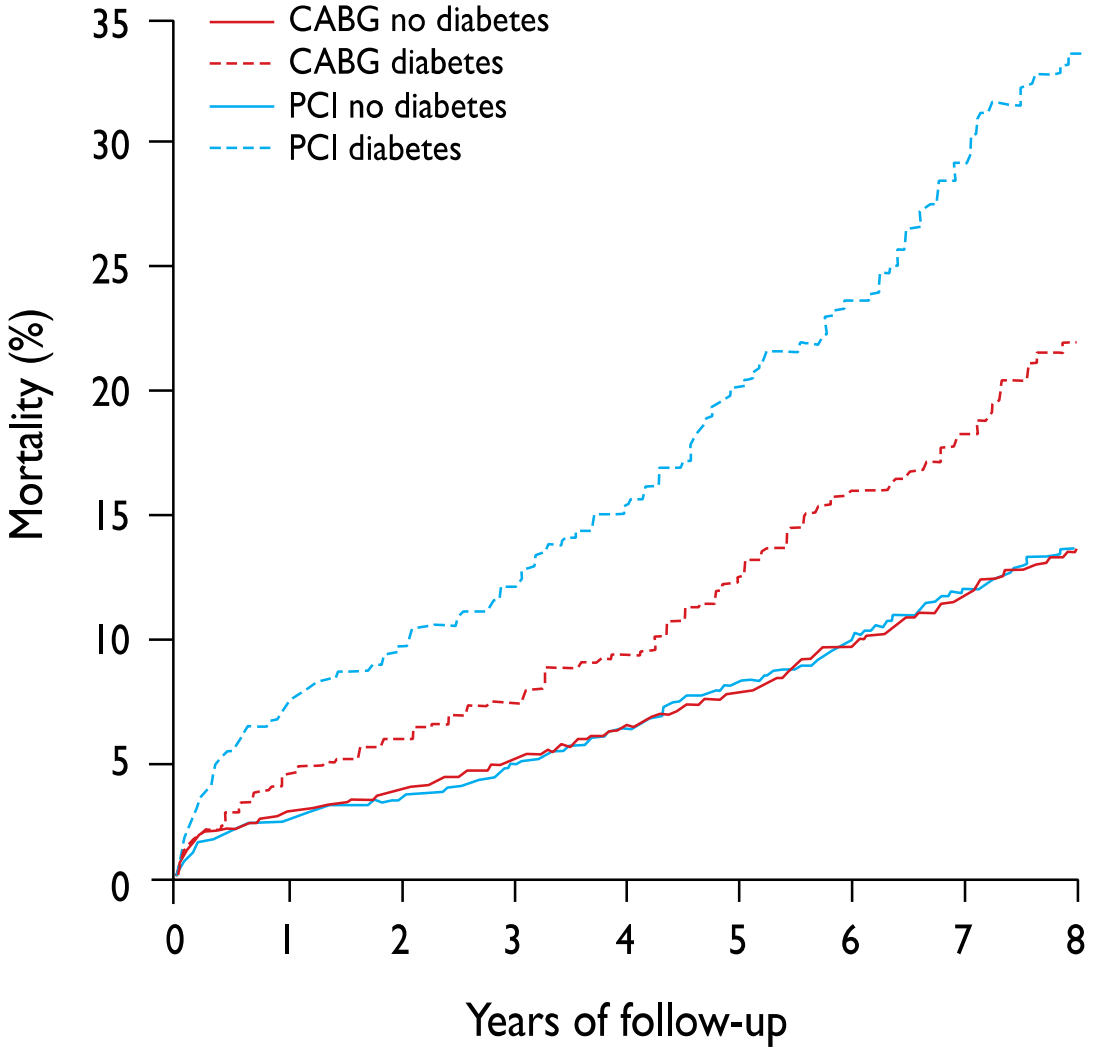


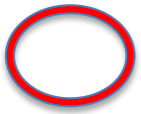


N Engl J Med 2012;367:2375-84.

.....2009..... **Metanalisi 10 studi randomizzati**

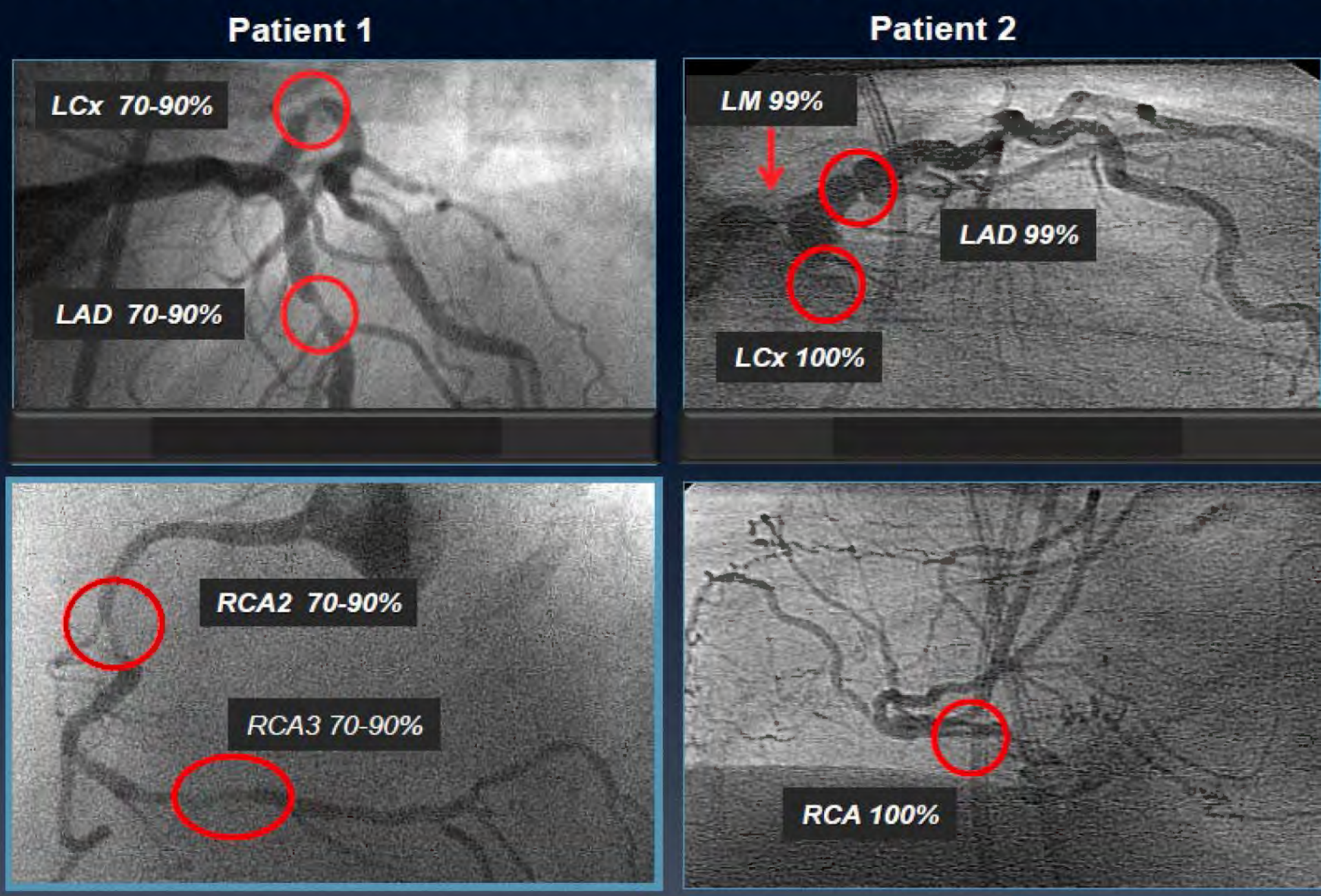
Lancet 2009; 373: 1190–97





uting stent.

There is '3-vessel disease' and '3-vessel disease'



Treatment Effect Gap Over Time in Diabetes

Potential Explanation for this.....

1. **Marked advances in PCI devices and adjunctive pharmacology**
2. **Marked improvement in background intensive medical therapy**

Manufacturer reported strut thickness.

CYPHER®	TAXUS EXPRESS®	TAXUS LIBERTE®	ENDEAVOR®	XIENCE V® PROMUS	new alloy DES
					
140µm	132µm	97µm	91µm	81µm	≤70 µm
14µm	14µm	14µm	6µm	7µm	≤7µm
154µm	146µm	111µm	97µm	81µm	≤70 µm
Stainless Steel	Stainless Steel	Stainless Steel	Cobalt Nickel	Cobalt Chrome	New alloy

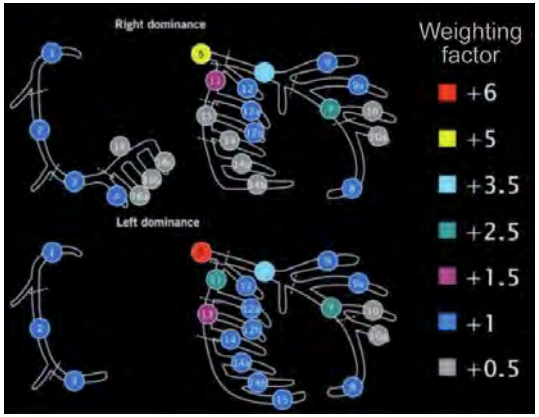
CARDIOVASCULAR RESEARCH FOUNDATION

SYNTAX TRIAL

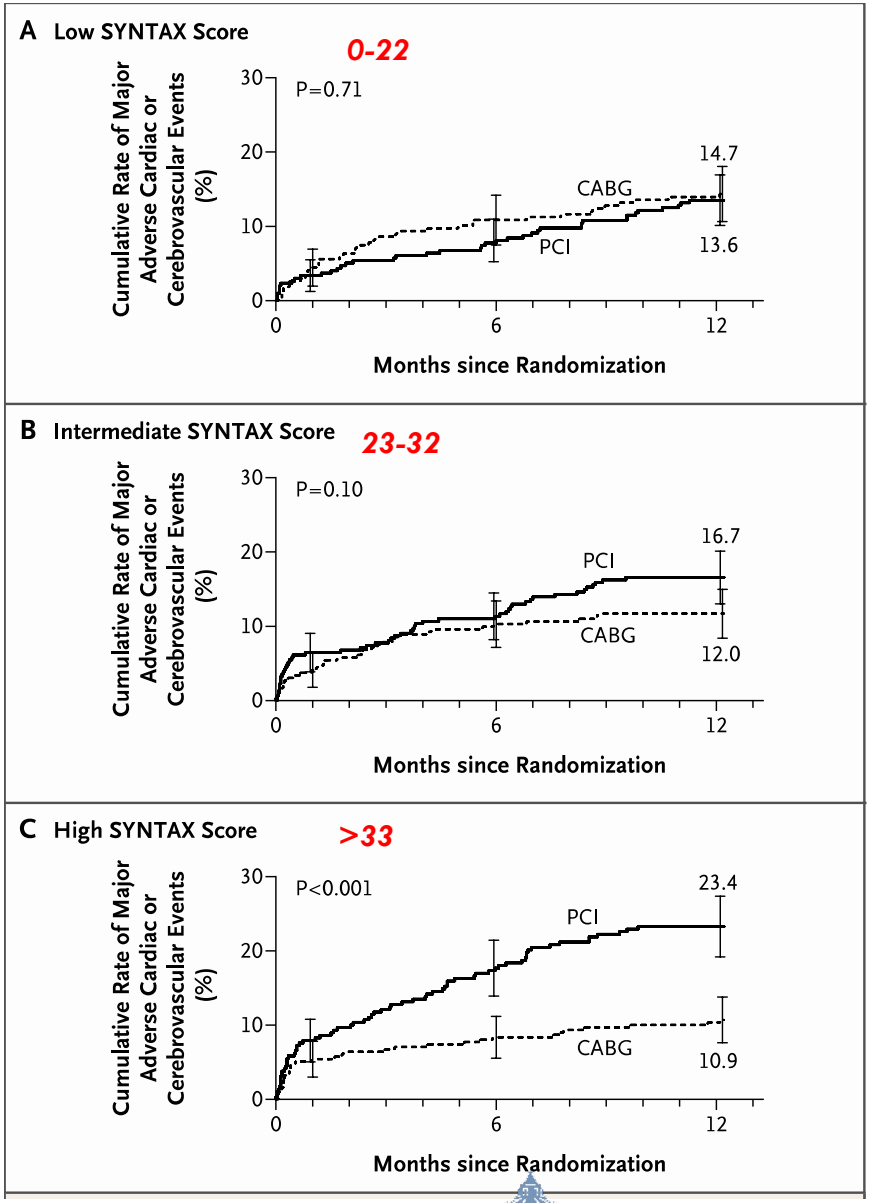
The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1812 MARCH 5, 2009 VOL. 360 NO. 10

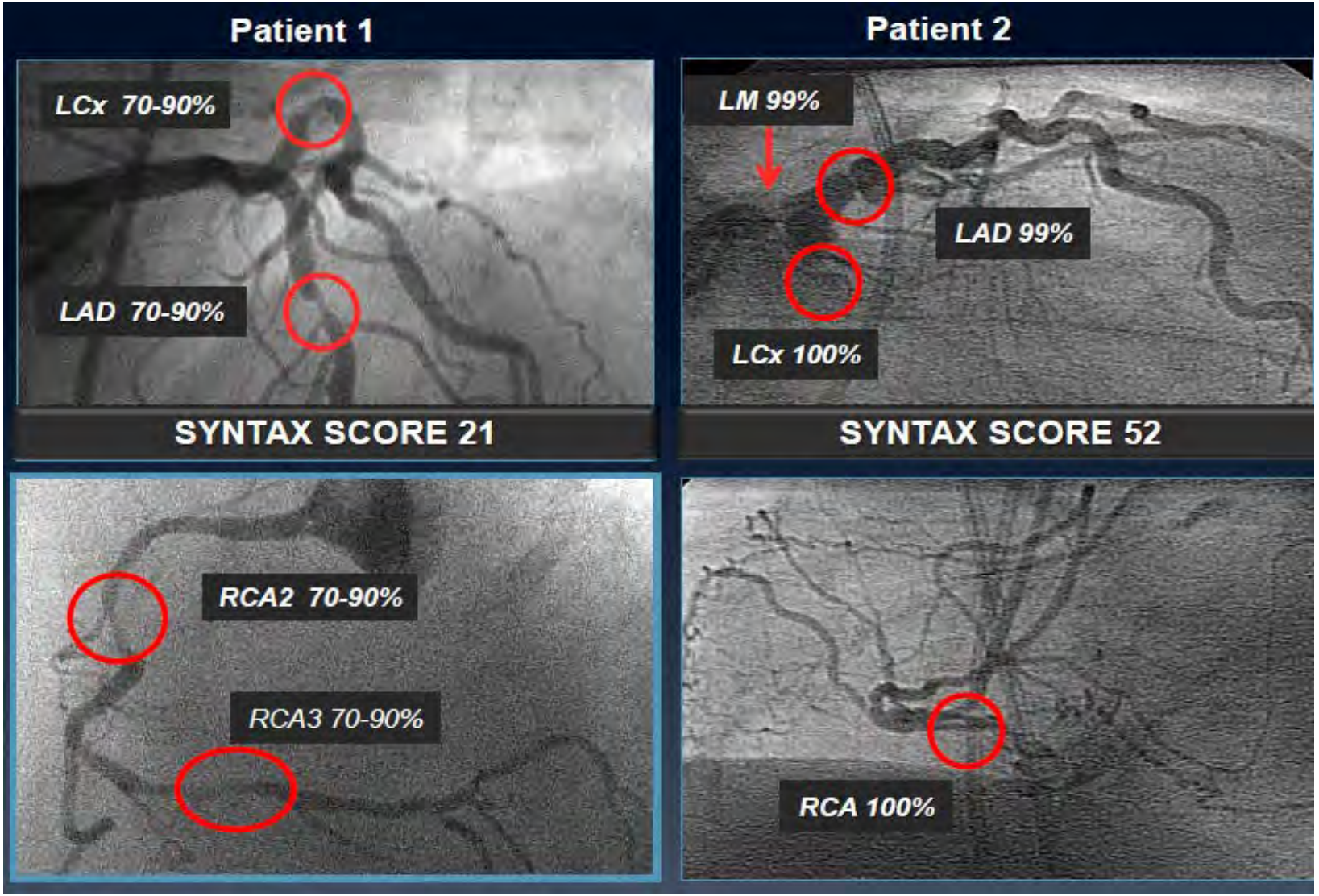
Percutaneous Coronary Intervention versus Coronary-Artery Bypass Grafting for Severe Coronary Artery Disease

Patrick W. Serruys, M.D., Ph.D., Marie-Claude Morice, M.D., A. Pieter Kappetein, M.D., Ph.D., Antonio Colombo, M.D., David R. Holmes, M.D., Michael J. Mack, M.D., Elsabeth Ståhle, M.D., Ted E. Feldman, M.D., Marcel van den Brand, M.D., Eric J. Bass, B.A., Nic Van Dyck, R.N., Katrin Leadley, M.D., Keith D. Dawkins, M.D., and Friedrich W. Mohr, M.D., Ph.D., for the SYNTAX Investigators*



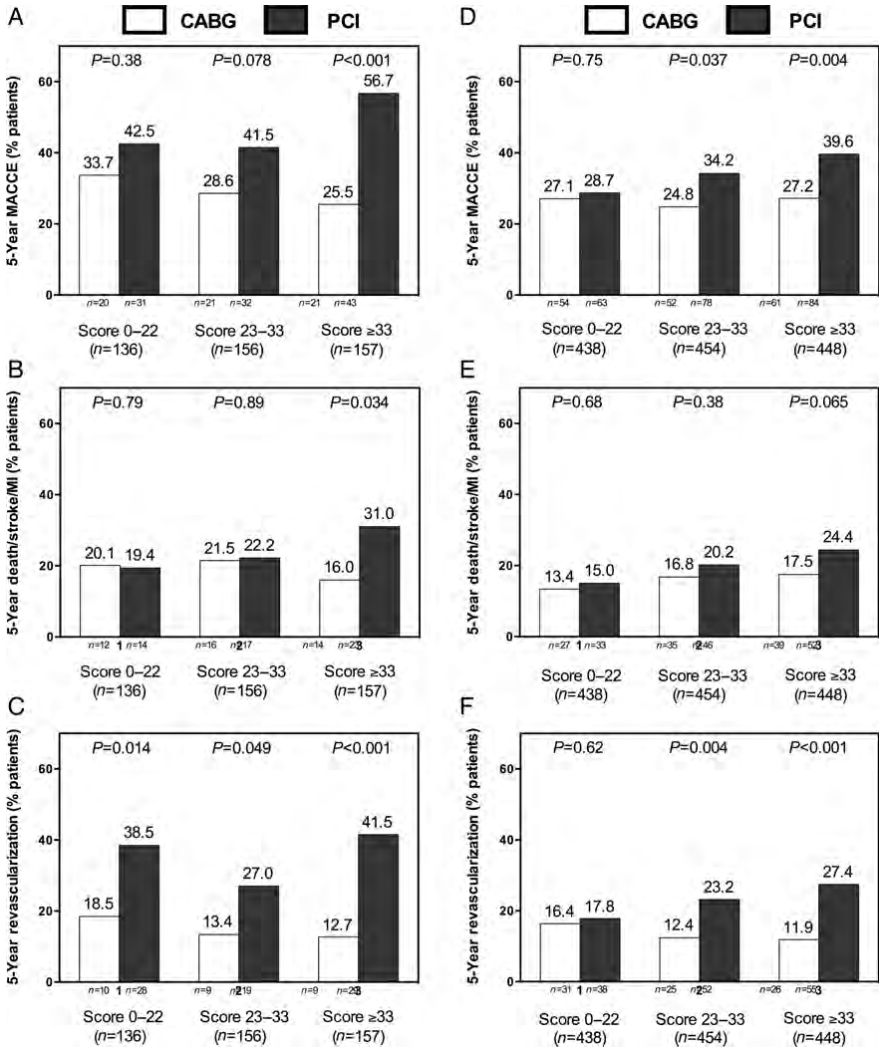
both <1.5 and ≥1.5 mm diameter
+0 if ≥1.5 mm diameter (i.e. bifurcation lesion)



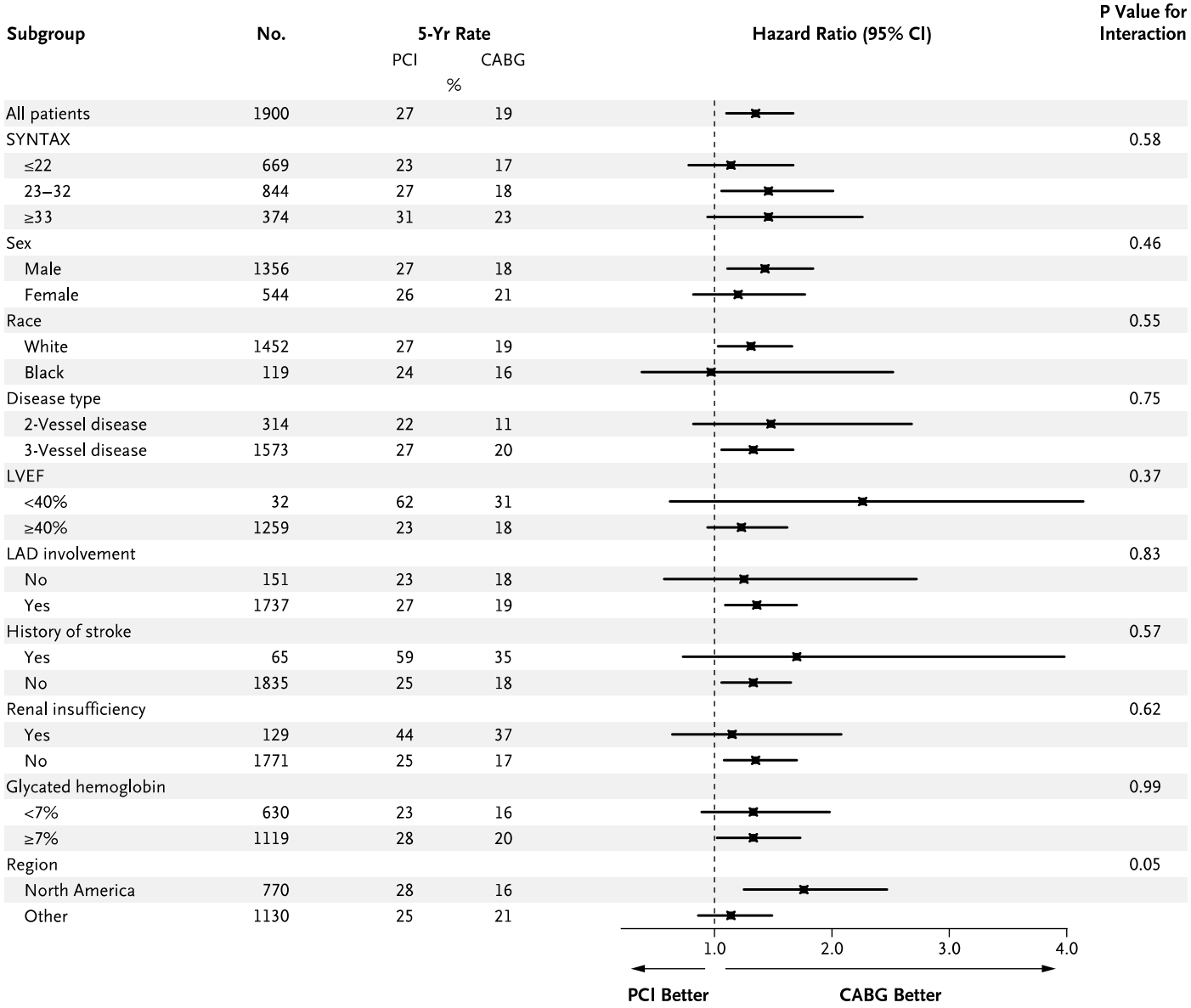

Patient 1
LCx 70-90%
LAD 70-90%
SYNTAX SCORE 21
Patient 2
LM 99%
LAD 99%
LCx 100%
SYNTAX SCORE 52
RCA2 70-90%
RCA3 70-90%
RCA 100%

SYNTAX TRIAL IMPACT OF DIABETES 5Y FOLLOW UP

European Journal of Cardio-Thoracic Surgery 43 (2013) 1006–1013



Diabetici Non Diabetici



N Engl J Med 2012;367:2375-84.

