



EXCEL

A Prospective, Randomized Trial Comparing Everolimus-Eluting Stents and Bypass Graft Surgery in Selected Patients with Left Main Coronary Artery Disease

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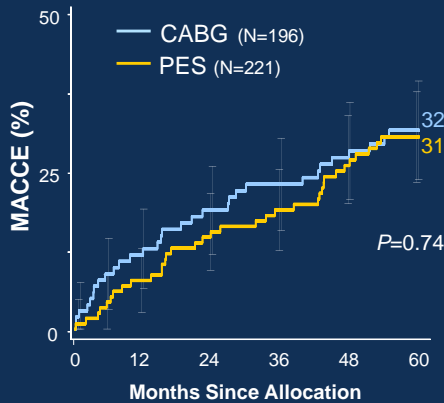


Background

- Patients with left main coronary artery disease (LMCAD) have high morbidity and mortality due to the large amount of myocardium at risk
- Most pts with LMCAD are treated with CABG
- Subset analysis from the SYNTAX trial suggested that DES may be an acceptable option for pts with LMCAD and low or moderate CAD complexity
- Since SYNTAX, PCI and surgical outcomes have both improved, necessitating a contemporary trial examining revascularization alternatives in LMCAD

SYNTAX Trial (n=1705)

5-year outcomes in pts with LMCAD and SYNTAX Score ≤ 32 (n=417)



	CABG	PES	P value
Death	15.1%	7.9%	0.02
Stroke	3.9%	1.4%	0.11
MI	3.8%	6.1%	0.33
Death, Stroke, or MI	19.8%	14.8%	0.16
Revasc.	18.6%	22.6%	0.36

Since SYNTAX, PCI and surgical outcomes have both improved, necessitating a contemporary trial examining revascularization alternatives in LMCAD

Morice MC et al. *Circulation*. 2014;129:2388-94



Study Design

2900 pts with unprotected left main disease

SYNTAX score ≤ 32

Consensus agreement of eligibility and equipoise by heart team

Yes

(N=1900)

No

(N=1000)

Enrollment
registry

Stratified by diabetes, SYNTAX score and center

R

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



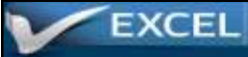
Design Imperatives

- Academically-driven trial organized and led equally by interventional cardiologists and cardiac surgeons
- PCI and CABG arms utilize the best available devices and techniques
- Large enough for a meaningful primary endpoint:
 - Death, stroke or MI at a median follow-up duration of 3 years
 - MI definition is prognostically important, identical for PCI and CABG, and chosen to minimize ascertainment bias (SCAI defn variation – large MI)
- Screening registry incorporated to evaluate the generalizability of the trial results



Major Inclusion Criteria

- Unprotected LMCAD with $\geq 70\%$ DS, *or* $\geq 50\%$ - $< 70\%$ with either i) non-invasive evidence of LM ischemia, ii) IVUS MLA $\leq 6.0 \text{ mm}^2$, or iii) FFR ≤ 0.80
- Syntax score ≤ 32
- Clinical and anatomic eligibility for both PCI and CABG as agreed to by the local Heart Team



Major Exclusion Criteria

- Prior CABG or LM PCI anytime
- Prior non-LM PCI within 1 year
- Need for cardiac surgery other than CABG
- Inability to tolerate DAPT for 1 year
- CK-MB >ULN



Protocol Procedures

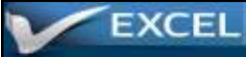
PCI recommendations

- Complete revasc of all ischemic territories with EES
- Provisional LM bifurcation treatment preferred
- IVUS guidance strongly recommended
- DAPT pre-loading and treatment for ≥ 1 year
- Routine angiographic follow-up not permitted

CABG recommendations

- Performed w/ or w/o CPB per operator discretion
- Complete anatomic revascularization of all vessels ≥ 1.5 mm in diameter with $\geq 50\%$ DS
- Arterial grafts strongly recommended
- Epi-aortic ultrasound and TEE recommended
- Clopidogrel use during FU allowed but not mandatory

