Integrating drug eluting balloon into regular pci practice – our experience in Singapore

Dr Paul Ong
Head of Interventional Services
Tan Tock Seng Hospital
National Healthcare Group, Singapore

Tan Tock Seng
HOSPITAL

Caring for you since 1844

Tan Tock Seng HOSPITAL

Outline

- **Current indications**
- **Registry**
  - **Clinical characteristics**
  - **Clinical outcomes**
  - **Case highlights**

Tan Tock Seng HOSPITAL

European Heart Journal (2010) **31**, 2501–2555
doi:10.1093/eurheartj/ehq277

ESC/EACTS GUIDELINES

Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Developed with the special contribution of the European Association for Percutaneous Cardiovascular Interventions (EAPCI)‡

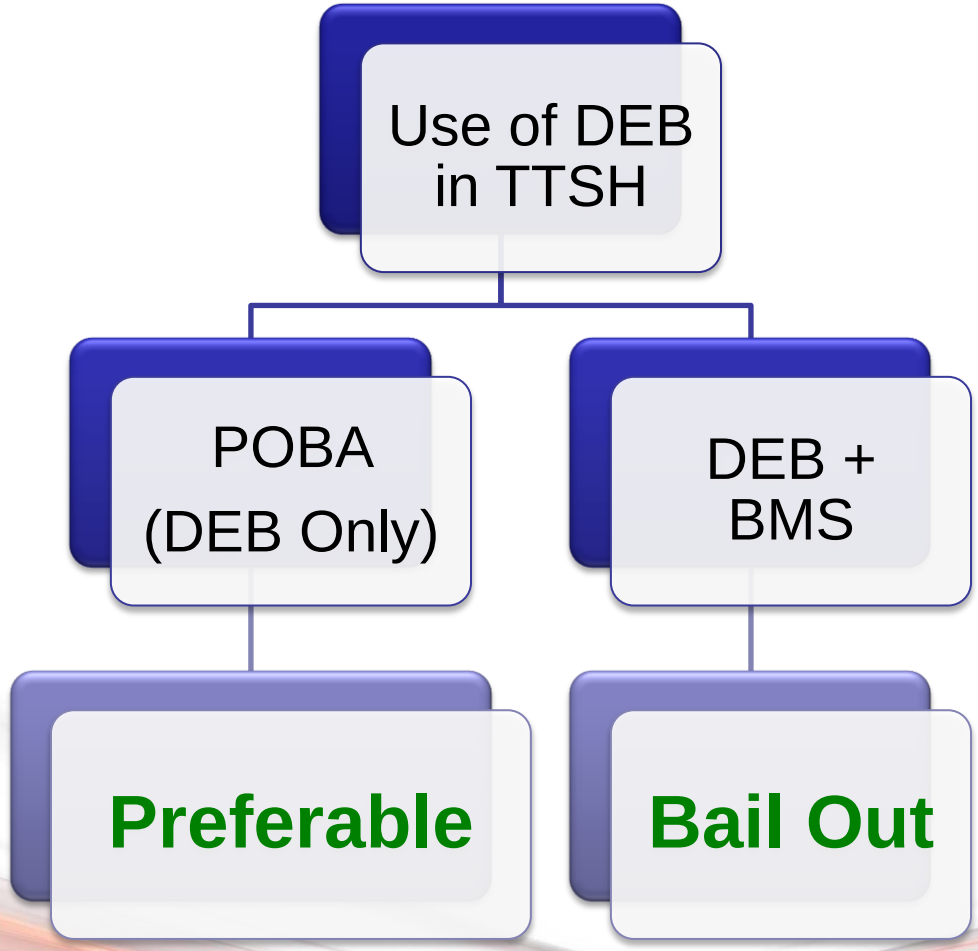
Table 33 Recommendations for specific percut

FFR-guided PCI is recommended for detection of ischaemia-relat ischaemia is not available.	I	A	15, 28
DES[d] are recommended for reduction of restenosis/re-occlusion, if no contraindication to extended DAPT.	I	A	45, 46, 55, 215
Distal embolic protection is recommended during PCI of SVG disease to avoid distal embolization of debris and prevent MI.	I	B	171, 213
Rotablation is recommended for preparation of heavily calcified or severely fibrotic lesions that cannot be crossed by a balloon or adequately dilated before planned stenting.	I	C	—
Manual catheter thrombus aspiration should be considered during PCI of the culprit lesion in STEMI.	IIa	A	204–208
For PCI of unstable lesions, i.v. abciximab should be considered for pharmacological treatment of no-reflow.	IIa	B	55, 209, 212
Drug-eluting balloons[d] should be considered for the treatment of in-stent restenosis after prior BMS.	IIa	B	
Proximal embolic protection may be considered for preparation before PCI of SVG disease.	IIb	B	214
For PCI of unstable lesions, intracoronary or i.v. adenosine may be considered for pharmacological treatment of no-reflow.	IIb	B	209
Tornus catheter may be used for preparation of heavily calcified or severely fibrotic lesions that cannot be crossed by a balloon or adequately dilated before planned stenting.	IIb	C	—
Cutting or scoring balloons may be considered for dilatation of in-stent restenosis, to avoid slipping-induced vessel trauma of adjacent segments.	IIb	C	—

Tan Tock Seng HOSPITAL

Current Indications for DEB

- **Bare metal ISR**
- **DES ISR**
- **Small vessel disease**



Conditions where DEB maybe useful in the real world

- **Patients who will benefit from shortened duration of DAPT e.g those with increased bleeding risk, who require long term anti-coagulation, requires early surgery, non-compliant to medications, etc.**
- **Specific situations in which stent implantation is to be avoided.**

Tan Tock Seng HOSPITAL

Important Principles

Use of DEB in PCI

DEB-only (preferred approach)

** Predilate lesion before treating with DEB

**** ADEQUATE LESION PREPARATION (Scoreflex/Angiosculpt)**

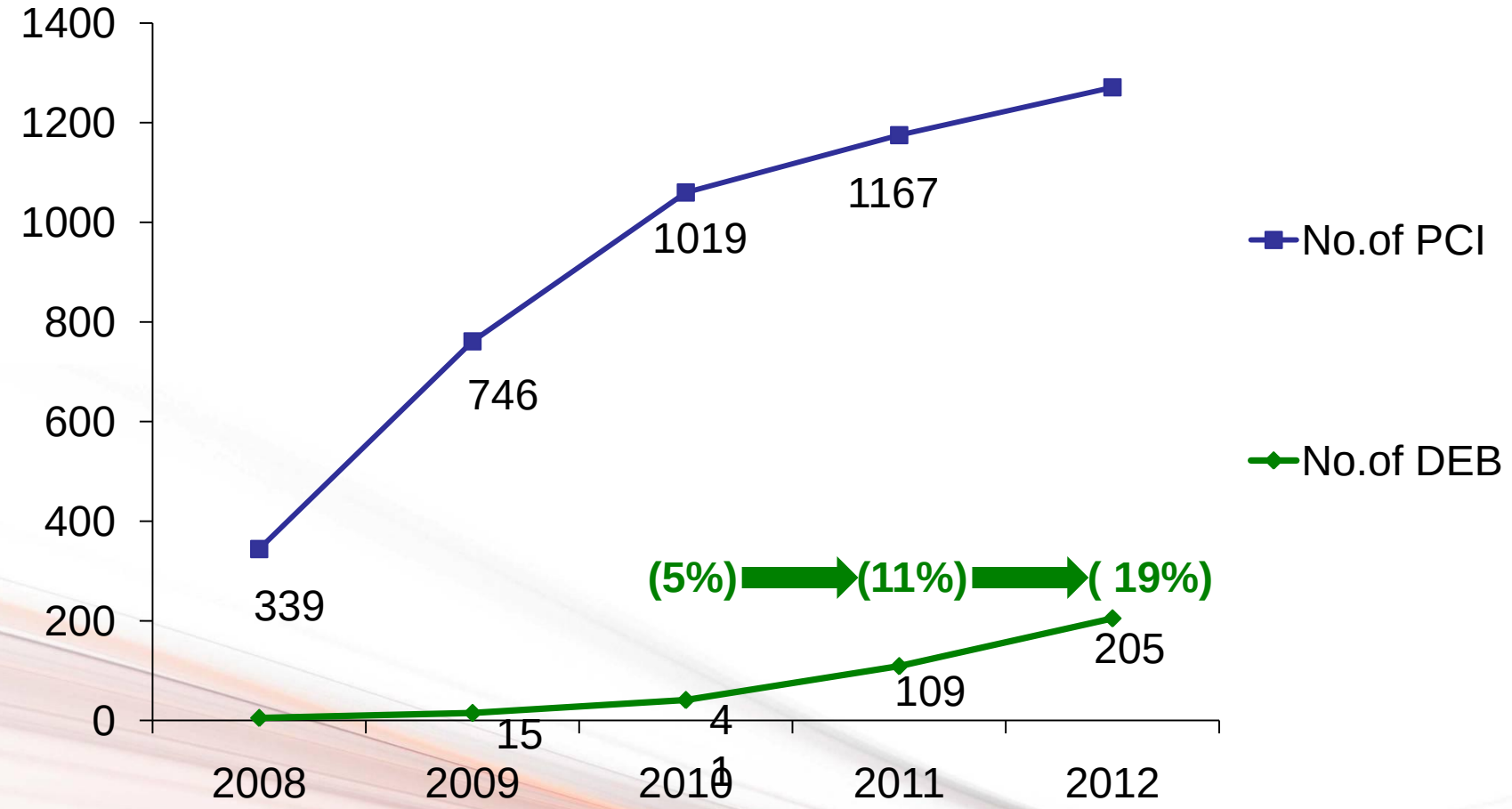
DAPT: 4 weeks

DEB + BMS

** Length of DEB > BMS

DAPT : 6 months

Angioplasty Trends in TTSH (Year 2008 to 2012)



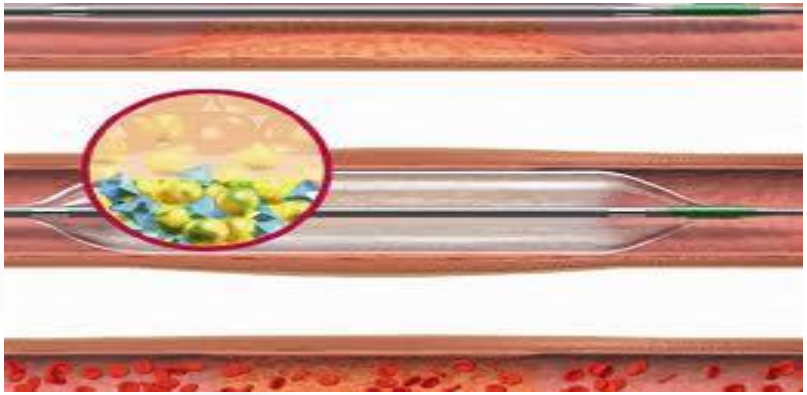
Tan Tock Seng HOSPITAL

SeQuent Please DEB

Paccocath Technology

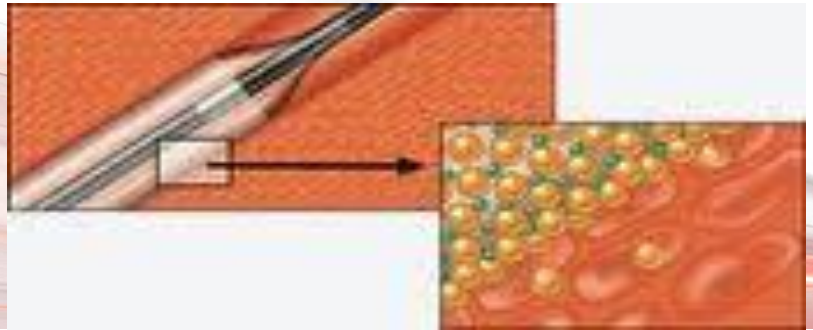
Combines targeted drug delivery with PTCA balloon

Balloon surface in contact with vessel wall



30s balloon inflation for effective drug delivery to vessel wall

Paclitaxel migrates into vessel wall



Paclitaxel migrates into SMC to prevent proliferation

TTSH SeQuent Please Registry

Study Period	Jan 2010 to	Dec 2012
Number of patients	339	
Number of lesions	356	
Gender M:F	76:24	
Mean age	**61.5 ± 11 yrs**	

Clinical Presentation	N	(%)
STEMI	51	(15)
NSTEMI / UAP	203	(60)
Angina	85	(25)
LVEF (%)		45 ± 13

Tan Tock Seng HOSPITAL

TTSH SeQuent Please Registry

Baseline Clinical Characteristics	%
Smoking	55.2
Diabetes	48.8
Hypertension	80.1
Hyperlipidaemia	81.7
Prior MI	31.5
Prior PCI	42.8
Prior CABG	7.4

Tan Tock Seng HOSPITAL

TTSH SeQuent Please Registry

Indications for DEB	N	(%)
Small Vessel Disease (≤2.8mm)	190	(53.4)
Instent Restenosis	78	(22)
Bifurcation	20	(5.6)
De novo (>2.8mm)	21	(5.9)
Others	47	(13.2)

Tan Tock Seng HOSPITAL

TTSH SeQuent Please Registry

Instent ReStenosis	N	(%)
Bare metal stent ISR	45	(58)
Drug eluting stent ISR	33	(42)

Types of ISR (Mehran Classification)		
Type I	41	(53)
Type II	21	(27)
Type III	5	(6)
Type IV	11	(14)

Tan Tock Seng HOSPITAL

TTSH SeQuent Please Registry

Angiographic and Procedural Variables:

No. of vessel disease	N	(%)
Single vessel disease	75	(22)
Double vessel disease	118	(35)
Triple vessel disease	146	(43)
Glycoprotein IIb/IIIa inhibitors	228	(67)

Tan Tock Seng HOSPITAL

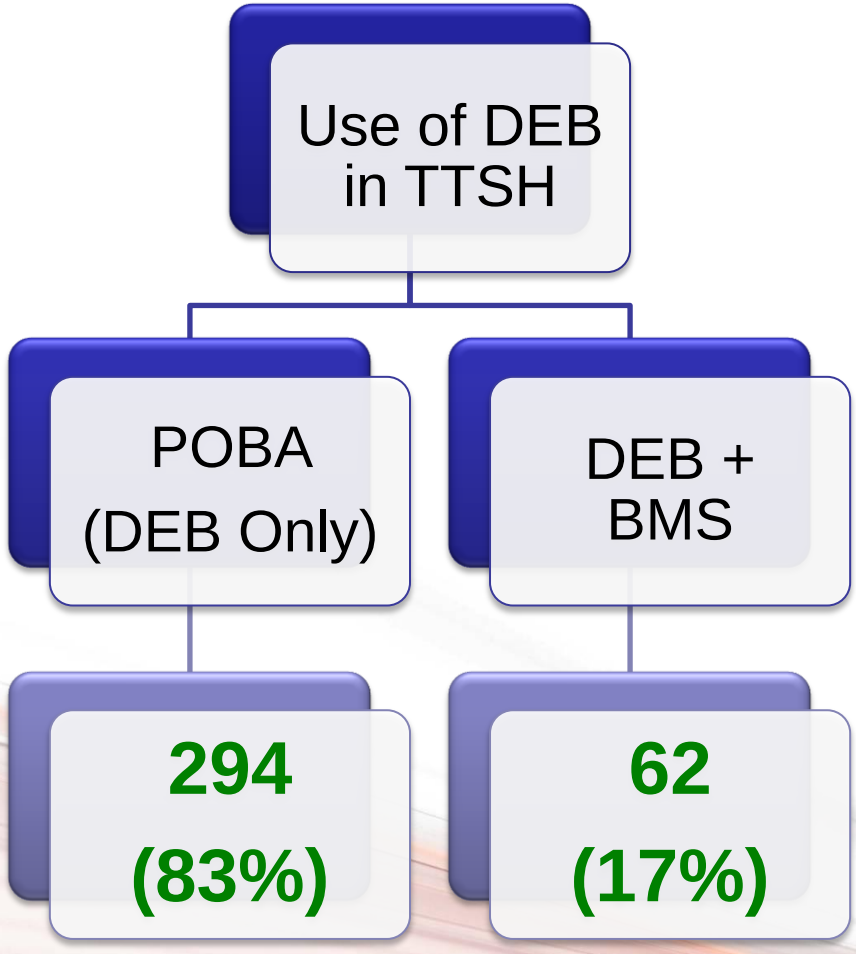
TTSH SeQuent Please Registry

Target Vessel for PCI	N	(%)
LAD	133	(37.0)
RCA	66	(18.5)
Circumflex	60	(17.0)
Others*	97	(27.5)

