Koronar müdaxilələrdə dərman örtüklü balonların istifadəsi: yeni perspektiv

Drug-coated balloon use in coronary intervention: a new perspective

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TURKIYE

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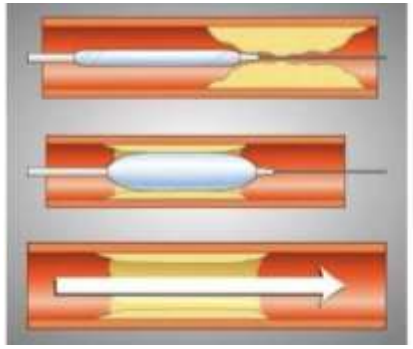
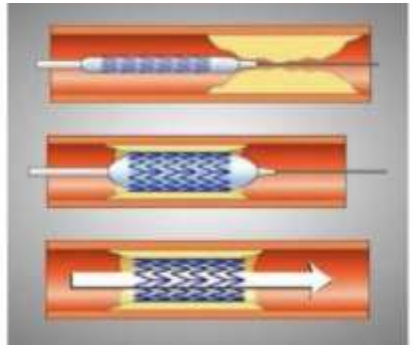
Percutaneous Coronary Intervention

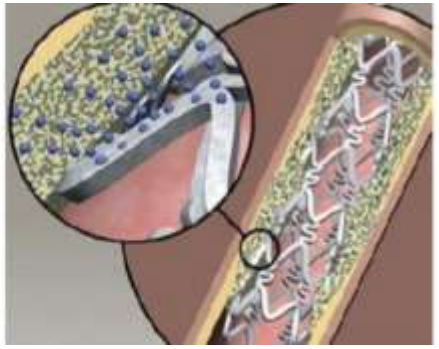
Balloon (PTCA)



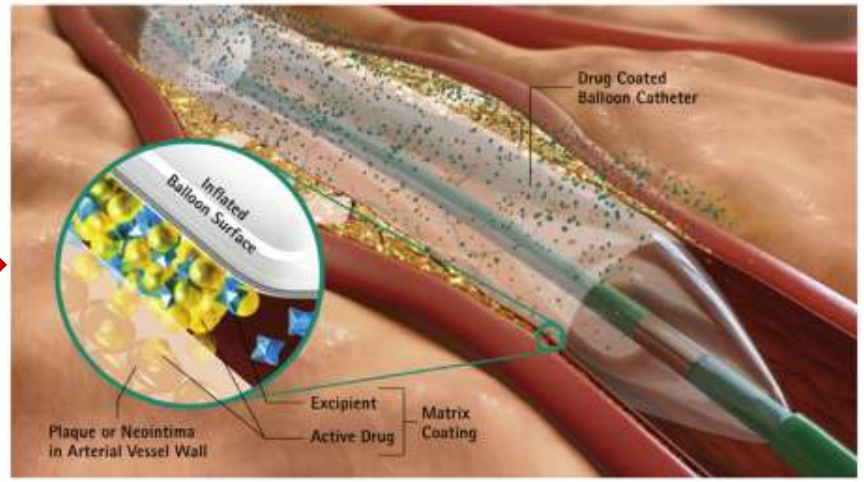
BARE Metal Stents (BMS)



Drug Eluting Stents (DES)



Drug Coated Balloon- (DCB)

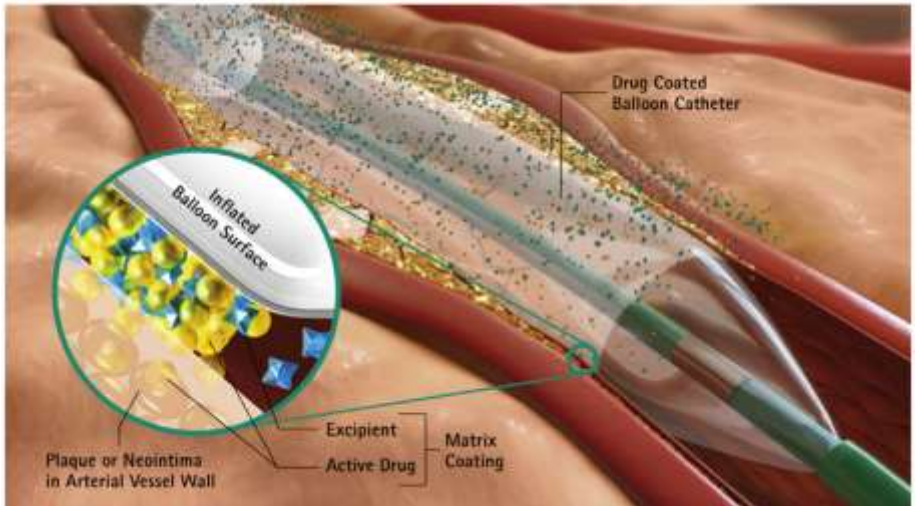


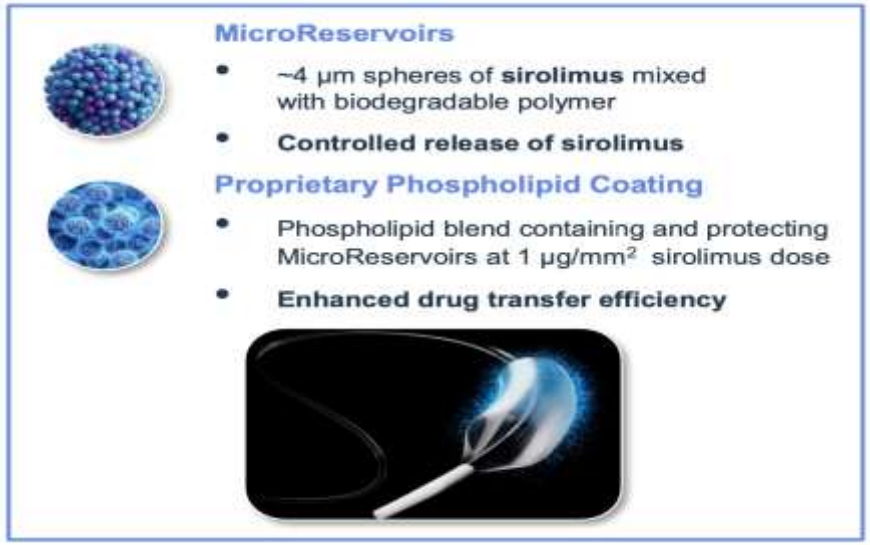
Without Drug Coating

With Drug Coating

Nothing to leave metal behind !!!

DCB: Coating formulation, Type of drug, Release kinetics





Coating formulation
the technique of the coating procedure,
thus resulting in different pharmacokinetic profiles

Therefore, the interaction among drug doses, formulations, release kinetics, and lesions seems to be crucial for the vascular response after DCB therapy.

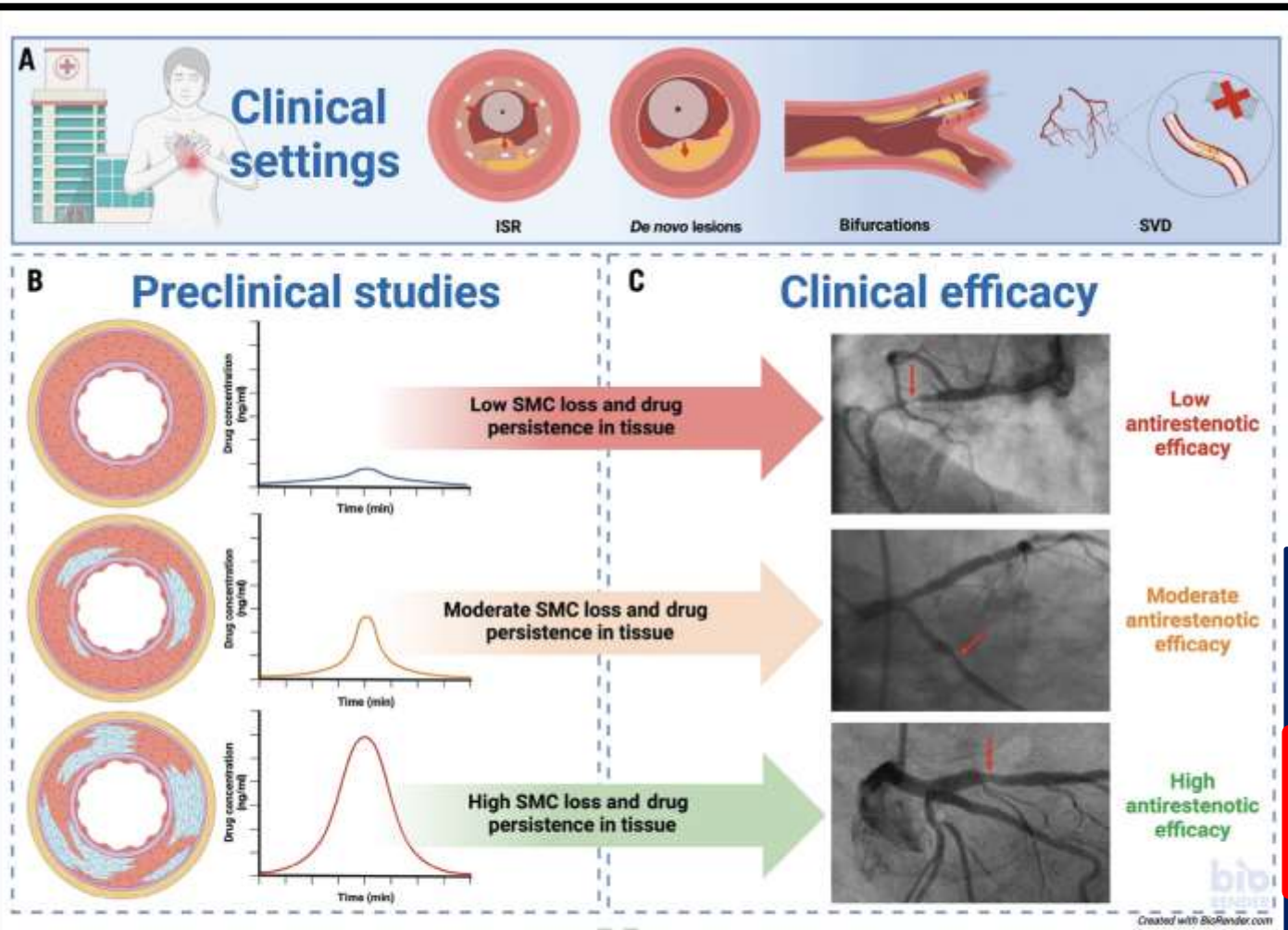


Figure 1. *Transferability of preclinical study results into clinical outcome. A) Clinical indications are shown for the use of DCBs. B) Preclinical studies: a schematic overview of the correlation between histopathological findings in the arterial wall (blue areas represent SMC loss in arteries stained with Movat Pentachrome) and drug tissue concentration. C) Clinical efficacy: representative angiographic findings of patients with varying degrees of stenosis. Red arrows indicate the stenotic area. ISR: in-stent restenosis; SMC: medial smooth muscle cells; SVD: small vessel disease*

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EDITORIAL

Comparative preclinical assessment of drug-coated balloons: a blessing and a curse for clinical translation

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comparators. The authors utilised established and sound preclinical methodology combining histopathological and pharmacological evaluations of the drugs' effects. With regards to histology, the loss of medial smooth muscle cells (SMCs) was previously established as a proxy of PTX-induced vascular reactions, where viable SMCs undergo apoptosis and get replaced by an extracellular matrix (proteoglycan deposition) – a phenomenon that can be visualised under the microscope when using specific histopathological stains[4]. PTX is a highly lipophilic molecule, able to pass through the lipid bilayer of cell membranes, that interferes with cell division by binding to microtubules, stabilising them and subsequently leading to cell death. SRL (an analogue of rapamycin), on the other hand, requires binding to an intracellular protein (FKBP-12), which in complex, results in the inhibition of mammalian target or rapamycin (mTOR), leading to disruption of multiple signalling pathway reactions involved in cell growth and proliferation. As SRL does not directly induce apoptosis, loss of SMCs is expectedly less evident with its vascular application. While both of the PCBs showed greater SMC loss compared to the SCB in the current study, which may suggest more effective drug transfer to the vessel wall, the validity of such a comparison must be questioned, as this preclinical endpoint has never been validated for SCBs to date.

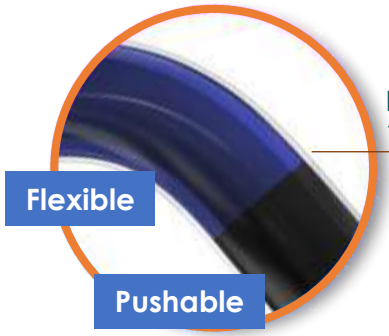
Furthermore, the authors report a higher ratio of non-target to target drug (muscle/artery ratio) persistence for the SCB relative to both the PCBs, which suggests that there is an increased downstream release of sirolimus during deployment and consequent accumulation in muscle tissue; this might result in less effective vascular transfer of the drug and greater loss into non-target organs. This particular ratio, however, has not previously been validated in dedicated preclinical studies and warrants further scrutiny. Along these lines, the authors failed to apply a preclinical model of in-stent restenosis, which would otherwise have allowed direct evaluation of the comparative antirestenotic efficacy of the DCBs tested.

Despite these important limitations, the authors have provided essential insights into the particularities and differences between various DCB-coating formulations. The clinician may ultimately remember these findings when interpreting

Mechanisms of DCB

Unmatched Flexibility[1]

Bi-segment inner shaft improves trackability in distal lesions



Delivery Force
157 g*cm

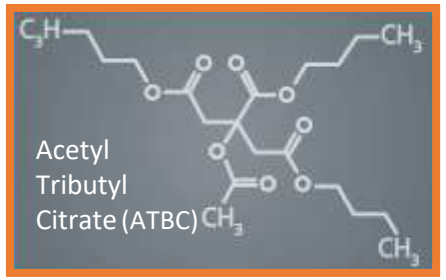
Unrivaled Profile[2]

Laser bonded tip improves crossability and reduced tip catch

Lesion Entry Profile
0.0167 In

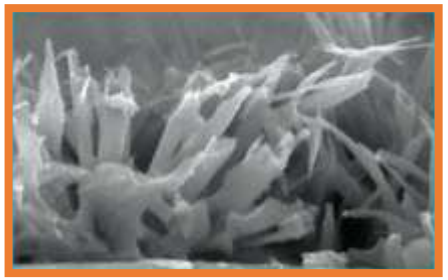
Targeted Transfer

Novel excipient maximizes balloon-to-target vessel transfer



Rapid Absorption

Sharp edge Ptx enhances tissue penetration



Sustained Retention

Crystalline formulation maintains therapy through the healing process

Drugs in DCB: Paclitaxel & Sirolimus

TABLE 1 Commercially Available DCBs

Drug and Device	Company	Additive	Substance Class	Dose (μg/mm²)	Approval
Paclitaxel					
Agent	Boston Scientific	Acetyl tributyl citrate	Plasticizer	2	CE certified
Elutax SV	Aachen Resonance	None		2.2	CE certified
Danubio	Minvasys	n-Butyryl tri-n-hexyl citrate	Plasticizer	2.5	CE certified
SeQuent Please	B. Braun	Iopromide	X-ray contrast medium	3	CE certified
Pantera Lux	Biotronik	n-Butyryl tri-n-hexyl citrate	Plasticizer	3	CE certified
RESTORE	Cardionovum	Shellac	Varnish	3	CE certified
AngioSculptX	Spectranetics	Nordihydroguaiaretic acid	Antioxidant	3	CE certified
Chocolate Touch	QT Vascular	Undisclosed		3	CE certified
Dior II, BioStream	Eurocor Biosensors	Shellac	Varnish	3	
Essential	iVascular	Undisclosed		3	CE certified
IN.PACT (Admiral, Pacific, Falcon)	Medtronic Vascular	Urea	Endogenous metabolite	3.5	CE certified, FDA approved (Admiral)
Sirolimus					
Selution	Med Alliance	Biodegradable polymer	Microreservoirs		
Virtue	Caliber Therapeutics	Biodegradable polyester-based polymers	Submicrometer nanoparticles		
Magic Touch	Concept Medical		Phospholipids		CE certified
Sequent Please SCB	B. Braun		Crystalline sirolimus	4	CE certified

CE = Conformité Européenne; DCB = drug-coated balloon; FDA = U.S. Food and Drug Administration.

Attribute	Limus	Paclitaxel
Nature of drug	Less lipophilic	Higly lipophilic
Ease of coating	Very hard	Easy
Tissue absorbtion and elution	More difficult	easier

Limitations of “limus” substances are basically the poorer transfer rate compared with paclitaxel and the necessary long persistence in tissue due to the reversible binding to the mammalian target of rapamycin receptor

Why we are talking about more DCB today ?

1) There is a 2% yearly adverse events following DES implantation, and this increases with long stents as well as in diabetic patients;
2) Stents negate positive remodelling and pulsatile function
3) A suboptimally implanted stent may be deleterious;
4) Sometimes stent delivery may be very complex;
5) Stent restenosis may be difficult to treat.

DCB Potential Treatment Indications

- In-Stent Restenosis
- Small Vessel Disease
- Bifurcation Lesions
- De-Novo Coronary Lesions

DCB: Randomized Trials in ISR

BMS-ISR

DES-ISR

Study Name (Ref. #)	Comparators to PCB	n	Follow-Up Duration	Angiographic Follow-Up	p Value	MACE (%)	p Value	TLR (%)	p Value
BMS ISR									
PACOCATH ISR I and II (14)	POBA	108	6 months (angio) 12 months (clinical)	LLL 0.03 ± 0.48 mm vs. 0.74 ± 0.86 mm	0.0002	4 vs. 31	0.01	0 vs. 23	0.02
			5 yrs (clinical)			27.8 vs. 59.3	0.009	9.3 vs. 38.9	0.004
PEPCAD II (97)	PES	131	6 months (angio) 12 months (clinical)	LLL 0.17 ± 0.42 mm vs. 0.38 ± 0.61 mm	0.03	9 vs. 22	0.08	6 vs. 15	0.15
			3 yrs (clinical)			34.8 vs. 41.5			
RIBS V (98)	EES	189	6-9 months (angio) 12 months (clinical)	LLL 0.14 ± 0.5 mm vs. 0.04 ± 0.5 mm,	0.14 0.22	8 vs. 6	0.60	6 vs. 1	0.09
			3 yrs (clinical)	binary restenosis 9.5% vs. 4.7%		12 vs. 10	0.64	8 vs. 2	0.04
SEDUCE (99)	EES	50	9 months (angio) 12 months (clinical)	LLL 0.28 mm vs. 0.07 mm, proportion uncovered struts (OCT) 1.4% vs. 3.1%	0.1 0.025			4.2 vs. 8	0.576
TIS (100)	EES	136	12 months	LLL 0.02 mm vs. 0.19 mm	0.0004	10.3 vs. 19.1	0.213	7.4 vs. 16.2 (TVR)	0.110
DES ISR									
PEPCAD-DES (101)	POBA	110	6 months (angio and clinical)	LLL 0.43 ± 0.61 mm vs. 1.03 ± 0.77 mm, restenosis 17.2% vs. 58.1%	<0.001 0.001	16.7 vs. 50.0	<0.001	15.3 vs. 36.8	0.005
			3 yrs			20.8 vs. 52.6	0.001	19.4 vs. 36.8	0.046
PEPCAD CHINA ISR (102)	PES	220	9 months (angio) 12 months (clinical)	vs. 0.55 ± 0.61 mm	0.0005*	16.5 vs. 16 (TLF)	0.92	15.6 vs. 12.3	0.48
			2 yrs (clinical)			16.8 vs. 18.6 (TLF)	0.73	15.9 vs. 13.7	0.66
ISAR DESIRE III (103)	PES vs. POBA	402	6-8 months (angio) 12 months (clinical)	Diameter stenosis 38% vs. 37.4%	0.007*	23·5 vs. 19·3 vs. 46·2	0.5 (PCB vs. PES)	22·1 vs. 13·5 vs. 43·5	0.09 (PCB vs. PES)
			3 yrs (clinical)			38.0 vs. 37.7 vs. 55.7	0.91 (PCB vs. PES)	33.3 vs. 24.2 vs. 50.8	0.11 (PCB vs. PES)
ISAR DESIRE IV (29)	Scoring and PCB	252	6-8 months (angio) 12 months (clinical)	LLL 0.31 ± 59 mm vs. 0.41 ± 0.74 mm	0.27	18.4 vs. 23.3	0.35	16.2 vs. 21.8	0.26
RIBS IV (104)	EES	309	6-9 months (angio) 12 months (clinical)	Binary restenosis 19% vs. 11%	0.06	18 vs. 10	0.04	16 vs. 8	0.035
RESTORE (105)	EES	172	9 months (angio) 12 months (clinical)	LLL 0.15 ± 0.49 mm vs. 0.19 ± 0.41 mm	0.54	7.0 vs. 4.7	0.51	5.8 vs. 1.2	0.10
FIM LIMUS DCB (25)	SCB	50	6 months (angio)	LLL 0.21 ± 0.54 mm vs. 0.17 ± 0.55 mm	0.794	16 vs. 12	>0.99	16 vs. 12	>0.99

ISR DCB-Paclitaxel vs Uncotaed balloon

JAMA

QUESTION Is treatment with a coronary paclitaxel-coated balloon superior to an uncoated balloon for 1-year target lesion failure in patients undergoing percutaneous coronary intervention for in-stent restenosis?

CONCLUSION This clinical trial found that treatment with a paclitaxel-coated balloon offers a potentially beneficial treatment strategy for the management of coronary in-stent restenosis.

© AMA

POPULATION

443 Men
157 Women

Adults with in-stent restenosis (lesion length <26 mm and reference vessel diameter >2.0 mm to ≤4.0 mm)

Mean age: 68 years

LOCATIONS

40 Centers in the US

INTERVENTION

600 Patients randomized

406 **Paclitaxel-coated balloon**
Coronary angioplasty with a paclitaxel-coated balloon

194 **Uncoated balloon**
Coronary angioplasty with an uncoated balloon

PRIMARY OUTCOME

1-year target lesion failure, defined as the composite of ischemia-driven target lesion revascularization, target vessel-related myocardial infarction, or cardiac death

FINDINGS

Target lesion failure

Paclitaxel-coated balloon
71 of 406 patients

Uncoated balloon
54 of 194 patients

Target lesion failure was significantly lower in the paclitaxel-coated balloon group:

Between-group difference, **−10.7%** (95% CI, −18.2% to −3.2%)

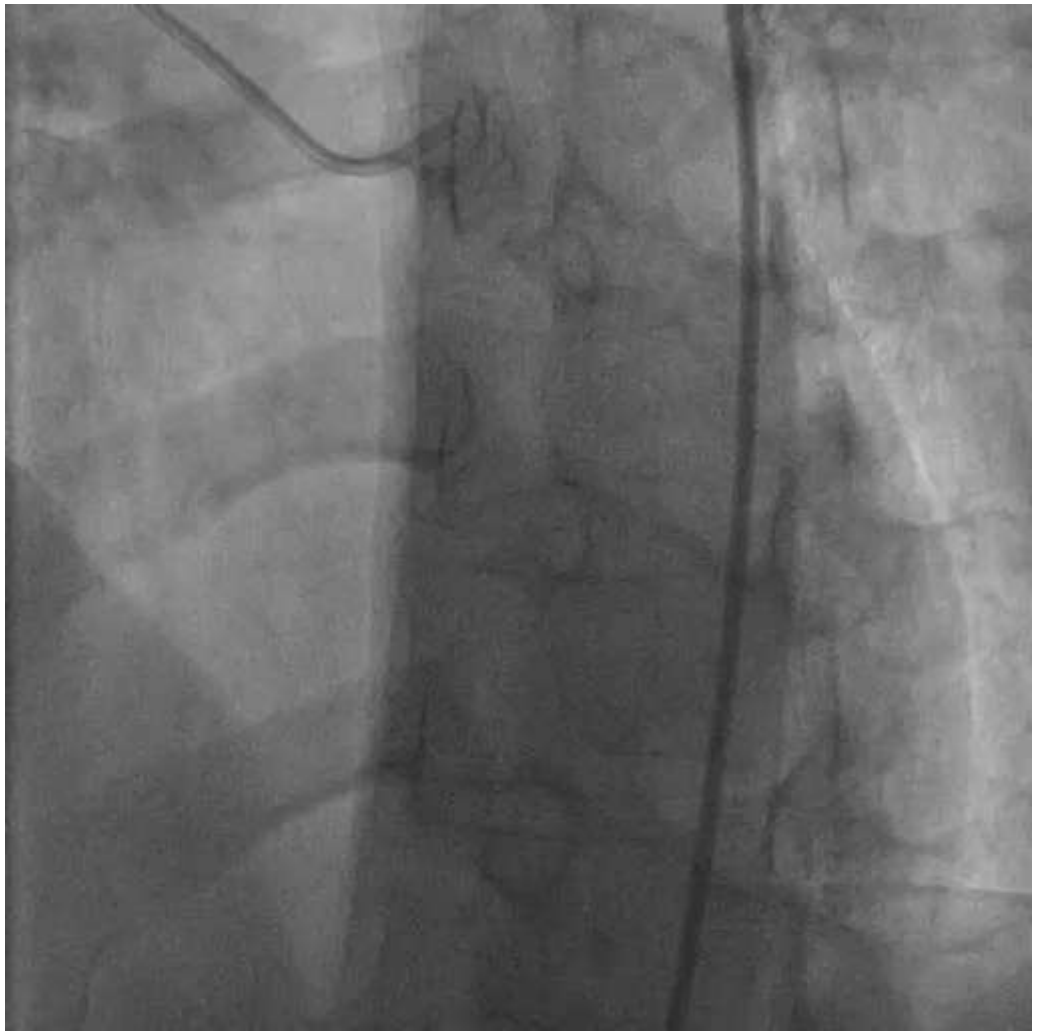
Hazard ratio, **0.59** (95% CI, 0.42 to 0.84)

Yeh RW, Shlofmitz R, Moses J, et al; AGENT IDE Investigators. Paclitaxel-coated balloon vs uncoated balloon for coronary in-stent restenosis: the AGENT IDE randomized clinical trial. *JAMA*. Published March 9, 2024. doi:10.1001/jama.2024.1361

CASE

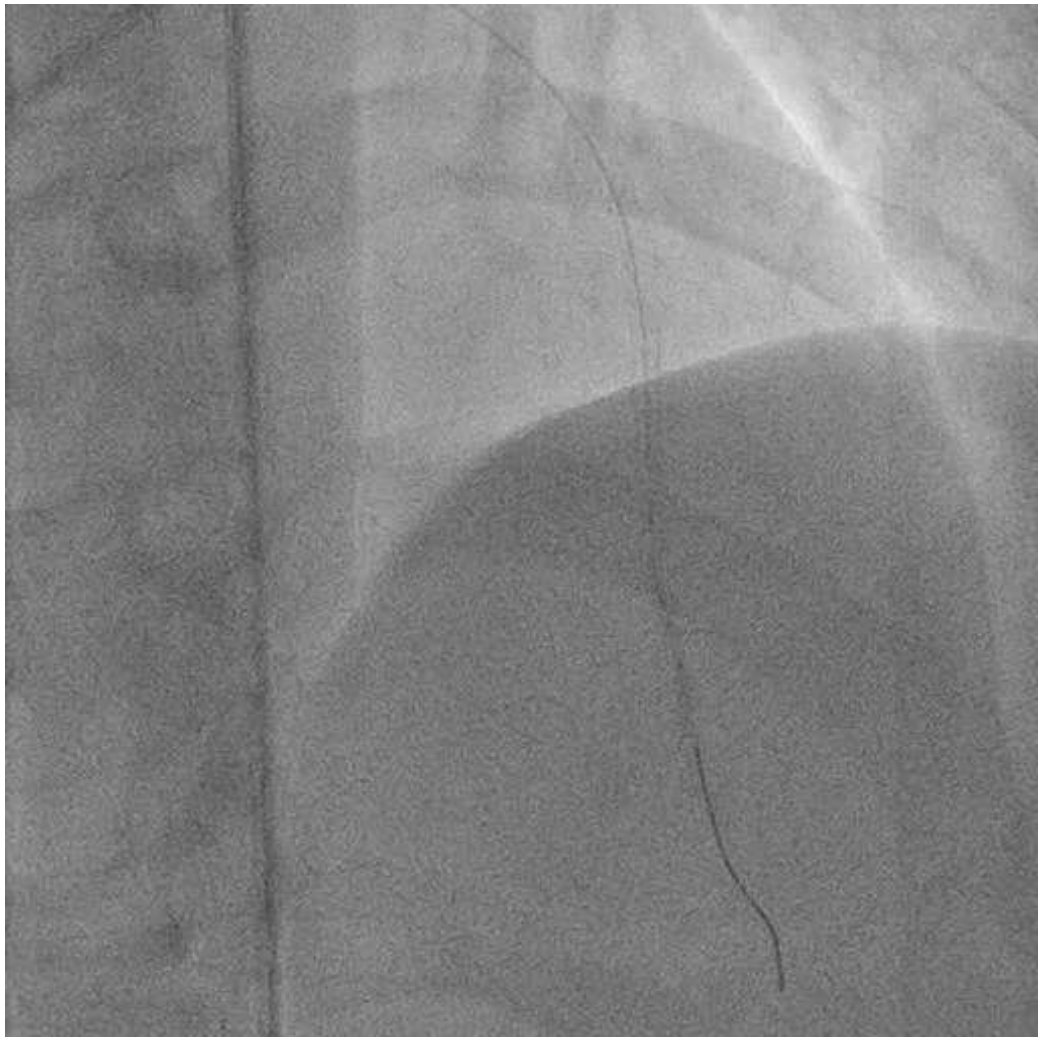
- 45 y, F
- ACS – LAD stent implantation 9 months ago
- Diabetes mellitus, smoker, SLE

LAD-ISR Treated with DCB (Paclitaxel)-2013



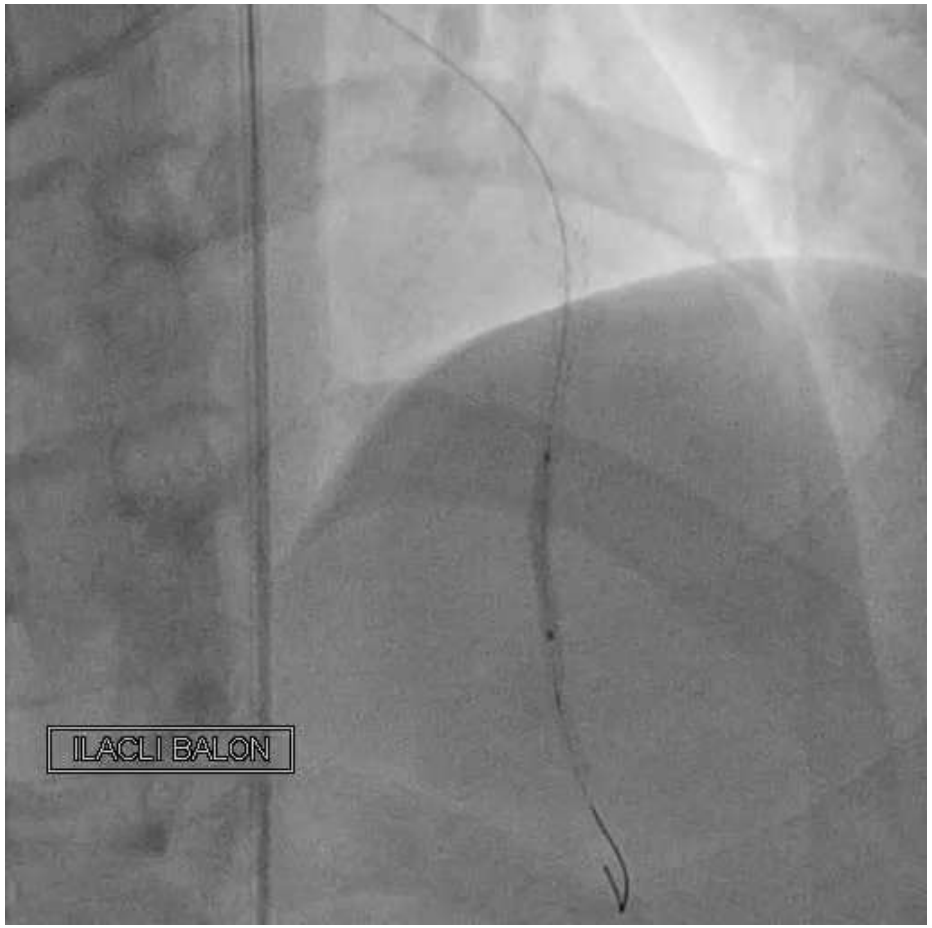
LAD-ISR Treated with DCB (Paclitaxel)-2013

