

*“Drug-eluting stent for left main
bifurcation stenosis:
Medium-term follow-up*

T. Santoso, MD,. PhD
Medistra Hospital,
Univ. of Indonesia Medical School,
Jakarta, Indonesia

Background

- PCI of unprotected LM stenosis is feasible & good long – term outcome has been reported particularly in pts with good LV
- PCI of unprotected LM bifurcation stenosis (ULMBS) is more challenging & risky, particularly if it is associated with multivessel disease or poor LV function
- Although preliminary experiences with the use of DES for ULMBS is encouraging, the results are still not consistent & medium - to - long term follow-up is still lacking

DES in LM Registries

Restenosis Rate



Purpose of study

- *The assess clinical & angiographic outcomes of DES as opposed to Bare Metal Stents (BMS) implantation in unprotected LM bifurcation stenosis*

Methods

- Comparison of all consecutive pts with unprotected LM bifurcation stenosis treated with DES with the historical control group of consecutive pts treated with BMS
- Clinical assessment & follow-up:
 - in-hospital, & at 3, 6 & 12 months
- Angiographic follow-up:
 - at 6 months or
 - earlier if clinical presentation or non-invasive evaluation suggested presence of ischemia

Methods

- Symptomatic or asymptomatic LM bifurcation stenosis of $\geq 50\%$ with documented ischemia, regardless of age, presence of MVD or LV function
- Exclusions:
 - AMI
 - Bail out situation
 - Instent restenosis
 - Contraindications to anti-thrombotic therapy
 - Patient's preference to CABG

Procedures

■ *Antiplatelets:*

- **BMS:** aspirin (indefinitely) + clopidogrel or ticlid (1 month)
- **DES:** aspirin (indefinitely) + clopidogrel (6-9 months)
± cilostazol ± GP IIb/IIIa inhibitor

■ *Stents:*

- **BMS:** Crossflex, Bx-velocity, JoStent, NIR, Be-stent, Crown, Tetra, Kalam Raju
- **DES:** Cypher, or Taxus (± BMS in LAD/LCX)

Patient characteristics (1)

	<i>DES</i>	<i>BMS</i>	<i>p</i>
No	78	56	
Age (yrs, mean \pm SD)	61.3 \pm 9.9	59.3 \pm 12.3	ns
Male	60 (77%)	44 (79%)	ns
Family history of CAD	20 (26%)	13 (23%)	ns
Diabetes	25 (32%)	12 (21%)	0.04
Hypertension	21 (27%)	12 (21%)	ns
Dyslipidemia	37 (47%)	26 (46%)	ns
Smoking	26 (33%)	21 (37%)	ns
Prior MI	13 (17%)	11 (20%)	ns
Prior CABG	3 (3%)	2 (4%)	ns
Prior PCI	9 (11%)	7 (12%)	ns

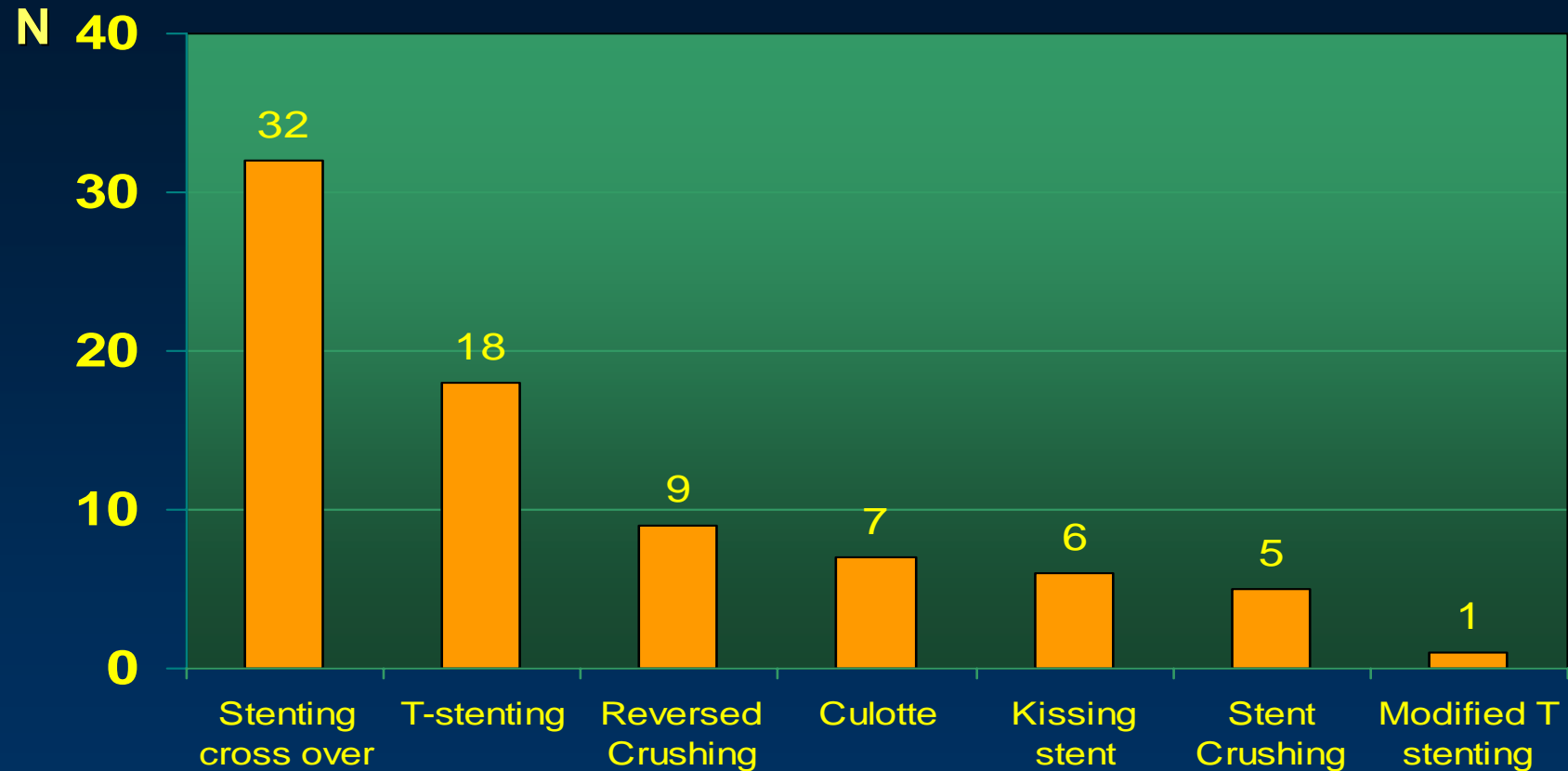
Patient characteristics (2)

	DES	BMS	p
No	78	56	
Angina			
• Stable	35 (45%)	25 (45%)	ns
• Unstable	33 (42%)	22 (39%)	
• Silent ischemia	10 (13%)	9 (16%)	
Extent of CAD			
• LM only	0 (0%)	0 (0%)	ns
• LM + 1VD	8 (10%)	6 (11%)	ns
• LM + 2VD	29 (37%)	28 (50%)	<.001
• LM + 3VD	41 (53%)	22 (39%)	<.001
LVEF (% , mean \pm SD)	52 \pm 25	51 \pm 21%	ns

Procedural Characteristics

	DES	BMS	p
<i>Stenting procedure</i>			
• Max. pressure (atm)	16.5 ± 2.9	15.3 ± 4.8	ns
• Final stent length (mm)	27.1 ± 13.0	17.1 ± 8.3	0.01
• Stent length / lesion length ratio	1.4 ± 0.8	1.5 ± 0.9	ns
• Stent overlap	60 (76%)	32 (56%)	0.02
<i>Antiplatelets</i>			
• Aspirin + Plavix / Ticlid	78 (100%)	56 (100%)	ns
• + Cilostazol	6 (8%)	0 (0%)	ns
• + GP IIb/IIIa inhibitors	5 (6%)	0 (0%)	ns
<i>Adjunctive procedure</i>			
■ Use of IVUS	0 (0%)	9 (16%)	<.001
■ Use of debulking			
■ Rotablation	0 (0%)	20 (36%)	<.001
■ DCA	5 (7%)	5 (9%)	ns
■ Silverhawk / Foxhollow	3 (4%)	0 (0%)	ns
■ Use of IABP	0 (0%)	0 (0%)	ns

Types of LM bifurcation stenting



- Always finish with kissing-balloon dilatation
- Always try to avoid gap between stents
- Always try to completely appose stent to the vessel wall

In-hospital results

	<i>DES</i>	<i>BMS</i>	<i>p</i>
<i>Success Rate:</i>			
■ Procedural	100 %	100%	ns
■ Clinical	100 %	98.2%	ns
<i>Complications:</i>			
■ Cardiac deaths	0	0	ns
■ Noncardiac deaths	0	1*	ns
■ Nonfatal QMI	0	0	ns
■ Nonfatal NQMI	0	1#	ns
■ Any nonfatal MI	0	0	ns
■ Emergent CABG	0	0	ns
■ PCI, TLR	0	0	ns
■ Acute thrombosis	0	0	ns

