DCB Application for Left Main and Non-Left Main Bifurcation PCI

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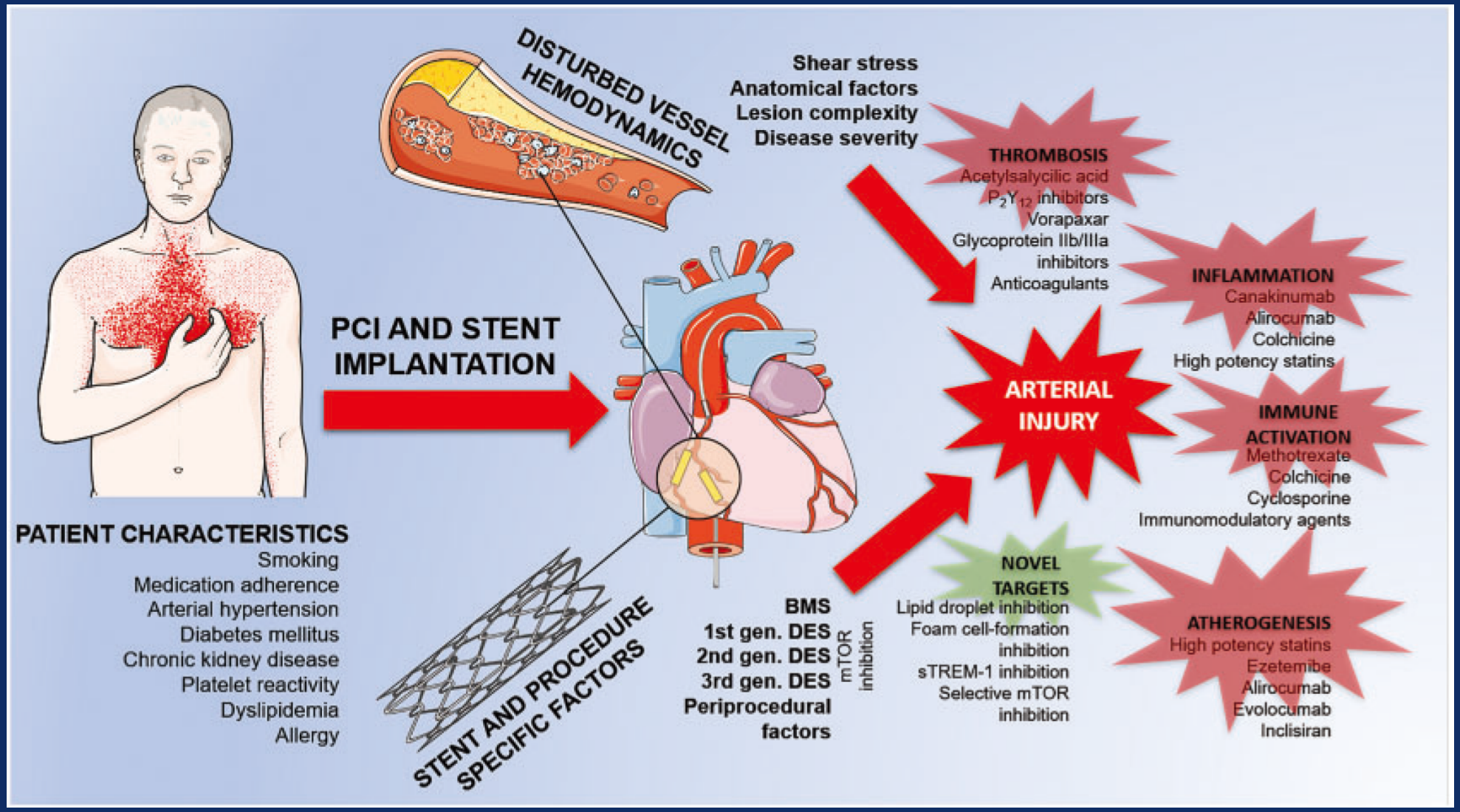
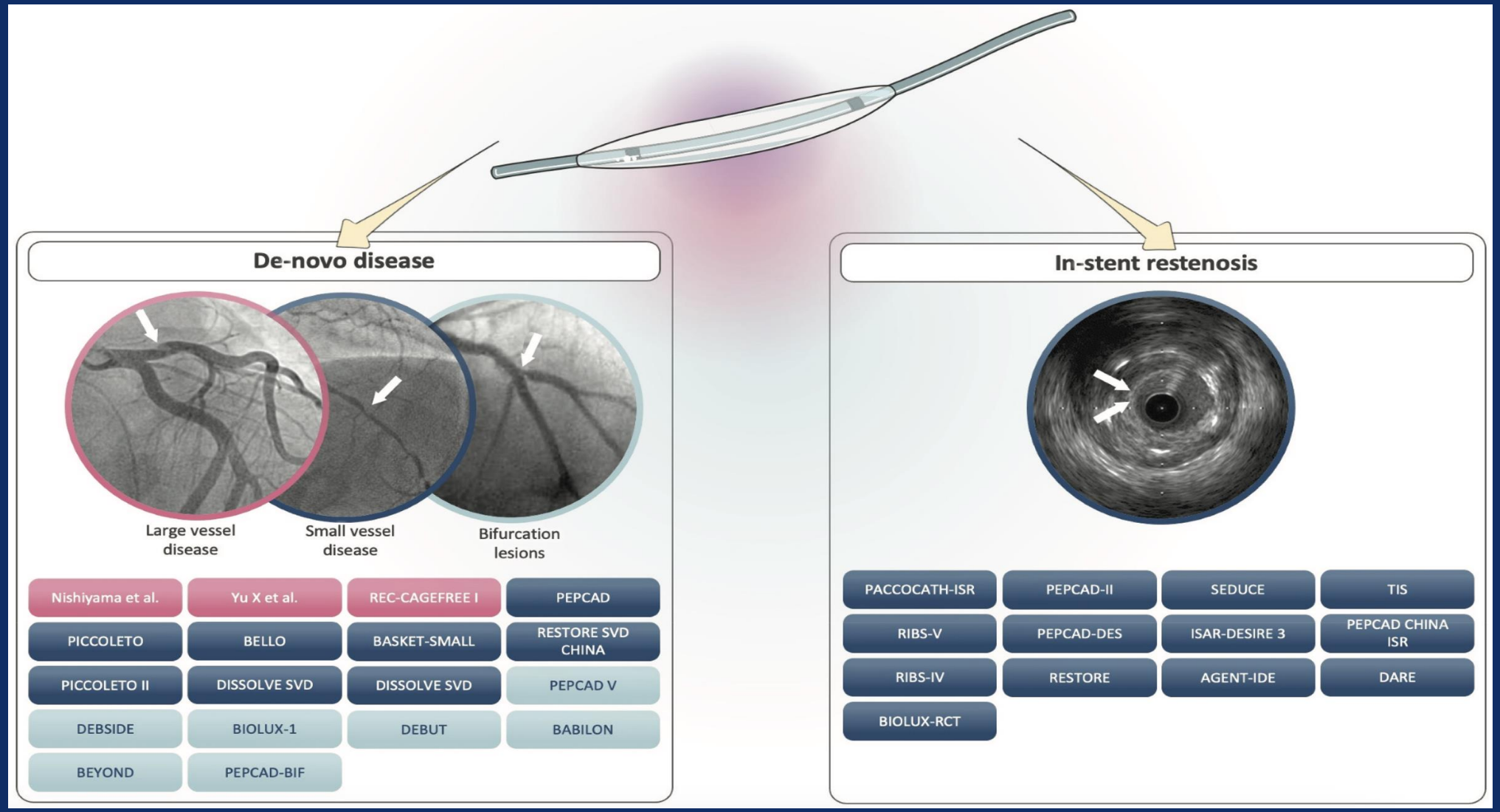
Stent failure: stent restenosis, stent thrombosis, neoatherosclerosis



