

Go Beyond Metal: Exploring Drug-Eluting Balloon technology in de-novo coronary lesions

Dissections: what we should and should not leave

Dr Mario Araya

Chile

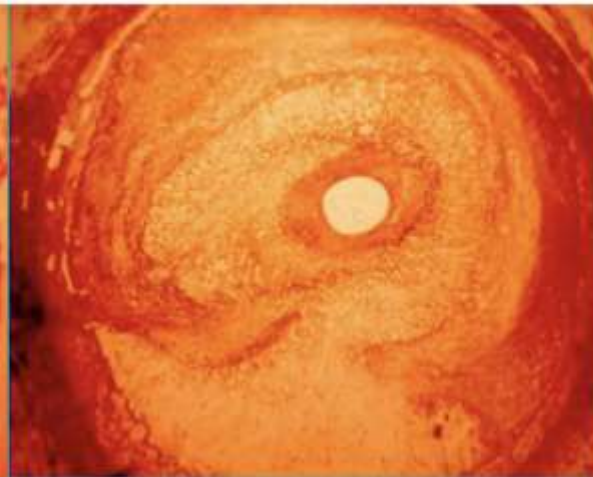
Dissections in POBA era

- POBA fractures the atherosclerotic intima at its point of least resistance, creating a dissection plane and space through dehiscence of the intima from the media + lumen gain through vessel expansion
- Risk of acute vessel closure
- Recoil (acute) and inflammation and proliferative reaction (0-4 months) leads to restenosis secondary to this barotrauma (“the more you gain, the more you loose”).

**A Dissection (barotrauma)
Post angioplasty**



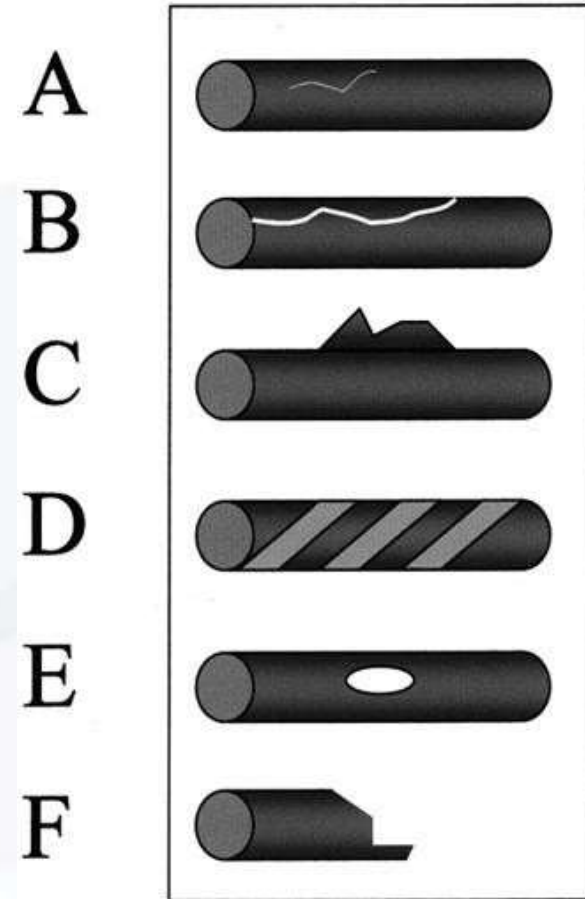
**B Restenosis
4 months later**









The National Heart, Lung and Blood Institute (NHLBI) classification system for intimal tears (2004)

Vessel threatening dissection:

- **Type A** dissections represent minor radiolucent areas within the coronary lumen during contrast injection with little or no persistence of contrast after the dye has cleared
- **Type B** dissections are parallel tracts, or a double lumen separated by a radiolucent area during contrast injection, with minimal or no persistence after dye clearance
- **Type C** dissections appear as contrast outside the coronary lumen ("extraluminal cap") with persistence of contrast after dye has cleared from the lumen
- **Type D** dissections represent spiral ("barber shop pole") luminal filling defects, frequently with excessive contrast staining of the dissected false lumen
- **Type E** dissections appear as new, persistent filling defects within the coronary lumen
- **Type F** dissections represent those that lead to total occlusion of the coronary lumen without distal antegrade flow



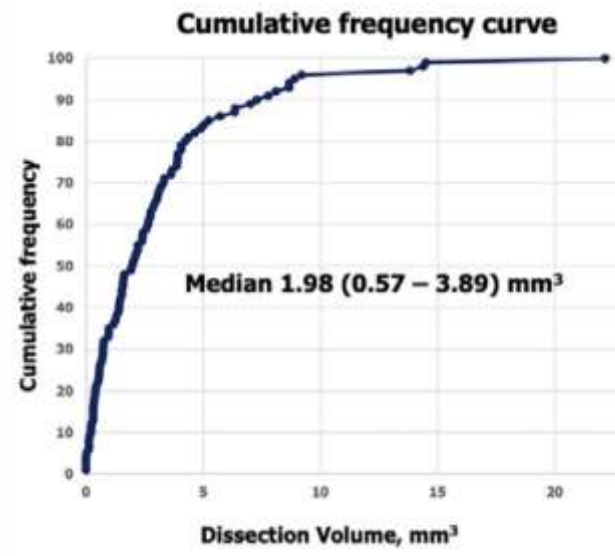
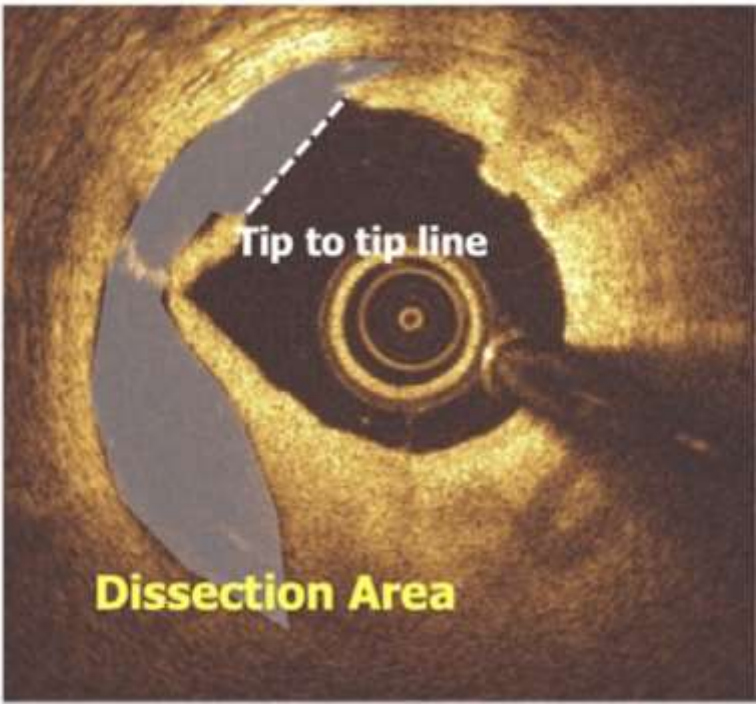
Type	Description	Angiographic Appearance	Accute Closure (%)
A *	Minor radiolucencies within the lumen during contrast injection with no persistence after dye clearance		-
B *	Parallel tracts or double lumen seperated by a radiolucent area during contrast injection with no persistence after dye clearance		3
C *	Extraluminal cap with persistence of contrast after dye clearance from the lumen		10
D *	Spiral luminal filling defects		30
E **	New persistent filling defects		9
F **	Non A-E types that lead to impaired flow or total occlusion		69

Dissection in DCB era

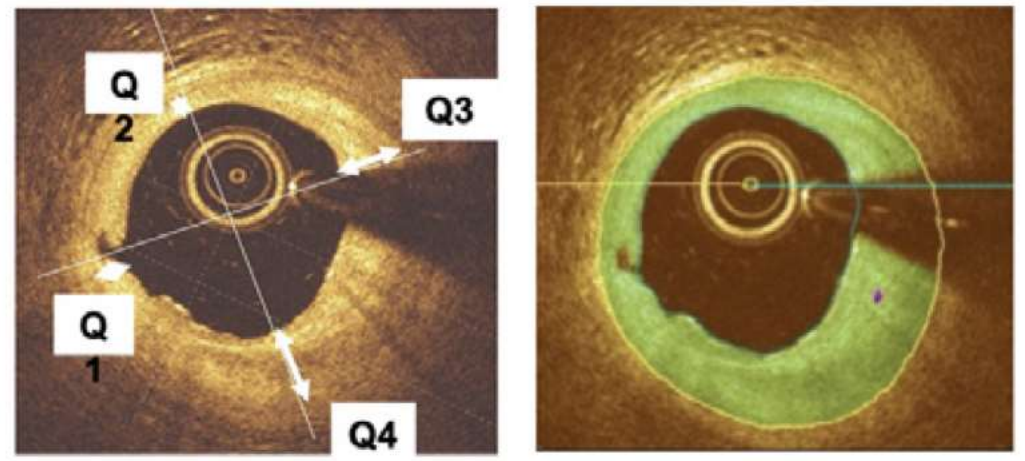
- Dissection may facilitate arrival of high drug concentration to media-adventitia.
- The risk of occlusion in minor degrees of dissections is very low due to potent DAPT strategies
- At médium or long term is not clear the relation between dissection and LLL or TLF
- Using IC imaging increase dissection recognition vs angio

Transform-1 trial : OCT data pre DCB use

Dissection was observed in 96% of cases vs 15% by angio



Where does fracture/dissection occur?



	Quartile1	Quartile2	Quartile3	Quartile4
Thickness, μm	320	510	540	485
Paired t-test (vs Q1)	-	<0.001	<0.001	0.001
Fibrous plaque	83%	56%	55%	63%

Fracture/dissection occurs at the thinnest site (320 μm) of fibrous intima (83%)

Serruys et al, Cardiovascular Revascularization Medicine (in press)

Risk of acute vessel closure?