* 1 Hemorrhagic stroke at day 6; # Guide wire perforation, tamponade, NQMI

6-month clinical outcome

	<i>DES</i>	<i>BMS</i>	<i>p</i>
• No	72 (92%)	55 (98%)	
• Cardiac deaths	2 (2.8%)	2 (3.6%)	ns
• Noncardiac deaths	0	1 (1.8%)	ns
• Nonfatal QMI	0	0	ns
• Nonfatal NQMI	0	0	ns
• CABG	3 (4.2%)	7 (12.7%)	<.001
• PCI, TLR	4 (5.6%)	4 (7.3%)	ns
• Angina	7 (9.7%)	14 (25.4%)	<.001
• Late thrombosis	0	0	ns
• MACE free survival	63 (88%)	42 (76%)	<.001

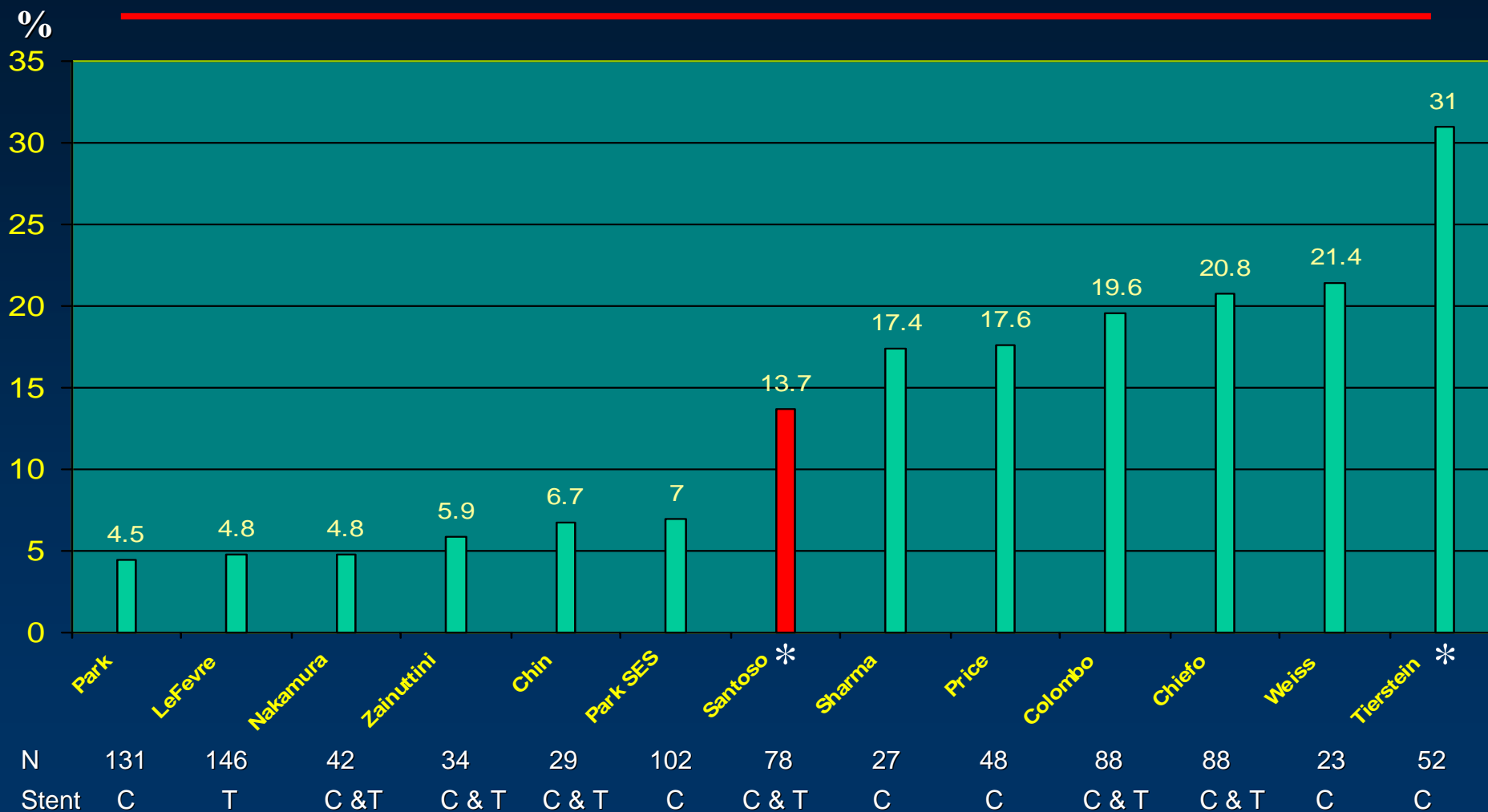
12-month clinical outcome

	<i>DES</i>	<i>BMS</i>	<i>p</i>
• No	57 (73%)	52 (74.3%)	
• Cardiac deaths	2 (3.5%)	4 (7.7%)	ns
• Noncardiac deaths	1 (1.8%)	1 (1.9%)	ns
• Nonfatal QMI	0	0	ns
• Nonfatal NQMI	0	0	ns
• CABG	3 (5.3%)	10 (19.2%)	<.001
• PCI, TLR	4 (7.0%)	5 (9.6%)	ns
• Angina	9 (15.8%)	18 (34.6%)	<.001
• Late thrombosis	0	0	ns
• MACE free survival	48 (84%)	33 (63%)	<.001

QCA: 6 month angiographic follow-up

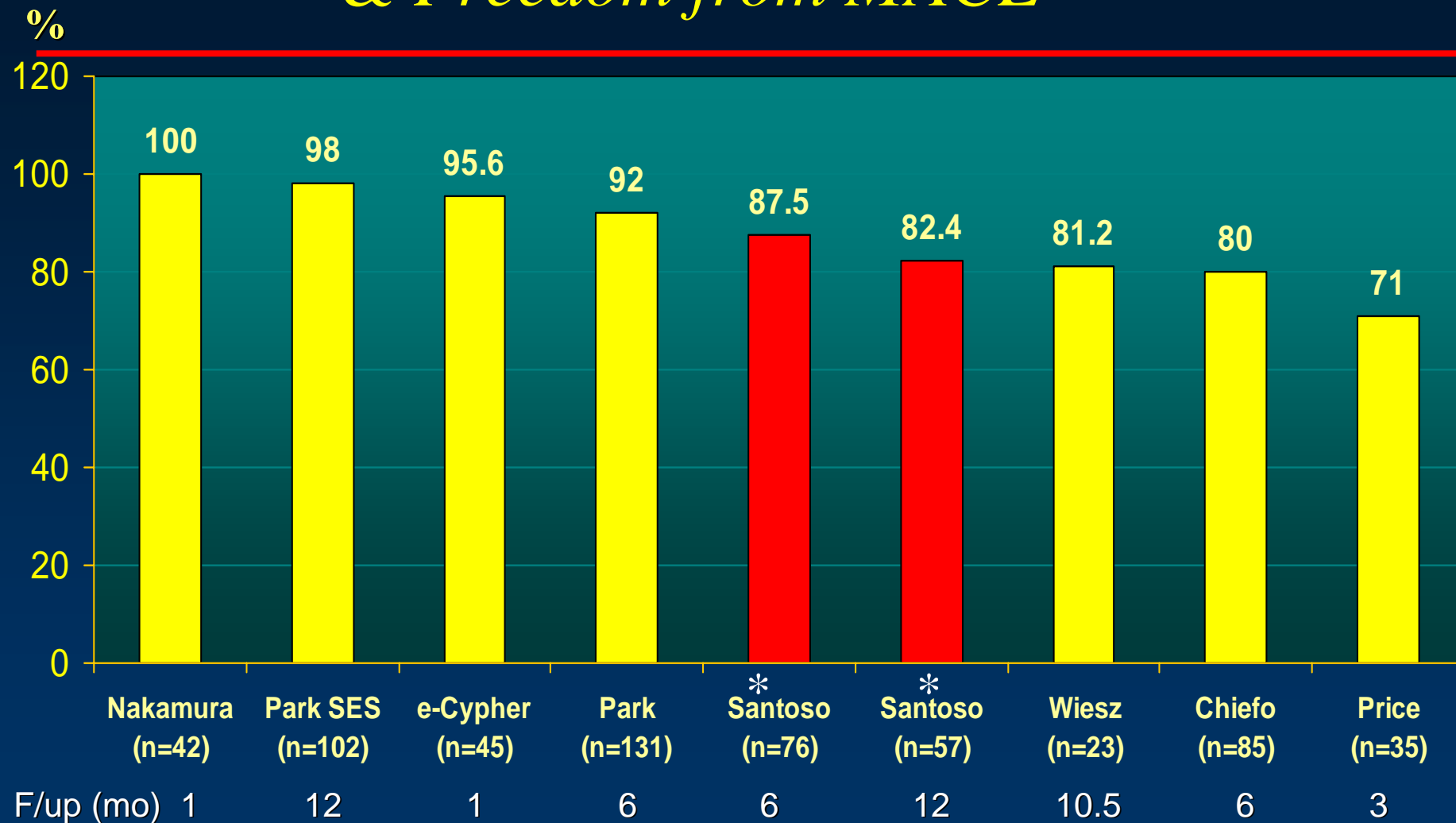
	<i>DES</i>	<i>BMS</i>	<i>p</i>
• No	51 (66%)	38 (68%)	
• Ref. diameter (mm)	3.64 ± 0.58	3.80 ± 0.41	0.05
• Lesion length (mm)	18.9 ± 13.2	11.4 ± 6.3	0.04
• MLD pre (mm)	1.12 ± 0.53	0.99 ± 0.56	ns
• MLD post (mm)	3.69 ± 0.53	3.74 ± 0.46	ns
• MLD f/up (mm)	3.47 ± 0.45	2.74 ± 1.07	<.001
• Late loss (mm)	0.22 ± 0.14	1.00 ± 1.02	<.001
• Binary restenosis (mm)	7 (13.7%)	12 (31.6%)	<.001

