

Left Main PCI: **Practical Issue and Updated Evidence**

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Disclosure

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Today's Key Topic

- Practical Issue of Left Main PCI
- Updated Evidence for Left Main PCI

Many Many Bifurcation Clubs

They Have Mainly Focused On Technical Concept:
POT, Re-POT, KIO, Kissing, DK-CRUSH, Culottes, etc...
Detail, Detail, and More Details....

Percutaneous coronary intervention for the left main stem and other bifurcation lesions: 12th consensus document from the European Bifurcation Club



Jens Fløsted Lassen^{1*}, MD, PhD; Francesco Burzotta², MD; Adrian P. Banning³, MD, PhD; Thierry Lefèvre⁴, MD; Olivier Darremont⁵, MD; David Hildick-Smith⁶, MD; Alaide Chieffo⁷, MD; Manuel Pan⁸, MD; Niels Ramsing Holm⁹, MD; Yves Louvard¹⁰, MD; Goran Stankovic¹¹, MD, PhD

Percutaneous coronary intervention in left main coronary artery disease: the 13th consensus document from the European Bifurcation Club



Francesco Burzotta^{1*}, MD, PhD; Jens Fløsted Lassen², MD, PhD; Adrian P. Banning³, MD, PhD; Thierry Lefèvre⁴, MD; David Hildick-Smith⁵, MD; Alaide Chieffo⁶, MD; Olivier Darremont⁷, MD; Manuel Pan⁸, MD; Yiannis S. Chatzizisis⁹, MD, PhD; Renzo Albiero¹⁰, MD; Yves Louvard¹¹, MD; Goran Stankovic¹², MD, PhD

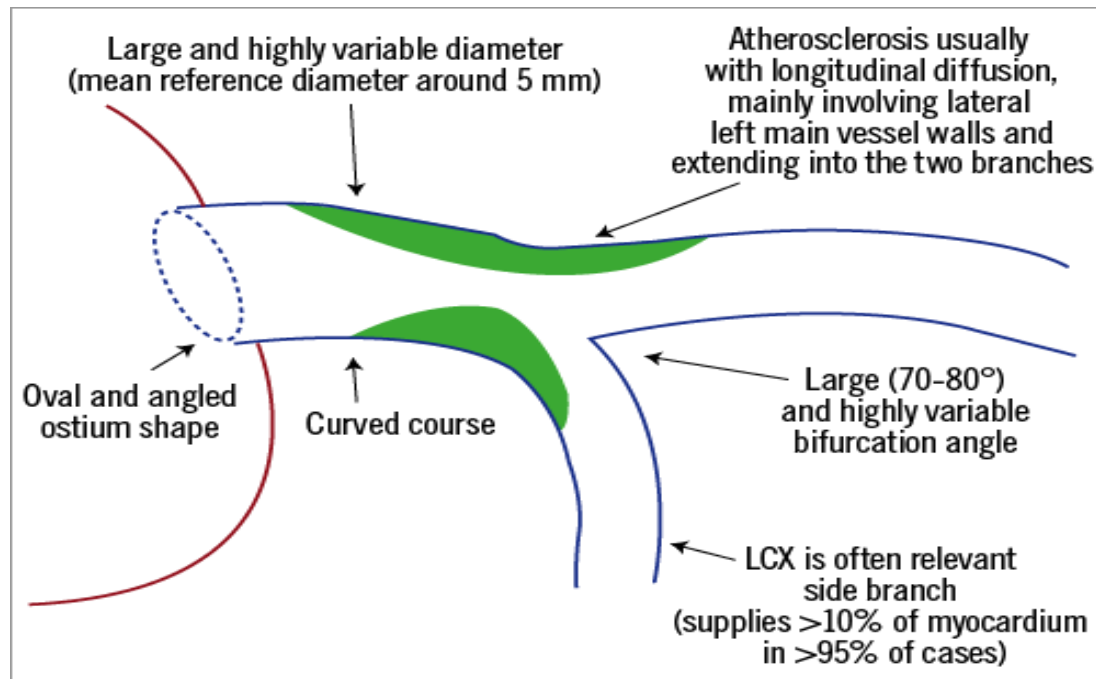
From 2006 until now EBC have published 18 consensus documents and edited two supplements on coronary bifurcation treatment in EuroIntervention



Distal LM Bifurcation With Only Angiographic Concept

Too Much Complex; angle, curves, diameter, longitudinal....

EuroIntervention

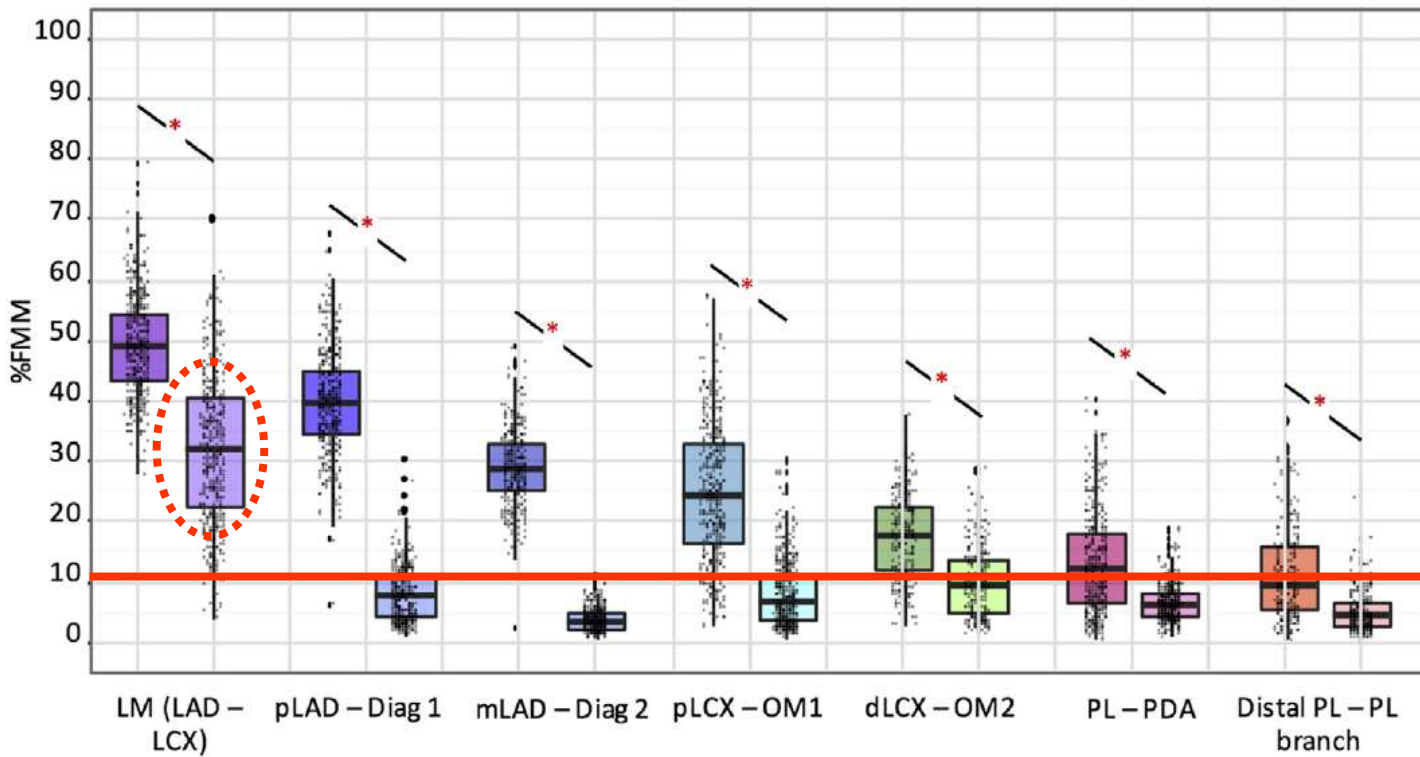


LM Bifurcation PCI = Statistical PCI

Side Branch (SB) Importance in LM Bifurcation PCI

%FMM distribution

CT-FFR: Myocardial Mass >10%



10%

How to Do LM Bifurcation PCI ?

1. One stent Cross Over
2. Two stent

LM Bifurcation PCI

1 Stent	<i>Normal or Diminutive LCX,</i> Small LCX with < 2.5 mm in diameter, Focal disease in distal LCX
2 Stent	<i>Diffuse Disease in Large LCX (>2.5 mm),</i> Diseased left dominant coronary system