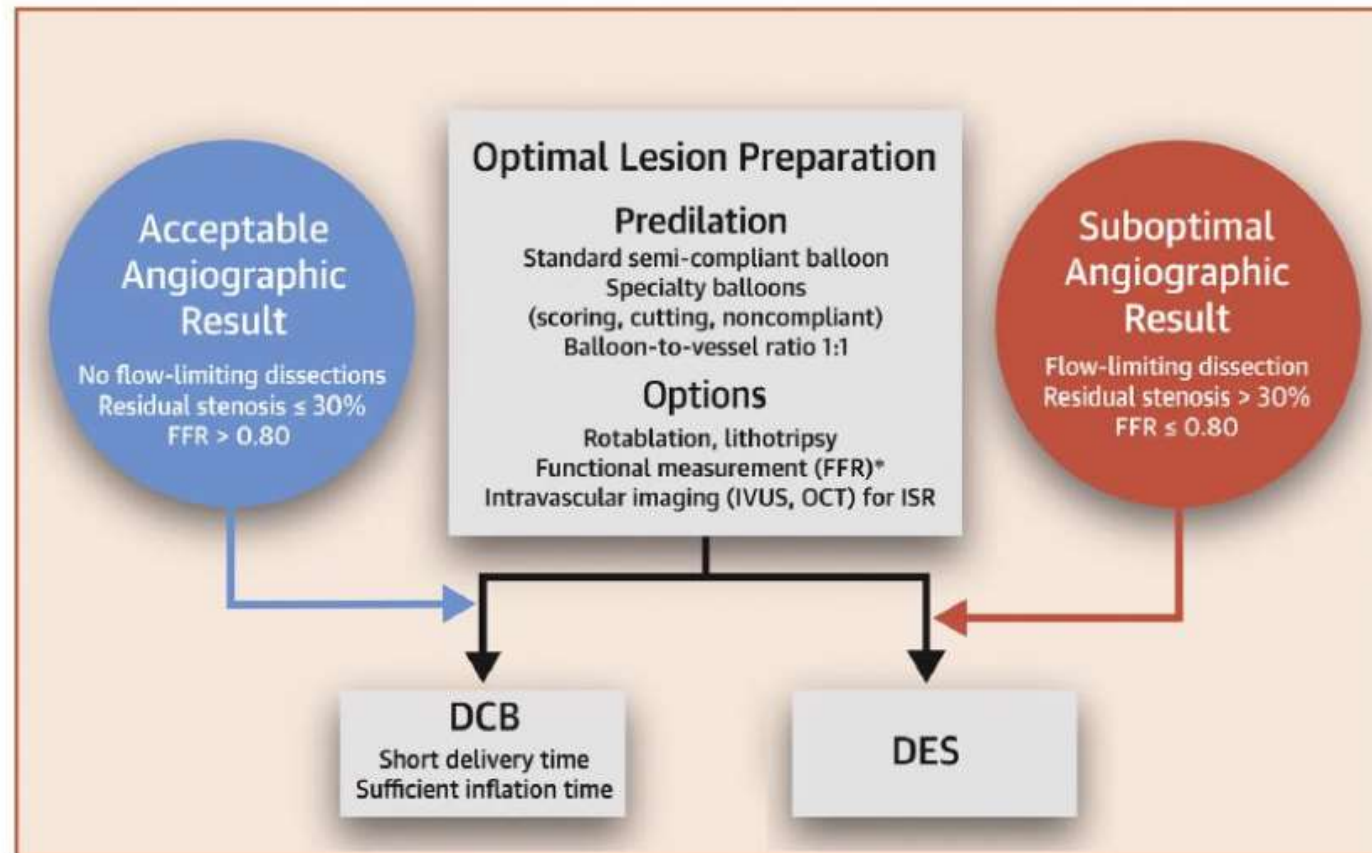
Drug-Coated Balloons for Coronary Artery Disease




Third Report of the International DCB Consensus Group

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CENTRAL ILLUSTRATION DCB-Only Strategy for PCI in Coronary Artery Disease



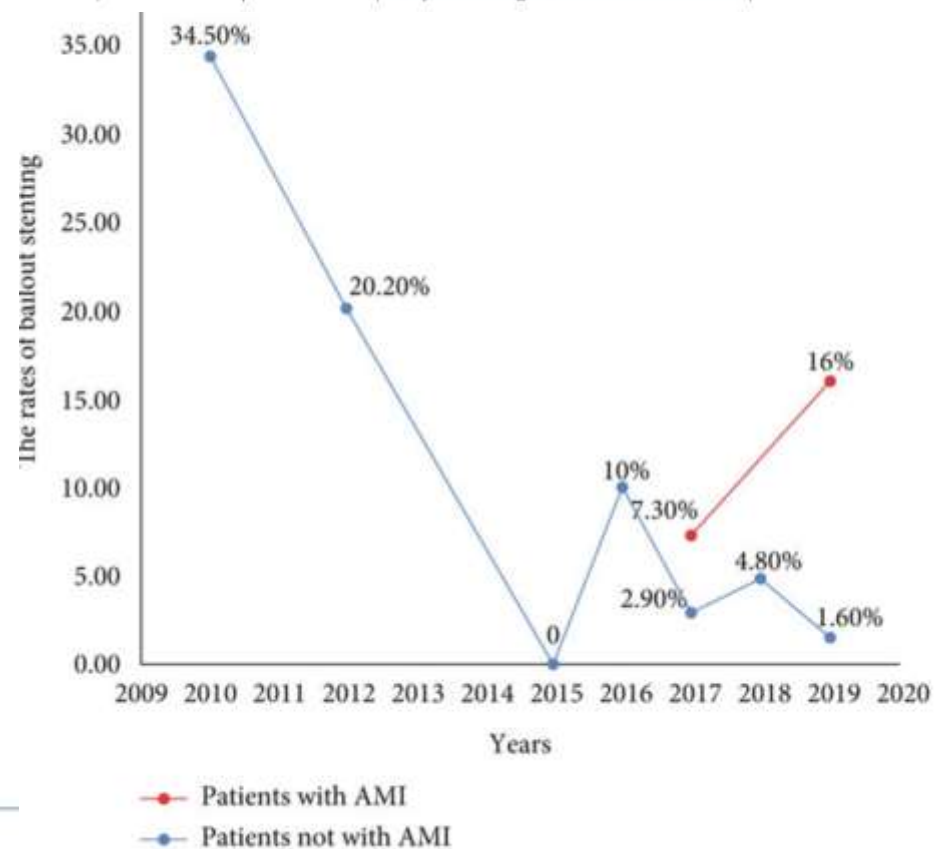
Risk of bail-out stenting-acute vessel closure-AMI

Research Article [Open Access](#)  

Drug-Coated Balloon for De Novo Coronary Artery Lesions: A Systematic Review and Trial Sequential Meta-analysis of Randomized Controlled Trials

Wei Liu, Min Zhang, Guangping Chen, Zongzhuang Li, Fang Wei 

First published: 01 September 2020 | <https://doi.org/10.1155/2020/4158363> | Citations: 7



Abrupt Vessel Closure

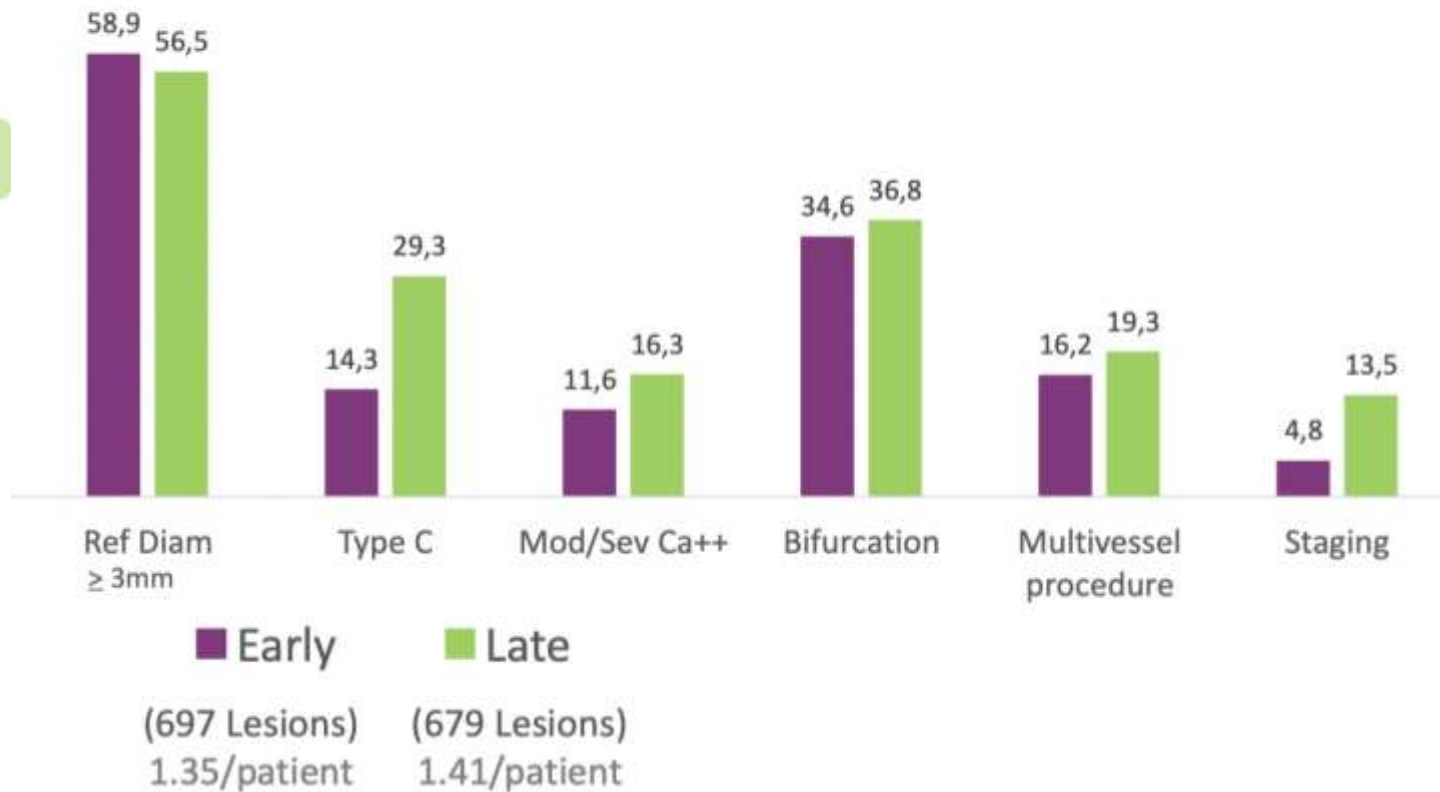
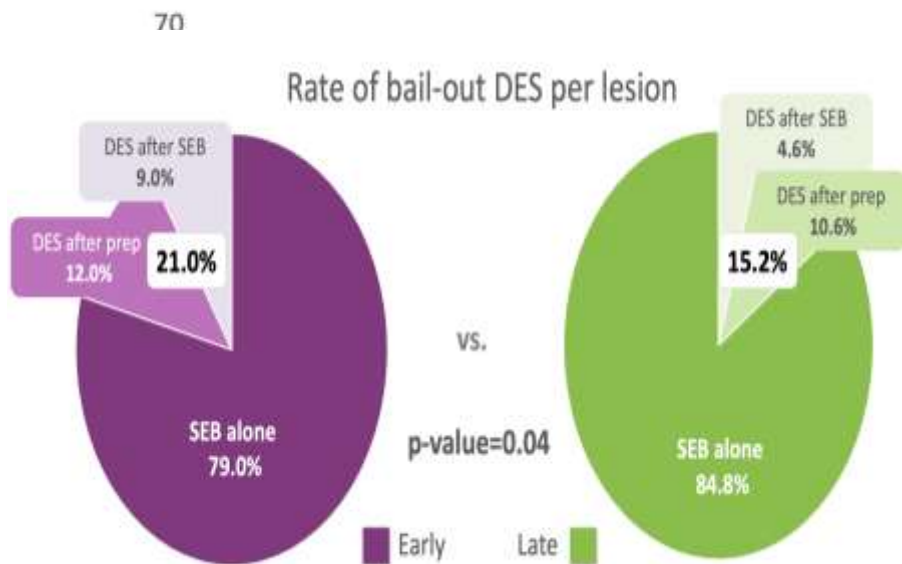
Pre-stent era	11%
Post-stent era	<1%
DCB:	0-1%