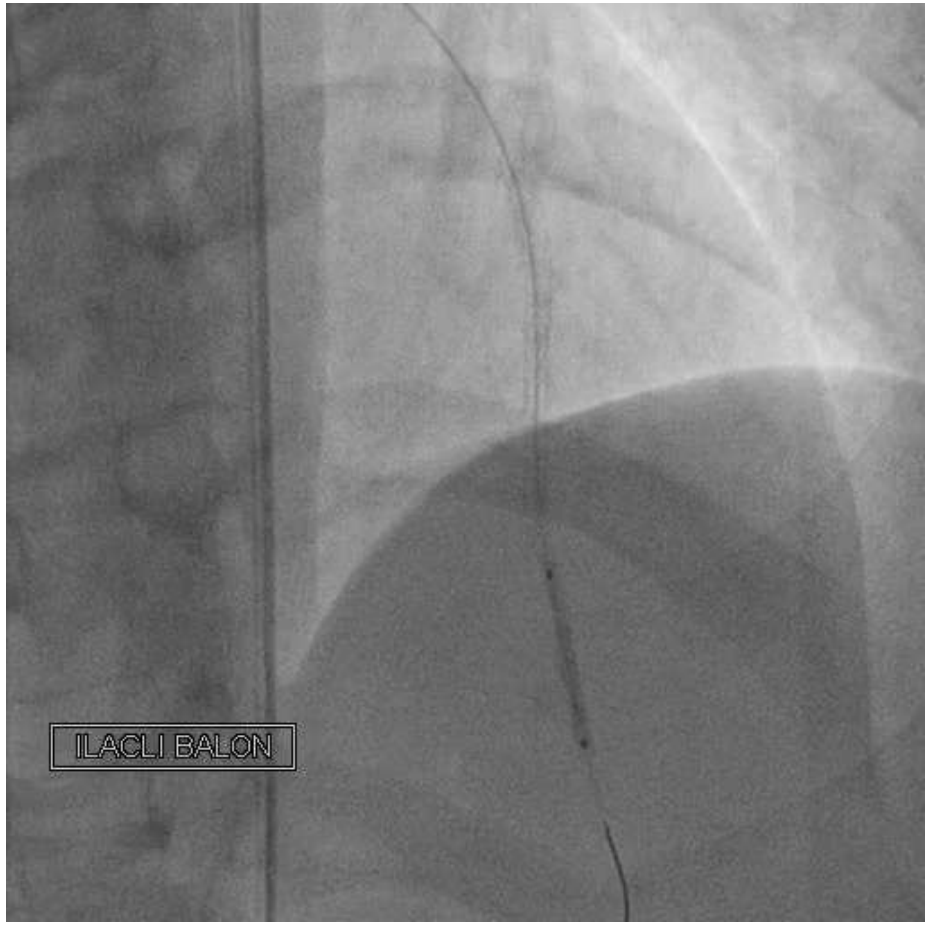
- Lesion Predilatation-Lesion Preparation



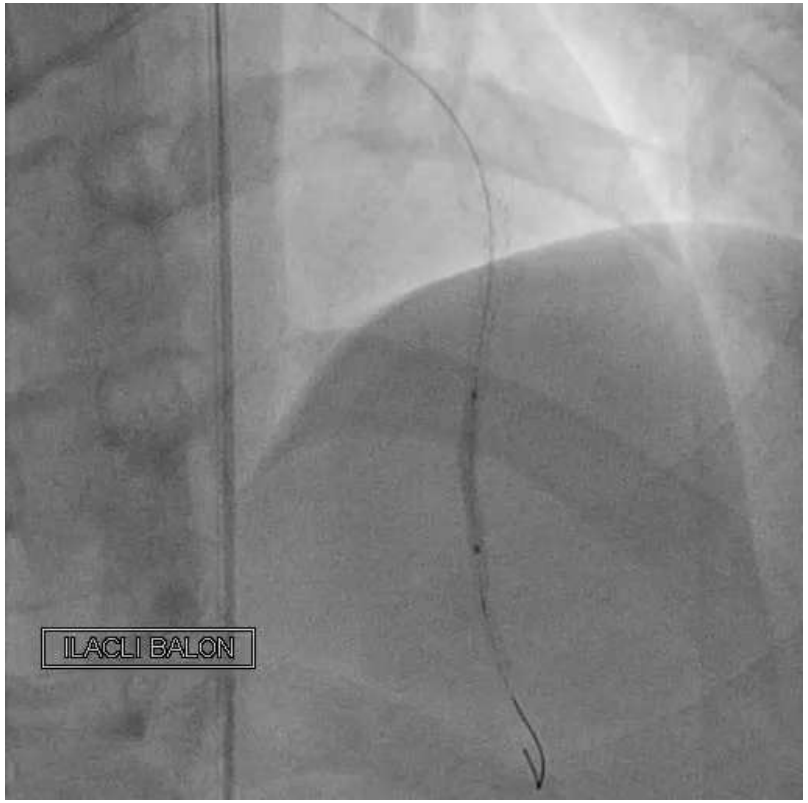
LAD-ISR Treated with DCB (Paclitaxel)-2013

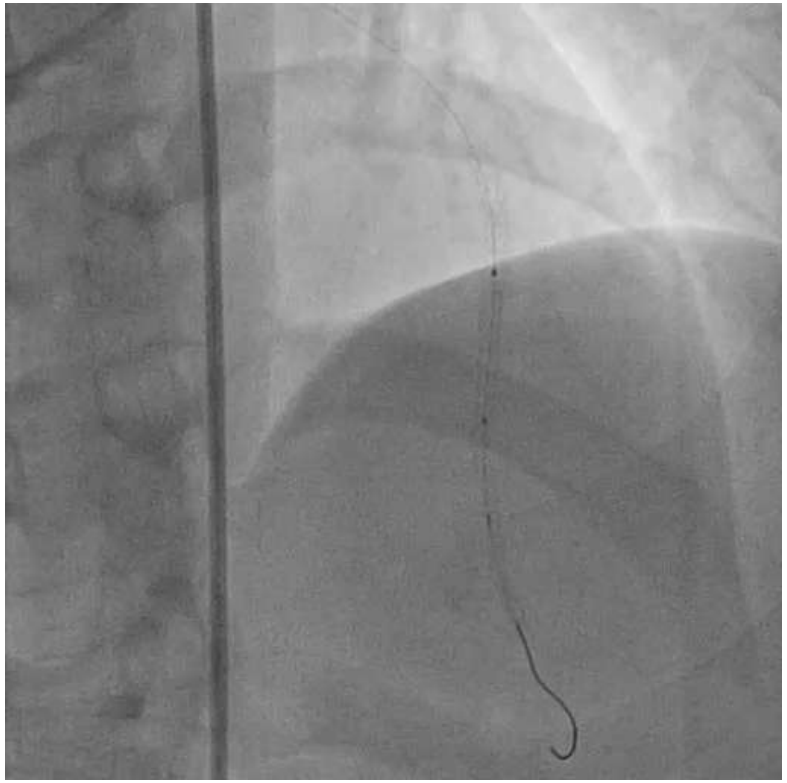
- DCB from distal to prox part of the lesion

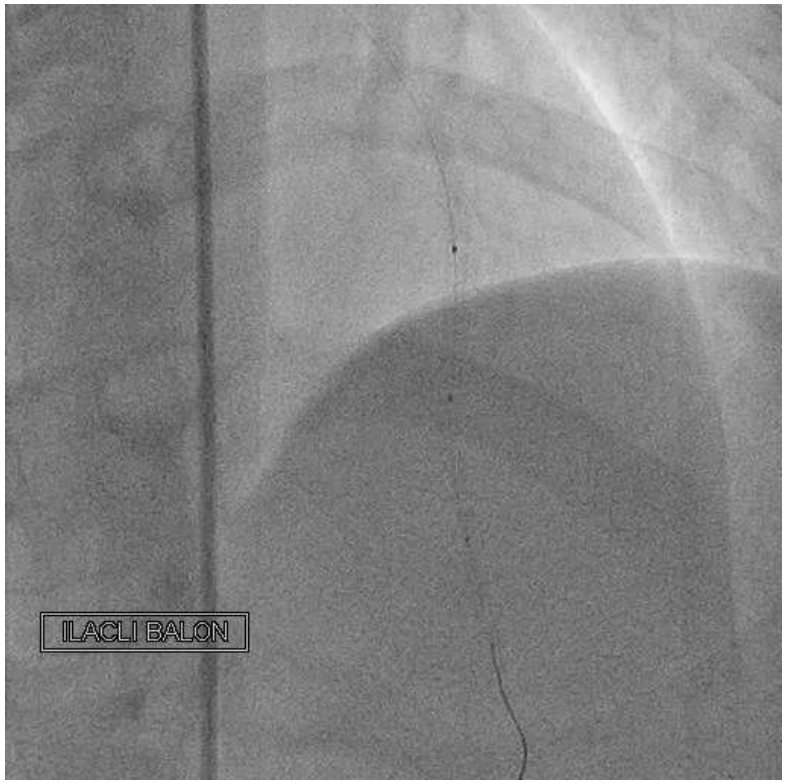




LAD-ISR Treated with DCB (Paclitaxel)-2013

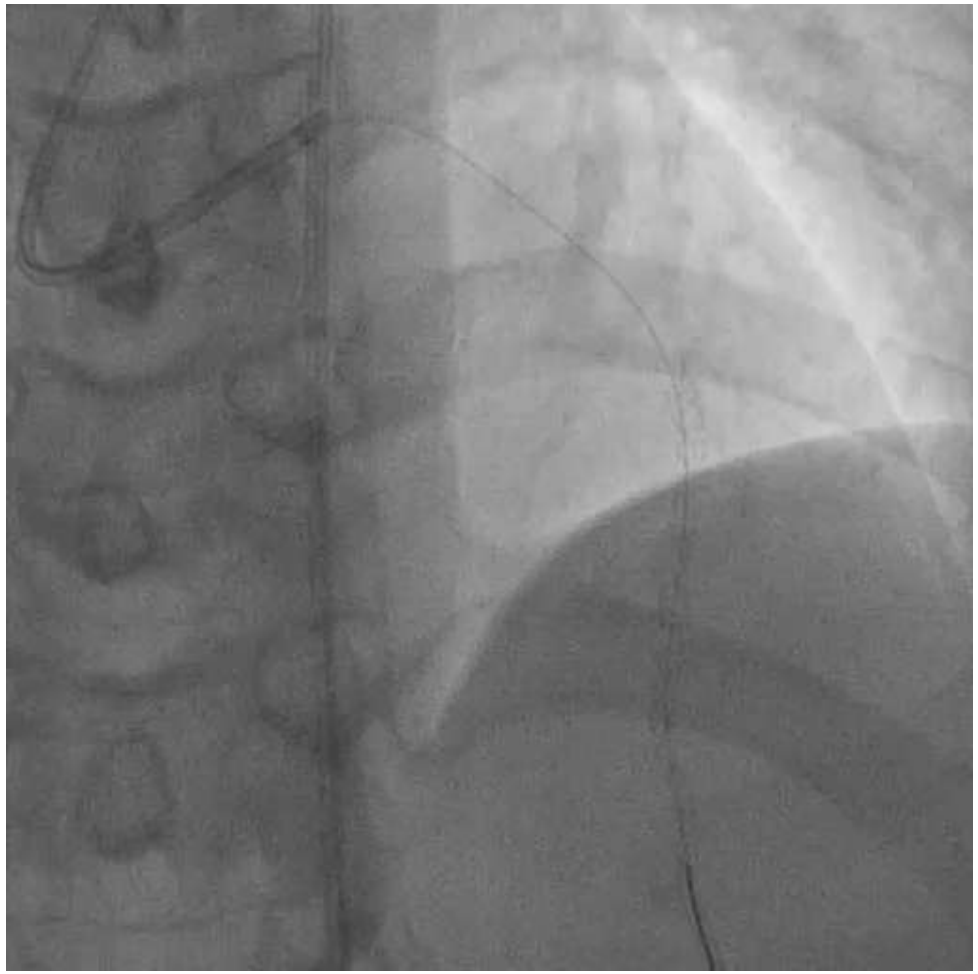




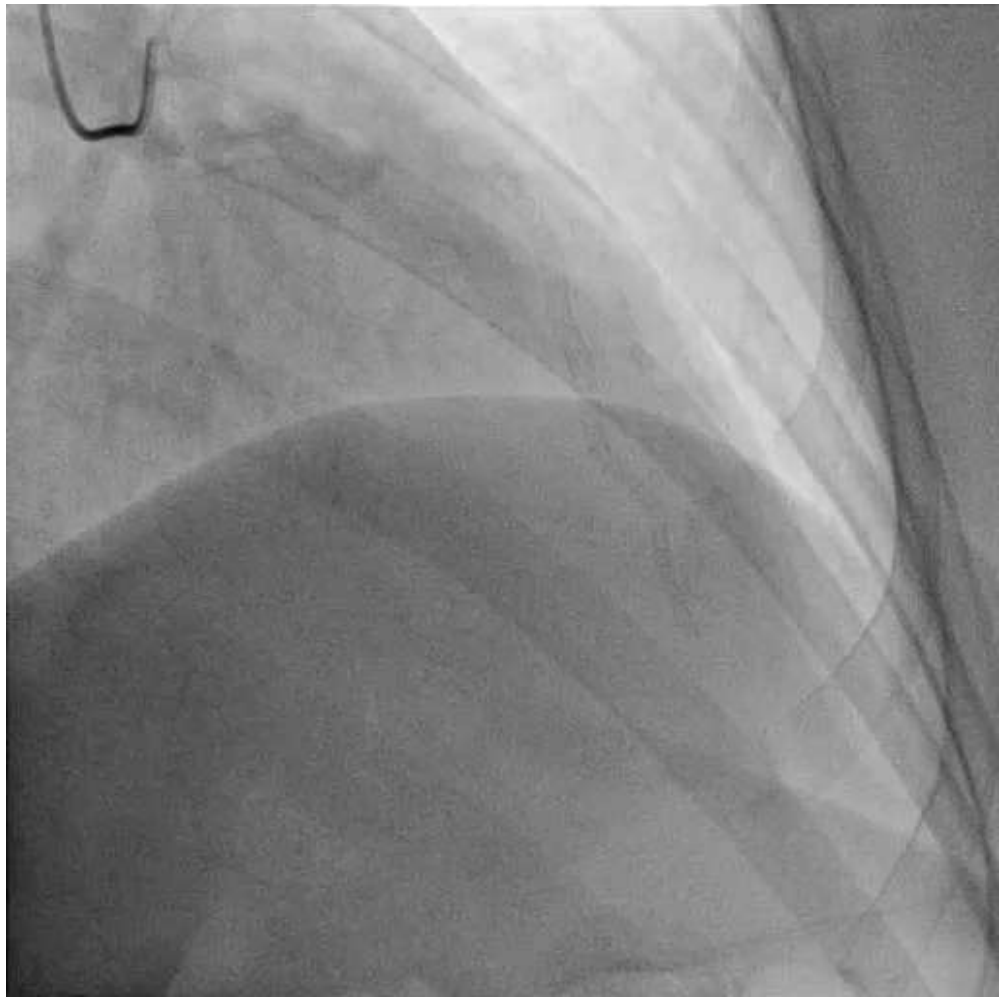


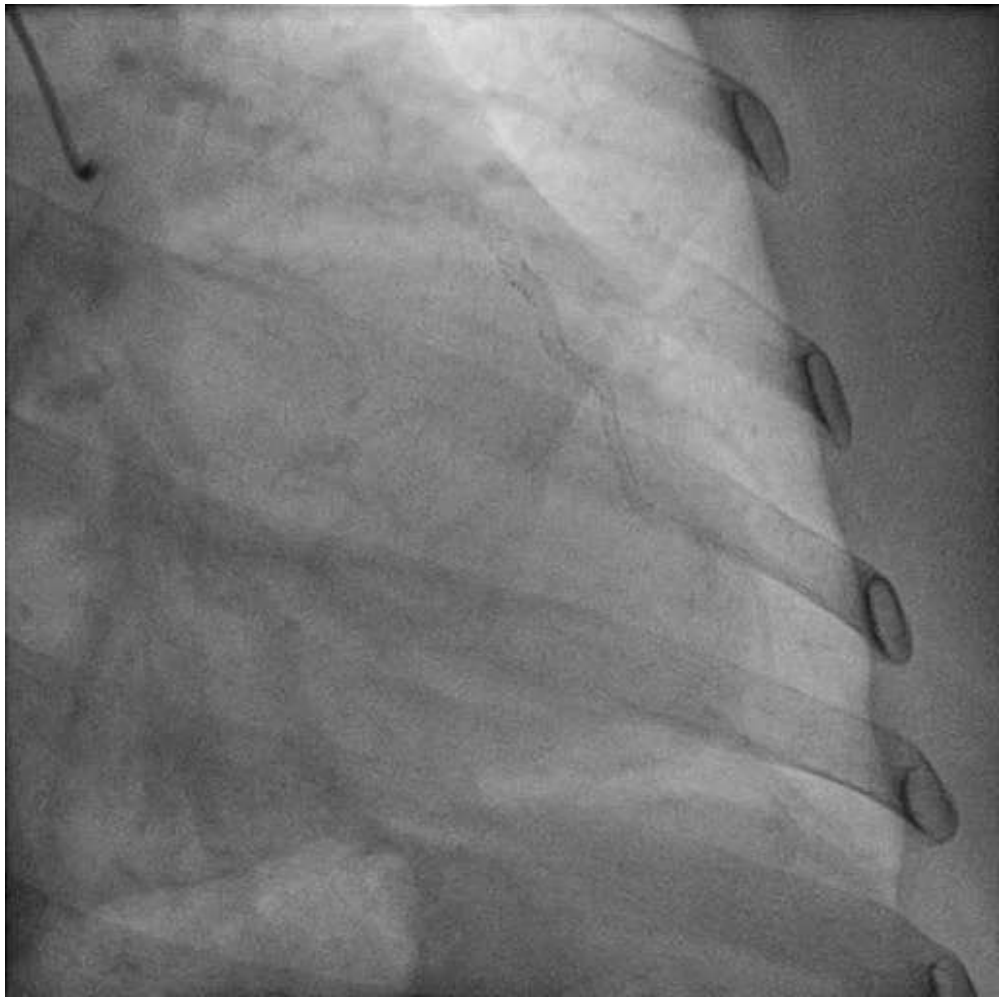
LAD-ISR Treated with DCB (Paclitaxel)-2013

- Final Result after DCB treatment



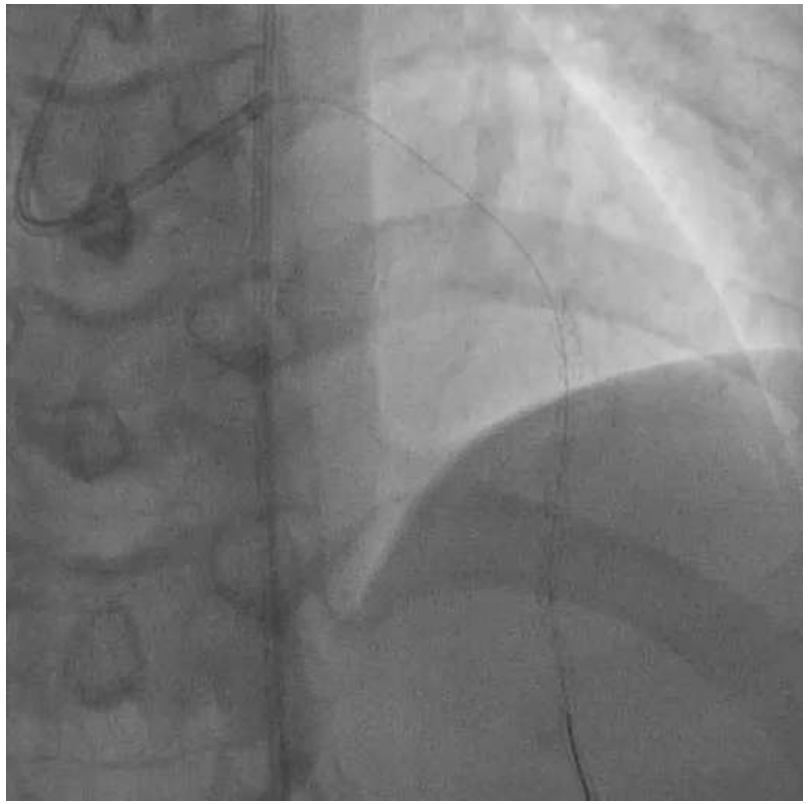
Follow-up DCB LAD-ISR 2021



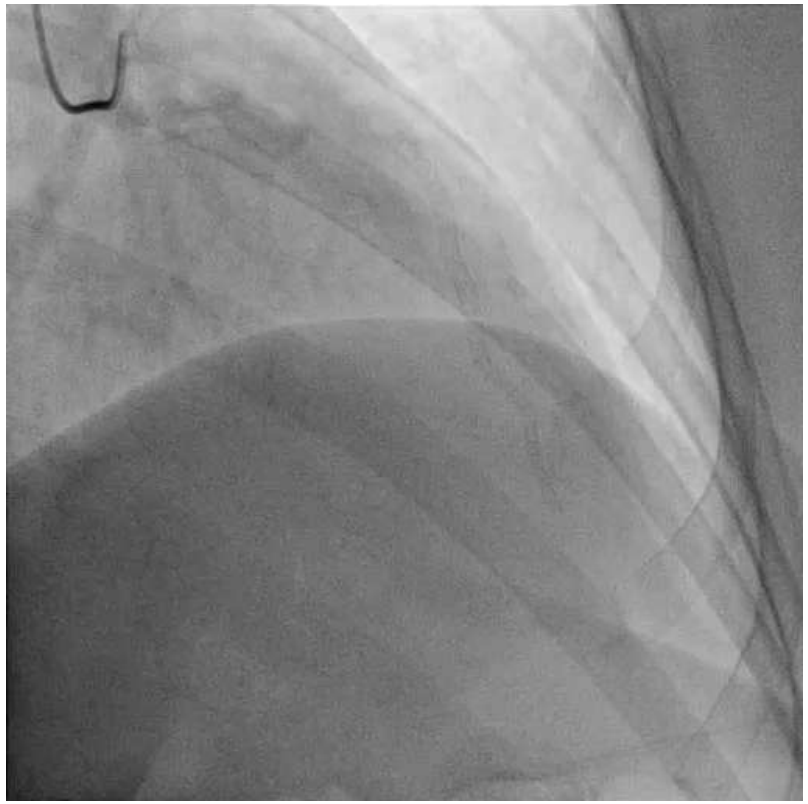


Year 2013
Pre-Procedure ISR

Year 2013
Post Procedure DCB to ISR



Year 2021
Follow-up



Small Vessel Disease

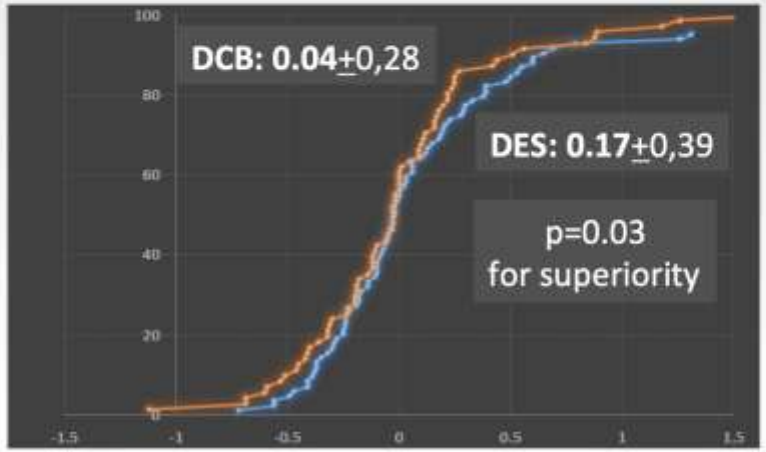
Bifurcation Lesions

DCB: De Novo Lesions of small coronary vessels

PICCOLETO II
Drug-coated balloon vs. drug eluting stent for small coronary vessel disease

Primary Endpoint

In-lesion late lumen loss @ 6-months (core lab)

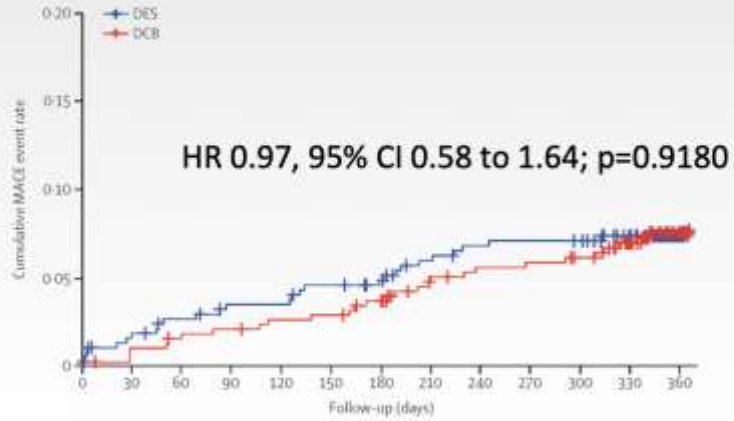


→ DCB is superior to DES

BASKET SMALL 2
Drug-coated balloons for small coronary artery disease

Primary Endpoint

Outcome @ 12 months: Cardiac death, non-fatal MI, TVR



→ DCB is non-inferior to DES

Jeger RV et al. Lancet 2018. http://dx.doi.org/10.1016/S0140-673

DCB: De Novo Lesions of small coronary vessels

TABLE 3 Randomized Controlled Trials of DCB Only in De Novo Lesions of Small Coronary Vessels

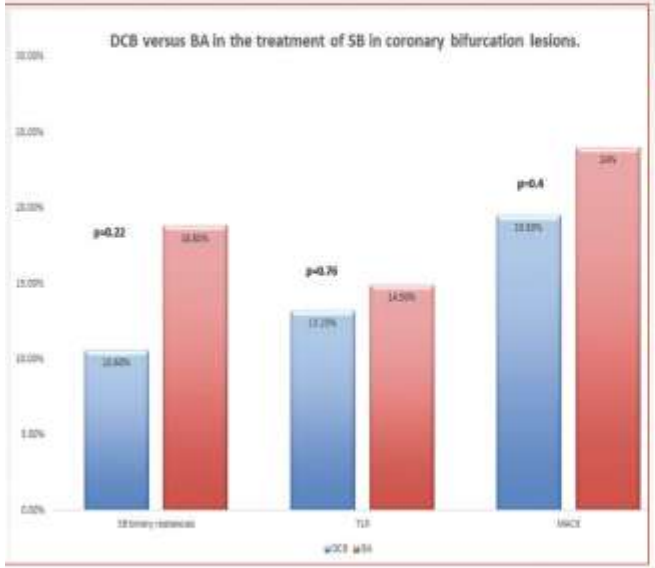
Study Name (Ref. #)	Comparators	n	Follow-Up Duration	Angiographic Follow-Up	p Value	MACE (%)	p Value	TLR (%)	p Value
PICCOLETO (58)	Dior PCB vs. TAXUS Liberté PES	57	6 months (angio) 9 months (clinical)	MLD 1.11 ± 0.65 mm vs. 1.94 ± 0.72 mm	0.0002	35.7 vs. 13.8	0.054	32.1 vs. 10.3	0.15
BELLO (59,66)	IN.PACT Falcon PCB vs. TAXUS Liberté PES	182	6 months (angio) 12 months (clinical) 3 yrs (clinical)	LLL 0.08 ± 0.38 mm vs. 0.29 ± 0.44 mm	0.001	10 vs. 16.3 14.4 vs. 30.4	0.21 0.015	4.4 vs. 7.6	0.37
RESTORE SVD (61)	Restore PCB vs. Resolute Integrity ZES	230	9-12 months (angio) 12 months (clinical)	LLL 0.26 ± 0.42 mm vs. 0.30 ± 0.35 mm, diameter stenosis 29.6 ± 2.0% vs. 24.1 ± 2.0%	0.41, <0.001	9.6 vs. 9.6	1.0	4.4 vs. 2.6	0.72
BASKET-SMALL 2 (60)	Sequent Please PCB vs. TAXUS Element PES and Xience EES	758	6 months (angio)* 12 months (clinical)	LLL 0.13 mm (−0.14 to 0.57 mm) vs. 0.10 mm (−0.16 to 0.34 mm)	0.72	8 vs. 8	0.918, 0.0152†	3.4 vs. 4.5	0.438

Only randomized controlled trials in patients with lesions in native coronary vessels ≤2.75 or 3.0 mm are included. *Only clinically indicated angiography. †Noninferiority.

ZES = zotarolimus-eluting stent; other abbreviations as in Tables 1 and 2.

DCB: Bifurcation Lesions

Outcomes With Drug-Coated Balloons for Treating the Side Branch of Coronary Bifurcation Lesions



- SB stenting was performed in 7.5% vs 8.6% in the DCB and BA groups.
- At angiographic FU (9.1±2.1 months) DCB associated with lower SB late lumen loss compared with BA (mean difference, -0.19 mm; 95%CI -0.37 to -0.01; p=0.04).
- No difference in SB binary restenosis (OR: 0.52; 95%CI, 0.18-1.47; p=0.22).
- Clinical FU (15.1±5.8 months), DCB and BA had similar risk of MACE (OR 0.76; 95%CI, 0.4-1.4; p=0.40), and TLR (OR, 0.85; 95%CI, 0.3-2.4; p=0.76).

Megaly M. et al. J Invas Cardiol 2018;30(11):393-399aria

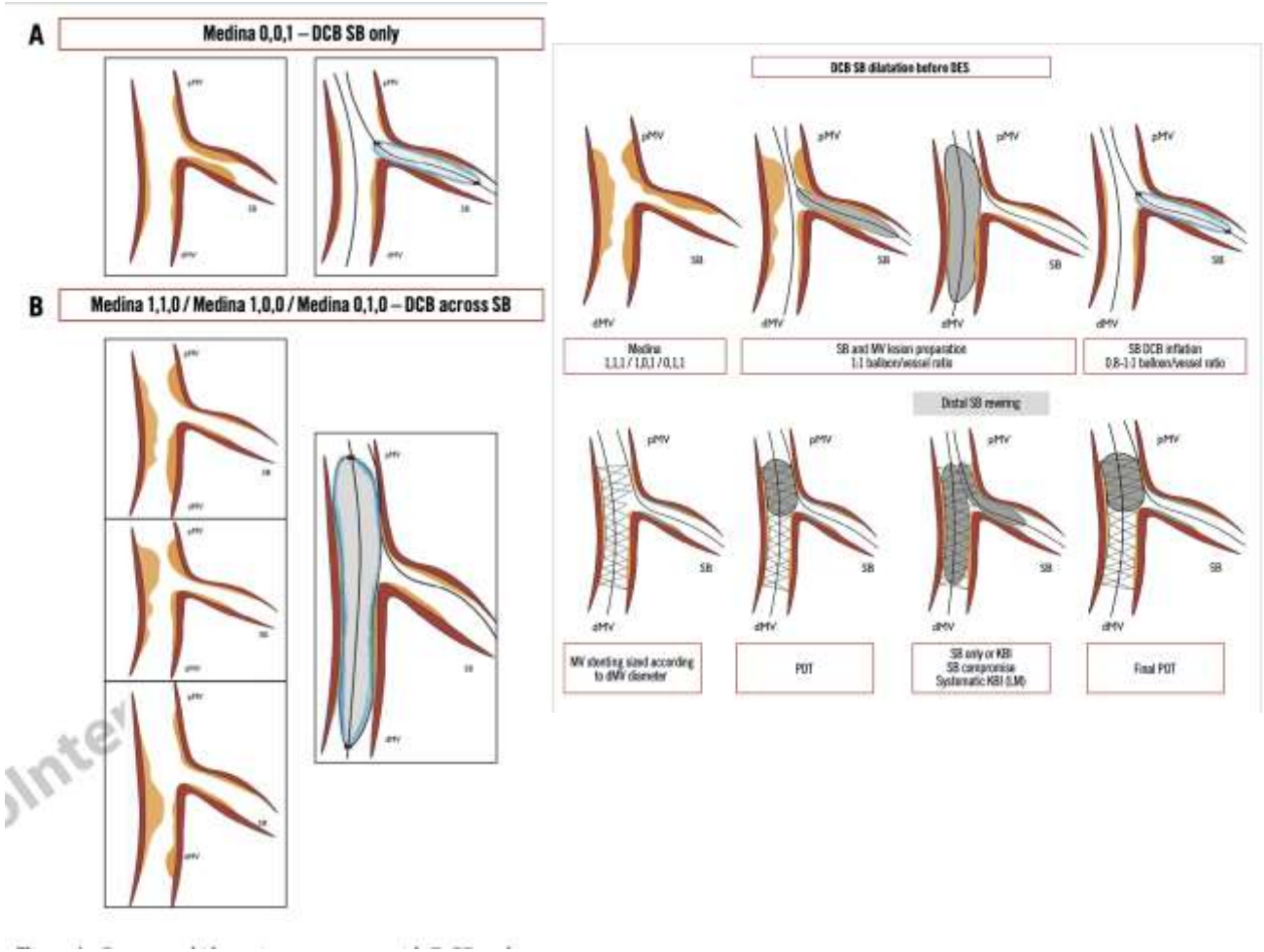
Treatment of Bifurcation Lesions

1st DCB SB - 2nd Stenting MB

→ To achive a circumferential contact with the drug at the ostium of SB prior to the stenting

→ To avoid any damage of the drug coating on DCB by crossing stent struts

DCB: Bifurcation Lesions



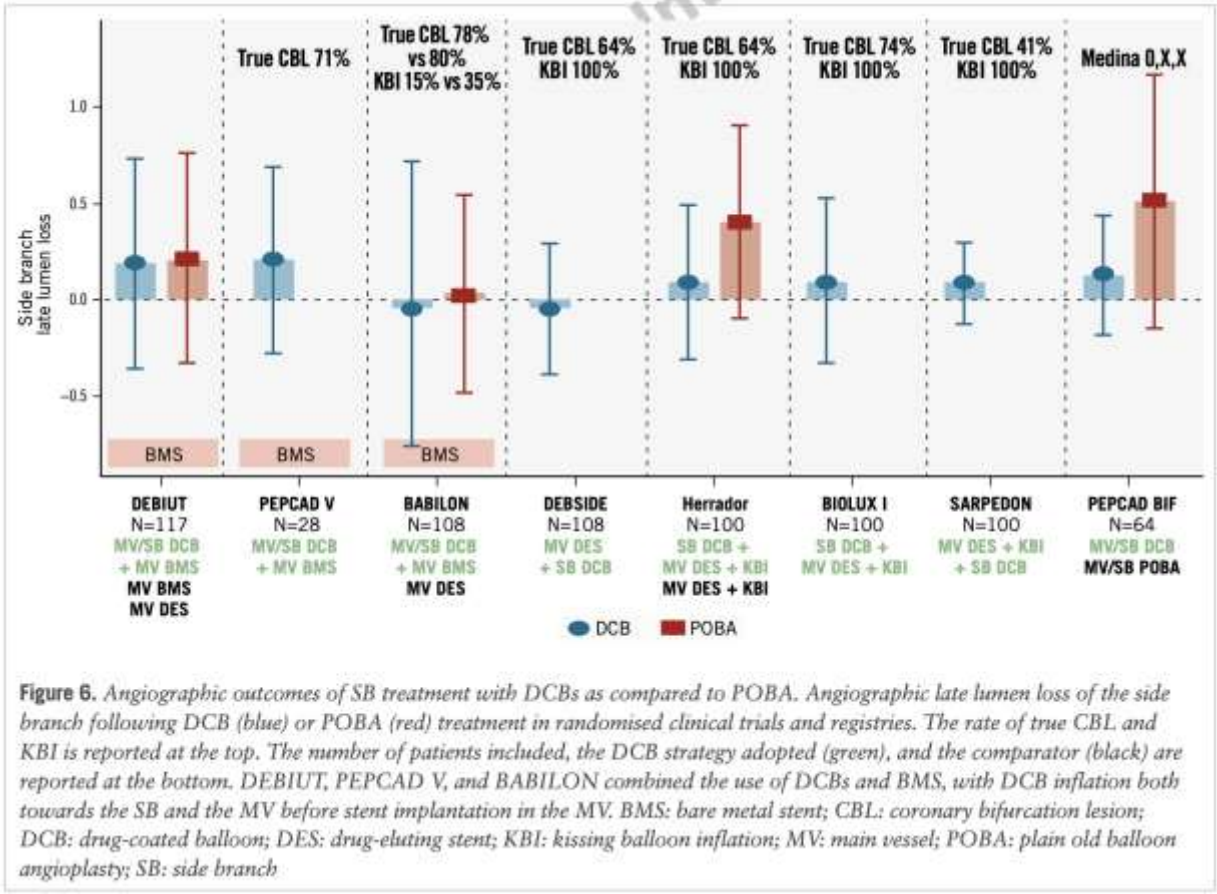
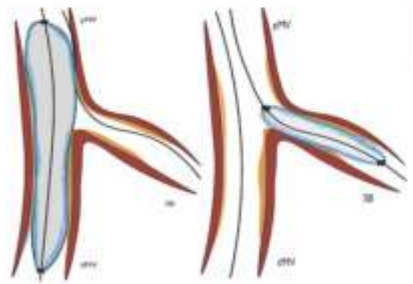


Figure 6. *Angiographic outcomes of SB treatment with DCBs as compared to POBA. Angiographic late lumen loss of the side branch following DCB (blue) or POBA (red) treatment in randomised clinical trials and registries. The rate of true CBL and KBI is reported at the top. The number of patients included, the DCB strategy adopted (green), and the comparator (black) are reported at the bottom. DEBIUT, PEPCAD V, and BABILON combined the use of DCBs and BMS, with DCB inflation both towards the SB and the MV before stent implantation in the MV. BMS: bare metal stent; CBL: coronary bifurcation lesion; DCB: drug-coated balloon; DES: drug-eluting stent; KBI: kissing balloon inflation; MV: main vessel; POBA: plain old balloon angioplasty; SB: side branch*

Drug-coated balloons for coronary bifurcation lesions: techniques, advantages, pitfalls, and state-of-the-art.