CHI RIVASCOLARIZZARE

COME RIVASCOLARIZZARE

QUANDO RIVASCOLARIZZARE

The NEW ENGLAND JOURNAL of MEDICINE
ESTABLISHED IN 1812 JUNE 11, 2009 VOL. 360 NO. 24

rivascolarizzazione immediata entro 6 mesi

A Randomized Trial of Therapies for Type 2 Diabetes and Coronary Artery Disease

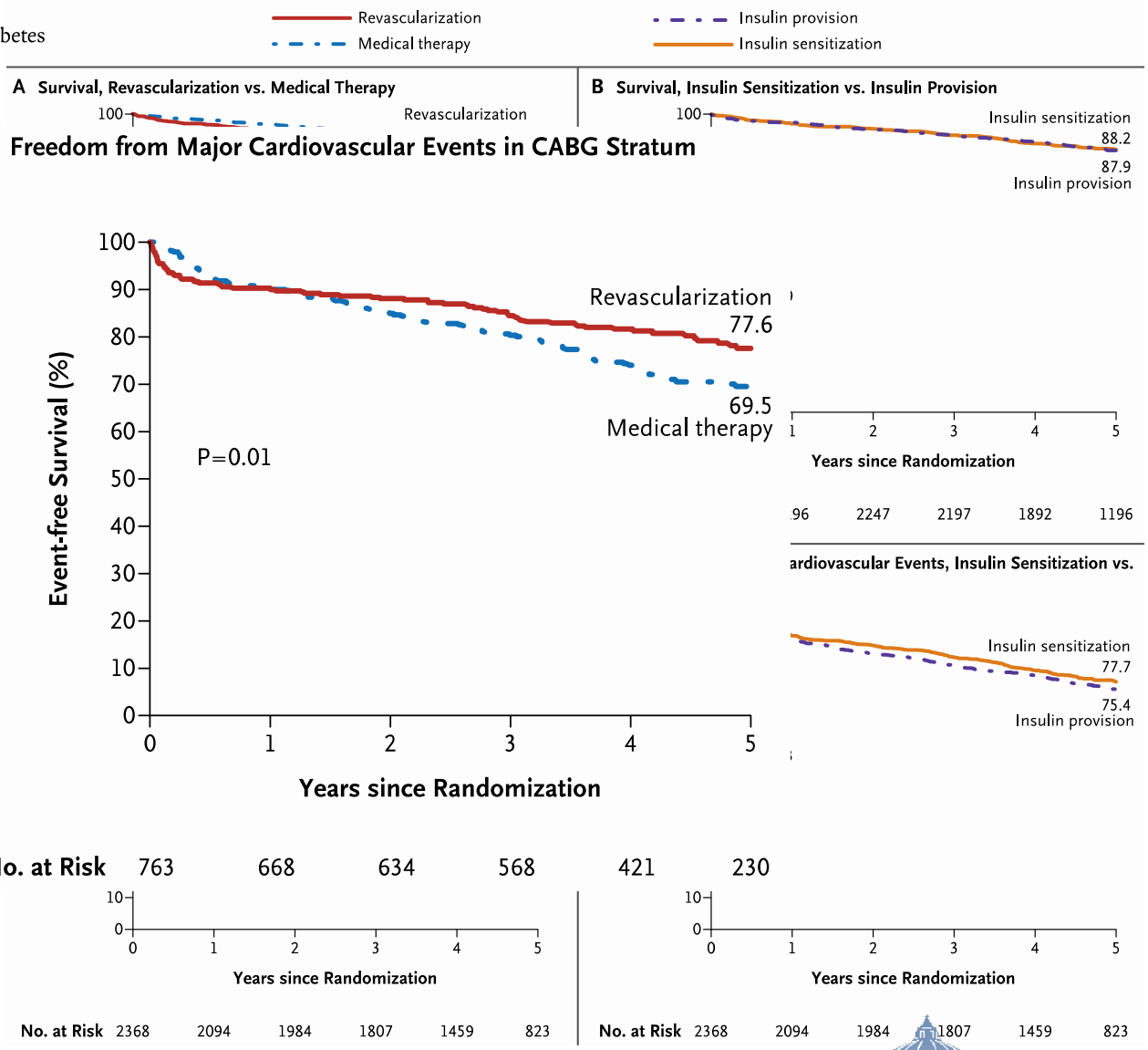
The BARI 2D Study Group*

n= 2368
FU 5 y

STUDIO BARI 2D

Durata diabete 10,4 aa

43% rivasc a 5 aa nel gruppo conservativo



Sottogruppo CABG:
Malattia coronarica complessa Multivasale,
IVA prossimale
Occlusione totale coronarica
Storia di infarto
Pregresse rivascolarizzazioni

CON ECCEZIONE DI MALATTIA CORONARICA COMPLESSA

(TRONCO COMUNE >50%, DISCENDENTE ANTERIORE PROSSIMALE O MALATTIA TRIVASALE CON O SENZA DISFUNZIONE DEL VENTRICOLO SINSITRO)

LA RIVASCOLARIZZAZIONE IMMEDIATA NEL DIABETICO CON CAD STABILE NON SEMBREREBBE MIGLIORARE LA SOPRAVVIVENZA RISPETTO ALLA TERAPIA MEDICA OTTIMALE

NB: POPOLAZIONE SELEZIONATA CON CREATININA <2, HB GLICATA <13, NYHA 1-2 SENZA PRECEDENTE RIVASCOLARIZZAIZONE (CABG O PCI)

European Heart Journal (2014) 35, 2541–2619
doi:10.1093/eurheartj/ehu278

2014 ESC/EACTS Guidelines on myocardial revascularization

REVASCULARIZATION IN PATIENTS WITH DIABETES

Recommendations	Class[a]	Level[b]	Ref[c]
In patients presenting with STEMI, primary PCI is recommended over fibrinolysis if it can be performed within recommended time limits.	I	A	363
In patients with NSTE-ACS, an early invasive strategy is recommended over non-invasive management.	I	A	180,338, 364–366
In stable patients with multivessel CAD and/or evidence of ischaemia, revascularization is indicated in order to reduce cardiac adverse events.	I	B	93,367
In patients with stable multivessel CAD and an acceptable surgical risk, CABG is recommended over PCI.	I	A	106,175,349
In patients with stable multivessel CAD and SYNTAX score ≤22, PCI should be considered as alternative to CABG.	IIa	B	346,350
New-generation DES are recommended over BMS.	I	A	351,352
Bilateral mammary artery grafting should be considered.	IIa	B	368
In patients on metformin, renal function should be carefully monitored for 2 to 3 days after coronary angiography/PCI.	I	C	

P.O.
90 aa
Ipertensione 3° grado,
diabete tipo 2
Pregressi TIA
Coronaropatia
bivasale 2012 ai limiti
PMK per bradi-tachi
Protesi valvolare biologica
Aortica (TAVI)

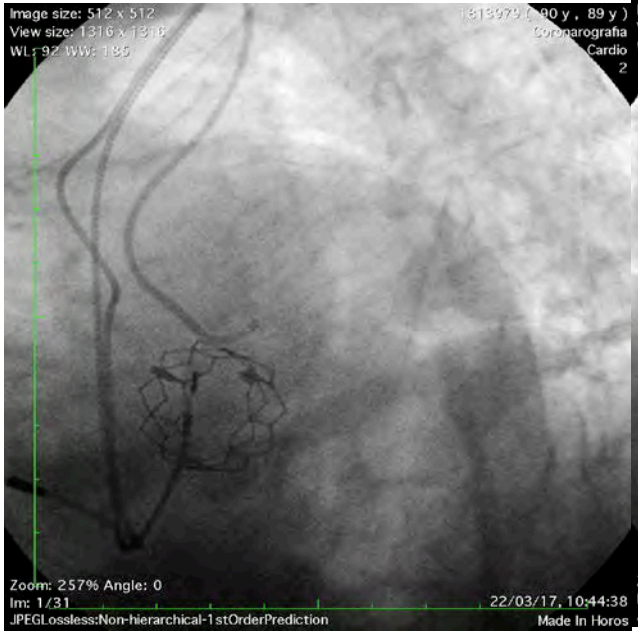
FEVSn 60%

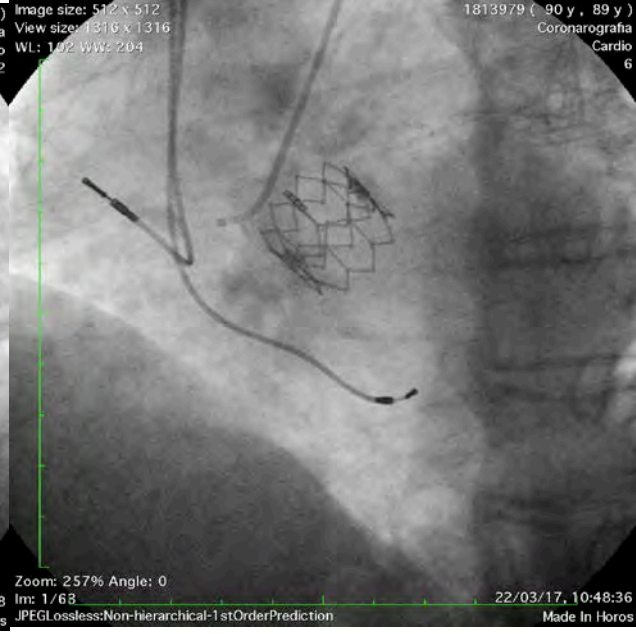
Angina CCS4 invalidante

Terapia medica massimale

Syntax score >22

GFR 36 ml/min





Event	30 Days after Procedure			12 Months after Procedure		
	PCI	CABG	P Value	PCI	CABG	P Value
	number (percent)			*number (percent)*		
Major adverse cardiovascular and cerebrovascular events	45 (4.8)	47 (5.2)	0.68	157 (16.8)	106 (11.8)	0.004
Death	8 (0.8)	15 (1.7)	0.12	32 (3.4)	38 (4.2)	0.35
Myocardial infarction	17 (1.8)	15 (1.7)	0.82	54 (5.8)	30 (3.4)	0.02
Stroke	3 (0.3)	16 (1.8)	0.002	8 (0.9)	17 (1.9)	0.06
Repeat revascularization	31 (3.3)	10 (1.1)	0.002	117 (12.6)	42 (4.8)	<0.001

N Engl J Med 2012;367:2375-84.

P.O.
90 aa
Ipertensione 3° grado,
diabete tipo 2
Pregressi TIA
Coronaropatia
bivasale 2012 ai limiti
PMK per bradi-tachi
Protesi valvolare biologica
Aortica (TAVI)

