

# Excel and Noble Trials : What Is the Impact on Clinical Practice Two Years Later

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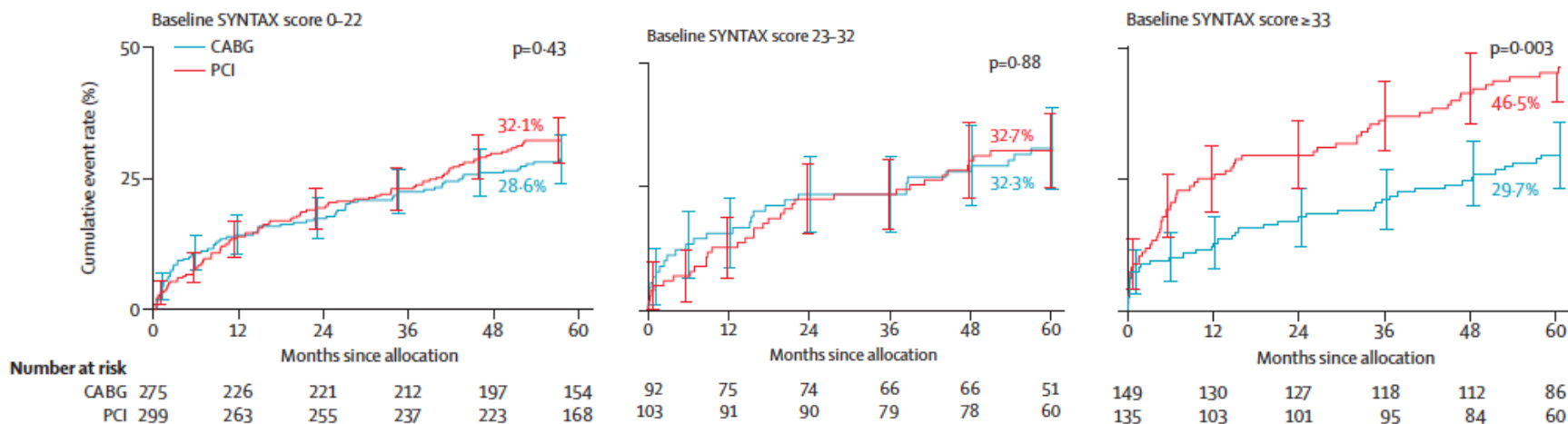
***Before EXCEL and NOBLE...***

# SYNTAX Trial : LM 5yrs Outcome

## SYNTAX Score 0-22

## SYNTAX Score 23-32

## SYNTAX Score ≥ 33



Eur Heart J. 2014;35:2821-2830

The Trial That Changed our Practice ...

## PCI vs CABG for LM Disease : 12 Meta-Analyses, 2009-2014

Author	Journal	Year	RCT	Non-RCT	Pts	FU
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### **DES vs. CABG for LM Disease** *Consensus from trials and meta-analysis*

- 1. Stroke is Higher in CABG.**
- 2. TVR is Higher in PCI.**
- 3. Outcomes of PCI with DES is Comparable with CABG in low and intermediate risk patients**
- 4. CABG is superior in patients with diffuse disease**

European Heart Journal Advance Access published August 29, 2014



European Heart Journal  
 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)

**Recommendation for the type of revascularization (CABG or PCI) in patients with SCAD with suitable coronary anatomy for both procedures and low predicted surgical mortality**

Left main disease with a SYNTAX score $\leq 22$ .	I	B	I	B	17,134,170
Left main disease with a SYNTAX score 23–32.	I	B	IIa	B	17
Left main disease with a SYNTAX score $>32$ .	I	B	III	B	17

CABG = coronary artery bypass grafting; LAD = left anterior descending coronary artery; PCI = percutaneous coronary intervention; SCAD = stable coronary artery disease.

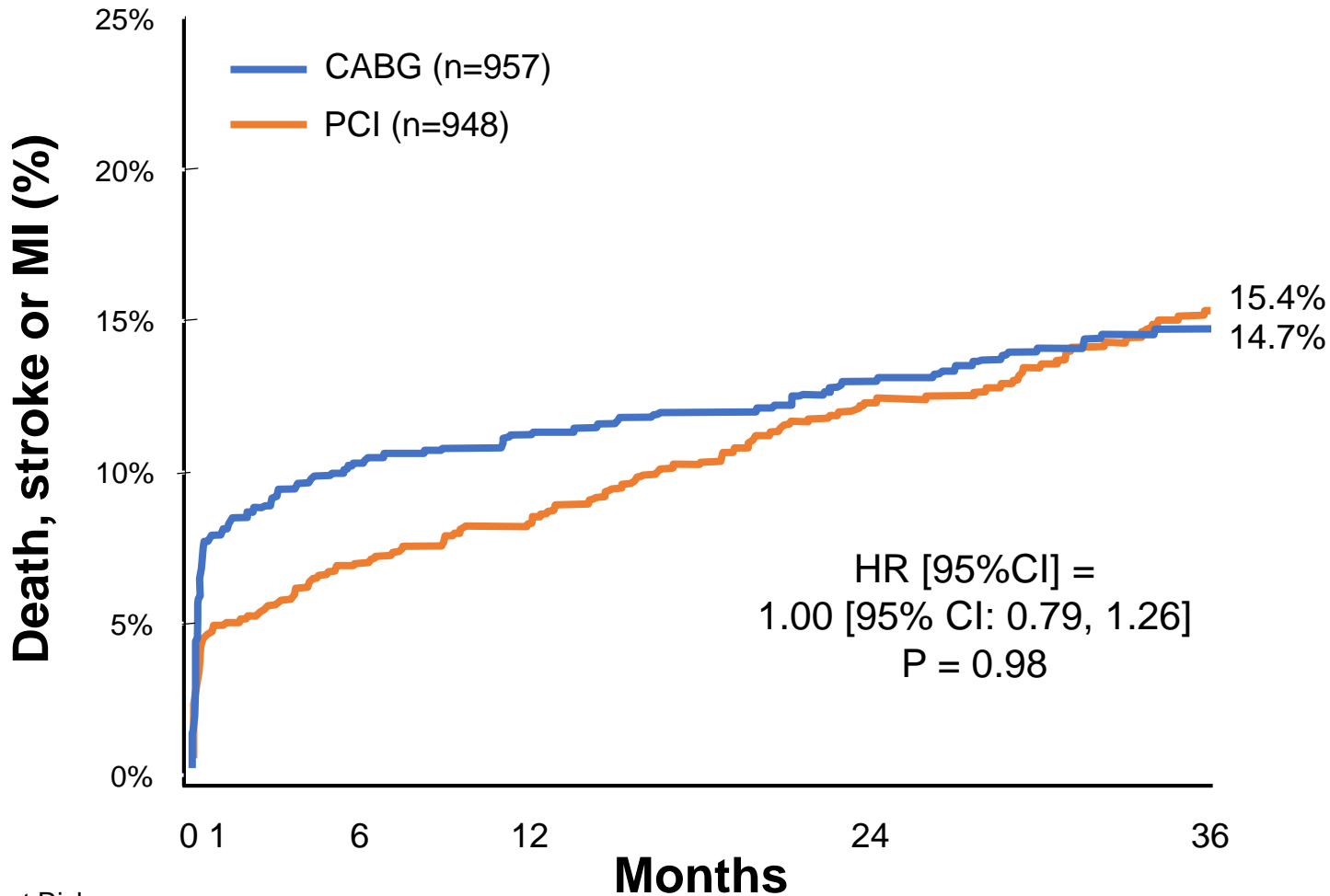
<sup>a</sup>Class of recommendation.

<sup>b</sup>Level of evidence.

<sup>c</sup>References.