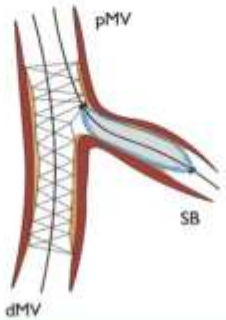
LEAVE NOTHING BEHIND



Advantages
- Efficient and sustained drug delivery
- No polymers or permanent implants
- Preserves vessel geometry and SB access
- DAPT de-escalation

Avoid DCB KBI
- Suboptimal delivery of the drug
- Proximal interaction of the two balloons
- Higher risk of dissection

BLENDED in the PROVISIONAL pathway



Advantages
- ↑ use of provisional vs 2-stent strategy
- ↓ stent burden
- Avoids issues related to polymer and strut crushing
- Allows SB late lumen enlargement

DCB to the SB after DES implantation
- Suboptimal drug delivery due to strut interference
- Limited deliverability in jailed SB

WHAT DO WE KNOW?
- DCB for SB treatment seems to be reasonable and supported by clinical and angiographic data and RCTs
- The use of PCB + BMS is inferior to new-generation DES
- The use of PCB + DES showed promising results in real-world registries
- "DCB-only strategy" is feasible and safe in case of Medina 0,X,X lesions

MORE DATA NEEDED
- RCTs used different study protocols, methods, and devices
- RCTs were relatively small, with no routine POT and a low KBI rate

Simone Fezzi *et al.* • *EuroIntervention* 2025;21:e1177-e1197 • DOI: 10.4244/EIJ-D-25-00201

BMS: bare metal stent; DCB: drug-coated balloon; DES: drug-eluting stent; dMV: distal main vessel; KBI: kissing balloon inflation; PCB: paclitaxel-coated balloon; pMV: proximal main vessel; POT: proximal optimisation technique; RCT: randomised controlled trial; SB: side branch

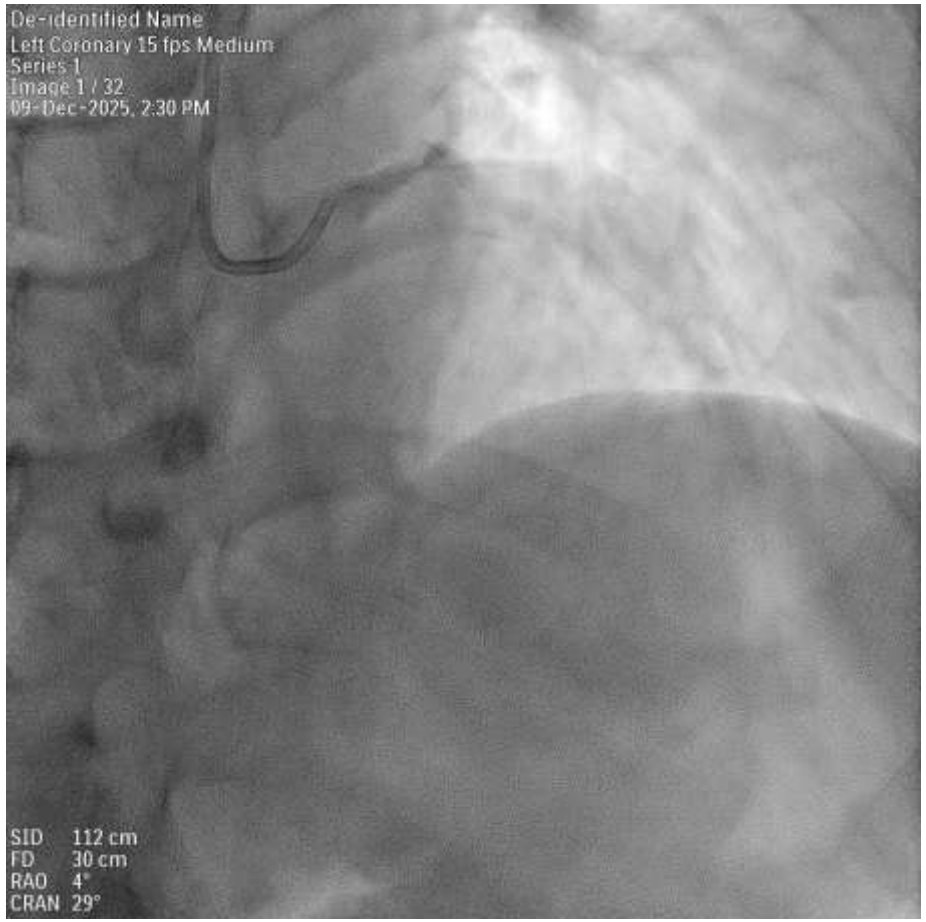
CASE

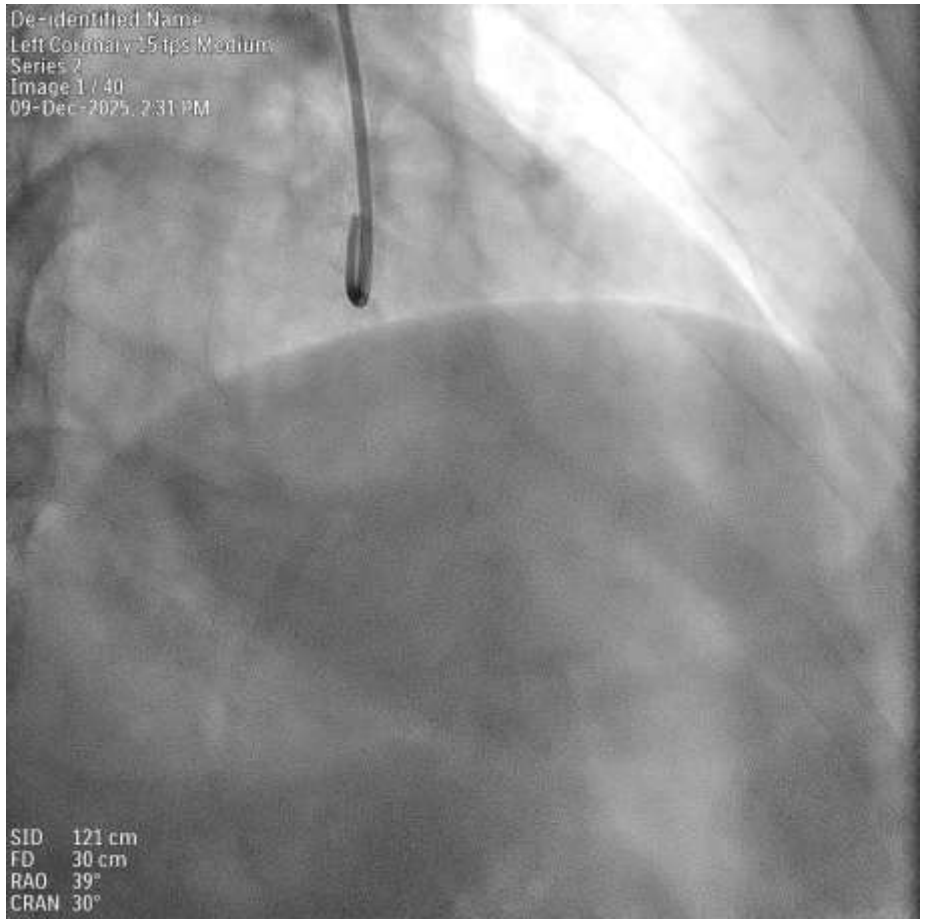
60 y M

Heavy smoker

Hyperlipidemia

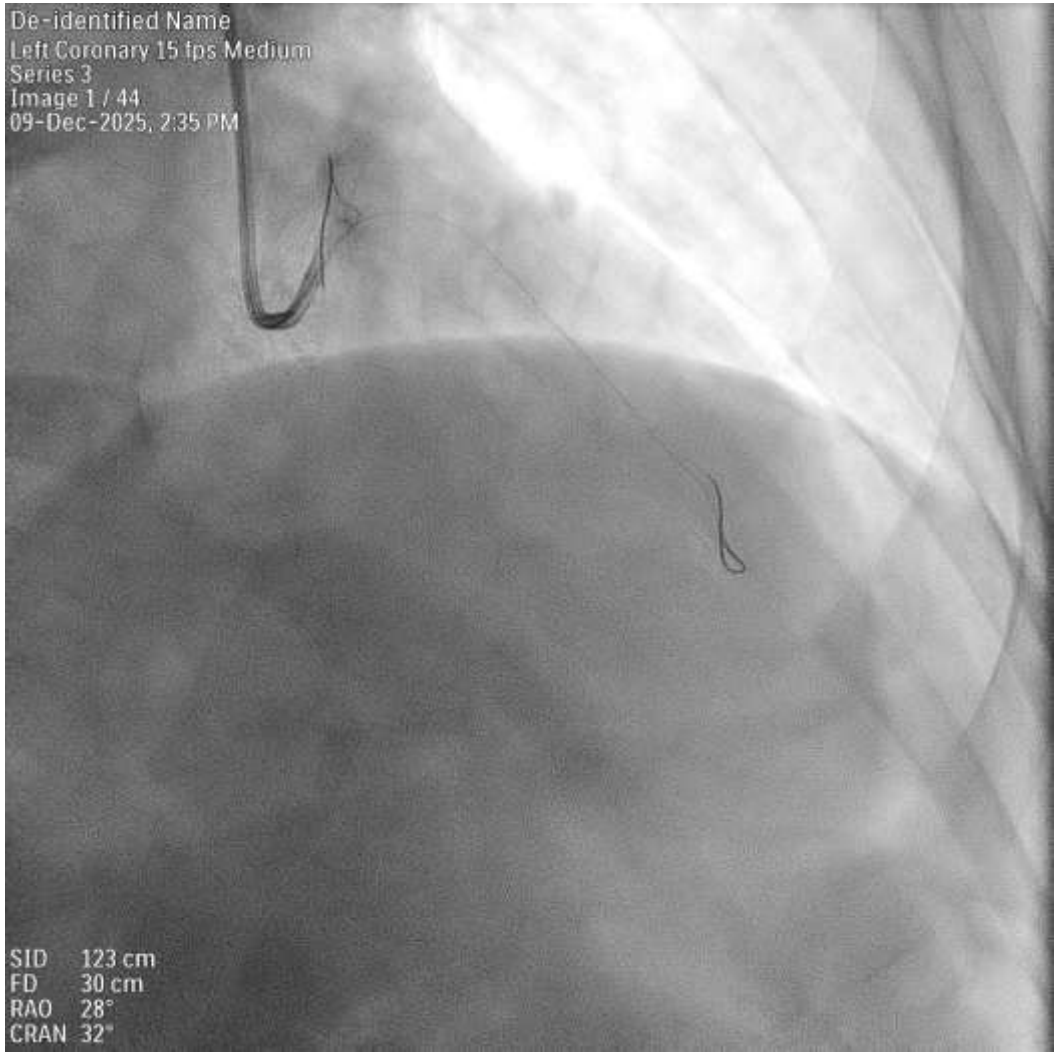
Distal LM Lesion

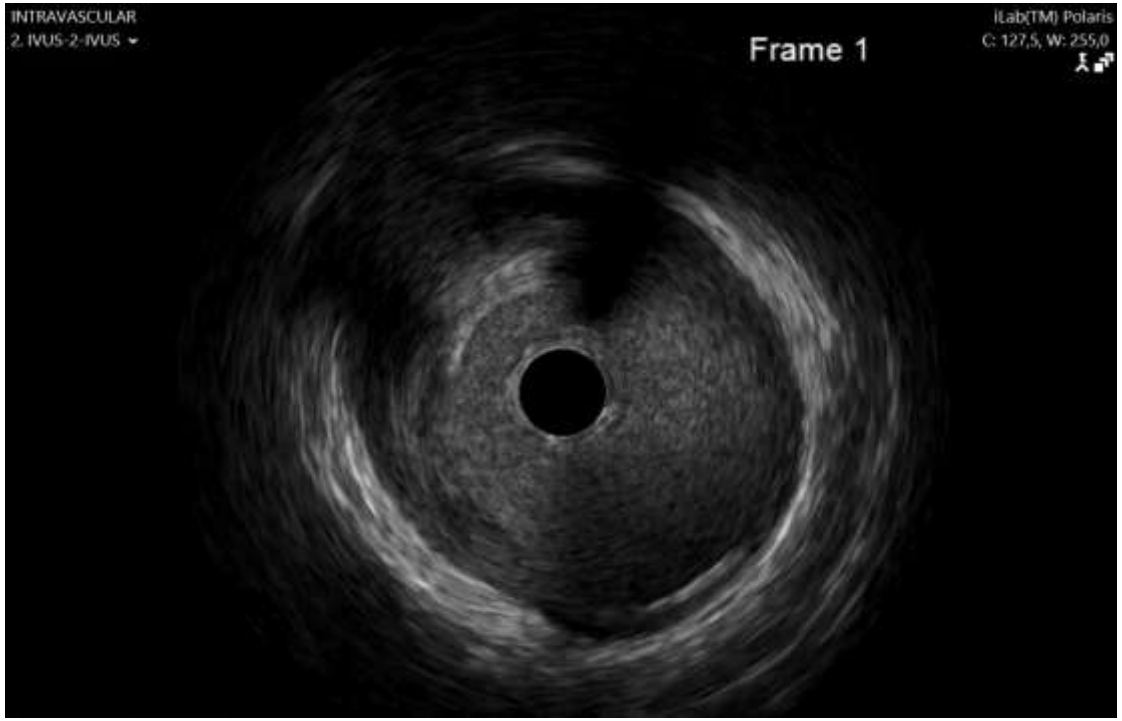




Z.k

IVUS Preformed: Calcified LAD and distal LM





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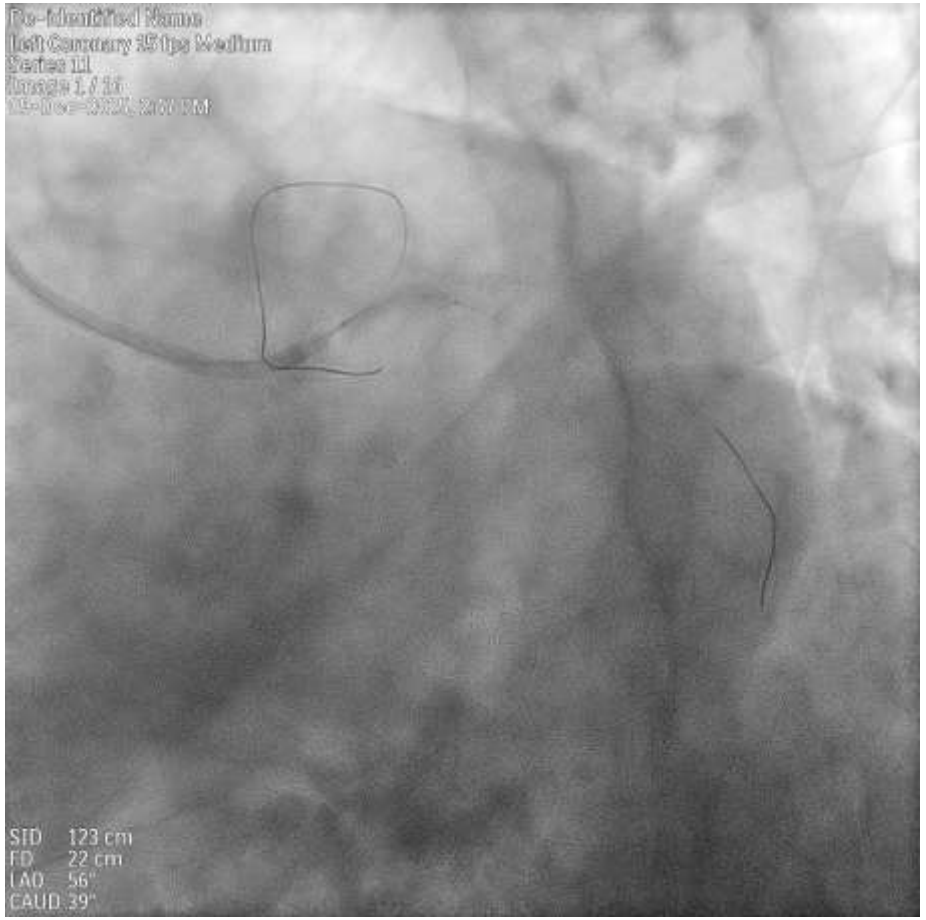
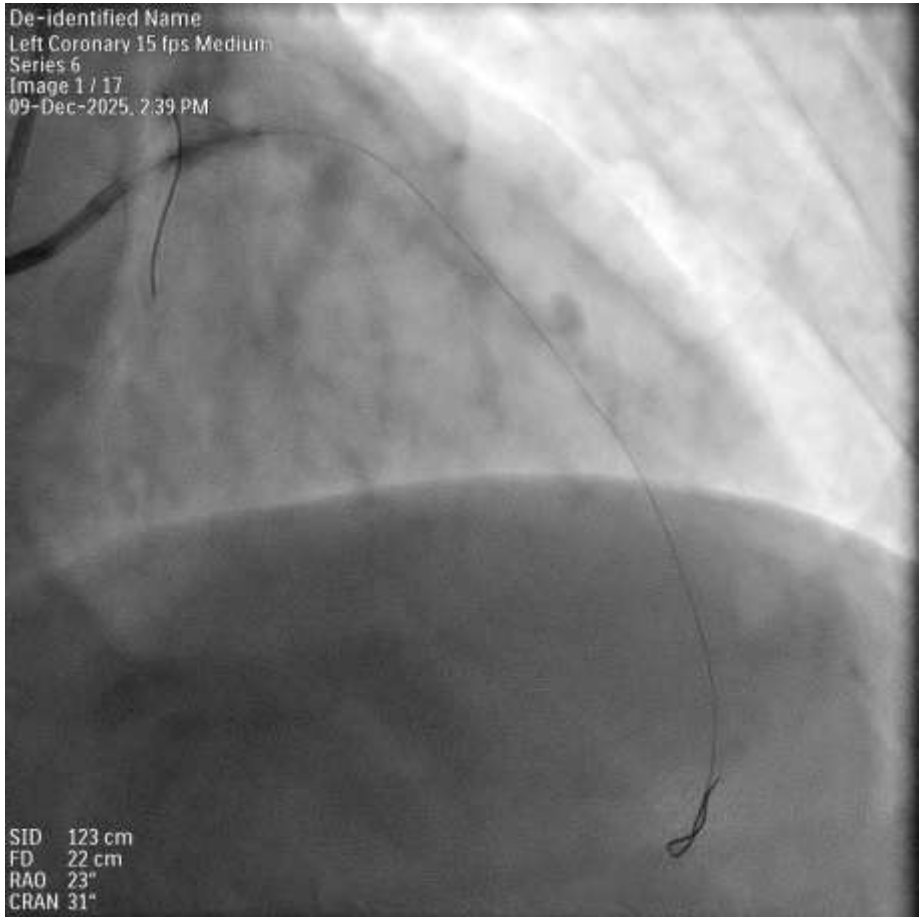
Predilatation and Lesion Preparation with Scoring Balloon 3.5x15 mm





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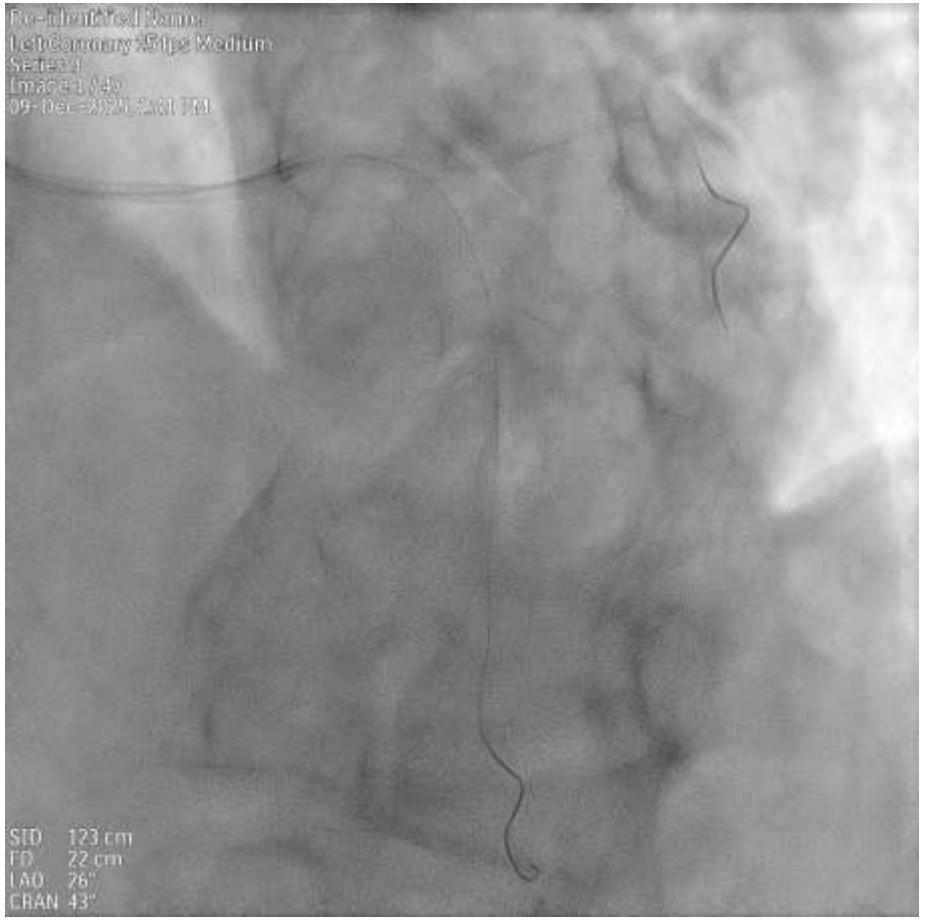
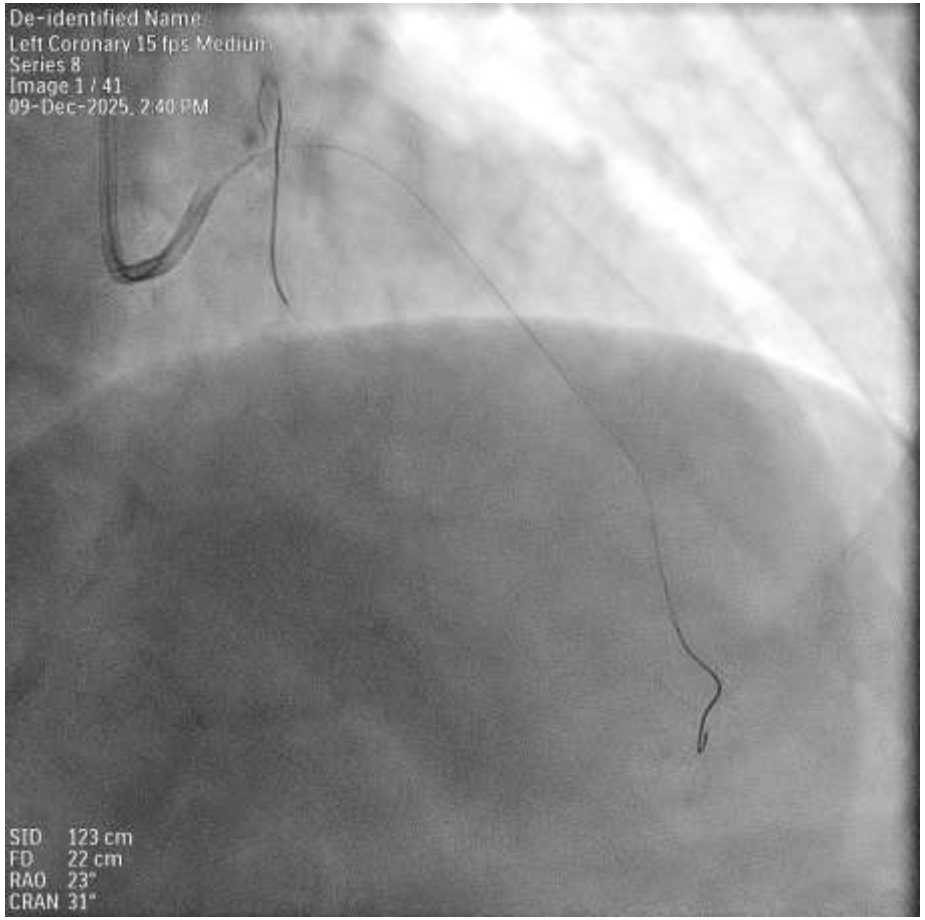
No Dissection and Flow limitation





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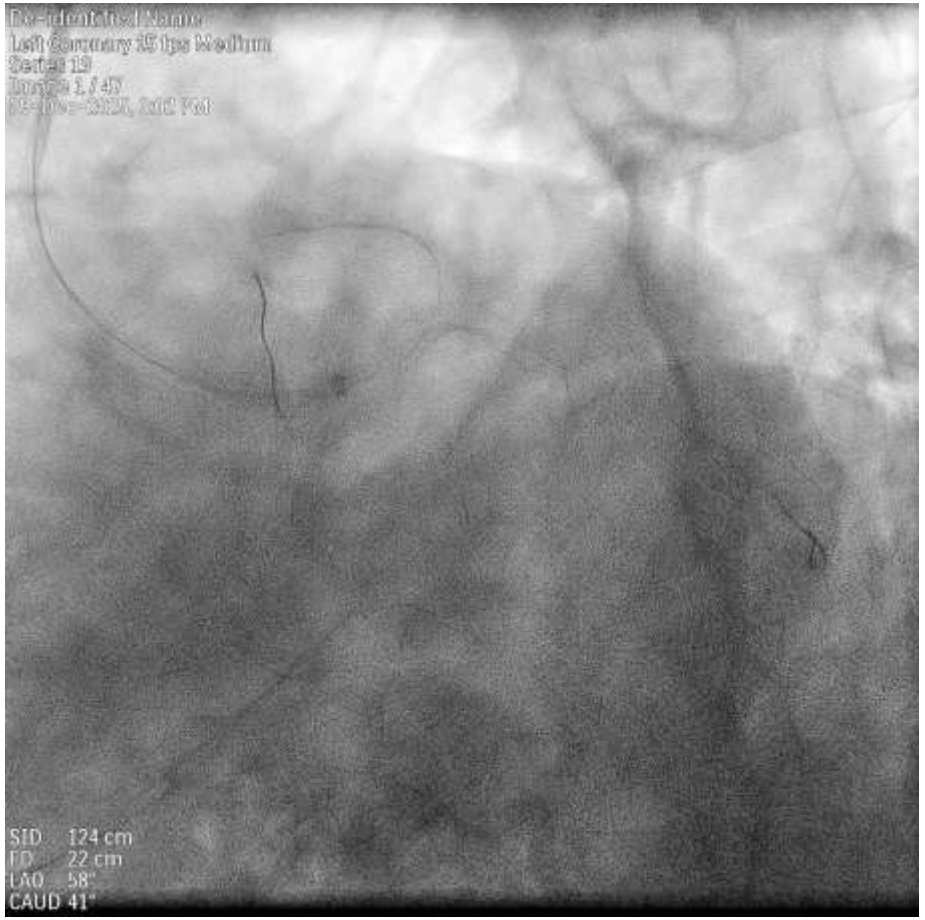
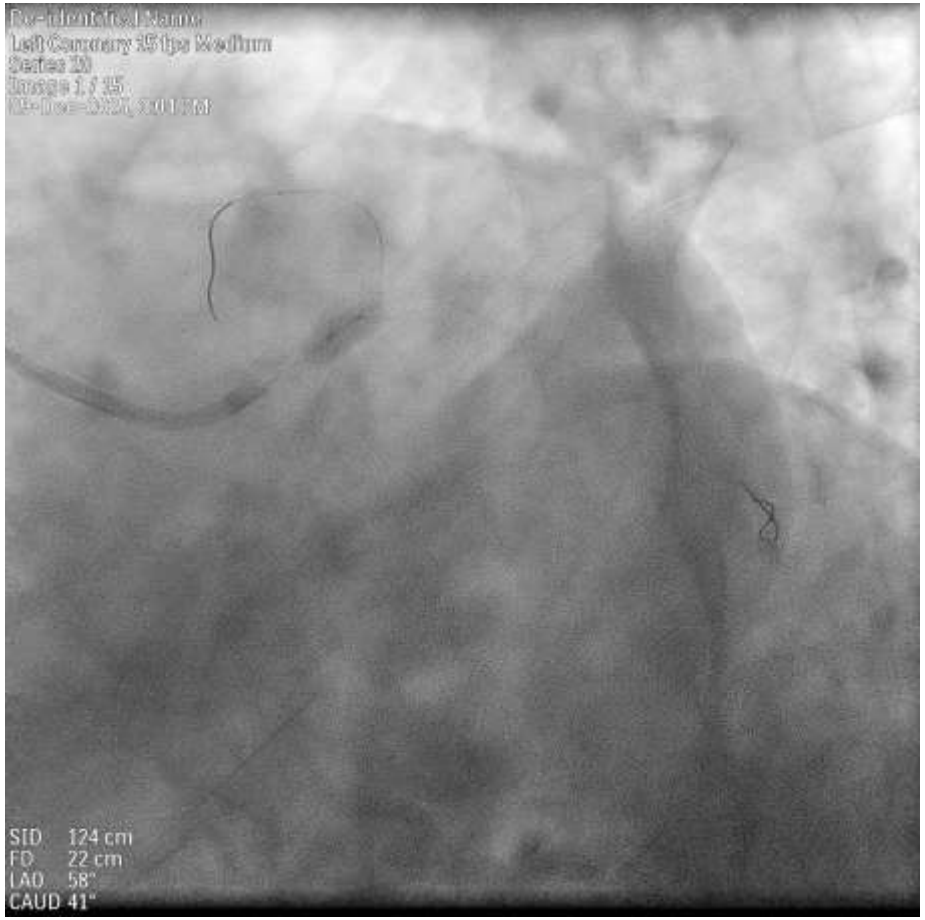
Stenting to LM-CX 4.0x22mm and POT 4.5x8 mm 20 atm performed





