Left Main Disease Reasons for PCI

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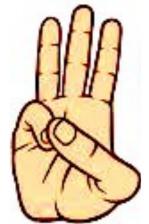
Why PCI should be the default treatment of LMD?



PCI more procedural advantages than CABG



Evidence clearly supports PCI for LMD



PCI (but not CABG) is continuously improving

We have to offer always the less invasive option

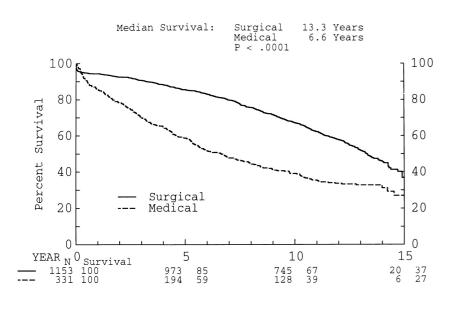




CABG for Left Main

PRO

- A longer history.
- First trials vs OMT.
- Frequently, more complete revascularization.

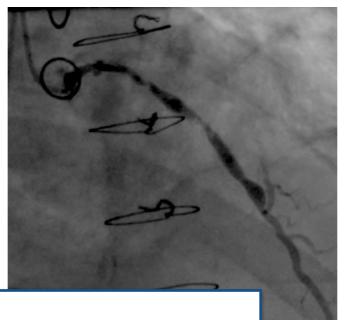


CON

- SVG disease.
- Quick progression of proximal disease.
- Usually, last chance.
- Longer hospital stay.
- Clearly more aggressive.
- Waiting list (no "ad-hoc").







NEWS ESC 2018

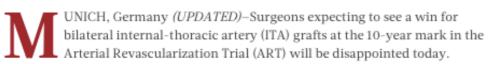
Ten-Year Follow-up Proves Disappointing for Bilateral Arterial Grafts in ART

Earlier results from the trial were also neutral, raising hopes that a decade of data would be the charm. Despite these findings, some see signs.



by Shelley Wood | August 26, 2018





Complications usually not included in primary end-point







PCI for LEFT MAIN

PRO

- Much less invasive.
- Possible ad-hoc.
- Wider availability.
- Quick return to normal life.
- No last opportunity.



- More TVR.
 - Stent restenosis.
 - Stent thromposis.

Almost solved with DES

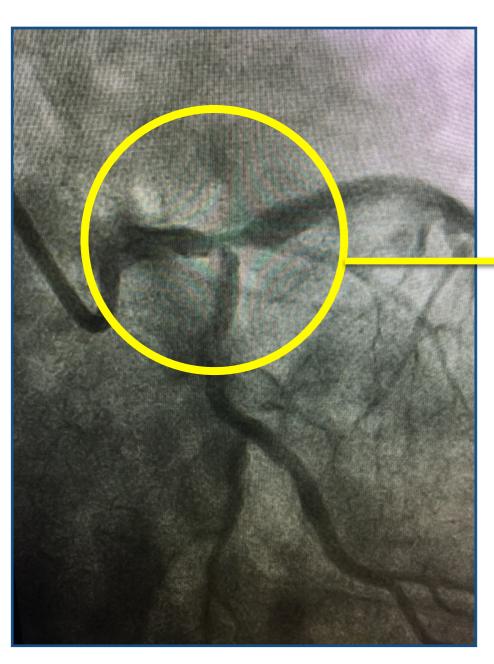
Very infrequent with 2nd DES

What would be TVR after CABG if treatment after graft failure was not so difficult?

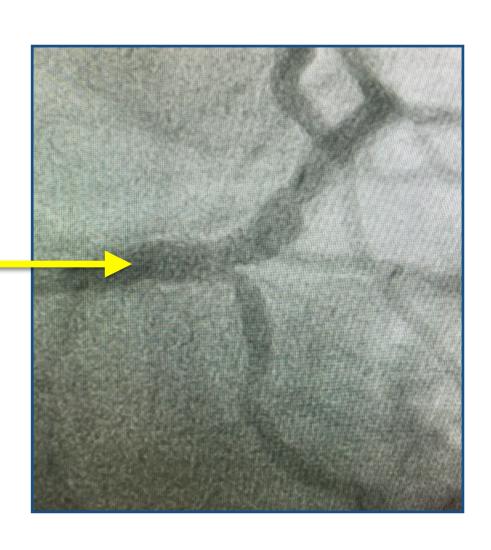




PCI for LMD is usually an easy, quick procedure



- Radial approach.
- PCI with DES.
- Total time: 20 min.
- 24 h discharge.

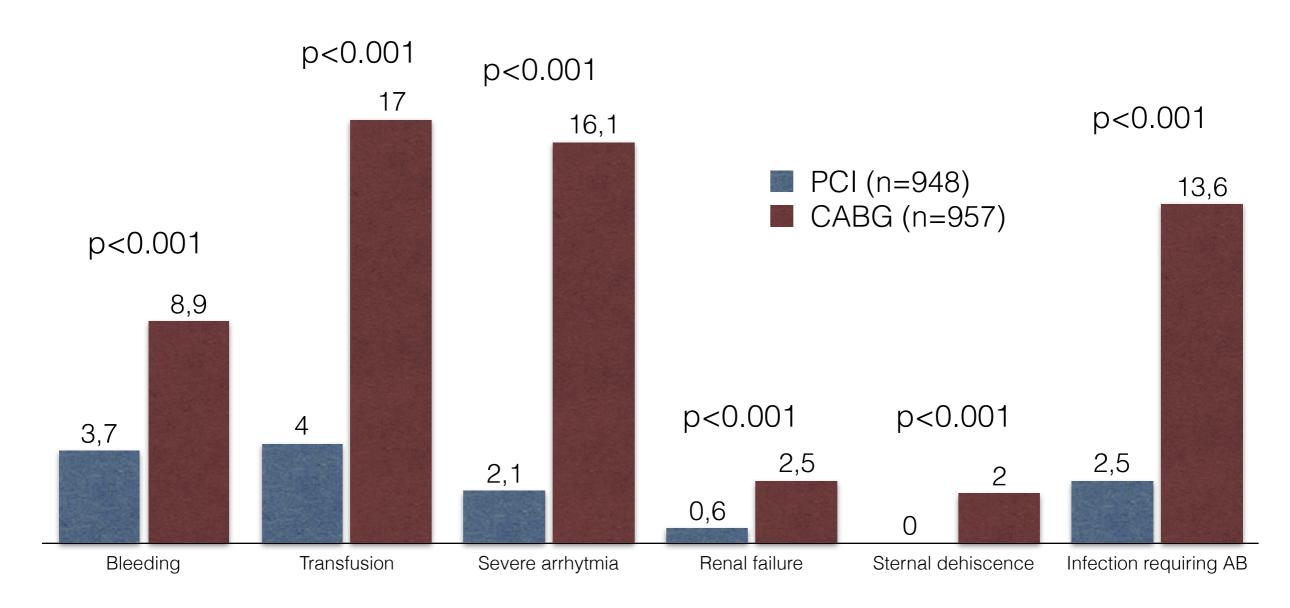






EXCEL trial.

Peri-procedural (30 d) complications (%)





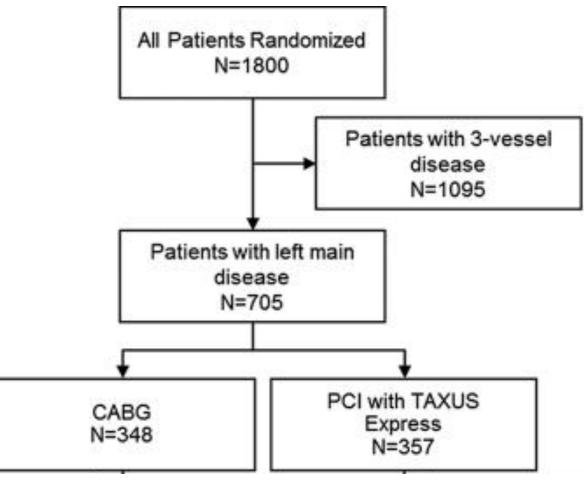


In few years, PCI for LMD has completely changed

Guidelines ESC 2012

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

The SYNTAX trial

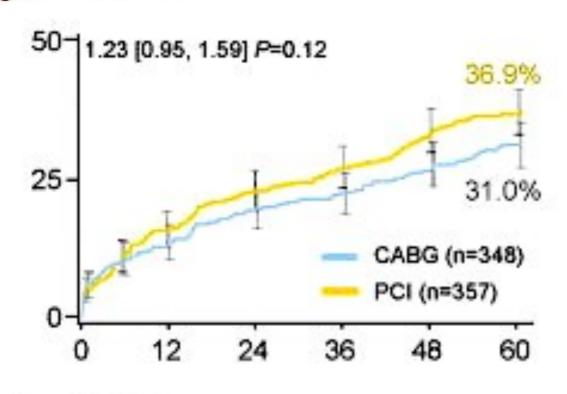


Serruys PW, et al. N Engl J Med 2009;360:961-72 Mohr FW, et al. Lancet 2013;381:629-38. Morice MC, et al. Circulation 2014;129:2388-94.

