# Intravascular Imaging-Guided Versus Angiography-Guided Complex PCI
# The RENOVATE-COMPLEX-PCI Trial


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**On behalf of RENOVATE-COMPLEX-PCI Investigators**


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# Disclosure

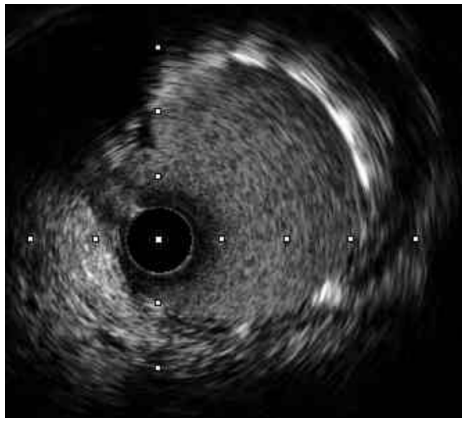
- The **RENOVATE-COMPLEX-PCI** trial was an investigator-initiated, prospective, randomized, open-label, multicenter, superiority trial.

- The **RENOVATE-COMPLEX-PCI** trial was funded by Boston Scientific and Abbott Vascular. The study funder had no role in trial design, data collection, analysis, interpretation, or manuscript writing.

# Background

- Patients with complex coronary artery lesions undergoing PCI have worse clinical outcomes than patients without complex coronary artery lesions.

- Intravascular imaging with intravascular ultrasound (IVUS) or optical coherence tomography (OCT) are used to select the appropriate stent size, to determine the stent landing zone, and to determine if the stent is underexpanded, or there is a stent edge dissection.



- Previous trials (CTO-IVUS, AVIO, HOME-DES-IVUS, IVUS-XPL, ULTIMATE) have reported lower rates of major adverse clinical events following IVUS-guided PCI compared with angiography-guided PCI but have not been considered definitive due to limited sample size, short follow-up duration, or inclusion of highly selected coronary lesion subsets.

**Randomized controlled trial is needed to confirm the prognostic benefit of intravascular imaging-guided PCI than angiography-guided PCI in patients with complex coronary artery lesions.**

# Study Objective

- To investigate whether intravascular imaging-guided PCI using IVUS or OCT would improve clinical outcomes compared with angiography-guided PCI in patients with complex coronary artery lesions.

## Primary Hypothesis

***Intravascular imaging-guided PCI would reduce target vessel failure (a composite of cardiac death, target vessel-related myocardial infarction, and target vessel revascularization), compared with angiography-guided PCI In treatment of patients with complex coronary artery lesions.***

# Study Design

## RENOVATE-COMPLEX-PCI Trial (NCT03381872)

### 1,620 Patients with Complex Coronary Artery Lesions Undergoing PCI

* Definition of Complex Coronary Artery Lesions
① True bifurcation (Median 1,1,1/1,0,1/0,1/0,1,1) with side branch ≥2.5mm
② Chronic total occlusion (≥3 months) as target lesion
③ PCI for unprotected left main disease
④ Implanted stent length ≥38mm

⑤ Multivessel PCI (≥2 vessels treated at one PCI session)
⑥ Multiple stent needed (≥3 more stent per patient)
⑦ In-stent restenosis lesion as target lesion
⑧ Severely calcified lesion (encircling calcium in angiography)
⑨ Ostial lesion in LAD, LCX, and RCA

**Randomization (2:1) for Treatment Strategy of Target Lesions**
(Stratified by acute coronary syndrome and participating centers)

**Imaging-Guided Strategy**
N = 1,080

**Angiography-Guided Strategy**
N = 540

**All patients were followed until 1 year after last patient enrollment.**

# 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 End Points

## Primary End Point

- **Target vessel failure**
  - A composite of cardiac death, target vessel-related MI, and clinically-driven target vessel revascularization.

## Secondary End Point

- Target vessel failure without procedure-related MI
- Cardiac death or target vessel-related MI
- Target vessel-related MI with or without procedure-related MI
- Non-target vessel-related MI
- Any MI with or without procedure-related MI
- Target lesion revascularization
- Target vessel revascularization
- Any revascularization (clinically-driven)
- Definite stent thrombosis
- Total amount of contrast
- Incidence of contrast-induced nephropathy
- Total procedural time
- Total medical cost (not reported in this publication)

**Definition of Clinical Events**

- Spontaneous MI according to 3rd Universal Definition[1]
- Other clinical events according to ARC-2 criteria[3]
- Procedure-related MI according to SCAI Definition[2]



1. Garcia-Garcia HM, McFadden EP, Farb A, et al. Circulation 2018;137:2635-50.
2. Thygesen K, Alpert JS, Jaffe AS, et al. Circulation 2012;126:2020-35.
3. Moussa ID, Klein LW, Shah B, et al. J Am Coll Cardiol 2013;62:1563-70.

# Sample Size Calculation

## Reported Event Rates in Previous Studies of Complex PCI

| Study | Sample Size | Timepoint | MACE | | |
|---|---|---|---|---|---|
| | | | Imaging-guided PCI | Angiography-guided PCI | Relative Risk Reduction, % |
| ADAPT-DES[1] | 8665 | 1 Year | 3.1% | 4.7% | 34.0% |
| AVIO trial[2] | 284 | 2 Year | 16.9% | 23.2% | 27.2% |
| HOME DES IVUS[3] | 210 | 1.6 Years | 11.0% | 12.0% | 8.3% |
| RESET[4] | 543 | 1 Year | 4.5% | 7.3% | 38.4% |
| CTO-IVUS[5] | 402 | 1 Year | 2.6% | 7.1% | 63.4% |
| IVUS-XPL[6] | 1400 | 1 Year | 2.9% | 5.8% | 50.0% |

- The current trial was designed as a superiority trial to follow enrolled patients until a prespecified follow-up duration of the last patient enrolled.