DES in LM Registries (2005): Restenosis Rate



* LM bifurcation

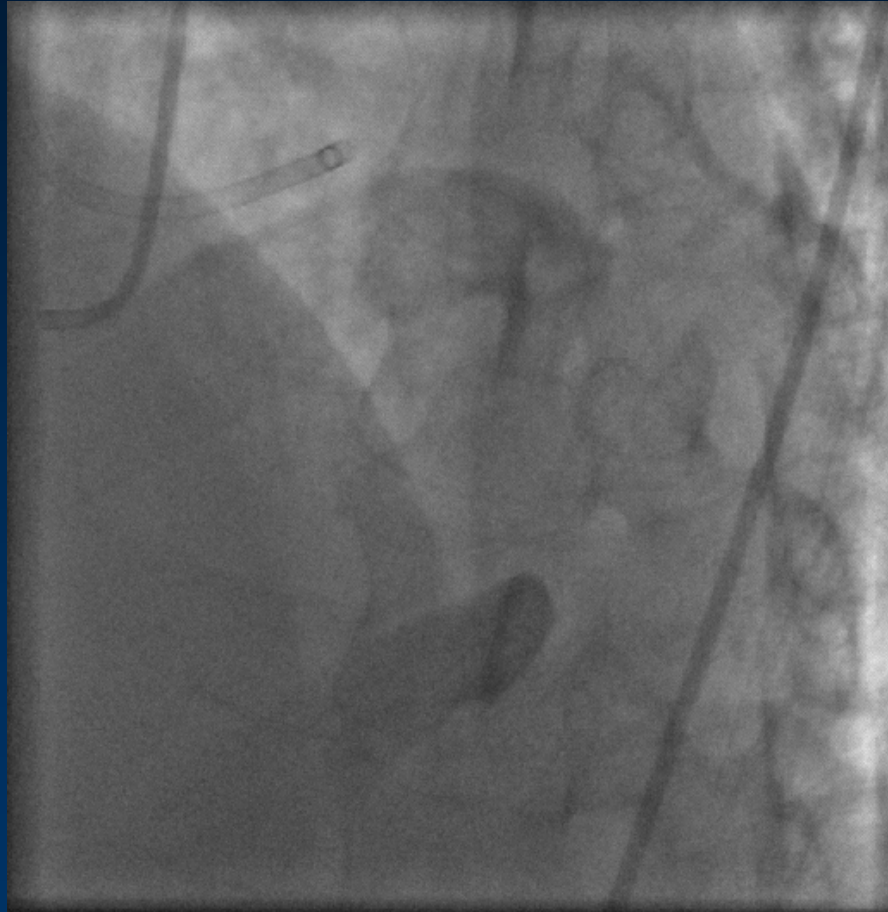
LM stenting with DES & Freedom from MACE



* LM bifurcation

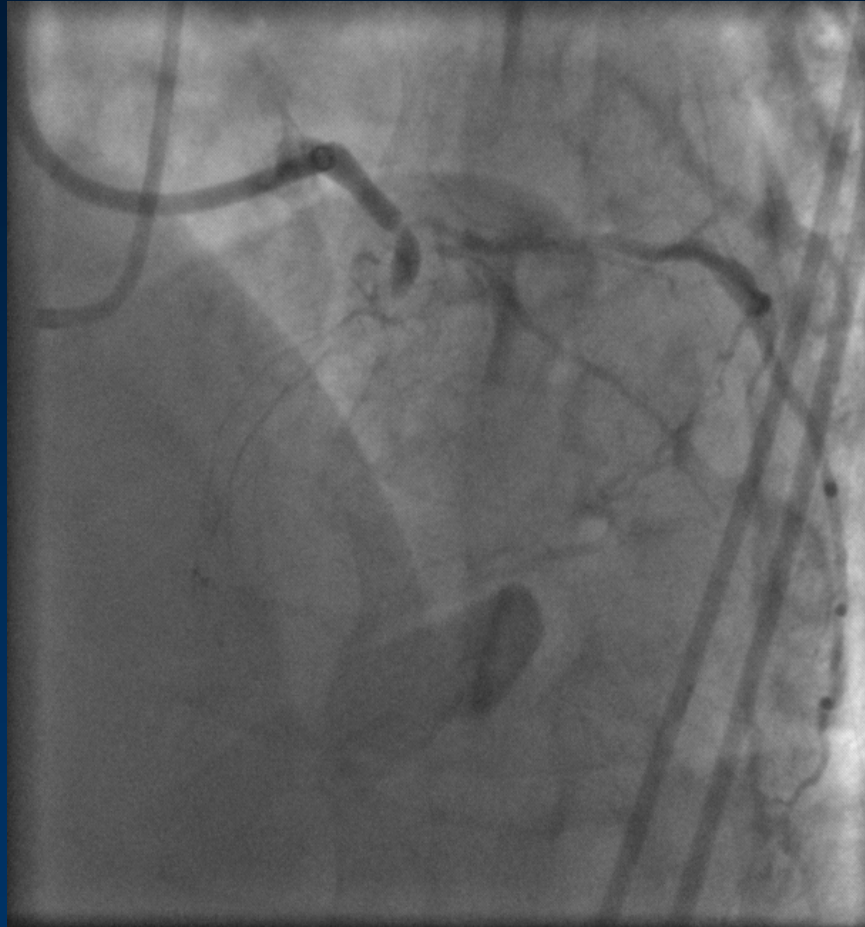
*Case 1: LM bifurcation stenosis,
& severe diffuse triple vessel disease*

