BRS for complex coronary lesions: learning from Cases and Multi-Center Registry in Taiwan

Kaohsiung Chang-Gung Memorial Hospital

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Complex PCI: make it simple, Organized by CVRF

Sheraton Grande Wakerhill,

Seoul, Korea , Dec. 1st, 2016

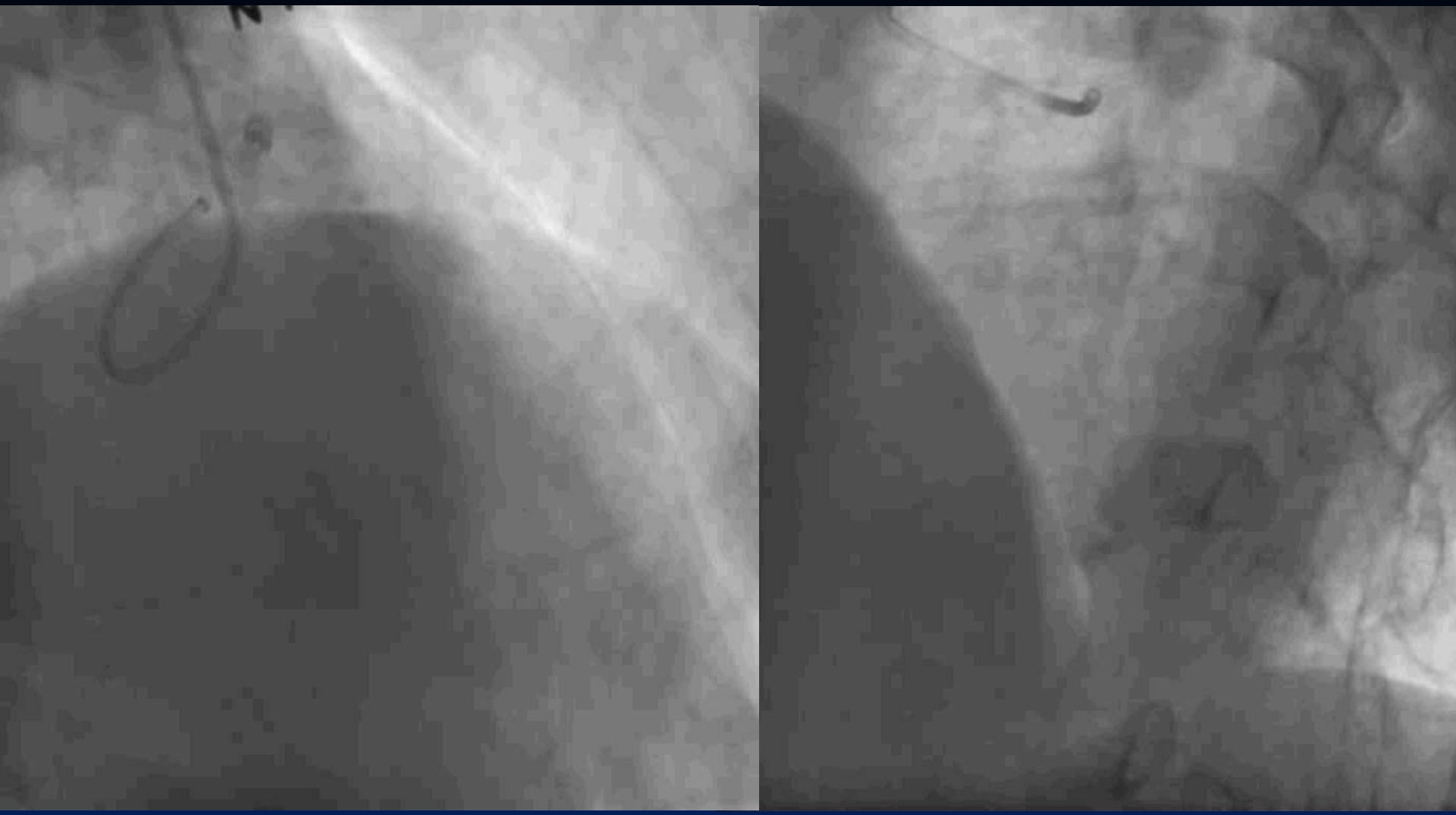
My Disclosure

- Nothing to declare for the presentation
- Co-PI on behalf of 2 Hospitals in Taiwan (NTUH and CGMH Kaohsiung) for Absorb-Extend Trial

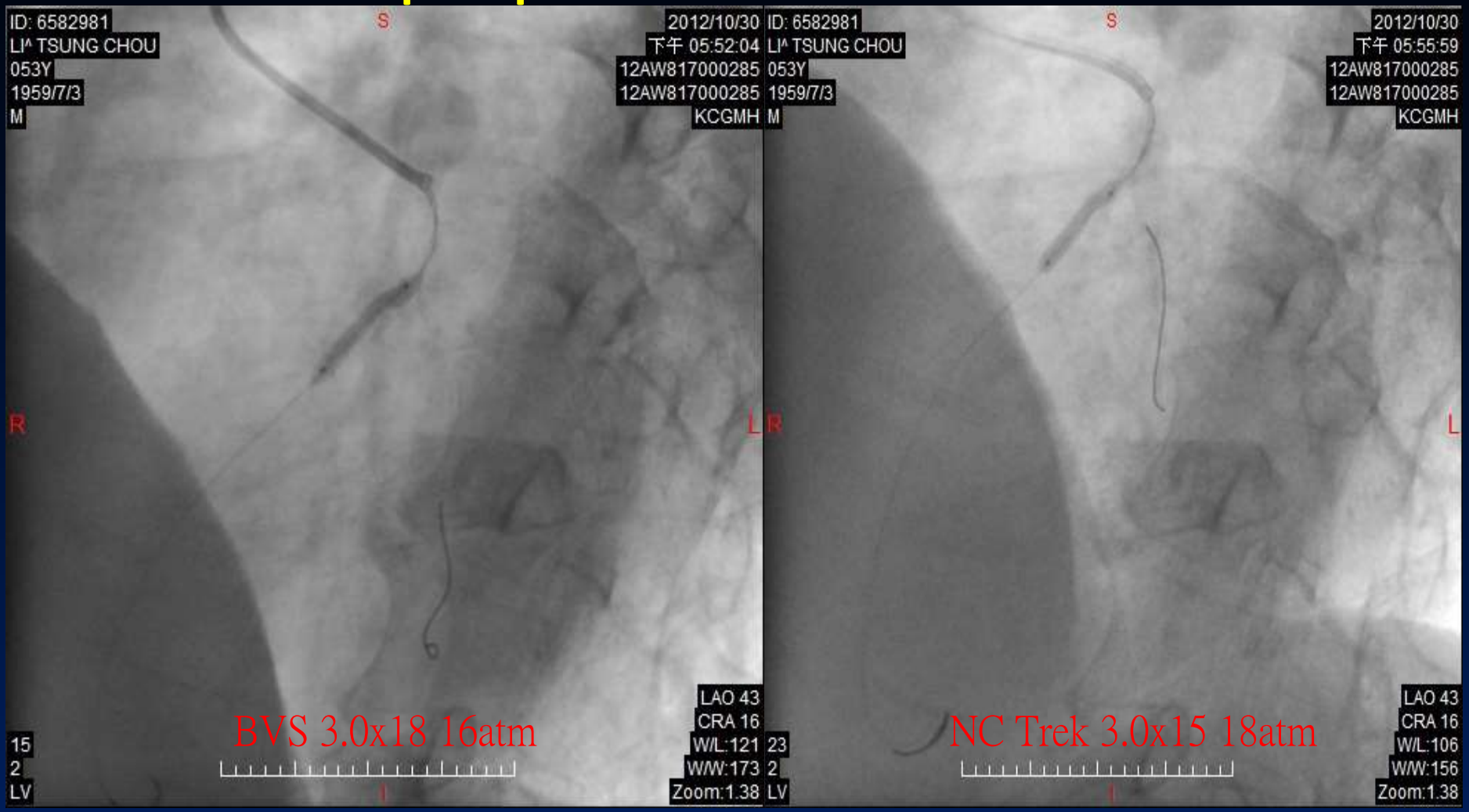
- **Name:** Mr. Lee (Absorb Extend Trial)
- A 54 y/o male

- **Risk factor:** HTN, Hyperlipidemia, current smoker
- **History:**
  - 2010-09-01: p-m RCA (**Taxus Liberte 2.75x38mm, 3.0x38mm**) without ISR
  - 2012-04-13 : m-LCX (**Vision 2.5x28mm**)
  - 2012-10-30 : p-LAD (**ABSORB 3.0x18mm x 2**)
  - LVEF: 80 %
- **Target lesion: ?**
- **Strategy: OCT BVS 3.5 year follow up**

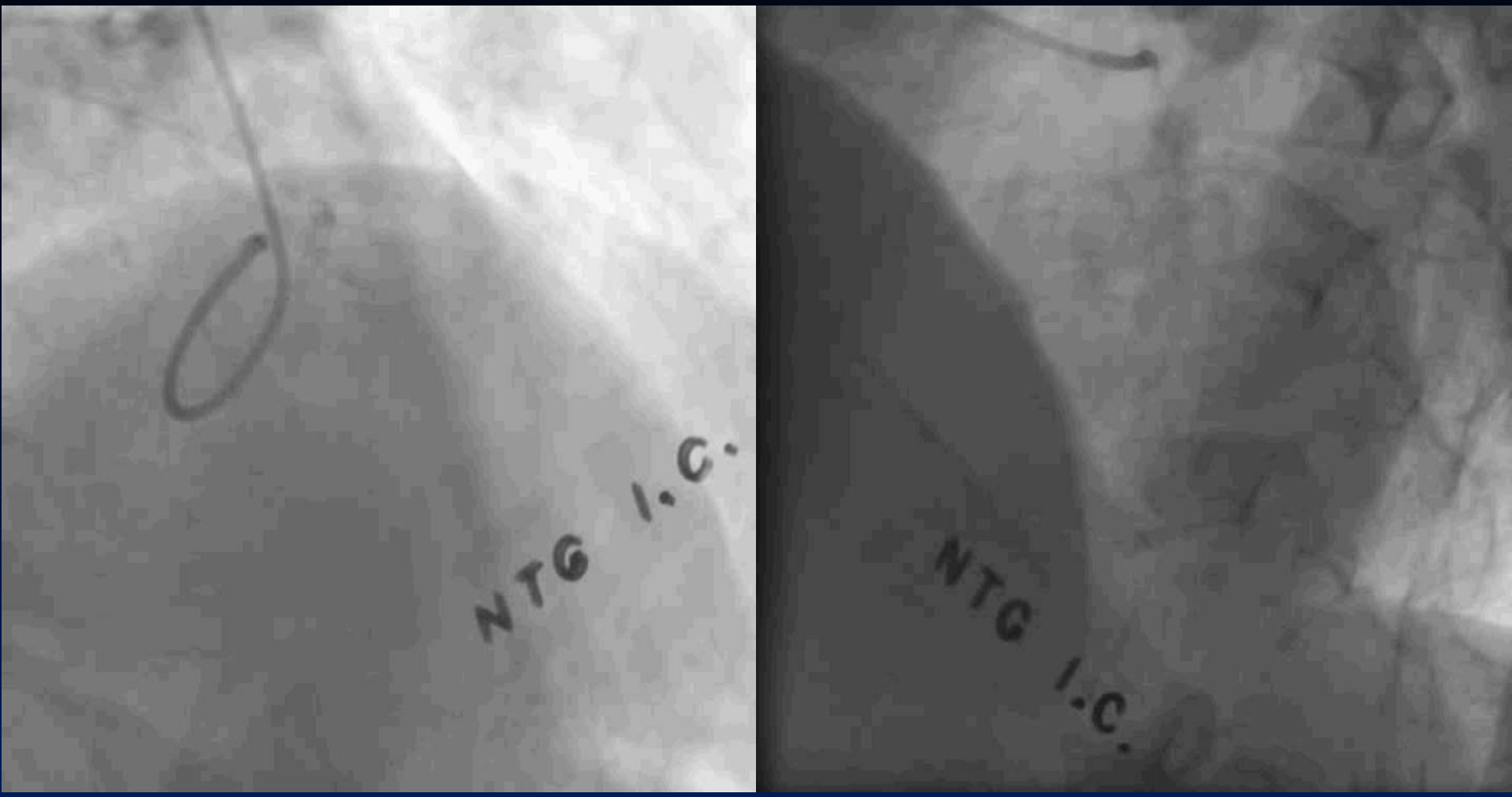
BVS preparation at 2012/10 baseline angiography via left radial approach



BVS-1 deployment and post HPB dilatation prepare for BVS-2

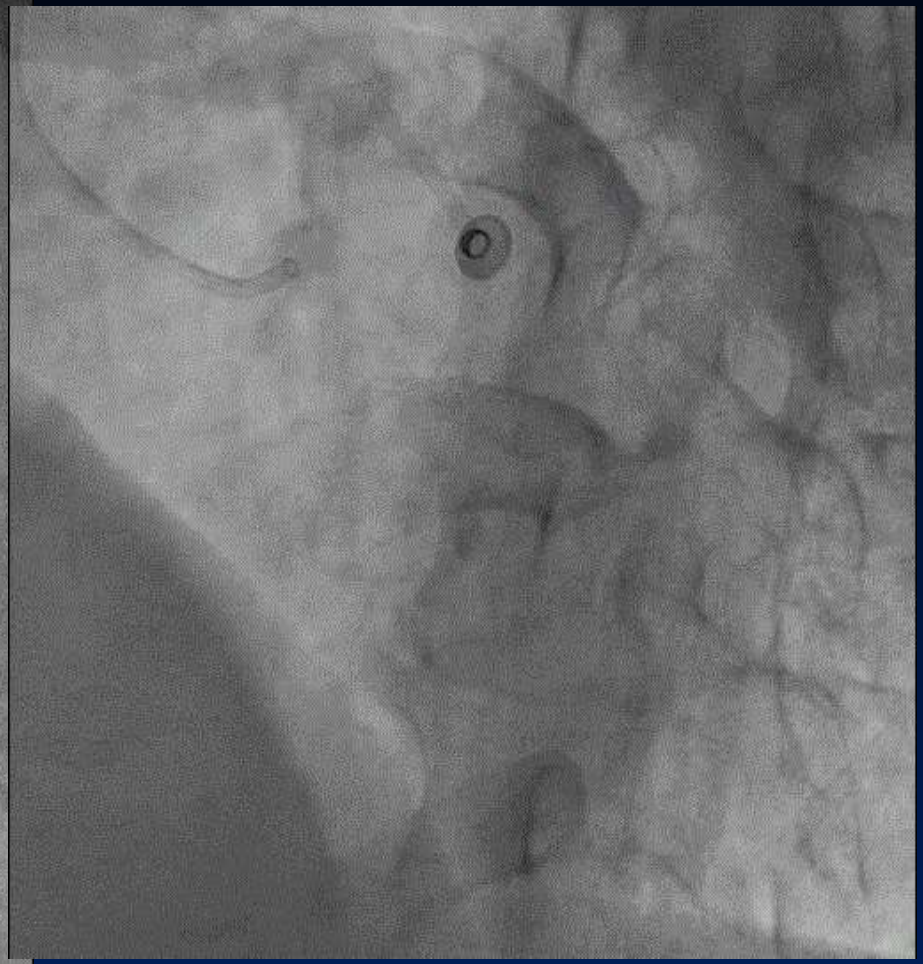


Final Angiography: after 2nd 3x18 mm BVS and HPB 18-24 atm

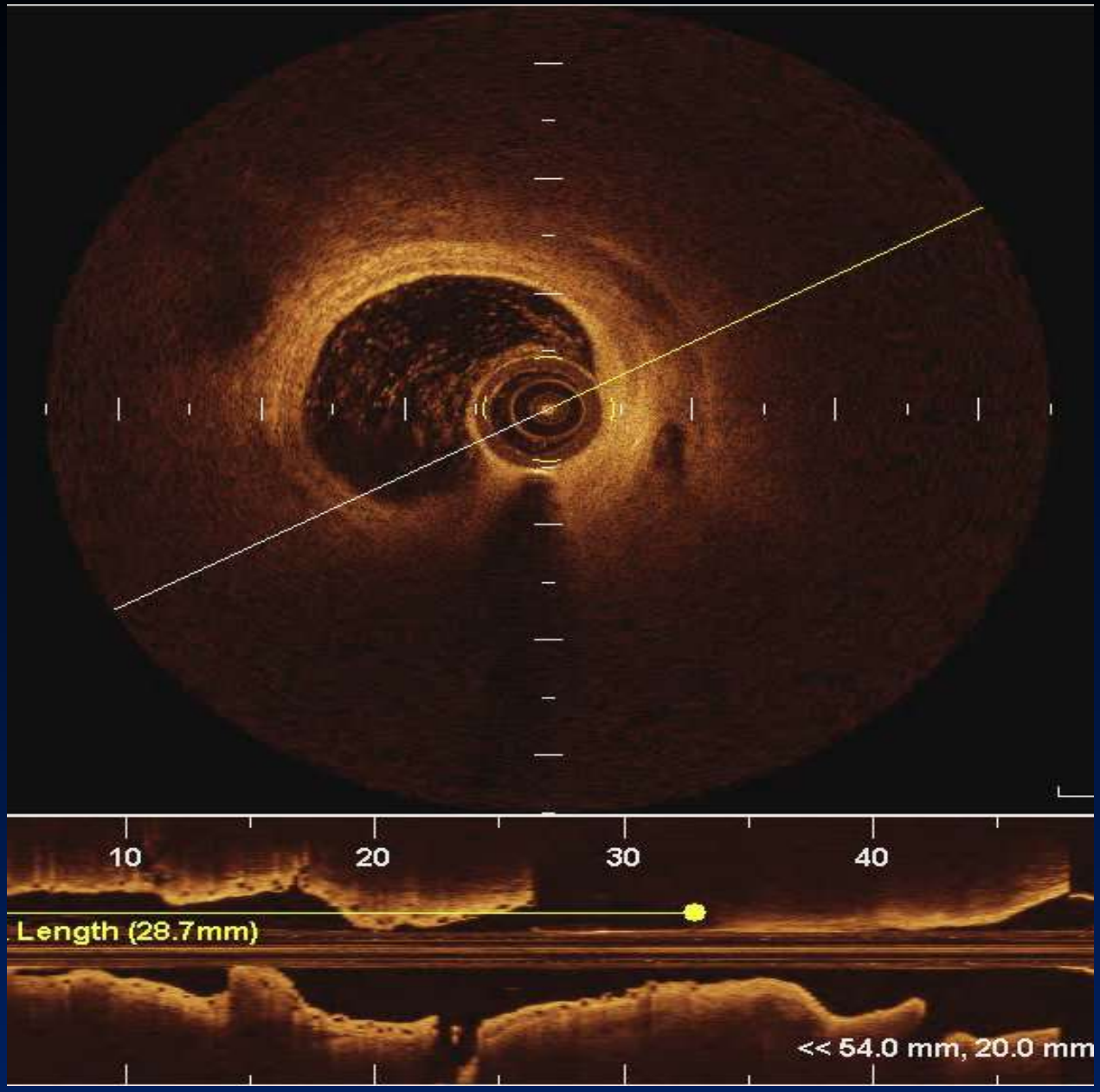


Overlapping 2-4 mm of BVS according to Absorb-extend protocoal

19 m/o CAG & OCT f/u

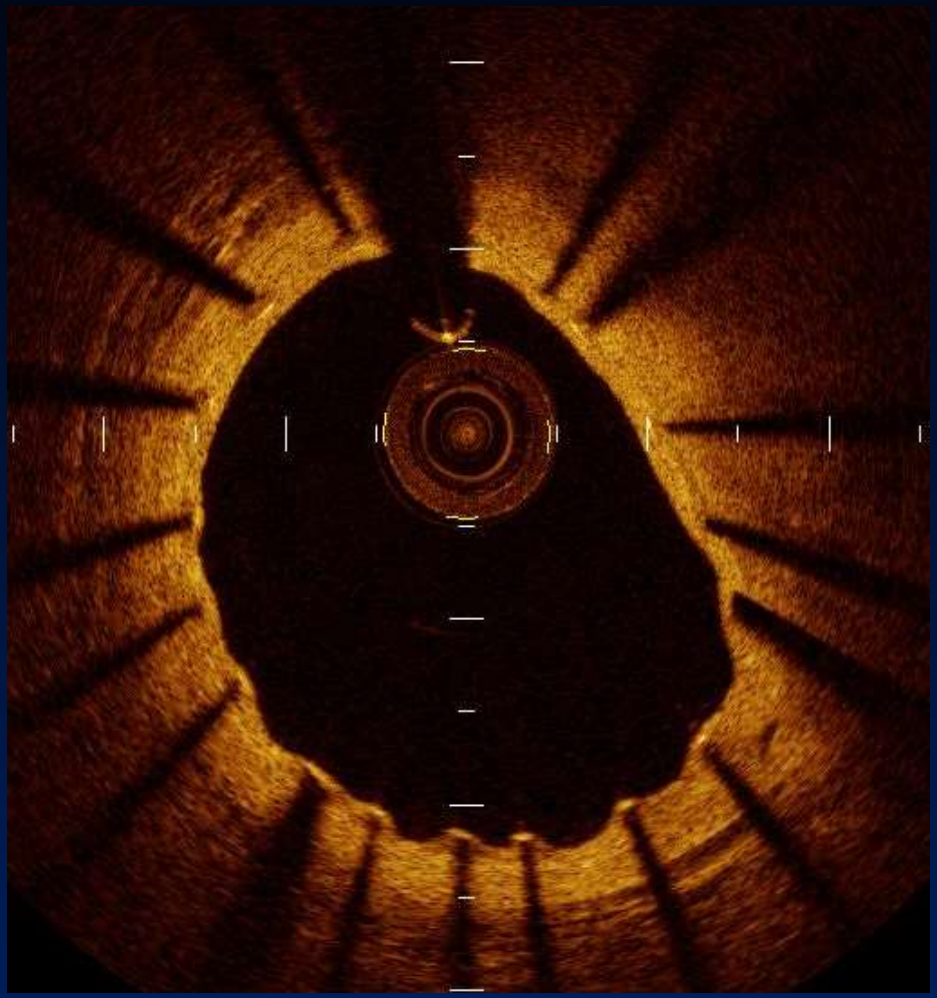


LAD BVS 19-mo OCT F/U



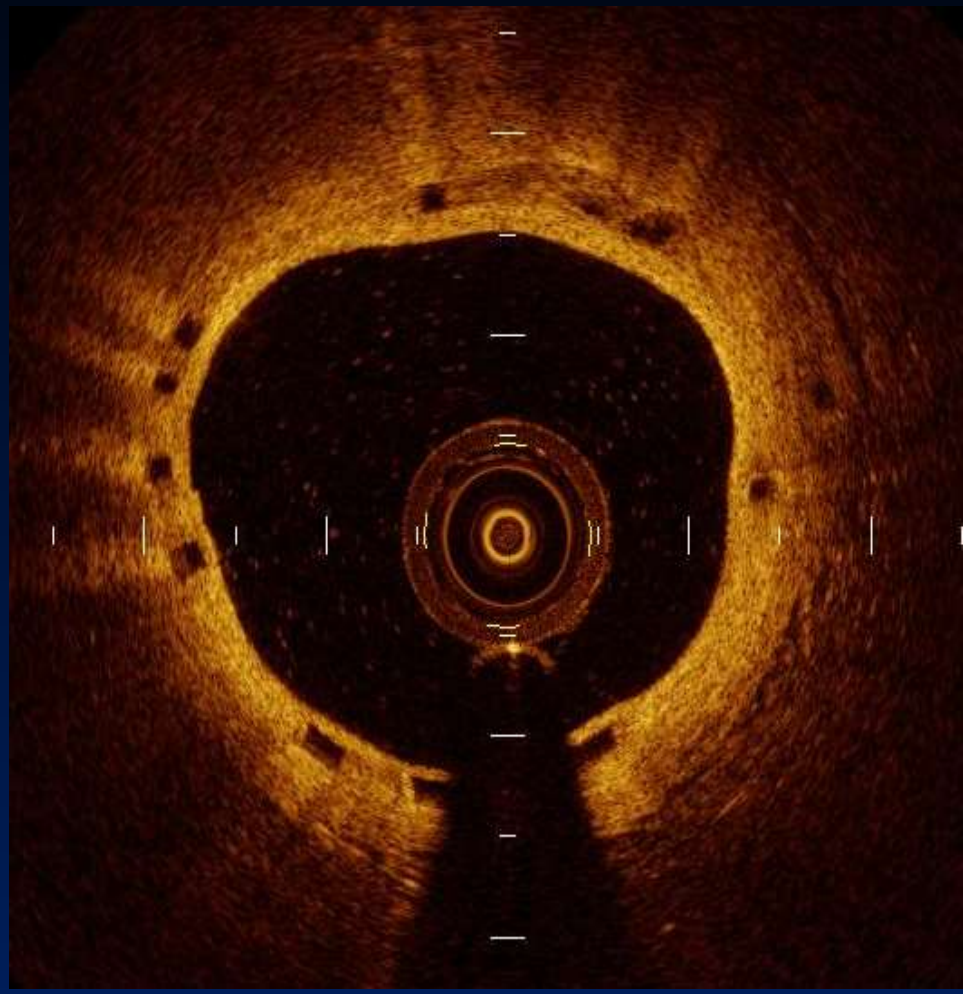
OCT DES

(RCA prior Taxus stent 44-mo)

