

3rd Dubrovnik Cardiology Highlights
An ESC Update Programme in Cardiology
26.09.-29.09.2013, Hotel Excelsior, Dubrovnik, Croatia

Patients in whom PCI is preferred over CABG

—

Aleksander Ernst
Clinical Hospital Center Zagreb
University of Zagreb School of Medicine
Zagreb, CROATIA

Potential conflicts of interest

Speaker's name: Aleksander Ernst

I do not have any potential conflict of interest

Recommendations for reperfusion strategies in ST-segment elevation myocardial infarction patients

<p>Primary PCI-capable centres should deliver 24 h per day/7 days per week on-call service, be able to start primary PCI as soon as possible and within 60 min from the initial call.</p>	<p>I</p>	<p>B</p>
<p>In case of fibrinolysis, pre-hospital initiation by properly equipped EMS should be considered and full dose administered.</p>	<p>IIa</p>	<p>A</p>
<p>With the exception of cardiogenic shock, PCI (whether primary, rescue, or post-fibrinolysis) should be limited to the culprit stenosis</p>	<p>IIa</p>	<p>B</p>


Reperfusion therapy - STEMI

Recommendations	Class	Level
Reperfusion therapy is indicated in all patients with symptoms of <12 h duration and persistent ST-segment elevation or (presumed) new LBBB.	I	A
Reperfusion therapy (preferably primary PCI) is indicated if there is evidence of ongoing ischaemia, even if symptoms may have started > 12 h beforehand or if pain and ECG changes have been stuttering.	I	C
Reperfusion therapy with primary PCI may be considered in stable patients presenting 12-24 h after symptom onset.	IIb	B
Routine PCI of a totally occluded artery > 24 h after symptom onset in stable patients without signs of ischaemia (regardless of whether fibrinolysis was given or not) is not recommended.	III	A


ECG = electrocardiogram; i.v. = intravenous; LBBB = left bundle branch block; PCI = percutaneous coronary intervention.

Recommendations for percutaneous coronary intervention in ST-segment elevation myocardial infarction

Indication	Time from FMC	Class ^a	Level ^b
Primary PCI			
Is recommended in patients with chest pain/discomfort <12 h + persistent ST-segment elevation or previously undocumented left bundle branch block.	As soon as possible and at any rate <2 h from FMC ^d	I	A
Should be considered in patients with ongoing chest pain/discomfort >12 h + persistent ST-segment elevation or previously undocumented left bundle branch block.	As soon as possible	IIa	C
May be considered in patients with history of chest pain/discomfort >12 h and <24 h + persistent ST-segment elevation or previously undocumented left bundle branch block.	As soon as possible	IIb	B
PCI after fibrinolysis			
Routine urgent PCI is indicated after successful fibrinolysis (resolved chest pain/discomfort and ST-segment elevation).	Within 24 h ^e	I	A
Rescue PCI should be considered in patients with failed fibrinolysis.	As soon as possible	IIa	A
Elective PCI/CABG			
Is indicated after documentation of angina/positive provocative tests.	Evaluation prior to hospital discharge	I	B



**Specific
recommendations for
diabetic
patients**



In patients presenting with STEMI, primary PCI is preferred over fibrinolysis if it can be performed within recommended time limits.

I

A

In stable patients with extensive CAD, revascularization is indicated in order to improve MACCE-free survival.

I

A

Use of DES is recommended in order to reduce restenosis and repeat TVR.

I

A

In patients on metformin, renal function should be carefully monitored after coronary angiography/PCI.

I

C

CABG should be considered, rather than PCI, when the extent of the CAD justifies a surgical approach (especially MVD), and the patient's risk profile is acceptable.

IIa

B

Recommendations for patients with chronic heart failure and systolic left ventricular dysfunction (ejection fraction $\leq 35\%$), presenting predominantly with anginal symptoms



	Class^a	Level^b
<p>CABG is recommended for:</p> <ul style="list-style-type: none"> ▪ significant LM stenosis ▪ LM equivalent (proximal stenosis of both LAD and LCx) ▪ proximal LAD stenosis with 2- or 3- vessel disease. 	I	B
<p>CABG with SVR may be considered in patients with LVESV index ≥ 60 mL/m² and scarred LAD territory.</p>	IIb	B
<p>PCI may be considered if anatomy is suitable, in the presence of viable myocardium.</p>	IIb	C

ESC/EACTS Guidelines
European Heart Journal
(2010) 31, 2501–2555

Crossed revascularization procedures

In early graft failure		
Coronary angiography is indicated for highly symptomatic patients, or in the event of post-operative instability, or with abnormal biomarkers/ECG suggestive of perioperative MI.	I	C
Decision of redo CABG or PCI should be made by the Heart Team.	I	C
PCI is a superior alternative to re-operation in patients with early ischaemia after CABG.	I	B
The preferred target for PCI is the native vessel or ITA graft, not the freshly occluded SVG.	I	C
For freshly occluded SVG, redo CABG is recommended rather than PCI if the native artery appears unsuitable for PCI or several important grafts are occluded.	I	C
In late graft failure following CABG		
PCI or redo CABG is indicated in patients with severe symptoms or extensive ischaemia despite OMT.	I	B
PCI is recommended as a first choice, rather than redo CABG.	I	B
PCI of the bypassed native artery is the preferred approach when stenosed grafts > 3 years old.	I	B
ITA is the conduit of choice for redo CABG.	I	B
Redo CABG should be considered for patients with several diseased grafts, reduced LV function, several CTO, or absence of a patent ITA.	IIa	C
PCI should be considered in patients with patent left ITA and amenable anatomy.	IIa	C

Recommendations for invasive evaluation and revascularization - NSTEMI

Recommendations	Class	Level
An invasive strategy (within 72 h after first presentation) is indicated in patients with: <ul style="list-style-type: none"> • at least one high-risk criterion, • recurrent symptoms. 	I	A
Urgent coronary angiography (< 2 h) is recommended in patients at very high ischaemic risk (refractory angina, with associated heart failure, life-threatening ventricular arrhythmias, or haemodynamic instability).	I	C
An early invasive strategy (< 24 h) is recommended in patients with a GRACE score > 140 or with at least one primary high-risk criterion.	I	A
Non-invasive documentation of inducible ischaemia is recommended in low-risk patients without recurrent symptoms before deciding for invasive evaluation.	I	A
The revascularization strategy (<i>ad-hoc</i> culprit lesion PCI/ multivessel PCI/CABG) should be based on the clinical status as well as the disease severity, i.e. distribution and angiographic lesion characteristics (e.g. SYNTAX score), according to the local 'Heart Team' protocol.	I	C
As there are no safety concerns related to the use of DESs in ACS, DESs are indicated based on an individual basis taking into account baseline characteristics, coronary anatomy, and bleeding risk.	I	A
PCI of non-significant lesions is not recommended.	III	C
Routine invasive evaluation of low-risk patients is not recommended.	III	A

Unresolved issues:

**HOW PCI MATCHES CABG
IN**

LMCA LESIONS

MULTIVESSEL CORONARY ARTERY DISEASE

MULTIVESSEL CAD IN DIABETICS

?

GLOBAL RISC CLASSIFICATION

Why not combine EuroSCORE and SYNTAX score?

Global Risk Classification

low, mid and high

Euro SCORE	SYNTAX score		
	<22	23-32	≥33
0-2	low	low	mid
3-5	low	low	mid
≥6	mid	mid	high

Global Risk Classification

EuroScore	SyntaxScore		
	<22	23-32	>33
0-2	LOW	LOW	MED
3-5	LOW	LOW	MED
≥6	MED	MED	HIGH

LOW: SyntaxSc <33 & EuroScore <6

MED: Either SyntaxSc <33 & EuroScore ≥6 or
EuroScore <6 & SyntaxScore ≥33

HIGH: SyntaxSc ≥33 and EuroSc ≥6

MACCE to 5 years by Syntax Score Tercile

Left Main Disease

SYNTAX score 0-22

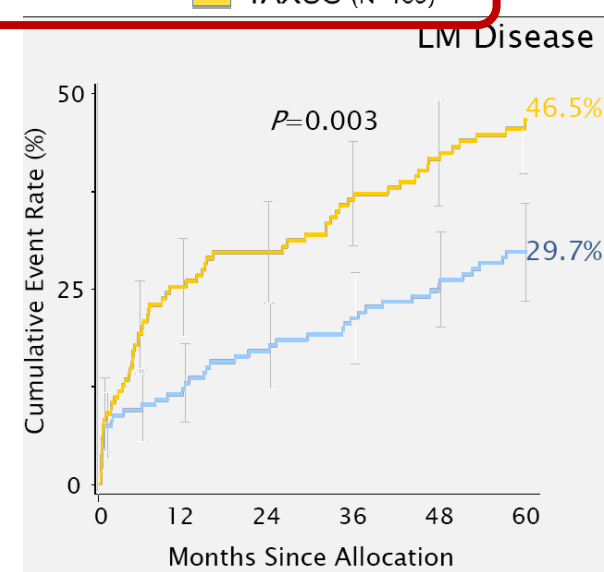
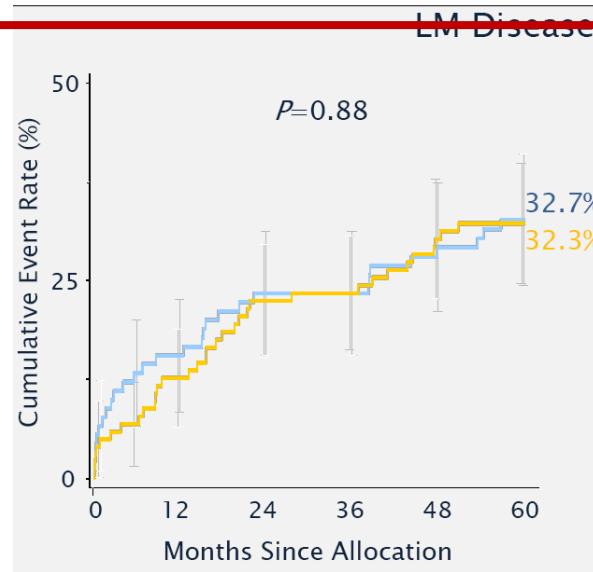
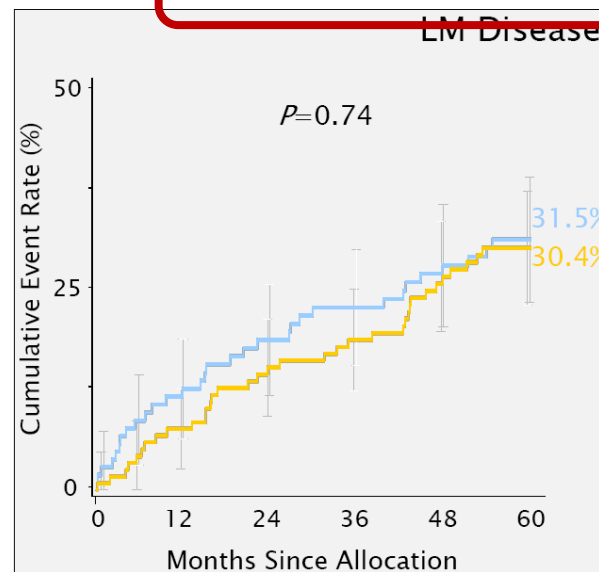
SYNTAX score 23-32

SYNTAX score ≥ 33

CABG (N=104)
TAXUS (N=118)

CABG (N=92)
TAXUS (N=108)

CABG (N=149)
TAXUS (N=135)