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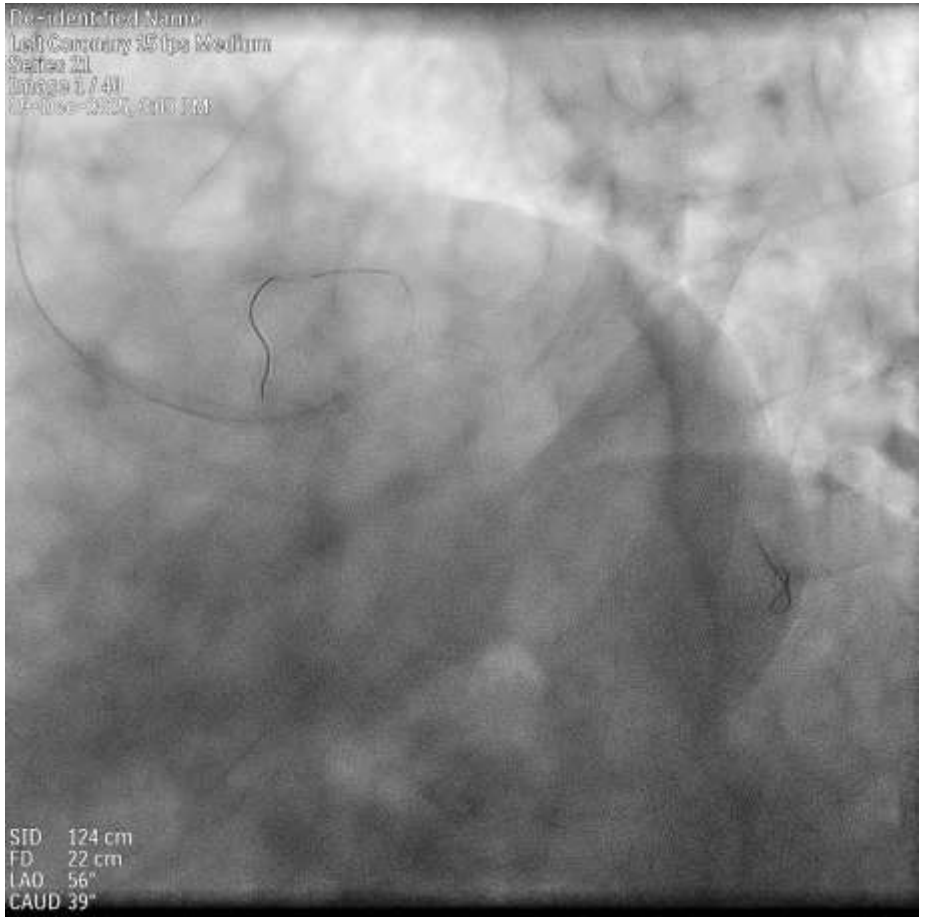
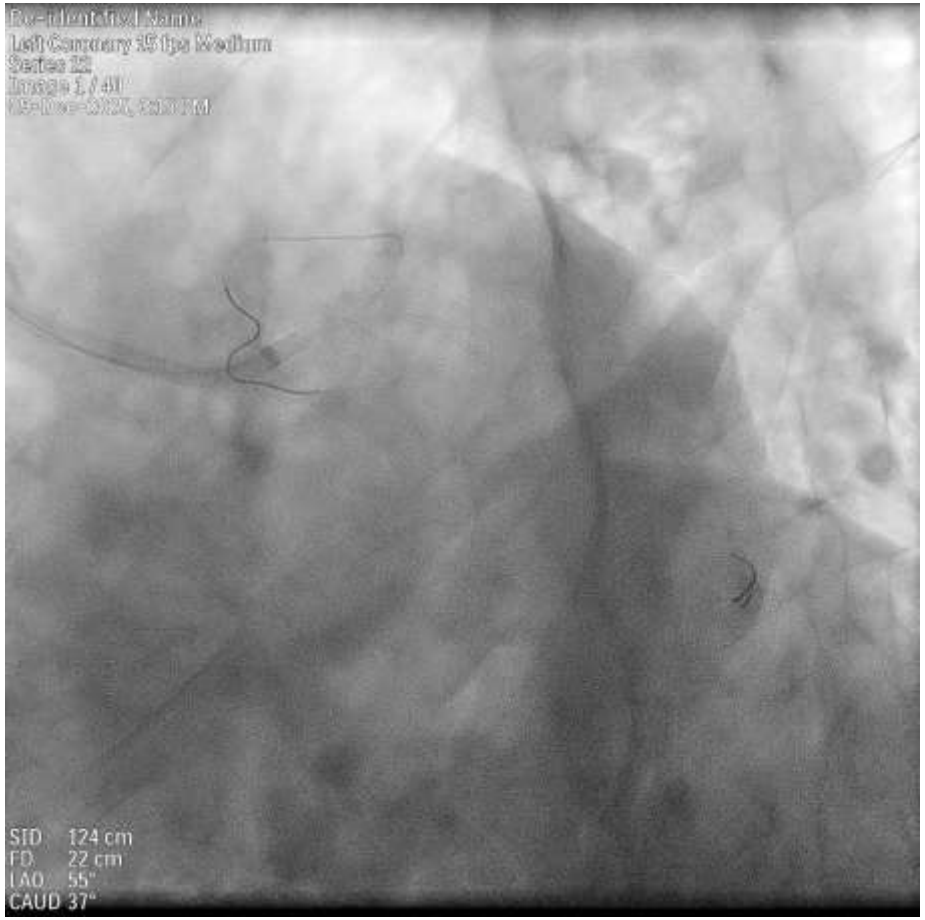
Stenting to LM-CX and POT performed





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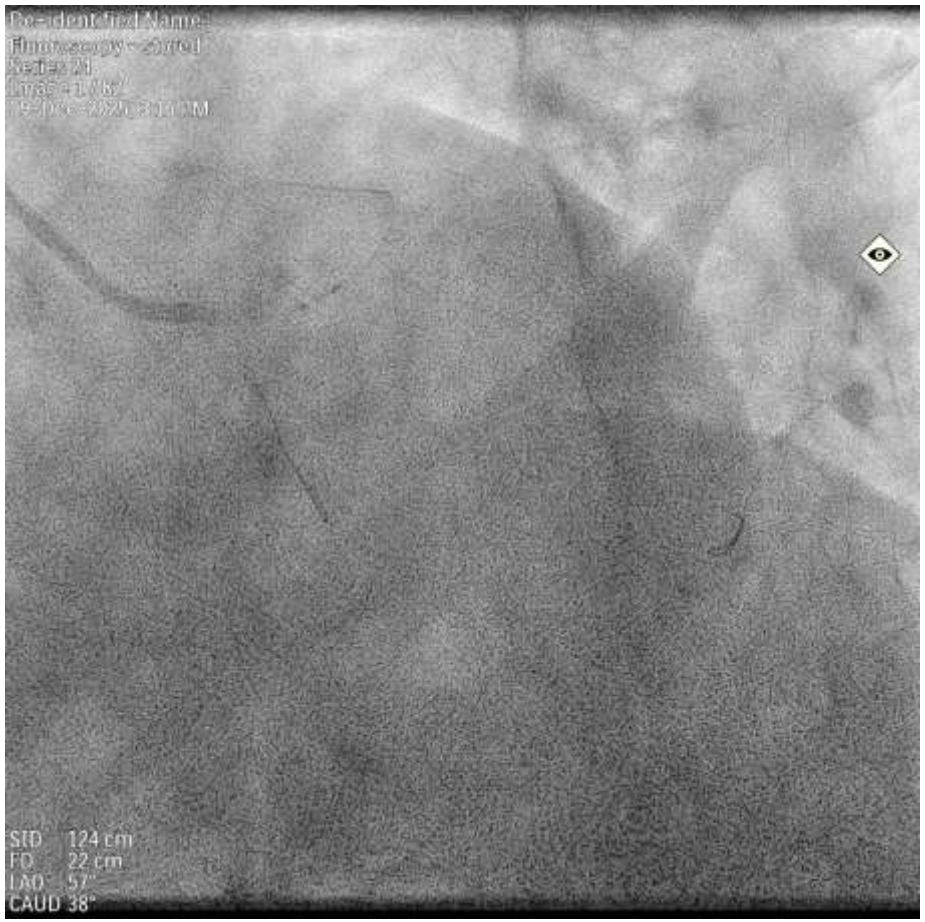
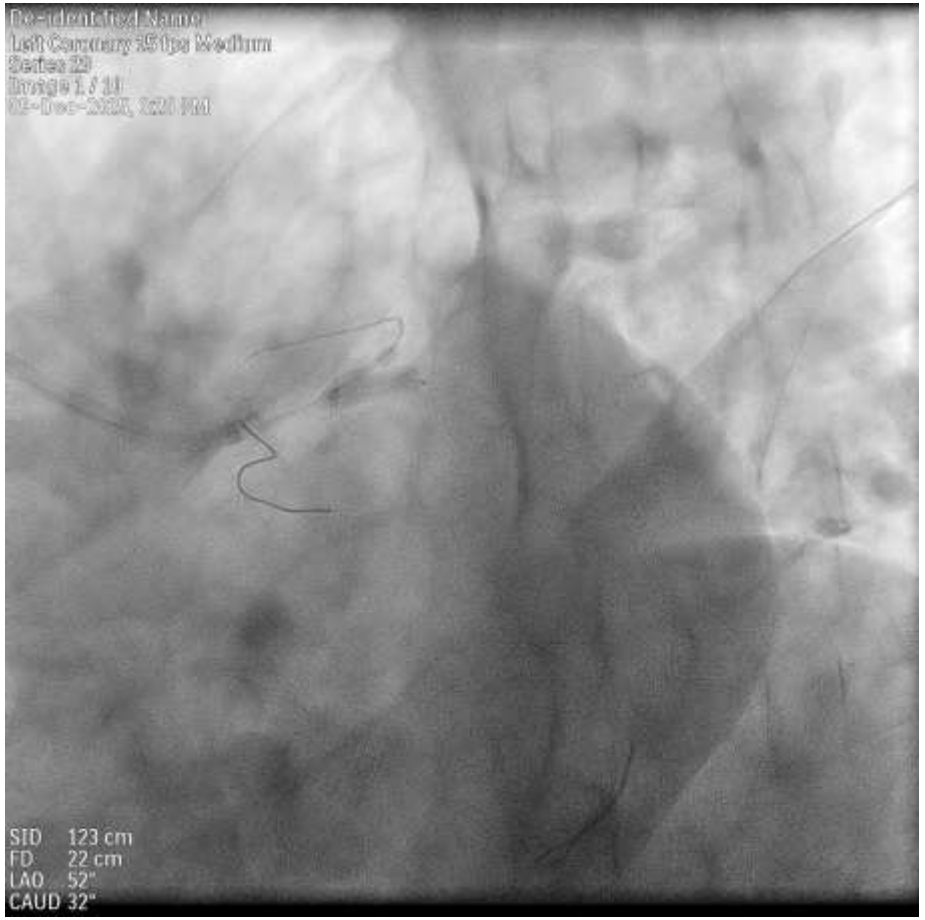
SID 124 cm
FD 22 cm
LAO 57°
CAUD 38°


SID 124 cm
FD 22 cm
LAO 57°
CAUD 38°

Z.k

Kissing Ballon and DCB to LM-LAD



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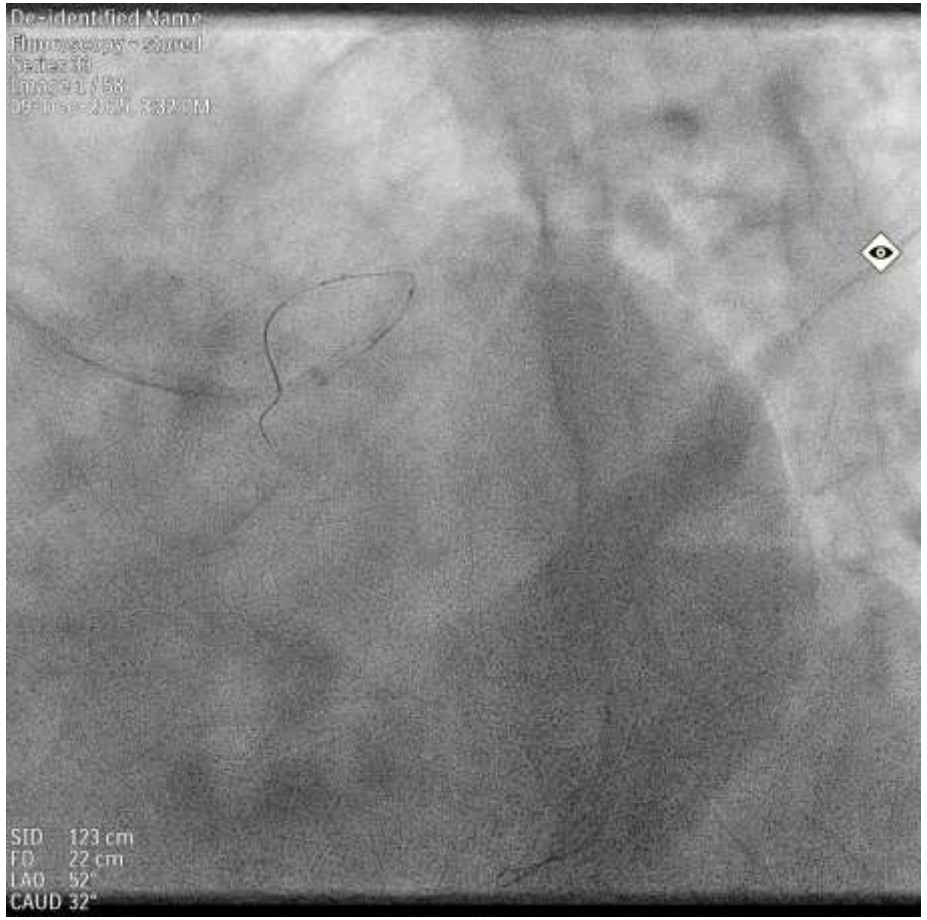
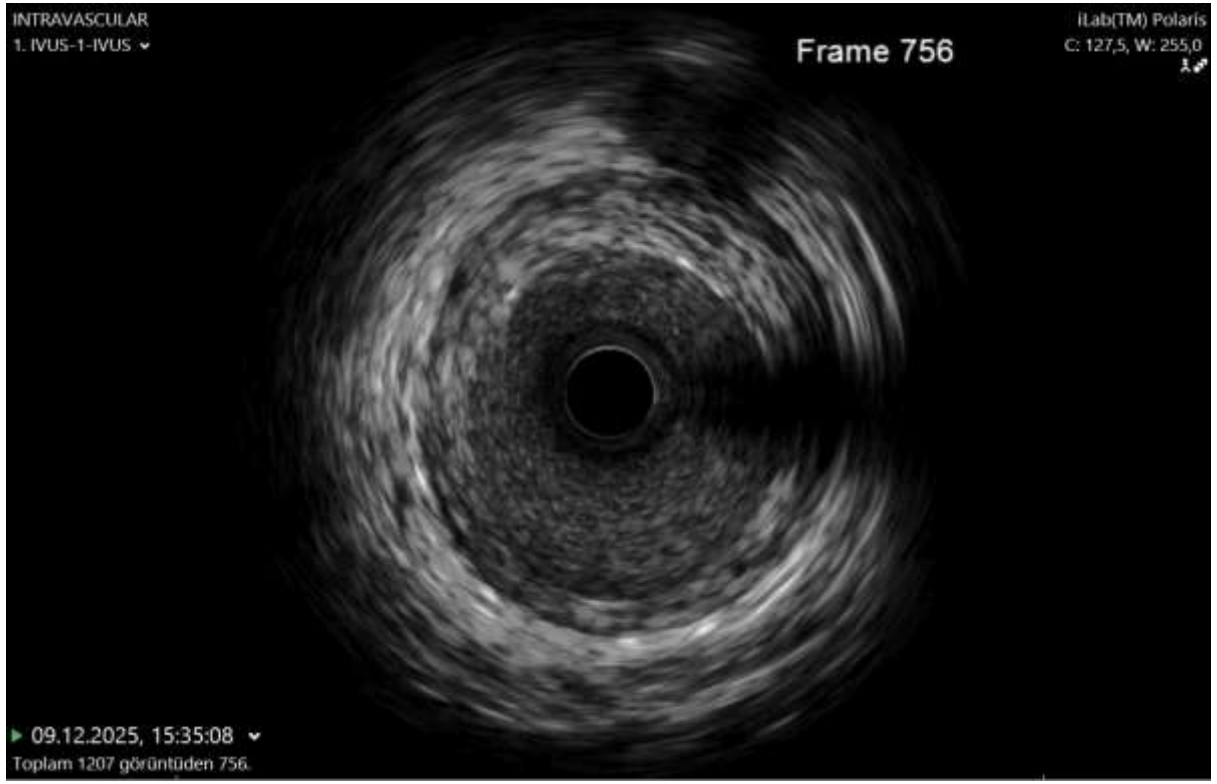
IVUS performed to see LM-LAD





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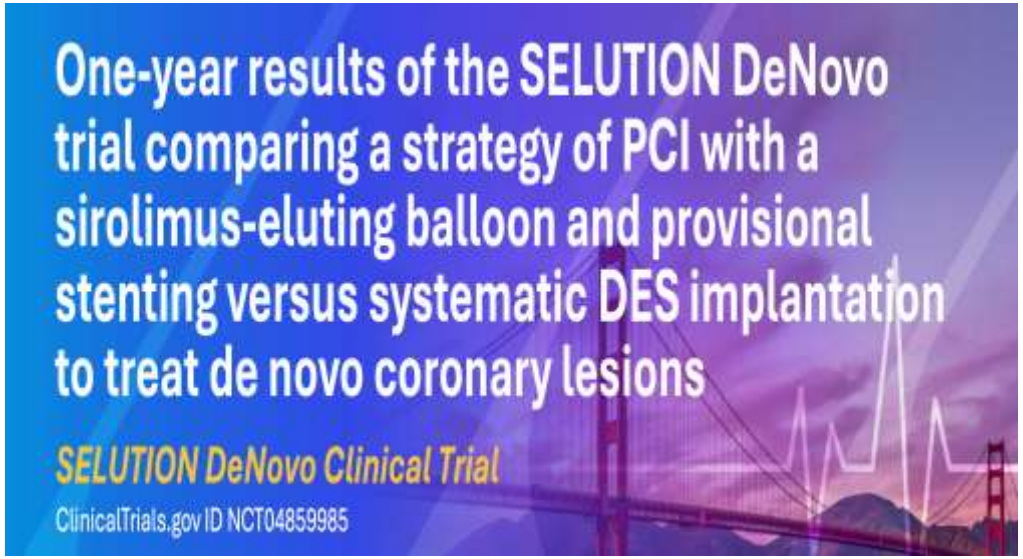
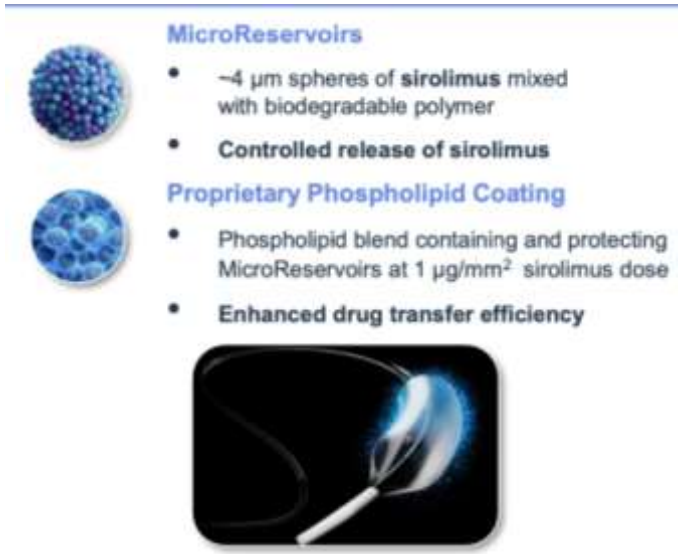
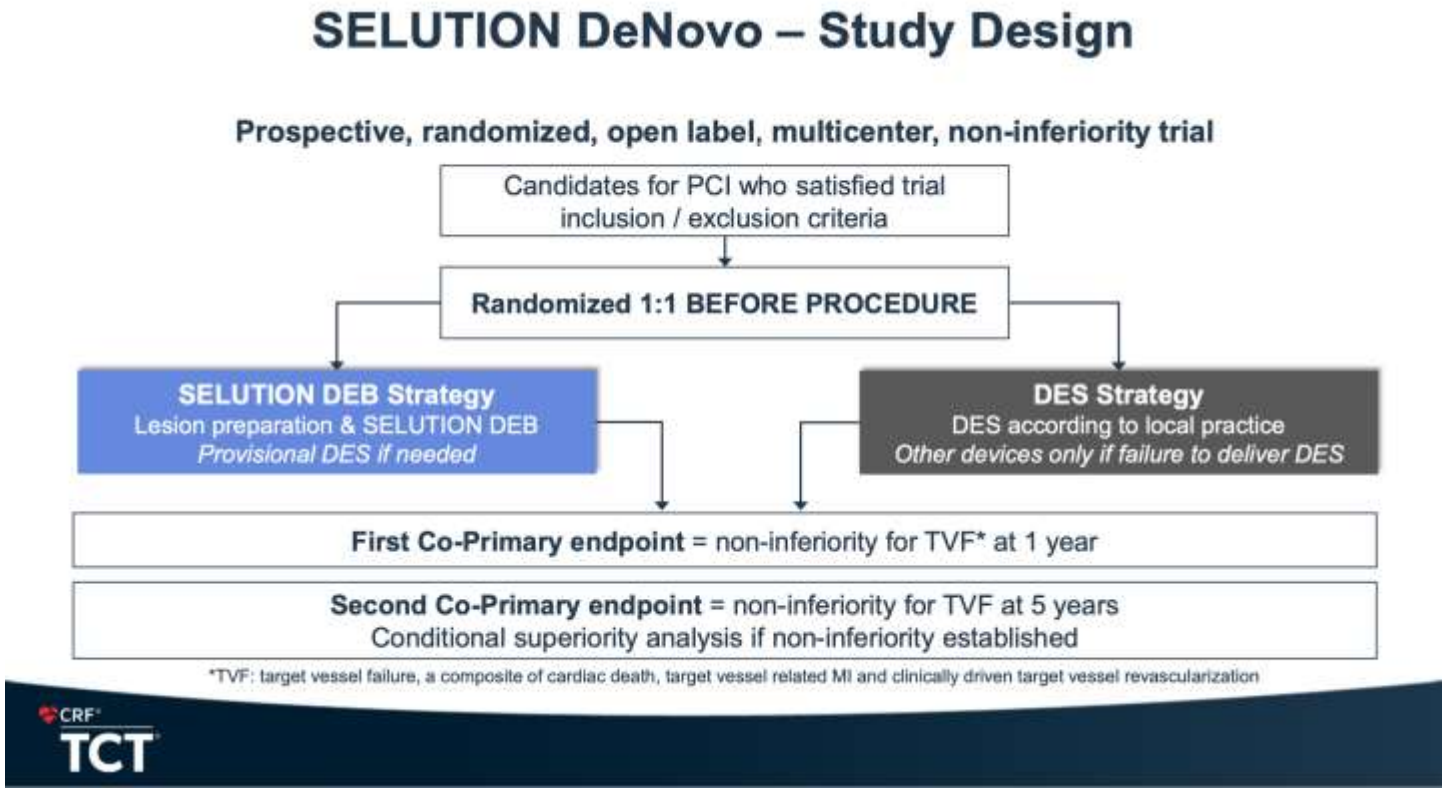
De-Novo Coronary Lesions

DCB in De Novo Lesion : SELUTION TRIAL







DCB in De Novo Lesion : SELUTION TRIAL

Angiographic Characteristics

Characteristic	SELUTION DEB Strategy	DES Strategy
Number of treated lesions	2243	2264
Treated lesions per patient	1.4 ± 0.6	1.4 ± 0.7
Patients with multivessel procedures (%)	15.8	17.1
Location of treated lesions (%)		
Left main	0.1	0.3
Left anterior descending artery	47.7	47.3
Proximal left anterior descending artery (%)	**18.0**	**19.3**
Left circumflex artery	26.7	26.4
Right coronary artery	25.6	26.3
Any device size ≥ 3.0 mm (%)	**67.3**	**63.4**
Bifurcation lesion (%)[1]	32.1	30.8
Moderate or severe calcified lesion (%)[1]	**24.6**	**22.4**
ACC/AHA type B2 or C lesion (%)[1]	**66.8**	**62.3**

CRF TCT

ACC/AHA: American College of Cardiology/American Heart Association
[1]Based on a qualitative analysis of available angiograms by the CoreLab

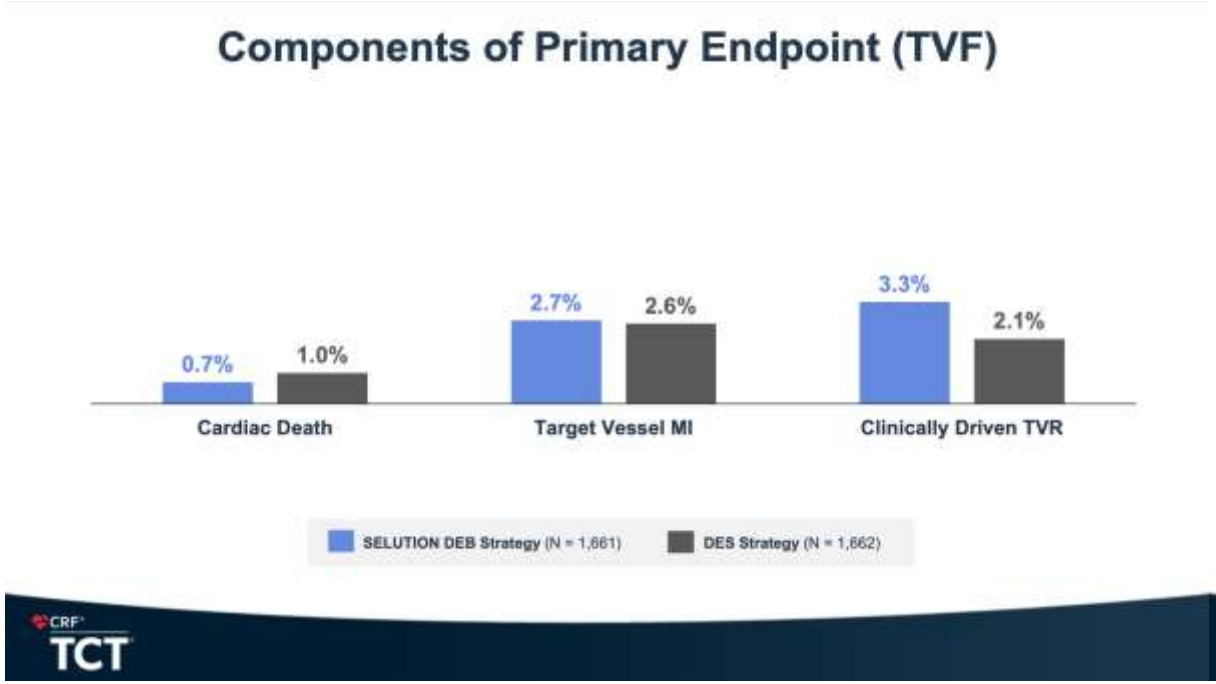
Procedural Characteristics

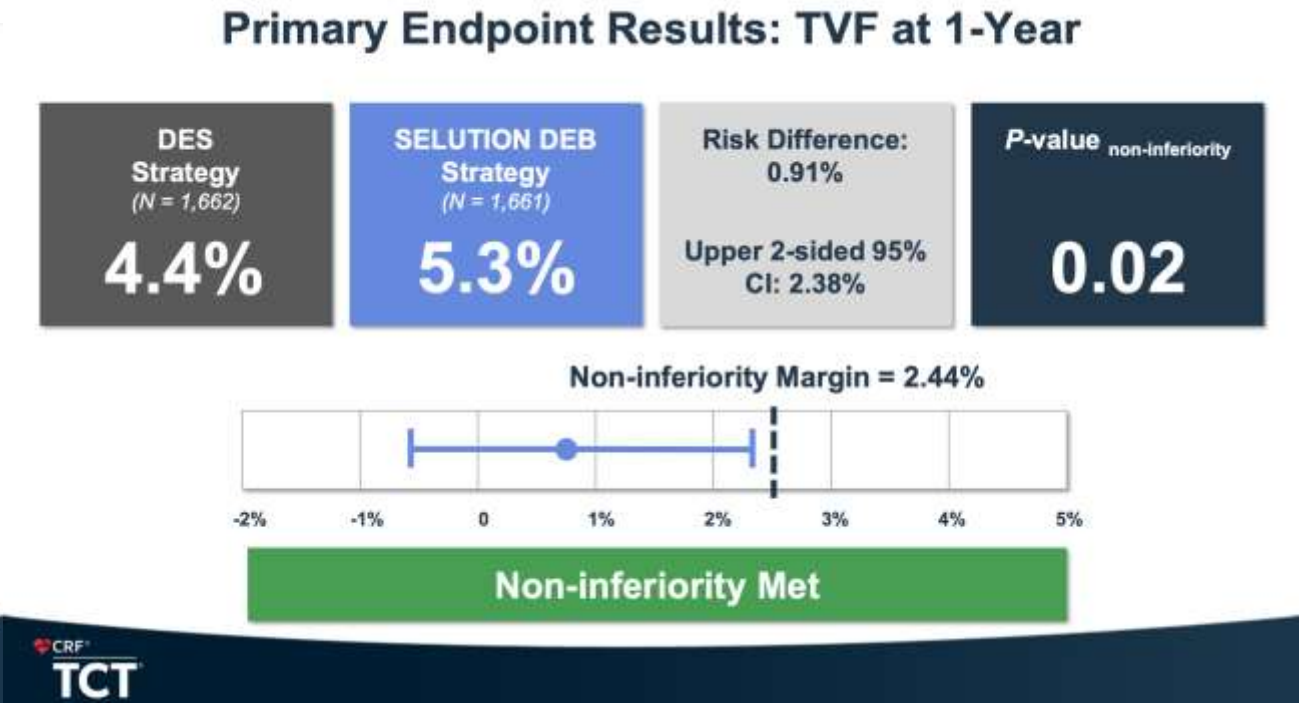
Characteristic	SELUTION DEB Strategy	DES Strategy
Number of procedures	1783	1776
Staged procedure (%)	6.6	6.3
Radial access (%)	**93.3**	**94.4**
Specialty balloon per lesion (%)[1]	**28.5**	**7.9**
Rotational atherectomy or IVL per lesion (%)	**3.6**	**2.5**
Intracoronary imaging per lesion (%)[2]	**15.8**	**18.8**
Number of devices per lesion	1.3 ± 0.6	1.2 ± 0.5
Number of devices per patient	1.7 ± 1.0	1.6 ± 0.9
Nominal device diameter (mm)	3.1 ± 0.5	3.1 ± 0.5
Mean inflation duration for SELUTION DEB (sec)	62.1 ± 28.9	NA
Total device length per lesion (mm)	31.6 ± 17.1	28.7 ± 15.1
Provisional device use per lesion (%)	**18.1**	**0.2[3]**
Provisional device use per patient (%)	**20.7**	**0.2[3]**
Procedure duration (min)	**55 ± 32**	**53 ± 35**

CRF TCT

[1]Specialty balloons include scoring, cutting and high-pressure balloons
[2]Intracoronary imaging includes intravascular ultrasound and optical coherence tomography
[3]Two sirolimus and two paclitaxel DCB's

DCB in De Novo Lesion : SELUTION TRIAL





DCB in De Novo Lesion : SELUTION TRIAL

Summary

- SELUTION DeNovo was a large, investigator-driven, pragmatic strategy study that randomized patients before lesion preparation
- There were no acute or late safety concerns – the SELUTION DEB strategy had low rates of cardiac death, lesion thrombosis, and TV-MI, similar to DES
- 80% of participants treated with the SELUTION DEB did not require a stent
- These results, with broad inclusion criteria, apply to a significant segment of PCI procedures including high-risk patients and complex lesions
- Five-year follow-up is planned to assess long-term non-inferiority and potential superiority of a SELUTION DEB strategy with minimal stenting

CRF TCT

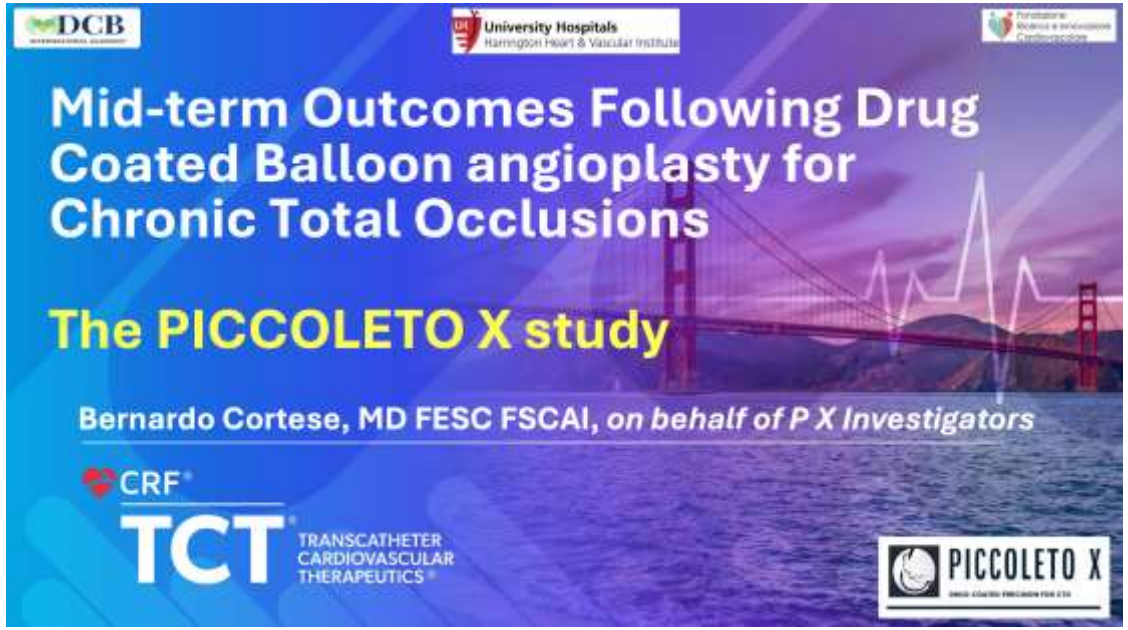
Key Learnings

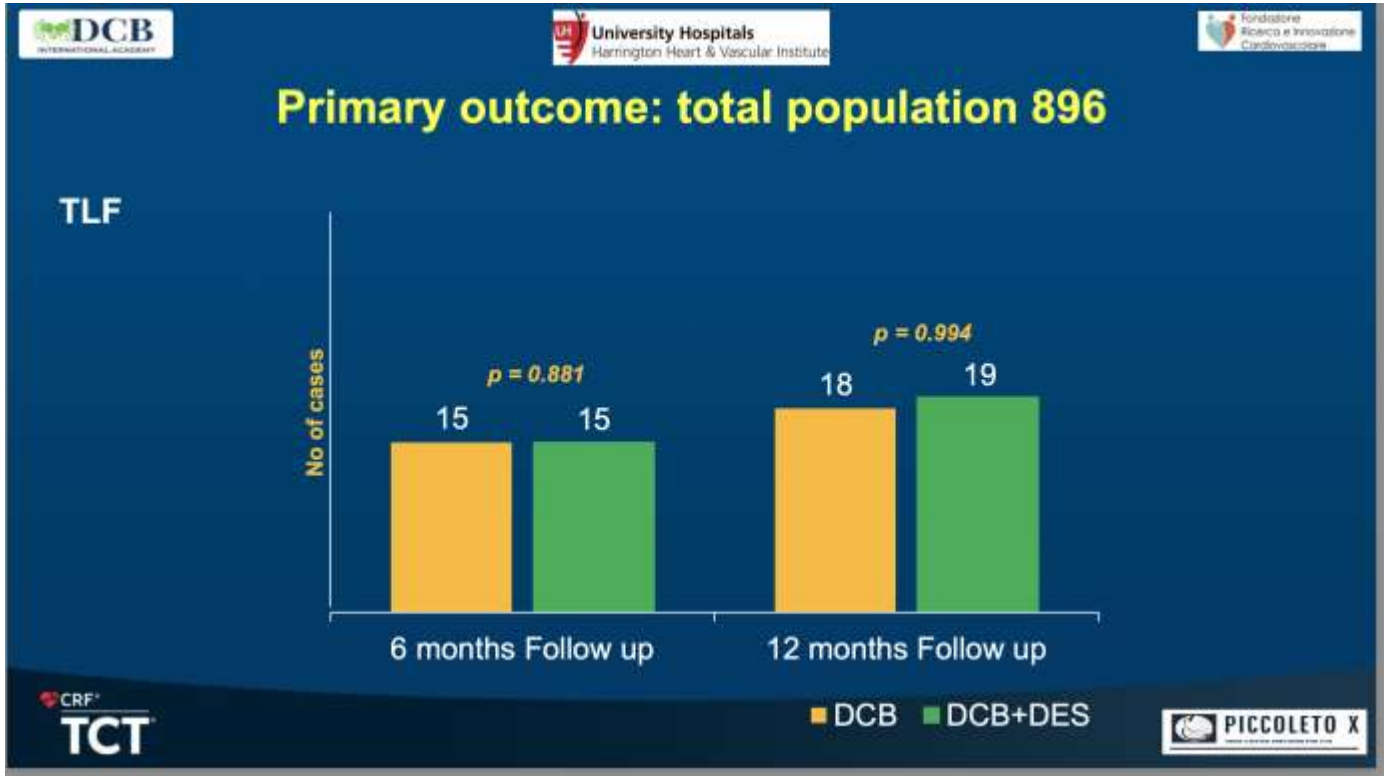
- SELUTION DeNovo was a large, investigator-driven, pragmatic strategy study that randomized patients before lesion preparation
- 80% of participants treated with the SELUTION DEB did not require a stent
- With experience stenting rates reduce. Ultimately provisional stenting was very low for this study

