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Implications of the New ESC/EACTS Guidelines for Myocardial Revascularization in 2011



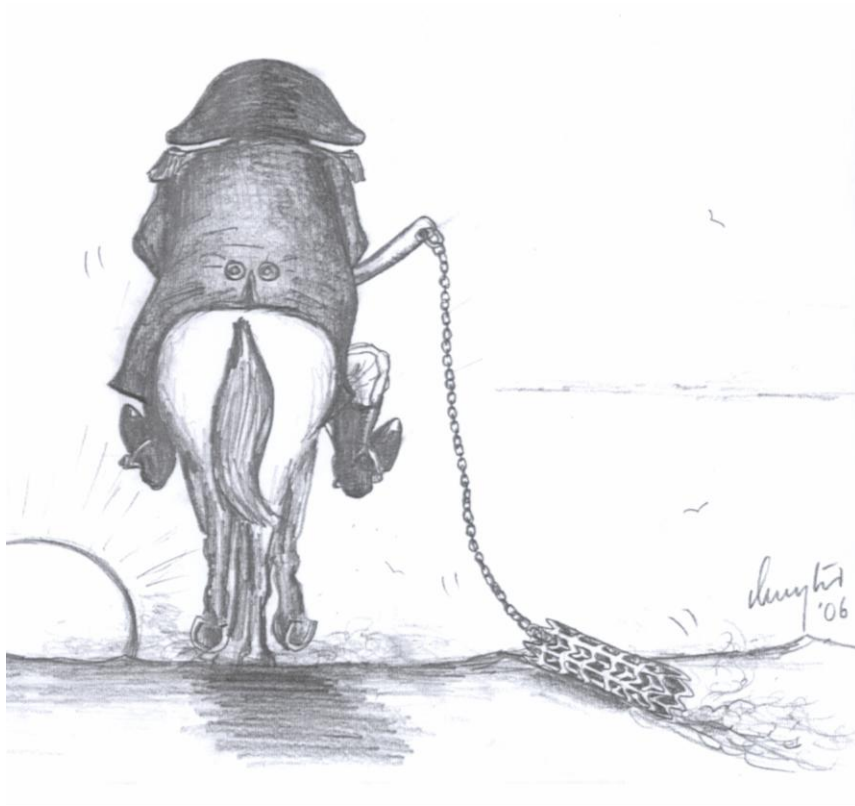
Prof. Dr. Volkmar Falk

Klinik für Herz- und Gefäßchirurgie,
Universitätsspital Zürich, Schweiz

In 2004 headlines were as such:

New devices for percutaneous coronary intervention are rapidly making bypass surgery obsolete

Donald S. Baim



... maybe not...



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)

Developed with the special contribution of the European Association for Percutaneous Cardiovascular Interventions (EAPCI)[†]

Authors/Task Force Members: William Wijns (Chairperson) (Belgium)*, Philippe Kolt (Chairperson) (Belgium)*, Nicolas Danchin (France), Carlo Di Mario (UK), Volkmar Falk (Switzerland), Thierry Folliguet (France), Scot Garg (The Netherlands), Kurt Huber (Austria), Stefan James (Sweden), Juhani Knuuti (Finland), Jose Lopez-Sendon (Spain), Jean Marco (France), Lorenzo Menicanti (Italy), Miodrag Ostojic (Serbia), Massimo F. Piepoli (Italy), Charles Pirlet (Belgium), Jose L. Pomar (Spain), Nicolaus Reifart (Germany), Flavio L. Ribichini (Italy), Martin J. Schalij (The Netherlands), Paul Sergeant (Belgium), Patrick W. Serruys (The Netherlands), Sigmund Silber (Germany), Miguel Sousa Uva (Portugal), David Taggart (UK)

- Joint Cardiology (ESC) and Cardiac Surgery (EACTS)
- 25 members from 13 European countries
 - 9 non interventional cardiologists
 - 9 interventional cardiologists
 - 8 cardiac surgeons
- Extensively reviewed by external referees

Reflects the
'Heart Team' !!!

Do we really need guidelines and multidisciplinary teams ?

Adherence of Catheterization Laboratory Cardiologists to American College of Cardiology/American Heart Association Guidelines for Percutaneous Coronary Interventions and Coronary Artery Bypass Graft Surgery

What Happens in Actual Practice?

Edward L. Hannan, PhD; Michael J. Racz, PhD; Jeffrey Gold, MD; Kimberly Cozzens, MA;
Nicholas J. Stamato, MD; Tia Powell, MD; Mary Hibberd, MD; Gary Walford, MD

Background—The American College of Cardiology and the American Heart Association have issued guidelines for the use of coronary artery bypass graft surgery (CABG) and percutaneous coronary interventions (PCI) for many years, but little

- 16142 catheter lab patients in New York 2005-07
- Treatment decision made by catheter lab cardiologist alone in 64%

angina/non-ST-elevation myocardial infarction between January 1, 2005, and August 31, 2007. The recommended treatment was compared with indications for these patients based on American College of Cardiology/American Heart

Conclusions—Patients with coronary artery disease receive more recommendations for PCI and fewer recommendations for CABG surgery than indicated in the American College of Cardiology/American Heart Association guidelines. (*Circulation*. 2010;121:267-275.)

CABG surgery and PCI, 93% were recommended for PCI and 5% for CABG surgery. Catheterization laboratory cardiologists in hospitals with PCI capability were more likely to recommend patients for PCI than hospitals in which only catheterization was performed.

Conclusions—Patients with coronary artery disease receive more recommendations for PCI and fewer recommendations for CABG surgery than indicated in the American College of Cardiology/American Heart Association guidelines. (*Circulation*. 2010;121:267-275.)

Routine non-adherence with guidelines

ACC/AHA Indication/Cath Lab Recommendation	CABG, n (%)	PCI, n (%)	Medical Treatment, n (%)	None, n (%)	Total, n (%)
CABG	712 (53)	455 (34)	156 (12)	14 (1)	1337 (100)
PCI	124 (2)	5660 (94)	255 (4)	12 (<1)	6051 (100)
CABG and PCI	84 (5)	1608 (93)	26 (2)	4 (<1)	1722 (100)
Neither CABG or PCI	70 (6)	261 (21)	873 (71)	19 (2)	1223 (100)
Total	990 (10)	7984 (77)	1310 (13)	49 (<1)	10 333 (100)

Cath Lab indicates catheterization laboratory.

- 92% of PCI procedures ad hoc (ie no time for real choice/ genuine consent)
- Chance of PCI increased in hospitals with PCI facilities

The variation in the percentage of patients in individual hospitals who were indicated for CABG but recommended for PCI was quite wide, with a range from 4% to 91% among

Hannan, Circ 2010;121:267

Widespread Patient Misconceptions Regarding the Benefits of **elective** Percutaneous Coronary Intervention

498 ELECTIVE PATIENTS Jan 2006-Oct 2007: 70% responded

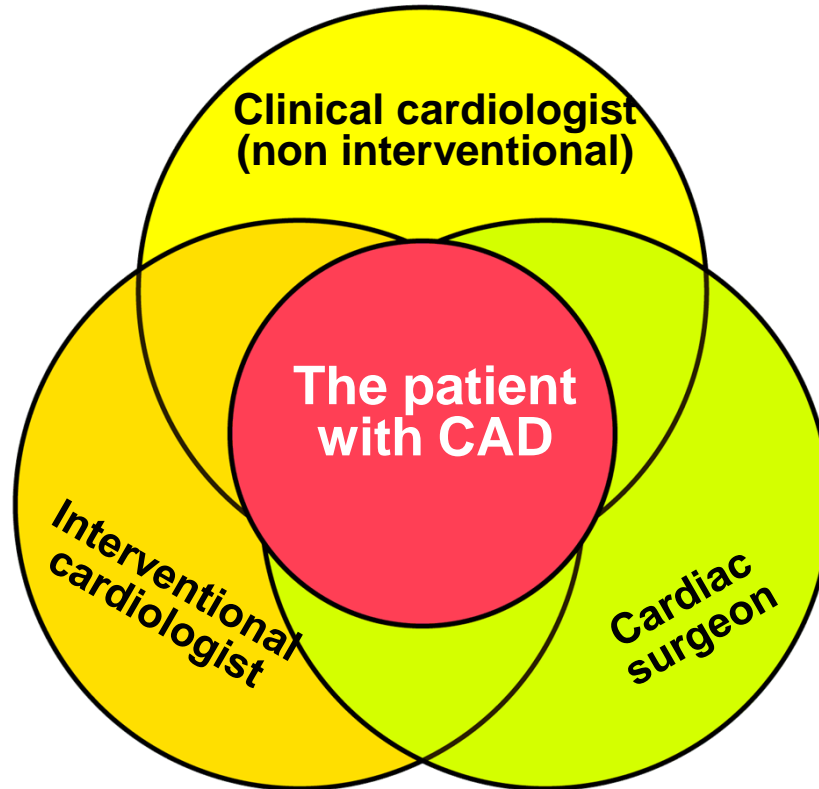
Patient perception	%	Correct ?
PCI was emergent rather than elective	33%	X
PCI would help angina	31%	✓
PCI had saved their life	42%	X
PCI would extend their life	66%	X
PCI would prevent further heart attacks	70%	X
Discussion of alternative therapies	32%	X
Offer of medical therapy	18%	X
Discussion of CABG	13%	X

- Presumably misunderstanding rather than misinformation but very worrying that so many patients completely misunderstood: 'ad hoc' PCI
- No surgical opinion in 87% !!!
- Need for MDT approach

Recommendations for decision making and patient information

	Class	Level
It is recommended that patients be adequately informed about the potential benefits and short- and long-term risks of a revascularisation procedure. Enough time should be spared for informed decision making.	I	C
The appropriate revascularisation strategy in patients with MVD should be discussed by the Heart Team.	I	C

The Heart Team



Task Force composition = 8 clinical cardiologists (non interventional)
+ 9 interventional cardiologists + 8 cardiac surgeons

Multidisciplinary Decision Pathways, Patient Informed Consent and Timing of Intervention

	Stable MVD	Stable with indication for ad hoc PCI*
Multidisciplinary decision making	Required.	According to predefined protocols.
Informed consent	Written informed consent#.	Written informed consent#.
Time to revascularisation	Elective: No time constraints.	Elective: No time constraints.
Procedure	Plan most appropriate intervention allowing enough time from diagnostic catheterization to intervention.	Proceed with intervention according to institutional protocol defined by local Heart Team.

