When to Use IVUS vs. OCT - Complementary vs. Competitive?

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Cardiovascular Research Foundation

- Is this lesion flow-limiting?
  - Non-LMCA
  - LMCA
- What is the culprit?
- Is this “other” lesion a vulnerable plaque that is at risk for future events?
- What is the likelihood of embolization during stent implantation?
- How do I optimize acute stent results?
- Is this jailed sidebranch significant?
- Why did this stent “fail”?

Randomized FFR Trials in Non-LMCA Lesions

- **DEFER showed that it was safe to defer PCI in lesions with FFR >0.75**
  - *Bech et al. Circulation 2001;103:2928-34*
  - *Pijls et al. J am Coll Cardiol 2007;49:2105-11 (5 year data)*
  - *Zimmerman et al. Eur Heart J 2015;36:3182-8 (15 year data)*
- **FAME-I showed that treating lesions with FFR >0.80 with first generation DES was harmful and that a deferred PCI strategy was safer and cost-saving**
  - *Tonino et al. N Engl J Med. 2009;360:213-24*
  - *Pijls et al. J am Coll Cardiol 2010;56:177-84 (2 year data)*
  - *Van Nunen et al. Lancet 2015;386:1853-60 (5 year data)*
  - *Fearon et al. Circulation 2010;122:2545-50*
- **FAME-II showed that deferring PCI in lesions with FFR <0.80 was harmful compared to optimal medical therapy. While more expensive at the beginning, the cost of this strategy decreased by 50% at 1 year. In addition, FAME-II confirmed the findings of DEFER.**
  - *De Bruyne et al. N Engl J Med 2012;367:991-1001*
  - *Fearon et al. Circulation 2013;17:1335-40*
  - *De Bruyne et al. N Engl J Med 2014;371:1208-17*

Reference	Versus	# of lesions	% abn	Inclusion criteria	Mean MLA (mm^2)	MLA cut-off (mm^2)	Other independent IVUS anatomic determinants	PPV	NPV
Abizaid AJC 1998	CFR<2.0	112	40%		4.4	4.0			
Nishioka JACC 1999	SPECT	70	65%		4.3	4.0			
Takagi Circulation 1999	FFR<0.75	51	49%		3.9	3.0			
Briguori AJC 2001	FFR<0.75	53	23%	40-70% DS	3.9	4.0	Lesion length	46%	96%
Takayama CCI 2001	FFR	14	50%	>2.5mm vessels	3.5		MLA divided by lesion length		
Lee AJC 2010	FFR<0.75	94	40%	30-75% DS <3mm vessels	2.3	2.0	Lesion length Plaque Burden		
Kang Circ Interv 2011	FFR<0.8	236	21%	30-75% DS	2.6	2.4	LAD Plaque burden	37%	96%
Ahn JACC Interv 2011	SPECT	170	26%		2.1	2.1		39%	91%
Kang AJC 2012	FFR<0.8	784	29%	30-90% DS		2.4	LAD Lesion length Plaque rupture Plaque burden	48%	90%
Ben-Dor EuroInterv 2011	FFR<0.75	92	19%	40-70% DS >2.5mm vessels	3.6	2.8	Lesion length		
	FFR<0.8					3.2			
Ben-Dor CRM 2012	FFR<0.8	205	26%	40-70% DS >2.5mm vessels		3.1			
Koo JACC Interv 2011	FFR<0.8	267	33%	30-70% DS Proximal or Mid	3.0	3.0	Proximal or Mid LAD	47%	
Gonzalo JACC 2012	FFR<0.8	51	46%	40-70% DS	2.6	2.4		67%	65%
Waksman JACC 2013	FFR<0.8	334	25%	40-80% DS >2.5mm vessels	5.6	3.1	LAD Plaque burden	40%	83%
Stone TCT 2013	FFR<0.80	544	31%	40-80% DS >2.75mm vessels		2.9	LAD vs LCX RCA vs LCX	47%	81%
Kwan CMJ 2012	FFR<0.8	169	59%	40-99% DS LAD	3.0	3.0	Plaque burden	84%	82%
Chen IJC 2013	FFR<0.8	323	54%	≥40% DS	2.9	3.0	Plaque burden LAD	73%	76%
Yang CCI 2014	FFR<0.8	206	44%	40-70% DS Prox/mid LAD >3.0mm vessel	3.1	3.2 (Prox) 2.5 (Mid)	Lesion length		
Kang JACCInterv 2013	FFR<0.8	493 males	43% males	>30% DS LAD	2.6	2.5		63% male	81% male
		207 females	27% females		2.5	2.5		42% female	93% female
Lopez-Palop REspCard 2013	FFR<0.8	61	49%	40-70% DS ≥20mm length	2.7	3.1	Lesion length	67%	93%
Naganuma CRM 2014	FFR<0.8	132	30%	40-70% DS	3.0	2.7	Plaque burden	59%	90%
Voros AJC 2014	FFR<0.75	70	27%	40-99% DS	3.7	2.7		39%	93%
Cui CMJ 2013	FFR<0.8	165	26%	40-70% DS >2.5mm vessels	3.9	3.2	Plaque burden	53%	85%
Han Cardiology 2014	FFR<0.8	822	39%		3.1	2.8		49%	73%
Koh JACCInterv 2012	FFR<0.8	38	37%	40-70% DS Ostial MV		3.5		69%	87%
		55	27%	40-70% DS Ostial SB				<50%	

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OCT vs FFR

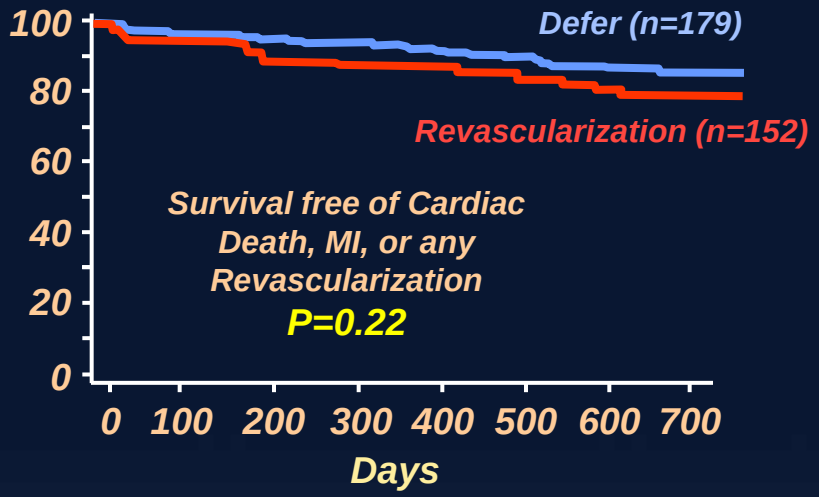
	#	% FFR <0.8 (<0.75)	Cut-off	AUC	Sens	Spec	PPV	NPV
Gonzalo et al, J Am Coll Cardiol 2012;59:1080-9	61	46%	2.0mm^2	0.70	82%	63%	66%	80%
Osue et al. Circulation 2012;126:A15191	69		1.8mm^2	0.83	82%	76%		
Shiono et al. Circ J 2012;76:2218-25	62	(50%)	1.9mm^2	0.90	93%	77%	81%	92%
Reith et al. Heart 2913;99:700-9	62	53%	1.6mm^2					
Pawlowski et al. Int J Cardiovasc Imaging 2013;29:1685-91	71	23%	2.1mm^2					
Pyraxis et al. Am Heart J 2013;166:1010-1018	55	26%	2.4mm^2	0.78	73%	71%		
Zafar et al. J Cardiol 2014;64:19-24	41	22%	1.6mm^2	0.80	70%	97%	89%	91%

