

drug coated balloon angioplasty – *where no stent is the best stent*

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Outline

- **Registry**
 - Are Asians different?
 - DCB in Small Vessel Disease
- **Positive Remodelling**
- **Case highlights**

ESC updated guidelines

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European Heart Journal
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ESC/EACTS GUIDELINES



2014 ESC/EACTS 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 of Percutaneous Cardiovascular Interventions (EAPCI)

Repeat revascularization

Recommendations	Class ^a	LoE ^b	Ref ^c
Early post-operative ischaemia and graft failure			
Coronary angiography is recommended for patients with: <ul style="list-style-type: none"> • symptoms of ischaemia and/or abnormal biomarkers suggestive of perioperative myocardial infarction • ischaemic ECG changes indicating large area of risk • new significant wall motion abnormalities • haemodynamic instability. 	I	C	
It is recommended to make the decision on redo CABG or PCI by <i>ad hoc</i> consultation in the Heart Team and based on feasibility of revascularization, area at risk, comorbidities and clinical status.	I	C	
PCI should be considered over re-operation in patients with early ischaemia after CABG if technically feasible.	IIa	C	
If PCI is performed, revascularization of the native vessels or IMA grafts rather than occluded or heavily diseased SVGs should be considered.	IIa	C	
Restenosis			
Repeat PCI is recommended, if technically feasible.	I	C	
			501 502 508
Drug-coated balloons are recommended for the treatment of in-stent restenosis (within BMS or DES).	I	A	
IVUS and/or OCT should be considered to detect stent-related mechanical problems.	IIa	C	

Real World Registry



Contents lists available at [ScienceDirect](#)

IJC Heart & Vessels

journal homepage: <http://www.journals.elsevier.com/ijc-heart-and-vessels>

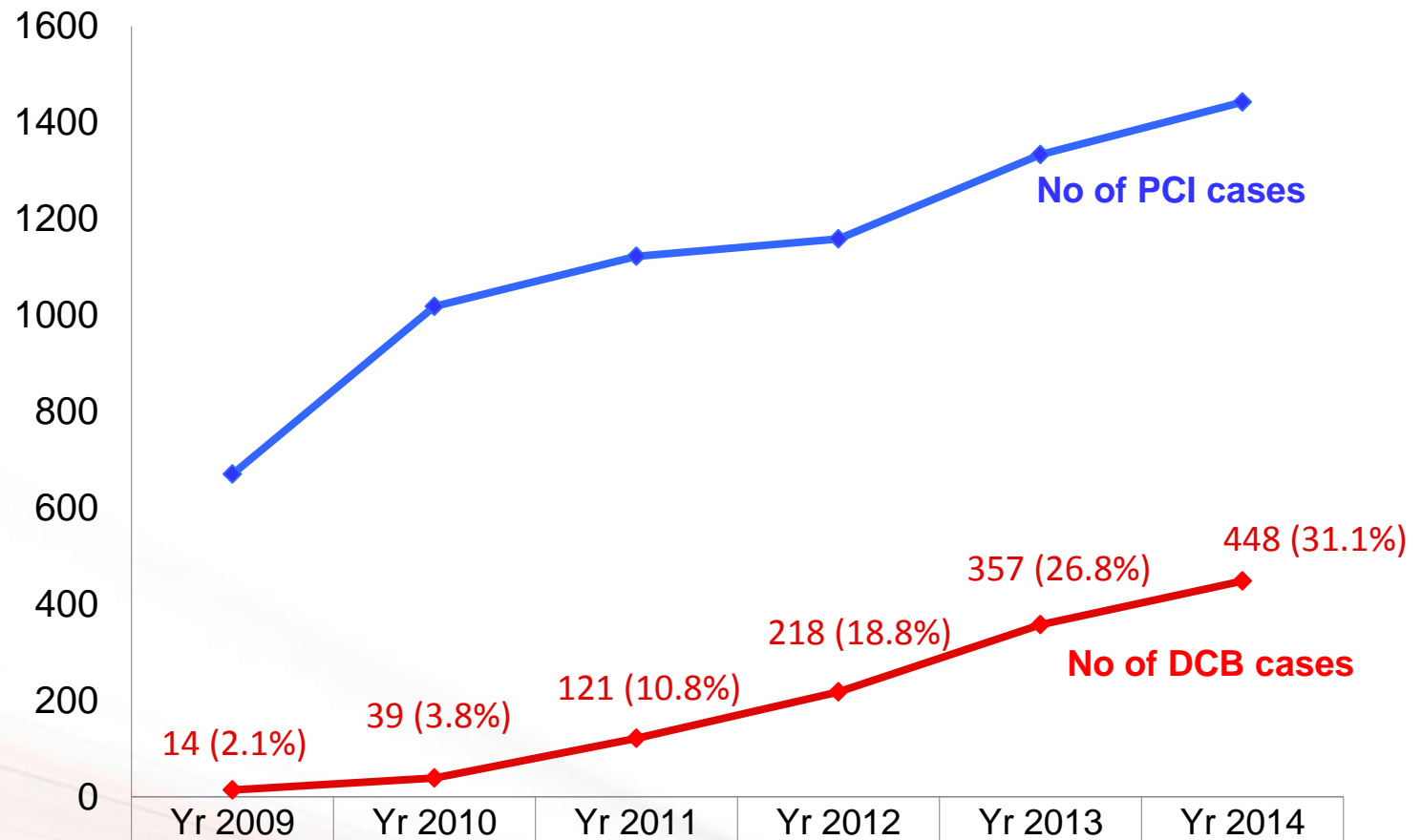


Clinical Efficacy and Safety of SeQuent Please Paclitaxel-Eluting Balloon in a Real-World Single-Center Registry of South-East Asian Patients☆☆☆

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Fahim Haider Jafary, Paul Jau Lueng Ong

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Angioplasty Trends in TTSH (Year 2009 to 2014)



◆ No of DEB cases	14	39	121	218	357	448
◆ No of PCI cases	670	1018	1122	1158	1333	1442
Percentage	2.1%	3.8%	10.8%	18.8%	26.8%	31.1%

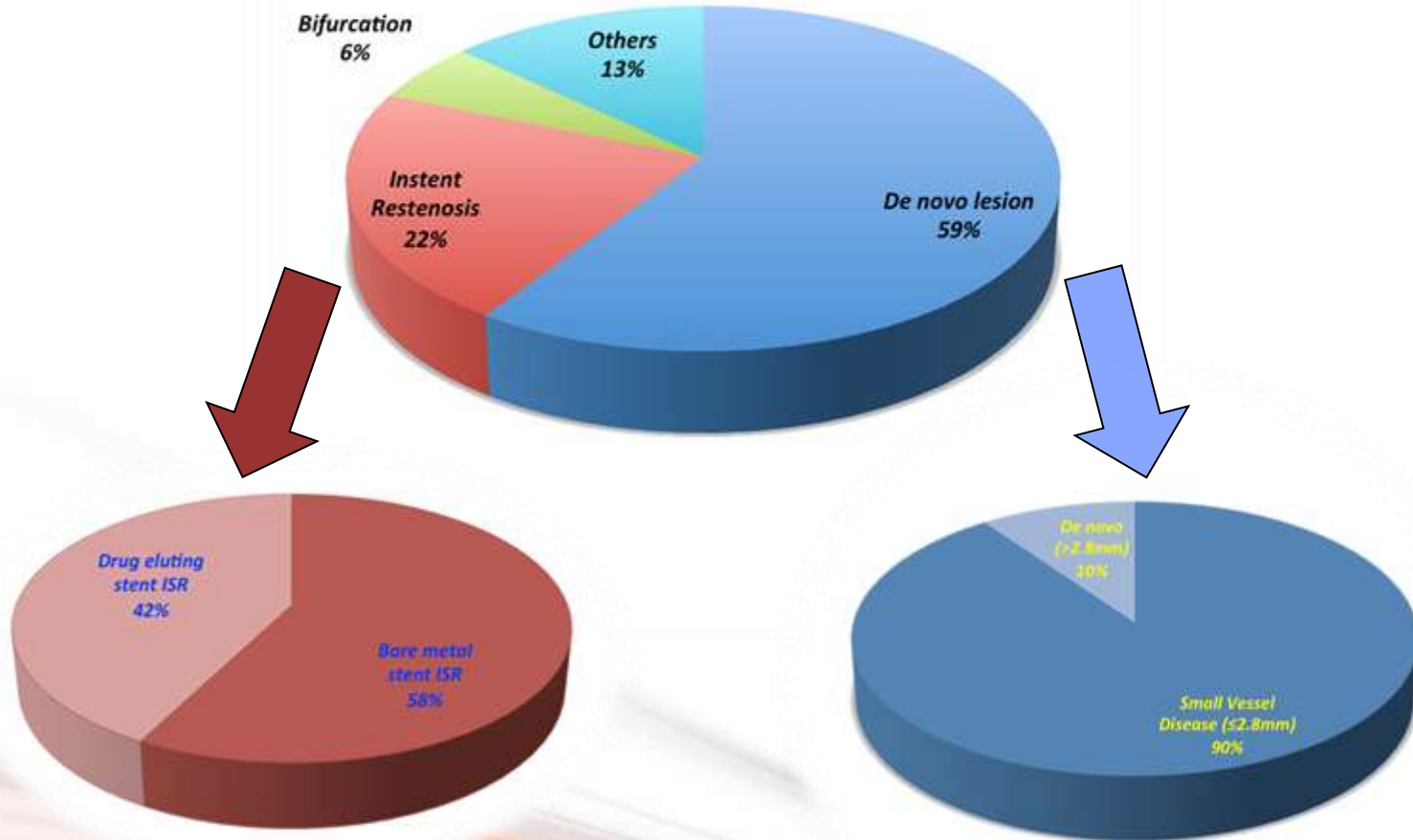
TTSH SeQuent Please Registry

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

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

Recap on our usage



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)

Disease pattern is different

Differences in clinical and angiographic profiles between Asian and Western patients with coronary artery disease: Insights from the prospective “real world” paclitaxel-coated balloon registry

