Imaging Based Plaque Modification for Left Main PCI

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Disclosures of Conflict of Interest

Speaker's name: Andrejs Erglis

☑ **I have the following** potential conflicts of interest to report:

☑ Research contracts (Abbott Vascular, Boston Scientific)
☑ Consulting, Speakers Bureau (Abbott Vascular, Biosensors, Biotronik, Boston Scientific, Cordis J&J, Medtronic, MVRx)
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ **I do not have any potential conflict of interest**

PCI Strategy in Complex Lesions

Strategy

Direct stenting

- Risk of not good expanded stent

Predilatation + stenting

- Risk of large uncontrolled dissections
- And/or not good expanded stent

Plaque modification **+ stenting**

- No large dissections
- Good stent apposition

Stenting + ***Stent optimization***

- Improved stent apposition

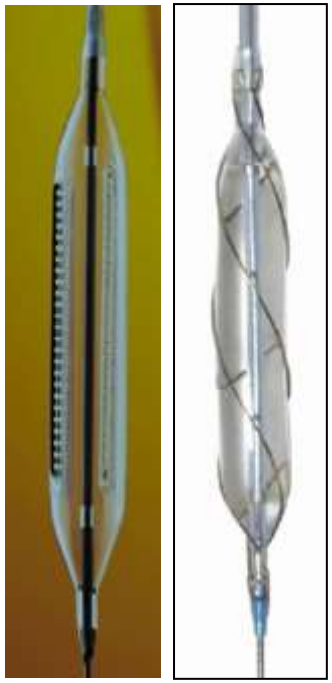
Plaque modification **+ Stenting +** ***Stent optimization***

- No large dissections
- Good stent expansion
- Improved stent apposition

Plaque modification
Cutting/scoring balloons

Conventional balloon

- High dilatation pressure
- Radial 3600 dilatation pressure
- High rate of elastic recoil
- Uncontroled dissections
- Neointimal proliferation (high inflamatory response to injury)



* **

Cutting/scoring balloon

- Lower dilatation pressure
- Max dilatation force only in points of blades
- Less elastic recoil
- More predictable dissections

*Cutting balloon: A non-compliant balloon with 3-4 microtomes mounted on its surface

**Angiosculpt: A semi-compliant balloon with an external Nitinol shape memory helical scoring edge

Possible advantages:

-"Controlled" dissections;

-Stent apposition improvement

Possible disadvantages:

- Profile & limited length
- Need for IVUS/OCT

REDUCE III: MACE Rates

521 patients were randomized: 260 to cutting-balloon angioplasty (CBA) before BMS (CBA-BMS) and 261 to balloon-angioplasty (BA) before BMS (BA-BMS). Intravascular ultrasound (IVUS)-guided procedures were performed in 279 (54%) patients

No LM included

	CBA with BMS (n=260)	BA with BMS (n=261)	p value
MACE			
SAT (n, %)	0 (0%)	1 (0.4%)*	0.336
LST (n, %)	0 (0%)	0 (0%)	1.000
Death (n, %)	1 (0.4%)	2 (0.8%)	0.564
Cardiac (n, %)	1 (0.4%)	1 (0.4%)	0.997
Non-cardiac (n, %)	0 (0%)	1 (0.4%)	0.317
MI (n, %)	2 (0.8%)	1 (0.4%)*	0.560
TLR (n, %)	25 (9.6%)	40 (15.3%)*	0.048
PCI (n, %)	25 (9.6%)	39 (14.9%)*	0.064
CABG (n, %)	0 (0%)	1 (0.4%)	0.317
PCI for a new lesion not in target vessel#	2 (0.8%)	0 (0%)	0.155
Overall MACE (n, %)$	30 (11.5%)	44 (16.8%)	0.082

Ozaki Y et al. Circ J. 2007 Jan;71(1):1-8.

Stent Expansion after Direct Stenting vs. Predilatation with SC vs. Angiosculpt

Non-randomized comparison of IVUS guided stenting

299 consecutive de novo lesions treated with 1 >2.5-mm DES (Cypher or Taxus) under IVUS guidance without postdilation, using 3 implantation strategies, were studied:

(1) direct stenting without predilation (n=145),
(2) predilation with a conventional semi-compliant balloon (n=117),
(3) predilation with the AngioSculpt balloon (n=37).

No LM included

Quantitative intravascular ultrasound assessment	Direct (n = 145)	Predilation (n = 117)	AngioSculpt (n = 37)	p Value
Postintervention lesion site				
Minimal stent diameter (mm)	2.6 ± 0.4	2.5 ± 0.4	2.8 ± 0.4	0.048*
Minimal stent CSA (mm^2)	6.0 ± 1.7	5.9 ± 1.6	6.8 ± 1.5	0.02*
IVUS/manufacturer-predicted stent diameter (%)	76 ± 10	76 ± 13	88 ± 18	<0.001*
IVUS/manufacturer-predicted stent area (%)	67 ± 16	70 ± 23	88 ± 32	<0.001*

Stent expansion = IVUS measured minimum stent diameter (MSD) divided by manufacturer's predicted MSD

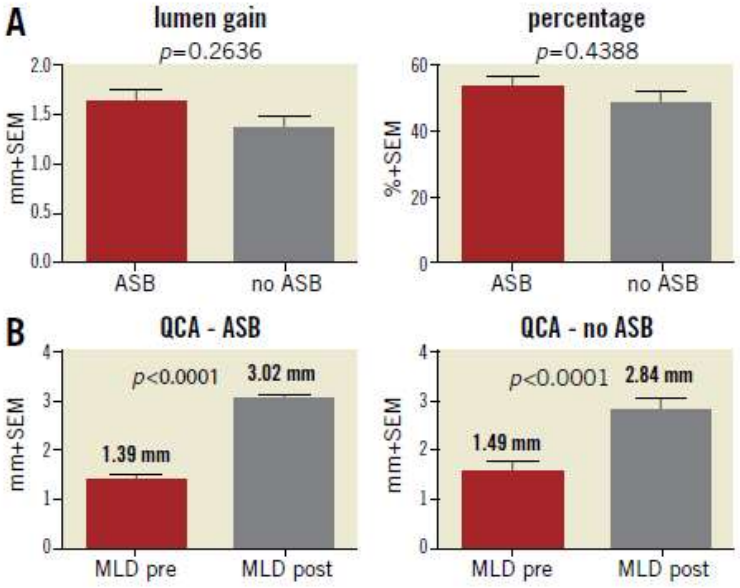
* p Value of AngioSculpt compared with the other 2 groups. There were no differences between the direct stenting and balloon predilation groups.

De Ribamar Costa J et al. Am J Cardiol. 2007 Sep 1;100(5):812-7.

ALSTER Left Main registry:

AngioSculpt Scoring Balloon in left maininterventions

1 centre Asklepios Klinik St. Georg, Hamburg, Germany, 47 patients (mean age 73.1 ±1.5 years, 85.1 % male) with a low or medium SYNTAX score who received an elective PCI for unprotected LM disease(2009-2012) with AngioSculpt Scoring Balloon (ASB) lesion preparation (N=34) and without ASB (N=13); IVUS in 53% in ASB group, 23% in no-ASB



Follow-up	All	ASB group	No ASB group	*p*-value
MACCE 12 months	13.3% (6/45)	12.5% (4/32)	15.4% (2/13)	0.39
myocardial infarction	0	0	0	
cardiovascular death	0	0	0	
all-cause death	6.7% (3/45)	6.3% (2/32)	7.7% (1/13)	1.0
cerebrovascular events	0	0	0	
interventional TLR	4.4% (2/45)	3.1% (1/32)	7.7% (1/13)	0.50
interventional TVR	0	0	0	
bypass surgery	2.2% (1/45)	3.1% (1/32)	0	1.0

Conclusions: Adding AngioSculpt Scoring Balloon (ASB) lesion preparation to the standard provisional T-stenting technique for ULMI is feasible and safe. Low TLR and TVR rates were observed. Lesion preparation led to a numerically larger lumen gain.

Schmidt T et al. EuroIntervention. 2016 Mar;11(12):1346-54.

Left Main PCI: Latvian Experience

90ties 2001 2004 2007

90ties: Emergency procedures in LM

Introduction of IVUS

2001: Latvian Unprotected LM registry

Elective PCI for LM

Refused CABG, "Syntax" < 20 etc.

