

TCT AP2013

Heart Team Should Meet Before PCI for All Left Main Disease

David P Taggart MD PhD FRCS FESC

Professor of Cardiovascular Surgery, University of Oxford



Conflicts of Interest:

- (i) **Clinical**: Cardiac Surgeon
- (ii) **Commercial**: Consultant to Medtronic, Abbott, AstraZeneca, Novadaq, VGS,
- (iii) **One of 25 ESC/EACTS Guidelines Writers** on Myocardial Revascularization
- (iv) **Chairman Surgical Committee of EXCEL trial**

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

Appropriate use of stents in LMS

Favorable Long-Term Outcome After Drug-Eluting Stent Implantation in Nonbifurcation Lesions That Involve Unprotected Left Main Coronary Artery

A Multicenter Registry [*Circulation*. 2007;116:158-162]

Alaide Chieffo, MD; Seung J. Park, MD, PhD; Marco Valgimigli, MD; Young H. Kim, MD, PhD; Joost Daemen, MD; Imad Sheiban, MD; Alessandra Truffa, MD; Matteo Montorfano, MD; Flavio Airoidi, MD; Giuseppe Sangiorgi, MD; Mauro Carlino, MD; lassen Michev, MD; Cheol W. Lee, MD, PhD; Myeong K. Hong, MD, PhD; Seong W. Park, MD, PhD; Claudio Moretti, MD; Erminio Bonizzoni, PhD; Renata Rogacka, MD; Patrick W. Serruys, MD, PhD; Antonio Colombo, MD

○ 790 LMS:

- 19% NonBifurcation Lesions
- ostial (52%) or mid shaft (28%) or both (+35% RCA disease)
- 1 hospital death
- 73% repeat angiogram at 6 months with 1 restenosis
- at 2.5 years 3.4% mortality and 5% revascularization

'Stent thrombosis could not be excluded in the 4 patients (2.7%) who died of unknown causes'

A collaborative systematic review and meta-analysis on 1278 patients undergoing percutaneous drug-eluting stenting for unprotected left main coronary artery disease

Am H J 2008

Giuseppe G.L. Biondi-Zoccai, MD,^{a*} Marzia Iotriante, MD,^{b,*} Claudio Moretti, MD,^a Emanuele Meliga, MD,^a Pierfrancesco Agostoni, MD,^c Marco Valgimigli, MD, PhD,^{d,*} Angela Migliorini, MD,^f David Antoniucci, MD,^f Didier Carrié, MD,^g Giuseppe Sangiorgi, MD,^{h,j} Alaide Chieffo, MD,^{h,j} Antonio Colombo, MD,^{h,j} Matthew J. Price, MD,^l Paul S. Teirstein, MD,^l Evald H. Christiansen, MD,^k Antonio Abbate, MD,ⁱ Luca Testa, MD,^b Julian P.G. Gunn, MD,^m Francesco Burzotta, MD,^b Antonio Laudito, MD,ⁿ Gian Paolo Trevi, MD,^o and Imad Sheiban, MD^o *Turin, Rome, Ferrara, Gussago, Florence, and Milan, Italy; Antwerp, Belgium; Toulouse, France; La Jolla, CA; Aarbus, Denmark; Richmond, VA; and Sheffield, United Kingdom*

CATEGORY	n	In-hospital (%) death	6-10 month follow up		
			death	TVR	MACE
All DES	1278	2.3	5.5	6.5	16.5
Nonbifurcation (25%)	285	0.9	4.1	6.7	14.7
Low -risk: ES<6	260	3	4.8	8.5	15.7
High-risk: ES>6	312	6.6	12	6.4	20.6

Emphasises 2 key issues regarding left main

- 1) Lesion: bifurcation vs non-bifurcation
- 2) Patient: low vs high risk

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

	PCI	CABG	
nos	357	348	p
Death	12.8	14.6 (+1.8%) *	.53
Cardiac Death	8.6	7.2 (-1.4%)	.46
MI	8.2	4.8 (-3.4%)	.10
CVA	1.5	4.3 (+2.8%) *	.03
D+C+M	19	20.8 (+1.8%)	.57
Revasc	26.7	15.5 (-11.2%)	<0.01

* = different from SYNTAX 3VD

EXCEL TRIAL (Abbott Vascular)

- 2600 patient RCT: PCI vs CABG
- only in SYNTAX Score <33
- 1000 registry patients now enrolled
- ie 3600 in total
- started Sept 2010
- >1250 RCT patients enrolled to date

Low <23	nos	118	104	
	death	7	11.3	.28
	CVA	1.8	4.1	.28
	MI	6.2	3.1	.32
	D+C+M	13.9	15.2	.71
	Revasc	23	20.3	.65

Intd 23-32	nos	103	92	
	death	8.9	19.3	.04
	CVA	1.0	3.6	.23
	MI	6.0	4.6	.71
	D+C+M	15.7	24.9	.11
	Revasc	22.2	16.6	.40

