Best Practices while using IVL in Complex Cases

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Learning objectives

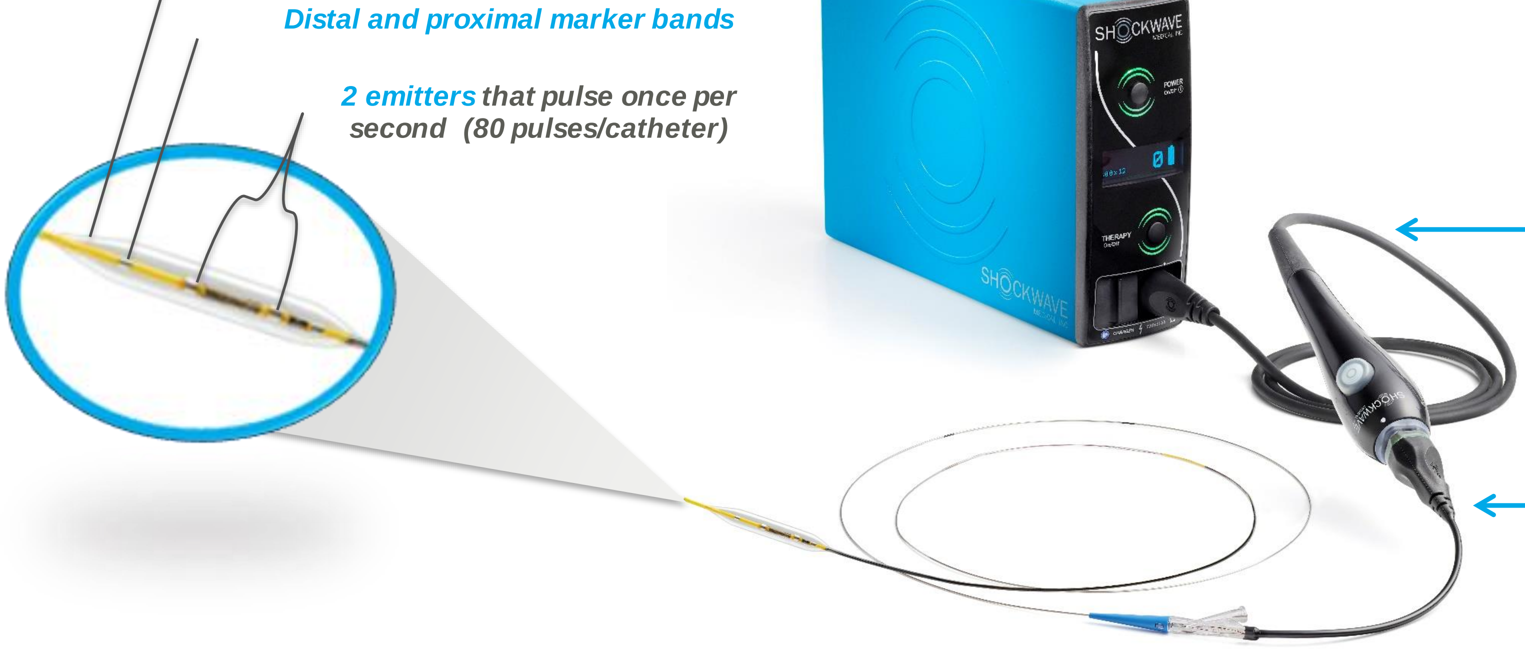
1. Mechanism of action of IVL when treating different types of calcified lesions
2. Suitable indications to IVL in order to optimize clinical outcomes of our patients
3. Long-term clinical data of coronary IVL from pooled DISRUPT CAD trials
4. Recent OCT long-term data analysis from pooled DISRUPT CAD trials
5. IVL off-label indications

Shockwave Coronary IVL System Components

***Integrated 12mm SC balloon** facilitates energy transfer; IVL=4 atm; Nominal=6atm; RBP=10 atm*

Distal and proximal marker bands

***2 emitters** that pulse once per second (80 pulses/catheter)*



Generator
Portable, IV-pole Mountable
Battery-Powered
No External Connections

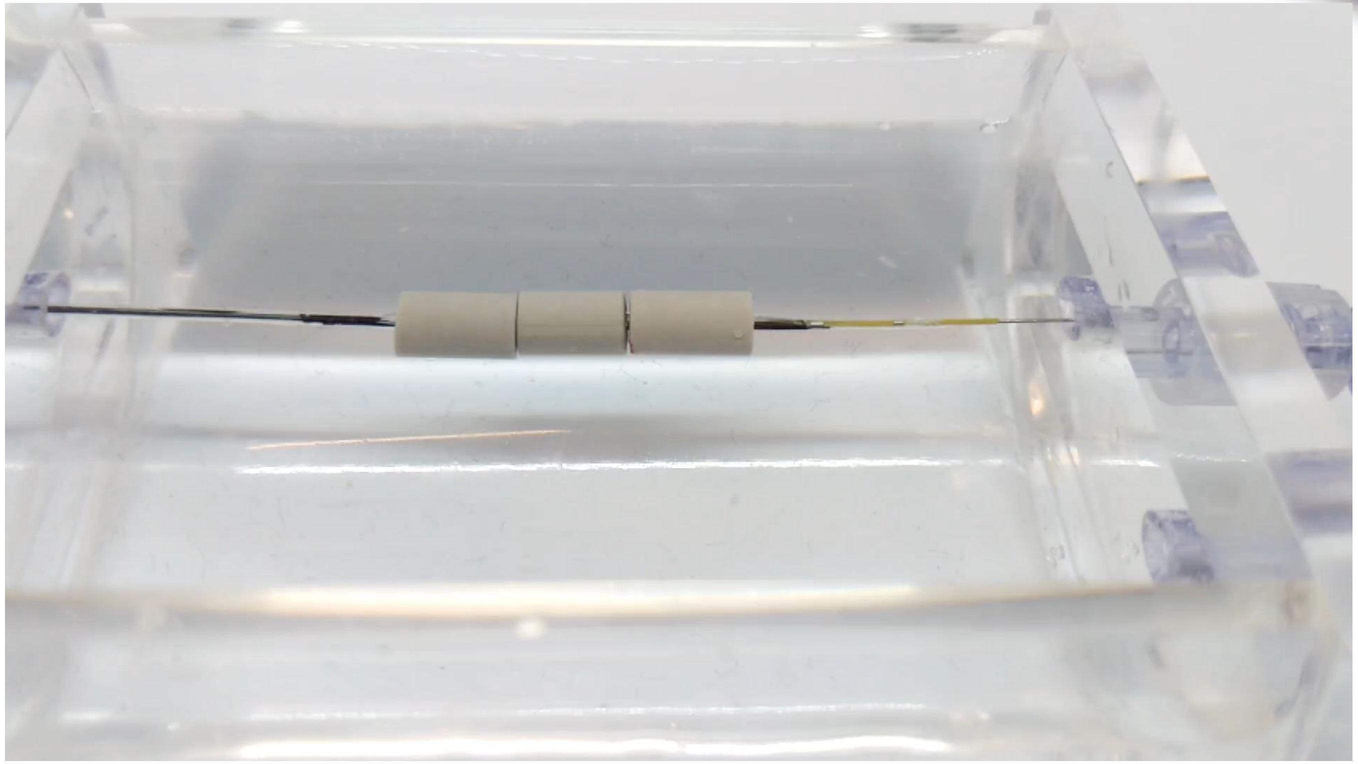
Connector Cable
Smart Magnetic Connection
Push-Button Activated

Catheter*
RX System
Any .014” Guidewire
Standard PCI Technique
80 Lithotripsy Pulses

Diameter	Length	Pulses	Guidewire	Guide Cath	Length	Tip Profile	Crossing Profile
2.5-3.0-3.5-4.0mm	12mm	80	0.014in	6F	138cm	0.023in	0.044-0.047in

IVL's Mechanism of Action

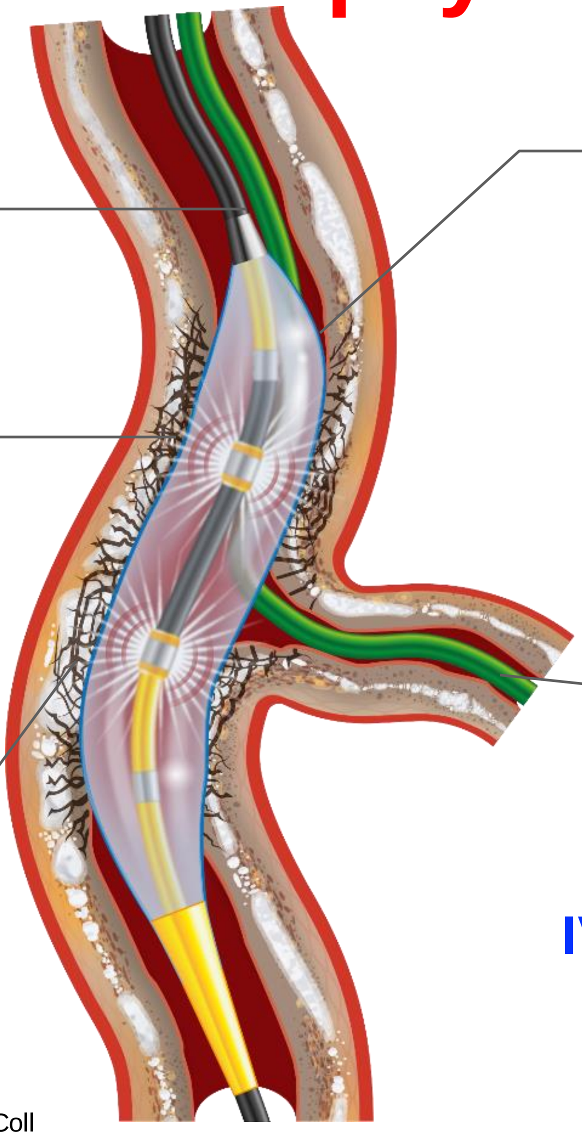
Electrical energy is delivered to the emitter, initiating the formation of steam bubble, which expands & collapses – **creating sonic pressure waves**



Impacts hard surfaces

Sonic pressure waves travel through the vessel with an effective pressure of ~50 atm

Opportunities for Coronary Intravascular Lithotripsy



No requirement for a specialized wire

Shockwaves pass through the plaque/vessel wall enabling modification of deep calcium

Disrupted calcium remains in vessel wall thereby reducing the risk of distal embolization

Lithotripsy allows calcium modification to be performed at low balloon pressure thereby avoiding the risk associated with high pressure inflations
&
increase the vessel compliance

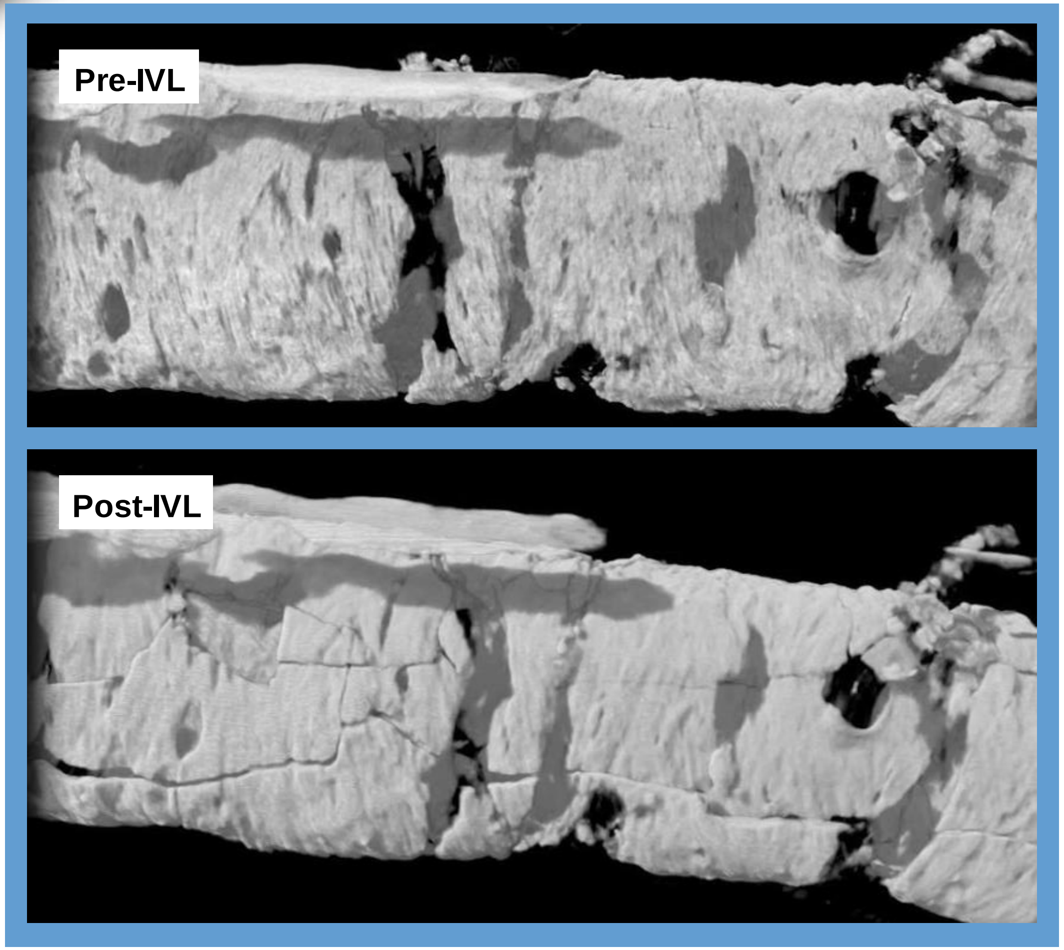
Able to protect side branch with second wire

IVL is easy to learn compared to other forms of calcium modification

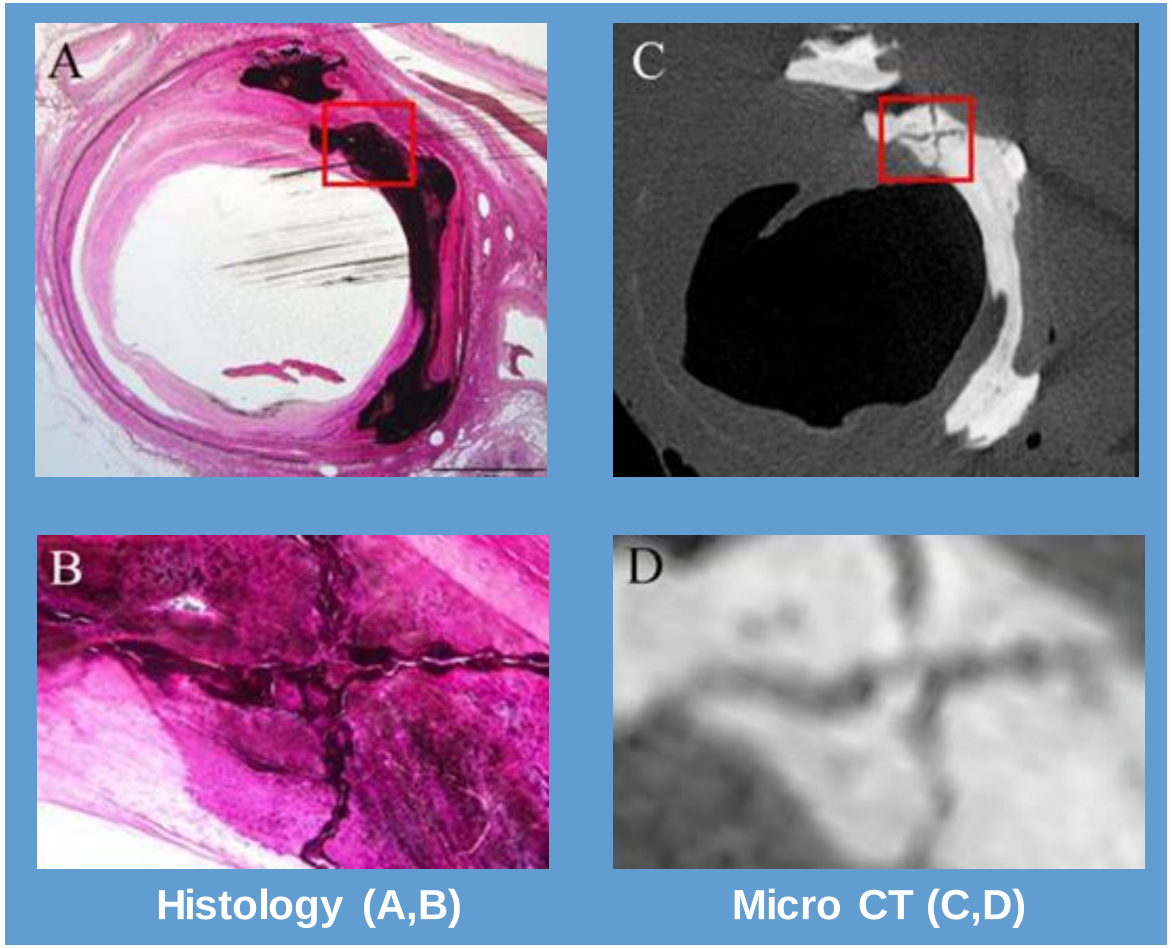
Hill J., Kereiakes D., et al. IVL for Severely Calcified Coronary Artery Disease. J Am Coll Cardiol. 2020 Dec, 76 (22) 2635–2646.

Microfractures occur beyond resolution of IVUS & OCT

Cadaveric Superficial Femoral Artery (Micro CT)



Histologic & Micro CT after IVL Treatment (SFA)

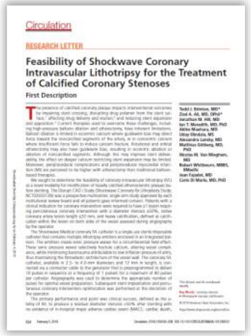


- Courtesy: Renu Virmani, MD, CV Path Institute

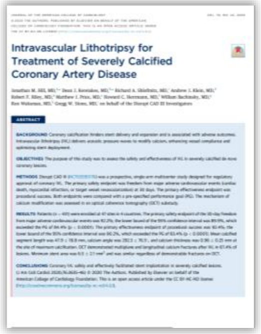
Coronary IVL Clinical Program

Excellent Outcomes in Core Lab Adjudicated Studies

	DISRUPT CAD I	DISRUPT CAD II	DISRUPT CAD III	DISRUPT CAD IV	DISRUPT CAD POOLED
Status	*Circ*	*Circ Intrv*	*JACC*	Circ Journal	JACC
Study design	Single arm, safety and feasibility	Single arm, post-market, safety and effectiveness	Single arm, IDE, safety and effectiveness	Single arm, pre-market safety and effectiveness	Individual patient-data (IPD) pooled analysis of the Disrupt CAD I-IV studies
# of patients	60	120	384	64	628
# of sites	7	15	47	8	72
Regions	AU, EU	EU	U.S., EU	Japan	U.S.,EU
OCT Sub-study	N=31	N=47	N=100	N=71	NA


Circulation
RESEARCH LETTER
Feasibility of Shockwave Coronary Intravascular Lithotripsy for the Treatment of Calcified Coronary Stenoses
First Description


Circulation: Cardiovascular Interventions
ORIGINAL ARTICLE
Safety and Effectiveness of Coronary Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Stenoses
The Disrupt CAD II Study


Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Artery Disease


Intravascular Lithotripsy for Vessel Preparation in Severely Calcified Coronary Arteries Prior to Stent Placement
Primary Outcomes From the Japanese Disrupt CAD IV Study


Intravascular Lithotripsy for Treatment of Calcified Coronary Lesions
Patient-Level Pooled Analysis of the Disrupt CAD Studies

>140

Peer-reviewed Journal Publications

>2,134

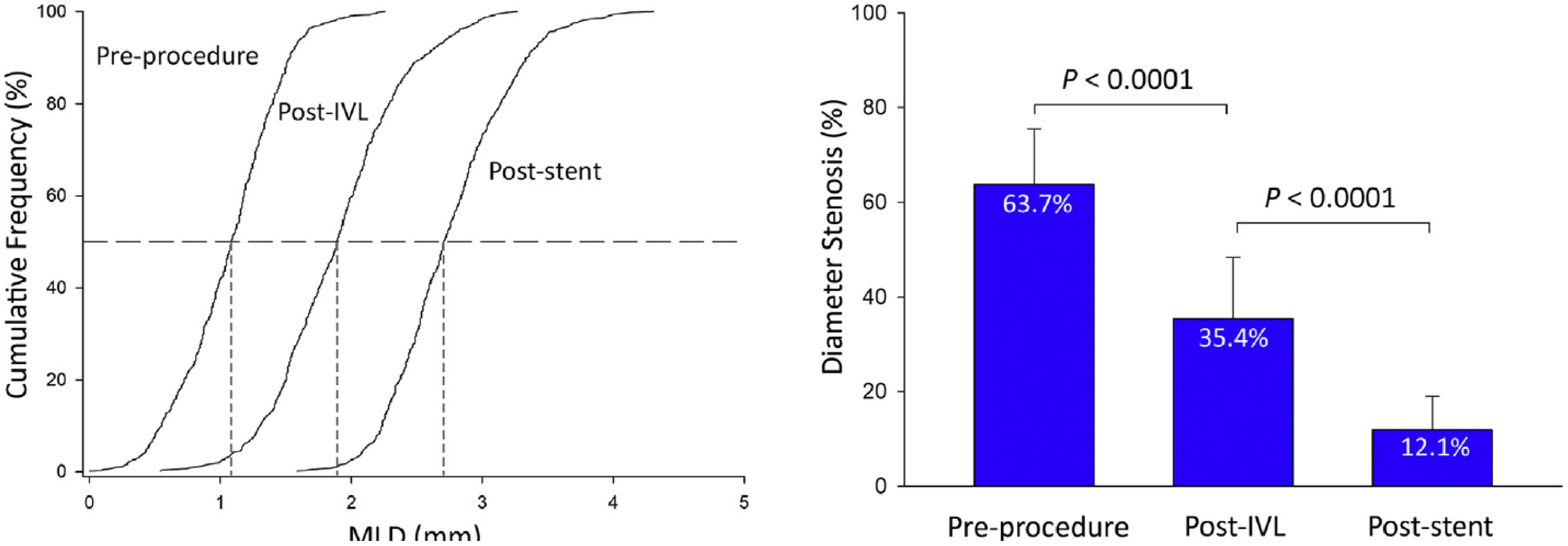
Published Patient Outcomes

Consistent outcomes across Disrupt CAD trials

	DISRUPT CAD I[1]	DISRUPT CAD II[2]	DISRUPT CAD III[3]	DISRUPT CAD IV[4]	DISRUPT CAD POOLED[5]
Patients	60	120	384	64	**628**
Severe Calcification	100%	94.2%	100%	100%	**97%**
Procedural Success	95%	94%	92.4%	93.8%	92.4%
Stent Delivery	100%	100%	99.2%	100%	99.5%
Final Severe Dissections	0%	0%	0.3%	0%	0.2%
Final Perforations	0%	0%	0.3%	0%	0.2%
Final Abrupt Closure	0%	0%	0.3%	0%	0.2%
Final Slow Flow/No Reflow	0%	0%	0%	0%	0%
Acute Lumen Gain (mm)	1.7	1.7	1.7	1.7	1.7
Final Residual Stenosis	12%	7.8%	11.9%	9.9%	12.1%
In-Hospital MACE	5.0%	5.8%	7.0%	6.3%	6.5%
Cardiac Death	0%	0%	0.3%	0%	0.2%
Q-Wave MI	0%	0%	1.0%	0%	0.6%
Non-Q-Wave MI	5.0%	5.8%	5.7%	6.3%	5.7%
30 d Target Vessel Revascularization	0%	0.8%	1.6%	0%	1.1%
30d MACE	5.0%	7.6%	7.8%	6.3%	7.3%

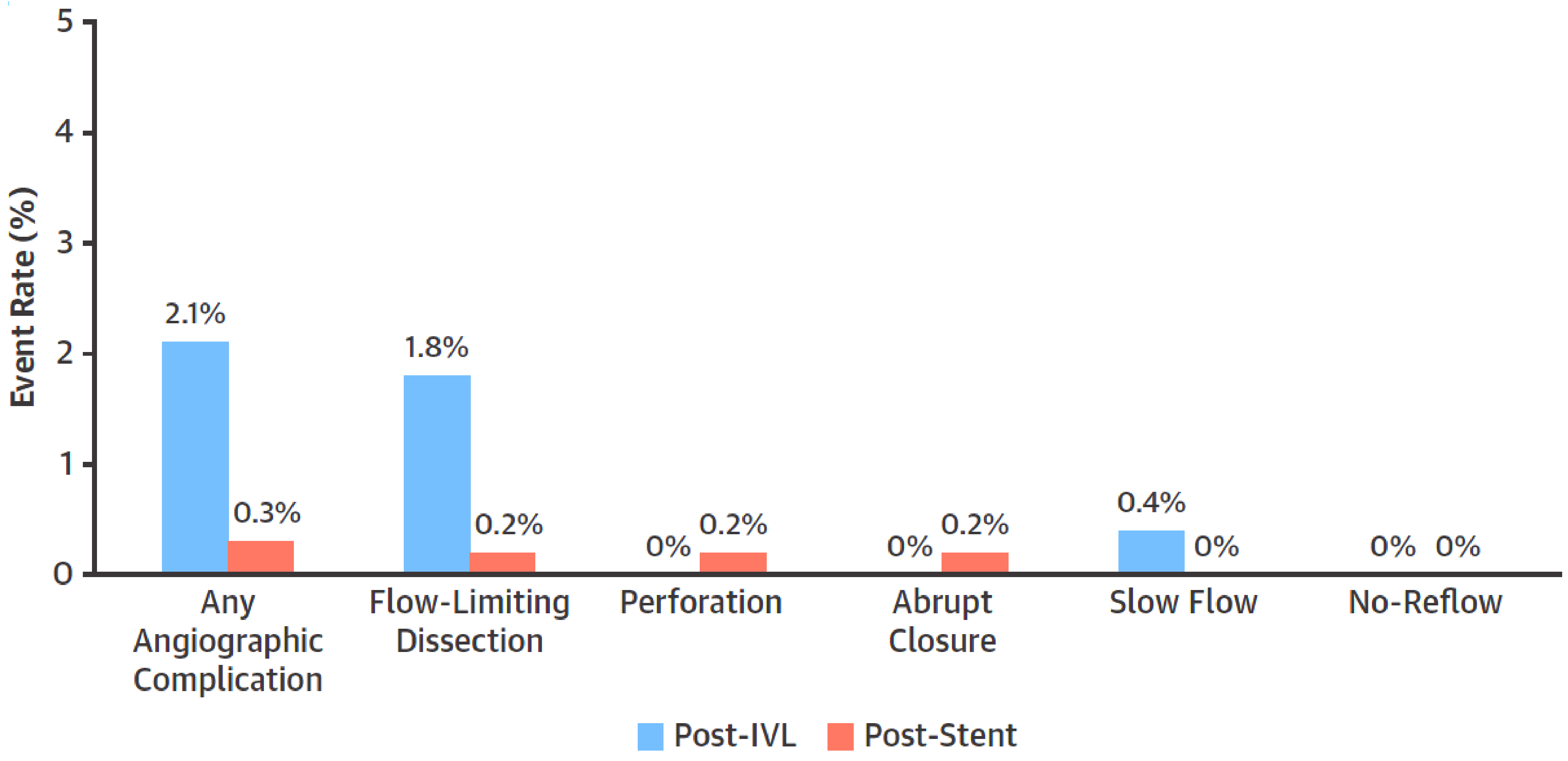
1 https://www.ahajournals.org/doi/full/10.1161/CIRCULATIONAHA.118.036531
2 https://www.ahajournals.org/doi/full/10.1161/CIRCINTERVENTIONS.119.008434
3 https://www.jacc.org/doi/full/10.1016/j.jacc.2020.09.603
4 Circulation Journal Circ J 2021; 85: 826 – 833
5. https://www.jacc.org/doi/10.1016/j.jcin.2021.04.015

Pooled Disrupt CAD trials



Kereiakes et al. J Am Coll Cardiol Intv 2021;14:1337–48

Pooled Disrupt CAD trials



Kereiakes et al. J Am Coll Cardiol Intv 2021;14:1337–48

Case_1

78 yo man

Risk Factors:

Hypertension. Type 2 Diabetes Mellitus

Prior History:

2000. Atrial Fibrillation. Anticoagulation.

2004. Inferior MI. No revascularization.

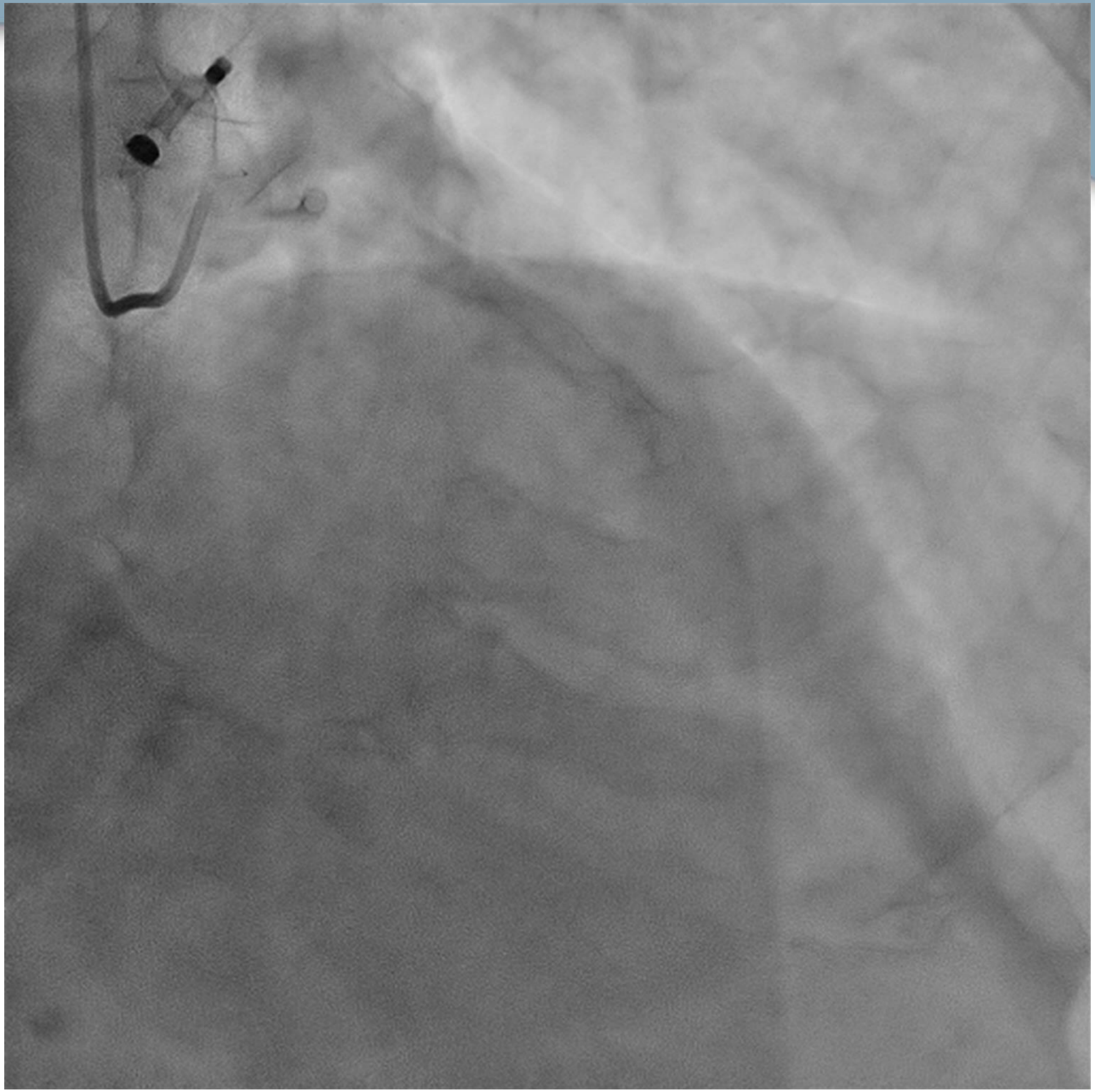
2005. Unstable angina – Stent in Prox CX

