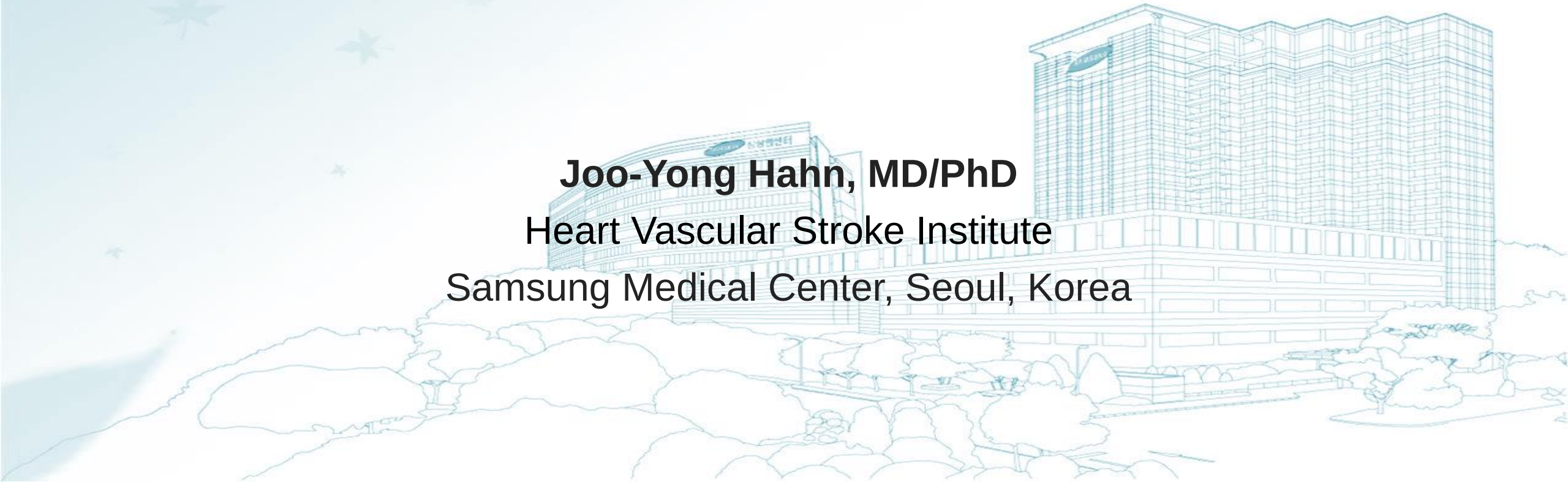
Samsung Medical Center
Sungkyunkwan University
School of Medicine

# Lesson from the Latest OCT Clinical Trials



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# Disclosure

## Grant support

- National Evidence-based Healthcare Collaborating Agency, Ministry of Health & Welfare, Republic of Korea
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- Abbott Vascular, Amgen, Astra Zeneca, Biosensors, Biotronik, Boston Scientific, Daiichi Sankyo, MSD Korea, Novartis, Pfizer, and Sanofi-Aventis

# Guidelines for Coronary Artery Revascularization

## 2021 ACC/AHA/SCAI

| COR | LOE | Recommendations |
|---|---|---|
| 2a | B-R | 1. 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.[1-10] |
| 2a | B-R | 2. In patients undergoing coronary stent implantation, OCT is a reasonable alternative to IVUS for procedural guidance, except in ostial left main disease.[11-13] |
| 2a | C-LD | 3. In patients with stent failure, IVUS or OCT is reasonable to determine the mechanism of stent failure.[14-17] |

## 2018 ESC/EACTS

| Recommendations | Class[a] | Level[b] |
|---|---|---|
| IVUS or OCT should be considered in selected patients to optimize stent implantation.[603,612,651–653] | IIa | B |
| IVUS should be considered to optimize treatment of unprotected left main lesions.[35] | IIa | B |

A randomized trial with adequate sample size is needed to confirm the benefit of intravascular imaging-guided PCI in patients with complex coronary artery lesions.

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  - 1,620 patients with complex lesions
- ILUMIEN IV (N Engl J Med 2023)
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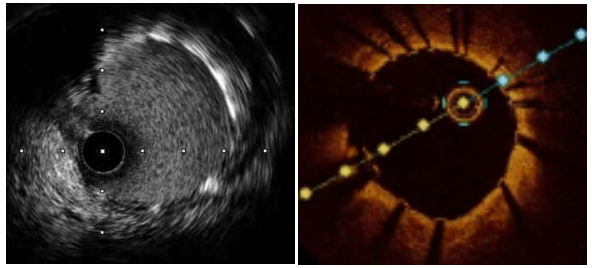
# Study Design

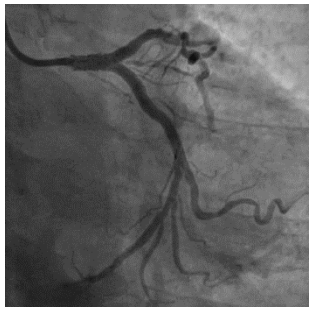
## RENOVATE-COMPLEX-PCI (NCT03381872)

An investigator-initiated, prospective, multicenter, randomized, open-label trial at 20 sites in Korea

**Patients with Complex Coronary Artery Lesions Undergoing PCI**



**Randomization (2:1) for Treatment Strategy of Target Lesions**



**Imaging-Guided Strategy**

**Angiography-Guided Strategy**

For patients who had been assigned to the intravascular imaging group, the choice of IVUS or OCT was made at the operators' discretion.
Primary end point: target vessel failure (a composite of cardiac death, target vessel-related MI, or clinically-driven TVR)

# Inclusion and Exclusion Criteria

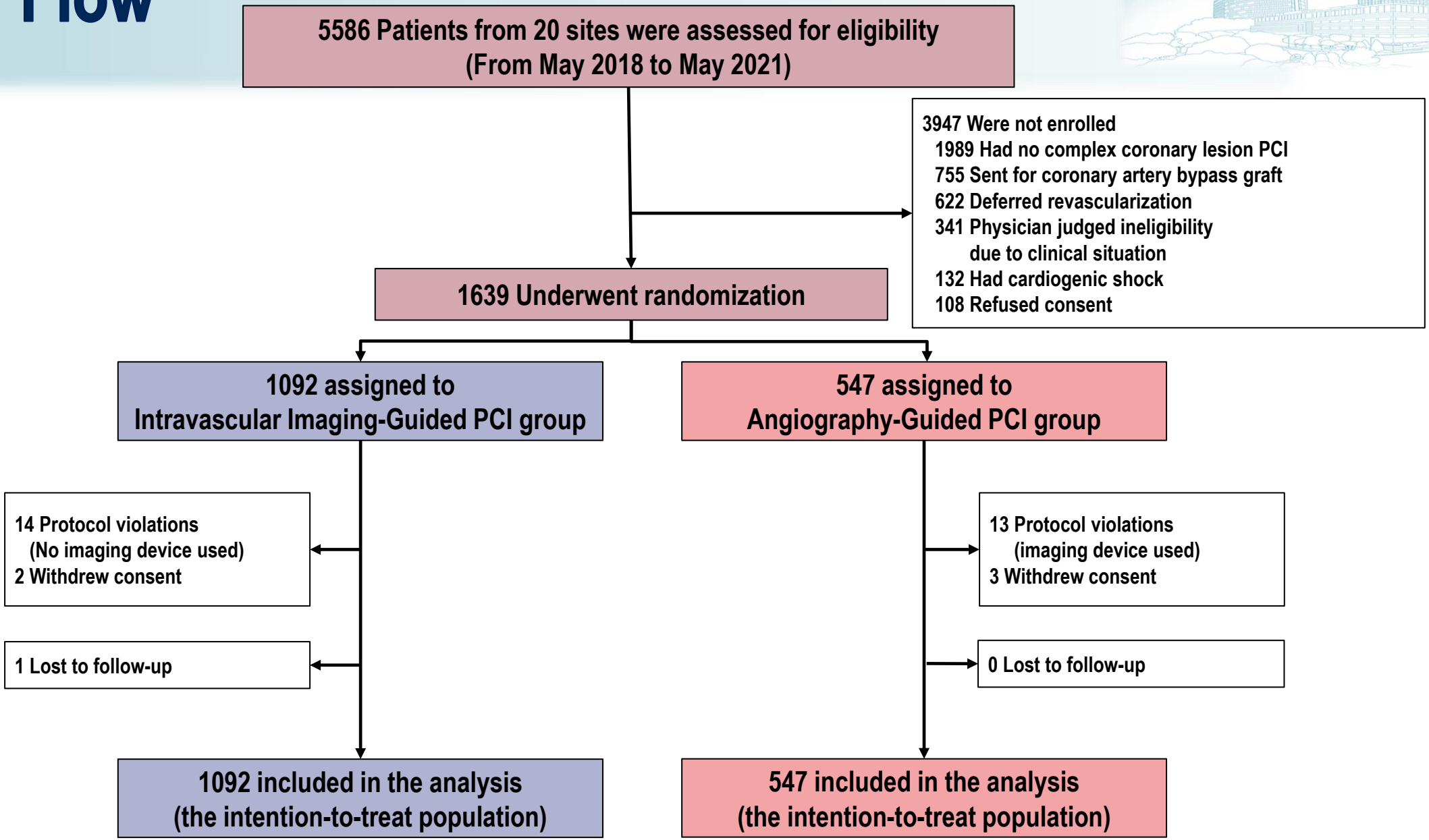
## INCLUSION

1. Patients (≥ 19 years) with coronary artery disease requiring PCI
2. Patients with a **complex coronary artery lesion** defined as:
   - True bifurcation lesion (Medina 1,1,1/1,0,1/0,1,1) with side branch ≥2.5mm
   - Chronic total occlusion (≥3 months) as target lesion
   - Unprotected LM disease PCI (LM ostium, body, distal LM bifurcation including non-true bifurcation)
   - Long coronary lesions (implanted stent ≥38 mm in length)
   - Multi-vessel PCI (≥2 vessels treated at one PCI session)
   - Multiple stents needed (≥3 more stent per patient)
   - In-stent restenosis lesion as target lesion
   - Severely calcified lesion (encircling calcium in angiography)
   - Ostial coronary lesion (LAD, LCX, RCA)