JA. Borovac, et al. EHJ - Cardiovascular Pharmacotherapy (2019) 5, 105–116

Current ESC/ACC guidelines: DCB for In-stent restenosis (I, A)
More evidence supporting wider use of DCB in *de novo* lesions



Greco A, et al. Expert Review of Medical Devices, 2025

Advantages and limitations of DCB in bifurcation lesions

	Advantages	Limitations
Bifurcation lesions	Reduction of stent burden in high event rate lesions	High variety in study design of available data
	May support the adage “Keep it Simple, Swift and Safe (KISS)” through DES in MB and DCB in SB (if indicated)	Current trials do not include all relevant factors predisposing to SB occlusion
	May be preferred in specific lesions, such as stent-in-stent, prior stenting with old generation DES, and small caliber SB	Future RCTs with larger sample sizes and angiographic FU (incl. invasive coronary imaging or intracoronary measurements) are warranted
	DCB-only strategy appears to yield comparable results to DES treatment	

Somsen YB, et al. Catheter Cardiovasc Interv, 2025.

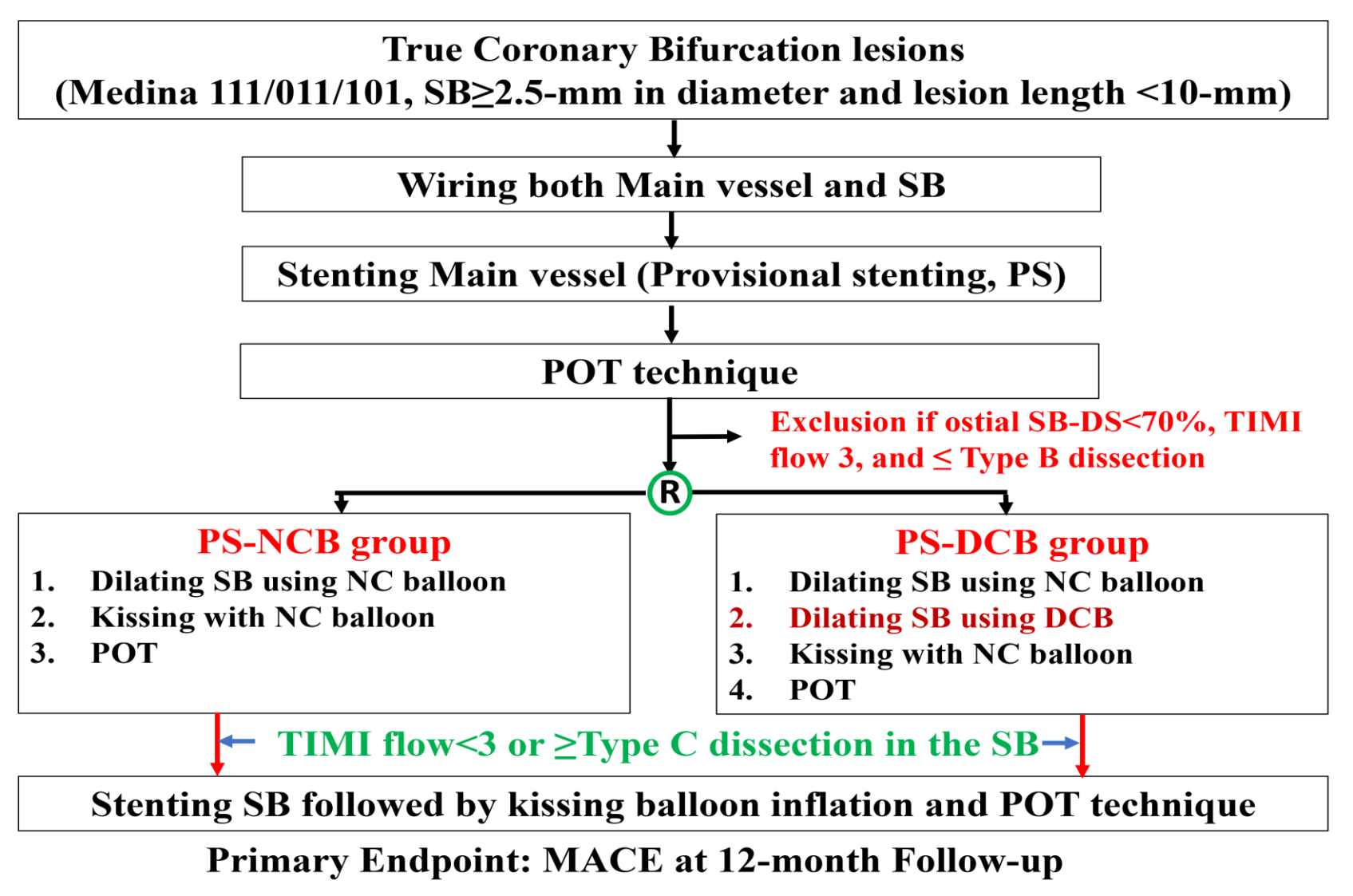
Randomized trials on the use of DCB for bifurcation lesions.

Lack of strong evidence (surrogate endpoints) before 2024

STUDY	Design	Follow-Up	Endpoints	*p*-Value
DCB in SB; DES/BMS in MB				
DCB Bifurcation Study (2013)	DES in MB, PCB in SB (n = 50) vs. DES in MB, POBA (n = 50) in SB	Angiographical and IVUS at 12 month and clinical at 12 month	LLL: 0.09 ± 0.4 mm vs. 0.40 ± 0.5 mm MACE: 11% vs. 24% TLR: 12% vs. 22%	**0.01** 0.11 0.16
BABILON (2014)	BMS in MB, PCB in SB (n = 52) vs. DES in MB (n = 56)	Angiographical at 9 months and clinical at 1–6–12–24 months	LLL: in MB: 0.31 ± 0.48 mm vs. 0.16 ± 0.38 mm In SB: −0.03 ± 0.51 mm vs. 0.04 ± 0.76 mm MACE: 17.3% vs. 7.1% TLR: 15.4% vs. 3.6%	0.15 0.983 0.105 **0.045**
BEYOND (2020)	DES in MB, PCB in SB (n = 113) vs. DES in MB, POBA (n = 109) in SB	Angiographical at 9 months and clinical at 1–6–9 months	LLL: 0.06 mm ± 0.32 mm vs. 0.18 mm ± 0.34 mm Restenosis rate: 28.7% vs. 40% MACE: 0.9% vs. 3.7% Non-fatal acute myocardial infarction: 0% vs. 0.9%	**<0.0001** **<0.0001** 0.16 0.49
DCB-only in SB				
PEPCAD-BIF (2016)	DCB (n = 32) vs. POBA (n = 32)	Angiographical at 9 months	LLL: 0.13 mm vs. 0.51 mm Restenosis rate: 6% vs. 26	**0.013** **0.045**

