

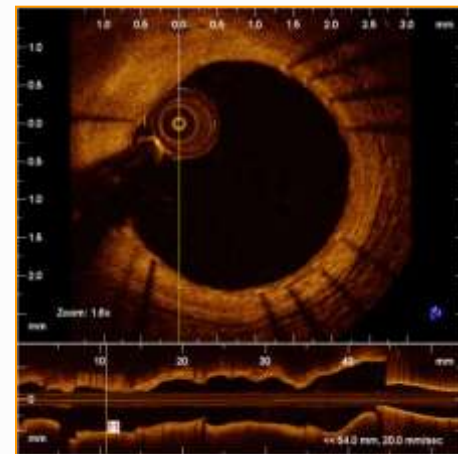
Lutonix paclitaxel DCB: device design and first report of the coronary DE NOVO pilot study



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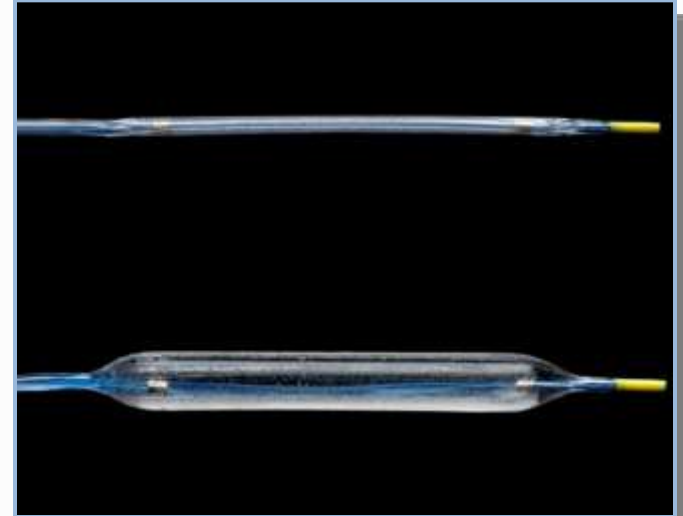
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Conflict of interests

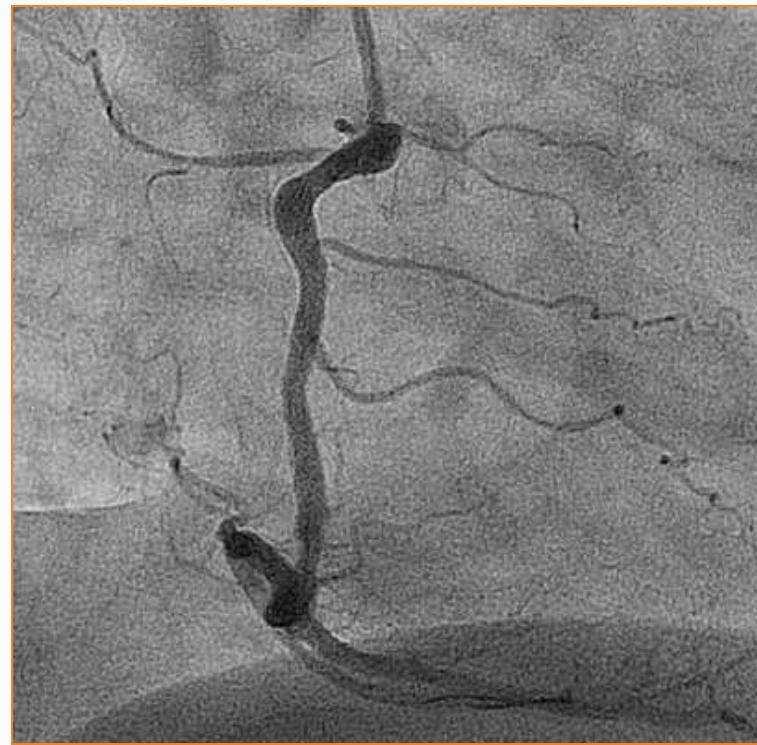
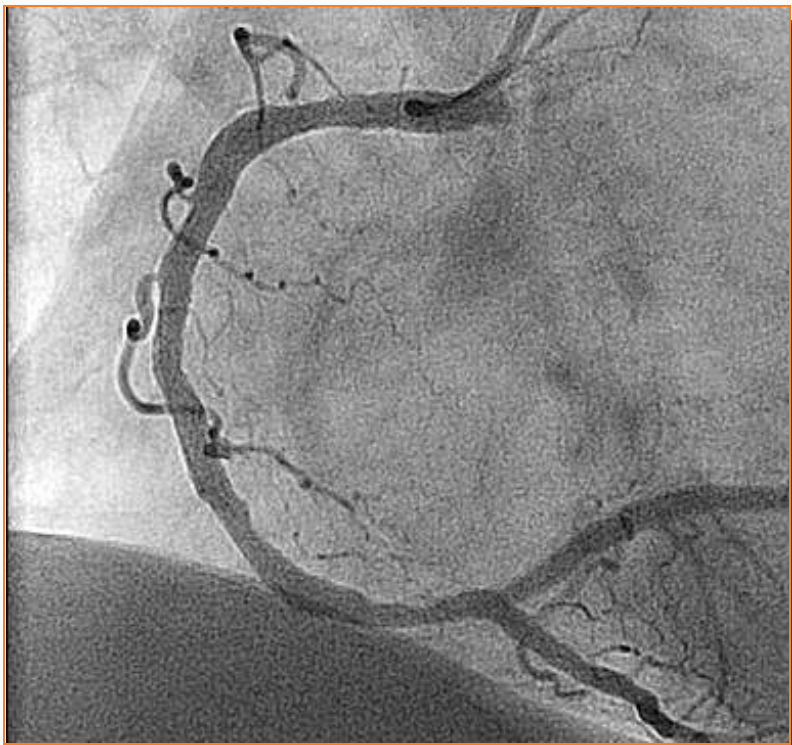
- I do not have any conflict of interests to disclose