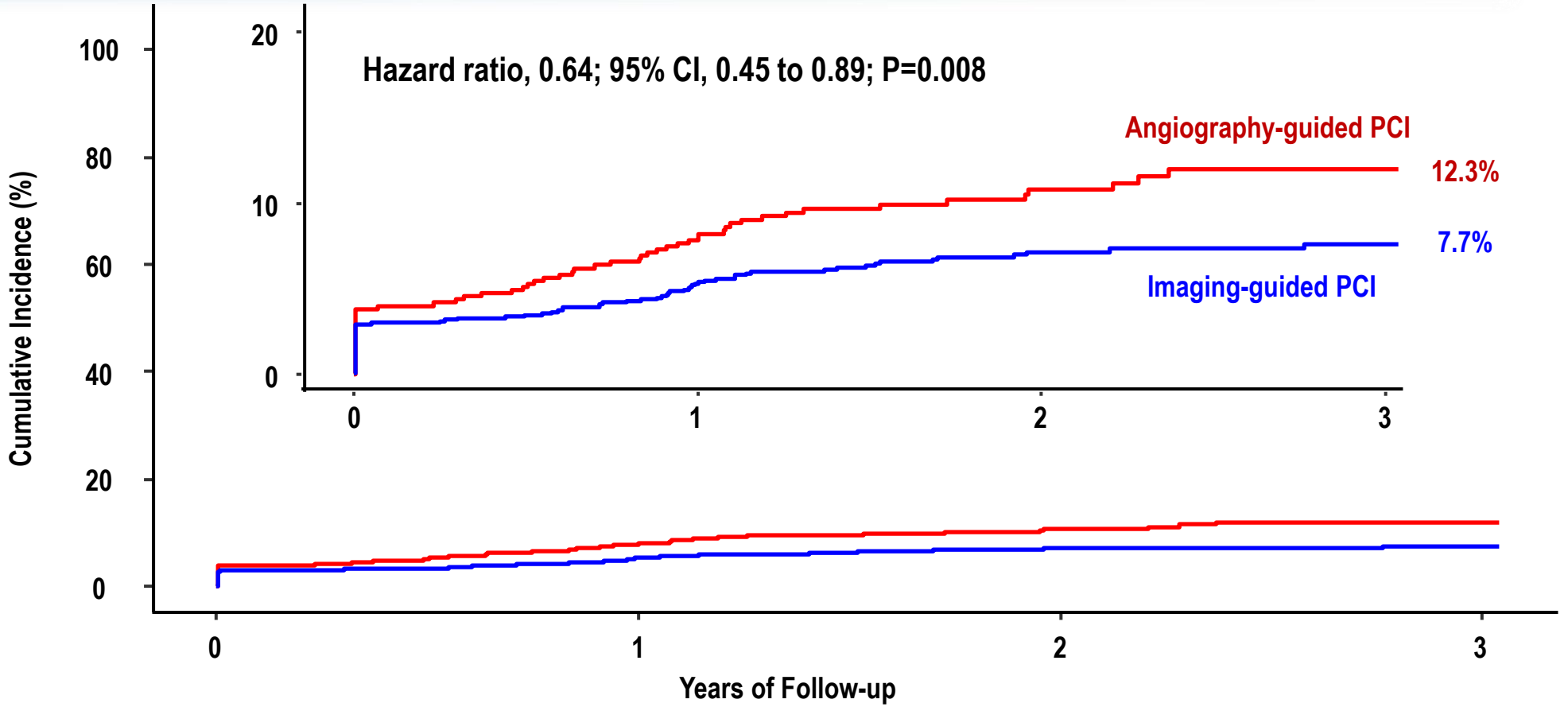
## KEY EXCLUSION

1. Target lesions not amenable to PCI by operators' decision
2. Cardiogenic shock (Killip class IV) at presentation
3. Intolerance to Aspirin, Clopidogrel, Prasugrel, Ticagrelor, Heparin, or Everolimus
4. Known true anaphylaxis to contrast medium (not allergic reaction but anaphylactic shock)
5. Pregnancy or breast feeding
6. Non-cardiac co-morbid conditions are present with life expectancy <1 year or that may result in protocol non-compliance (per site investigator's medical judgment)
7. Unwillingness or inability to comply with the procedures described in this protocol.

# Study Flow


5586 Patients from 20 sites were assessed for eligibility
(From May 2018 to May 2021)
3947 Were not enrolled
1989 Had no complex coronary lesion PCI
755 Sent for coronary artery bypass graft
622 Deferred revascularization
341 Physician judged ineligibility
due to clinical situation
132 Had cardiogenic shock
108 Refused consent
1639 Underwent randomization
1092 assigned to
Intravascular Imaging-Guided PCI group
547 assigned to
Angiography-Guided PCI group
14 Protocol violations
(No imaging device used)
2 Withdrew consent
1 Lost to follow-up
13 Protocol violations
(imaging device used)
3 Withdrew consent
0 Lost to follow-up
1092 included in the analysis
(the intention-to-treat population)
547 included in the analysis
(the intention-to-treat population)

# Primary End Point: TVF




| Number at risk | | | | |
|---|---|---|---|---|
| Angiography-guided PCI | 547 | 496 | 280 | 120 |
| Imaging-guided PCI | 1092 | 1023 | 591 | 255 |

# Primary and Secondary End Points

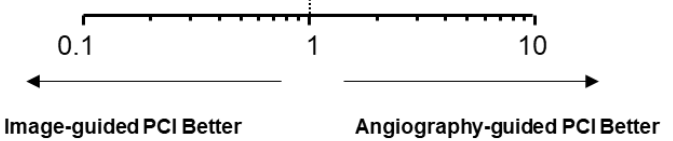
| End Point | Total (N=1639) | Imaging-guided PCI (N=1092) | Angiography-guided PCI (N=547) | Hazard Ratio (95% CI)* | P Value |
|---|---|---|---|---|---|
| **Primary end point — no. (%)** | | | | | |
| **Target vessel failure** | **136 (9.2)** | **76 (7.7)** | **60 (12.3)** | **0.64 (0.45-0.89)** | **0.008** |
| **Secondary end points — no. (%)** | | | | | |
| **Target vessel failure without procedure-related MI** | 88 (6.3) | 48 (5.1) | 40 (8.7) | 0.59 (0.39-0.90) | |
| **Cardiac death or target-vessel related MI** | 96 (6.4) | 53 (5.3) | 43 (8.5) | 0.63 (0.42-0.93) | |
| **All-cause death** | 70 (5.6) | 42 (5.3) | 28 (6.4) | 0.71 (0.44–1.15) | |
| **Cardiac death** | 33 (2.4) | 16 (1.7) | 17 (3.8) | 0.47 (0.24-0.93) | |
| **Myocardial infarction** | 75 (5.0) | 43 (4.4) | 32 (6.2) | 0.78 (0.48-1.25) | |
| **Target-vessel related MI** | 68 (4.3) | 38 (3.7) | 30 (5.6) | 0.74 (0.45-1.22) | |
| **Spontaneous MI** | 17 (1.2) | 8 (0.9) | 9 (1.8) | 0.66 (0.23-1.90) | |
| **Procedure-related MI** | 52 (3.2) | 30 (2.7) | 22 (4.0) | 0.77 (0.43-1.35) | |
| **Non-target vessel related MI** | 8 (0.8) | 5 (0.8) | 3 (0.8) | 1.24 (0.24-6.40) | |
| **Repeat revascularization** | 87 (6.6) | 55 (6.3) | 32 (7.1) | 0.95 (0.60-1.48) | |
| **Target vessel revascularization** | 57 (4.1) | 32 (3.4) | 25 (5.5) | 0.69 (0.40-1.18) | |
| **Target lesion revascularization** | 44 (3.2) | 24 (2.6) | 20 (4.4) | 0.66 (0.36-1.22) | |
| **Definite stent thrombosis** | 5 (0.3) | 1 (0.1) | 4 (0.7) | 0.25 (0.02-2.75) | |
| **Contrast induced nephropathy†** | 40 (2.4) | 26 (2.4) | 14 (2.6) | 0.99 (0.51-1.92) | |

# Conclusion

- ***Among patients with complex coronary artery lesions,*** **intravascular imaging-guided PCI reduced a composite of cardiac death, target vessel-related myocardial infarction, or clinically driven target vessel revascularization** compared with **angiography-guided PCI.**
- The **RENOVATE-COMPLEX-PCI** supports the intravascular imaging-guided PCI in patients with complex coronary lesions.

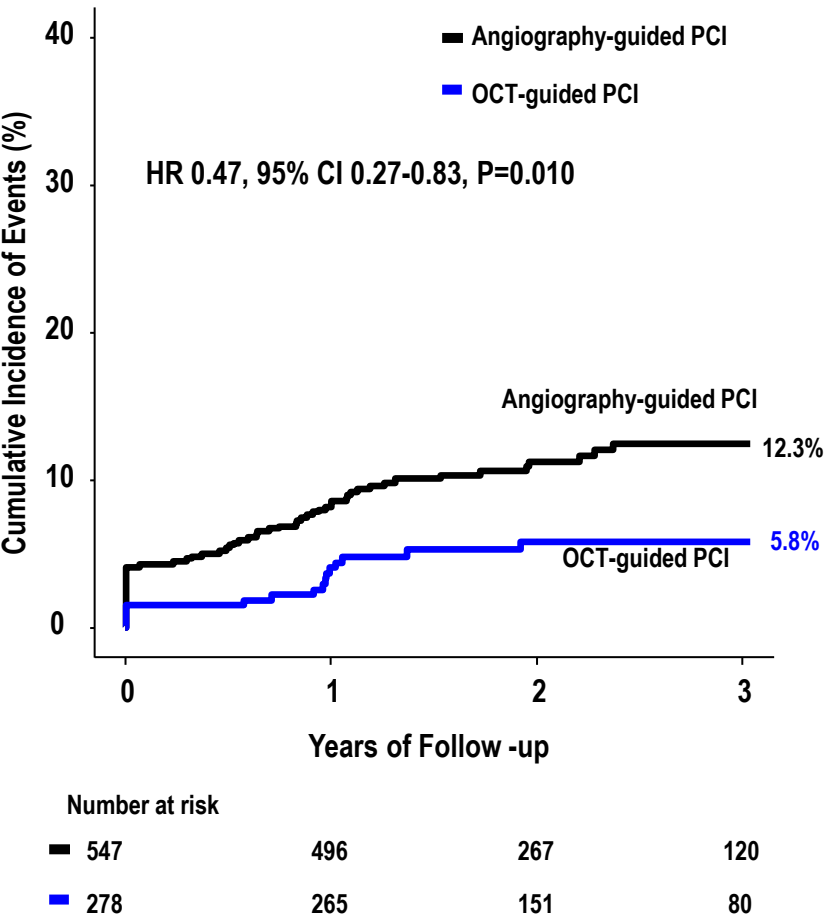
# Prespecified Subgroup Analysis

| Subgroup | Imaging-guided PCI | Angiography-guided PCI | Hazard ratio (95% CI) |
|---|---|---|---|
| | No. of events / total no. of patients (cumulative incidence, %) | | |
| **Overall** | 76/1092 (7.7%) | 60/547 (12.3%) | 0.64 (0.45-0.89) |
| **Type of imaging devices** | | | |
| **IVUS** | 59/800 (8.0%) | 60/547 (12.3%) | 0.66 (0.46-0.95) |
| **OCT** | 15/278 (5.8%) | 60/547 (12.3%) | 0.47 (0.27-0.83) |
| **Initial Presentation** | | | |
| **Stable ischemic heart disease** | 25/532 (5.0%) | 27/275 (10.4%) | 0.46 (0.27-0.80) |
| **Acute coronary syndrome** | 51/560 (10.4%) | 33/272 (14.6%) | 0.74 (0.48-1.15) |
| **Age** | | | |
| **<65 years** | 36/517 (7.8%) | 23/238 (10.6%) | 0.72 (0.42-1.21) |
| **≥65 years** | 40/575 (7.4%) | 37/309 (13.6%) | 0.57 (0.36-0.88) |
| **Sex** | | | |
| **Male** | 66/869 (8.3%) | 46/431 (11.7%) | 0.70 (0.48-1.02) |
| **Female** | 10/223 (5.2%) | 14/116 (14.5%) | 0.35 (0.16-0.80) |
| **Diabetes mellitus** | | | |
| **Presence** | 45/394 (12.9%) | 26/223 (12.3%) | 0.97 (0.60-1.57) |
| **Absence** | 31/698 (4.7%) | 34/324 (12.2%) | 0.41 (0.25-0.67) |
| **Chronic kidney disease** | | | |
| **Presence** | 22/203 (13.3%) | 19/93 (23.3%) | 0.51 (0.27-0.93) |
| **Absence** | 54/889 (6.4%) | 41/454 (9.9%) | 0.66 (0.44-0.99) |
| **Left ventricular ejection fraction** | | | |
| **<50%** | 22/210 (12.0%) | 12/84 (15.0%) | 0.72 (0.35-1.45) |
| **≥50%** | 54/882 (6.7%) | 48/463 (11.8%) | 0.58 (0.39-0.85) |

