OCTIVUS Trial

Do-Yoon Kang, MD

Division of Cardiology, Asan Medical Center,

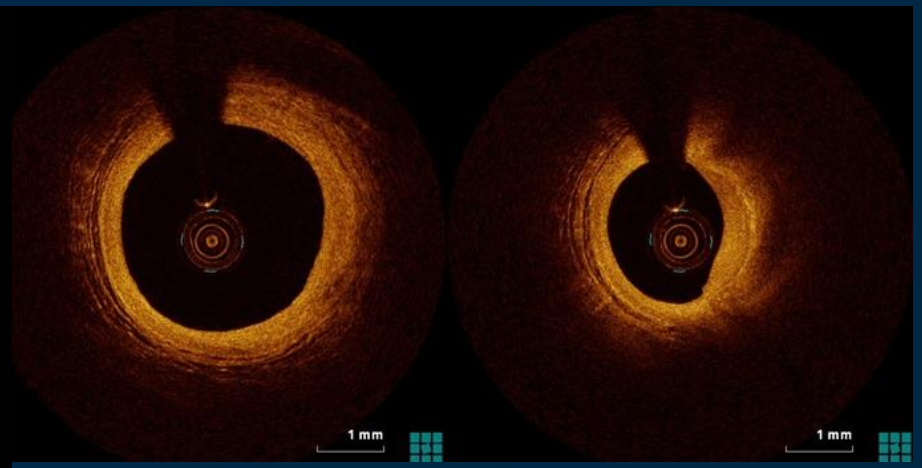
University of Ulsan College of Medicine, Seoul, Korea

Disclosure

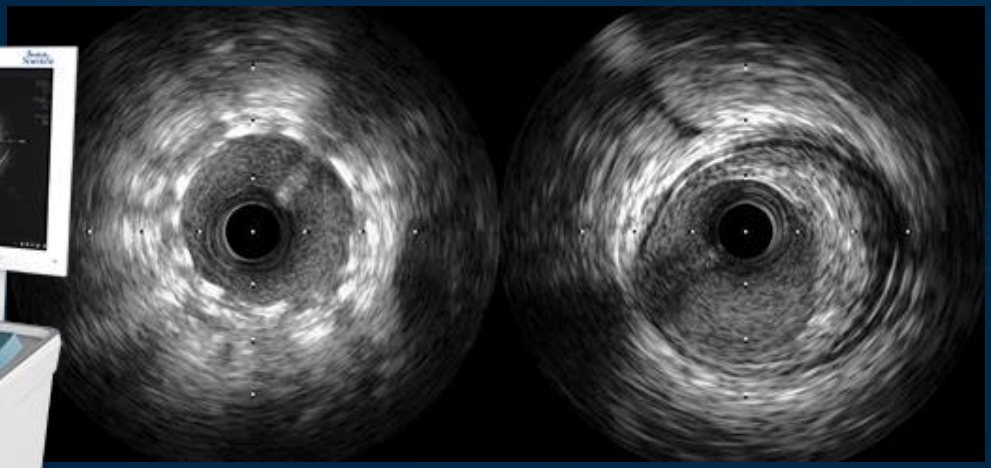
- I, Do-Yoon Kang, DO NOT have a conflict of interest related to this presentation.