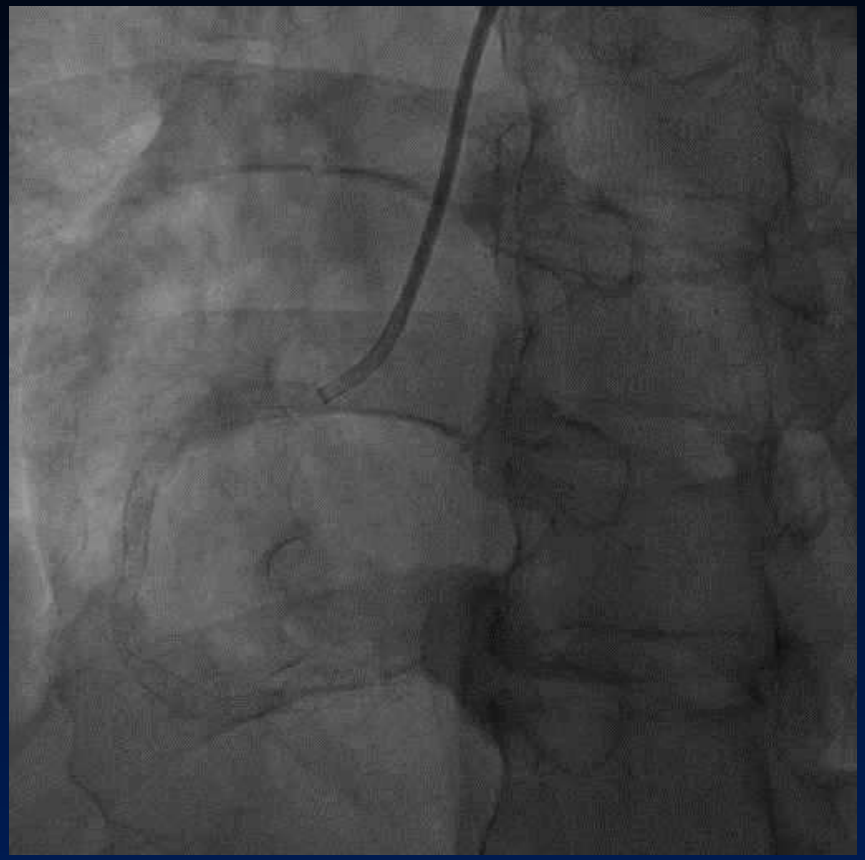


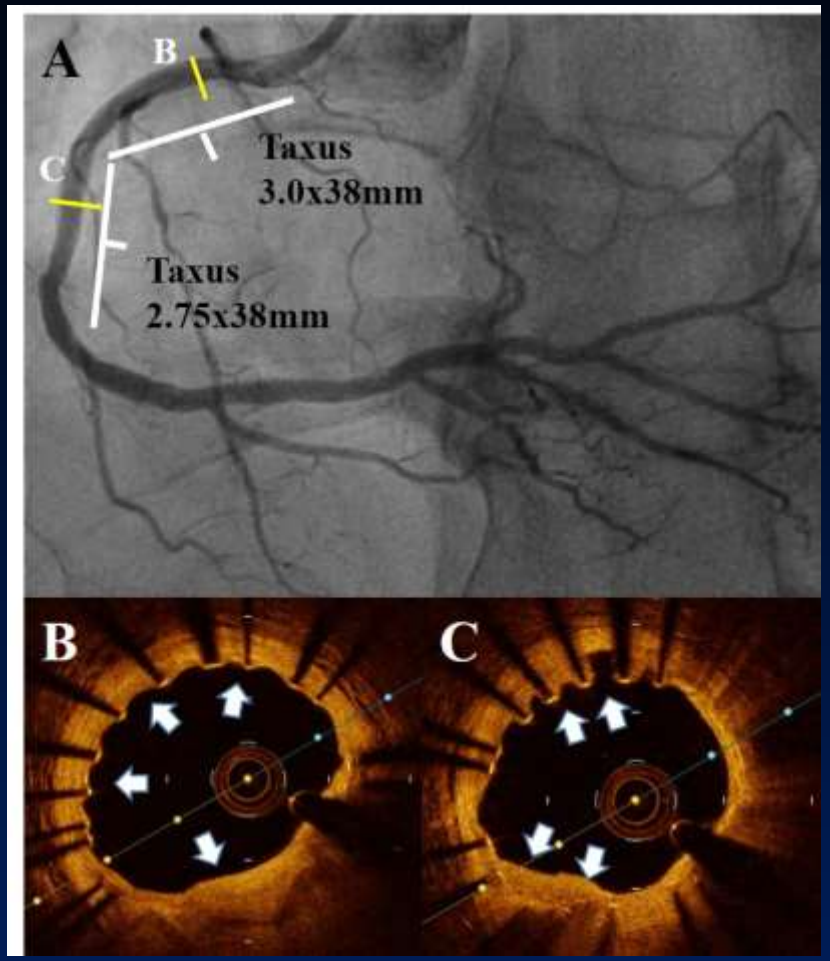
OCT BVS LAD

(19-mo)

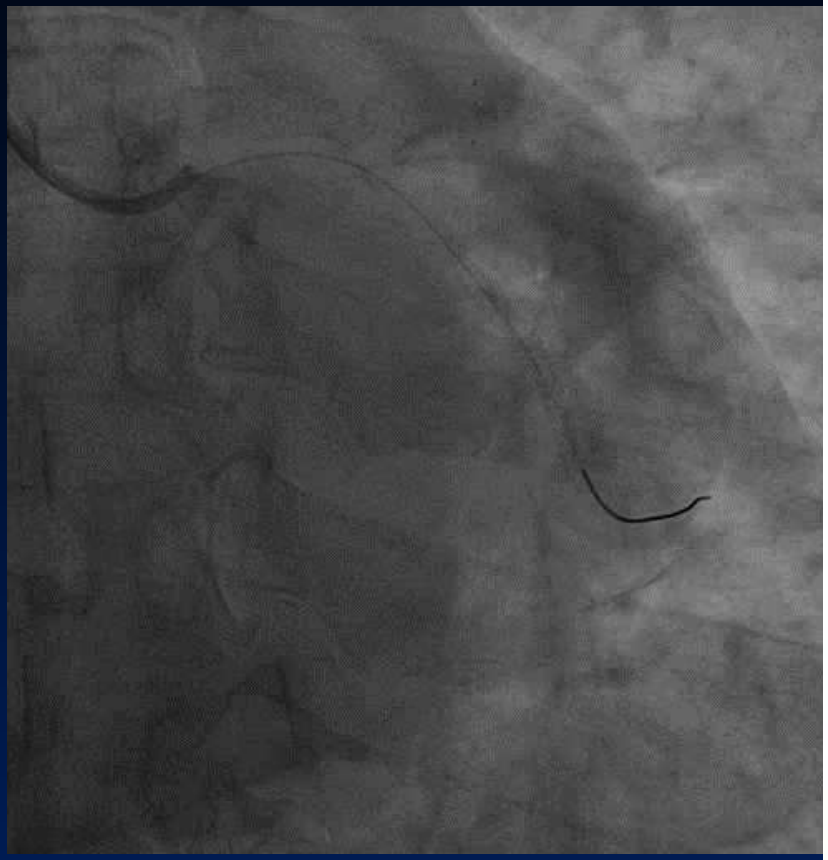


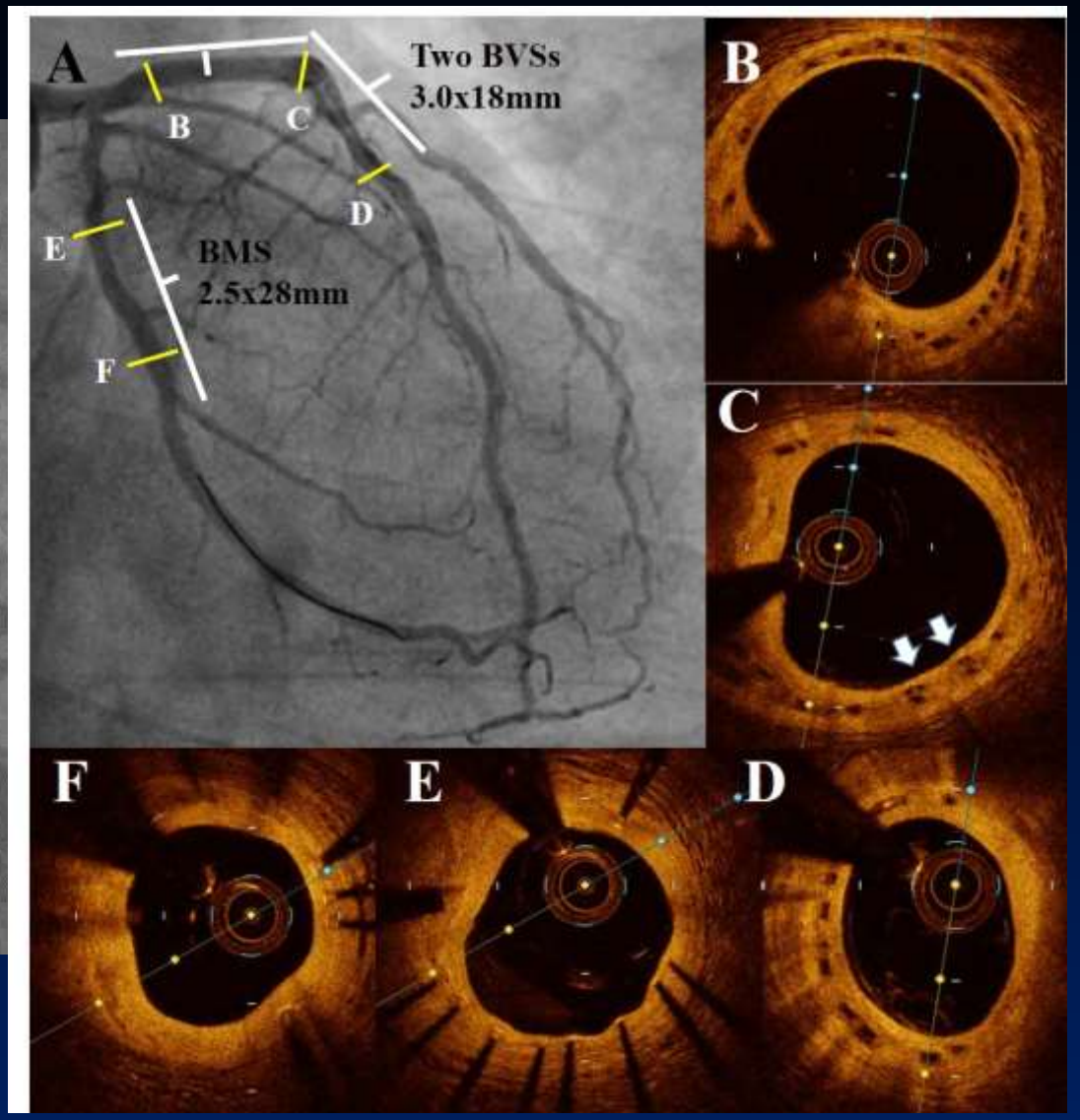
RCA f/u angio. at 2016-4-16 (67-mo post Taxus-Liberte DES)





LCA F/U angio. 2016-4-16 Absorb Extend Trial (3.5 yr s/p BVS 3x18 x II in LAD)



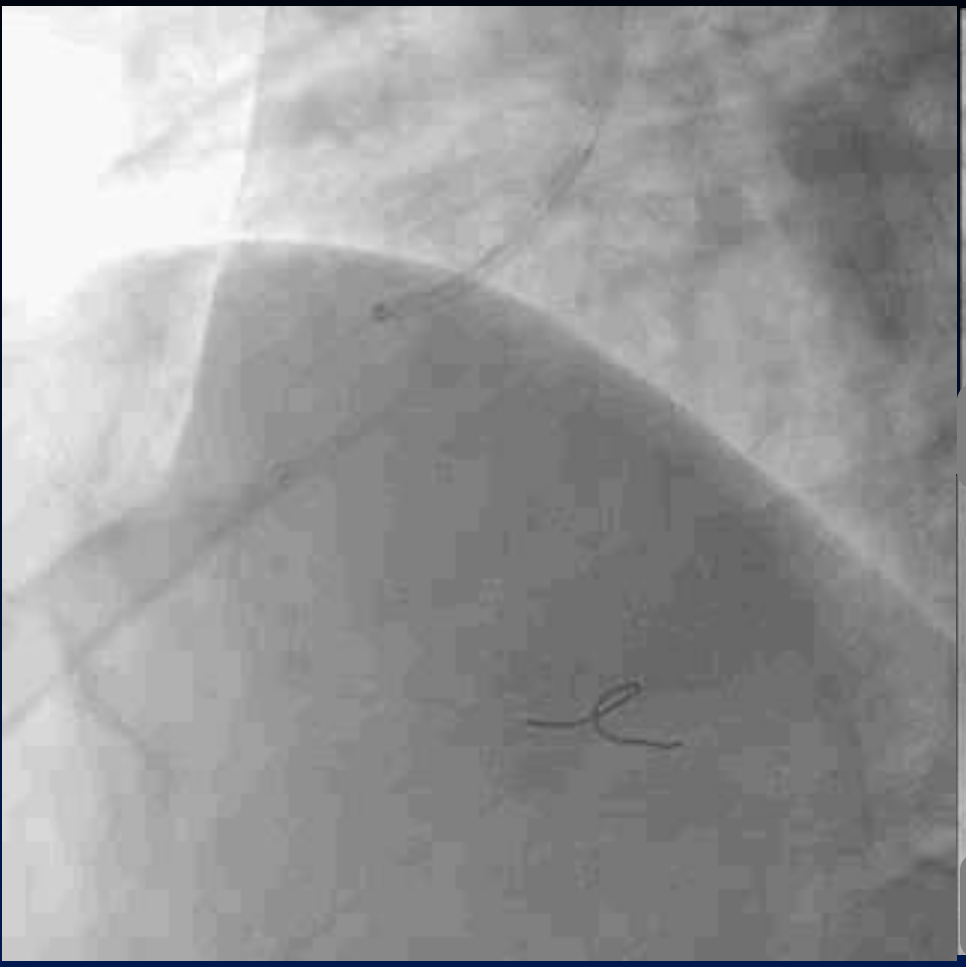


Case No. 2: Triple vessel with CTO at proximal LCX s/p Dx cath., but refused CABG

History

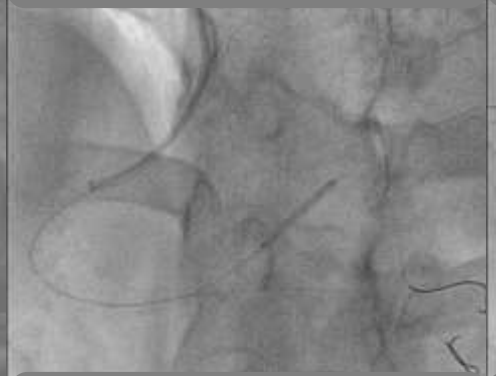
- A 42 y/o male, smoker had hx of dyslipidemia
- Chest pain, CCS 4, Non-STEMI
- EKG: Normal
- Echo: LVEF: 51%, anterior and anterior septal hypokinesia , Adequate LV performance

RCA lesion preparation



Trek 2.0x20 10atm

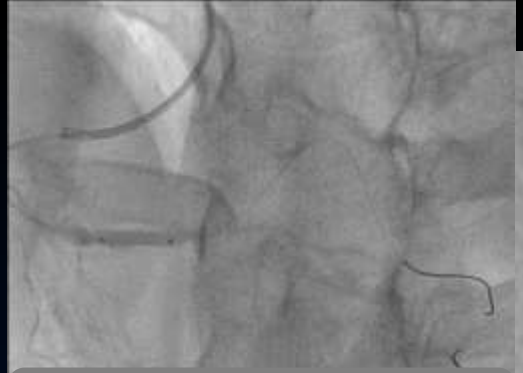
Trek 2.0x20 14atm



Trek 2.0x20 16atm

Trek 2.0x20 20atm

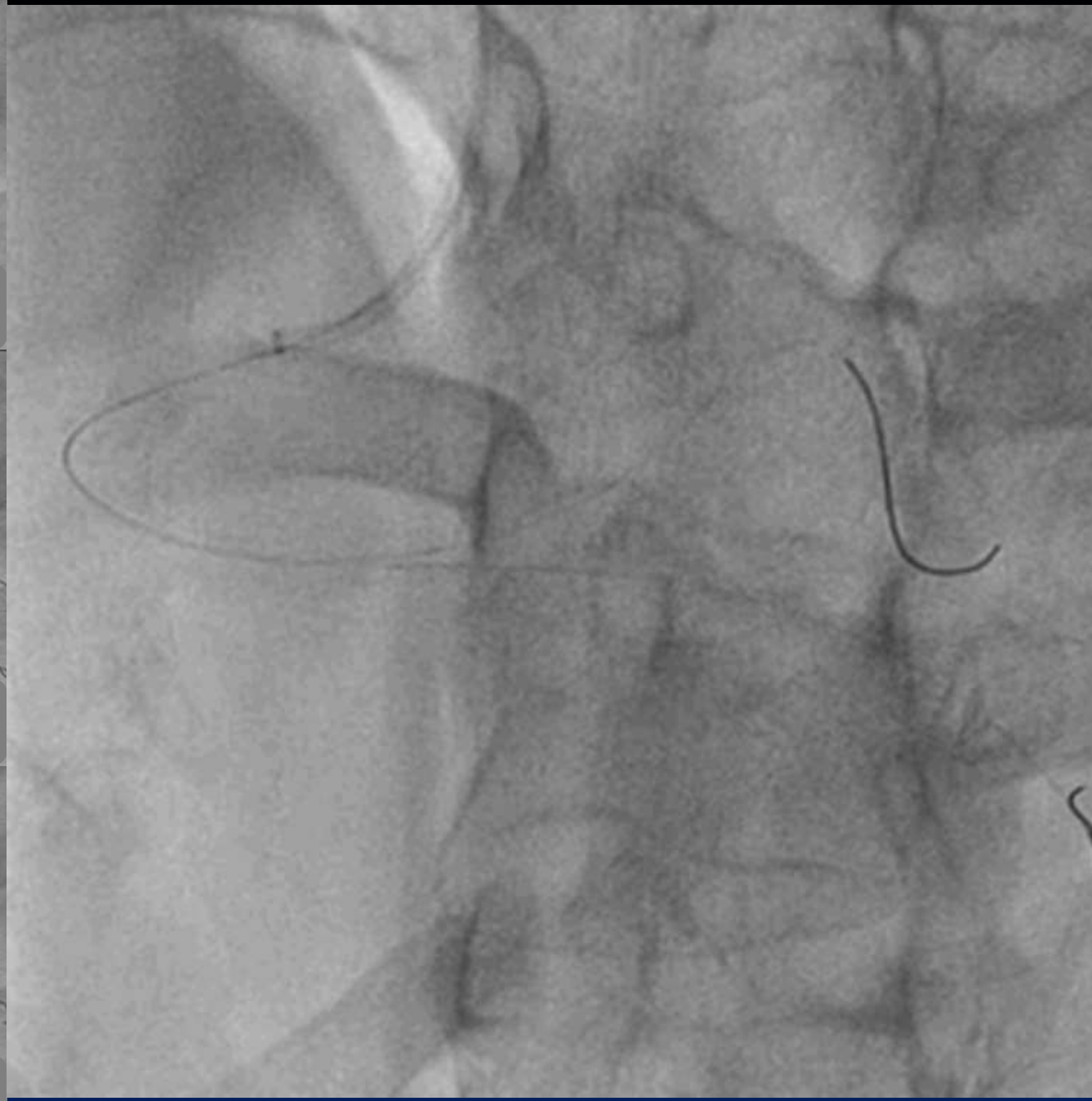
IVUS study after pre-dilatation for sizing