Lutonix Moxy DCB

- 2 $\mu\text{g}/\text{mm}^2$ paclitaxel coating with hydrophilic non-polymeric carrier
 - Uniform thickness $\sim 7 \mu\text{m}$
- Formulation balances drug retention during transit and uptake upon inflation
- Drug delivered during single 30sec inflation

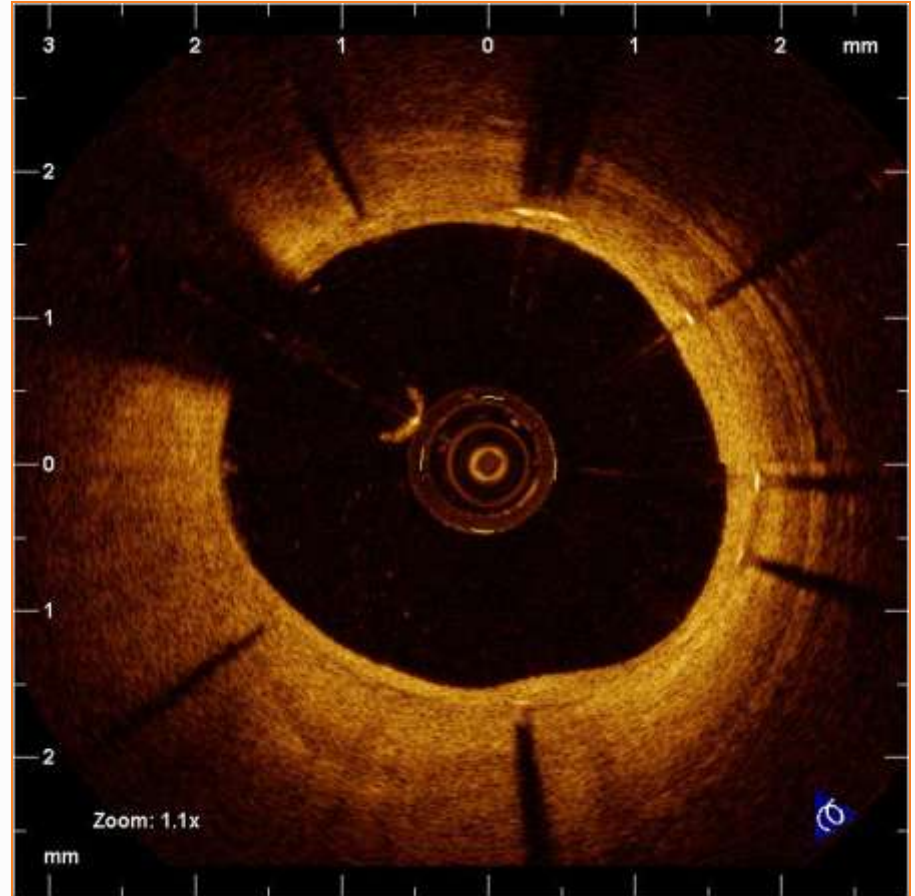


Lutonix Moxy DCB: Clinical case



- Predilatation
- BMS 3x18mm
- Moxy DCB 3x30mm
 - Transit time 1'55''