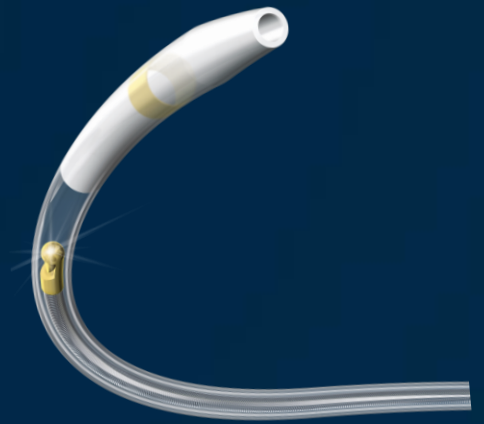
Intracoronary Imaging for PCI Guidance

Optical Coherent Tomography



Intravascular Ultrasound





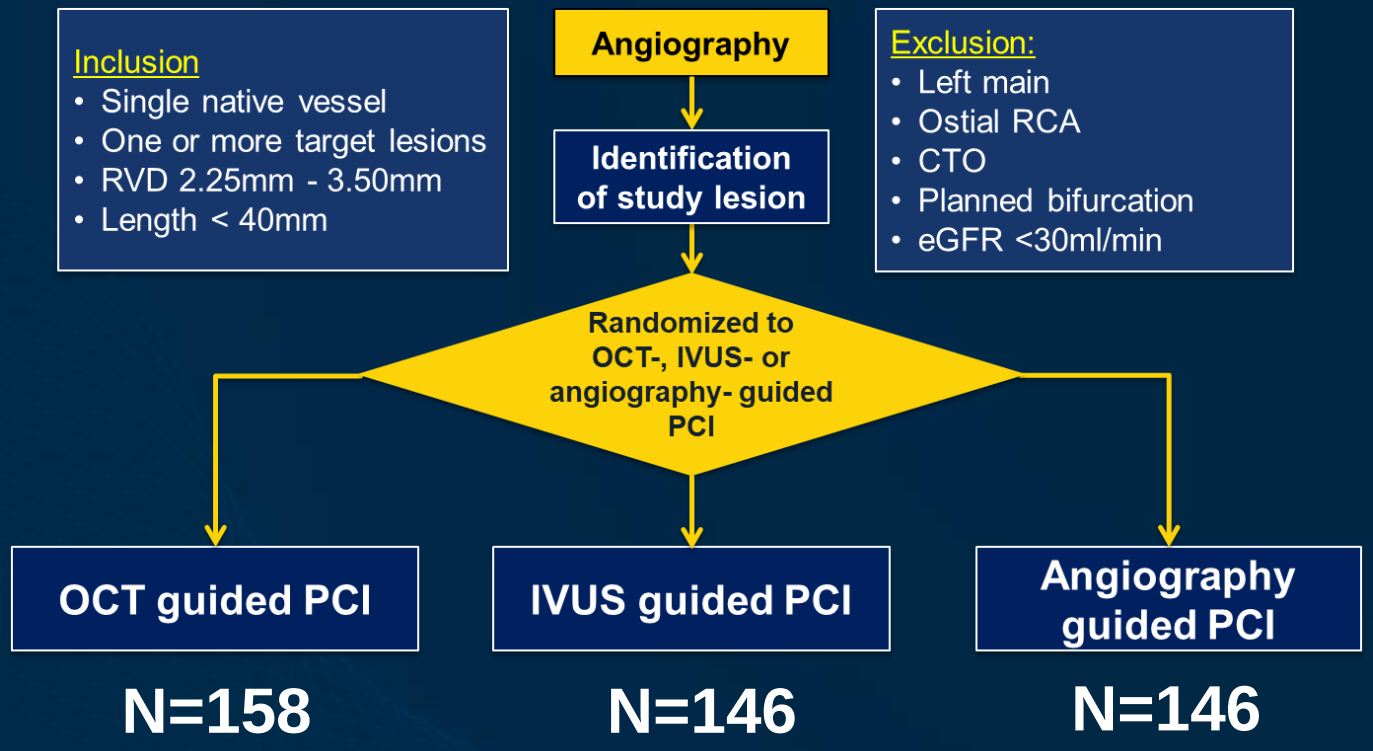
2021 ACC/AHA PCI Guideline for Intracoronary Imaging

	COR	LOE
➢ In patients undergoing coronary stent implantation, IVUS can be useful for procedural guidance, particularly in cases of left main or complex coronary artery stenting, to reduce ischemic events	IIa	B-R
➢ In patients undergoing coronary stent implantation, OCT is a reasonable alternative to IVUS for procedural guidance, except in ostial left main disease	IIa	B-R
➢ In patients with stent failure, IVUS or OCT is reasonable to determine the mechanism of stent failure	IIa	C

