

# How May Imaging Help in LM PCI?

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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.

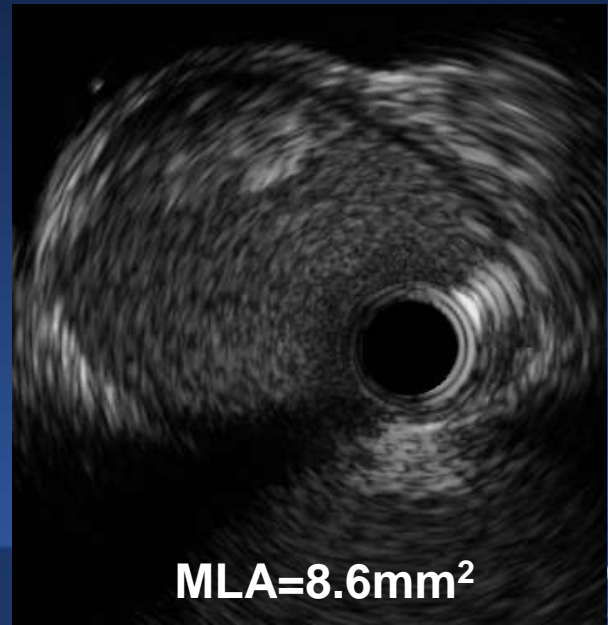
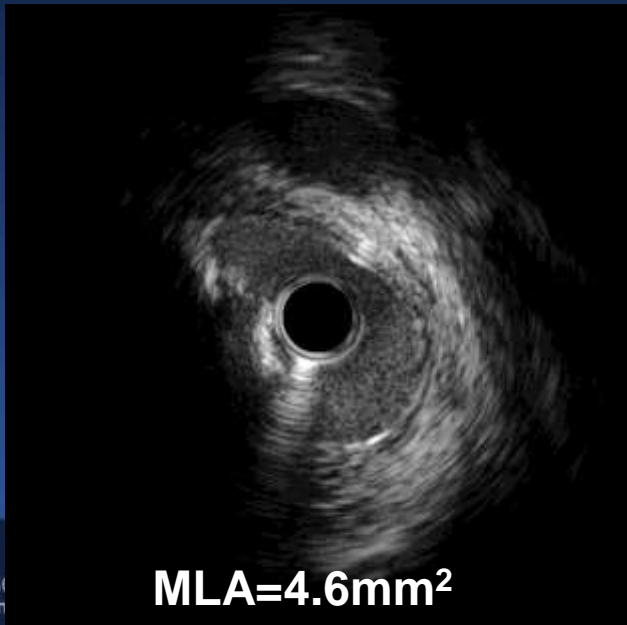
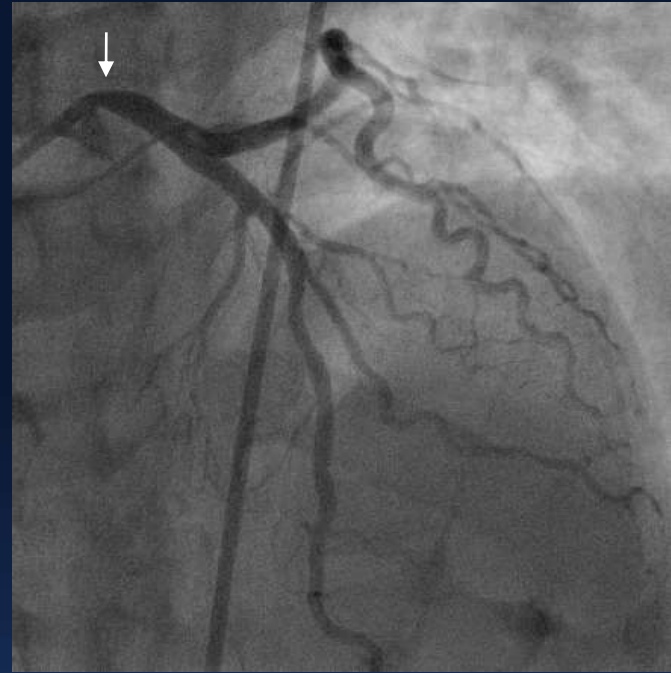
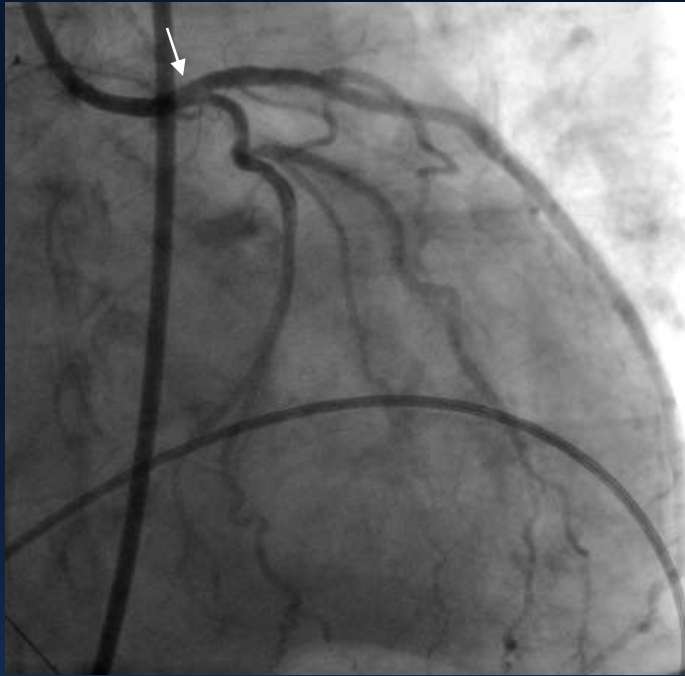
## Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria

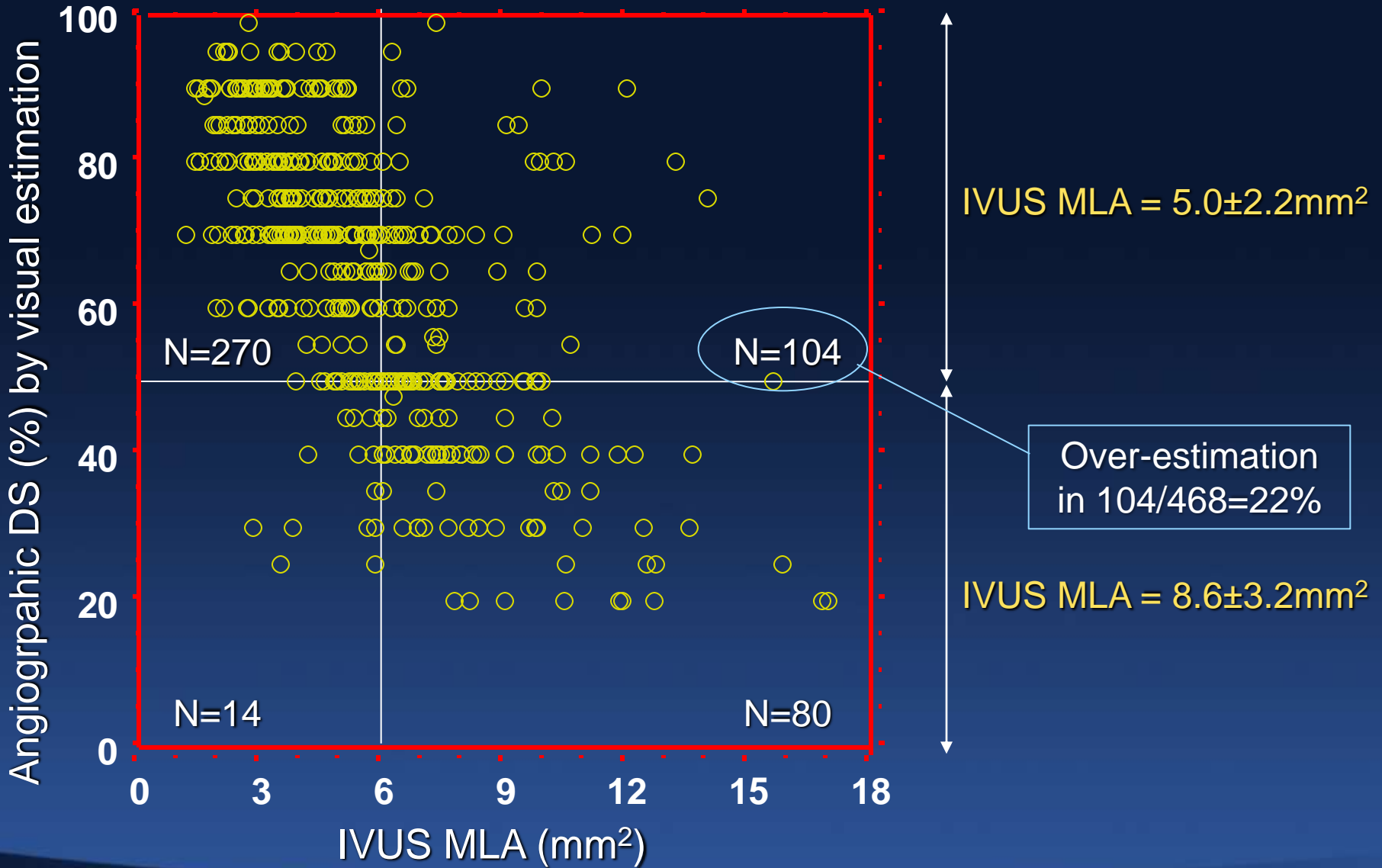
## Company

- Boston Scientific, St Jude Medical
- Boston Scientific, OCT Medical Imaging Inc.

# Discrepancy between Angio and IVUS

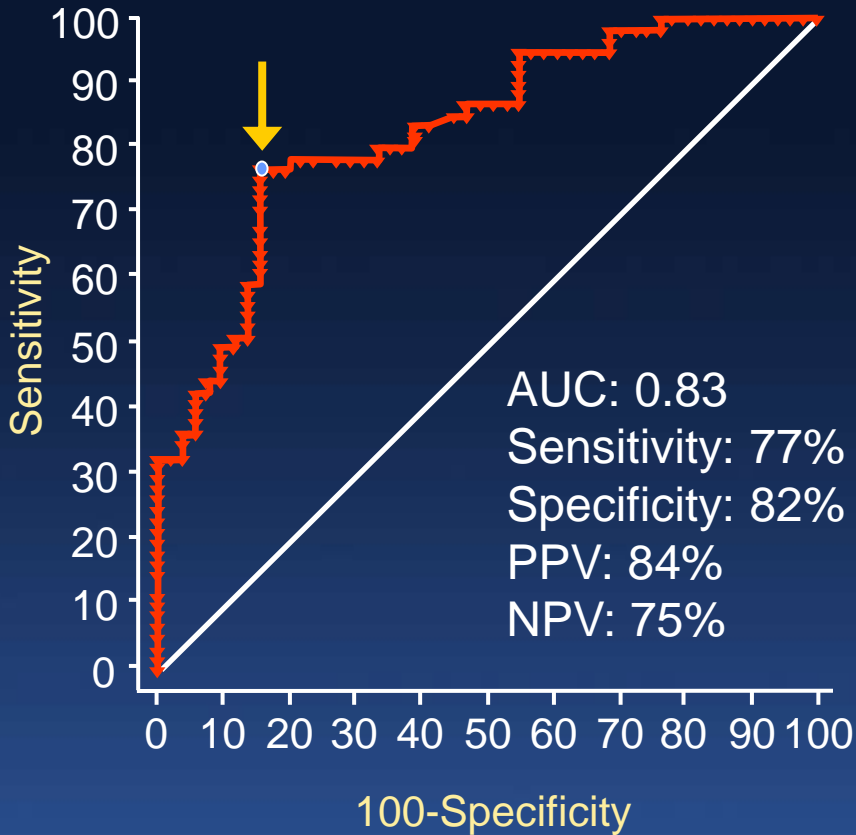


# Comparison of Angiography vs IVUS (n=468)



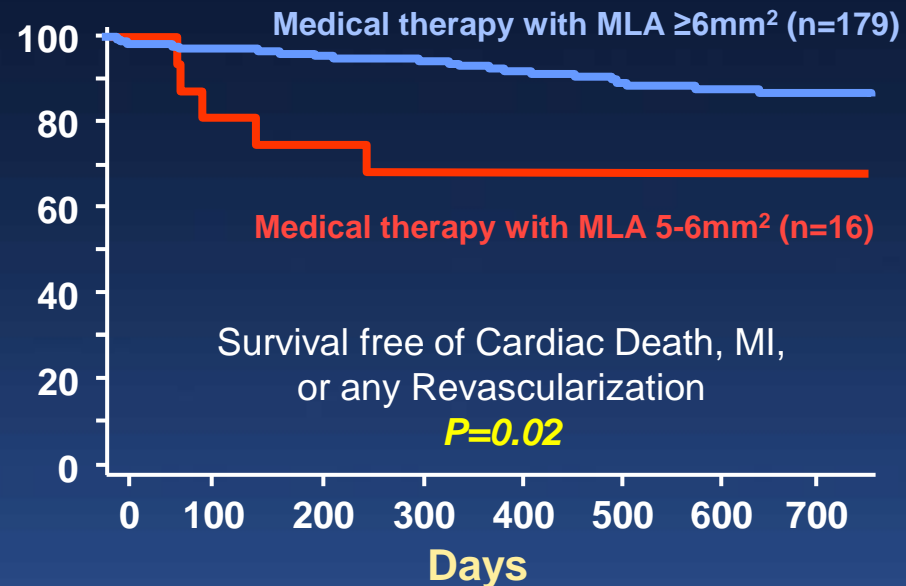
# IVUS MLA determinants of LM FFR (n=112)