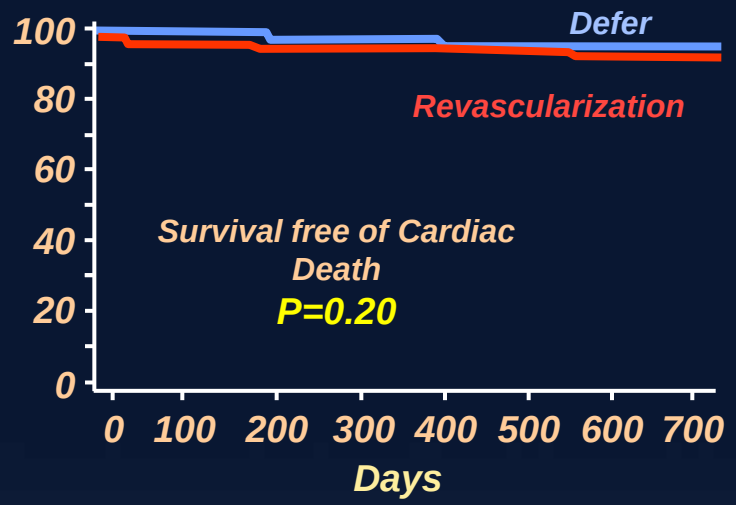
Meta-analysis 6 LMCA FFR deferral studies involving 525 patients with a mean follow-up of 26.5 months

	Deferral	CABG or PCI (94% CABG)	OR	p
#	217	308		
MACE	19.4%	14.2%	1.43	0.15
Death	4.5%	8.8%	0.50	0.06
Non-fatal MI			1.23	0.76
Revascularization			3.24	0.002

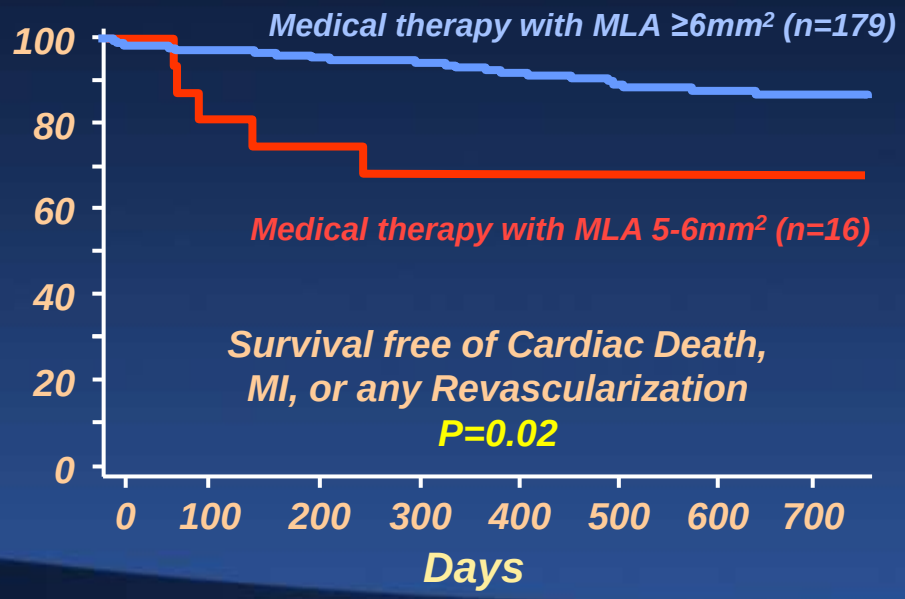
Mallidi et al. Cathet Cardiovasc Interv 2015, in press

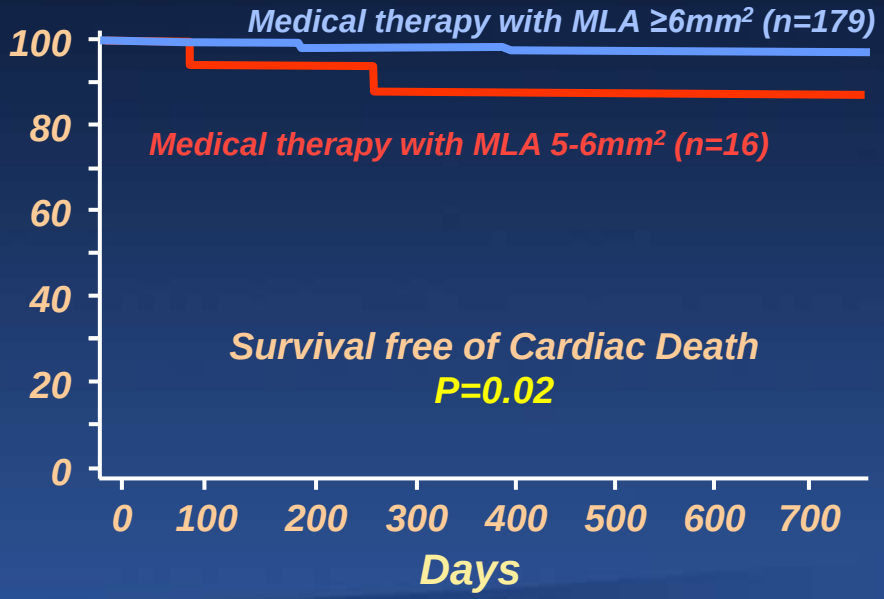
Clinical Outcome of Pts With vs Without Revascularization





