

DCB as a New Paradigm of PCI

TCTAP 2021

**Eun-Seok Shin, MD/PhD
Ulsan University Hospital
Ulsan, Korea**

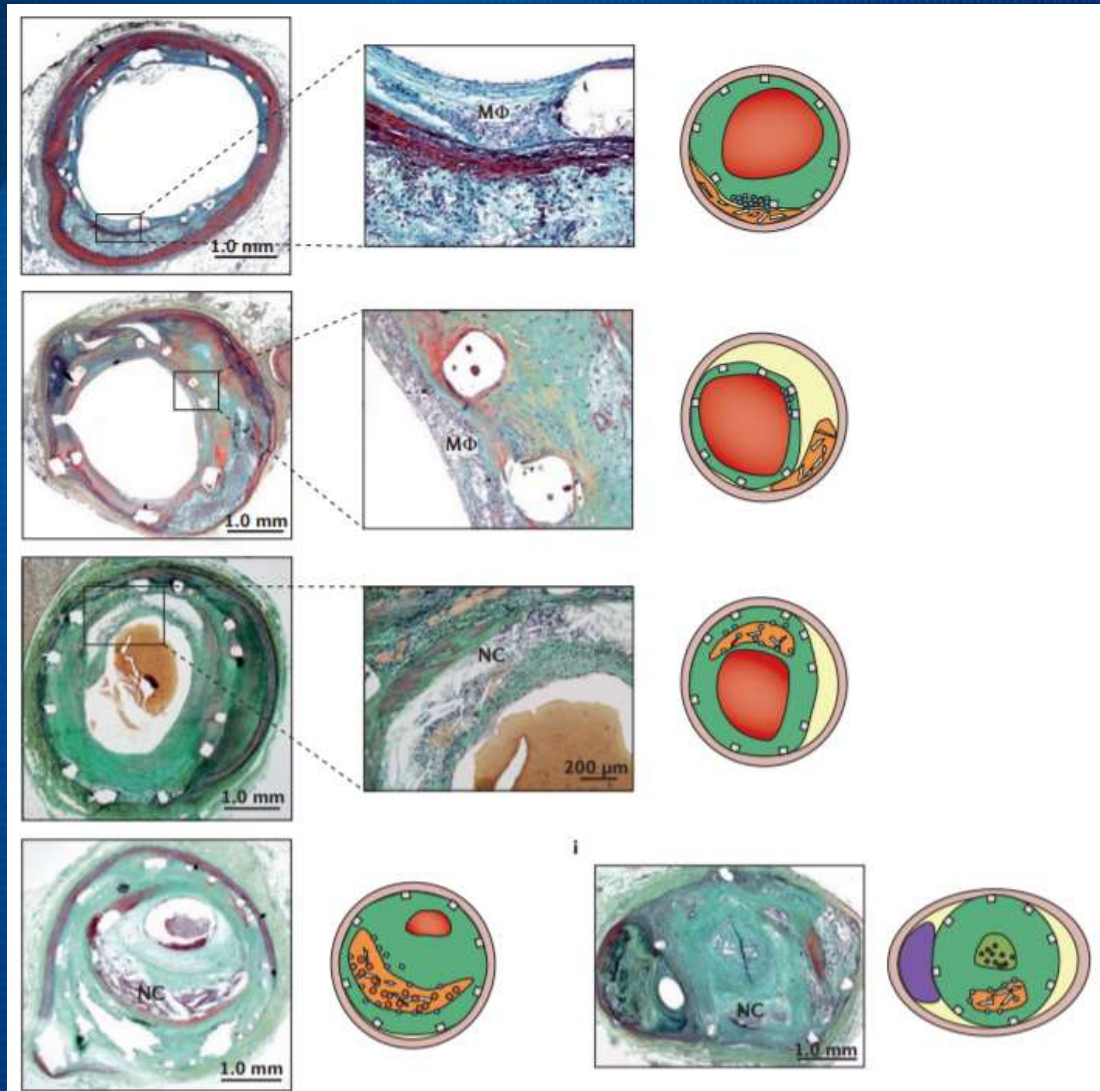
2 major causes of stent failure

0.6%/y (1st DES) → 0.3%/y (2nd DES) 10% (Angiographic) → 5% (Clinical)



***Final pathway of stent failure: Neoatherosclerosis
(70% of late ST, 50% of ISR)***

Various treatments for CAD, such as CABG and PCI, have led to accelerated atherosclerosis!

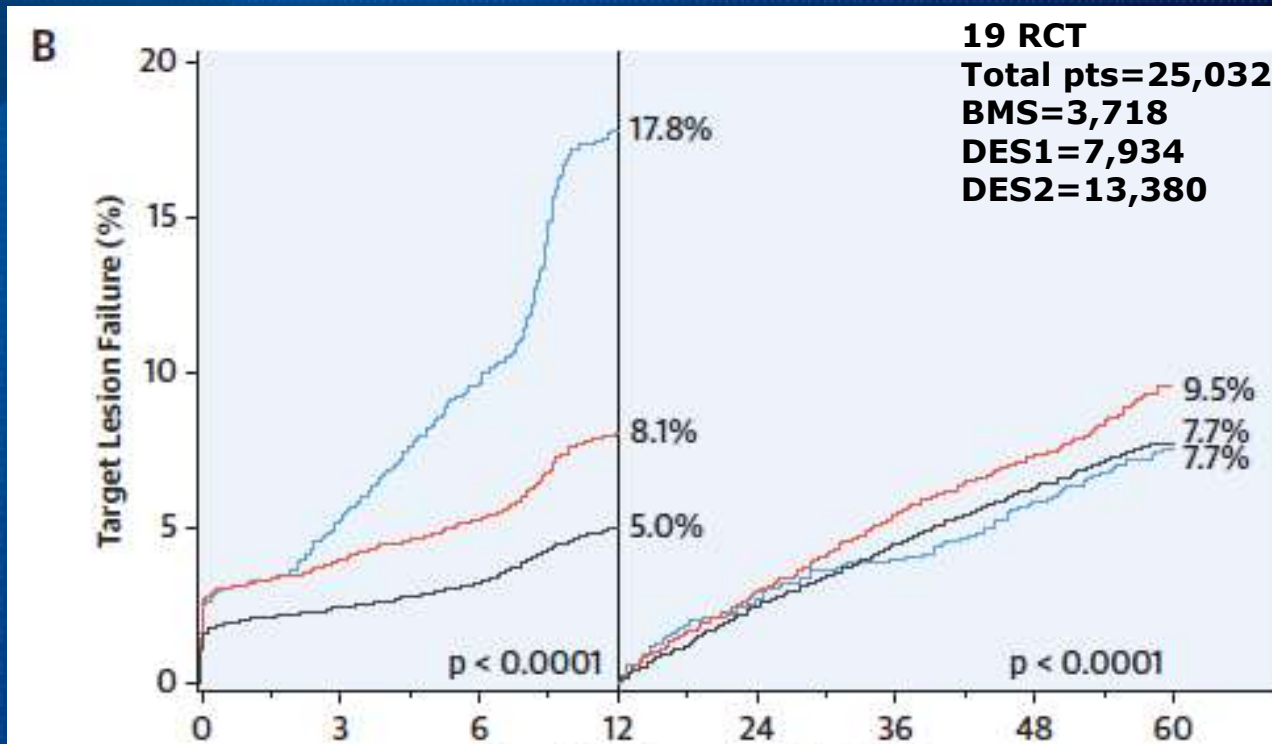


Neoatherosclerosis occur within months to years, compared with the decades for native CAD

Nat Rev Cardiol. 2016;13(2):79-98.

- | | | | | |
|-------------------------|----------------------|--------------------|-------------|-------------------|
| ● Artery wall | ● Collagen | ● Calcified plaque | ● Thrombus | ● Healed thrombus |
| ● Lumen | ● Necrotic core | ● Angiogenesis | ● Neointima | |
| ● Macrophage foam cells | ● Cholesterol clefts | ● Haemorrhage | □ Strut | |

Very-late stent related CV events (cardiac death, MI, TLR)

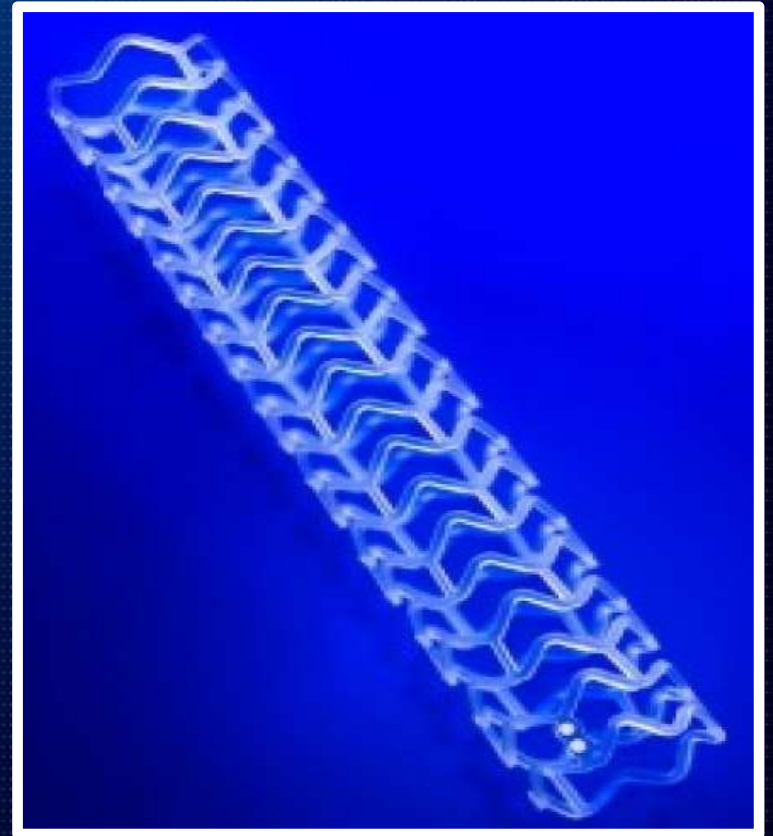
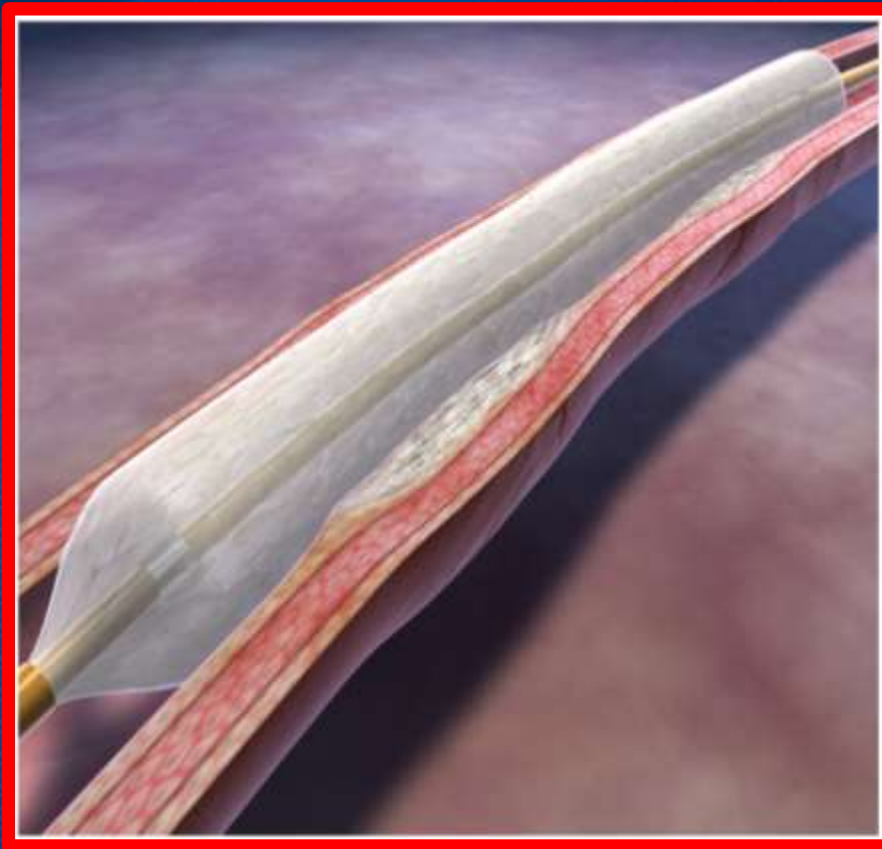


~2%/year CV events with all stent types

Without plateau in ongoing risk

New approaches are required to improve long-term outcomes after PCI.