Guideline-directed medical therapy for both groups



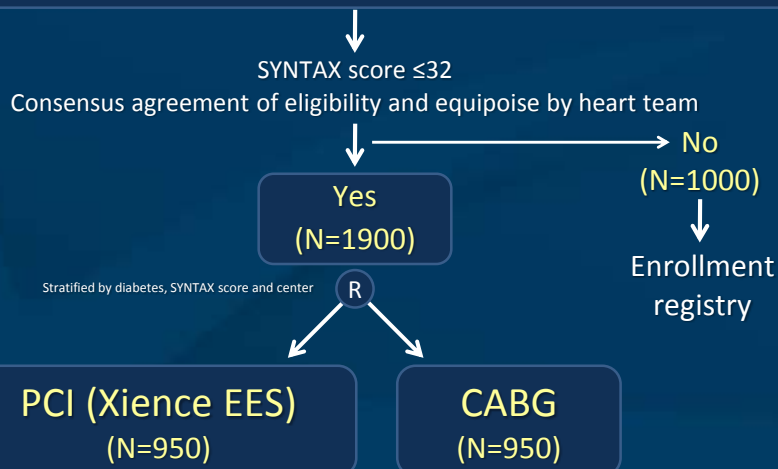
Primary Endpoint Definitions

- **Death:** Adjudicated due to CV, non-CV, or undetermined causes
- **Peri-procedural MI (<72 hrs):** CK-MB >10x URL, *or* >5x URL *plus* either i) new pathological Q waves in ≥ 2 contiguous leads *or* new LBBB, *or* ii) angio documented graft or coronary artery occlusion or new severe stenosis with thrombosis, *or* iii) imaging evidence of new loss of viable myocardium or new regional wall motion abnormality
- **Spontaneous MI (≥ 72 hrs):** CK-MB or troponin >1x URL *plus* new ST-segment elevation or depression *or* other findings as above
- **Stroke:** Requires: 1) Rapid onset of a focal/global neurological deficit with no other readily identifiable non-stroke cause; 2) Duration ≥ 24 hrs, or <24 hrs if i) pharmacologic or non-pharmacologic Rx; *or* ii) positive brain imaging; *or* iii) death; 3) Confirmation by neurologist *plus* confirmatory brain imaging or LP; 4) ≥ 1 increase in modified Rankin Scale (mRS)



Study Design

2900 pts with unprotected left main disease



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



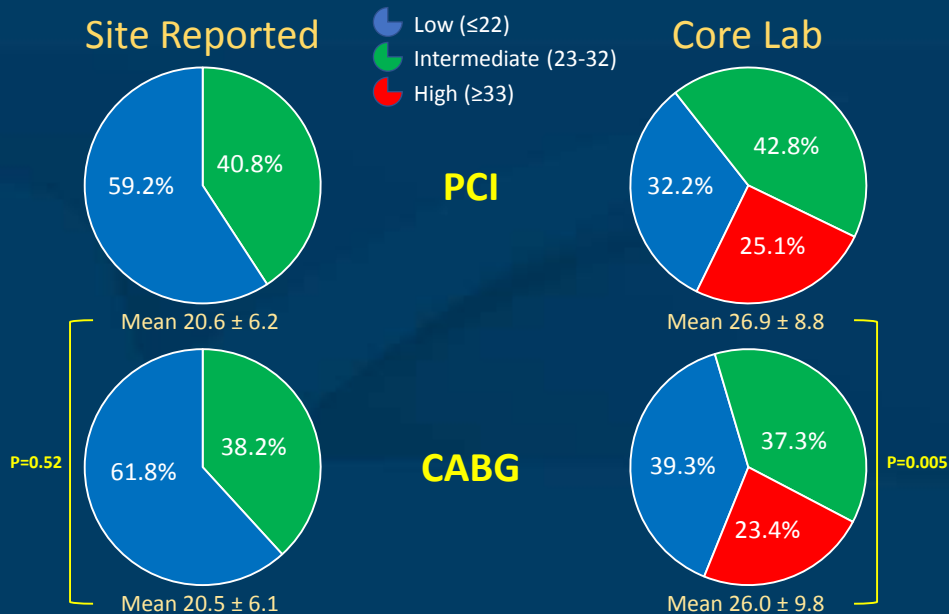
Selected Baseline Data

	PCI (N=942)	CABG (N=936)
Age (years)	66.0 ± 9.6	65.9 ± 9.5
Male	76.2%	77.5%
Diabetes	30.2%	28.0%
Clinical presentation		
- Recent MI (within 7 days)	15.0%	14.8%
- Unstable angina, biomarker negative	24.2%	24.6%
- Stable angina	53.1%	53.2%
- Silent ischemia or other	7.7%	7.4%
Distal LM bifurcation or trifurcation ds.*	81.8%	79.2%
# Diseased non-LM coronary arteries*		
- 0	17.3%	17.8%
- 1	31.0%	31.2%
- 2	34.5%	31.5%
- 3	17.2%	19.4%

*DS ≥50% by QCA (core lab analysis)



SYNTAX Score





PCI Procedure

935 patients, 1021 planned procedures, 2287 stents

Planned staged procedures	9.1%	# Vessels treated per pt**	1.7 ± 0.8
Arterial access site*		- LM	100.0%**
- Femoral	72.9%	- LAD	28.3%
- Radial	26.9%	- LCX	16.6%
- Brachial	0.2%	- RCA	26.7%
IVUS guidance	77.2%	# Lesions treated per pt*	1.9 ± 1.1
FFR assessment	9.0%	# Stents implanted per pt*	2.4 ± 1.5
Hemodynamic support device*	5.2%	- Total stent length (mm)*	49.1 ± 35.6
Contrast use* (cc)	256 ± 127	Type of stents implanted*	
Fluoroscopy time* (min)	24 ± 16	- DES	99.8%
		- EES	99.2%
		- XIENCE	98.4%

*All procedures (index + planned staged); **Excludes pts with LM equivalent ds;
 †Max 4 vessels, including LM as a separate vessel



