

Imaging Guided PCI vs. Angio Guided PCI Focusing on OCT

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Disclosure

➤ Grant support

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- Abbott Vascular, Biosensors, Biotronik, Boston Scientific, Daiichi Sankyo, Donga-ST, Hanmi Pharmaceutical, and Medtronic

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- Abbott Vascular, Amgen, Astra Zeneca, Biosensors, Biotronik, Boston Scientific, Daiichi Sankyo, MSD Korea, Novartis, Pfizer, and Sanofi-Aventis

Background

- Previous trials (CTO-IVUS, AVIO, HOME-DES-IVUS, IVUS-XPL, and ULTIMATE) have shown lower rates of major adverse clinical events after intravascular ultrasound (IVUS)-guided percutaneous coronary intervention (PCI) than after angiography-guided PCI but have not been considered definitive owing to limited sample size, short follow-up duration, or the inclusion of highly selected coronary-lesion subsets.
- Our group has already reported the long-term benefit of the use of IVUS in patients undergoing complex PCI in an observational study.¹

However, a randomized trial is needed to confirm the benefit of intravascular imaging-guided PCI in patients with complex coronary artery lesions.

1. Choi KH, Song YB, ..., Hahn JY. JACC Cardiovasc Interv. 2019

Study Objective

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

Working 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 (NCT03381872)

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

Patients with Complex Coronary Artery Lesions Undergoing PCI

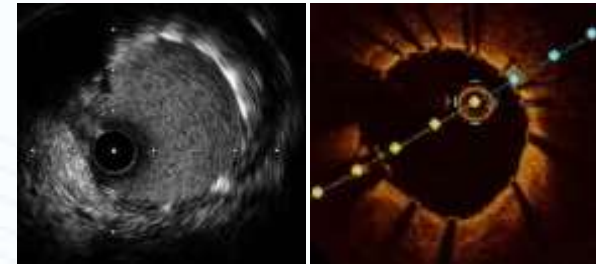
Randomization (2:1) for Treatment Strategy of Target Lesions

Imaging-Guided Strategy

Angiography-Guided Strategy

Primary end point: target vessel failure

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 ≥ 2.5 mm
 - 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

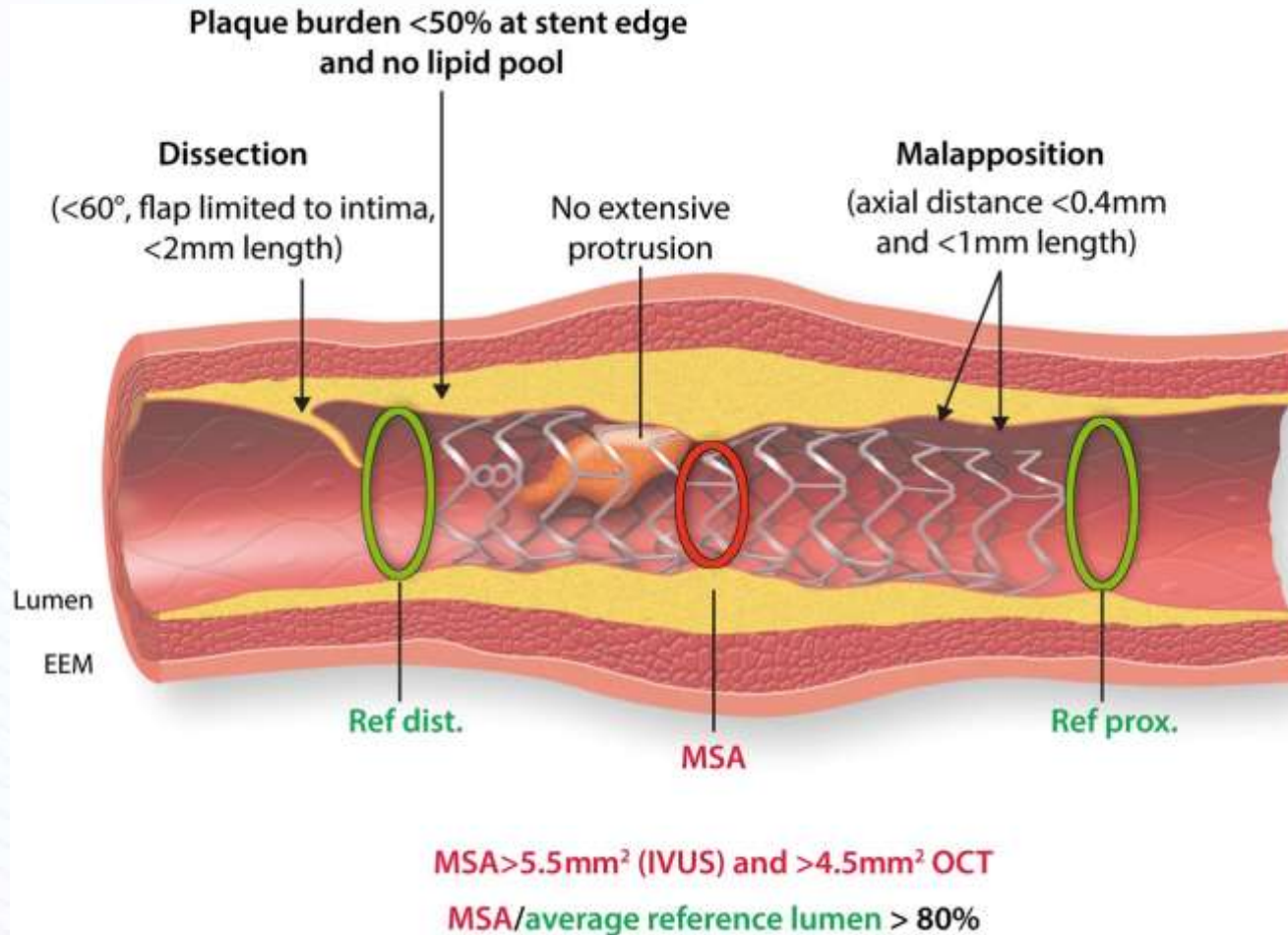
1. Target lesions not amenable to PCI by operators' decision
2. Cardiogenic shock (Killip class IV) at presentation
3. Intolerance to Aspirin, Clopidogrel, Prasugrel, Ticagrelor, Heparin, or Everolimus
4. Known true anaphylaxis to contrast medium (not allergic reaction but anaphylactic shock)
5. Pregnancy 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.

PCI and Intravascular Imaging

- PCI and Intravascular image acquisition were performed with the use of standard techniques.
 - Intracoronary NG
 - Automatic pullback
- For patients who had been assigned to the intravascular imaging group, the choice of IVUS or OCT was made at the operators' discretion.
- Intravascular imaging could be used at any time during the PCI procedure but was mandated after stent implantation to determine whether the stented segment was optimized.

Criteria of PCI Optimization by Intravascular Imaging

An expert consensus document of the European Association of PCI¹



- Standardized protocols for selection of reference size, stent size, and length
- In left main lesions, MSA >7 mm² for a distal left main coronary artery stenosis and >8 mm² for a proximal left main coronary artery stenosis
- If stent optimization did not occur, additional dilation of the stent or additional stent implantation was recommended, and repeat evaluation on intravascular imaging was mandated.

Study End Points

Primary End Point

- **Target vessel failure**

- A composite of cardiac death, target vessel-related MI, or clinically-driven target vessel revascularization.

Secondary End Points

- 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

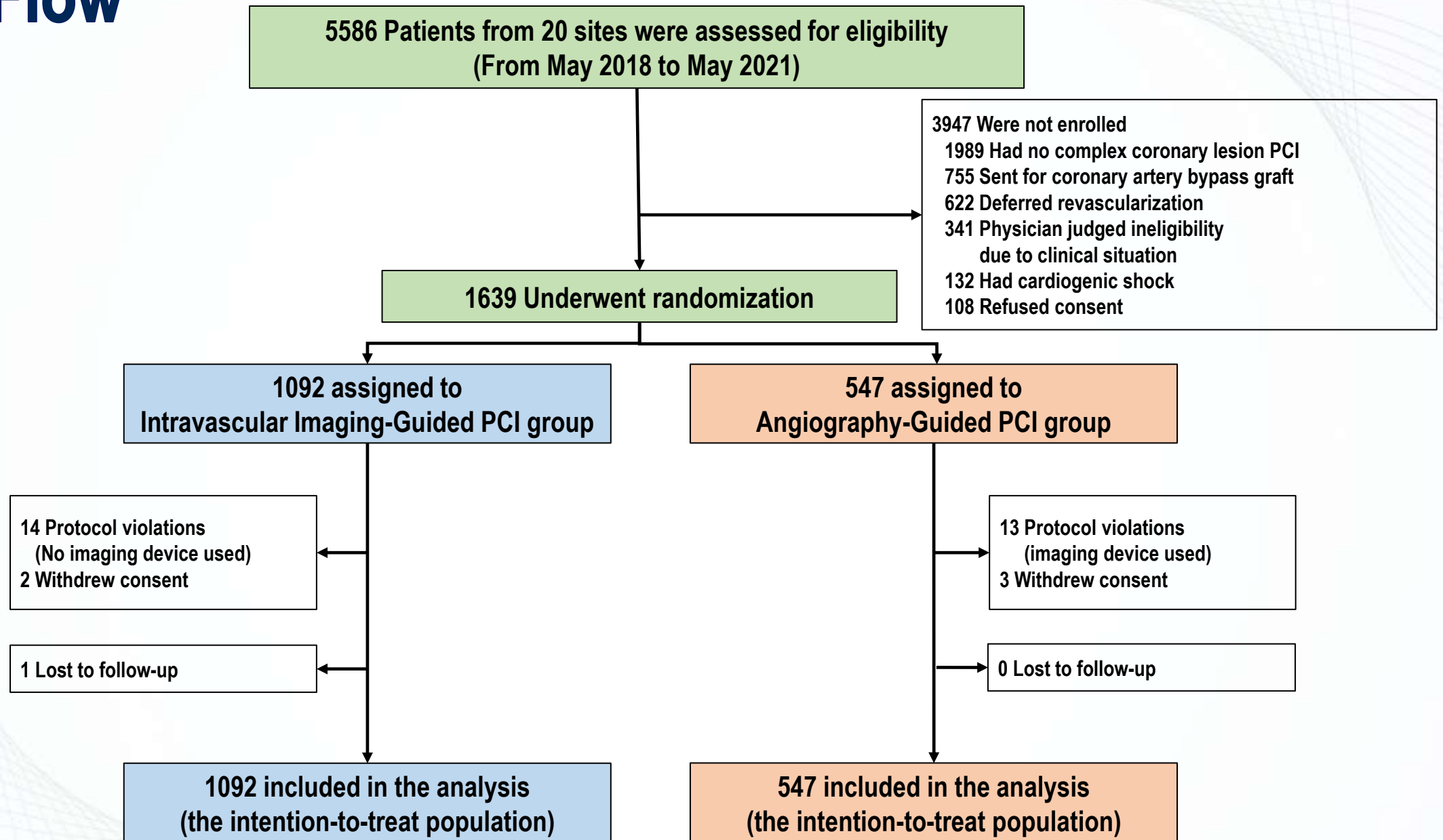
- Spontaneous MI according to 3rd Universal Definition¹
- Other clinical events according to ARC-2 criteria³
- Procedure-related MI according to SCAI Definition²

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.

