

TCTAP
2010

When is Surgery the Preferred Therapy ?

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Conflicts of Interest:

- (i) Clinical: Cardiac Surgeon
- (ii) Political: President SCTS GB and Ireland
- (iii) Commercial: Consultant to Medtronic, Novadaq, VGS, Abbott



○ CABG: Most intensively studied surgical procedure with >45 yrs follow up

All UK Cardiac Surgery 2004-08

	CABG	MORTALITY	
		All	Elective
Total	114300	1.8%	1.1%
NoLMS	69775 (70%)	1.5%	0.9%
LMS	30218 (30%)	2.5%	1.5%

- ART Trial
- SIMA vs BIMA
- 3102 patients
- 28 Hospitals in 7 countries
- 30 day mortality 1.2%
- 1 year mortality 2.4%

Hospital mortality for elective CABG should be around 1% and <3% @ 1 yr

Cardiac Surgery

The Society for
Cardiothoracic Surgery
in Great Britain & Ireland



Sixth
National Adult Cardiac
Surgical Database Report
2008

Demonstrating quality

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1. EVIDENCE FROM RCT of PCI vs CABG (Pre-SYNTAX)

Articles

Lancet 2009; 373;1190-97

➤  Coronary artery bypass surgery compared with percutaneous coronary interventions for multivessel disease: a collaborative analysis of individual patient data from ten randomised trials

Mark A Hlatky, Derek B Boothroyd, Dana M Bravata, Eric Boersma, Jean Booth, Maria M Brooks, Didier Carrié, Tim C Clayton, Nicola Panchin, Marcus Flather, Christian W Gohlke, Michael Hahn, Jan Käthe, Cheryl F Keeley, Sander K King, Andrzej Kusnierek, Paul S Lips, Kathryn M McDonald, Alfredo Rodriguez, Patrick Serruys, Ulrich Sigwart, Rodney H Stables, Douglas K Owens, Stuart J Pocock

24 authors... not a single surgeon !!!

- 7812 patients with median follow up of 6 years
 - >2/3 with 1 or 2 vessel disease and normal LV function
 - **ie low risk patients known to have no prognostic benefit of CABG**
- Overall CABG mortality lower: **HR = 0.91** (95% CI 0.82-1.02; p=0.12)]
- CABG mortality significantly lower in
 - diabetes (**HR 0.70**; 95% CI 0.56-0.87; p=0.014) [vs BARI-2D NEJM 2009]
 - patients >65 years (**HR 0.82**; 95% CI 0.70-0.97; p=0.002)
- Pre-specified composite end point of death/repeat intervention
 - CABG 10% vs 25% PCI (p< 0.0001)

2. EVIDENCE FROM REGISTRIES of PCI vs CABG (Pre-SYNTAX)

NEJM 2005

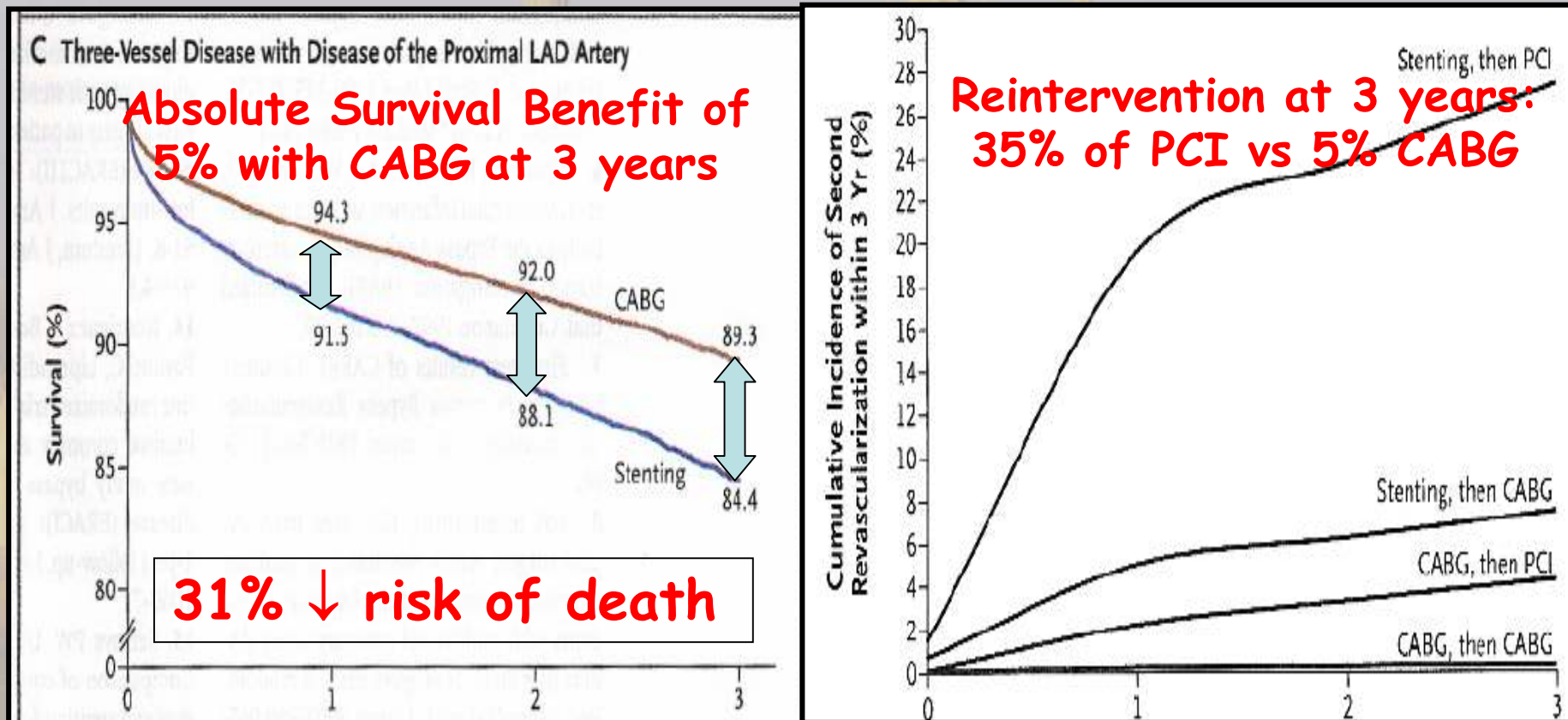
The NEW ENGLAND JOURNAL of MEDICINE

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.

- New York Registry: 37,212 CABG and 22,102 PCI (BMS) patients with > 2VD
- Propensity matched for cardiac and non-cardiac co-morbidity risk



Survival benefit and freedom from reintervention with CABG accrue with time

CABG Has Survival Benefit Over PCI in Routine Clinical 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

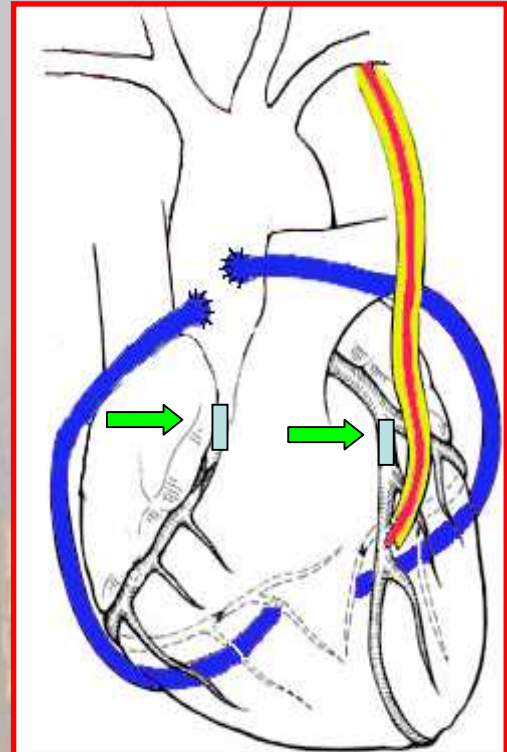
- In >100,000 mainly propensity matched patients by 3-5 years PCI
- decreases ABSOLUTE survival by around 5%
- increases reintervention x5 vs CABG

Fundamental Question

WHY DOES CABG HAVE SUCH A SURVIVAL BENEFIT OVER PCI ?

Anatomically, atheroma is mainly located in the proximal coronary vessels

1. During CABG bypass grafts are placed to the mid coronary vessel which has **two** effects
 - (i) treats the '**CULPRIT**' lesion (of any complexity)
 - (ii) over the long term, CABG offers prophylaxis against **FUTURE** 'culprit' lesions by protecting whole zones of vulnerable proximal myocardium in diffusely unstable coronary endothelium
 - In contrast, PCI with stents (▮) only deals with '**suitable**' localised proximal culprit lesions but has **no prophylactic benefit against new disease** (proximal to, within or distal to the stent)



2. PCI means incomplete revascularization (Hannan Circ 2006)
 - Of 22,000 PCI 69% had incomplete revascularization
 - >2 vessels (+/- CTO) HR for mortality 1.4 (95% CI = 1.1-1.7)

PCI will 'never' match the results of CABG for LM/MVD (POBA;BMS;DES)

SYNTAX: Patients (n=3075) and the Treatments (NEJM 09)

SYNTAX	RCT (n=1800) [59%]		Registry (n=1275) [41%]	
	CABG: 897	PCI:903	CABG: 1077 (84%)	PCI: 198
age	65 (10)	65 (10)	66 (9)	71 (10)
male (%)	79	76	81	70
DM (%)	29	28	30	35
Unstable (%)	28	29	22	38
Euroscore (Surgical Risk)	3.8 (2.7)	3.8 (2.6)	3.9 (2.7)	5.8 (3.1)
Syntax score (severity CAD)	29(11)	28 (11)	38 (13)	32 (12)
EF	-	-	-	-
LMS (any) (%)	34	35		
3 vd (%)	66	65		
Anastomoses/lesions	3.2 (0.9)	3.6 (1.6)		
% Off Pump; % BIMA	15%; 28%	-	19%; 16%	
Nos stents	-	4.6 (2.3)		3.1 (1.8)
Stent length	-	86 (48)		59 (41)

- 35% of All patients (1077/3075) were only candidates for CABG (not randomized)
- 6% of All patients (198/3075) were only candidates for PCI (not randomized)

SYNTAX RCT Results (2/5 Years): ALL, 3 Vessel, Left Main

	OVERALL (1800)			3 vessel (1095)			Left Main (705)		
	PCI	CABG	p	PCI	CABG	p	PCI	CABG	p
numbers	903	897		546	549		357	348	
Death %	6.2	4.9 (-21%)	0.24	6.5	4.1 (-37%)	0.07	5.6	6.2 (+11%)	0.77
CVA %	1.4	2.8 (+50%)	0.03	1.7	2.3 (+35%)	0.47	0.9	3.7 (+410%)	0.01
MI %	5.9	3.3 (-44%)	0.01	6.1	2.8 (-54%)	0.009	5.5	4.1 (-25%)	0.45
Revasc %	17.4	8.6 (-51%)	<0.001	17.4	7.5 (-57%)	<0.001	17.3	10.4 (-40%)	0.01
MACCE %	23.4	16.3 (-35%)	<0.001	23.8	14.4 (-41%)	<0.001	22.9	19.3 (-16%)	0.27