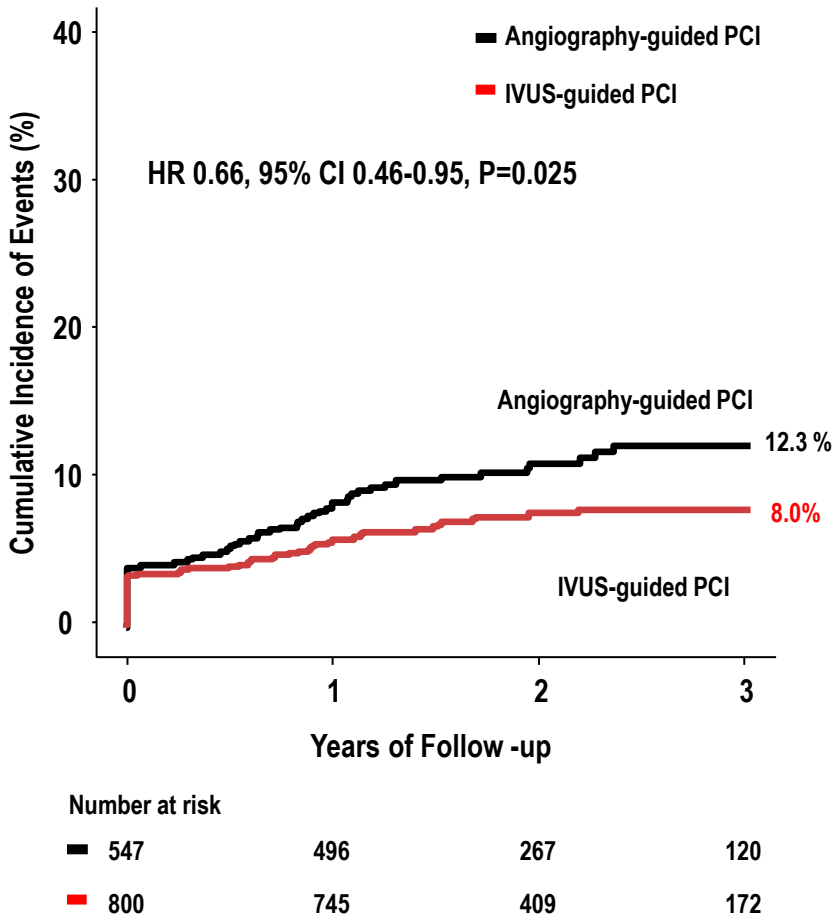


# OCT-guided PCI vs. IVUS-guided PCI vs. Angiography-PCI

## OCT-guided PCI vs. Angiography-guided PCI




## IVUS-guided PCI vs. Angiography-guided PCI

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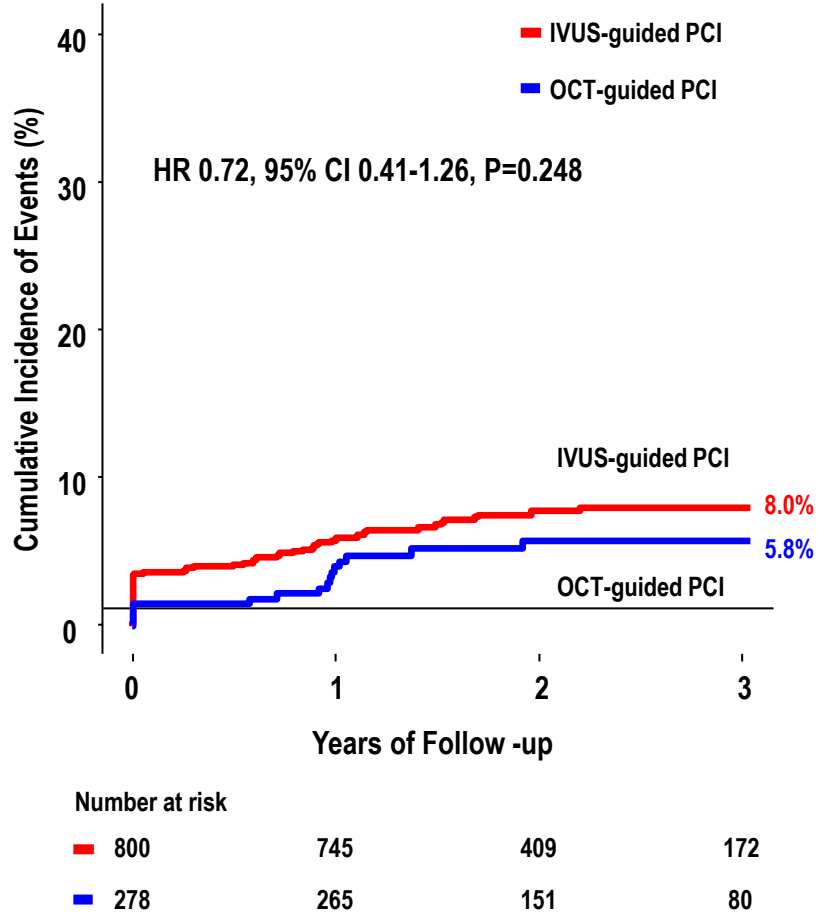


Kwon WC, …, Hahn JY. JACC Imaging 2023

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# ILUMIEN IV: Background

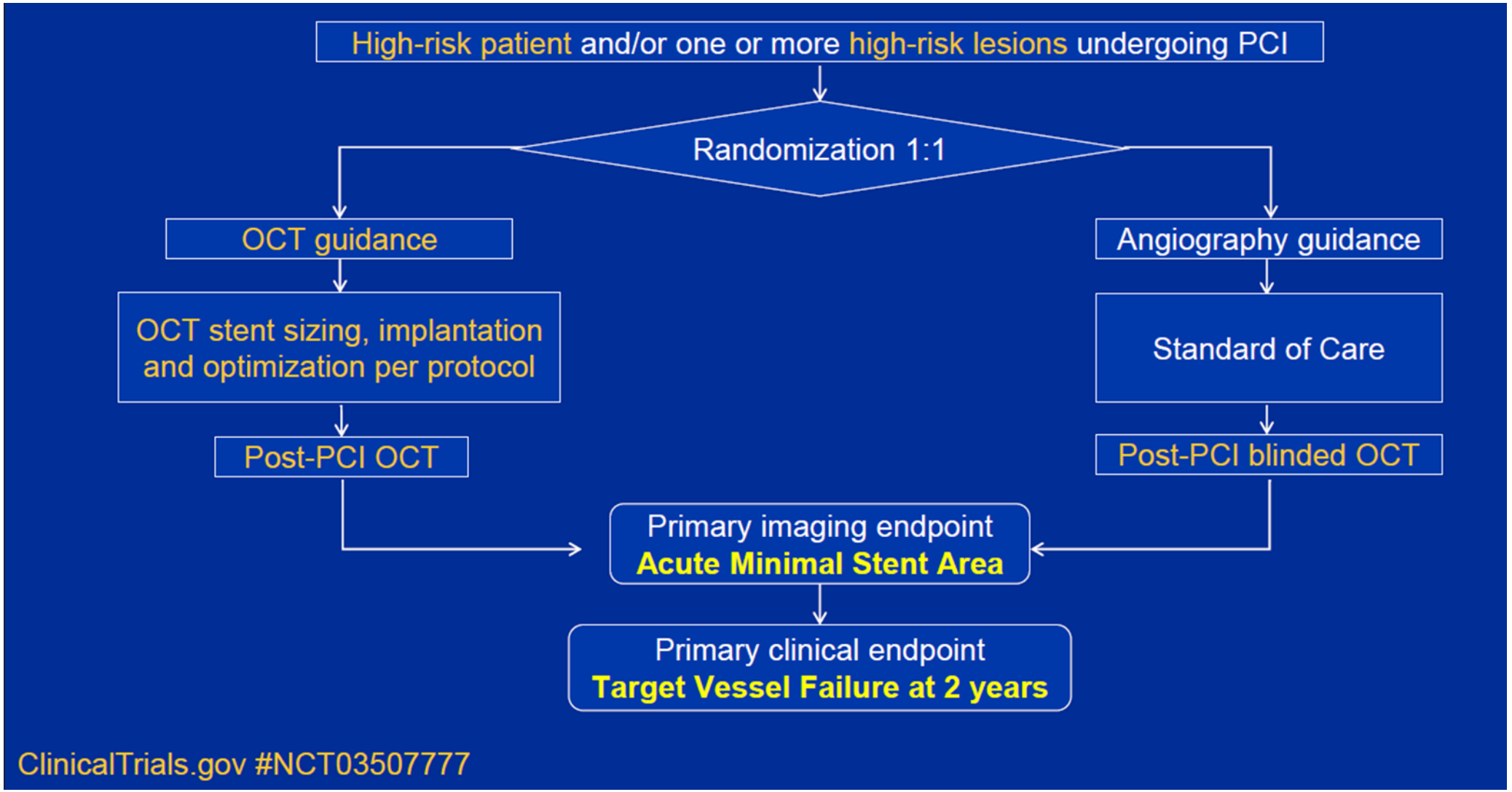
- OCT is a high-resolution intravascular imaging modality that can be used to guide and optimize PCI

- In ILUMIEN III[1], OCT guidance improved procedural success compared with angiography guidance
  - Greater stent expansion
  - Reduced major malapposition and major dissection

- Whether OCT can improve clinical outcomes is unknown

[1]Lancet. 2016 Nov 26;388:2618-2628.

# ILUMIEN IV: Study Flow



# ILUMIEN IV: Qualifying High-risk Criteria

**High-risk Patient**

- Medication-treated diabetes mellitus

**High-risk Lesion**

- NSTEMI
- STEMI >24 hours from symptom onset
- Long or multiple lesions (planned total stent length ≥28 mm)
- Diffuse or multi-focal in-stent restenosis
- Angiographic severe calcification
- Chronic total occlusion
- Bifurcation, planned to be treated with 2 stents

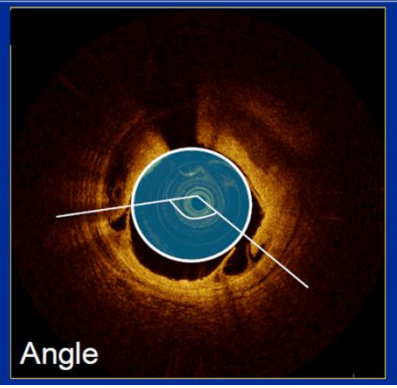
# Primary Imaging Endpoint

## Final post-PCI MSA by OCT ($mm^2$)

| OCT L=1222 | Angio L=1328 | Difference [95% CI] | P-Value |
|---|---|---|---|
| 5.72 ± 2.04 | 5.36 ± 1.87 | 0.36 (0.21, 0.51) | <0.001 |

## Post-procedure OCT Findings

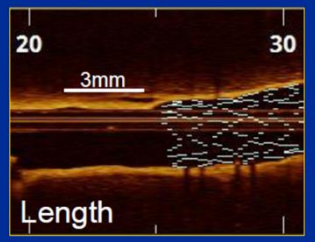
| | OCT (L=1228) | Angio (L=1329) | Difference [95% CI] |
|---|---|---|---|
| Dissection, any | 32.0% | 34.2% | -2.2% (-5.9, 1.4) |
| Major | 2.9% | 5.1% | -2.2% (-3.9, -0.6) |
| Minor | 22.7% | 19.4% | 3.3% (-0.1, 6.6) |




**Major Dissection**

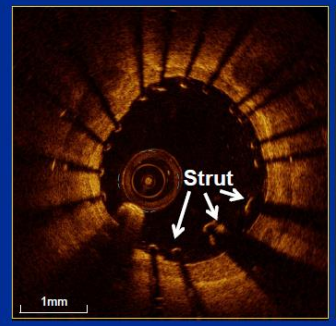
1) Angle >60°

2) Length >3 mm




## Post-procedure OCT Findings

| | OCT (L=1228) | Angio (L=1329) | Difference [95% CI] |
|---|---|---|---|
| Malapposition, any | 55.3% | 69.7% | -14.4% (-18.1, -10.6) |
| Major | 15.8% | 33.2% | -17.4% (-20.6, -14.1) |
| Minor | 39.4% | 36.5% | 3.0% (-0.8, 6.7) |