*** Others include side-branches, SVG and left main**

Tan Tock Seng HOSPITAL

TTSH SeQuent Please Registry



Mean number of DEB	**1.25 ± 0.5**
Mean size of DEB, mm	**2.6 ± 0.6**
Length of DEB, mm	**24.6 ± 12.1**

Tan Tock Seng HOSPITAL

TTSH SeQuent Please Registry

Clinical Outcomes (In-hospital)	N	(%)
CVS mortality*	**3**	**(0.9)**
MI	**0**	**(0)**
TLR	**0**	**(0)**
Lesion thrombosis	**0**	**(0)**

**3 deaths : AMI and cardiogenic shock*

Tan Tock Seng HOSPITAL

TTSH SeQuent Please Registry

Clinical Outcomes (9 month)	N = 195	(%)
CVS mortality*	0	(0)
MI	5	(2.5)
TLR	8	(4.1)
Lesion thrombosis	0	(0)

Composite MACE at 9 months: 4.6% (9 patients)

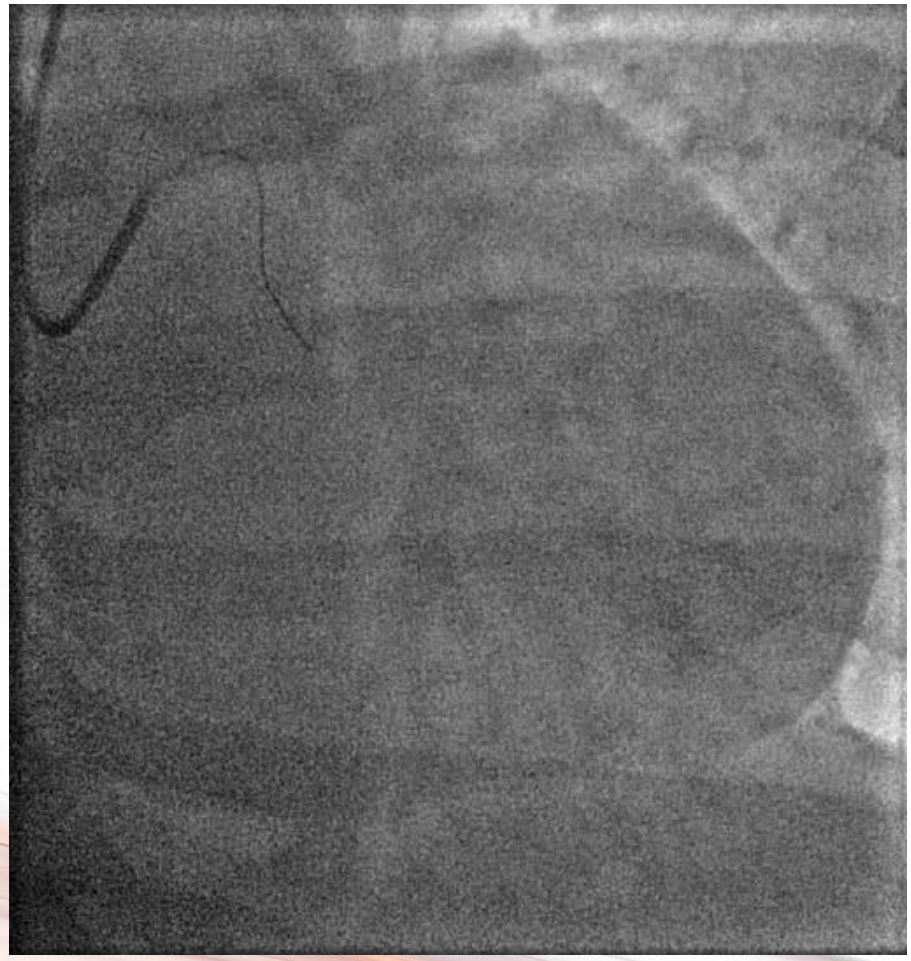
CASE HIGHLIGHTS

Tan Tock Seng HOSPITAL

DEB for NSTEMI

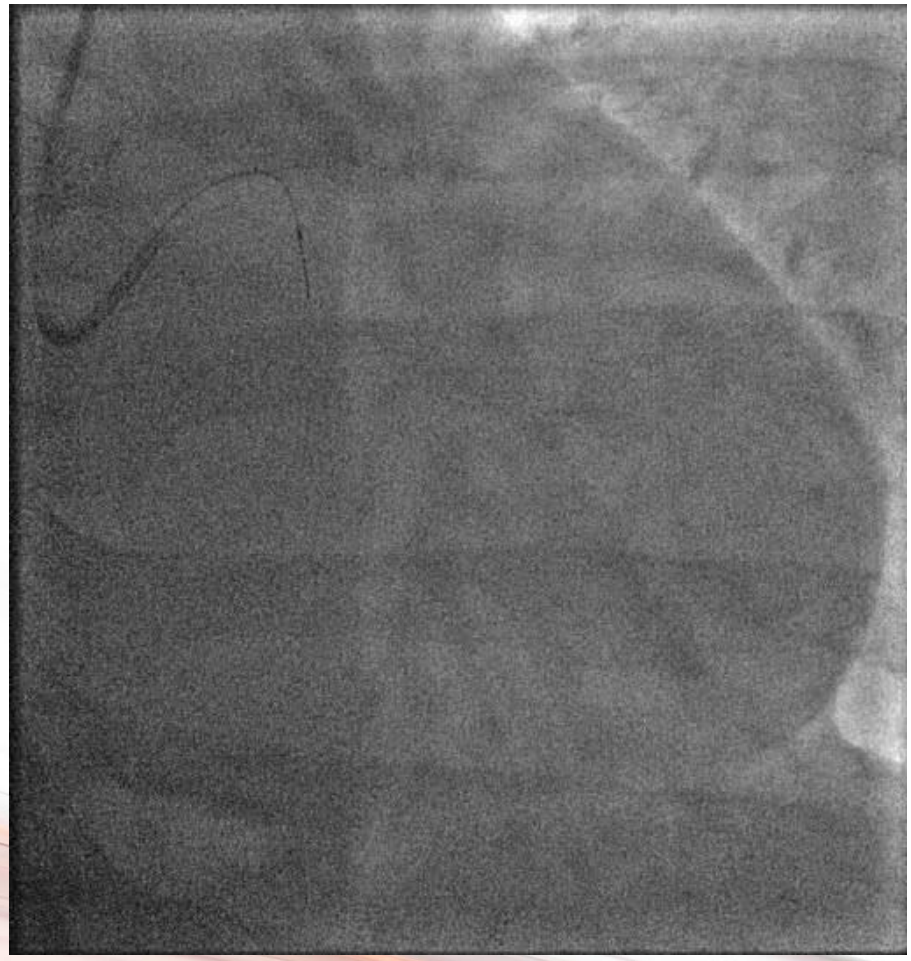
F/40 **Presented with** anginal chest pain, raised Troponin with no ECG changes