Hiryu 3.0x15 20atm

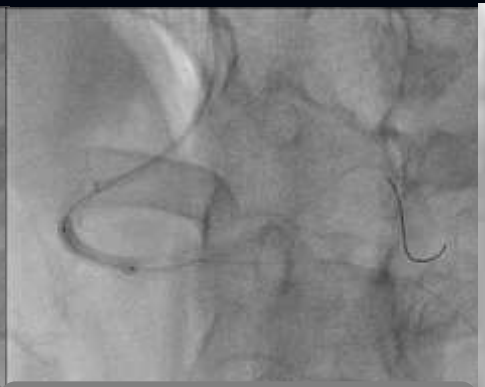
Hiryu 3.0x15 24atm

Hiryu 3.0x15 26atm

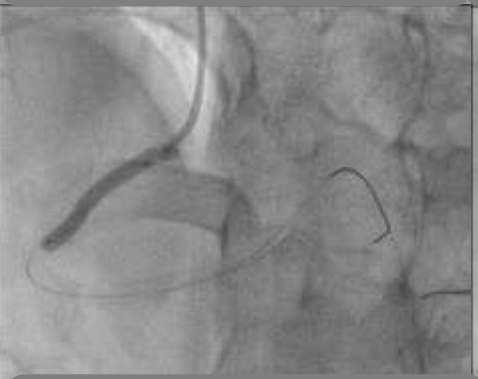


RCA stenting: hybrid use of BVS & DES

Xience Prime 3.0x38
10atm

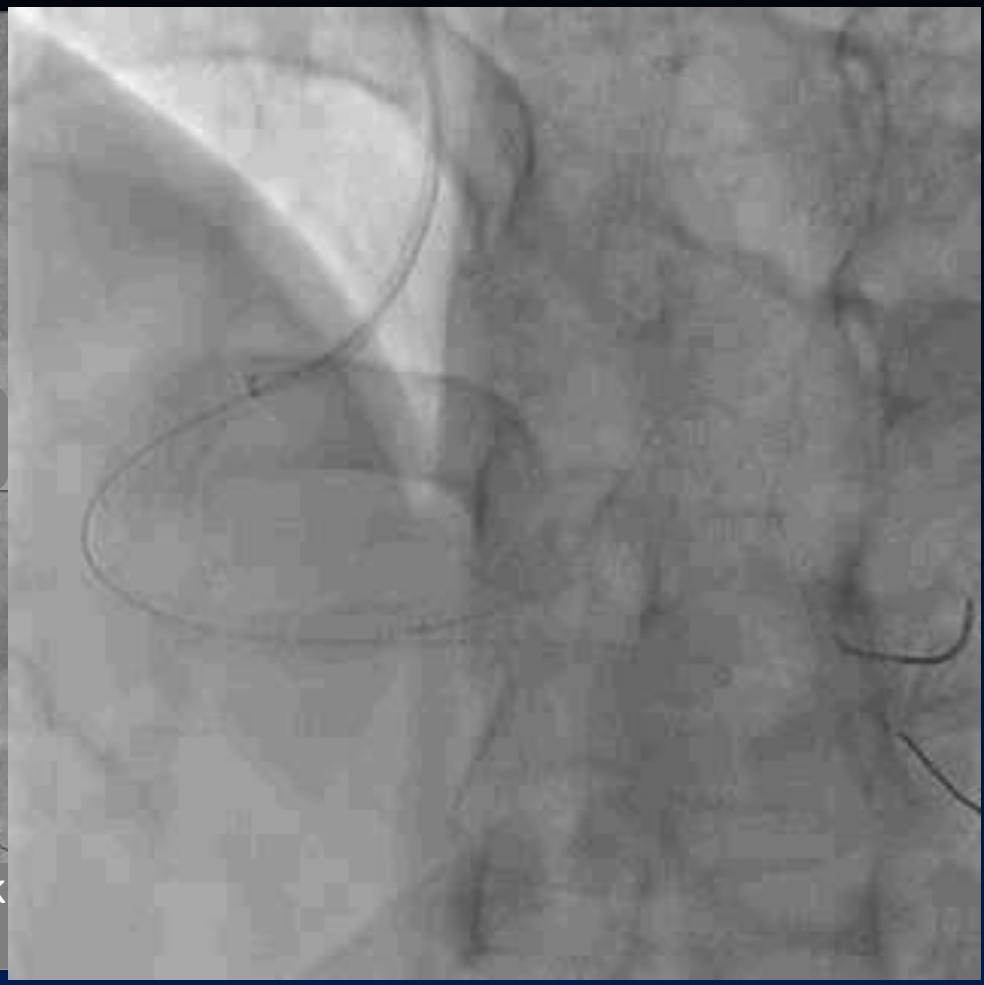


BVS 3.5x28 16atm



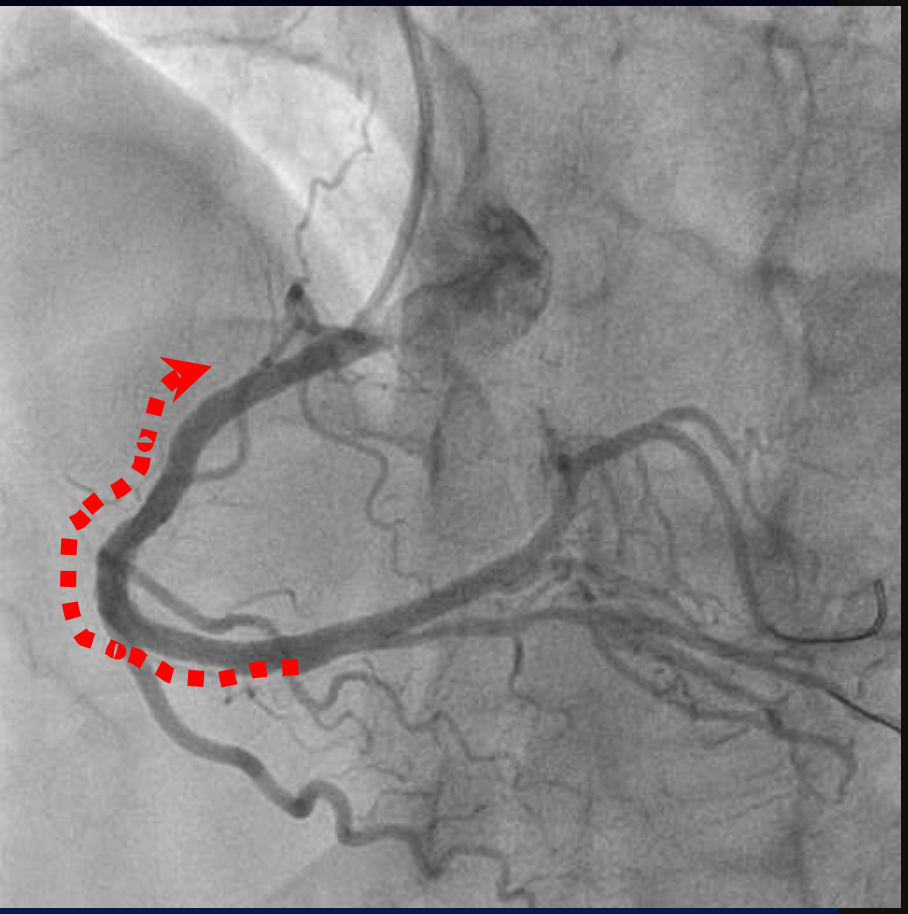
BVS 3.5x28 16atm

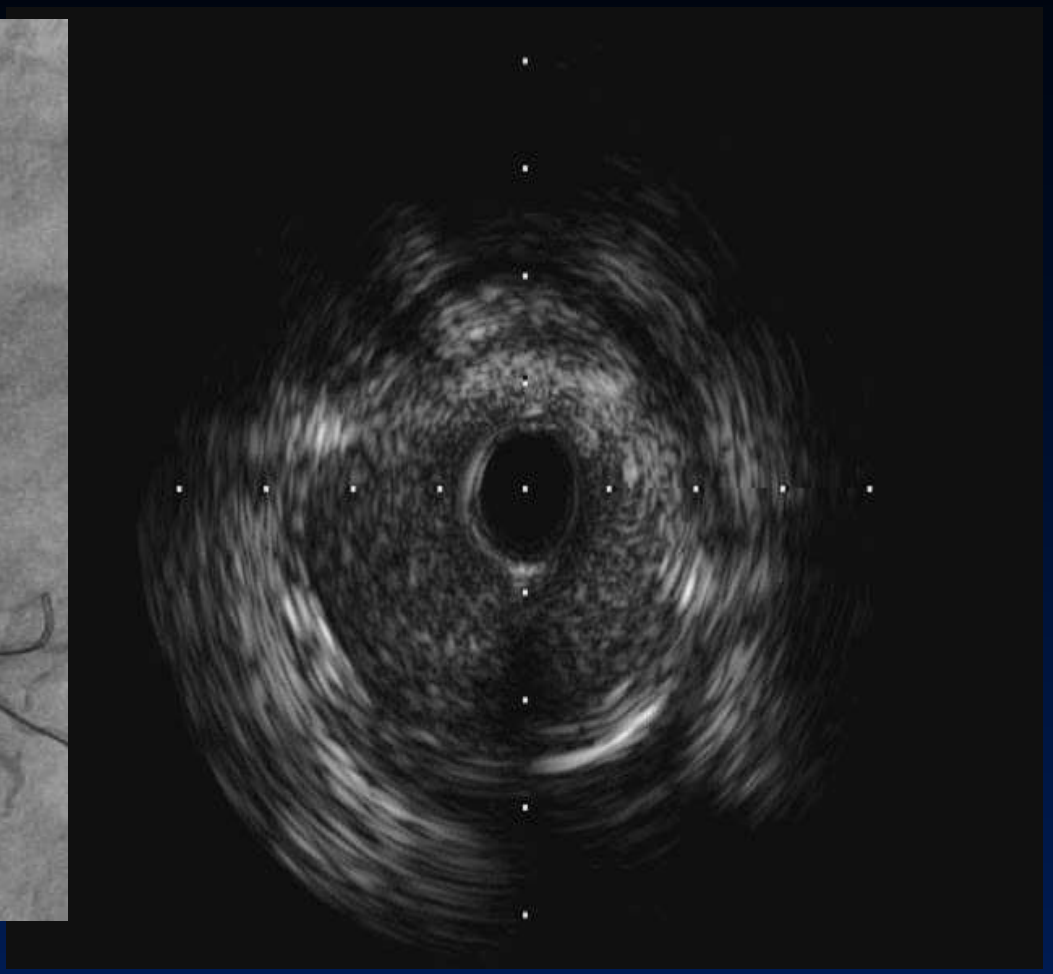
KBT Hiryu 3.0x15 Trek
2.0x20 x 12atm



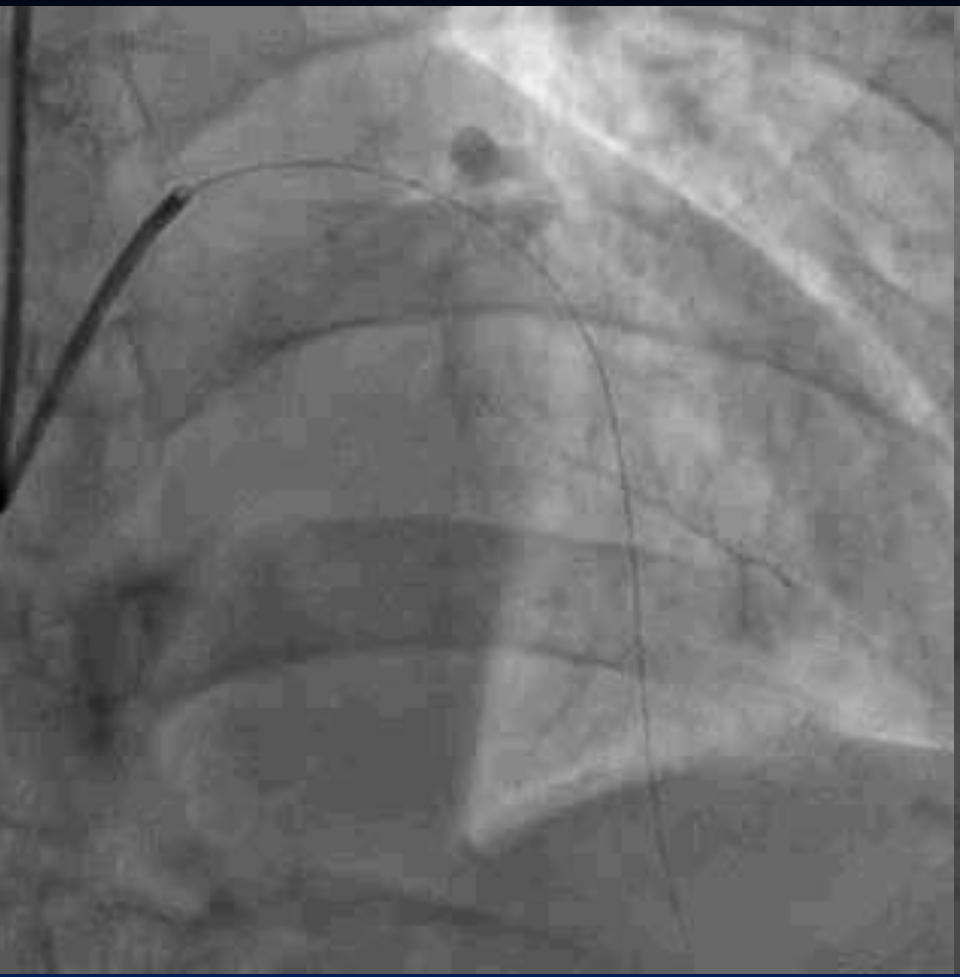
Non-compliant balloon 3.5x15 mm High pressure 18-20-24 atm

