Left Main Program and Latest Rotterdam-Poznan Clinical Data

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• Tryton
• Consulting Fees/Honoraria	• Company Two
• Major Stock Shareholder/Equity	• Company Three
• Royalty Income	• Company Four
• Ownership/Founder	• Company Five
• Intellectual Property Rights	• Company Six
• Other Financial Benefit	• Company Seven

The Rotterdam-Poznan Tryton Registry: Real World Evaluation

Original Studies

Six-Month Clinical Follow-Up of the Tryton Side Branch Stent for the Treatment of Bifurcation Lesions: A Two Center Registry Analysis

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Catheterization and Cardiovascular Interventions 00:000–000 (2010)

Rotterdam-Poznan Tryton Registry:

- *Prospective "all comer" registry*
- *Two-centre : Rotterdam, The Netherlands*
  Poznan, Poland
- *Consecutive enrolment*
- *6 months FU*
- *Primary endpoints : Procedural success*
  Death, MI, TVR, ST at follow-up

Results of the first 100 lesions

Characteristics	N=96
Male	72 (75%)
Age, years (mean±SD)	63.9 ± 8.8
Diabetes mellitus	30 (31%)
Hypertension	58 (60%)
Hypercholesterolaemia	60 (63%)
Family History of CAD	46 (48%)
Smoker	17 (18%)
Previous myocardial infarction	42 (44%)
Previous PCI	40 (42%)
Previous CABG	8 (8%)
Stable Angina	69 (72%)
Unstable Angina	24 (25%)
ST elevation Myocardial infarction	3 (3%)

Results of the first 100 lesions

Lesions	N=100
Left Main	8
Left Anterior Descending / Diagonal	72
Left Circumflex / Obtuse Marginal	11
Posterolateral / Posterior Descending	5
Saphenous Vein Graft / Native Vessel	2
Other	2
Stable Angina	69 (72%)
Unstable Angina	24 (25%)
ST elevation Myocardial infarction	3 (3%)
Multivessel disease	62 (66%)
Chronic total occlusion	2

Medina Classification	
1,0,0	10
1,1,0	11
0,1,0	3
0,0,1	6
1,0,1	13
0,1,1	3
1,1,1	54

Procedural Characteristics

Predilation	
Side Branch	69 (70%)
Main Vessel	83 (84%)
Separate Postdilation	71 (72%)
Final Kissing	70 (71%)
Additional overlapping stent implantation	
Side Branch	15 (16%)
Main Vessel	19 (20%)
Total stents implanted	275
Stents per bifurcation	2.4 ± 0.7
Stents per patient	2.9 ± 1.3
Multivessel stenting in index procedure	26 (26%)

Acute procedural outcome	N=100
Device success	99
Angiographic success	95
PCI related MI	2
Procedural success	94

In-hospital and 6 month clinical outcome

In-hospital outcome	N=96
Cardiac Death	1
Myocardial Infarction	2
Target Lesion Revascularisation	0
Target Vessel Revascularisation	0
Definite/Probable stent thrombosis	0
Cardiac death or MI	2
MACE (cardiac death, MI, CABG or TLR)	2
Median 6 month outcome (cumulative)	N=96
Cardiac Death	1
Myocardial Infarction	3
Target Lesion Revascularisation	4
Target Vessel Revascularisation	4
Definite/Probable stent thrombosis	0
Cardiac death or MI	3
MACE (cardiac death, MI, CABG or TLR)	8
Device/PCI strategy-related MACE	8