2017. NSTEMI - Stent in Mid LAD

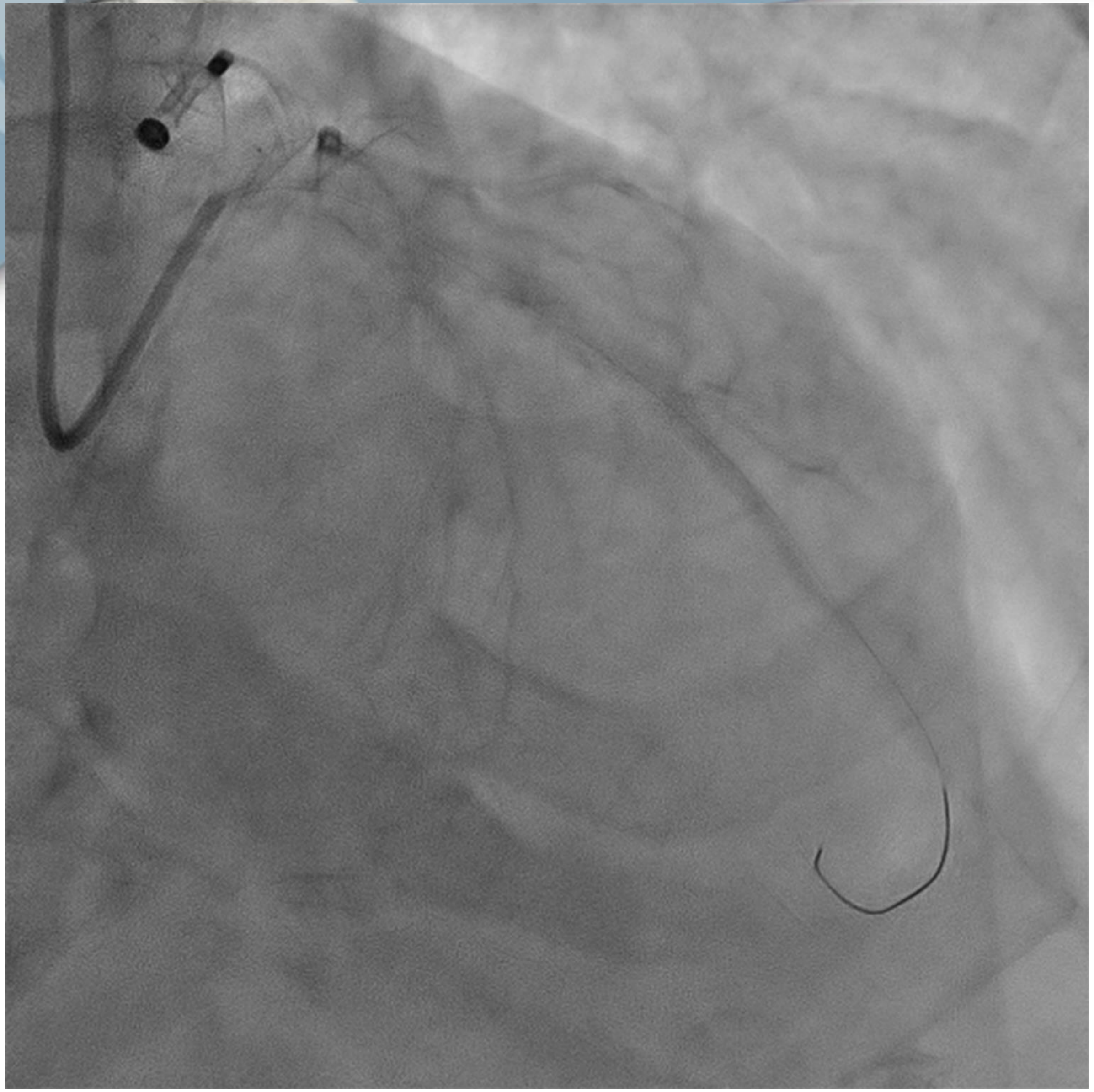
2018. Unstable angina. Under-expanded – Laser

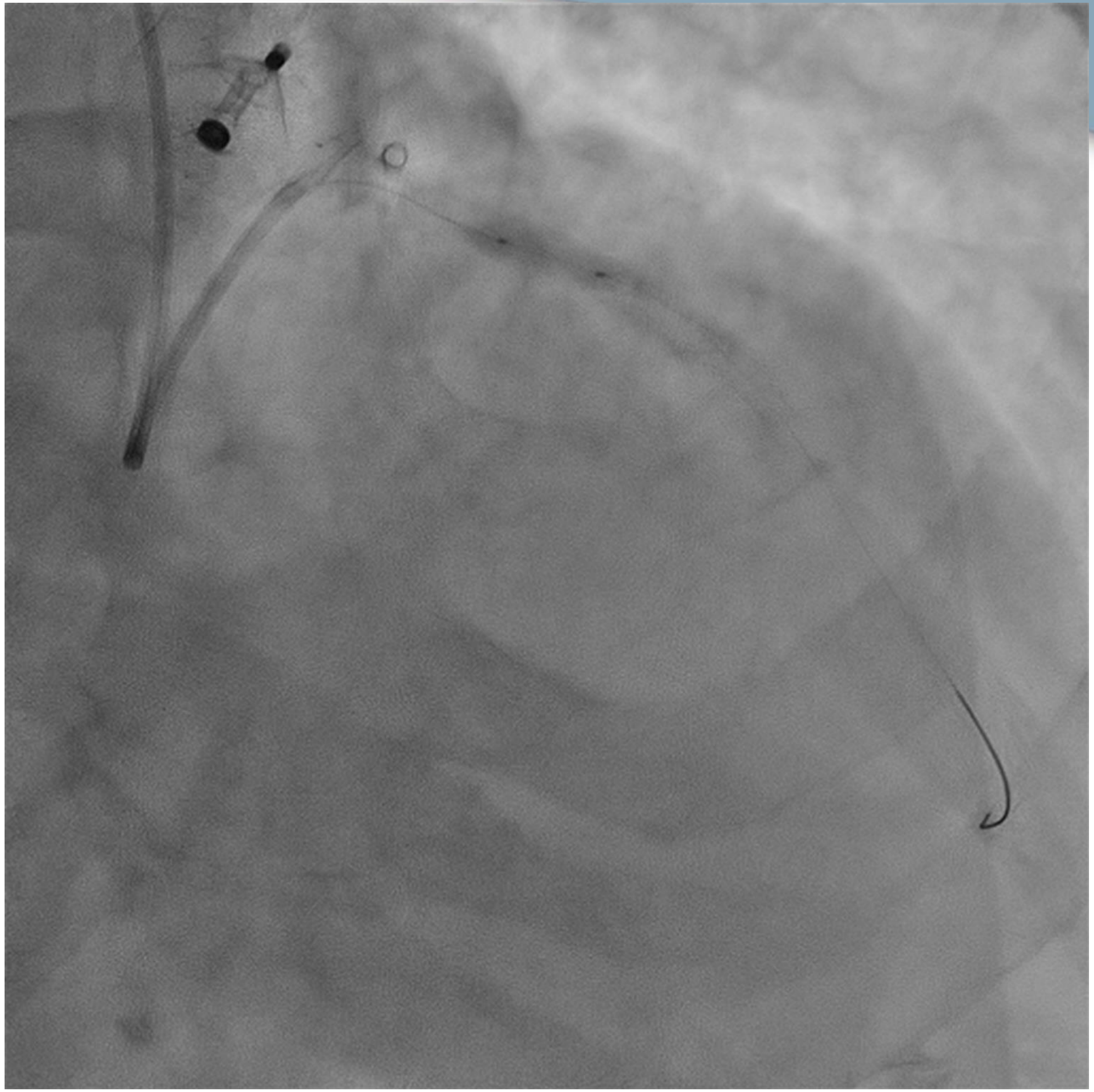
2019. LAA Oclussion (bleeding)

2021. Unstable angina (angina at rest)



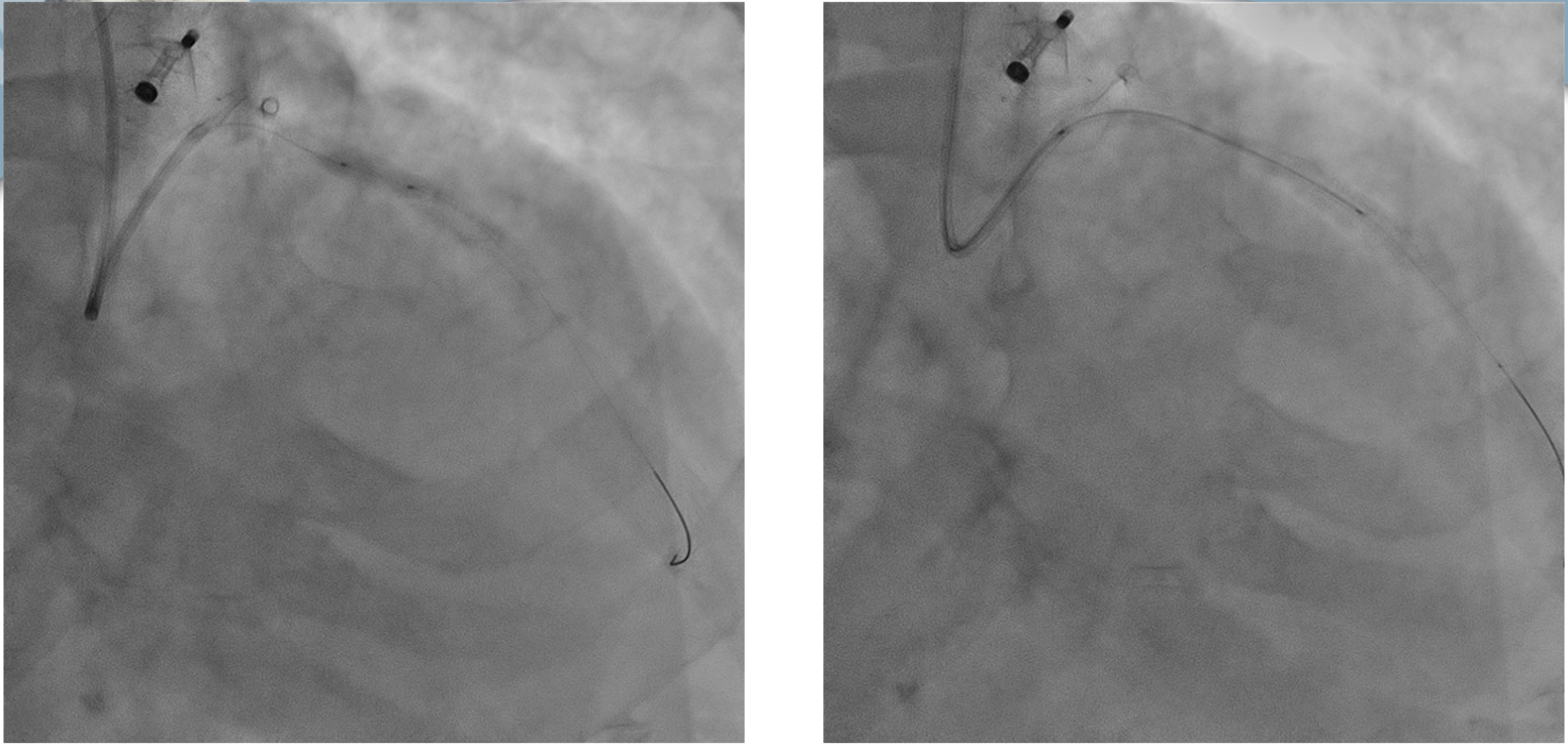
Case_1





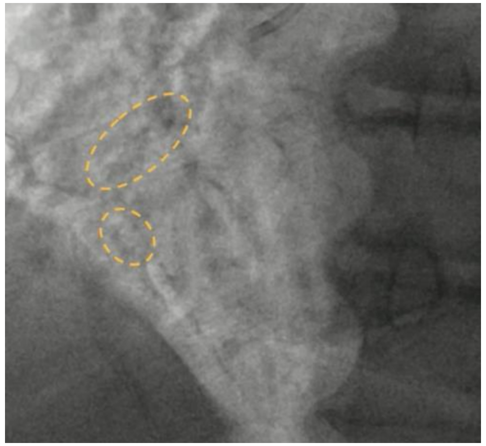
WOLVERINE Cutting Balloon 3 x15 mm

Case_1



OPN NC 3.5x15 mm

SCAI 2020 Algorithm for treating calcium



- Moderate-severe coronary calcium by fluoroscopy and/or
- Inadequate balloon expansion during lesion preparation

Step 1 Intravascular imaging

Uncrossable Lesion → Go to A or B

Imaging catheter before or after undersized balloon will not cross calcified lesion

Successful Imaging Assessment

Multiple complex calcium imaging features?
Arc >180°; Length > 5 mm; Thickness > 0.5 mm

No → **Step 2** Full expansion with 1:1 NC or cutting/scoring balloon?

Yes → **Step 3** Stenting and image-guided optimization → **SUCCESS**

Step 2: No → A / B / C

Successful Imaging Assessment: Yes → A / B / C

A MECHANICAL ATHERECTOMY

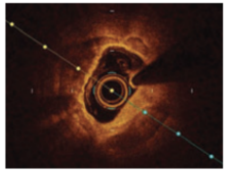
Utilize a microcatheter to exchange for a dedicated atherectomy wire, or free wire across the lesion with a dedicated atherectomy wire

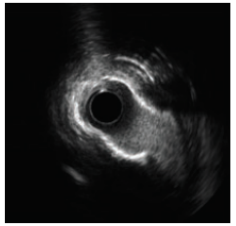
B LASER ATHERECTOMY

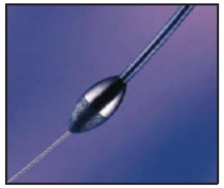
Perform laser atherectomy over prior wire that had crossed lesion (off-label use)

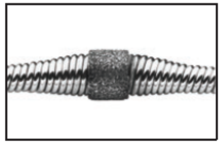
C LITHOPLASTY

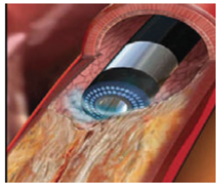
Go to Step 2;
Consider additional imaging

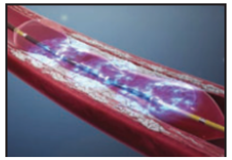






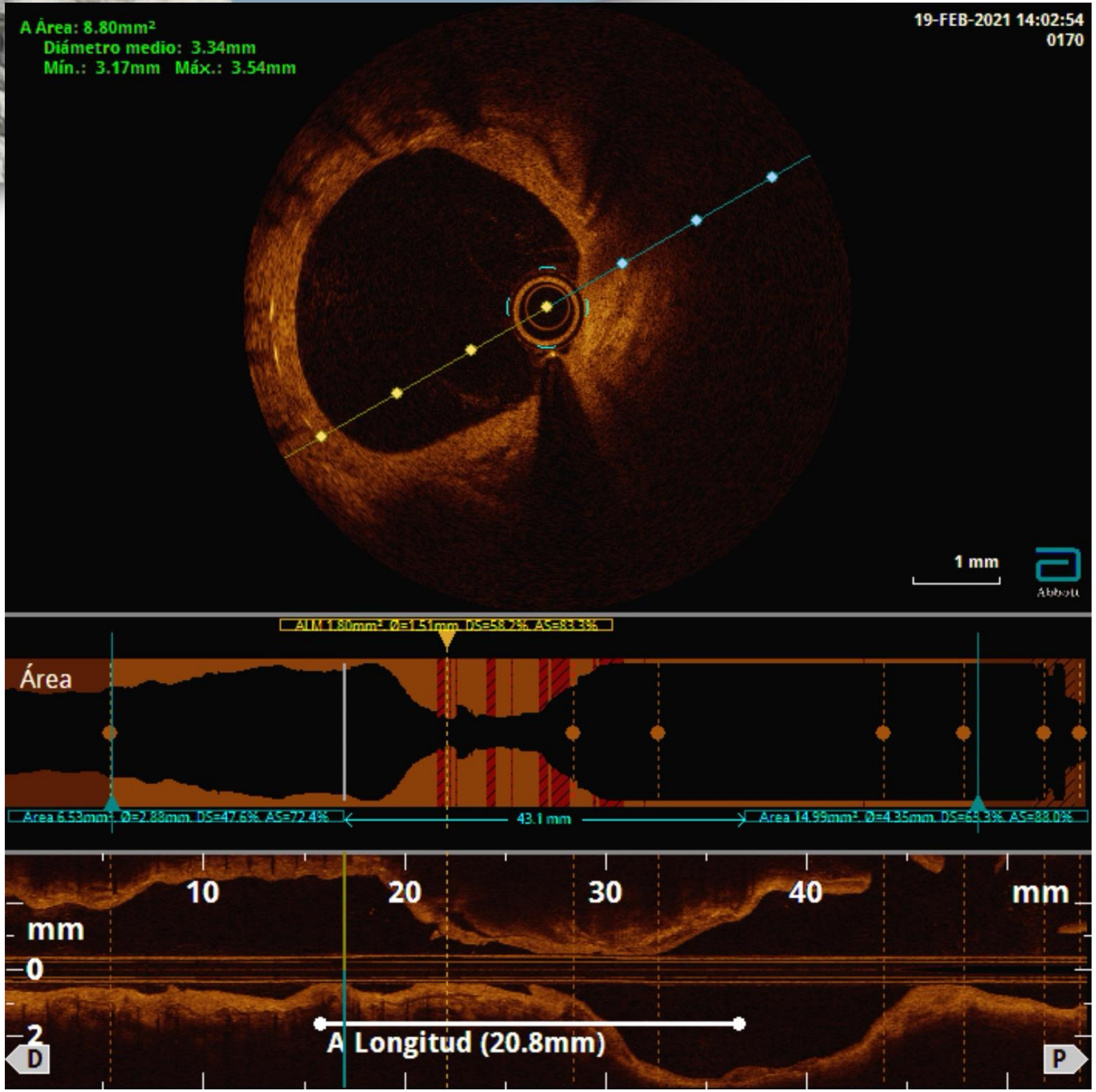


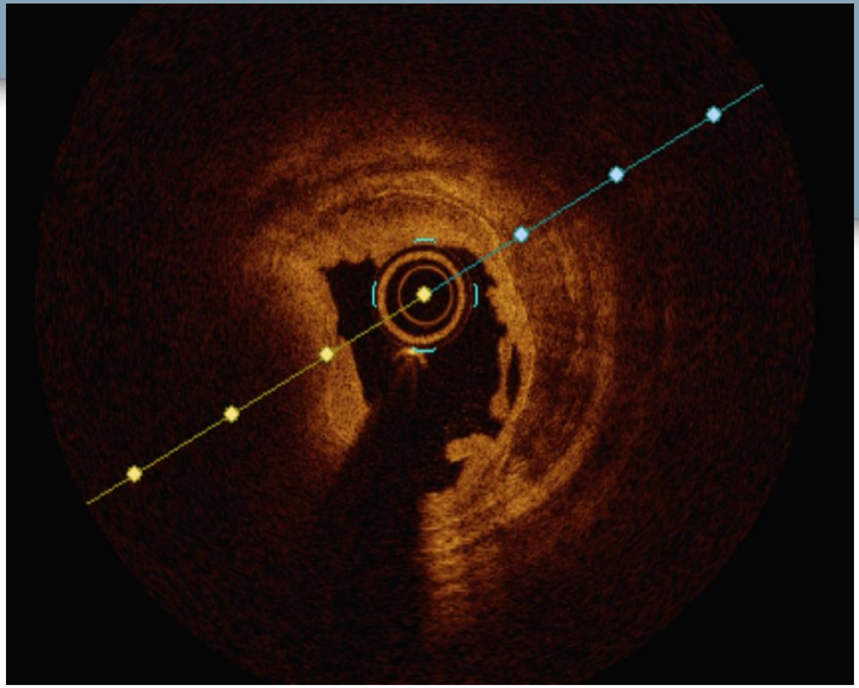


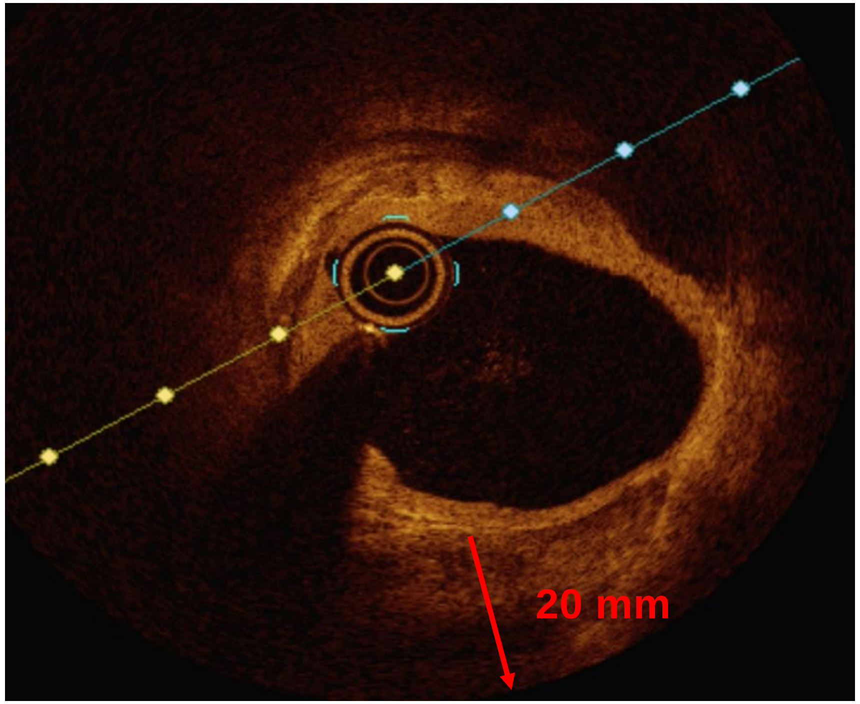


Riley et al. Catheter Cardiovasc Interv. 2020;96:346–362

Case_1


A Área: 8.80mm²
Diámetro medio: 3.34mm
Mín.: 3.17mm Máx.: 3.54mm
19-FEB-2021 14:02:54
0170
1 mm
Área
43.1 mm
10
20
30
40
mm
mm
0
2
A Longitud (20.8mm)
D
P



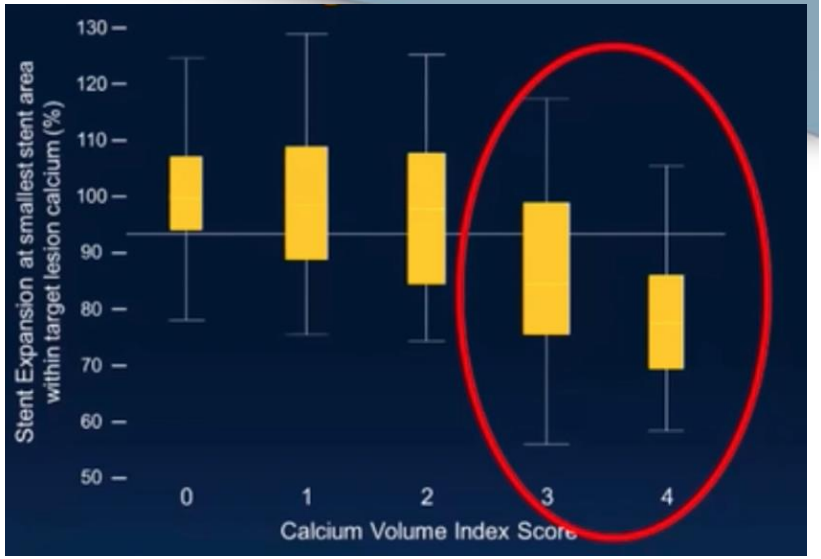

20 mm

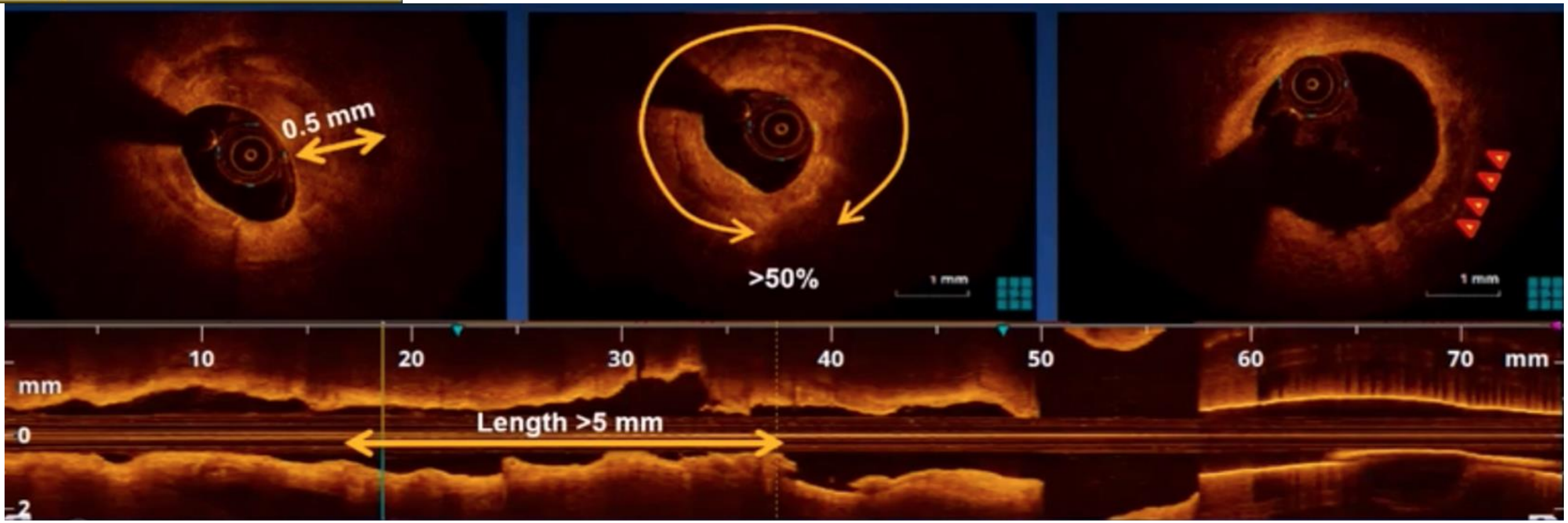
OCT Calcium Score

OCT-based Calcium Volume Index Score	
1. Maximum Calcium Angle (°)	≤ 90° ➡ 0 point 90° < Angle ≤180° ➡ 1 point > 180° ➡ 2 points
2. Maximum Calcium Thickness (mm)	≤ 0.5 mm ➡ 0 point > 0.5 mm ➡ 1 point
3. Calcium Length (mm)	≤ 5.0 mm ➡ 0 point > 5.0 mm ➡ 1 point
Total score	**0 to 4 points**

Rule of 5´s

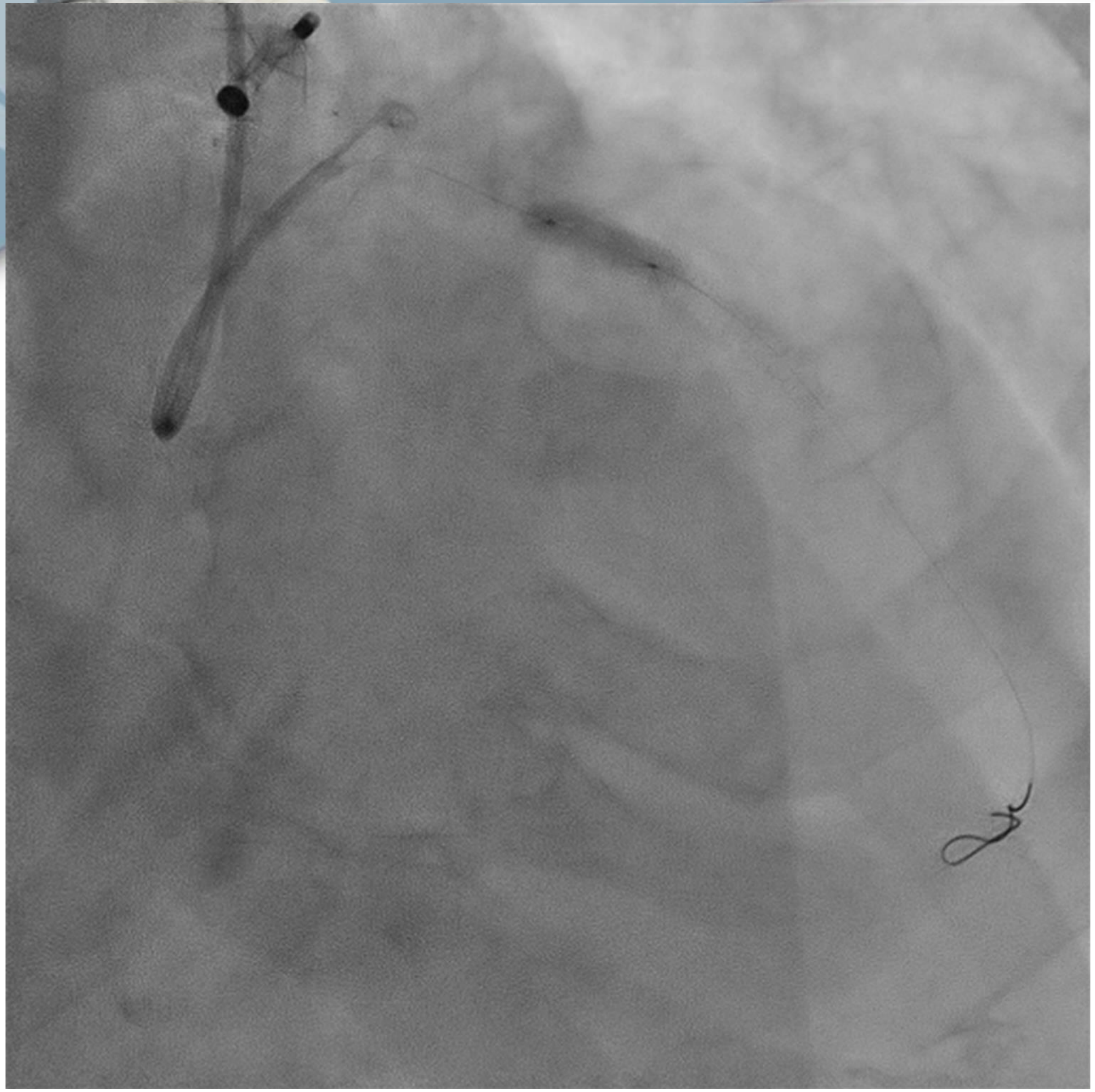
- 0.5 mm thickness
- 5 mm long
- 50% vessel arc



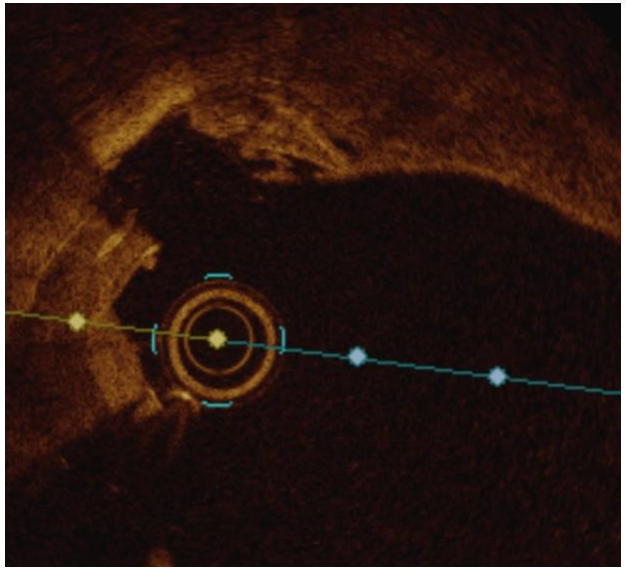


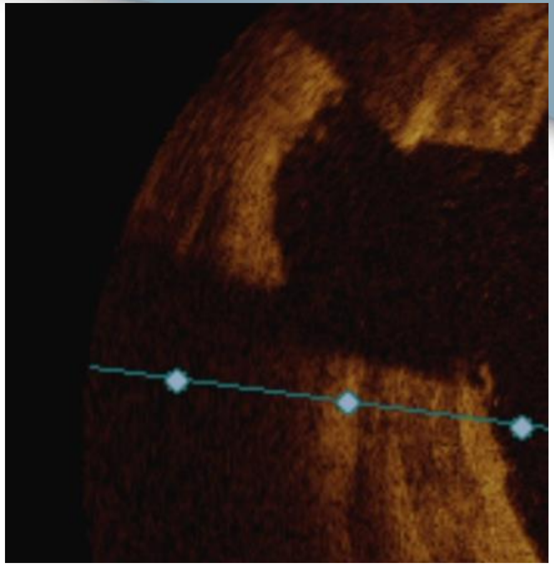
Fujino & Maehara. Eurointervention 2018;13:e2182-89

