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Intravascular Imaging–Guided Versus Angiography-Guided Complex PCI

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The RENOVATE-COMPLEX-PCI Trial

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ORIGINAL ARTICLE

Intravascular Imaging–Guided or Angiography-Guided Complex PCI

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for the RENOVATE-COMPLEX-PCI Investigators*

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 1,1,1/1,0,1/0,1,1) with side branch ≥ 2.5 mm
- ② Chronic total occlusion (≥ 3 months) as target lesion
- ③ PCI for unprotected left main disease
- ④ Implanted stent length ≥ 38 mm

- 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.

Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Total (N = 1639)	Intravascular Imaging- Guided PCI Group (N = 1092)	Angiography-Guided PCI Group (N = 547)
Age — yr	65.6±10.2	65.3±10.3	66.0±10.0
Male sex — no. (%)	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-STEMI	258 (15.7)	171 (15.7)	87 (15.9)
STEMI	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)
Insulin-treated diabetes mellitus	51 (3.1)	28 (2.6)	23 (4.2)
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)
Previous stroke	112 (6.8)	70 (6.4)	42 (7.7)
Peripheral arterial disease	44 (2.7)	27 (2.5)	17 (3.1)
Left ventricular ejection fraction — %	58.7±11.6	58.4±11.9	59.3±11.0
Medication at discharge — no. (%)			
Aspirin	1606 (98.0)	1069 (97.9)	537 (98.2)
P2Y ₁₂ inhibitor	1603 (97.8)	1067 (97.7)	536 (98.0)
Clopidogrel	1216 (74.2)	799 (73.2)	417 (76.2)
Ticagrelor	209 (12.8)	148 (13.6)	61 (11.2)
Prasugrel	178 (10.9)	120 (11.0)	58 (10.6)
Oral anticoagulant	75 (4.6)	46 (4.2)	29 (5.3)
Statin	1567 (95.6)	1041 (95.3)	526 (96.2)
Beta-blocker	710 (43.3)	466 (42.7)	244 (44.6)
ACE inhibitor or ARB	945 (57.7)	622 (57.0)	323 (59.0)

* Plus-minus values are means ±SD. ACE denotes angiotensin-converting enzyme, ARB angiotensin-receptor blocker, PCI percutaneous coronary intervention, and STEMI ST-segment elevation myocardial infarction.

Table 2. Target-Lesion and Procedural Characteristics.*

Characteristic	Total (N = 1639)	Intravascular Imaging– Guided PCI Group (N = 1092)	Angiography-Guided PCI Group (N = 547)
Target-lesion characteristics			
Complex coronary lesions — no. (%)†			
True bifurcation lesion	359 (21.9)	233 (21.3)	126 (23.0)
Chronic total occlusion	319 (19.5)	220 (20.1)	99 (18.1)
Unprotected left main coronary artery disease	192 (11.7)	138 (12.6)	54 (9.9)
Diffuse long coronary-artery lesion	898 (54.8)	617 (56.5)	281 (51.4)
Multivessel PCI involving ≥2 major coronary arteries	622 (37.9)	409 (37.5)	213 (38.9)
Lesion necessitating use of ≥3 stents	305 (18.6)	208 (19.0)	97 (17.7)
Lesion with in-stent restenosis	236 (14.4)	158 (14.5)	78 (14.3)
Severely calcified lesion	231 (14.1)	157 (14.4)	74 (13.5)
Ostial lesions of major coronary artery	251 (15.3)	182 (16.7)	69 (12.6)
≥3 Complex coronary lesions — no. (%)	505 (30.8)	352 (32.2)	153 (28.0)
No. of vessels with disease — no. (%)			
1	526 (32.1)	342 (31.3)	184 (33.6)
2	621 (37.9)	420 (38.5)	201 (36.7)
3	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 device used — no./total no. (%)‡			
Intravascular ultrasonography	813/1091 (74.5)	800/1078 (74.2)	13/13 (100)
Optical coherence tomography	278/1091 (25.5)	278/1078 (25.8)	0/13
Volume of contrast media used — ml	207.3±116.5	214.2±118.5	193.7±111.3
Median procedural time (IQR) — min	65 (47–89)	70 (51–95)	53.5 (40–75)
Procedural success — no. (%)	1613 (98.4)	1073 (98.3)	540 (98.7)

* Plus-minus values are means ±SD. Percentages may not total 100 because of rounding. IQR denotes interquartile range.

