DEB in small vessels

Dr Mario Araya

Chile

- Honoraria fees from Terumo , Cordis

RISK OF BINARY ANGIOGRAPHIC RESTENOSIS AFTER PERCUTANEOUS CORONARY INTERVENTION ACCORDING TO REFERENCE VESSEL DIAMETER OF THE TARGET SEGMENT

	SMALL (<2.75 mm)	MEDIUM (2.75-3.25 mm)	LARGE (>3.25 mm)
Balloon-only PTCA	35-55%	25-40%	20-35%
Bare-metal stents	25-50%	15-35%	15-20%
Drug-eluting stents with			
relatively high late loss (eg Endeavor™)	30-35%	20-30%	5-12.5%
medium late loss (eg Taxus™)	20-25%	10-20%	2.5-7.5%
low late loss (eg Cypher™ or Xience™)	10-15%	5-10%	0-5%

Data from Agostoni et al, C-SIRIUS, ENDEAVOR-2, ENDEAVOR-3, MICROSCOPE, SES-SMART, SIRIUS, SIRTAX, SPIRIT-2, SPIRIT-3, TAXUS-5, and TAXUS-6, or estimated from other unpublished sources

Small vessel PCI with DES-1 year outcome

Prospective-SPIRIT SV trial

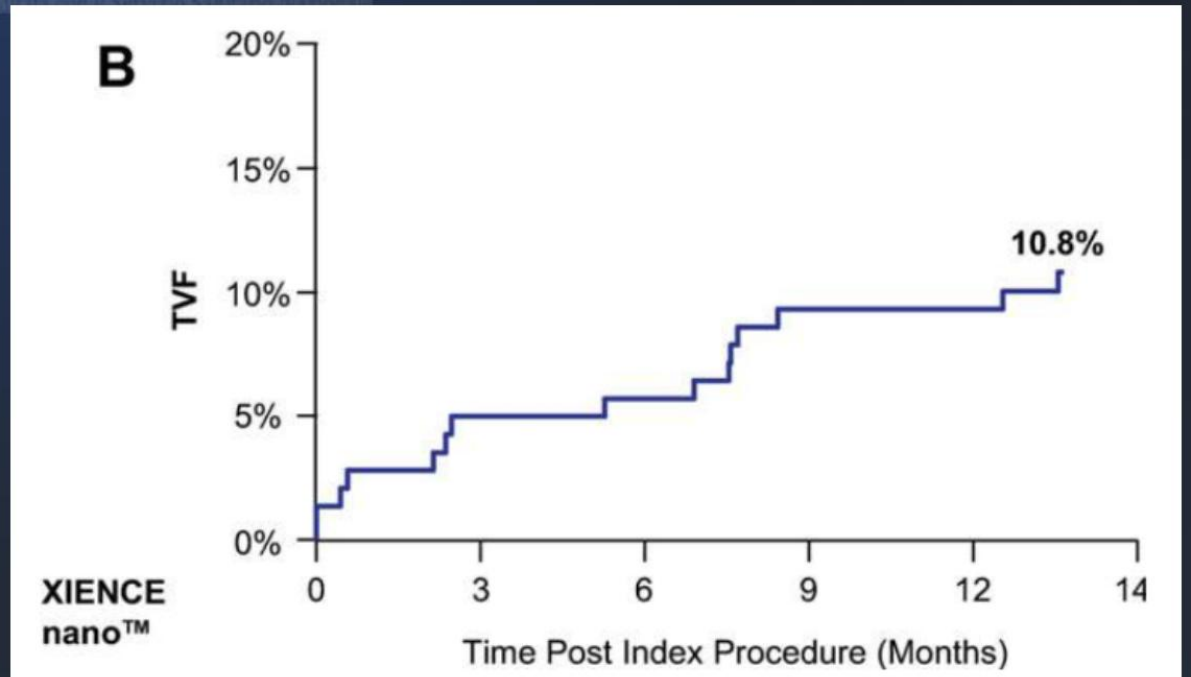
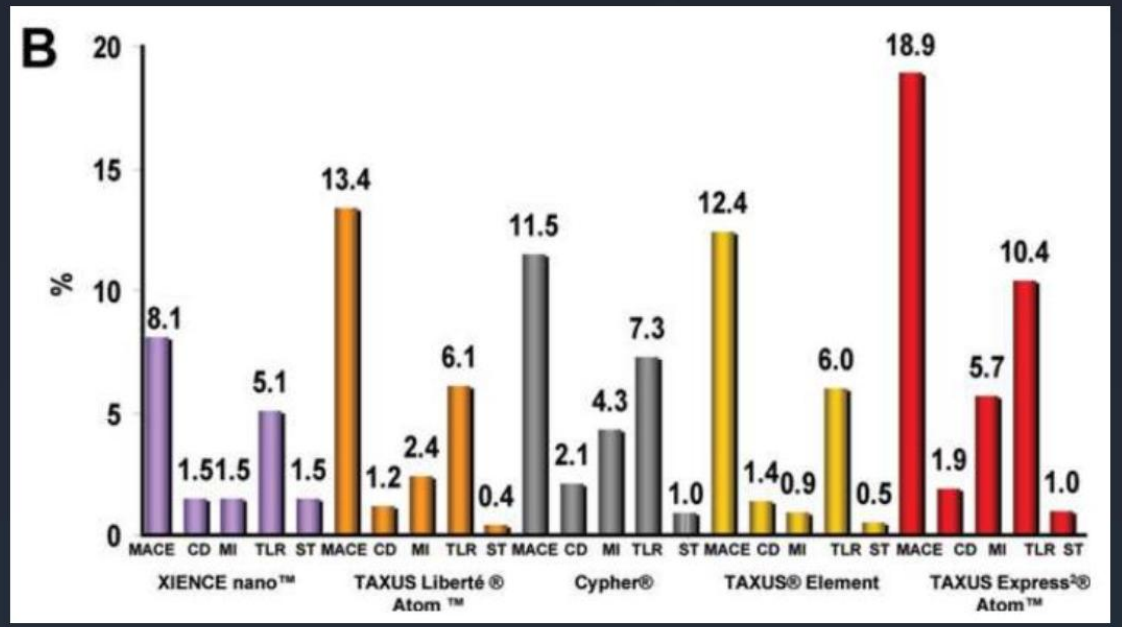
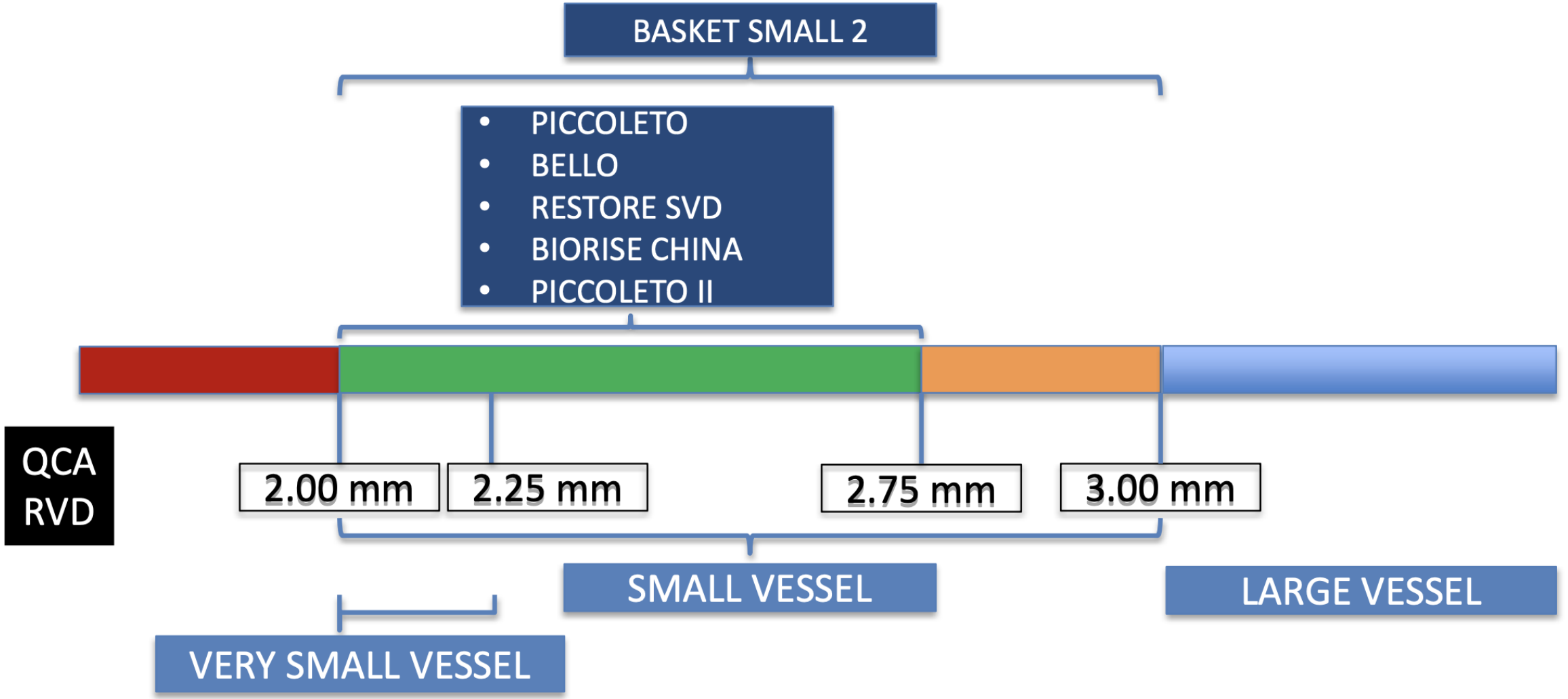


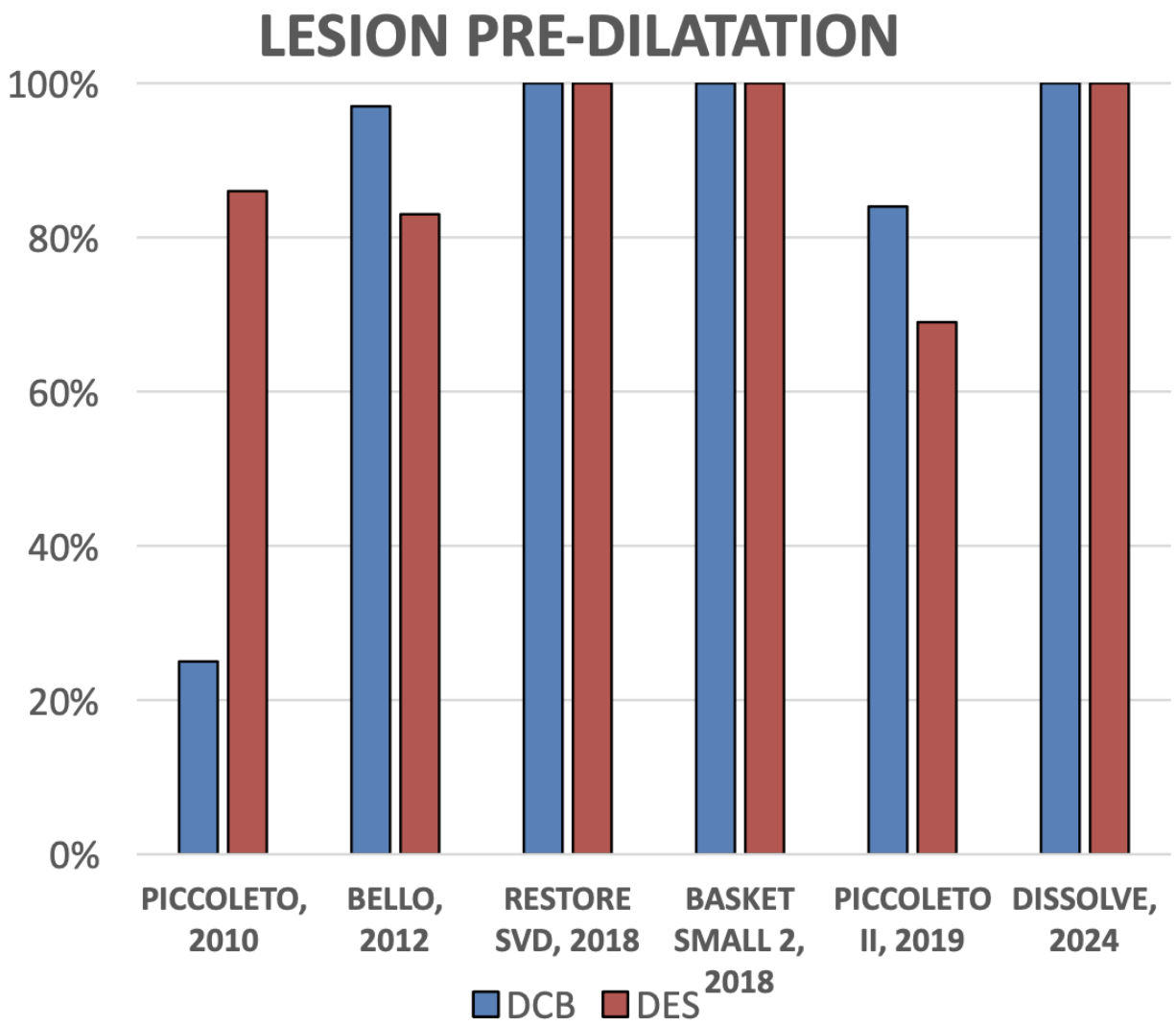
Fig. 2. Kaplan–Meier curve for the (a) primary endpoint target lesion failure and (b) secondary composite endpoint target vessel failure. All patients included were treated with the XIENCE nano EECSS.

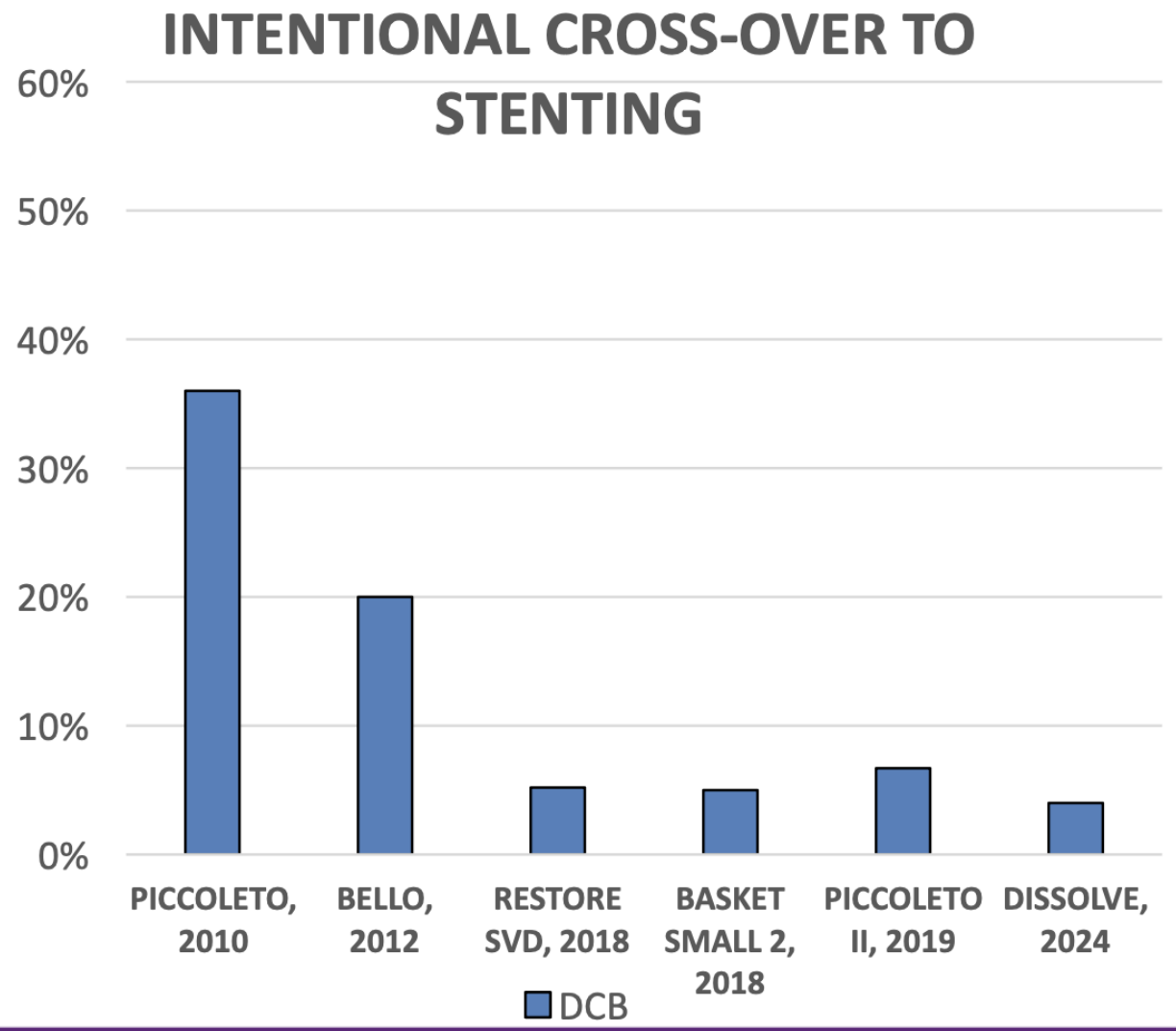


Cannon, CCI 2012


BASKET SMALL 2
PICCOLETO
BELLO
RESTORE SVD
BIORISE CHINA
PICCOLETO II
QCA
RVD
2.00 mm
2.25 mm
2.75 mm
3.00 mm
SMALL VESSEL
LARGE VESSEL
VERY SMALL VESSEL

Study name	DCB	Comparator	n	Reference vessel	Follow-up (clinical-angio)	Primary endpoint
PICCOLETO, 2010	**DIOR PCB**	TAXUS Libertè PES	57	<2.75	6 M angio 9 M clinical	6M DS (ITT)
BELLO, 2012	**INPACT FALCON PCB**	TAXUS Libertè PES	182	<2.8	6 M angio 12-36 M clinical	6M LLL (ITT)
RESTORE SVD, 2018, 2020	**RESTORE PCB**	Resolute Integrity ZES	230	2.00-2.75 Length<26	9-12 M angio 12-24 M clinical	9M DS (ITT)
BASKET-SMALL2, 2018,2020	**SEQUENT PLEASE PCB**	TAXUS PES and XIENCE EES	758	RVD 2.00-3.00	12-36 M clinical	12M MACE (non inferiority)
PICCOLETO II, 2019, 2022	**ELUTAX SV/EMPEROR PCB**	Xience EES	232	RVD 2.00-2.75 Length≤25	6 M angio 12-36 M clinical	6M LLL (ITT)
DISSOLVE, 2024	**Dissolve PCB**	Resolute DES	247	RVD 2-2.75	9M angio 12 M clinical	9M DS (ITT)


LESION PRE-DILATATION
100%
80%
60%
40%
20%
0%
PICCOLETO, 2010
BELLO, 2012
RESTORE SVD, 2018
BASKET SMALL 2, 2018
PICCOLETO II, 2019
DISSOLVE, 2024
DCB
DES


INTENTIONAL CROSS-OVER TO STENTING
60%
50%
40%
30%
20%
10%
0%
PICCOLETO, 2010
BELLO, 2012
RESTORE SVD, 2018
BASKET SMALL 2, 2018
PICCOLETO II, 2019
DISSOLVE, 2024
DCB

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MEXICO CITY

Drug-coated balloon vs. drug eluting stent for small coronary vessel disease: 6-mo. primary outcome of the PICCOLETO II randomized clinical trial.