Cut-off value: 4.5 mm<sup>2</sup>



# Clinical Outcome of Pts Treated Medically According to MLA (=195)

Cut-off value: 6.0 mm<sup>2</sup>

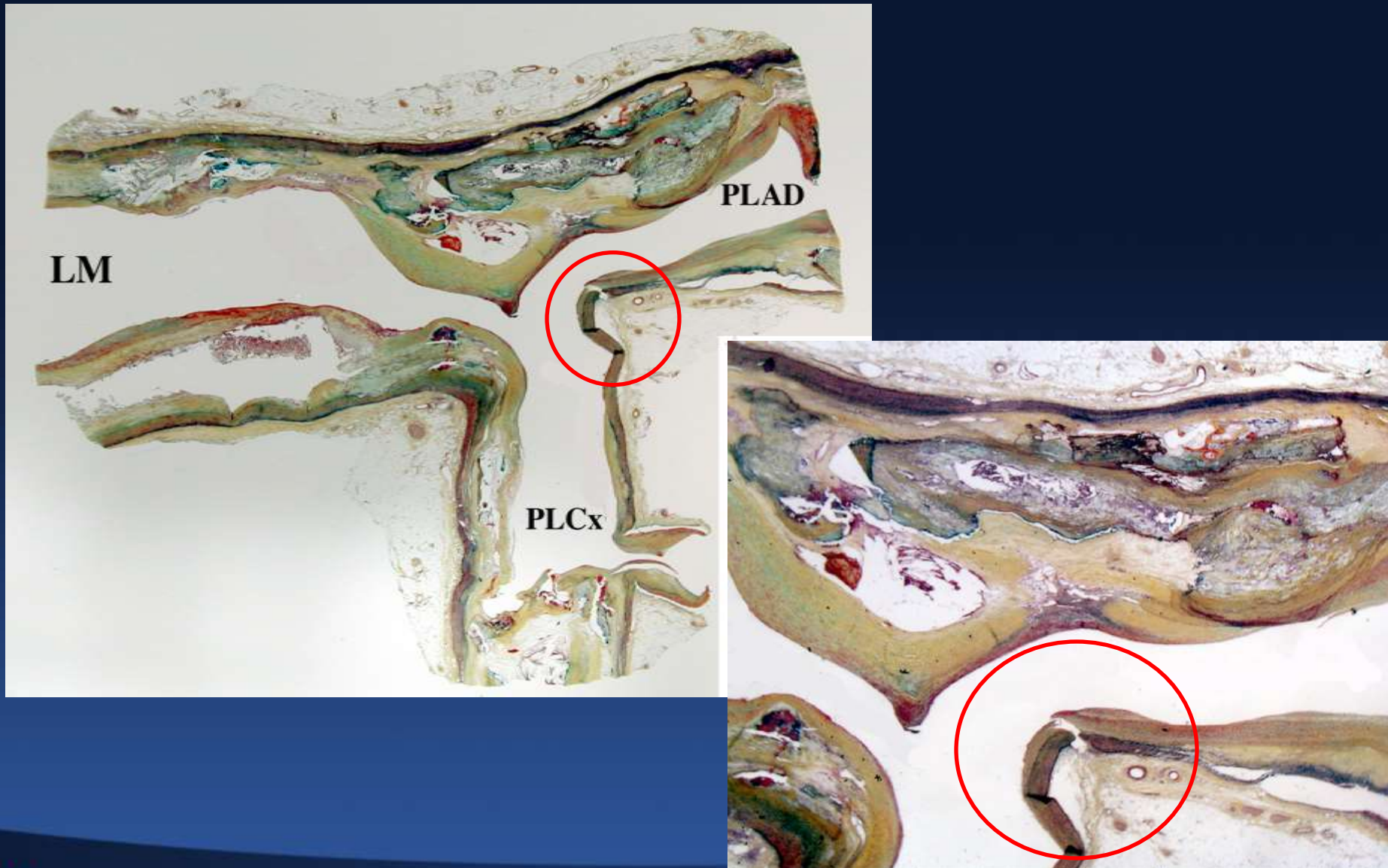


Park et al. J Am Coll Cardiol Intv 2014;7:868-74

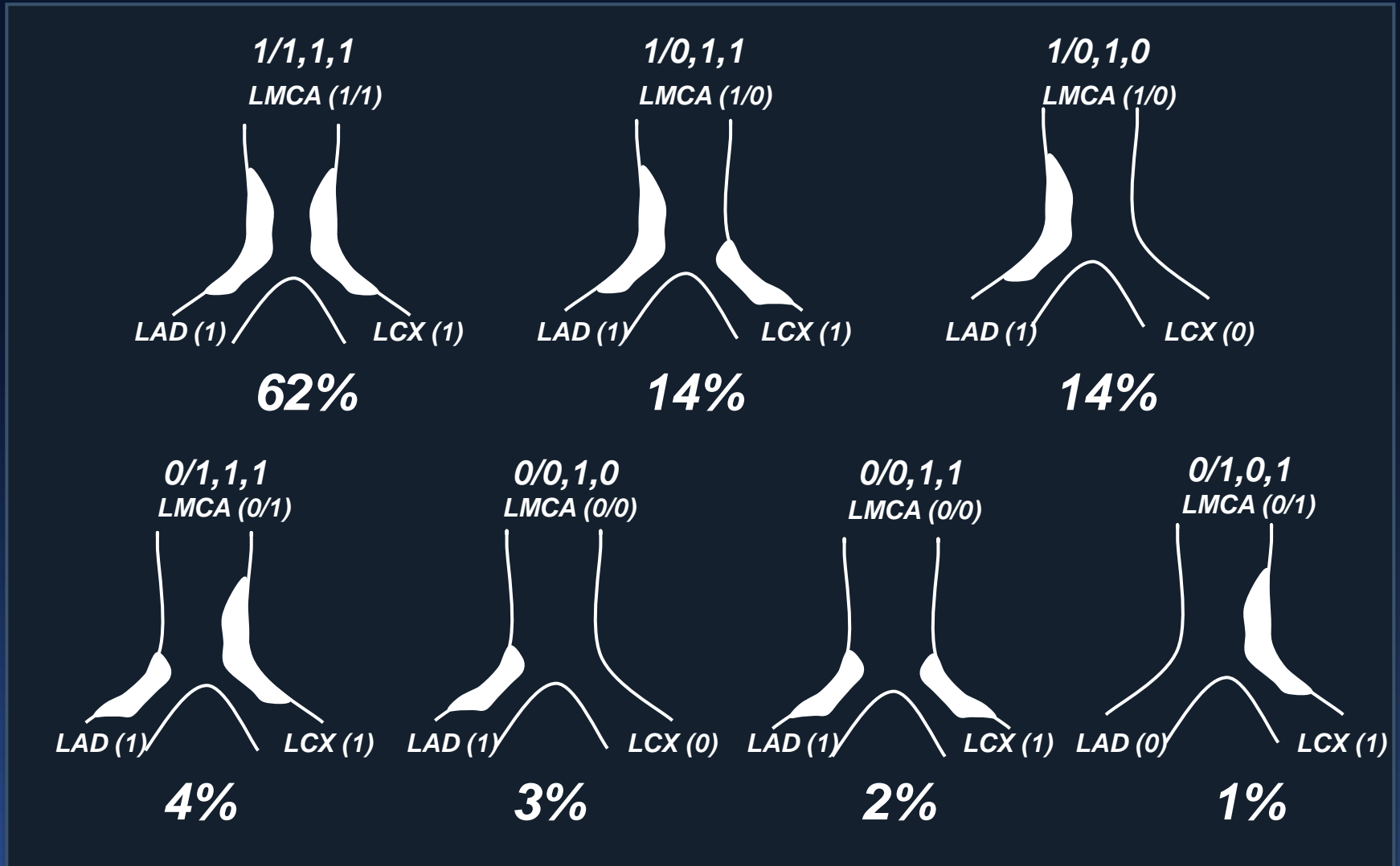
De La Torre Hernandez et al. J Am Coll Cardiol 2011;58:351-8



# Plaque Formation

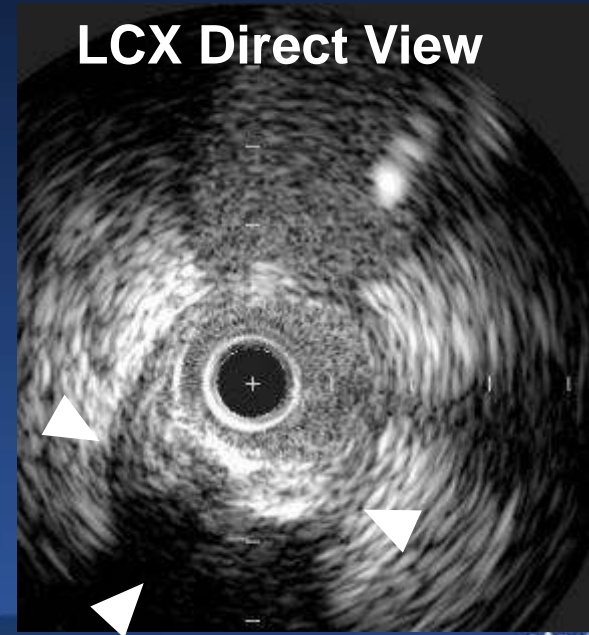
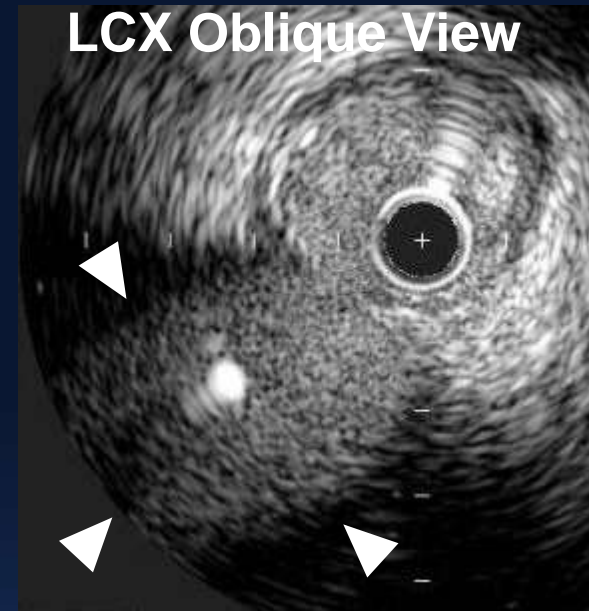


# Plaque Distribution by IVUS (n=140)



**In 90% plaque extends from LMCA-LAD**

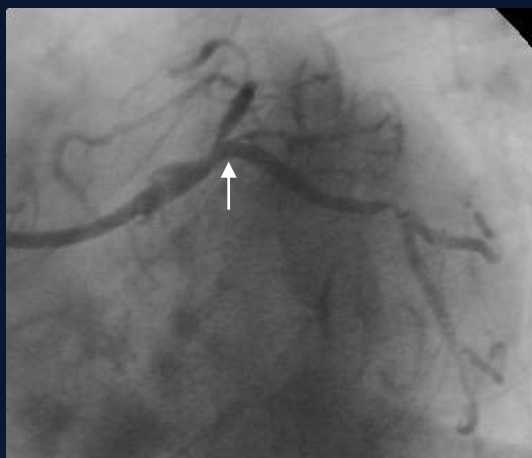
- Though you don't see anything, this is not true.
- If you see something, this may be true.



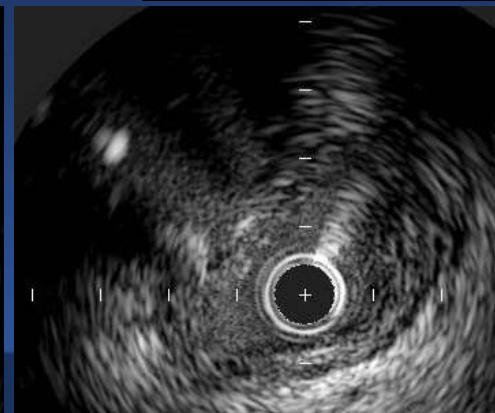
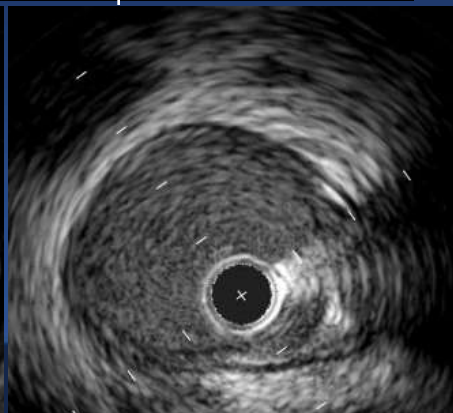
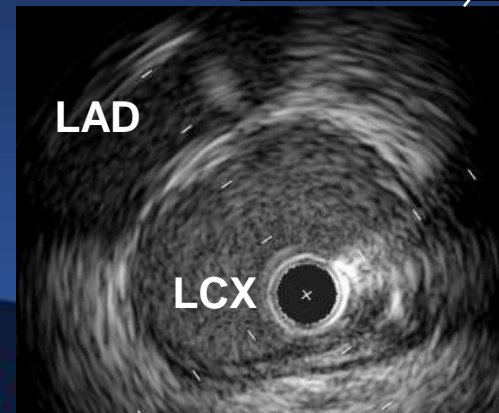
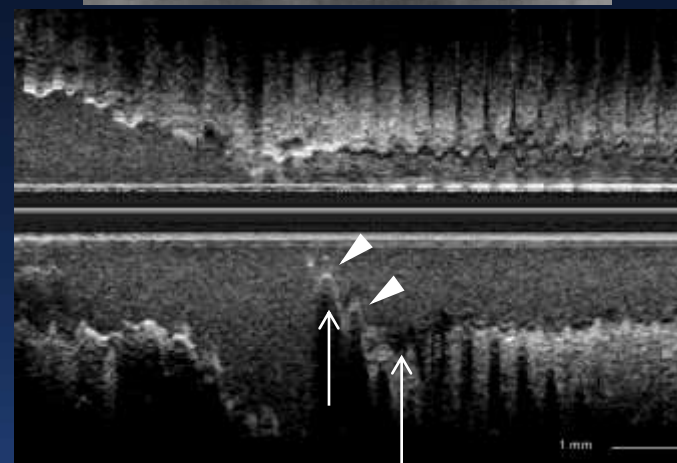
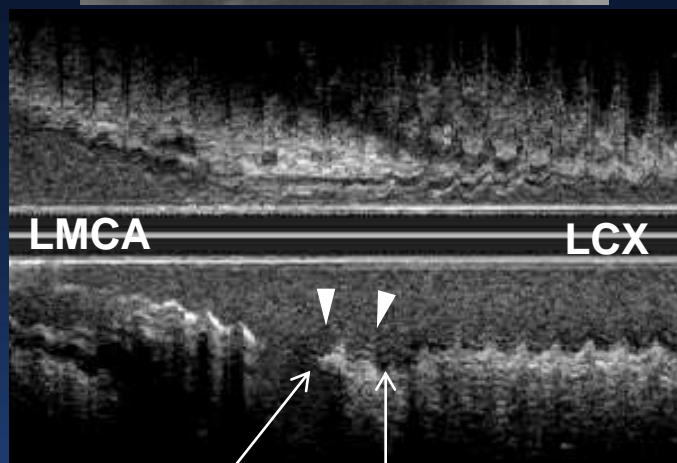
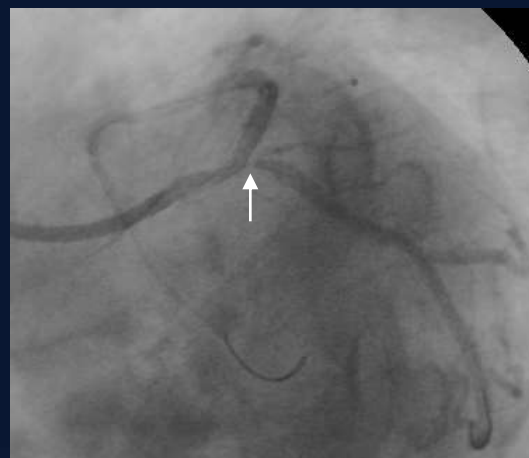


# Carina Shift

Pre -PCI



Final



# Outcome of LCX after Cross-Over Stenting

43 Patients with distal LMCA lesions  
without LCX disease (DS<50%)

LAD-LMCA Cross-Over Stenting

LCX DS>50%  
N=18 (42%)

LCX DS≤50%  
N=25

FFR<0.8  
N=3 (7%)

