

DCB for complex lesions - are we there yet ?

LUCCA 5.0 Luzern Switzerland

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Disclosures

- B Braun: consultation fee, research grant
- Shockwave: consultation fee
- Boston Scientific: consultation fee
- Abbott: consultation fee
- Biotronik: consultation fee
- Cordis: consultation fee
- EPS: consultation fee

Recent data on DCB in
non-complex lesions

CageFree 1 trial of DCB in non-complex PCI

Inclusion and Key exclusion

ACS or CCS

De novo lesion, regardless of treated vessel diameter

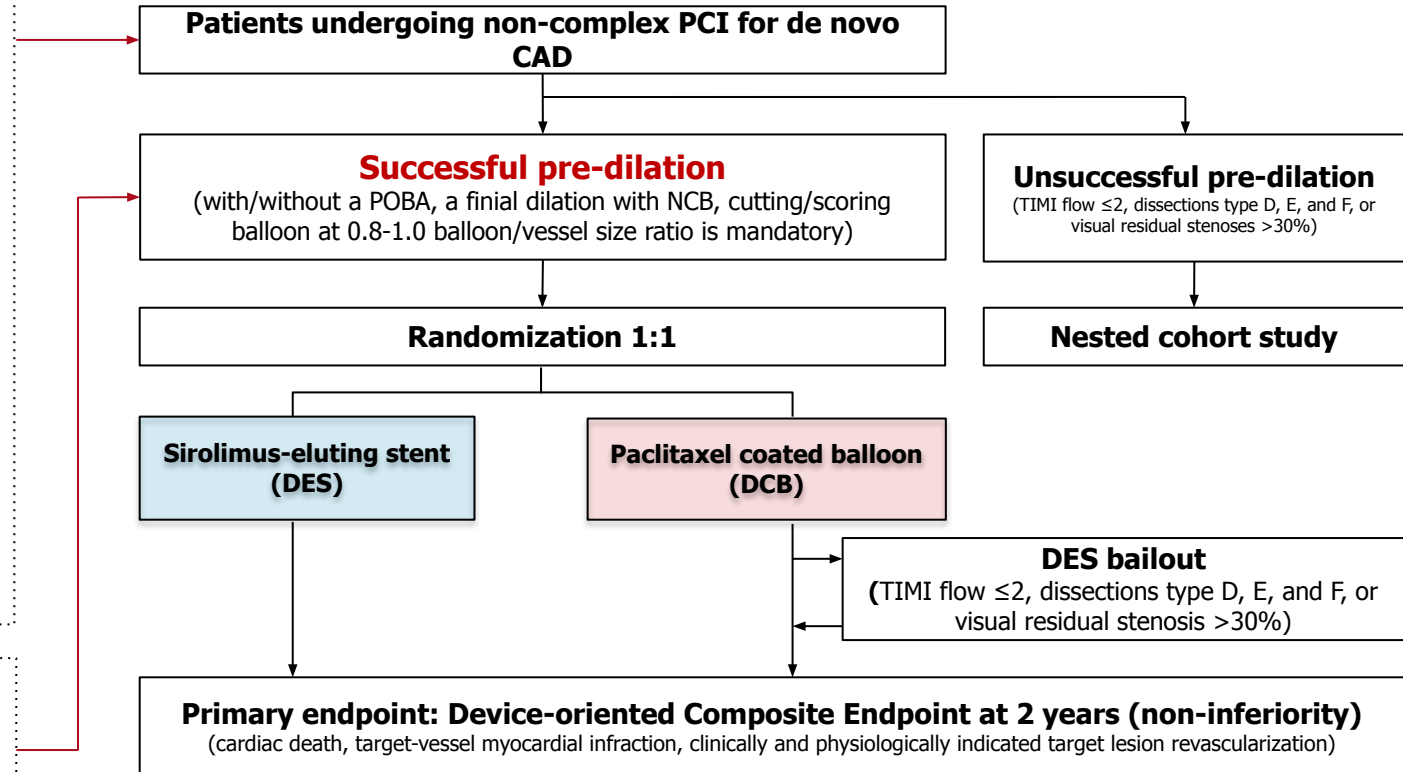
Non-Complex PCI, which is defined as

- One or two target lesions or vessels, one or two planned DES or DCB devices, planned total DES or DCB length of 60 mm or shorter
- bifurcations not requiring treatment in both main and side branch
- Non-left main lesion
- Non-venous or arterial graft lesion
- Non-chronic total occlusion lesion
- Do not require the use of atherectomy device

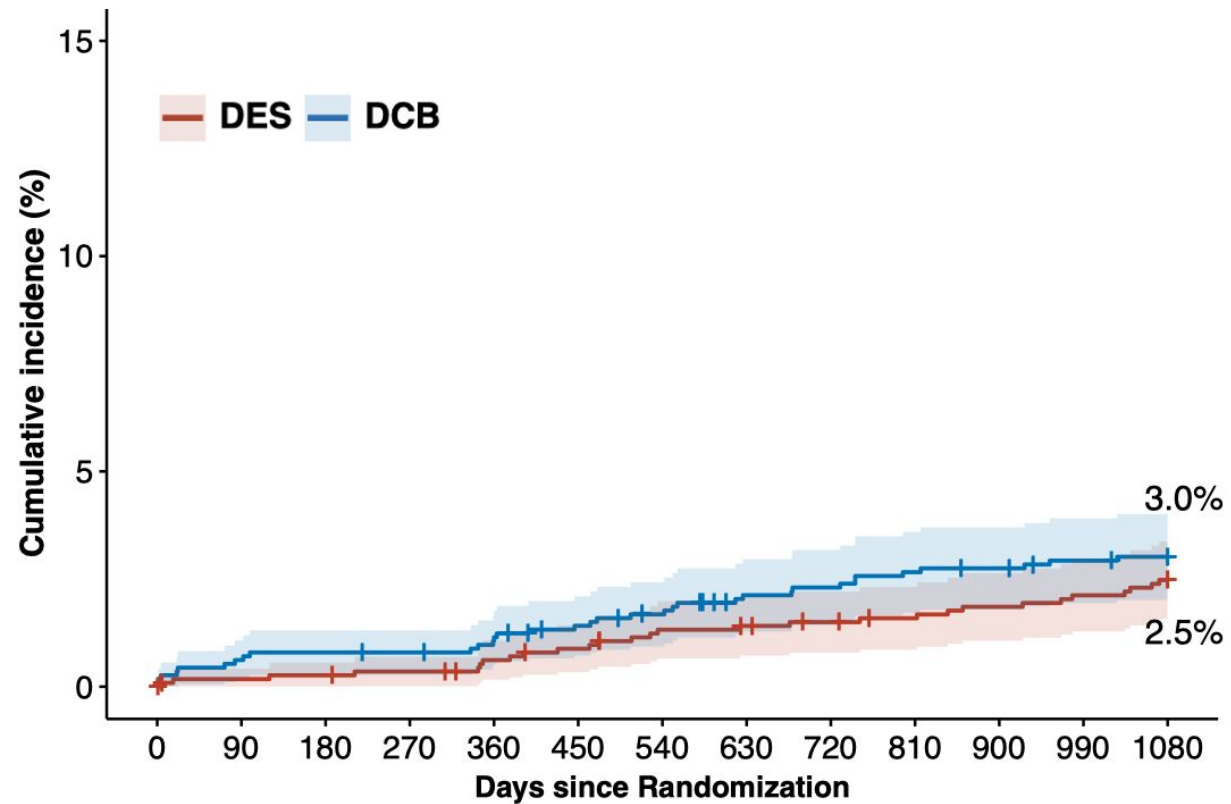
Exclude: cardiogenic shock and in-stent restenosis

