

QUE HACER Y CÓMO RESOLVER

SESIÓN DEB

UN ABORDAJE INNOVADOR: TRATANDO LAS BIFURCACIONES “SOLO” CON BALÓN LIBERADOR DE FÁRMACO

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Suiza

DISCLOSURES

Speaker's name : PD Juan F. Iglesias MD FESC FACC

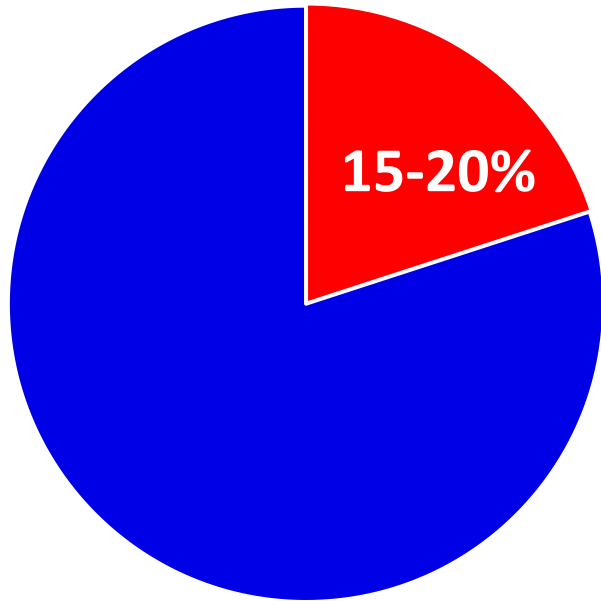
I have the following potential conflicts of interest to report:

- Consultant: BIOTRONIK, CORDIS, MEDTRONIC, RECOR MEDICAL.
- Honoraria/speaker's fee: ASTRA ZENECA, BIOTRONIK, BIOSENSORS, BRSITOL MYERS SQUIBB/PFIZER, CORDIS, CONCEPT MEDICAL, MEDTRONIC, NOVARTIS, PENUMBRA, PFIZER, TERUMO, PHILIPS VOLCANO, RECOR MEDICAL.
- Institutional grant/research support: ABBOTT VASCULAR, ASTRA ZENECA, BIOTRONIK, CONCEPT MEDICAL, PHILIPS VOLCANO, TERUMO.