Tan Tock Seng
HOSPITAL

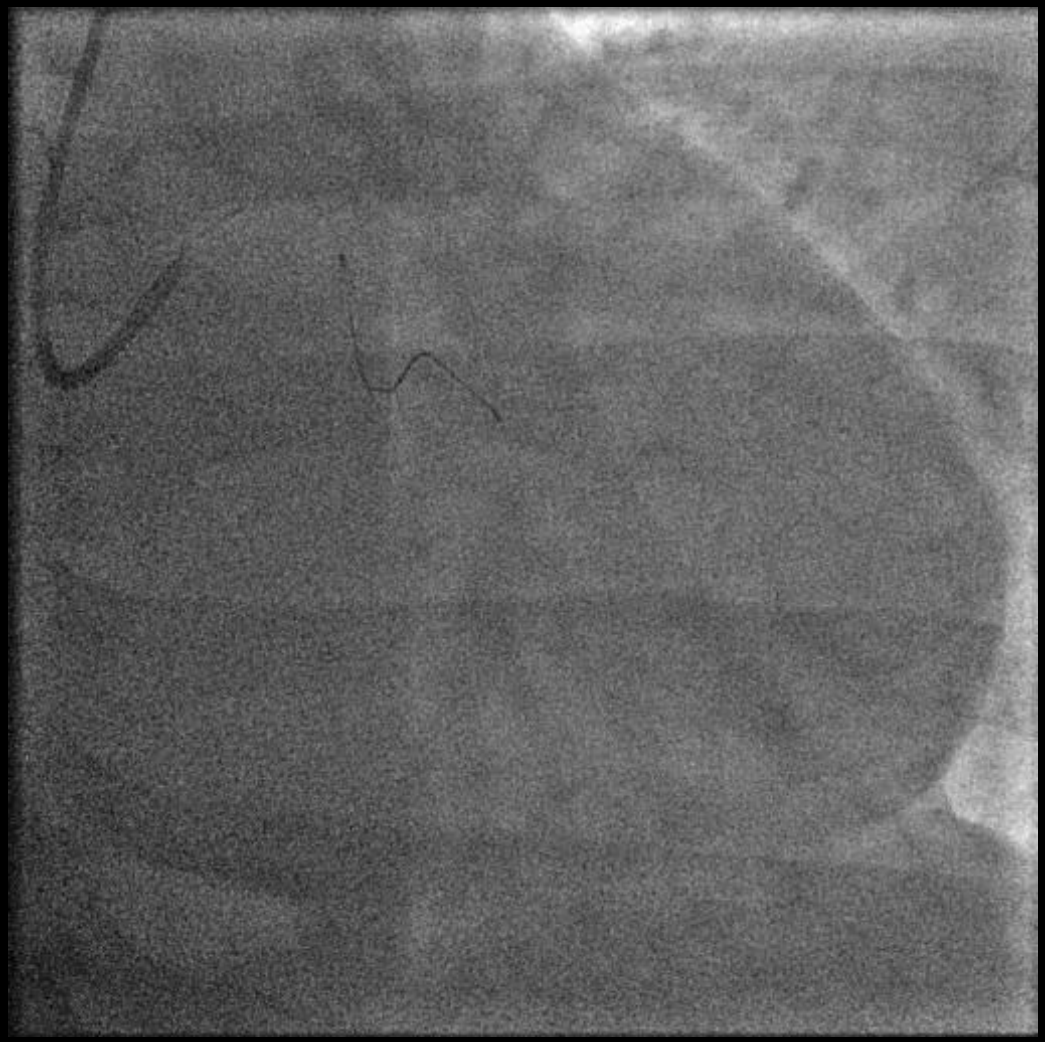


Tan Tock Seng HOSPITAL

Bifurcation lesion in Cx

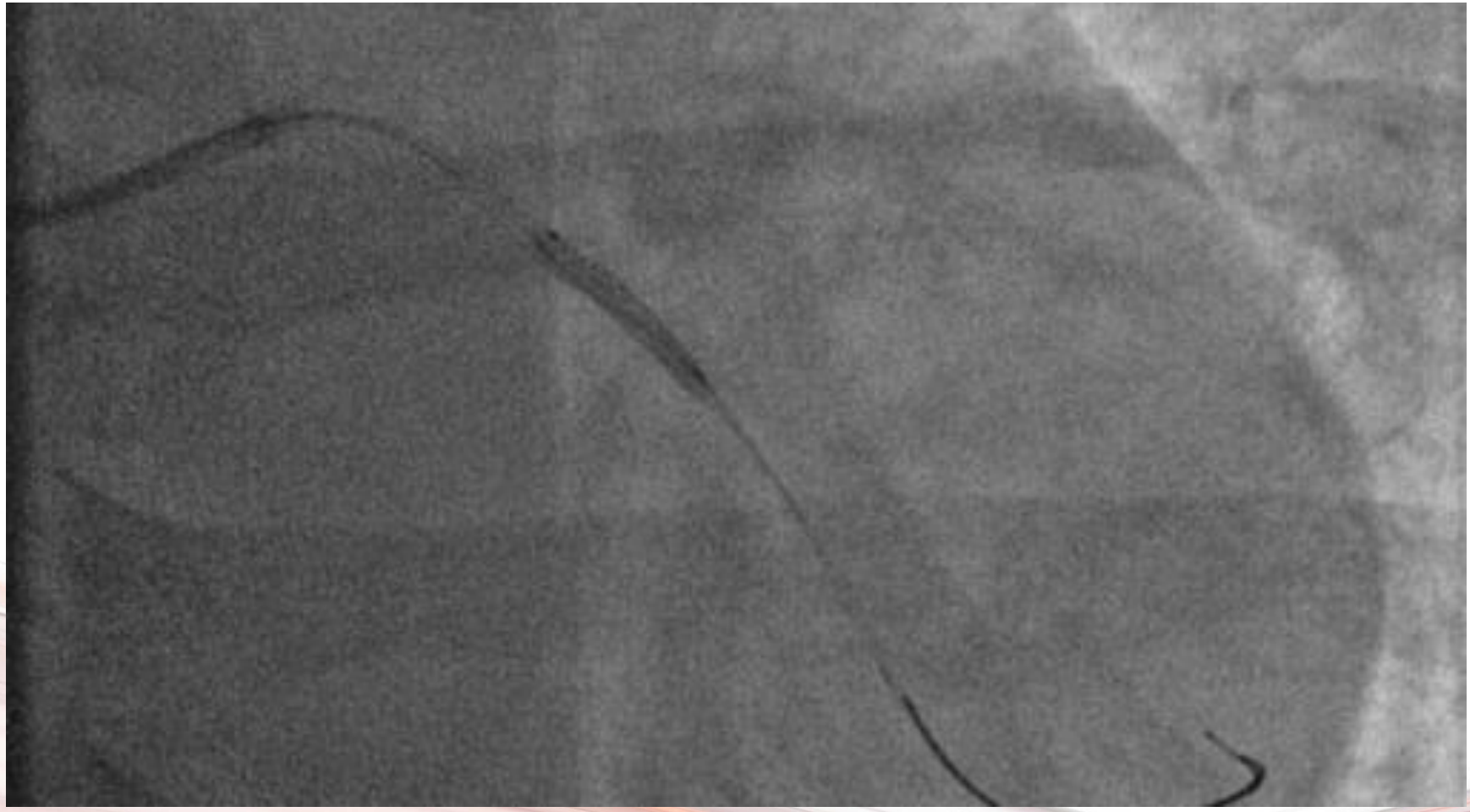


Tortuous OM1



Tan Tock Seng
HOSPITAL

Scoreflex 1:1 ratio

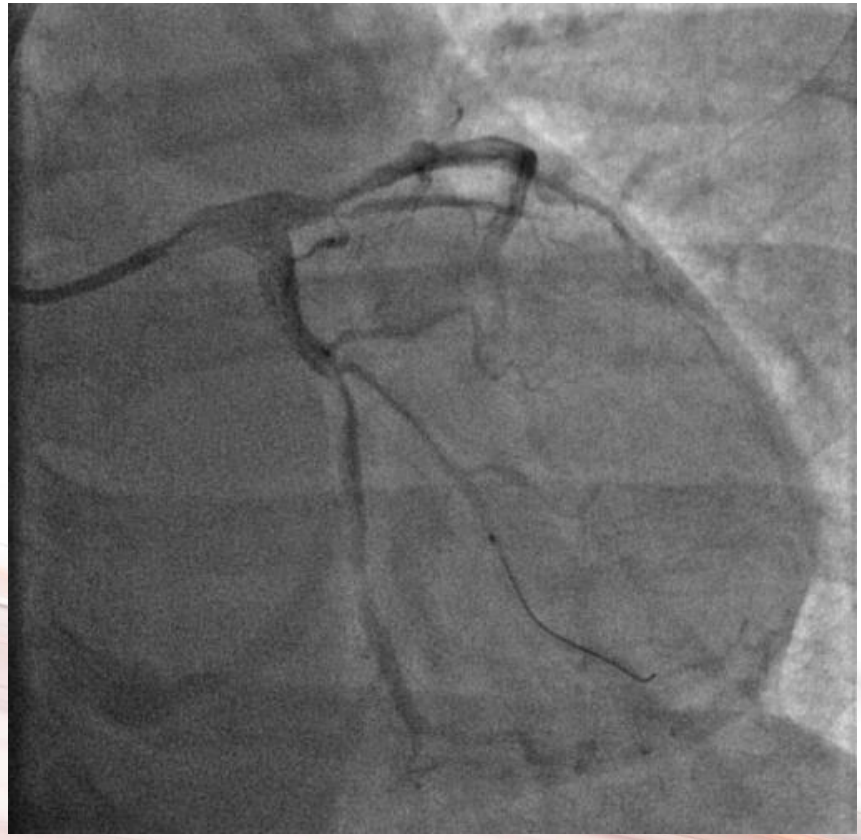


Post POBA

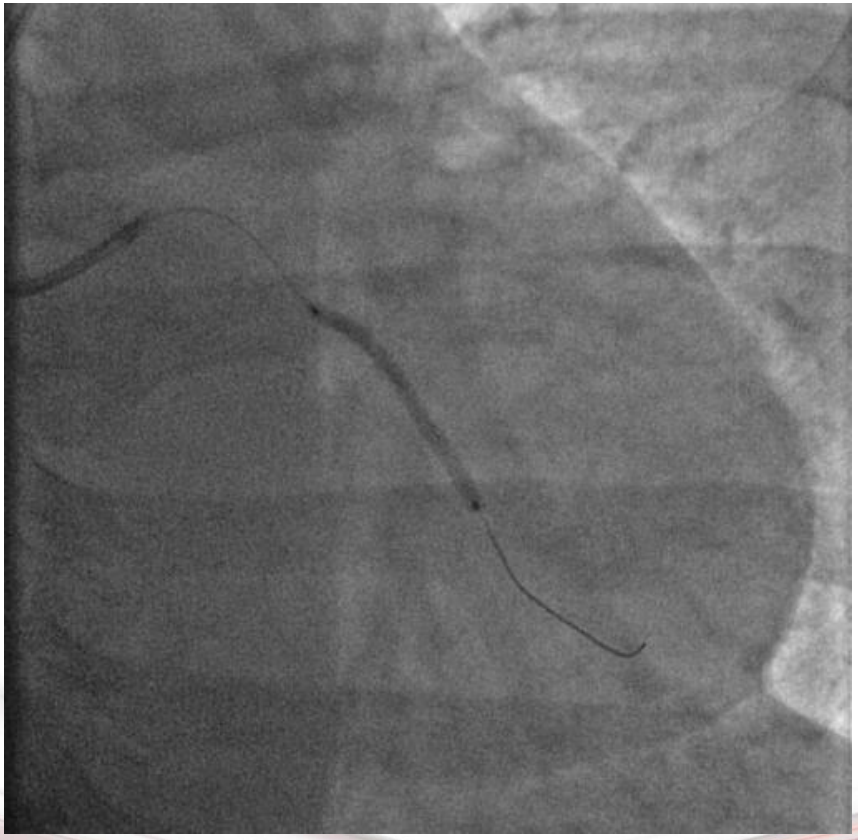
Tan Tock Seng HOSPITAL

DEB for NSTEMI

Positioning DEB (no mismatch)

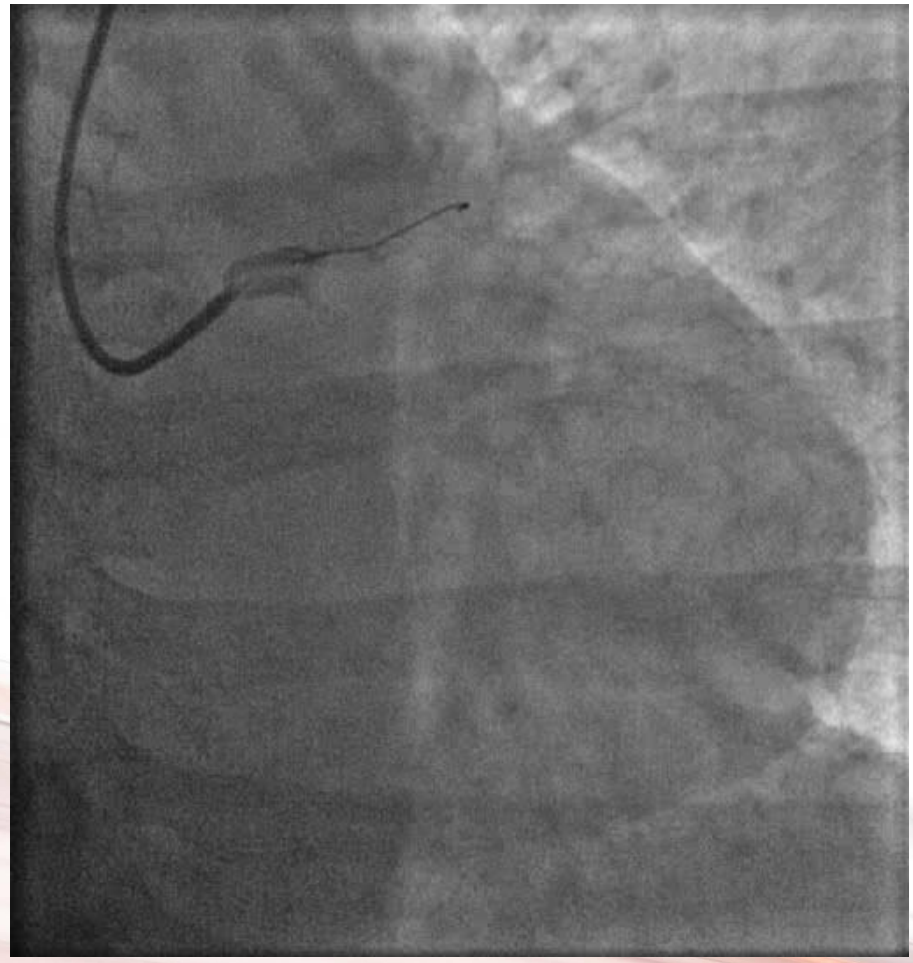


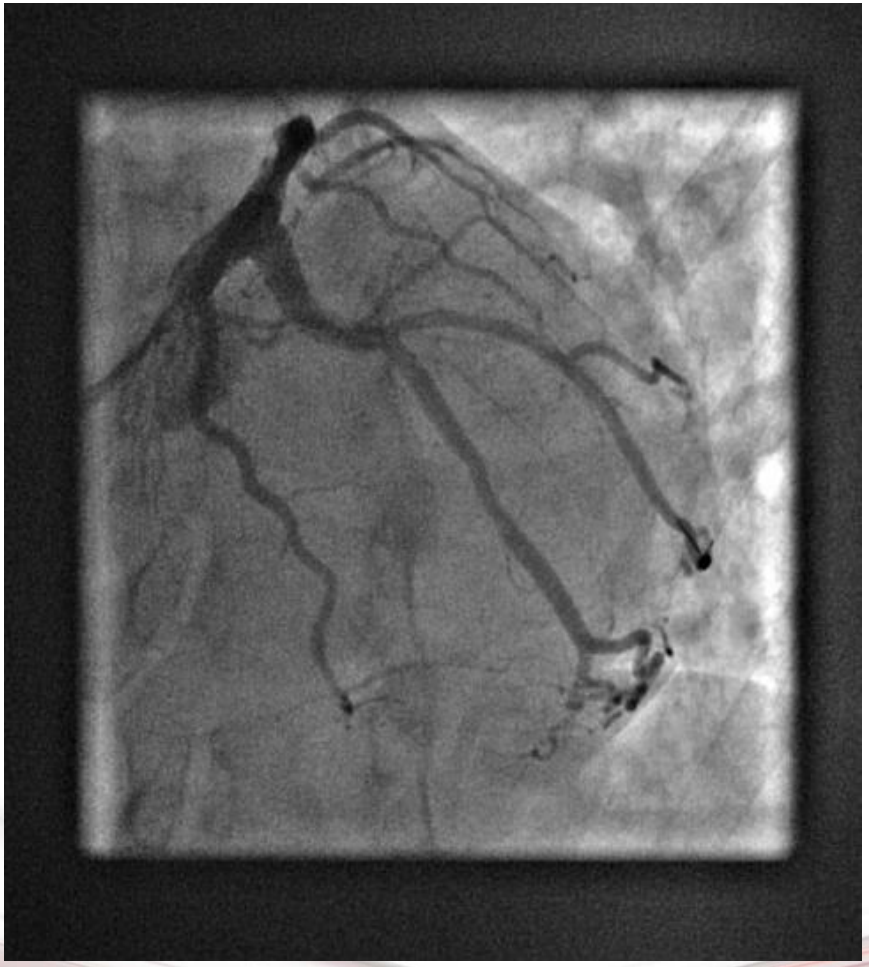
SeQuent Please 2.5*30mm



Tan Tock Seng HOSPITAL

Final Result





FFR or LAD > 0.80

Tan Tock Seng HOSPITAL

Tips

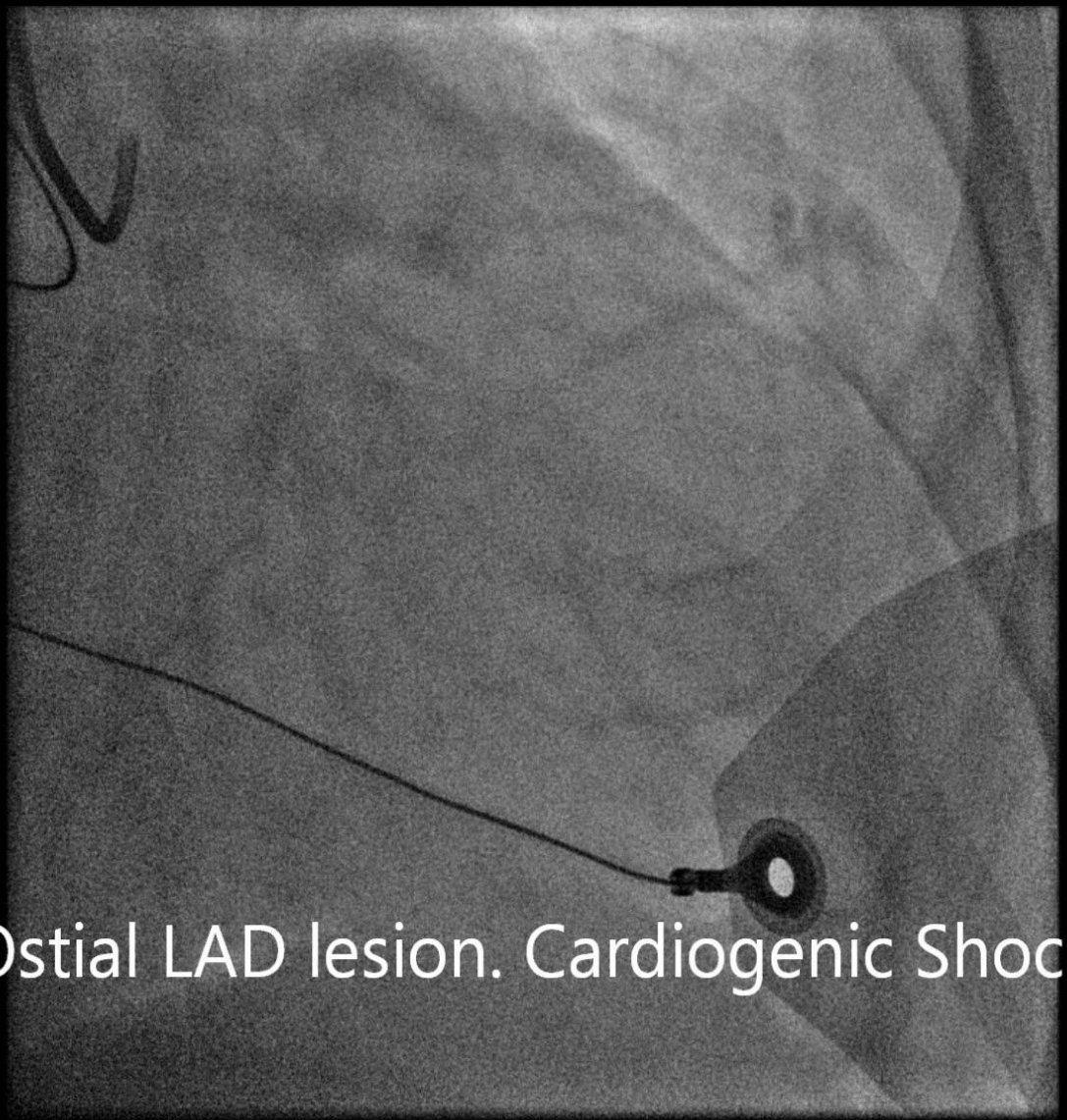
- Adequate predilatation
- Residual restenosis <30%
- Cutting balloon used
- Avoid geographic mismatch ie DEB always cover POBA'd segment
- Low pressure deployment of DEB at 8 atm
- 30s to 45s inflation time

Tan Tock Seng HOSPITAL

Tips

- Hybrid approach
- DES to proximal segment
- DEB to distal segment to ensure good outflow

