TCTAP 2017

Left Main is Still Surgical Disease (for most patients)

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 Medistim, Medtronic, VGS, Somahlution, Stryker)
(iii) **One of 25 ESC/EACTS Guidelines Writers** on Myocardial Revascularization
(iv) **Chairman of Surgical Committee of the EXCEL trial**

PCI vs CABG for LM in 2017

THREE KEY QUESTIONS

1. What is the anatomical severity of CAD ?

Need SYNTAX SCORE to recommend best EVIDENCE BASED treatment

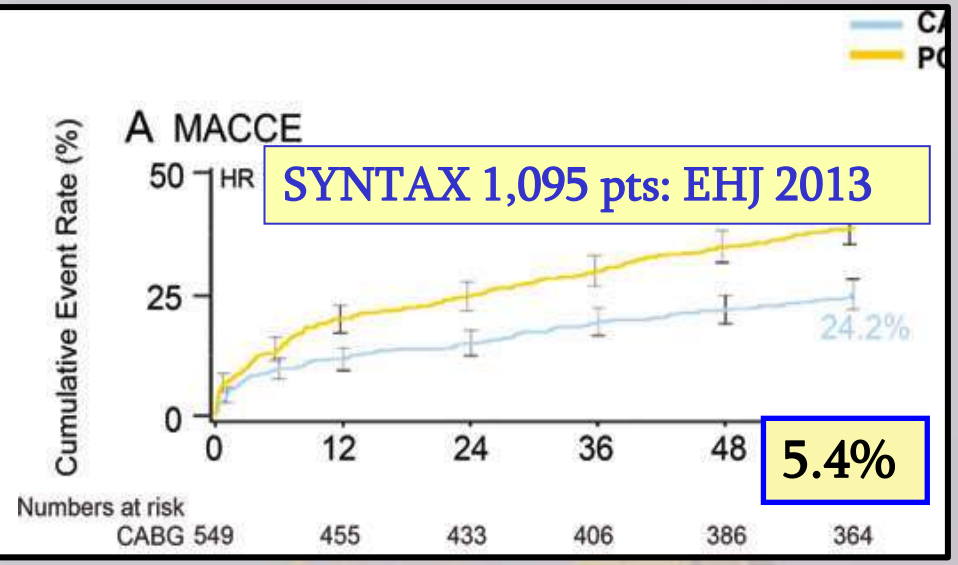
2. Duration of Follow-Up: Must be at least 5 yrs (ideally > 10 yrs)

Benefits of CABG (improved survival, reduced MI and repeat revasc) continue to increase with time (< 5yr follow up is only an 'interim' analyses)

3. Use of Guideline Based medical Therapy (GBMT)

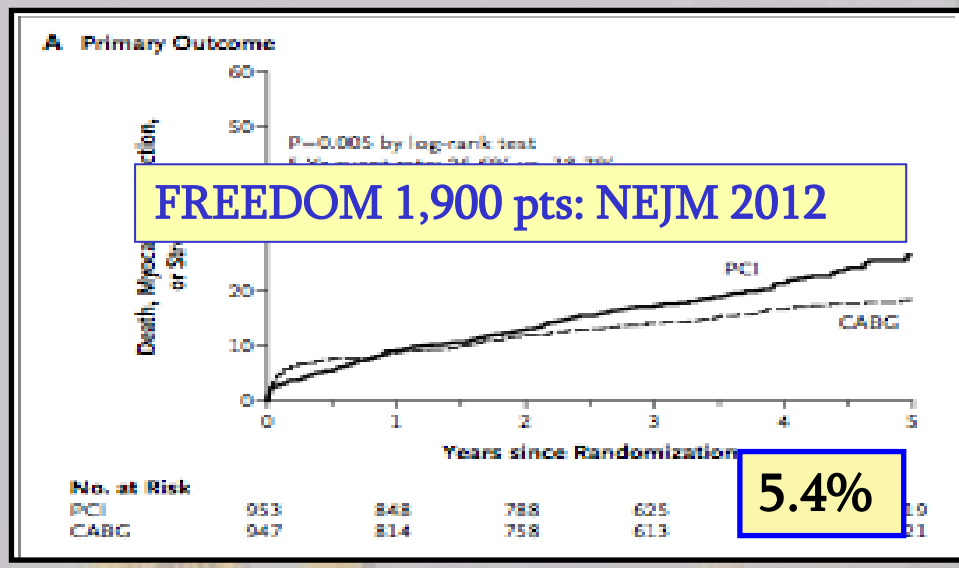
In most trials CABG patients received substantially inferior GBMT vs PCI patients leading to increased mortality and MACCE

Survival benefit of CABG increases with time (< 5 yr follow-up is 'interim' analyses)



SYNTAX 1,095 pts: EHJ 2013

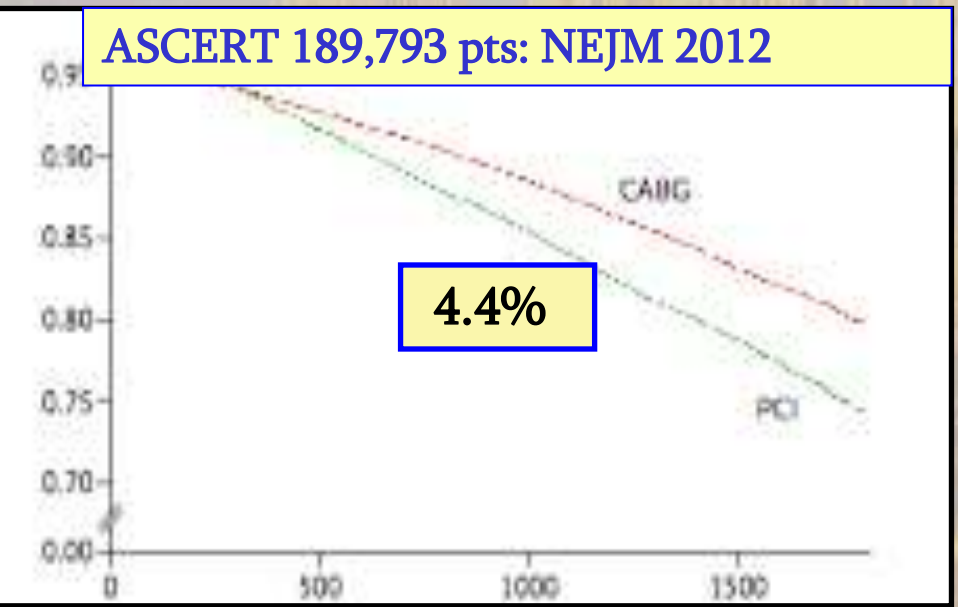
5.4%



FREEDOM 1,900 pts: NEJM 2012

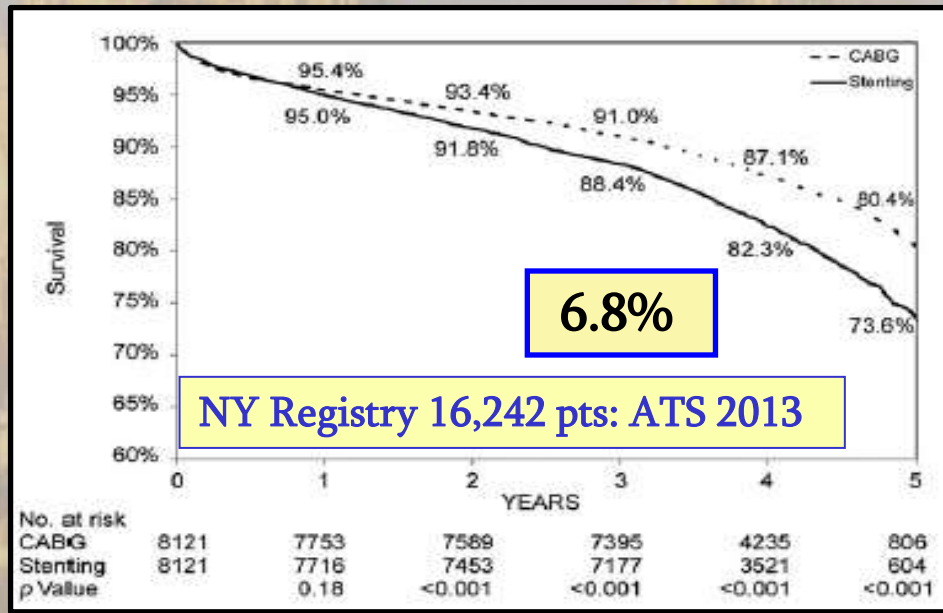
5.4%

- DIVERGING SURVIVAL CURVES @ 5 YEARS FAVOUR CABG
- Results at 10 years?



ASCERT 189,793 pts: NEJM 2012

4.4%

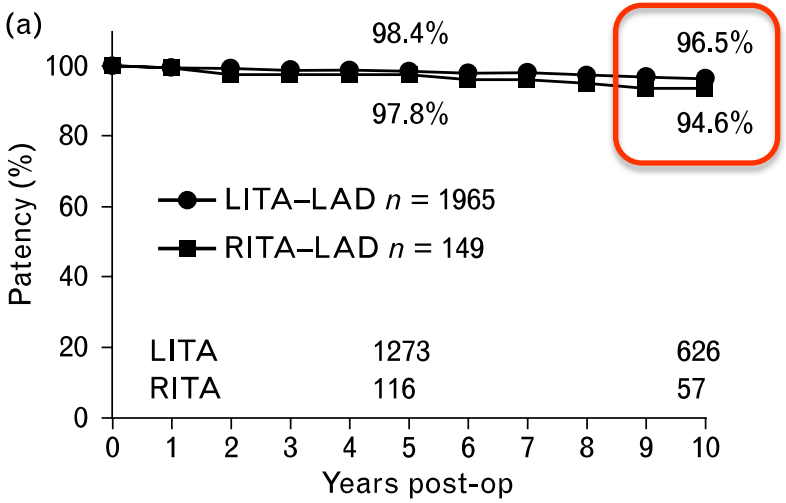


6.8%

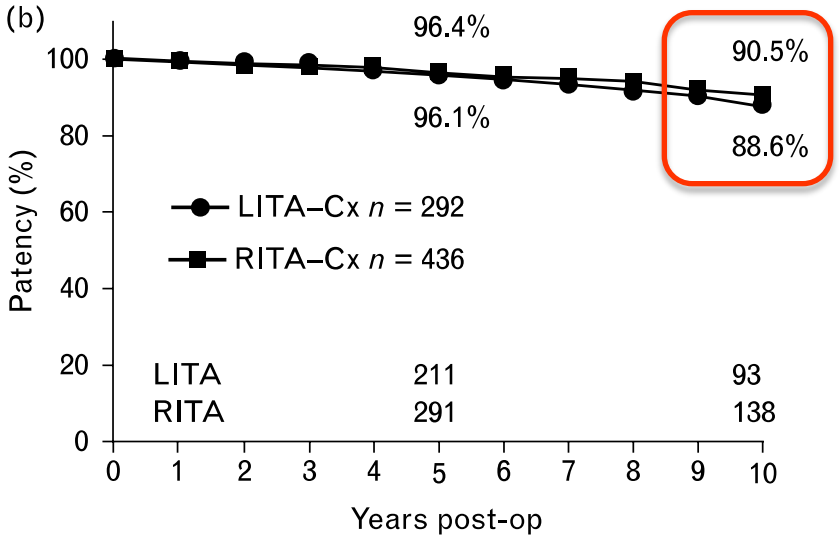
NY Registry 16,242 pts: ATS 2013

The right internal thoracic artery: is it underutilized?