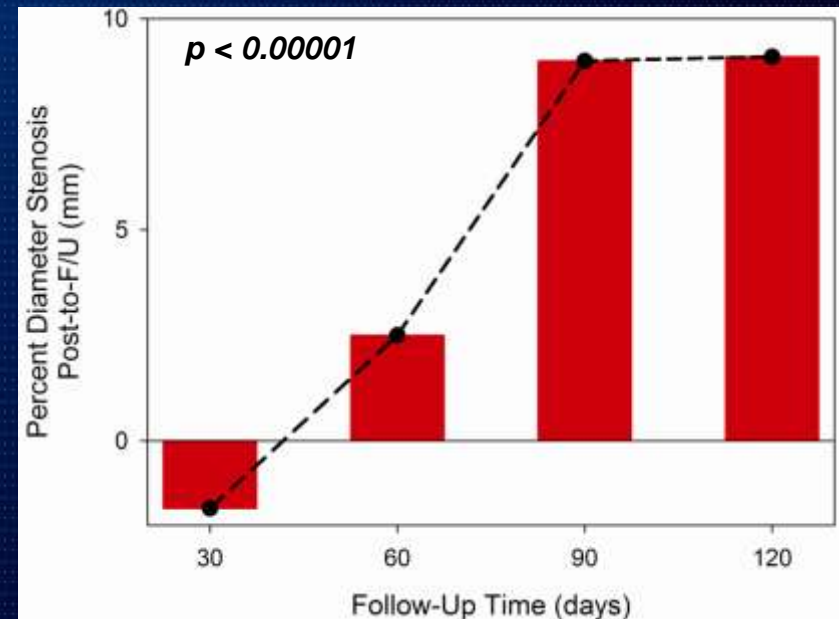
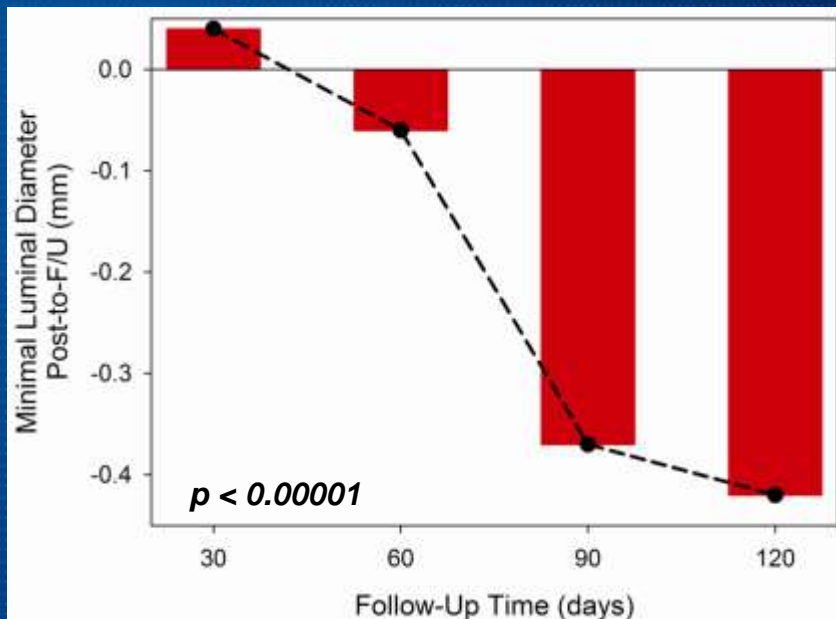
2 New Paradigm of PCI



Incidence of restenosis after successful coronary angioplasty: a time-related phenomenon

Scaffolding of the Vessel is Only a Transient Need

n = 342 patients (n = 93 at 30-day F/U; n = 79 at 60-day F/U; n = 82 at 90-day F/U; n = 88 at 120-day F/U)



The lumen appears to stabilize approximately three months after PTCA.

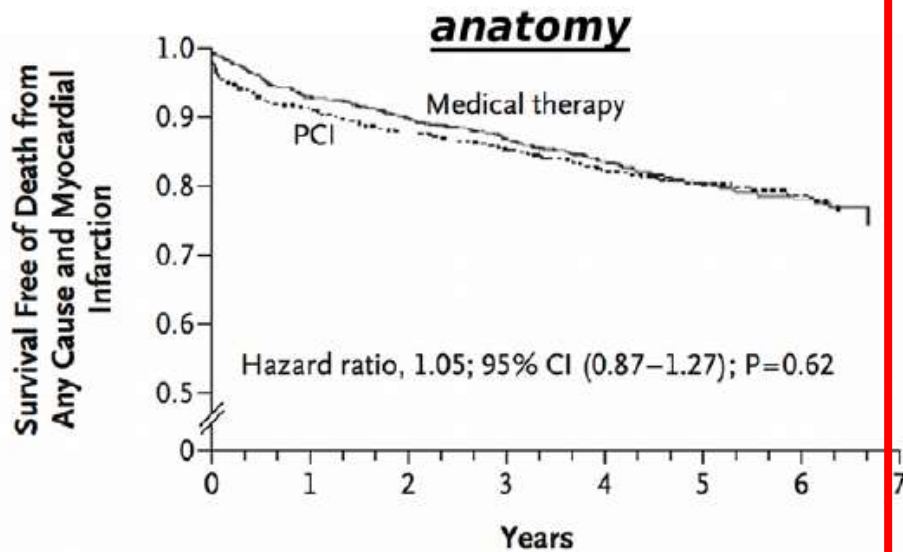
The purpose of PCI is to reduce ischemia, not just stenosis!

Ischemia > flow > stenosis

The purpose of PCI is to reduce ischemia, not just stenosis!