True Distal Bifurcation Lesion: Diversity of SB Narrowing

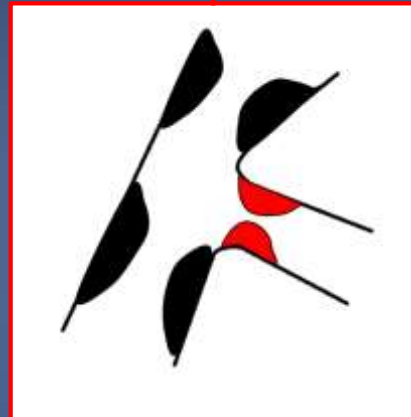


Initial Provisional Strategy

Upfront 2-stent Strategy



Focal moderate lesion in SB



Focal severe lesion in SB



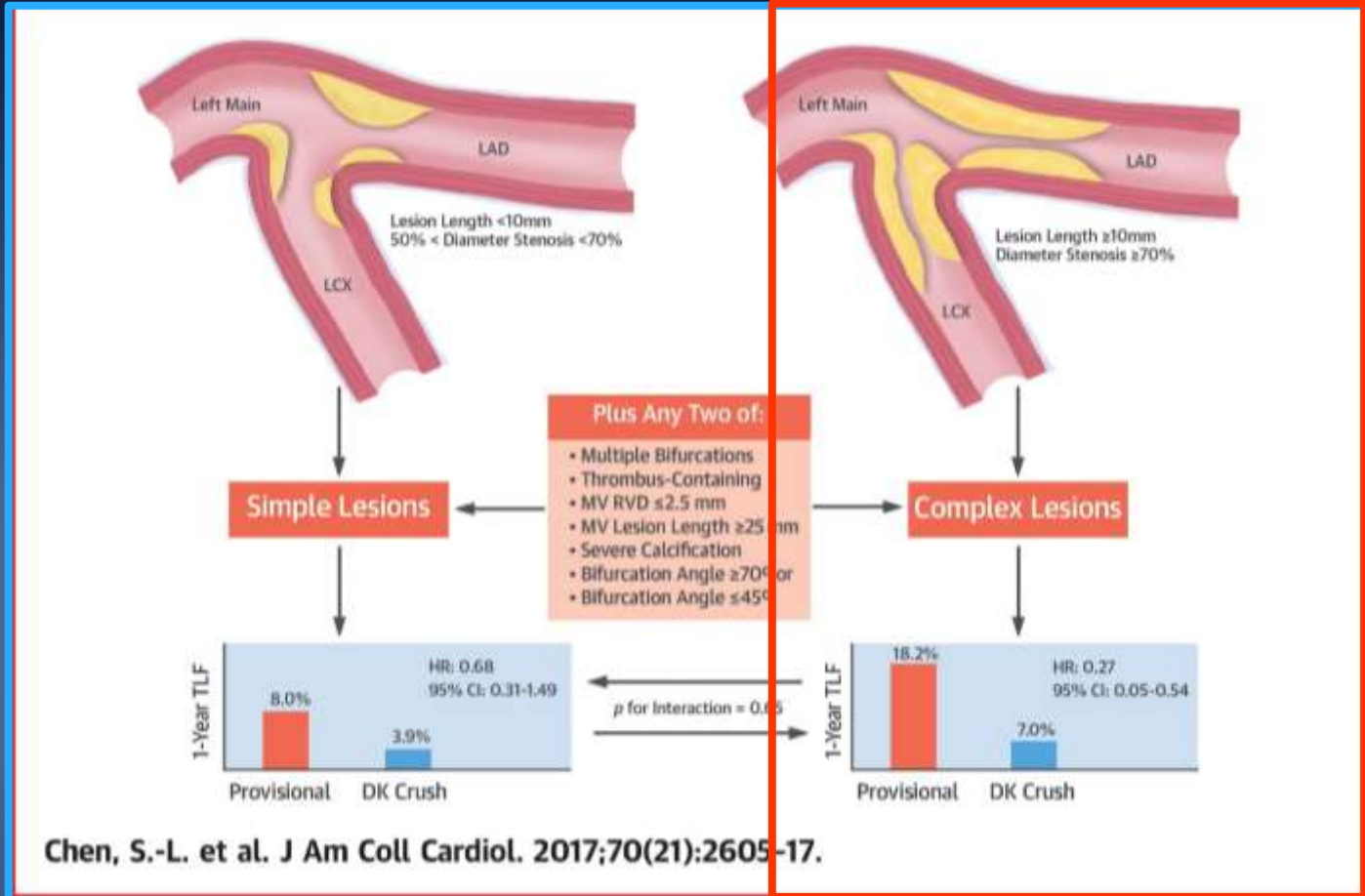
Diffuse lesion in SB

Different bifurcation features can impact on decision of bifurcation PCI strategies

If There Are LCX Disease,
Upfront 2 Stent Strategies
Are Recommended for LM Bifurcations.

- 1. Large SB with Disease Is Worthy of Treatment.***
- 2. Clinical Outcomes of 2 Stents Are Good.***
- 3. We Can Avoid Risk of SB closure during Main Vessel PCI. Stabilizing/Treating SB first has Advantages.***

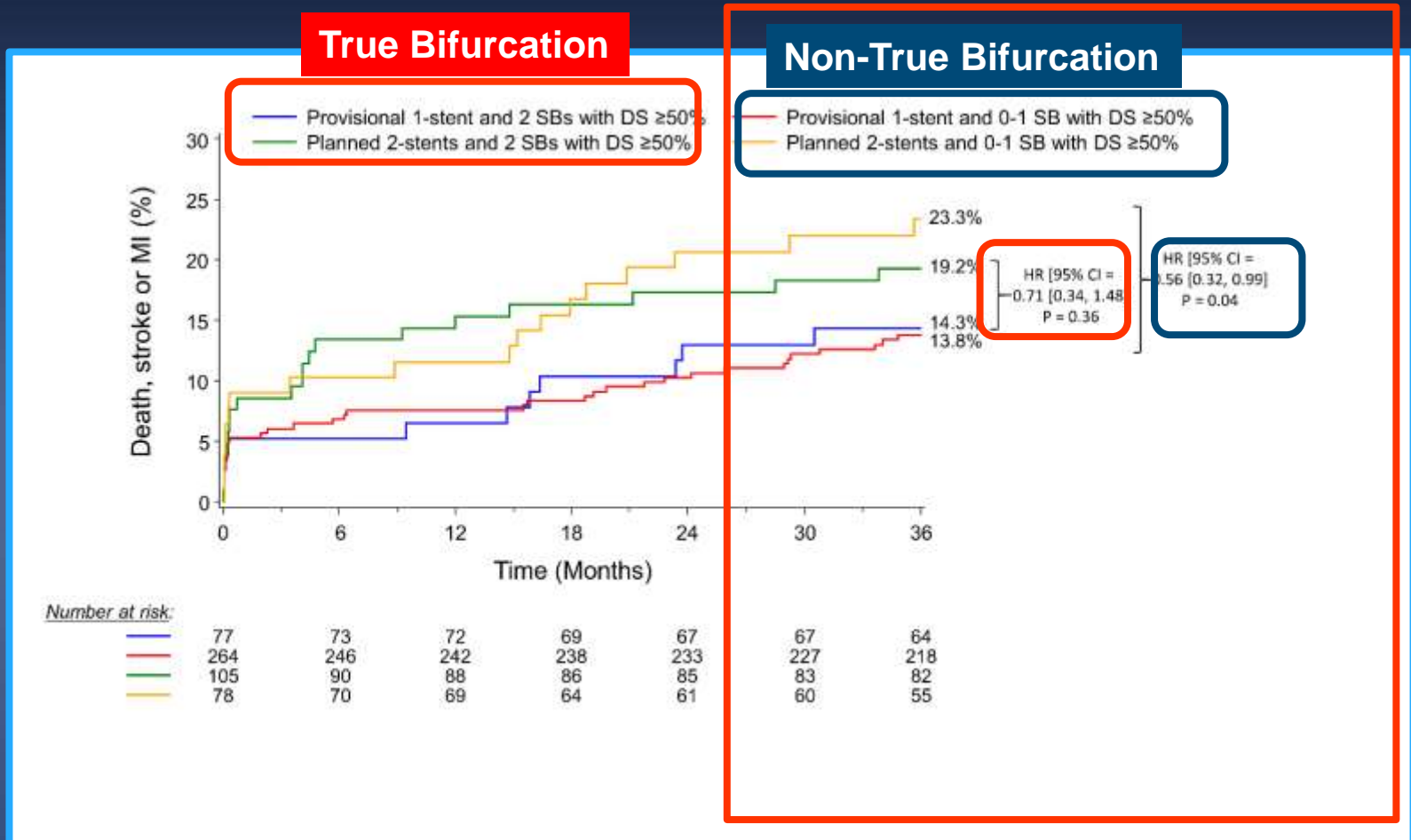
DK CRUSH-V Key Message : Up-Front 2-Stent Strategy Is Good



Don't Do One Stent For **True, Severe** Bifurcation

EXCEL Substudy

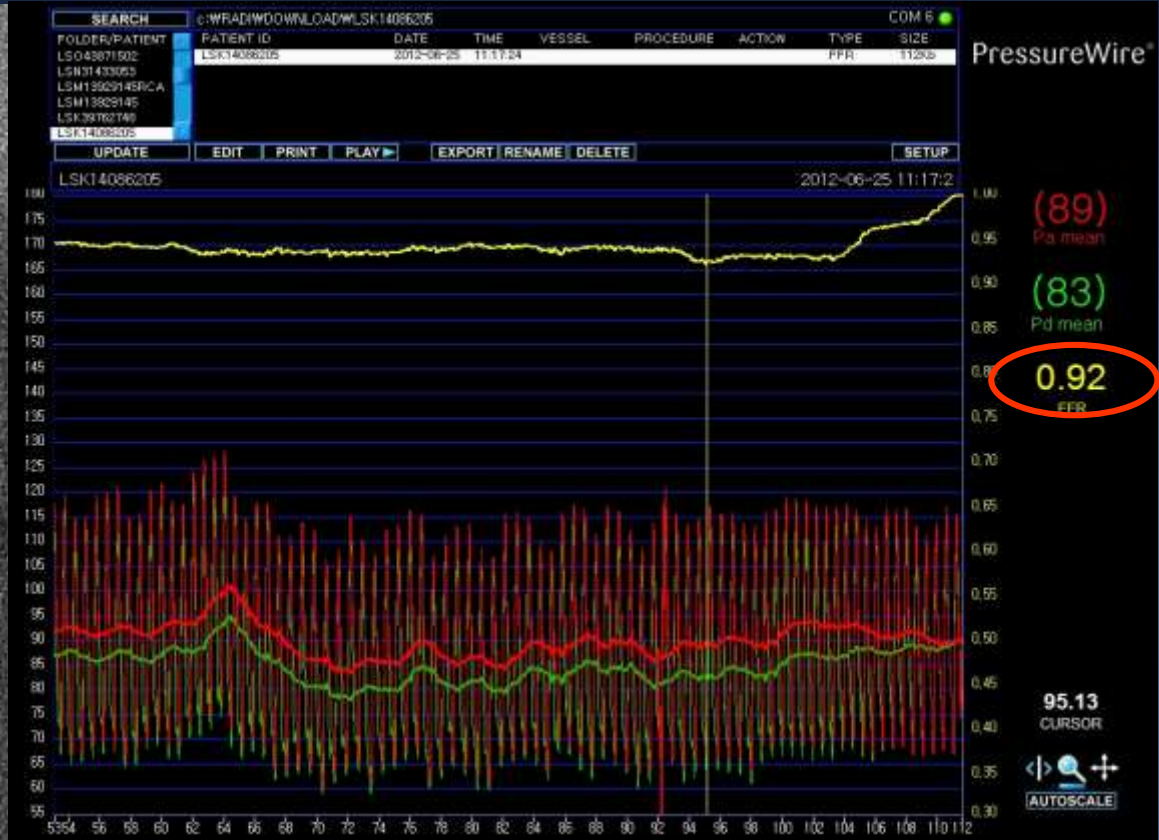
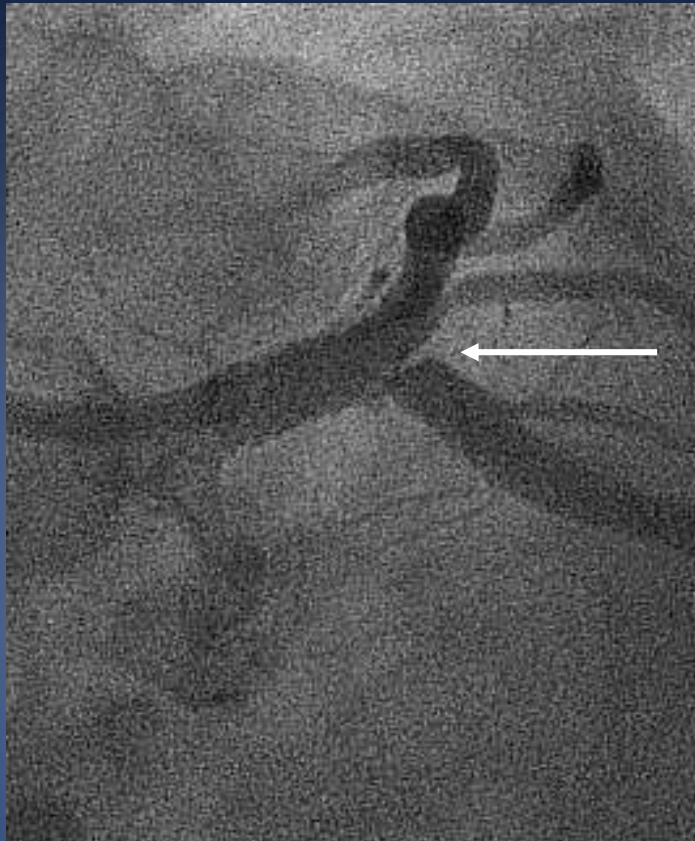
Provisional 1-Stent vs. Planned 2-Stents