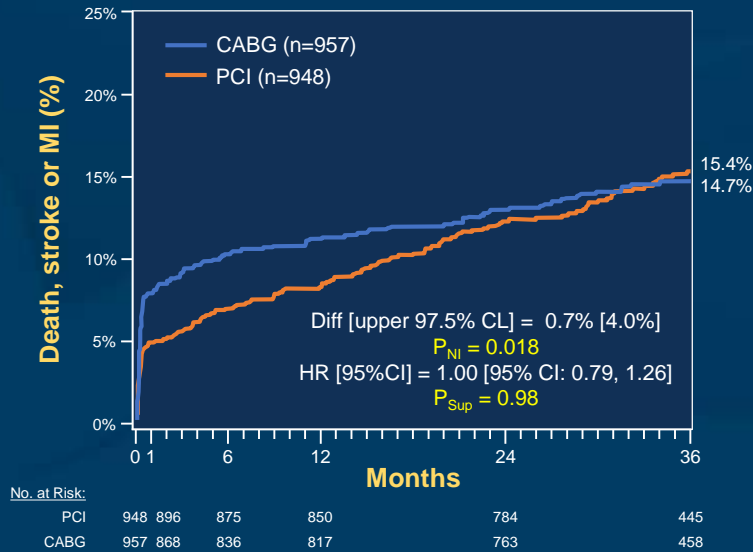
CABG Procedure

923 patients and procedures

Off-pump CABG	29.4%	# Conduits per pt	2.6 ± 0.8
On-pump bypass duration (min)	83 ± 45	- Arterial conduits	1.4 ± 0.6
- Cross clamp duration (min)	55 ± 27	- Venous conduits	1.2 ± 0.9
Epi-aortic ultrasound	13.1%	Any IMA used	98.8%
Transesophageal ultrasound	42.3%	Bilateral IMA used	28.8%
Hemodynamic support device	3.5%	Any radial artery used	6.0%
		Only arterial conduits used	24.8%
		Vessels bypassed per pt	
		- LAD	98.8%
		- LCX	88.2%
		- RCA	37.8%



Primary Endpoint Death, Stroke or MI at 3 Years



Adjudicated Outcomes at 30 Days

	PCI (n=948)	CABG (n=957)	HR [95%CI]	P-value
Death, stroke or MI	4.9%	7.9%	0.61 [0.42, 0.88]	0.008
- Death	1.0%	1.1%	0.90 [0.37, 2.22]	0.82
- Stroke	0.6%	1.3%	0.50 [0.19, 1.33]	0.15
- MI	3.9%	6.2%	0.63 [0.42, 0.95]	0.02
- Peri-procedural	3.6%	5.9%	0.61 [0.40, 0.93]	0.02
- Spontaneous	0.3%	0.3%	1.00 [0.20, 4.95]	1.00
- STEMI	0.7%	2.3%	0.32 [0.14, 0.74]	0.005
- Non-STEMI	3.2%	3.9%	0.82 [0.50, 1.32]	0.41
Death, stroke, MI or IDR	4.9%	8.4%	0.57 [0.40, 0.82]	0.002
- Ischemia-driven revasc (IDR)	0.6%	1.4%	0.46 [0.18, 1.21]	0.11
Stent thrombosis, def/prob	0.6%	0.0%	-	0.01
Graft occlusion, symptomatic	0.0%	1.2%	-	<0.001
Definite stent thrombosis or symptomatic graft occlusion	0.3%	1.2%	0.27 [0.08, 0.97]	0.03



Major Adverse Events Within 30 Days

	PCI (n=948)	CABG (n=957)	RR [95%CI]	P-value
Peri-procedural MAE, any	8.1%	23.0%	0.35 [0.28, 0.45]	<0.001
- Death*	0.9%	1.0%	0.91 [0.39, 2.23]	0.83
- Stroke*	0.6%	1.3%	0.50 [0.19, 1.34]	0.16
- Myocardial infarction*	3.9%	6.2%	0.63 [0.42, 0.95]	0.02
- Ischemia-driven revascularization*	0.6%	1.4%	0.47 [0.18, 1.22]	0.11
- TIMI major/minor bleeding	3.7%	8.9%	0.42 [0.28, 0.61]	<0.001
- Transfusion \geq 2 units	4.0%	17.0%	0.24 [0.17, 0.33]	<0.001
- Major arrhythmia**	2.1%	16.1%	0.13 [0.08, 0.21]	<0.001
- Surgery/radiologic procedure	1.3%	4.1%	0.31 [0.16, 0.59]	<0.001
- Renal failure†	0.6%	2.5%	0.25 [0.10, 0.61]	<0.001
- Sternal wound dehiscence	0.0%	2.0%	0.03 [0.00, 0.43]	<0.001
- Infection requiring antibiotics	2.5%	13.6%	0.18 [0.12, 0.28]	<0.001
- Prolonged intubation (>48 hours)	0.4%	2.9%	0.14 [0.05, 0.41]	<0.001
- Post-pericardiotomy syndrome	0.0%	0.4%	0.11 [0.01, 2.08]	0.12

*Adjudicated events; others are site-reported. **SVT requiring cardioversion, VT or VF requiring treatment, or bradyarrhythmia requiring temporary or permanent pacemaker.
†Serum creatinine increased by \geq 0.5 mg/dL from baseline or need for dialysis.