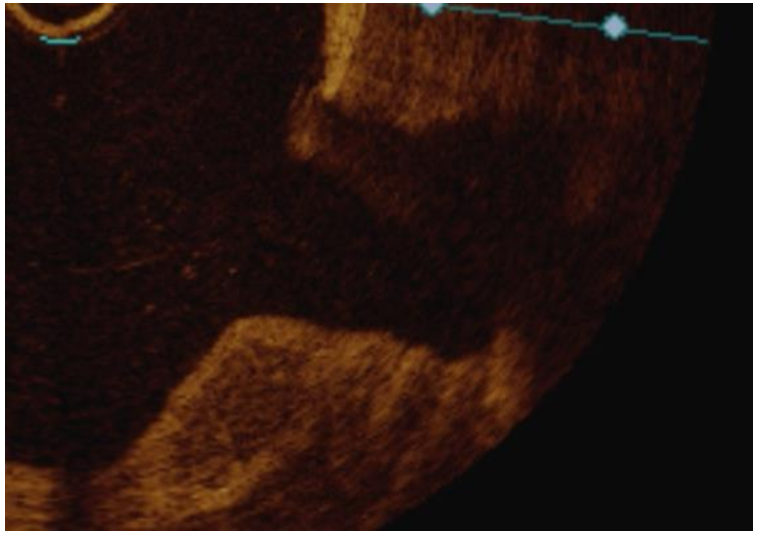
Case_1



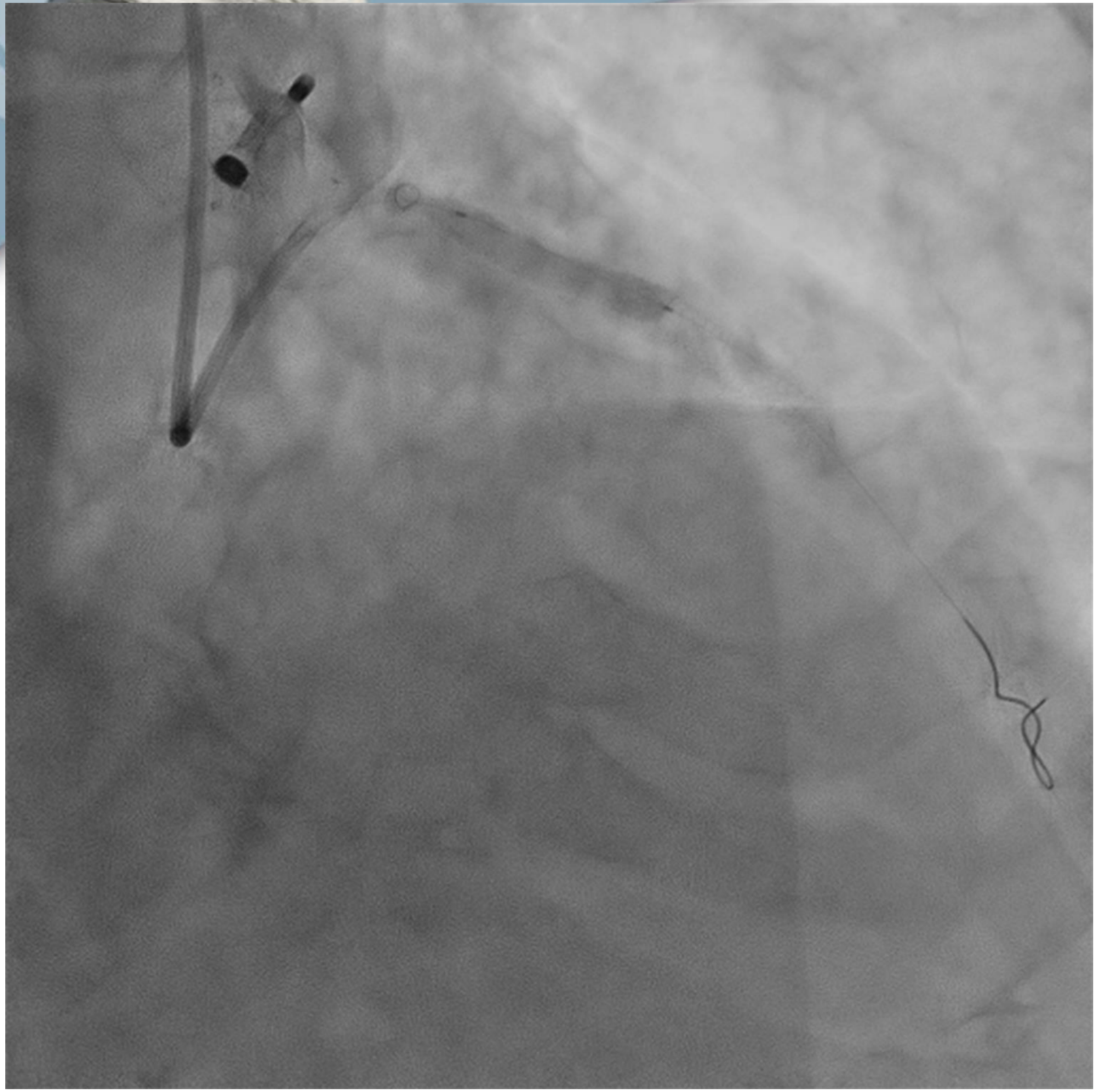
IVL balloon 4 x 12 mm



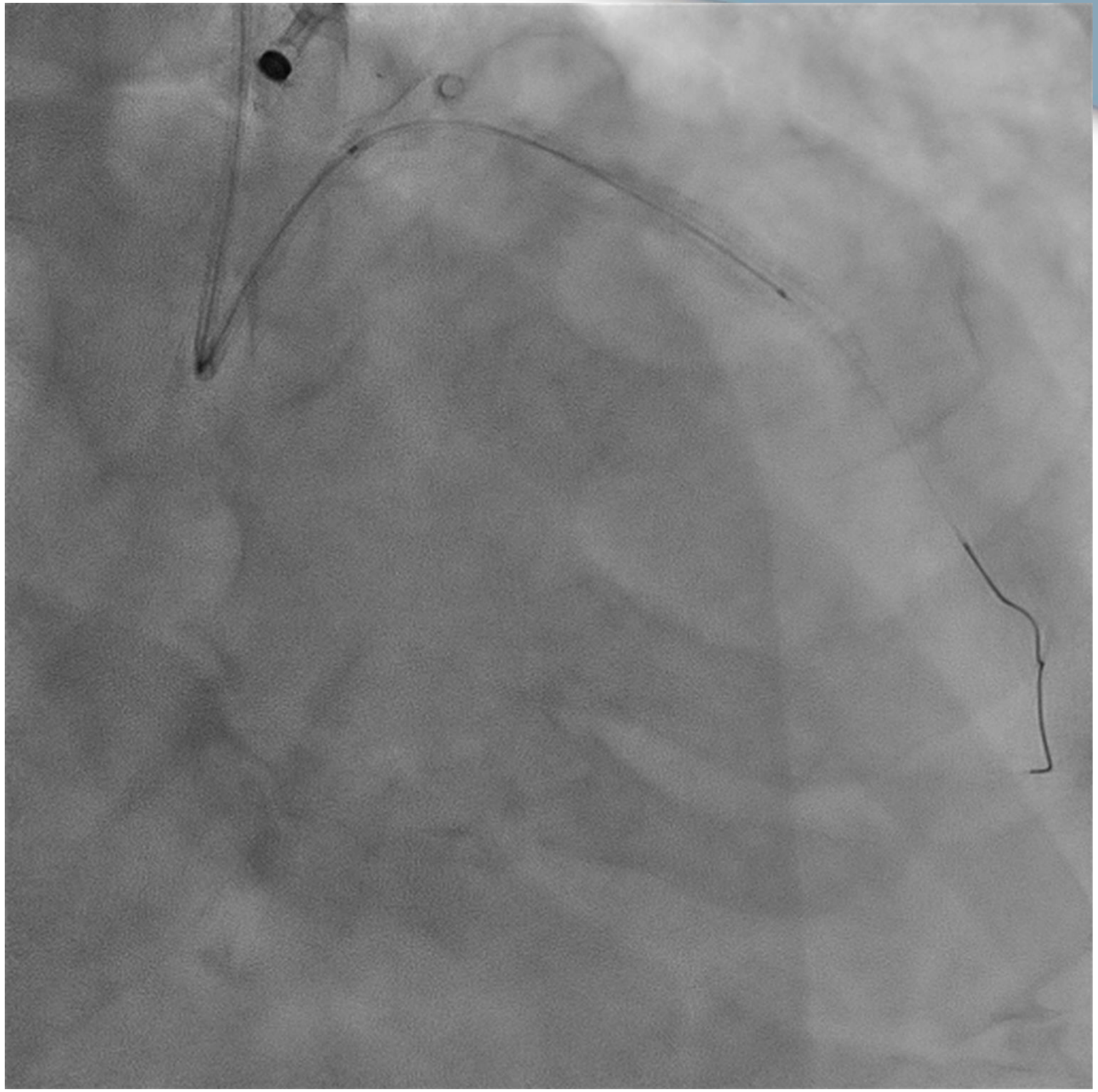




Case_1

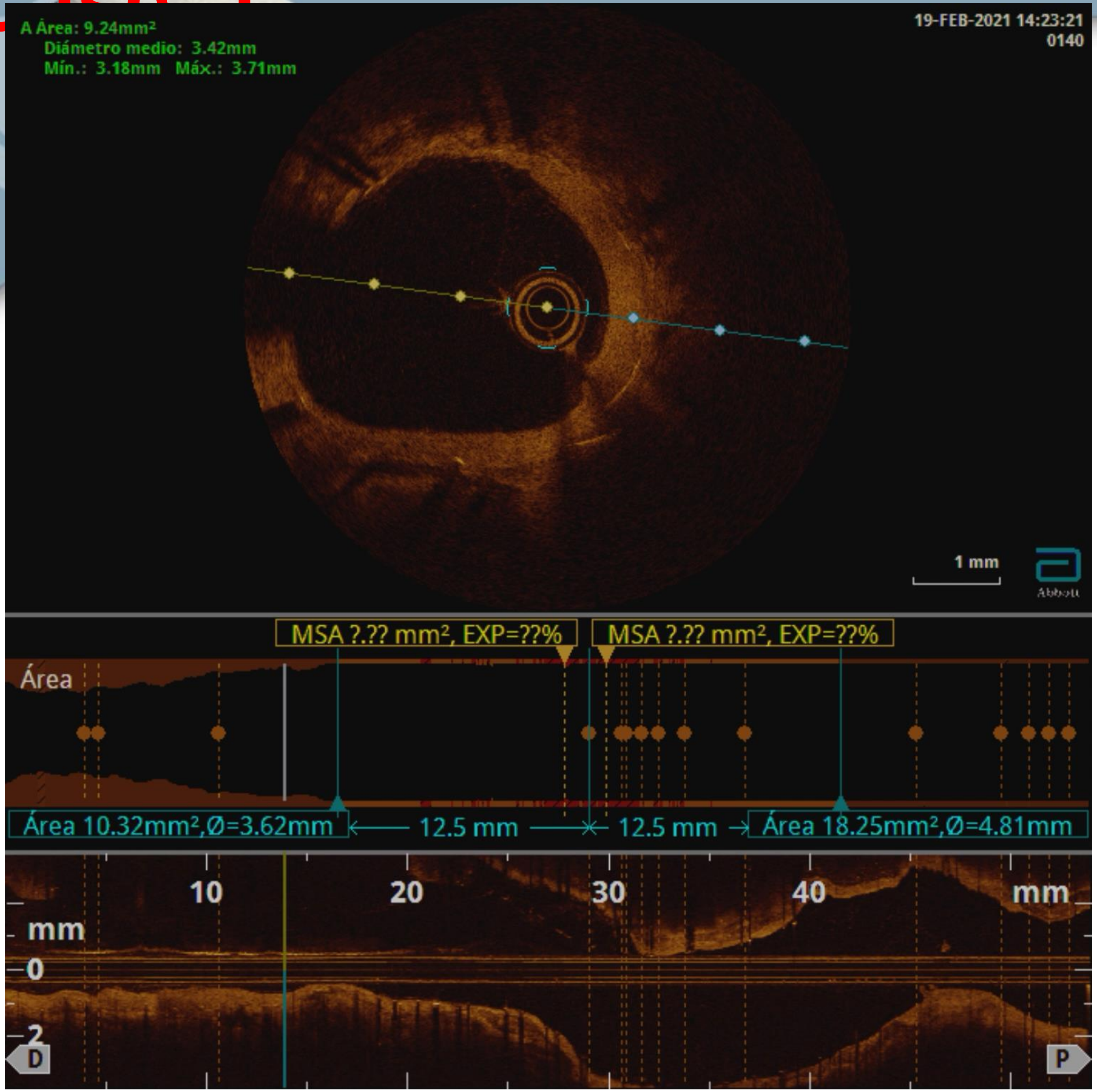


DES 4x28 mm



Angio Post-Stent OCT

Caso 1


A Área: 9.24mm²
Diámetro medio: 3.42mm
Mín.: 3.18mm Máx.: 3.71mm
19-FEB-2021 14:23:21
0140
1 mm
MSA ?.?? mm², EXP=??%
MSA ?.?? mm², EXP=??%
Área
Área 10.32mm²,Ø=3.62mm
12.5 mm
12.5 mm
Área 18.25mm²,Ø=4.81mm
10
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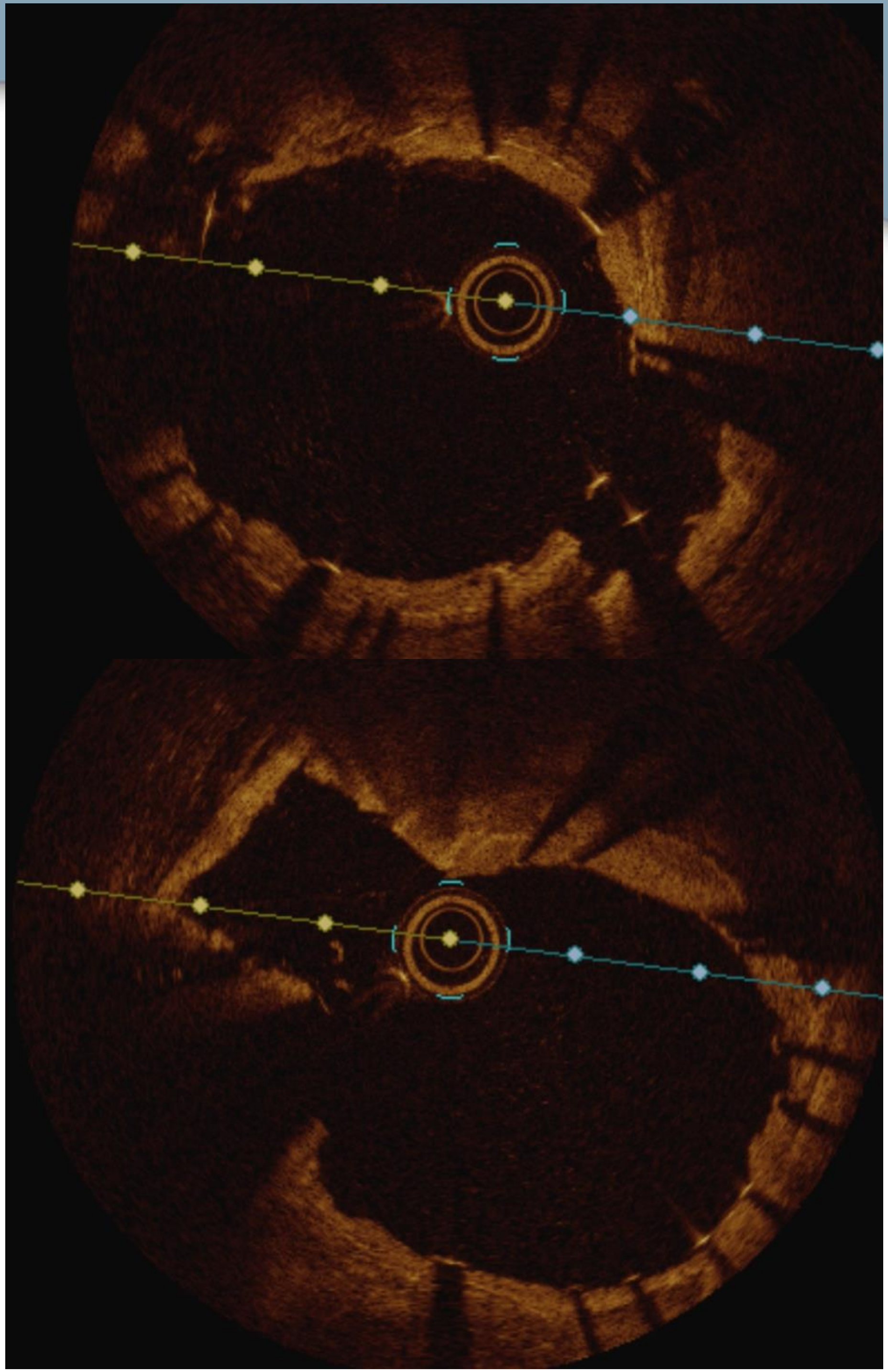
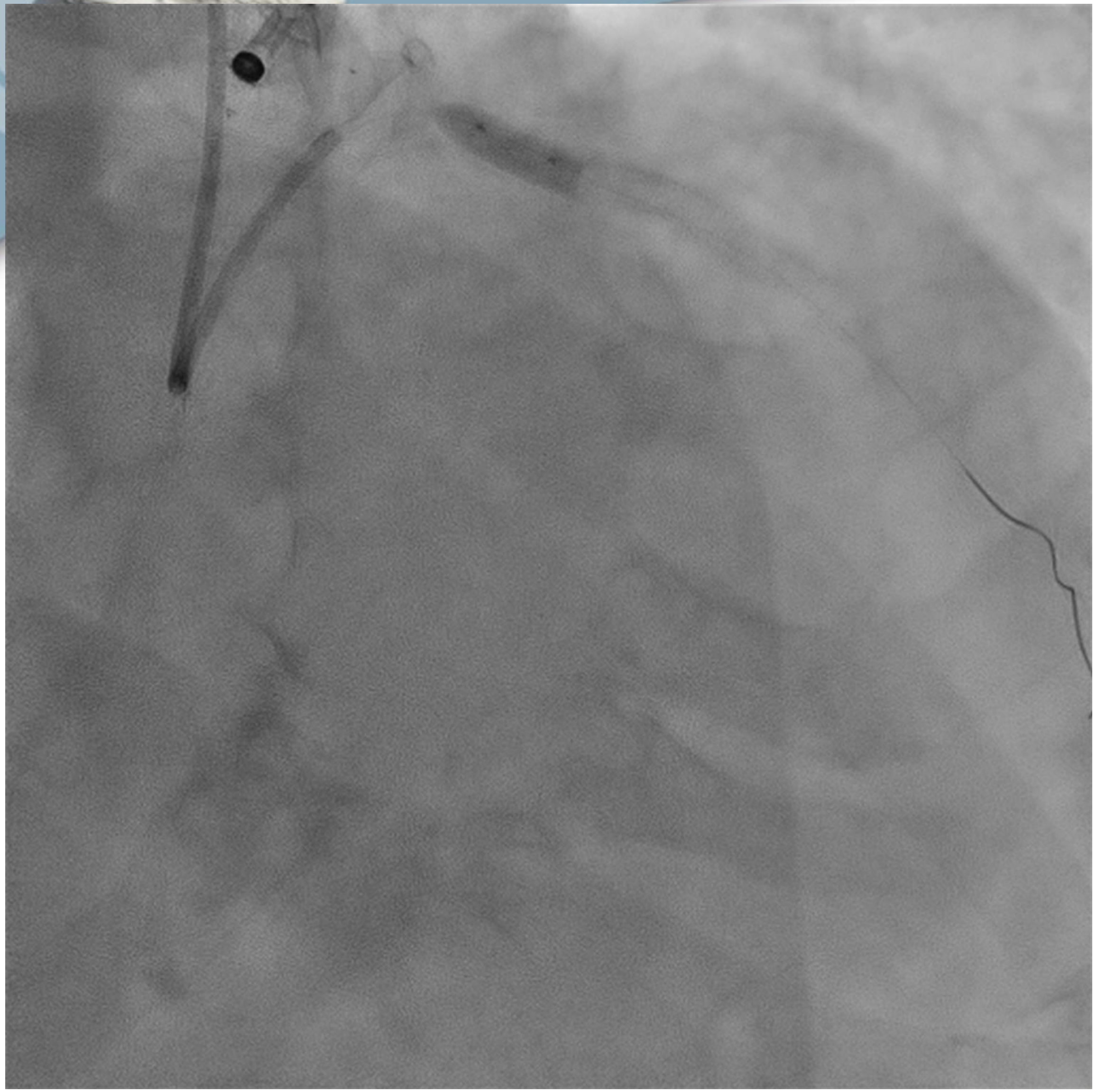
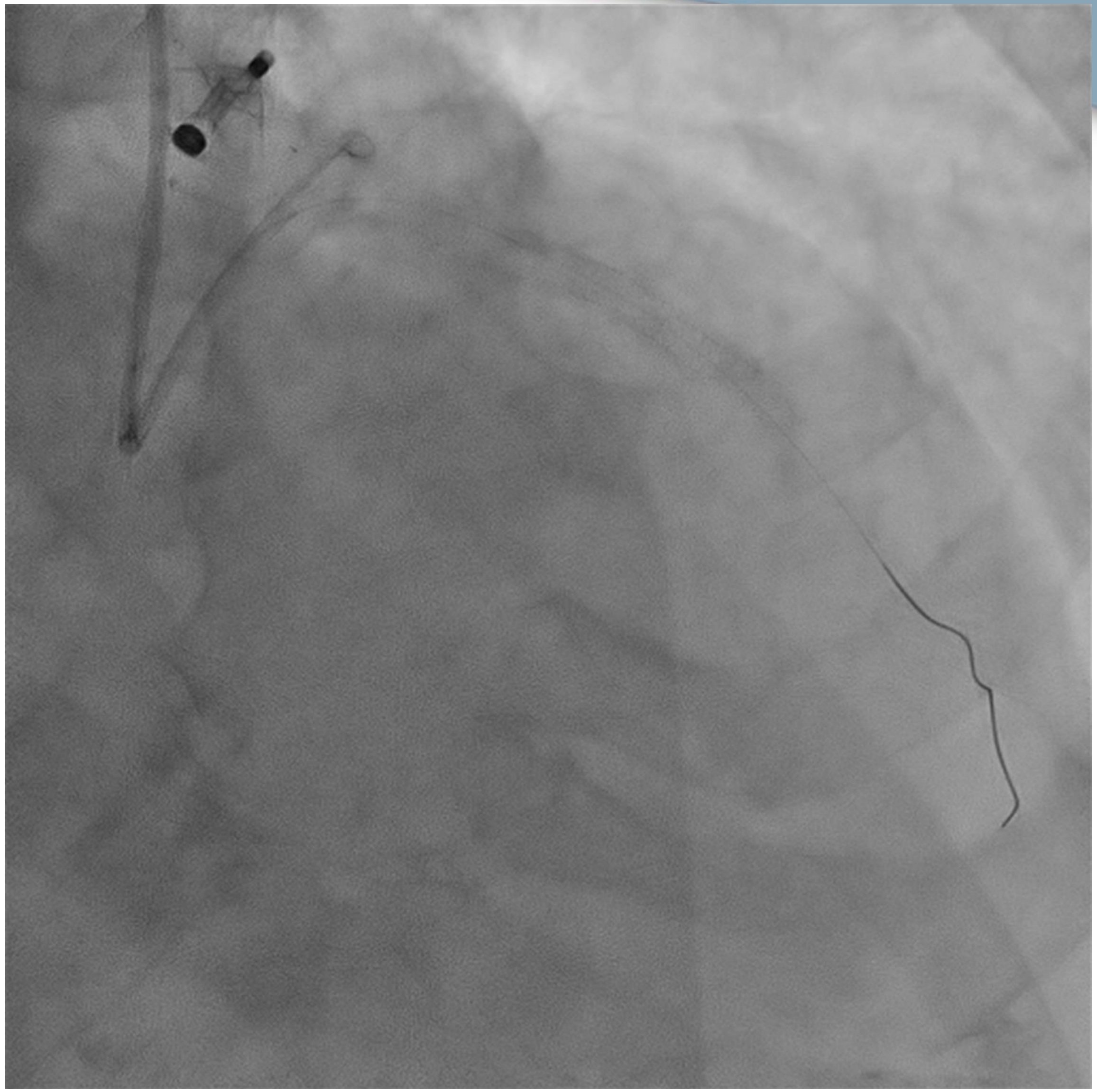


Case_1



NC balloon 4.5x10 mm



Final Result

Pooled analysis of OCT findings in DISRUPT CAD studies

Disrupt CAD I-IV: OCT Sub-studies

	CAD I	CAD II	CAD III	CAD IV	Pooled
Enrollment	Dec 2015 – Sep 2016	May 2018 – Mar 2019	Jan 2019 – Mar 2020	Nov 2019 – Apr 2020	Dec 2015 – Apr 2020
Study design	Prospective, multi-center, single-arm				
ITT (N)	60[1]	120[3]	384[4]	64[5]	628[6]
OCT Analysis[*] (N)	28[2]	57	106[†]	71[†]	**262**
OCT core laboratory	Cardiovascular Research Foundation New York, NY				
Target lesions	Severely calcified[*], *de novo* coronary artery lesions				
Target lesion RVD	2.5mm – 4.0mm				
Target lesion stenosis	≥50% and <100%	≥50% and <100%	≥70% and <100%	≥70% and <100%	

[*]Patient enrollment in OCT sub-studies was open to all sites participating in the Disrupt CAD studies that routinely perform OCT imaging. [†]Includes patients from the roll-in cohort.

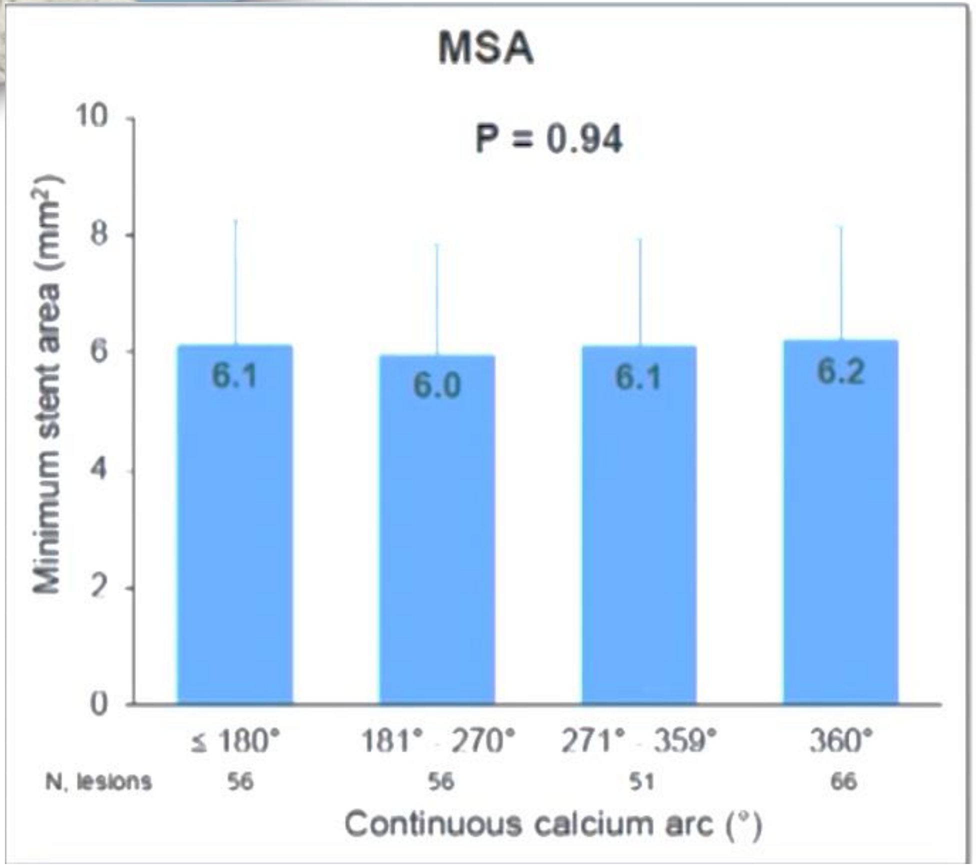
Largest evidence on plaque modification by IVL

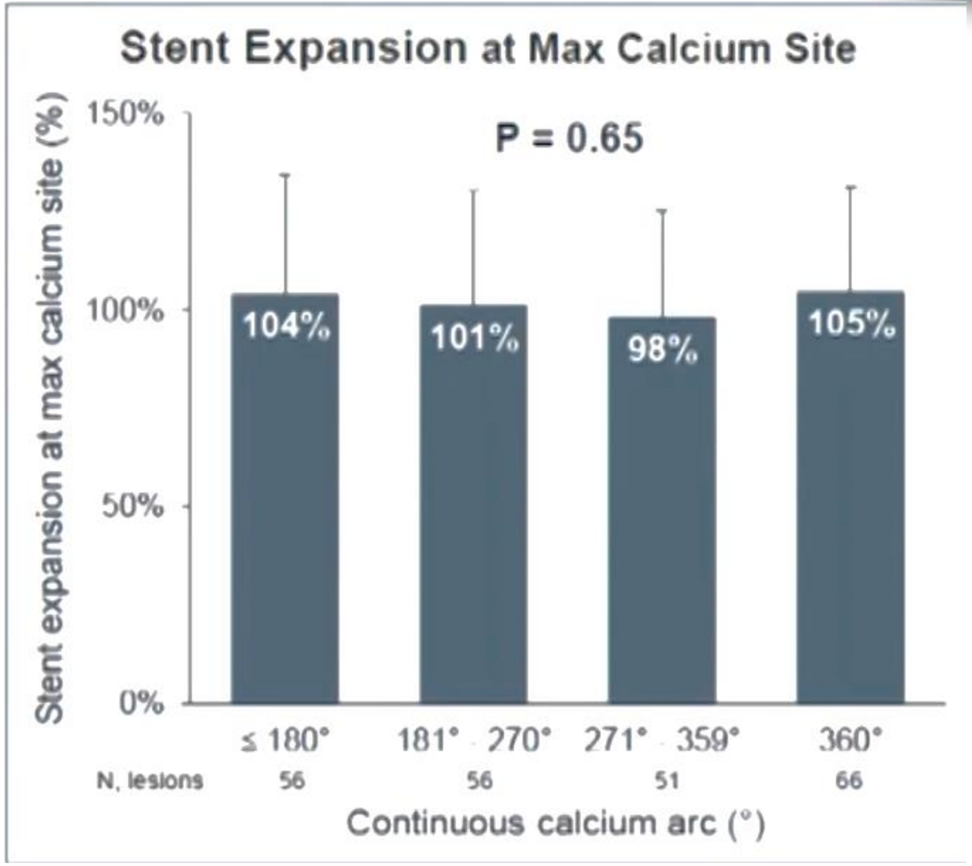
OCT-DISRUPT CAD: procedural characteristics

Core Lab Analysis	Arc of calcium in OCT ≤ 180° N=56	181° - 270° N=56	271° - 359° N=51	360° N=66	*P* value
Procedure time, min	70.1 ± 31.1	65.8 ± 31.6	67.6 ± 30.0	69.7 ± 31.9	0.87
Contrast volume, ml	215.5 ± 89.6	198.1 ± 76.4	208.5 ± 68.6	206.6 ± 65.8	0.68
Pre-dilatation, %	21.4%	29.8%	25.5%	39.4%	0.15
IVL catheters per patient	1.3 ± 0.6	1.4 ± 0.9	1.5 ± 0.8	1.5 ± 0.6	0.47
Max IVL inflation pressure	6.0 ± 0.3	6.0 ± 0.6	6.0 ± 0.8	6.0 ± 0.6	0.92
IVL balloon to artery ratio	1.3 ± 0.2	1.2 ± 0.2	1.3 ± 0.2	1.3 ± 0.2	0.87
Pulses delivered	86.6 ± 44.6	87.8 ± 60.6	83.3 ± 49.8	90.9 ± 38.1	0.91
Post-IVL dilatation, %	3.6%	8.8%	5.9%	10.6%	0.47
Stents placed per patient	1.3 ± 0.5	1.3 ± 0.6	1.4 ± 0.6	1.4 ± 0.5	0.80
Post-stent dilatation	94.6%	98.2%	96.1%	98.5%	0.57

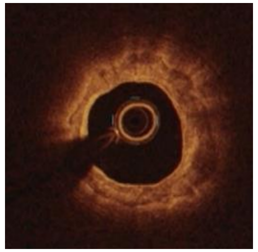
There were no significant procedural differences accross the subgroups of lesions defined by the arc of Calcium in the vessel

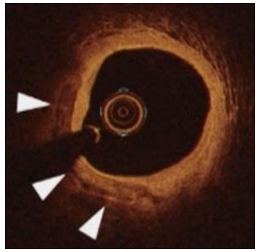
OCT-DISRUPT CAD: Stent expansion by arc of calcium





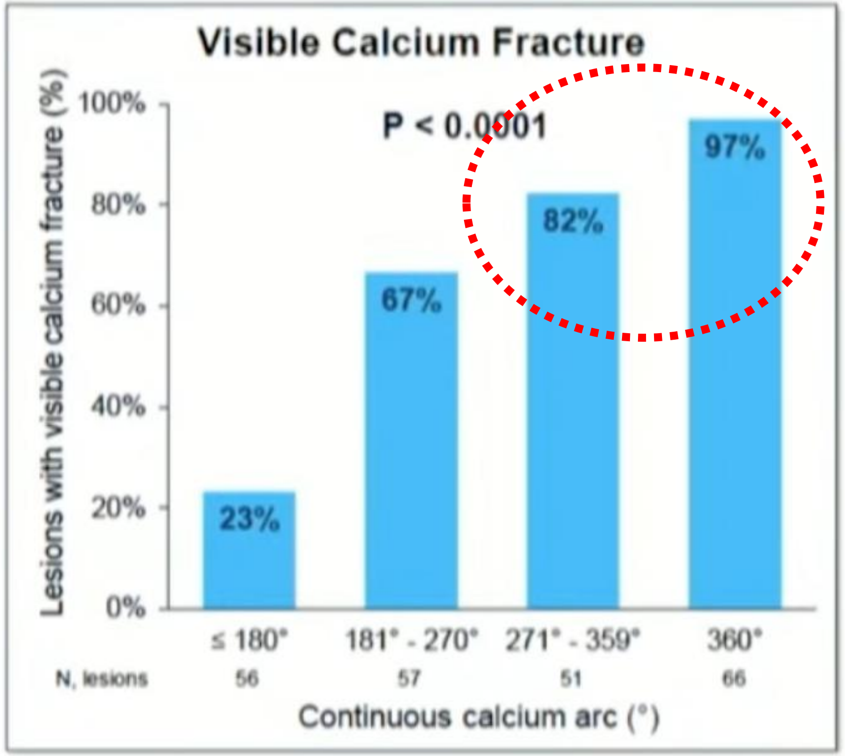
Concentric vs Eccentric:



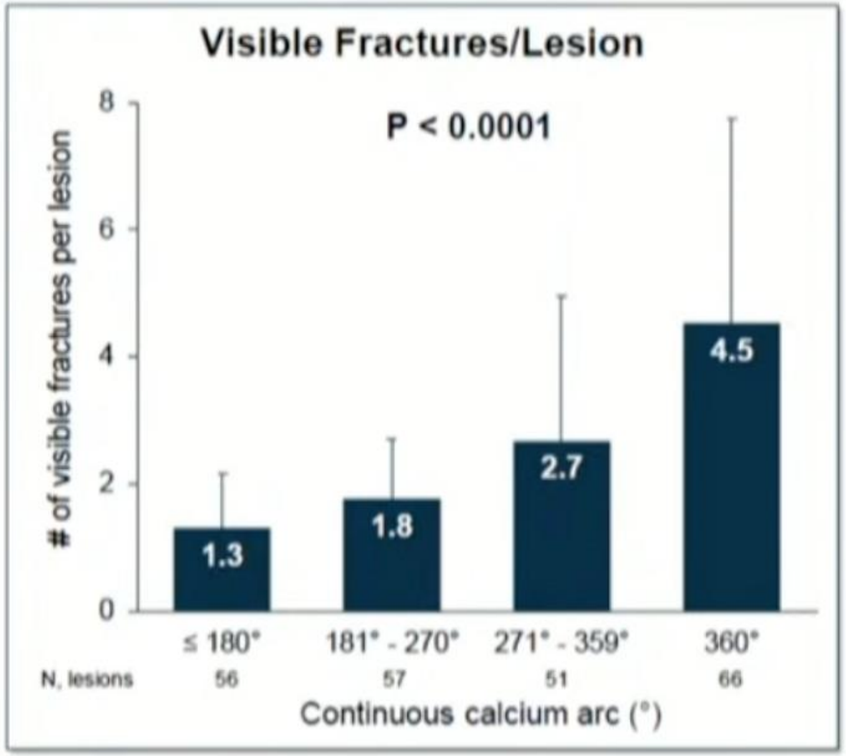


No differences in minimal stent area nor in % stent expansion

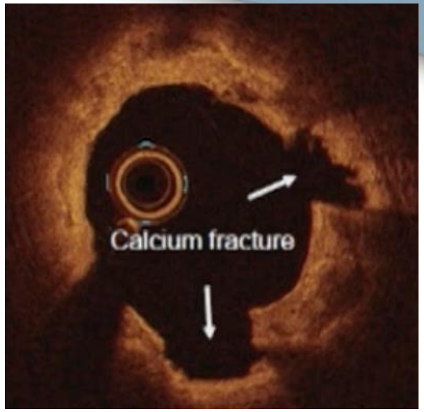
OCT-DISRUPT CAD: Ca distribution and visible fractures