Don't Do Two Stent For **Non-True** Bifurcation

FFR Determines Strategy

Consider FFR, First !

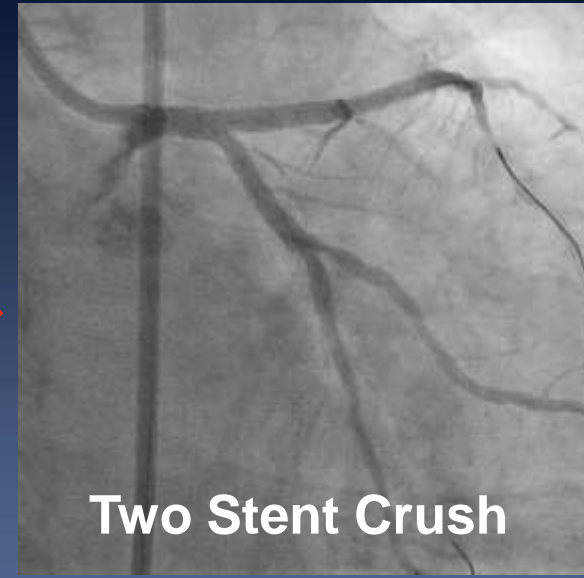


Just Defer !

IVUS Determines Strategy



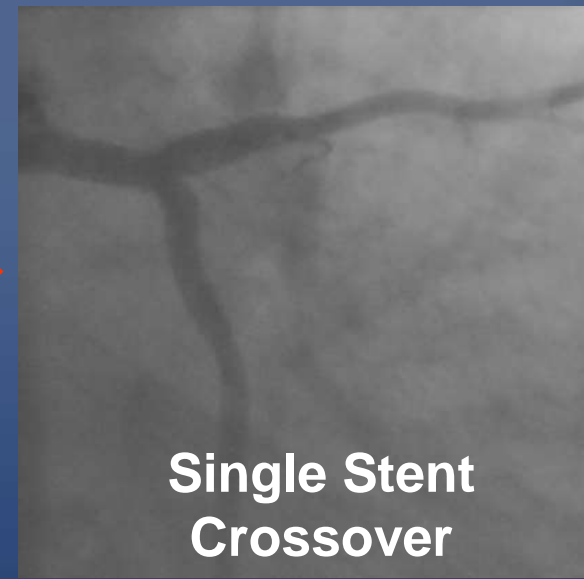
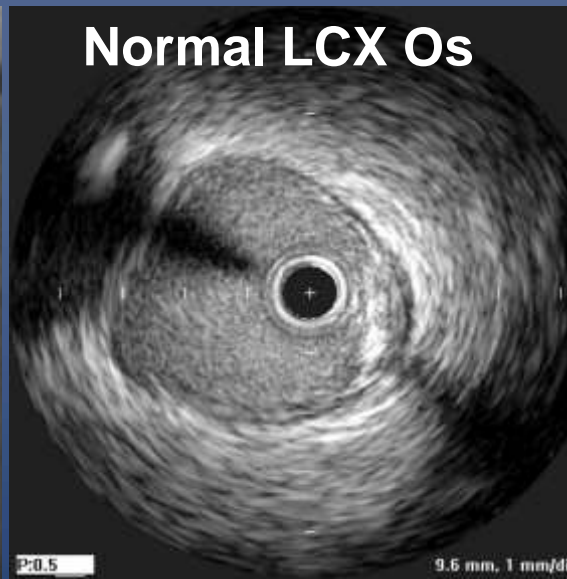
Severe Disease,
LCX-Os



Two Stent Crush



Normal LCX Os

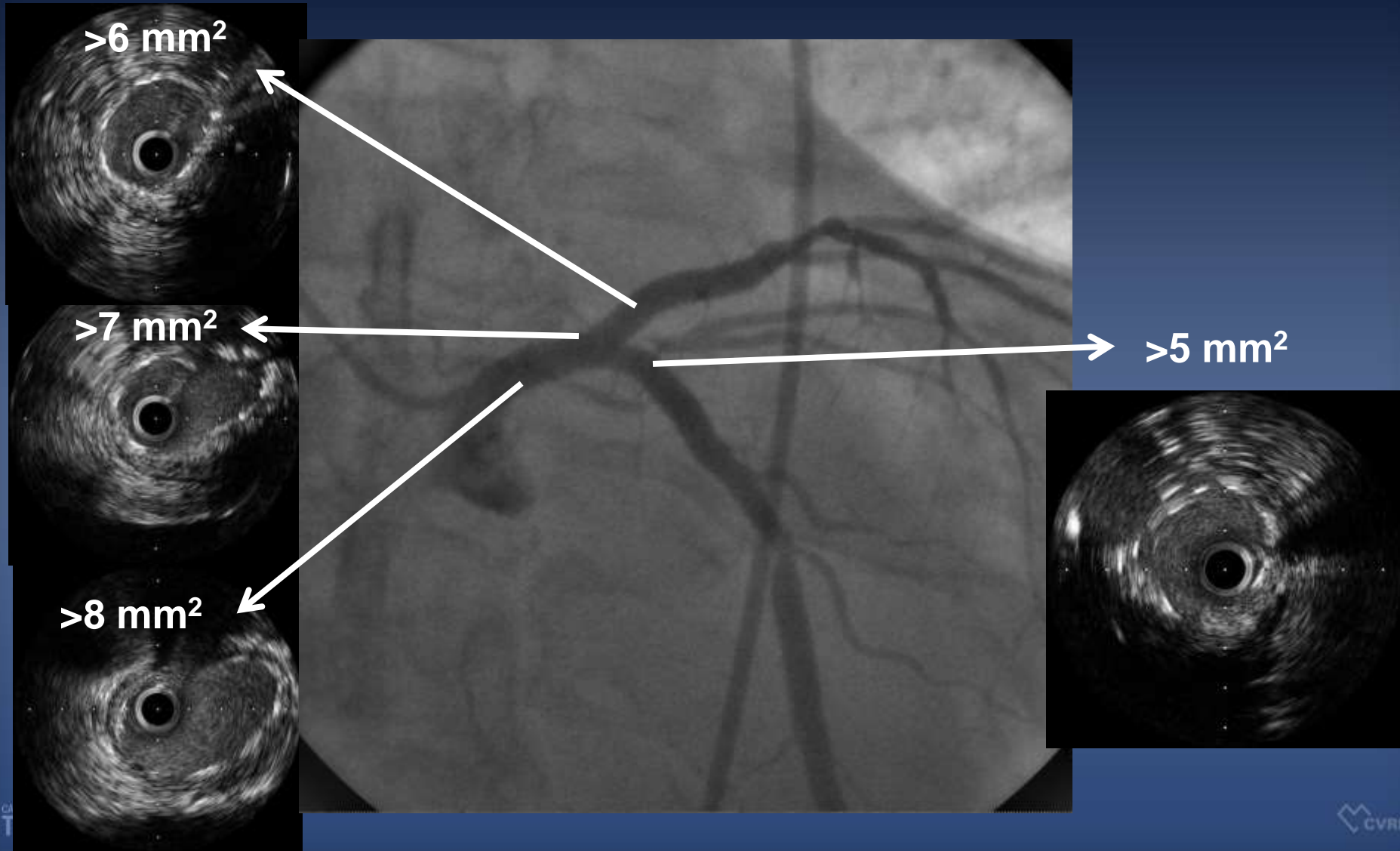


Single Stent
Crossover

IVUS Impact in LM Bifurcation PCI:

Effective Stent Area – 2 Stent PCI (Rule of 5,6,7,8 mm²)

Restenosis Rate < 5% and TLR < 2%



Practical Guideline

LM Bifurcation PCI

Single Stent

(75%)



After Stent Cross-Over

Any 2 Stents

(25%)



How to Optimize ?