2004: Latvian Randomized trial (n=103)

2005: SYNTAX study (n=40)

Introduction of OCT

2007: Local guidelines for LM PCI

IVUS guidance

Plaque modification (CB)

DES implantation

Provisional stenting in bifurcations

Clinical follow-up + stress test

9 mo angio, IVUS follow-up

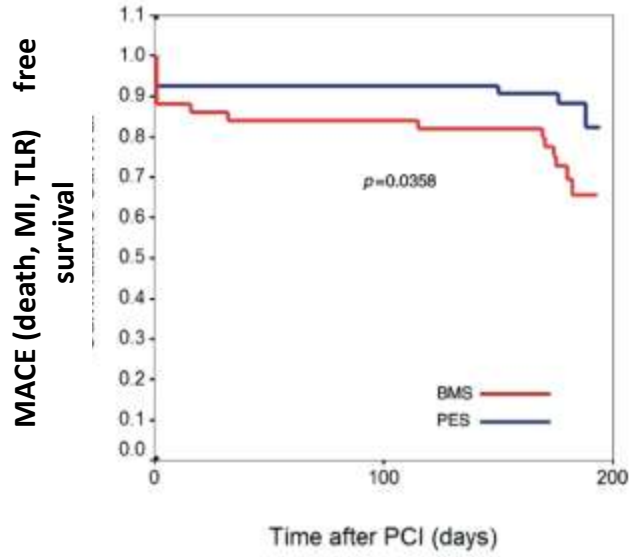
2010: NOBLE study

EXCEL study

2016: Latvian Unprotected LM registry ongoing

The Latvian Randomized trial of BMS vs PES in ULM

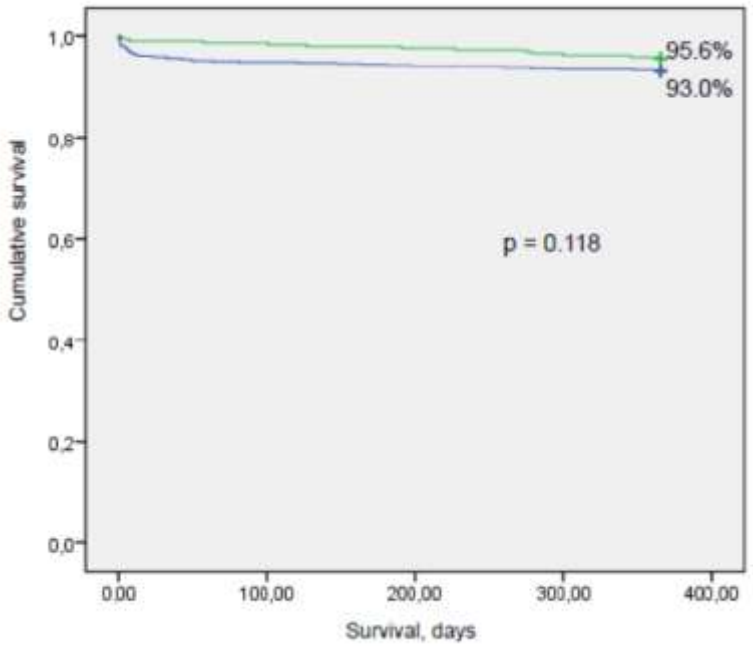
Between Feb 2004 and Nov 2005 PCI on unprotected LM: IVUS guidance, cutting balloon pretreatment mandatory, randomization: BMS n=50 vs PES n=53

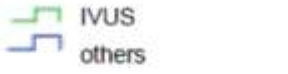


Erglis A, et al. *JACC* 2007;50;491-497

Survival according to use cutting balloon and IVUS

Unprotected LM registry at Latvian Centre of Cardiology

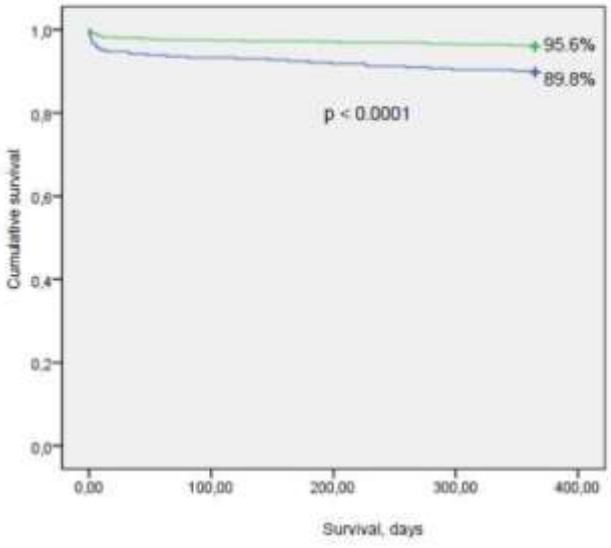


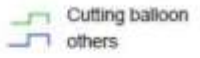


IVUS - 95.6% (13/294)

others - 93.0% (47/671)

p = 0.118





Cutting balloon - 95.6% (25/615)

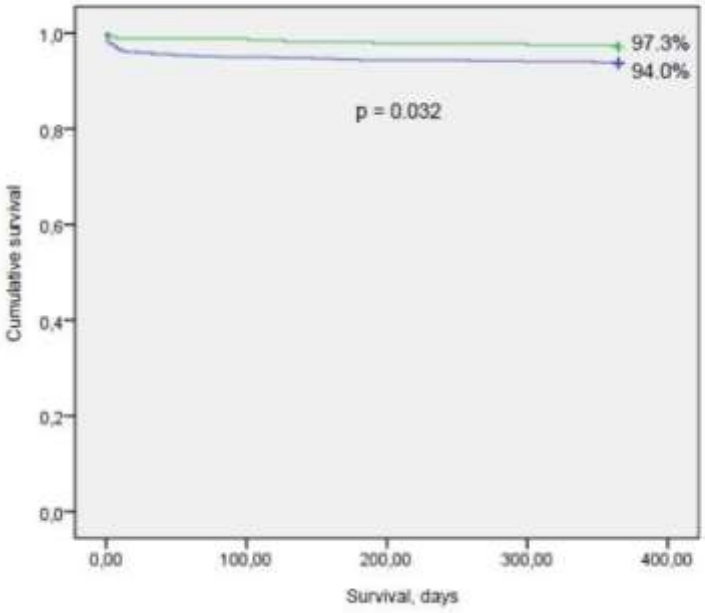
others - 89.8% (35/343)

p < 0.0001

Narbute I et al. EuroPCR 2012

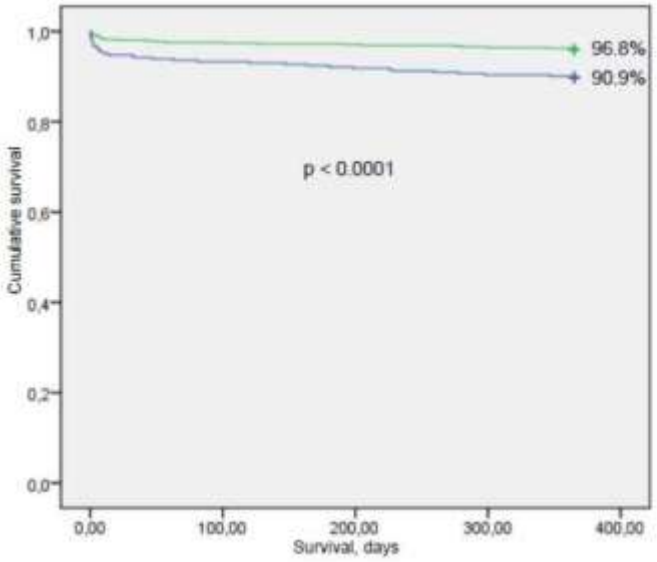
Cardiovascular survival according to use cutting balloon and IVUS

Unprotected LM registry at Latvian Centre of Cardiology



IVUS
others

IVUS - 97.3% (8/294)
others - 94.0% (40/631)
p = 0.032



Cutting balloon
others

Cutting balloon - 96.9% (19/596)
others - 91.5% (29/343)
p < 0.0001

Narbute et al. EuroPCR 2012

Case Example

LM: distal trifurcation 95% stenosis

RCA: diffuse disease.

<u>Femoral approach</u> 7F EBU 3.75; GPIIb/IIIa

Female 76 y.o.

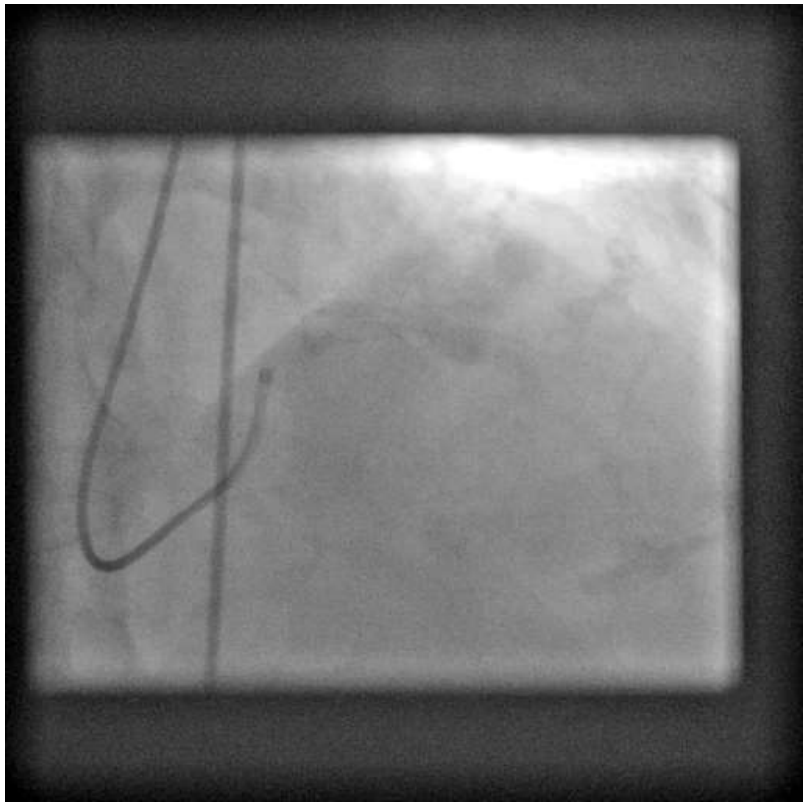
<u>Clinical presentation:</u>

Stable angina III-IV.