Two bifurcation lesions

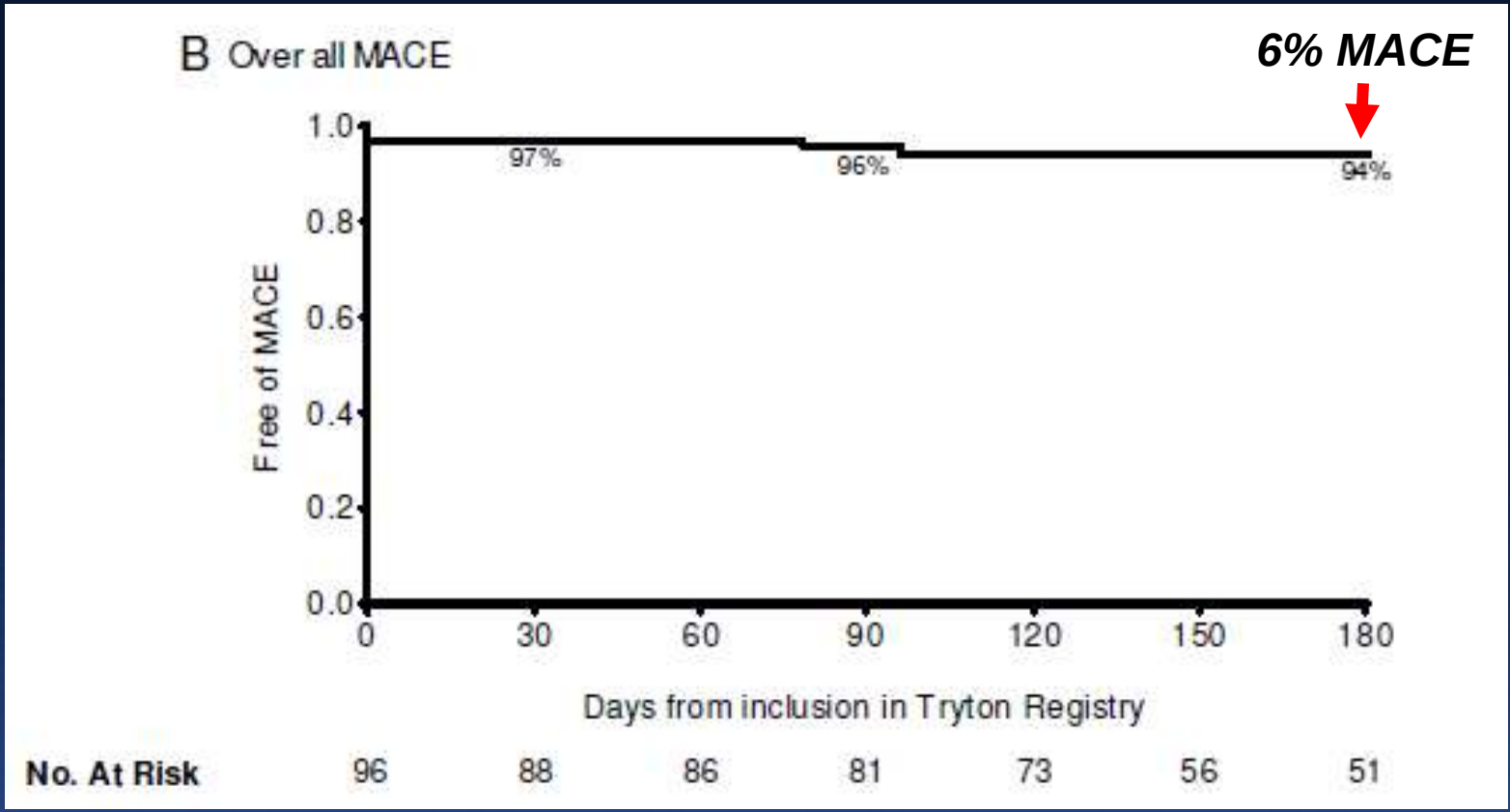
LSO view – left coronary

Final angiographic result

Tryton 2 x 2.5/3.5 x 19

Endeavor Resolute 2.75x 30 + 3.0 x 24

In-hospital and 6 month clinical outcome



Conclusions

In a 'real world' population including patients presenting with:

- *Acute STEMI*
- *CTO*
- *Left Main lesions,*
- *Saphenovenous grafts*

At median 6 months follow-up:

The Tryton Side Branch Stent is safe : *MI of 3%*
Cardiac death 1%

and effective : *TLR rate was 4%*

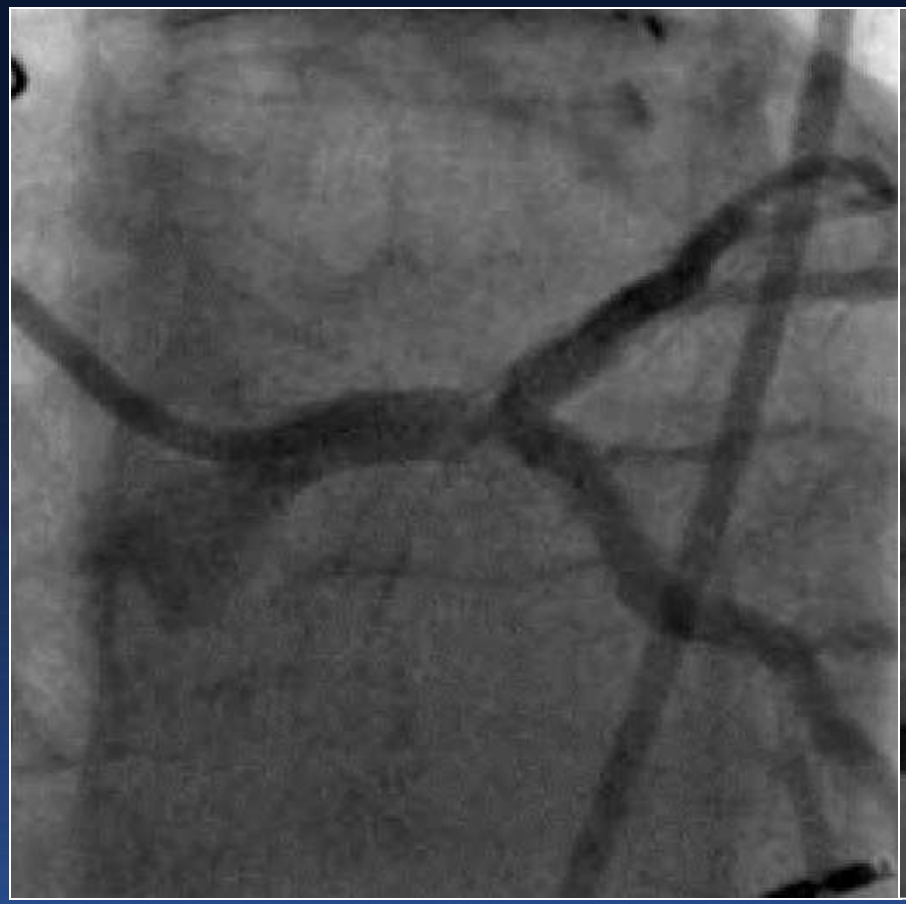
Cumulative MACE rate reached 8%.

No cases of definite/probable stent thrombosis occurred.

European Tryton registry 2011

- Real world Registry: MACE as primary endpoint
- >1000 Patients
  - E-Tryton-150,
  - E-Tryton-Benelux,
  - E-Tryton-Spain,
  - E-Tryton-Italy
- Newly started centers
- Enrolment till December 31st 2010
- Follow-up: > 3 months
- Results: EuroPCR 2011