RCA IVUS





Pre-PCI of left coronary arteries
6Fr IL4.0 Left radial approach

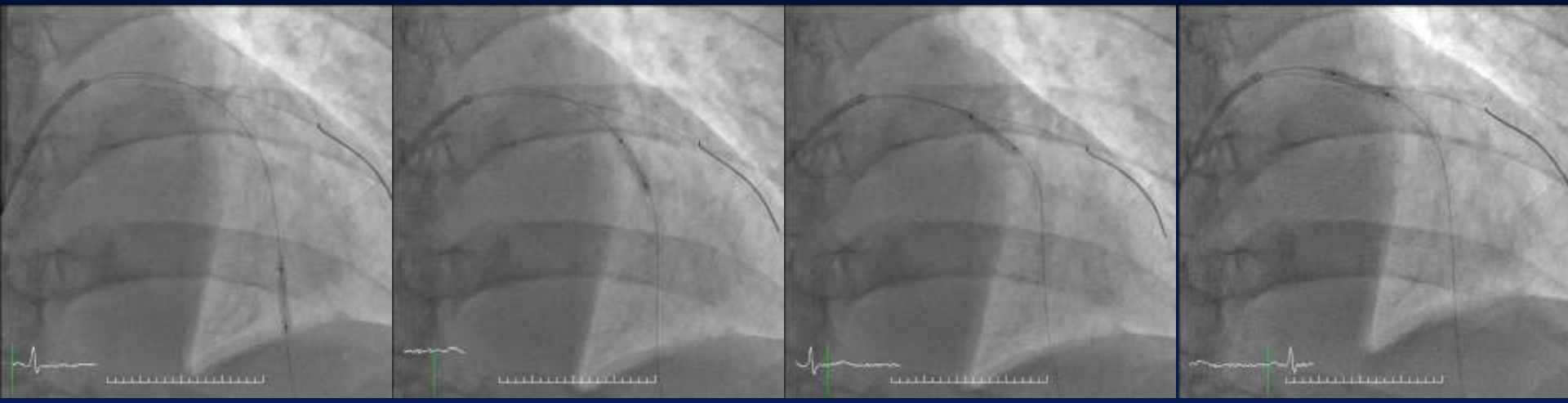


AP-cranial view

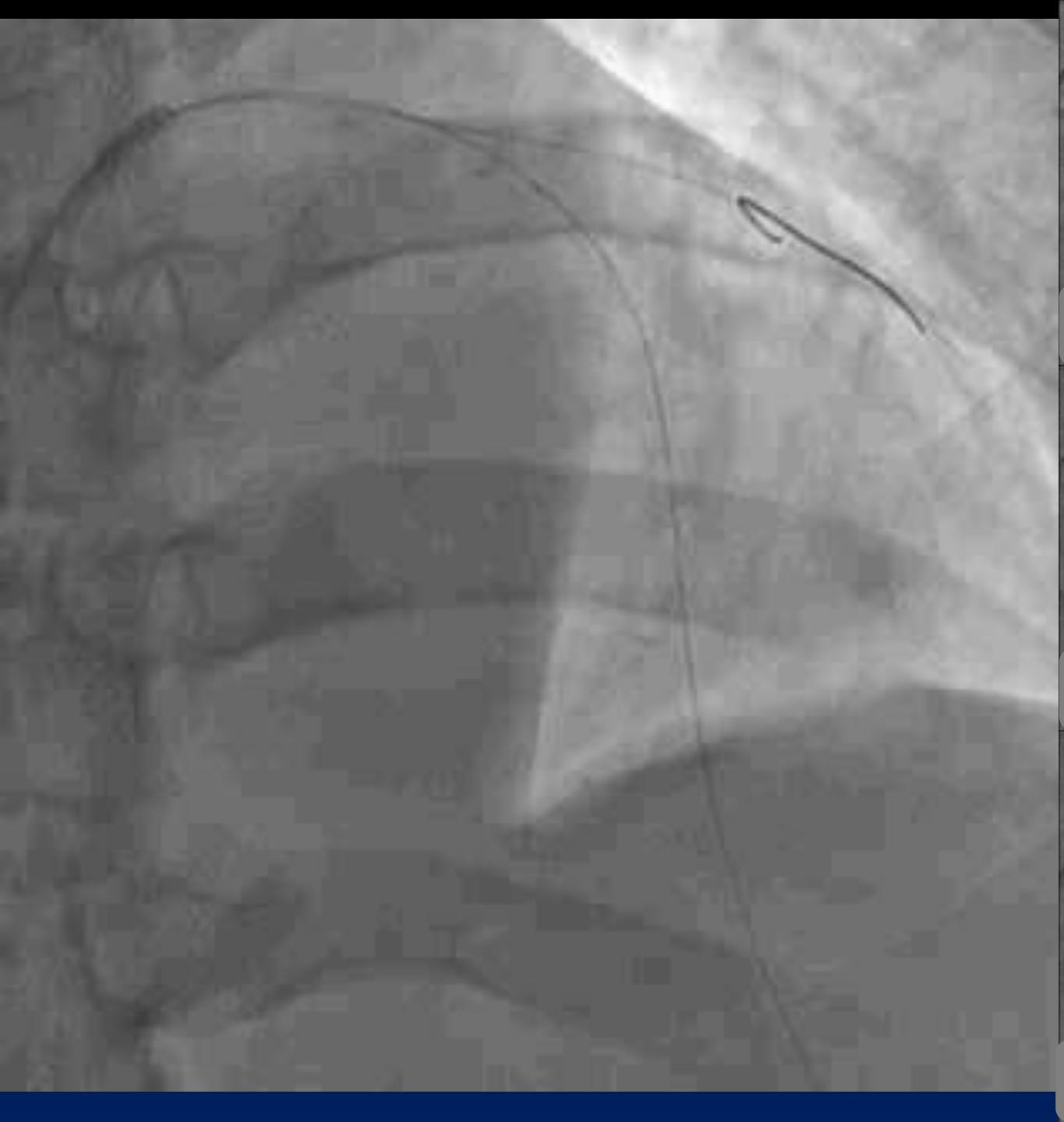
RAO-caudal view

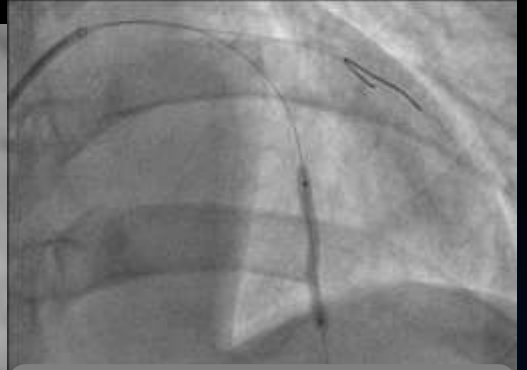
Well Prepare the lesions in LAD & IVUS

Tazuna 2.0x20 16-20atm

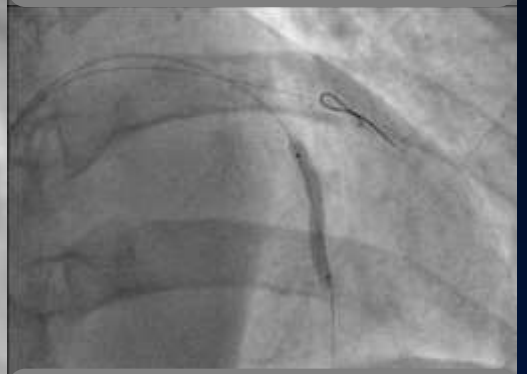


After IVUS sizing, further POBA with Hiryu 3.0x15 14-22atm

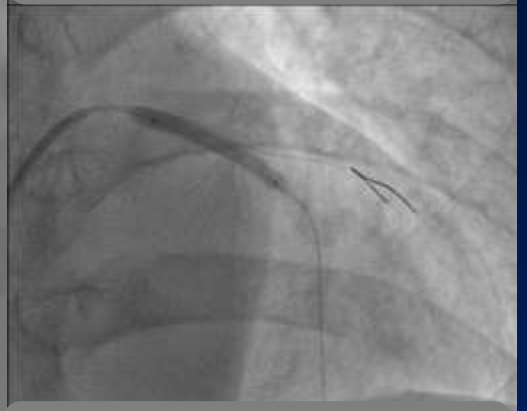




BVS 2.5x28 x 10atm

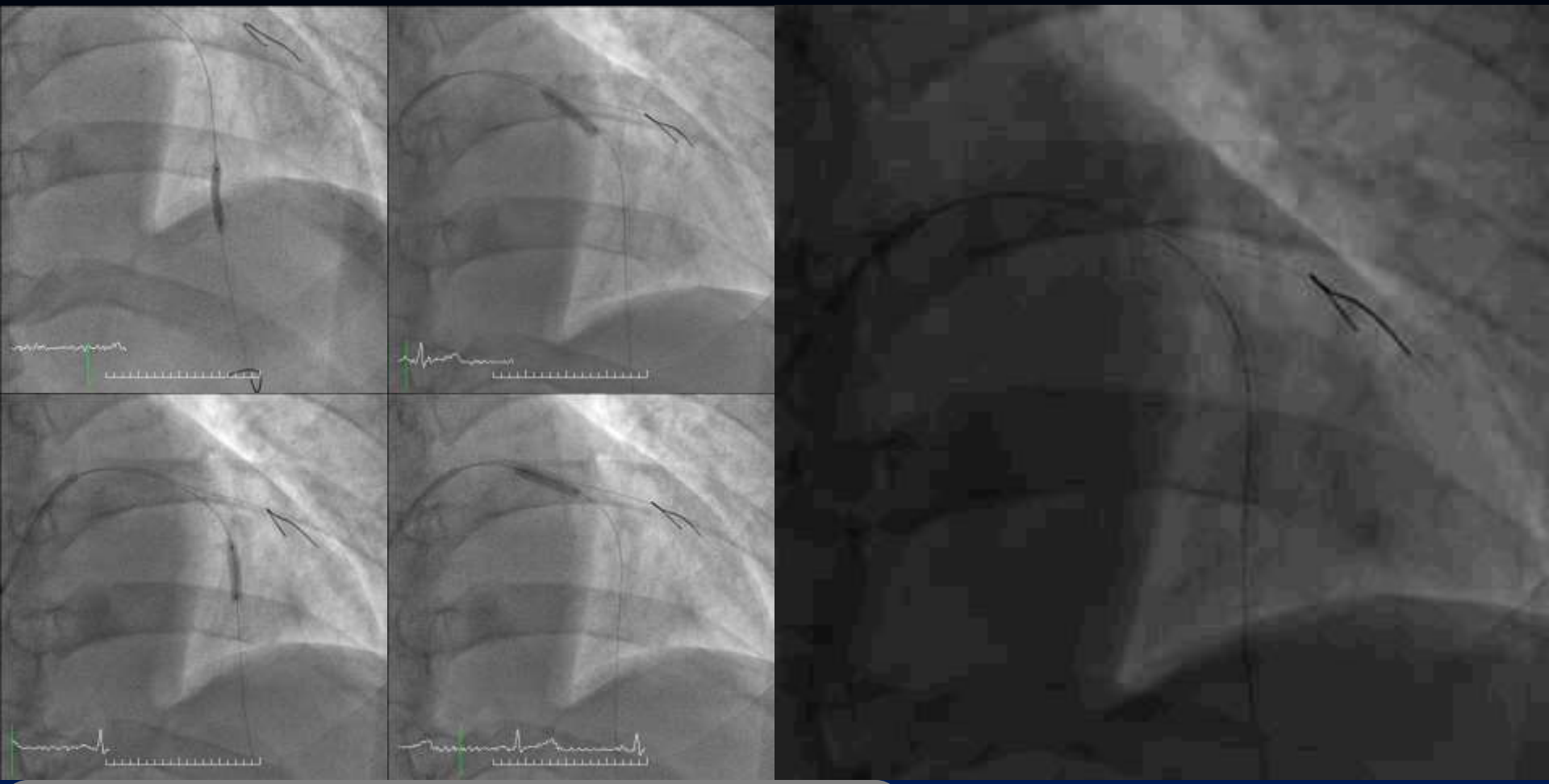


BVS 3.0x28 x 16atm



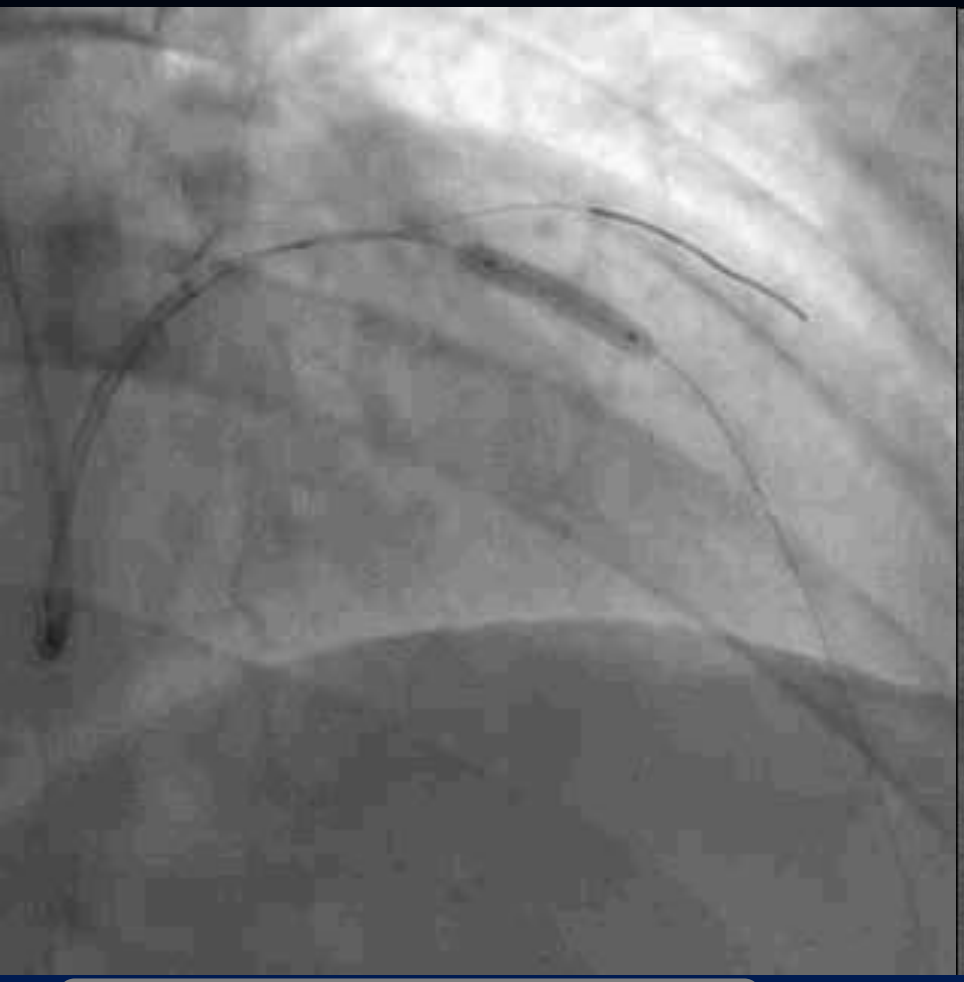
BVS3.5x28 x 16atm

Post dilation

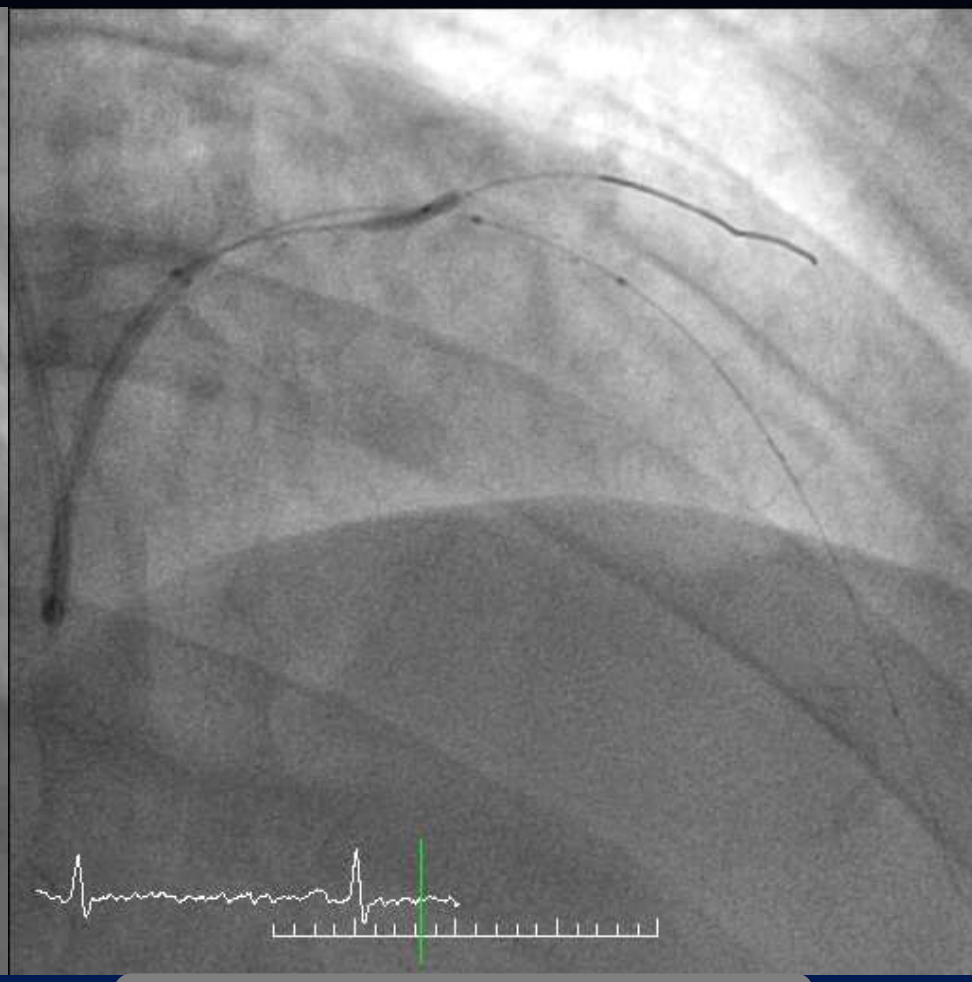


NC Trek 3.5x15 18-24 atm for LAD-m-p
NC-treck 3x15 mm at 16-24 atm for LAD-d-mid

D1-Side branch protection: preserve collateral to CTO of LCX

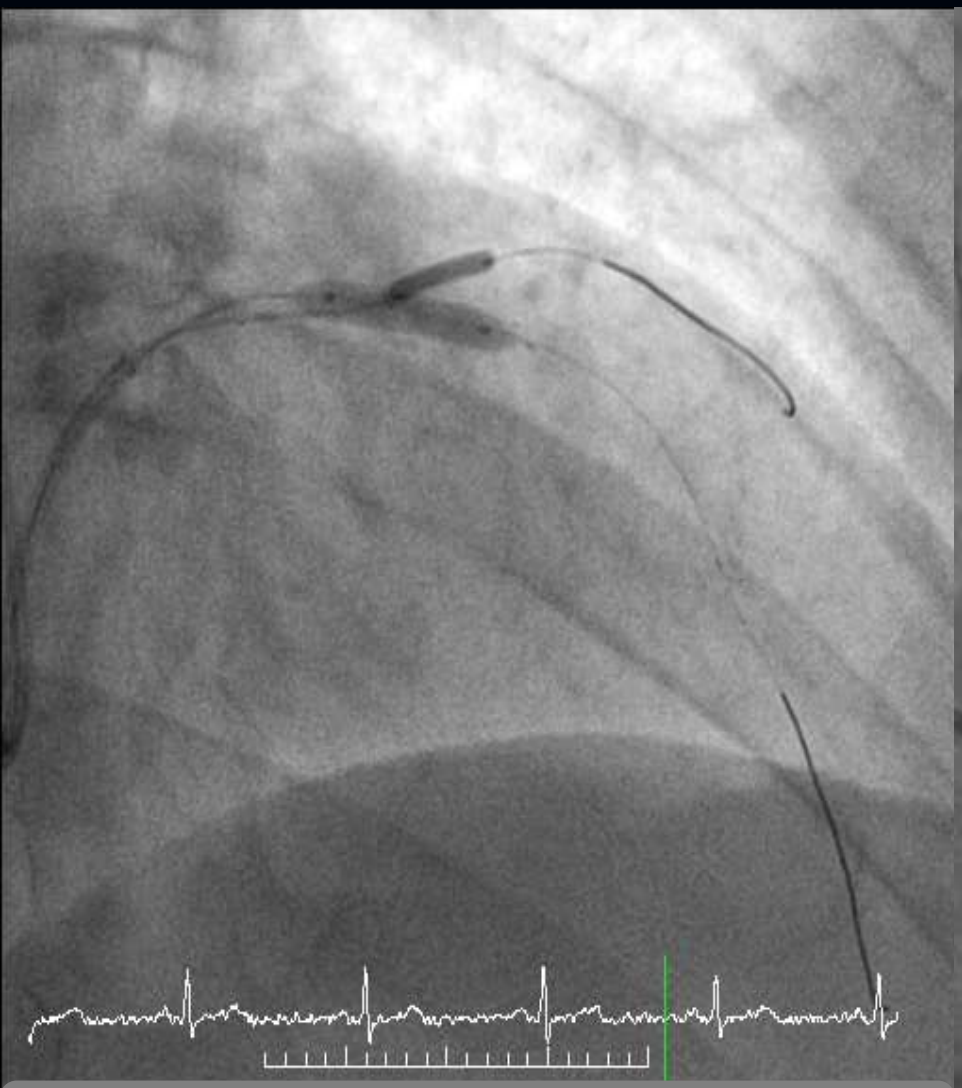


Anchor to pass BVS strut



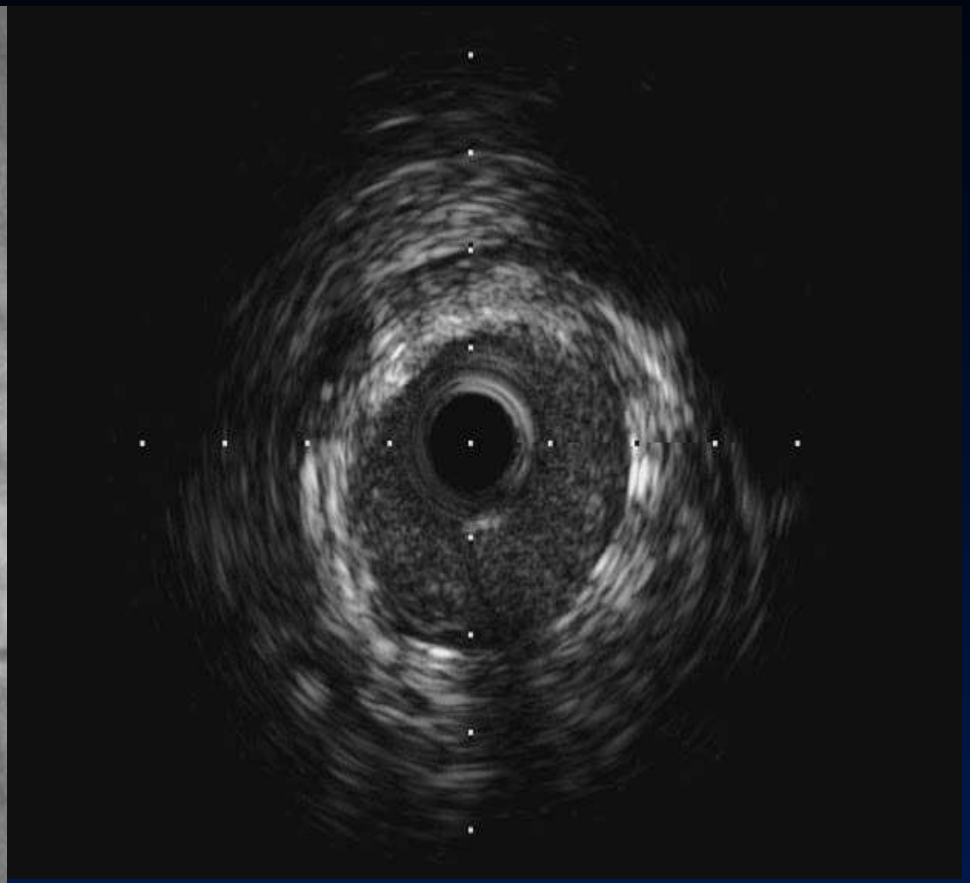
Trek 2.0x12 16atm

Final snuggle kissing ballooning



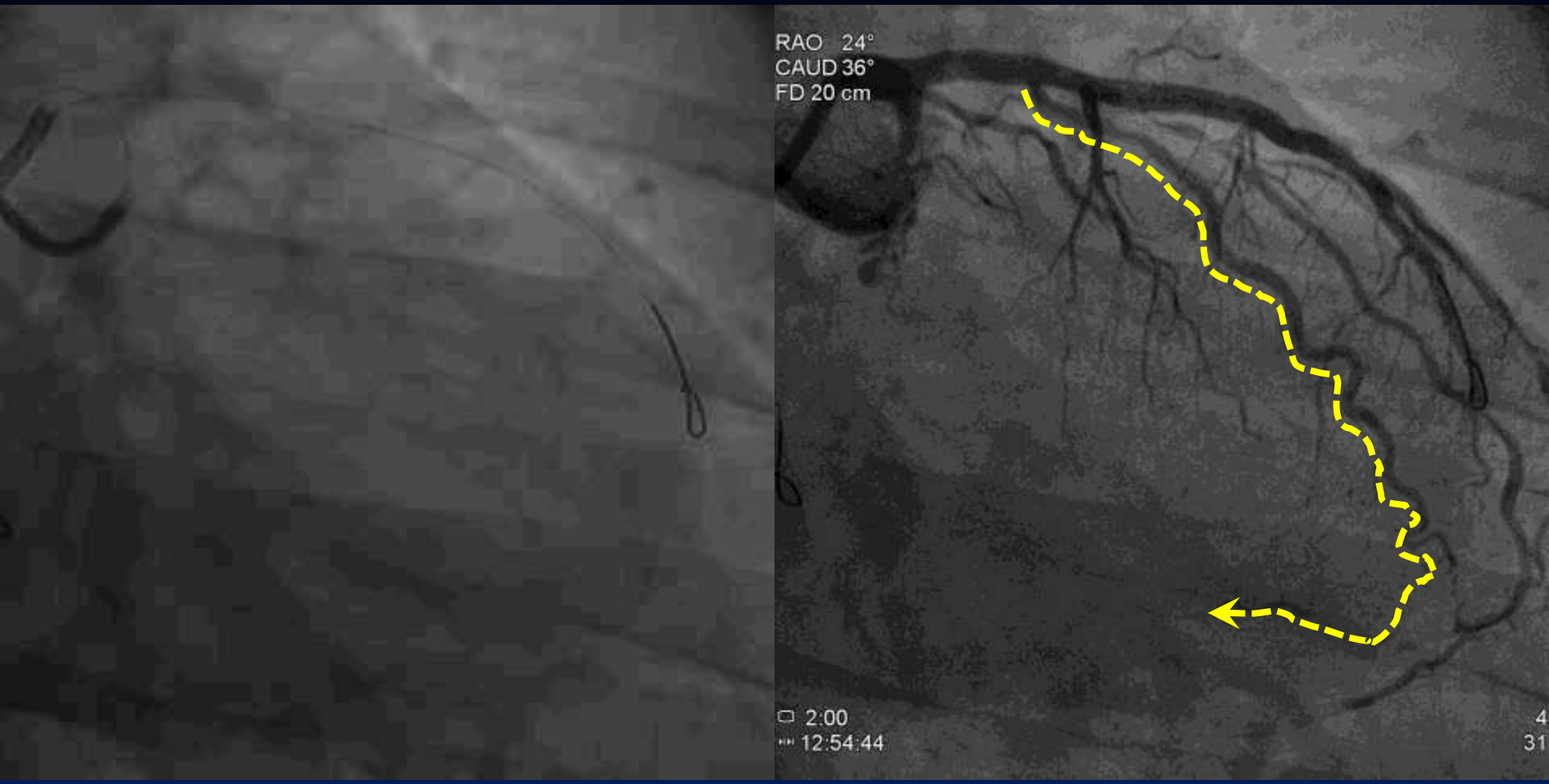
Trek 2.0x12-NC/NC Trek 3.5x15 16/16 atm

LCA final IVUS

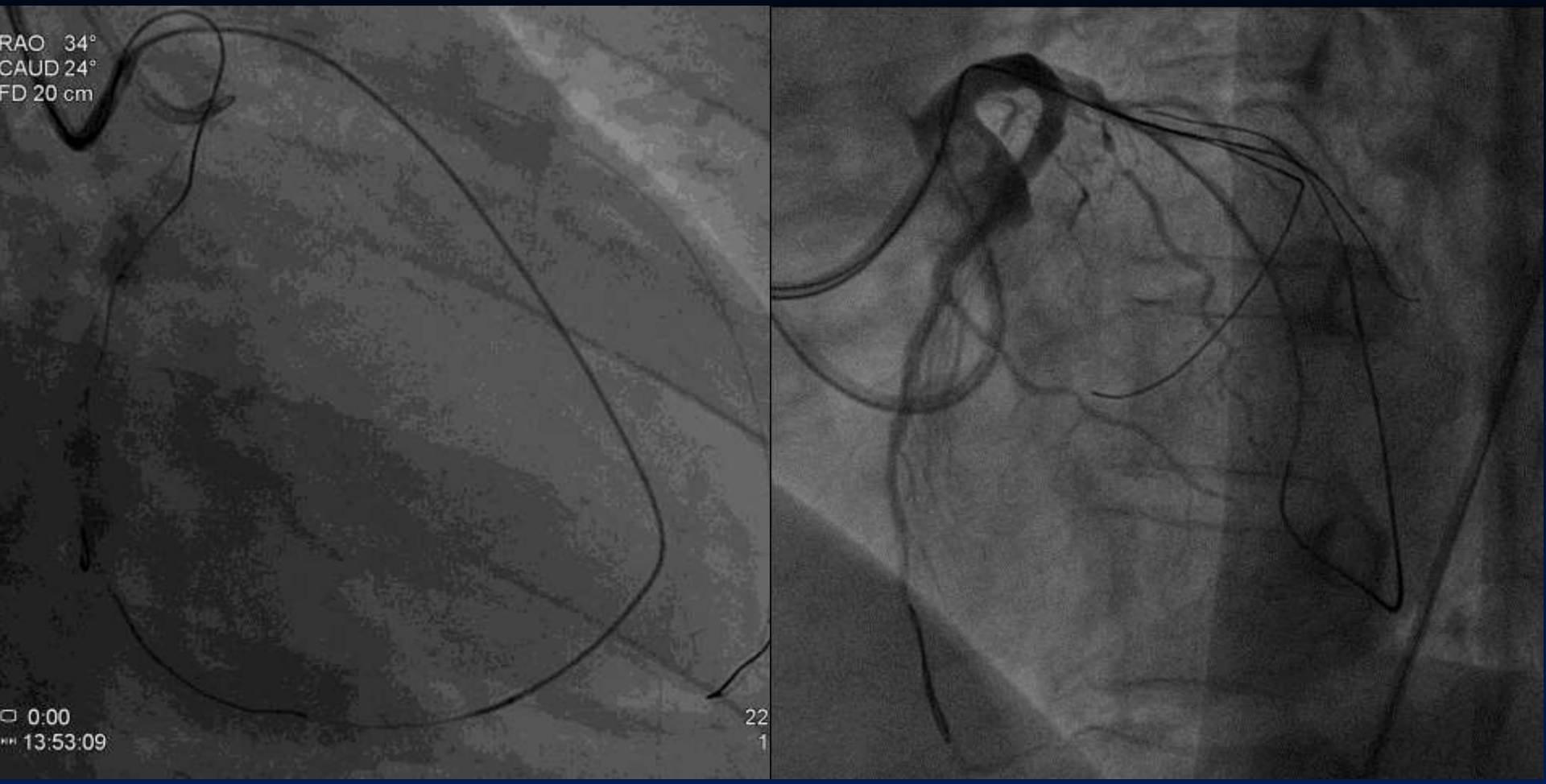


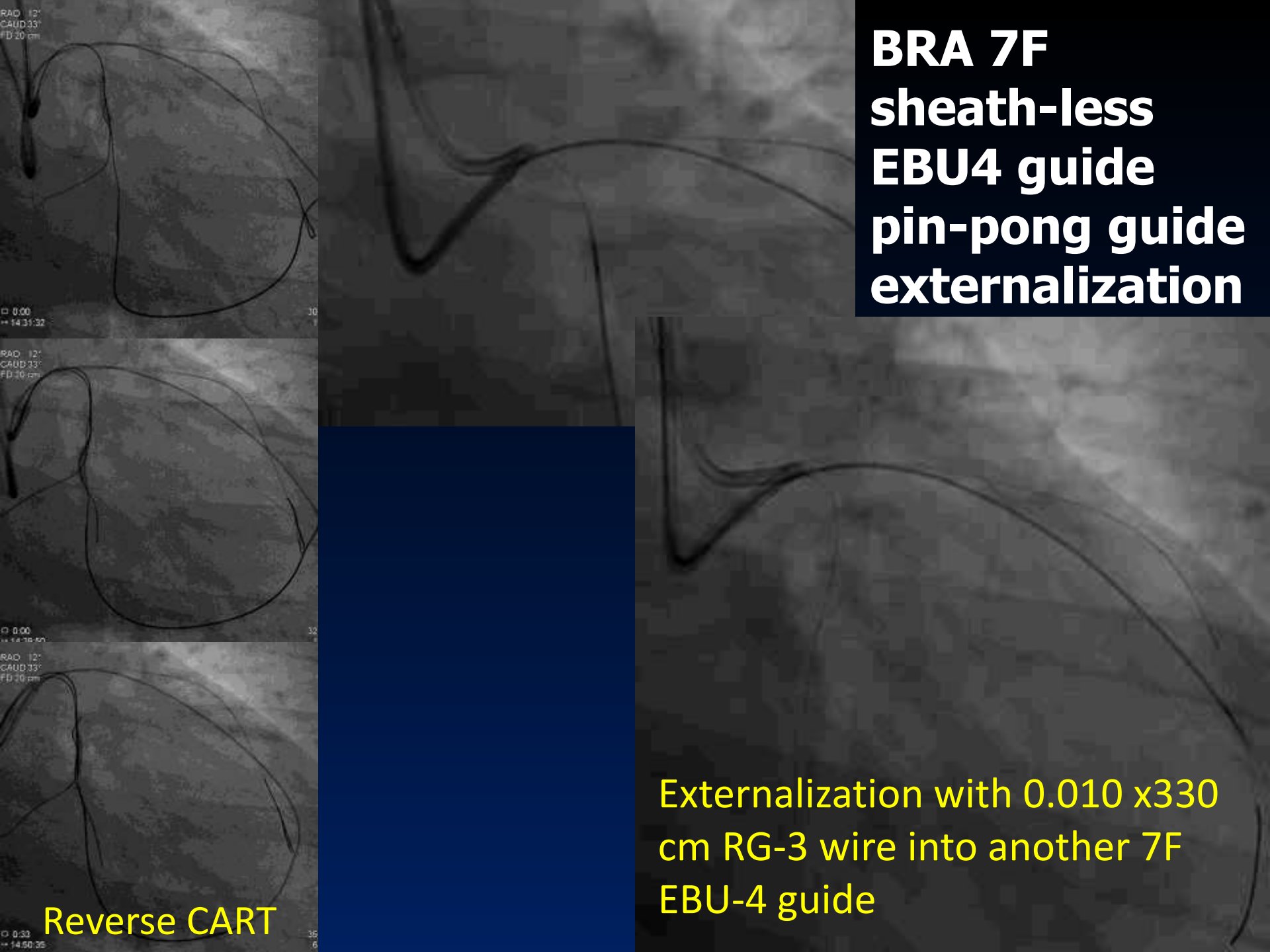
LCX CTO recanalization

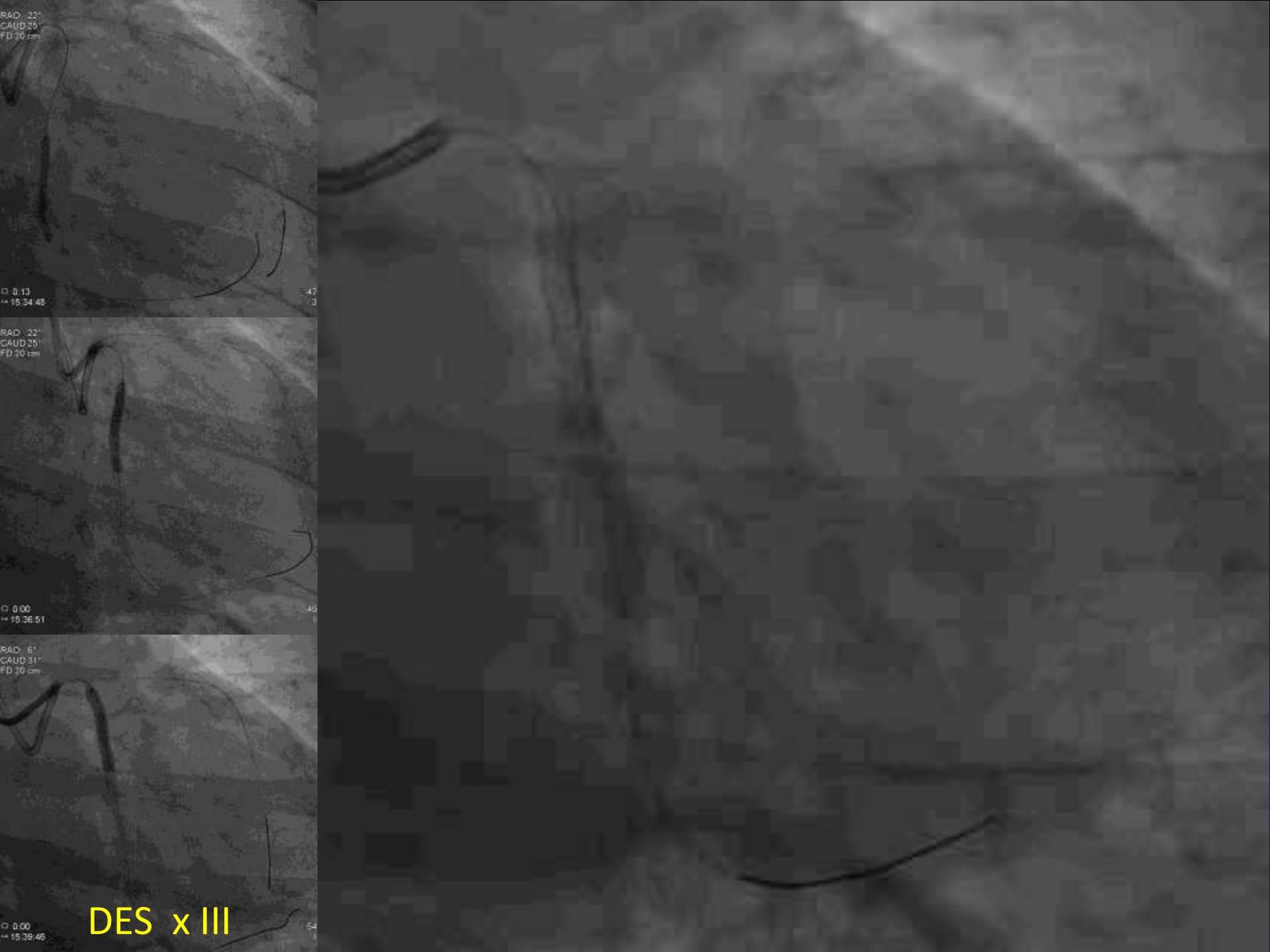
LCA:7Fr EBU4 RCA:6Fr JR4 TRI-sheathless



Return LCX via LAD-D1 retrograde wiring




BRA 7F
sheath-less
EBU4 guide
pin-pong guide
externalization
Externalization with 0.010 x330 cm RG-3 wire into another 7F EBU-4 guide
Reverse CART


