DES or DCB
Hybrid Approach in diffuse disease

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7th November 2024

Disclaimers

Personal fees:

Abbott, Boston, Medtronic, Palex, Biosensors, Meril, Cordis.

Unit fees:

Terumo, Boston, Cordis

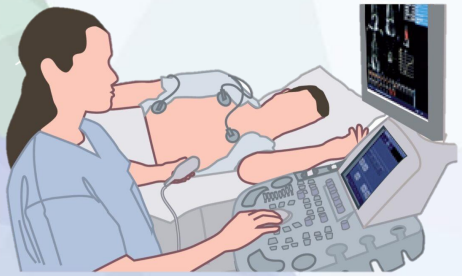
66-year-old male

CV Risk Factors

- Previous smoker
- Dyslipidaemia

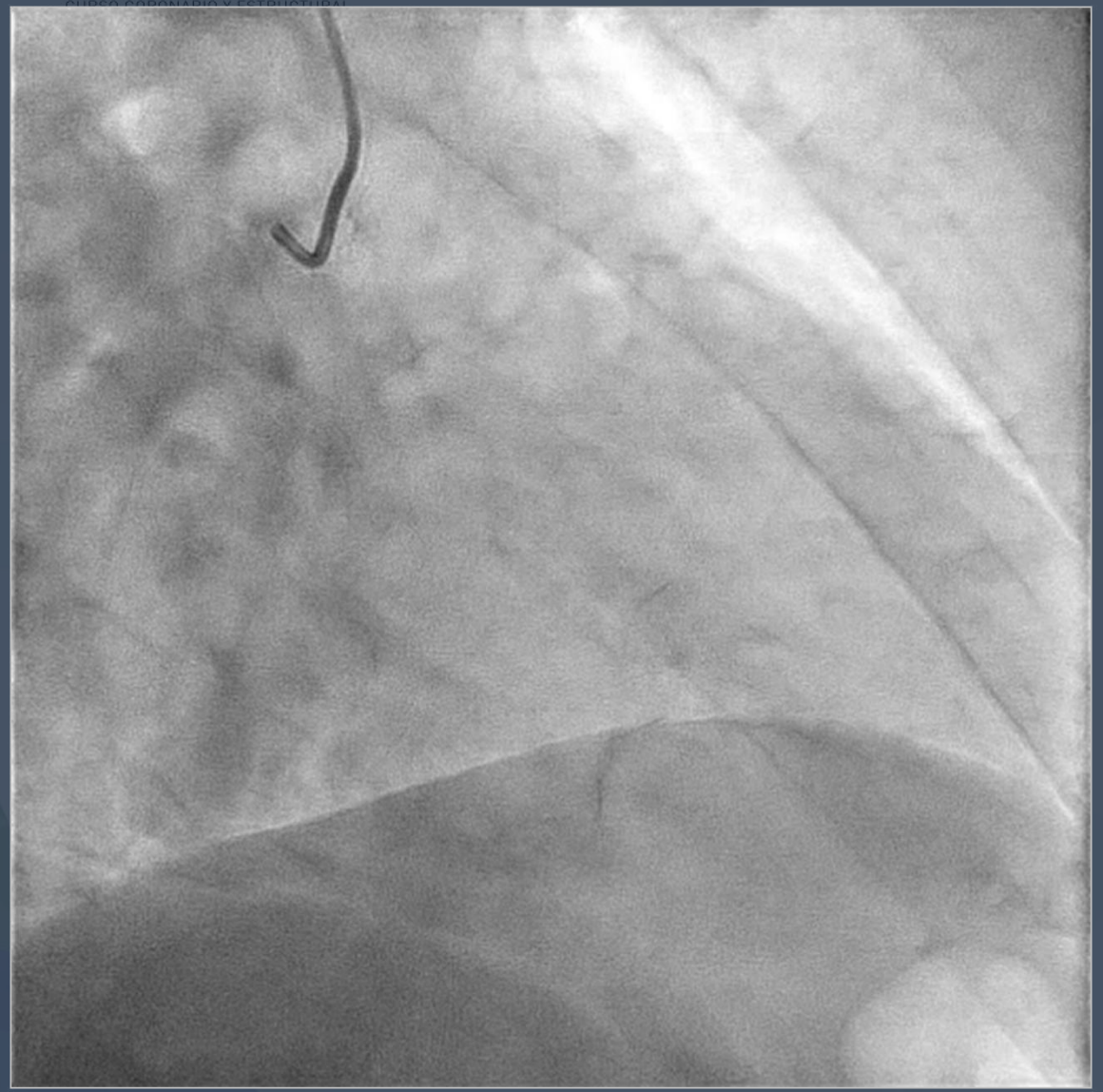
Current Admission

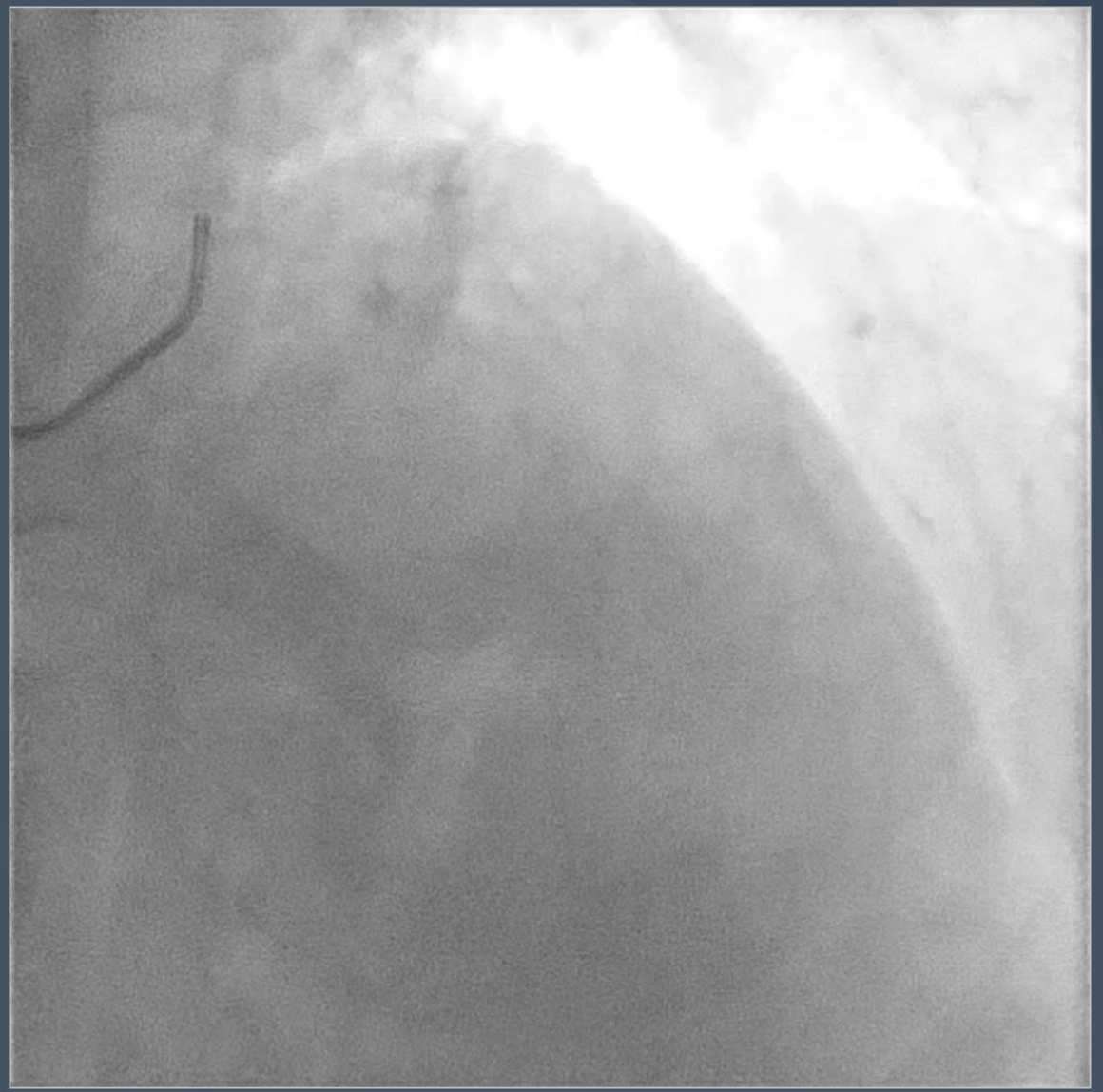
- De novo angina
- ECG: normal
- Troponin normal. Normal renal function