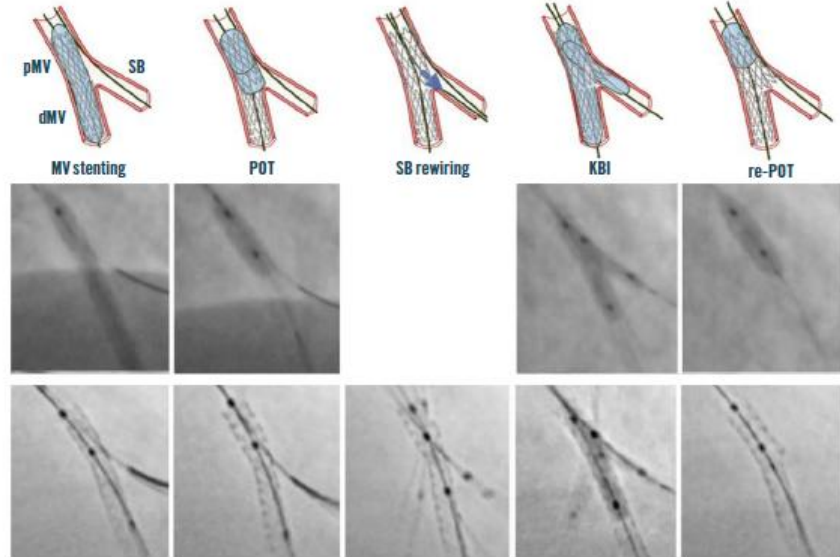
CORONARY BIFURCATION LESIONS

EUROPEAN BIFURCATION CLUB – 18th consensus document

Burzotta F, et al. EuroIntervention. 2024;20(15):e915-e926



■ Bifurcation ■ Non bifurcation



A STEPWISE PROVISIONAL STRATEGY IS THE RECOMMENDED APPROACH FOR THE MAJORITY OF TRUE LM AND NON-LM BIFURCATION LESIONS

PCI FOR BIFURCATION LESIONS

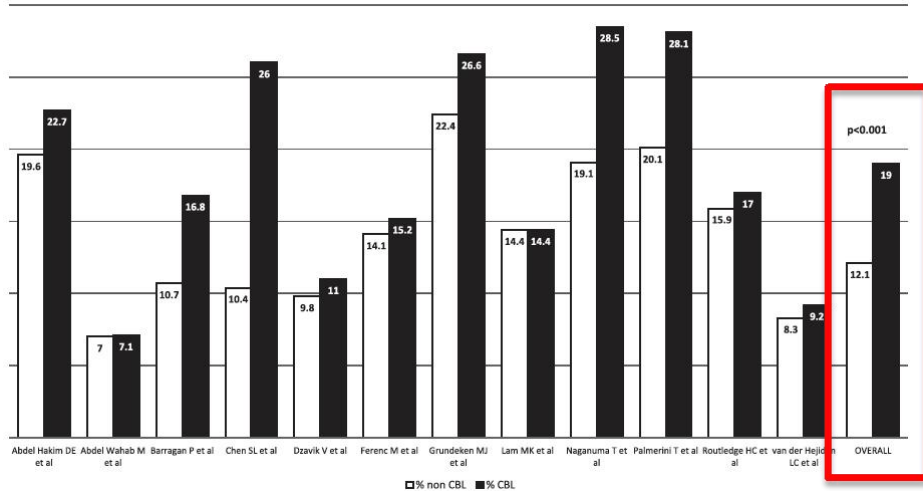
BIFURCATION vs. NON BIFURCATION LESIONS

STUDY-LEVEL META-ANALYSIS

15 studies, n=23,891

Burzotta F, et al., *Coron Artery Dis.* 2020;31(5):438-445

ALL-CAUSE DEATH, MI, or TVR



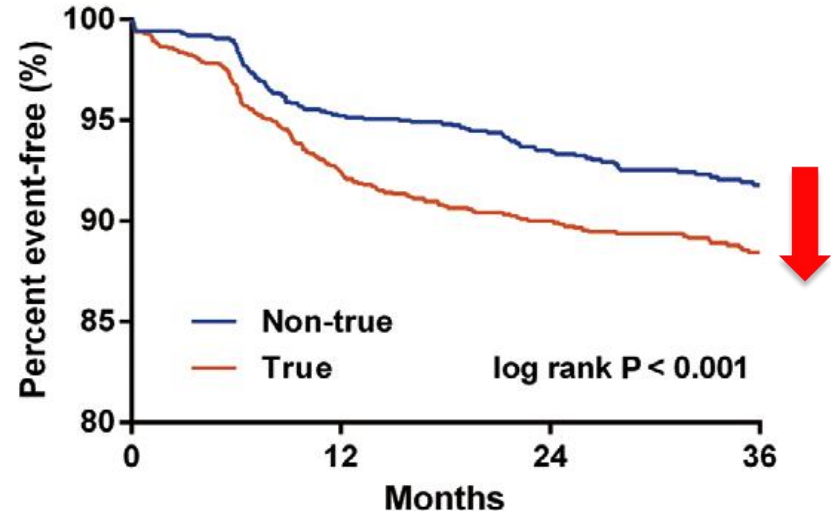
TRUE vs. NON TRUE BIFURCATION LESIONS

COBIS-II REGISTRY

n= 2,897

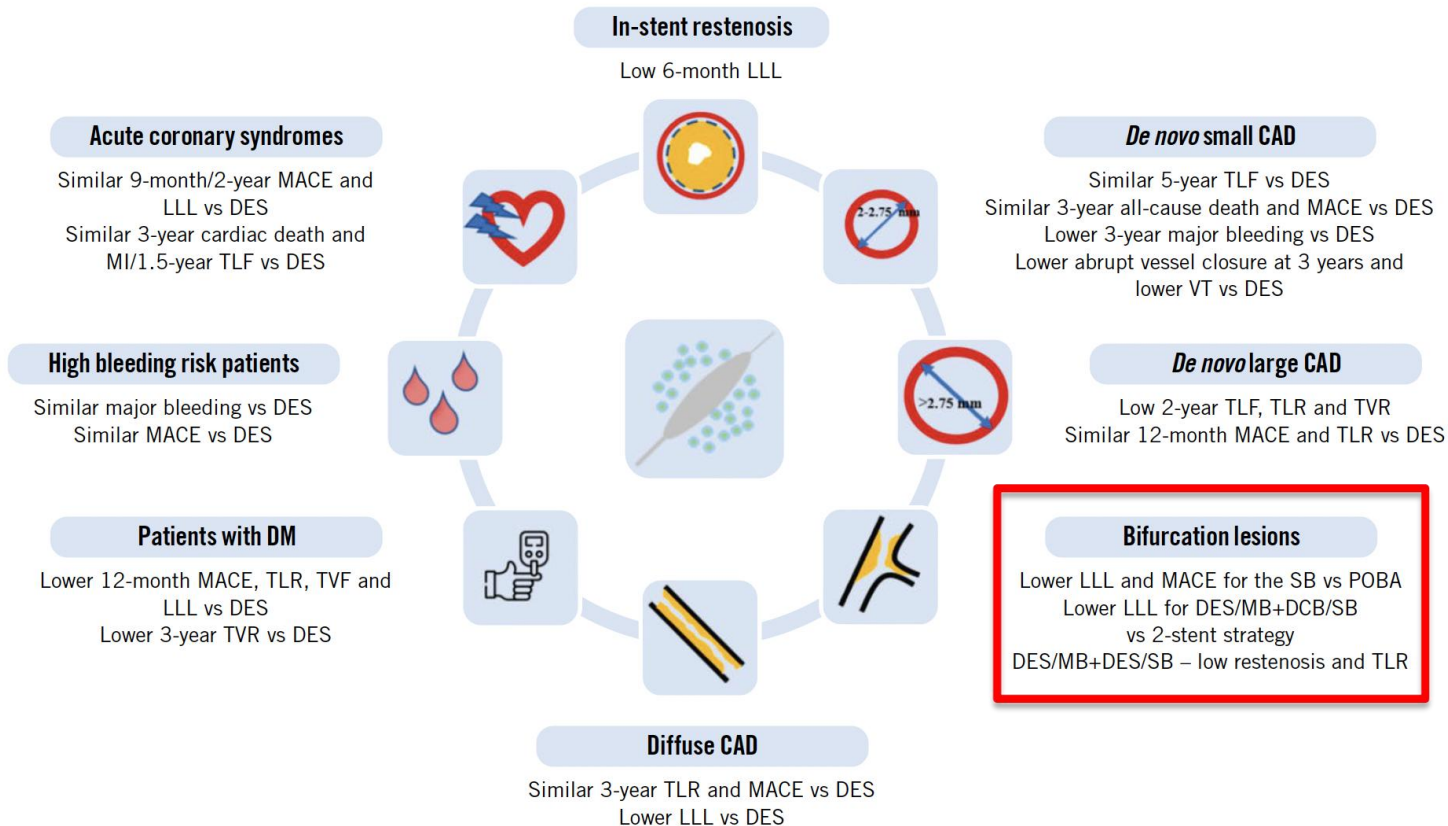
Park TK, et al., *Circ J.* 2015;79(9):1954-62

CV DEATH, MI, or TLR



POTENTIAL INDICATIONS OF DCB FOR CORONARY INTERVENTIONS

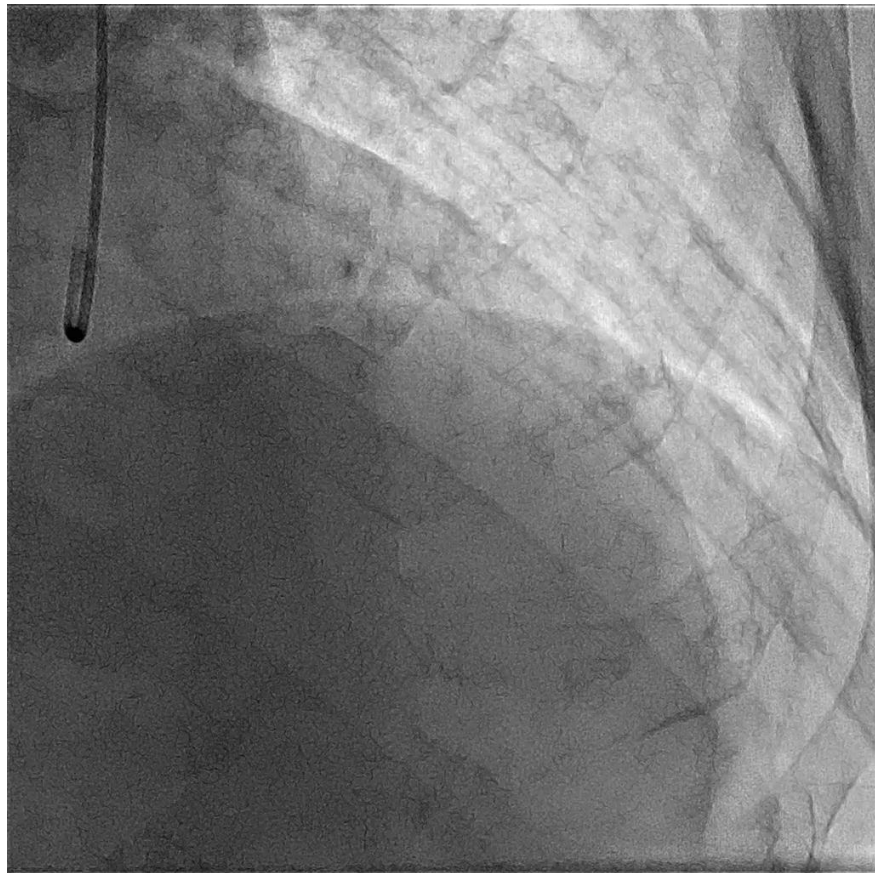
Lazar FL, et al. *AsiaIntervention* 2024;10(1):15-25