DES x III

Lessons from the case:

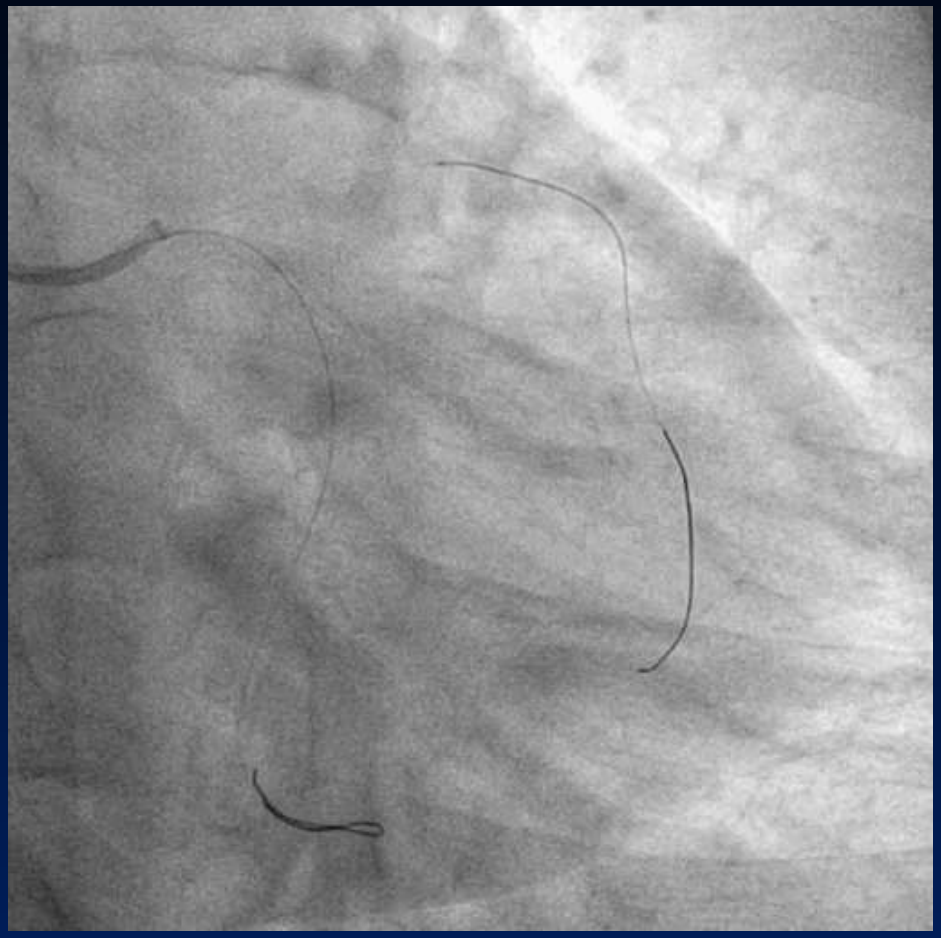
- Complete revascularization of 3 vessel CAD with hybrid use of BVS (LAD, RCA) and metallic DES (LCX) in young pt might be equivalent to conventional CABG (MACE free & asymptomatic for 2 years)
- Snuggle kiss for keeping D1-LCX epicardiac retrograde route is the key of PCI success of LCX CTO
- Aborted BVS due to CX size of > 4.2 mm for avoiding scaffold malapposition

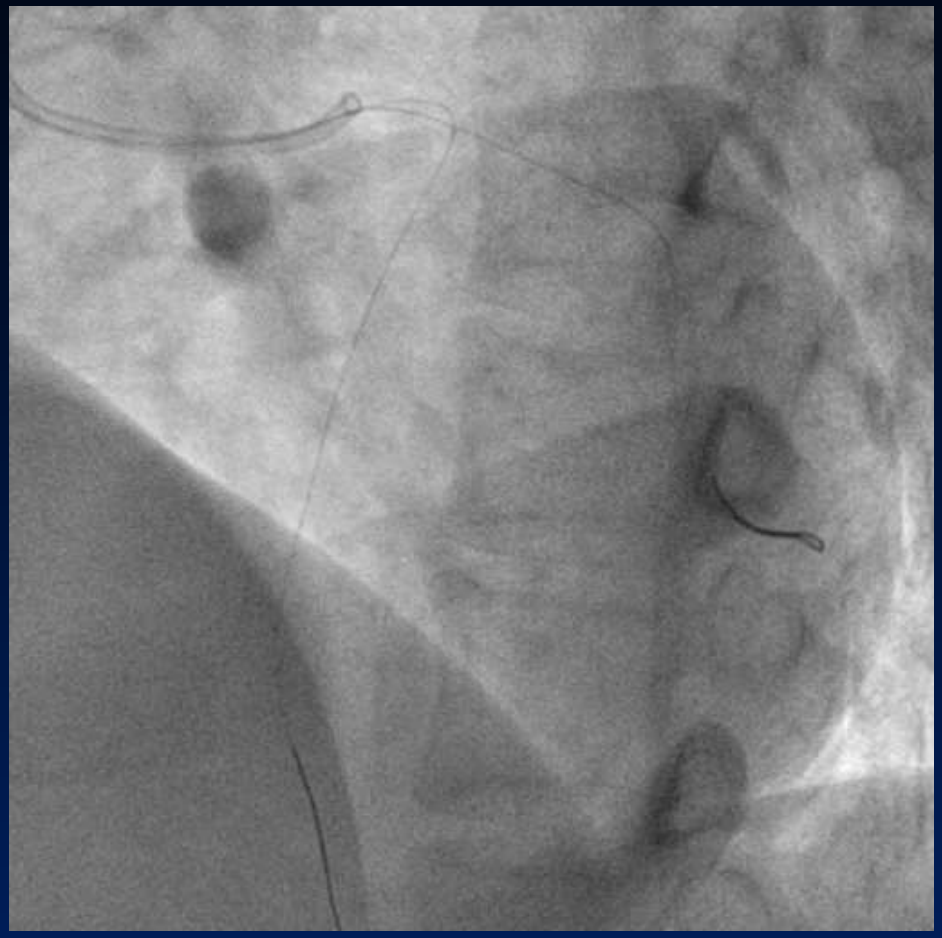
Brief history: case No. 3

- A 27 y/o male
- **Risk factor:** HTN, Hyperlipidemia, Smoking
- **History:**
  - 2016-08-21 : Referred from General Fu-Jou Hospital, Fu-Chien Province, China with LM and Triple vessel CAD, refused CABG and PCI with metallic DES
  - Request for 2nd opinion to Taiwan

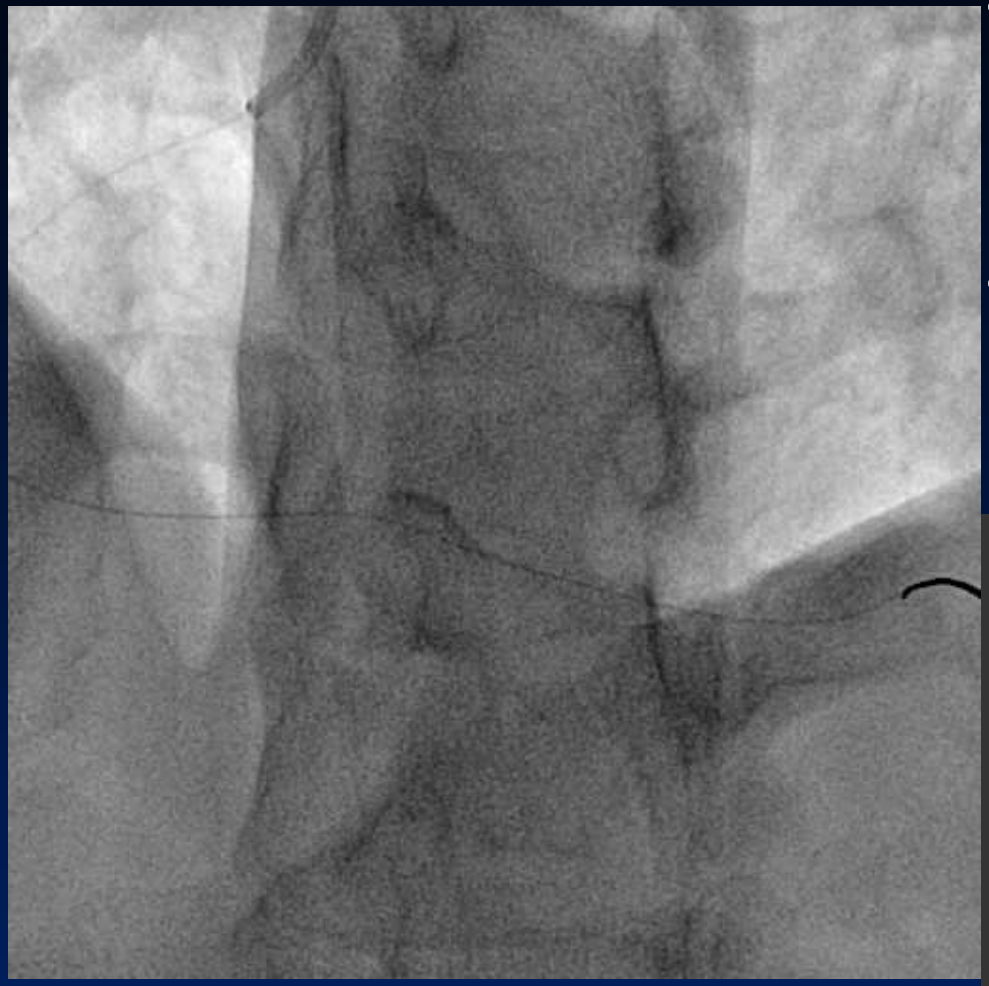
LCA baseline

LCA baseline

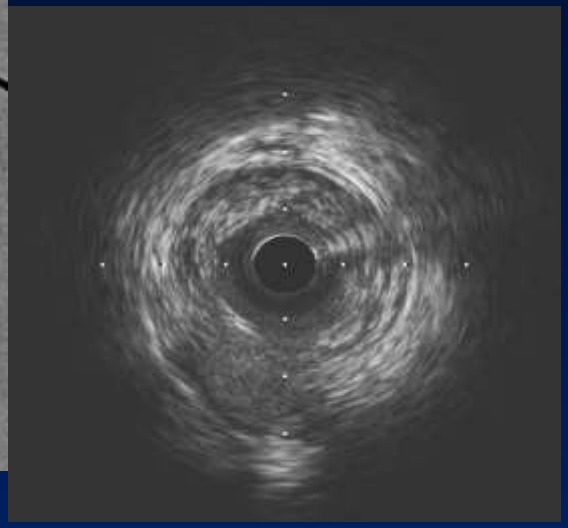




RCA angiogram and PCI Strategy

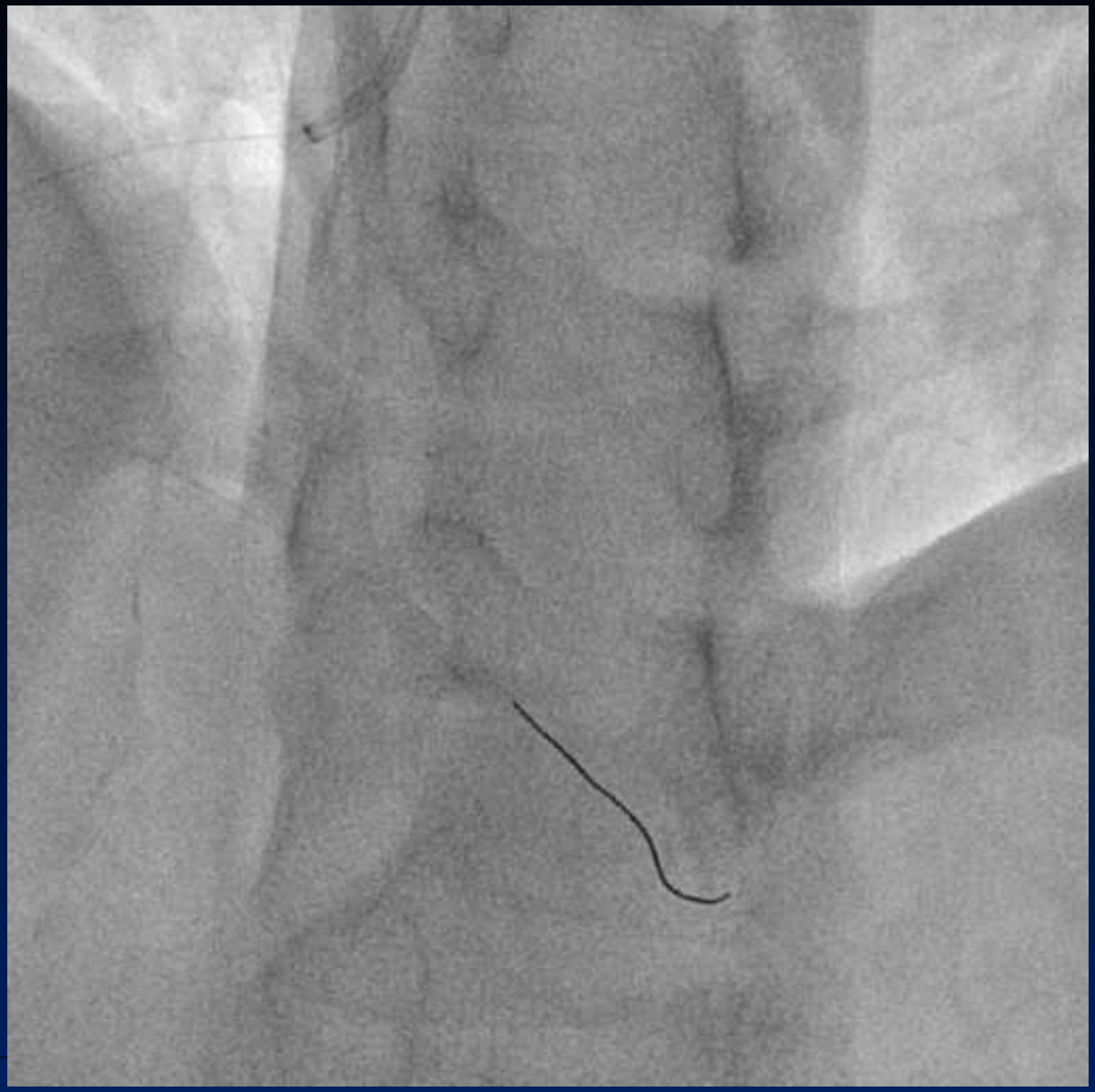


- Ostium RCA had eccentric plaque and MLA of 4.1 mm2
- Two BVS at PLB (ABSORB 2.5x28mm, 3.0x18mm) under IVUS guidance

