

Revascularization for Left Main CAD: *Updated Guidelines and Beyond*

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Disclosures

Grant Support/Drugs

- MyoKardia/BMS

Grant Support/Devices

- Edwards Lifesciences
- Boston Scientific
- Corvia
- I-Rhythm
- Abbott Vascular
- CathWorks
- Phillips
- Zoll/Therox

Consulting/Advisory Boards

- Medtronic
- Boston Scientific
- Corvia
- Edwards Lifesciences
- Abbott Vascular
- Impulse Dynamics

Revascularization Controversies

December 2019

NEWS • Daily News

EACTS Pulls Out of Left Main Guidelines After BBC Bombshell Alleging EXCEL Trial Cover-up

RESOURCE TYPE: PRESS RELEASE

AATS NOT ENDORSING THE 2021 ACC/AHA/SCAI CORONARY REVASCULARIZATION GUIDELINES

December 23, 2021

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ESC/EACTS Guidelines: Left Main Disease

Indications for Revascularization

Extent of CAD (anatomical and/or functional)		Class ^a	Level ^b
For Prognosis	Left main disease with stenosis >50%. ^{c 68-71}	I	A

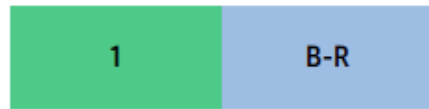
Type of Revascularization

	CABG		PCI	
	Class	Level	Class	Level
Left main CAD				
Left main disease with low SYNTAX score (0 - 22). ^{69,121,122,124,145-148}	I	A	I	A
Left main disease with intermediate SYNTAX score (23 - 32). ^{69,121,122,124,145-148}	I	A	IIa	A
Left main disease with high SYNTAX score (≥ 33). ^{c 69,121,122,124,146-148}	I	A	III	B

AHA/ACC/SCAI Guidelines: Left Main Disease

Revascularization to Improve Survival c/w Medical Therapy

Left main CAD



3. In patients with SIHD and significant left main stenosis, CABG is recommended to improve survival (9-12).



4. In selected patients with SIHD and significant left main stenosis for whom PCI can provide equivalent revascularization to that possible with CABG, PCI is reasonable to improve survival (9).

Left Main PCI: Unresolved Issues

- Should CABG be preferred for most patients?
- Role of mechanical circulatory support
- 1-stent vs. 2-stent strategies

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PCI vs. CABG for LM Disease

Percutaneous coronary intervention with drug-eluting stents versus coronary artery bypass grafting in left main coronary artery disease: an individual patient data meta-analysis



Man S Sabatine*, Brian A Bergmark*, Tobiasa A Murphy, Patrick T D Gaha, Peter K Smith, Patrick W Serruys, A Peter Kappertain, Sanghyung Park, Da-Woo Park, Ewald H Christiansen, Niels H Mahns, Per H Nielsen, Gregg W Stone, Joseph F Sabik, Eugene Braunwald

Summary

Background The optimal revascularisation strategy for patients with left main coronary artery disease is uncertain. We therefore aimed to evaluate long-term outcomes for patients treated with percutaneous coronary intervention (PCI) with drug-eluting stents versus coronary artery bypass grafting (CABG).

Methods In this individual patient data meta-analysis, we searched MEDLINE, Embase, and the Cochrane database using the search terms “left main”, “percutaneous coronary intervention” or “stent”, and “coronary artery bypass graft” to identify randomised controlled trials (RCTs) published in English between database inception and Aug 31, 2021, comparing PCI with drug-eluting stents with CABG in patients with left main coronary artery disease that had at least 5 years of patient follow-up for all-cause mortality. Two authors (MSS and BAB) identified studies meeting the criteria. The primary endpoint was 5-year all-cause mortality. Secondary endpoints were cardiovascular death, spontaneous myocardial infarction, procedural myocardial infarction, stroke, and repeat revascularisation. We used a one-stage approach; event rates were calculated by use of the Kaplan-Meier method and treatment group comparisons were made by use of a Cox frailty model, with trial as a random effect. In Bayesian analyses, the probabilities of absolute risk differences in the primary endpoint between PCI and CABG being more than 0·0%, and at least 1·0%, 2·5%, or 5·0%, were calculated.