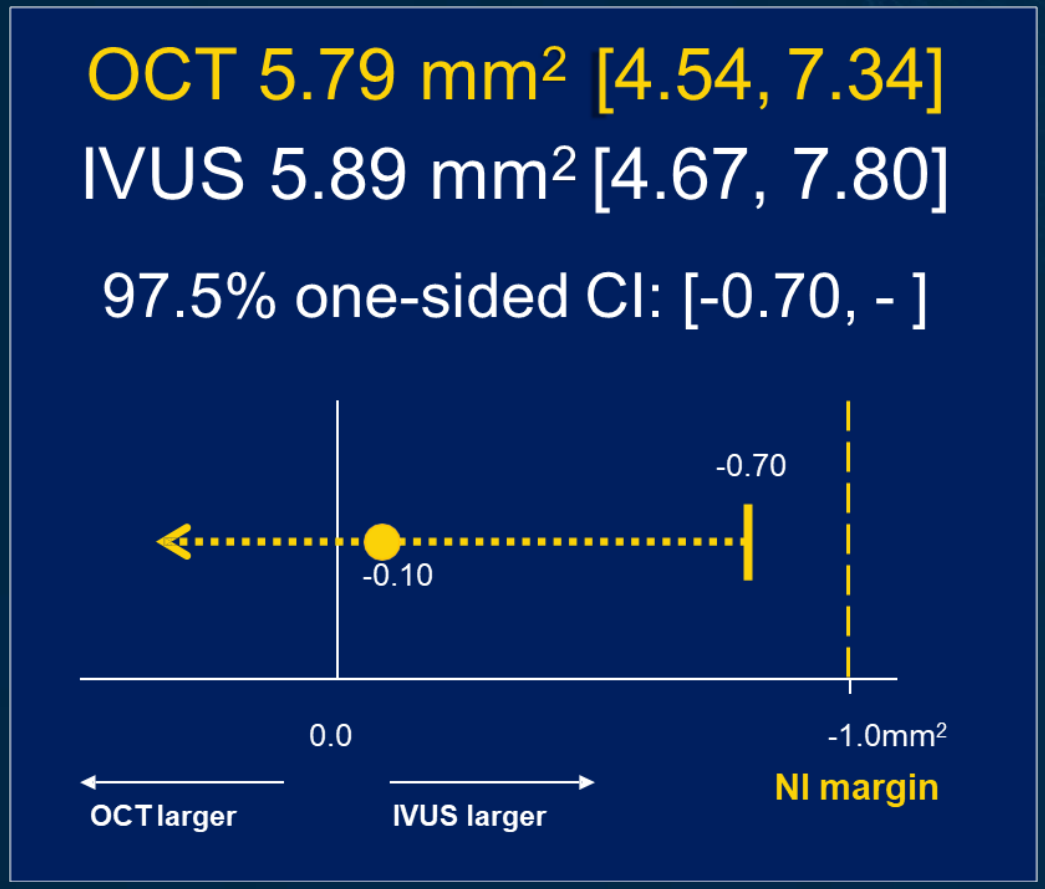
Lawton JS et al. JACC 2021.

RCT of OCT vs. IVUS for PCI Guidance (1)

ILUMIEN III – OPTIMIZE PCI



Primary endpoint : Final post-PCI MSA by OCT



Ali ZA et al. Lancet 2016:388;2618-28

$P_{noninferiority} = 0.001$

RCT of OCT vs. IVUS for PCI Guidance (2)