Lutonix Moxy DCB: Clinical case



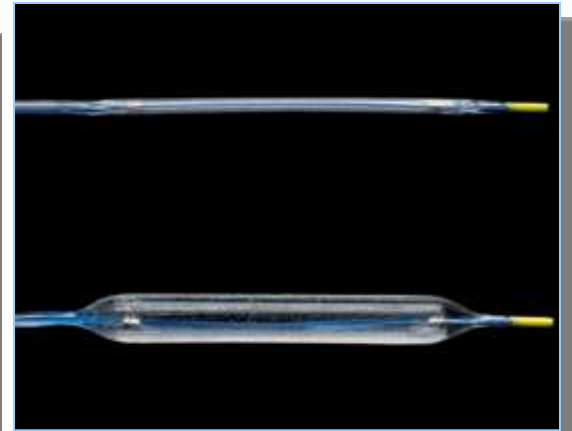
6 months FU

De Novo Pilot Study: Purpose & Rationale

- Evaluate with OCT the ability of Lutonix formulation to inhibit Neointimal Hyperplasia
- Assess Safety of DCB + BMS
- Determine if sequence of application plays a role in the efficacy
 - DCB before BMS
 - DCB after BMS

De Novo pilot study: Design

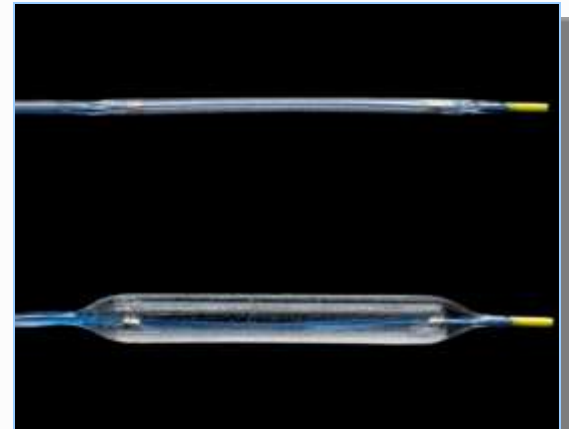
- Primary endpoint
 - % volume obstruction by OCT
- Secondary endpoints
 - OCT
 - Incomplete stent apposition (ISA)
 - Tissue coverage
 - QCA
 - Late loss
 - Binary restenosis
 - Clinical endpoints
 - Death
 - MI
 - TVR / TLR
 - Safety endpoints
 - Stent thrombosis



De Novo pilot study: Design

- **Inclusion criteria**

- **Clinical: Documented ischemia**
- **Angiographic lesion:**
 - De novo
 - Diam stenosis $\geq 50\%$ $< 100\%$
 - RVD ≥ 2.5 ≤ 3.25 mm
 - Length ≤ 18 mm
 - Guidewire able to cross



- **Exclusion criteria**

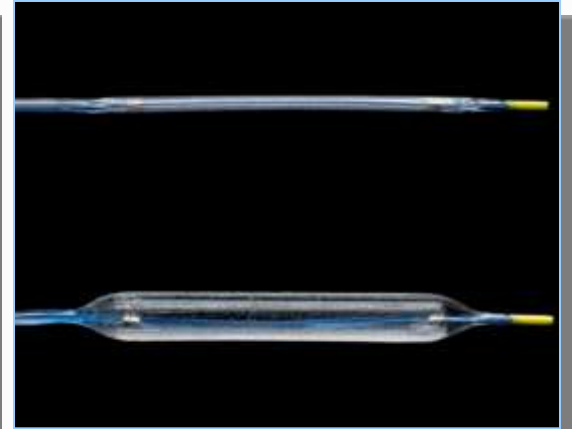
- **Clinical**
 - MI ≤ 72 h
 - LVEF $< 25\%$
 - Coronary revascularization ≤ 60 d
 - Prior PCI/CABG of the target vessel
- **Angiographic**
 - Left Main
 - Bifurcation ≥ 2.5 mm diameter
 - Planned use of adjunctive devices