## Primary Endpoint Death, Stroke or MI at 3 Years



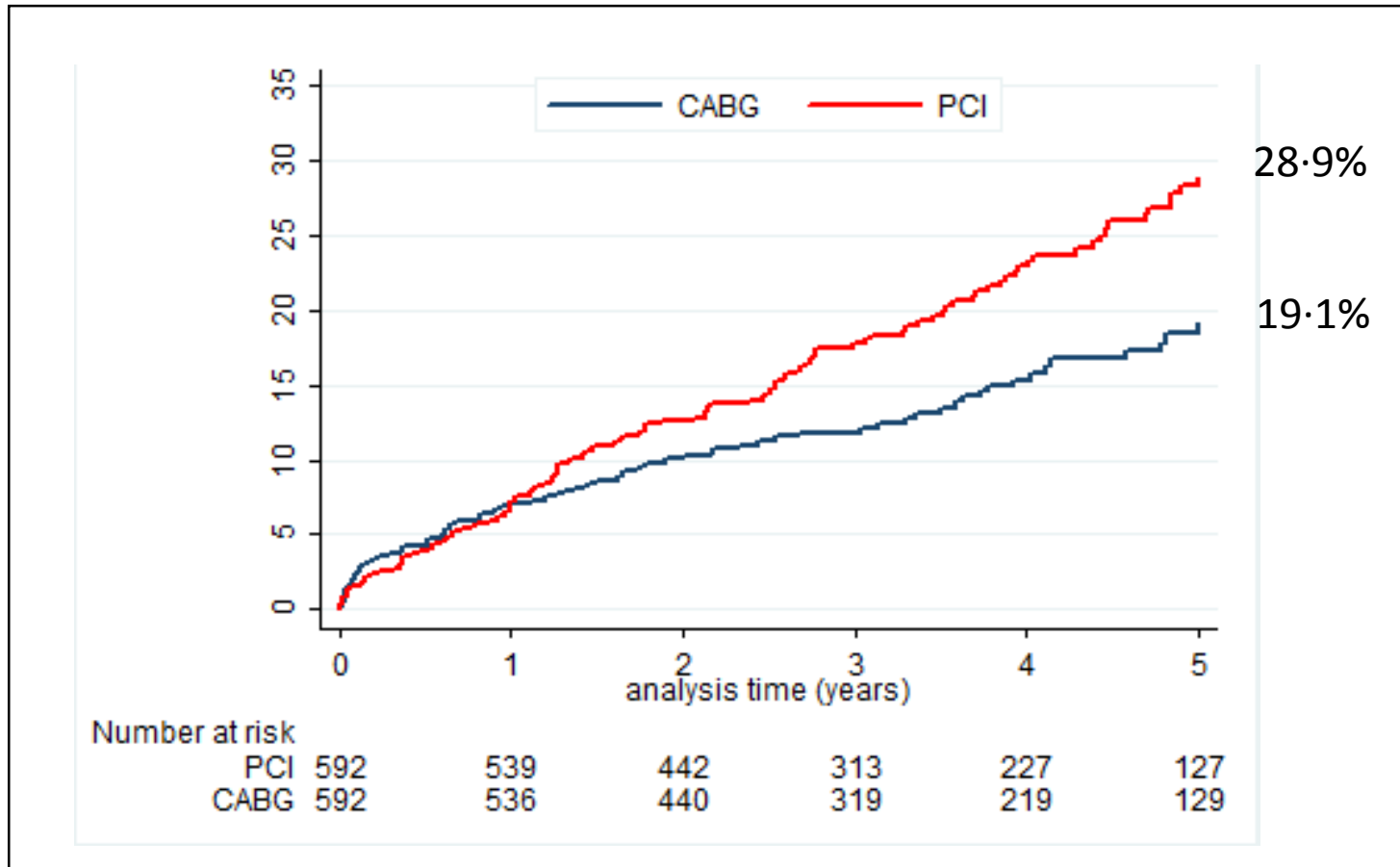
No. at Risk:

	0	1	6	12	24	36
PCI	948	896	875	850	784	445
CABG	957	868	836	817	763	458

**NOBLE**

# Primary endpoint: MACCE

(All cause-Mortality, Non-procedural MI, RR, Stroke )



## EXCEL and NOBLE Trials : Similarities and Differences

Variables	NOBLE trial	EXCEL trial
Trial design		
Patient characteristics	STEMI within 24 h excluded	All ACS eligible
Anatomic characteristics	ULMCAD stenosis >50% or FFR<0.80; no more than 3 additional lesion or complex addition lesion	ULMCAD stenosis >70% or if 50–70% then FFR<0.80; SYNTAX <32
Primary endpoint	Death, spontaneous MI, stroke or revascularization	Death, any MI or stroke
Geographic region	100% Europe	56% Europe, 40% North America, 4% Other*
Sample size	1,201	1,905
Median follow-up time	3.1 years	3.0 years
Study population		
SYNTAX score	22.5±7.5	20.6±6.2
ACS	18%	15% (1.4% STEMI)
LVEF	60% (IQR 55–65%)	57%±10%
Diabetes	PCI group: 15%; CABG group: 15%	PCI group: 32.2%; CABG group: 28.0%
Procedural characteristics		
Stent used	89% biolimus-eluting stent (BIOMATRIX™), 11% 1 <sup>st</sup> Gen DES	100% everolimus-eluting stent (XIENCE™)
Distal/bifurcation disease	81%	81%
IVUS guidance	Pre-stent evaluation: 47%; post-stent evaluation: 77%	IVUS guidance: 77%
2-stents used	37%	NR
2-stent technique	Culotte: 24%; crush: 4%; other: 9%	NR
LIMA to LAD	96%	98.8%
Only arterial grafts used	14.3%	24.8%



## EXCEL and NOBLE Trials : Similarities and Differences

Variables	NOBLE trial	EXCEL trial
Trial design		
Results: PCI vs. CABG		
Primary endpoint	Favors CABG	No difference
All-cause-mortality	No difference	No difference
Cardiac mortality	No difference	No difference
Total MI	NR	No difference
Spontaneous MI	Favors CABG	No difference
Stroke	No difference	No difference
Total revascularization	Favors CABG	Favors CABG
Target-lesion revascularization	No difference	No difference
LMCA revascularization	No difference	NR
Stent thrombosis	2% <sup>†</sup> , 0.8% (BIOMATRIX™ DES only) <sup>†</sup>	0.7% <sup>‡</sup>

***After EXCEL and NOBLE : 2016 .....***

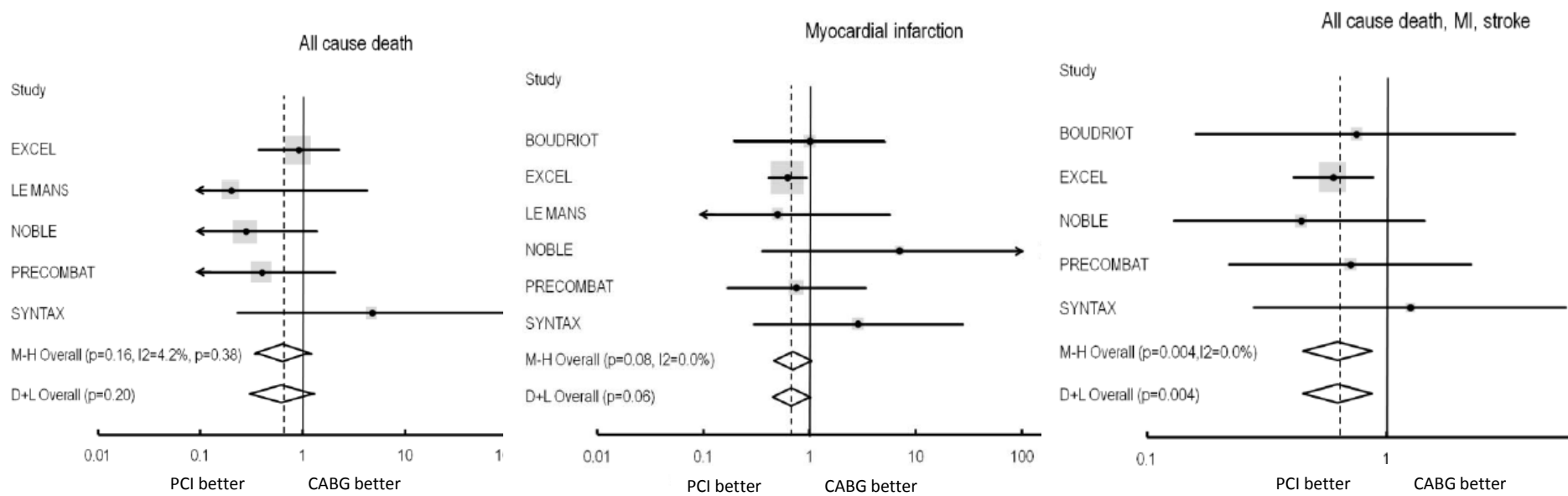
## Summary of Major Clinical Trials Endpoints Evaluating PCI vs CABG for Management of Unprotected Left Main Coronary Artery Disease

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- No difference in mortality between the two treatment strategies
- Meta-analysis including the SYNTAX, PRECOMBAT, Buodriot et al., NOBLE and EXCEL show no difference in safety endpoints.
- In patients with high-risk anatomy with LM and MV disease CABG is clearly the better strategy with superior long-term outcomes.
- Patients with low or intermediate risk anatomy (SYNTAX score  $\leq 32$ ) either PCI or CABG are reasonable with PCI being associated with less morbidity, hospital stays and lower stroke rates in the periprocedural period but with higher TLR over time despite use of II generation DES, intravascular imaging, procedural techniques and medical therapy.

# PCI vs CABG for LM – a Meta-Analysis of Six Randomized Trials and 4,686 pts

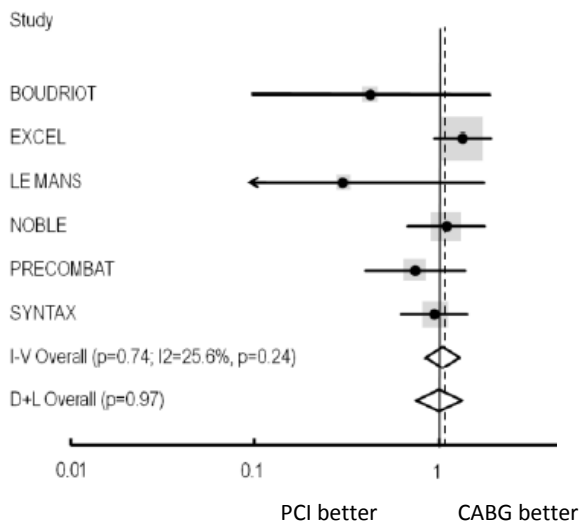
## 30-day outcomes



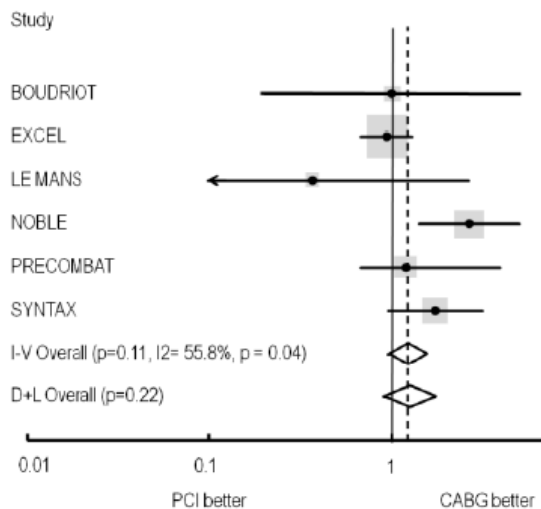
# PCI vs CABG for LM – a Meta-Analysis of Six Randomized Trials and 4,686 pts