PCI or CABG

PCI or CABG

CABG

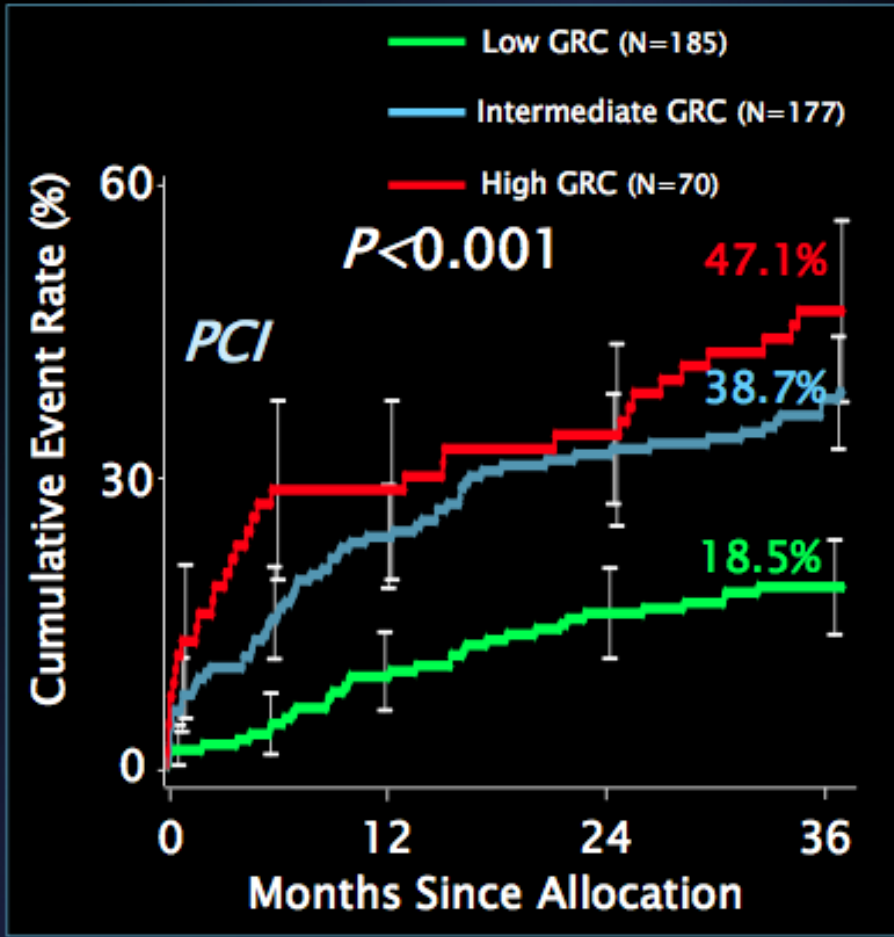
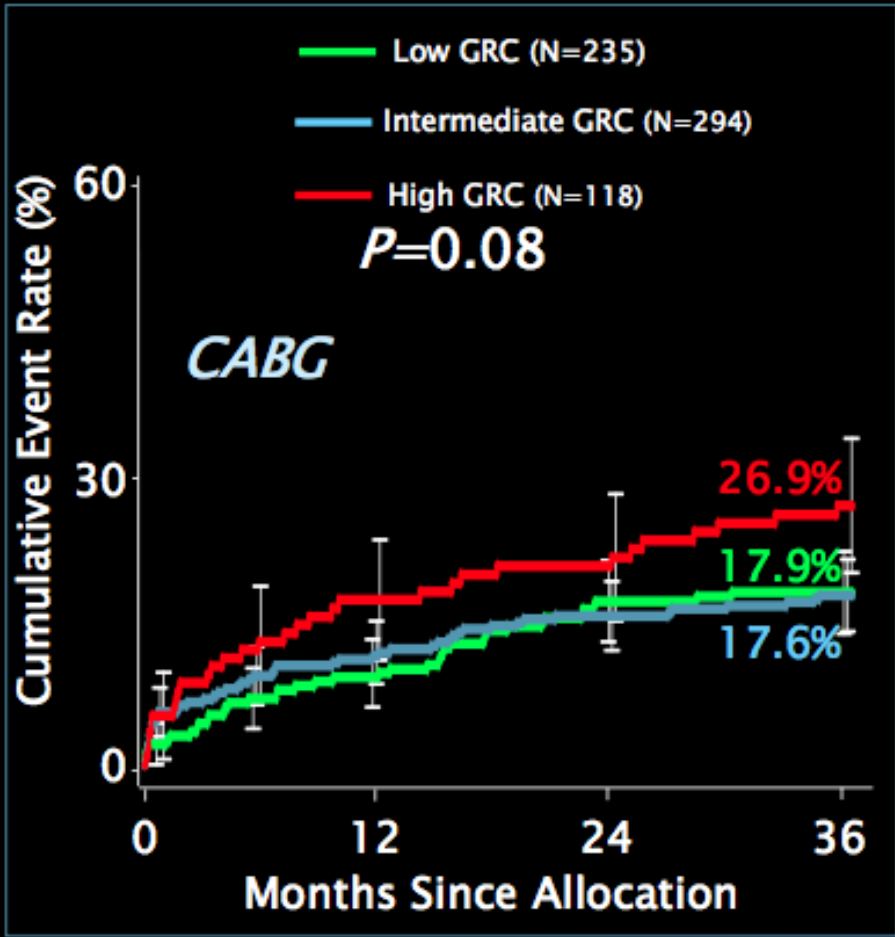
MACCE to 3 years

LM Patients (randomized + registry)

N=1079 (CABG N=647; PCI N=432)

39% (N=420) can be treated with PCI

Euro SCORE	SX Score		
	<22	23-32	>33
0-2	low	low	mid
3-5	low	low	mid
≥6	mid	mid	high

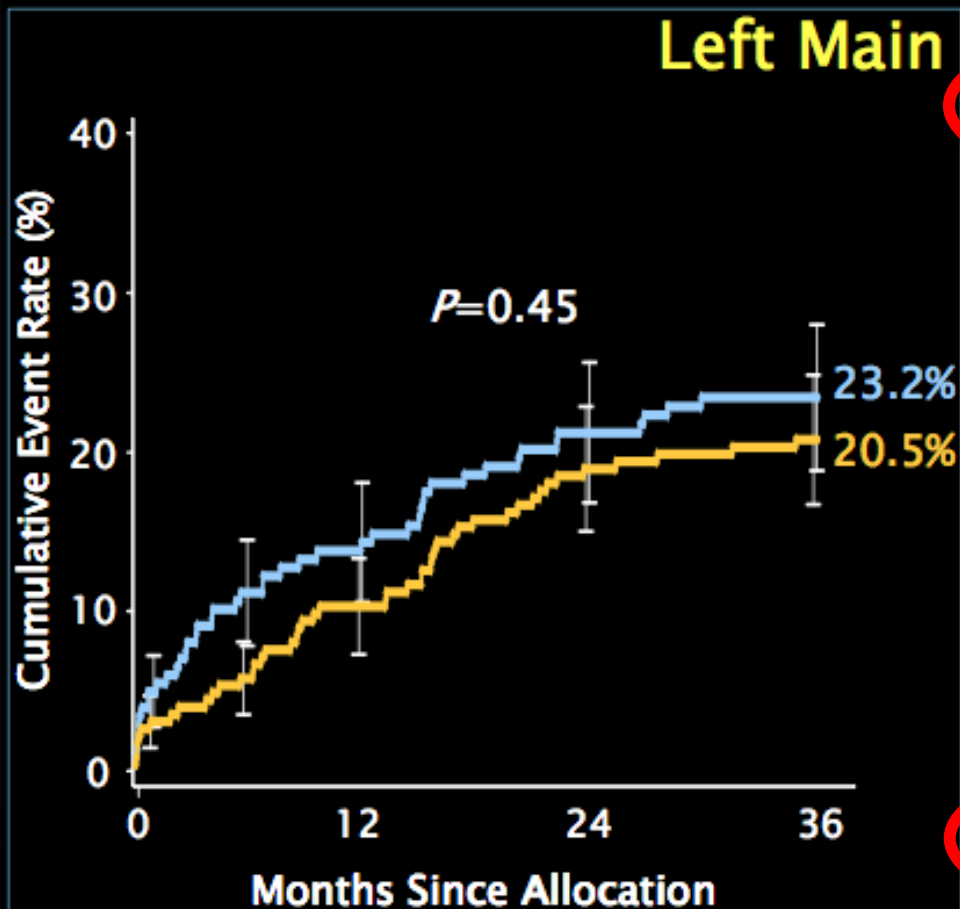


Cumulative KM Event Rate \pm 1.5 SE; log-rank P value

Randomized ITT population, Registry As-Treated Population

MACCE to 3 Years by SYNTAX Score Tercile *Low to Intermediate Scores (0-32)*

■ CABG (N=196)
■ TAXUS (N=221)

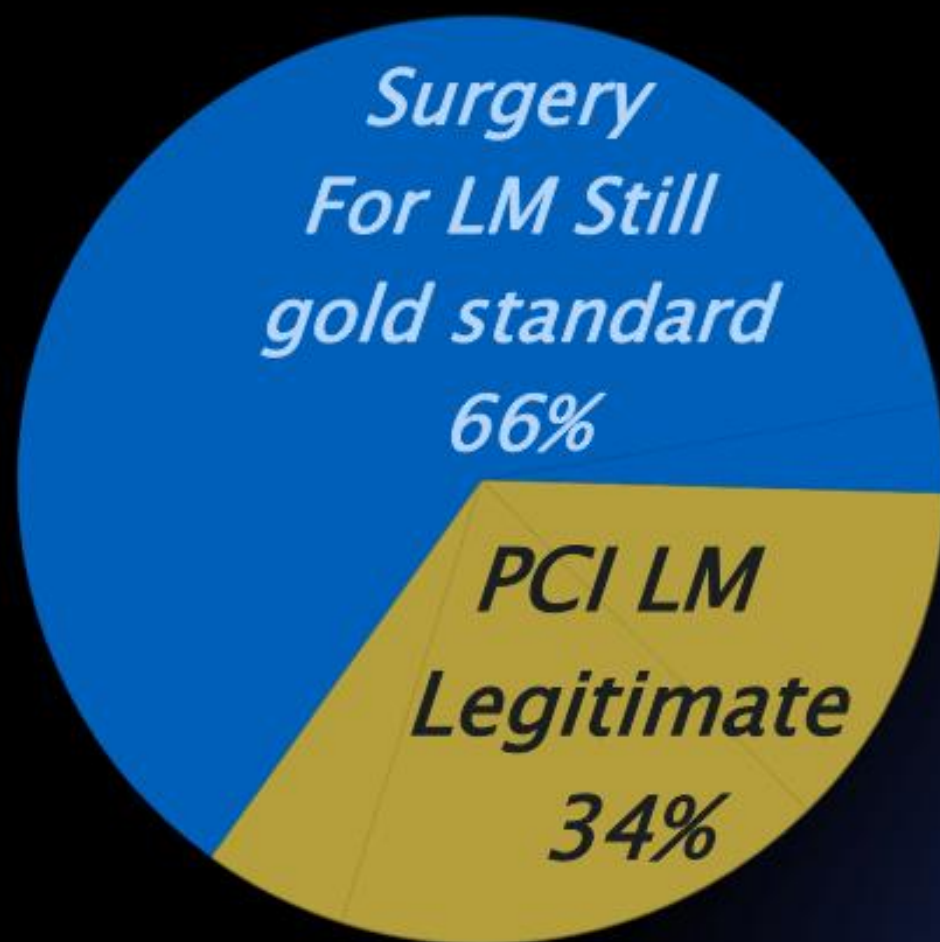


	CABG	PCI	Pvalue
Death	9.0% $>$	3.7%	0.02
CVA	3.3% $>$	0.9%	0.09
MI	2.6% $<$	4.6%	0.33
Death, CVA or MI	13.2% $>$	8.7%	0.12
Revasc.	13.7% $<$	15.7%	0.61