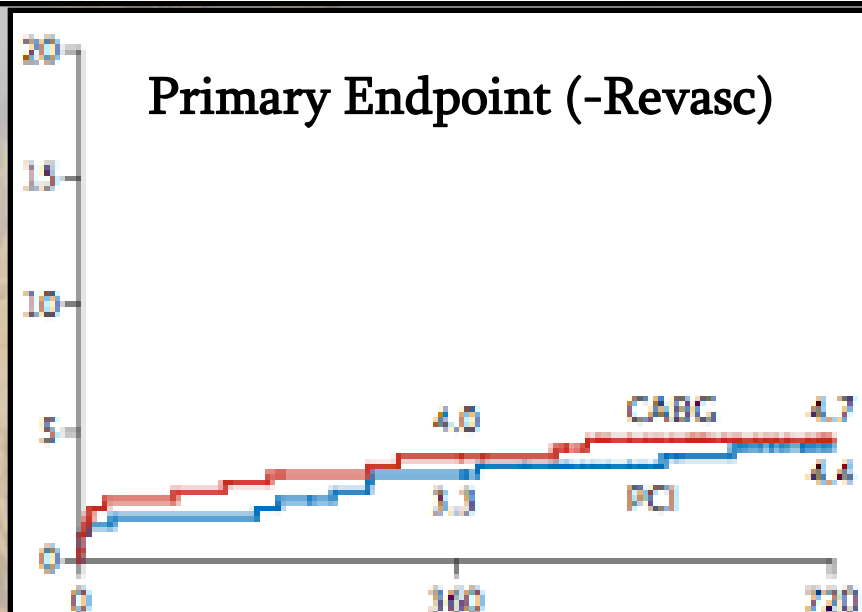
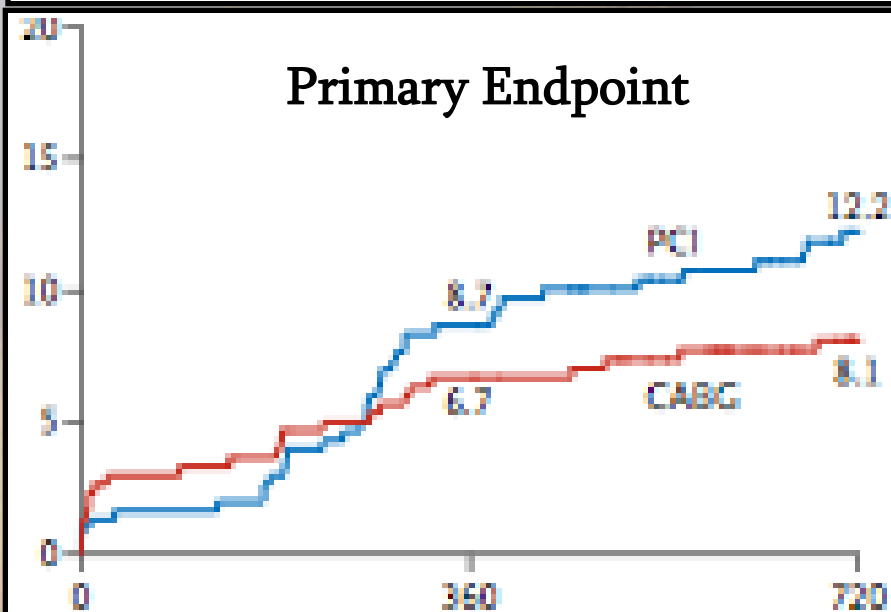
High >32	nos	135	149	
	death	20.9	14.1	.11
	CVA	1.6	4.9	.13
	MI	11.7	6.1	.40
	D+C+M	26.1	22.1	.33
	Revasc	34.1	11.6	<.001

Randomized Trial of Stents versus Bypass Surgery for Left Main Coronary Artery Disease

Seung-Jung Park, M.D., Young-Hak Kim, M.D., Duk-Woo Park, M.D.,

‘PRECOMBAT’: 600 patient RCT (300 PCI vs 300 CABG)

- Cohort of 1454 LM patients (59% NOT randomized)
- Mean SYNTAX score: 25 (vs 30 in SYNTAX)
- Mean Euroscore: 2.7 (vs 3.8 in SYNTAX)
- Primary endpoint: Death; CVA; MI; Repeat Revasc



○ Incidence of stroke 0.4% PCI vs 0.7% CABG

○ No increase in mortality or stroke with CABG (vs SYNTAX)

Meta-Analysis of Three Randomized Trials and Nine Observational Studies Comparing Drug-Eluting Stents Versus Coronary Artery Bypass Grafting for Unprotected Left Main Coronary Artery Disease Am J Cardiol 2012

Jae-Sik Jang, MD, PhD^a, Kyu-Nam Choi, MD^a, Han-Young Jin, MD^a, Jeong-Soo Kim, MD^a, Tae-Hyun Yang, MD, PhD^a, Dae-Kyeong Kim, MD, PhD^a, Dong-Sik Park, MD, PhD^a, Sang-Hwa Urm, MD, PhD^b, Jin Ho Chun, MD, PhD^b, Seung-Wan Lee, MD, PhD^c, Duk-Woo Park, MD, PhD^c, Seung-Whan Lee, MD, PhD^c, Seung-Ho Park, MD, PhD^c, Cheol Whan Lee, MD, PhD^c, Seong-Wook Park, MD, PhD^c, Seung-Jung Park, MD, PhD^{c,*}

Twelve clinical studies (3 randomized trials and 9 observational studies)

- 5,079 patients, 3-year follow-up
- DES vs CABG
- ✓ ↓ risk of death (odds ratio [OR] 0.68, 95% [CI] 0.45 to 1.02)
- ✓ and composite of death, MI, or stroke (OR 0.70, 95% CI 0.49 to 1.00)
- ✓ higher target vessel revascularization (OR 3.52, 95% CI 2.72 to 4.56).

SURVIVAL BENEFIT OF CABG APPEARS AROUND 3 YEARS !!