CASE PRESENTATION

- 70 yo gentleman.
- Risk factors: HTN, dyslipidemia, positive family history.
- **6-month history of typical chest pain on exertion.**
- Echocardiogram: Preserved LV function, no RWMA.
- CTCA: Agatston score 231 (81st percentile according to age), **short >70% mid-RCA stenosis, 50% mid-LAD stenosis.**
- Medication: Atorvastatin, Valsartan.
- **Referred for coronary angiogram**

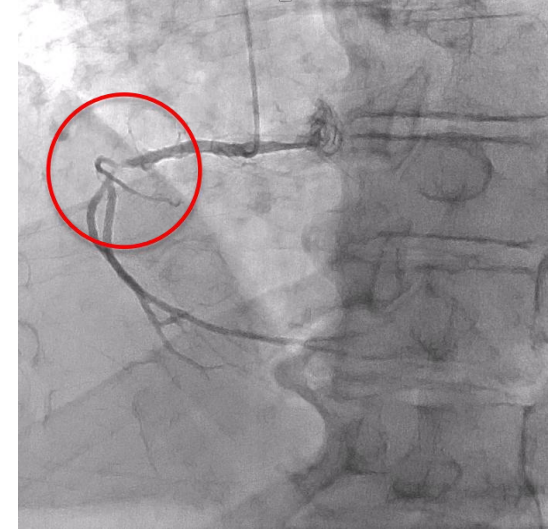
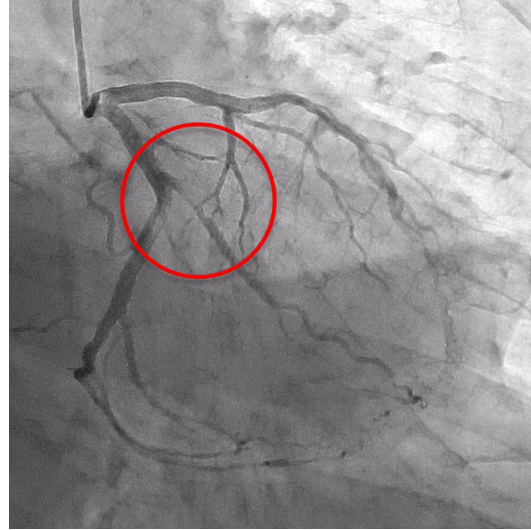
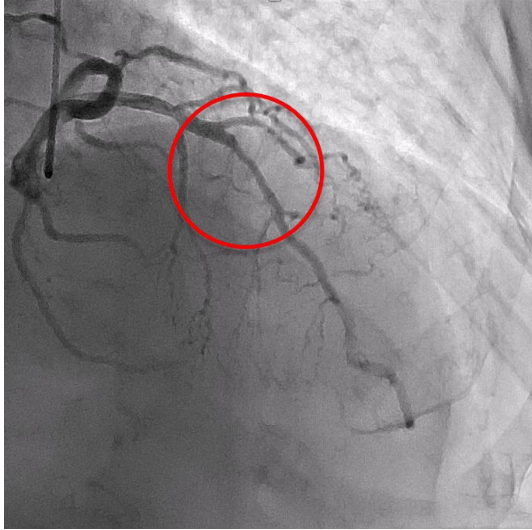
CORONARY ANGIOGRAM @ BASELINE