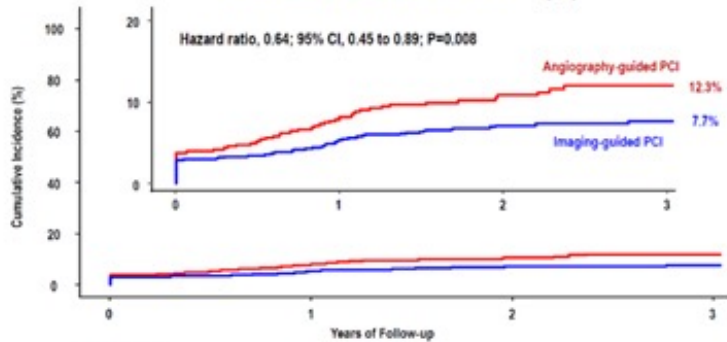
† Diffuse long coronary-artery lesions were defined as the use of an implanted stent of at least 38 mm in length. Multivessel PCI involved at least two major coronary arteries undergoing PCI during one session. Severely calcified lesions were those with encircling calcium seen on angiography.

‡ A total of 14 patients in the intravascular imaging group did not have intravascular imaging used during their PCI procedure owing to failure to pass the device (in 9 patients), failed PCI (in 4), or hemodynamic instability during the procedure (in 1). A total of 13 patients in the angiography-guided group had intravascular imaging used during the procedure at the operator's discretion for the treatment of long coronary lesion (in 2 patients), unprotected left main disease (in 2), chronic total occlusion (in 2), severe calcification (in 3), unclear lesion length (in 2), ostial lesion (in 1), or hemodynamic instability during the procedure (in 1).

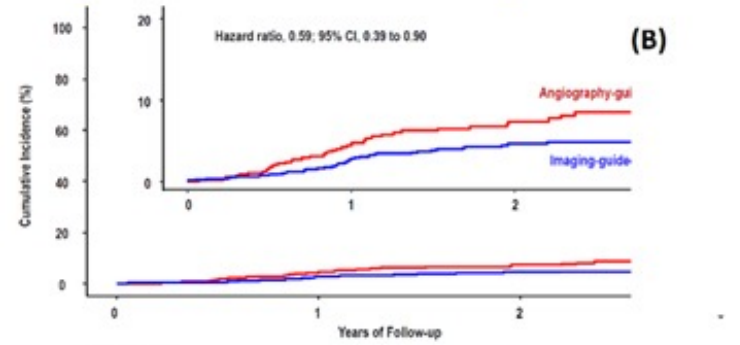
Table 3. Primary and Secondary End Points According to Competing-Risk Analyses.*

End Point	Total (N = 1639)	Intravascular Imaging– Guided PCI Group (N = 1092)	Angiography-Guided PCI Group (N = 547)	Hazard Ratio (95% CI)
		<i>number (cumulative incidence, %)</i>		
Primary end point: target-vessel failure†	136 (9.2)	76 (7.7)	60 (12.3)	0.64 (0.45–0.89)‡
Secondary end points§				
Target-vessel failure without procedure-related myocardial infarction	88 (6.3)	48 (5.1)	40 (8.7)	0.59 (0.39–0.90)
Target-vessel–related myocardial infarction or death from cardiac causes	96 (6.4)	53 (5.3)	43 (8.5)	0.63 (0.42–0.93)
Death from any cause¶	70 (5.6)	42 (5.3)	28 (6.4)	0.71 (0.44–1.15)
Death from cardiac causes	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 myocardial infarction	68 (4.3)	38 (3.7)	30 (5.6)	0.74 (0.45–1.22)
Spontaneous myocardial infarction	17 (1.2)	8 (0.9)	9 (1.8)	0.66 (0.23–1.90)
Procedure-related myocardial infarction	52 (3.2)	30 (2.7)	22 (4.0)	0.77 (0.43–1.35)
Non–target-vessel–related myocardial infarction	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)

Primary End Point (A)



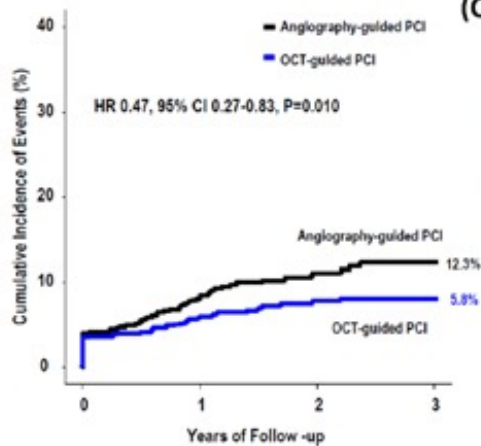
Target Vessel Failure excluding Procedural MI (B)