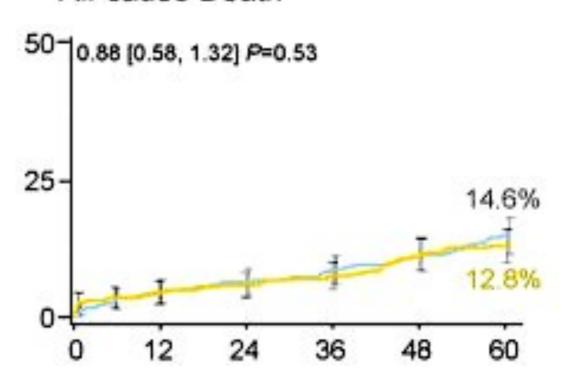


LMD in SYNTAX trial: 5-yr follow-up

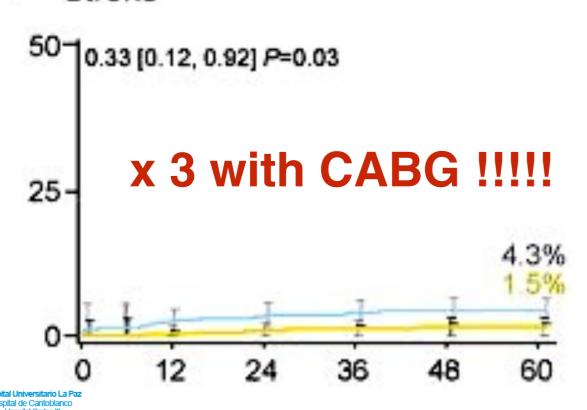




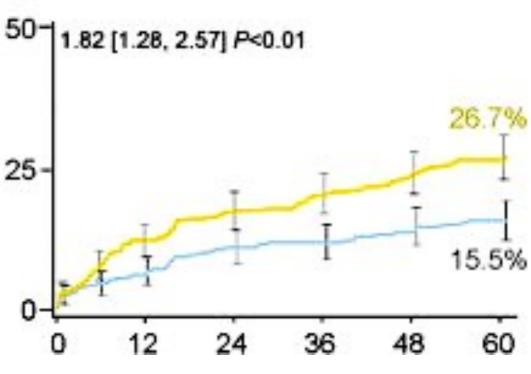
All-cause Death

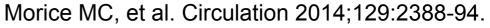


Stroke



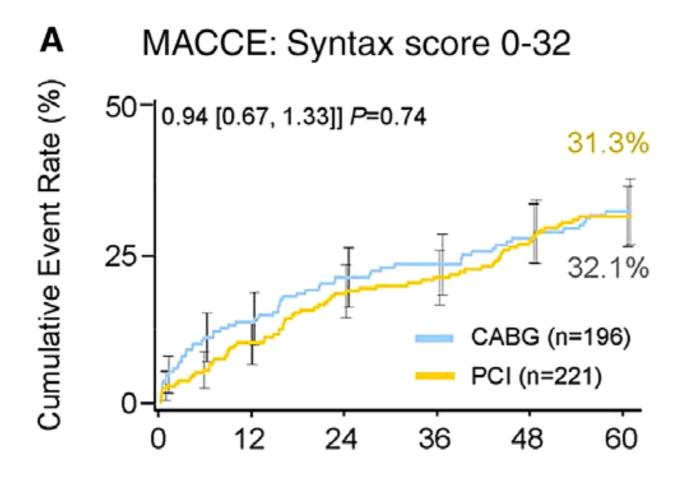
Repeat Revascularization

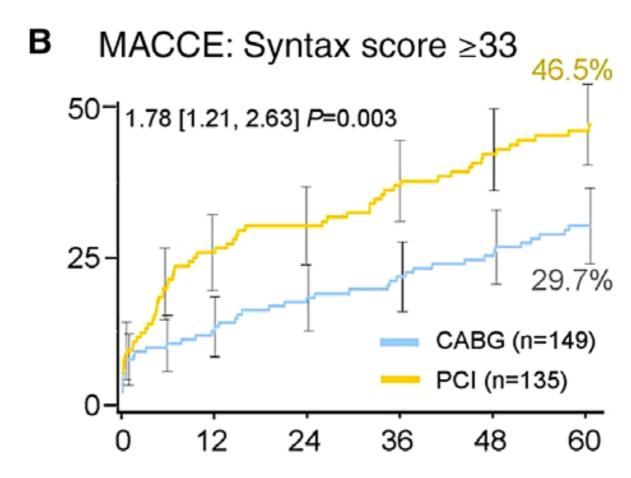






SYNTAX 5-yr. Left main subgroups



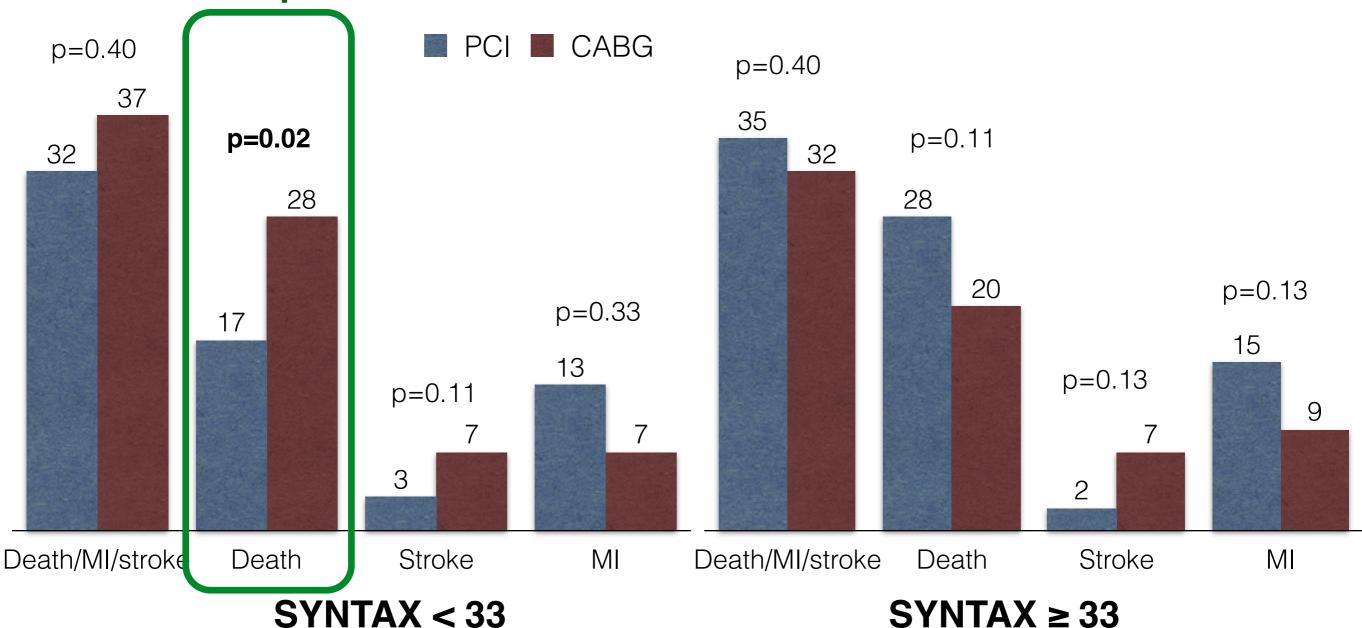






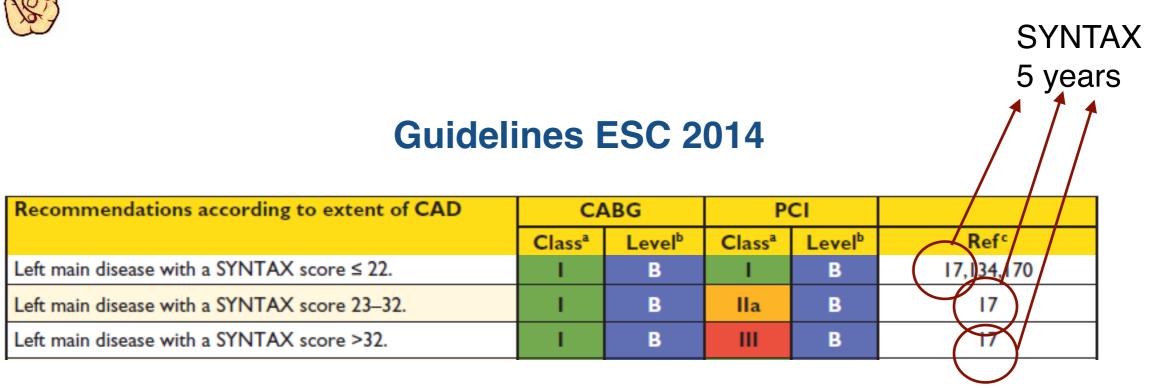
SYNTAX 5-yr. Left main subgroups

Nuestro paciente









Windecker S, et al. Eur Heart J 2014; 35, 2541-2619

Guidelines ESC 2018

Left main CAD								
Left main disease with low SYNTAX score (0 - 22). 69,121,122,124,145-148	1	A	1	A				
Left main disease with intermediate SYNTAX score (23 - 32). ^{69,121,122,124,145-148}	1	A	lla	A				
Left main disease with high SYNTAX score (≥33).c 69,121,122,124,146–148	1	A	III	В				

Neumann FJ, et al. Eur Heart J 2018.