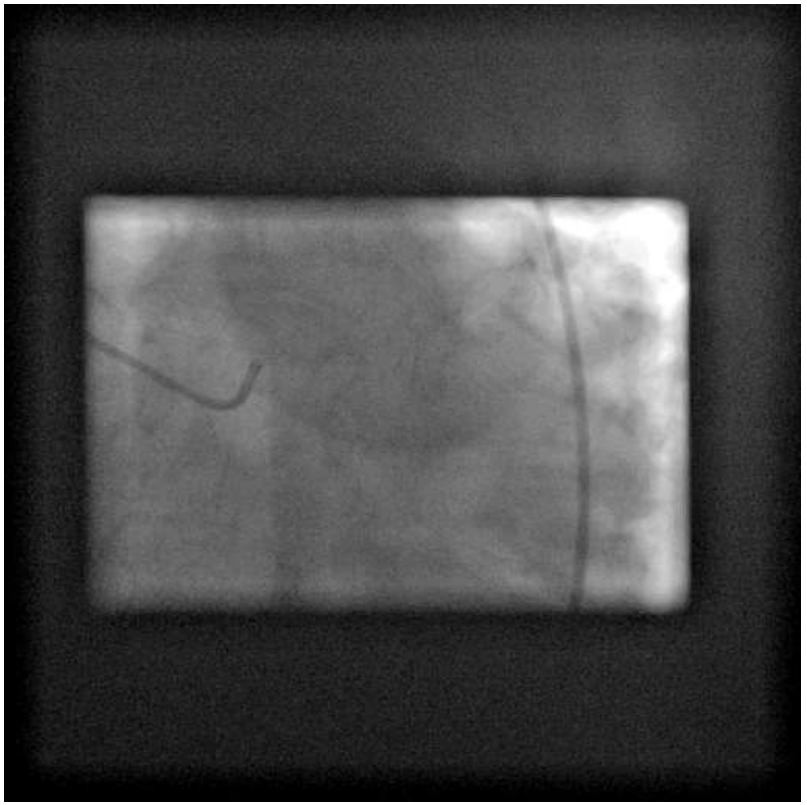
Arterial hypertension.

Dyslipidemia.

<u>Syntax score 0-22</u>



LAD



LCX

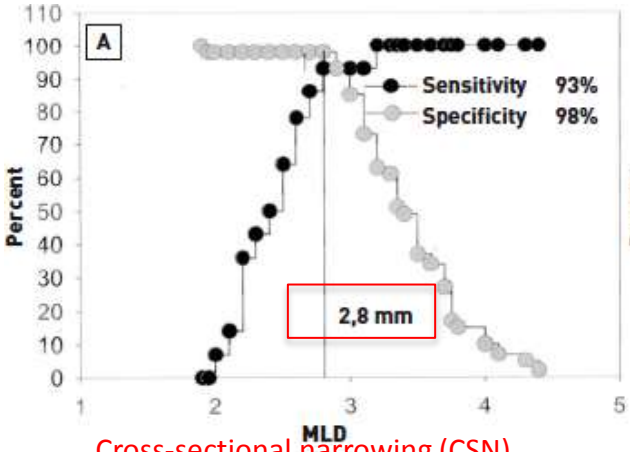
Should I stent?

Ischemic cut point of FFR and IVUS parameters for LM lesions

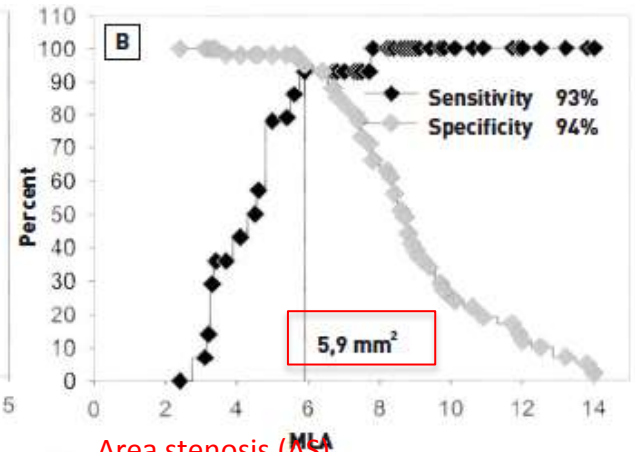
FFR and IVUS performed in 55 patients with an angiographically ambiguous LM stenosis

Sensitivity and specificity curves of ischemic cut point of FFR<0.75 and IVUS parameters

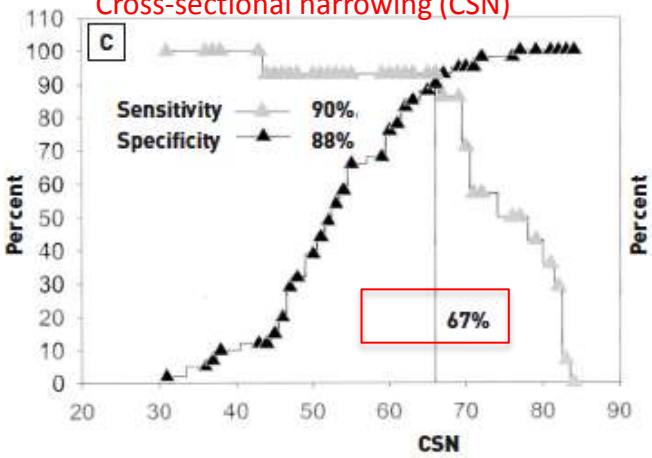
Minimum lumen diameter (MLD)



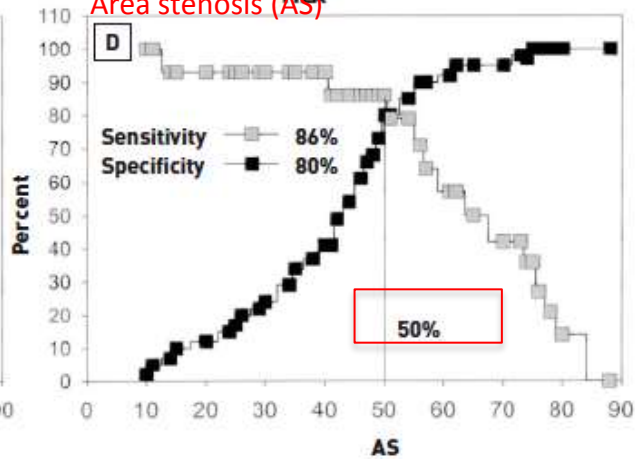
Minimum lumen area (MLA),



Cross-sectional narrowing (CSN)



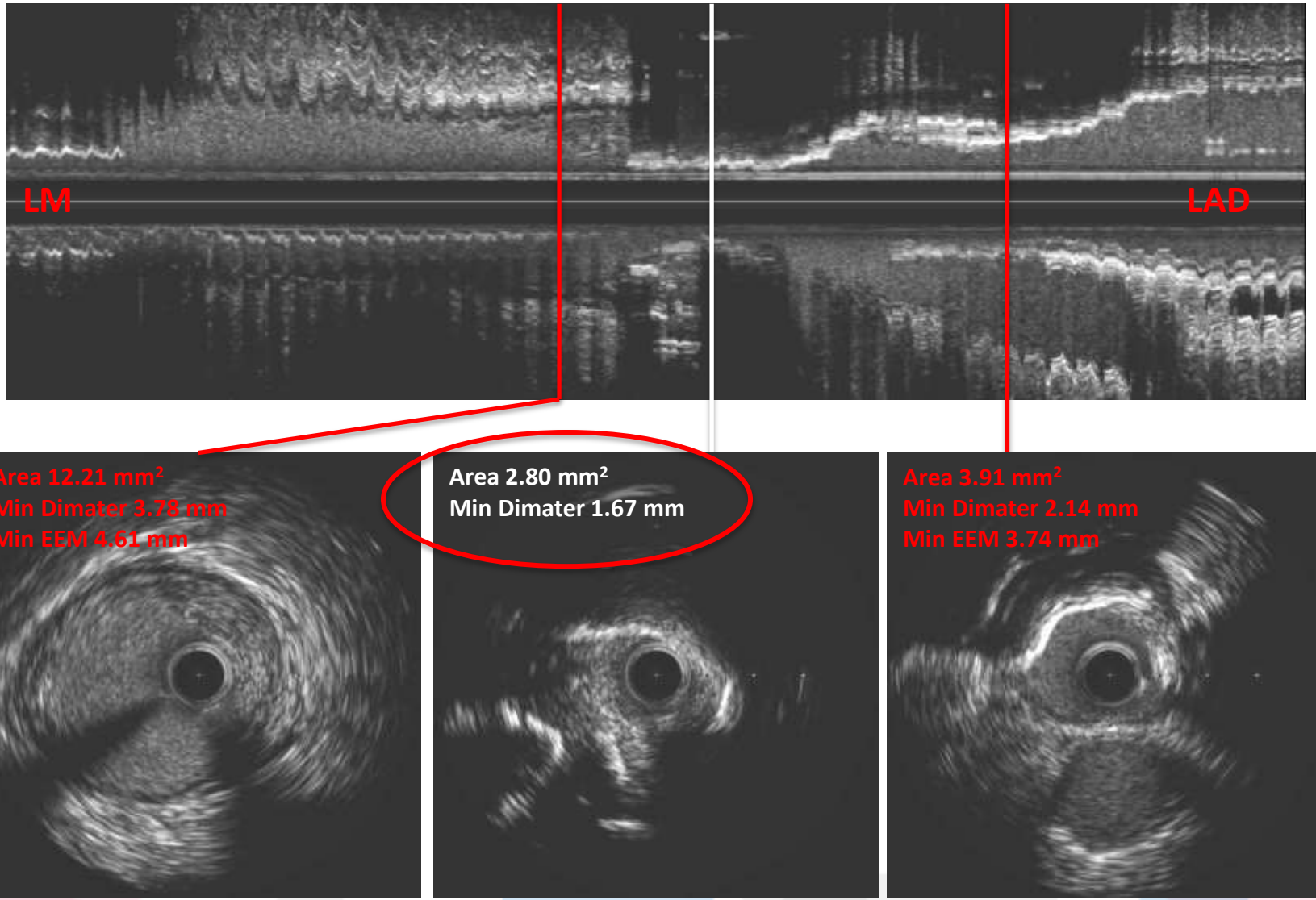
Area stenosis (AS)