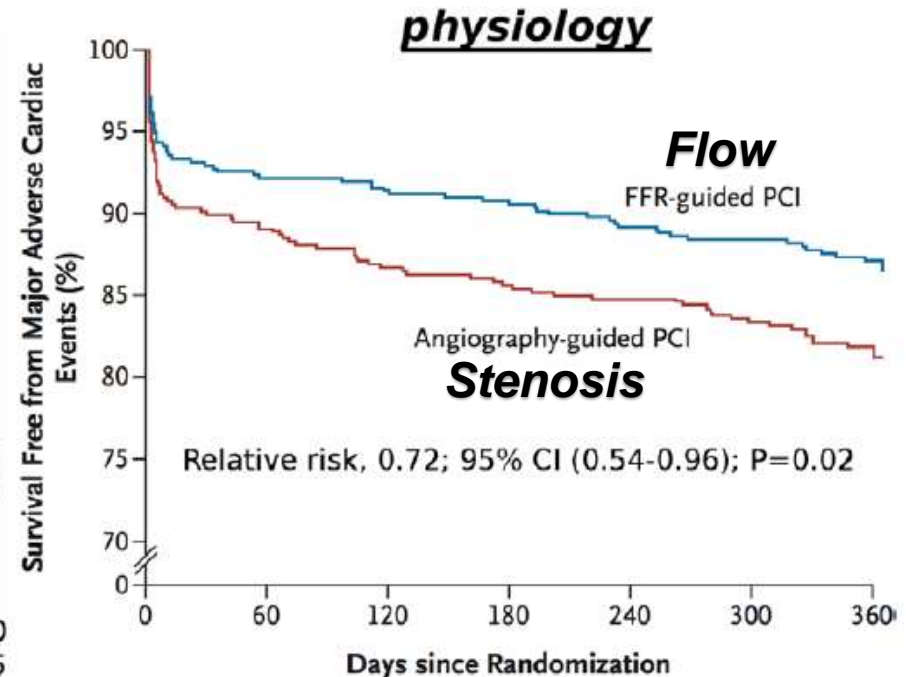
Ischemia > flow > stenosis

Flow-guided treatment is better than stenosis-based therapy

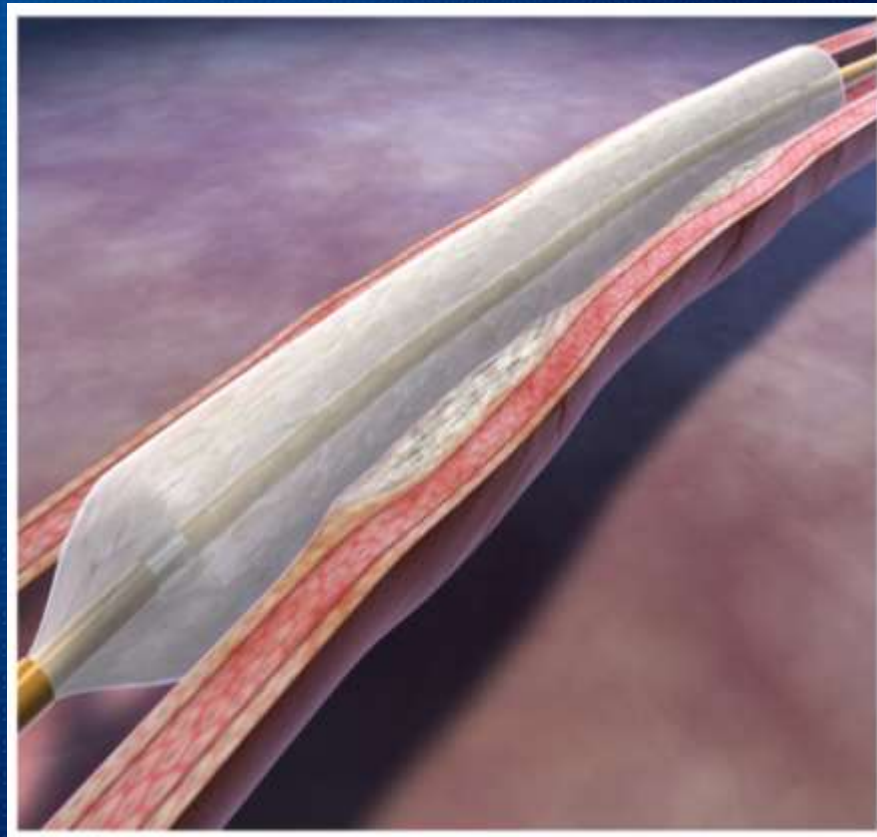


No. at Risk

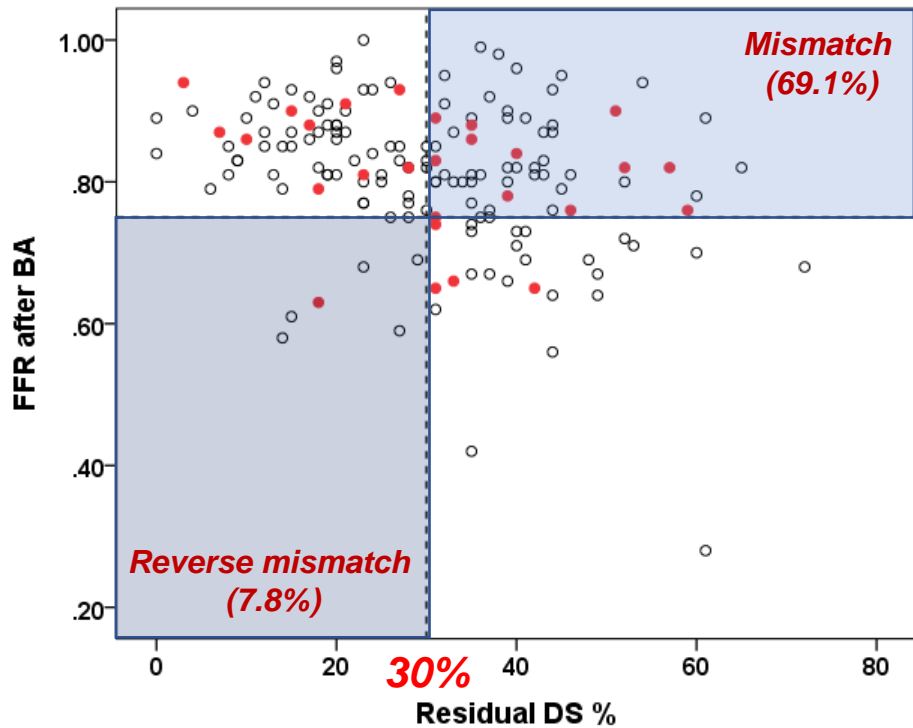
Medical therapy	1138	1017	959	834	638	408	192	80
PCI	1149	1013	952	833	637	417	200	85



How about DCB?



How about after DCB? FFR vs. DS



Angio-guided

Stent: 92

DCB: 66

FFR-guided

Stent: 31

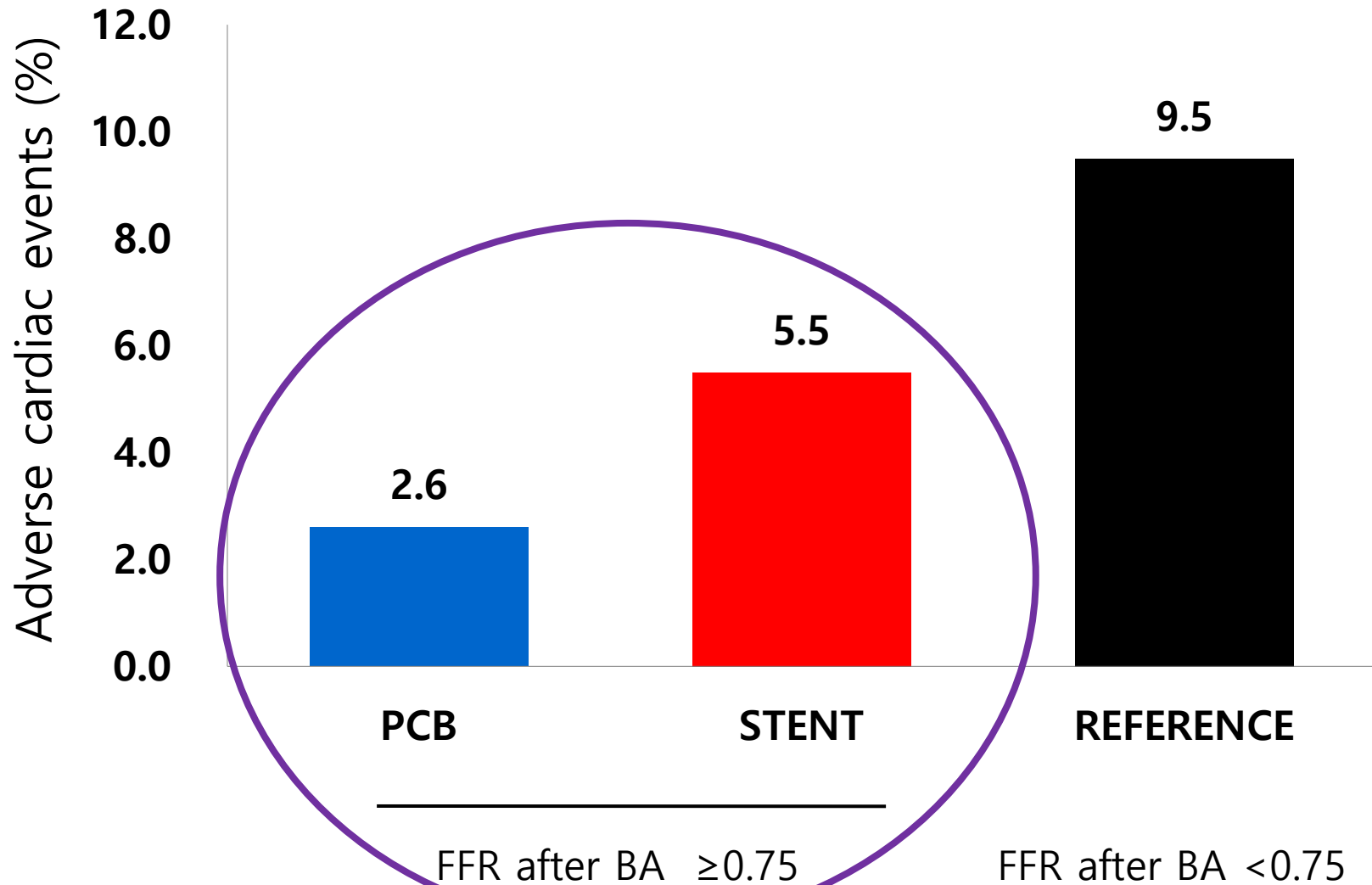
DCB: 127

**66% reduction
of stent usage with FFR**

- Dissection type ≤ B
- Dissection type ≥ C

Cardiac death, MI, TVR

200 patients



DCB for CAD

- **After DCB treatment, there is a relatively higher residual stenosis than stent, but the flow is the same.**
 - **Comparable outcome to DES**
- **No metal left.**
 - **Never stent-related events, esp. stent thrombosis**

CTO PCI with Stent



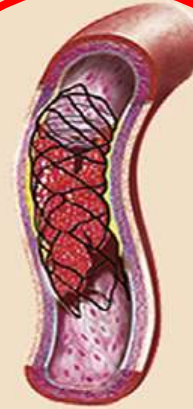
Improved angina



Improved exercise capacity



Improved quality of life



Stent thrombosis



In-stent restenosis

CTO PCI with DCB

Baseline



Post-DCB



After 6-month

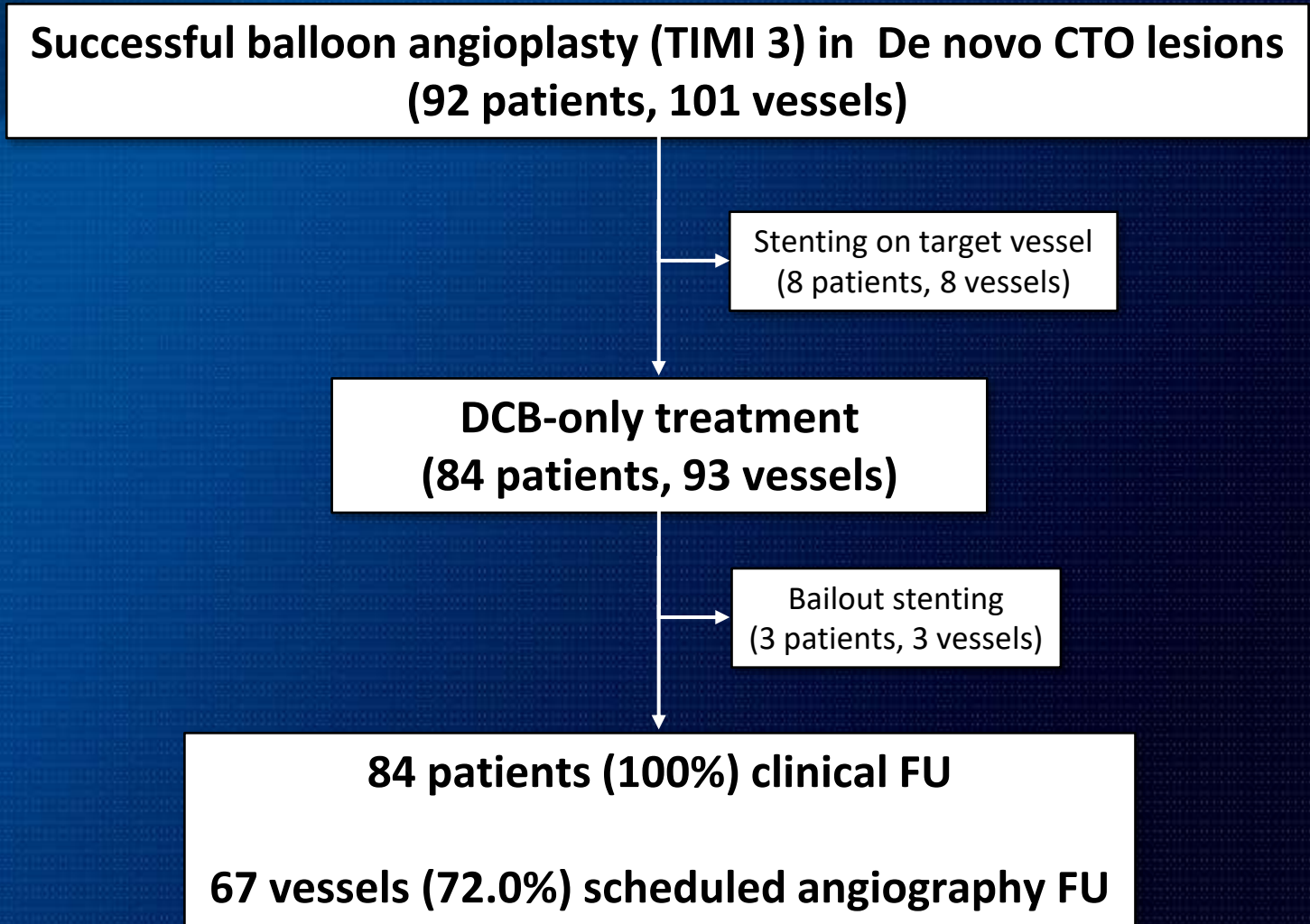


No Stent-related events forever!