Cumulative KM Event Rate \pm 1.5 SE; log-rank Pvalue

Site-reported Data; ITT population

SYNTAX Trial Patient Distribution

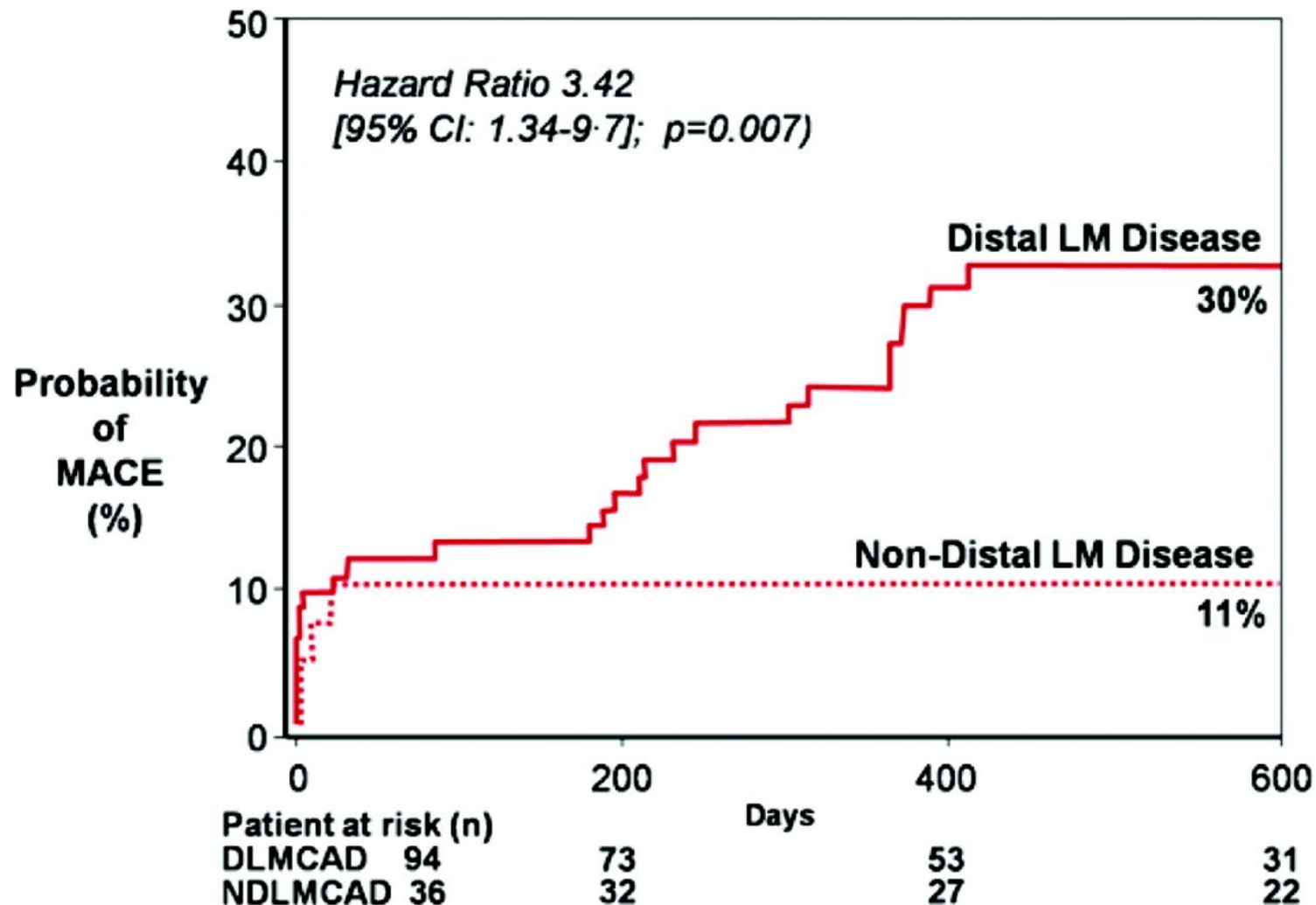


*Surgery
For LM Still
gold standard
66%*

*PCI LM
Legitimate
34%*

*Results of the
SYNTAX trial
suggest that
34 % of all
patients with Left
Main Stem are
best treated with
PCI , an excellent
alternative to
surgery... up to
three year*

Figure 4. Adverse events in patients treated with DES for distal LMCA disease (DLMCAD) compared with patients treated for nondistal LMCA disease (NDLMCAD).



Smith C R Circulation 2009;119:1013-1020

Guidelines on myocardial revascularization

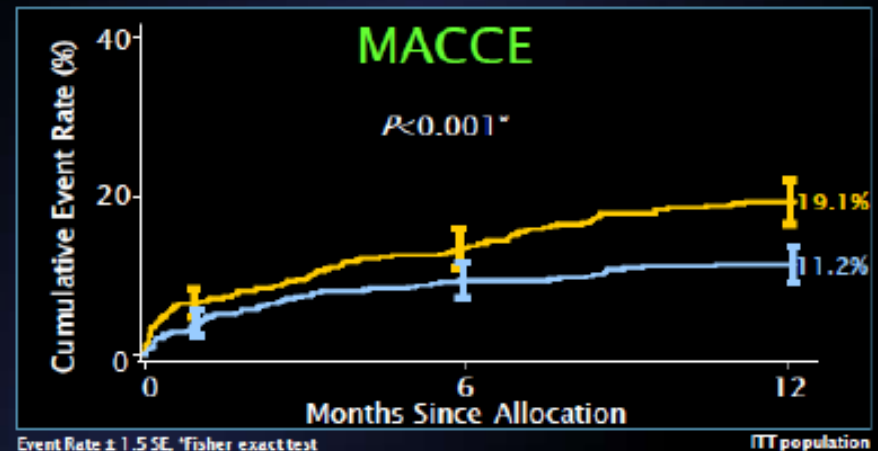
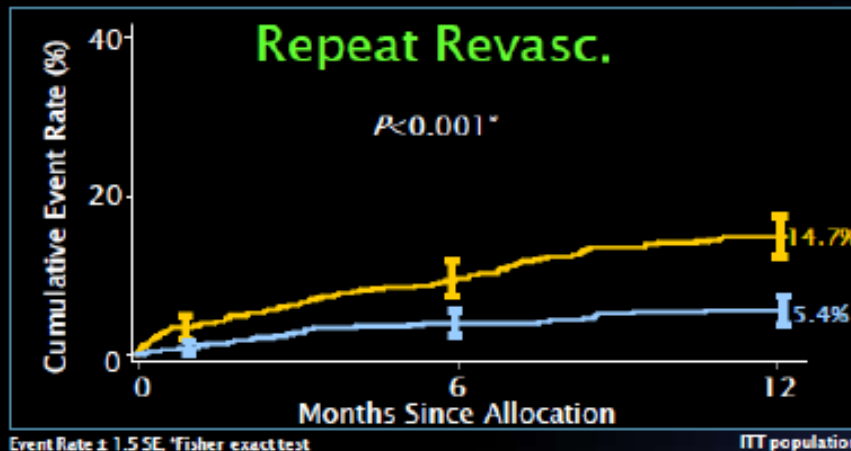
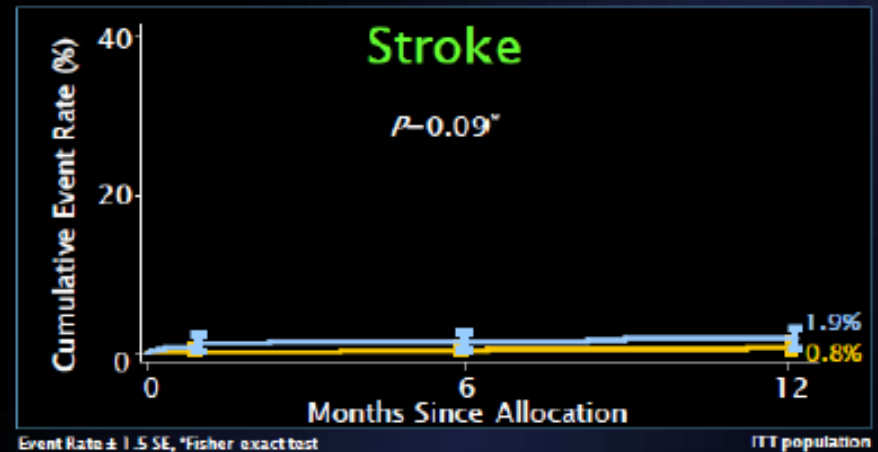
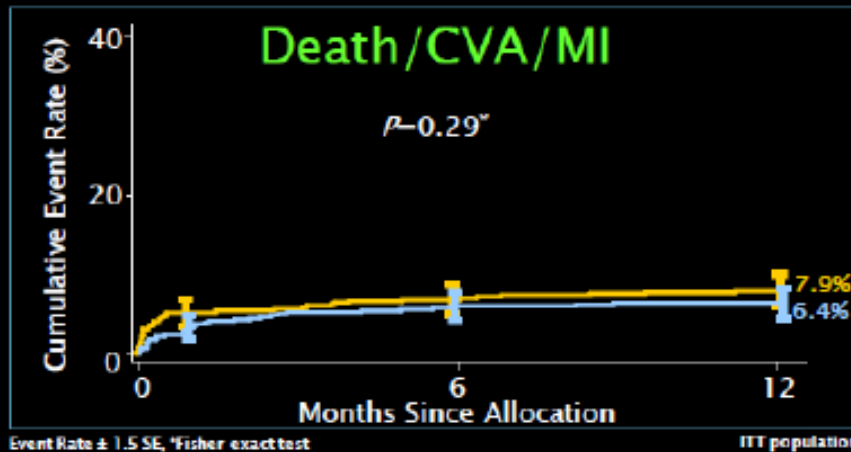
The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Subset of CAD by anatomy	Favours CABG	Favours PCI
Left main (isolated or 1VD, ostium/shaft)	I A	IIa B
Left main (isolated or 1VD, distal bifurcation)	I A	IIb B
Left main + 2VD or 3VD, SYNTAX score ≤ 32	I A	IIb B
Left main + 2VD or 3VD, SYNTAX score ≥ 33	I A	III B

Classes of recommendations	Definition	Level of evidence	Data derived from multiple randomized clinical trials or meta-analyses.
Class IIa	<i>Weight of evidence/opinion is in favour of usefulness/efficacy.</i>	Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Class IIb	<i>Usefulness/efficacy is less well established by evidence/opinion.</i>	Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

Summary of 1-Year Results

3VD Subset

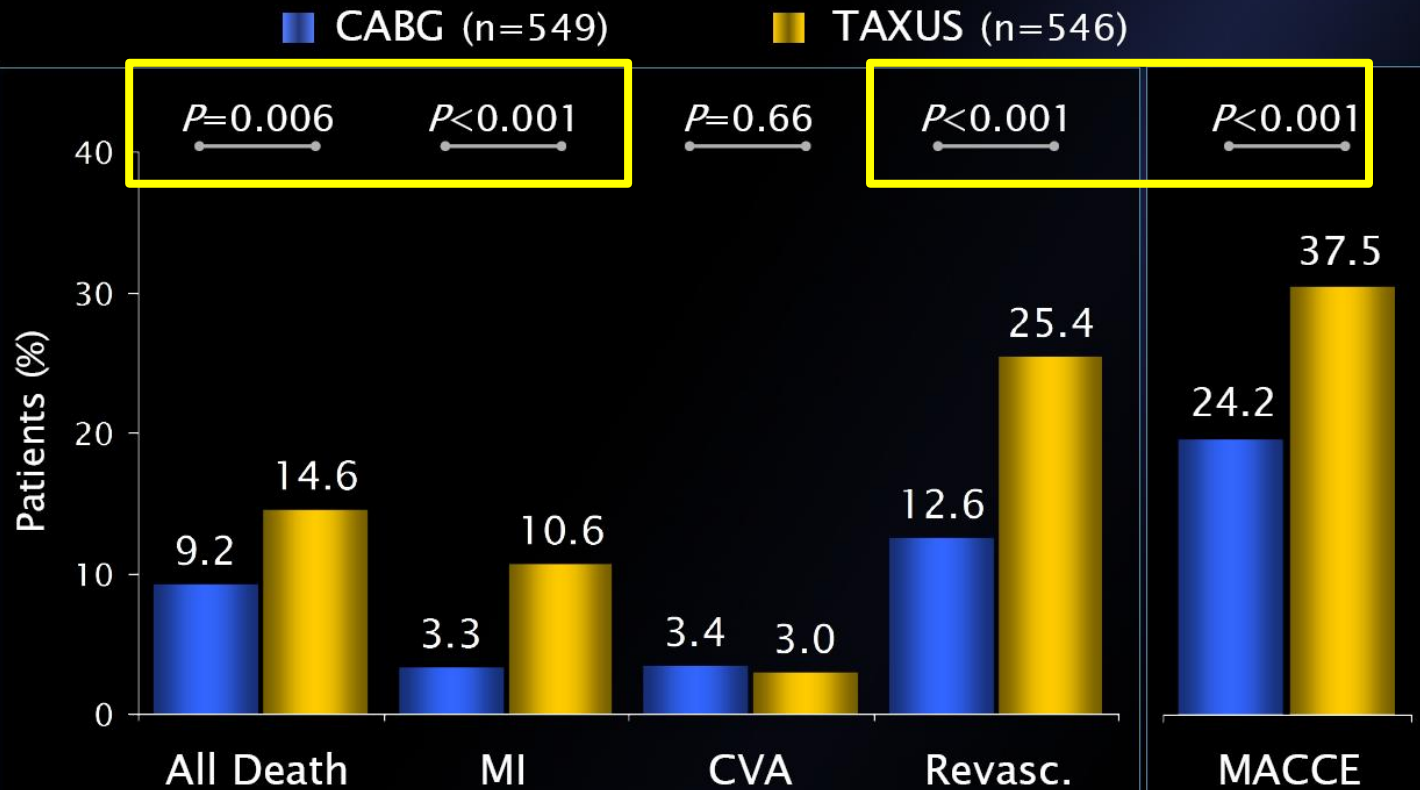


- Death/Stroke/MI rates were similar between CABG and PCI
- Stroke was not significantly increased in CABG
- Repeat revascularization and MACCE were increased in PCI vs CABG