Characteristic	SELUTION DEB Strategy	DES Strategy
Primary device use per patient (%)	79.4	99.8
Primary device + Provisional use per patient (%)	20.6	0.2
Provisional device use per lesion (%)	18.1	0.2

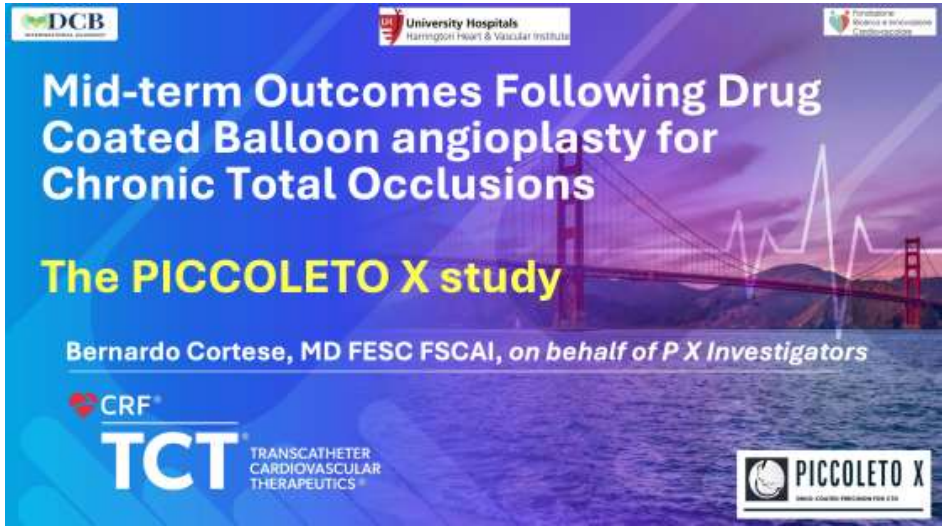
CRF TCT

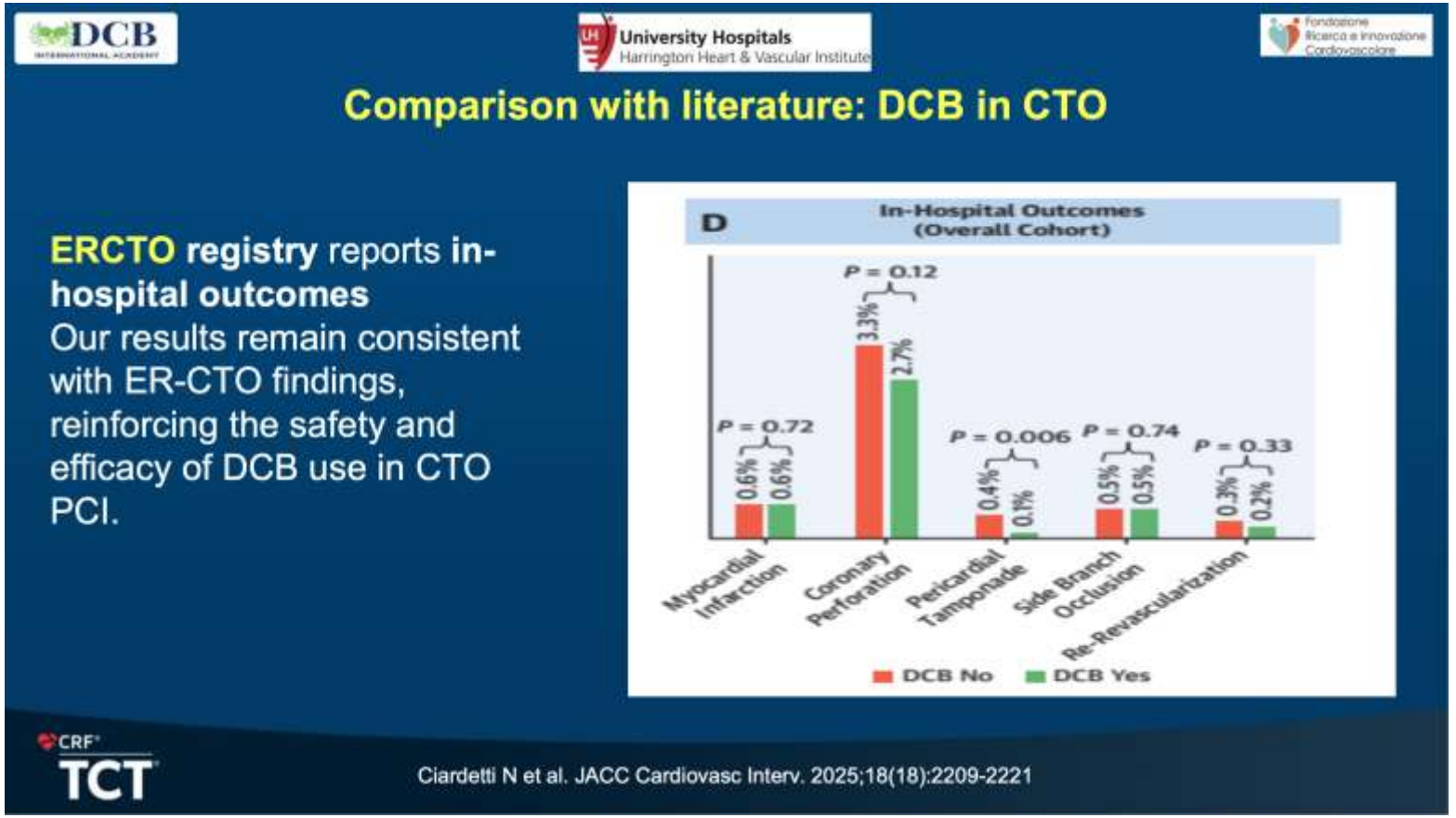
DCB in CTO patients

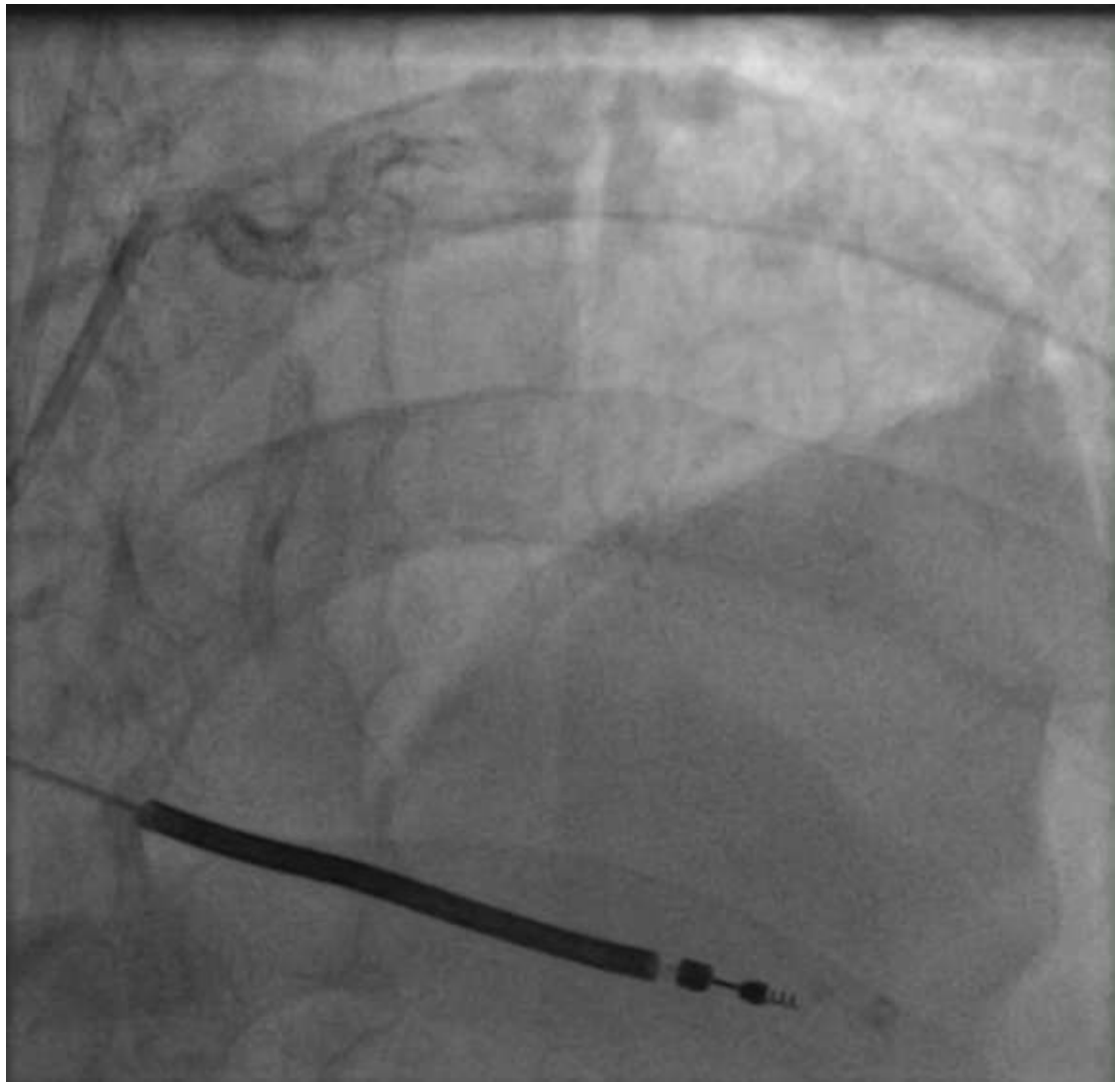


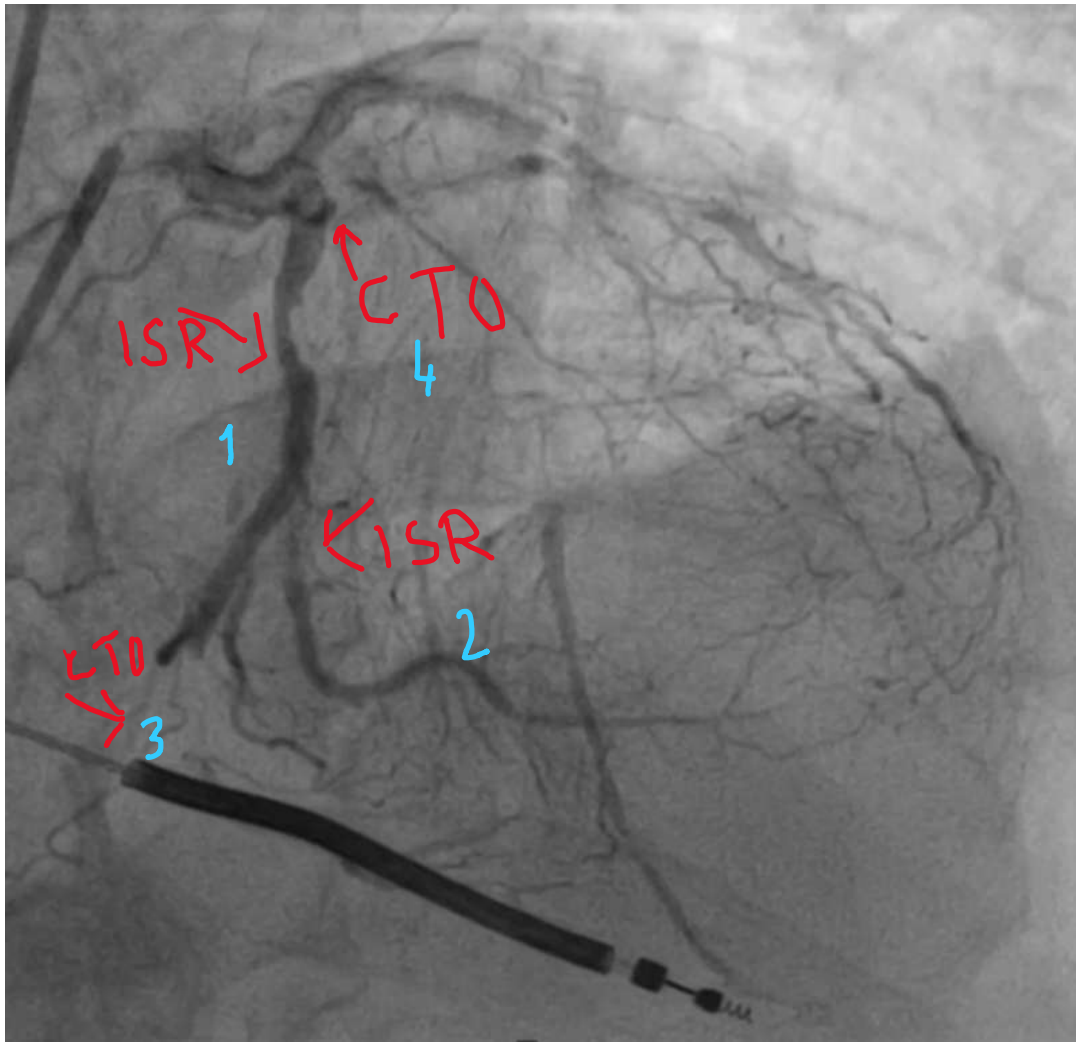


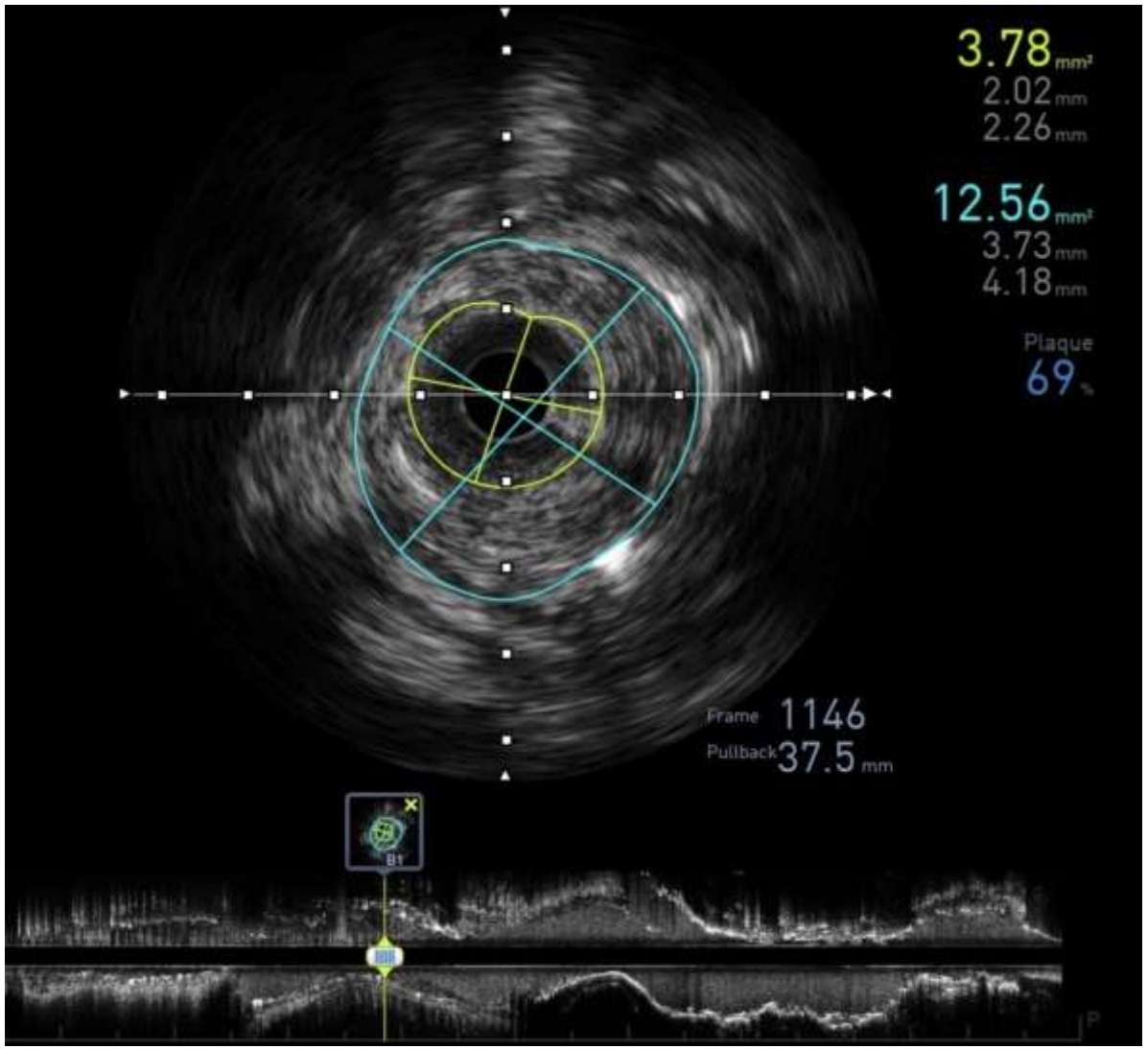
DCB in CTO patients

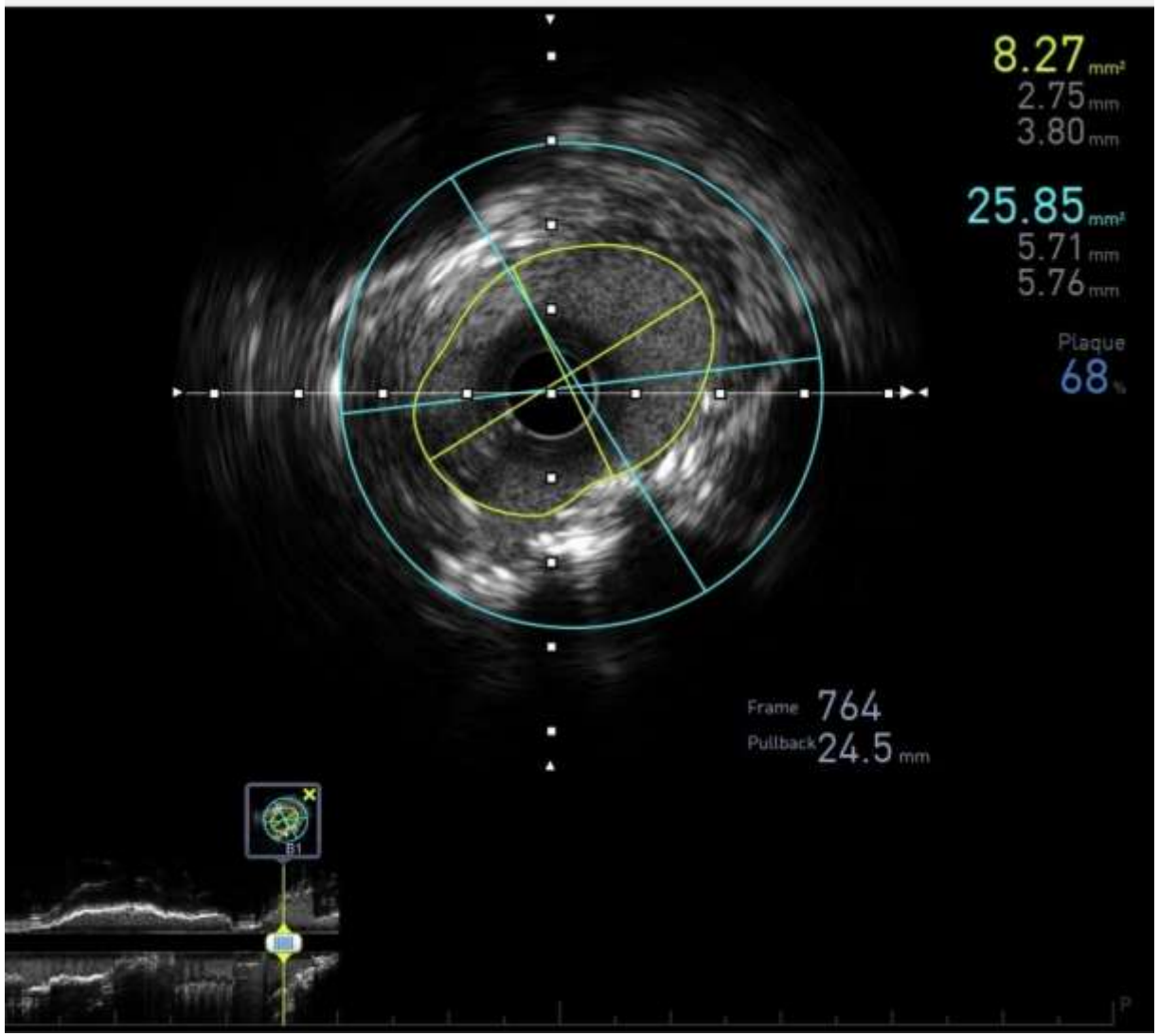


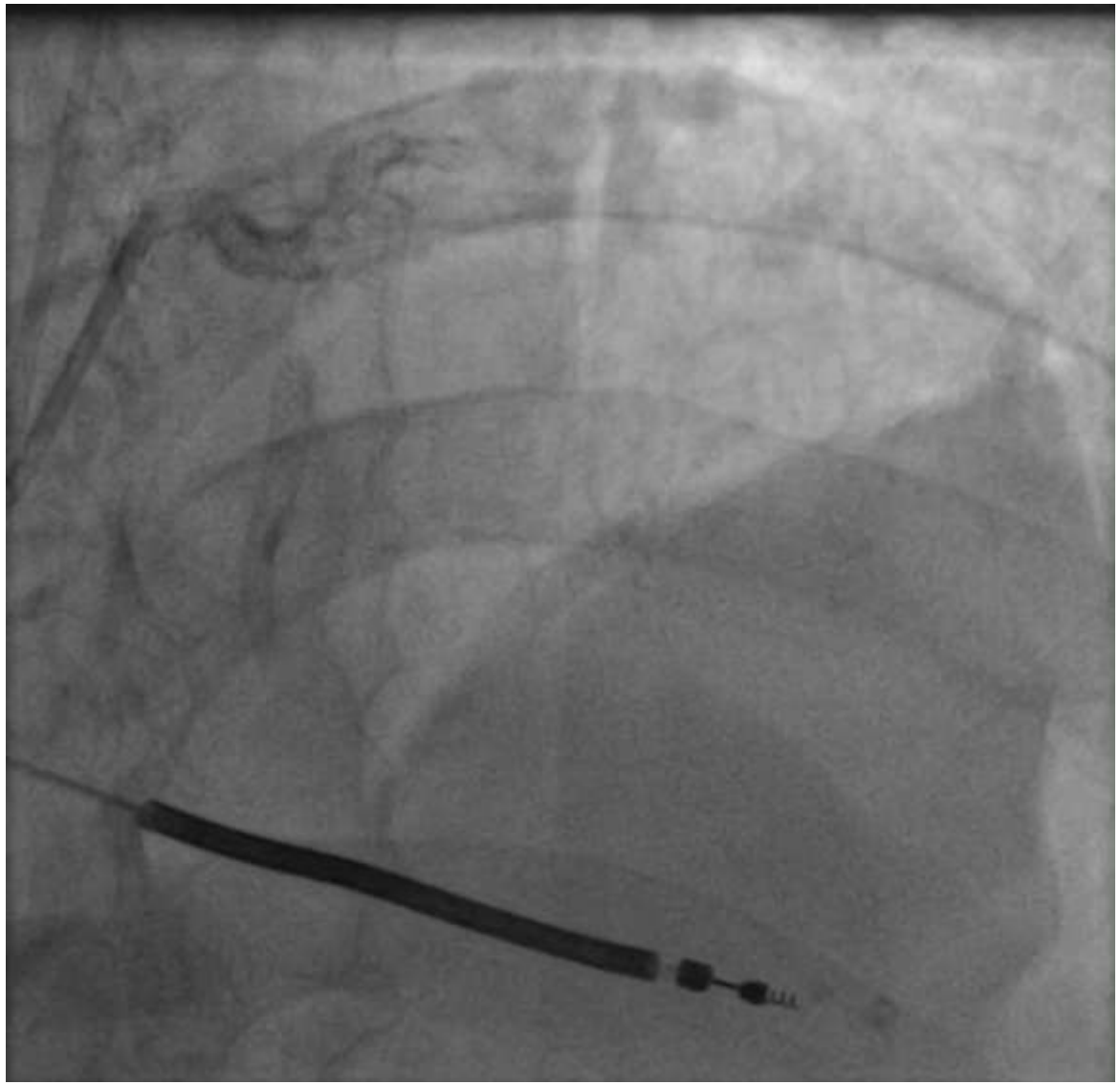


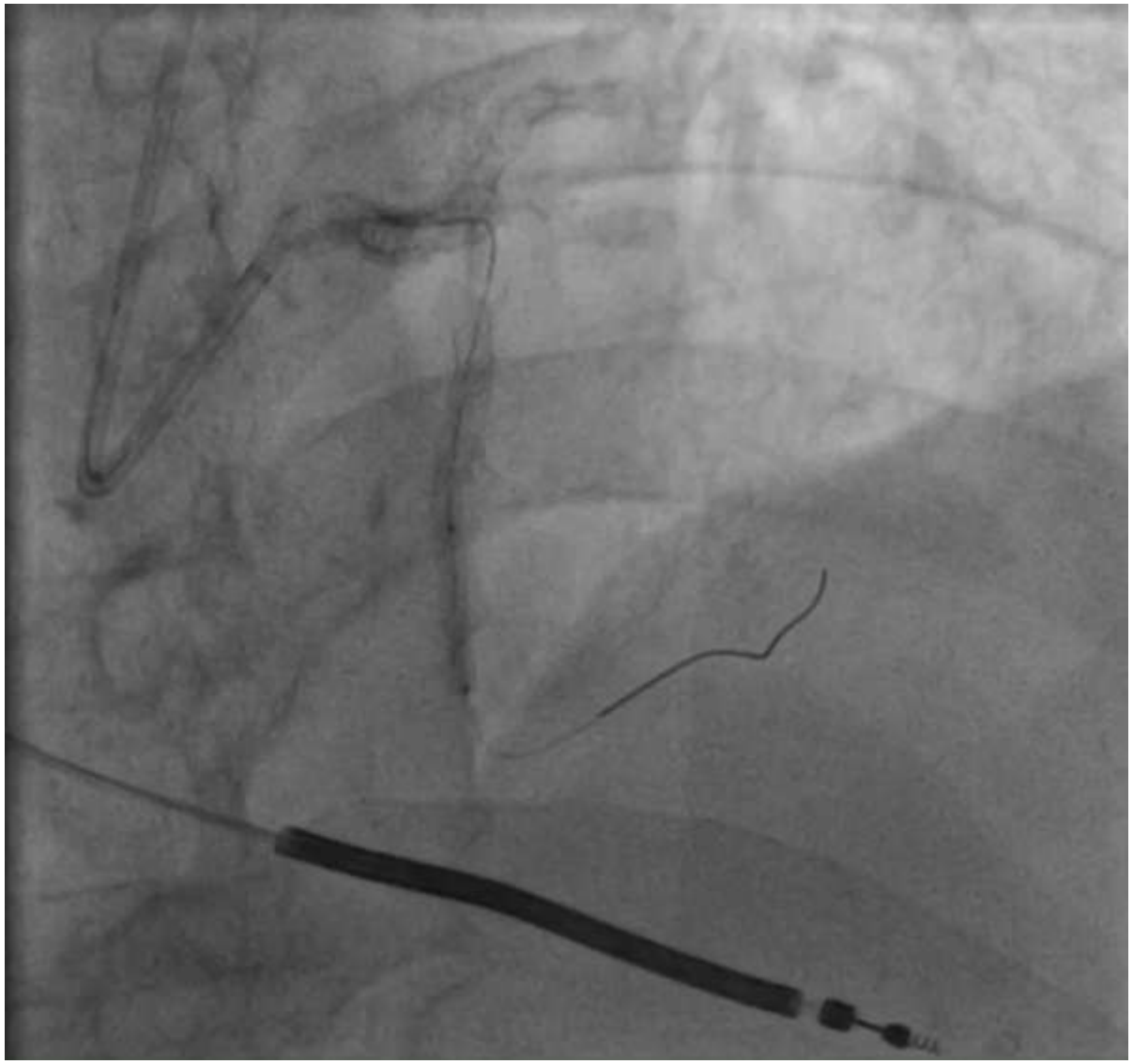


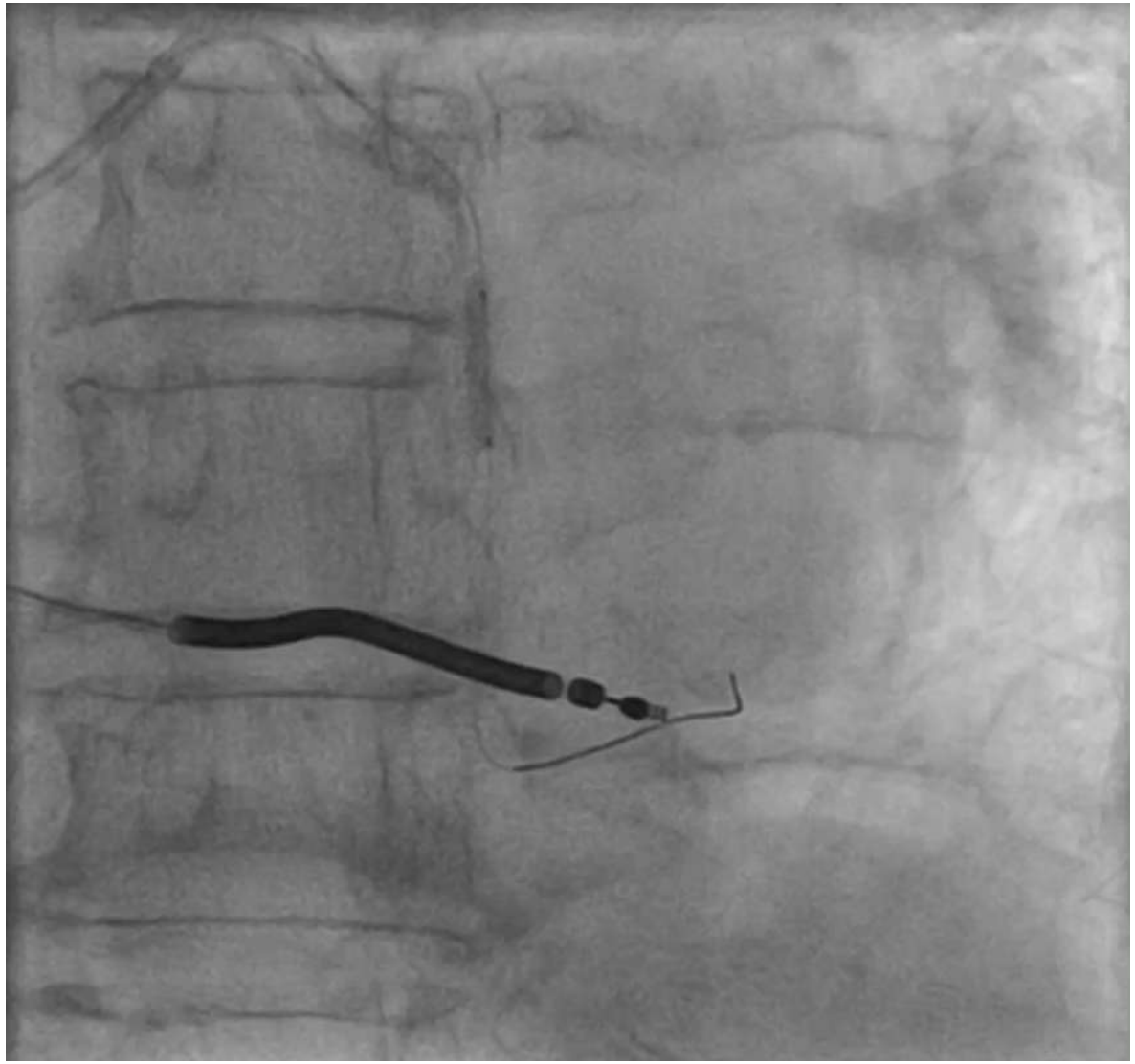

ISR
1
CTO
4
ISR
2
CTO
3

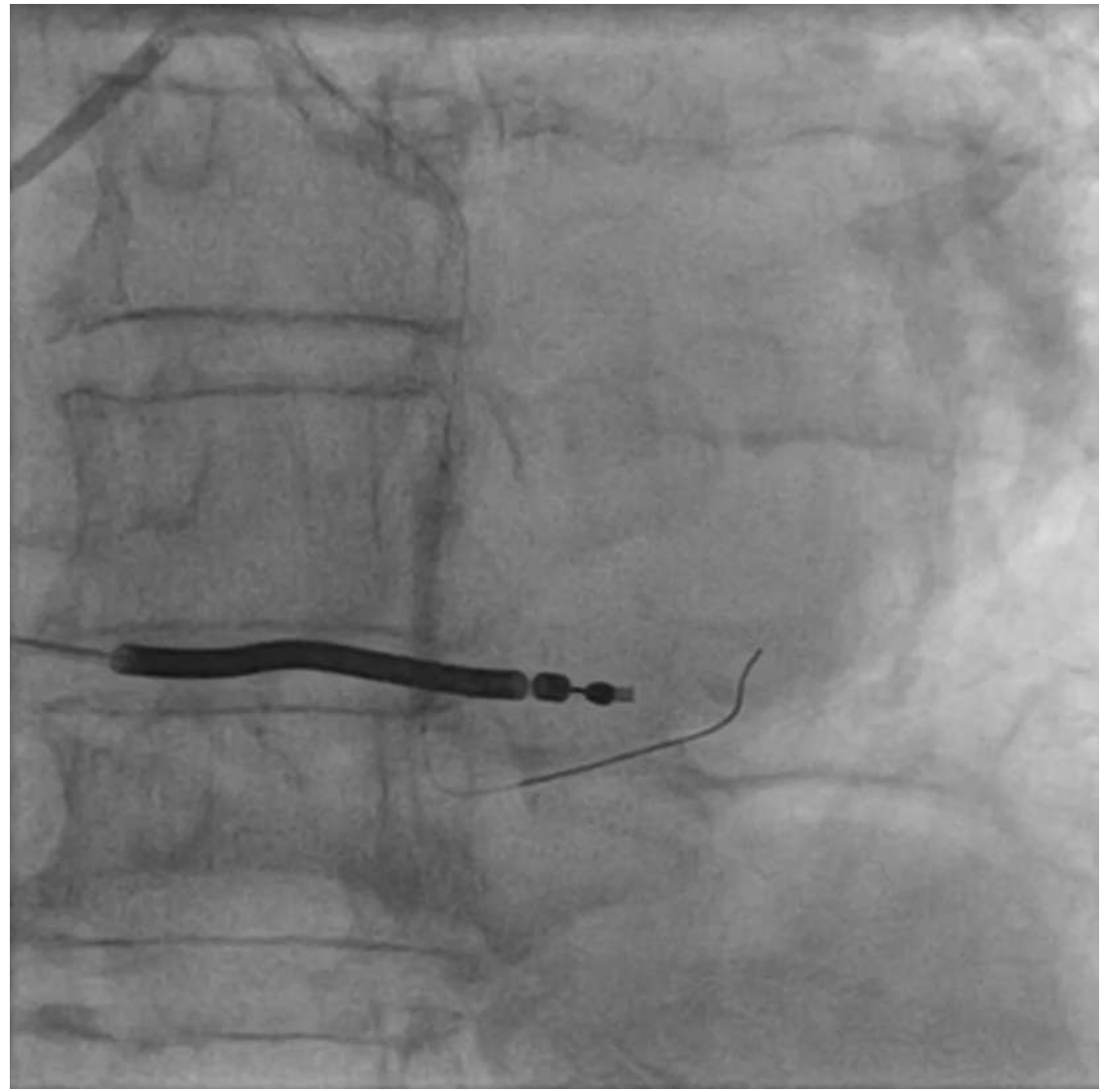

3.78 mm²
2.02 mm
2.26 mm
12.56 mm²
3.73 mm
4.18 mm
Plaque
69 %
Frame 1146
Pullback 37.5 mm
B1