A study from the Italian Society of Interventional Cardiology GISE.
(NCT 03899818)

Bernardo Cortese, MD, FESC

Multicenter, investigator-driven, open-label, prospective RCT

170 screened and not enrolled

patients with *de novo* lesions in SVD
(diameter ≤2.75 mm)

January 2015-May 2018

232 enrolled
centralized blocks RANDOMIZATION 1:1 (prior to GW)

118 Elutax SV DCB
Predilatation, DCB dilatation for at least 30" (better 60")

5 lost
8 refused

114 Xience EES
Predilatation, stent dilatation and postdilatation at operator's discretion

3 lost
7 refused

105 with angio *(89%)*

104 with angio *(90%)*

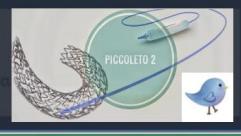
Primary endpoint
(6 months)
Core lab

112 6-mo. clinical fup

108 6-mo. clinical fup

108 12-mo. clinical fup

106 12-mo. clinical fup



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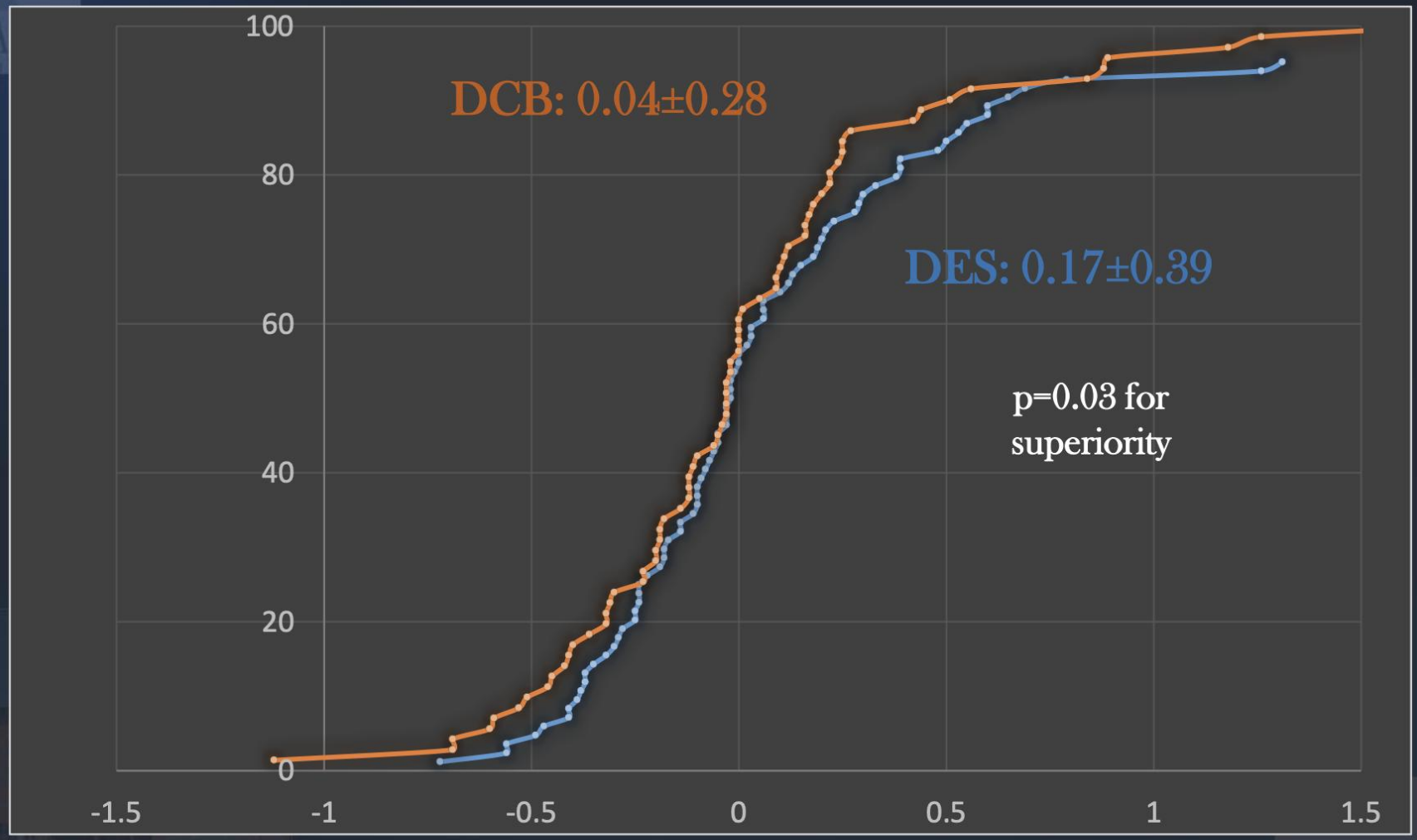
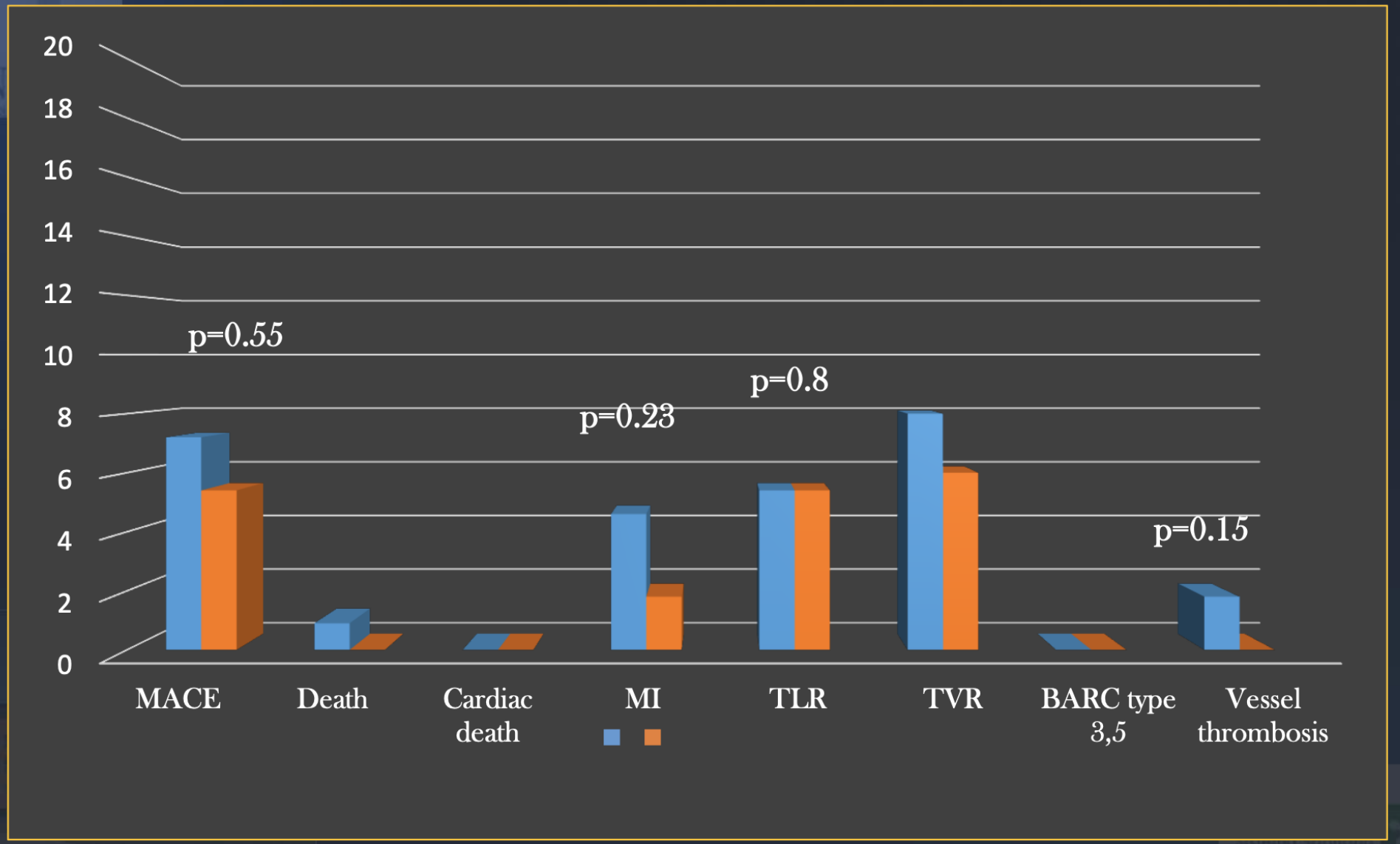
Baseline procedural characteristics

	DES	DCB	p
Number of patients and lesions	114	118	
Predilatation, n (%)	78 (69)	99 (84)	0.007
Postdilatation, n (%)	66 (59.4)	4 (3.3)	0.001
Number of devices used (mean), n	1.12	1.03	0.04
Length of device used (mean), mm (SD)	18.3 (6.9)	21.8 (8.2)	0.04
Mean inflation pressure, atm (SD)	13.7 (2.5)	11.4 (3.3)	0.07
Mean duration of inflation, sec (SD)	21.4 (11.8)	49.2 (14.5)	0.003
Bailout stenting, n (%)	-	8 (6.8)	-
Angiographic success, n (%)	113 (99.1)	116 (98.3)	0.88
Procedural success, n (%)	112 (98.2)	116 (98.3)	0.92

In-lesion LLL (primary study endpoint)



Clinical outcome (12 months)



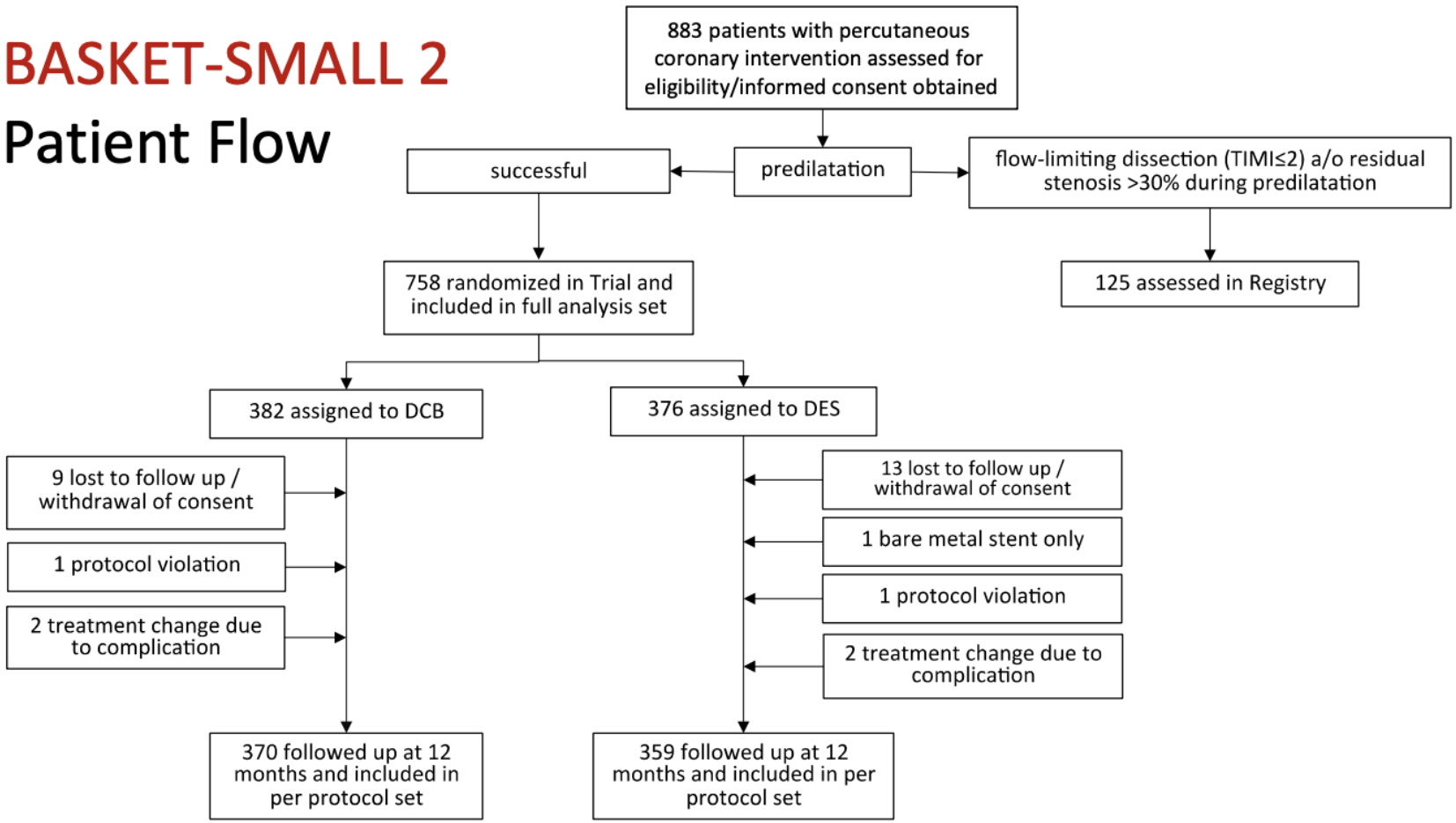
Drug-Coated Balloons for Small Coronary Artery Disease: BASKET-SMALL 2

Raban V. Jeger, Ahmed Farah, Marc-Alexander Ohlow, Norman Mangner, Sven Möbius-Winkler, Gregor Leibundgut, Daniel Weilenmann, Jochen Wöhrle, Stefan Richter, Matthias Schreiber, Felix Mahfoud, Axel Linke, Frank-Peter Stephan, Christian Mueller, Peter Rickenbacher, Michael Coslovsky, Nicole Gilgen, Stefan Osswald, Christoph Kaiser, and Bruno Scheller, for the BASKET-SMALL 2 Investigators

ESC Congress
Munich 2018

BASKET-SMALL 2

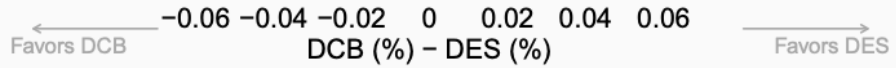
Patient Flow



BASKET-SMALL 2

Primary Endpoint (Non-Inferiority MACE 12 Months)

Set	Level	Events	Difference	CI	p
PPS	DES	27 / 359 (7.52%)			
	DCB	28 / 370 (7.57%)	0.0005	[−0.038, 0.039]	0.0217
FAS	DES	28 / 376 (7.45%)			
	DCB	28 / 382 (7.33%)	−0.0012	[−0.040, 0.037]	0.0152



ESC Congress
Munich 2018

PPS, per protocol set; FAS, full analysis set.

BASKET-SMALL 2

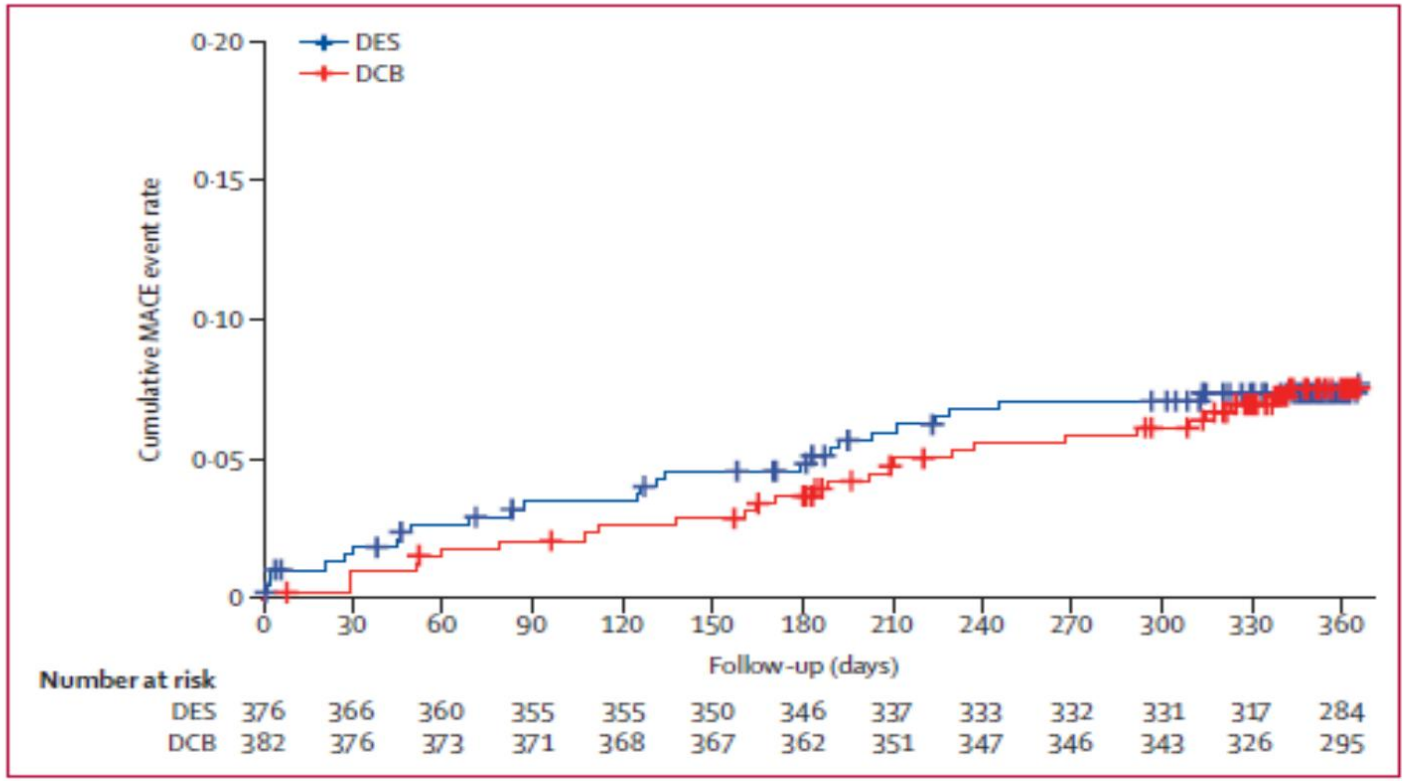


***Figure 3*: Cumulative incidence rates for MACE**
Full analysis population. MACE=major adverse cardiac events. DCB=drug-coated balloons. DES=drug-eluting stents.