All end-points in favour of CABG

3VD Disease 5-year Outcomes (N=1095)

SYNTAX

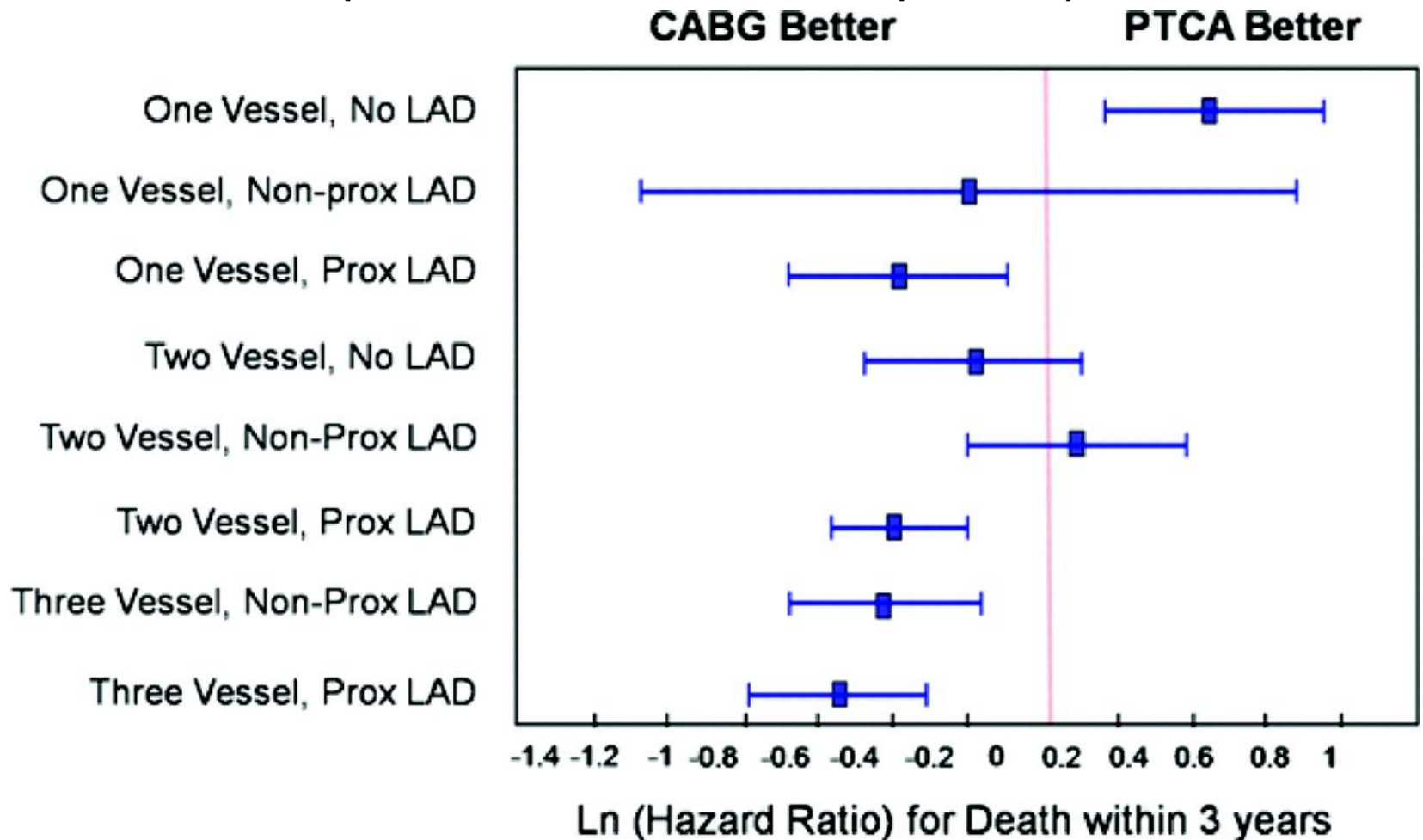


Cumulative KM Event Rate; log-rank P value

SYNTAX 3VD 5-year Outcomes • TCT 2012 • Mohr • 23 October 2012 • Slide 15

ITT population

Figure 6. The 95% CI for Ln (adjusted hazard ratio) of CABG patient death and percutaneous transluminal coronary angioplasty (PTCA) patient death within a 3-year period (excluding patients with MI <24 hours before procedure).



Smith C. Circulation 2009;119:1013-1020

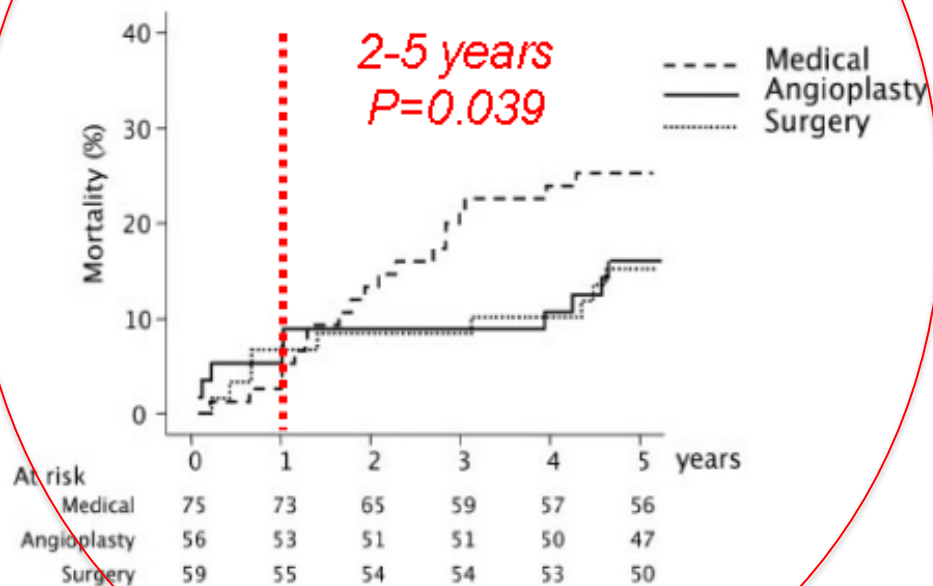
Table 9 Indications for coronary artery bypass grafting vs. percutaneous coronary intervention in stable patients with lesions suitable for both procedures and low predicted surgical mortality

Subset of CAD by anatomy	Favours CABG	Favours PCI	Ref.
IVD or 2VD - non-proximal LAD	IIb C	I C	—
IVD or 2VD - proximal LAD	I A	IIa B	30, 31, 50, 51
3VD simple lesions, full functional revascularization achievable with PCI, SYNTAX score ≤ 22	I A	IIa B	4, 30–37, 53
3VD complex lesions, incomplete revascularization achievable with PCI, SYNTAX score >22	I A	III A	4, 30–37, 53
Left main (isolated or IVD, ostium/shaft)	I A	IIa B	4, 54
Left main (isolated or IVD, distal bifurcation)	I A	IIb B	4, 54
Left main + 2VD or 3VD, SYNTAX score ≤ 32	I A	IIb B	4, 54
Left main + 2VD or 3VD, SYNTAX score ≥ 33	I A	III B	4, 54

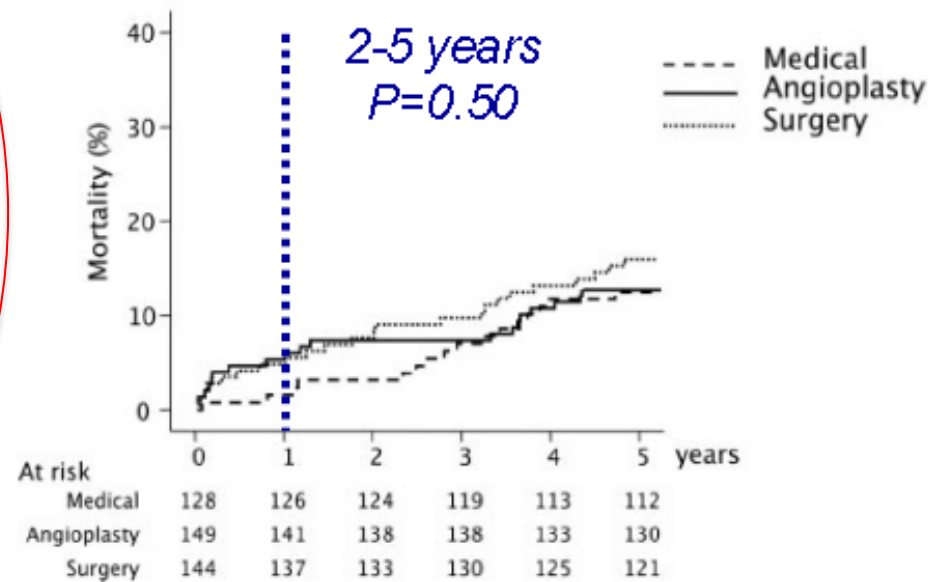


Impact of Revascularization on Mortality in Diabetic Patients with Multivessel Disease - *MASS II Trial*