Adjudicated Outcomes at 3 Years (i)

	PCI (n=948)	CABG (n=957)	HR [95%CI]	P-value
Death, stroke or MI (1 st endpoint)	15.4%	14.7%	1.00 [0.79, 1.26]	0.98
- Death	8.2%	5.9%	1.34 [0.94, 1.91]	0.11
- Definite cardiovascular	3.7%	3.4%	1.10 [0.67, 1.80]	0.71
- Definite non-cardiovascular	3.9%	2.3%	1.60 [0.91, 2.80]	0.10
- Undetermined cause	0.8%	0.3%	2.00 [0.50, 7.98]	0.32
- Stroke	2.3%	2.9%	0.77 [0.43, 1.37]	0.37
- MI	8.0%	8.3%	0.93 [0.67, 1.28]	0.64
- Peri-procedural	3.8%	6.0%	0.63 [0.42, 0.96]	0.03
- Spontaneous	4.3%	2.7%	1.60 [0.95, 2.70]	0.07
- STEMI	1.3%	2.8%	0.46 [0.23, 0.91]	0.02
- Non-STEMI	7.0%	5.9%	1.15 [0.80, 1.65]	0.46



Adjudicated 3-Year Death

	PCI (n=948)	CABG (n=957)	HR [95%CI]	P-value
All-cause death	8.2%	5.9%	1.34 [0.94, 1.91]	0.11
- Definite cardiovascular	3.7%	3.4%	1.10 [0.67, 1.80]	0.71
- Sudden cardiac death	1.4%	0.7%		0.11
- Myocardial infarction	0.7%	0.6%		0.56
- HF or cardiogenic shock	0.3%	0.6%		0.48
- Stroke	0.8%	0.8%		1.00
- Bleeding	0.0%	0.3%		0.08
- Other CV cause	0.4%	0.4%		0.70
- Definite non-cardiovascular	3.9%	2.3%	1.60 [0.91, 2.80]	0.10
- Pulmonary	0.3%	0.1%		0.56
- Infection (includes sepsis)	1.5%	0.7%		0.11
- Gastrointestinal	0.1%	0.3%		0.57
- Malignancy	1.7%	0.9%		0.27
- Accident/trauma	0.2%	0.1%		0.57
- Non-CV organ failure	0.1%	0.0%		0.32
- Other non-CV cause	0.0%	0.2%		0.16
- Undetermined cause	0.8%	0.3%	2.00 [0.50, 7.98]	0.32



Adjudicated Outcomes at 3 Years (ii)

	PCI (n=948)	CABG (n=957)	HR [95%CI]	P-value
Death, stroke, MI or IDR	23.1%	19.1%	1.18 [0.97, 1.45]	0.10
- Ischemia-driven revasc (IDR)	12.6%	7.5%	1.72 [1.27, 2.33]	<0.001
- PCI	10.3%	6.8%	1.57 [1.13, 2.18]	0.006
- CABG	3.5%	0.8%	4.29 [1.88, 9.77]	<0.001
All revascularization	12.9%	7.6%	1.72 [1.27, 2.33]	<0.001
Stent thrombosis, def/prob	1.3%	0.0%	-	<0.001
- Definite	0.7%	0.0%	-	0.01
- Probable	0.7%	0.0%	-	0.01
- Early (0 - 30 days)	0.7%	0.0%	-	0.008
- Late (30 days - 1 year)	0.1%	0.0%	-	0.32
- Very late (1 year - 3 years)	0.5%	0.0%	-	0.05
Graft occlusion, symptomatic	0.0%	5.4%	-	<0.001
Definite stent thrombosis or symptomatic graft occlusion	0.7%	5.4%	0.12 [0.05, 0.28]	<0.001



Primary Endpoint Analysis (post hoc) Landmark

	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

Stroke and MI rates are non-hierarchical; i.e. include fatal and non-fatal events. The 30-day to 3-year landmark period includes all randomized pts at day 30 except those who died before day 30. Thus there may be some patients with a stroke or MI within 30 days who have a second event between 30 days and 3 years.