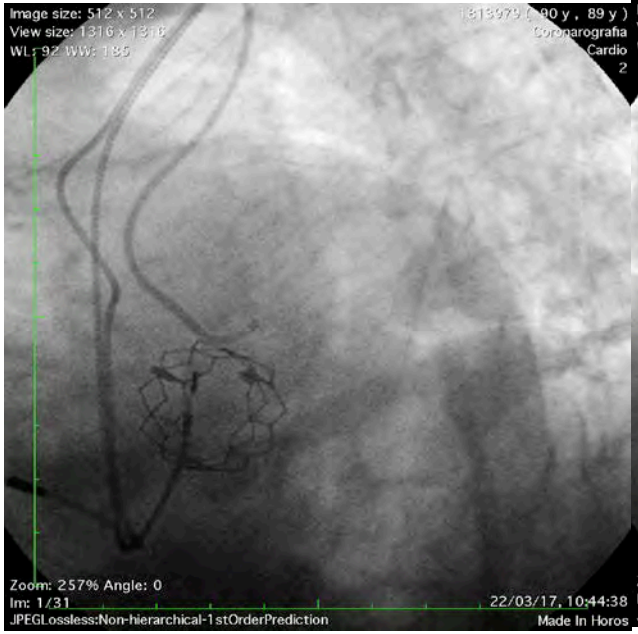
FEVSn 60%

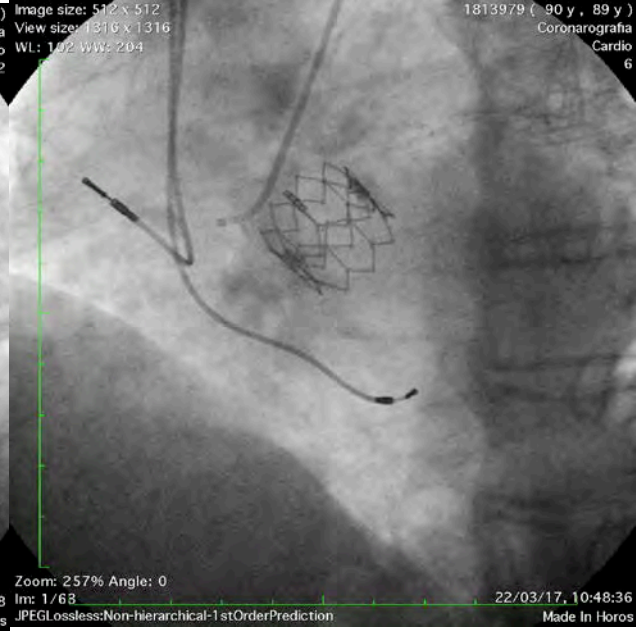
Angina CCS4 invalidante

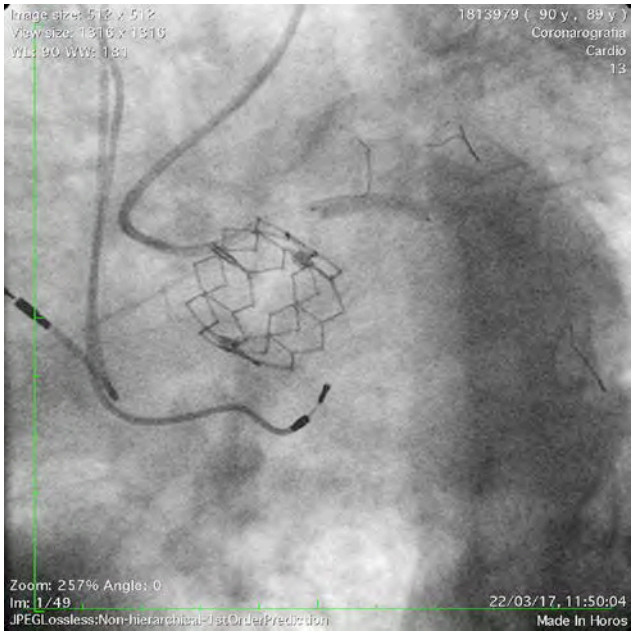
Terapia medica massimale

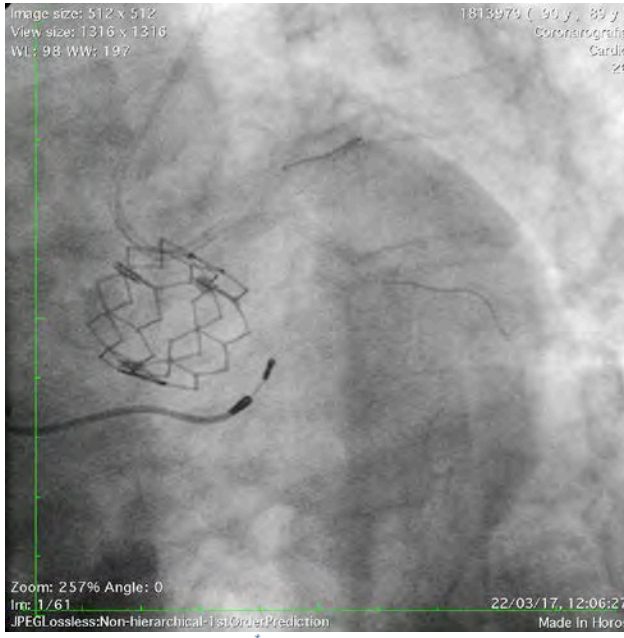
Syntax score >33

GFR 36 ml/min

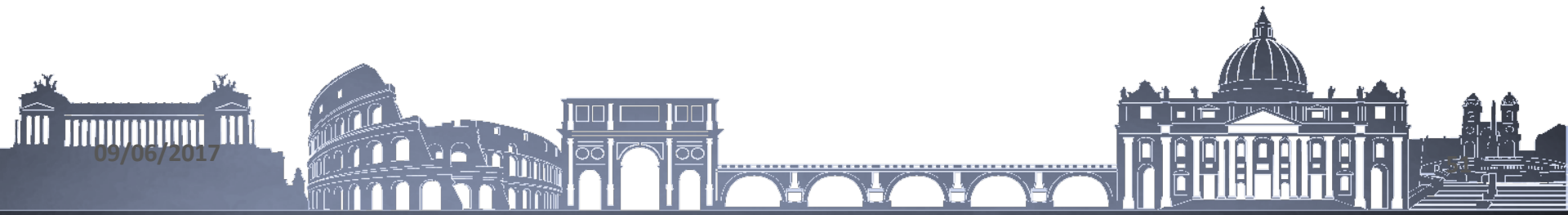




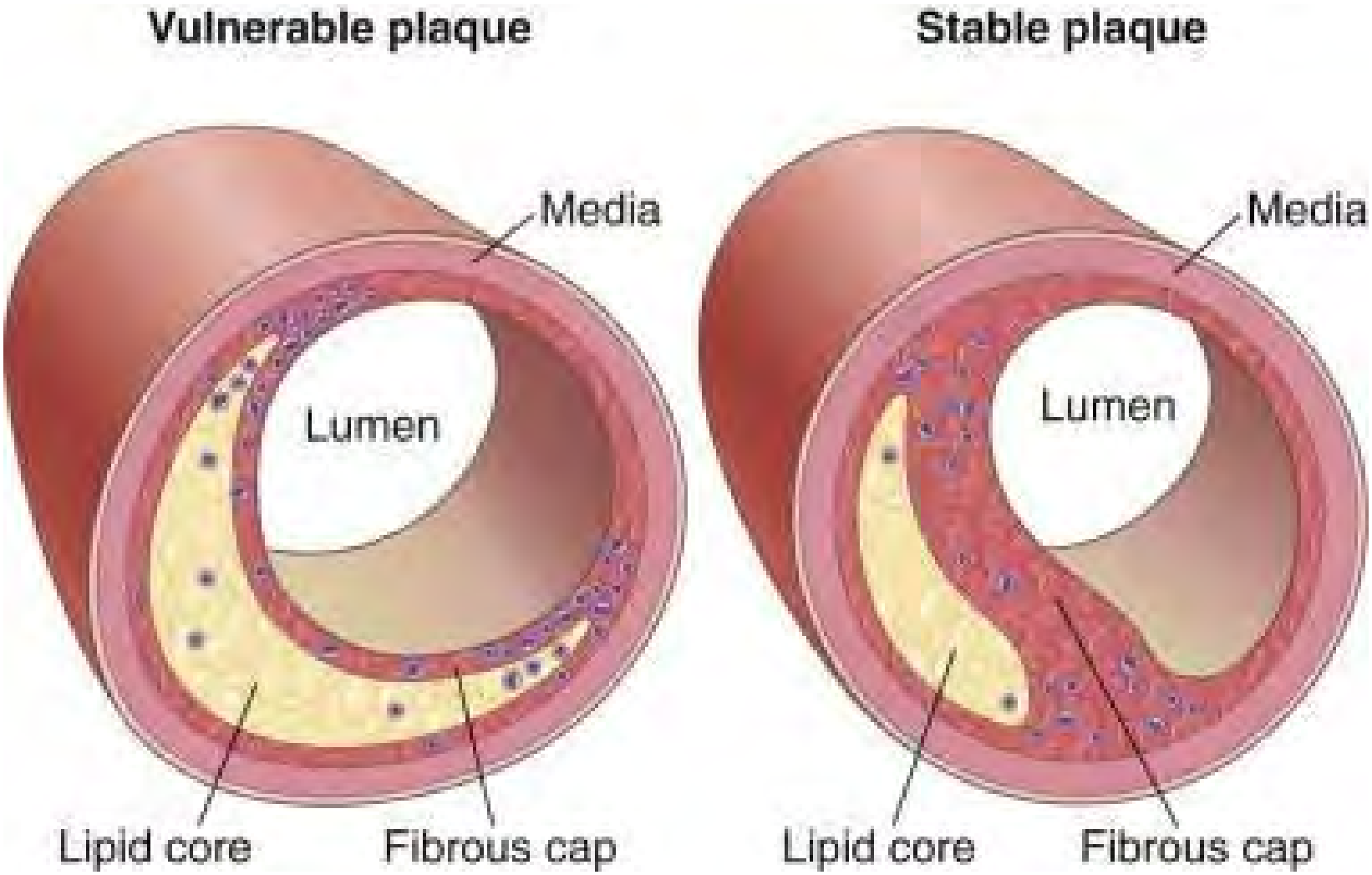


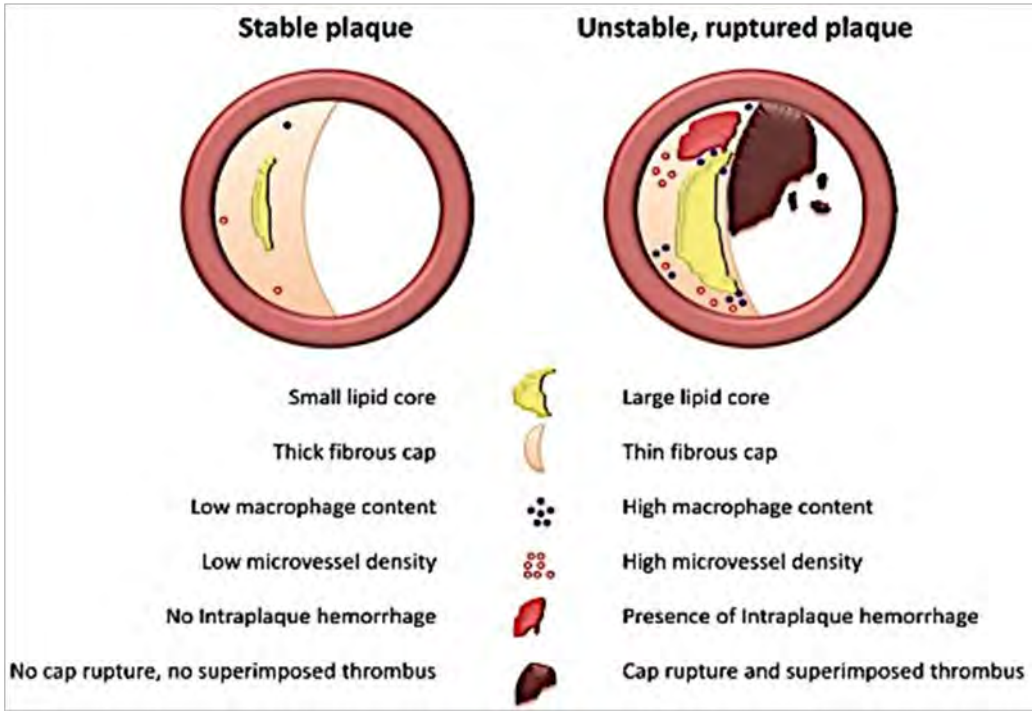


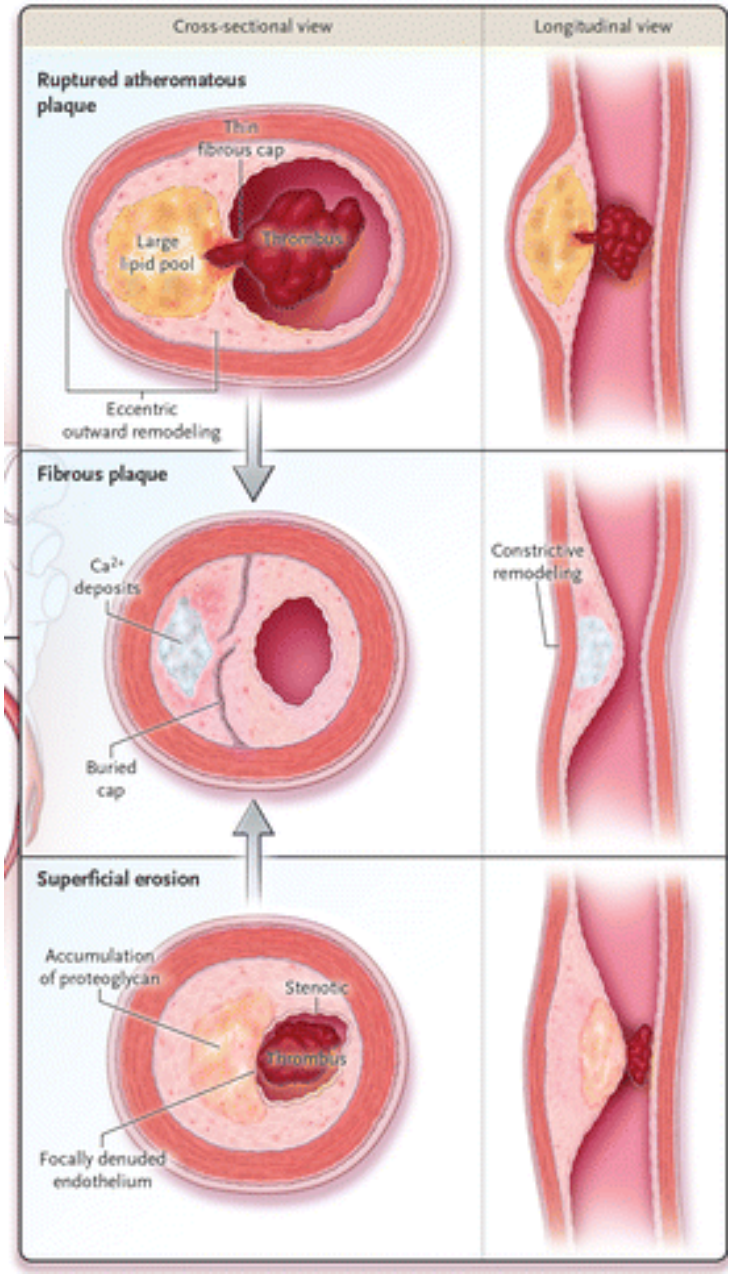
Grazie



CONCLUSIONI


Vulnerable plaque
Media
Lumen
Lipid core
Fibrous cap
Stable plaque
Media
Lumen
Lipid core
Fibrous cap


Stable plaque
Unstable, ruptured plaque
Small lipid core
Large lipid core
Thick fibrous cap
Thin fibrous cap
Low macrophage content
High macrophage content
Low microvessel density
High microvessel density
No Intraplaque hemorrhage
Presence of Intraplaque hemorrhage
No cap rupture, no superimposed thrombus
Cap rupture and superimposed thrombus


Cross-sectional view
Longitudinal view
Ruptured atheromatous plaque
Thin fibrous cap
Large lipid pool
Thrombus
Eccentric outward remodeling
Fibrous plaque
Ca^{2+} deposits
Buried cap
Constrictive remodeling
Superficial erosion
Accumulation of proteoglycan
Stenotic
Thrombus
Focally denuded endothelium

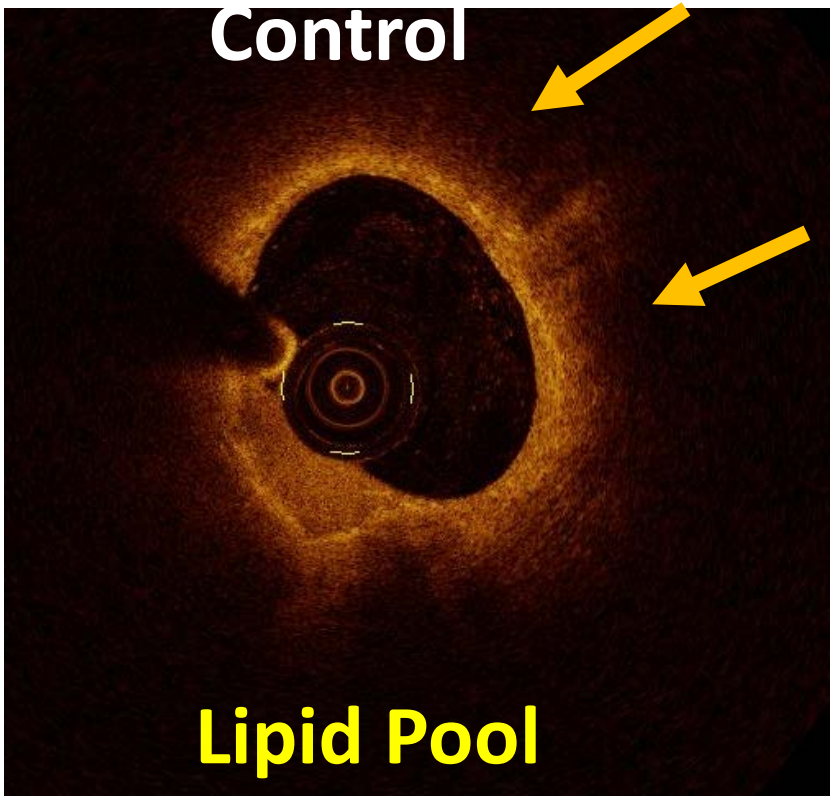
Angiographic severity and extent of coronary artery disease in patients with type 1 diabetes mellitus.

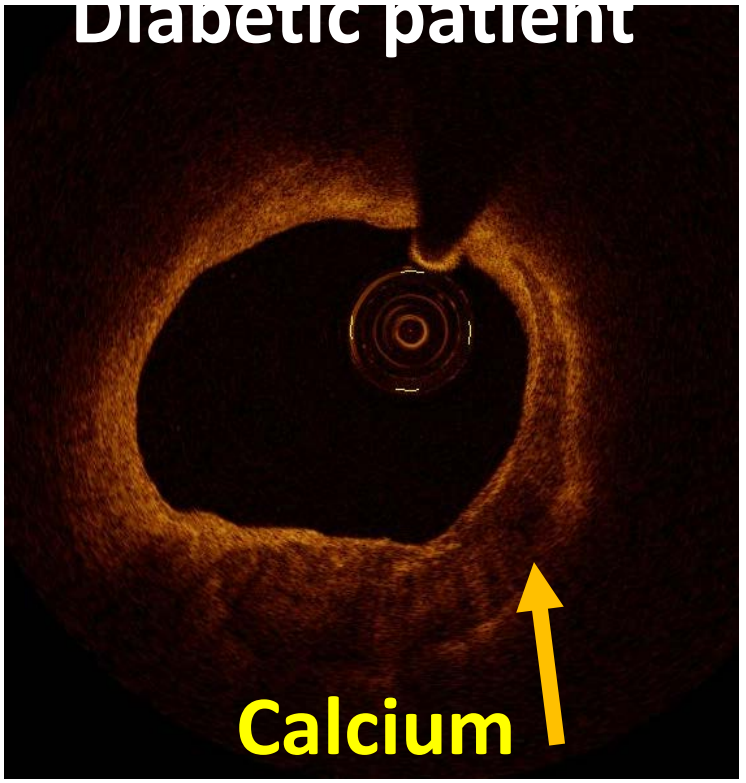
- 64 (24 women and 40 men) type 1 diabetic patients and nondiabetic control subjects.
- QCA adopted to estimate the severity, extent, and overall "atheroma burden" of CAD.
- Type 1 diabetic patients had greater global severity ($p < 0.001$), global extent ($p < 0.001$), and global atheroma burden ($p < 0.001$) indexes than nondiabetic control subjects.
- Women had more severe, extensive, and distal type of CAD than individually matched non-diabetic control patients.

Pajunen P et al. Am J Cardiol. 2000 Nov 15;86(10):1080-5.

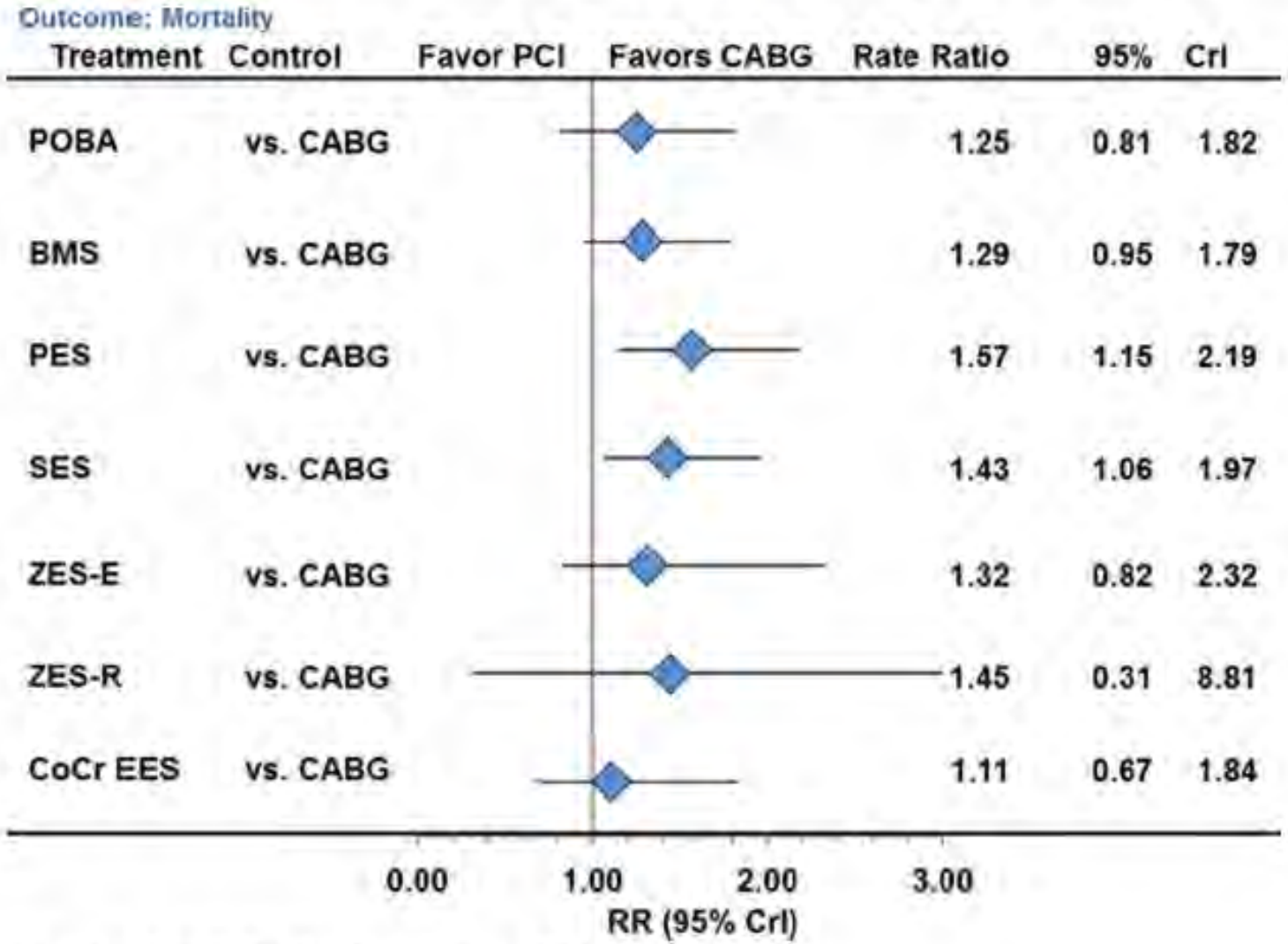
Niccoli et al. Eur Heart J 2013

Diabetes: More calcium, less lipid pools





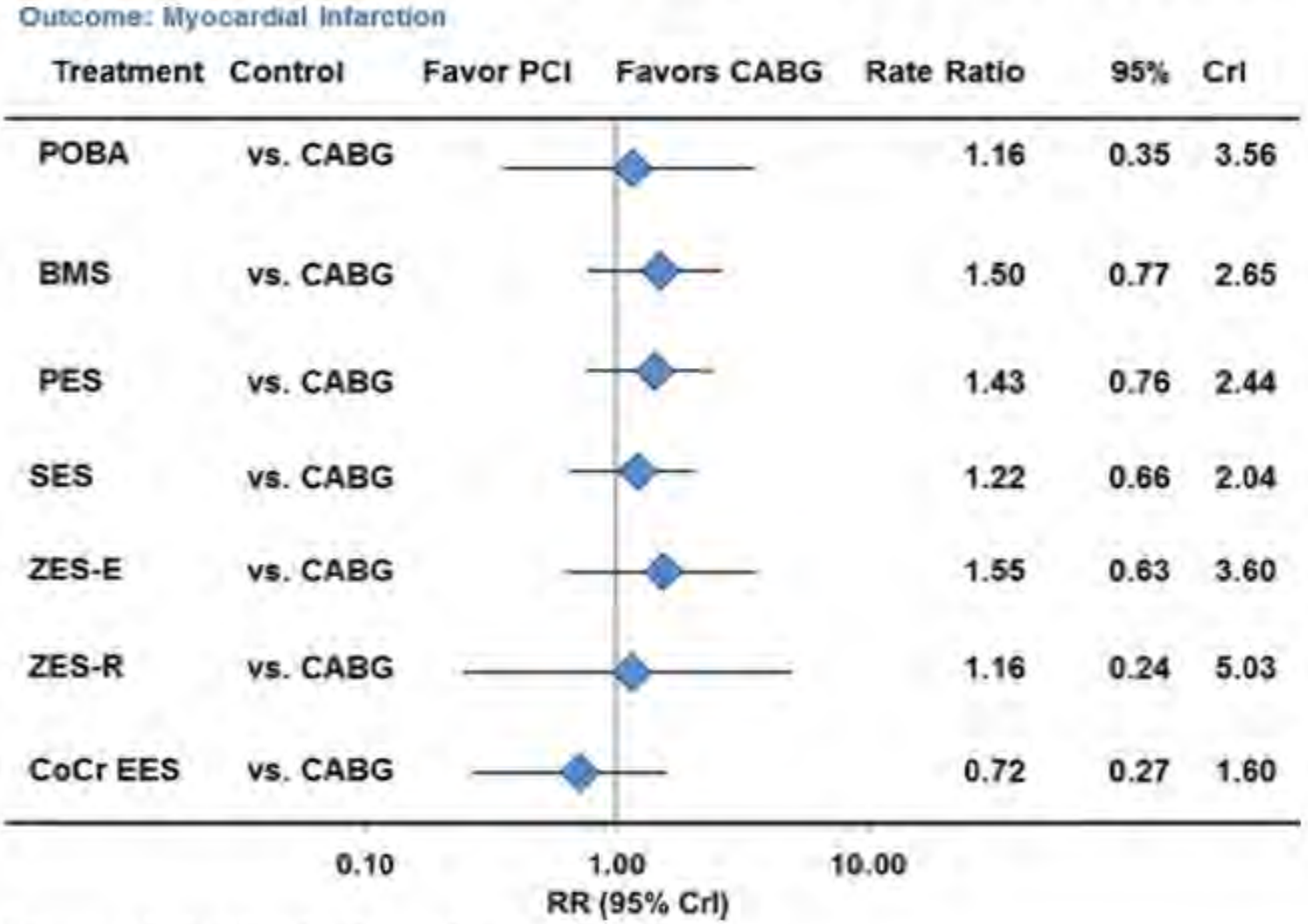
Mixed treatment comparison analyses for coronary artery bypass graft surgery (CABG) vs percutaneous coronary intervention (PCI) for the outcome of all-cause mortality.