Study Flow



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

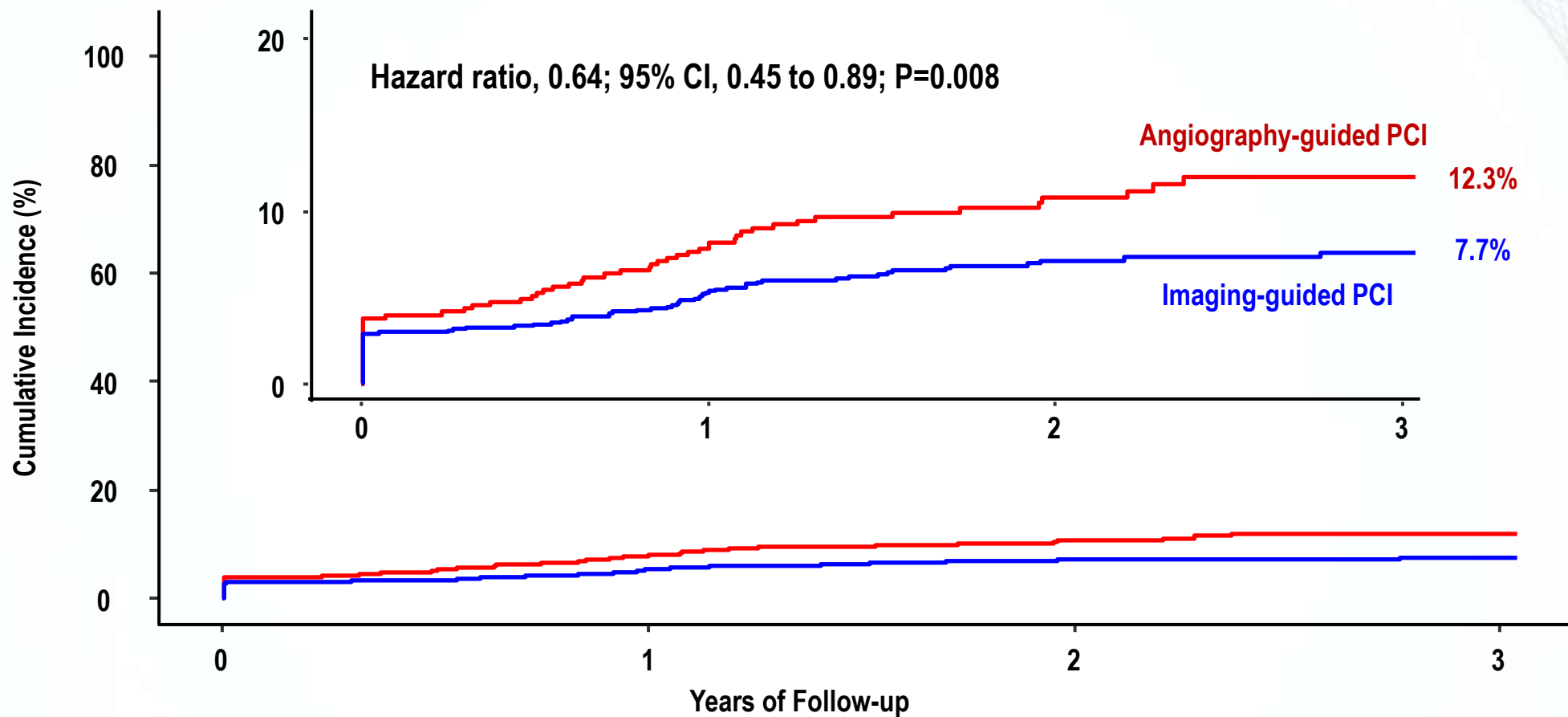
Baseline Angiographic and Procedural Characteristics

Characteristics	Total (N=1639)	Imaging-guided PCI (N=1092)	Angio-guided PCI (N=547)
Complex coronary lesions — no. (%)			
True bifurcation lesion with side branch ≥ 2.5 mm	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			
Radial artery access — no. (%)	1253 (76.4%)	827 (75.7%)	426 (77.9%)
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 \pm 116.5	214.2 \pm 118.5	193.7 \pm 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)

Lesion-level Analysis

Characteristic	Total (N=2438)	Imaging-guided PCI (N=1623)	Angiography-guided PCI (N=815)
Quantitative coronary angiography			
Pre-PCI QCA			
Proximal reference vessel diameter — mm	3.2±0.5	3.2±0.5	3.1±0.5
Distal reference vessel diameter — mm	2.7±0.5	2.7±0.5	2.7±0.4
Minimum lumen diameter — mm	0.44±0.37	0.44±0.37	0.44±0.36
Diameter stenosis — %	85.4±11.6	85.4±11.5	85.2±11.7
Lesion length — mm	27.9±15.6	28.4±15.9	26.8±14.8
Post-PCI QCA			
Minimum lumen diameter — mm	2.8±0.5	2.8±0.5	2.7±0.5
Diameter stenosis — %	9.8±8.8	9.8±8.9	10.0±8.6
Post-PCI residual stenosis<10% — no. (%)	1638/2346 (69.8)	1098/1560 (70.4)	540/786 (68.7)
Profile of intravascular imaging use — no./total no. (%)			
Pre-PCI evaluation only	18/1569 (1.1)	16/1549 (1.0)	2/20 (10.0)
Post-PCI evaluation only	371/1569 (23.6)	366/1549 (23.6)	5/20 (25.0)
Both pre- and post-PCI evaluation	1180/1569 (75.2)	1167/1549 (75.3)	13/20 (65.0)
Adjunctive non-compliant balloon used — no. (%)			
Size of adjunctive balloon — mm	3.5±0.6	3.5±0.6	3.5±0.5
Maximum inflation pressure — atm	18.9±4.6	18.7±4.6	19.2±4.6

Primary End Point



Number at risk

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

Primary and Secondary End Points

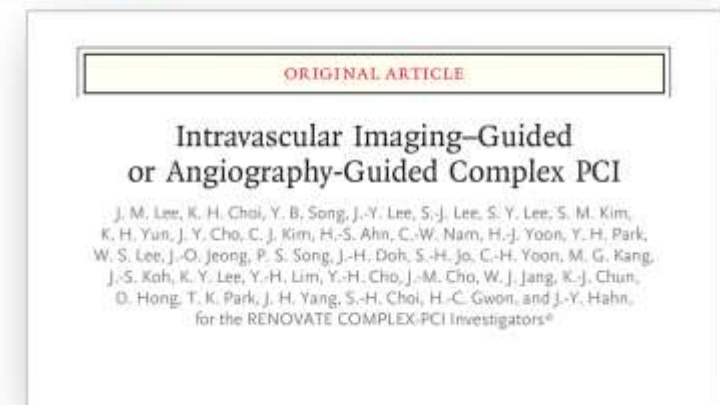
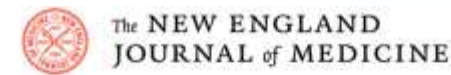
End Point	Total (N=1639)	Imaging-guided PCI (N=1092)	Angiography-guided PCI (N=547)	Hazard Ratio (95% CI)*	P Value
Primary end point — no. (%)					
Target vessel failure	136 (9.2)	76 (7.7)	60 (12.3)	0.64 (0.45-0.89)	0.008
Secondary end points — no. (%)					
Target vessel failure without procedure-related 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)	

Limitations

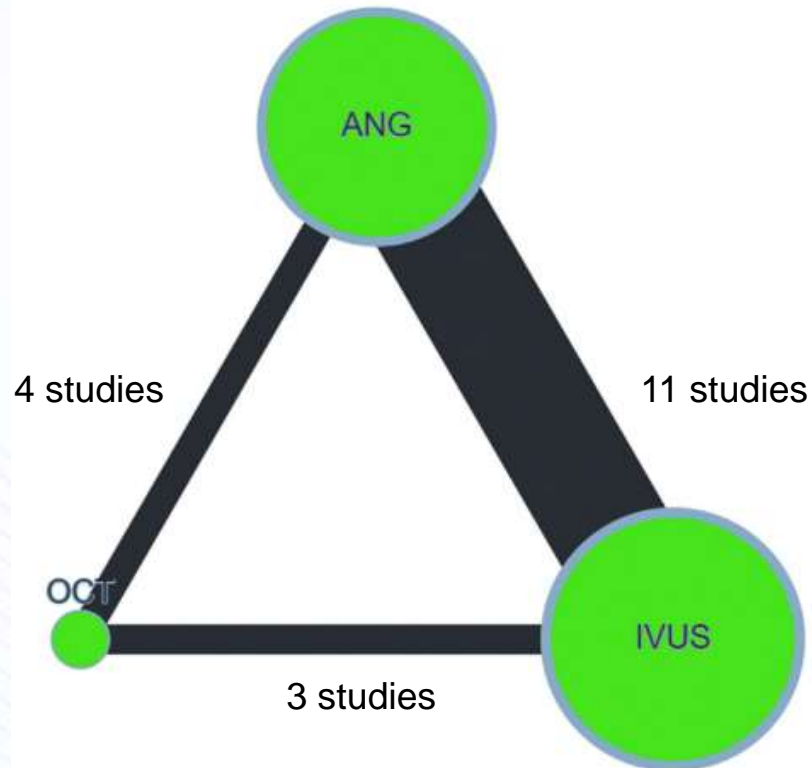
- The trial was unblinded, and it was not possible for the operators to be unaware of the patient's assigned trial group. However, we minimized the risk of bias by using an end-point analysis with precisely defined criteria, by having angiographic and imaging analyses performed at the core laboratories, and by having clinical events adjudicated by a committee.
- Intravascular imaging-defined stent optimization was achieved in only 45.4% of patients. One possible explanation may be that we focused our trial only on complex coronary artery lesions.
- Given patients in the angiography-guided PCI group did not undergo intravascular imaging, we could assess stent optimization in this group only by means of QCA.

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.