Findings : In **small** native coronary artery disease, **DCB was non-inferior to DES** regarding MACE up to 12 months, with similar event rates for both treatment groups.

BASKET-SMALL 2 at 3 years

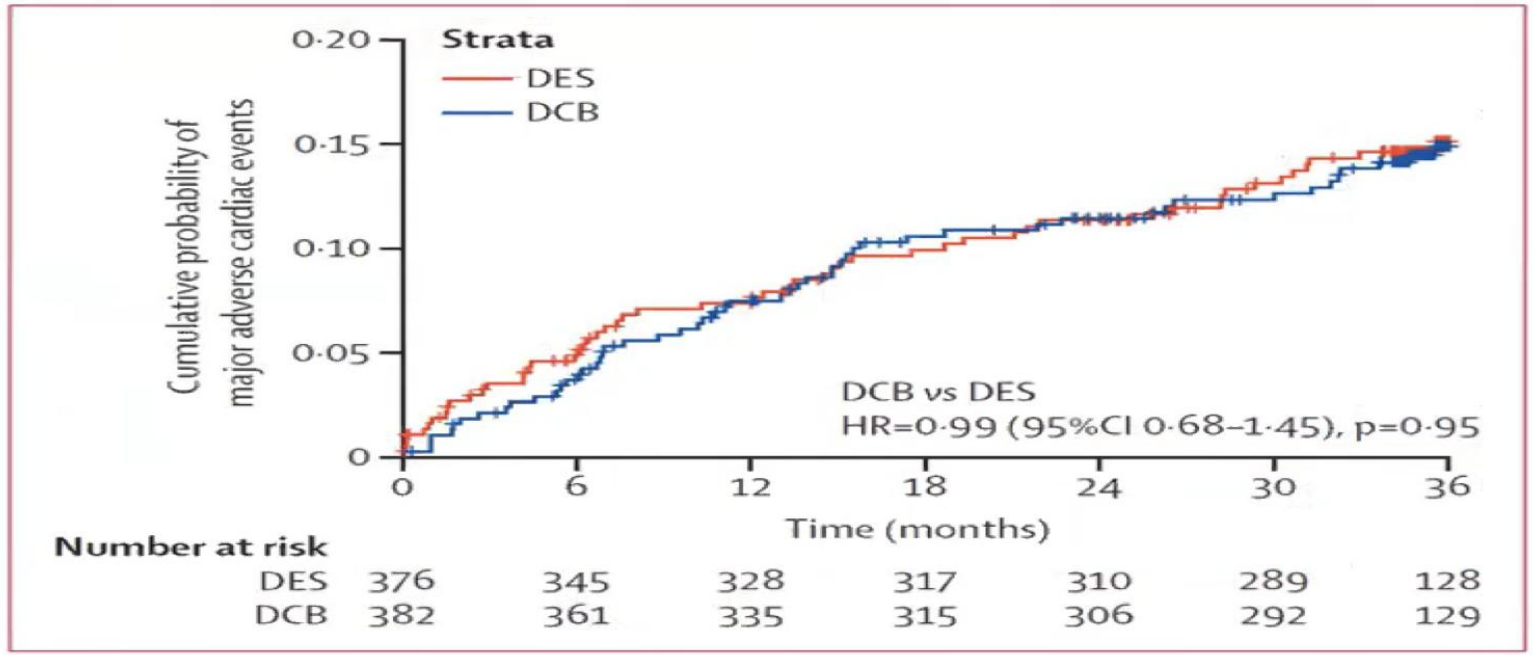


Figure 2: **Kaplan-Meier estimates of the cumulative probabilities of major adverse cardiac events in the two study groups during 3 years for the full analysis set**

DCB=drug-coated balloons. DES=drug-eluting stents. HR=hazard ratio.

Lancet 2020 Nov 7;396(10261):1504-1510

Angiographic Outcome at Follow-up

	DES (n = 66)	DCB (n = 51)	Estimate (95%CI)	p-Value
Time until follow-up, days	175 (77-224)	170 (82-229)		0.70
Minimal diameter, mm				
In-segment	1.49 (1.26-1.76)	1.27 (1.12-1.52)	-0.19 (-0.38-0.00)	0.048
In-stent/in-balloon	1.76 (1.47-2.02)	1.35 (1.13-1.70)	-0.35 (-0.54--0.17)	<0.001
Diameter stenosis, %				
In-segment	29.0 (20.3-45.5)	35.8 (24.8-44.9)	7.18 (0.08-14.28)	0.047
In-stent/in-balloon	18.8 (9.6-35.8)	34.5 (19.1-42.8)	14.7 (7.7-21.6)	<0.001
Late lumen loss, mm				
In-segment	0.06 (-0.15-0.40)	0.10 (-0.14-0.26)	0.09 (-0.05-0.23)	0.20
In-stent/in-balloon	0.13 (-0.14-0.57)	0.10 (-0.16-0.34)	0.03 (-0.13-0.19)	0.72
Net gain, mm				
In-segment	1.40 (0.75-1.89)	1.18 (0.89-1.59)	-0.29 (-0.56--0.01)	0.045
In-stent/in-balloon	1.46 (0.93-2.08)	1.24 (0.84-1.86)	-0.39 (-0.70--0.09)	0.011
Binary restenosis, %			OR	
In-segment	21.5 (14)	20.4 (10)	0.91 (0.35-2.25)	0.83
In-stent/in-balloon	18.5 (12)	16.3 (8)	1.01 (1.00-1-03)	0.66

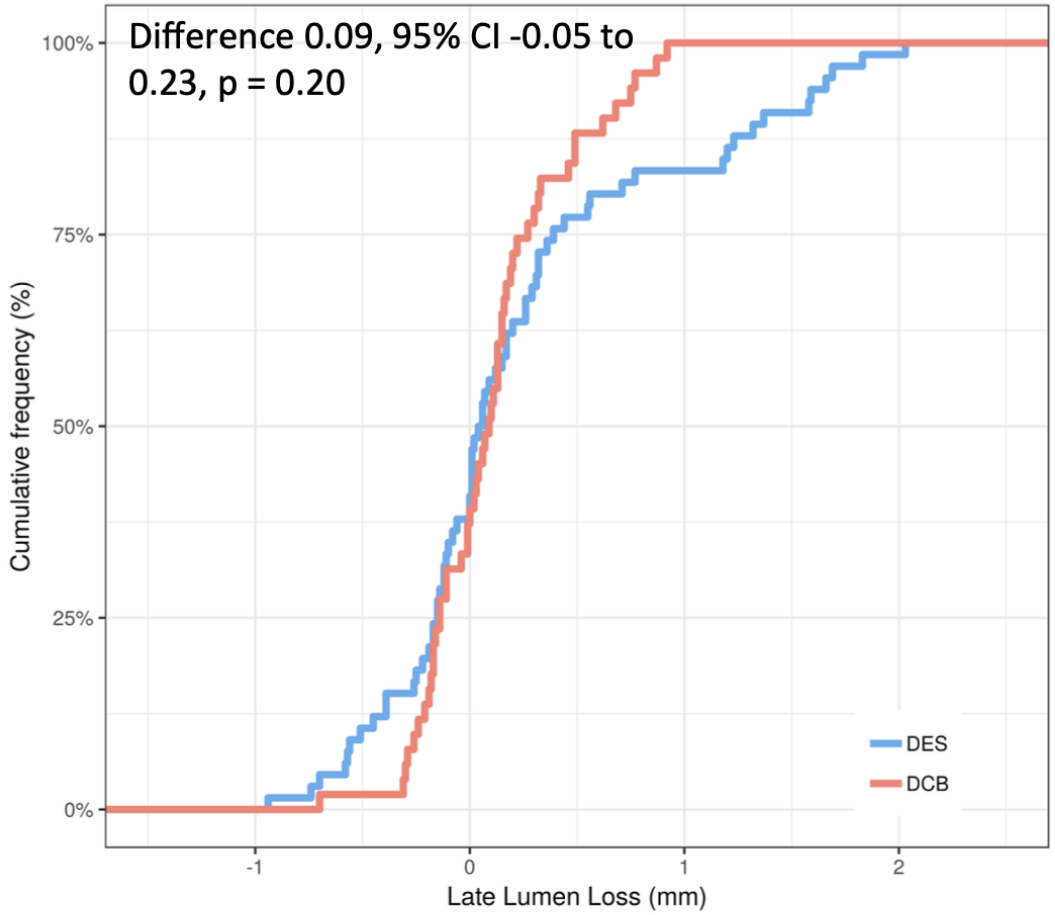
Difference between post-procedure and follow-up angiography

Diameter stenosis (In-stent/In-balloon)

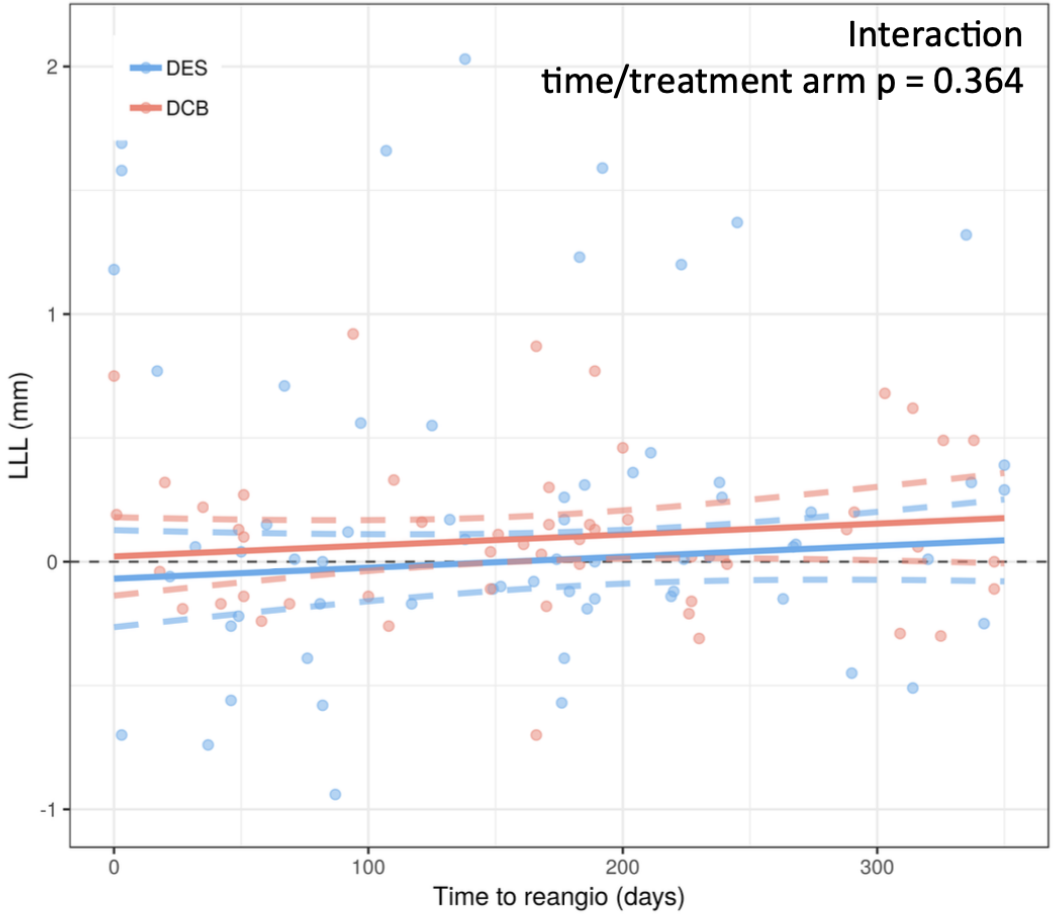
DES +10.0%
DCB +6.8%

Angio subgroup

In-segment Late Lumen Loss Distribution



In-segment Late Lumen Loss by Time

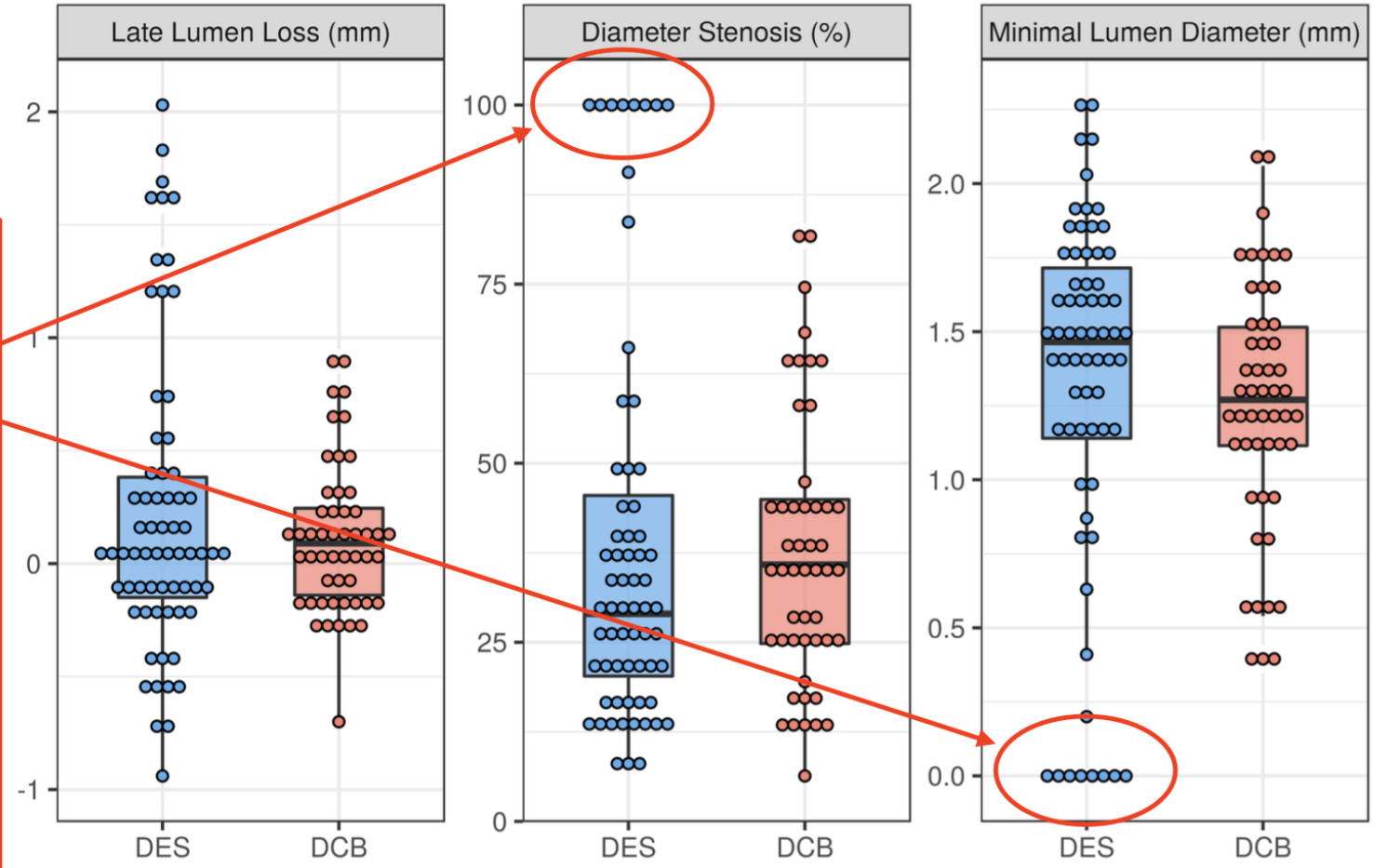


Angio subgroup

Complete thrombotic vessel occlusion in 8 patients with DES (Xience n=5, Taxus n=3) vs. none with DCB (p = 0.009)

Clinical presentation:
- 3 STEMI
- 1 NSTEMI
- 3 unstable angina
- 1 heart failure