Verde N, et al. Journal of Clinical Medicine. 2024

DCB-BIF Trial



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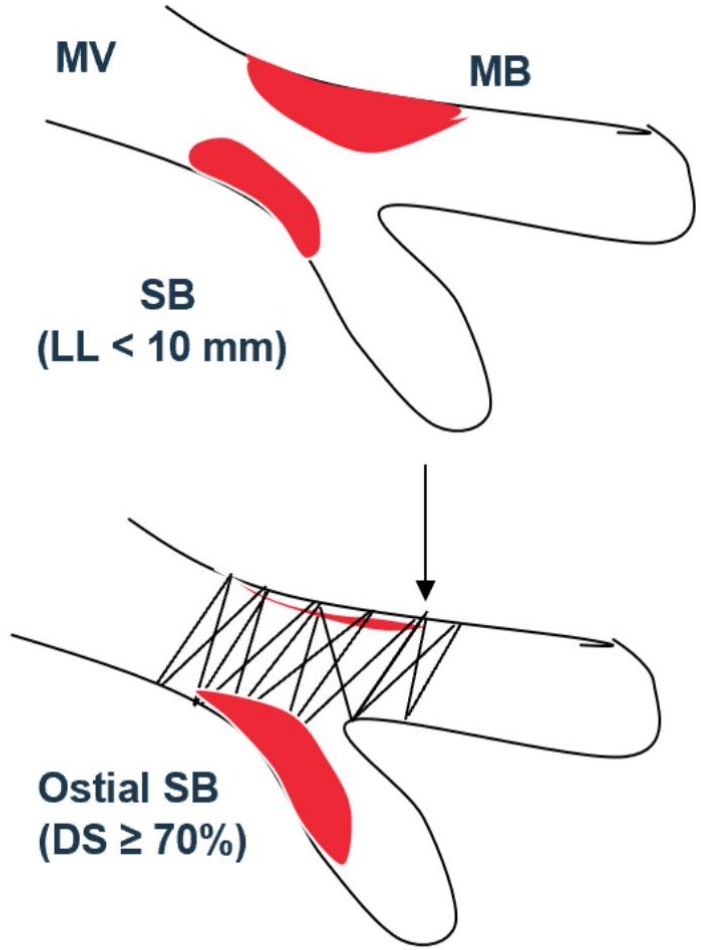
Major inclusion criteria

- ✓ Patients aged 18 years or older
- ✓ Silent ischemia, angina, or AMI >1 week
- ✓ A reference vessel diameter of ≥ 2.5 mm
- ✓ Baseline diameter stenosis of ≥ 50%
- ✓ SB lesion length of <10 mm
- ✓ Ostial SB diameter stenosis of ≥ 70%

  after MV stenting



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Major exclusion criteria

- ✓ Allergy to the study devices or medications
- ✓ Intolerable to dual antiplatelet therapy
- ✓ Life expectancy of <12 months
- ✓ Pregnancy or in nursing
- ✓ Restenotic lesion
- ✓ Severe calcification requiring rotational atherectomy; and hemodynamic instability

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Primary and secondary endpoints

- **Primary endpoint:**
  -- 1-year composite of target-lesion failure (TLF; including cardiac death, target-vessel MI, or clinically-driven TLR)

- **Secondary endpoints:**
  -- TVF without procedural MI
  -- Individual components of the primary endpoint (TLF)
  -- TVR
  -- Stent thrombosis

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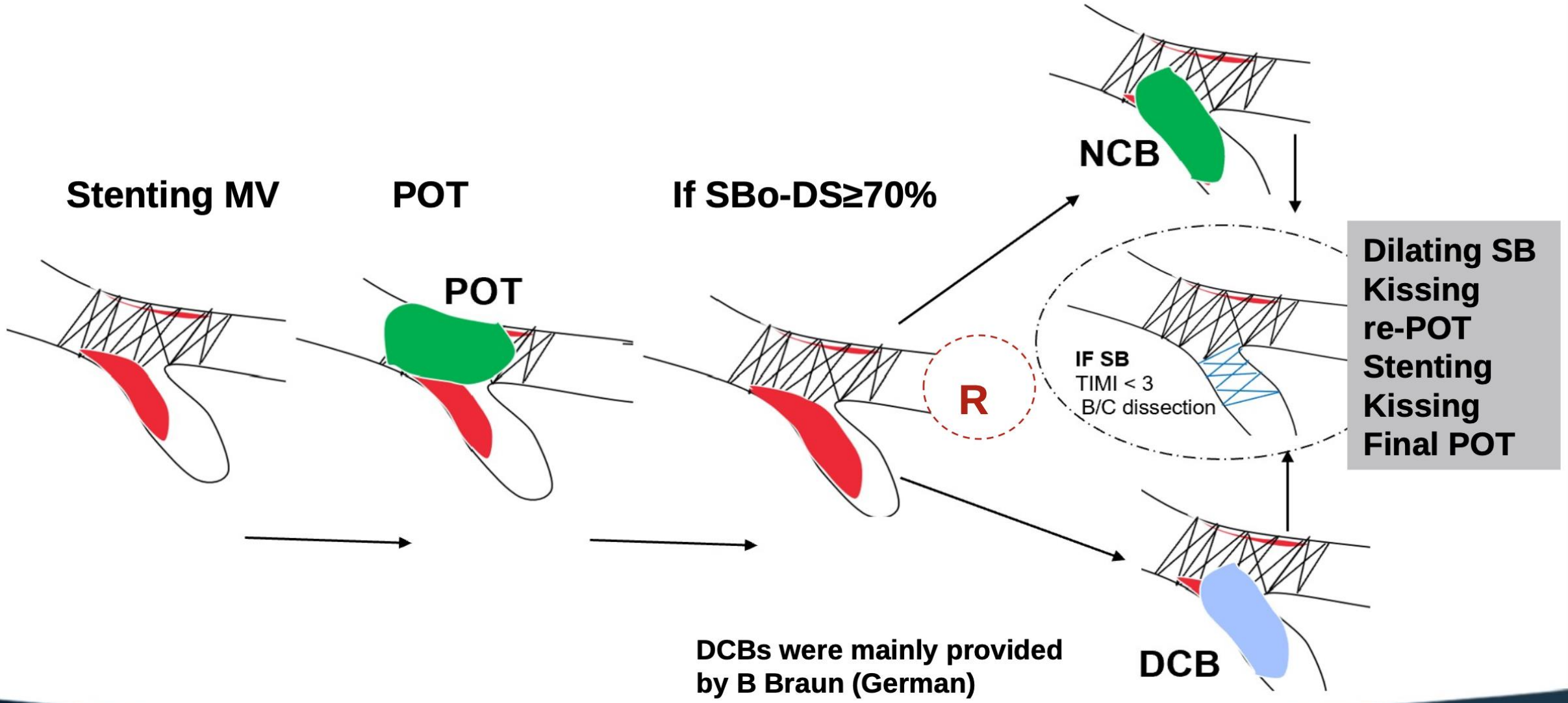
Stenting procedures



DCBs were mainly provided by B Braun (German)