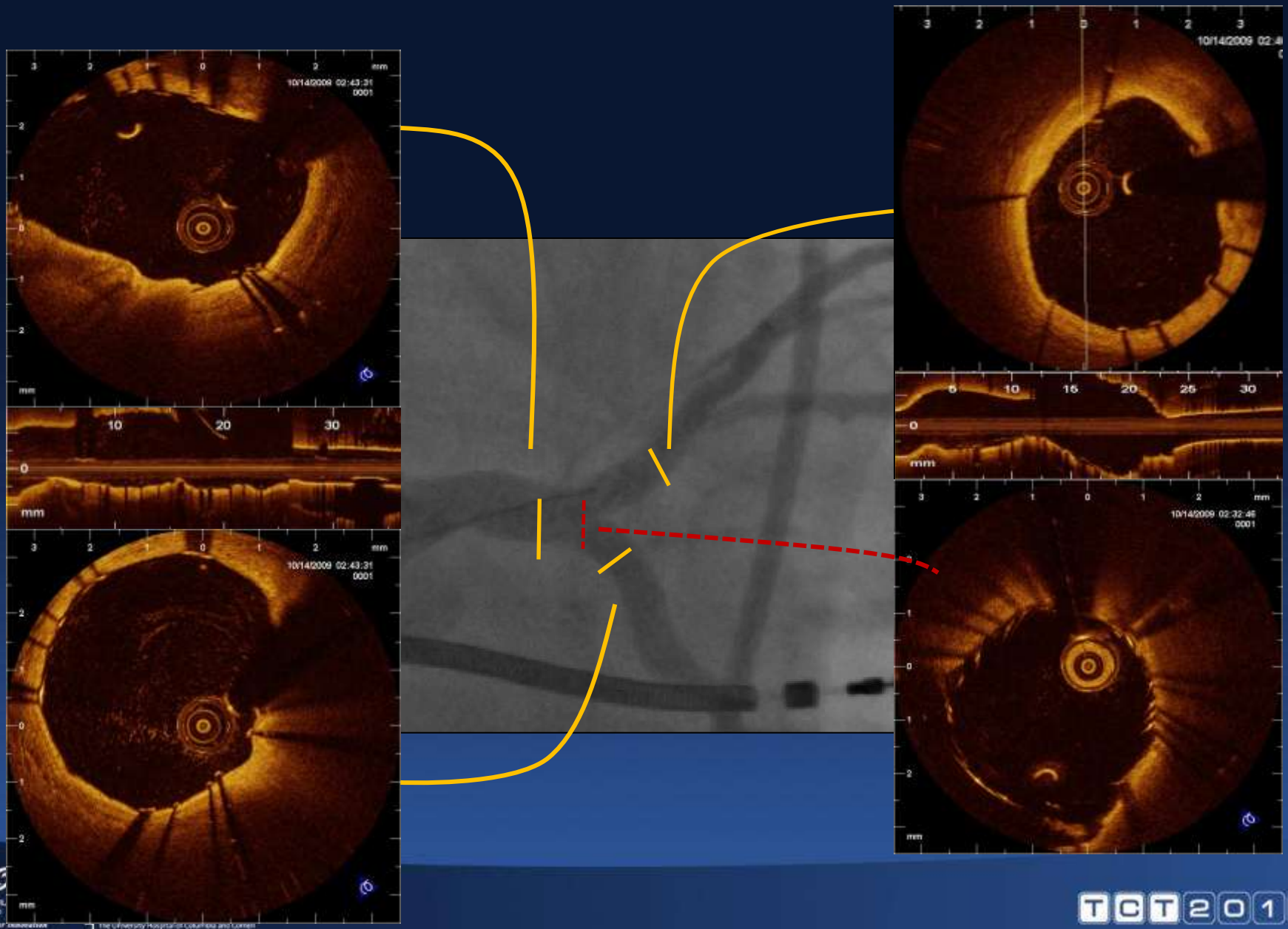
Tryton Sidebranch Stent in Left Main



Diagnostic Angiogram

Final angiographic result

OCT evaluation of Tryton Stent + Main vessel stent



LM stenting with Tryton in Europe

	Hospital	City
Manuel Almeida	Hospital de Santa Cruz – CHLO	Lisboa
Antonio Bartorelli	Monzino	Milano
Peter Stella	UMCU	Utrecht
Maciej Lesiak	University of Lord's Transfiguration	Poznan
Robert-jan van Geuns	Thoraxcenter, ErasmusMC	Rotterdam
Piers Clifford	Hammersmith	London
David Foley	Beaumont	Dublin
Juan Sánchez-Rubio	Hospital Univ. Miguel Servet	Zaragoza
Ramiro Trillo	Complejo Hospitalario Univ. Santiago	Santiago de Compostela
Imre Ungi	University of Szeged	Szeged

Total: 30-50 patients treated

QCA pre, post and if available FU

Prospective LM-study: 'Straw Man'

Prospective, single arm study characterizing the Safety and Efficacy of the Tryton Side Branch Stent in conjunction with a 'workhorse' DES to treat distal left main coronary lesions

- **N (patients): 30**
- **Centers: Up to 5 in the Netherlands and Poland**
- **Primary Endpoint:** - **MACE at 6 months**
- **Secondary Endpoints:** - **Binary Restenosis rate**
  - **Minimal Luminal Diameter (MLD);**
  - **Late Luminal Loss;**
  - **Percent Diameter Stenosis (%DS) of the main branch**
  - **POC % area loss**
- **Estimated start: 2011**