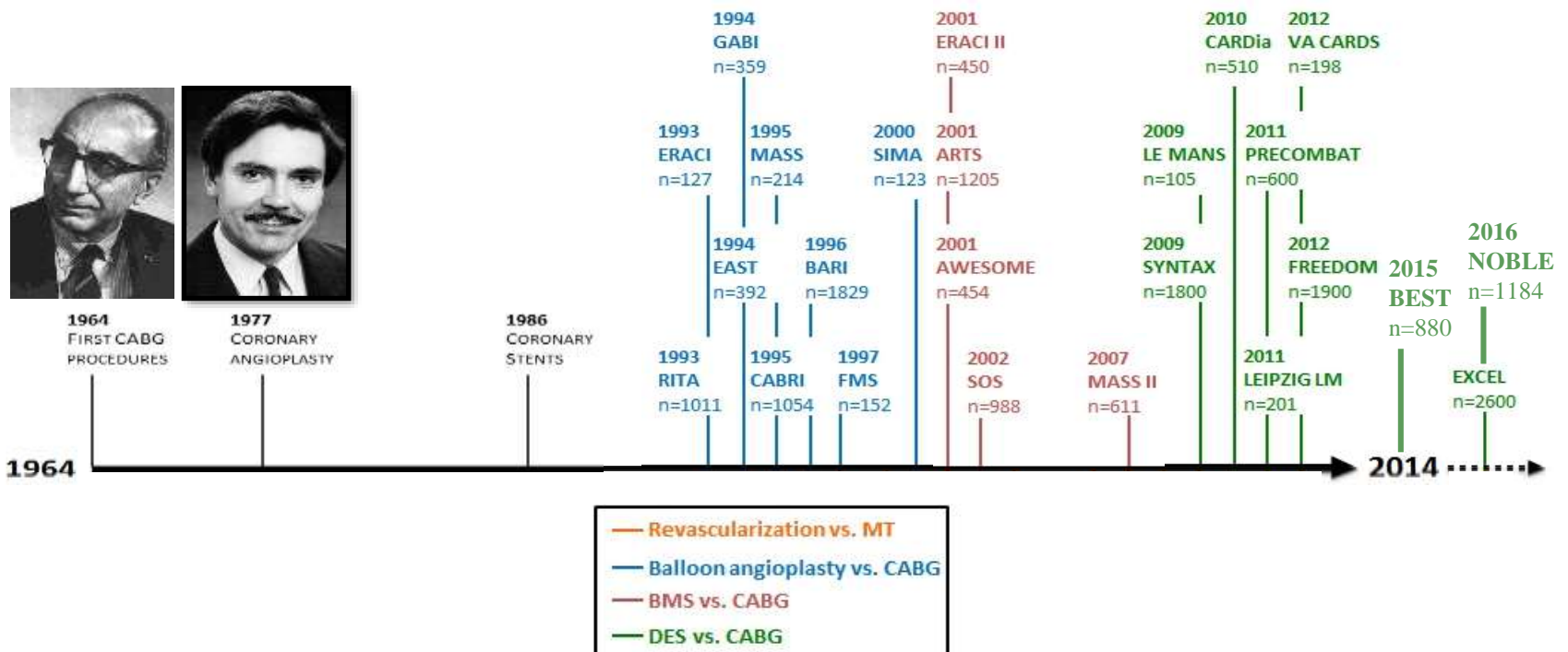
- Do You Want to Treat the Jailed Side Branch ?
- How to Treat ?

IVUS Minimal Stent CSA Criteria 5-6-7-8 mm²
May Improve Long-term Clinical Outcomes.

Today's Key Topic

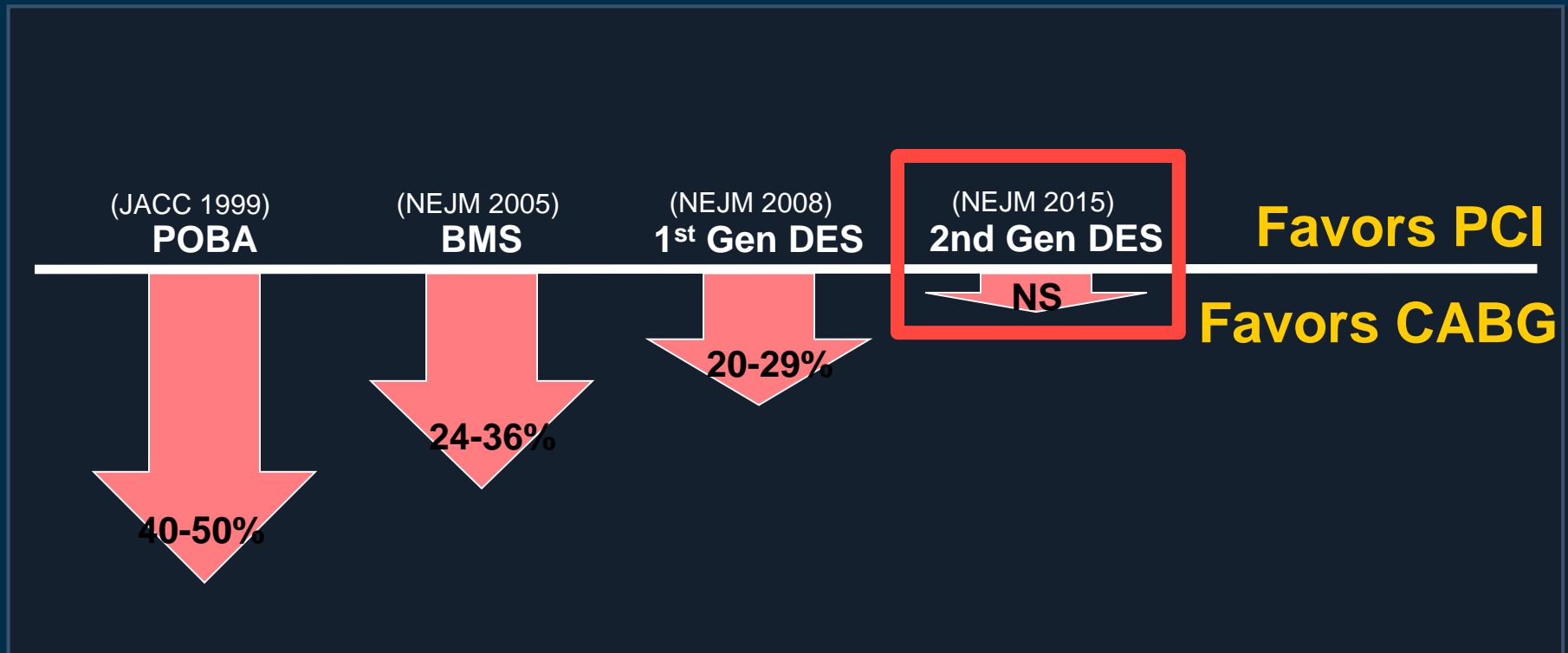
- Practical Issue of Left Main PCI
- Updated Evidence for Left Main PCI

RCTs ON REVASCULARIZATION



Continuous Big Match

Diminishing Mortality Gap between PCI and CABG in Left Main Over Time



PCI vs. CABG in LM Disease, **2019**

However, The Game Is Just Begun !

One Important Remaining Point:

We Are Demanding Very Long-Term
(ie,10-Year) Results of PCI and CABG for LM
disease

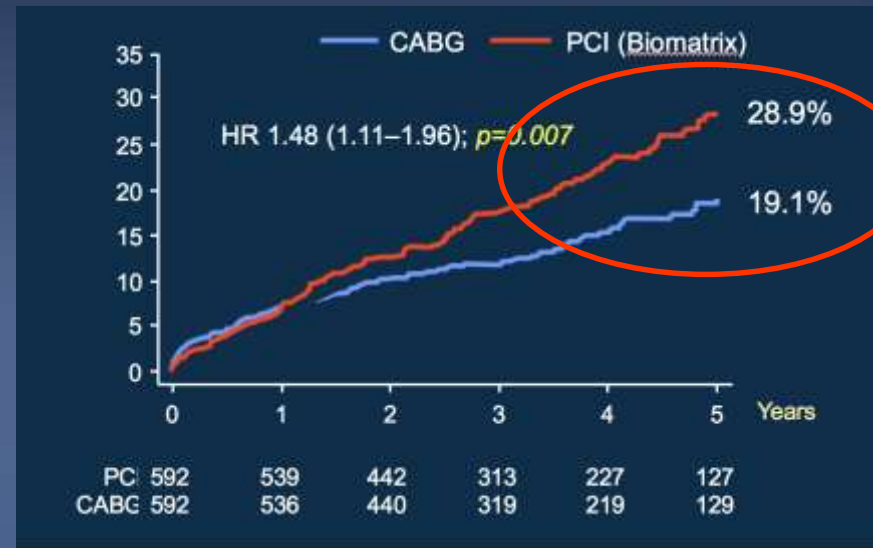
Why We Need Very Long-Term Comparative Outcomes of PCI vs. CABG in LM Disease?

There Is Some Signals...

EXCEL



NOBLE



Late Catch-Up? Cross-Over? Favoring CABG over PCI

INDIVIDUAL PATIENT-DATA POOLED ANALYSIS OF 11,518 PATIENTS FROM 11 RANDOMIZED TRIALS

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, Milan Milojevic, Joost Daemen, Jung-Min Ahn, Eric Boersma, Evald H Christiansen, Michael J Domanski, Michael E Farkouh, Marcus Flather, Valentin Fuster, Mark A Hlatky, Niels R Holm, Whady A Hueb, Masoor Kamalesh, Young-Hak Kim, Timo Mäkikallio, Friedrich W Mohr, Grigorios Papageorgiou, Seung-Jung Park, Alfredo E Rodriguez, Joseph F Sabik 3rd, Rodney H Stables, Gregg W Stone, Patrick W Serruys, Arie Pieter Kappetein