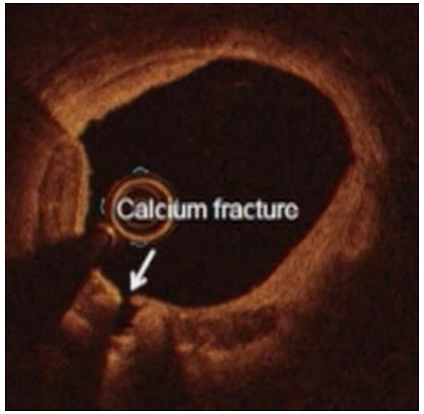


Visible Fractures



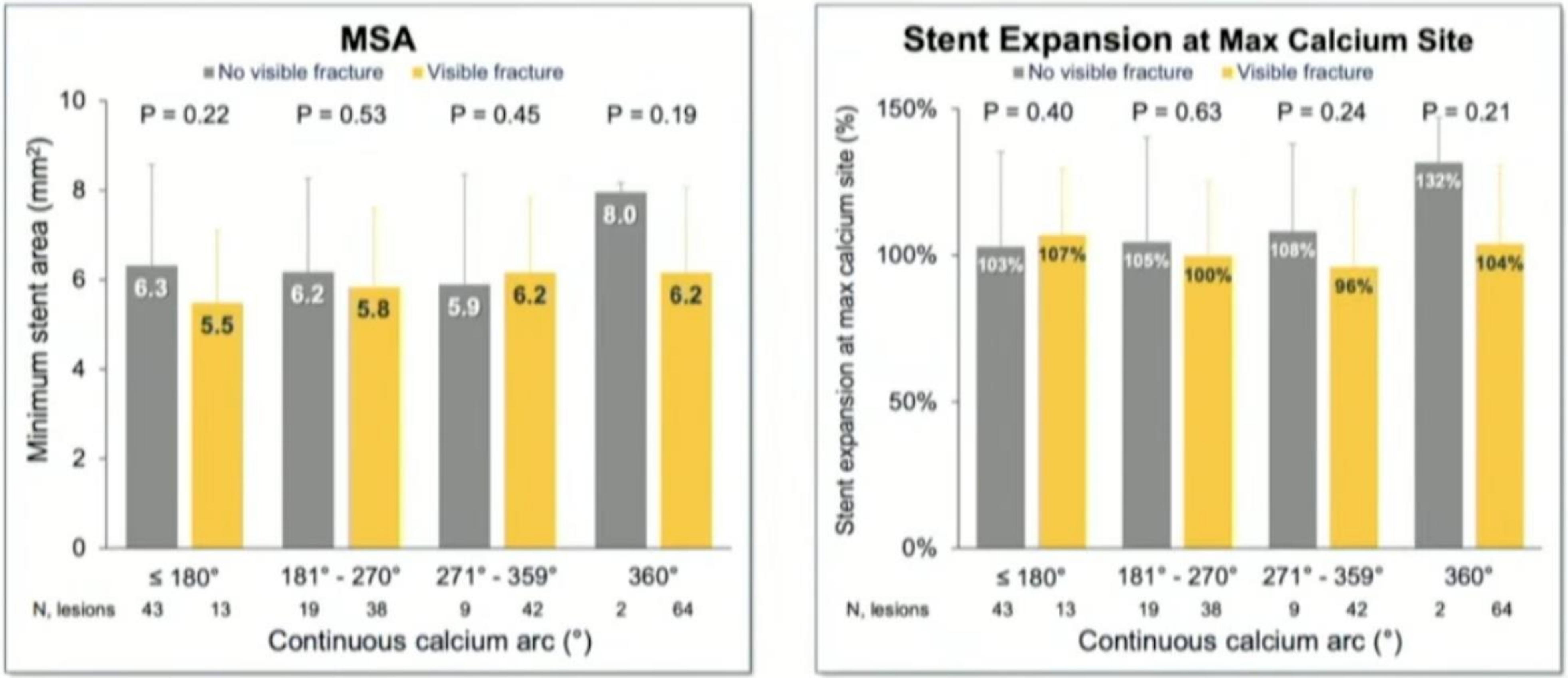
\# Fractures





After IVL – visible fractures were observed in 68% of lesions (*3.2 fractures/lesion*) – more frequently in circumferential calcified plaques

Pooled análisis of OCT findings in DISRUPT CAD studies



Regardless of fracture visibility in OCT – stenting deployment after IVL was associated to similar MSA & stent expansion

Case_1

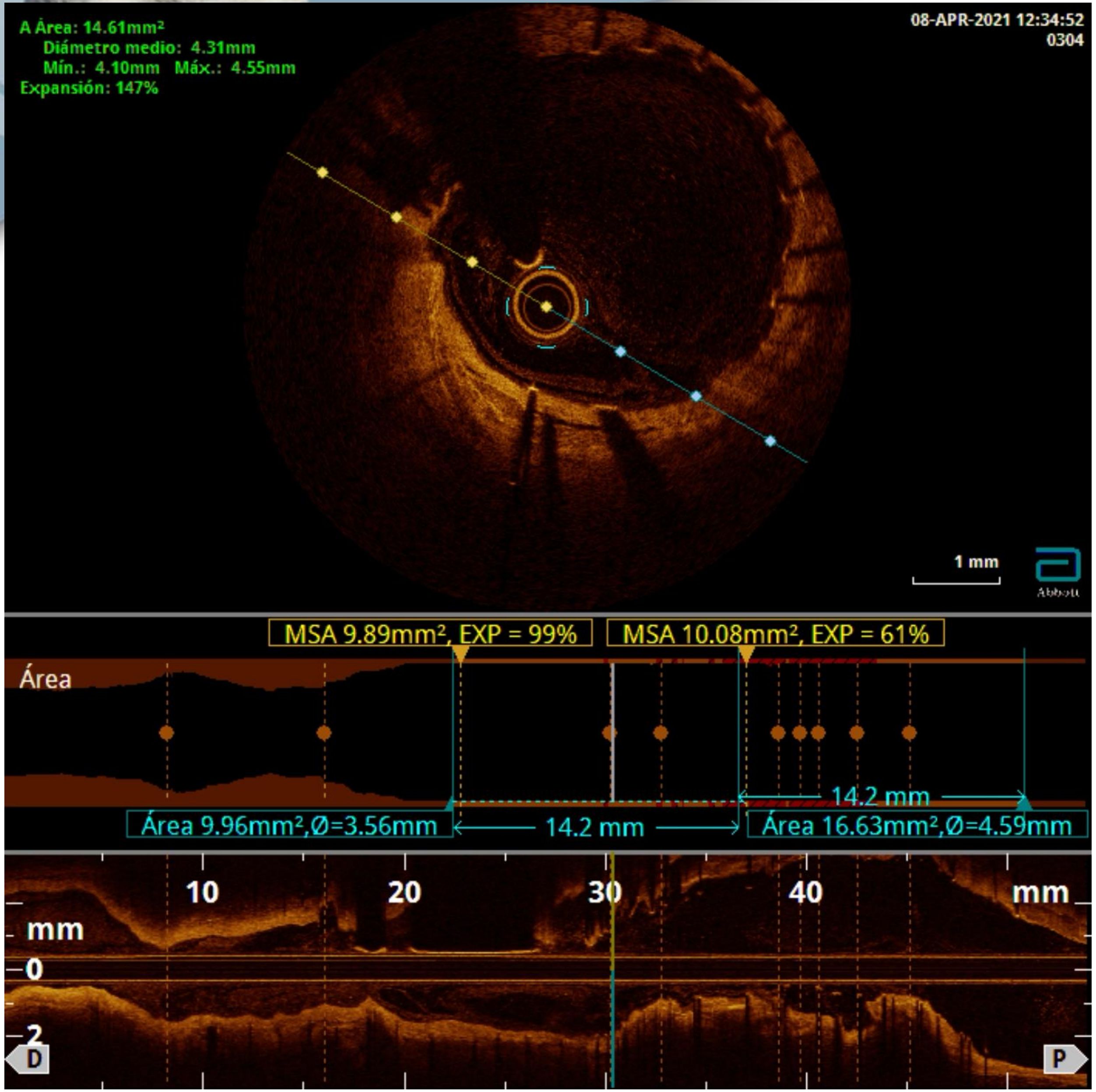
1-year FU

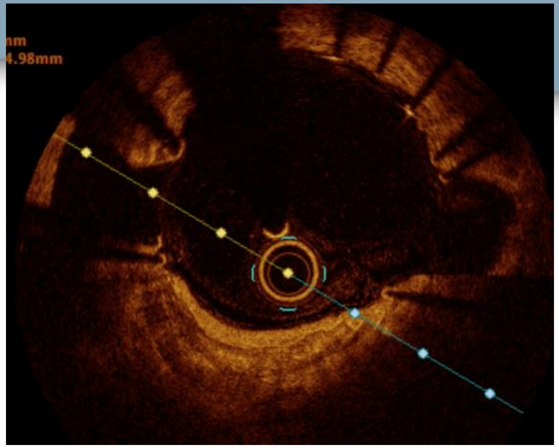
- Elective Angiography

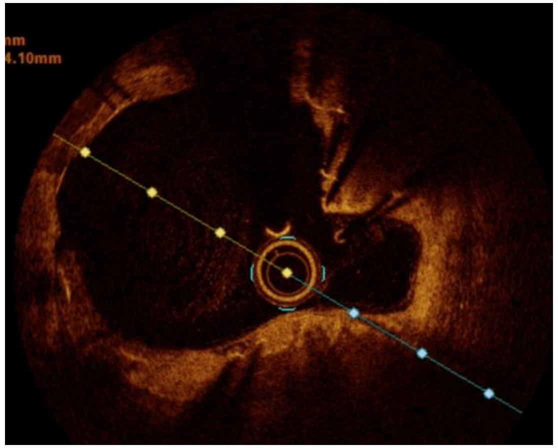
- Asymptomatic

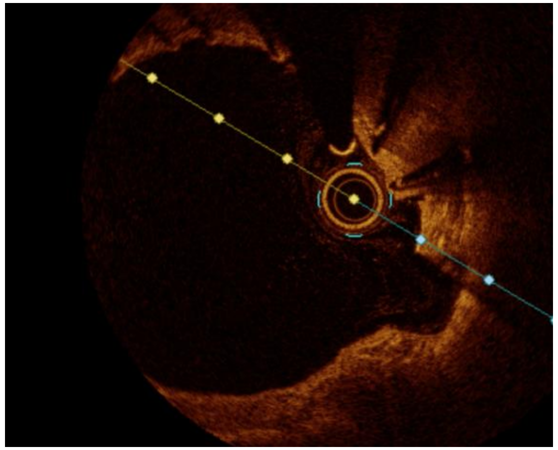
- Single Antiplatelet therapy

Case_1



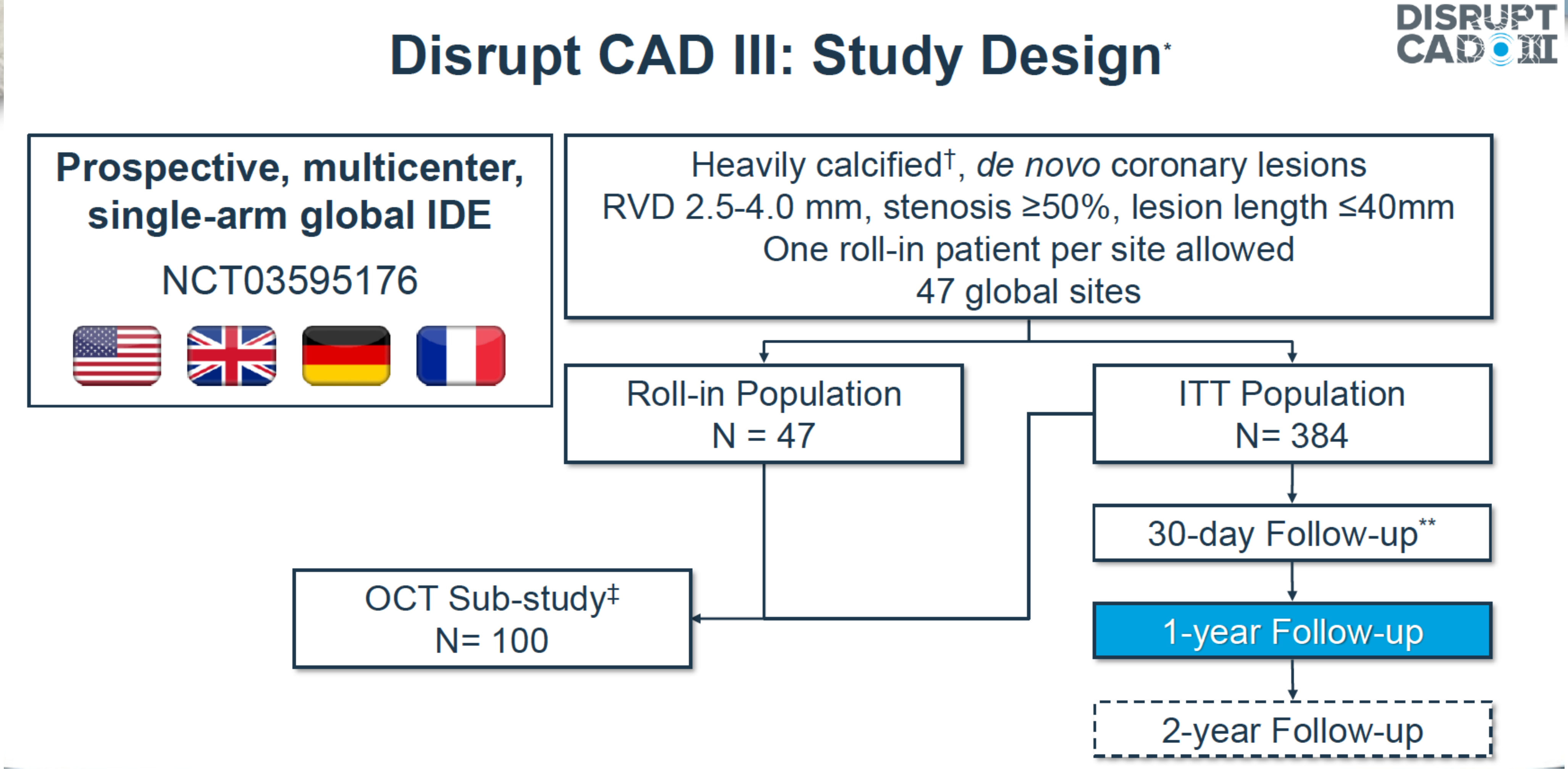






OCT 1 year FU

1-Year results of Disrupt CAD III



Largest and longest clinical follow-up available in pts treated with IVL

1-Year results of Disrupt CAD III

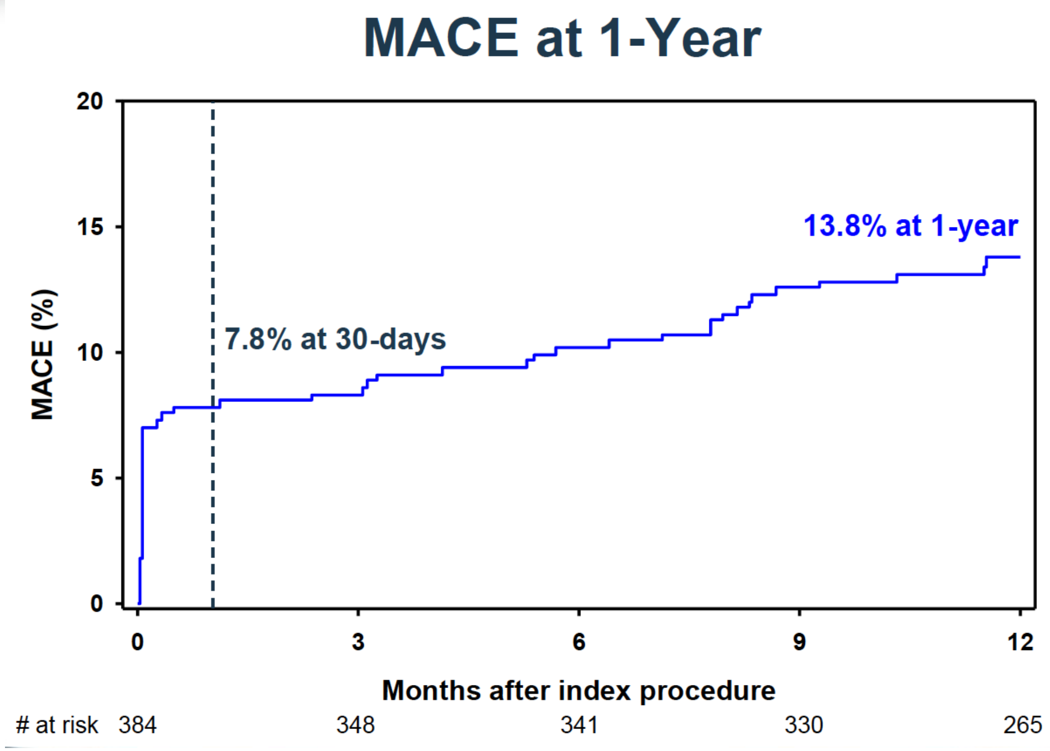
Baseline Clinical & Lesion Characteristics

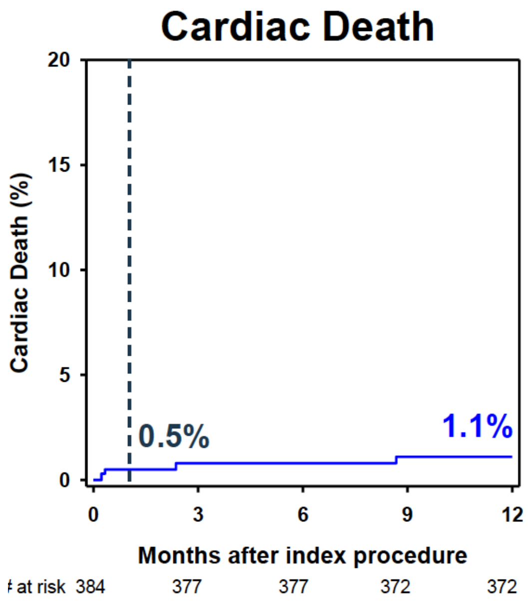
DISRUPT CAD III

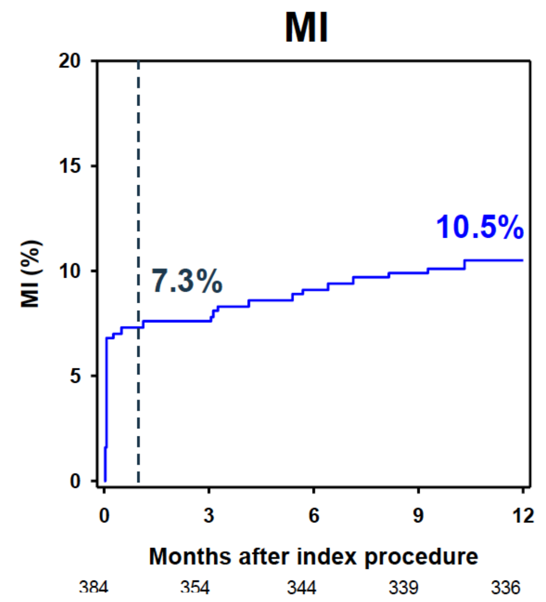
Characteristic	N=384
Age	71.2 ± 8.6
Male	76%
Hypertension	89%
Hyperlipidemia	89%
Diabetes mellitus	40%
Current smoker	12%
Prior MI	18%
Prior CABG	9%
Prior Stroke	8%
Renal insufficiency*	26%

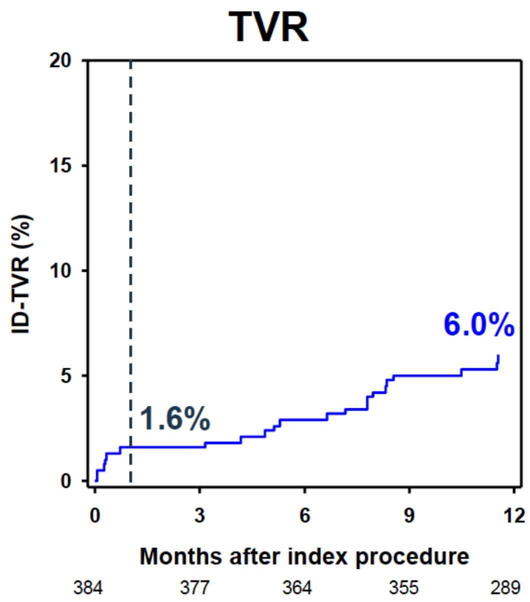
Core Lab Analysis		N=384
Target vessel	LAD	56.5%
	LCx	12.8%
	RCA	29.2%
	LM	1.6%
Reference vessel diameter, mm		3.0 ± 0.5
Minimum lumen diameter, mm		1.1 ± 0.4
Diameter stenosis		65.1 ± 10.8%
Lesion length, mm		26.0 ± 11.7
Calcified length, mm		47.9 ± 18.8
Severe calcification		100%

1-Year results of Disrupt CAD III

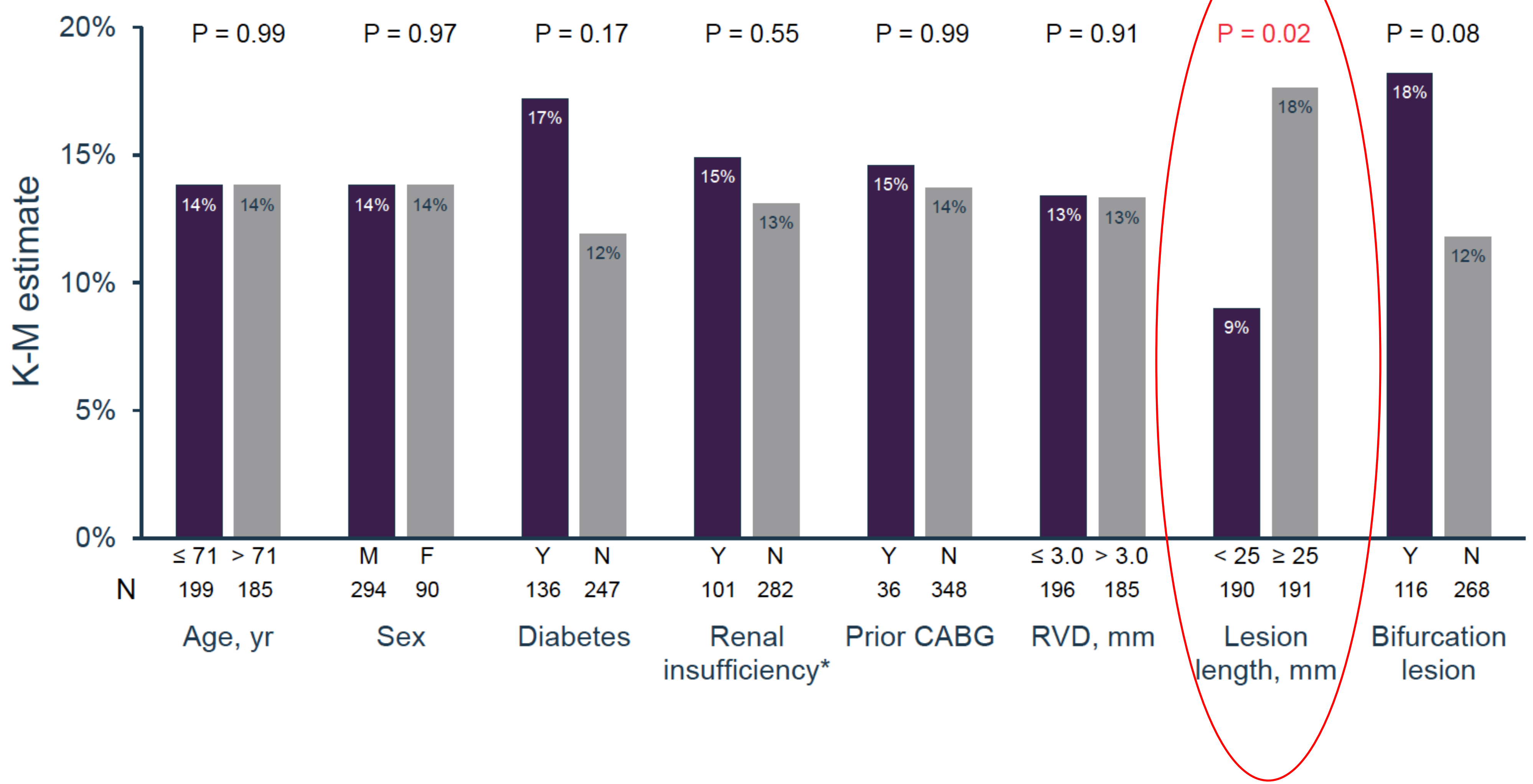








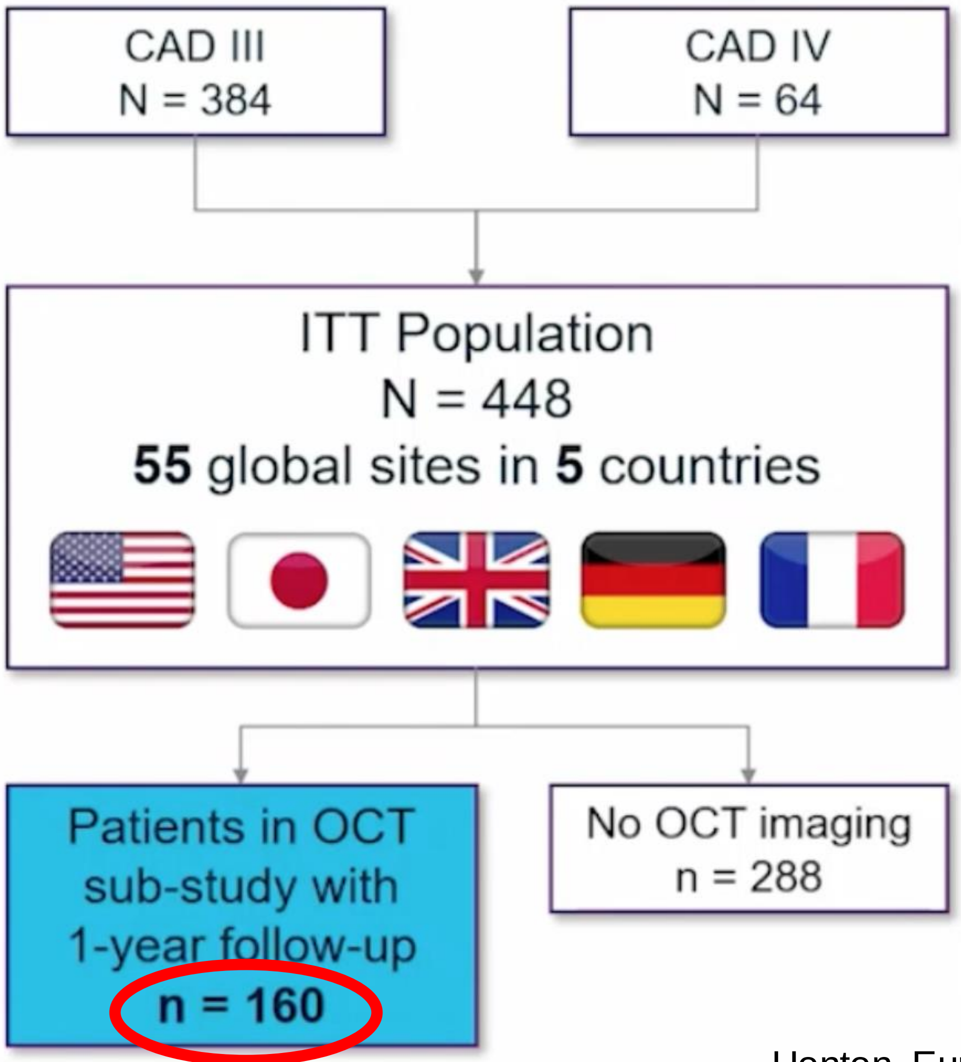
1-Year results of Disrupt CAD III



Long-term clinical impact OCT findings

1-Year patient-level pooled analysis of Disrupt CAD III & IV studies

- **Objective:** To evaluate the relationship between OCT findings following IVL treatment and 1-year clinical outcomes.
- **Population:** Patient-level pooled analysis of the Disrupt CAD III-IV studies
  - Uniform study criteria, endpoints, adjudication, follow-up at 1-year
- **Endpoints:** Target lesion failure (TLF) and stent thrombosis (definite or probable) at 1-year
  - TLF defined as CEC-adjudicated Cardiac death, Target-vessel myocardial infarction, or Ischemia-driven target lesion revascularization
- Analysis of TLF and stent thrombosis by calcium morphology
  - Lesions with calcified nodules
  - Lesions with eccentric calcium



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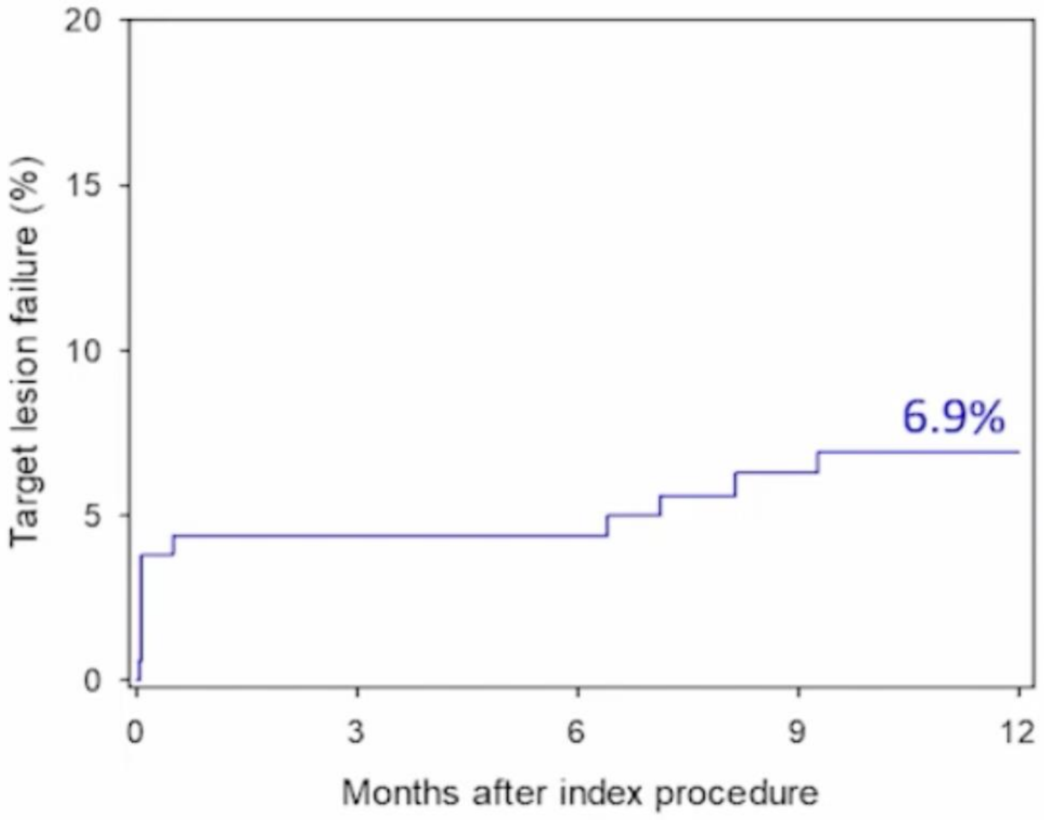
Target Lesion Failure & Stent thrombosis at 1-Year



K-M Estimate	N=160
Target lesion failure	11 (6.9)
Cardiac death	0.0
TV-MI	11 (6.9)
ID-TLR	4 (2.5)
Stent thrombosis (definite or probable)	1 (0.6)

Low rate of TLF at 1-year driven by TV-MI (all NQWMI)
Only 1 definite or probable subacute stent thrombosis event (Day 22)

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1-Year Baseline OCT Findings (CAD III-IV)

Core lab assessment	Patients *without* TLF N=144	Patients *with* TLF N=11	P value
MLA, mm^2	2.0 ± 0.8	1.8 ± 0.6	0.39
Area stenosis, %	73 ± 12	73 ± 7	0.93
Max calcium angle	273 ± 80	328 ± 48	0.03
Max continuous calcium angle			0.16
≤ 180°	22%	0%	
181° to 270°	28%	10%	
271° to 359°	20%	20%	
360°	30%	70%	
Max calcium thickness	0.97 ± 0.26	0.95 ± 0.24	0.73
Lesions with calcified nodule	18%	27%	0.42

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1-Year Post-Stent OCT Findings

Core lab assessment	Patients *without* TLF N=144	Patients *with* TLF N=10	P value
MLA, mm^2	6.3 ± 1.9	5.6 ± 1.2	0.27
Area stenosis, %	17.7 ± 20.4	13.3 ± 7.9	0.55
Acute gain, %	4.4 ± 1.7	4.0 ± 1.0	0.49
MSA, mm^2	6.1 ± 1.9	6.3 ± 2.1	0.79
Stent expansion @max Ca site	102 ± 30	110 ± 25	0.43
Mean stent expansion	106 ± 30	108 ± 17	0.84
Stent length	35.8 ± 8.9	31.7 ± 10.9	0.25
Asymmetry index	0.63 ± 0.08	0.66 ± 0.08	0.16
Eccentricity index	0.71 ± 0.07	0.74 ± 0.08	0.26
Any strut malapposition	3.5 ± 4.2	4.4 ± 3.5	0.53