De Novo pilot study: Design

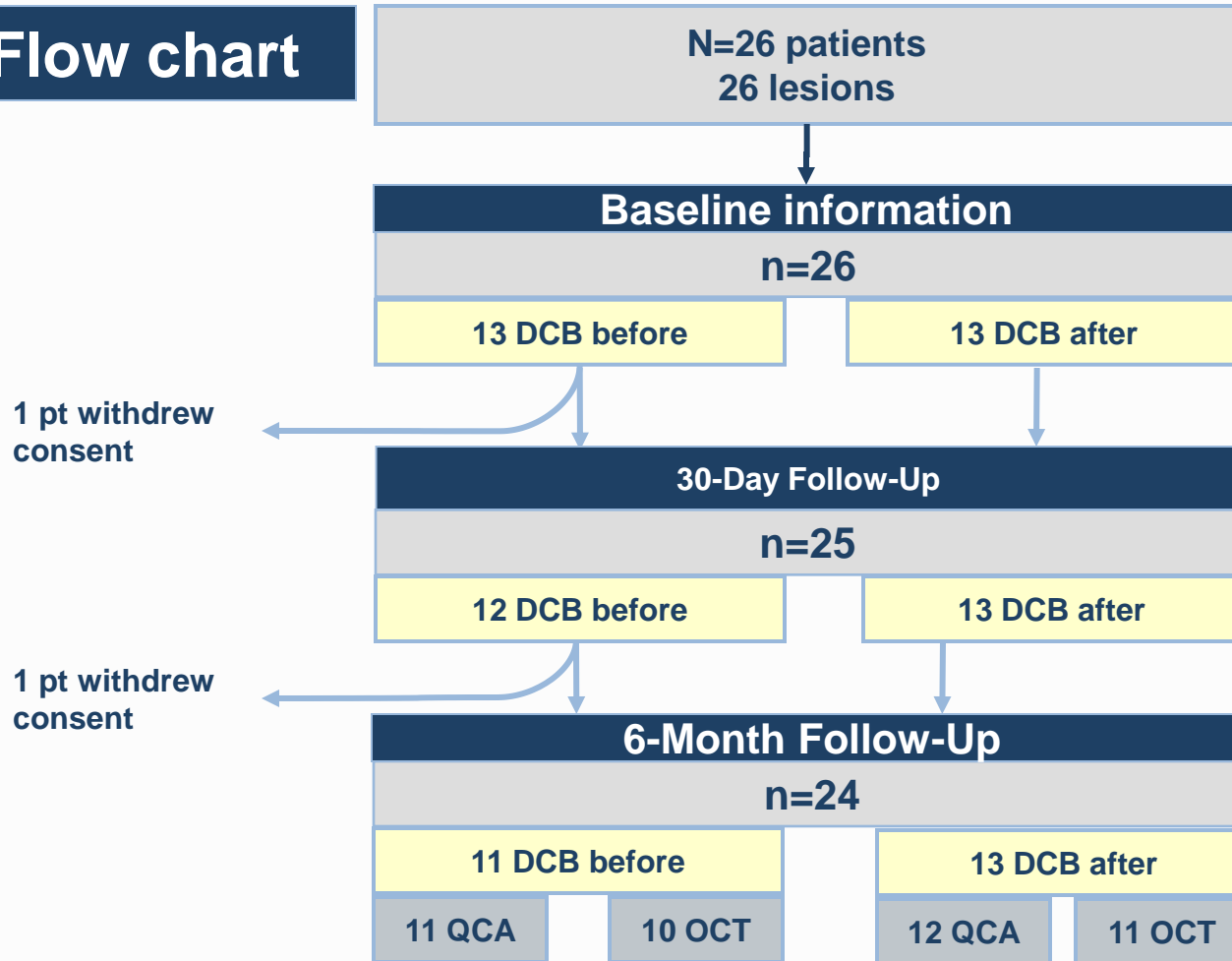
● Procedure

- Predilation mandatory
- Stent: ML VISION (Abbott, Santa Clara, CA)
- DCB
 - Length 18 / 30mm
 - Diameter 2.5 / 3mm
 - Transit time ≤ 3 min
 - Avoid longitudinal mismatch (geographic miss)
 - Single application ≥ 30 sec
- Dual antiplatelets for 3 months



De Novo pilot study

Flow chart



12 & 24 Month Clinical Follow-Up Ongoing

De Novo pilot study: Baseline characteristics

Baseline characteristics	DCB before BMS n=13	DCB after BMS n=13
Age (years)	57.4 10.9	58.2 11.0
Male	76.9	69.2
Hypertension	53.8	53.8
Hypercholesterolemia	69.2	76.9
Diabetes mellitus	23.1	15.4
Smoking	69.2	46.2
Ex-smoker	46.2	30.8
Current smoker	23.1	15.4
Family history	69.2	46.2
Renal insufficiency	7.7	0.0
Stroke/TIA	7.7	0.0
Previous MI	30.8	30.8
Previous PCI	15.4	7.7