Summary

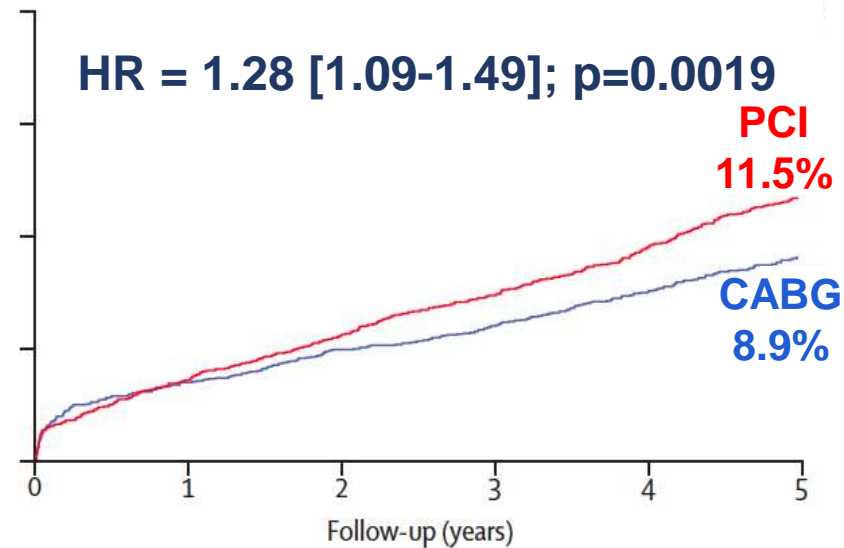
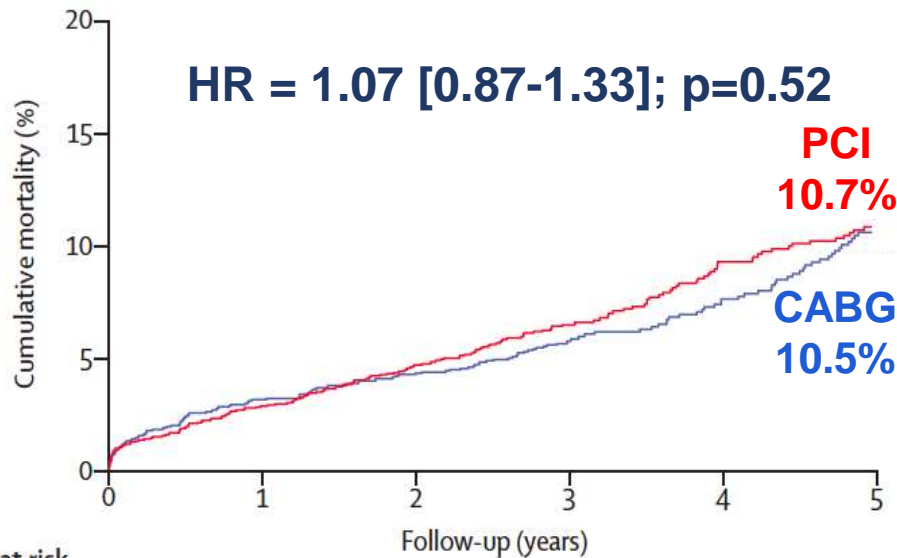
Background Numerous randomised trials have compared coronary artery bypass grafting (CABG) with percutaneous coronary intervention (PCI) for patients with coronary artery disease. However, no studies have been powered to detect a difference in mortality between the revascularisation strategies.

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IMPACT OF LM OR MULTIVESSEL DISEASE

Left main disease (n=4478)

Multivessel disease (n=7040)



Number at risk

CABG	2245	2086	1903	932	804	406	3520	3274	3091	2829	2495	1856
PCI	2233	2120	1946	978	849	478	3520	3338	3155	2875	2533	1928

Updated Longer-Term Data on PCI vs. CABG in Left Main Disease: **What Are New?**

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



Duk-Woo Park, MD,^{a,*} Jung-Min Ahn, MD,^{a,*} Sung-Cheol Yun, PhD,^b Yong-Hoon Yoon, MD,^a Do-Yoon Kang, MD,^a Pil Hyung Lee, MD,^a Seung-Whan Lee, MD,^a Seong-Wook Park, MD,^a Ki Bae Seung, MD,^c Hyeon-Cheol Gwon, MD,^d Myung-Ho Jeong, MD,^e Yangsoo Jang, MD,^f Hyo-Soo Kim, MD,^g In-Whan Seong, MD,^h Hun Sik Park, MD,ⁱ Taehoon Ahn, MD,^j In-Ho Chae, MD,^k Seung-Jea Tahk, MD,^l Seung-Jung Park, MD^a

ABSTRACT

BACKGROUND Comparative outcomes of coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) for left main coronary artery (LMCA) disease were previously reported. However, data on very long-term (>10 years) outcomes are limited.

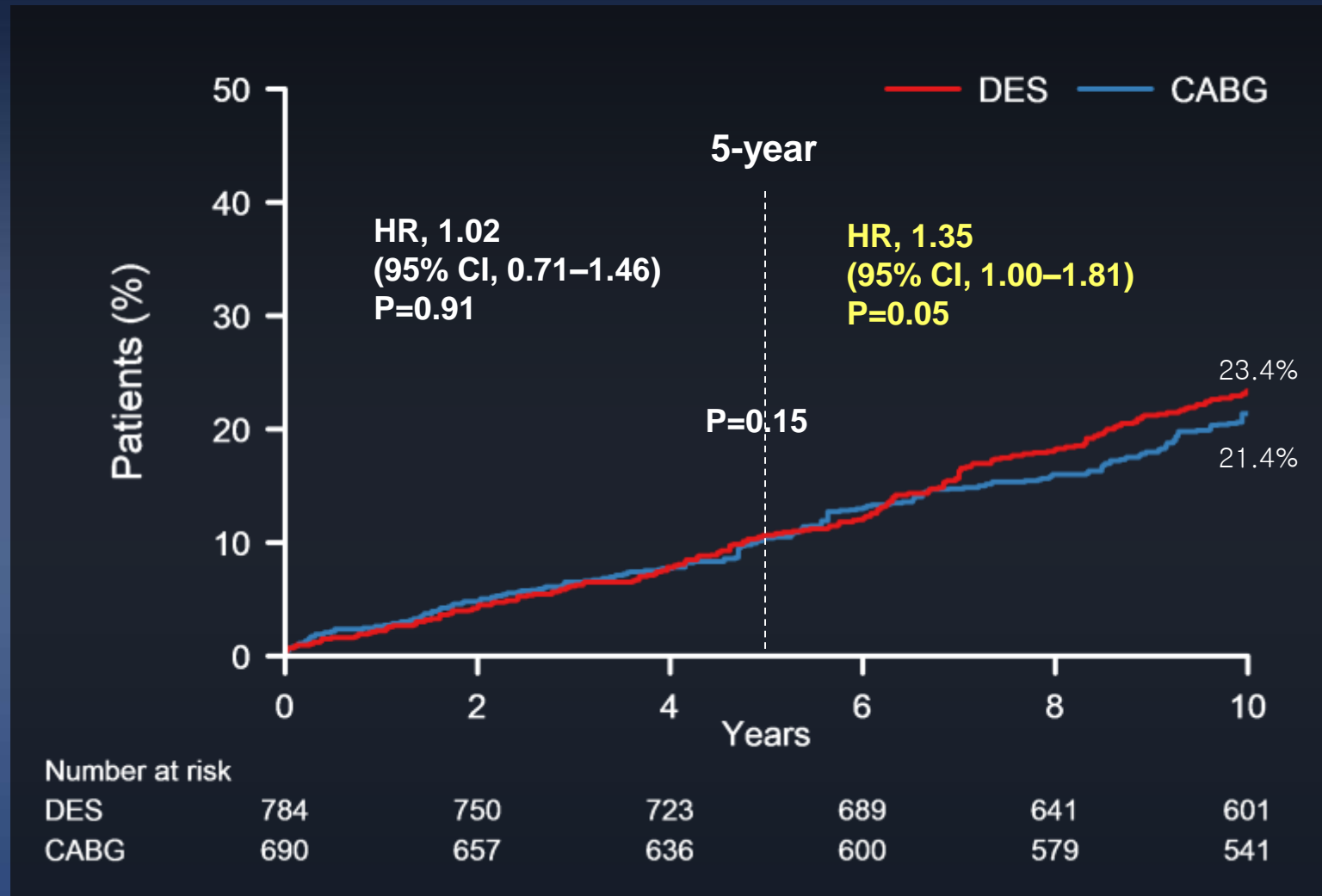
OBJECTIVES The authors compare 10-year outcomes after PCI and CABG for LMCA disease.

METHODS In this observational study of the MAIN-COMPARE (Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty versus Surgical Revascularization) registry, the authors evaluated 2,240 patients with unprotected LMCA disease who underwent PCI (n = 1,102) or underwent CABG (n = 1,138) between January 2000 and June 2006. Adverse outcomes (death; a composite outcome of death, Q-wave myocardial infarction, or stroke; and target-vessel revascularization) were compared with the use of propensity scores and inverse-probability-weighting adjustment. The follow-up was extended to at least 10 years of all patients (median 12.0 years).