Large Diameter Tryton

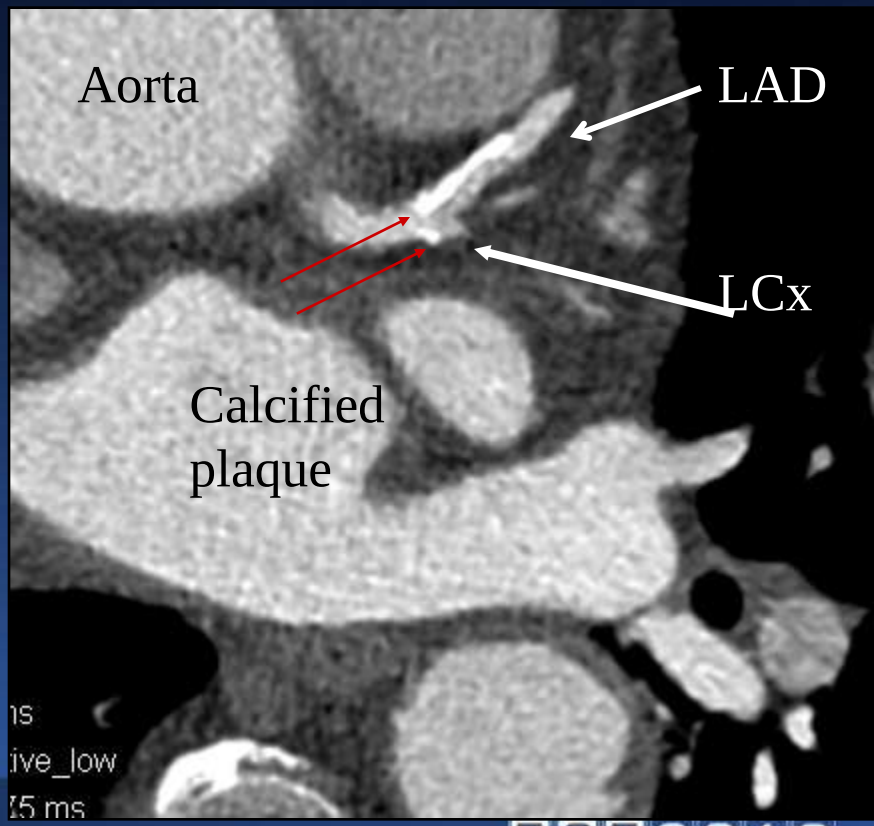
Catalog No.	Side Branch Dia. (mm)	Main Branch Dia. (mm)	Stent Length (mm)	Min. Guide Cath.
Current Design				
T5-2525-191	2.5	2.5	19	5 French
T5-2530-191	2.5	3.0		
T5-2535-191	2.5	3.5		
Large Design				
T5-3035-181	3.0	3.5	18	6 French
T5-3540-181	3.5	4.0		

Shorter stent: 15mm ?