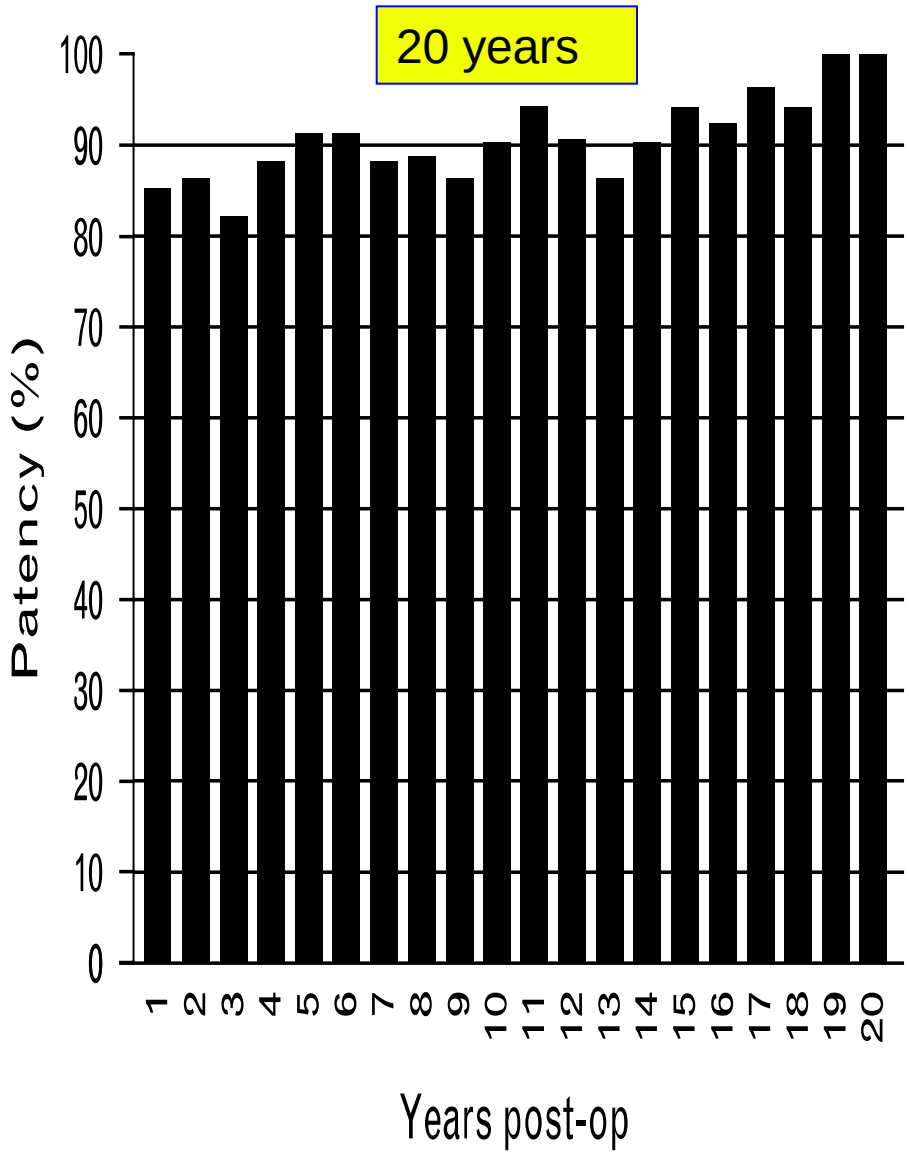
James Tatoulis[a,c], Brian F. Buxton[b,c] and John A. Fuller[b] [2011]



10 years



20 years

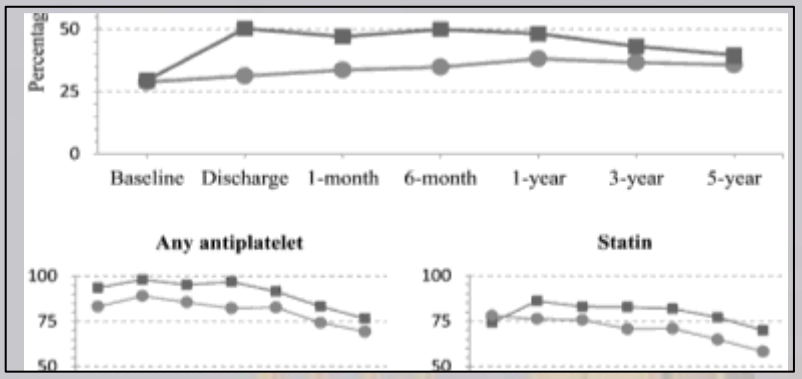


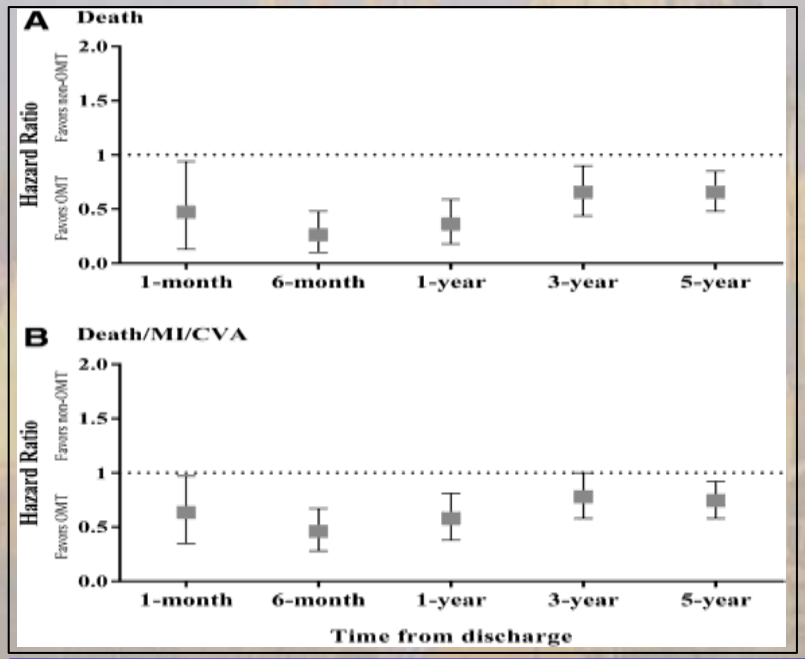
Optimal Medical Therapy Improves Clinical Outcomes in Patients Undergoing Revascularization With Percutaneous Coronary Intervention or Coronary Artery Bypass Grafting

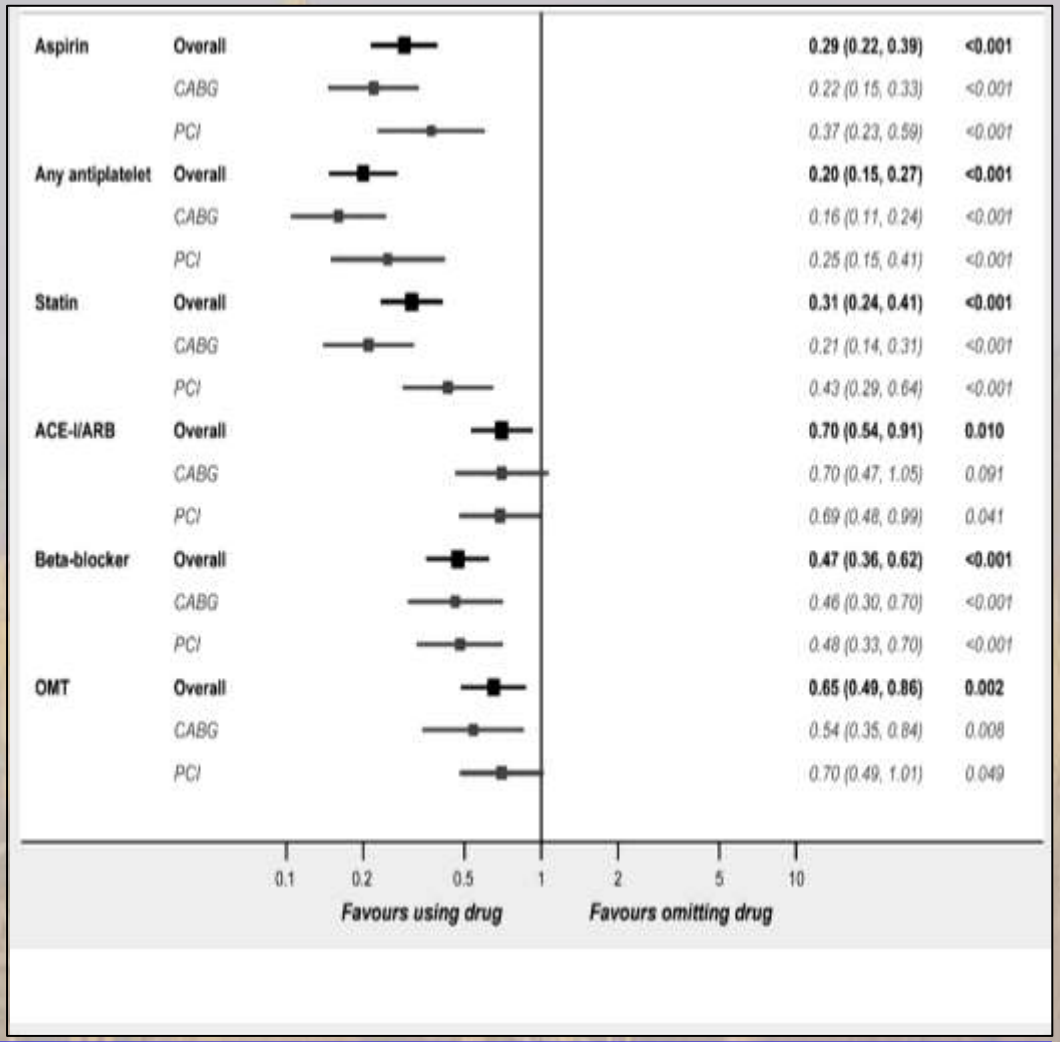
Insights From the Synergy Between Percutaneous Coronary Intervention With TAXUS and Cardiac Surgery (SYNTAX) Trial at the 5-Year Follow-Up

CIRC 2015

Javaid Iqbal, MRCP, PhD*; Yao-Jun Zhang, MD*; David R. Holmes, MD;







Substantially inferior OMT in CABG group ↑ mortality and MACCE

[March 4th 2008]

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doi:10.1016/j.jacc.2007.09.067

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

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 24, 2008 VOL. 358 NO. 17

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

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.

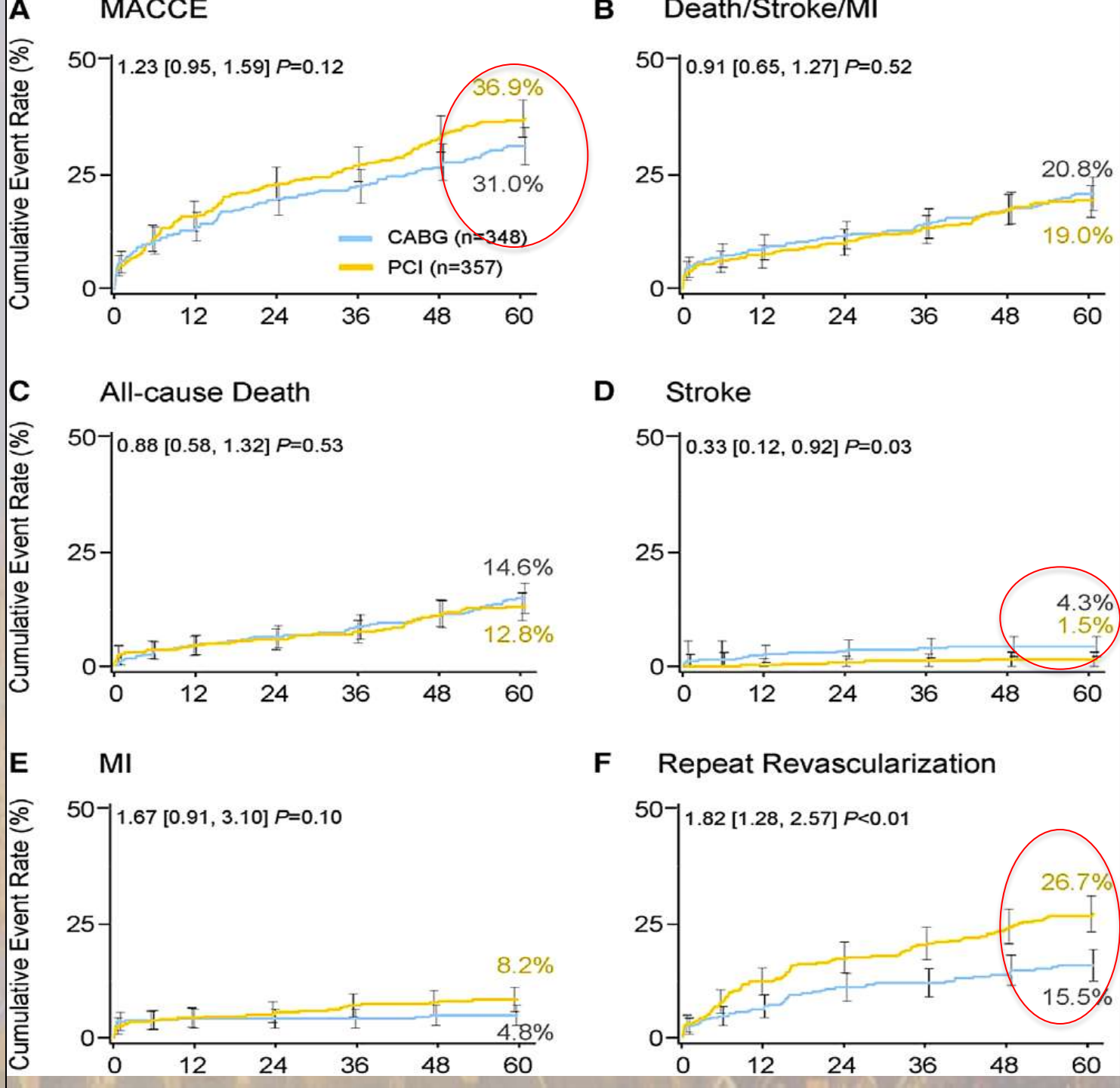
MAIN-COMPARE Registry of UPLM disease in 2240 Patients: 1102 stents and 1138 CABG followed for 3 years

Table 3. Hazard Ratios for Clinical Outcomes after Stenting as Compared with after CABG among Propensity-Matched Patients.*

Outcome	Overall Cohort (N=542 pairs)		BMS (N=207 pairs)		DES (N=396 pairs)	
	Hazard Ratio (95% CI)	P Value	Hazard Ratio (95% CI)	P Value	Hazard Ratio (95% CI)	P Value
Death	1.18 (0.77–1.80)	0.45	1.04 (0.59–1.83)	0.90	1.36 (0.80–2.30)	0.26
Composite outcome of death, Q-wave myocardial infarction, or stroke	1.10 (0.75–1.62)	0.61	0.86 (0.50–1.49)	0.59	1.40 (0.88–2.22)	0.15
Target-vessel revascularization	4.76 (2.80–8.11)	<0.001	10.70 (3.80–29.90)	<0.001	5.96 (2.51–14.10)	<0.001