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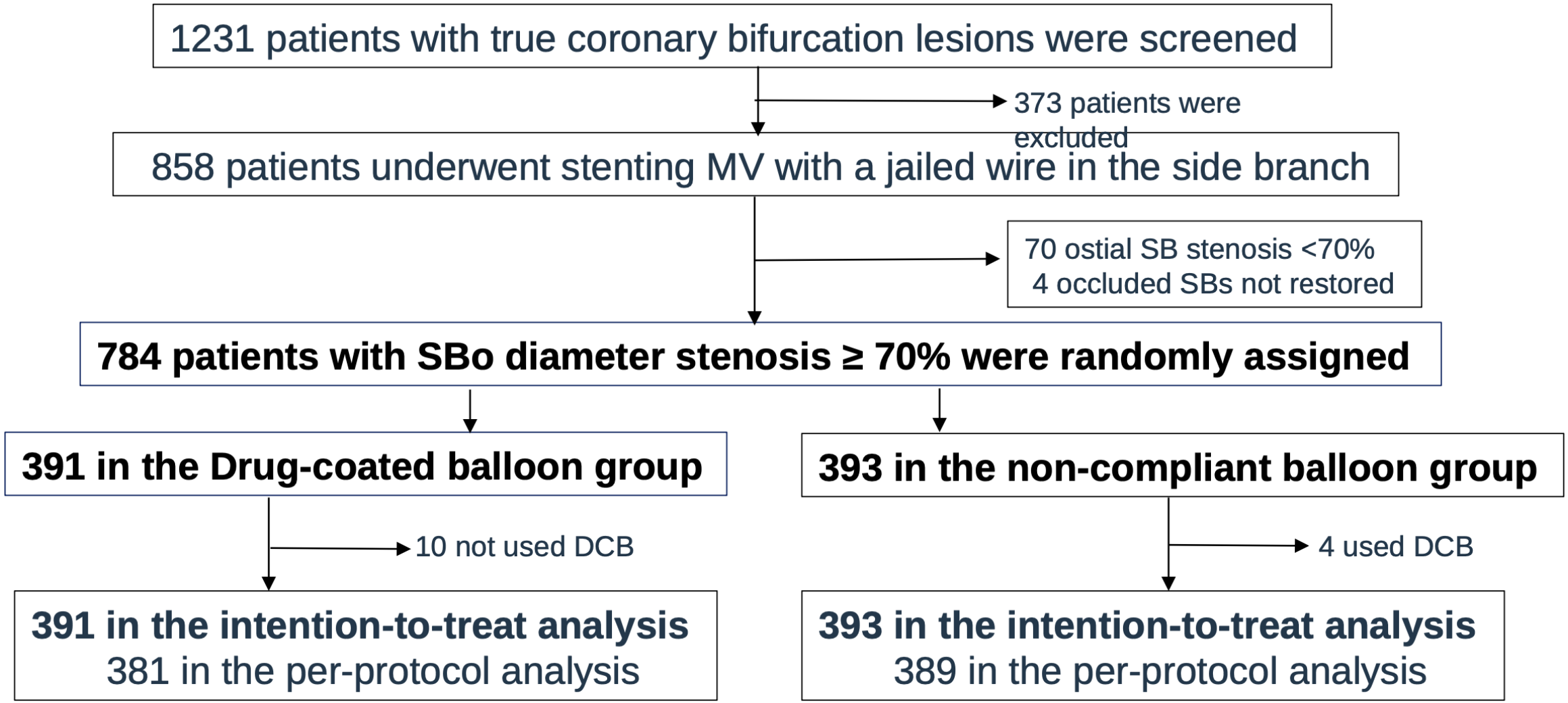
Randomization and study flowchart



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Baseline clinical characteristics

	Drug-coated balloon (n=391)	Non-complaint balloon (n=393)
Age, years	63.8 ± 10.6	63.6 ± 10.5
Male sex, n (%)	305 (78.0)	297 (75.6)
Hypertension	257 (65.7)	246 (62.6)
Diabetes mellitus	147 (37.6)	140 (35.6)
Dyslipidemia	251 (64.2)	236 (60.1)
Heart failure	25 (6.4)	23 (5.9)
Presentation		
Unstable angina	238 (60.9)	239 (60.8)
Non-STEMI	97 (24.8)	95 (24.2)
STEMI	22 (5.6)	23 (5.9)

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Lesions and procedural characteristics

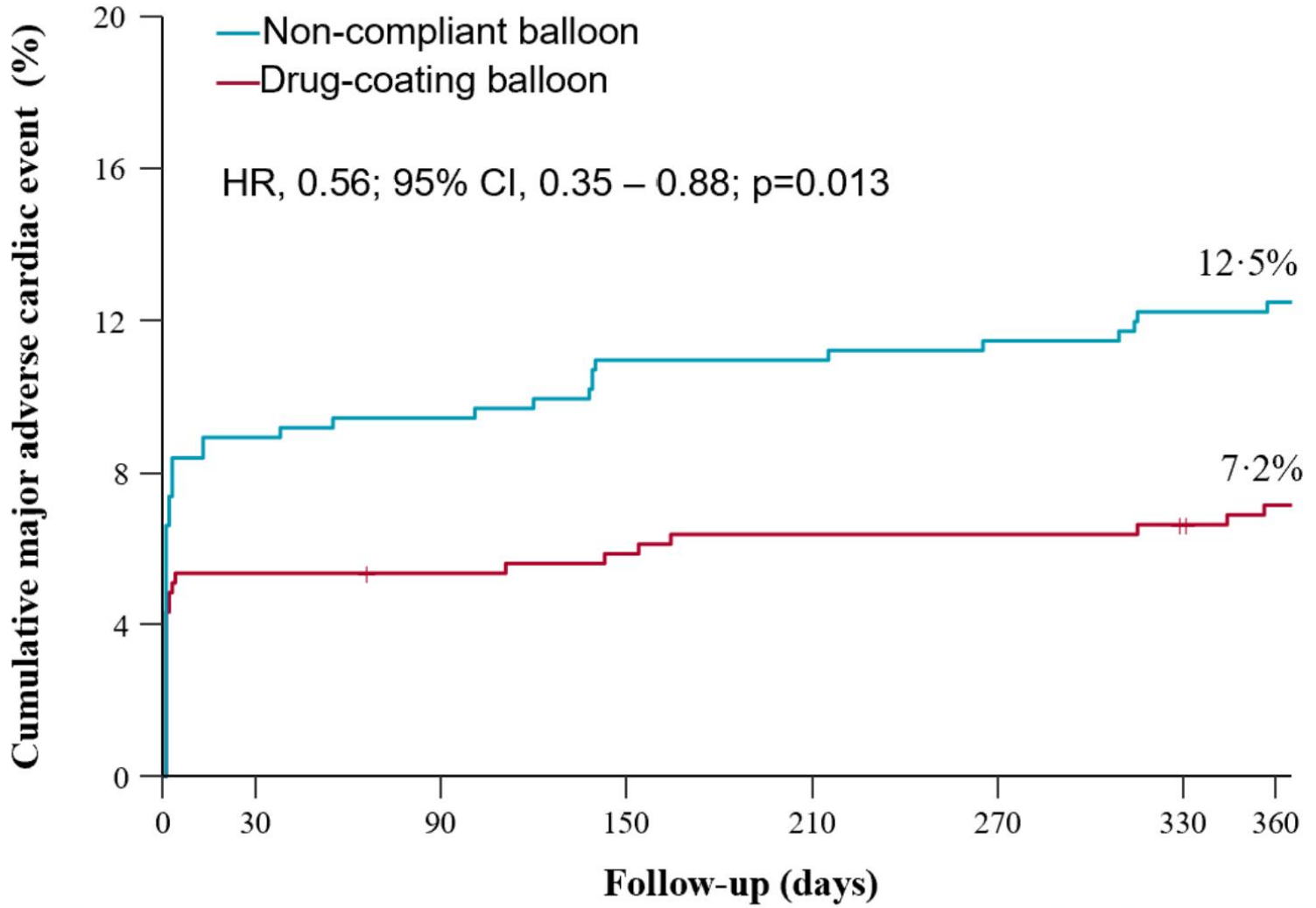
	Drug-coated balloon (n=391)	Non-compliant balloon (n=393)	p value
Multi-vessel disease, n (%)	248 (73.4)	264 (77.2)	0.29
Medina 1,1,1/0,1,1, n (%)	366 (93.6%)	367 (93.4)	0.27
Unprotected left main, n (%)	63 (16.1)	56 (14.2)	0.47
Transradial access, n (%)	379 (96.9)	385 (98.0)	0.38
Predilation for SB, n (%)	80 (20.5)	68 (17.3)	0.27
POT after stenting MV, n (%)	337 (86.2)	351 (89.3)	0.18
KBI after SB ballooning, n (%)	371 (94.9)	389 (98.9)	<0.001
Re-POT after KBI, n (%)	325 (83.1)	333 (84.7)	0.56
Cross-over to two-stent, n (%)	**15 (3.8)**	**13 (3.3)**	**0.69**
Intravascular imagining guidance, n (%)	101 (25.8)	111 (28.2)	0.45
Complete revascularization, n (%)	248 (63.4)	235 (59.8)	0.31
Contrast media, mL	188 ± 55	187 ± 60	0.76
Procedural time, min	58 ± 30	55 ± 35	0.30