	0	1	2	3		0	1	2	3
Angiography-guided PCI	547	496	280	120	Angiography-guided PCI	547	516	284	121
Imaging-guided PCI	1092	1023	591	255	Imaging-guided PCI	1092	1051	596	256

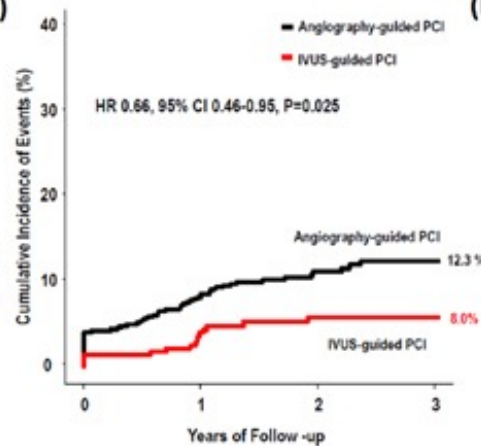
OCT-guided PCI vs. IVUS-guided PCI vs. Angiography-PCI

OCT-guided PCI vs. Angiography-guided PCI (C)



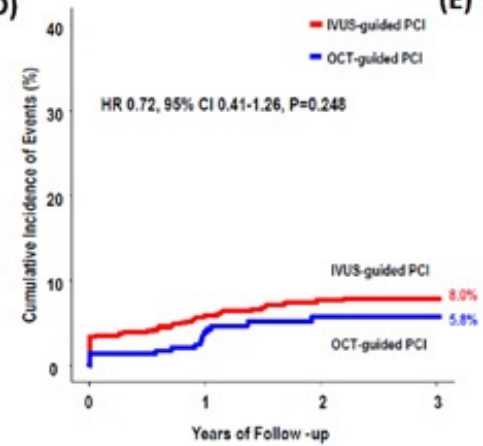
	0	1	2	3
Angiography-guided PCI	547	496	267	120
OCT-guided PCI	278	265	151	80

IVUS-guided PCI vs. Angiography-guided PCI (D)



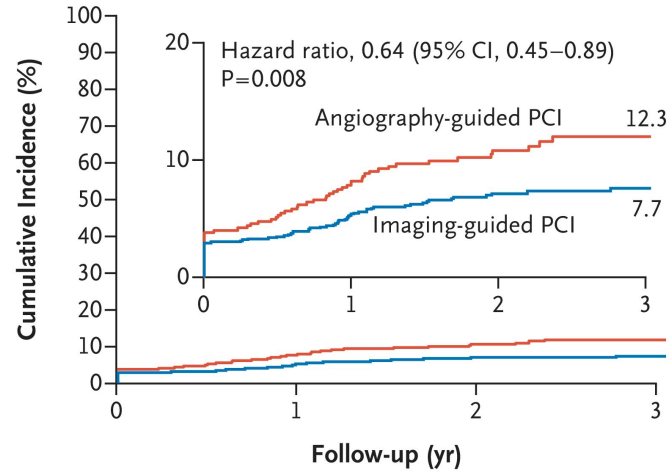
	0	1	2	3
Angiography-guided PCI	547	496	267	120
IVUS-guided PCI	800	745	409	172

OCT-guided PCI vs. IVUS-guided PCI (E)



	0	1	2	3
IVUS-guided PCI	800	745	409	172
OCT-guided PCI	278	265	151	80

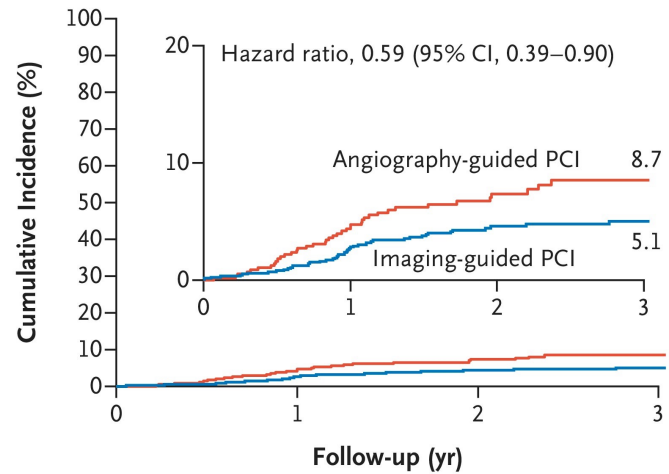
A Target-Vessel Failure



No. at Risk

Angiography-guided PCI	547	496	280	120
Imaging-guided PCI	1092	1023	591	255

B Target-Vessel Failure without Procedure-Related Myocardial Infarction



No. at Risk

Angiography-guided PCI	547	516	284	121
Imaging-guided PCI	1092	1051	596	256