Network Meta-analysis: IVUS vs. OCT vs. Angiography



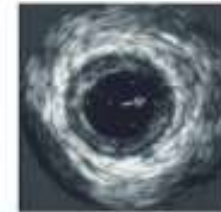
OUTCOMES

- MACE
- Myocardial Infarction
- Target Vessel Revascularization
- All-Cause mortality
- Cardiovascular mortality

ANGIOGRAPHY



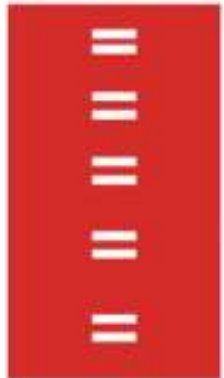
IVUS



OCT

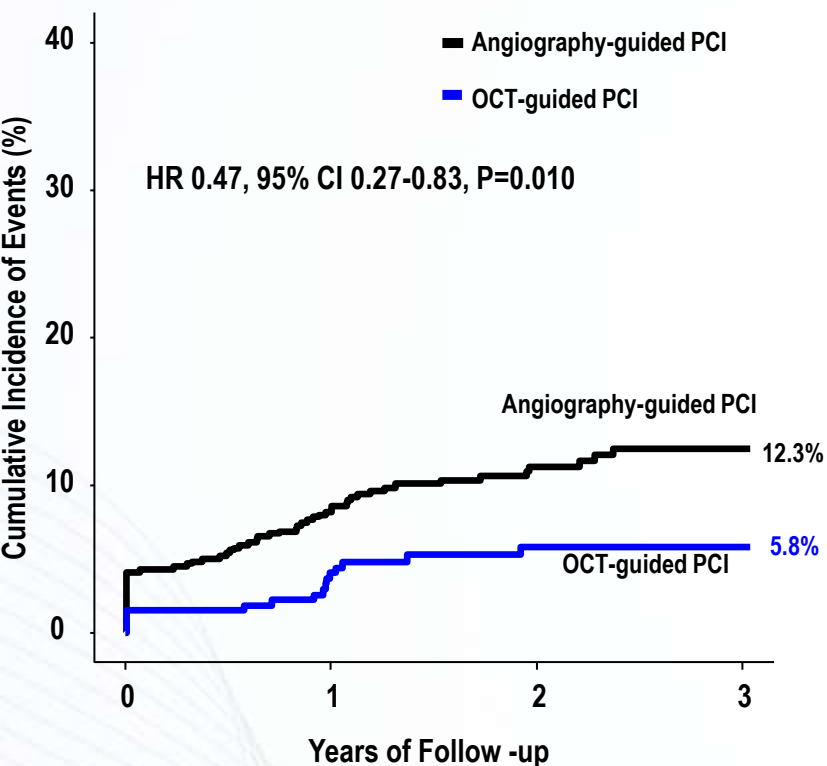


COMPARISON



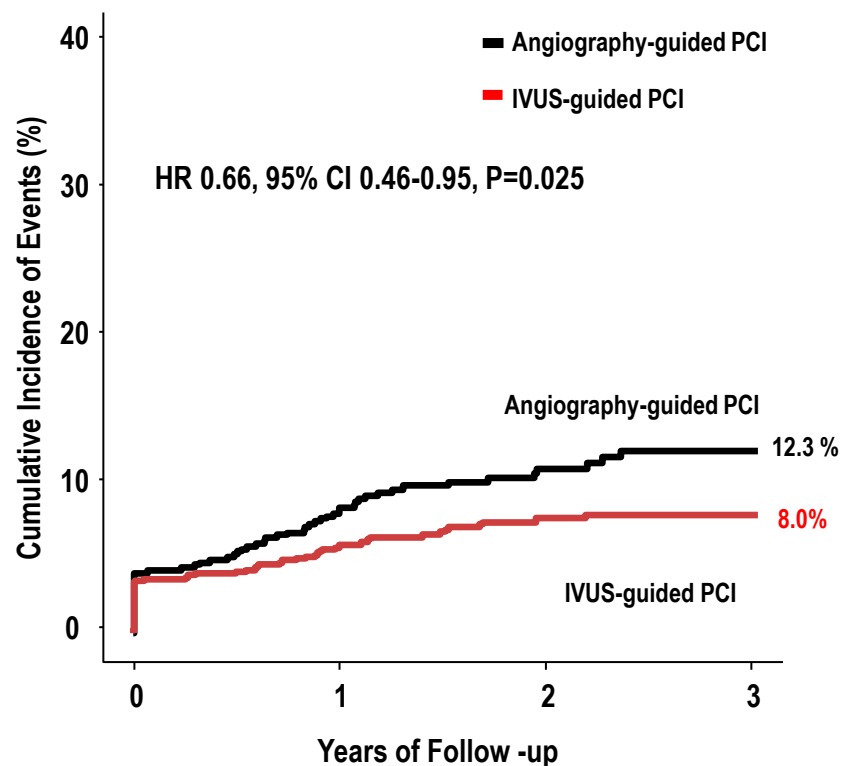
OCT-guided PCI vs. IVUS-guided PCI vs. Angiography-PCI

OCT-guided PCI vs. Angiography-guided PCI



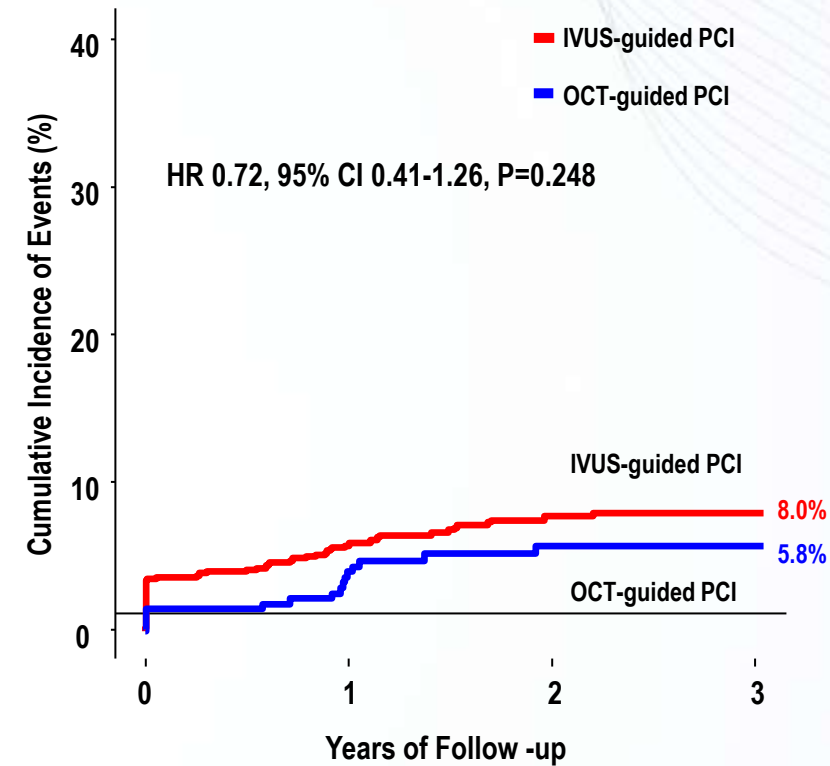
Number at risk				
547	496	267	120	
278	265	151	80	

IVUS-guided PCI vs. Angiography-guided PCI



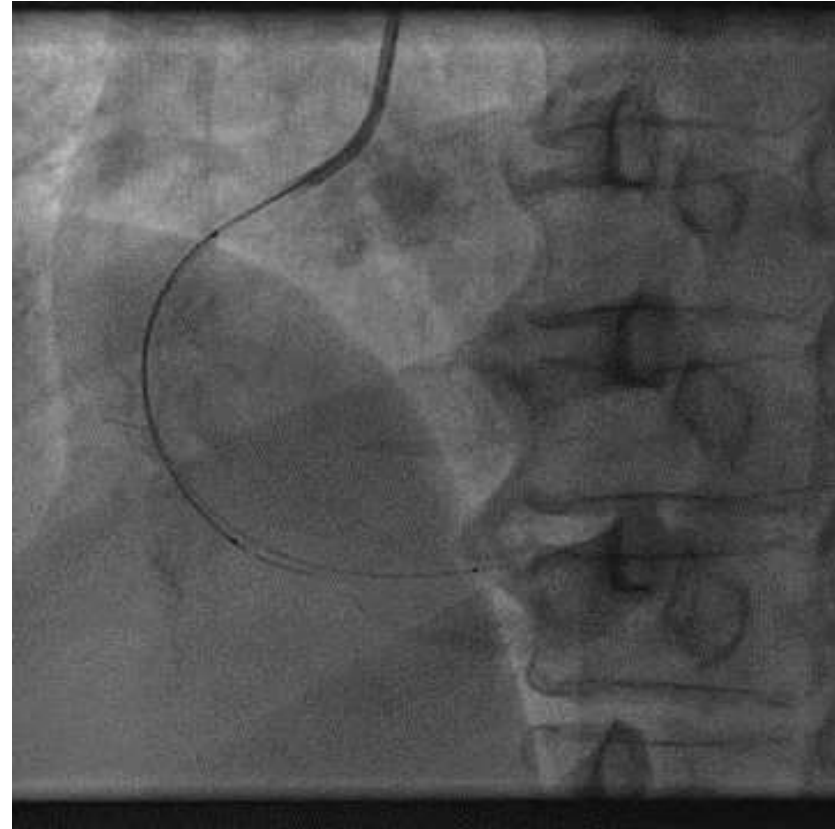
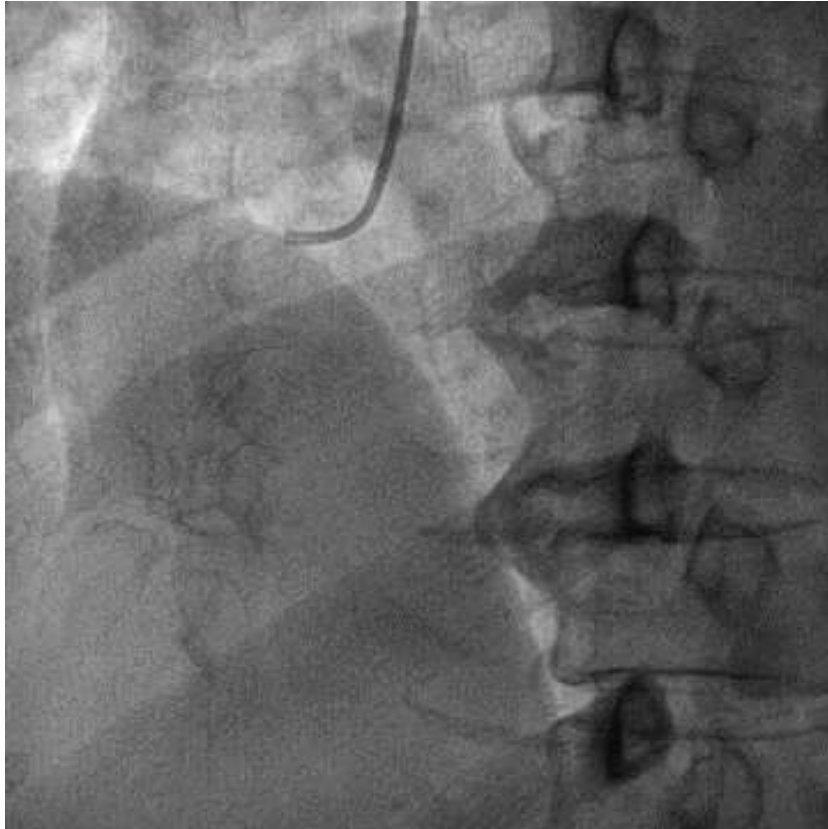
Number at risk				
547	496	267	120	
800	745	409	172	