RCT DES vs CABG in Left Main Disease

Stainless-steel DES ("pre-EXCEL era")

RCT	n	Stent	Alloy	Strut thickness	
Boudriot et al	201	Cypher	SS	140 µm	
LEMANS	105	2/3 BMS	SS		
PRECOMBAT	600	Cypher	SS	140 µm	
SYNTAX	SYNTAX 705 Taxus Express		SS	132 µm	
NOBLE 1,201		Biomatrix	SS	120 µm	

Current DES

CC / CP 60-81 µm



Boudriot E, et al. J Am Coll Cardiol 2011;57:538–45.

Park SJ, et al. N Engl J Med 2011;364:1718-27.

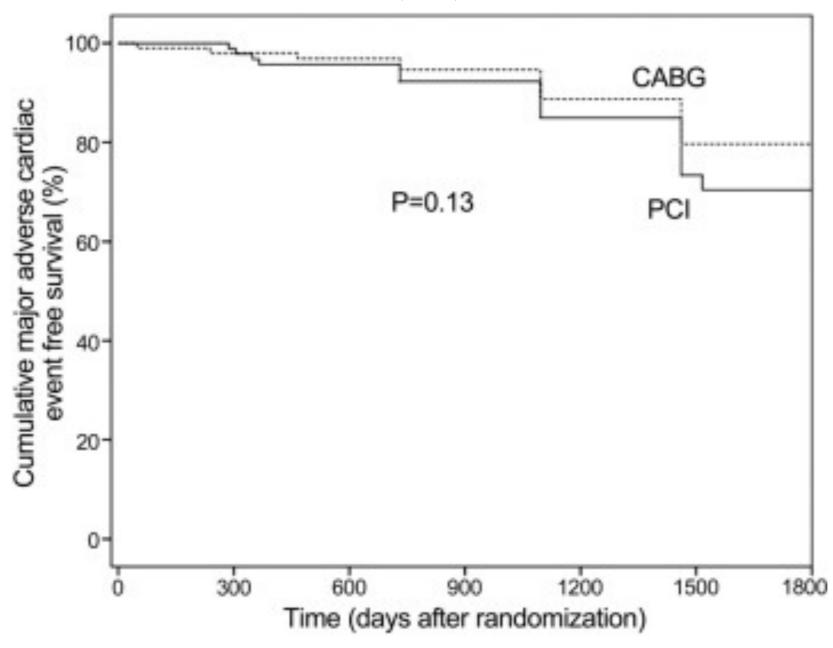
Buszman PE, et al. J Am Coll Cardiol 2008;51:538–45.

Räber L, et al. J Am Coll Cardiol 2011;57:2143–51. Serruys PW, et al. N Engl J Med 2009;360:961-72. Mäkikaltio T, et al. Lancet 2016;388:2743-52.



201 patients with LMD, randomized to CABG vs PCI (Cypher stent)



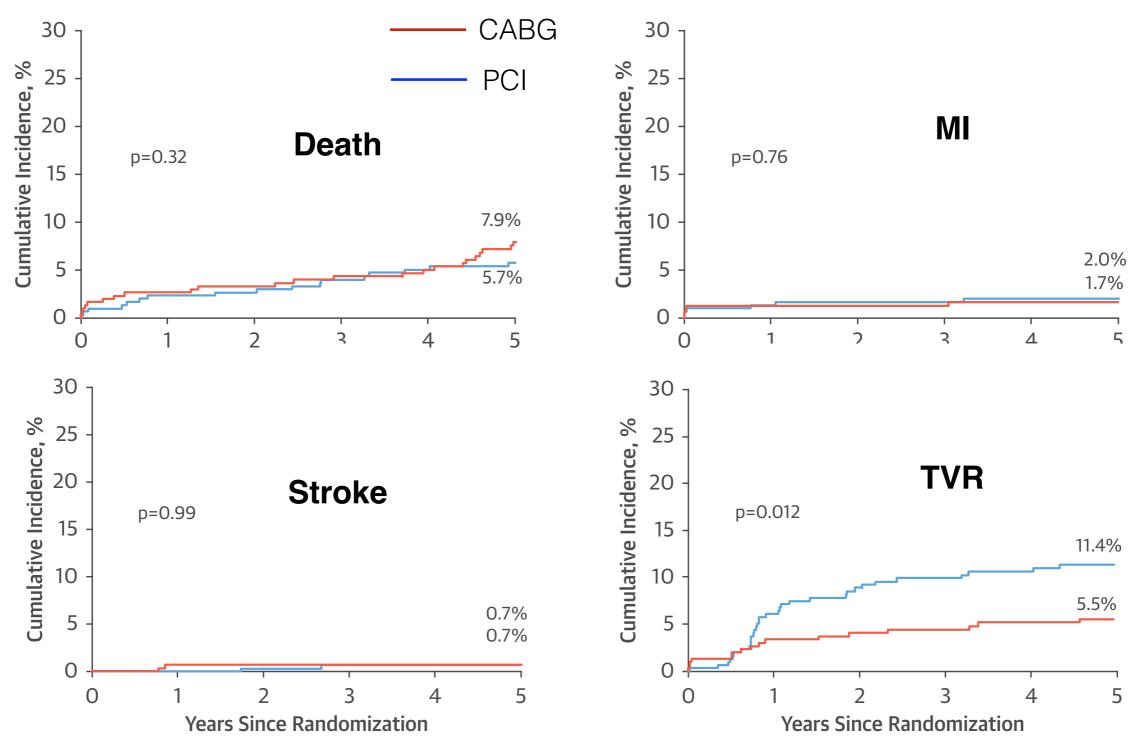






PRECOMBAT

600 patients with LMD, randomized to CABG vs PCI (Cypher stent)





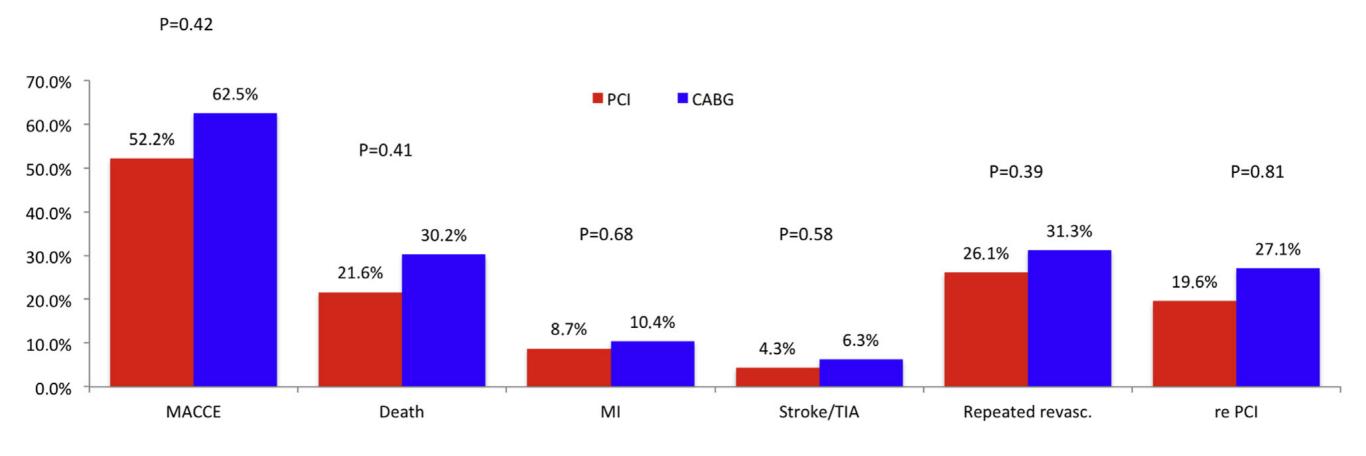
. Ahn



LEMANS

105 patients with LMD, randomized to CABG vs PCI (2/3 BMS)

10-year follow-up





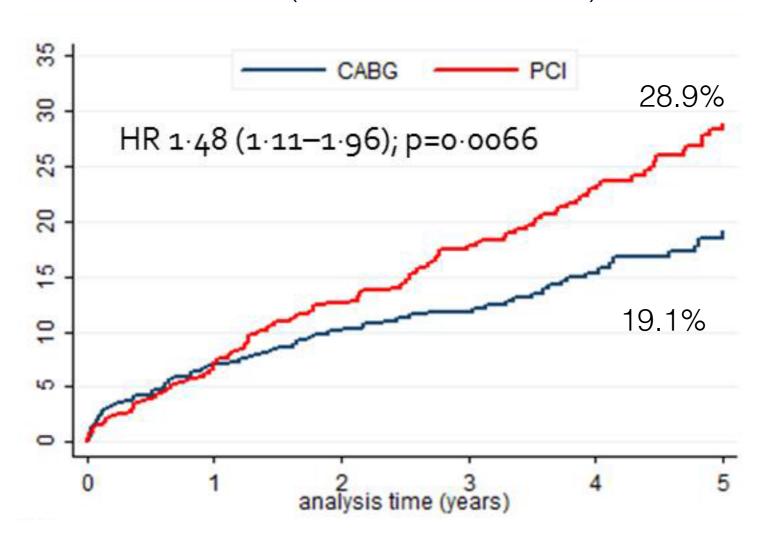
JACC: Cardiovasc Intervent 2016;9:318-27