FFR≥0.8  
N=40

KBT  
N=2

KBT  
N=4

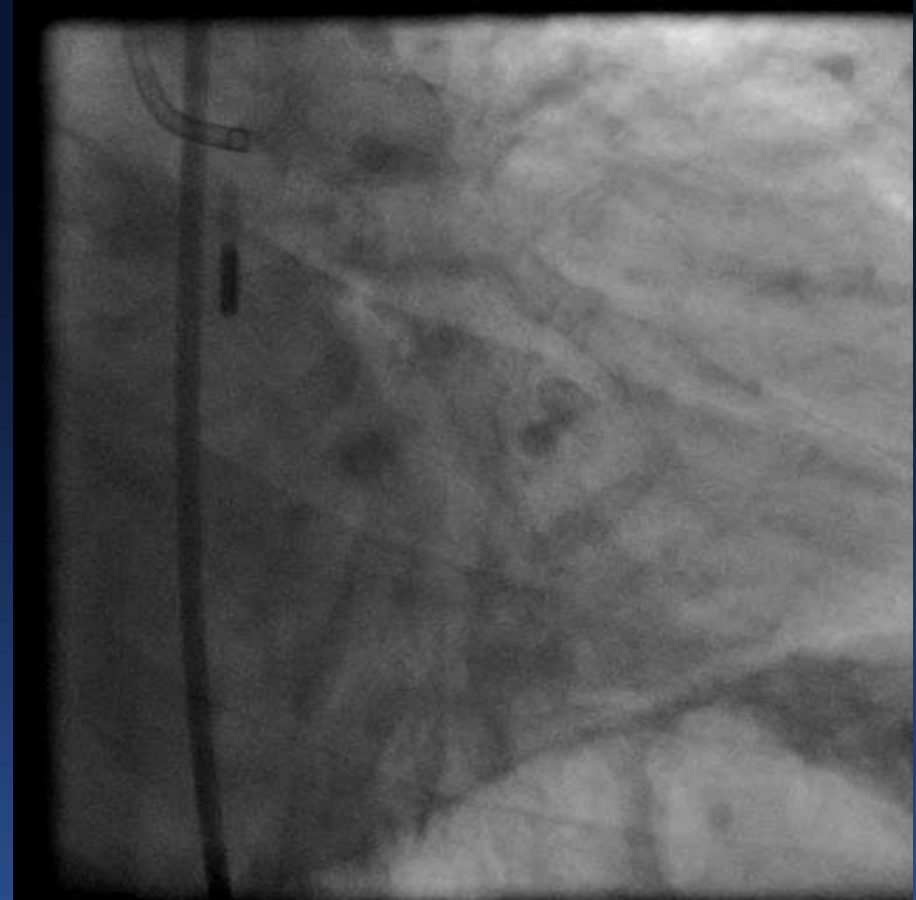
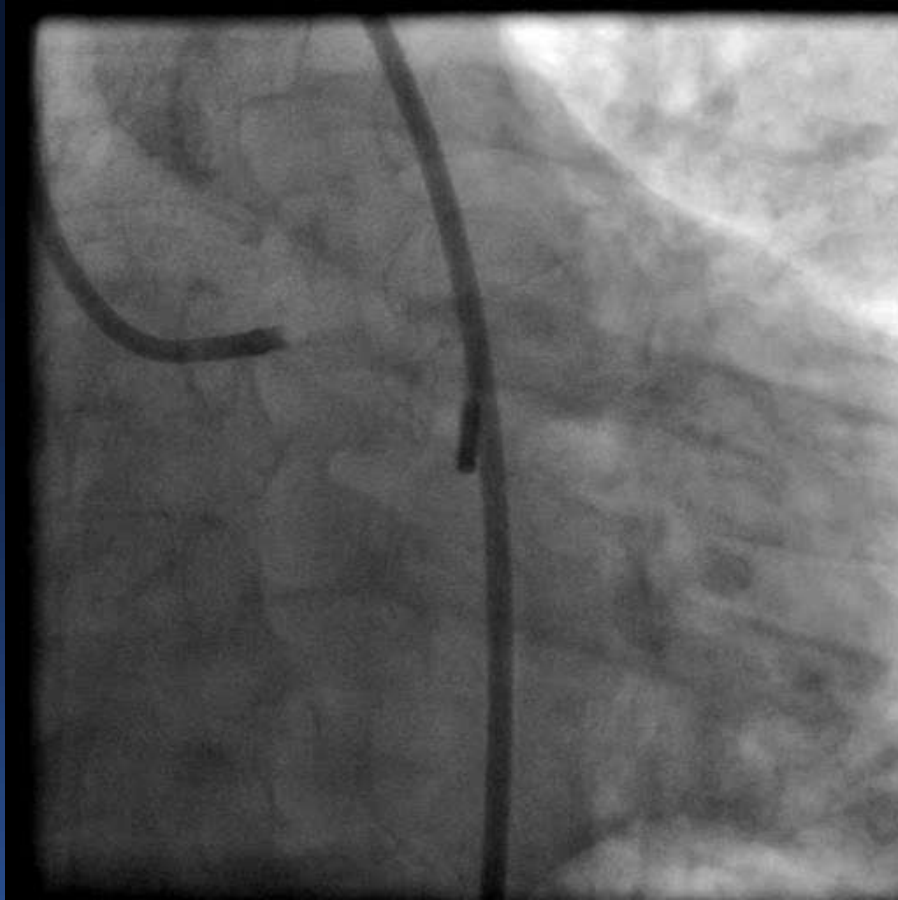
No KBT  
N=37

1 Unknown death  
in 83 yo patient

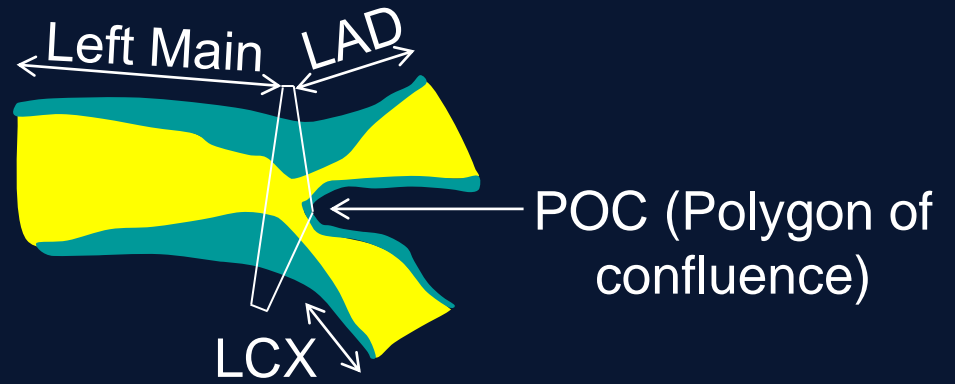
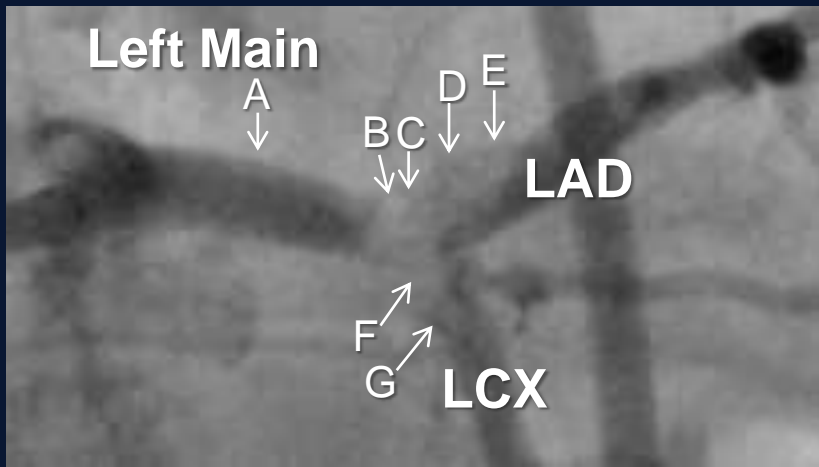
1 Unknown death  
in 85 yo patient

- Overall MACE =4.7% (2/43)
- No Ischemic TLR, MI

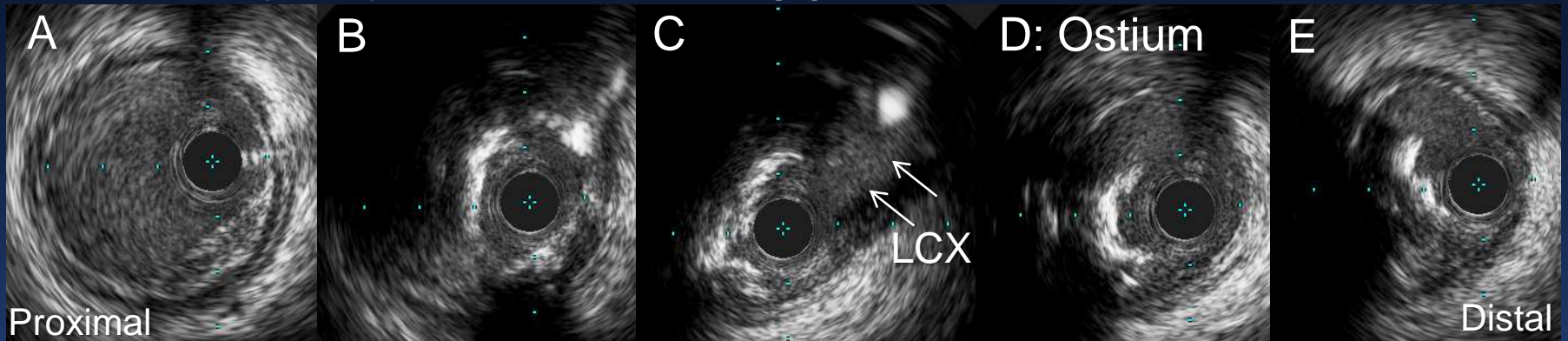
# Optimal Stent Expansion



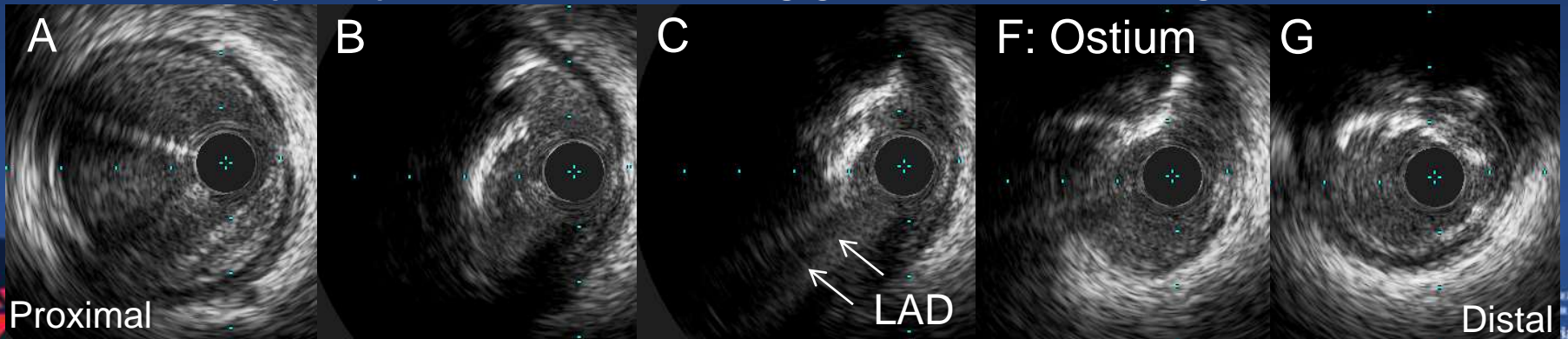


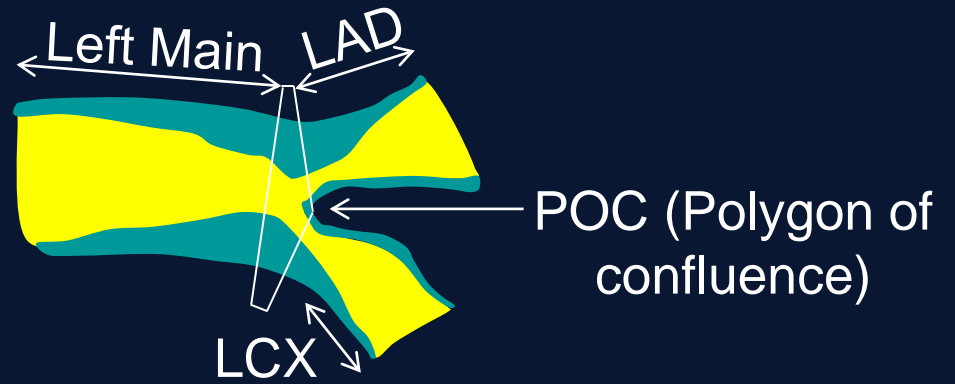
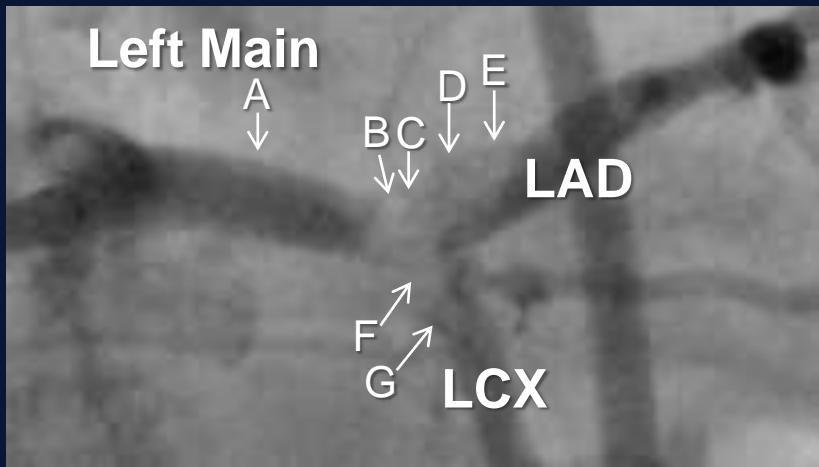


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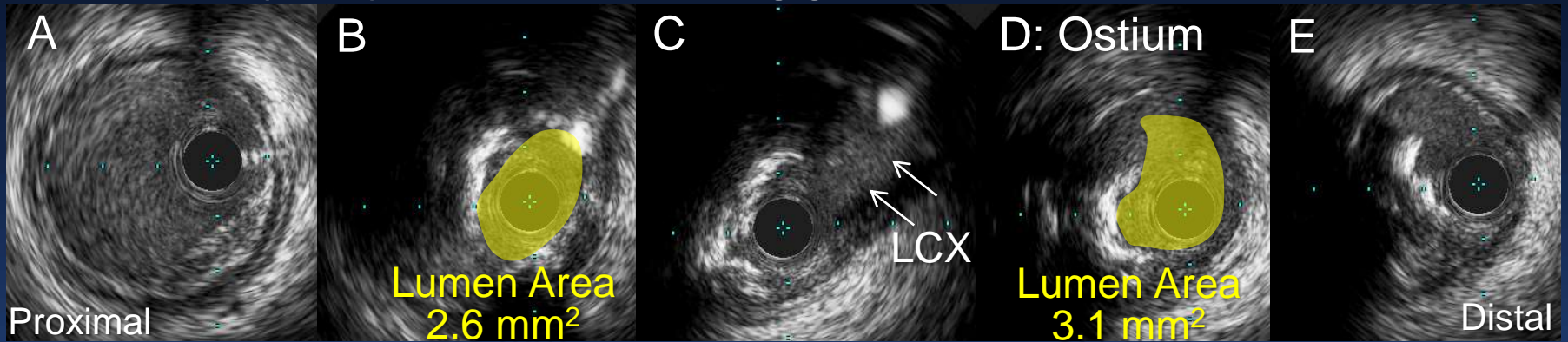