Jasti V et al. Circulation. 2004;110:2831-2836

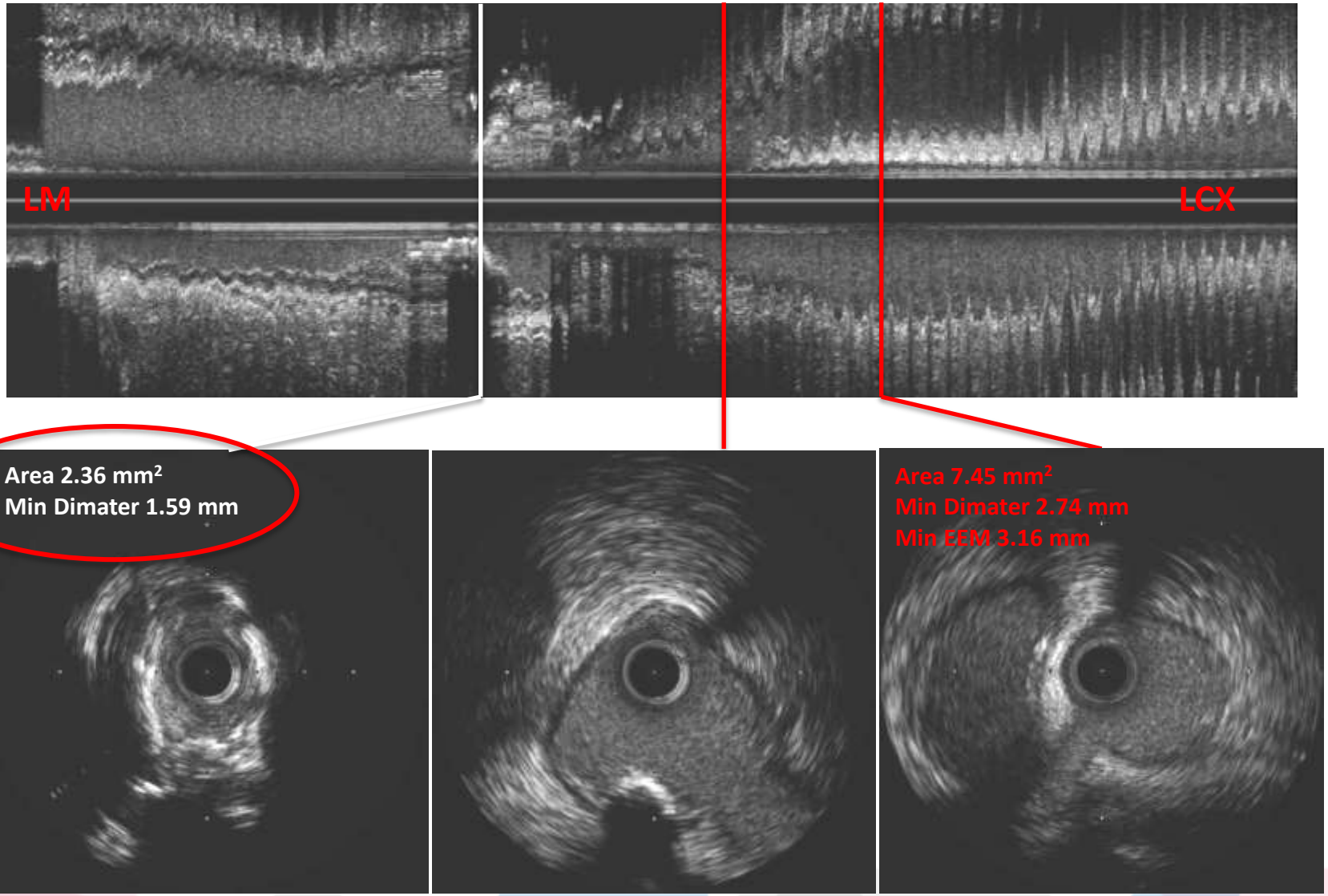
How should I stent?

Preintervention IVUS LAD-LM



How should I stent?

Preintervention IVUS LCX-LM



How should I stent?

Preintervention IVUS

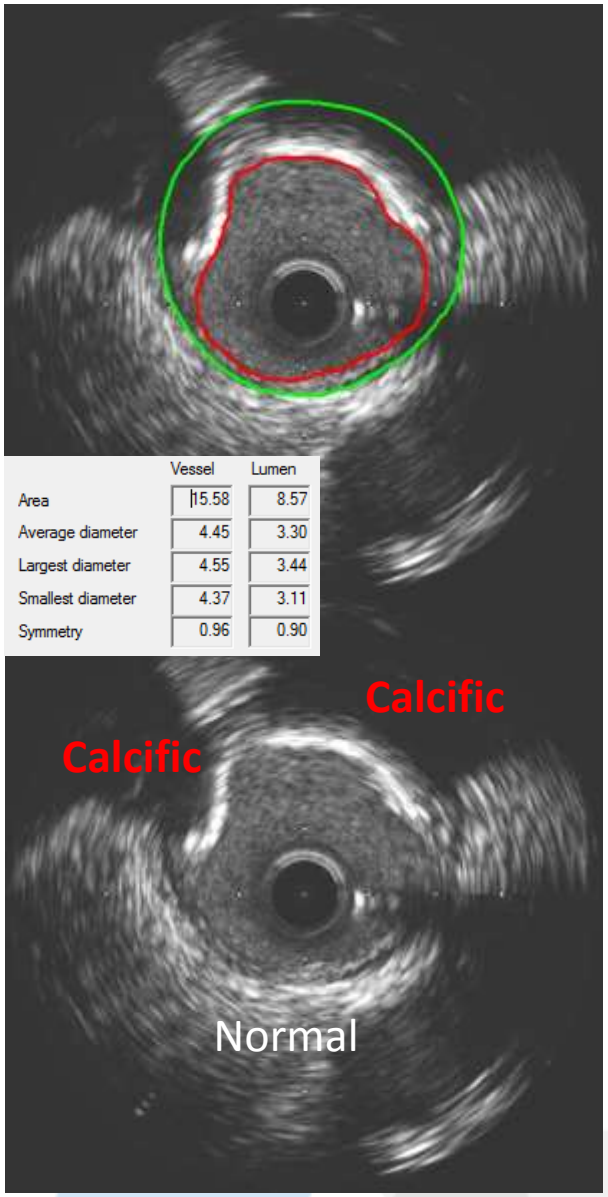
Device Sizing (Diameter and Length):

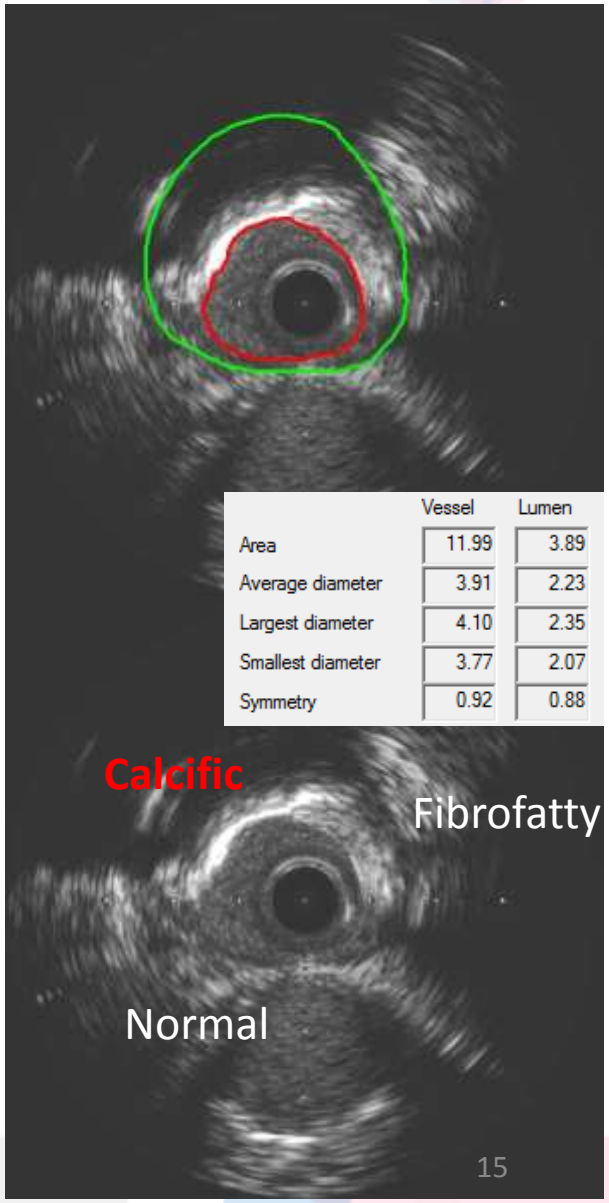
Increasingly aggresive

- Largest reference lumen (prox or dist)
- Midwall
- Media-to-media (typically discounted)