	Lowest (0-22): 31%		Inter (23-32): 33%		Highest (>33): 34%	
	PCI	CABG	PCI	CABG	PCI	CABG
numbers	299	275	310	300	290	315
Death	3.4%	5.3% (+56%)	5.9%	6.4% (+8%)	9.4%	3.3%* (-65%)
CVA	1.1%	2.7% (+245%)	1.7%	2.8% (+65%)	1.5%	3.0% (+200%)
MI	3.8%	3.4% (-11%)	6.2%	2.8%* (-55%)	7.7%	3.9%* (-49%)
Revasc	15.8%	8.6%* (-46%)	15.7%	9.0%* (-43%)	20.5%	8.4%* (-78%)
MACCE	19%	17.4% (-8%)	22.8%	16.4% (-28%)	28.2%	15.4%* (-45%)

- 79% of all 3vd (SYNTAX >22) and 65% of all LM (SYNTAX >32)
- CVA higher for CABG esp LM (but much lower use of 2y prevention)

STATE-OF-THE-ART PAPER AND COMMENTARY

Revascularization for Unprotected Left Main Stem Coronary Artery Stenosis

- <90% of LM are distal (high risk of restenosis; often asymptomatic)
- Even with DES 20% reintervention at 1 year (SYNTAX 17% @ 2 yrs)
- Much better results for PCI in isolated ostial and mid shaft lesions
- <90% have multivessel CAD (CABG already offers survival benefit)

Richard J. Shemin, MD, FACC, Peter K. Smith, MD, FACC,||

- For SYNTAX >32: 2 yr mortality 4% for CABG vs 10% PCI
- For SYNTAX <32: 2 yr mortality 7.5% for CABG vs 3% PCI
- Will be subject of new RCT: EXCEL Trial; 2500 patients; Sept 2010

For coronary artery disease with unprotected left main stem (LMS) stenosis, coronary artery bypass grafting (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

Stents versus Coronary-Artery Bypass Grafting for Left Main Coronary Artery Disease

NEJM 2008

Ki Bae Seung, M.D., Duk-Woo Park, M.D., Young-Hak Kim, M.D., Seung-Whan Lee, M.D., Cheol Whan Lee, M.D., Myeong-Ki Hong, M.D., Seong-Wook Park, M.D., Sung-Cheol Yun, Ph.D., Hyeon-Cheol Gwon, M.D., Myung-Ho Jeong, M.D., Yangsoo Jang, M.D., Hyo-Soo Kim, M.D., Pum Joon Kim, M.D., In-Whan Seong, M.D., Hun Sik Park, M.D., Taehoon Ahn, M.D., In-Ho Chae, M.D., Seung-Jea Tahk, M.D., Wook-Sung Chung, M.D., and Seung-Jung Park, M.D.

- 2240 patients (1102 PCI; 1138 CABG)
- PCI vs CABG: Distal LM 49% vs 54%; 3VD 25% vs 57%

Conclusions In a cohort (n2240) of patients with unprotected left main coronary artery disease, we found no significant difference in rates of death or of the composite end point of death, Q-wave myocardial infarction, or stroke between patients receiving stents and CABG. **However, stenting, even with DES, was associated with higher rates of target-vessel revascularization than was CABG.**

- At 3 yrs 108 DES and 179 CABG with respective
 - Survival 91% vs 93.1% (+2.1%)
 - Freedom from death/Q wave MI/CVA: 88.5 vs 92% (+3.5%)
 - Freedom from TVR: 90.7 vs 98.4 (+7.7%)

‘... our analysis was underpowered to detect significant differences in mortality, **especially in the comparison of DES with CABG.** ... Nonsignificant trends toward higher event rates were seen in the group that received DES; these trends might have been significant with a larger cohort of patients’.

A Meta-Analysis of 3,773 Patients Treated With Percutaneous Coronary Intervention or Surgery for Unprotected Left Main Coronary Artery Stenosis

JACC Int 2009

Hursh Naik, MD,* Anthony J. White, MBBS, PhD,* Tarun Chakravarty, MD,* James Forrester, MD,* Gregory Fontana, MD,* Saibal Kar, MD,* Prediman K. Shah, MD,* Robert E. Weiss, PhD,† Raj Makkar, MD*

Meta-analyses showed that death, MI, CVA were similar at 1, 2 and 3 years but that TVR was increased x 4 for whole study

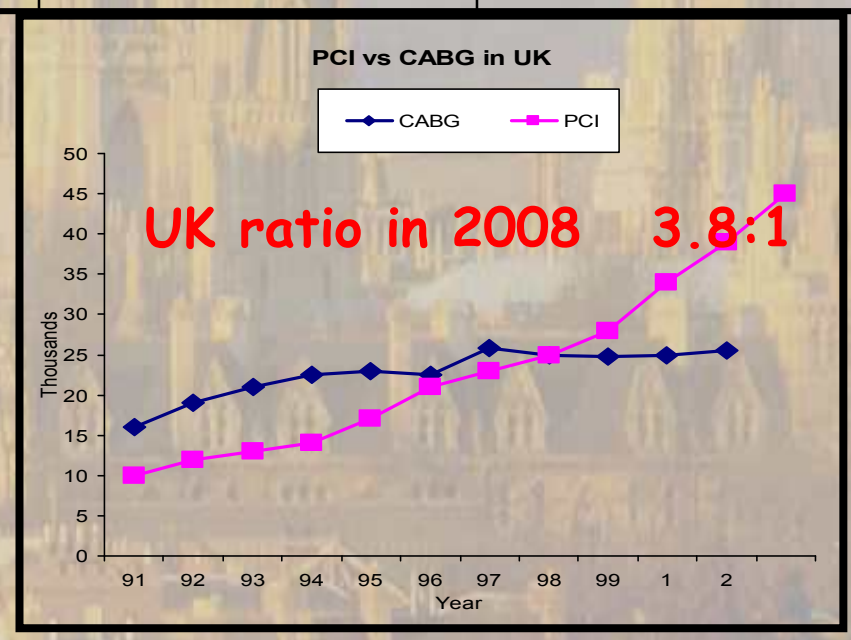
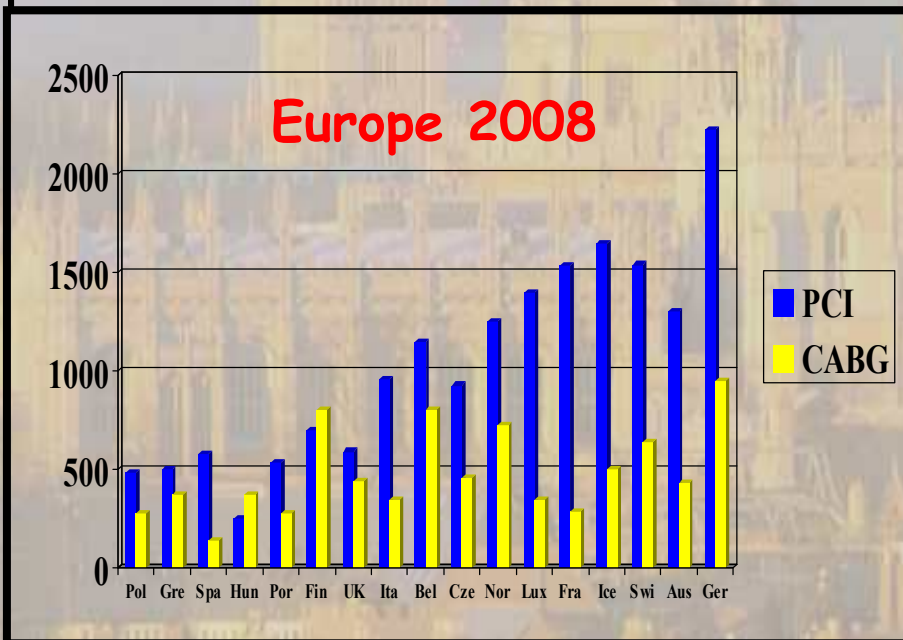
- Seven important weaknesses
- No definition of how PCI or CABG was chosen (ie potential confounding)
- No actual mortality rates (1 yr CABG mortality of 13%; 18% in 2 studies)
- 3 year data actually available in only 45% of patients
- Different number of patients 2114 CABG (56%) vs 1659 (44%) PCI
- 10 studies: 2 RCT (810/3773 patients from RCT ie 21%)
- Cumulatively 50 years of recruitment ie 7.5 pts per study per year
- 1789/3773 (47%) recruited from SYNTAX and MAIN-COMPARE
- Propensity matching can only be done towards lower risk populations

When is Surgery the Preferred Therapy ?

- 79% of 3v CAD (SYNTAX score >22) and 65% LM (SYNTAX score >32)
 - CABG offers superior survival and better clinical outcome at 2 years
 - Consistent with existing evidence in the literature
 - CABG has a 0.6% increase in risk of CVA for 3vd but 2.8% for LM
 - Benefits of CABG greater in diabetic patients
 - CABG is a more cost effective treatment over the longer term
- In lower SYNTAX scores at 2 years (<23 for PCI and <33 for LM) PCI has same/better survival with less CVA but with more interventions
- PCI may be best treatment for ostial/mid shaft (EXCEL trial)
- PCI has an important role in patients unfit for or who refuse CABG
- SYNTAX Trial Investigators make two very important contributions
 - SYNTAX score will be important in guiding recommendations
 - SYNTAX reminded of the importance of MDT/Heart Team
- CABG could be performed to higher standard
 - More use of arterial grafts (especially 2nd IMA)
 - More off pump CABG in higher risk patients

PCI vs CABG: History and Current Trends...the Future?

	CABG	PCI
Initial use	1962 (>48 yrs)	1977 (>33 yrs)
Use: Multivessel (MV) and Left Main (LM)	>40 years	>15 years
Evidence of clinical efficacy in MVD and LM	STRONG	WEAK
Evidence of Cost-effectiveness (QUALY)	STRONG	Proven NOT
Improved medical therapy	Aspirin, statins, ACE I,	
Technical advances	Arterial grafts OPCABG	Stents (DES)



Background PCI vs CABG in STABLE CAD

OPCI: GENERAL PERSPECTIVE

- Used appropriately PCI can be a very effective treatment
 - especially in unstable haemodynamics/ acute MI
 - in **some** patients with multivessel/left main stem disease
- "Patients want less invasive treatment"
 - (assumes that therapies are otherwise equally effective)

○ BUT THREE IMPORTANT QUESTIONS REGARDING PCI

1. Is the routine use of PCI in multivessel/LM disease appropriate?
 - is it evidence based? (Dichotomy of evidence from RCT vs Registry)
2. Is consent for PCI obtained appropriately ?
 - are patients told that CABG is more effective + better survival?
 - are the real **risks** and **limitations** of PCI explained?
 - ✓? Essential in UK under GMC 'Good Medical Practice'
 - ? But does it really happen in routine clinical practice
3. Is PCI a cost effective treatment?
 - do numerous/ repeat PCI make economic/medical sense?