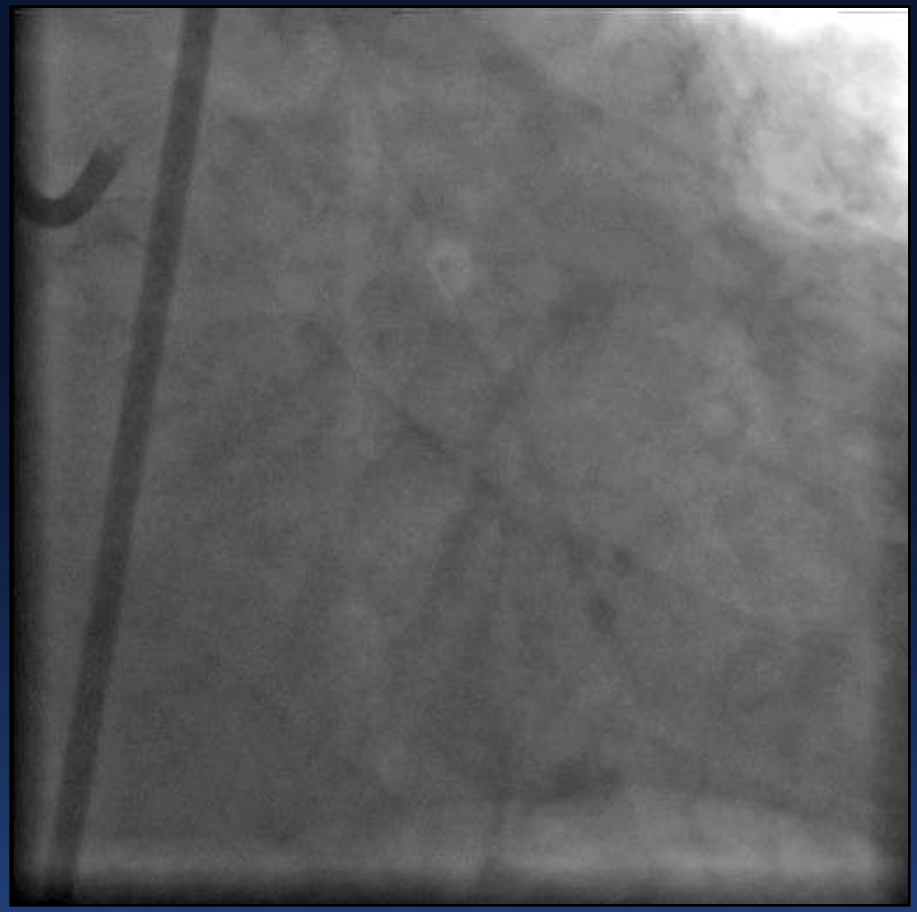
Case 2 – clinical history

74 year old gentleman with unstable angina pectoris

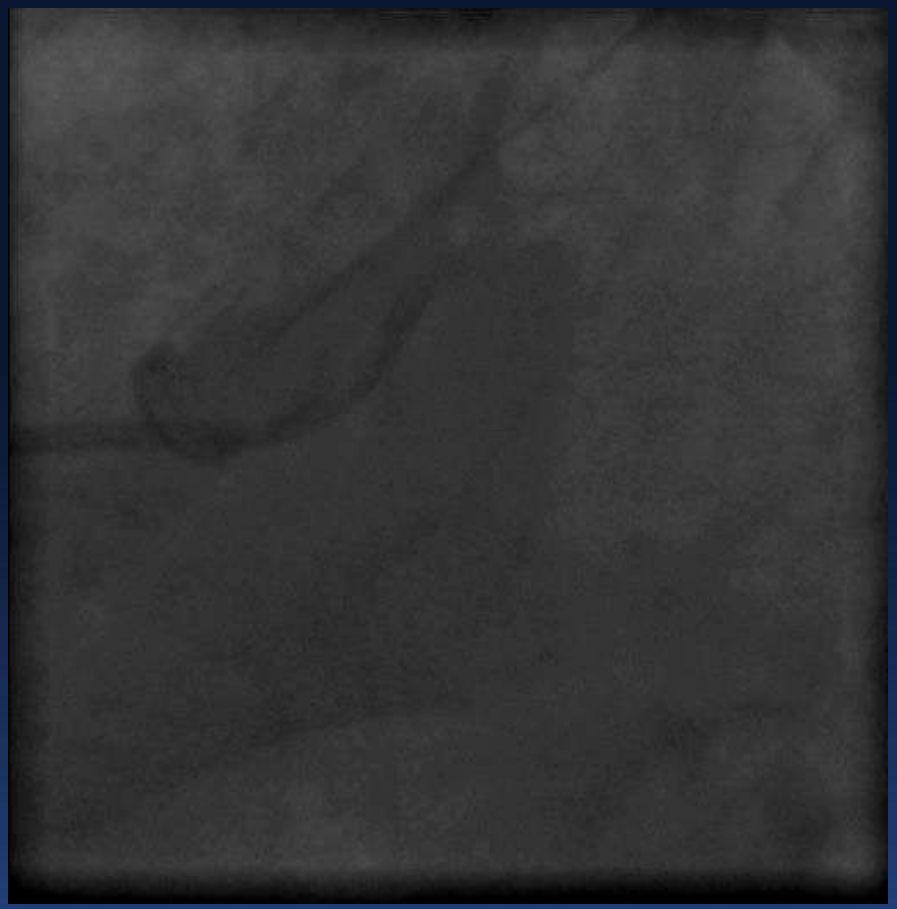
- History of PCI to RCA for inferior myocardial infarction
- Left main disease with calcified plaque on MSCT
- Hypercholesterolaemia