Plaque Characterization and Lesion Preparation Options

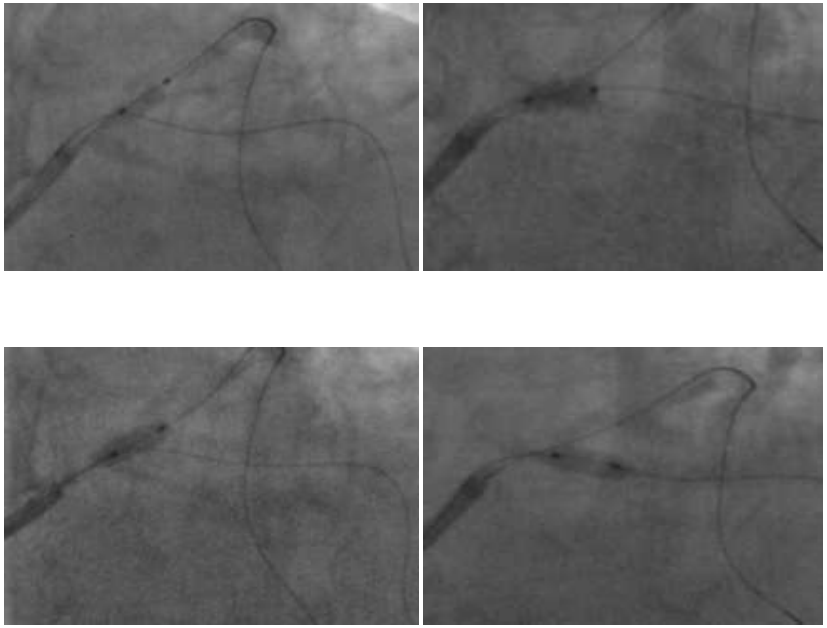
- POBA (fatty, fibrofatty)
- **Cutting balloon (fibrotic, fibro-calcific, calcific)**
- ROTA (Calcific)





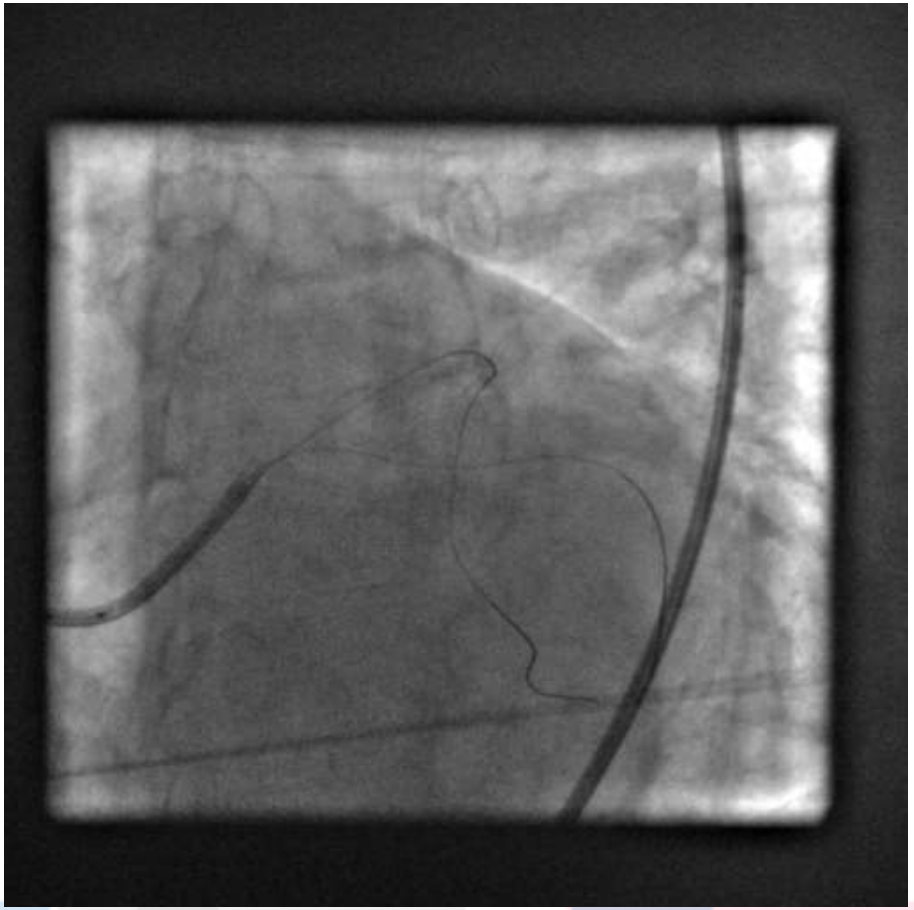
Plaque pretreatment

Predilatation of LM/LAD
Cutting balloon 3.25x6 mm
8,10,12 bar

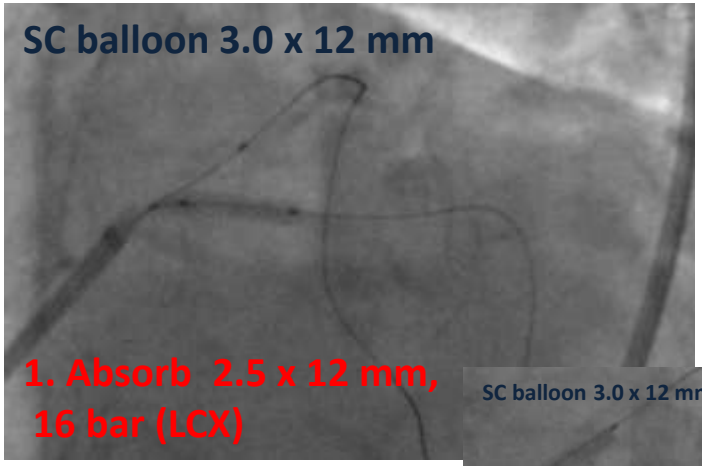


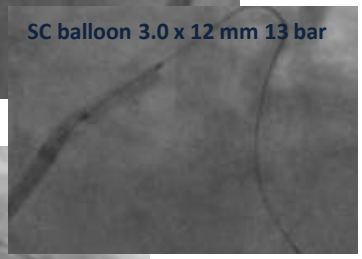
Predilatation of LM/LCX
Cutting balloon 3.25x6 mm
8,10,12 bar

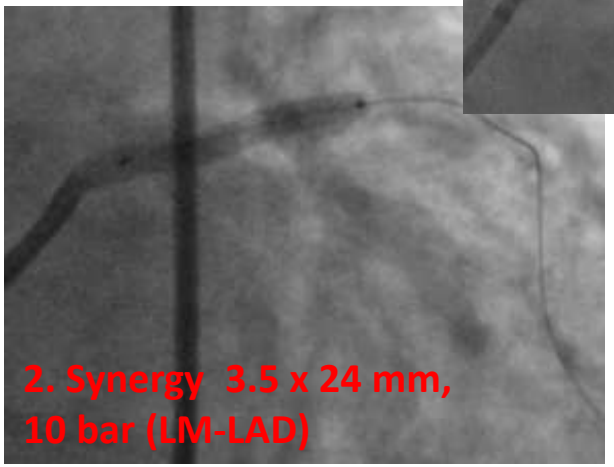
After plaque pretreatment

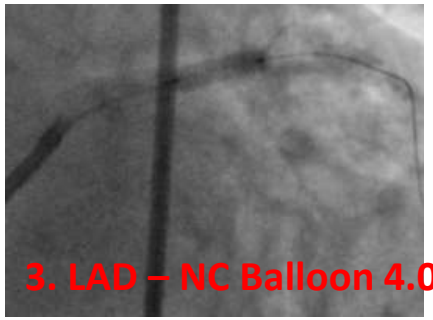


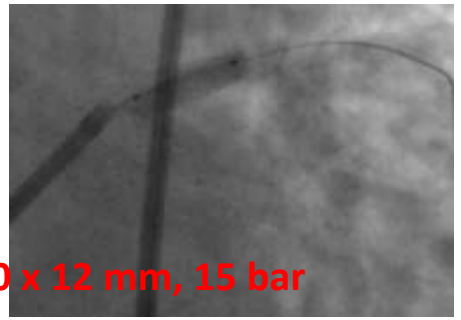
T-Stenting

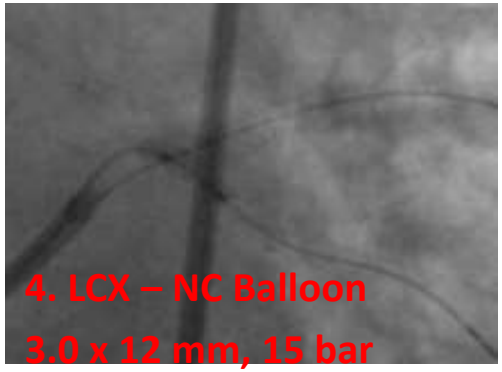

SC balloon 3.0 x 12 mm
1. Absorb 2.5 x 12 mm,
16 bar (LCX)