15 RCT of PCI vs CABG in 'Multivessel' Disease [Taggart ATS 2006]

TRIAL	nos	stent	% pop	% 1 or 2VD	EF >5 0%	%Left Main	Proximal LAD (%)	%DM	% IMA
RITA	1011	-	4%	88	-	0	-	6	74
ERACI	127	-	9%	55	100	0	-	11	75
LAUSANNE	134	-	3%	100	-	0	100	12	100
GABI	359	-	4%	82	-	0	-	10	37
EAST	392	-	4%	60	100	0	70	25	-
CABRI	1054	-	3%	60	100	0	-	12	75
MASS	142	-	69%	-	100	0	100	21	100
BARI	1829	-	12%	59	100	0	36	24	80
TOULOUSE	152	-	3%	71	-	0	-	14	58
SIMA	121	-	-	-	100	0	100	11	100
ERACI II	450	+	2%	44	-	0	-	17	88
AWESOME	454	+	-	55	-	0	-	-	70
MASS II	408	+	2%	59		0			
ARTS	1205	+	?5%	68	100	0	-	19	93
SOS	988	+	?5%	62	100	0	45	14	81
SUMMARY	8826		5%	65%	100%	0%	41%	16%	79%
CABG (UK)				<10%	70%	>20%	>90%	25%	>90%

RCT were biased against survival benefit of CABG by exclusion of patients who are known to benefit from CABG in favour of those who do not !!!

Taggart DP. Lancet 2009; 373:1150-2

Ⓜ PCI or CABG in coronary artery disease?

' however, it is necessary to consider two potentially important limitations of the current analyses. 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 DP. Thomas B. Ferguson Lecture. Coronary artery bypass grafting is still the best treatment for multivessel and left main disease, but patients need to know. Ann Thorac Surg 2006;82:1966-75.

[3] Yusuf S, et al. Effect of coronary artery bypass graft surgery on survival: overview of 10-year results from randomised trials by the Coronary Artery Bypass Graft Surgery Trialists Collaboration. Lancet 1994 ;344:563-70.

BARI 2D: [NEJM 2009]

(i) optimal medical therapy vs prompt revascularization (prespecified to PCI/CABG)

(ii) Insulin provision vs sensitization

2368 patients (2001-05)	PCI (1605)		CABG (763)	
Age (sd) [% male]	62 (9); [68%]		63 (8); [76%]	
Diabetes (years); [% insulin]	10(9); [31%]		11(8); [22%]	
Unstable angina; prior revasc	11%; 29%		7%; 13%	
3 vessel disease	20%		52%	
Significant LAD disease	10%		19%	
Ejection Fraction	57 (11)		57 (11)	
	Medical	PCI	Medical	CABG
	807	798	385	378
5 years Death	11.9%	12.8%	16.9%	14%
5 years MI	10.2%	11.3%	14.6%	7.4%*
5 years Stroke	2.9%	2.9%	2.6%	1.9%
5 years Death,MI,Stroke	20.8%	23.4%	29.9%	20.9%*

By 5 years 42% of medical group required revascularization

○ EDITORIAL: Boden WE; Taggart DP: N Engl J Med. 2009 Jun 11;360(24):2570-2.

○ Very low severity CAD does not benefit prognostically from PCI or CABG

○ CABG group had more severe disease (prespecified)

• CABG halved the risk of MI and (17% relative reduction in risk of death)

○ High risk of subsequent revascularization in medical group (42%)

Are Current Guidelines for PCI in MVD Appropriate ?

Society	Recommendations for PCI	Written by
ACC/AHA Circulation 2006	'Patients with 2 or 3 vessel disease who are otherwise eligible for CABG including diabetes' NO SURGICAL OPINION RECOMMENDED	23 cardiologists 1 surgeon
ESC Eur Heart J 2005	'all patients except diabetics with multivessel disease, unprotected left main, chronic total occlusions' NO SURGICAL OPINION RECOMMENDED	46 cardiologists 0 surgeon
BCS Heart 2005	'patients to be fully informed in decisions, treatment options' (GMC Good Medical Practice) NO SURGICAL OPINION RECOMMENDED	8 cardiologists 1 surgeon
Summary	almost all patients can be treated by PCI NONE RECOMMEND SURGICAL OPINION	77 cardiologists 2 surgeons

Based on 15 'manufactured' RCT of PCI vs CABG !!

- New ESC/EACTS Guidelines (2010) Guideline Writing Committee has 21 members
 - (7 interventional cardiologists, 7 non-interventional cardiologists, 7 surgeons)
- Will strongly recommend need for MDT/'Heart Team' approach to consent
- Will recommend separation of angiogram and proceed (no 'ad hoc' PCI)
 - Documentation of this approach will be new quality matrix for ESC badge

AHA 2008

Abstract 6224: John H Lee; Kenny Chuu; John Spertus; James H O'Keefe Widespread Patient Misconceptions Regarding the Benefits of Elective Percutaneous Coronary Intervention

498 ELECTIVE PATIENTS Jan 2006-Oct 2007

70% responded; mean age 69; 76% male

Patient perception	%	Correct ?
PCI was emergent rather than elective	33%	X
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

○ No surgical opinion in 87% !!!

○ Need for MDT approach

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, Michael J. Racz, Jeffrey Gold, Kimberly Cozzens, Nicholas J. Stamato, Tia Powell, Mary Hibberd and Gary Walford

Circulation 2010;121:267-275; originally published online Jan 4, 2010;

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

ACC/AHA Recommendation	Numbers	% CABG	% PCI	% Medical	None
CABG	1337	53	34	12	1
PCI	6071	2	94	4	<1
CABG or PCI	1722	5	93	2	<1
Neither	1223	6	21	71	2
Total	10333	10	77	13	<1

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

Get With the Guidelines: A New Chapter ?

Raymond J. Gibbons, MD

A final potential explanation, and in my view the most concerning, is that these recommendations for PCI in patients indicated for CABG reflect a “grow the business” and “make it up on volume” mentality in response to declining reimbursement rates. **There are compelling financial incentives for cardiologists performing intervention to do more procedures, even when the patient might be better treated with CABG.**

Should surgical consultation be encouraged, as suggested by the authors? For patients for whom ad hoc PCI remains the best option, particularly those with refractory unstable angina, the risk of delay to permit such a consultation does not seem justified. However, there are many other patients with stable symptoms for whom issues of contrast load, and the need for further discussion with the patient, dictate that PCI is performed on a different day. **In such patients surgical consultation should be considered, but not mandated.**

Both the SCAI and ACC/AHA guidelines have indicated that ad hoc PCI should not be a standard strategy for all patients. For patients in stable condition we should consider less ad hoc PCI.

The Controversy and the Solution

○ Patients are denied access to the 'gold standard' treatment by the the interventional cardiologist ('the gatekeeper')

Califf RM. Stenting or Surgery JACC 2005; 46: 589-91 :

“It is likely that most people undergoing coronary angiography are not told the entire story when a decision is made about undergoing PCI ... self-referral.. financial incentives ..without surgical opinion the patient is in no position to have rational input into the decision”

- The solution is the Multidisciplinary Team (MDT) [BMJ 2005,2007]
 - As for lung cancer
 - No doctor with the real interests of the patient would object to an MDT
 - MDT should include non-interventional and interventional cardiologist, surgeon and payer (economic implications)
- In elective patients ALL MVD/proximal LAD should be agreed by an MDT
 - Ensure (i) transparency (ii) real patient choice (iii) genuine informed consent
 - Being given a few minutes to consent to a procedure in a catheter lab with a catheter in the groin ('ad hoc PCI') is not informed consent
 - Will become ESC recommendation in 2010 and be 'quality index'
- If MDT is not agreed voluntarily then should be enforced by external regulatory/statutory bodies to protect the best interests of patients

Is PCI in stable coronary artery disease Evidence Based?

1. Is PCI more more effective than medical therapy ?

NO: Meta-analysis of 11 RCT PCI vs Medical Therapy (Katristsis Circ 2005)

- 2950 patients with 1-7 yr follow up

CONCLUSION 'In patients with chronic stable coronary artery disease PCI does not offer any benefit in terms of death, myocardial infarction or subsequent revascularization'

COURAGE: 2287 pts OMT vs OMT+PCI: 5 yr Survival and MI same

2. Is PCI with stents more effective than PCI without stents ?

NO: Meta-analysis of 29 RCT of PCI +/- Stenting (Brophy Ann Int Med 2003)

- 9918 patients with 16 month follow up

CONCLUSION 'Stenting is safe but not associated with important reductions in mortality, myocardial infarction or CABG

3. Are DES more effective than BMS ?

NO: Five meta-analysis (Lancet/EHJ 2004;AJC 2005;EHJ 2006)

- 5103, 5747, 5066, 8221 patients followed for 2 years

- 4958 pts in 14 RCT up to 5 yrs (Kastrati NEJM 2007)