Exclusion:
- 3VD, LM, Ostial, CTO, graft, ISR,
- CHF, eGFR <30

OPINION

Patients scheduled for PCI using DES
Jun 2013 – Jul 2014, n = 800

1:1

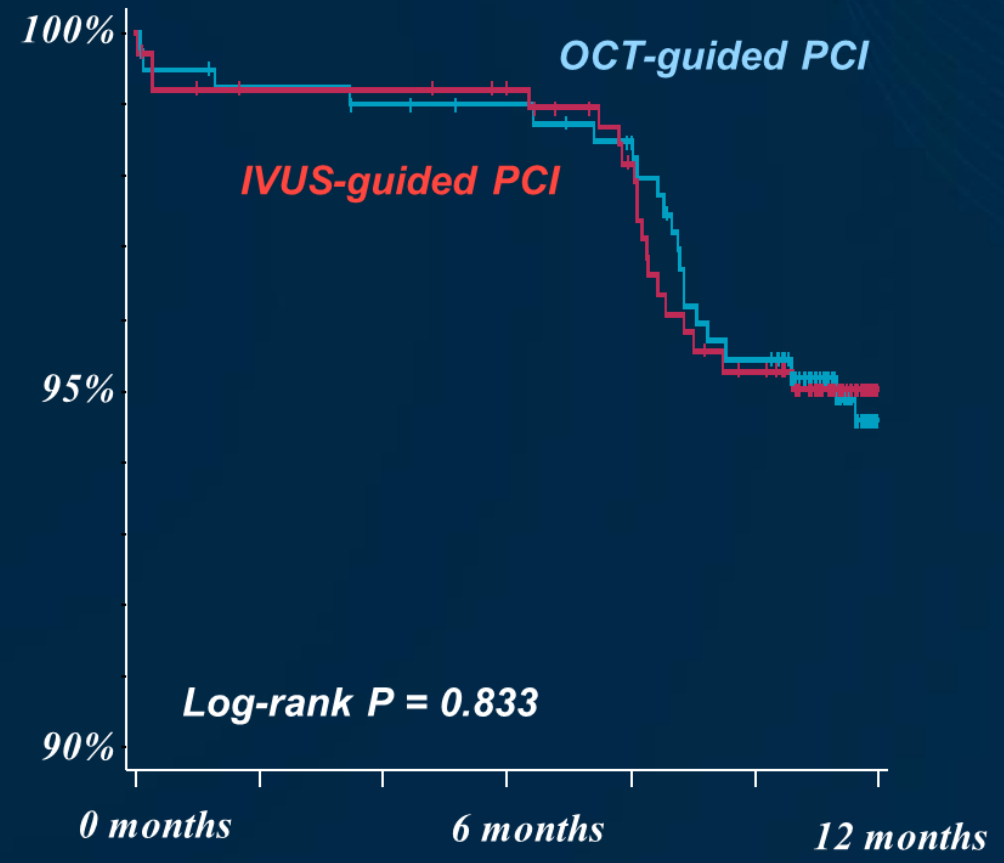
OCT-guided PCI
n = 400

IVUS-guided PCI
n = 400

8 months: Follow-up coronary angiography

12 months: Clinical follow-up

Primary endpoint
: Target Vessel Failure at 12 mo



Kubo T et al., Eur Heart J 2017:38;3139-47

$P_{noninferiority} < 0.05$

RCT of OCT vs. IVUS for PCI Guidance (3)

Exclusion:
- LM, CTO, ISR Bifurcation, Long, Calcification
- Recent ACS, HF, eGFR <45

