

Drug eluting balloon (DEB) in Real World -Insight from Kurashiki Central Hospital

Kazushige Kadota
Kurashiki Central Hospital
Japan



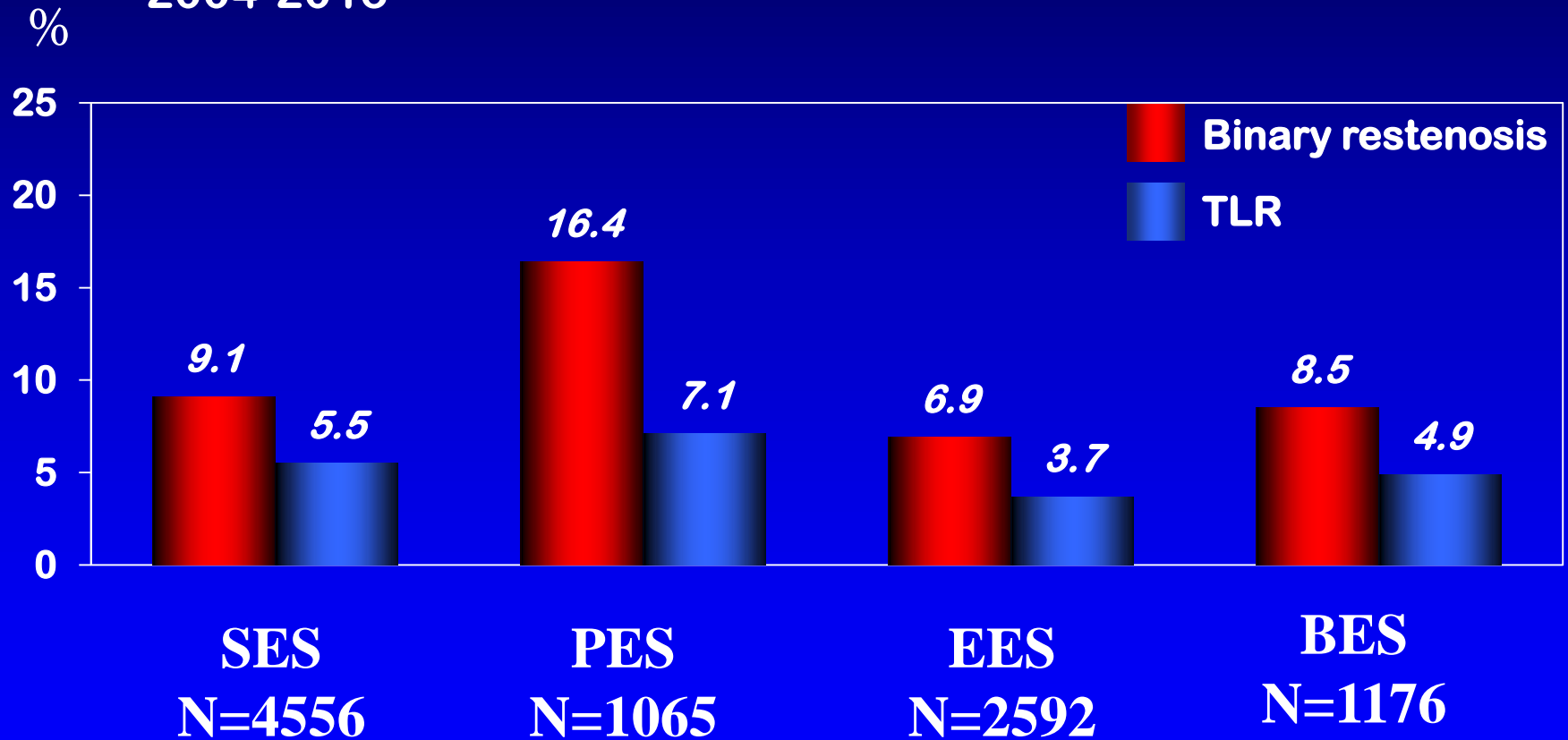
Kurashiki Central Hospital

Angiographical Outcomes after Drug-eluting Stent Implantation

At 8-months Angiographic Follow-up

f/u rate:80.2% (9489/11834)

2004-2013



Drug eluting stent restenosis

Drug-eluting stents have dramatically reduced restenosis risks compared with bare metal stents and conventional balloon angioplasty.

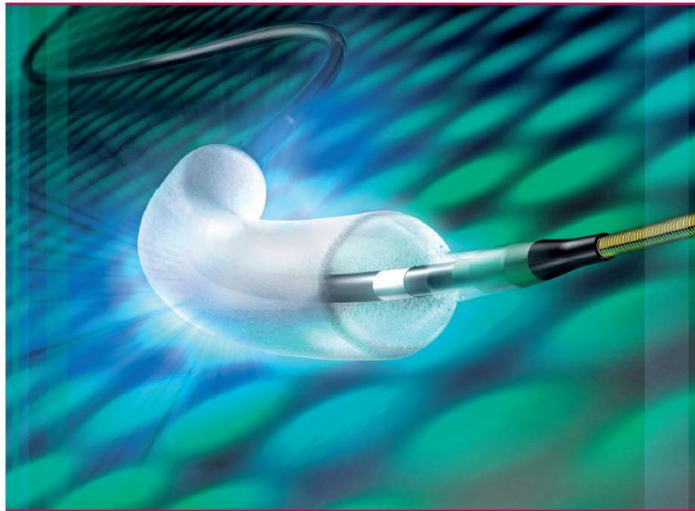
However, recurrent restenosis may still occur in some cases.



SeQuent[®] Please Paclitaxel-coated Balloon

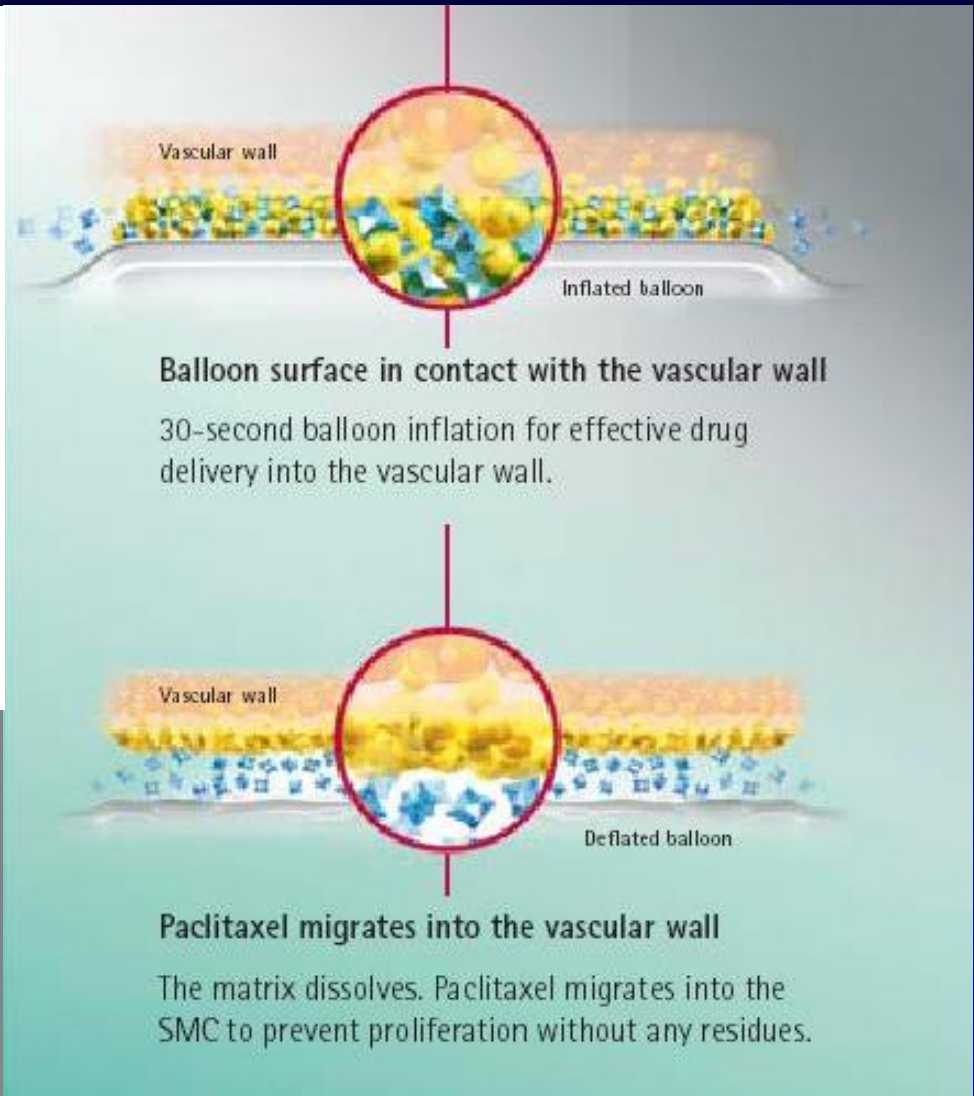
B. Braun Vascular Systems SeQuent[®] Please

Clinically proven Paclitaxel releasing
coronary balloon catheter



SeQuent[®] Please

Combines targeted drug delivery with PTCA balloon-like flexibility and handling.



Treatment of BMS Restenosis with DCB PACCOCATH ISR I, II

ISR I : n=52

ISR II : n=56

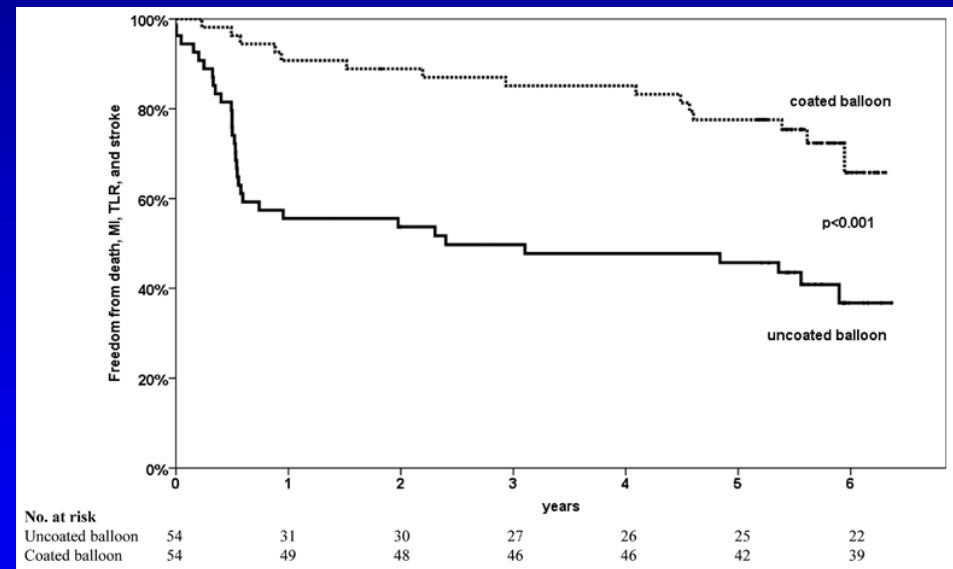
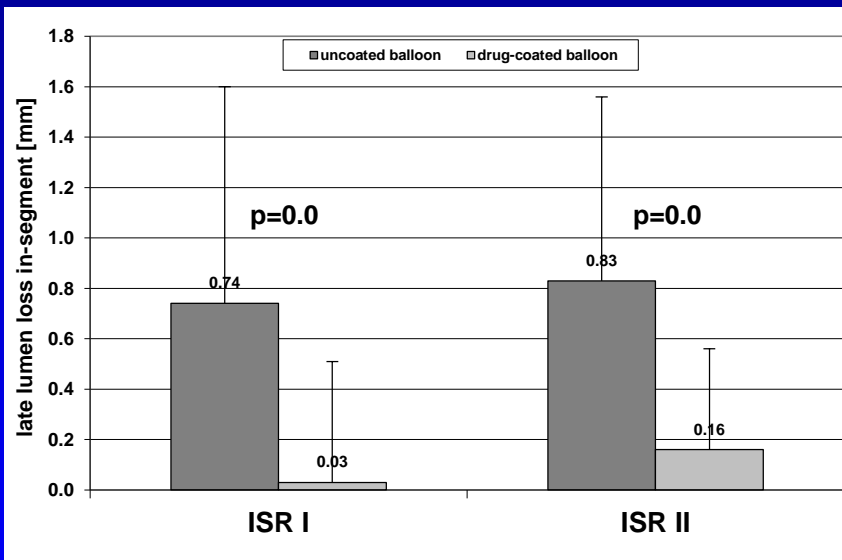


Paclitaxel-coated balloon catheter : n=54

Non-coated balloon : n=54

Late luminal loss in-segment

Freedom from death, MI, TLR and stroke



Scheller B. et al. *New Engl J Med* 2006;355:2113-24.

Scheller B. et al. *JACC: Cardiovascular Interventions* 2012;5:323-30.



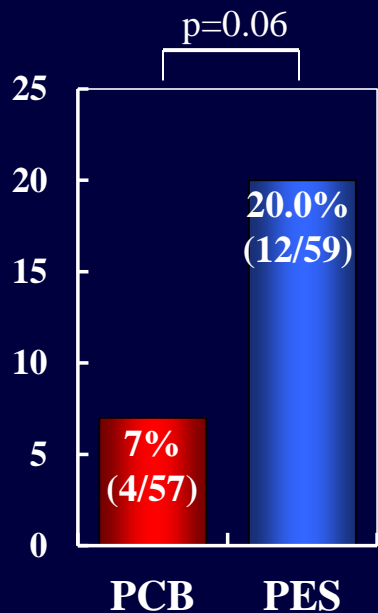
DCB Versus DES for BMS Restenosis

PEPCAD II

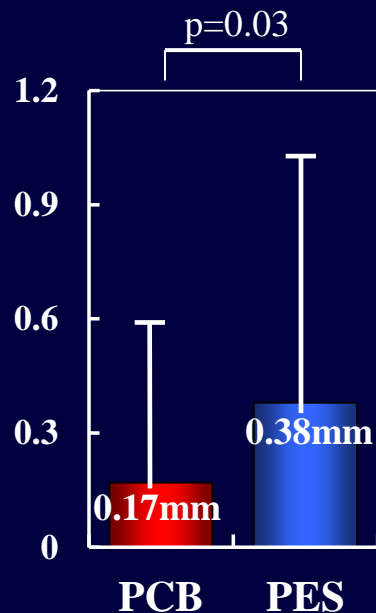
Paclitaxel-coated balloon : n=66

Paclitaxel-eluting stent : n=65

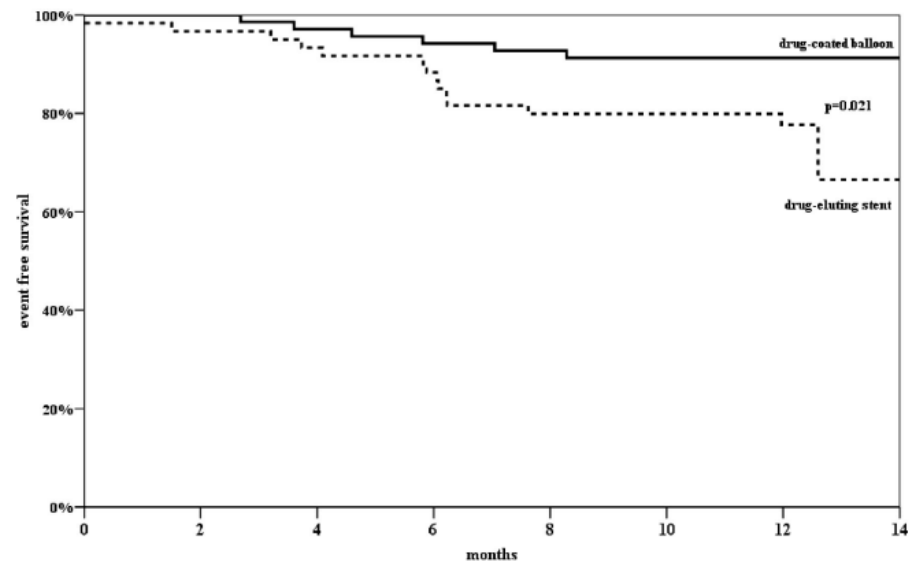
Angiographic restenosis @ 6 months



Late lumen loss @ 6 months



Freedom from stent thrombosis, TLR, myocardial infarction, and death @ 12 months



PCB vs. POBA for SES Restenosis

The aim of this study was to investigate the efficacy of paclitaxel-coated balloon for the treatment of sirolimus-eluting stent restenosis. This study was a prospective single-blind randomized trial conducted in 50 patients with sirolimus-eluting stent restenosis.