Successful pre-dilatation

- *No type D, E, F dissections*
- *TIMI flow = 3*
- *Visual residual stenoses $\leq 30\%$*



Cardiovascular death

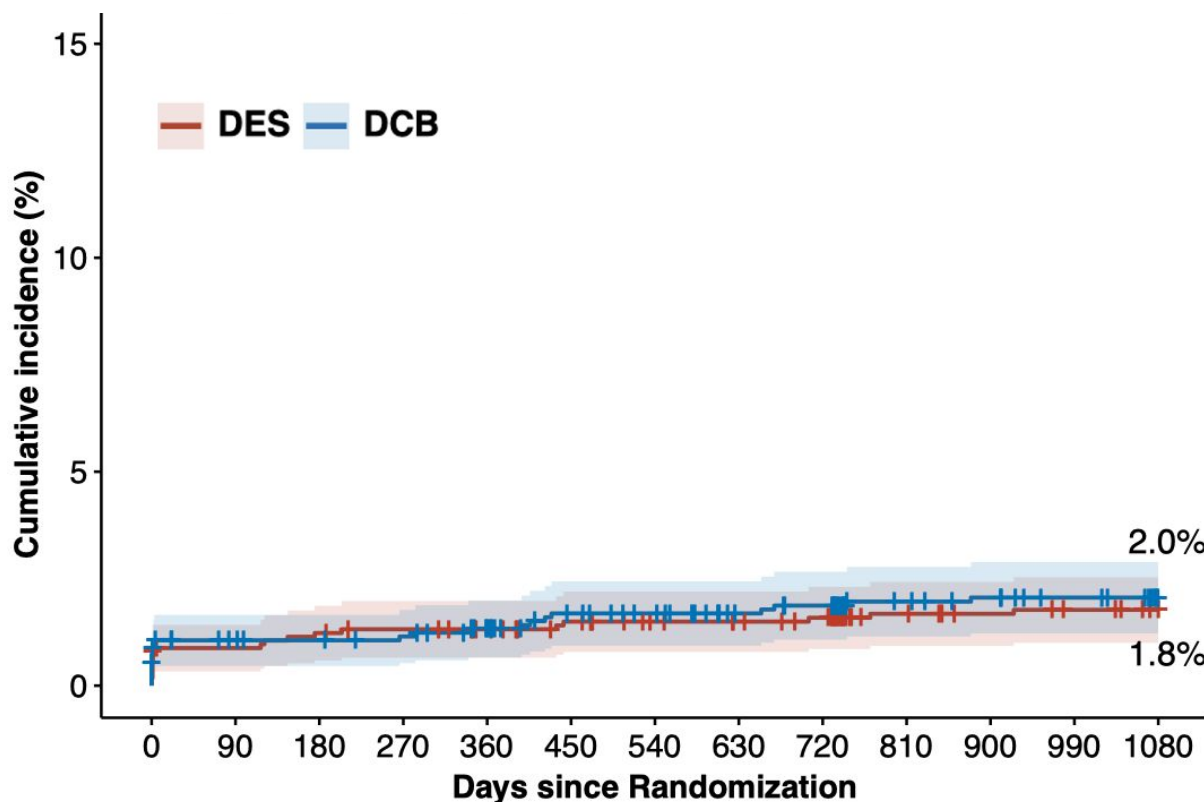


Difference, % (95%CI): 0.54 (-0.80 to 1.88), p=0.432

Number at risk

DES	1139	1135	1134	1132	1127	1123	1116	1114	1111	1108	1105	1102	1098
DCB	1133	1126	1124	1123	1119	1112	1107	1098	1096	1092	1090	1086	1084

Target-vessel myocardial infarction

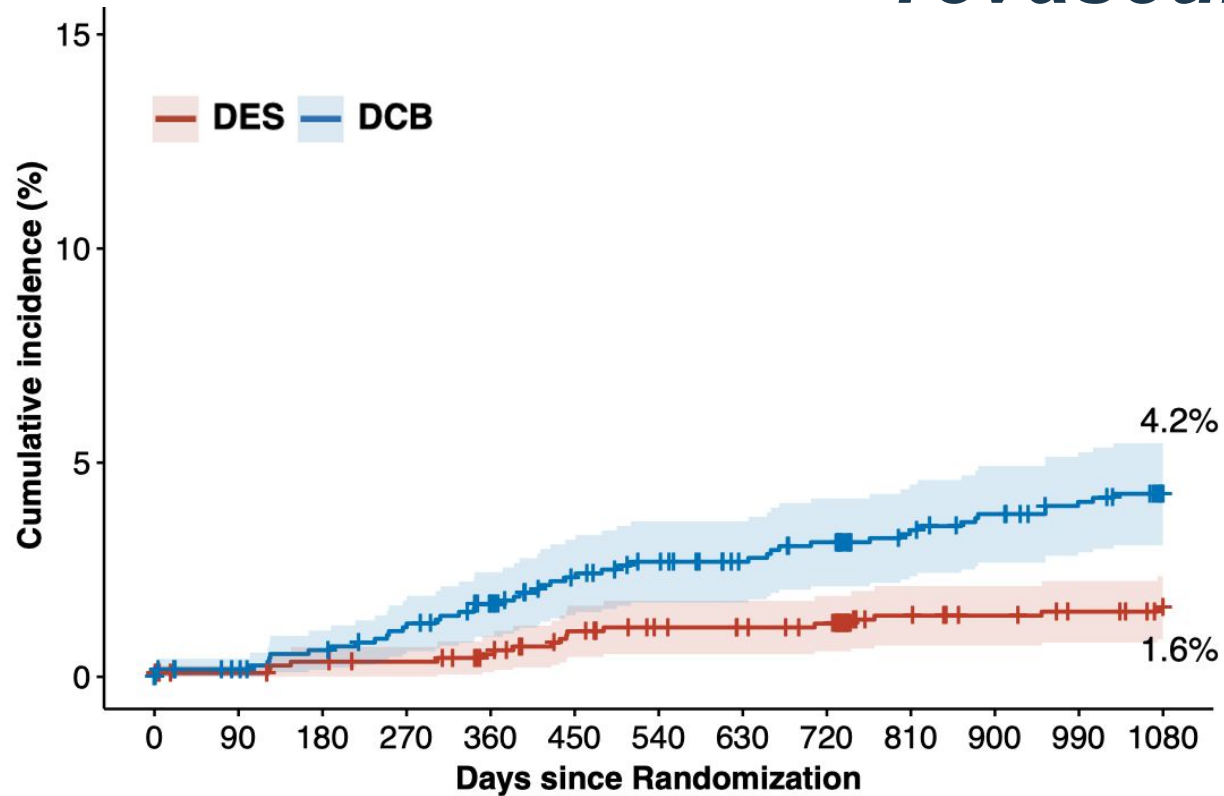


Difference,% (95%CI): 0.27 (-0.85 to 1.40), p=0.633

Number at risk

DES	1139	1126	1122	1119	1114	1107	1100	1097	1093	1063	1059	1056	1052
DCB	1133	1114	1112	1109	1101	1089	1084	1074	1070	1048	1044	1039	1030