Similar outcomes at 3 years for Death, and Composite Death/MI/Stroke but Much Greater Need for Target Vessel Revascularization with Stents

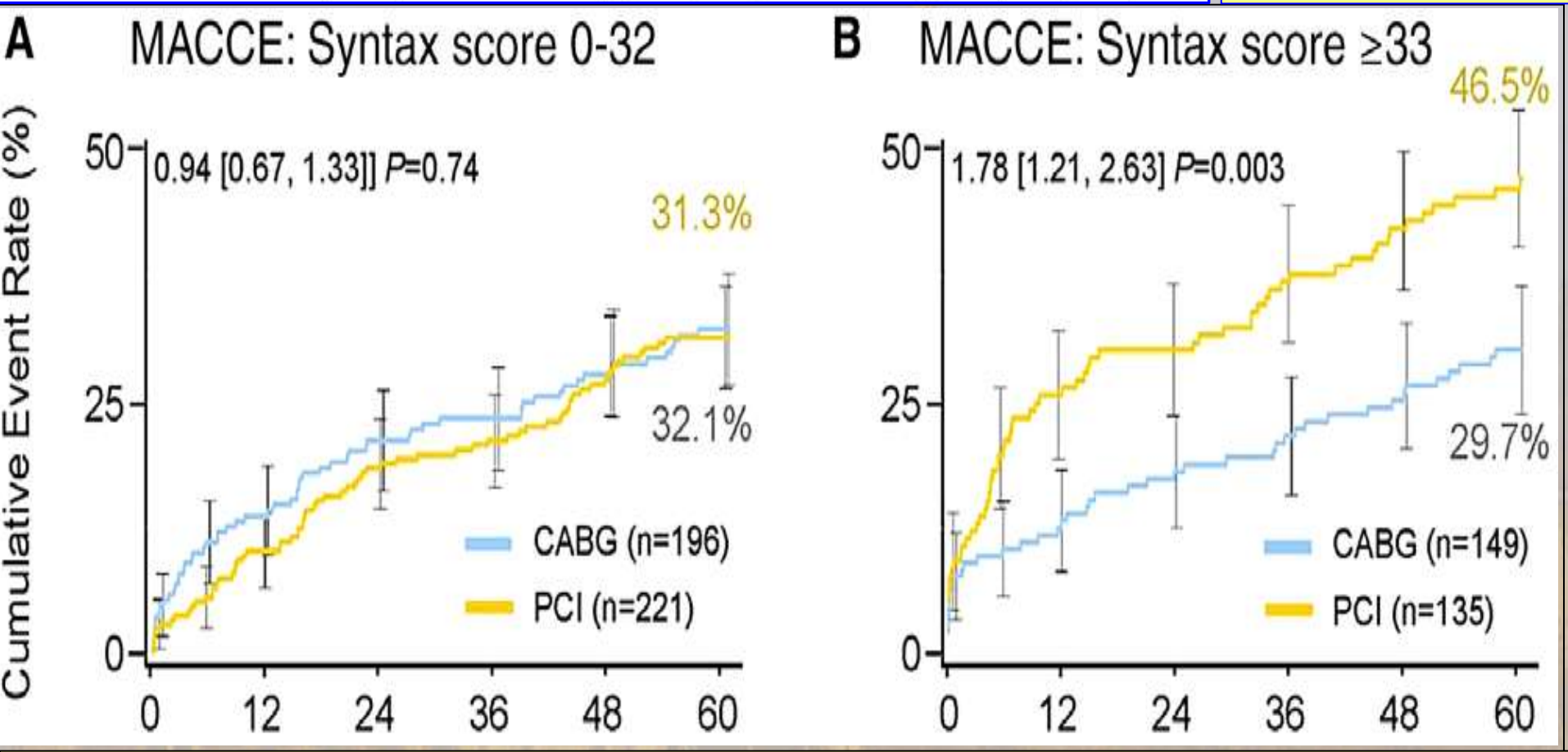
LEFT MAIN
SYNTAX trial
705 RCT patients
@5 years
CIRC 2014



Five-Year Outcomes in Patients With Left Main Disease Treated With Either Percutaneous Coronary Intervention or Coronary Artery Bypass Grafting in the Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery Trial

Marie-Claude Morice, MD; Patrick W. Serruys, MD, PhD; A. Pieter Kappetein, MD, PhD;

LEFT MAIN
SYNTAX trial
705 RCT patients
@5 years
CIRC 2014



- Low SYNTAX scores indicate less proximal CAD and therefore increased competitive flow for bypass grafts
- Accelerating Divergence of Survival Curves in Favour of CABG in >32

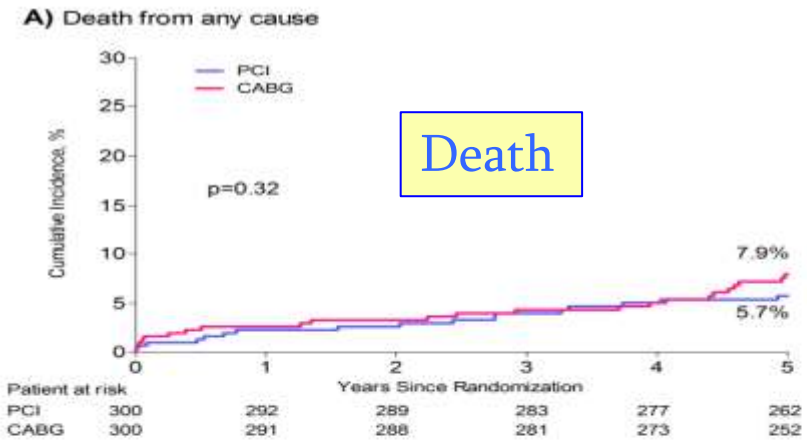
LEFT MAIN
PRECOMBAT trial
600 RCT patients
@5 years
JACC 2015

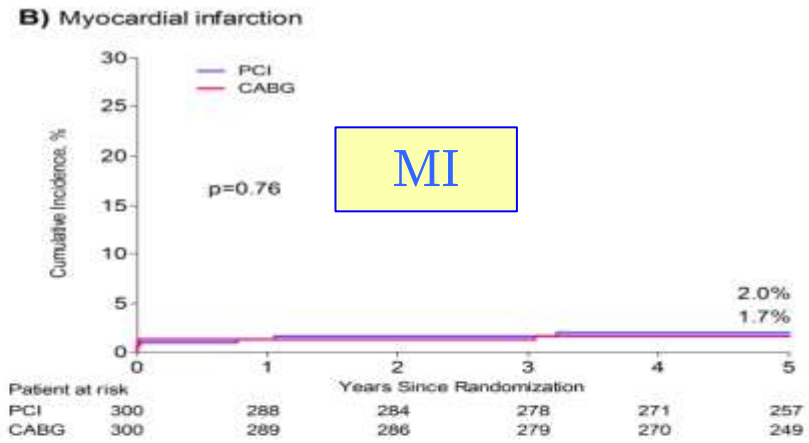
Randomized Trial of Stents versus Bypass Surgery for Left Main Coronary Artery Disease: Five-Year Outcomes of the PRECOMBAT Study

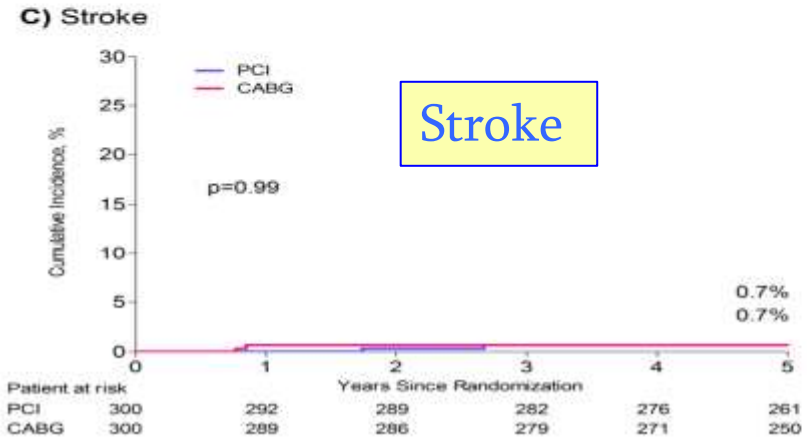
[JACC 2015]

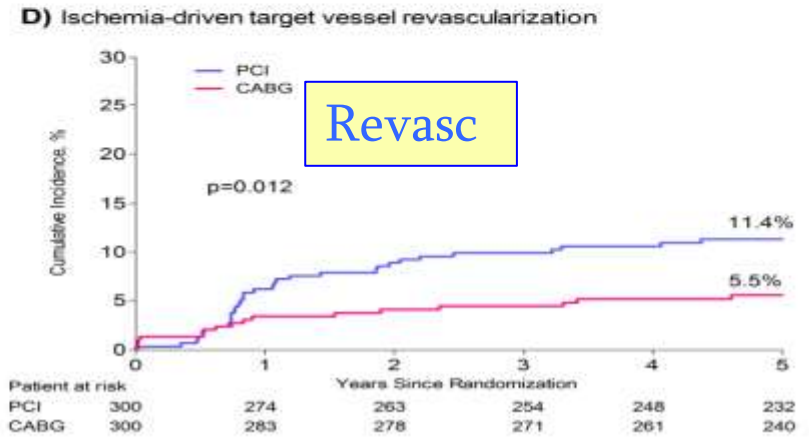
Authors: Jung-Min Ahn, MD*, Jae-Hyung Roh, MD*, Young-Hak Kim, MD, Duk-Woo Park,

Mean SYNTAX score of 22







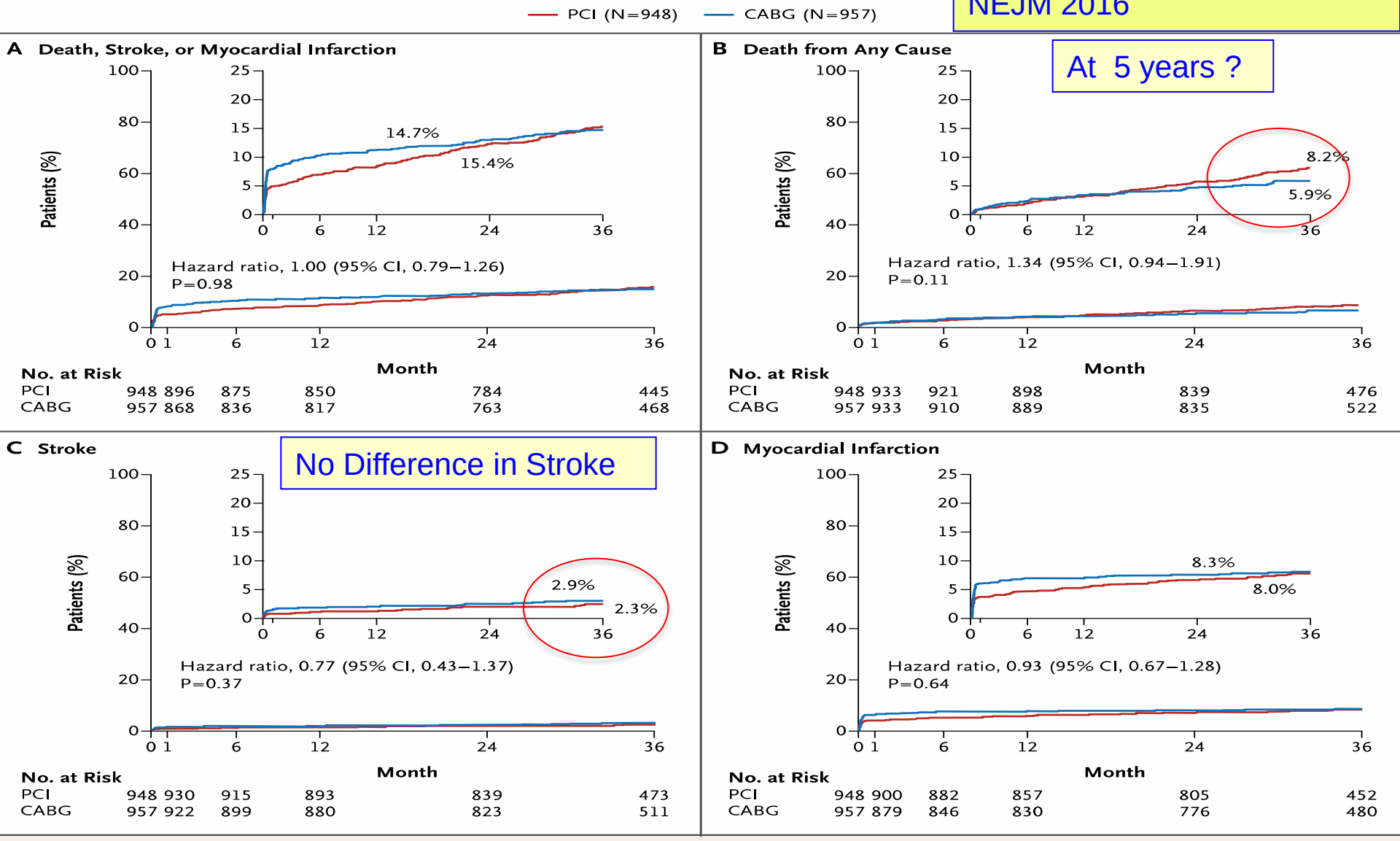


Despite substantially inferior medical therapy in CABG group

Everolimus-Eluting Stents or Bypass Surgery for Left Main Coronary Artery Disease