Study Periods:
Sep 2008- Nov 2009

Patients randomized
N=50

Randomization

**Paclitaxel-coated
Balloon
(PCB group) n=25**

**Conventional
Balloon Angioplasty
(BA group) n=25**

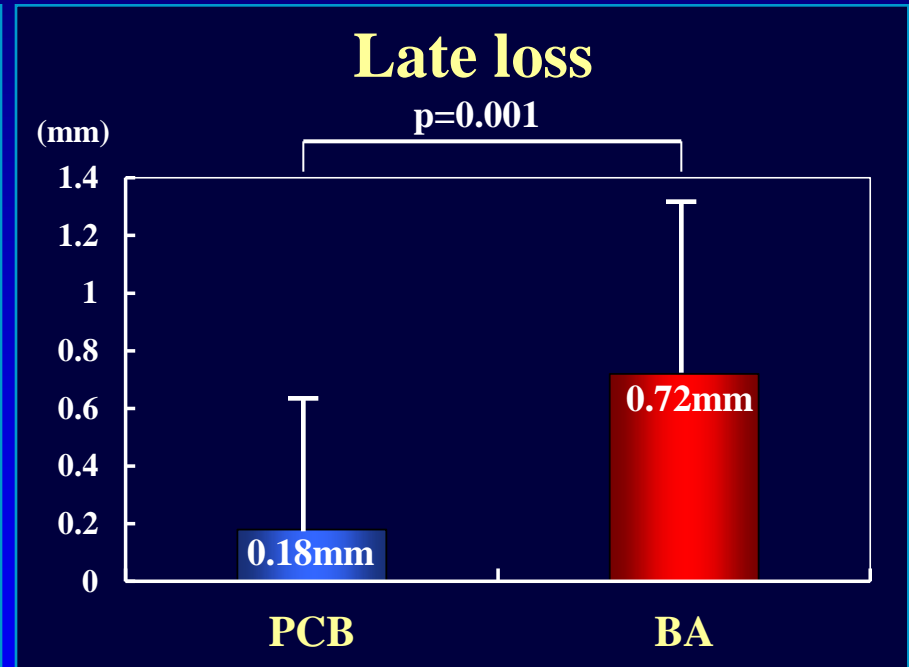
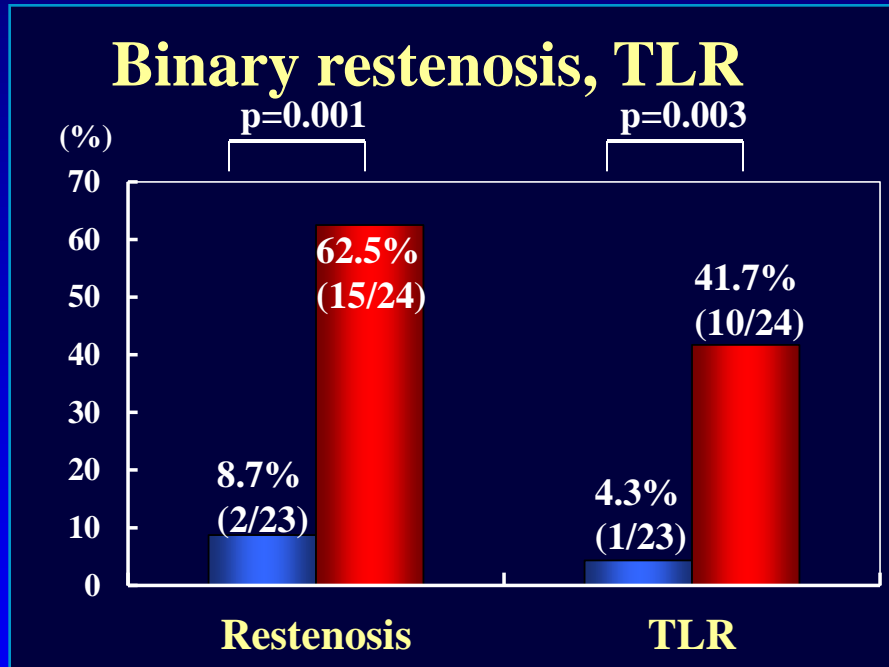


PCB vs. POBA for SES Restenosis

Six-months Angiographic Follow-up

Follow-up rate : 94% (47/50 Lesions)

PCB group:23 BA group:24



■ PCB group
■ BA group



2014 ESC/EACTS Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Restenosis			
Repeat PCI is recommended, if technically feasible.	I	C	
DES are recommended for the treatment of in-stent restenosis (within BMS or DES).	I	A	501,502,508 511,524
Drug-coated balloons are recommended for the treatment of in-stent restenosis (within BMS or DES).	I	A	507– 511,524
IVUS and/or OCT should be considered to detect stent-related mechanical problems.	IIa	C	



DCB or re DES for DES ISR

Which strategy is better ?





(Januray 2010 – August 2013)

*Inclusion Criteria
Informed Consent* →

**309 Pts DES-ISR
Randomization**

← *Rx Centralized
Stratification:
ISR Length & Edge*

Xience Prime
(Abbott Vascular)

**155 Pts
EES**

**154 Pts
DEB**

SeQuent Please
(B. Braun)

100% Angiographic Success

← *4 Died
18 Refused*

*3 Died
12 Refused* →

Mean: 279 days
(Median: 248)

**133 Pts
Angio FU**

**QCA
Primary
End-point**

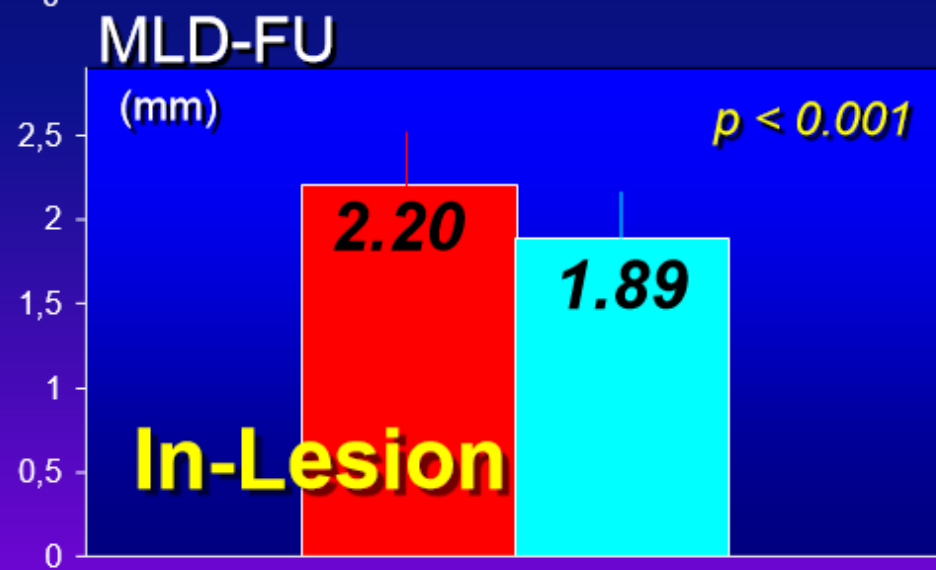
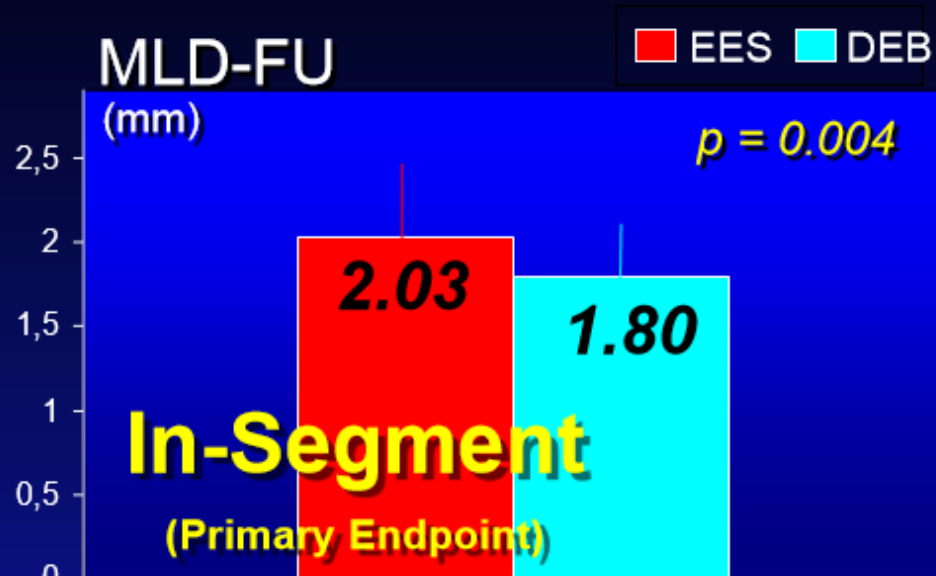
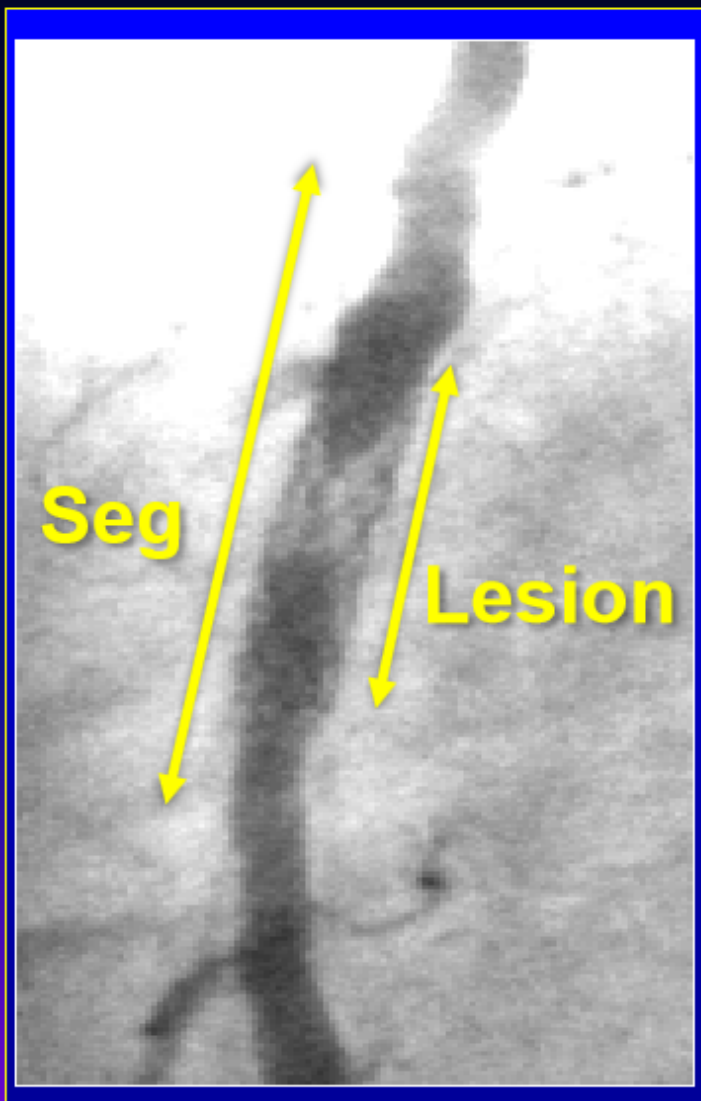
**139 Pts
Angio FU**

Mean: 266 days
(Median: 246)

(272 Patients: 90% of Eligible)



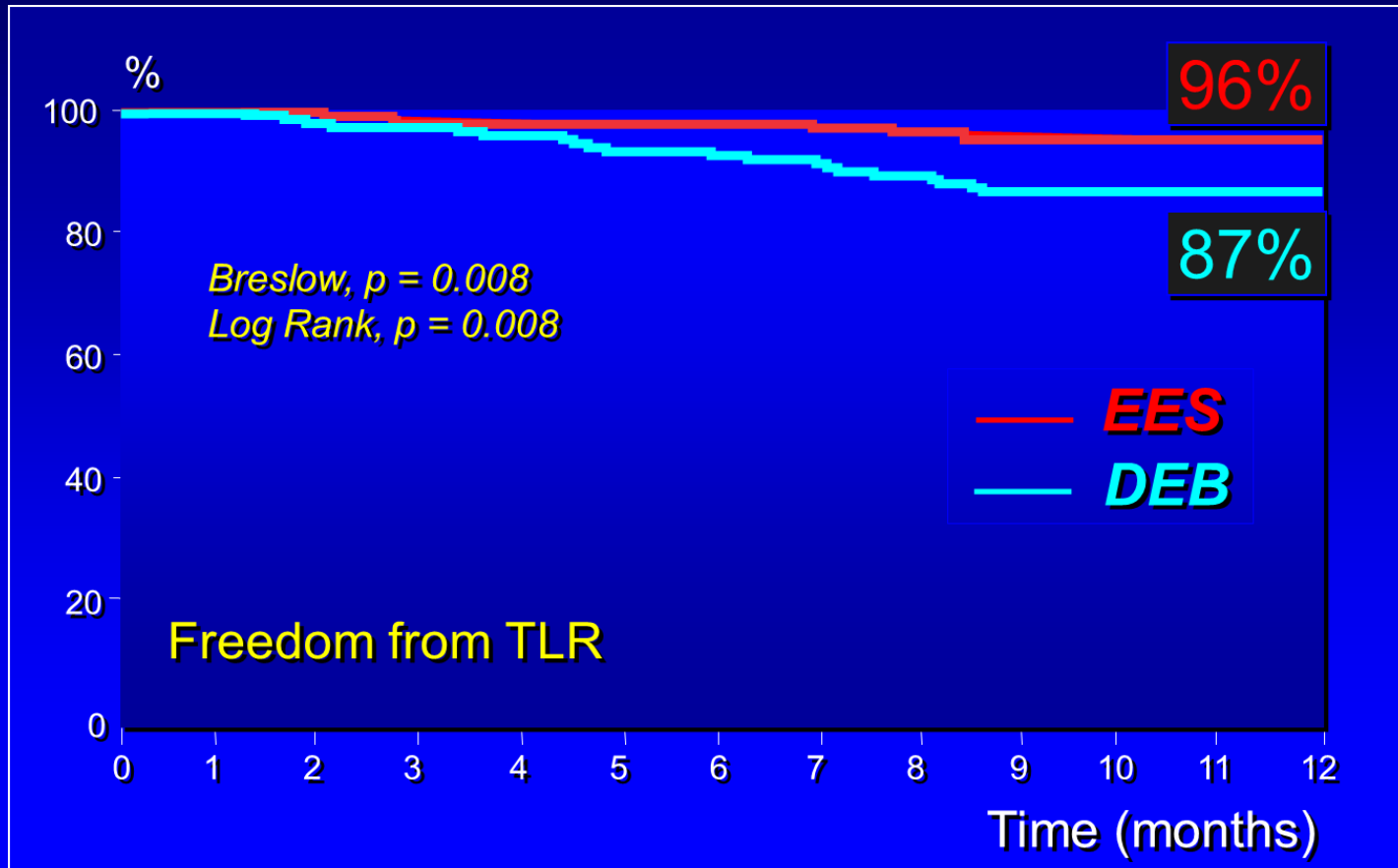
QCA: MLD at FU



The RIBS IV Clinical Trial

Clinical Follow-up: TLR

1 Year FU 309 Patients (100%); FU Time 360_±35 days

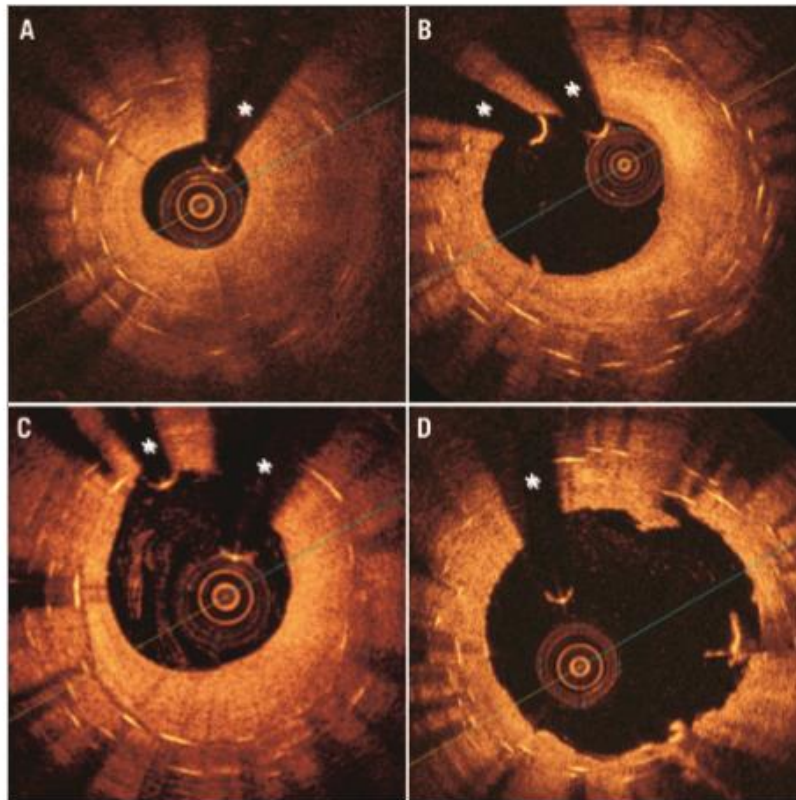


Management of recurrent in-stent restenosis: onion skin full metal jacket?