Case 2 – diagnostic angiography

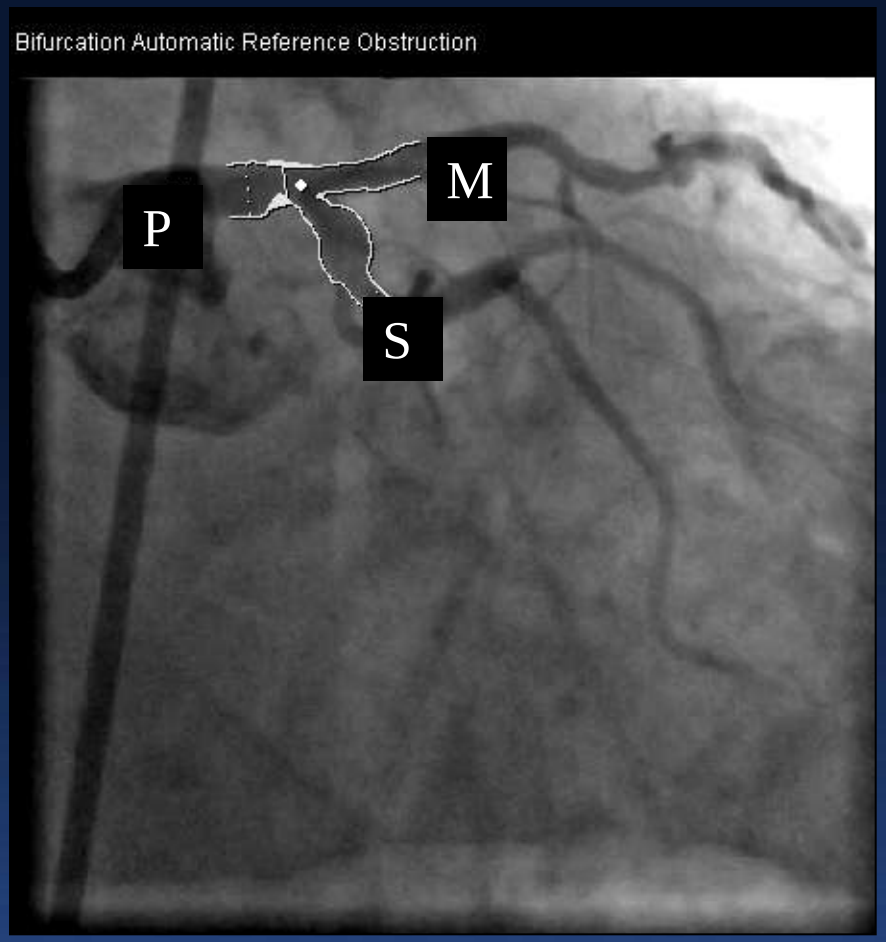


RIO- left coronary angiography



LIO- left coronary angiography

Case 2 – quantitative coronary angiography



LM/LCx bifurcation lesion

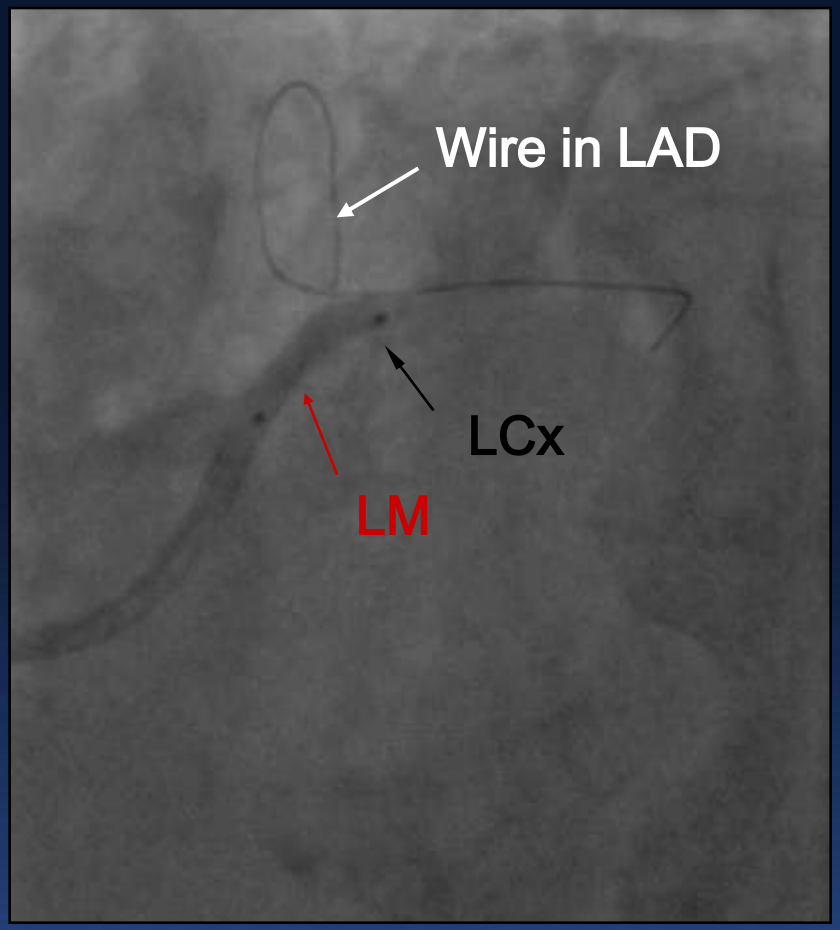
MEDINA 1, 0, 1

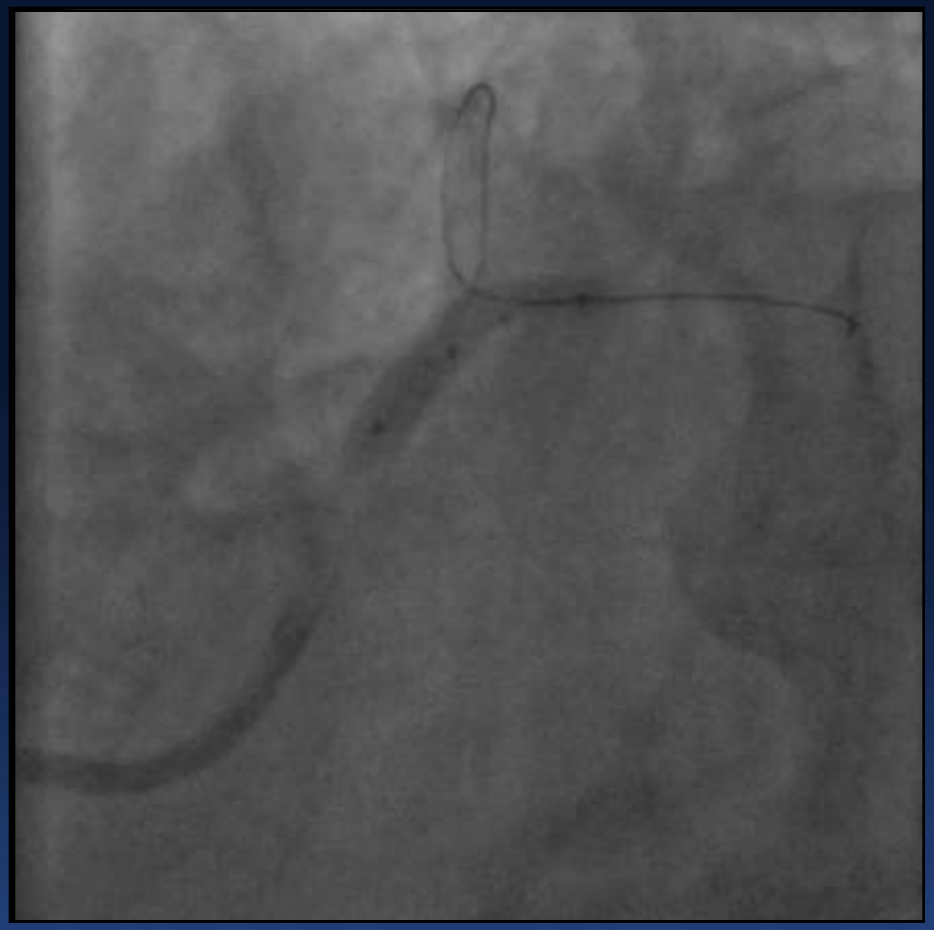