NOBLE trial

1,201 patients with LMD, randomized to CABG vs PCI (mostly BES)

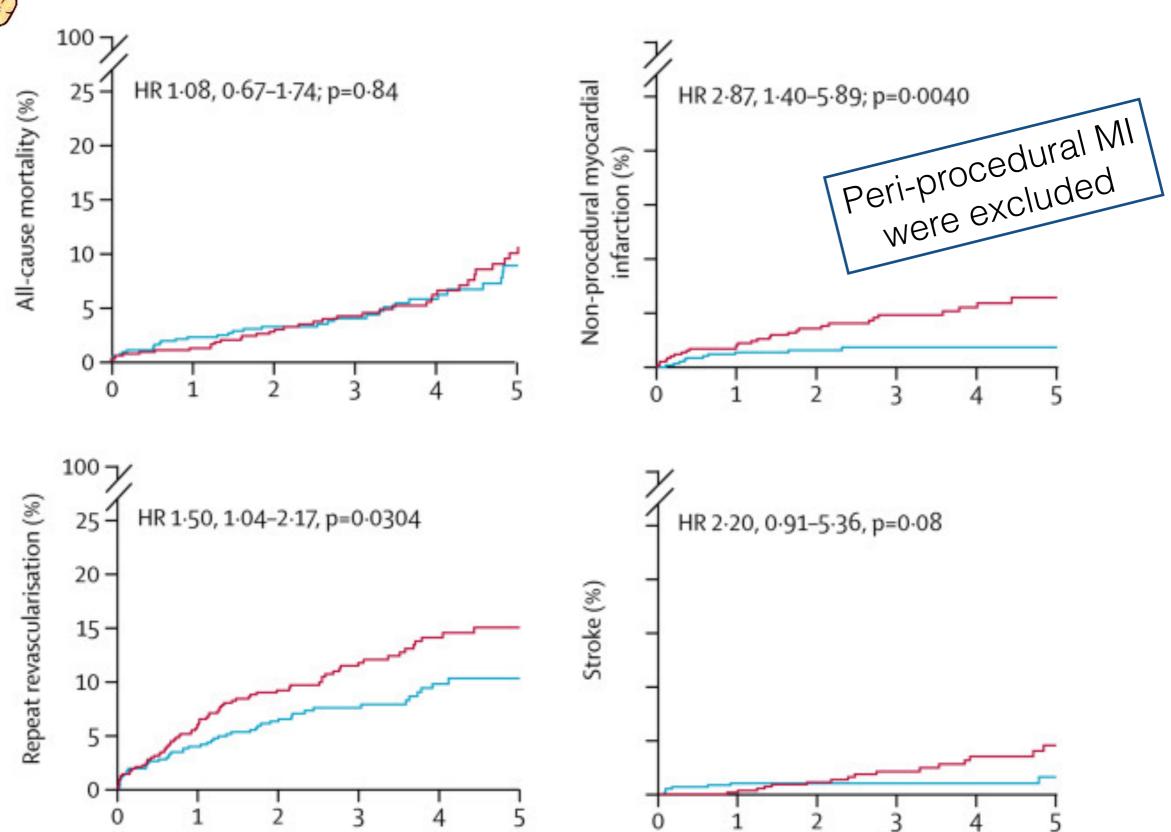
MACCE (death/MI/stroke/TVR)