← Left Main → ← POC → ← LCX →

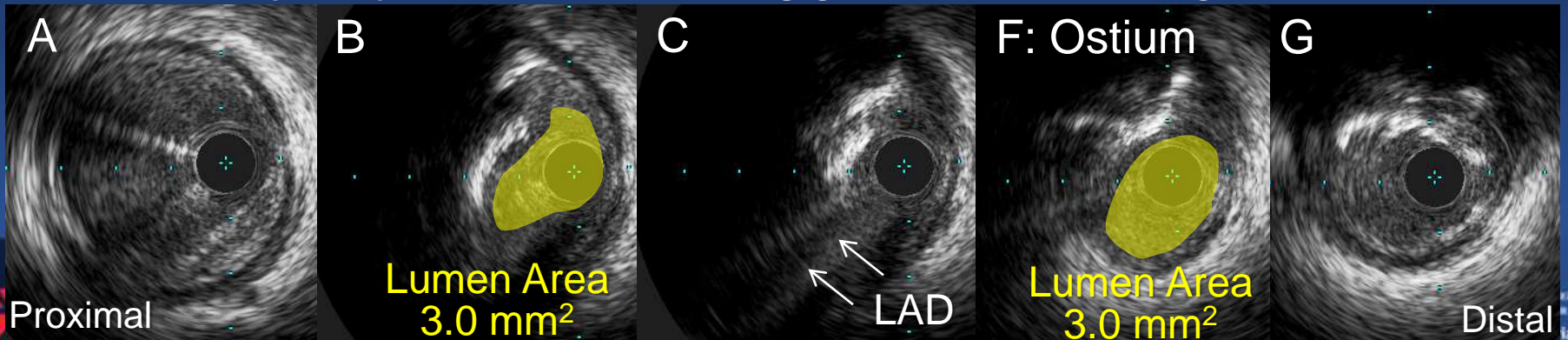




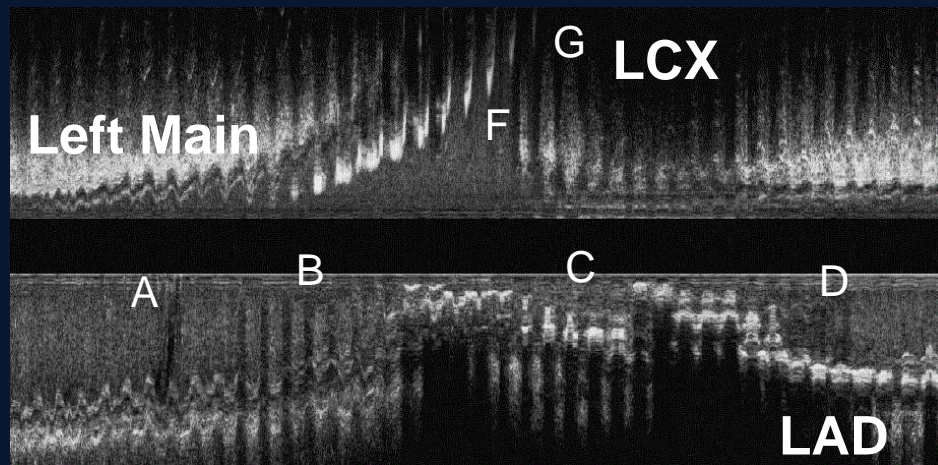
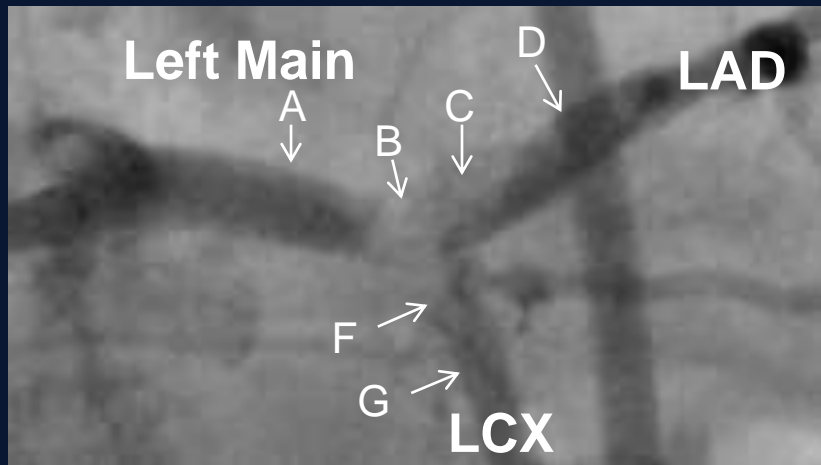
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← Left Main → ← POC → ← LCX →

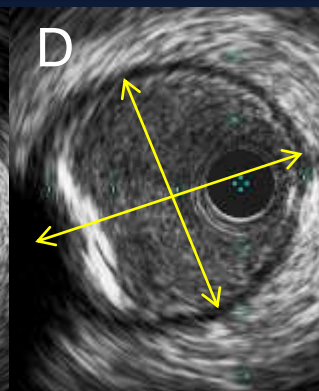
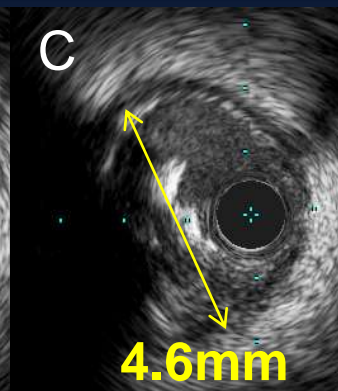
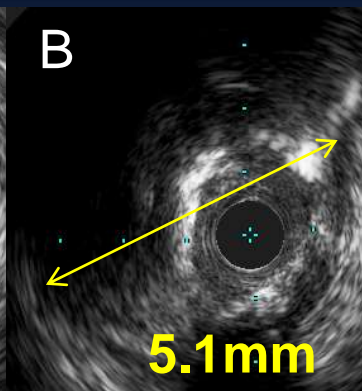
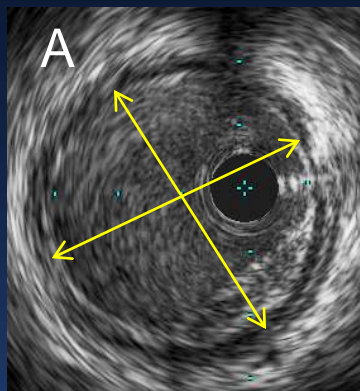






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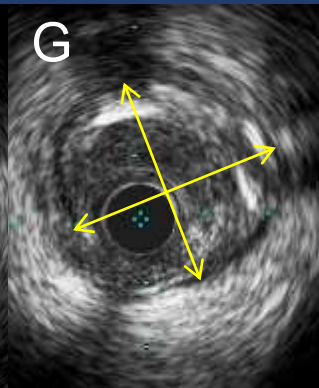
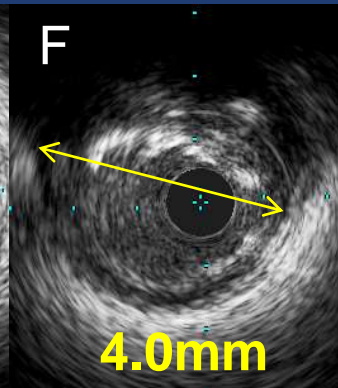
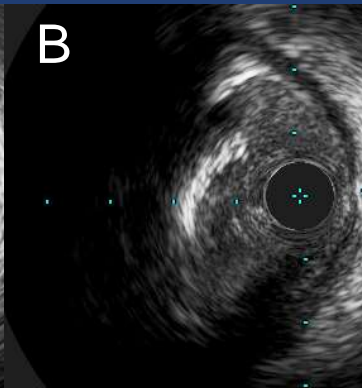
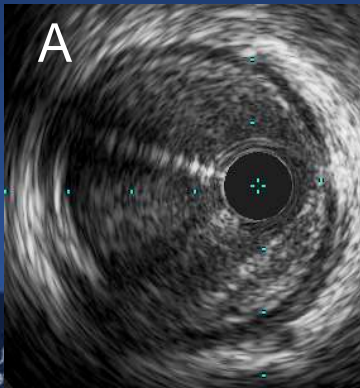
← LAD →



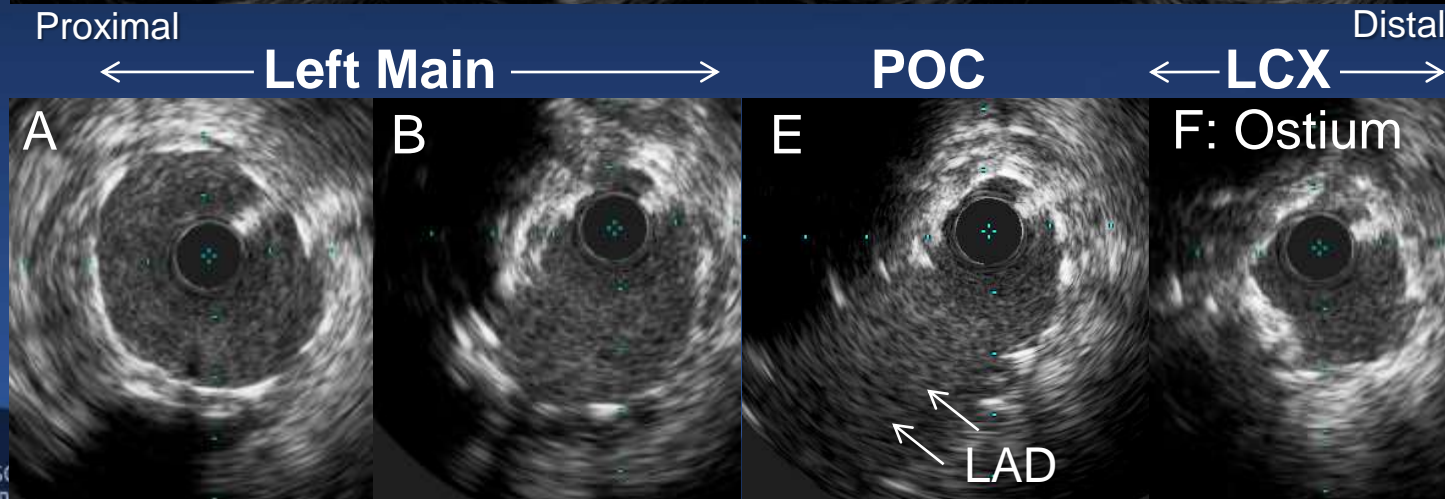
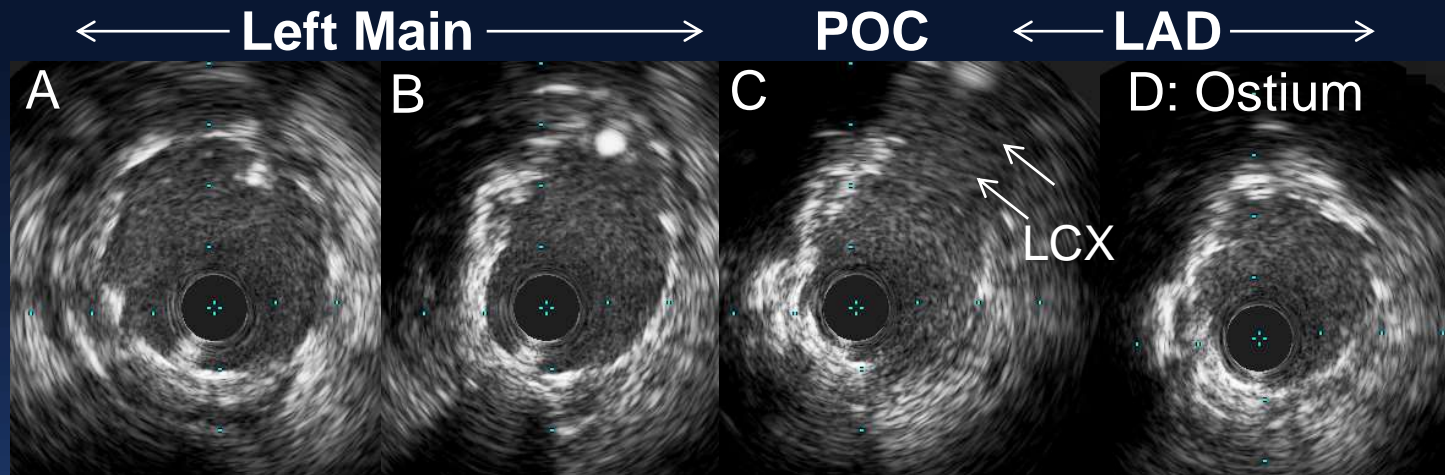
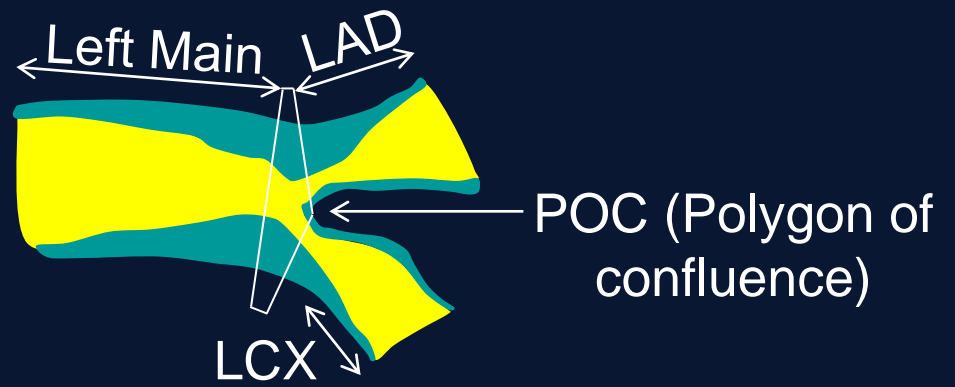
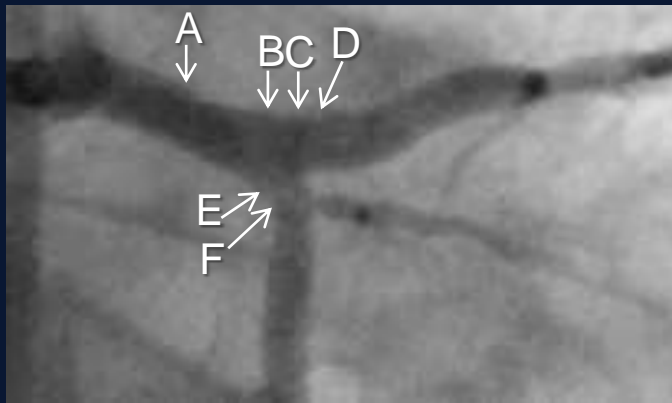
4.5mm×  
4.6mm  
4.6mm×  
4.0mm