## Long Term outcomes

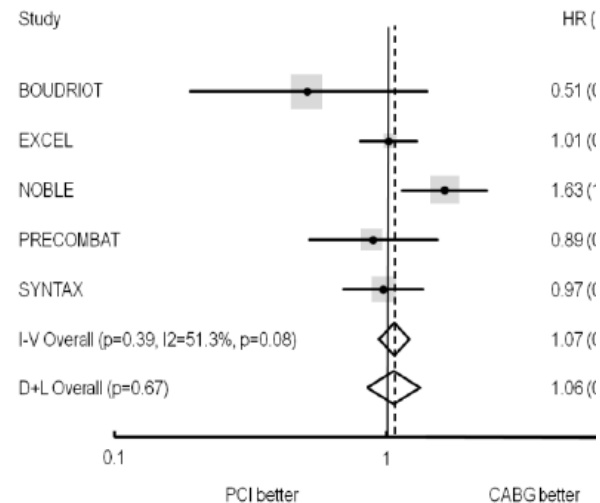
All cause death



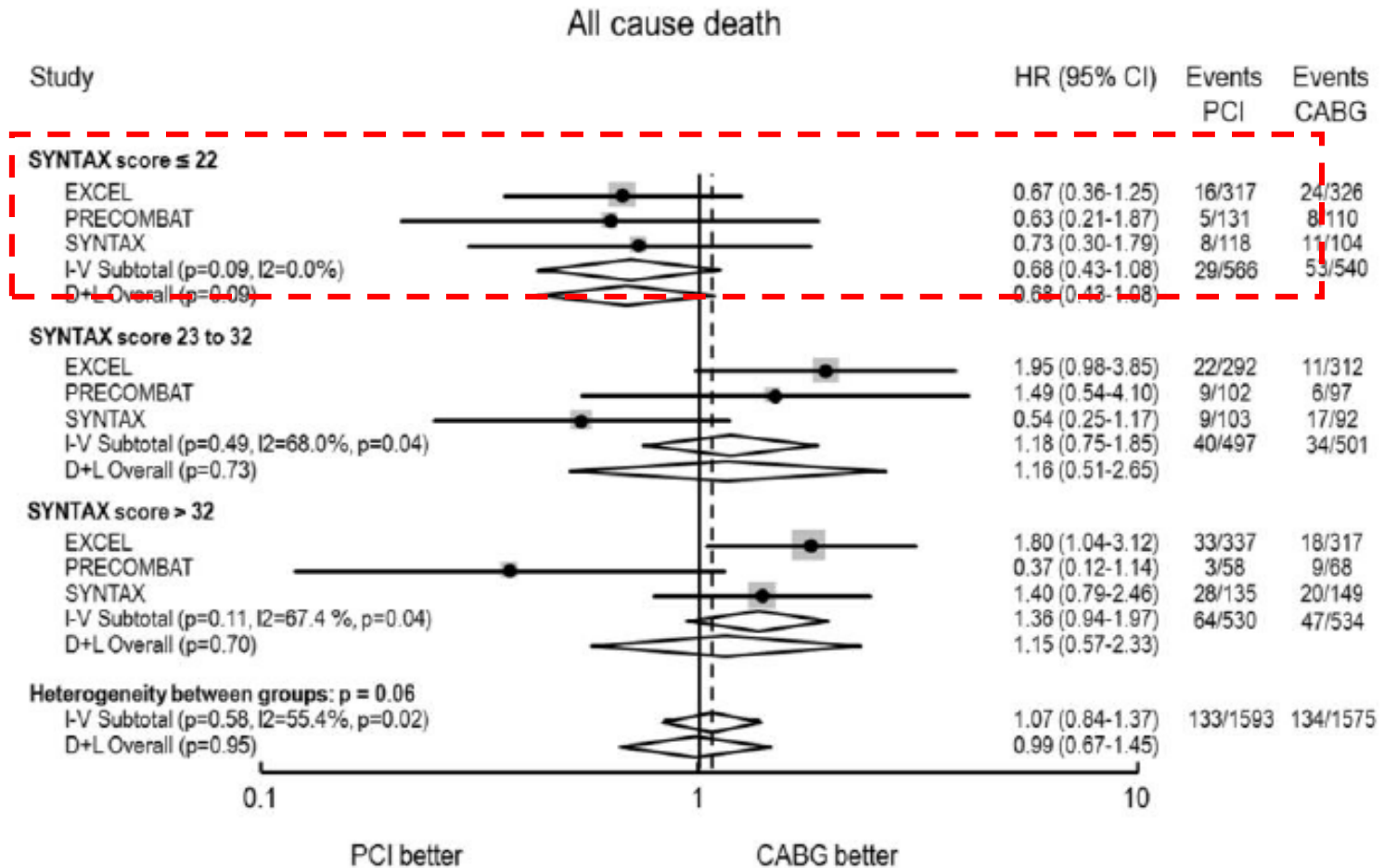
Myocardial infarction



All cause death, MI, stroke



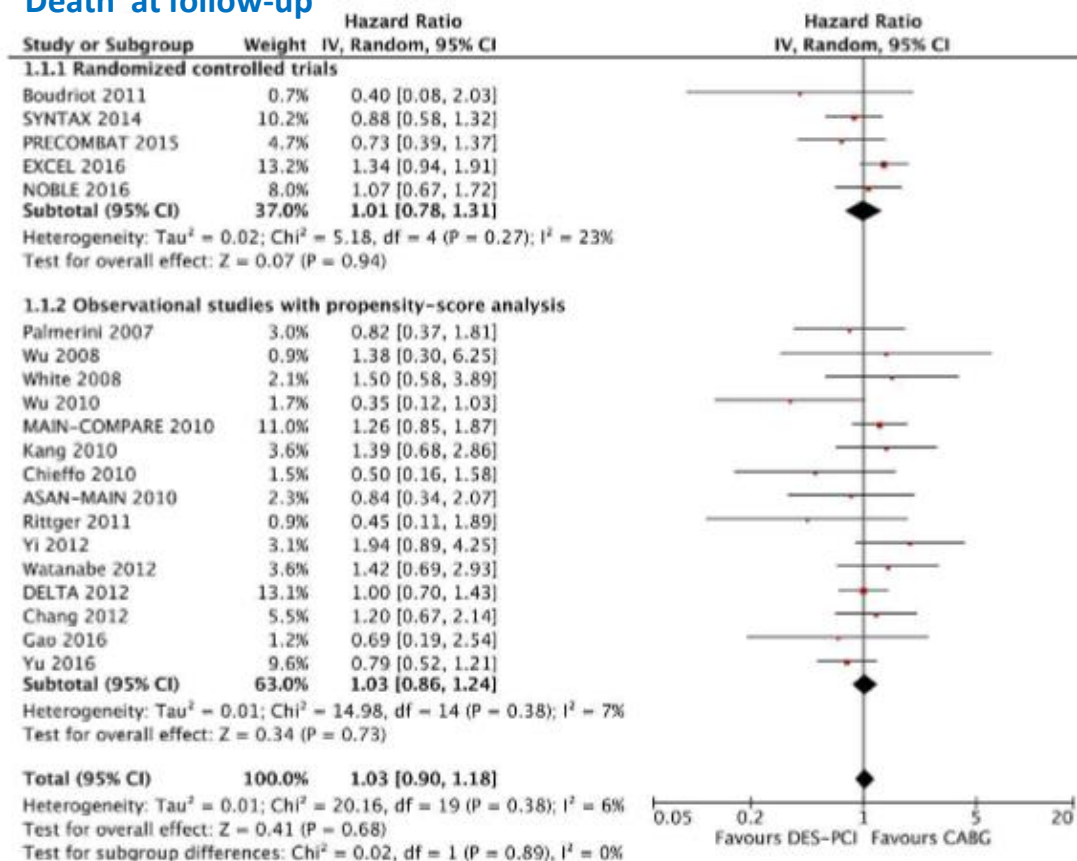
## PCI vs CABG for LM – a Meta-Analysis of Six Randomized Trials and 4,686 pts





## Drug-eluting stents versus coronary artery bypass grafting for left-main coronary artery disease

Hisato Takagi, MD, PhD<sup>1</sup> | Tomo Ando, MD<sup>2</sup> | Takuya Umemoto, MD, PhD<sup>1</sup> |  
for the ALICE (All-Literature Investigation of Cardiovascular Evidence) Group