Proximal MV diameter: 3.15 mm

Distal MV diameter: 2.75mm

SB diameter: 2.15mm

Case 2 – PCI LM/LCx



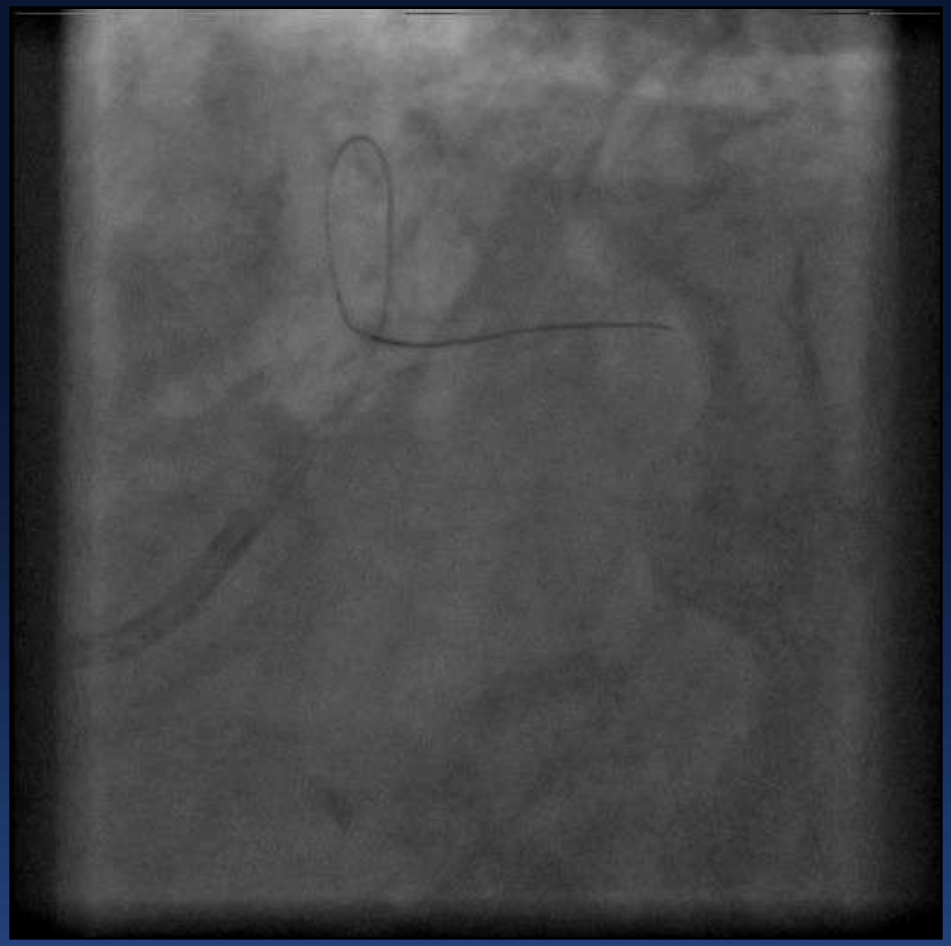


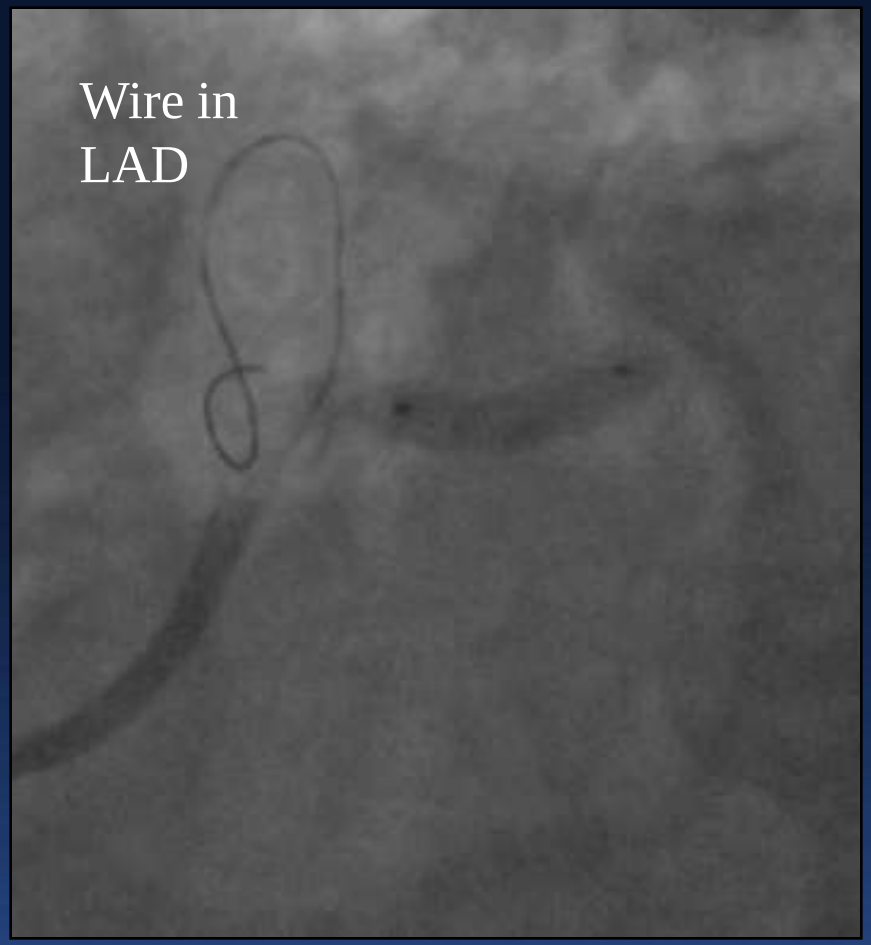
Predilation of lesion with 2.5 x 15mm Voyager RX balloon

Positioning of Tyron 2.5-3.5 x 19mm stent across LM and proximal LCx

Inflation to 20 atm.