Myocardial Infarction

BELLO: 6-Months	DCB 1% vs DES 5.5%
DEBUT: 9-Months	DCB 0% vs BMS 6%
Basket-Small: 12-Months	DCB 2% vs DES 4%

Selution DE Novo Trial

Baseline angiographic characteristics (site reported)



Short-Term Safety of Drug-Coated Balloons Compared to Drug-Eluting Stents in De Novo Coronary Disease



N. Corballis, I. Merinopoulos, T. Gunawardena, R. Natarajan, A. Clark, V. Vassiliou and S. Eccleshall
Cardiovascular Revascularization Medicine, 2024-08-01, Volume 65, Pages 34-35, Copyright © 2024

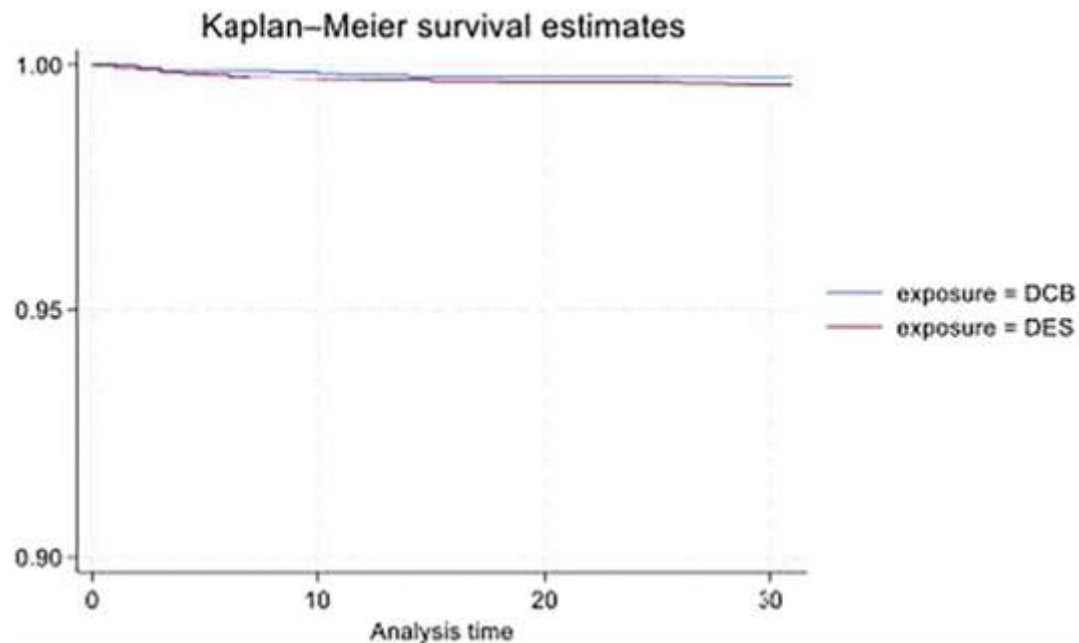


Cardiovascular
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Medicine

Volume 65

Background: There is an expanding role in the use of drug coated balloons (DCBs) in de novo coronary disease. Whilst stents evolved to facilitate bail out in vessel threatening dissection, their safety benefit against DCB has not been evaluated. We sought to identify any short-term safety concerns when comparing DCB with 2nd generation drug eluting stent (DES) for de novo coronary disease.

N: 9975 all-comer patients and 10,922 lesions treated with either a DCB (3506 lesions) or 2nd generation DES (7416 lesions) de novo coronary disease.



30-day target vessel MI: 19 (0.5%) DCB v 51 (0.7%) DES,
acute vessel MI : 10 (0.3%) DCB v 22 (0.3%) DES
All-cause mortality: 34 (1.0%) DCB v. 71 (1.1%) DES,

This has led us to modify our approach to dissections into 1) Type 1 (non-vessel threatening dissection and 2) type 2 (vessel threatening dissection).

Angio dissection post DCB and risk

Type A: luminal haziness: minor radiolucent areas within the coronary lumen during contrast injection with no persistence of contrast after the dye has cleared



Type B: linear dissection: parallel tracts or a double lumen, with no persistence of dye



Type C: xtra-luminal contrast staining: extra luminal "cap" of dye with persistence of contrast



Type D: spiral dissection, usually with excessive contrast staining of the false lumen



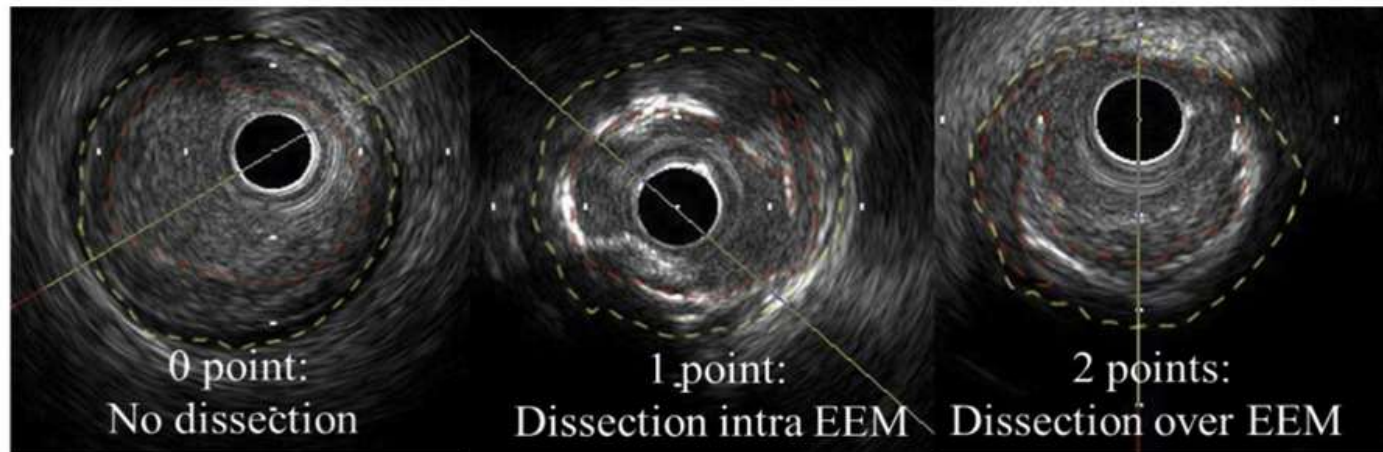
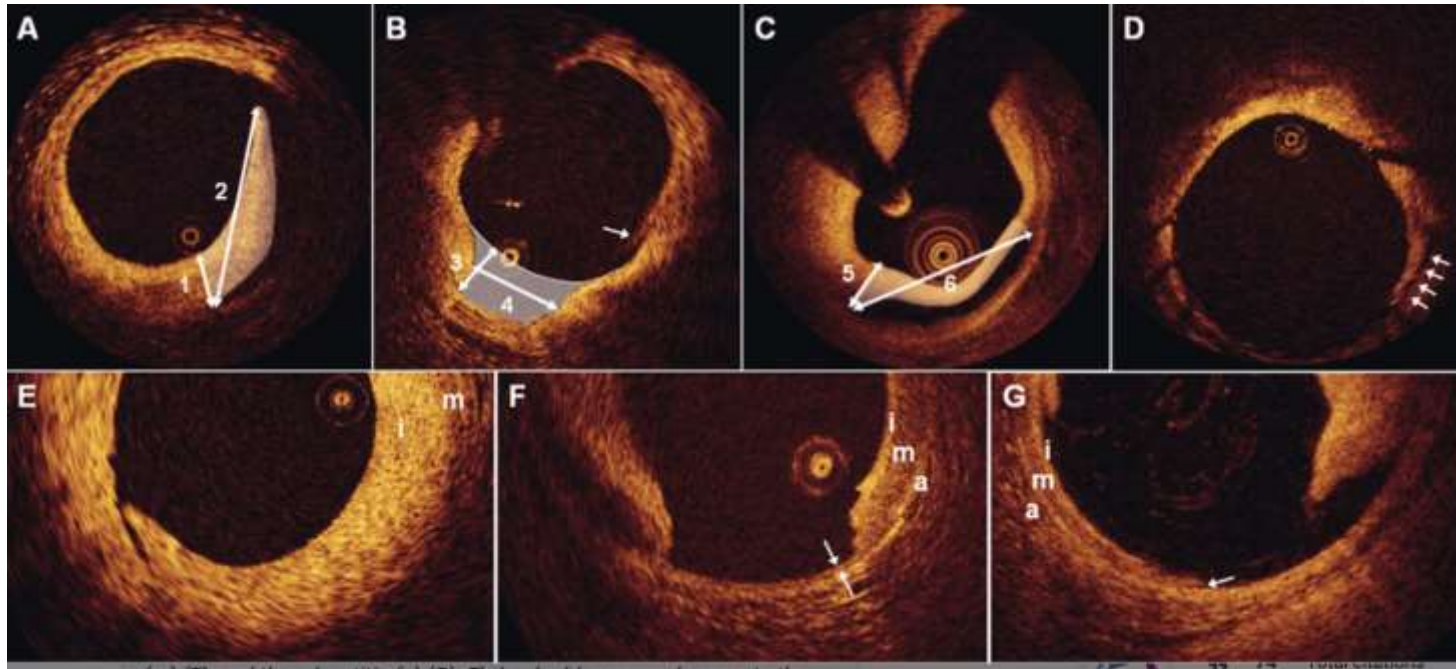
Type E: dissection with persistent filling defects in the coronary lumen