- Since the follow-up duration of the previous studies varied, we assumed that the annual incidence of target vessel failure in the angiography-guided PCI group would be 6.0%, especially based on the results of the CTO-IVUS, RESET, and IVUS-XPL studies. These 3 studies were selected because they were randomized trials conducted in South Korea and the follow-up duration was 1 year. The relative risk reduction of target vessel failure of the 3 studies ranged from 38% to 60%.

- **To be conservative, we assumed that the relative risk reduction at 1 year would be 40% and, in turn, the annual incidence of target vessel failure in the intravascular imaging-guided PCI would be 3.6%.**
- **Accrual time – 3 years**
- **Total follow-up time – 1 year after last patient enrollment**
- **2:1 randomization, Drop-out rate – 5.0%**

- **Based on these assumption, a total of 1620 patients would provide a statistical power of 90% with significance level of 0.05 (2-sided).**



1. Witzenbichler B, Maehara A, Weisz G, et al. Circulation 2014;129:463-70.
2. Chieffo A, Latib A, Caussin C, et al. Am Heart J 2013;165:65-72.
3. Jakabcin J, Spacek R, Bystron M, et al. Catheter Cardiovasc Interv 2010;75:578-83.
4. Kim JS, Kang TS, Mintz GS, et al. JACC Cardiovasc Interv 2013;6:369-76.
5. Kim BK, Shin DH, Hong MK, et al. Circ Cardiovasc Interv 2015;8:e002592.
6. Hong SJ, Kim BK, Shin DH, et al. JAMA 2015;314:2155-63.

# Randomization, Data Collection, Statistical Analysis

- **Randomization**
  - Eligible patients were randomized via a web-based randomization sequence (S-Soft), in permutated blocks, with block sized of 6.
  - Stratified by acute coronary syndrome and by participating centers.

- **Data collection and management**
  - Data collected by a web-based electronic case report form.
  - Imaging data and angiograms were analyzed by core laboratories.
  - An independent Data and Safety Monitoring Boards monitored trial.
  - All clinical events were adjudicated by an independent Clinical Events Adjudication Committee.

- **Statistical analysis**
  - The main analysis were performed according to the intention-to-treat principle and the primary outcome analysis included an estimation of the cumulative incidence function of target vessel failure and a comparison of randomization groups with the use of the method of Fine and Gray to adjust for the potential competing risk of non-cardiac death.

# Procedures

- **Drug-eluting Stents**
  - Biodegradable polymer-coated everolimus eluting stents (Synergy stent system, Boston Scientific Corporation)
  - Biocompatible polymer-coated everolimus-eluting stents (Xience stent system family, Abbott Vascular).

- **Intravascular Imaging Devices**
  - IVUS (Opticross™, Boston Scientific Corporation) or OCT (Dragonfly™, Abbott Vascular)
  - Protocols for selecting the reference segments for the lesion, for selecting the appropriate size of the stent, and for stent optimization were prespecified based on previous reports in the literature.[1]
  - While use of intravascular imaging devices was allowed at any step of the PCI procedure, **intravascular imaging evaluation after PCI was mandated for optimization of the stented segment.**

## Standardized Protocols of Intravascular Imaging and Optimization

| | IVUS | OCT |
|---|---|---|
| **Reference Sites** | Largest size vessel lumen<br>Plaque burden <50%<br>At least 5 mm apart from target lesion | Most normal looking segment<br>No lipid-containing plaque<br>At least 5 mm apart from target lesion |
| **Stent Sizing** | By mean EEM diameter of proximal and distal reference segment | By mean EEM diameter at distal reference segment (rounded down to the nearest 0.25 mm).<br>By mean Lumen diameter at distal reference segment (rounded up to the nearest 0.25 mm). |
| **Stent Length** | By measuring the distance from the distal to the proximal reference site. | |
| **Stent Optimization** | | |
| ● **Stent Expansion** | Visually assess that the residual angiographic diameter stenosis is <10% "AND"<br>● Non-left main coronary artery lesions: MSA > 80% of the average reference lumen area "OR" a MSA of >5.5 $mm^2$ by IVUS and >4.5 $mm^2$ by OCT.<br>● Left main coronary artery lesions: MSA of >7 $mm^2$ for a distal left main coronary artery stenosis and >8 $mm^2$ for a proximal left main coronary artery stenosis by IVUS. | |
| ● **Stent Apposition** | No major malapposition (defined as an acute malapposition of ≥0.4 mm with longitudinal extension >1 mm) of the stent over its entire length against the vessel wall. | |
| ● **Edge Dissection** | No major edge dissection in the proximal or distal reference segments, defined as a location that is 5 mm from the edge of the stent, extends to the medial layer with potential to provoke flow disturbances (defined as ≥60° of the circumference of the vessel at site of dissection and/or ≥3 mm in length of the dissection flap) | |
| **Additional Procedure** | **If any of above findings are identified, additional procedural intervention, including additional post-dilatation of the stent or additional stent implantation is recommended.** | |