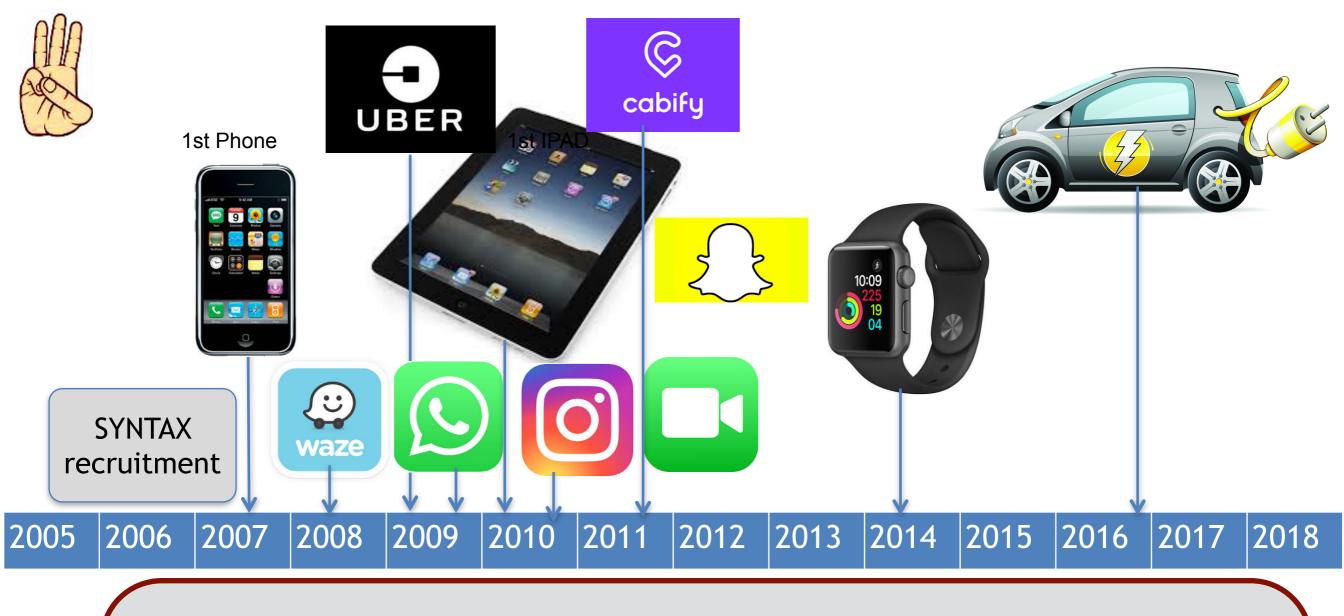


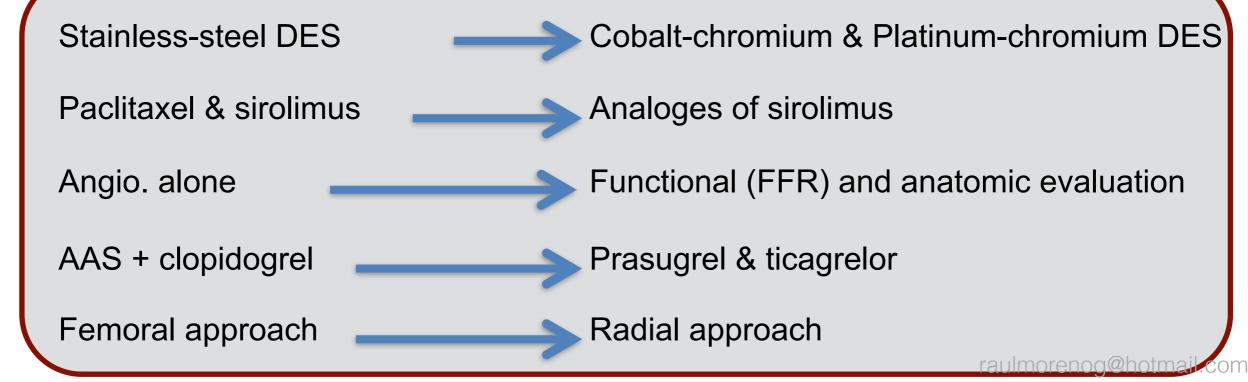


NOBLE trial



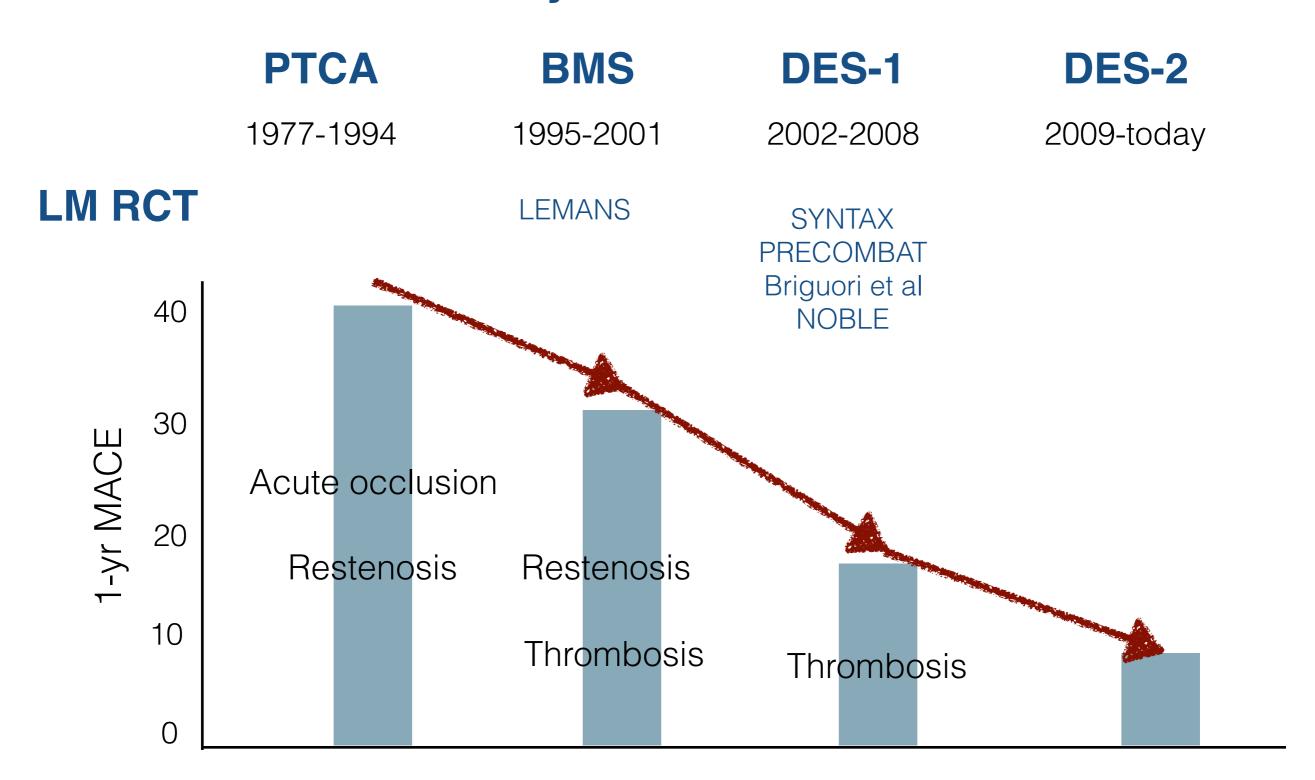








The history of PCI: clinical events

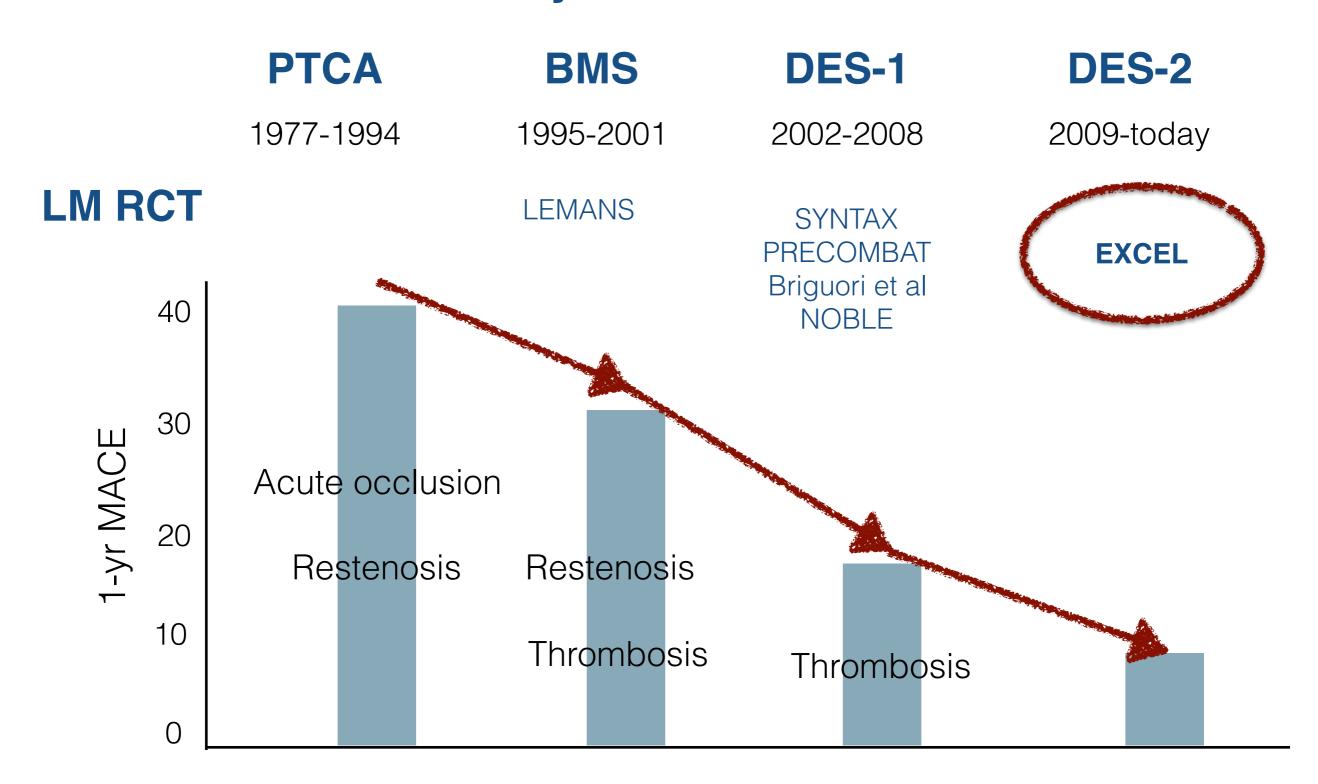


Serruys PW, et al. N Engl J Med 1994;331:489-95. Stone GW,, et al. JAMA. 2008;299:1903-13. Moreno R, et al. Am J Cardiol. 2007;99:621-5. Moreno R, et al. Eur Heart J. 2007;28:1583-91.

Morice MC, et al. N Engl J Med. 2002;346:1773-80. Moreno R. Rev Esp Cardiol. 2005;58:842-62. Moreno R, et al. J Am Coll Cardiol. 2005;45:954-9. Moreno R, et al. EuroIntervention. 2011;6:1003-10.



The history of PCI: clinical events



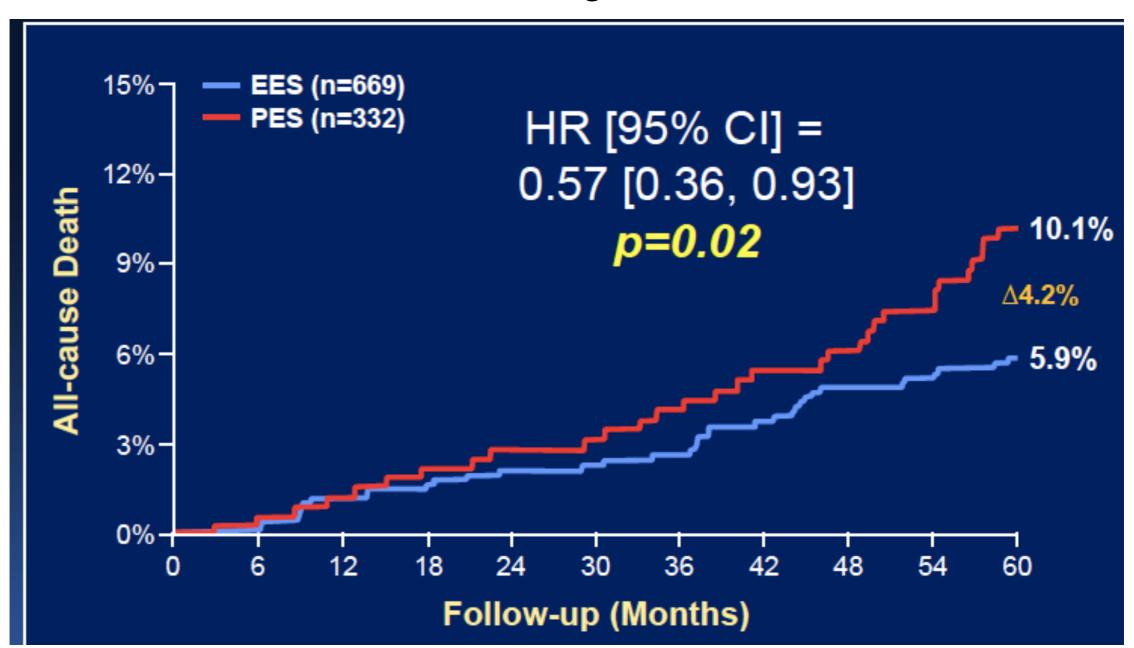
Serruys PW, et al. N Engl J Med 1994;331:489-95. Stone GW,, et al. JAMA. 2008;299:1903-13. Moreno R, et al. Am J Cardiol. 2007;99:621-5. Moreno R, et al. Eur Heart J. 2007;28:1583-91.

Morice MC, et al. N Engl J Med. 2002;346:1773-80. Moreno R. Rev Esp Cardiol. 2005;58:842-62. Moreno R, et al. J Am Coll Cardiol. 2005;45:954-9. Moreno R, et al. EuroIntervention. 2011;6:1003-10.