Clinically and physiologically indicated target lesion revascularization



Difference, % (95%CI): 2.59 (1.21 to 3.97), $p < 0.001$

Number at risk

DES	1139	1134	1130	1128	1121	1110	1102	1099	1095	1064	1060	1056	1051
DCB	1133	1124	1117	1109	1097	1081	1072	1063	1056	1030	1023	1015	1005

One-year results of the SELUTION DeNovo trial comparing a strategy of PCI with a sirolimus-eluting balloon and provisional stenting versus systematic DES implantation to treat de novo coronary lesions

SELUTION DeNovo Clinical Trial

ClinicalTrials.gov ID NCT04859985

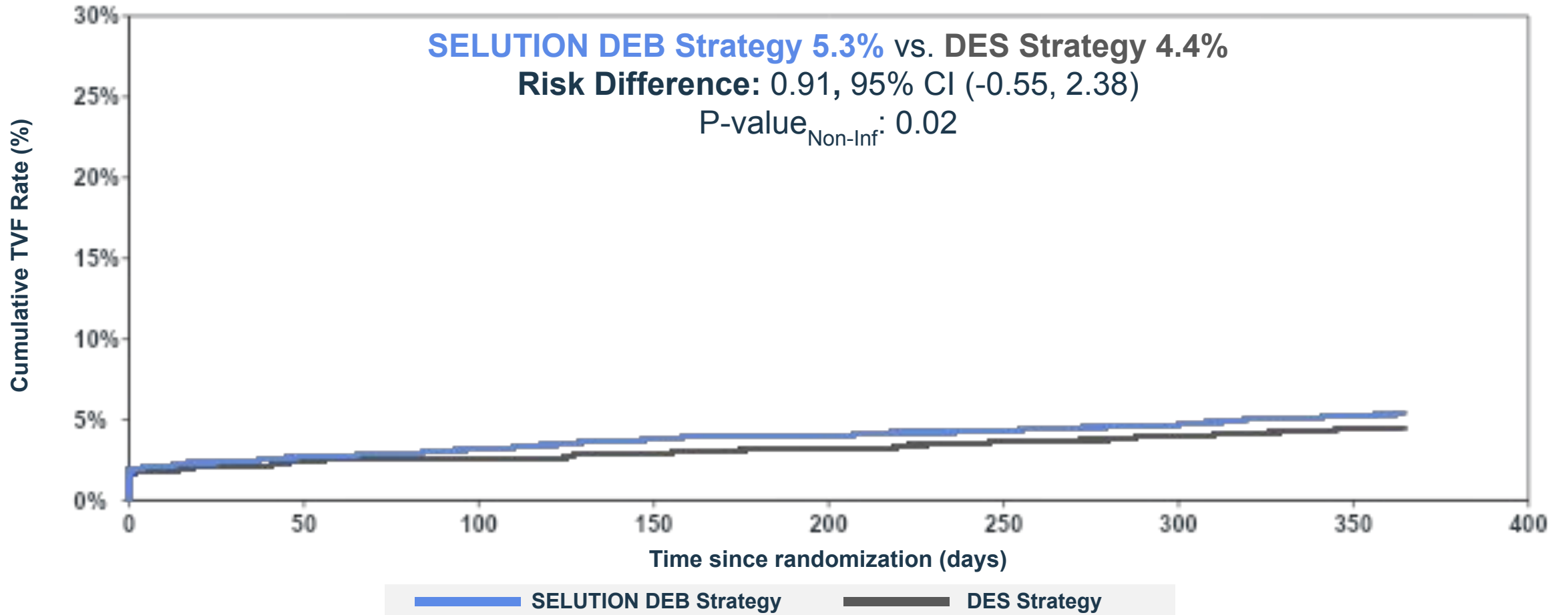
Christian Spaulding MD PhD, Simon Eccleshall MD,
Florian Krackhardt MD, Kris Bogaerts PhD, Philip Urban MD PhD,
for the SELUTION DeNovo Investigators



TCT[®]

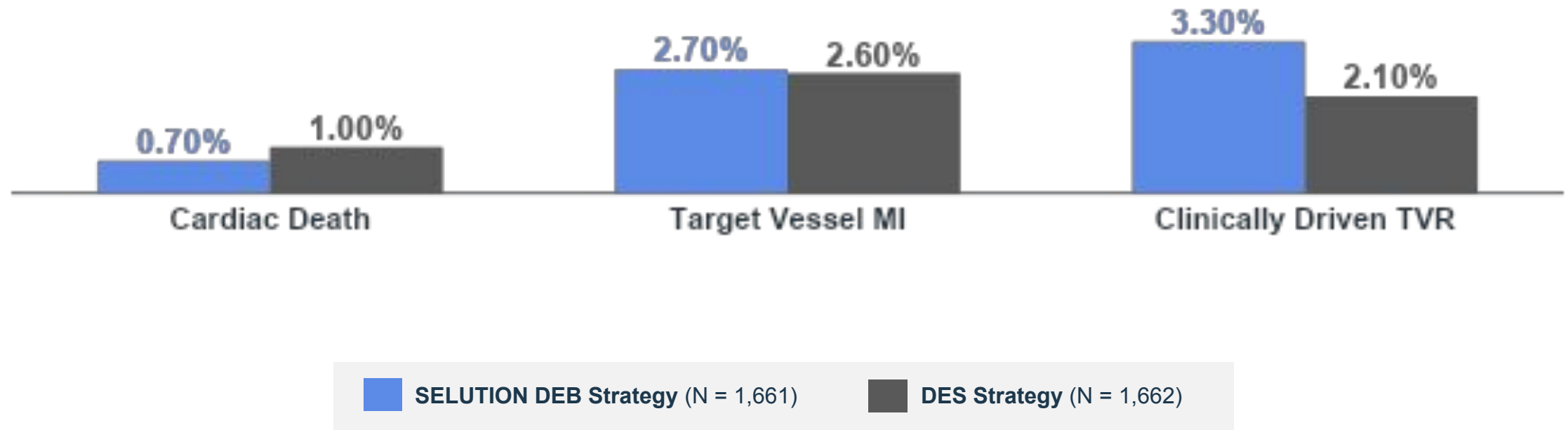
TRANSCATHETER
CARDIOVASCULAR
THERAPEUTICS[®]

