Drug-eluting balloon: is it useful?

EAPCI
European Society of Cardiology

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Chair of EAPCI Gender & Disparities Committee

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1977

1. Balloon (PTCA):

Andreas Gruntzig performs the first PTCA in Zurich, Switzerland

1988

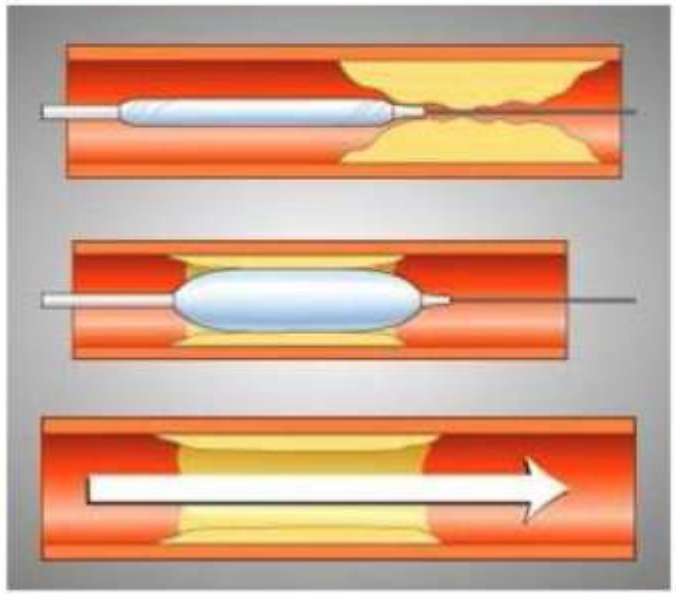
2. Bare Metal Stent (BMS):

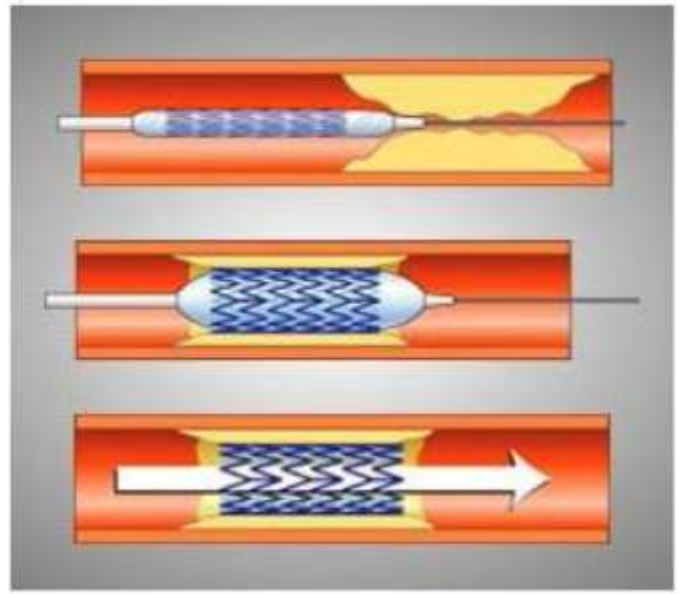
Julio Palmaz and Richard Schatz develop a stainless steel stent for coronary applications

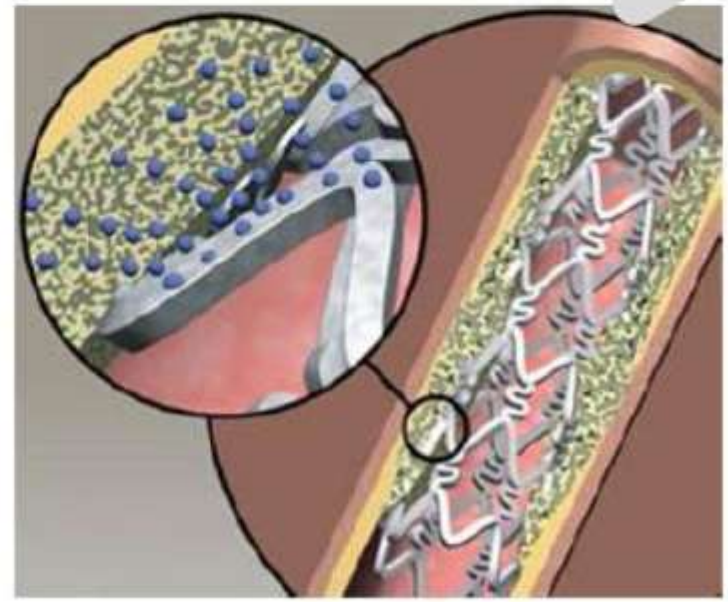
2002 - 2003

3. Drug-eluting stents (DES):

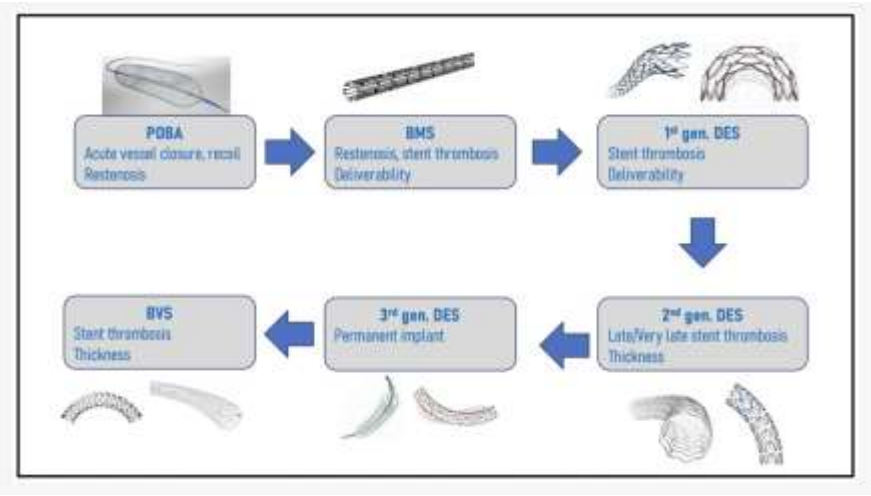
introduced to the European and U.S. markets



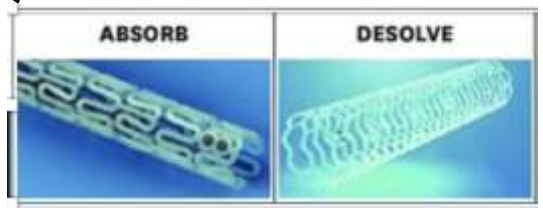


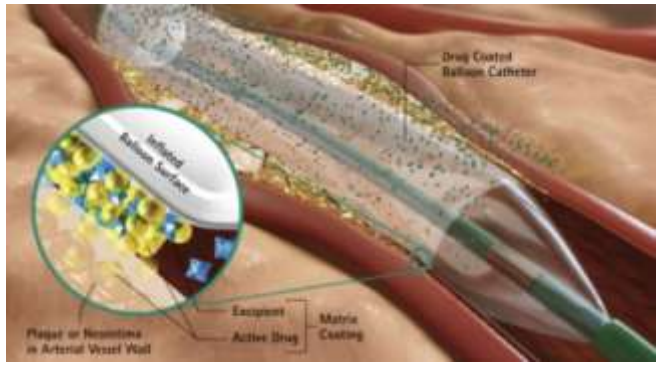


Concept of **“leave nothing behind”**



BVS



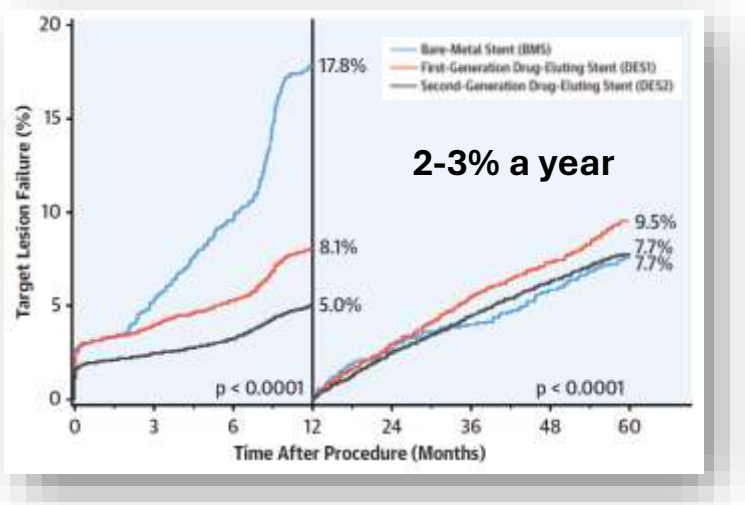


DCB

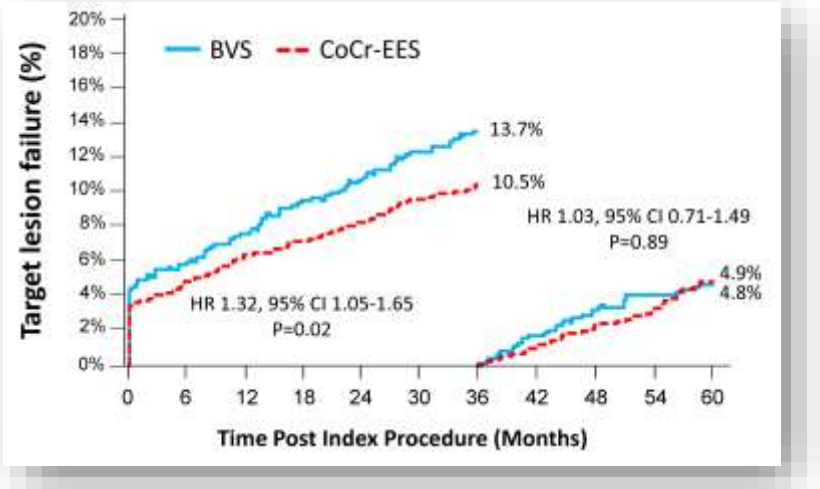
Jeger et al. JACC: CARDIOVASCULARINTERVENTIONS VOL.13, NO.12,2020

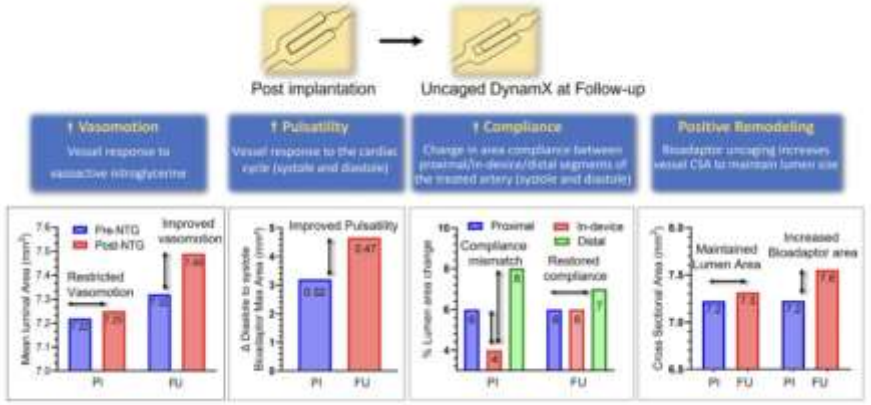
Concept of **“leave nothing behind”**

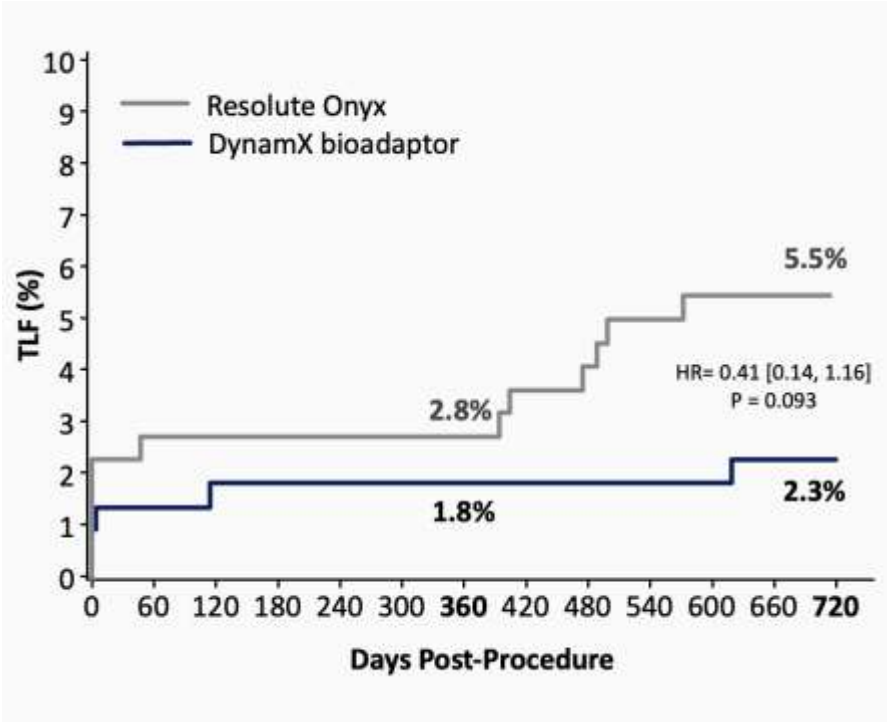
Stent related adverse events continue to accrue after the first year at a non-plateauing rate of 2-3% a year, with no difference between 2nd generation DES, 1st generation DES and BMS[1].



“Leave nothing behind” concept of Bioresorbable Scaffolds failed at improving short or long-term outcomes compared to DES, driven by poor acute performance and loss of long-term vessel dynamic support following scaffold resorption[2].



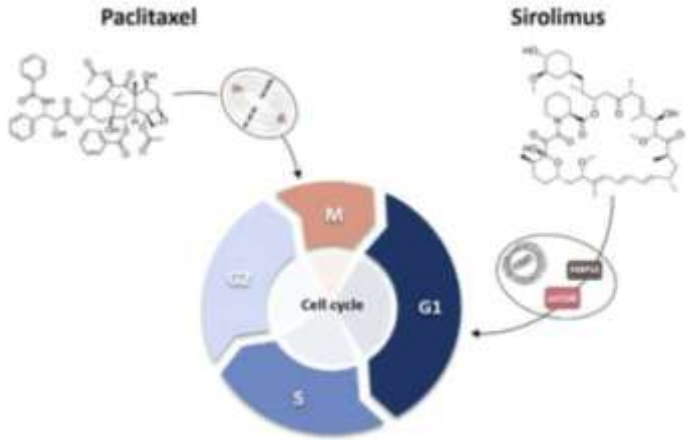




1. Madhavan MV et al. J Am Coll Cardiol 2020;75:590-604
2. Stone GW et al. Five-Year Clinical Outcomes After Coronary Bioresorbable Scaffolds and Drug-Eluting Stents: The ABSORB IV Randomized Trial. J Am Coll Cardiol 2023
3. Saito S et al. 12-Months Outcomes BIODAPTOR-RCT. The Lancet eClinicalMedicine. 2023;65:102304.
4. Saito S. BIOADAPTOR-RCT 24-month Clinical Outcomes. EuroPCR 2024

Drug-coalted balloon

Drug-eluting balloon: is it useful?



Pharmacodynamics	Cytotoxic	Cytostatic
Inhibition of cell proliferation	↑↑	↑
Pharmacokinetics	High lipophilicity Fast uptake and longer tissue retention	Low lipophilicity Requires encapsulation into nanocarriers
Efficacy	Smaller LLL and more frequent LLE in de novo CAD (positive remodelling phenomenon) Similar clinical outcomes in de novo CAD (underpowered comparative studies)	Comparable angiographic and clinical results for the treatment of DES-related ISR
Safety	Potential arterial and downstream tissue injury due to narrower therapeutic range Theoretical concern for distal embolization and systemic toxicity	Wider safety therapeutic range

Sirolimus

- Cytostatic
- Wide therapeutic range
- Slow tissue absorption
- Short tissue retention
- Effective during hypoxia

Paclitaxel

- Cytostatic
- Narrow therapeutic range
- Fast tissue absorption
- Long tissue retention
- Effective in normoxic conditions

Cardiology Journal 2025, Vol. 32, No. 3, 308–320
Future Pharmacol. **2024**, *4*(4), 775-787

Drug-eluting balloon: is it useful?