The benefit of second-generation DES

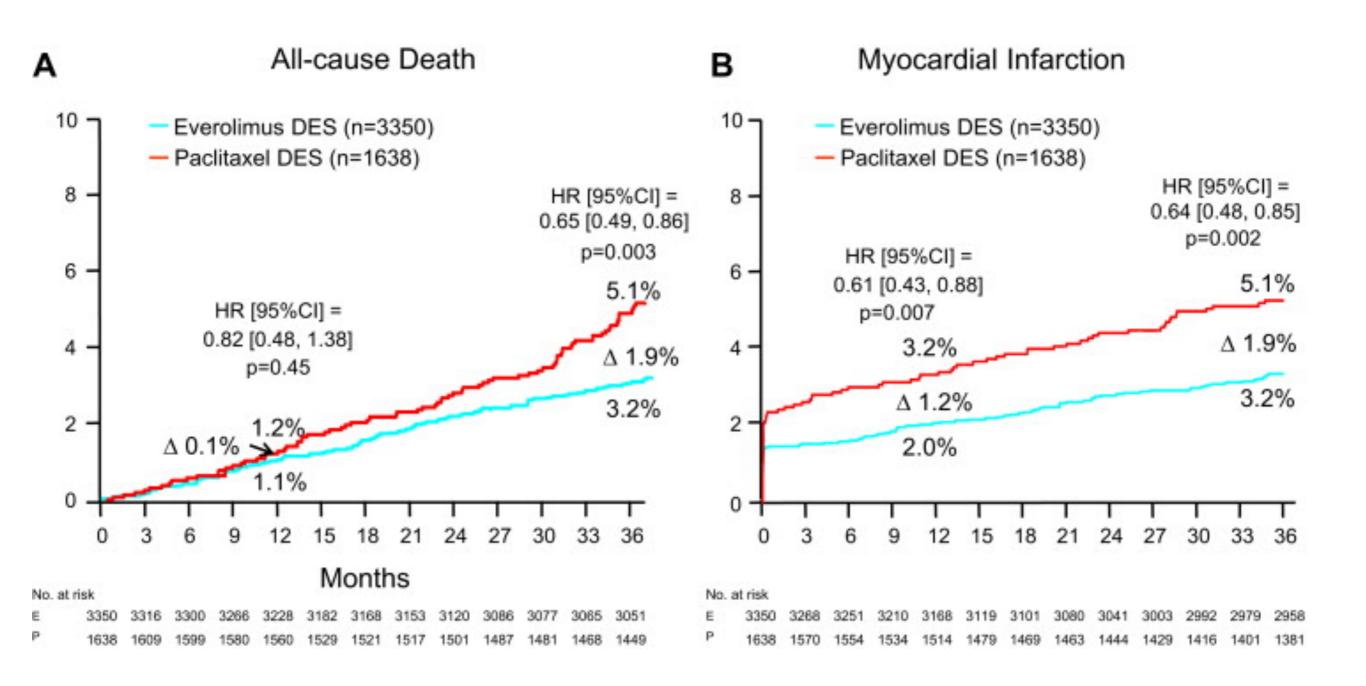
5-Year Survival Benefit of 2nd generation DES: SPIRIT III





The benefit of second-generation DES

Meta-analysis from the SPIRIT trials







Study Design

2900 pts with unprotected left main disease

SYNTAX score ≤32
Consensus agreement of eligibility and equipoise by heart team

∫ ———— No

Yes (N=1900)

Stratified by diabetes, SYNTAX score and center

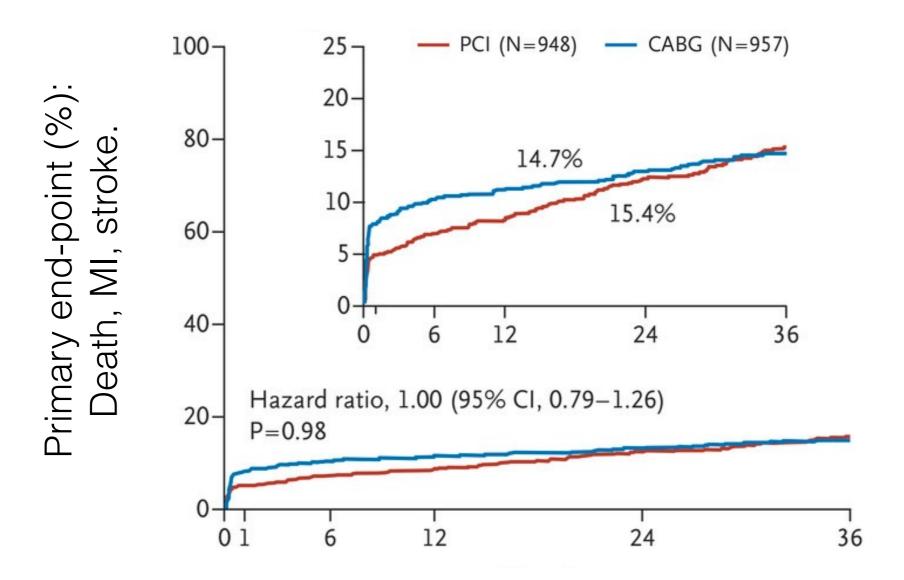
Enrollment registry

(N=1000)

PCI (Xience EES) (N=950) CABG (N=950)

Follow-up: 1 month, 6 months, 1 year, annually through 5 years Primary endpoint: Measured at a median 3-yr FU, minimum 2-yr FU

EXCEL



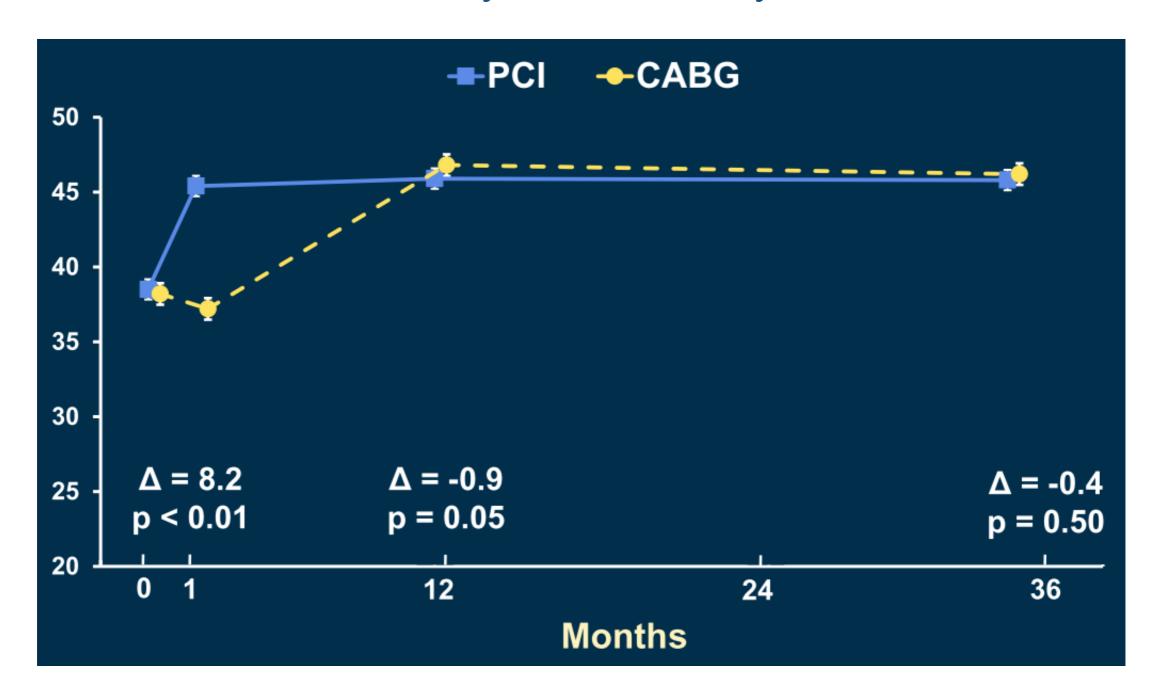
	PCI (N=948)		CABG (N=957)				Hazard R	atio (95% CI)	P Value for Interaction		
	Events/total patients	Event rate	Events/total patients	Event rate			1			0.49	
≤22	28/294	10.3	46/364	13.3		-	-		0.71 (0.44-1.13)		
23-32	65/391	17.6	55/345	16.5			-		1.02 (0.71-1.47)		
≥33	37/229	16.9	30/217	14.3					1.15 (0.71-1.87)		
					0.1	0.5	0.8 1.0	1.5 2.0	5.0		
						PCI Bette	r	CABG Bette	r		

G.W. Stone et al. N Engl J Med. 2016;375:2223-35.