Plan most appropriate intervention allowing enough time from diagnostic catheterization to intervention

3VD
(No Left Main)

NY-Registry: The “pre-Syntax” real world

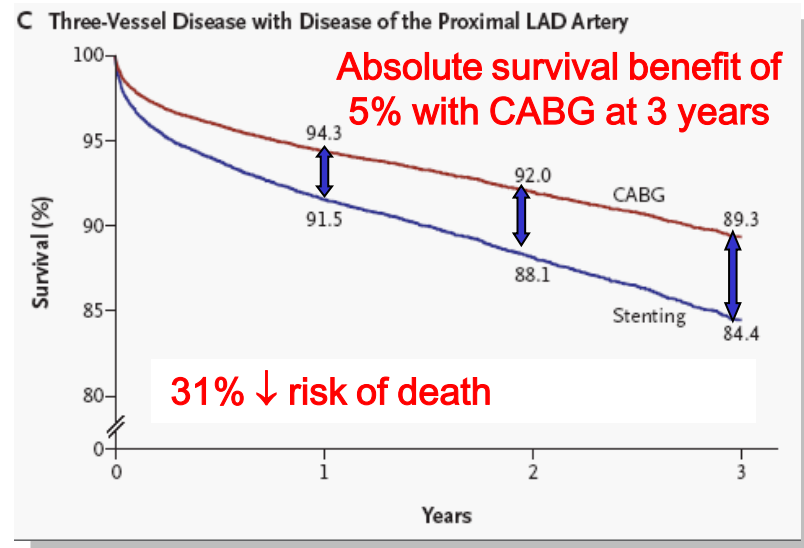
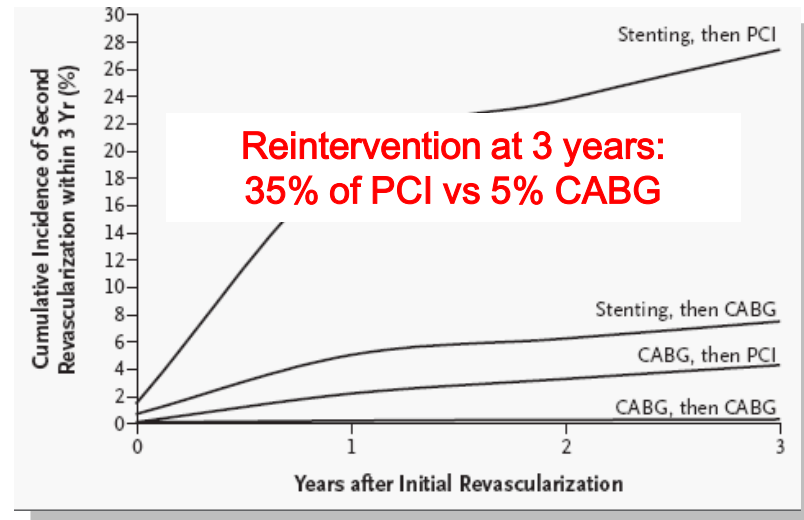
ORIGINAL ARTICLE

Long-Term Outcomes of Coronary-Artery Bypass Grafting versus Stent Implantation

Edward L. Hannan, Ph.D., Michael J. Racz, Ph.D., Gary Walford, M.D., Robert H. Jones, M.D., Thomas J. Ryan, M.D., Edward Bennett, M.D., Alfred T. Culliford, M.D., O. Wayne Isom, M.D., Jeffrey P. Gold, M.D., and Eric A. Rose, M.D.

37,212 CABG and 22,102
PCI (BMS) pts. c > 2VD
Propensity matched for
cardiac and non-cardiac co-
morbidity risk

CABG: Survival + freedom from
revascularization increase with time!



CABG has survival benefit over PCI in routine practice

Author	Year	Patients	DM	Stents	Follow-Up	CABG vs PCI
Hannan	NEJM 2008	17,400p	-	DES	1.5 yrs	HR 0.8 (p=0.03)
Bair	CIRC 2007	6,369	-	DES	5 yrs	HR 0.85 (p<0.001)
Javaid	CIRC 2007	1,680	-	DES	1 yr	97% vs 89%
Hannan	NEJM 2005	59,314p	-	BMS	3 yrs	↓ mortality 5%
Malenka	CIRC 2005	14,493	-	BMS	7 yrs	HR 0.6 (p <0.01)
BARI	JACC 2007	353	+	-	10 yrs	58% vs 46%
Javaid	CIRC 2007	601	+	DES	1 yr	3% vs 12-18%
Niles	JACC 2001	2,766	+	-	5 yrs	HR 0.25-0.5
SUMMARY		102,976			1-10 yrs	↓ mortality

- In >100,000 (mainly propensity matched) patients by 3-5 years
- PCI decreases absolute survival by around 5%
- PCI increases absolute reintervention x5 vs CABG

Taggart DP. Lancet 2009; 373:1150-2

Ⓜ PCI or CABG in coronary artery disease?

‘Most significantly, the randomized trials only enrolled around 5%-10% of the eligible population, the majority of whom had single or double vessel disease and normal left ventricular function [2], a group in whom it was already well established that there was no prognostic benefit of CABG [3]. By largely excluding patients with a known survival benefit from CABG (left main+/- triple vessel coronary artery disease and especially with impaired ventricular function [3]), the trials ignored the prognostic benefit of surgery in more complex coronary artery disease. **Nevertheless, the inappropriate generalization of the trial results from their highly select populations to most patients with multivessel disease has been ubiquitous in the literature and has, at least in part, justified the explosive growth in PCI in developed countries.**’

[2] Taggart D, ATS 2006;82:1966-75

[3] Yusuf S, Lancet 1994 ;344:563-70

The 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

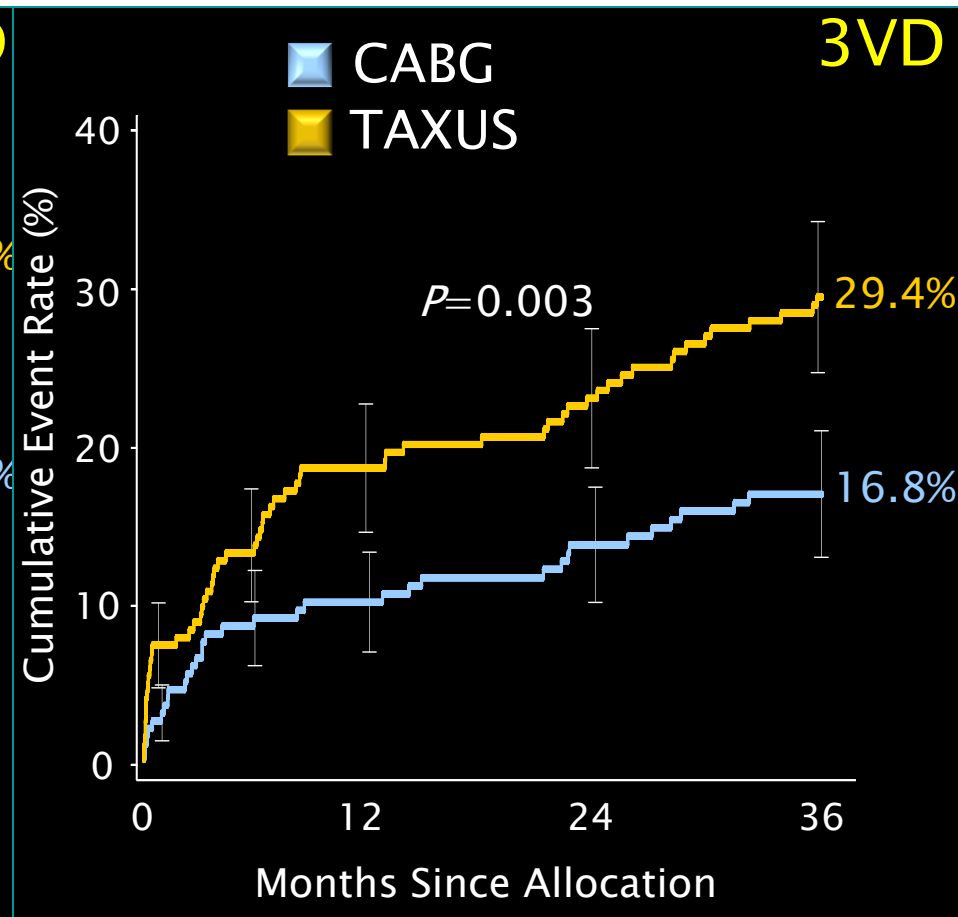
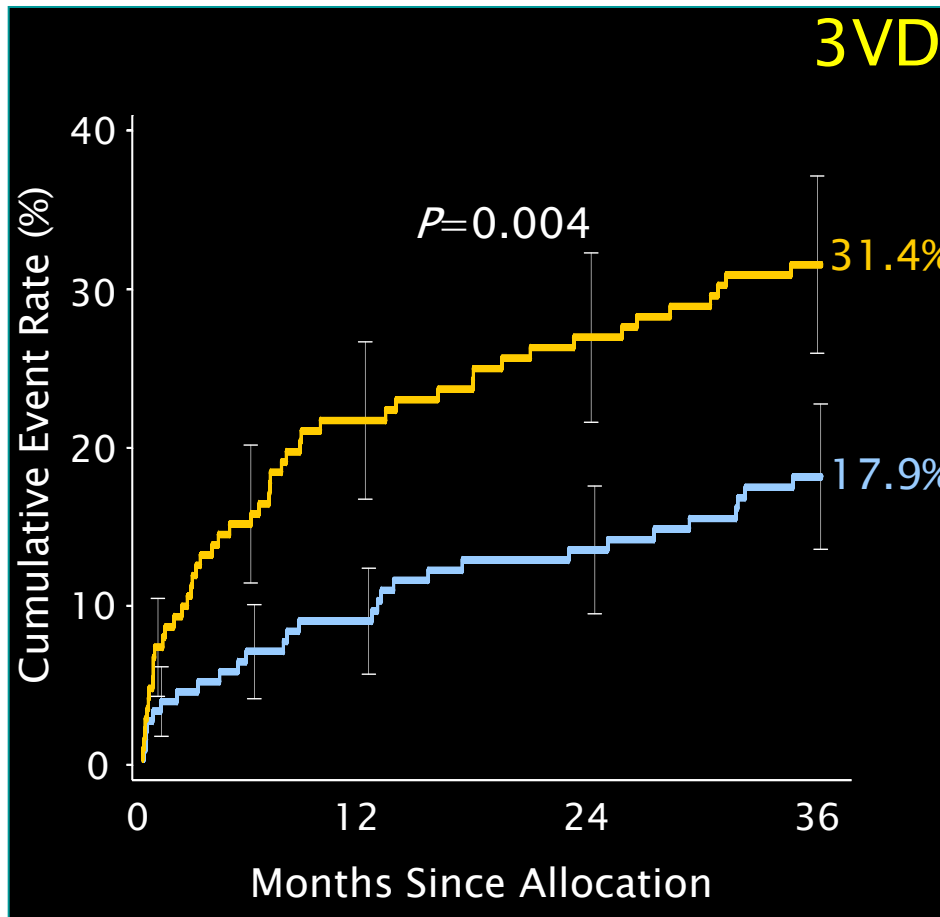
Patrick W. Serruys, M.D., Ph.D., Marie-Claude Morice, M.D., A. Pieter Kappetein, M.D., Ph.D.,
Antonio Colombo, M.D., David R. Holmes, M.D., Michael J. Mack, M.D., Elisabeth Stähle, M.D.,
Ted E. Feldman, M.D., Marcel van den Brand, M.D., Eric J. Bass, B.A., Nic Van Dyck, R.N., Katrin Leadley, M.D.,
Keith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

- Landmark trial (most important trial ever of PCI vs CABG)
- Designed to look at 5 year outcomes death and MACCE
- 'All comer' trial (rather than highly select patients)
- Parallel Registry (**35% of patients straight to CABG !!**)

MACCE to 3 Years by SYNTAX Score Tercile

High Scores (≥ 33)

Intermediate Scores (>22)



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

SYNTAX results (3/5 Years): 3 Vessel

3 vessel (1095)			
	PCI	CABG	p
nos	546	549	
Death	9.5	5.7 (-40%)	0.02
CVA	2.6	2.9 (+12%)	0.64
MI	7.1	3.3 (-54%)	0.005
D+C+M	19.4	10 (-48%)	<0.001
Revasc	28.8	19 (-35%)	<0.001

- 79% of ALL 3VD (SYNTAX >22) better survival with CABG
- CVA similar with PCI and CABG
- Entirely consistent with propensity matched Registry Data

Joint ESC/EACTS Guidelines for Myocardial Revascularization 2010

Table 9. Indications for CABG versus PCI in stable patients with lesions suitable for both procedures and low predicted surgical mortality

Subset of CAD by anatomy	Favours CABG	Favours PCI
1VD or 2VD - non-proximal LAD	IIb C	I C
1VD or 2VD - proximal LAD	I A	IIa B
3VD simple lesions, full functional revascularisation achievable with PCI, SYNTAX score ≤ 22	I A	IIa B
3VD complex lesions, incomplete revascularisation achievable with PCI, SYNTAX score > 22	I A	III A
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

- In the most severe patterns of CAD, CABG appears to offer a survival advantage as well as a marked reduction in the need for repeat revascularisation.