1. Raber L, Mintz GS, Koskinas KC, et al. Eur Heart J 2018;39:3281-300.

# Study Organization

- ***Principal Investigator***
  Joo-Yong Hahn

- ***Executive Committee***
  Joo-Yong Hahn
  Young Bin Song
  Jeong Hoon Yang
  Joo Myung Lee

- ***Clinical Event Adjudication Committee***
  Hyun-Jong Lee (Chair)
  Dong Ryeol Ryu
  Kyu Tae Park

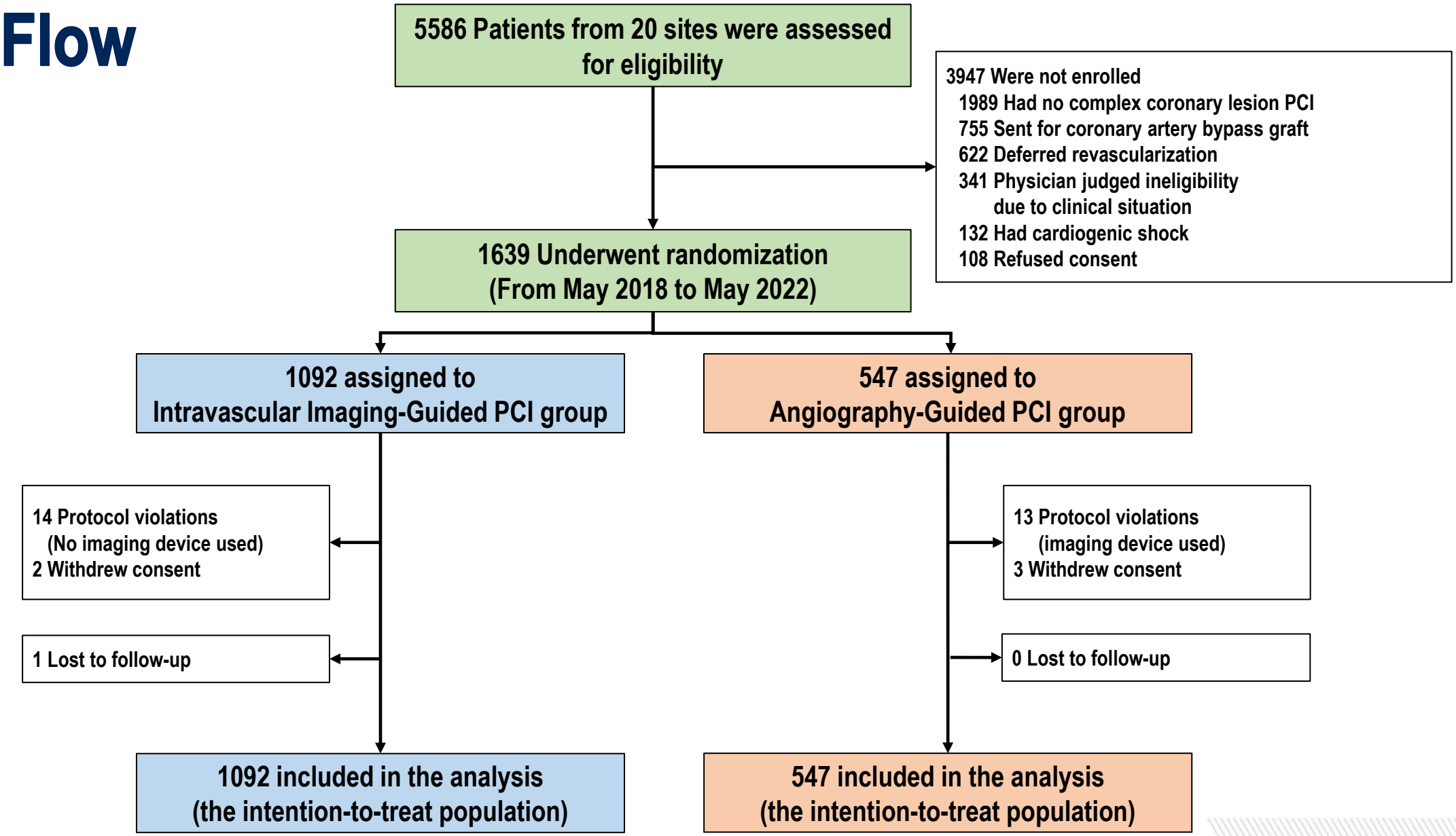
- ***Data Safety and Monitoring Board***
  Kiyuk Change (Chair)
  Seonwoo Kim (statistician)
  Dong-Yeon Kim

- ***Data Coordination and Management***
  Suyoun Shin
  Jinshil Kim
  Jaeyoung Park
  Seunghyun Lee
  Euna Kim
  Hyein Kang
  Su Jin Hwang
  Yeonhui Lee

- ***Angiography Core Laboratory***
  Hyein Kang
  Hyun Sung Joh
  Ki Hong Choi

- ***Intravascular Imaging Core Laboratory***
  Joo Myung Lee
  Hyein Kang
  Se Young Im

# Study Flow


5586 Patients from 20 sites were assessed for eligibility
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 (From May 2018 to May 2022)
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)