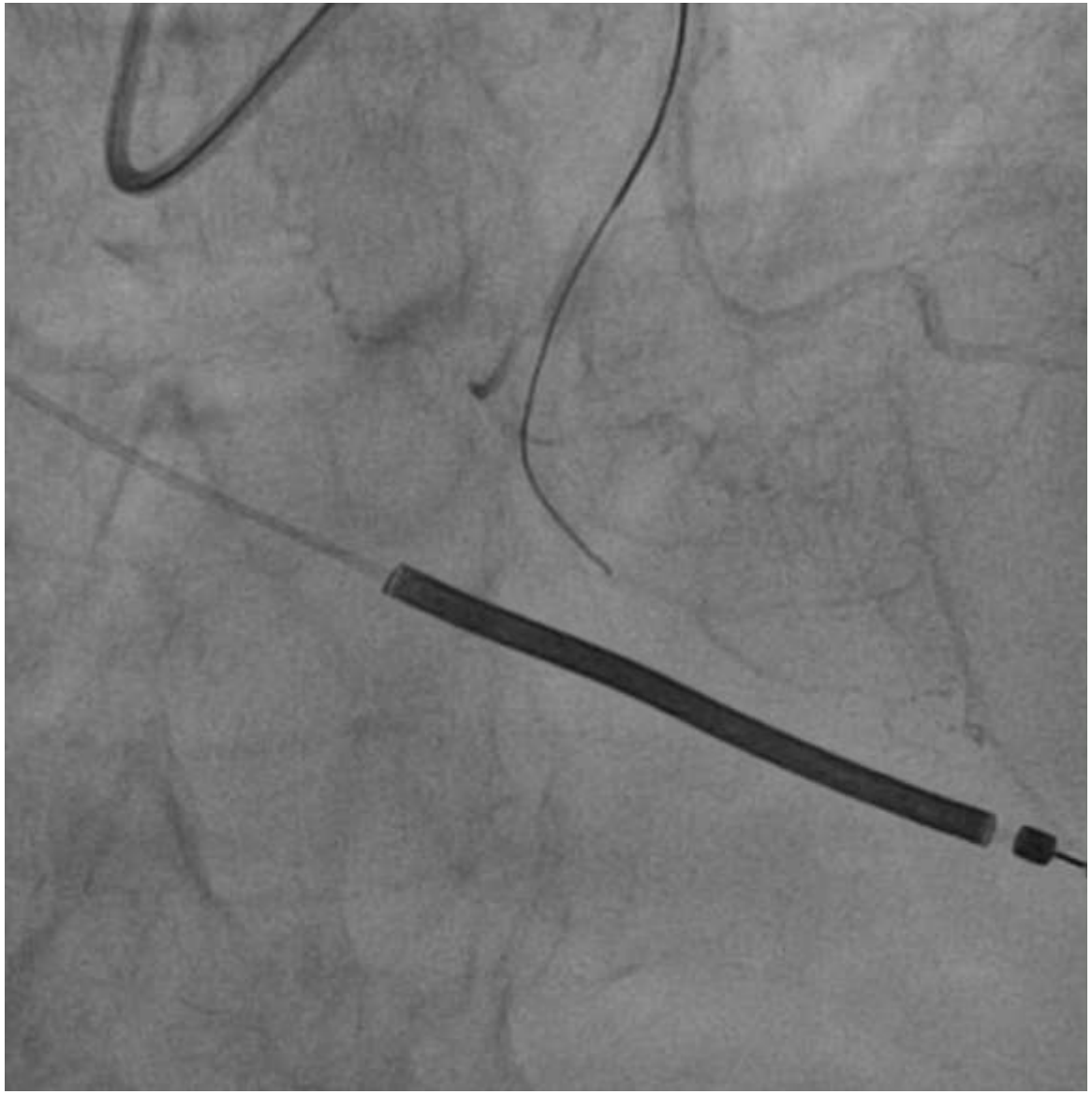

8.27 mm²
2.75 mm
3.80 mm
25.85 mm²
5.71 mm
5.76 mm
Plaque
68 %
Frame 764
Pullback 24.5 mm
B1