A retrospective observational study

- 2 centers (Queen Elizabeth Hospital II and Ulsan Medical Center)
- Inclusion criteria: patients with de novo CTO lesions who received DCB successfully
- Exclusion criteria: in-stent restenosis lesion, STEMI, unstable hemodynamics at presentation, life expectancy <1 year.

Flow chart of the study



Baseline patient characteristics (n = 84 patients)

Age, years	56.1 ± 9.9
Male	72 (85.7)
Hypertension	49 (58.3)
Hypercholesterolemia	40 (47.6)
Diabetes	32 (38.1)
Current smoker	16 (19.0)
Previous MI	21 (25.0)
Previous PCI	21 (25.0)
Ejection fraction, % (n=74)	50.35 ± 12.93
Serum creatinine, mg/dl	1.09 ± 0.70
Clinical presentation	
Stable angina	52 (61.9)
ACS	32 (38.1)

Angiographic & procedural characteristics (n = 93 vessels)

Number of diseased vessels	1.75 ± 0.82
Treated vessel	
LAD	45 (48.4)
LCX	24 (25.8)
RCA	24 (25.8)
Pre-dilation balloon size, mm	2.37 ± 0.48
DCB type	
SeQuent please family	109 (78.4)
Inpact falcon	30 (21.6)
Number of DCB used	1.49 ± 0.60
DCB size, mm	2.70 ± 0.36
DCB to reference vessel ratio	1.03 ± 0.19
DCB length, mm	42.29 ± 17.11
DCB maximal pressure, atm	9.39 ± 2.70
DCB inflation time, second	72.01 ± 29.70
Dissection type after DCB	
None	25 (26.9)
A	22 (23.7)
B	40 (43.0)
C	4 (4.3)
D	1 (1.1)
E	1 (1.1)
Bail-out stenting	3 (3.2)

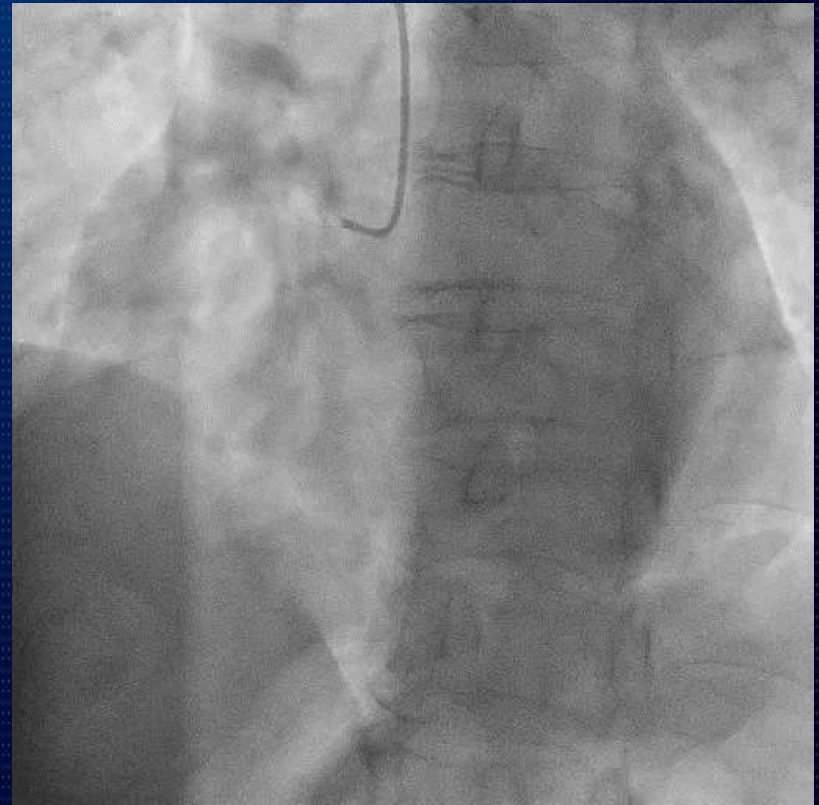
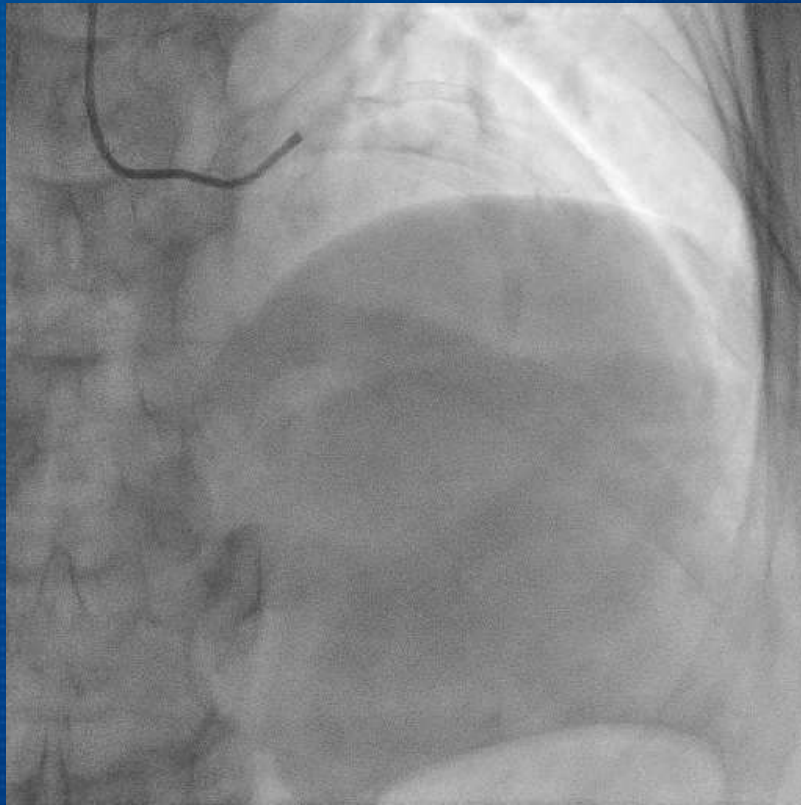
Quantitative coronary angiography

Post-DCB	N = 93
Reference vessel diameter, mm	2.32 ± 0.45
Lesion length, mm	42.37 ± 17.03
Minimal lumen diameter, mm	1.61 ± 0.36
Diameter stenosis, %	30.56 ± 9.31
Acute lumen gain, mm	1.61 ± 0.36
Follow-up	N = 67
Reference vessel diameter, mm	2.49 ± 0.68
Lesion length, mm	43.74 ± 16.81
Minimal lumen diameter, mm	1.56 ± 0.59
Diameter stenosis, %	37.81 ± 17.28
Late lumen loss, mm (N =67)	0.03 ± 0.53
Binary restenosis	10 (14.9)
Follow-up duration (median; IQR)	186.0 (134.0-291.0)

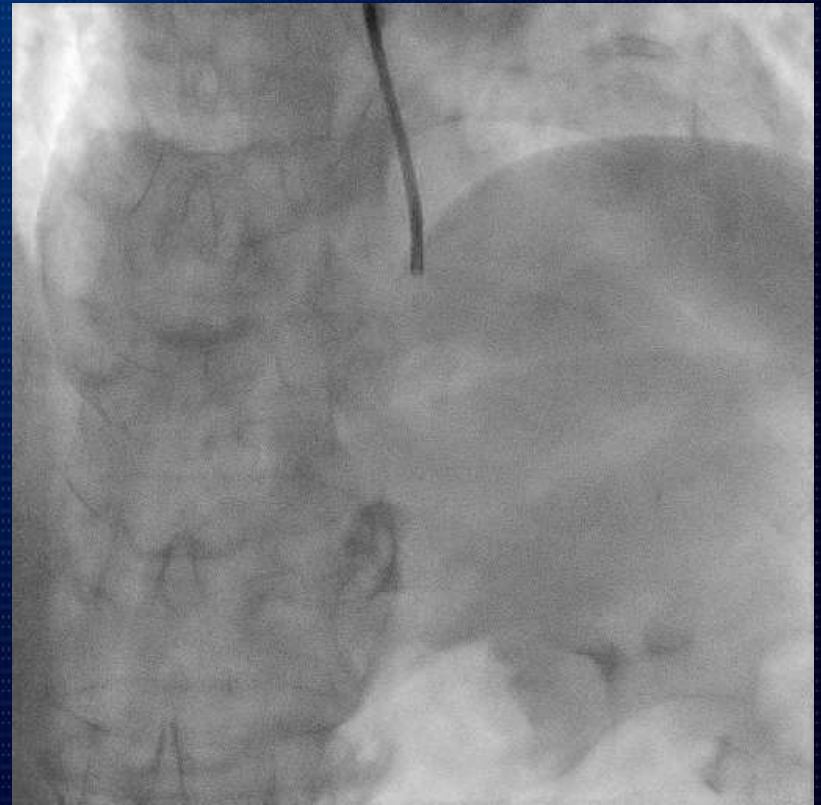
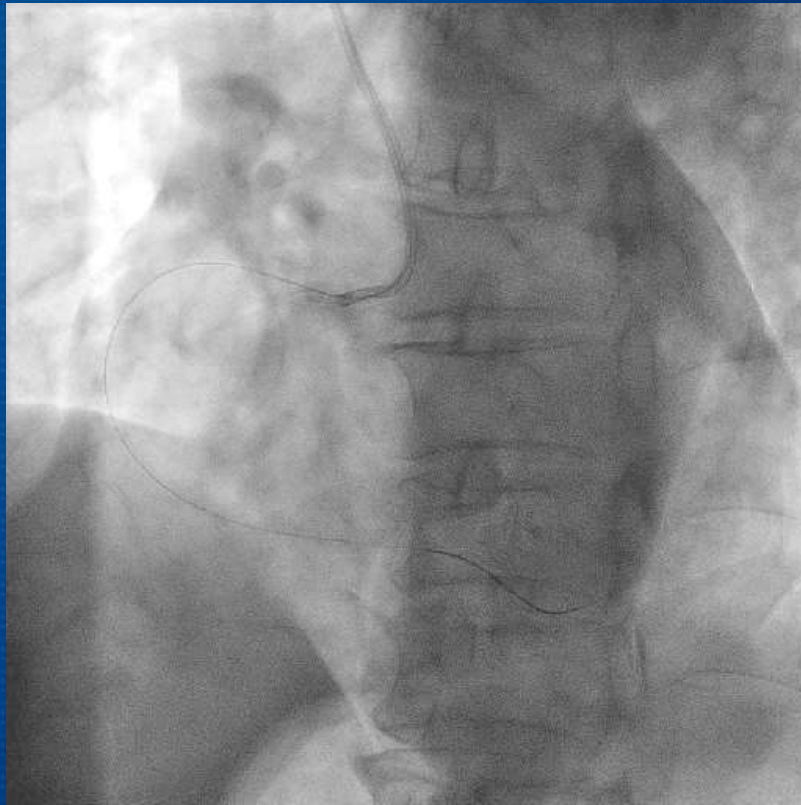
Procedural complications & clinical outcomes