Clinical Outcome of Pts Treated Medically According to MLA





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

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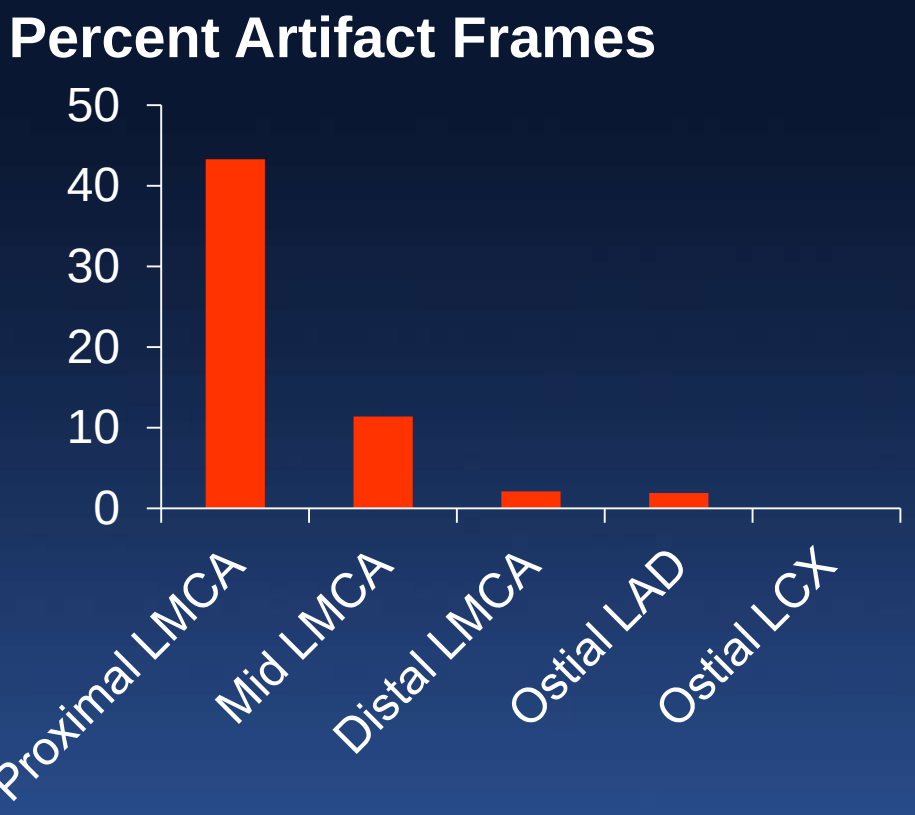
IVUS vs OCT assessing LMCA severity (n=35)

	IVUS	OCT	p
Unable to cross	5.7%	8.6%	0.3
Pullbacks per lesion	1	1.25*	0.003
Pts with repeat pullbacks	0	25%*	0.004
Inadequate assessment of LMCA ostium	*6.1%*	*87.5%*	*<0.001*
MLA (mm^2)	*3.46*	*2.94*	*0.002*

***repeat pullbacks in 8 pts were mostly due to insufficient blood clearance**

Fujino et al. Cathet Cardiovasc Interv 2013;82:E173-83

OFDI assessment of LMCA (38 LAD to LMCA, 11 LCX to LMCA, and 5 both LAD and LCX to LMCA)



Burzotta et al. EuroIntervention 2015;10:e1-8

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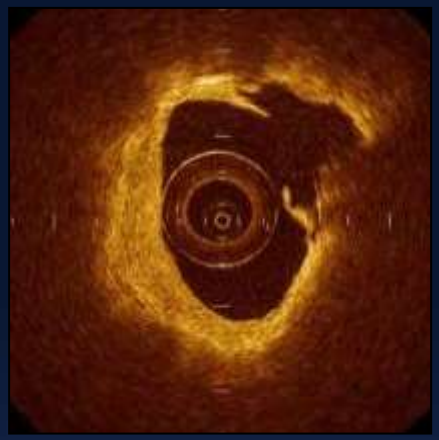
	IVUS	OCT
Assessing lesion severity		
Non-LMCA		
LMCA	+	
Identifying the culprit lesion		
Predicting distal embolization		
Optimizing stent implantation		
Jailed sidebranch		
Assessing stent failure		

What is the culprit lesion?

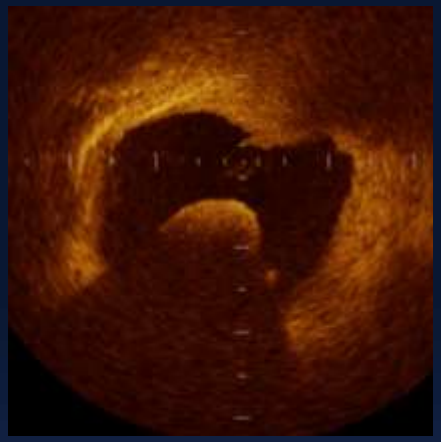
As seen in the VANQWISH Trial, as many as 50% of ACS patients either have no identifiable culprit or have multiple potential culprits. . .

Kerensky et al. J Am Coll Cardiol 2002;39:1456-64

Plaque rupture

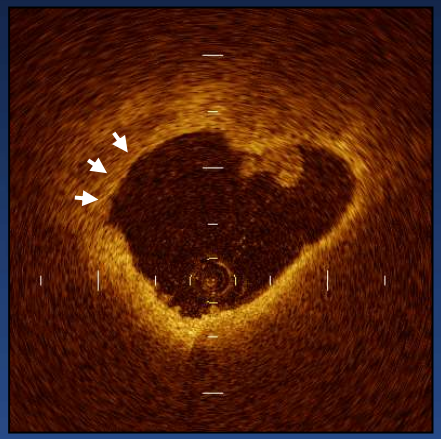


Red thrombus



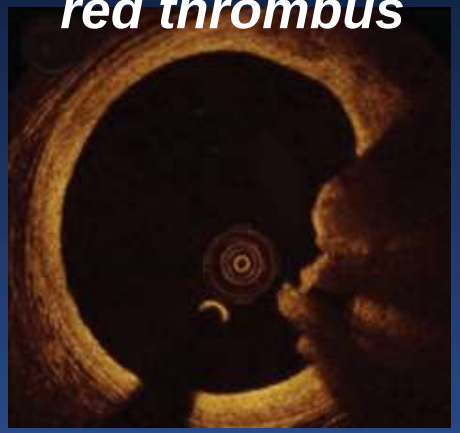
Calcified nodule

Plaque erosion



White thrombus

Calcified nodule with red thrombus



Kubo et al. J Am Coll Cardiol 2007;50:933-9
Kume et al. Am J Cardiol 2006;97:1713-7
Otsuka et al. Nature Reviews Cardiolog 2014;11:379-89