Numbers are %

1 pt = 7.7%

De Novo pilot study: Procedural characteristics

Procedural characteristics		DCB before BMS n=13	DCB after BMS n=13
Treatment vessel	RCA	38.5	15.4
	LAD	38.5	46.2
	LCX	23.1	38.5
Moderate/heavy calcification		15.4	7.7
DCB	Transit time (seconds)	65.3	68.7
	Time inflation (seconds)	56.0	61.2
	Max inflation press (atm)	9.0	8.5
Stent	# stents implanted per pt	1.2	1.1
	Need for additional stents	23.1	7.7
Device success		100.0	100.0
Geographic miss		23.1	0.0
Coronary dissection		7.7	0.0

Numbers are means or %

De Novo pilot study: Results

QCA		DCB before BMS			DCB after BMS		
		Pre n=13	Post n=13	6m FU n=11	Pre n=13	Post n=12	6m FU n=12
Missing		0	0	2	0	1	1
In-DCB	Length (mm)	10.7			11.2		
	RVD (mm)	2.81	2.94	2.73	2.41	2.52	2.34
	MLD (mm)	1.07	2.49	1.98	0.91	2.03	1.61
	% diam stenosis	62	15	27	62	20	32
	Late loss (mm)			0.53			0.45
	Binary restenosis			9.1 (1)			16.7 (2)

Numbers are means or %

Binary restenosis: % (n)

In-DCB: In the region treated by DCB

De Novo pilot study: Results

OCT (paired analysis)		DCB before BMS 11 stents		
		Post	6m FU	Δ
Stent length (mm)		14.9	14.1	-1.1%
Stent	Min area (mm ²)	7.77	7.38	-4.9%
	Mean area (mm ²)	9.11	8.94	-2.5%
	Volume (mm ³)	135.0	125.3	-3.5%
Lumen	MLA (mm ²)	7.88	4.94	-41%
	Mean area (mm ²)	9.09	6.86	-26%
	Volume (mm ³)	134.1	95.8	-26%
Neoint hyperpl	Max area (mm ²)	0.71	4.02	3.3
	Volume (mm ³)	2.98	30.1	27.2
	% volume obstruction	2.2	25.3	23.1
ISA	Max area (mm ²)	1.21	0.43	-27%
	Volume (mm ³)	2.14	0.56	-58%

Numbers are means

ISA: Incomplete stent apposition

De Novo pilot study: Results

OCT (paired analysis)		DCB after BMS 11 stents		
		Post	6m FU	Δ
Stent length (mm)		17.5	17.8	-3.7%
Stent	Min area (mm ²)	5.30	5.44	1.6%
	Mean area (mm ²)	6.50	6.66	0.5%
	Volume (mm ³)	114.7	118.0	3.4%
Lumen	MLA (mm ²)	5.20	3.48	-38%
	Mean area (mm ²)	6.39	5.14	-23%
	Volume (mm ³)	112.8	90.7	-26%
Neoint hyperpl	Max area (mm ²)	0.47	2.93	2.4
	Volume (mm ³)	2.66	27.4	24.5
	% volume obstruction	2.3	24.9	22.5
ISA	Max area (mm ²)	0.47	0.03	-97%
	Volume (mm ³)	0.70	0.02	-98%