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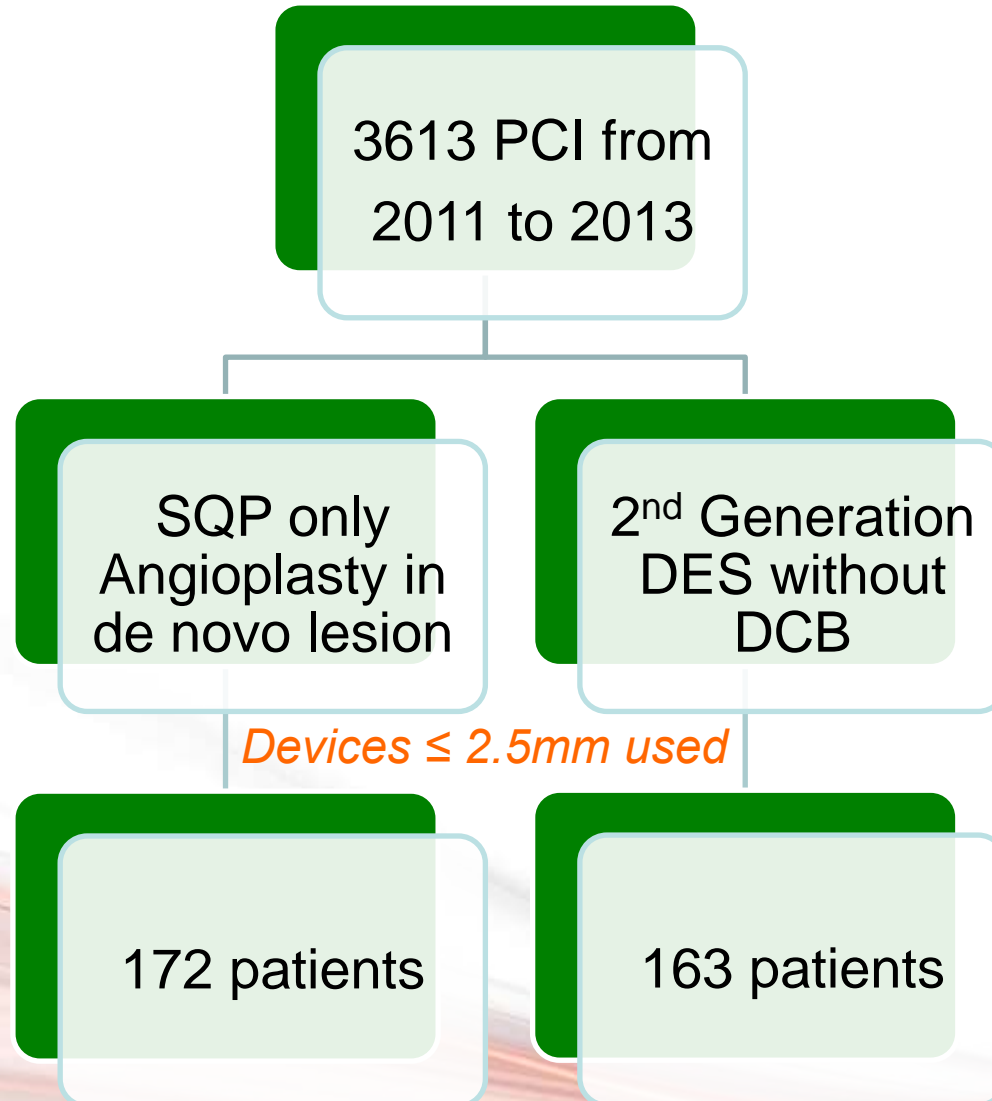
^c Medical Scientific Affairs, B. Braun Melsungen AG, Melsungen, Germany

Asians have more DM (46.6% vs 34.8% p=0.06), Longer lesion and smaller vessels but Same success with SQP

Angiographic features, procedural data and clinical outcomes.

	All Patients (N = 447)	Asian (N = 73)	Western (N = 374)	p-Value
Number of lesions	471	82	389	
<i>Target vessel</i>				
LAD, n,%	193 (41.0)	34 (41.4)	159 (40.9)	0.17
LCx, n,%	126 (26.8)	25 (30.5)	101 (26.0)	
RCA, n,%	94 (20.0)	19 (23.2)	75 (19.3)	
Others, n,%	58 (12.3)	4 (4.9)	54 (13.9)	
Calcification, n,%	112 (23.8)	8 (9.8)	104 (26.7)	0.001*
Bifurcation, n,%	45 (9.6)	6 (7.3)	39 (10.0)	0.43
Severe tortuosity, n,%	45 (9.6)	1 (1.2)	44 (11.3)	<0.001*
AHA/ACC type B2/C lesion	182 (38.6)	29 (35.4)	153 (39.3)	0.53
Reference vessel diameter, mm	2.14 ± 0.35	2.03 ± 0.17	2.17 ± 0.38	0.02*
Lesion length, mm	15.5 ± 7.0	17.9 ± 10.7	15.0 ± 6.0	0.003*
No. of PCB, n	478	82	396	
PCB diameter, mm	2.33 ± 0.31	2.29 ± 0.26	2.34 ± 0.32	0.06
PCB length, mm	19.2 ± 4.5	20.4 ± 4.6	18.9 ± 4.4	0.002*
Overall technical success, n,%	473 (99.0)	81 (98.8)	392 (99.0)	-
<i>Clinical outcomes</i>				
30-day MACE, n,%	1 (0.3)	0 (0)	1 (0.3)	0.62
9-month MACE, n,%	18 (4.7)	2 (2.7)	16 (5.1)	0.38
9-month TLR, n,%	14 (3.6)	1 (1.4)	13 (4.2)	0.25
9-month MI, n,%	7 (1.8)	1 (1.4)	6 (1.9)	0.75
9-month cardiac death, n,%	0 (0)	0 (0)	0 (0)	-

SQP in SVD <2.5mm vs 2nd Generation DES



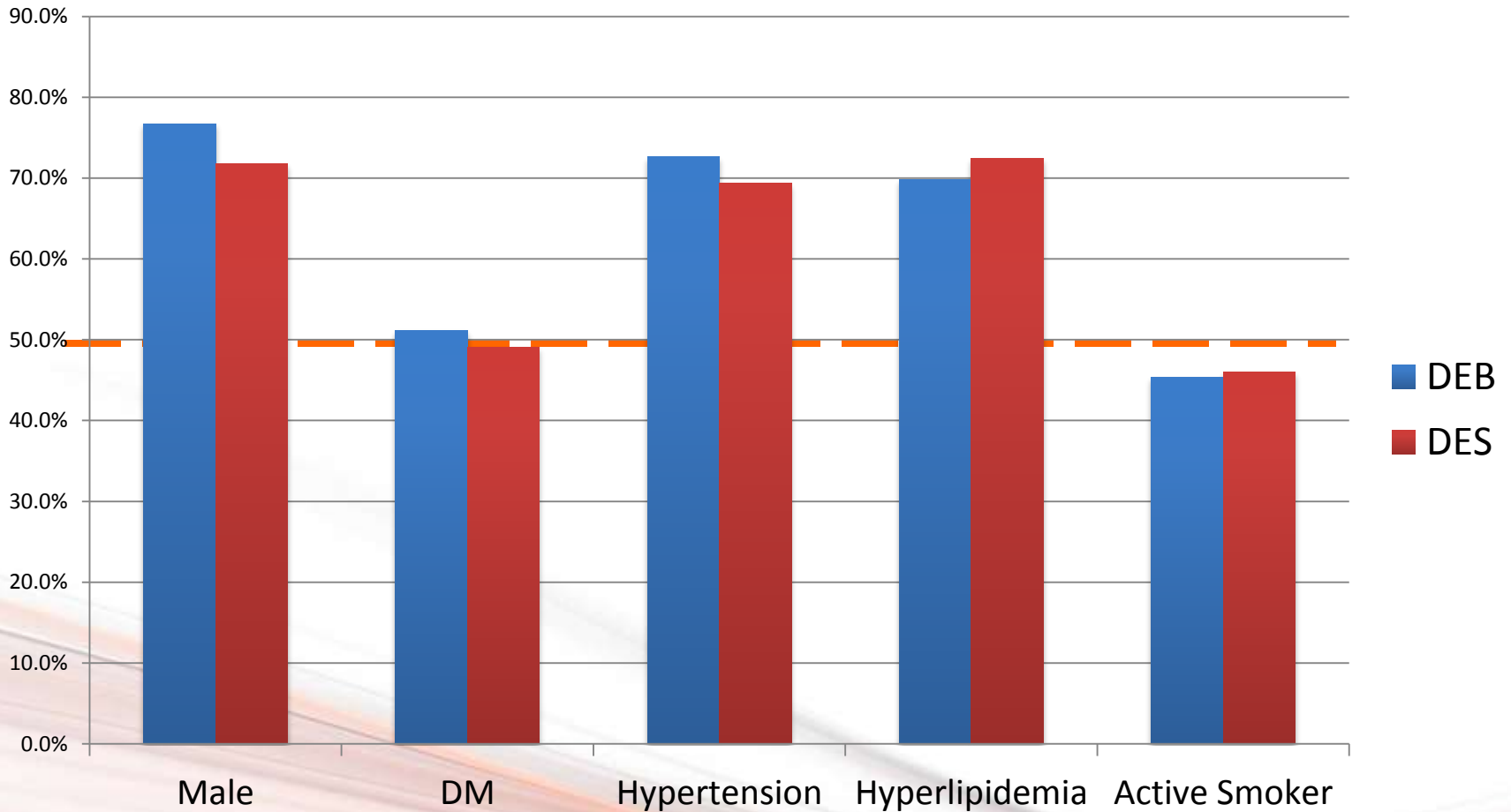
SQP in SVD <2.5mm vs 2nd Generation DES

- Single centre retrospective study
 - 2011 to 2013
 - Clinical follow up of patients receiving DCB only angioplasty or 2nd Generation DES in de novo lesions
 - Device size < 2.5mm diameter as cut off
-
- | | |
|------------------|--------------|
| • DCB (100% SQP) | 172 patients |
| • DES | 163 patients |

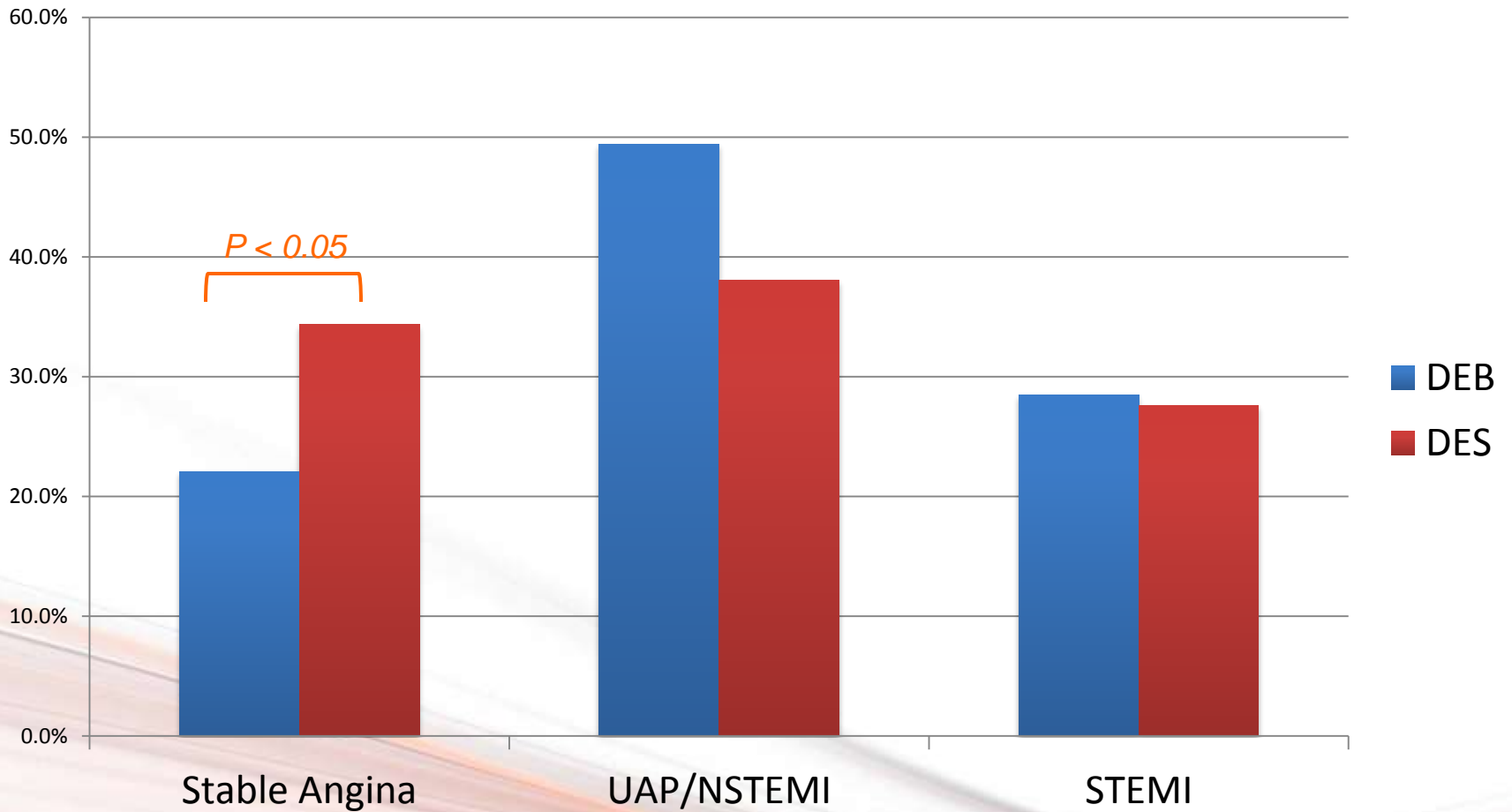
163 patients - 2nd Generation DES $\leq 2.5\text{mm}$