Findings Our literature search yielded 1599 results, of which four RCTs—SYNTAX, FRECOMBAT, NOBLE, and EXCEL—meeting our inclusion criteria were included in our meta-analysis. 4394 patients, with a median SYNTAX score of 25·0 (IQR 18·0–31·0), were randomly assigned to PCI (n=2197) or CABG (n=2197). The Kaplan-Meier estimate of 5-year all-cause death was 11·2% (95% CI 9·9–12·6) with PCI and 10·2% (9·0–11·6) with CABG (hazard ratio 1·10, 95% CI 0·91–1·32; p=0·33), resulting in a non-statistically significant absolute risk difference of 0·9% (95% CI –0·9 to 2·8). In Bayesian analyses, there was an 85·7% probability that death at 5 years was greater with PCI than with CABG; this difference was more likely than not less than 1·0% (<0·2% per year). The numerical difference in mortality was comprised more of non-cardiovascular than cardiovascular death. Spontaneous myocardial infarction (6·2%, 95% CI 5·2–7·3 vs 2·6%, 2·0–3·4; hazard ratio [HR] 2·35, 95% CI 1·71–3·23; p<0·0001) and repeat revascularisation (18·3%, 16·7–20·0 vs 10·7%, 9·4–12·1; HR 1·78, 1·51–2·10; p<0·0001) were more common with PCI than with CABG. Differences in procedural myocardial infarction between strategies depended on the definition used. Overall, there was no difference in the risk of stroke between PCI (2·7%, 2·0–3·5) and CABG (3·1%, 2·4–3·9; HR 0·84, 0·59–1·21; p=0·36), but the risk was lower with PCI in the first year after randomisation (HR 0·37, 0·19–0·69).

Interpretation Among patients with left main coronary artery disease and, largely, low or intermediate coronary anatomical complexity, there was no statistically significant difference in 5-year all-cause death between PCI and CABG, although a Bayesian approach suggested a difference probably exists (more likely than not <0·2% per year) favouring CABG. There were trade-offs in terms of the risk of myocardial infarction, stroke, and revascularisation. A heart team approach to communicate expected outcome differences might be useful to assist patients in reaching a treatment decision.

Funding No external funding.

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Introduction

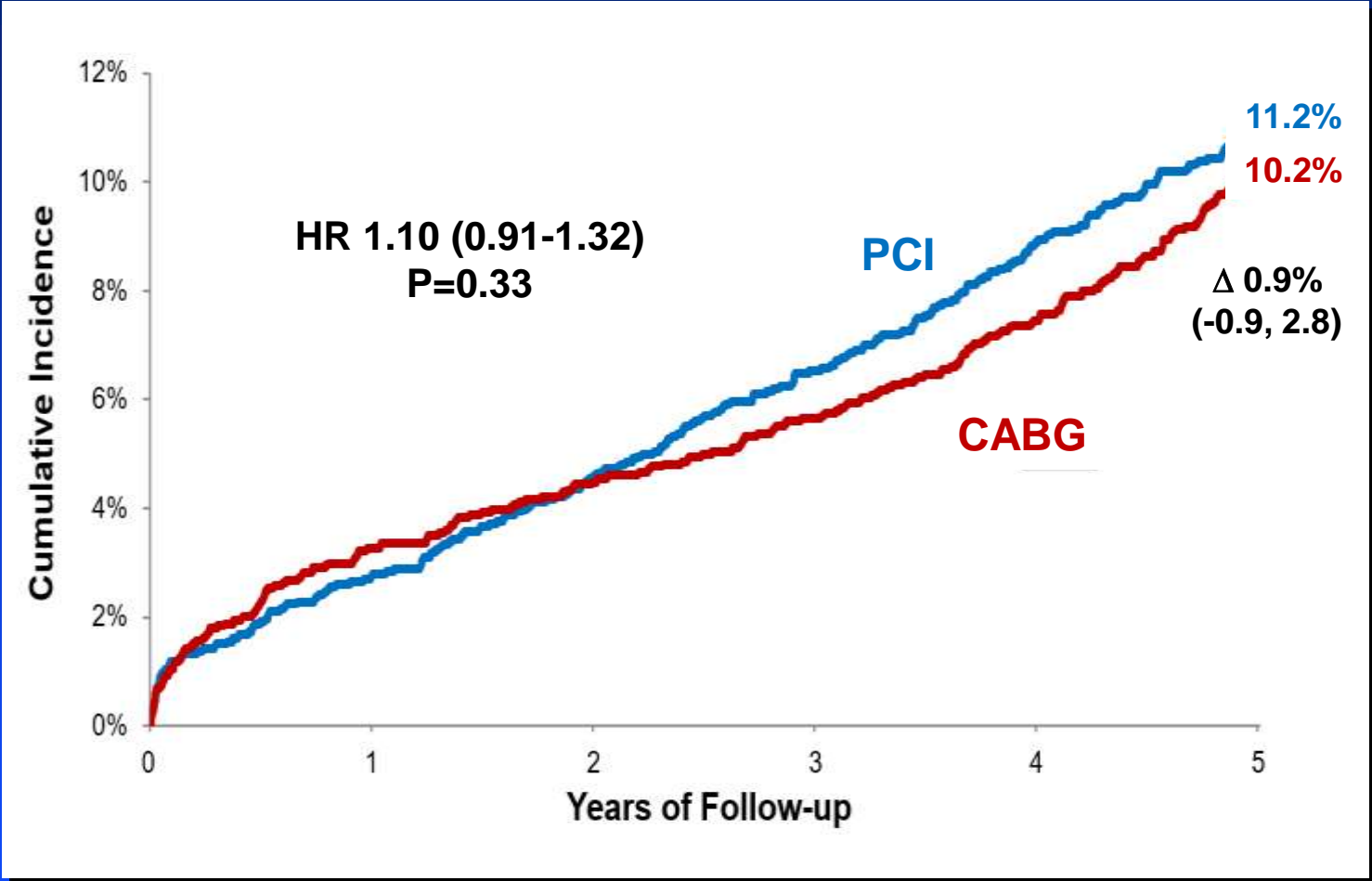
Percutaneous coronary intervention (PCI) with drug-eluting stents or coronary artery bypass grafting (CABG)