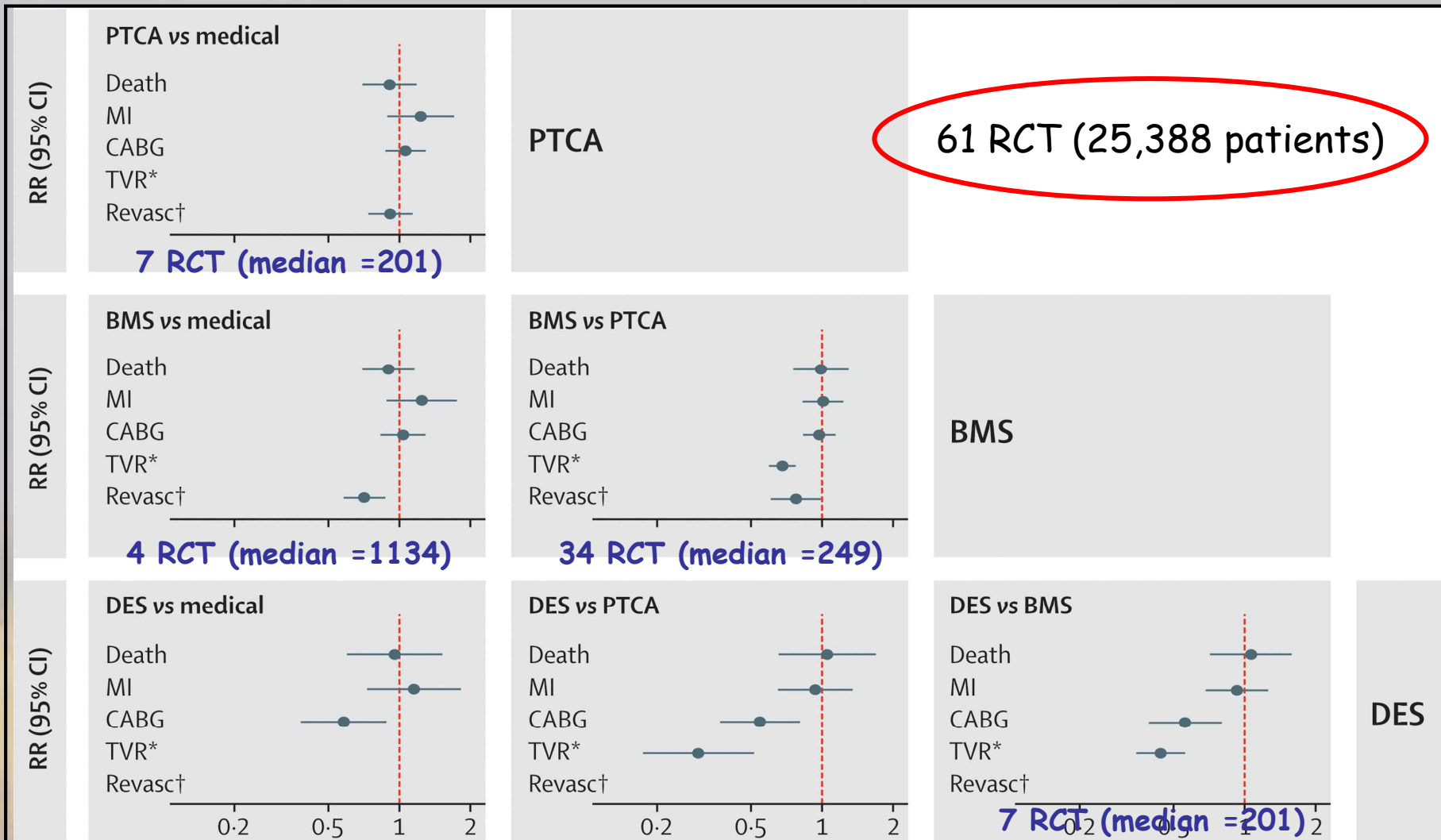
- 18000 pts in 38 trials up to 4 yrs (Stettler Lancet 2007)

CONCLUSION: "DES decrease risk of restenosis in low risk coronary lesions but not the risk of mortality or MI at 2-5 years"

- 1% decrease in risk of MI over 4 years (Stettler Lancet 2007)

Percutaneous coronary interventions for non-acute coronary artery disease: a quantitative 20-year synopsis and a network meta-analysis [Lancet 2009]

Thomas A Trikalinos, Alawi A Alsheikh-Ali, Athina Tatsioni, Brahmajee K Nallamothu, David M Kent



‘INTERPRETATION: Sequential innovations in the catheter-based treatment of non-acute coronary artery disease showed no evidence of an effect on death or myocardial infarction when compared with medical therapy.’

PCI is less invasive than CABGbut is it safer ?

FACT 1: An initial strategy of PCI vs CABG increases 3 year mortality by 5%
(Hannan NEJM 2005; Malenka 2005; Brener 2004, Bair 2007, Javaid 2007)

FACT 2: REAL rate of restenosis with DES is 10%-28% at 1 year

- 10% RESEARCH Registry (Circ 2004); 20% DELIVER trial (Circ 2004)
- 28% Bifurcating Lesions (Tanabe Am J Cardiol 2004)

FACT 3: DES do NOT improve clinical outcome vs BMS

- Five Meta-analysis of 11 RCT of DES vs (BMS) of 18000 patients
- (Lancet 2004; Eur HJ 2004; Am J Cardiol 2005; Eur H J 2006; Lancet 2007)

FACT 4: DES predispose to THROMBOSIS (incomplete re-endothelialization)
Risk of 1-5% per annum and 40% mortality (NEJM 2007)
Especially if antiplatelets stopped (Lancet 2004, JAMA 2005)
Complexity of coronary lesions and patient groups

FACT 5: DES cause endothelial dysfunction proximal and distal to stent
[Togni JACC 2005; Joner and Virmani JACC 2006; Luscher and Virmani Circ 2007]

FACT 6: 10% of PCI cause SIGNIFICANT Myocardial Infarct

- 37% of patients have raised troponin (Selvanygam 2005, Thomas 2005)
- of whom 28% have MRI defined mean loss of 6g of LV muscle (ie 5% LV mass)

FACT 7: Previous PCI increases CABG mortality (OR: 3.01; p<0.0017) and MACES (OR: 2.31; p<0.004)[Hassan 2005; Thielman 2006; Chocron EHJ 2008]

FACT 8: Risk of cognitive dysfunction SAME for PCI and CABG

- SoS trial: 1yr (Wahrborg P Circ 2004); BARI trial: 5 yr (Hlatky Circ 1997)

Health Economists: Drug Eluting Stents (DES) vs CABG

Coronary artery stents: a rapid systematic review and economic evaluation

R Hill,¹ A Bagust,¹ A Bakhai,² R Dickson,^{1*}
Y Dündar,¹ A Haycox,¹ R Mujica Mota,¹
A Reaney,³ D Roberts,⁴ P Williamson⁵ and
T Walley¹

NICE 2003/
HTA 2004

'in the absence of substantive clinical evidence of the superiority of stenting with DES over CABG (for 2 and 3 vessel disease), to encourage the widespread use of DES will drive up the cost of stenting and if allowed to displace CABG, reduce the gain in quality and possibly duration of life arising from CABG in the long term

Cost-effectiveness of Stents and CABG (Griffin et al; *BMJ* 2007)

Appropriateness of Coronary Revascularization (ACRE) *NEJM* 2001

2552 patients (1353 CABG; 908 PCI; 521 either) therapy by panel of 9 experts

CONCLUSION: Both CABG and medical therapy (BUT NOT Stents) are cost effective at a conventional QALY of £30K (\$60K)

...'additional benefit of Stents over medical therapy is 'too small to justify its additional costs'

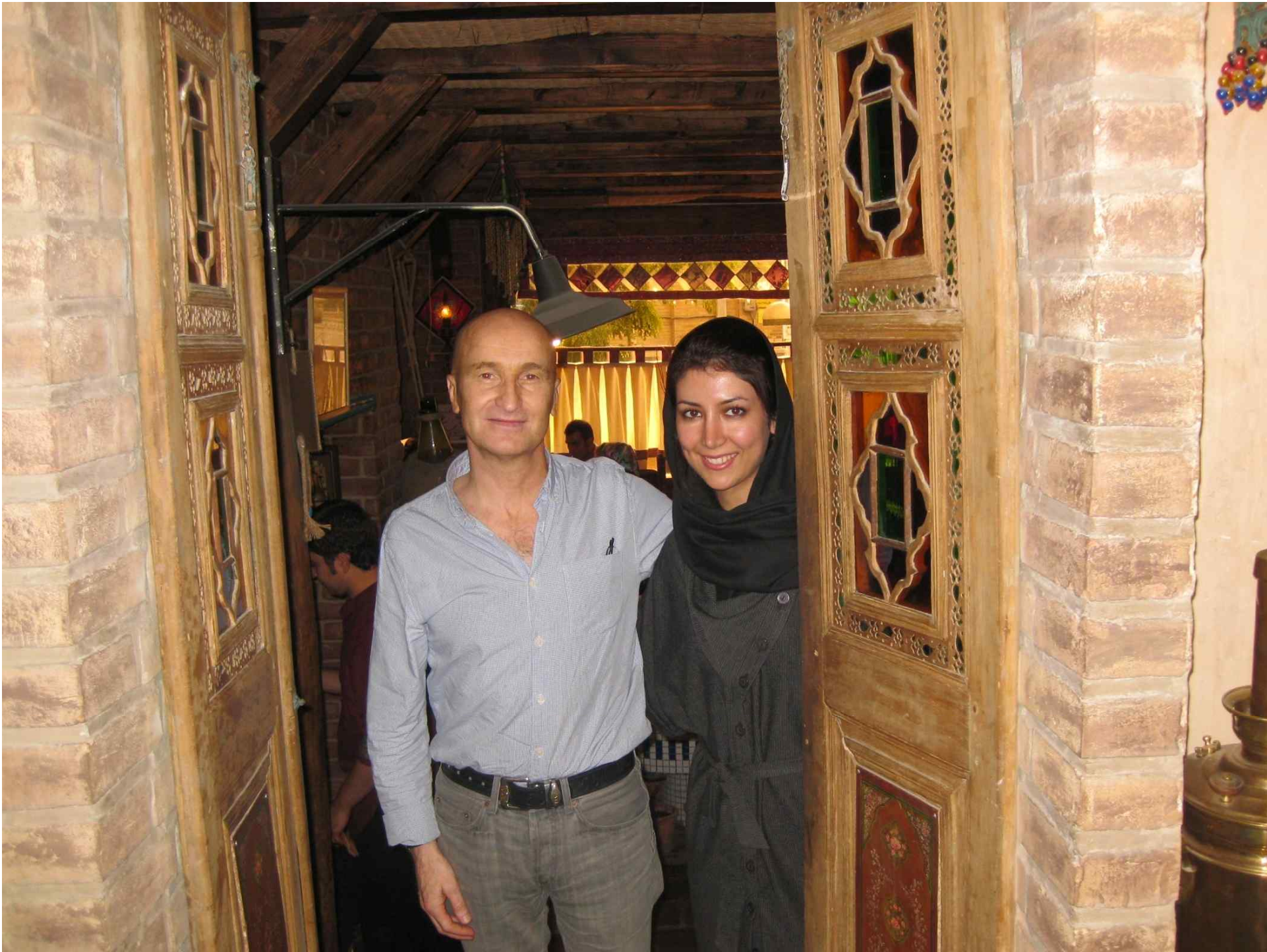
NICE (Recommendation TA 152) July 2008

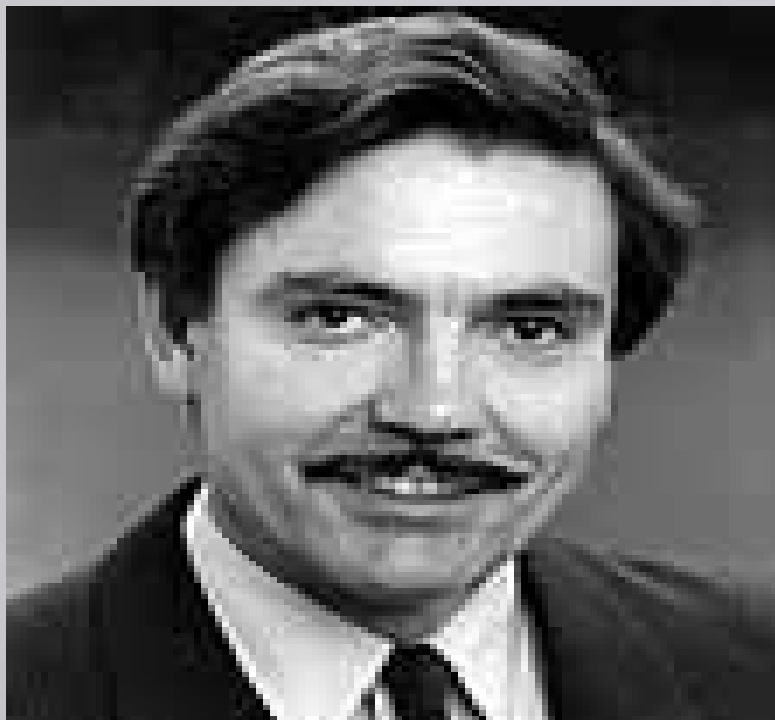
DES are recommended as a possible treatment only if:

- the artery to be treated is less than 3 mm in diameter or the affected section of the artery is longer than 15 mm, and
- the additional cost of the DES over bare-metal stents is £300 or less.