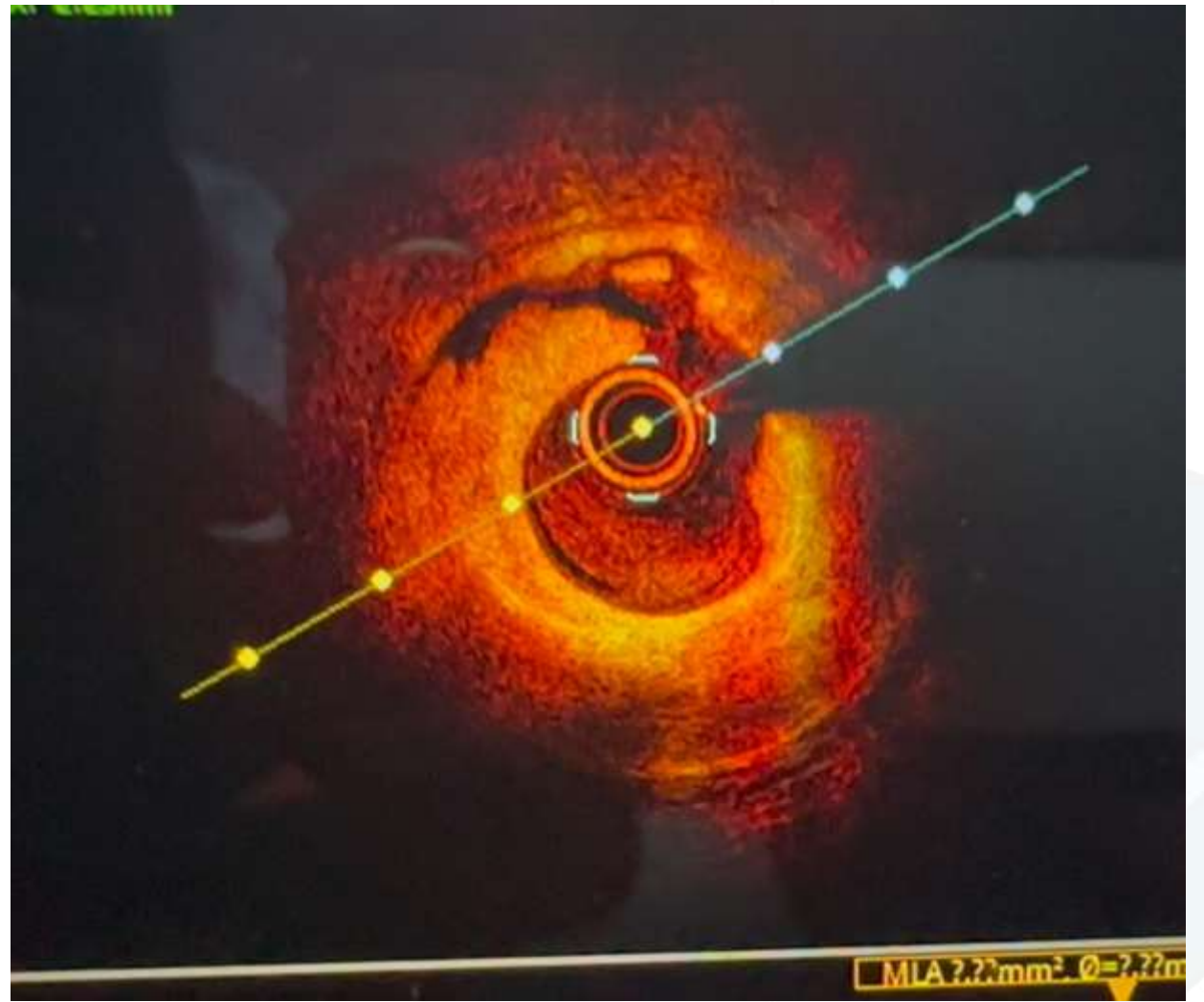
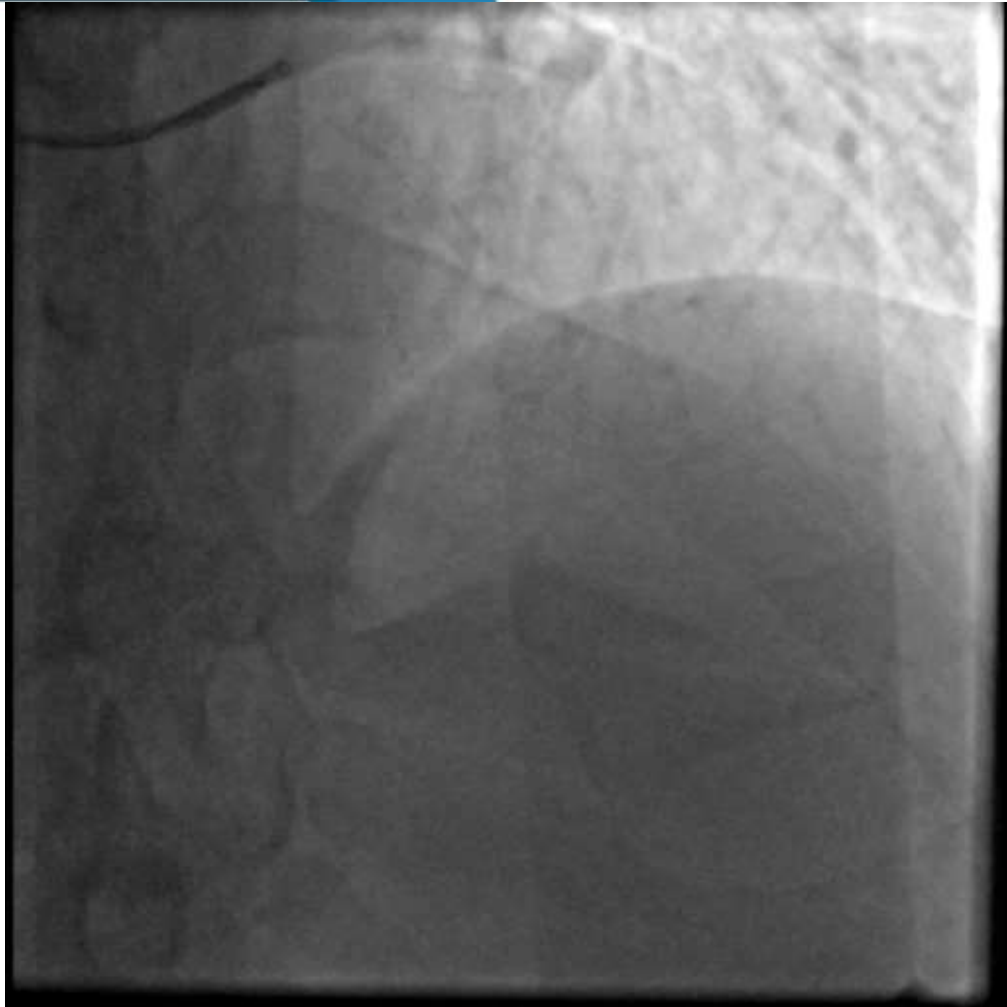


Type F: dissection with total occlusion of the coronary lumen and no distal antegrade flow



IC imaging dissection post DCB





- A **non-flow limiting intimal dissection** can be left untreated.
- Using IV imaging the presence of medial dissection, intramural hematoma, or extramedial injury should be fixed with “bail-out” stenting.