can be considered for the treatment of unprotected left main coronary artery disease in patients with low-to-intermediate anatomical complexity.^{1,2} The data

Published Online November 10, 2021
[https://doi.org/10.1016/S0140-6736\(21\)00254-0](https://doi.org/10.1016/S0140-6736(21)00254-0)
 See Online Comment [https://doi.org/10.1016/S0140-6736\(21\)00254-0](https://doi.org/10.1016/S0140-6736(21)00254-0)
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 The study is a Myocardial Infarction Study Group (Prof M T Lubars MD, S A Bergmark MD, S A Murphy MD, Prof F Braunwald MD) and Division of Cardiovascular Medicine (Prof M S Sabatine, S A Bergmark, S A Murphy, Prof P T Gaha MD, Prof J Baxendale, Brighton and Western Hospital and Harvard Medical School, Boston, MA, USA, Department of Surgery (Cardiothoracic), Duke University School of Medicine, Duke Clinical Research Institute, Durham, NC, USA, Prof F Gombosi MD, Department of Cardiology, National University of Ireland Galway, Galway, Ireland, Prof P W Serruys MD, National Heart and Lung Institute, Imperial College London, London, UK, Prof P H Serruys MD, Department of Cardiovascular Surgery, Erasmus University Medical Centre, Rotterdam, Netherlands, Prof A P Kappertain MD, Maastricht, Maastricht, Netherlands, Prof A P Kappertain MD, Department of Cardiology, Aachen Medical Centre, Aachen, South Korea (Prof S J Park MD), Prof G W Stone MD, Department of Cardiology, @ HChristiansen MD, N H Mahns MD, and Department of Cardiothoracic and Vascular Surgery (Prof H Nielsen MD), Aarhus University Hospital, Aarhus, Denmark, The Zena and Michael A Wilson Cardiovascular Institute, Umeå

- Individual patient data meta-analysis of 4 RCTs of DES-PCI vs. CABG for LM dz (n=4394)
- Angiographic characteristics
 - Median SYNTAX score = 25 (68% low/intermediate)
 - 75% distal bifurcation dz
 - IC imaging used in 67% of PCIs
- Primary endpoint: 5-year all-cause mortality