Primary and secondary endpoints

	Drug-coated balloon group (n=391)	Non-compliant balloon group (n=393)	Hazard ratio or difference (95% CI)	p value
Primary endpoint				
Target lesion failure	28 (7.2)	49 (12.5)	0.56 (0.35-0.88)	0.013
Secondary endpoint				
Cardiac death	4 (1.0)	2 (0.5)	2.46 (0.38-11.31)	0.45
TLF without PMI	10 (2.6)	20 (5.1)	0.48 (0.23-1.03)	0.09
Target vessel MI	22 (5.6)	43 (10.9)	0.50 (0.30-0.84)	0.009
Periprocedural MI	18 (4.6)	29 (7.4)	-2.8 (-6.23-0.59)**	0.13
Spontaneous MI	**4 (1.0)**	**14 (3.6)**	**0.27 (0.09-0.81)**	**0.029**
Clinically driven TLR	5 (1.3)	6 (1.5)	0.81 (0.25-2.66)	1.00
Stent thrombosis#	4 (1.0)	0	1.0 (-0.13 - 2.60)**	0.06

**** indicated the difference and 95% CI; # indicated 2 definite ST**

Primary endpoint: Target-lesion failure



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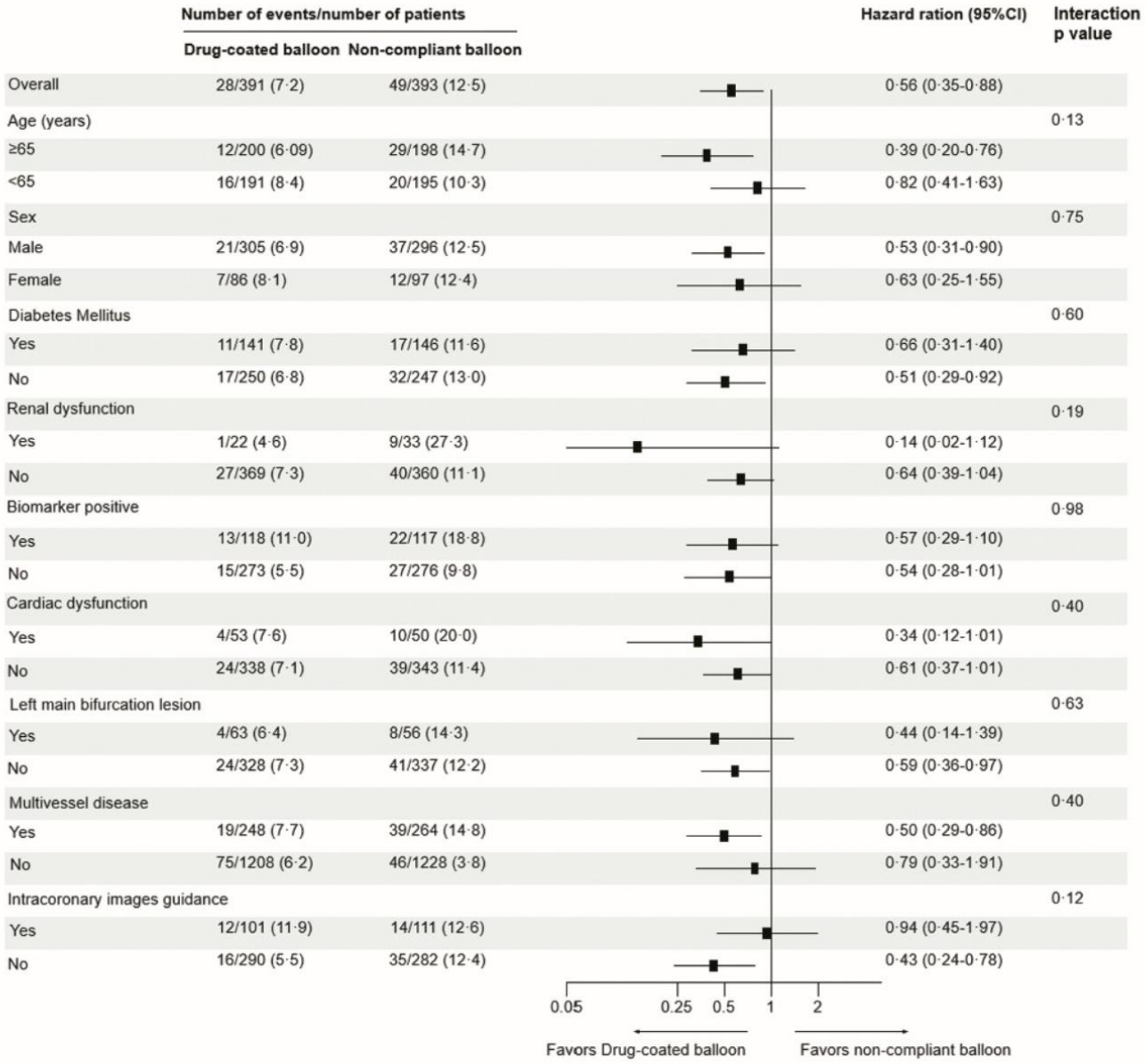
Subgroup analysis

- There was no interaction between subgroups
- More profound benefits were detected in patients ≥ 65 years, non-LM bif, non-IVI guidance



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ORIGINAL RESEARCH

Drug-Coated Balloon Angioplasty of the Side Branch During Provisional Stenting

The Multicenter Randomized DCB-BIF Trial

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ABSTRACT

BACKGROUND Side branch stenting is often required during provisional stenting, leading to suboptimal results. Drug-coated balloons (DCB) for the compromised side branch have emerged as an attractive strategy. However, the benefit of DCB for coronary bifurcations remains unclear.