MISTIC-1

Patients scheduled for PCI using DES*
Jun 2014 – Aug 2016, n = 109

1:1

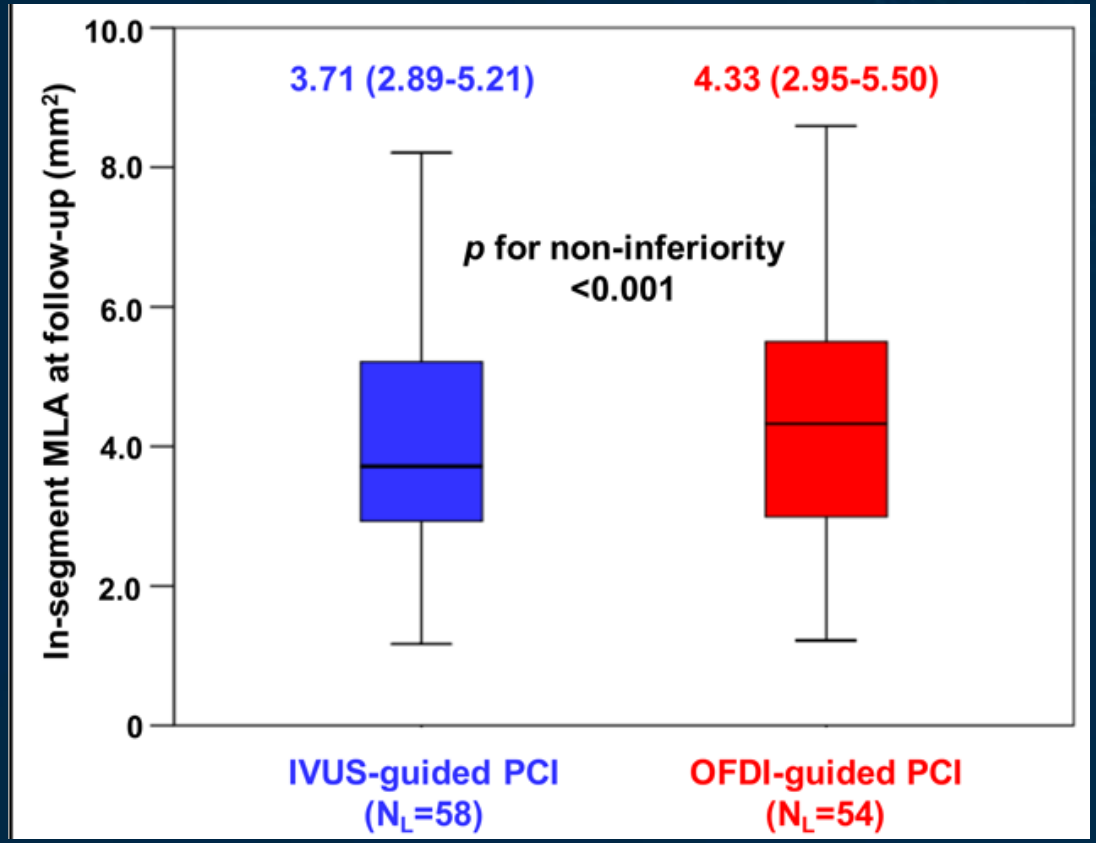
OCT-guided PCI
n = 54

IVUS-guided PCI
n = 55

8 months: Follow-up coronary angiography

36 months: Clinical follow-up

Primary endpoint
: In-segment MLA by OCT at 8 mo



Muramatsu T et al., Circ CV Interv 2020:13;e009314

$P_{noninferiority} < 0.001$

Limitations of Prior 3 RCTs

- **Relatively small number of participants**
  - 158 (ILUMIEN-3), 400 (OPINION), 54 (MISTIC-3) in OCT group
  - Underpowered for clinical outcome

- **Complex lesions were excluded**
  - LM or 3VD, Ostial lesion, CTO, In-stent restenosis, bypass graft

- **Follow-up angiography was performed (OPINION, MISTIC-3)**

OCT-guidance vs. IVUS-guidance for All-comer (including Complex) PCI, Which is better ?