OCT-guided PCI vs. IVUS-guided PCI

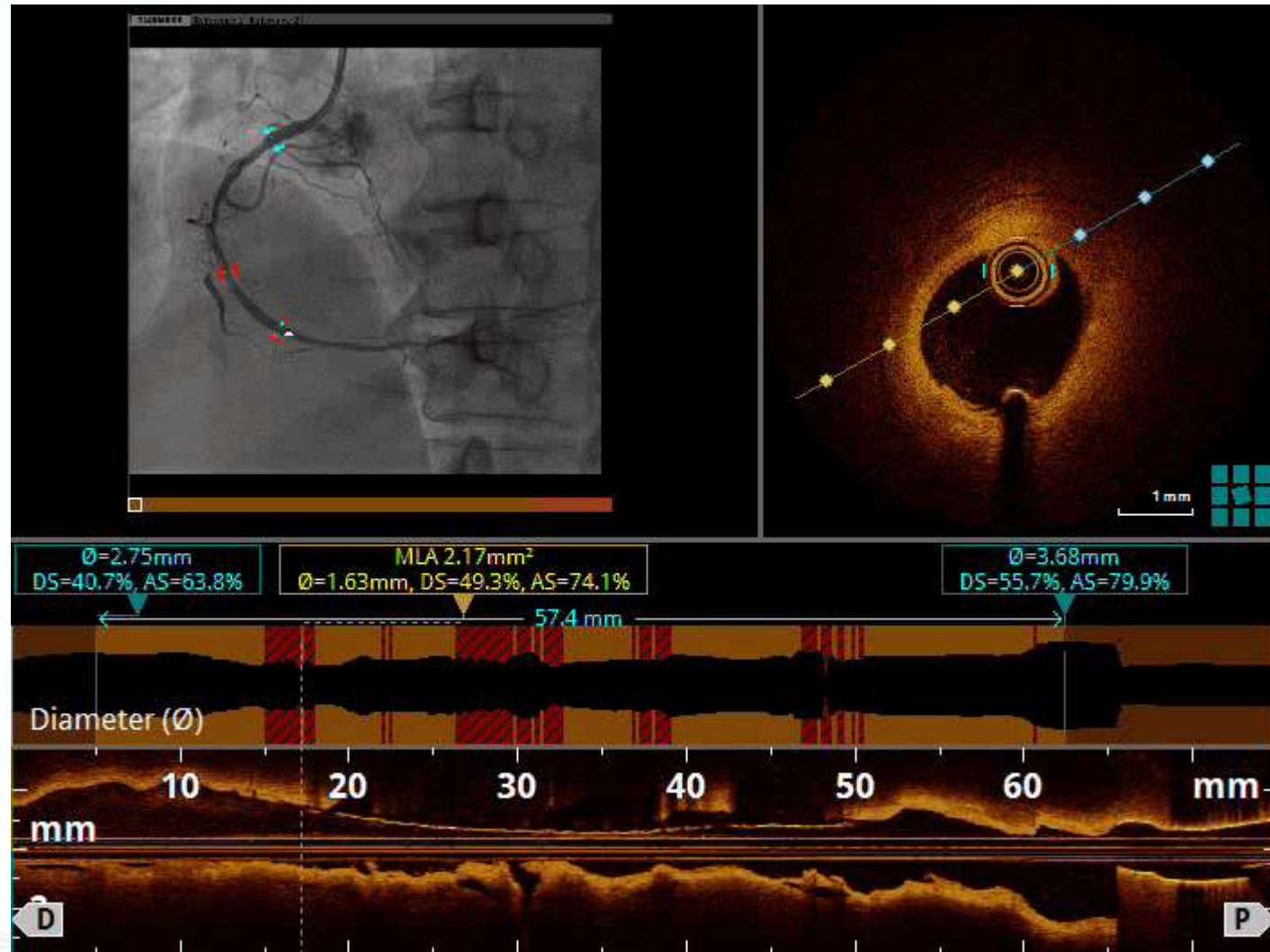


Number at risk				
800	745	409	172	
278	265	151	80	

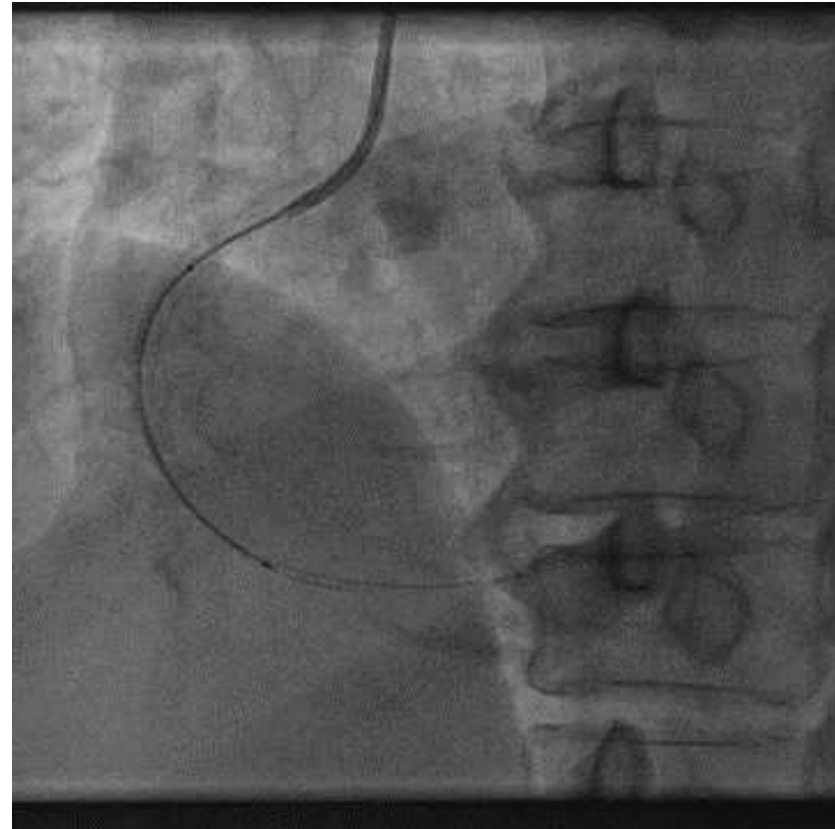
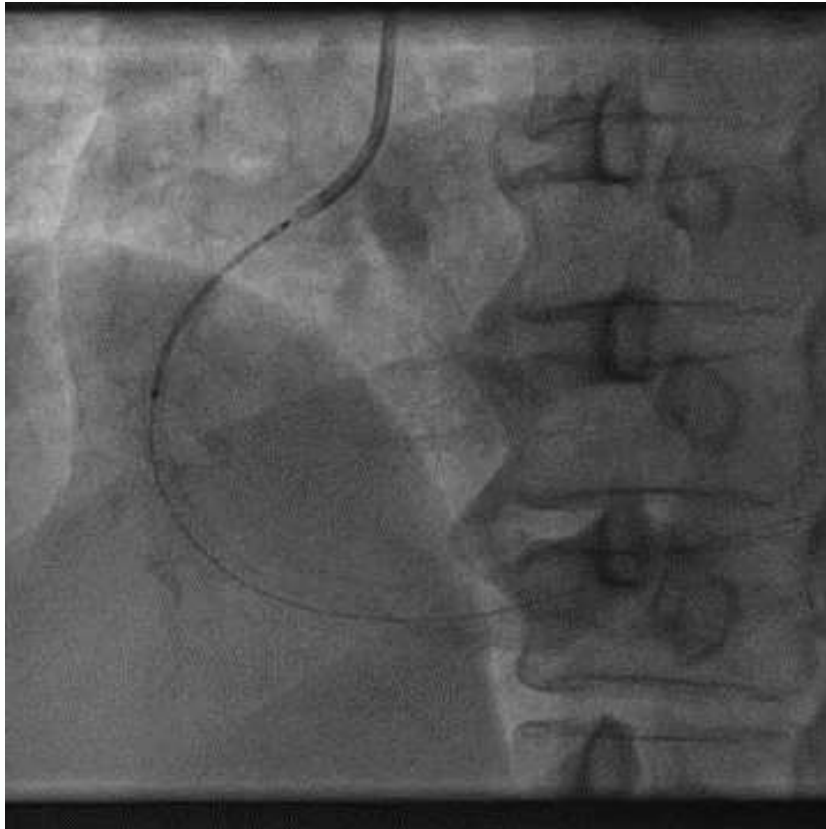
Case #1: Diffuse long lesion