Bangalore S et al. Circ Cardiovasc Interv. 2014;7:518-525

American Heart Association

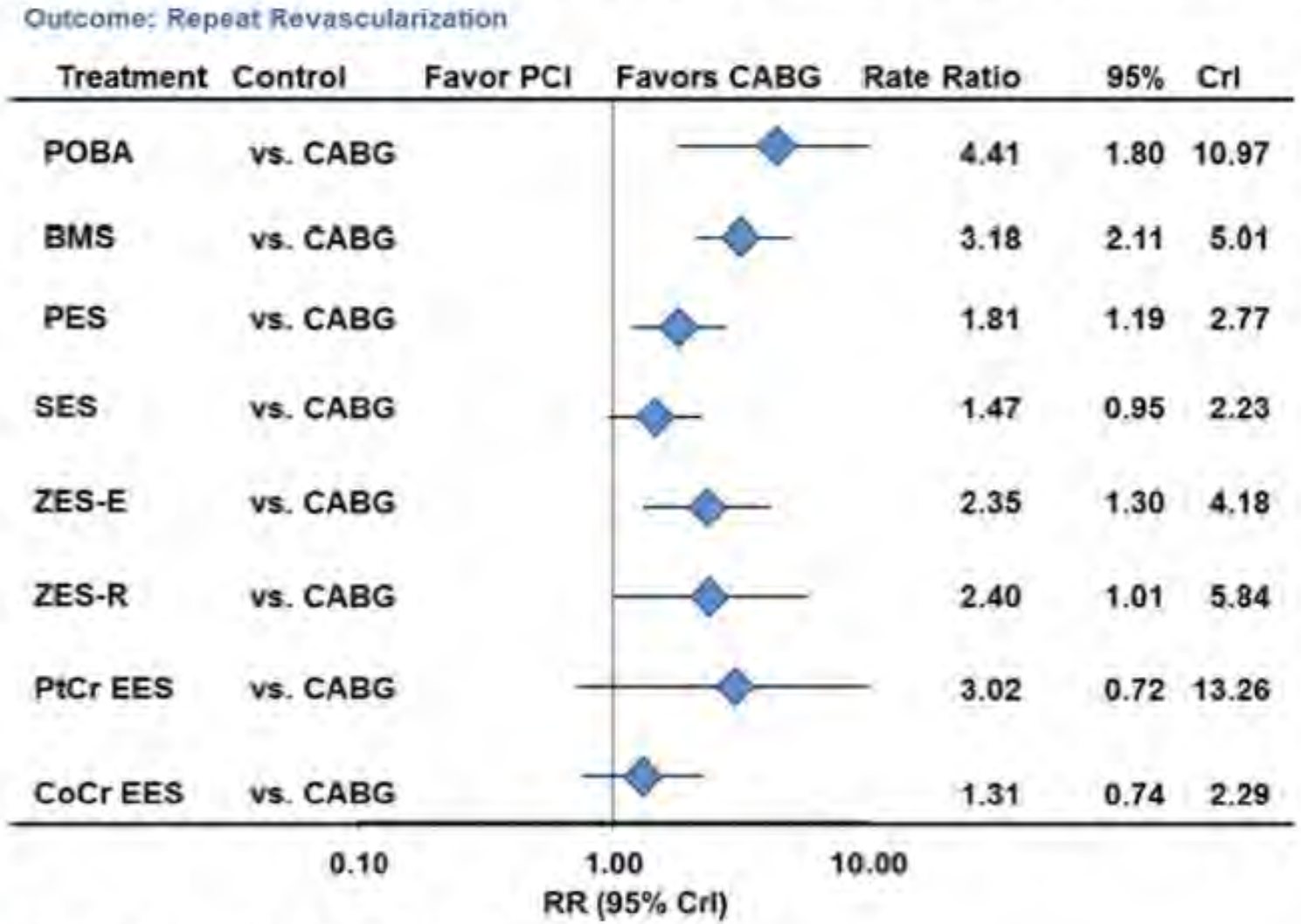
Mixed treatment comparison analyses for coronary artery bypass graft surgery (CABG) vs percutaneous coronary intervention (PCI) for the outcome of myocardial infarction.



Bangalore S et al. Circ Cardiovasc Interv. 2014;7:518-525

American Heart Association.

Mixed treatment comparison analyses for coronary artery bypass graft surgery (CABG) vs percutaneous coronary intervention (PCI) for the outcome of repeat revascularization.



Bangalore S et al. Circ Cardiovasc Interv. 2014;7:518-525

American Heart Association.

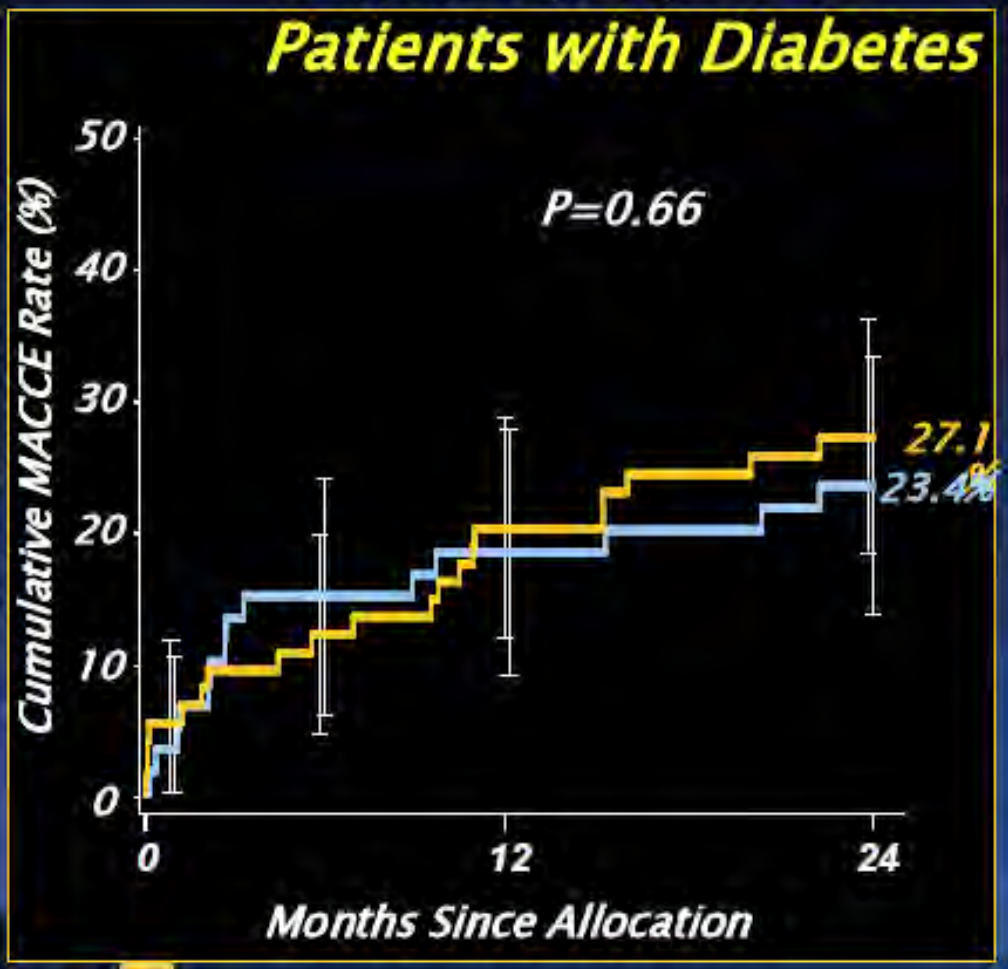
FRREDOM – Syntax Score Subgroup Analysis

- **What is the association between baseline syntax score and cardiovascular outcomes following CABG or PCI?**

Subgroup	No.	5-Yr Rate PCI %	5-Yr Rate CABG %	Hazard Ratio (95% CI)	P Value for Interaction
All patients	1900	27	19	HR	
SYNTAX					0.58
≤22	669	23	17	1.14	
23–32	844	27	18	1.46	
≥33	374	31	23	1.46	

MACCE to 2 Years by SYNTAX Score Tercile

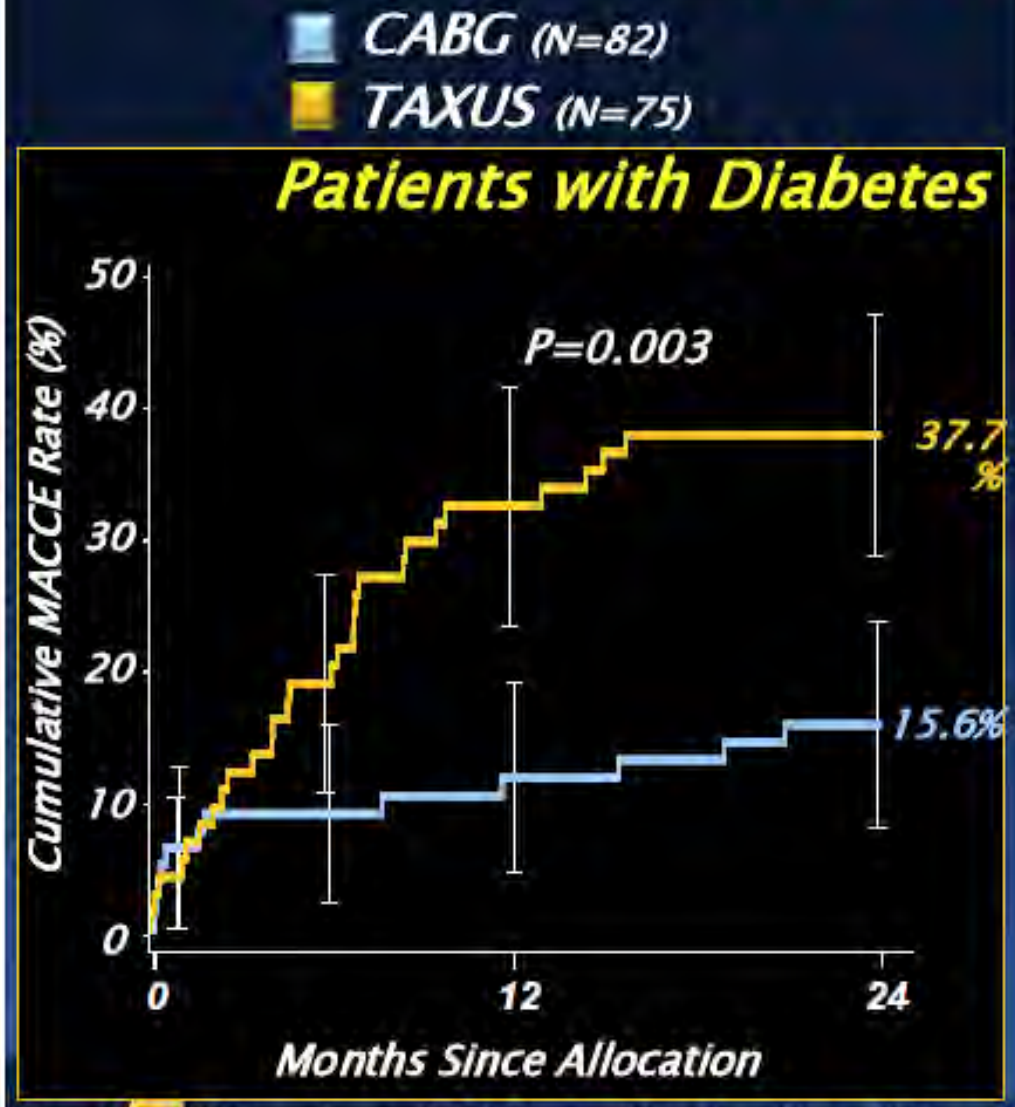
With Diabetes,* Low Scores (0-22)



	CABG	PCI	*P* value
Death	10.0%	5.4%	0.33
CVA	3.7%	0.0%	0.11
MI	8.4%	4.4%	0.31
Death, CVA or MI	16.7%	7.0%	0.08
Revasc.	8.9%	27.1%	0.01

MACCE to 2 Years by SYNTAX Score Tercile

With Diabetes, High Scores (≥33)*



	CABG	PCI	*P* value
Death	3.8%	14.8%	0.02
CVA	2.7%	4.5%	0.59
MI	3.8%	7.1%	0.43
Death, CVA or MI	8.9%	18.8%	0.10
Revasc.	9.7%	29.8%	0.002

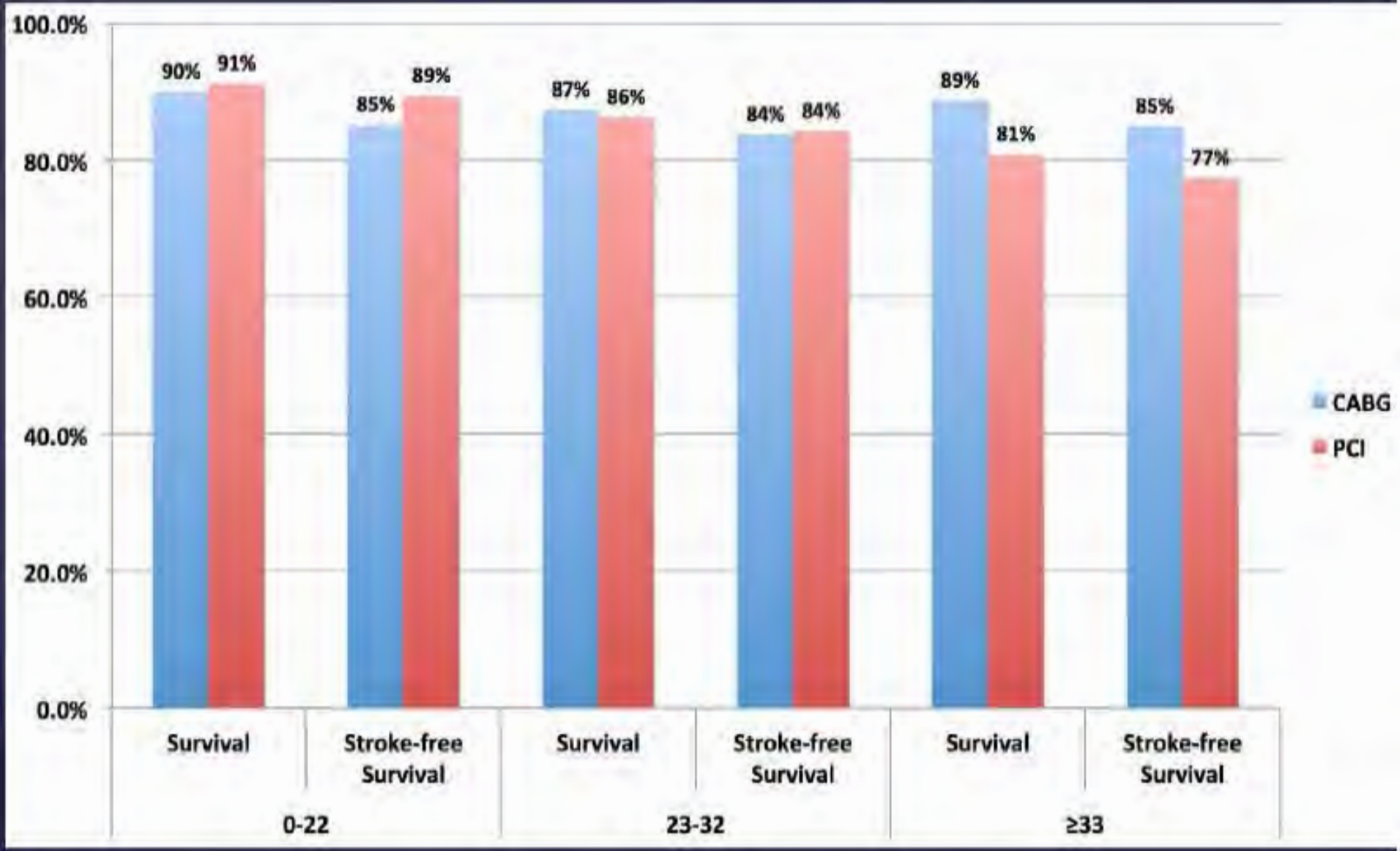
*Cumulative KM Event Rate ± 1.5 SE; log-rank P value, *Medically Treated Diabetes*

ITT pop

SYTNAX Trial Insulin Treated Patients

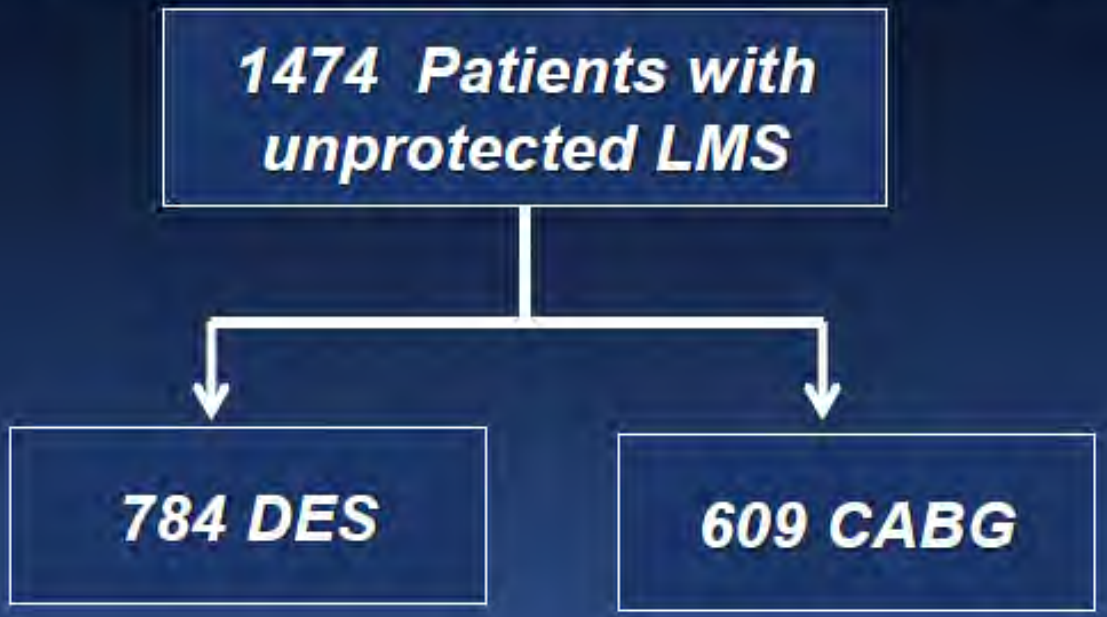
	Oral Hypoglycemic Agents N=270				Insulin Treatment N=182			
	CABG N=128	PES N=142	RR (95%CI)	P	CABG N=93	PES N=89	RR (95%CI)	P
MACE	12.0	7.2	0.60 (0.28-1.3)	0.19	8.0	14.8	1.84 (0.77-4.38)	0.16
Death	6.8	5.8	0.84 (0.33–2.17)	0.72	5.7	12.5	2.18 (0.79–6.0)	0.12
CVD	4.3	5.0	1.18 (0.38–3.62)	0.77	3.4	10.2	2.97 (0.83–10.59)	0.08
CVA	4.3	0.7	0.17 (0.02–1.42)	1.1	0	1.1	NA	NA
MI	4.3	5.0	1.18 (0.38–3.62)	0.77	4.6	4.5	0.99 (0.26–3.83)	0.99

SYNTAX 5-year Endpoints



Impact of Diabetes Mellitus on theTreatment Effect of Percutaneous or Surgical Revascularization for Patients WithUnprotected Left Main Coronary Artery Disease

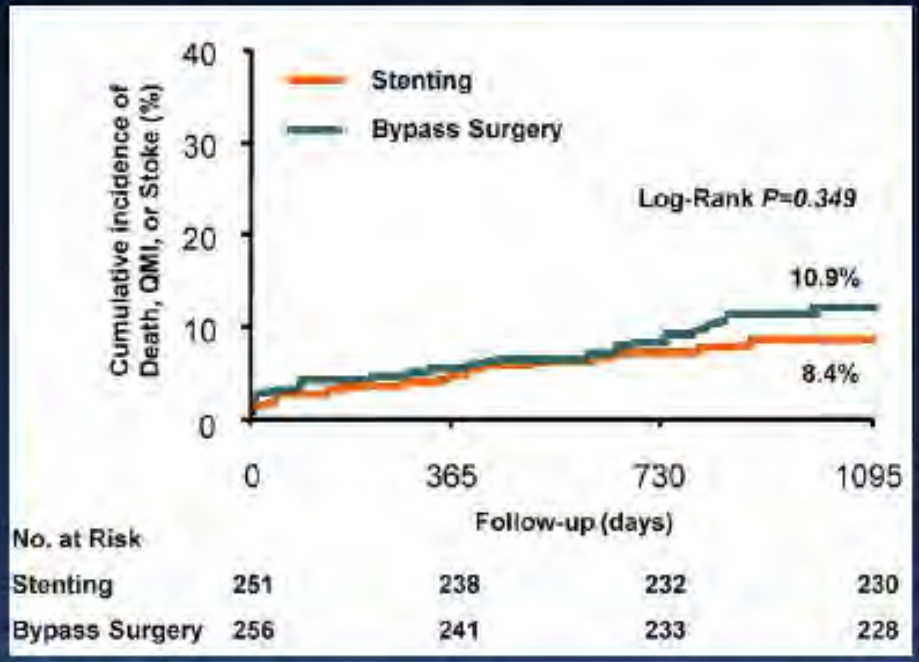
A Subgroup Analysis of the MAIN-COMPARE Study