All but one on DAPT



p = 0.878

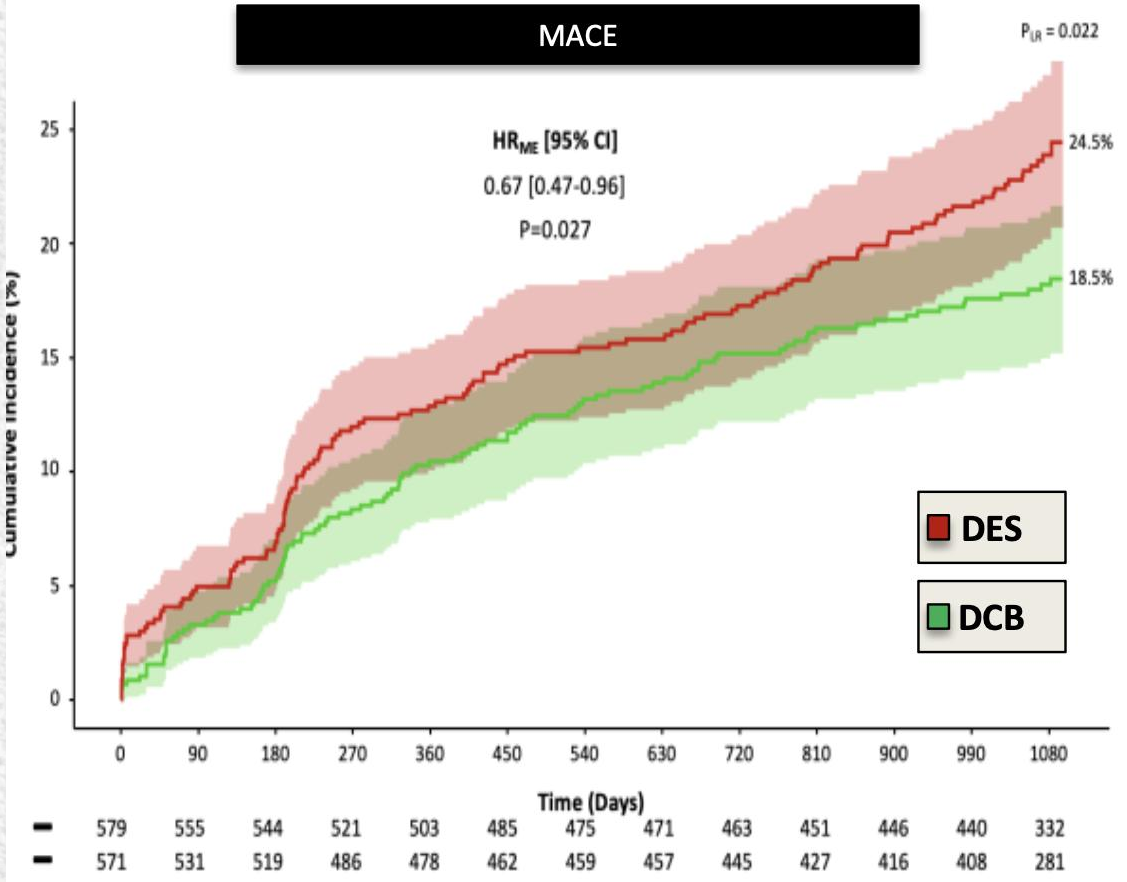
p = 0.406

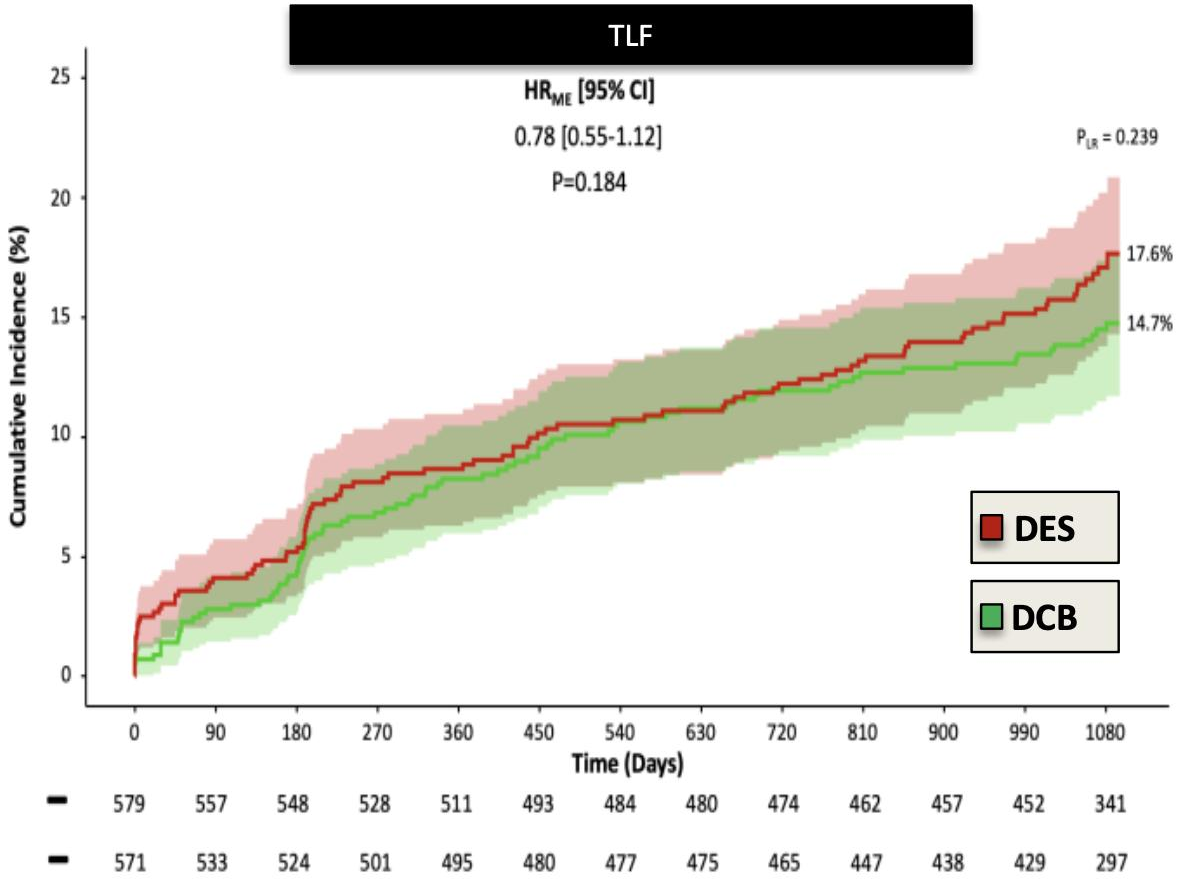
p = 0.124

DCB vs DES in small vessels. Andromeda Metanalisis

Comprehensive, investigator-initiated, collaborative, **individual patient** data meta-analysis (CRD42023479035)

N= 1154 patients (582 DCB; 572 DES)





Cortese et al. CRT 2024

Drug-coated balloons versus drug-eluting stents for small non-complex de novo coronary artery lesions: A segment-level propensity score matched analysis from SCAAR

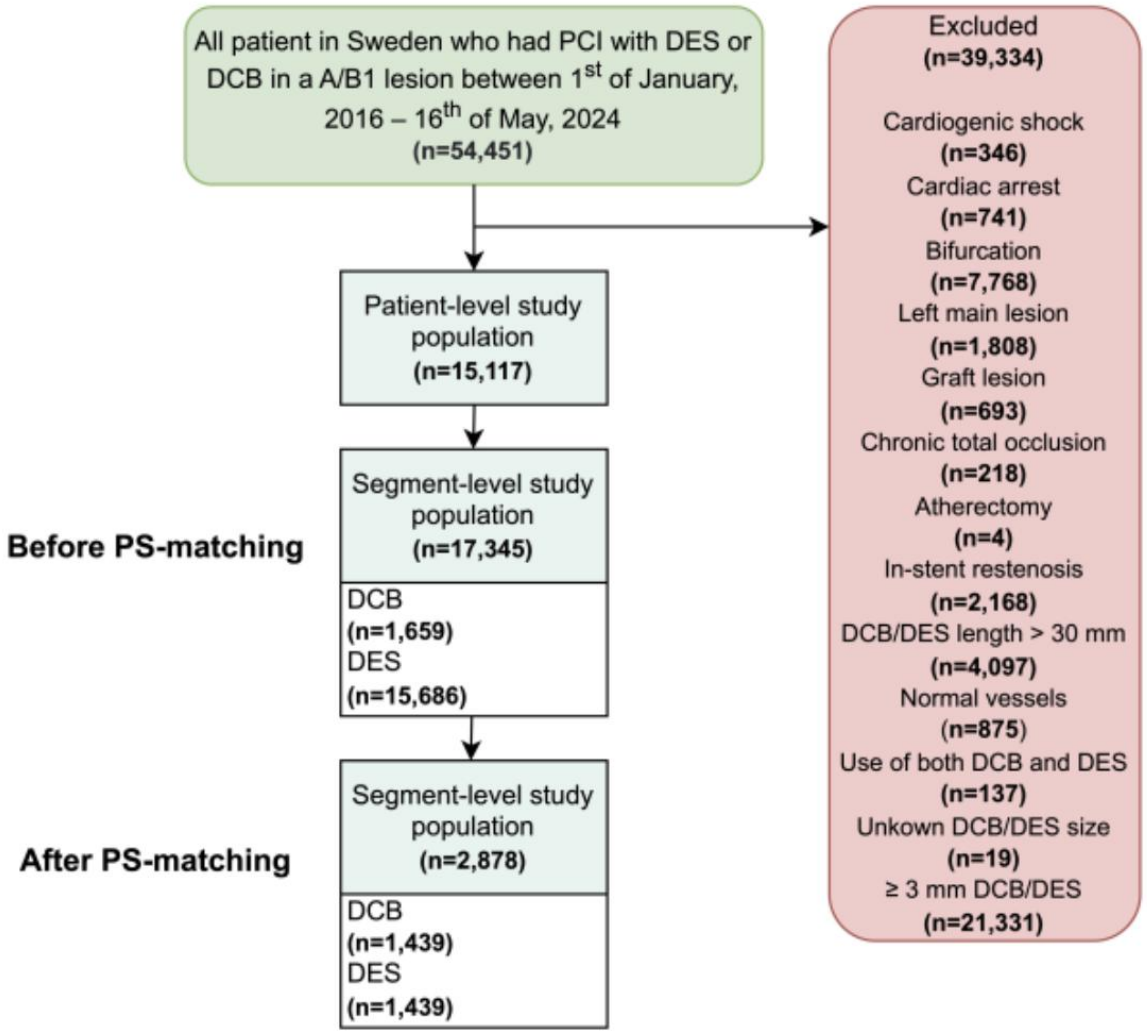
Presenter: Sacharias von Koch

2025

- **Study period**: 1/Jan/2016 – 16/May/2024

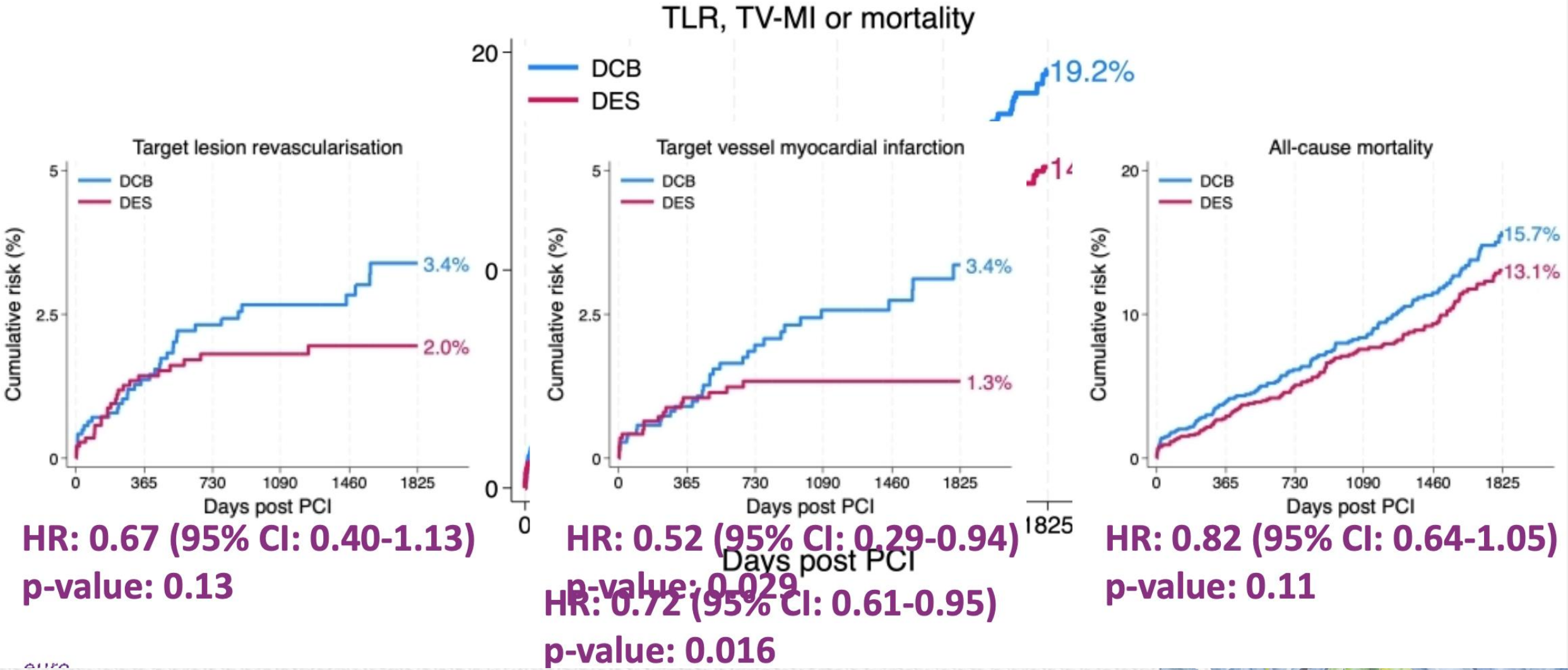
- **Study population**: All patients undergoing PCI in non-complex small small vessels. All complex procedures were excluded

- **Statistics**: PS-matching was used to address confounding. Kaplan-Meier estimates and Cox regression was used to assess outcome through 5 years



- Overall similar baseline characteristics after PS-matching
- Large proportion of acute coronary syndrome

Patient-characteristics Mean (SD) or %		DCB N=1,439	DES N=1,439
Age		68.9 (11.2)	68.7 (10.8)
Female		27.4	26.6
Active smoker		12.0	13.8
Diabetes mellitus		25.3	24.8
Hypertension		70.1	70.5
Previous MI		26.8	26.1
Previous PCI		32.2	30.9
ACS		66.0	64.2
3 vessel disease		13.8	15.1
Use of IVUS/OCT		4.1	4.0
DCB/DES diameter	<2.5 mm	51.3	50.9
	2.5-<3.0mm	48.7	49.1



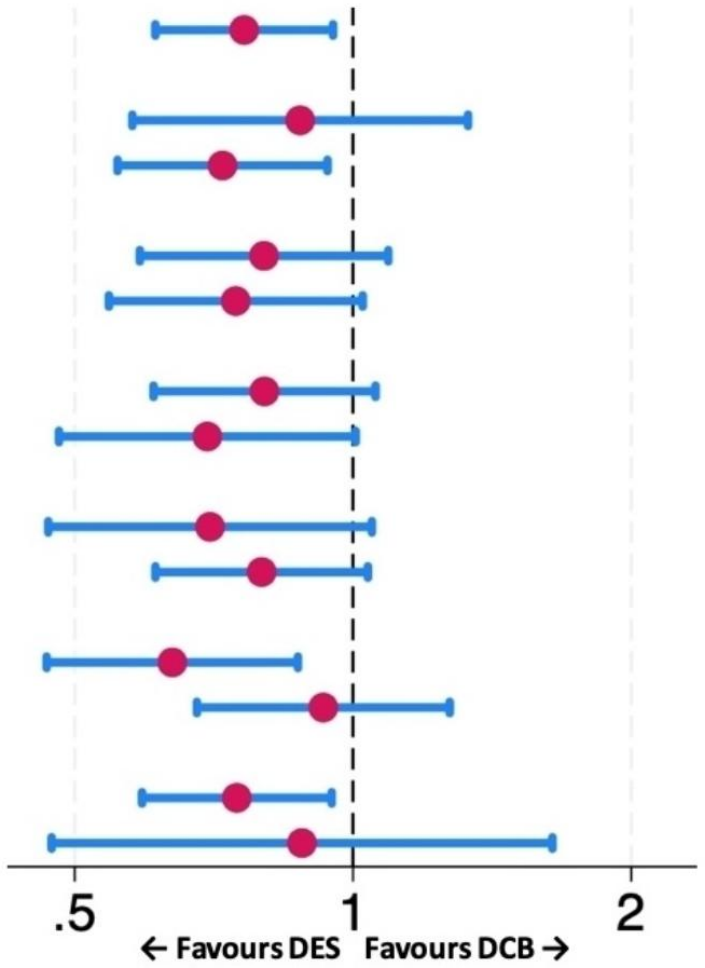
HR: 0.67 (95% CI: 0.40-1.13)
p-value: 0.13

HR: 0.52 (95% CI: 0.29-0.94)
p-value: 0.029

HR: 0.72 (95% CI: 0.61-0.95)
p-value: 0.016

HR: 0.82 (95% CI: 0.64-1.05)
p-value: 0.11

	Number of segments (%)	Hazard-ratio (95% confidence interval), p-value	P-value of interaction
All segments	2878 (100.0%)	HR, 0.76; 95%CI, 0.61-0.95; P = 0.016	
Sex			0.429
Female	777 (27.0%)	HR, 0.88; 95%CI, 0.58-1.33; P = 0.54	
Male	2101 (73.0%)	HR, 0.72; 95%CI, 0.56-0.94; P = 0.015	
Age			0.758
Age < 75 years	1892 (65.7%)	HR, 0.80; 95%CI, 0.59-1.09; P = 0.16	
Age ≥ 75 years	986 (34.3%)	HR, 0.75; 95%CI, 0.54-1.02; P = 0.07	
Diabetes mellitus			0.537
No diabetes mellitus	2157 (74.9%)	HR, 0.80; 95%CI, 0.61-1.06; P = 0.12	
Diabetes mellitus	721 (25.1%)	HR, 0.70; 95%CI, 0.48-1.01; P = 0.05	
Indication			0.593
CCS or other indication	1006 (35.0%)	HR, 0.70; 95%CI, 0.47-1.05; P = 0.08	
ACS	1872 (65.0%)	HR, 0.80; 95%CI, 0.61-1.04; P = 0.09	
DCB/DES size			0.101
≥ 2.5 mm	1407 (48.9%)	HR, 0.64; 95%CI, 0.47-0.87; P = 0.005	
≤ 2.25 mm	1471 (51.1%)	HR, 0.93; 95%CI, 0.68-1.27; P = 0.65	
Occlusion			0.666
No acute occlusion	2599 (90.3%)	HR, 0.75; 95%CI, 0.59-0.95; P = 0.016	
Acute occlusion	279 (9.7%)	HR, 0.88; 95%CI, 0.47-1.64; P = 0.69	



- RCT based Evidence show that is safe to treat small vessels with DCB
- However some real world registries show DES superiority.
- I believe the problem is the technique

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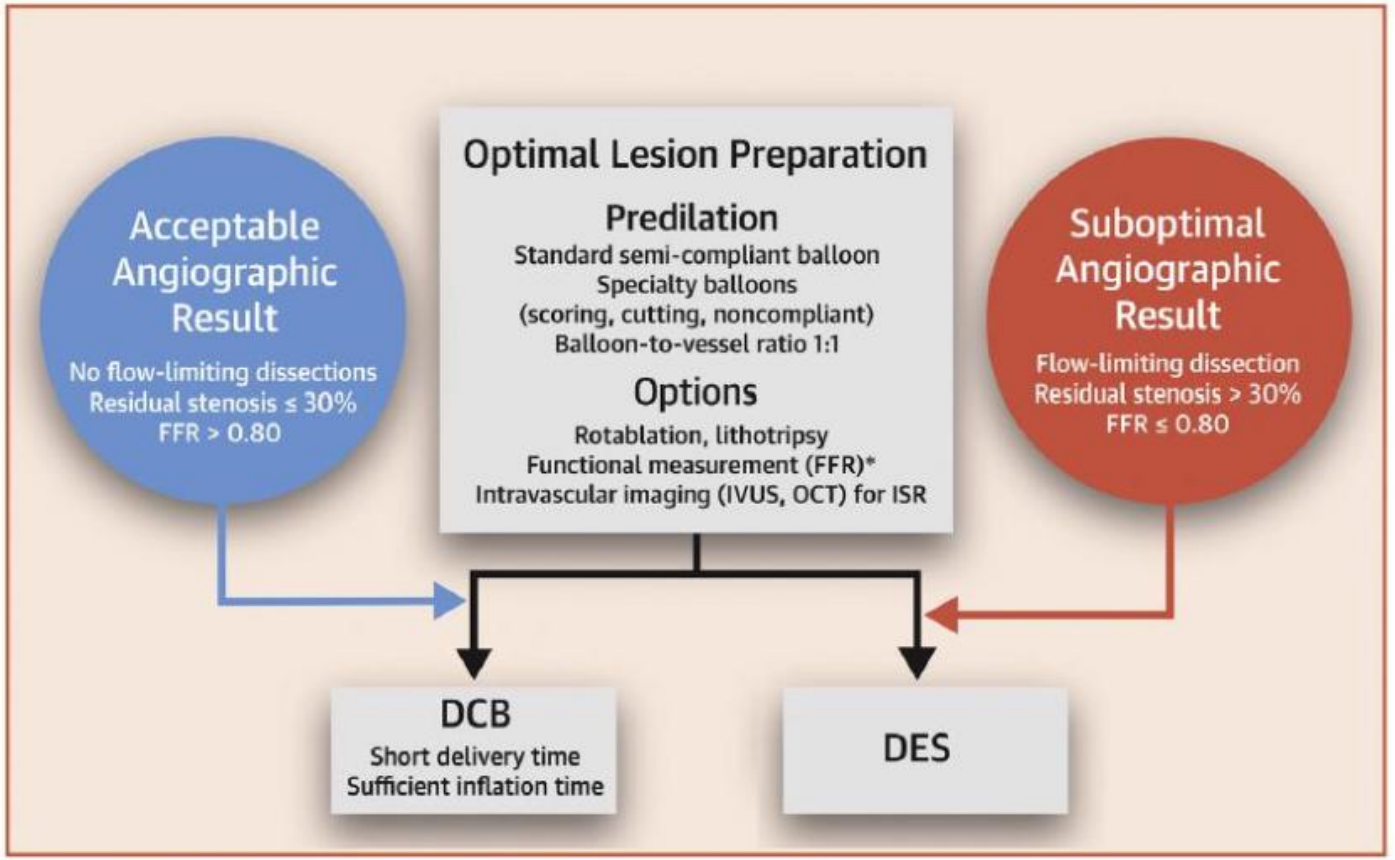
Drug-Coated Balloons for Coronary Artery Disease

Third Report of the International DCB Consensus Group

Raban V. Jeger, MD,[a] Simon Eccleshall, MD,[b] Wan Azman Wan Ahmad, MD,[c] Junbo Ge, MD,[d] Tudor C. Poerner, MD,[e] Eun-Seok Shin, MD,[f] Fernando Alfonso, MD,[g] Azeem Latib, MD,[h] Paul J. Ong, MD,[i] Tuomas T. Rissanen, MD,[j] Jorge Saucedo, MD,[k] Bruno Scheller, MD,[l] Franz X. Kleber, MD,[m] for the International DCB Consensus Group

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



Jeger, R.V. et al. J Am Coll Cardiol Intv. 2020;13(12):1391-402.