Pre-stenting OCT

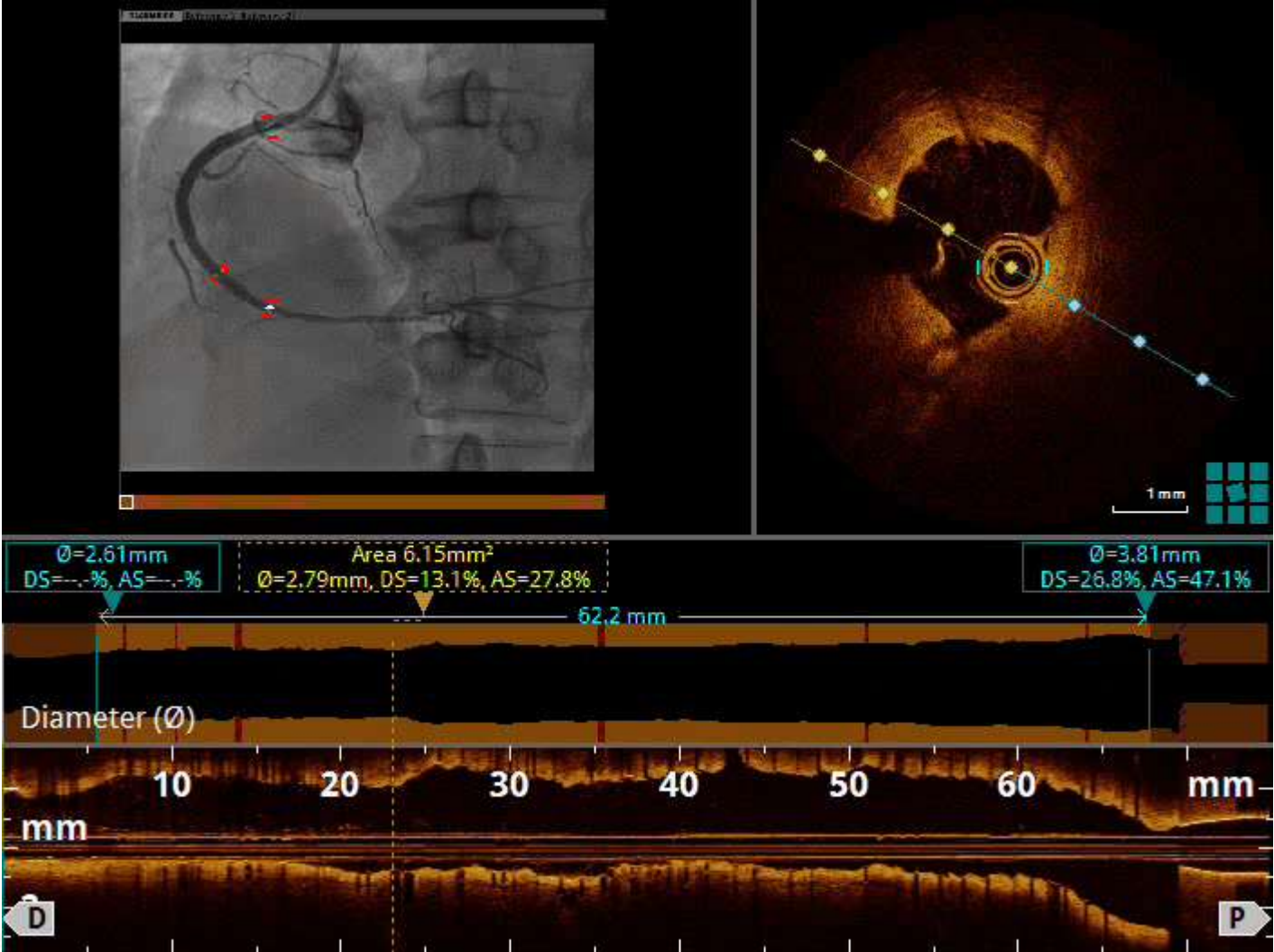


Stenting

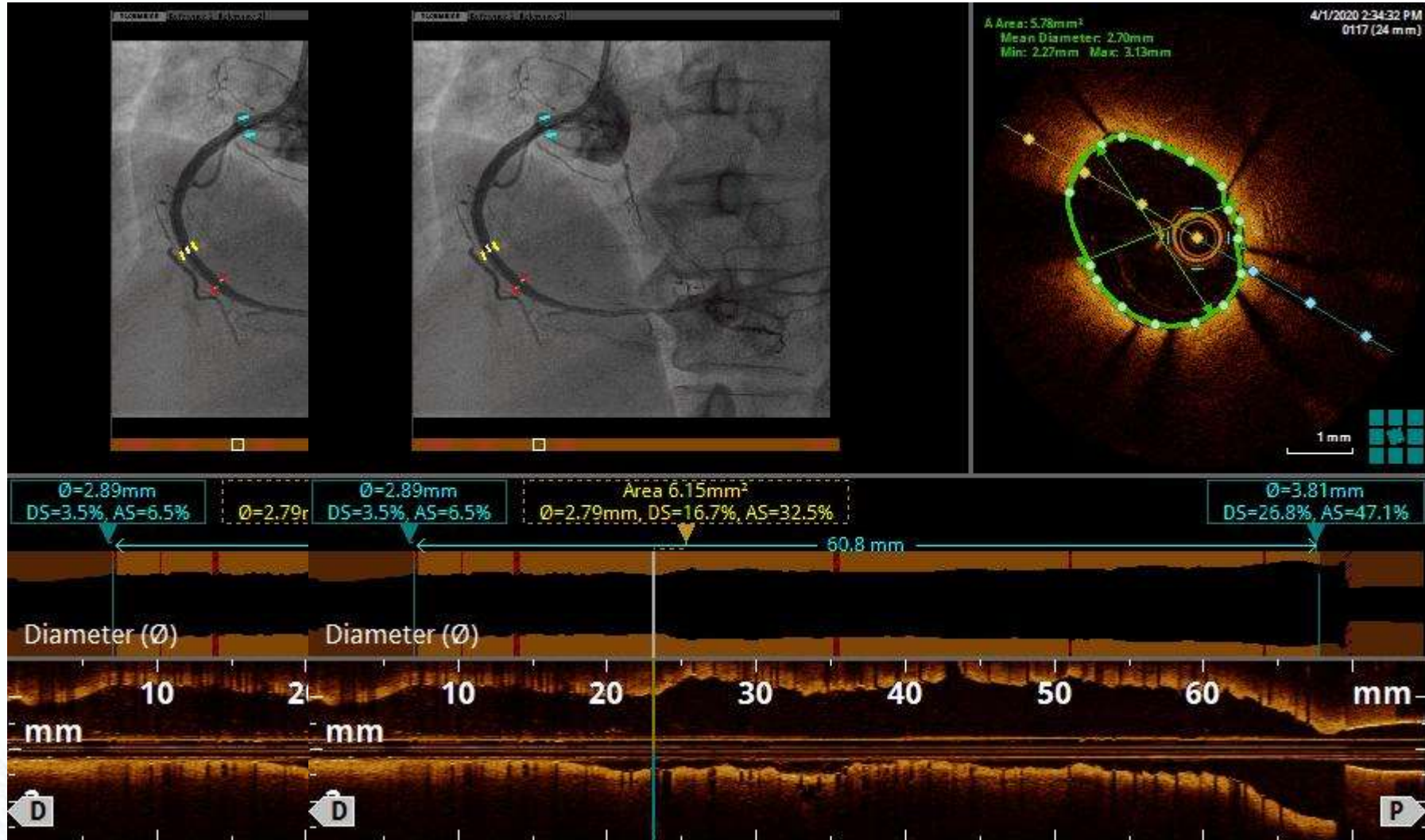


Xience Sierra 3.0*33 at m-dRCA
Xience Sierra 3.5*33 at p-mRCA

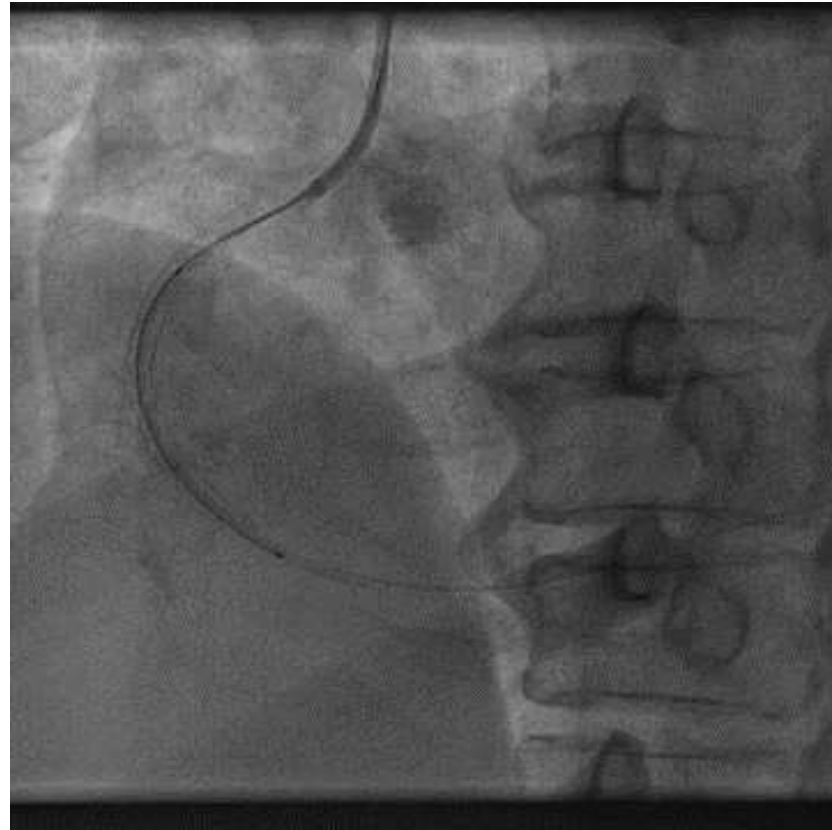
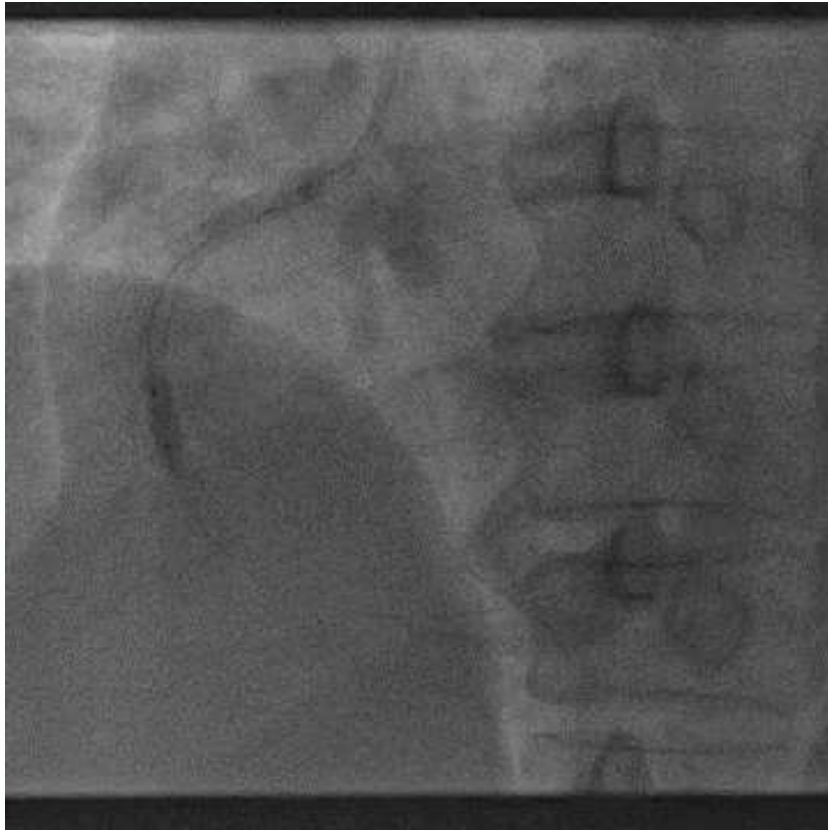
Post-stenting OCT