Provisional drug-coated balloon treatment guided by physiology on de novo coronary lesion

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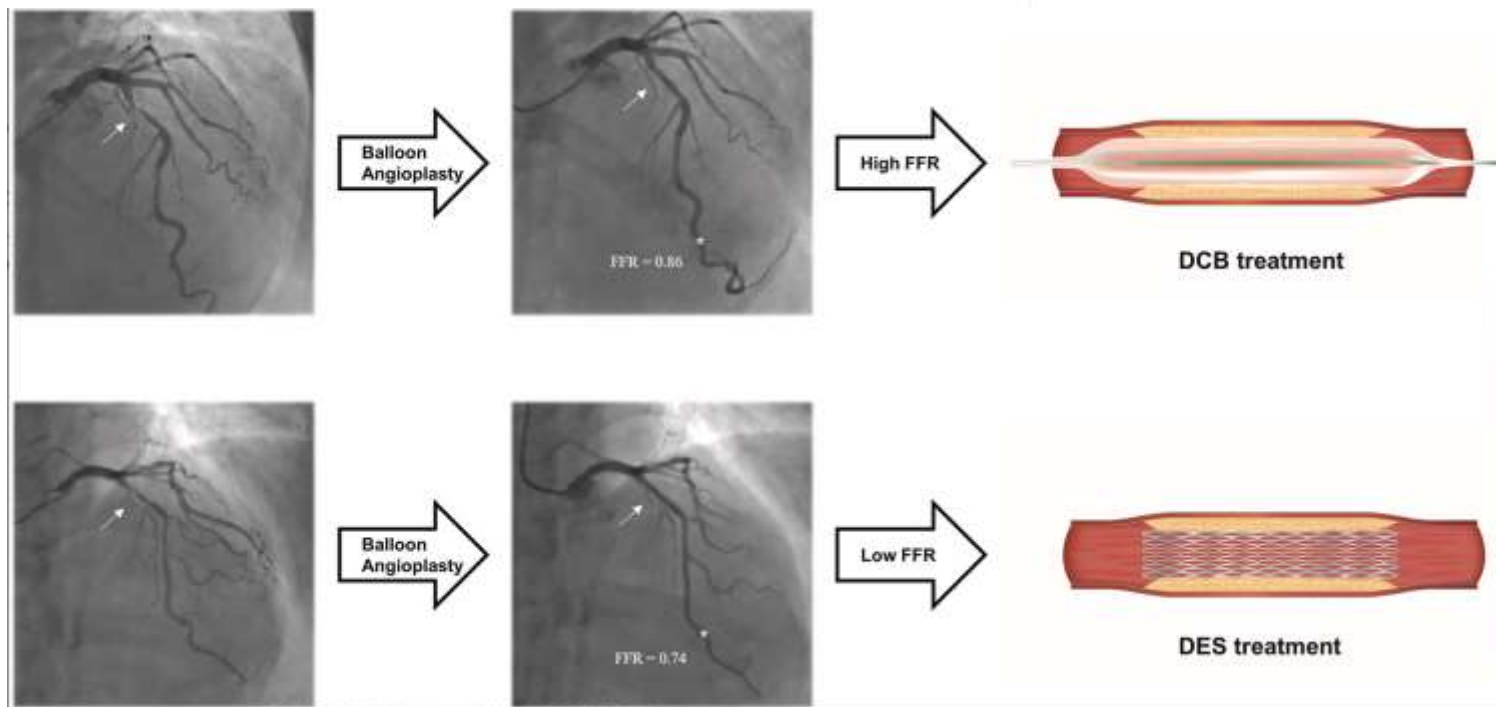
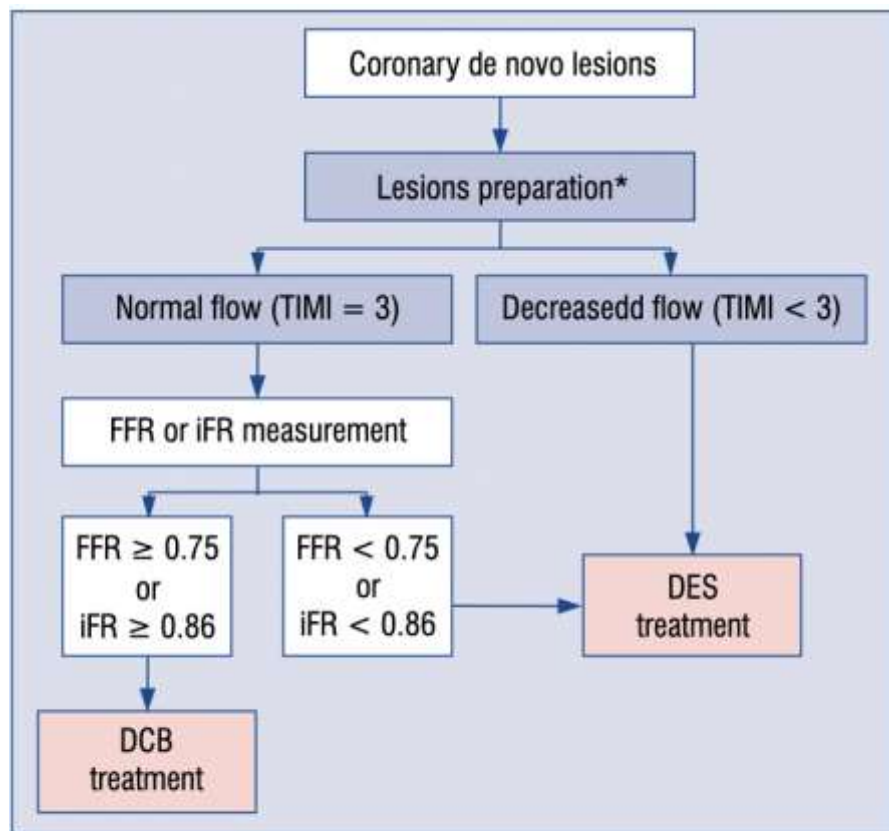


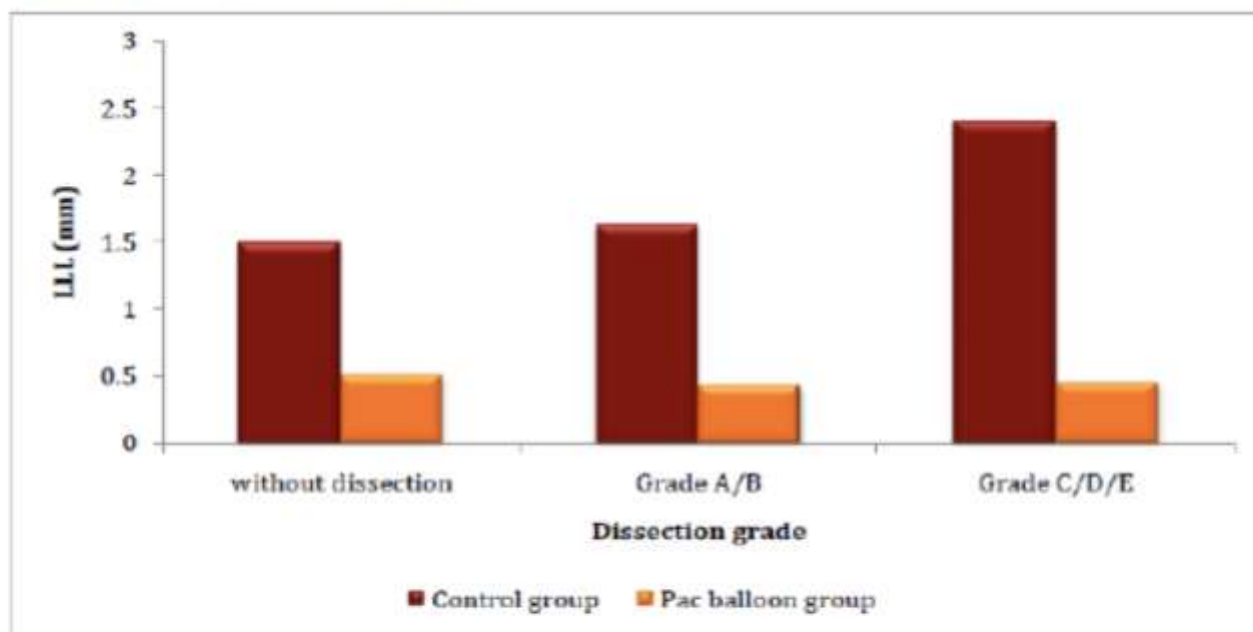
Figure 3. Provisional drug-coated balloon (DCB) strategy guided by fractional flow reserve (FFR). The acceptable angiographic and functional criteria after balloon

Risk of TLR-AMI in FU?

High-Grade, Non-Flow-Limiting Dissections Do Not Negatively Impact Long-term Outcome After Paclitaxel-Coated Balloon Angioplasty: An Additional Analysis From the THUNDER Study

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Figure 4: LLL by dissection grade



LLL: Late Lumen Loss



Effect of Drug-Coated Balloons in Native Coronary Artery Disease Left With a Dissection

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TABLE 3 Angiographic Follow-Up of Patients With Dissection After DCB PCI

	Dissection Cohort (n = 48)
Reference vessel diameter, mm	2.87 (2.11 to 2.98)
Minimal lumen diameter, mm	2.42 (2.22 to 2.66)
Diameter stenosis, %	12 (8 to 20)
LLL, mm	0.14 (-0.14 to 0.42)
Complete vessel healing	45 (93.8)
Binary restenosis	3 (6.2)