Results of CABG for Left Main

Cardiac Surgery

The Society for
Cardiothoracic Surgery
in Great Britain & Ireland



Sixth
National Adult Cardiac
Surgical Database Report
2008

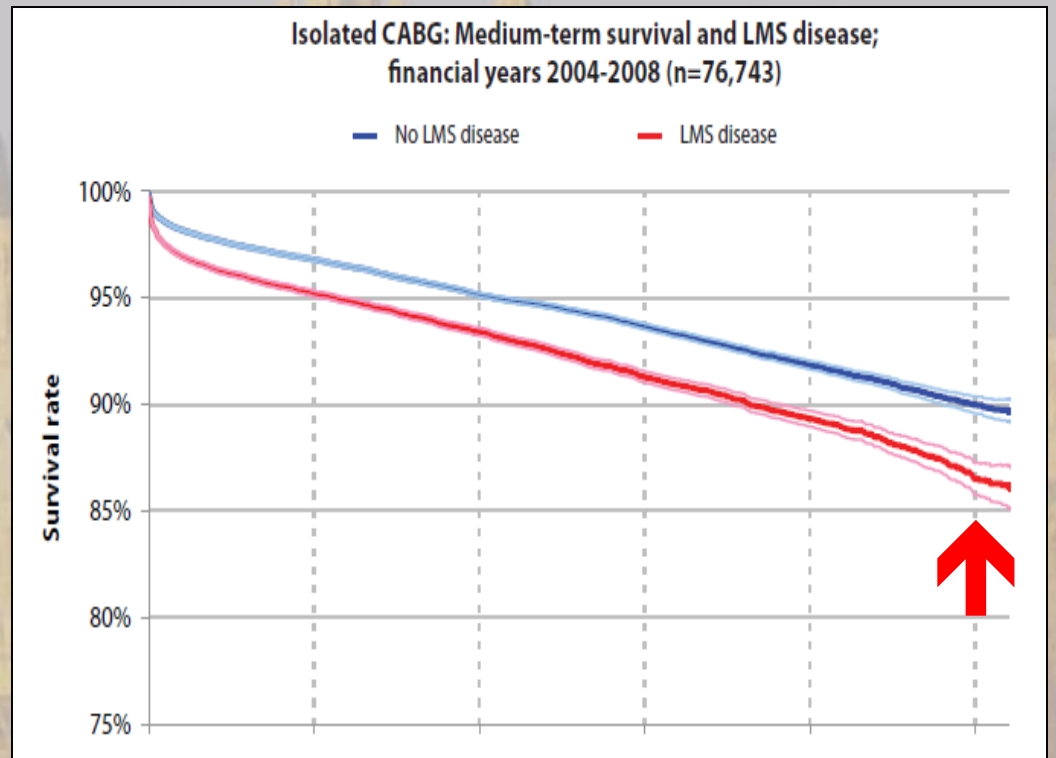
Demonstrating quality

Prepared by

Ben Bridgewater PhD FRCS
Bruce Keogh KBE DSc MD FRCS FRCP
on behalf of the Society for Cardiothoracic Surgery
in Great Britain & Ireland

Robin Kinsman BSc PhD
Peter Walton MA MB BChir MBA
Dendrite Clinical Systems

	2004-08	MORTALITY	
		All	Elective
Total CABG	114300	1.8%	1.1%
No LMS	69775 (70%)	1.5%	0.9%
LMS	30218 (30%)	2.5%	1.5%



5 yr mortality No LM = 10% (9% in SYNTAX)
5 yr mortality LMS = 14% (same as SYNTAX)

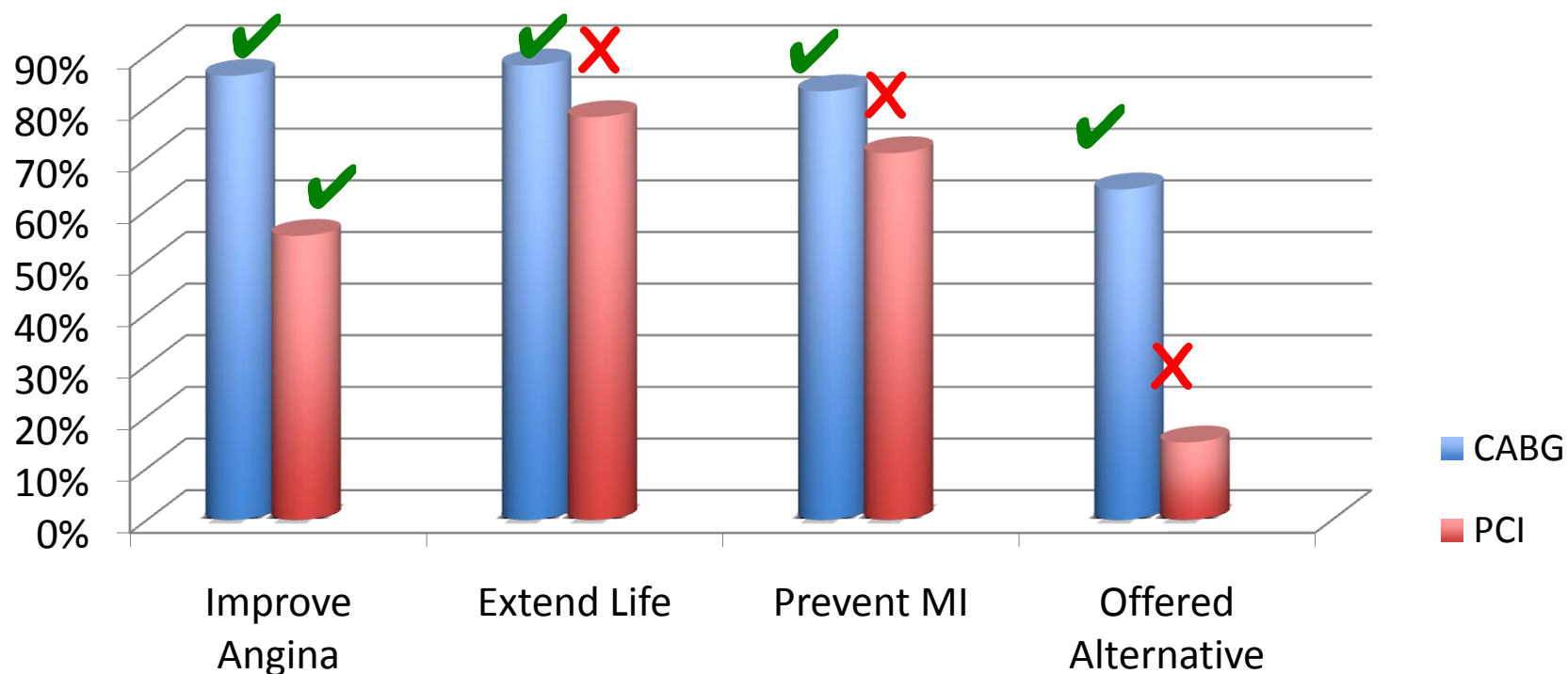
NO Heart Team/Guidelines leads to low rates of informed consent