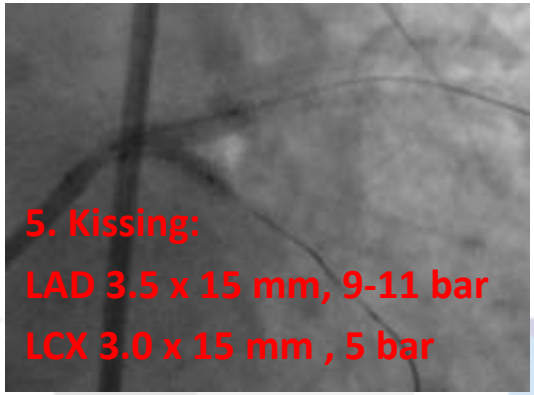

SC balloon 3.0 x 12 mm 13 bar


2. Synergy 3.5 x 24 mm,
10 bar (LM-LAD)

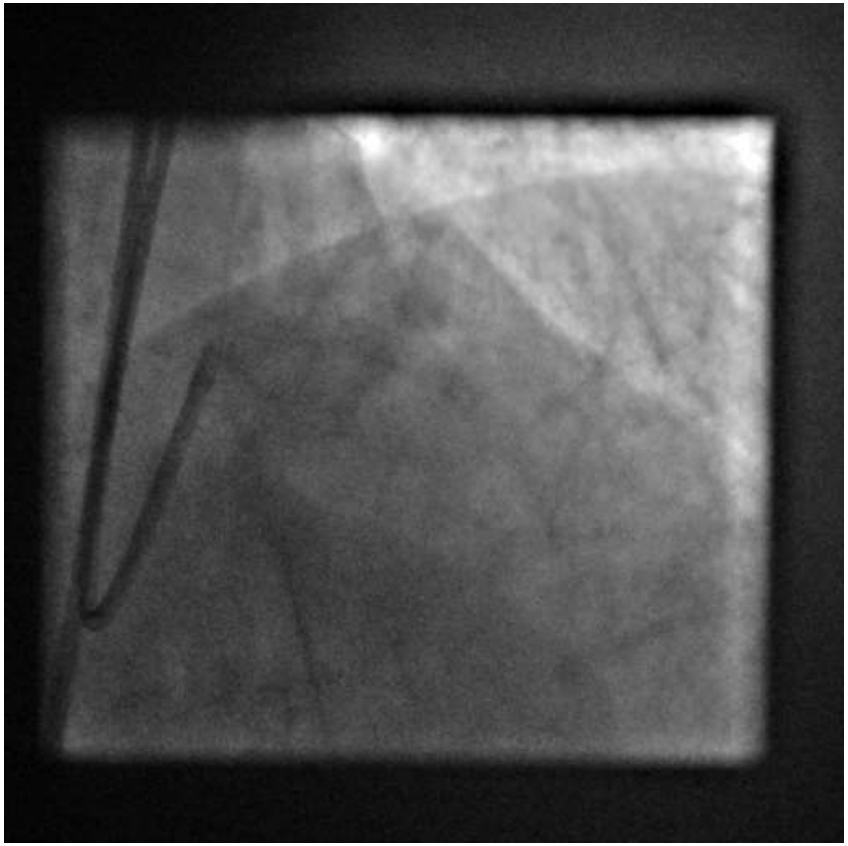

3. LAD – NC Balloon 4.0 x 12 mm, 15 bar




4. LCX – NC Balloon
3.0 x 12 mm, 15 bar

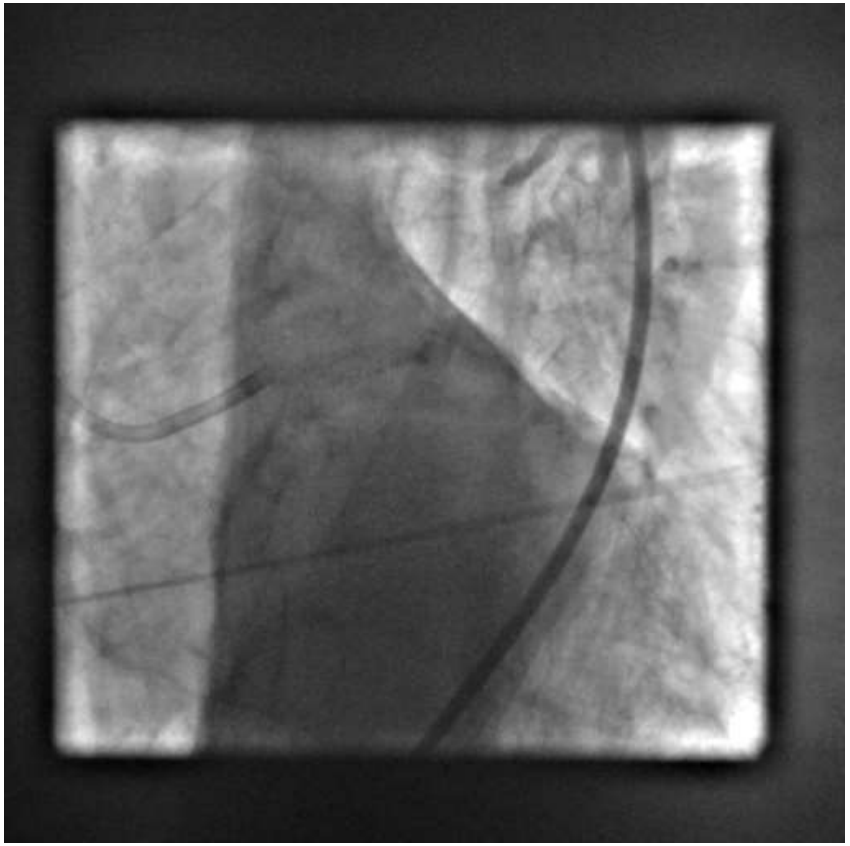

5. Kissing:
LAD 3.5 x 15 mm, 9-11 bar
LCX 3.0 x 15 mm , 5 bar

Final Result after PCI



LAD

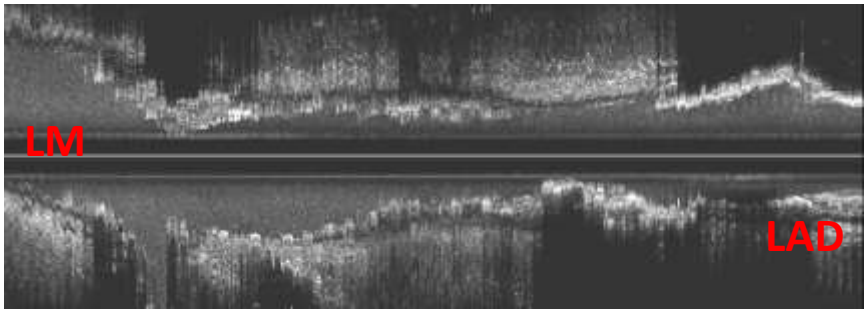
FFR	0.87
Pd/Pa	0.87
Pa:iPa	61: 55
Pd:iPd	53: 41

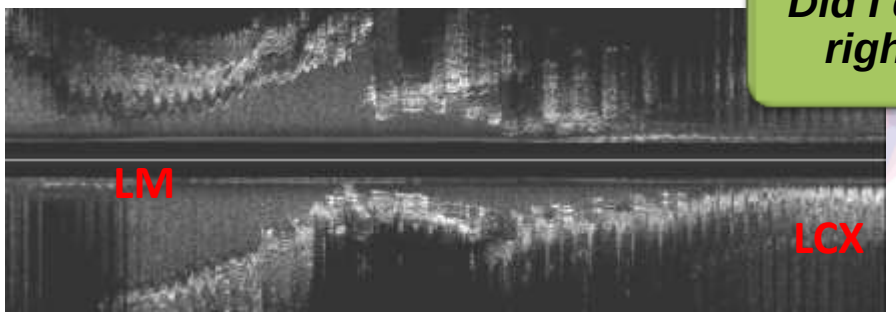


LCX

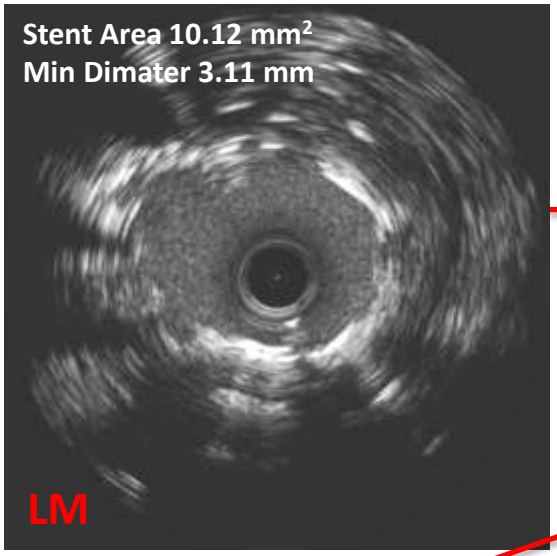
FFR	0.89
Pd/Pa	0.89
Pa:iPa	44: 41
Pd:iPd	39: 38