# Baseline Clinical Characteristics

| Characteristics | Total (N=1639) | Imaging-guided PCI (N=1092) | Angio-guided PCI (N=547) |
|---|---|---|---|
| Age — yr | 65.6±10.2 | 65.3±10.3 | 66.0±10.0 |
| Male — n (%) | 1300 (79.3) | 869 (79.6) | 431 (78.8) |
| Initial presentation — no. (%) | | | |
| Stable ischemic heart disease | 807 (49.2) | 532 (48.7) | 275 (50.3) |
| Acute coronary syndrome | 832 (50.8) | 560 (51.3) | 272 (49.7) |
| Unstable angina | 534 (32.6) | 361 (33.1) | 173 (31.6) |
| Acute myocardial infarction | 298 (18.2) | 199 (18.2) | 99 (18.1) |
| Non-ST-segment elevation myocardial infarction | 258 (15.7) | 171 (15.7) | 87 (15.9) |
| ST-segment elevation myocardial infarction | 40 (2.4) | 28 (2.6) | 12 (2.2) |
| Medical history — no. (%) | | | |
| Hypertension | 1005 (61.3) | 682 (62.5) | 323 (59.0) |
| Diabetes mellitus | 617 (37.6) | 394 (36.1) | 223 (40.8) |
| Dyslipidemia | 840 (51.3) | 560 (51.3) | 280 (51.2) |
| Current smoking | 307 (18.7) | 212 (19.4) | 95 (17.4) |
| Chronic renal insufficiency | 296 (18.1) | 203 (18.6) | 93 (17.0) |
| Previous PCI | 395 (24.1) | 268 (24.5) | 127 (23.2) |
| Previous myocardial infarction | 117 (7.1) | 75 (6.9) | 42 (7.7) |
| LV ejection fraction —(%) | 58.7±11.6 | 58.4±11.9 | 59.3±11.0 |