CORONARY ANGIOGRAM @ BASELINE



CASE SUMMARY



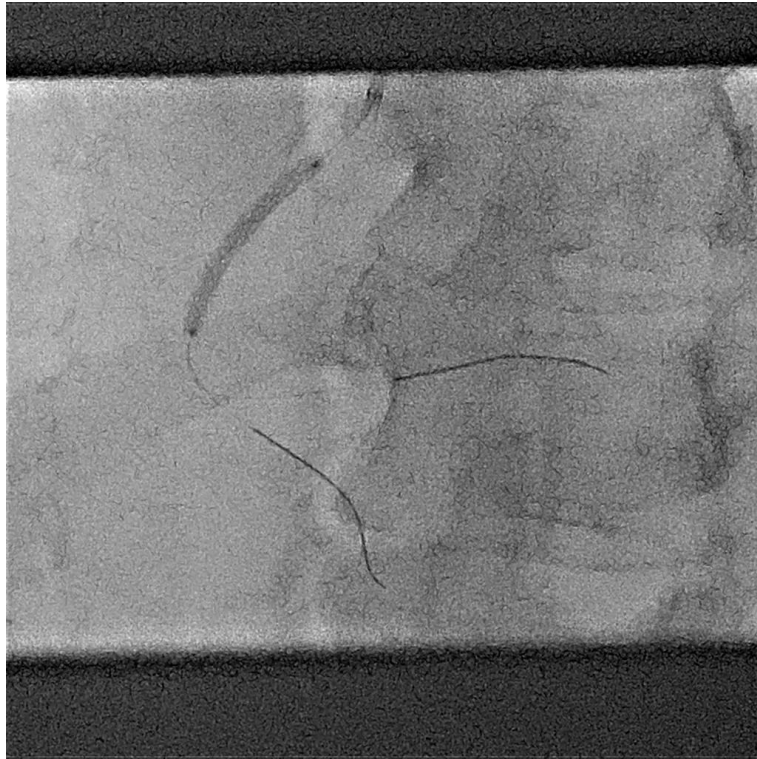
Medina 1;1;0

3-VESSEL CAD, SYNTAX SCORE I: 13

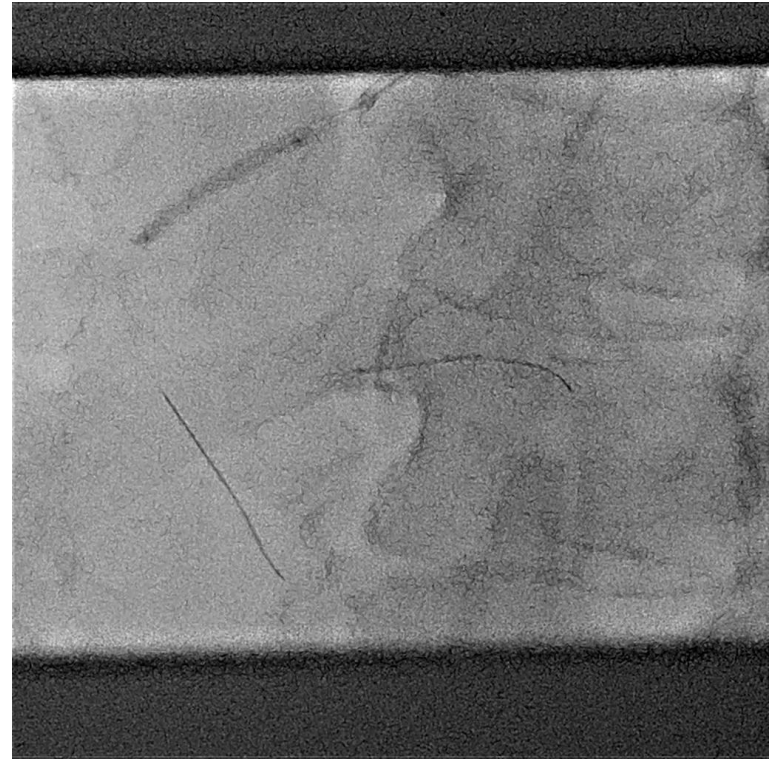
SYNTAX II SCORE: 4y mortality 6.3% PCI vs. 7.3% CABG

PRE-DILATATION WITH NON-COMPLIANT BALLOON

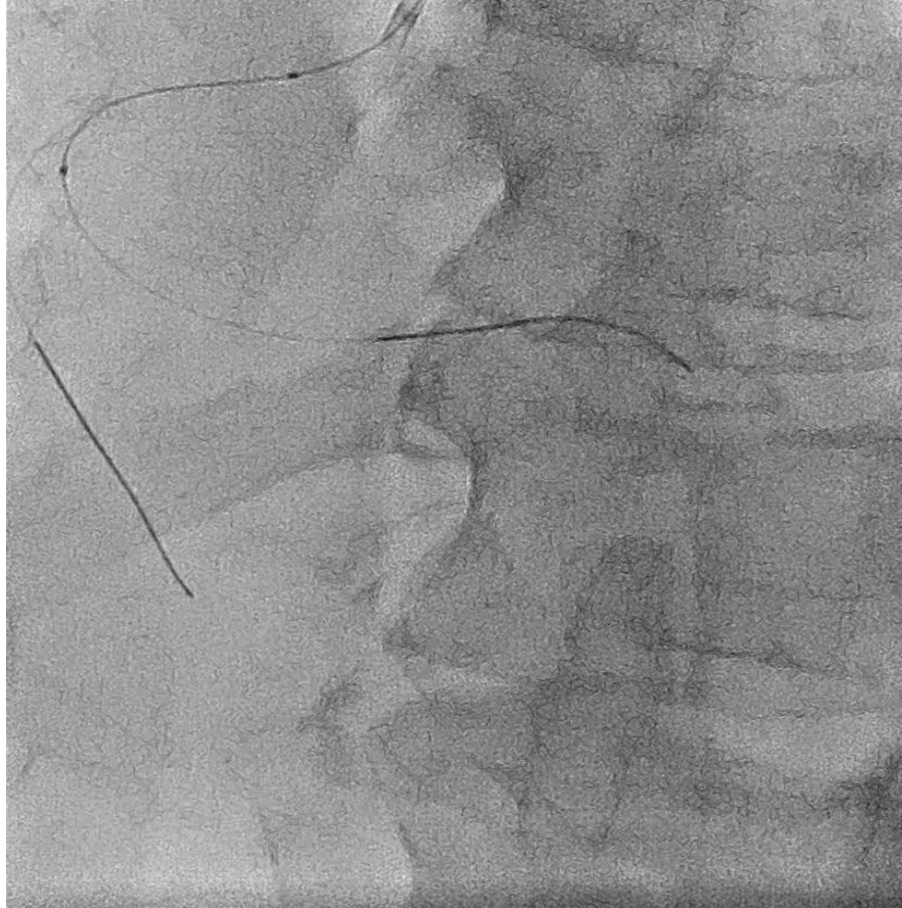
NCB 2.5x30 mm @ 20 atm
(pRCA to PLV)



NCB 2.0x30 mm @ 20 atm
(pRCA to PDA)



INTERMEDIATE ANGIOGRAPHIC RESULT

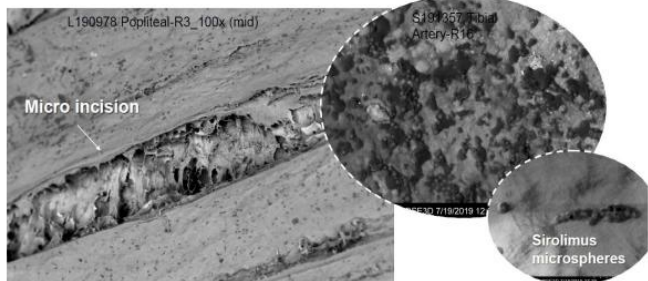
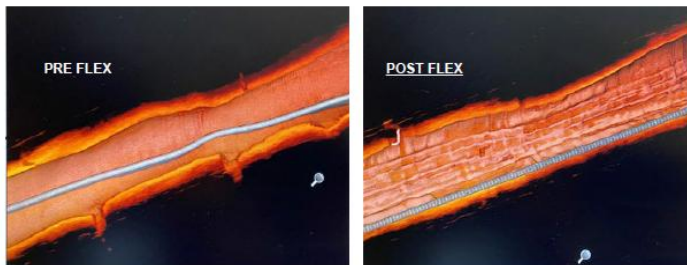