G.W. Stone, J.F. Sabik, P.W. Serruys, C.A. Simonton, P. Généreux, J. Puskas, D.E. Kandzari, M.-C. Morice, N. Lembo, W.M. Brown III, D.P. Taggart,

LM: EXCEL Trial
SYNTAX scores <33
1905 RCT patients (of 2600)
1000 Registry Patients
@3 years follow-up
NEJM 2016



EXCEL: The 'Money' Shot

	From randomization to 30 days				From 30 days to 3 years			
	PCI (n=948)	CABG (n=957)	HR [95%CI]	P value	PCI (n=939)	CABG (n=947)	HR [95%CI]	P value
Death, stroke or MI	4.9%	7.9%	0.61 [0.42, 0.88]	0.008	11.5%	7.9%	1.44 [1.06, 1.96]	0.02
- Death	1.0%	1.1%	0.90 [0.37, 2.22]	0.82	7.3%	4.9%	1.44 [0.98, 2.13]	0.06
- Stroke	0.6%	1.3%	0.50 [0.19, 1.33]	0.15	1.8%	1.8%	1.00 [0.49, 2.05]	1.00
- MI	3.9%	6.2%	0.63 [0.42, 0.95]	0.02	4.2%	2.5%	1.71 [1.00, 2.93]	0.05

Repeat Revasc 12.6% PCI vs 7.5% CABG (p<0.001)

By 3 years overall CABG mortality 2.3% lower (p=0.06) BUT:

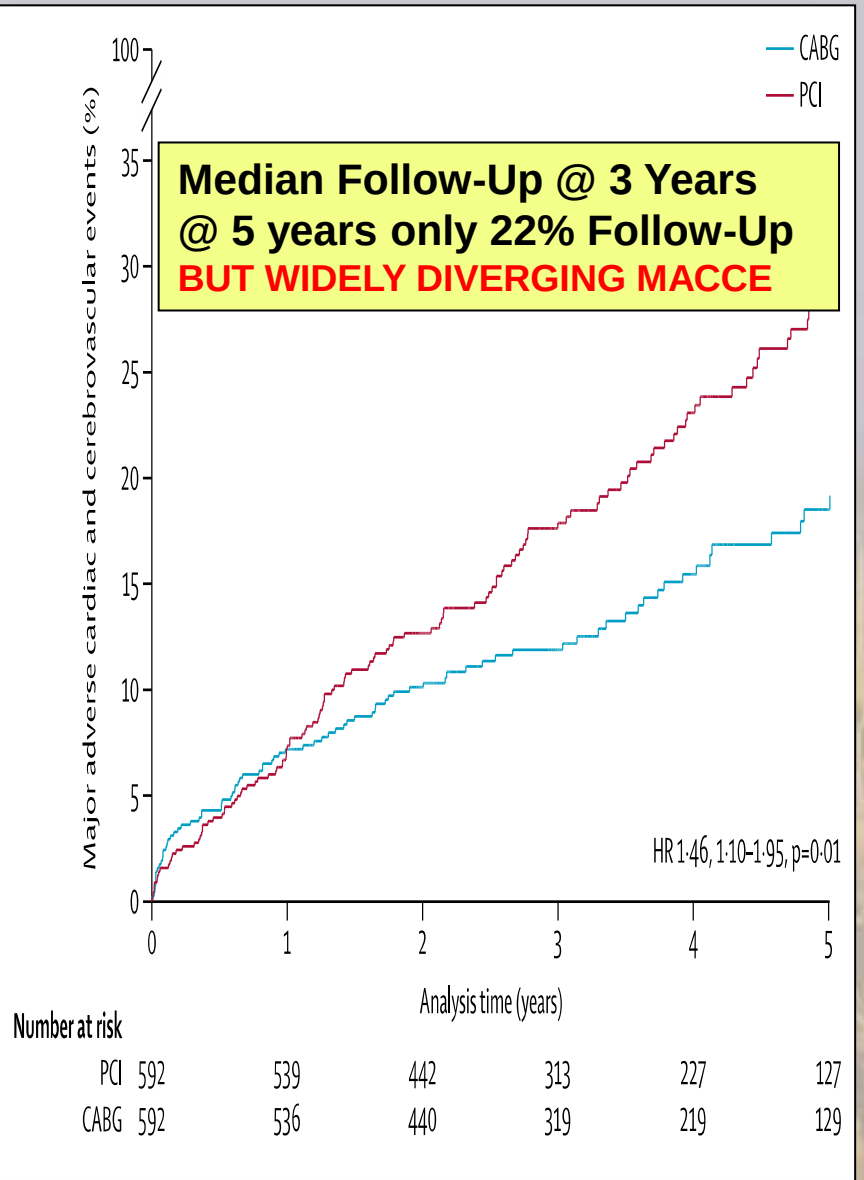
① DIVERGING SURVIVAL CURVES in favour of CABG !!

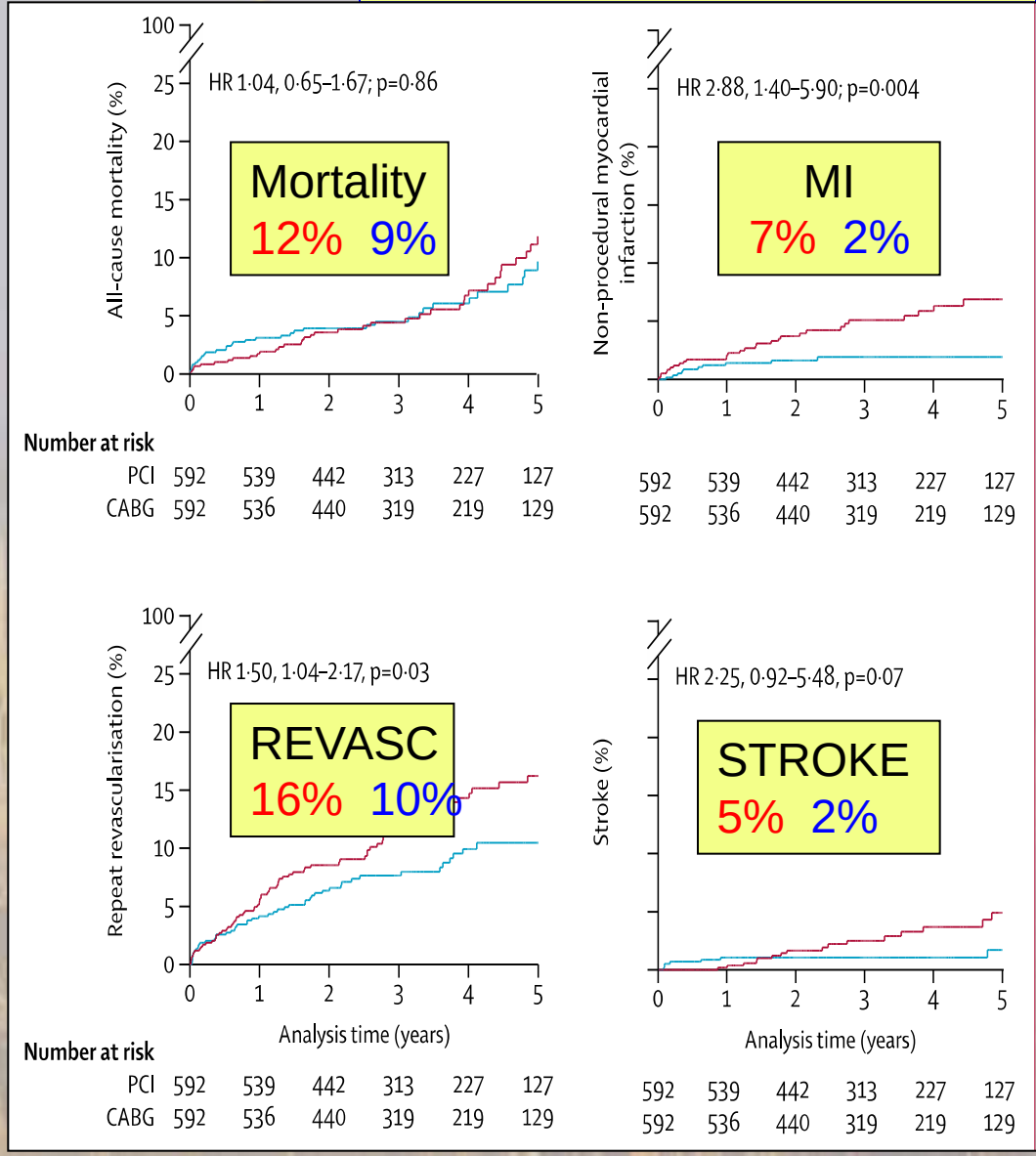
② NO increased risk of stroke with CABG

Percutaneous coronary angioplasty versus coronary artery bypass grafting in treatment of unprotected left main stenosis (NOBLE): a prospective, randomised, open-label, non-inferiority trial

Timo Mäkikallio, Niels R Holm, Mitchell Lindsay, Mark S Spence, Andrejs Erglis, Ian B A Menown, Thor Trovik, Markku Eskola, Hannu Romppanen,

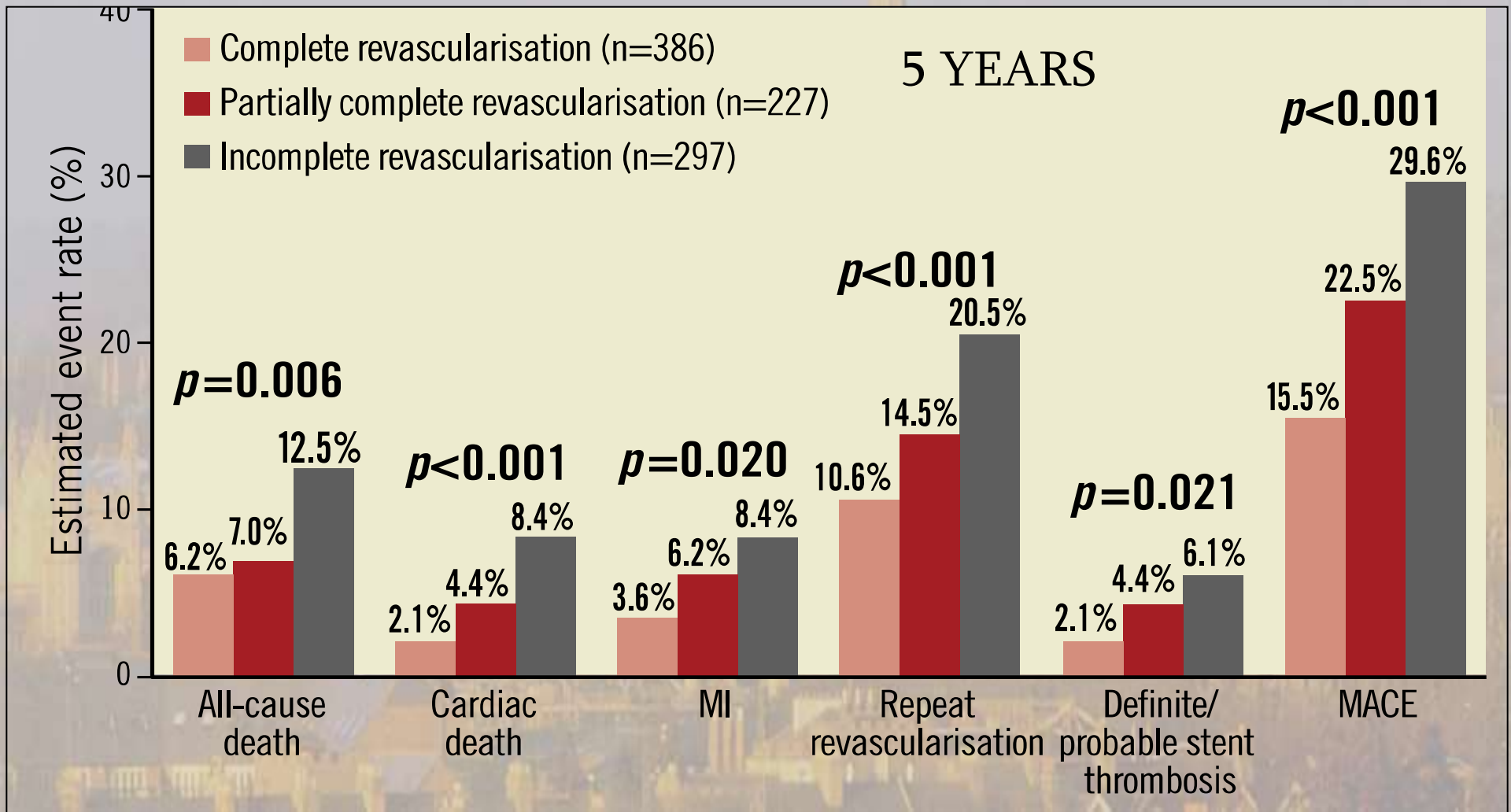
LM: NOBLE
1201 RCT patients @ 5 years
No SYNTAX RESTRICTION
Lancet 2016