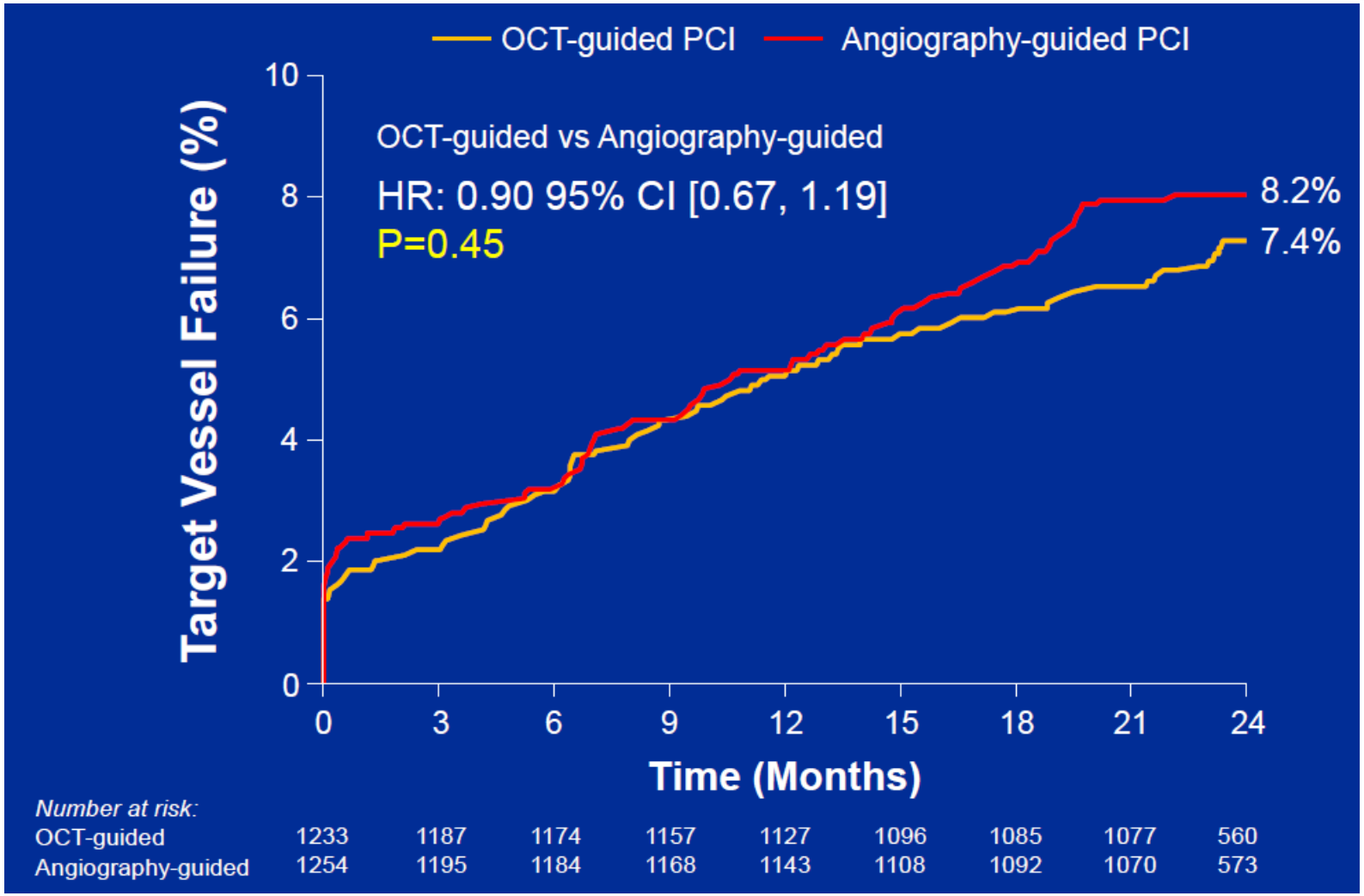




**Major**

Strut(s) >0.2 mm from vessel edge and stent underexpansion

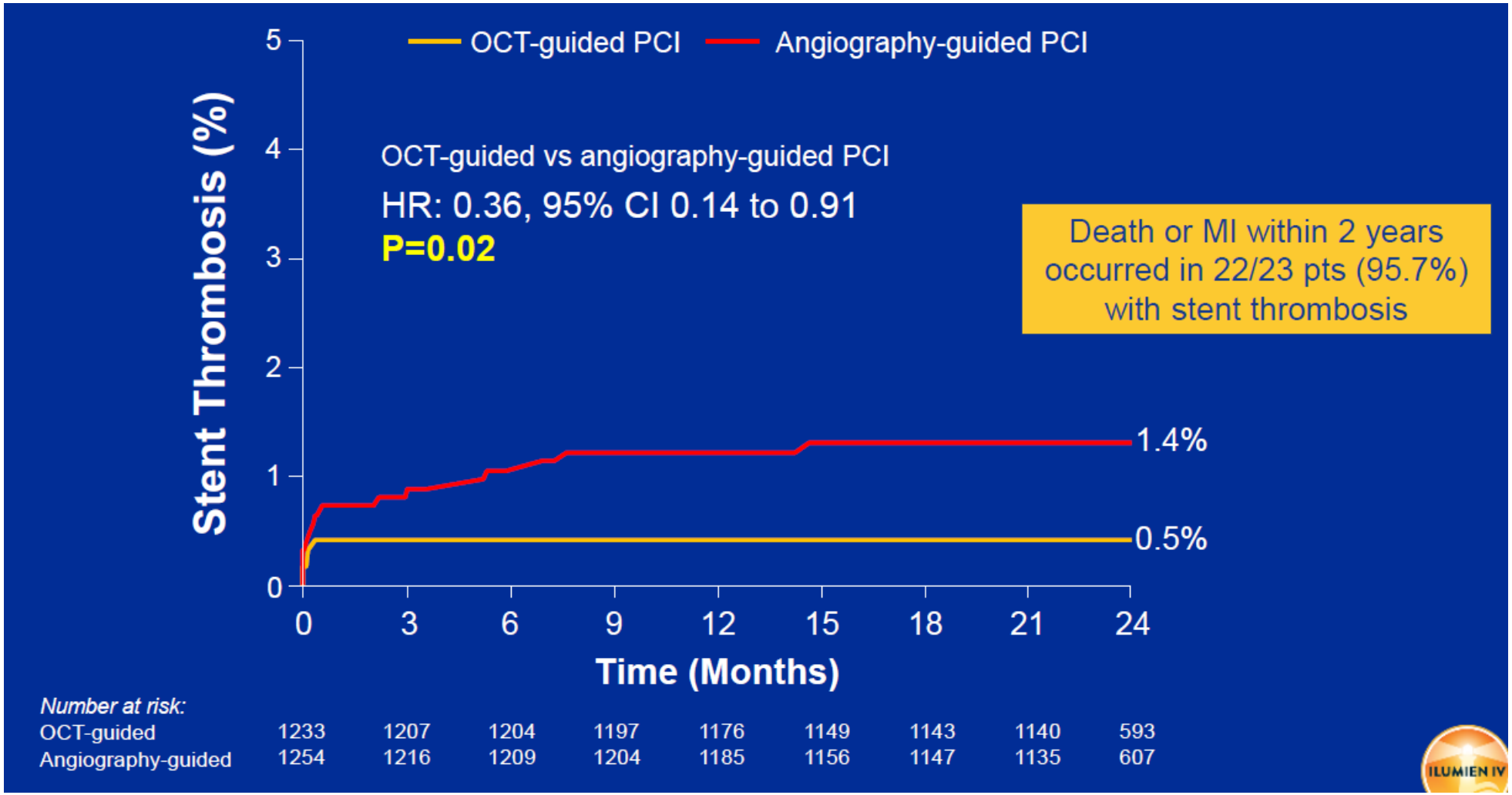
# ILUMIEN IV: Primary Clinical Endpoint – TVF



# ILUMIEN IV: 2-Year Clinical Outcomes

| | OCT (n=1233) | Angio (n=1254) | Hazard Ratio (95% CI) |
|---|---|---|---|
| All-cause mortality | 2.7% | 3.6% | 0.73 (0.47, 1.16) |
| -Cardiac | 0.8% | 1.3% | 0.57 (0.25, 1.29) |
| -Vascular | 0.3% | 0.3% | 0.76 (0.17, 3.38) |
| -Non-cardiovascular | 1.7% | 2.0% | 0.84 (0.46, 1.52) |
| All MI | 4.8% | 6.0% | 0.80 (0.56, 1.13) |
| -TV-MI | 2.5% | 3.3% | 0.77 (0.48, 1.22) |
| -Periprocedural MI | 1.4% | 1.7% | 0.82 (0.43, 1.56) |
| -Non-periprocedural MI | 3.4% | 4.4% | 0.77 (0.51, 1.17) |
| All revascularization | 9.4% | 10.1% | 0.94 (0.72, 1.21) |
| - ID-TVR | 5.6% | 5.6% | 0.99 (0.71, 1.40) |
| - ID-TLR | 4.5% | 4.3% | 1.05 (0.71, 1.54) |
| - ID-TVR/non-TLR | 1.8% | 2.4% | 0.79 (0.45, 1.38) |

# ILUMIEN IV: Stent Thrombosis (Def/Prob)



# ILUMIEN IV: Conclusions

- OCT-guidance resulted in a larger MSA than angiography guidance, with greater stent expansion.
- OCT-guidance led to fewer major dissections, major malapposition, major tissue protrusion and untreated focal reference segment disease.
- The 2-year rates of TVF were not statistically different between OCT-guided and angiography-guided PCI.
- OCT-guided PCI significantly reduced stent thrombosis.