USE OF SCORING/CUTTING DEVICES FOR DCB PCI

PRECLINICAL STUDY

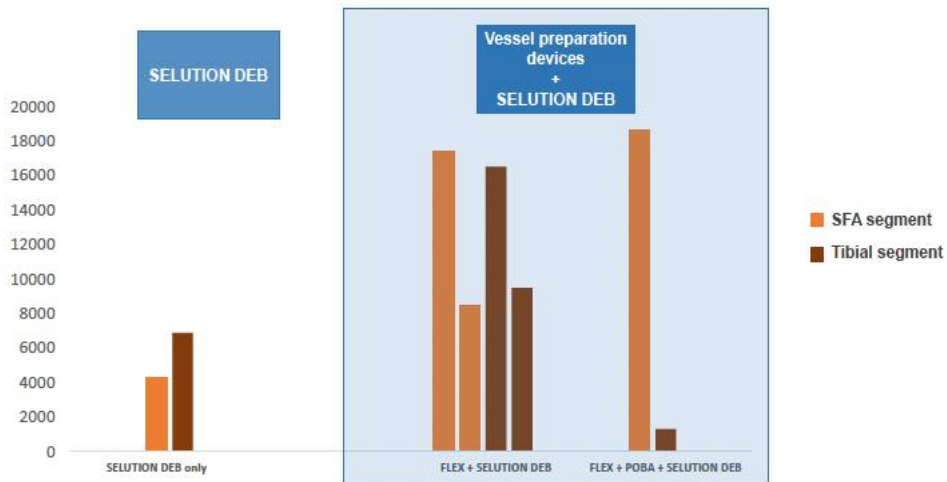
8 peripheral lower limb cadaver vessels, SELUTION SLR with (scoring device \pm POBA) vs. without vessel preparation
Shulze J, TCT Conference 2022, Boston, USA

PRESENCE OF SIROLIMUS IN MICRO-INCISION CHANNELS



DRUG CONCENTRATION IN TISSUE

Drug extraction concentration (ng/g)

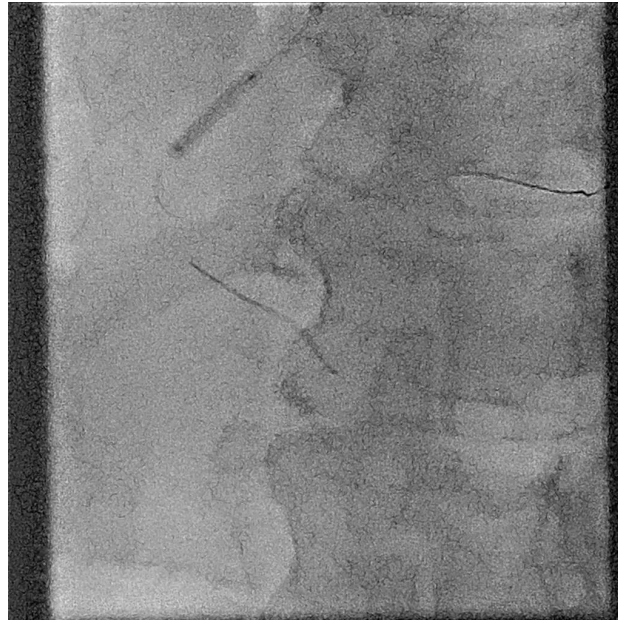


PRE-DILATATION WITH CUTTING BALLOONS

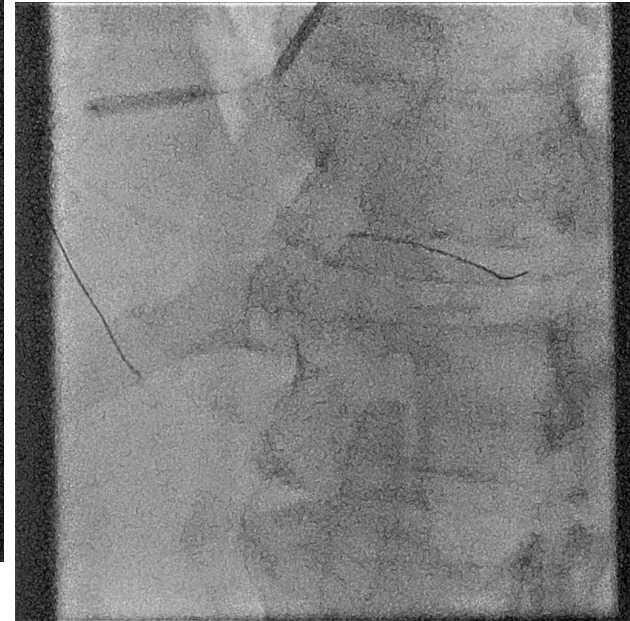
**Wolverine 2.5x15 mm
@ 16 atm (pRCA to PLV)**



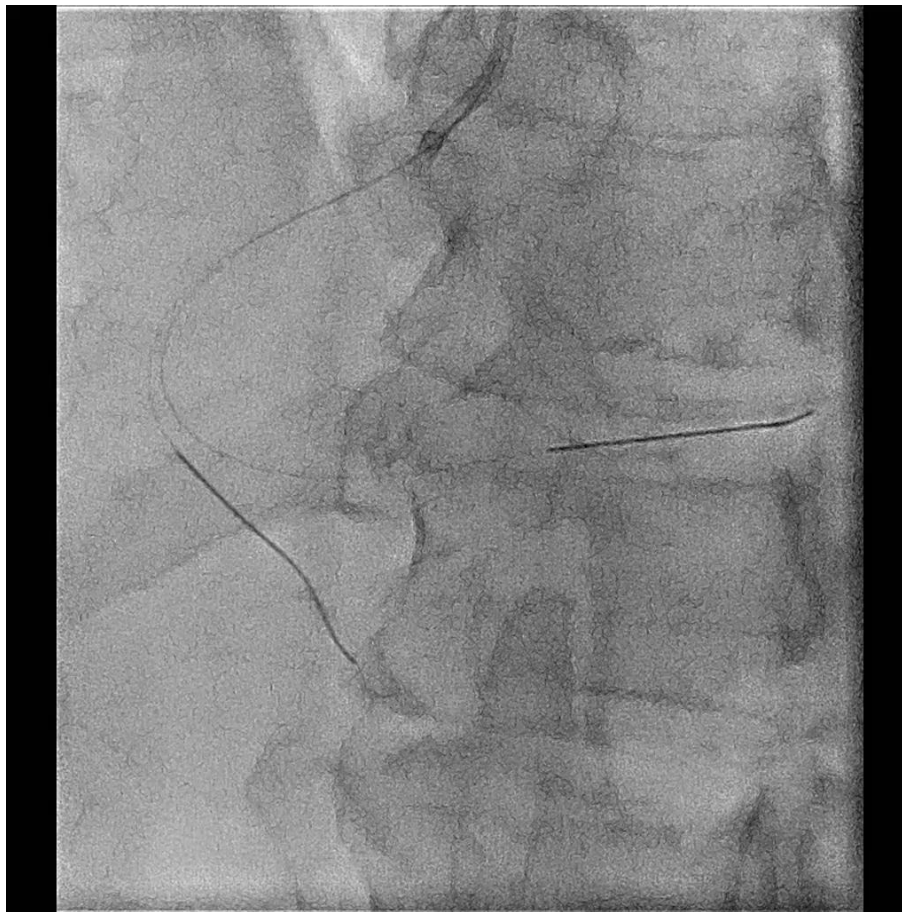
**Wolverine 2.5x15 mm
@ 16 atm (pRCA to PDA)**