Left main

STATE-OF-THE-ART PAPER AND COMMENTARY

Revascularization for Unprotected Left Main Stem Coronary Artery Stenosis

Stenting or Surgery

David P. Taggart, MD (HONS), PhD, FRCS,* Sanjay Kaul, MD, FACC,†
William E. Boden, MD, FACC,‡ T. Bruce Ferguson, JR, MD, FACC,§
Robert A. Guyton, MD, FACC,¶ Michael J. Mack, MD,# Paul T. Sergeant, MD, PhD,††
Richard J. Shemin, MD, FACC,** Peter K. Smith, MD, FACC,||
Salim Yusuf, DPHIL, FRCPC, FRSC, FACC‡‡

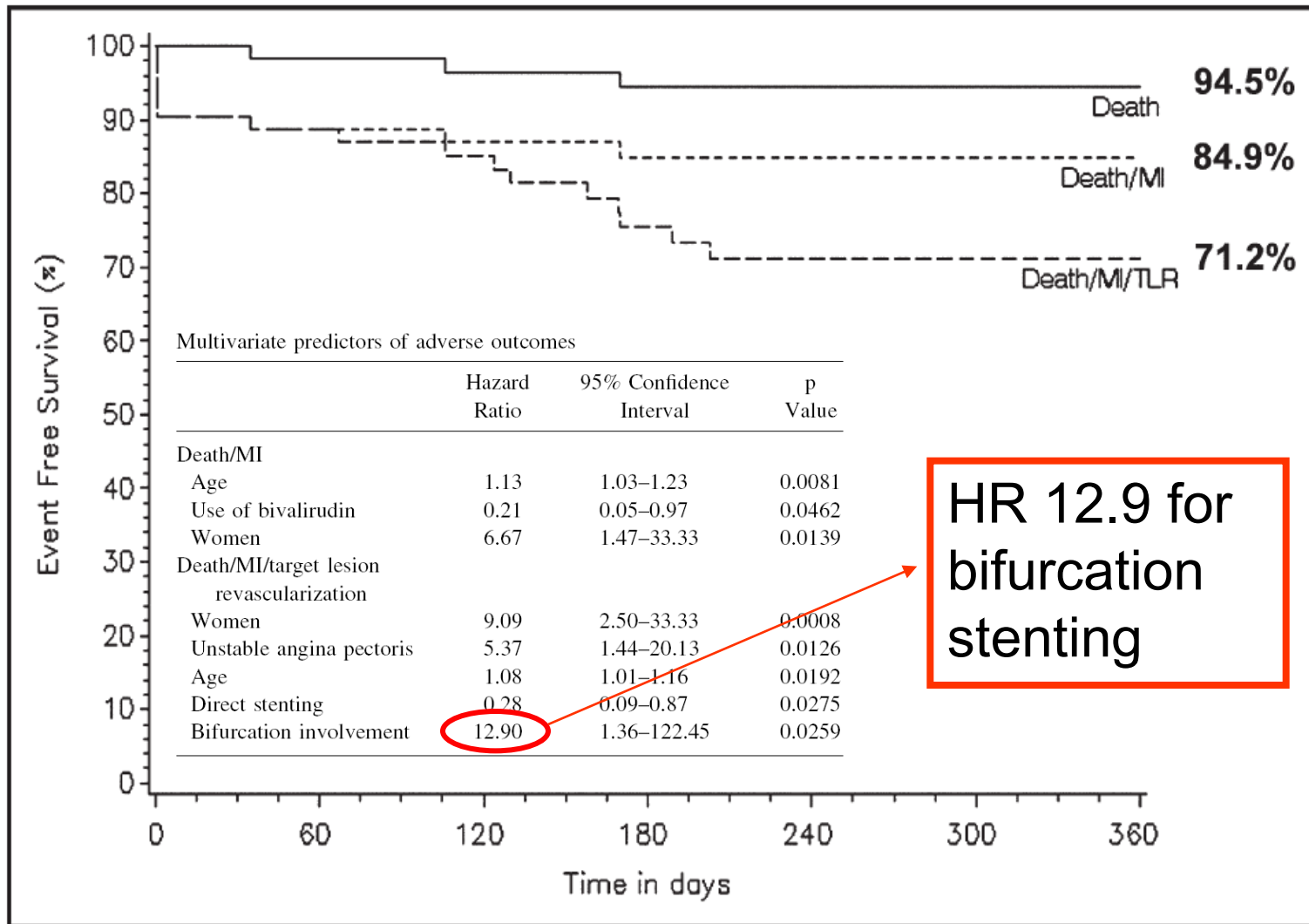
Oxford, United Kingdom; Los Angeles, California; Buffalo, New York; Greenville and Durham,

- <90% of LMS are distal/bifurcation (very high risk of restenosis)
- <90% have multivessel CAD (CABG already offers survival benefit)

(CABG) is traditionally regarded as the “standard of care” because of its well-documented and durable survival advantage. There is now an increasing trend to use drug-eluting stents for LMS stenosis rather than CABG despite very little high-quality data to inform clinical practice. We herein: 1) evaluate the current evidence in support of the use of percutaneous revascularization for unprotected LMS; 2) assess the underlying justification for randomized controlled trials of stenting versus surgery for unprotected LMS; and 3) examine the optimum approach to informed consent. We conclude that CABG should indeed remain the preferred revascularization treatment in good surgical candidates with unprotected LMS stenosis. (J Am Coll Cardiol 2008;51:885–92) © 2008 by the American College of Cardiology Foundation

PCI of unprotected LM stenosis

Event free survival DES, 1 y FU



SYNTAX RCT Results (3/5 Years): Left Main: n=705

	PCI	CABG	p
n	357	348	
Death	7.3	8.4 (+15%)	0.64
CVA	1.2	4.0 (+333%)	0.02
MI	6.9	4.1 (-40%)	0.14
D+C+M	20	11.1 (-45%)	0.004
Revasc	26.8	22.3 (-17%)	0.20

EXCEL Trial (started Sept 2010)
 2500 patient RCT of PCI vs CABG
 in SYNTAX LM <33

Low <23	n	118	104	p
	death	2.6	6.0	.21
	CVA	0.9	4.1	.12
	MI	4.3	2.0	.36
	D+C+M	6.9	11	.26
	Revasc	15.4	13.4	.69

Intd 23-32	n	103	92	p
	death	4.9	12.4	.06
	CVA	1.0	2.3	.46
	MI	5.0	3.3	.63
	D+C+M	10.8	15.6	.29
	Revasc	15.9	14.0	.75

High >32	n	135	149	p
	death	13.4	7.6	.10
	CVA	1.6	4.9	.13
	MI	10.9	6.1	.17
	D+C+M	20.1	15.7	.34
	Revasc	27.7	9.2	.001

Joint ESC/EACTS Guidelines for Myocardial Revascularization 2010

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- In the most severe patterns of CAD, CABG appears to offer a survival advantage as well as a marked reduction in the need for repeat revascularisation.

Unprotected Left Main Stenoses: Evidence for CABG

UK: all 114,300 CABG patients 2004-08 (Blue Book June 2009)

	NO LMS	LMS	
	69,775	30,128	
In hospital mortality	1.5%	2.5%	<0.001
1 year survival	97%	95%	<0.001
5 year survival	90%	87%	<0.001

- All-comer including 1/3 'high risk' (urgent, elderly, poor LV function)
- Mortality in elective patients 40% lower ie 1.5%
- Results far superior than in SYNTAX
- Patients with LMS have more comorbidity and more severe CAD ("high calcific load")

How can we improve?

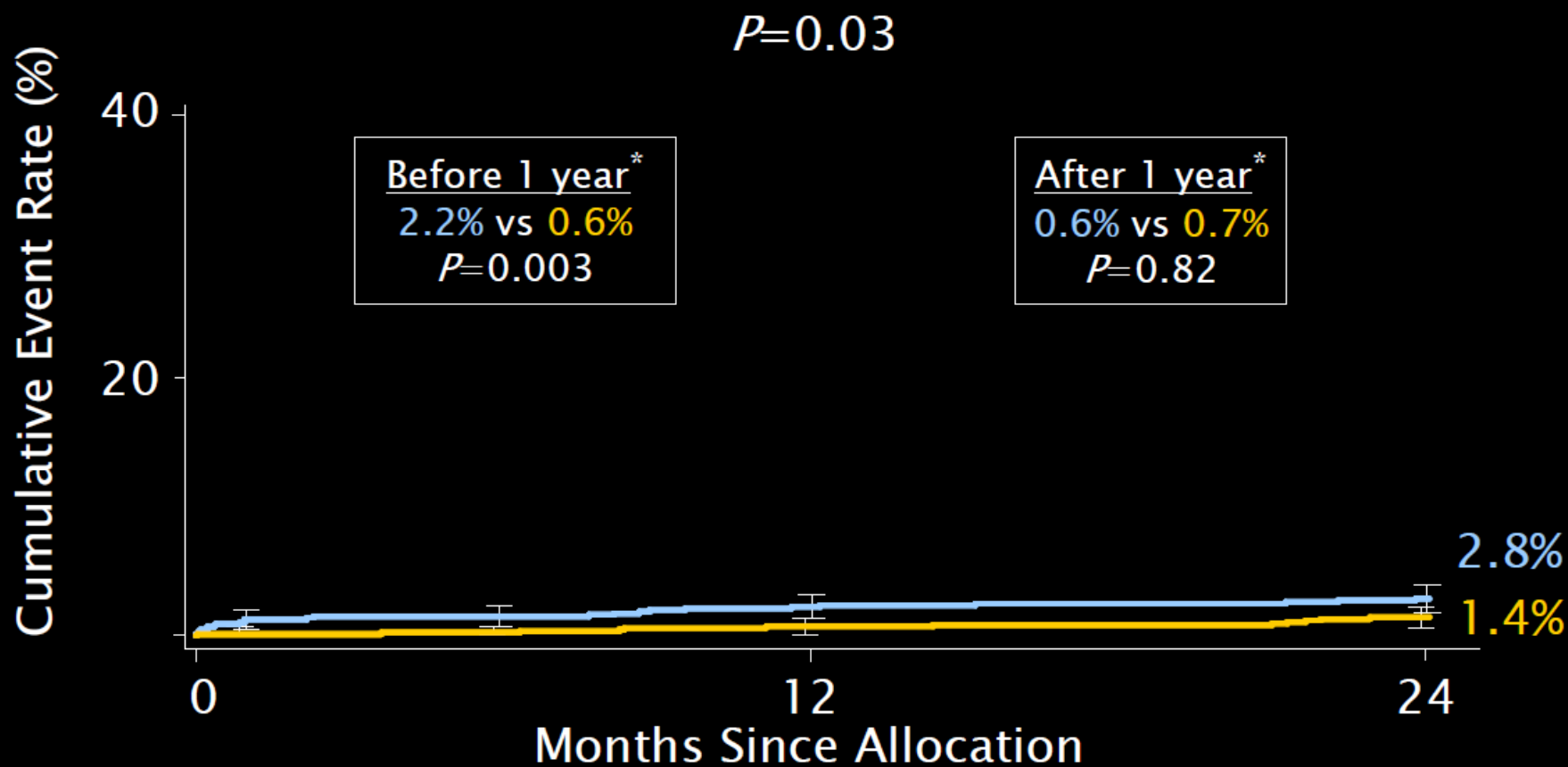
- Reduce stroke rate
- Use arterial grafting
- Use of functional Imaging