Absorb	2	1.23%
Biomatrix	42	25.77%
Resolute Integrity	55	33.74%
Nobori	11	6.75%
Promus	10	6.13%
Xience Prime	43	26.38%

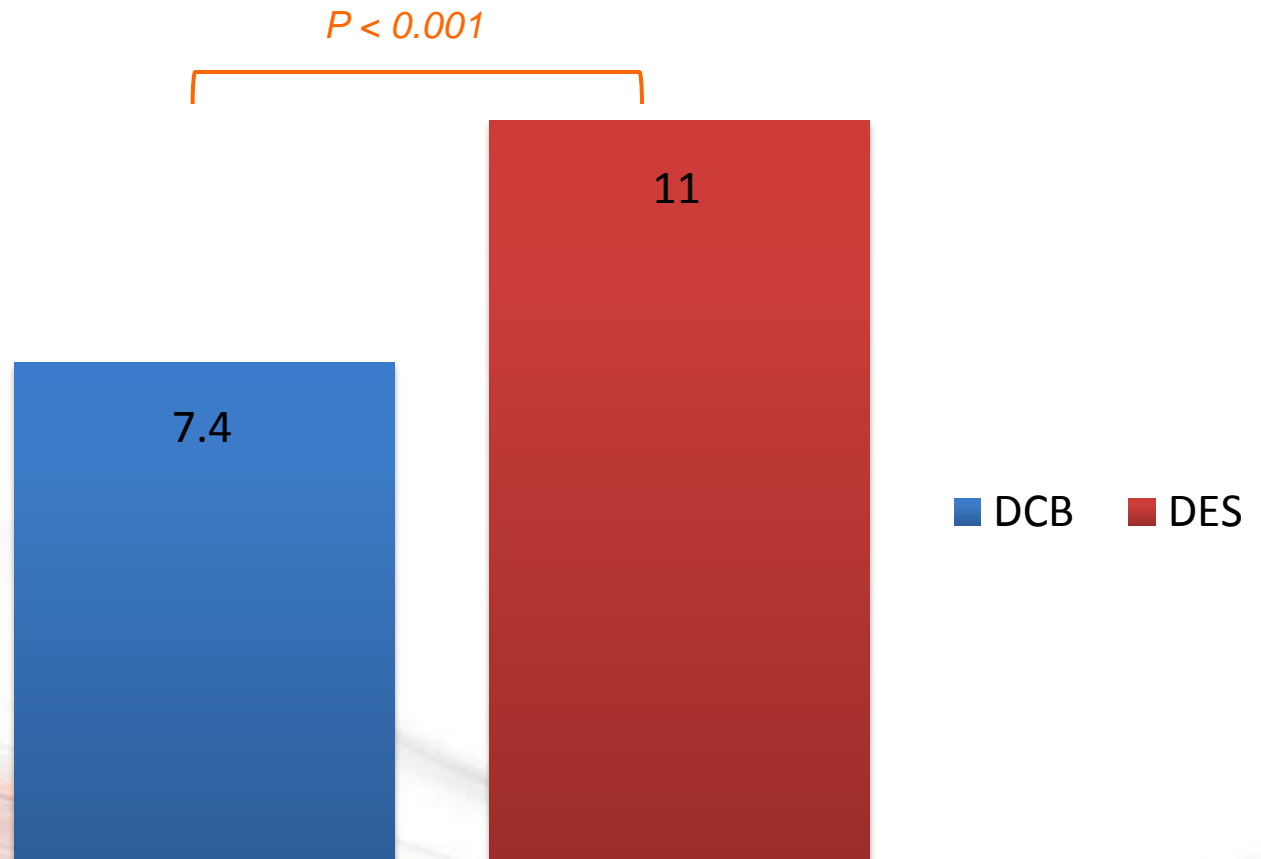
SQLP in SVD <2.5mm vs 2nd Generation DES



Presentation



DAPT Duration (months)



SQP in SVD <2.5mm vs 2nd Generation DES

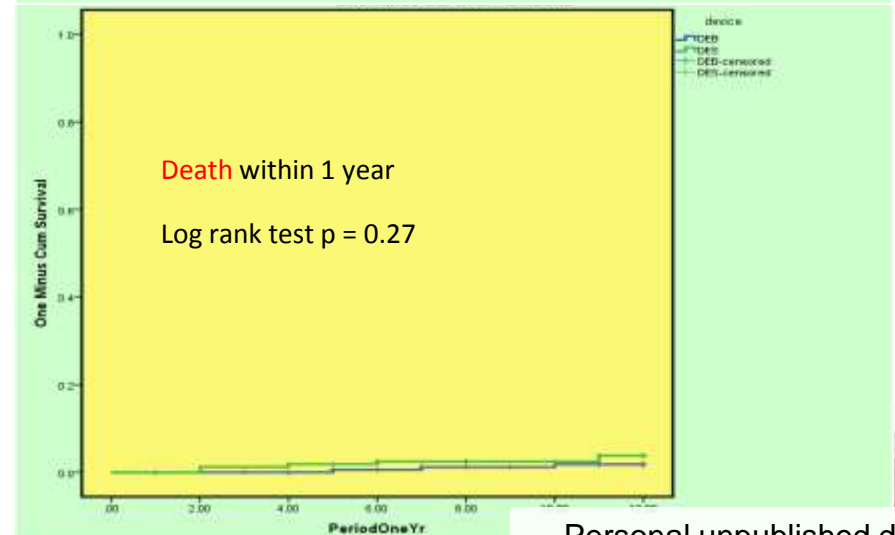
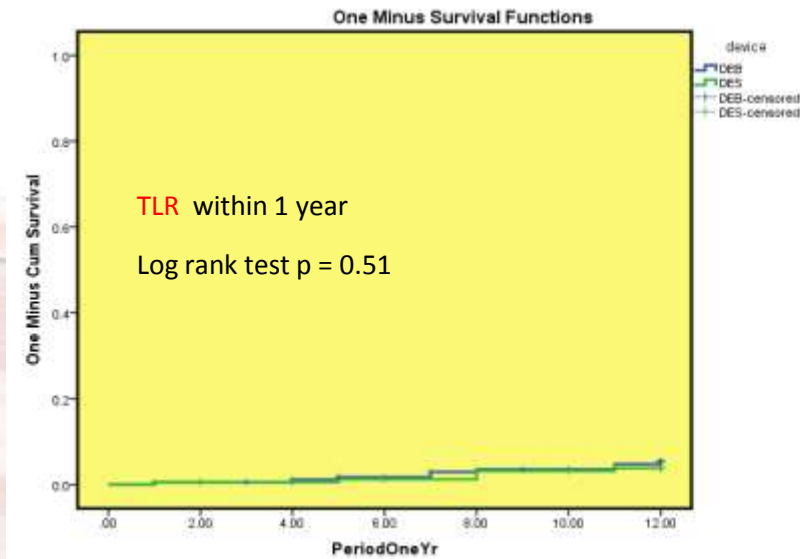
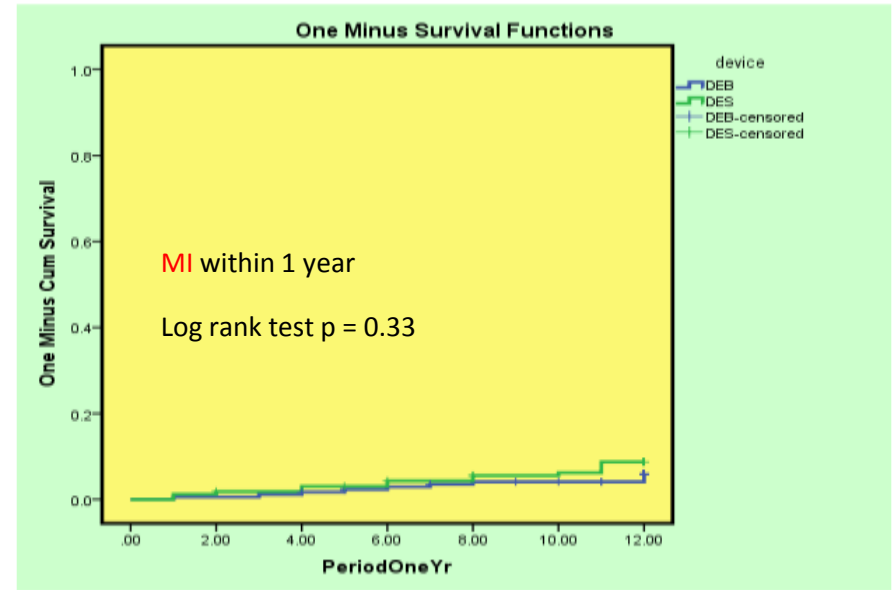
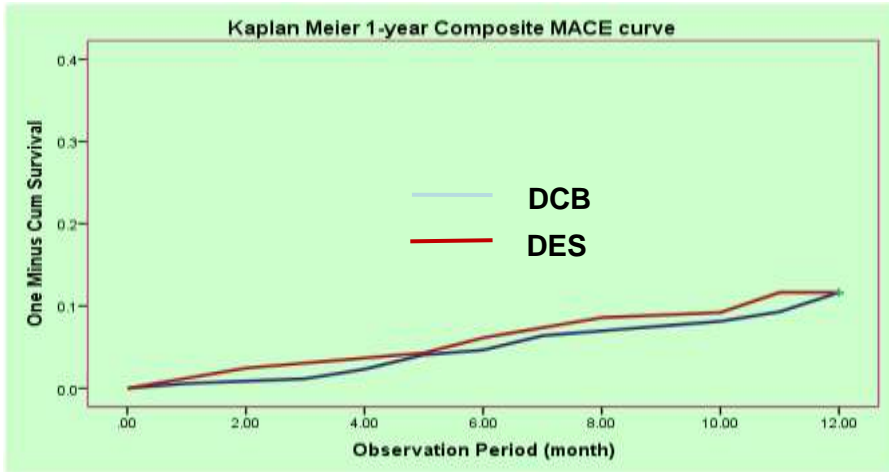
QCA	DCB	DES	P value
Reference Diameter	2.22 ± 0.29	2.43 ± 0.19	<0.001
Acute luminal gain	1.01 ± 0.52	1.72 ± 0.46	0.087
Diameter	2.28 ± 0.21	2.38 ± 0.12	<0.001
Length	20.1 ± 6.0	22.1 ± 7.2	<0.001