**Wolverine 3.0x15 mm
@ 16 atm (pRCA)**

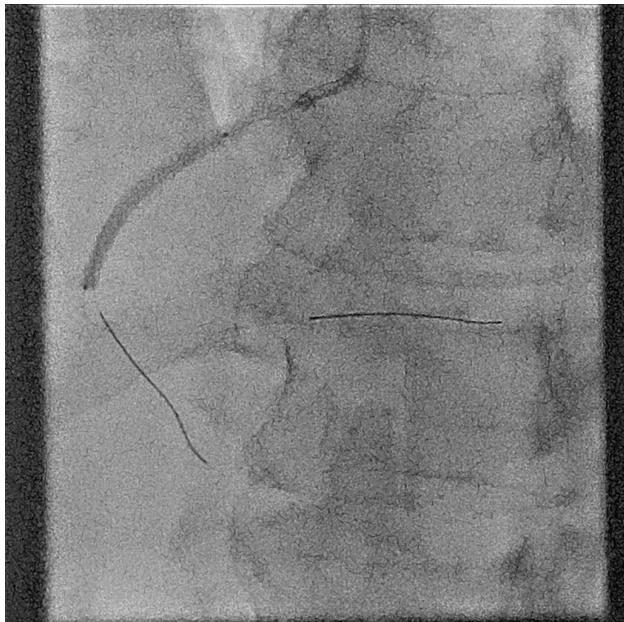


INTERMEDIATE ANGIOGRAPHIC RESULT

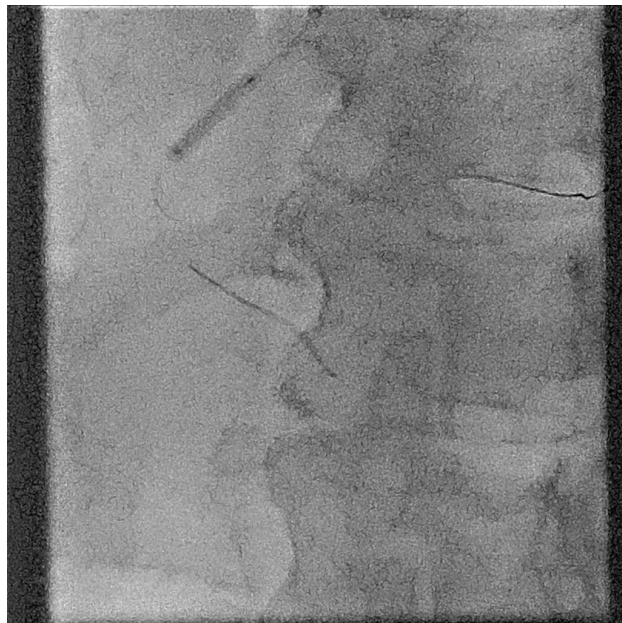


PRE-DILATATION WITH 1:1 NON-COMPLIANT BALLOON

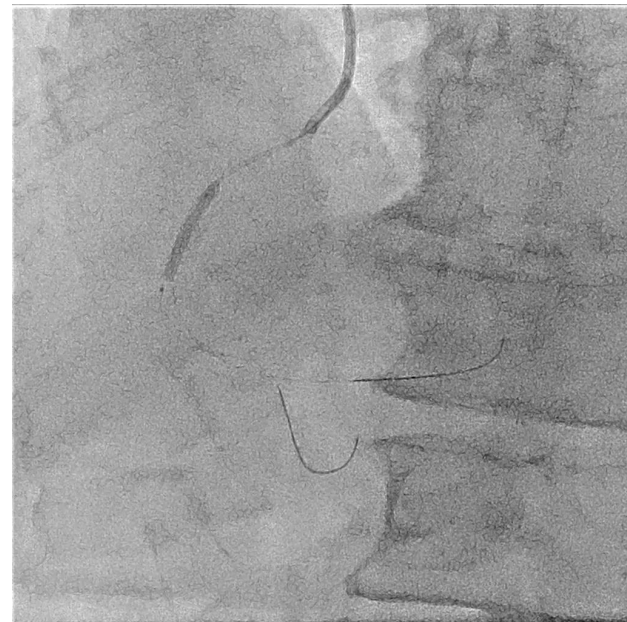
NCB 3.0x30 mm @ 10 atm
pRCA to PLV



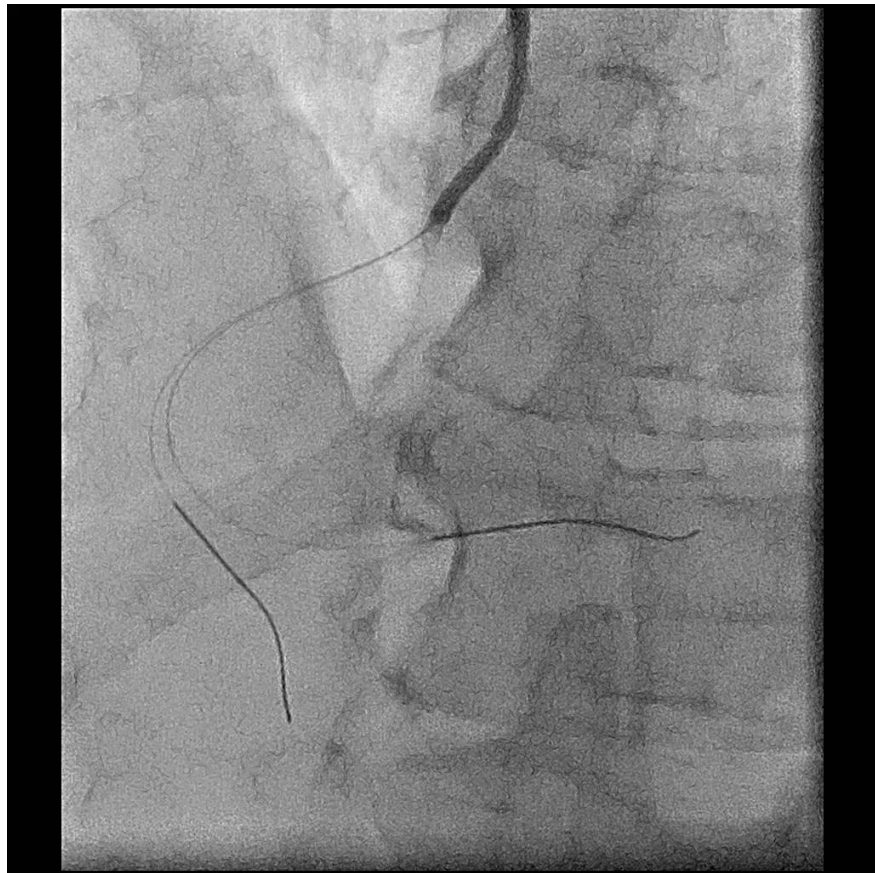
NCB 3.5x20 mm @ 12 atm
pRCA



NCB 2.5x20 mm @ 10 atm
pRCA to PDA



INTERMEDIATE ANGIOGRAPHIC RESULT



KISSING BALLOONS: SELUTION SLR 2.5x20 mm @ 6 atm (mRCA to PDA) and SELUTION SLR 3.0x20 mm @ 6 atm (mid-RCA to PLV)