### Death at follow-up

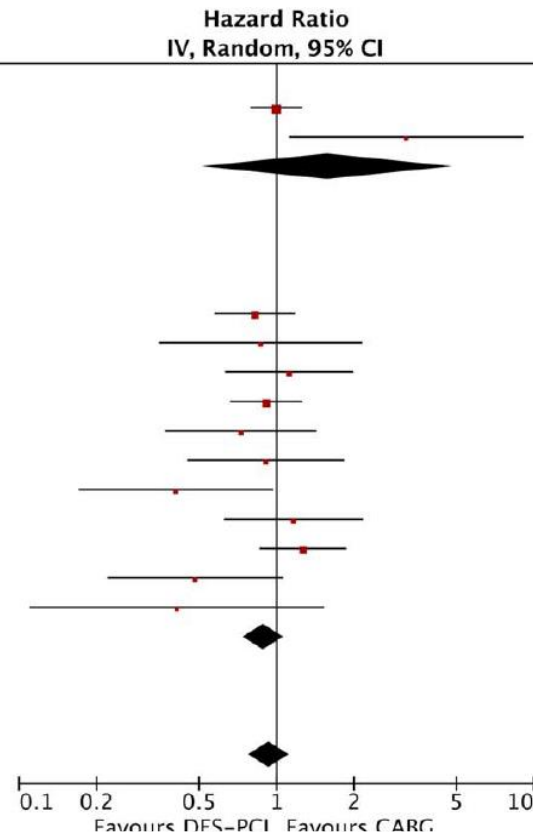


# Drug-eluting stents versus coronary artery bypass grafting for left-main coronary artery disease

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## Composite of death / MI at follow-up

Study or Subgroup	Weight	Hazard Ratio IV, Random, 95% CI
<b>1.8.1 Randomized controlled trials</b>		
EXCEL 2016	19.1%	1.00 [0.79, 1.26]
Boudriot 2011	2.7%	3.19 [1.12, 9.09]
<b>Subtotal (95% CI)</b>	<b>21.8%</b>	<b>1.59 [0.52, 4.84]</b>
Heterogeneity: Tau <sup>2</sup> = 0.53; Chi <sup>2</sup> = 4.51, df = 1 (P = 0.03); I <sup>2</sup> = 78%		
Test for overall effect: Z = 0.81 (P = 0.42)		
<b>1.8.2 Observational studies with propensity-score analysis</b>		
Yu 2016	13.3%	0.83 [0.58, 1.18]
Gao 2016	3.5%	0.87 [0.35, 2.15]
Chang 2012	7.3%	1.12 [0.63, 1.99]
DELTA 2012	14.7%	0.91 [0.66, 1.26]
CUSTOMIZE 2011	5.7%	0.73 [0.37, 1.43]
ASAN-MAIN 2010	5.3%	0.91 [0.45, 1.83]
Chieffo 2010	3.7%	0.41 [0.17, 0.97]
Kang 2010	6.4%	1.17 [0.63, 2.17]
MAIN-COMPARE 2010	12.2%	1.27 [0.86, 1.87]
Wu 2008	4.4%	0.48 [0.22, 1.06]
Ghenim 2009	1.8%	0.41 [0.11, 1.53]
<b>Subtotal (95% CI)</b>	<b>78.2%</b>	<b>0.89 [0.74, 1.07]</b>
Heterogeneity: Tau <sup>2</sup> = 0.01; Chi <sup>2</sup> = 11.81, df = 10 (P = 0.30); I <sup>2</sup> = 15%		
Test for overall effect: Z = 1.25 (P = 0.21)		
<b>Total (95% CI)</b>	<b>100.0%</b>	<b>0.93 [0.78, 1.12]</b>
Heterogeneity: Tau <sup>2</sup> = 0.03; Chi <sup>2</sup> = 17.53, df = 12 (P = 0.13); I <sup>2</sup> = 32%		
Test for overall effect: Z = 0.77 (P = 0.44)		

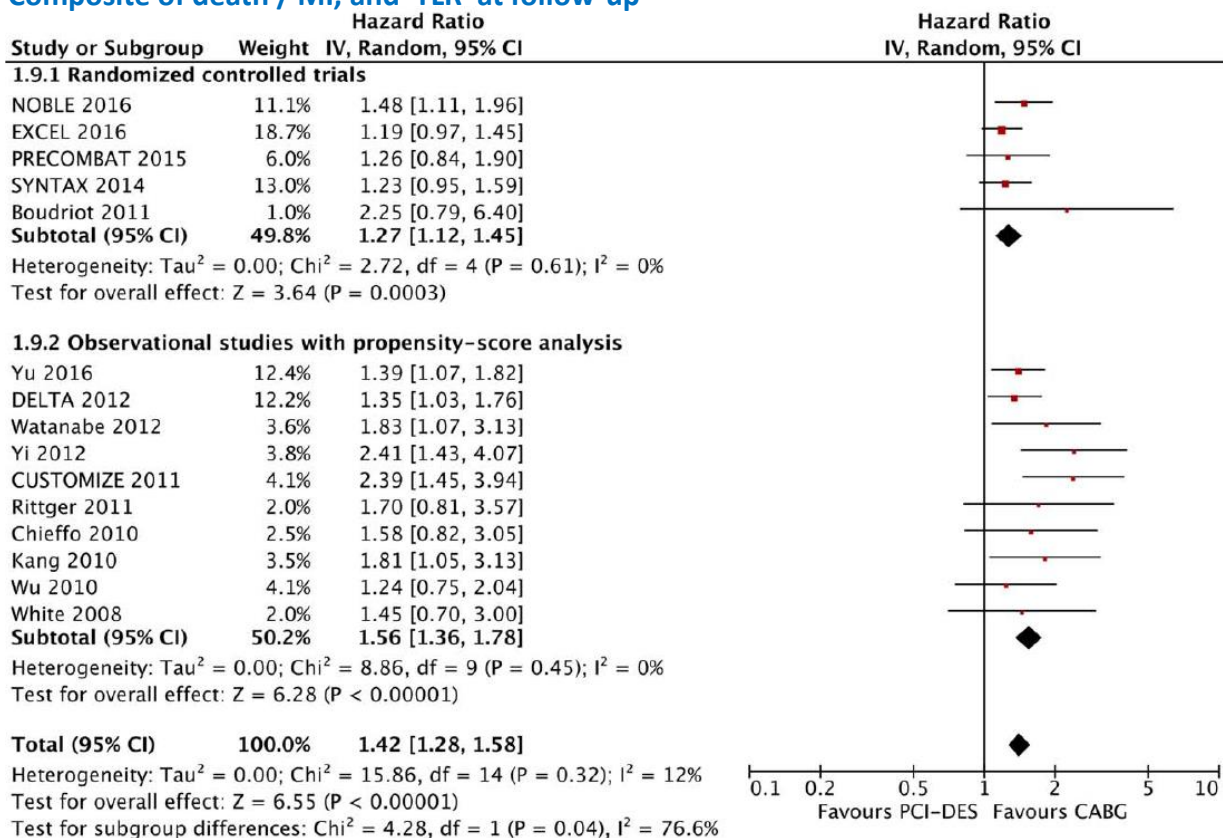




## Drug-eluting stents versus coronary artery bypass grafting for left-main coronary artery disease

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### Composite of death / MI, and TLR at follow-up



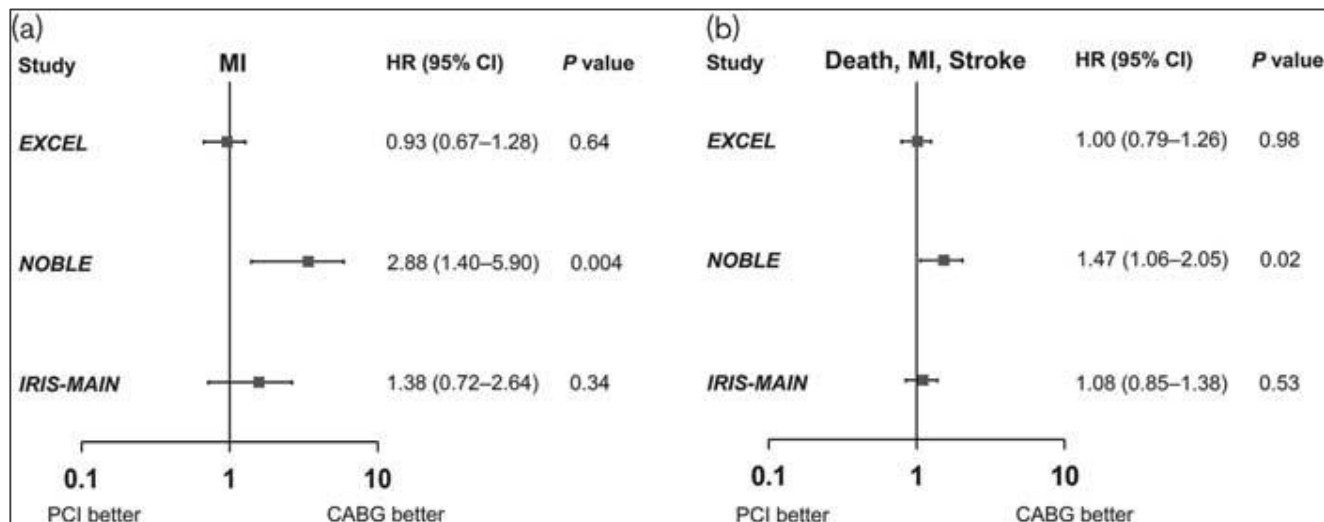
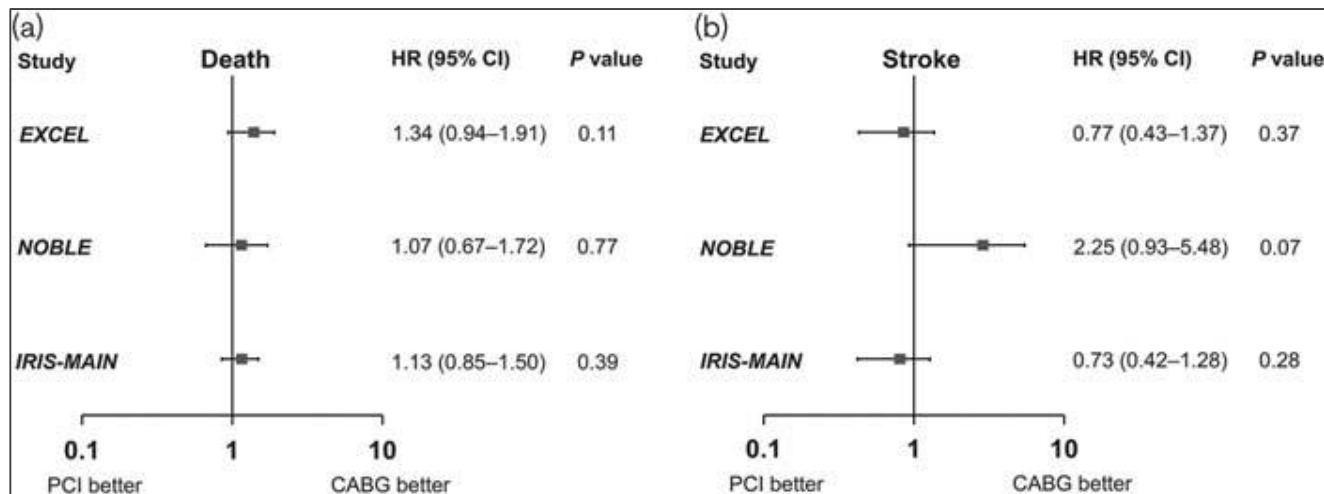
# Generalizability of EXCEL and NOBLE results to a large registry population with unprotected left main coronary artery disease