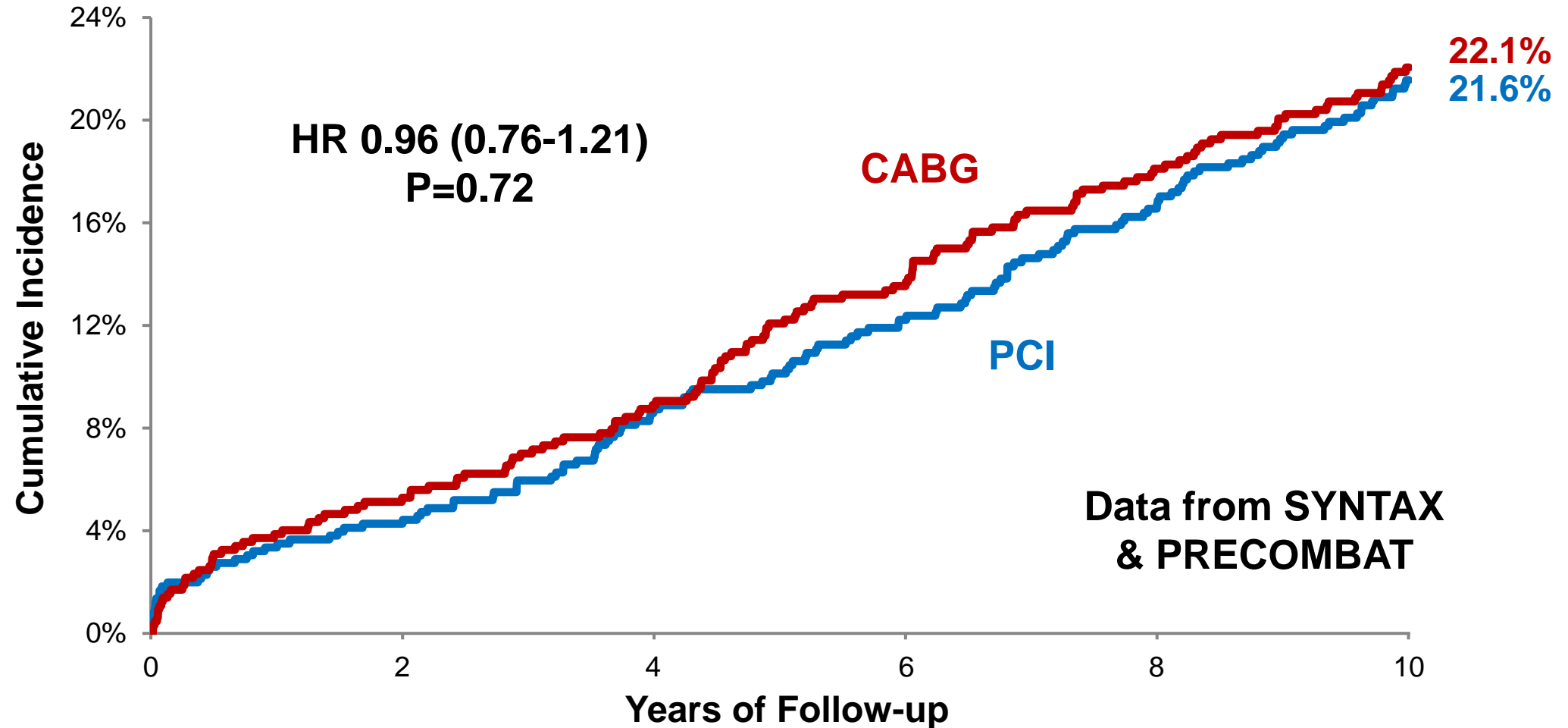
Primary Endpoint: 5-year all-cause Mortality



- No significant difference in 5-year all-cause mortality
- Bayesian analysis:
 - 49% probability of survival diff > 0.2%/year
 - 15% probability of survival diff > 0.5%/year