Cumulative Incidence: TVF

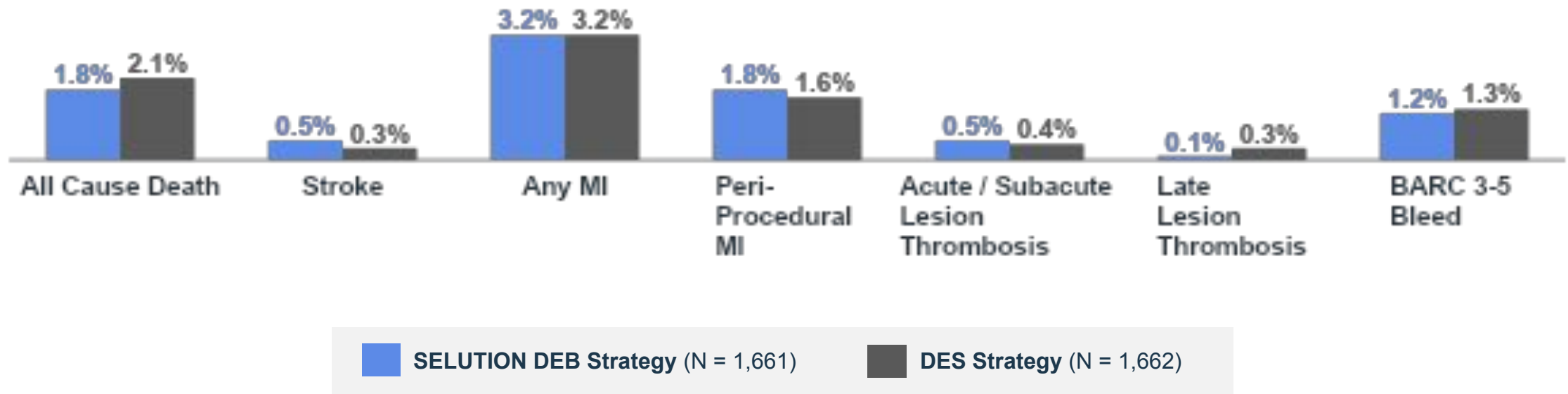


SELUTION DEB Strategy	1,661	1,595	1,571	1,550	1,527
DES Strategy	1,662	1,606	1,594	1,571	1,543

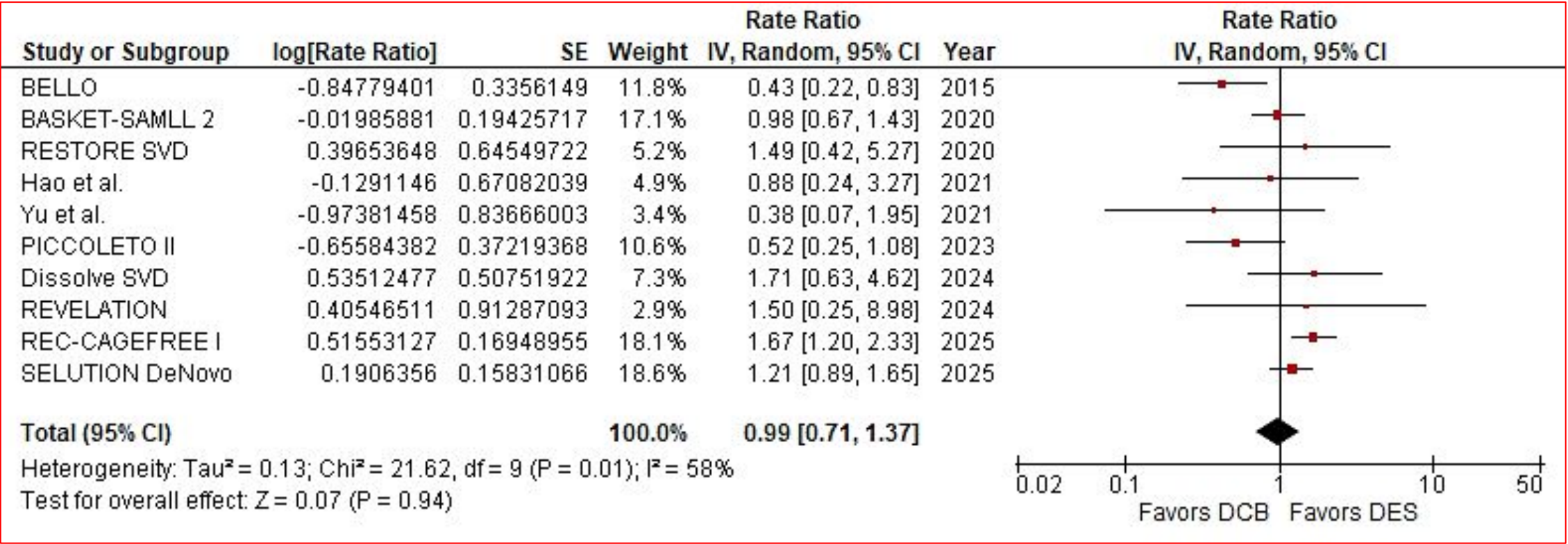
Components of Primary Endpoint (TVF)