OCTIVUS Trial

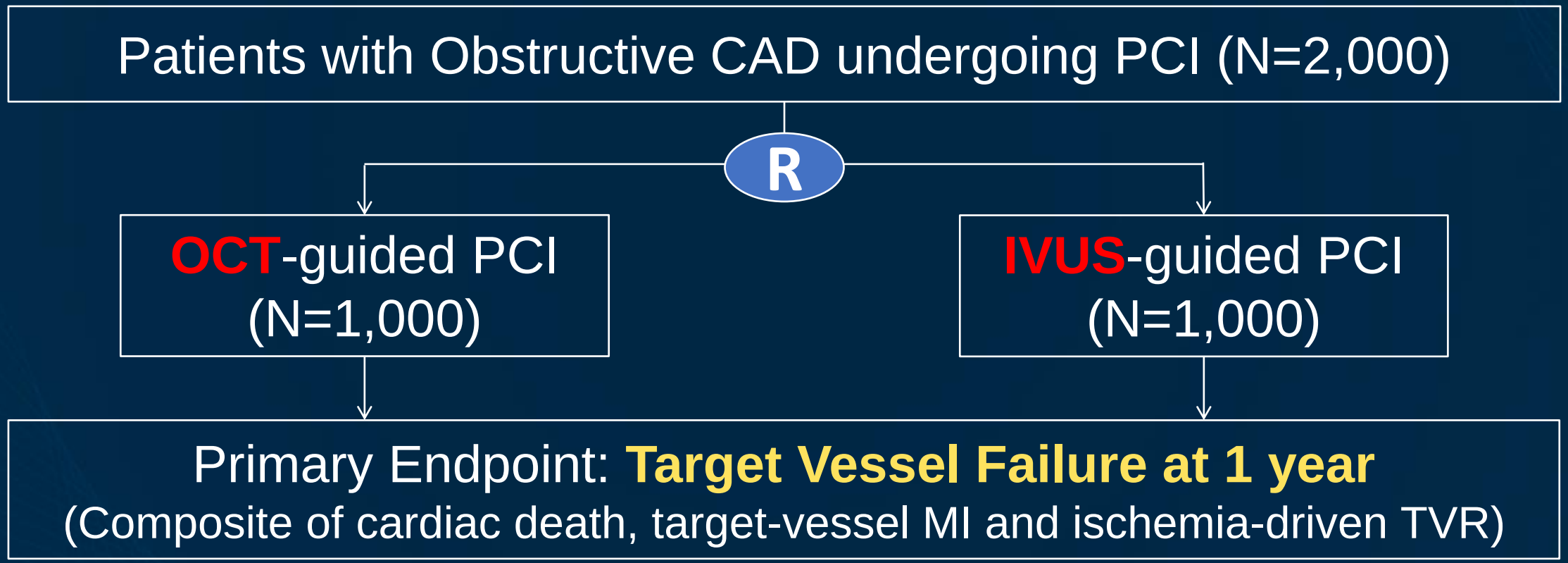
Optical Coherence Tomography-versus IntraVascular UltraSound-Guided Percutaneous Coronary Intervention

Seung-Jung Park (Trial Chair)
Heart Institute, Asan Medical Center,
University of Ulsan College of Medicine, Seoul, Korea

https://clinicaltrials.gov/ct2/show/NCT03394079

Optical Coherence Tomography versus Intravascular Ultrasound Guided Percutaneous Coronary Intervention

OCTIVUS Trial



Kang DY et al. Am Heart J. 2020 Oct;228:72-80.

Study Overview

- Investigator-initiated, prospective, multicenter, pragmatic, randomized, open-label trial conducted at 9 sites in South Korea since Apr 2018

- **Study Hypothesis**
  - OCT-guided PCI is **noninferior** to IVUS-guided PCI with respect to target-vessel failure (cardiac death, target-vessel MI, or ischemia-driven target-vessel revascularization) at 1 year.

Kang DY et al. Am Heart J. 2020 Oct;228:72-80.

Study Participants

- **Inclusion Criteria**
  - Patients at least 19 years old
  - Subjects with obstructive CAD undergoing PCI under intravascular imaging guidance

- **Exclusion Criteria**
  - STEMI
  - Severe renal dysfunction (eGFR <30 mL/min/1.73 m^2) without renal replacement therapy
  - Cardiogenic shock or decompensated HF with severe LV dysfunction (LV EF<30%)
  - Life expectancy < 1 year
  - Lesion characteristics with expected inability to deliver the imaging catheter

Kang DY et al. Am Heart J. 2020 Oct;228:72-80.