DCB vessels have smaller ref diameter using smaller device
 DCB achieved smaller absolute acute luminal gain

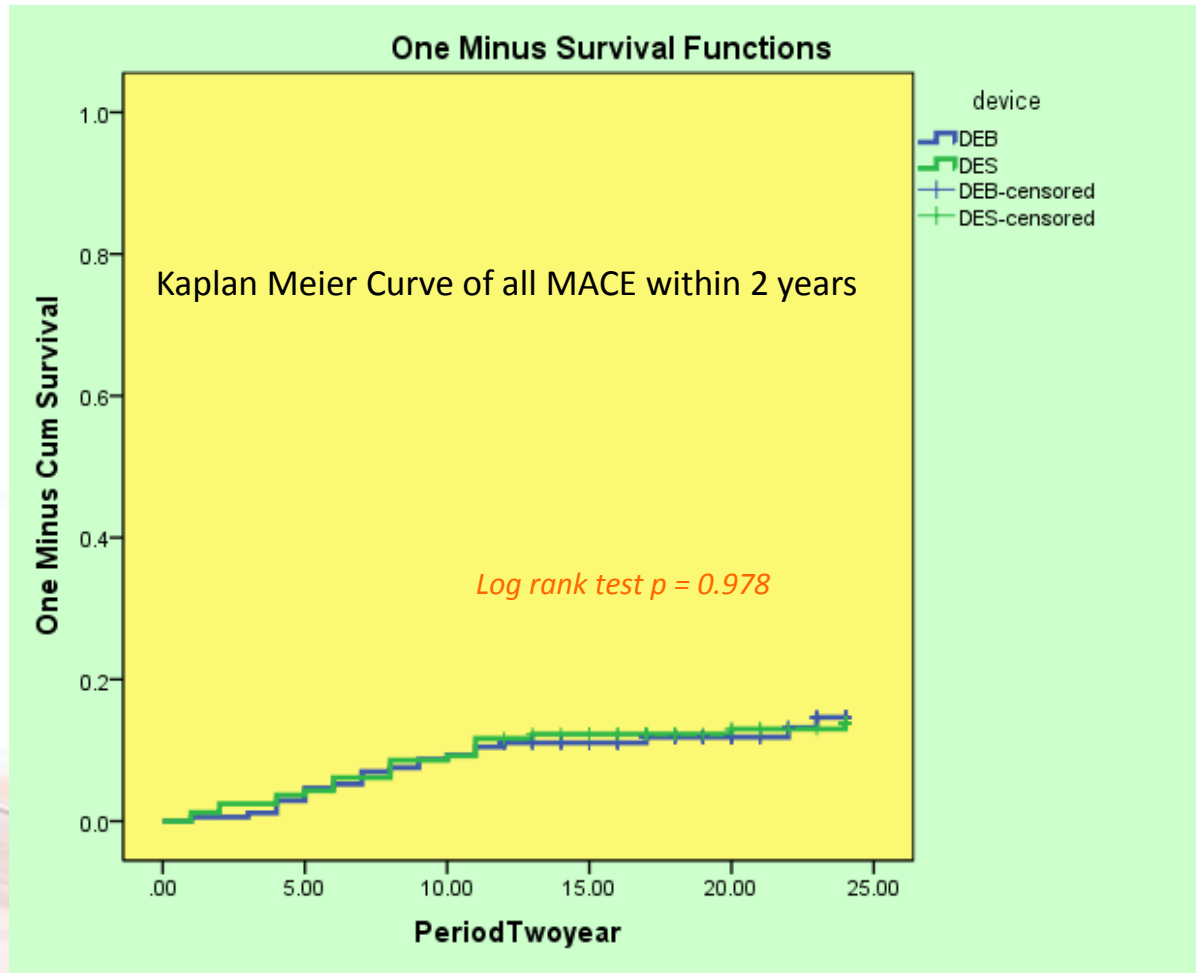
1 year outcome

	DCB N = 172		DES N = 163		p value
Composite MACE	20	11.63%	19	11.66%	1
Death	3	1.74%	6	3.68%	0.326
MI	10	5.81%	14	8.59%	0.398
TLR	9	5.23%	6	3.68%	0.601
CVA	2	1.16%	1	0.61%	1

STP in SVD <0.25mm vs 2nd Generation DES 1 Year



SQLP in SVD <2.5mm vs 2nd Generation DES 2 Years



Recap

- In small vessel disease <2.5mm
- DCB did not achieve the same absolute lumen gain compared to DES
- However, such anatomical advantage did not translate into clinical superiority in terms of TLR, Death or MI.
- There were minimal increase in MACE after the first year in both groups
- **DCB use in de novo SVD appeared to be as safe and effective when compared to modern DES**

Recap

- In small vessel disease <2.5mm
- DCB did not achieve the same absolute lumen gain compared to DES
- Such anatomical advantage did not translate into clinical superiority in terms of TLR, Death or MI.
- There were minimal increase in MACE after the first year in both groups
- **SQP use in de novo SVD appeared to be as safe and effective when compared to modern DES**
- **SQP use in de novo SVD is associated with shorter DAPT duration**

Positive Remodelling

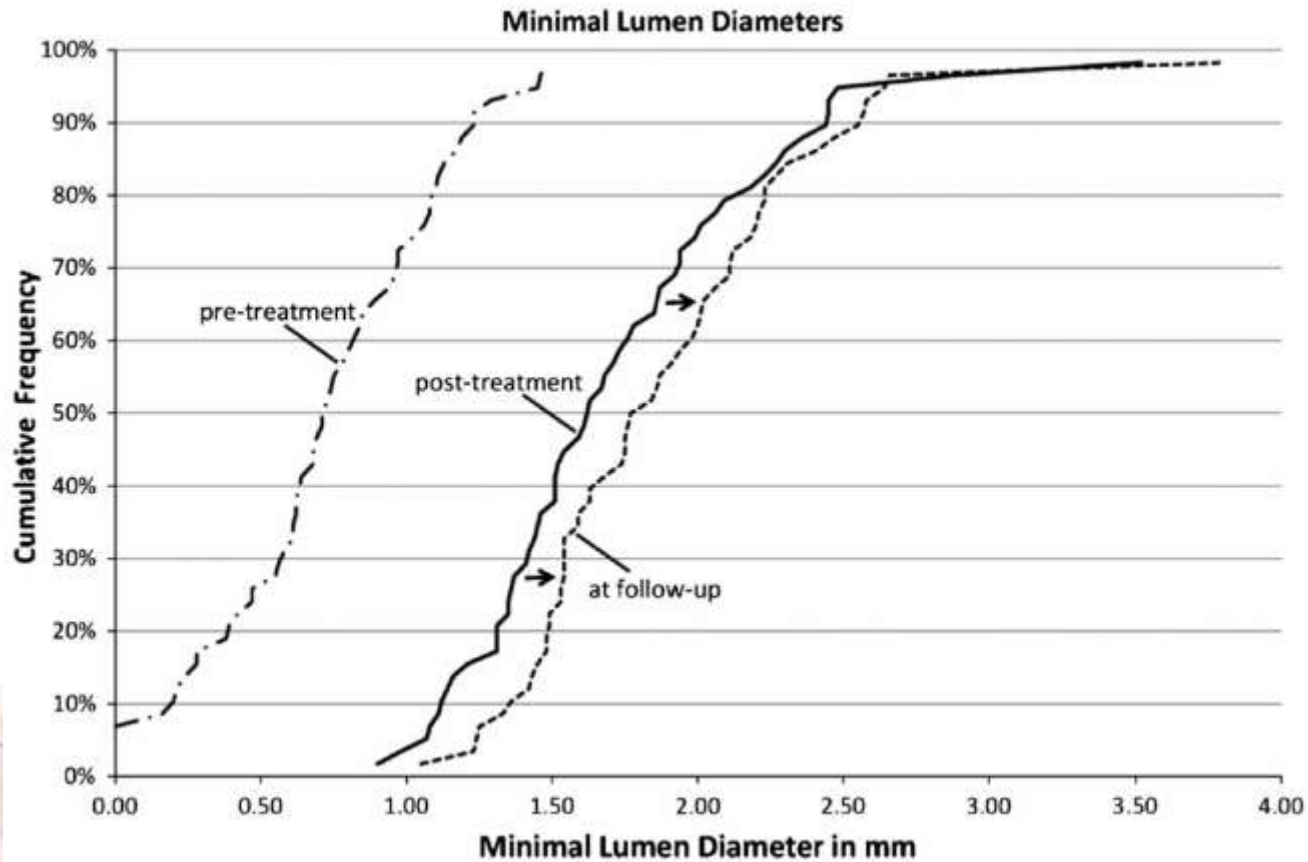
Clin Res Cardiol
DOI 10.1007/s00392-014-0775-2

ORIGINAL PAPER

Local paclitaxel induces late lumen enlargement in coronary arteries after balloon angioplasty

**Franz X. Kleber · Antonia Schulz · Matthias Waliszewski ·
Telse Hauschild · Michael Böhm · Ulrich Dietz · Bodo Cremers ·
Bruno Scheller · Yvonne P. Clever**

angiographic follow-up at 4.1 ± 2.1 months



CASE HIGHLIGHTS



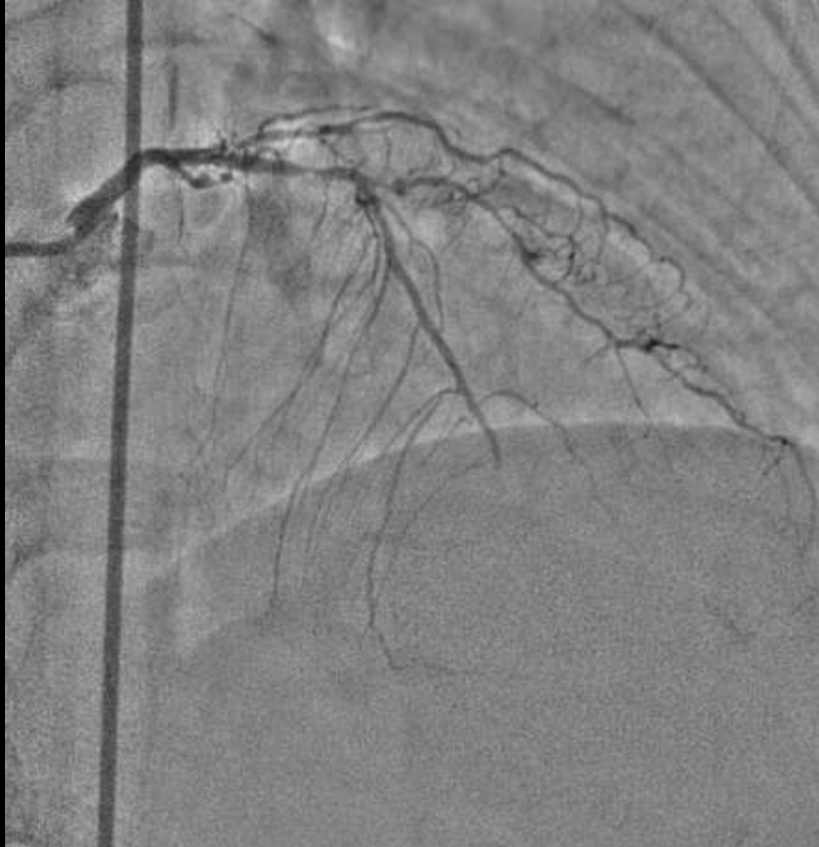
Lumen restored
and re-endothelialized

SQP angioplasty – *it gets better with time*

- ♥ Age 73 yr old Malay lady
- ♥ Poorly controlled DM Hba1c 10.4
- ♥ NCNC anaemia Hb 10.6
- ♥ Hypertension
- ♥ Hyperlipidaemia