OBJECTIVES This study aimed to investigate whether DCB, compared with a noncompliant balloon (NCB), for the pinched side branch improves the outcomes of provisional stenting in patients with simple, true coronary bifurcations.

METHODS In this multicenter, randomized controlled trial, patients with true coronary bifurcations who had side branch diameter stenosis of ≥70% after main vessel stenting at 22 centers in China, Indonesia, Italy, and Korea were randomly assigned to either DCB or NCB intervention. The primary endpoint was major adverse cardiac events, a composite of cardiac death, target vessel myocardial infarction, or clinically driven target-lesion revascularization at the 1-year follow-up.

RESULTS Between September 8, 2020, and June 2, 2023, 784 patients with true coronary bifurcation lesions undergoing main vessel stenting and having a severely compromised side branch were randomly assigned to the DCB (n = 391) or NCB (n = 393) group. One-year follow-up was completed in all patients. The primary endpoint occurred in 28 patients in the DCB group and 49 patients in the NCB group (Kaplan-Meier rate: 7.2% vs 12.5%; HR: 0.56; 95% CI: 0.35-0.88; *P* = 0.013), driven by a reduction in myocardial infarction. There were no significant differences between groups in procedural success, crossover to a 2-stent approach, all-cause death, revascularization, or stent thrombosis.

CONCLUSIONS In patients with simple and true coronary bifurcation lesions undergoing provisional stenting, main vessel stenting with a DCB for the compromised side branch resulted in a lower 1-year rate of the composite outcome compared with an NCB intervention for the side branch. The high rates of periprocedural myocardial infarction, which occurred early and did not lead to revascularization, are of unclear clinical significance. (JACC. 2025;85:1-15) © 2025 by the American College of Cardiology Foundation.

Listen to this manuscript's audio summary by Editor Emeritus Dr Valentin Fuster on www.jacc.org/journal/jacc.

From the [a]Nanjing First Hospital, Nanjing Medical University, Nanjing, China; [b]Yulin First People's Hospital, Yulin, China; [c]West China Hospital, Sichuan University, Chengdu, China; [d]Pederzoli Hospital, Peschiera del Garda, Verona, Italy; [e]Nanchong Municipal Central Hospital, Nanchong, China; [f]Xiamen Heart Center, Xiamen University, Xiamen, China; [g]Medistra Hospital, Medistra University, Jakarta, Indonesia; [h]Ulsan University Hospital, University of Ulsan College of Medicine, Ulsan, Republic of Korea; [i]Binawaluya Cardiac Center, Jakarta, Indonesia; [j]Tianjin Fourth Central Hospital, Tianjin, China; [k]Qingdao Municipal Hospital, Qingdao, China; [l]Beijing Anzhen Hospital, Capital Medical University, Beijing, China; [m]First Hospital, Harbin Medical University, Harbin, China; [n]Xinyang Central Hospital, Xinyang, China; [o]School of Medicine, Shantou University, Shantou, China; and the [p]Shaanxi Provincial People's Hospital, Xi'an, China. *Drs Gao, Tian, and Kan contributed equally to this work.

The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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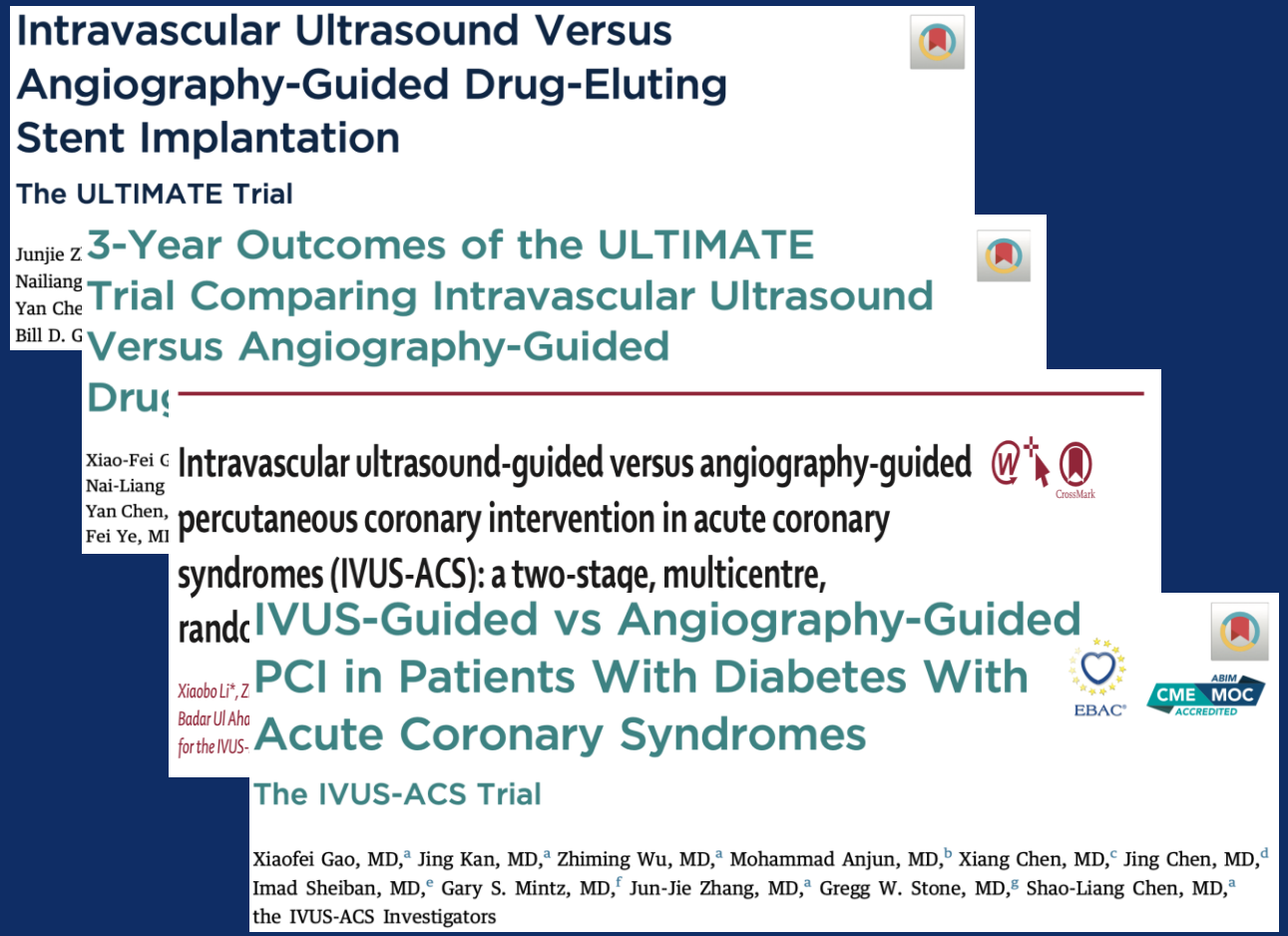
Conclusion of DCB-BIF trial

- DCB-BIF is the first powered RCT to compare DCB vs. NCB during provisional stenting for true but simple coronary bifurcation lesions.
- Stenting the MV with SB-DCB results in a lower 1-year risk of target lesion failure than stenting the MV with SB-NCB.
- The high rates of MI did not lead to revascularization, are of unclear clinical significance (may be due to lower TLR rate among simple bifurcations).