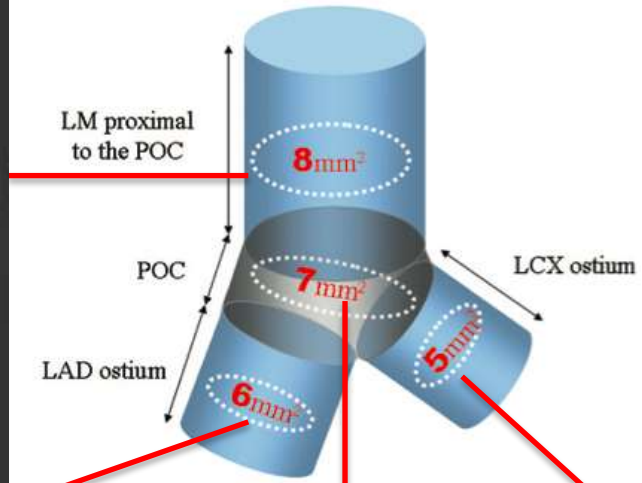
Did I do it right?

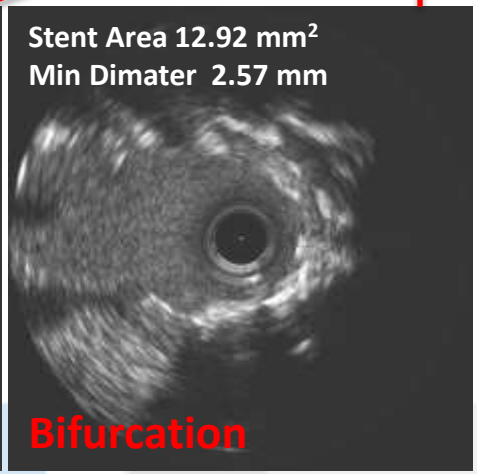


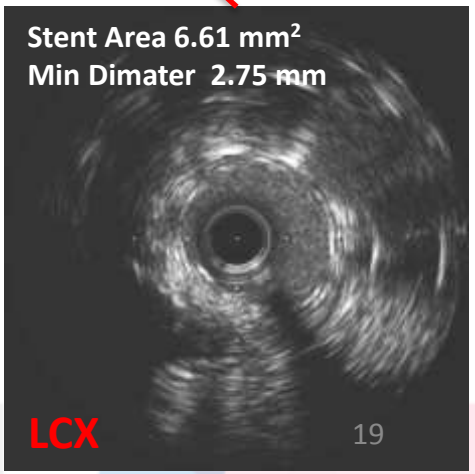


Post-PCI IVUS







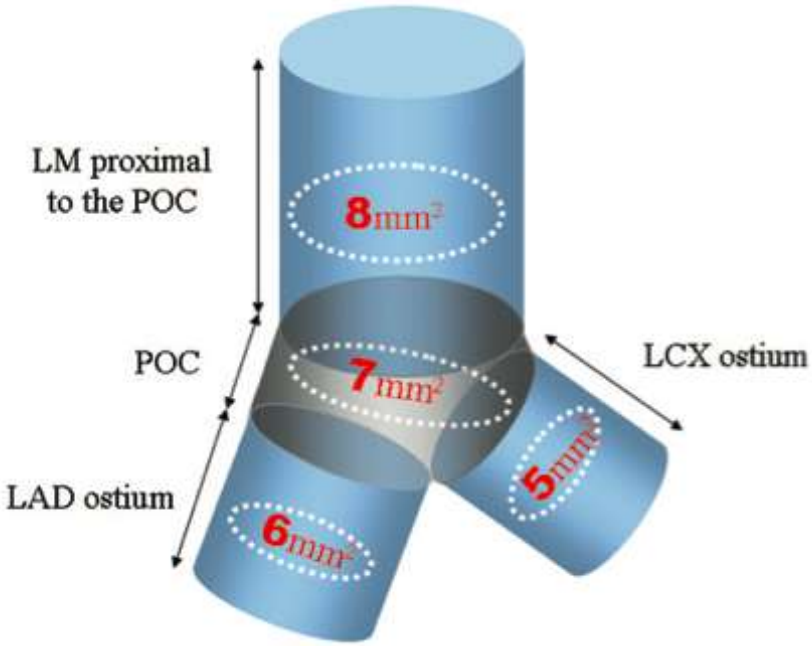


Did I do it right?

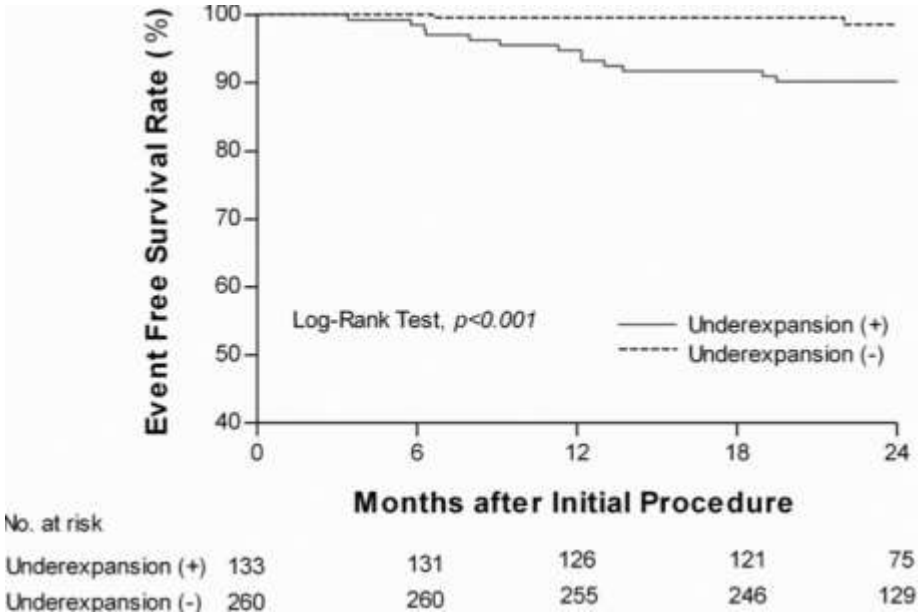
IVUS for optimisation in LM PCI

403 patient with unprotected LM disease had immediate poststenting IVUS and 9-month follow-up angiography
46 (11.4%) showed angiographic restenosis at 9 months

MLA cutoff values for the prediction of angiographic in-stent restenosis (ISR)



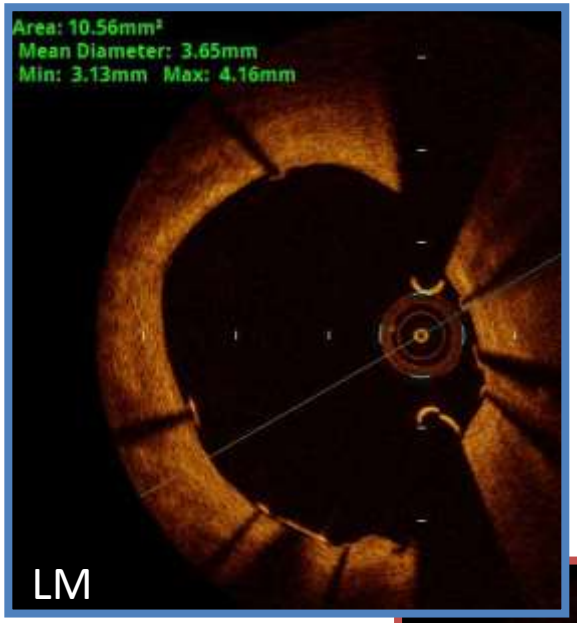
Kaplan-Meier curve for major adverse cardiac event (MACE)-free survival.