TH, male, 45 yrs. old, severe AP,
LM & severe diffuse triple vessel disease

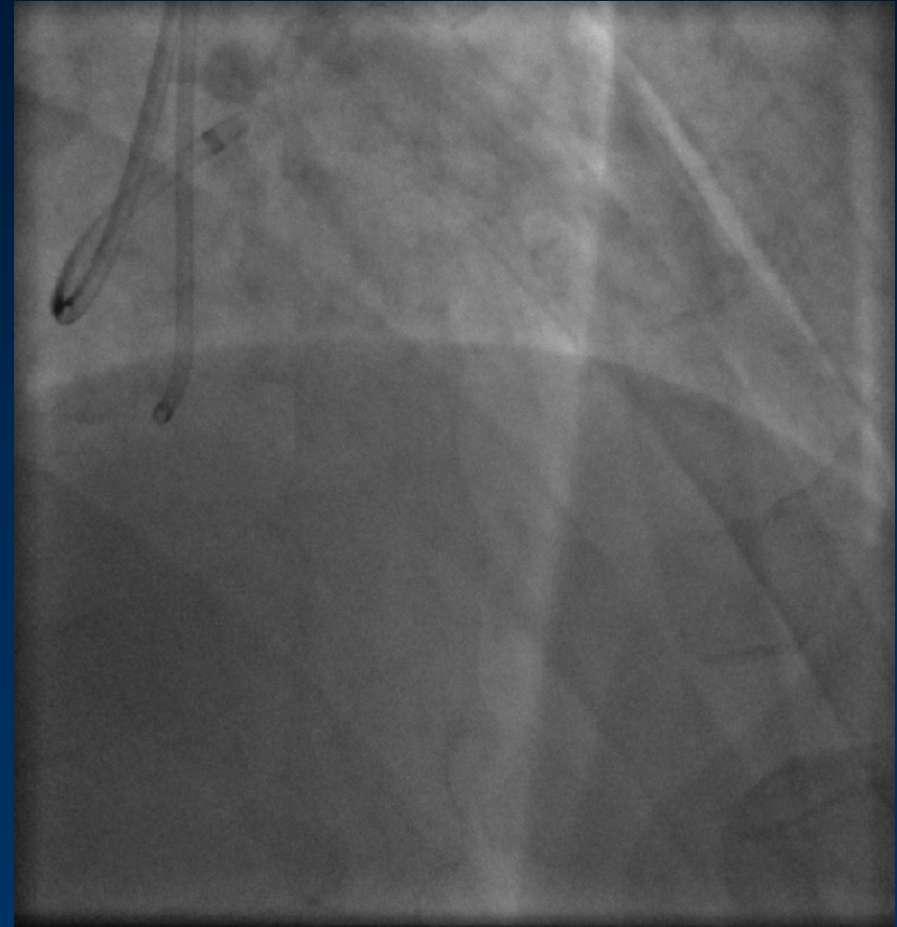


Baseline, LSO view

TH, male, 45 yrs. old, severe AP,
LM & severe diffuse triple vessel disease



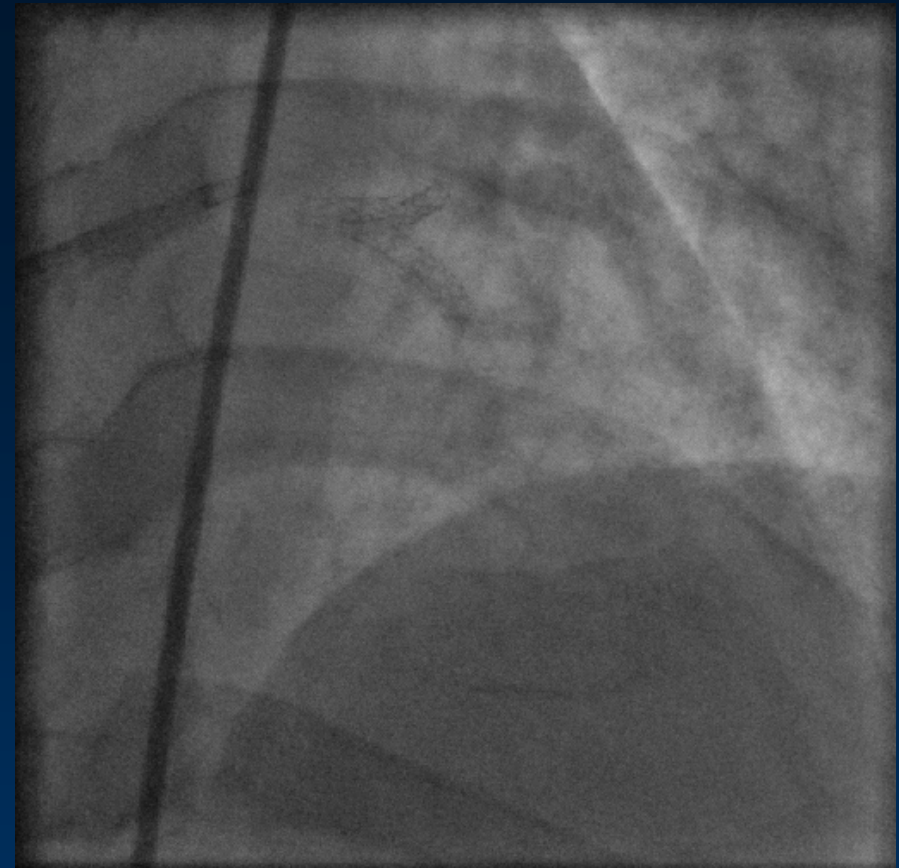
Baseline, LSO view



Baseline, RSO view



Final, LSO view

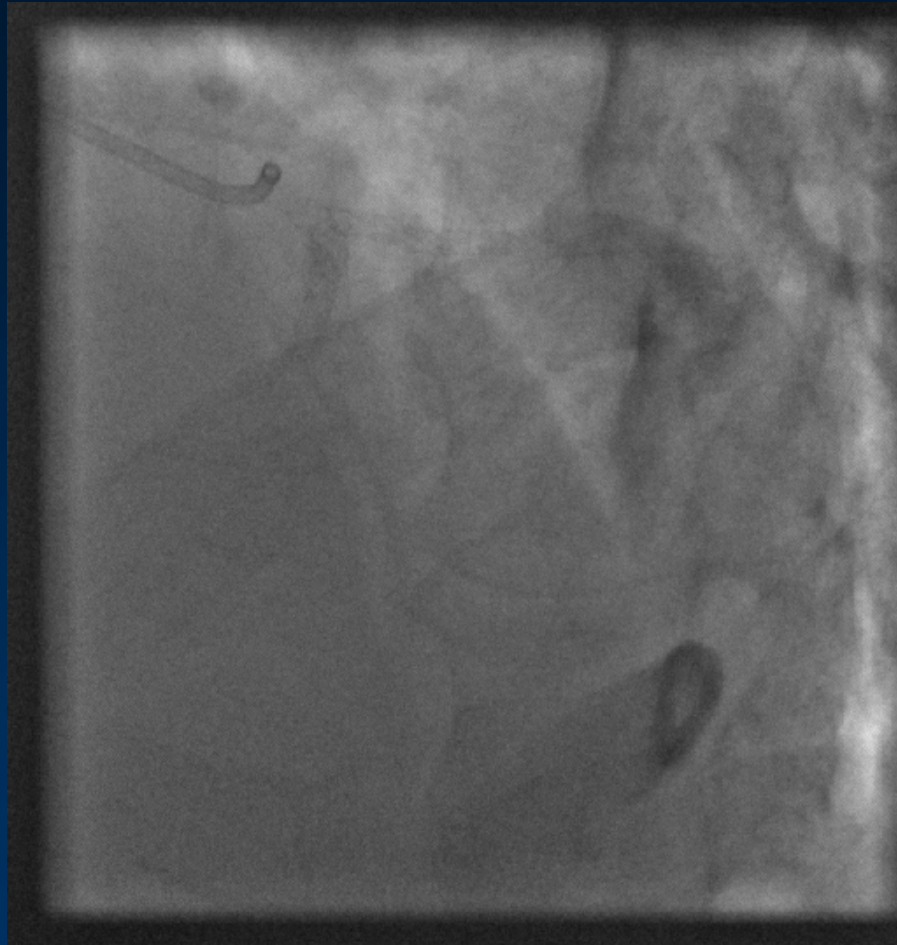


Final, RSO view

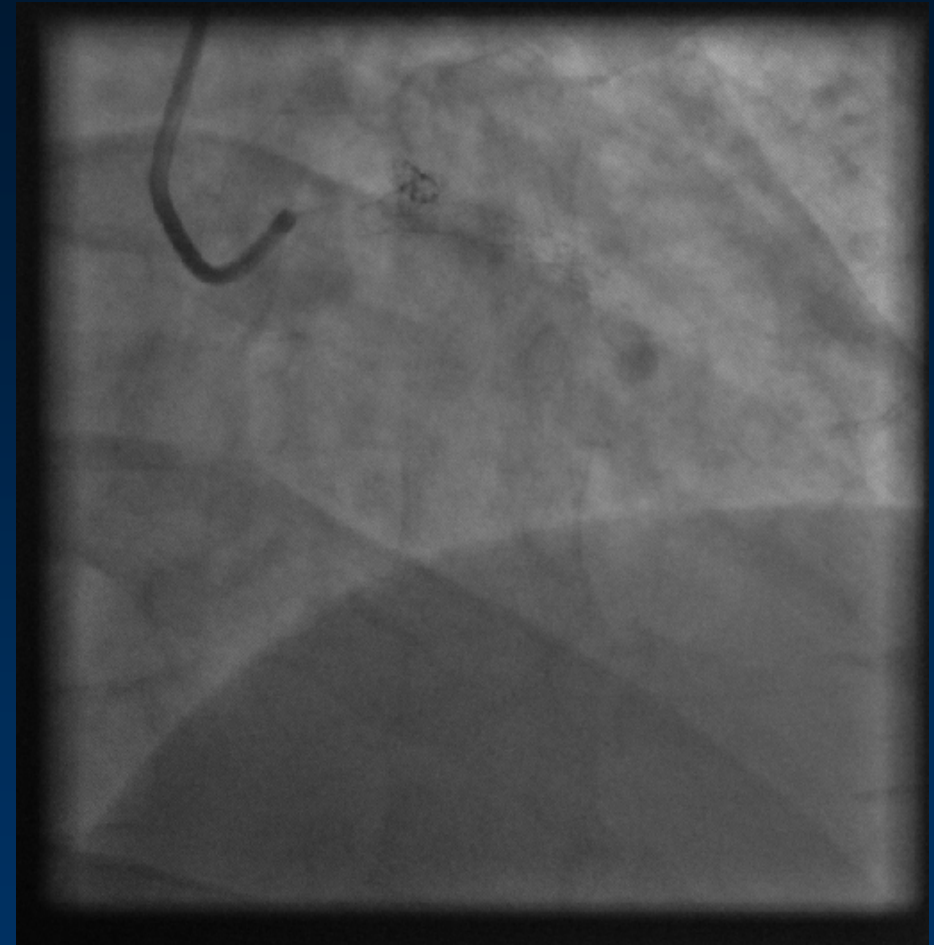
After **Y-stenting of LM bifurcation**:

- one Cypher stent in LM-LAD
(overlapping with another Cypher stent in LADp) &
- one Cypher in LM-LCX
(overlapping with another 2.5/13 mm Bx-sonic stent in LCXp)

6- month angiographic follow-up



LSO view

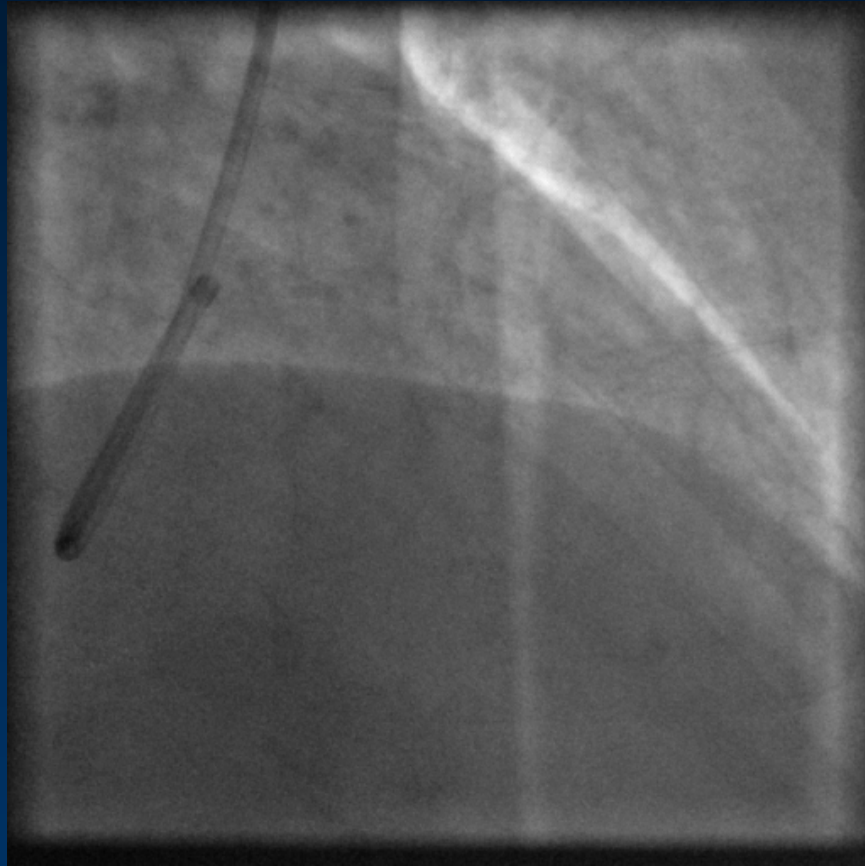


RSO view

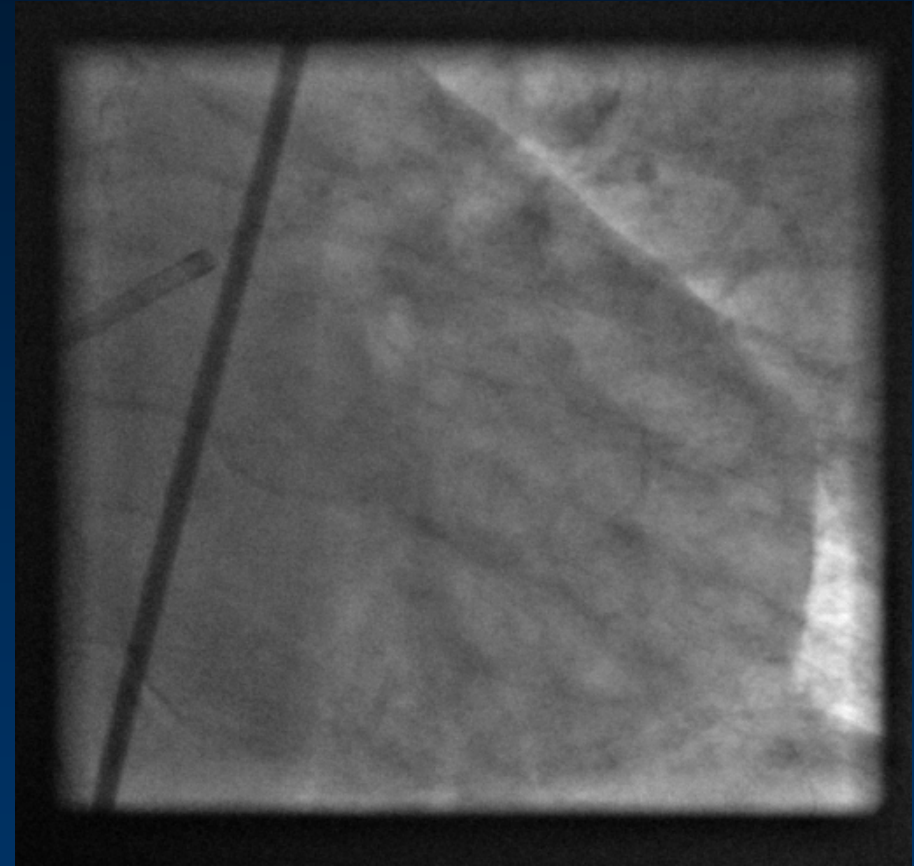
Restenosis only at the overlapped site of
Cypher & Bx sonic stents in LCXp

*Case 2: LM bifurcation stenosis
treated with modified T-stenting*

LM bifurcation + LADp & LCXp stenoses (Baseline)



RSO view

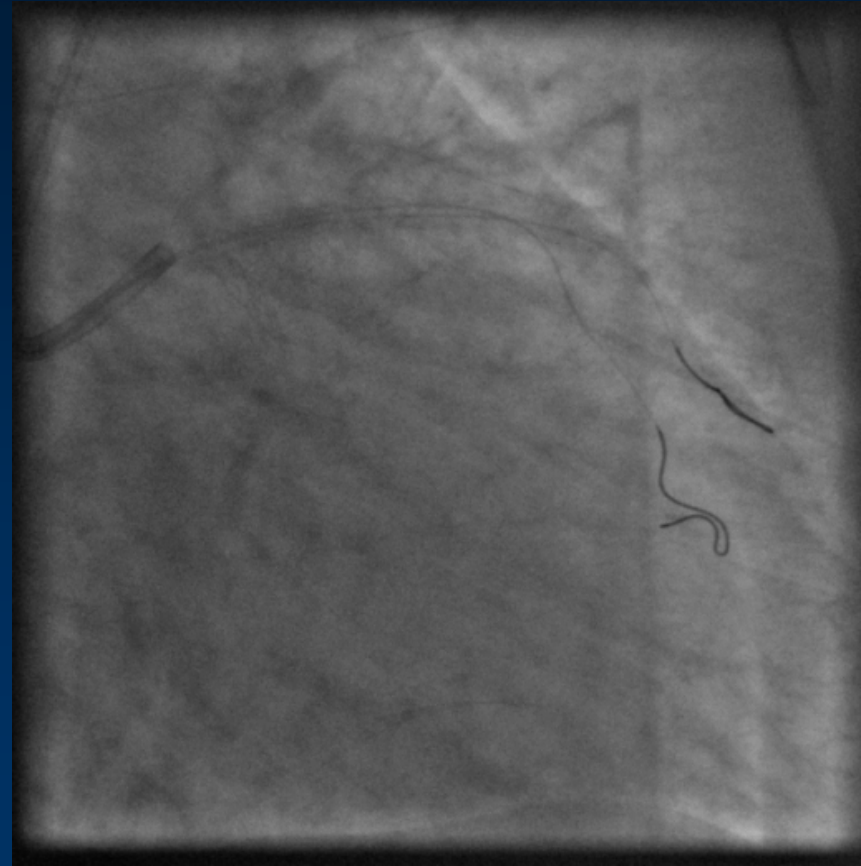


PA-Caudal view

After Modified T-stenting with 2 Cypher stents:
LM-LAD = 3.0/33 mm & LM-LCX = 2.5/18 mm