Fernando Alfonso^{1*}, MD, PhD, FESC; Bruno Scheller², MD, PhD

1. Cardiac Department, Hospital Universitario de La Princesa, IIS-IP, Universidad Autónoma de Madrid, Madrid, Spain;

2. Clinical and Experimental Interventional Cardiology, University of Saarland, Homburg/Saar, Germany



Onion Skin Appearance !

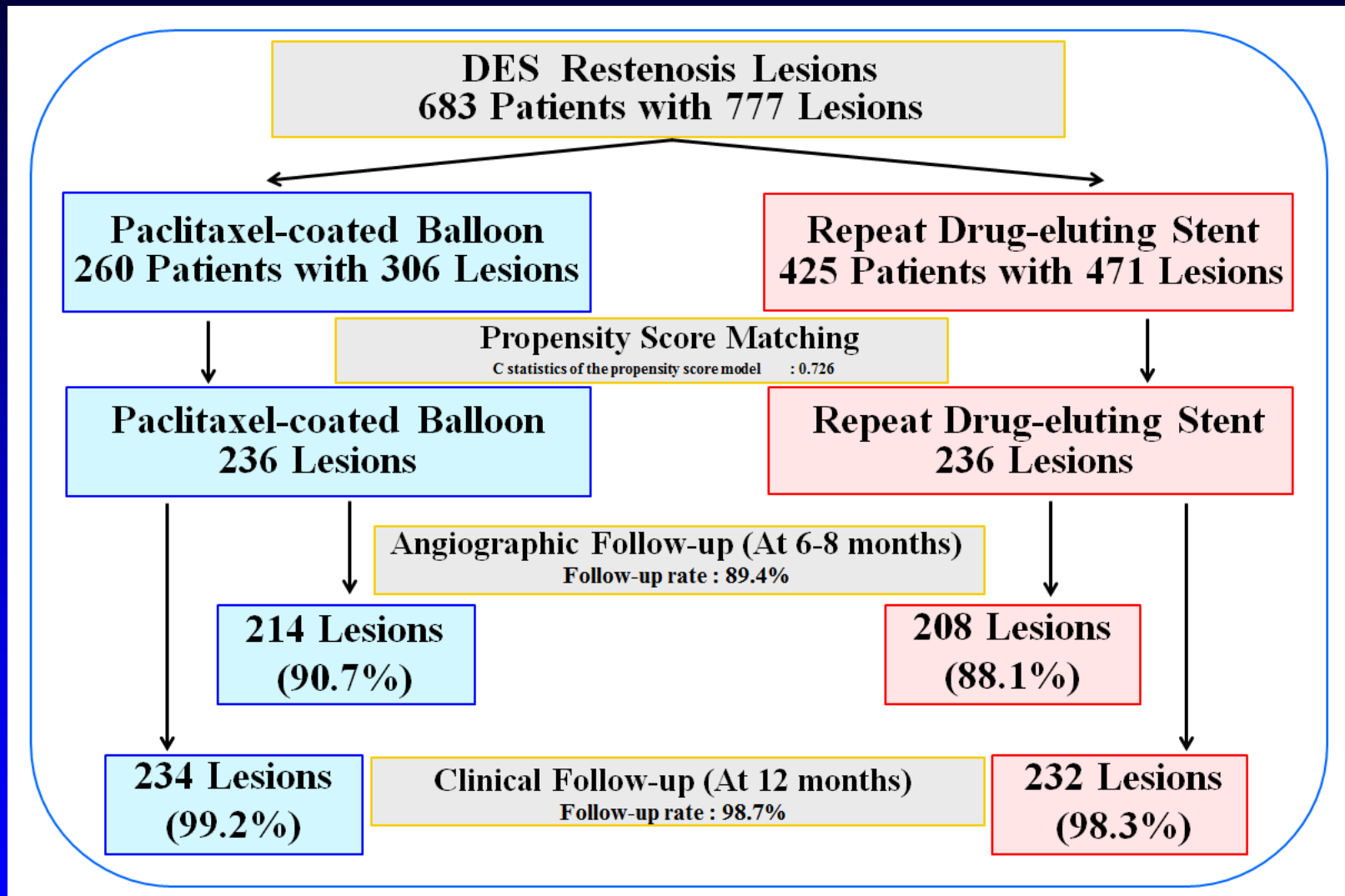
Paclitaxel-coated balloon catheter compared with drug-eluting stent for drug-eluting stent restenosis in routine clinical practice

Seiji Habara*, MD; Kazushige Kadota, MD; Takenori Kanazawa, MD; Tahei Ichinohe, MD; Shunsuke Kubo, MD; Yusuke Hyodo, MD; Suguru Otsuru, MD; Daiji Hasegawa, MD; Takeshi Tada, MD; Hiroyuki Tanaka, MD; Yasushi Fuku, MD; Tsuyoshi Goto, MD; Kazuaki Mitsudo, MD

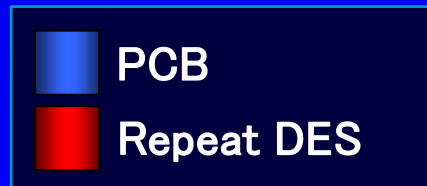
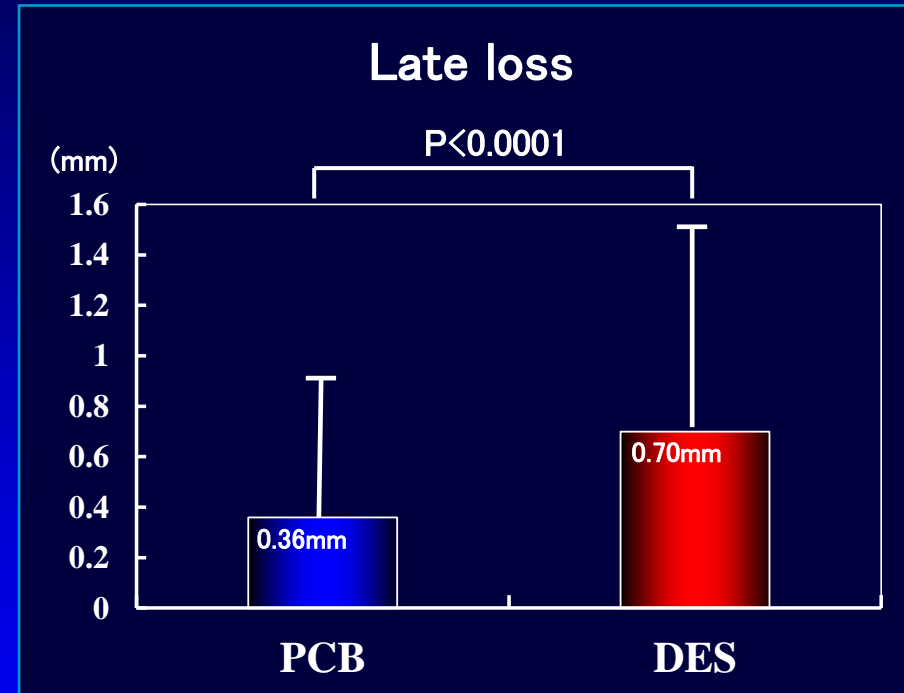
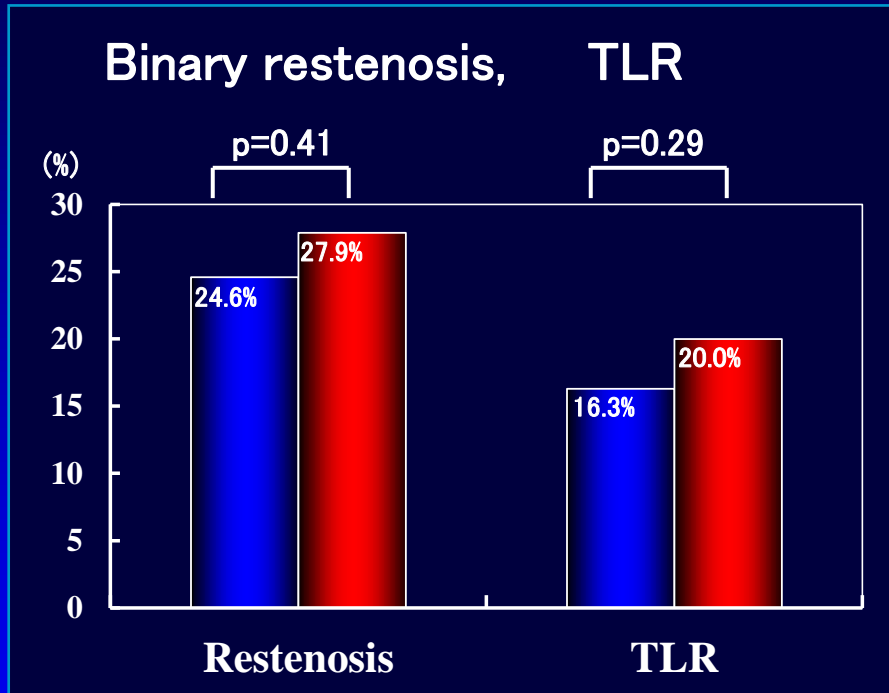
Department of Cardiology, Kurashiki Central Hospital, Kurashiki, Japan



Propensity Score Matching

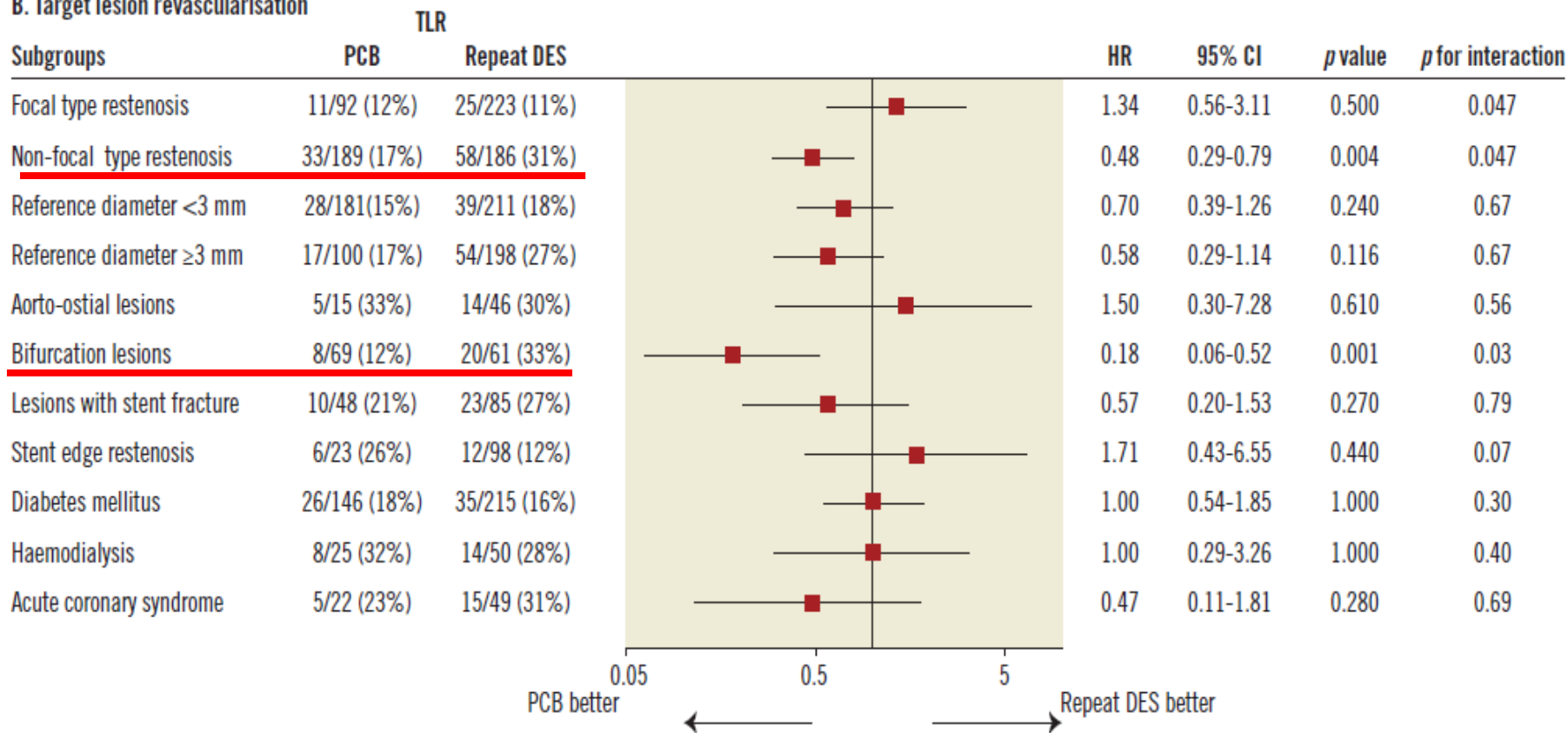


Six to Eight-months Angiographic Follow-up -Propensity matching study-

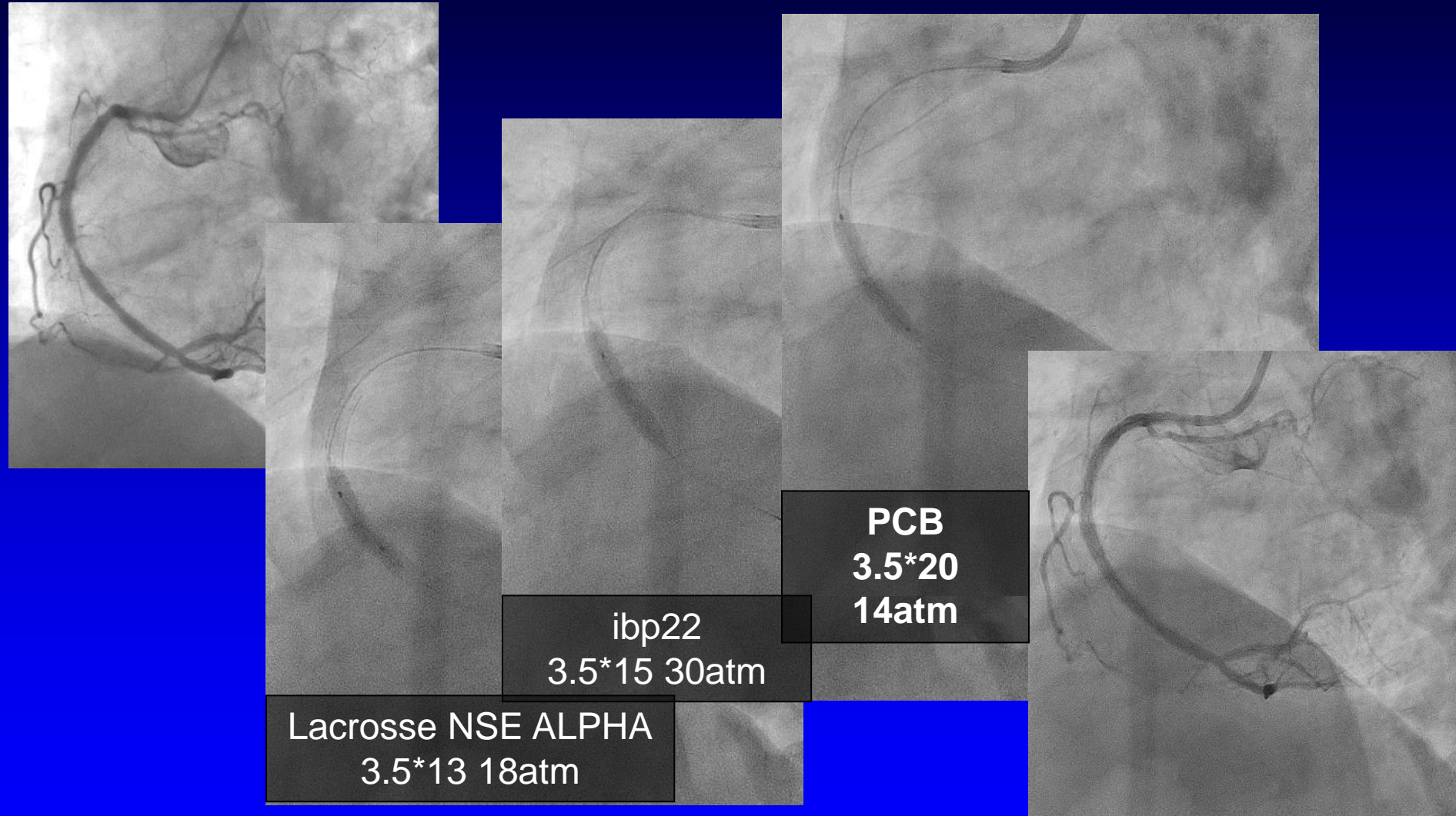


Comparison of TLR for Subgroups.