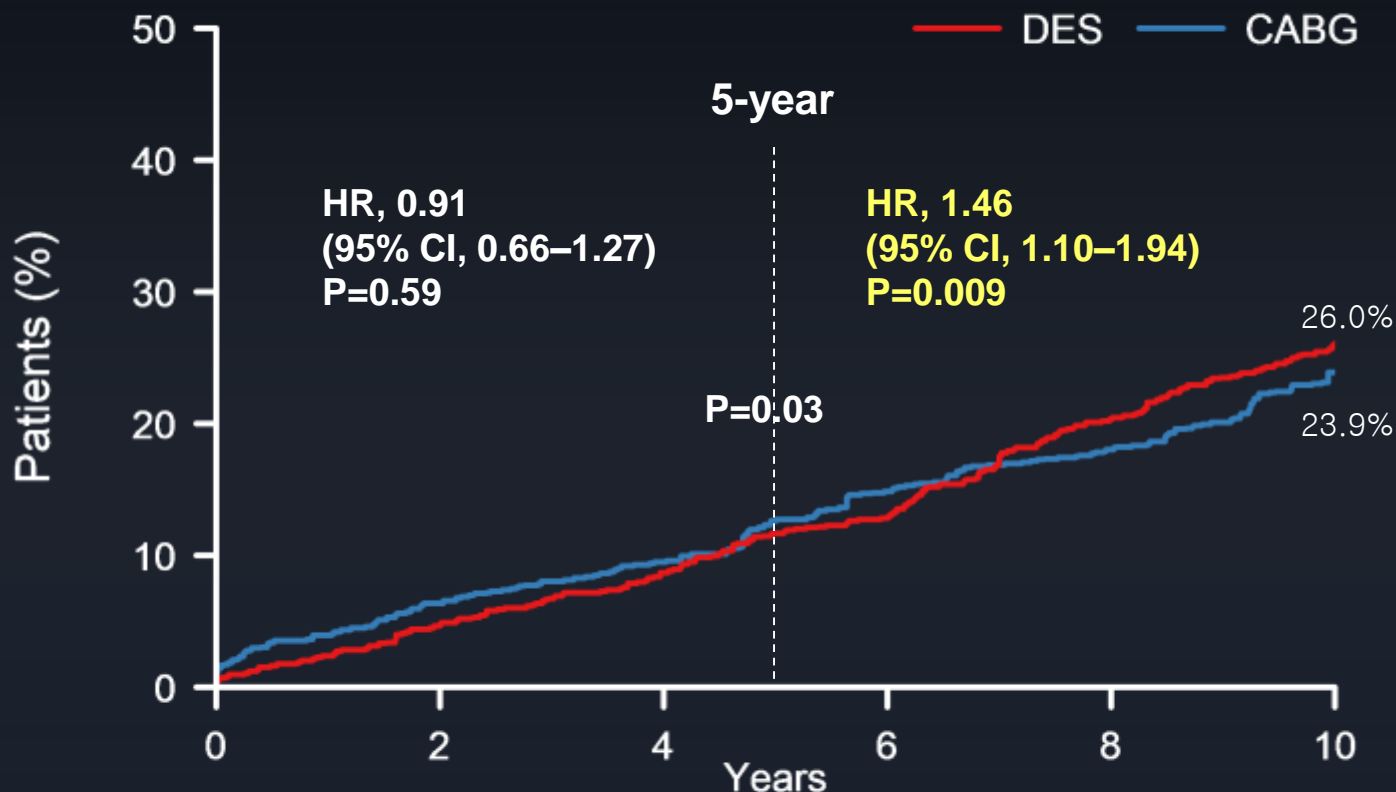
RESULTS In the overall cohort, there was no significant difference in adjusted risks of death and the composite outcome between the groups up to 10 years. The risk of target-vessel revascularization was significantly higher in the PCI group. In the cohort comparing drug-eluting stents and concurrent CABG, the 2 study groups did not differ significantly in the risks of death and the composite outcome at 5 years. However, after 5 years, drug-eluting stents were associated with higher risks of death (hazard ratio: 1.35; 95% confidence interval: 1.00 to 1.81) and the composite outcome (hazard ratio: 1.46; 95% confidence interval: 1.10 to 1.94) compared with CABG.

CONCLUSIONS In patients with significant LMCA disease, as compared with CABG, PCI showed similar rates of death and serious composite outcomes, but a higher rate of target-vessel revascularization at 10 years. However, CABG showed lower mortality and serious composite outcome rates compared with PCI with drug-eluting stents after 5 years. (Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty versus Surgical Revascularization [MAIN-COMPARE]; [NCT02791412](https://clinicaltrials.gov/ct2/show/study/NCT02791412)) (J Am Coll Cardiol 2018;72:2813-22) © 2018 by the American College of Cardiology Foundation.

IPTW-Adjusted, Wave 2 (DES vs CABG) Death



IPTW-Adjusted, Wave 2 (DES vs CABG) Death, Q-MI, or Stroke



Number at risk

DES	784	747	716	683	624	580
CABG	690	646	624	587	565	524

Percutaneous coronary intervention versus coronary artery bypass grafting in patients with three-vessel or left main coronary artery disease: 10-year follow-up of the multicentre randomised controlled SYNTAX trial



Daniel J F M Thuijs, A Pieter Kappetein, Patrick W Serruys, Friedrich-Wilhelm Mohr, Marie-Claude Morice, Michael J Mack, David R Holmes Jr, Nick Curzen, Piroze Davierwala, Thilo Noack, Milan Milojevic, Keith D Dawkins, Bruno R da Costa, Peter Juni, Stuart J Head, for the SYNTAX Extended Survival Investigators*

Summary

Background The Synergy between PCI with Taxus and Cardiac Surgery (SYNTAX) trial was a non-inferiority trial that compared percutaneous coronary intervention (PCI) using first-generation paclitaxel-eluting stents with coronary artery bypass grafting (CABG) in patients with de-novo three-vessel and left main coronary artery disease, and reported results up to 5 years. We now report 10-year all-cause death results.

Methods The SYNTAX Extended Survival (SYNTAXES) study is an investigator-driven extension of follow-up of a multicentre, randomised controlled trial done in 85 hospitals across 18 North American and European countries. Patients with de-novo three-vessel and left main coronary artery disease were randomly assigned (1:1) to the PCI group or CABG group. Patients with a history of PCI or CABG, acute myocardial infarction, or an indication for concomitant cardiac surgery were excluded. The primary endpoint of the SYNTAXES study was 10-year all-cause death, which was assessed according to the intention-to-treat principle. Prespecified subgroup analyses were performed according to the presence or absence of left main coronary artery disease and diabetes, and according to coronary complexity defined by core laboratory SYNTAX score tertiles. This study is registered with ClinicalTrials.gov, NCT03417050.

Findings From March, 2005, to April, 2007, 1800 patients were randomly assigned to the PCI (n=903) or CABG (n=897) group. Vital status information at 10 years was complete for 841 (93%) patients in the PCI group and 848 (95%) patients in the CABG group. At 10 years, 244 (27%) patients had died after PCI and 211 (24%) after CABG (hazard ratio 1.17 [95% CI 0.97–1.41], p=0.092). Among patients with three-vessel disease, 151 (28%) of 546 had died after PCI versus 113 (21%) of 549 after CABG (hazard ratio 1.41 [95% CI 1.10–1.80]), and among patients with left main coronary artery disease, 93 (26%) of 357 had died after PCI versus 98 (28%) of 348 after CABG (0.90 [0.68–1.20], $p_{\text{interaction}}=0.019$). There was no treatment-by-subgroup interaction with diabetes ($p_{\text{interaction}}=0.66$) and no linear trend across SYNTAX score tertiles ($p_{\text{trend}}=0.30$).

Interpretation At 10 years, no significant difference existed in all-cause death between PCI using first-generation paclitaxel-eluting stents and CABG. However, CABG provided a significant survival benefit in patients with three-vessel disease, but not in patients with left main coronary artery disease.

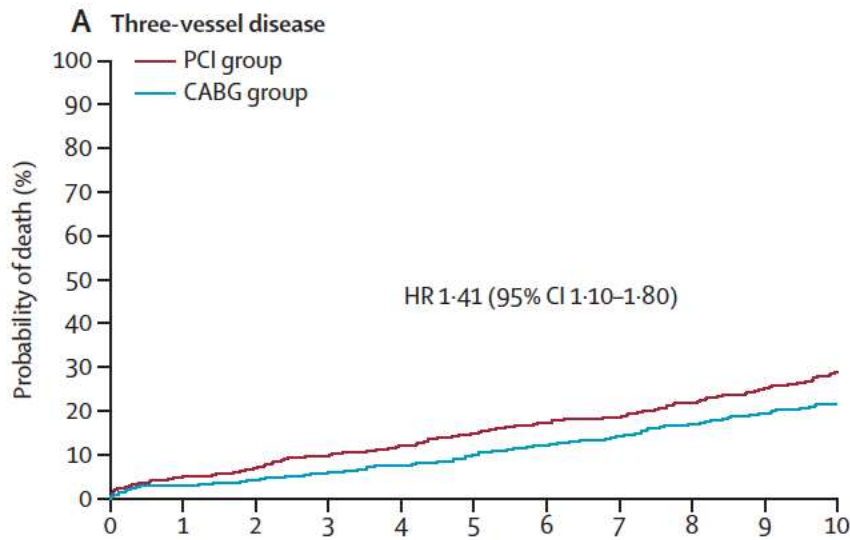
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See Online/Comment
[http://dx.doi.org/10.1016/S0140-6736\(19\)32040-9](http://dx.doi.org/10.1016/S0140-6736(19)32040-9)

*Investigators are listed in the appendix

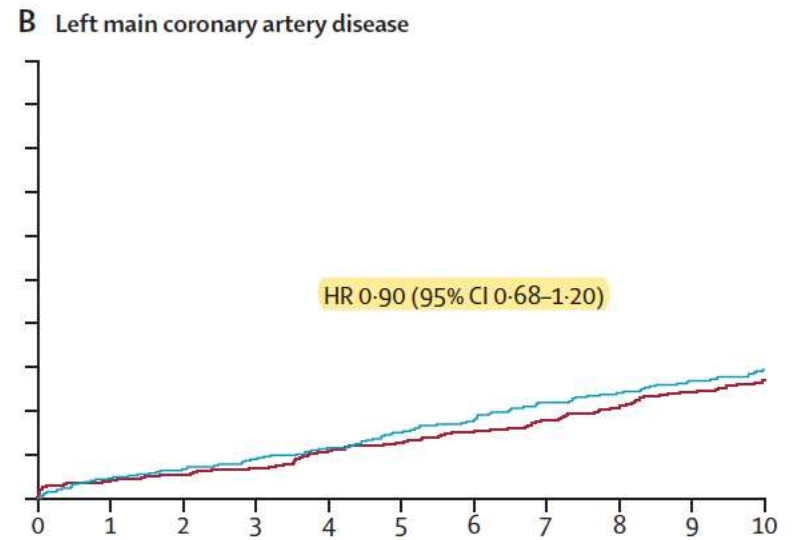
Department of Cardiothoracic Surgery, Erasmus University Medical Centre, Rotterdam, Netherlands
(D J F M Thuijs MD, Prof A P Kappetein PhD, M Milojevic PhD, S J Head PhD); Medtronic, Maastricht, Netherlands

(Prof A P Kappetein); Department of Cardiology, Imperial College London, London, UK (Prof P W Serruys PhD); University Department of Cardiac Surgery, Heart Centre Leipzig, Leipzig, Germany (Prof F-W Mohr PhD, P Davierwala MD, T Noack MD); Department of Cardiology, Cardiovascular Institute Paris-Sud, Hôpital Privé Jacques Cartier, Ramsay Générale de Santé, Massy, France