Confirmation of MSA

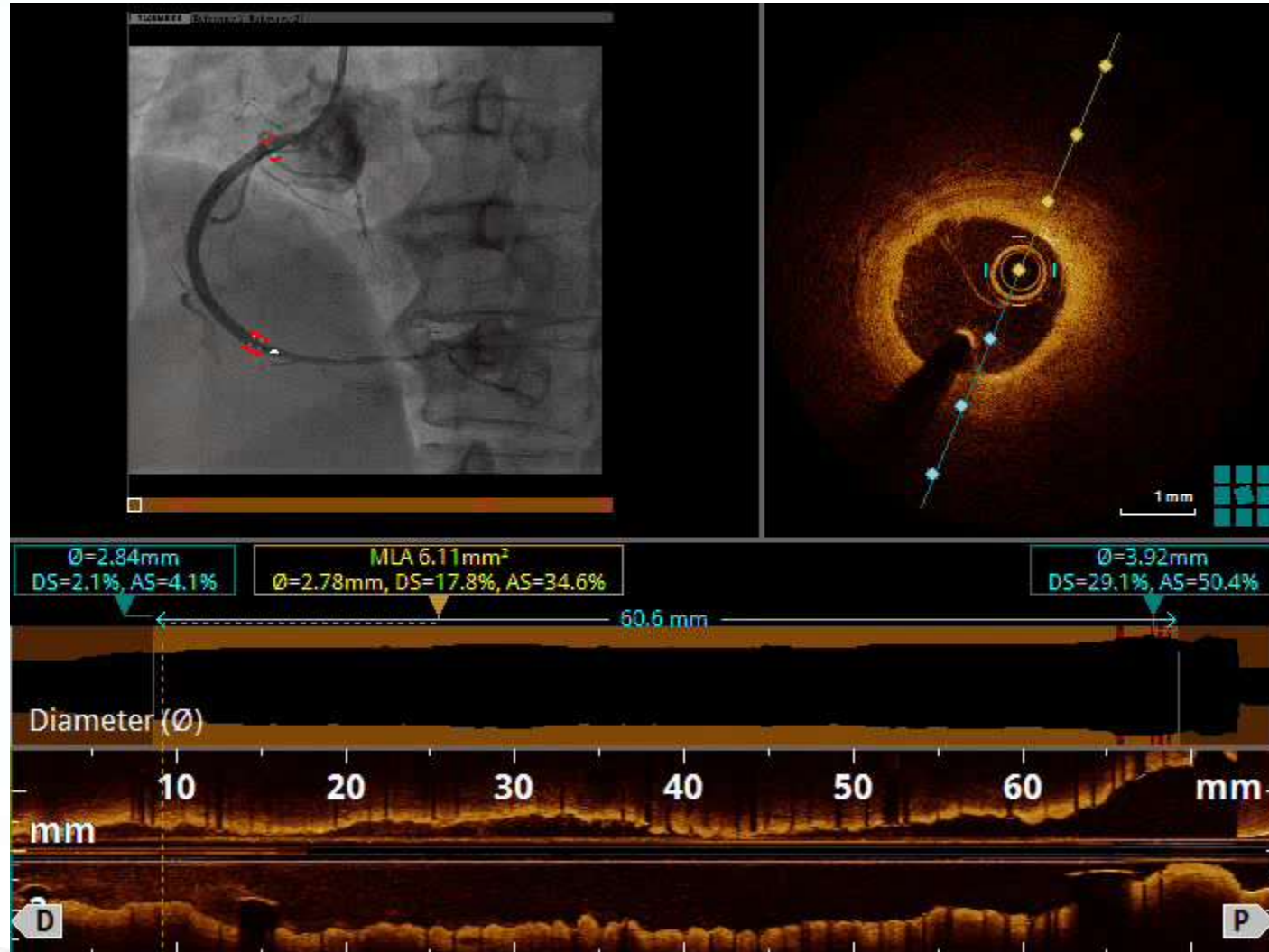


Postdilatation

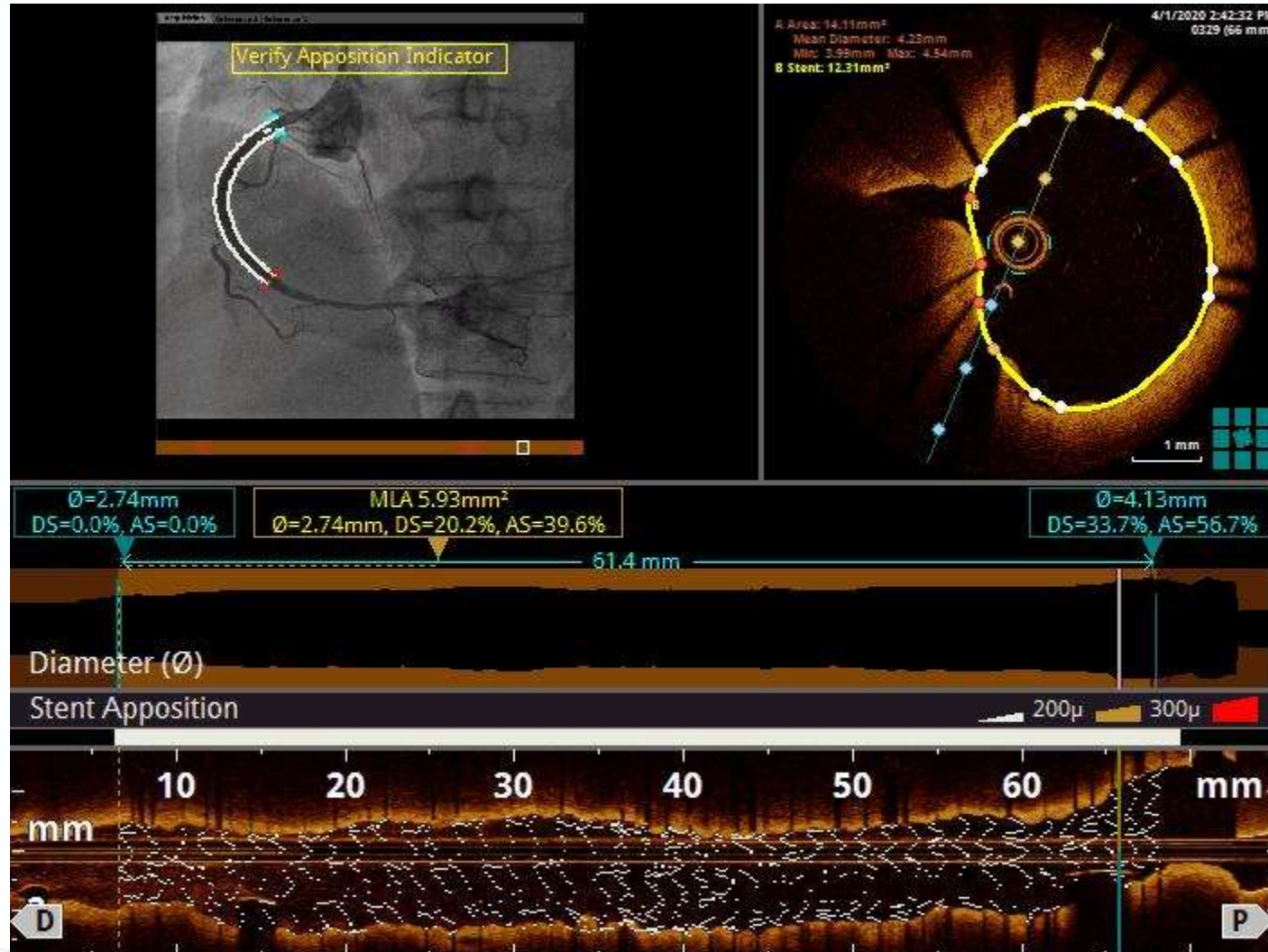


3.5*10 NC balloon

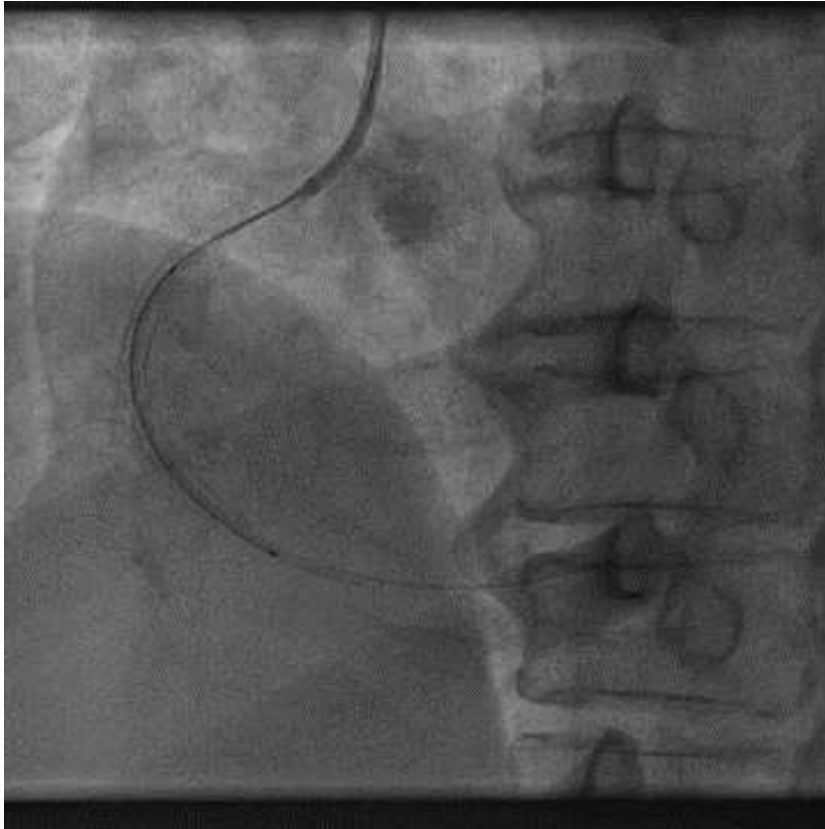
Final OCT



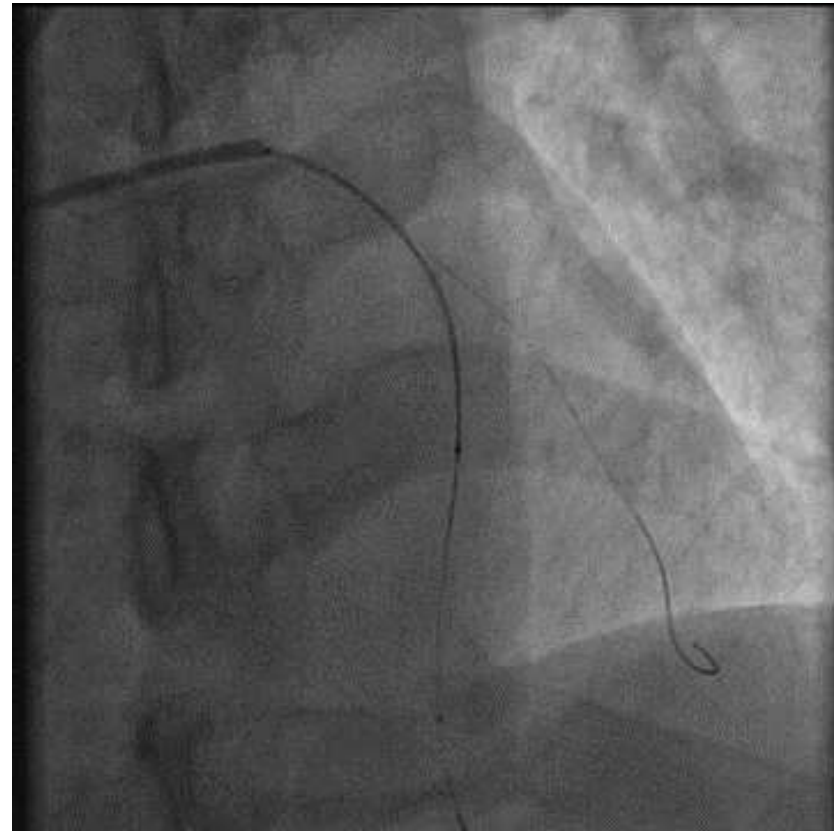
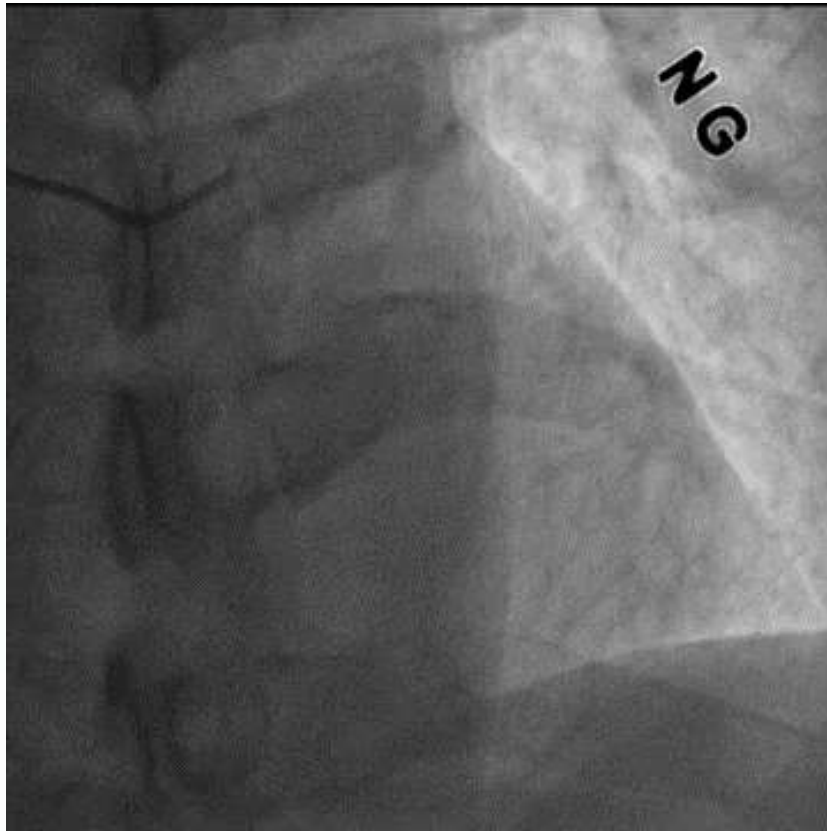
Final OCT: stent apposition