Diabetic Patients

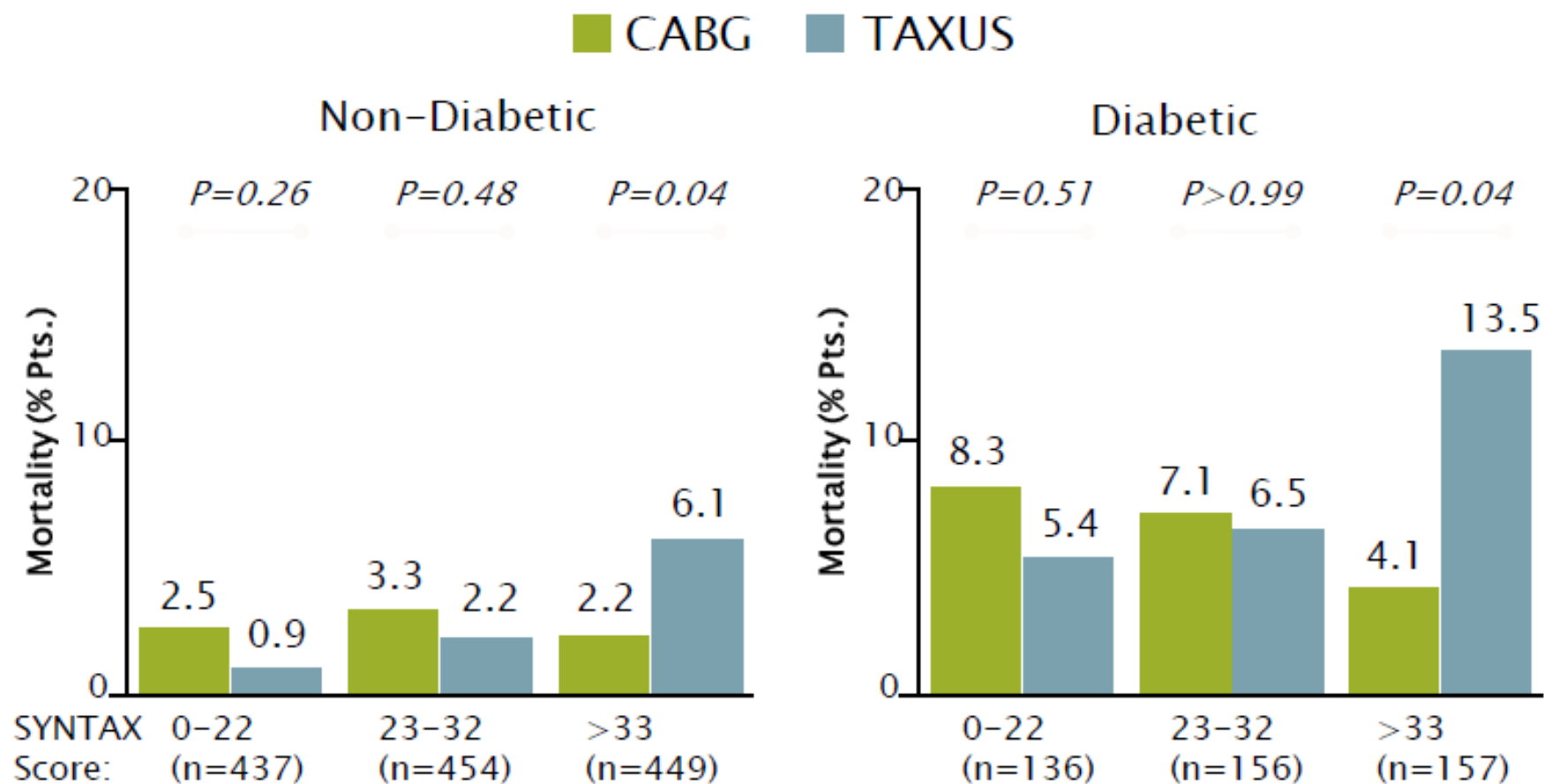


Non-Diabetic Patients



Mortality by SYNTAX score

3VD/LM diabetic and non-diabetic patients



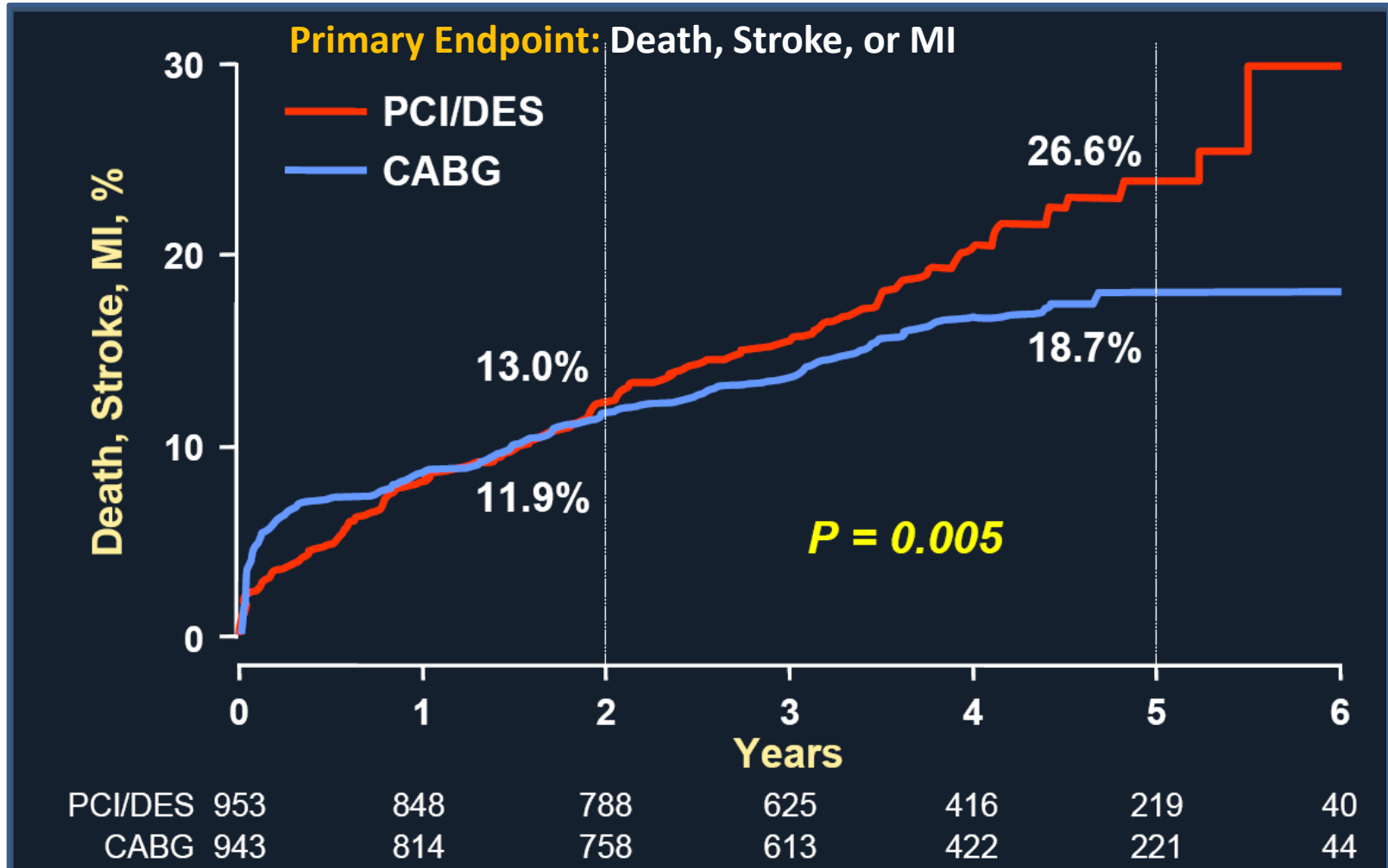
Conclusion

		Diabetes		
		Non Diabetic	Oral Meds	Insulin
Lesion complexity	High	CABG	CABG	CABG
	Medium	TAXUS or CABG	TAXUS or CABG	CABG
	Low	TAXUS or CABG	TAXUS or CABG	CABG

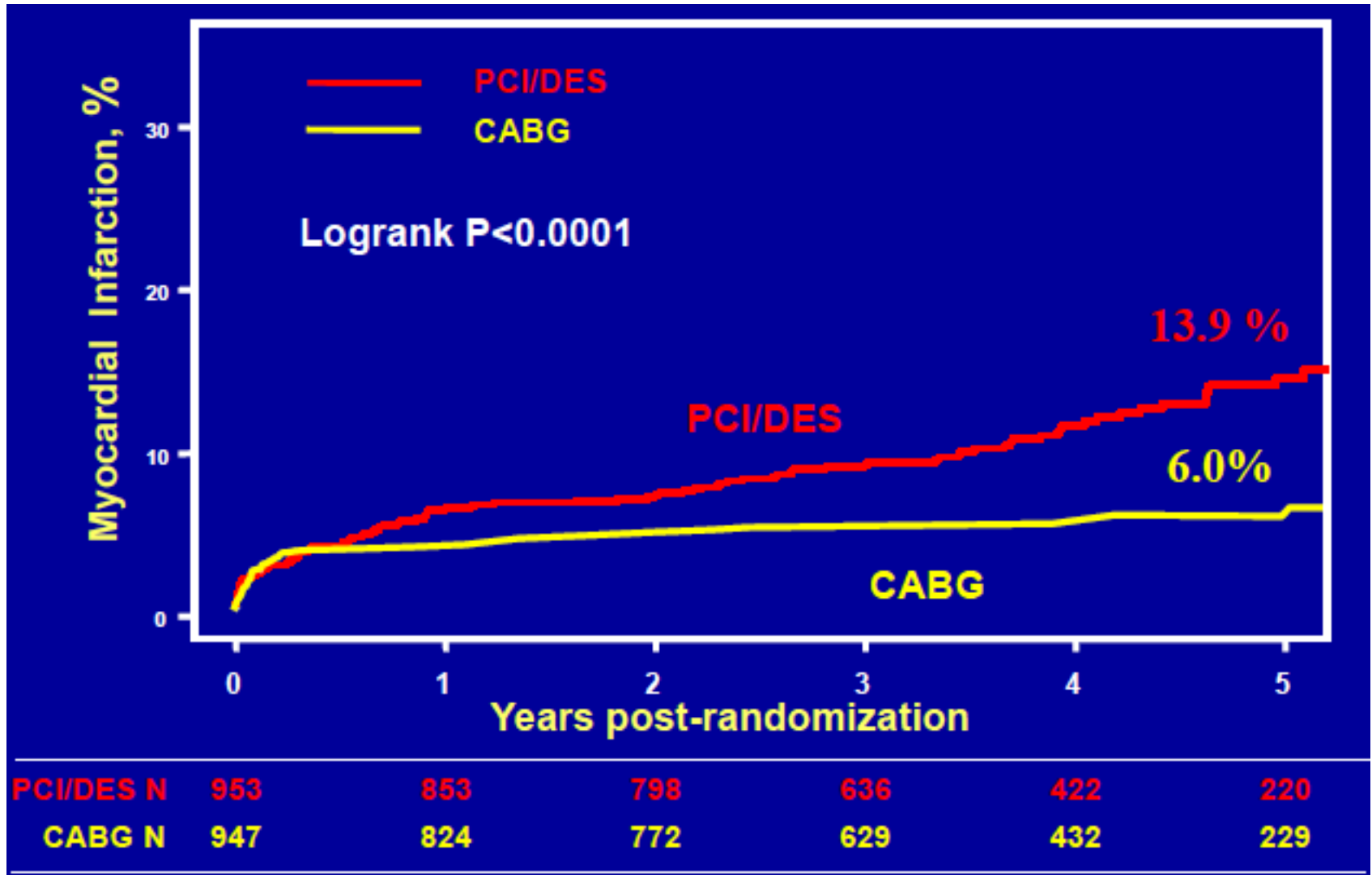
PCI vs. CABG in Diabetes



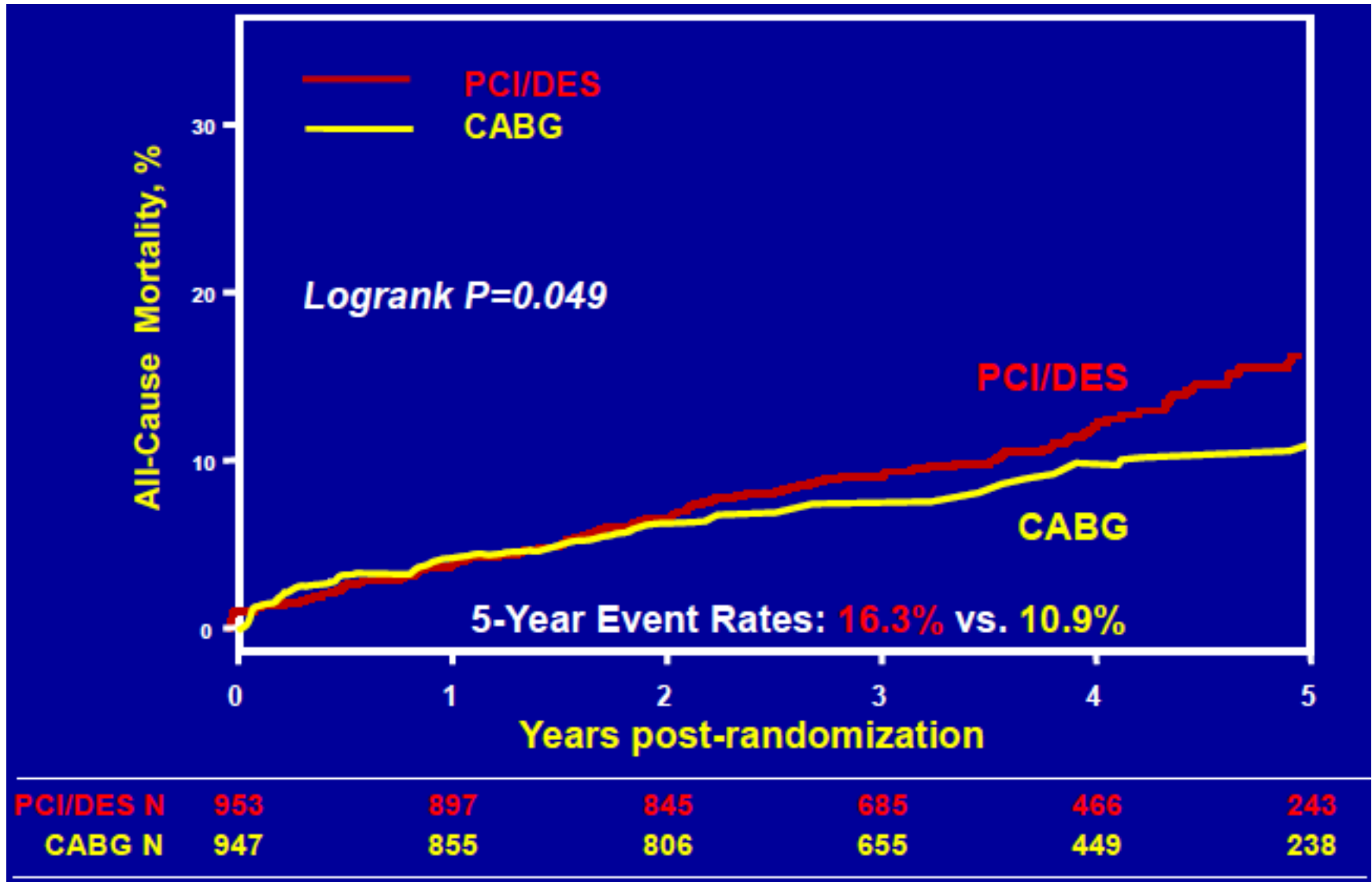
- **FREEDOM:** 1900 pts with diabetes + MVD
- Randomized to SES/PES vs CABG