← Left Main →

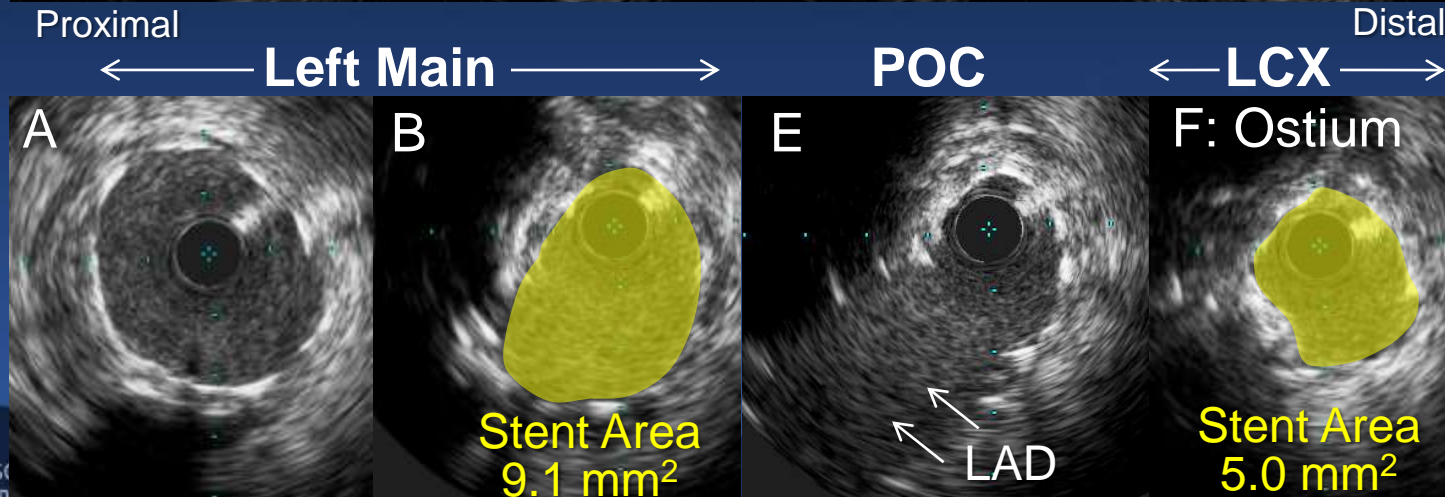
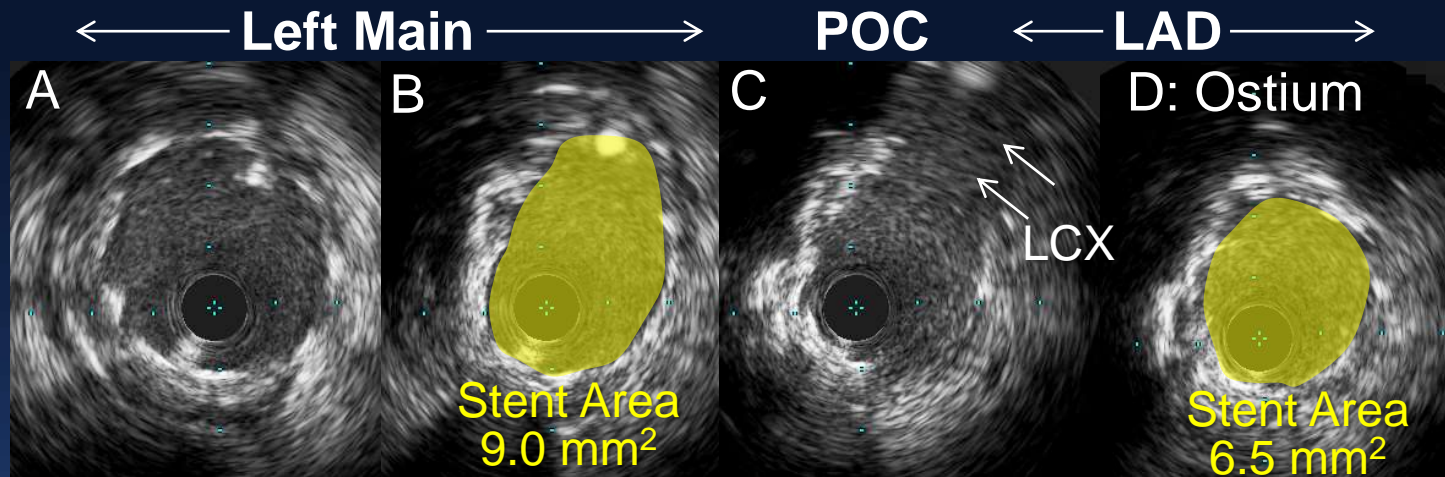
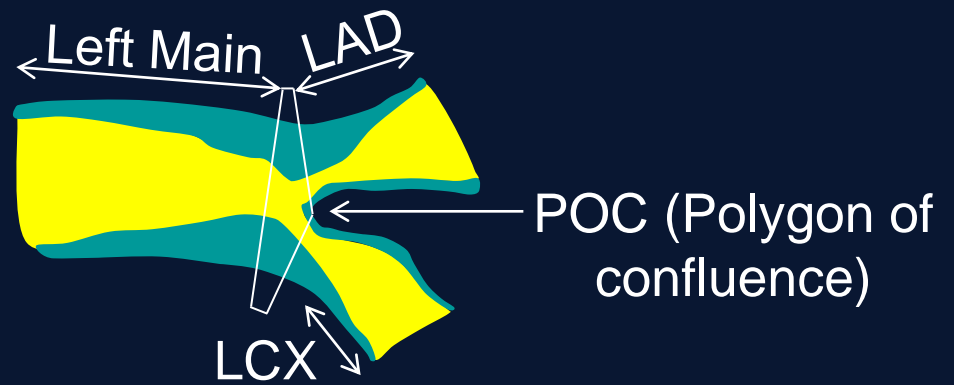
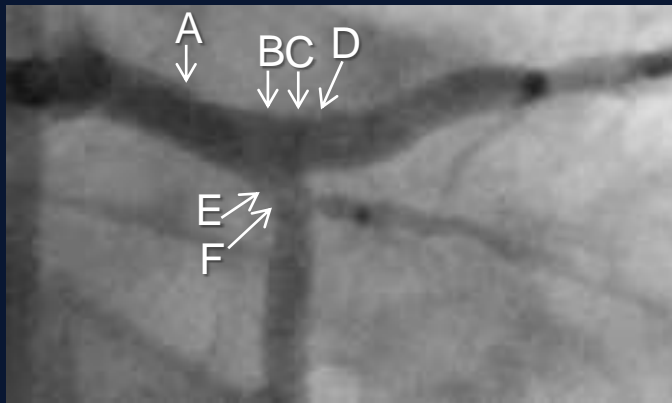
← LCX →



3.5mm×  
3.4mm

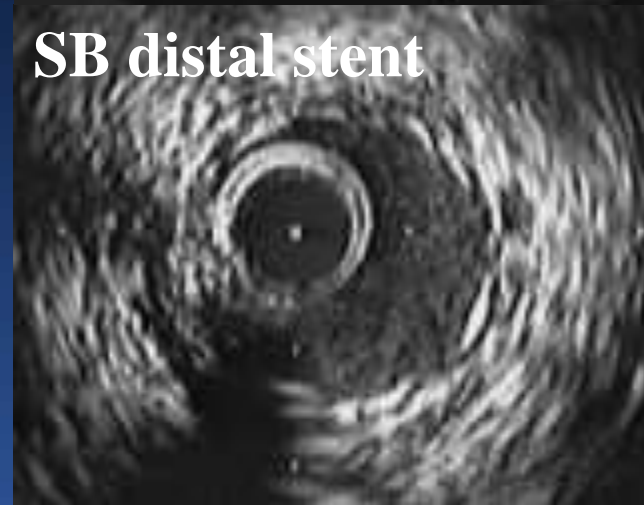
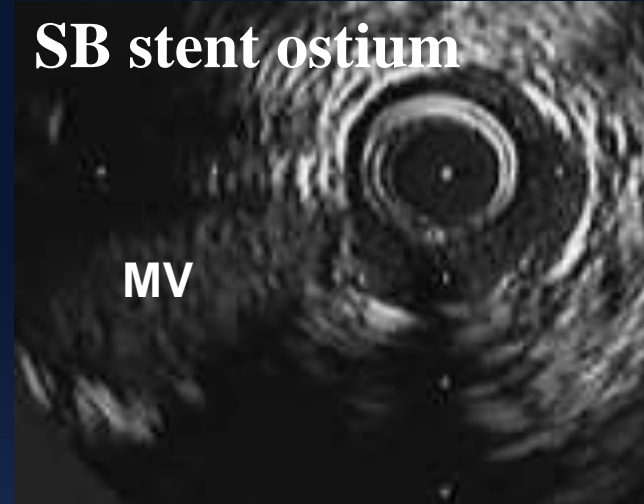
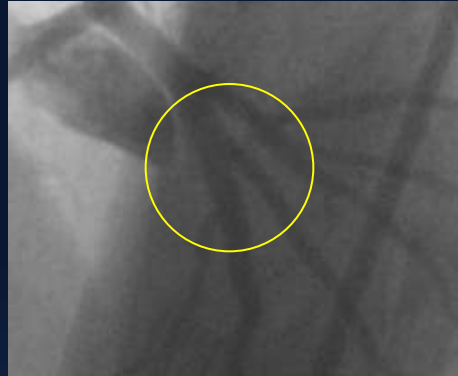
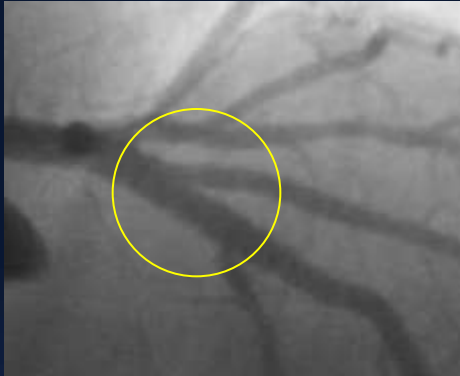






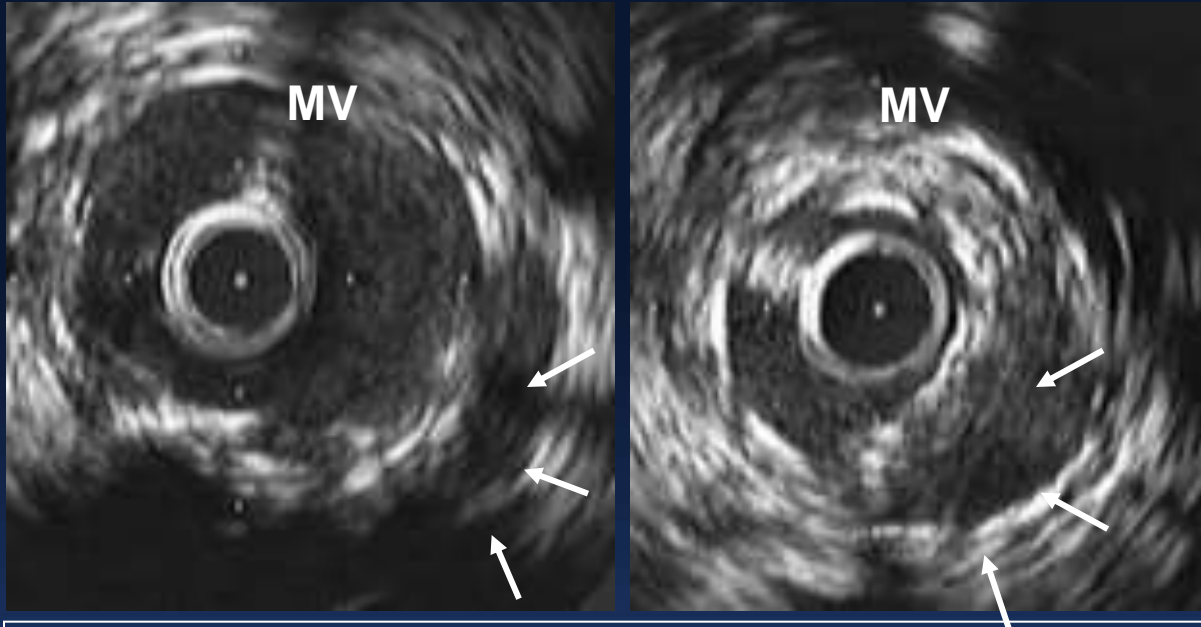
# SB Stent Underexpansion After Crush

Final angiographic result



	MV	SB
MSA, mm <sup>2</sup>	6.5±1.7	<b>3.9±1.0</b>
Stent expansion, %	92.1±16.6	<b>79.9±12.3</b>
MSA <4 mm <sup>2</sup>	10% (2/20)	<b>55%</b> <b>(11/20)</b>
MSA <5 mm <sup>2</sup>	20% (4/20)	<b>90%</b> <b>(18/20)</b>

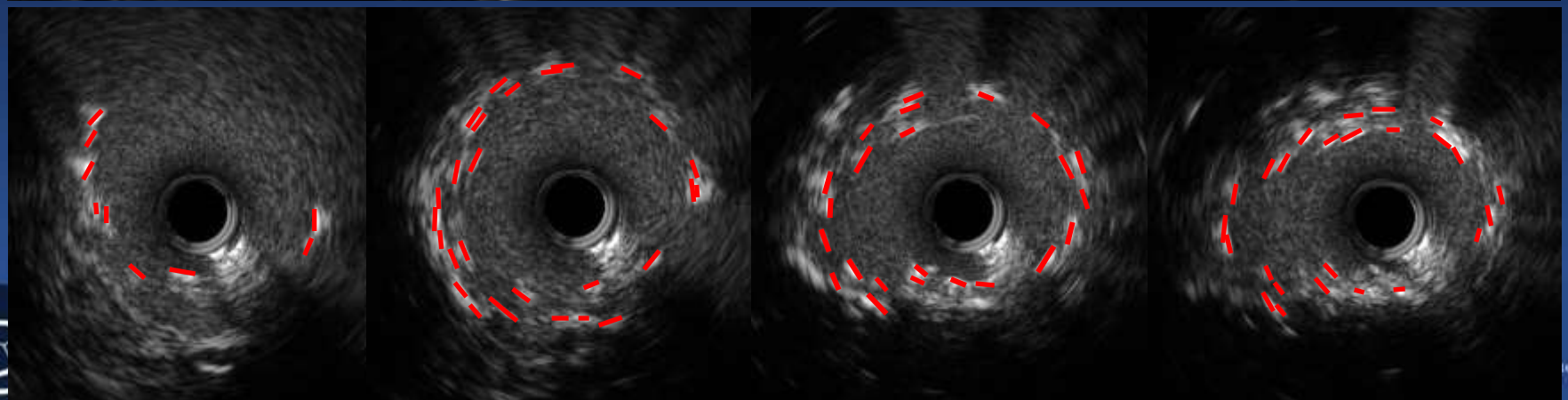
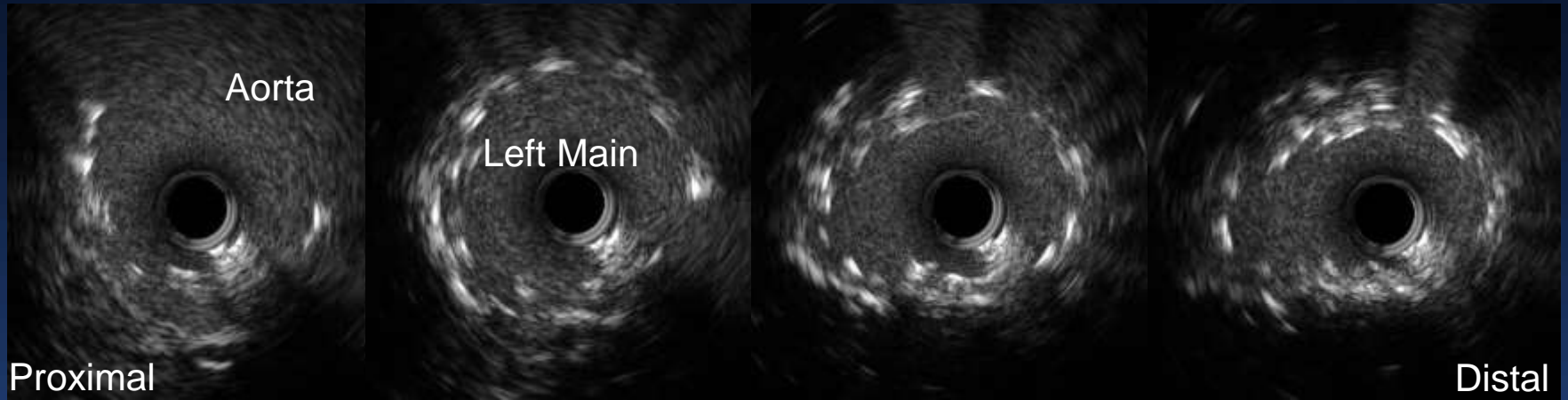
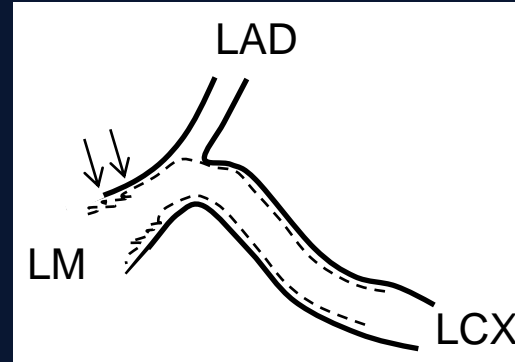
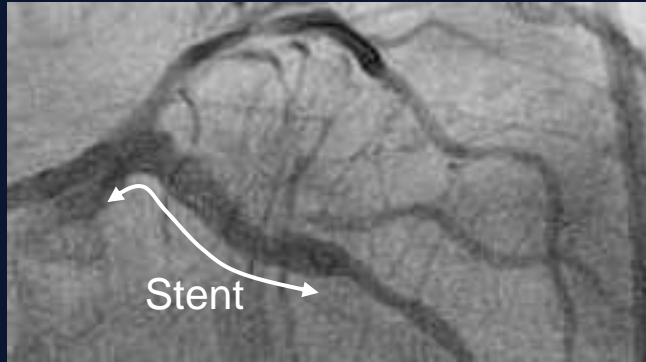
# Incomplete Crush Apposition



