# Presenter Disclosure Information

**David R. Holmes, Jr., M.D.**

**"PCI vs CABG for Left Main in 2018**
**Expert's View on U.S. Future Guideline Change"**

**The following relationships exist related to this presentation:**

**None**

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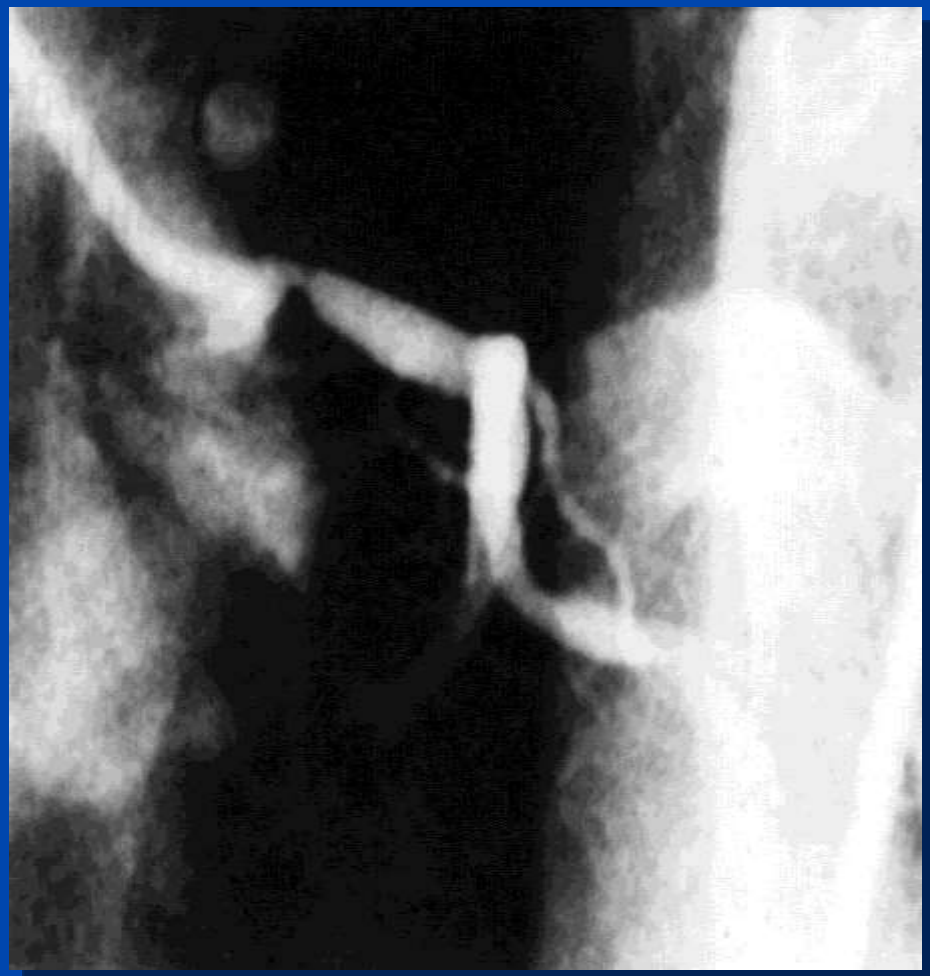
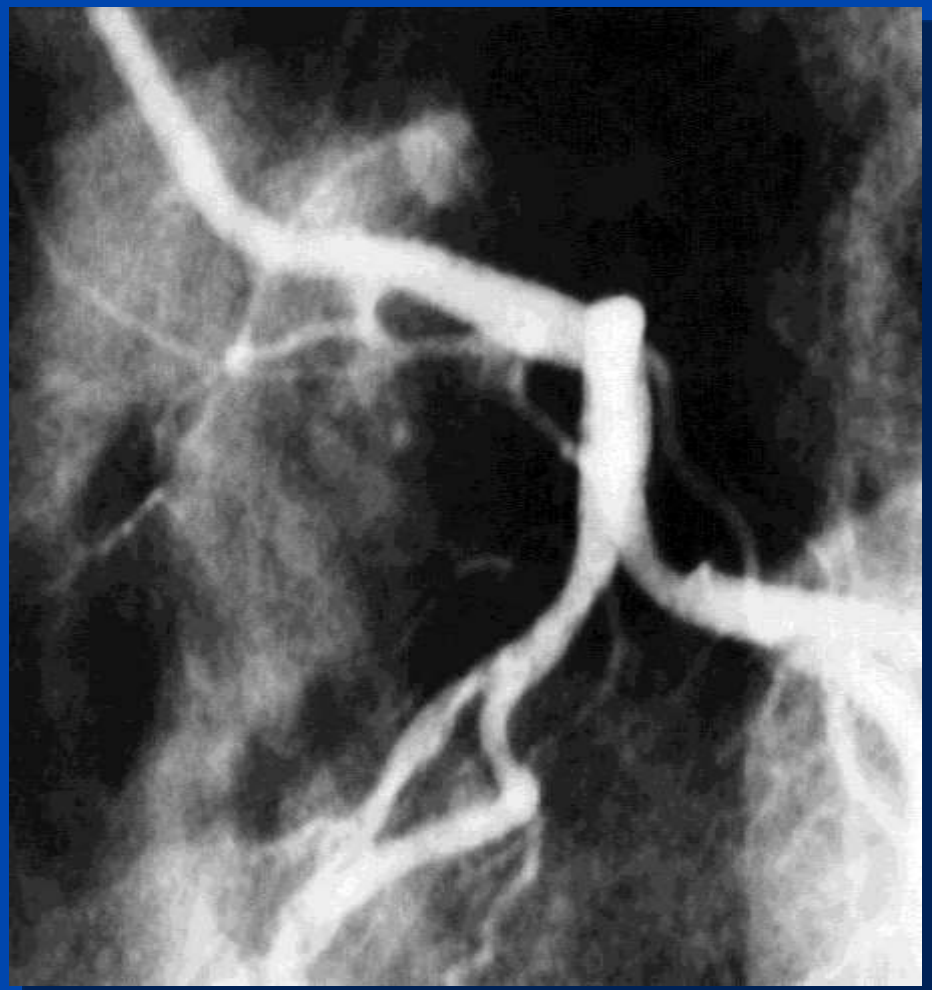
# Plain old PTCA