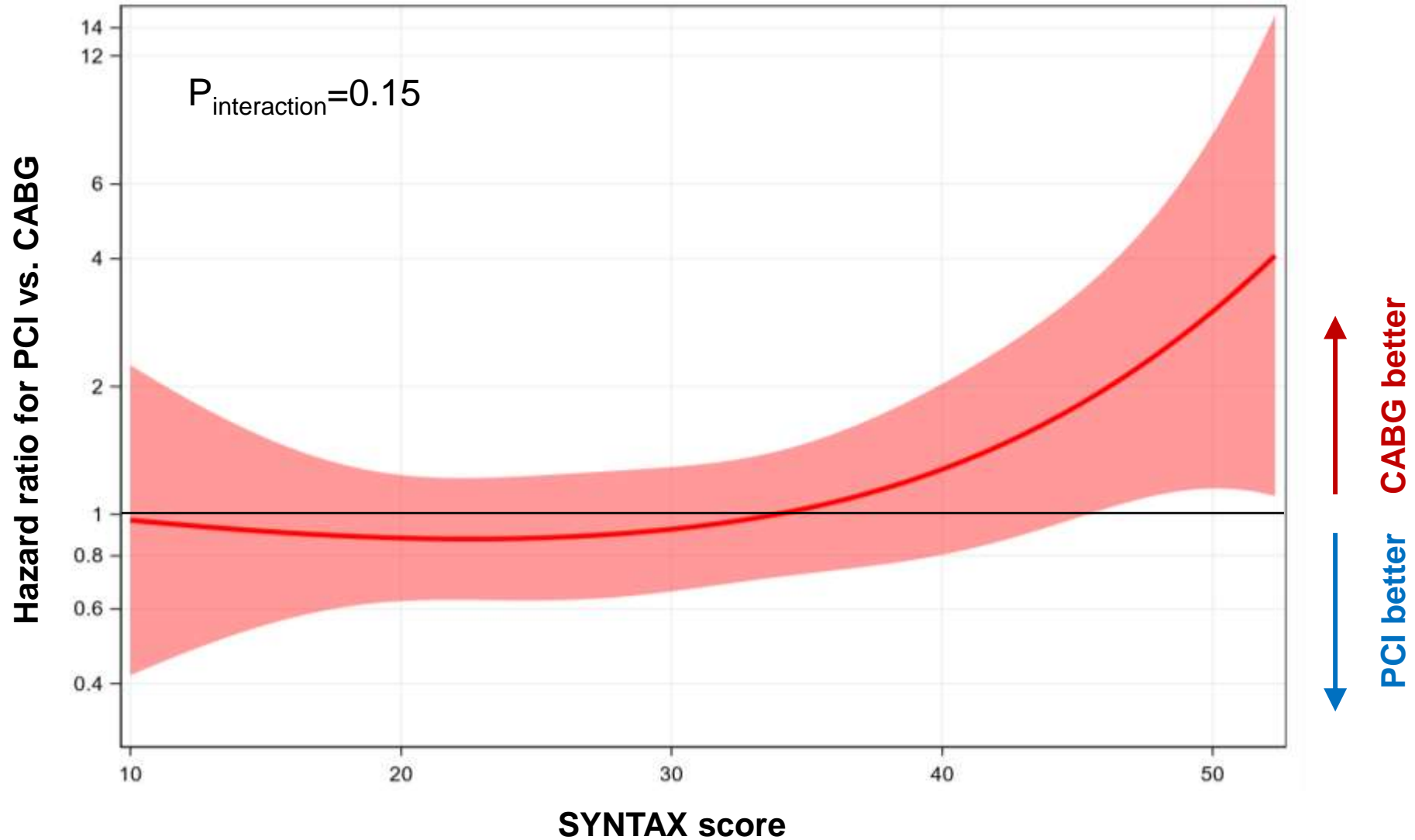


10-Year Mortality (2 trials)





CV Mortality and SYNTAX Score



What *else* should the guidelines have said?