Procedural complication	
Perforation	0
Pericardiocentesis	0
Emergency CABG	0
Stroke	0
Clinical outcomes	
MACE (CD, MI, TVR, thrombosis)	14 (16.7)
Cardiac death	2 (2.4)
Non-fatal myocardial infarction	3 (3.6)
Target lesion revascularization	11 (13.1)
Target vessel revascularization	11 (13.1)
New vessel revascularization	9 (10.7)
Target vessel thrombosis	0
Stroke	2 (2.4)
Clinical follow-up duration (median; IQR)	720.0 (405.5-1268.0)

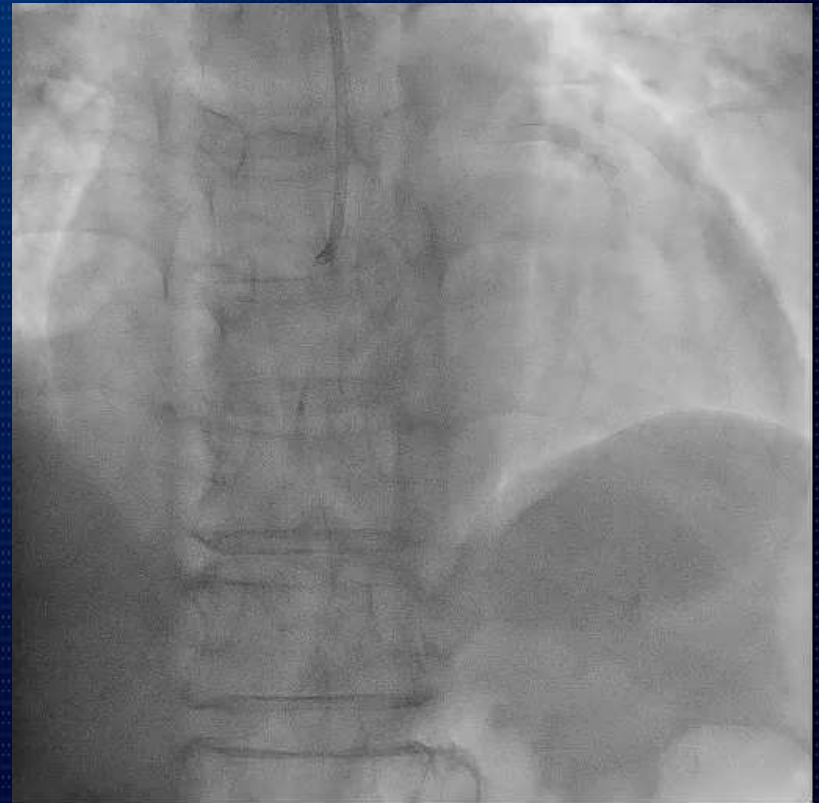
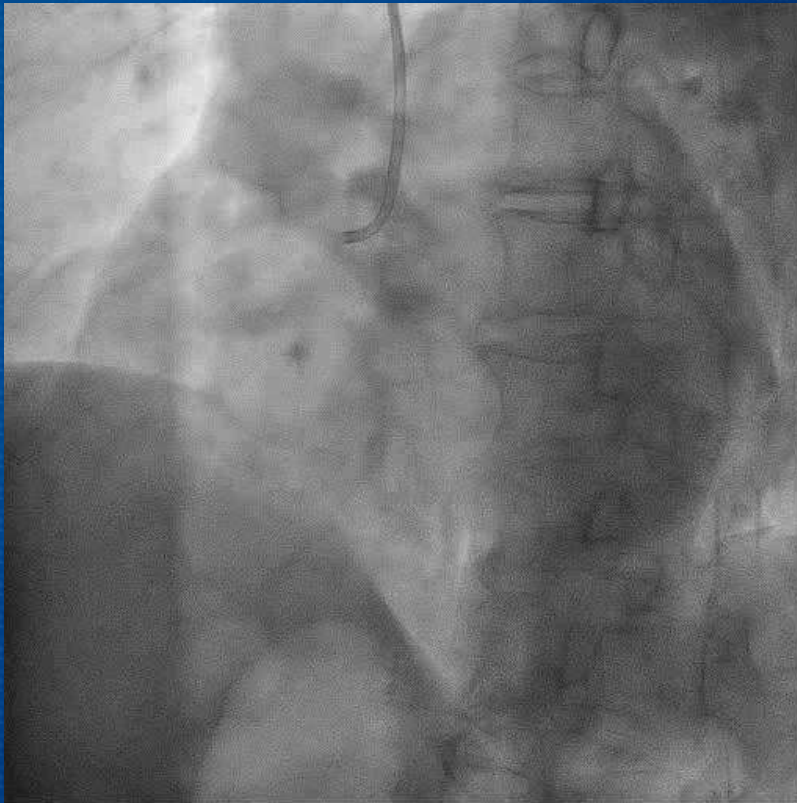
Case: 66/F, SA



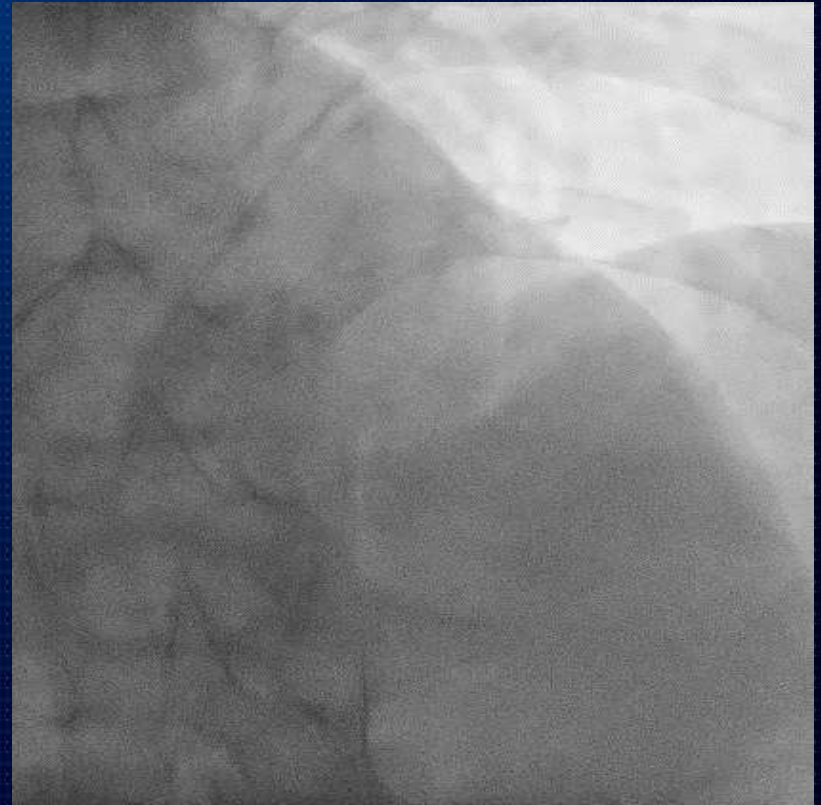
Post-DCB



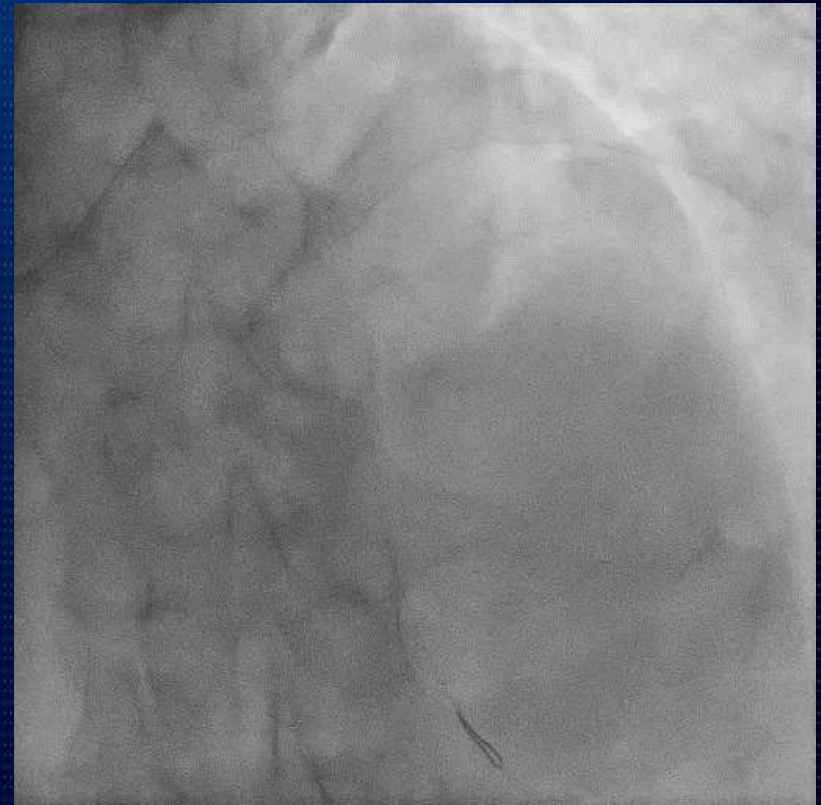
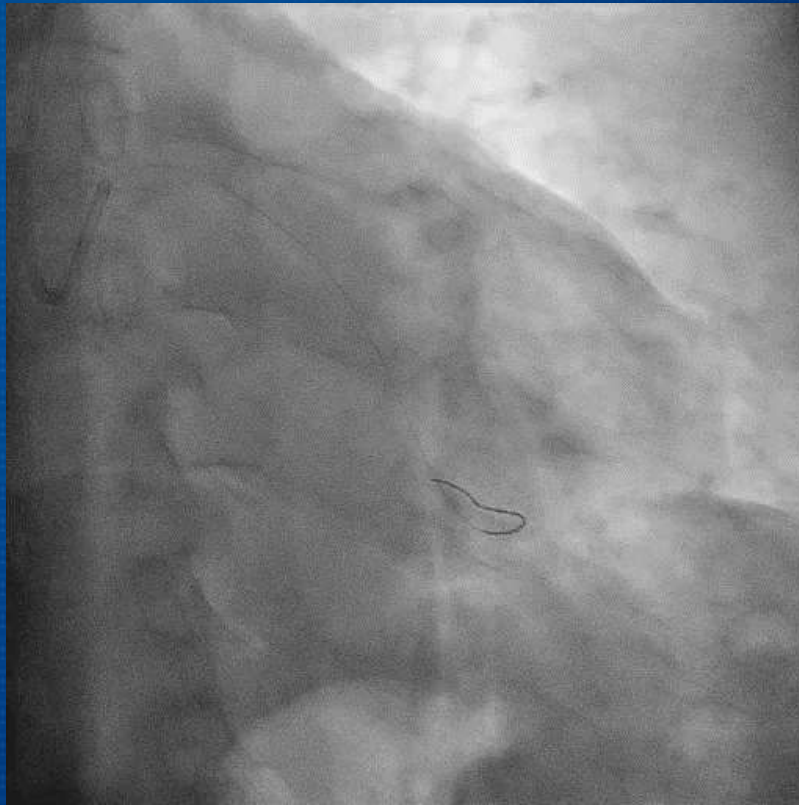
After 6-month