CVA to 2 Years



■ CABG (N=897)

■ TAXUS (N=903)



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

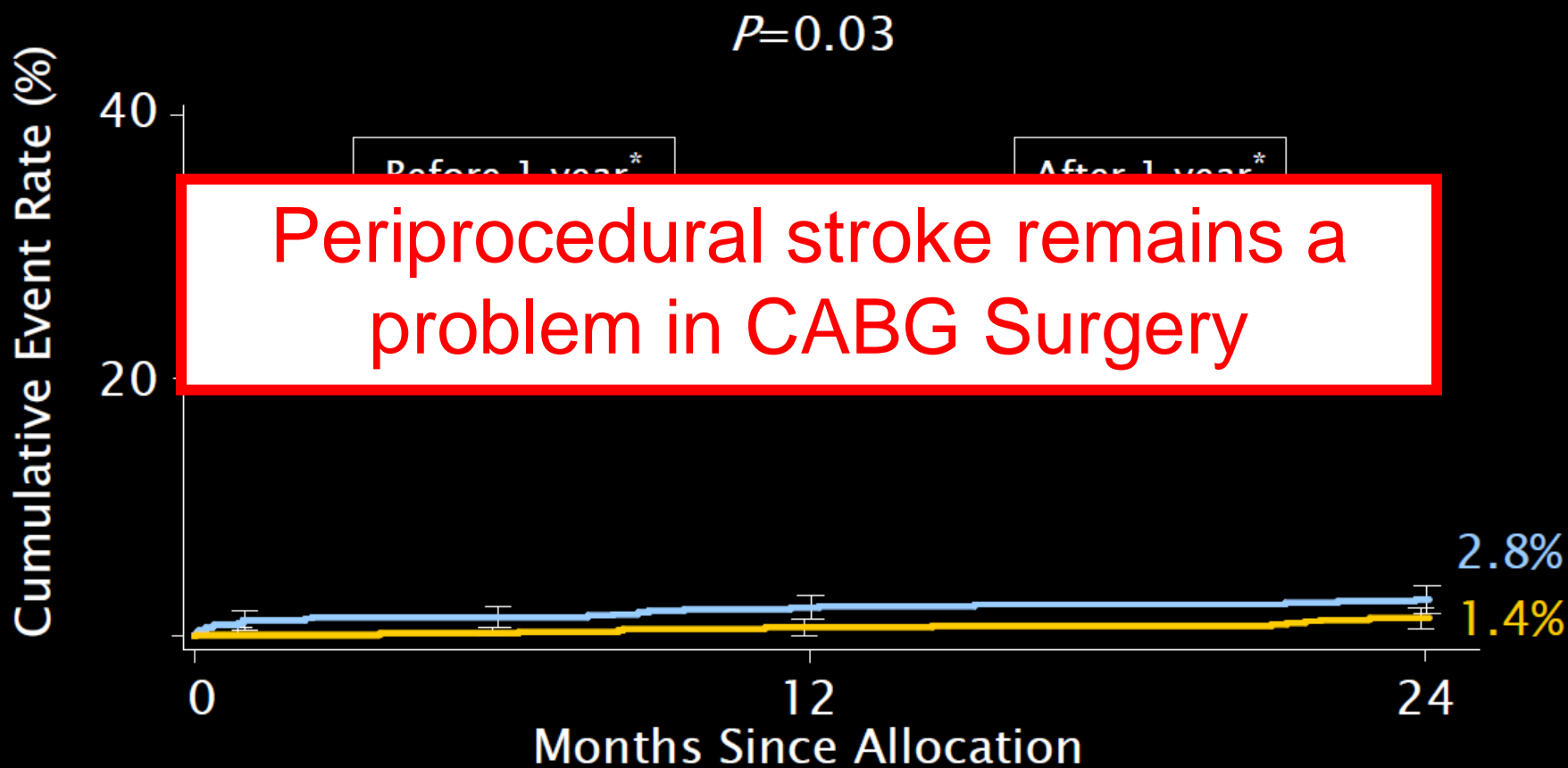
ITT population

CVA to 2 Years



■ CABG (N=897)

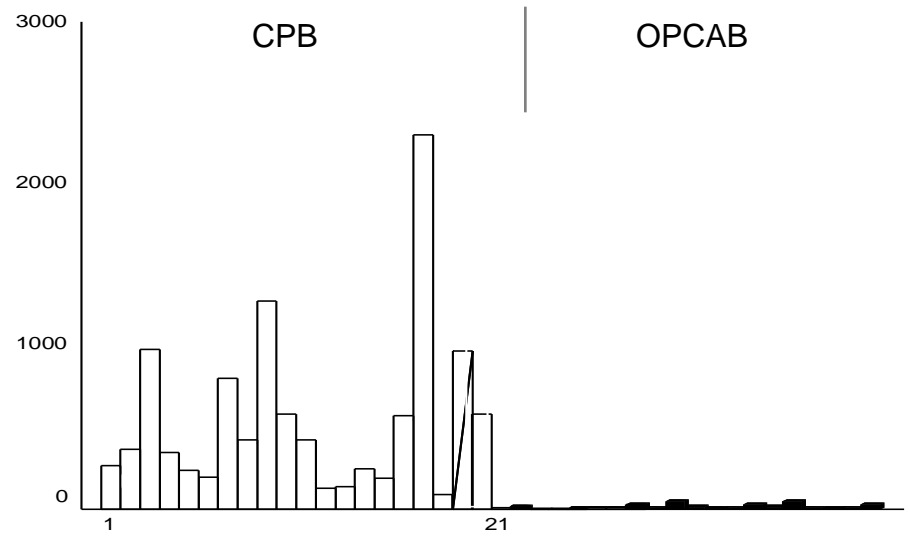
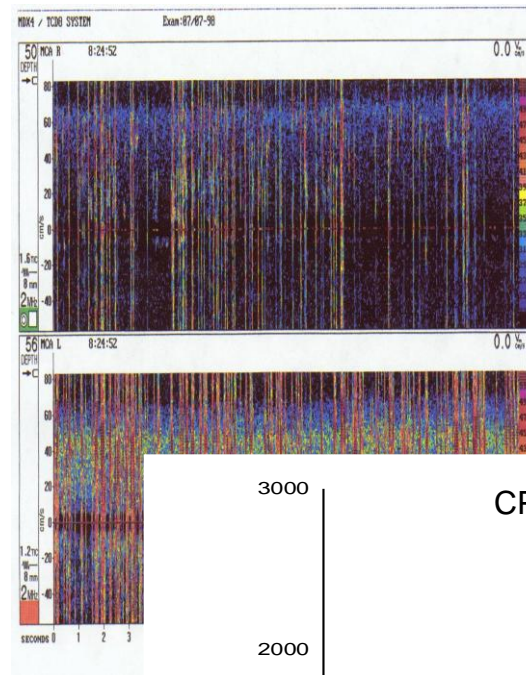
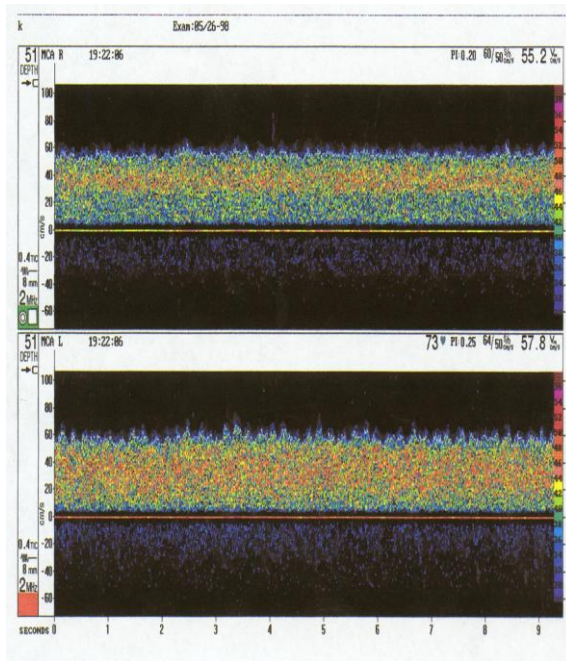
■ TAXUS (N=903)



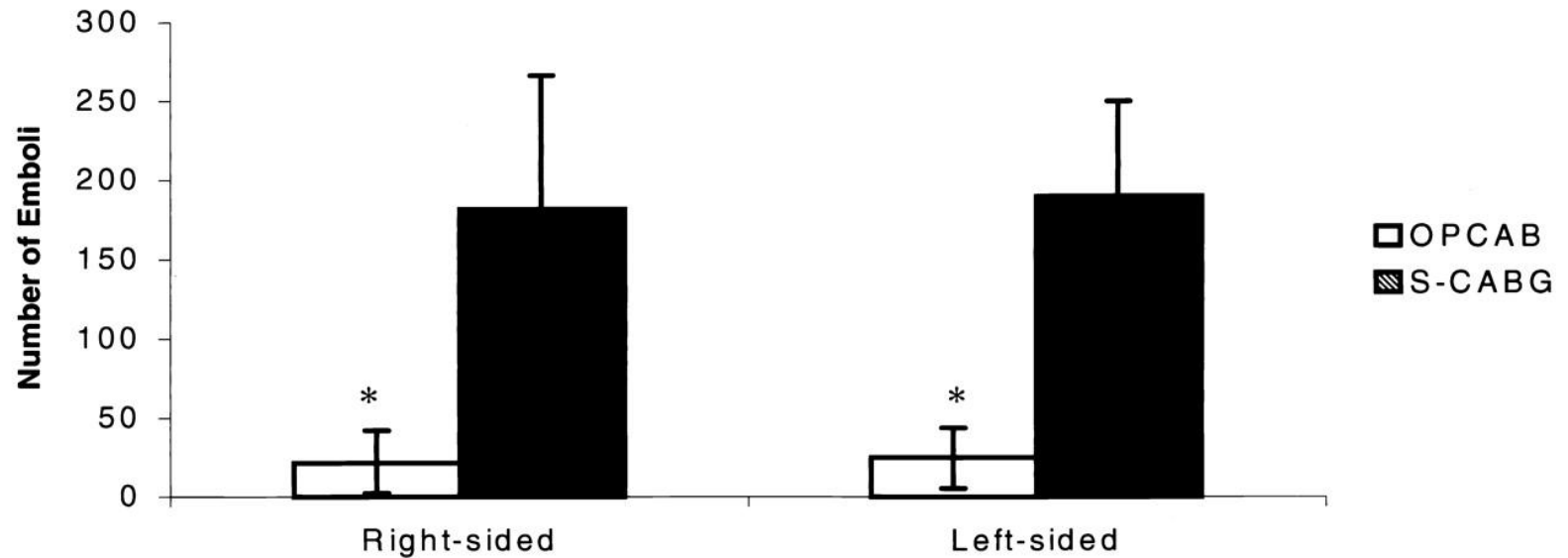
Cumulative KM Event Rate \pm 1.5 SE; log-rank P value; *Binary rates