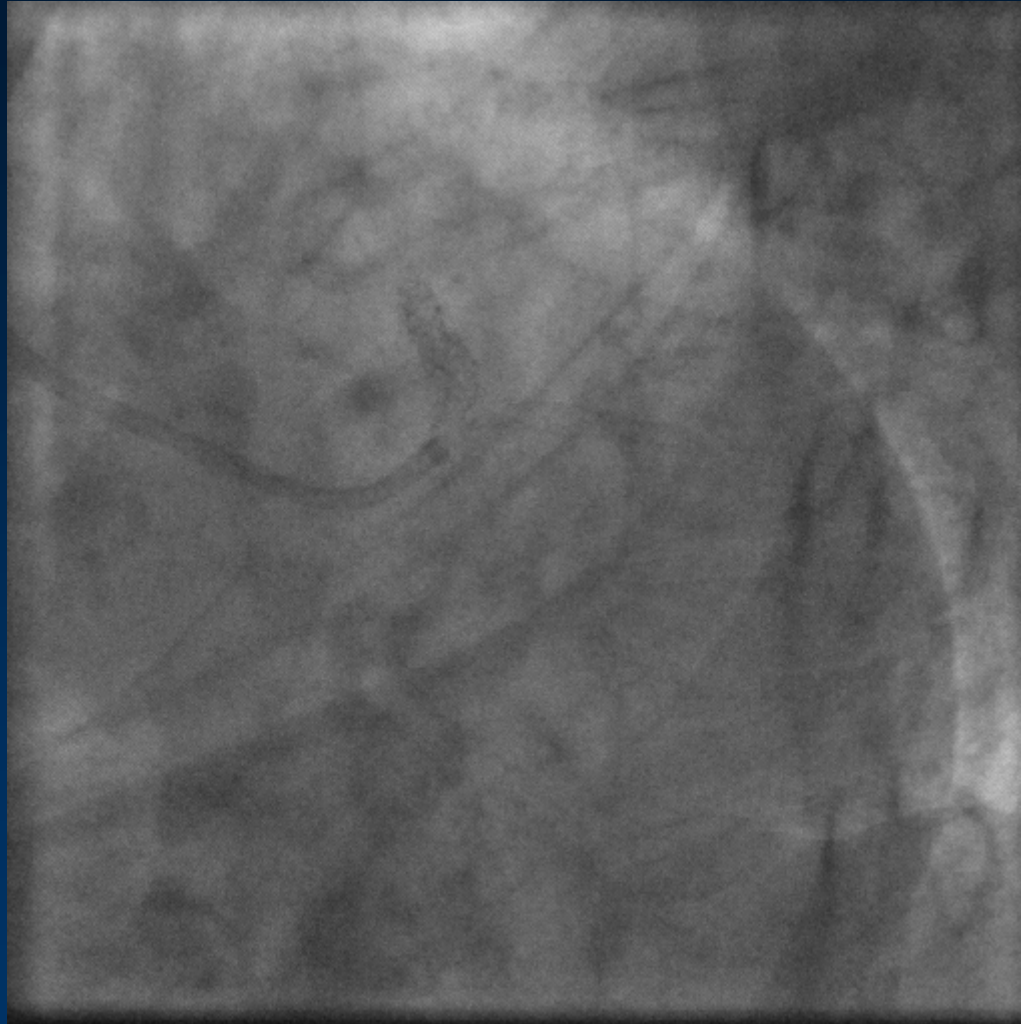
RSO view



PA-Caudal view

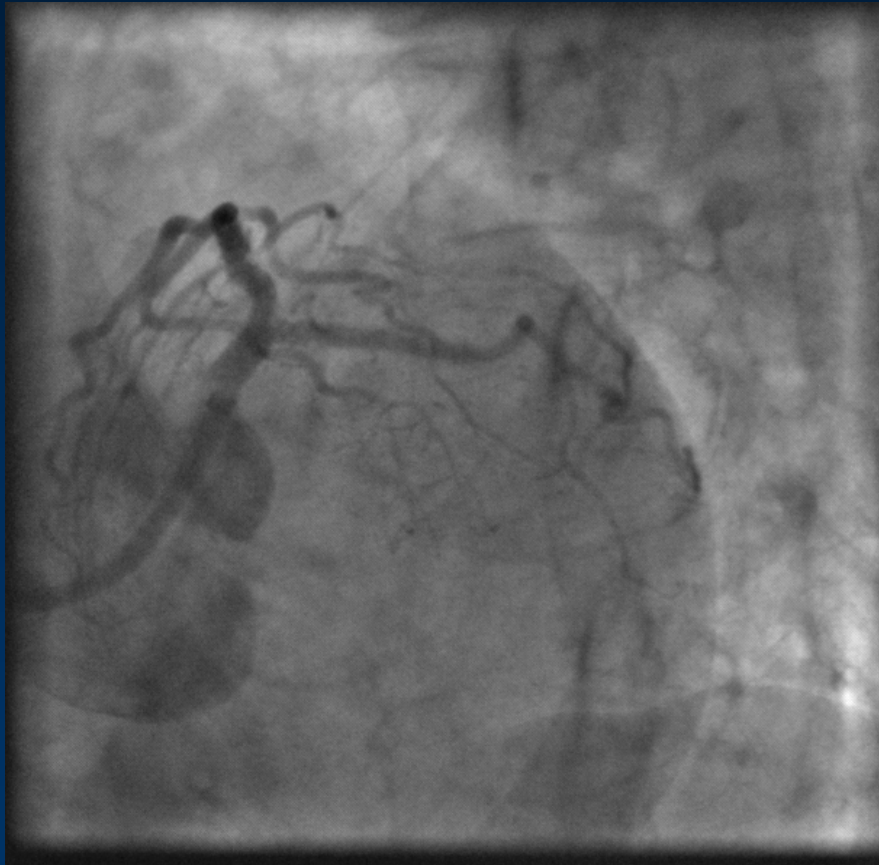
6-month angiographic follow-up

LIO view



Restenosis at LCX ostium, in the gap between both stents

Good result after 2nd PCI:
Implantation of another Cypher 3.0/8 mm to LM-
LCX & kissing balloon dilatation