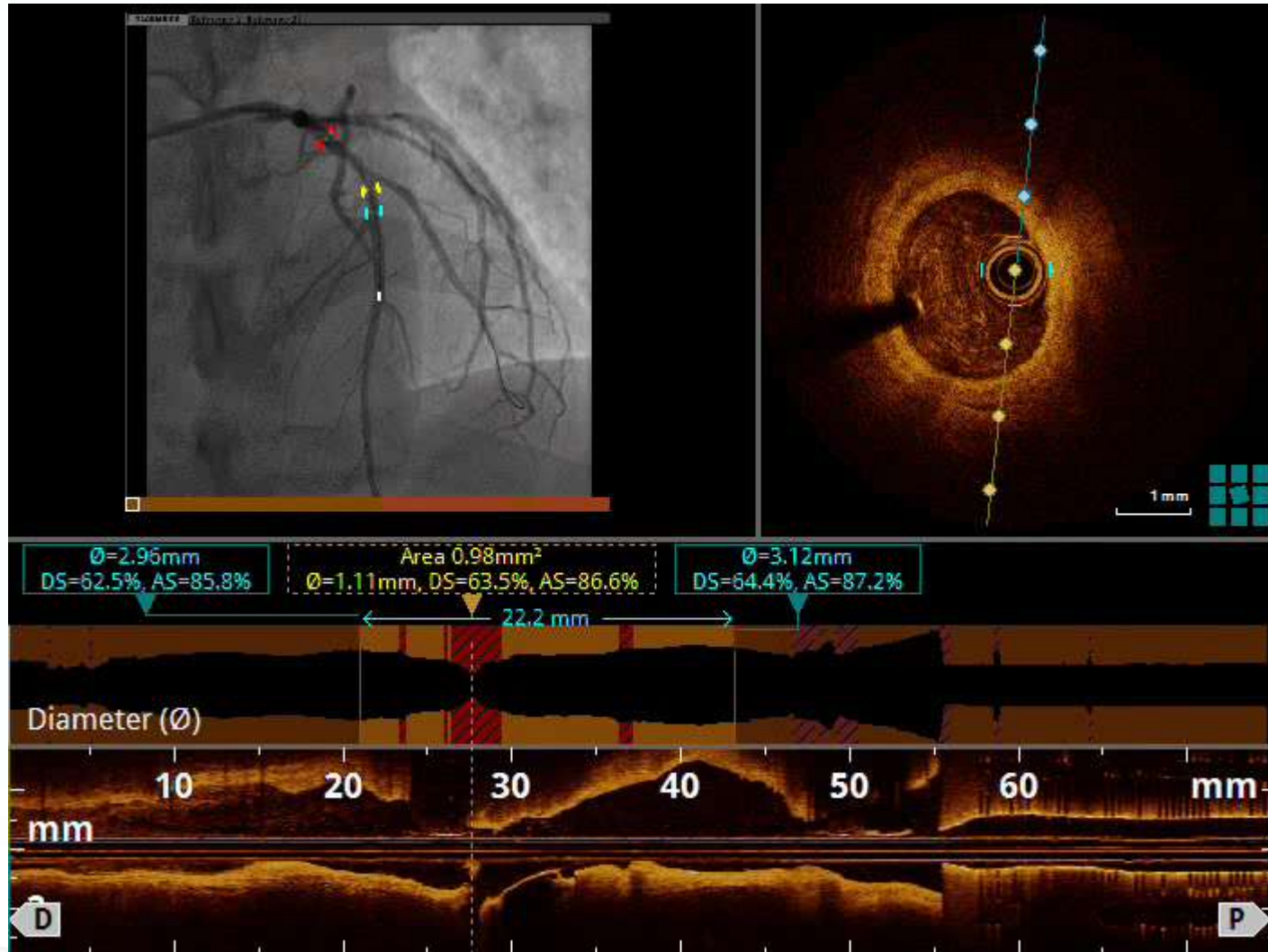
Final angiography



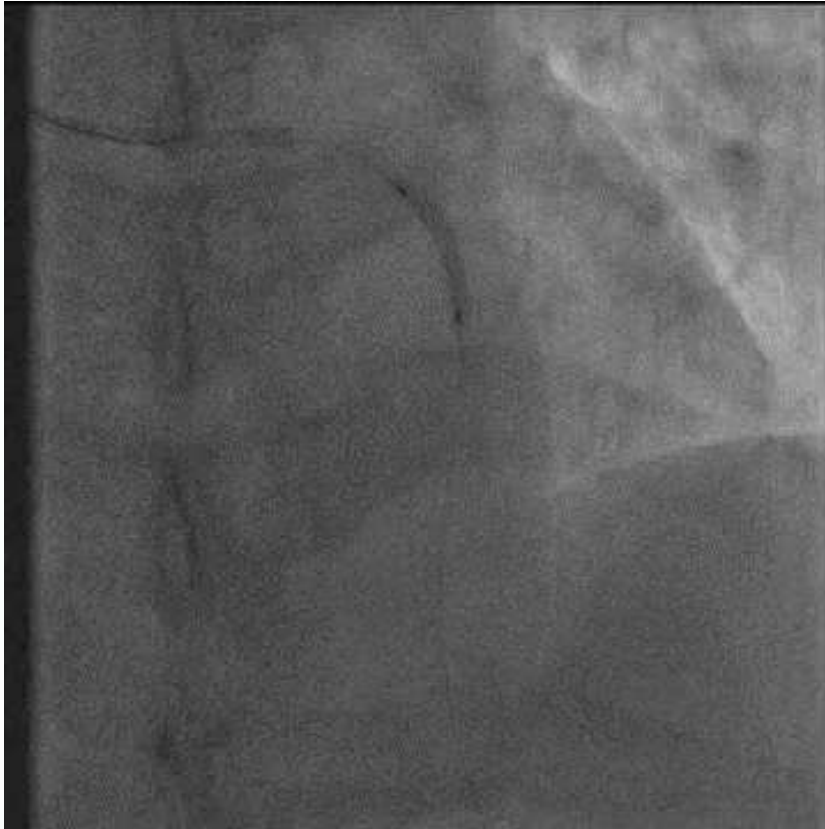
Case #2: Bifurcation lesion



Pre-stenting OCT



Mini-crush technique

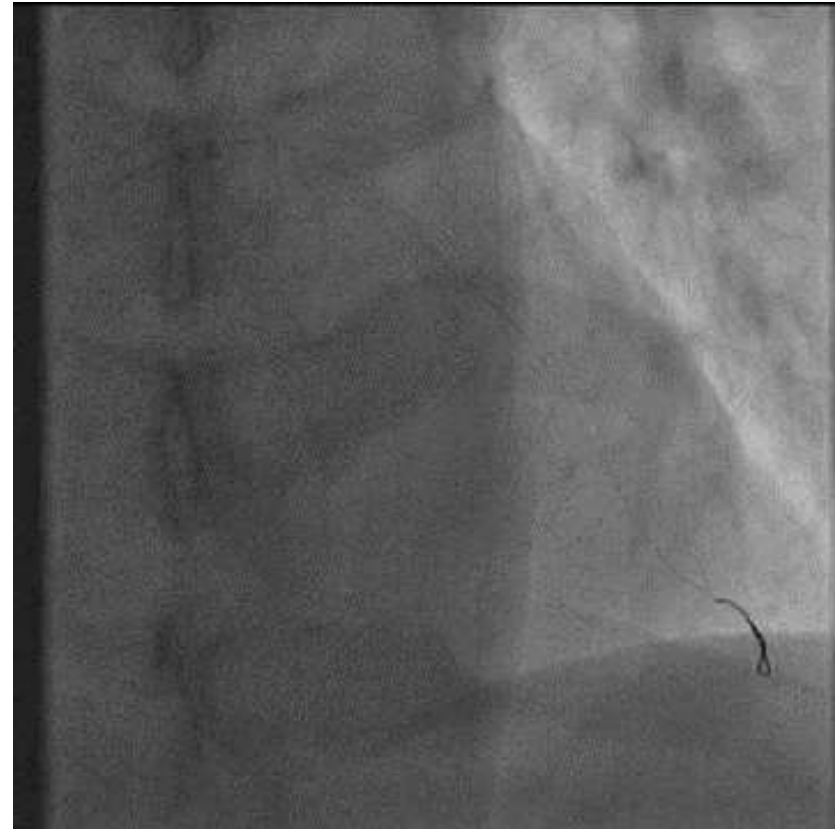


Xience Sierra 2.75*18 at D1
Balloon crush

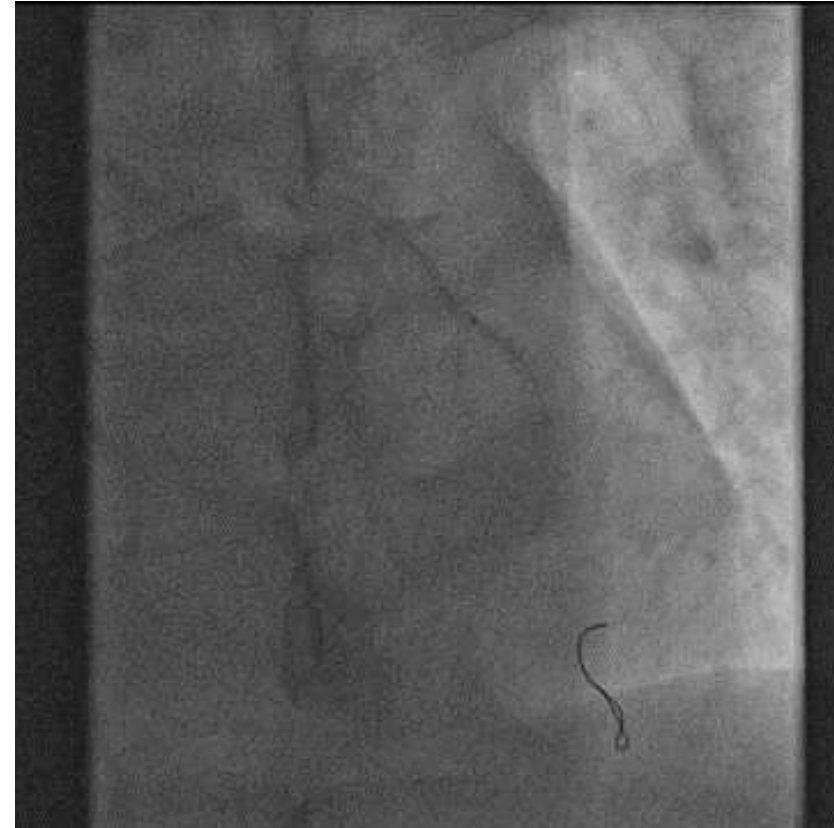
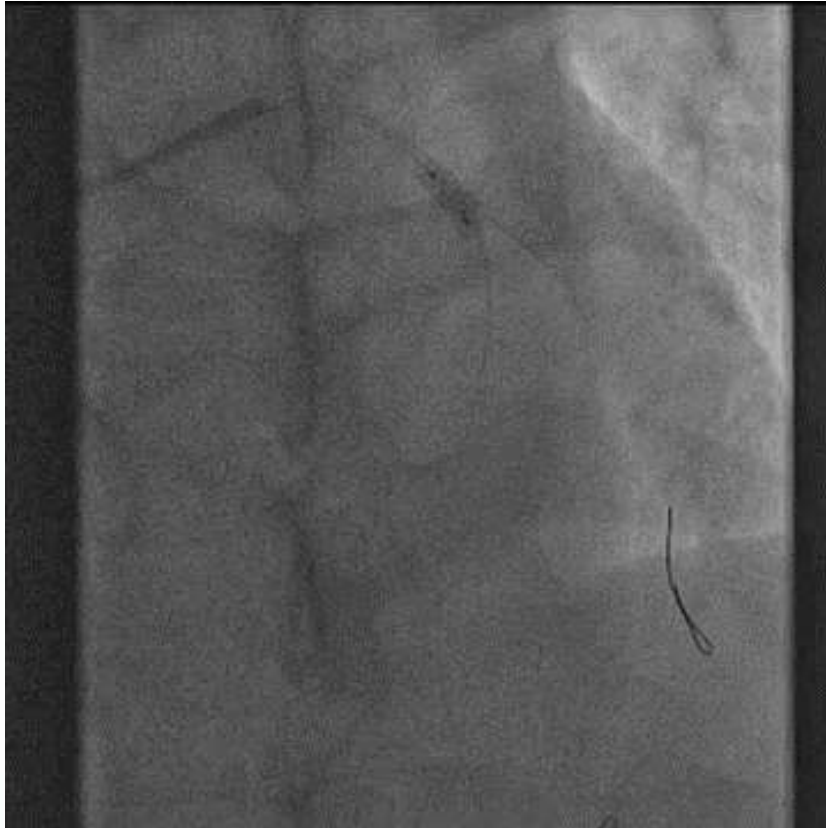


Xience Sierra 3.0*23 at pLAD

After stenting

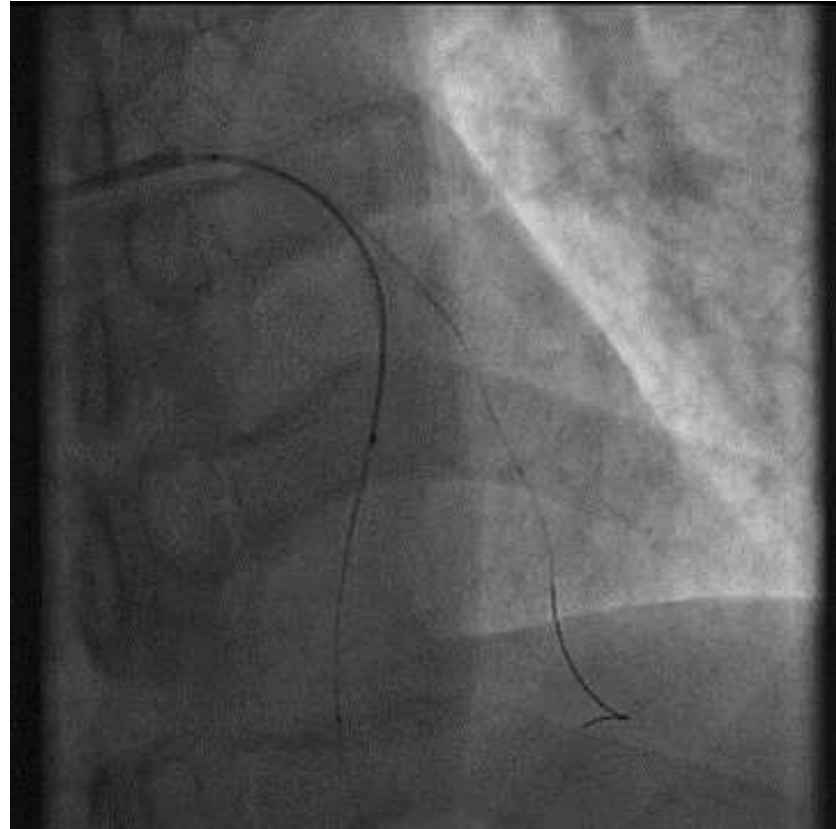