Clinical outcomes of "complete, partially complete, and incomplete" revascularisation at five-year follow-up after percutaneous intervention of unprotected left main coronary artery disease with drug-eluting stents [EUROINTERVENTION 2016]

Yao-Jun Zhang[1,2], PhD; Javaid Iqbal[2], MRCP, PhD; Bo Xu[3], MBBS; Fei Ye[1], MD; Jun-Jie Zhang[1], MD, FSCAI; Christos V. Bourantas[2], MD; Dao-Rong Pan[1], MSc; Nai-Liang Tian[4], MD; Jing Kan[4], MD; Xue-Song Qian[5], MD; Shi-Qing Ding[6], MD; Feng Li[7], MD; Ai-Ping Zhang[8], MD; Yue-Qiang Liu[9], MD; Takashi Muramatsu[2], PhD; Yoshinobu Onuma[2], MD; Hector M. Garcia-Garcia[2], MD; Patrick W. Serruys[2], MD, FESC; Shao-Liang Chen*[1,4], MD, PhD, FACC



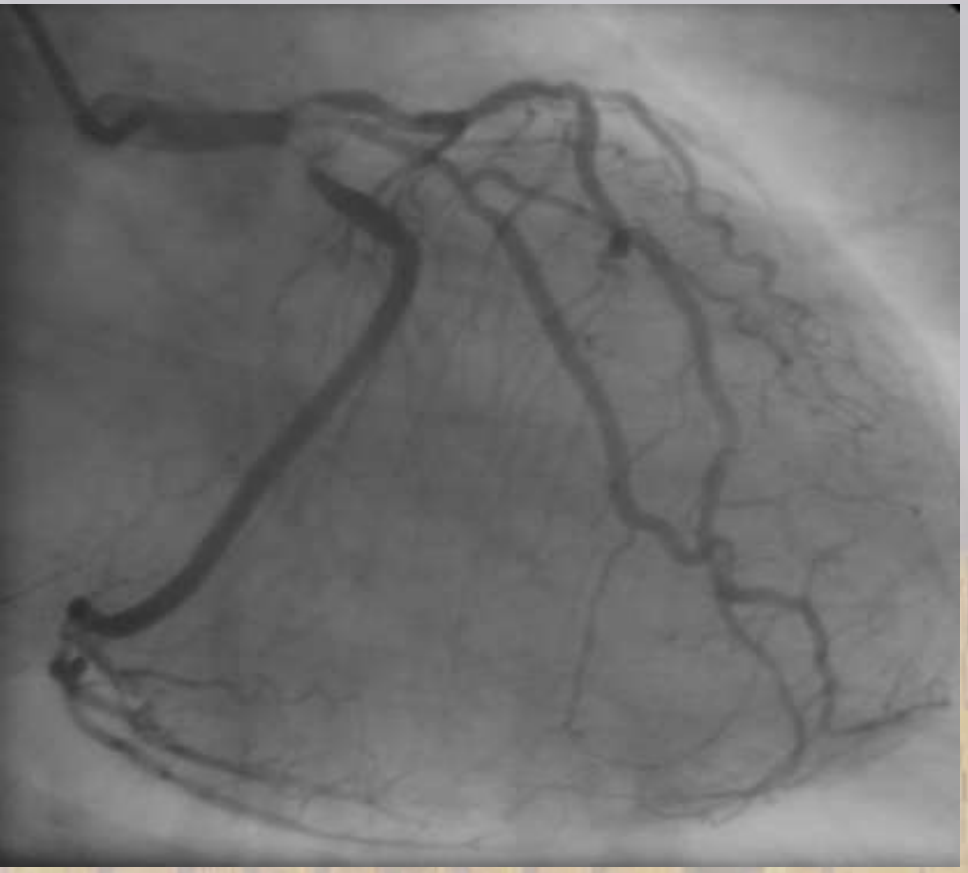
What do the Guidelines Say for Left Main ?

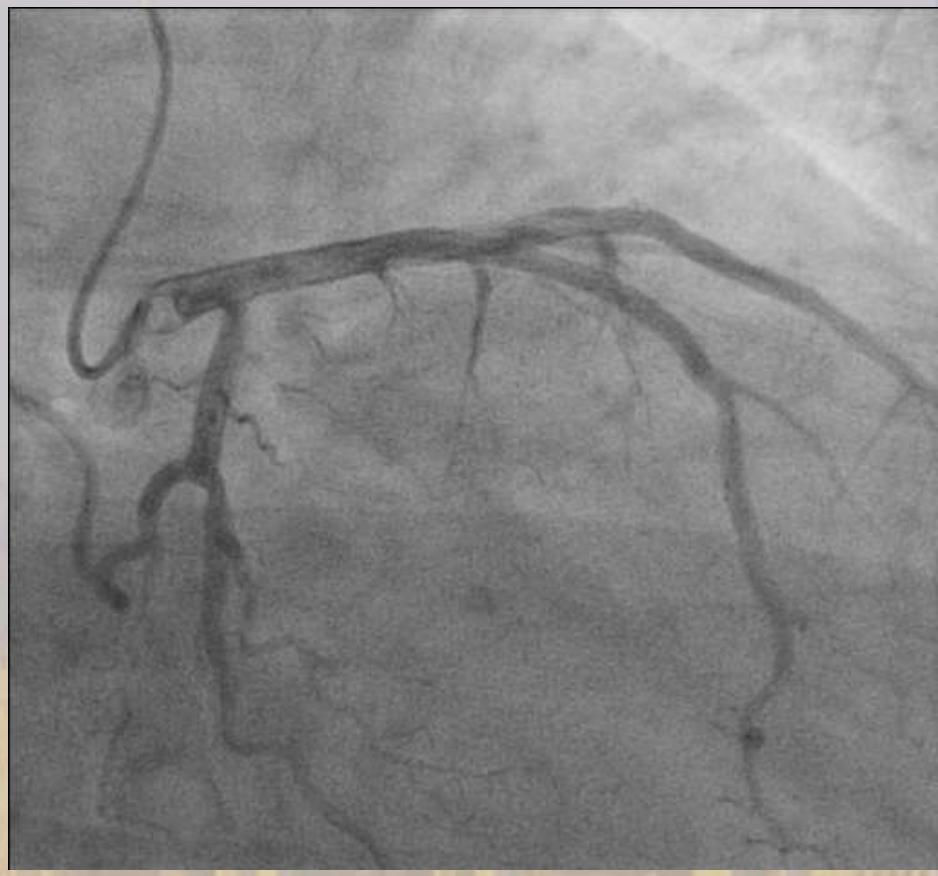
ESC/EACTS Guidelines	CABG	PCI	CABG	PCI
	2010	2010	2014	2014
LM SYNTAX <22	IA	IIaB	IB	IB
LM SYNTAX 23-32	IA	IIbB	IB	IIA
LM SYNTAX >32 60%	IA	IIIB	IB	IIIB

What will be the Impact of NOBLE and EXCEL (@ 5 Yrs) ?

CABG for LM-Are they all operable ? YES

And how ? DEPENDS as THERE IS LMD AND THERE IS LMD





Complex LM equivalent
High Syntax Score
CABG x 3 (arterial grafts)
Little competitive flow

OSTIAL LM
LOW SYNTAX score
CABG x ? (? arterial grafts)
Much competitive flow

LM Summary and Conclusions

- In comparing PCI vs CABG need to know (i) SYNTAX scores, (ii) Duration of Follow Up and (iii) Use of GBMT
- Previous concept that LM is exclusive surgical disease is no longer viable (SYNTAX and PRECOMBAT @ 5 years)
- CABG is a clear 'winner' for most 3VD and LM >32 (despite substantially inferior GBMT)
- CABG is a clear 'winner' @ 5 years in NOBLE
- Equipoise for PCI and CABG @ 3 years in EXCEL but diverging survival !!
- Completeness of revasc crucial in LM for mortality and MACCE
- PCI may produce superior results in isolated ostial and mid shaft LM (without additional proximal CAD) where there is excessive competitive flow for bypass grafts

3-Year Death, Stroke or MI

Subgroup	PCI (N=948)	CABG (N=957)	HR [95% CI]	P (Int)
All patients	15.4%	14.7%	1.00 [0.79, 1.26]	
Age (median cutoff)				
- ≥67 years	18.7%	15.0%	1.22 [0.89, 1.69]	0.07
- <67 years	12.2%	14.4%	0.78 [0.55, 1.11]	
Gender				
- Male	14.0%	14.9%	0.87 [0.66, 1.14]	0.06
- Female	19.7%	14.1%	1.48 [0.93, 2.41]	
Diabetes mellitus				
- Yes	21.2%	19.4%	1.04 [0.70, 1.55]	0.77
- No	13.3%	13.1%	0.97 [0.72, 1.30]	
Chronic kidney disease				
- eGFR ≤60 ml/min	24.5%	19.3%	1.24 [0.75, 2.07]	0.36
- eGFR >60 ml/min	13.5%	13.6%	0.95 [0.72, 1.25]	
Geographic location				
- North America	15.5%	12.4%	1.22 [0.82, 1.82]	0.14
- Europe	15.5%	15.6%	0.95 [0.69, 1.29]	
- Other	9.5%	22.2%	0.37 [0.08, 1.20]	

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JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 6, NO. 12, 2013
DECEMBER 2013:1219–30

Left Main Coronary Artery Stenosis

A Meta-Analysis of Drug-Eluting Stents Versus Coronary Artery Bypass Grafting

Objectives The goal of this study was to provide a systematic review comparing the long-term outcomes of percutaneous coronary intervention (PCI) with drug-eluting stents (DES) versus coronary artery bypass graft surgery (CABG) for unprotected left main coronary artery (UPLM) stenosis.

Background One-year outcomes from randomized controlled trials, observational studies, and pooled analyses have demonstrated the safety and efficacy of PCI of the UPLM when compared with CABG. However, there remain concerns over the sustainability of PCI with DES at longer follow-up.

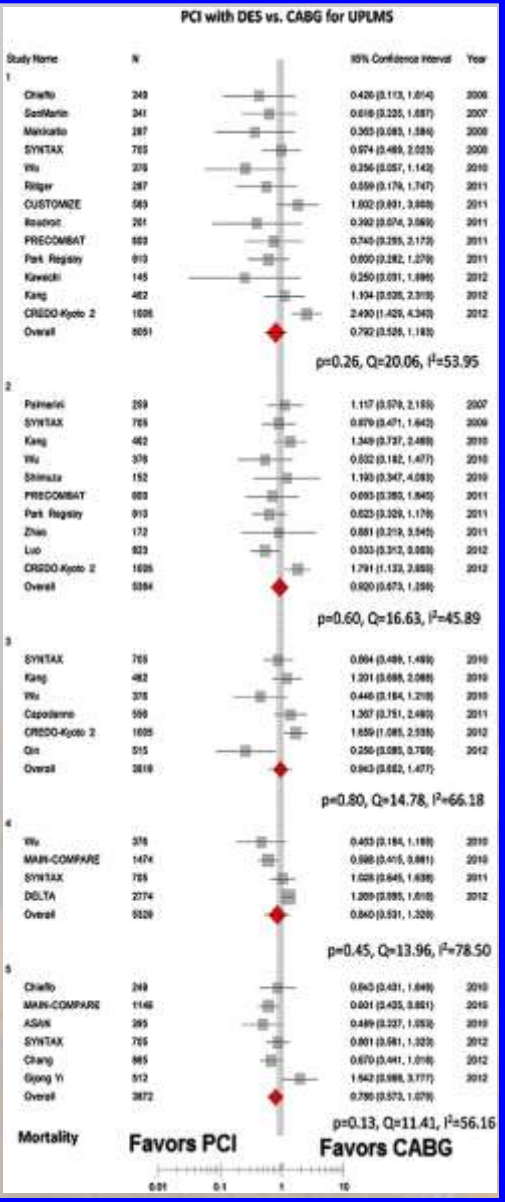
Methods Studies published between January 2000 and December 2012 of PCI versus CABG for UPLM stenosis were identified using an electronic search and reviewed using meta-analytical techniques.