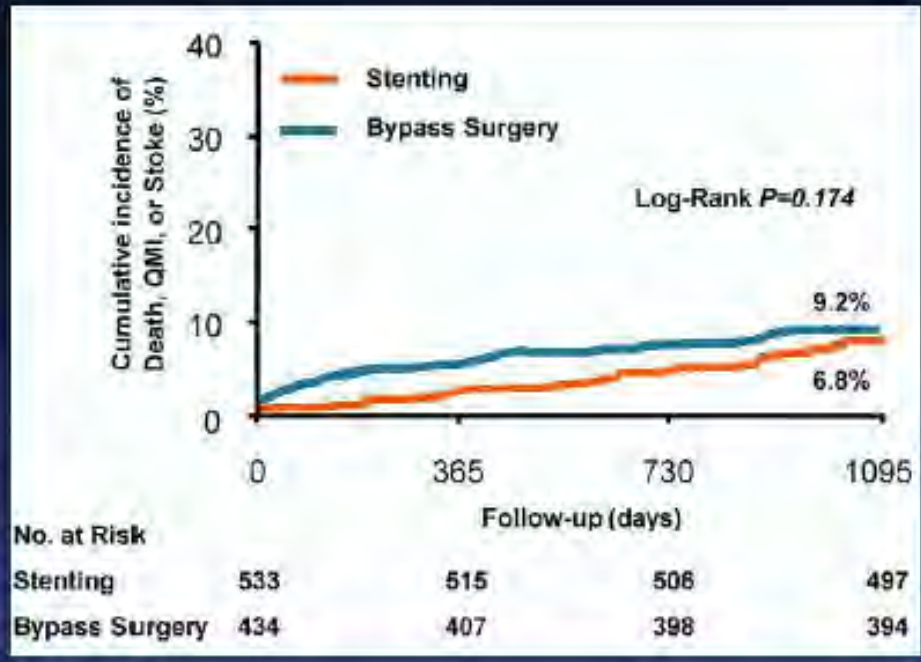
Kim et al. J Am Coll Cardiol Intv 2009;2:956–63

A Subgroup Analysis of the MAIN-COMPARE Study

A total of 1,474 patients with unprotected LMCA stenosis
DES (n = 784) or CABG (n = 690)



Diabetic patients



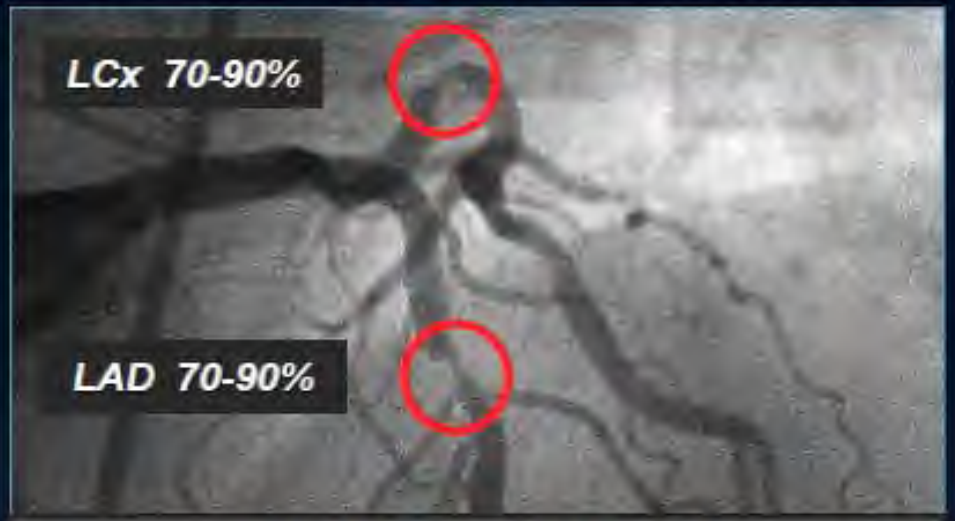
Non diabetes patients

Kim et al. J Am Coll Cardiol Intv 2009;2:956–63

- **Is Diabetes per se a true risk factor?**

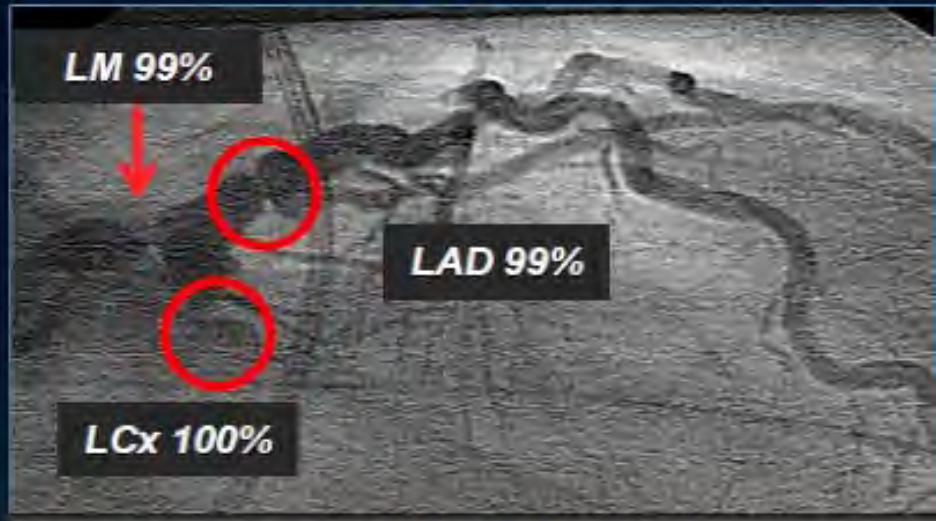
There is '3-vessel disease' and '3-vessel disease'

Patient 1

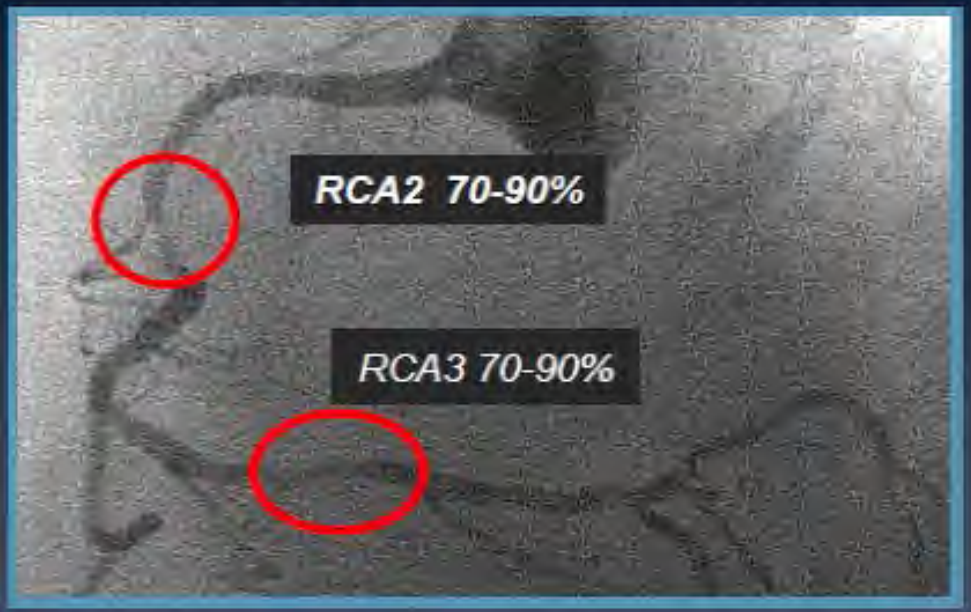


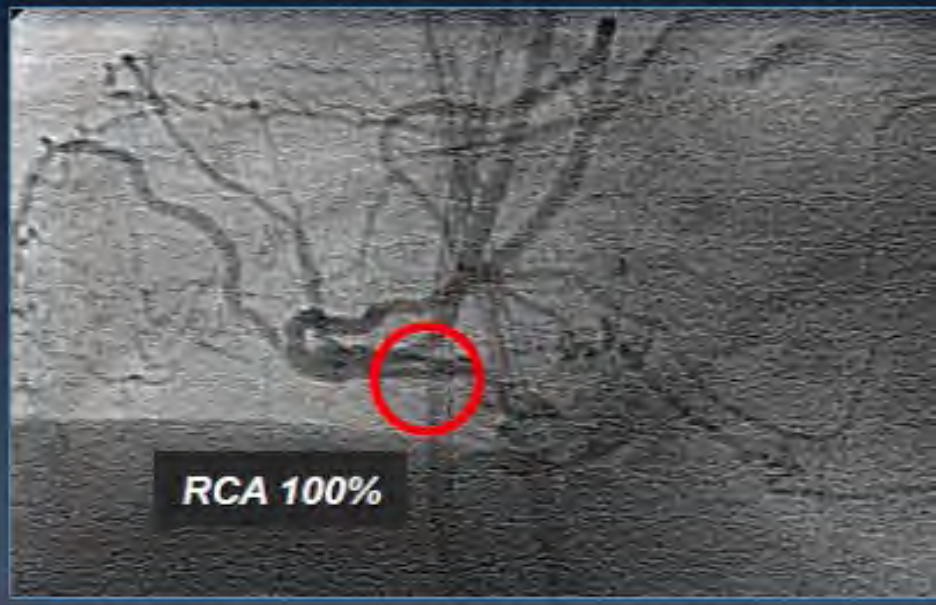
SYNTAX SCORE 21

Patient 2

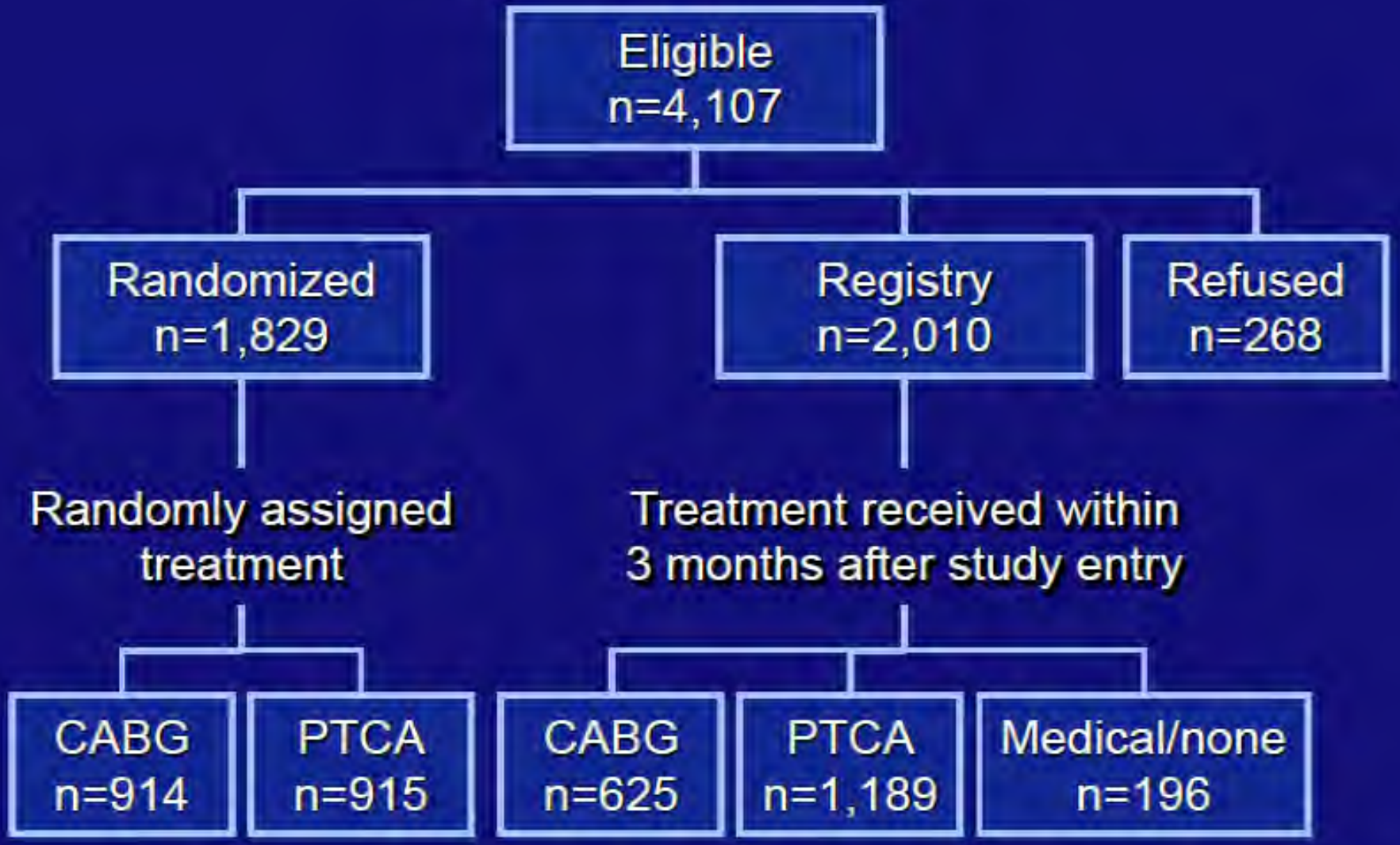


SYNTAX SCORE 52



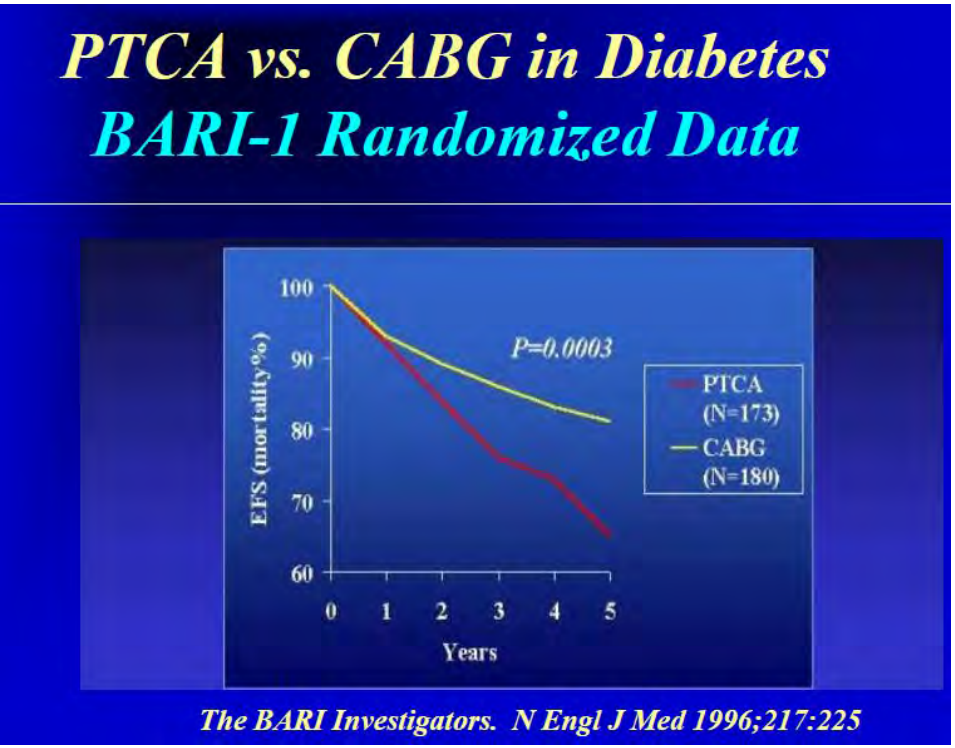


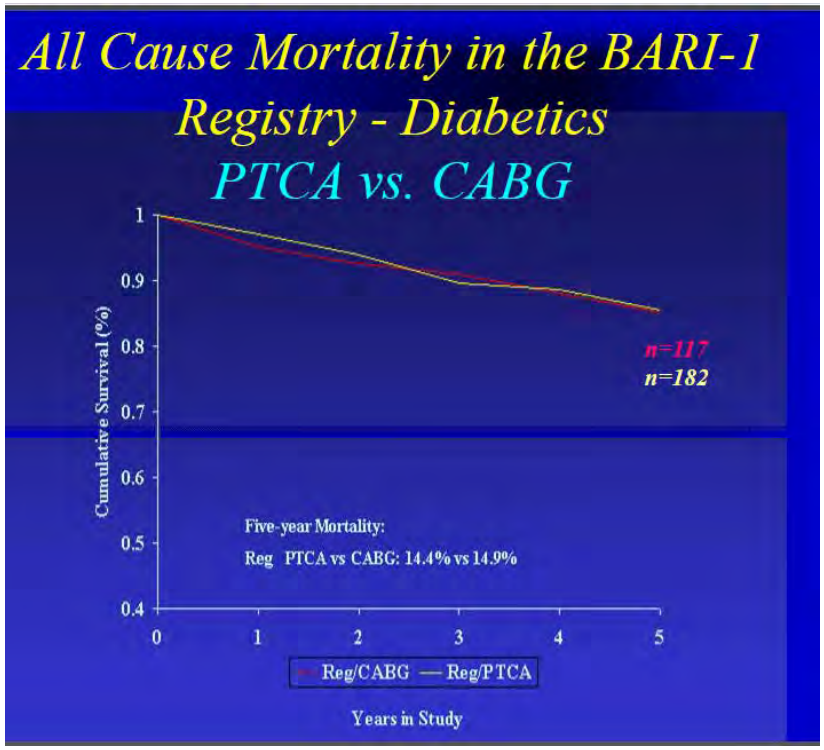
BARI Study



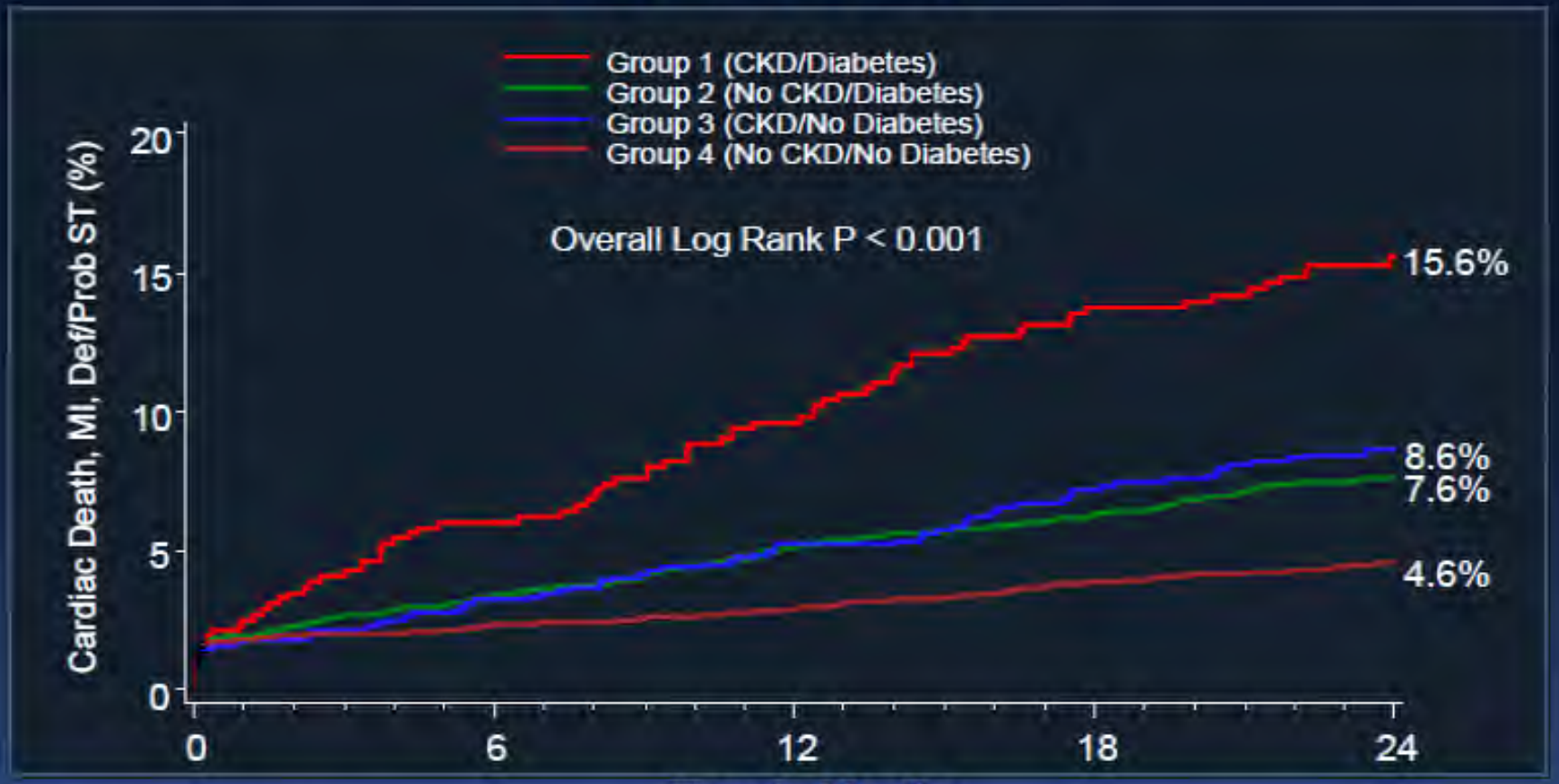
1: Feit et al. *Circulation*. 2000;101:2795-280

BARI TRIAL


PTCA vs. CABG in Diabetes
BARI-1 Randomized Data
EFS (mortality %)
100
90
80
70
60
0
1
2
3
4
5
Years
P=0.0003
PTCA
(N=173)
CABG
(N=180)
The BARI Investigators. N Engl J Med 1996;217:225