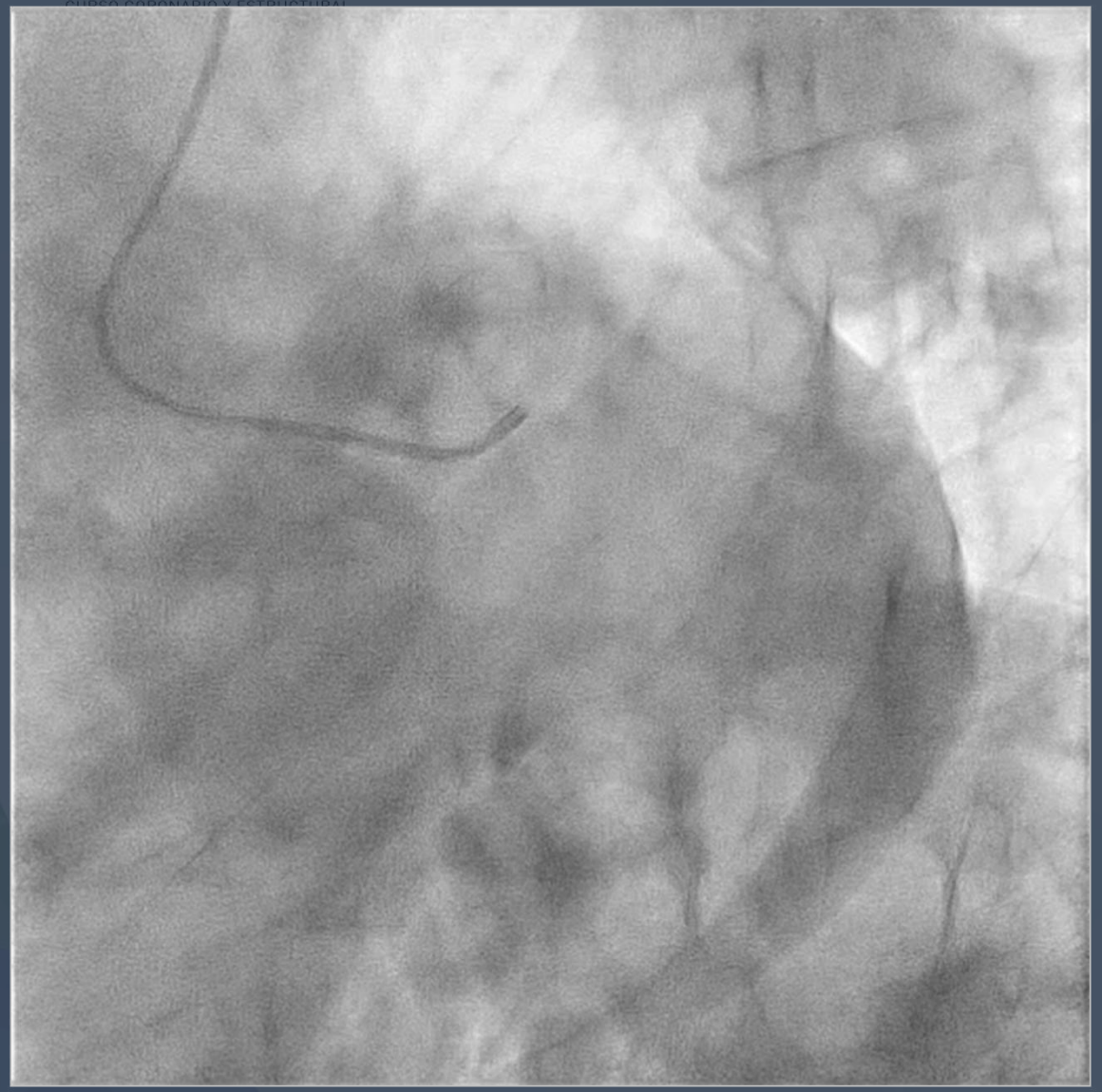


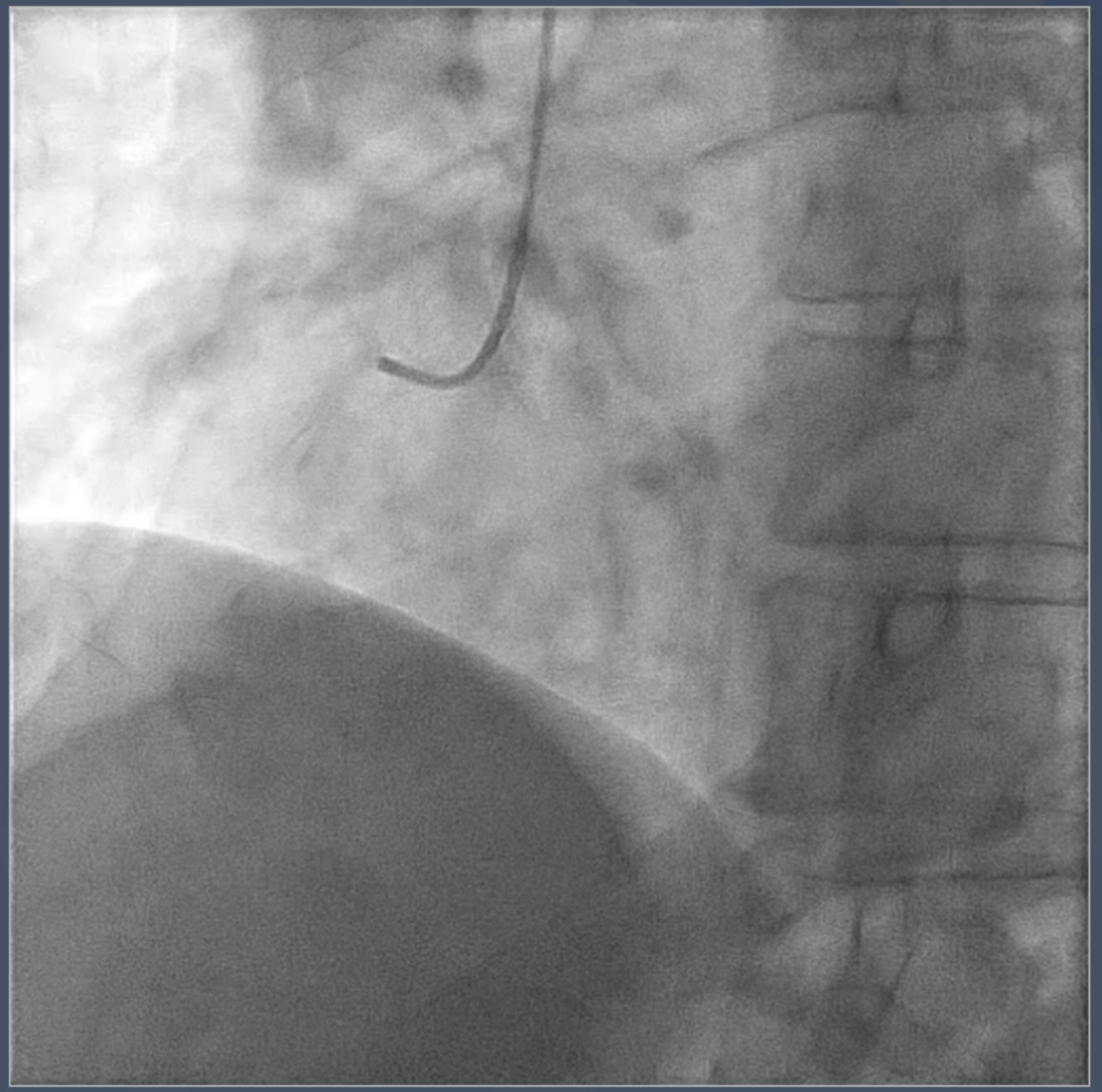
Echo

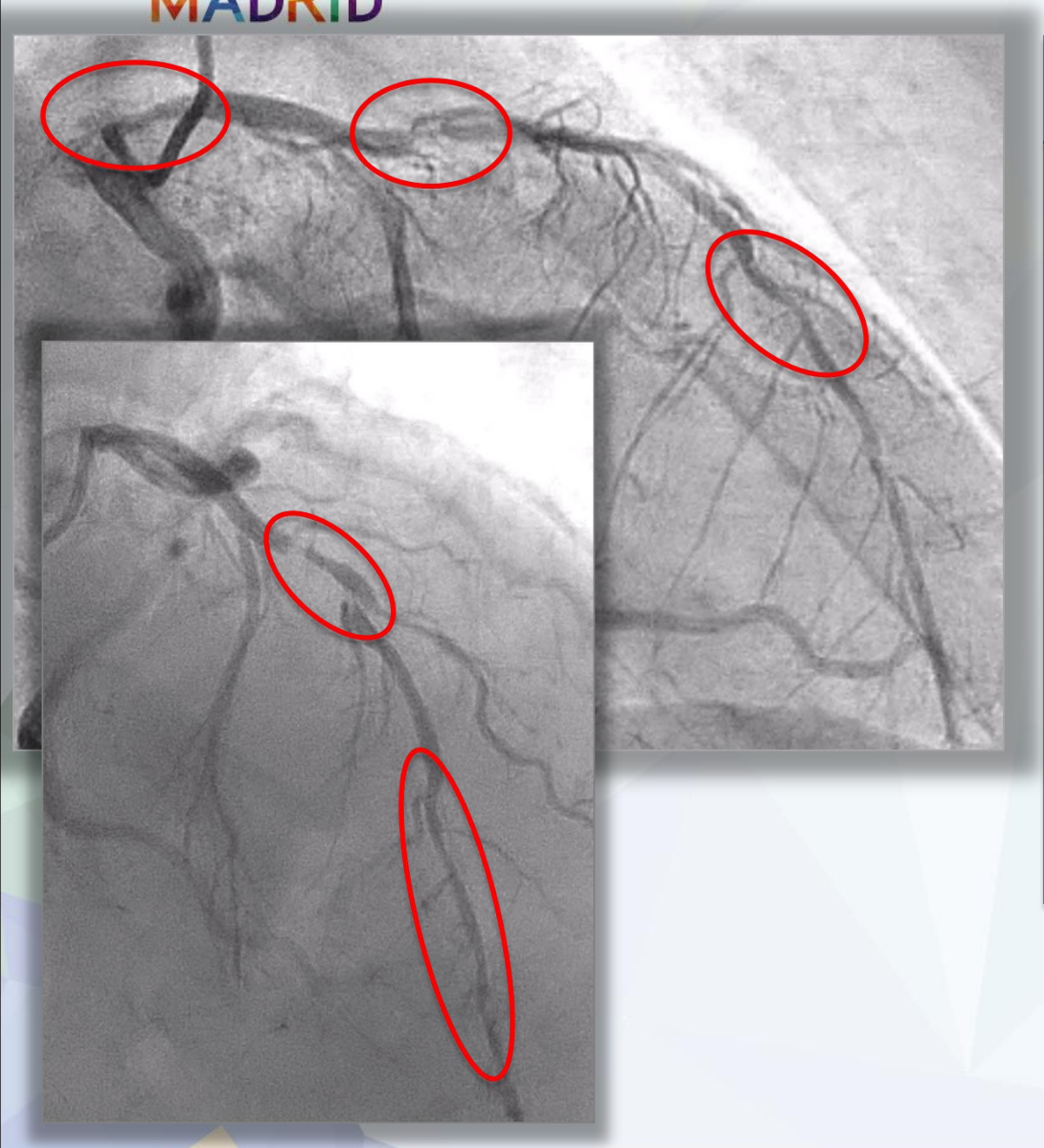
- TTE: preserved LVEF
- Anterior hypokinesia











Strategy?

1) Only DCB (DES just in case of dissection more than C).
2) DES x 3 (Full metal jacket).
3) Hybrid strategy: DES proximal, DCB distal.
4) Surgery: nothing to do in front to LIMA to LAD.
5) Optimal Medical Treatment.