SELUTION SLR 3.5x20 mm @ 8 atm (mRCA)

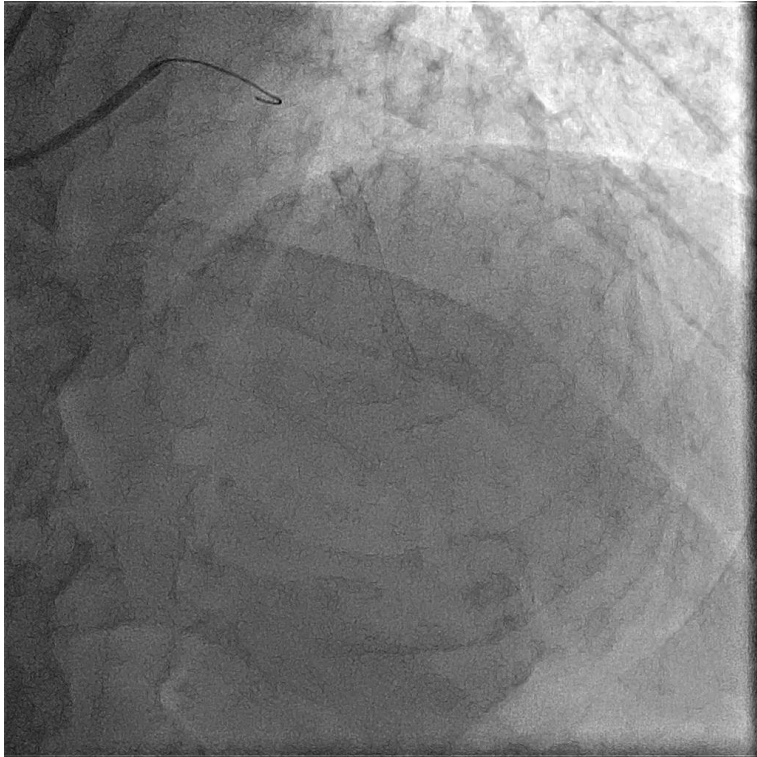


FINAL ANGIOGRAPHIC RESULT

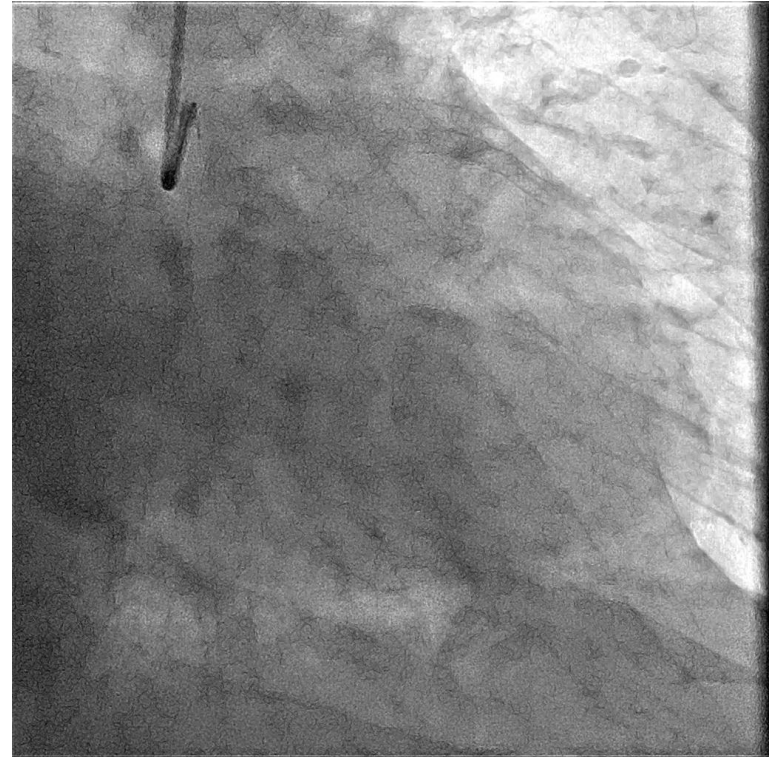


ELECTIVE PCI TO LCx AND LAD

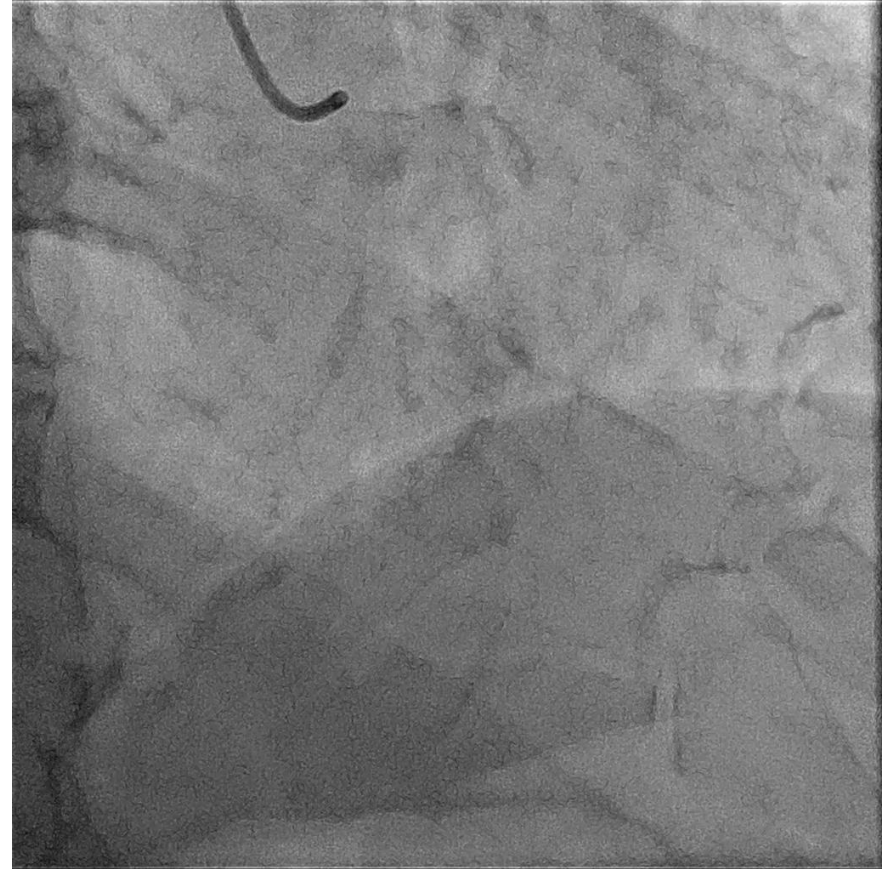
DP-ZES 3.5x34 mm (mLAD)