Follow-up rate: 94% (47/50 Lesions, PEB group: 23, BA group: 24)

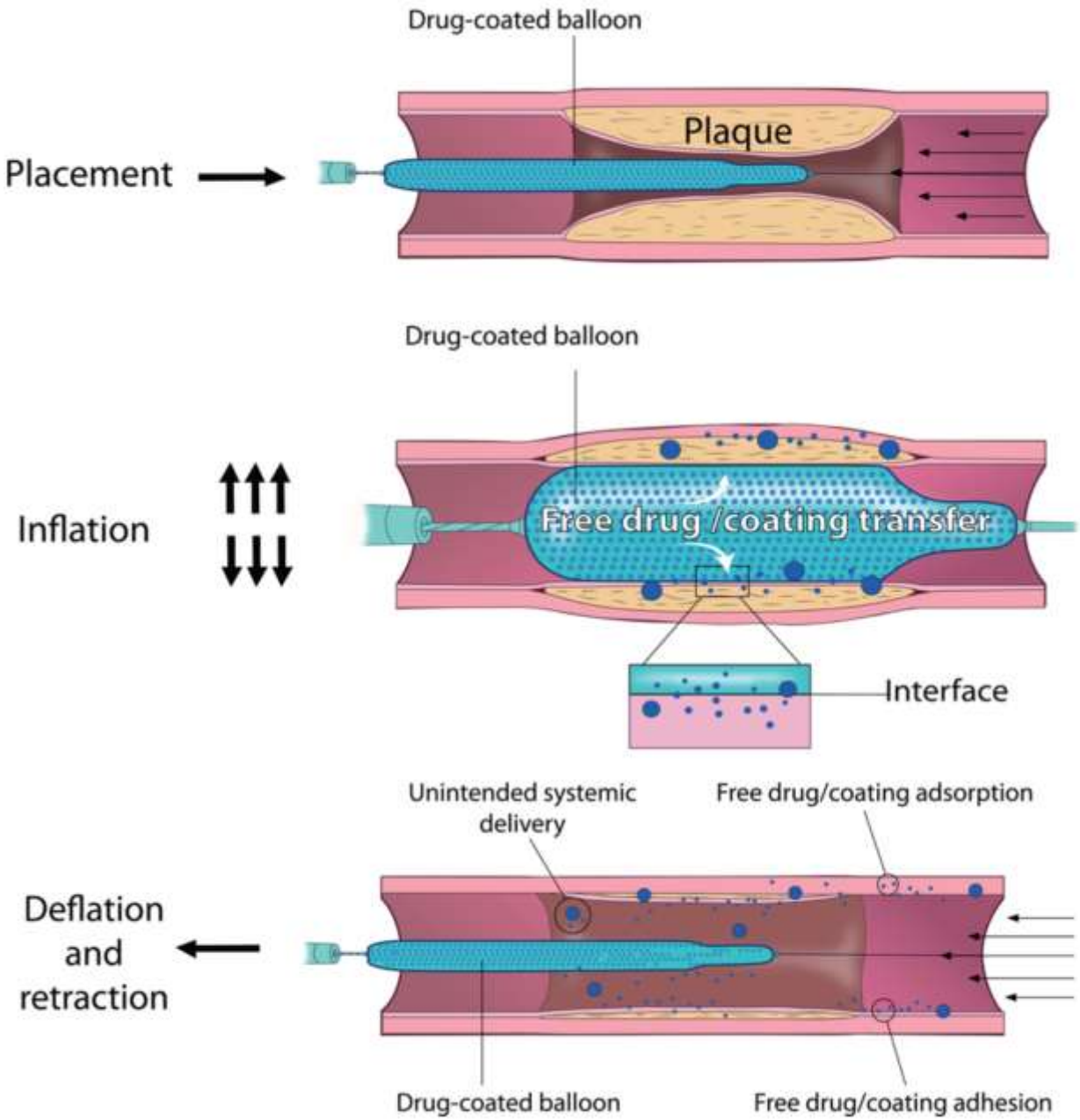
	Paclitaxel-Eluting Balloon	Conventional Balloon Angioplasty	
Late luminal loss (in-lesion)	0.17 ± 0.45	0.72 ± 0.56	0.001
Late luminal loss (in-segment)	0.18 ± 0.45	0.72 ± 0.55	0.001
Binary restenosis	2 (8.7)	15 (62.5)	0.0001
Target lesion revascularization)	1 (4.3)	10 (41.7)	0.003

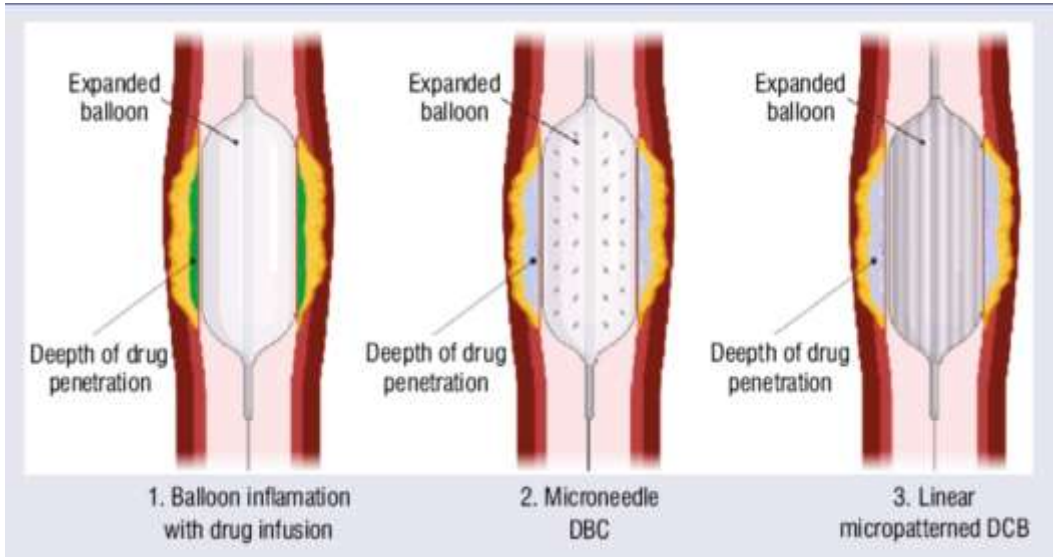
Without Drug Coating

With Drug Coating

JACC: Cardiovascular Interventions , 2011; 4: 149-54

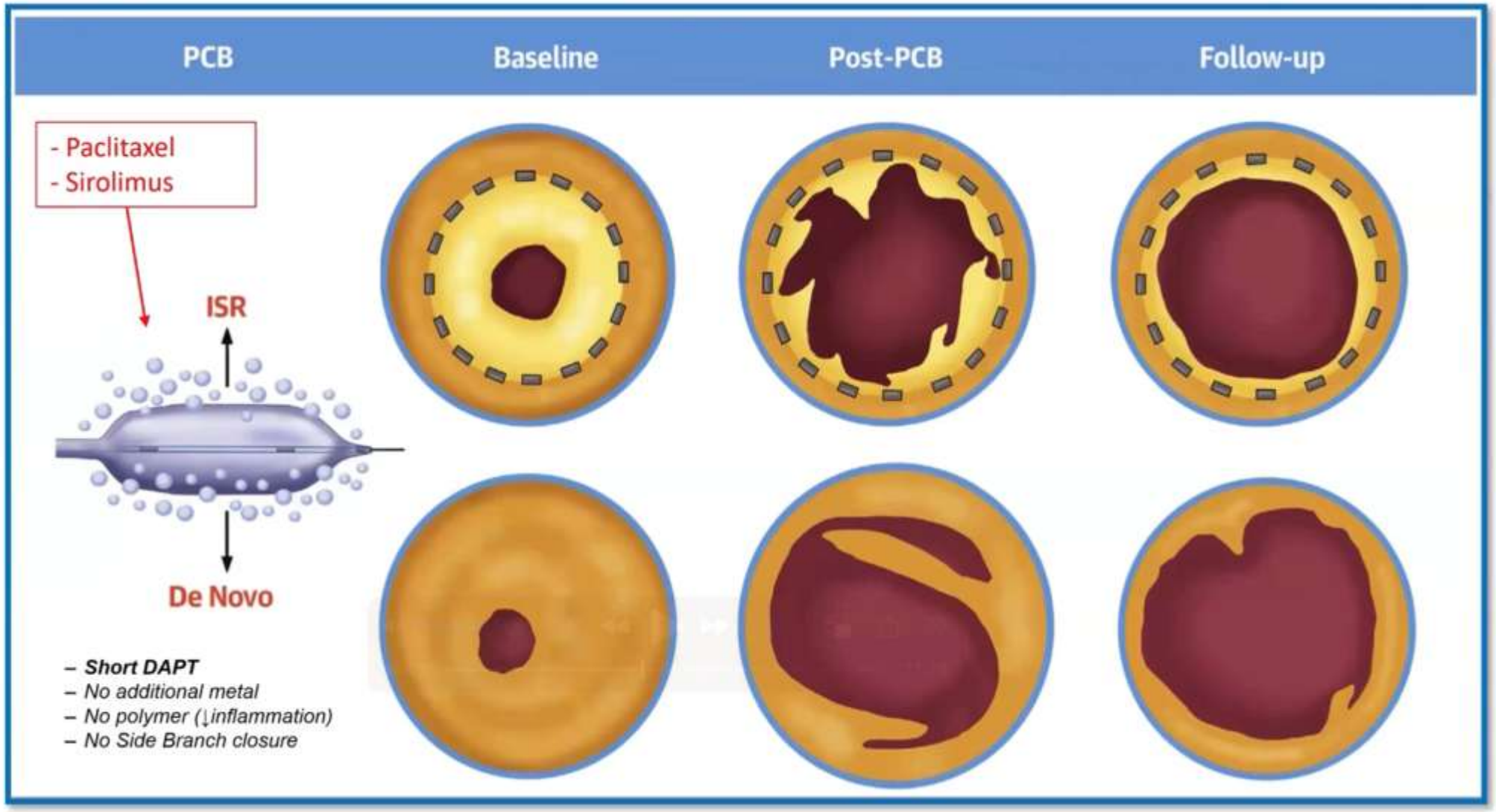
Drug-eluting balloon: is it useful?





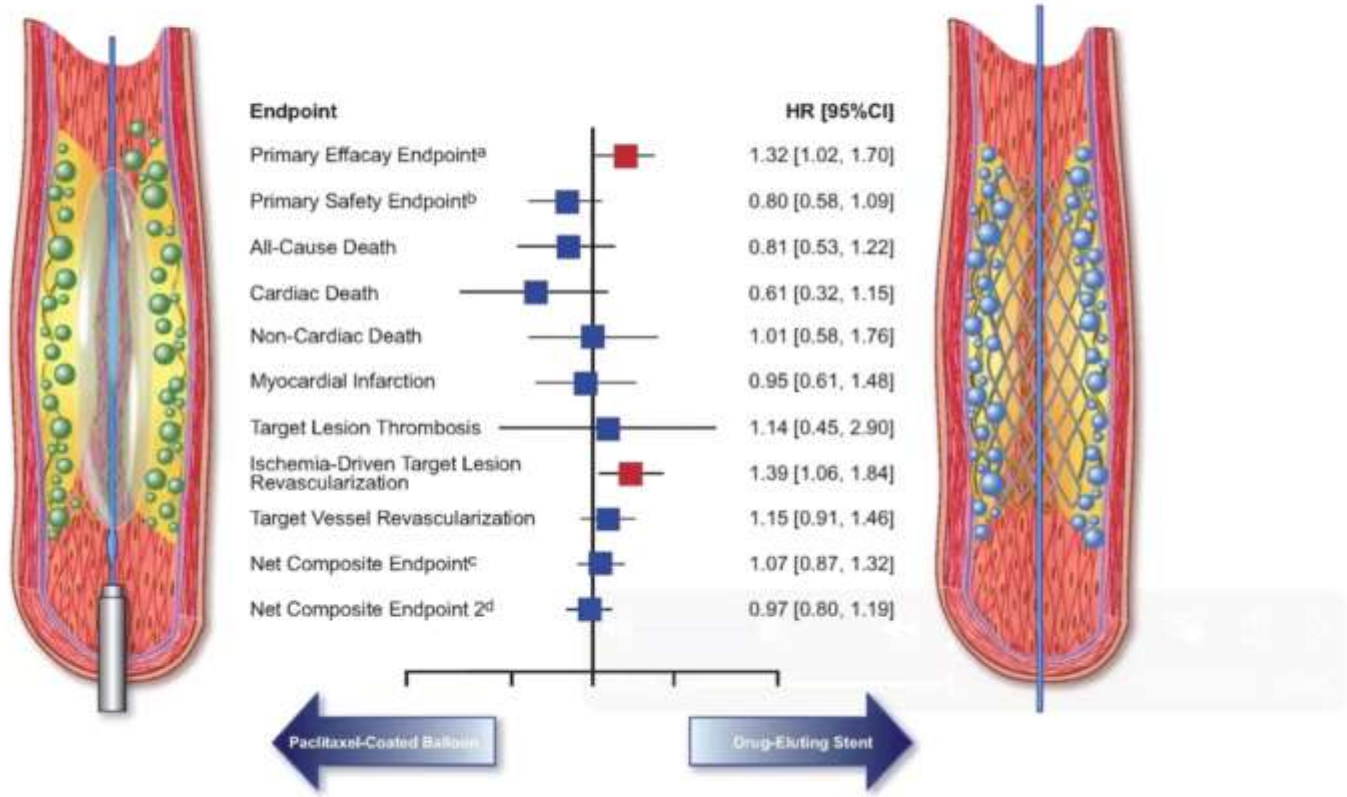
Bioeng Transl Med. 2023;8:e10370
Cardiology Journal2025, Vol. 32, No. 3, 308–320

Drug-eluting balloon: is it useful?

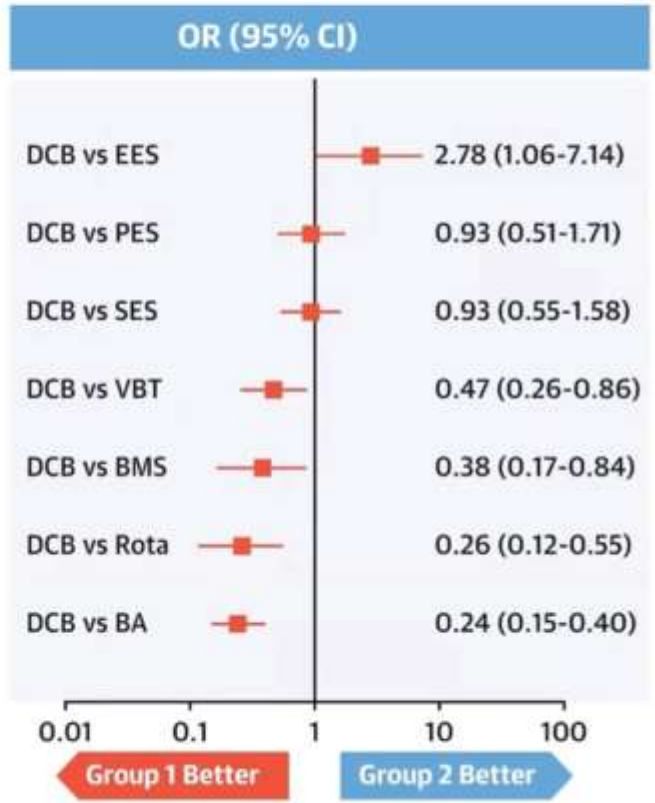


Drug-eluting balloon: is it useful?
DCB „in-stent restenosis”

DEDALUS IPD meta-analysis (N= 1,976 patients)
Paclitaxel-coated balloon vs. DES for coronary ISR



Network meta-analysis (N=5,923 patients)
DCB vs. other treatment options for ISR

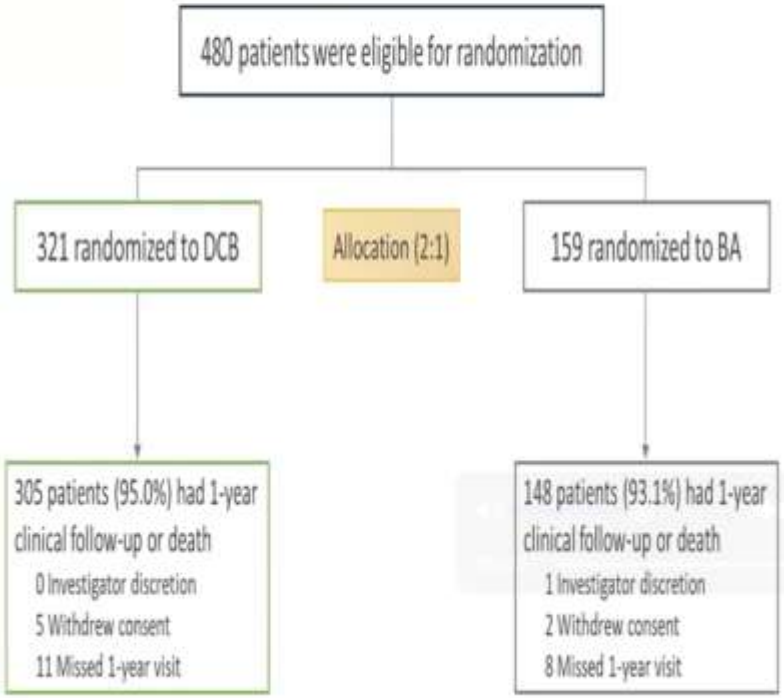


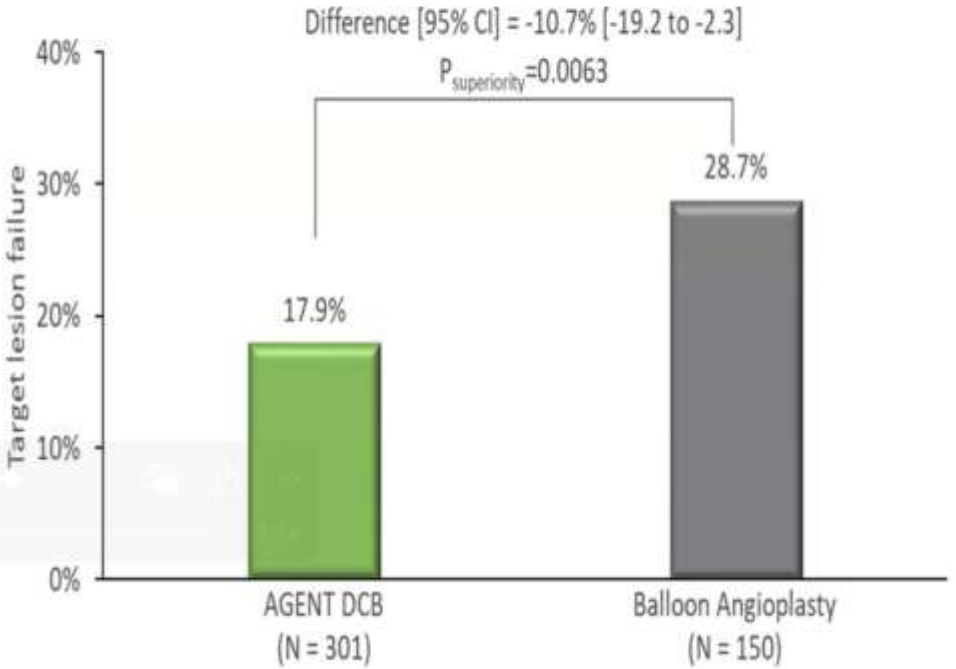
DCB **non-inferior to DES** for clinical outcomes in ISR

Giacoppo D. et al, EHJ 2020; Siontis GMS et al, Lancet 2015

AGENT IDE Trial

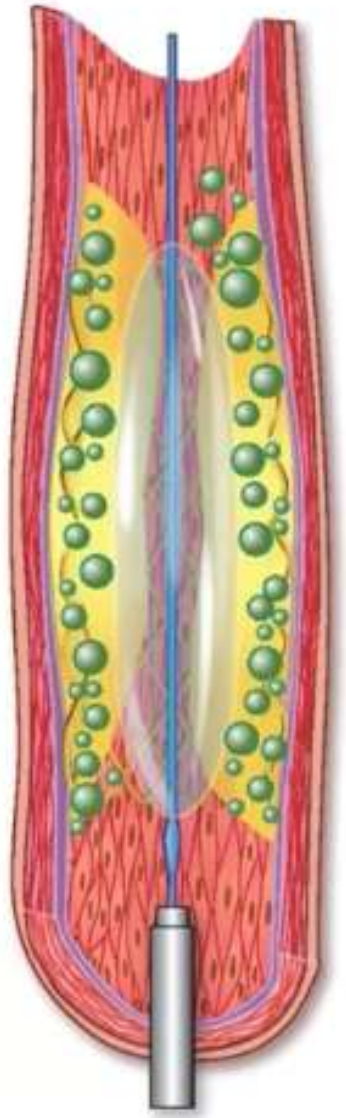
First randomized controlled trial comparing a DCB (Agent Paclitaxel-coated Balloon, Boston Scientific) vs. Balloon Angioplasty for the treatment of in-stent restenosis in the United States