B. Target lesion revascularisation



PCB for EES ISR



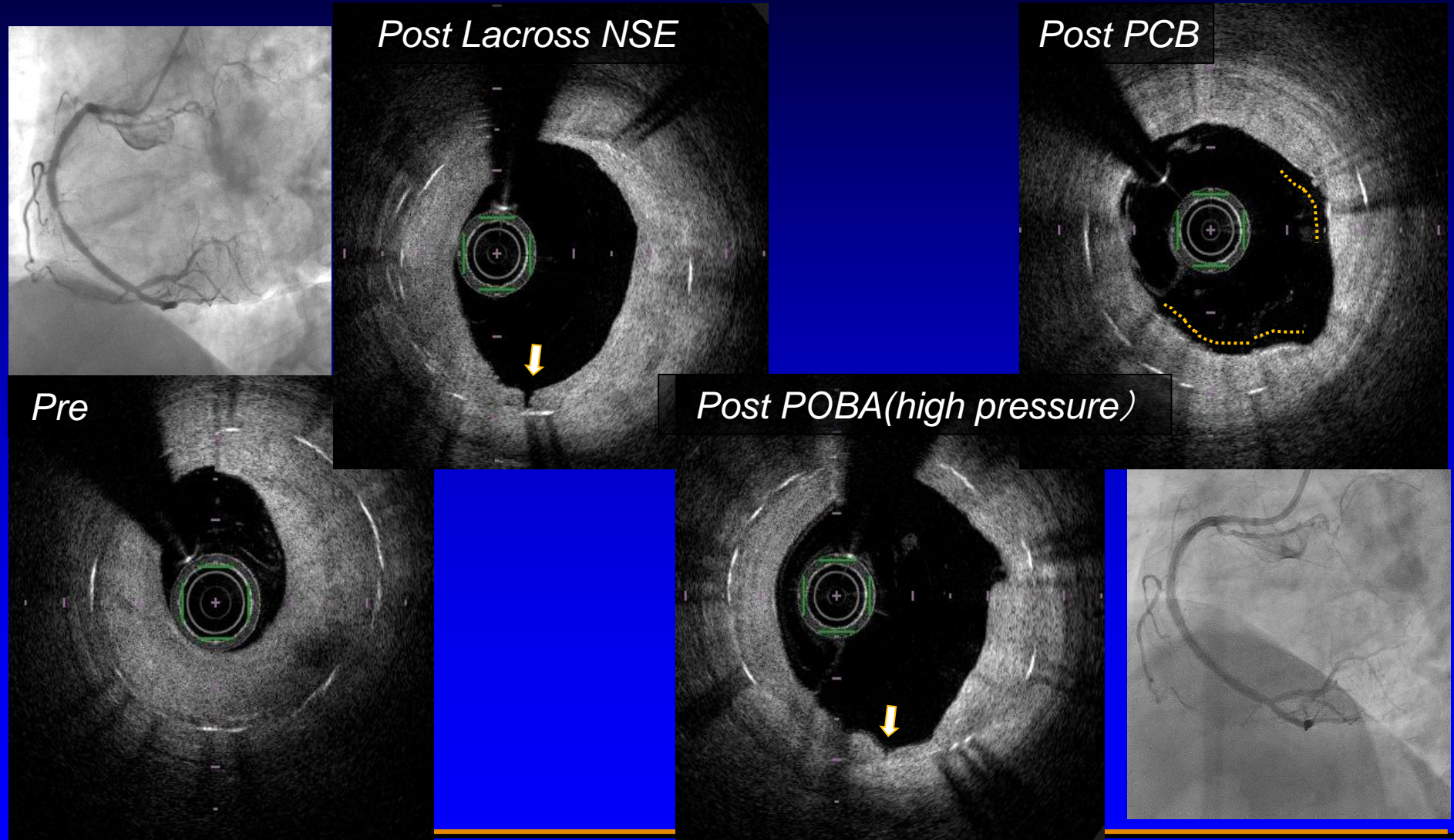
Lacrosse NSE ALPHA
3.5*13 18atm

ibp22
3.5*15 30atm

PCB
3.5*20
14atm

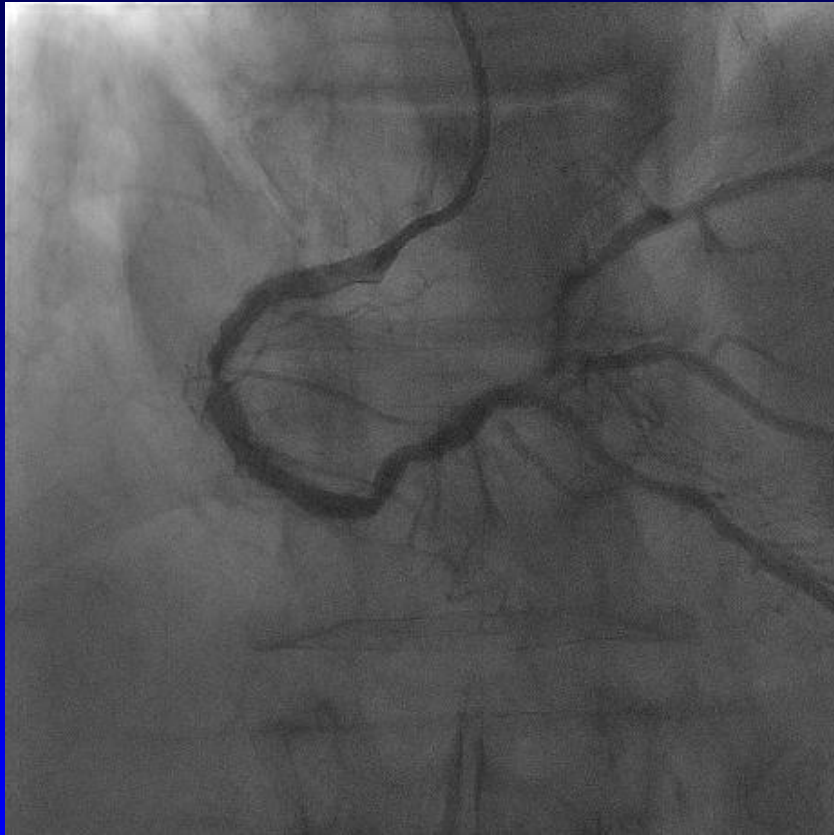


OFDI Guided PCI PCB for EES ISR

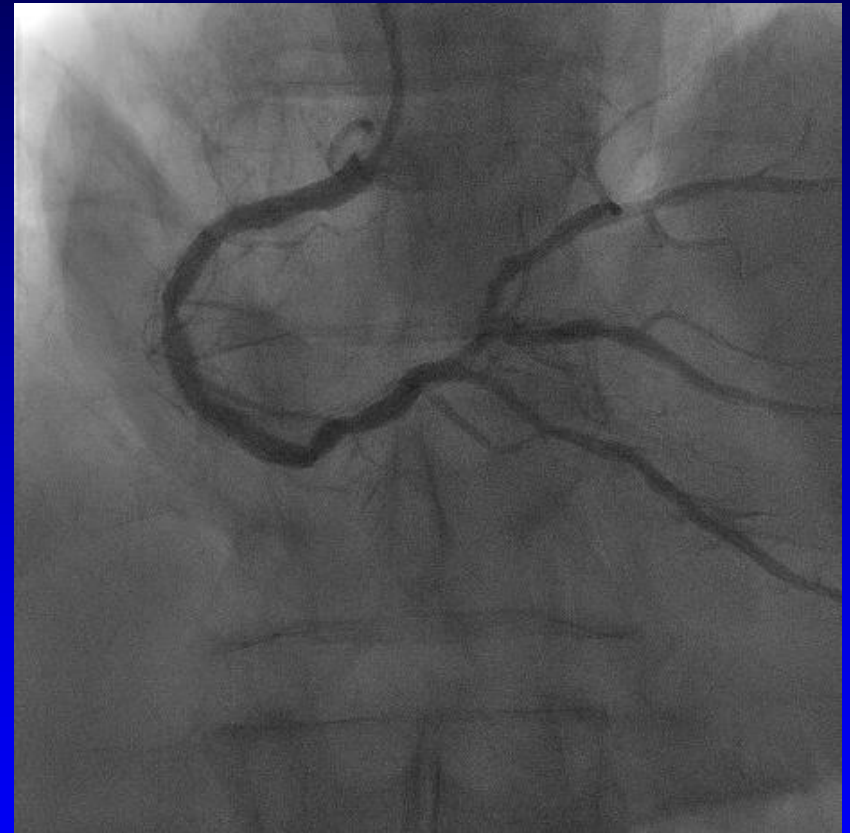


PCI for recurrent DCB failure ISR case

pre



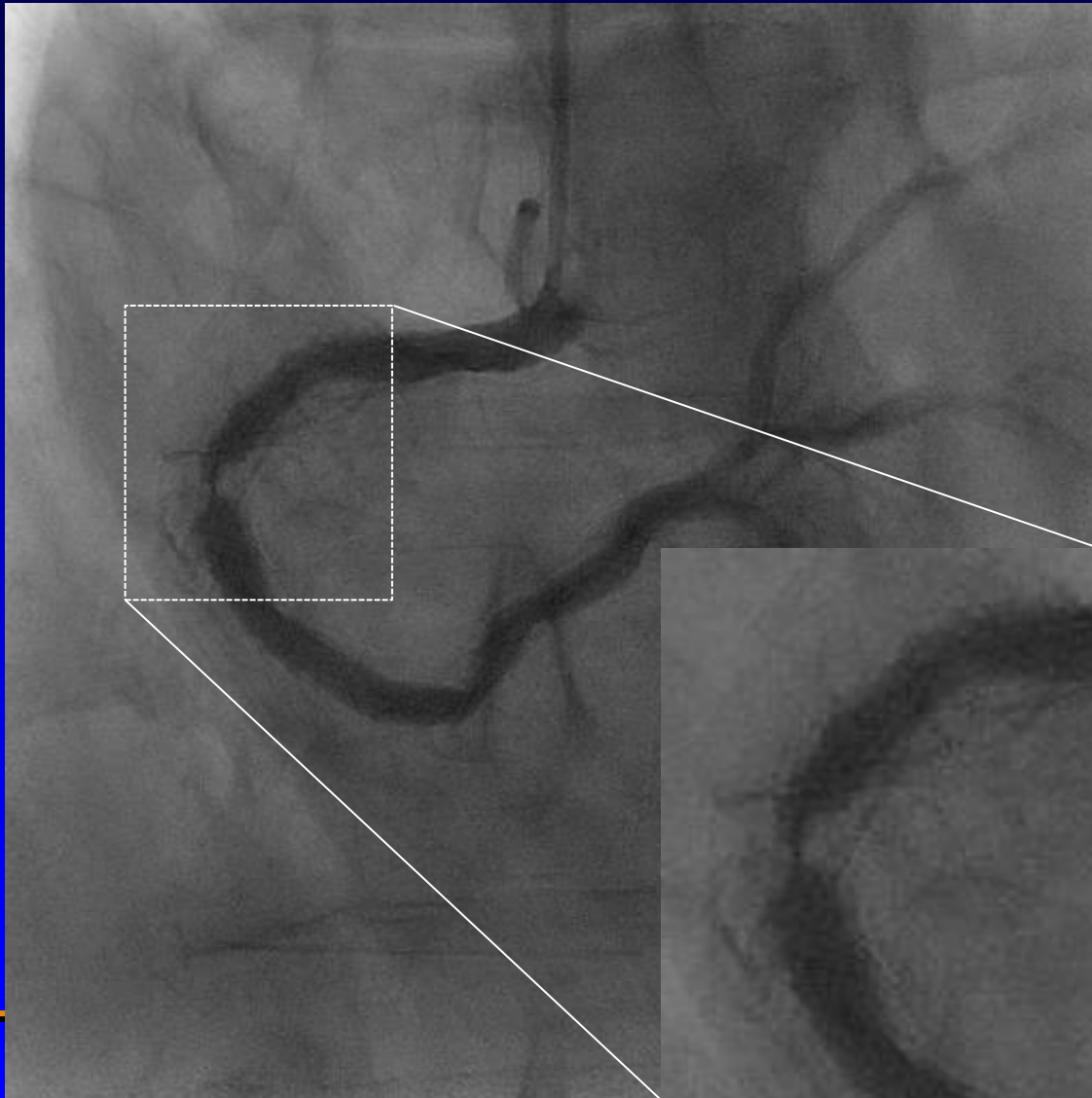
post



Lacross NSE 4.0*13mm→Cutting balloon 4.0*10mm→iBP4D 4.0*15mm→DCB 4.0*15mm



12m f/u CAG



BMS 4.0mm × 18mm

PES 3.5mm × 28mm

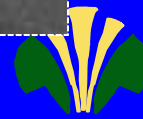
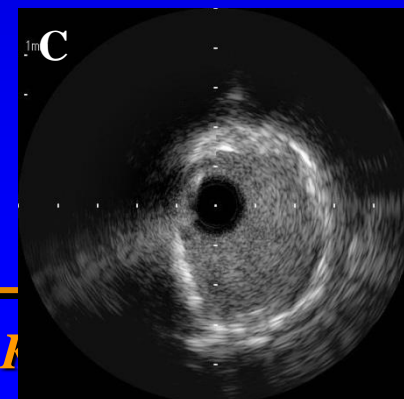
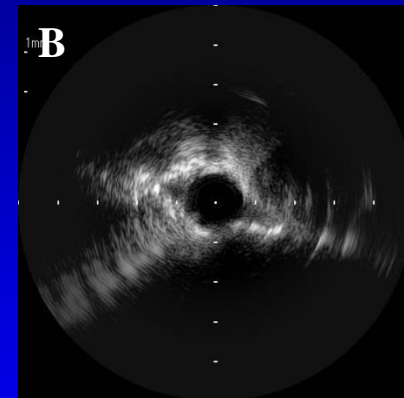
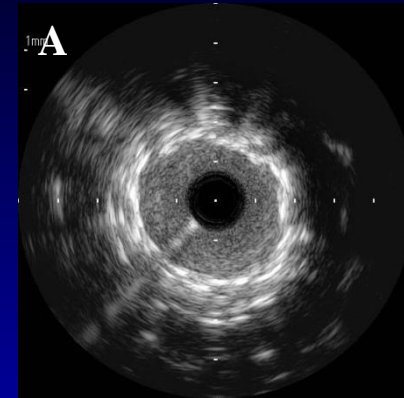
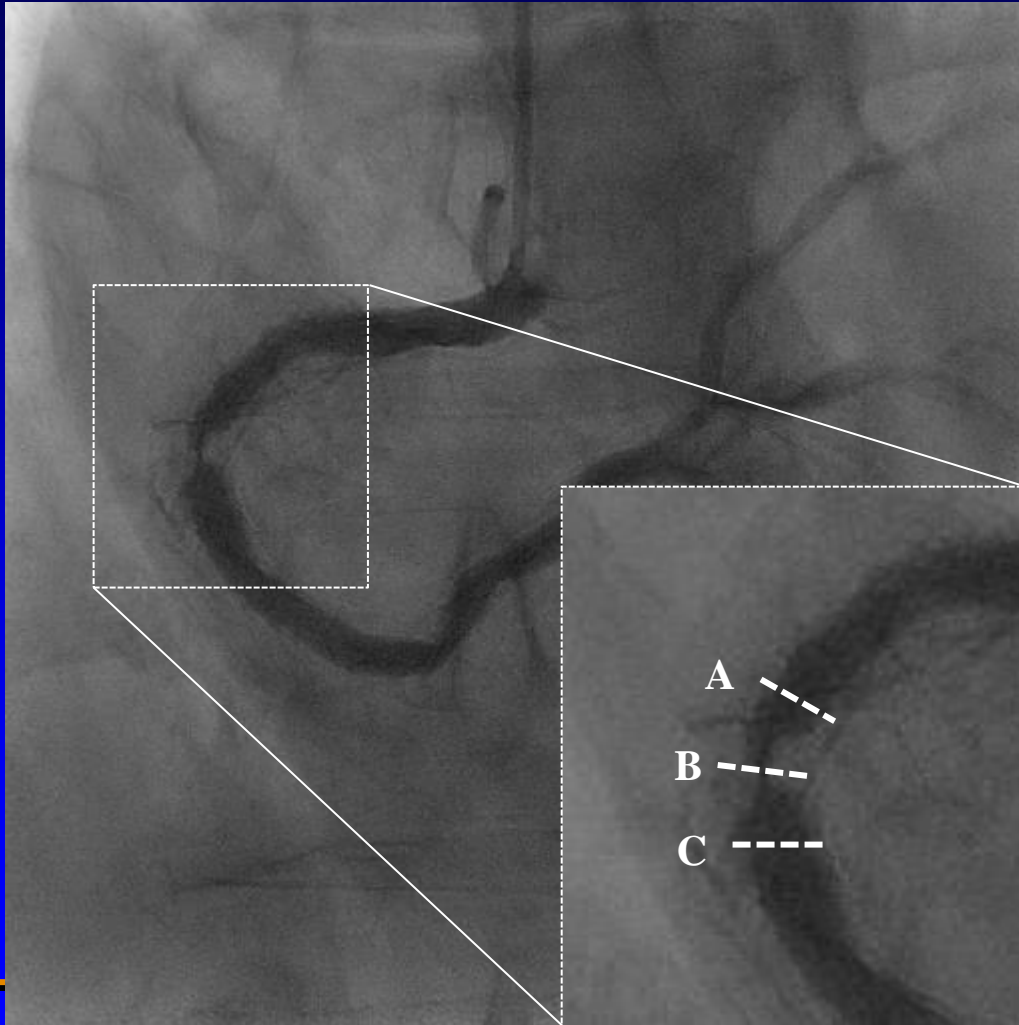
SES 3.5mm × 28mm

SES 3.5mm × 28mm

EES 3.5mm × 15mm

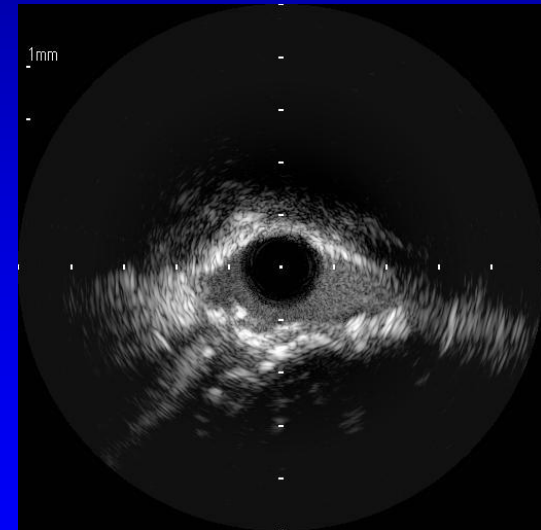