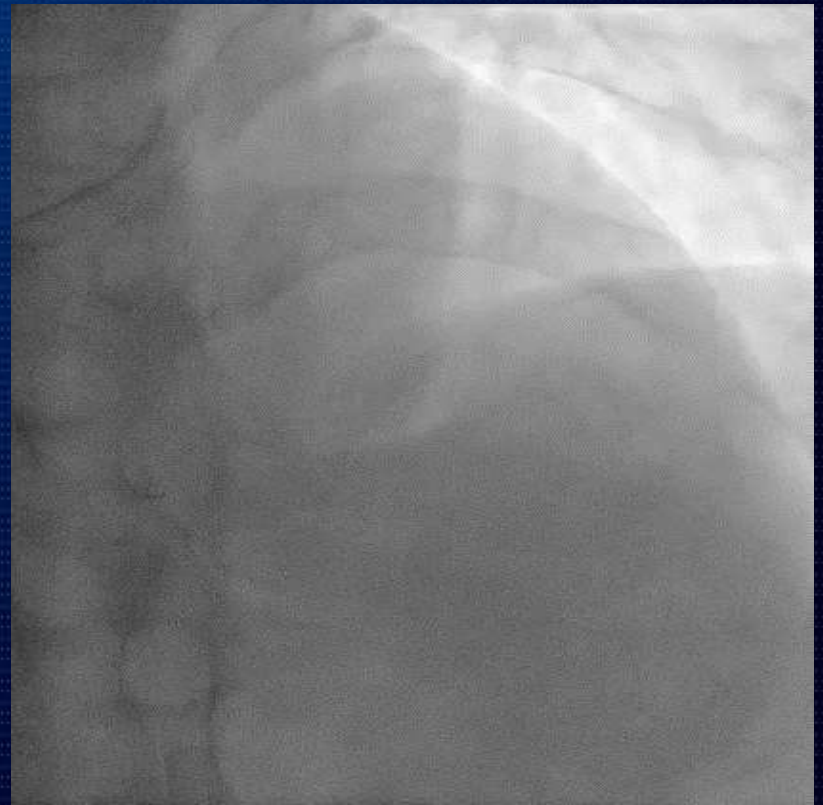
Case: 51/M, UA



Post-DCB treatment

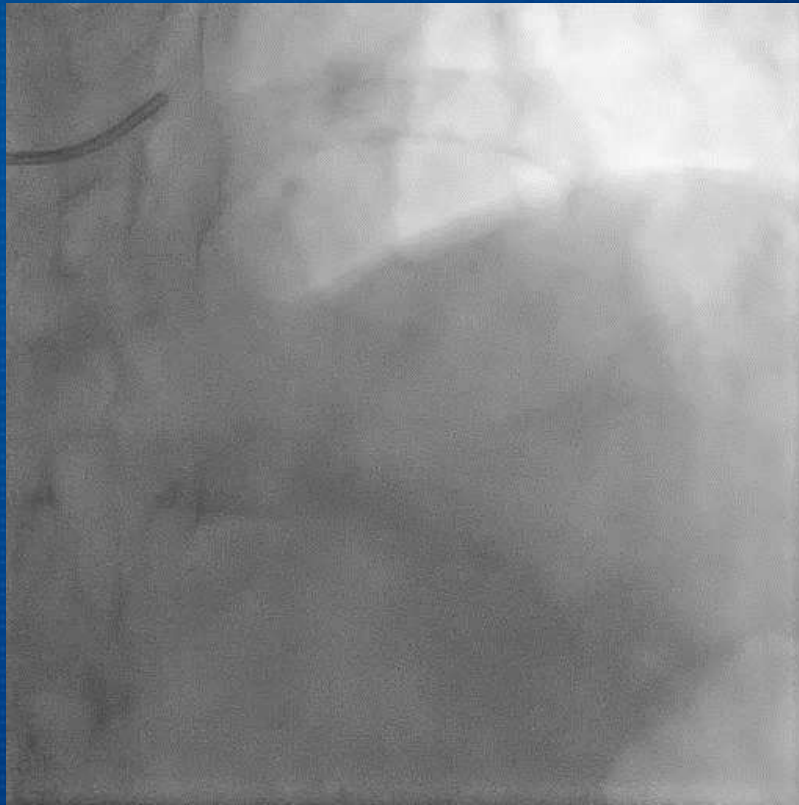


FU CAG

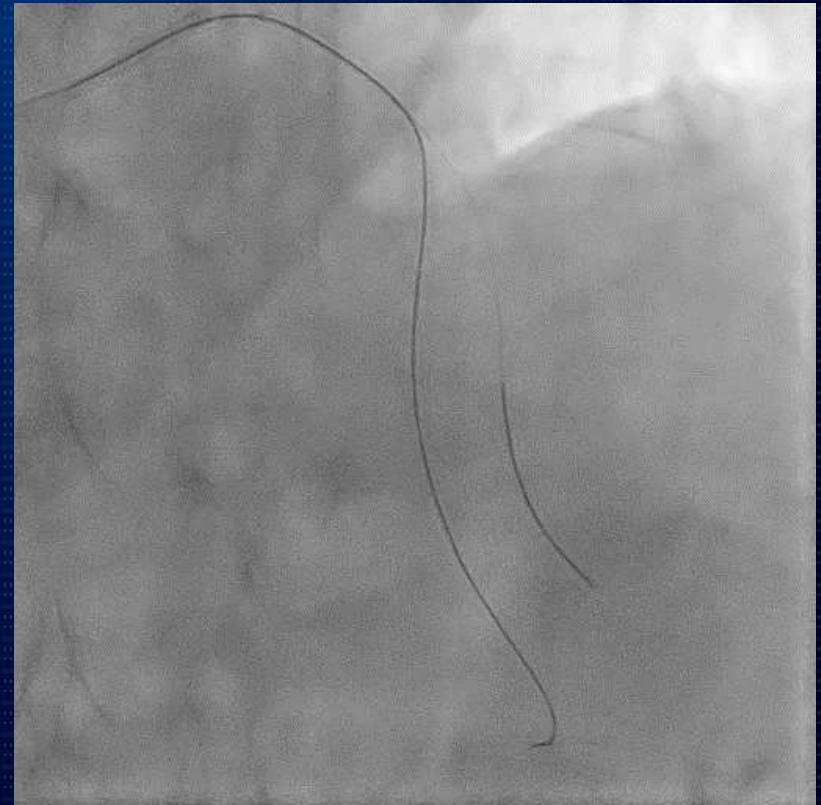


Case: F/82, SA

Baseline

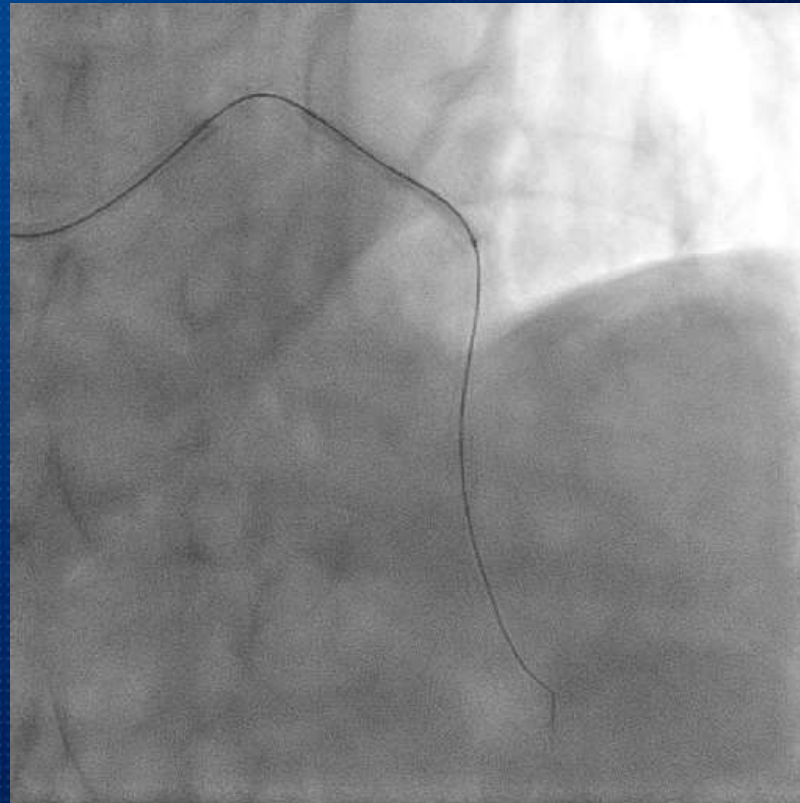