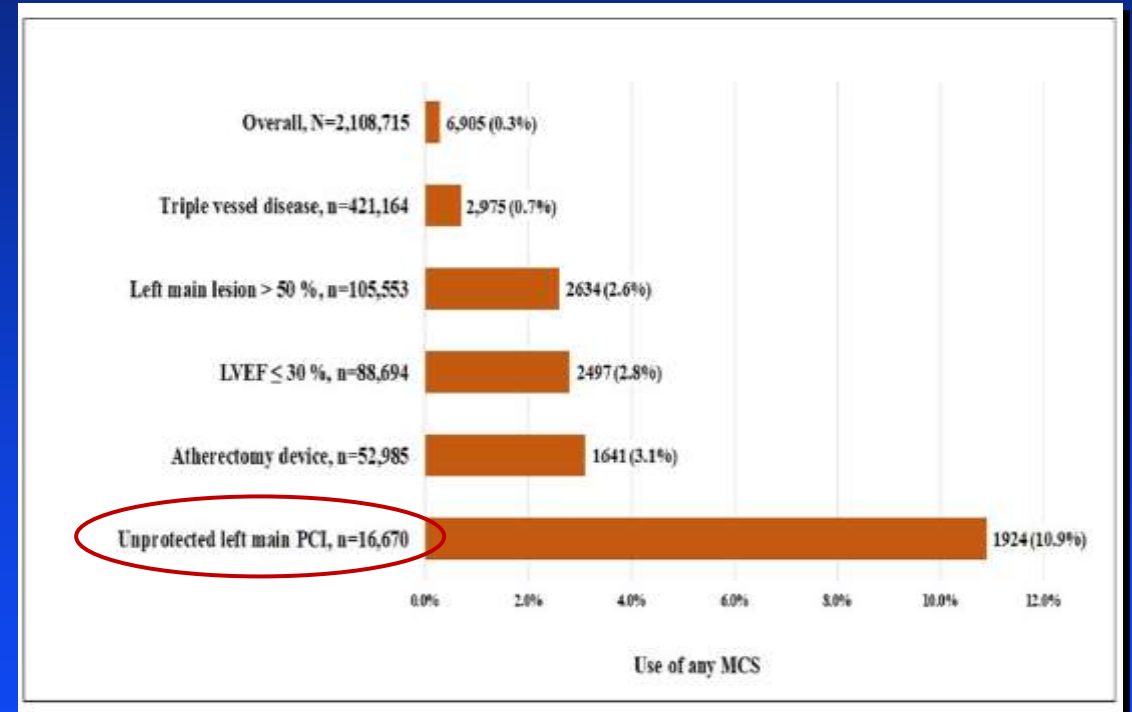
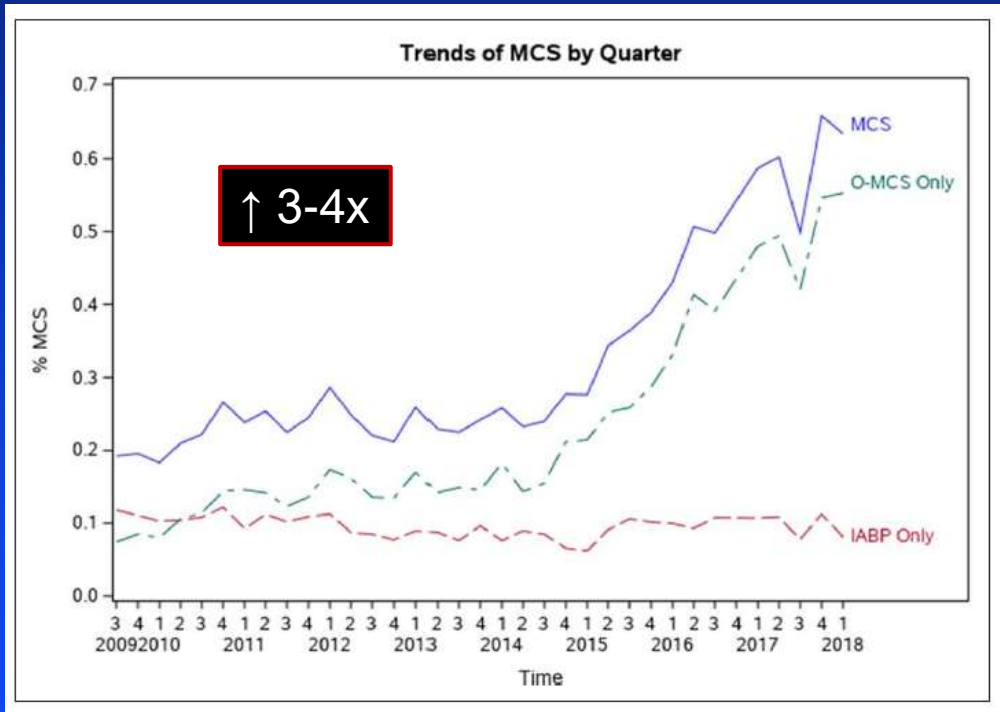
Choice of Revascularization Strategy

Based on updated evidence, both the ESC and ACC/AHA guidelines got both the indications for revascularization and selection of an initial revascularization strategy right

Left Main PCI: Unresolved Issues

- Should CABG be preferred for most patients?
- Role of mechanical circulatory support
- 1-stent vs. 2-stent strategies

NCDR Cath PCI: MCS Use in Elective PCI



What is the evidence for MCS in LM PCI?