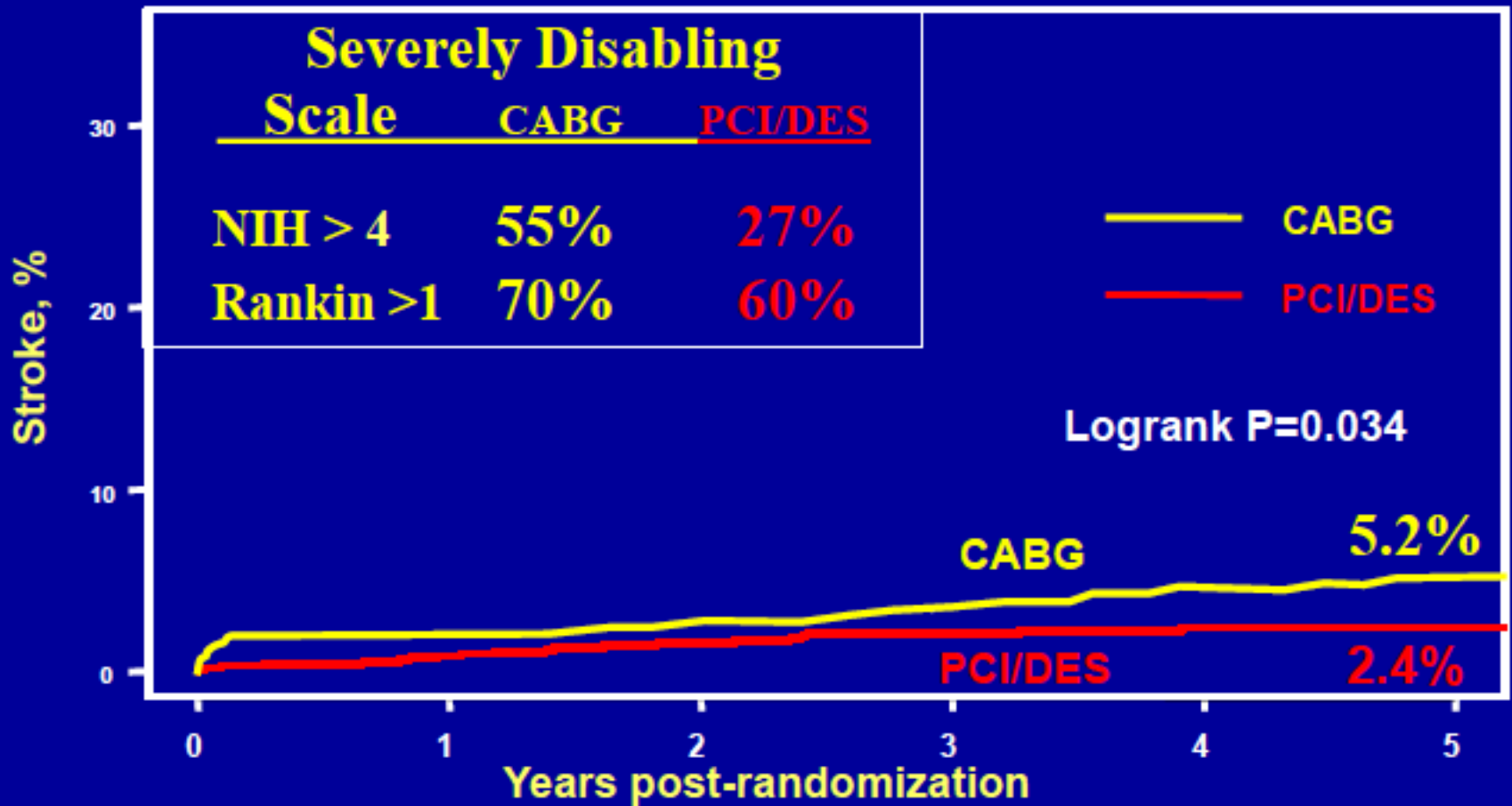
Freedom - Myocardial Infarction



Freedom – All cause of death

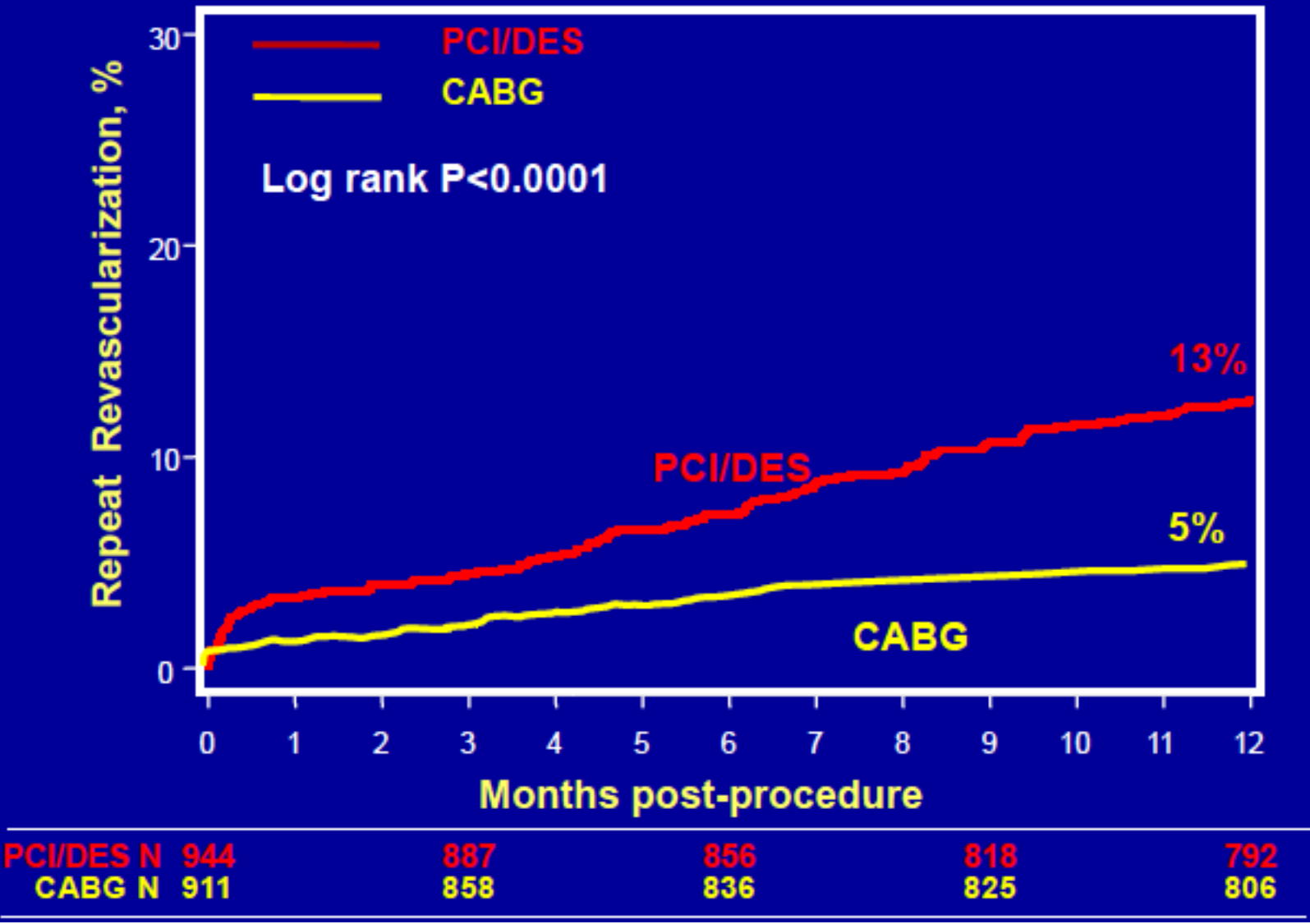


Freedom – Stroke



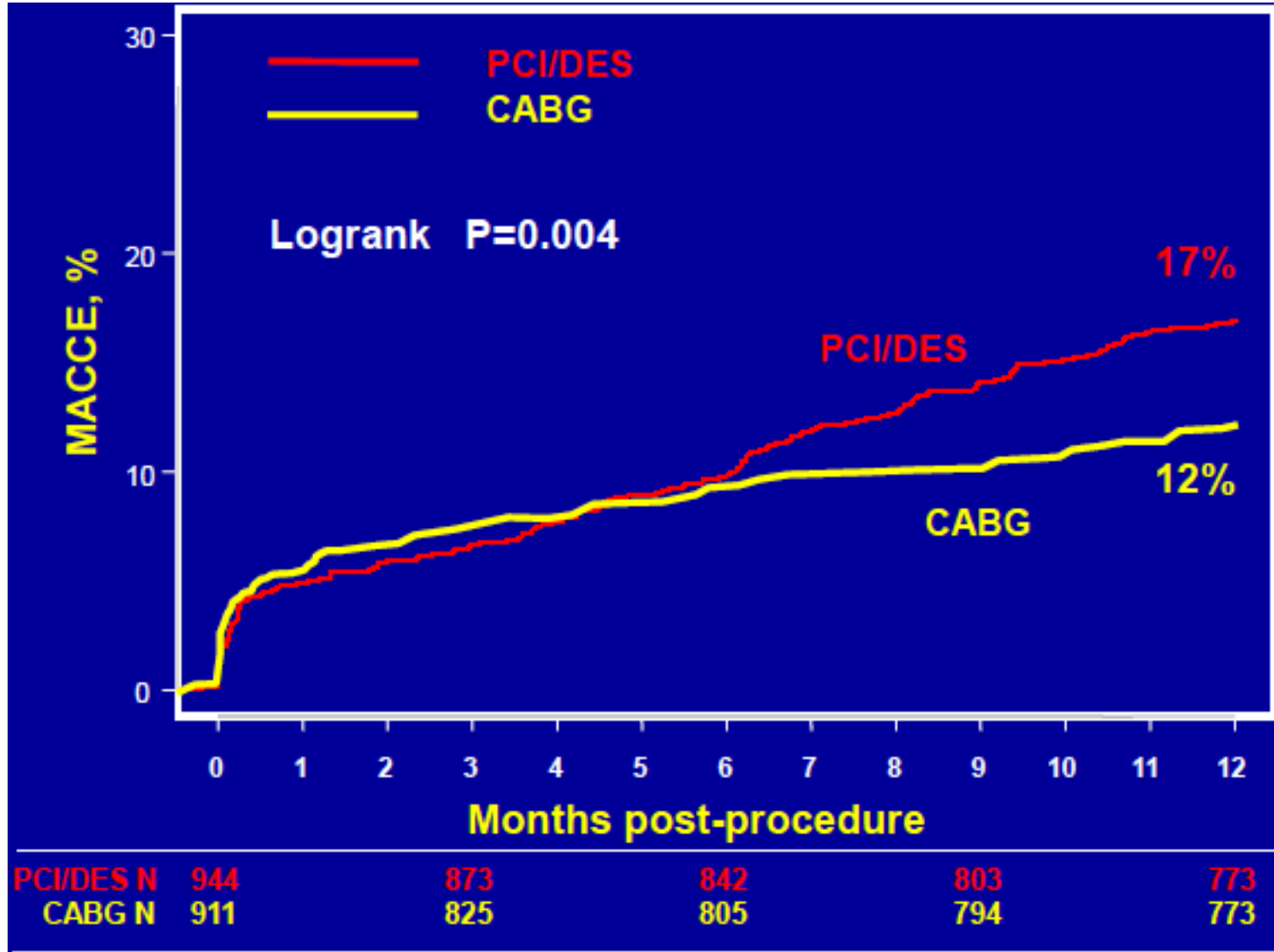
PCI/DES N	953	891	833	673	460	241
CABG N	947	844	791	640	439	230