1 Only DCB

2 Only DES

3 Hybrid Approach: DES + DCB

4 OMT

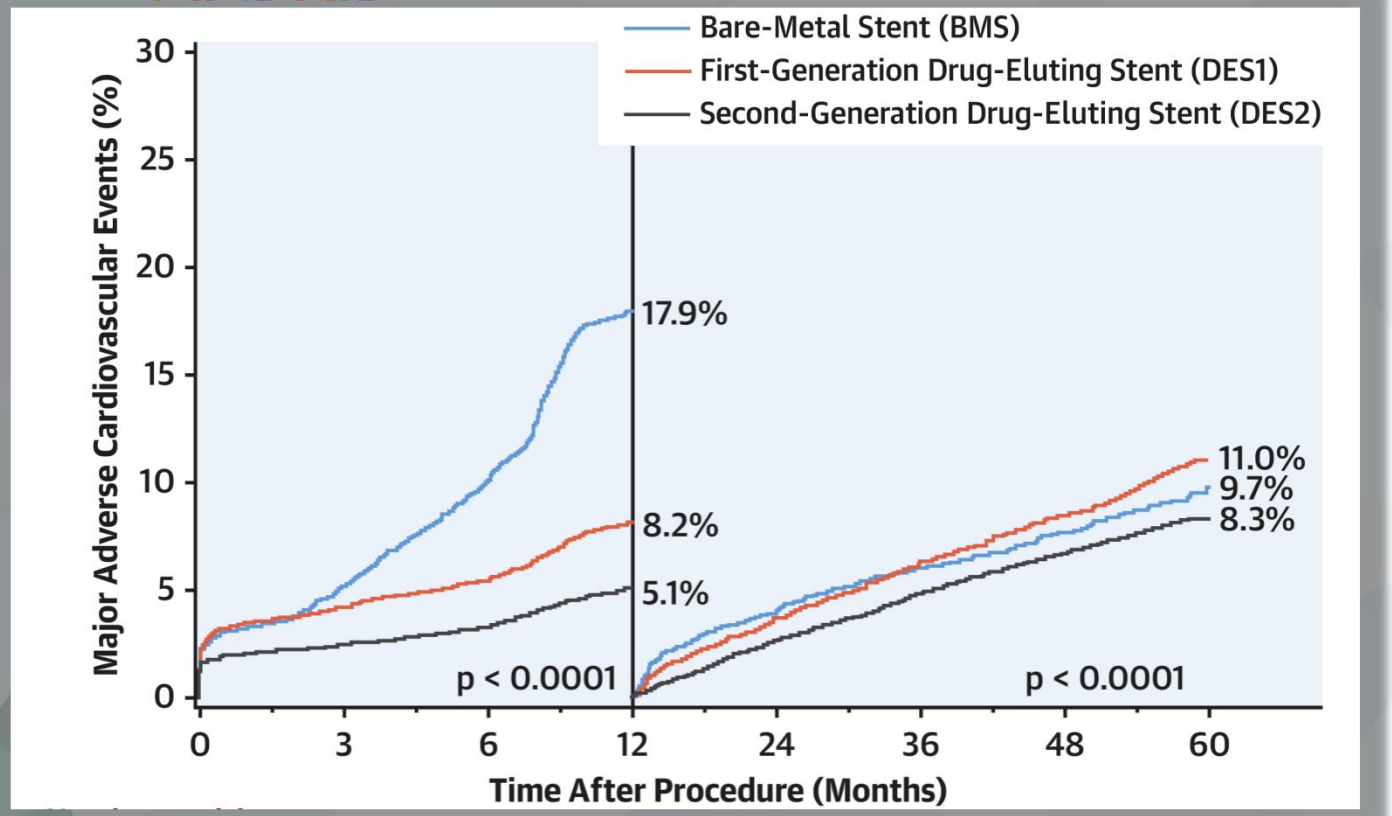
1 Only DCB

2 Only DES

3 Hybrid Approach: DES + DCB

4 OMT

Long-term effects of coronary stents



Stent-Related Adverse Events >1 Year After Percutaneous Coronary Intervention

Mahesh V. Madhavan, MD,[a,b] Ajay J. Kirtane, MD, SM,[a,b] Björn Redfors, MD, PhD,[b,c] Philippe Généreux, MD,[b,d,e] Ori Ben-Yehuda, MD,[a,b] Tullio Palmerini, MD,[f] Umberto Benedetto, MD, PhD,[g] Giuseppe Biondi-Zoccai, MD, MSTAT,[h,i] Pieter C. Smits, MD,[j] Clemens von Birgelen, MD, PhD,[k] Roxana Mehran, MD,[b,l] Thomas McAndrew, PhD,[b] Patrick W. Serruys, MD,[m] Martin B. Leon, MD,[a,b] Stuart J. Pocock, PhD,[n] Gregg W. Stone, MD[b,l]

Very-late stent-related ischemic events **~2%/year after PCI** with all stent types

No plateau through 5-year follow-up

- Late **inflammatory and hypersensitivity** reactions to the drug or polymer
- **Mechanical problems**: stent fracture, longitudinal deformation
- **Side branch** obstruction

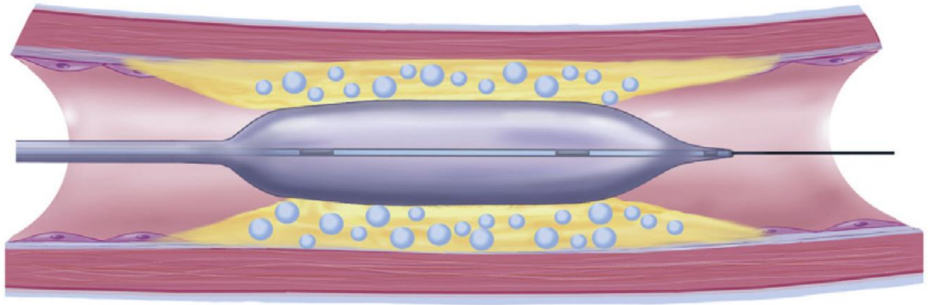
- Very late effects of a **permanent metallic scaffold**: loss of vasomotor function and adaptive vascular remodelling, neoatherosclerosis
- **Stent Malapposition**

Madhavan MV, et al. *J Am Coll Cardiol*. 2020;75:590-604

Joner M, et al. *J Am Coll Cardiol* 2006;48:193–202

Advantages of DCB vs DES

- **Immediate delivery of the drug to the endothelium** without the need of metal/polymer
- **Homogeneous** release of the drug to the vessel wall
- **Low risk** of acute vessel occlusion
- **No risk** of stent thrombosis
- **No struts** caging the origin of lateral branches



- Allows maintenance **of post-PCI vasomotor function**
- **Late-lumen enlargement** (~70% with Paclitaxel and ~30% with Sirolimus-DCB)
- Ease of continued treatment with DCB, stents, CABG
- Possibility of **shortening / simplifying** antiplaletet therapy

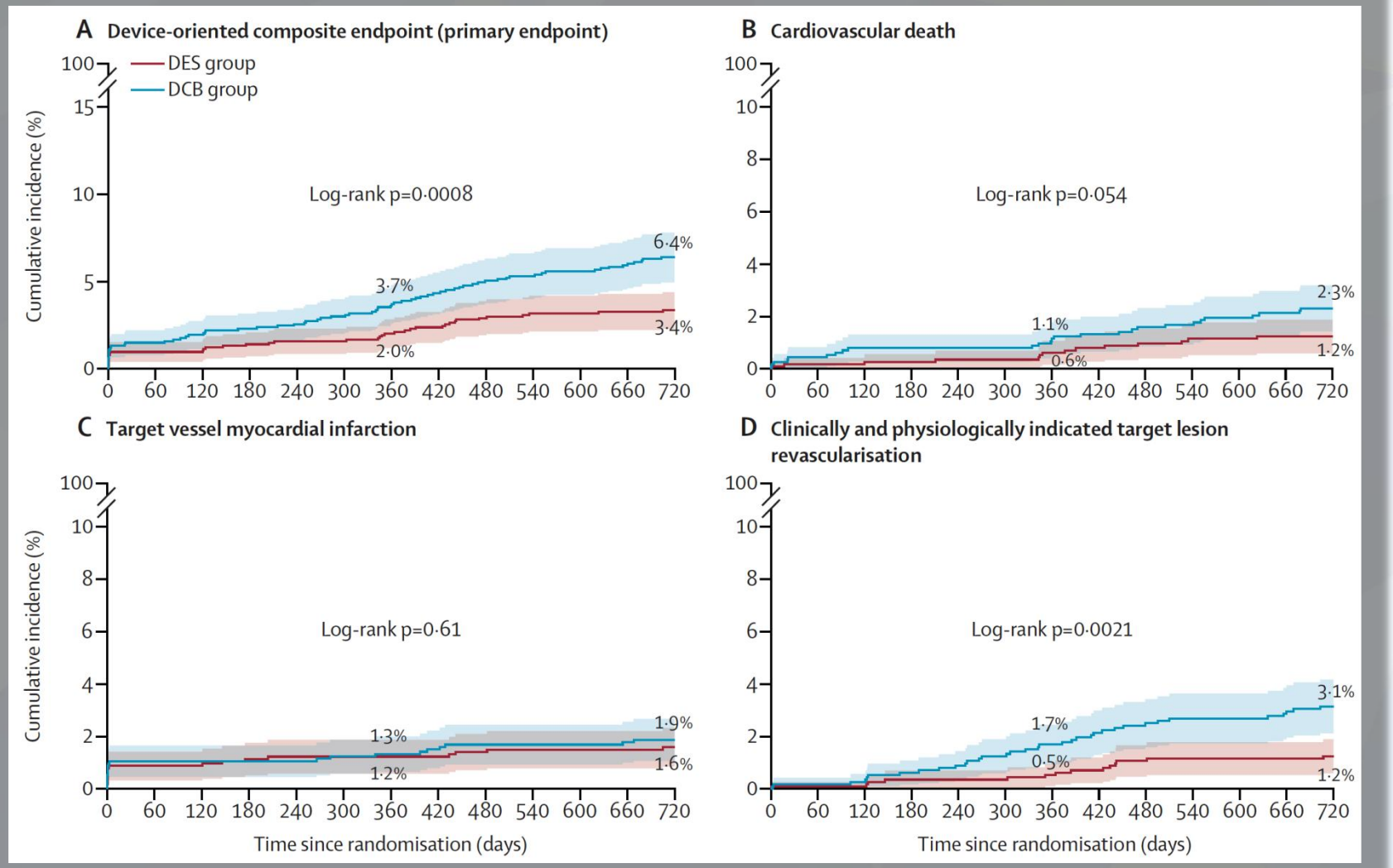
1 Only DCB

2 Only DES

3 Hybrid Approach: DES + DCB

4 OMT

Drug-coated balloon angioplasty with rescue stenting versus intended stenting for the treatment of patients with de novo coronary artery lesions (REC-CAGEFREE I): an open-label, randomised, non-inferiority trial



Gao C for the REC-CAGEFREE I Investigators. Lancet 2024 Sep 14;404(10457):1040-1050.