Table 1 Key features of each clinical study

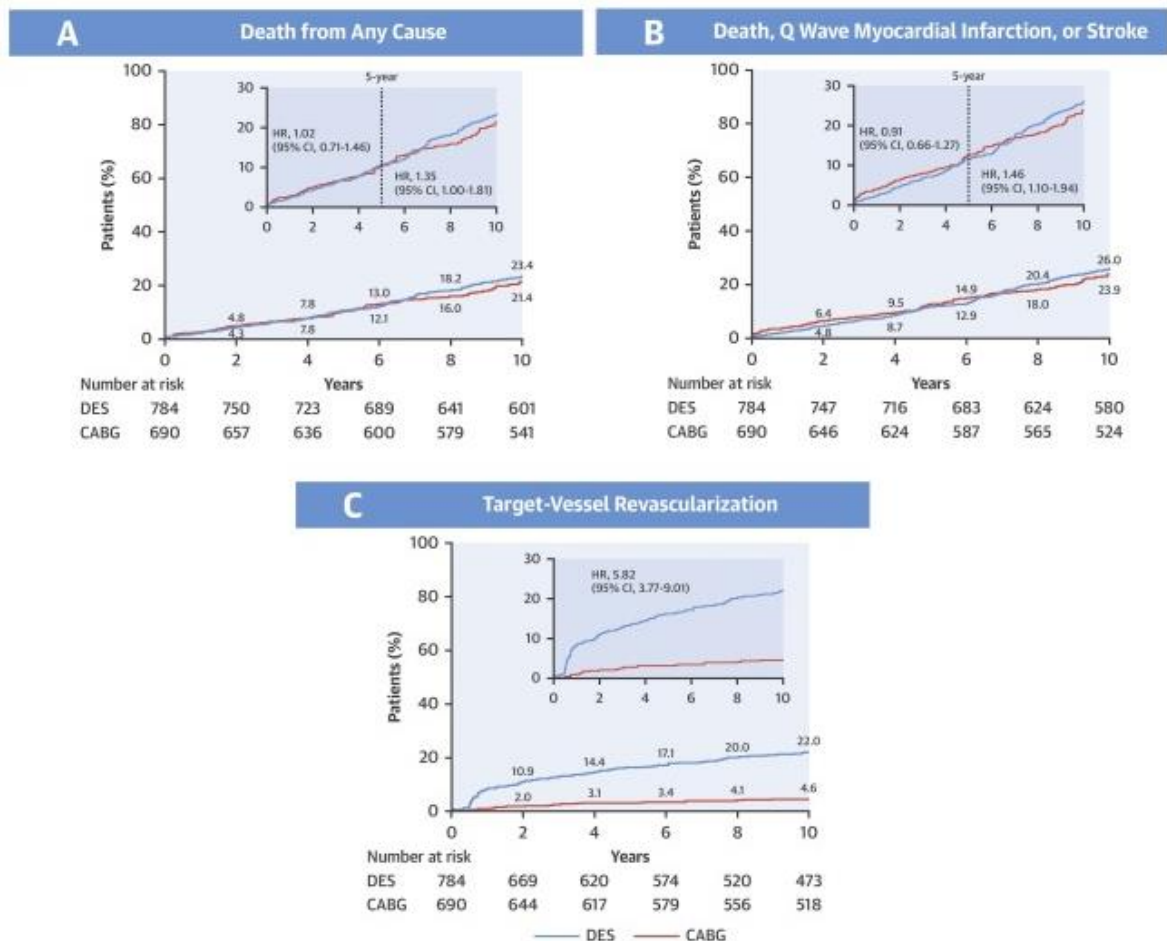
Designs	EXCEL trial	NOBLE trial	IRIS–MAIN registry
Study type	Multicenter (126 sites in North/South America, Europe, Asia Pacific), prospective, open-label, randomized, noninferiority design trial comparing PCI and CABG	Multicenter (36 sites in northern Europe), prospective, open-label, randomized, noninferiority design trial comparing PCI and CABG	Multicenter (50 sites in Asia), prospective, nonrandomized observational registry including PCI, CABG, or medication alone
Main inclusion criteria	Unprotected LMCA disease with angiographic DS > 70%, as estimated visually, or 50% ≤ DS < 70% with at least one of following: (a) noninvasive evidence of ischemia referable to LMCA lesion; (b) IVUS MLA ≤ 6.0 mm <sup>2</sup> ; or (c) FFR ≤ 0.80	Unprotected LMCA disease with angiographic DS > 50%, as estimated visually, or FFR < 0.8	Unprotected LMCA disease with angiographic DS > 50%, as estimated visually
Key exclusion criteria	SYNTAX score ≥ 33, prior PCI at left main (any time) or any other coronary artery (within 1 year), prior CABG, concomitant valvular or aortic surgery, CK-MB more than normal or recent MI with CK-MB still elevated, left main reference vessel diameter < 2.25 or > 4.25 mm	STEMI within 24 h, > 3 or complex additional coronary lesions (length > 25 mm, chronic total occlusion, two-stent bifurcation, calcified or tortuous vessel morphology), patient is too high risk for CABG or PCI, expected survival < 1 year	Minimal exclusion criteria (prior CABG, concomitant valvular or aortic surgery)
Primary endpoint	Composite of all-cause death, MI, or stroke	Composite rate of all-cause death, nonprocedural MI, repeat revascularization, or stroke	Outcomes of interest were death, MI, stroke, repeat revascularization, and its composite outcome
Recruitment period	September 2010–March 2014	December 2008–January 2015	November 2006–December 2013
Follow-up period (median) (years)	3.0 (2.4–3.0)	3.1 (2.0–5.0)	3.0 (2.0–4.1)
Number of CABG patients	957	592	774
Number of PCI patients	948	592	1707
Stent type used for PCI	XIENCE cobalt–chromium everolimus-eluting stent	BioMatrix biolimus-eluting stent recommended since March 2010, but other CE-marked DES allowed	Any second generation DES available in each participating center

CABG, coronary artery bypass grafting; CK-MB, creatine kinase-myocardial band; DES, drug-eluting stent; DS, diameter stenosis; EXCEL, Evaluation of XIENCE Everolimus-Eluting Stent Versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization; FFR, fractional flow reserve; IRIS–MAIN, Interventional Research Incorporation Society–Left MAIN Revascularization; IVUS, intravascular ultrasound; LMCA, left main coronary artery; MI, myocardial infarction; MLA, minimal lumen area; NOBLE, Nordic–Baltic–British Left Main Revascularization Study; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction; SYNTAX, Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery.

## Generalizability of EXCEL and NOBLE results to a large registry population with unprotected left main coronary artery disease



## 10-Year Outcomes of Stents Versus Coronary Artery Bypass Grafting for Left Main Coronary Artery Disease



Systematic Review

ORIGINAL ARTICLE

# Meta-analysis of coronary intervention in multivessel and left main coronary artery disease: clinical outcomes at long-term follow-up

Waleed E. Al, MD<sup>1,2</sup>, Kingsley L. Choudhary,

Drug-eluting stents in multivessel and left main coronary artery disease

Pedro José Nogueira, Antonio Thomas

Hospital Dr Carlos A. Gairán (HEC),<sup>1</sup> Fortal

Abstract

Background: Drug-eluting stents (DES) versus conventional DES versus CABG

Objective: To evaluate the long-term clinical outcomes of DES versus CABG

Method: Data from 11 randomised controlled trials (RCTs) comparing DES versus CABG

Results: In the pooled analysis, the risk of all-cause mortality at 30 days was significantly lower in the DES group (p = 0.003; OR 0.41, 95% CI 0.23-0.74).

Conclusion: The use of DES is associated with a significantly lower risk of mortality at 30 days compared with CABG in patients with multivessel and left main coronary artery disease.