PTCA, eds Vlietstra and Holmes, 1987



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# Guidelines
## A Work in Progress

- Initial guideline published 1984 - Pacemakers
- Evolution
  - 'Why' → 'How'
- IOM recommendation
  - 'Clinical Practice Guidelines (CPG) are statements that include recommendations intended to optimize patient care that are informed by a systematic review of the evidence and an assessment of the benefits and harms of alternative care options.'

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Jacobs et al: Circulation; doi:10.1161/CIR 2014

# Guidelines
## A Work in Progress

- Class I
  - Strongest, based on size, strength and positive or negative benefit-risk estimate
- Class II
  - A: intermediate strength and less benefit in proportion to risk
  - B: weakest strength, address measures associated with marginal benefits
- Class III
  - No benefit

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# Guidelines
# Class (Strength) of Recommendation

**Class I (Strong) Benefit >>> Risk**

**Suggested phrases for writing recommendations**

- **Is recommended**
- **Is indicated/useful/effective/beneficial**
- **Should be performed/administered/other**
- **Comparative-effectiveness phrases**
  - **Treatment/strategy A is recommended/indicated in preference to treatment B**
  - **Treatment A should be chosen over treatment B**

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# Guidelines
# Class (Strength) of Recommendation

**Class II (Moderate) Benefit >> Risk**

**Suggested phrases for writing recommendations**

- Is reasonable
- Can be useful/effective/beneficial
- Comparative-effectiveness phrases
  - Treatment/strategy A is probably recommended/indicated in preference to treatment B
  - It is reasonable to choose treatment A over treatment B

**Class IIb (Weak) Benefit ≥ Risk**

**Suggested phrases for writing recommendations**

- May/might be reasonable
- May/might be considered
- Usefulness/effectiveness is unknown/unclear/uncertain or not well established