BA at LAD & Diagonal



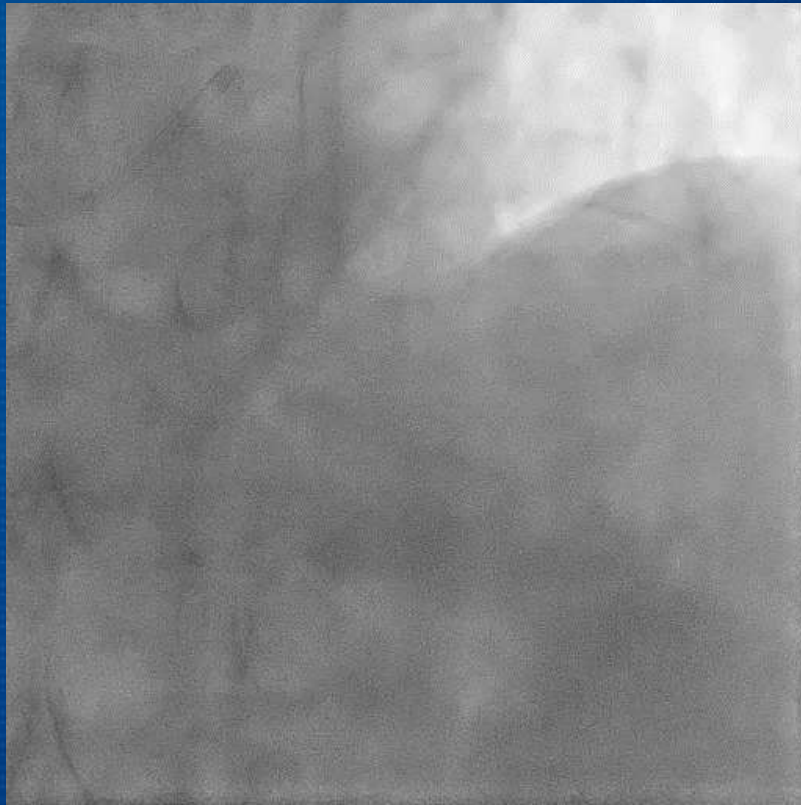
DCB at pLAD

DCB at pLAD

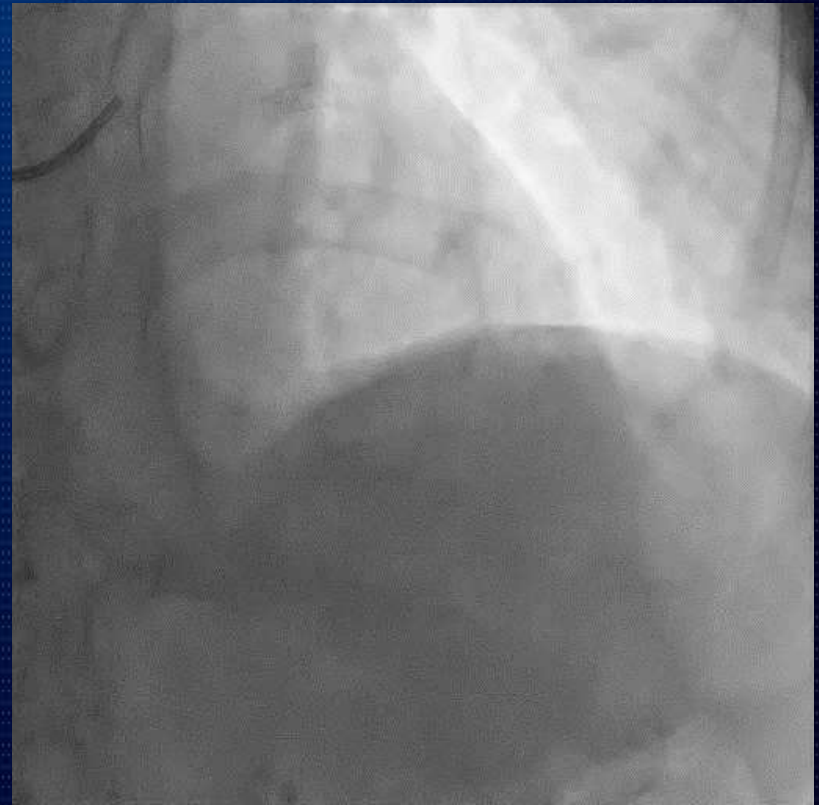


DCB treatment & FU

Post DCB



After 3 months

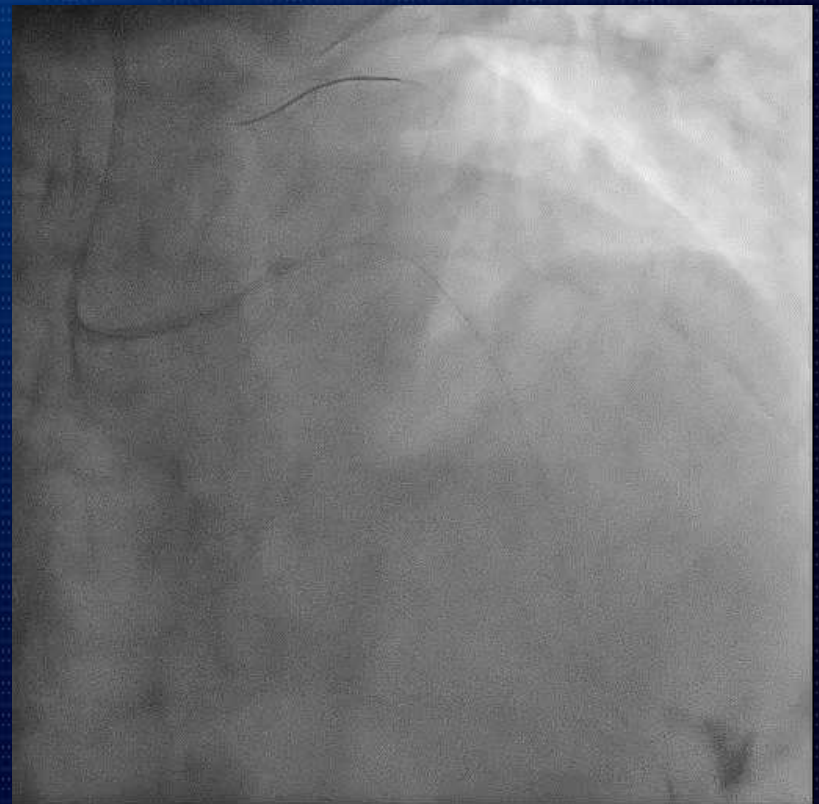
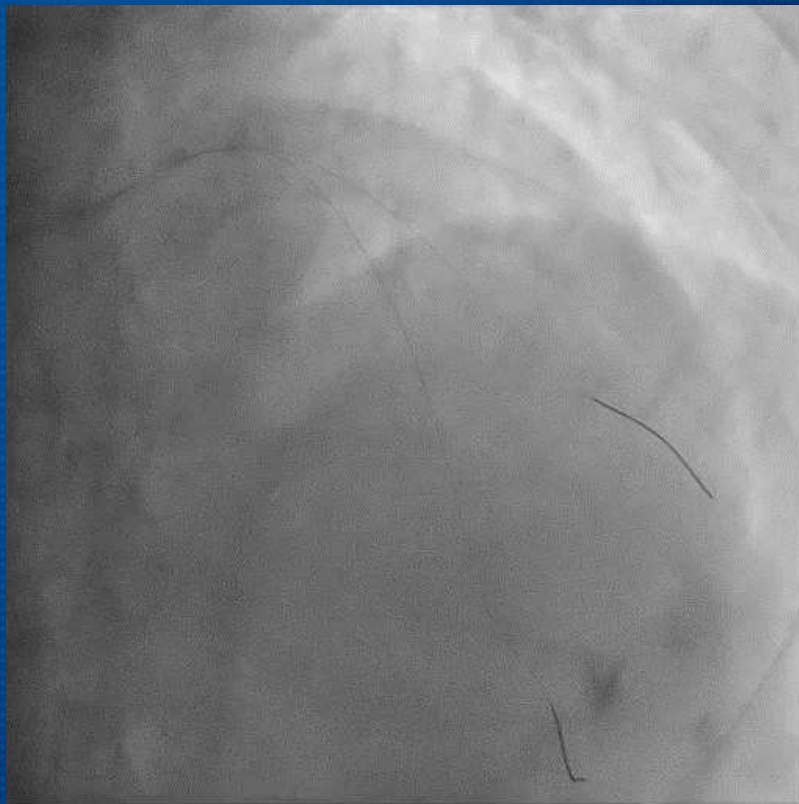