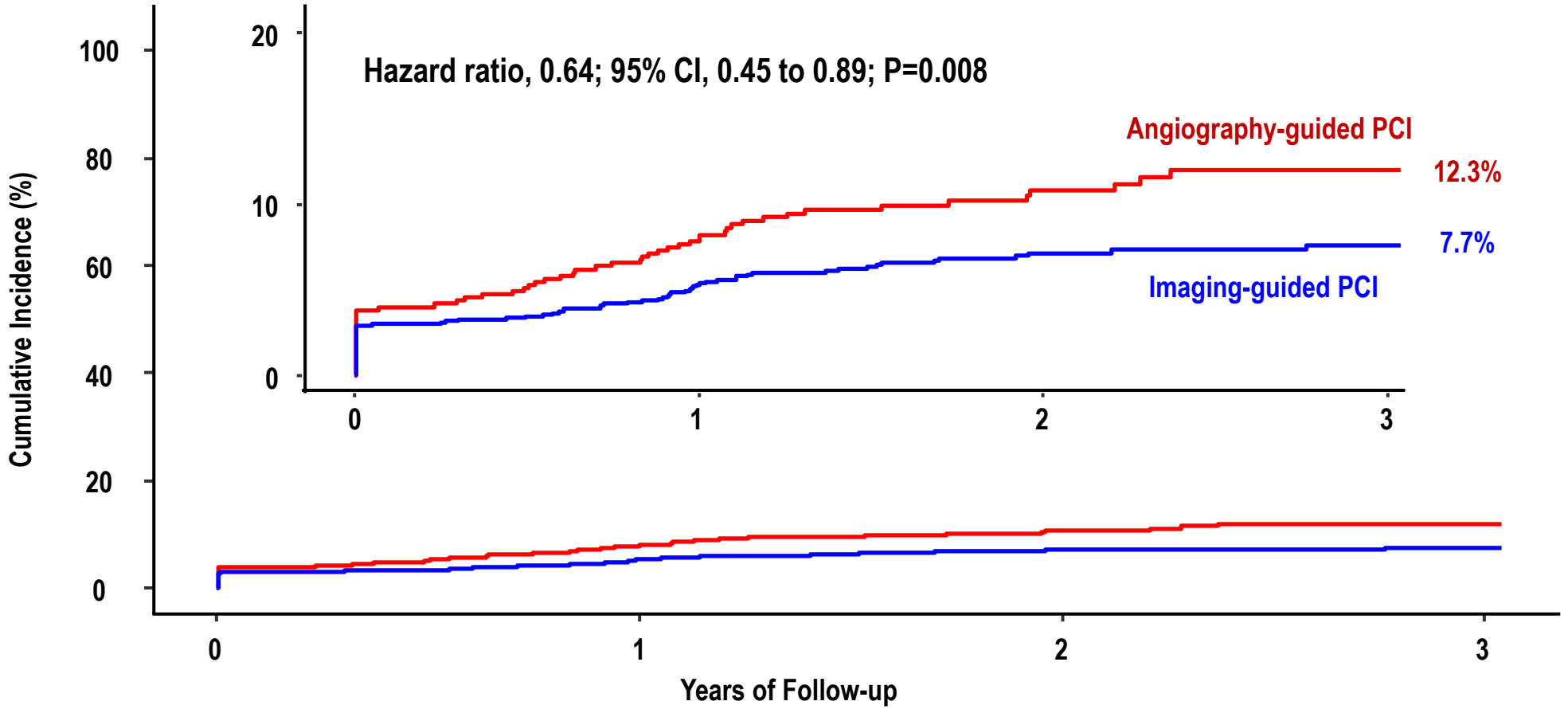
# Discharge Medications

| Characteristics | Total (N=1639) | Imaging-guided PCI (N=1092) | Angio-guided PCI (N=547) |
|---|---|---|---|
| Discharge medication — no. (%) | | | |
| Aspirin | 1606 (98.0) | 1069 (97.9) | 537 (98.2) |
| $P2Y_{12}$ inhibitor | | | |
| Any | 1603 (97.8) | 1067 (97.7) | 536 (98.0) |
| Clopidogrel | 1217 (74.3) | 799 (73.2) | 418 (76.4) |
| Ticagrelor | 209 (12.8) | 148 (13.6) | 61 (11.2) |
| Prasugrel | 178 (10.9) | 120 (11.0) | 58 (10.6) |
| Oral anticoagulant — no. (%) | 75 (4.6) | 46 (4.2) | 29 (5.3) |
| Statin — no. (%) | 1567 (95.6) | 1041 (95.3) | 526 (96.2) |
| Beta blocker — no. (%) | 710 (43.3) | 466 (42.7) | 244 (44.6) |
| ACE inhibitor or ARB — no. (%) | 945 (57.7) | 622 (57.0) | 323 (59.0) |

# Baseline Procedural Characteristics

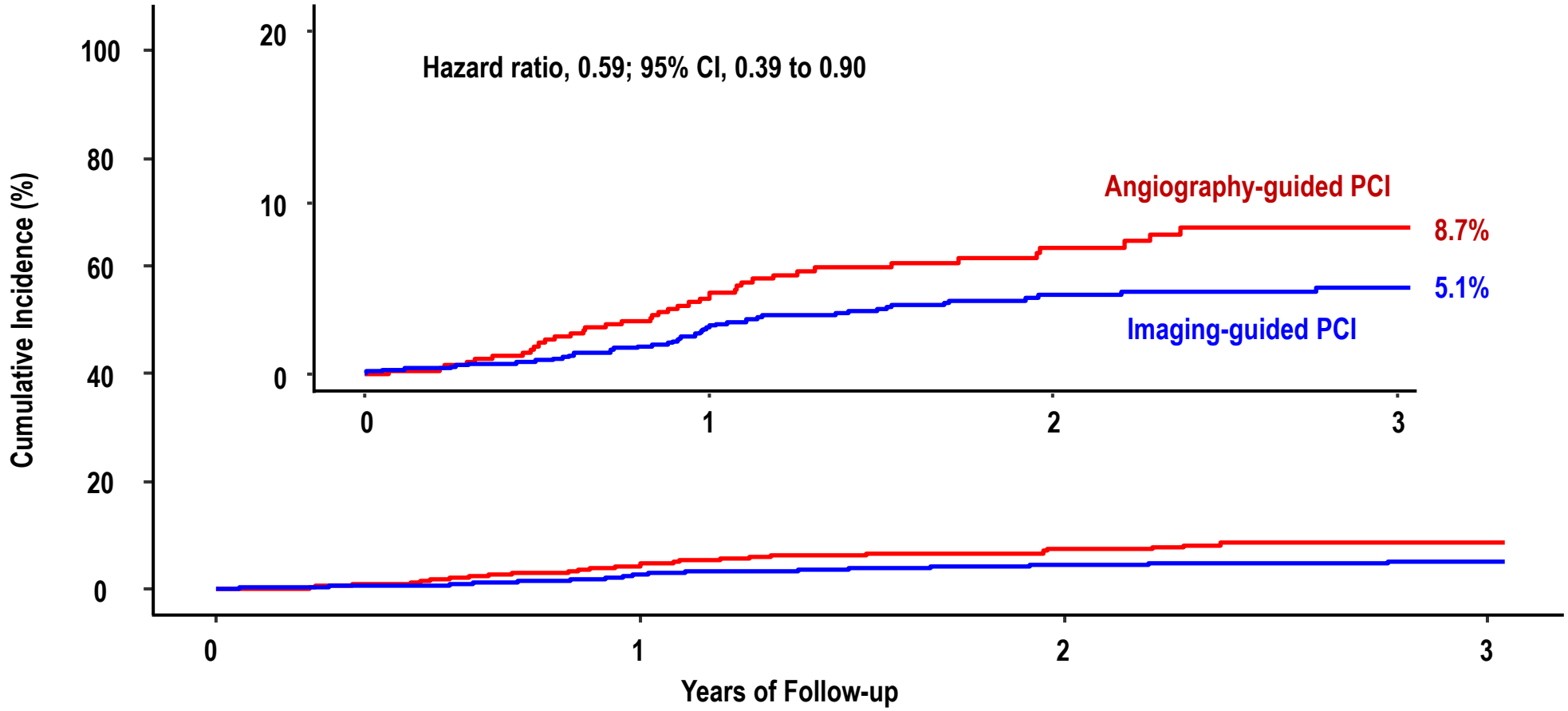
| Characteristics | Total (N=1639) | Imaging-guided PCI (N=1092) | Angio-guided PCI (N=547) |
|---|---|---|---|
| Complex coronary lesions — no. (%) | | | |
| True bifurcation lesion with side branch ≥2.5mm | 359 (21.9) | 233 (21.3) | 126 (23.0) |
| Chronic total occlusion (≥3 months) | 319 (19.5) | 220 (20.1) | 99 (18.1) |
| Unprotected left main coronary artery disease | 192 (11.7) | 138 (12.6) | 54 (9.9) |
| Long coronary lesion (implanted stent ≥38 mm in length) | 898 (54.8) | 617 (56.5) | 281 (51.4) |
| Multivessel PCI (≥2 vessels treated at one PCI session) | 622 (37.9) | 409 (37.5) | 213 (38.9) |
| Multiple stents (≥3 more stent per patient) | 305 (18.6) | 208 (19.0) | 97 (17.7) |
| In-stent restenosis | 236 (14.4) | 158 (14.5) | 78 (14.3) |
| Severely calcified (encircling calcium in angiography) | 231 (14.1) | 157 (14.4) | 74 (13.5) |
| Ostial coronary lesion (LAD, LCX, RCA) | 251 (15.3) | 182 (16.7) | 69 (12.6) |
| Number of vessels with disease — no. (%) | | | |
| 1-vessel disease | 526 (32.1) | 342 (31.3) | 184 (33.6) |
| 2-vessel disease | 621 (37.9) | 420 (38.5) | 201 (36.7) |
| 3-vessel disease | 492 (30.0) | 330 (30.2) | 162 (29.6) |
| Procedural characteristics | | | |
| Total no. of target lesions treated | 1.5±0.7 | 1.5±0.7 | 1.5±0.7 |
| Intravascular imaging devices used — no./total no. (%) † | 1091/1639 (66.6) | 1078/1092 (98.7) | 13/547 (2.4) |
| Intravascular ultrasound | 813/1091 (74.5) | 800/1078 (74.2) | 13/13 (100.0) |
| Optical coherence tomography | 278/1091 (25.5) | 278/1078 (25.8) | 0/13 (0.0) |
| Volume of contrast media used — ml | 207.3±116.5 | 214.2±118.5 | 193.7±111.3 |
| Procedural time — min | 65.0 (47.0-89.0) | 70.0 (51.0-95.0) | 53.5 (40.0-75.0) |
| Procedural success — no. (%) | 1613 (98.4) | 1073 (98.3) | 540 (98.7) |