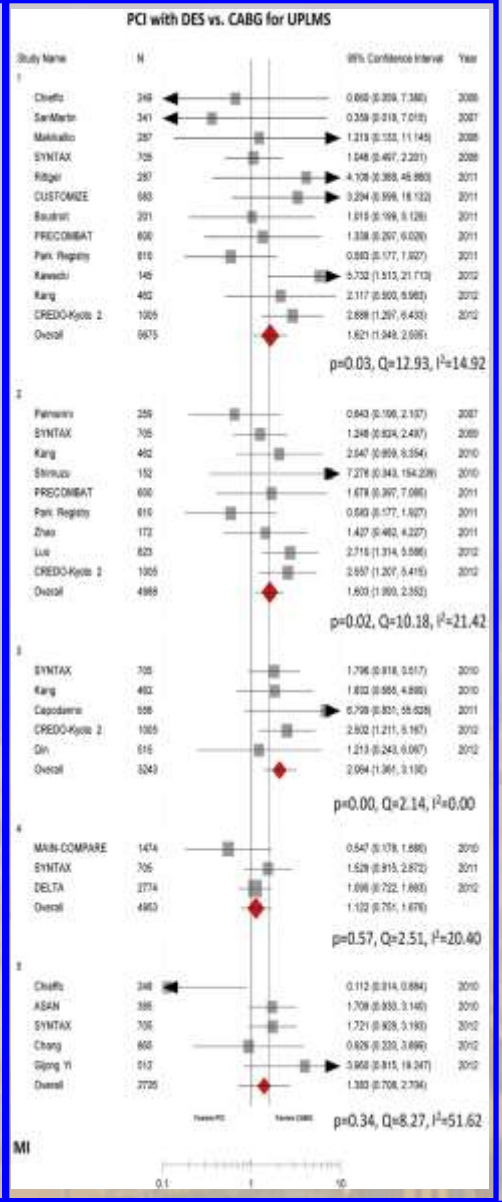
Results Twenty-four studies comprising 14,203 patients were included in the analysis. There was no significant difference for all-cause mortality between PCI or CABG at 1 year (odds ratio [OR]: 0.792, 95% confidence interval [CI]: 0.53 to 1.19), 2 years (OR: 0.920, 95% CI: 0.67 to 1.26), 3 years (OR: 0.94, 95% CI: 0.60 to 1.48), 4 years (OR: 0.84, 95% CI: 0.53 to 1.33), and 5 years (OR: 0.79, 95% CI: 0.57 to 1.08). The need for target vessel revascularization (TVR) was significantly higher in patients undergoing PCI at all time points. The occurrence of stroke, however, was significantly less frequent in patients treated with PCI. The occurrence of nonfatal myocardial infarction showed a statistically significant trend towards a lower incidence in CABG patients at 1 year (OR: 1.62, 95% CI: 1.05 to 2.50), 2 years (OR: 1.60, 95% CI: 1.09 to 2.35), and 3 years (OR: 2.06, 95% CI: 1.36 to 3.1). There was no significant difference in combined major adverse cardiovascular and cerebrovascular events between the 2 groups.

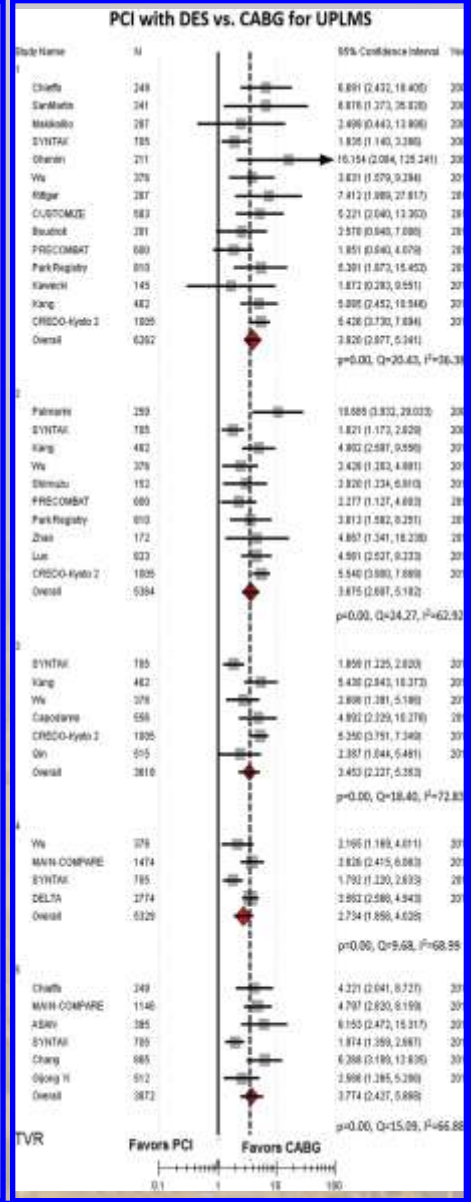
Conclusions Our findings suggest that PCI with DES is a safe and durable alternative to CABG for the revascularization of UPLM stenosis in select patients at long-term follow-up. (J Am Coll Cardiol Intv 2013;6:1219–30)

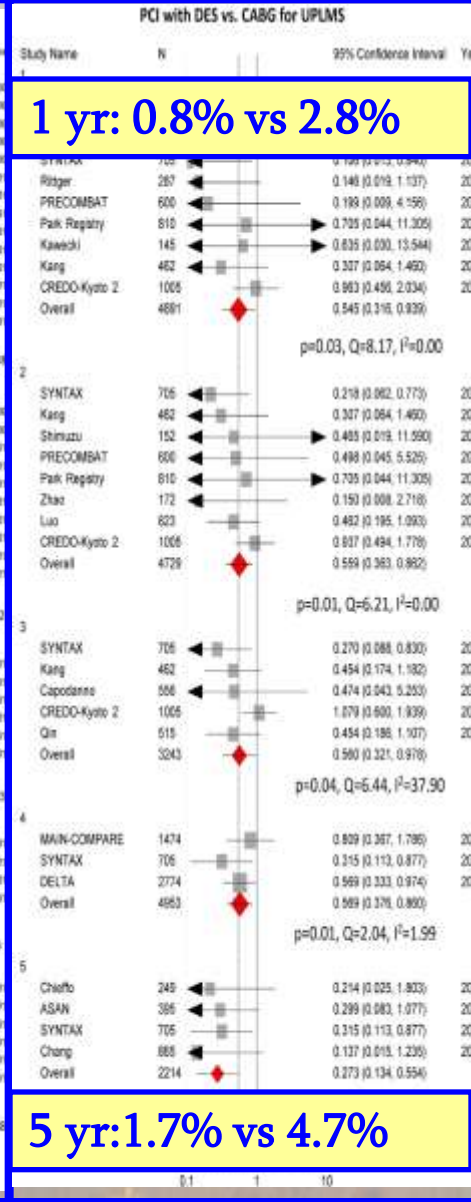
24 studies (3 RCTs) with 14,203 patients followed up to 5 years

DEATH (5 yr): No Difference	MI: (↑ PCI @ 1-3yrs)	TVR: (↑ PCI @ 1-5 yr)	CVA: (↑ CABG @ 1-5yr)



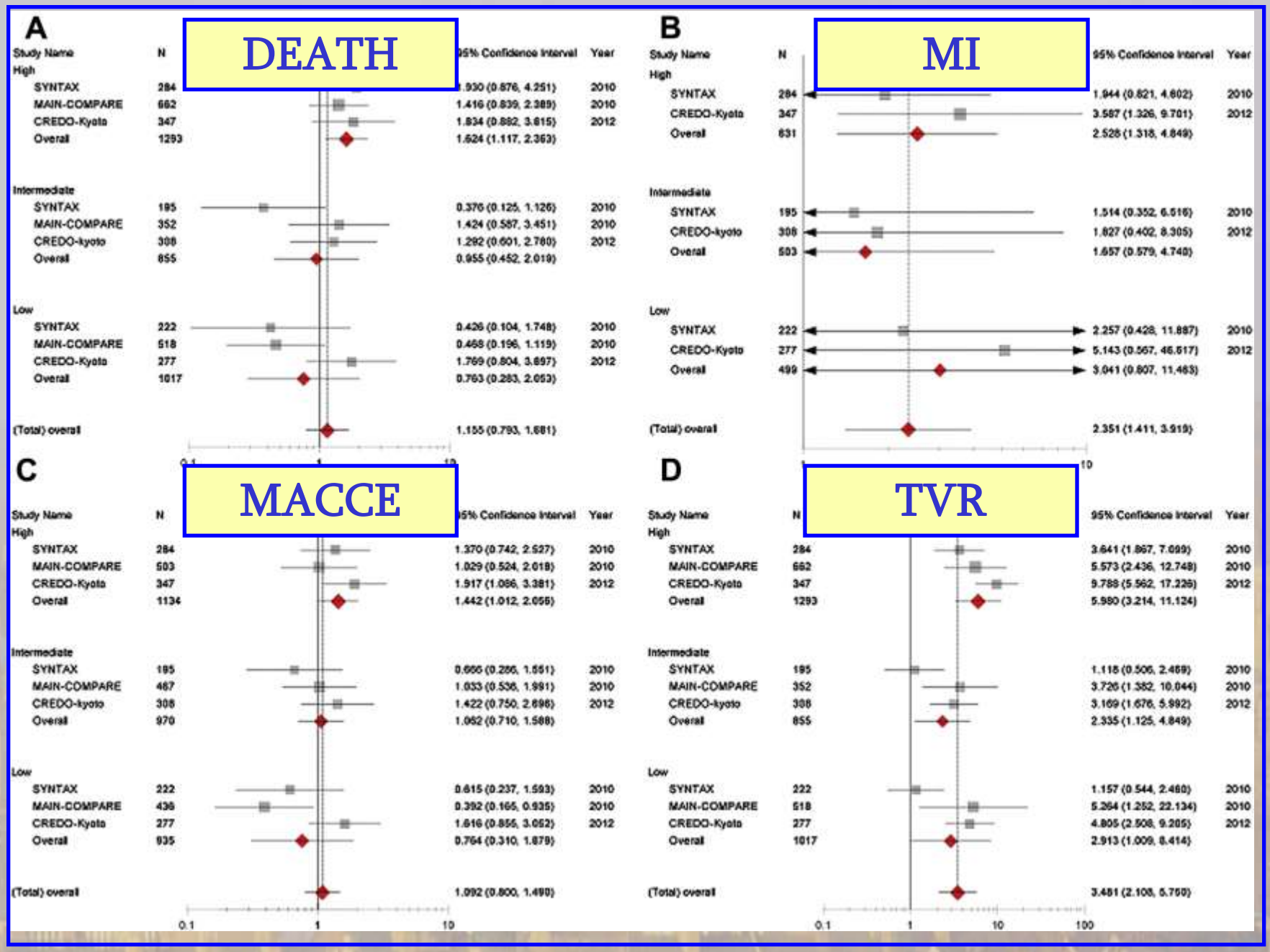






Different from 3VD where CABG ↓death, MI, RR and NS for CVA

LM: CABG BEST ONLY FOR HIGH TERCILES (>32)



PCI vs CABG: What is the difference between LM and 3VD ?

HYPOTHESIS: Unlike 3 VD, LM without additional proximal CAD may result in excessive competitive flow for bypass grafts?

Left Main Disease:Trials of CABG vs PCI

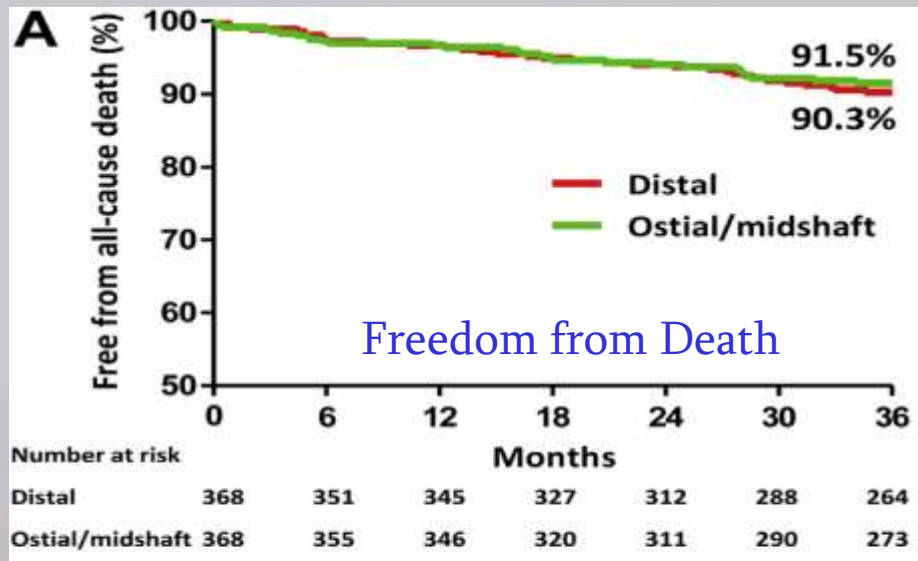
NOBLE Trial (recruited 1200 patients)

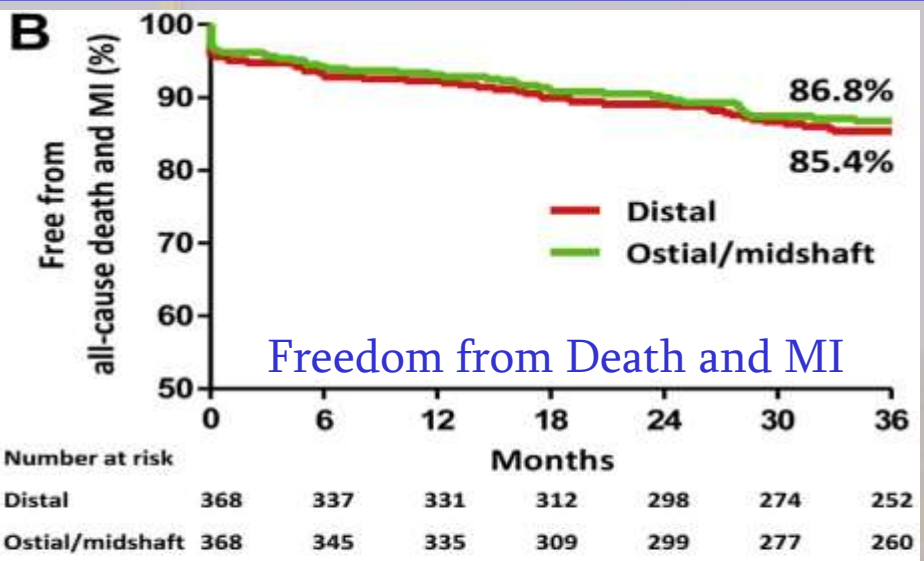
EXCEL Trial (Abbott Vascular) started Sept 2010