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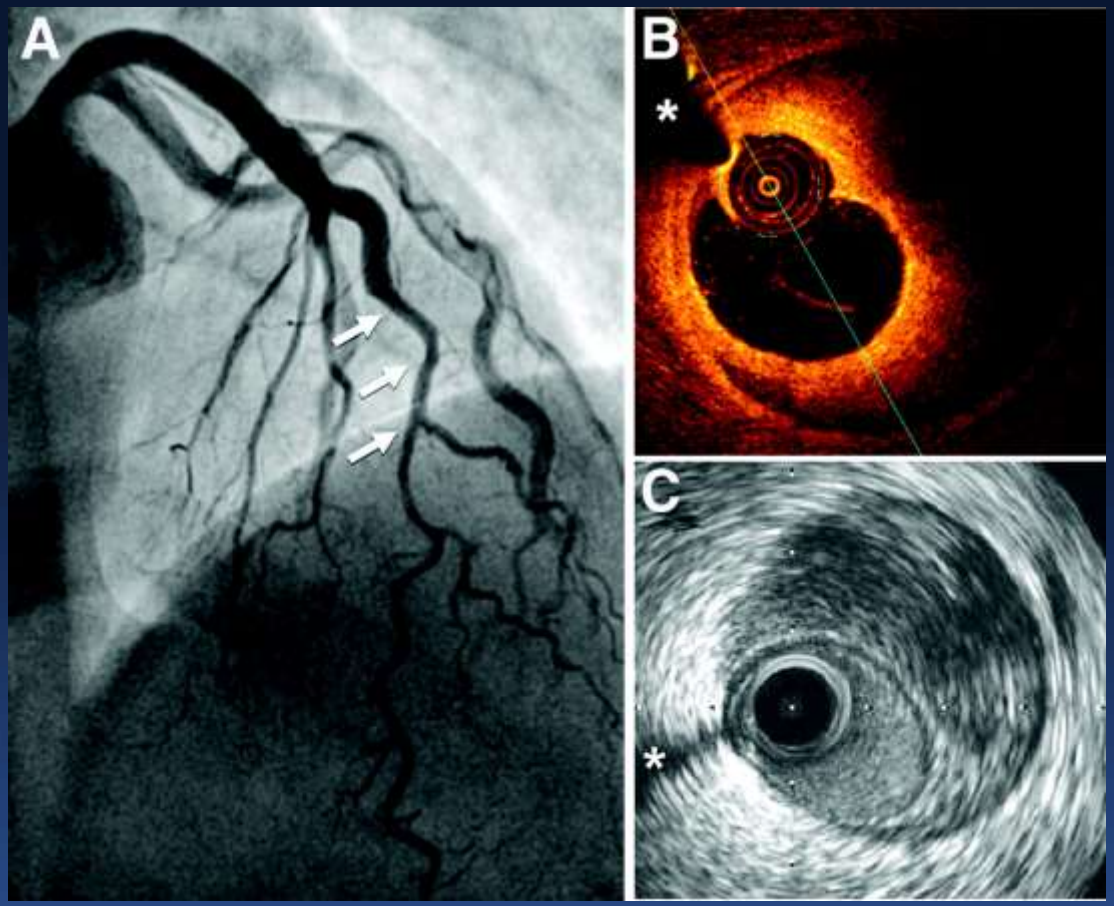
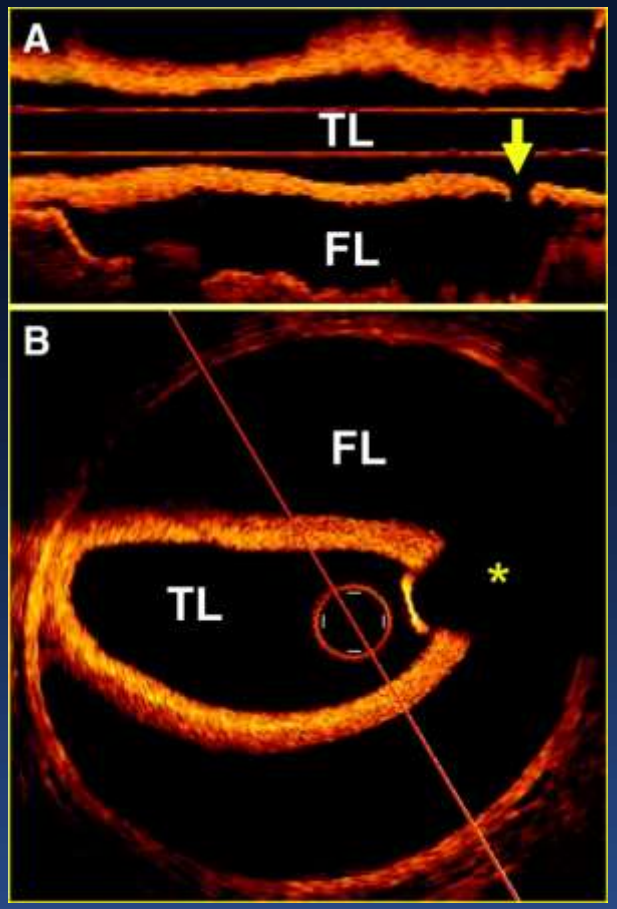
Spontaneous Coronary Artery Dissection (SCAD)





Alfonso. Circulation 2012;126:667-70

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	IVUS	OCT
Assessing lesion severity		
Non-LMCA		
LMCA	+	
Identifying the culprit lesion		+
Predicting distal embolization		
Optimizing stent implantation		
Jailed sidebranch		
Assessing stent failure		

What is the likelihood of distal embolization or peri-procedural MI during stent implantation?

Peri-procedural CK-MB elevation occurred in 20.4%

Peri-procedure CK-MB >3xULN occurred in 16.9%

An ACC National Cardiovascular Data Registry (NCDR) report indicated that no-reflow occurred in 2.3% of primary PCI and was associated with greater in-hospital mortality (12.6% vs. 3.8%, p<0.001)

Jeremias et al. J Am Coll Cardiol. 2004;44:1210-14
Stone et al Circulation 2001;104:642-7
Harrison et al. Am J Cardiol 2013;111:178-84

Distal embolization during PCI is caused by a fibroatheroma, in particularly a TCFA. *Low probability* of distal embolization predictable by *absence of*

- Attenuated plaque – grayscale IVUS
- VH-TCFA or large necrotic core
- OCT-TCFA or plaque rupture
- Lipid rich plaque - NIRS

	IVUS	OCT
Assessing lesion severity		
Non-LMCA		
LMCA	+	
Identifying the culprit lesion		+
Predicting distal embolization	+ (high NPV, but low PPV)	
Optimizing stent implantation		
Jailed sidebranch		
Assessing stent failure		

How do I optimize acute stent results?