Review

Informed consent for interventions in stable coronary artery disease: problems, etiologies, and solutions

Deepak P. Chandrasekharan, David P. Taggart *

10 studies of 1458 patients (1016 PCI; 442 CABG)



○ 70% of patients misunderstand rationale for PCI (thinking that it extends life and prevents further MI)

○ No surgical opinion in 85% !!!

○ Need for Guideline/Heart Team approach to recommend intervention

NO Heart Team/Guidelines increases rate of wrong interventions

Adherence of Catheterization Laboratory Cardiologists to ACC/AHA Guidelines for PCI and CABG: What happens in Actual Practice ? [Hannan et al Circ 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

The Guidelines...what do they recommend ?

Subset of CAD by anatomy	CABG			PCI		
	ESC	ACC		ESC	ACC	
Heart team Approach for LM or complex CAD	I C	I C		I C	I C	
1 VD: NON proximal LAD	IIb C	III B		I C	III B	
1 VD: proximal LAD	I A	IIa B		IIa B	IIb B	
2 VD: NON proximal LAD	IIb C	IIa B	IIb C	I C	IIb B	
2 VD: proximal LAD	I A	I B		IIa B	IIb B	
3 VD, simple lesions, full functional revasc achievable with PCI, SYNTAX scores <22	I A	I B		IIa B	IIb B	III B
3 VD, complex lesions, incomplete revasc achievable with PCI, SYNTAX scores >22	I A	I B		III A	IIb B	III B
LM (isolated or 1VD, ostium/shaft)	I A	I B		IIa B	IIa B	
LM (isolated or 1VD, distal bifurcation)	I A	I B		IIb B	IIb B	III B
LM + 2VD or 3VD, SYNTAX scores <33	I A	I B		IIb B	IIb B	III B
LM + 2VD or 3VD, SYNTAX scores >32	I A	I B		III B	IIb B	III B

79%

66%

Summary and Conclusions

- ① 65% of all left main disease (SYNTAX >32) have strong survival advantage with CABG by 5 years (6.8% by 5 years)
- ② Conflicting data between SYNTAX and PRECOMBAT about risk of death and stroke with CABG vs PCI in low and intermediate Left Main groups (SYNTAX <33) ...EXCEL TRIAL
- ③ Possible to improve PCI results with more use of IVUS,FFR and interval staging
- ④ Possible to improve results of CABG with lower mortality and risk of stroke
- ⑤ Possible that CABG is disadvantaged in lower severity left main by the presence of too much competitive flow (but NOT if additional 2 or 3 vessel coronary artery disease)
- ⑥ Following guidelines avoids need to discuss all patients; reserve MDT for interventions which do not follow guidelines
- ⑦ Guidelines are transparent and protect the best interests of patients and doctors
- ⑧ Statutory bodies/payers should only pay for interventions which follow guidelines or are otherwise agreed by MDT

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 (vs highly select patients in all previous RCTs)
- Parallel Registry (35% of patients straight to CABG !!)

ACC/AHASCAI guidelines for PCI focussed update 2009 [JACC 2009]

- PCI is CLASS III indication in virtually all Left Main patients (2001)
- PCI is CLASS III indication in Left Main candidate for CABG (2005)
- PCI is CLASS IIbB if low risk for PCI and increased risk for CABG (2009)
- PCI is CLASS IIa/b if easy anatomy and low risk, otherwise III (2011)

Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology. [Eur Heart J 2005;26:804-47]

○ 'Stenting for unprotected Left Main disease should only be considered in the absence of other revascularization options'

Joint ESC/EACTS Guidelines for Myocardial Revascularization

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

	CABG	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

65%

PCI or CABG in LMS: How to Decide ?

2 key issues regarding left main

- 1) Lesion: bifurcation vs non-bifurcation
- 2) Patient: low vs high risk

			NON Bifurcation	Bifurcation
Lesion Factors	Complex CAD (Syntax >32)	No	PCI > CABG	CABG > PCI
		Yes	CABG	CABG
	Stenosis Complexity	Easy	PCI > CABG	CABG > PCI
		Difficult	CABG	CABG
Patient Factors	Significant Co-morbidity	No	PCI > CABG	CABG > PCI
		Yes	PCI	PCI
	Contraindication to dual antiplatelets	No	PCI > CABG	CABG > PCI
		Yes	CABG	CABG
	Diabetes	No	PCI > CABG	CABG > PCI
		Yes	CABG	CABG
	Age	Young	PCI = CABG	CABG > PCI
		Old	PCI	PCI > CABG
Patient Preference		Both	Both	

Percutaneous Coronary Intervention Versus Coronary Artery Bypass Graft Surgery in Left Main Coronary Artery Disease

A Meta-Analysis of Randomized Clinical Data

Davide Capodanno, MD,* Gregg W. Stone, MD,† Marie C. Morice, MD,‡ Theodore A. Bass, MD,§ Corrado Tamburino, MD, PhD*