Secondary Safety Endpoints



Updated meta-analysis of DCB vs DES in de novo lesions

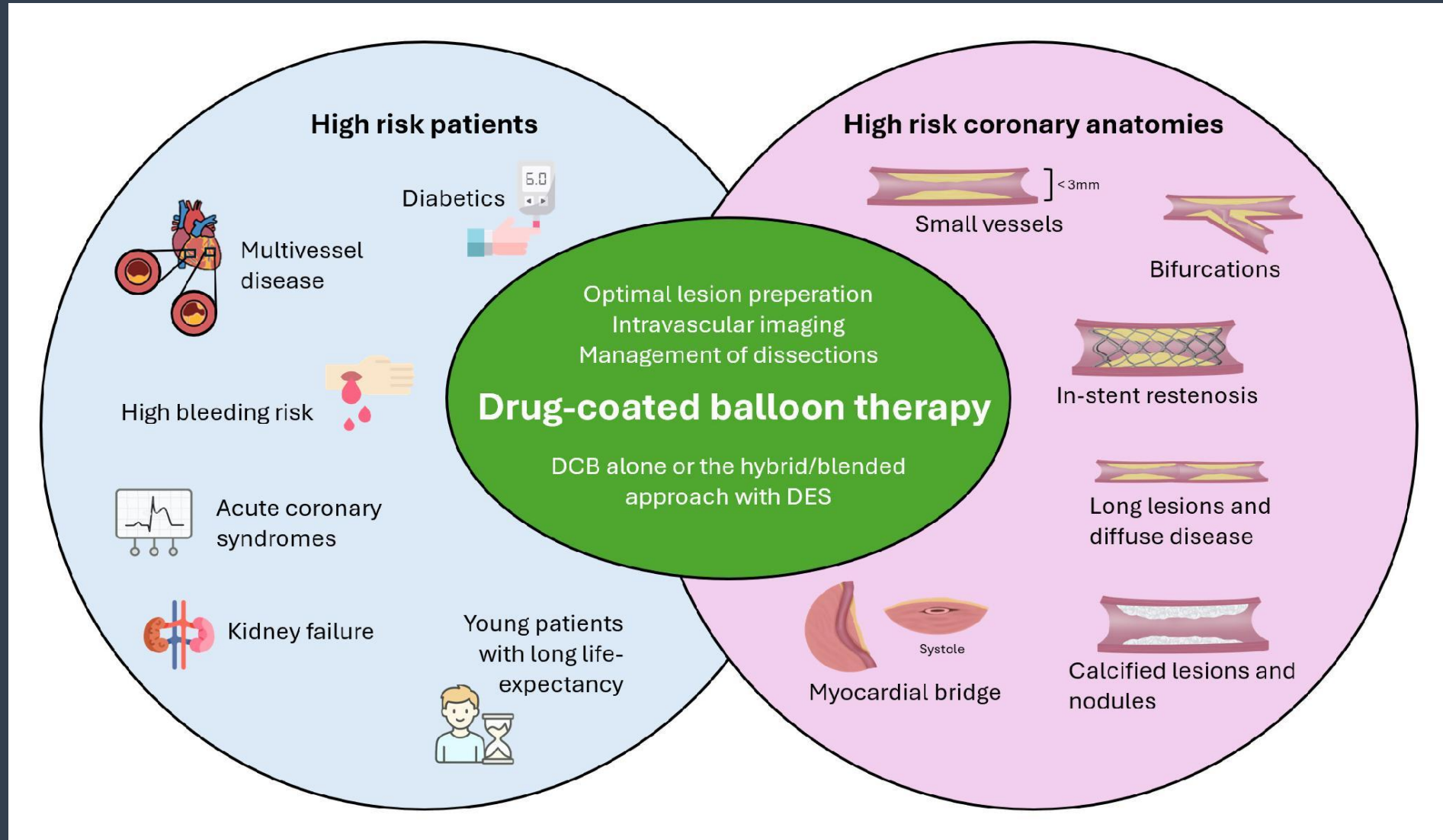


BELLO (2012, 2015)	MACE: Death, MI, TVR
BASKET-SMALL 2 (2018,2020)	MACE: Cardiac death, non-fatal MI, TVR
RESTORE SVD* (2018, 2020)	TLF: defined as cardiac death, target vessel myocardial infarction, or ischaemia driven target lesion revascularization.
REVELATION (2019, 2022, 2024)	MACE Definition: Cardiac death, non-fatal myocardial infarction, ischaemia driven target lesion revascularization
PICCOLETO II (2020, 2023)	MACE:Cardiac death, all MI, TVR
Hao et al. (2021)	MACE: cardiovascular death during follow-up, re-infarction or revascularization of target lesion
Yu et al (2021)	MACE: death, non-fatal MI, TLR, TVR
Dissolve SVD (2024)	TLF: cardiac death, target vessel myocardial infarction, or target lesion revascularization
REC-CAGEFREE I (2024, 2025)*	TLF: defined as cardiac death, target vessel myocardial infarction (TV-MI), and clinically indicated target lesion revascularization (CPI-TLR)
SELUTION DeNovo (2025)*	TVF: defined as cardiac death, target vessel related MI, or clinically driven TVR