IVUS Predictors of DES Early Thrombosis & Restenosis

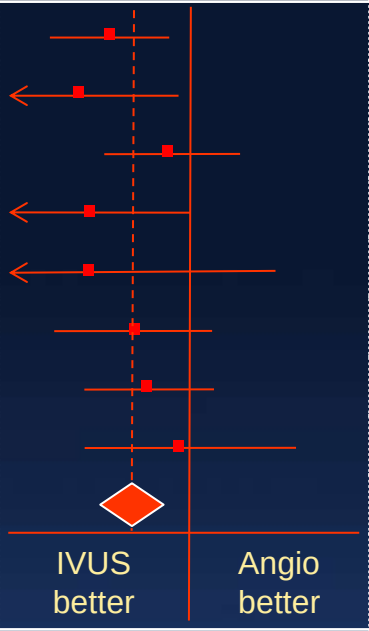
	Early Thrombosis	Restenosis
Small MSA or underexpansion in stable lesions **Small MLA in ACS/MI lesions**	•*Fujii et al. J Am Coll Cardiol 2005;45:995-8* •*Okabe et al. Am J Cardiol. 2007;100:615-20* •*Liu et al. JACC Cardiovasc Interv. 2009;2:428-34* •*Choi et al. Circ Cardiovasc Interv 2011;4:239-47*	•*Sonoda et al. J Am Coll Cardiol 2004;43:1959-63* •*Hong et al. Eur Heart J 2006;27:1305-10* •*Doi et al JACC Cardiovasc Interv. 2009;2:1269-75* •*Fujii et al. Circulation 2004;109:1085-1088* •*Kang et al. Circ Cardiovasc Interv 2011;4:9-14* •*Choi et al. Am J Cardiol 2012;109:455-60* •*Song et al. Catheter Cardiovasc Interv 2014;83:873-8*
Edge problems (geographic miss, secondary lesions, large plaque burden, dissections, etc)	•*Fujii et al. J Am Coll Cardiol 2005;45:995-8* •*Okabe et al., Am J Cardiol. 2007;100:615-20* •*Liu et al. JACC Cardiovasc Interv. 2009;2:428-34* •*Choi et al. Circ Cardiovasc Interv 2011;4:239-47*	•*Sakurai et al. Am J Cardiol 2005;96:1251-3* •*Liu et al. Am J Cardiol 2009;103:501-6* •*Costa et al, Am J Cardiol, 2008;101:1704-11* •*Kang et al. Am J Cardiol 2013;111:1408-14* •*Kobayashi et al. ACC2014*
Stent length (>40mm)		•*Hong et al. Eur Heart J 2006;27:1305-10*

Five meta-analyses assessing IVUS vs angiography-guided DES implantation

					HR (p-values)					
Reference	**Yr**	**RCT**	**Non-RCT**	**Pts**	**MACE**	**Death**	**MI**	**ST**	**TLR**	**TVR**
Zhang et al Eurointervention	2012	1	10	19,619	0.87 (p=0.008)	0.59 (p<0.001)	0.82 (p=0.13)	0.58 (p<0.001)	0.90 (p=0.3)	0.90 (p=0.2)
Propensity score matched sub-analysis				5,300	0.86 (p=0.06)	0.73 (p=0.04)	0.63 (p=0.01)	0.57 (p=0.004)	0.85 (p=0.3)	0.94 (p=0.6)
Klersy et al Int J Cardiol	2013	3	9	18,707	0.80 (p<0.001)	0.60 (p<0.001)	0.59 (p=0.001)	0.58 (p=0.007)	0.95 (p=0.8)	
Jang et al. JACC Cardiovasc Interv	2014	3	12	24,869	0.79 (p=0.001)	0.64 (p<0.001)	0.57 (p<0.001)	0.59 (p=0.002)	0.76 (p=0.01)	0.81 (p=0.01)
Propensity score matched sub-analysis				13,545	0.79 (p=0.01)	0.58 (p=0.01)	0.56 (p=0.04)	0.52 (p=0.004)	0.85 (p=0.3)	0.93 (p=0.3)
Ahn et al. Am J Cardiol	2014	3	14	26,503	0.74 (p<0.001)	0.61 (p<0.001)	0.57 (p<0.001)	0.59 (p<0.001)	0.81 (p=0.046)	0.82 (p=0.022)
Zhang et al. BMC Cardiovaasc Disorders	2015	3	17	29,068	0.77 (p<0.001)	0.62 (p<0.001)	0.64 (p<0.001)	0.59 (p<0.001)	0.81 P=0.005)	0.86 (p=0.012)
Propensity score matched sub-analysis				8,331	0.79 (p<0.001)	0.64 (p<0.001)	0.69 (p<0.001)	0.55 (p<0.001)	0.92 (p=0.34)	0.82 (p=0.028)
Complex lesions or ACS				6,393	0.69 (p<0.001)	0.52 (p<0.001)		0.64 (p<0.001)		

Meta-analysis of 8 Randomized Trials of IVUS vs Angio-Guided DES Implantation

Study	Year	#	OR	IVUS MACE	Angio MACE
IVUS-XLP	2015	1400	0.49	19/700	39/700
CTO-IVUS	2015	402	0.37	5/201	14/201
AIR-CTO	2015	230	0.82	25/115	29/115
Tan-LM	2015	123	0.42	8/61	17/62
MOZART	2014	83	0.41	2/41	5/42
RESET	2013	543	0.60	12/269	20/274
AVIO	2013	284	0.67	24/142	33/142
Home-DES	2010	210	0.91	11/105	12/105
OVERALL		3275	0.59	106/1634	169/1641
				6.5%	10.3%



Event	IVUS events	Angio events	OR	95% CI	P-value
MACE	6.5%	10.3%	0.59	0.46-0.76	<0.0001
CV mortality	0.5%	1.2%	0.46	0.21-1.00	0.05
MI	0.9%	1.6%	0.58	0.30-1.11	0.10
TLR	4.1%	6.6%	0.60	0.43-0.84	0.003
TVR	5.5%	8.7%	0.61	0.41-0.91	0.02
ST	0.6%	1.3%	0.49	0.24-0.99	0.04

Elgendy et al. Circ Cardiovasc Interv 2016, in press

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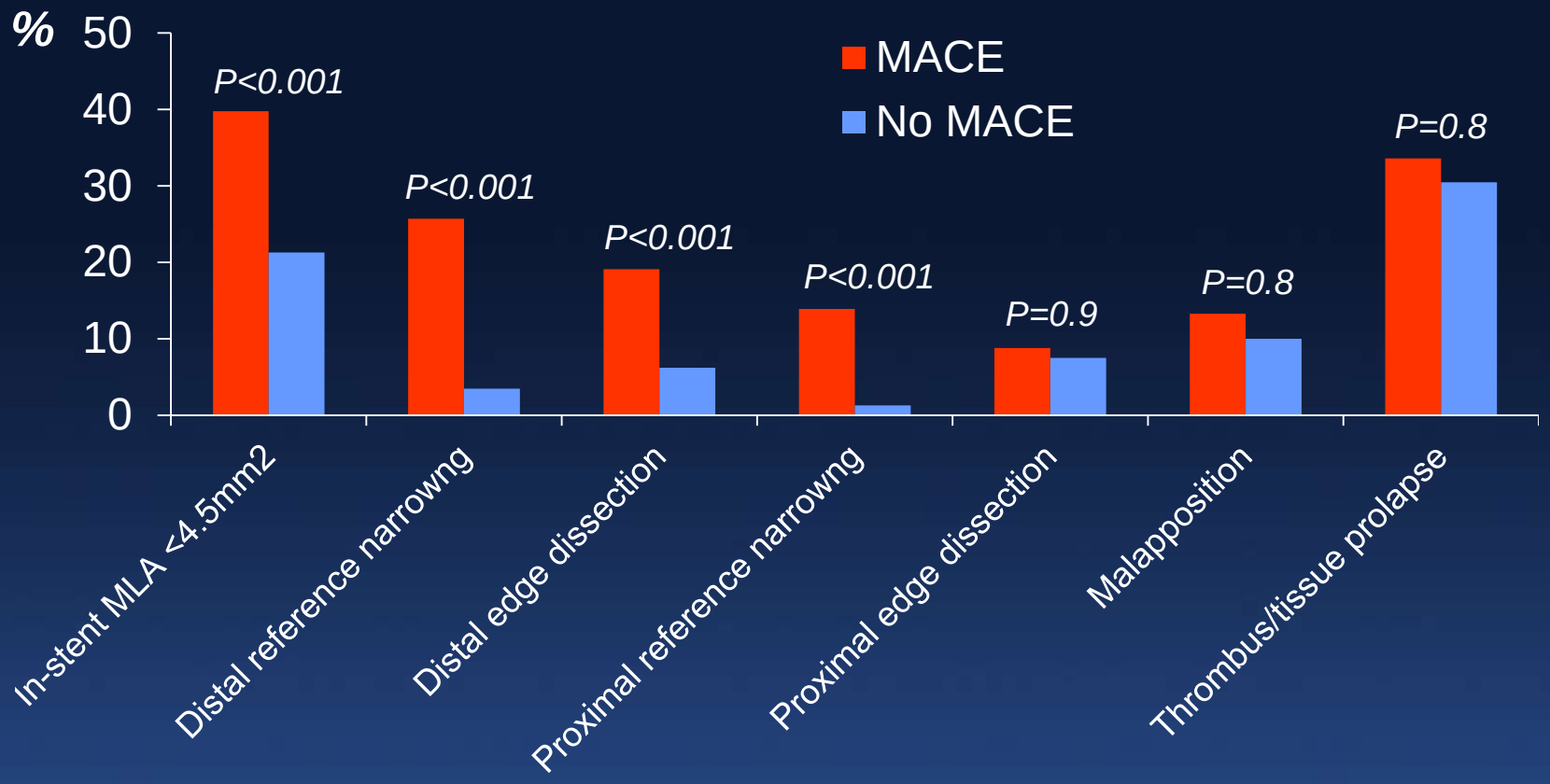
929 pts (989 lesions) in CLI-OPI II registry