Yeh R. et al, JAMA. 2024;331(12):1015-1024

Drug-eluting balloon: is it useful?
DCB - in-stent restenosis

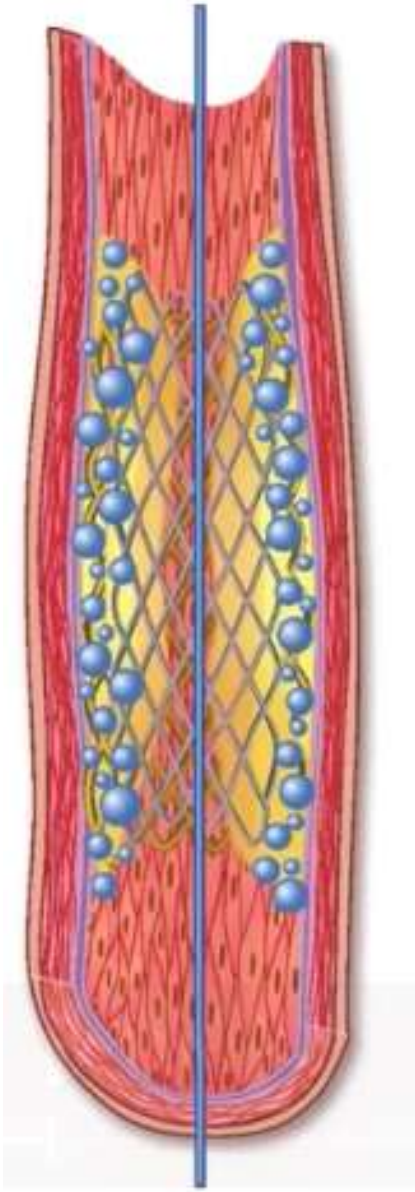


DCB preferred

- Focal ISR
- First ISR
- ISR of BMS
- Multiple metal layers

DES preferred

- Suboptimal predilatation result
- Diffuse ISR
- Loss of mechnical integrity
- Failed DCB strategy



Drug-eluting balloon: is it useful?
DCB - in-stent restenosis

ESC European Society of Cardiology
European Heart Journal (2024) **45**, 3415–3537
https://doi.org/10.1093/eurheartj/ehae177

ESC GUIDELINES

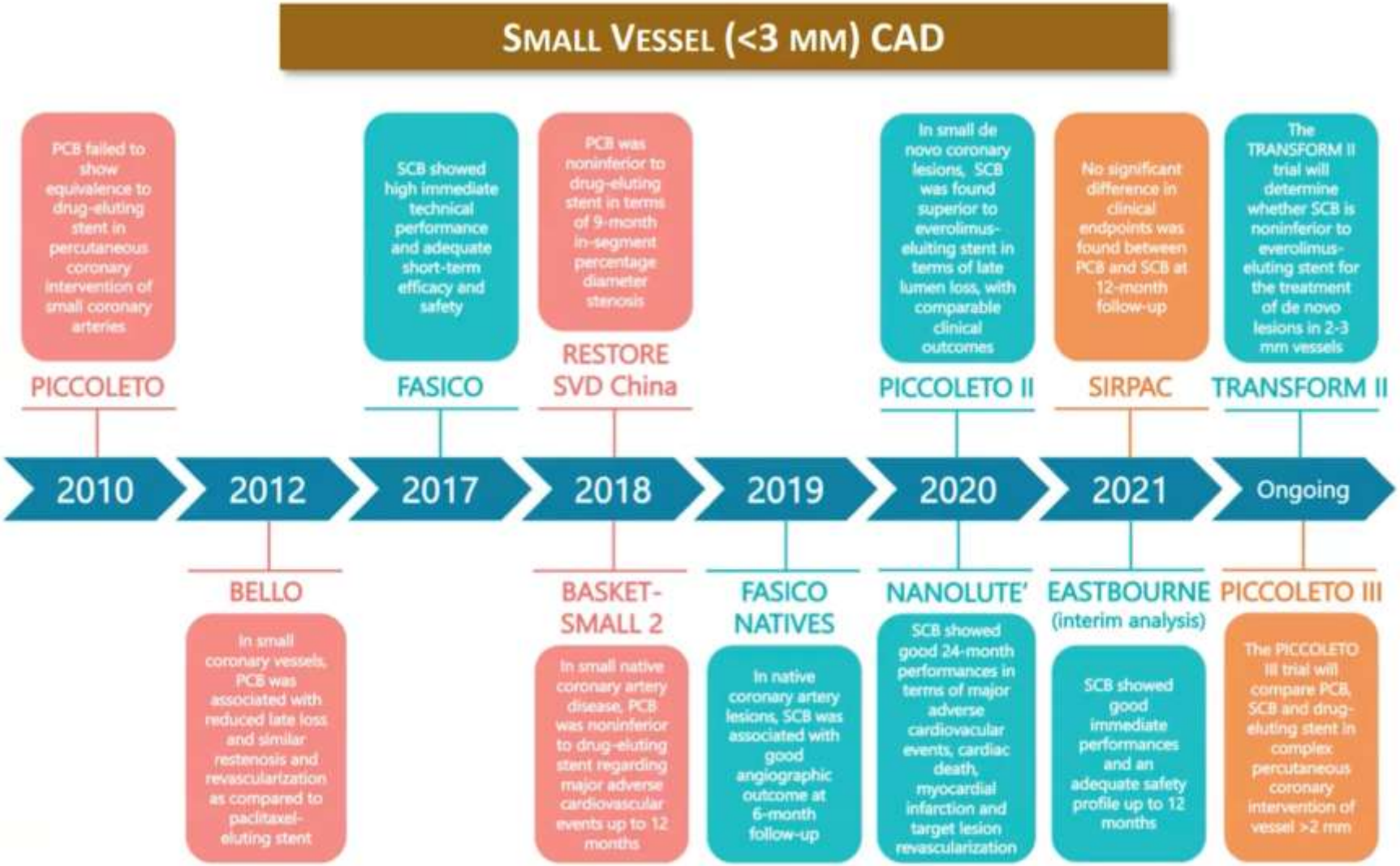
2024 ESC Guidelines for the management of chronic coronary syndromes

Developed by the task force for the management of chronic coronary syndromes of the European Society of Cardiology (ESC)

Endorsed by the European Association for Cardio-Thoracic Surgery (EACTS)

DES is recommended over drug-coated balloons for treatment of in-DES restenosis.[1186–1188]	I	A

Drug-eluting balloon: is it useful?
DCB - *de novo* lesions



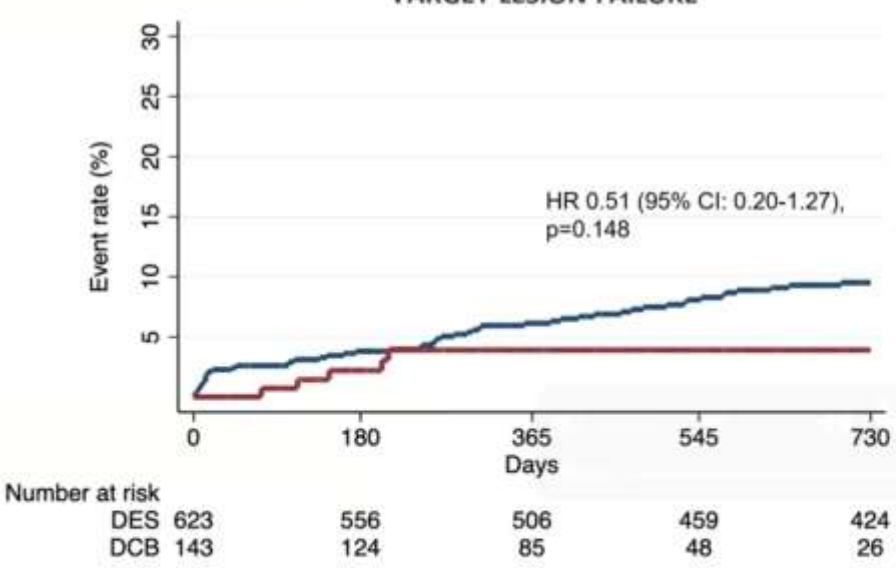
Greco A. et al, Catheter Cardiovasc Interv. 2022 Oct;100(4):544-552

Drug-eluting balloon: is it useful?
DCB - *de novo* lesions → diffuse CAD

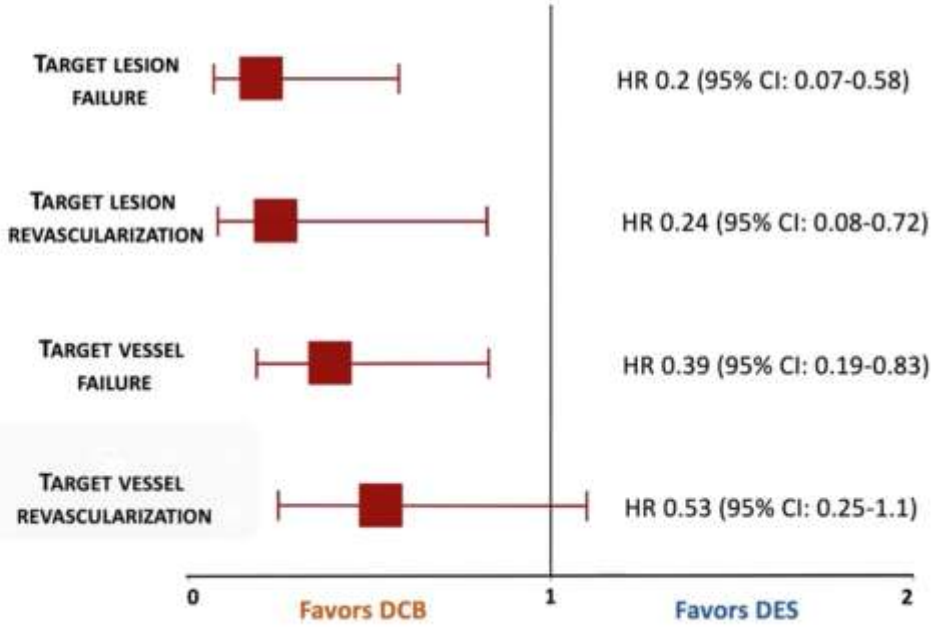
Propensity score matched comparison (N=848 pts)
DCB-based PCI (N=147 pts) vs. DES-only PCI (N=701 pts) for long *de novo* LAD lesions

- 43 patients (29.2%) DCB only
- 104 (70.8%) DCB+DES

Similar TLF rate in the overall cohort



Lower risk of TLF, TLR and TVF with DCB after propensity score matching



Gitto M., Colombo A. et al, Circ Cardiovasc Interv. 2023 Dec;16(12):e013232

Total treated length was higher in the DCB group (65 [40-82] versus 56 [46-66] mm; *P*=0.002)

Conclusions: A DCB-based treatment approach for left anterior descending revascularization allows a significantly reduced stent burden, thereby potentially limiting target lesion failure risk at midterm follow-up

Drug-eluting balloon: is it useful?
DCB - *de novo* lesions → all types

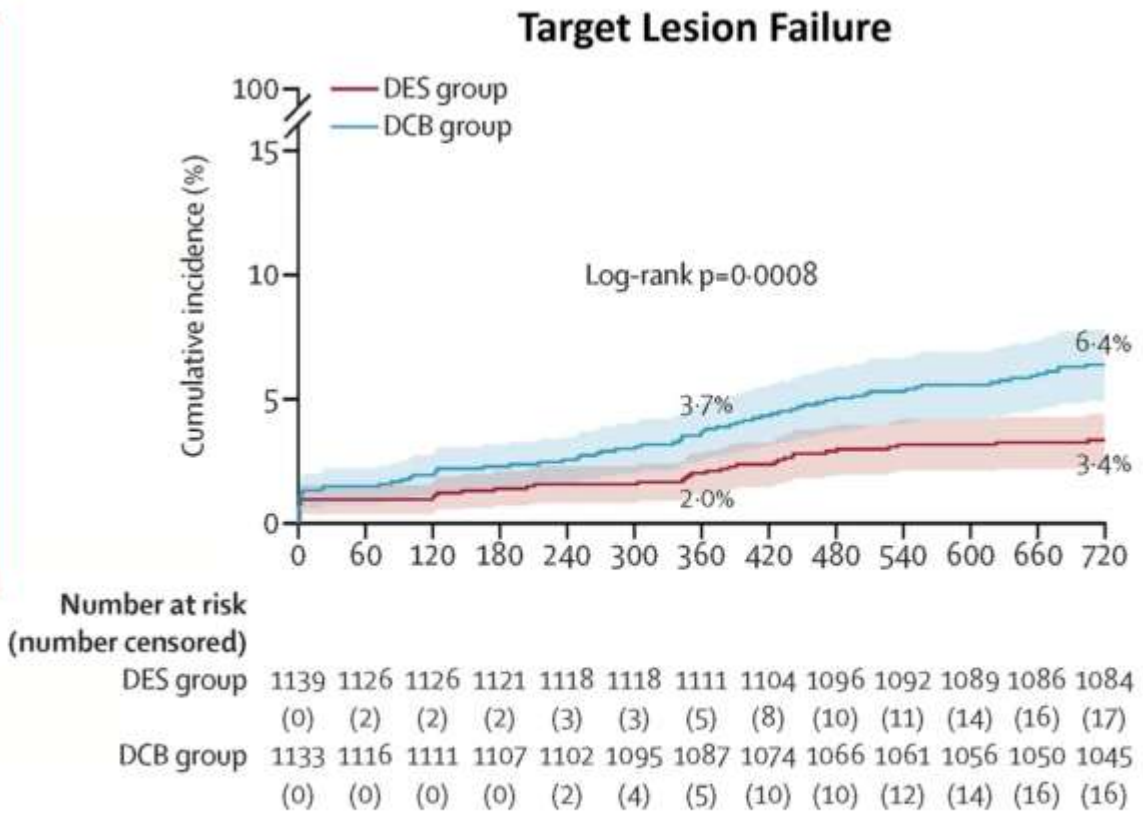
DCB vs DES w zmianach *de novo*
REC-CAGEFREE Trial

Device oriented composite endpoint (DoCE): cardiovascular death, target vessel myocardial infarction, and clinically and physiologically indicated target lesion revascularisation → assessed at 24 months

N=2,272 patients undergoing non-complex PCI in China

- **Inclusion criteria**: de novo, non-complex target lesions
- **Exclusion criteria**
  - 3-vessel disease
  - total device length >60 mm
  - true bifurcations
  - left main disease
  - CTO
  - calcific lesions requiring atherectomy

Lesion types at higher risk of stent failure (long lesions, calcific lesions, CTO, bifurcations) have been excluded from this trial!!



Gao PC et al, Lancet. 2024 Sep 14;404(10457):1040-1050

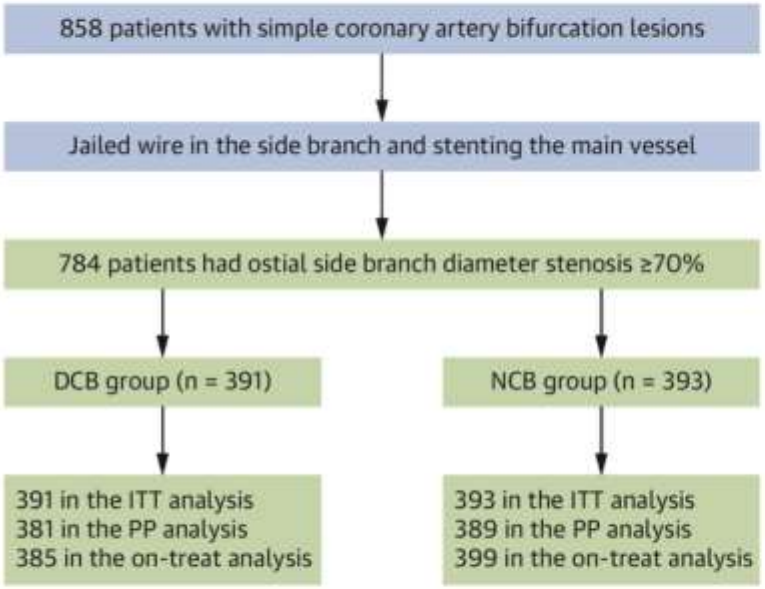
Interpretation
In patients with de novo, non-complex coronary artery disease, irrespective of vessel diameter, a strategy of DCB angioplasty with rescue stenting did not achieve non-inferiority compared with the intended DES implantation in terms of the DoCE at 2 years, which indicates that DES should remain the preferred treatment for this patient population

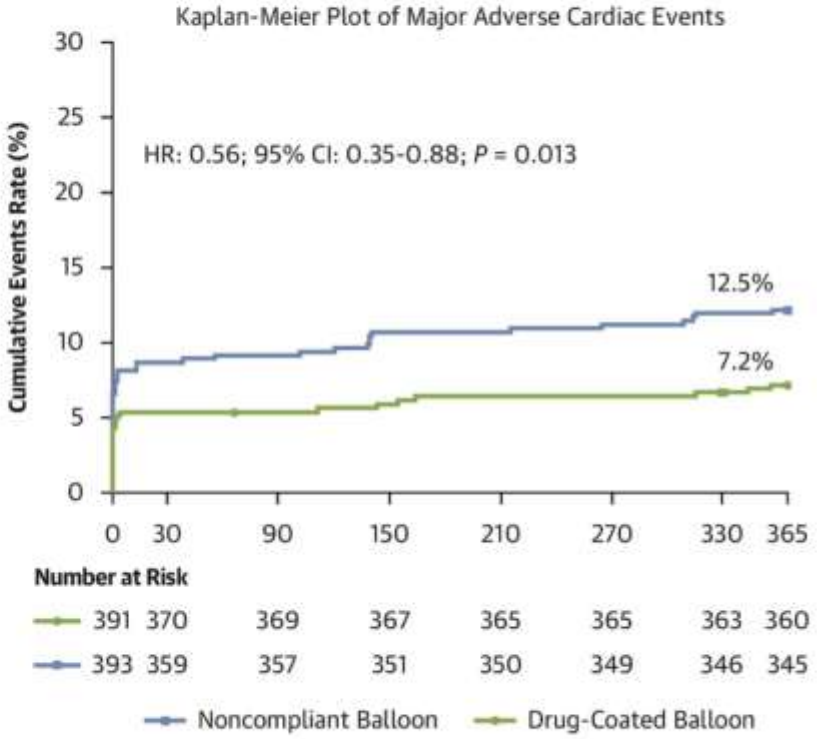
Drug-eluting balloon: is it useful?
DCB - bifurcations

Key results from the DCB-BIF Trial

Key question: A second side branch stent is commonly required during provisional stenting procedures, which leads to high rates of restenosis, stent thrombosis, and revascularization.