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Case_2

82 yo woman

Risk Factors:

Type 2 Diabetes. Hypertension. Dyslipidemia

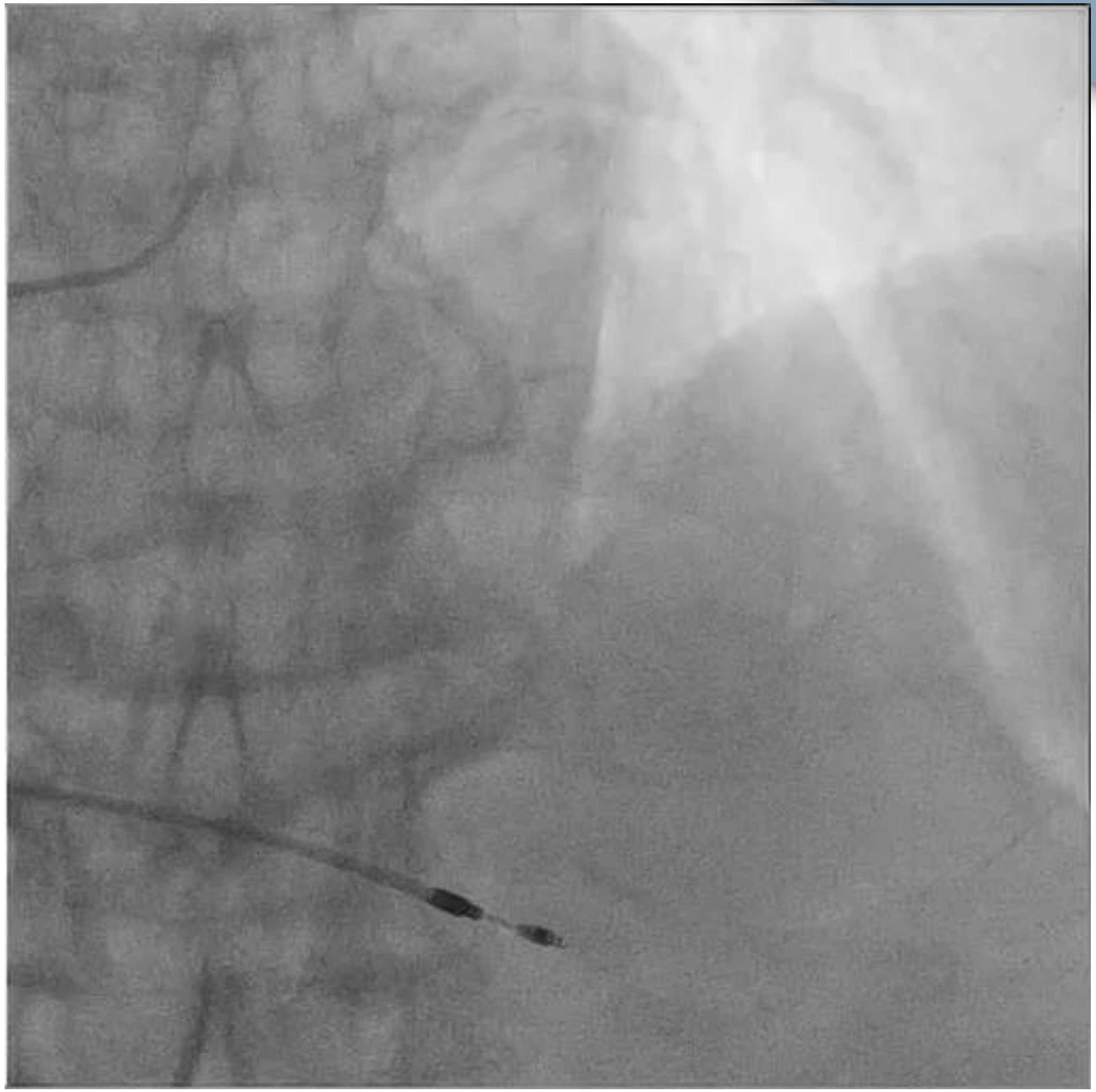
CKD (GFR 30)

June 2022. Inferior ST-segment elevation MI

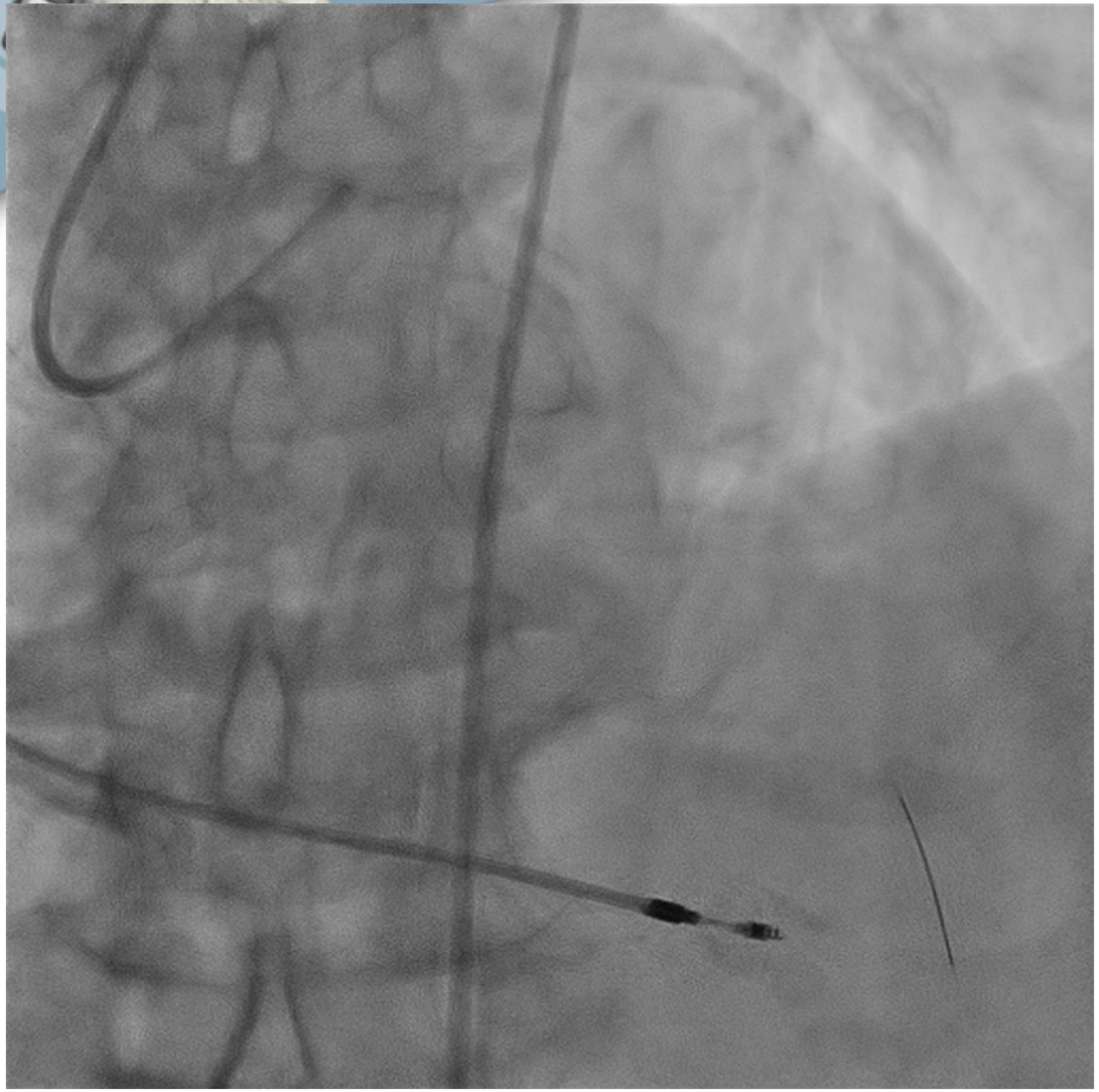
Primary PCI: stent in mid RCA

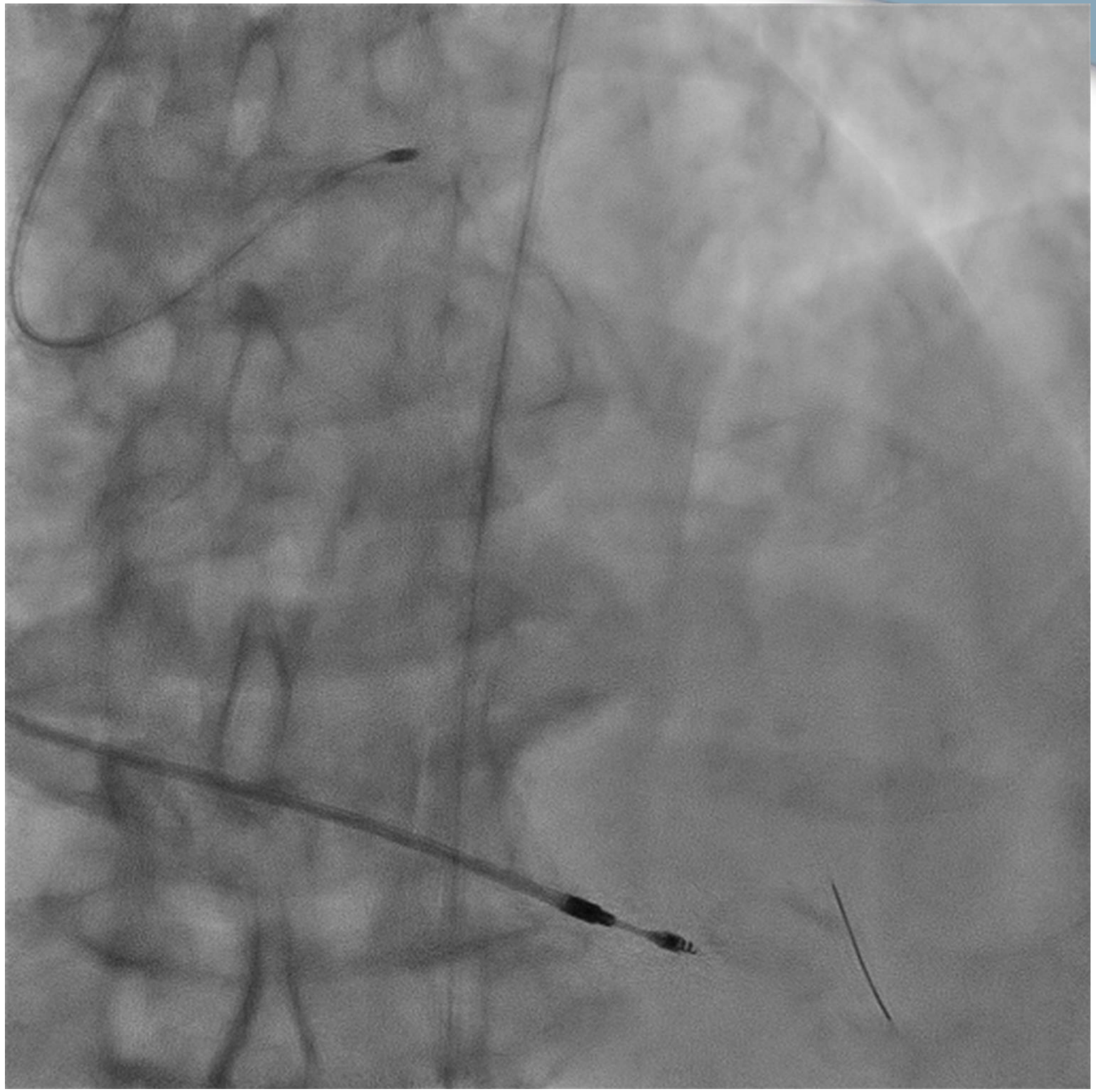
Second procedure: severe calcified lesion