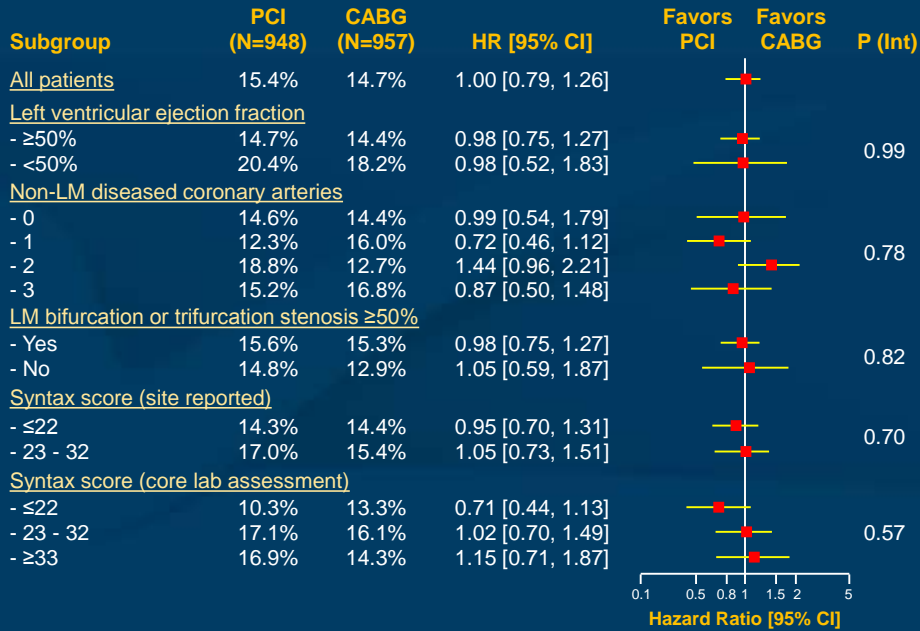
3-Year Death, Stroke or MI

Subgroup	PCI (N=948)	CABG (N=957)	HR [95% CI]	Favors PCI	Favors CABG	P (Int)
<u>All patients</u>	15.4%	14.7%	1.00 [0.79, 1.26]			
<u>Age (median cutoff)</u>						
- ≥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]			
<u>Gender</u>						
- Male	14.0%	14.9%	0.87 [0.66, 1.14]			0.06
- Female	19.7%	14.1%	1.48 [0.93, 2.41]			
<u>Diabetes mellitus</u>						
- Yes	21.2%	19.4%	1.04 [0.70, 1.55]			0.77
- No	13.3%	13.1%	0.97 [0.72, 1.30]			
<u>Chronic kidney disease</u>						
- 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]			
<u>Geographic location</u>						
- 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]			

Hazard Ratio [95% CI]



3-Year Death, Stroke or MI



Conclusions

- Treatment of patients with LMCAD and low or intermediate SYNTAX scores with CoCr-EES resulted in similar rates of the primary endpoint of death, stroke or MI at 3 years, with fewer adverse events within 30 days compared to CABG
- PCI may thus be considered an acceptable or even preferred revascularization modality for selected patients with LMCAD, a decision which should be made after heart team discussion, taking into account each patient's individual circumstances and preferences

NOBLE Trial

LM disease + ≤3 additional non-complex lesions

Clinical equipoise for PCI vs. CABG

Excluded: CTO, 2-stent bif, severe calc/tortuous

N=1201

PCI (n=598)

CABG (n=603)

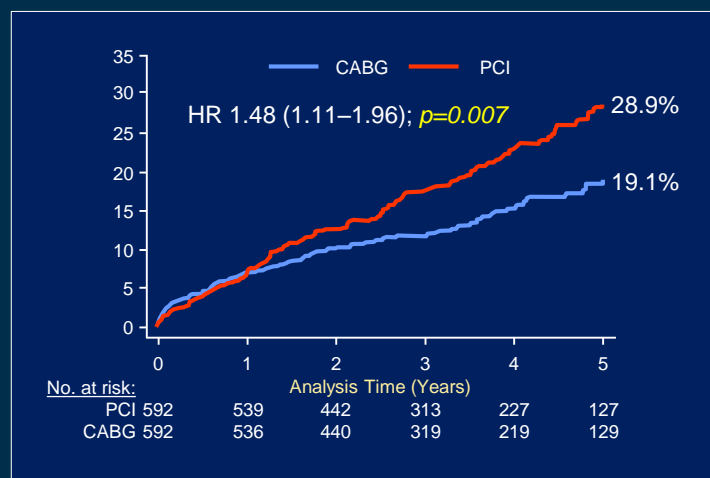
Primary endpoint

MACCE: death, non-procedural MI, repeat revasc, stroke at median 3 years (with FU up to 5 years)

Makikallio T et al. Lancet 2016;388:2743–52

NOBLE

Primary Endpoint: MACCE (w/o proc MI)



PCI did not show non-inferiority and CABG was superior to PCI

Makikallio T et al. Lancet 2016;388:2743–52

NOBLE: 5-Year Results

	PCI (n=592)	CABG (n=592)	Hazard Ratio (95% CI)	p Value
MACCE	29% (121)	19% (81)	1.48 (1.11-1.96)	0.007
All-cause mortality	12% (36)	9% (33)	1.07 (0.67-1.72)	0.77
- Cardiac death	3% (14)	3% (15)	0.93 (0.45-1.92)	0.84
- Vascular death	1% (2)	<1 (1)	1.96 (0.18-21.66)	0.55
Non-procedural-related MI	7% (29)	2% (10)	2.88 (1.40-5.90)	0.004
Revascularization (total)	16% (71)	10% (47)	1.50 (1.04-2.17)	0.03
- Revasc with PCI	13% (56)	10% (45)	1.23 (0.83-1.83)	0.29
- Revasc with CABG	4% (19)	<1 (2)	9.40 (2.19-40.38)	0.003
- Target lesion revasc	12% (50)	8% (36)	1.38 (0.90-2.12)	0.14
- Target LMCA revasc	10% (41)	9% (33)	1.23 (0.78-1.94)	0.37
- De-novo lesion revasc	6% (24)	3% (11)	2.34 (1.16-4.74)	0.02
Symptomatic graft occlusion or definite stent thrombosis	3% (9)	4% (15)	0.59 (0.26-1.36)	0.22
Possible stent thrombosis	1% (4)	0	-	-
Probable stent thrombosis	<1% (2)	0	-	-
Stroke	5% (16)	2% (7)	2.25 (0.93-5.48)	0.07

Makikallio T et al. *Lancet* 2016;388:2743-52



EXCEL vs NOBLE

	EXCEL	NOBLE
Number of patients	1905	1201
Number of centers	126	36
Number of countries	17 (US, EU, SA, Asia Pacific, Middle East)	7 (UK, Scandinavia)
SYNTAX score inclusion	≤32	No restriction
Primary endpoint	D, MI or stroke	D, MI, stroke or revasc
- Included peri-procedural MI	Yes	No
Stent	Xience	Biomatrix
- 3-year definite ST rate	0.7%	3%
- Def ST < symptomatic graft occlusion	Yes	No
Stroke: PCI vs CABG	Less with PCI	More with PCI!
Worse PCI prognosis with higher SYNTAX score	Yes	No!