Catania, Italy; New York, New York; Massy, France; and Jacksonville, Florida

Objectives	The purpose of this study was to determine the safety and efficacy of percutaneous coronary intervention (PCI) compared with coronary artery bypass graft (CABG) in patients with left main coronary artery (LMCA) disease.
Background	Previous meta-analyses of PCI versus CABG in LMCA disease mainly included nonprospective, observational studies. Several new randomized trials have recently been reported.
Methods	We identified 1,611 patients from 4 randomized clinical trials for the present meta-analysis. The primary end-point was the 1-year incidence of major adverse cardiac and cerebrovascular events (MACCE), defined as death, myocardial infarction (MI), target vessel revascularization (TVR), or stroke.
Results	PCI was associated with a nonsignificantly higher 1-year rate of MACCE compared with CABG (14.5% vs. 11.8%; odds ratio [OR]: 1.28; 95% confidence interval [CI]: 0.95 to 1.72; $p = 0.11$), driven by increased TVR (11.4% vs. 5.4%; OR: 2.25; 95% CI: 1.54 to 3.29; $p < 0.001$). Conversely, stroke occurred less frequently with PCI (0.1% vs. 1.7%; OR: 0.15; 95% CI: 0.03 to 0.67; $p = 0.013$). There were no significant differences in death (3.0% vs. 4.1%; OR: 0.74; 95% CI: 0.43 to 1.29; $p = 0.29$) or MI (2.8% vs. 2.9%; OR: 0.98; 95% CI: 0.54 to 1.78; $p = 0.95$).
Conclusions	In patients with LMCA disease, PCI was associated with nonsignificantly different 1-year rates of MACCE, death, and MI, a lower risk of stroke, and a higher risk of TVR compared with CABG. (J Am Coll Cardiol 2011;58:1426-32) © 2011 by the American College of Cardiology Foundation

1611 patients from 4 RCT (81% from SYNTAX + PRECOMBAT)

1 year outcomes: MACCE 14.5% PCI vs 11.8% CABG; $p=0.11$

No difference in death or MI

With CABG stroke higher (1.7% vs 0.1%; $p=0.013$) and revasc lower (5.4 vs 11.4; $p<0.001$)

Long-Term Safety and Efficacy of Stenting Versus Coronary Artery Bypass Grafting for Unprotected Left Main Coronary Artery Disease

5-Year Results From the MAIN-COMPARE
(Revascularization for Unprotected Left Main
Coronary Artery Stenosis: Comparison of Percutaneous
Coronary Angioplasty Versus Surgical Revascularization) Registry

- 2240 patients: 1102 PCI (71%DES) vs 1138 CABG
- At 5 yrs similar rates of death, MI, CVA
- BUT x5 increase in repeat intervention with PCI

	PCI	CABG	p
LM +/-1VD	49%	17%	<0.001
LM +/- 2 or 3 VD	51%	83%	<0.001
RCA disease	36%	71%	<0.001

Long-Term Clinical Results Following Stenting of the Left Main Stem

Insights From RESEARCH (Rapamycin-Eluting Stent Evaluated at Rotterdam Cardiology Hospital) and T-SEARCH (Taxus-Stent Evaluated at Rotterdam Cardiology Hospital) Registries

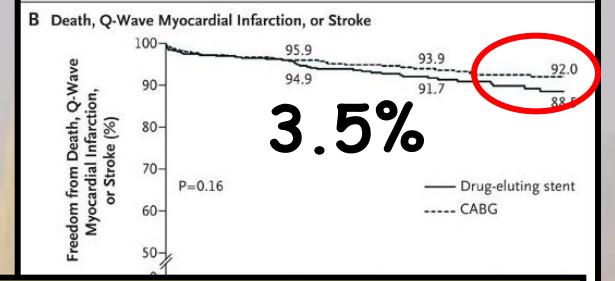
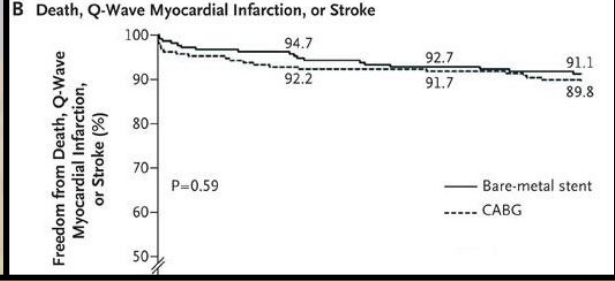
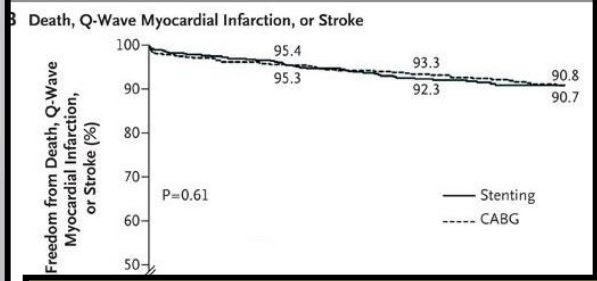
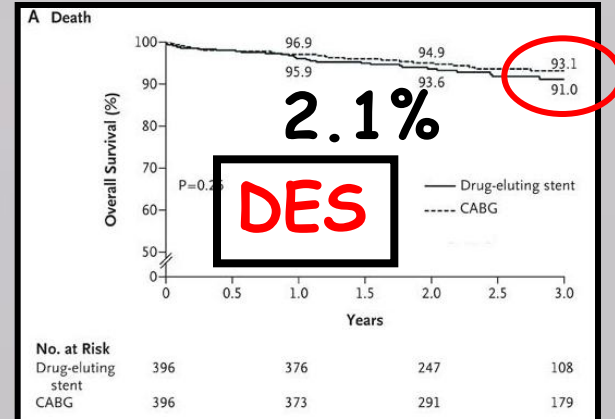
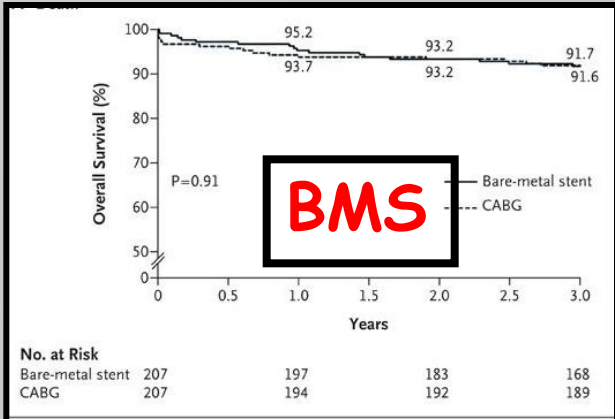
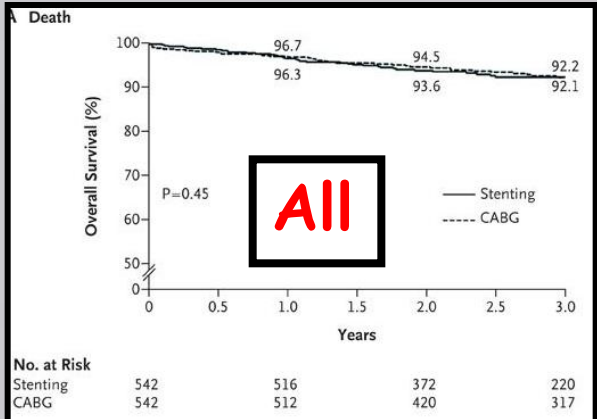
Yoshinobu Onuma, MD,* Chrysafios Girasis, MD,* Nicolo Piazza, MD,*
Hector M. Garcia-Garcia, MD,* Neville Kukreja, MA,* Scot Garg, MD,*
Jannet Eindhoven, MSc,* Jin-Ming Cheng, MSc,* Marco Valgimigli, MD, PhD,†
Ron van Domburg, PhD,* Patrick W. Serruys, MD, PhD,* on behalf of Interventional
Cardiologists at Thoraxcenter 2000–2005