Jacobs et al: Circulation; doi:10.1161/CIR 2014

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# Guidelines
# Class (Strength) of Recommendation

## Class III: No Benefit (Moderate) Benefit = Risk
(generally, LOE A or B use only)

**Suggested phrases for writing recommendations**

- Is not recommended
- Is not indicated/useful/effective/beneficial
- Should not be performed/administered/other

## Class III: Harm (Strong) Benefit > Risk

**Suggested phrases for writing recommendations**

- Potentially harmful
- Causes harm
- Associated with excess morbidity/mortality
- Should not be performed/administered/other

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Jacobs et al: Circulation; doi:10.1161/CIR 2014

 

# Guidelines
# Class (Quality) of Evidence

**Level A**

- High-quality evidence from more than 1 RCTs
- Meta-analysis of high-quality RCTs
- One or more RCTs corroborated by high-quality registry studies

**Level B-R (randomized)**

- Moderate-quality evidence from 1 or more RCTs
- Meta-analysis of moderate-quality RCTs

**Level B-NR (nonrandomized)**

- Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analysis of such studies

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Jacobs et al: Circulation; doi:10.1161/CIR 2014

 

# Guidelines
# Class (Quality) of Evidence

## Level C

- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analysis of such studies
- Physiological or mechanistic studies in human subjects

## Level E

Consensus of expert opinion based on clinical experience when evidence is insufficient, vague, or conflicting

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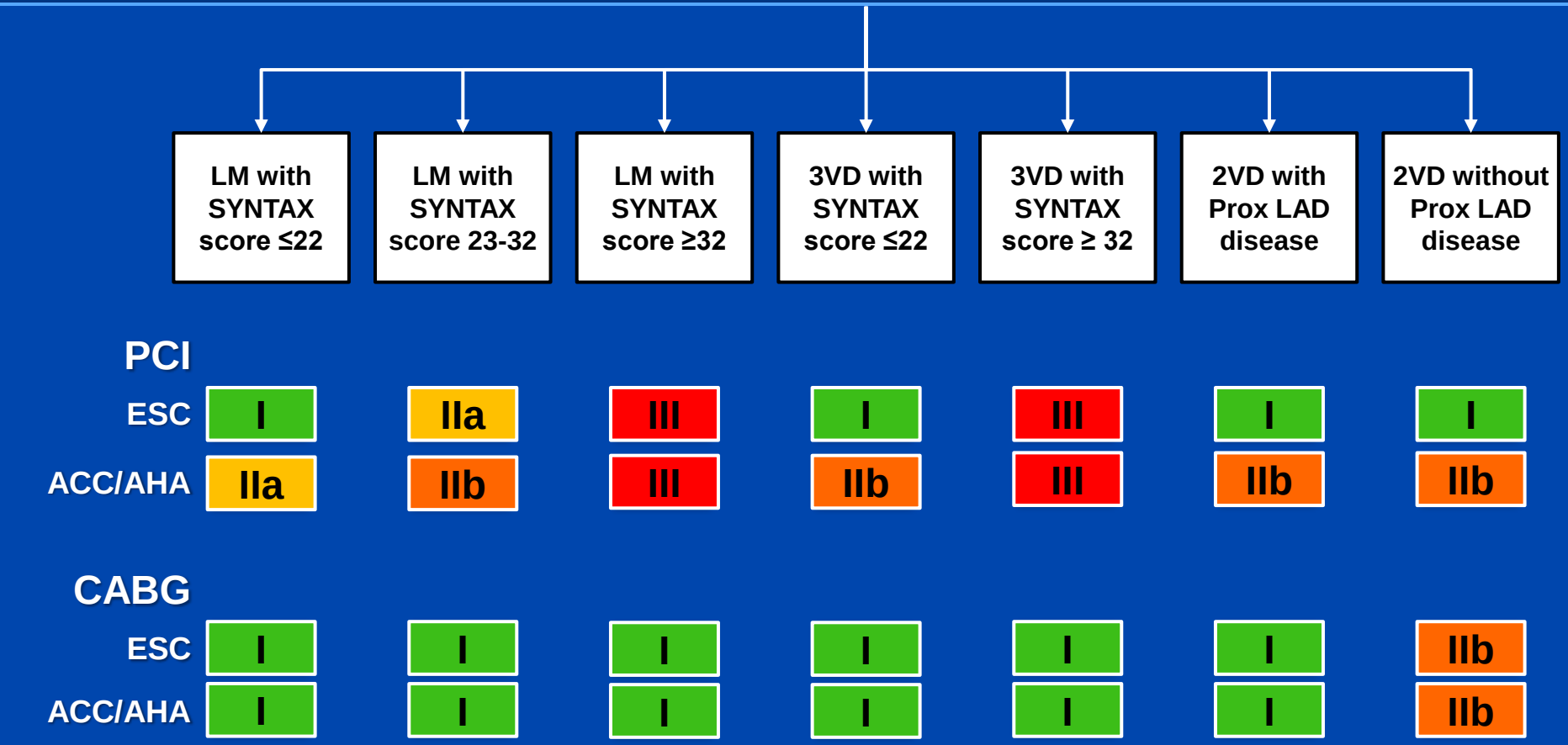
# Guideline Recommended Revascularization Techniques in Coronary Artery Disease for Amenable Patients to Both Strategies