Novel Use of DEB

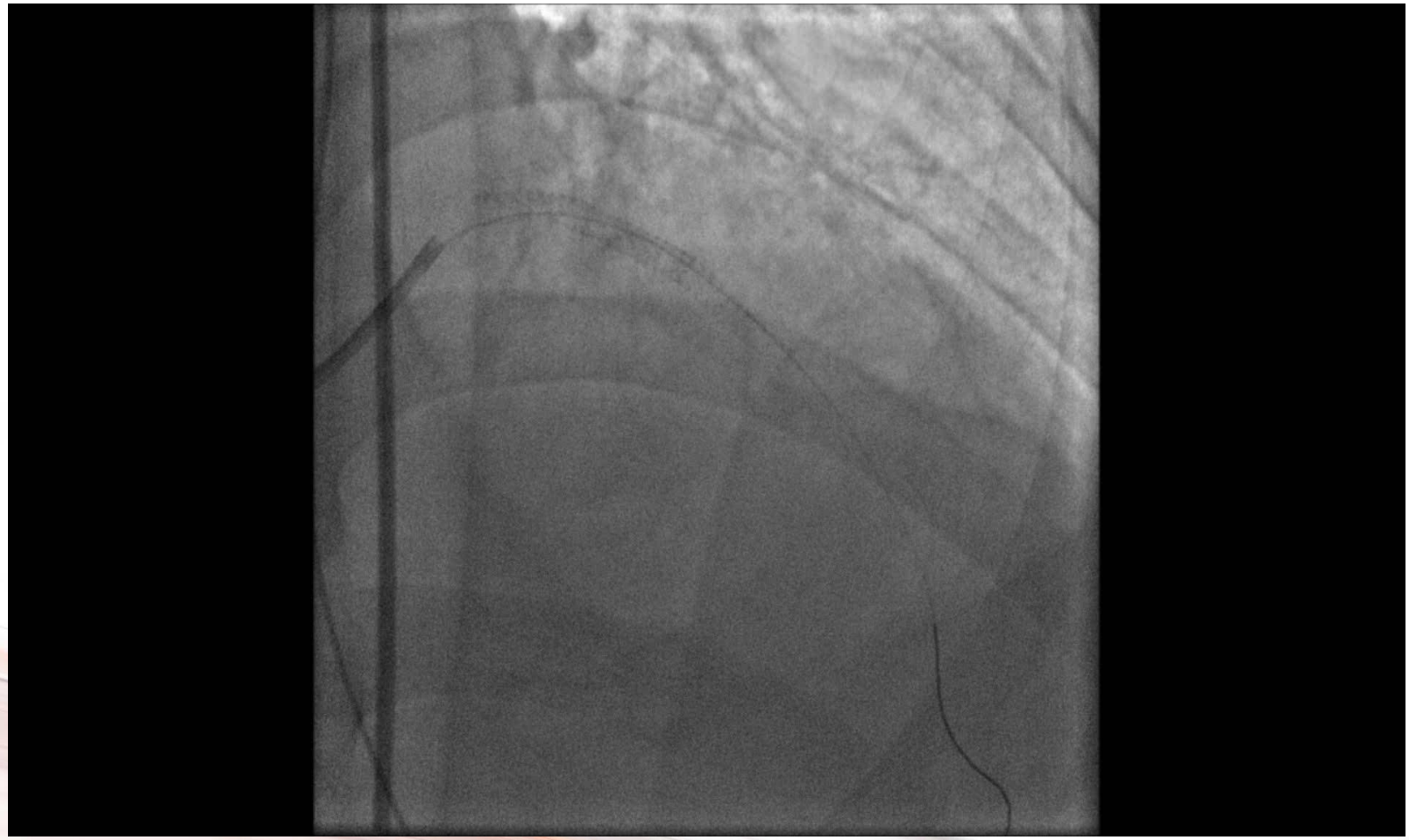


Ostial LAD lesion. Cardiogenic Shock

Tan Tock Seng HOSPITAL

CTO of RCA. On triple inotropes

IABP plus NA, Dopamine and Dobutamine with SBP at 50mmHg Intermittent CPR



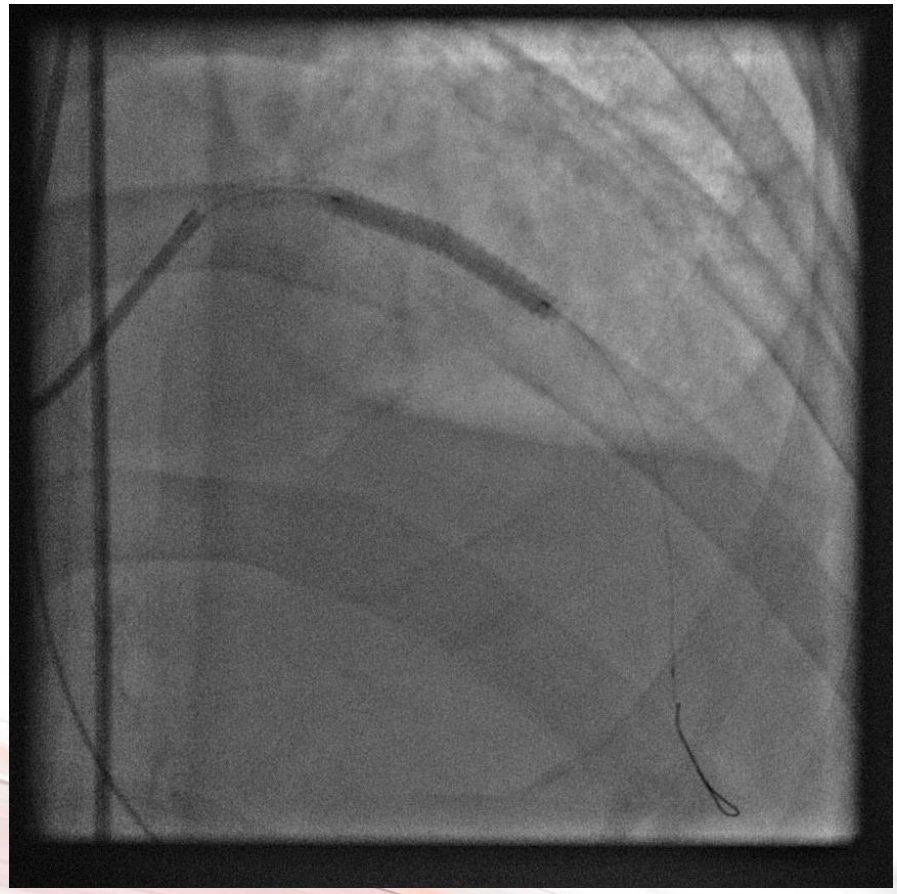
2 long bare metal stents in left main-LAD
3.5 x 28mm ; 3.0 x 18mm stents

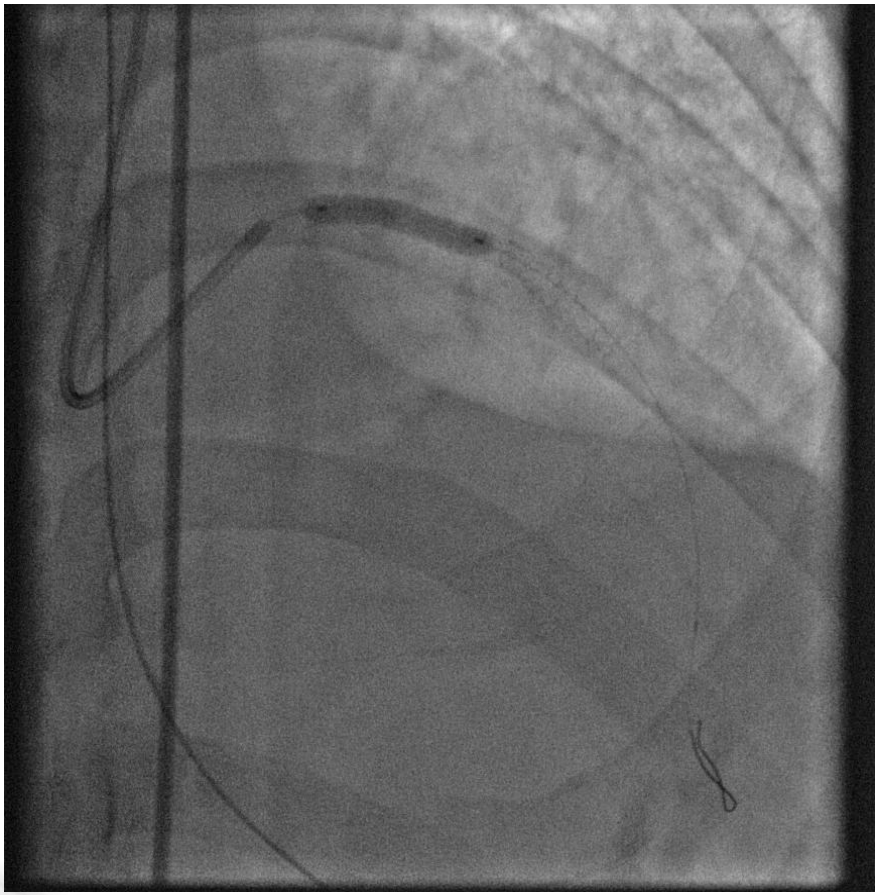
Tan Tock Seng HOSPITAL

Novel Use of DEB

- **Pt was critically ill and required IABP and triple inotropes with intermittent CPR**
- **Condition stabilised and improved**
- **Brought back to cath.lab 2 days later for relook angiogram + IVUS +/- stent optimisation**
- **IVUS showed underexpanded stents in left main and LAD**

Tan Tock Seng
HOSPITAL

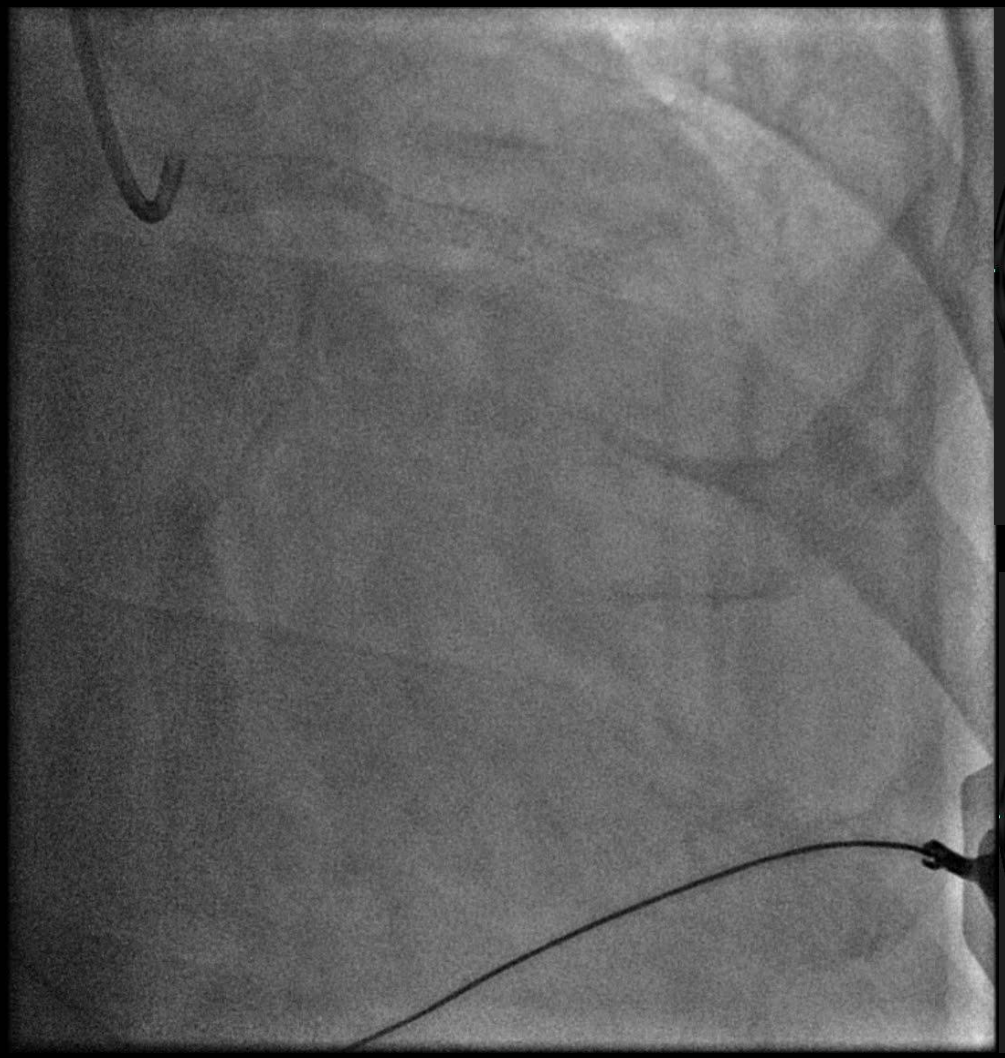


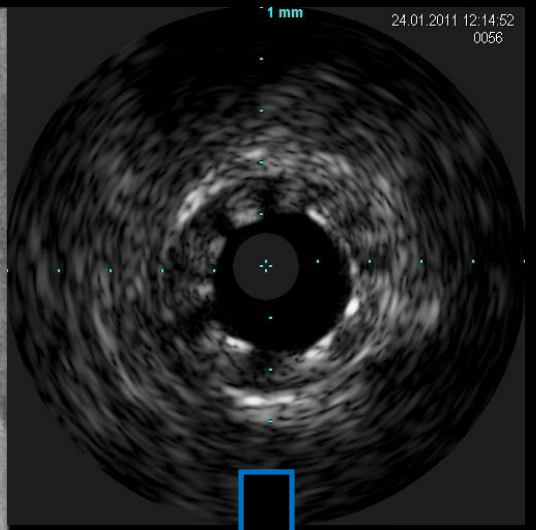


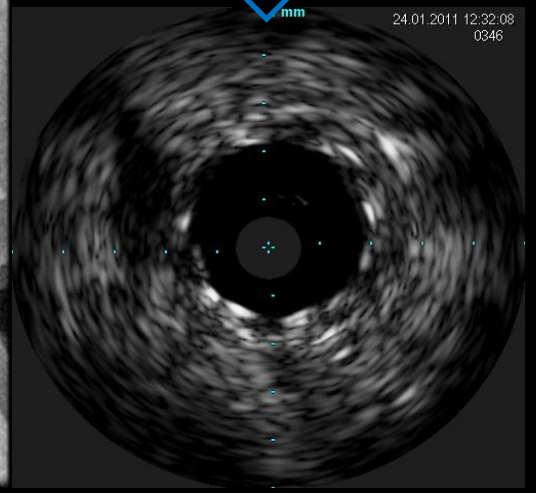
Stent optimisation with SP 3.5 x 30mm balloon