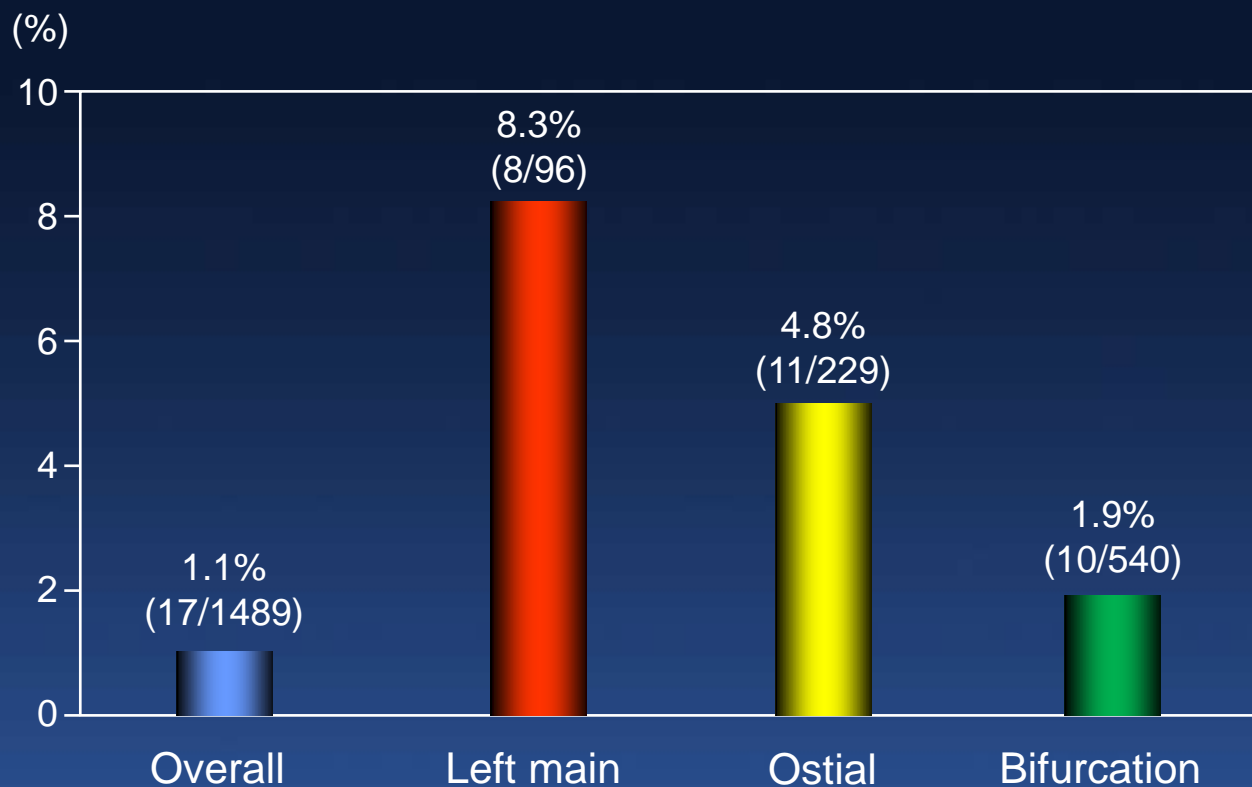
Incomplete crushing – incomplete apposition of the SB or MV stent struts against the MV wall proximal to the carina – was found in >60% of non-LM lesions



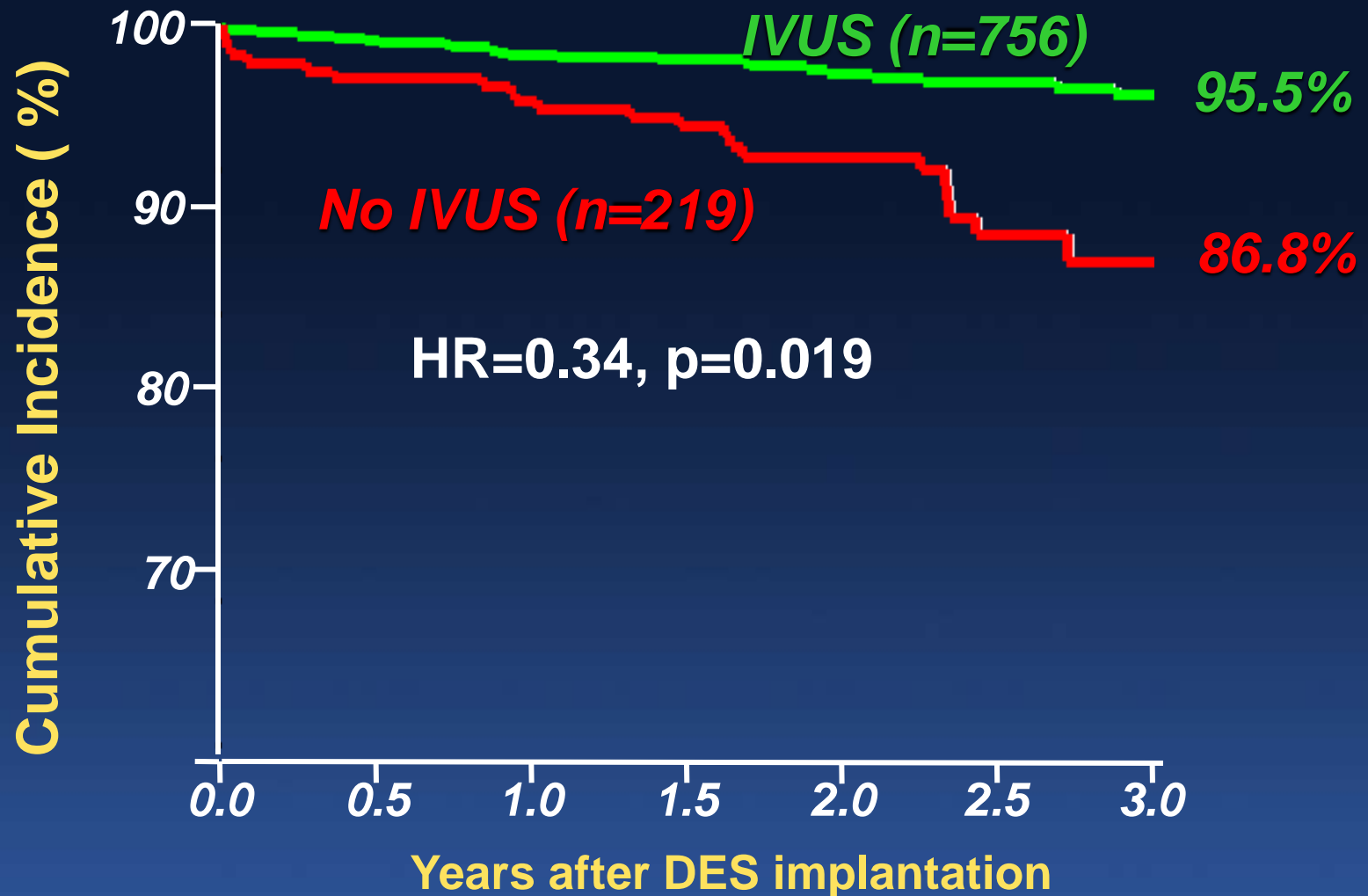
# Stent Deformation



# Prevalence of Stent Deformation

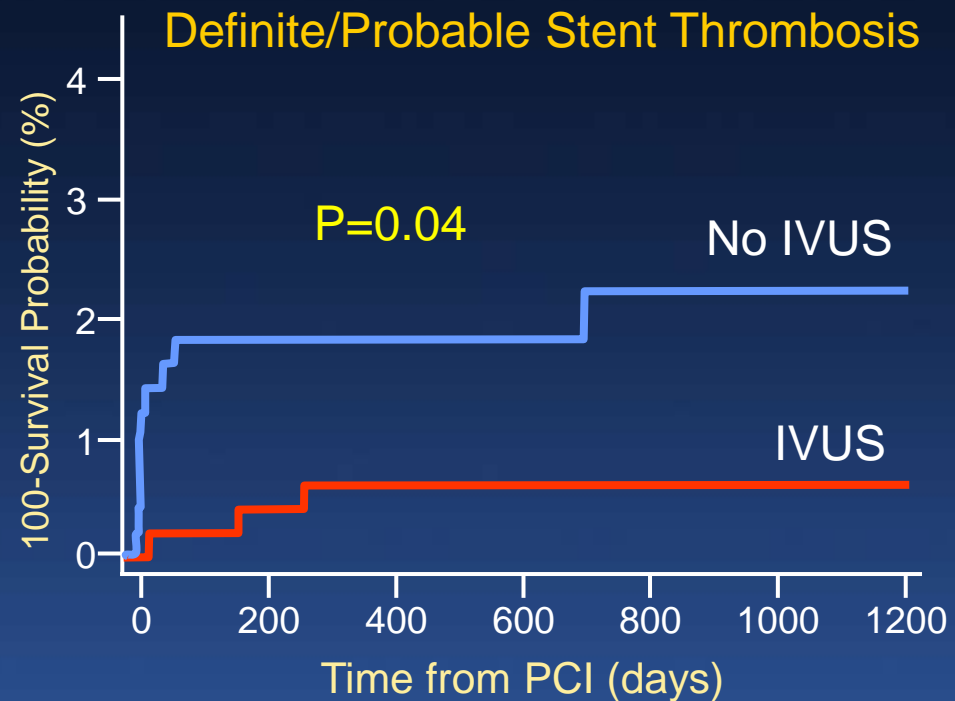
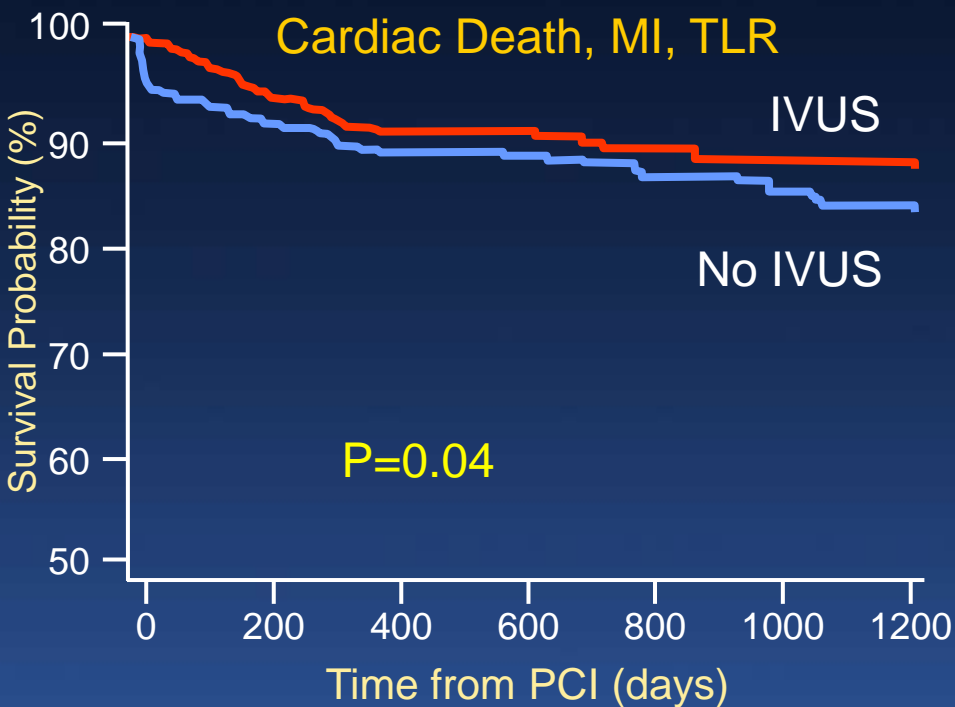


# All-cause Mortality after LMCA DES Implantation: Impact of IVUS Guidance



# Impact of IVUS Guidance of Unprotected LM Propensity Matched 1010 pts from 4 Registries

- Distal LM lesion ~60%, 2 stent technique ~13%
- IVUS guidance was an independent predictor of MACE