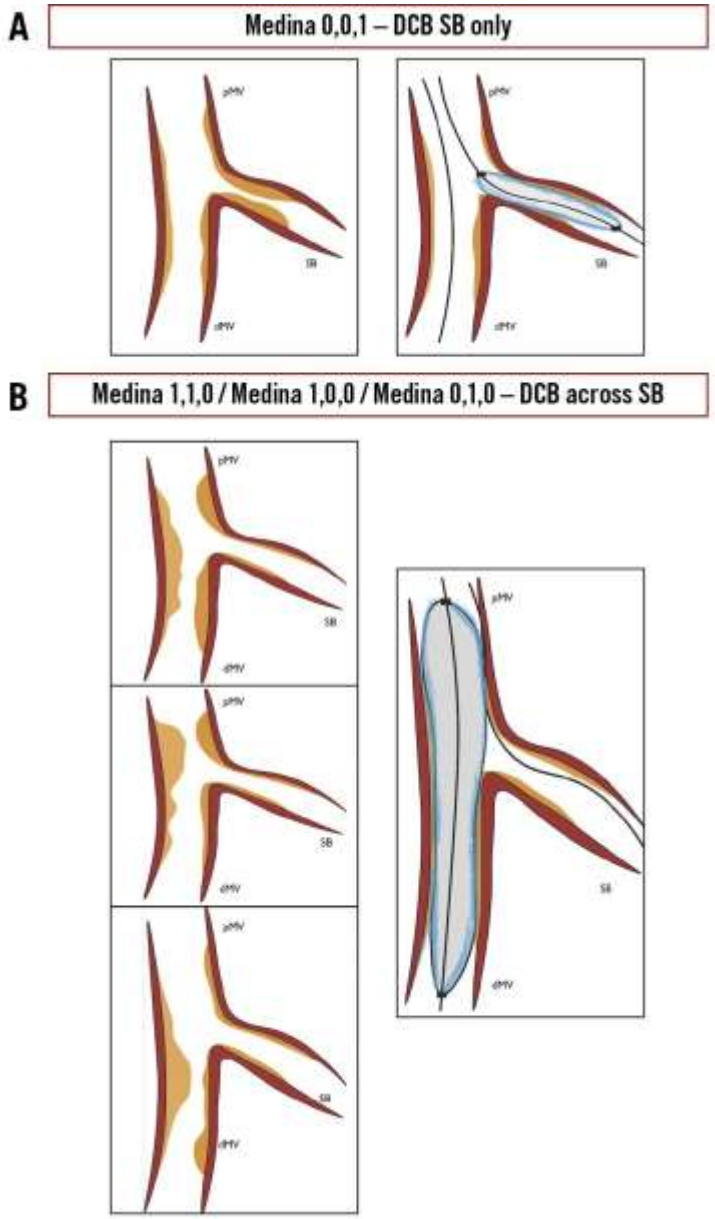
Key finding: Stenting the main vessel using a drug-eluting stent and side branch intervention using a drug-coated balloon is associated with a significant reduction in major adverse cardiac event.





Gao X, et al. JACC. 2025;85(1):1-15.

Drug-eluting balloon: is it useful?
DCB - bifurcations



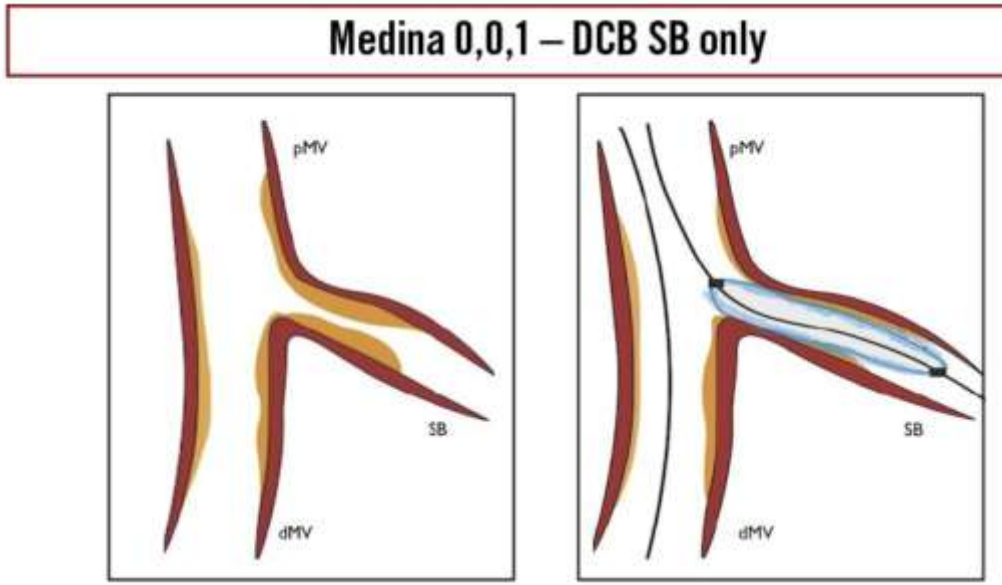
EuroIntervention
2025;21:e1179-e1199
published online ahead of print October 2025
DOI: 10.4244/EIJ-D-25-00201

EXPERT REVIEW

Drug-coated balloons for coronary bifurcation lesions

Simone Fezzi[1], MD, MSc; Bruno Scheller[2], MD, PhD; Tuomas T. Rissanen[3], MD, PhD; Renata Malivojevic[4], MD; Domenico Tavella[5], MD; Mattia Lunardi[6], MD, MSc, PhD; Bernardo Cortese[7,8*], MD, PhD; Adrian Banning[9], MD, PhD; Gabriele Pesarini[1], MD, PhD; Flavio Ribichini[1], MD; Roberto Scarsini[1*], MD, PhD

Coronary bifurcation treatment with DCB only



DCB in the SB only is the preferred strategy in an isolated SB stenosis (Medina 0,0,1). Following MV and SB wiring and adequate lesion preparation (scoring and cutting balloons preferred), DCB inflation is applied specifically to the SB, **extending the DCB 2 mm into the MV** to ensure proper drug concentration in the ostium

EuroIntervention 2025;21:e1179-e1199 published online ahead of print October 2025

Drug-eluting balloon: is it useful?
DCB - bifurcations

EXPERT REVIEW

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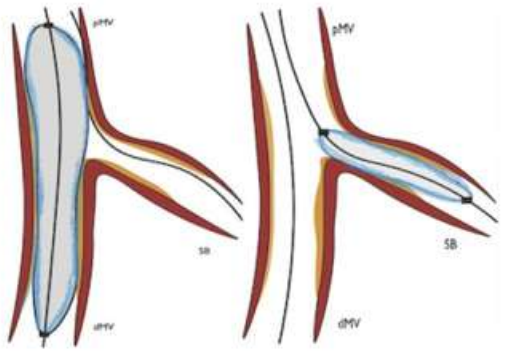
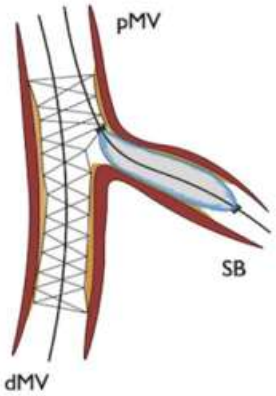
LEAVE NOTHING BEHIND



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



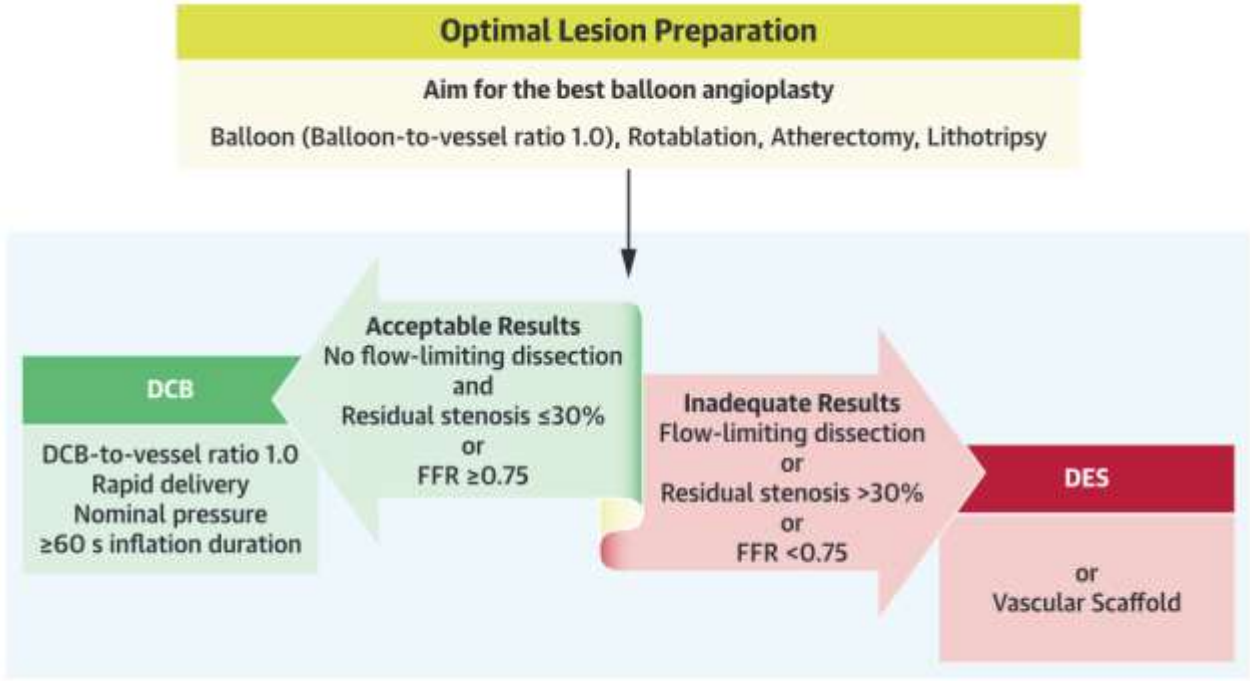
Advantages
- ↑ use of provisional vs 2-stent strategy
- ↓ stent burden
- Avoids issues related to polymer and strut crushing
- Allows SB late lumen enlargement

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

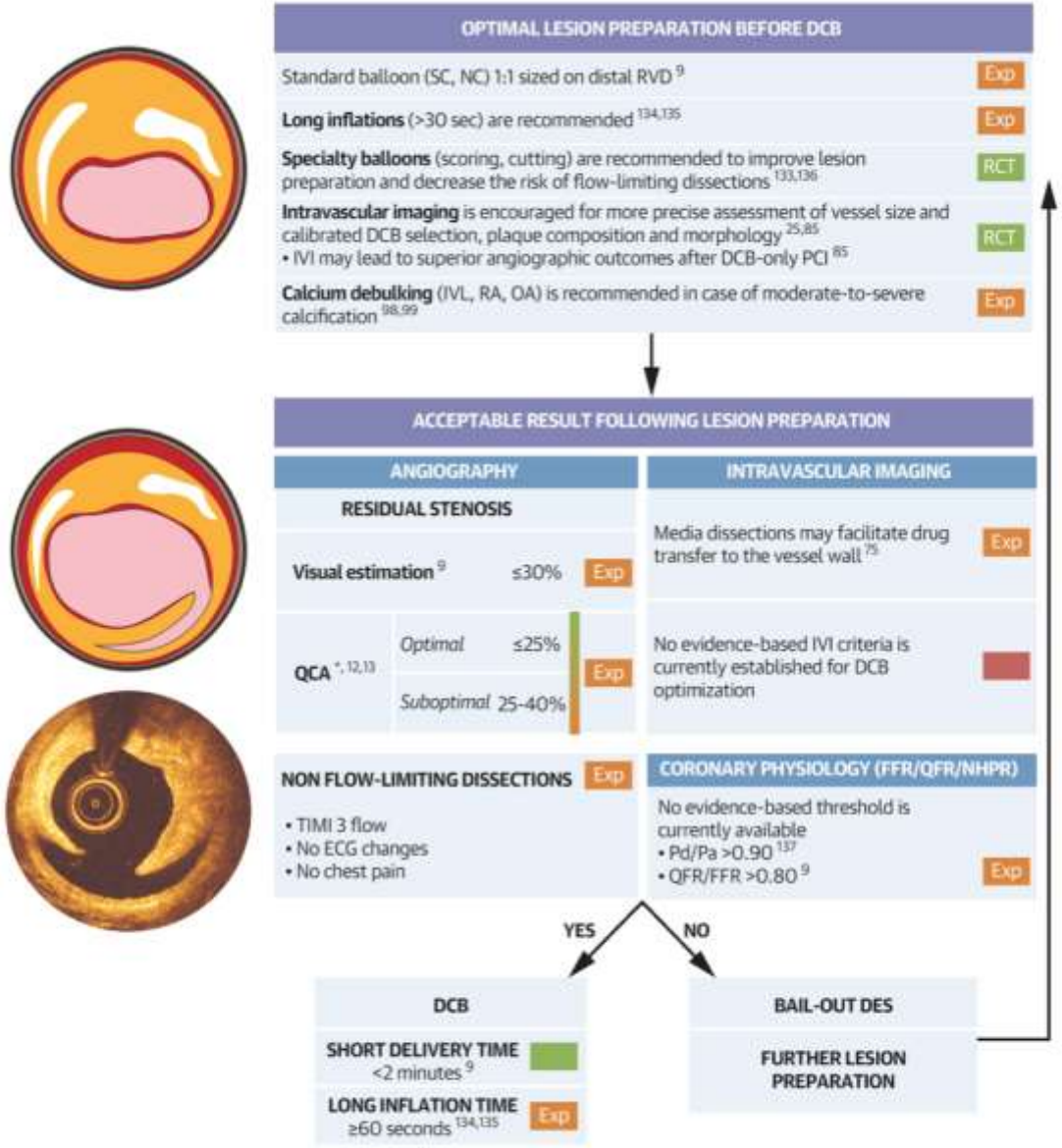
WHAT DO WE KNOW?
- DCB for SB treatment seems to be reasonable and supported by clinical and angiographic data and RCTs
- The use of PCB + BMS is inferior to new-generation DES
- The use of PCB + DES showed promising results in real-world registries
- "DCB-only strategy" is feasible and safe in case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

Drug-eluting balloon: is it useful?
Step-by-step approach for the DCB only strategy

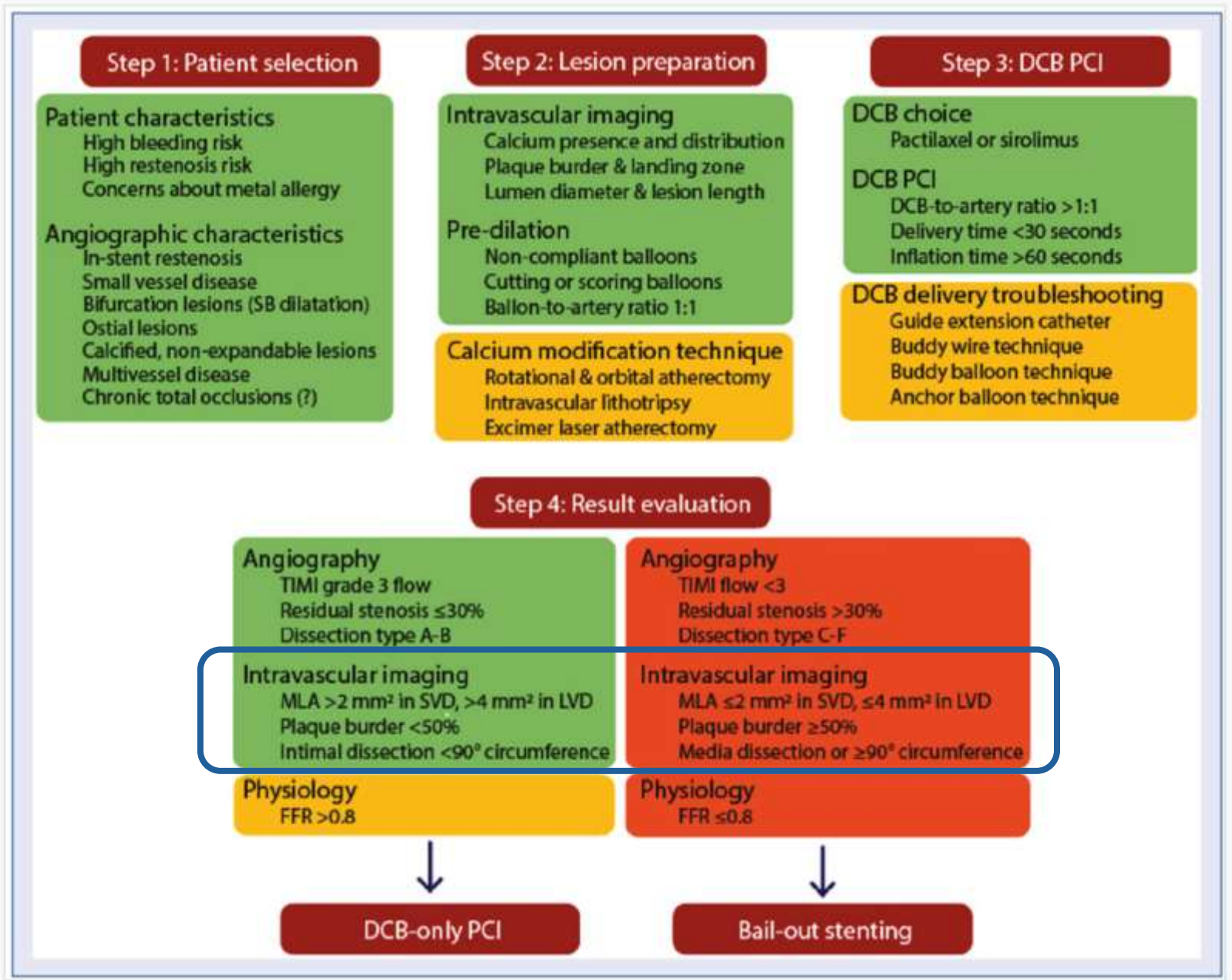


Her A-Y, et al. JACC Asia. 2025;5(6):701-717.



Fezzi S, et al. JACC. 2025;86(15):1170-1202.