Was Peri-procedural MI as Defined in EXCEL a Valid Component of the Primary Endpoint?

Peri-procedural MI was defined as the occurrence within 72° after either PCI or CABG of:

- CK-MB >10x upper reference limit (URL)*, OR
- CK-MB >5x URL*, PLUS
 - new pathological Q waves in at least 2 contiguous leads or new persistent non-rate related LBBB, or
 - angiographically documented graft or native coronary artery occlusion or new severe stenosis with thrombosis and/or diminished epicardial flow, or
 - imaging evidence of new loss of viable myocardium or new regional wall motion abnormality

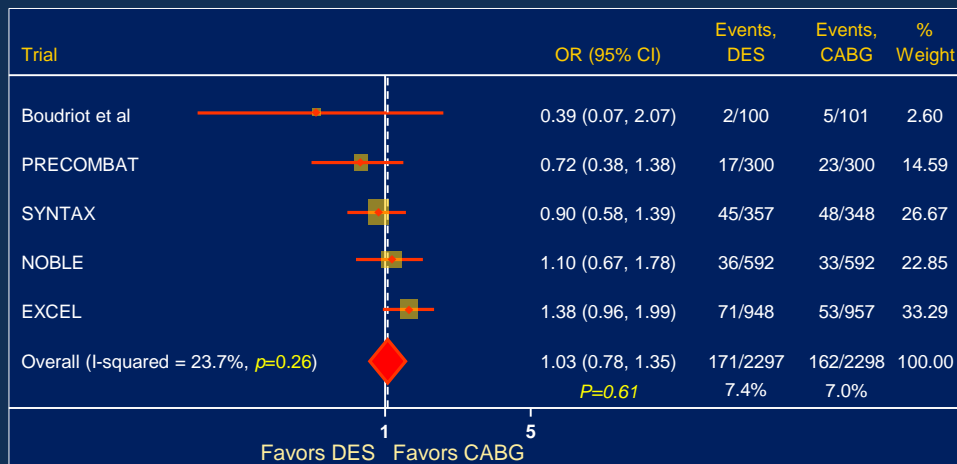
	Frequency	HR [95%CI] of 3-year mortality
PCI	3.6%	3.04 [1.39, 6.63]
CABG	5.9%	2.44 [1.10, 5.40]

Updated Meta-analysis of LM DES Trials

5 RCTs, 4,594 pts, longest FU data used

(EXCEL, NOBLE, SYNTAX, PRECOMBAT, Boudriot et al)

Death



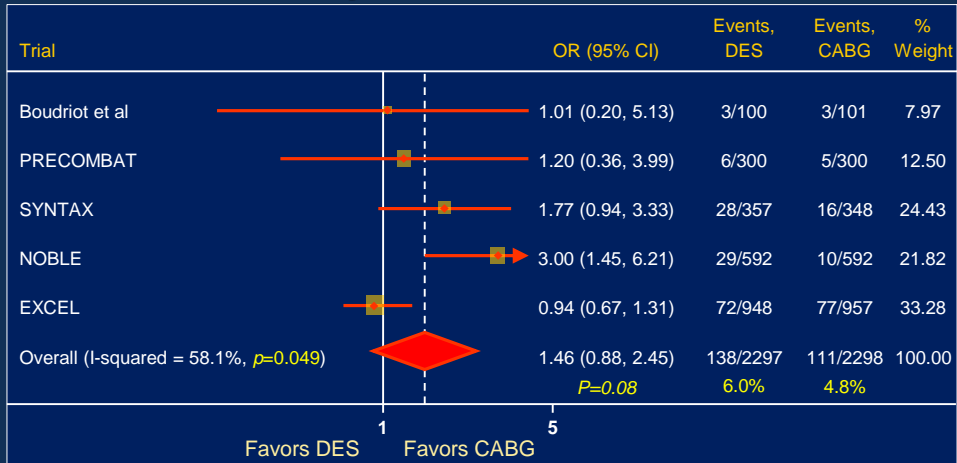
Nerlekar N et al. *Circ Int* 2016;9:e004729

Updated Meta-analysis of LM DES Trials

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(EXCEL, NOBLE, SYNTAX, PRECOMBAT, Boudriot et al)