in prox LAD and LMCA



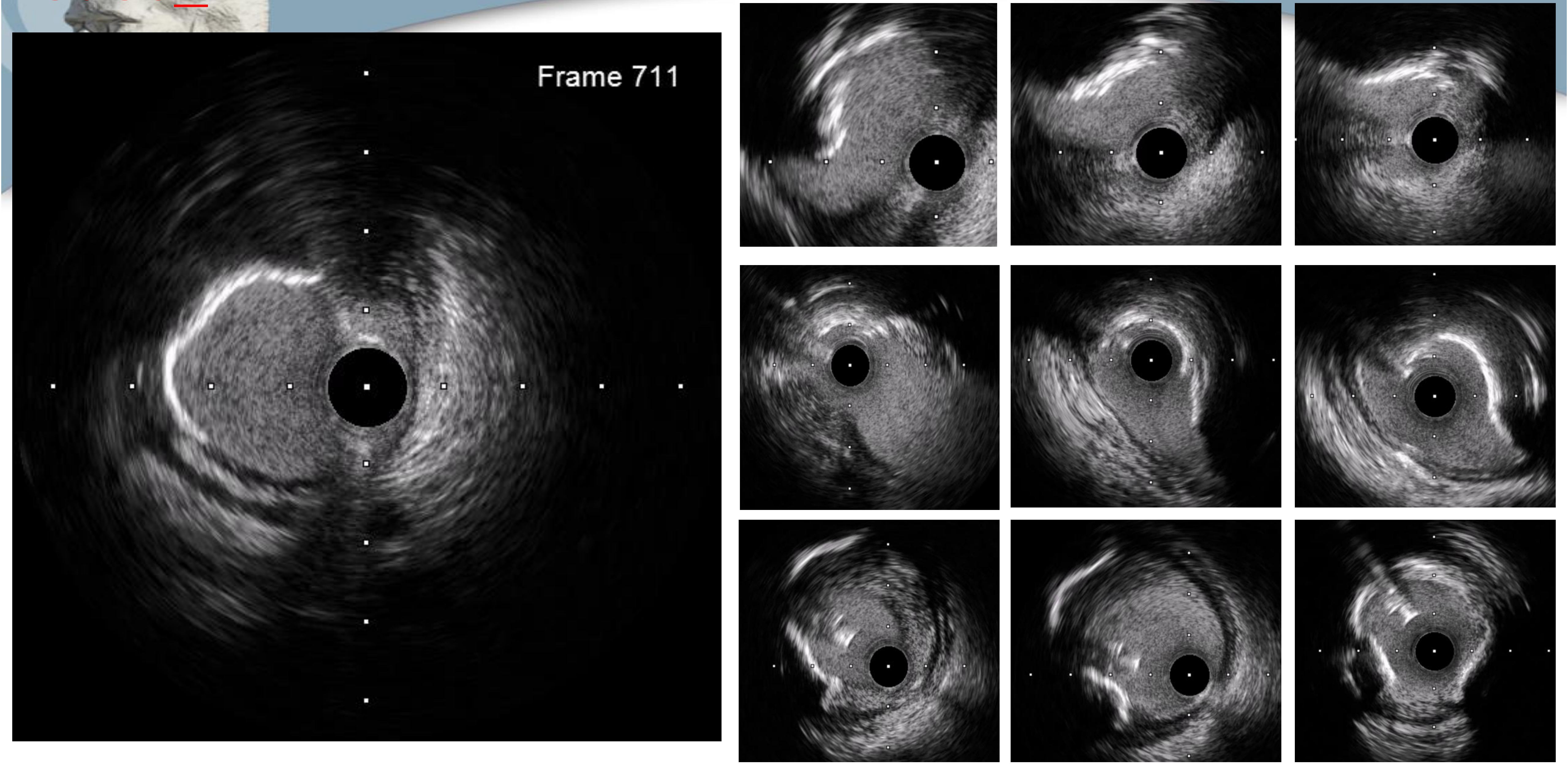
Case_2



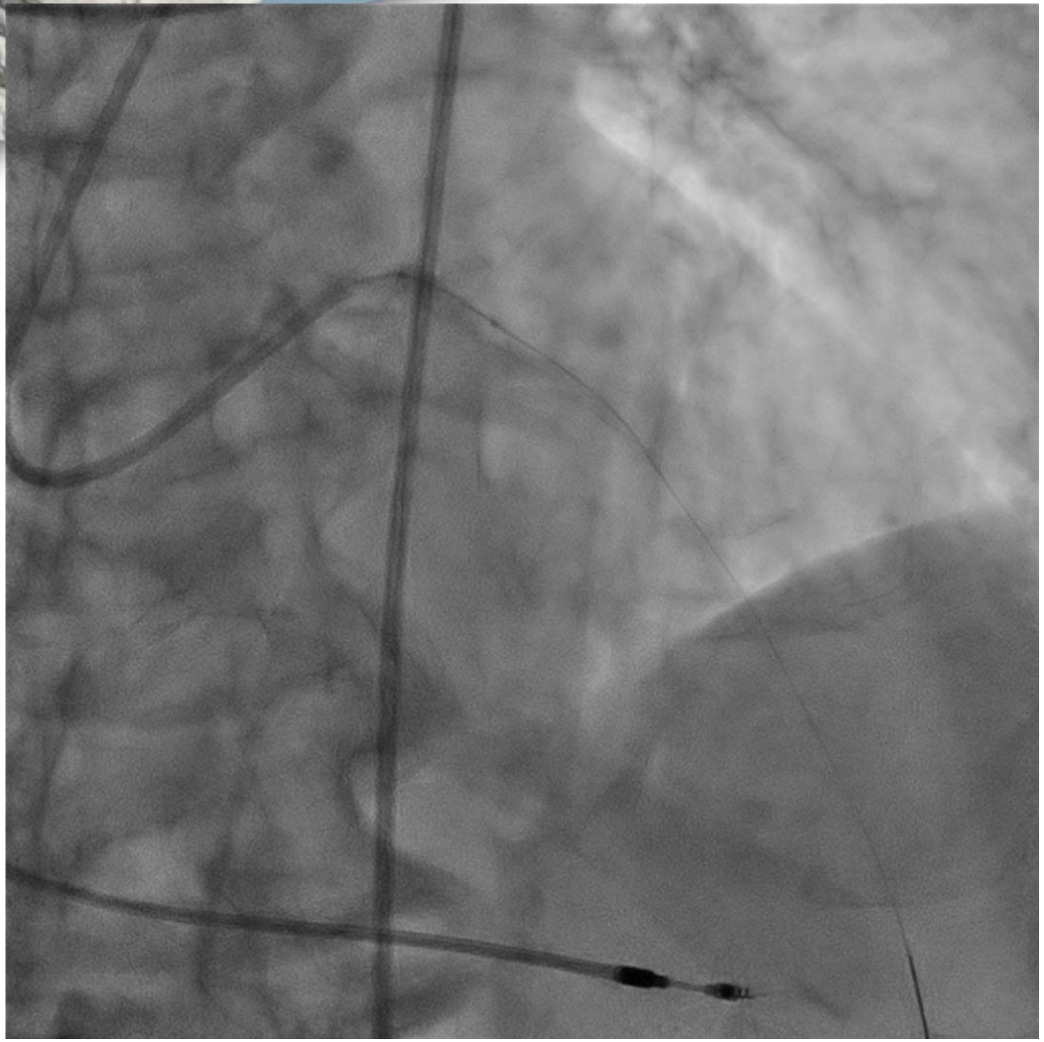


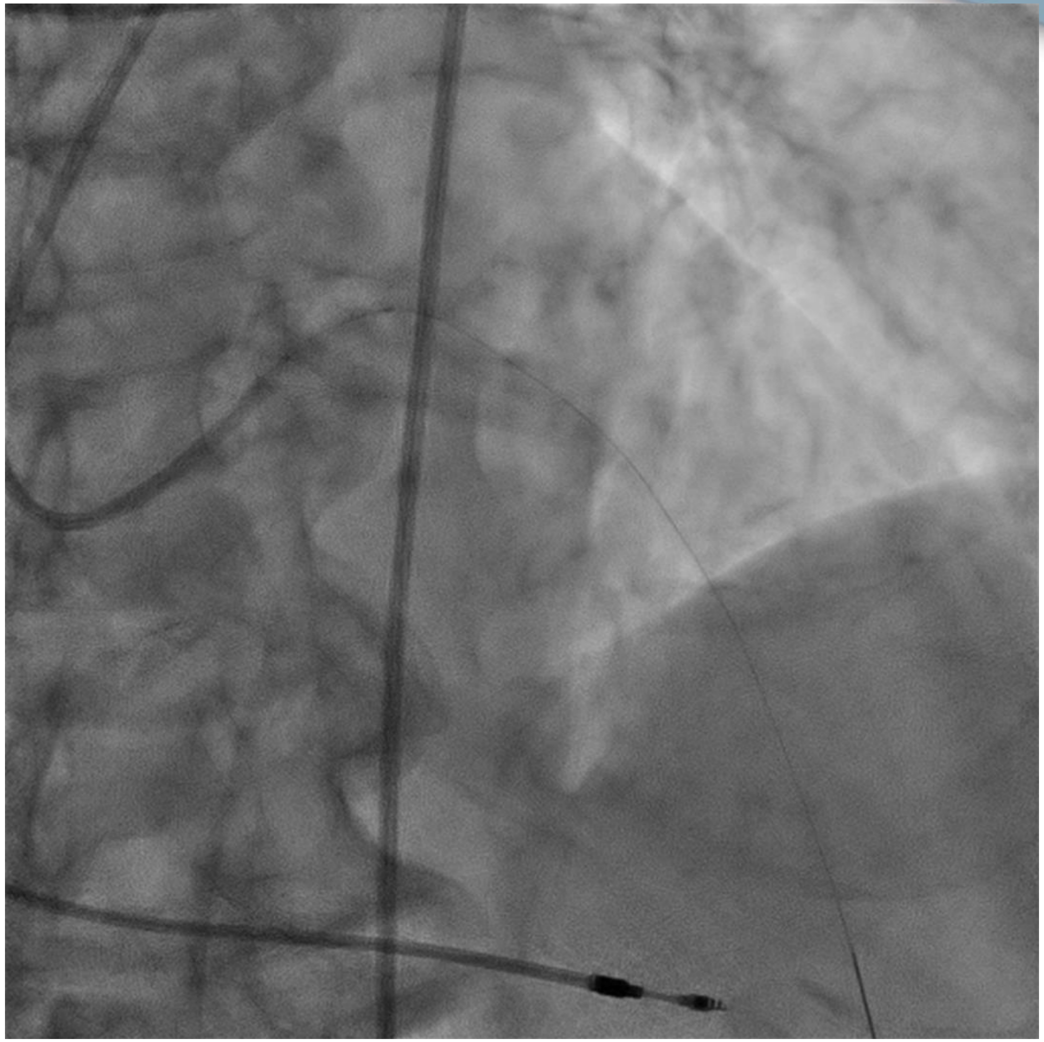
RA 1.5 burr

Case_2



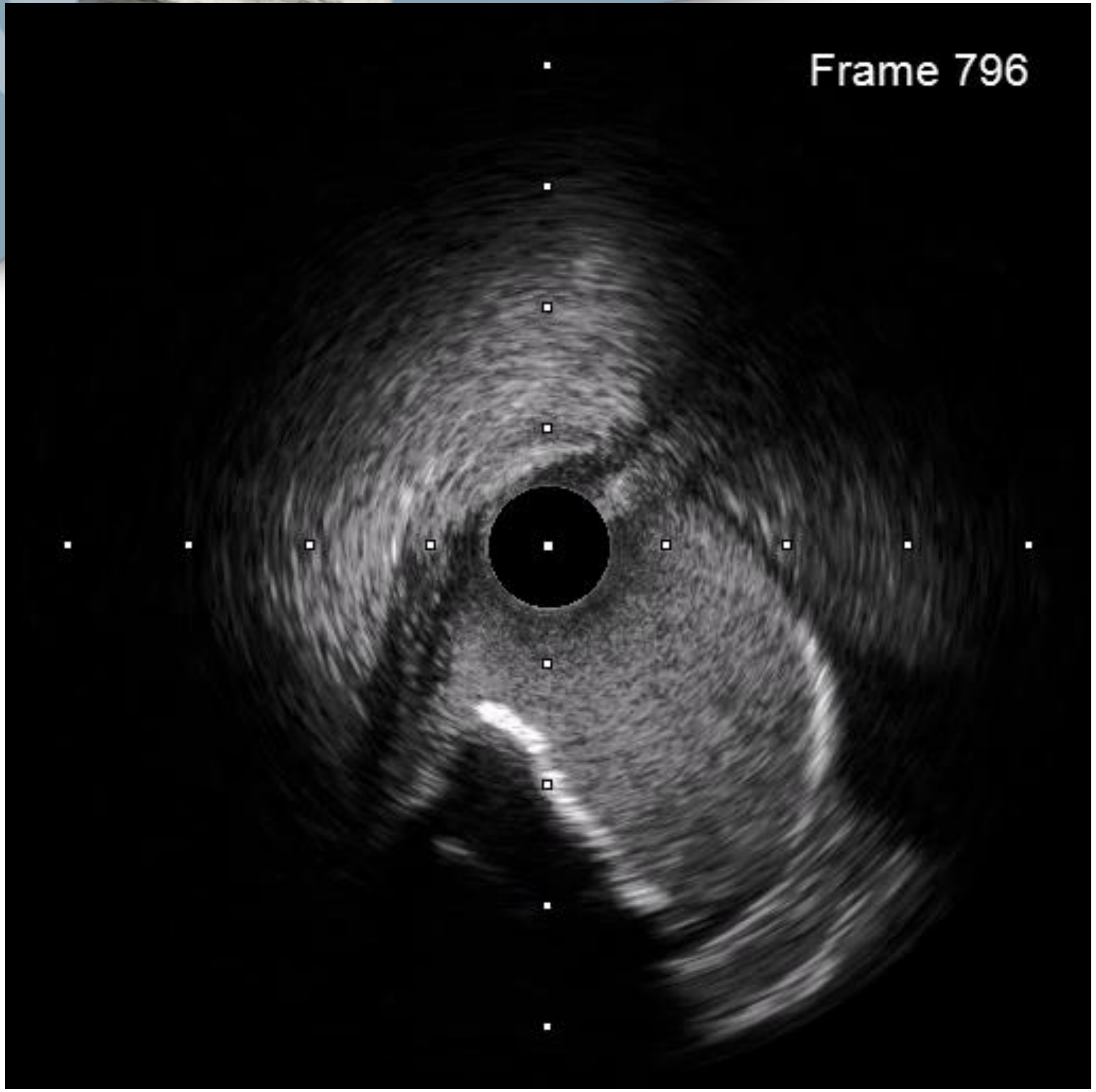
Case_2

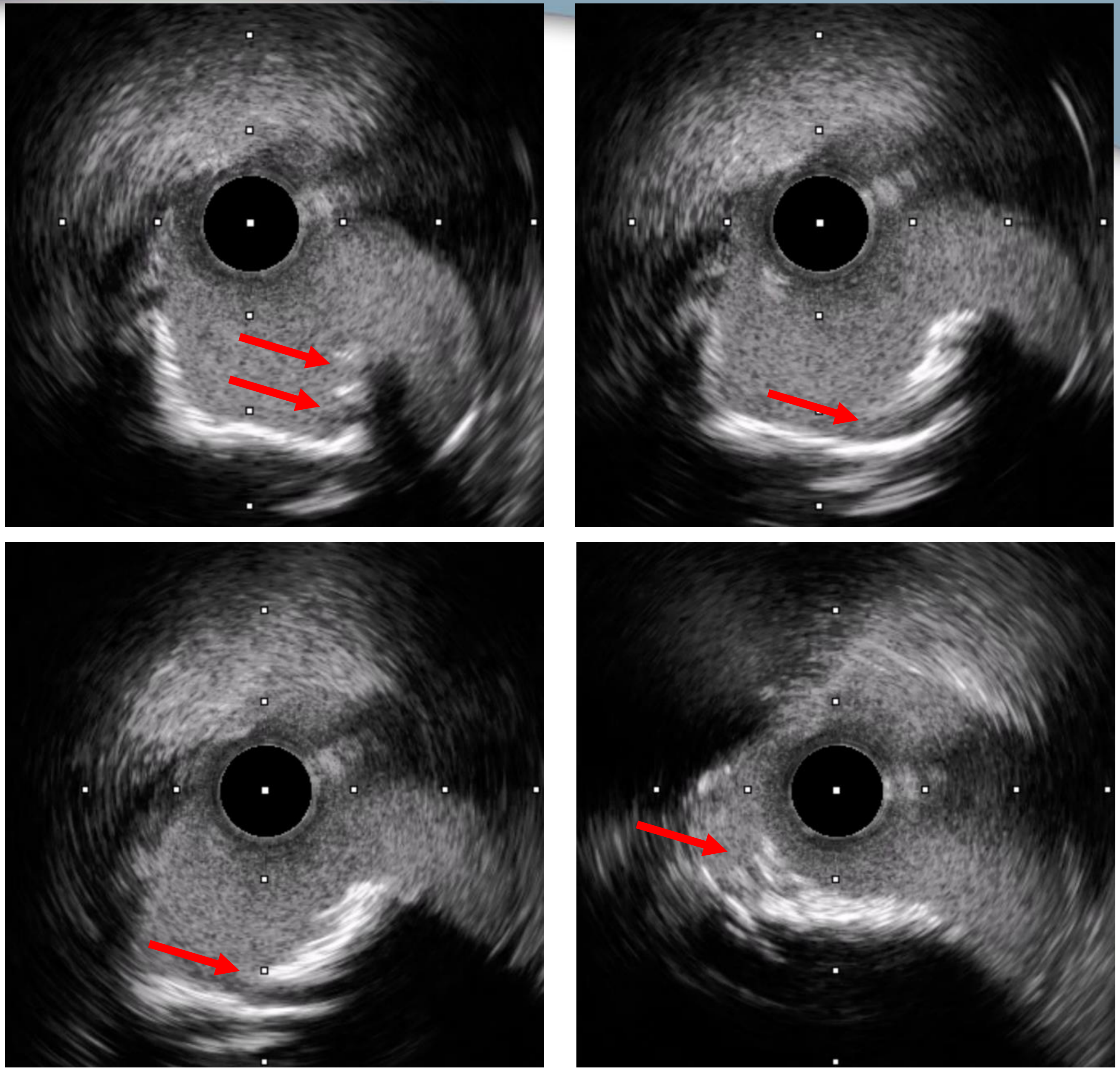




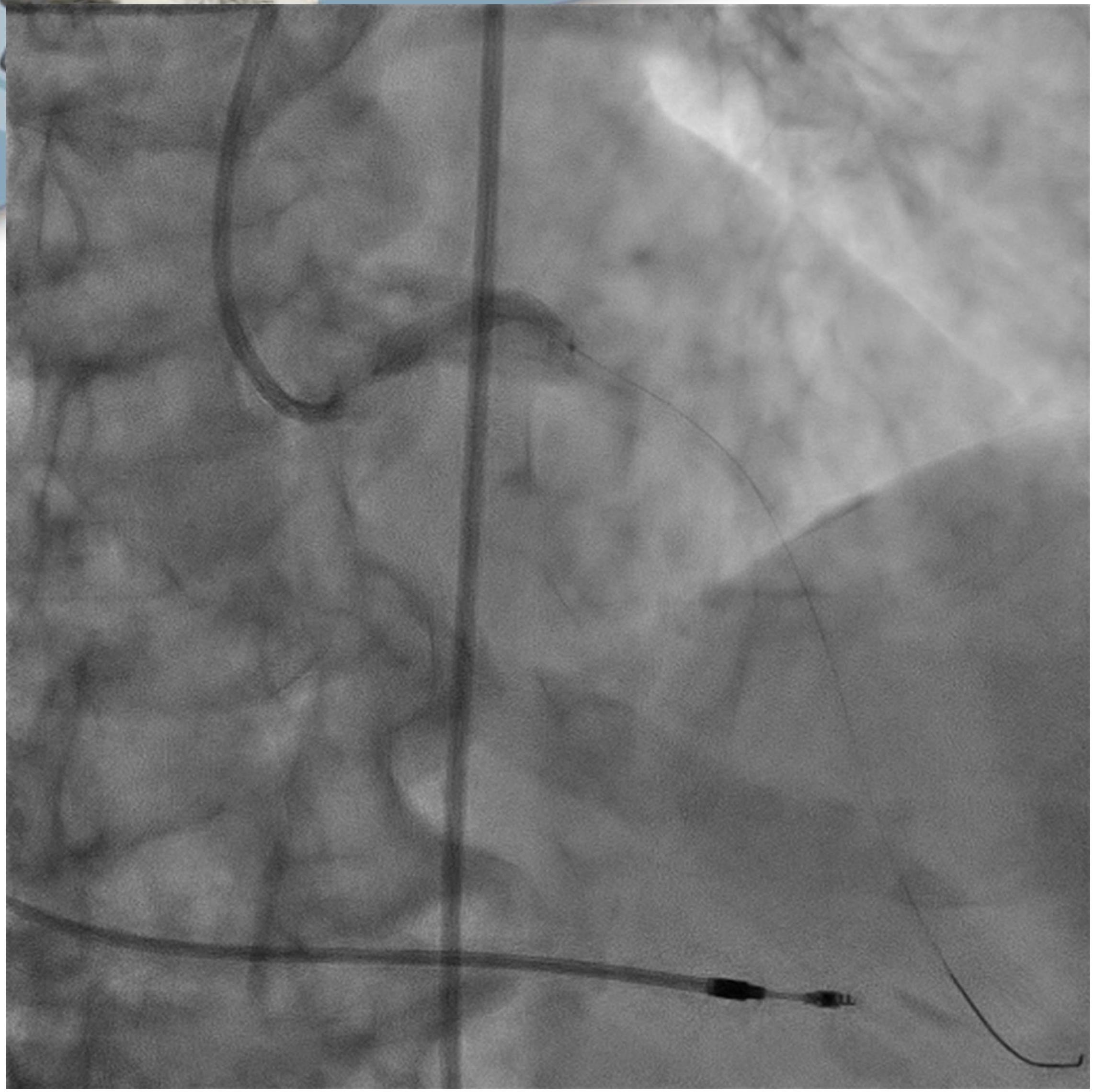
IVL balloon 3.5x12 mm

Case_2

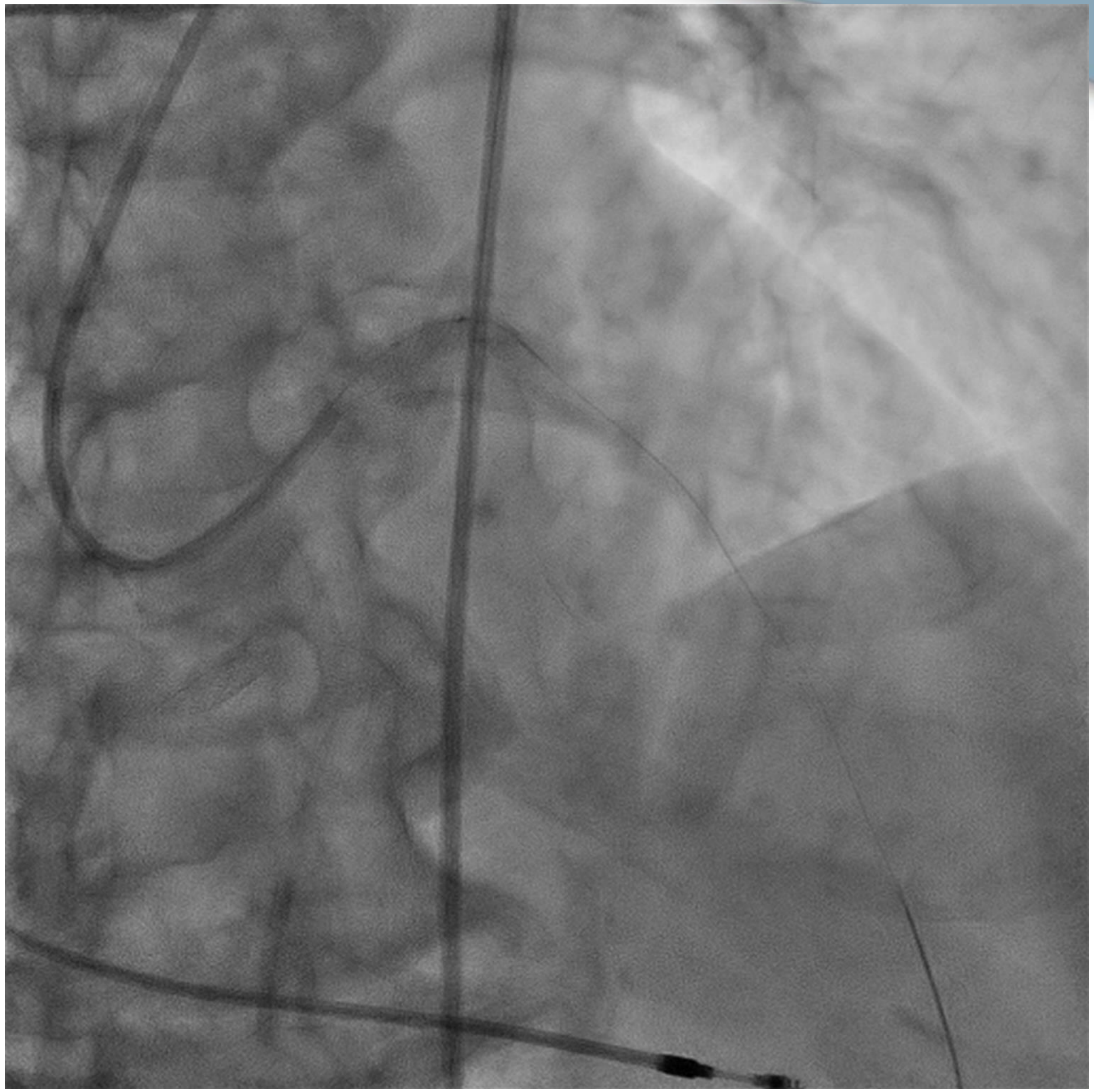




Case_2

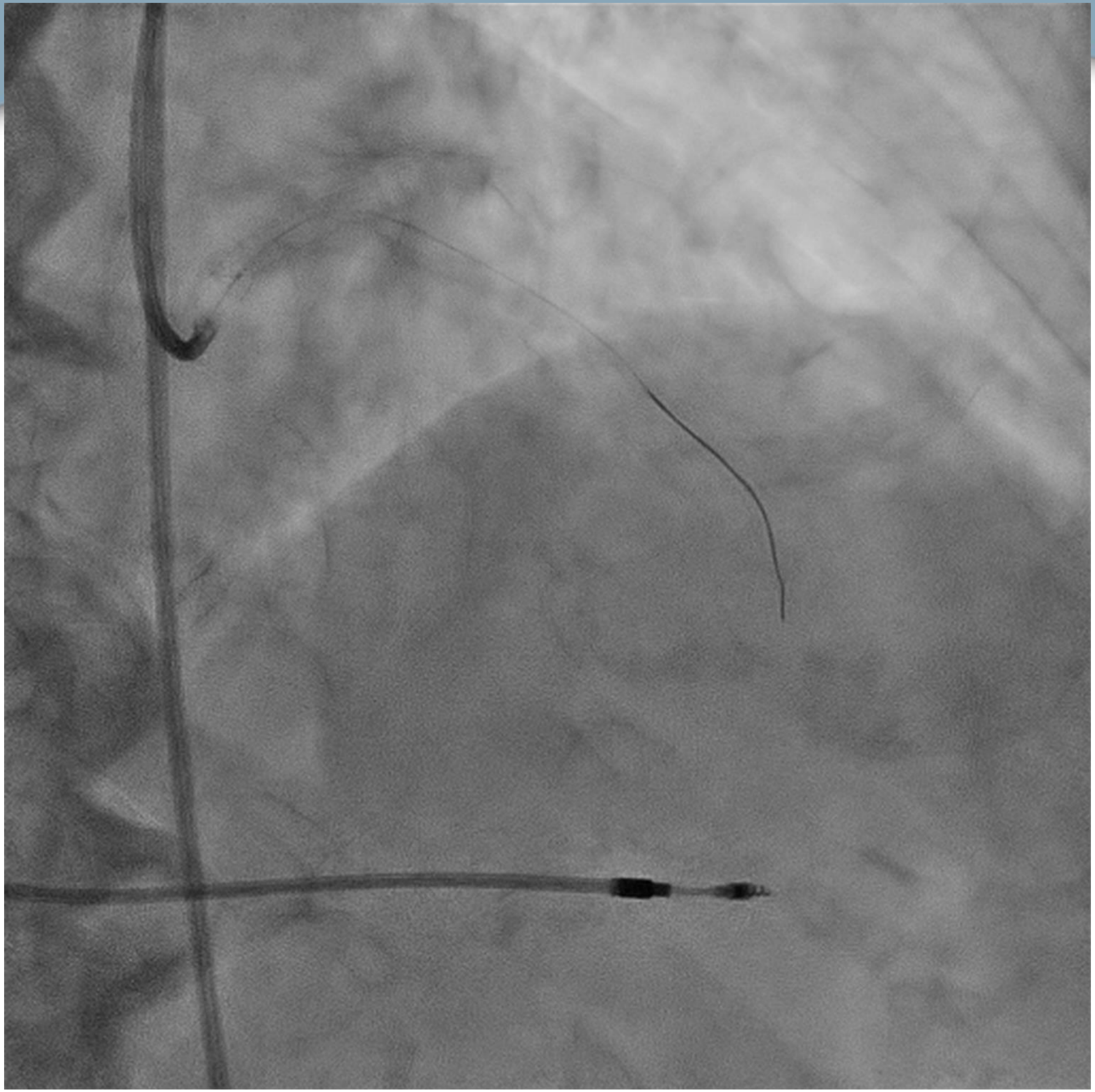


DES 3.5 x 24 mm

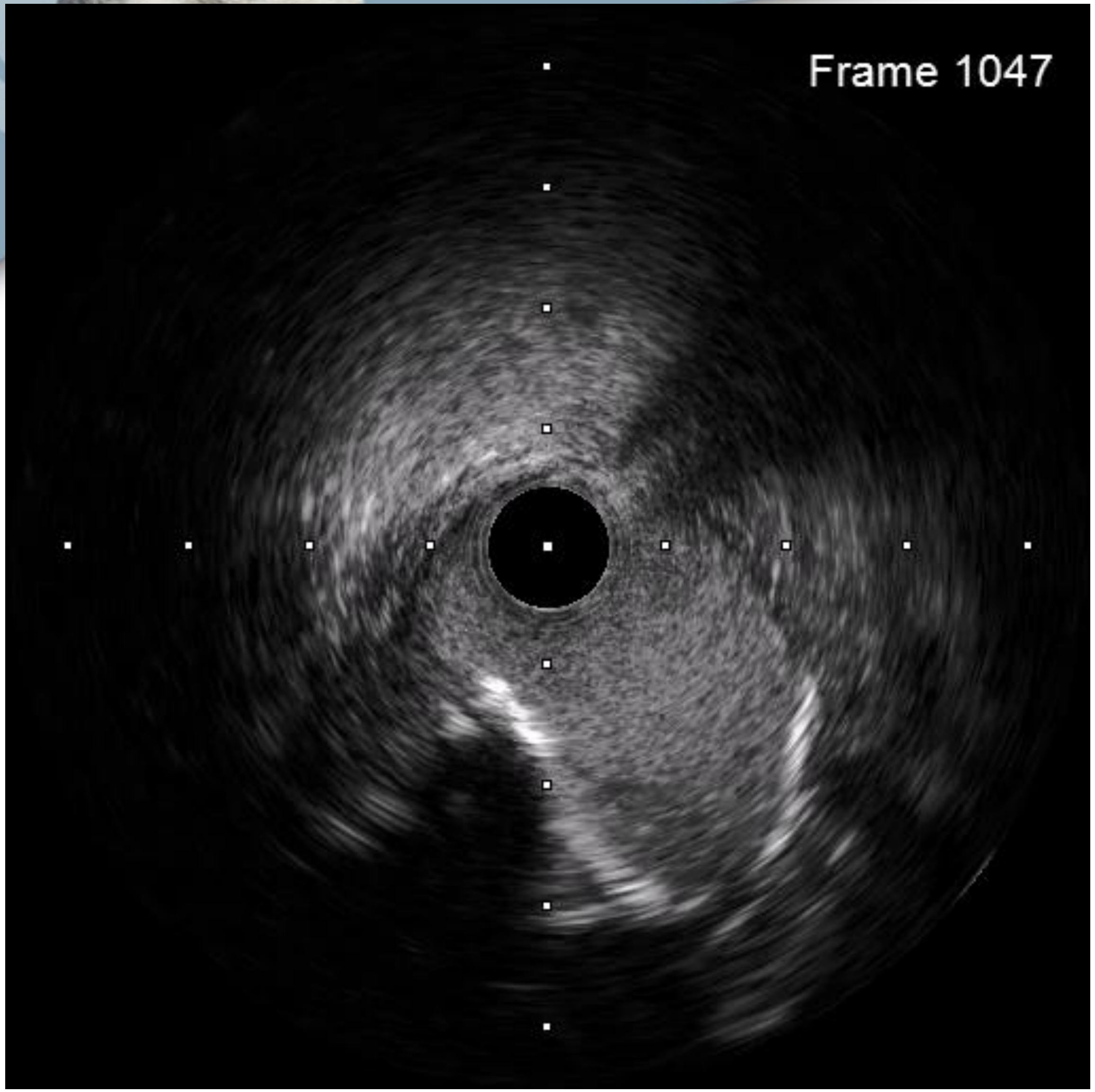


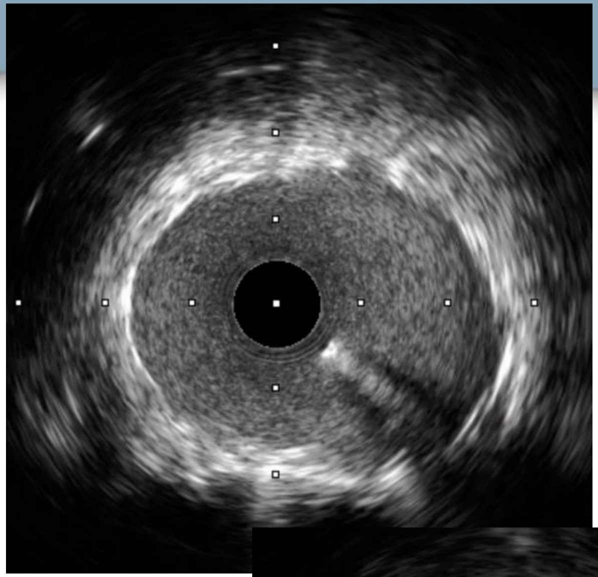
POT NC balloon 4.5x12 mm

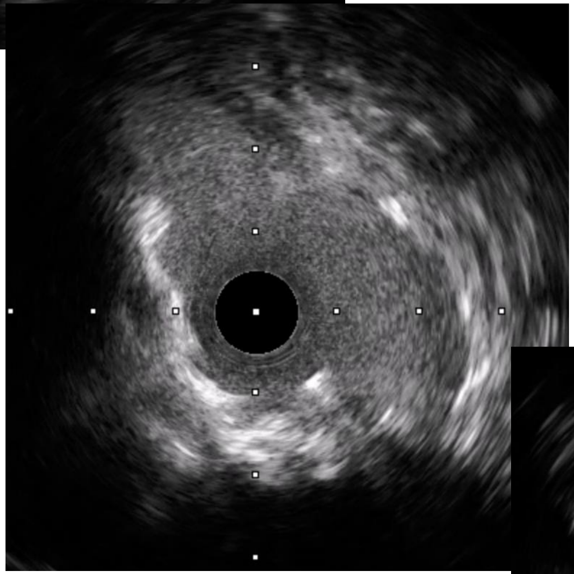
Case_2

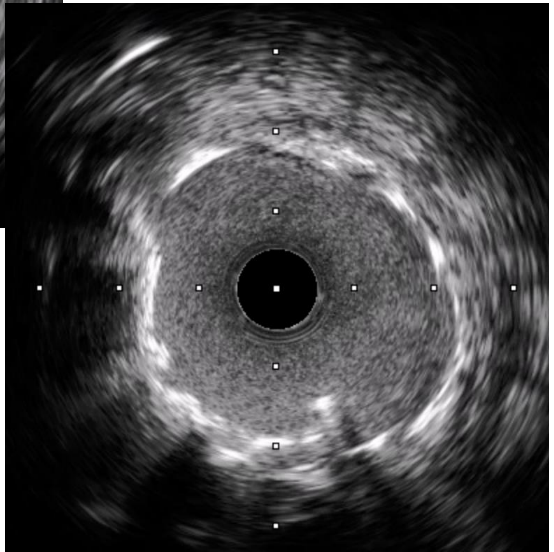


Case_2

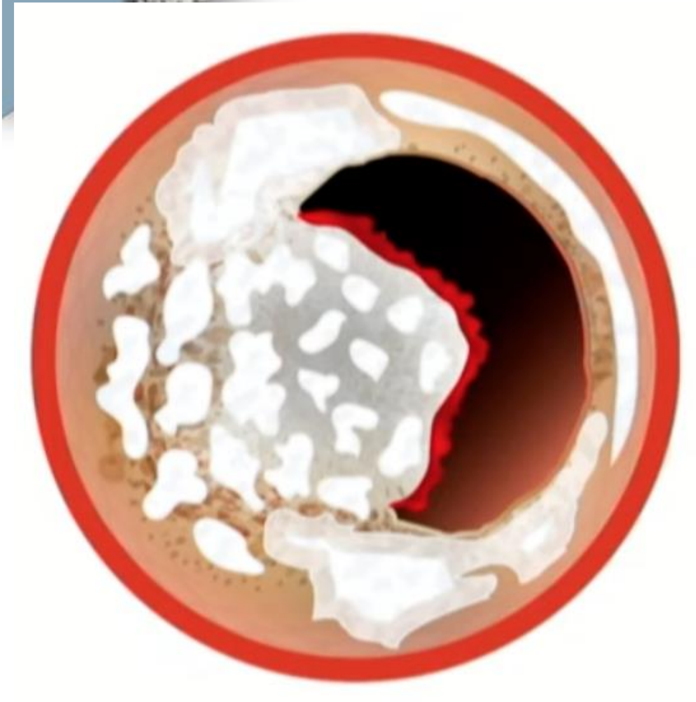


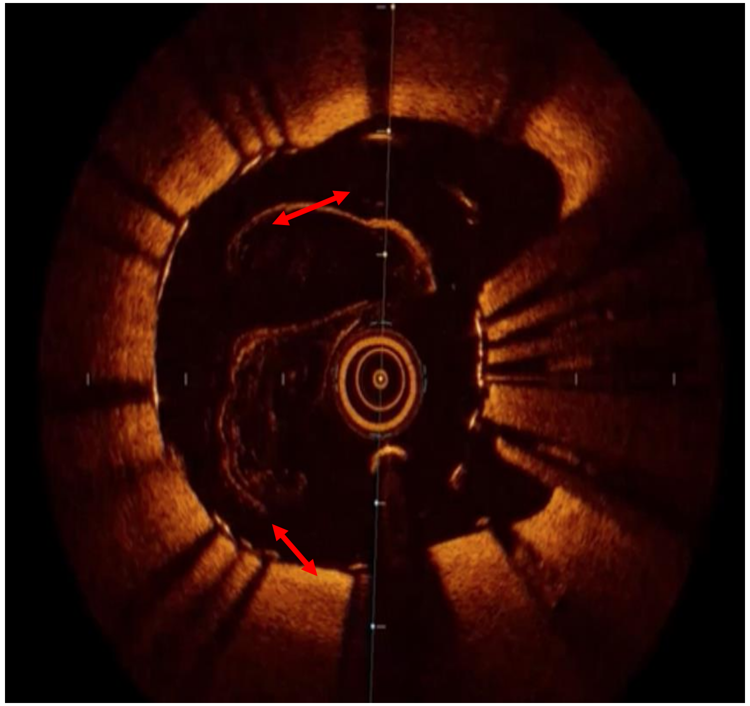






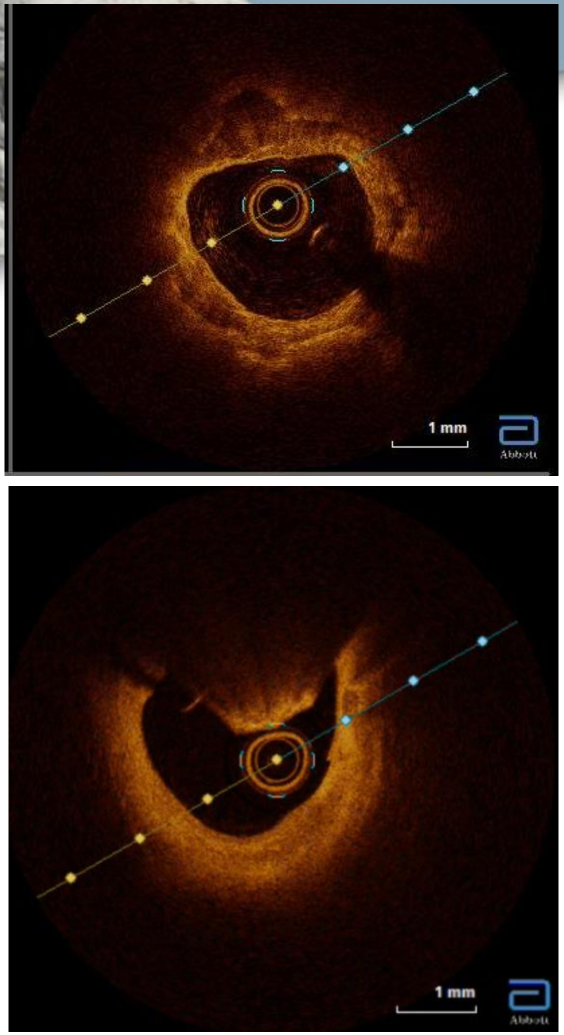
Nodular Calcium

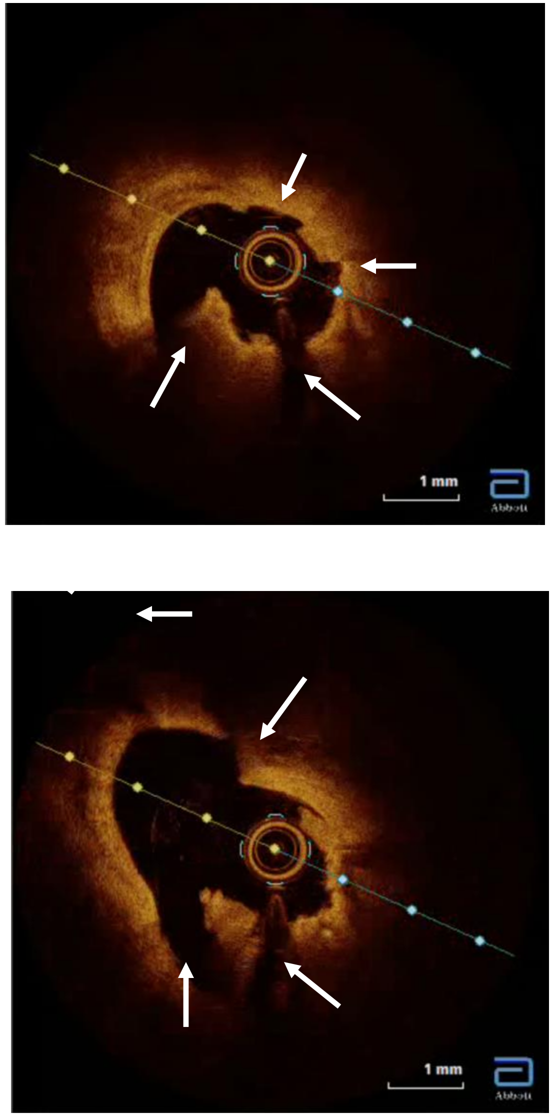


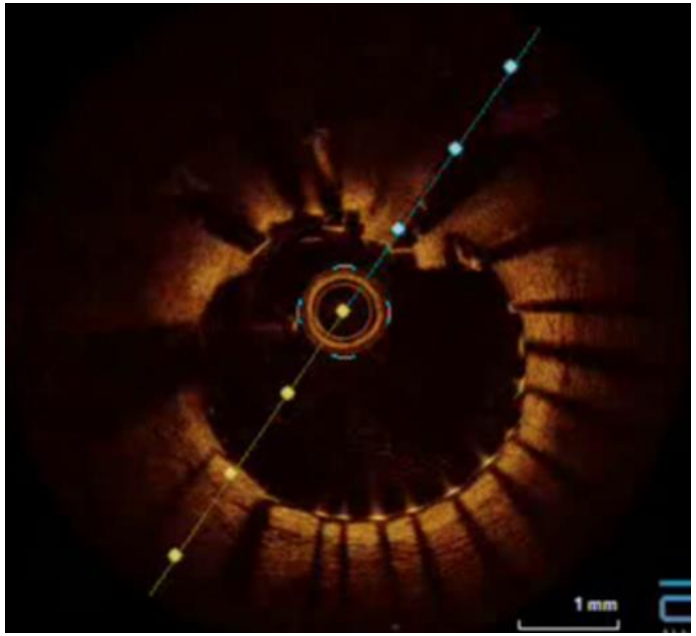


Underexpansion
Asymetric expansion
Stent malapposition

Nodular Calcium



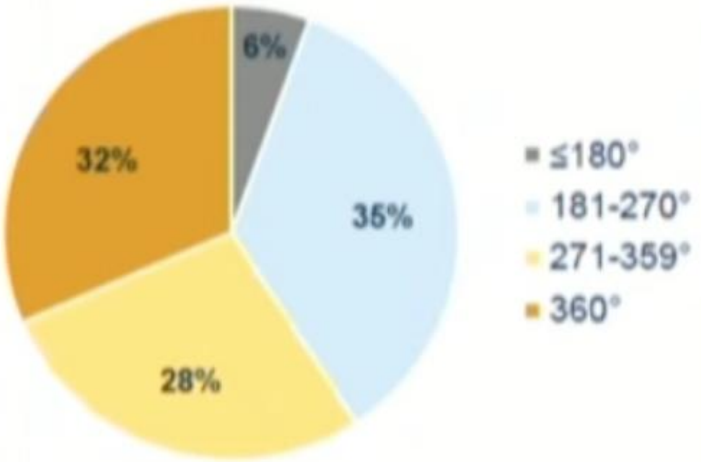




OCT-Disrupt CAD: Calcium nodules

	CN lesion N=54	Non-CN lesion N=194	*P* value
ACL			
Target vessel			
Left main	3.7%	0%	0.05
LAD	29.6%	77.8%	<0.0001
Circumflex	14.8%	5.7%	0.04
RCA	51.9%	16.5%	<0.0001
Lesion length, mm	24.8 ± 12.3	26.1 ± 11.1	0.44
Calcification length, mm	43.5 ± 22.9	42.6 ± 20.7	0.78
Diameter stenosis, %	66.5 ± 14.4	61.3 ± 10.4	0.02
OCT			
MLA, mm^2	2.3 ± 1.3	2.0 ± 0.8	0.19
Area stenosis @MLA, %	71.0 ± 13.4	72.1 ± 11.0	0.92
Max Ca angle @MCS	287.9 ± 70.9	264.8 ± 83.4	0.10
Ca thickness @MCS	1.00 ± 0.24	0.95 ± 0.25	0.10

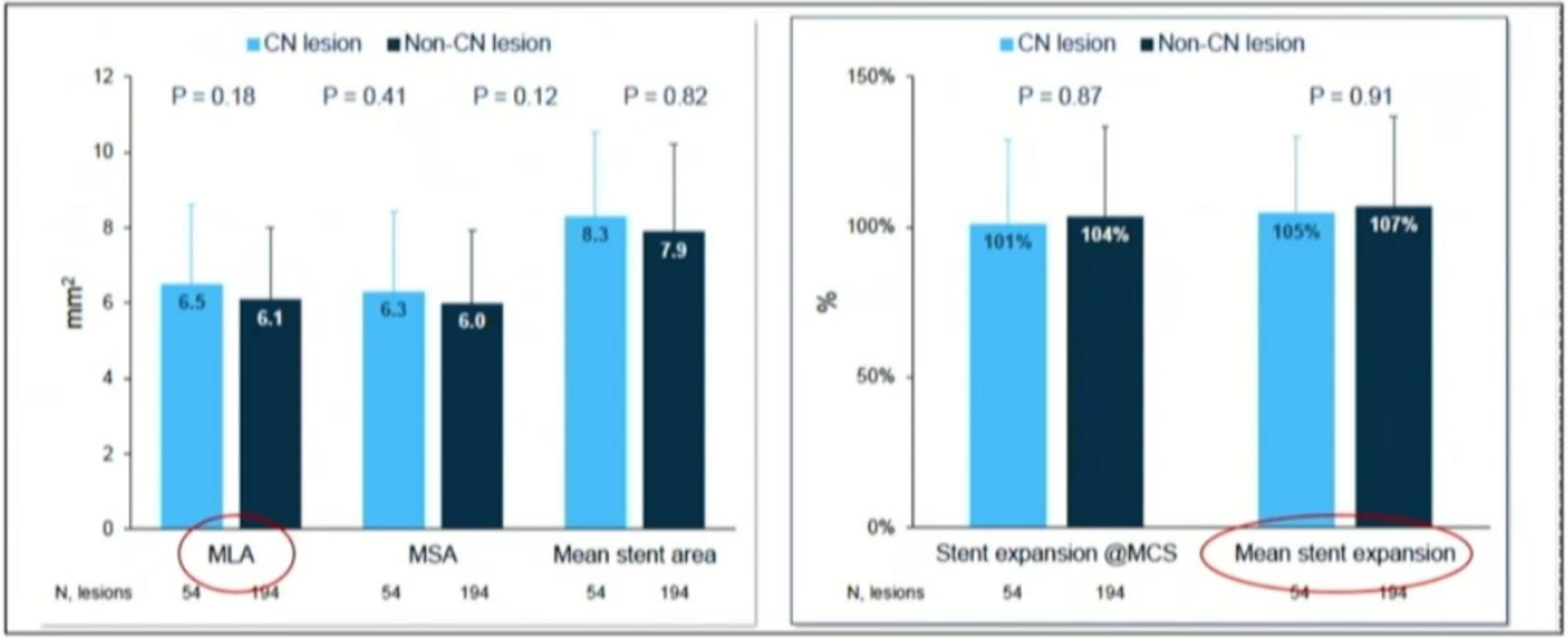
Association of CN with Maximum Calcium Angle



CN identified in **22%** of lesions and are associated with **concentric** calcium

94% CN had >180° arc of calcium

OCT-Disrupt CAD: Calcium nodules



OCT-Disrupt CAD: Calcium nodules

Core Lab Analysis	CN lesion N=54	Non-CN lesion N=194	*P* value
Visible calcium fracture	79%	65%	0.07
Visible fractures/lesion	4.1 ± 3.6	2.9 ± 2.5	0.04
Acute lumen gain at MLA site, mm^2	2.6 ± 2.1	2.6 ± 1.8	0.83
Mean lumen area, mm^2	8.8 ± 2.4	8.1 ± 2.2	0.05
Mean stent area, mm^2	8.3 ± 2.2	7.9 ± 2.3	0.12
Mean stent expansion, mm^2	104.7 ± 25.3	106.9 ± 29.8	0.91
Any malapposition strut, %	5.8 ± 5.8	3.4 ± 4.2	0.0003

Greater number of visible calcium fractures in CN lesions

More malapposition strut in CN lesions

1-Year Post-Stent OCT Findings

Post-stent Outcomes Core lab adjudicated	+ CN N=26	- CN N=128	P-value
MLA, mm^2	6.5 ± 2.0	6.2 ± 1.9	0.51
Area stenosis, %	21 ± 15	17 ± 21	0.34
MSA, mm^2	6.2 ± 2.0	6.1 ± 1.9	0.80
Stent expansion @max calcium site, %	98 ± 27	103 ± 30	0.54
Mean stent expansion, %	101 ± 18	107 ± 31	0.59
Visible calcium fracture	81%	63%	0.11
Any malapposition strut, %	4.6 ± 3.3	3.3 ± 4.2	0.006

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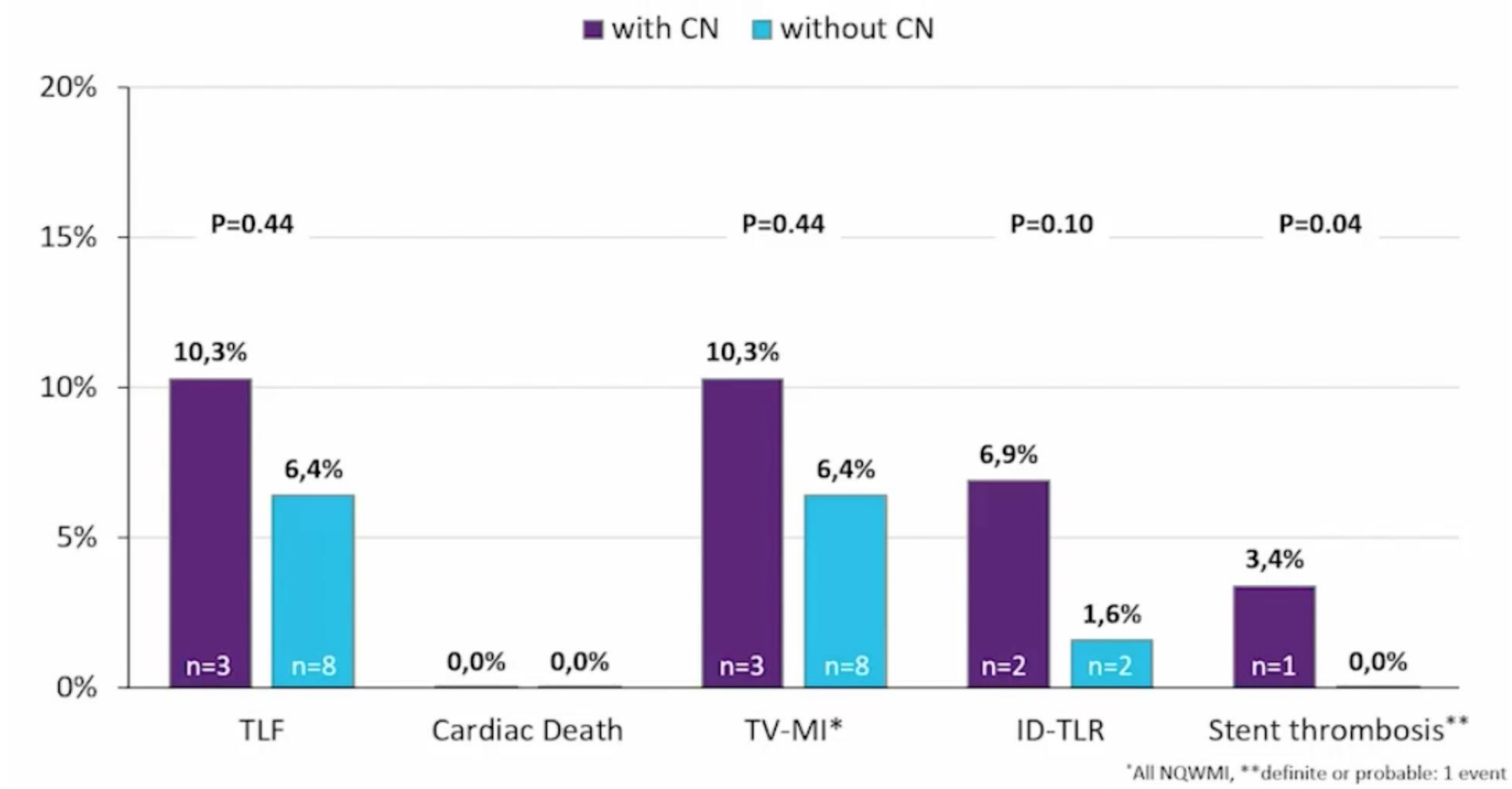
TLF & Stent Thrombosis at 1-Year CN vs Non-CN