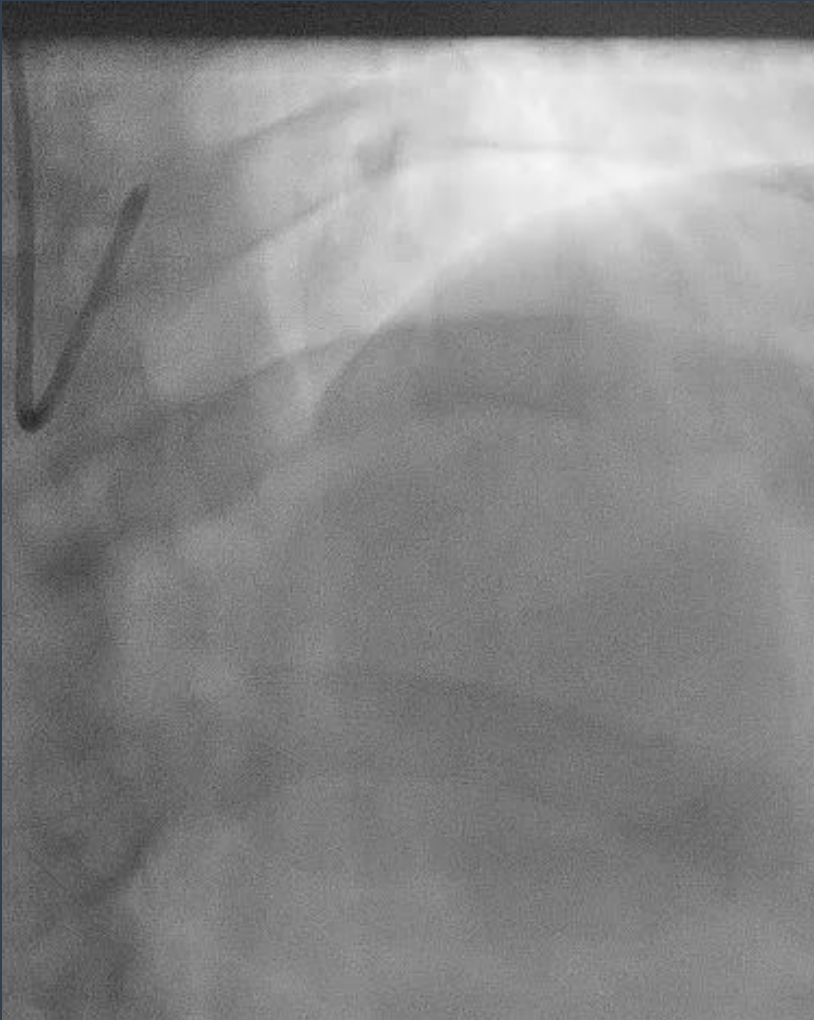


Byrne R
TCT 2025

The sweet spot of DCB is where DES performs suboptimally



Diffuse calcified LAD-D1-D2 Medina 1:1:1 and DCB-only in DM2 patient



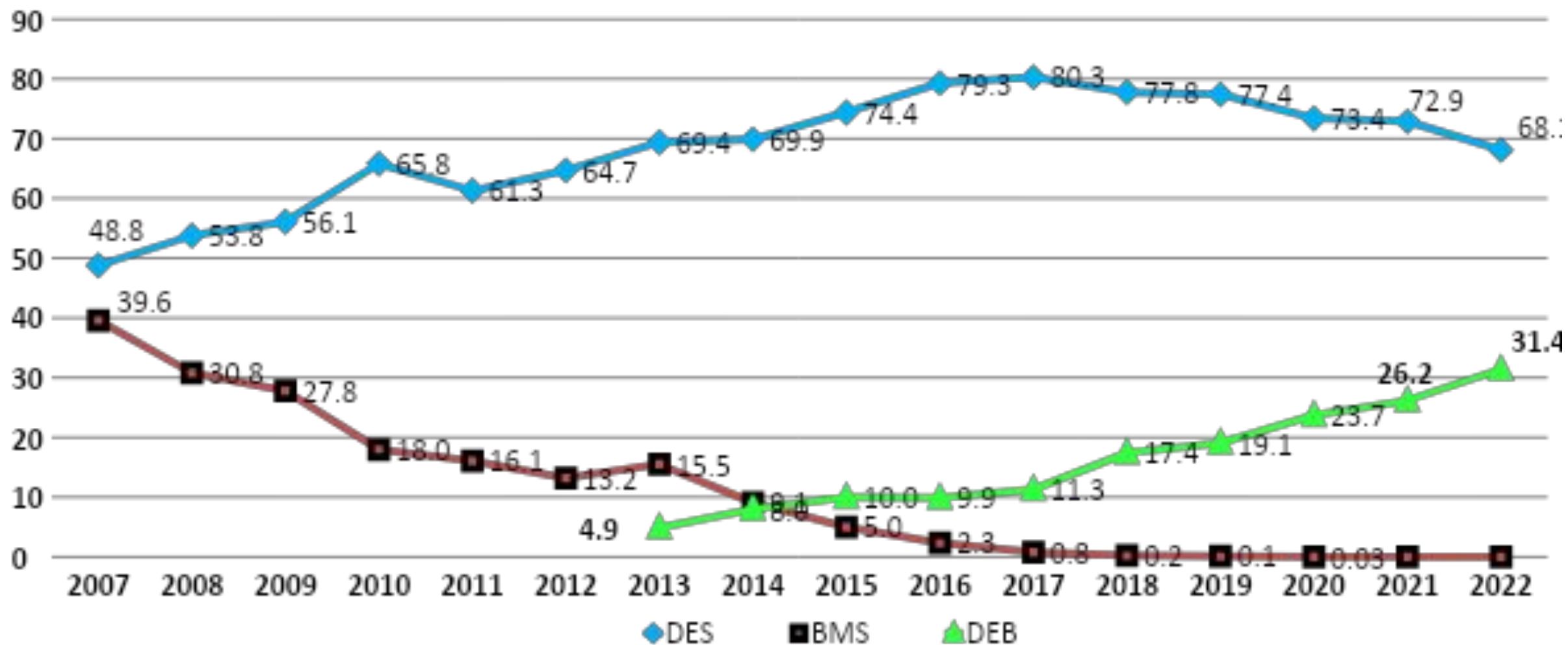
IVL 3.5mm, cutting, full paclitaxel (Agent) DCB in LAD, D1 and D2

3 months later
Asymptomatic

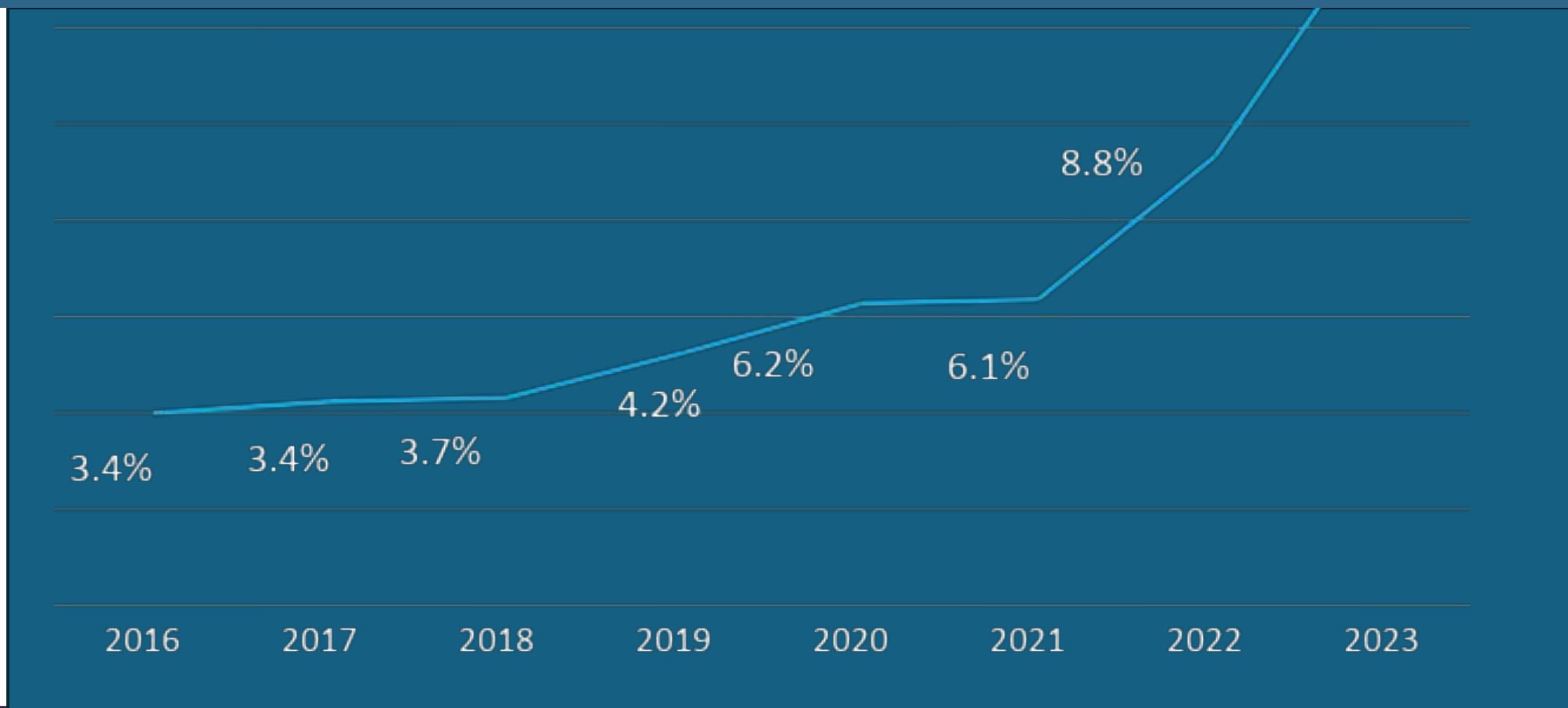


The use of DCB is growing

Types of devices used, Malaysian NCVD-PCI Registry, 2007-2022; (%)



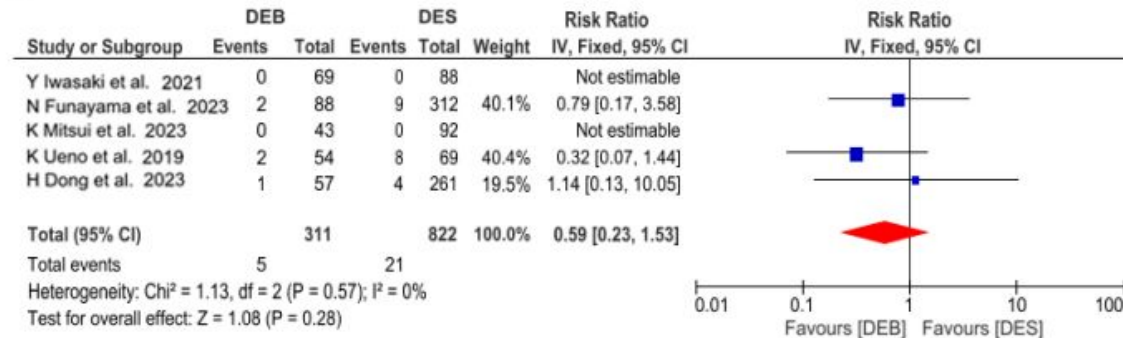
DCB use in CTO PCI in Europe



There are data, aren't there?