PCI

Pre PCI



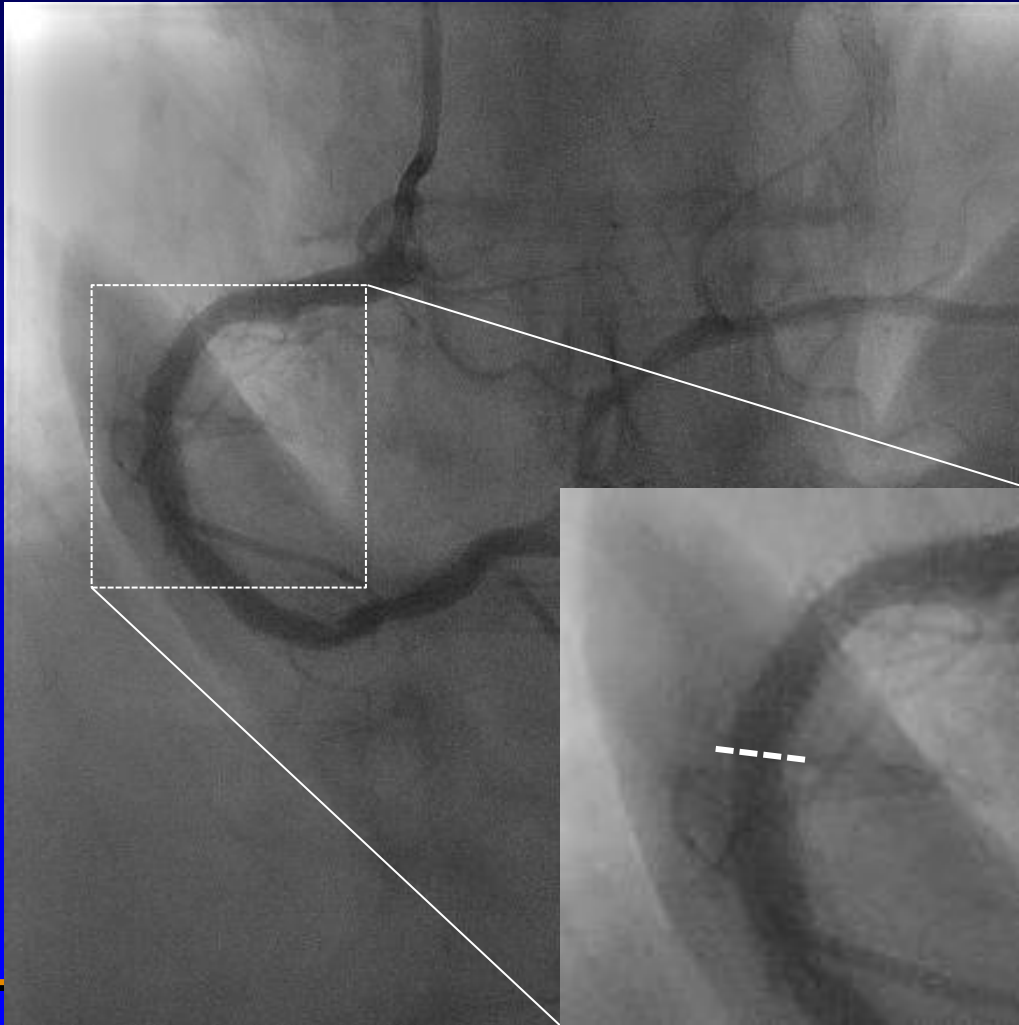
PCI after POBA

Scoring balloon(Angiosculpt)
3.5*6mm
→NC balloon 4.0*15mm

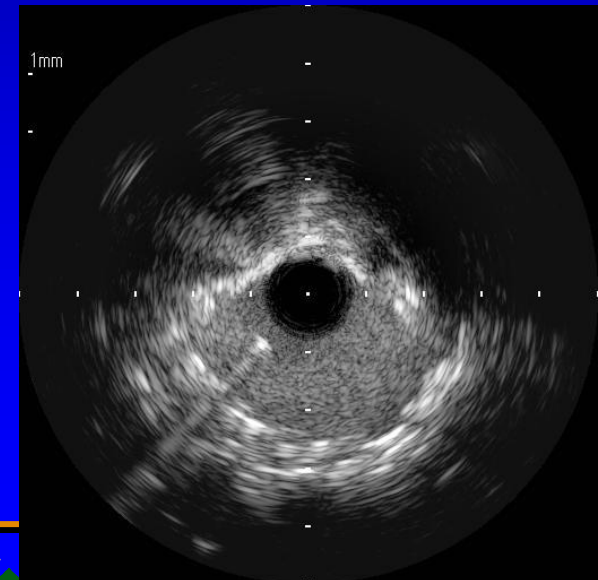


PCI

post



Scoring balloon 3.5*6mm
→NC balloon 4.0*15mm
→BES 3.5*14mm



RIBS IV vs KCH Experience

	RIBS IV		KCH	
	PCB	DES	PCB	DES
RD(mm)	2.59±0.5	2.67±0.5	2.92±0.44	2.95±0.44
LL(mm)	10.7±5.0	10.4 ±0.5	16.4±8.4	15.6±8.5
Scoring Balloon	?		(+)	
IVUS,OCT,OFDI	(-)		(+)	



DCB more effective DES ISR lesion type



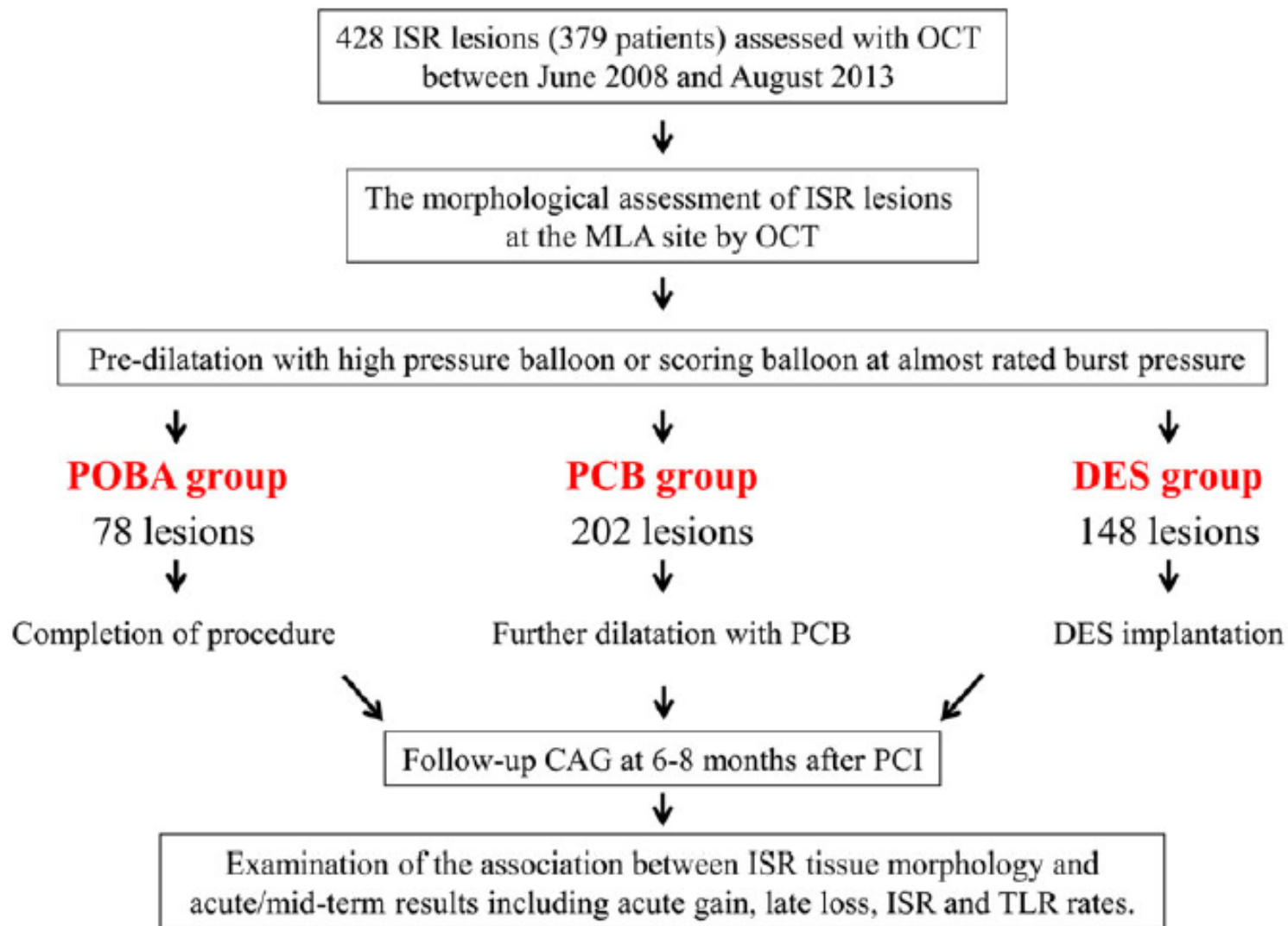
How about the effect of OCT finding of ISR lesion on mid term results of re PCI?

-POBA, DCB, DES-

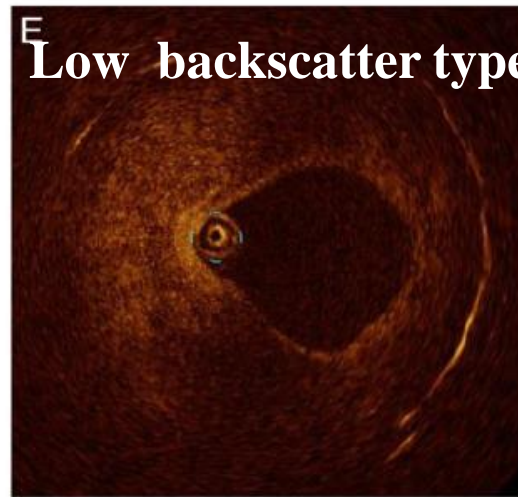
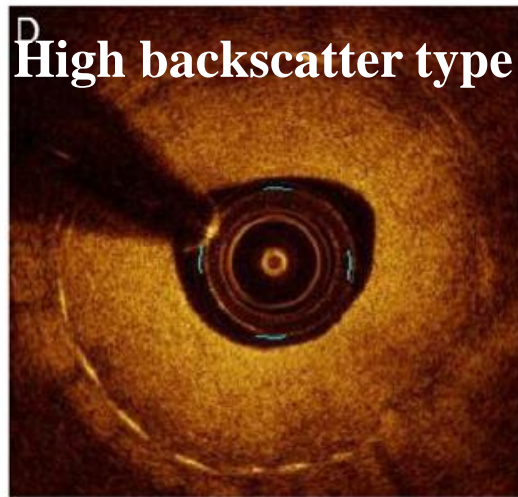
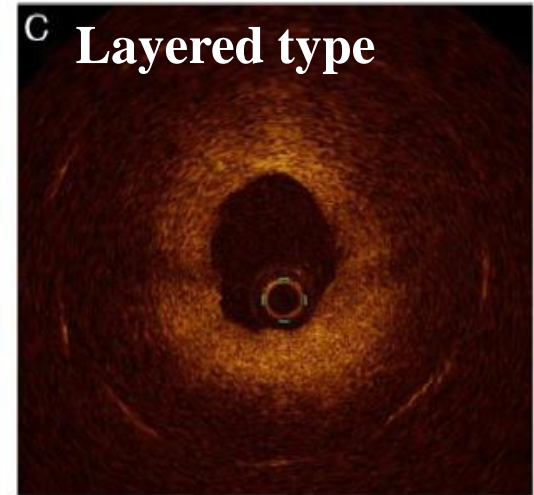
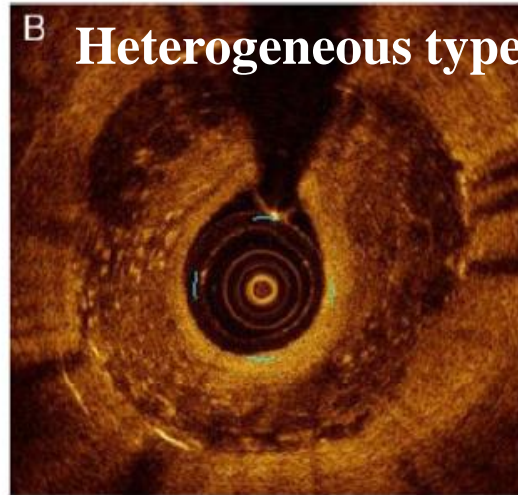