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# PCI vs CABG
## Systematic Review & Meta-Analysis

- SYNTAX
- PRECOMBAT
- EXCEL
- NOBLE

4,394 patients with clinical follow-up of ≥3 years

- Objective
  - Compare long-term safety
  - DES vs CABG
  - Primary endpoint – all-cause death, MI, stroke

Giacoppo et al: JAMA Cardiol, 2017;2:1079-88

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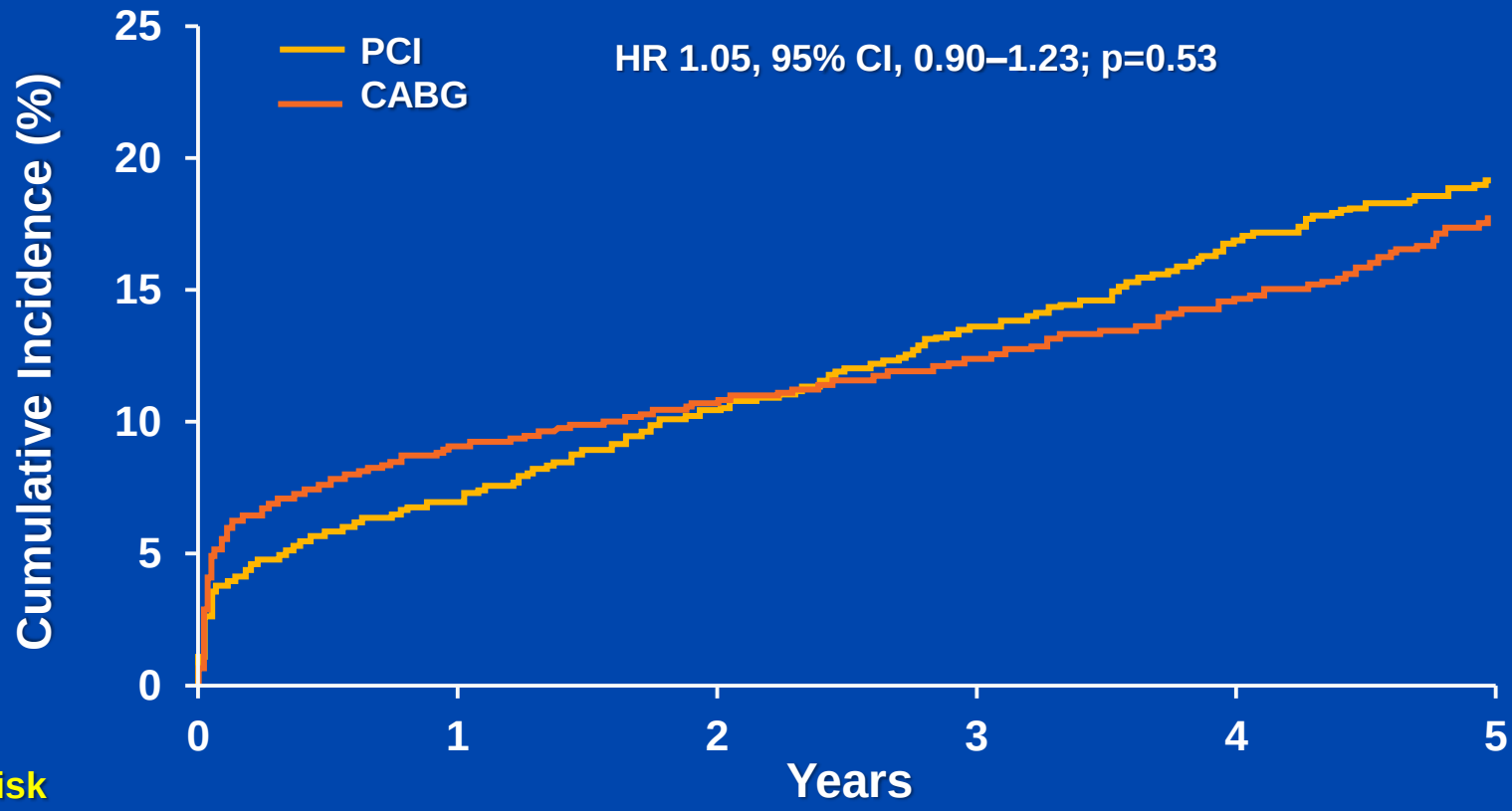
# PCI vs CABG for LMCA