EXCEL: quality of life

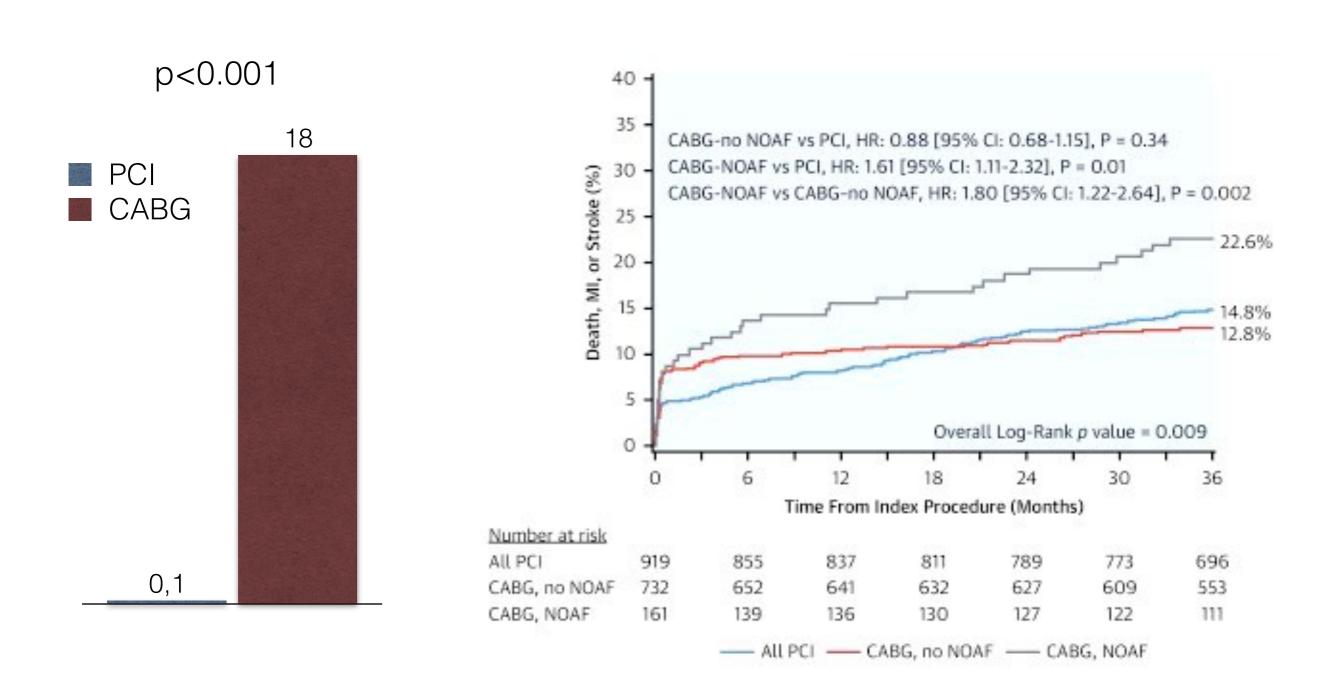
SF-12 Physical summary scale



All revascularization at 3 yr: 12.9% vs 7.6% < 0.001



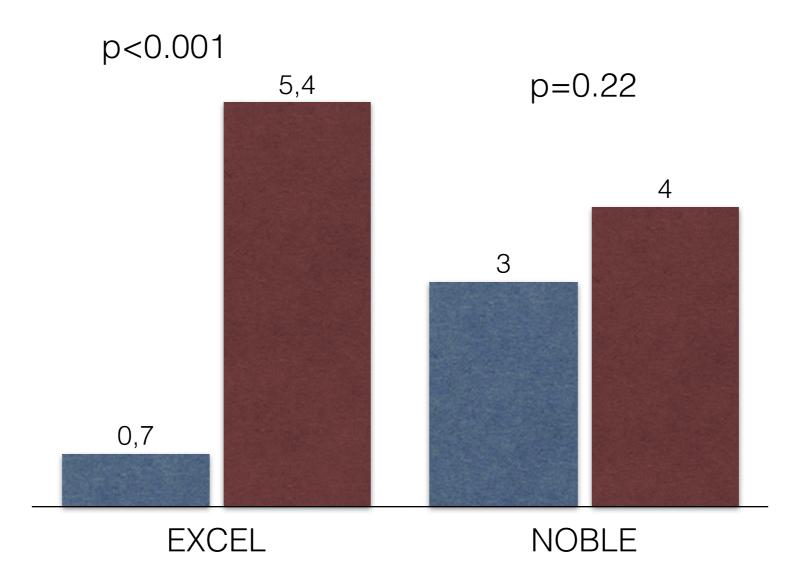
EXCEL: new-onset AF after revascularization





Definitive stent thrombosis vs symptomatic graft occlusion

- PCI (stent thrombosis)
- CABG (symptomatic graft occlusion)

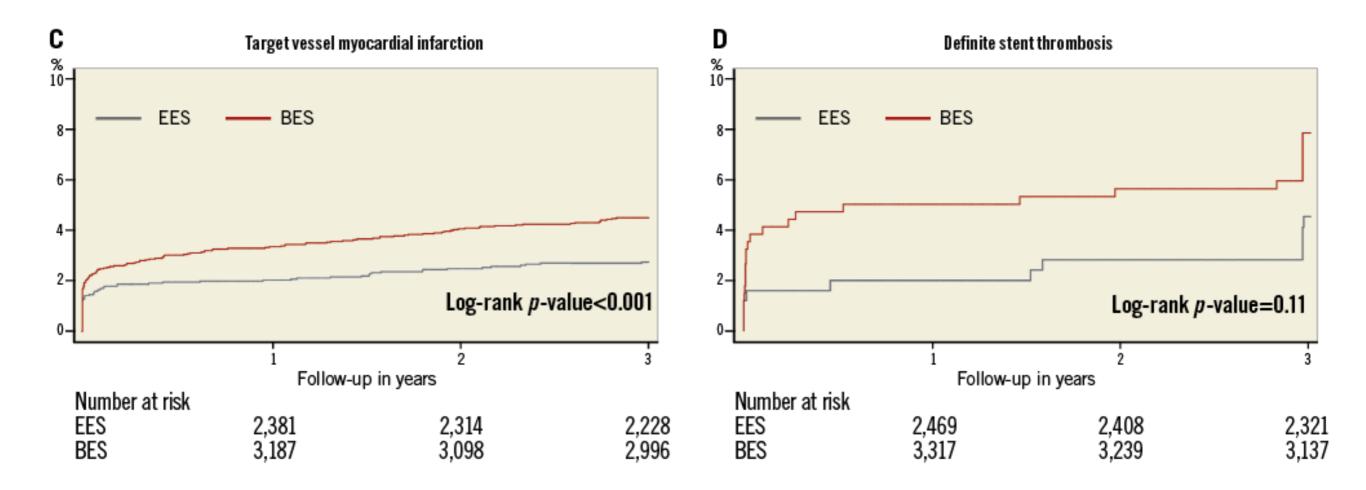


Stone GW et al. N Engl J Med 2016;375:2223-35 Makikallio T et al. Lancet 2016;388:2743–52



NOBLE and EXCEL: is this a controversy between 2 different types of DES?

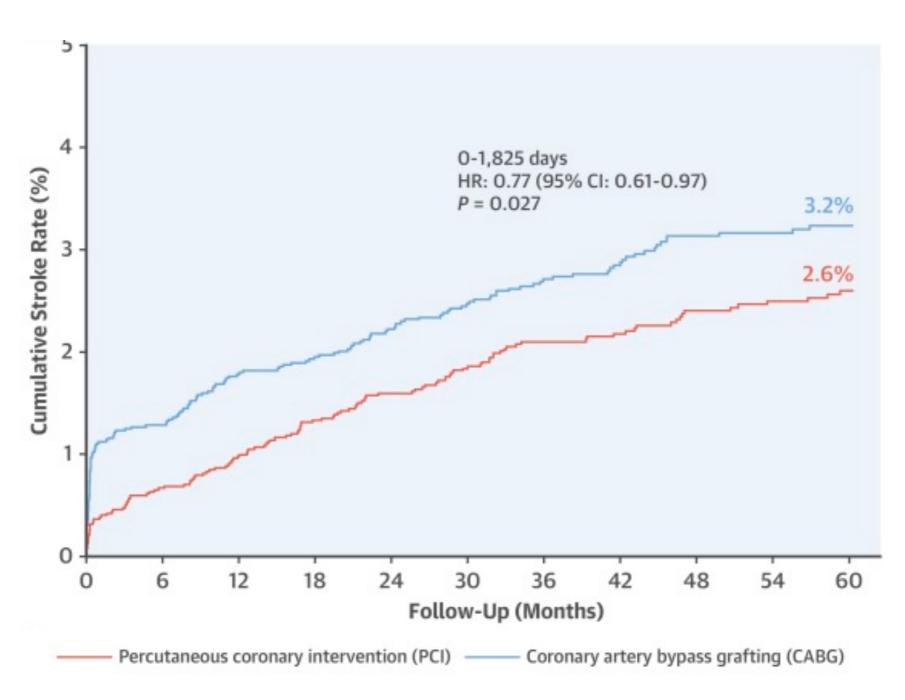
all-comers NEXT and COMPARE II clinical trials randomly assigned 5,942 patients to BP-BES (N=3,412) or DP-EES (N=2,530).