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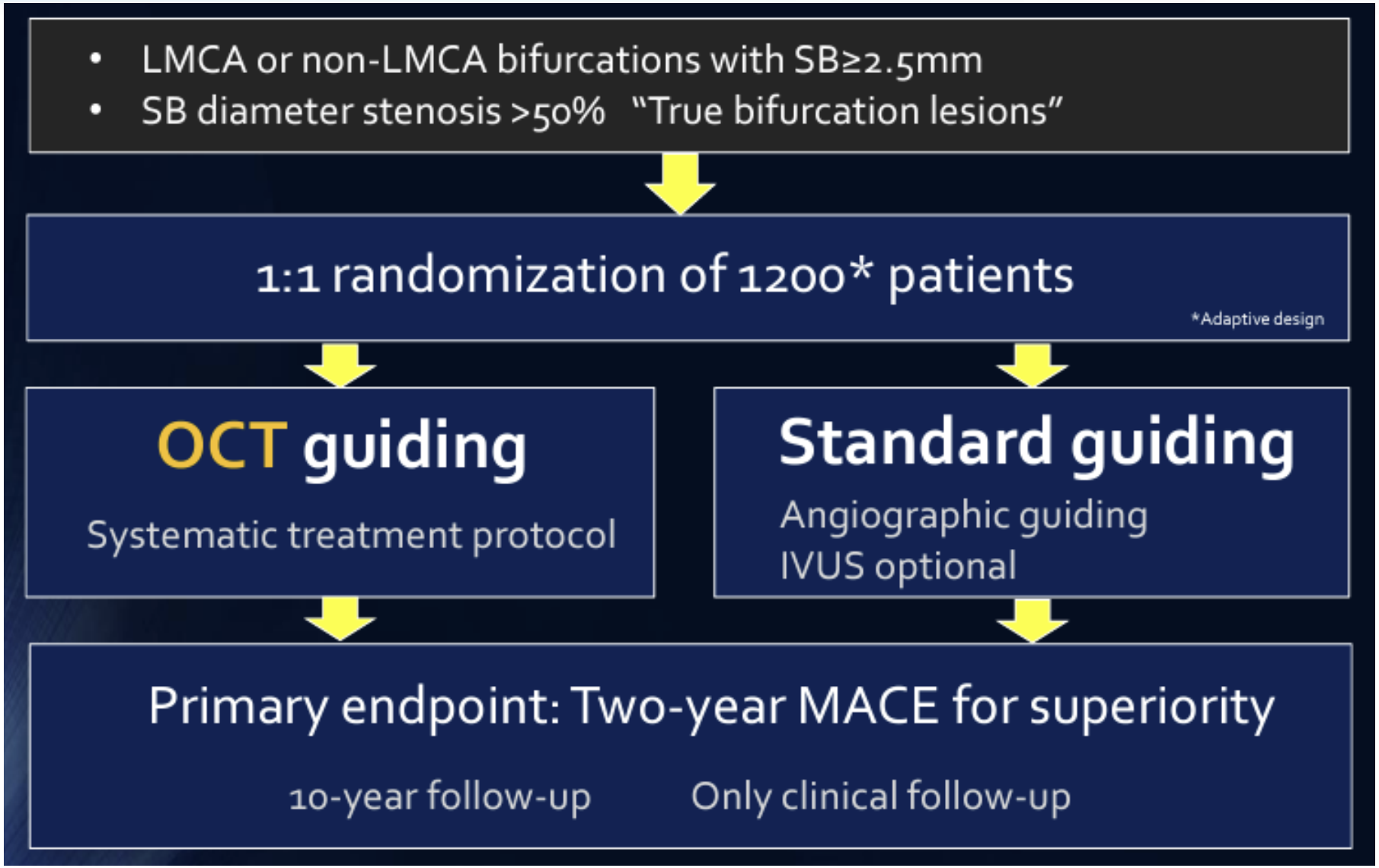
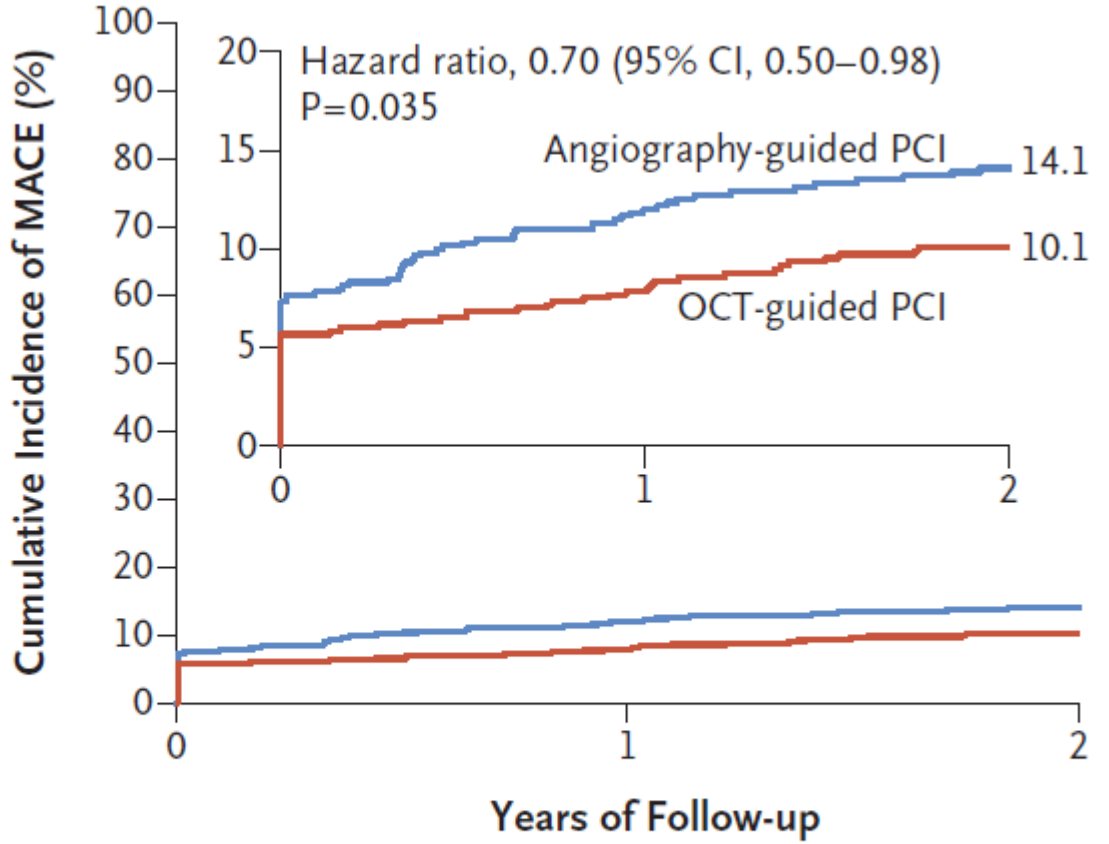
# OCTOBER: Design



# OCTOBER: Procedural Characteristics

| Characteristic | Total (N=1201) | OCT-Guided PCI (N=600) | Angiography-Guided PCI (N=601) |
|---|---|---|---|
| Median no. of diseased vessels (IQR) | 2 (2–2) | 2 (2–2) | 2 (2–2) |
| Median no. of lesions to be treated (IQR) | 1 (1–1) | 1 (1–1) | 1 (1–1) |
| Trial bifurcation vessels — no. of patients (%) | | | |
| LMCA–LAD–LCx | 227 (18.9) | 111 (18.5) | 116 (19.3) |
| LAD-D | 847 (70.5) | 425 (70.8) | 422 (70.2) |
| LCx–OM | 111 (9.2) | 55 (9.2) | 56 (9.3) |
| RCA–PDA–PLA | 16 (1.3) | 9 (1.5) | 7 (1.2) |
| Main-vessel treatment, median total stent length (IQR) — mm | 36 (24–50) | 38 (28–51) | 33 (23–48) |
| Side-branch treatment | | | |
| Side branch stented — no. of patients/total no. (%) | 770/1198 (64.3) | 388/597 (65.0) | 382/601 (63.6) |
| Median total stent length (IQR) — mm | 23 (15–28) | 23 (15–28) | 23 (15–28) |
| Median total balloons (IQR) — no. | 7 (5–9) | 7 (5–10) | 6 (5–9) |
| Largest balloon diameter — mm | 4.1±0.02 | 4.2±0.03 | 4.0±0.02 |
| Secondary lesions treated — no. of patients (%) | 231 (19.2) | 106 (17.7) | 125 (20.8) |

# OCTOBER: Primary End Point




**No. at Risk**

| | | | |
|---|---|---|---|
| Angiography-guided PCI | 601 | 509 | 408 |
| OCT-guided PCI | 600 | 537 | 439 |

*MACE: death from a cardiac cause, target-lesion MI, or ischemia-driven TLR

# OCTOBER: Clinical Outcomes

| End Point | Total (N=1201) | OCT-Guided PCI (N=600) | Angiography-Guided PCI (N=601) | Hazard Ratio (95% CI) |
|---|---|---|---|---|
| | *events* | *events (estimated percentage)* | | |
| Primary end point: MACE† | 142 | 59 (10.1) | 83 (14.1) | 0.70 (0.50–0.98) |
| Clinical secondary end points | | | | |
| Patient-oriented composite end point‡ | 182 | 79 (13.6) | 103 (17.7) | 0.76 (0.56–1.01) |
| Death from any cause | 36 | 13 (2.4) | 23 (4.0) | 0.56 (0.28–1.10) |
| Death from a cardiac cause | 23 | 8 (1.4) | 15 (2.6) | 0.53 (0.22–1.25) |
| Target-lesion myocardial infarction | 97 | 46 (7.8) | 51 (8.5) | 0.90 (0.60–1.34) |
| Ischemia-driven target-lesion revascularization§ | 42 | 16 (2.8) | 26 (4.6) | 0.61 (0.32–1.13) |
| Stent thrombosis | 29 | 12 (2.1) | 17 (3.0) | 0.70 (0.34–1.47) |
| Definite | 7 | 3 (0.5) | 4 (0.7) | 0.75 (0.17–3.34) |
| Probable | 3 | 2 (0.3) | 1 (0.2) | 1.99 (0.18–22.0) |
| Possible | 19 | 7 (1.3) | 12 (2.1) | 0.58 (0.23–1.47) |

# OCTOBER: Conclusions

- Among patients with complex coronary-artery bifurcation lesions, OCT-guided PCI was associated with a lower median 2-year incidence of MACE than angiography-guided PCI.
- The incidence of procedure-related complications was low, and there was no notable difference between the two groups.

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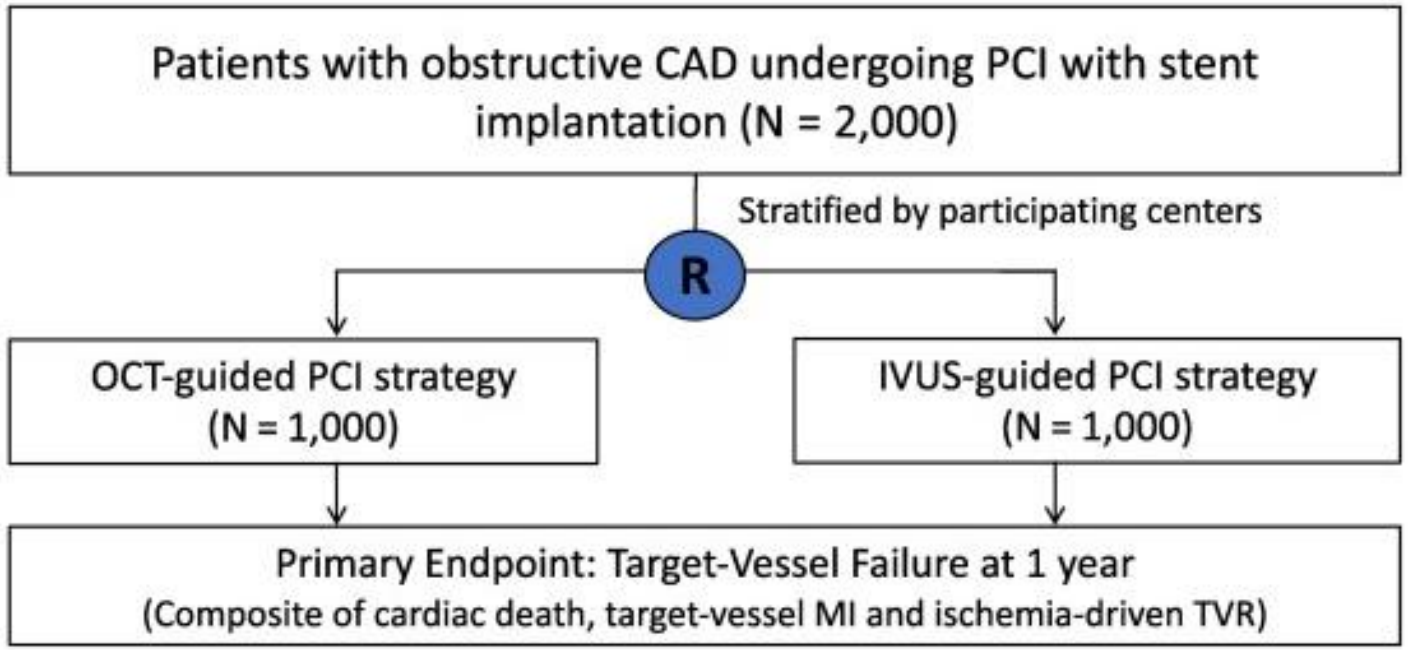
  - OCT vs. IVUS-guided PCI
  - 2,000 patients