## MACCE Endpoints




**No. at risk**

| | | | | | | |
|---|---|---|---|---|---|---|
| PCI | 2197 | 1993 | 1817 | 1419 | 778 | 680 |
| CABG | 2197 | 1939 | 1772 | 1368 | 746 | 631 |

In Kaplan-Meier analysis, cumulative incidence across the 5 years of follow-up did not show significant difference between techniques.

Giacoppo et al. JAMA Cardiol. 2017;2(10):1079-1088.

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# PCI vs CABG
## Systematic Review & Meta-Analysis

- **Discussion: The main finding of this meta-analysis is that, in patients with significant LMCA stenosis, both PCI with DESs and CABG are associated with a comparable risk of all-cause death, myocardial infarction, or stroke at long-term follow-up. Cumulative Kaplan-Meier curve reconstruction did not show significant differences over time, and long-term safety was acceptable with both PCI and CABG. The risk of repeat revascularization is the most important difference between techniques, with a higher risk for PCI at long-term follow-up compared with CABG.**

Giacoppo et al: JAMA Cardiol, 2017;2:1079-88

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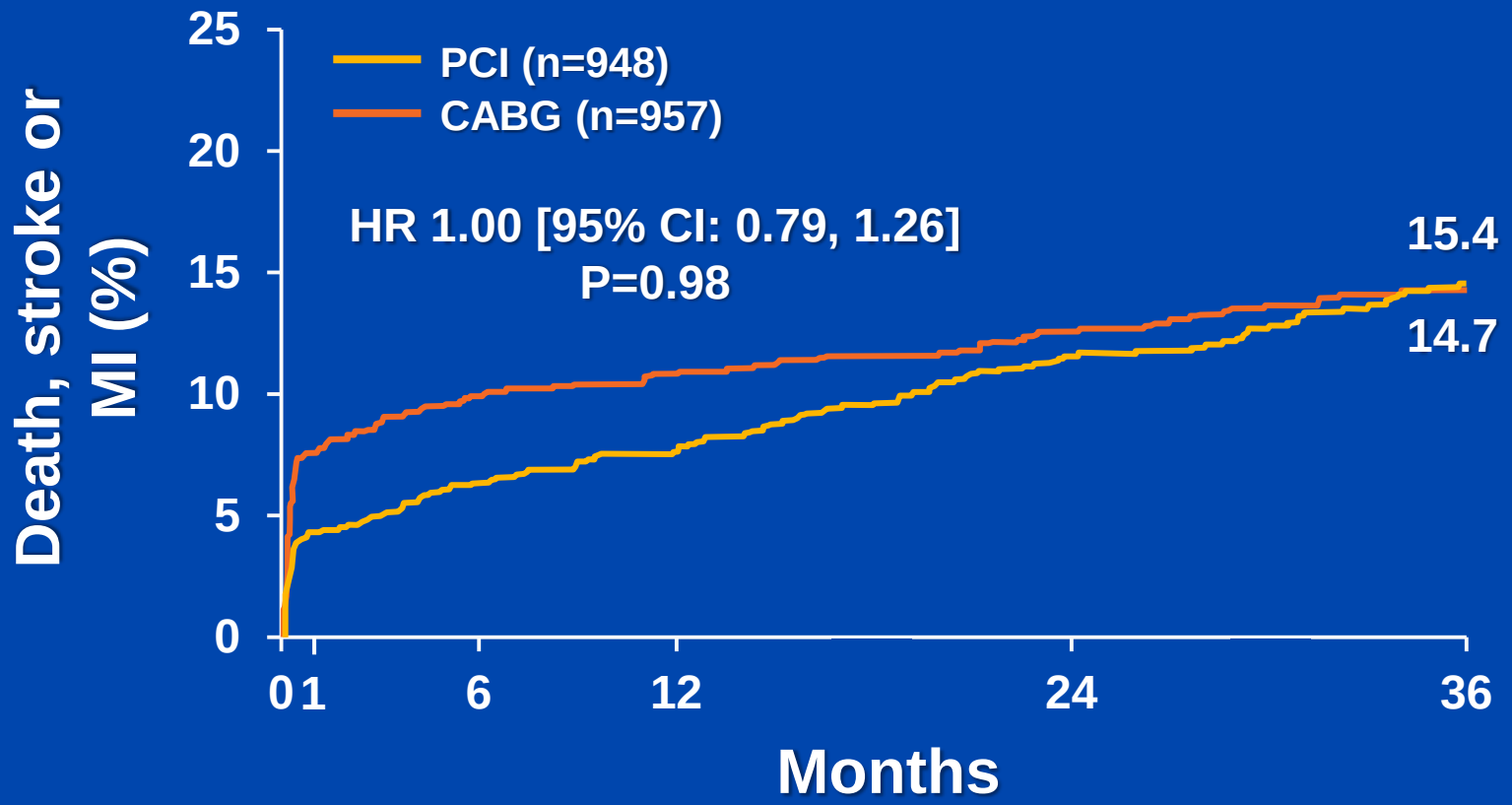
# EXCEL
## Death, MI, or Stroke at 3 Years




| No. at risk | | | | | | |
|---|---|---|---|---|---|---|
| PCI | 948 | 896 | 875 | 850 | 784 | 445 |
| CABG | 957 | 868 | 836 | 817 | 763 | 458 |