# Primary End Point




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

# Target Vessel Failure excluding Procedural MI




| Number at risk | | | | |
|---|---|---|---|---|
| Angiography-guided PCI | 547 | 516 | 284 | 121 |
| Imaging-guided PCI | 1092 | 1051 | 596 | 256 |

# 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 | - | - | - | - | |
| 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) | |

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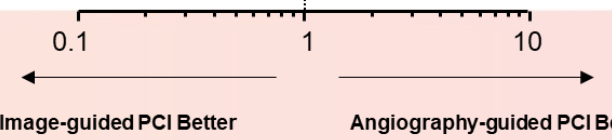
* Percentages are the cumulative incidence at 3 years. Hazard Ratio and 95% Confidence Intervals were calculated by Competing risk analysis using Fine and Gray methods.

† Contrast-induced nephropathy is defined as an increase in serum creatinine of ≥0.5 mg/dL or ≥25% from baseline within 48-72 hours after contrast agent exposure. Event rate is presented as proportion among group.

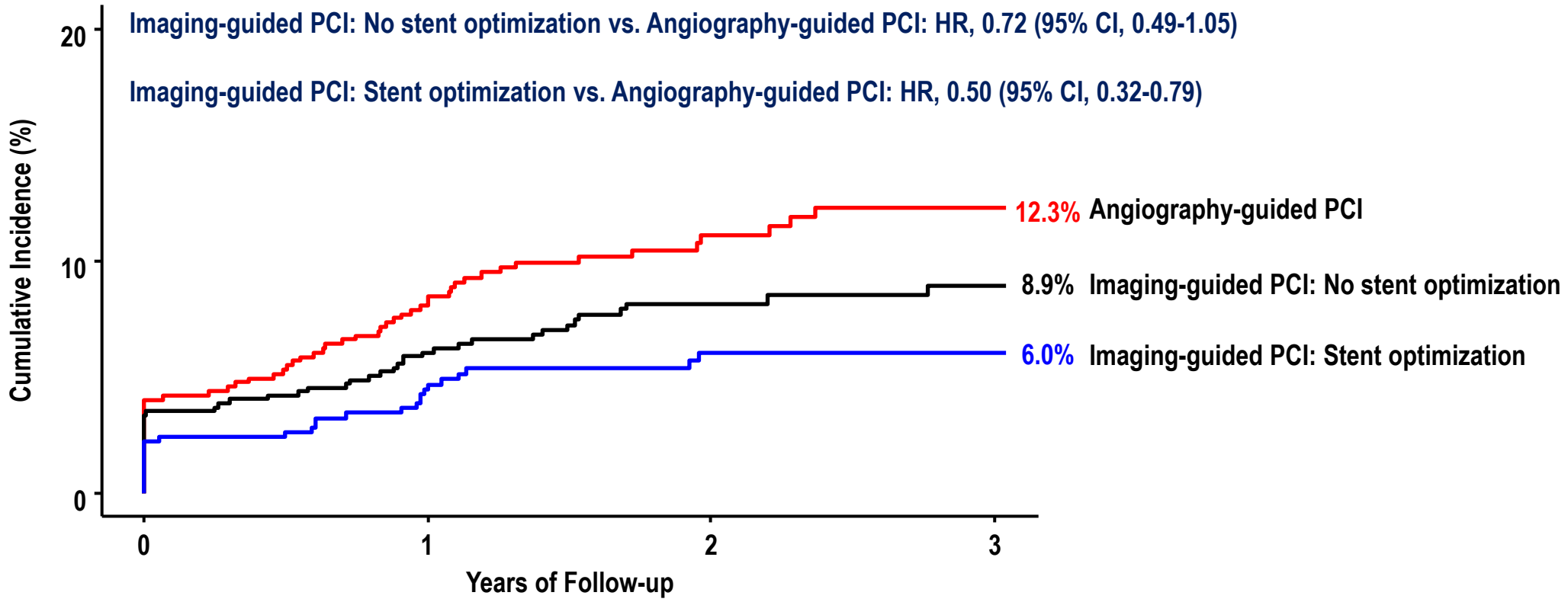
Because the statistical analysis plan did not include a provision for correcting for multiplicity when conducting tests for secondary outcomes, results are reported as point estimates and 95% CIs. The widths of the CIs have not been adjusted for multiplicity, so the intervals should not be used to infer definitive treatment effects for secondary outcomes. All the models were adjusted for the clinical presentation and participating centers (stratification factors).