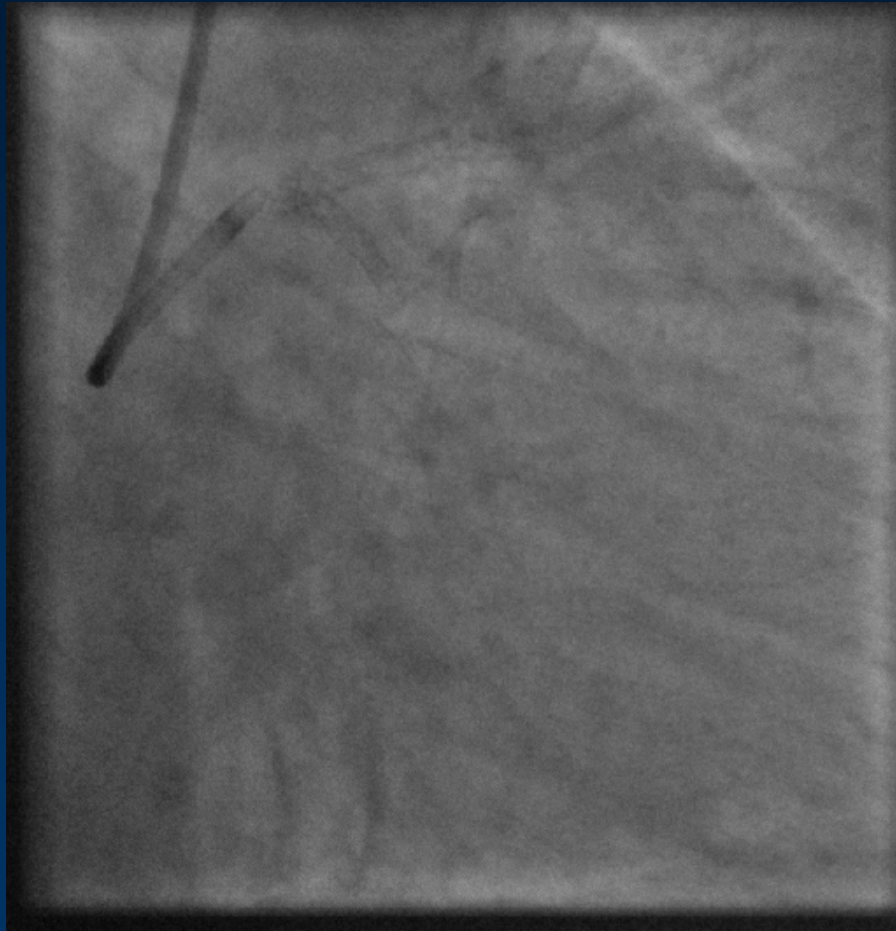


LIO view



PACaudal view

Severe Instant restenosis after 6 months

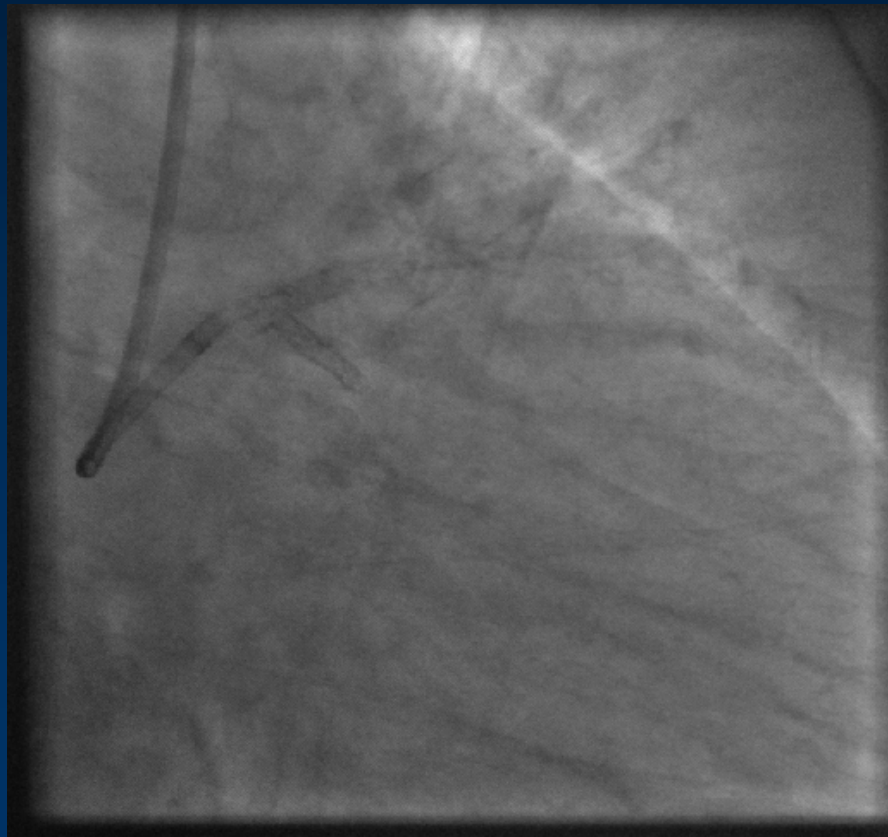


RIO view



LIO view

Good result after 3rd PCI:
Implantation of another Cypher 3.0/13 mm to
LM-LAD & TAXUS 2.75/20 to LM-LCX,
kissing stent technique



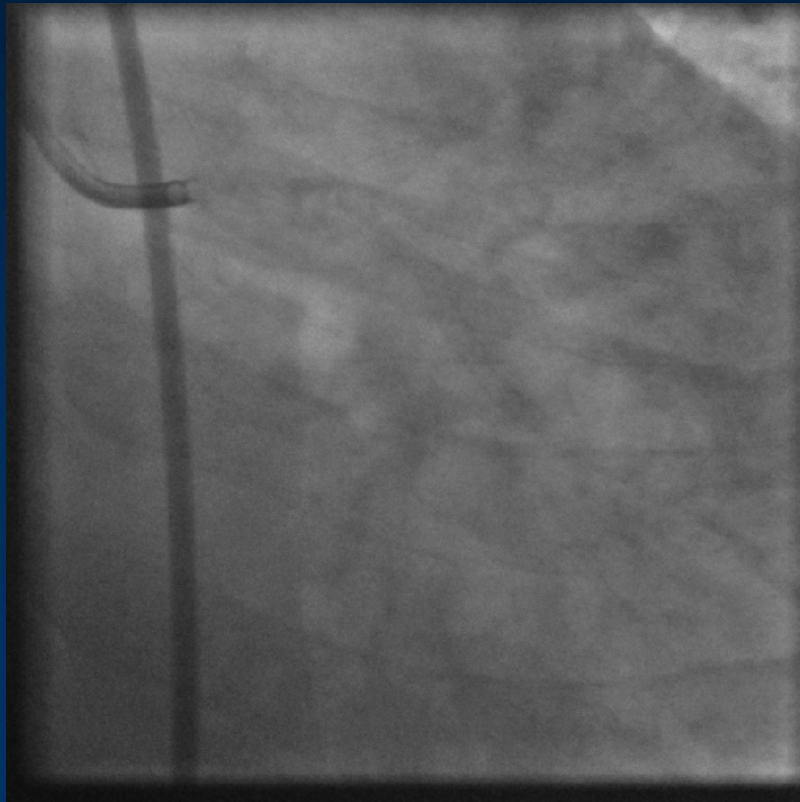
RIO view



LIO view

*Case 3: Atherectomy + DES
in a patient with LM bifurcation
& proximal LAD stenosis (1)*

*Case 3: SilverHawk atherectomy + DES
in a patient with LM bifurcation
& proximal LAD stenosis (1)*



Baseline: PA Caudal view

*Case 3: SilverHawk atherectomy + DES
in a patient with LM bifurcation
& proximal LAD stenosis (1)*

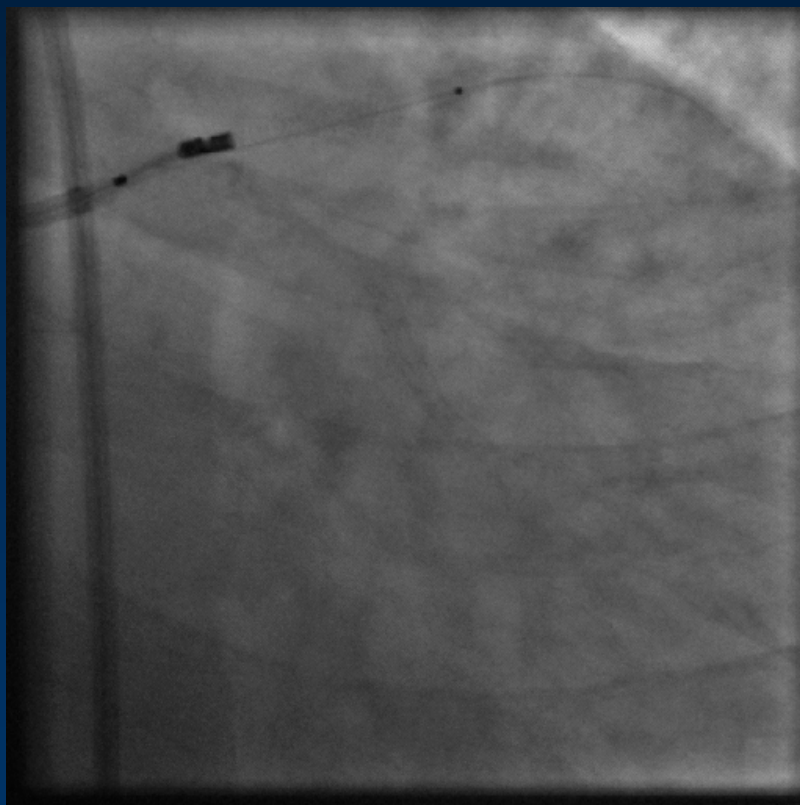


Baseline: PA Caudal view

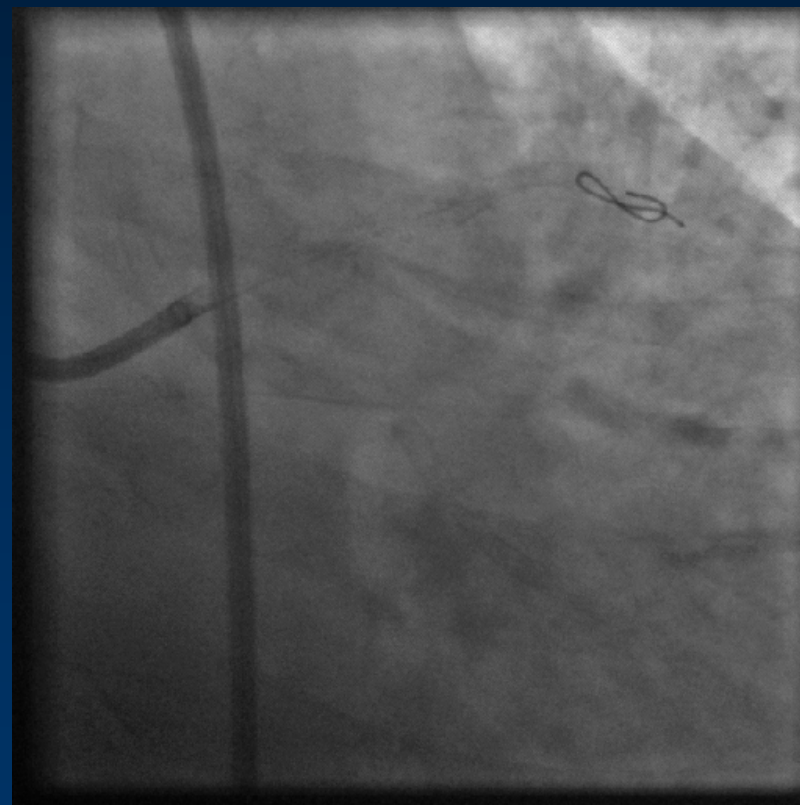


Baseline: LIO view

*Case 3: SilverHawk atherectomy + DES
in a patient with LM bifurcation
& proximal LAD stenosis (2)*