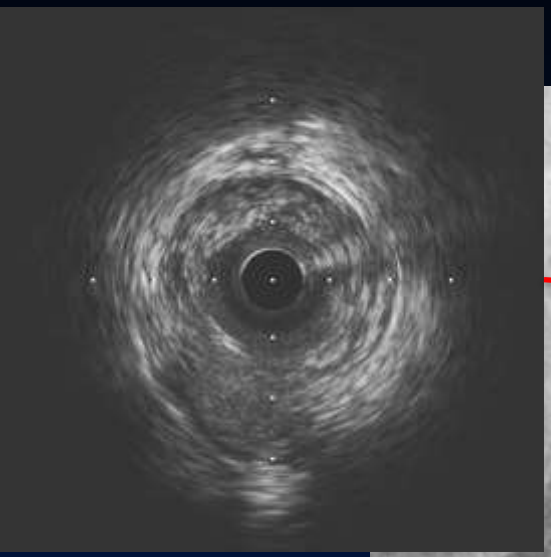


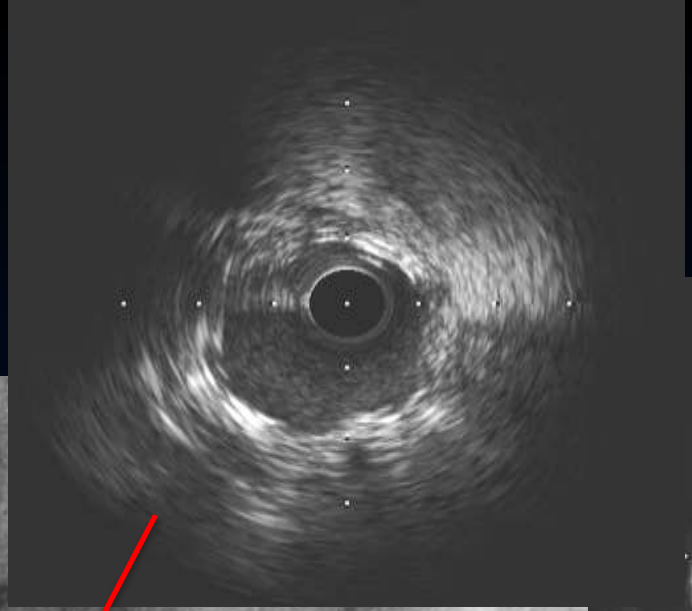
Ostium RCA
MLA : 4.1mm2

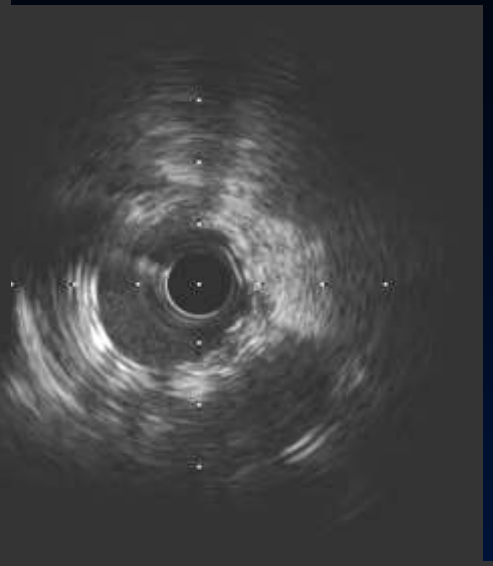
RCA Final

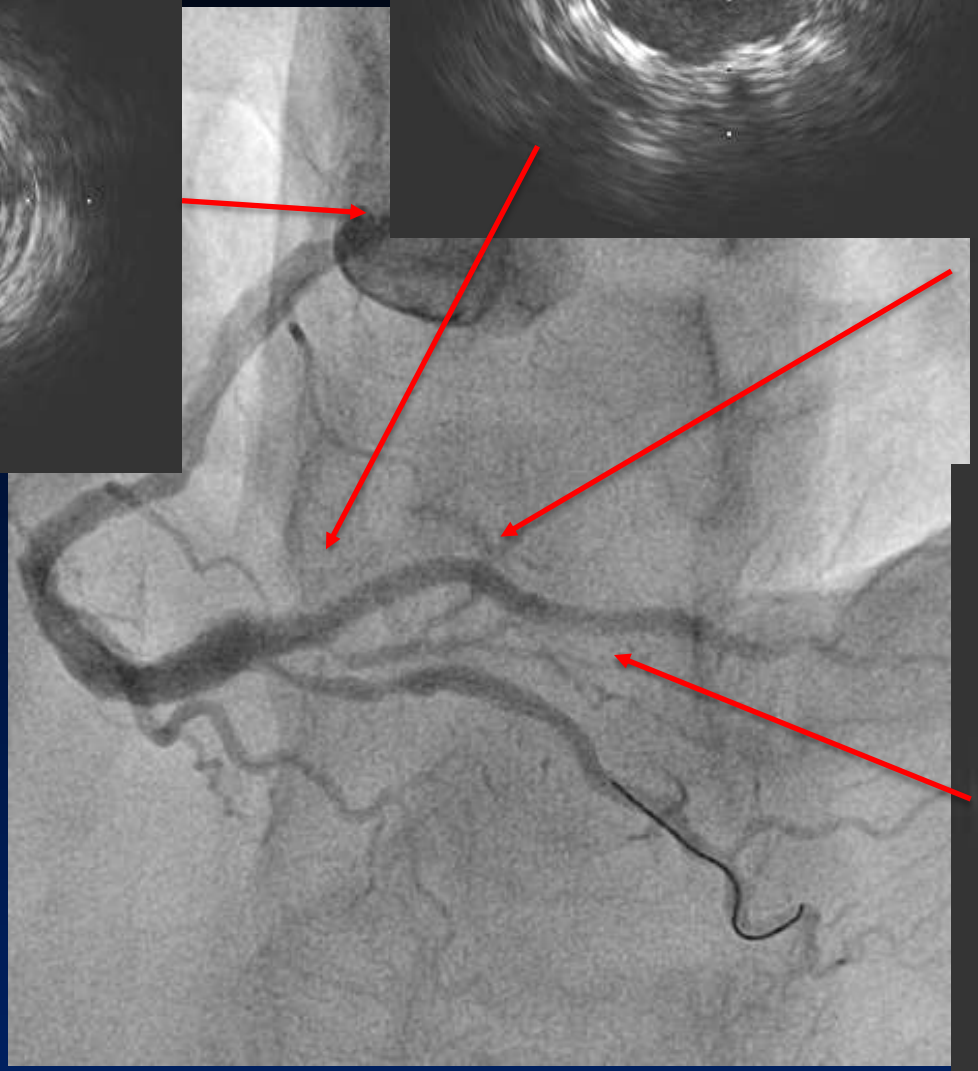


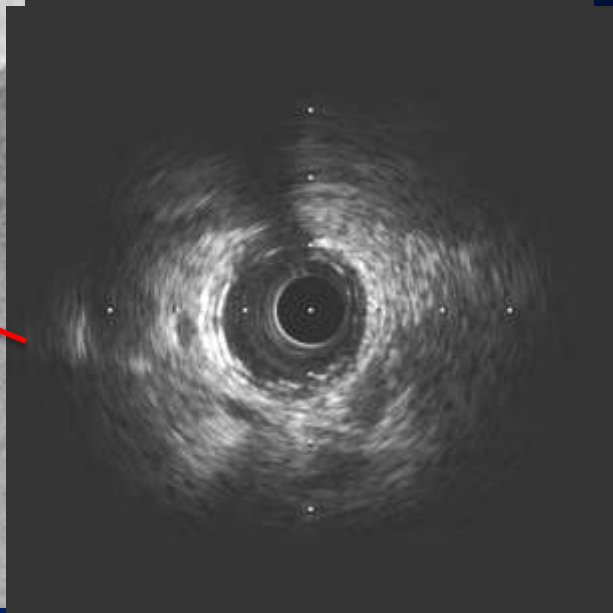
RCA Final IVUS







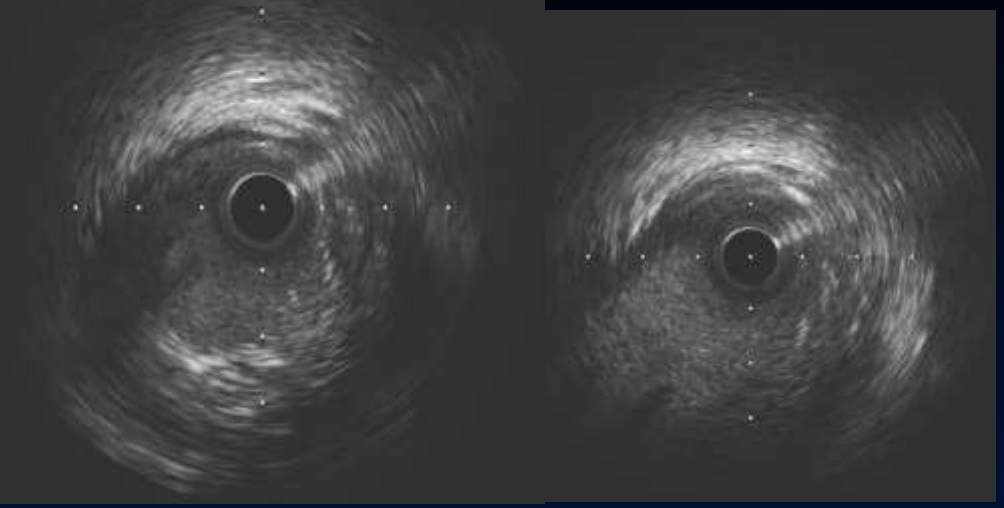




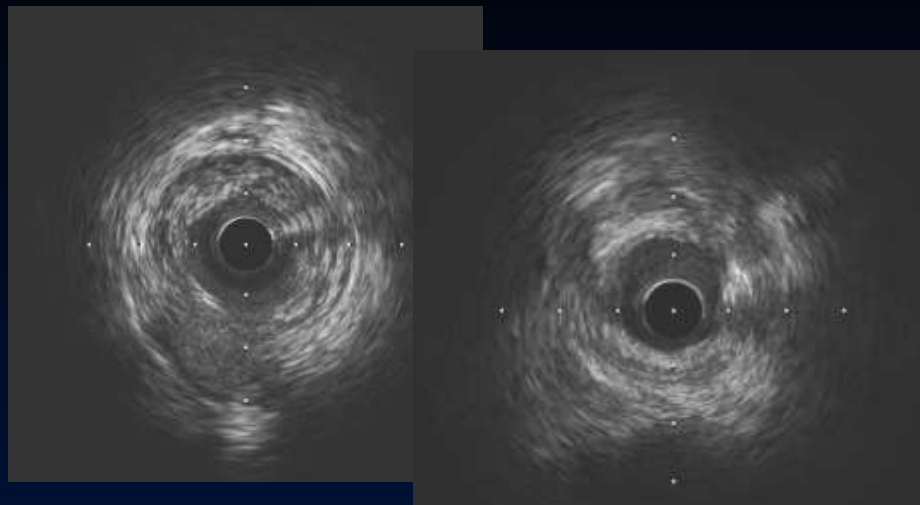
RCA-os
MLA:4.1 mm2

IVUS from LCx to LM

LM-distal

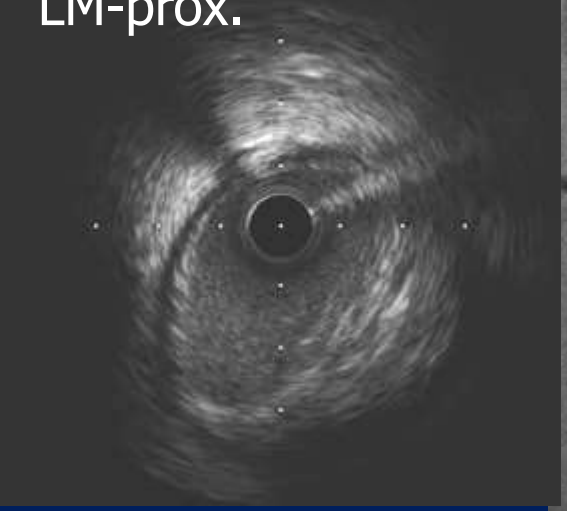


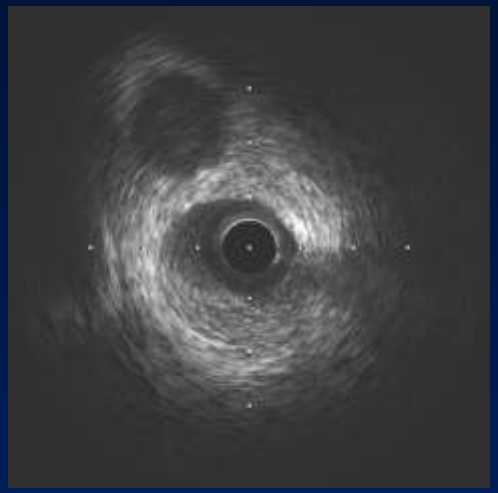
MLA:4.5mm2



MLA:2.61mm2

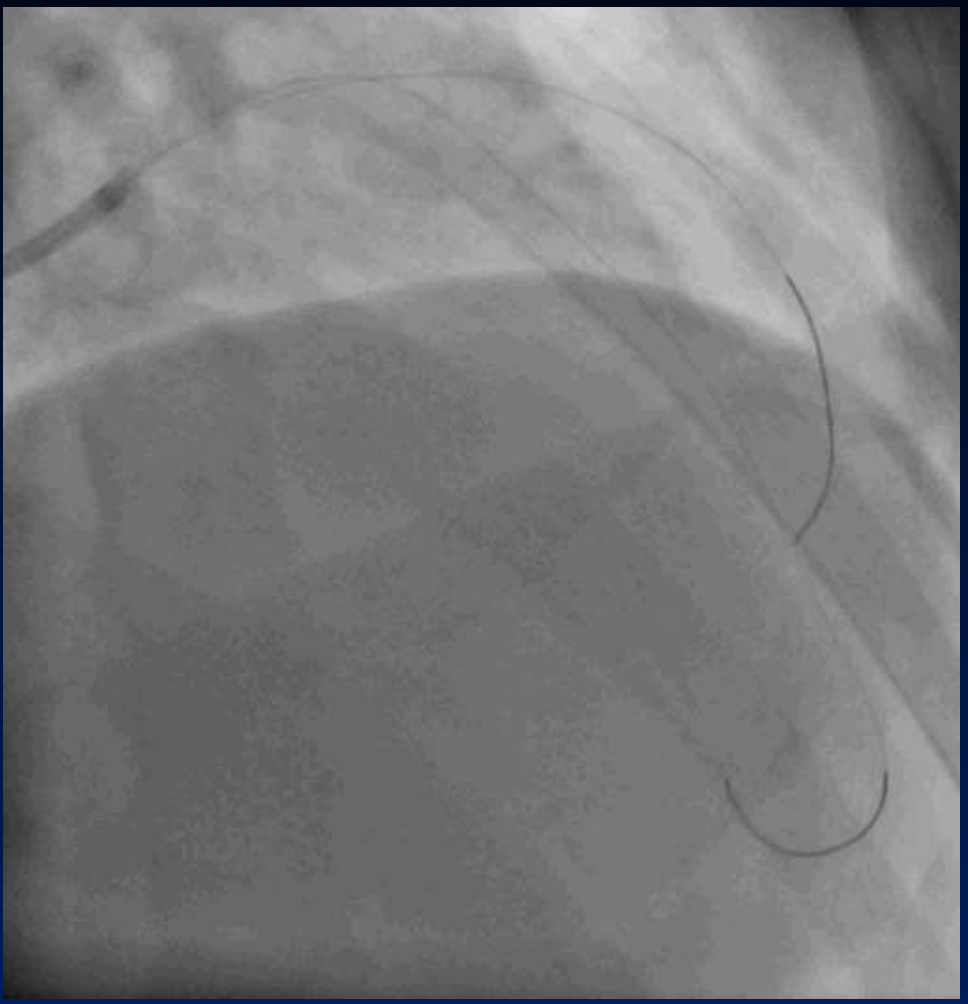
LM-prox.

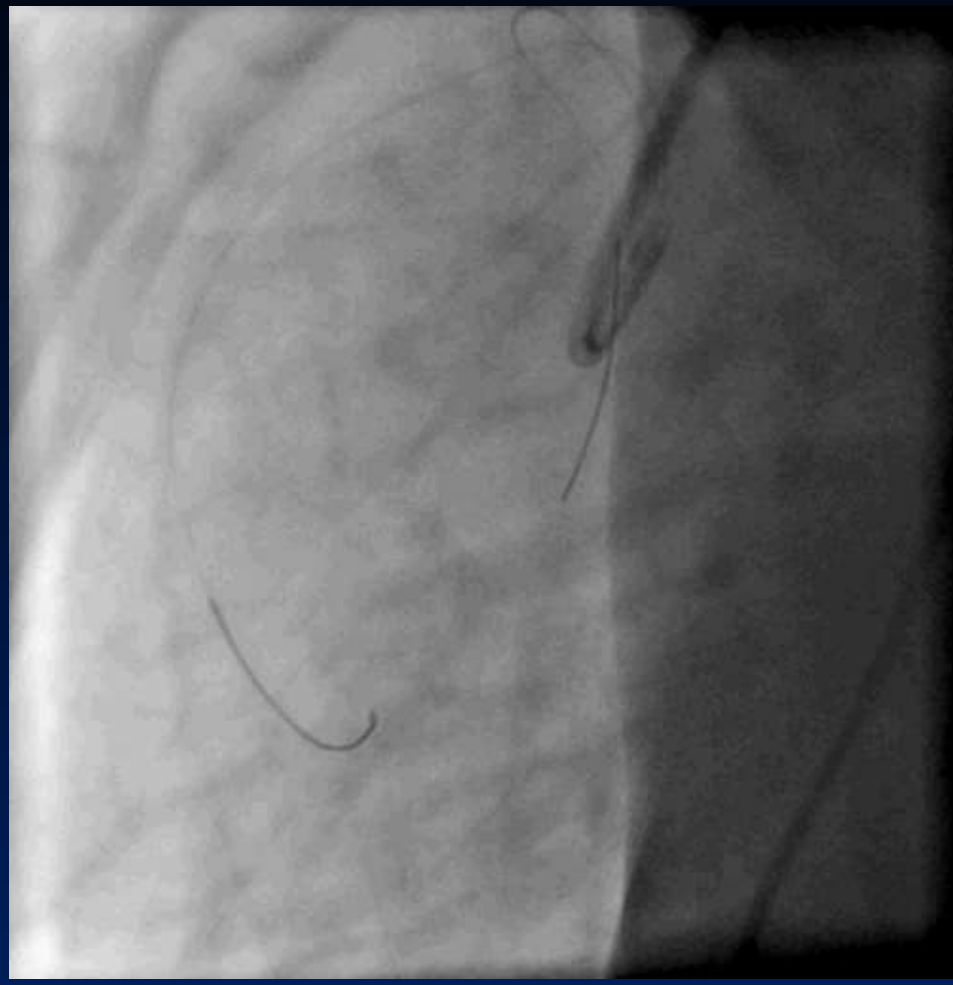




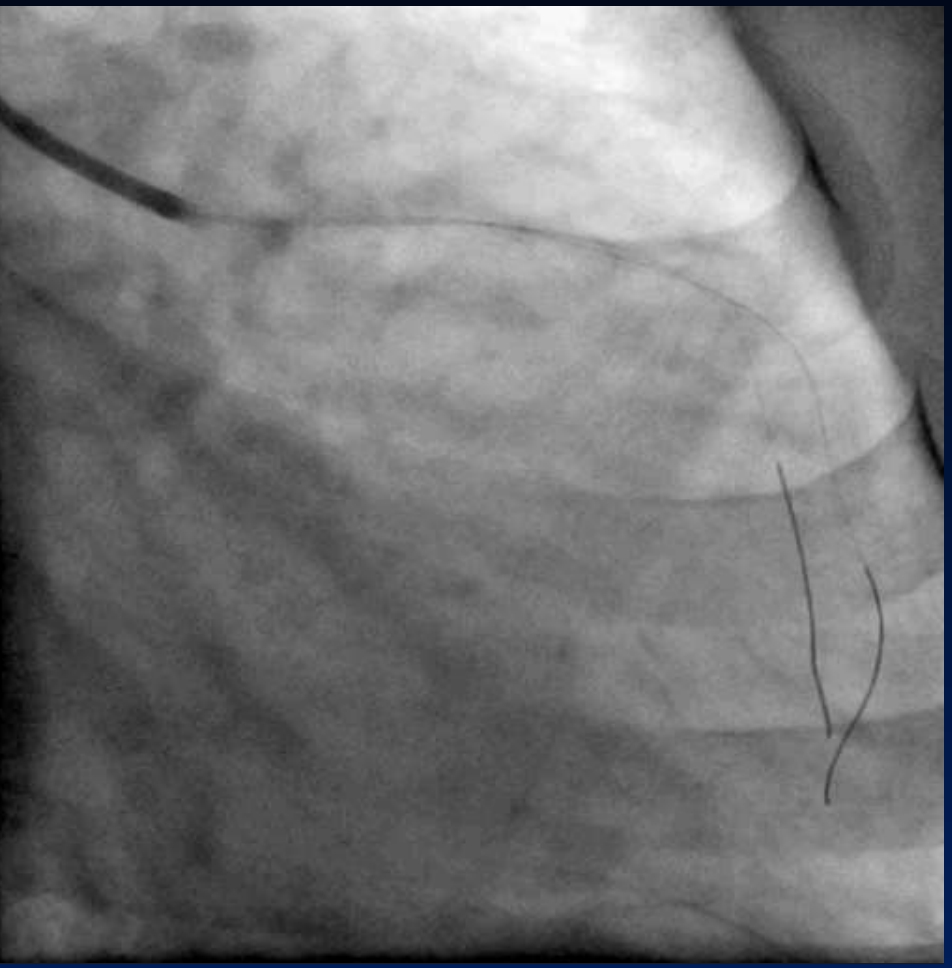
Two Days Later: Live Demo. For AICT-2016

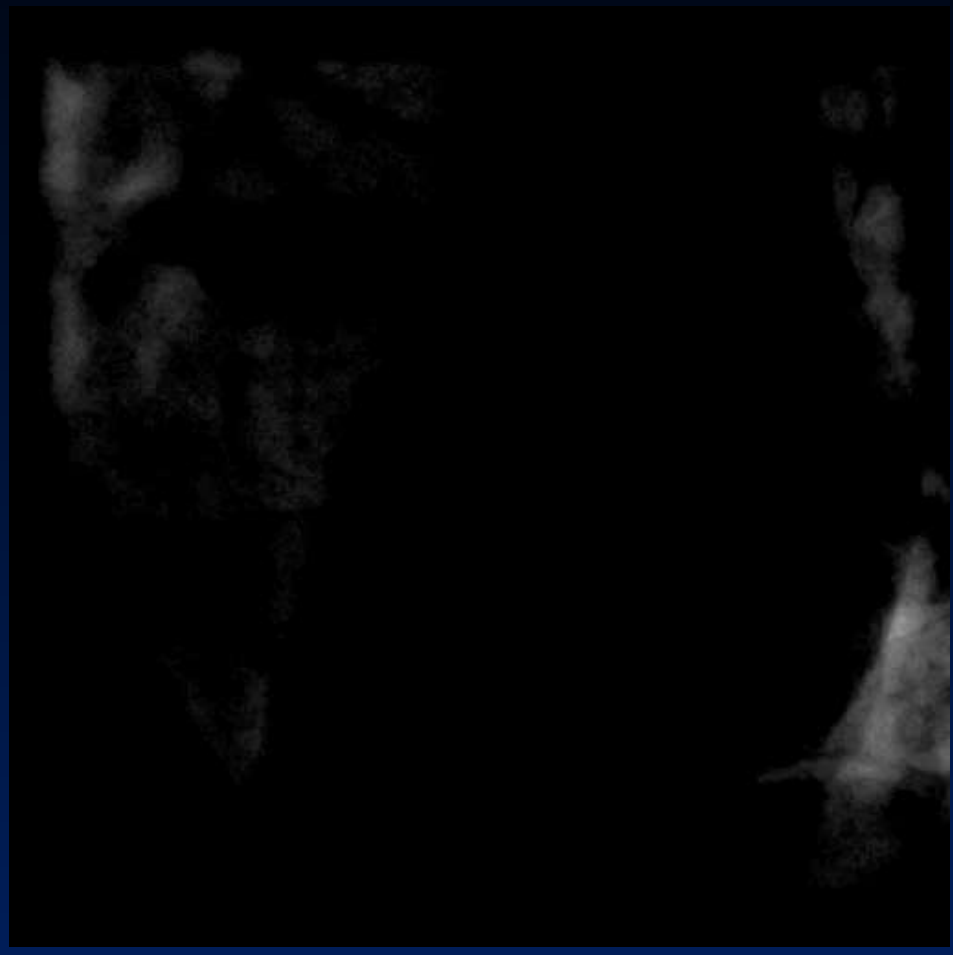
LCA angiogram: TR 7F EBU 3.5 with Glide-sheath



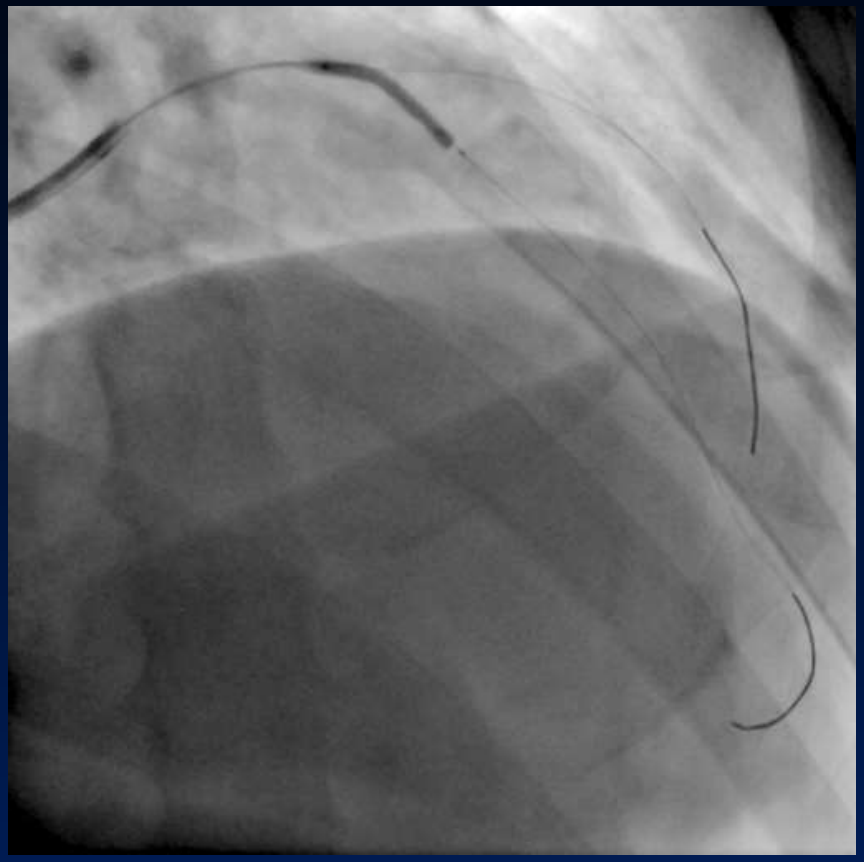


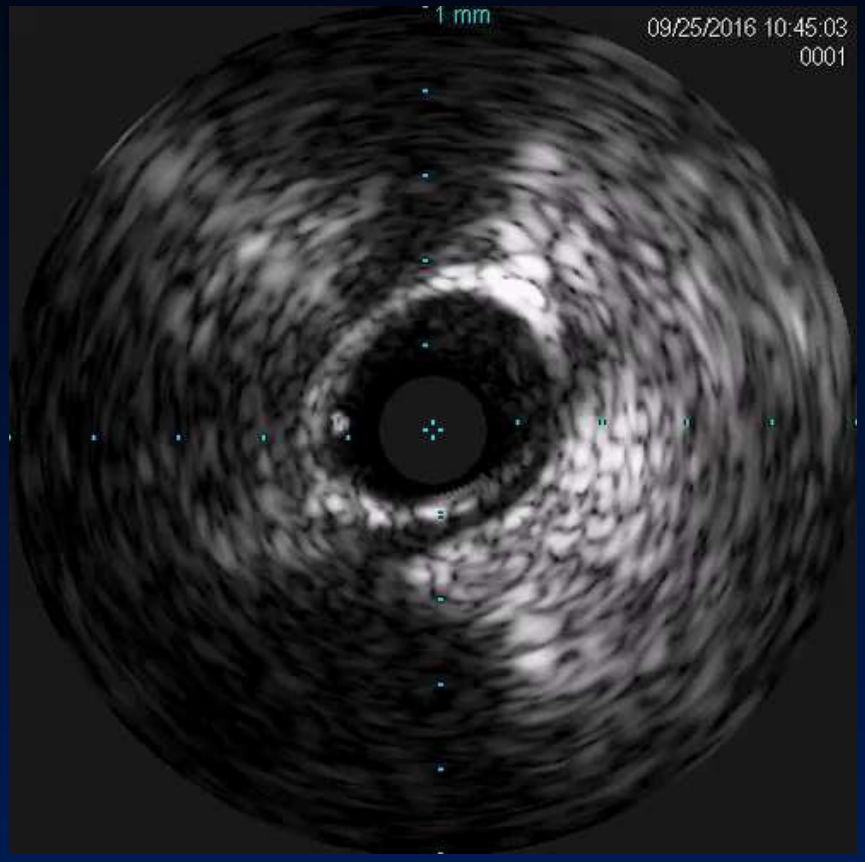
LCA angiogram: easy damping at LM-os engagement