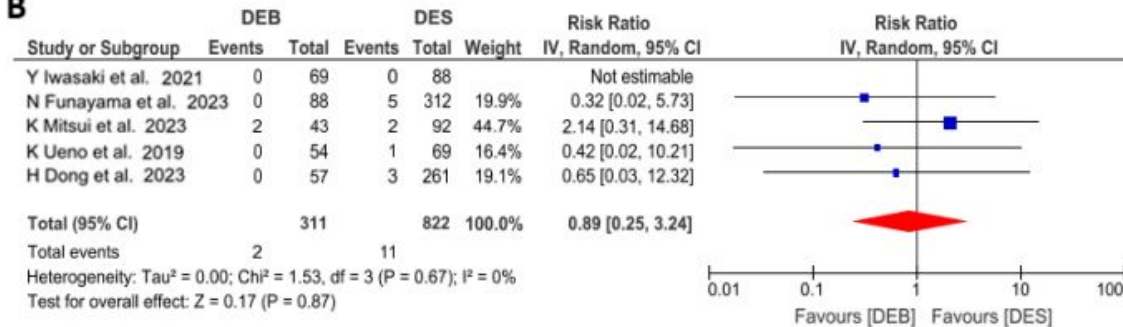
Meta-analysis DCB vs DES after rotational atherectomy

A



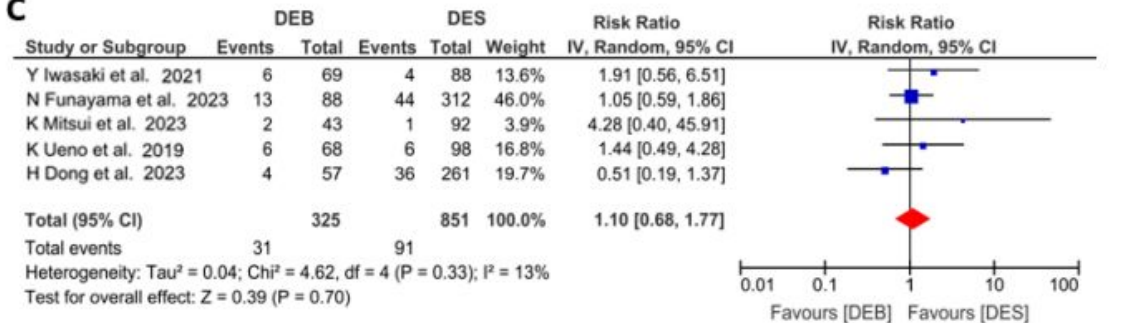
Cardiac death

B



Myocardial infarction

C



Target lesion revascularization



OPEN ACCESS

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Safety and feasibility of the treatment of calcified *de novo* coronary artery lesions with drug-coated balloon angioplasty after intravascular lithotripsy

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¹Heart Center, North Karelia Central Hospital, Joensuu, Finland, ²University of Eastern Finland, Joensuu, Finland

Results: There were no acute vessel closures or perioperative myocardial infarctions. During 12-month follow-up, the primary end point occurred in 15% ($n = 5$) of the patients, primarily driven by CV death (9%, $n = 3$) and one type-2 MI (3%). There was only one ischemia driven TLR within 12 months (3%). The rate of Bleeding Academic Research Consortium (BARC) 2–5 and BARC 3–5 bleeding events was 24% and 6% at twelve months, respectively.

At six months: TLR 3%, MI 3%, MACE 15%
N=34

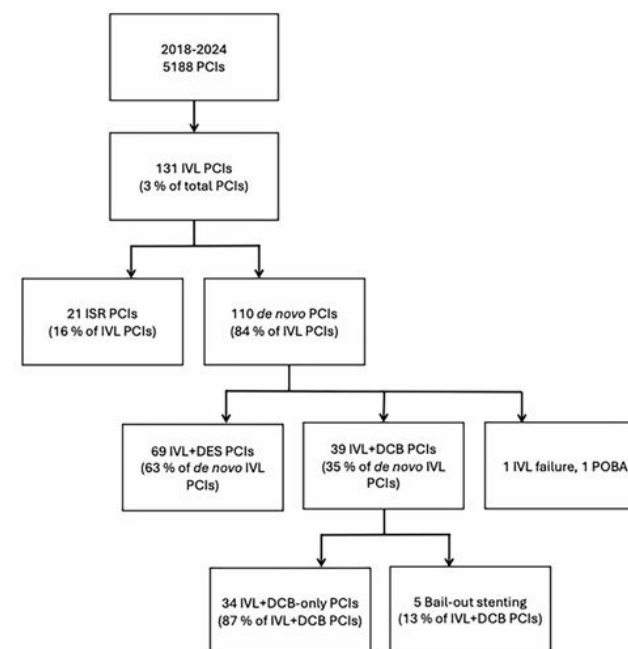
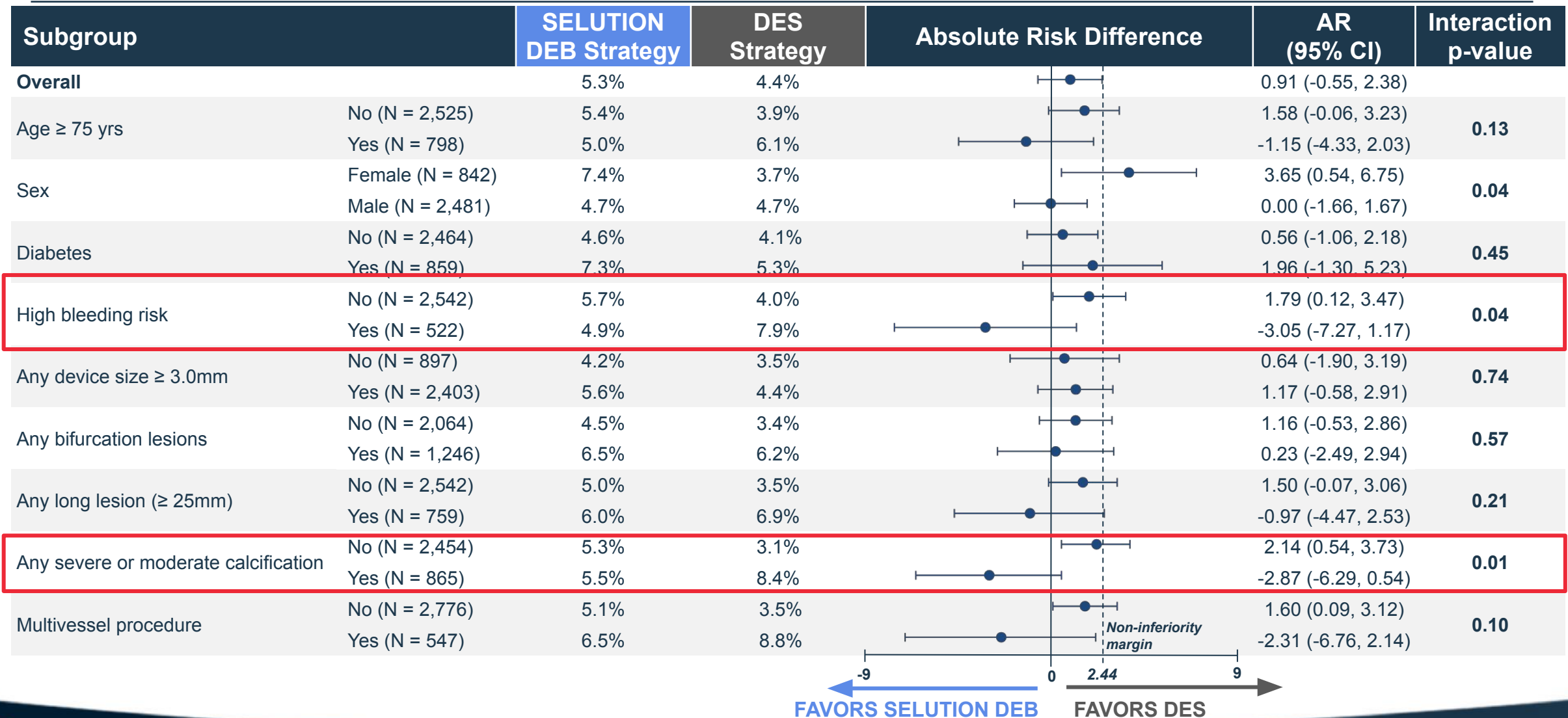