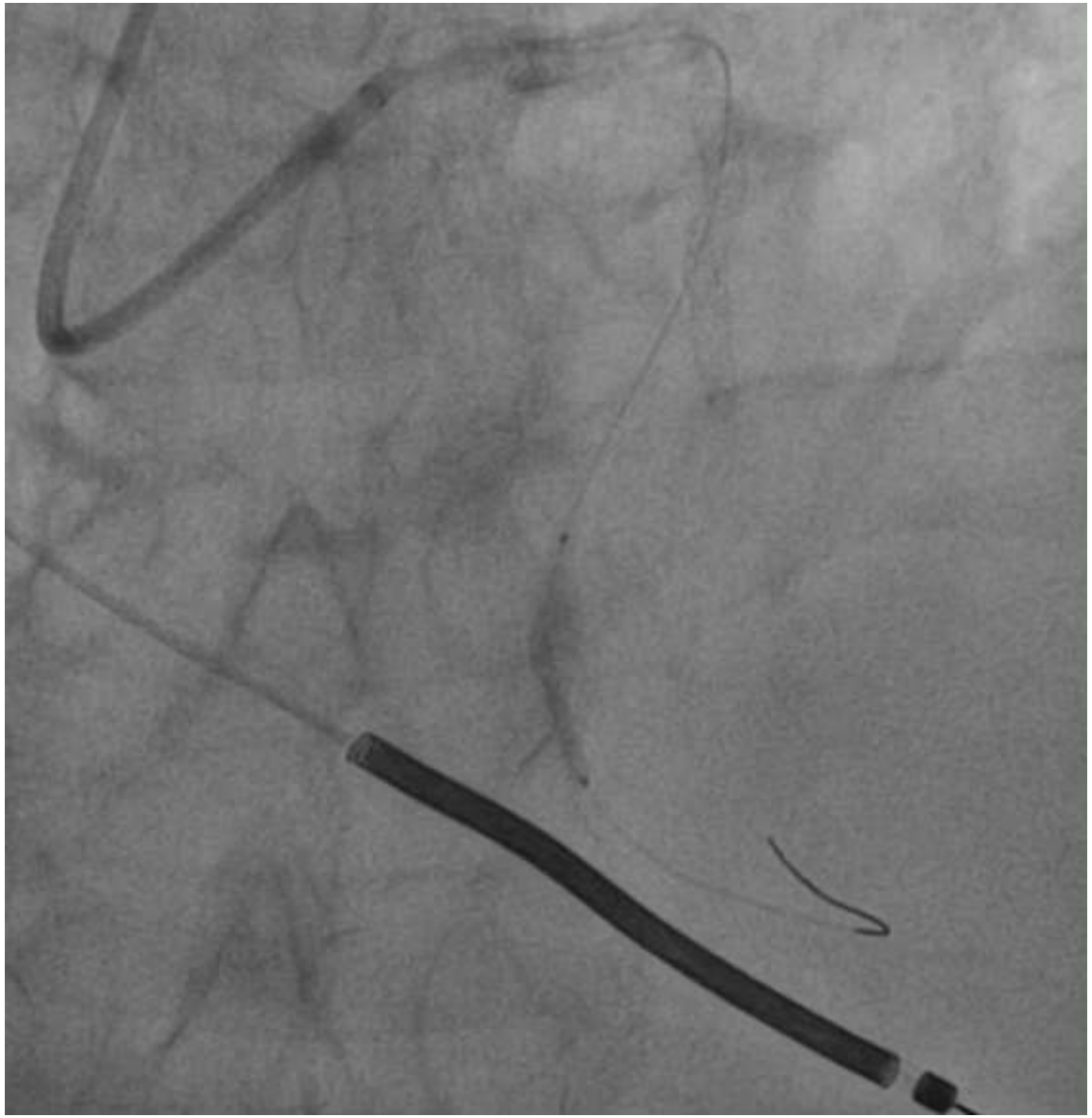


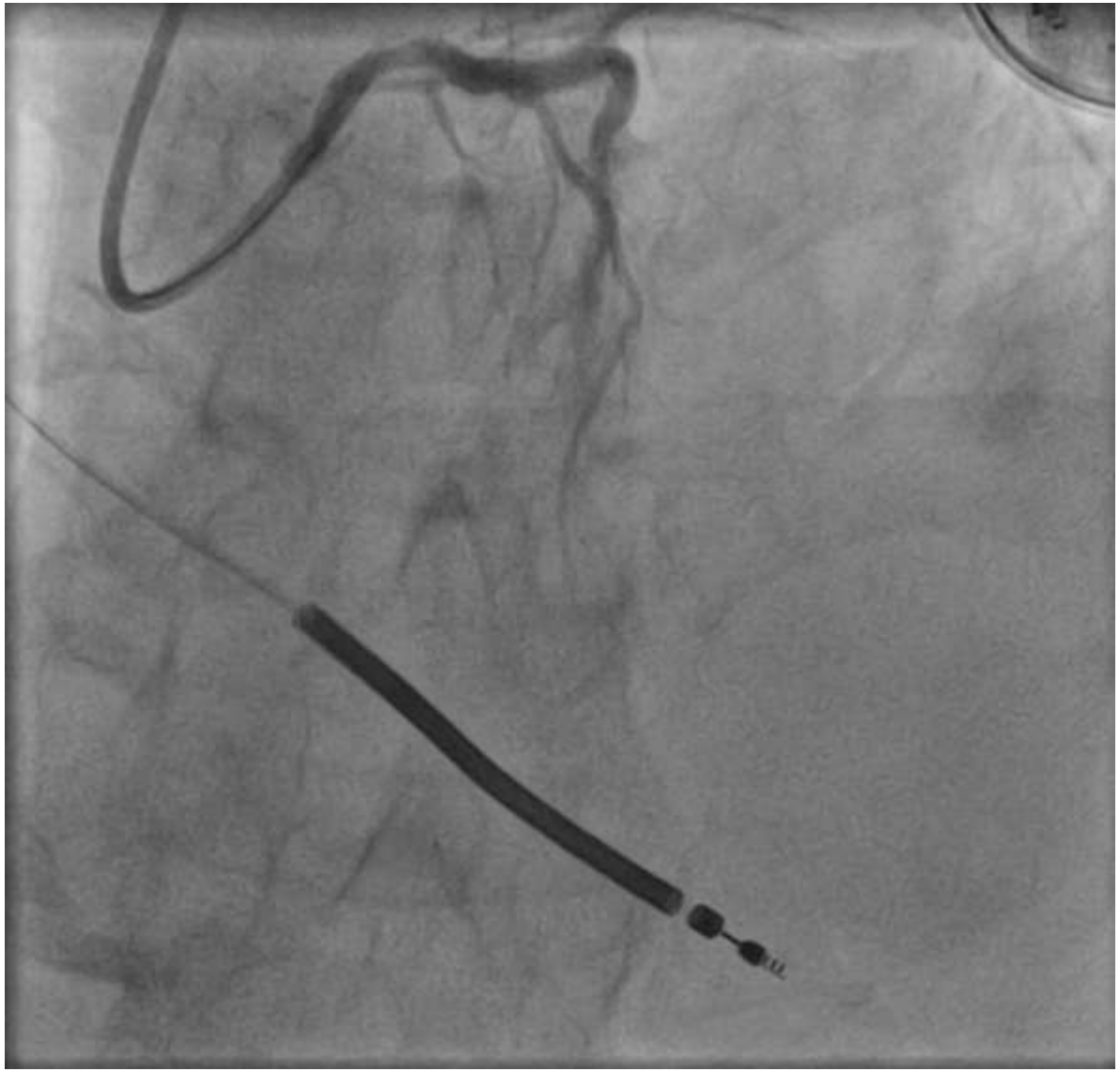


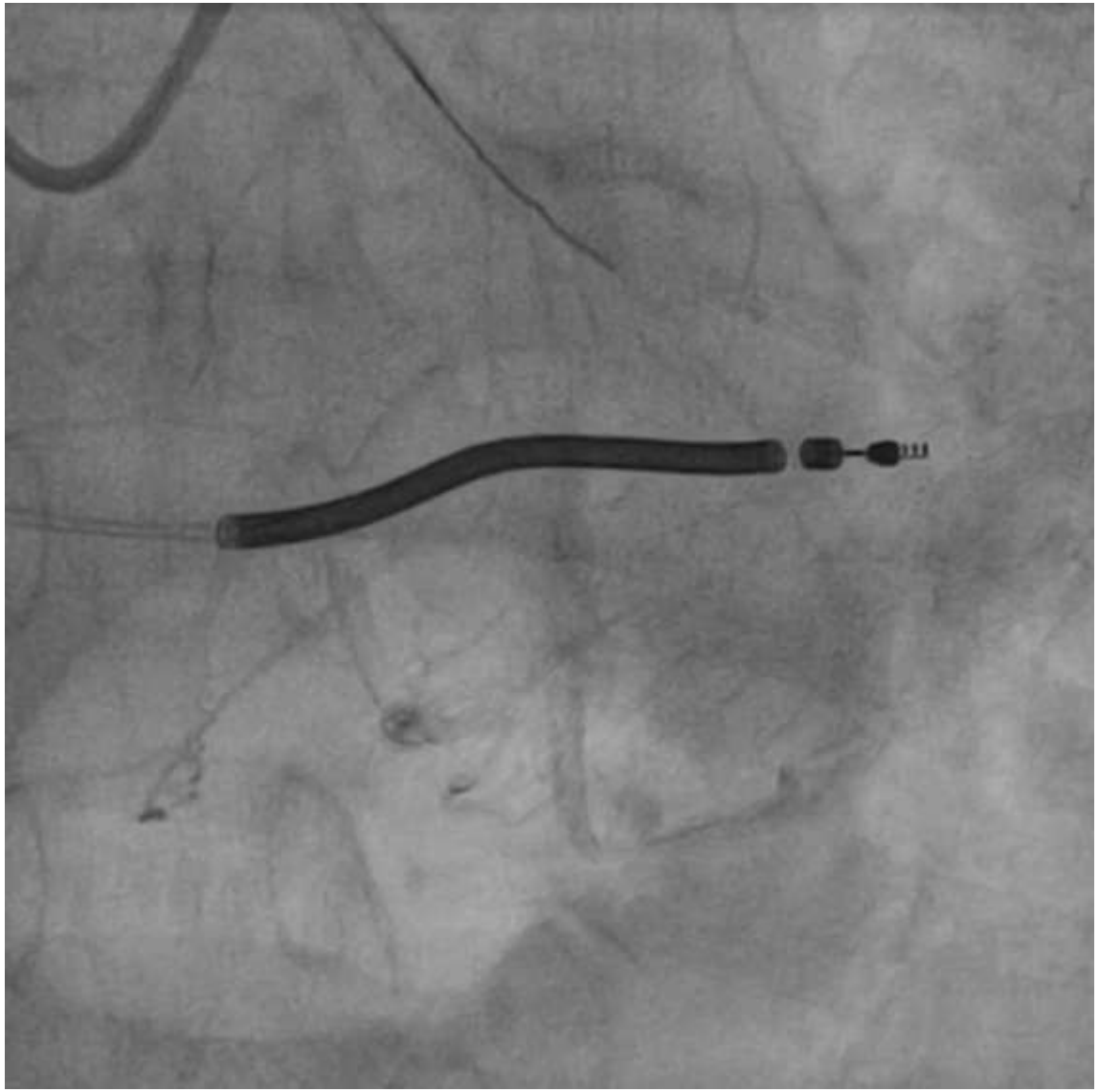


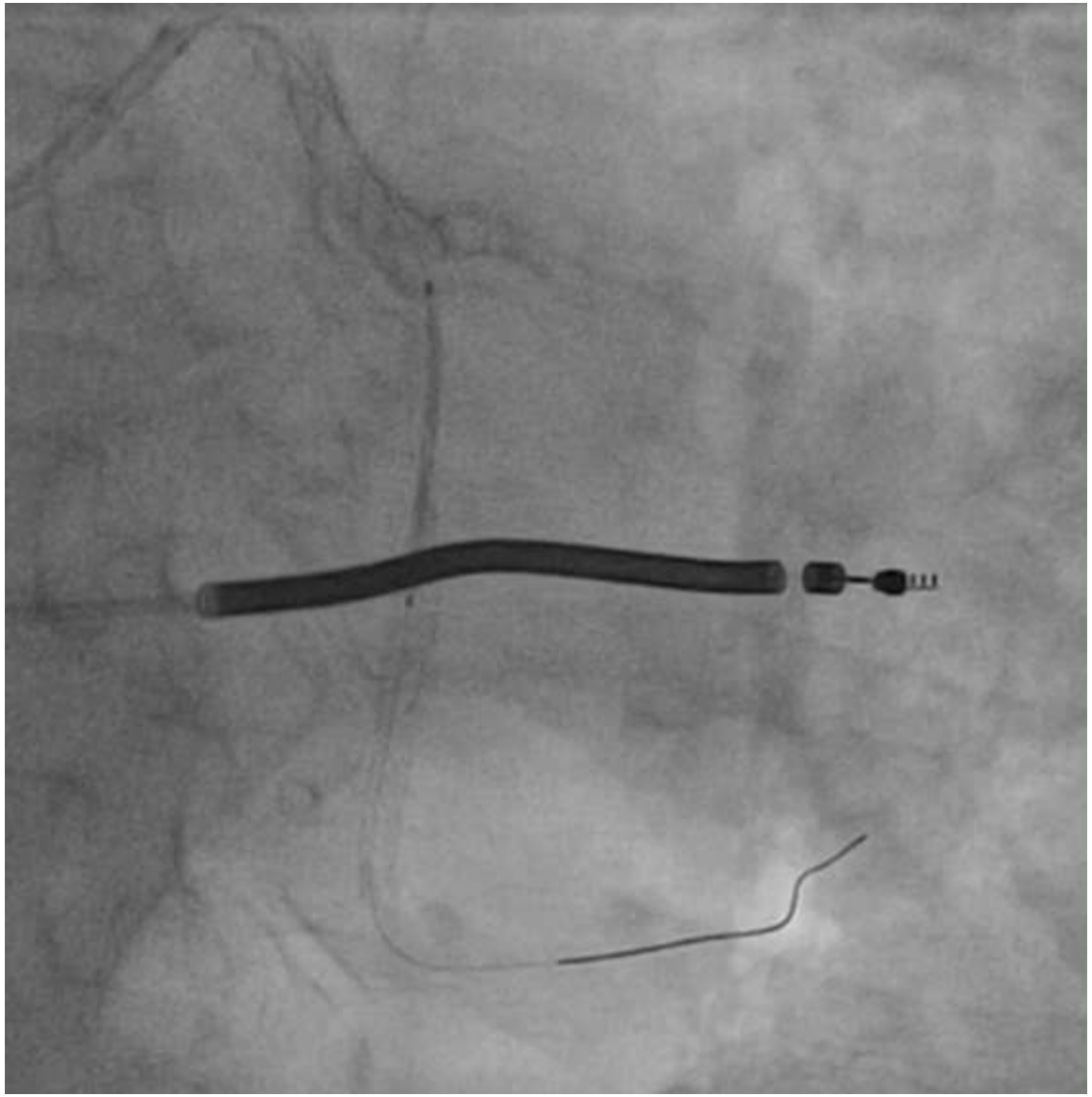


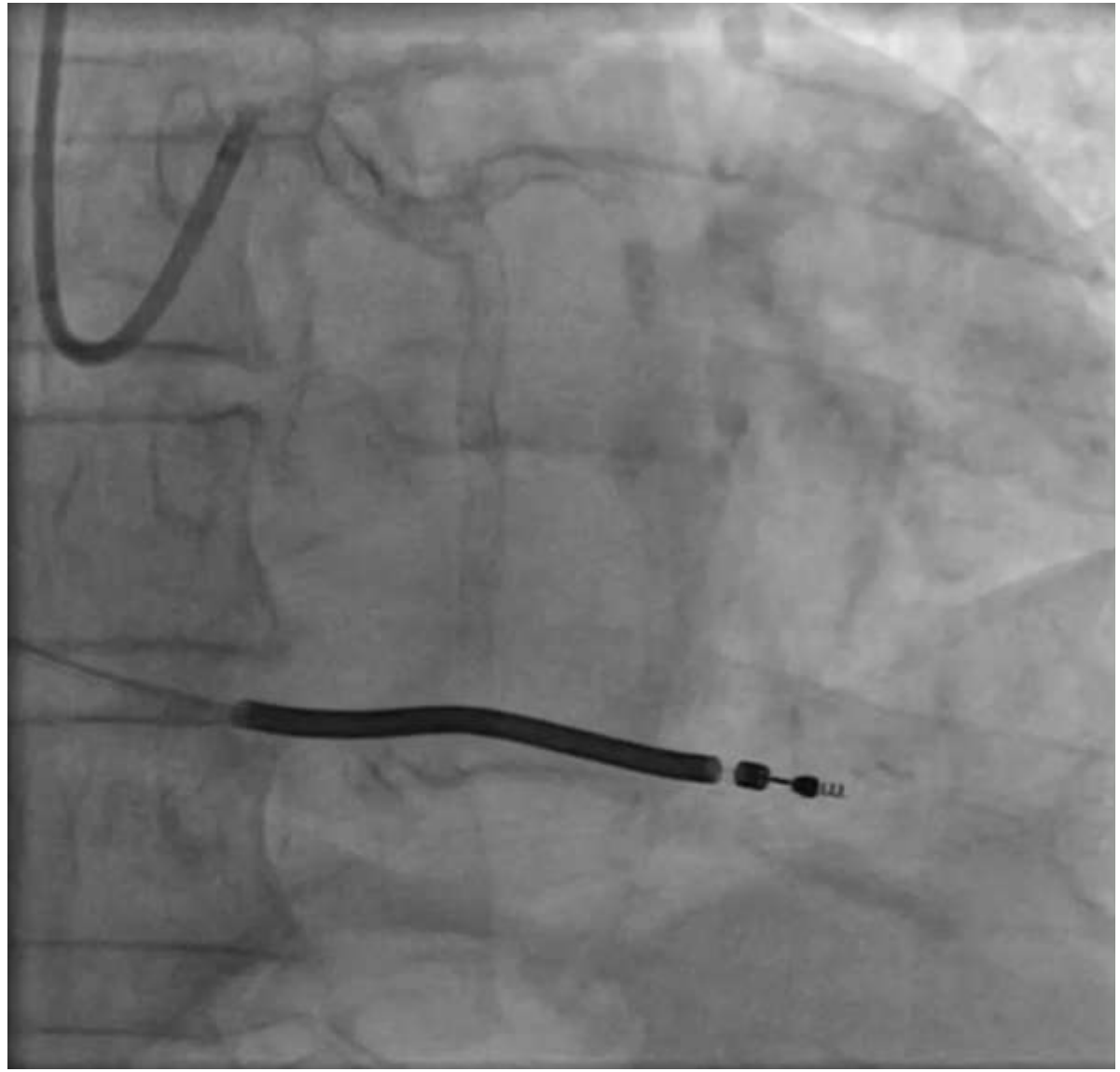






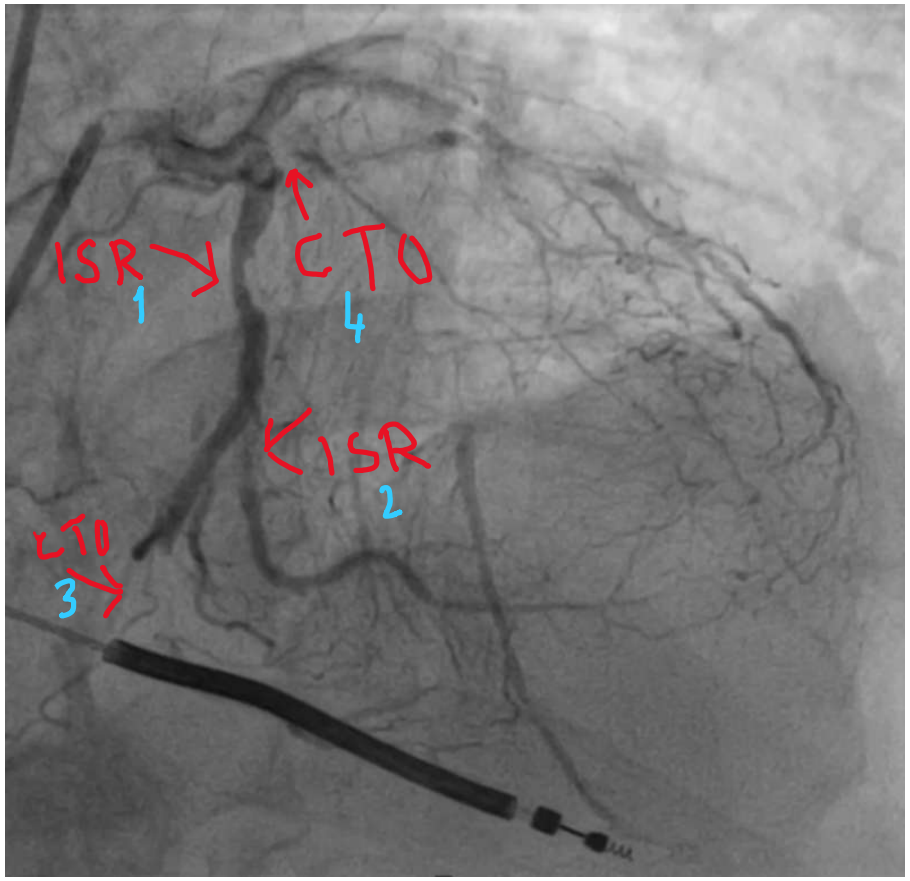






1. Case 4 DCB using for different Lesion types

Pre-Procedure



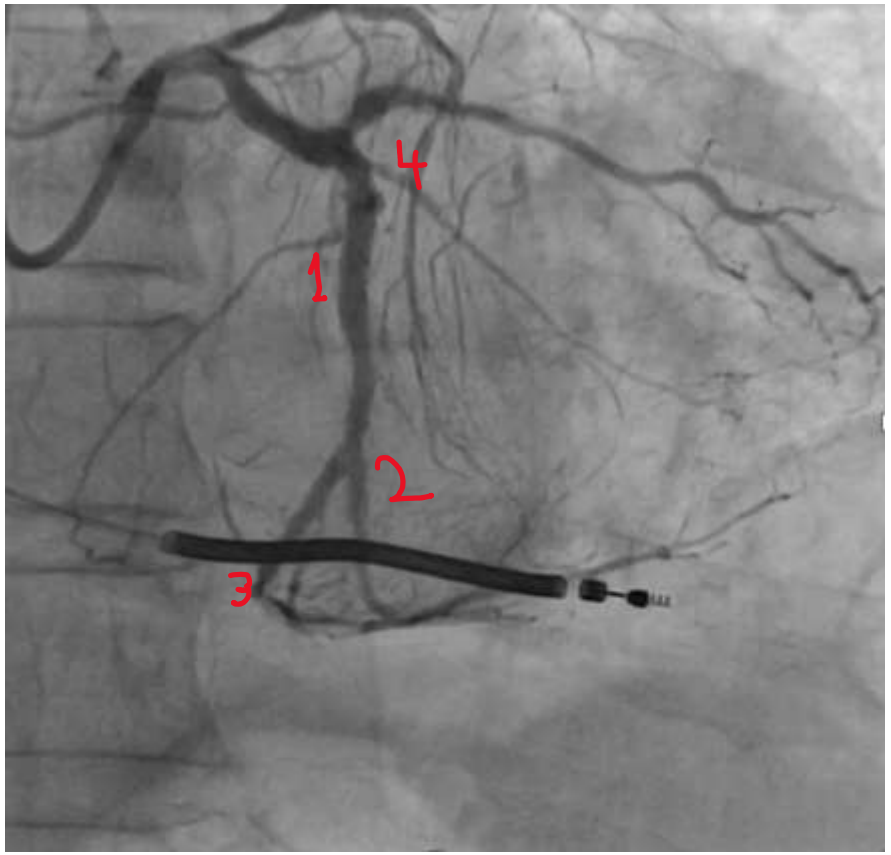
1. ISR-PCB-DES

2. ISR PCB-Bifurcation

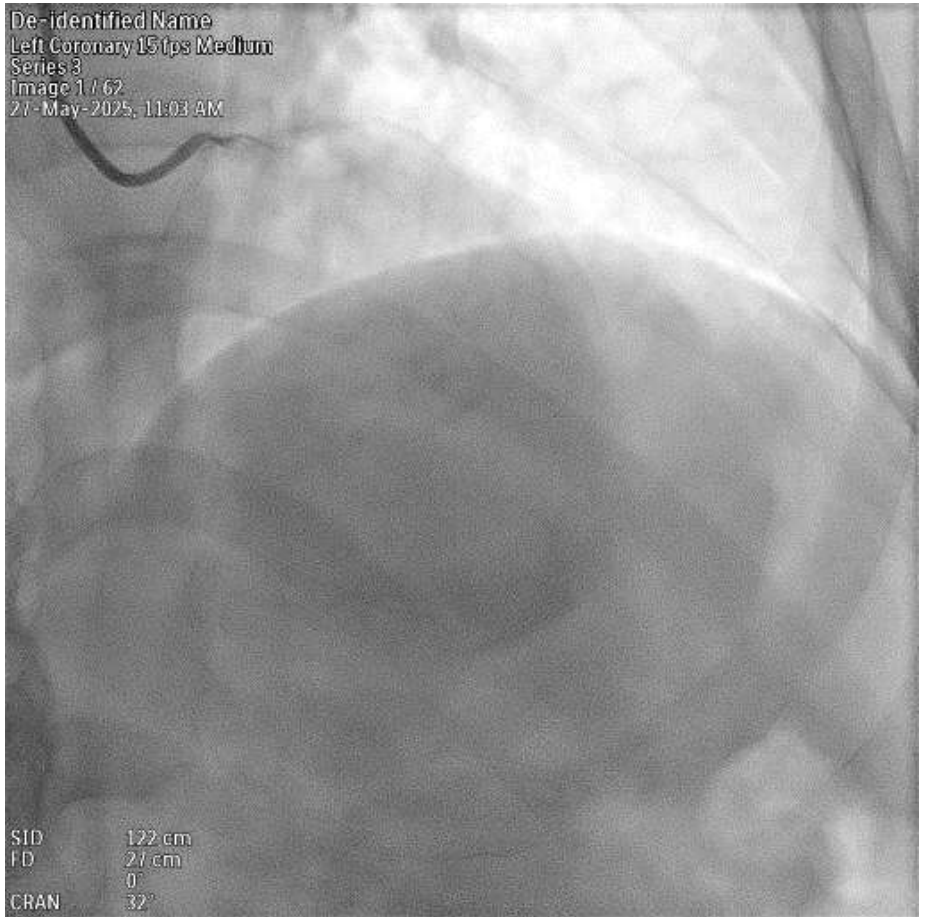
3. cto-denovo-smallvessel-PCB-

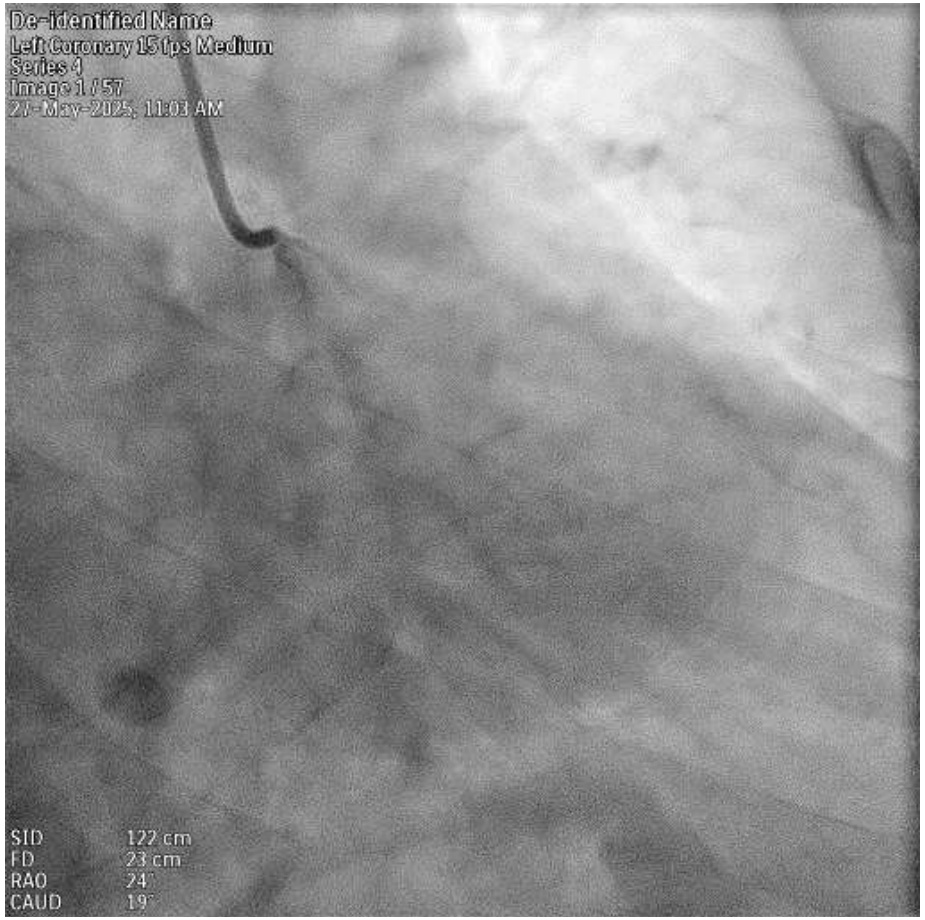
4. cto-denovo-small vessel-PCB

Post Procedure

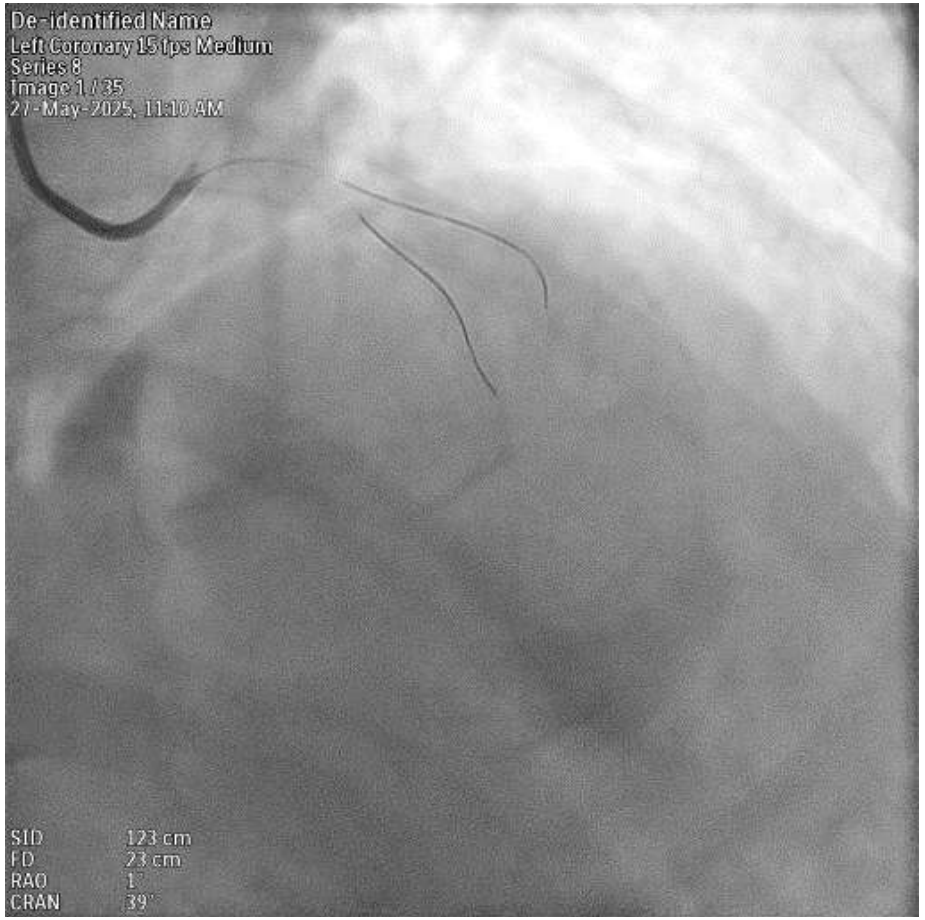


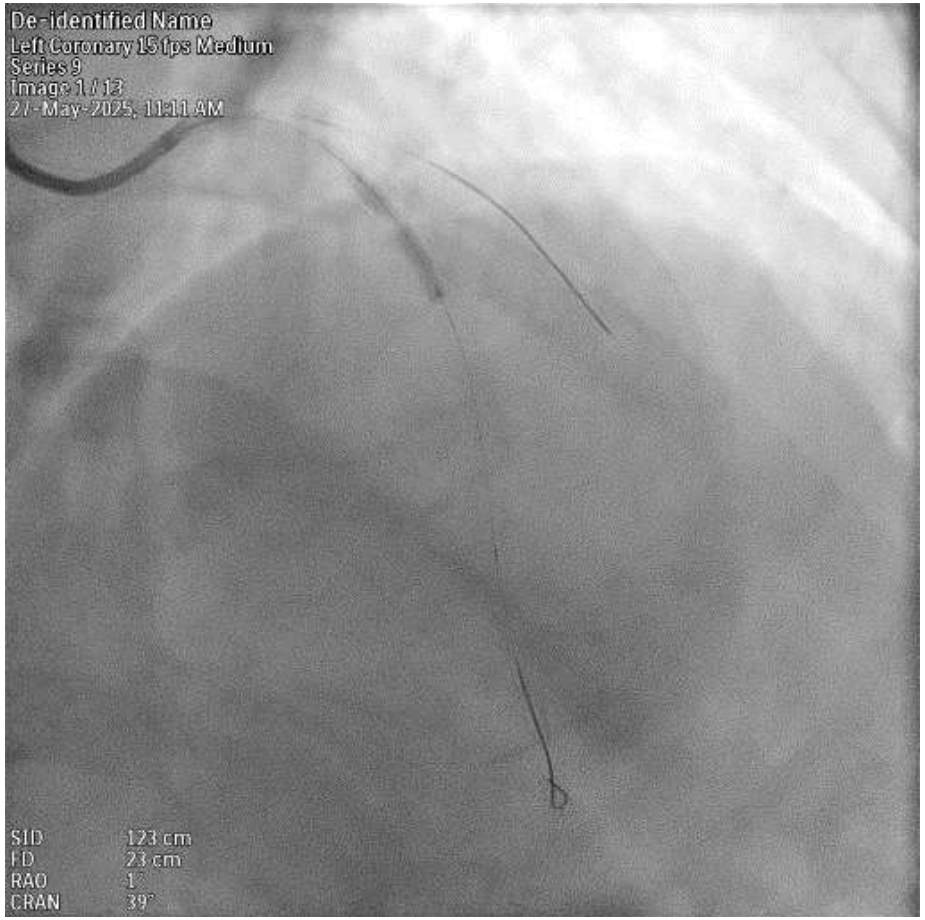
LAD, CX OM1 and OM2 DCB only; Nothing left behind ☺



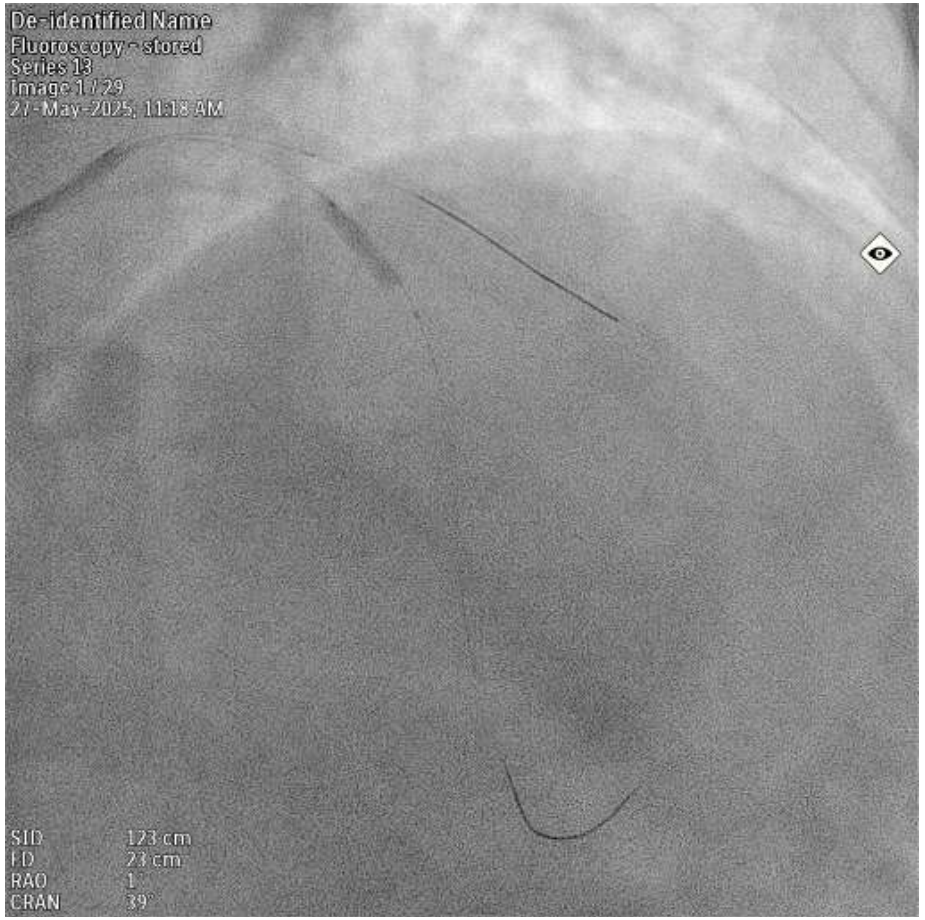


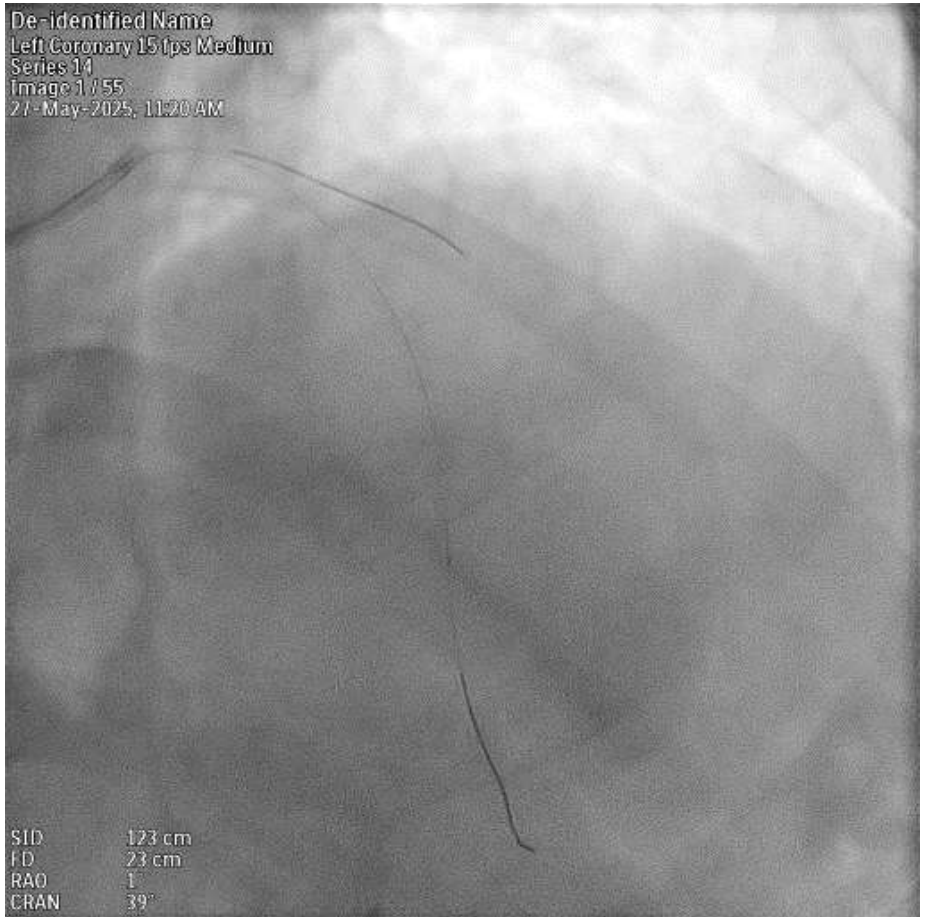
LAD, CX OM1 and OM2 DCB only; Nothing left behind ☺



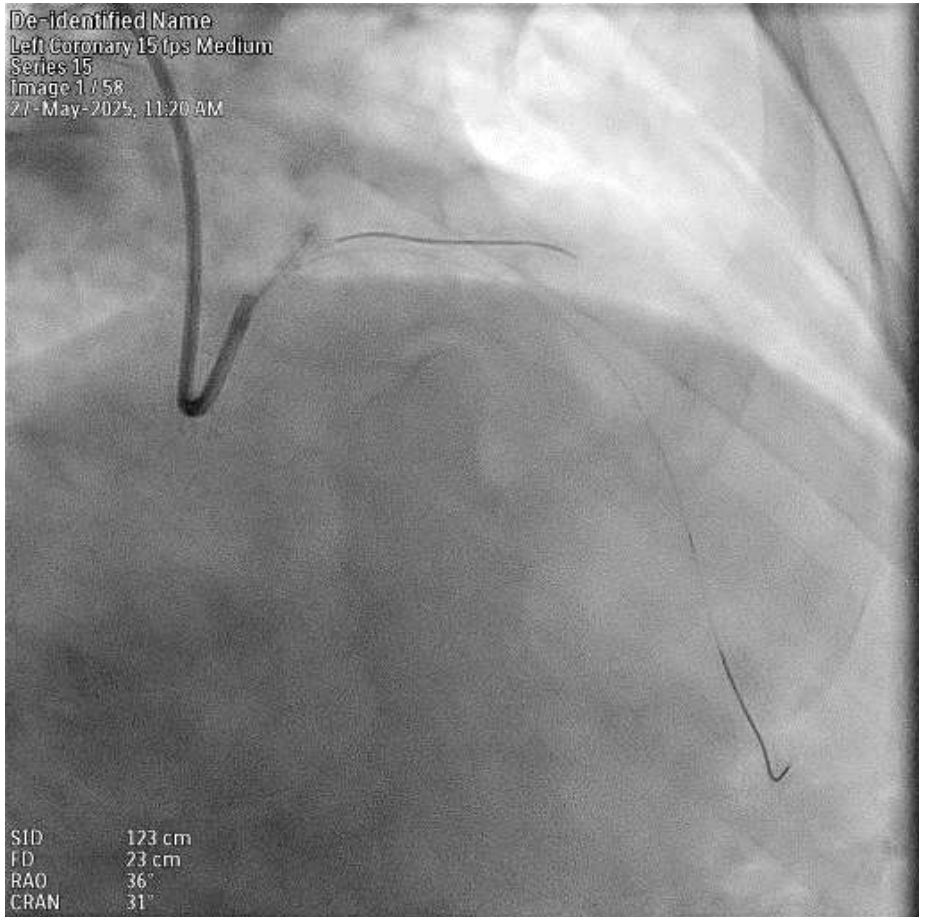


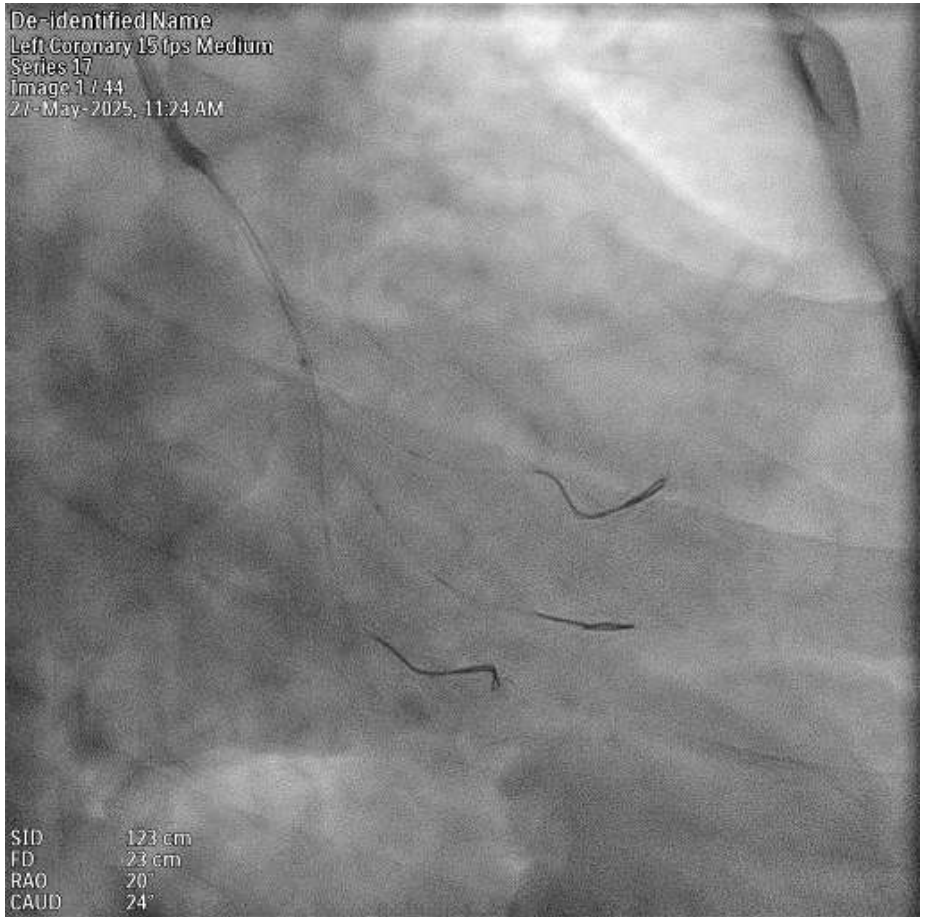
Predilatation and Lesion Preparation 1:1 1: 0.8 Ballooning following 1:1 DCB