Drug-eluting balloon: is it useful?
Step-by-step approach for the DCB only strategy



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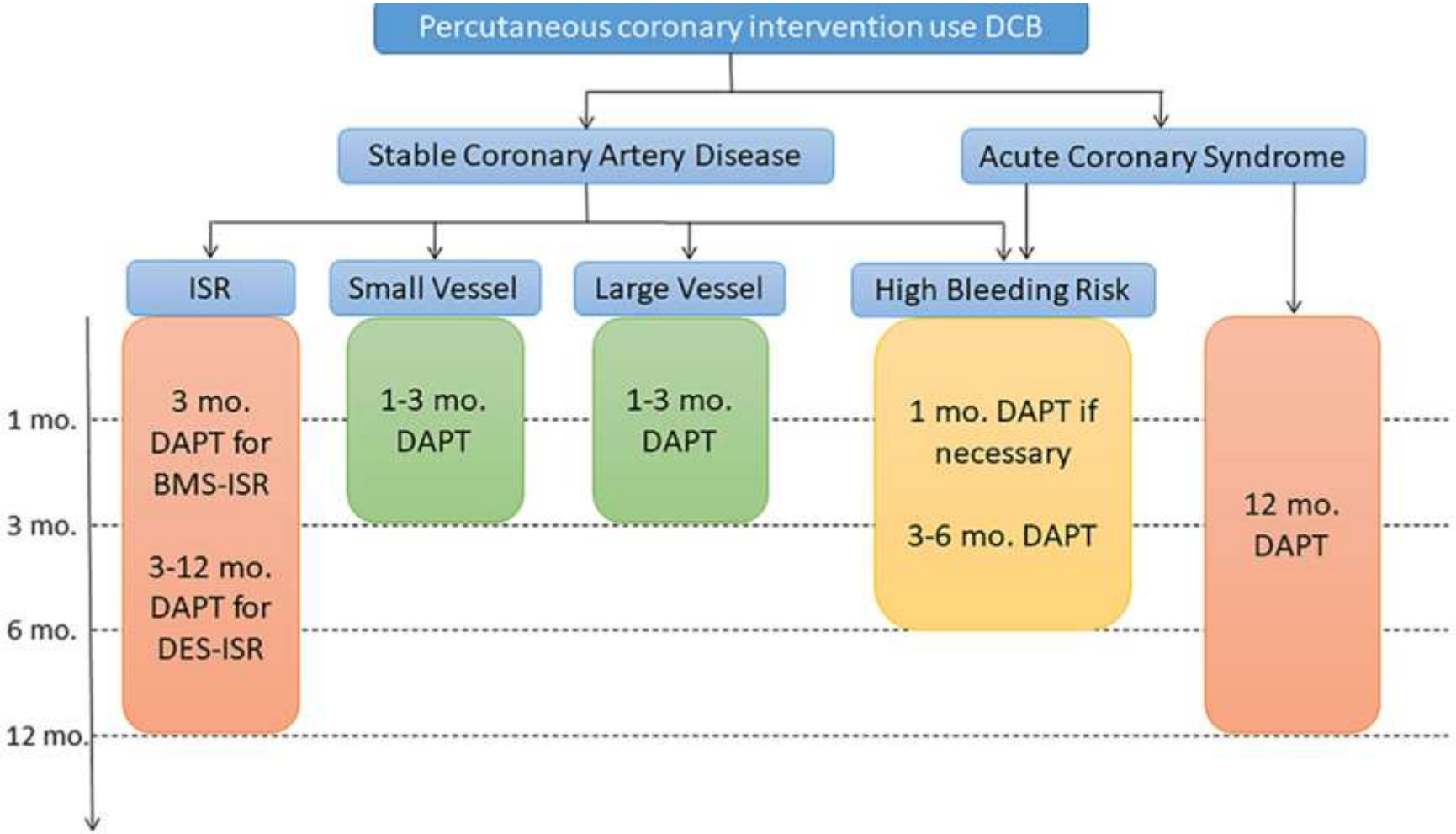
Drug-eluting balloon: is it useful?
HBR & Short DAPT Strategy

frontiers in Cardiovascular Medicine
REVIEW
published: 01 December 2021
doi: 10.3389/fcvm.2021.782391

Duration of Dual Antiplatelet Therapy After Implantation of Drug-Coated Balloon

Yuxuan Zhang†, Xinyi Zhang†, Qichao Dong†, Delong Chen†, Yi Xu‡ and Jun Jiang*



CASE: LM PCI only with kissing drug-coated balloons as a treatment strategy in young female with active systemic lupus erythematosus and cardiogenic shock after CABG

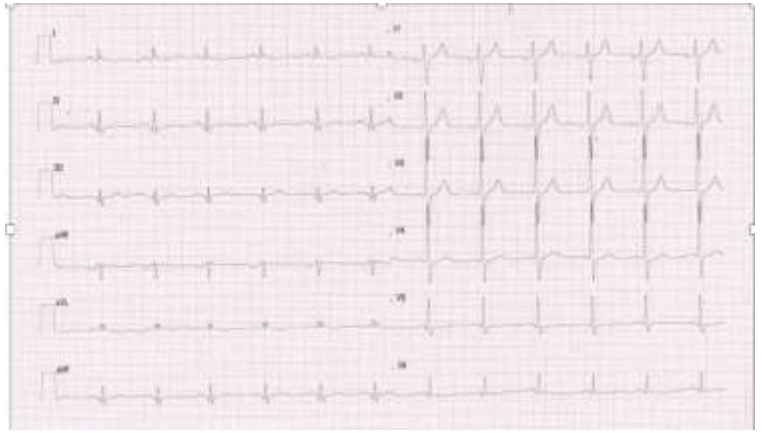
34-year-old female patient with unstable angina → planned CABG due to mulitivessel disease

Medical history:

- Systemic lupus erythematosus (SLE)
- Mixed hyperlipidemia,
- Stage 5 CKD requiring peritoneal dialysis
- HA

MIs:

- STEMI inferior + PCI RCA (2014, age 24 years)
- NSTEMI + PCI LAD (2019, age 29 years)
- NSTEMI + PCI OM (2020, age 30 years)



SR 75/min
Q wave in II, III, aVF

Preserved LVEF (50%)

CABG due to MVD → hemodynamic collapse

Baseline coronary angiography

CABG due to multivessel disease
- severe LM stenosis (75%)
- severe LAD med stenosis (85%)
- severe IM ostial stenosis (90%)
- severe OM-1 med stenosis (75%) – in-stent restenosis

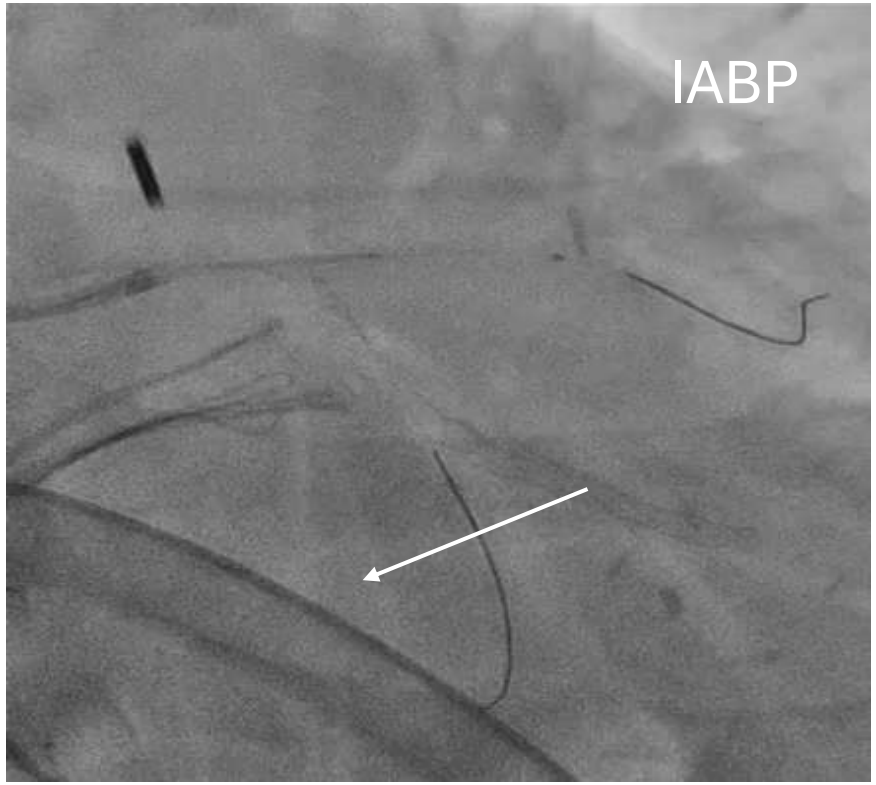
- Two SVBGs were performed: to LAD and to OM-1
- The procedure was complicated by dissection of the OM-1 requiring suturing, resulting in no-flow to the distal part of the artery

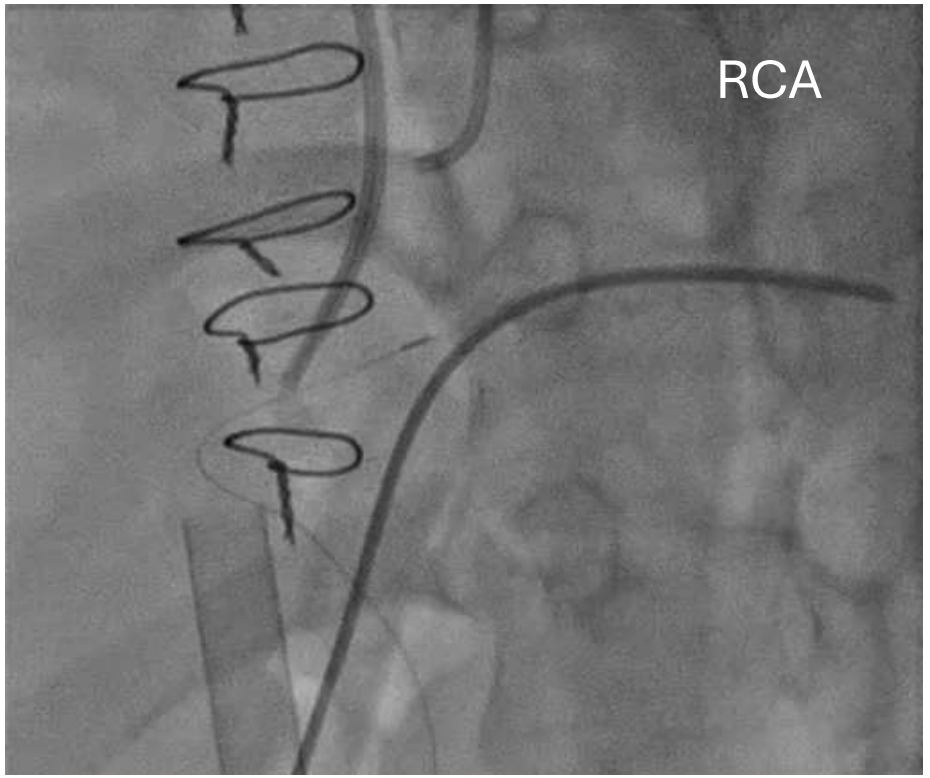
Hemodynamic collapse 2 days after CABG → IABP insertion → the next day upgrade to V-A ECMO

Additionally, a decompression of 300 ml of pericardial effusion was performed
High levels of hsTropI > 90.000 ug/L↑

CathLab

Coronary angiography via **left brachial access** – no other vascular access available (ultrasound guided);
6Fr sheat

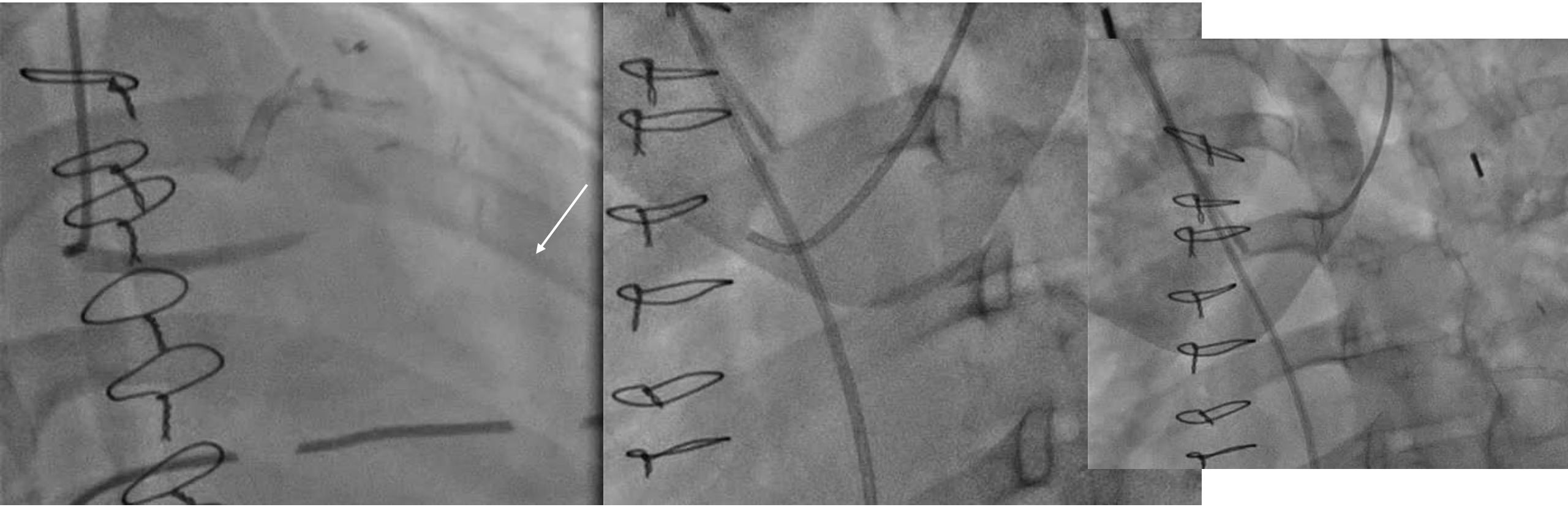




LCA

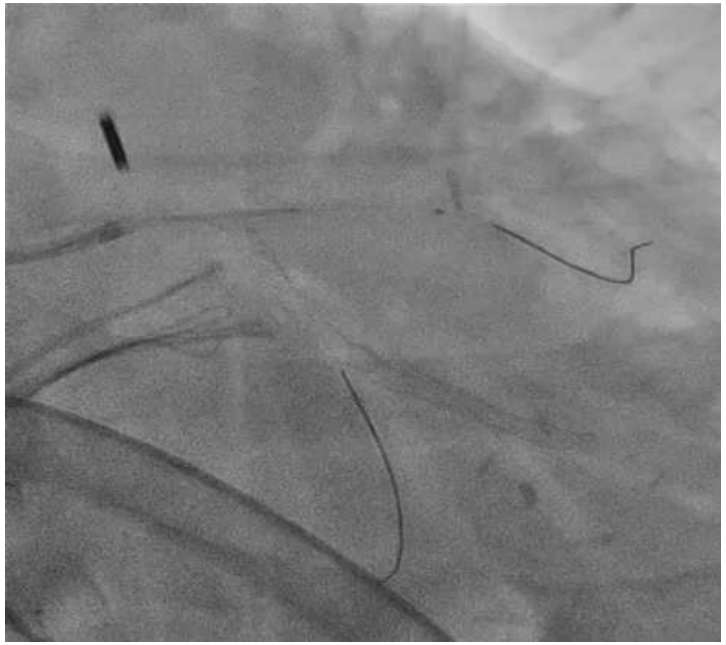
Severe stenosis of distal LM (75%) – white arrow
Sissection of OM-1 and its occlusion in the distal segment – yellow arrows

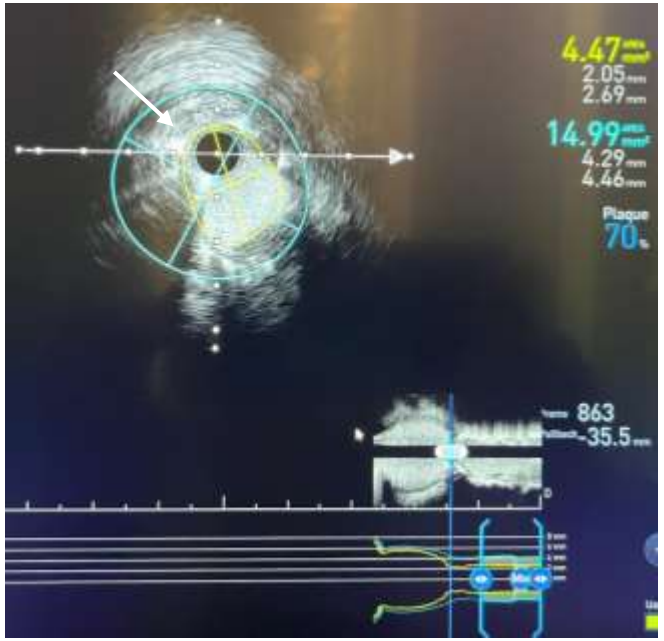
Grafts



SVBG to LAD - patent with significant difference in lumen diameter between graft and coronary artery
SVG to OM-1 - occluded