ITT population

TCD - Normal flow-pattern MCA during CPB + HITS

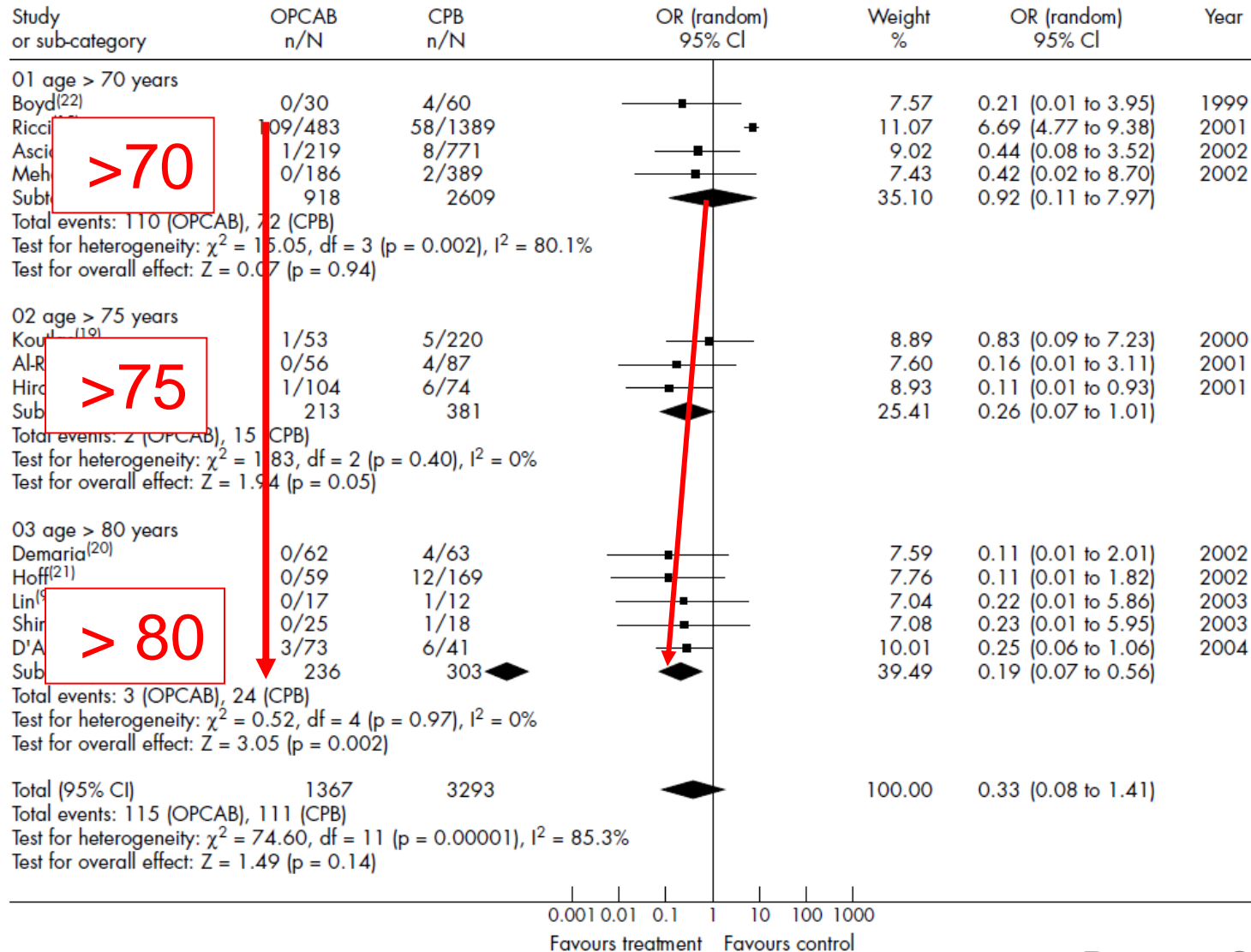


OPCAB reduces embolic load



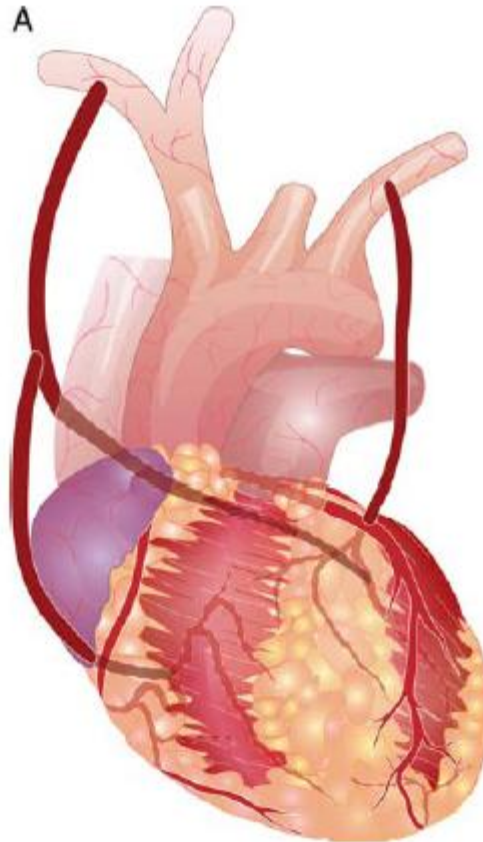
Comparison of mean cerebral embolic counts OPCAB and CPB-CABG groups

OPCAB reduces stroke in elderly



Stay off-pump and do not touch the aorta!

Volkmar Falk*



The Zurich Experience

Partial Clamping vs. Heartstring No Touch for Proximal Anastomosis

n	technique	Stroke
567	partial Clamping (PC)	2.3%
1368	``no touch`` with Heartstring (HS)	0.7%
268	no touch all arterial grafting	0.7%
2111	On-pump Control Group	2.4%

Non Adjusted Comparison PC vs. HS

OR 0.28 95% CI 0.1-0.6 P<0.001

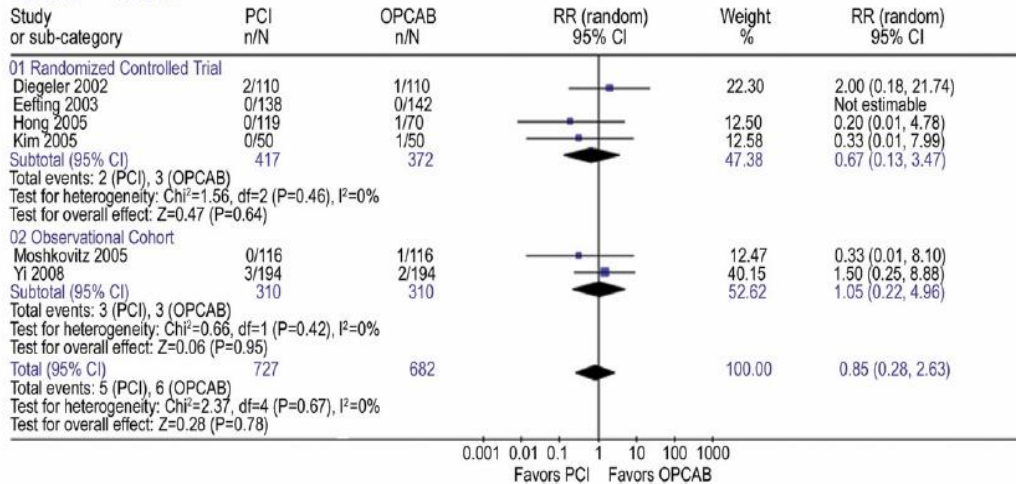
Propensity Adjusted Comparison PC vs. HS

OR 0.39 95% CI 0.1-0.8 P=0.04

The risk of intra-operative stroke can be minimized by surgical technique but not completely eliminated! This also applies to all arterial grafting as well as PCI.

Off-Pump vs. PCI Meta Analysis

Review: Percutaneous Coronary Intervention versus Off-pump Coronary Artery Bypass Grafting
 Comparison: 01 PCI versus OPCAB
 Outcome: 01 Stroke



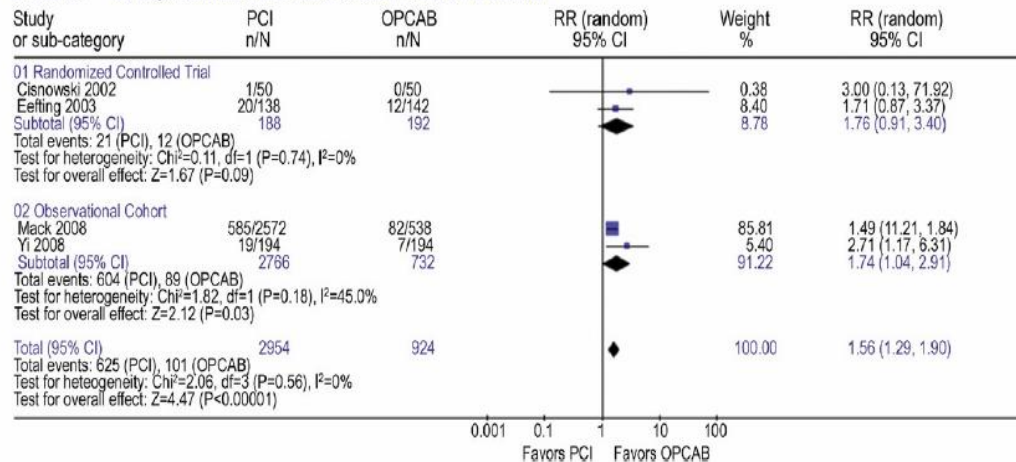
10 studies

4,821 patients 3,450
 PCI, 1,371 OPCAB

Similar rates of stroke,
 myocardial infarction,
 cardiac mortality, and all-
 cause mortality

At 12-month MACCE
 and need for repeat
 revasc. significantly
 lower in OPCAB group

Review: Percutaneous Coronary Intervention versus Off-pump Coronary Artery Bypass Grafting
 Comparison: 01 PCI versus OPCAB
 Outcome: 08 Major Cardiac and Cerebrovascular Events at 12 Months



Technical recommendations for CABG

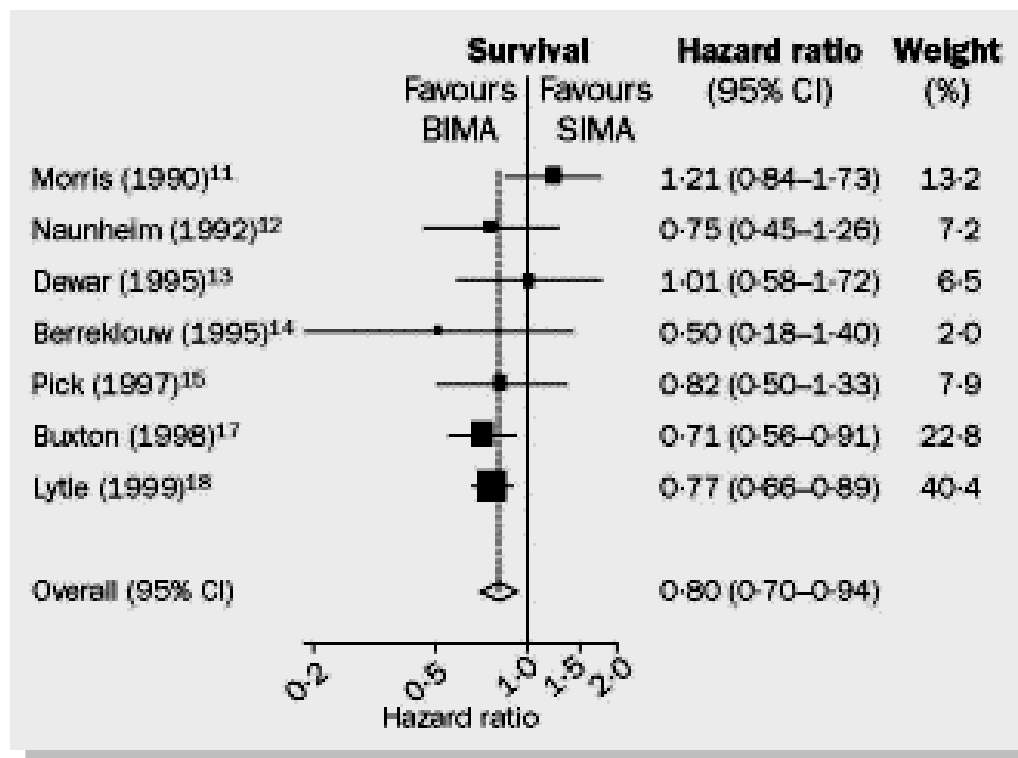
	Class	Level
Procedures should be performed in a hospital structure and by a team specialized in cardiac surgery, using written protocols.	I	B
Arterial grafting to the LAD system is indicated.	I	A
Complete revascularisation with arterial grafting to non-LAD coronary systems is indicated in patients with reasonable life-expectancy.	I	A
Minimisation of the aortic manipulation is recommended.	I	C
Graft evaluation is recommended before leaving the operating theatre.	I	C

- Patients admitted for surgical revascularisation are usually taking many medications, including β -blockers, angiotensin-converting enzyme inhibitors, statins, and anti-platelet drugs. β -blockers should not be stopped to avoid acute ischaemia upon discontinuation.