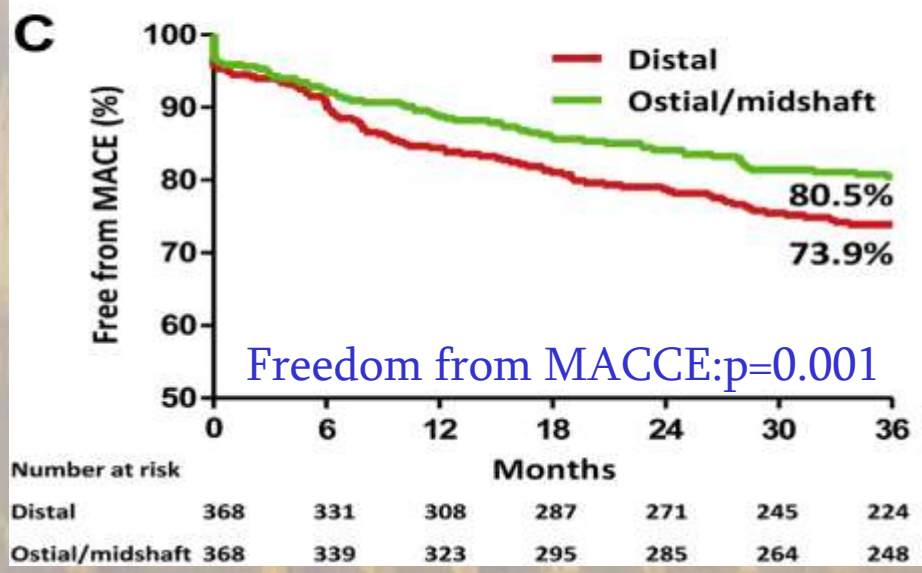
- only in SYNTAX Score <33
- 3600 patient trial (2600 RCT+1000 Registry)
- 1000 registry patients now enrolled
- >1905 RCT patients enrolled (stop 03/2014 for financial reasons)

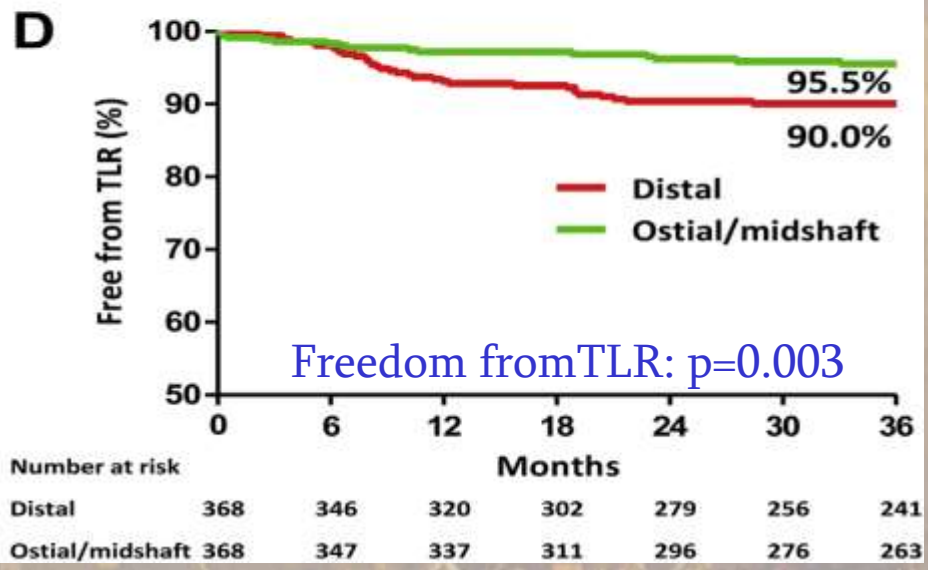
LM LOCATION: Ostial/Mid-shaft vs Distal LM

DELTA REGISTRY: [JACC 2013]
736 PM patients (from total of 1612) at a median of 3.2 years









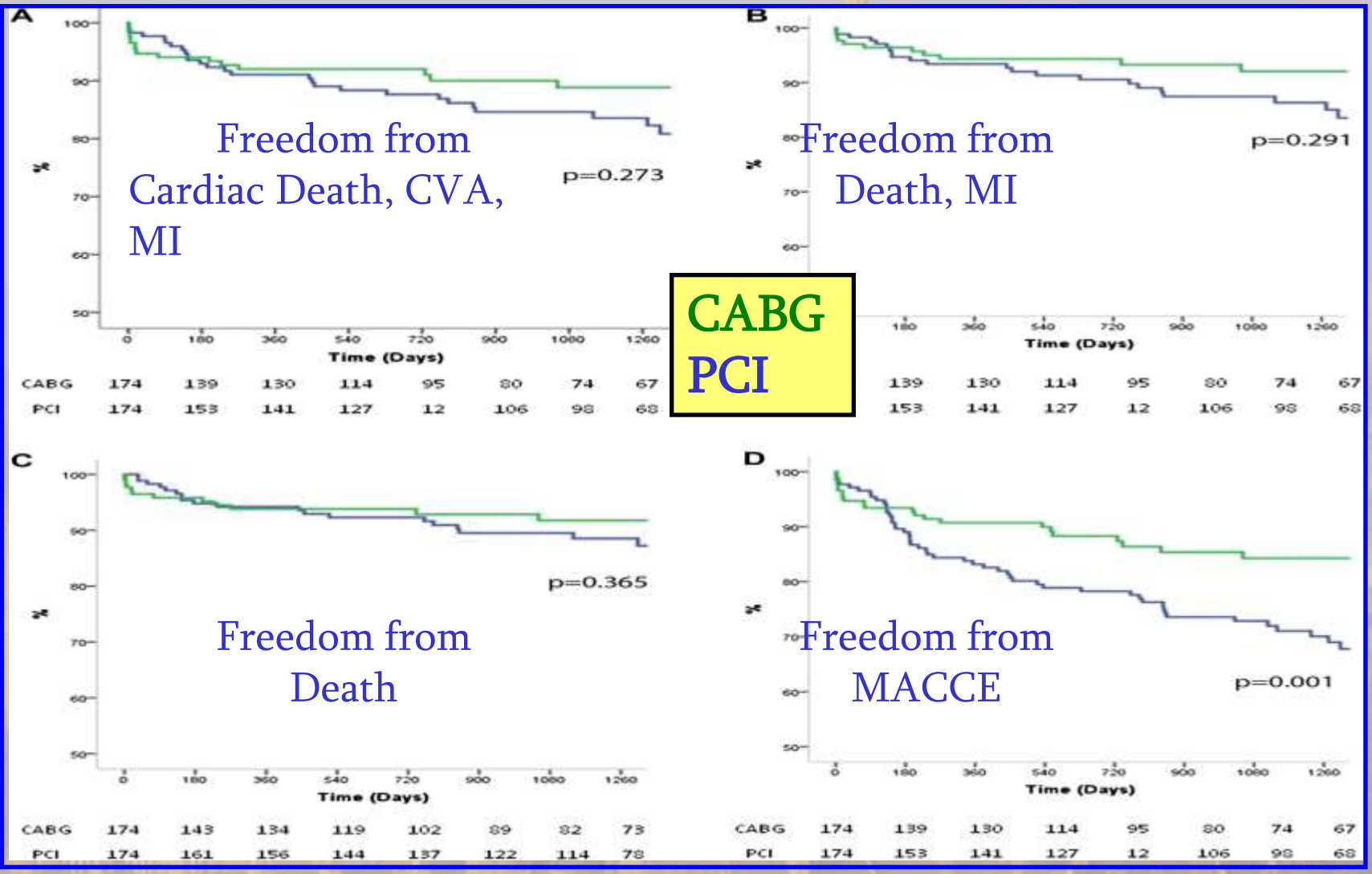
LM Diabetes

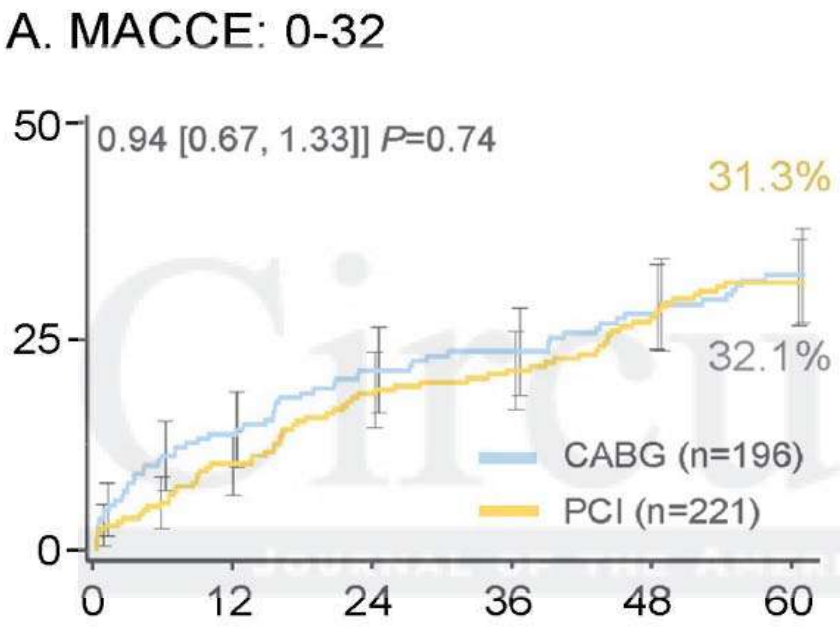
Coronary artery bypass graft versus percutaneous coronary intervention with drug-eluting stent implantation for diabetic patients with unprotected left main coronary artery disease: the D-DELTA registry. [Eurointervention 2013]
Meliga E1, De Benedictis M, Chieffo A et al

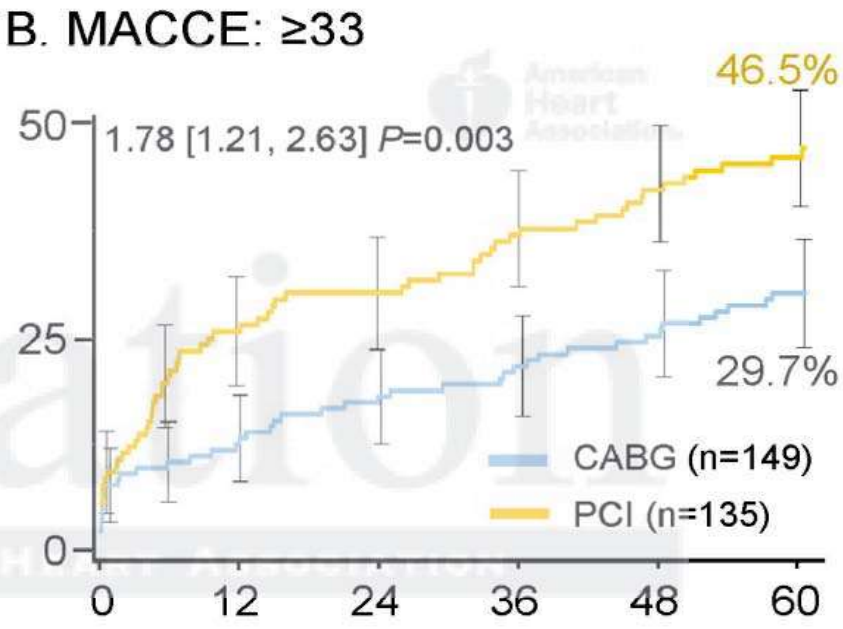
4yrs	DES (520)	CABG (306)	Δ (%)	p
Death	17.5	12.6	-4.9	0.12
Death, MI, CVA	21.1	14.6	-6.5	0.11
TVR	20.6	4.6	-16	<0.001
MACCE	35.3	18.1	-17.2	<0.001

LM and Gender

DELTA REGISTRY: WOMEN [AM J Cardiol 2014]
350 (from total of 817) PM women at median of 3.2 years
SYNTAX SCORE: PCI 26.6 vs CABG 34







HYPOTHESIS: Unlike 3 VD, LM without additional proximal CAD may result in excessive competitive flow for bypass grafts?