1st PCI: Zurich 1977

AR Gruentzig 1939-1985

(NEJM 1979) "We estimate that only about 10 to 15 per cent of candidates for bypass surgery have lesions suitable for PCI. A prospective randomized trial will be necessary to evaluate its usefulness in comparison with surgical and medical management."

Opie LH, Commerford PJ, Gersh BJ
Lancet 2006; 367:69-78

07 Jan 2006
367
9504

ELSEVIER

CURRENT ISSUE - NOT to be taken away

HEALTH CARE LIBRARIES

THE LANCET

Volume 367 Number 9504 Pages 1-84 January 7-13, 2006 www.thelancet.com

"In view of the survival benefit shown for coronary-artery bypass grafting, the real controversy is why patients with symptoms and anatomy known to benefit from the procedure are still submitted to percutaneous coronary intervention."

See Series page 69

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Articles	Articles	Articles	Articles	Seminar
Etanercept in psoriasis See page 29	Maternal vitamin D and bone mass in children at age 9 years See page 36	Mortality in Democratic Republic of Congo See page 44	Deaths from liver cirrhosis in UK See page 52	Urinary incontinence in women See page 57

Current PCI vs CABG: over enthusiastic vs over complacent ?

1. CABG only survives because of single IMA..so why not 2 IMA ?

Effect of arterial revascularisation on survival: a systematic review of studies comparing bilateral and single internal mammary arteries

David P Taggart, Roberto D'Amico, Douglas G Altman Lancet;2001:870-5

○ 4693 BIMA vs 11269 SIMA (from 7 databases)

○ NOT RCT but Matched for age, gender, LV function, DM

○ HR for death with BIMA: 0.80 [95% CI=0.70 to 0.94]

○ NNT of 13-16 (to prevent one death)

- 30 day mortality in 3102 ART patients 1.2%
- USA /Europe BIMA <5%; (Syntax < 30%)

2. OFF PUMP CABG

- 37 RCT and recent ROOBY trial show no mortality benefit in **low risk** patients
- Numerous observational/propensity studies (high risk patients) show consistent decreased mortality and all morbidity (especially stroke)
- Current use < 20% eg Syntax (surgeons >90% vs surgeons 0%)

3. Confirm graft patency in OR (unusual in UK, Europe, USA)

- Intuitive (cardiologists do routinely for PCI. Technically less challenging)
- 3-5% of grafts occluded in OR .. if IMA major adverse prognosis

The NEW ENGLAND JOURNAL of MEDICINE

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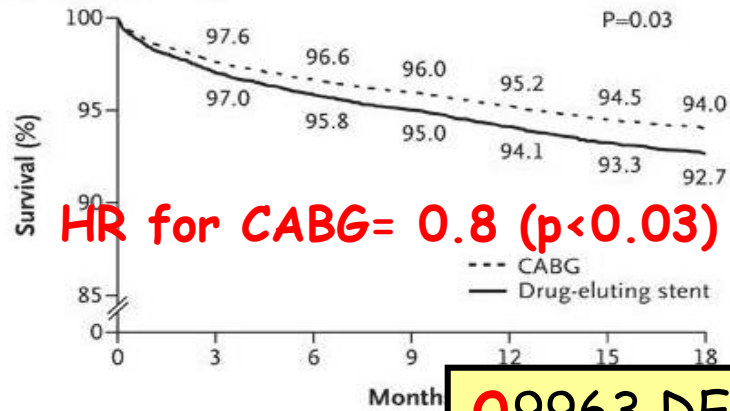
JANUARY 24, 2008

VOL. 358 NO. 4

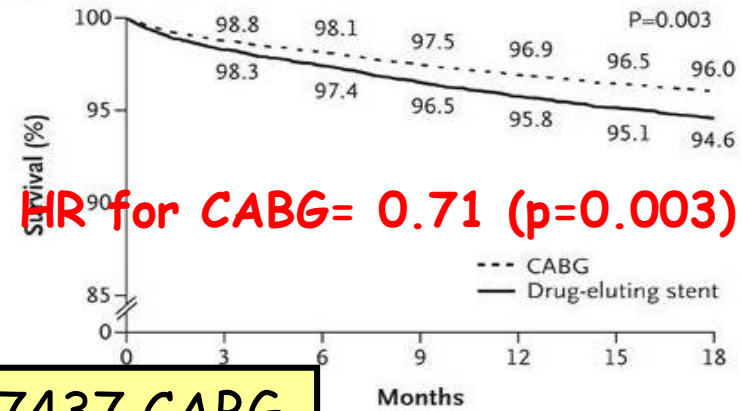
Drug-Eluting Stents vs. Coronary-Artery Bypass Grafting in Multivessel Coronary Disease

Edward L. Hannan, Ph.D., Chuntao Wu, M.D., Ph.D., Gary Walford, M.D., Alfred T. Culliford, M.D., Jeffrey P. Gold, M.D., Craig R. Smith, M.D., Robert S.D. Higgins, M.D., Russell E. Carlson, M.D., and Robert H. Jones, M.D.

A Three-Vessel Disease

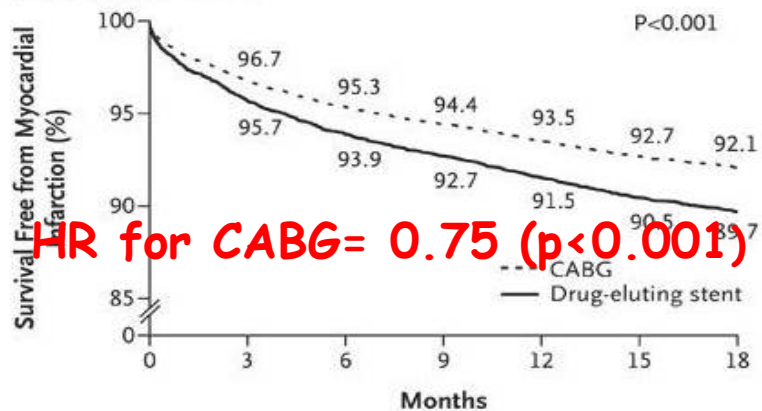


B Two-Vessel Disease

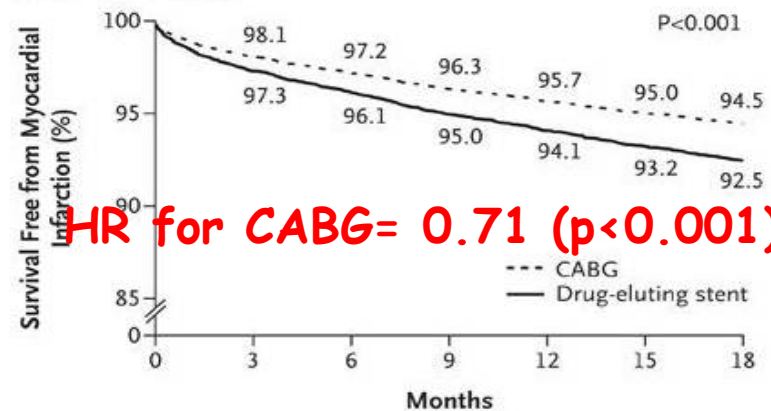


09963 DES vs 7437 CABG

C Three-Vessel Disease



D Two-Vessel Disease



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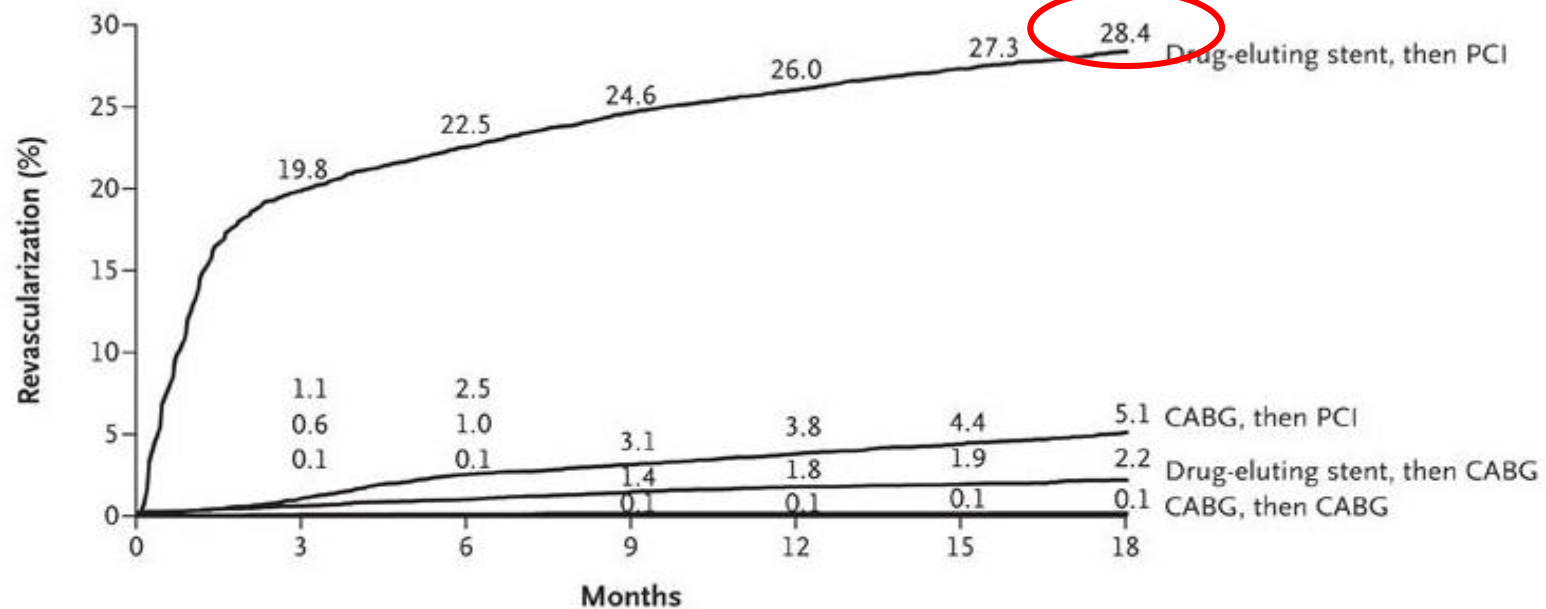
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Drug-Eluting Stents vs. Coronary-Artery Bypass Grafting in Multivessel Coronary Disease

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Craig R. Smith, M.D., Robert S.D. Higgins, M.D., Russell E. Carlson, M.D., and Robert H. Jones, M.D.