Myocardial infarction



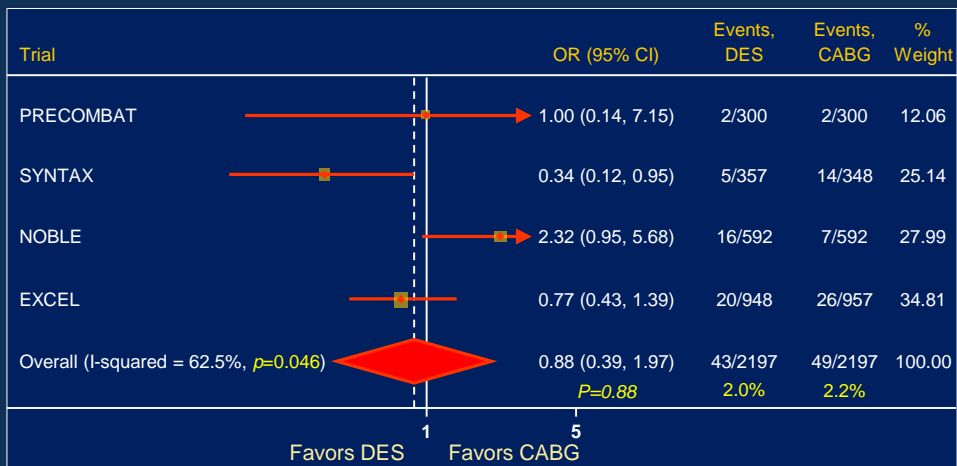
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(EXCEL, NOBLE, SYNTAX, PRECOMBAT, Boudriot et al)

Stroke



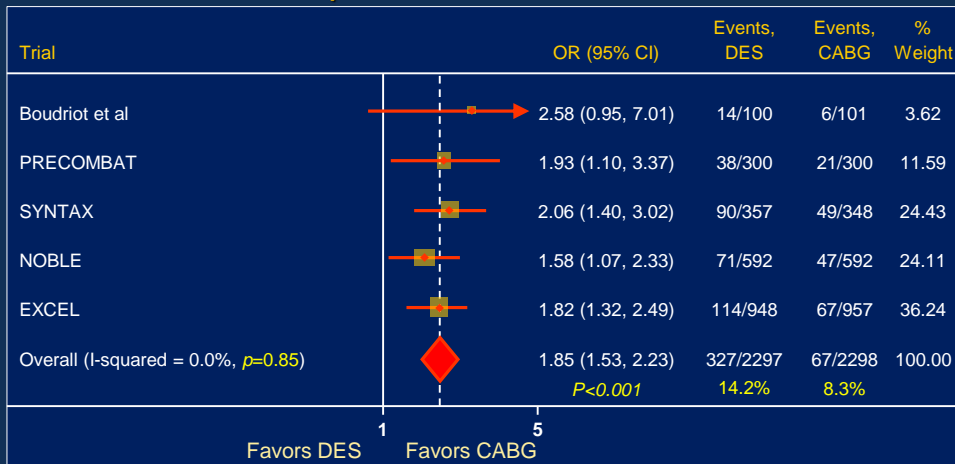
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Repeat revascularization



Nerlekar N et al. *Circ Int* 2016;9:e004729

LM Revascularization with Low/Int SS CABG vs. PCI with Contemporary DES

- **Mortality through 5 years:** Similar with PCI and CABG
- **MI:** Lower with PCI in the peri-procedural period; higher with PCI during long-term FU – similar through 5 years
- **Stroke:** Not a major reason to prefer PCI over CABG
- **Short-term morbidity:** Substantially less with PCI
- **Revascularization:** Less with CABG than PCI (~5%)

PCI with contemporary DES (especially Xience, as proven in EXCEL) may be considered an acceptable or even preferred revascularization modality for selected pts with LMCAD, a decision which should be made after heart team discussion, taking into account each patient's individual circumstances and preferences – and yes, I do think PCI should be class I



Outcomes of DES in Diabetic and Nondiabetic Patients with Complex Coronary Artery Disease after Risk Stratification by the SYNTAX Score



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ABSTRACT

Diabetes mellitus (DM) increases the risk of adverse outcomes after coronary revascularization. Controversy persists regarding the optimal revascularization strategy for diabetic patients with multivessel coronary artery disease (MVD).

AIM: The aim of this study was to assess the outcomes of drug-eluting stent (DES) insertion in DM and non-DM patients with complex coronary artery disease (CAD) after risk stratification by the percutaneous coronary intervention with taxus and cardiac surgery (SYNTAX) score.

METHODS AND RESULTS: We performed multivessel percutaneous coronary intervention (PCI) for 601 lesions in 243 DM patients and 1,029 lesions in 401 non-DM patients. All included patients had MVD and one or more lesions of type B2/C. The two-year outcomes and event rates were estimated in the DM and non-DM patients using Kaplan-Meier analyses. The baseline SYNTAX score was ≤ 22 in 84.8% vs. 84%, $P = 0.804$, and 23–52 in 15.2% vs. 16%, $P = 0.804$, of the DM and non-DM patients, respectively. The number of diseased segments treated (2.57 ± 0.75 vs. 2.47 ± 0.72 ; $P = 0.066$) and stents implanted per patient (2.41 ± 0.63 vs. 2.32 ± 0.54 ; $P = 0.134$) were similar in both groups. After a mean follow-up of 642 ± 173 days, there were no differences in the major adverse cardiac and cerebrovascular events (MACCE; 26.7% vs. 20.9%; $P = 0.091$), composite end point of all-cause death/myocardial infarction (MI)/stroke (12.3% vs. 9%; $P = 0.172$), individual MACCE components of death (3.7% vs. 3.2%; $P = 0.754$), MI (6.6% vs. 4%; $P = 0.142$), and absence of stroke in the DM and non-DM patients. An increased need for repeat revascularization was observed in DM patients (18.5% vs. 10.2%; $P = 0.003$). In the multivariate analysis, DM was an independent predictor of repeat revascularization (hazard ratio: 1.818; 95% confidence interval: 1.162–2.843; $P = 0.009$).