Stent optimisation with SP 4.0 x 20mm balloon

Novel Use of DEB





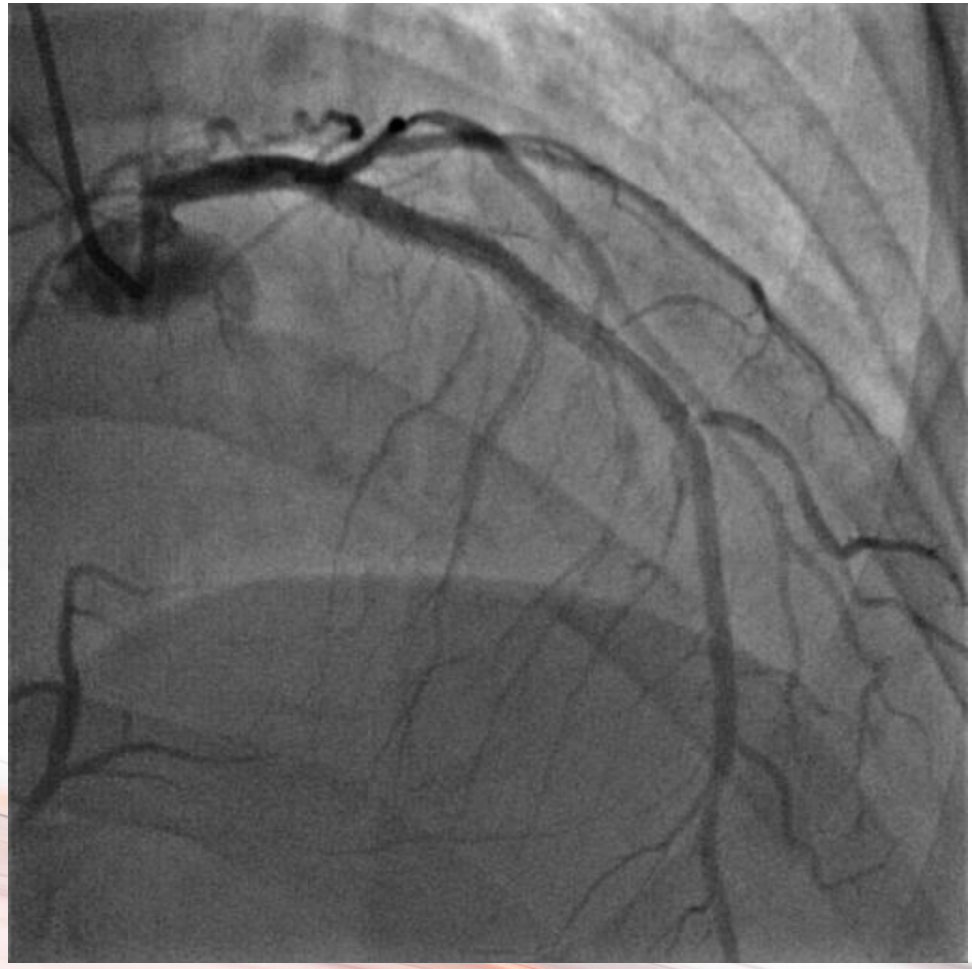


Final angiogram

Well expanded stent

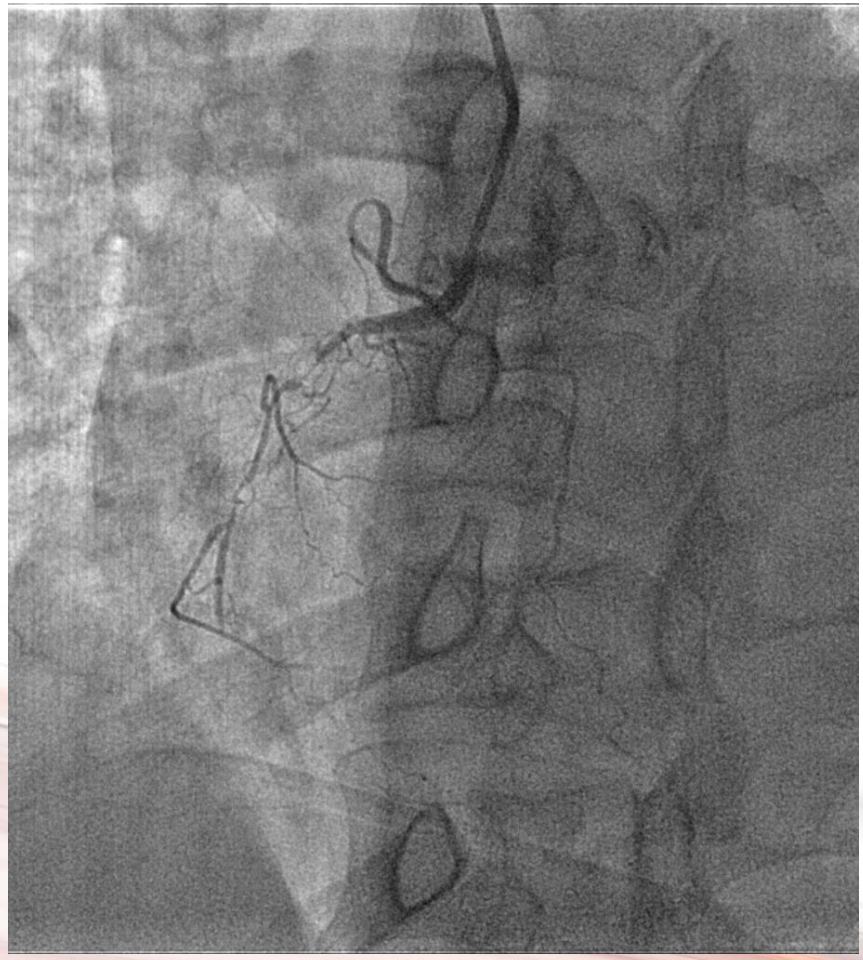
Tan Tock Seng HOSPITAL

Routine restudy at 2 months prior to CTO RCA



Tan Tock Seng HOSPITAL

RCA

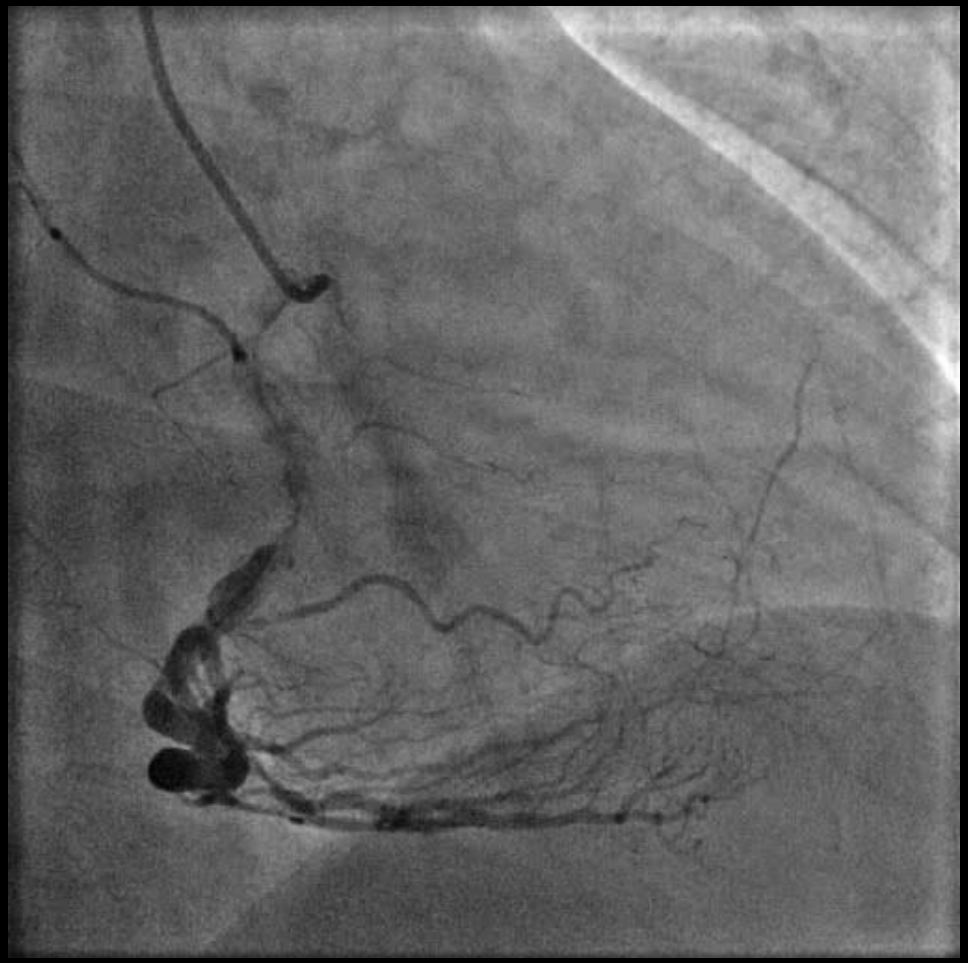


Diffuse LAD disease

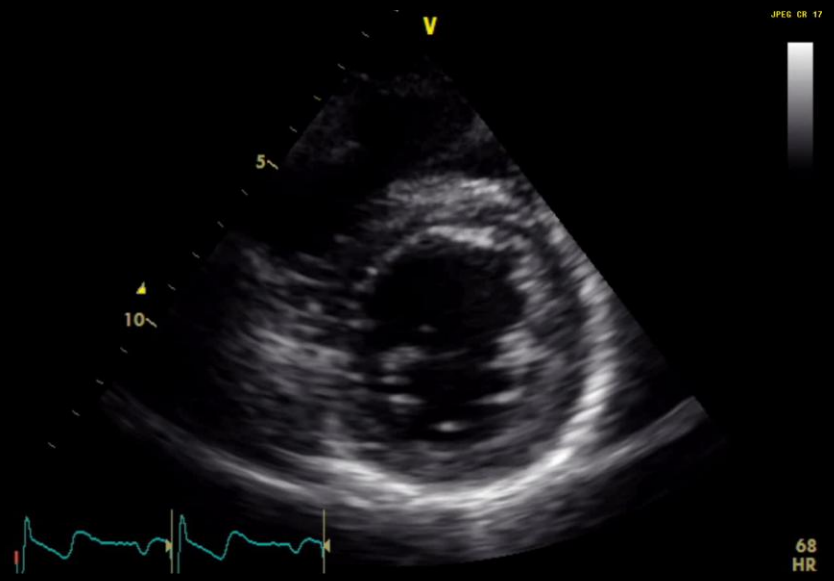
Occluded LAD and Cx

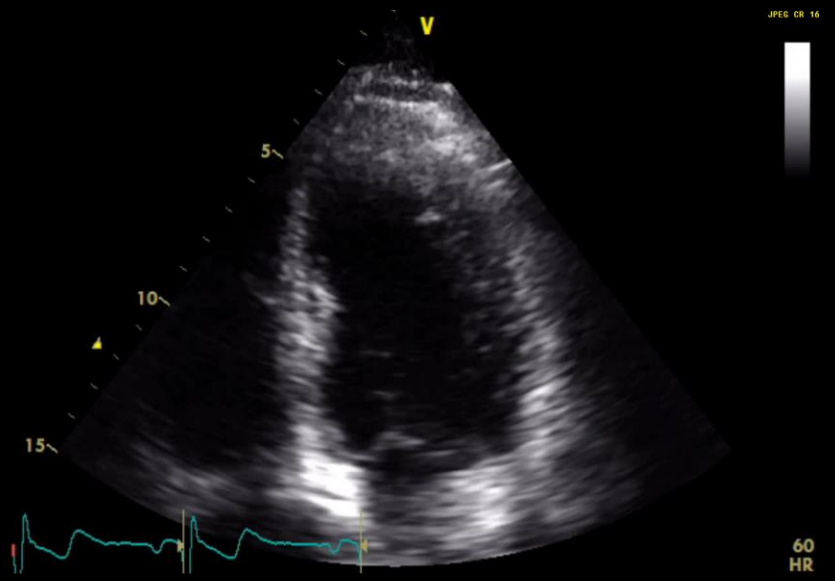
Diseased RCA

Collaterals to LAD



LV function preserved



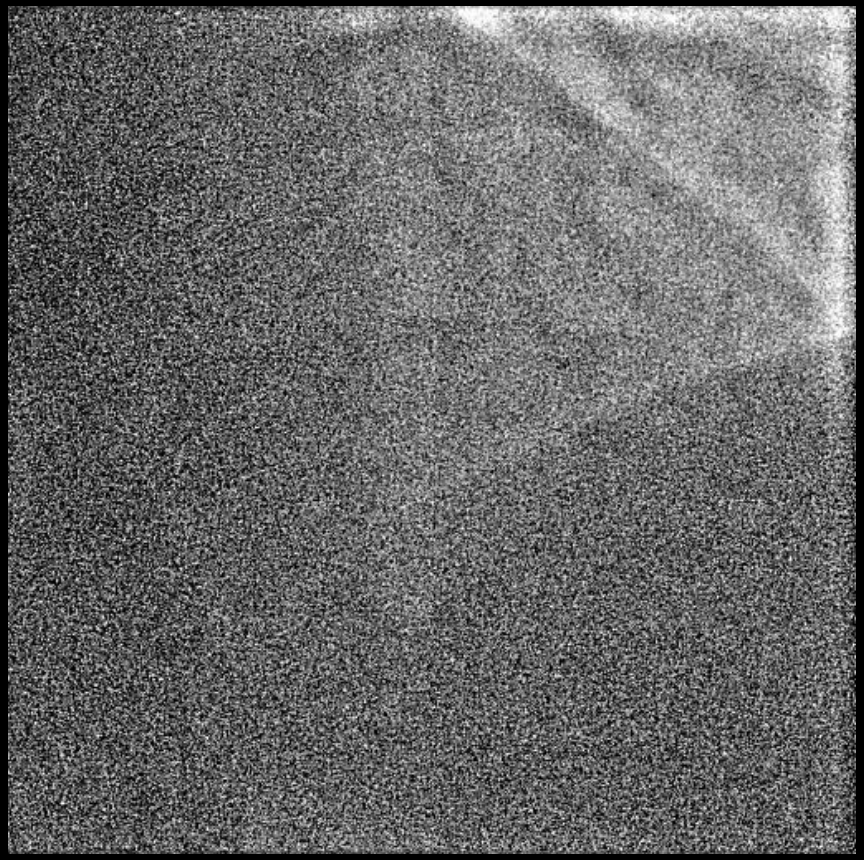


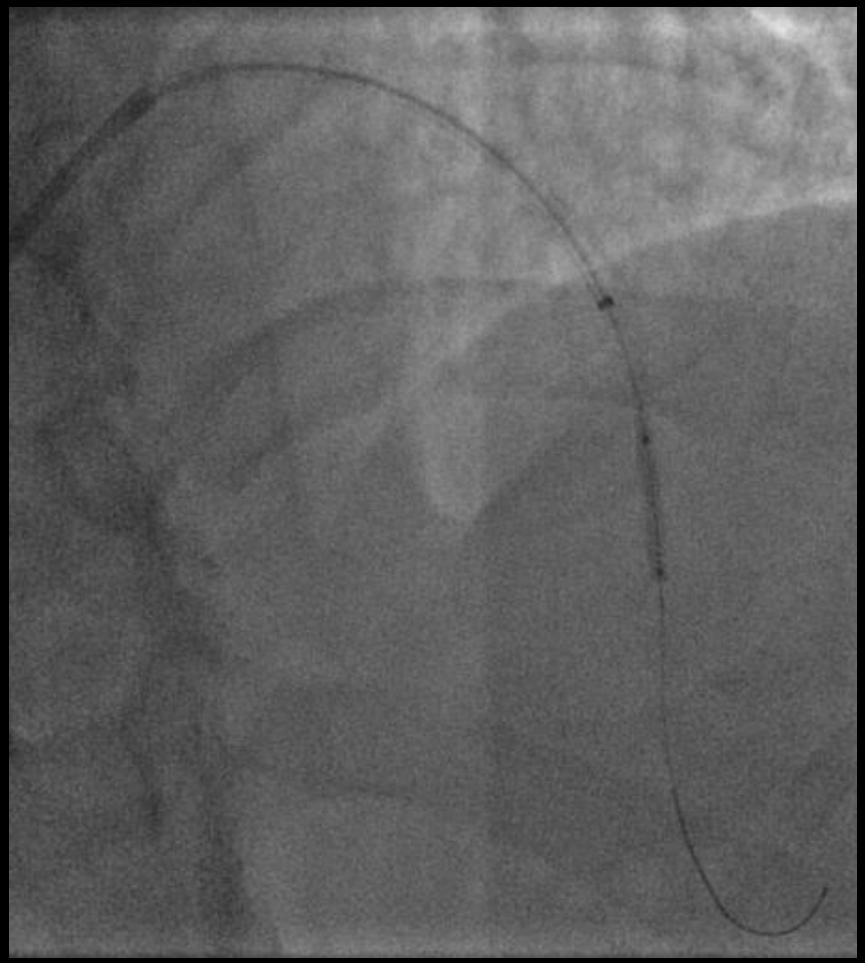
How to treat this patient?

- Classical angina
- Poor target for CABG esp LAD
- 44 years old only
- Non diabetic
- Smoker

PCI LAD

- RRA 6FS
- VL3.0 guide
- Whisper wire crossed with OTW support.
- 1.0 balloon eventually crossed the lesion with Guideliner support
- Aggressive predilation done with scoring balloon.





After POBA and Scoring balloon

Devices?

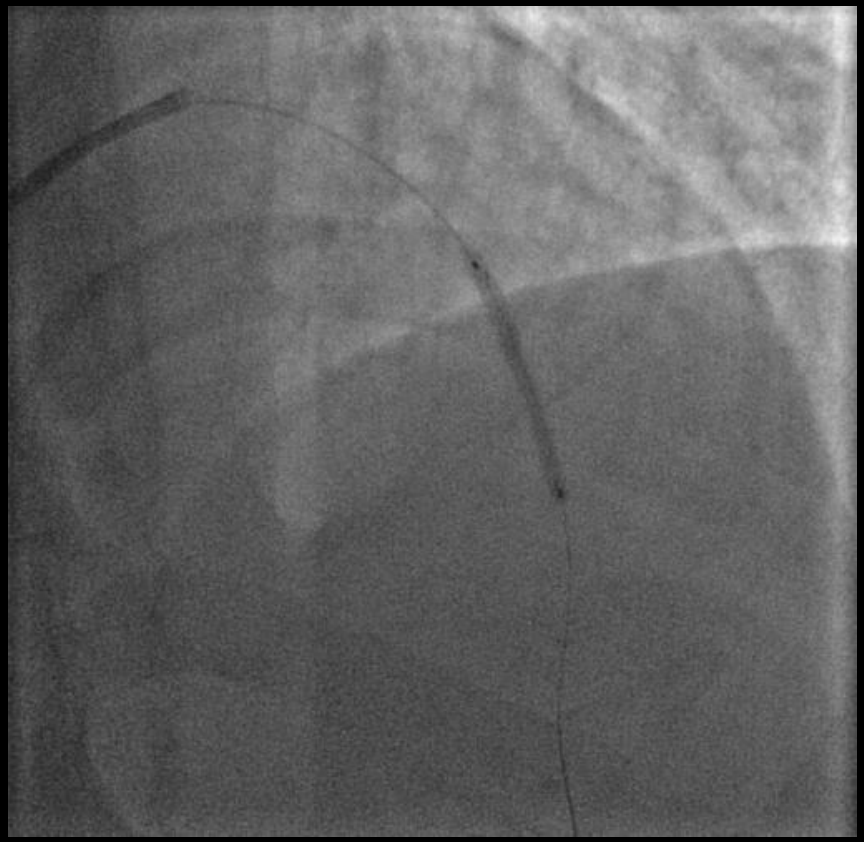
- SeQuent Please
  - 2.0 by 20mm
  - 8 atm
  - 45 s