Association between tissue characteristics assessed with optical coherence tomography and mid-term results after percutaneous coronary intervention for in-stent restenosis lesions: a comparison between balloon angioplasty, paclitaxel-coated balloon dilatation, and drug-eluting stent implantation

Takeshi Tada^{1*}, Kazushige Kadota¹, Shingo Hosogi², Koshi Miyake¹, Masanobu Ohya¹, Hideo Amano¹, Yu Izawa¹, Takenori Kanazawa¹, Shunsuke Kubo¹, Tahei Ichinohe¹, Yusuke Hyoudou¹, Yuki Hayakawa¹, Mahmoud Mohamed Hassan Sabbah³, Suguru Otsuru¹, Daiji Hasegawa¹, Seiji Habara¹, Hiroyuki Tanaka¹, Yasushi Fuku¹, Harumi Katoh¹, Tsuyoshi Goto¹, and Kazuaki Mitsudo¹

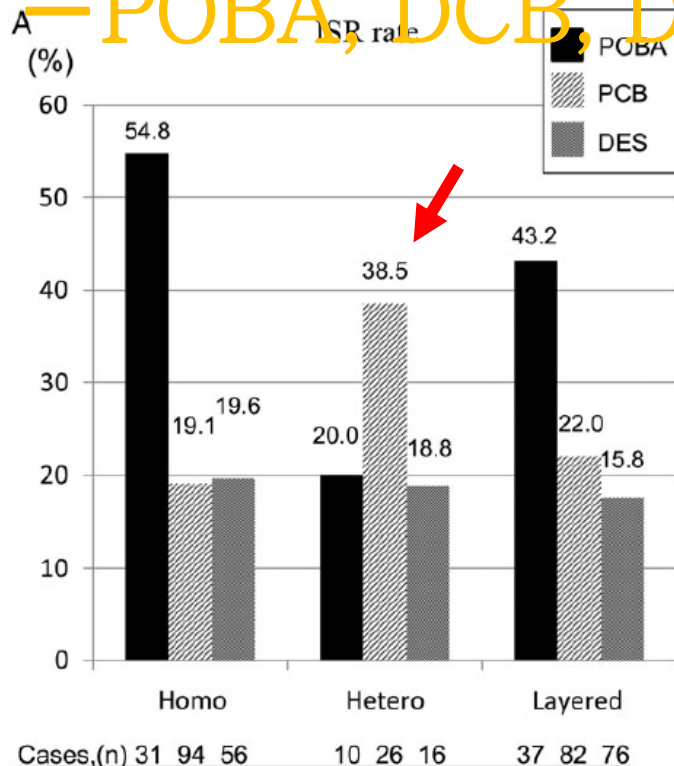


Tissue morphologic assessment with OCT

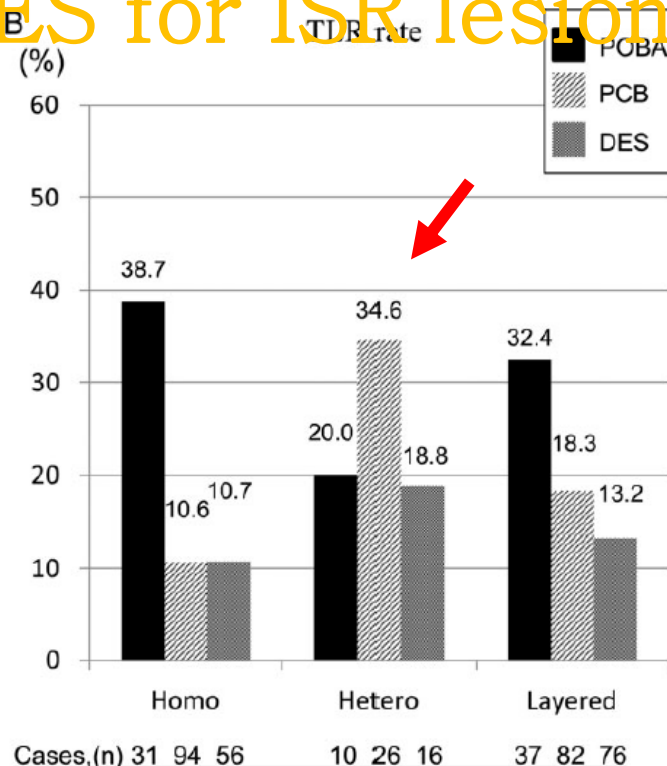


Restenotic tissue structure and mid-term results

— POBA, DCB, DES for ISR lesion —



p value	Homo	Hetero	Layered
POBA vs. PCB	<0.001	0.438	0.027
POBA vs. DES	0.002	1.000	0.002
PCB vs. DES	1.000	0.303	0.417



p value	Homo	Hetero	Layered
POBA vs. PCB	<0.001	0.688	0.102
POBA vs. DES	0.005	1.000	0.022
PCB vs. DES	1.000	0.316	0.394



OCT guided device selection for DES ISR lesion



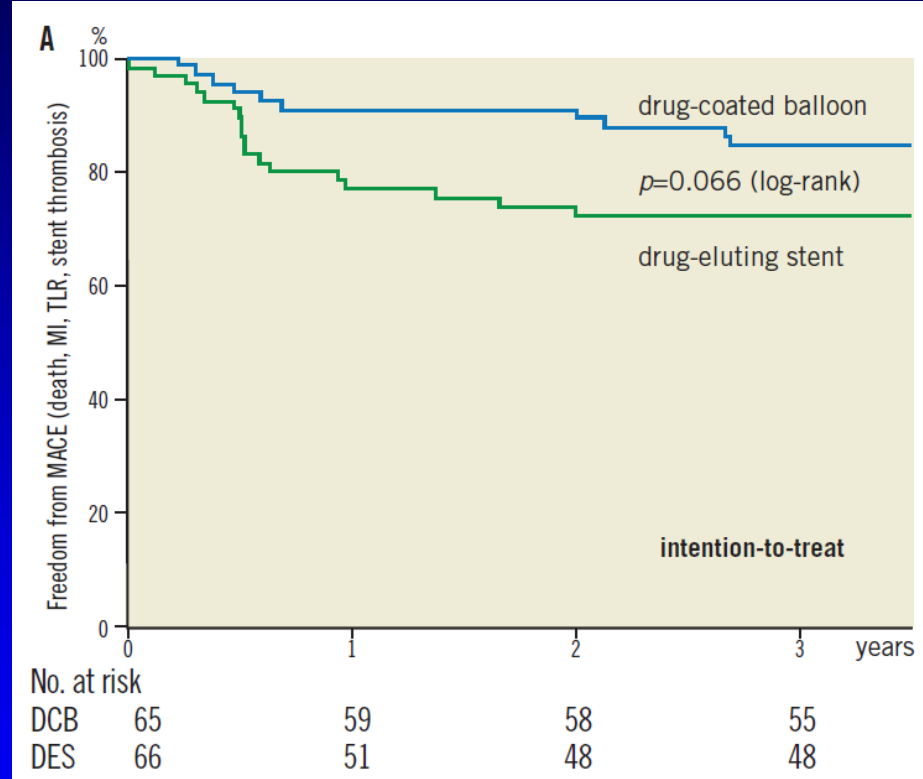
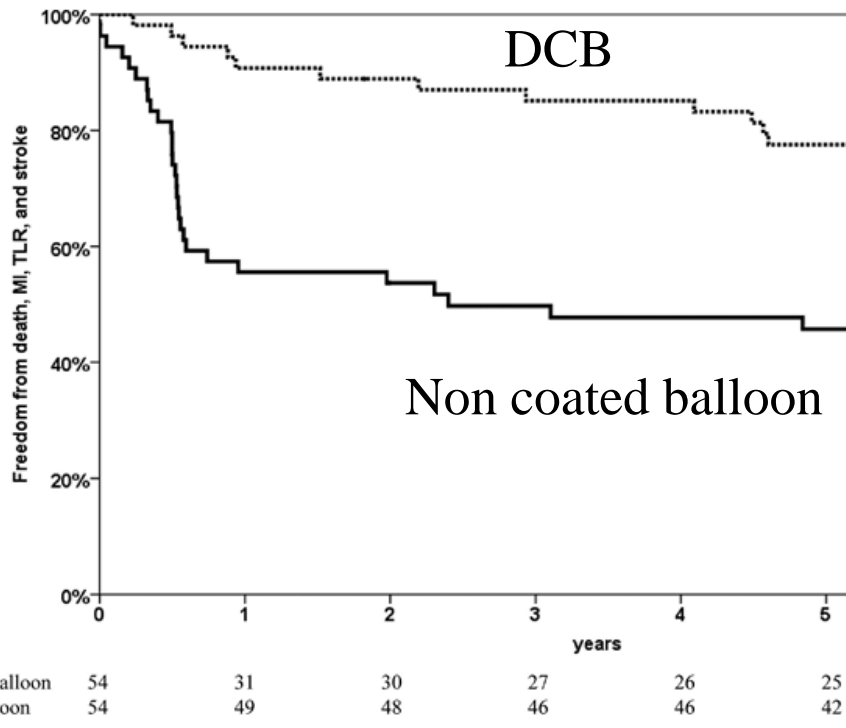
How about the long term results
of DCB ?



DCB for BMS ISR; long term data

The Five-year results of the PACCOATH ISR I, II

The three-year results of the PEPCAD II ISR

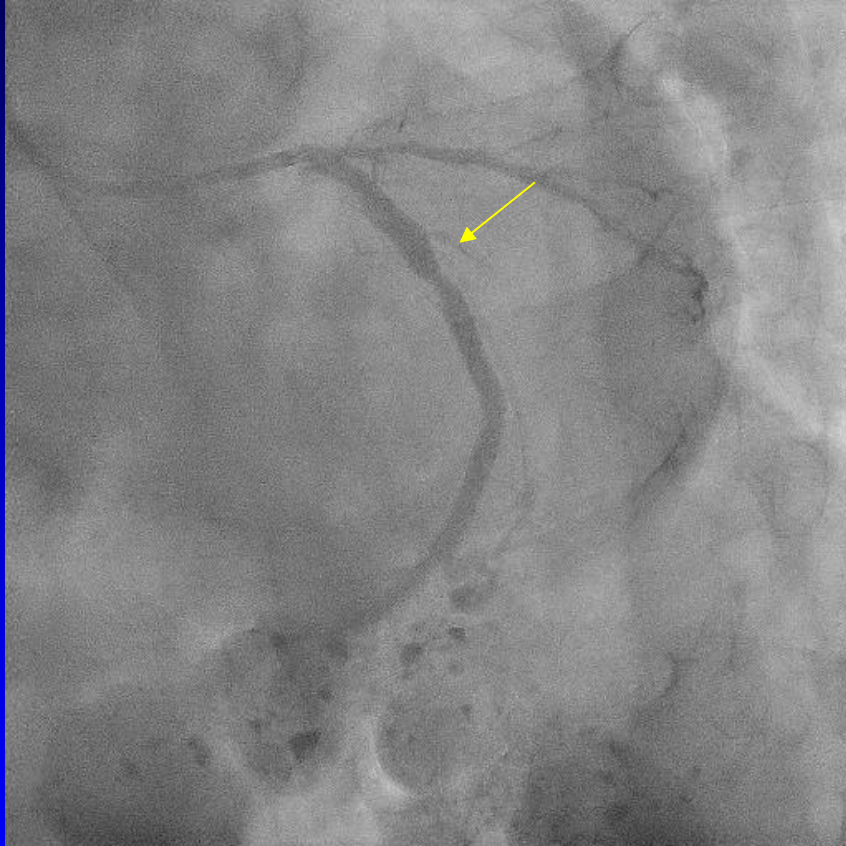


- ✓ The efficacy of PCB have been shown to extend up to 3-5 years.
- ✓ However, there are concerns about the long-term efficacy and safety of PCB angioplasty for DES restenosis.

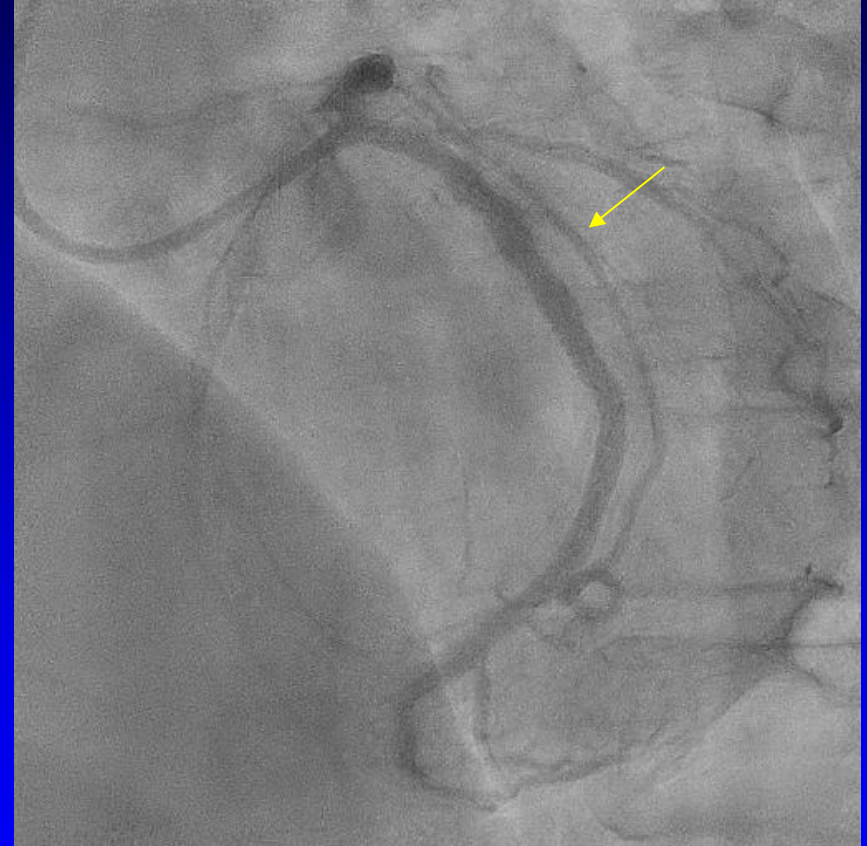


DCB for DES ISR

pre



post



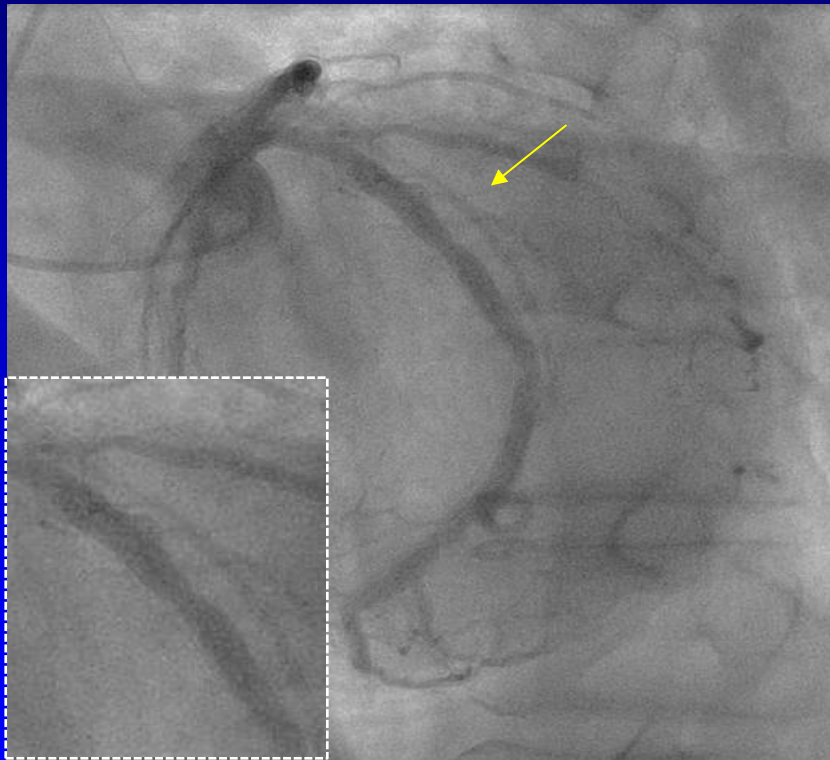
Lacross NSE 4.0*13mm → DCB 4.0*15mm



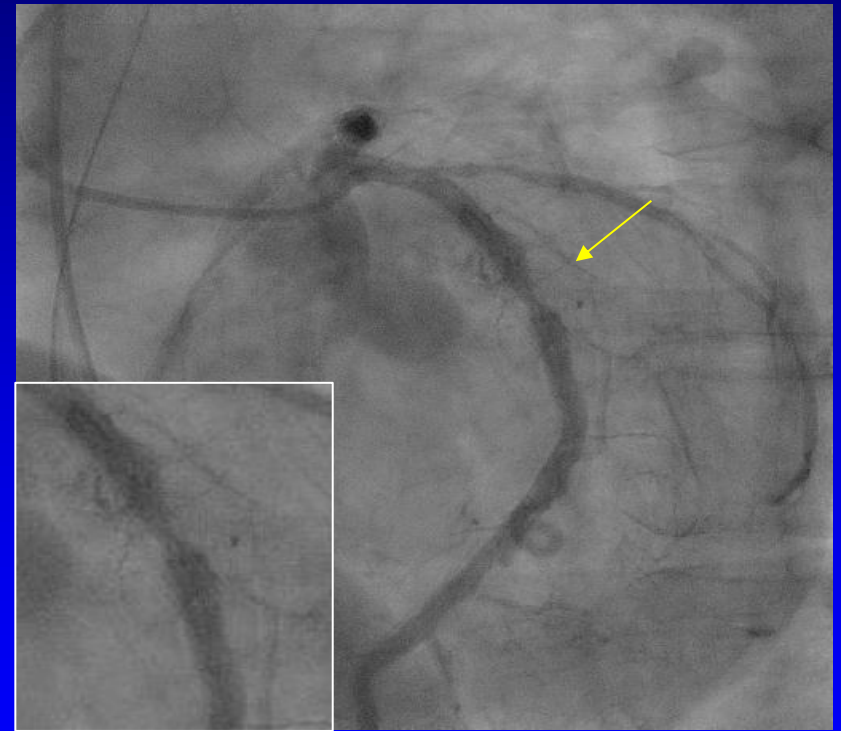
Kurashiki Central Hospital

Late Restenosis After DCB for DES-ISR

6m f/u CAG



18m f/u CAG



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<http://dx.doi.org/10.1016/j.jacc.2015.05.002>