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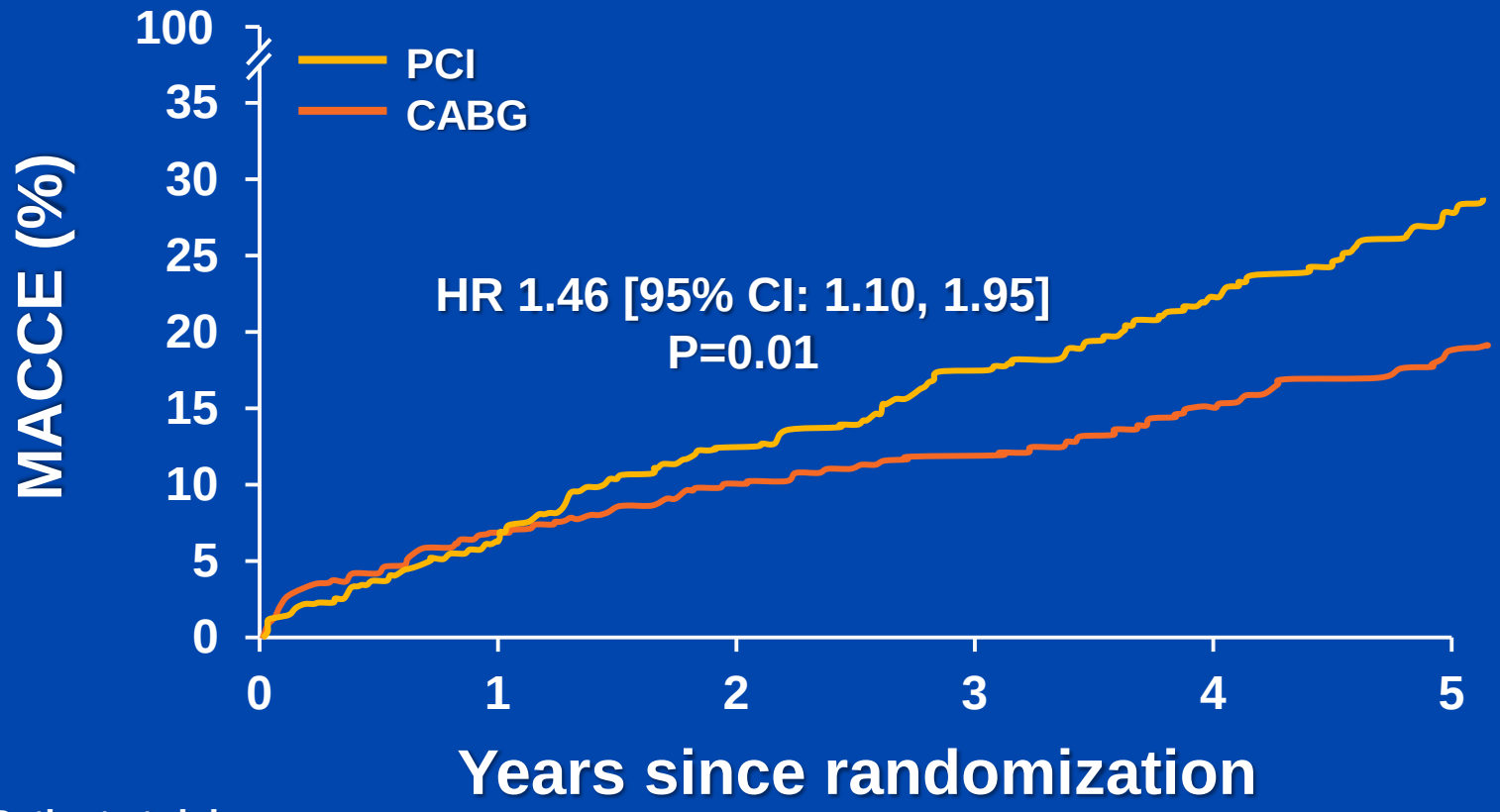
# NOBLE

## Death, non-procedural MI, Stroke, or RR




| Patient at risk | | | | | | |
|---|---|---|---|---|---|---|
| PCI | 592 | 539 | 442 | 313 | 227 | 127 |
| CABG | 592 | 536 | 440 | 319 | 219 | 129 |

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# PCI vs CABG:
# Where are we after NOBLE & EXCEL


## Summary

The generalizability of these trials is limited by the use of young, healthy patients at highly skilled centers that rarely reflect typical clinical practice. If these studies are to maintain relevance, trialists must address the lack of protocolization of surgical interventions and inconsistent medical therapies. Unfortunately, the limitations of NOBLE and EXCEL mean that we are no closer to answering the question of what is the optimal treatment for patients with LMCAS.