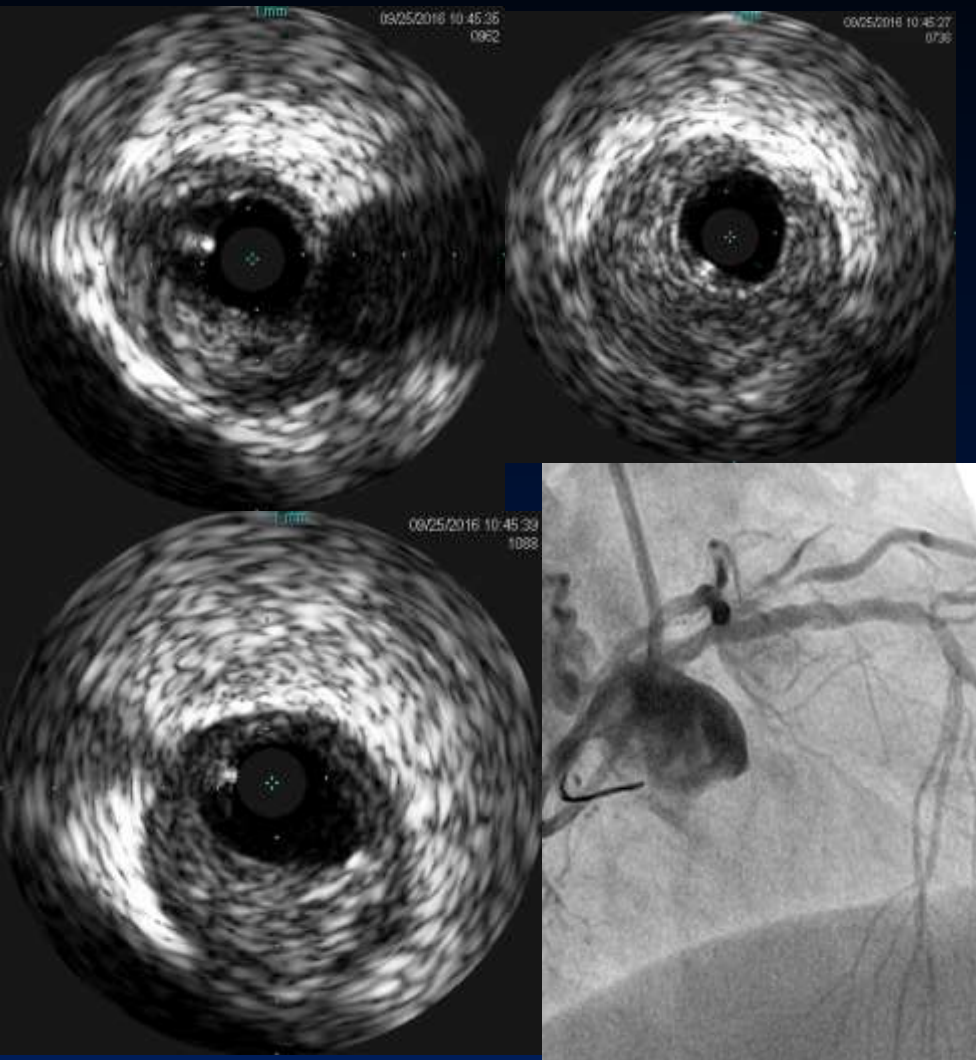
Balloon for LAD and IVUS

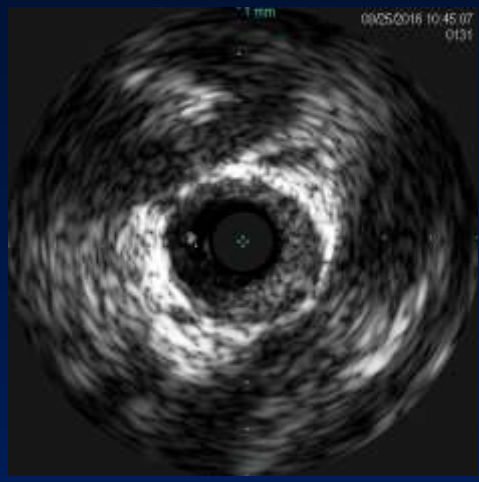




2.0 balloon for LAD and D1

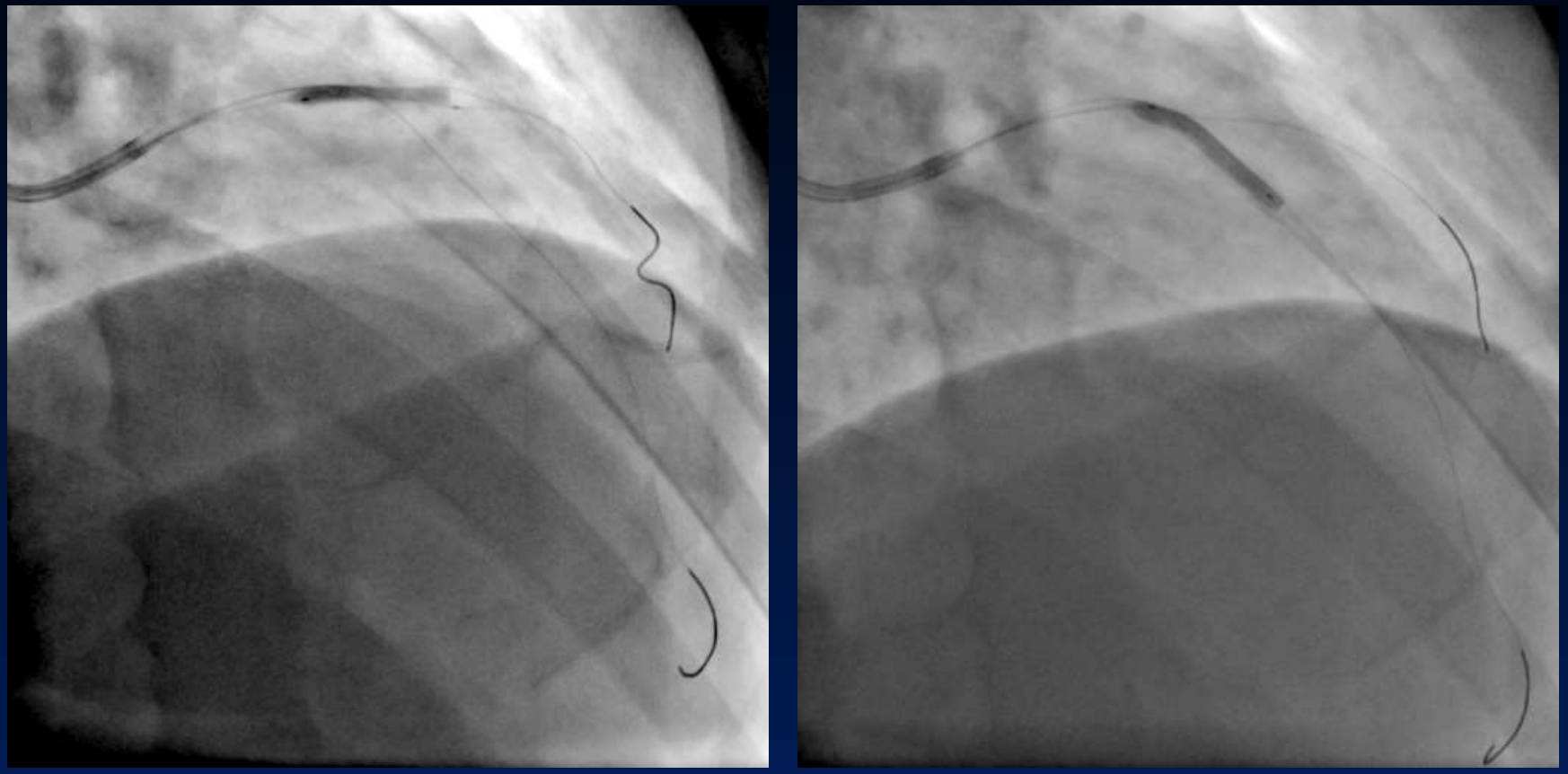
IVUS to LAD-LM





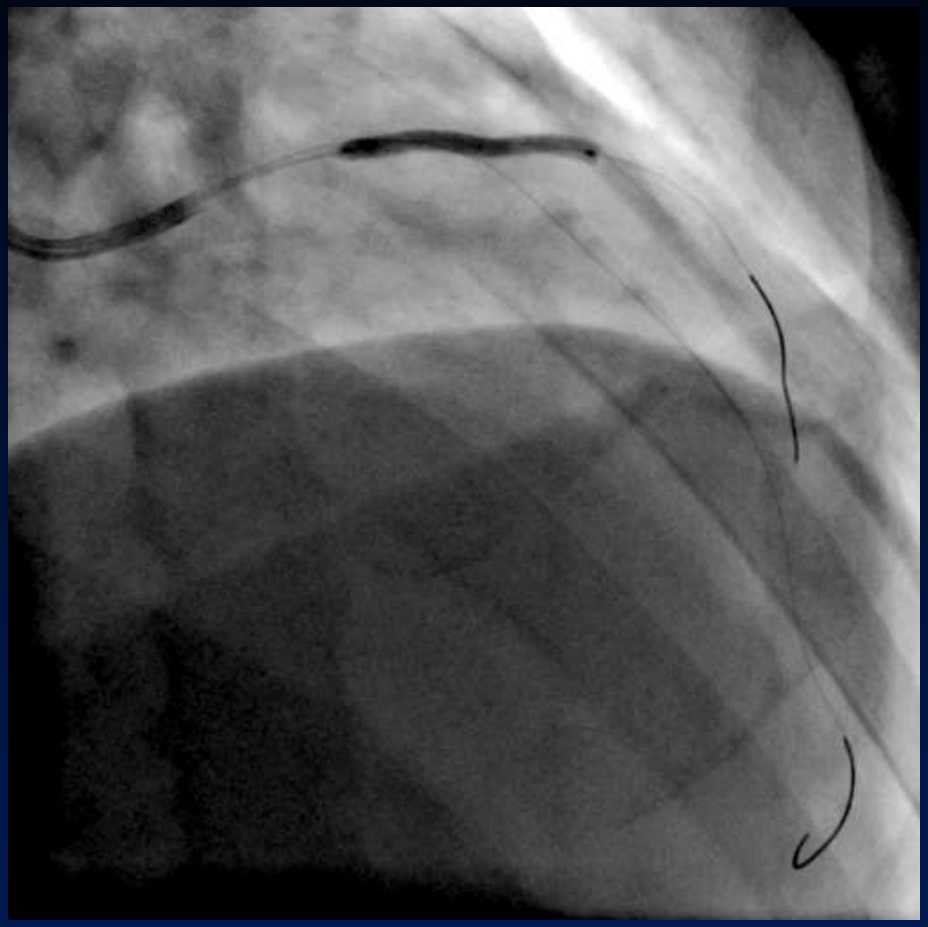
LM-d MLA = 4.3 mm2

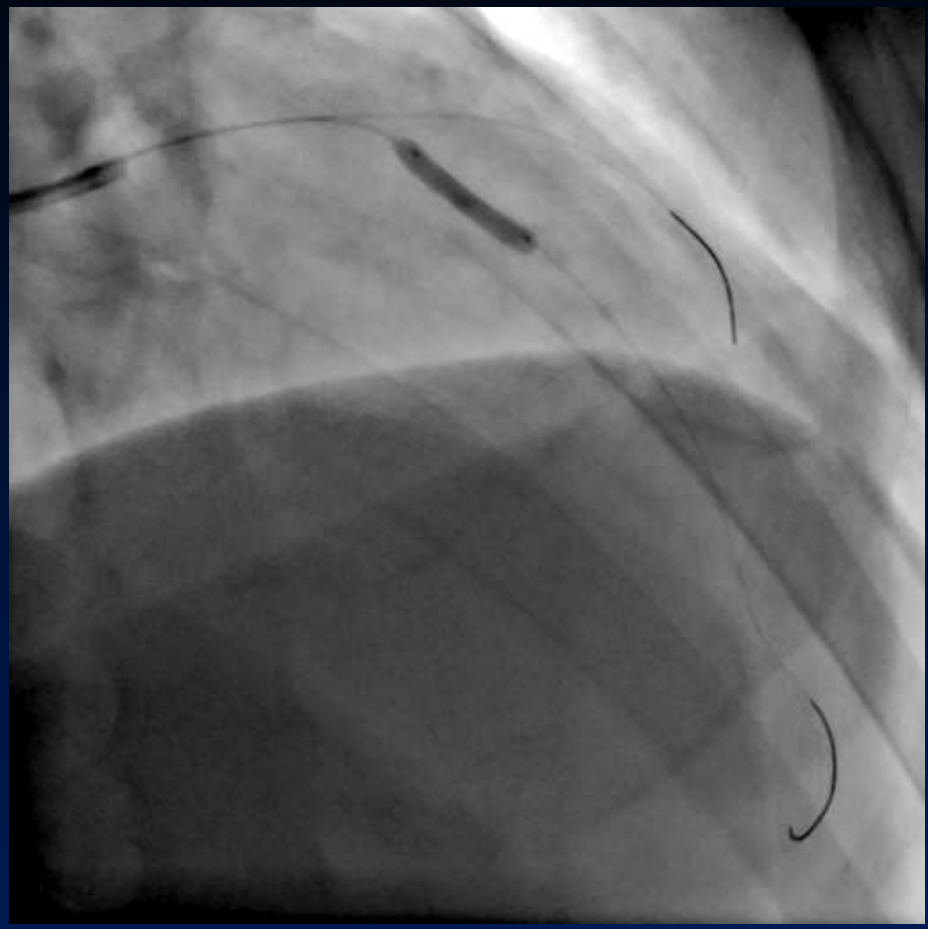
Scoreflex balloon to Diagonal and LAD



ScoreFlex balloon 2.5x20mm for D1 (6-8 atm) and LAD (16 atm)

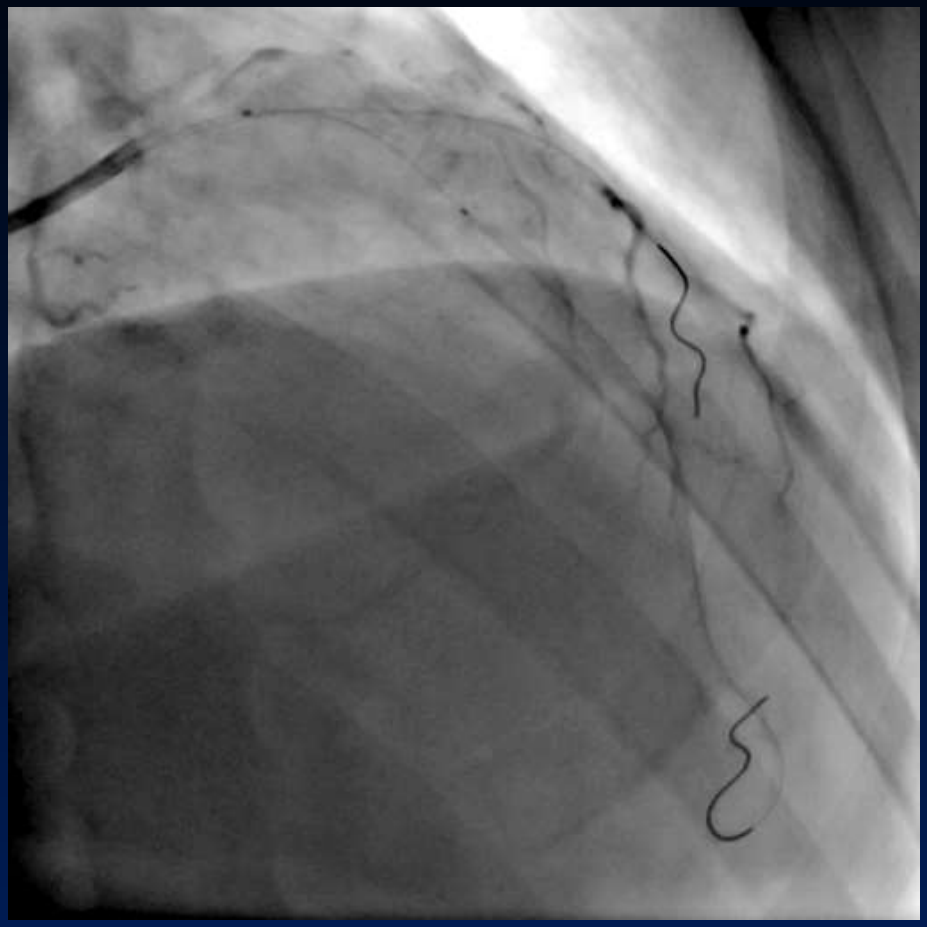
DEB to Diagonal and HPB to LAD

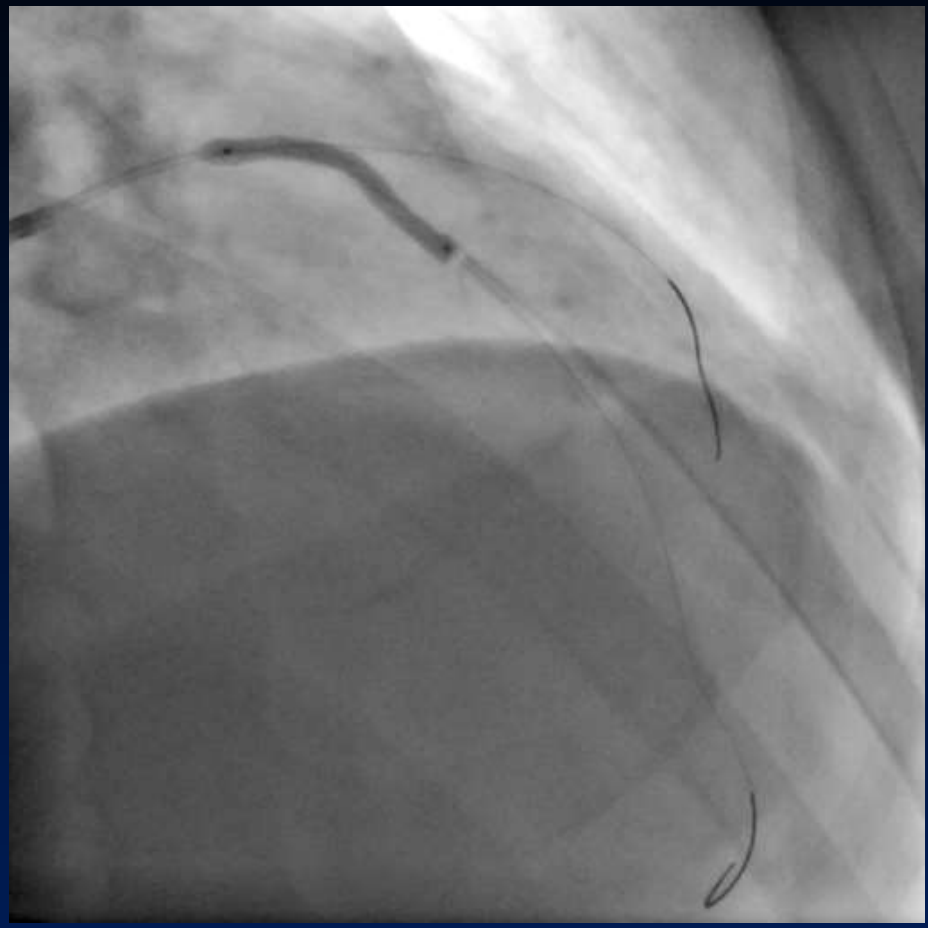




B. Bruan Sequent Please 2.5x26mm for D1 (8atm) 60 secs and 3.0x15 mm to LAD (24atm)

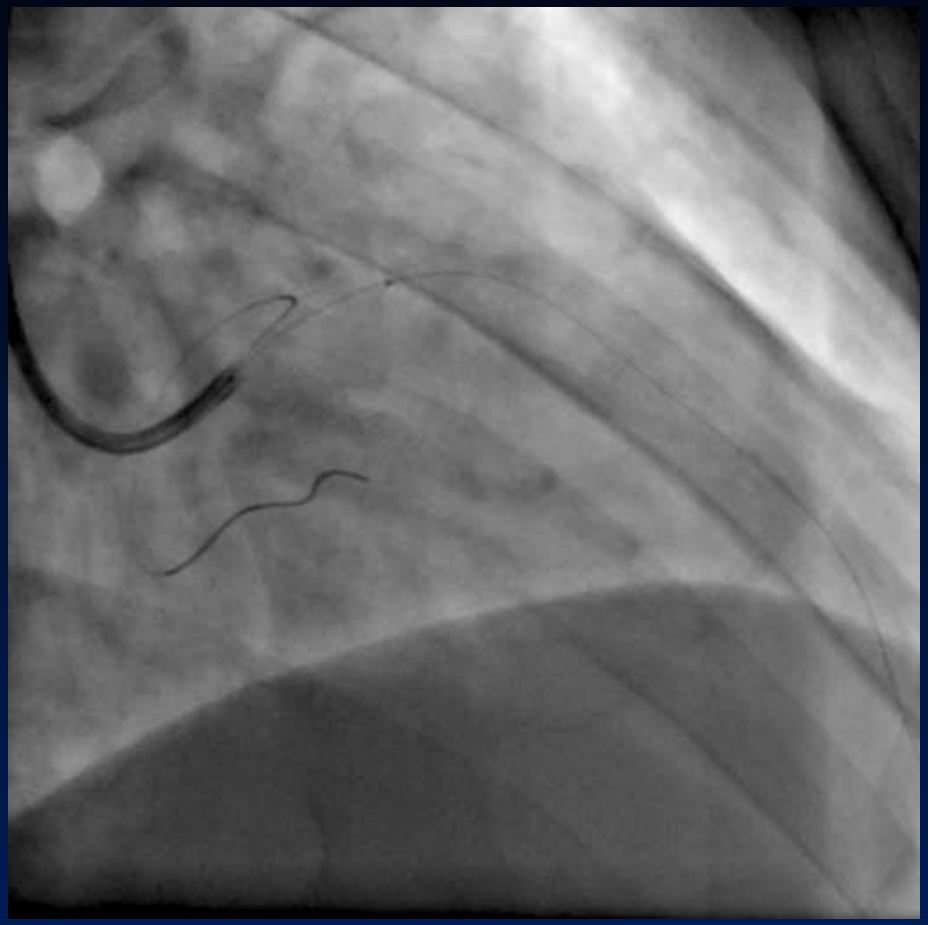
BVS from mid-proximal LAD with wire protection at D1

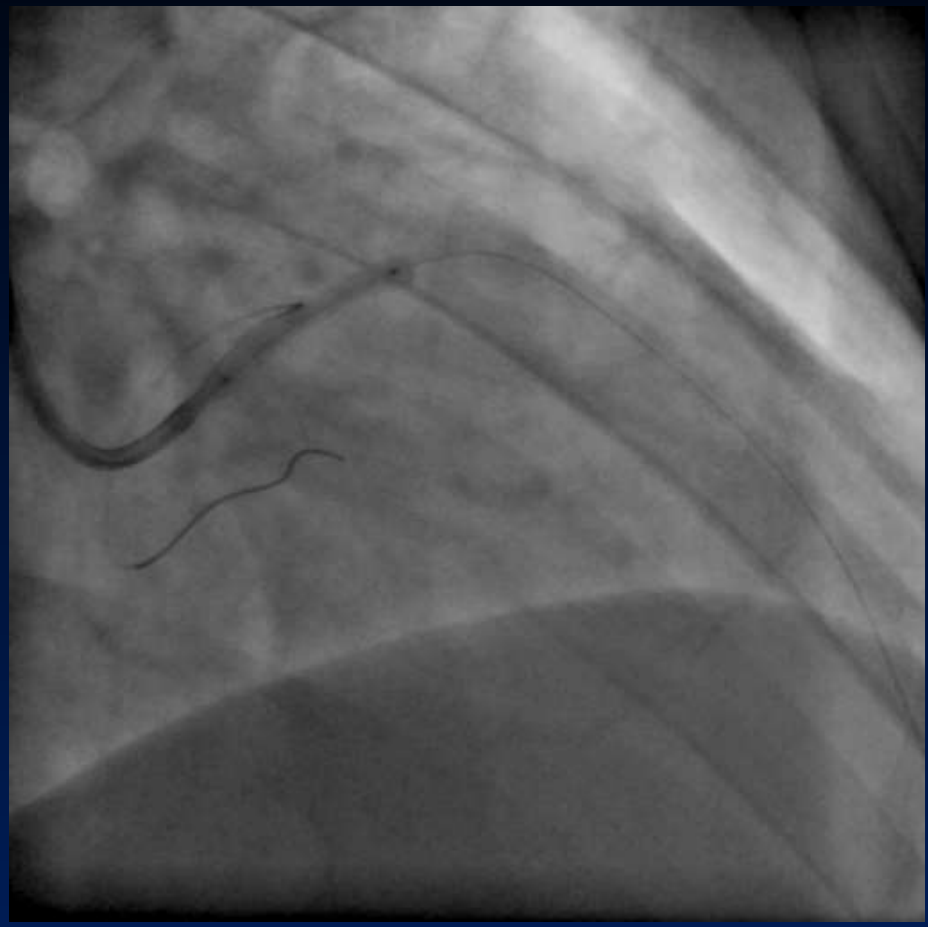




ABSORB GT1 3.0x28 mm (slowly inflation at 10 atm), post-dilate 3x15 mm at 20-24 atm

BVS from Proximal LAD to ostium LM with minimal overlap





ABSORB 3.5x23 mm (10 atm)

Proximal Optimization Technique (POT)

Hiryu 4.0x10mm up to 28 atm

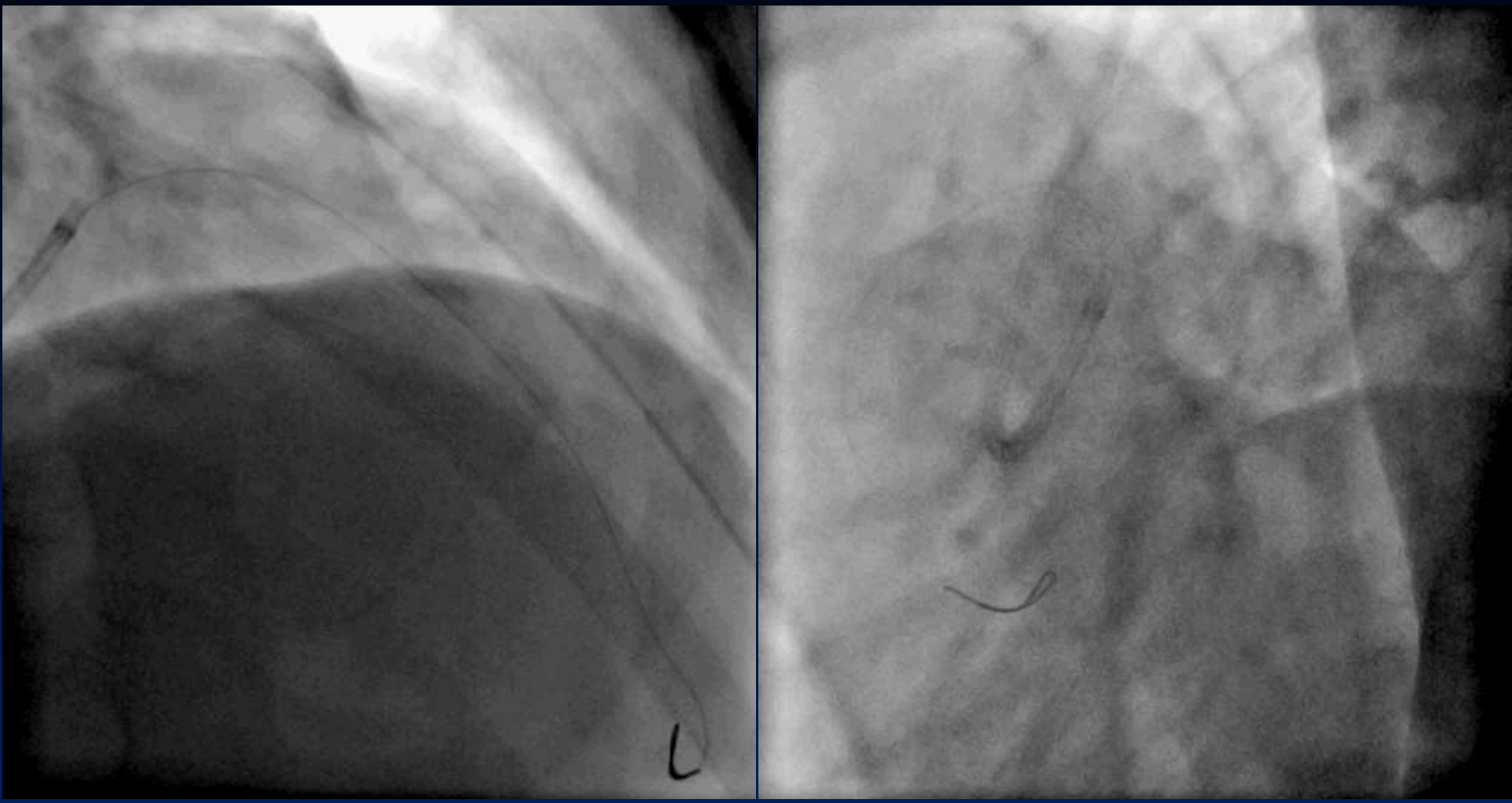
Wire recross to LCX open scaffold strut and DEB to LM-LCX