Trials of CABG vs PCI in Left Main Disease

- NOBLE Trial (planned recruitment of 1200 patients)
- EXCEL Trial (Abbott Vascular) started Sept 2010
- only in SYNTAX Score <33
- 3600 patient trial of PCI vs CABG (2600 RCT+1000 Registry)
- 1000 registry patients now enrolled
- >1906 RCT patients enrolled to date
- Enrolment stopped for financial costs (march 2014)

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 Airoldi, MD; Giuseppe Sangiorgi, MD; Mauro Carlino, MD; Iassen 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'

SYNTAX n=705 PRECOMBAT n=600

Low <23	nos	118	104		129	104		
	death	7	11.3	.28	3.9	7		
	CVA	1.8	4.1	.28	1.6	0		
	MI	6.2	3.1	.32	2.4	1.1		
	D+C+M	13.9	15.2	.71				
	Revasc	23	20.3	.65	10.3	8.1		
Intd 23-32	nos	103	92		102	97		
	death	8.9	19.3	.04	10.9	7.4		
	CVA	1.0	3.6	.23	0	1		
	MI	6.0	4.6	.71	2	0		
	D+C+M	15.7	24.9	.11				
	Revasc	22.2	16.6	.40	13.2	7.5		
High >32	nos	135	149		58	68		
	death	20.9	14.1	.11	5.2	13.3	.	
	CVA	1.6	4.9	.13	0	1.5		
	MI	11.7	6.1	.40	1.7	1.7		
	D+C+M	26.1	22.1	.33				
	Revasc	34.1	11.6	<.001	21.7	6	<0.131	

Late Stroke: Comparison of Percutaneous Coronary Intervention Versus Coronary Artery Bypass Grafting in Patients With Multivessel Disease and Unprotected Left Main Disease: A Meta-Analysis and Review of Literature

Ganesh Athappan, Paul Chacko, Eshan Patvardhan, Rama Dilip Gajulapalli, Emin Murat Tuzcu and Samir R. Kapadia

CIRC 2014

80,314patients (9 RCT and 48 non-randomized studies)

		nos	PCI%	CABG%	delta	OR
EARLY		38908	0.004	1.4	1.4	0.26 (0.25-0.35)
ALL	1yr	39497	1.2	2.2	1	0.55 (0.42-0.71)
	5y	22518	3.5	4.4	0.9	0.79 (0.69-0.91)
MVD	1 yr	27890	0.01	2.1	2.1	0.55 (0.41-0.74)
	5yr	20333	3.8	4.6	0.8	0.82 (0.72-0.95)
LM	1yr	5247	0.8	2.8	2	0.47 (0.28-0.78)
	5yr	1605	1.7	4.7	3	0.36 (0.19-0.69)
DM	1yr	6966	1	2.3	1.3	0.50 (0.33-0.76)
	5yr	4530	3.8	5.3	1.5	0.71 (0.53-0.94)

TIME 30d	OR
1yr	0.98 (0.68-1.35)
2yr	1.04 (0.86-1.28)
3 yr	0.90 (0.73-1.11)
4 yr	0.92 (0.74-1.12)
5 yr	0.83 (0.60-1.55)
10yr	0.79 (0.40-1.55)

Readmission Rate After Coronary Artery Bypass Grafting Versus Percutaneous Coronary Intervention for Unprotected Left Main Coronary Artery Narrowing.

Am J Cardiol. 2014 Mar 1 [Epub ahead of print]

Roh JH, Kim YH, Ahn JM, Yun SH, Lee JB, Ge J, Le W, Park GM, Lee JY, Park DW, Kang SJ1, Lee SW, Lee CW, Park SW, Park SJ.

- unadjusted and adjusted risk of readmissions in 1,352 patients (783 PCI and 569 CABG)
- consecutively enrolled in a multicenter registry of ULMCA stenosis (PRECOMBAT)

- At a median of 48.7 ± 16.0 months of follow-up 26.3% PCI vs 14.8% CABG patients experienced at least 1 readmission after the index procedure during ($p < 0.001$).

- The most frequent causes of readmission were repeat revascularization after PCI (41%) and noncardiac readmissions after CABG (48%).

- PCI was associated with more readmissions than CABG (HR 2.0: 95% CI 1.5 to 2.7, $p < 0.001$), being an independent predictor of readmission (HR 1.8, 95% CI 1.4 to 2.31; $p < 0.001$).

- Except for the first 3 months, when there was no significant difference in readmission rate, a higher rate after PCI was consistently observed over the remainder of the follow-up period.

In conclusion, PCI was associated with a higher risk of readmission than CABG in treating ULMCA. This higher risk was attributable to more frequent revascularization in the PCI group.

Summary and Conclusions

① Traditional view that CABG is the only treatment for LM disease is no longer tenable and there is consistent evidence from RCTs and registries that some LM disease is, at least, as effectively treated by stents as CABG for at least for 4-5 years

② Increasing evidence that PCI provides equal if not superior benefit to CABG in patients with lower severity left main (excessive competitive flow for bypass grafts ?)

③ CABG results in increased risk of stroke in LM (vs MVD). ?greater burden of aortic disease and a higher incidence of carotid disease

④ Some evidence that patients with DM and women may have better outcomes with CABG (certainly the case for 3VD); ?distal LM

⑤ CABG: fewer readmissions than PCI mainly because of lower TVR

⑥ NOBLE and EXCEL trials are likely to give definitive guidance regarding optimal treatment for LM with SYNTAX scores <32

⑦ 40% to 65% of all left main disease have SYNTAX scores >32 and appear to have strong survival advantage with CABG by 3 years and continuing to increase past 5 years

⑧ Comparisons of survival outcome of PCI vs CABG should have a minimum follow-up of 5 years

The 2010 Guidelines…what do they recommend ?

	CABG		PCI	
Subset of CAD by anatomy	ESC/EA CTS	ACC	ESC/EA CTS	ACC
Heart team 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	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 **79%**	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 **66%**	I A	I B	III B	IIb B / III B

Broad agreement between European and North American Guidelines

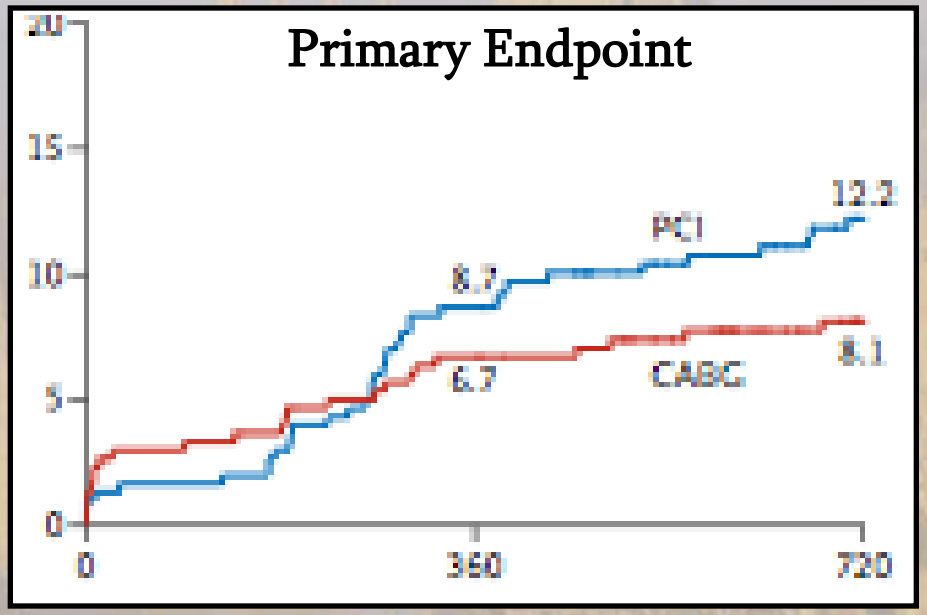
Randomized Trial of Stents versus Bypass Surgery for Left Main Coronary Artery Disease

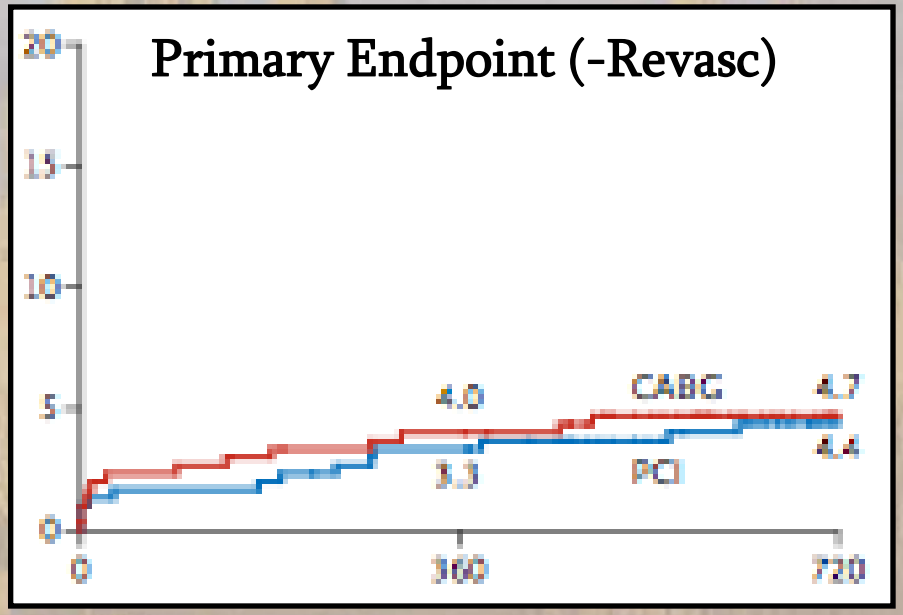
NEJM 2011

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 at 2years





- Incidence of stroke 0.4% PCI vs 0.7% CABG
- No difference in mortality or stroke with CABG

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
- >1906 RCT patients enrolled to date
- Enrolment stopped for financial costs

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

3 REASONS WHY CABG HAS A SURVIVAL BENEFIT OVER PCI

1 **Anatomically, atheroma is mainly located in the proximal coronary arteries**
Placing bypass grafts to the **MID CORONARY VESSEL** has **TWO** effects
(i) Complexity of proximal '**CULPRIT**' lesion is irrelevant
(ii) over the long term offers prophylaxis against **FUTURE** 'culprit' lesions
In contrast, PCI only treats **'SUITABLE'** localised proximal 'culprit' lesions but has **NO PROPHYLACTIC BENEFIT** against new disease

2

THE NEW ENGLAND JOURNAL OF MEDICINE Aug. 25, 1988

IMA elutes NO into coronary circulation reducing risk of further disease

DIFFERENCE BETWEEN ENDOTHELIUM-DEPENDENT RELAXATION IN ARTERIAL AND IN VENOUS CORONARY BYPASS GRAFTS

THOMAS F. LÜSCHER, M.D., DENNIS DIEDERICH, M.D., ROBERT SIEBENMANN, M.D., KURT LEHMANN, M.D.,

Drug-Eluting Stent and Coronary Thrombosis
Biological Mechanisms and Clinical Implications [CIRC 2007]

Thomas F. Lüscher, MD; Jan Steffel, MD; Franz R. Eberli, MD; Michael Joner, MD;

impairs re-endothelialization, downstream endothelial function and creates pro-thrombotic milieu

3 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)
Residual SYNTAX score >8 increases mortality and MACCE (Farooq, Serruys CIRC 2013)

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

European Heart Journal (2014) 35, 2541–2819
doi:10.1093/eurheartj/ehu278

ESC/EACTS GUIDELINES

2014 ESC/EACTS Guidelines on myocardial revascularization

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

Recommendations according to extent of CAD Complex CAD should be discussed by Heart Team IC	CABG		PCI	
	Class[a]	Level[b]	Class[a]	Level[b]
One or two-vessel disease without proximal LAD stenosis.	IIb	C	I	C
One-vessel disease with proximal LAD stenosis.	I	A	I	A
Two-vessel disease with proximal LAD stenosis.	I	B	I	C
Left main disease with a SYNTAX score ≤ 22.	I	B	I	B
Left main disease with a SYNTAX score 23–32.	I	B	IIa	B
Left main disease with a SYNTAX score >32.	I	B	III	B
Three-vessel disease with a SYNTAX score ≤ 22.	I	A	I	B
Three-vessel disease with a SYNTAX score 23–32.	I	A	III	B
Three-vessel disease with a SYNTAX score >32.	I	A	III	B

66%

79%

CABG would be even better with more arterial grafts and greater use of OMT

Summary and Conclusions: PCI vs CABG 2016

① 79% of patients with 3 vessel CAD (SYNTAX >22) and 66% with LM (SYNTAX >32) have strong survival advantage with CABG (reduced MI and repeat revasc) by 3 years and continuing to increase past 5 years

② CABG is superior to PCI despite inferior 'OMT' and 80% of all grafts being vein grafts (would be even better with widespread use of arterial grafts)

③ In 21% of patients with 3VD (SYNTAX scores <23) and 34% with LM (SYNTAX scores <33), similar 5 year survival between CABG and PCI but less repeat revasc with CABG

④ Contemporary CABG does NOT cause a significant increase in stroke with 3VD or LM disease

⑤ Consistent 'unwarranted' variation in ratios of PCI:CABG between countries and within countries

⑥ ABSENCE of Heart Team (using approved guidelines) results both in most elective PCI patients failing to understand its rationale and also a large number of inappropriate or wrong PCI interventions

⑦ Guidelines are transparent and protect the patients (from receiving wrong interventions) and doctors (from administering wrong interventions) and should be mandatory

⑧ Professional bodies should persuade statutory bodies/payers that they only reimburse interventions which are approved by the Heart Team based on official guidelines (or clear documentation why guidelines were not followed).