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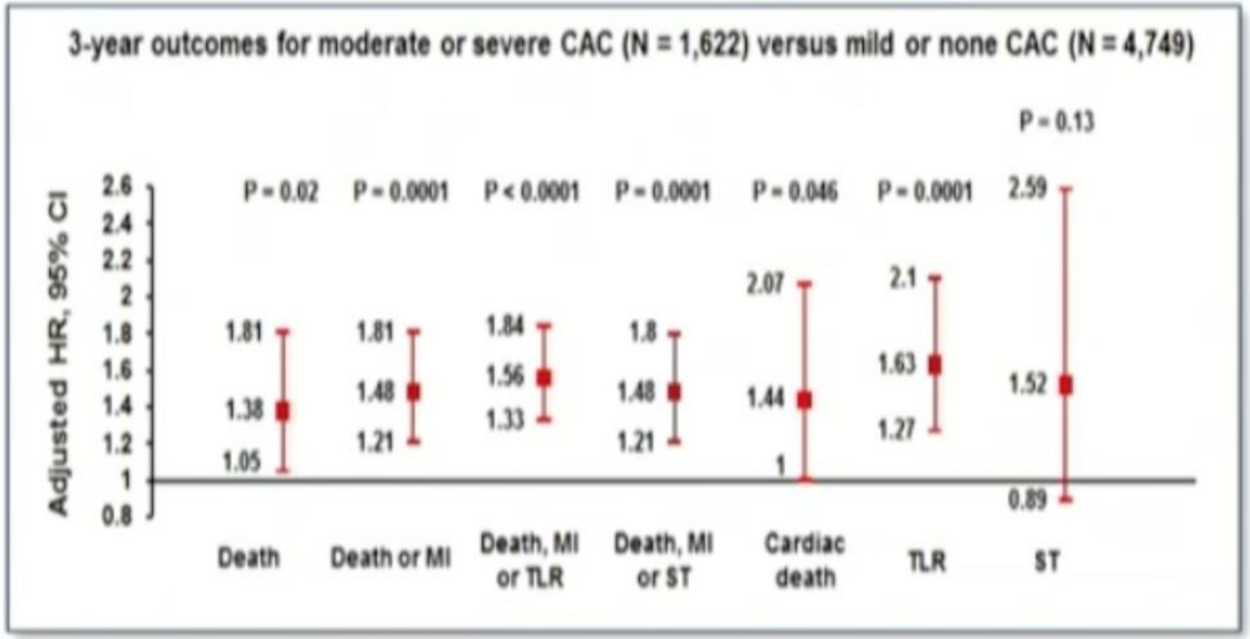
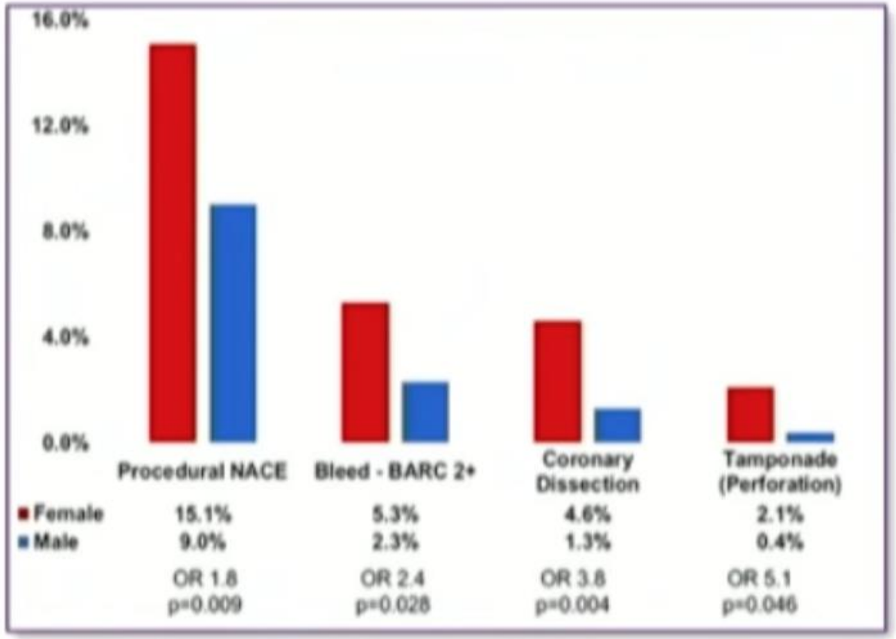
Gender differences in complex PCI

Pooled analysis of 6,371 women in DES studies (25.5% with moderate or severe CAC)



[1]Giustino et al., *JACC Cardiovasc Int* 2016

765 patients after rotational atherectomy

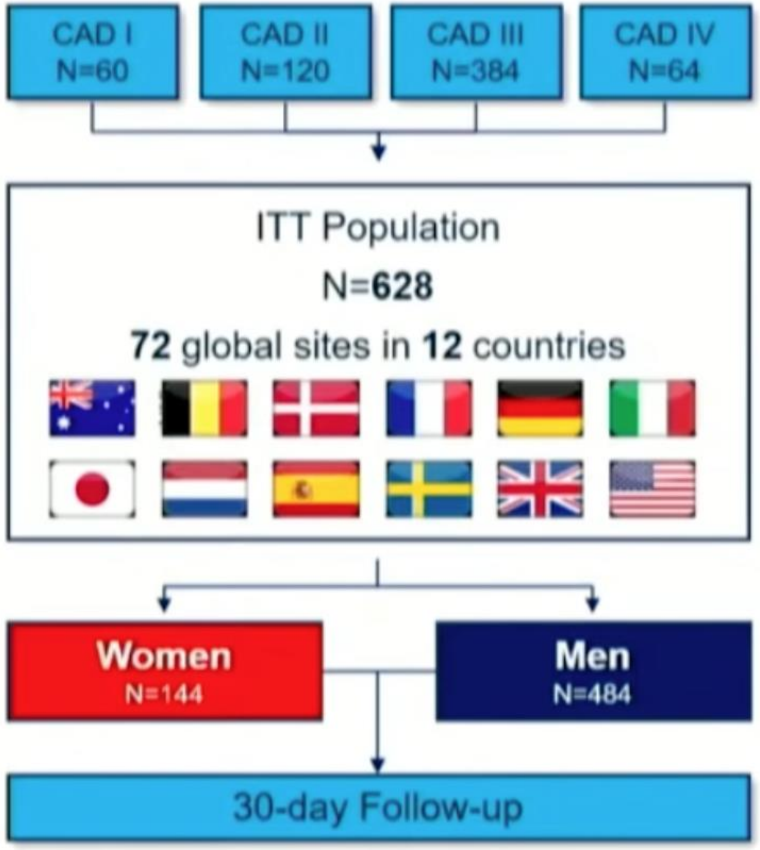


[2]Ford et al., *Catheter Cardiovasc Interv* 2020

- Women with coronary artery calcification (CAC) undergoing PCI are at increased risk for adverse clinical outcomes[1]
- Women have high procedural complications following atheroablative treatment of calcified lesions[2]

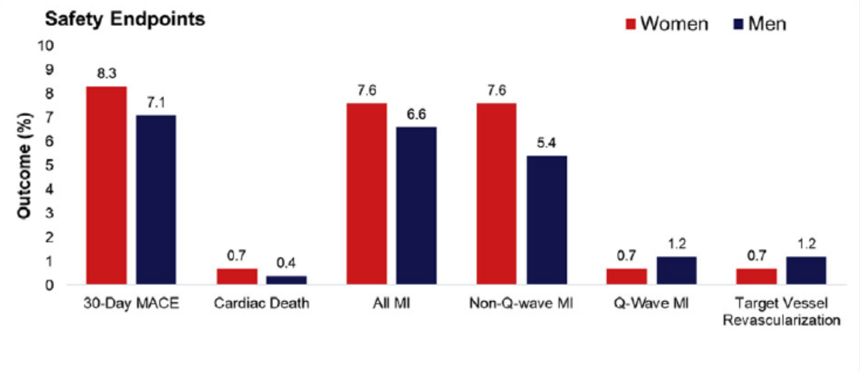
Di Mario. EuroPCR 2022

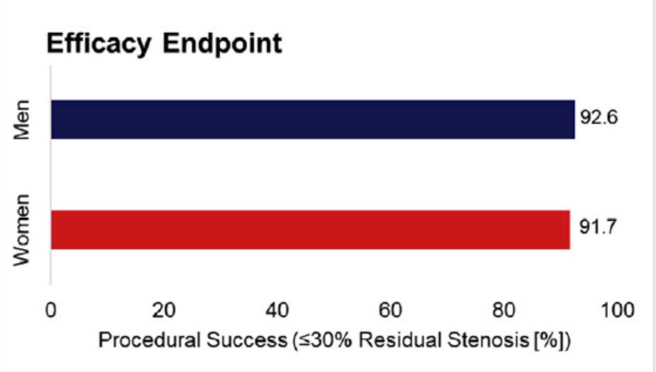
IVL treatment Men vs Women

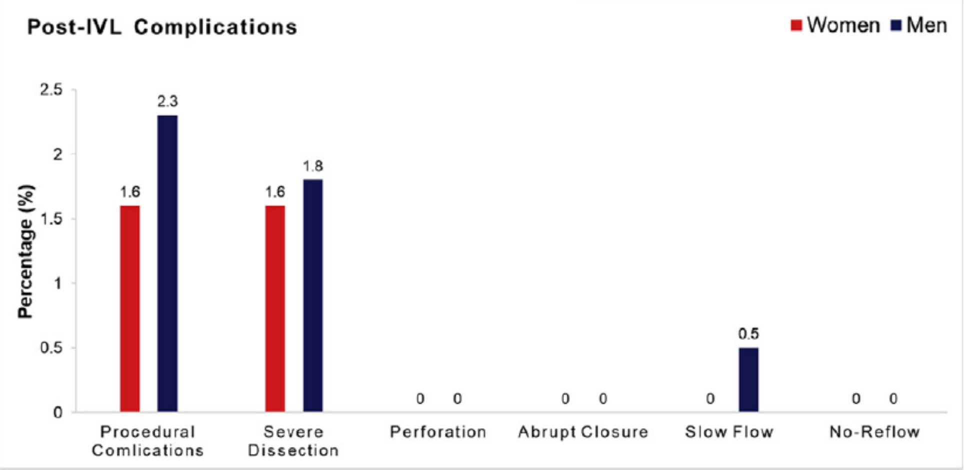


Baseline Characteristics

Older Age
More Hyperlipidemia
More Renal Insufficiency
Shorter Lesion Length
Smaller RVD

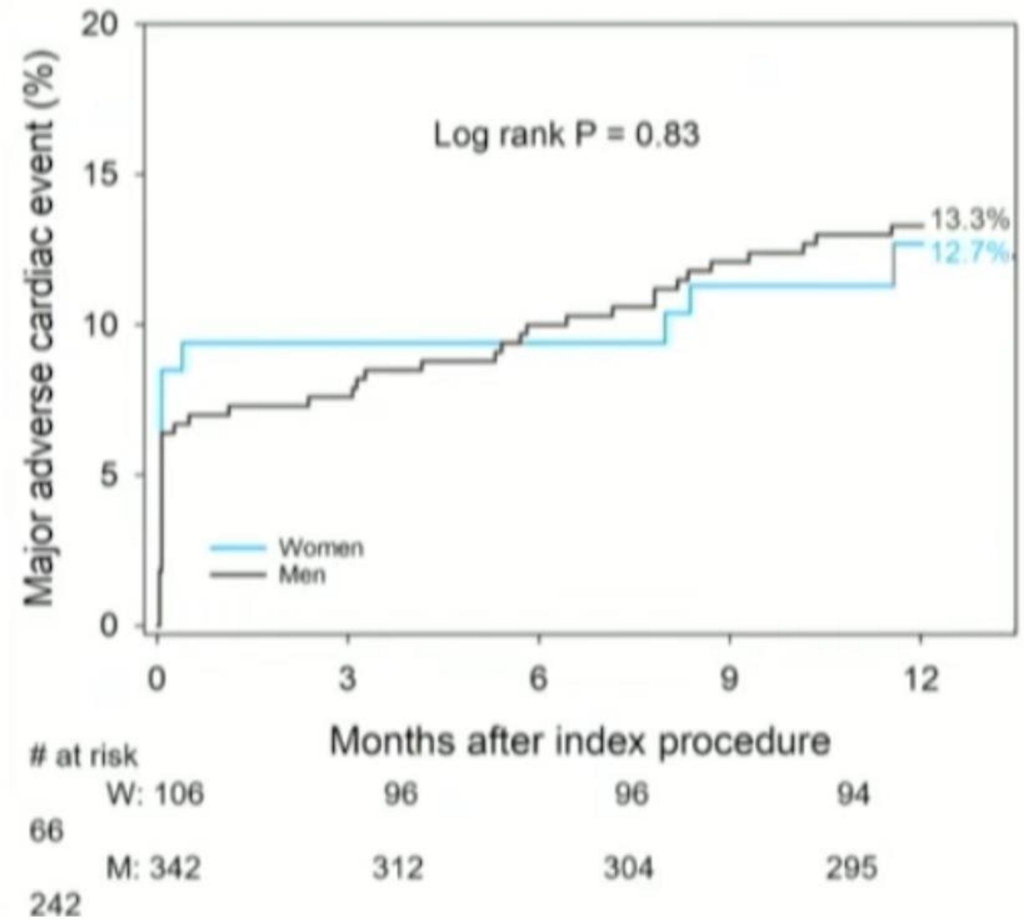


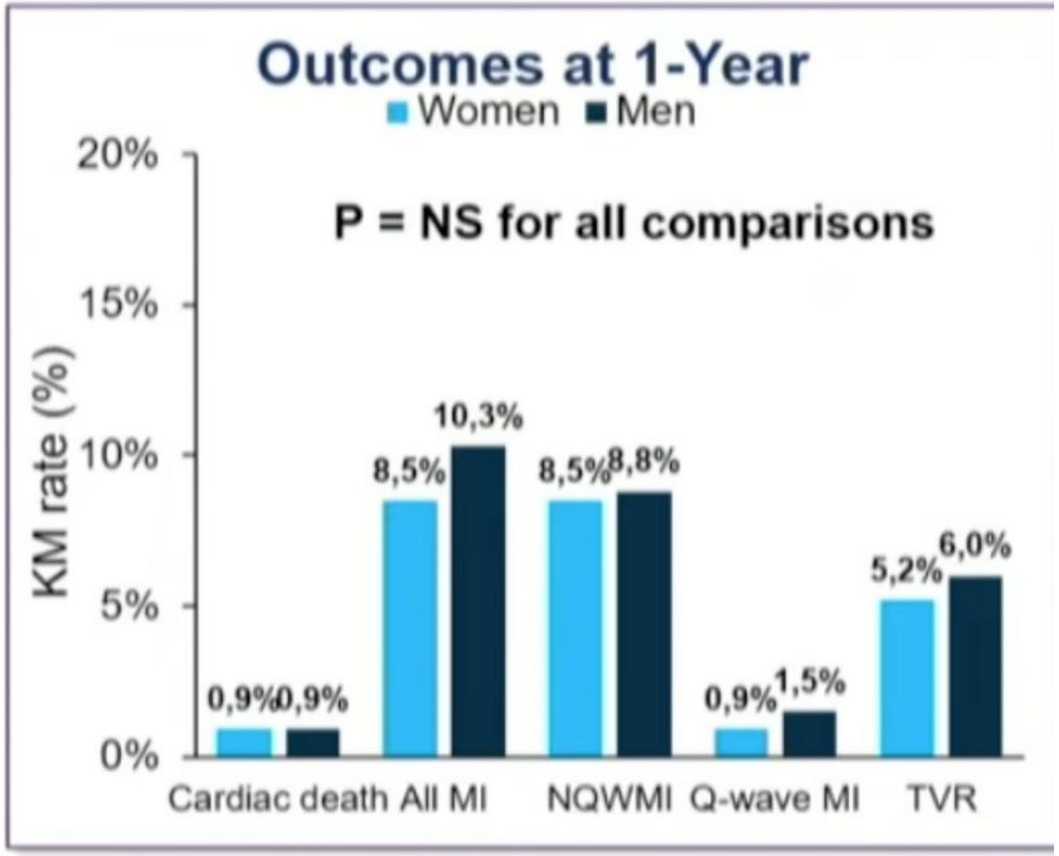




Journal of the Society for Cardiovascular Angiography & Interventions 1 (2022) 100011

1y MACE Men vs Women





Case_3

84 yo man

Risk Factors:

Diabetes, Dyslipidemia, Hypertension

Prior Clinical History:

2010. Previous PCI – stent in RCA

2015. PM implantation for High-grade AV-Block

May- 2022:

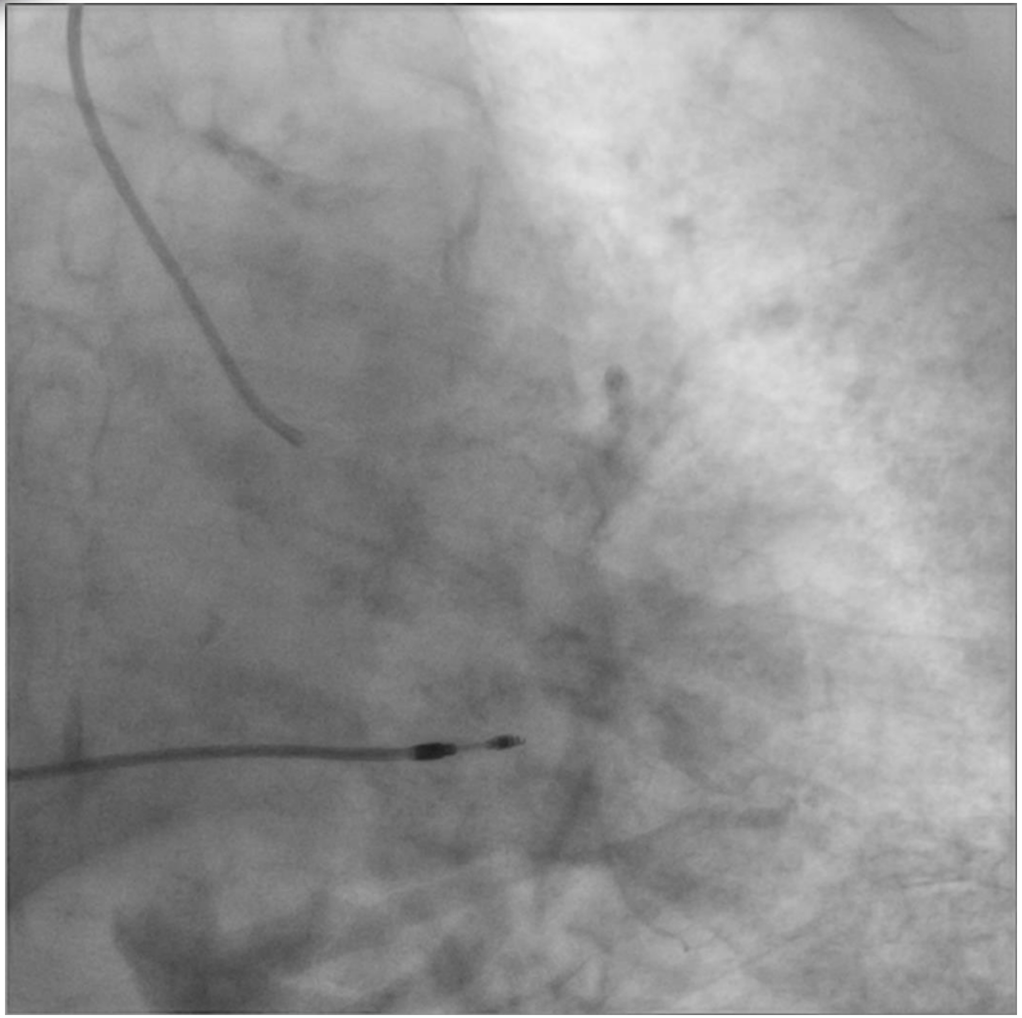
Acute chest pain

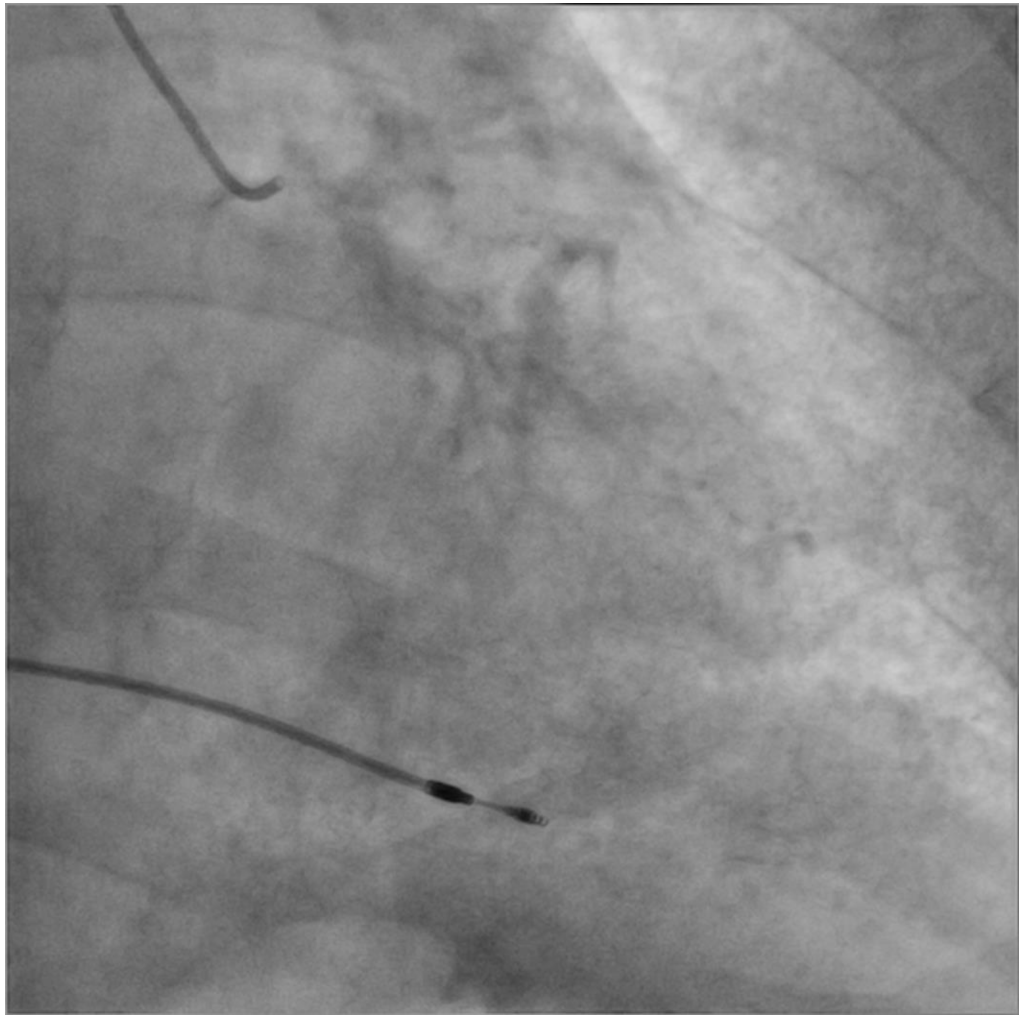
EKG: PM rhythm + ST depression lateral leads