Rotterdam, the Netherlands; and Ferrara, Italy

When compared with a historical cohort who received bare-metal stents for ULMCA treatment, landmark analysis performed after the first 2 years of follow-up demonstrated that the DES cohort had significantly higher patient-oriented composite end point over the last 2 years of follow-up (26% vs. 8%, $p = 0.02$). EuroSCORE (European System for Cardiac Operative Risk Evaluation), cardiogenic shock, and SYNTAX score were identified as independent predictors for the 4-year patient-oriented composite, whereas bifurcation angle was not.

Conclusions Late increase in patient-oriented composite end points after DES implantation for ULMCA warrants careful and long-term follow-up. SYNTAX score and EuroSCORE appear to have a significant prognostic value in long-term patient risk. (J Am Coll Cardiol Intv 2010;3:584–94) © 2010 by the American College of Cardiology Foundation

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

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

Surgery as 'gold standard' in LMS stenosis

- CABG: a safe, durable, effective procedure with > 40 yrs follow-up data
- 10 year survival benefit of CABG in LMS [Cohen and Gorlin Circ 1975]
- 3 RCT and numerous prospective studies confirm this over next 30 yrs

Comparison of Surgical and Medical Group Survival in Patients With Left Main Coronary Artery Disease. Long-term CASS

• 1484 LMS (>50% stenosis) [ACC/AHA 2004 Guideline Update for CABG]

Experience: Caracciolo E.A. Circ 1995; 91:2325-34

'The benefit of surgery over medical treatment ... is little argued. The median survival for surgically treated patients is 13.3 years versus 6.6 years in medically treated patients'

Current Results of CABG in LM stenosis [Taggart et al JACC 2008]

Six studies with at least 300 patients published within last 10 years

Author	Year	Nos	% urgent	30 day mortality
Jonsson (2006)	1970-1999	1888	26%	2.7%
Lu (2005)	1997-2003	1197	5%	2.6%
UK SCTS (2003)	2003	5003	-	3%
Dewey (2001)	1998-1999	728	46%	4.2%
Yeatman (2001)	1996-2000	387	57%	2.6%
Ellis (1998)	1990-1995	1585	47%	2.3%
SUMMARY		10788	32%	2.8%

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

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*

Conclusions Our analysis reveals no difference in mortality or major adverse cardiovascular or cerebrovascular events, for up to 3 years, between PCI and CABG for the treatment of ULMCA stenosis. However, PCI patients had a significantly higher risk of target vessel revascularization. In selected patients with ULMCA stenosis, PCI is emerging as an acceptable option. (J Am Coll Cardiol Intv 2009;2:739–47) © 2009 by the American College of Cardiology Foundation

- Six important facts not even mentioned in Abstract
- 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
- 3 year data actually available in only 45% of patients
- No definition of how PCI or CABG was chosen (ie confounding)
- Propensity matching can only be done towards lower risk populations

Longest Available Clinical Outcomes After Drug-Eluting Stent Implantation for Unprotected Left Main Coronary Artery Disease