Sixfold increase in repeat intervention with PCI at 18 months

The Controversy and the Solution

○ Patients are denied access to the 'gold standard' treatment by the the interventional cardiologist ('the gatekeeper')

Califf RM. Stenting or Surgery JACC 2005; 46: 589-91 :

“It is likely that most people undergoing coronary angiography are not told the entire story when a decision is made about undergoing PCI ... self-referral.. financial incentives ..without surgical opinion the patient is in no position to have rational input into the decision”

○ The solution is the Multidisciplinary Team (MDT) [BMJ 2005,2007]

- As for lung cancer
- No doctor with the real interests of the patient would object to an MDT
- MDT should include non-interventional and interventional cardiologist, surgeon and payer (economic implications)

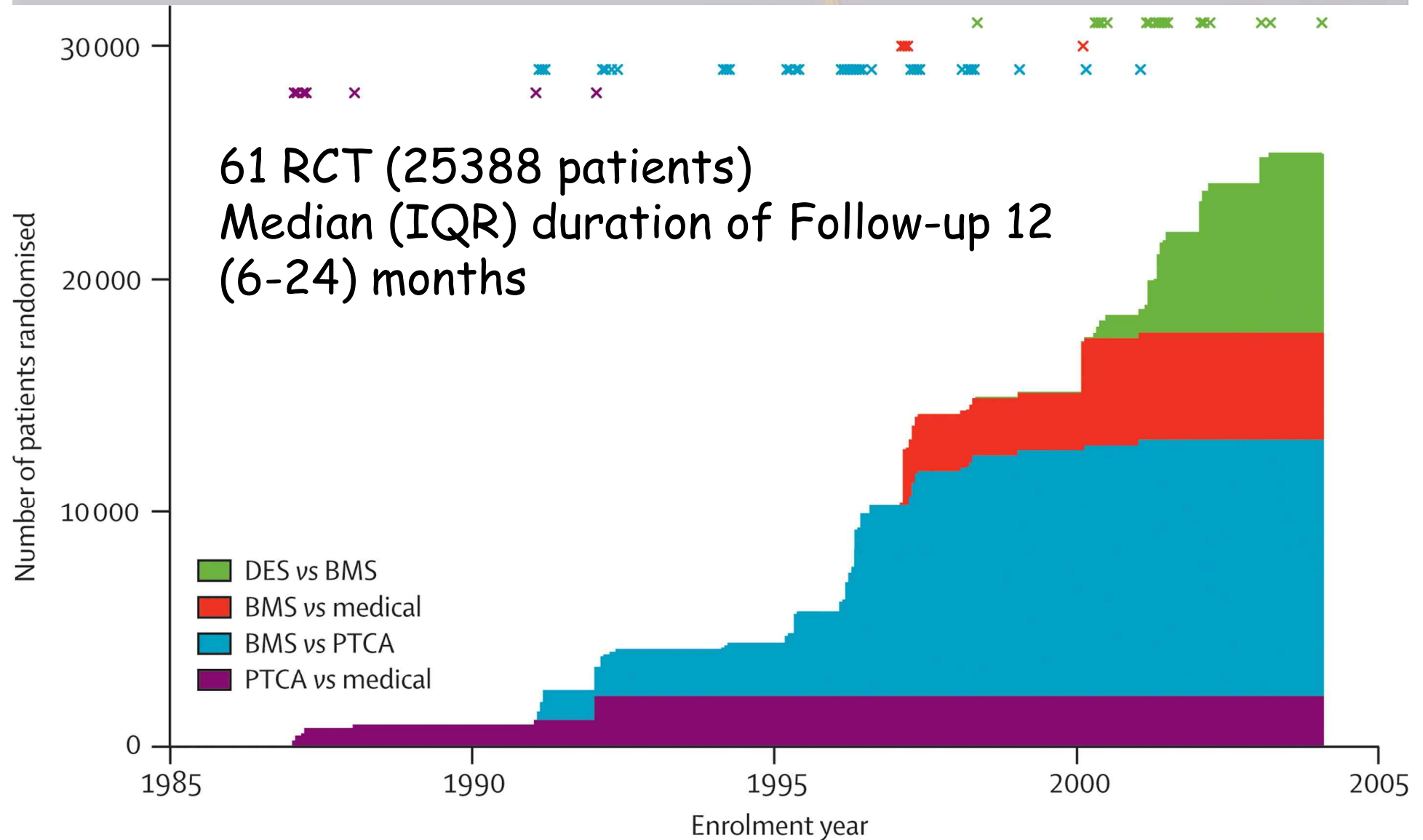
○ In elective patients ALL interventions should be agreed by an MDT

- Ensure real patient choice and genuine informed consent
- Being given a few minutes to consent to a procedure in a cath lab with a catheter in the groin is not informed consent

○ If MDT is not agreed voluntarily then should be enforced by external regulatory/statutory bodies to protect the best interests of patients

Percutaneous coronary interventions for non-acute coronary artery disease: a quantitative 20-year synopsis and a network meta-analysis [Lancet 2009]

Thomas A Trikalinos, Alawi A Alsheikh-Ali, Athina Tatsioni, Brahmajee K Nallamothu, David M Kent



SYNTAX Results: Left Main (2 years)

	OVERALL (n=705)			Lowest (n=212) (0-22)			Intermediate (n=195) (23-32)			Highest (n=284) (>33)		
	PCI	CABG	p	PCI	CABG	p	PCI	CABG	p	PCI	CABG	p
numbers	357	348		118	104		103	92		135	149	
Death	5.6	6.2	0.77	0.9	4.9	0.07	4.9	11.3	0.10	10.4	4.1	0.04
CVA	0.9	3.7	0.01	0.9	4.1	0.12	1.0	2.3	0.46	0.8	4.2	0.08
MI	5.5	4.1	0.45	3.6	2.0	0.53	4.0	3.3	0.86	8.4	6.1	0.48
Revasc	17.3	10.4	0.01	14.7	10.1	0.37	14.9	12.8	0.72	21.8	9.2	0.003
MACCE	22.9	19.3	0.27									

- CABG best in 65% of All LMS (507 Registry+284 (SYNTAX >33); 791/1212)
- UK CABG 2004-08: 30,218 LMS vs 69,775 NO LMS (2.5% vs 1.5% DEATH)
- 2 yr mortality 6% for LMS vs 5% NO LMS
- PCI provides equivalent/superior mortality in SYNTAX <33 (1/3 of all LMS)
- Large new RCT in this cohort sponsored by Abbott (announced TCT 2009)

EVIDENCE BASIS FOR CABG: STRONG SCIENTIFIC RATIONALE

Effect of coronary artery bypass graft surgery on survival: overview of 10-year results from randomised trials by the Coronary Artery Bypass Graft Surgery Trialists Collaboration* LANCET 1994

Salim Yusuf, David Zucker, Peter Peduzzi, Lloyd D Fisher, Timothy Takaro, J Ward Kennedy, Kathryn Davis, Thomas Killip, Eugene Passamani, Robin Norris, Cynthia Morris, Virendra Mathur, Ed Varnauskas, Thomas C Chalmers

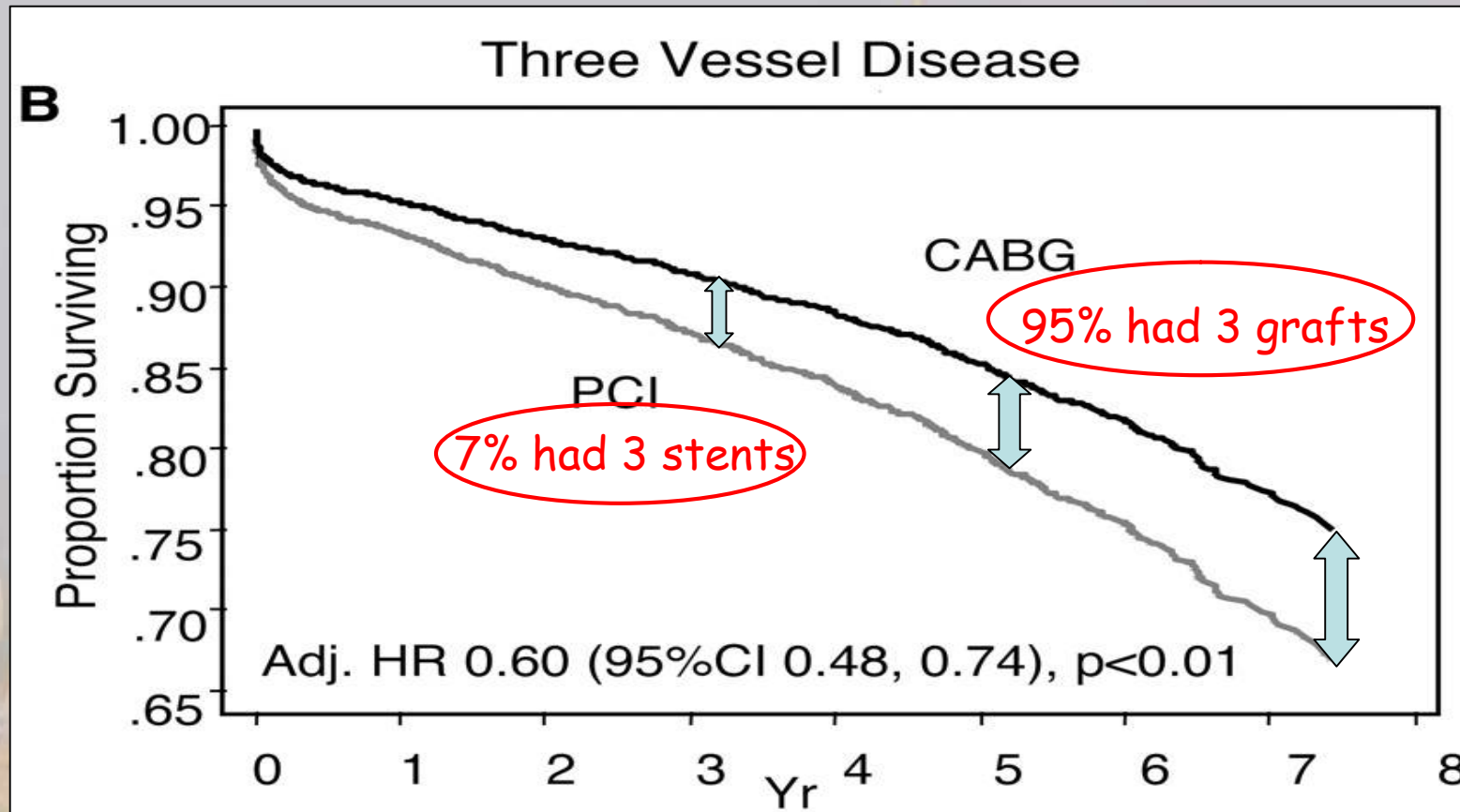
- 7 RCT of CABG vs medical therapy (2650 patients followed for 10 years)
- CABG improved SURVIVAL and symptom relief
- L main stem, TRIPLE vessel disease (esp proximal LAD disease)
- Benefits greater if severe symptoms, +ve exercise ECG, impaired LV