IVI-guided DES implantation in complex lesions (I, A)



2024 ESC guideline

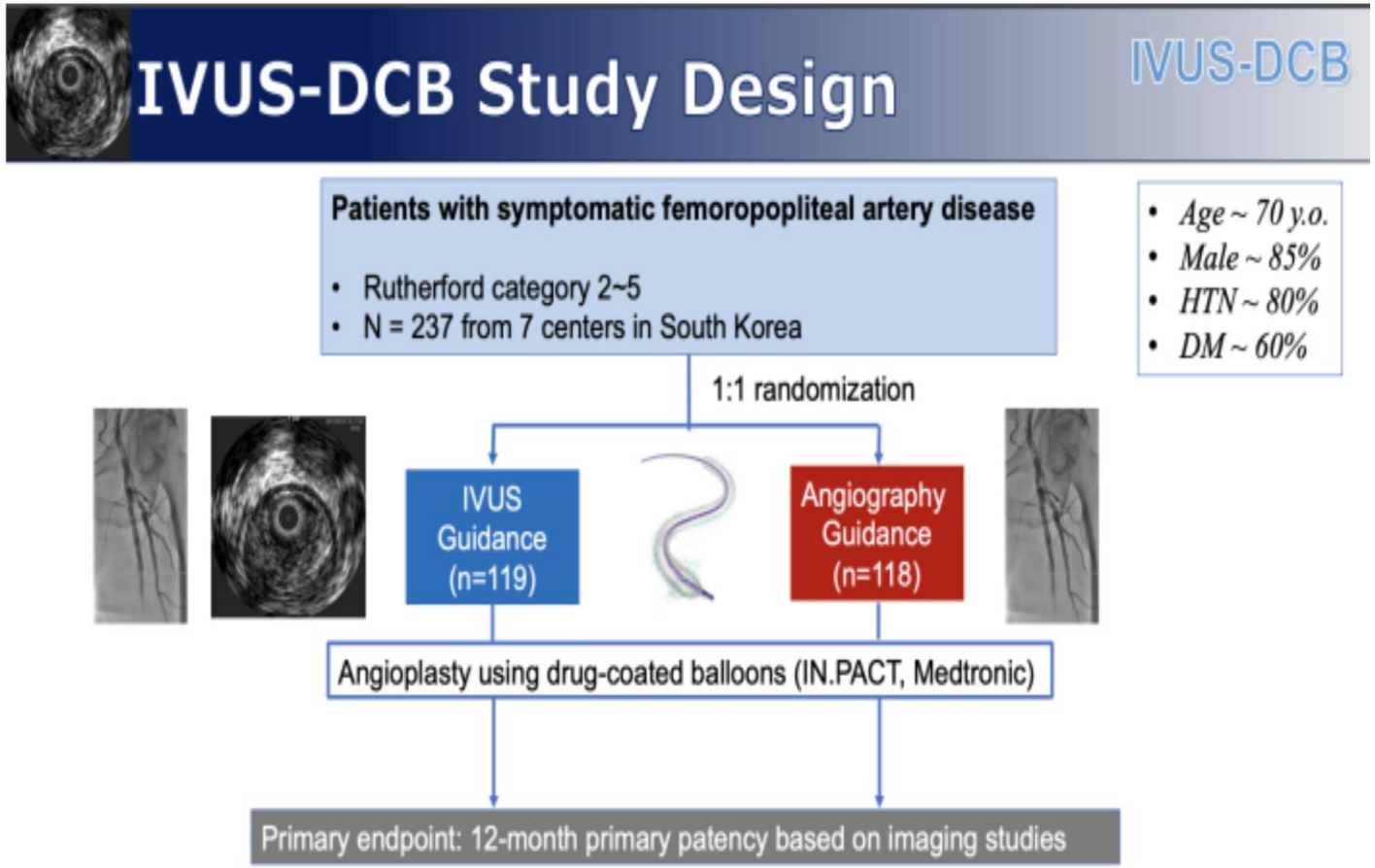
Assessment of procedural risks and post-procedural outcomes		
Intracoronary imaging guidance by IVUS or OCT is recommended for performing PCI on anatomically complex lesions, in particular left main stem, true bifurcations and long lesions.	I	A
Intracoronary pressure measurement (FFR or iFR) or computation (QFR):		
• is recommended to guide lesion selection for intervention in patients with multivessel disease;	I	A
• should be considered at the end of the procedure to identify patients at high risk of persistent angina and subsequent clinical events;	IIa	B
• may be considered at the end of the procedure to identify lesions potentially amenable to treatment with additional PCI.	IIb	B

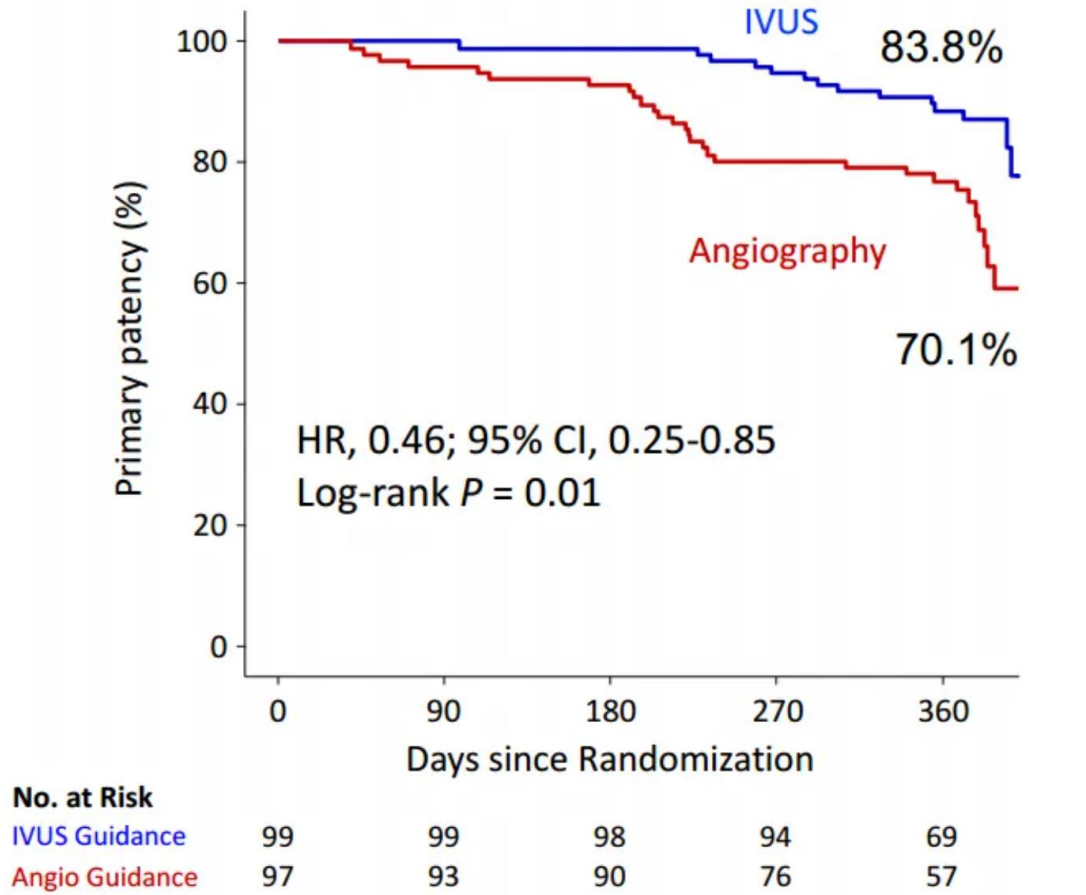
2025 ACC/AHA guideline

COR	LOE	Recommendation
1	A	1. In patients with ACS undergoing coronary stent implantation in left main artery or in complex lesions, intracoronary imaging with intravascular ultrasound (IVUS) or optical coherence tomography (OCT) is recommended for procedural guidance to reduce ischemic events.*1–11