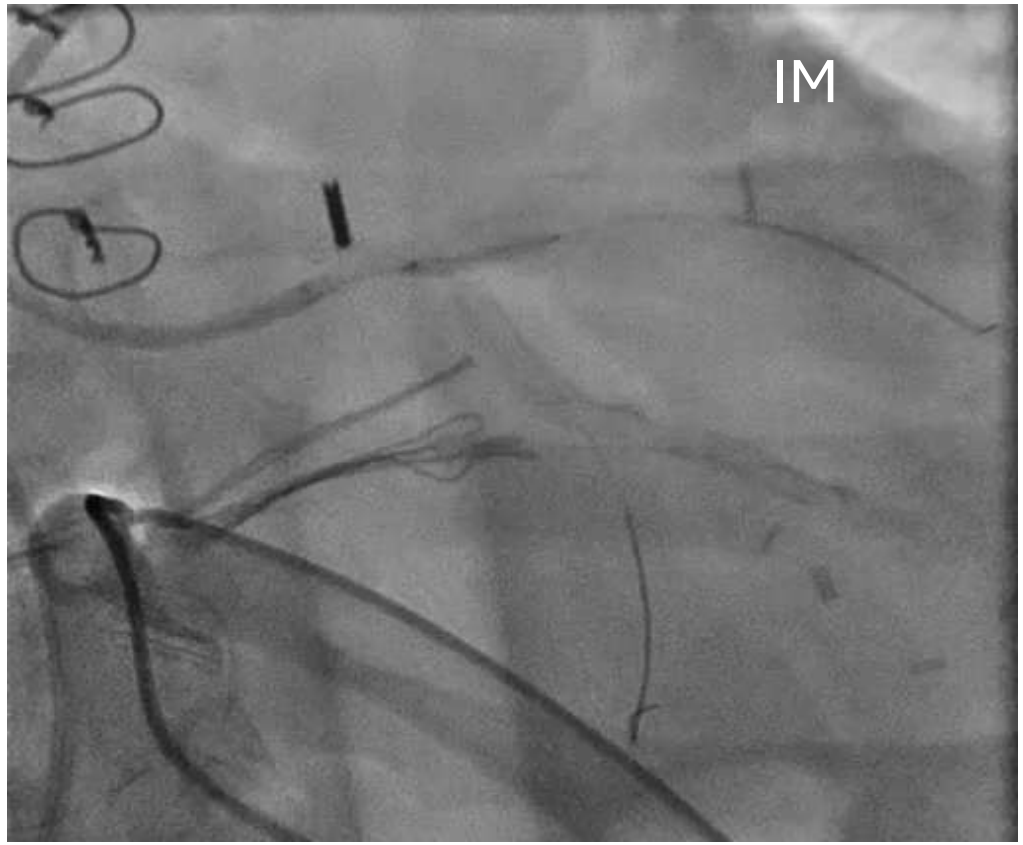
IVUS of LM



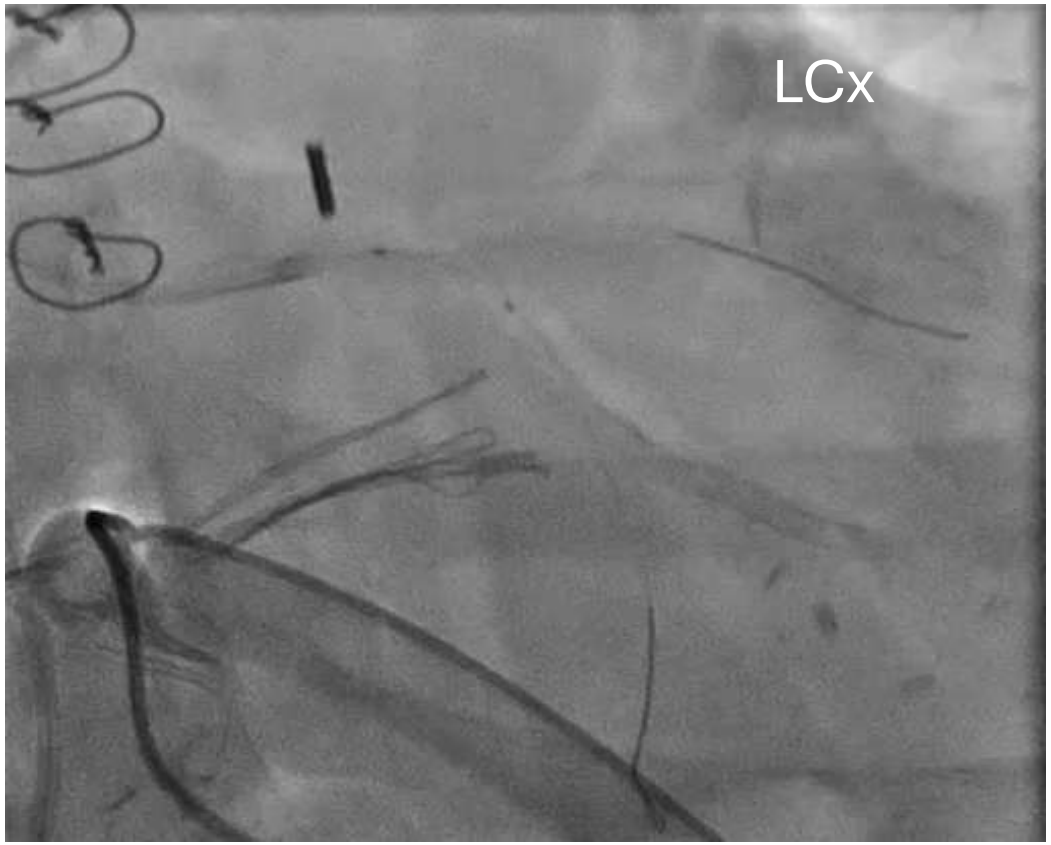


LM: IVUS imaging (Boston Scientific®) showing fibrous atherosclerotic plaque with significant luminal narrowing
→ MLA 4,47mm^2

Lesion preparation

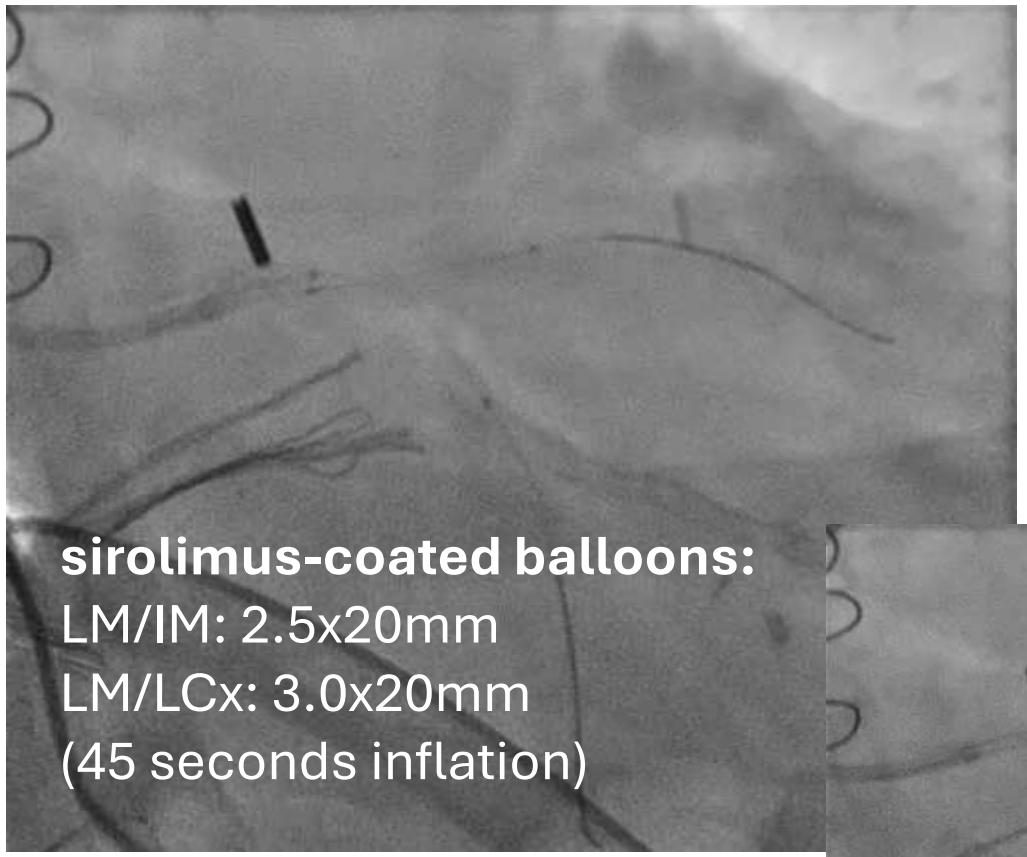


SC balloon: 2.0mm
NC balloon: 2.5mm

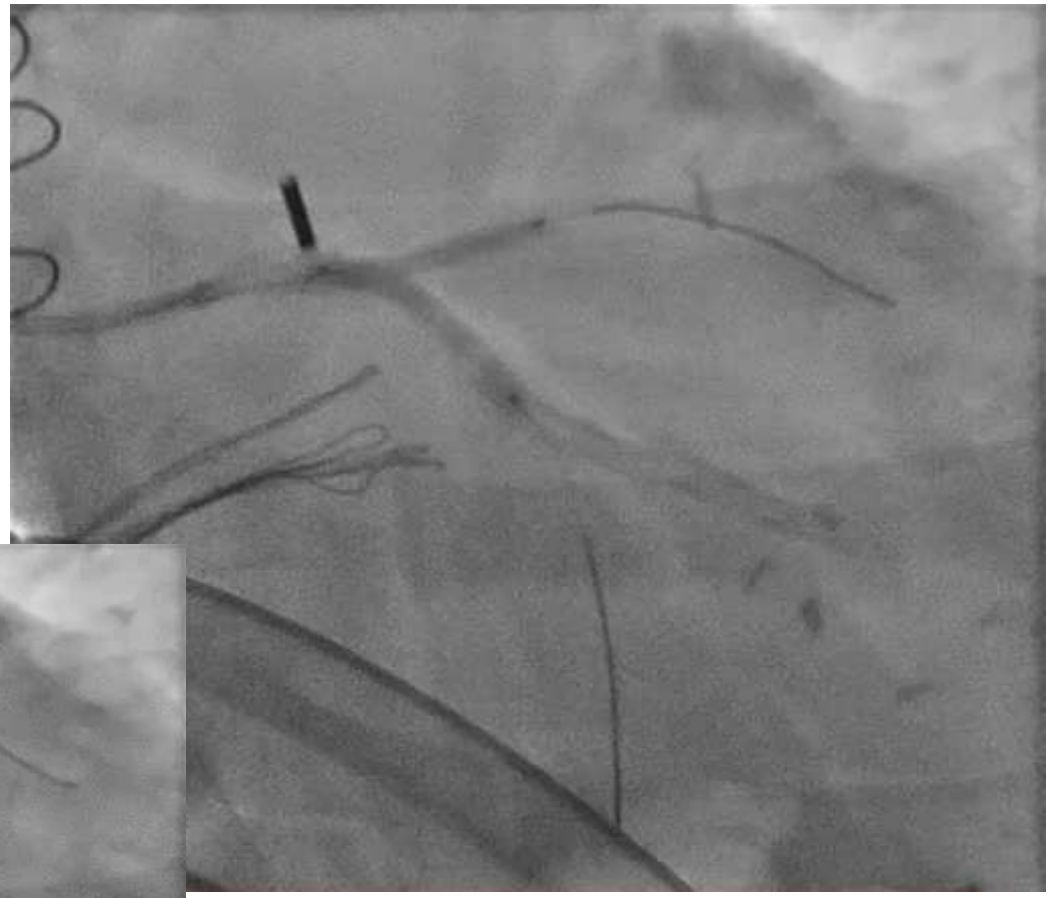


SC balloon: 2.0mm, 2.5mm
NC balloon: 3.0mm

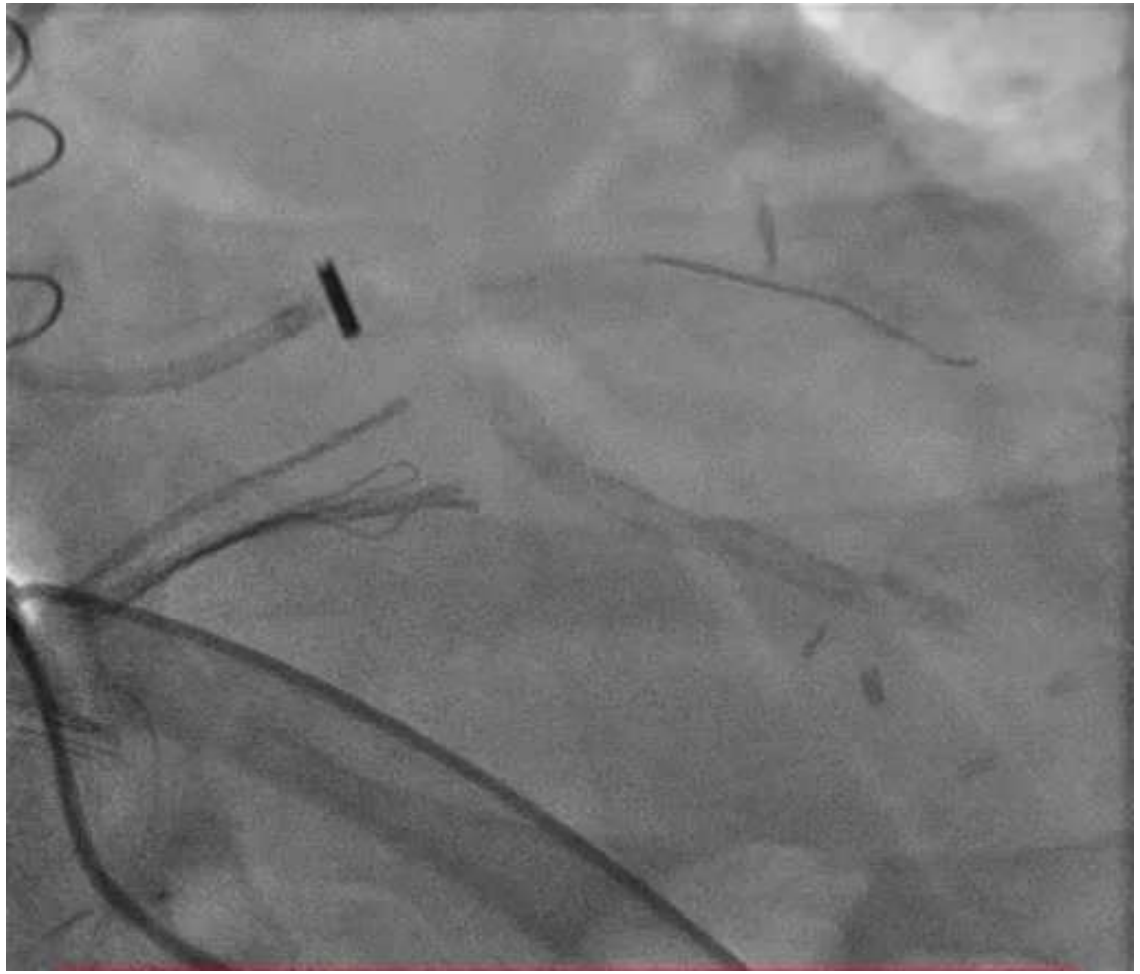
Kissing balloons

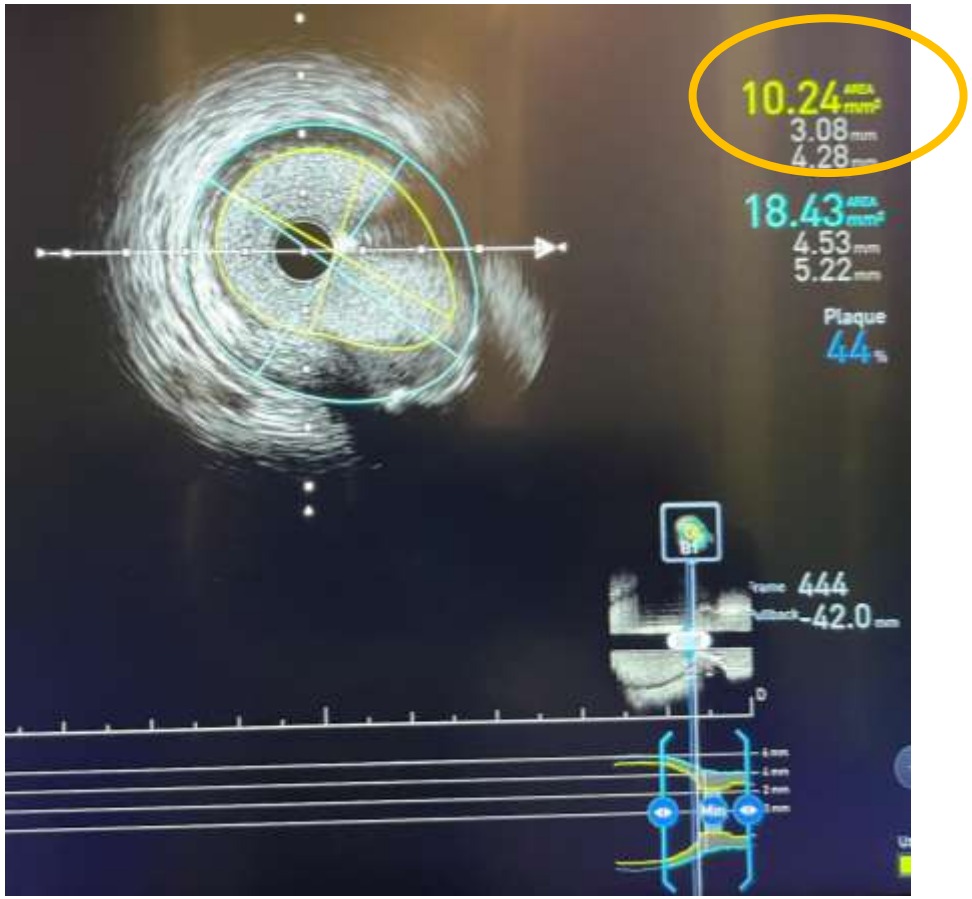


sirolimus-coated balloons:
LM/IM: 2.5x20mm
LM/LCx: 3.0x20mm
(45 seconds inflation)



Final result





Follow-up & summary

- Hemodynamic status began to stabilize allowing the explantation of V-A ECMO (after 3 days) and IABP (after 7 days)
- Discharged on the 24th day of hospitalization on DAPT (ASA and clopidogrel), atorvastatin 80mg/day, bisoprolol, ramipril and methylprednisolone 4mg/day
- 5-month follow-up - free of cardiovascular events

Summary - SLE:

- Autoimmune diseases like systemic lupus erythematosus (SLE) often cause severe cardiovascular disruption, with myocardial infarction (MI) frequently being the first clinical manifestation [1]
- PCI have a significantly higher risk of major adverse cardiovascular events (MACEs), MIs and repeated revascularizations in these patients compared with the average population, frequently due to in-stent restenosis [2]
- CABG can be performed with acceptable results [3]
- Studies on detailed management of patients with SLE undergoing PCI are missing

1. Ayyad M, et al. Cureus. 2023; 2. Bundhun PK, et al. Medicine. 2016; 95: e3200.; 3. Sakowitz S, et al. The American Surgeon™. 2023; 89: 4025-4030

Summary

Summary:

- PCI using DCBs in patients with active SLE may be a promising method of treating CAD, as it seems to reduce the risk of in-stent restenosis, due to the absence of a foreign body in vessels → "leaving nothing behind"
- To our knowledge, this is the first case of an SLE patient with severe LM stenosis treated only with DCBs