MACE (death, MI, ST, or TLR in 12.2%) @ 1 yr



Indepdent predictors of MACE were in-stent MLA <4.5mm^2, proximal or distal reference narrowing, or distal edge dissection

Prati et al. JACC Cardiovasc Imaging 2015;8:1297-305

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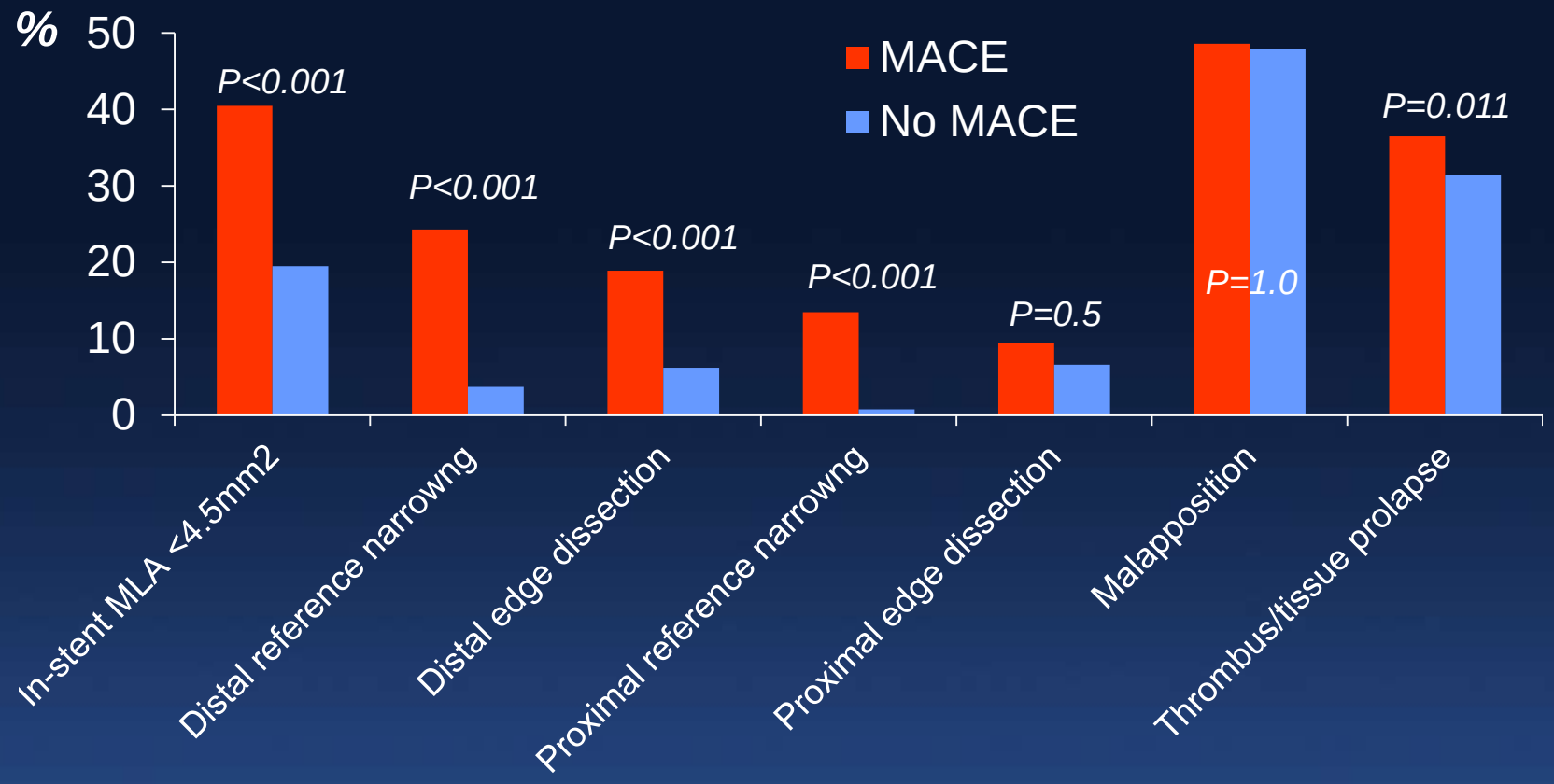
507 pts (588 lesions) in CLI-OPI ACS registry

MACE (death, MI, ST, or TLR in 12.6%) @ 9 mos



Presence of at least one OCT finding was found to be an independent predictor of worse outcome (HR=4.05, CI 95% 1.8-9.0, p=0.001) - especially the presence of a residual intrastent plaque/thrombus ptrotrusion (HR=2.96, CI 95% 1.4-6.3, p=0.005).