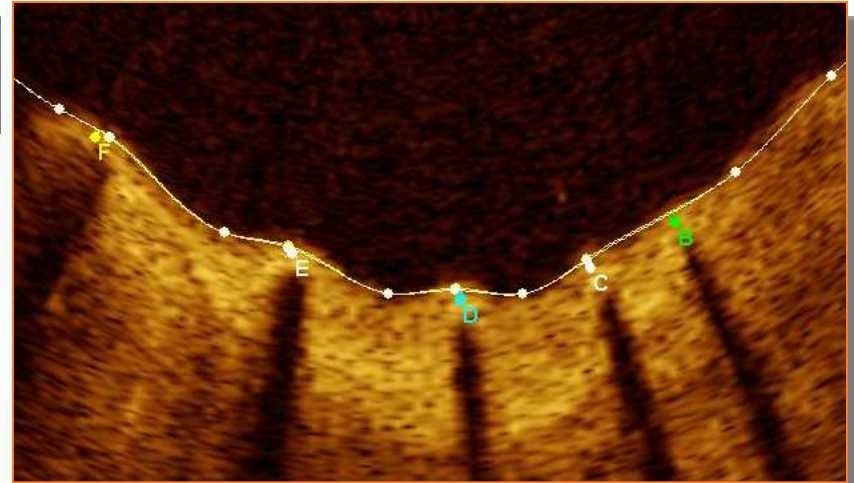
Numbers are means

ISA: Incomplete stent apposition

NIH: Neointimal hyperplasia

De Novo pilot study: Results

3874 struts analyzed at BL
3365 struts analyzed at 6m



OCT per strut analysis

OCT per strut analysis		DCB before BMS 10 pt, 11 stents	DCB after BMS 12 pt, 12 stents	All 22 pt, 23 stents
Apposition	% ISA at BL	10.1	5.4	7.7
	% ISA at FU	2.3	0.1	1.2
Tissue coverage (6m)	% uncovered	9.1	5.3	7.1
	weighted	6.1	5.2	5.6
	Thickness (µm)*	200 (60; 400)	180 (80 – 310)	190 (70 – 350)

ISA: Incomplete stent apposition * Median (p25 – p75)

De Novo pilot study: Results

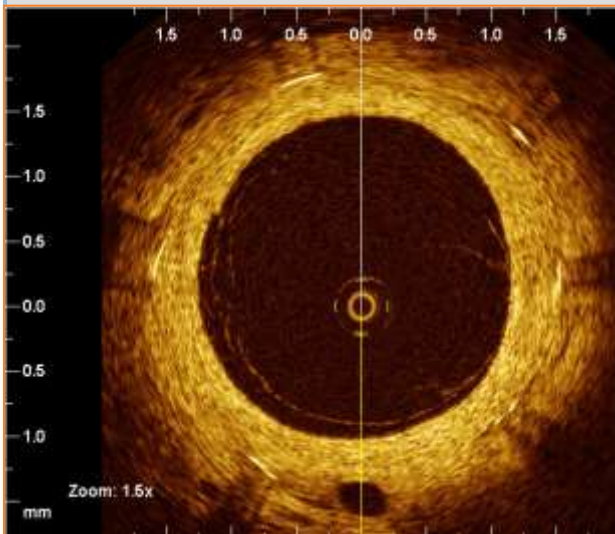
MACE	30d			6m		
	DCB <i>before</i> BMS n=13	DCB <i>after</i> BMS n=13	All n=26	DCB <i>before</i> BMS n=13	DCB <i>after</i> BMS n=13	All n=26
Death	0.0	0.0	0.0	0.0	0.0	0.0
MI (WHO)	0.0	7.7	3.8	0.0	15.4	7.7
TV-related	0.0	7.7	3.8	0.0	7.7	3.8
TVR	7.7	0.0	3.8	23.1	15.4	19.2
TLR	0.0	0.0	0.0	15.4	15.4	15.4
Death, MI, TLR	0.0	7.7	3.8	15.4	30.8	23.1
Stent thrombosis	0.0	0.0	0.0	0.0	0.0	0.0

All MI are NSTEMI
All TLR but 1 are Re-PCI

1 pt = 7.7% 1 pt = 3.8%

Conclusions

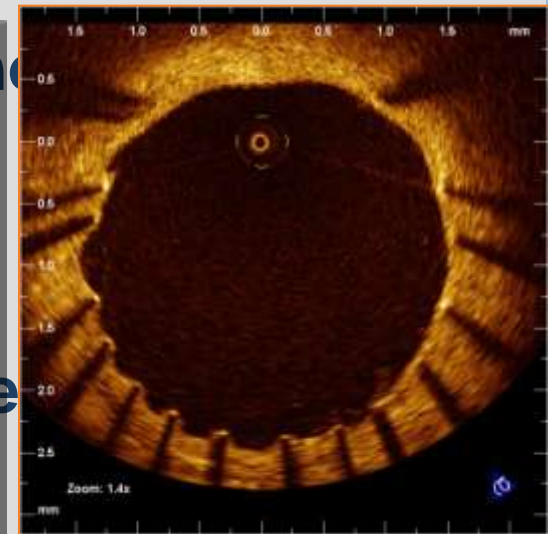
- Evidence of a biological effect
 - Neointimal inhibition demonstrated by OCT



BMS



DCB + BMS



DES

- Further investigation required to optimize outcomes