Trial	Population	Intervention	Results
BCIS-1	LVEF <30% with BCIS jeopardy score $\geq 8/12$ (29% UPLM dz)	IABP vs. No IABP	<ul style="list-style-type: none">• No diff in in-hospital MACE• \downarrow mortality at 5 years
PROTECT-2	UPLM/Last conduit/3Vdz and LVEF < 35% (24% UPLM dz)	Impella 2.5 vs. IABP	<ul style="list-style-type: none">• No difference in 30-day MAE (ITT)• Trend toward benefit at 90-days

*In the 4 major RCTs of LM-PCI vs. CABG, use of any MCS (including IABP) was 5% or less

What *else* should the guidelines have said?

Role of Mechanical Support in Left Main PCI

- Among patients undergoing UPLM PCI with normal LV function, planned MCS is rarely needed
- Use of MCS should be considered for UPLM PCI when...
 - *LM anatomy is complex (distal bifurcation lesion, severe calcification requiring atheroablation) AND cardiac reserve is limited (EF < 30%, PCWP > 30 mmHg)*
 - *LM anatomy is complex AND RCA is supplied by L → R collaterals*

Left Main PCI: Unresolved Issues

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1-Stent vs. 2-Stent Approach

DK-CRUSH V

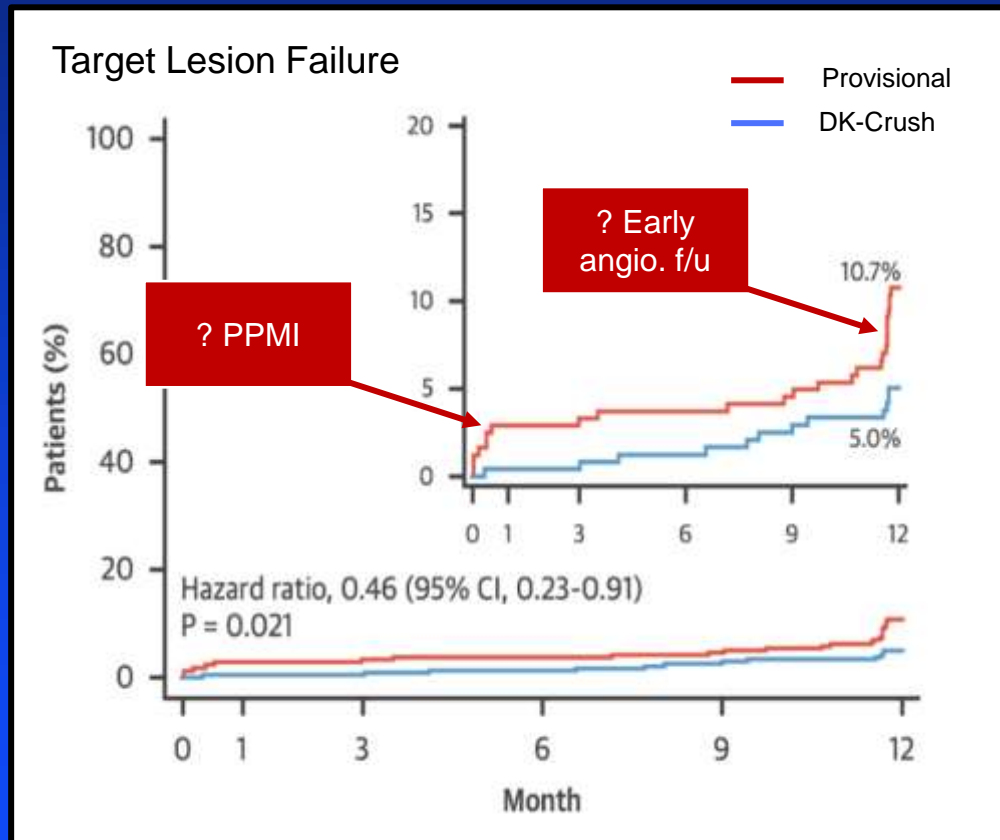
- 482 patients from with true distal LM bifurcation lesions (Medina 1,1,1 or 0,1,1) randomized to **provisional stenting vs. DK-crush stenting**
- Primary Endpoint:
1-year TLF → **lesion centered**
- Routine **angiographic f/u** was scheduled after ascertainment of the primary endpoint