- ♥ Recurrent admission with angina and or CCF
- ♥ 8 admissions under various teams in 2 years
- ♥ Triple vessels disease surgical turn down
- ♥ EF 40% with RWMA consistent with multivessels disease

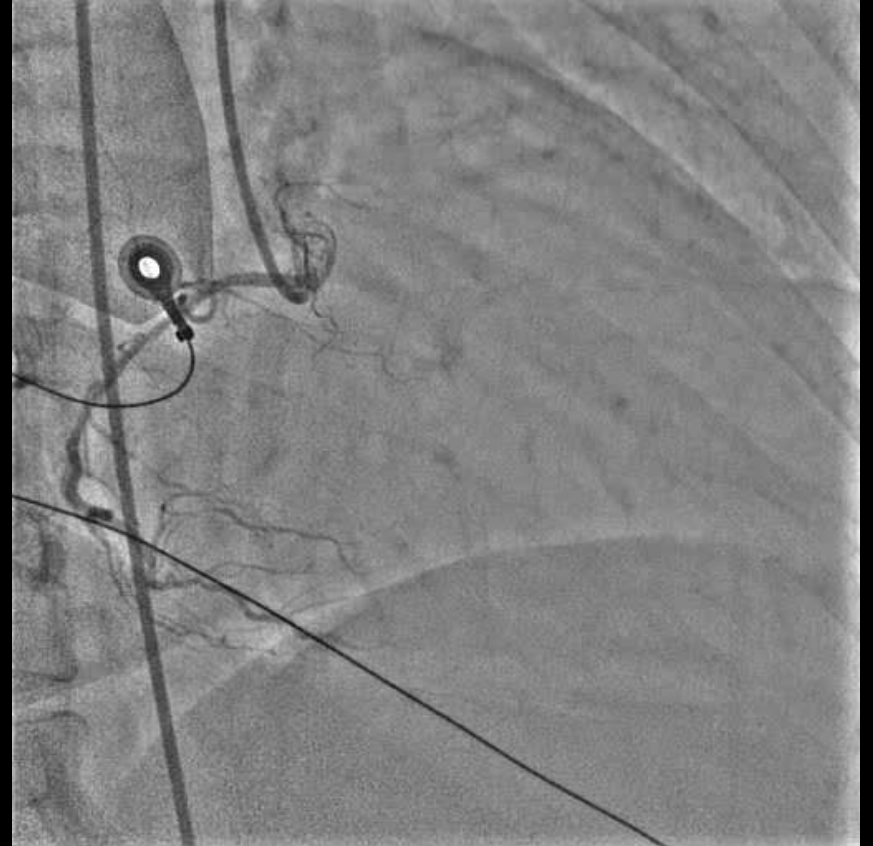
2009



2009



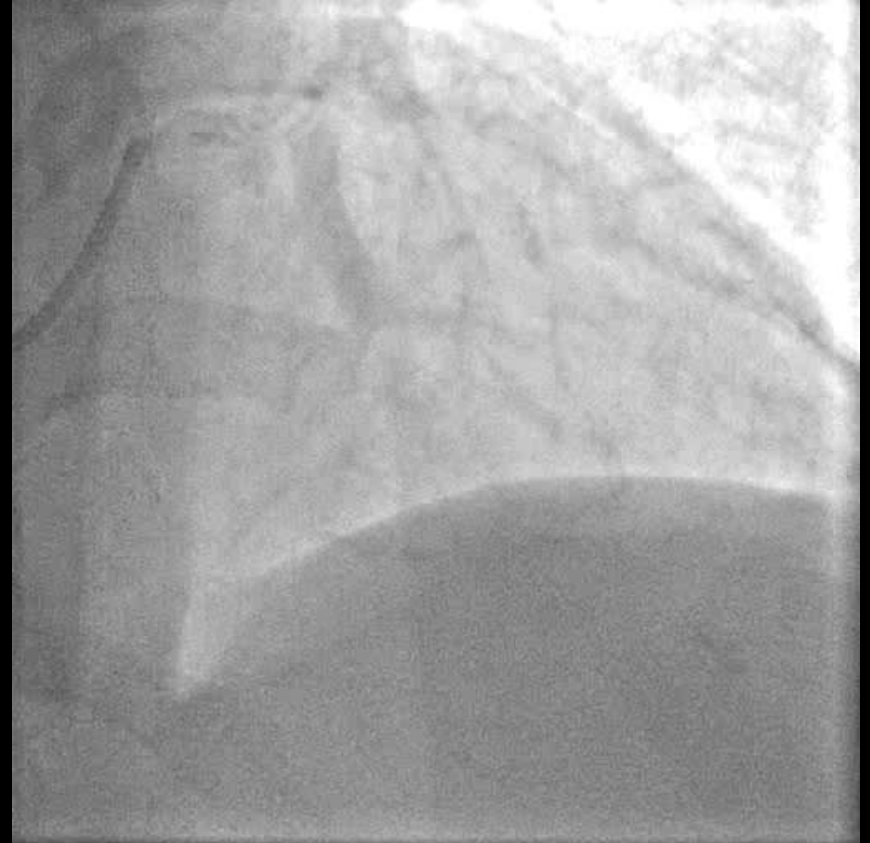
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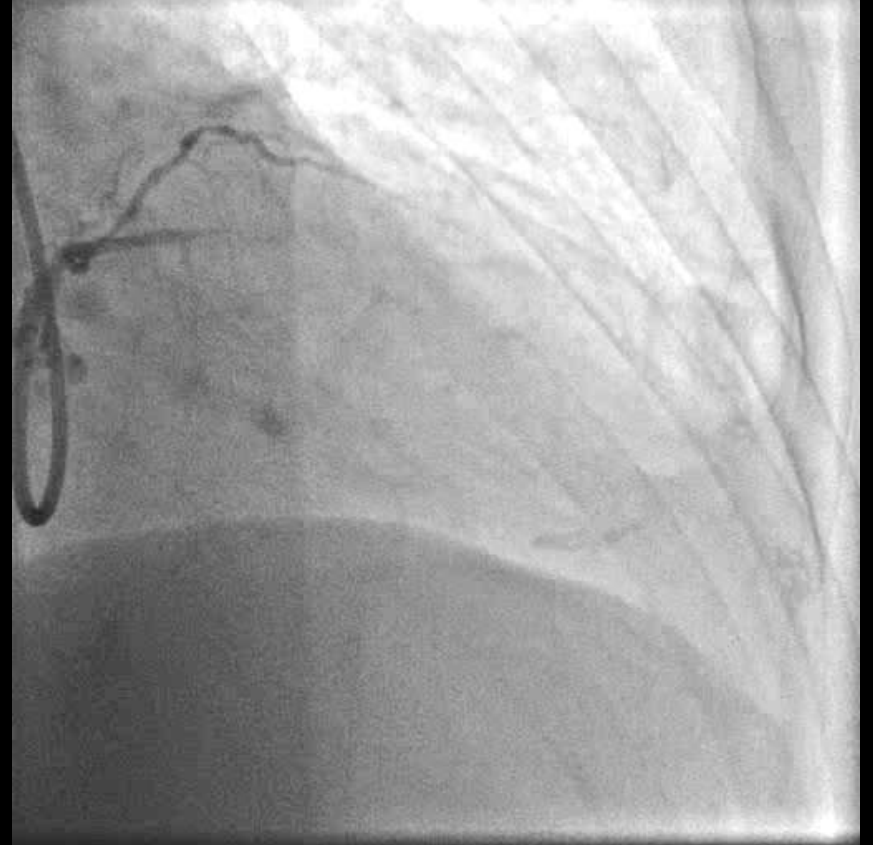
2011

- 5 successive admissions over 2 years with heart failure
- Some angina but not really doing much at home/ cannot do much at home