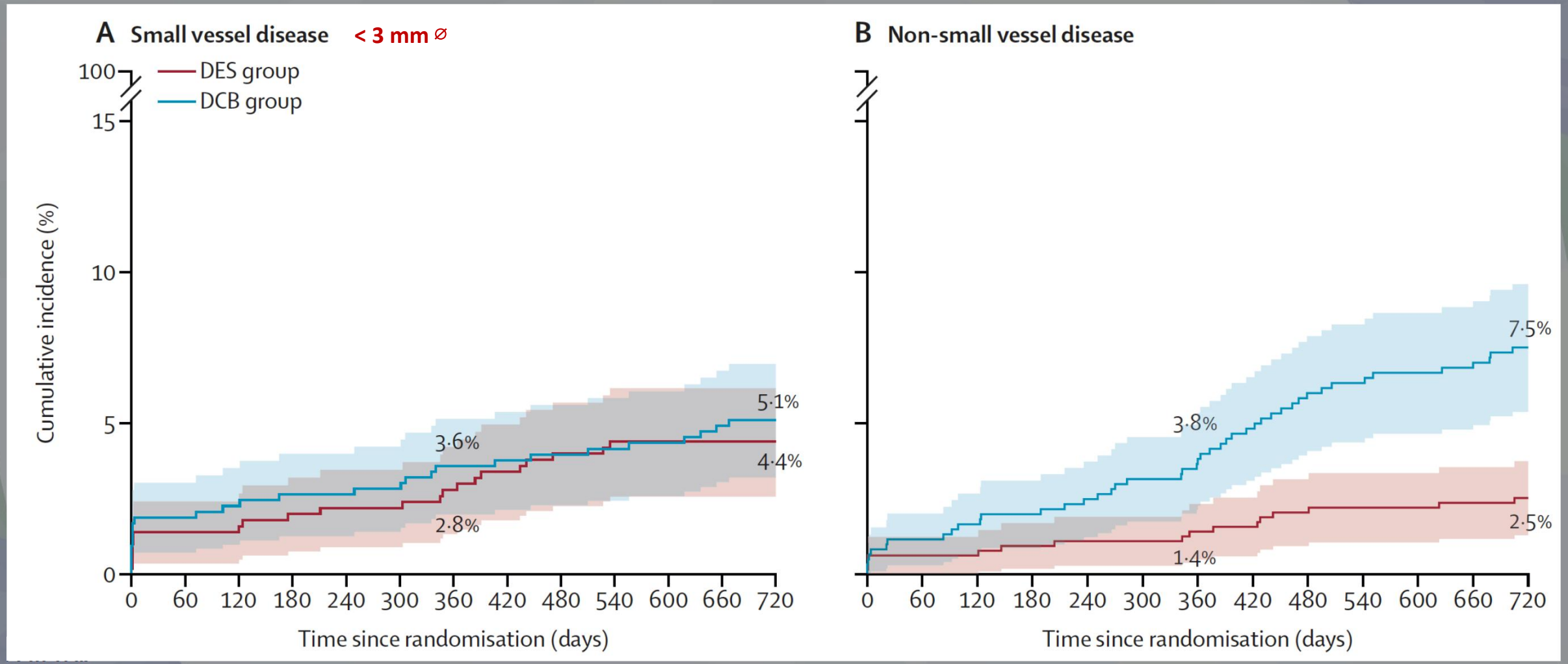
1 Only DCB

2 Only DES

3 **Hybrid Approach: DES + DCB**

4 OMT

Drug-coated balloon angioplasty with rescue stenting versus intended stenting for the treatment of patients with de novo coronary artery lesions (REC-CAGEFREE I): an open-label, randomised, non-inferiority trial



Gao C for the REC-CAGEFREE I Investigators. Lancet 2024 Sep 14;404(10457):1040-1050.

1 Only DCB

2 Only DES

3 Hybrid Approach: DES + DCB

4 **OMT**

2024 ESC Guidelines for the management of chronic coronary syndromes

Single- or double-vessel disease involving the proximal LAD		
In CCS patients with significant single- or double-vessel disease involving the proximal LAD and insufficient response to guideline-directed medical therapy, CABG or PCI is recommended over medical therapy alone to improve symptoms and outcomes.[52,321,719,791,792]	I	A
In CCS patients with complex significant single- or double-vessel disease involving the proximal LAD, less amenable to PCI, and insufficient response to guideline-directed medical therapy, CABG is recommended to improve symptoms and reduce revascularization rates.[877–879]	I	B

Recommendations for definition of high risk of adverse events		
An initial stratification of risk of adverse events is recommended based on basic clinical assessment (e.g. age, ECG, anginal threshold, diabetes, CKD, LVEF).	I	B
The use of one or more of the following test results is recommended to identify individuals at high risk of adverse events: • Exercise ECG: o Duke Treadmill Score < −10; • stress SPECT or PET perfusion imaging: o Area of ischaemia ≥10% of the LV myocardium; • Stress echocardiography: o ≥3 of 16 segments with stress-induced hypokinesia or akinesia; • stress CMR: o ≥2 of 16 segments with stress perfusion defects or ≥3 dobutamine-induced dysfunctional segments; • CCTA: o left main disease with ≥50% stenosis, three-vessel disease with ≥70 stenosis, or two-vessel disease with ≥70% stenosis, including the proximal LAD or one-vessel disease of the proximal LAD with ≥70% stenosis and FFR-CT ≤0.8.	I	B

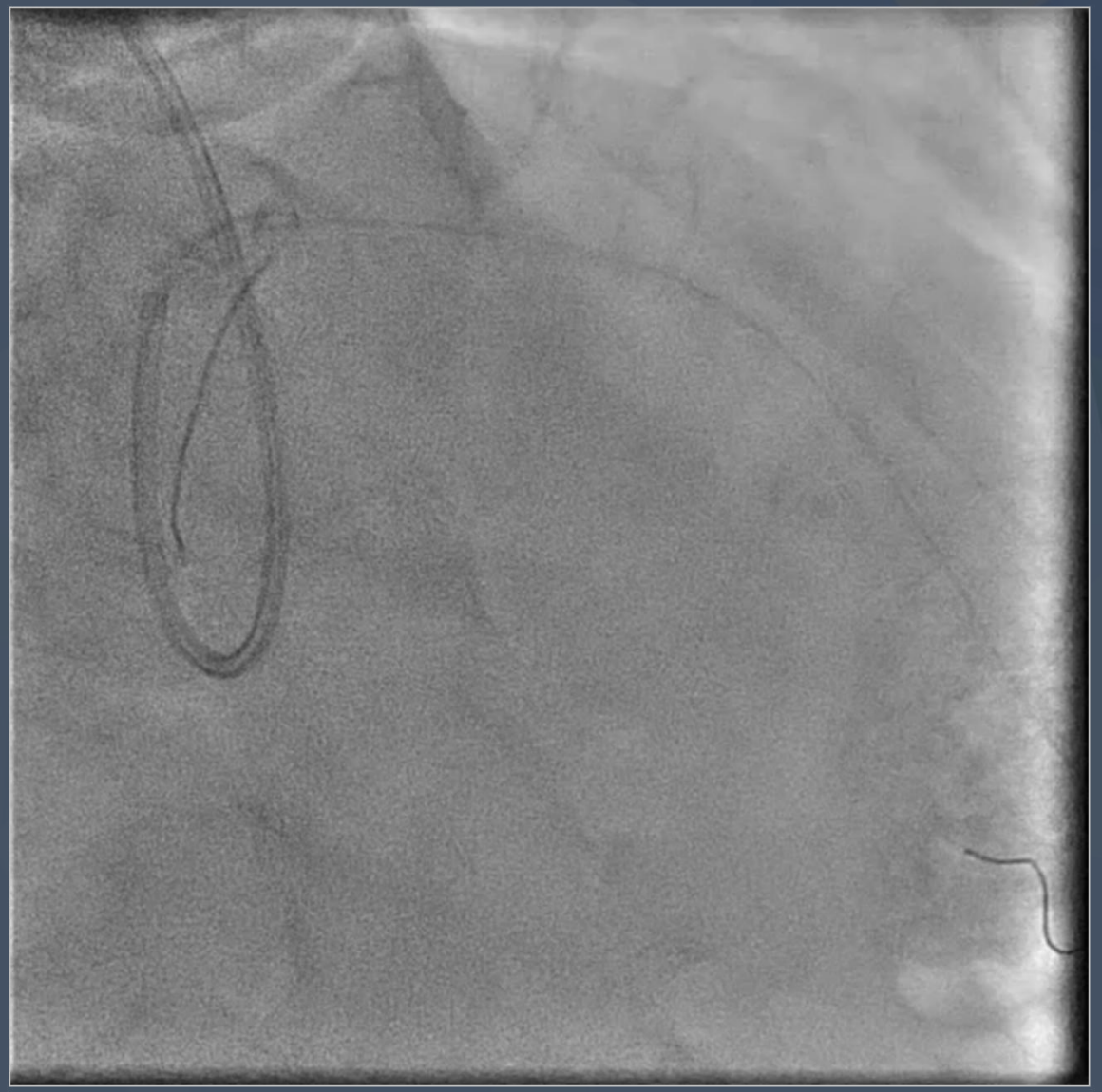
Wiring

Predilation: 1,5 mm balloon

Predilation: 2,0 x 15 mm balloon

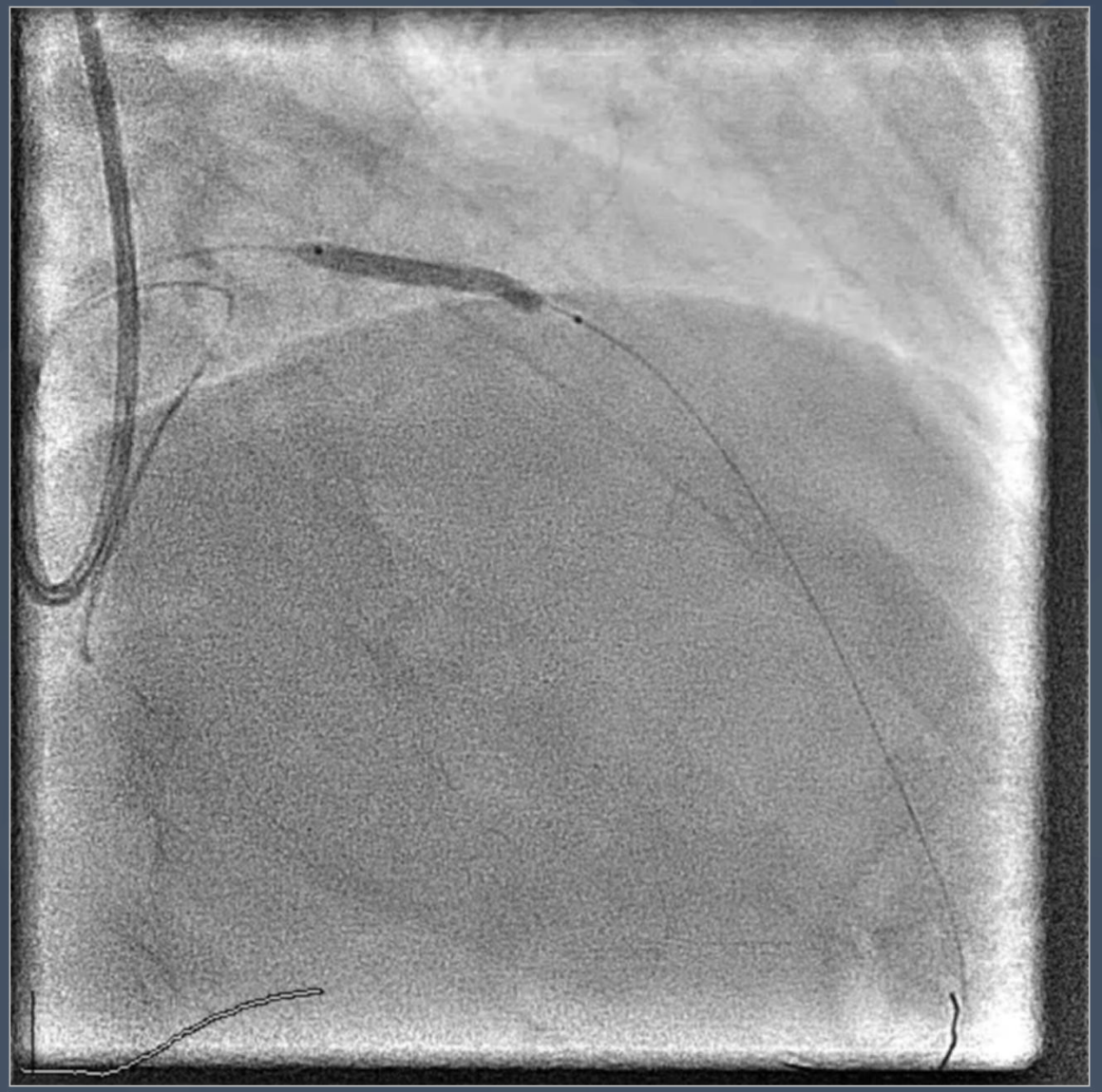
Vesel Preparation: Wolverine 2,5 x 10 mm & 3,0 x 10 mm