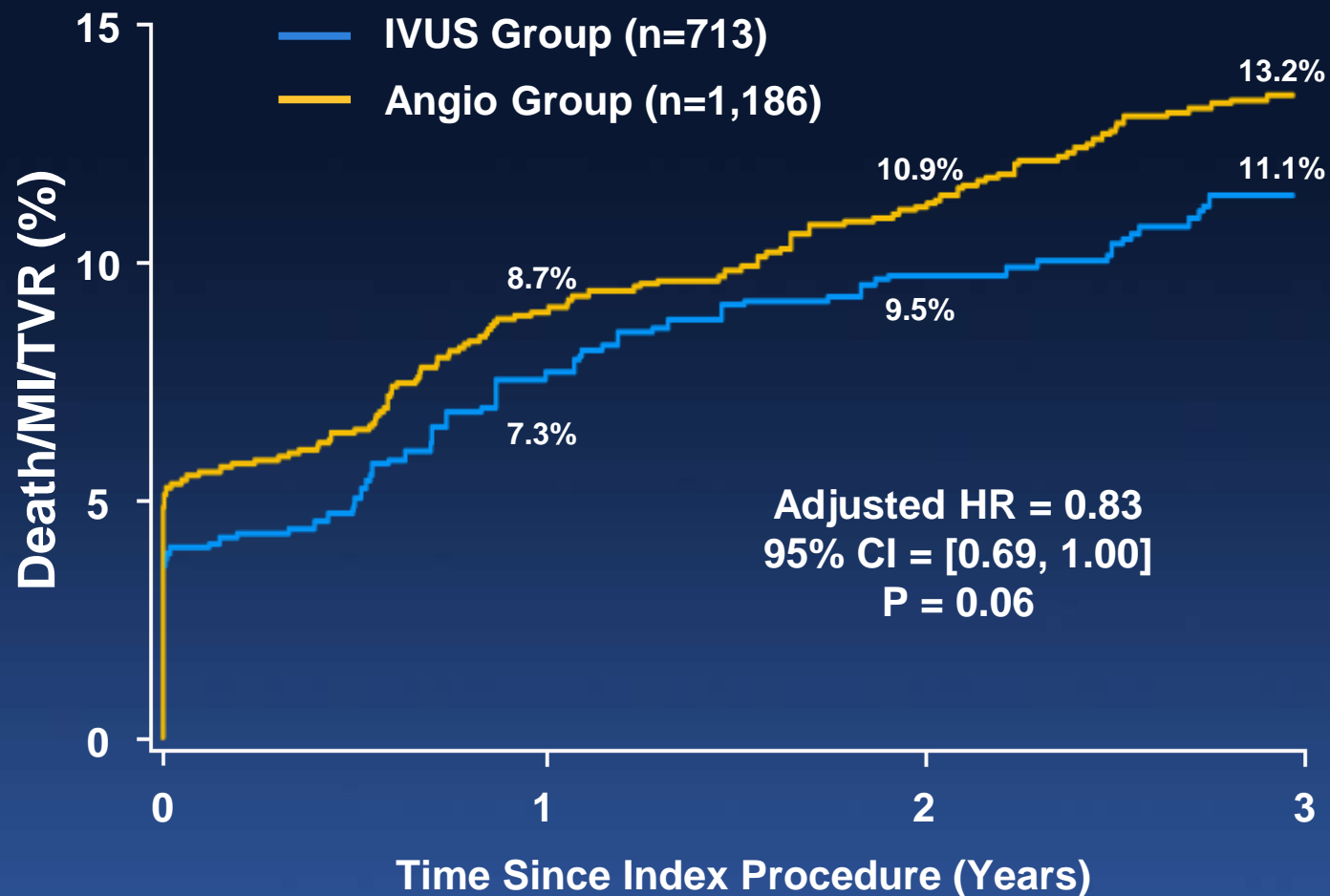


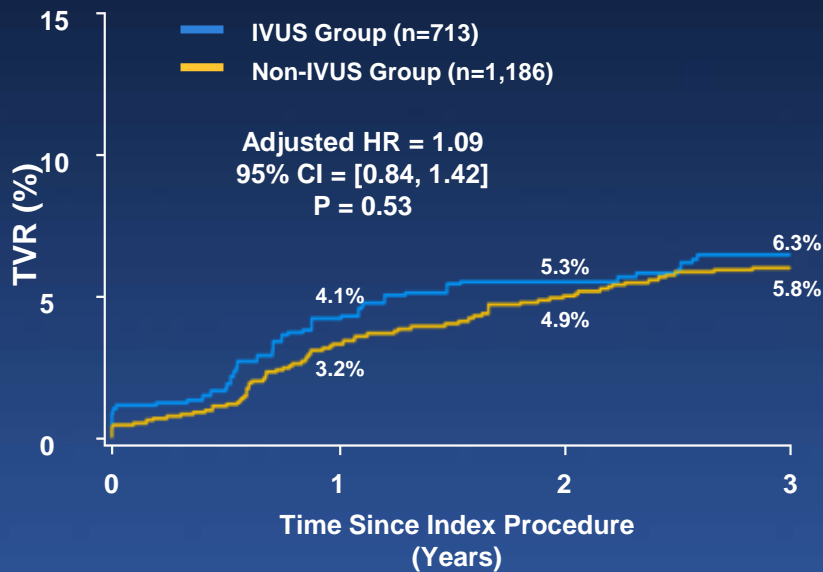
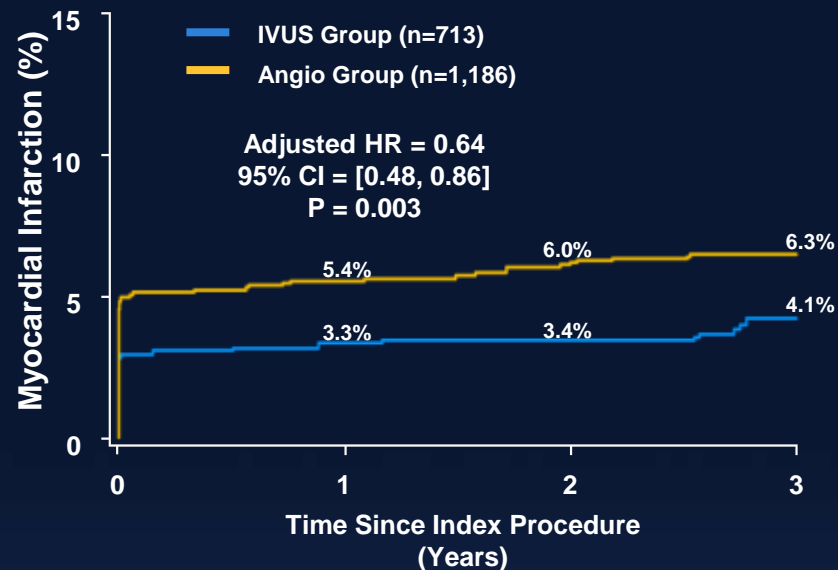
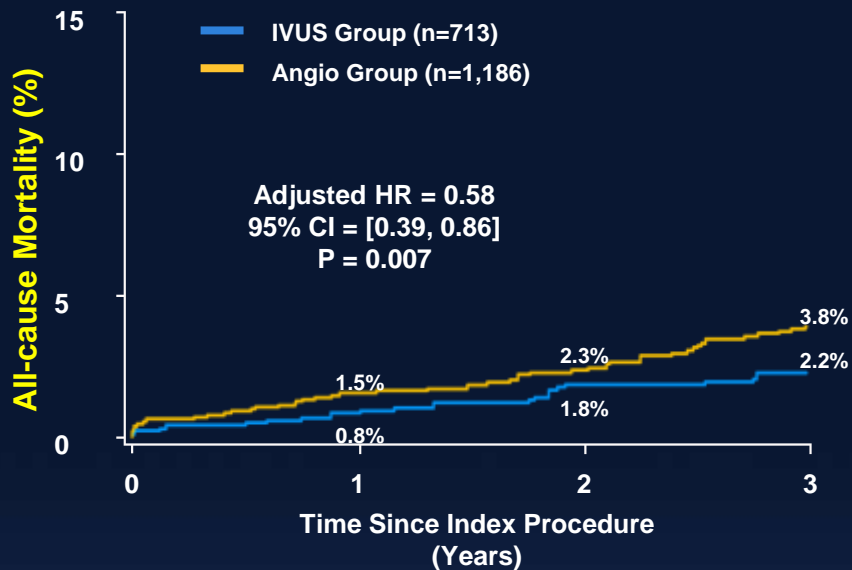
# IVUS-guided LM PCI with DES vs a propensity score-matched group of pts treated without IVUS guidance from 4 Spanish registries

	IVUS	No IVUS	P
<u>All lesions</u>	505	505	
Cardiac death	3.3%	6.0%	0.07
MI	4.5%	6.5%	0.4
TLR	7.7%	6.3%	0.7
Definite/probable ST	0.6%	2.2%	0.04
Cardiac death+MI+TLR	11.7%	16.0%	0.04
<u>Distal lesions</u>	221	226	
Cardiac death+MI+TLR	11.0%	19.0%	0.03
<u>Distal lesions - 2 stents</u>	63	62	
Cardiac death+MI+TLR	16.7%	41.0%	0.02

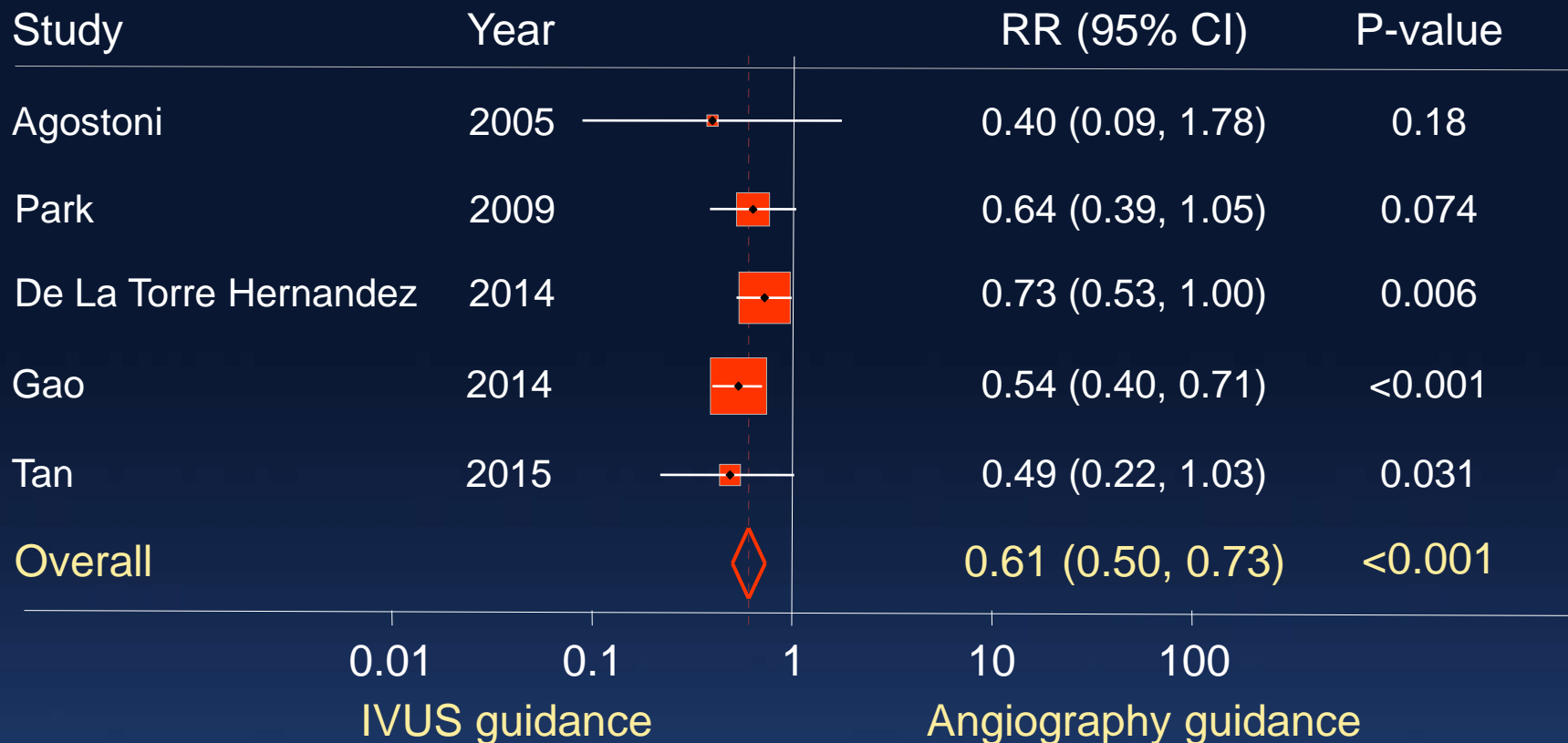


# IVUS vs angiography-guided LMCA PCI at FuWai Hospital (N=1,899)



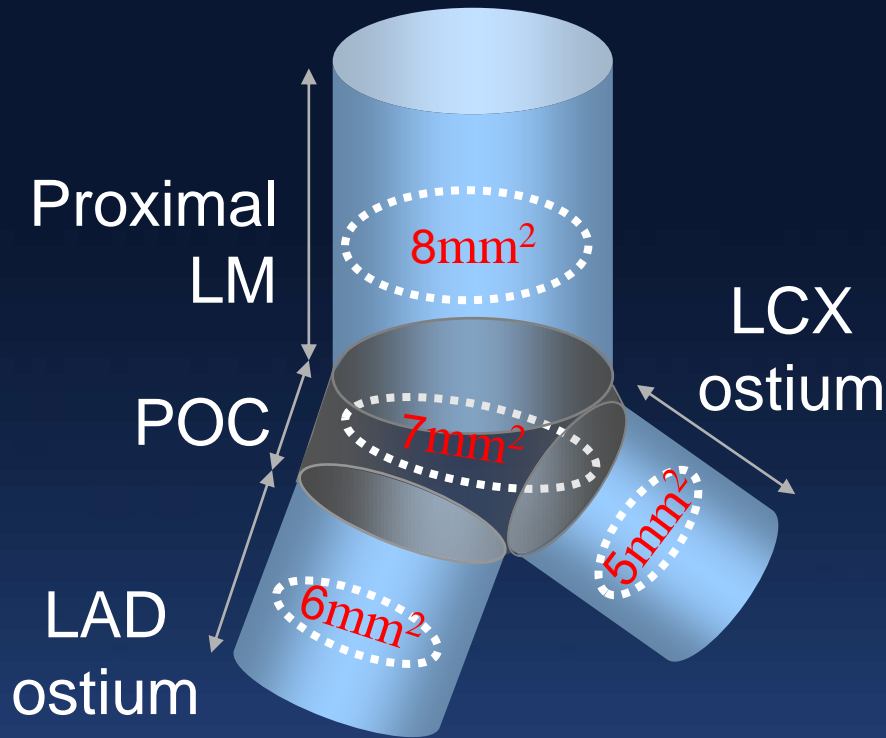


# Meta-Analysis of MACE in 5 published studies

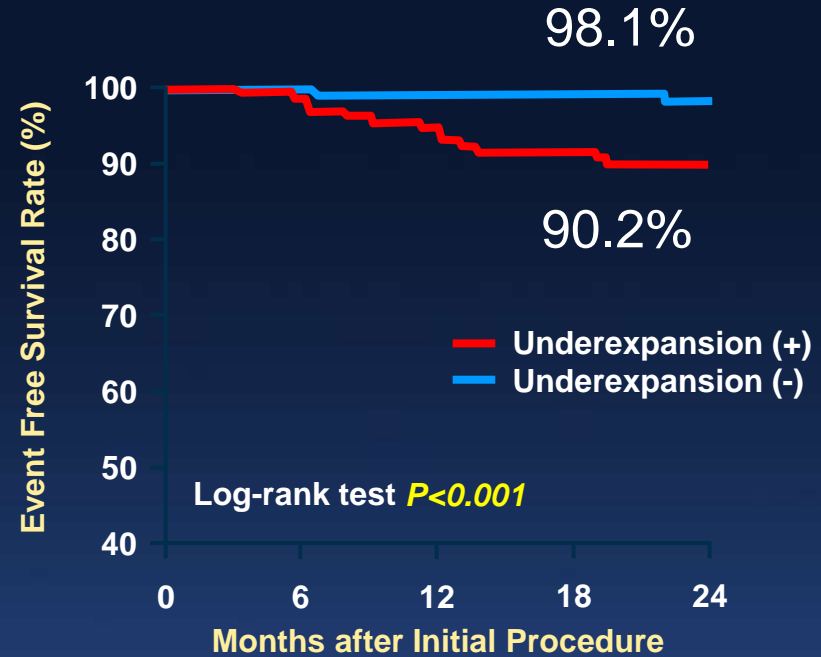


- IVUS-guided DES implantation into LMCA lesions was associated with a significant reduction in
  - MACE (RR: 0.61, 95% CI: 0.50 to 0.73,  $p < 0.001$ )
  - All-cause Death (RR: 0.53, 95% CI: 0.37 to 0.76,  $p = 0.001$ )
  - Cardiac Death (RR: 0.40, 95% CI: 0.24 to 0.64,  $p < 0.001$ )
  - Myocardial Infarction (RR: 0.69, 95% CI: 0.53 to 0.89,  $p < 0.001$ )
  - Stent Thrombosis (RR: 0.27, 95% CI: 0.11 to 0.65,  $p = 0.004$ ).
- However, there was no significant statistical difference regarding TLR (RR: 0.41, 95% CI: 0.09 to 1.91,  $p = 0.255$ ) and only a trend to reduced TVR (RR: 0.45, 95% CI: 0.16 to 1.27,  $p = 0.132$ ).