All Cause Mortality in the BARI-1
Registry - Diabetics
PTCA vs. CABG
Cumulative Survival (%)
1
0.9
0.8
0.7
0.6
0.5
0.4
0
1
2
3
4
5
n=117
n=182
Five-year Mortality:
Reg PTCA vs CABG: 14.4% vs 14.9%
Reg/CABG
Reg/PTCA
Years in Study

Additive Impact of CKD and DM on Risk after PCI: ADAPT DES



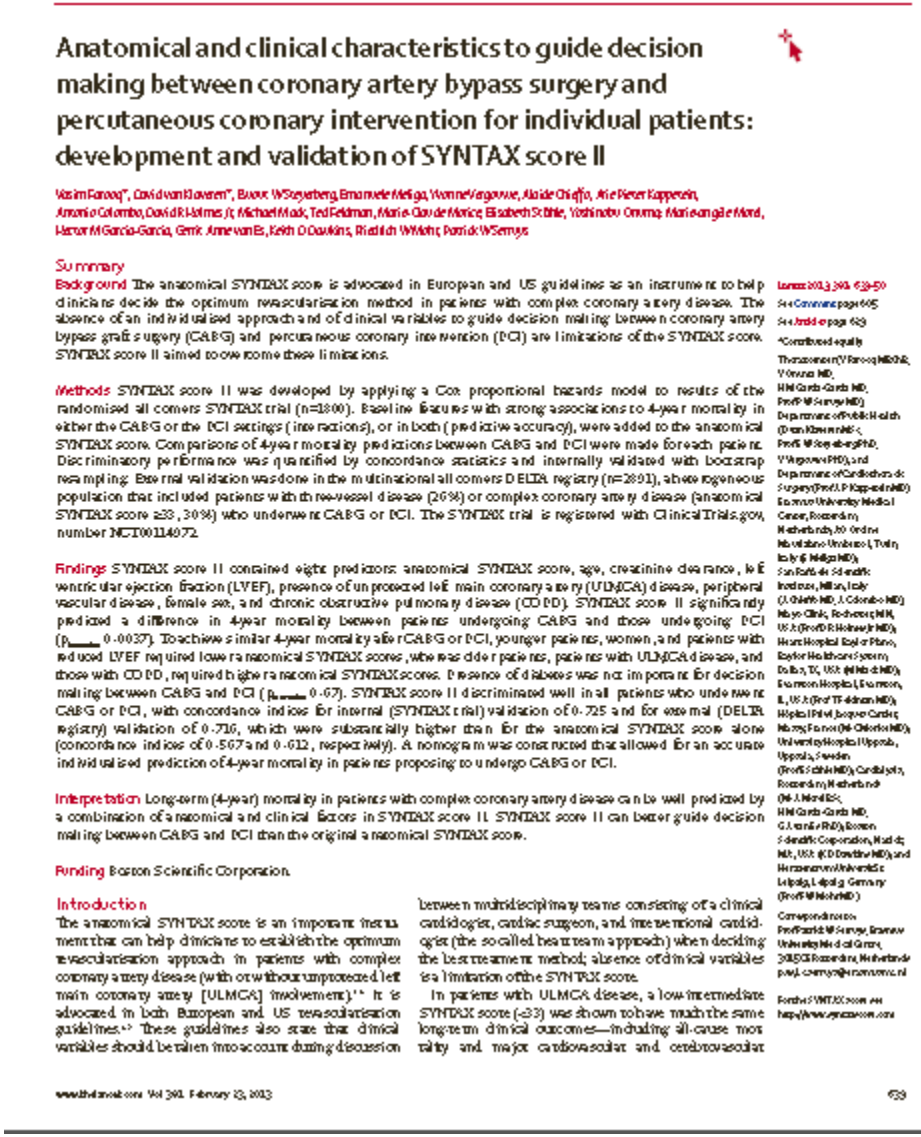
Number at risk:

Group 1	521	478	443	409	213
Group 2	2,258	2,126	2,043	1,954	1,033
Group 3	881	825	793	743	399
Group 3	4,883	4,653	4,546	4,388	2,260

tct2014

Baber et al., TCT 2014

CARDIOVASCULAR RESEARCH FOUNDATION



Anatomical and clinical characteristics to guide decision making between coronary artery bypass surgery and percutaneous coronary intervention for individual patients: development and validation of SYNTAX score II

Vasim Farooq*, David van Klaveren*, Ewout W Steyerberg, Emanuele Meliga, Yvonne Vergouwe, Alaide Chieffo, Arie Pieter Kappetein, Antonio Colombo, David R Holmes Jr, Michael Mack, Ted Feldman, Marie-Claude Morice, Elisabeth Stähle, Yoshinobu Onuma, Marie-angèle Morel, Héctor M García-García, Gerrit Anne van Es, Keith D Dawkins, Friedrich W Mohr, Patrick W Serruys

Summary

Background The anatomical SYNTAX score is advocated in European and US guidelines as an instrument to help clinicians decide the optimum revascularisation method in patients with complex coronary artery disease. The absence of an individualised approach and of clinical variables to guide decision making between coronary artery bypass graft surgery (CABG) and percutaneous coronary intervention (PCI) are limitations of the SYNTAX score. SYNTAX score II aimed to overcome these limitations.

Methods SYNTAX score II was developed by applying a Cox proportional hazards model to results of the randomised all comers SYNTAX trial (n=1800). Baseline features with strong associations to 4-year mortality in either the CABG or the PCI settings (interactions), or in both (predictive accuracy), were added to the anatomical SYNTAX score. Comparisons of 4-year mortality predictions between CABG and PCI were made for each patient. Discriminatory performance was quantified by concordance statistics and internally validated with bootstrap resampling. External validation was done in the multinational all comers DELTA registry (n=2891), a heterogeneous population that included patients with three-vessel disease (26%) or complex coronary artery disease (anatomical SYNTAX score ≥33, 30%) who underwent CABG or PCI. The SYNTAX trial is registered with ClinicalTrials.gov, number NCT00114072.

Findings SYNTAX score II contained eight predictors: anatomical SYNTAX score, age, creatinine clearance, left ventricular ejection fraction (LVEF), presence of unprotected left main coronary artery (ULMCA) disease, peripheral vascular disease, female sex, and chronic obstructive pulmonary disease (COPD). SYNTAX score II significantly predicted a difference in 4-year mortality between patients undergoing CABG and those undergoing PCI ($p_{interaction}$ 0·0037). To achieve similar 4-year mortality after CABG or PCI, younger patients, women, and patients with reduced LVEF required lower anatomical SYNTAX scores, whereas older patients, patients with ULMCA disease, and those with COPD required higher anatomical SYNTAX scores. Presence of diabetes was not important for decision making between CABG and PCI ($p_{interaction}$ 0·67). SYNTAX score II discriminated well in all patients who underwent CABG or PCI, with concordance indices for internal (SYNTAX trial) validation of 0·725 and for external (DELTA registry) validation of 0·716, which were substantially higher than for the anatomical SYNTAX score alone (concordance indices of 0·567 and 0·612, respectively). A nomogram was constructed that allowed for an accurate individualised prediction of 4-year mortality in patients proposing to undergo CABG or PCI.

Interpretation Long-term (4-year) mortality in patients with complex coronary artery disease can be well predicted by a combination of anatomical and clinical factors in SYNTAX score II. SYNTAX score II can better guide decision making between CABG and PCI than the original anatomical SYNTAX score.

Funding Boston Scientific Corporation.

Introduction

The anatomical SYNTAX score is an important instrument that can help clinicians to establish the optimum revascularisation approach in patients with complex coronary artery disease (with or without unprotected left main coronary artery [ULMCA] involvement).[1–4] It is advocated in both European and US revascularisation guidelines.[5,6] These guidelines also state that clinical variables should be taken into account during discussion between multidisciplinary teams consisting of a clinical cardiologist, cardiac surgeon, and interventional cardiologist (the so-called heart team approach) when deciding the best treatment method; absence of clinical variables is a limitation of the SYNTAX score.

In patients with ULMCA disease, a low intermediate SYNTAX score (≤33) was shown to have much the same long-term clinical outcomes—including all-cause mortality and major cardiovascular and cerebrovascular

Lancet 2013; 381: 639–50

See Comment page 605

See Articles page 639

*Contributed equally

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Correspondence to:
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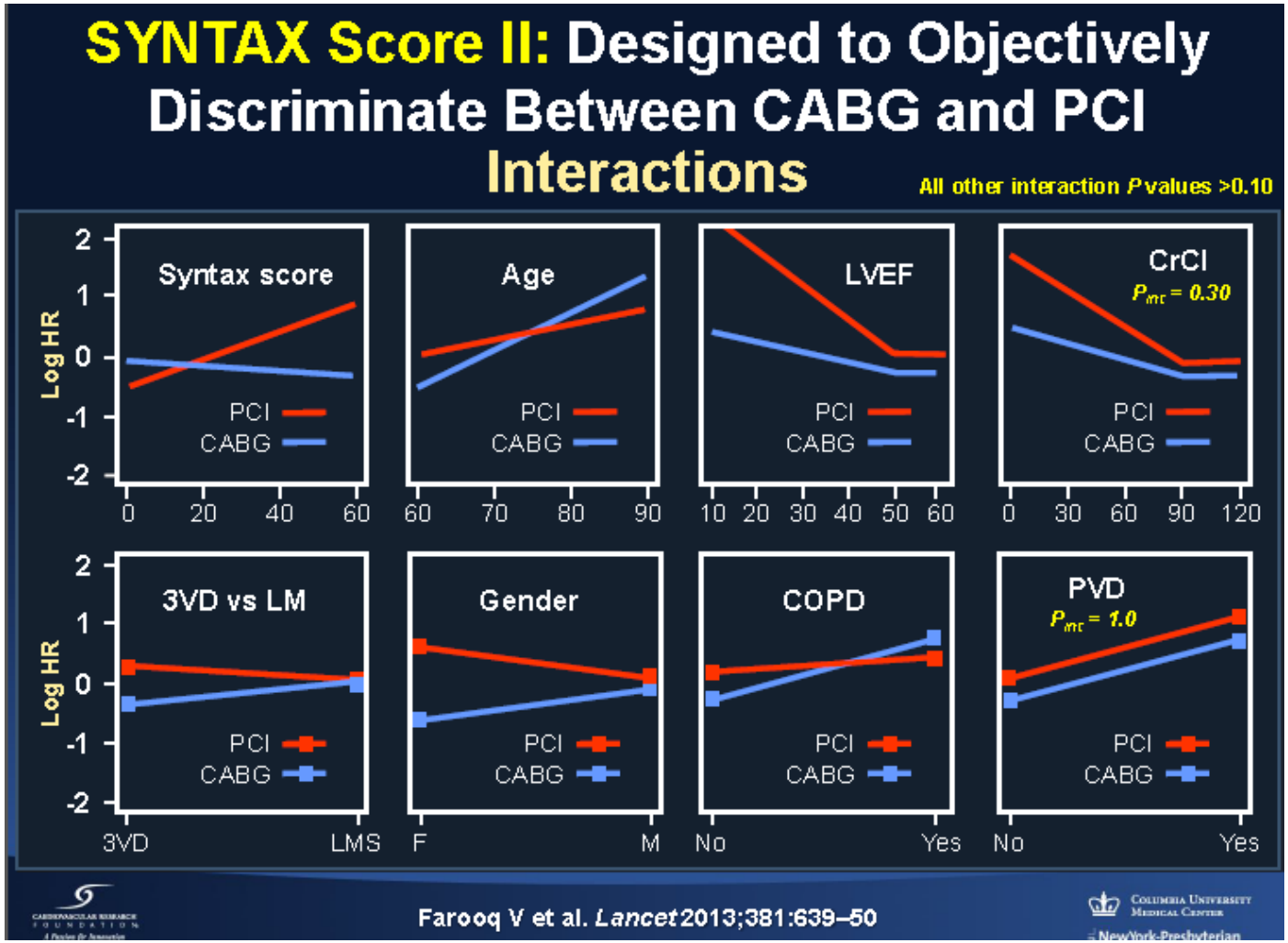
For the SYNTAX score see http://www.syntaxscore.com

- **Diabetes is not an independent predictor of mortality in the CABG and PCI groups of the SYNTAX trial, and in a pooled analysis of seven contemporary stent trials (n>6000)**

…….after SYNTAX score, age, creatinine clearance, and LVEF were accounted

Farooq Lancet 2013



Farooq
Lancet 2013

Sintax Score,Age, LVEF, ULMCA disease, COPD, and female sex: moderate to strong interaction effect in affecting long-term mortality predictions with CABG and PCI (p. interaction<0,10). Creatinine clearance and peripheral vascular disease weak or negligible interaction effect.

SYNTAX Score I vs II: The SYNTAX Trial

Interactions: Diabetes

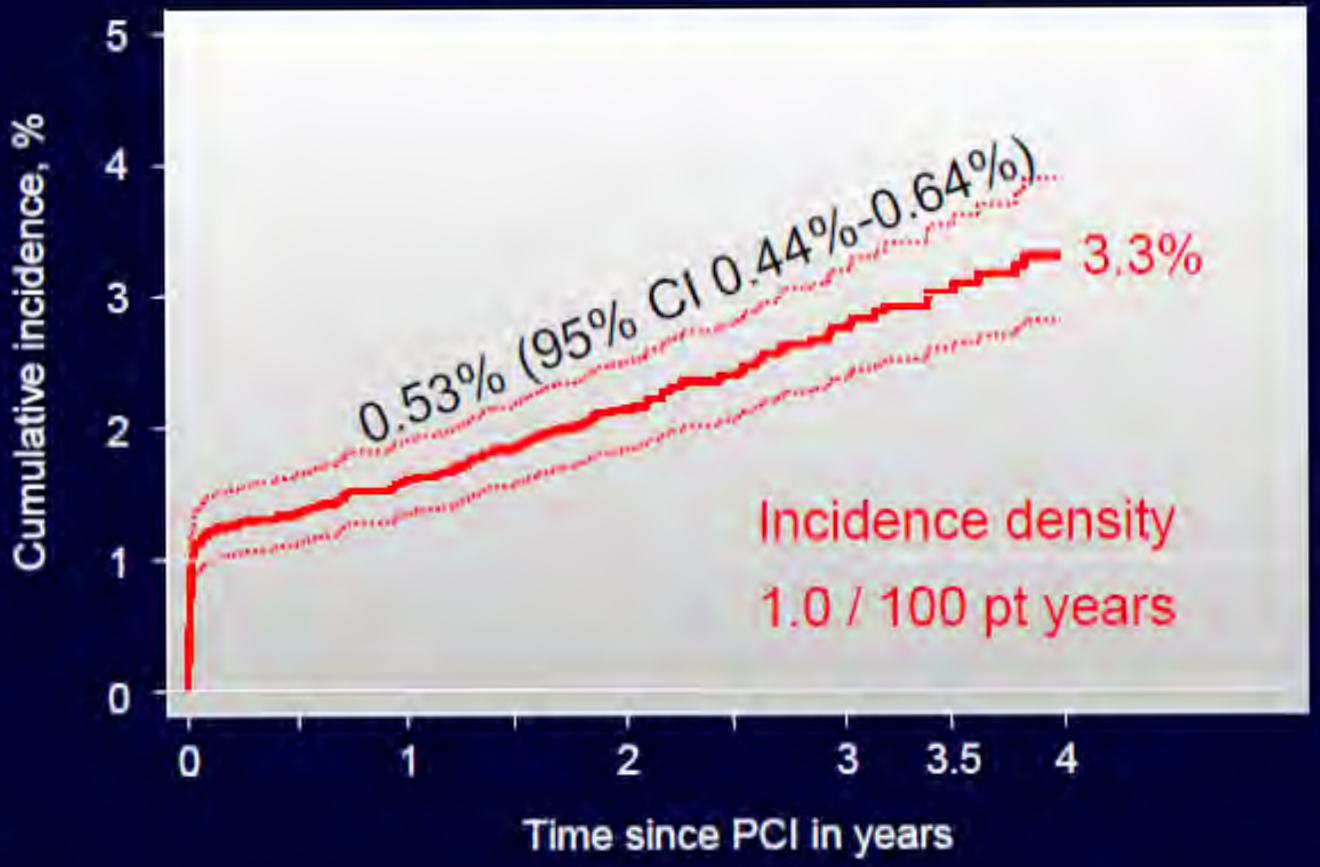
Diabetes was not an independent predictor of mortality or MACE **in either the CABG or** PCI arm, and had a negative interaction effect

Farooq V et al. *Lancet* 2013;381:639–50

- **Is Diabetes per se a true risk factor?**
- **Should we compare CABG vs new DES?**

Definite Stent Thrombosis With DES: Bern - Rotterdam Cohort Study

Daemen J et al. *Lancet* 2007;369:667-78



Updated

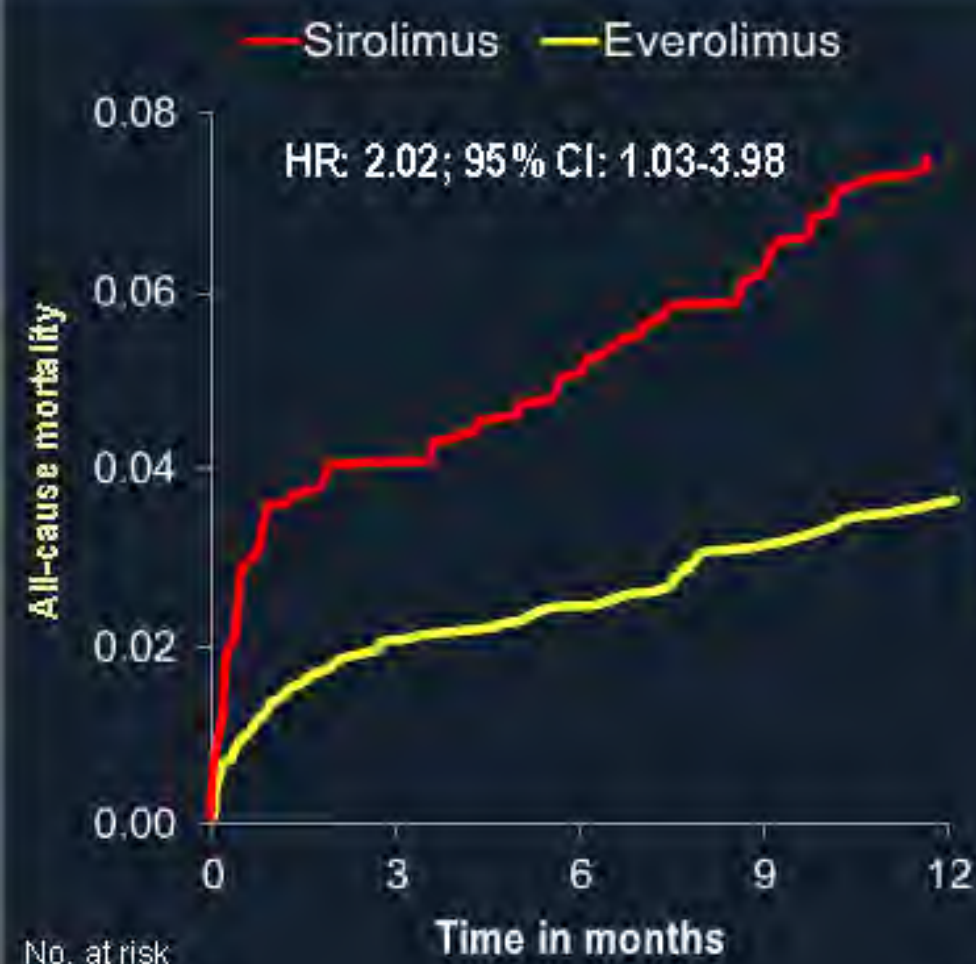
Follow-up to

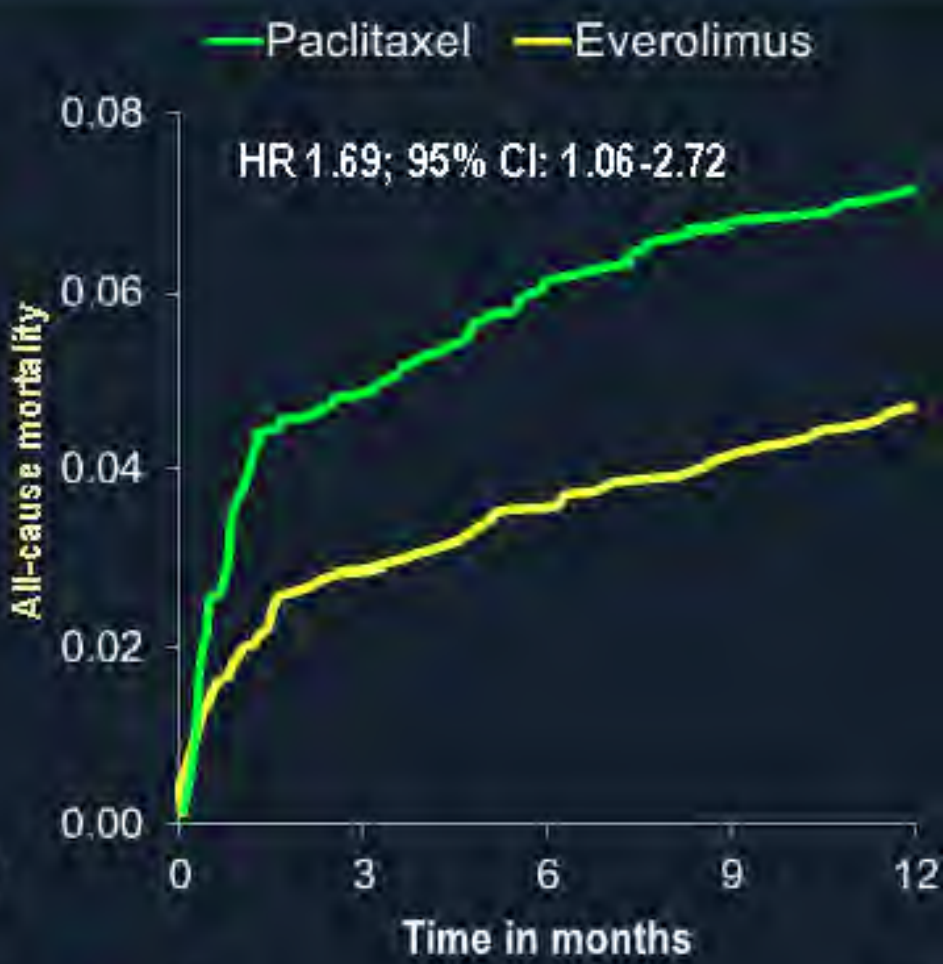
4 Years

192 ST cases in a cohort of 8.146 patients

Months	1	12	24	36	48
Cumulative incidence, %	1.2	1.6	2.1	2.7	3.3
Patients at risk	7538	7210	5164	2790	1051