# OCTIVUS: Study Design



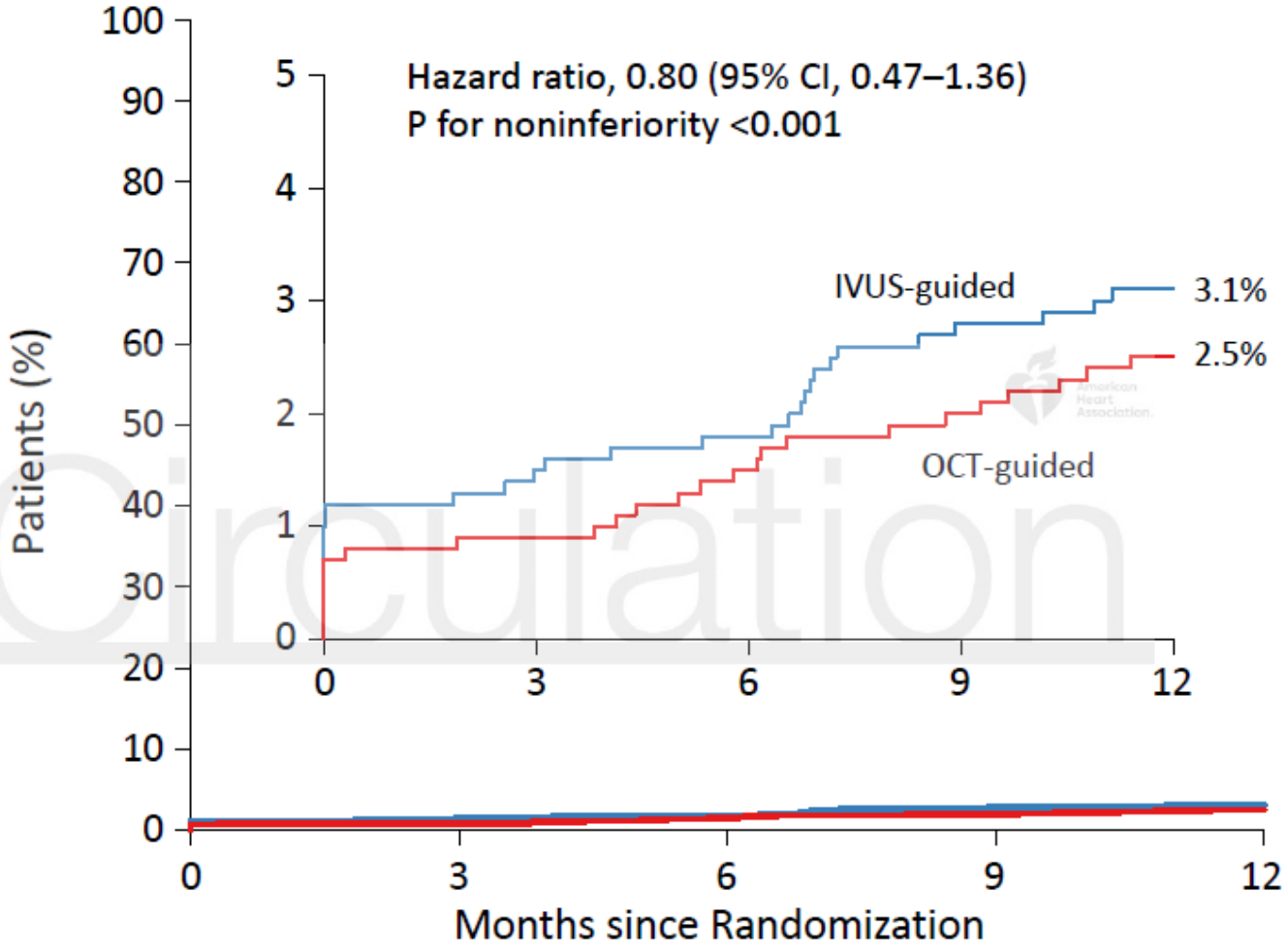

Practical recommendation for PCI optimization by IVUS or OCT

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

# OCTIVUS: Procedural Characteristics

| | | | |
|---|---|---|---|
| PCI approach | | | 0.99 |
| Radial access | 639 (63.6) | 638 (63.6) | |
| Femoral access | 366 (36.4) | 365 (36.4) | |
| PCI modality | | | |
| Use of drug-eluting stents | 970 (96.5) | 973 (97.1) | 0.45 |
| Used of drug-coated balloons (only for in-stent restenotic lesion) | 35 (3.5) | 29 (2.9) | |
| Total no. of lesions treated per patient | 1.3±0.6 | 1.4±0.6 | 0.36 |
| Mean number of stents per patient | 1.6±1.0 | 1.6±1.0 | 0.38 |
| Total stent length per patient — mm | 47.2±32.4 | 47.8±32.2 | 0.69 |
| Post-dilatation with larger balloon or high-pressure balloon use — no. (%)¶ | 931 (92.6) | 917 (91.5) | 0.35 |
| Total amount of contrast media used — mL | 238.3±112.4 | 199.8±109.7 | <0.001 |
| Total PCI time — min | 46.1±23.6 | 48.9±25.1 | <0.001 |
| Procedural success — no. (%) | | | |
| Angiography-based‖ | 993 (98.8) | 990 (98.7) | 0.84 |
| Imaging-based** | 476 / 986 (48.3) | 546 / 995 (54.9) | 0.003 |
| Procedural complications requiring active intervention — no. (%)†† | | | |
| Any | 22 (2.2) | 37 (3.7) | 0.047 |
| IVUS or OCT procedure related complications | 0 (0) | 0 (0) | |

# OCTIVUS: Primary End Point



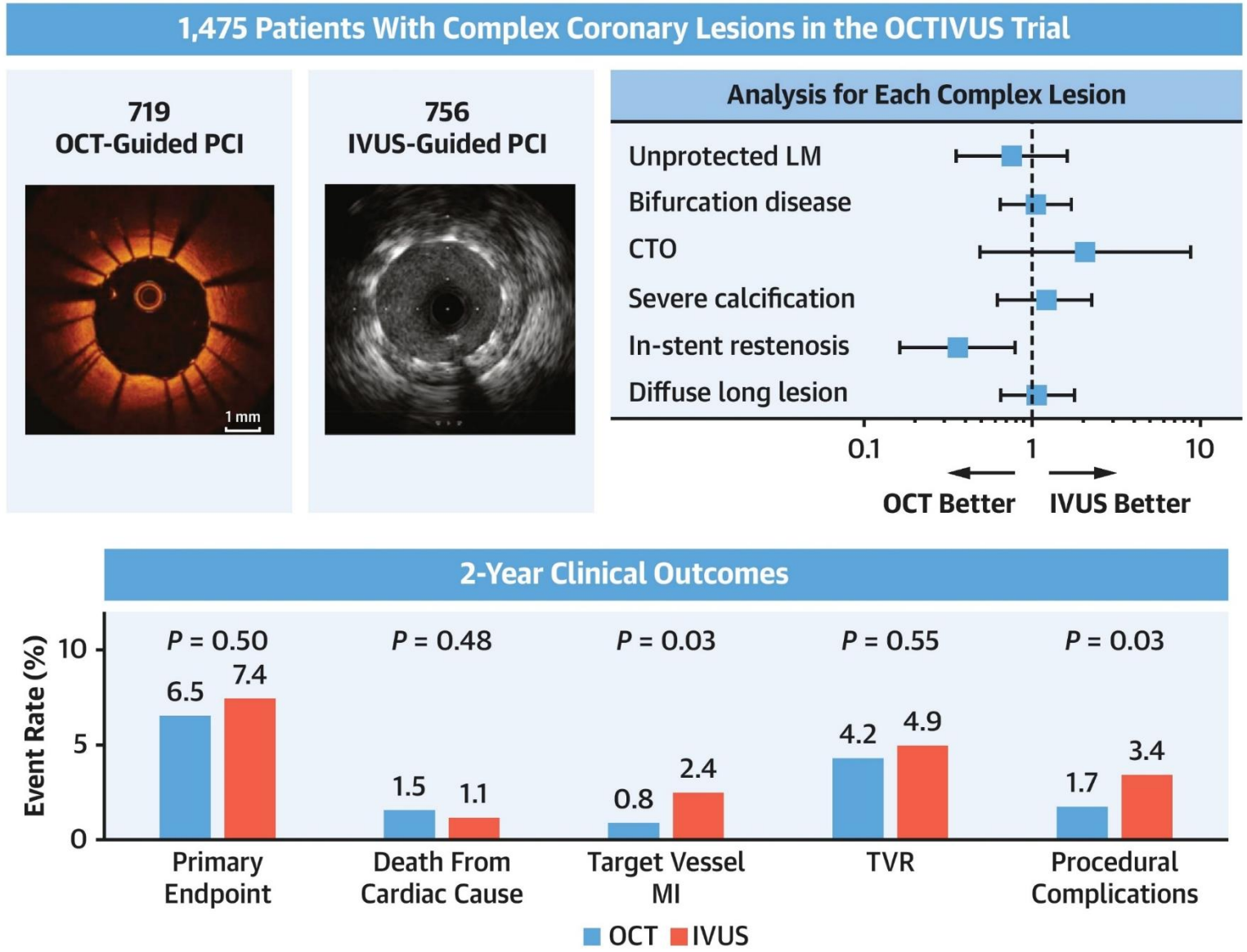

| No. at Risk | | | | | |
|---|---|---|---|---|---|
| OCT-guided PCI | 1005 | 990 | 984 | 979 | 912 |
| IVUS-guided PCI | 1003 | 985 | 981 | 969 | 893 |

# OCTIVUS: Clinical Outcomes

| Outcome* | OCT-Guided PCI (N = 1005) | IVUS-Guided PCI (N = 1003) | Risk Difference (95% CI) | HR (95% CI)† |
|---|---|---|---|---|
| **Primary composite outcome‡** | 25 (2.5 %) | 31 (3.1 %) | –0.6 ( –2.0 to 0.8) | 0.80 (0.47 to 1.36) |
| **Secondary outcomes** | | | | |
| Target-lesion failure§ | 22 (2.2%) | 29 (2.9%) | –0.7 (–2.1 to 0.7) | 0.76 (0.43 to 1.31) |
| Death | 10 (1.0%) | 14 (1.4%) | –0.4 (–1.4 to 0.6) | 0.71 (0.32 to 1.60) |
| From cardiac cause | 3 (0.3%) | 6 (0.6%) | –0.3 (–0.9 to 0.3) | 0.71 (0.32 to 1.60) |
| From noncardiac cause | 7 (0.7%) | 8 (0.8%) | –0.1 (–0.9 to 0.6) | 0.87 (0.32 to 2.40) |
| Target-vessel myocardial infarction | 9 (0.9%) | 14 (1.4%) | –0.5 (–1.4 to 0.4) | 0.64 (0.28 to 1.48) |
| Periprocedural | 7 (0.7%) | 11 (1.1%) | –0.4 (–1.2 to 0.4) | 0.64 (0.25 to 1.64) |
| Spontaneous | 2 (0.2%) | 3 (0.3%) | –0.1 (–0.5 to 0.3) | 0.67 (0.11 to 3.98) |
| Repeat revascularization | 16 (1.6%) | 19 (1.9%) | –0.3 (–1.5 to 0.8) | 0.84 (0.43 to 1.63) |
| Target-lesion revascularization | 11 (1.1%) | 14 (1.4%) | –0.3 (–1.3 to 0.7) | 0.78 (0.36 to 1.72) |
| Target-vessel revascularization | 14 (1.4%) | 16 (1.6%) | –0.2 (–1.3 to 0.9) | 0.87 (0.43 to 1.79) |
| Contrast-induced nephropathy — no. (%)** | 14 (1.4%) | 15 (1.5%) | –0.1 ( –1.1 to 0.9) | 0.93 (0.45 to 1.91) |

# OCTIVUS: Conclusion

- In patients with diverse anatomical or clinical characteristics, we found that OCT-guided PCI was noninferior to IVUS-guided PCI procedures with respect to the TVR at 1 year.
- The incidence of procedure-related complications during the index PCI was lower in the OCT group than in the IVUS group.
- The amount of contrast dye used during the procedures was higher in the OCT group than in the IVUS group, but it was not related to an increase of contrast-induced nephropathy.