# MACE-free Survival in LMCA Lesions



## MACE



No. at risk

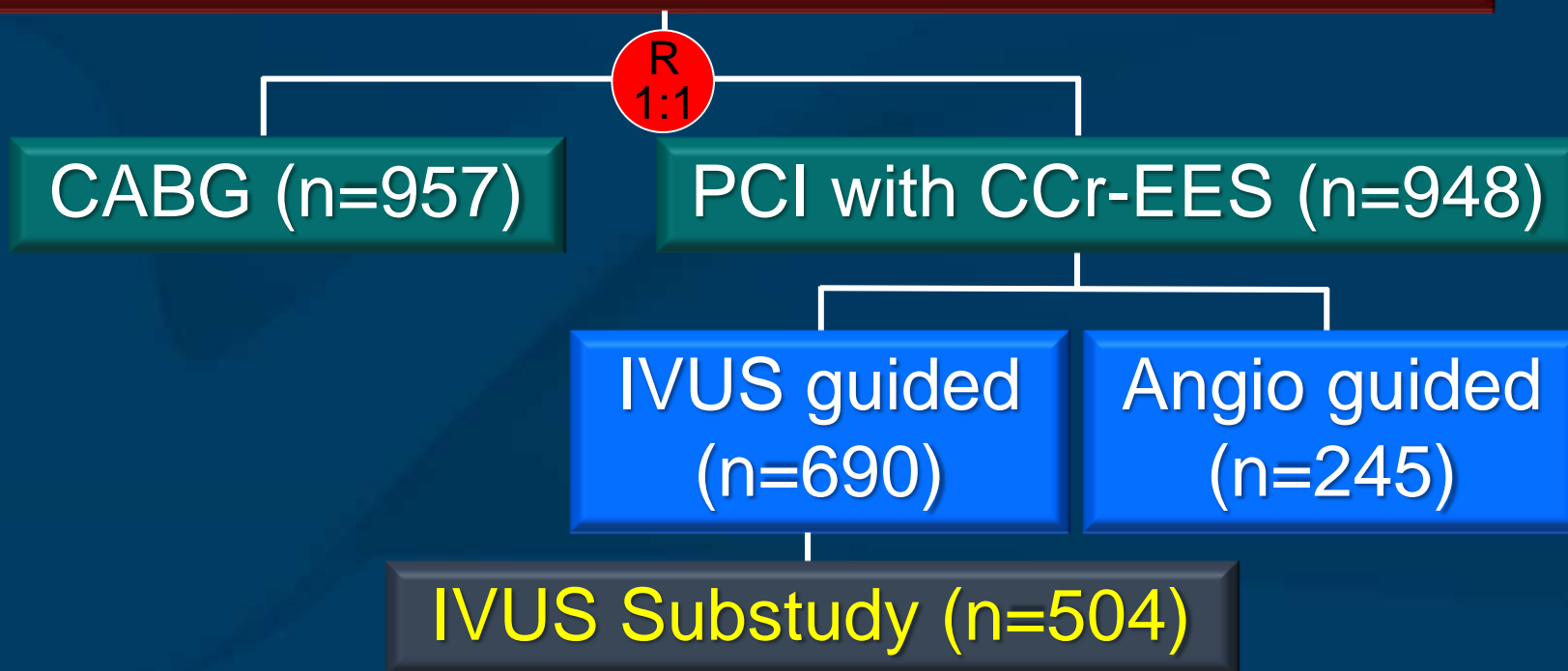
Underexpansion (+)	133	131	126	121	75
Underexpansion (-)	260	260	255	246	129

Kang et al. *Circulation*  
*Cardiovasc Interv.* 2011;4:562-9

# EXCEL Trial

Evaluation of **X**ience versus **C**oronary Artery Bypass Surgery for  
Effectiveness of **L**eft Main Revascularization

1,905 pts with unprotected LMCAD at 126 sites in  
17 countries were prospectively enrolled



Clinical FU at 30 days, 1 year, 2 years, 3 years

## Major Inclusion Criteria

- Unprotected LMCAD with  $\geq 70\%$  DS, *or*  $\geq 50\%$  -  $< 70\%$  with either i) non-invasive evidence of LM ischemia, ii) IVUS MLA  $\leq 6.0 \text{ mm}^2$ , *or* iii) FFR  $\leq 0.80$

## PCI recommendations

- Complete revascularization of all ischemic territories with EES
- Provisional LM bifurcation treatment preferred
- IVUS guidance strongly recommended
- Routine angiographic follow-up not permitted



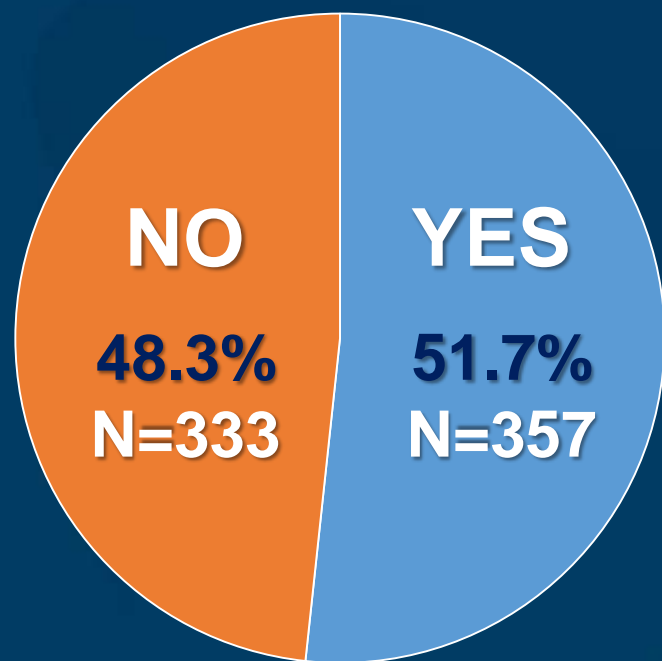
# Primary and Secondary Endpoints

## Tested hierarchically to preserve alpha

Endpoint	Timing of follow-up	Powered for
Primary endpoint: Death, stroke or MI	Median 3 years, minimum 2 years	Non-inferiority
Secondary endpoint #1: Death, stroke or MI	30 days	Non-inferiority
Secondary endpoint #2a: Death, stroke, MI or IDR	Median 3 years, minimum 2 years	Non-inferiority
Secondary endpoint #2b: Death, stroke or MI	Median 3 years, minimum 2 years	Superiority
Post-hoc endpoint: Cardiac death, MI/stent thrombosis/IDR relates to LM lesion	Median 3 years, minimum 2 years	NA

If the primary endpoint and secondary endpoint #1 both pass, secondary endpoints #2a and #2b are tested simultaneously  
IDR = ischemia-driven revascularization

# Change in LMCAD stenting by IVUS



Any IVUS usage for LM lesion (n=690)

- Used larger balloon: 30% (107)
- Post-dilated: 29% (102)
- Used higher pressure: 17% (62)
- Treated stent under-expansion: 16% (57)
- Led to provisional 1 stent strategy rather than planned 2 stents: 11% (41)
- Led to planned 2 stent strategy rather than provisional 1 stent: 9% (33)

# Patient Characteristics

IVUS MSA tertiles (range)	Low: 4.4-8.7 (n=172)	Inter: 8.8-10.9 (n=169)	High: 11.0-17.8 (n=163)	P Value
Age (years)	65.5±9.8	65.3±9.2	65.7±9.7	0.94
Female	32.0%	22.5%	24.5%	0.11
Diabetes mellitus	33.7%	29.0%	24.5%	0.18
Insulin treated	9.9%	7.7%	4.3%	0.14
Hyperlipidemia	76.6%	68.7%	73.6%	0.26
Hypertension	76.5%	77.4%	67.5%	0.08
Current smoking	25.7%	27.9%	23.6%	0.68
Renal insufficiency*	18.0%	15.5%	14.9%	0.72
Prior MI	16.5%	22.3%	16.3%	0.27
Prior PCI	17.4%	17.9%	21.5%	0.59

\*Defined as Cockcroft-Gault equation <60ml/min

# Angio and Procedural Characteristics

IVUS MSA tertiles (range)	Low: 4.4-8.7 (n=172)	Inter: 8.8-10.9 (n=169)	High: 11.0-17.8 (n=163)	P Value
Distal left main lesion	81.7%	77.4%	78.4%	0.60
Ostial LAD $\geq$ 50%	45.3%	44.4%	47.9%	0.81
Ostial LCX $\geq$ 50%	44.8%	35.5%	37.4%	0.18
LM + 2 vessel disease	36.0%	32.0%	25.8%	0.13
LM + 3 vessel disease	16.3%	20.7%	15.3%	0.39
Syntax score baseline	26.8 $\pm$ 8.4	26.9 $\pm$ 8.4	26.5 $\pm$ 9.0	0.92
>32	21.8%	26.1%	23.9%	0.67
Residual Syntax score	6.1 $\pm$ 5.8	6.3 $\pm$ 6.0	6.3 $\pm$ 6.5	0.96
Total LM stent length (mm)	27.3 $\pm$ 15.2	27.8 $\pm$ 15.6	27.3 $\pm$ 16.4	0.96
LM stent diameter (mm)	3.3 $\pm$ 0.4	3.5 $\pm$ 0.4	3.7 $\pm$ 0.4	<b>&lt;0.01</b>
PCI for non-LM lesions	54.7%	53.8%	52.1%	0.90
Total non-LM stent length (mm)	35.6 $\pm$ 25.1	40.7 $\pm$ 28.7	36.2 $\pm$ 26.5	0.40



# IVUS Characteristics

IVUS MSA tertiles (range)	Low: 4.4-8.7 (n=172)	Inter: 8.8-10.9 (n=169)	High: 11.0-17.8 (n=163)	P Value
<u>Left main segment</u>				
Distal bifurcation location	84.3%	81.7%	78.5%	0.52
MSA, mm <sup>2</sup>	7.5±1.0	9.9±0.7	12.5±1.4	<0.01
Vessel area at MSA, mm <sup>2</sup>	19.3±4.0	21.8±3.7	24.8±4.2	<0.01
Mean stent area, mm <sup>3</sup> /mm	8.9±1.5	11.2±1.2	13.6±1.6	<0.01
Mean vessel area, mm <sup>3</sup> /mm	19.0±3.5	22.1±3.7	25.1±4.1	<0.01
<u>Any target lesion segment</u>				
Attenuated plaque	75.6%	76.3%	69.9%	0.35
Tissue protrusion	8.1%	10.1%	11.7%	0.56
Stent malapposition	18.6%	21.3%	23.3%	0.57
Stent deformation/fracture	9.4%	4.7%	5.6%	0.18
Edge dissection	13.4%	12.4%	12.3%	0.95

# Overall 3-Year Outcomes

IVUS MSA tertiles (range)	Low: 4.4-8.7 (n=172)	Inter: 8.8-10.9 (n=169)	High: 11.0-17.8 (n=163)	P L vs I	P L vs H
Death/MI/stroke	19.4% (32)	16.1% (26)	9.6% (15)	0.45	<b>0.01</b>
Death/MI/stroke/IDR*	26.6% (44)	23.8% (39)	18.3% (29)	0.66	0.08
All cause death	13.8% (22)	10.0% (16)	5.2% (8)	0.34	<b>0.01</b>
Cardiovascular death	7.4% (12)	4.8% (8)	4.0% (6)	0.39	0.16
MI	10.5% (17)	8.2% (13)	3.7% (6)	0.49	<b>0.02</b>
Stroke	1.8% (3)	1.2% (2)	2.1% (3)	0.66	0.98
Stent thrombosis (D/P)	3.1% (5)	1.2% (2)	0.0% (0)	0.26	<b>0.03</b>
Target lesion IDR	12.0% (19)	8.3% (13)	8.8% (14)	0.30	0.41
Target vessel IDR	12.0% (19)	10.8% (17)	9.4% (15)	0.79	0.52

\*IDR: ischemia driven revascularization

# 3-Year Left Main Related Outcomes

IVUS MSA tertiles (range)	Low: 4.4-8.7 (n=172)	Inter: 8.8-10.9 (n=169)	High: 11.0-17.8 (n=163)	P L vs I	P L vs H
Cardiac death, MI/ST/IDR of LM	19.7 (32)	12.9% (21)	11.3% (18)	0.14	<b>0.05</b>
Cardiac death	6.8% (11)	3.0% (5)	1.9% (3)	0.14	<b>0.03</b>
MI of LM	9.4% (15)	4.3% (7)	3.1% (5)	0.09	<b>0.03</b>
Peri-procedural	4.1% (7)	2.4% (4)	1.8% (3)	0.38	0.23
Spontaneous	4.5% (7)	1.2% (2)	0.6% (1)	0.10	<b>0.03</b>
Stent thrombosis (D/P)	3.1% (5)	0.6% (1)	0% (0)	0.11	<b>0.03</b>
LM ischemia driven TLR	10.2% (16)	8.3% (13)	7.6% (12)	0.61	0.47
LM ischemia driven TVR	10.2% (16)	10.2% (16)	8.2% (13)	0.94	0.61

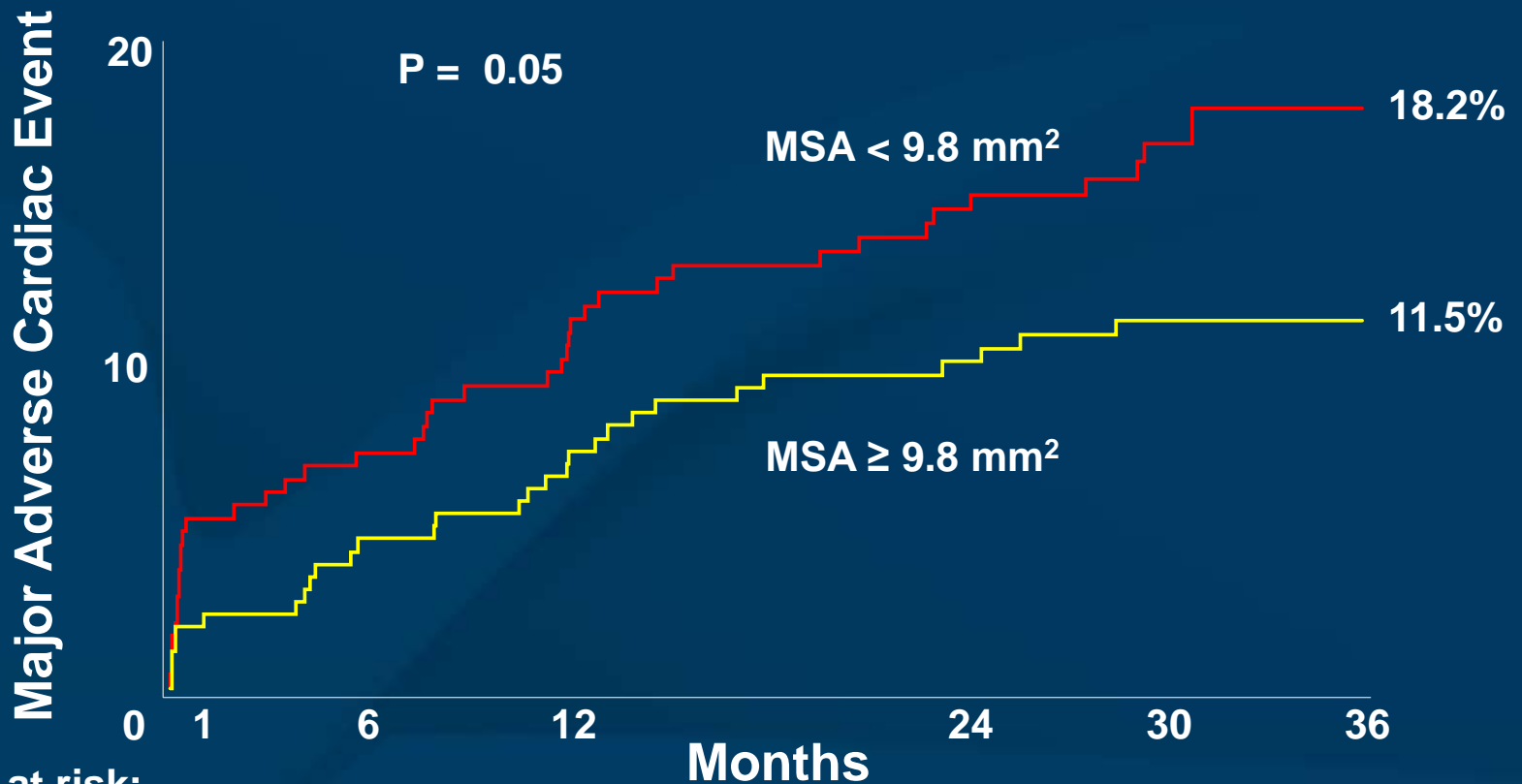
# LM MSA to predict LM related Events

	Adjusted Hazard Ratio (95% CI)	P-value
<b>Final IVUS LM MSA (mm<sup>2</sup>)</b>	<b>0.89 (0.80-0.99)</b>	<b>0.03</b>
Distal left main lesion location	2.10 (1.0-5.33)	0.05
Diabetes mellitus	1.63 (1.0-2.64)	0.049
Acute coronary syndrome presentation	0.60 (0.36-0.99)	0.045
Male	0.69 (0.41-1.12)	0.16
Age (years)	1.01 (0.99-1.04)	0.32
History of heart failure (NYHA III/ IV)	1.23 (0.38-3.99)	0.73
Left main with 3 vessel disease	1.21 (0.67-2.20)	0.53

**Cut off of LM MSA= 9.8 mm<sup>2</sup> (AUC:0.58)**



# KM-Curve stratified by MSA Cut-off



Number at risk:

$MSA < 9.8$	245	232	224	212	188	97
$MSA \geq 9.8$	259	252	244	235	220	139

# Conclusions

1. IVUS is useful for the diagnosis of severity and distribution of left main disease, optimization of stent, and evaluation of complication.
2. In the EXCEL trial, 68% of PCI cases were performed using IVUS guidance. In the half of IVUS guidance cases, the procedure was changed by the IVUS findings.
3. After treatment with CoCr-EES, a small final MSA of the left main coronary artery measured by IVUS was strongly associated with cardiac death, MI, stent thrombosis, and TLR related LM during 3 year follow-up.