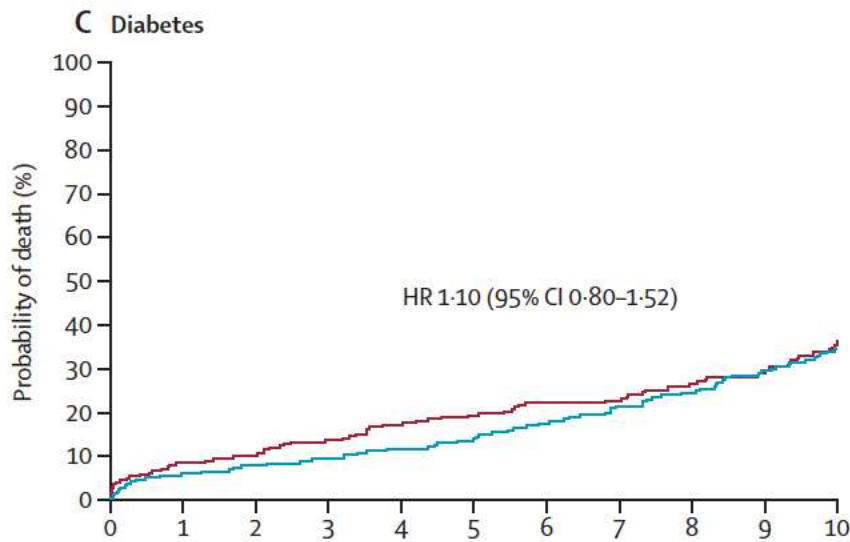


Number at risk

PCI group	546	517	506	490	477	449	417	407	389	372	346
CABG group	549	524	515	506	494	470	446	436	422	409	397

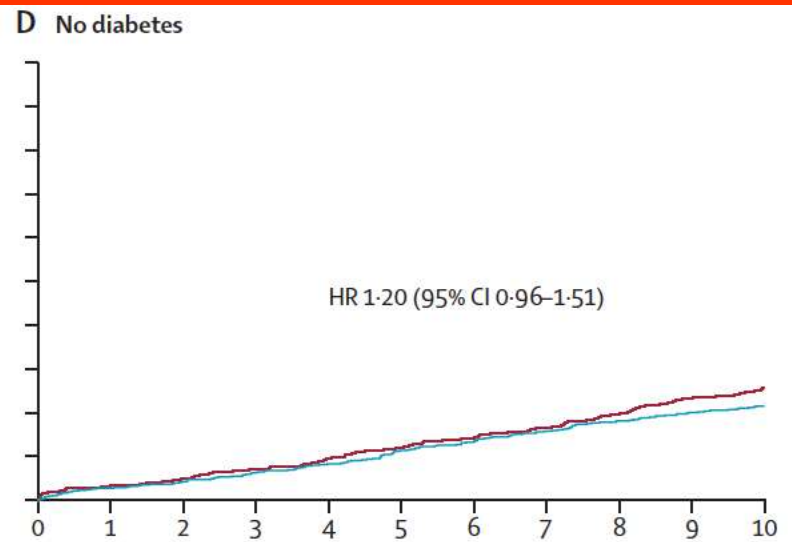


PCI group	357	343	338	332	318	295	282	273	262	249	237
CABG group	348	332	323	314	305	283	265	251	244	235	223



Number at risk

PCI group	231	210	206	198	190	178	164	160	151	146	128
CABG group	221	206	199	196	190	177	165	157	151	141	131



PCI group	672	650	638	624	605	566	535	520	500	475	455
CABG group	676	650	639	624	609	576	546	530	515	503	489

ORIGINAL ARTICLE

Five-Year Outcomes after PCI or CABG for Left Main Coronary Disease

G.W. Stone, A.P. Kappetein, J.F. Sabik, S.J. Pocock, M.-C. Morice, J. Puskas, D.E. Kandzari, D. Karpaliotis, W.M. Brown III, N.J. Lembo, A. Banning, B. Merkely, F. Horkay, P.W. Boonstra, A.J. van Boven, I. Ungi, G. Bogáts, S. Mansour, N. Noiseux, M. Sabaté, J. Pomar, M. Hickey, A. Gershlick, P.E. Buszman, A. Bochenek, E. Schampaert, P. Pagé, R. Modolo, J. Gregson, C.A. Simonton, R. Mehran, I. Kosmidou, P. Généreux, A. Crowley, O. Dressler, and P.W. Serruys, for the EXCEL Trial Investigators*

ABSTRACT

BACKGROUND

Long-term outcomes after percutaneous coronary intervention (PCI) with contemporary drug-eluting stents, as compared with coronary-artery bypass grafting (CABG), in patients with left main coronary artery disease are not clearly established.

METHODS

We randomly assigned 1905 patients with left main coronary artery disease of low or intermediate anatomical complexity (according to assessment at the participating centers) to undergo either PCI with fluoropolymer-based cobalt–chromium everolimus-eluting stents (PCI group, 948 patients) or CABG (CABG group, 957 patients). The primary outcome was a composite of death, stroke, or myocardial infarction.

RESULTS

At 5 years, a primary outcome event had occurred in 22.0% of the patients in the PCI group and in 19.2% of the patients in the CABG group (difference, 2.8 percentage points; 95% confidence interval [CI], -0.9 to 6.5 ; $P=0.13$). Death from any cause

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Address reprint requests to Dr. Stone at the Cardiovascular Research Foundation, 1700 Broadway, 8th Fl., New York, NY 10019, or at gstone@crf.org.

*A complete list of investigators, institutions, and research organizations participating in the EXCEL trial is provided in the Supplementary Appendix, available at NEJM.org.

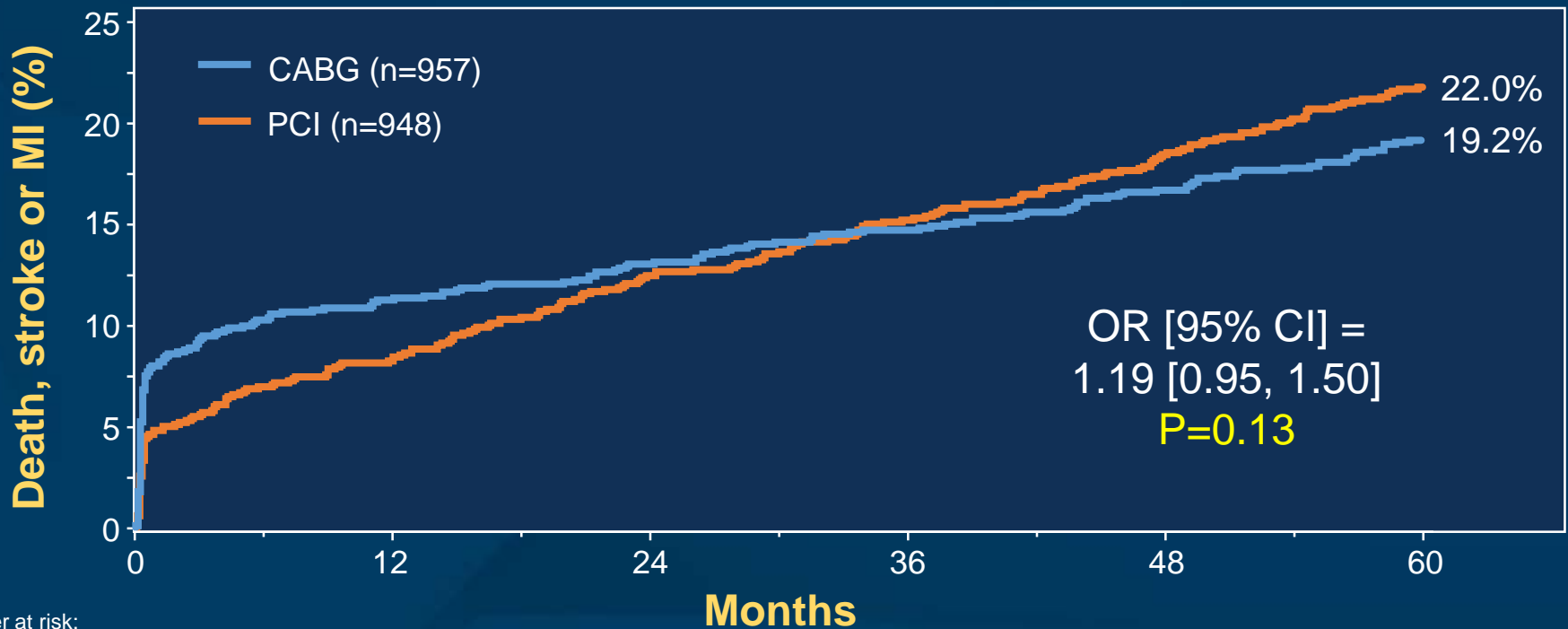
This article was published on September 28, 2019, at NEJM.org.