DEB in small distal vessels

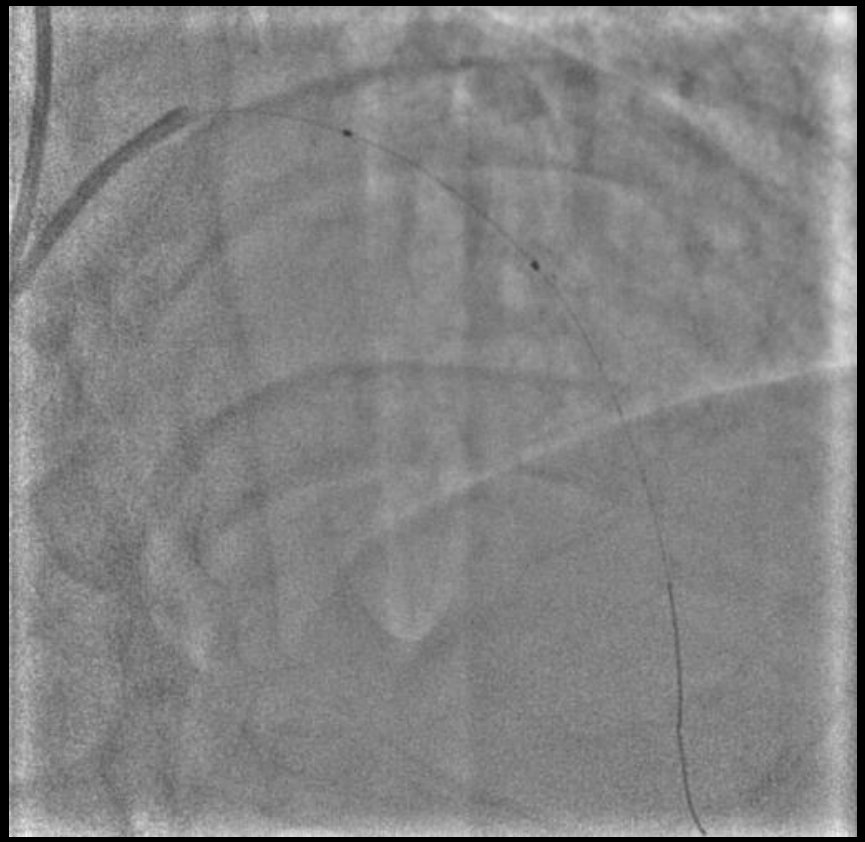
Where no stent has gone before……

Bioabsorbable stents

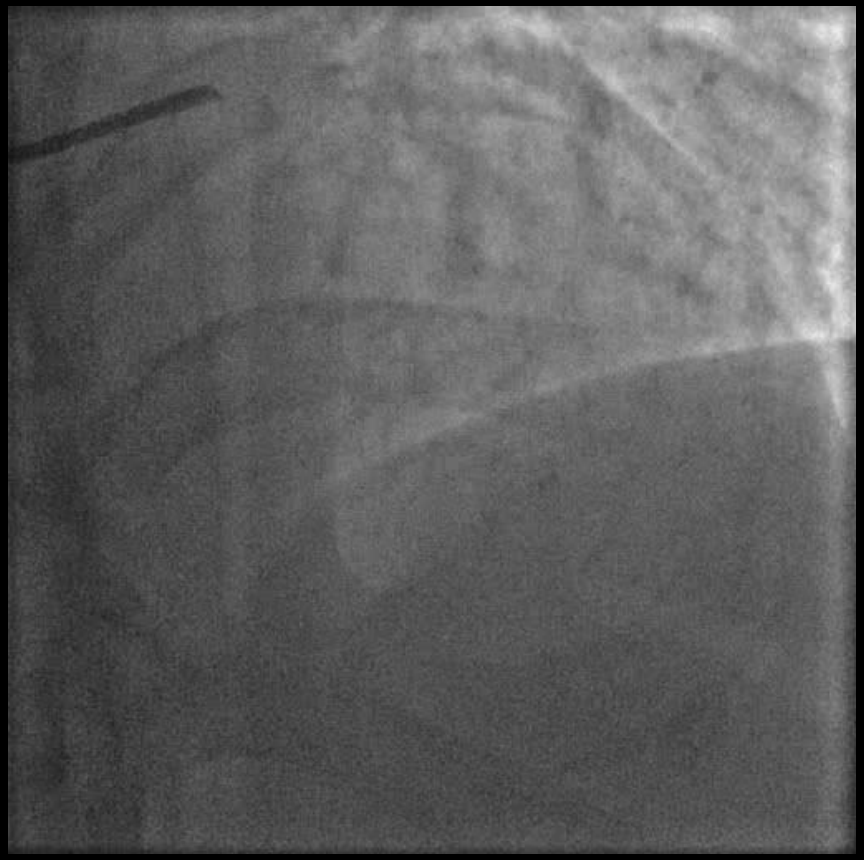
Absorb 2.5 by 28mm



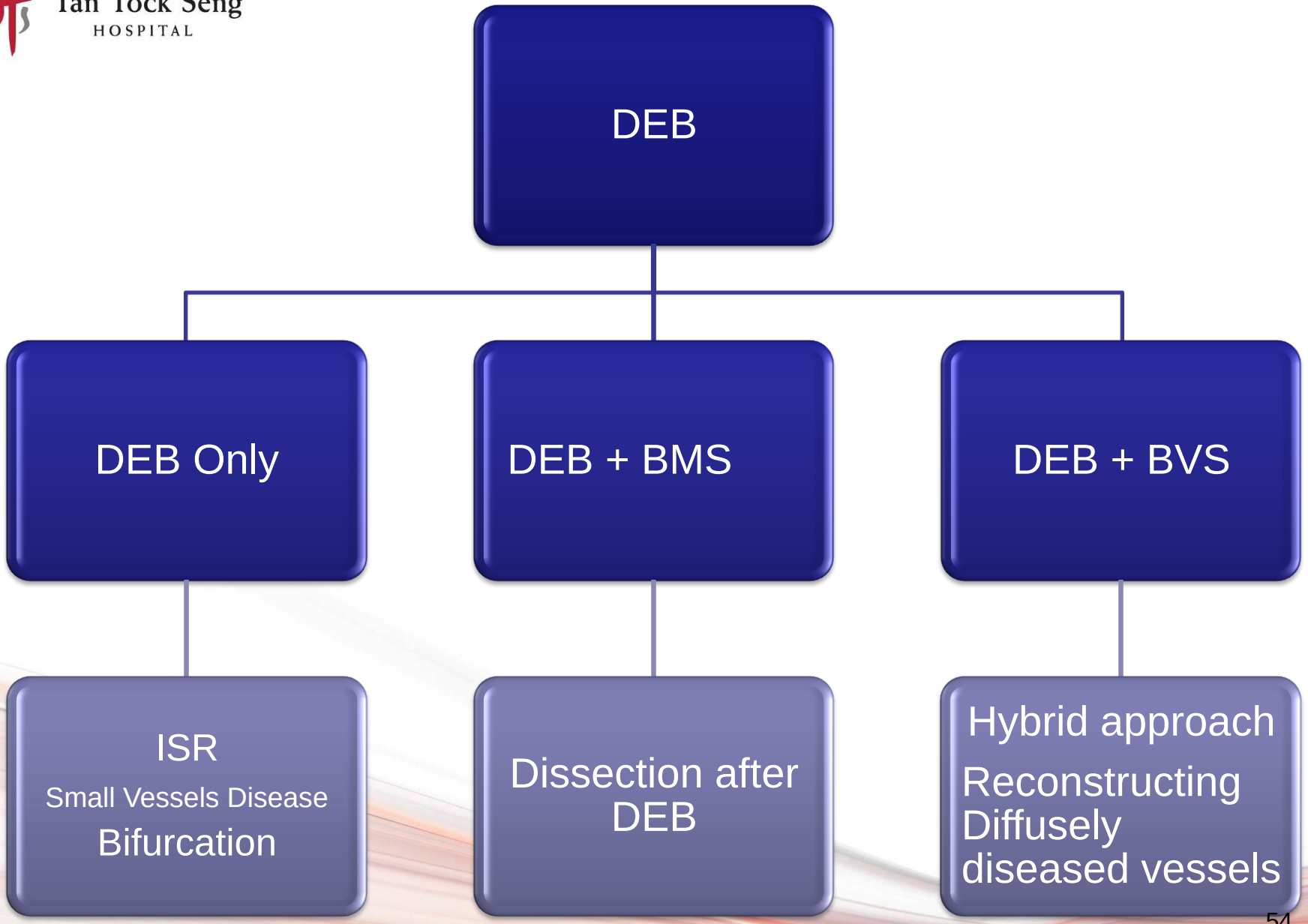
Absorb 3.0 by 28mm



Final result



Tan Tock Seng HOSPITAL



There is Life after Bioabsorbable stent

DEB

- Does not look for perfection
- 30% residual stenosis is acceptable
- Great promise in small vessel disease 2.0 to 2.5mm
- 1 months DAPT
- CE Mark since 2009
- IIa recommendation for ISR
- Strut?

BVS

- Needs meticulous scaffold deployment
- OCT or IVUS
- Smallest stent size is 2.5mm
- Largest 3.5mm
- Minimum of 6 months DAPT
- CE Mark since 2011
- Only for de novel lesion
- 150 µm strut thickness

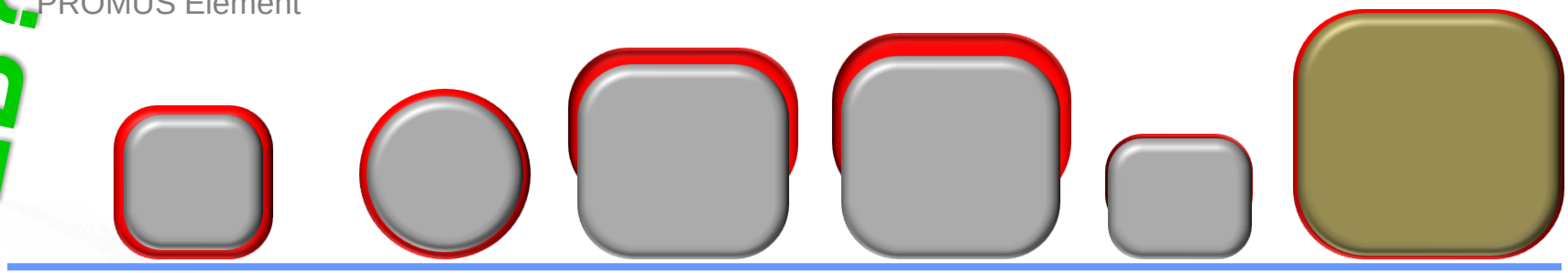
Strut and Coating Thickness In Perspective

Thicker struts = larger stent profile and less deliverable

Tan Tock Seng HOSPITAL

Durable Polymer Coated Stents		Bioabsorbable Polymer Coated Stents			Bioabsorbable Stent
Xience V™/PROMUS™ Xience Prime™ TAXUS Element™ PROMUS Element™	Resolute Integrity™	BioMatrix Flex™	Nobori™	SYNERGY™	ABSORB™ BVS

DEB?



Strut Thickness	**81 µm (0.0032”)**	89 µm (0.0035”)	120 µm (0.0047”)	125 µm (0.0049”)	74 µm (0.0029”)	150 µm (0.0059”)
Polymer Coating Type & Thickness	Conformable 7-8µm / side	Conformable 6µm / side	Abluminal 11µm	Abluminal 20µm	Abluminal 3-4µm	Conformable 3µm / side

Representative drawings are not to scale. [1] Wilson GW, *EuroIntervention* 2012;8:250-257 , and Soucy NV, EuroIntervention 2010;6:630-637.