Kang D-Y, et al. J Am Coll Cardiol. 2024;83(3):401-413.

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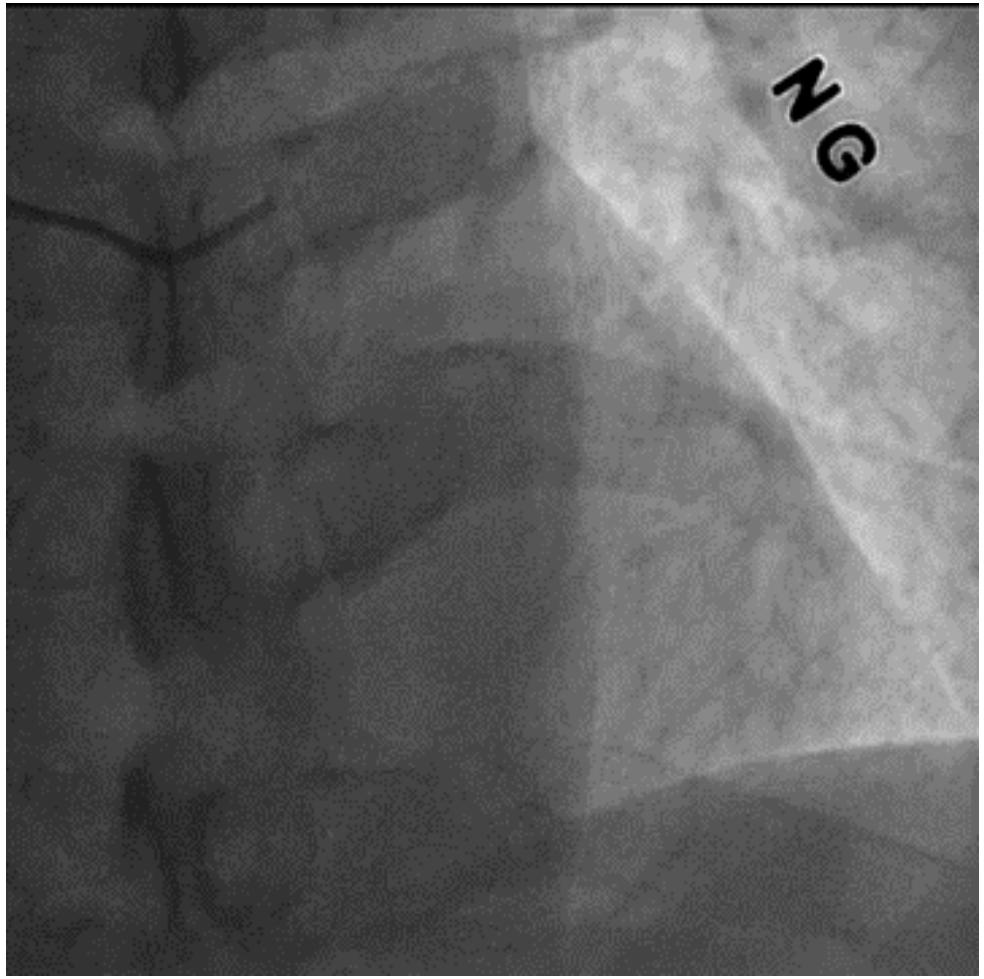
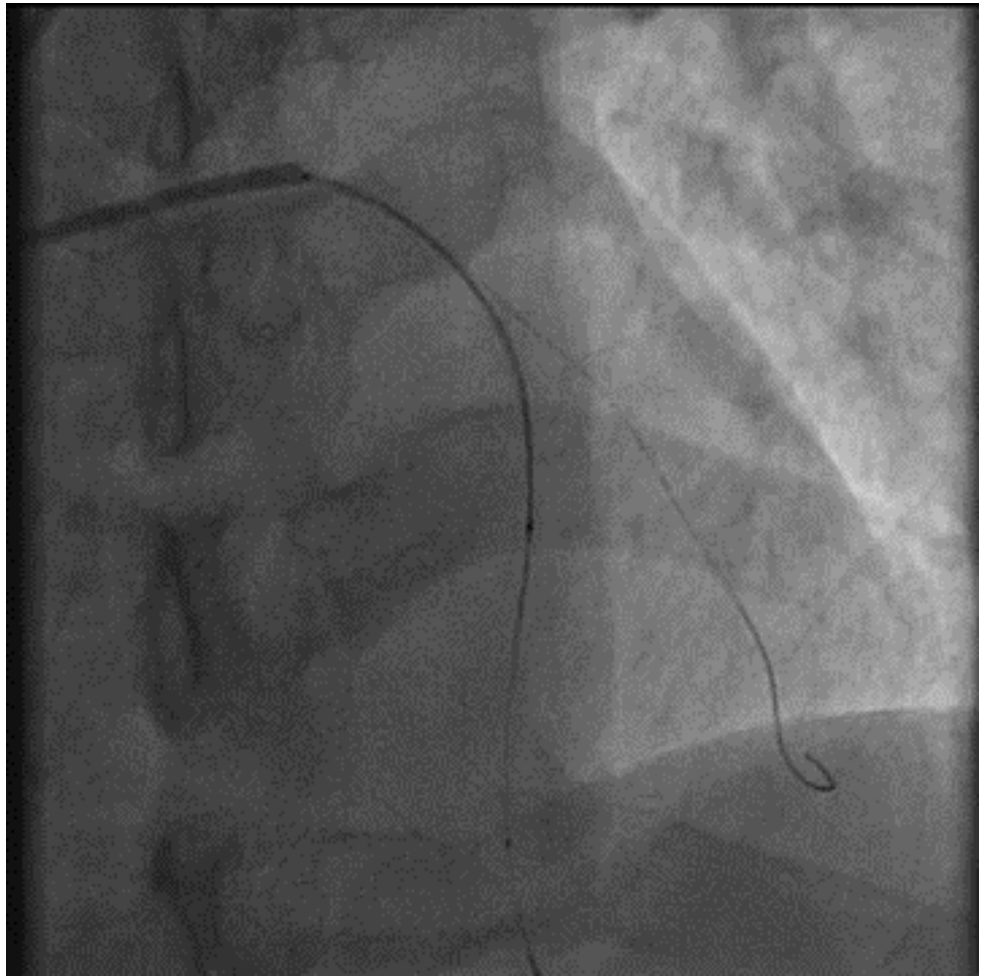
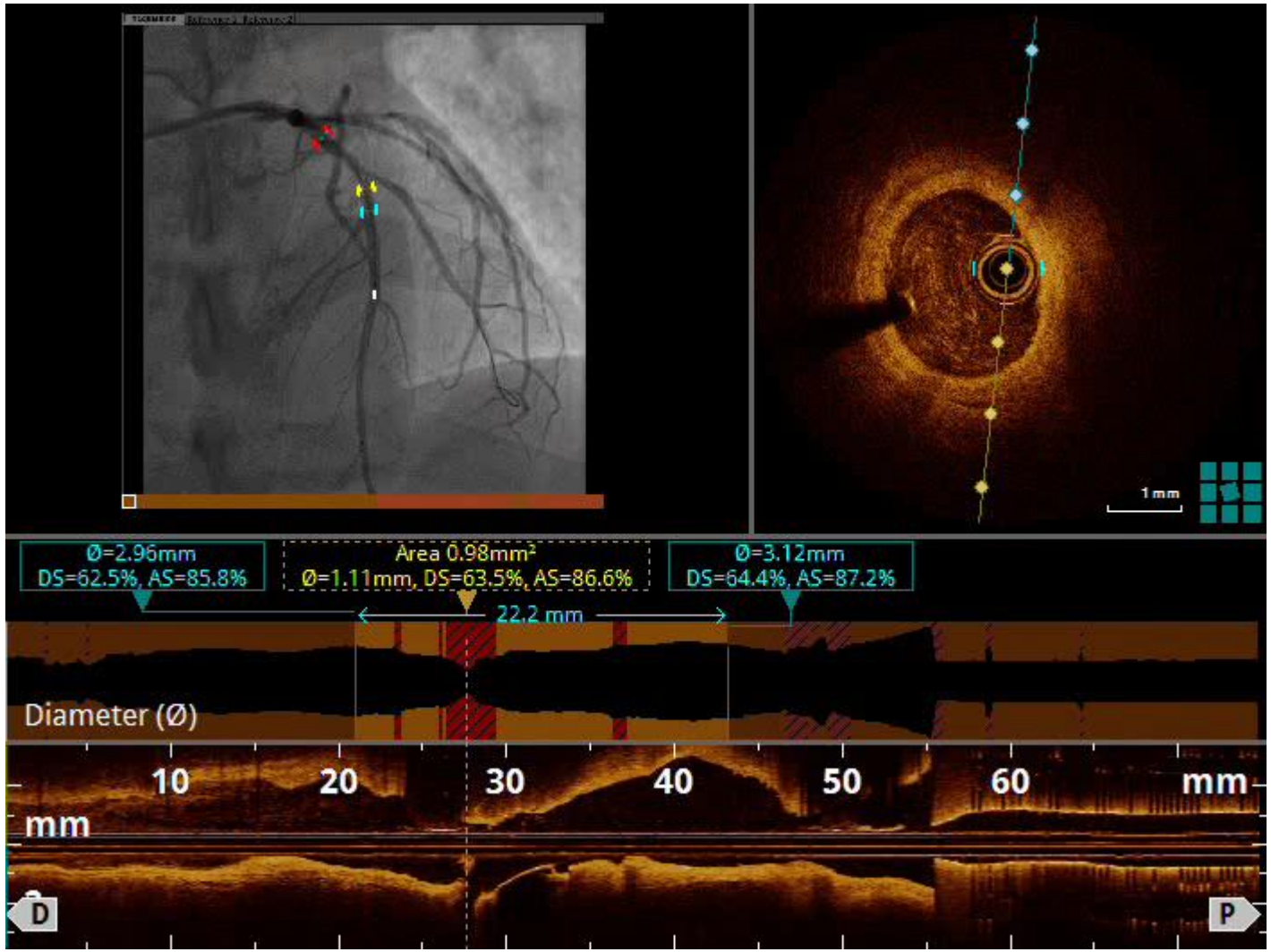
  - 2,000 patients