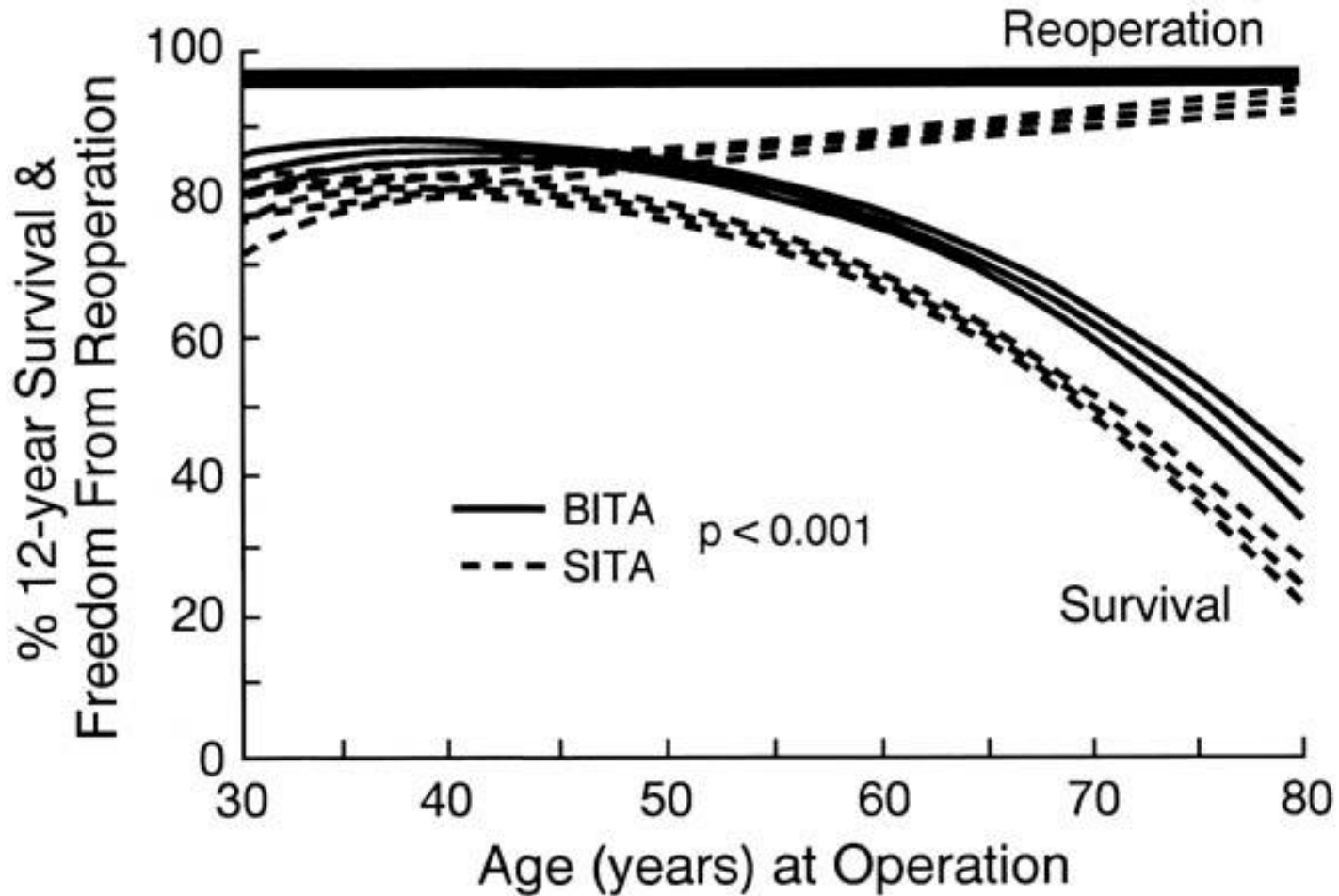
How can we improve?

- Reduce stroke rate
- Use arterial grafting
- Use of functional Imaging

Survival benefit for bilateral IMA



Bilateral ITA – no reoperation!




Technical recommendations for CABG

	Class	Level
Procedures should be performed in a hospital structure and by a team specialized in cardiac surgery, using written protocols.	I	B
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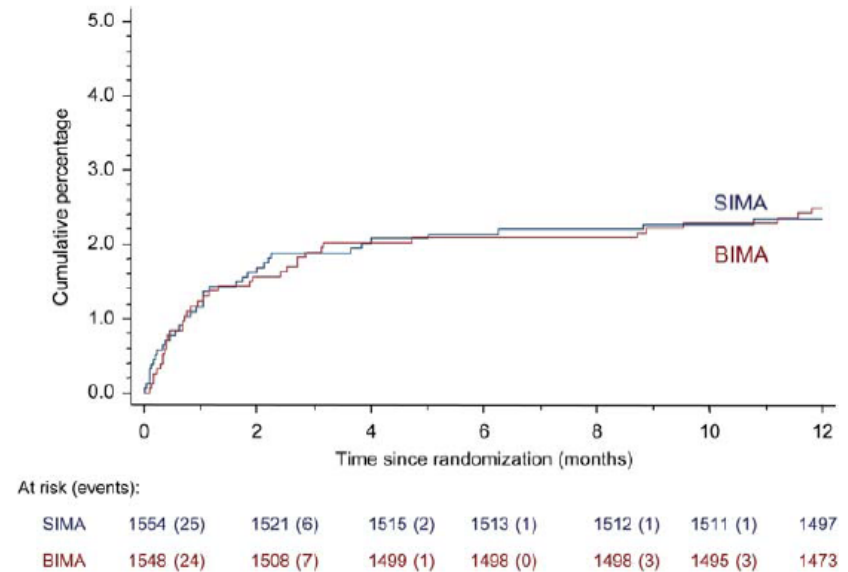
Results of contemporary CABG are excellent!

 European Heart Journal
doi:10.1093/eurheartj/ehq318

**FASTTRACK
ESC HOT LINE**

Randomized trial to compare bilateral vs. single internal mammary coronary artery bypass grafting: 1-year results of the Arterial Revascularisation Trial (ART)

David P. Taggart^{1*}, Douglas G. Altman², Alastair M. Gray³, Belinda Lees^{4,5}, Fiona Nugara⁴, Ly-Mee Yu², Helen Campbell³ and Marcus Flather^{4,5}, on behalf of the ART Investigators



- 3102 patients randomized to single or bilateral IMA grafts
- 67 surgeons, 28 centres, seven countries
- 30 day mortality 1.2%, 1 yr mortality 2.4%
- 1 year incidence of stroke, MI, repeat revascularization all < 2%

How can we improve?

- Reduce stroke rate
- Use arterial grafting
- Use of functional Imaging

Function matters!

The **NEW ENGLAND**
JOURNAL *of* **MEDICINE**

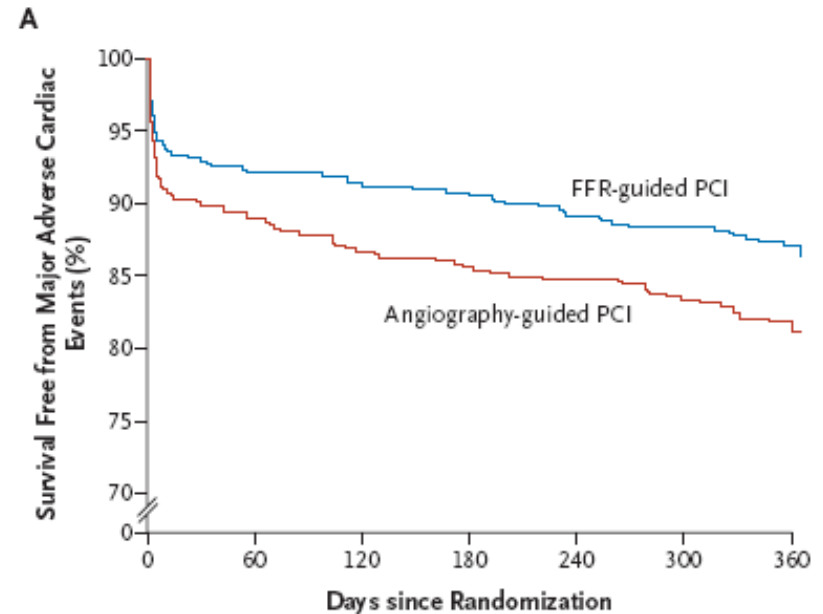
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Fractional Flow Reserve versus Angiography for Guiding Percutaneous Coronary Intervention

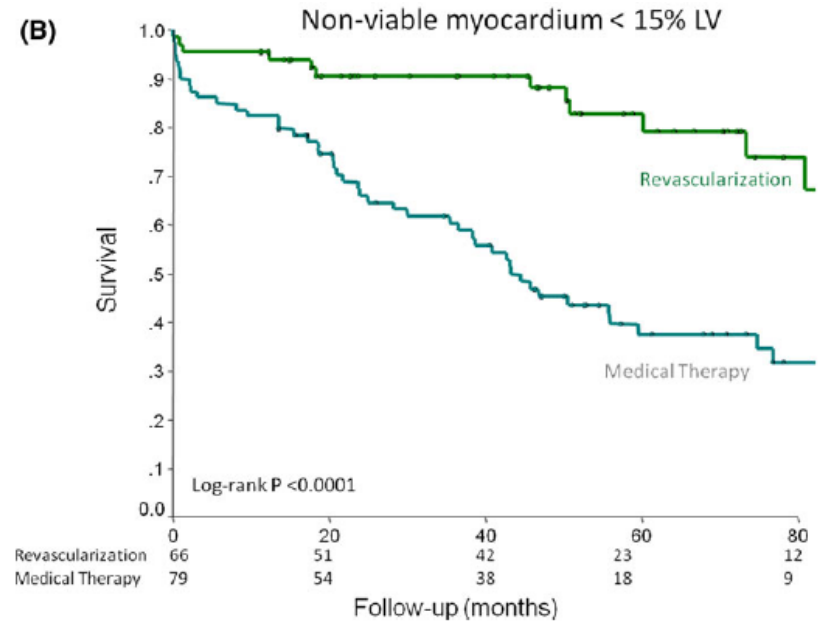
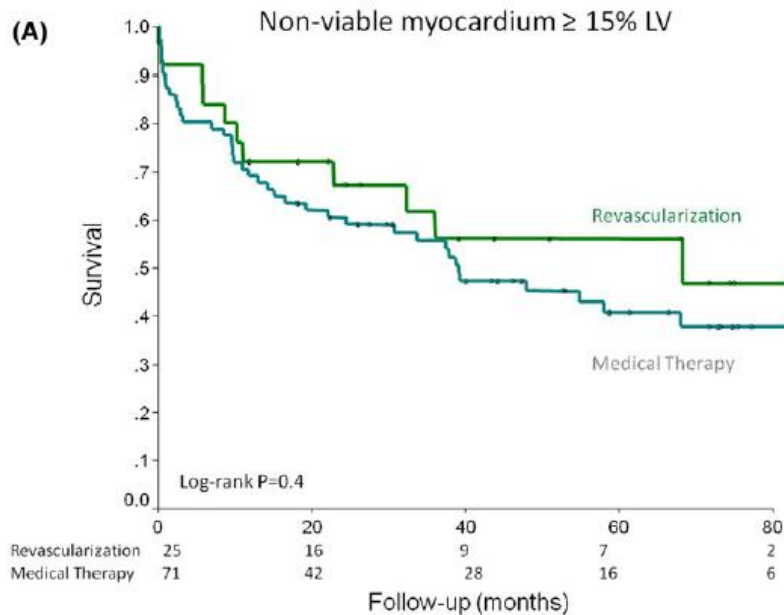
Pim A.L. Tonino, M.D., Bernard De Bruyne, M.D., Ph.D., Nico H.J. Pijls, M.D., Ph.D.,
Uwe Siebert, M.D., M.P.H., Sc.D., Fumiaki Ikeno, M.D., Marcel van 't Veer, M.Sc., Volker Klauss, M.D., Ph.D.,
Ganesh Manoharan, M.D., Thomas Engström, M.D., Ph.D., Keith G. Oldroyd, M.D., Peter N. Ver Lee, M.D.,
Philip A. McCarthy, M.D., Ph.D., and William F. Fearon, M.D., for the FAME Study Investigators*