POT and small ballooning

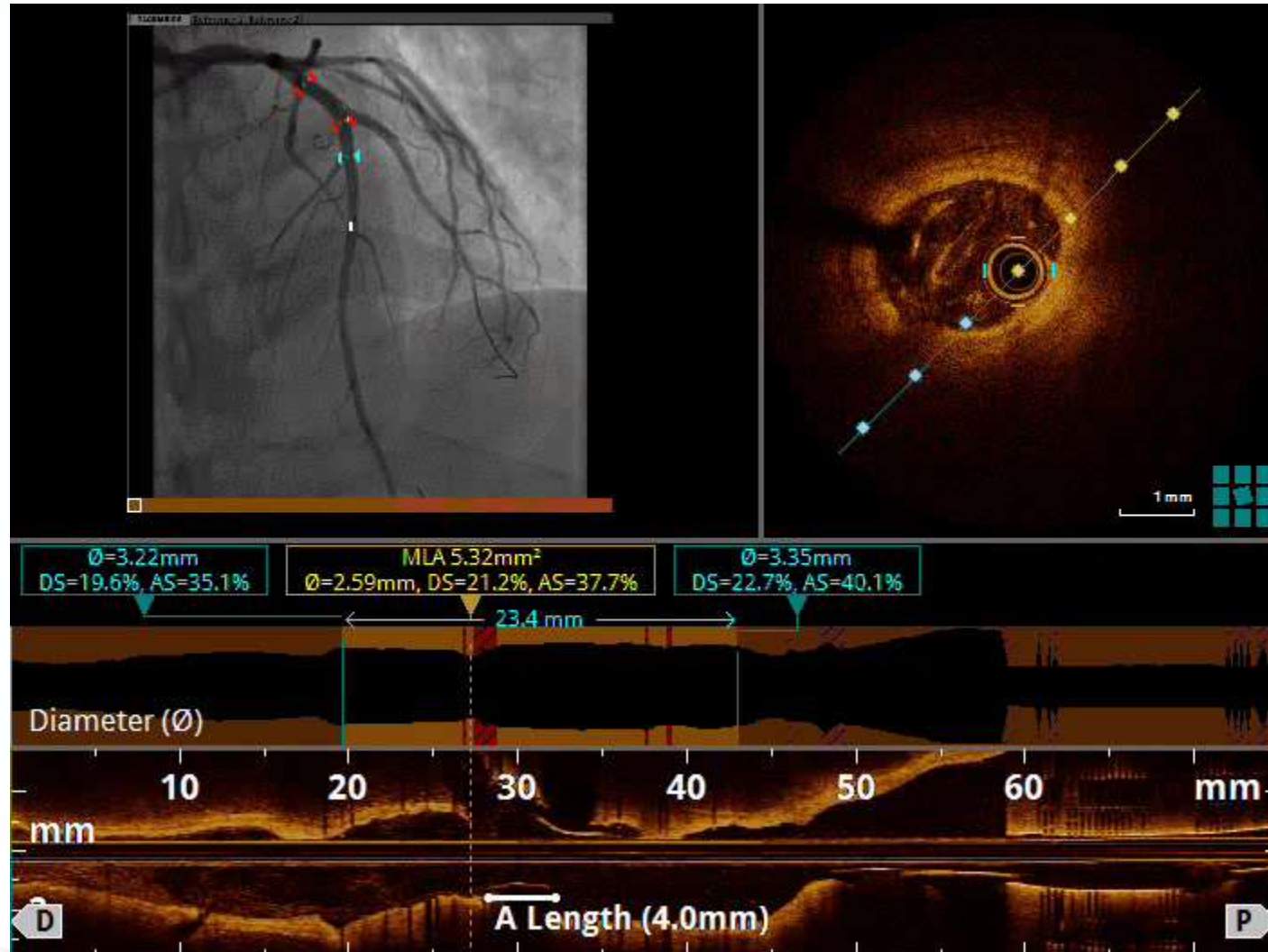


3.5*10 NC ballooning

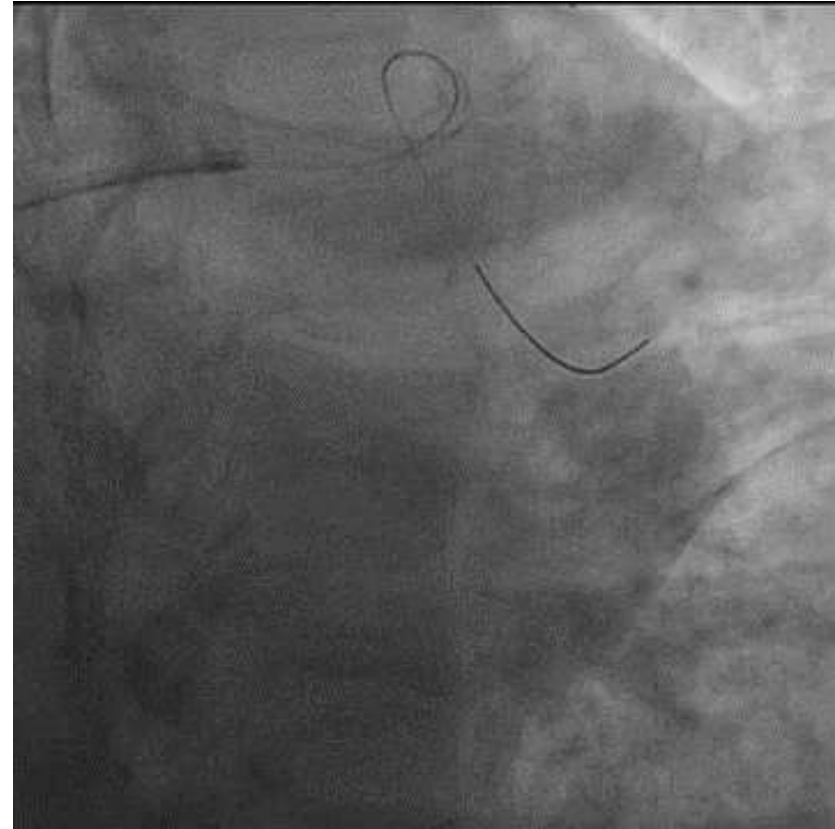
Final kissing ballooning



Post-PCI OCT



Final angiography



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
 - Numerically lower event rates with OCT
- OCT, compared with IVUS, has several advantages such as higher resolution, rapid pullback, and automatized analysis.