All current studies show that these conclusions remain valid

- 1 ○ "benefits of CABG in more extensive disease are underestimated"
 - (i) relatively low-risk patients
 - (ii) results analysed on ITT basis (40% of medical group had CABG)
 - (iii) only 10% of CABG patients received an IMA graft (now >90%)
- 2 ○ BUT: "no survival benefit for CABG if 1 or 2 VD and normal LV function"
- 3 ○ Recommendations for future trials of PCI vs CABG
"should include a high proportion of patients for whom CABG is known to be superior to medical therapy"

PCI is not as effective as CABG in the 'real' world

Long Term Survival in patients with multivessel disease after CABG or PCI
Malenka, D. J. et al. Circulation 2005



○ Effect true for all groups (elderly, gender, diabetics, stents, EF $< / >$ 40%)

Conclusion: 'In contemporary practice survival for patients with 3-vessel coronary artery disease is better after CABG than PCI, an observation that patients and physicians should carefully consider when deciding on revascularization strategy'

PCI is not as effective as CABG in the 'real' world

Propensity Analysis of Long-Term Survival After Surgical or Percutaneous Revascularization in Patients With Multivessel Coronary Artery Disease and High-Risk Features

Sorin J. Brener, MD; Bruce W. Lytle, MD; Ivan P. Casserly, MD; Jakob P. Schneider, RN; Eric J. Topol, MD; Michael S. Lauer, MD **Circ 2004**

- **6033 risk matched patients: PCI ↑ 5 yr mortality × 2.3 (95% CI × 2-3)**

Coronary Artery Disease

CIRC 2007

Results From the Intermountain Heart Registry

Tami L. Bair, BS; Joseph B. Muhlestein, MD; Heidi T. May, MSPH; Kent G. Meredith, MD; Benjamin D. Horne, PhD, MPH; Robert R. Pearson, PharmD; Qunyu Li, MD; Kurt R. Jensen, MS; Jeffrey L. Anderson, MD; Donald L. Lappé, MD

- **6369 patients: CABG: 5yr HR death =0.85 (p<0.001) for MACE=0.51**

Outcomes of Coronary Artery Bypass Grafting Versus Percutaneous Coronary Intervention With Drug-Eluting Stents for Patients With Multivessel Coronary Artery Disease **CIRC 2007**

Aamir Javaid, MD; Daniel H. Steinberg, MD; Ashesh N. Buch, MBChB; Paul J. Corso, MD; Steven W. Boyce, MD; Tina L. Pinto Slottow, MD; Probal K. Roy, MD; Peter Hill, MD; Teruo Okabe, MD; Rebecca Torguson, MPH; Kimberly A. Smith, BS; Zhenyi Xue, MS; Natalie Gevorkian, MD; William O. Suddath, MD; Kenneth M. Kent, MD; Lowell F. Satler, MD; Augusto D. Pichard, MD; Ron Waksman, MD

- **1680 patients: CABG: 1 yr mortality 3% vs 11% for PCI with DES**

CABG offers survival benefit in DIABETES

Survival of Patients With Diabetes and Multivessel Coronary Artery Disease After Surgical or Percutaneous Coronary Revascularization: Results of a Large Regional Prospective Study

Nathaniel W. Niles, MD,* Paul D. McGrath, MD, FACC,† David Malenka, MD, FACC,* **JACC 2001**

- **2766 risk matched DIABETICS: PCI ↑ 5 yr mortality x 2 - 4**

Journal of the American College of Cardiology
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Vol. 49, No. 15, 2007
ISSN 0735-1097/07/\$32.00
doi:10.1016/j.jacc.2006.11.048

- **10 yr survival: 58% for CABG vs 45% for PCI (p=0.02)**

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

JACC 2007

Outcomes of Coronary Artery Bypass Grafting Versus Percutaneous Coronary Intervention With Drug-Eluting Stents for Patients With Multivessel Coronary Artery Disease

CIRC 2007

Aamir Javaid, MD; Daniel H. Steinberg, MD; Ashesh N. Buch, MBChB; Paul J. Corso, MD;

- **1 yr mortality in 601 DM pts: 3% CABG vs 12%-18% PCI/DES (p<0.001)**

Nathan S. Givon, MD; William C. Suddath, MD; Kenneth M. Kohn, MD; Edward F. Saver, MD; Augusto D. Pichard, MD; Ron Waksman, MD

HR for CABG vs PCI in DM HR 0.70 (95% CI 0.56-0.87); p=0.014
Hlatky et al Collaborative Analysis Lancet 2009

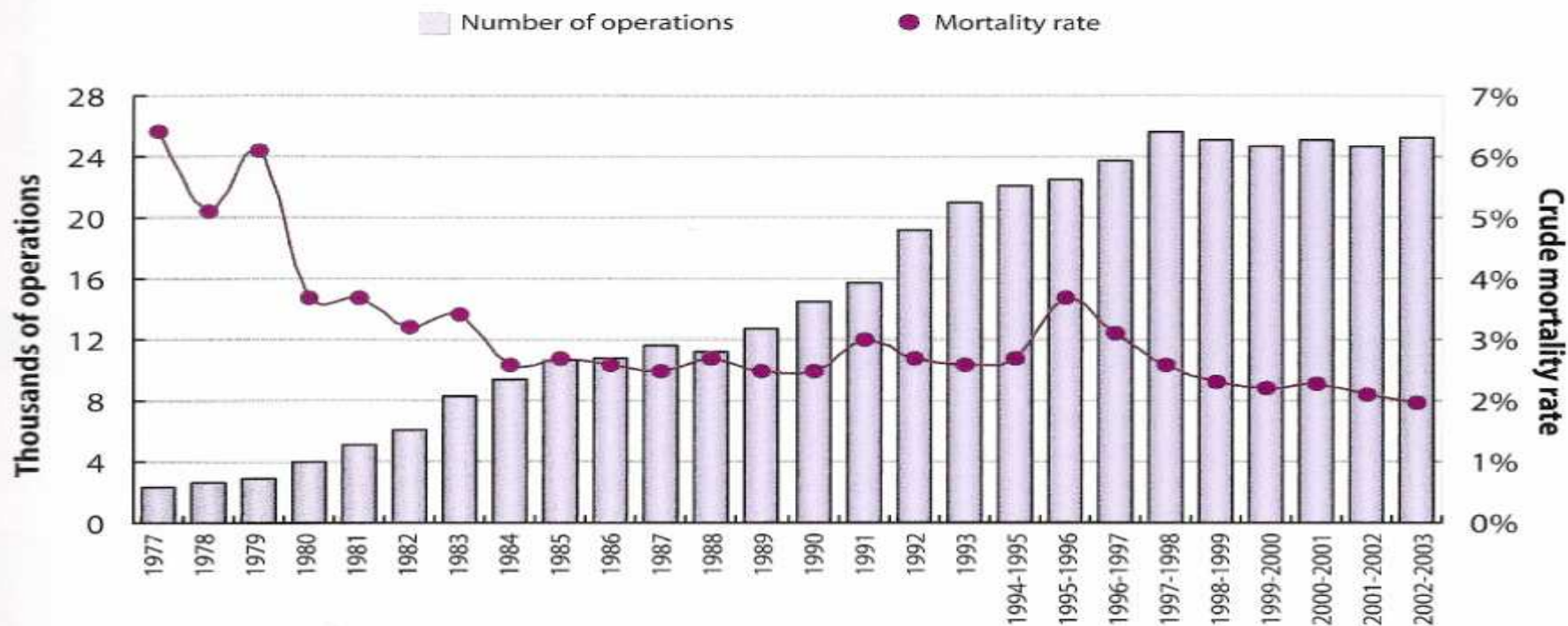
"There is no survival difference between CABG and PCI"

- The most widely perpetuated **myth** in cardiovascular medicine
 - ubiquitous in the literature,
 - endlessly repeated in cardiology lectures,
 - frequently - but erroneously- told to patients
- *"The great enemy of the truth is very often not the lie - deliberate, contrived and dishonest - but the **myth** - persistent, persuasive and unrealistic."* (JF Kennedy; S Yusuf)
- Securing the myth
 - Based on 15 RCT where results were stacked against CABG
 - Ignoring evidence from numerous large databases which consistently demonstrates a survival benefit of CABG



CABG: a very safe, effective procedure (with >45 yr follow-up data)
 • Most intensively studied surgical procedure ever undertaken

UKCSR: Activity and mortality trends for isolated coronary surgery (n=386,745)