EBC-Main

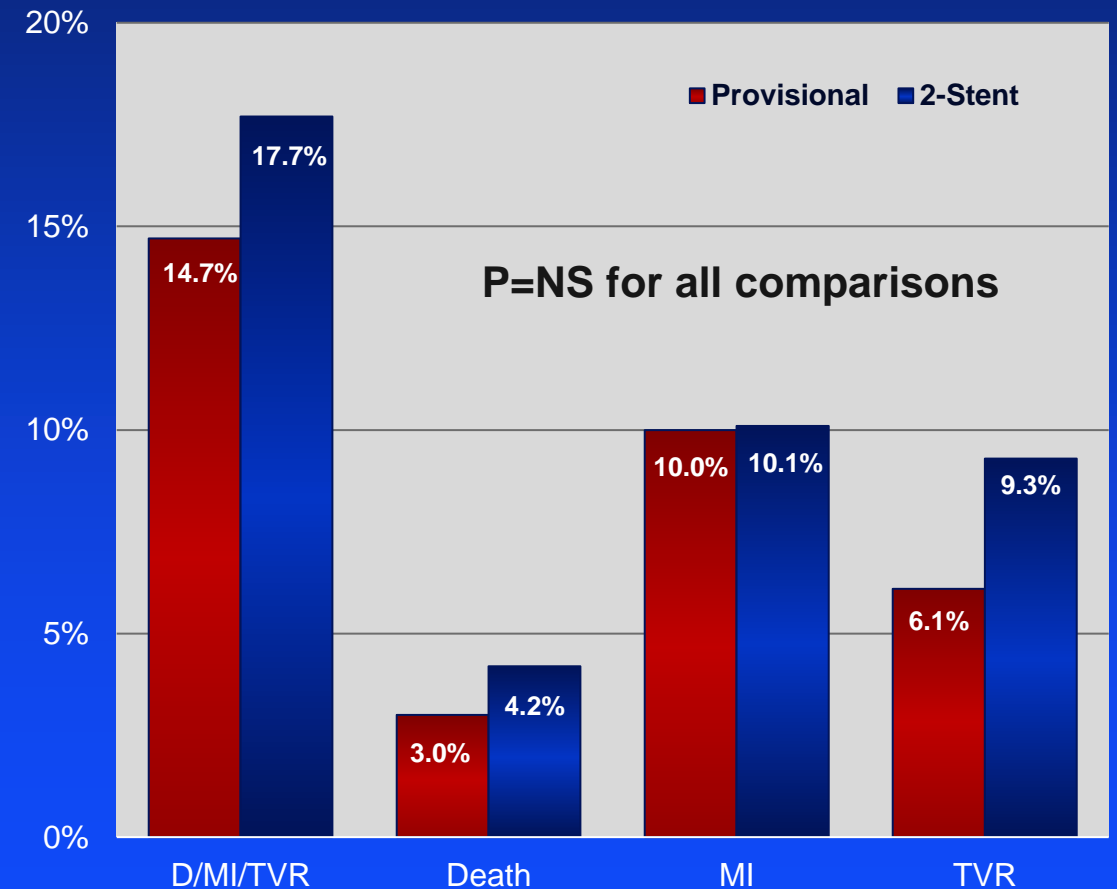
- 467 patients from with true distal LM bifurcation lesions randomized **provisional stenting vs. up-front 2-stent strategy**
- Approach to 2-stent strategy at operator discretion (culotte, T/TAP, DK crush)
- Primary Endpoint: 1-year death, MI, TLR → **patient-centered**
- **No angiographic f/u**

1-Stent vs. 2-Stent Approach: 1-Year Outcomes

DK-CRUSH V



EBC-Main



What *else* should the guidelines have said?

Stent Strategy

- Optimal stent strategy (provisional vs. planned 2-stent approach) remains uncertain
- Choice of strategy should be based on angiographic features (vessel size, sidebranch involvement, lesion length) as well as operator expertise
- Intracoronary imaging should be mandatory both pre and post-stent implantation

Summary

- Revascularization strongly recommended for LM stenosis $\geq 70\%$ (less certain in 50-60% range)
- CABG preferred for patients with high SYNTAX score or LM + 3-vessel dz; PCI reasonable for less complex disease → Heart team discussion and shared decision making reasonable for all patients
- Imaging guidance recommended for all LM PCI
- Mechanical circulatory support rarely needed unless patient also has limited cardiac reserve
- Optimal stent strategy remains uncertain