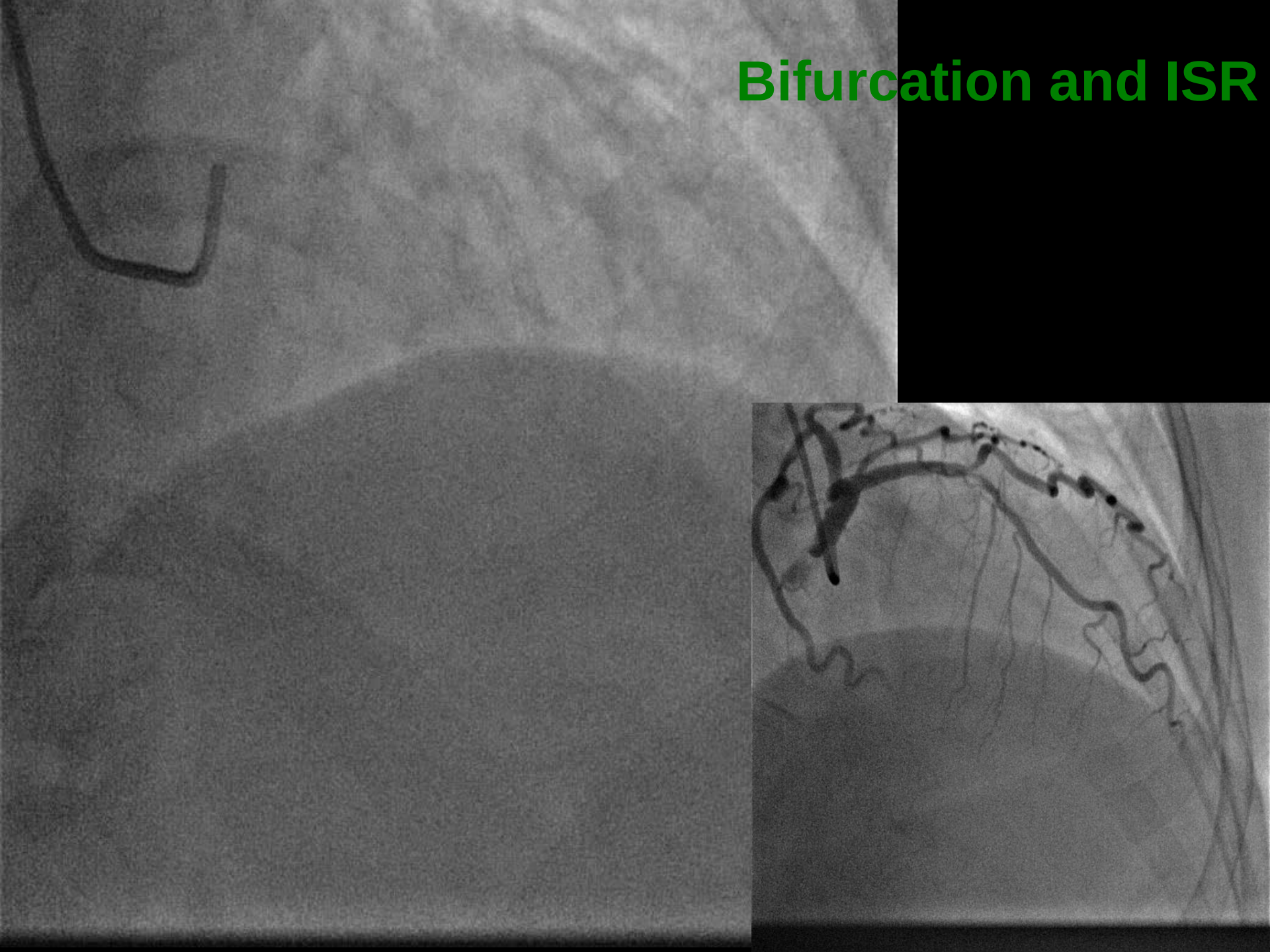
Tan Tock Seng HOSPITAL

POBA vs DEB POBA

Old Technology

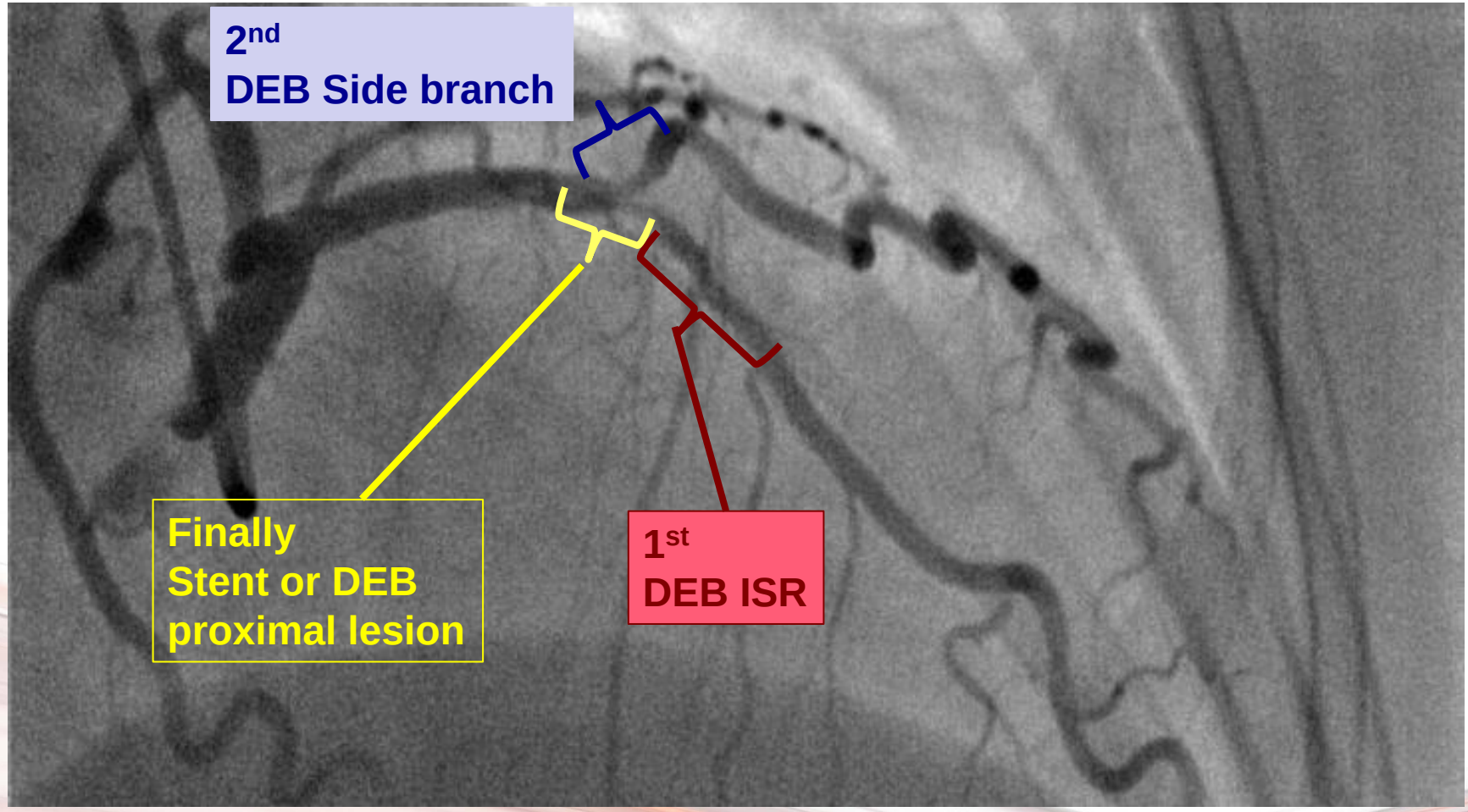
With a Modern Take

Bifurcation and ISR

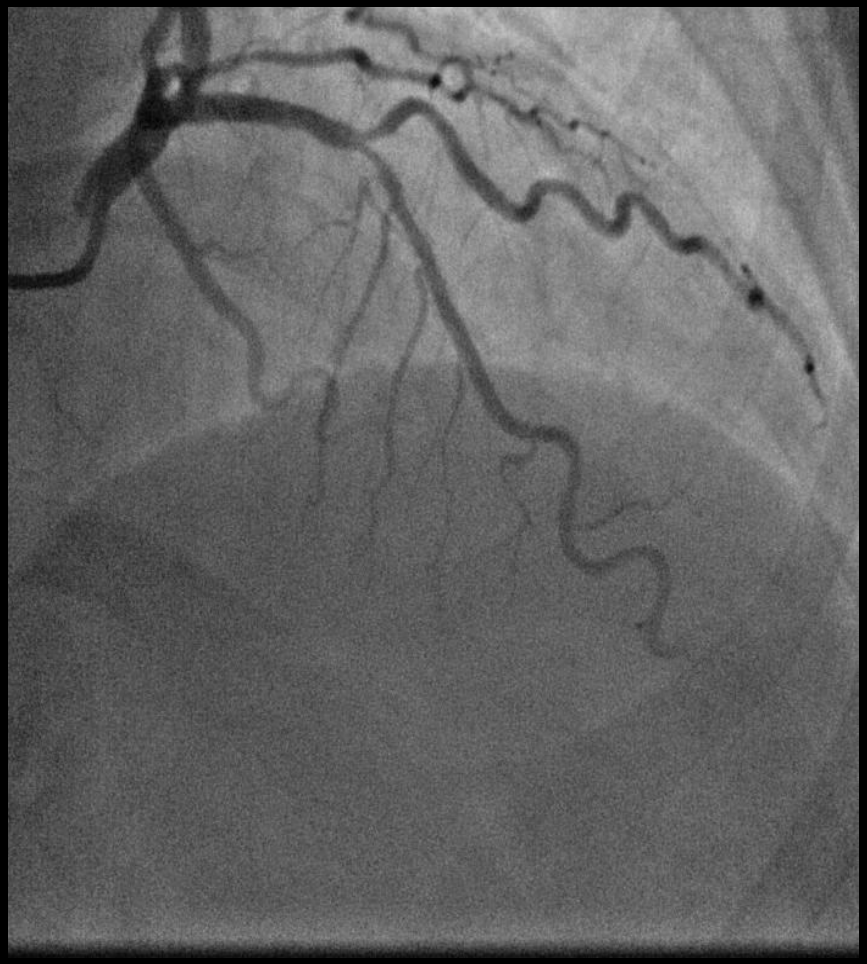


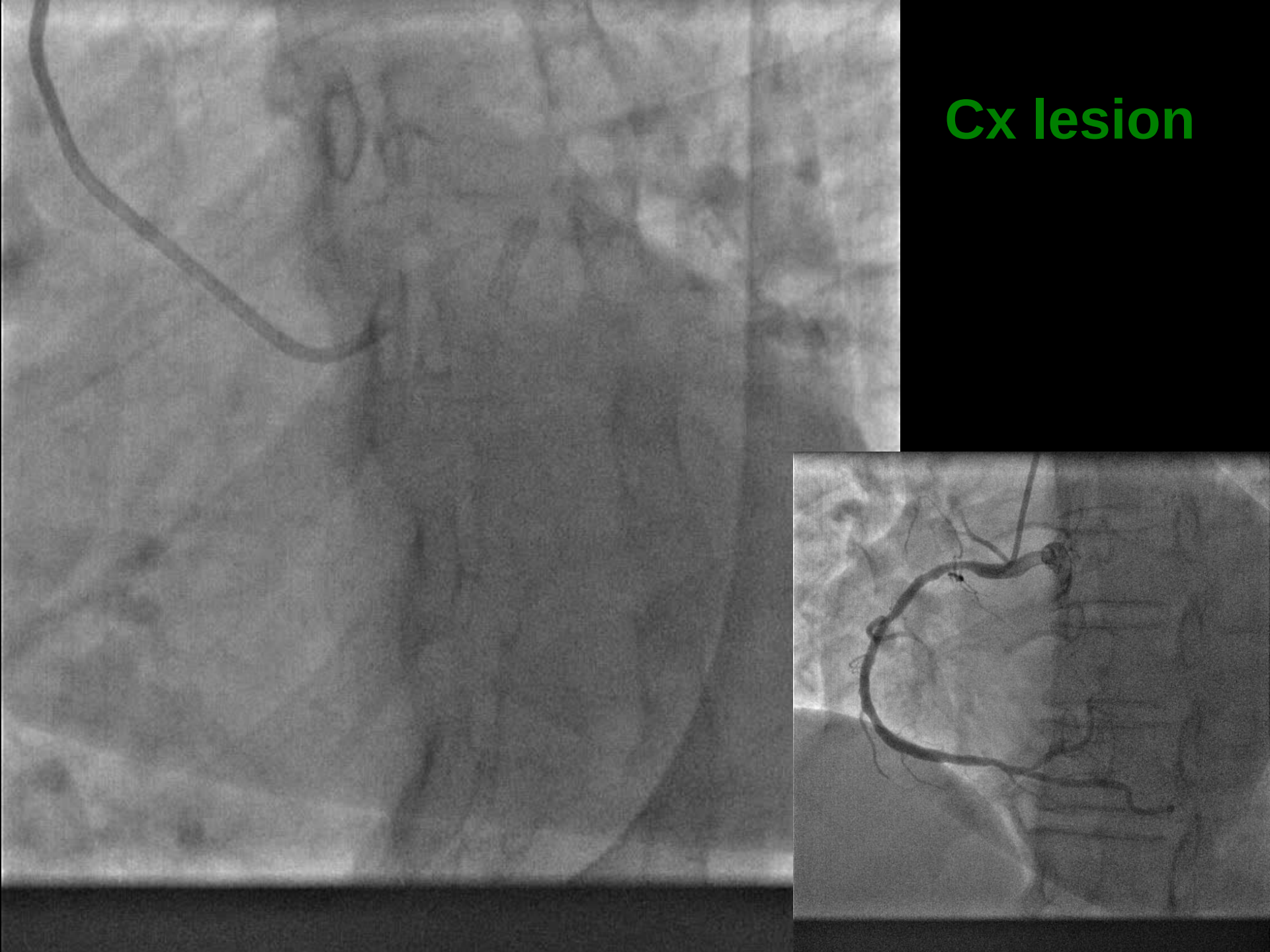
Tan Tock Seng HOSPITAL

Strategy



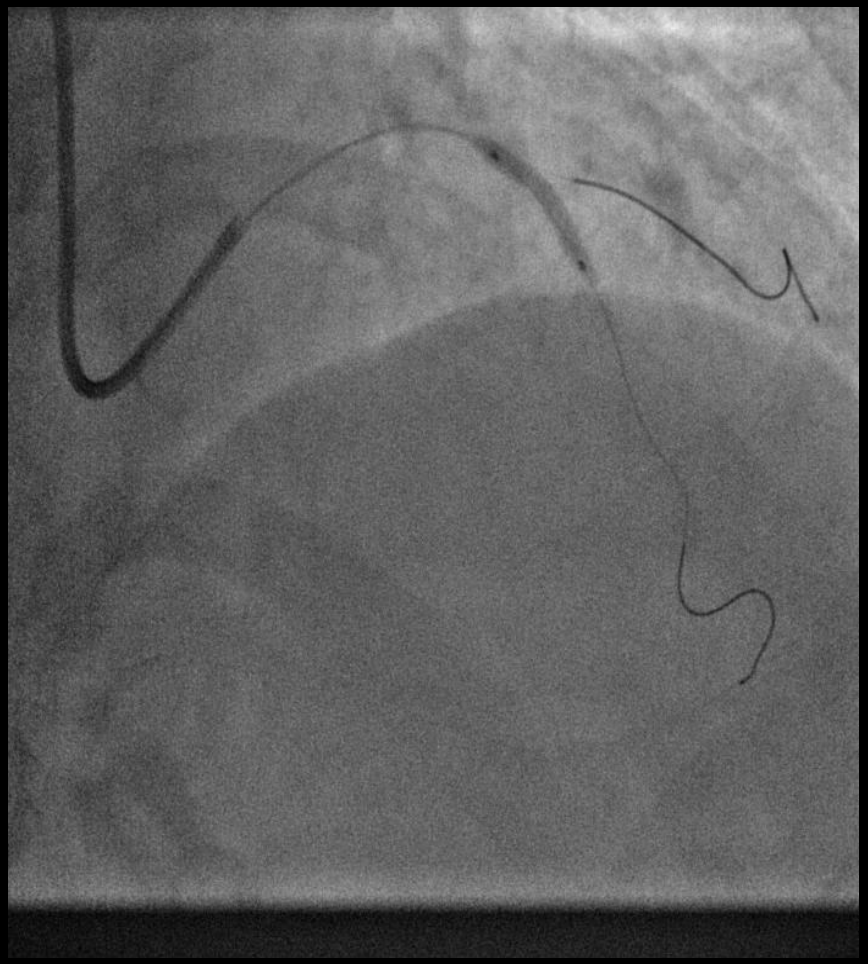
LAD Bifurcation

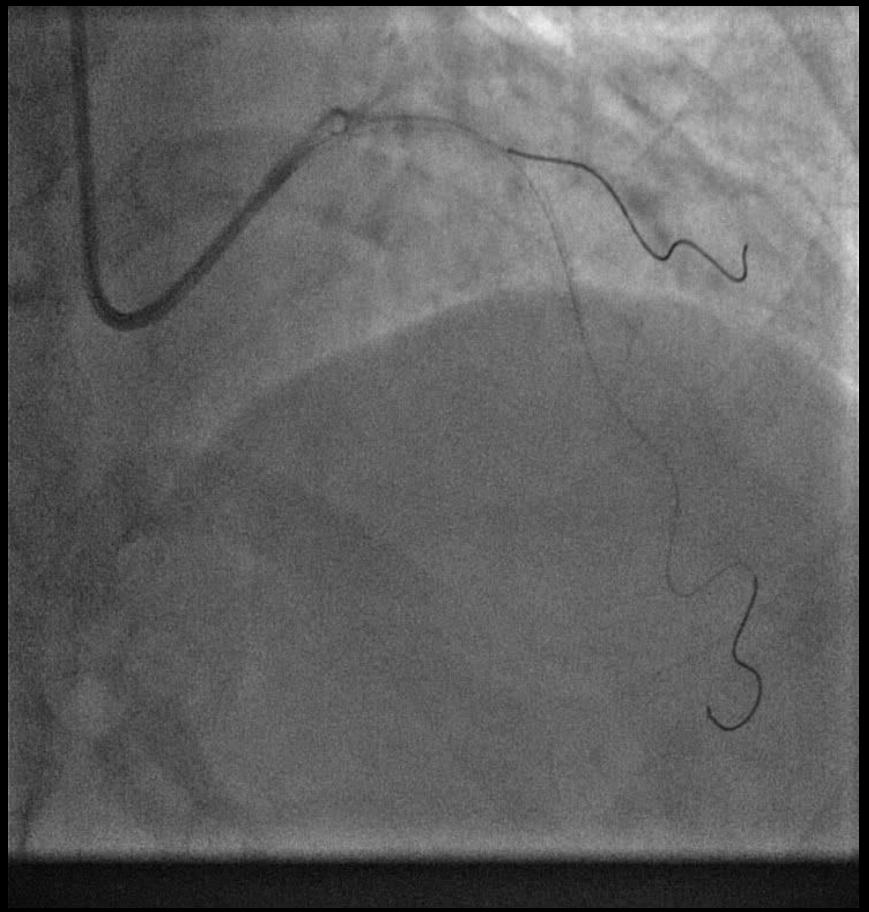



Cx lesion

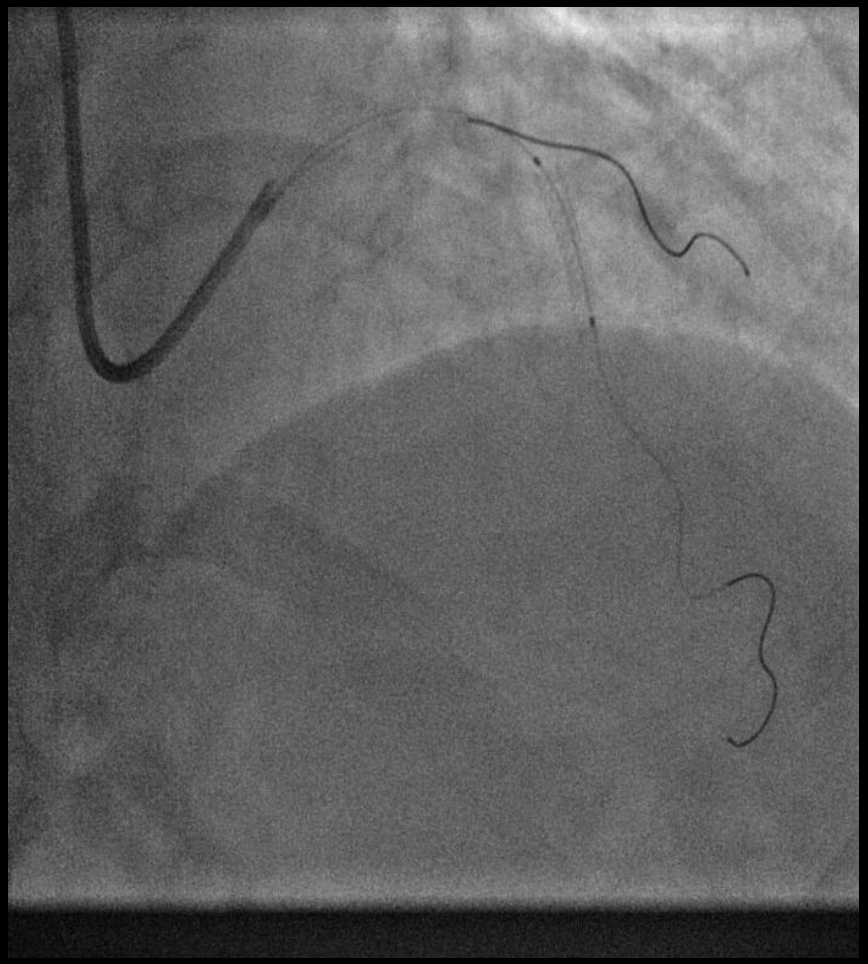
3.5 by 12mm Absorb Stent

Predilated with 2.5x15mm