The DELFT (Drug Eluting stent for LeFT main) Registry

Emanuele Meliga, MD,*† Hector Manuel Garcia-Garcia, MD, MSc,* Marco Valgimigli, MD, PhD,‡
Alaide Chieffo, MD, PhD,§ Giuseppe Biondi-Zoccai, MD,† Andrew O. Maree, MD,||
Stephen Cook, MD,¶ Lindsay Reardon, MD,|| Claudio Moretti, MD,† Stefano De Servi, MD,#
Igor F. Palacios, MD, FACC,|| Stephen Windecker, MD,¶ Antonio Colombo, MD, FACC, FESC,§
Ron van Domburg, PhD,* Imad Sheiban, MD,† Patrick W. Serruys, MD, PhD, FACC, FESC*
Rotterdam, the Netherlands; Turin, Ferrara, and Milan, Italy; Boston, Massachusetts; and Bern, Switzerland

		30 day	1yr	3yr
ARC defined CARDIAC DEATH (%)	All (358)	3.3	6.7	9.2
	Elective (288)	0.7	3.8	6.2
	Urgent (70)	14.3	18.6	21.4
TVR (%)	All (358)	0.8	10	14.2
	Elective (288)	0.7	11.1	16
	Urgent (70)	1.4	5.7	7.1

- Incomplete Reporting: How many 'non-cardiac' deaths occurred ?
- 680 patients underwent CABG..how was intervention decided?
- Increasing cardiac deaths between 1 and 3 years in all groups

A Meta-Analysis of 17 Randomized Trials of a Percutaneous Coronary Intervention-Based Strategy in Patients With Stable Coronary Artery Disease

Albert Schömig, MD, Julinda Mehilli, MD, Antoinette de Waha, MD, Melchior Seyfarth, MD, Jürgen Pache, MD, Adnan Kastrati, MD

Munich, Germany

Results In the PCI group 271 patients died compared with 335 in the medical treatment group, which corresponds to a 20% reduction in OR of all cause death (OR:0.80; 95% CI 0.64 to 0.99, $p=0.263$ for heterogeneity)

- Strange presentation of results without %
- Mortality 7.3% PCI vs 8.7% medical therapy (absolute difference 1.4%)
- 4 RCT (28% of patients) used CABG in 20-41% of the 'PCI' group
- 4 RCT (20% of patients) had MI within last 4 weeks (SWISSI II)
- Exclude CABG and recent MI: HR=0.91 (95% CI 0.74-1.12) ie NS

Considerations in LMS: Patient and Lesion Factors

○ PATIENT

- Age
- Comorbidity/Contraindication to CABG
- Diabetes
- Contraindication to dual antiplatelet medication
- Patient Preference ?

○ LMS LESION

- Bifurcation vs Non-bifurcation ?
- Other significant coronary artery disease ?
- Severity of LMS important as competitive flow inversely proportional to % stenoses (and may contraindicate arterial grafts)

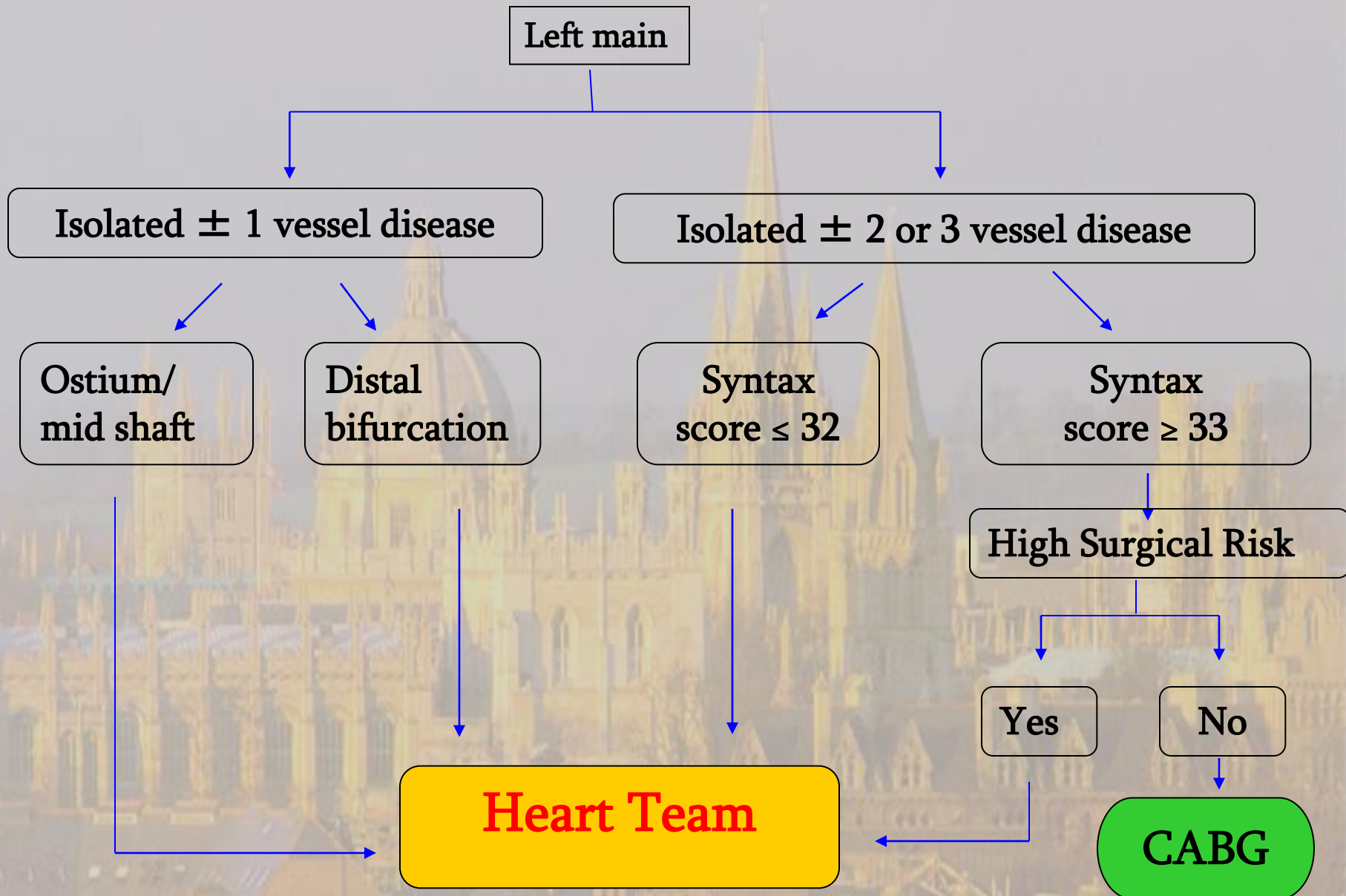
NON-bifurcation LMS Stenoses: Evidence for DES