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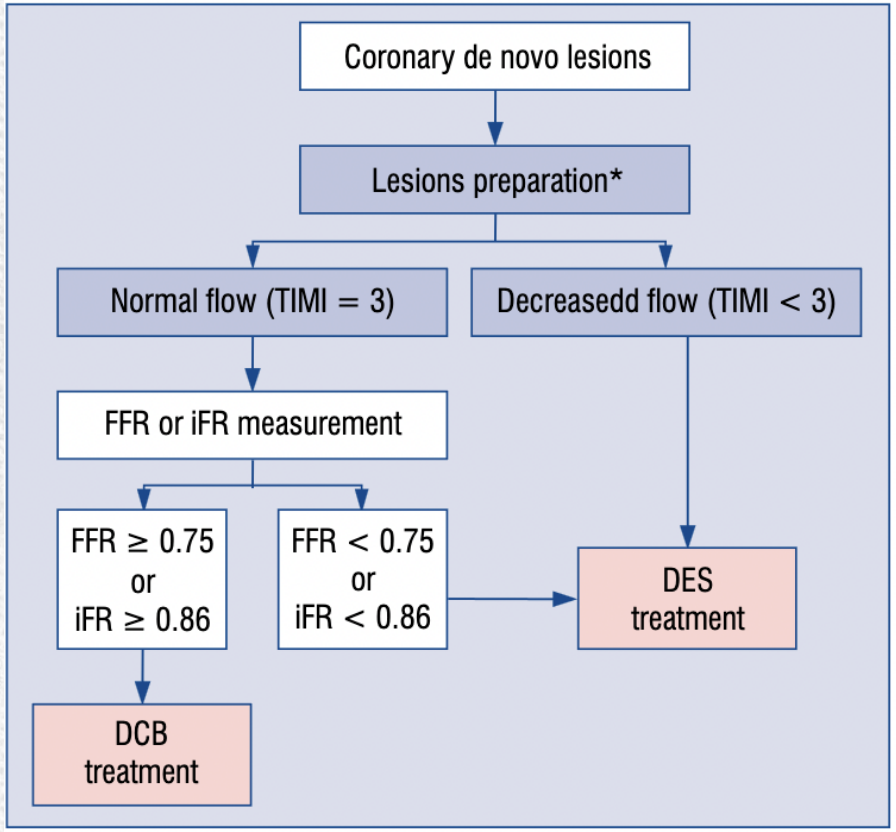
Provisional drug-coated balloon treatment guided by physiology on de novo coronary lesion

Eun-Seok Shin[1], Liew Houng Bang[2], Eun Jung Jun[1], Ae-Young Her[3], Ju-Hyun Chung[1], Scot Garg[4], Joo Myung Lee[5], Joon-Hyung Doh[6], Chang-Wook Nam[7], Bon-Kwon Koo[8], Qiang Tang[9]



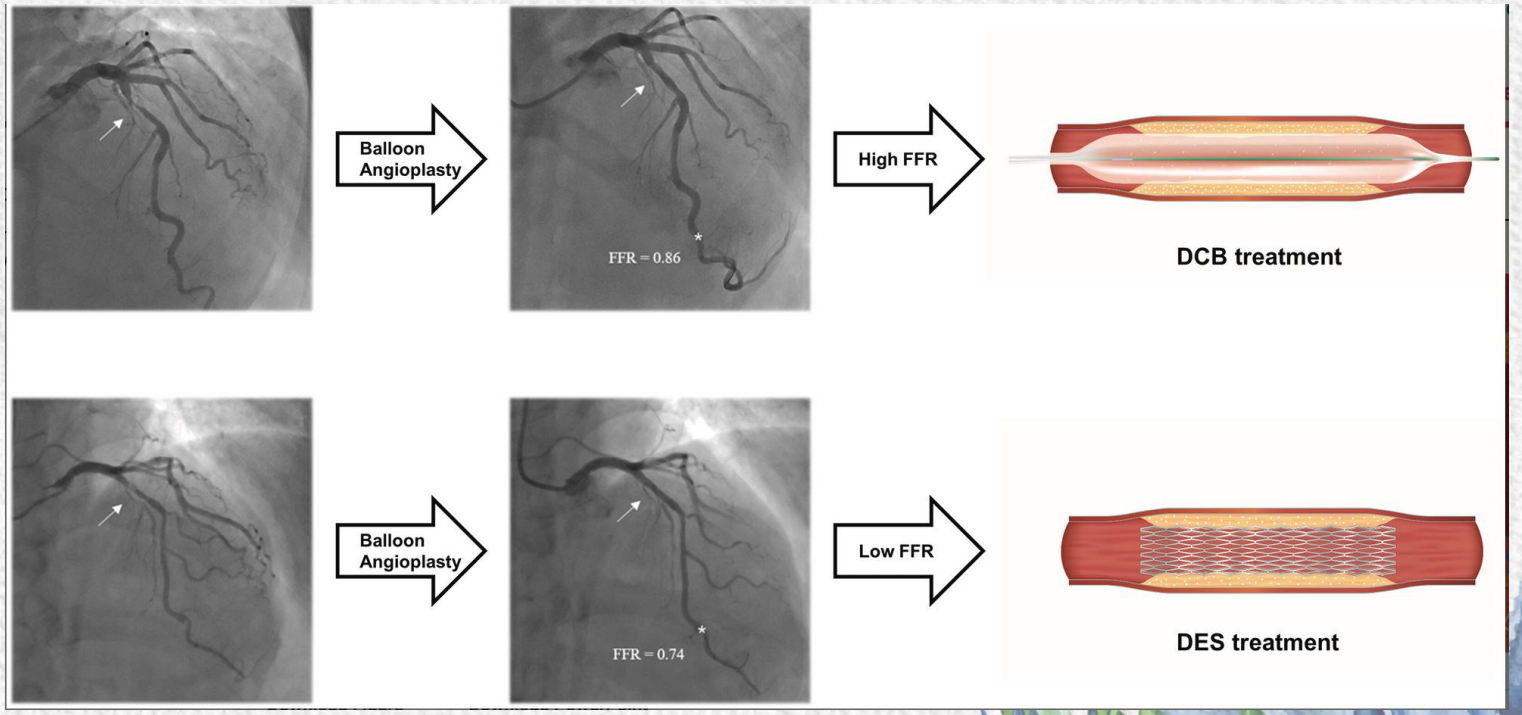


Figure 3. Provisional drug-coated balloon (DCB) strategy guided by fractional flow reserve (FFR). The acceptable angiographic and functional criteria after balloon

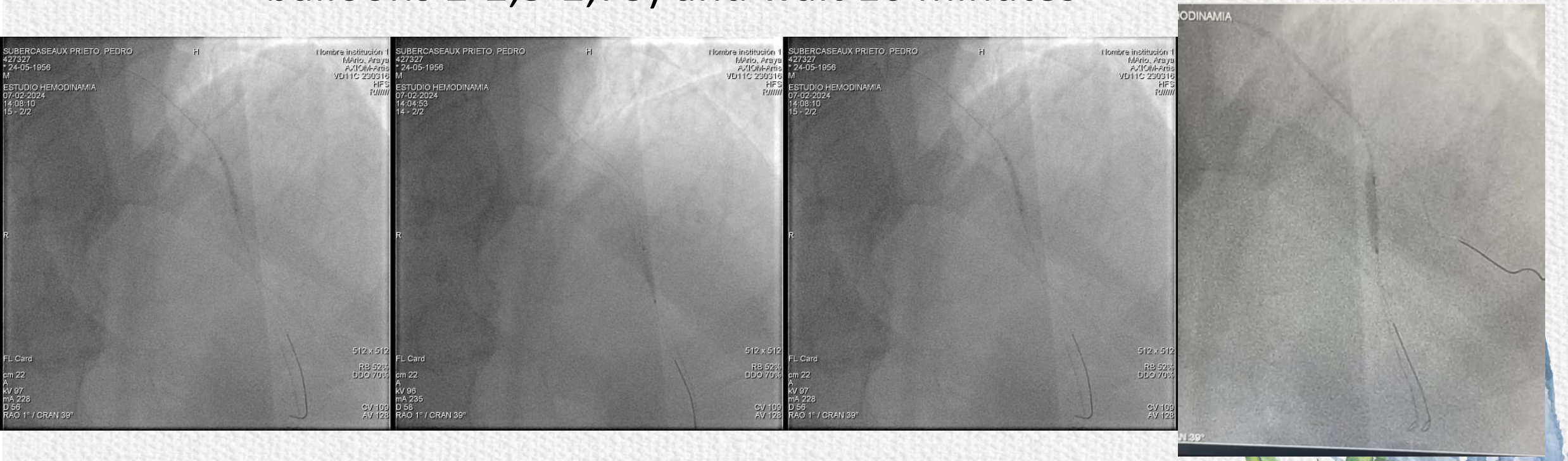
- 75 yo male
- Previous inferior AMI
- Chronic stable angina FC 2
- Prostate cancer (need for surgery ASAP)

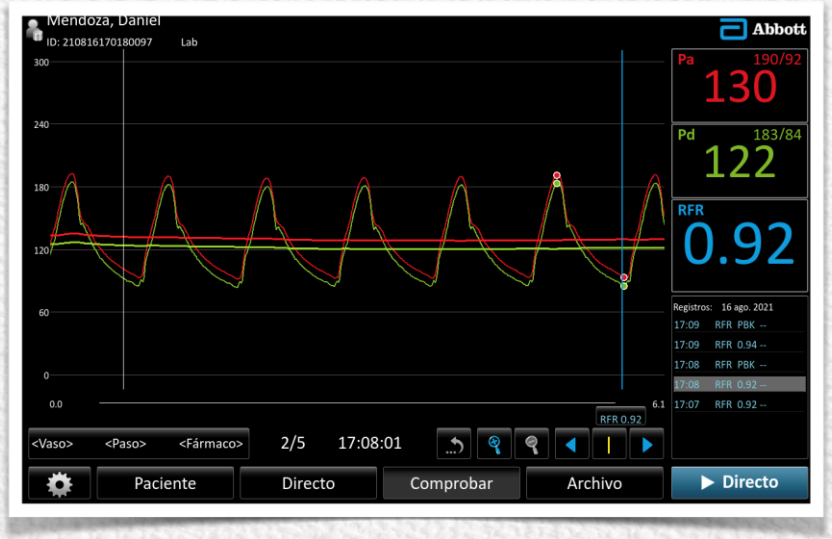
- SPECT: anterior and apical ischemia 15%

RFR 0,79

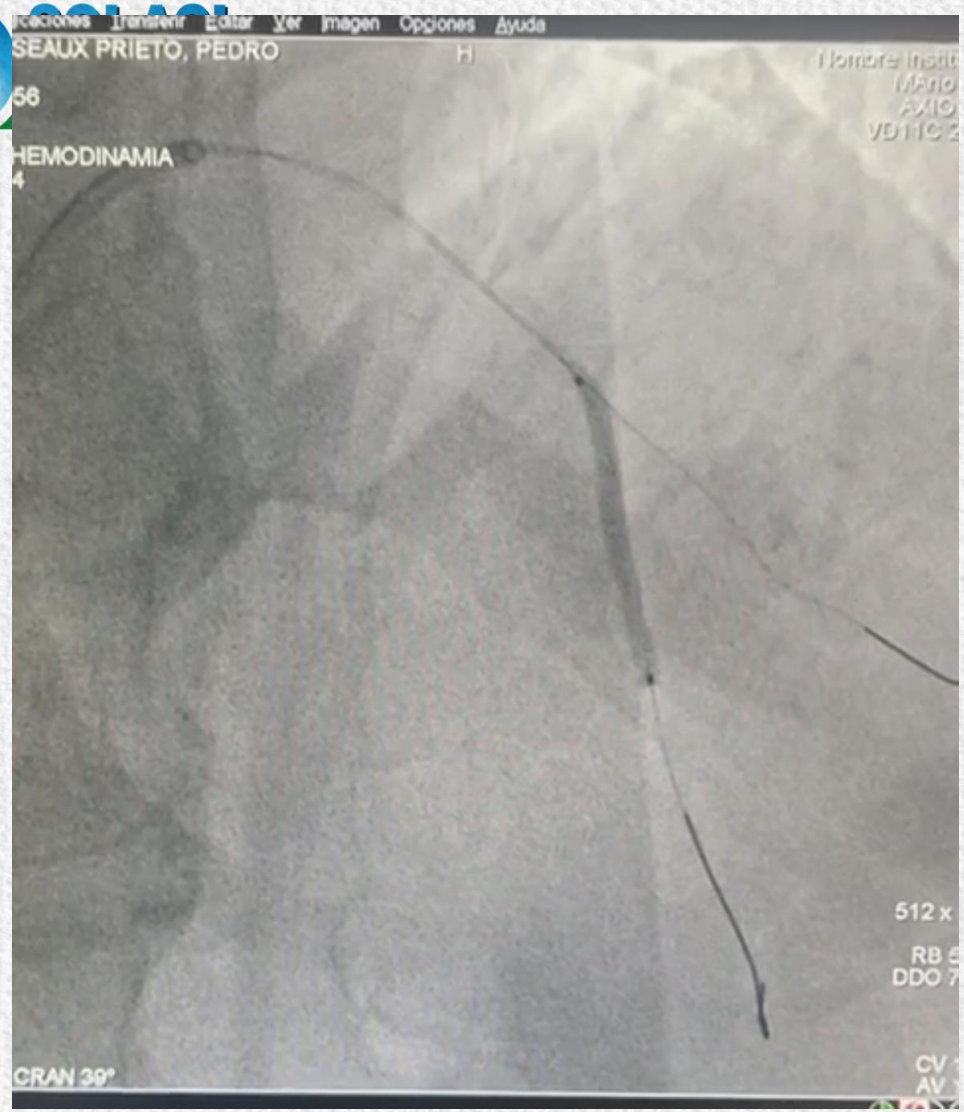
Significant jump in mid LAD pullback

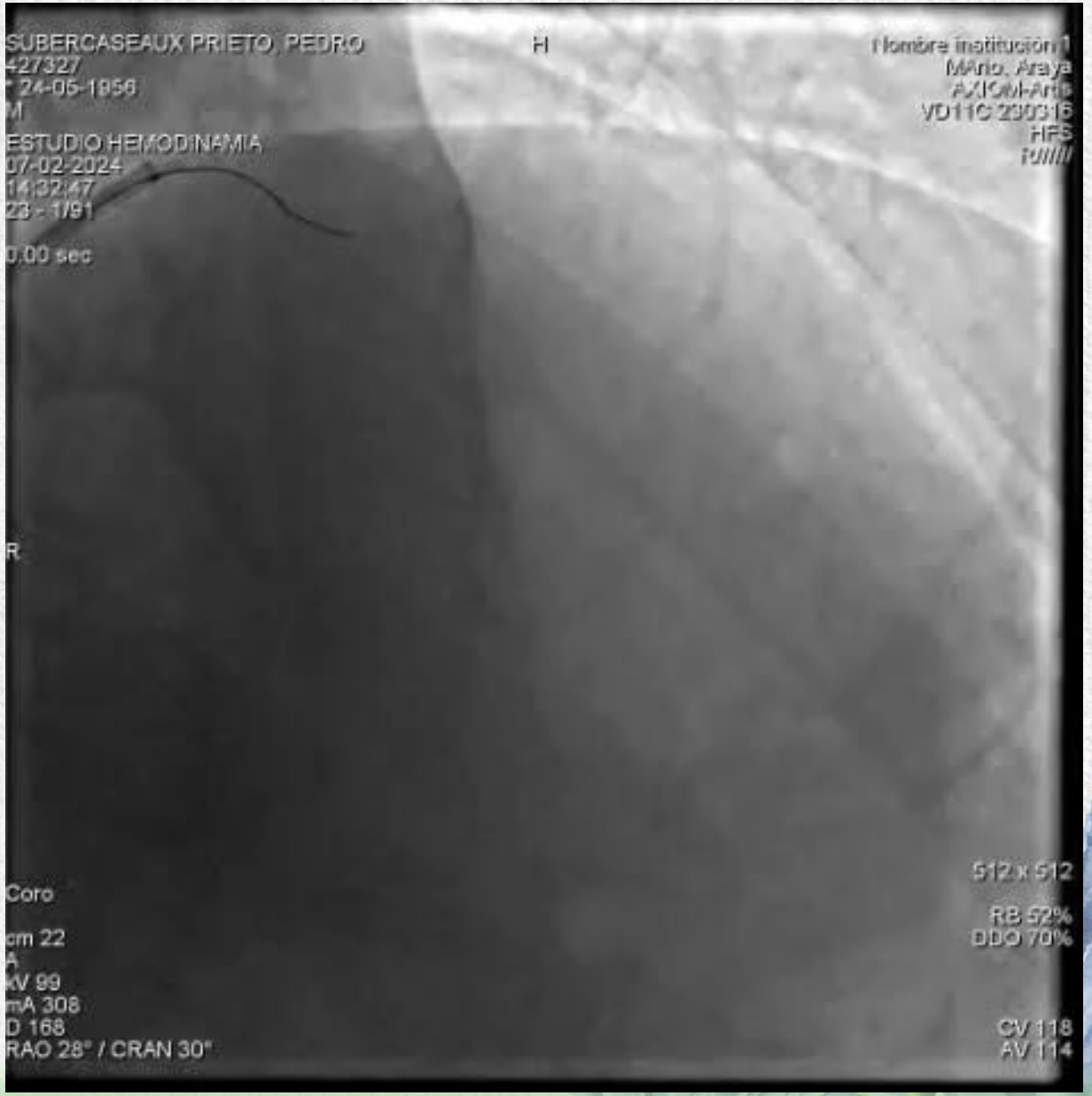
Careful and progressive predilatation (SC balloons 2-2,5-2,75) and wait 10 minutes