Late Restenosis After Paclitaxel-Coated Balloon Angioplasty Occurs in Patients With Drug-Eluting Stent Restenosis

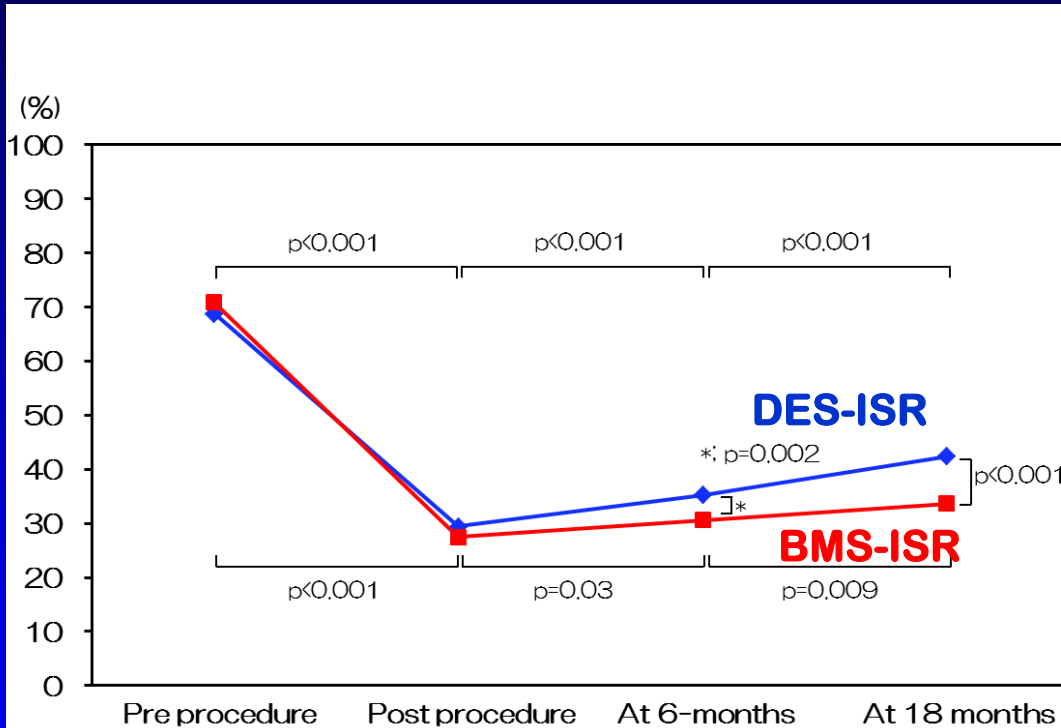


Seiji Habara, MD, Kazushige Kadota, MD, Takenobu Shimada, MD, Masanobu Ohya, MD, Hidewo Amano, MD, Yu Izawa, MD, Shunsuke Kubo, MD, Yusuke Hyodo, MD, Suguru Otsuru, MD, Daiji Hasegawa, MD, Takeshi Tada, MD, Hiroyuki Tanaka, MD, Yasushi Fuku, MD, Tsuyoshi Goto, MD, Kazuaki Mitsudo, MD

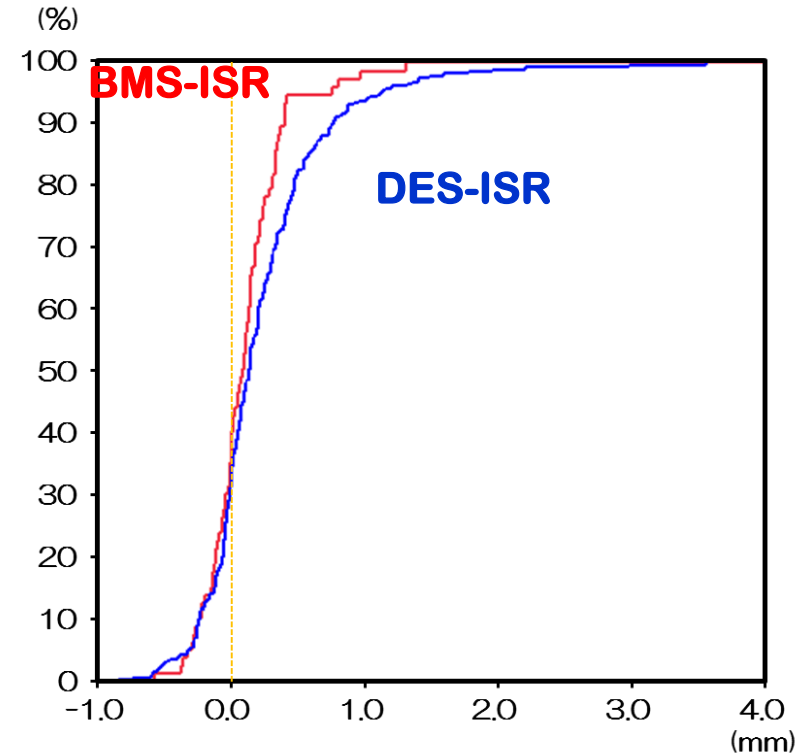


Changes in %DS and Delayed Late Loss

Changes in Percentage Diameter Stenosis

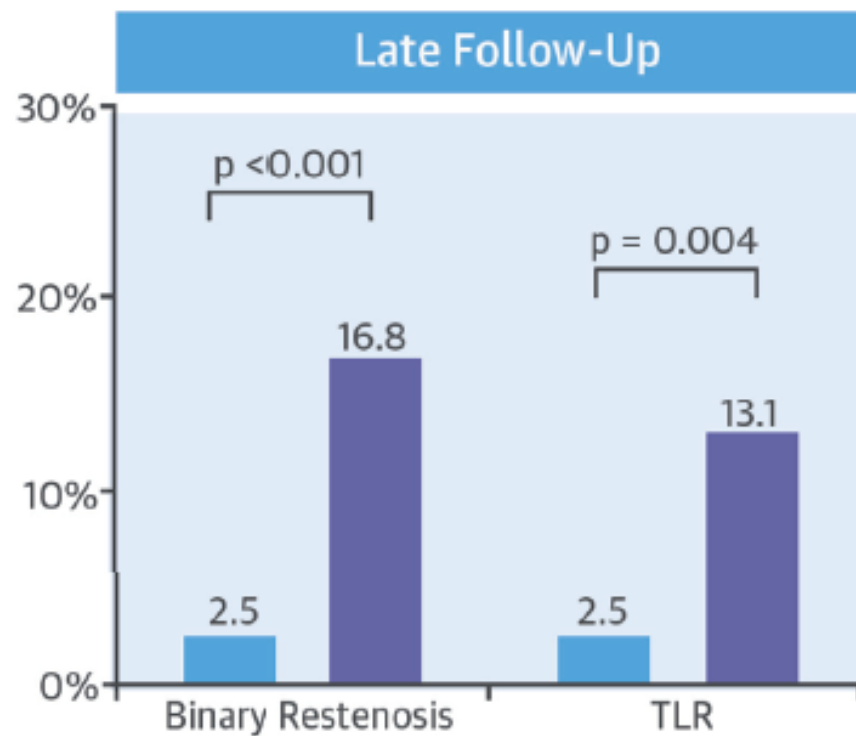
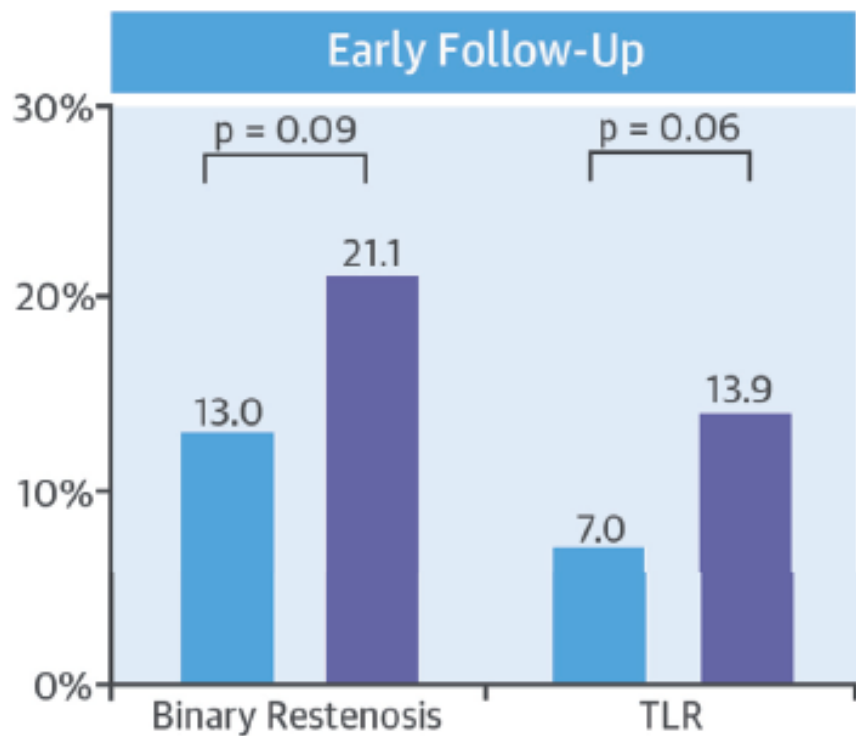


Cumulative frequency distribution of delayed late lumen loss.



Angiographic Outcomes

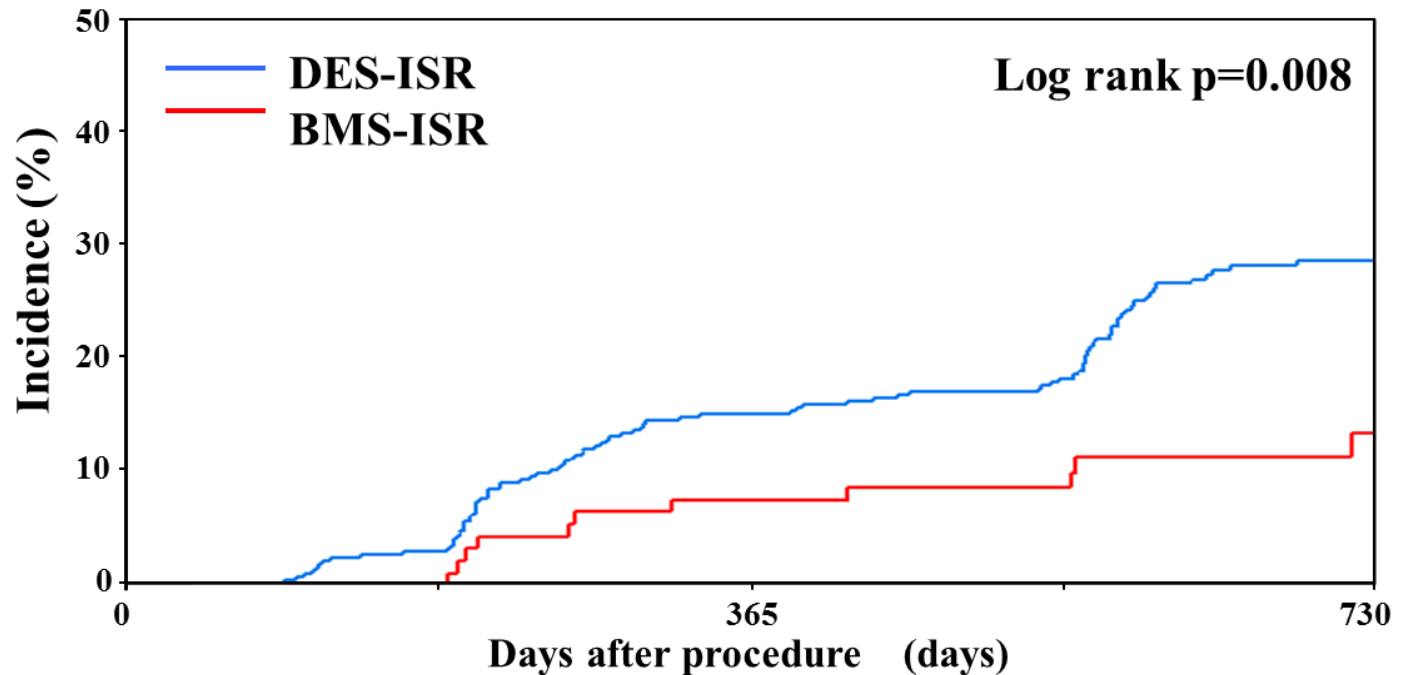
Early(6months) and Late (18 months) Follow up



■ BMS-ISR ■ DES-ISR



Kaplan-Meier Curve of MACE -DES ISR vs BM ISR-



	0days	6months	12months	18months	24months
Number of lesions at risk					
DES-ISR	371	354	304	278	156
BMS-ISR	97	95	85	79	40



Conclusions

Although DCB is mandatory for DES ISR lesion in real world practice, some concerns of DCB for ISR still remains. Further study to evaluate the optimal strategy for ISR lesion.





Kurashiki Central Hospital

How to treat DCB failure ?