# Prespecified Subgroup Analysis

| Subgroup | Imaging-guided PCI<br>No. of events / total no. of patients (cumulative incidence, %) | Angiography-guided PCI<br>No. of events / total no. of patients (cumulative incidence, %) | Hazard ratio (95% CI) |
|---|---|---|---|
| **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) |



# Imaging-guided Procedural Optimization

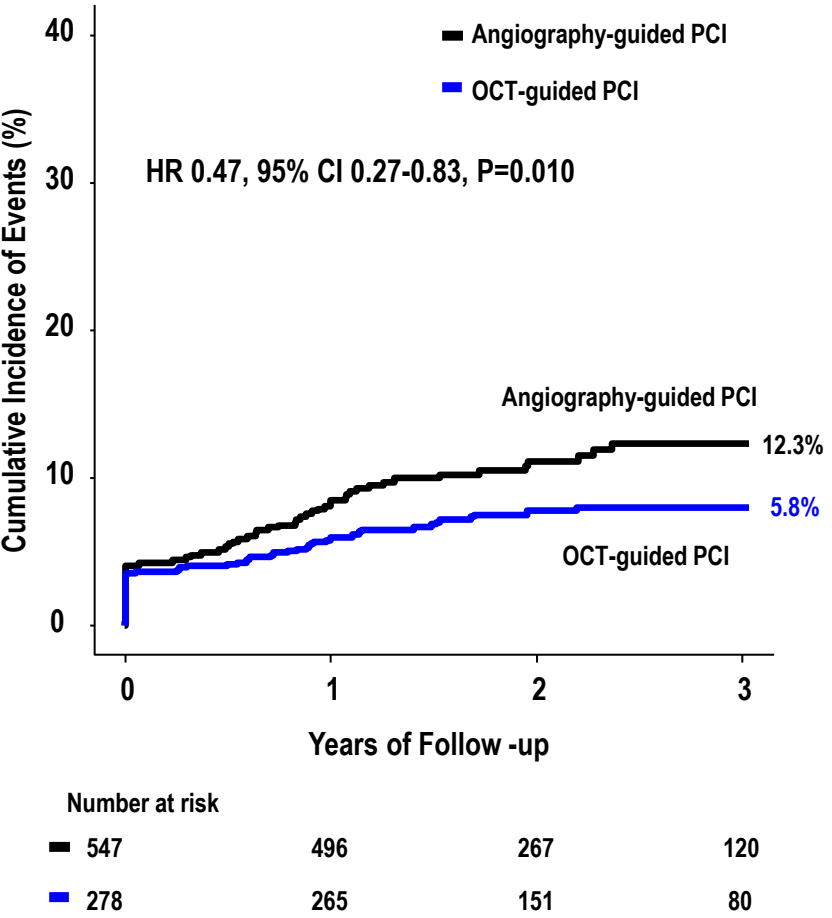



**No. at Risk**

| | | | | |
|---|---|---|---|---|
| Angiography-guided PCI | 547 | 496 | 267 | 120 |
| Imaging-guided PCI: No stent optimization | 596 | 556 | 307 | 152 |
| Imaging-guided PCI: Stent optimization | 496 | 467 | 260 | 103 |

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

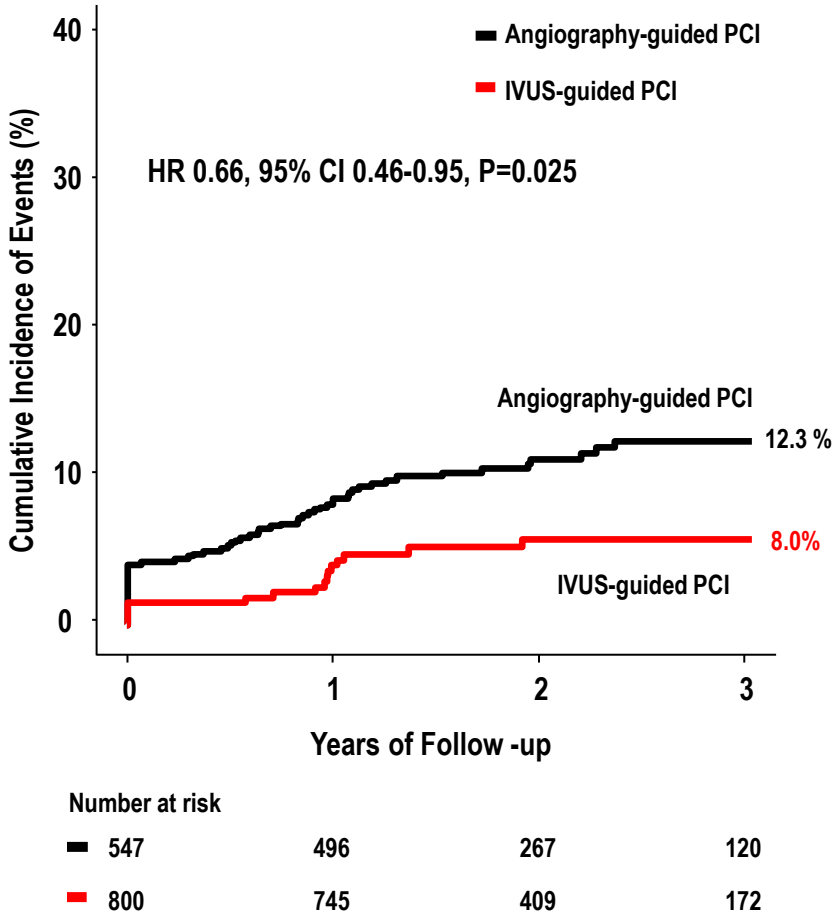
## OCT-guided PCI vs. Angiography-guided PCI