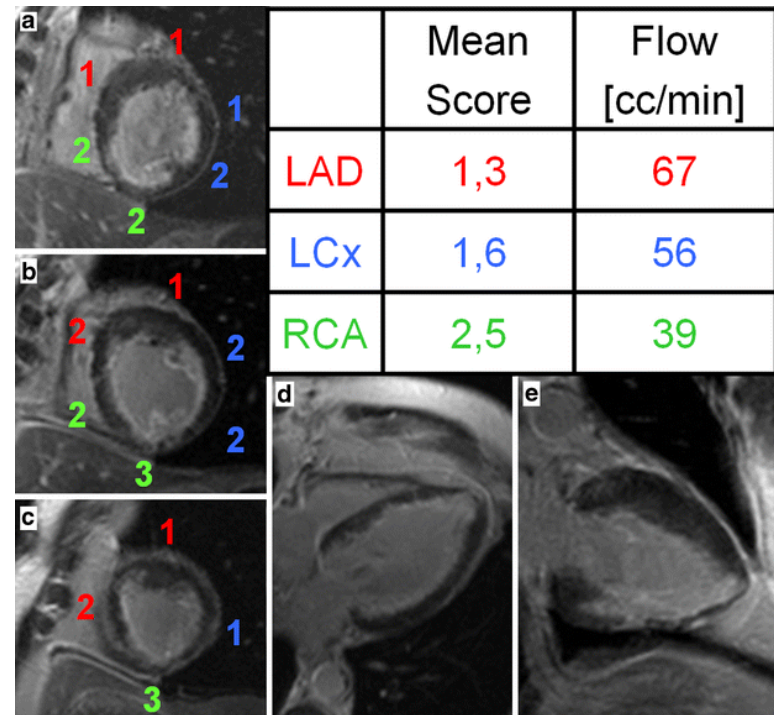
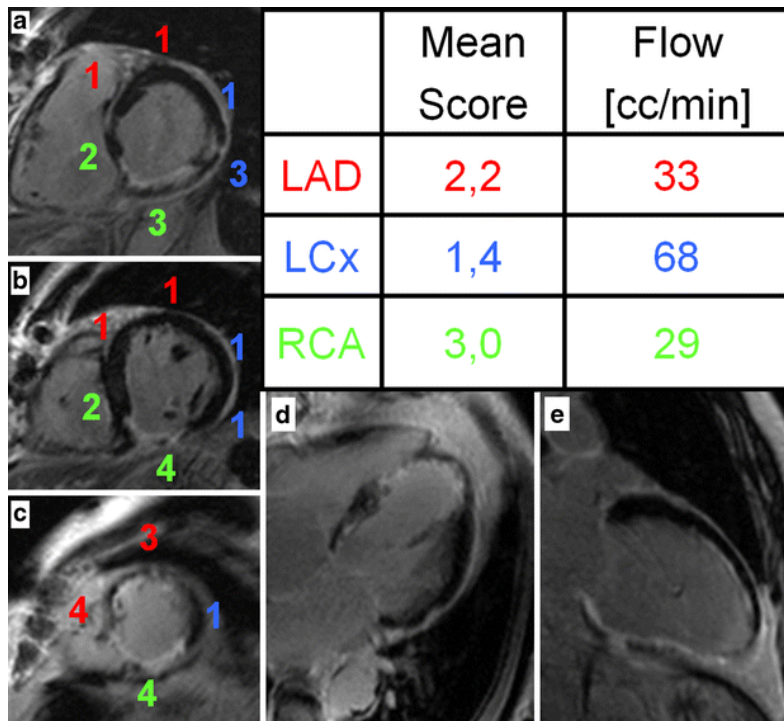
CONCLUSIONS

Routine measurement of FFR in patients with multivessel coronary artery disease who are undergoing PCI with drug-eluting stents significantly reduces the rate of the composite end point of death, nonfatal myocardial infarction, and repeat revascularization at 1 year. (ClinicalTrials.gov number, NCT00267774.)

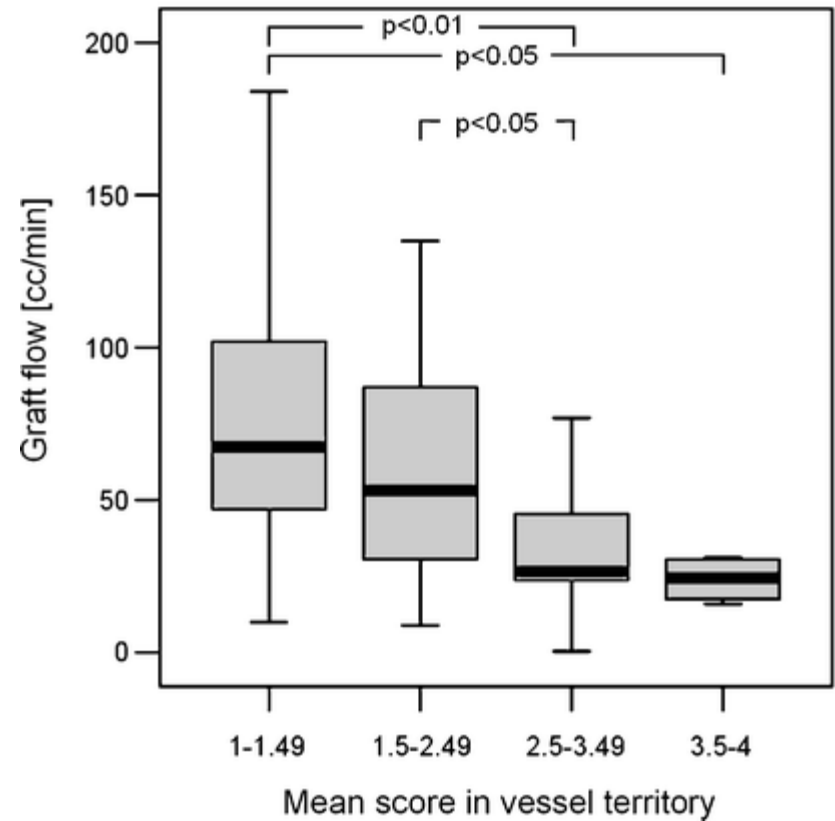
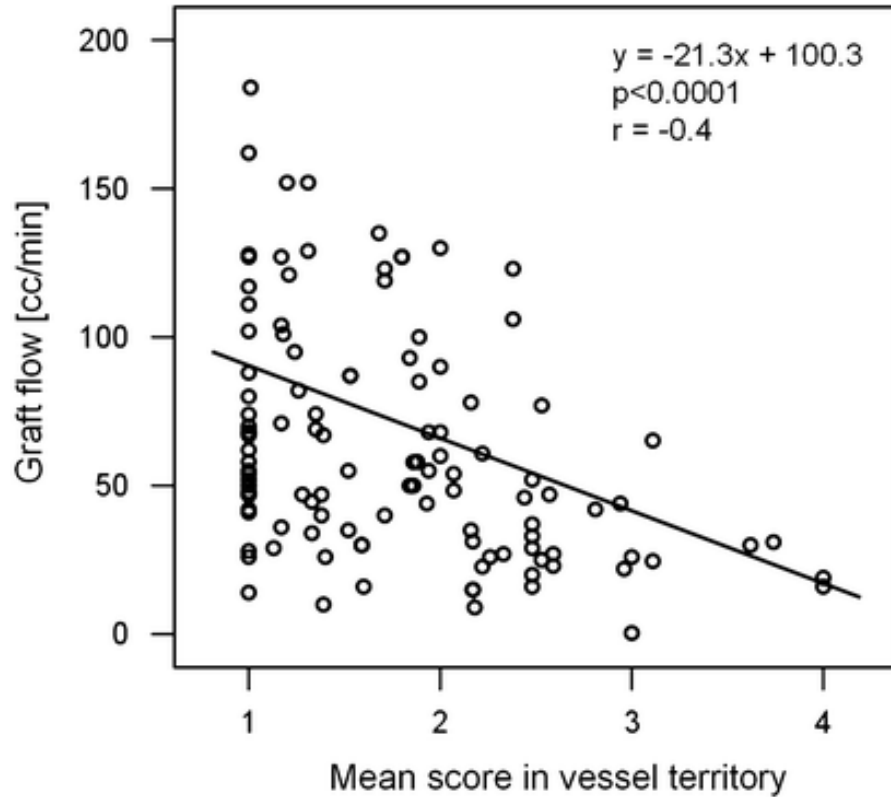
No benefit for revascularizing non viable / scar tissue



Scar Score (MRI) vs Bypass Flow (intraoperative Flow)