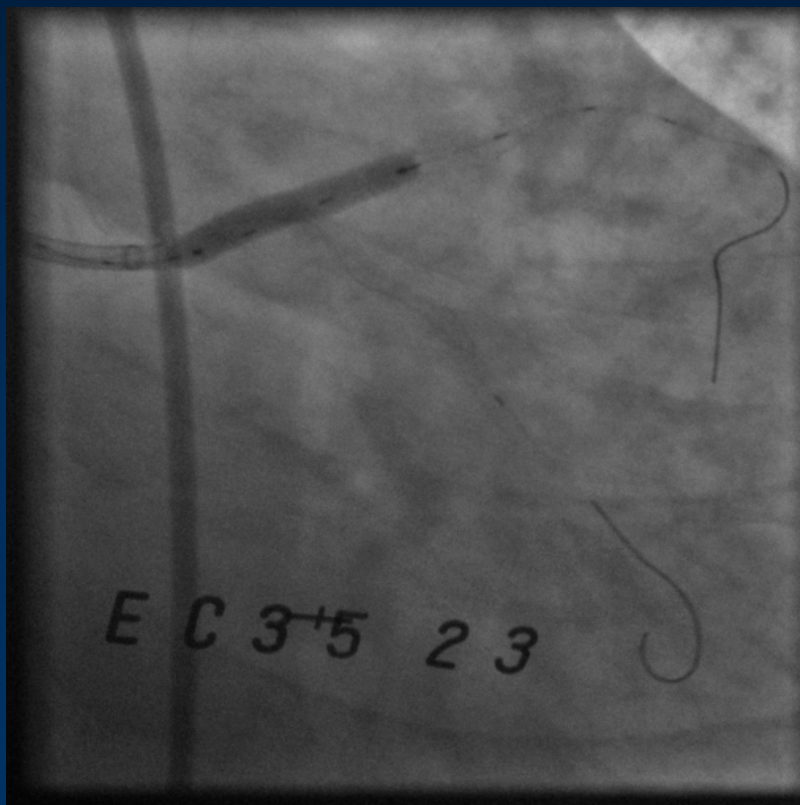


Atherectomy using SilverHawk
2740

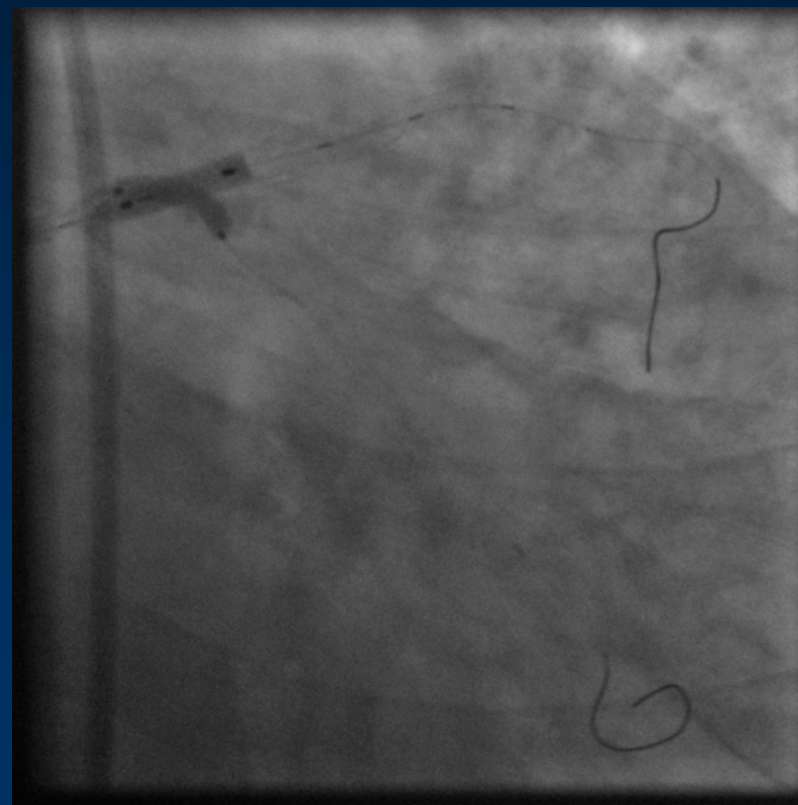


Post-atherectomy

*Case 3: SilverHawk atherectomy + DES
in a patient with LM bifurcation
& proximal LAD stenosis (3)*

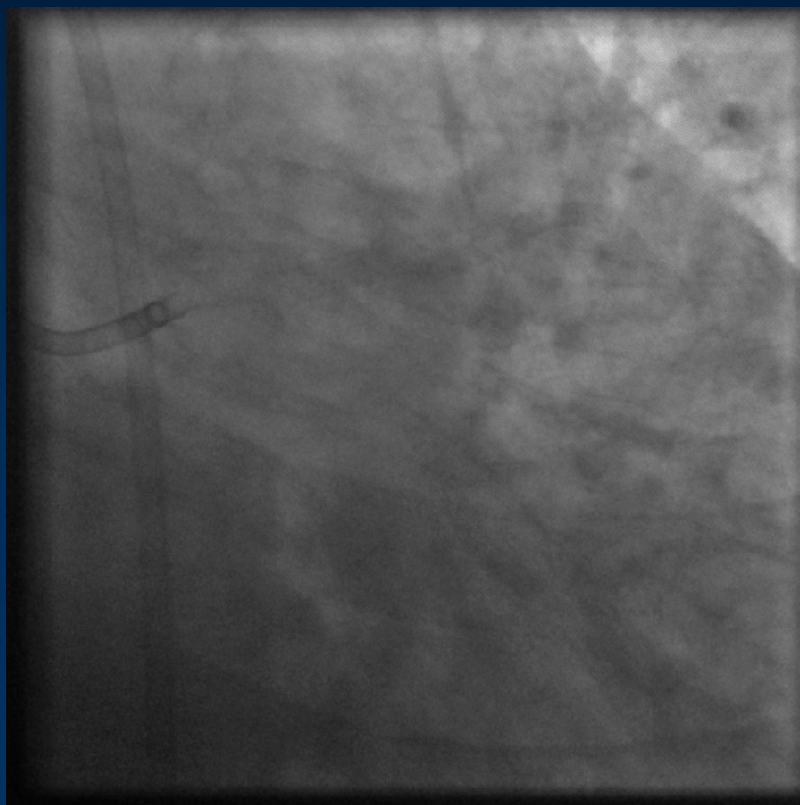


Placement of EXCEL stent



Kissing balloon post-dilatation

*Case 3: SilverHawk atherectomy + DES
in a patient with LM bifurcation
& proximal LAD stenosis (4)*

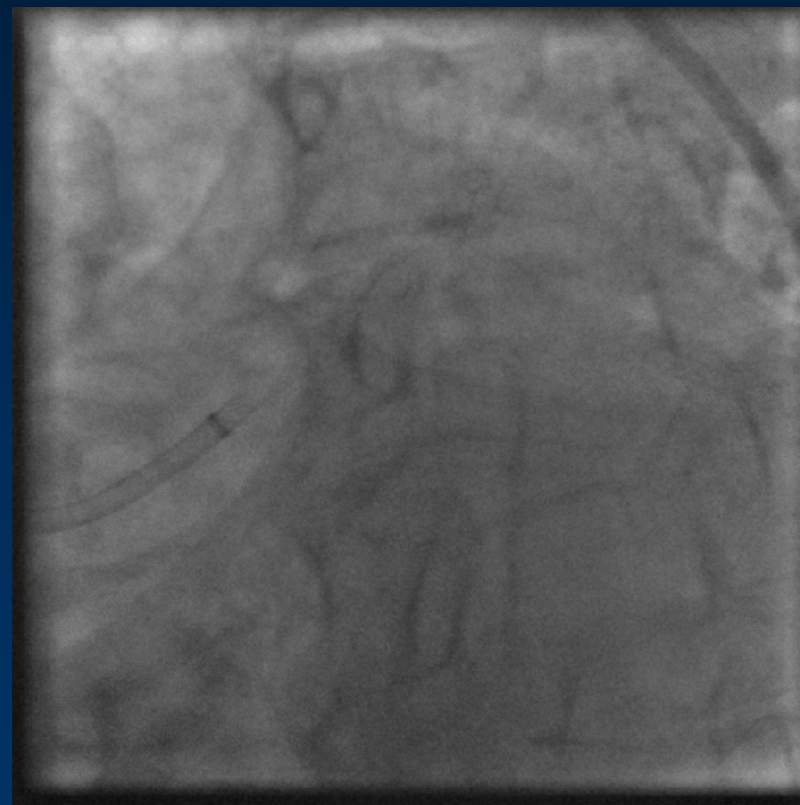


Final result: PA Caudal view

*Case 3: SilverHawk atherectomy + DES
in a patient with LM bifurcation
& proximal LAD stenosis (4)*



Final result: PA Caudal view



Final result: LIO view

Conclusions

- Despite all the limitations of the study (non-randomized, enrollment of “all-comers” population, heterogeneous population, differences in technique & drug protocol, etc). the use of drug-eluting stent in unprotected LM bifurcation stenosis is safe & feasible with acceptable short & medium term result
- Further studies with extended follow-up are warranted to confirm these preliminary results (SYNTAX, COMBAT)