CASE: LCx ostial lesion

52-year-old male patient → CCS, angina CCS III

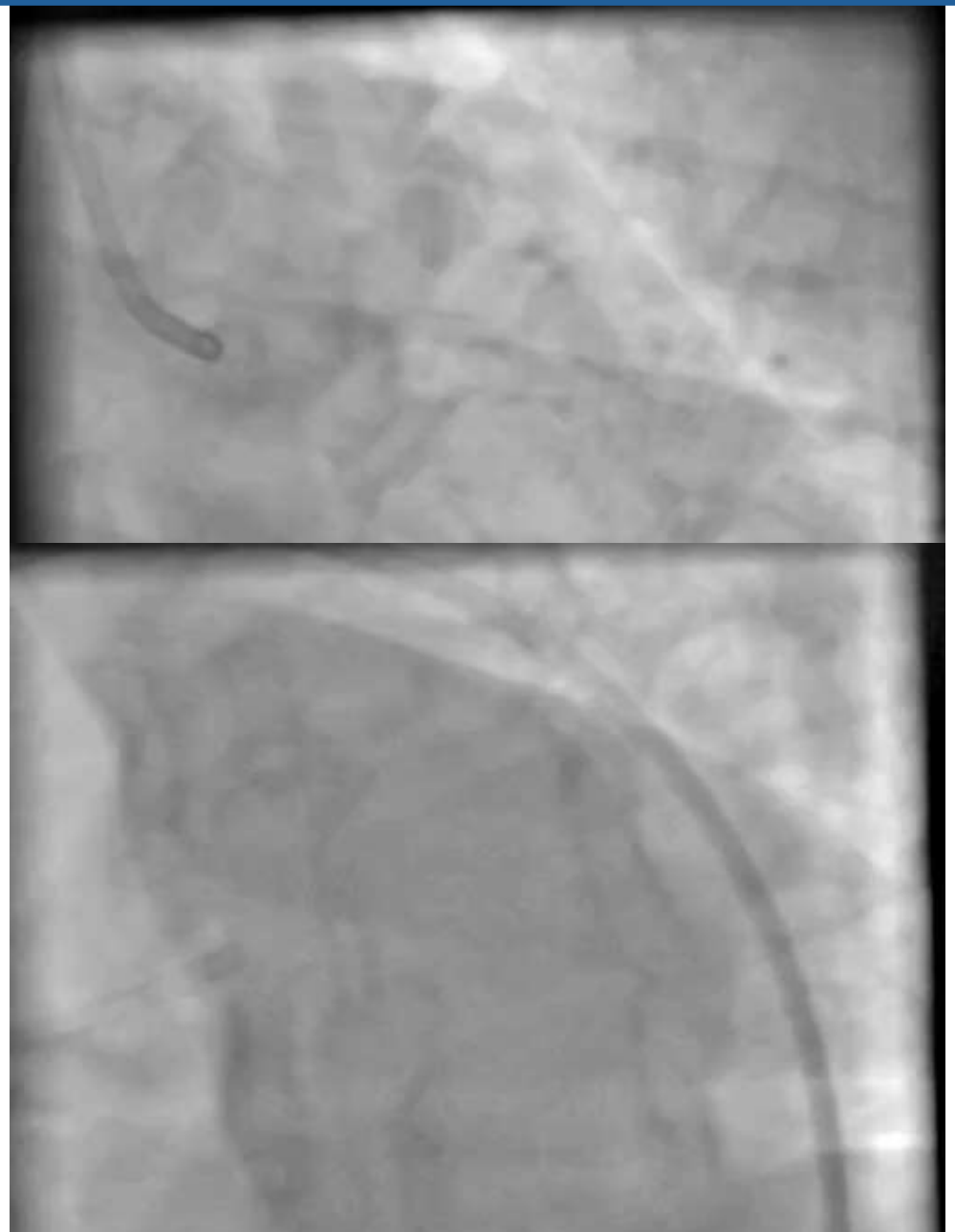
Medical history:

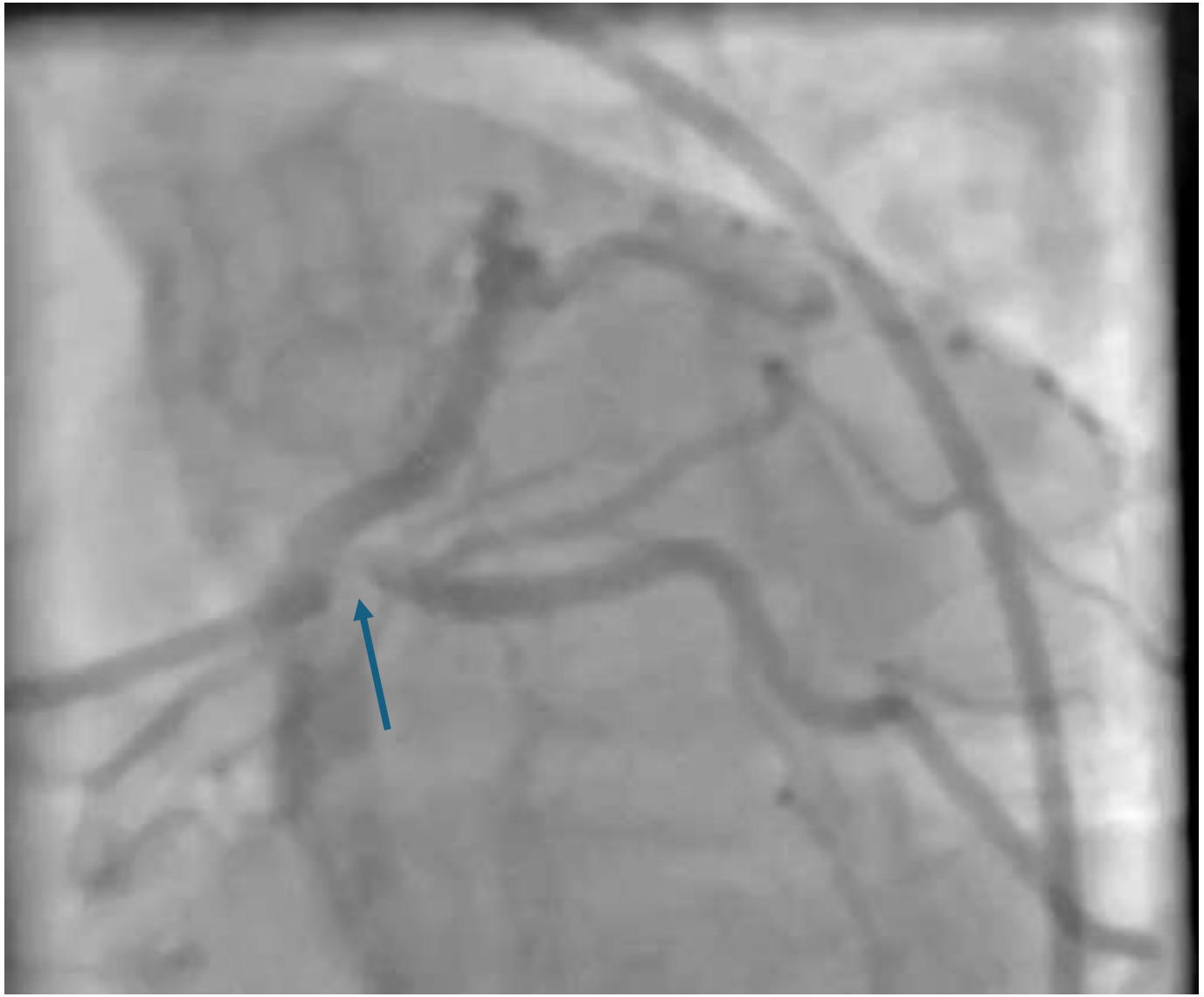
- Hyperlipidemia,
- HA
- Family history → mother MI 52 year old

Hypertrophy of LV walls, LVEF 60%

➢ Positive dobutamine test in the basal segments of the inferior and posterior wall

Coronary angiography



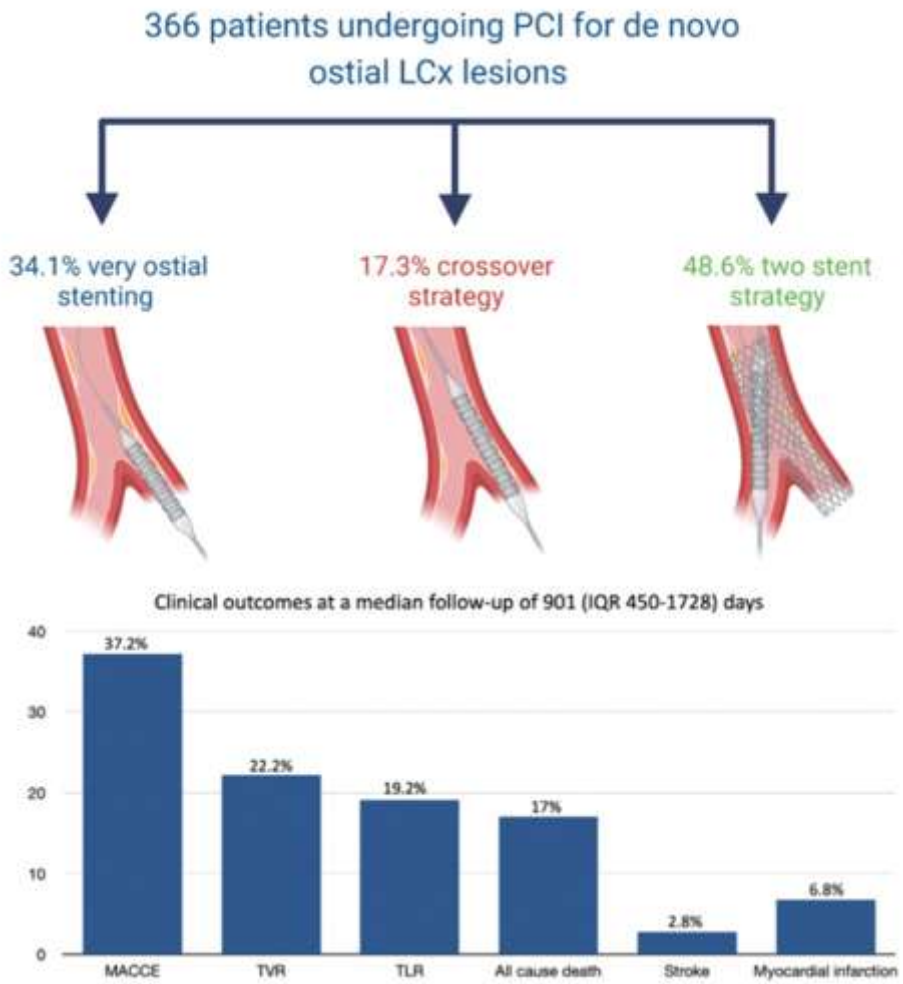


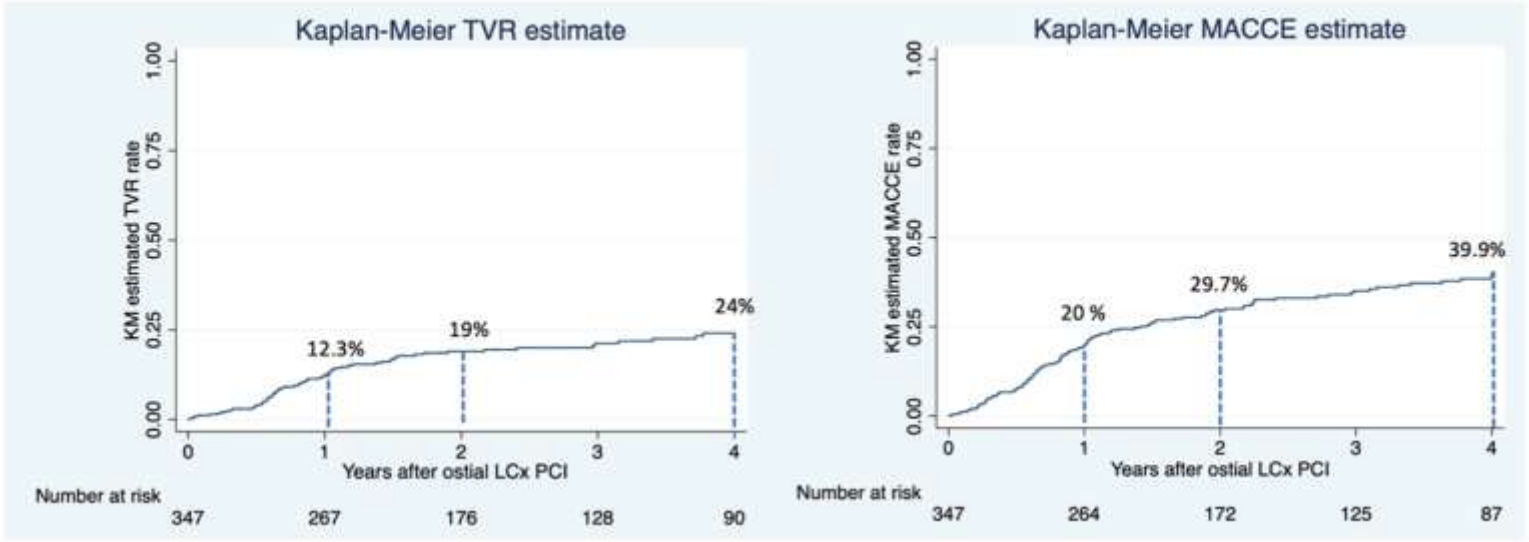
Precise stent placement at the ostium

Received: 10 August 2023 | Revised: 2 October 2023 | Accepted: 22 October 2023
DOI: 10.1002/ccd.30903

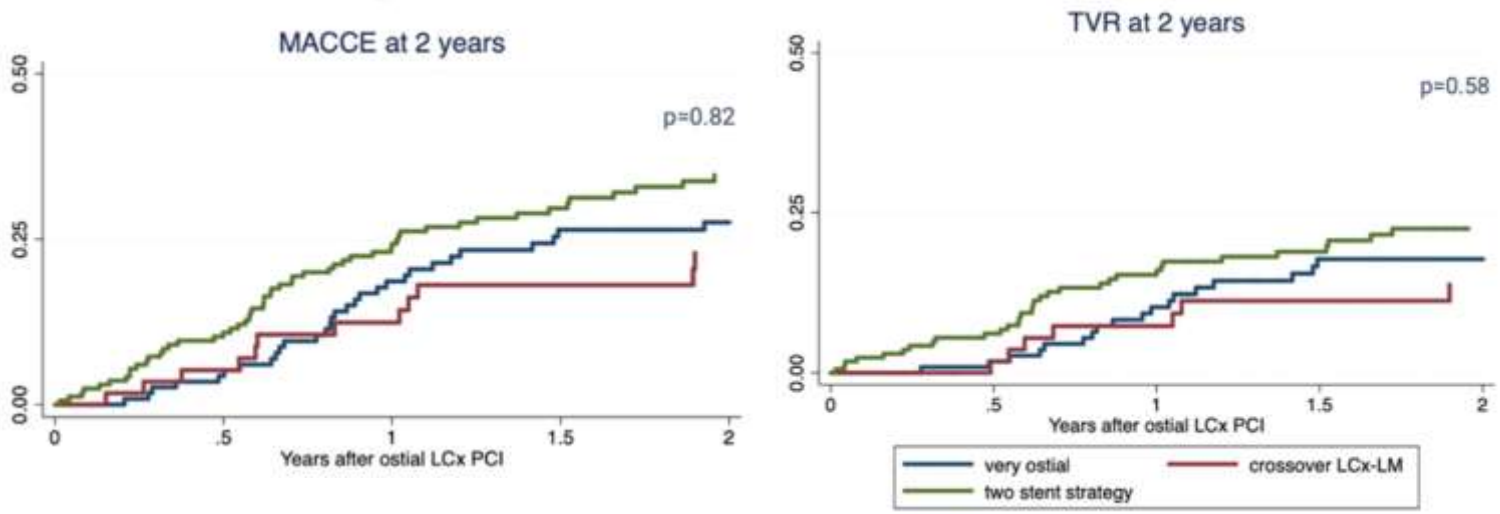
WILEY

Clinical and procedural outcomes of percutaneous coronary intervention for de novo lesions involving the ostial left circumflex coronary artery





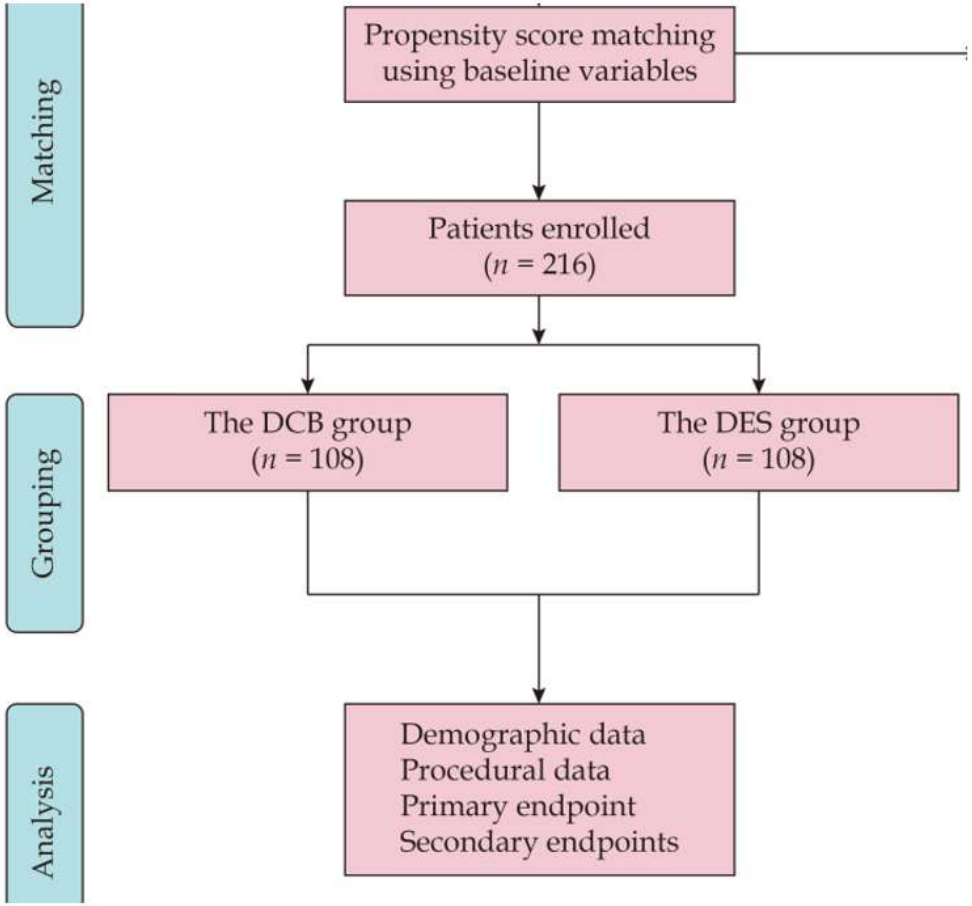
In the overall population, the incidence of TVR at 2 years was 19.0% while MACCE rate was 25.7%.



Percutaneous revascularization of the ostial LCx is associated with a high rate of TVR, regardless of the stenting strategy. Intracoronary imaging and proper stent sizing may reduce the failure rates.