Case 2 – PCI LM/LCx

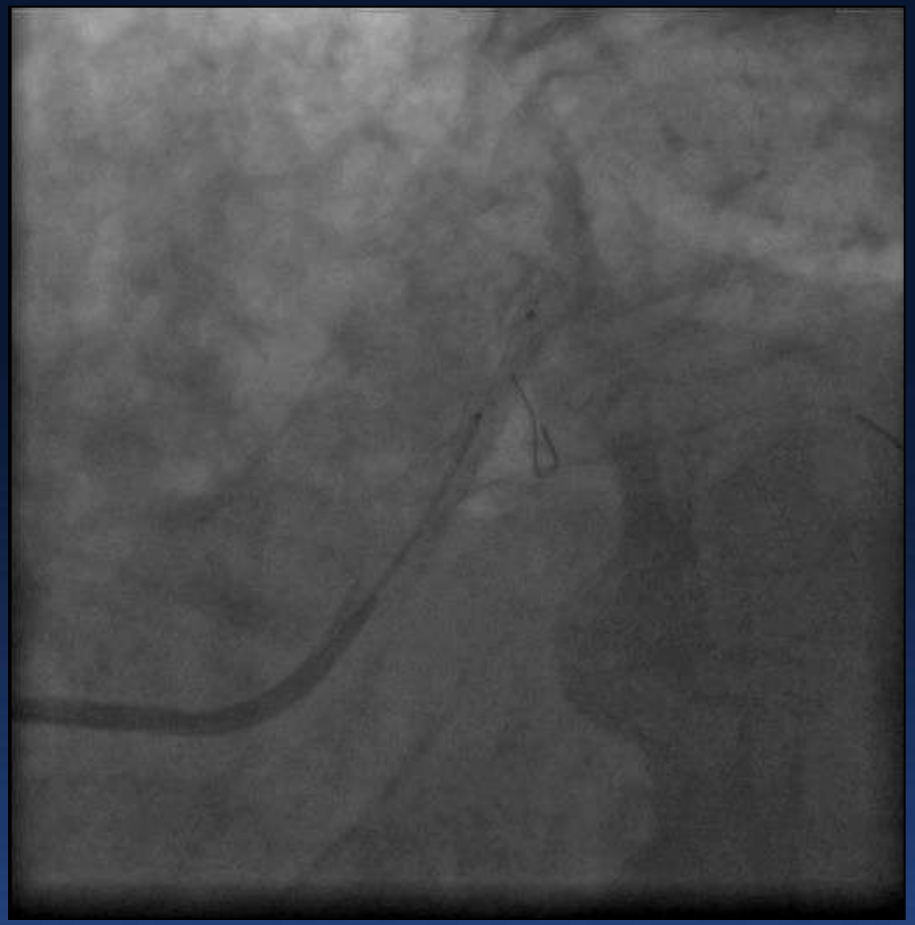




After Tryton stent deployment.

Xience V 3.5 x 15 mm deployed in LCx overlapping Tryton stent

Case 2 – PCI LM/ LCx



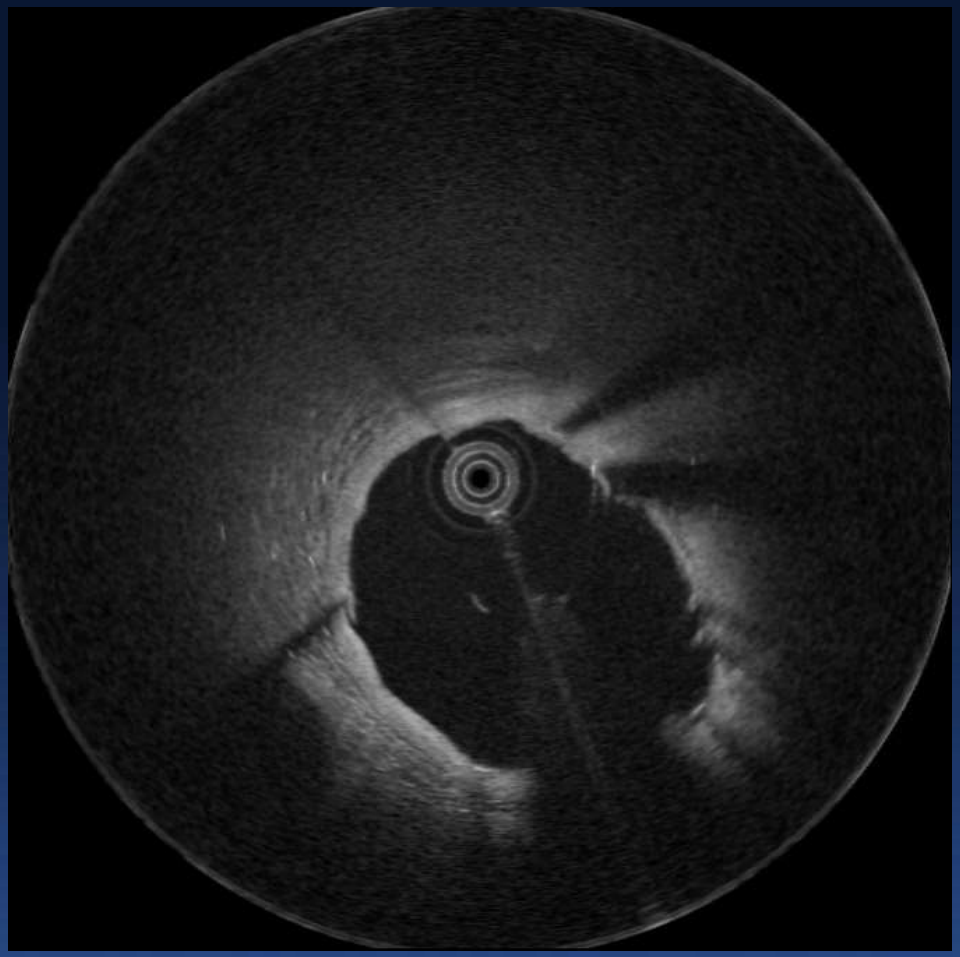
Positioning of Xience V 3.5 x 18mm

Post dilatation with 4.5 x 10 mm

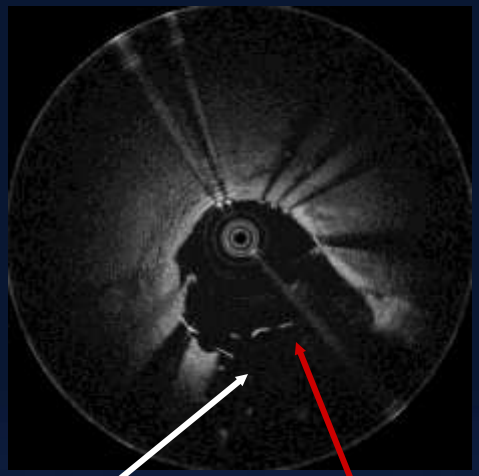
Final angiographic result after kissing balloon.

MGH OFDI catheter in LM

Case 2 – optical frequency domain imaging of LM/LCx treatment



Pullback clip of proximal LAD, LM/LCx bifurcation and LM



LM/LCx bifurcation

Stent struts

Stent struts at carina

Guide wire