RFR post dilstation

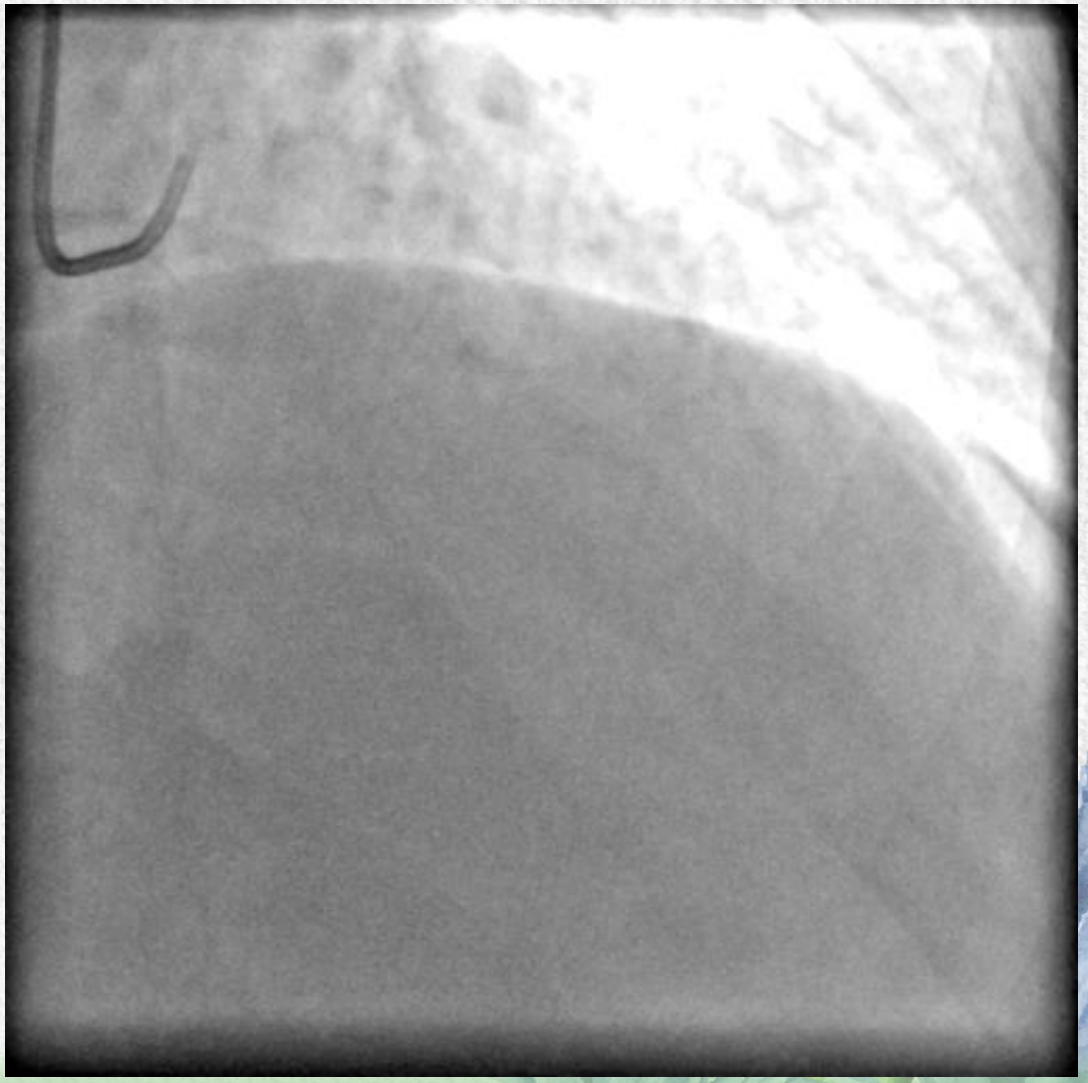




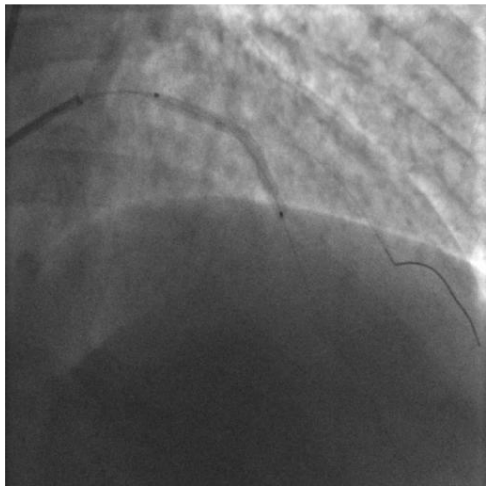
Selution DEB

2,75 mm x 30 mm 1 min

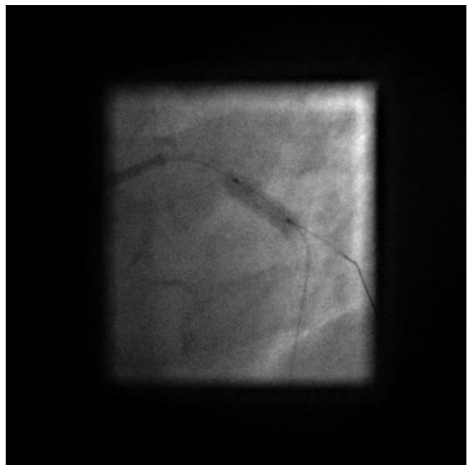
- Male 65. Previous NSTEMI
- Chest pain and treadmill test with ST abn
- Need for gallbladder surgery



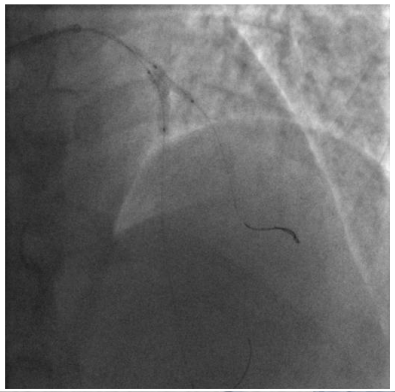
- Predilatation 1:1. LAD and Dg
- Class C dissection in mid LAD
- So we continue with provisional stenting and blend treatment with DEB to SB



Orsiro stent 3 x 35 mm

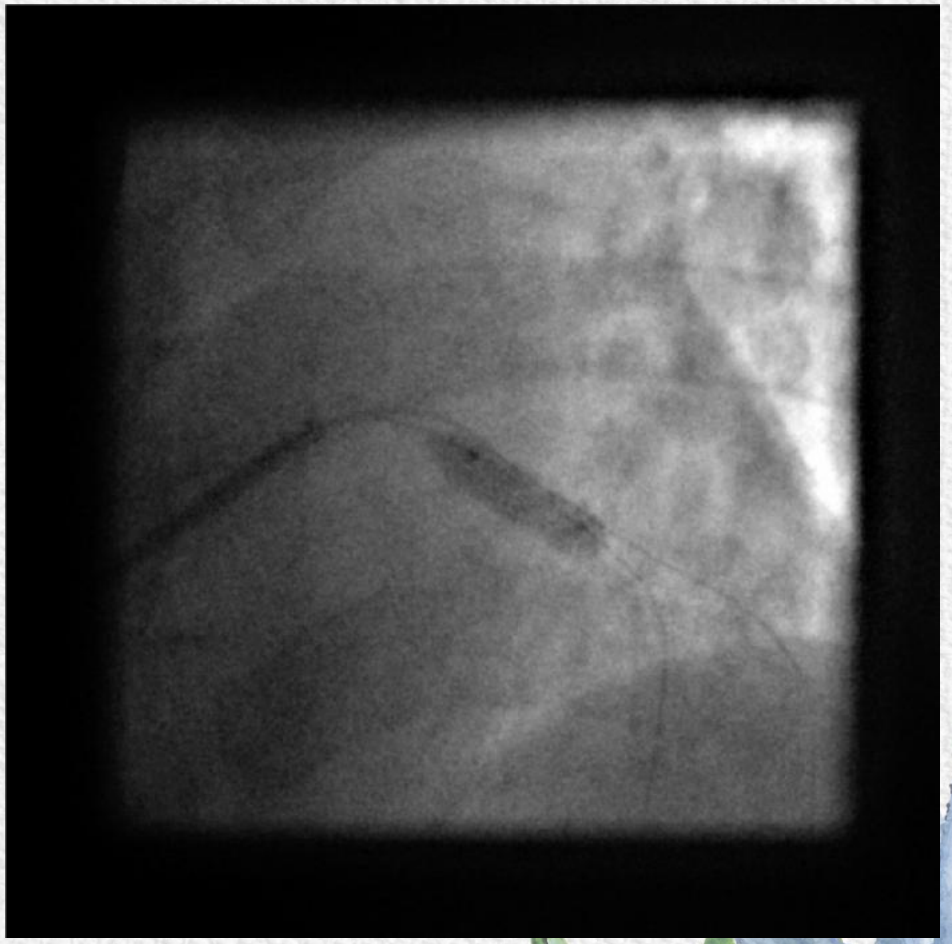


POT NC 3,75 and wire exchange

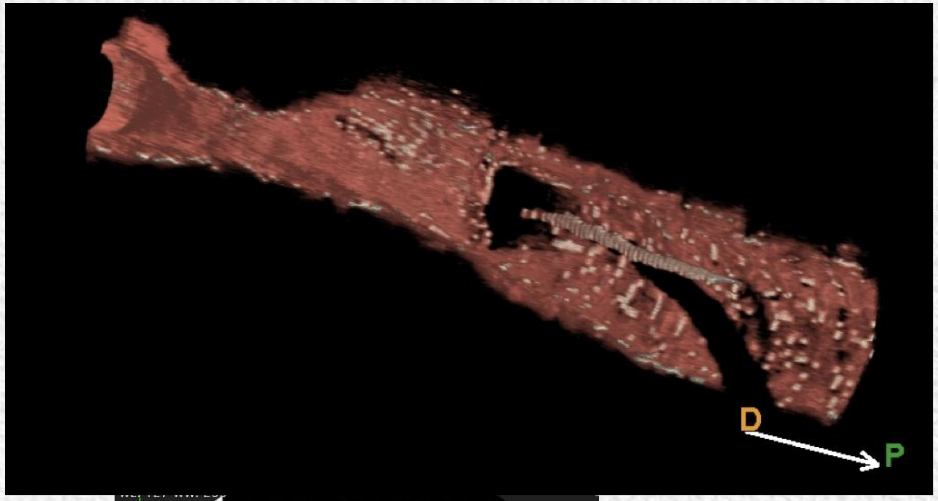


kiss 3,0 and 2,5 NC balloons

Selution 2,5 x 30 mm



RePOT


D
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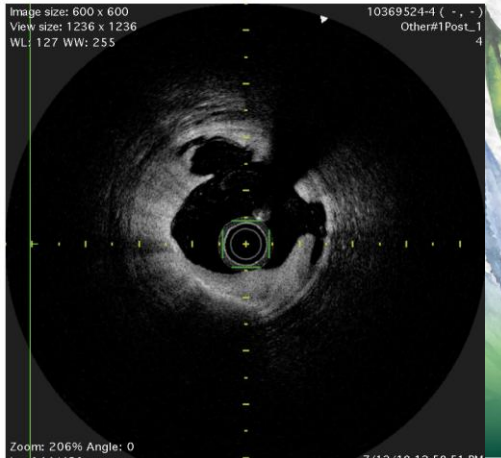
Zoom: 206% Angle: 0
Im: 302/324
Uncompressed
7/13/18 12:55:23 PM
Made In Horos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View size: 1236 x 1236
WL: 127 WW: 255
10369524-4 (-, -)
Other#1Post_1
4
Zoom: 206% Angle: 0

LAD

Dg

- 4 months FU of blend tx

Ollscoil na Gaillimhe
University of Galway

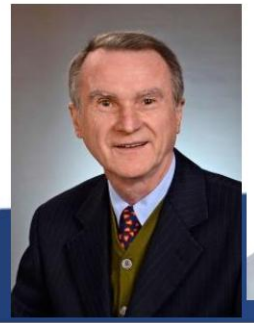
CORRIB CORE LAB:

A Prospective, Multicenter, Randomized Trial Comparing Sirolimus-Coated Balloon with Paclitaxel-Coated Balloon in De-novo Small Vessels

TRANSFORM I Trial

Patrick Serruys, MD, PhD

Kai Ninomiya, Antonio Colombo, Bernhard Reimers, Sandeep Basavarajaiah, Faisal Sharif, Luca Testa, Carlo Di Mario, Roberto Nerla, Jouke Dijkstra, Bernardo Cortese, Yoshinobu Onuma



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Sponsor: Concept Medical

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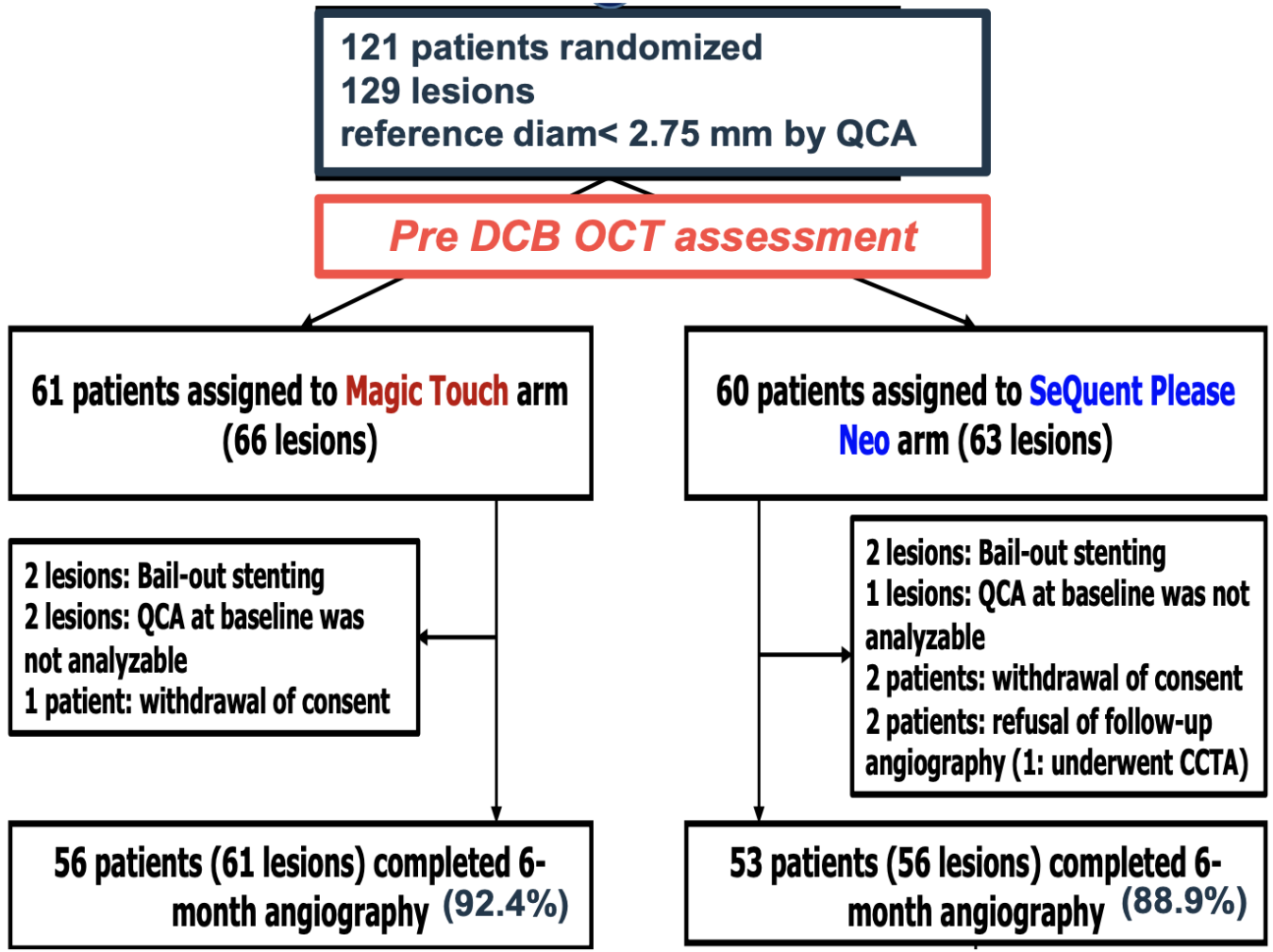
The transform one trial is :

Design: Prospective, randomized, multicentre, open-label ***non-inferiority trial***

Primary Endpoint:
Angiographic net gain in a per protocol analysis (exclusion of bail-out stenting)