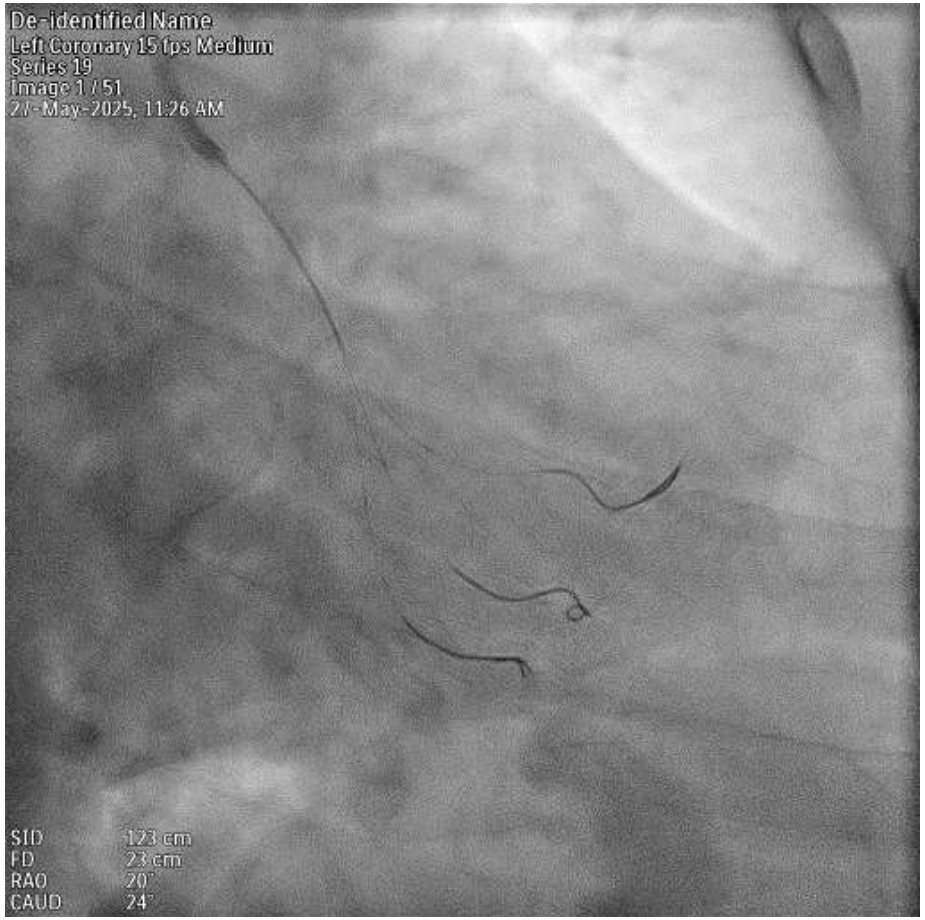


Predilatation and Lesion Preparation 1:1 1: 0.8 Ballooning following 1:1 DCB

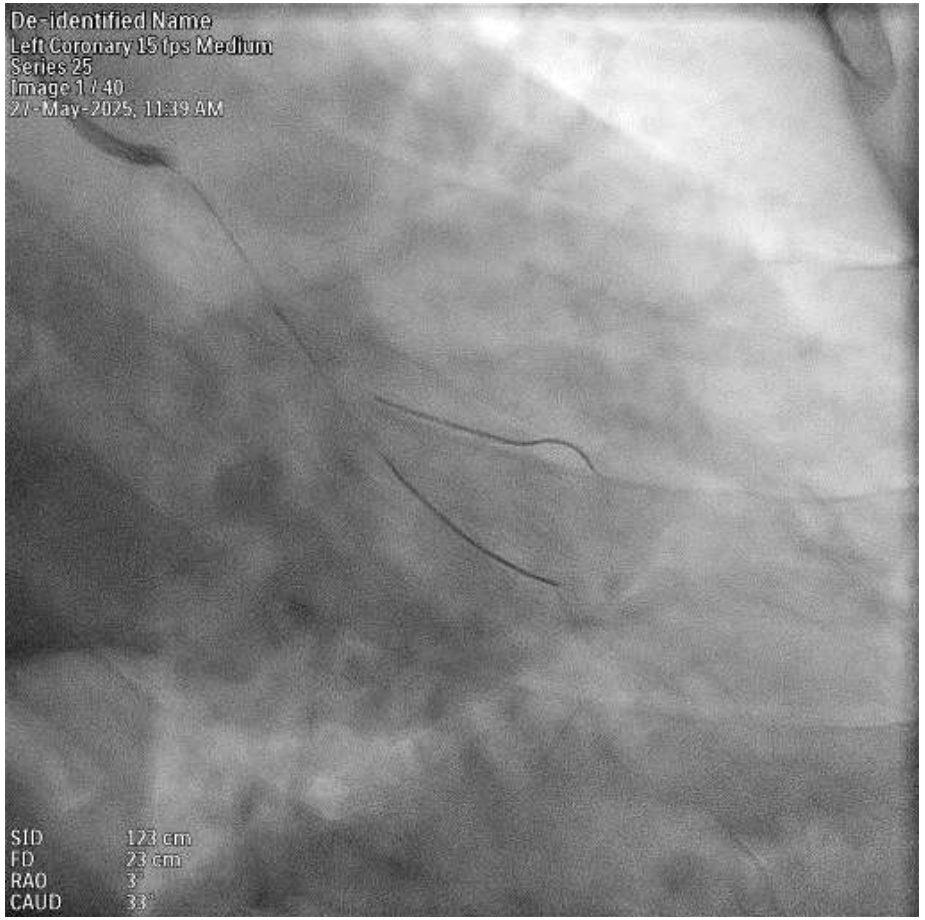


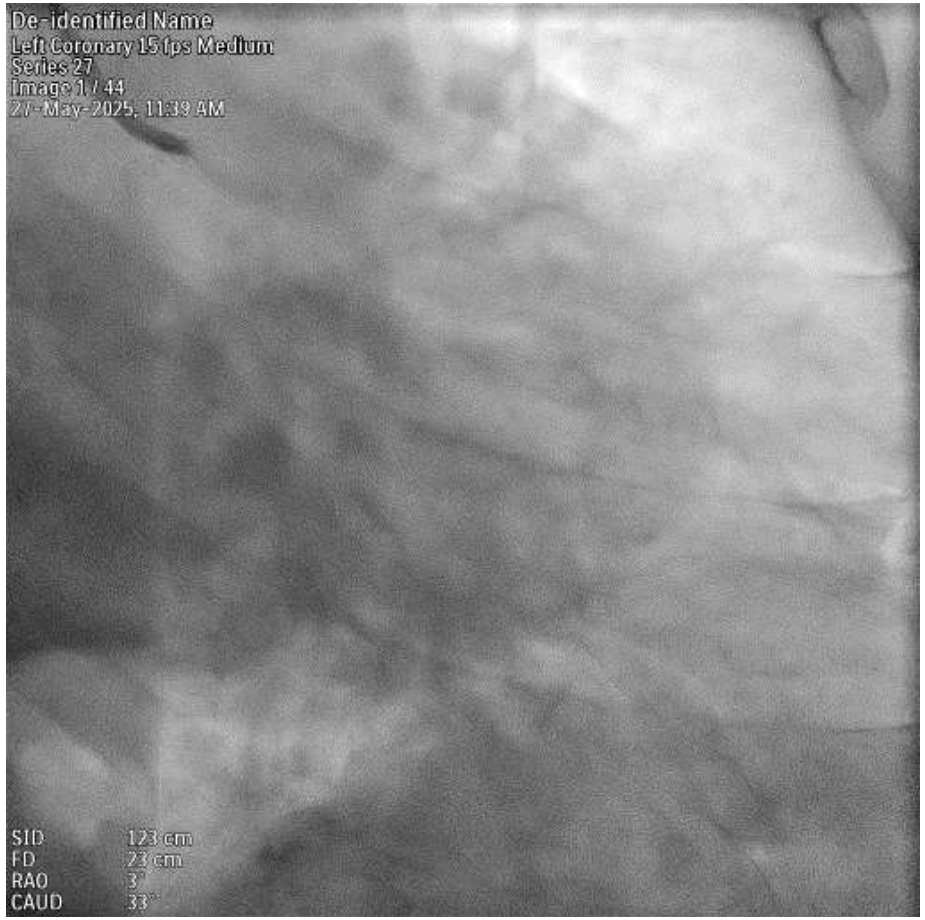


Bifurcation Lesions separate DCB Ballooning

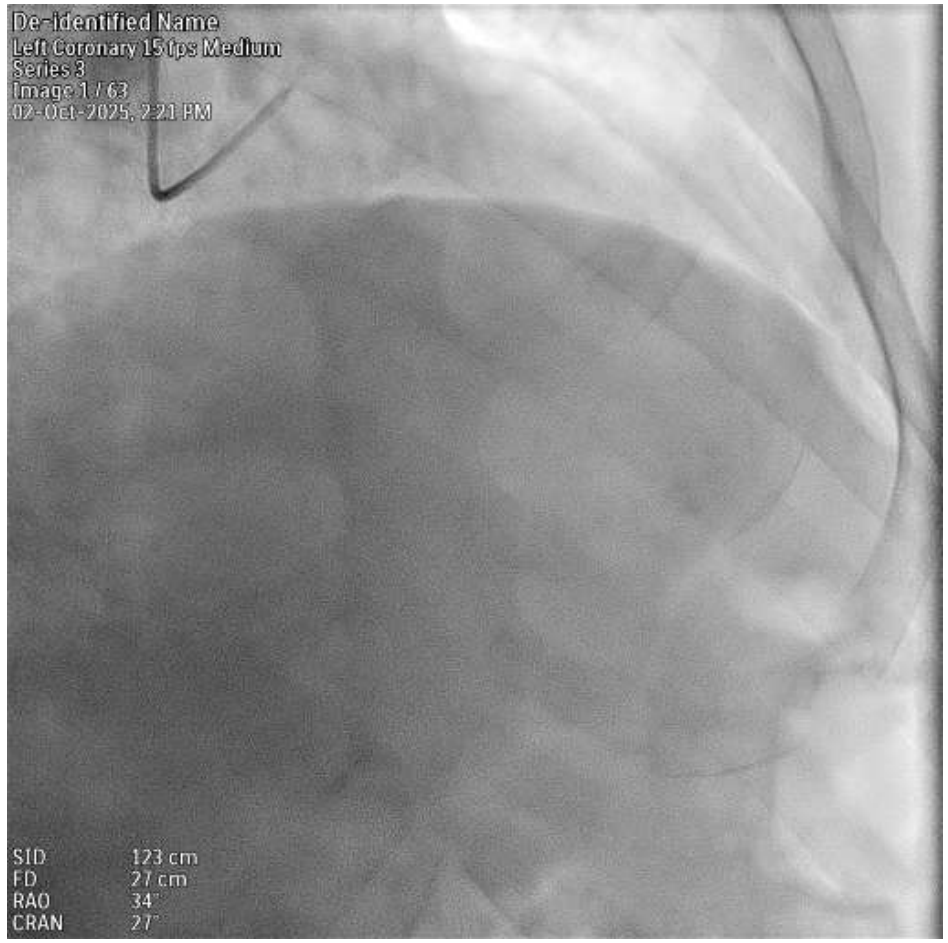


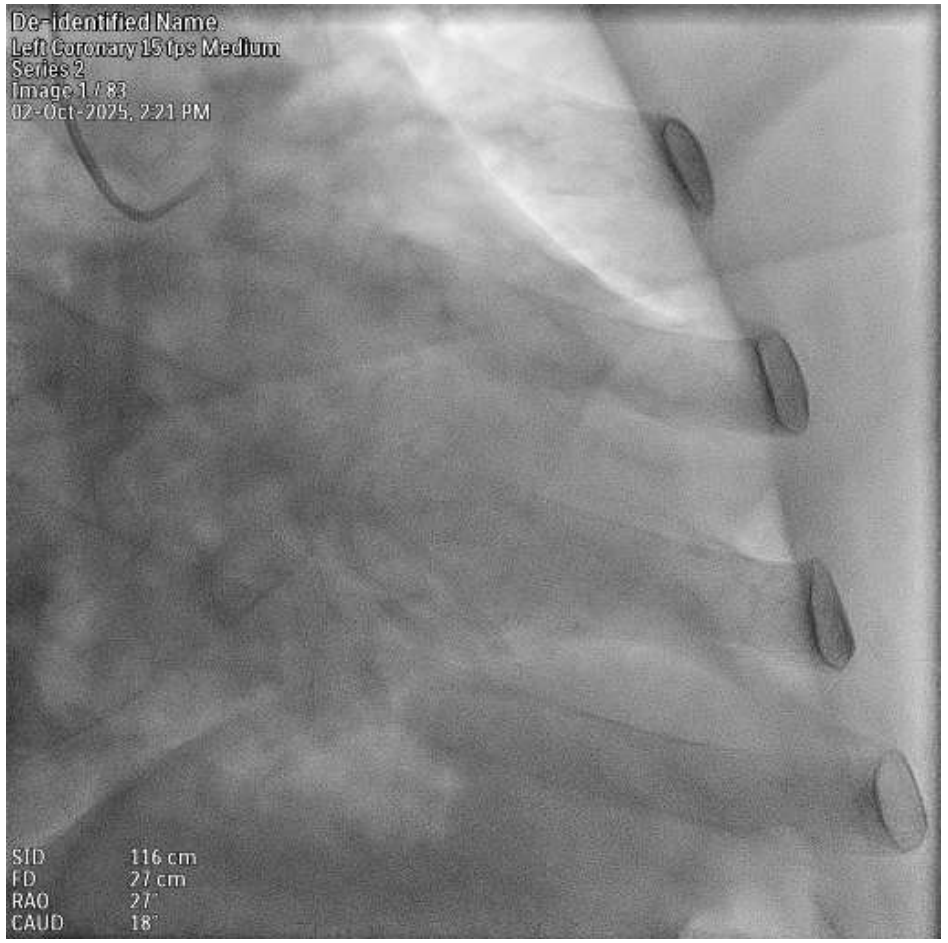
Final results





6.M after Follow-up angiography





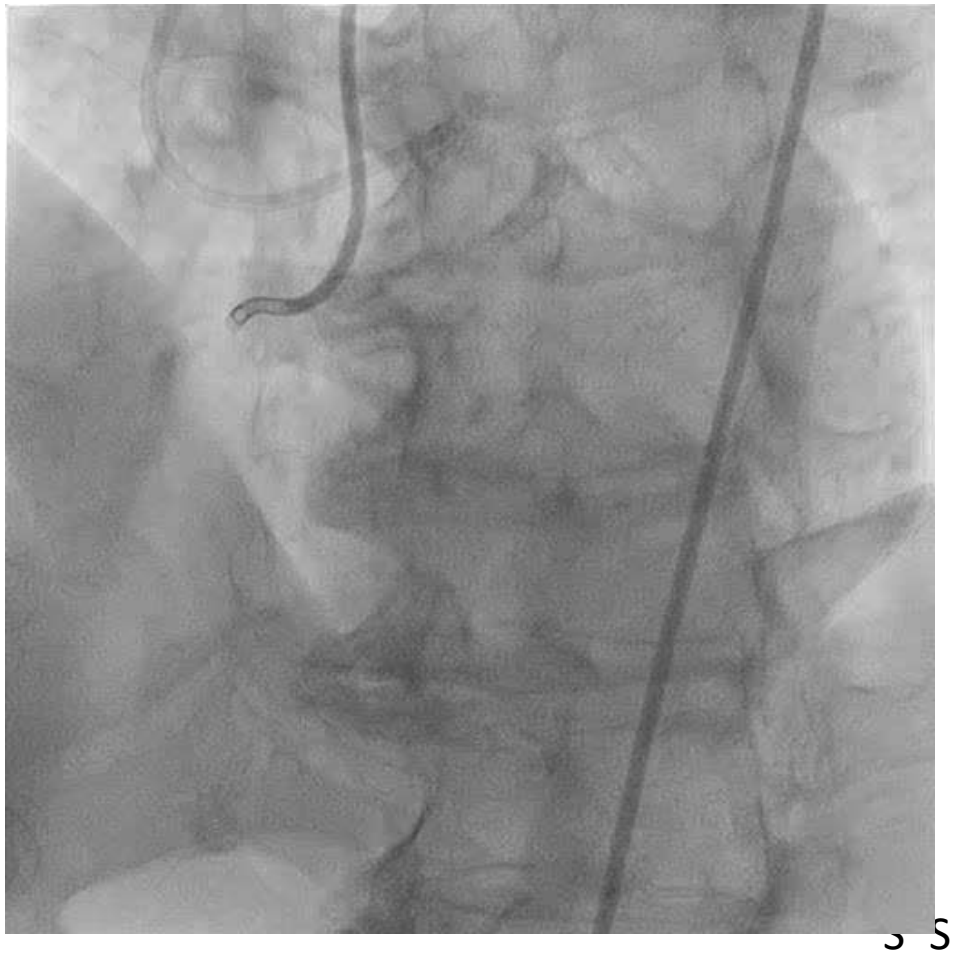
R.A_DCB

Case-4

3 vessels Rota
24 years ago CABG
RCA-CX CTO & Calcification
LAD Calcification

S_S_3VRota

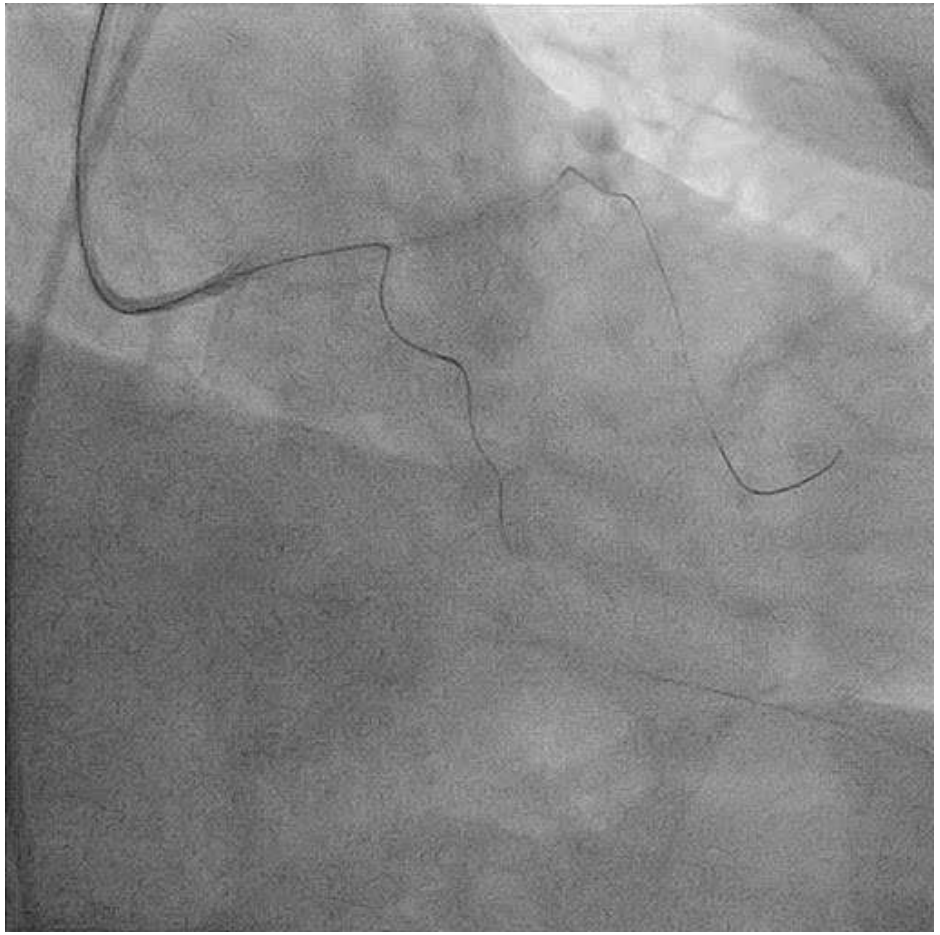
CTO of RCA & CX and Severe Calcification

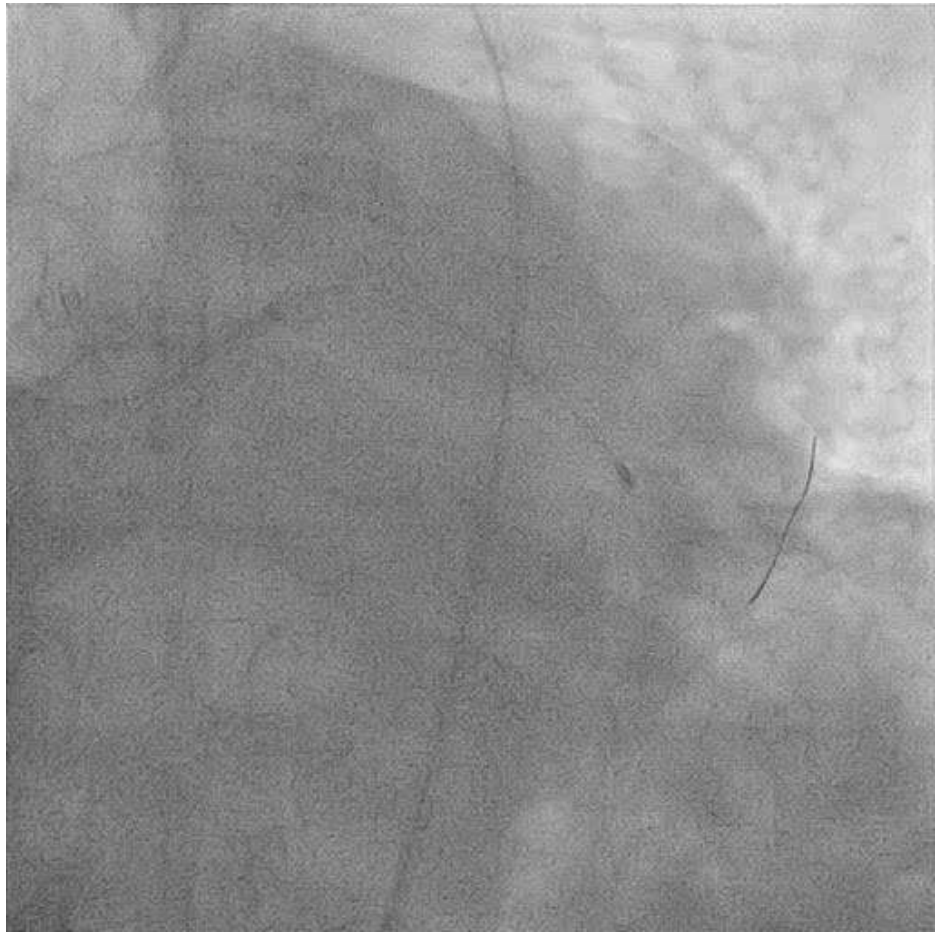


S_S_3VRota

CTO of RCA & CX and Severe Calcification

First CX CTO, Gaia 3 and Caravel then ROTA 1.5 mm 180000 rpm

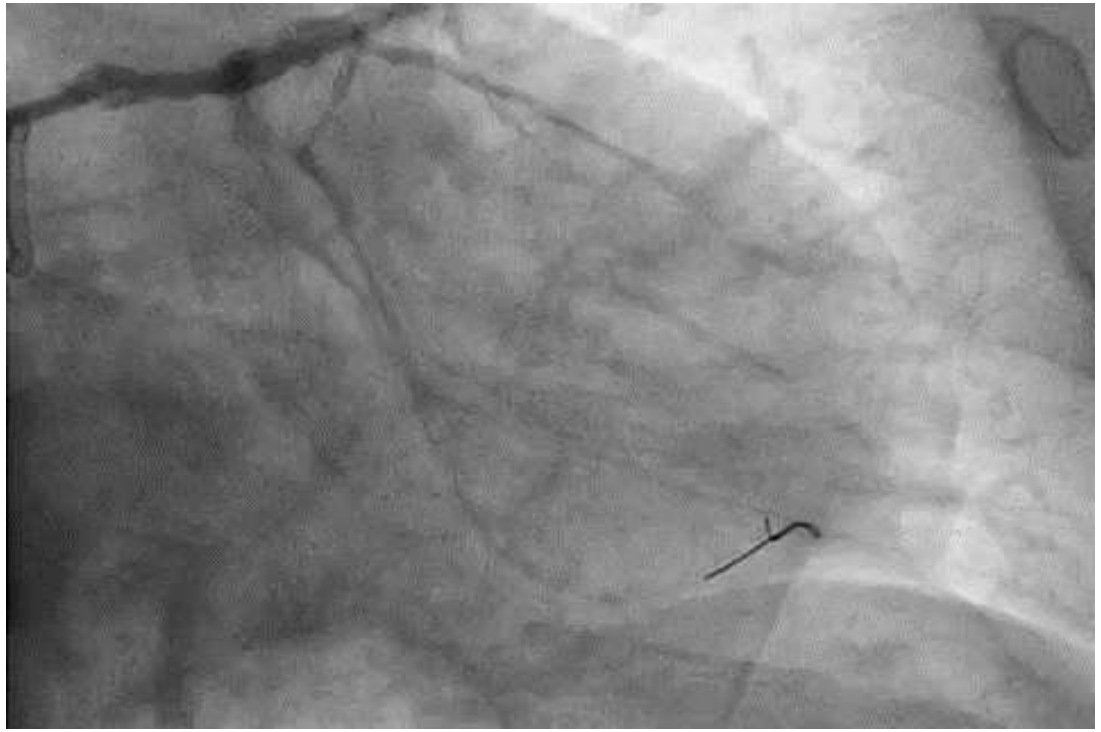




CTO of RCA & CX and Severe Calcification

Rota to CX first

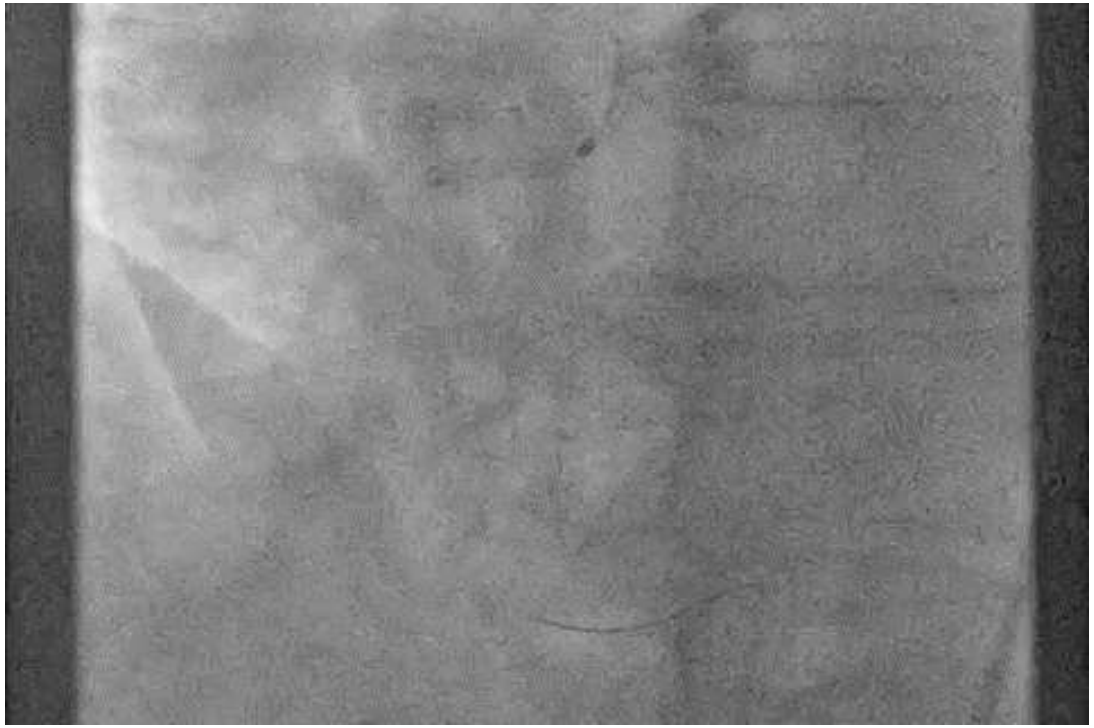
Only DCB to CX

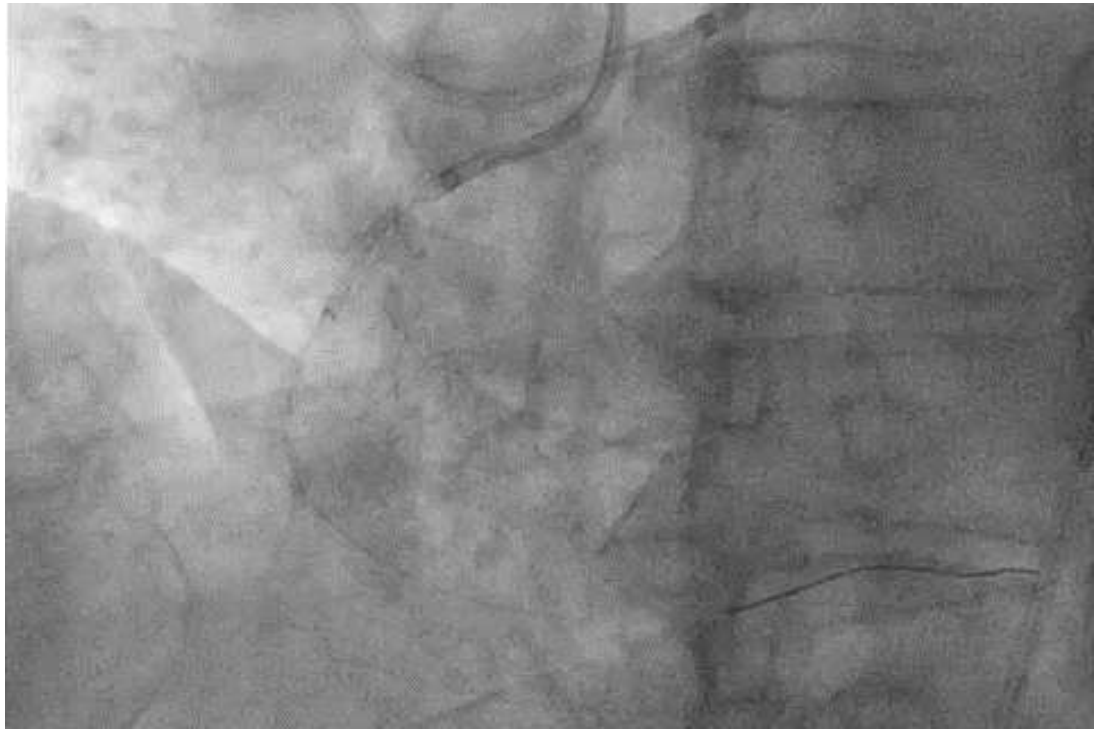


S_S_3VRota

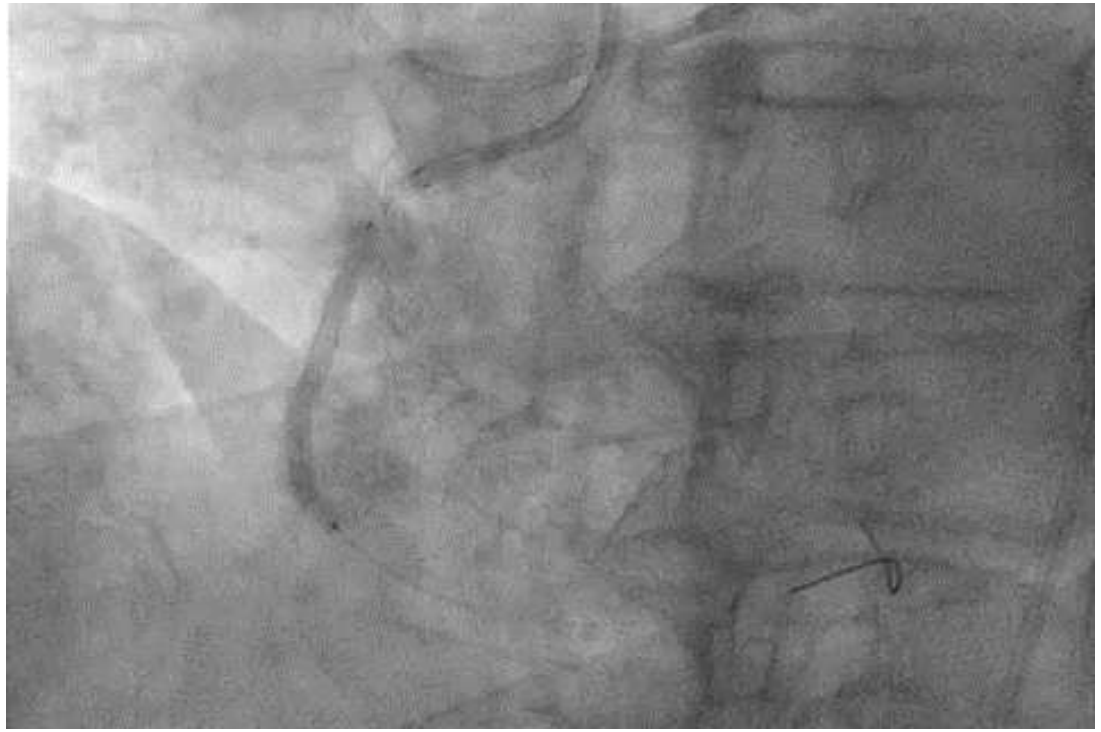
CTO and Severe Calcification

2. RCA CTO, ROTA 1.5 mm 180000 rpm

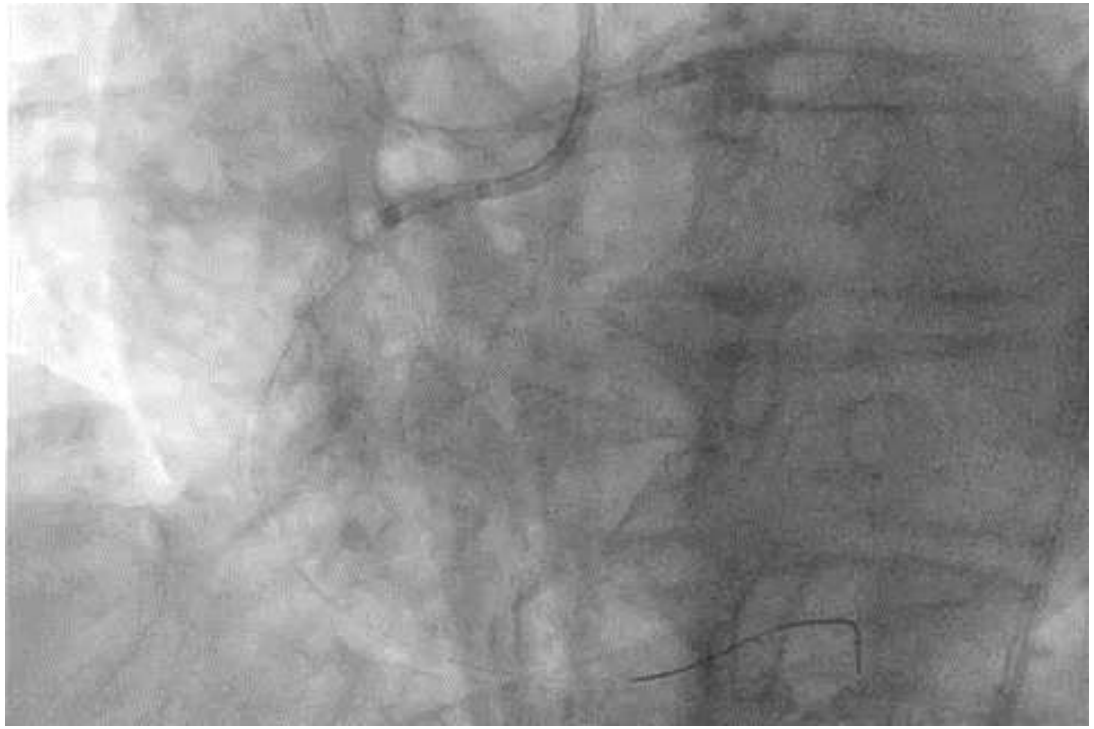


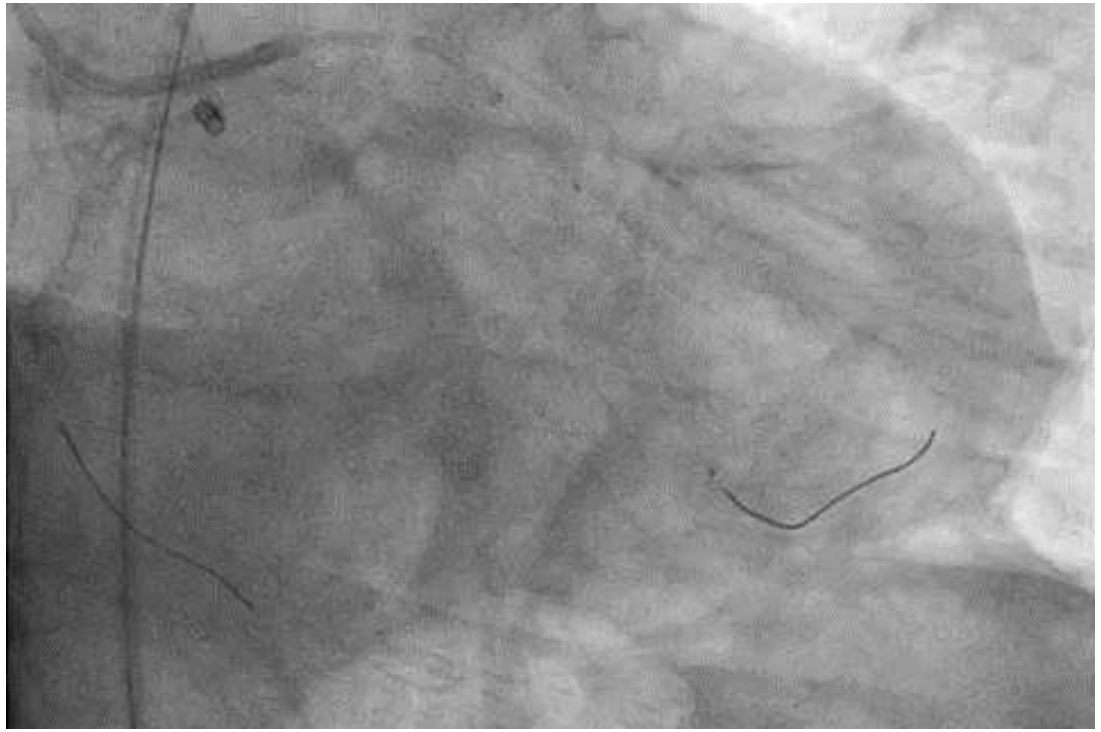


S_S_3VRota



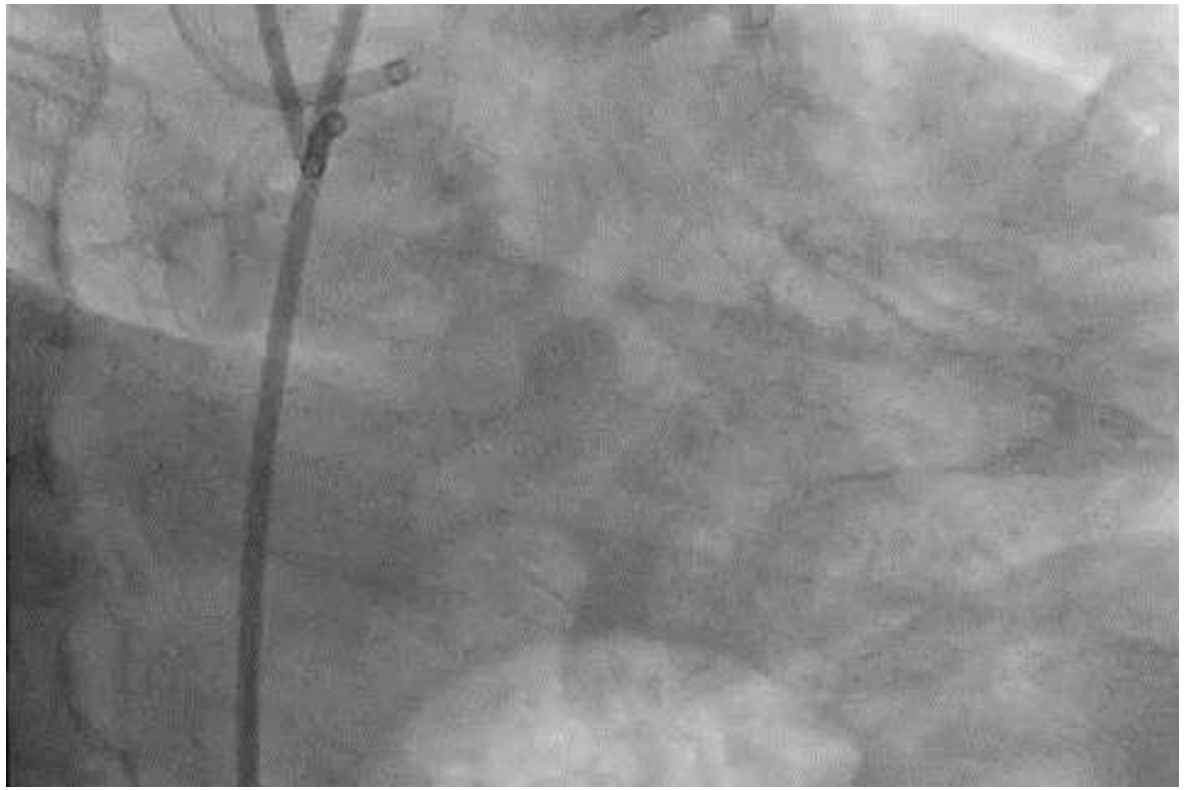
S_S_3VRota





S_S_3VRota

Final Results: RCA & CX CTO Rota, LAD Rota and stenting



S_S_3VRota

2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

10.8. Treatment of Patients With Stent Restenosis

Recommendations for Treatment of Patients With Stent Restenosis Referenced studies that support the recommendations are summarized in Online Data Supplement 30.

COR	LOE	Recommendations
1	A	1. In patients who develop clinical in-stent restenosis (ISR) for whom repeat PCI is planned, a DES should be used to improve outcomes if anatomic factors are appropriate and the patient is able to comply with DAPT.[1-4]
2a	C-EO	2. In patients with symptomatic recurrent diffuse ISR with an indication for revascularization, CABG can be useful over repeat PCI to reduce recurrent events.
2b	B-NR	3. In patients who develop recurrent ISR, brachytherapy may be considered to improve symptoms.[5]

Recommendation-Specific Supportive Text

1. In patients with ISR, studies have shown that treatment with a DES resulted in lower rates of target-vessel restenosis in follow-up than those seen with BMS or balloon angioplasty.[3,4,17] Network meta-analyses comparing various treatment options (DES, BMS, vascular brachytherapy, drug-coated balloons, conventional balloons, or rotational atherectomy) have shown that PCI with a DES was associated with the lowest rates of restenosis and target-vessel revascularization. Of the different DES stent types, everolimus-eluting stents appeared to have the best efficacy.[1,2] In these studies, there were no significant differences in other clinical outcomes, including death or MI, among the therapies examined.

ESC European Society of Cardiology
European Heart Journal (2019) **40**, 87–165
doi:10.1093/eurheartj/ehy394

2018 ESC/EACTS Guidelines on myocardial revascularization

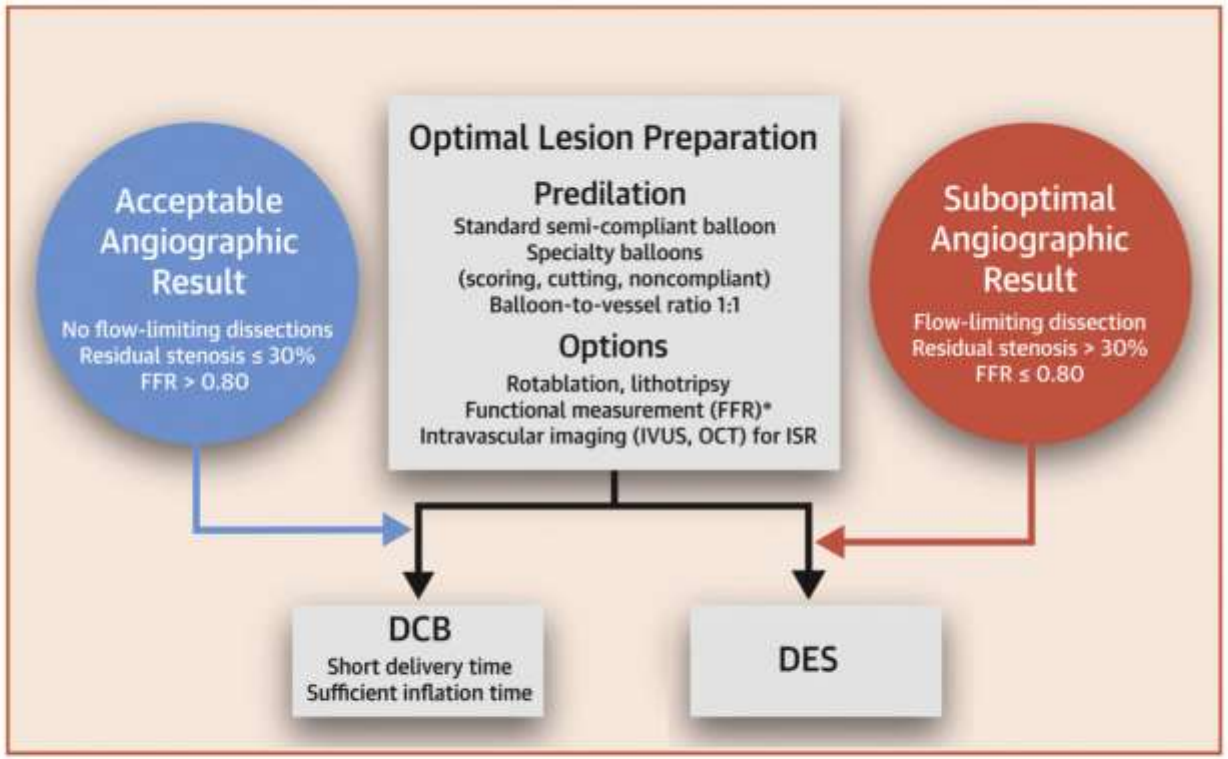
16.1.4 Drug-coated balloons

The rationale for using DCBs is based on the concept that with highly lipophilic drugs, even short contact times between the balloon surface and the vessel wall are sufficient for effective drug delivery. There are various types of DCB that are approved for use in Europe and their main characteristics are listed in Supplementary *Table 8*. Although specifically designed comparative randomized trials are lacking, a class effect for all DCBs cannot be assumed.[598] Randomized trial data supporting the use of DCB angioplasty are limited to the treatment of in-stent restenosis (see section 13.4). In terms of the use of DCB angioplasty for *de novo* disease, a number of small randomized trials have been reported with somewhat conflicting results.[599–601] At present, there are no convincing data to support the use of DCB angioplasty for this indication.

Restenosis		
DES are recommended for the treatment of in-stent restenosis of BMS or DES.[373,375,378,379]	**I**	**A**
Drug-coated balloons are recommended for the treatment of in-stent restenosis of BMS or DES.[373,375,378,379]	**I**	**A**
In patients with recurrent episodes of diffuse in-stent restenosis, CABG should be considered by the Heart Team over a new PCI attempt.	**IIa**	**C**
IVUS and/or OCT should be considered to detect stent-related mechanical problems leading to restenosis.	**IIa**	**C**

DCB: Lesion Preparation for Successful Results

CENTRAL ILLUSTRATION **DCB-Only Strategy for PCI in Coronary Artery Disease**



Jeger, R.V. et al. J Am Coll Cardiol Intv. 2020;13(12):1391–402.

*FFR >0.80 may be a good compromise to guide angioplasty. DCB = drug-coated balloon; DES = drug-eluting stent; FFR = fractional flow reserve; ISR = in-stent restenosis; IVUS = intravascular ultrasound; OCT = optical coherence tomography; PCI = percutaneous coronary intervention.

THANK YOU FOR YOUR ATTENTION…