Prati et al. unpublished

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Baseline OCT and 1 year follow-up (900 stents in 786 patients)

Independent predictors of 1 year events				
	Device oriented clinical events		TLR	
	OR	P-value	OR	P-value
Age, years			0.98	0.4
Male gender	**3.13**	0.068	36%	
BMS	**1.75**	0.005	1.80	0.002
Irregular protrusion	**2.64**	0.003	2.66	0.003
Small MSA	**2.54**	0.012	2.54	0.011

- Irregular protrusion = protrusion of material with an irregular surface (>100 microns) into the lumen between stent struts.
- Small MSA defined by ROC analysis = 5.0mm^2 for DES (AUC=0.63) and 5.6mm^2 for BMS (AUC=0.59)
- Neither edge dissection nor acute malapposition nor relative stent underexpansion predicted events at 1 year of follow-up

Soeda et al. Circulation 2015;132:1020-9

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OPINION

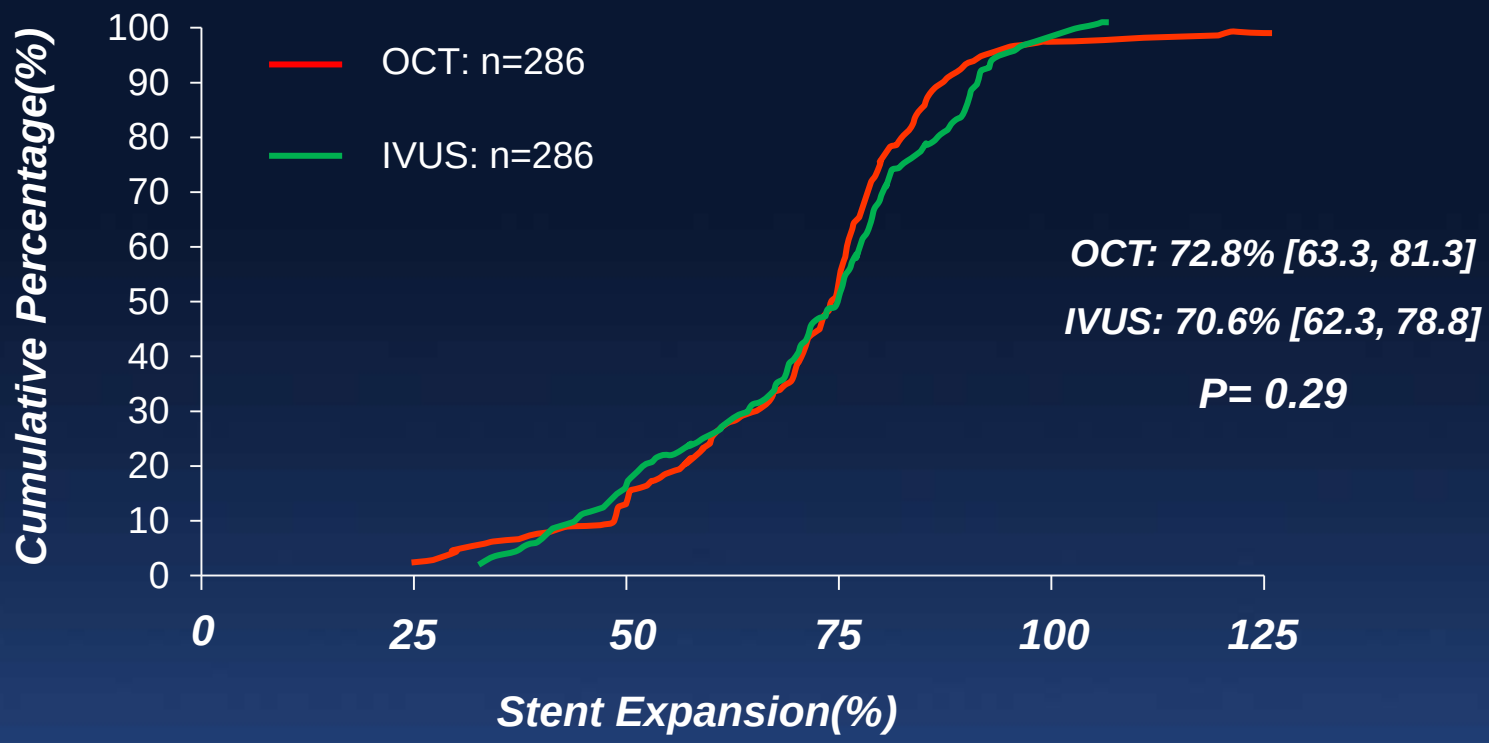
Randomized comparison of OCT vs IVUS

	OCT	IVUS	P value
#	400	400	
Heavy calcification	8%	13%	0.011
Total contrast, ml	164±66	138±56	<0.001
Stent diameter. mm	2.93±0.39	2.99±0.40	0.032
Maximum balloon, mm	3.15±0.79	3.28±1.20	0.072
In-stent			
MLD, mm	2.56±0.44	2.63±0.46	0.058
DS	12±6	11±5	0.021
Acute gain, mm	1.63±0.49	1.75±050	0.003
In-segment			
MLD, mm	2.25±0.52	2.28±0.52	0.5
DS	21±9	21±9	0.9
Acute gain, mm	1.33±0.54	1.40±0.53	0.11

Akasaka, EurpPCR 2015

ILUMIEN II

(OCT-guided stenting pts in ILUMIEN I matched to IVUS-guided stenting pts in ADAPT-DES)



Matched for 4 potential confounders: the presence of moderate or severe angiographic calcification; angiographic lesion length and reference vessel diameter; and whether proximal and/or distal) were available for calculation of stent expansion (an OCT lesion with both references was matched with a corresponding IVUS lesion with both references, and an OCT lesion with only a proximal or distal reference was matched with a corresponding IVUS lesion with only a proximal or distal reference)

Maehara et al. JACC Cardiovasc Interv .2015;8:1704-14

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MACE in 7 Studies of IVUS vs Angio-guided DES for LMCA Disease

Study	# Pts	Follow-up	Angio-guided	IVUS-guided	HR	95%CI	P-value
Agostoni et al. Am J Cardiol 2005;95:644-7	58	1.5 years	20%	8%			0.18
Park et al. Circ Cardiovasc Interv 2009;2:167-77	682	3 years			0.31	0.19-0.51	
Propensity score matched	290				0.64	0.39-1.04	0.074
de la Torre Hernandez et al. JACC Cardiovasc Interv 2014;7:244-54*	1010	3 years	11.7%	16.0%			0.006
Gao et al. Patient Pref Adherence 2014;8:1-11	1016	1 year	14.8%	27.7%			<0.001
Propensity score matched	582		16.2%	24.4%			0.014
Tan et al. Saudi Med J 2015;36:549-53**	123	2 years	13.1%	29.3%			0.031
XuBo. TCT2015	1899	3 years	11.1%	13.2%	0.83	0.69-1.00	0.06
ADAPT-DES	317	2 years	10.2%	5.6%	0.54	0.23-1.26	0.15

**propensity-score matched*
***randomized*

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IVUS vs OCT assessing LMCA stenting (n=35)