Mini-Trek 2.0x20mm up to 12 atm, B. Bruan Sequent Please 2.5 x 26 mm for LM-LCX (10 atm) 60 secs

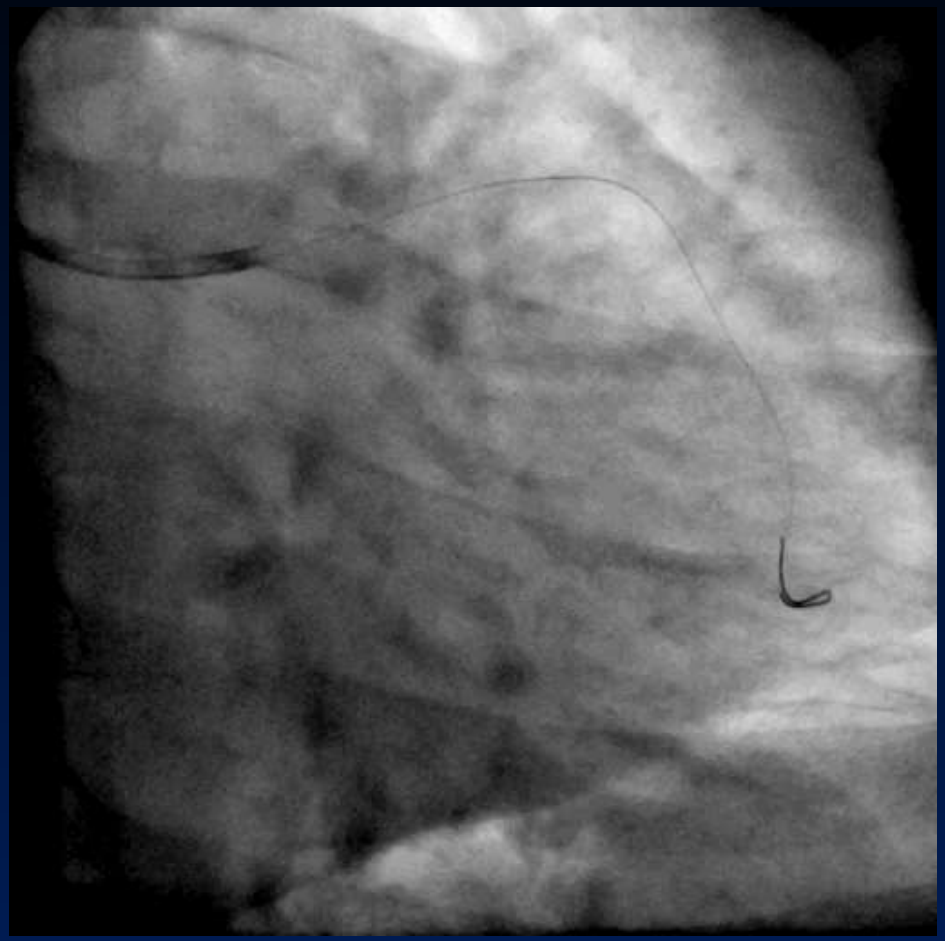
Final Proximal Optimization Technique (POT) again

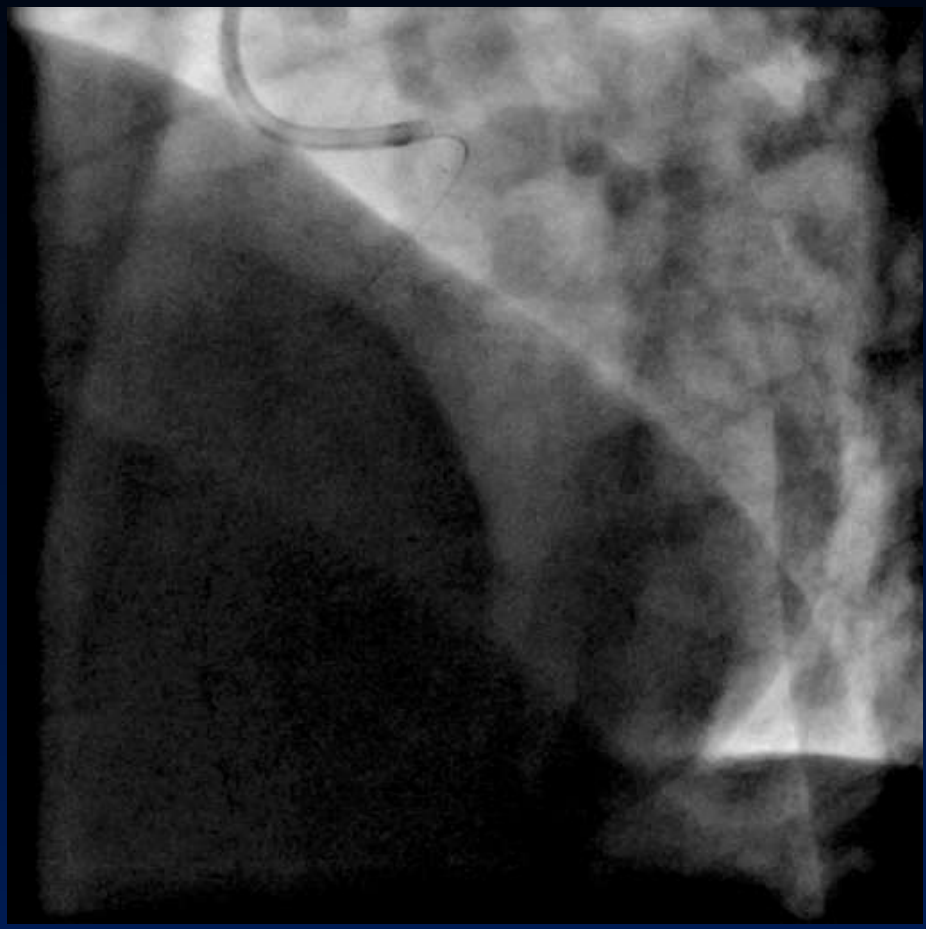
Hiryu 4.0x10mm up to 28 atm

Final LCA angiogram



Final LCA angiogram: no more damping after BVS for LM-os



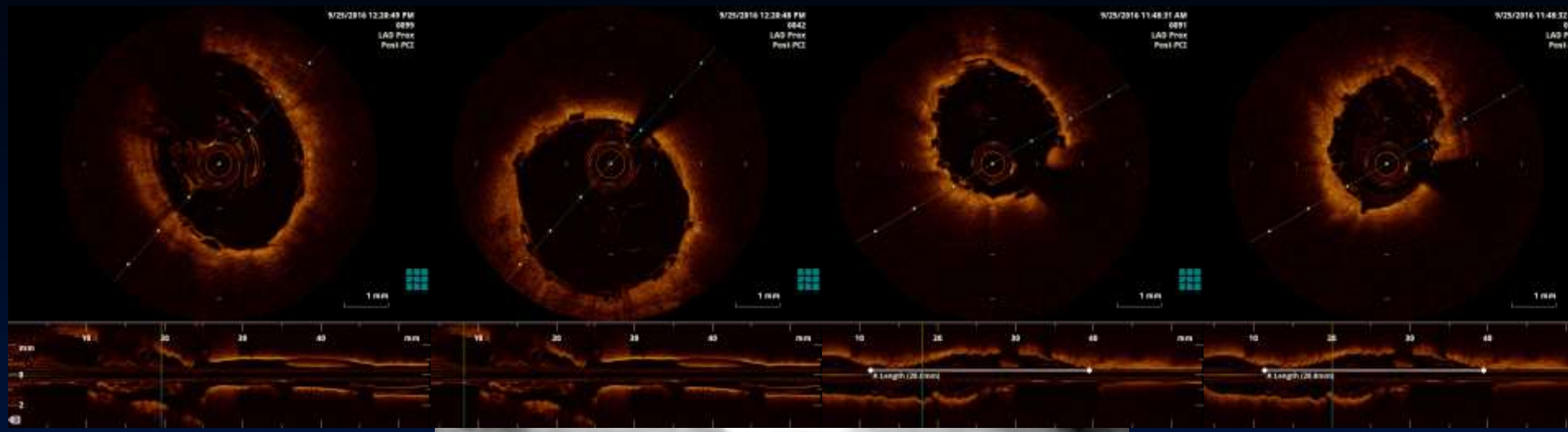


OCT from LAD-LM

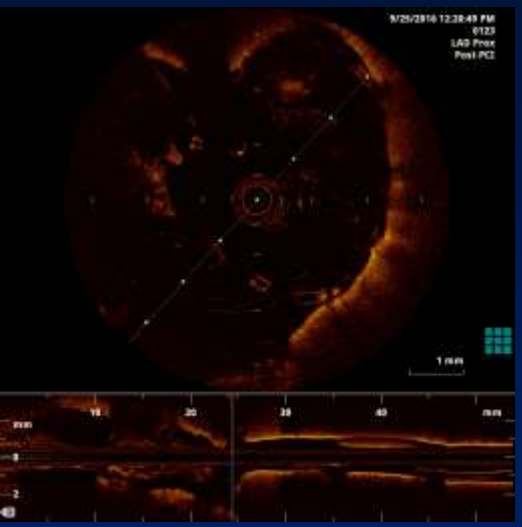
LM-distal

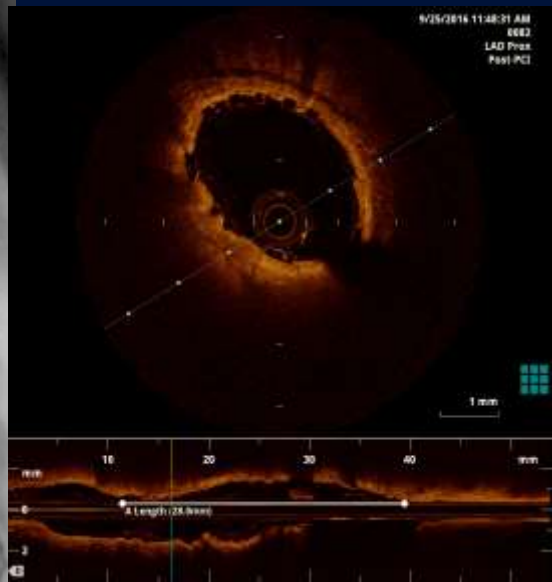
LAD-os

LAD proximal to mid



LM-orifice





BVS and the Left Main: Limiting Factors

Problem	Consequence
✦ Limited overexpansion capability	Risk of incomplete apposition for left main diameters > 4.3 mm
✦ Concerns of lower radial strength in vivo compared to metallic stent platforms	Caution in ostial lesions (recoil)
✦ Limited side branch fenestration capabilities	Risk of fracture
✦ **Slow and prolonged inflation times are required**	Ischemia in a large territory

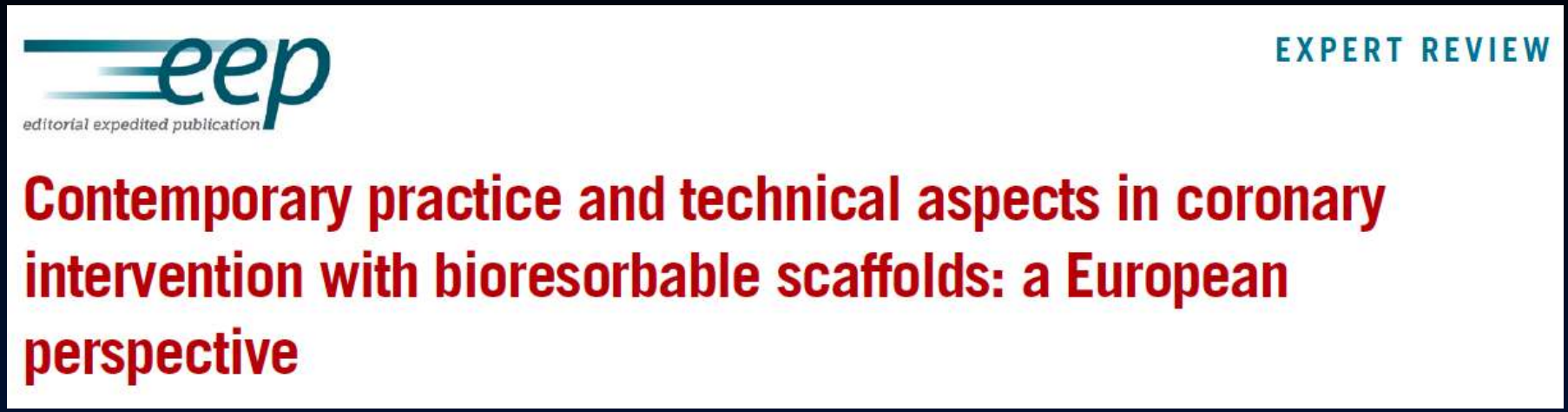
Everaert B, et al, EuroIntervention. 2015;11:V135-8

BVS and the Left Main Bifurcation
ESC Consensus – 10th anniversary

- **General recommendations**
  - Implantation of BVS in bifurcations with SB diameter larger than 2 mm should preferably only be done in randomized trial until firm data on efficacy and safety are available
  - The provisional approach remains the default technique with BVS

Lassen J, et al, EuroIntervention. 2014;10:545-60

BVS and the Left Main Bifurcation

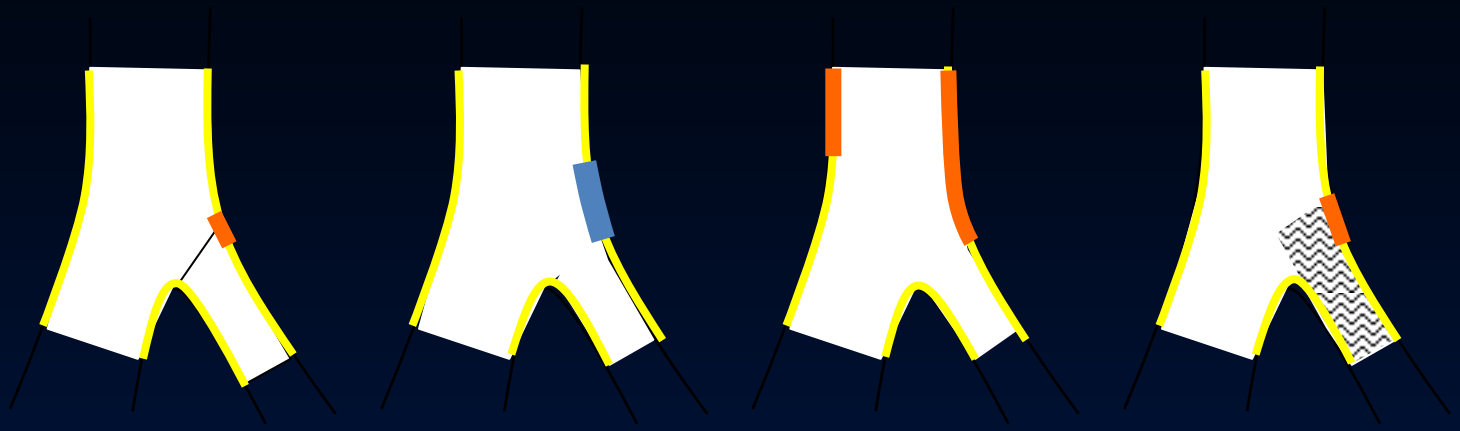


About bifurcation lesions

- Complex bifurcation scaffolding procedures should ideally be avoided with BVS or undertaken under intravascular imaging guidance to detect and correct possible scaffold fractures or deformations

Tamburino C, et al. EuroIntervention. 2015;11:45-52

Systematic complex strategies with BVS for LM-bifurcation



	T stenting	Mini-crush	Culotte	TAP
Triple layer		++		
With BVS		468 μm		
Double layer			+++	+
With BVS			312 μm	312 μm

Cheng Hsin General Hospital

143 patients

Lin-ko Chang Gung Memorial Hospital

94 patients

Kaohsiung Chang Gung Memorial Hospital

156 patients

Baseline characteristics

Baseline characteristics of study patients	
	Patients (N=366)
General demographics	
Age (year)	59.45 ± 10.12
Male gender (%)	85
Clinical condition	
Acute coronary syndrome (%)	63.7
STEMI or NSTEMI (%)	28.7
Unstable angina (%)	35.0
Stable angina (%)	36.3
Risk factors	
Hypertension (%)	70.5
Diabetes (%)	32.5
Current smoker (%)	36.3
Prior myocardial infarction (%)	6.0
Hyperlipidemia (%)	66.7
Prior CABG (%)	2.2
ESRD on maintenance hemodialysis (%)	0.8
Multiple vessel disease (%)	49.7
Syntax score	12.20 ± 8.69

Data are expressed as mean ± SD or as number (percentage).

Procedure and lesion characteristics

Lesion and procedural characteristics

	Lesions (N = 508)
Patient number	366
Lesion number	508
Lesion type (%)	
Type B2 and C lesion	61.0
Bifurcation lesion	18.9
Left main	1.6
Non left main	17.3
Ostial lesion	4.1
Left main lesion	1.2
Chronic total occlusion	4.1
In-stent restenosis lesion	2.6
The average of BVS use	1.46 ± 0.74
Scaffolds	
Diameter (mm)	3.02 ± 0.37
Length (mm)	23.69 ± 5.02
Intravascular imaging (%)	43.7

Data are expressed as mean ± SD or as number (percentage).

ABSORB III

Ghost EU

Millan

68.7%

53.5%

74.8%

exclude

23.1%

46.8%

20.5±7.2

32.6±23.0

53.2±32.5

11.2%

14.4%

85.8%

One-year clinical outcomes

One-year clinical outcomes of study patients and lesions

	Patients (N=366) Lesions (N=508)	Millan
One-year clinical outcomes		
Target lesion failure (TLF) (%)	14 (2.8)	7.9%
Myocardial infarction (%)	4 (1.1)	
STEMI	1 (0.3)	
NSTEMI	3 (0.8)	
Treated vessel MI	4 (1.1)	1.8%
Definite or possible scaffold thr	2 (0.5)	1.2%
Cardiovascular mortality (%)	2 (0.5)	
All-cause mortality (%)	2 (0.5)	

ABSORB III: 7.8% | Ghost EU: 4.4% at 6 mo | 1.5% | 2.0%

*Target lesion failure (TLF) was defined as cardiac death, target vessel myocardial infarction or ischemic-driven target lesion revascularization

Conclusion (I)

- The major causes of acute scaffold thrombosis were: overlap, residual plaque at BVS both edge, scaffold malapposition or oversizing

Karanasos, et al. Circ Cardiovasc Interv 2015 ; Jaguszewski, et al. Eur Heart J ; Sabate, et at. Eur Heart J

- Acute disruption and late discontinuities could also related to scaffold thrombosis *Onuma, et al. JACC Interv 2014*
- In a meta-analysis of 7 trial with 2568 patients, scaffold thrombosis may decrease in patients who underwent IVUS/OCT ($p<0.001$) and the use of routine post-dilatation ($p<0.001$)

D'Ascenzo F, et al. Eur Heart J, submitted

Conclusion (II)

- From GHOST-EU registry, diabetes mellitus was the only independent predictor of TLF (Hazard ratio 2.41, p=0.006)

Capodanno D et al. EuroIntervention 2015; 10: 1144-53

- In our analysis, diabetes mellitus, ostial lesion, bifurcation lesions and non-standarize of DAPT were the independent predictor of TLF

Lee et al. J of Interventional Cardiology, Submitted

- Careful lesion Preparation of complex coronary anatomy, using imaging guide for BVS **S**izing & Post-dilatation are the key of success which may reduce future MACE

PSP OBJECTIVES

P PREPARE THE LESION

OBJECTIVE
- Prepare lesion to receive scaffold
- Facilitate delivery
- Enable full expansion of pre-dilatation balloon to facilitate full scaffold expansion

S SIZE APPROPRIATELY

OBJECTIVE
- Accurately size the vessel
- Select appropriate scaffold for "best fit"

P POST-DILATE

OBJECTIVE
- Achieve **<10% final residual stenosis**
- Ensure full strut apposition

PRESCRIBE DAPT

Consider current ACC/AHA and ESC DAPT guidelines: Aspirin (*minimum 81 mg PO QD*), Clopidogrel (*minimum 300 mg load at procedure and 75 mg PO QD*)
As with any DES procedure, patients should be selected who will be able to comply with DAPT for the duration prescribed by their physician; the Absorb GT1 Instructions For Use (IFU) recommends a minimum of 6 months DAPT

Wright, RS, et al., Circulation. 2011; 123: 2022-2060. / Wijns, W, et al., European Heart Journal. 2010; 31: 2501-2555. / Levine, GN, et al., Circulation. 2011; 124: 2574-2651. / Steg, PG, et al., European Heart Journal. 2012; 33: 2569-2619. / O'Gara, PT, et al., Circulation. 2012; 127: e368-e425.

LEARNING CURVE

A BVS-SPECIFIC IMPLANTATION STRATEGY CAN IMPROVE OUTCOMES

P PREPARE THE LESION **S** SIZE APPROPRIATELY **P** POST-DILATE

2011 2012 2013 2014 2015 2016

4 Cities
International Registry
N~1,300

Enrollment & Follow-Up 1 Y

P Nitrates

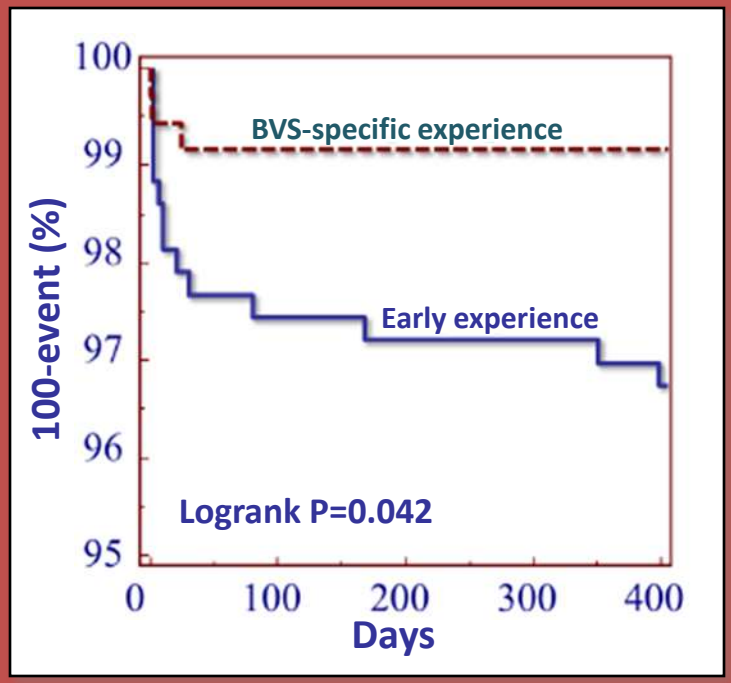
P Pre-dilate
Sizing with balloon (1:1:1)
2 angiographic planes

S Low threshold for
Intravascular imaging

Implant Following IFU

P NC post-dilatation (+0.5mm)

Do not accept:
MLD <2,5/2.9mm
MLA <4.9/6.6mm^2




Thanks for your attention !
LAD-os BVS ISR s/p
cutting and DEB


TTT
2017
TAIWAN
TRANSCATHETER
THERAPEUTICS
LIVE COURSE
JAN 07-08, 2017
NTUH International
Convention Center,
Taipei, Taiwan