FIGURE 4 The Fate of Dissections After DCB Angioplasty

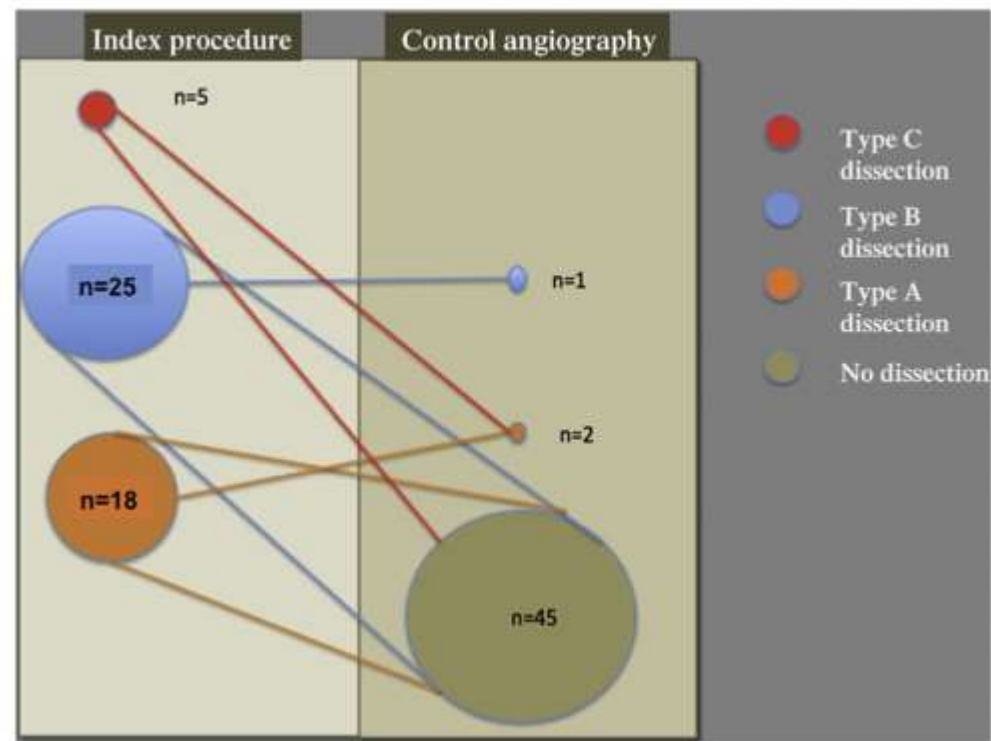
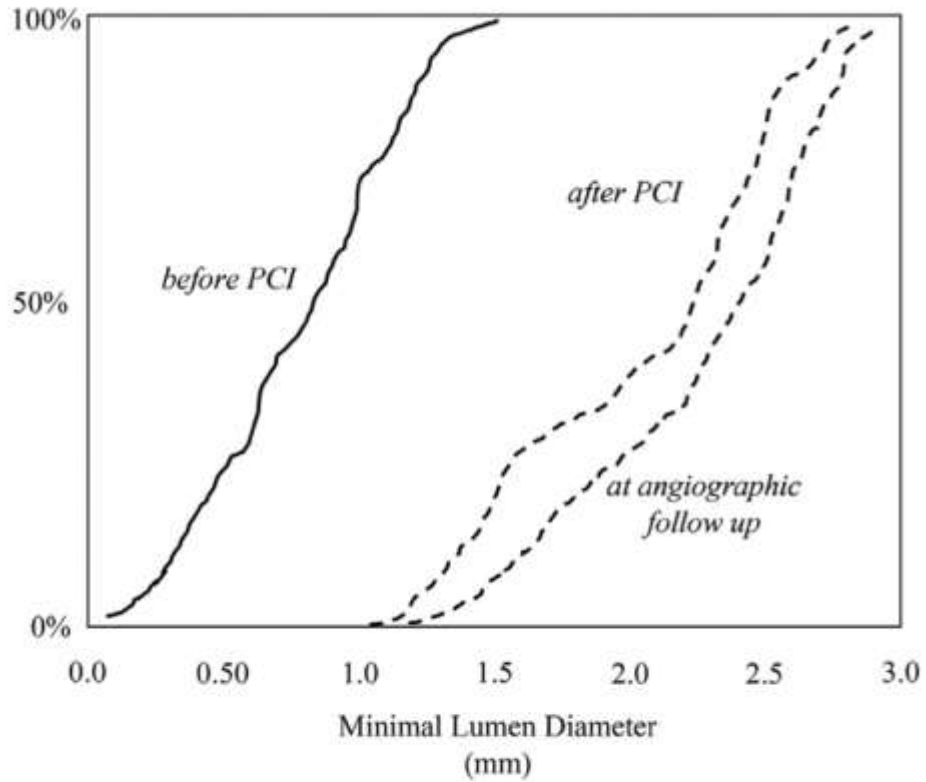
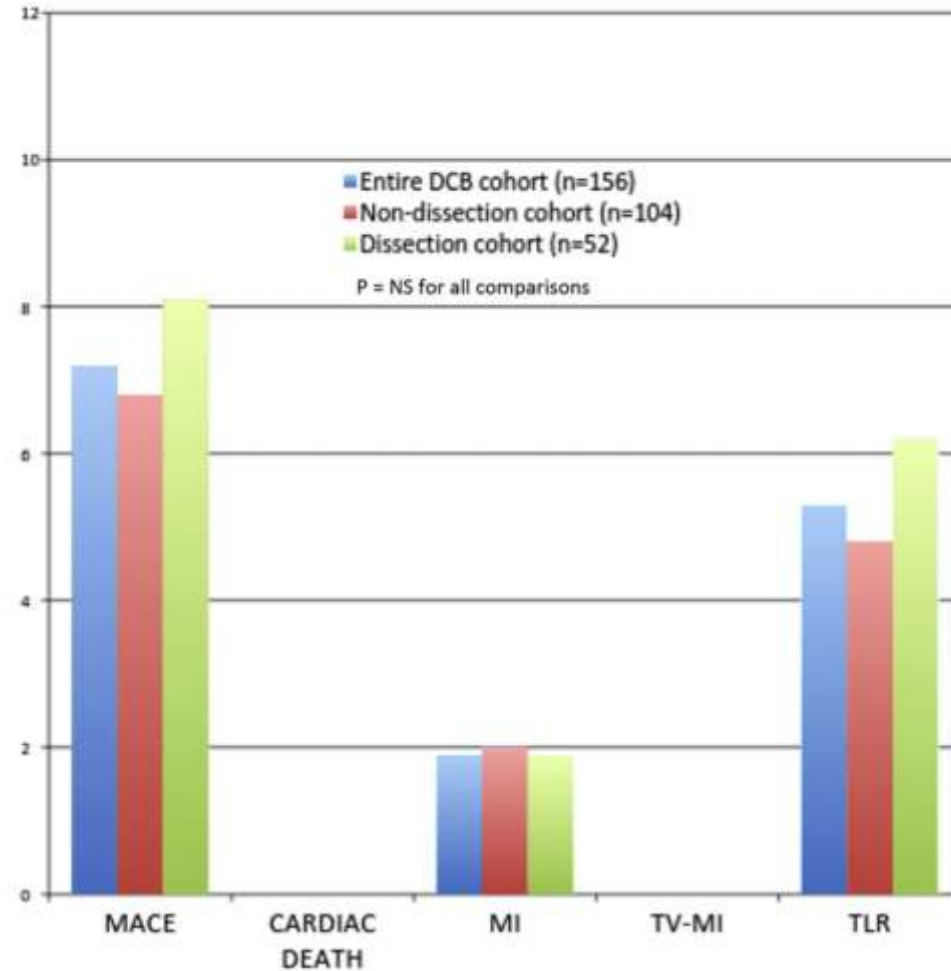


FIGURE 1 MLD Before DCB PCI, After DCB PCI, and at Angiographic Follow-Up in Patients Left With a Dissection



Notably, there was a diffuse lumen enlargement at angiographic control. DCB = drug-coated balloon; MLD = minimal lumen diameter; PCI = percutaneous coronary intervention.

FIGURE 3 Clinical Follow-Up After 9 Months in the Entire Population and in the Dissection and No-Dissection Cohorts



Possible mechanism of late lumen enlargement after treatment for de novo coronary lesions with drug-coated balloon

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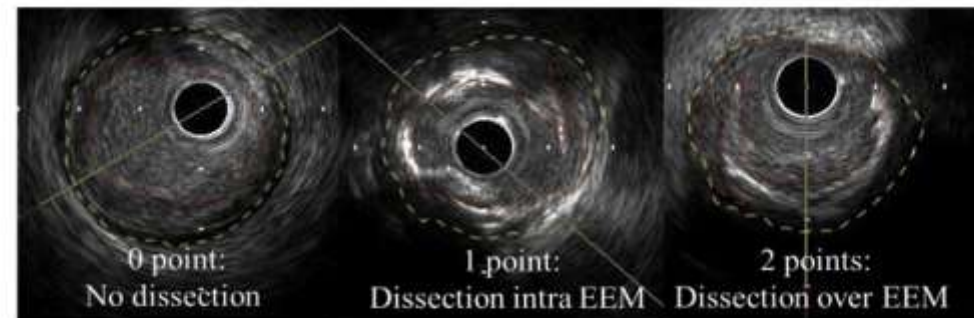
ABSTRACT

Background: Drug-coated balloon (DCB) treatment for de novo coronary artery disease has demonstrated late lumen enlargement (LLE) in mid-term follow-up and it was considered as clinical benefit; however, its mecha-

46 pts
DCB PCI (Sequent please neo Paclitaxel)
IVUS in index procedure and at 9 months

28 pts non Flow limiting angio dissection (no bail-out stent)
43 pts IVUS dissection
Mean Dissection index 0,44

**At 9 months: evidence of Late lumen enlargement
evidence of plaque regression
near 90% healed-dissections
TLR 3,7 % (2 pts)**



Dissection index =
Sum of each dissection point in every 1-mm interval / lesion length

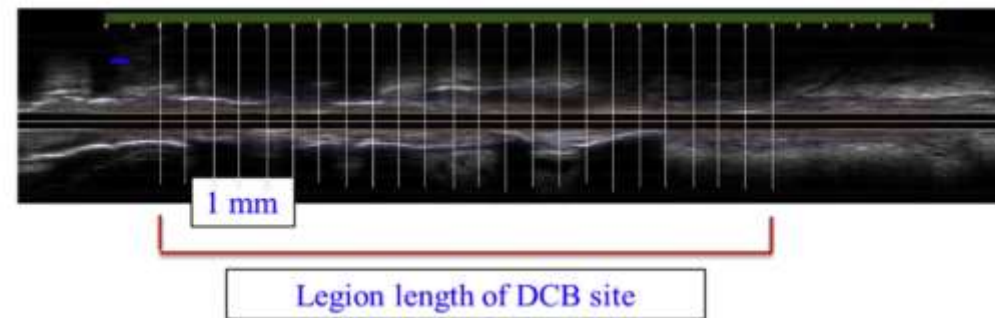
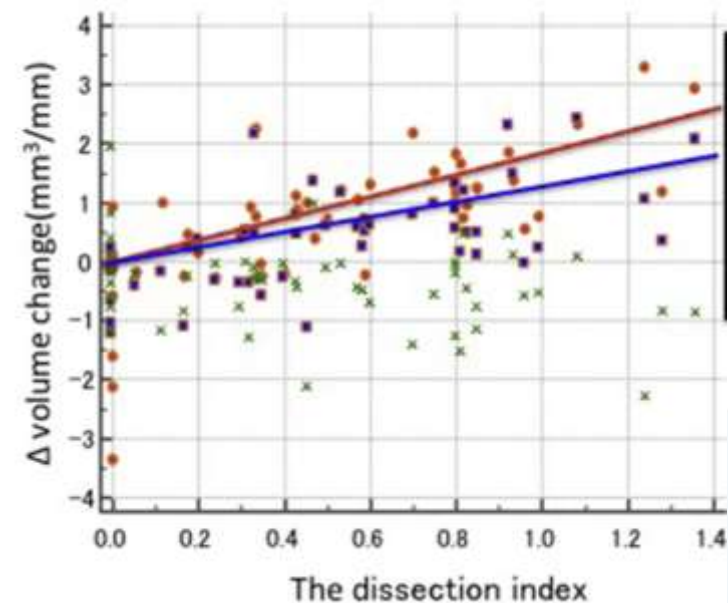


Table 4
Regression analysis for predicting changing Δ mean lumen volume.