Vessel Preparation: 3,0 x 30 mm SC balloon

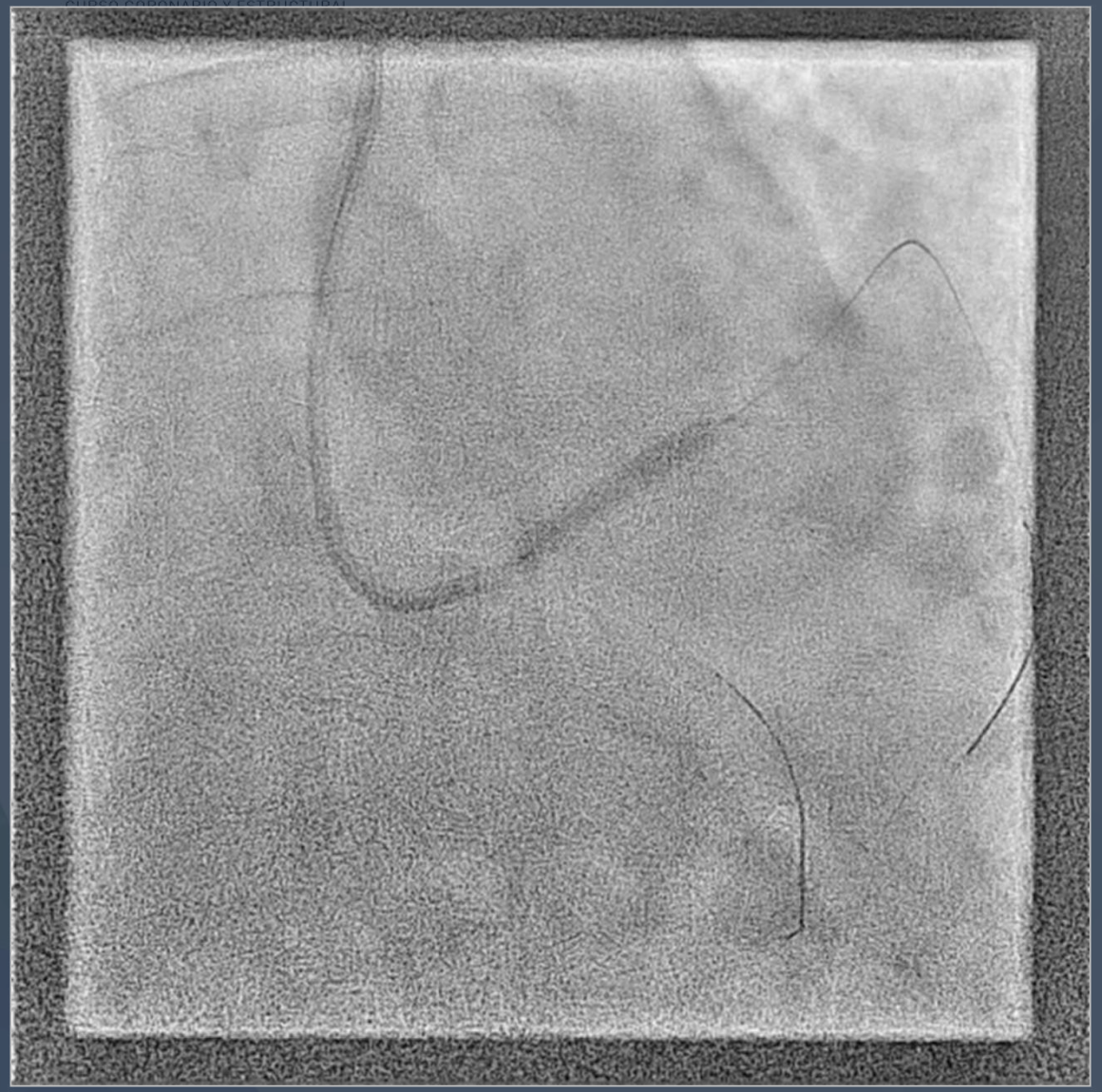


Result

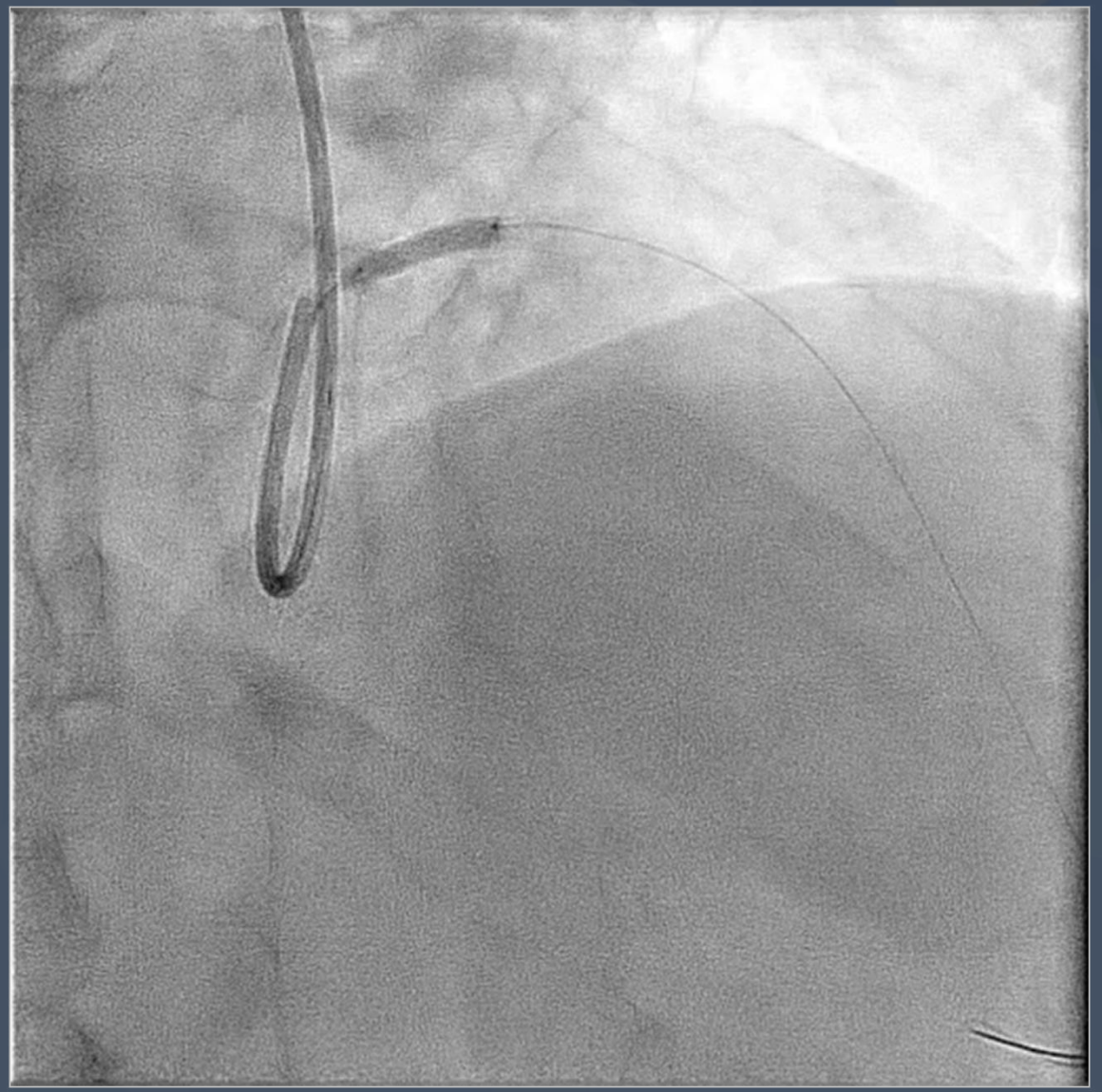
Restore 2,5 x 30 mm



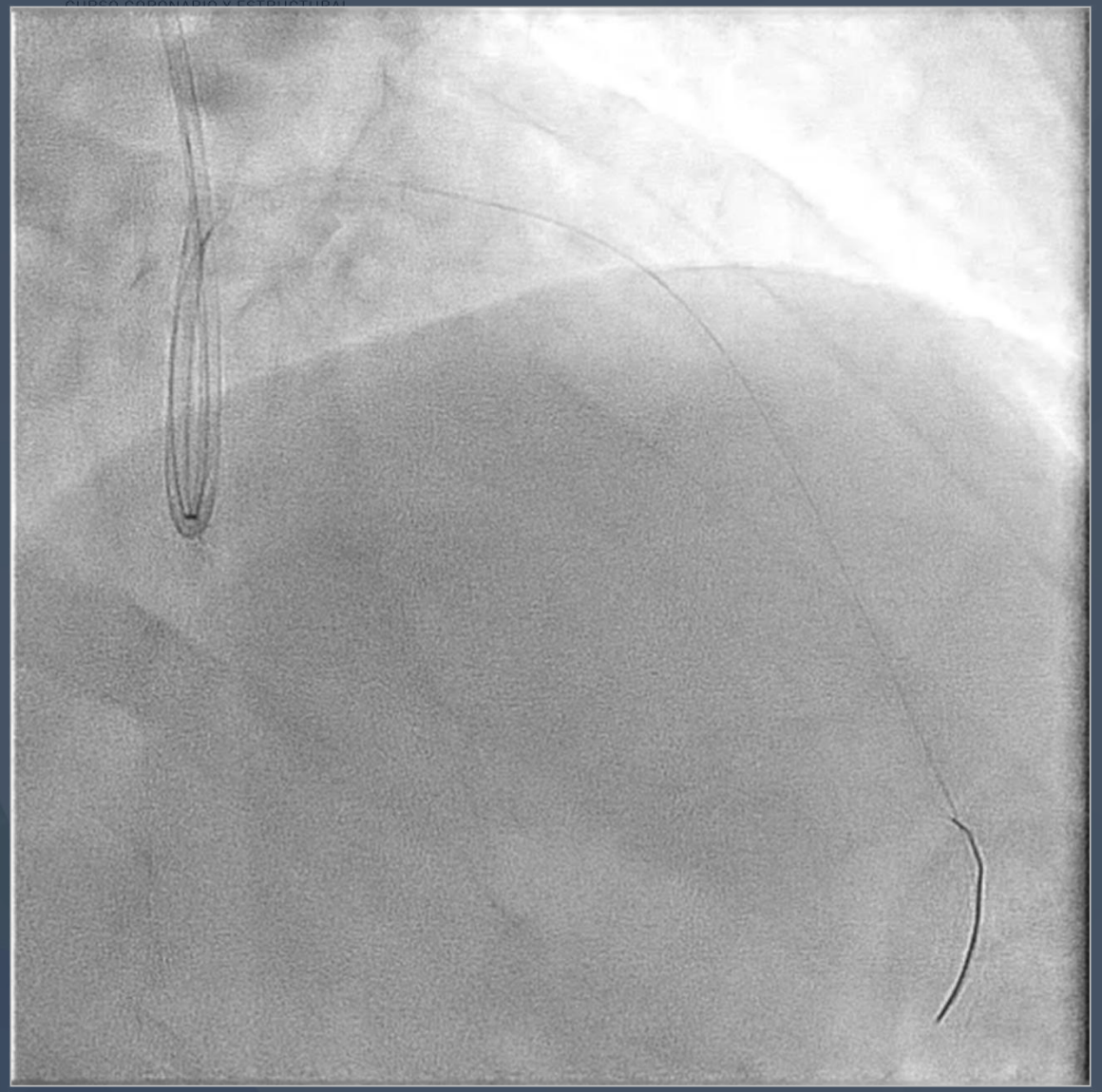
Restore 3,0 x 30 mm



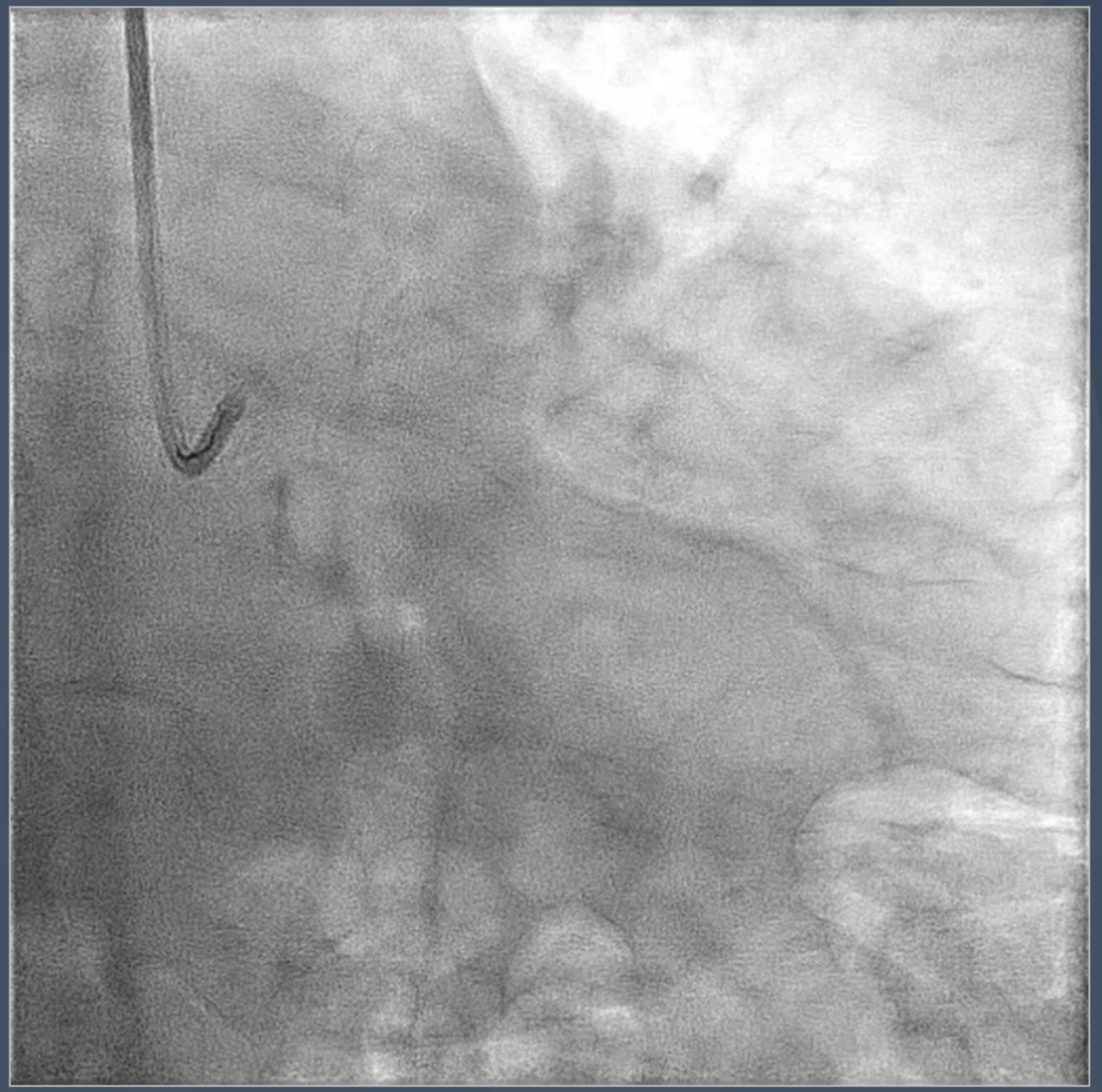
DES 3,0 x 24 mm



Post-dil NC balloon 3,5 x 15 mm



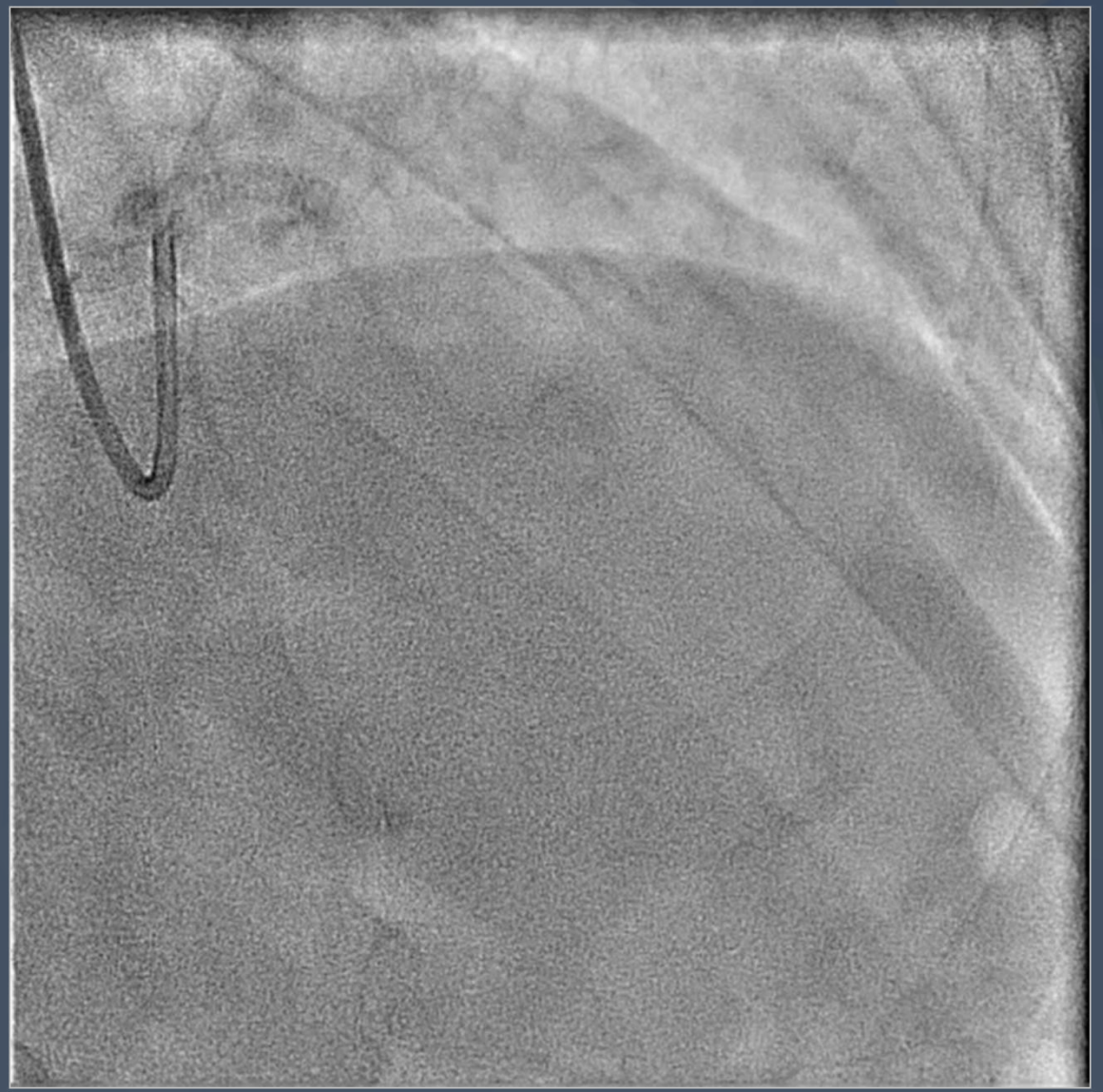
Result

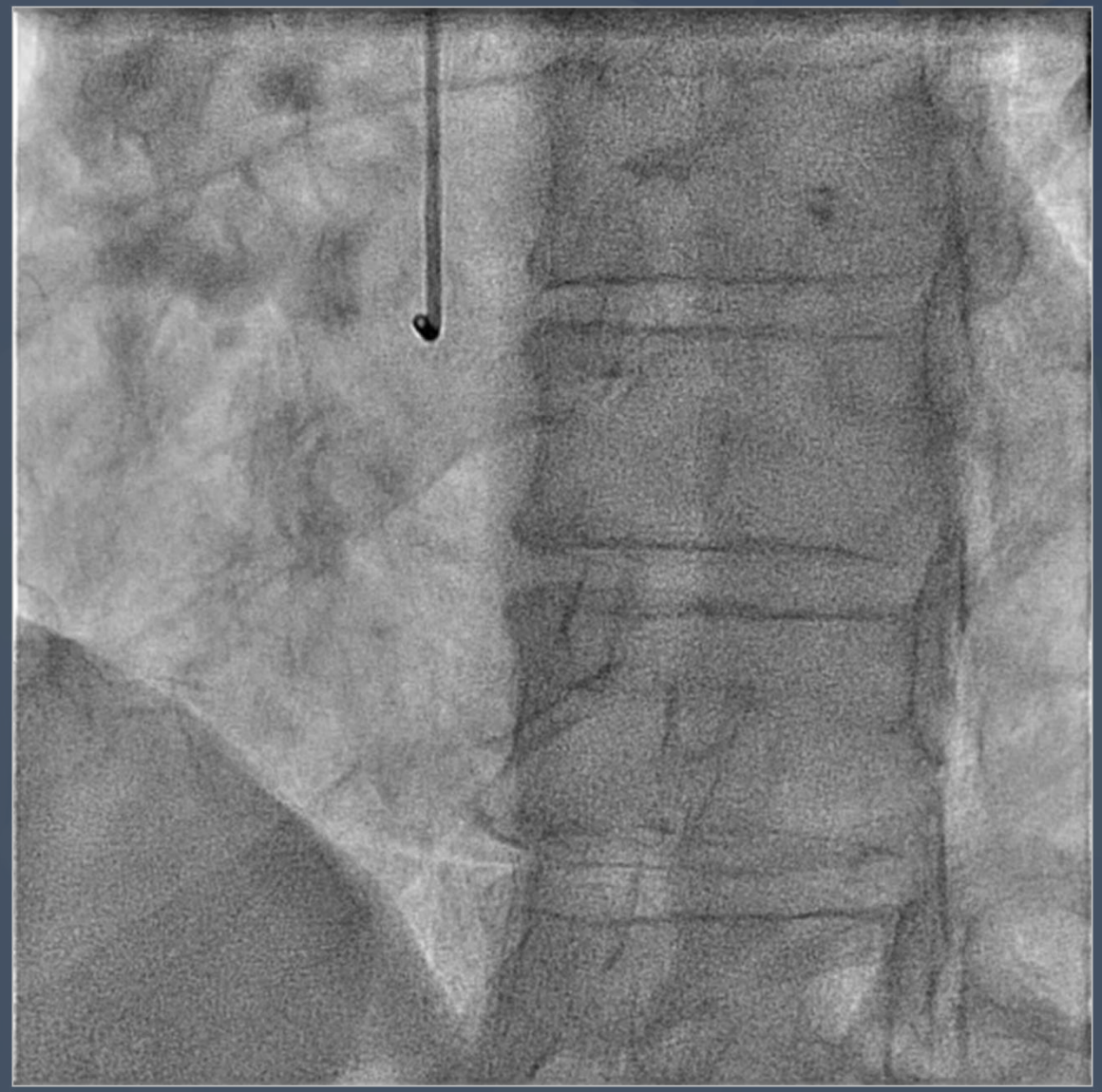


Final Result

5 months FU

- Rehabilitation Program.
- Asymptomatic.
- Treadmill Stress Test: Negative 94% de la FCMT.



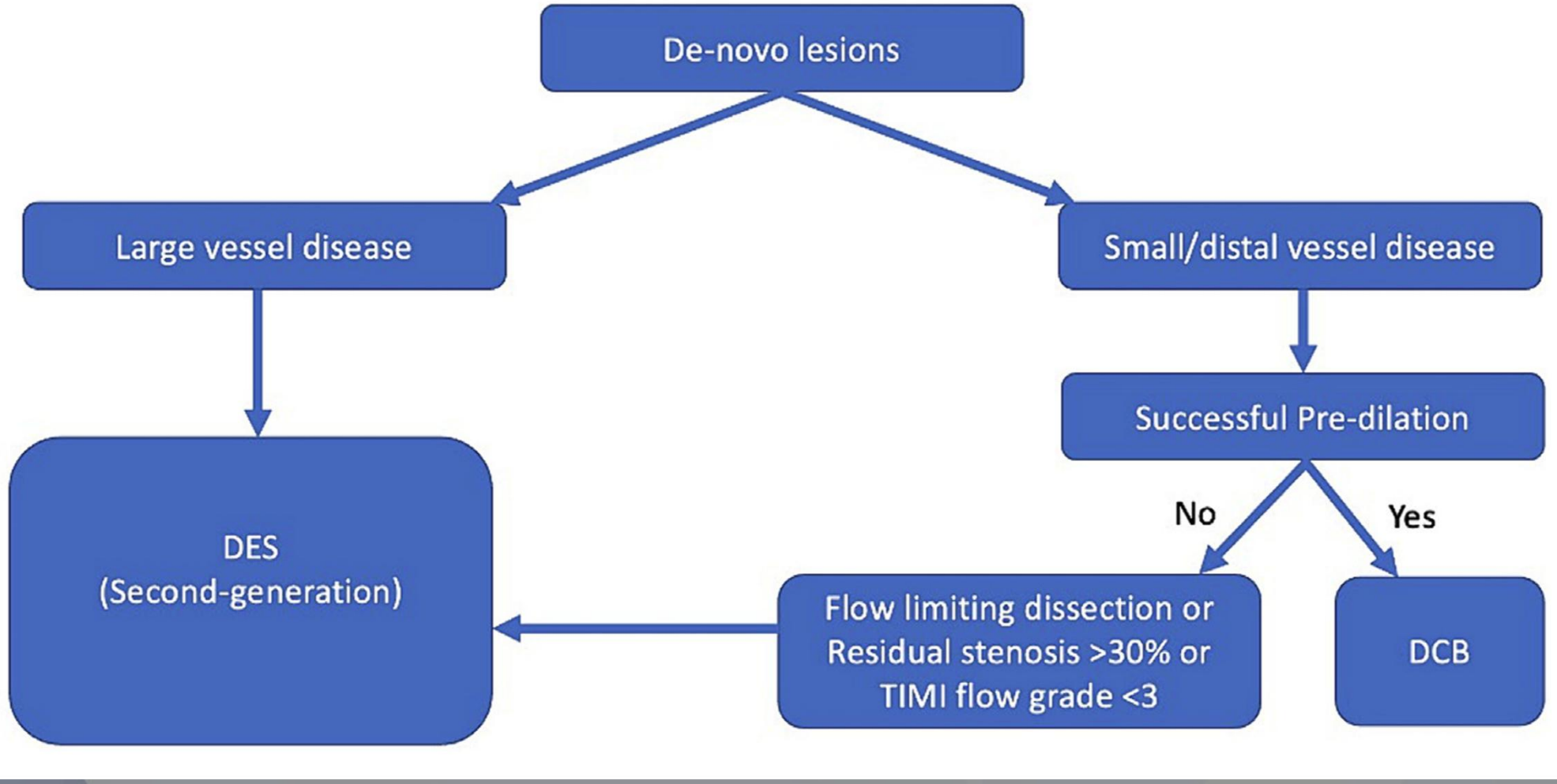


CONCLUSIONS

Drug-coated balloons for coronary artery disease: An updated review with future perspectives