Number at risk

| | | | | |
|---|---|---|---|---|
| 547 | 496 | 267 | 120 |
| 278 | 265 | 151 | 80 |

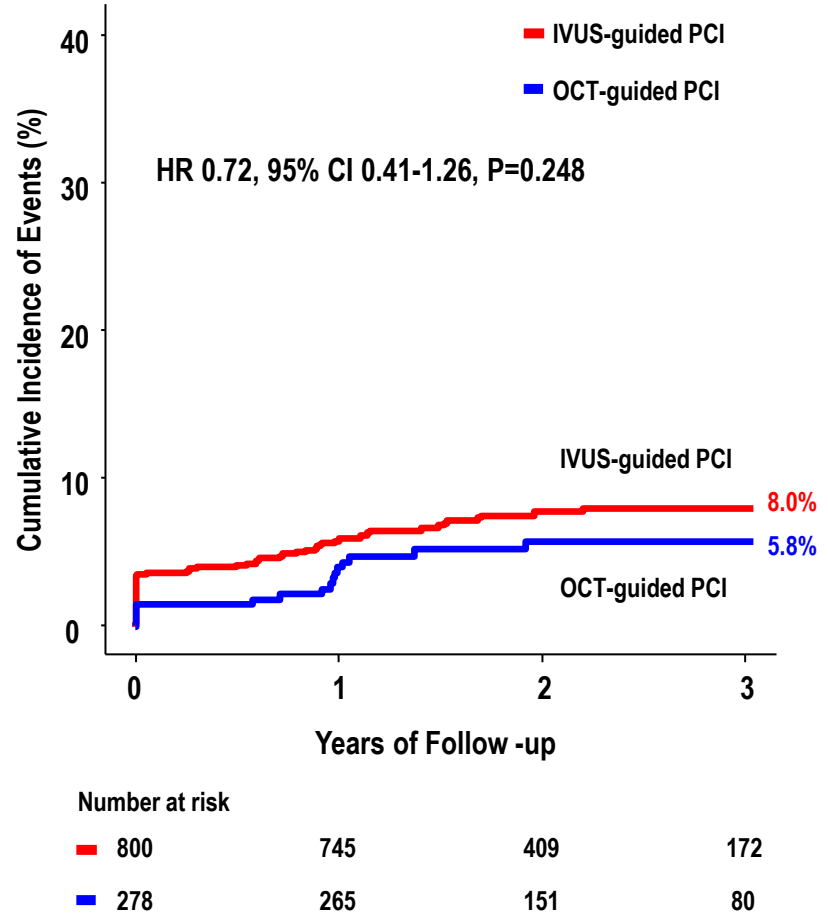
## IVUS-guided PCI vs. Angiography-guided PCI




Number at risk

| | | | | |
|---|---|---|---|---|
| 547 | 496 | 267 | 120 |
| 800 | 745 | 409 | 172 |

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




Number at risk

| | | | | |
|---|---|---|---|---|
| 800 | 745 | 409 | 172 |
| 278 | 265 | 151 | 80 |

# Limitations

- The trial was unblinded and it was not possible to mask the operator to the study arm. However, precisely defined criteria was used for endpoint analysis, core laboratories were done, and clinical events were adjudicated by a independent committee.
- Intravascular imaging-defined stent optimization was achieved in only 45.4% of patients. One possible explanation may be that we focused our study only on complex coronary artery lesions.
- Since patients in the angiography-guided PCI group did not undergo intravascular imaging, we can only assess stent optimization in this group by quantitative coronary angiography when examining the relationship between stent optimization and clinical differences between the groups.

# Conclusion

***Among patients with complex coronary artery lesions,***

- **Intravascular imaging-guided PCI** was associated with a **lower incidence of a composite of cardiac death, target vessel-related myocardial infarction, or clinically driven target vessel revascularization** compared to **angiography-guided PCI.**
- The **RENOVATE-COMPLEX-PCI** trial support the intravascular imaging-guided PCI in treatment of patients with complex coronary artery lesions undergoing PCI.

# Thank You Very Much!

I would like to thank **patients** enrolled, **research nurses**, **study coordinators**, and **participating investigators**.

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# Intravascular Imaging–Guided or Angiography-Guided Complex PCI

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