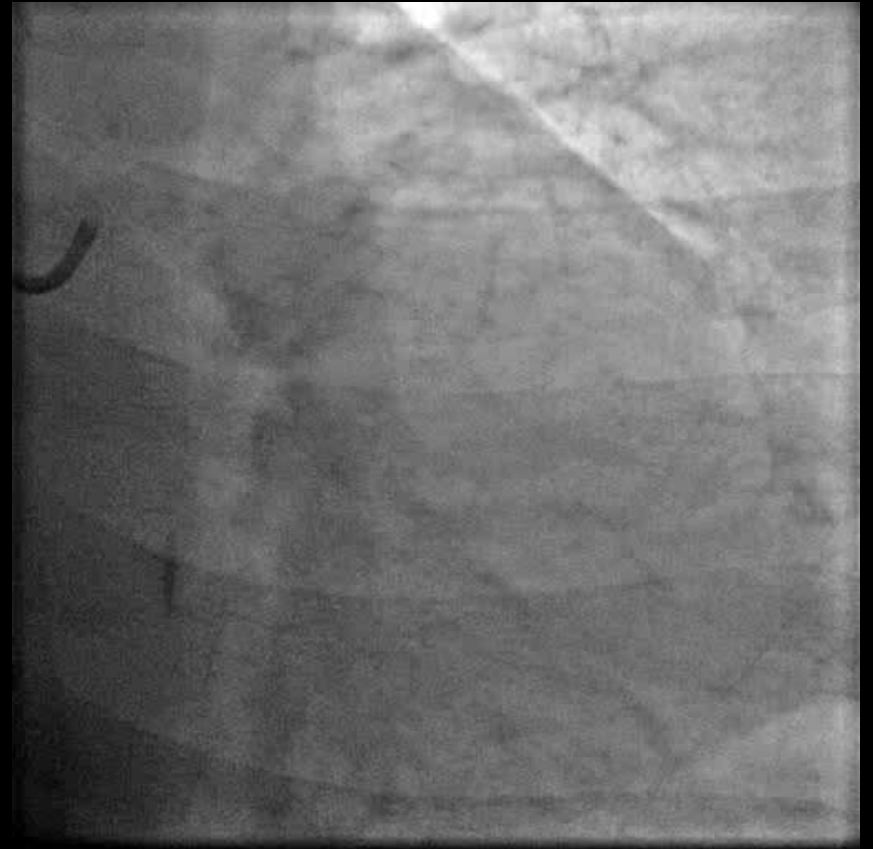
2011



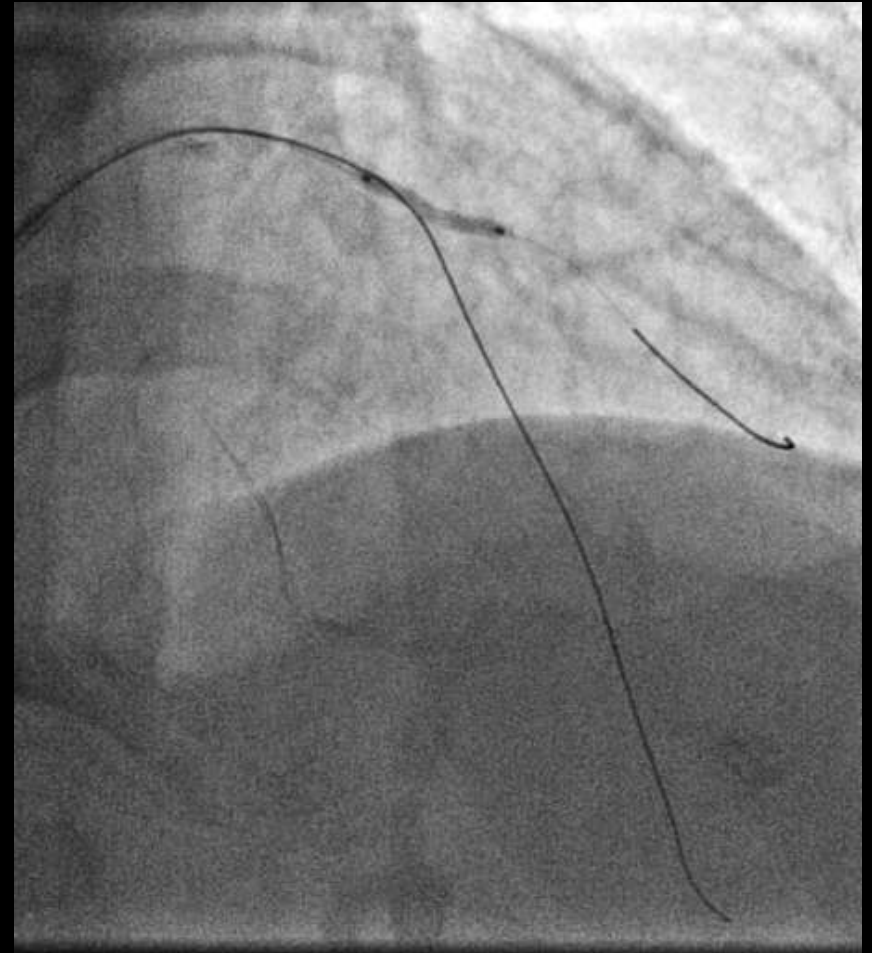
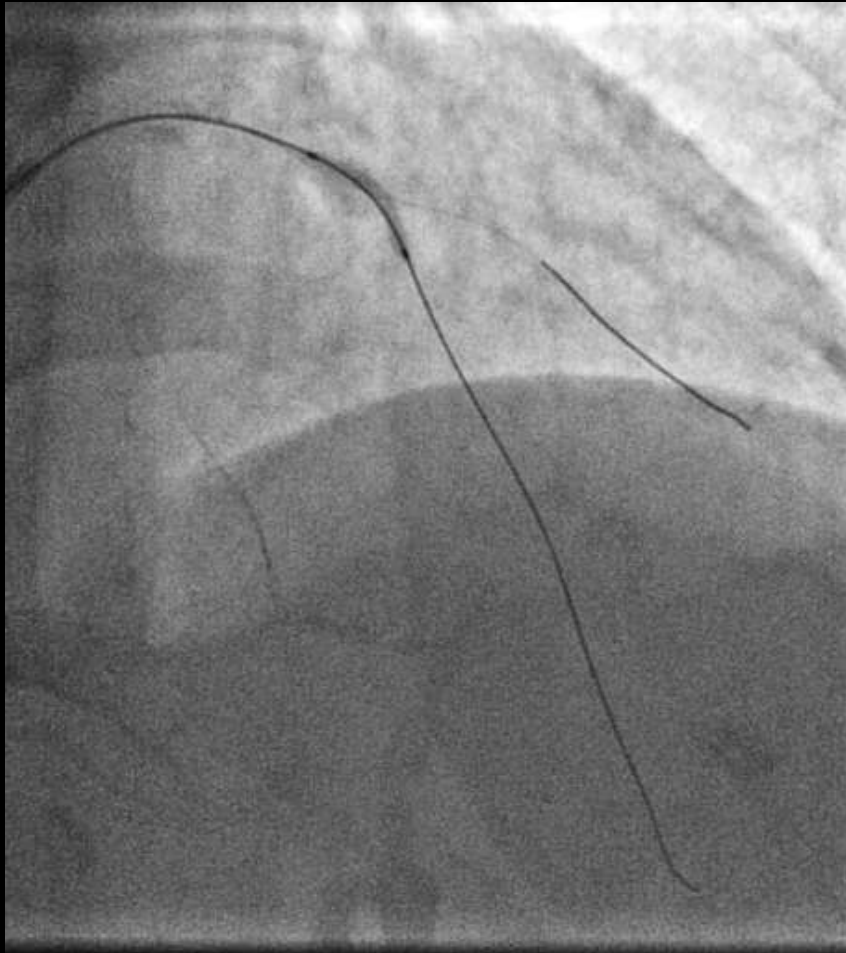
2011



2011



Reluctantly 2011



2011

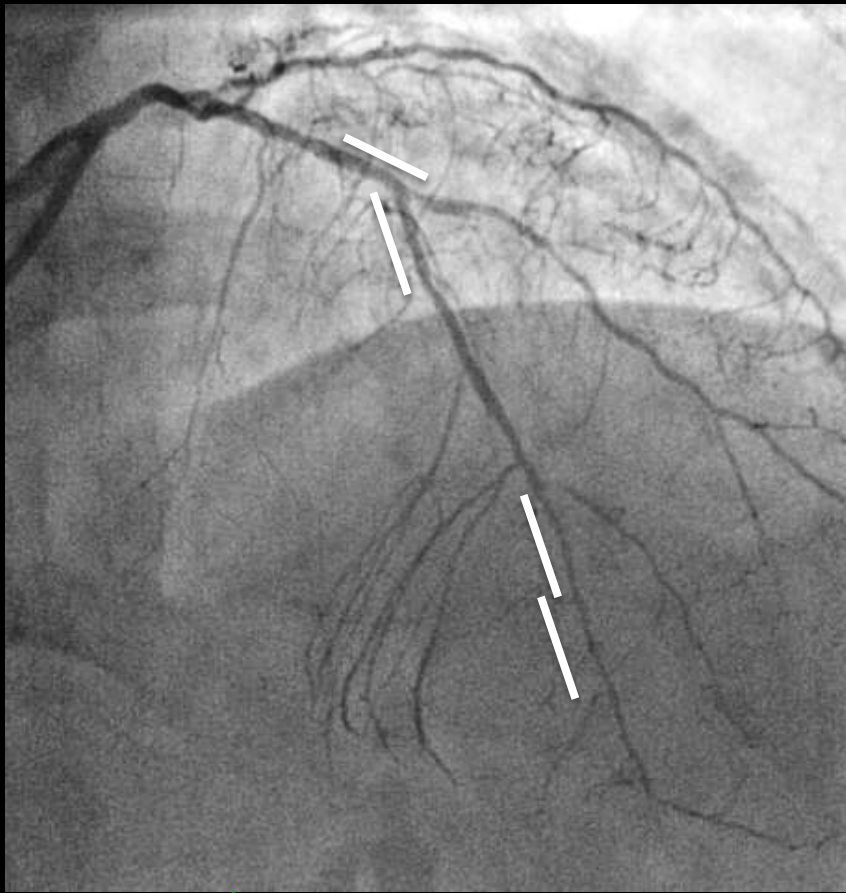


2011



- After a lot of pre dilatation and GTN
- What would you do next?
- Where would you place the devices?

10/2011



Final result



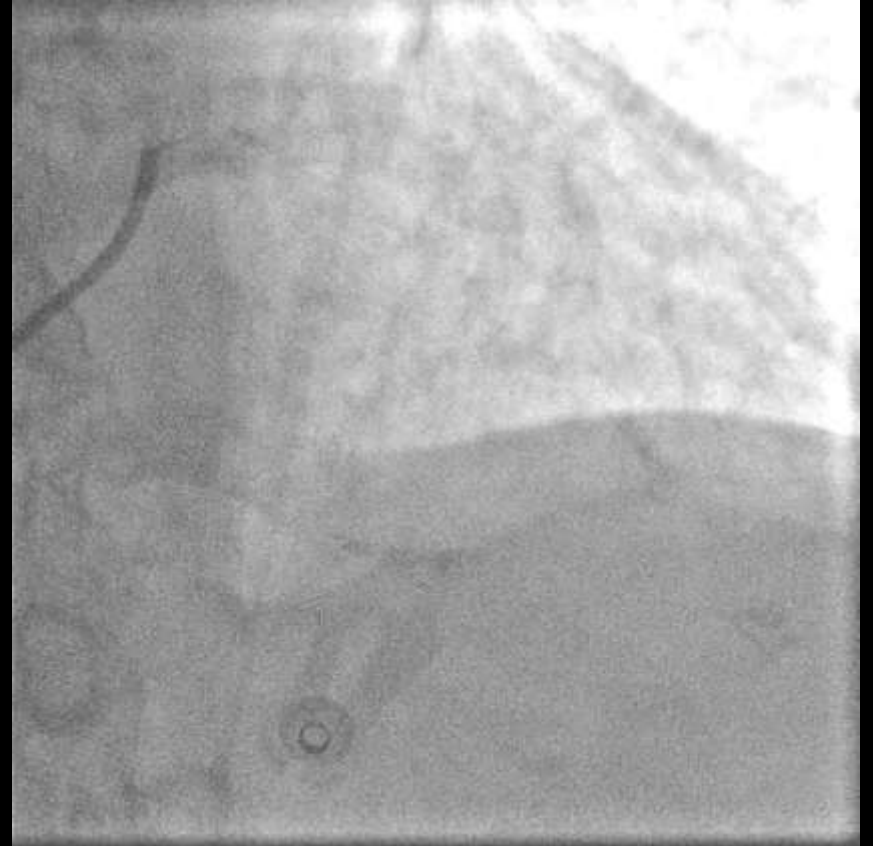
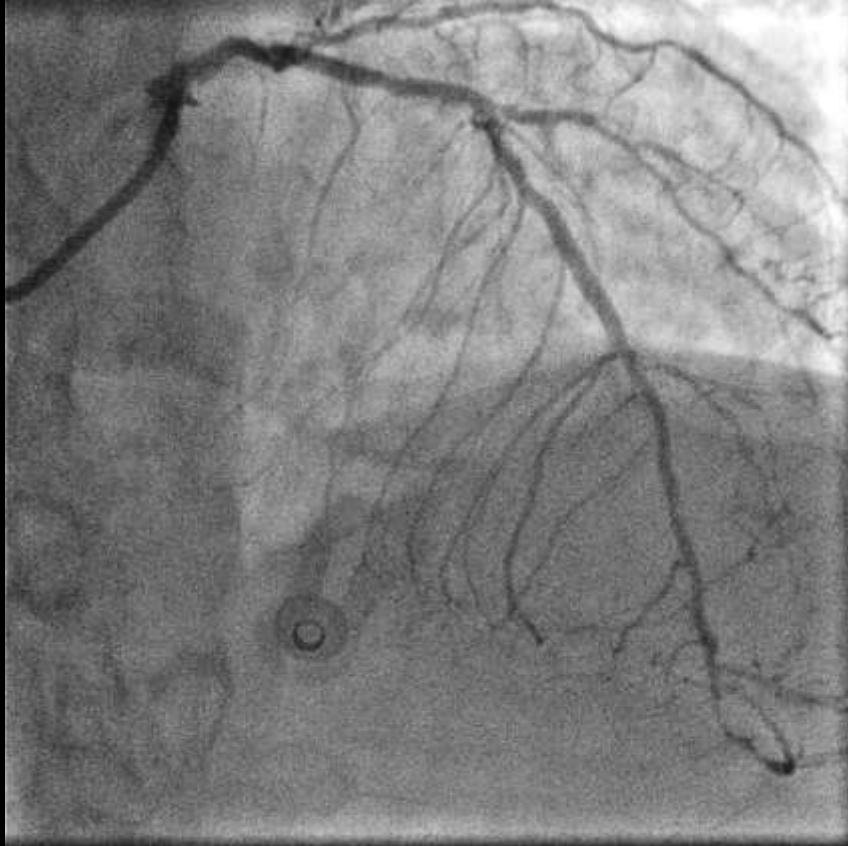
SeQuent Please