# OCT for bifurcation lesion

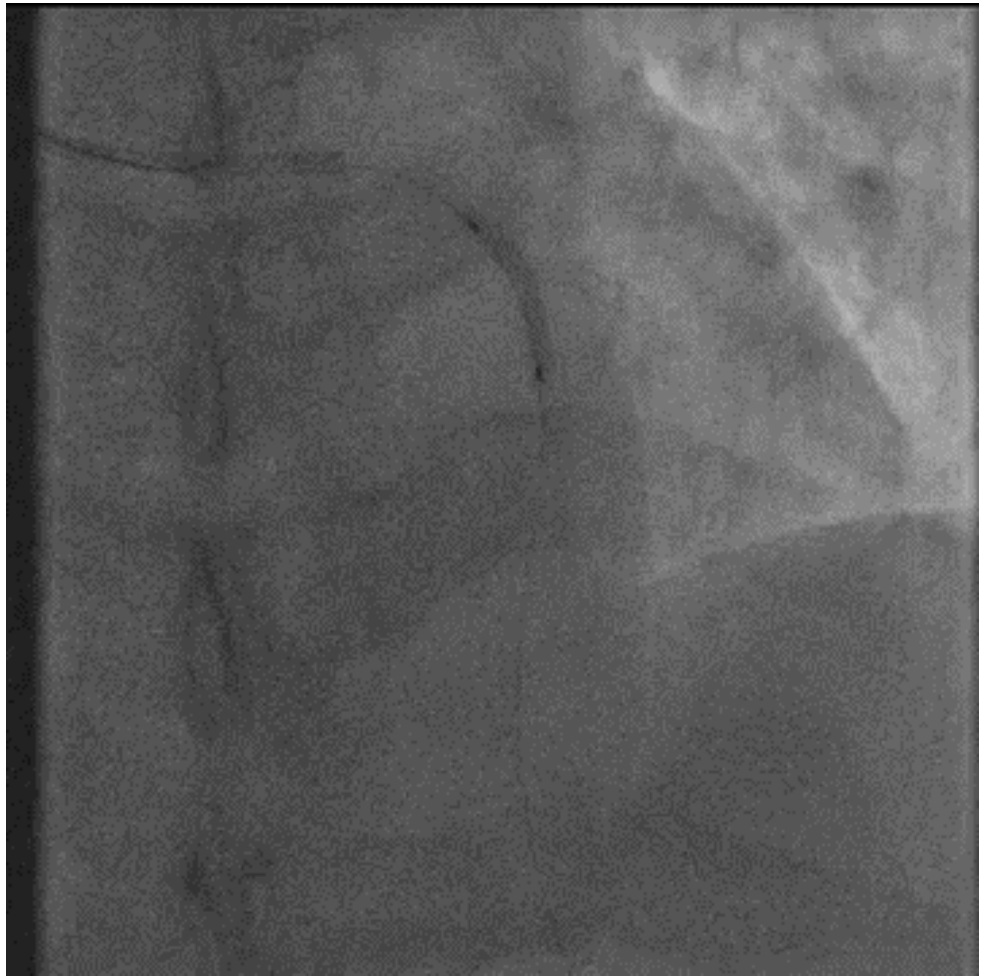


# Pre-stenting OCT



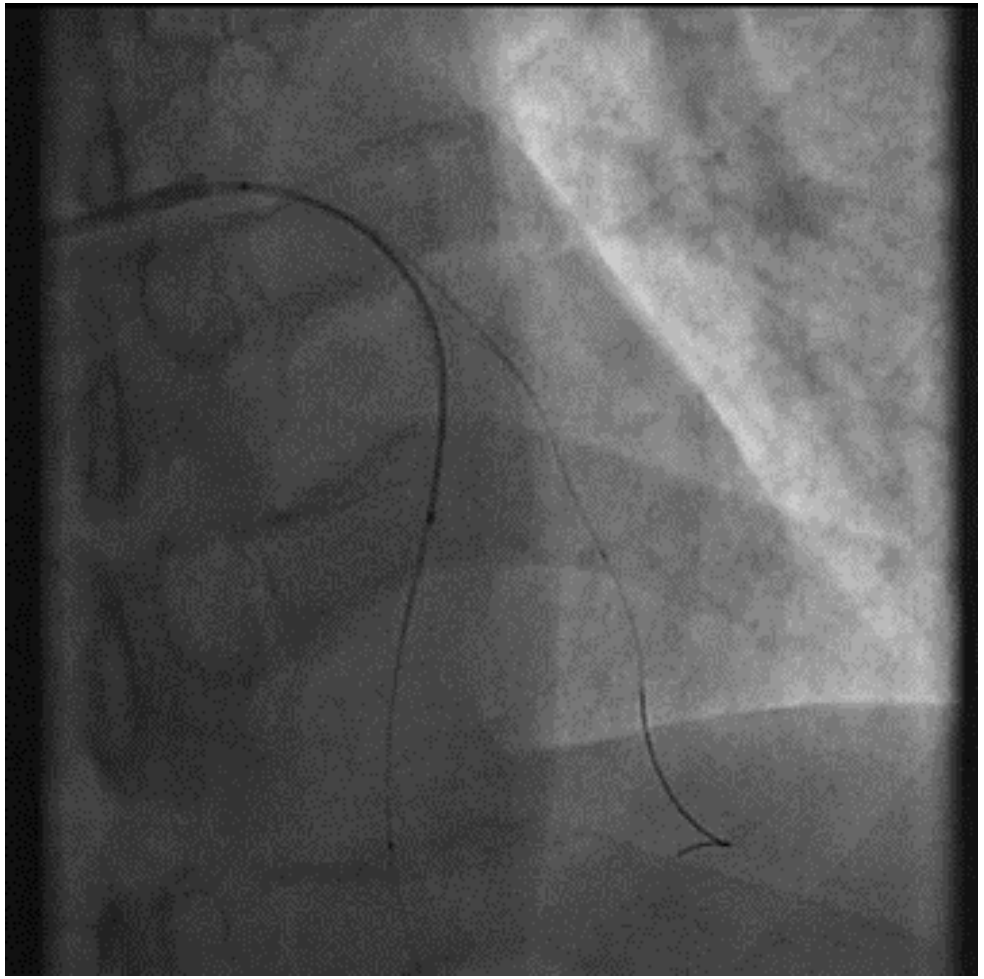
# Mini-crush technique



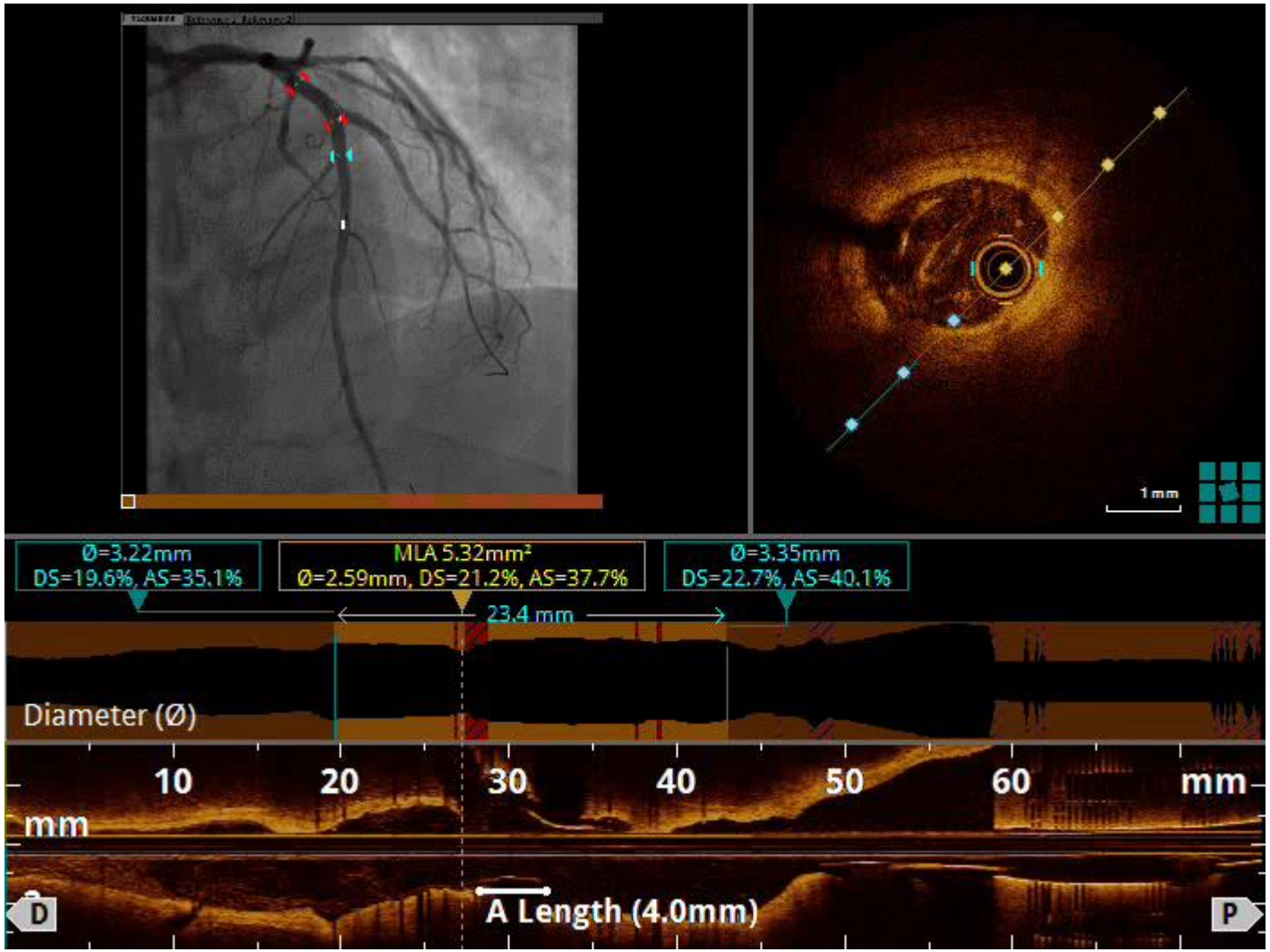
Xience Sierra 2.75*18 at D1
Balloon crush

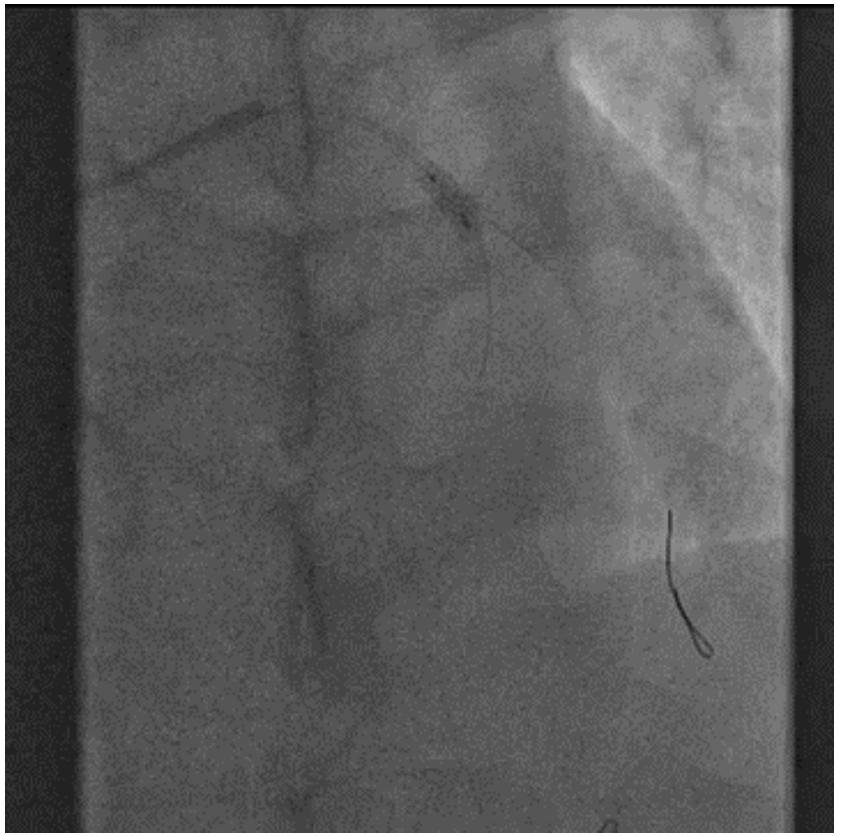
Xience Sierra 3.0*23 at pLAD

# Kissing ballooning



# Post-PCI OCT


1 mm
Ø=3.22mm
DS=19.6%, AS=35.1%
MLA 5.32mm²
Ø=2.59mm, DS=21.2%, AS=37.7%
Ø=3.35mm
DS=22.7%, AS=40.1%
23.4 mm
Diameter (Ø)
10
20
30
40
50
60
mm
mm
D
A Length (4.0mm)
P



# Summary

- Among patients with complex coronary artery lesions, OCT-guided PCI reduced a risk of TVF compared with angiography-guided PCI.
- OCT was comparable to IVUS in complex PCI
- OCT, compared with IVUS, has several advantages such as higher resolution, rapid pullback, and automatized analysis.