SELUTION SLR 3.0x25 mm (OM1)



ANGIOGRAPHIC FOLLOW-UP @ 6 MONTHS



EVIDENCE FOR DCB IN BIFURCATION LESIONS

STRATEGY	STUDY	DESIGN	PATIENTS	ANGIOGRAPHIC OUTCOMES	CLINICAL OUTCOMES
DCB alone vs. CB in SB	PEPCAD-BIF (2016) (Sequent Please; B. Braun, Germany)	RCT	64	LLL: 0.08 ± 0.31 mm vs. 0.47 ± 0.61 mm (p=0.006)	Restenosis: 6% vs 26% TLR: 3% vs. 9%
BMS in MB DCB vs. CB in SB	DEBIUT (2012) (Dior-I, Eurocor GmbH, Germany) Group A: DCB in both branches, BMS in MB; Group B: BMS in MB, CB in SB; Group C: PES in MB, CB in SB	RCT	117	LLL in SB: 0.19 ± 0.66 mm (group A), 0.21 ± 0.57 mm (group B), and 0.11 ± 0.43 mm (group C) (p=0.001). LLL in MB: 0.31 ± 0.48 mm (group A) vs. 0.16 ± 0.38 mm (group B) (p=0.15)	Binary restenosis: 24.2%, 28.6%, and 15% (p=0.45) in groups A, B, and C, respectively. MACE: 20%, 29.7%, and 17.5% (p=0.40) in groups A, B, and C, respectively.
	BABILON (2014) (Sequent Please; B. Braun, Germany) A) BMS in MB; DCB in both branches. B) EES in MB; CB in SB	RCT	108	LLL in SB: -0.04 ± 0.76 mm (group A) vs. -0.03 ± 0.51 mm (group B) (p=0.983)	MACE: 17.3% vs 7.1% (p=0.10) TLR in MB (group A): 15.4% vs 3.6% (p=0.045) Restenosis in MB: 13.5% vs. 1.8% (p=0.027)
PES in MB CB vs. DCB in SB	Herrador et al. (2013) (Sequent Please; B. Braun, Germany)	RCT	50	LLL: 0.40 ± 0.50 mm vs. 0.09 ± 0.40 mm (p=0.01)	Restenosis: 20% vs. 7% (p=0.08) TLR: 22% vs. 12% (p=0.16) MACE @12 months: 24% vs. 11% (p=0.11)
Sirolimus-analogue DES in MB; CB vs. DCB in SB	BEYOND (2020) (Bingo, Yinyi Biotech, China)	RCT	222	LLL: -0.06 ± 0.32 mm vs. 0.18 ± 0.34 mm (p<0.0001)	Restenosis: 28.7% vs. 40% (p<0.0001) MACE: 0.9% vs. 3.7% (p=0.16) MI: 0% vs 0.9%, (p=0.49)
	Li et al. (2022) (Sequent Please; B. Braun, Germany)	Prospective, observational	219	LLL in SB: 0.11 ± 0.18 mm vs. 0.19 ± 0.25 mm (p=0.024) @ 12 months	MACE: 23.9% vs. 12.8% (p=0.03)
	DCB-BIF (2024) (Paclitaxel-coated balloon)	RCT	784	Acute gain in SB: 0.63 ± 0.45 mm vs. 0.55 ± 0.48 ; p=0.041	MACE @12 months: 7.2% vs. 12.5%; HR, 0.56; 95%CI, 0.35-0.88; p=0.013) TV-MI @12 months: 5.6 vs. 10.9; HR, 0.50; 95%CI, 0.30-0.84; p=0.009

HYBRID PCI

EVIDENCE FOR *DCB-ONLY* IN BIFURCATION LESIONS

STRATEGY	STUDY	PATIENTS	CLINICAL OUTCOMES	
DCB alone in both branches	Schulz et al. (2014) (Sequent Please; B. Braun, Germany)	39	Restenosis: 10% (all in LM coronary artery bifurcation)	
	Bruch et al. (2016) (Sequent Please; B. Braun, Germany)	127	TLR: 4.5% MACE: 6.1%	Bail-out stent: 45%
DCB alone in 1 branch	Her et al. (2016) (Sequent Please; B. Braun, Germany) Only in MB	16	Mean SB ostial lumen area: 1.42±1.18 mm ² @ 9 months vs. 1.03±0.77 mm ² post-procedure. SB ostial lumen area gain: 0.37±0.64 mm ² between post-procedure and 9 months. Ostial lumen area: increase by 3.9% between pre- and post-procedure, 52.1% between post-procedure and 9 months and 76.1% between pre-procedure and 9 months.	
	Vaquerizo et al. (Eurocor GmbH, Germany) Only in SB and Medina 0;0;1 lesions	31	LLL in SB: 0.32 ± 0.73 mm ² Binary restenosis and TLR: 22.5% MI: n=1, 3.2%	Bail-out BMS: 14%

SMALL, PROSPECTIVE, NON-RANDOMIZED STUDIES WITH NO CONTROL GROUP

CONCLUSIONS

- **PCI with newer-generation DES for coronary bifurcation lesions remains a clinical challenge** and is associated with an **increased risk for stent-related adverse outcomes** compared to **non-bifurcation lesions**.
- **DCB alone (*DCB-only PCI*) or combined with newer-generation DES (*hybrid PCI*)** have emerged as a promising **alternative strategy** to a **DES-based approach** for patients with **bifurcation lesions** to potentially **reduce** persisting **long-term stent-related adverse events**.
- Large-scale **randomized clinical outcome trials** are needed to confirm the **safety** and **efficacy** of a **DCB-only PCI strategy** for **true bifurcation lesions** and **demonstrate** its **potential superiority** compared with a **DES-based approach** with respect to **long-term device-related clinical outcomes**.

GRACIAS POR SU ATENCIÓN