Drug eluting balloon for ostial LCx or LAD

A retrospective analysis of 397 patients with de novo ostial lesions in the LAD (n=315) or LCx (n=82)

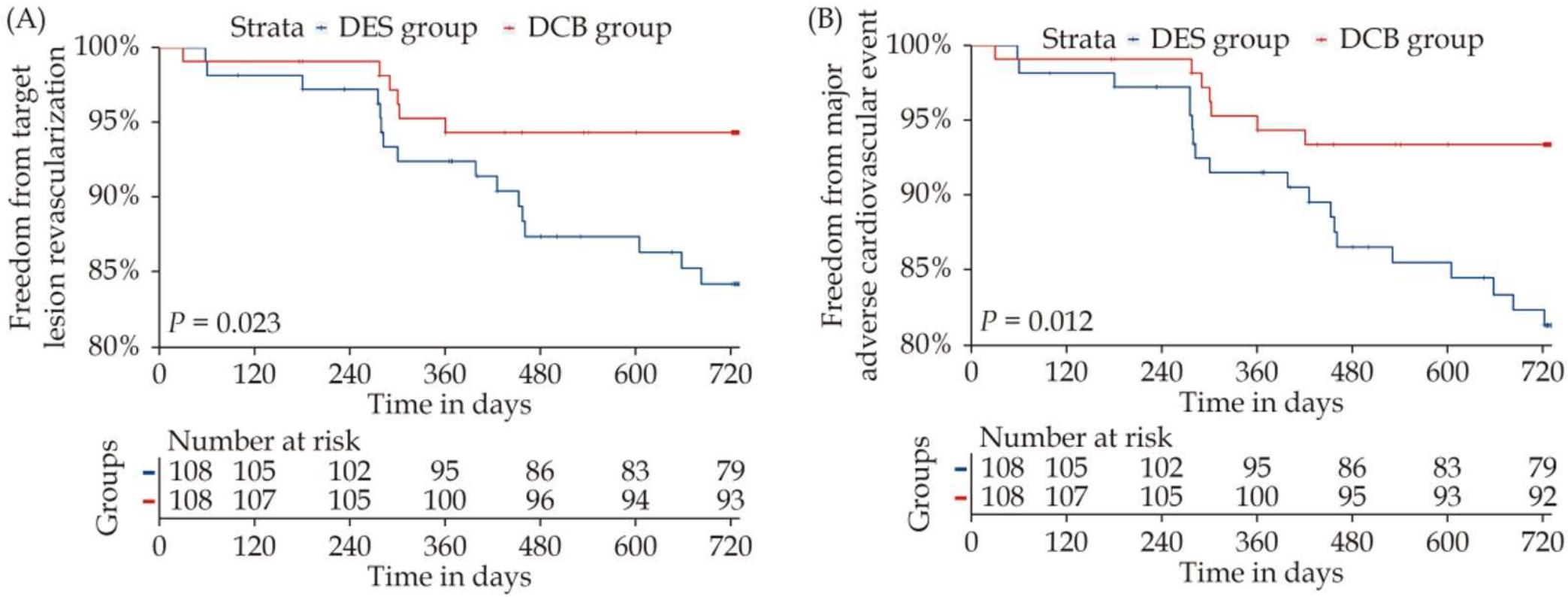


DCB group – balloon only or hybrid strategy (DCB + BMS)

DES group – crossover or precise stent positioning

Pan L et al. J Geriatr Cardiol 2023; 20(10): 716–727

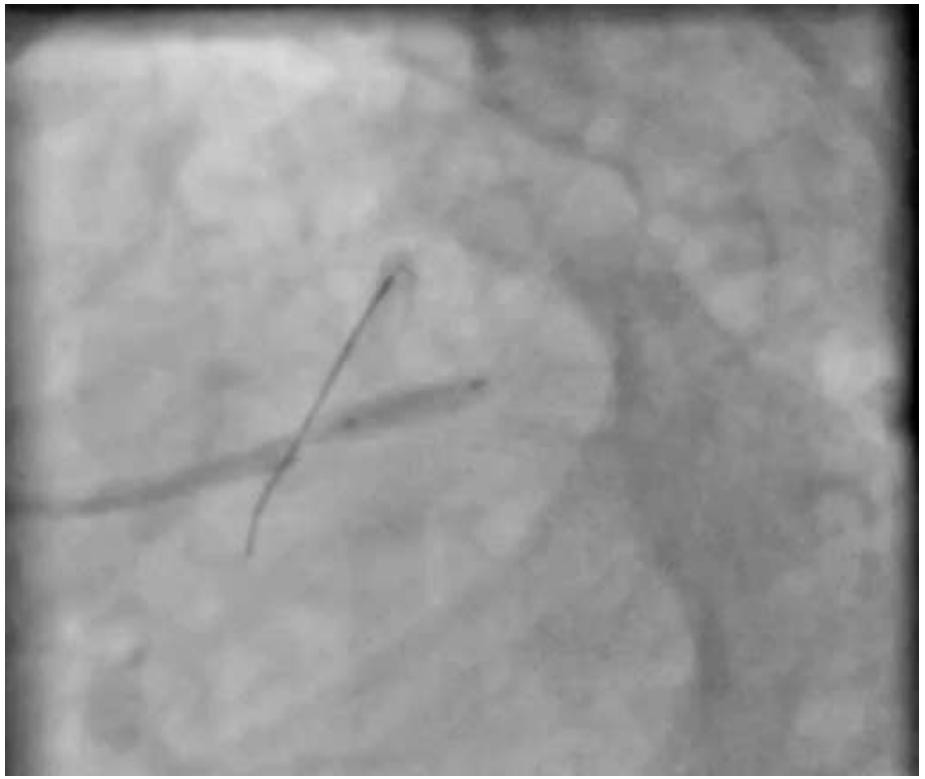
Drug eluting balloon for ostial LCx or LAD

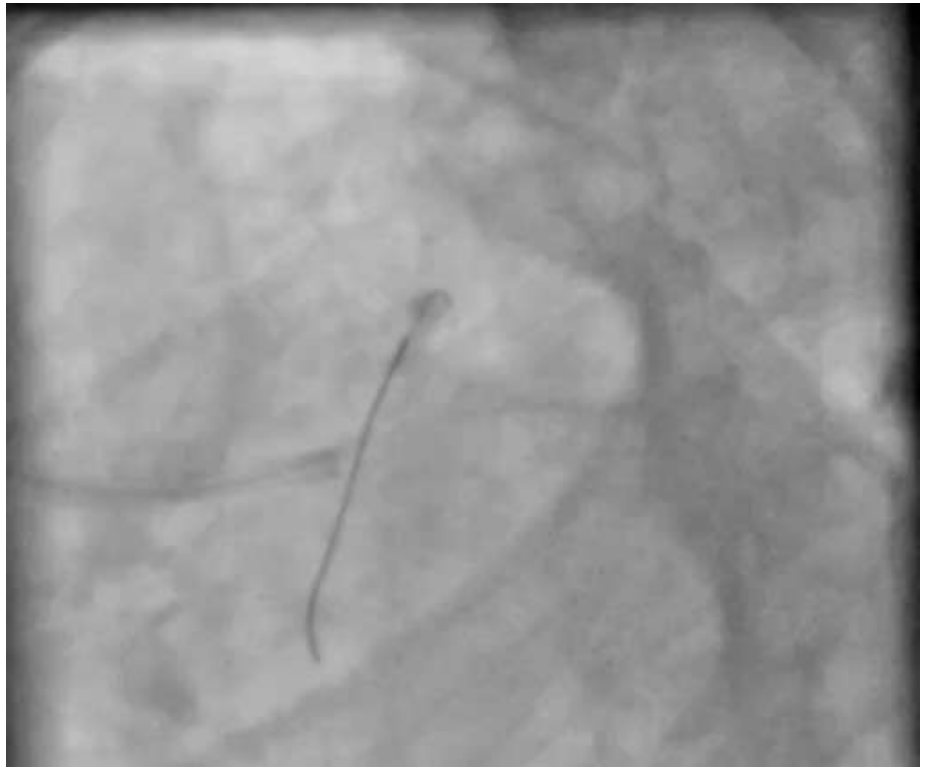


Two-year follow-up of the propensity score-matched cohort

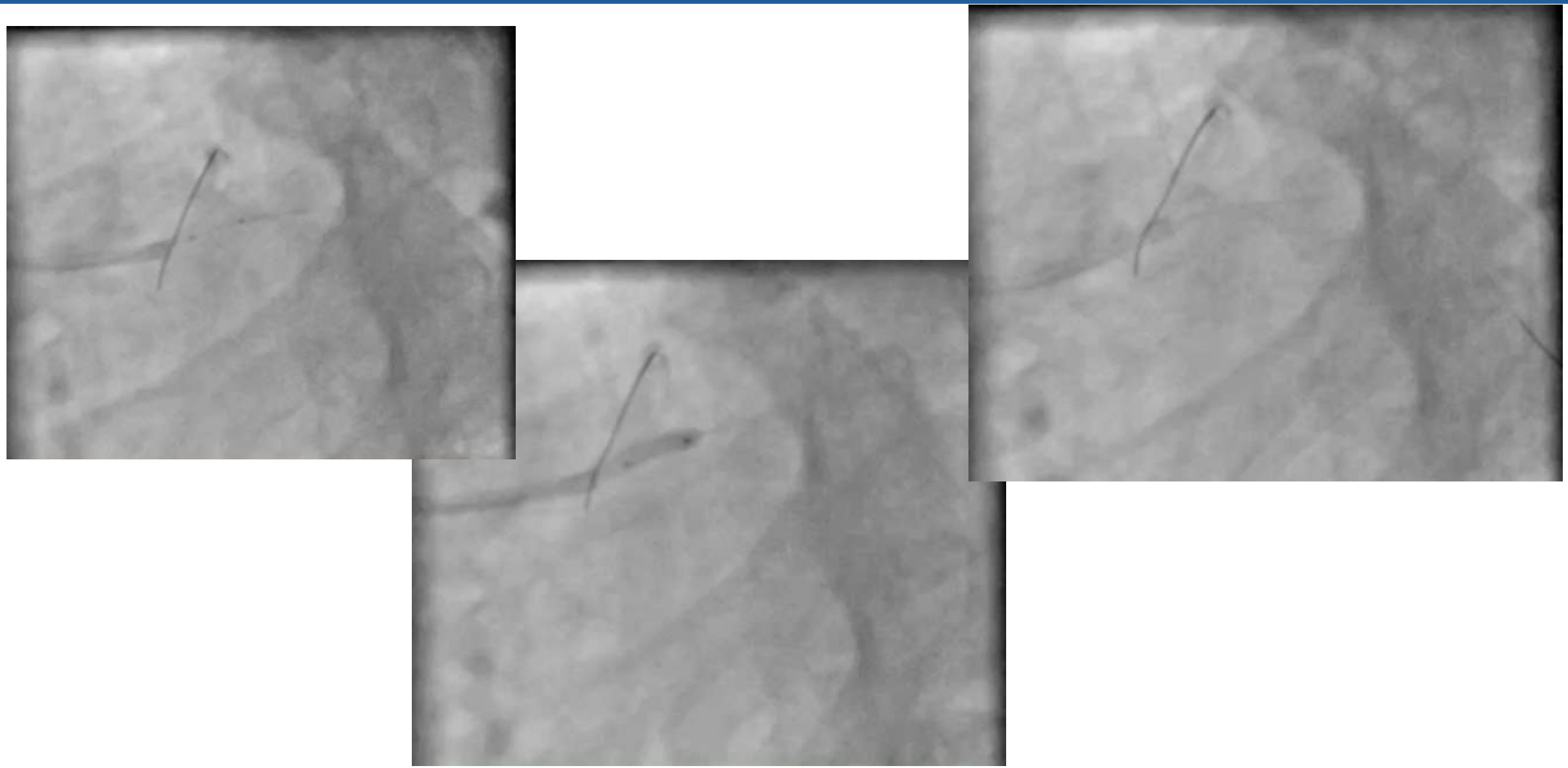
Pan L et al. J Geriatr Cardiol 2023; 20(10): 716–727

PCI: predilatation - NC balloon 2.75x12mm

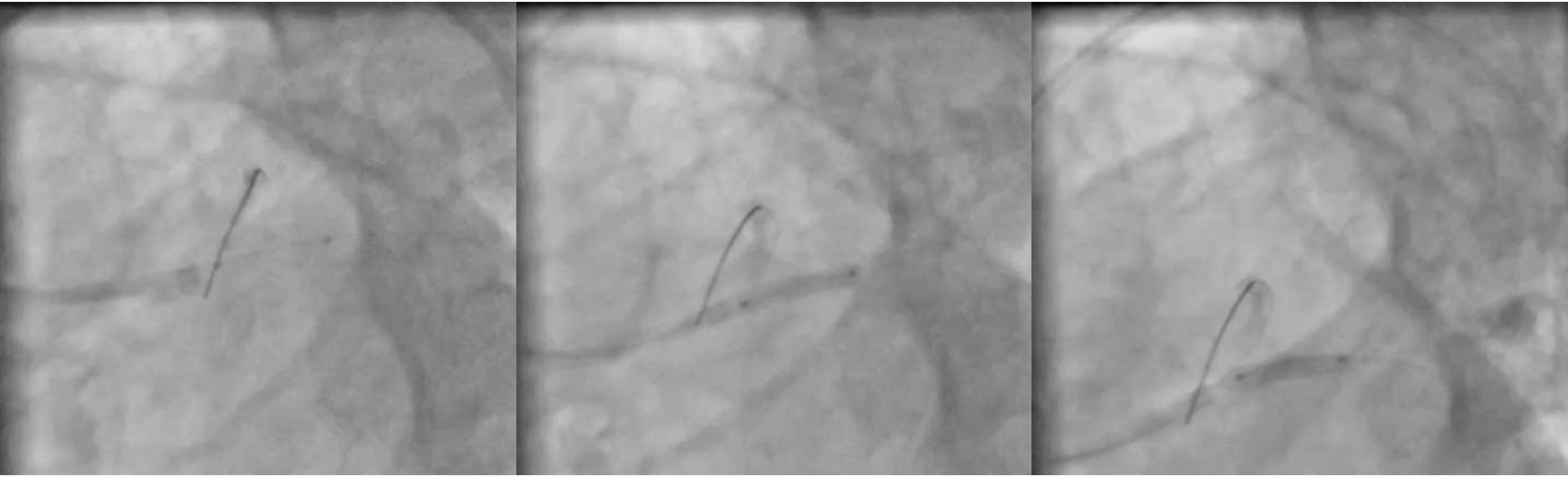




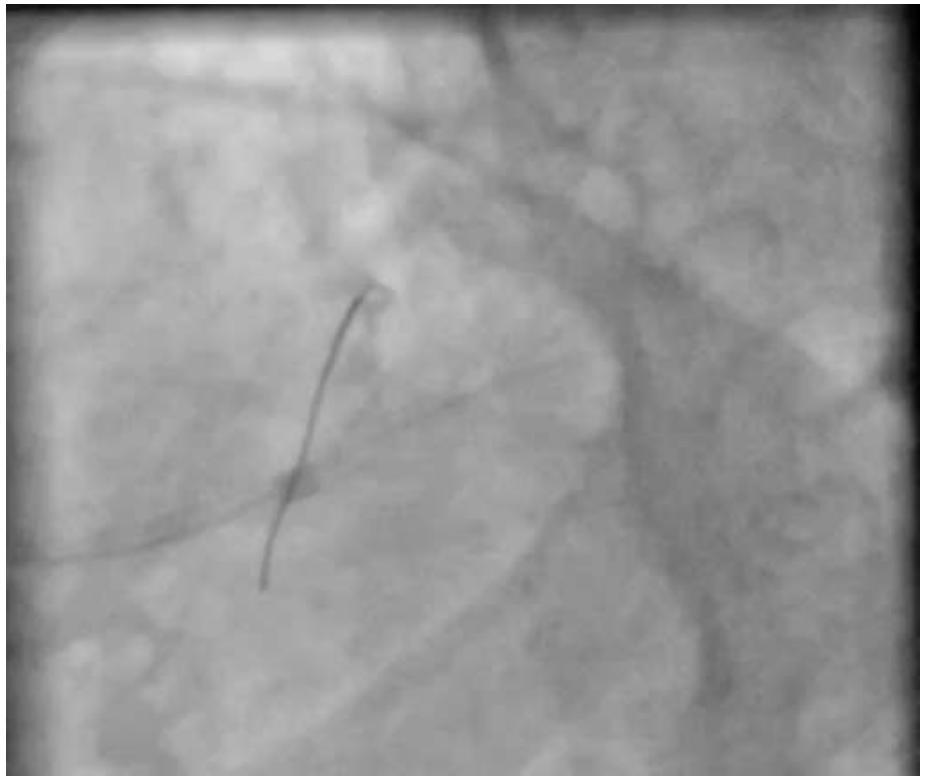
PCI: predilatation - NC balloon 3.0x12mm

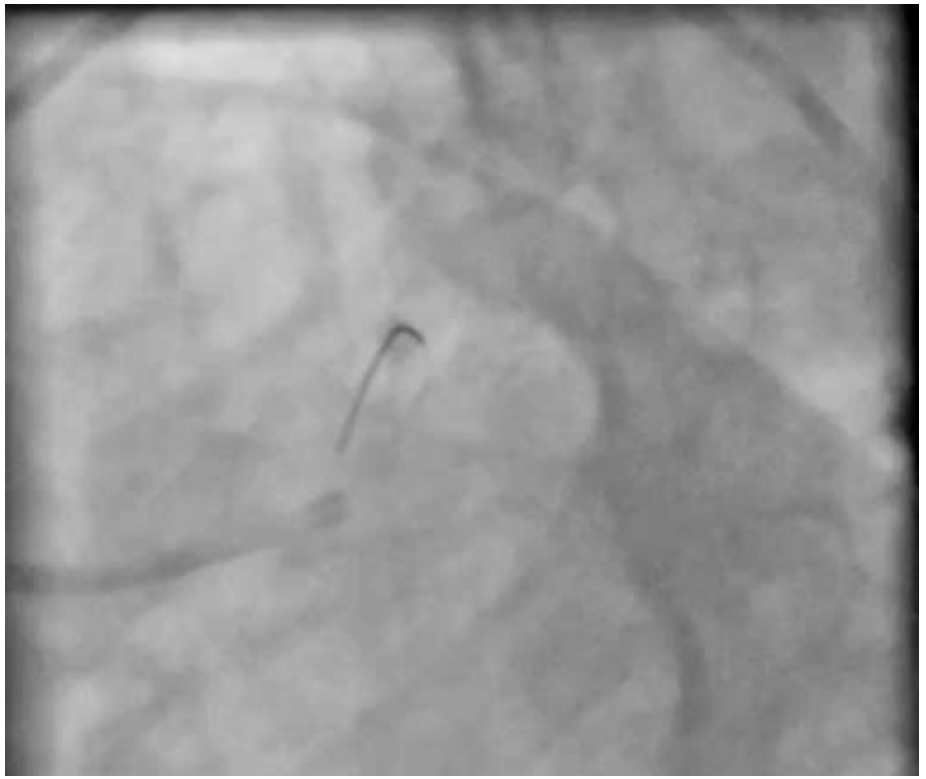


PCI: SEB BDC 3.0x 14mm; 10 atm, 60 sek



Final result





Summary

- The LM bifurcation is the most important bifurcation, and the LCx is the most significant coronary artery side branch
- Significant LCx stenosis often causes extensive ischemia

- However, when treating LCx stenosis, the main vessel should not be sacrificed → with DCB?

Drug-eluting balloon: is it useful?
Summary

In-stent restenosis

Small vessel disease

Bifurcation lesions

De novo coronary lesions?

Drug-eluting balloon: is it useful?
Bottom Line for Cath Lab Strategy

✓ Use DCB **confidently for ISR**
✓ Use **selectively for small vessels**, especially **metal avoidance strategy**
✓ Consider in **HBR / bifurcation / side branch** but have **bailout DES ready**
✓ **Technique and imaging matter more than device choice**