Freedom – Repeat Revascularization



Freedom – MACCE

(death,stroke,MI,repeat revascularization)

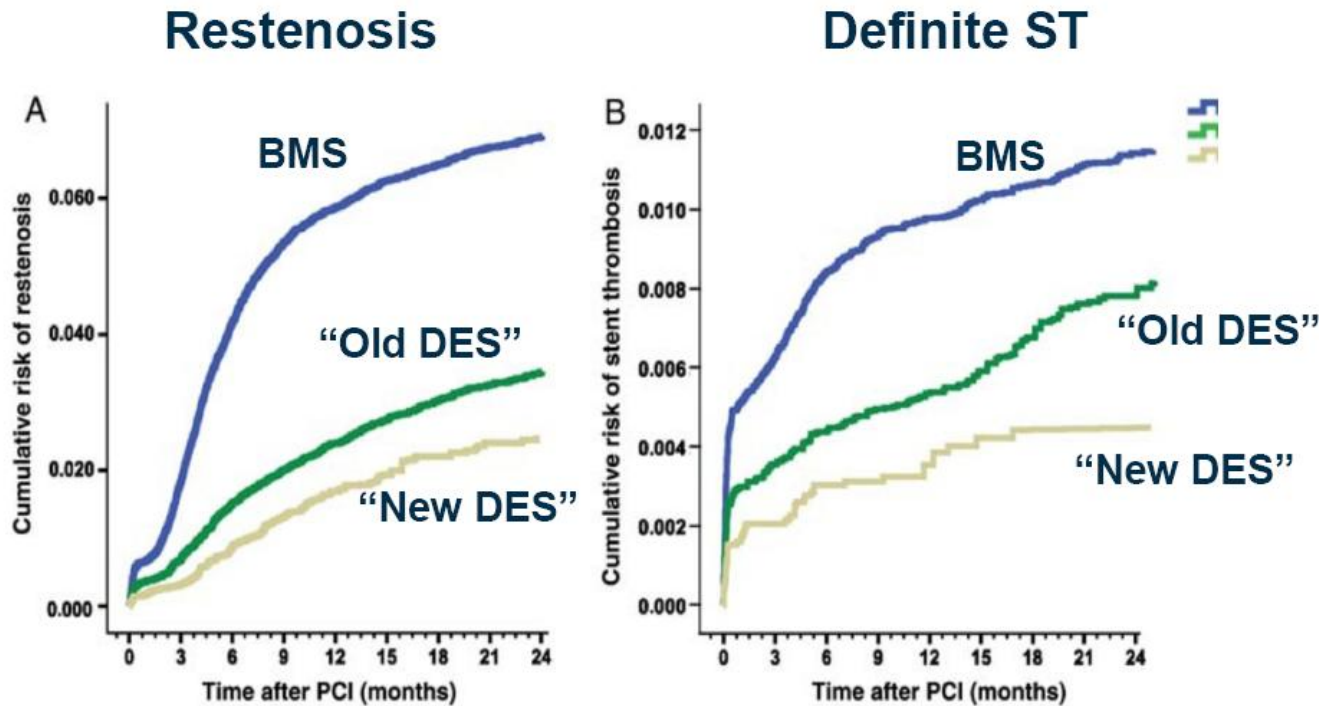


Recommendations for diabetic patients - NSTEMI

Recommendations	Class	Level
All patients with NSTEMI-ACS should be screened for diabetes. Blood glucose levels should be monitored frequently in patients with known diabetes or admission hyperglycaemia.	I	C
Treatment of elevated blood glucose should avoid both excessive hyperglycaemia [10-11 mmol/L (> 180-200 mg/dL)] and hypoglycaemia [< 5 mmol/L (< 90 mg/dL)].	I	B
Antithrombotic treatment is indicated as in non-diabetic patients.	I	C
Renal function should be closely monitored following contrast exposure.	I	C
An early invasive strategy is recommended.	I	A
DESs are recommended to reduce rates of repeat revascularization.	I	A
CABG surgery should be favoured over PCI in diabetic patients with main stem lesions and/or advanced multivessel disease.	I	B

SCAAR Registry (94,384 pts)

Adjusted Risks of Adverse Events at 2 yrs



n at risk	0 months	6 months	12 months	18 months	24 months
BMS	64 631	56 070	47 968	40 539	32 698
o-DES	19 202	17 862	16 014	13 517	10 533
n-DES	10 551	8 092	4 188	2 005	847

Sarno et al, Eur Heart J 2012

From: **Coronary Revascularization Trends in the United States, 2001-2008**

JAMA. 2011;305(17):1769-1776. doi:10.1001/jama.2011.551

Table 1. Annual Rates of Coronary Revascularization Procedures^a

Revascularization Procedure	No. (%) [95% CI] of Average Annual Procedures per Million Adults During the 2-Year Period				P for Trend ^c
	2001-2002 (n = 42.7 million ^b)	2003-2004 (n = 43.6 million ^b)	2005-2006 (n = 44.6 million ^b)	2007-2008 (n = 45.6 million ^b)	
CABG surgery	1742 (31) [1663-1825]	1457 (27) [1413-1502]	1261 (24) [1223-1300]	1081 (23) [1032-1133]	<.001
PCIs	3827 (69) [3578-4092]	3873 (73) [3708-4046]	4101 (76) [3926-4284]	3667 (77) [3429-3922]	.74
Bare metal stents	3326 (60) [3090-3579]	1557 (29) [1425-1700]	468 (9) [393-559]	1167 (25) [1048-1300]	<.001
Drug-eluting stents	NA	2040 (38) [1905-2185]	3507 (65) [3339-3683]	2383 (50) [2225-2552]	NA ^d
Angioplasty (no stent)	501 (9) [399-630]	276 (5) [238-321]	126 (2) [109-147]	117 (2) [93-147]	<.001
Total	5569 (100) [5315-5835]	5330 (100) [5170-5494]	5362 (100) [5202-5528]	4748 (100) [4532-4975]	<.001

Abbreviations: CABG, coronary artery bypass graft; CI, confidence interval; NA, not applicable; NIS, Nationwide Inpatient Sample; PCI, percutaneous coronary intervention.

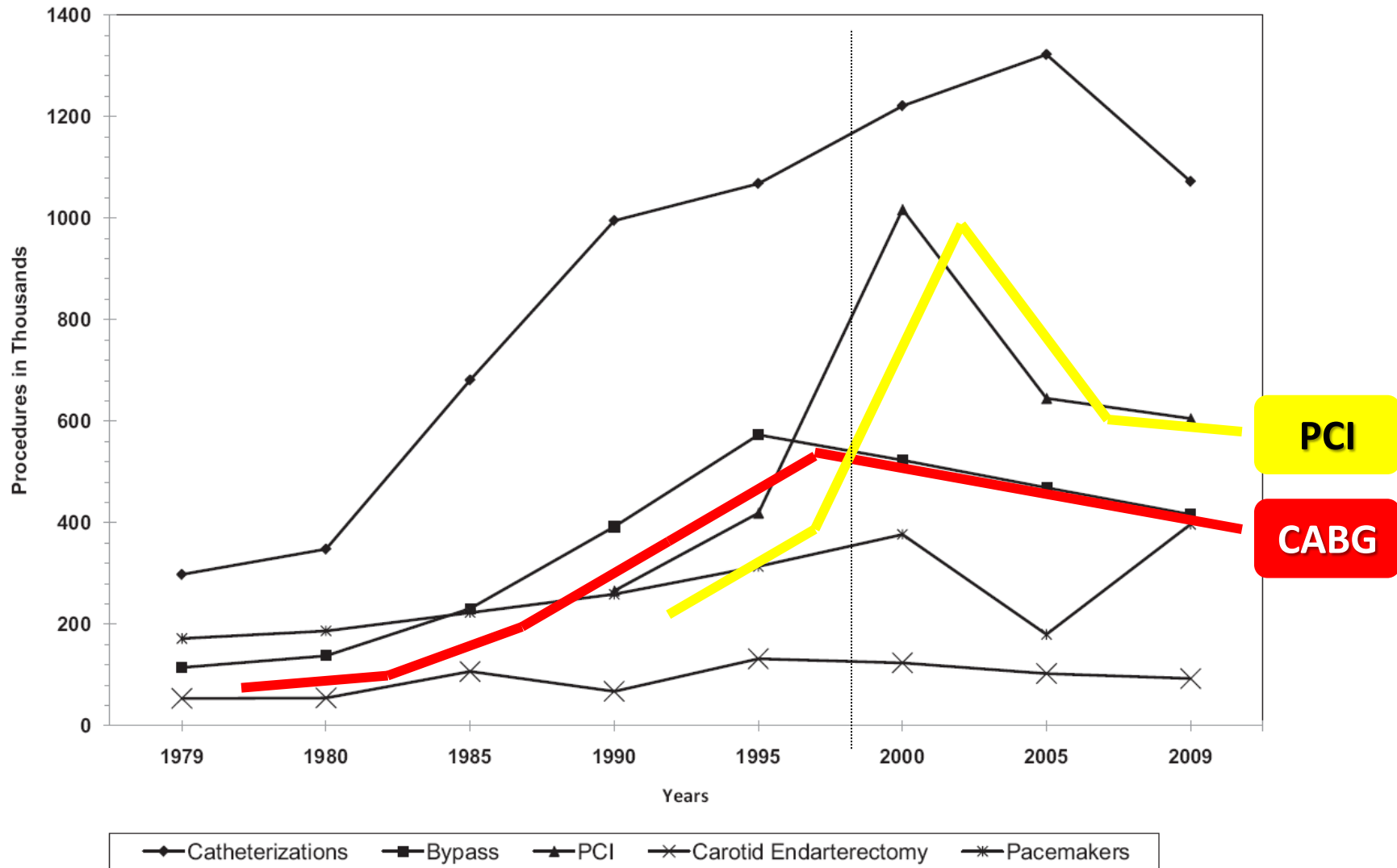
^aData in parentheses indicate the percentages of total revascularizations in the 2-year period. Percentages may not add to 100, or to the subgroup total, due to rounding.

^bIndicates millions of adult patients at risk for inclusion in the NIS. The NIS is designed to represent the hospital services provided to a random 20% of the US population. Because this study excluded pediatric procedures, the NIS at risk population was therefore a 20% random sample of US adults. Population size estimates for this sample were obtained from US Census interim reports.¹⁶
^cTrends tested with negative binomial regressions on quarterly count data from 2001-2008 reported in the 20% NIS, offset by catchment population size.

^dAn increasing trend was observed in drug-eluting stents rate from 2003-2006 ($P = .001$) and a decreasing trend in drug-eluting stents rate from 2006-2008 ($P = .003$).

Figure Legend:

"Real life data"



Real world data

The annual rate of revascularization decreased significantly, but by only 15% ($p < 0.001$).

The CABG rate decreased significantly, by nearly 40%,
from 1742 surgeries per million adults per year to 1081
($p < 0.001$).

PCI rates did not change significantly (from 3827 procedures per million adults per year to 3667 procedures, $p = 0.74$).

The number of hospitals that provide CABG increased, resulting in a 28% decrease in the median CABG caseload per hospital. The results, write the authors, “suggest the possibility that several thousand patients who underwent PCI in 2008 would have undergone CABG surgery had patterns of care not changed markedly between 2001 and 2008. Our data imply a sizeable shift in cardiovascular clinical practice patterns away from surgical treatment toward percutaneous, catheter-based interventions.”