Currently asymptomatic for 25 months

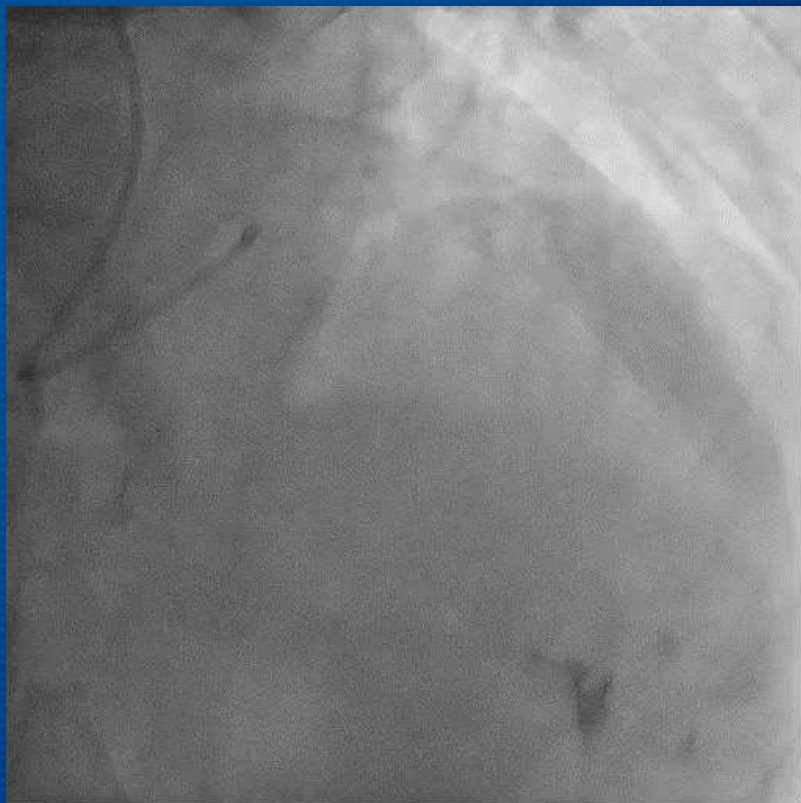
Case: 57/M, UA



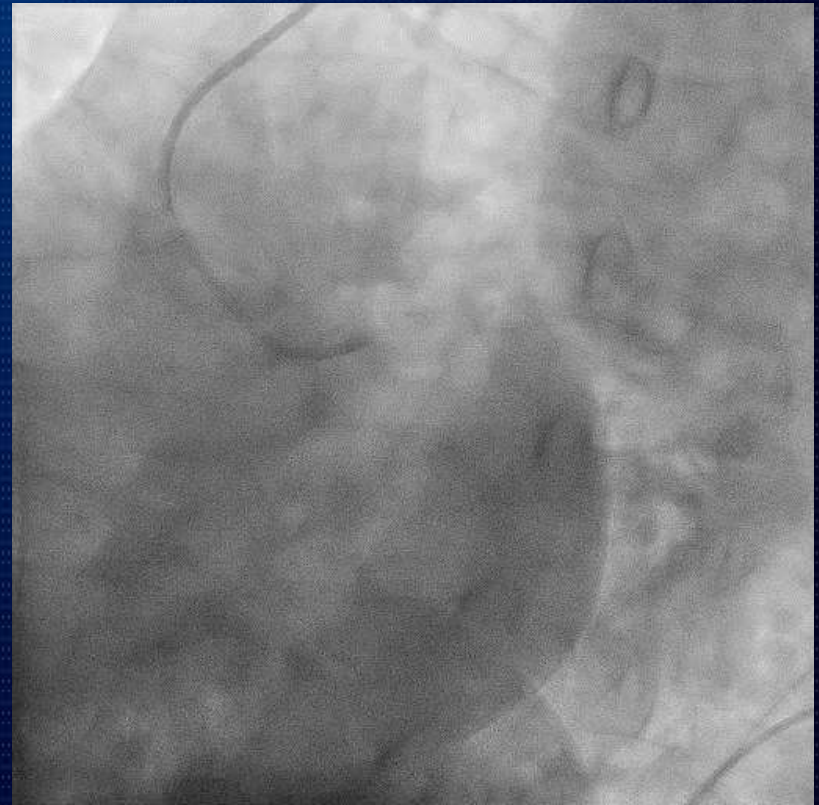
Sequential BA & DCB at mLAD



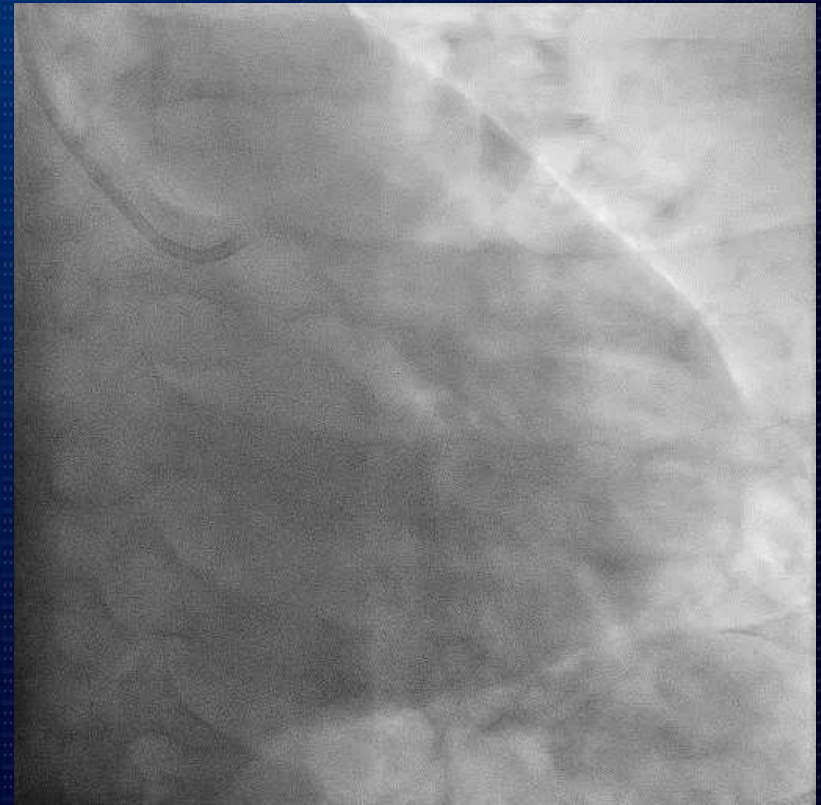
DCB at LM to LAD, RI, LCX



After 6 months



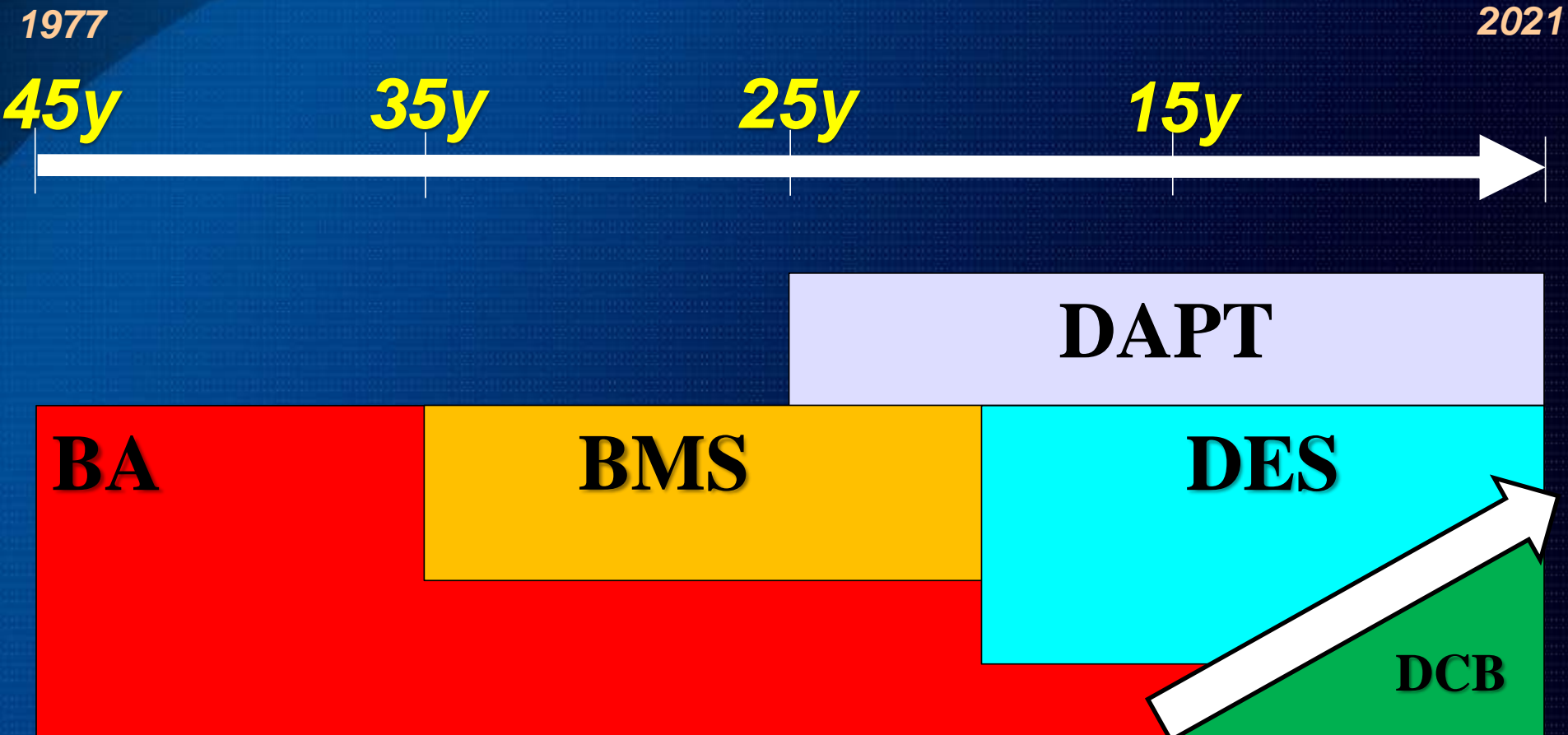
Baseline vs. 6 months



Advantages of DCB in CAD

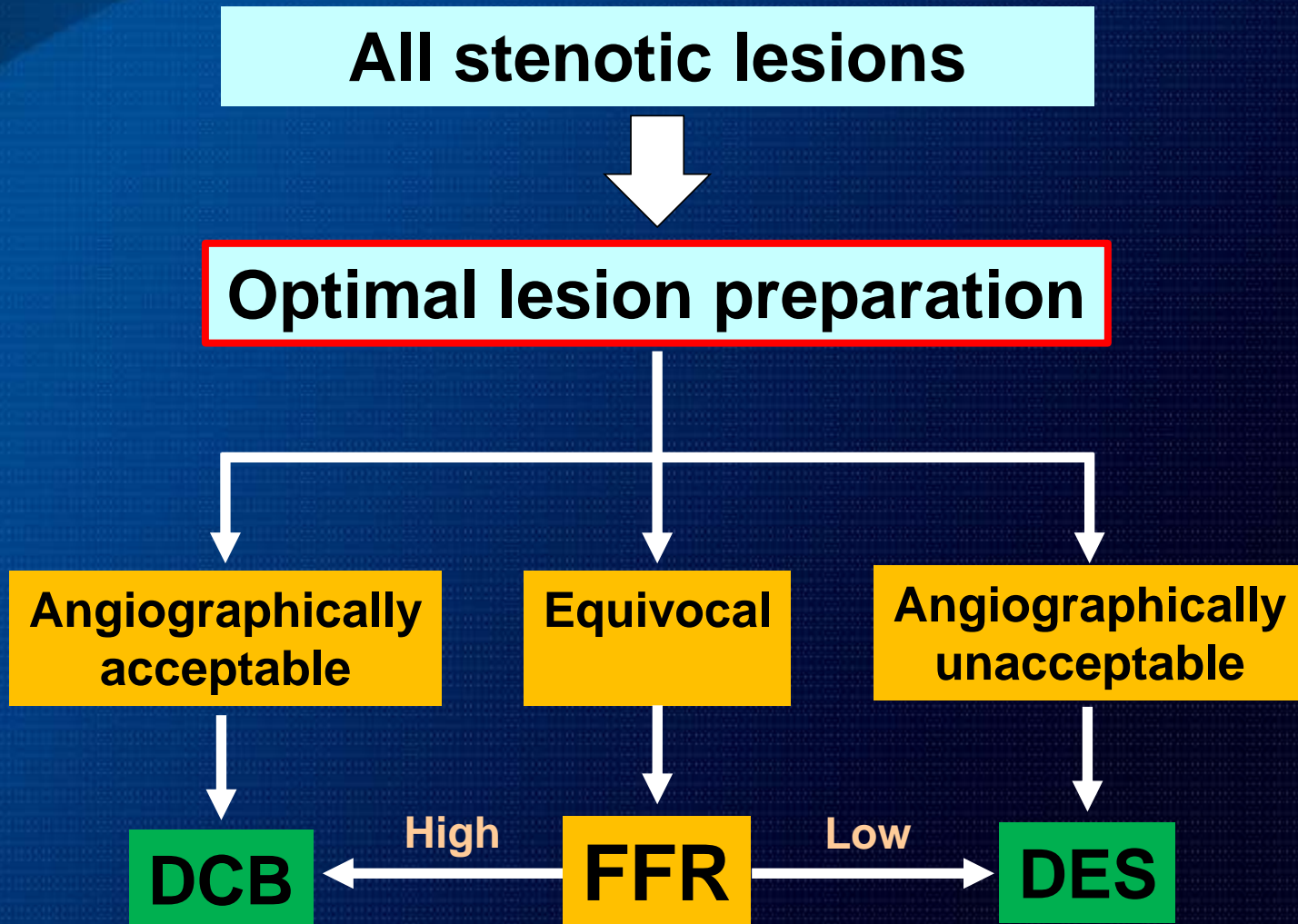
- Homogeneous drug transfer to the whole vessel wall
- Much lower inflammatory stimulus
- Lower rate of (very) late lesion thrombosis and restenosis
- Shorter duration of dual antiplatelet therapy

History of PCI



DCB as a New Paradigm of PCI

Provisional DCB strategy



Take Home Messages

- 1. The purpose of PCI is to reduce ischemia.**
- 2. Hyperemic flow is maintained up to 50% of DS → No need to make 0% residual DS with stenting**
- 3. 2% TLF after stent PCI continues to occur annually without plateau in ongoing risk.**
- 4. DCB is free from antiplatelet therapy and nevertheless rarely causes thrombotic events.**
- 5. DCB treatment without stenting is safe and effective treatment method for CTO lesions if the predilatation result is good with TIMI 3 flow.**
- 6. Randomized and controlled trials are necessary to further evaluate the DCB-only approach in all-comer lesions.**



Let's go to the next revolution!