EES in Patients with Diabetes: SCAAR





No. at risk

SES	717	696	665
EES	1915	1574	1014

PES	1386	1318	1272
EES	1915	1574	1014

Kedhi et al. JACC Card Int 2012;5:1141-9

RESOLUTE Pooled – Small Vessel DM

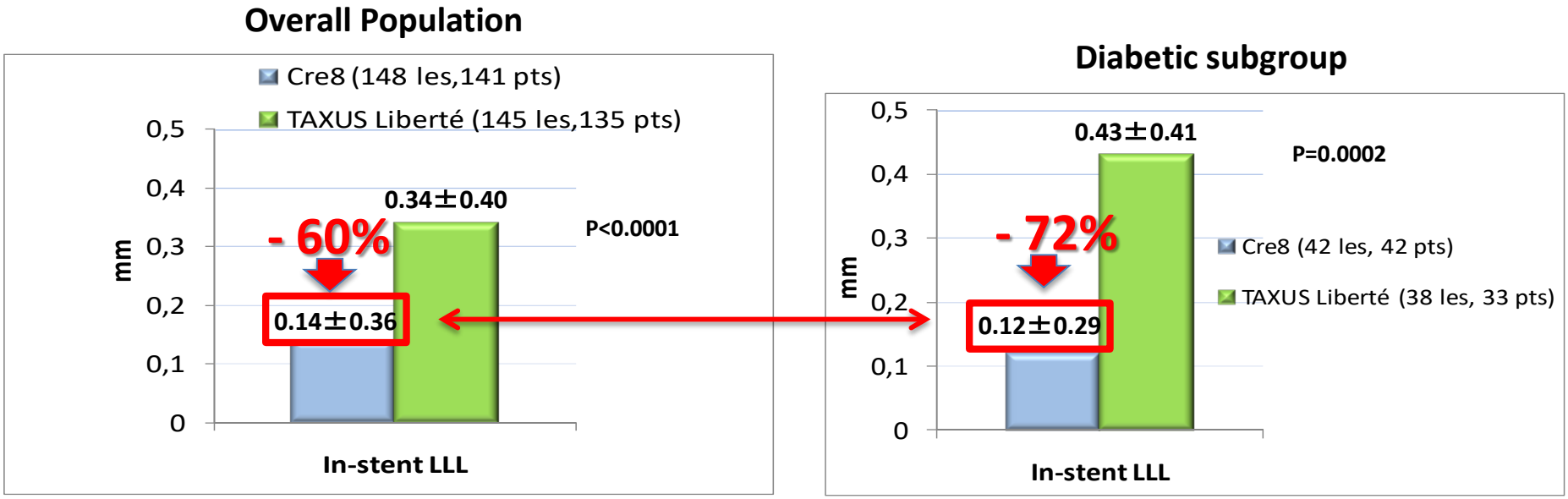
Cardiac Death / TVMI to 3 Years

No. at risk

Non-Diabetics	1764	1735	1656	1222
Non-IDDM	725	722	681	465
IDDM	233	227	213	196

NEXT: 6-month in-stent LLL

Primary Endpoint:
6-month in-stent Late Lumen Loss

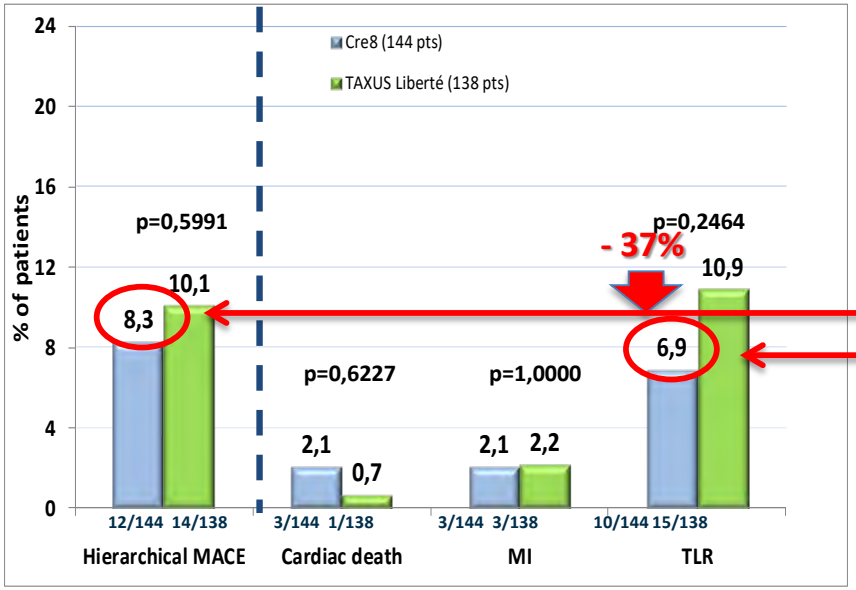


- The Late Lumen Loss in the diabetic subgroup is comparable to the Late Lumen Loss obtained in the overall population (never seen before)

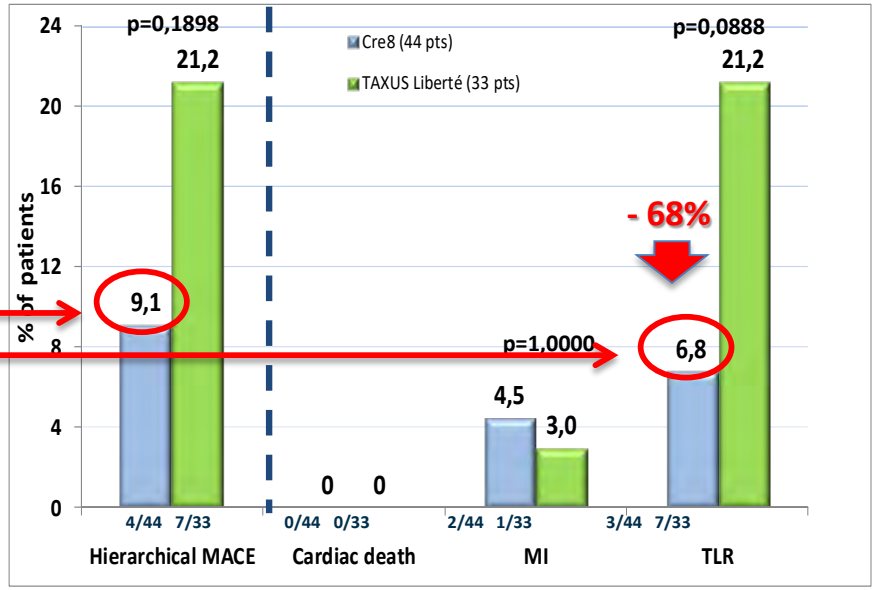
NEXT: 36-month clinical results

36-month cumulative MACE
(Cardiac death, all MI, all TLR)

Overall population



Diabetic population



- Cre8 has shown that MACE and TLR in the diabetic subgroup are comparable to MACE and TLR obtained in the overall population!

Questions

- **Is Diabetes per se a true risk factor?**
- **Should we compare CABG vs new DES?**
- **Do we need more potent anti-thrombotic treatment?**
- **Disparity between Symtax and Freedom. (CABG improved outcome irrespective of vessel anatomy)**

Greater Clinical Benefit of More Intensive Oral Antiplatelet Therapy With Prasugrel in Patients With Diabetes Mellitus in the Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition With Prasugrel–Thrombolysis in Myocardial Infarction 38

Stephen D. Wiviott, MD; Eugene Braunwald, MD; Dominick J. Angiolillo, MD, PhD; Simha Meisel, MD; Anthony J. Dalby, MD; Freek W.A. Verheugt, MD; Shaun G. Goodman, MD; Ramon Corbalan, MD; Drew A. Purdy, MD; Sabina A. Murphy, MPH; Carolyn H. McCabe, BS; Elliott M. Antman, MD; for the TRITON-TIMI 38 Investigators

Background—Patients with diabetes mellitus (DM) are at high risk for recurrent cardiovascular events after acute coronary syndromes, in part because of increased platelet reactivity. The Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition With Prasugrel–Thrombolysis in Myocardial Infarction 38 (TRITON-TIMI 38) showed an overall reduction in ischemic events with more intensive antiplatelet therapy with prasugrel than with clopidogrel but with more bleeding. We compared prasugrel with clopidogrel among subjects with DM in TRITON-TIMI 38.

Methods and Results—We classified 13 608 subjects on the basis of preexisting history of DM and further according to insulin use. Prespecified analyses of the primary (cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke) and key secondary end points, including net clinical benefit (death, nonfatal myocardial infarction, nonfatal stroke, and nonfatal TIMI major bleeding) were compared by use of the log-rank test. We found that 3146 subjects had a preexisting history of DM, including 776 receiving insulin. The primary end point was reduced significantly with prasugrel among subjects without DM (9.2% versus 10.6%; hazard ratio [HR], 0.86; $P=0.02$) and with DM (12.2% versus 17.0%; HR, 0.70; $P<0.001$, $P_{interaction}=0.09$). A benefit for prasugrel was observed among DM subjects on insulin (14.3% versus 22.2%; HR, 0.63; $P=0.009$) and those not on insulin (11.5% versus 15.3%; HR, 0.74; $P=0.009$). Myocardial infarction was reduced with prasugrel by 18% among subjects without DM (7.2% versus 8.7%; HR, 0.82; $P=0.006$) and by 40% among subjects with DM (8.2% versus 13.2%; HR, 0.60; $P<0.001$, $P_{interaction}=0.02$). Although TIMI major hemorrhage was increased among subjects without DM on prasugrel (1.6% versus 2.4%; HR, 1.43; $P=0.02$), the rates were similar among subjects with DM for clopidogrel and prasugrel (2.6% versus 2.5%; HR, 1.06; $P=0.81$, $P_{interaction}=0.29$). Net clinical benefit with prasugrel was greater for subjects with DM (14.6% versus 19.2%; HR, 0.74; $P=0.001$) than for subjects without DM (11.5% versus 12.3%; HR, 0.92; $P=0.16$, $P_{interaction}=0.05$).

Conclusions—Subjects with DM tended to have a greater reduction in ischemic events without an observed increase in TIMI major bleeding and therefore a greater net treatment benefit with prasugrel compared with clopidogrel. These data demonstrate that the more intensive oral antiplatelet therapy provided with prasugrel is of particular benefit to patients with DM. (***Circulation*. 2008;118:1626-1636.**)

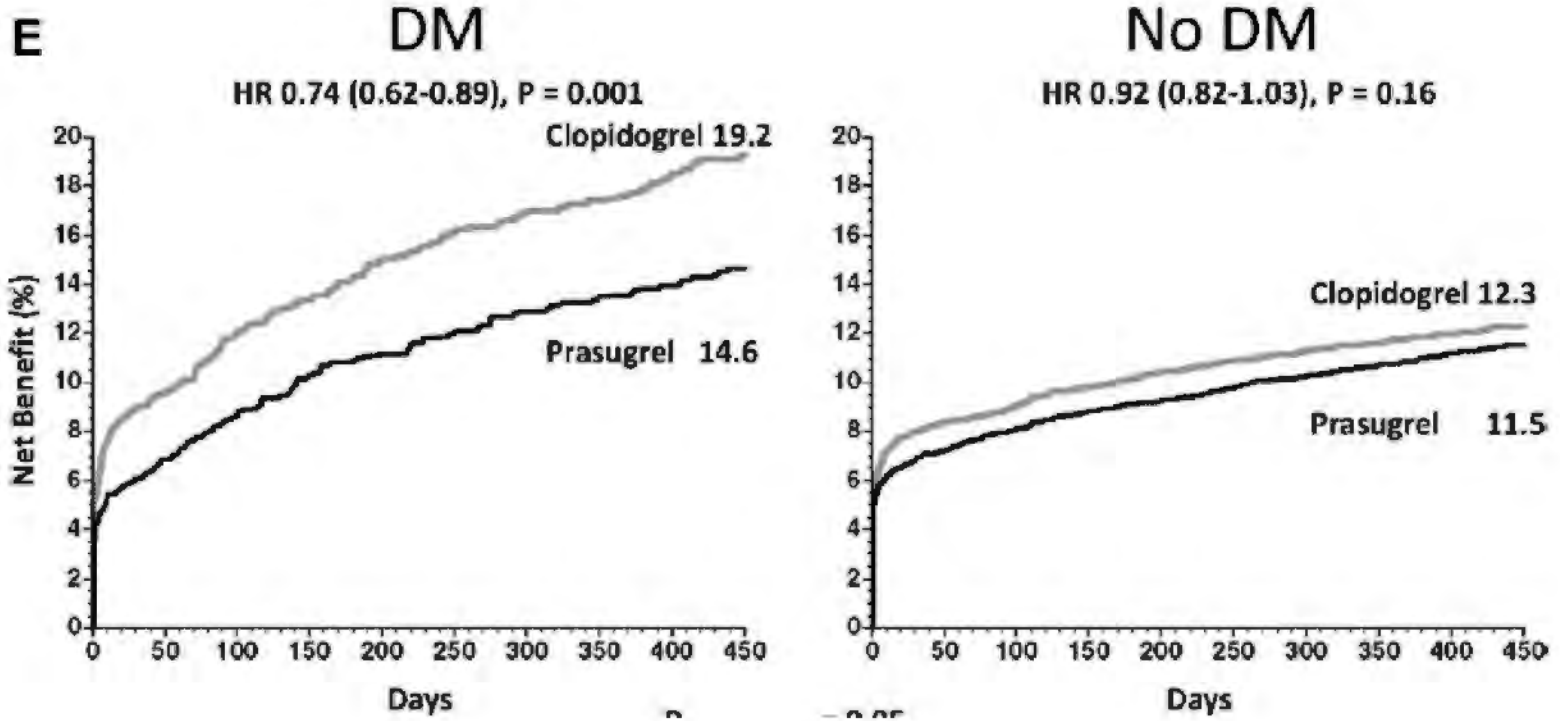
Key Words: angioplasty ■ anticoagulants ■ myocardial infarction ■ platelets ■ diabetes mellitus

Greater Clinical Benefit of More Intensive Oral Antiplatelet Therapy With Prasugrel in Patients With Diabetes Mellitus in the Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition With Prasugrel–Thrombolysis in Myocardial Infarction 38

Stephen D. Wiviott, MD; Eugene Braunwald, MD; Dominick J. Angiolillo, MD, PhD; Simha Meisel, MD; Anthony J. Dalby, MD; Freek W.A. Verheugt, MD; Shaun G. Goodman, MD; Ramon Corbalan, MD; Drew A. Purdy, MD; Sabina A. Murphy, MPH; Carolyn H. McCabe, BS; Elliott M. Antman, MD; for the TRITON-TIMI 38 Investigators

Background—Patients with diabetes mellitus (DM) are at high risk for recurrent cardiovascular events after acute coronary

E



Diabetes: Clopidogrel response & outcome

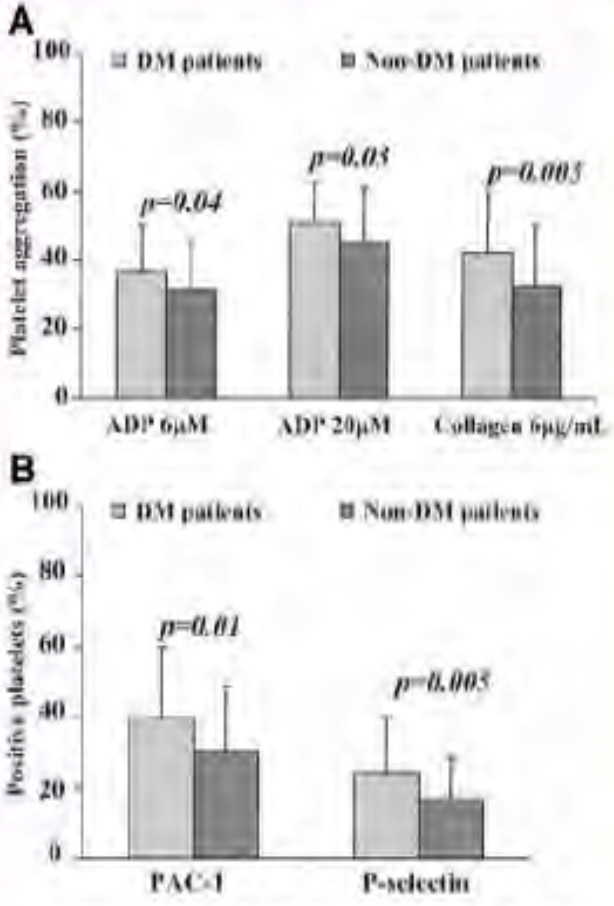


FIG. 3. Platelet aggregation following ADP (6 and 20 μmol/l) and collagen (6 μg/ml) stimuli (*A*) and platelet activation (PAC-1 binding and P-selectin expression) following ADP (2 μmol/l) stimuli (*B*) in diabetic (DM) ($n = 60$) compared with nondiabetic ($n = 60$) patients on sustained aspirin and clopidogrel treatment.

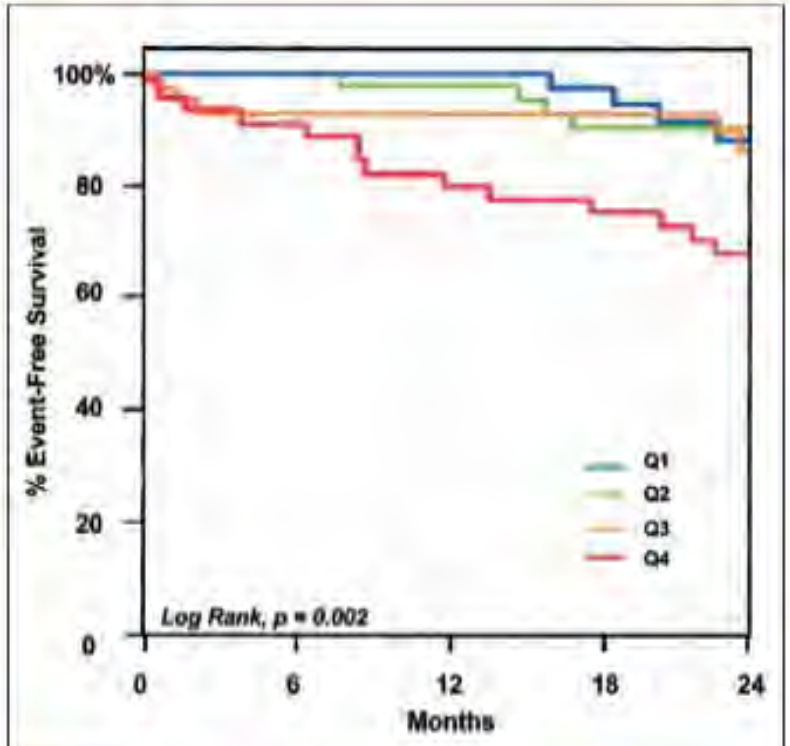
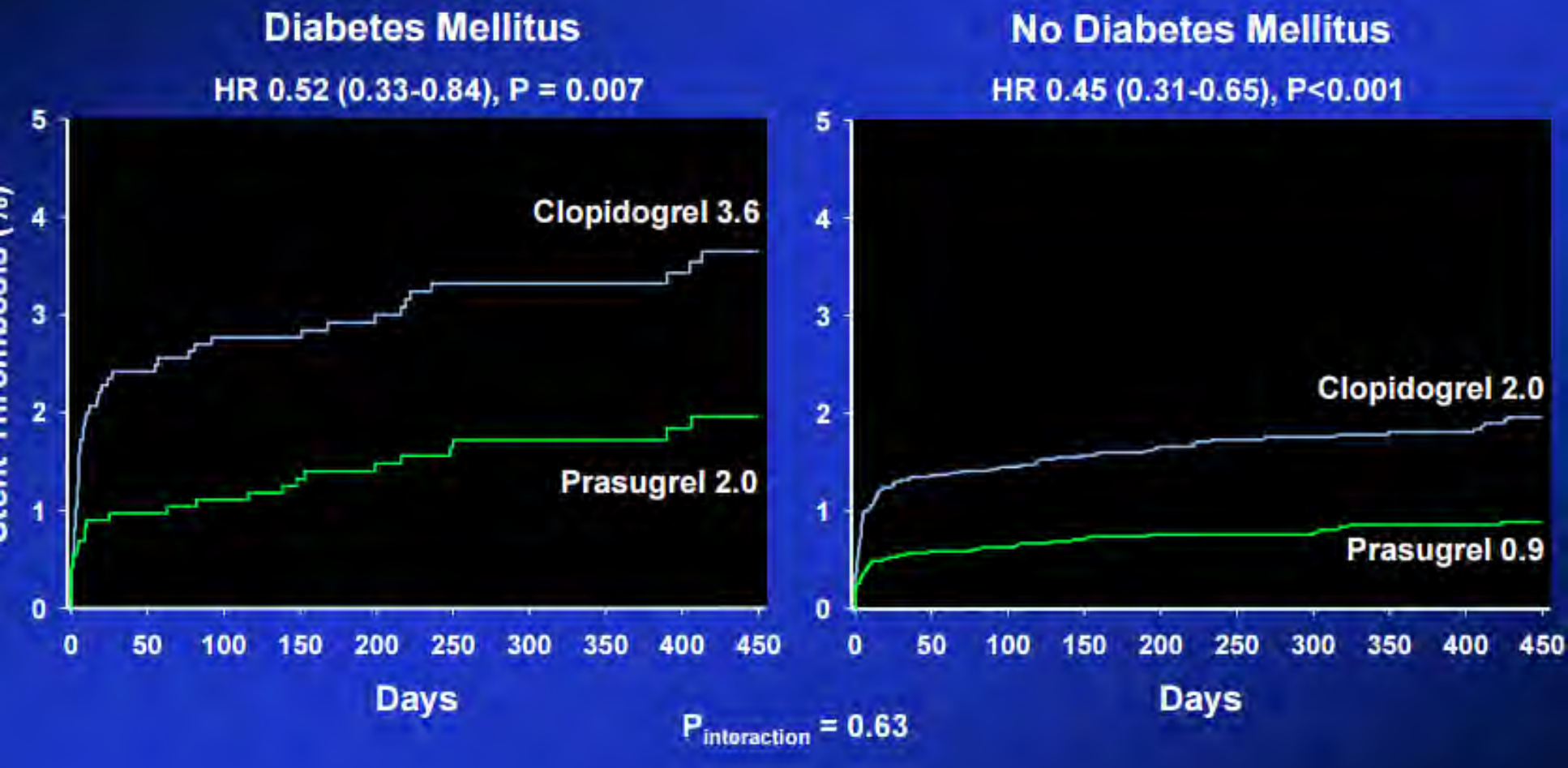


Figure 3 Cumulative Event-Free Survival According to Quartile Distribution of Platelet Aggregation

Cumulative event-free survival from cardiovascular events according to quartile (Q) distribution of maximal adenosine diphosphate (20 μmol/l)-induced platelet aggregation.