	Chieffo et al (Circ 2007)	Biondi (Am H J 2008)	SYNTAX
Total LMS	790	1278	705
Non Bifurcation LMS	147 (19%)	285 (25%)	?
In hospital mortality	0.7%	0.9%	?
1 year mortality	-	4.1%	?
1 year repeat revascularization	-	6.7%	?
2.5 year mortality	3.4%*	-	?
2.5 year repeat revascularization	5.4%	-	?

*'Stent thrombosis could not be excluded in the 4 patients (2.7%) who died of unknown causes'

Low in hospital mortality with DES but conflicting evidence of risk of subsequent mortality at longer follow up

PCI or CABG in stable CAD (Left Main) requiring revascularization (ESCCVWG/ESC)



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

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*

Conclusions Our analysis reveals no difference in mortality or major adverse cardiovascular or cerebrovascular events, for up to 3 years, between PCI and CABG for the treatment of ULMCA stenosis. However, PCI patients had a significantly higher risk of target vessel revascularization. In selected patients with ULMCA stenosis, PCI is emerging as an acceptable option. (J Am Coll Cardiol Intv 2009;2:739–47) © 2009 by the American College of Cardiology Foundation

- Six important facts not even mentioned in Abstract
- 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
- 3 year data actually available in only 45% of patients
- No definition of how PCI or CABG was chosen (ie confounding)
- Propensity matching can only be done towards lower risk populations

PCI vs CABG in Unprotected LMS

		NON-bifurcation	Bifurcation
Age	Younger	CABG	CABG
	Older	PCI/CABG	CABG
Significant Comorbidity	No	PCI/CABG	CABG
	Yes	PCI ✓	CABG unless severe
Diabetes	No	PCI/CABG	CABG
	Yes	CABG	CABG
Contraindication to dual antiplatelets	No	PCI	CABG
	Yes	CABG ✓	CABG
Stenosis Complexity	Easy	PCI	CABG
	Difficult	PCI/CABG	CABG
Severe Coronary Artery Disease (SYNTAX >33)	No	PCI/CABG	CABG
	Yes	CABG ✓	CABG ✓

Evidence Basis for an Intervention

	RCT The Gold standard	Registries (Propensity Matched)
Strengths	No Bias	Large Numbers of Patients (often tens of thousands) Represent real clinical practice
Potential Weaknesses	Small numbers of patients Small % of eligible population Atypical patient populations Short duration of follow-up Large numbers of cross-overs	Confounding/Bias

Frontiers in cardiovascular medicine

Current management of left main coronary artery disease

Jean Fajadet^{1*} and Alaide Chieffo²

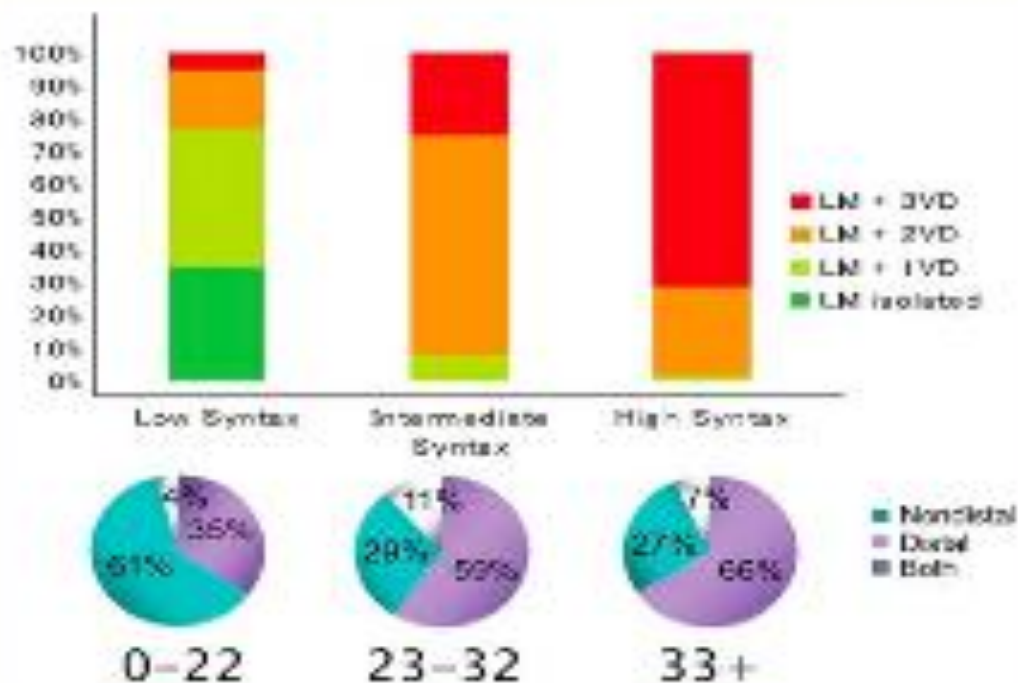


Figure 2 Vessel distribution in left main population according to SYNTAX score terciles.

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