1.2024 ESC/EACTS. EHJ. 2024
2.2025 ACC/AHA/ACEP/NAEMSP/SCAI. Circulation. 2025

IVUS-DCB study in peripheral artery disease





Presented at ACC 2024

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ORIGINAL RESEARCH

Intravascular Ultrasound vs Angiography-Guided Drug-Coated Balloon Angioplasty

The ULTIMATE III Trial

Xiao-Fei Gao, MD,[a,*] Zhen Ge, MD,[a,*] Xiang-Quan Kong, PhD,[a,*] Xiang Chen, MD,[b] Leng Han, MD,[c] Xue-Song Qian, MD,[d] Guang-Feng Zuo, MD,[a] Zhi-Mei Wang, MD,[a] Juan Wang, MD,[c] Jia-Xian Song, MD,[d] Ling Lin, MSc,[a] Tao Pan, MD,[a] Fei Ye, MD,[a] Yan Wang, MD,[b] Jun-Jie Zhang, MD, PhD,[a] Shao-Liang Chen, MD, PhD,[a] the ULTIMATE III Investigators

ABSTRACT

BACKGROUND Drug-coated balloon (DCB) angioplasty seems a safe and effective option for specific de novo coronary lesions. However, the beneficial effect of intravascular ultrasound (IVUS)-guided DCB angioplasty in de novo lesions remains uncertain.

OBJECTIVES This study aimed to assess the benefits of IVUS guidance over angiography guidance during DCB angioplasty in de novo coronary lesions.

METHODS A total of 260 patients with high bleeding risk who had a de novo coronary lesion (reference vessel diameter 2.0-4.0 mm, and lesion length ≤15 mm) were randomly assigned to either an IVUS-guided or an angioplasty-guided DCB angioplasty group. The primary endpoint was in-segment late lumen loss (LLL) at 7 months after procedure. The secondary endpoint was target vessel failure at 6 months.

RESULTS A total of 2 patients in the angiography-guided group and 7 patients in the IVUS-guided group underwent bailout stent implantation ($P = 0.172$). The primary endpoint of 7-month LLL was 0.03 ± 0.52 mm with angiography guidance vs −0.10 ± 0.34 mm with IVUS guidance (mean difference 0.14 mm; 95% CI: 0.02-0.26; $P = 0.025$). IVUS guidance was also associated with a larger 7-month minimal lumen diameter (2.06 ± 0.62 mm vs 1.75 ± 0.63 mm; $P < 0.001$) and a smaller diameter stenosis (28.15% ± 13.88% vs 35.83% ± 17.69%; $P = 0.001$) compared with angiography guidance. Five target vessel failures occurred at 6 months, with 4 (3.1%) in the angiography-guided group and 1 (0.8%) in the IVUS-guided group ($P = 0.370$).

CONCLUSIONS This study demonstrated that IVUS-guided DCB angioplasty is associated with a lower LLL in patients with a de novo coronary lesion compared with angiography guidance. (Intravascular Ultrasound Versus Angiography Guided Drug-Coated Balloon [ULTIMATE-III]; NCT04255043) (J Am Coll Cardiol Intv 2024;■:■-■) © 2024 by the American College of Cardiology Foundation.

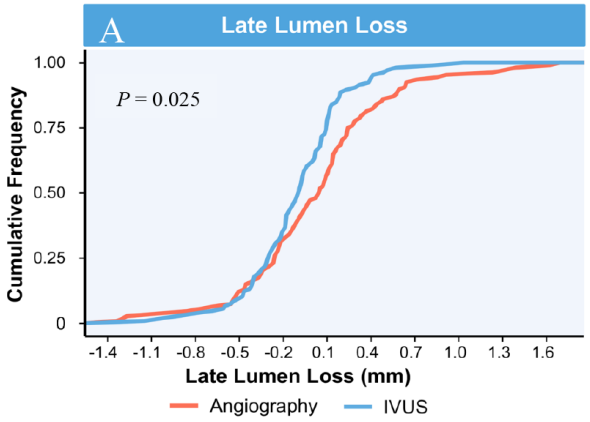
Central Illustration

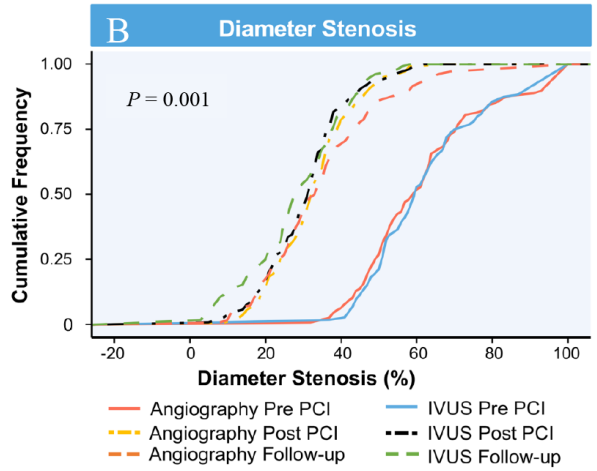
IVUS Guidance Versus Angiography Guidance During DCB Angioplasty in De Novo Coronary Lesions: The ULTIMATE III trial

Patients with a coronary de novo lesion (N = 260)

- **Angiography-guided DCB Angioplasty (n = 130)**
- **IVUS-guided DCB Angioplasty (n = 130)**

Primary Endpoint: in-segment late lumen loss 7 months after procedure





- IVUS guidance was associated with lower in-segment late lumen loss (mean difference 0.14 mm) and smaller diameter stenosis (28% vs. 36%, $P = 0.001$) than angiography guidance.

Take Home Message

- DCB-BIF is the first powered RCT to compare DCB vs. NCB during provisional stenting for true but simple coronary bifurcation lesions.
- Stenting the MV with SB-DCB results in a lower 1-year risk of target lesion failure than stenting the MV with SB-NCB.
- Further randomized trials are warranted to investigate whether IVUS-guided DCB angioplasty could improve clinical outcomes in complex coronary bifurcation PCI.

doi:10.1093/eurheartj/ehaa112

Cardiac centre of excellence

Introduction to the Department of Cardiology in Nanjing First Hospital of Nanjing Medical University, China

History and current status of Nanjing First Hospital

Nanjing City, used to be the capital of China during a period of 10 dynasties, located at the Yantz Triangle area, a location named as the most active economic zone.

Nanjing First Hospital (NFH) was built in May 1935, just before WWII. As an only government-run hospital during WWII, NFH contributed very much to the national recovery and growth since the beginning of WWII. The splendid achievements and unique characteristics of the Nanjing population have nourished this city and encouraged NFH to catch up with innovation in medicine.

Nanjing First Hospital consists of three campuses, one campus for the original tertiary NFH and two for Nanjing Heart Center (NHC),

Thanks for your attention!