Keywords: coronary artery disease, drug-eluting stents, CABG, DES, mortality, long-term follow-up



Clinical outcomes of revascularization surgery in patients with multivessel and left main coronary artery disease: a meta-analysis of 4,686 patients

## Meta-Analysis of Artery Bypass Grafting versus Percutaneous Coronary Intervention in Multivessel and Left Main Coronary Artery Disease

Partha Sardar, MD<sup>1</sup>, Amartya Kundu, MD<sup>1</sup>, Mukherjee, MD, DM<sup>1</sup>

PlumX Metrics

DOI: <https://doi.org/10.1016/j.amjcard.2019.07.008>

Article Info

Abstract Full Text

Patients with unprotectable multivessel coronary artery disease (MVD) or left main coronary artery disease (LMCAD) were compared with CABG for long-term clinical outcomes. The pooled analysis of 11 random-effects RCTs comparing DES versus CABG showed a significantly lower risk of mortality at 30 days in the DES group (p = 0.003; OR 0.41, 95% CI 0.23-0.74). The risk of any cause mortality at 30 days was significantly lower in the DES group (OR 1.85, 95% CI 1.08-3.17) compared with CABG in patients with MVD. The risk of any cause mortality at 30 days was significantly lower in the DES group (OR 1.85, 95% CI 1.08-3.17) compared with CABG in patients with LMCAD. The risk of any cause mortality at 30 days was significantly lower in the DES group (OR 1.85, 95% CI 1.08-3.17) compared with CABG in patients with MVD and LMCAD. The risk of any cause mortality at 30 days was significantly lower in the DES group (OR 1.85, 95% CI 1.08-3.17) compared with CABG in patients with MVD and LMCAD.

Tullio Palmerini, MD, Patrizio Basso, MD, Letizia Bacchi F. DMSc, Timo Makikallio, MThiele, MD, Enno Boudrig Raphael Cavalcante, MD.

PlumX Metrics

DOI: <https://doi.org/10.1016/j.amjcard.2019.07.008>

Article Info

Abstract Full Text

Background

Some but not all randomised controlled trials (RCTs) comparing percutaneous coronary intervention (PCI) with drug-eluting stents (DES) versus CABG for long-term clinical outcomes. The pooled analysis of 11 random-effects RCTs comparing DES versus CABG showed a significantly lower risk of mortality at 30 days in the DES group (p = 0.003; OR 0.41, 95% CI 0.23-0.74). The risk of any cause mortality at 30 days was significantly lower in the DES group (OR 1.85, 95% CI 1.08-3.17) compared with CABG in patients with MVD. The risk of any cause mortality at 30 days was significantly lower in the DES group (OR 1.85, 95% CI 1.08-3.17) compared with CABG in patients with LMCAD. The risk of any cause mortality at 30 days was significantly lower in the DES group (OR 1.85, 95% CI 1.08-3.17) compared with CABG in patients with MVD and LMCAD.

Methods

Randomised controlled trials (RCTs) comparing DES versus CABG for long-term clinical outcomes.

Results

Six trials including 4,686 patients were included in the pooled analysis. The risk of all-cause mortality at 30 days was significantly lower in the DES group (p = 0.003; OR 0.41, 95% CI 0.23-0.74). The risk of any cause mortality at 30 days was significantly lower in the DES group (OR 1.85, 95% CI 1.08-3.17) compared with CABG in patients with MVD. The risk of any cause mortality at 30 days was significantly lower in the DES group (OR 1.85, 95% CI 1.08-3.17) compared with CABG in patients with LMCAD. The risk of any cause mortality at 30 days was significantly lower in the DES group (OR 1.85, 95% CI 1.08-3.17) compared with CABG in patients with MVD and LMCAD.

Conclusions

In patients undergoing revascularization surgery for MVD or LMCAD, the use of DES is associated with a significantly lower risk of mortality at 30 days compared with CABG. The risk of any cause mortality at 30 days was significantly lower in the DES group (OR 1.85, 95% CI 1.08-3.17) compared with CABG in patients with MVD and LMCAD.

Systematic Review

# Meta-analysis of coronary intervention in multivessel and left main coronary artery disease: clinical outcomes at long-term follow-up

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**THE LANCET**

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Volume 391, No. 10124, p939-948, 10 March 2018

### Mortality after coronary artery bypass grafting versus percutaneous coronary intervention with stenting for coronary artery disease: a pooled analysis of individual patient data

Stuart J Head, MD<sup>1,2</sup>, Milan Mikojevic, MD, Joost Daemen, MD, Jung Min Ahn, MD, Prof Eric Boersma, PhD, Ewald H Christensen, MD, Prof Michael J Domanski, MD, Prof Michael E Farkouch, MD, Prof Marcus Flather, MBBS, Valentin Fuster, MD, Prof Mark A Hatala, MD, Niels R Hofm, MD, Whady A Haeb, MD, Masoor Kamlesh, MD, Young-Hak Kim, MD, Timo Makikallio, MD, Prof Friedrich W Mohr, MD, Grigoris Papageorgiou, MSc, Seung-Jung Park, MD, Alfredo E Rodriguez, MD, Joseph F Sabik 3rd, MD, Rodney H Stables, DM, Prof Gregg W Stone, MD, Prof Patrick W Serruys, MD, Prof Arie Pieter Kappetein, MD

Published: 22 February 2018

DOI: [https://doi.org/10.1016/S0140-6736\(18\)30402-0](https://doi.org/10.1016/S0140-6736(18)30402-0)

Article Info

Summary Full Text Tables and Figures References Supplementary Material

**Summary**

**Background**

Numerous randomised trials have compared coronary artery bypass grafting (CABG) with percutaneous coronary intervention (PCI) for patients with coronary artery disease. However, no studies have been powered to detect a difference in mortality between the revascularisation strategies.

**Methods**

We did a systematic review up to July 19, 2017, to identify randomised clinical trials comparing CABG with PCI using stents. Eligible studies included patients with multivessel or left main coronary artery disease who did not present with acute myocardial infarction, did PCI with stents (bare-metal or drug-eluting), and had more than 1 year of follow-up for all-cause mortality. In a collaborative, pooled analysis of individual patient data from the identified trials, we estimated all-cause mortality up to 5 years using Kaplan-Meier analyses and compared PCI with CABG using a random-effects Cox proportional-hazards model stratified by trial. Consistency of treatment effect was explored in subgroup analyses, with subgroups defined according to baseline clinical and anatomical characteristics.

**Findings**

We included 11 randomised trials involving 11 518 patients selected by heart teams who were assigned to PCI (n=5753) or to CABG (n=5765). 976 patients died over a mean follow-up of 3.8 years (SD 1.4). Mean Synergy between PCI with Taxus and Cardiac Surgery (SYNTAX) score was 26.0 (SD 9.5), with 1798 (22.1%) mortality was 11.2% at p=0.0038). 5 year all-cause mortality was significantly lower in the DES group (p=0.003; OR 0.41, 95% CI 0.23-0.74). The risk of any cause mortality at 30 days was significantly lower in the DES group (OR 1.85, 95% CI 1.08-3.17) compared with CABG in patients with MVD. The risk of any cause mortality at 30 days was significantly lower in the DES group (OR 1.85, 95% CI 1.08-3.17) compared with CABG in patients with LMCAD. The risk of any cause mortality at 30 days was significantly lower in the DES group (OR 1.85, 95% CI 1.08-3.17) compared with CABG in patients with MVD and LMCAD.

**Interpretation**

CABG had a mortality in patients with MVD and higher mortality in patients with LMCAD compared with PCI. Longer follow-up is needed to better define mortality differences between the revascularisation strategies.