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Primary Endpoint

All-cause Death, Stroke or MI at 5 Years



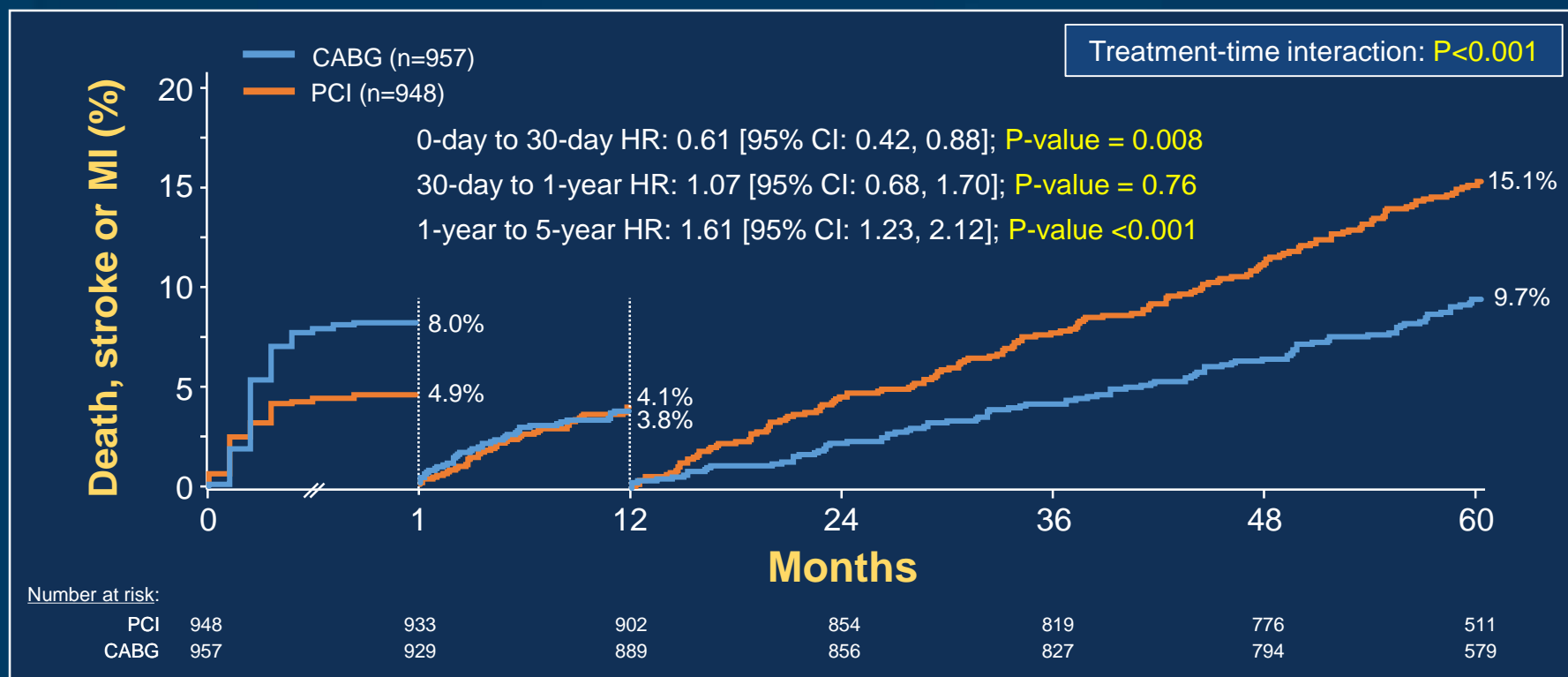
Number at risk:

	0	12	24	36	48	60
PCI	948	854	809	778	738	486
CABG	957	818	789	763	734	532

Piecewise Hazards

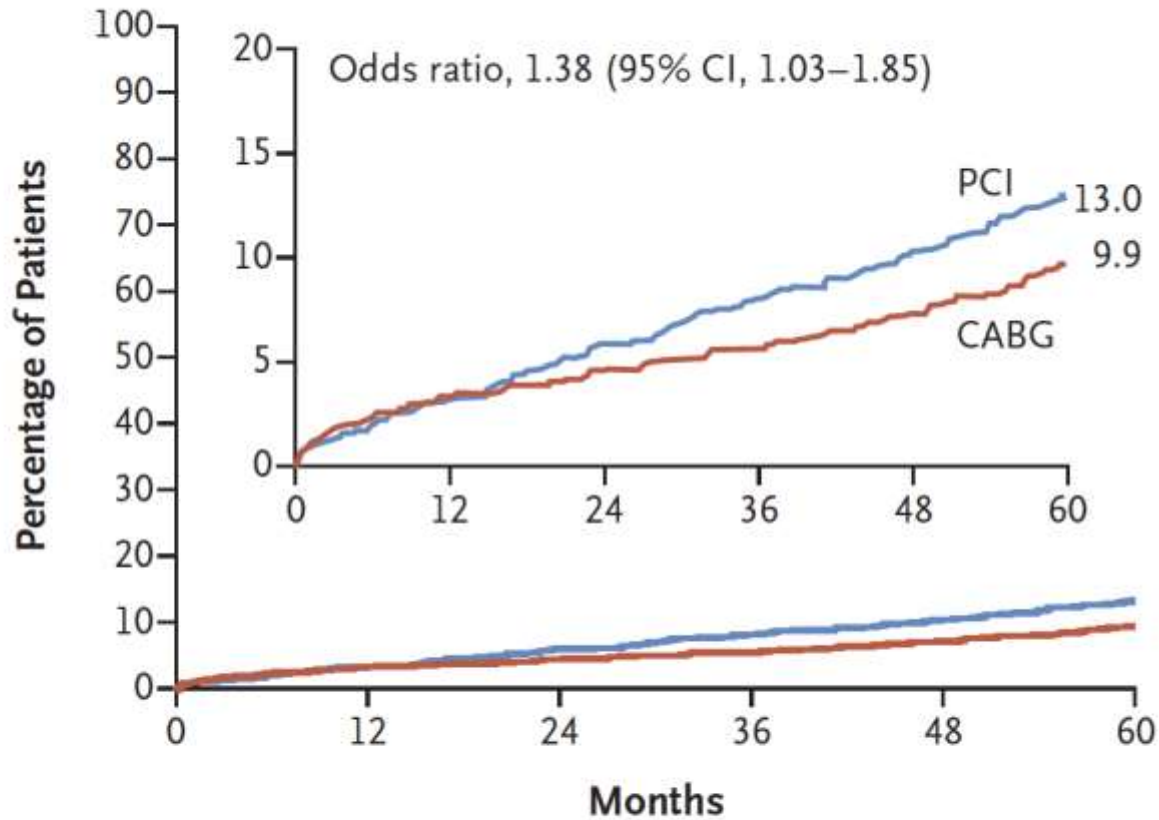
All-cause Death, Stroke or MI

Three distinct periods of varying relative risk



All-Cause Mortality

A Death from Any Cause



No. at Risk

PCI	948	902	868	841	810	545
CABG	957	889	865	844	815	596

Endless Debates

NEWS • INTERVENTIONAL

Former EXCEL Investigator Alleges Trial Manipulation, Prompting Vehement Denials

Surgeon David Taggart set the EACTS meeting ablaze when he accused EXCEL researchers of stacking the deck in PCI's favor.



By Michael O'Riordan | October 07, 2019



LISBON, Portugal (*UPDATED*)—A leading academic cardiovascular surgeon has broken from the EXCEL trial over his interpretation of the recently published 5-year results comparing PCI versus CABG surgery for the treatment of patients with left main coronary artery disease (LMCAD).

David Taggart, MD, PhD (University of Oxford, England), the chairman of the EXCEL surgical committee during the design and recruitment phase of the trial, believes the investigators downplayed the increased risk of all-cause mortality

PRECOMBAT Trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

Seung-Jung Park, M.D., Young-Hak Kim, M.D., Duk-Woo Park, M.D., Sung-Cheol Yun, Ph.D., Jung-Min Ahn, M.D., Hae Geun Song, M.D., Jong-Young Lee, M.D., Won-Jang Kim, M.D., Soo-Jin Kang, M.D., Seung-Whan Lee, M.D., Cheol Whan Lee, M.D., Seong-Wook Park, M.D., Cheol-Hyun Chung, M.D., Jae-Won Lee, M.D., Do-Sun Lim, M.D., Seung-Woon Rha, M.D., Sang-Gon Lee, M.D., Hyeon-Cheol Gwon, M.D., Hyo-Soo Kim, M.D., In-Ho Chae, M.D., Yangsoo Jang, M.D., Myung-Ho Jeong, M.D., Seung-Jea Tahk, M.D., and Ki Bae Seung, M.D.

ABSTRACT

BACKGROUND

Percutaneous coronary intervention (PCI) is increasingly used to treat unprotected left main coronary artery stenosis, although coronary-artery bypass grafting (CABG) has been considered to be the treatment of choice.

METHODS

We randomly assigned patients with unprotected left main coronary artery stenosis to undergo CABG (300 patients) or PCI with sirolimus-eluting stents (300 patients). Using a wide margin for noninferiority, we compared the groups with respect to the primary composite end point of major adverse cardiac or cerebrovascular events (death from any cause, myocardial infarction, stroke, or ischemia-driven target-vessel revascularization) at 1 year. Event rates at 2 years were also compared between the two groups.

RESULTS

The primary end point occurred in 26 patients assigned to PCI as compared with 20 patients assigned to CABG (cumulative event rate, 8.7% vs. 6.7%; absolute risk difference, 2.0 percentage points; 95% confidence interval [CI], -1.6 to 5.6; $P=0.01$ for noninferiority). By 2 years, the primary end point had occurred in 36 patients in the PCI group as compared with 24 in the CABG group (cumulative event rate, 12.2% vs. 8.1%; hazard ratio with PCI, 1.50; 95% CI, 0.90 to 2.52; $P=0.12$). The composite rate of death,

From the Heart Institute (S.-J.P., Y.-H.K., D.-W.P., J.-M.A., H.G.S., J.-Y.L., W.-J.K., S.-J.K., S.-W.L., C.W.L., S.-W.P., C.-H.C., J.-W.L.) and Division of Biostatistics (S.-C.Y.), Center for Medical Research and Information, University of Ulsan College of Medicine, Asan Medical Center; Korea University Anam (D.-S.L.) and Guro (S.-W.R.) Hospitals; Samsung Medical Center (H.-C.G.); Seoul National University Hospital (H.-S.K.); Yonsei University Severance Hospital (Y.); and Catholic University of Korea, St. Mary's Hospital (K.B.S.) — all in Seoul; Ulsan University Hospital, Ulsan (S.-G.L.); Seoul National University Hospital, Bundang (I.-H.C.); Chonnam National University Hospital, Gwangju (M.-H.); and Ajou University Medical Center, Suwon (S.-J.T.) — all in Korea. Address reprint requests to Dr. S.-J. Park at the Heart Institute, Asan Medical Center, University of Ulsan, 388-1 Pungnap-dong, Songpa-gu, Seoul, 138-736, South Korea, or at sjpark@amc.seoul.kr.

Final full 10-year report (96% complete follow-up of all patients) of the PRECOMBAT trial will be presented at the ACC 2020, Chicago....

PCI vs. CABG

for LM Disease 2019-2020

1. Meta-analysis showed a similar mortality and serious composite outcome between PCI with DES and CABG.
2. The 10-Year report of the MAIN-COMPARE registry suggested higher risks of death and serious composite outcomes after DES than after CABG beyond 5 years.
3. SYNTAXES showed a similar 10-year all-cause mortality between PCI and CABG.
4. EXCEL showed a similar 5-year rate of primary composite of death, MI, or stroke, but a higher all-cause mortality after PCI than after CABG.

PCI vs. CABG

for LM Disease 2019-2020

1. Some conflicting findings should be confirmed or refuted through extended follow-up of landmark clinical trials, such as PRECOMBAT, BEST, EXCEL and NOBLE.