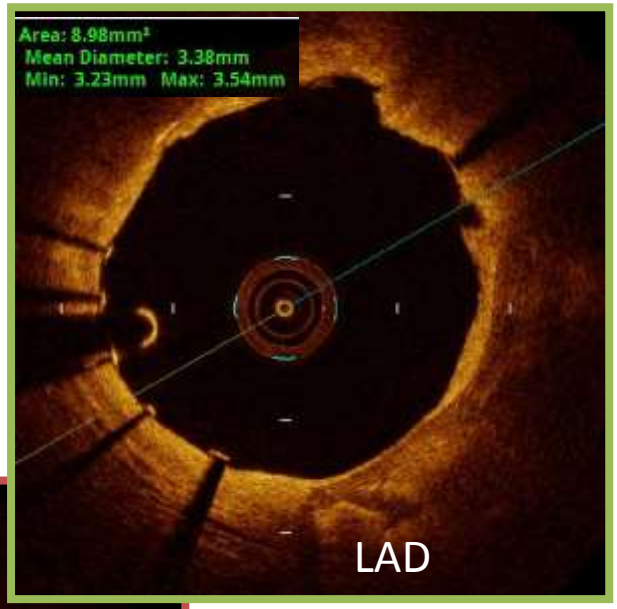


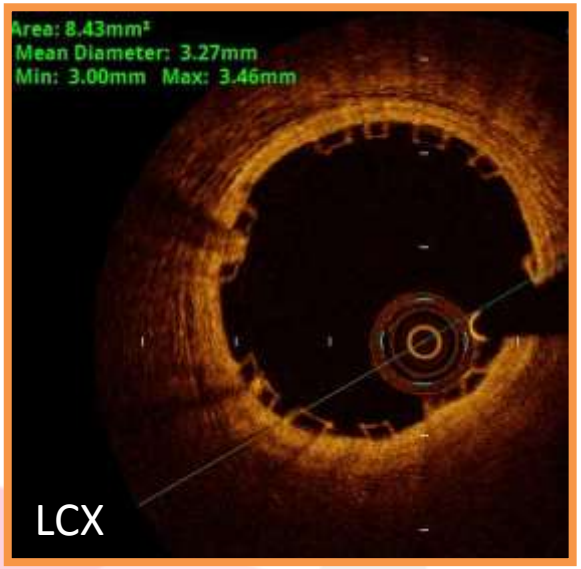
Kang S-J et al. Circ Cardiovasc Interv. 2011;4:562-569

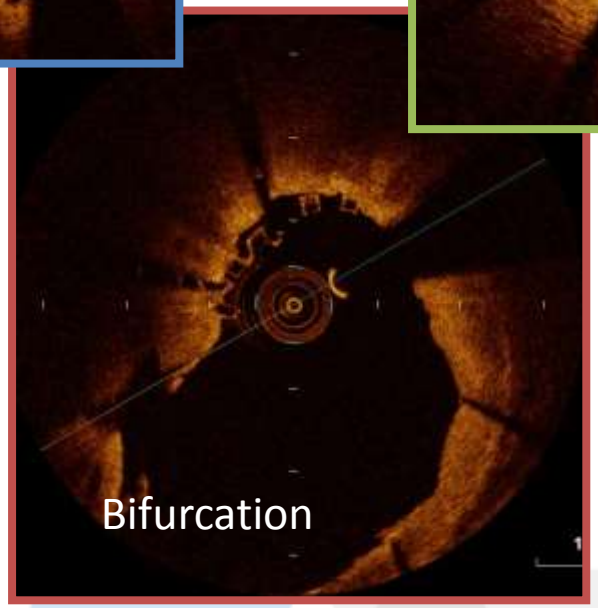
Did I do it right?

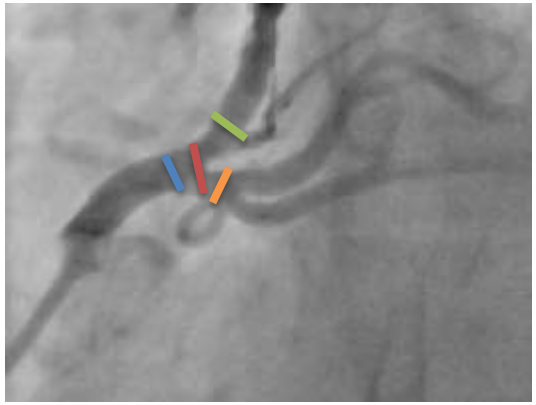
Post-PCI OCT





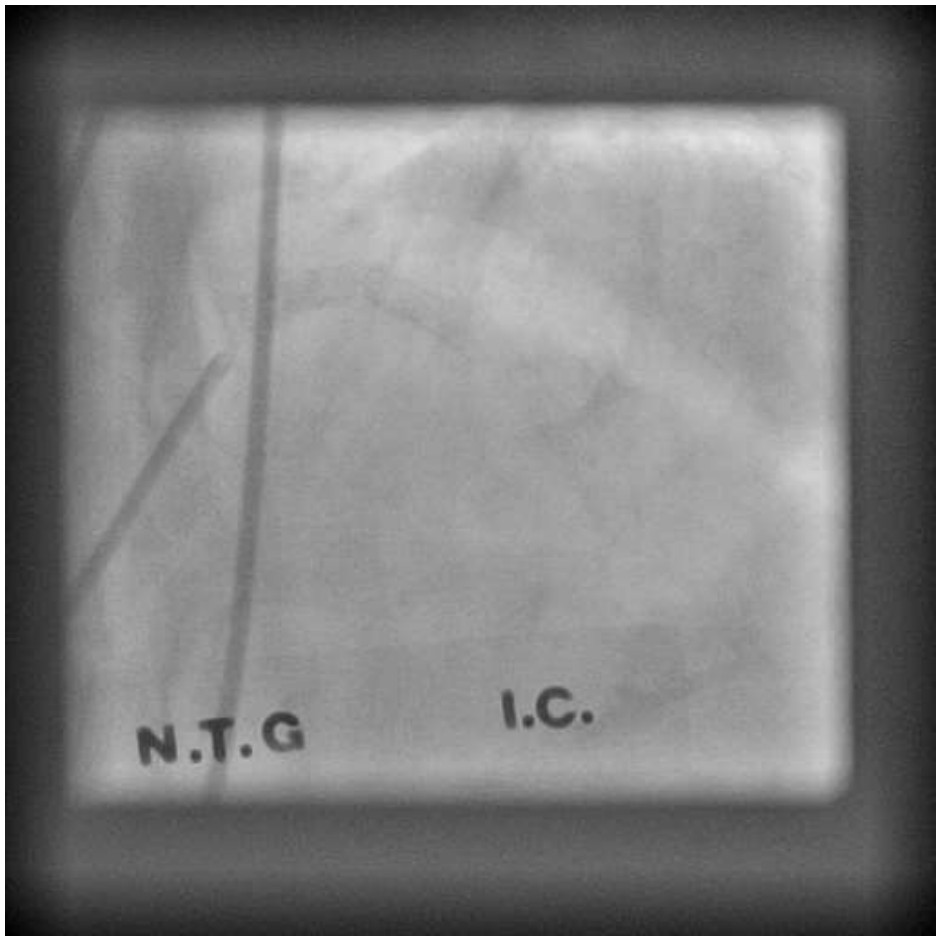


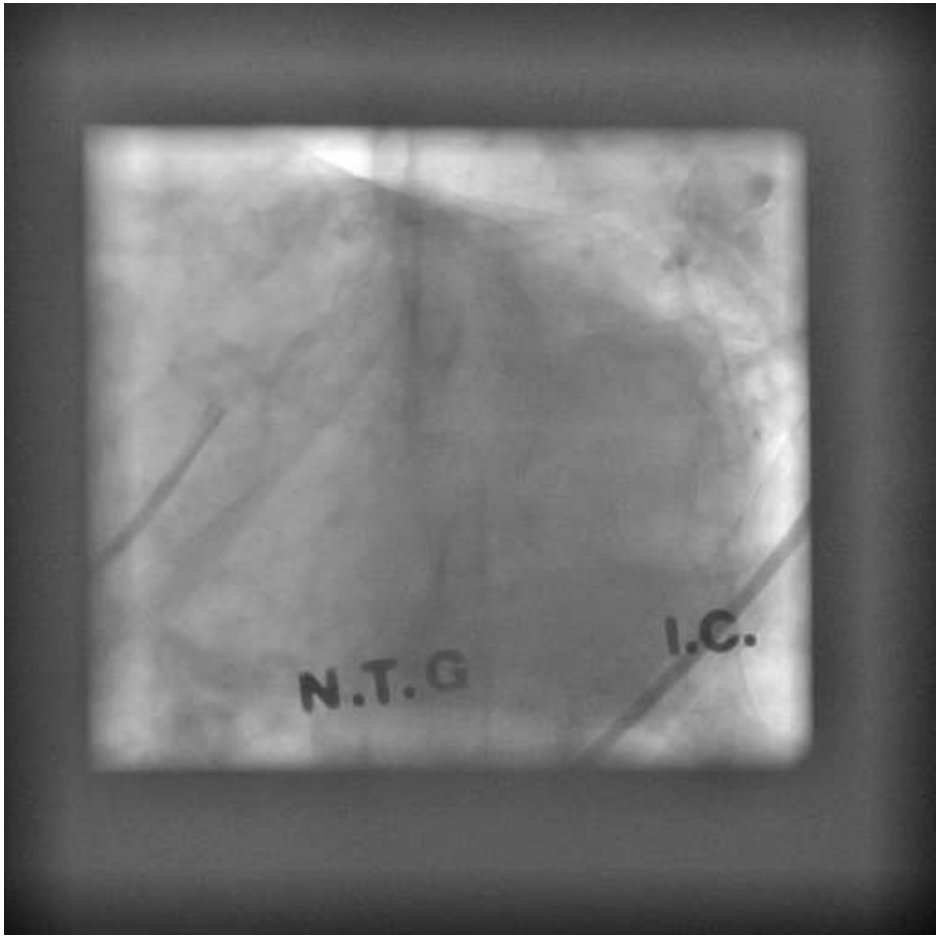




Follow-up

Patient is symptom free





Conclusions

- We have found a cutting balloon to be a reasonable and safe tool for pre-treatment of atherosclerotic plaque before stent deployment.
- However, a randomized trial of left main stenting with versus without cutting balloon plaque modification is required to establish the safety of benefits of this technique.
- Intravascular imaging is recommeded before plaque modification for precise assessement vessel dimensions and plaque characterictic