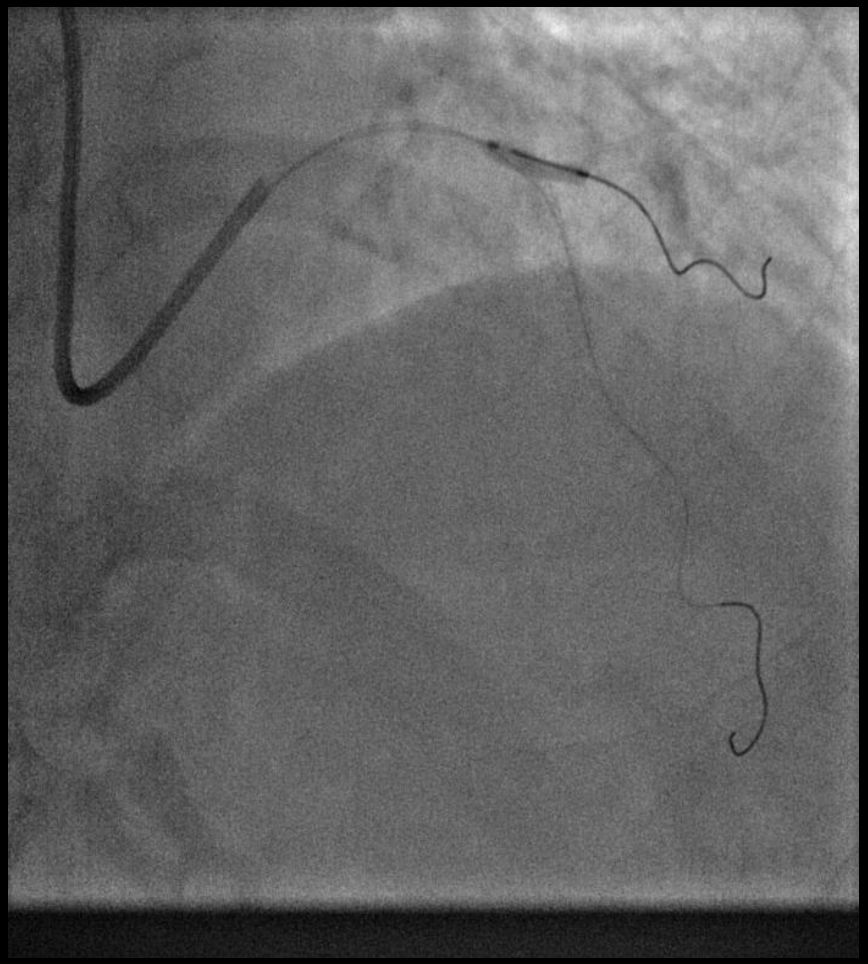


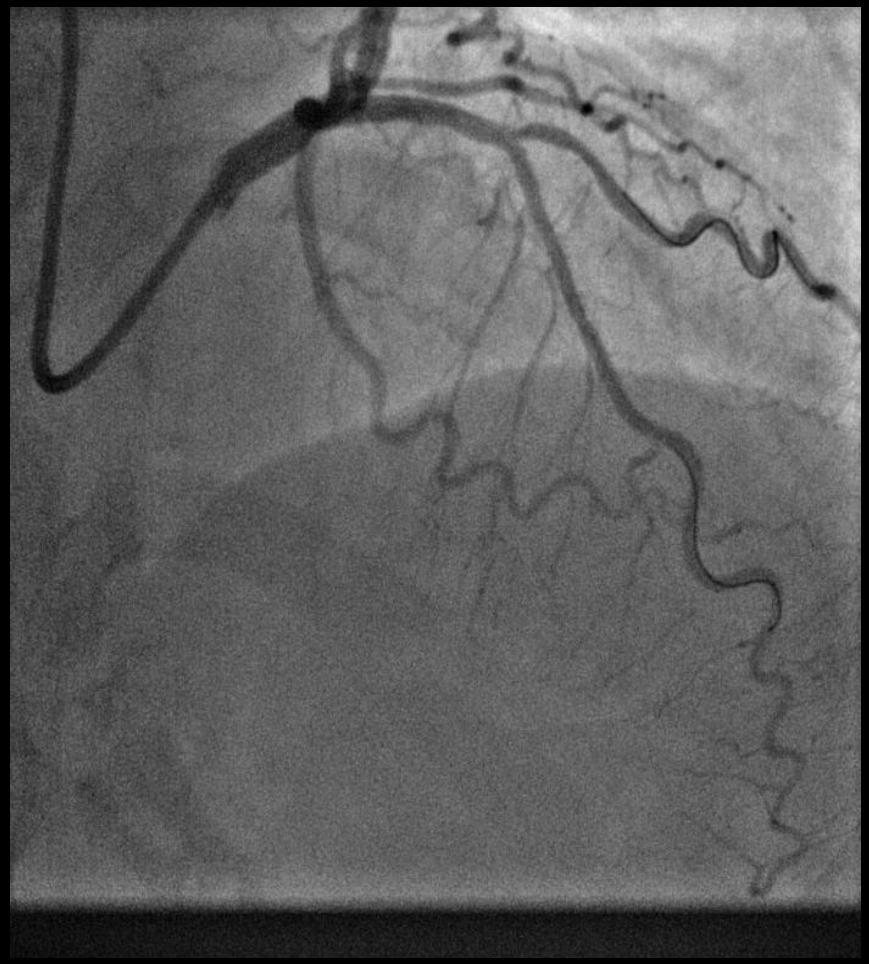
DEB 2.5x17mm treating ISR at 10 atm



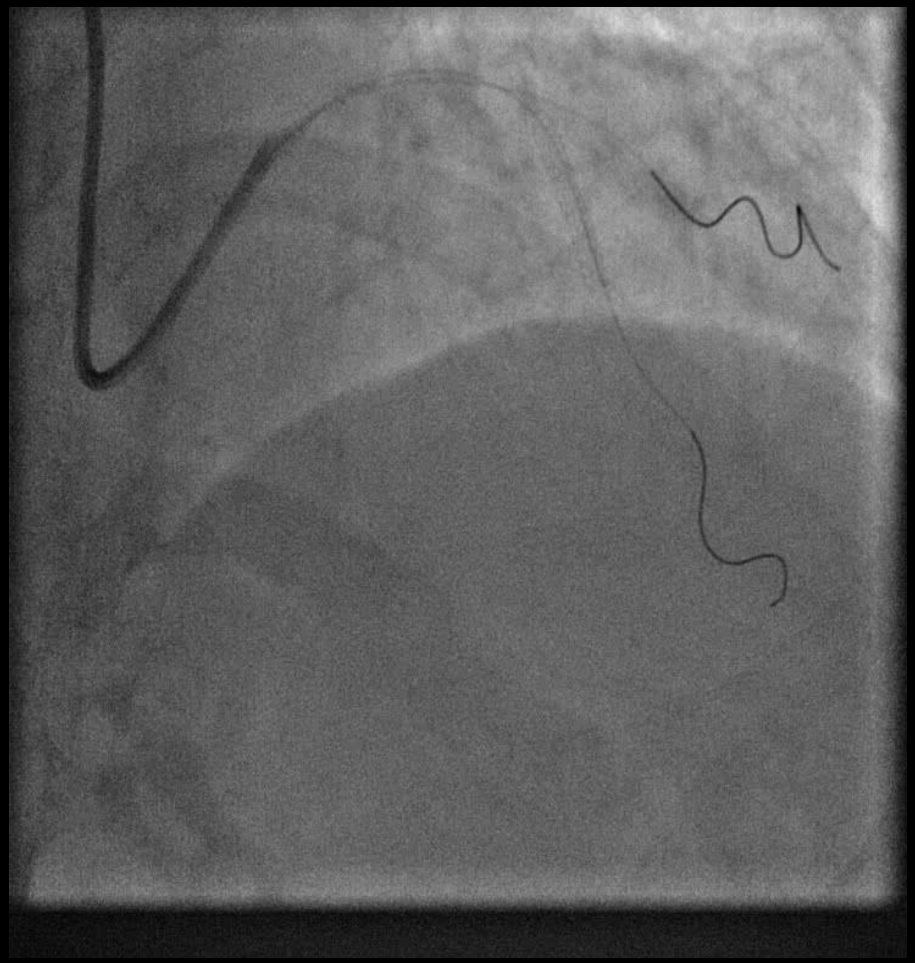
ISR well expanded by ostial D1 untidy

DEB 2.5 by 10mm to D1 ostium at 8 atm

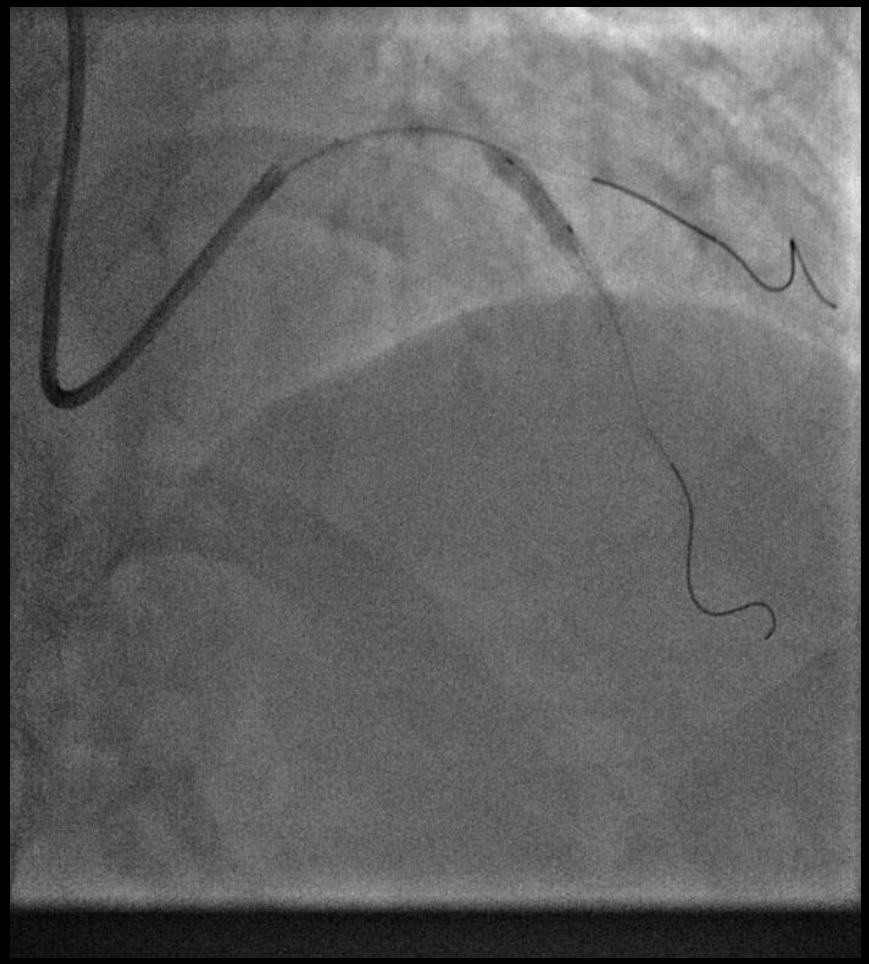




To stent or not to stent?

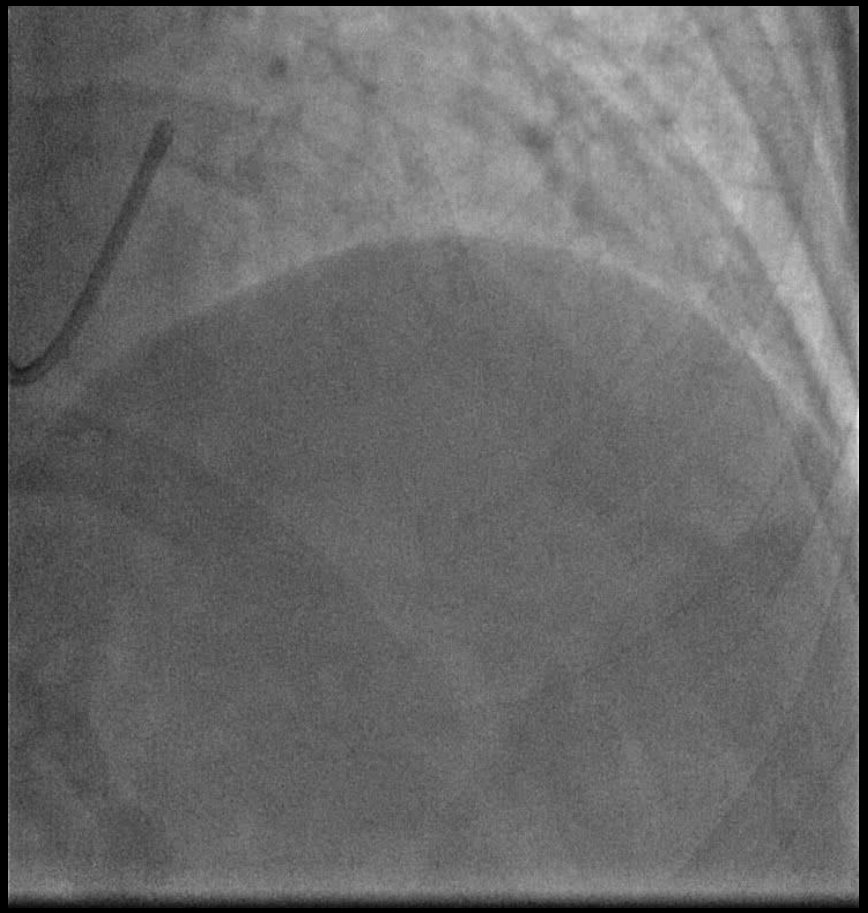


DEB 3.0 by 10mm at 8 atm
Avoid Geographical mismatch



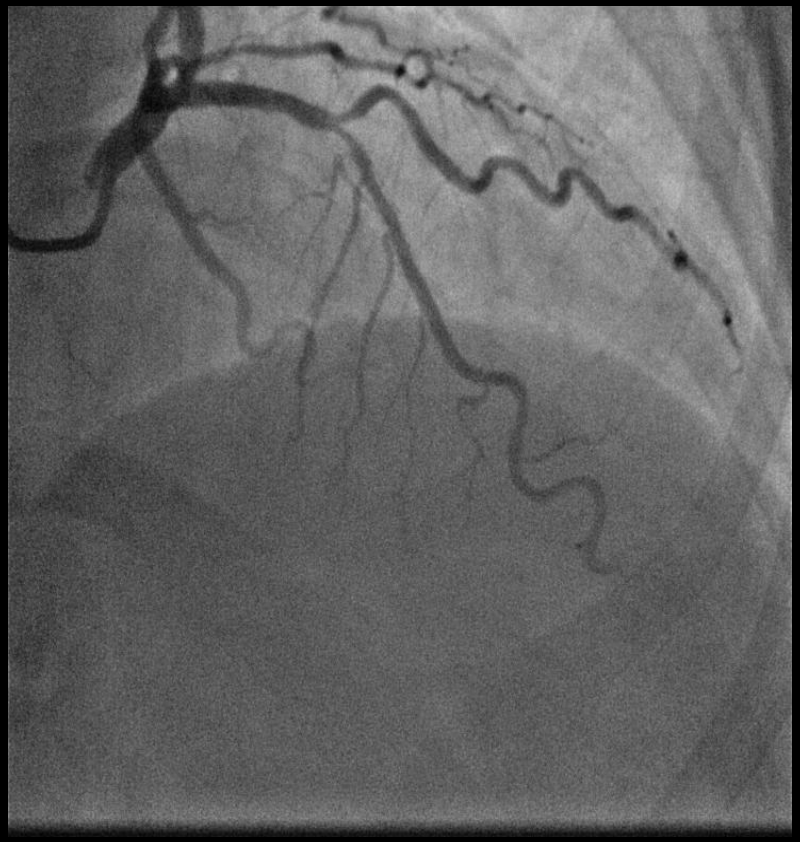
LAO Cranial

AP cranial



Final result

Before



After DEB

Final result

Before

After DEB