Sukhdeep Bhogal [a], Andrew P. Hill [b], Ilan Merdler [a], Jason P. Wermers [a], Itsik Ben-Dor [a], Ron Waksman [a,*]

REVASCULARIZATION STRATEGY



Bhogal S, et al. *Cardiovasc Revasc Med.* 2024 May 23:S1553-8389(24)00496-2. doi: 10.1016/j.carrev.2024.05.027. Epub ahead of print.

Clinical expert consensus document on drug-coated balloon for coronary artery disease from the Japanese Association of Cardiovascular Intervention and Therapeutics

1st Step: *Suitability for DCB*

Patients with
- multiple metallic stents implanted
- concerns about long-term presence of metallic stents (e.g., young adults, suspected metal allergy)
- high bleeding risk

Angiographic conditions with
- in-stent restenosis
- small vessel lesions
- ostial lesions
- bifurcation lesions requiring side branch dilatation
- calcified lesions not expected to be well expandable (e.g., nodular calcification)

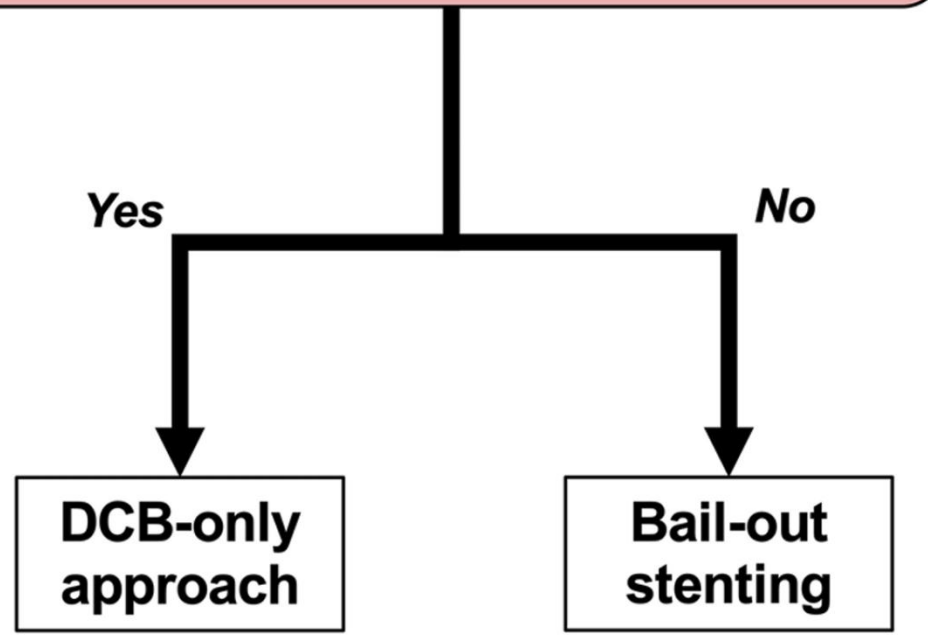
2nd Step: *Optimal lesion preparation before using DCB*

Pre-dilatation with
- modified balloons (cutting or scoring) are recommended.
- balloon-to-artery ratio 1:1
- Intracoronary imaging guidance is encouraged.

If moderate to severe calcification is evident, adjunctive rotational atherectomy, orbital atherectomy, or lithotripsy should be considered.