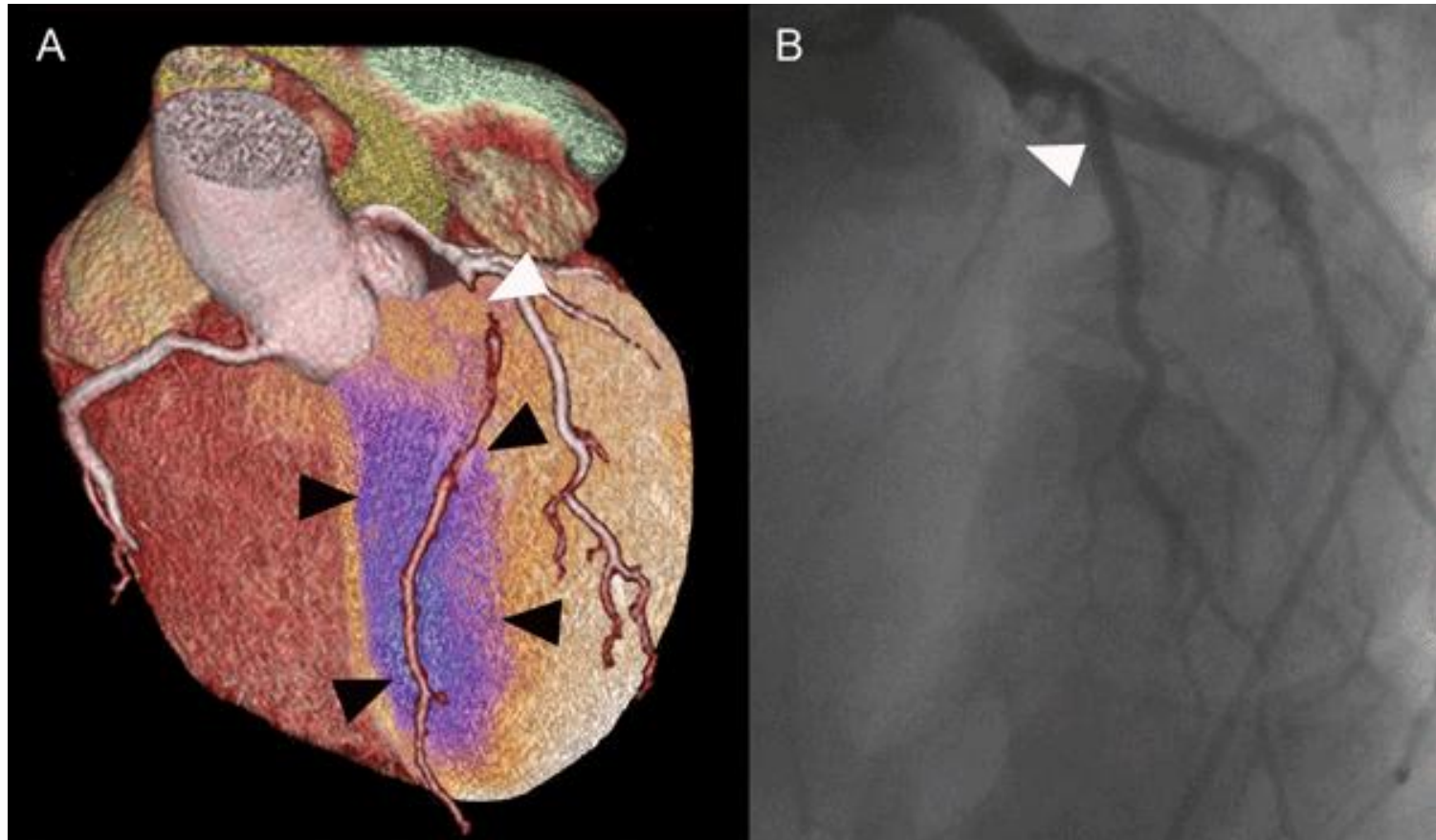
More scar – less flow



Scar tissue and graft patency

- Large extent of transmural scar in MRI and ventricular dysfunction:
No functional recovery can be expected, initial bypass graft flow will be low and high midterm probability of graft occlusion.
- No scar in MRI but ventricular dysfunction:
High probability of functional improvement, these segments should be grafted. High bypass flow can be expected and probability of midterm patency is high.
- Large extent of subendocardial or smaller areas of transmural scar:
Sufficiently high graft flow with respect to midterm prognosis is possible under optimal circumstances.

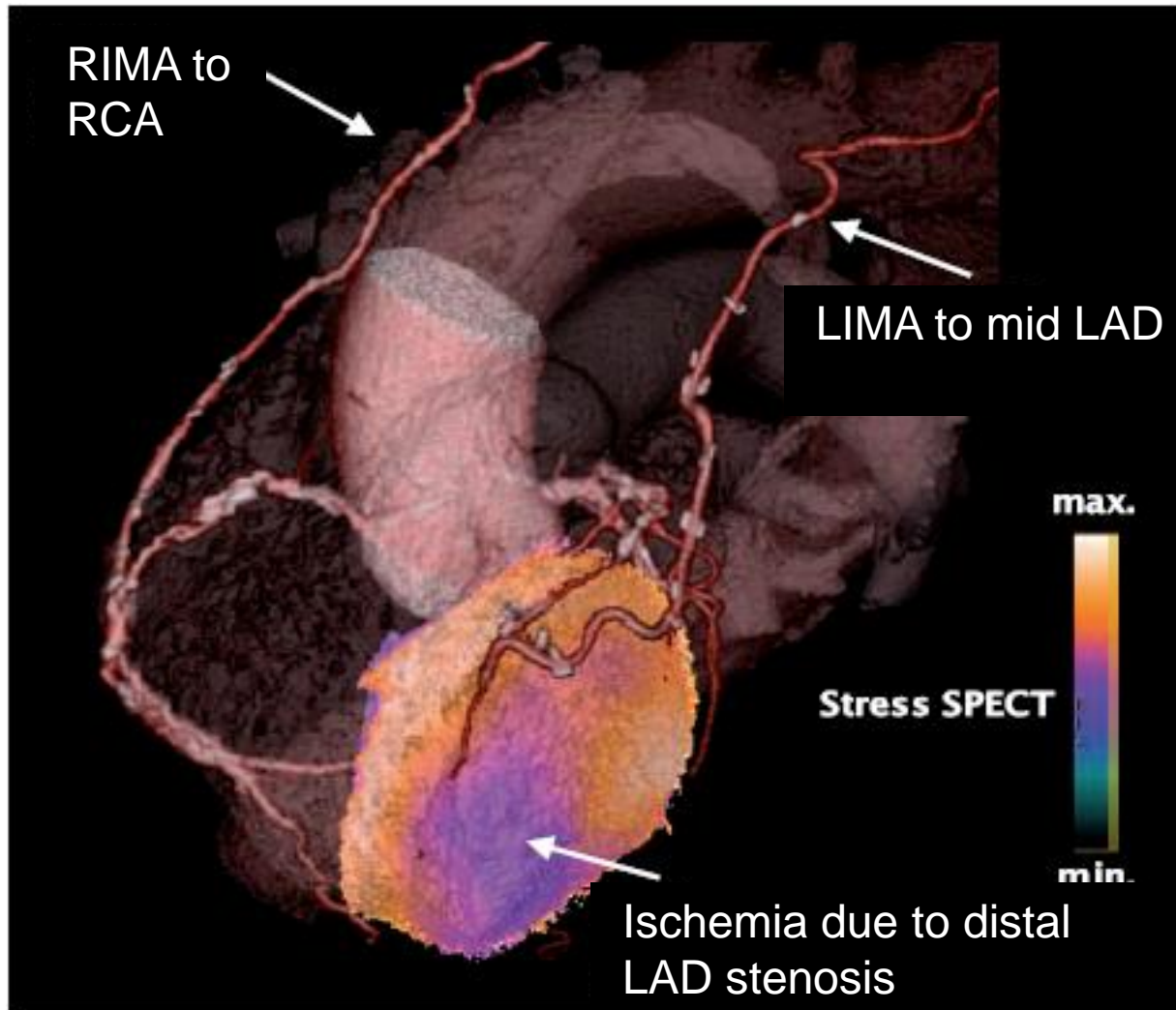
CTO of LAD



Ischemia -> MIDCAB

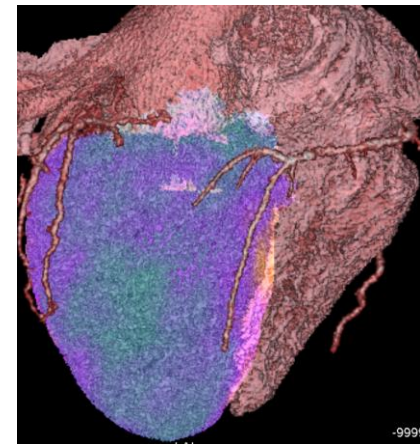
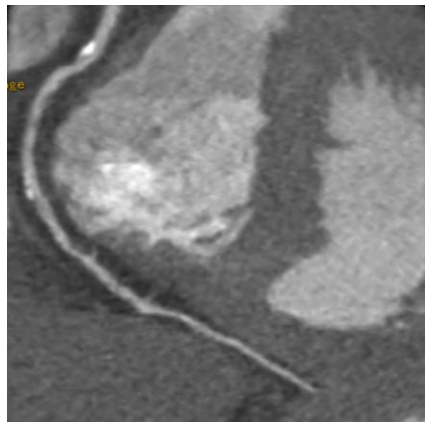
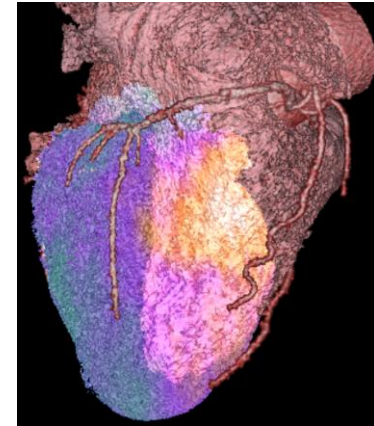
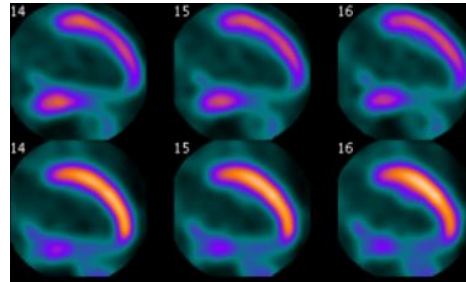
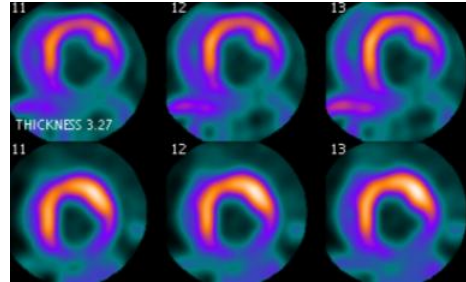
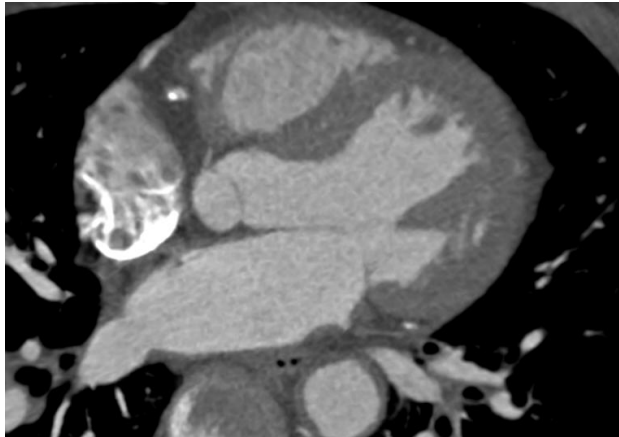
Herzog A EHJ 2009;30;644

Ischemia despite patent grafts



Ischemia
->
PCI distal LAD

Multiple RCA stenosis inferior scar



No Graft/Intervention

	Asymptomatic (screening)	Symptomatic			Prognostic value of positive result ^a	Prognostic value of negative result ^a
		Pretest likelihood ^b of obstructive disease				
		Low	Intermediate	High		
Anatomical test						
Invasive angiography	III A	III A	IIb A	I A	I A	I A
MDCT angiography	III B ^c	IIb B	IIa B	III B	IIb B	IIa B
MRI angiography	III B	III B	III B	III B	III C	III C
Functional test						
Stress echo	III A	III A	I A	III A ^d	I A	I A
Nuclear imaging	III A	III A	I A	III A ^d	I A	I A
Stress MRI	III B	III C	IIa B	III B ^d	IIa B	IIa B
PET perfusion	III B	III C	IIa B	III B ^d	IIa B	IIa B

Another indication for non-invasive imaging is the detection of myocardial viability in patients with poor LV-function. Patients who have viable but dysfunctional myocardium are at higher risk if not revascularized, while the prognosis of patients without viable myocardium is not improved by revascularization

Summary

- Adherence with Guidelines may improve results for both PCI and CABG
- Off-pump no-touch technique should be applied in high risk patients
- Image guided revascularization strategy contra oculostenotic reflex
- Secondary Prevention essential for long-term outcomes after Surgery