	IVUS	OCT	p
Pullbacks per lesion	1.09±0.28	1.29±0.46	0.006
Patients with repeat pullbacks	8.6%	29.4%	0.004
Adequate assessment of proximal stent edge	90.9%	18.2%	<0.001
Adequate assessment of distal stent edge	100%	100%	1.0
MSA (mm^2)	6.88±2.03	6.79±2.09	0.5
Malapposition area (mm^2)	0.12±0.36	0.43±0.51	<0.001
Tissue prolapse area (mm^2)	0.11±0.07	0.23±0.09	<0.001
Thrombus	0	5.9%	0.15
Proximal edge dissection	0	3%	0.3
Distal edge dissection	6.1%	30.3%	0.011

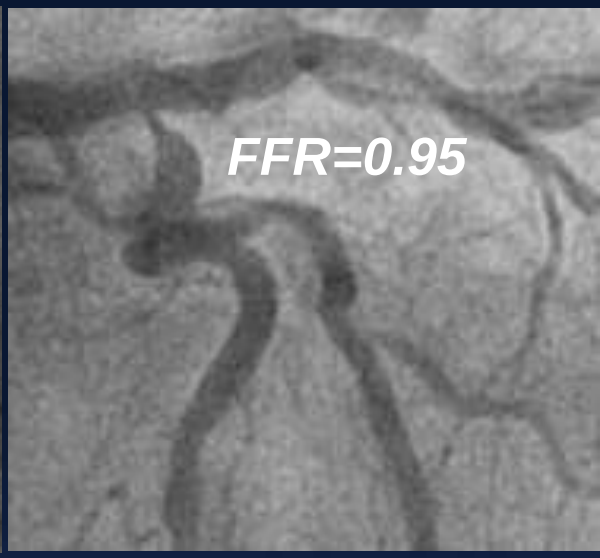
Fujino et al. Cathet Cardiovasc Interv 2013;82:E173-83

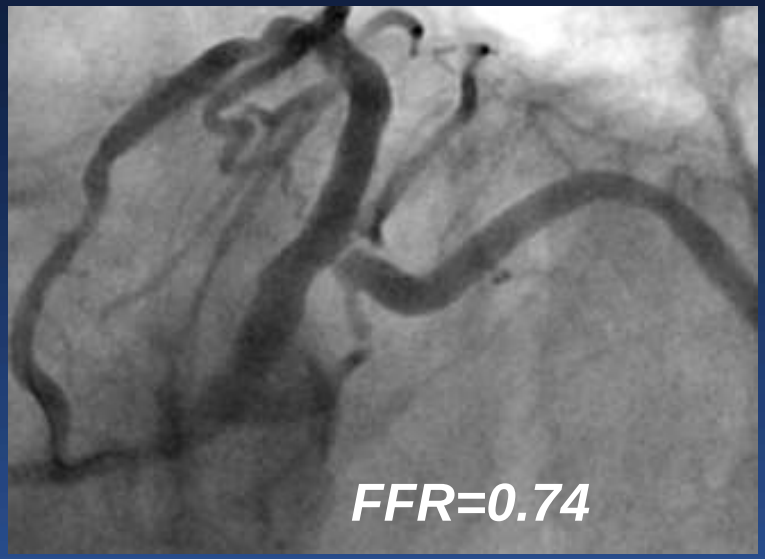
IVUS Guidance to Minimize the Use of Iodine Contrast in PCI

- MOZART - Mariani et al. JACC Cardiovasc Interv 2014;7:1287-93
  - 83 pts randomized to IVUS vs angiographic guidance with a pre-specified PCI strategy designed to reduce contrast usage in both groups
  - **Reduction in contrast use (primary endpoint) from 64.5ml (IQR 42.8-97ml, range 19-170ml) to 20.0ml (IQR 12.5-30.0ml, range 3-54ml): p<0.0001**
  - No difference in 4-month outcomes although there was a trend toward a less common increase in serum Cr >0.5mg/dl (7.3% vs 19.0%, p=0.2)
- Ali et al. Eur Heart J, in press
  - 31 pts with median creatinine of 4.2mg/dL (IQR 3.1-4.8)
  - Successful **zero contrast PCI** was performed at least 1 week after diagnostic angiography using real-time IVUS guidance and pre- and post-PCI FFR and CRF to confirm physiologic improvement
  - No MACE and preservation of renal function in all pts at a median follow-up of 79 days (IQR 33-107).

	IVUS	OCT
Assessing lesion severity		
Non-LMCA		
LMCA	+	
Identifying the culprit lesion		+
Predicting distal embolization	+ (high NPV, but low PPV)	
Optimizing stent implantation	+ (Although the current data favors IVUS, IMHO eventually this will be a matter of preference)	
CTO	+	
LMCA	+	
Chronic renal insufficiency	+	
BRS		
Jailed sidebranch		
Assessing stent failure		

Is this jailed sidebranch significant?





Bon-Kwon Koo. TCT2013

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	IVUS	OCT
Assessing lesion severity		
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LMCA	+	
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CTO	+	
LMCA	+	
Chronic renal insufficiency	+	
BRS		
Jailed sidebranch		
Assessing stent failure		

Why did this stent fail?

Causes of Stent failure

	Bare Metal Stents				Drug-eluting Stents				
	Stent Thrombosis		Restenosis		Stent Thrombosis			Restenosis	
	<30d	>1y	<5y	>5y	<30d	30d - 1y	>1y	<18m	>18m
Intimal hyperplasia			x					x	
Procedure-related complications incl. underexpansion	x		x		x			x	
Late malapposition or aneurysm							x		
Vessel wall inflammation							x		
Stent fracture	x	x			x		x		x
Delayed healing						x			
Uncovered stent struts/fibrin deposition						x	x		
Neoatherosclerosis		x		x			x		x

Causes of Stent Failure

	Bare Metal Stents				Drug-eluting Stents				
	Stent Thrombosis		Restenosis		Stent Thrombosis			Restenosis	
	<30d	>1y	<5y	>5y	<30d	30d - 1y	>1y	<18m	>18m
Intimal hyperplasia			IVUS OCT					IVUS OCT	
Procedure-related complications incl. underexpansion	IVUS OCT		IVUS OCT		IVUS OCT			IVUS OCT	
Late malapposition or aneurysm							IVUS OCT		
Vessel wall inflammation							x		
Stent fracture	IVUS OCT	IVUS OCT			IVUS OCT		IVUS OCT		IVUS OCT
Delayed healing						x			
Uncovered stent struts/fibrin deposition						OCT	OCT		
Neoatherosclerosis		OCT		OCT			OCT		OCT

	IVUS	OCT
Assessing lesion severity		
Non-LMCA		
LMCA	+	
Identifying the culprit lesion		+
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Optimizing stent implantation	+ (Although the current data favors IVUS, IMHO eventually this will be a matter of preference)	
CTO	+	
LMCA	+	
Chronic renal insufficiency	+	
BRS		
Jailed sidebranch		
Assessing stent failure	Early/Late	Early, Late, or Very Late

Finally, OCT vs IVUS is the wrong question. The correct question is still OCT or IVUS vs angiography alone.