2.5*17, 2.5*20, 2.0*20 and 2.0*20

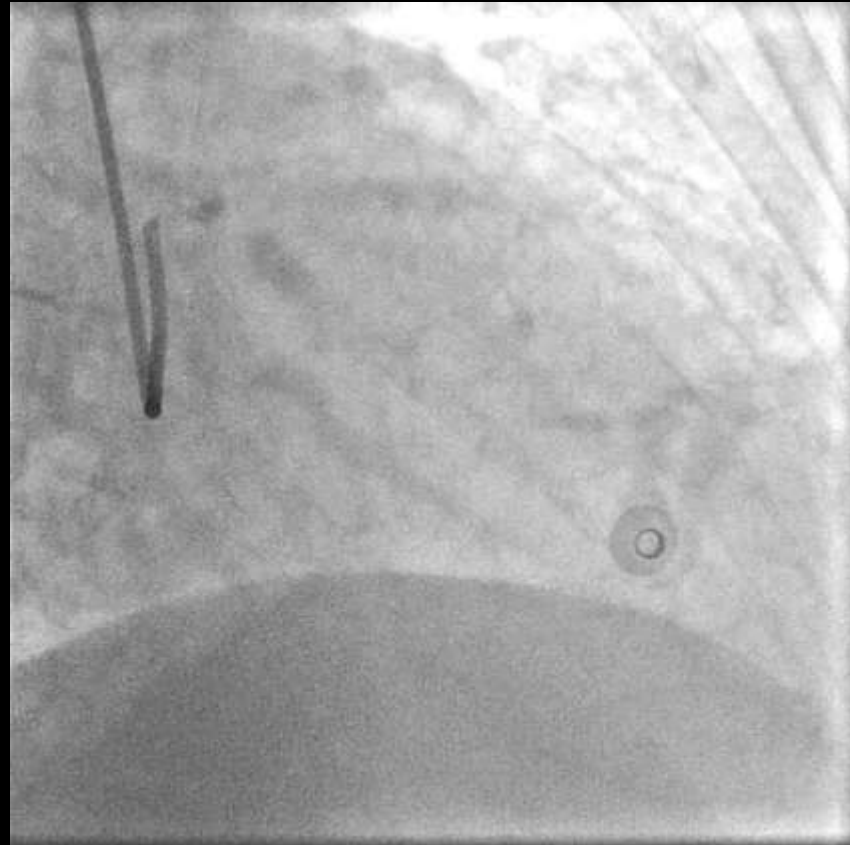
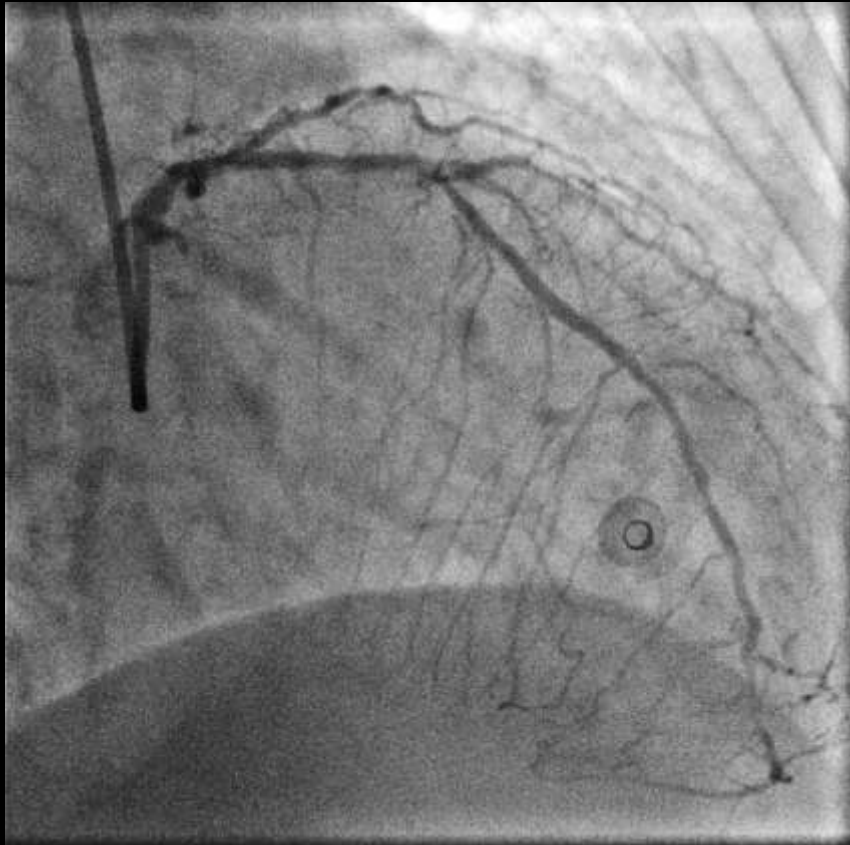
3 Year Repeat Angiography

- 1st readmission after 3 years
- SOB and Troponin leak
- Took opportunity to recheck angio