Variable	Univariate		Multivariate	
	t	p-value	t	p-value
Minimal lumen diameter of post DCB	-1.504	0.14		
% area stenosis of post DCB	-0.099	0.92		
Acute gain	0.081	0.94		
NHLBI dissection classification	1.901	0.06		
Mean EEM volume of post DCB	-2.080	0.04	-0.342	0.73
Mean lumen volume of post DCB	-2.231	0.03	-0.571	0.57
Mean plaque volume of post DCB	-1.816	0.08		
Mean %plaque volume of post DCB	-0.131	0.90		
Minimum lumen area of post DCB	-1.794	0.09		
Balloon / lumen ratio	2.531	0.01	-0.295	0.77
DCB / lumen ratio	1.319	0.19		
Dissection in IVUS image	5.114	<0.0001	4.647	<0.0001
Dissection index	7.349	<0.0001	7.249	<0.0001
Remodeling index	-1.425	0.16		
Eccentricity index	0.921	0.36		

NHLBI; The National Heart, Lung and Blood Institute, EEM; external elastic membrane.
DCB; drug coated balloon, IVUS; intravascular ultrasound.



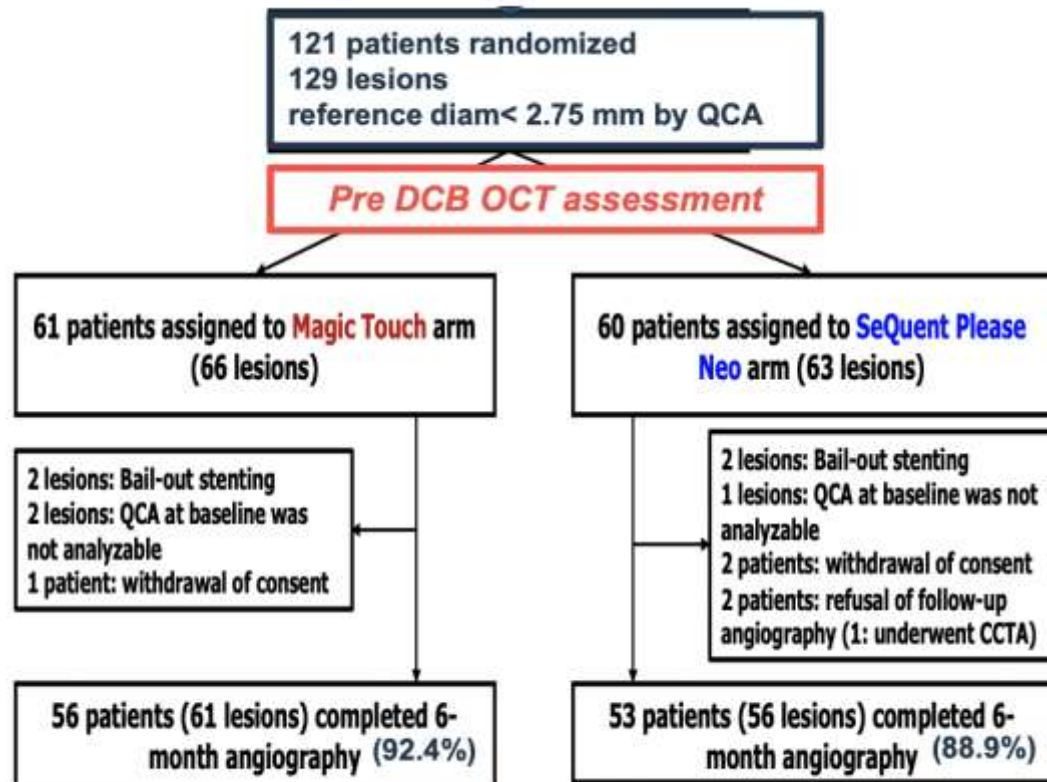
- Δ mean lumen volume $R=0.713$ $p<0.0001$
- Δ mean vessel volume $R=0.602$ $p<0.0001$
- × Δ mean plaque volume $R=-0.232$ $p=0.082$

A Prospective Randomized Trial Comparing Sirolimus-Coated Balloon With Paclitaxel-Coated Balloon in De Novo Small Vessels

Kai Ninomiya MD, Patrick W. Serruys MD, PhD, Antonio Colombo MD, Bernhard Reimers MD, Sandeep Basavarajiah MD, PhD, Faisal Sharif MD, PhD, Luca Testa MD, PhD, Carlo Di Mario MD, PhD, Roberto Nerla MD, Daixin Ding MSc, Jiayue Huang MSc, Nozomi Kotoku MD, Shigetaka Kageyama MD, Momoko Kageyama MD, Emelyne Sevestre BA, Simone Fezzi MD, Jouke Dijkstra PhD, Neil O'Leary PhD, Marie Angele Morel BSc, Scot Garg MD, PhD, Bernardo Cortese MD, PhD and Yoshinobu Onuma MD, PhD
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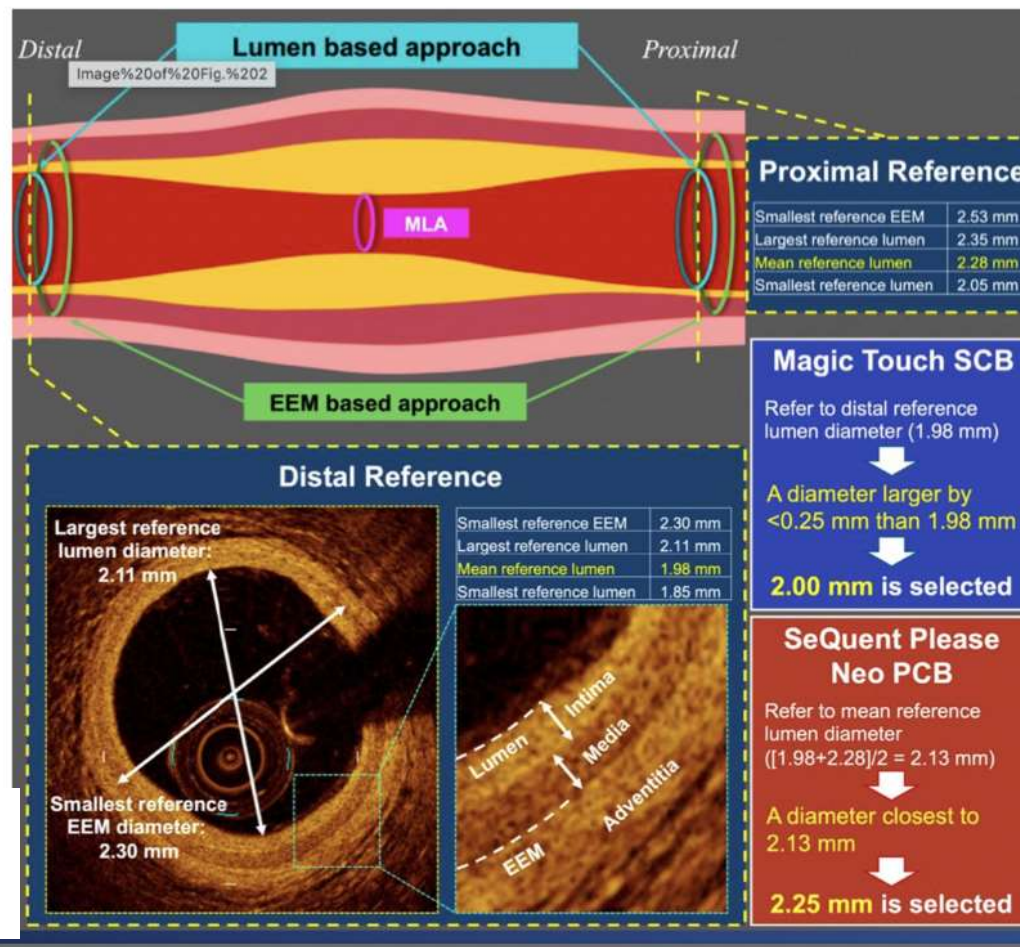
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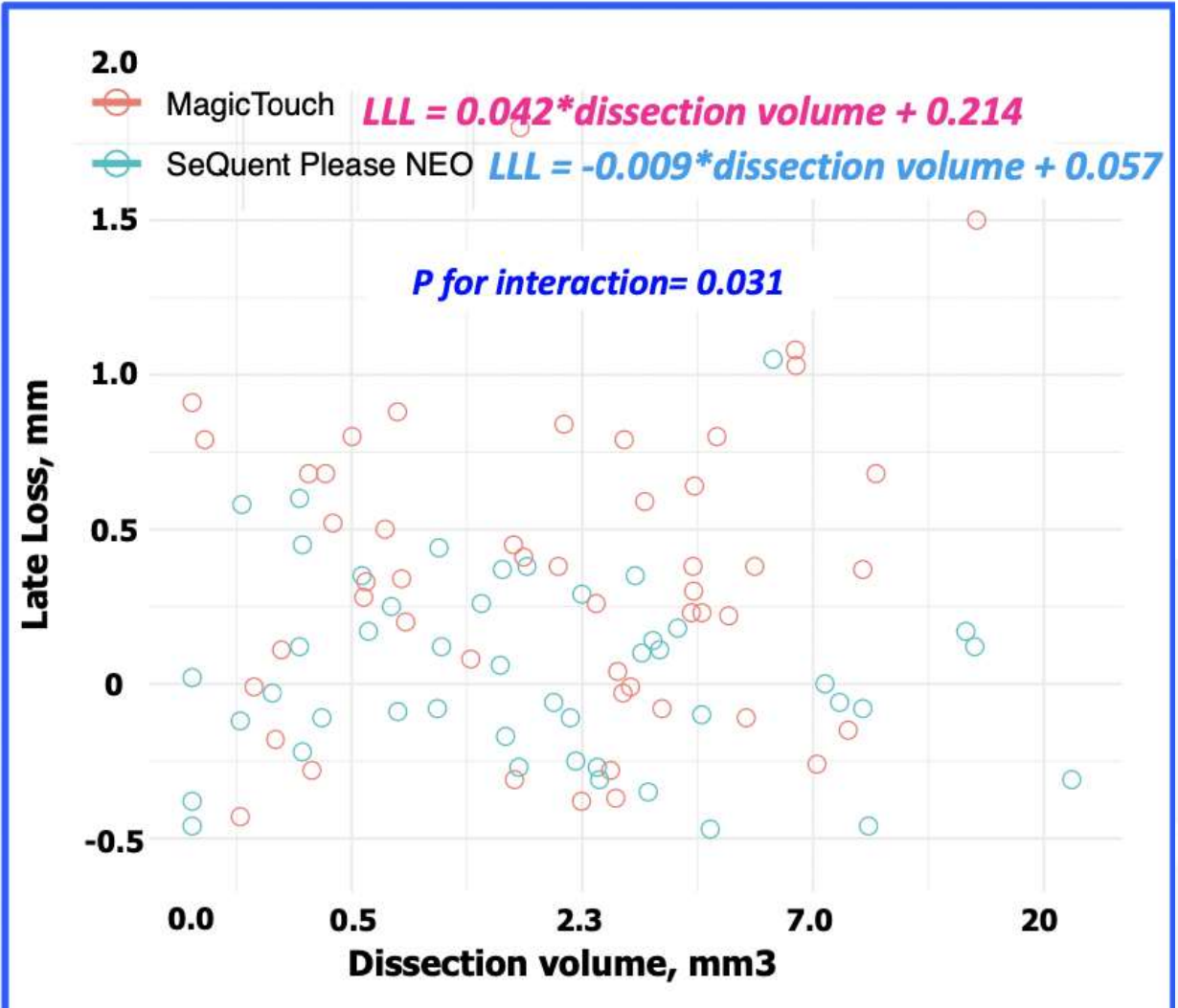
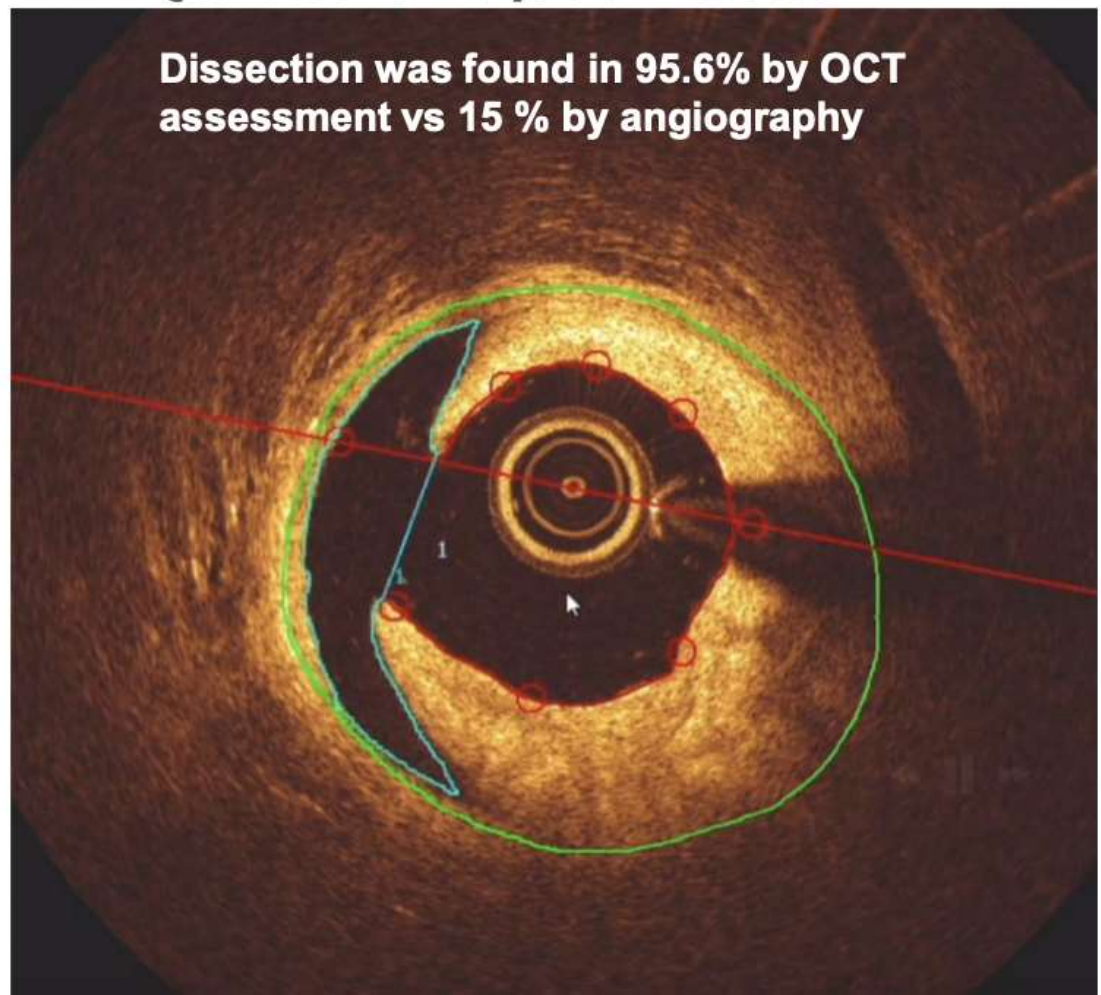
The Rationale for the Pre DCB OCT Assessment is to obtain OCT-derived lumen measurement for DCB balloon-sizing