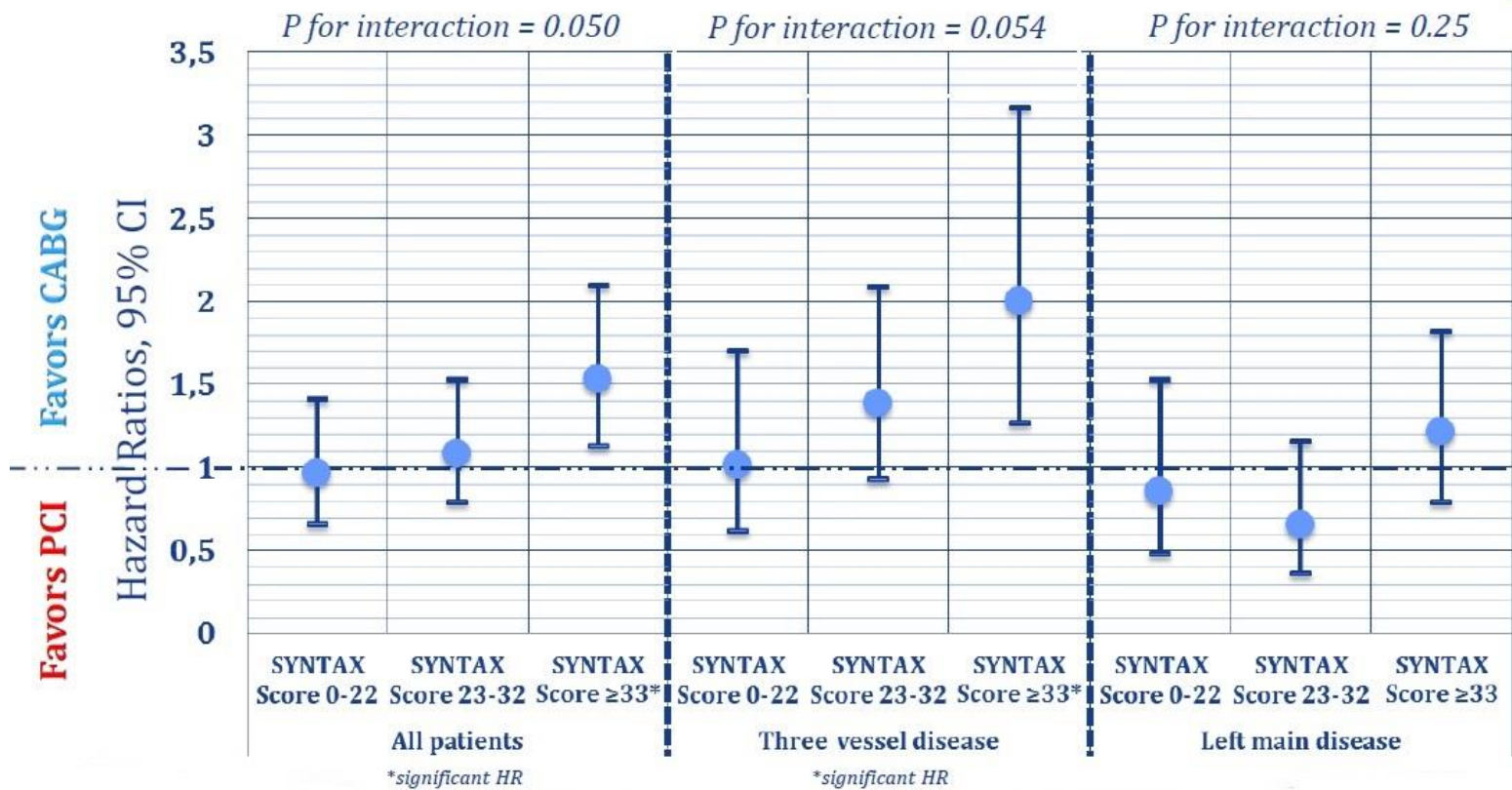
- Higher mortality in patients with MVD (particularly in those with diabetes) in PCI group as compared to CABG,
- No benefit from CABG was seen in patients with LM disease

Waleed E. Al, MD<sup>1,2</sup>, Kingsley L. Choudhary, Pedro José Nogueira, Antonio Thomas, Hospital Dr Carlos A. Gairán (HEC),<sup>1</sup> Fortal

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Received 27 October 2017; revised 10 February 2018; accepted 10 February 2018.

# SYNTAX scores – 10 Year All-Cause Mortality





ESC  
European Society  
of Cardiology

European Heart Journal (2019) 40, 87–165  
doi:10.1093/eurheartj/ehy394

ESC/EACTS GUIDELINES

## 2018 ESC/EACTS Guidelines on myocardial revascularization

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

Developed with the special contribution of the European Association for Percutaneous Cardiovascular Interventions (EAPCI)

Recommendations according to extent of CAD	CABG		PCI	
	Class <sup>a</sup>	Level <sup>b</sup>	Class <sup>a</sup>	Level <sup>b</sup>
<b>One-vessel CAD</b>				
Without proximal LAD stenosis.	IIb	C	I	C
With proximal LAD stenosis. <sup>68,101,139–144</sup>	I	A	I	A
<b>Two-vessel CAD</b>				
Without proximal LAD stenosis.	IIb	C	I	C
With proximal LAD stenosis. <sup>68,70,73</sup>	I	B	I	C
<b>Left main CAD</b>				
Left main disease with low SYNTAX score (0–22). <sup>69,121,122,124,145–148</sup>	I	A	I	A
Left main disease with intermediate SYNTAX score (23–32). <sup>69,121,122,124,145–148</sup>	I	A	IIa	A
Left main disease with high SYNTAX score (≥33). <sup>c 69,121,122,124,146–148</sup>	I	A	III	B
<b>Three-vessel CAD without diabetes mellitus</b>				
Three-vessel disease with low SYNTAX score (0–22). <sup>102,105,121,123,124,135,149</sup>	I	A	I	A
Three-vessel disease with intermediate or high SYNTAX score (>22). <sup>c 102,105,121,123,124,135,149</sup>	I	A	III	A
<b>Three-vessel CAD with diabetes mellitus</b>				
Three-vessel disease with low SYNTAX score 0–22. <sup>102,105,121,123,124,135,150–157</sup>	I	A	IIb	A
Three-vessel disease with intermediate or high SYNTAX score (>22). <sup>c 102,105,121,123,124,135,150–157</sup>	I	A	III	A

- **Data available from Clinical Trials and meta-analysis provide a high level of evidence for optimal management of LMCA disease in selected patients ( low / intermediate SYNTAX Score)**
- **The issue is not Left Main but extension of coronary artery disease . Patients with MVD ( particularly Diabetic Patients) and high SYNTAX Score should clearly be considered for Surgery as first Option**
- **The Heart Team approach has a very relevant role in guiding individual patient decision-making and for patient-centered care.**
- **Long-term follow-up studies up to 10 years for LMCA revascularization are still limited which might penalize the surgery since benefit of CABG is often seen after extended follow-up**
- **Waiting for long-term follow up results, efforts should be targeted to proceed in technical and procedural advances which can influence PCI outcomes in complex patients**



## SYNTAX II Trial

- SYNTAX Score II (incorporating clinical and anatomical variables) to guide Heart Team decisions on myocardial revascularisation.
- Physiology-based revascularisation (hybrid use of iFR and FFR).
- Second generation DES (thin strut, biodegradable polymer, everolimus-eluting Synergy™ stent [EES]).
- IVUS-guided optimisation of stent deployment (modified MUSIC criteria).
- Contemporary CTO revascularization techniques.
- Guideline-directed medical therapy.

Escaned J et al. EuroInterven6on. 2016 Jun 12;12(2):e224-34

- **Primary endpoint:** Composite of major adverse cardiac and cerebrovascular events (MACCE) at one-year follow-up.
- **Comparator:** Predefined PCI cohort (n=315) from the original SYNTAX-I trial selected on the basis of equipoise 4-year mortality between CABG and PCI

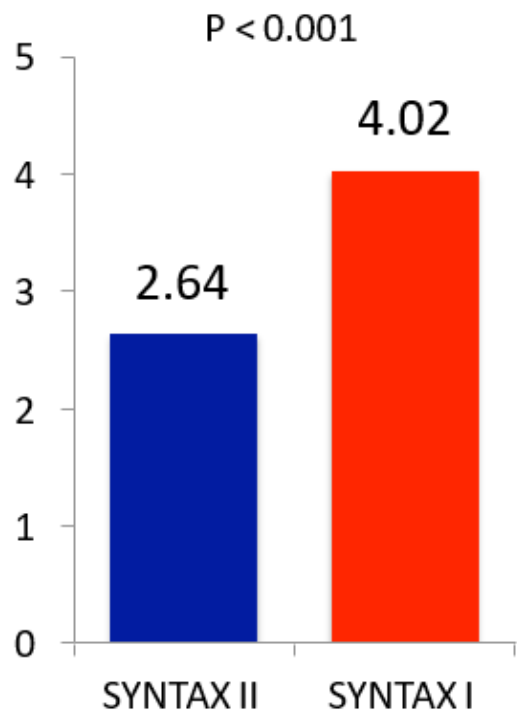
# SYNTAX II Trial

## Baseline Characteristics

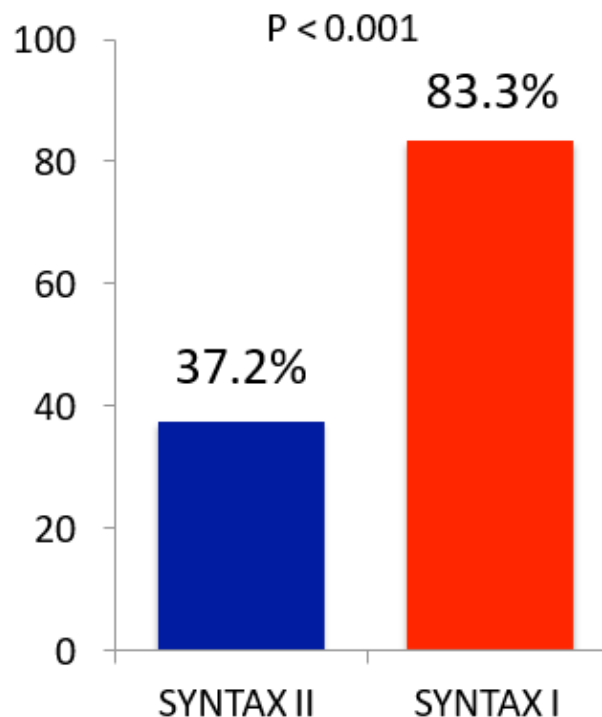
	SYNTAX II (n=454)	SYNTAX I PCI arm (n=315)	P value
Age (years)	66.7 ± 9.7	66.7 ± 9.1	0.99
Male	93.2%	93.0%	0.93
BMI (kg/m <sup>2</sup> )	28.9 ± 4.7	28.2 ± 4.4	0.032
DM	30.3%	29.2%	0.75
Current Smoker	14.7%	17.8%	0.26
Previous MI	12.5%	28.7%	<0.001
Previous Stroke	5.6%	1.9%	0.010
Hypertension	77.0%	73.4%	0.26
Hyperlipidemia	77.3%	74.4%	0.35
Clinical Presenta&on			<0.001
Silent Ischemia	5.5%	13.3%	
Stable angina	68.8%	61.6%	
Unstable angina	25.6%	25.1%	