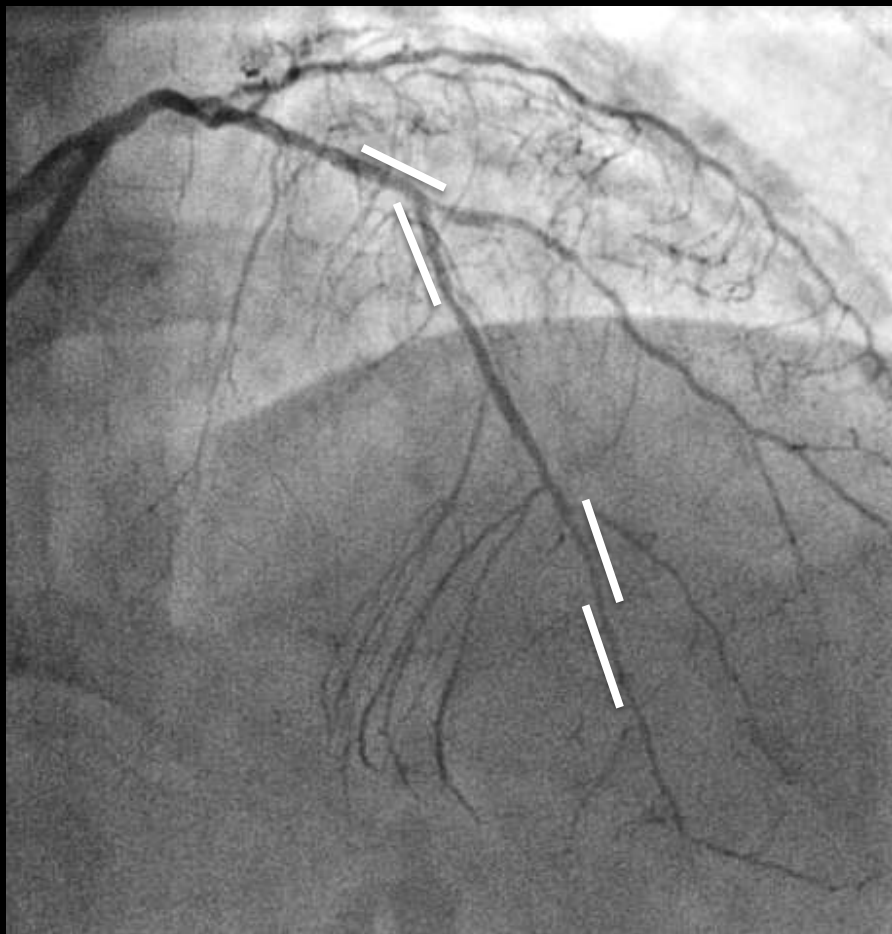
10/2014



10/2014



Oct 2011



Oct 2014

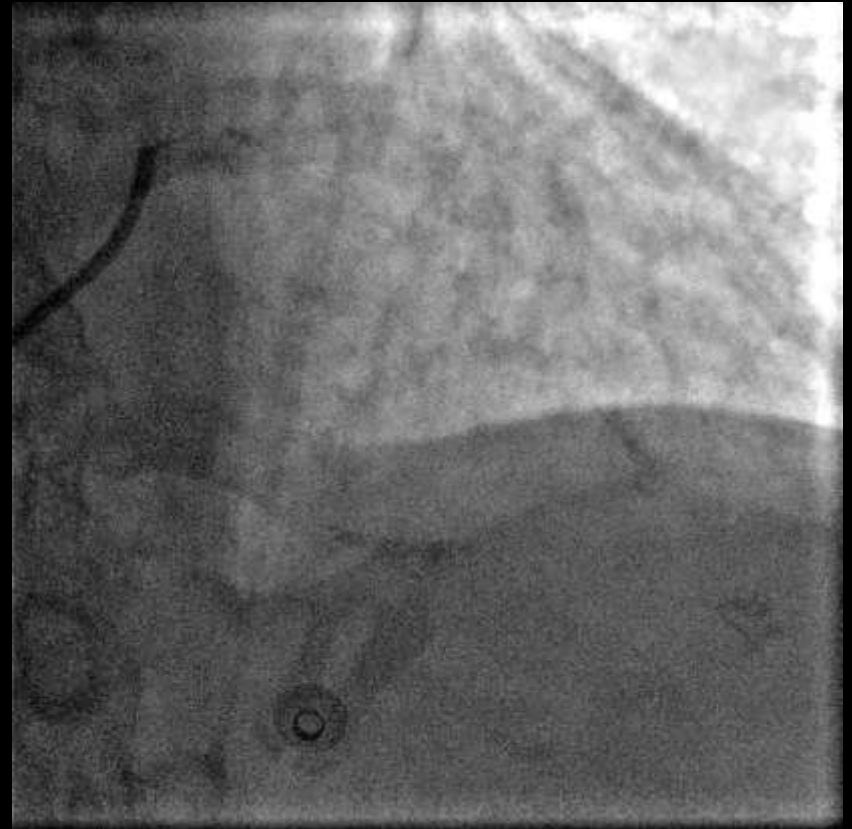


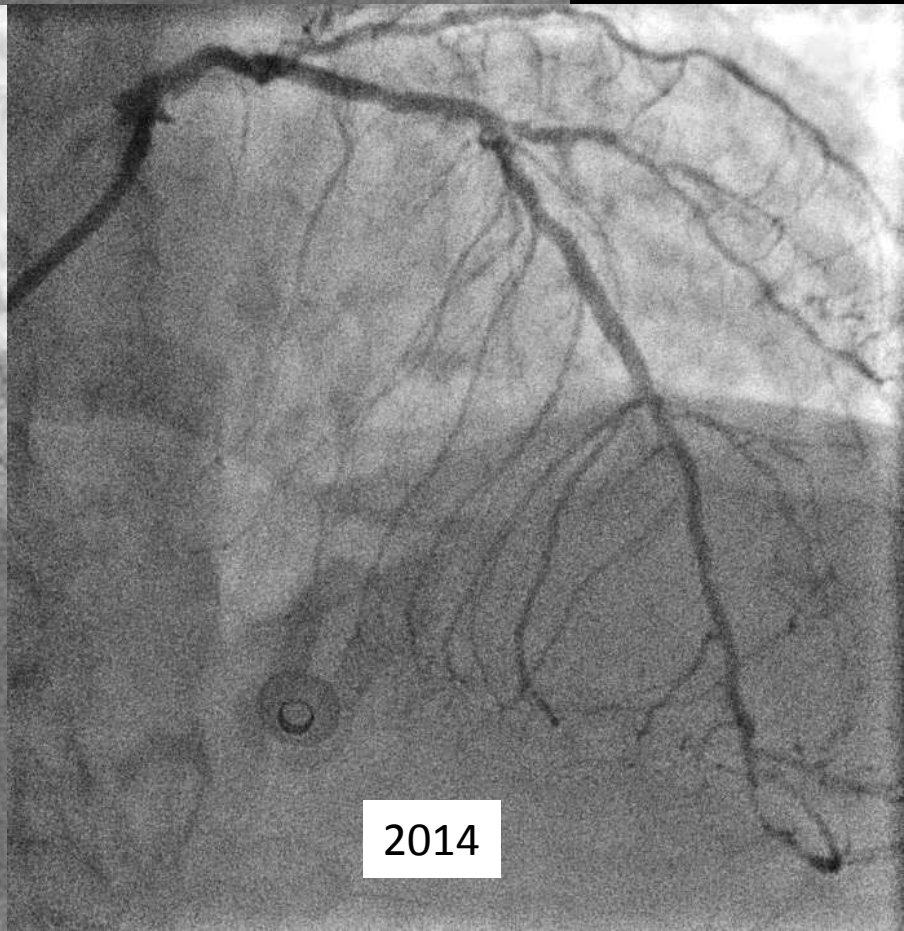
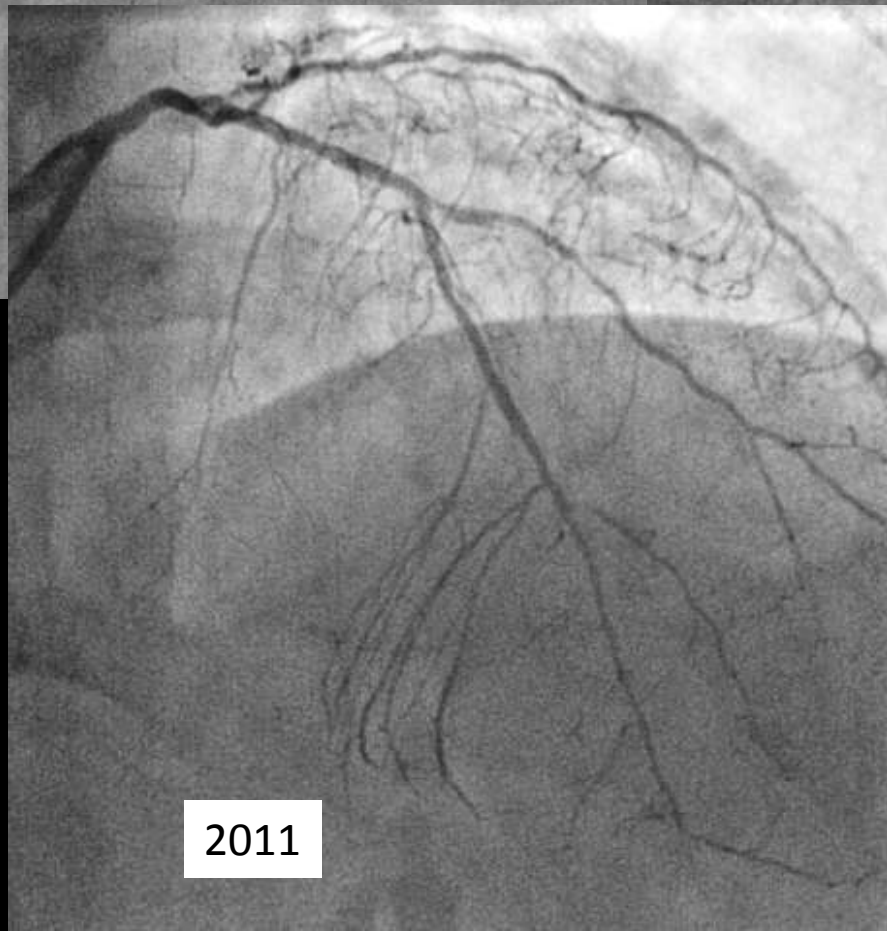
3 Years follow up angio Positive Remodelling?

Oct 2011

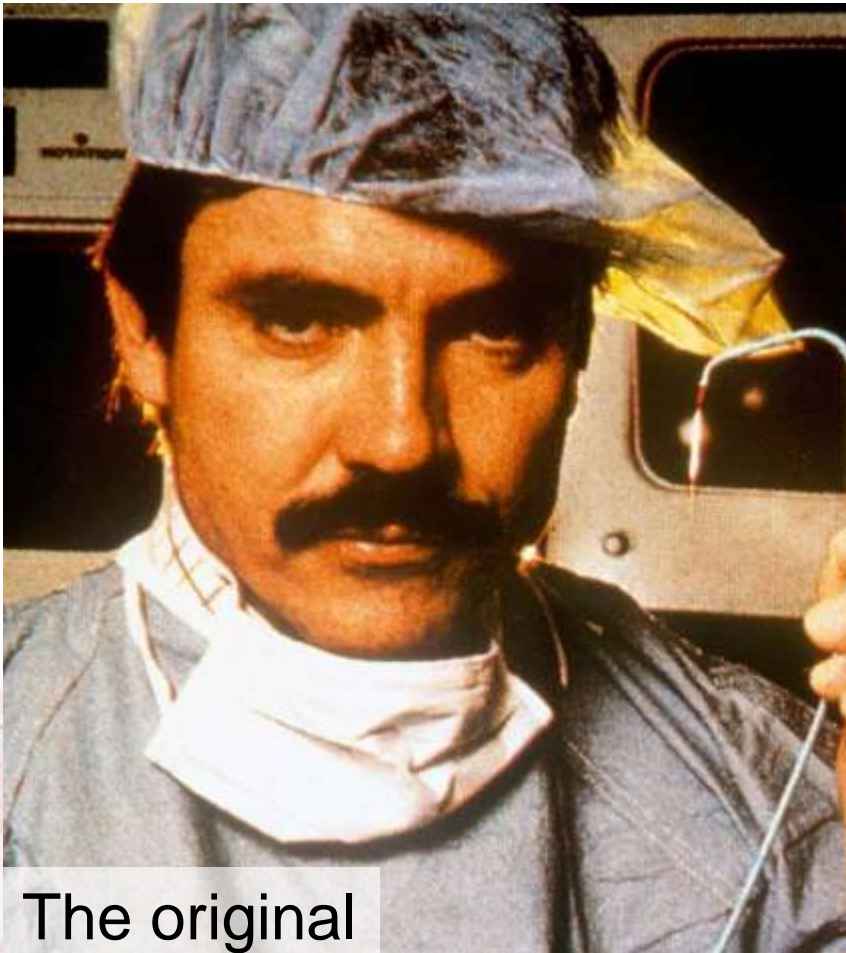


Oct 2014

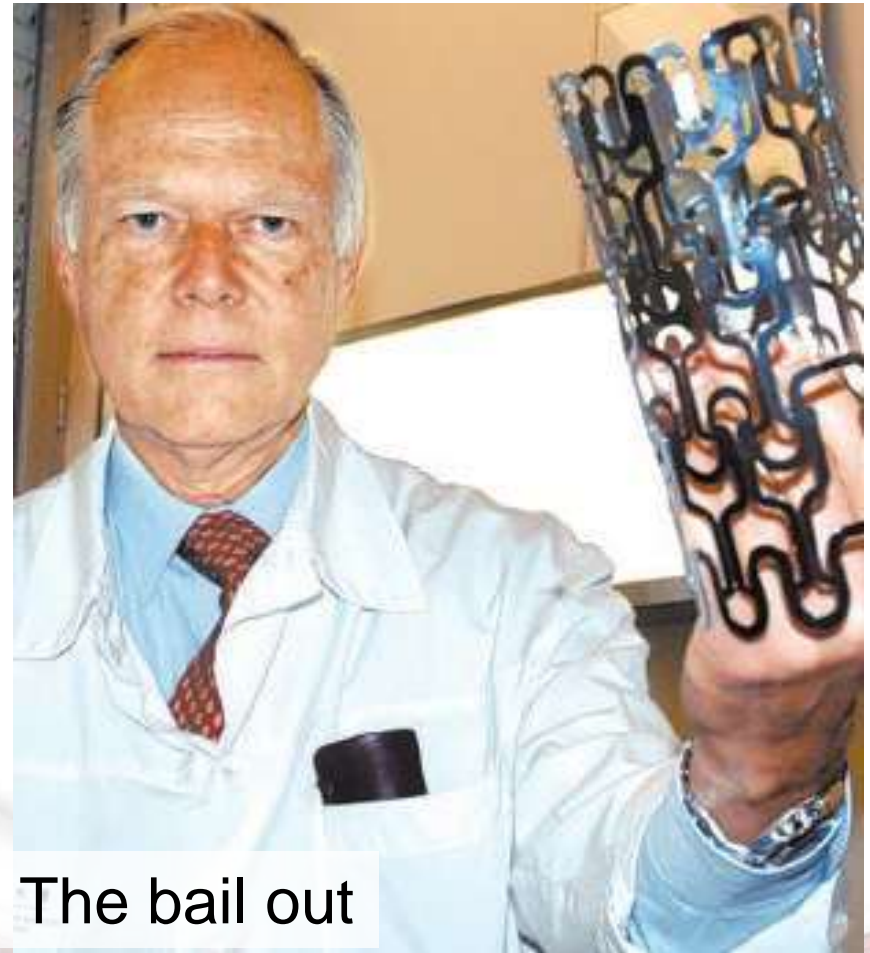




Stent was only meant to be a bail out strategy



The original



The bail out

Vascular Restorative Therapy

- Free of any permanent structure inside the arterial wall
- No caging effect
- Vessel can expand and contract in a normal physiological manner
- No longer term worries like very late stent thrombosis
- Much shorter DAPT duration
- Positive remodelling observed in follow up angiography with larger lumen size