3rd Step: *Assessment after pre-dilatation*

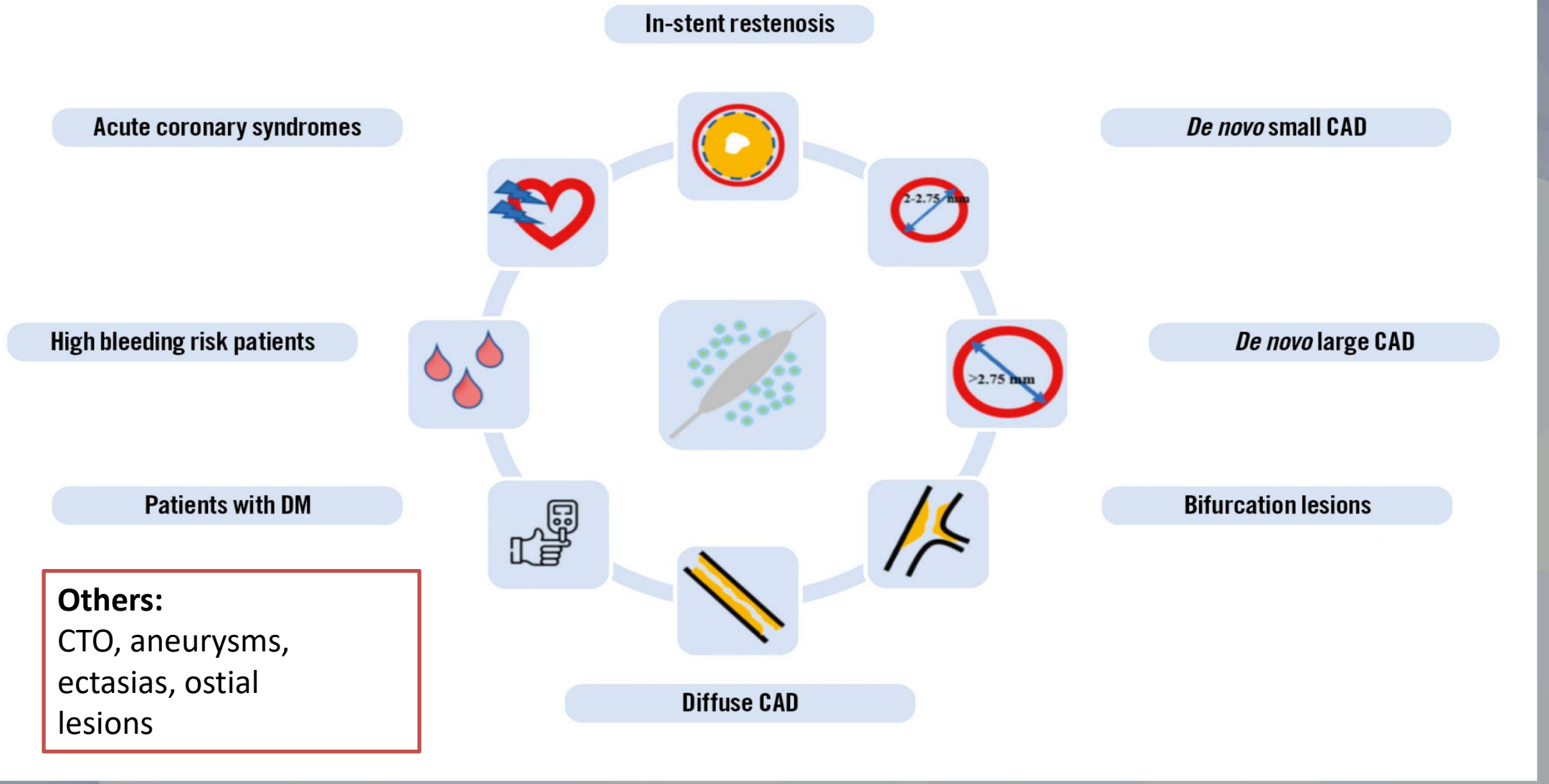
To be confirmed
- TIMI grade 3 flow (non-flow limiting)
- angiographic residual stenosis ≤30 %
- absence of major dissection (type C-F in angiography, or medial involvement or hematoma detected in IVUS/OCT)
- absence of findings suggestive of thrombus
- fractional flow reserve (FFR) >0.80 (option)



Cardiovascular Intervention and Therapeutics 2023; 38: 166.

Thank you

Potential favourable scenarios for DCB



Others:
CTO, aneurysms, ectasias, ostial lesions

Introduction: Questions

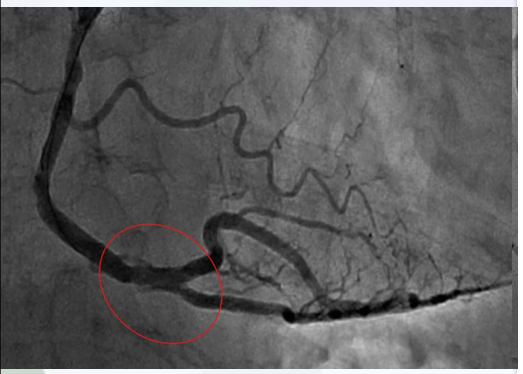
Do you routinely use DCB in your cath-lab?

- Yes,
- No, only in in-stent-restenosis

What is your indication for DCB?

- ISR
- Bifurcation
- Diffuse disease

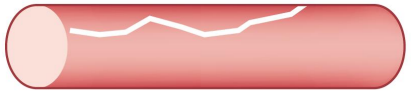
Dissection after balloon dilatation



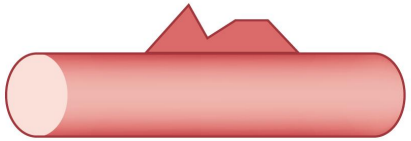
NHLBI classification

Type A: luminal haziness: minor radiolucent areas within the coronary lumen during contrast injection with no persistence of contrast after the dye has cleared

Type B: linear dissection: parallel tracts or a double lumen, with no persistence of dye

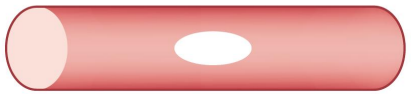


Type C: xtra-luminal contrast staining: extra luminal "cap" of dye with persistence of contrast

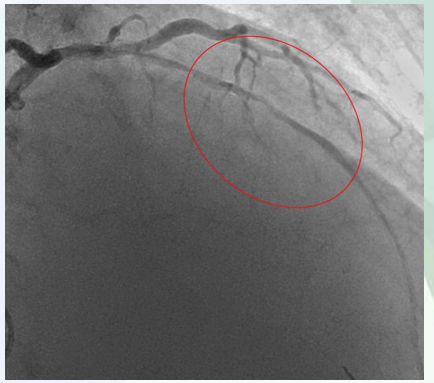


Type D: spiral dissection, usually with excessive contrast staining of the false lumen

Type E: dissection with persistent filling defects in the coronary lumen



Type F: dissection with total occlusion of the coronary lumen and no distal anterograde flow



Rogers JH, Lasala JM. J Invasive Cardiol. 2004;16 : 493-499.

Dissection after balloon dilatation

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Effect of Drug-Coated Balloons in Native Coronary Artery Disease Left With a Dissection

Bernardo Cortese, MD,* Pedro Silva Orrego, MD,* Pierfrancesco Agostoni, MD, PhD,† Dario Buccheri, MD,*‡ Davide Piraino, MD,*‡ Giuseppe Andolina, MD,‡ Romano Giuseppe Seregni, MD*

156 pts treated with DCB

52 pts had a final dissection, 4 were stented (3 flow impairment, 1 type D dissection)

Normal flow in the non-stented dissections
Angio f-up 6 to 9 months

FIGURE 4 The Fate of Dissections After DCB Angioplasty

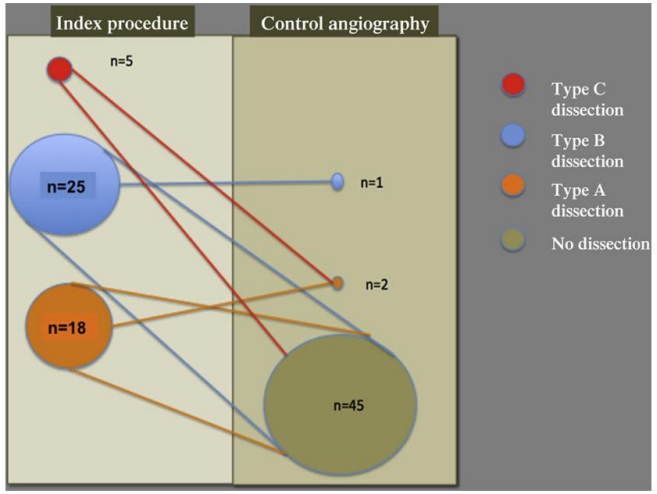
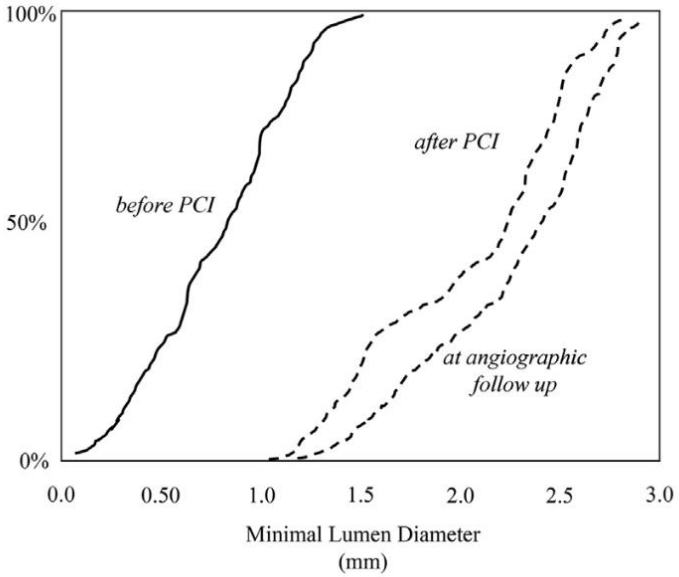


Figure shows what happened to dissections at 6-month angiography: 45 were healed and 3 were chronic. There was not an apparent correlation between the type of initial dissection left after DCB angioplasty and its fate. We followed the NHLBI classification for coronary dissections. DCB = drug-coated balloon; NHLBI = National Heart, Lung, and Blood Institute.

FIGURE 1 MLD Before DCB PCI, After DCB PCI, and at Angiographic Follow-Up in Patients Left With a Dissection



Notably, there was a diffuse lumen enlargement at angiographic control. DCB = drug-coated balloon; MLD = minimal lumen diameter; PCI = percutaneous coronary intervention.

Comparable event rates between the dissection / no dissection cohorts