Sample Size Calculation

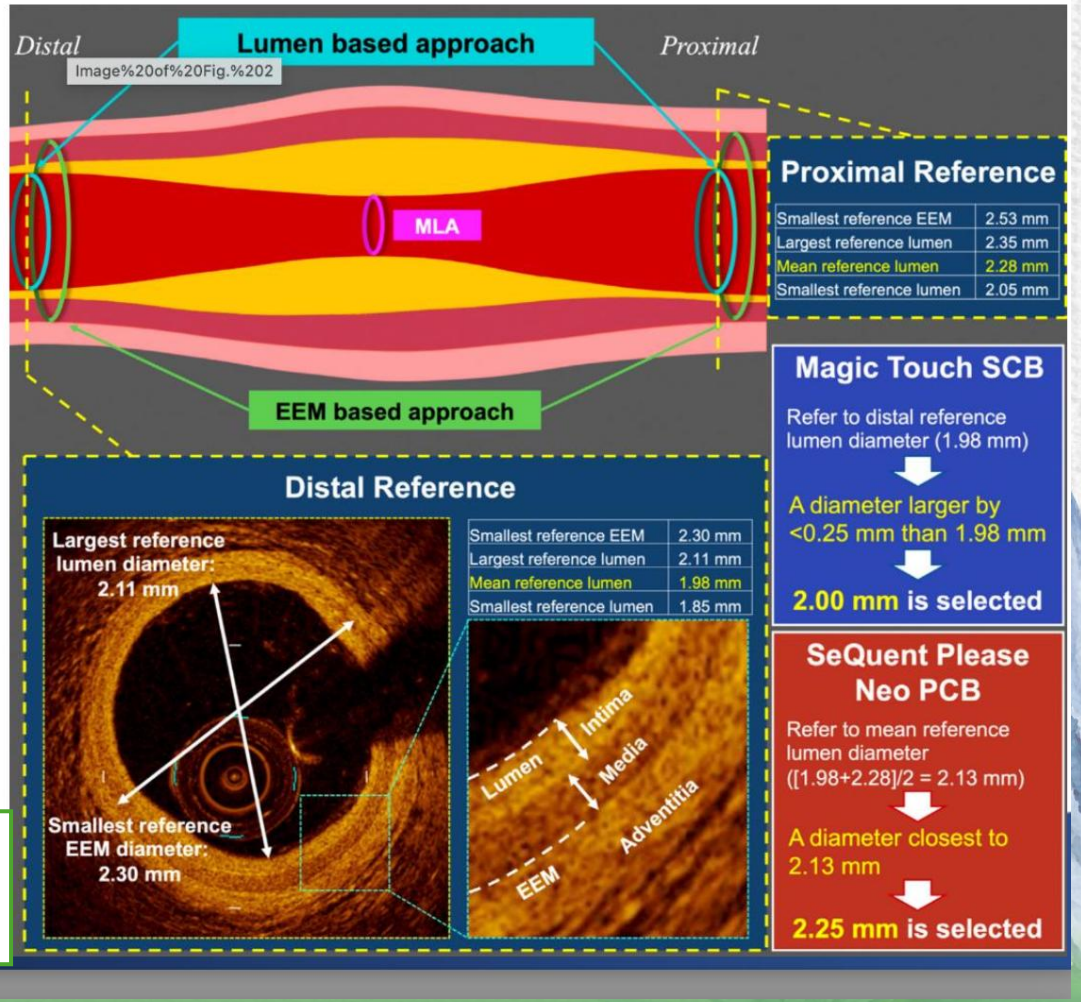
- **A one-sided significance level (alpha) of 5%**
- **88% Power to show non-inferiority of Magic Touch to SeQuent Please Neo**
- **A non-inferiority margin of 0.3 mm**
- **SeQuent Net Gain 0.87 ± 0.51mm at 6 months (PEDCAD study)**
- **Maximum attrition rate of 17%**
- **Sample size 114 patients**



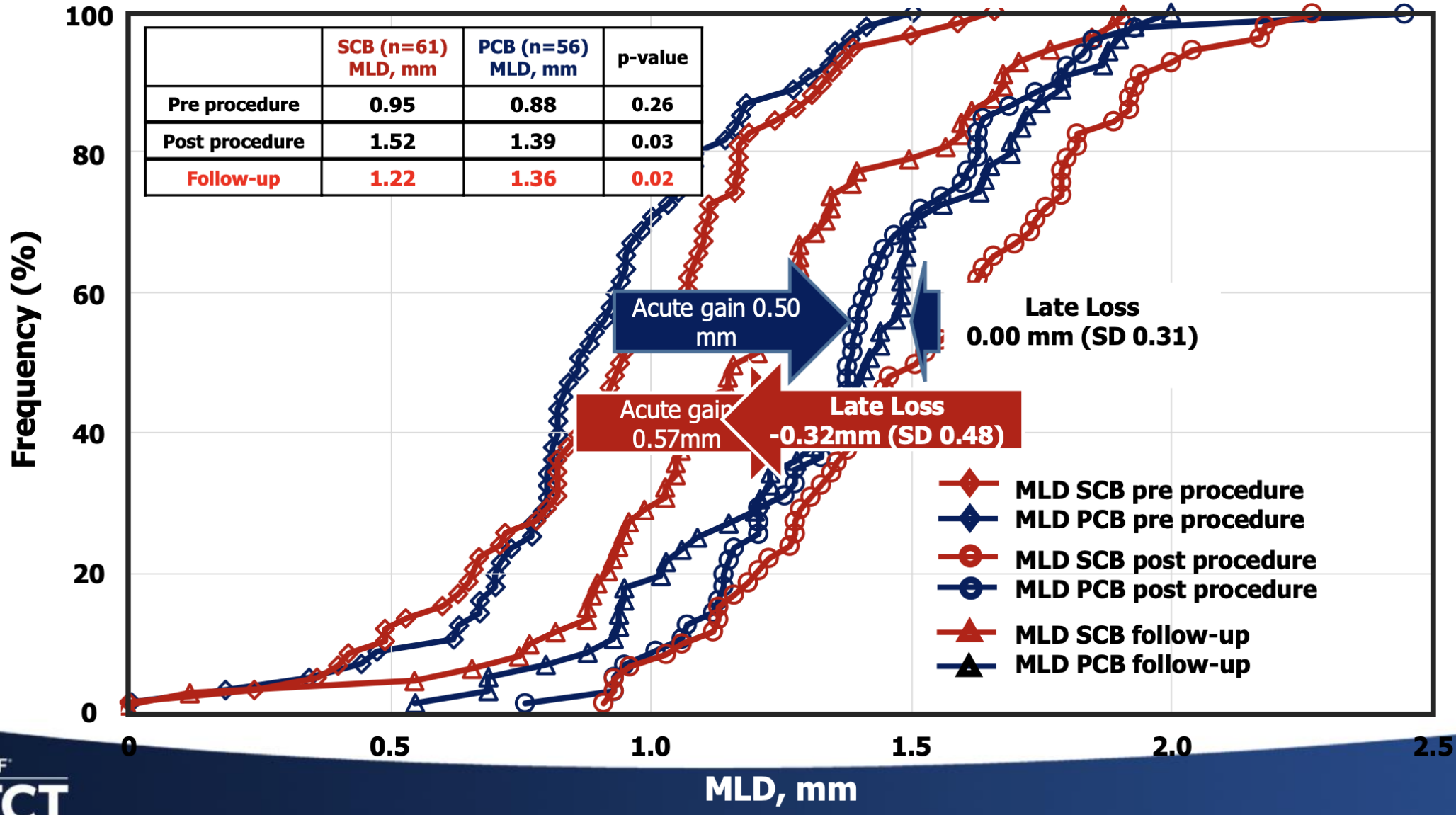
The Rationale for the Pre DCB OCT Assessment is to obtain OCT-derived lumen measurement for DCB balloon-sizing

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



Cumulative frequency distribution of minimal lumen diameter (MLD)



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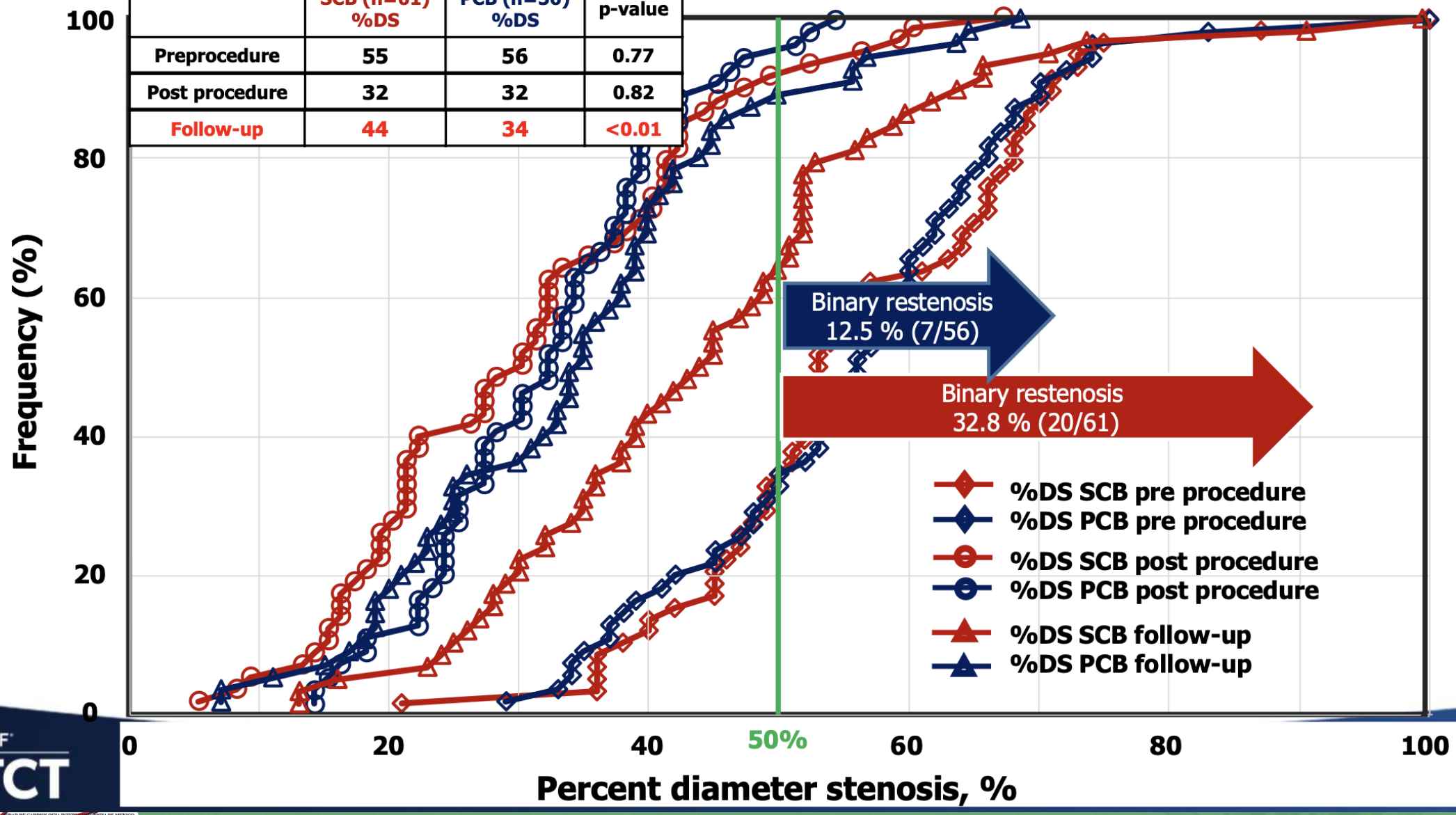
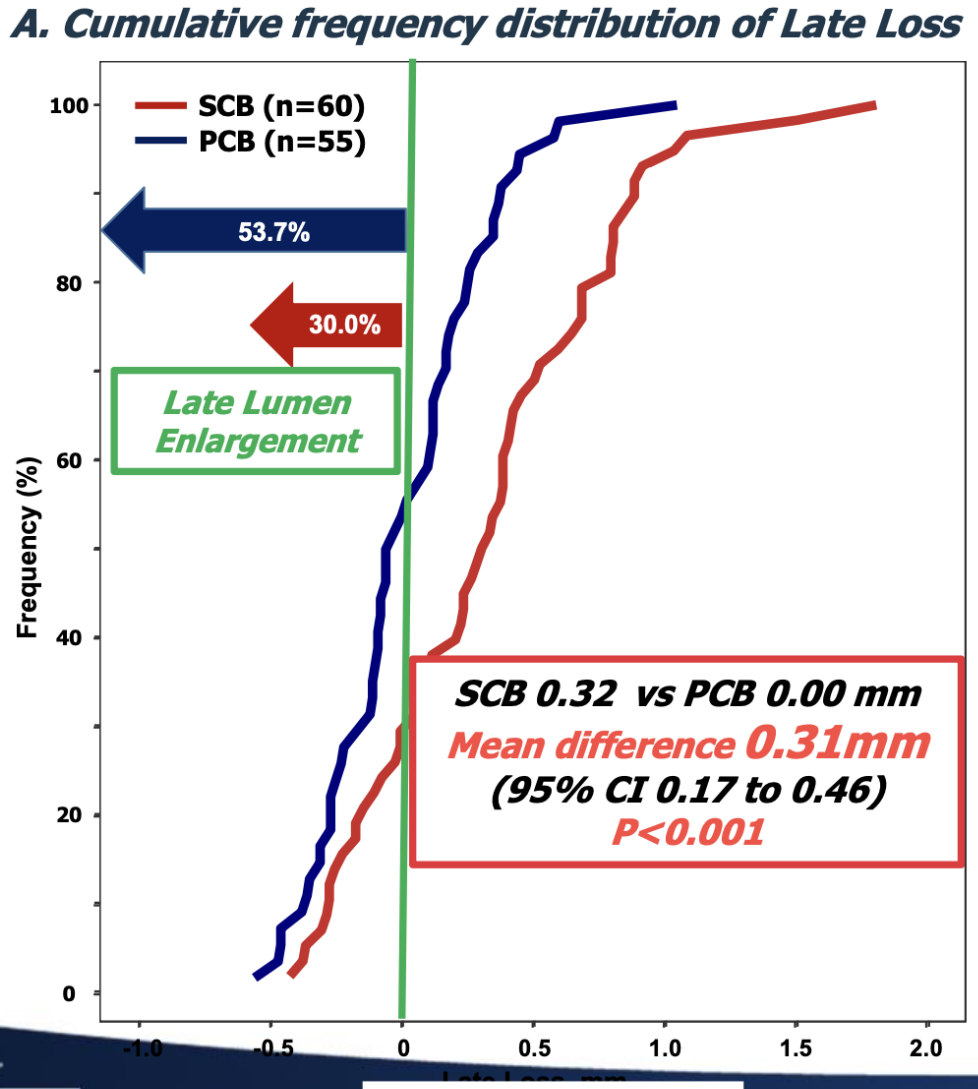
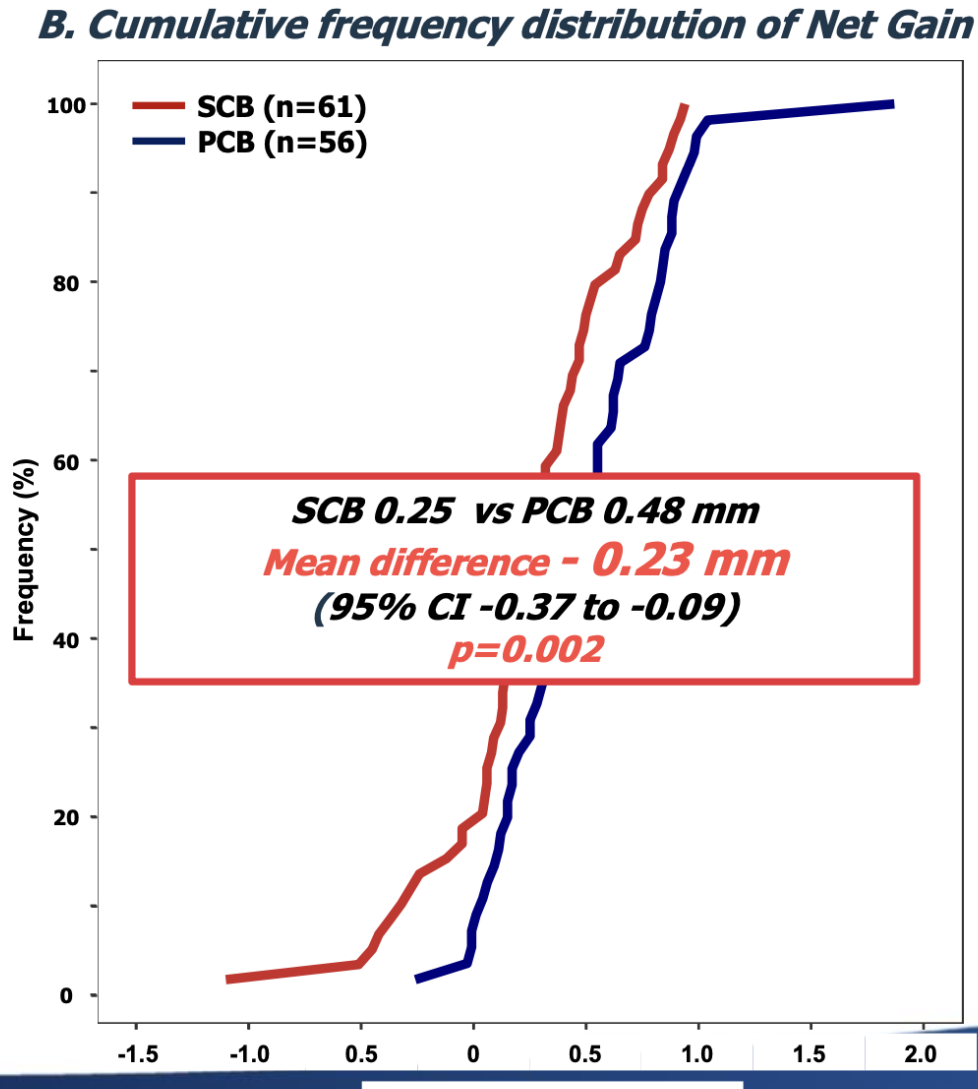
Cumulative frequency distribution of percent diameter stenosis (%DS)

	SCB (n=61) %DS	PCB (n=56) %DS	p-value
Preprocedure	55	56	0.77
Post procedure	32	32	0.82
Follow-up	44	34	<0.01