## SYNTAX II Trial

Lesions treated per patient (n)  
in SYNTAX II and SYNTAX I



Cases of three-vessel PCI (%)  
in SYNTAX II and SYNTAX I

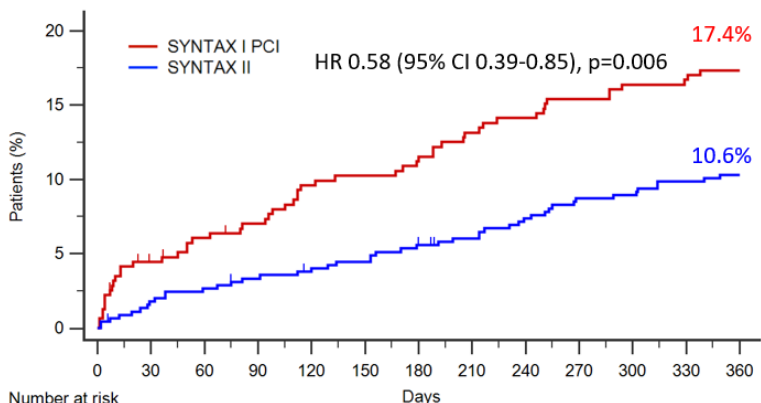


IVUS Guidance :  
CTO procedures

84.1 % ( Syntax II ) vs 4.8% ( Syntax I )  
87% ( Syntax II ) vs 53% ( Syntax I )

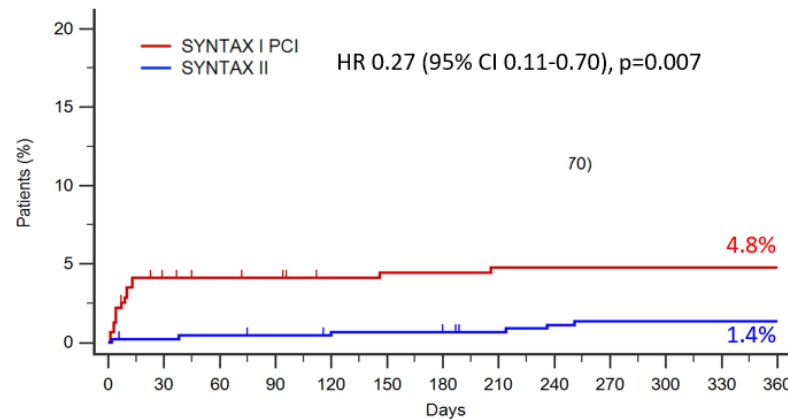
# SYNTAX II Trial

## Primary Endpoints



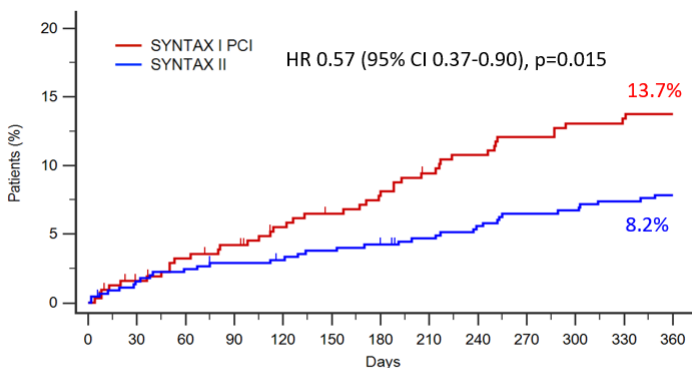
Group	SYNTAX I PCI	SYNTAX II
Number at risk	315	450
30	298	441
60	292	437
90	288	433
120	280	429
150	278	427
180	274	421
210	269	417
240	266	411
270	262	405
300	259	404
330	258	400
360	256	398

## MI



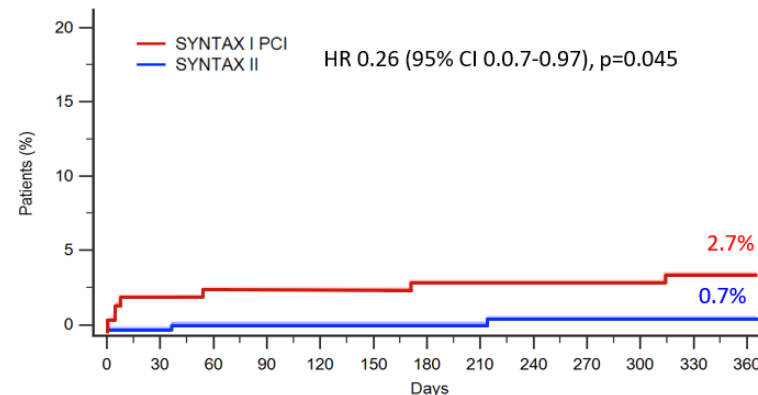
Group	SYNTAX I PCI	SYNTAX II
Number at risk	315	450
30	299	448
60	297	447
90	296	446
120	293	444
150	292	444
180	292	443
210	291	441
240	291	439
270	291	438
300	291	438
330	291	438
360	291	438

## TLR



Group	SYNTAX I PCI	SYNTAX II
Number at risk	315	450
30	305	442
60	299	438
90	295	435
120	288	433
150	284	430
180	279	427
210	274	423
240	270	419
270	266	415
300	263	414
330	262	411
360	261	409

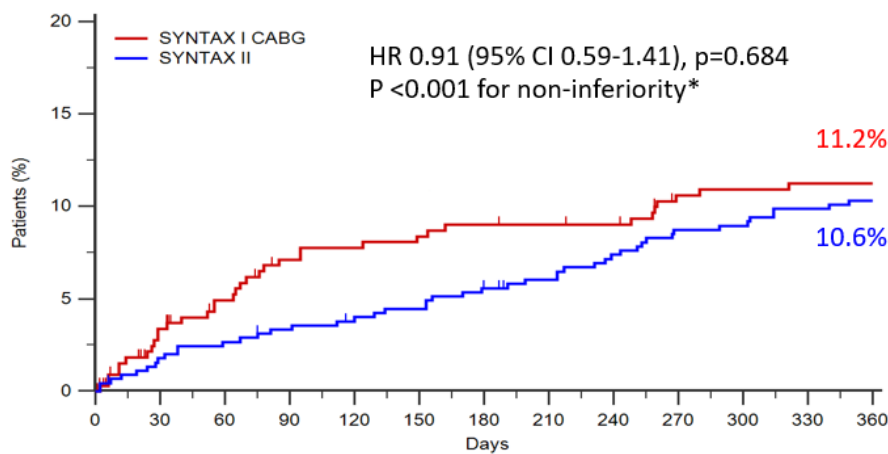
## Definite ST



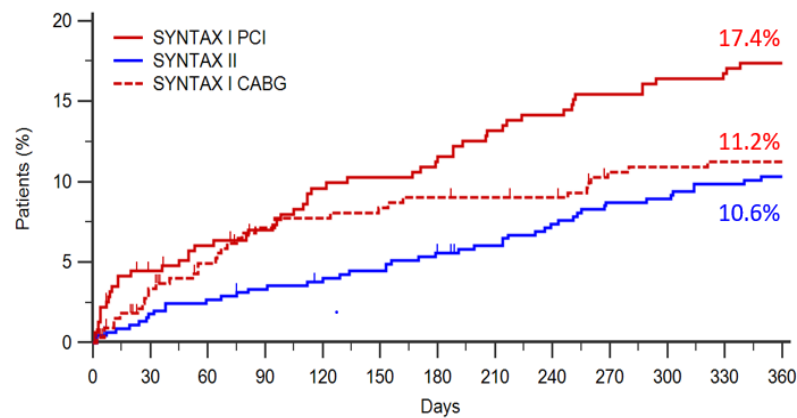
Group	SYNTAX I PCI	SYNTAX II
Number at risk	315	450
30	299	447
60	297	446
90	296	444
120	292	441
150	292	441
180	292	437
210	291	435
240	291	431
270	291	428
300	291	428
330	291	427
360	290	427

# SYNTAX II Trial

## Exploratory End-Point: MACCE PCI vs. CABG



## MACCE SYNTAX II and SYNTAX I PCI / CABG



	0	30	60	90	120	150	180	210	240	270	300	330	360
SYNTAX I CABG	334	313	304	295	293	291	289	288	287	279	278	277	277
SYNTAX II	450	441	437	433	429	427	421	417	411	405	404	400	398

	0	30	60	90	120	150	180	210	240	270	300	330	360
SYNTAX I PCI	315	298	292	288	280	278	274	269	266	262	259	258	256
SYNTAX II	450	441	437	433	429	427	421	417	411	405	404	400	398
SYNTAX I CABG	334	313	304	295	293	291	289	288	287	279	278	277	277



European Heart Journal  
 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)

Developed with the special contribution of the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

### 2014

Left main disease with a SYNTAX score $\leq 22$ .	I	B	I	B	17,134,170
Left main disease with a SYNTAX score 23–32.	I	B	IIa	B	17
Left main disease with a SYNTAX score $>32$ .	I	B	III	B	17

### 2018

Left main CAD					
Left main disease with low SYNTAX score (0 - 22). <sup>69,121,122,124,145–148</sup>	I	A	I	A	
Left main disease with intermediate SYNTAX score (23 - 32). <sup>69,121,122,124,145–148</sup>	I	A	IIa	A	

**No Significant impact , but we should keep going on doing better improving our techniques and outcomes in both PCI and CABG , waiting for longer follow-up data ( 10 yrs ?)**