(JAMA. 2011;305[17]1769-1776.)

Emerging new Scoring Systems

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, Hector M Garcia-Garcia, Gerrit Anne van Es, Keith D Dawkins, Friedrich W Mohr, Patrick W Serruys

Anatomical (2)

» **Syntax score**

» **LMCA**

Clinical (6)

» **Age**

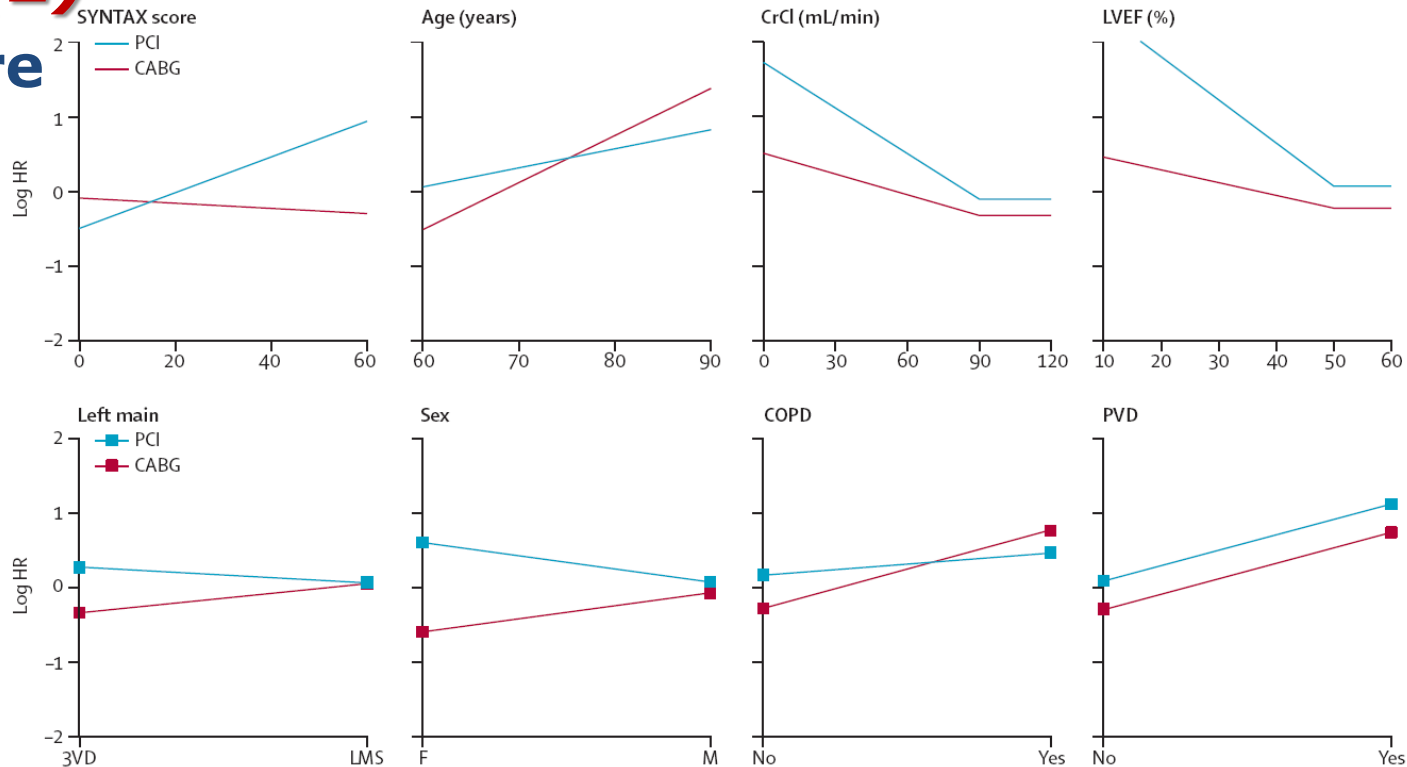
» **CrCl**

» **LV EF**

» **Sex**

» **COPD**

» **PVD**



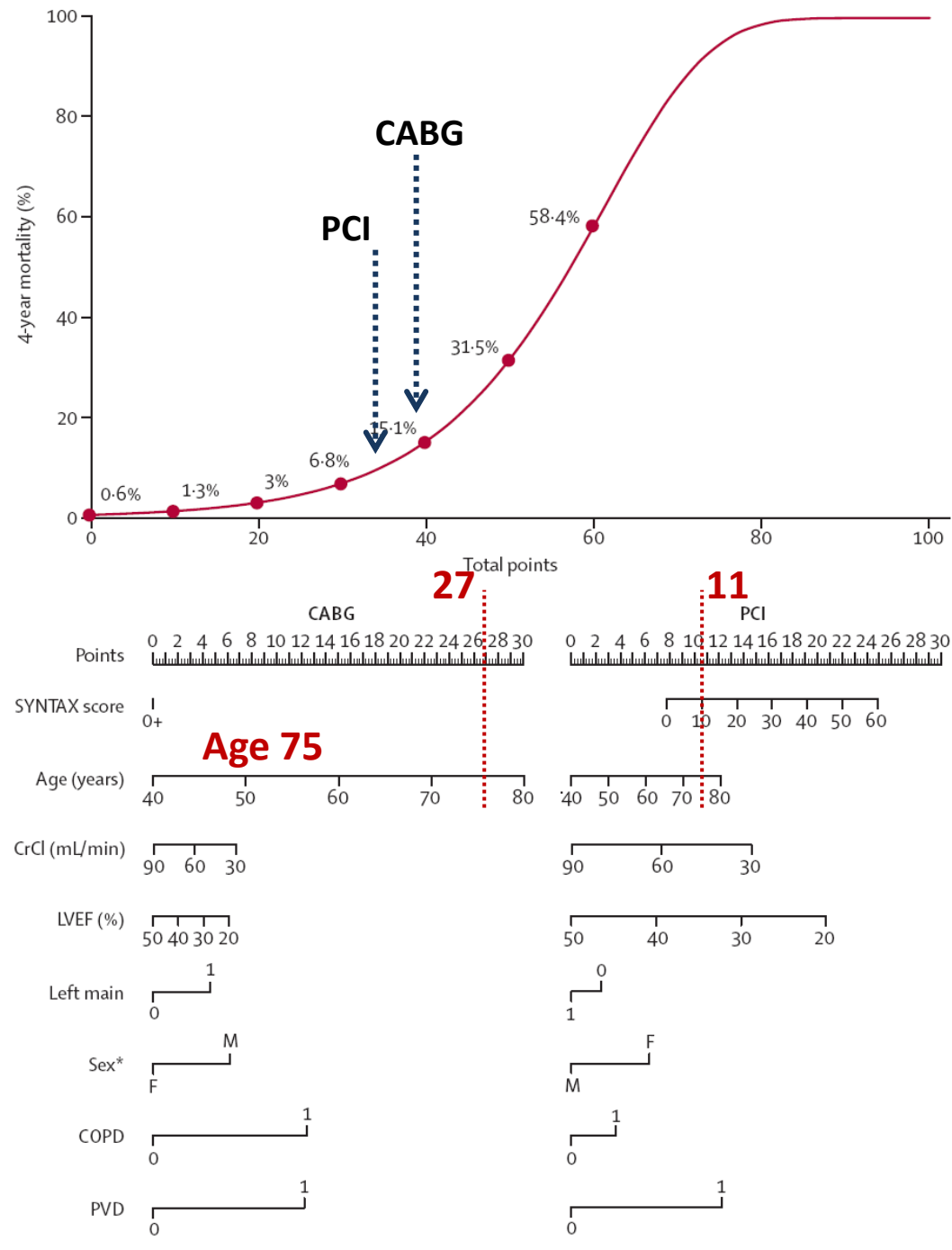
Syntax score II

CABG – 40.0

» 4y mortality 15.1%

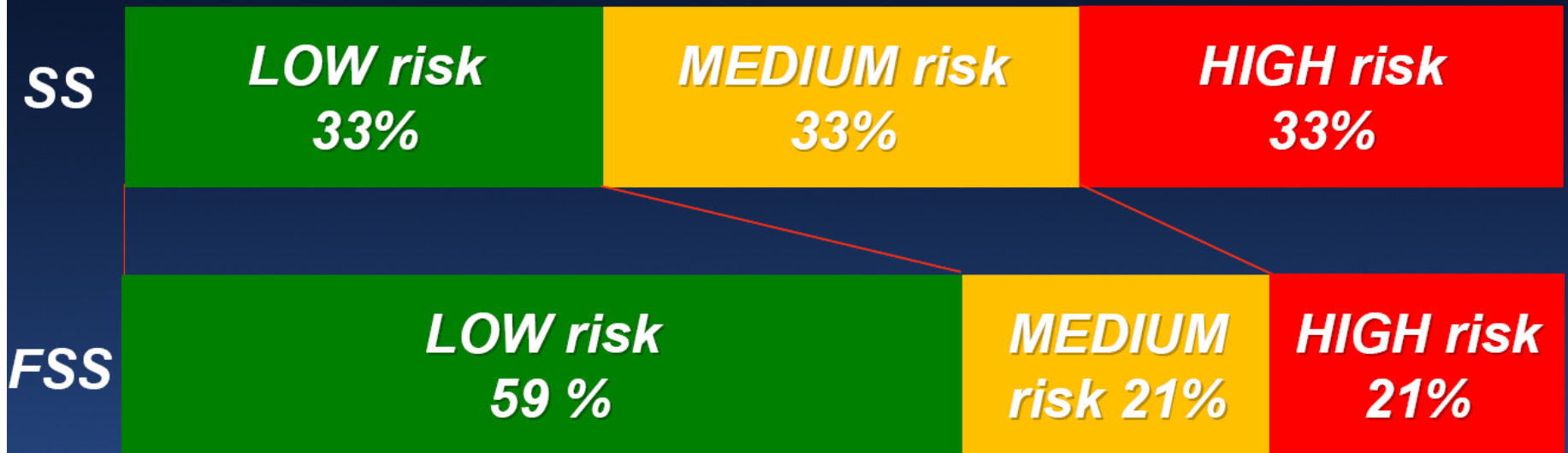
PCI - 35.0

» 4y mortality 9.8%



FFR-guided SYNTAX Score (FSS) vs. Conventional SYNTAX Score (SS)

- 497 patients of the FFR-arm of FAME I
- Syntax Score re-calculated by 3 independent reviewers
- Pts. divided into tertiles based on SS



32% of patients moved to a lower-risk group

CONCLUSIONS

**PCI
PREFERRED
IN**

- 1. STEMI**
- 2. NSTEMI (CULPRIT LESION only)**
- 3. NSTEMI W. CARDIOGENIC SHOCK – MV PCI)**
- 4. LMCA (OSTIUM, SHAFT) + 1 VD**
- 5. EARLY GRAFT FAILURE AFTER CABG**
- 6. LATE GRAFT FAILURE AFTER CABG**

CONCLUSIONS

**PCI OR CABG
TO BE
DISCUSSED
BY HEART
TEAM**

- 1. STEMI**
- 2. NSTEMI MVD EXCEPT CULPRIT LESION**
- 3. DISTAL LMCA**
- 4. MVD DISEASE GRC <32**
- 5. MVD IN DIABETICS GRC <32**

CONCLUSIONS

**CABG
remains standard
of care for more
complex
disease
and diabetics**

- 1. LMCA DISTAL
(BIFURCATION)+MVD**
- 2. MVD WITH GRC>33**
- 3. MVD IN DIABETICS<32**

PATIENT INFORMATION & CONSENT



When asked, most patients will prefer the less invasive PCI over surgery

MY PERSONAL VIEW

**UNFAVOURABLE ANATOMY IS THE ONLY REASON
FOR NOT PERFORMING PCI IN THE DES ERA:**

feasibility = indication

**feasibility = ability to perform the complex procedure
safely at a reasonable and acceptable risk**

Ethic of reciprocity – “Golden Rule”

“Do not unto others what you would not have others do to you! This is the whole law; the rest, merely commentaries upon it!”

Rabbi Hillel Hannasi, The Babylonian, 110 BC – 10 AD, Talmud