DCB Failure

From November 2008 to October 2011,
599 lesions treated with first PCB angioplasty for ISR lesions

121 lesions undergoing PCI for recurrent ISR lesions of PCB failure

Excluded of 28 lesions which treated with other modalities
8 lesions : balloon angioplasty
11 lesions : biolimus-eluting stent
2 lesions : paclitaxel-eluting stent
3 lesions : sirolimus-eluting stent
4 lesions : zotarolimus-eluting stent

Study population
93 recurrent ISR lesions in 89 patients

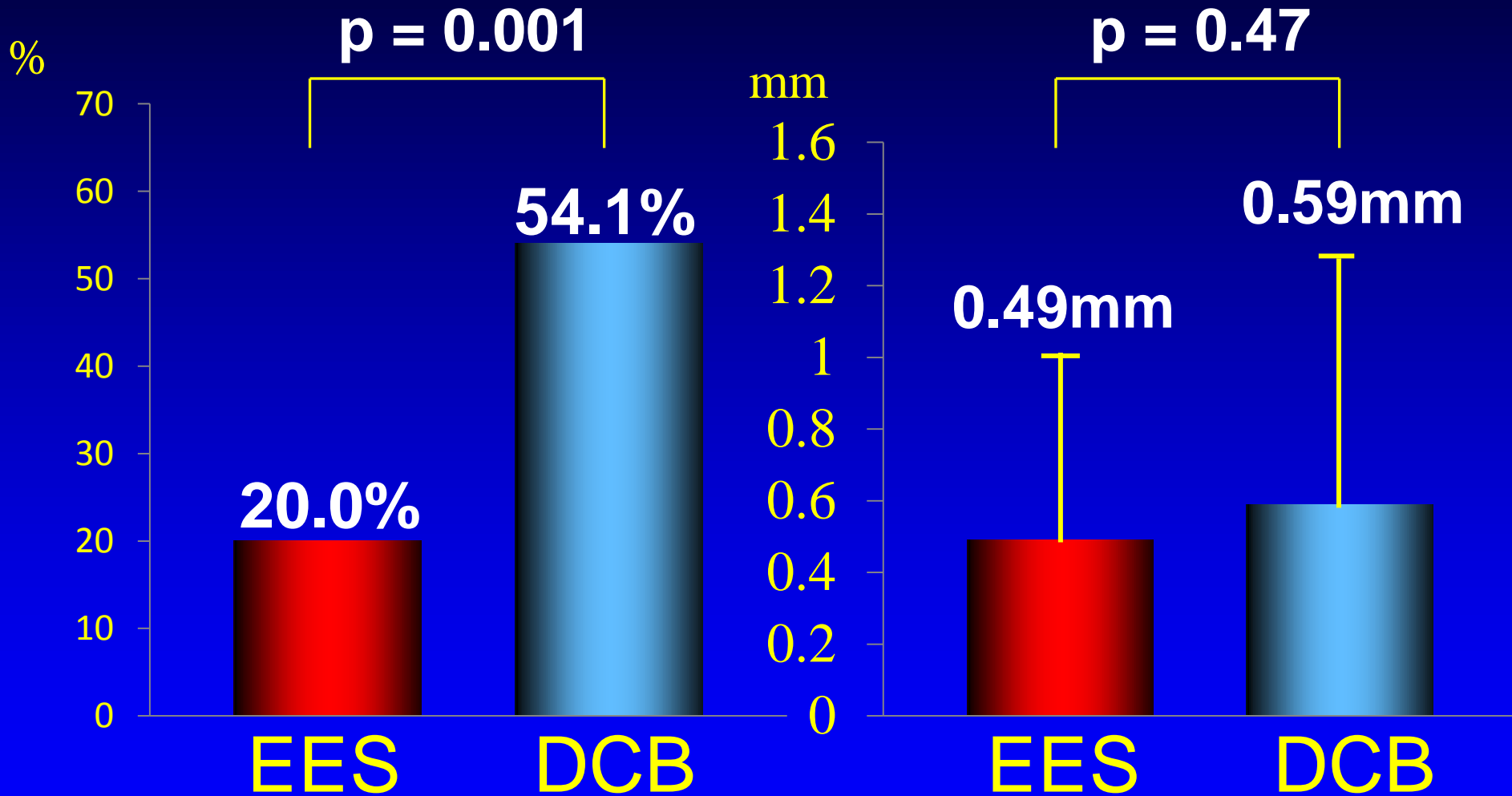
EES implantation
53 lesions in 52 patients

Repeat PCB angioplasty
40 lesions in 37 patients

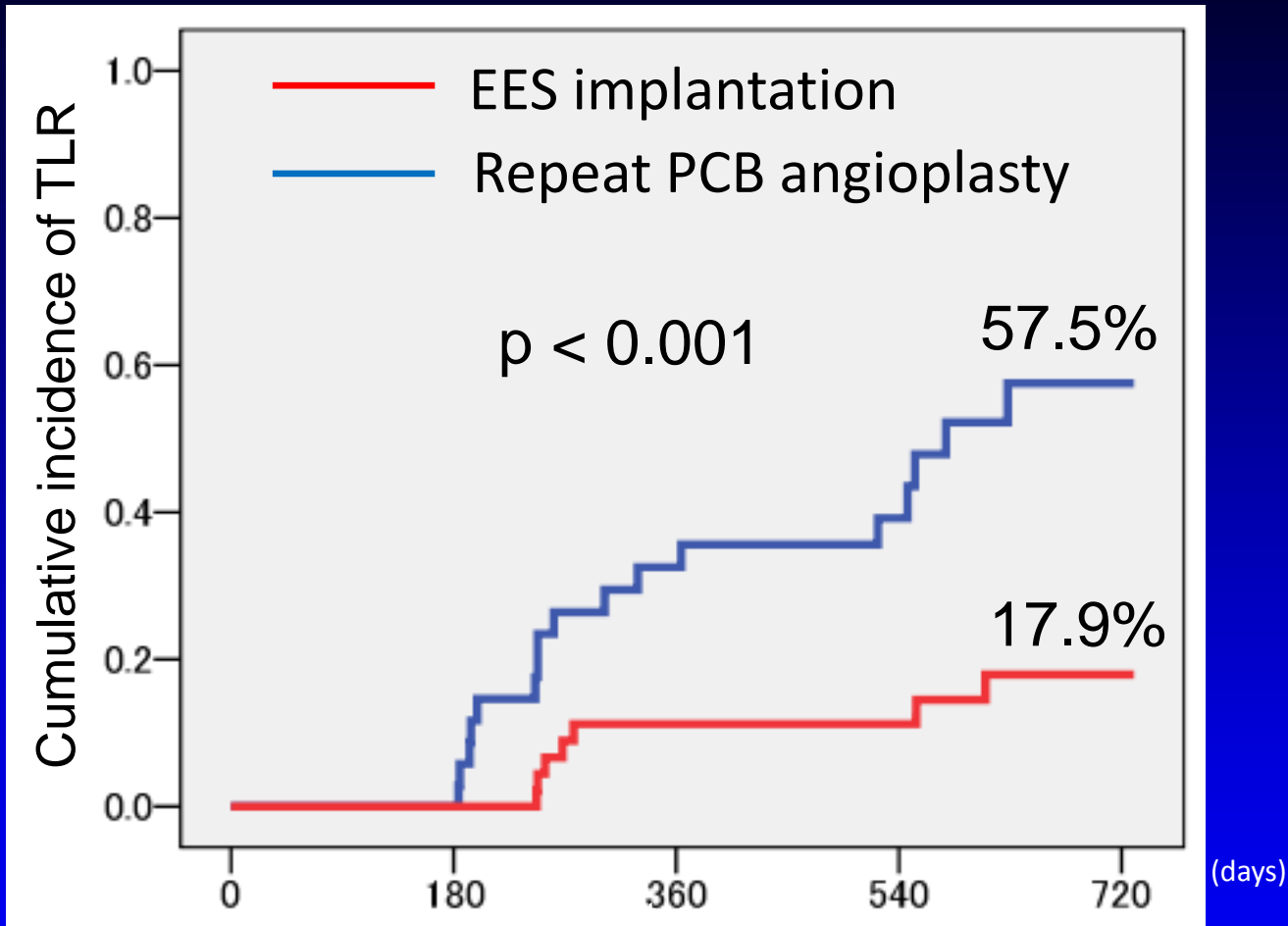


Binary restenosis

Late lumen loss



Incidence of TLR



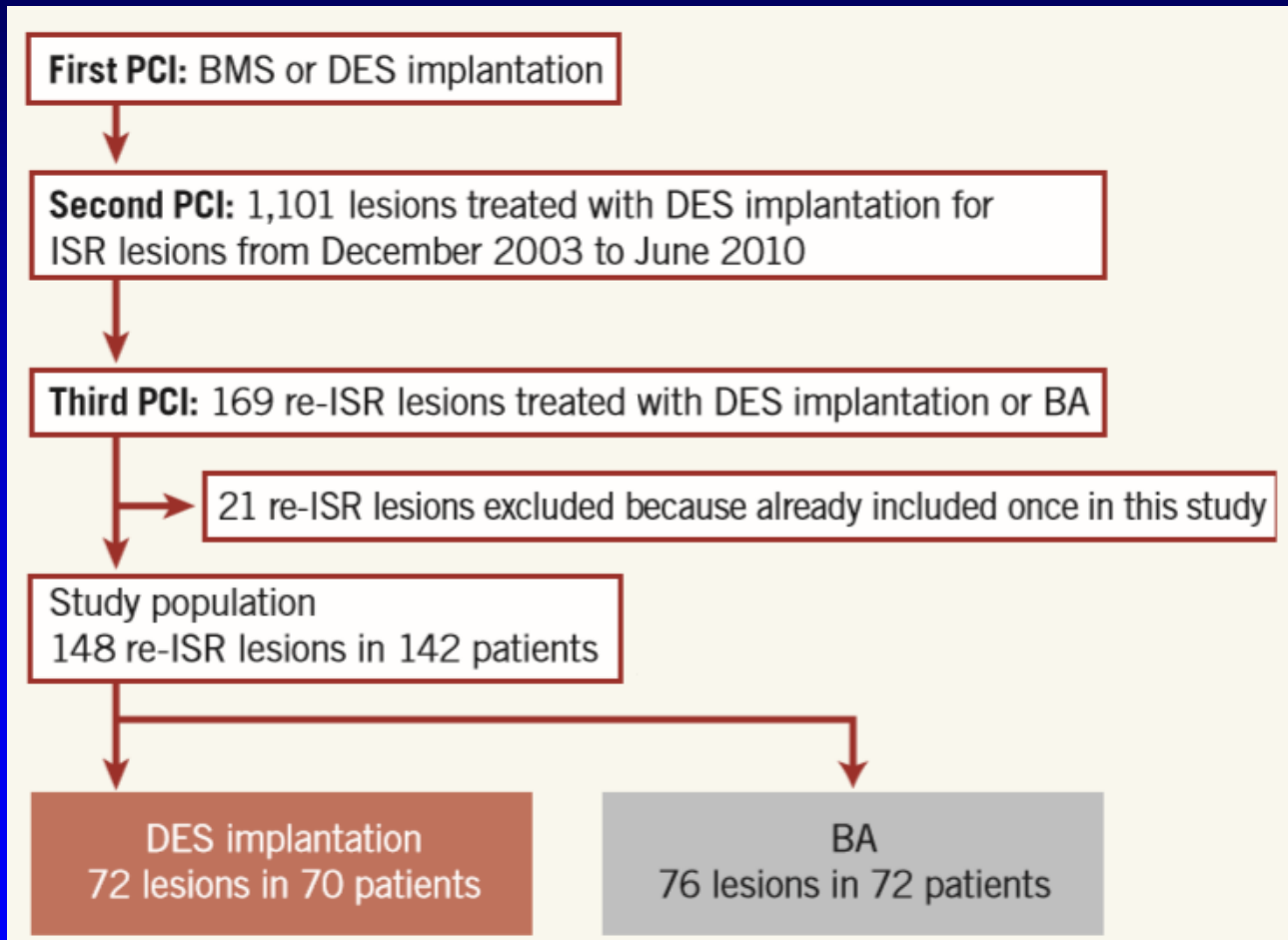
No. at risk	0	180	360	540	720
EES implantation	52	51	36	28	20
Repeat PCB	37	35	22	15	6

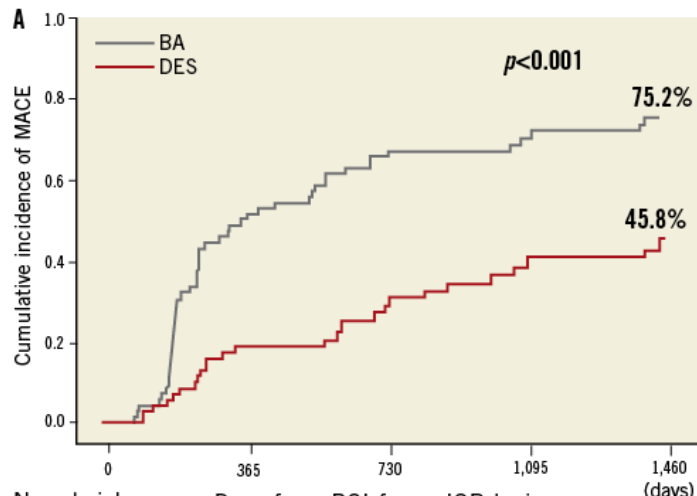


Optimal treatment of recurrent restenosis lesions after drug-eluting stent implantation for in-stent restenosis lesions

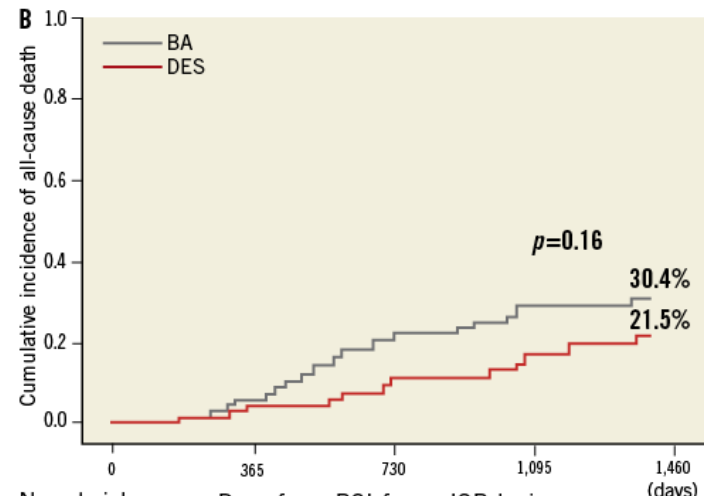
Shunsuke Kubo*, MD; Kazushige Kadota, MD, PhD; Suguru Otsuru, MD; Daiji Hasegawa, MD; Yoshikazu Shigemoto, MD; Seiji Habara, MD; Takeshi Tada, MD, PhD; Hiroyuki Tanaka, MD; Yasushi Fuku, MD; Harumi Katoh, MD, PhD; Tsuyoshi Goto, MD; Kazuaki Mitsudo, MD

Department of Cardiology, Kurashiki Central Hospital, Kurashiki, Japan

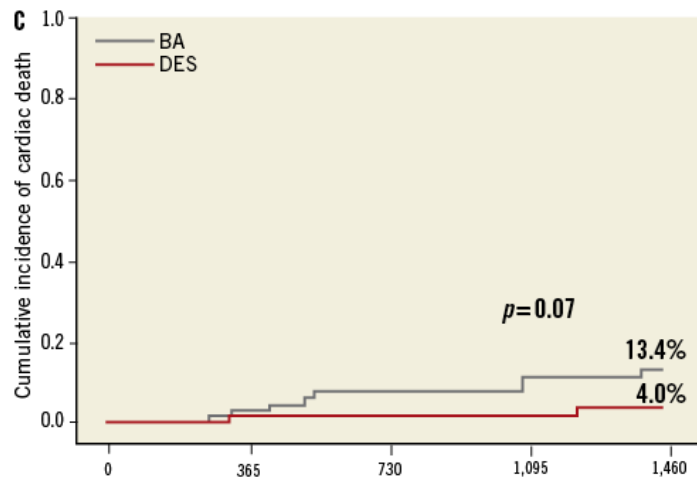




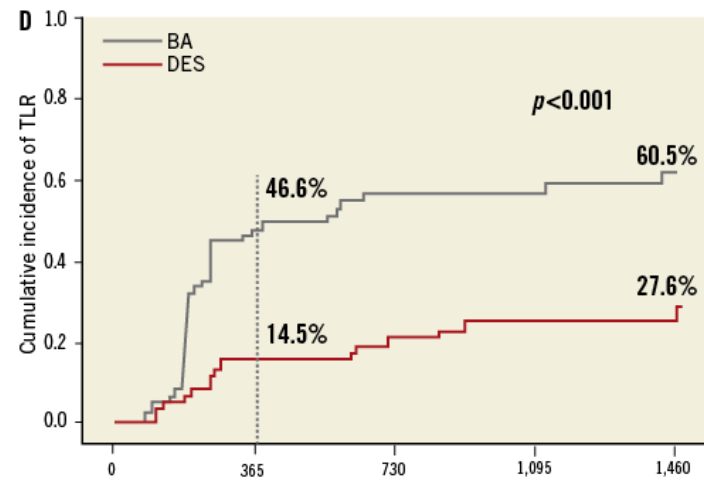
No. at risk	Days from PCI for re-ISR lesions				
	0	365	730	1,095	1,460
BA	72	35	24	17	14
DES	70	55	41	29	21



No. at risk	Days from PCI for re-ISR lesions				
	0	365	730	1,095	1,460
BA	72	68	57	46	39
DES	70	65	55	43	31



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