Study Procedure

- **Randomization in a 1:1 ratio to OCT or IVUS-guided PCI**
  - Interactive web response system by use of computer-generated random sequence
  - Permutated block size of 4 or 6 stratified by the participating site

- **PCI Procedure**
  - OCT or IVUS can be used before, during, and immediately after PCI.
  - PCI was guided by real-time online evaluation of OCT or IVUS.
  - PCI procedure is performed using standard technique without restriction of catheters, wires, balloons, and stents used.

Kang DY et al. Am Heart J. 2020 Oct;228:72-80.

Practical Recommendation for PCI Optimization

- “Pragmatic”
- Distal lumen reference-based (mean distal lumen diameter with up-rounding of stent size [0–0.25 mm]) or EEM reference-based (mean EEM with down-rounding of stent diameter to the nearest 0.25 mm) sizing strategy is recommended
- Avoidance of a landing zone in a plaque burden >50% and particularly lipid-rich tissue at the stent edge
- Co-registration of angiography and OCT / IVUS for determining stent length and precise stent placement
- A relative stent expansion of >80% (MSA divided by average reference lumen area) as an optimization criteria

Kang DY et al. Am Heart J. 2020 Oct;228:72-80.

Primary Endpoint

- **Target Vessel Failure at 1 year**
  - A composite of Cardiac Death, Target Vessel-related MI, and Ischemia-driven Target Vessel Revascularization

  - Periprocedural MI by SCAI definition
  - MI events will be also evaluated with the 4th UDMI and ARC-2 definition.

  - Clinical endpoints are adjudicated by independent events adjudication committee.

  - Extended long-term follow-up at 3 and 5 years is also planned.

Kang DY et al. Am Heart J. 2020 Oct;228:72-80.

Sample Size Calculation

- **Hypothesis**: OCT is **non-inferior** to IVUS (Conditional test for superiority)
  - We assumed the incidence of the TVF at 1 year to be 8.0% in the IVUS-guided PCI group.
  - Non-inferiority margin of 3.1% was chosen, which represented 39% of the expected percentage of patients with an event.
  - A sample of 964 patients in each group would provide more than 80% of power with one-sided type I error of 0.05.
  - Under an assumption that 3% of the patients would be lost to follow-up, a total of 2,000 patients was deemed to be sufficient to evaluate the primary endpoint.

Kang DY et al. Am Heart J. 2020 Oct;228:72-80.

Statistical Analysis

- All principal analyses will be performed in the **intention-to-treat** population.
- Sensitivity analysis will be also performed on a per-protocol and as-treated basis.
- Subgroup analyses of the primary and secondary end points will be performed for age, sex, ACS, DM, renal function, LV EF, and lesion characteristics like left main, bifurcation, and multivessel disease.

Kang DY et al. Am Heart J. 2020 Oct;228:72-80.

Source of Funding

- CardioVascular Research Foundation (Seoul, Korea)
- Abbott Vascular (Santa Clara, CA, USA)
- Medtronic (Santa Rosa, CA, USA)

- Other than financial sponsorship, the company has no role in protocol development or the implementation, management, data collection, and analysis of this study.

Kang DY et al. Am Heart J. 2020 Oct;228:72-80.

Current Status

- A total of 2,008 patients were randomized from Apr 2016 through Jan 2022.
- About 99% of enrolled patients completed 1-year clinical follow-up.

Conclusion

- The OCTIVUS trial is an investigator-initiated, multicenter, open-label, pragmatic RCT to compare the efficacy and safety of OCT- versus IVUS-guided PCI strategies in patients receiving PCI in daily clinical practice.

- The primary results will be available this year. The OCTIVUS will provide compelling evidence regarding the comparative efficacy of OCT and IVUS in optimizing PCI in terms of relevant clinical endpoints.