Fortier et al: Curr Opinion Cardiol 32:699-706, 2017

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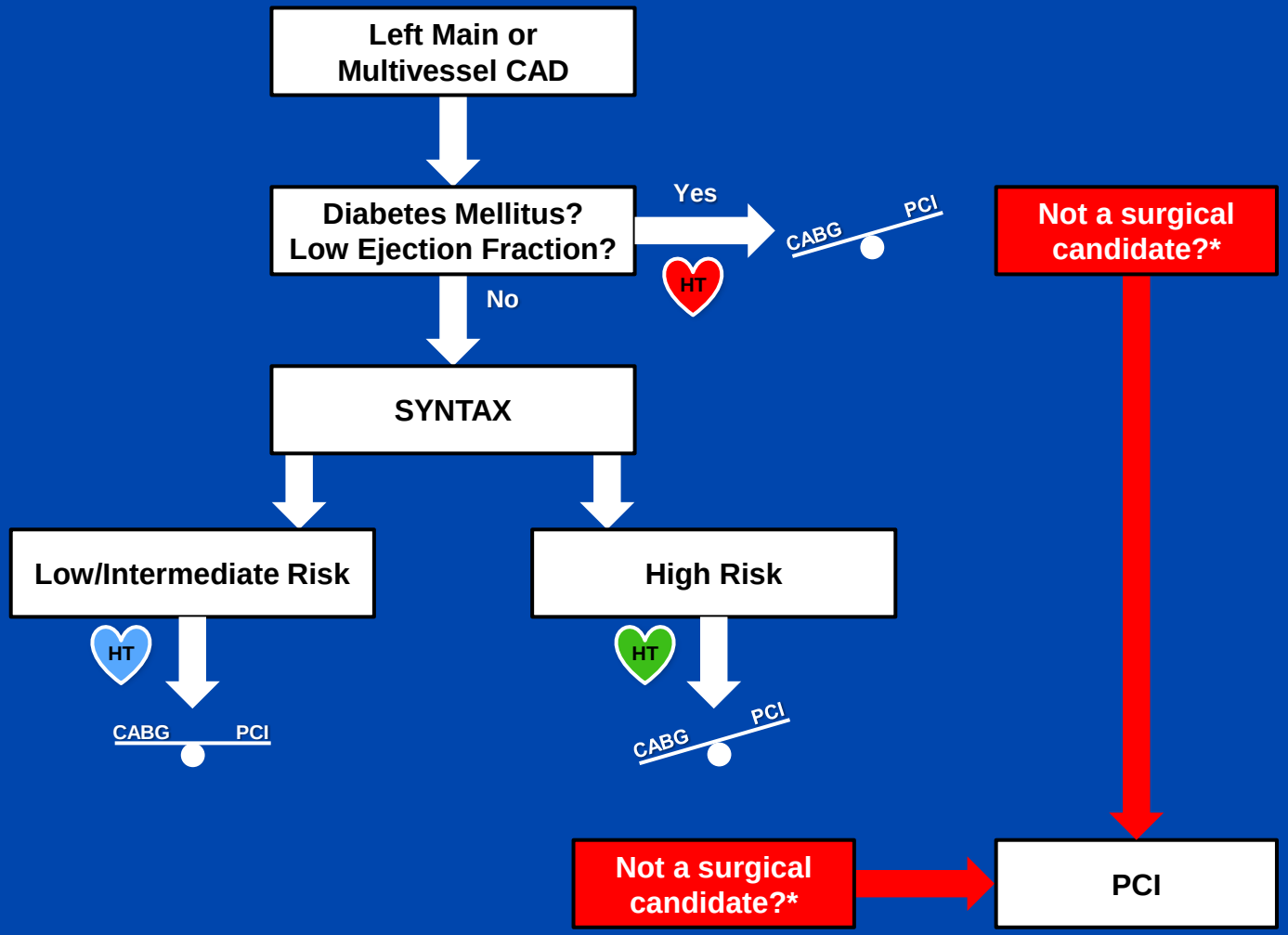


HT: Heart Team Discussion

HT CABG has clear survival benefit with slight increased risk of stroke in diabetes. Low EF-CABG showed improved survival- never studied in PCI

HT Similar composite endpoint of death, MI and stroke between CABG and PCI

HT CABG has potential survival benefit, lower repeat revascularization, MI at the expense of longer perioperative recovery time and stroke

*Not a surgical candidate due to high risk of surgery using conventional scores, comorbidities that portend >5% risk of operative mortality, frailty, or patient refusing surgery

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