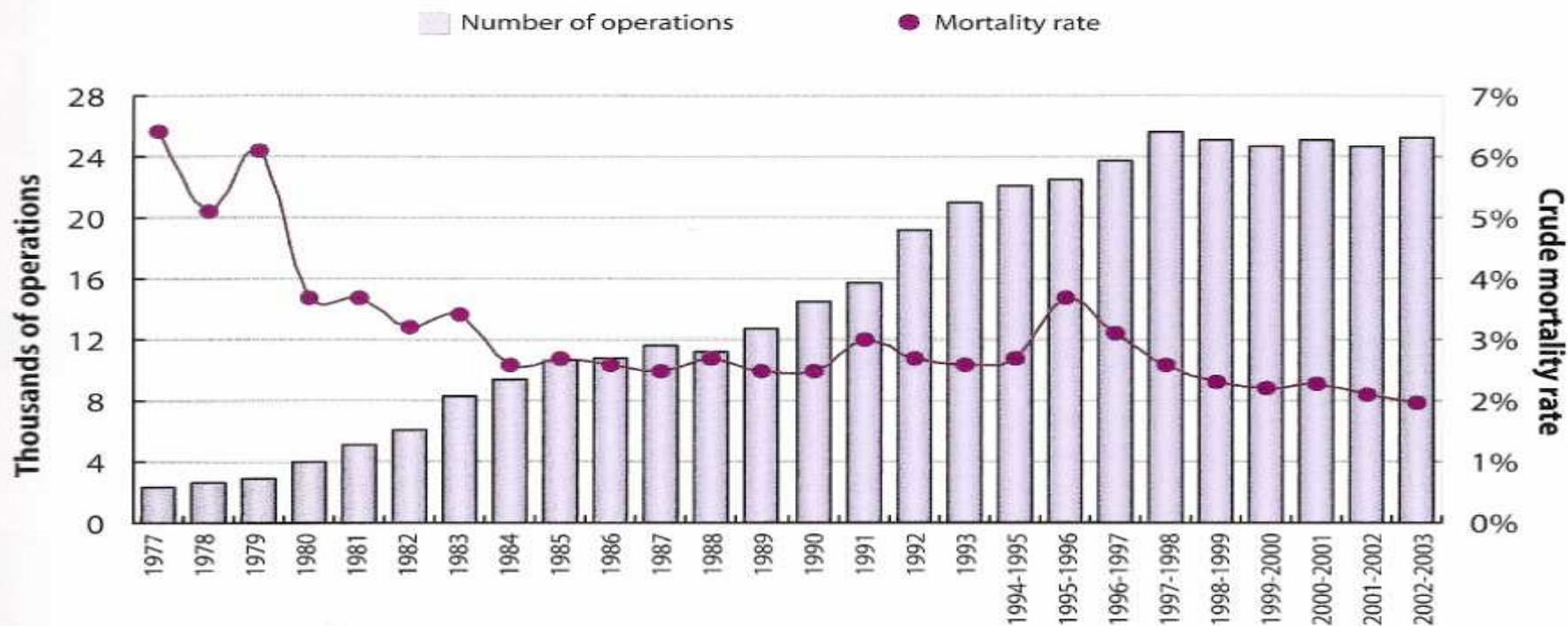


- Current UK results for **ALL** 114,000 FIRST TIME CABG (2004-2008) [July 2009]
 - Overall 30 day mortality 1.8% (despite marked increase in age + comorbidity)
 - Includes >30% who are high risk (urgent, elderly, poor LV)
 - **In elective patients (>78,000 [70%]) 30 day mortality 1.1%**

- MRC/BHF ART trial of 2 vs 1 IMA: 30 day mortality in 3102 pts 1.2%
 - 28 centres in 7 countries

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 - 28 centres in 7 countries

Get With the Guidelines: A New Chapter?

Raymond J. Gibbons, MD

A final potential explanation, and in my view the most concerning, is that these recommendations for PCI in patients indicated for CABG reflect a “grow the business” and “make it up on volume” mentality in response to declining reimbursement rates.⁷ I believe that this attitude accounts for at least some of the dramatic growth in imaging over the past decade. The current reimbursement system favors tests and procedures. There are compelling financial incentives for cardiologists performing intervention to do more procedures, even when the patient might be better treated with CABG.

Should surgical consultation be encouraged, as suggested by the authors? For patients for whom ad hoc PCI remains the best option, particularly those with refractory unstable angina, the risk of delay to permit such a consultation does not seem justified. However, there are many other patients with stable symptoms for whom issues of contrast load, and the need for further discussion with the patient, dictate that PCI is best performed on a different day. In such patients, surgical consultation should be considered but not mandated.

Both the SCAI and ACC/AHA guidelines have indicated that ad hoc PCI should not be a standard strategy for all patients. For patients in stable condition we should consider less ad hoc PCI.

Revascularization for Unprotected Left Main Stem Coronary Artery Stenosis

Stenting or Surgery

David P. Taggart, MD (HONS), PHD, FRCS,* Sanjay Kaul, MD, FACC,†

		BMS	DES
studies		8	7
patients		1150	599
In hospital mortality		6%	2.4%
1 year	mortality	-	7%
	repeat revascularization	-	21%*
2 year	mortality	17%	
	repeat revascularization	29%	

* 20% - 40% restenosis asymptomatic

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 (patients ineligible for randomization)

Stents versus Coronary-Artery Bypass Grafting for Left Main Coronary Artery Disease

NEJM 2008

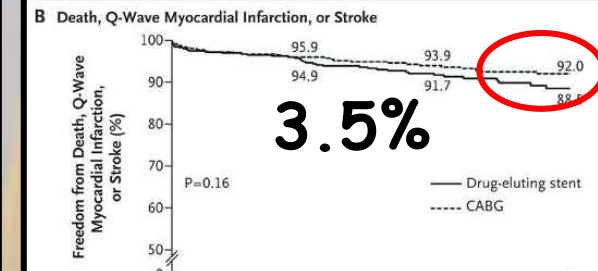
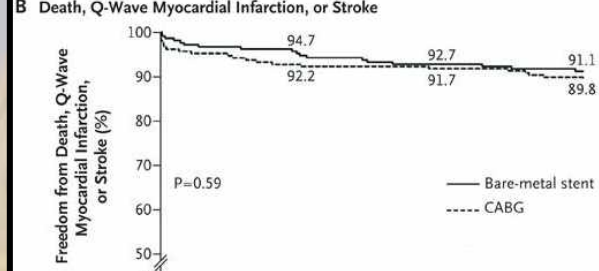
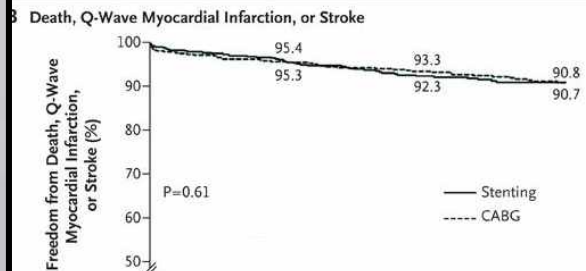
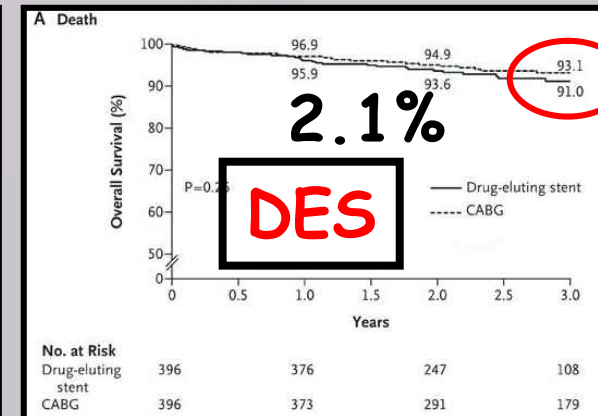
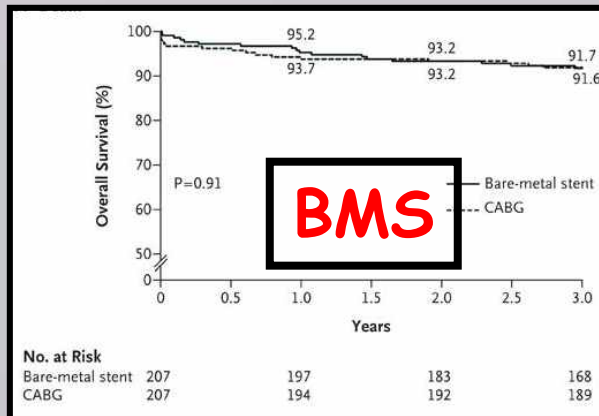
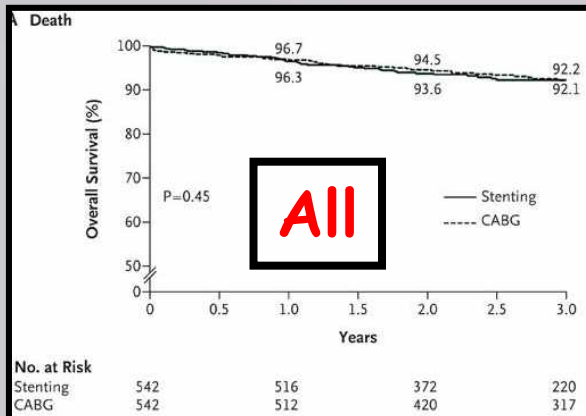
Ki Bae Seung, M.D., Duk-Woo Park, M.D., Young-Hak Kim, M.D., Seung-Whan Lee, M.D., Cheol Whan Lee, M.D., Myeong-Ki Hong, M.D., Seong-Wook Park, M.D., Sung-Cheol Yun, Ph.D., Hyeon-Cheol Gwon, M.D., Myung-Ho Jeong, M.D., Yangsoo Jang, M.D., Hyo-Soo Kim, M.D., Pum Joon Kim, M.D., In-Whan Seong, M.D., Hun Sik Park, M.D., Taehoon Ahn, M.D., In-Ho Chae, M.D., Seung-Jea Tahk, M.D., Wook-Sung Chung, M.D., and Seung-Jung Park, M.D.

Conclusions In a cohort (n2240) of patients with unprotected left main coronary artery disease, we found no significant difference in rates of death or of the composite end point of death, Q-wave myocardial infarction, or stroke between patients receiving stents and CABG. **However, stenting, even with drug-eluting stents, was associated with higher rates of target-vessel revascularization than was CABG.**

		PCI (1102)	CABG (1138)	
Peripheral Vascular Disease		1.5%	5.4%	<0.001
Unstable angina		55%	68%	<0.001
Distal LMS		49%	54%	0.04
LMS	alone	25	6	<0.001
	1VD	24	11	
	2VD	26	26	
	3VD	25%	57%	
	RCA	36%	71%	

- Superb registry data
- Overall relatively low rate of distal LMS and 3 vessel CAD esp PCI (SYNTAX <33 ???)
- applicable in Europe/USA ???
- NO ROUTINE SURGICAL OPINION

Outcome in PCI and CABG propensity matched patients: All; BMS; DES



‘... our analysis was underpowered to detect significant differences in mortality, especially in the comparison of DES with CABG. ... Nonsignificant trends toward higher event rates were seen in the group that received DES; these trends might have been significant with a larger cohort of patients’

Propensity matching to lower risk PCI patients !!

Stenting	542	471	331	193
CABG	542	503	408	305

Bare-metal stent	207	167	154	141
CABG	207	194	190	187

Drug-eluting stent	396	371	288	176
CABG	396	371	288	176

ALL TVR: HR x5

BMS TVR: HR x11

DES TVR: HR x6

Summary and Conclusions

- For 3 vCAD 79% patients have SYNTAX score > 22
 - CABG offers better clinical and survival outcome
 - Benefits of CABG magnified in diabetic patients
 - CABG is a more cost effective treatment
 - PCI may have role in some patients with lower SYNTAX score
 - PCI may have a role in patients unfit for or who refuse CABG
- For LMS 65% patients have SYNTAX score >32
 - CABG offers better clinical and survival outcome
 - CABG is a more cost effective treatment
 - PCI may offer similar/better outcome for isolated ostial/mid shaft lesions
 - PCI may have a role in patients unfit for or who refuse CABG
- With regards to the widespread use of PCI in multivessel CAD
 - The best available evidence does not support this practice
 - A large proportion of patients misunderstand indication for PCI
- CABG could be performed to higher standard
 - More use of arterial grafts (especially 2nd IMA)
 - More off pump CABG in higher risk patients