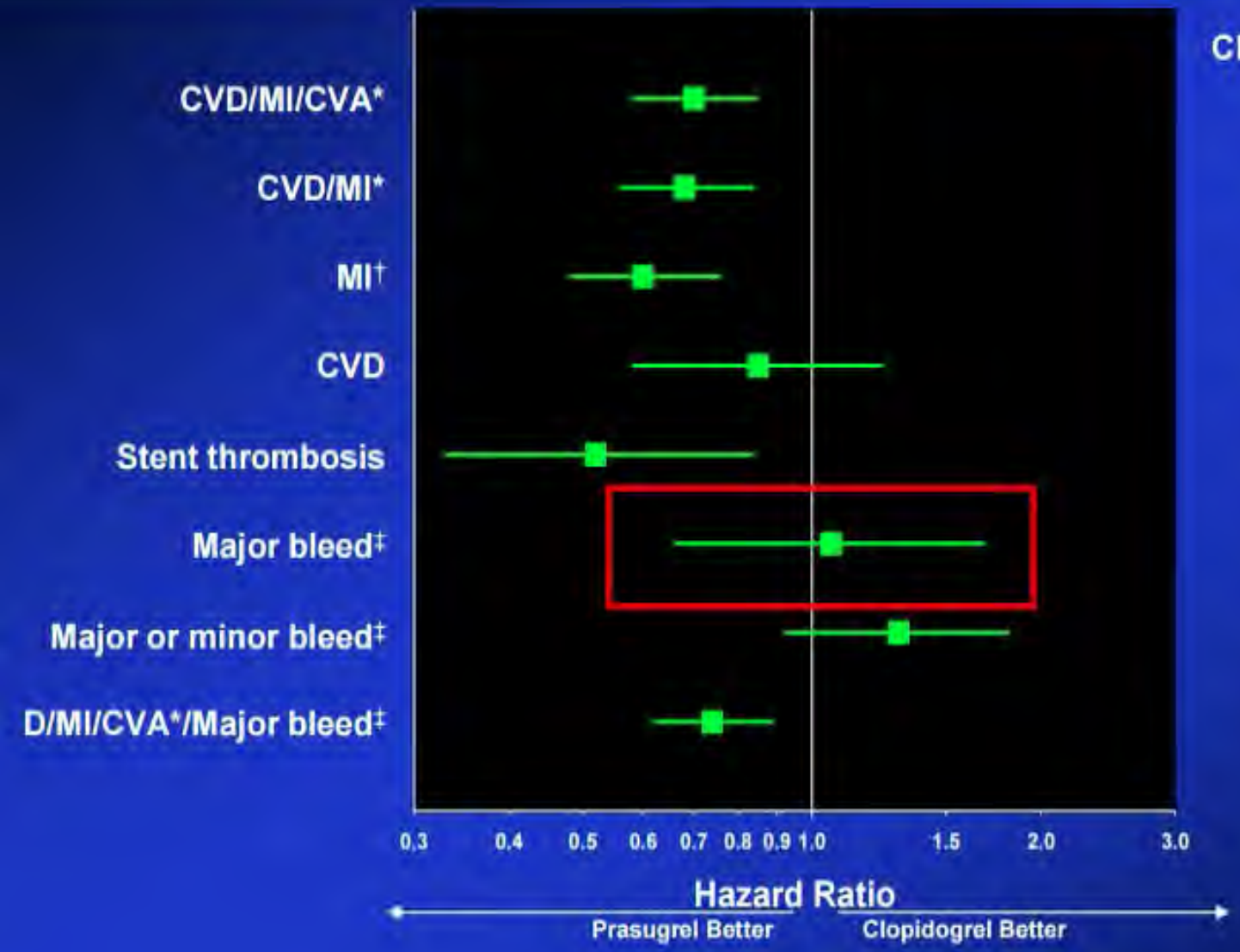
TRITON TIMI 38: The Diabetics



$P_{interaction} = 0.63$

Wiviott SD, et al. *Circulation*. 2008;118(16):1626-1636

TRITON TIMI 38: The Diabetics



	Clopidogrel (%)	Prasugrel (%
CVD/MI/CVA*	17.0	12.2
CVD/MI*	15.4	10.8
MI†	13.2	8.2
CVD	4.2	3.4
Stent thrombosis	3.6	2.0
Major bleed‡	2.6	2.5
Major or minor bleed‡	4.3	5.3
D/MI/CVA*/Major bleed‡	19.2	14.6

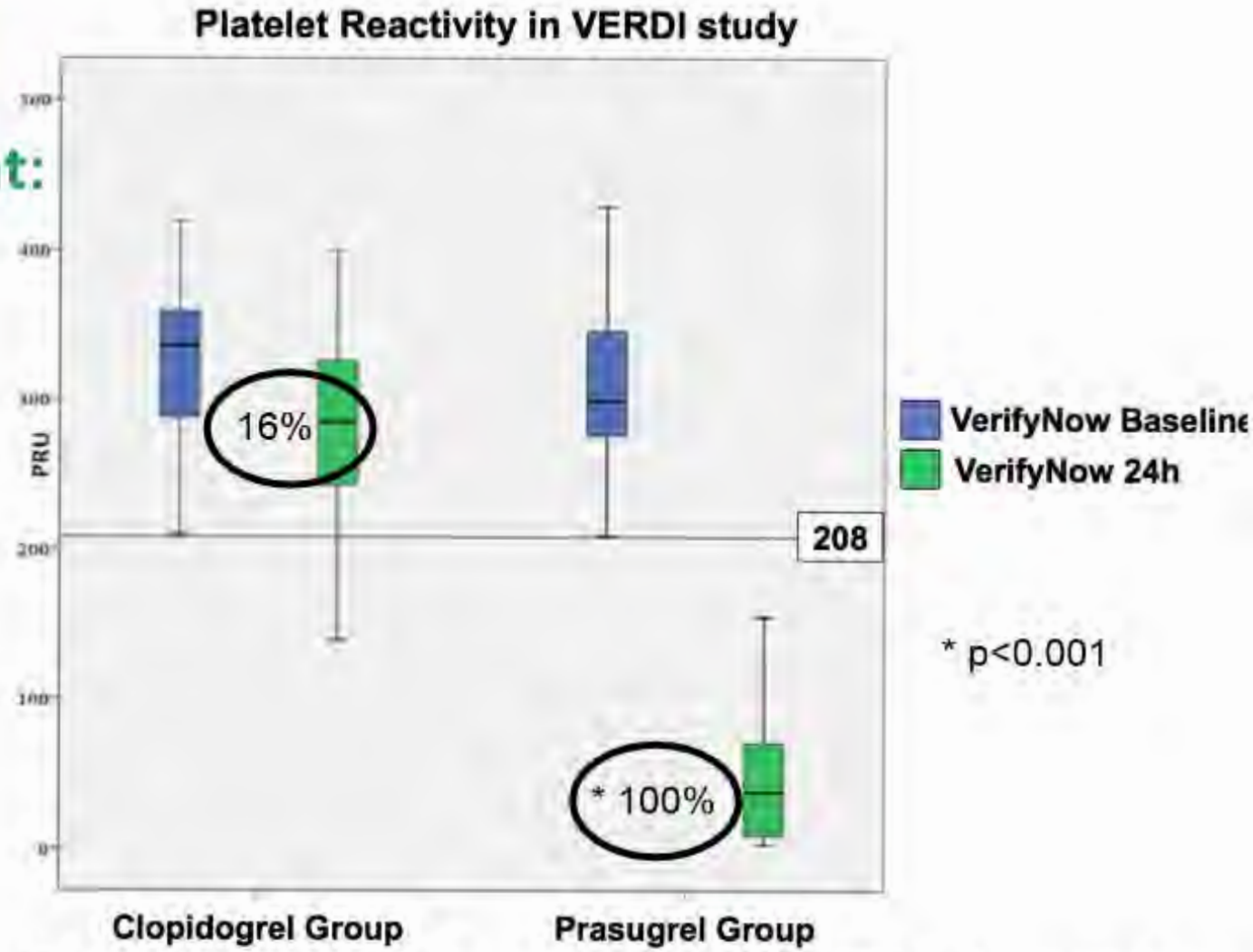
Purpose

VERDI Study

- Diabetic patients with acute coronary syndrome (ACS) undergoing percutaneous coronary intervention (PCI) frequently exhibit high platelet reactivity (HPR) while on clopidogrel.
- We hypothesized that in diabetic ACS patients undergoing PCI, who exhibit HPR after standard treatment with clopidogrel, a 60-mg prasugrel loading dose is superior to standard treatment with clopidogrel for optimal P2Y12 inhibition within the first 24 h post-PCI.

Results:

Primary Endpoint:



The non-HPR rate (PRU <208) at 24 h post-PCI was higher with prasugrel; 25 patients (100%) in the prasugrel group achieved optimal antiaggregation vs. 4 patients (16%) in the clopidogrel group (p<0.001).
No significant acute bleeding was documented in either group.

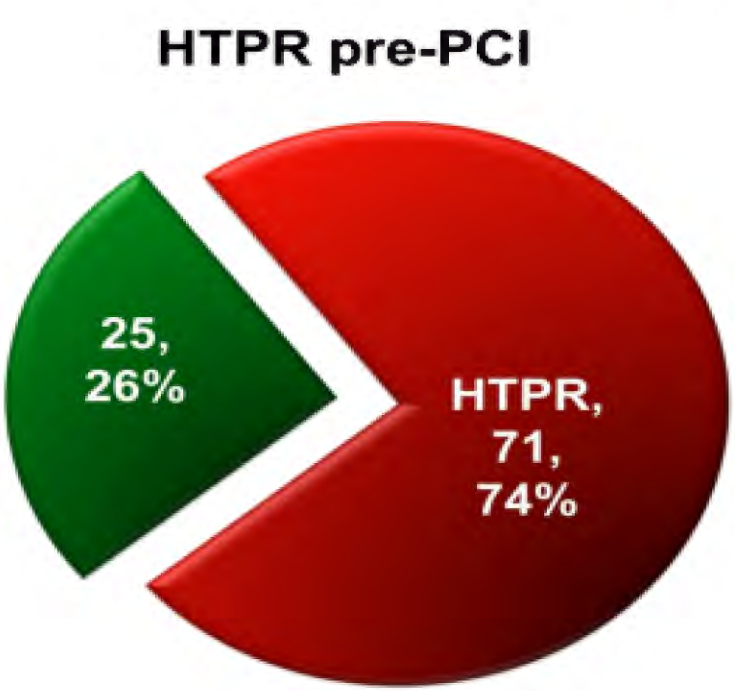
ESCAPADA

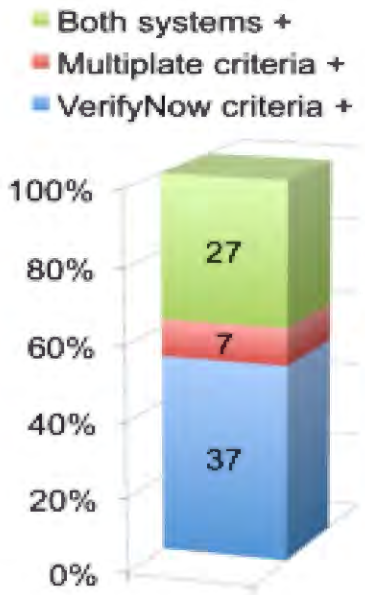
Efficacy and safety of switching from clopidogrel to prasugrel in diabetic patients with acute coronary syndromes treated with drug-eluting stents: Results of the ESCAPADA study

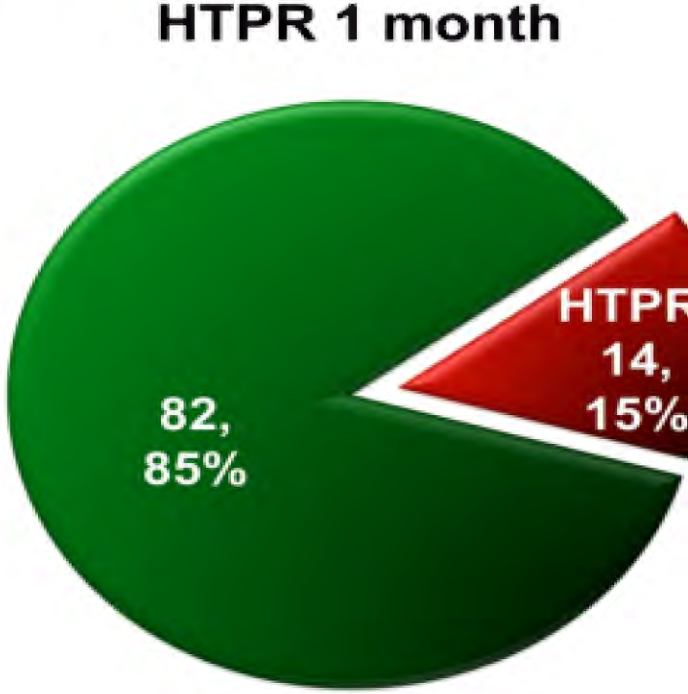
A. Pérez de Prado[1], B. Cid[2], P. Carrillo Saez[3], A. Diego[4], C. Cuellas[1], D. Lopez-Otero[2], A. Cordero[3], M. López-Benito[1], R. Ocaranza-Sanchez[2], T. Rodriguez-Gabella[4], A. Frutos[3], R. Estevez-Loureiro[1], S. Merchan Gomez[4], R. Trillo[2], R. Lopez Palop[3], F.Fernández-Vázquez[1]

[1]Hospital Universitario de Leon, [2]Hospital Universitario de Santiago de Compostela, [3]Hospital Universitario San Juan, Alicante, [4]Hospital Universitario de Salamanca, Spain

Results: Efficacy







4 patients were on clopidogrel @1 month:
3 of whom (75%) showed HTPR

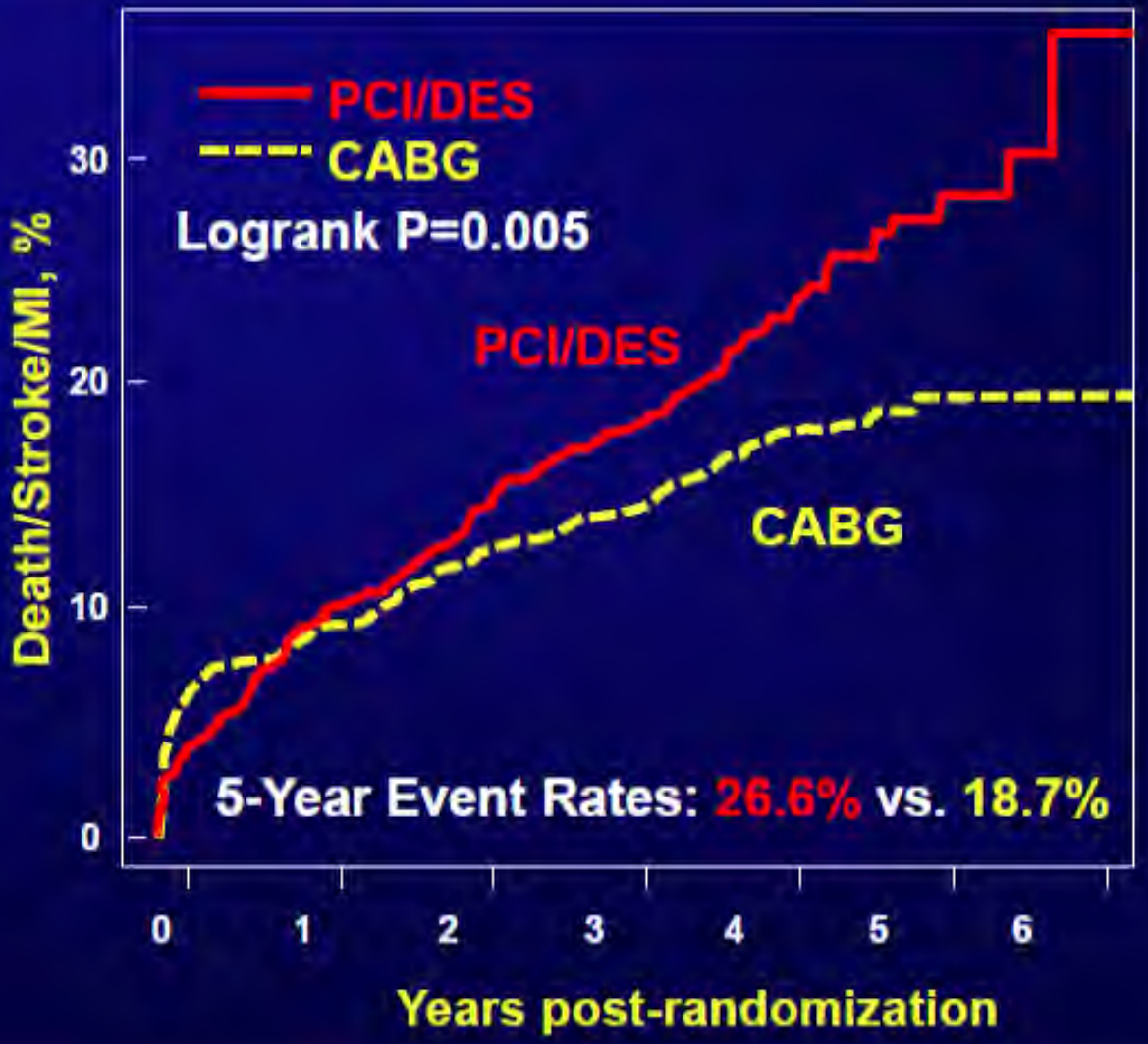
Results: Safety

- **5 bleeding events were recorded during 1-month follow-up:**
  - 1 case of pericardial tamponade after coronary perforation @PCI
  - 1 case of significant groin hematoma
  - 3 minor bleedings (epistaxis, skin hematoma)
- **No subsequent changes in the treatment were needed**

- **Is Diabetes per se a true risk factor?**

- **Do we need more potent anti-thrombotic treatment?**
- **Disparity between Symtax and Freedom. (CABG improved outcome irrespective of vessel anatomy)**

PRIMARY OUTCOME – DEATH / STROKE / MI



PCI/DES N	953	848	788	625	416	219	40
CABG N	943	814	758	613	422	221	44

I pazienti con diabete mellito possono essere molto diversi

- **Caratteristiche dell'aterosclerosi:**
  - **Estensione della malattia**
  - **Syntax score**
  - **Dimensione delle coronarie**
  - **Frazione d'eiezione**
- **Comorbidità**

Conclusioni

- **Gli stent medicati di seconda generazione sembrano migliorare ulteriormente i risultati dell'angioplastica**
- **I nuovi farmaci tienopiridinici migliorano la prognosi nei pz con SCA trattati con angioplastica**