Stroke after PI vs CABG

Meta-analysis from 11 RCT (11,518)



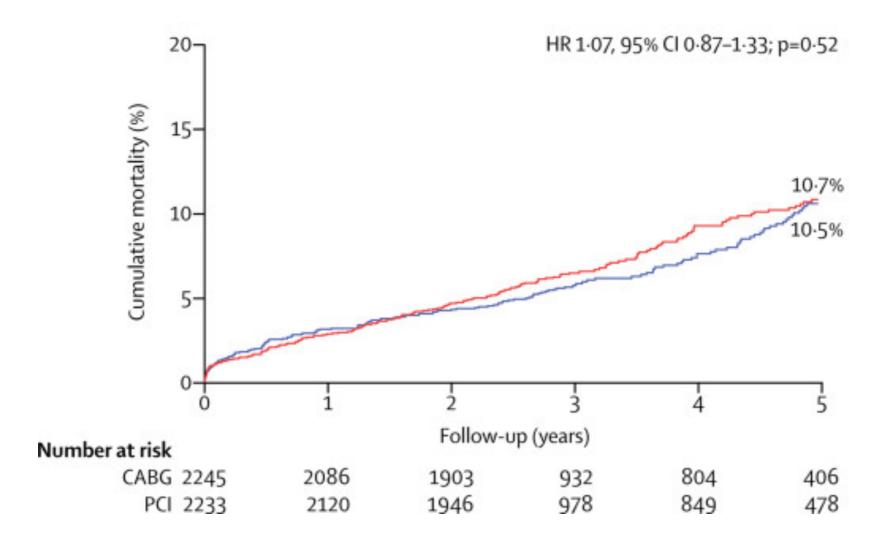


MORTALITY

Meta-analysis from 11 RCT (11,518) comparing PCI and CABG

This is what really matters

4,478 (38.9%) with LMD

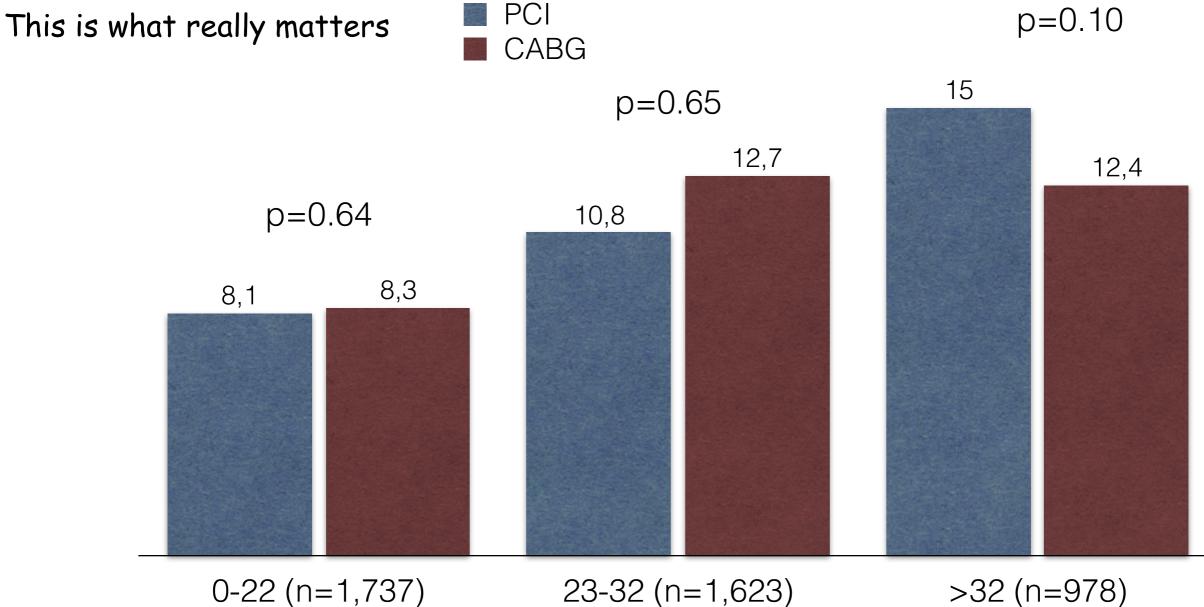






Meta-analysis from 11 RCT (11,518) comparing PCI and CABG

4,478 (38.9%) with LMD



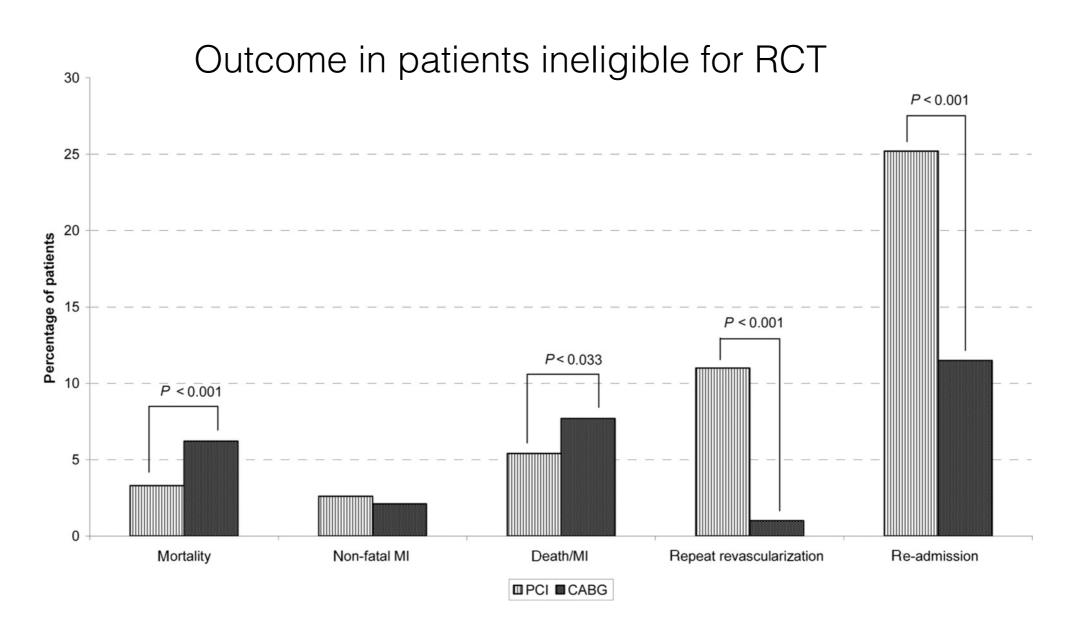




What happens in real life?

Euro HEART Survey on revascularization

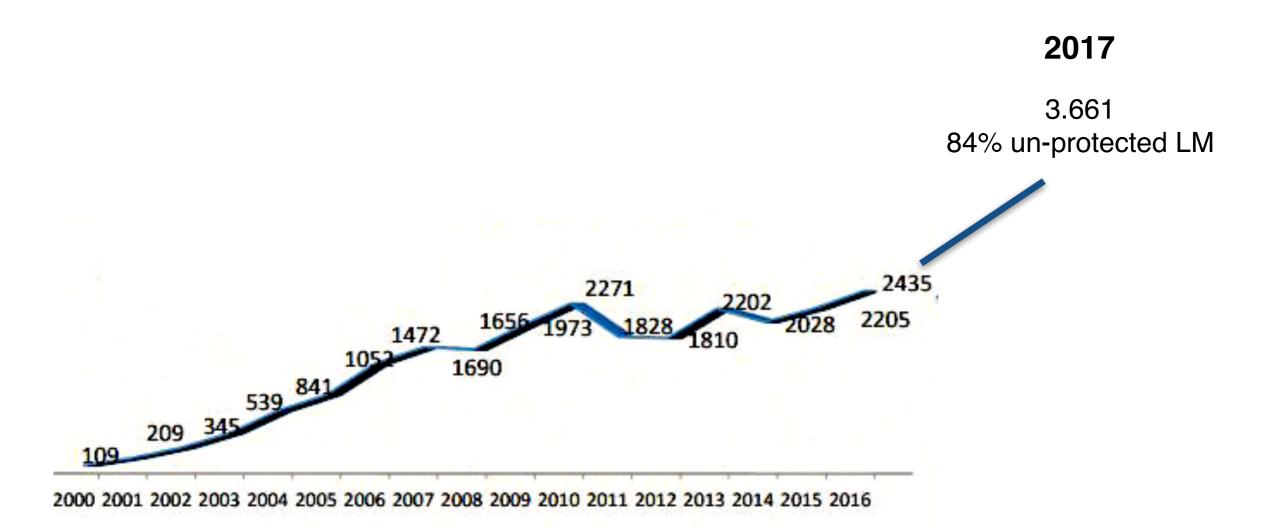
Only 36% of patients are eligible for RCT





What happens in real life?

Data in Spain





PCI vs CABG in Left Main Disease

- Similar mortality at long term for both strategies.
- PCI: less invasive, earlier recovery (QOL).
- PCI: less complications (renal failure, stroke, arrhythmia, bleeding, infection, etc).
- CABG: less new revascularizations. But!
 - NNT is ≈ 20.
 - Symptomatic graft occlusion is more frequent than ST

(graft occlusion usually not treated).

- So, the majority of LM cases should be treated with PCI.
- Which cases could be left for surgery in the current era (second-generation DES)? Those with Syntax score ≥ 33 AND low surgical risk.



A proposal for LMD

SYNTAX SCORE