1. To “calibrate” the Drug Coating balloon
2. To optimize wall apposition and drug transfer to the vessel wall.
3. To elucidate the impact of the dissection volume on angiographic late loss, assessed by quantitative OCT (QCU-CMS).

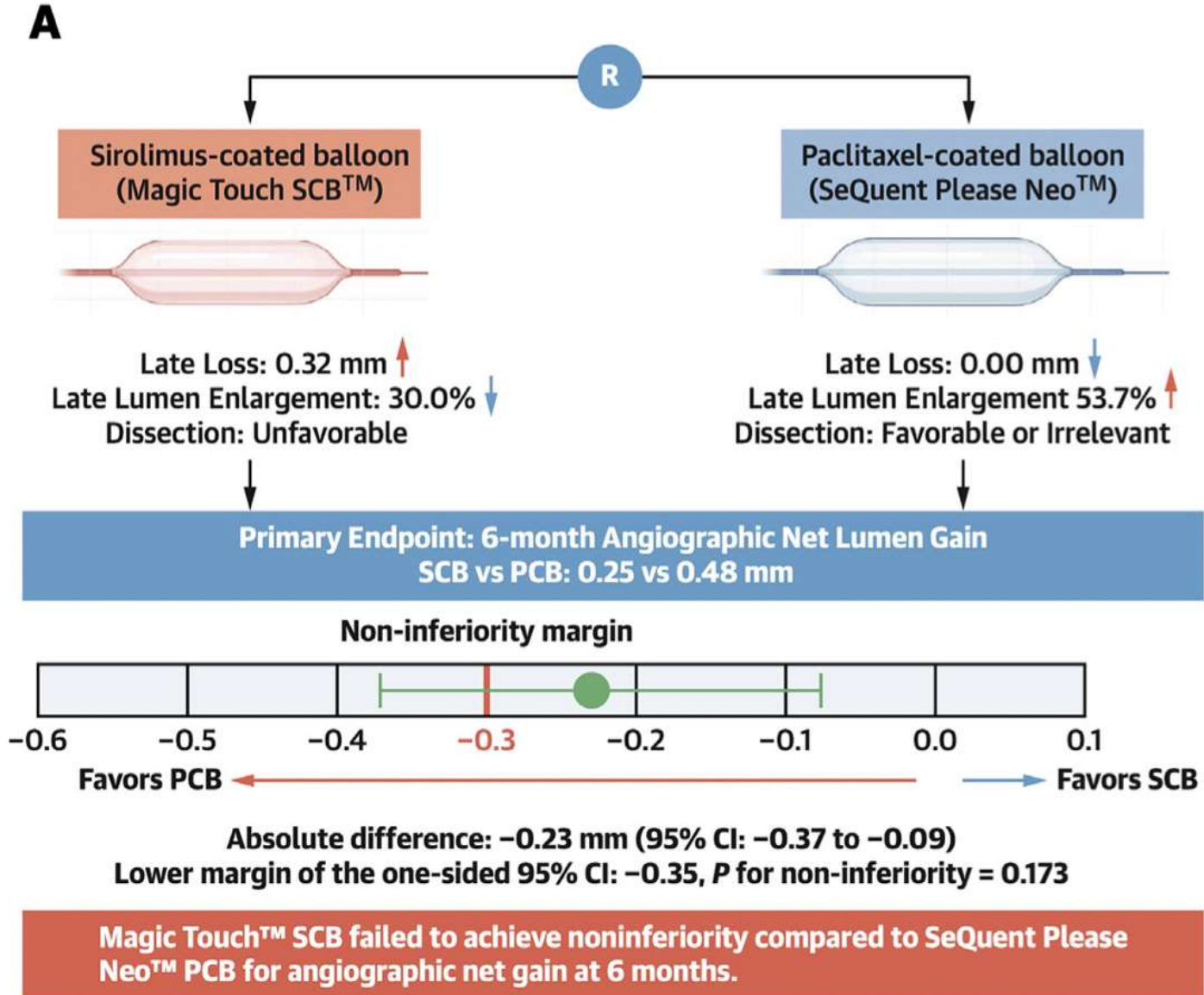
DCB size / reference lumen diameter Ratio by OCT was 1.03



Quantitative Analysis of Dissection



With SCB, late loss increases as a function of dissection volume, while with PCB, late loss is not related to dissection and even decreases as a function of the increase in dissection volume.



In summary

- Leaving dissections untreated in 2024 after DCB appears to be **safe if there is no Flow-limiting lesions** and IC imaging rule out media dissection or hemathoma
- Incidence of **acute vessel closure is similar to stenting** following recommendations and contemporary DAPT
- No big effect of dissection in LLL or mid term clinical outcomes (seem to be beneficial in paclitaxel DCB)