Primary PCI

Case_3

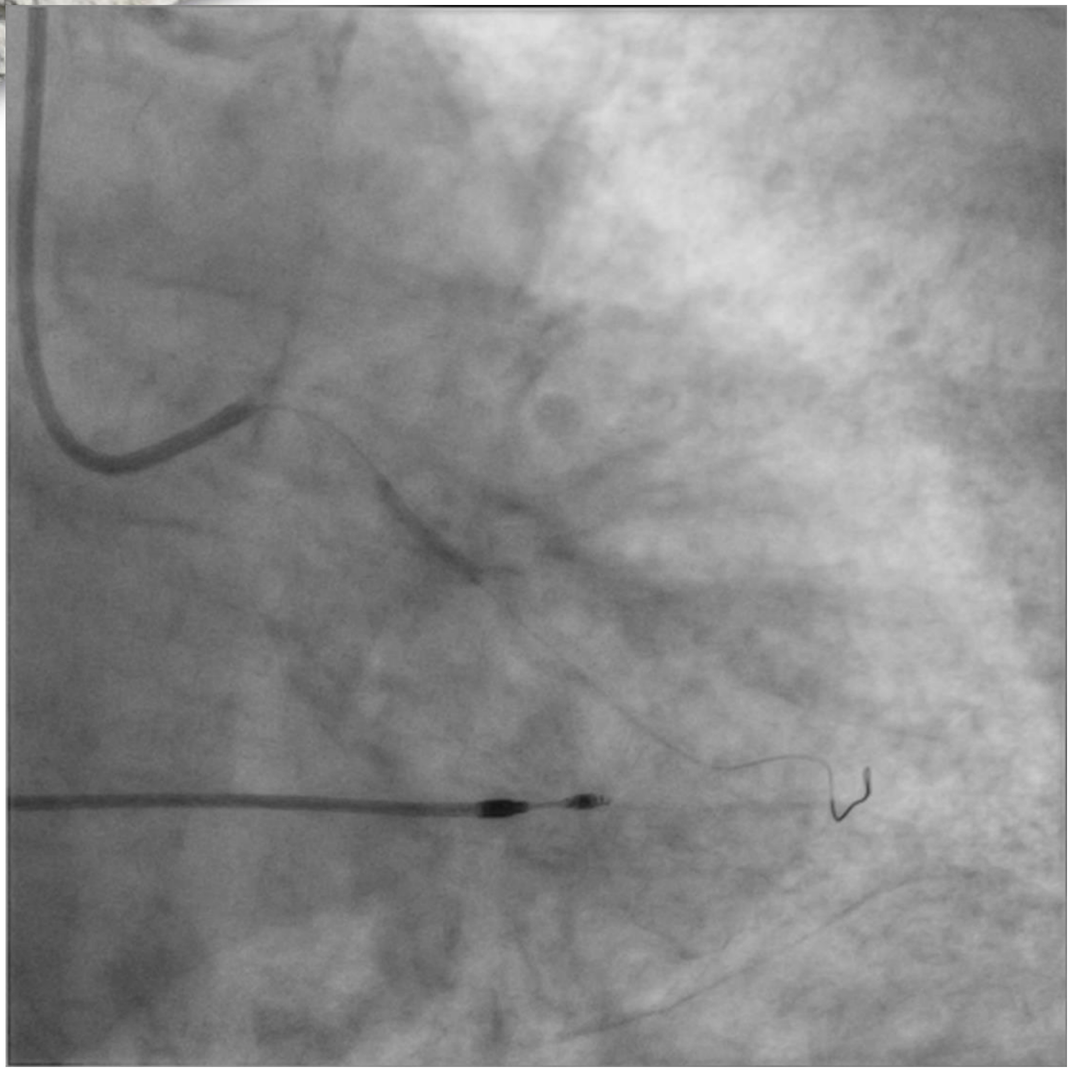
Baseline Left coronary angiography

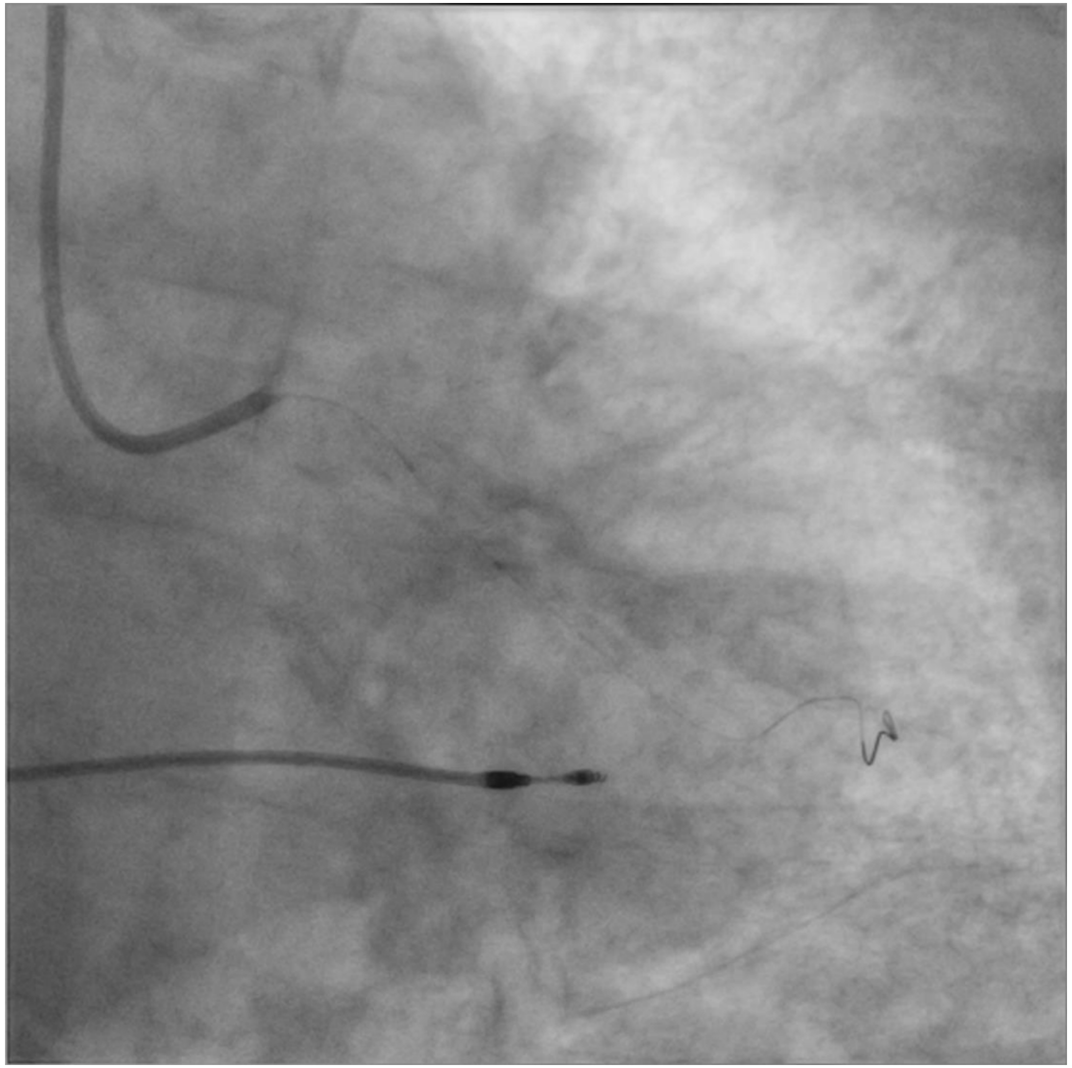




Case_3

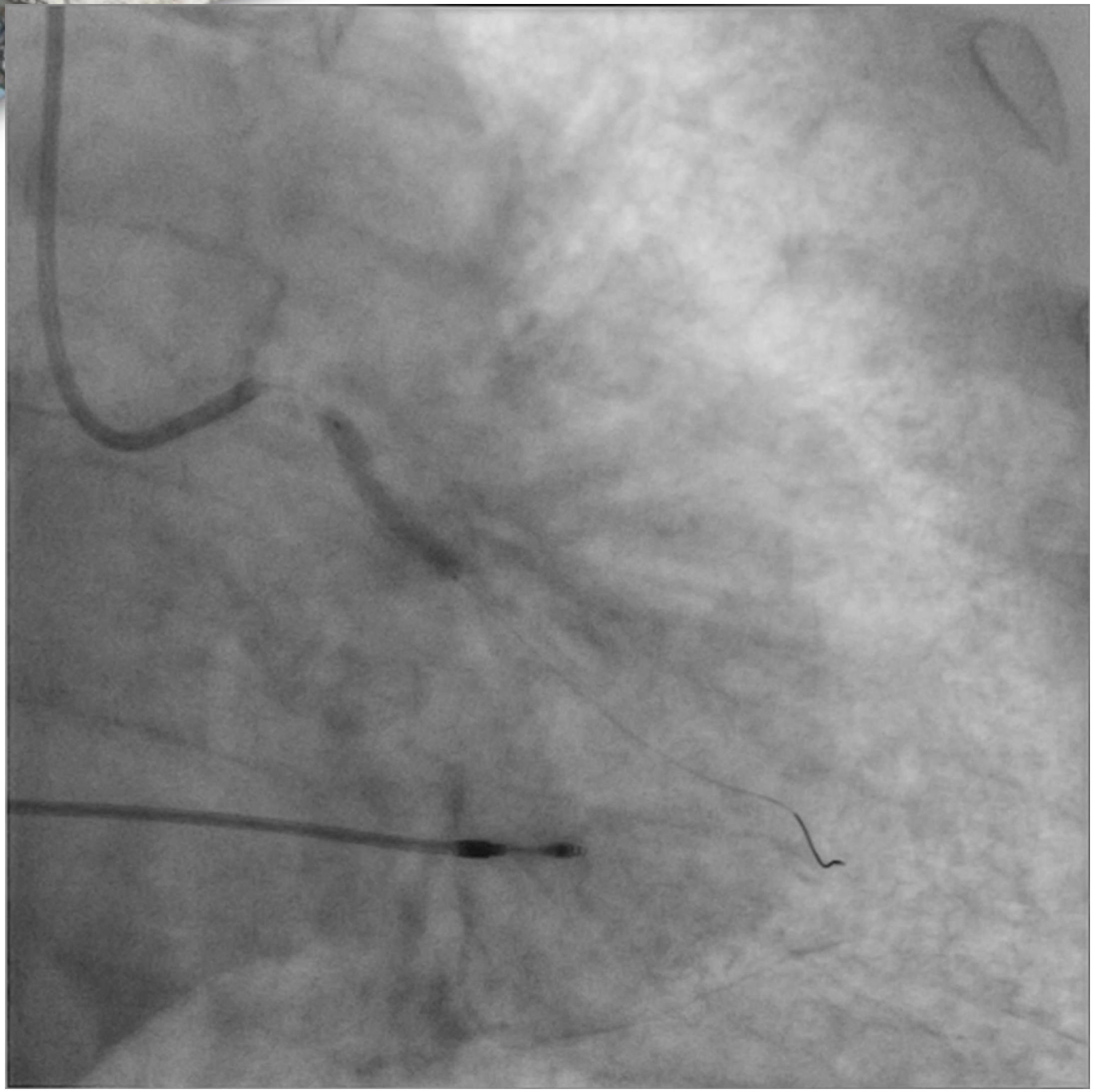
Compliant balloon 2x15 mm

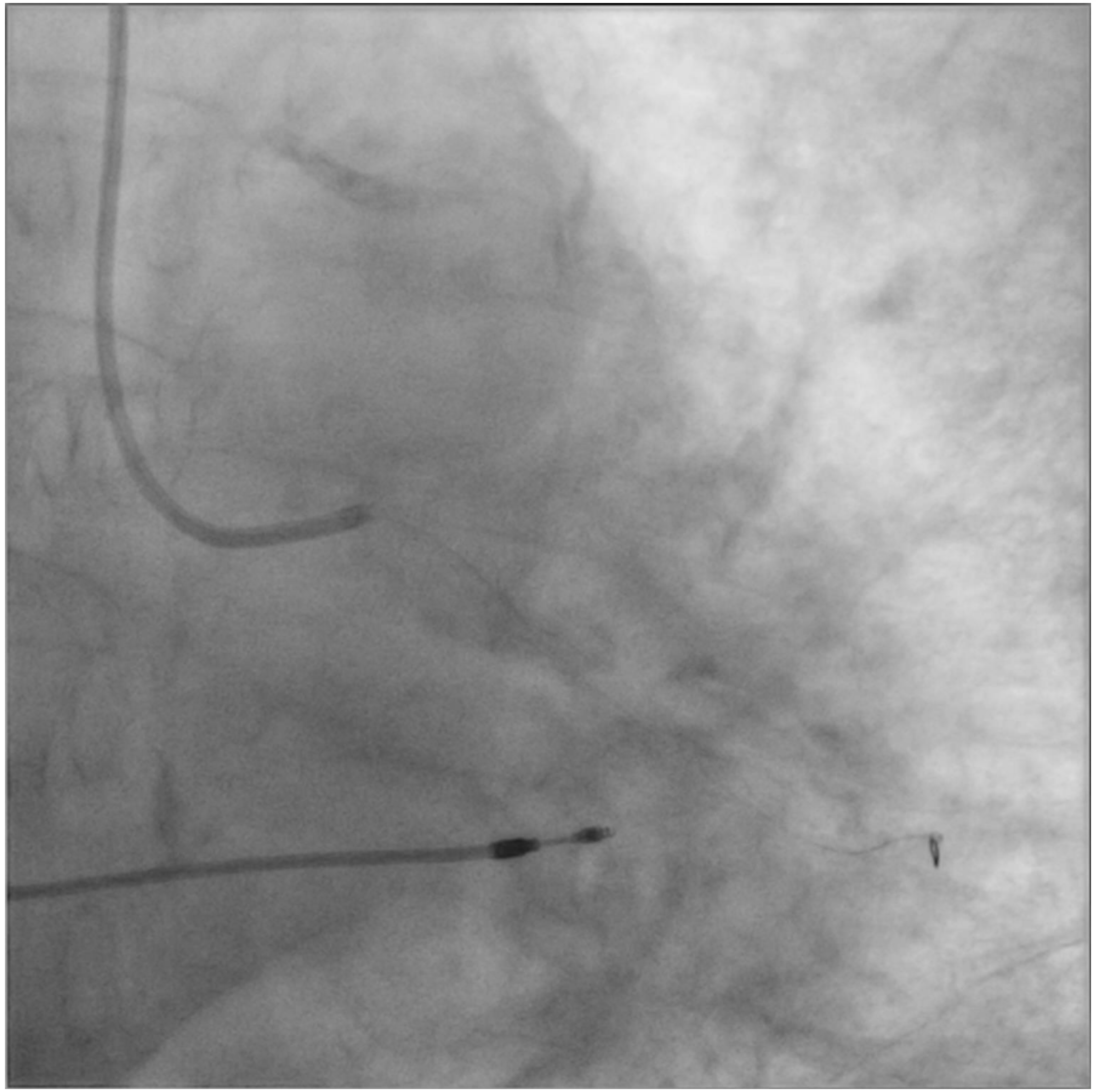




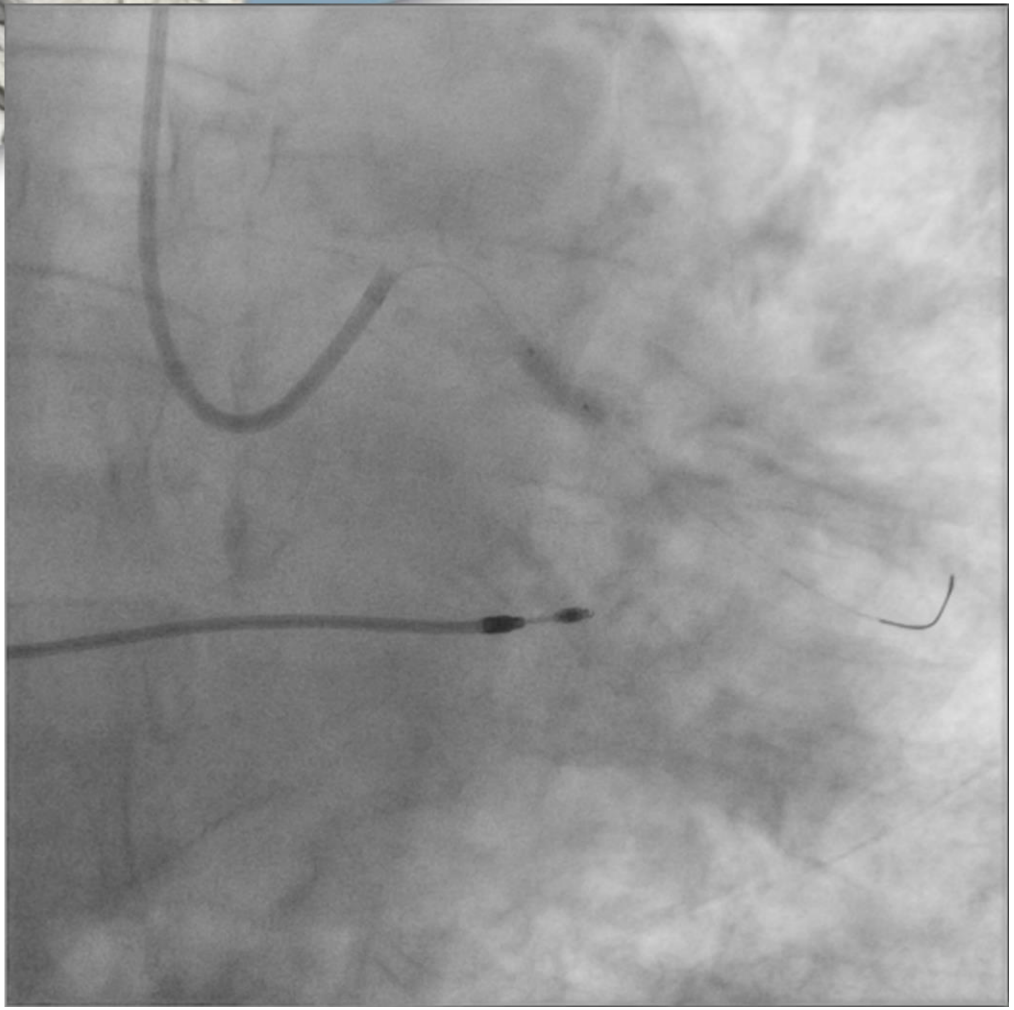
Case_3

DES 3.5x19 mm

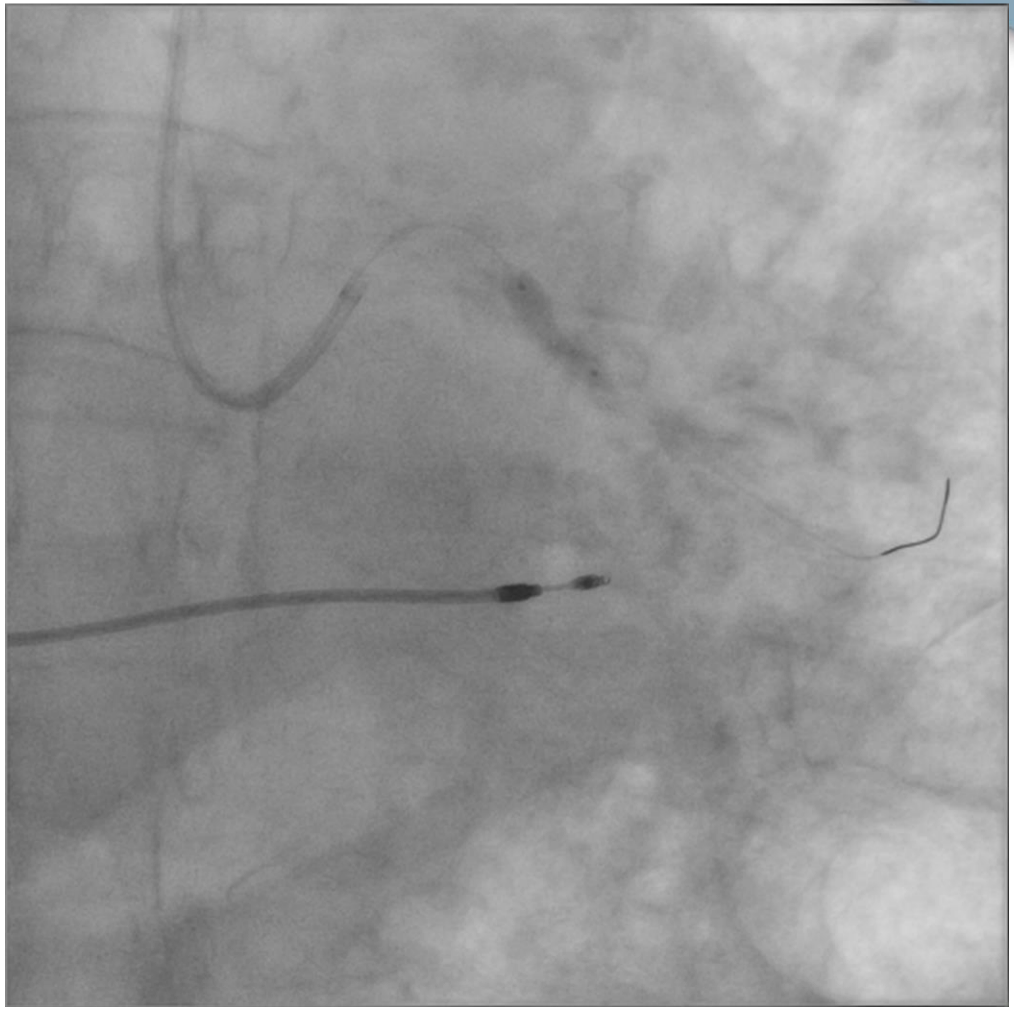




Case_3

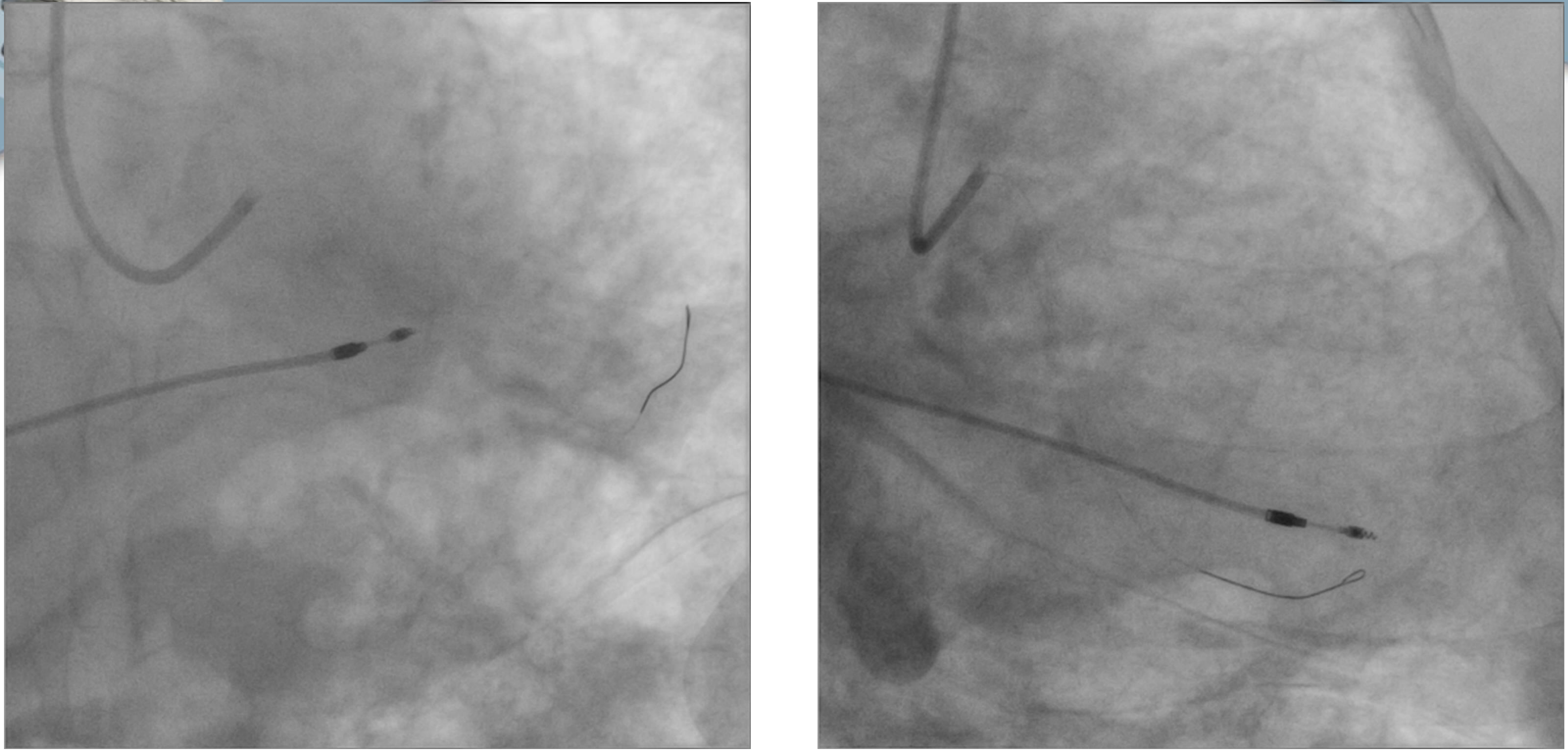


NC Balloon 3.5x8 mm



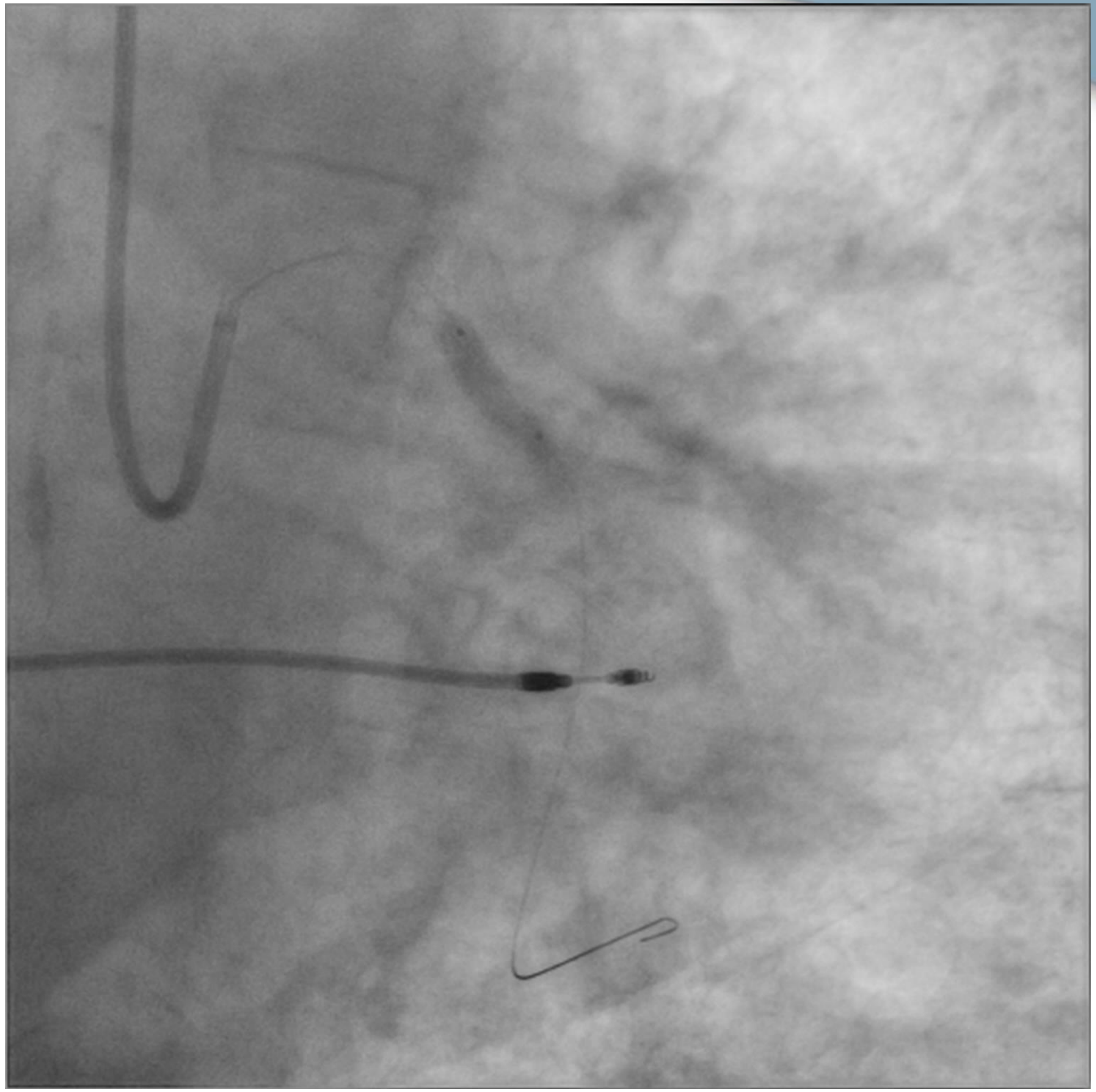
NC Balloon 3.75x15 mm

Case_3



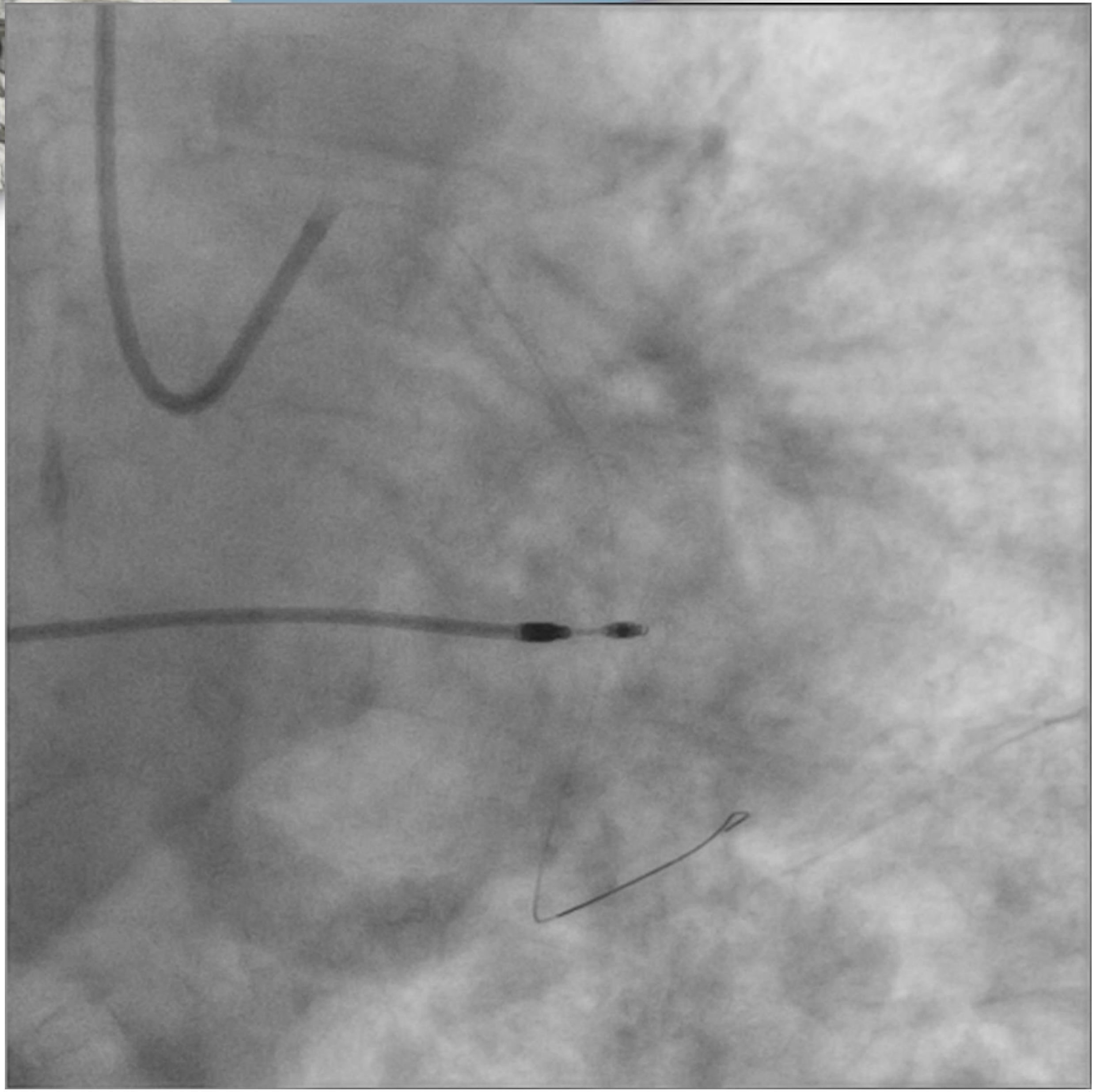
Case_3

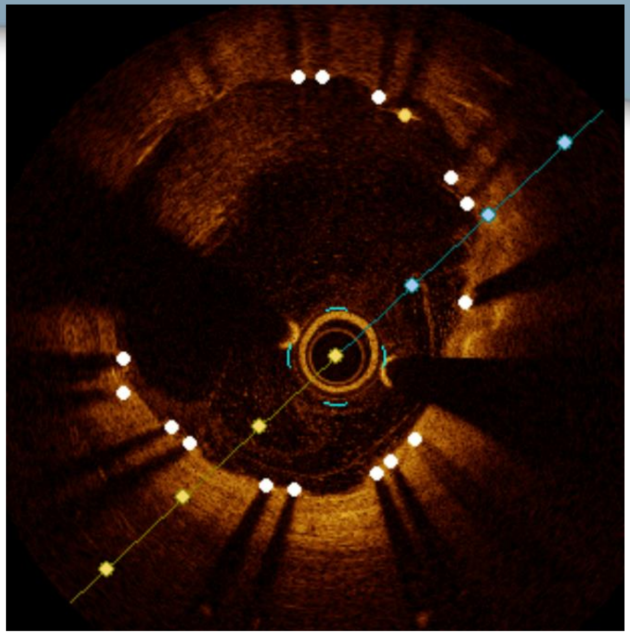
IVL Balloon 3.5x12

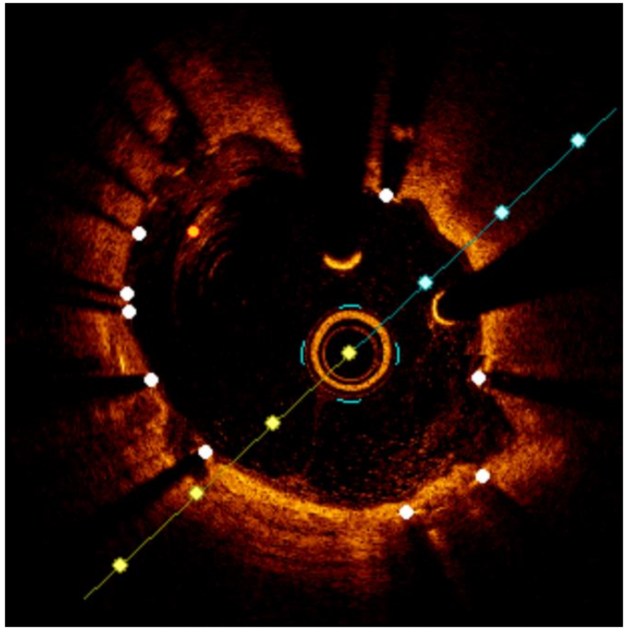


NC Balloon 3.75x15 mm

Case_3



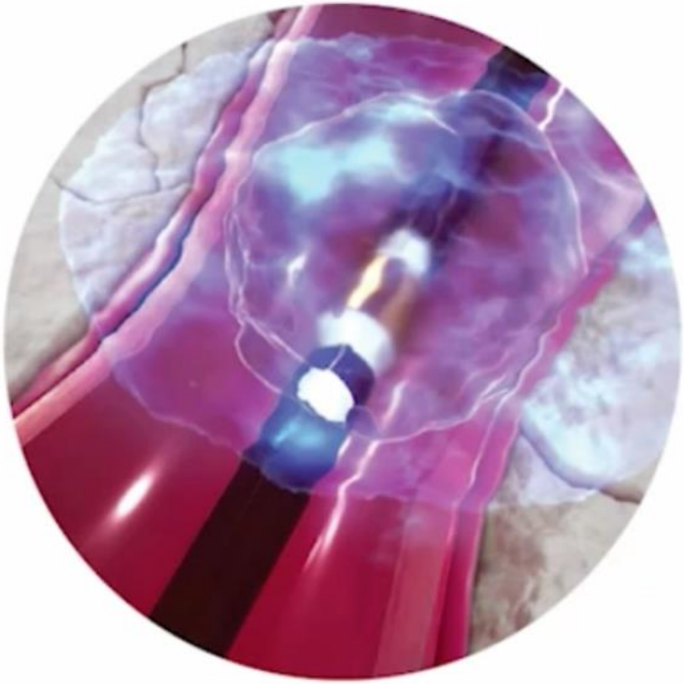


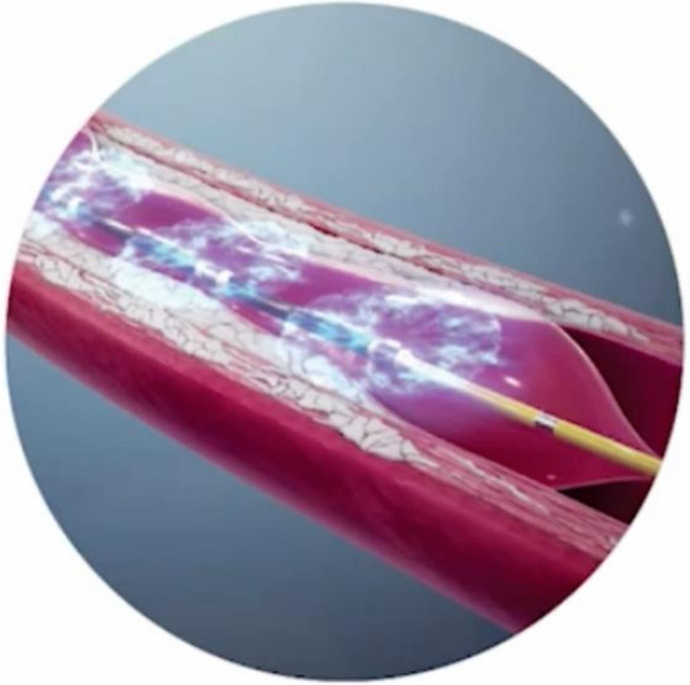


Stent Under-expansion

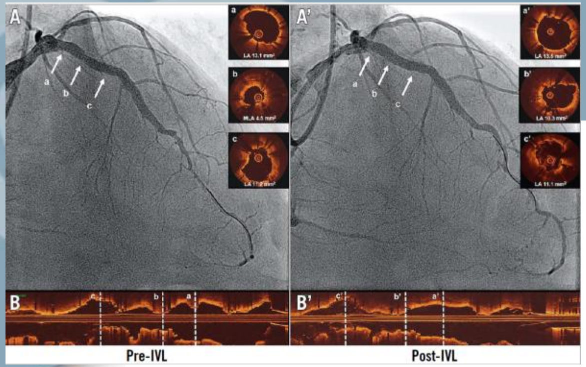
IVL within a stent is currently "OFF LABEL" INDICATION

- Conceptual concerns that the electrohydraulic lithotripsy discharge could damage the polymer, drug or indeed the metallic stent itself





IVL in Stent Underexpansion



CORONARY INTERVENTIONS
CLINICAL RESEARCH

EuroIntervention 2022;17-online publish-ahead-of-print March 2022

Coronary lithotripsy for the treatment of underexpanded stents; the international multicentre CRUNCH registry

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Abstract

Background: Stent underexpansion increases the risk of cardiac adverse events. At present, there are limited options to treat refractory stent underexpansion. In this context, the intravascular lithotripsy (IVL) system might be a safe and effective strategy.

Aims: To evaluate the safety and efficacy of IVL in addressing resistant stent underexpansion due to heavy underlying calcification.

Methods: This was an international multicentre registry including patients receiving IVL therapy to treat stent underexpansion from December 2017 to August 2020. Angiographic and intracoronary imaging data were collected. The efficacy endpoint was device success (technical success with a final percentage diameter stenosis <50%). The safety endpoint was in-hospital major adverse cardiac events (MACE).

Results: Seventy patients were included, the mean age was 73±9.2 years and 76% were male. The median time from stent implantation to IVL therapy was 49 days (0-2537). Adjuvant treatment with non-compliant balloon dilatations pre- and post-IVL was performed in 72.3% and 76.8% of patients, respectively, and additional stenting was performed in 22.4%. Device success was 92.3%. Minimum lumen diameter increased from 1.49±0.73 mm to 2.41±0.67 mm (p<0.001) and stent expansion increased by 124.93±138.19% (p=0.016). No IVL-related procedural complications or MACE were observed. The use of bailout IVL therapy directly after stenting and the presence of ostial underexpanded lesions negatively predicted lumen diameter gain.

Conclusions: Coronary lithotripsy is safe and effective in increasing lumen and stent dimensions in underexpanded stents secondary to heavily calcified lesions.

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Cardiovascular Revascularization Medicine

CRM

IntravaScular lithotripsy for the Management of undILatable coronary stEnt: The SMILE Registry☆,☆☆,☆☆☆

Alfonso Ielasi[a,*,1], Elisabetta Moscarella[b,1], Luca Testa[c], Gaetano Gioffrè[d], Gaetano Morabito[e], Bernardo Cortese[f], Salvatore Colangelo[g], Fabrizio Tomai[h], Franceso Arioli[i], Mauro Maioli[j], Massimo Leoncini[k], Gabriele Tumminello[l], Stefano Benedetto[m], Piergiuseppe Greco Lucchina[n], Matteo Pennesi[o], Fabrizio Ugo[g], Elena Viganò[f], Mario Bollati[c], Bindo Missiroli[e], Achille Gaspardone[d], Paolo Calabrò[b], Francesco Bedogni[c], Maurizio Tespili[a]

Background: Intravascular lithotripsy (IVL) showed to be effective in dilating heavily calcified de novo coronary lesions but little is known about its performance in under-expanded stents management. Aim of this study was to assess the feasibility, effectiveness and safety of IVL for the treatment of stent underexpansion refractory to balloon dilatation.

Methods: A multicentre, retrospective cohort analysis was performed in patients undergoing IVL to treat under-expanded stents following non-compliant balloon expansion failure. Primary endpoint was successful IVL dilatation defined as IVL balloon delivery and application at the target site followed by an increase of at least 1 mm^2 in minimal stent cross-sectional area (MSA) on intracoronary imaging or an increase of at least 20% in minimal stent diameter (MSD) by quantitative coronary analysis (QCA).

Results: Thirty-nine under-expanded stents (34 patients) were included. Two cases (5.1%) of multiple stent layers and one (2.5%) acutely under-expanded stent were treated. The median IVL balloon diameter was 3.1 mm (IQR: 2.5–3.5 mm) while the number of pulses emitted was 56.7 (IQR: 30–80). IVL was successful in 34 cases (87.1%), with significant improvement in MSD (post: 3.23 mm [IQR: 3–3.5 mm] vs. pre: 0.81 mm [IQR: 0.35–1.2], $p < 0.00001$) and MSA (post: 7.61mm^2 [IQR: 6.43–7.79mm^2] vs. pre: 3.35 [IQR: 2.8–4 mm^2], $p < 0.00001$). Non-fatal peri-procedural ST-elevation myocardial infarction occurred in one case (2.5%) due to IVL balloon rupture. No cardiac death, target lesion revascularization and stent thrombosis occurred in-hospital and at 30-day follow-up.

Conclusions: Bailout IVL was feasible, efficacious and safe to improve refractory stent under-expansion.

Conclusion

IVL has shown sustained low rates of clinical events at 1 year

OCT substudies have demostrated consistent results regarding stent expansion in all different types of calcium morphologies

OCT substudies suggested sustained stent expansion and adequate vessel healing at long-term follow-up

Excellent procedural safety and effectiveness outcomes to 1 year in women after IVL – 1st-line therapy for plaque modification

Off-label use of IVL may be safer and more readily available than laser or rotational atherectomy in under-expanded stent

OPTIMA Algorithm for treating calcium

- ✓ **Large guide catheters + catheter extension**
- ✓ **Strong guide support + supportive shapes**
- ✓ **Intravascular Imaging**
- ✓ **Atherectomy (Rotational, Orbital) + other plaque modification strategies (Lithotripsy, ELCA)**