CONCLUSIONS: DES implantation provides favorable early and mid-term results in both DM and non-DM patients undergoing PCI for complex lesions. After a mean follow-up of two years, DM and non-DM patients with complex CAD treated by PCI using new-generation DES showed no differences with regard to MACCE and other secondary end points. However, higher rates of ischemia-driven repeat revascularization were observed in DM patients.

Study Design

Prospective, non-randomized, two-center study,
644 patients [DM 243 pts, non-DM 401 pts]
Risk Stratification by Syntax Score (SS)

Patient Selection

MVD: Stenosis >70% in ≥ 2 epicardial vessels involving at least two separate coronary artery territories confirmed with angiography and ≥ 1 lesion of type B2/C
Diabetics: Type 1 or 2 diabetics meeting ADA criteria

Treatment

MVD treated with ≥ 2 second generation DES (everolimus-eluting stents)

Clinical Follow-up

30 d

3 mo

6 mo

9 mo

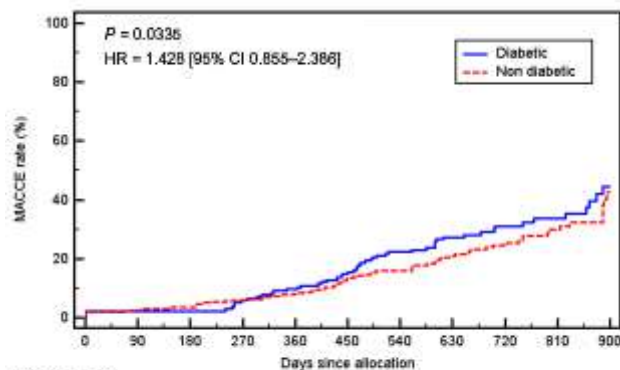
12 mo

24 mo

Primary Endpoint

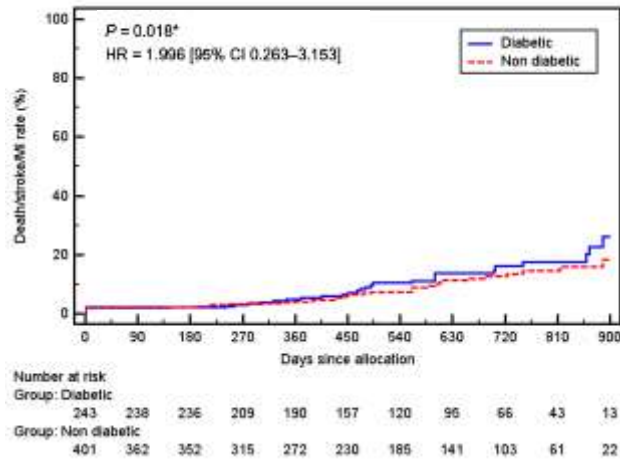
Major adverse cardiac and cerebrovascular events (MACCE) at 2 year (Death, MI, ischemia driven -TLR and stroke)

The Kaplan-Meier MACCE rates in diabetic and non-diabetic patients

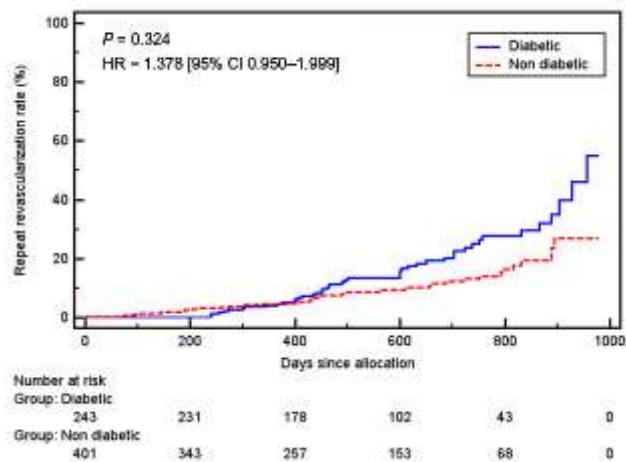


Number at risk	0	90	180	270	360	450	540	630	720	810	900
Group: Diabetic	243	238	236	209	190	157	120	95	66	43	13
Group: Non diabetic	401	362	352	315	272	230	185	141	103	61	22

The Kaplan-Meier death/MI/stroke rates in diabetic and non-diabetic patients



The Kaplan-Meier repeat revascularization rates in diabetic and non-diabetic patients



CONCLUSIONS

- After a mean follow up of 2 years DM and non-DM patients with complex CAD treated by PCI using new generation DES had favourable early- and mid-term results with no differences as regards MACCE and other secondary end points.
 - However, higher rates of ischemia-driven repeat revascularization were observed in DM patients.
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