Cumulative frequency distribution of Late Loss and Net Gain





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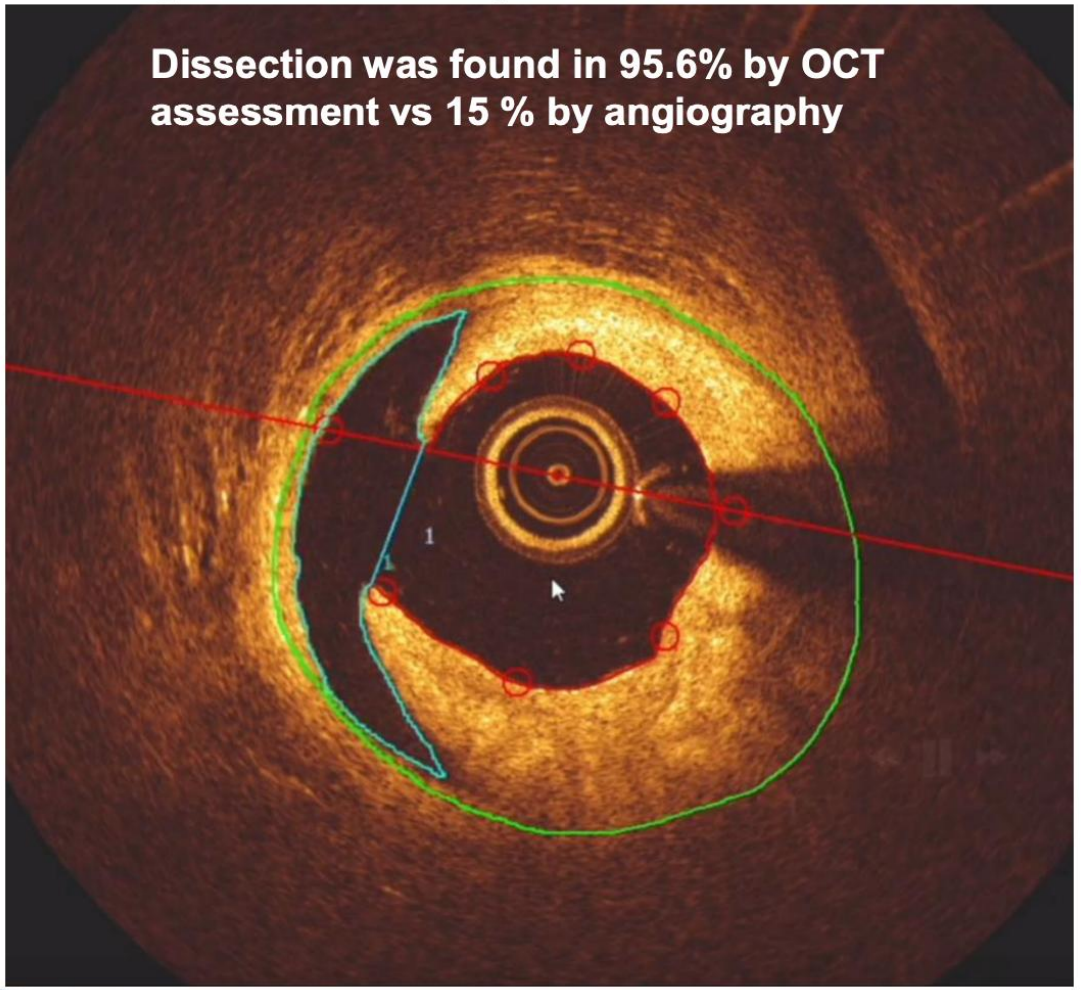
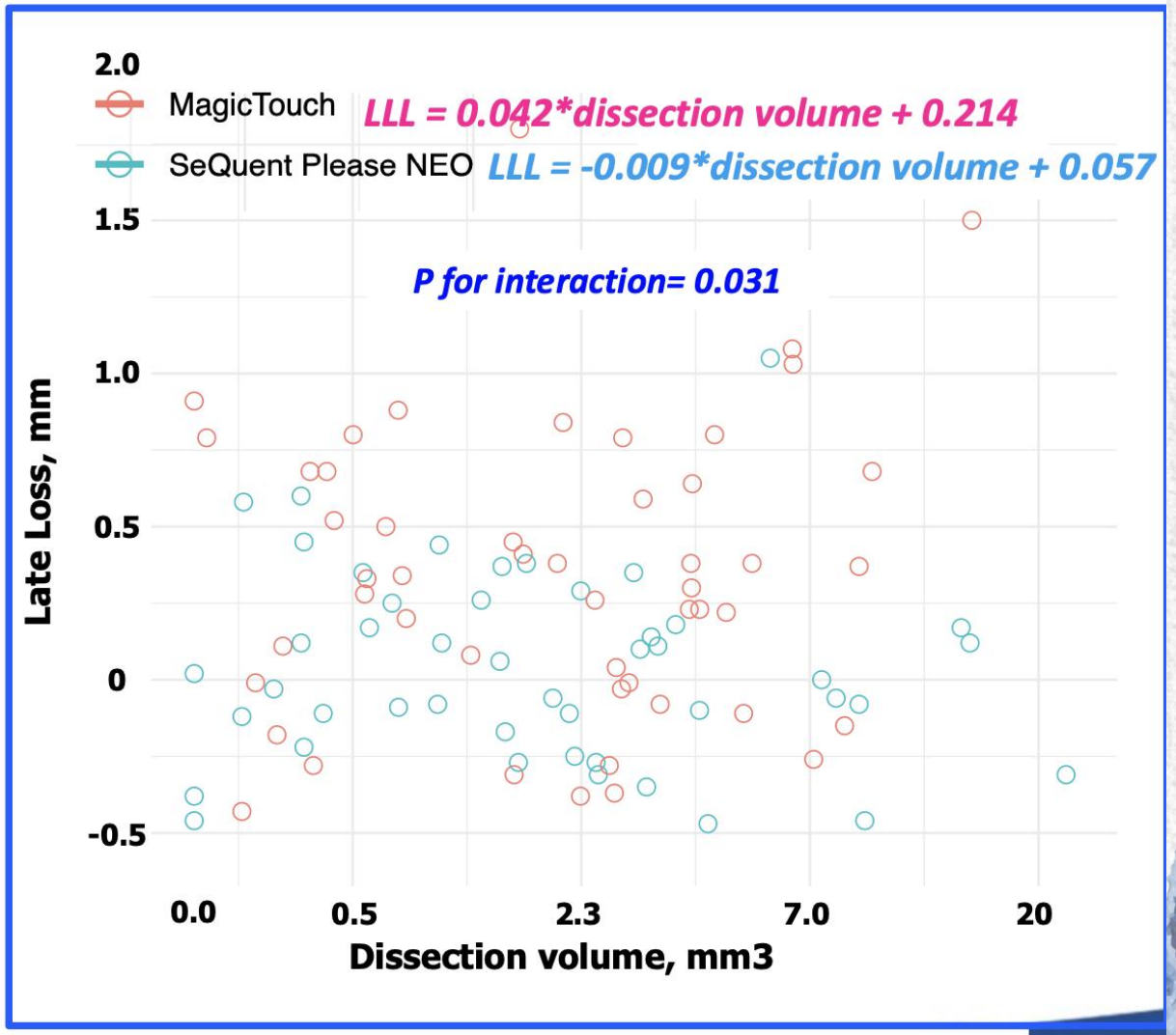
Relationship between dissection volume on OCT and angiographic late loss

Quantitative Analysis of Dissection

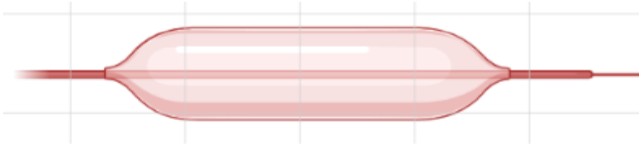




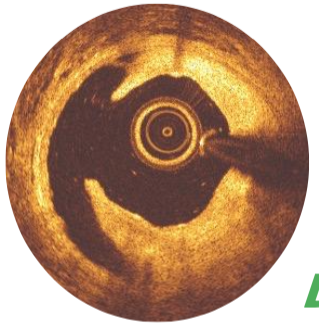
With SCB, late loss increases as a function of dissection volume, while with PCB, late loss is not related to dissection and even decreases as a function of the increase in dissection volume.

Summary of the results

Sirolimus-coated balloon (Magic Touch SCB™)



Late Loss: 0.32mm
Late Lumen Enlargement: 30.0%
Dissection: Unfavorable

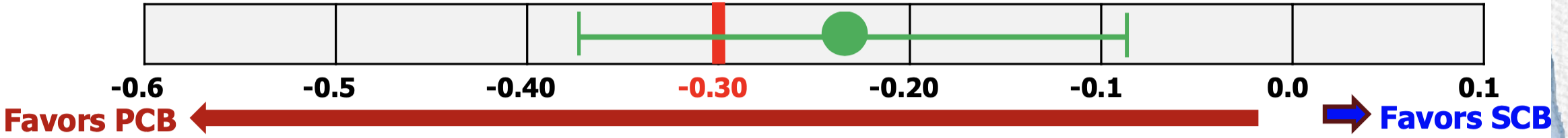


Paclitaxel-coated balloon (SeQuent Please Neo™)

Late Loss 0.00mm
Late Lumen Enlargement 53.7%
Dissection: or Irrelevant or Favorable

Primary Endpoint: 6-month Angiographic Net Lumen Gain
SCB vs PCB: 0.25 vs 0.48mm

Non-inferiority margin



Absolute difference in net gain : -0.23mm (95% CI: -0.37 to -0.09)
Lower margin of the one-sided 95% CI: -0.37mm ,P for non-inferiority = 0.173

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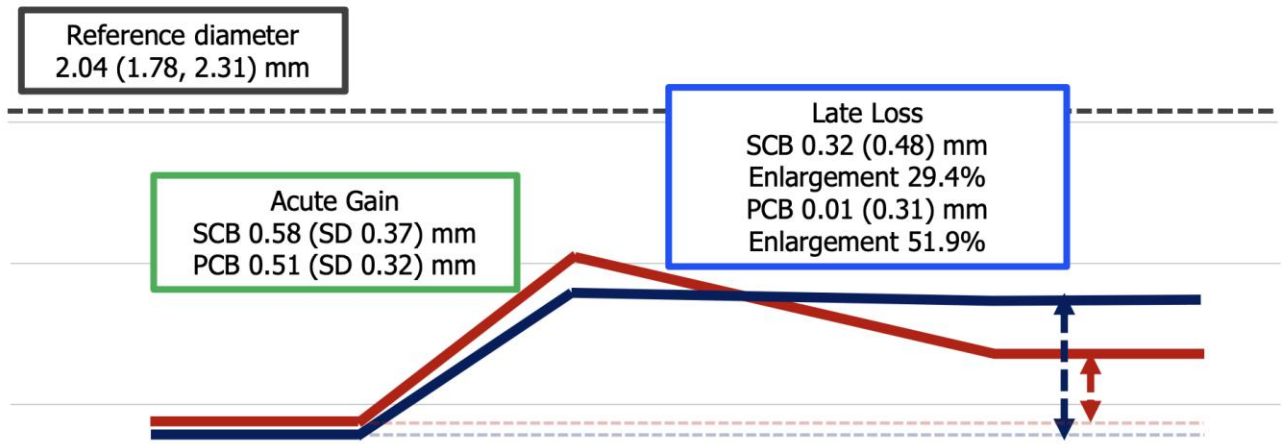
TAKE HOME MESSAGES

- Treatment of small vessels (< 3 .0 mm) with DCB is safe and effective, considering technical factors
- So i start the treatment of this vessels in the DCB strategy
- Nowadays data suggest better results with paclitaxel DCBs
- Putting a stent also is a Good option if you do it properly

Clinical Outcomes

	Overall	SCB	PCB	Odds ratio (95%CI)
Number of patient	121	61	60	
Discharge				
Periprocedural MI*	5 (4.1%)	4 (6.6%)	1 (1.7%)	4.08 (0.44, 37.7)
Acute closure/thrombosis	0	0	0	NA
6 months				
DoCE **	11 (9.1%)	7 (11.5%)	4 (6.7%)	1.81 (0.50, 6.54)
Death	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA
MI	5 (4.1%)	4 (6.6%)	1 (1.7%)	4.08 (0.44, 37.7)
TV-MI	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA
TLR **	11 (9.1%)	7 (11.5%)	4 (6.7%)	1.81 (0.50, 6.54)
Clinically or physiologically indicated TLR**	8 (6.6%)	6 (9.8%)	2 (3.3%)	3.16 (0.61, 16.3)
TVR (including TLR)	15 (12.4%)	9 (14.8%)	6 (10.0%)	1.56 (0.52, 4.69)
non-TVR	14 (11.6%)	7 (11.5%)	7 (11.7%)	0.98 (0.32, 2.99)
Late closure/thrombosis	1 (0.8%)	1 (1.6%)	0 (0.0%)	NA

Serial Changes of MLD



	SCB (n=59) MLD, mm	PCB (n=55) MLD, mm
	0.93 (0.33)	0.88 (0.28)
	1.51 (0.34)	1.40 (0.29)
Follow-up	1.19 (0.38)	1.37 (0.35)

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Pre procedure | Post DCB | 6-month follow-up

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Comparing a strategy of sirolimus-eluting balloon treatment to drug-eluting stent implantation in de novo coronary lesions in all-comers: Design and rationale of the SELUTION DeNovo Trial

Christian Spaulding, MD, PhD[a,*], Florian Krackhardt, MD[b,*], Kris Bogaerts, PhD[c,d], Philip Urban, MD[e], Susanne Meis, BA[f], Marie-Claude Morice, MD[g], and Simon Eccleshall, MD[h] *Paris, France; Berlin, Germany*

** Up to 30% provisional DES is anticipated
Actual Rate after 1200 patients is 21%.

3326 candidates for PCI who satisfy trial inclusion/exclusion criteria * from 50-60 sites in Europe and Asia

* **Major inclusion criteria**
- Single or multiple lesions suitable for treatment by either SEB or DES
- No limitation in the number of lesions/vessels to be treated.
- Anticipated need for bailout DES < 30%
- Target lesion diameter between 2 and 5 mm

Major exclusion criteria
- Target lesion in LM or SVG, and/or is CTO or ISR
- Prior PCI in target vessel at any time
- Prior PCI of non-target vessel < 30 days
- ST segment elevation myocardial infarction or unstable NSTEMI

Randomisation 1:1 before procedure

SEB strategy

Lesion preparation & SEB for all target lesions (with bail-out DES if needed**)

** **Bail-out DES implantation** if:
- Flow-limiting dissection
- Residual stenosis > 30%
- FFR < 0.8 or iFR < 0.89

DES strategy

DES for all target lesions according to local practice (with SEB if stent not deliverable)

Staging of multivessel procedures allowed within 45 days

Follow-up at 30 days, 6 months, and 1 year then annually for 5 years

*** **Target Vessel Failure (TVF)**
- Cardiac dearth
- Target vessel related MI
- Target vessel revasc.

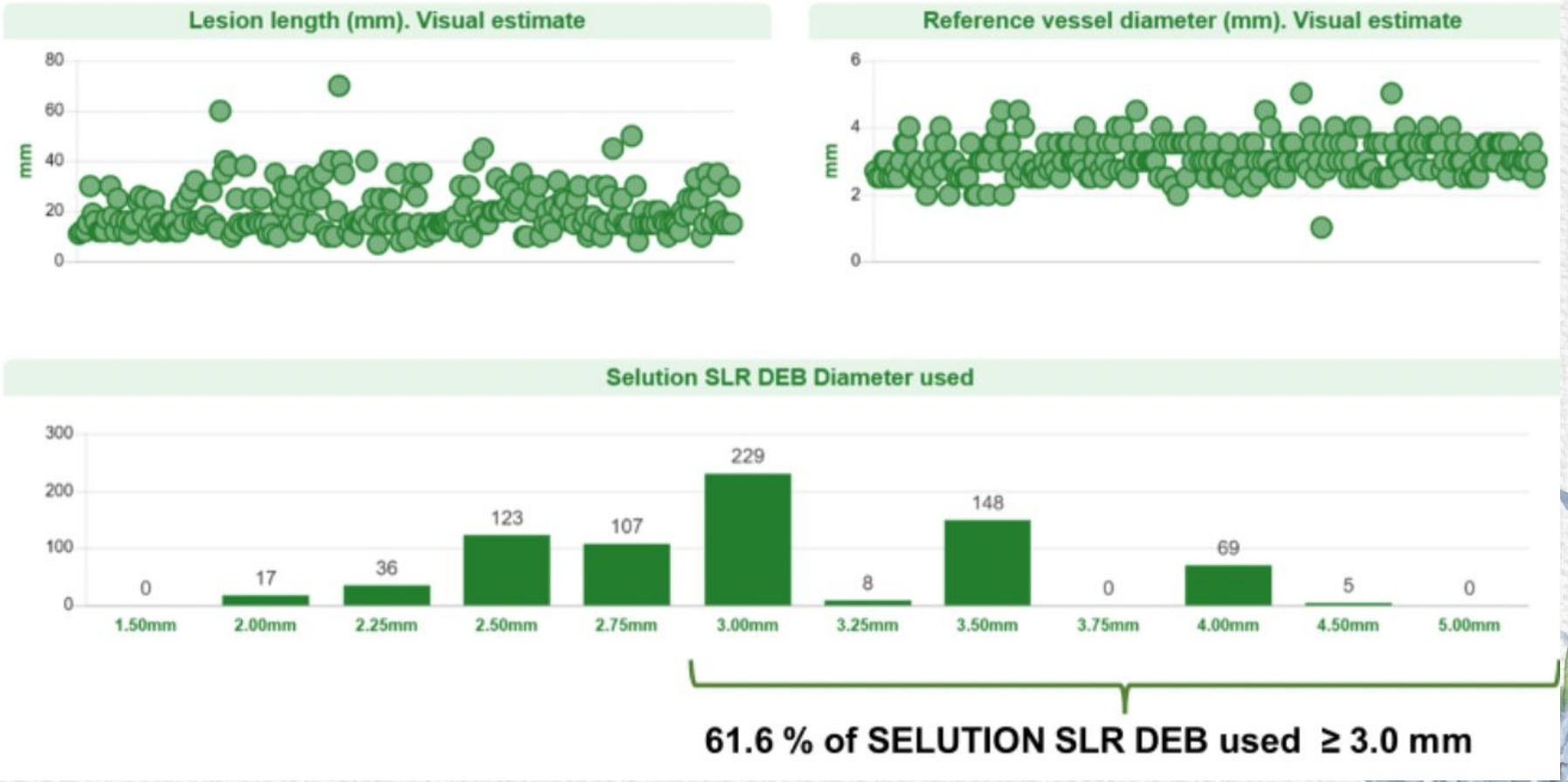
Primary endpoints = non-inferiority for TVF*** at 1 year and at 5 years

Conditional superiority analysis if non-inferiority established at 5 years

Selution DeNovo Study

PCI: Percutaneous Coronary Intervention; SEB: Selution Eluting Balloon; DES: Drug Eluting Stent; LM: Left Main; SVG: Saphenous Vein Graft; CTO: Chronic Total occlusion; ISR: In-Stent Restenosis; NSTEMI: Non-ST Segment Elevation Myocardial Infarction; FFR: Fractional Flow Ratio; iFR: instantaneous Flow Ratio; TVF: Target Vessel Failure

Balloon Size correlated to Lesion Length & Vessel Size



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