FIGURE 1
Flow chart of the study. PCI, percutaneous coronary intervention; IVL, intravascular lithotripsy; ISR, in-stent restenosis; DES, drug-eluting stent; DCB, drug-coated balloon; POBA, plain old balloon angioplasty.

Subgroup Analysis of Selution de novo trial





MARCH 07 - MARCH 10, 2026

WASHINGTON HILTON | WASHINGTON, DC

DCB-Only PCI for De-novo CTO: **Insights From The Multicentre International** **CTO-DENOVO Registry**

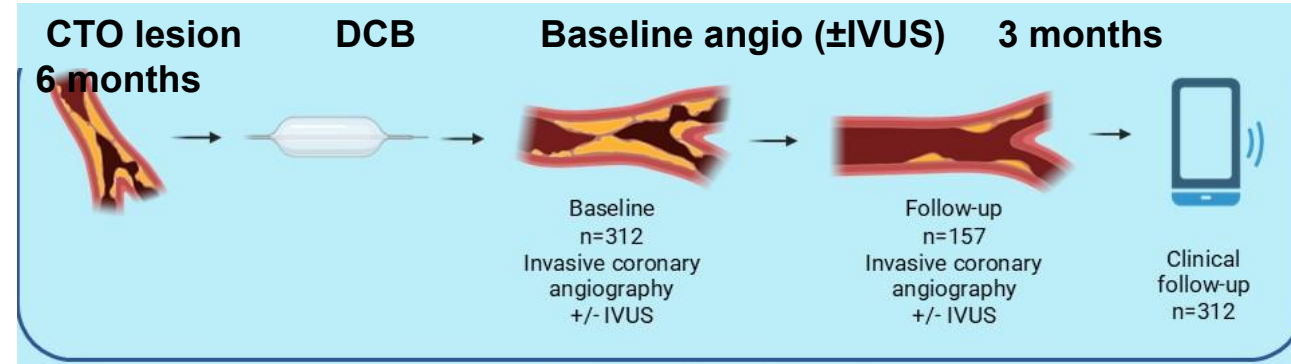
In press, The American Journal of Cardiology, 2026

Maksymilian P. Opolski, MD,¹ Magdalena M. Dobrolinska, MD,² Sina Porouchani, MD,^{3,4} Grzegorz Sobieszek, MD,⁵ Bartosz Zieba, MD,⁵ Felix J. Woitek, MD,⁶ Michal Kryjak, MD,⁷ Mihajlo Kovacic, MD,⁸ Umberto Barbero, MD,⁹ Zoltán Ruzsa, MD,^{10,11} Kornél Kákonyi, MD,¹⁰ Ilya Litovchik, MD,¹² Jakub Drozd, MD,¹³ David Neves, MD,¹⁴ Ignacio Amat-Santos, MD,^{15,16} Mihnea T. Nichita-Brendea, MD,¹⁷ Claudiu Ungureanu, MD,¹⁸ Sylwia Iwanczyk, MD,¹⁹ Vojtěch Novotný, MD,²⁰ Alexander Geppert, MD,²¹ Paul Felix Harbich, MD,²¹ Sanghoon Shin, MD,²² Mauro Gitto, MD,^{23,24} Gabriele Gasparini, MD,²³ Stefan Harb, MD,²⁵ Michele Cacia, MD,²⁶ Wojciech Zimoch, MD,^{27,28} Mihai Cocoi, MD,²⁹ Daniel Rzeznik, MD,³⁰ Paweł Kleczynski, MD,^{30,31} Roman Stipal, MD,³² Rocco Giunta, MD,³³ Mateusz Tajstra, MD,³⁴ Lukasz Pyka, MD,³⁴ Leszek Bryniarski, MD,^{35,36} Pavol Tomasov, MD,³⁷ Piotr Wanczura, MD,^{38,39} Wojciech Stecko, MD,³⁸ Sławomir Golebiewski, MD,⁴⁰ Piotr Pawluczuk, MD,⁴¹ Grzegorz Horszczaruk, MD,^{42,43} Marin Postu, MD,⁴⁴ Tibor Szük, MD,⁴⁵ Rostislav Prog, MD,⁴⁶ Olli-Pekka Piira, MD,⁴⁷ Paweł Radecki, MD,⁴⁸ Marcin Makowski, MD,⁴⁹ Szymon Glodala, MD,⁵⁰ Marek Jankiewicz, MD,⁵¹ Bilal Iqbal, MD,⁵² Tuomas T. Rissanen, MD,^{53,54}



DENOVO-CTO Study Design

- Retrospective international multicentre registry study
- 42 sites (40 in Europe, 1 in Korea and 1 in Canada)
- 309 consecutive patients with successful CTO PCI using DCB-only strategy in *de novo* coronary artery disease
- Exclusion criteria:
 - In-stent CTO
 - *De novo* CTO lesion treated with DES at the occlusion site
- Follow-up: Clinical FU at 6 months and subgroup of control angio at 3 months



Primary and secondary outcomes

- **Primary outcome:**

- 6-month Target Lesion Failure (cardiac death, TV-MI, clinically-driven TLR)

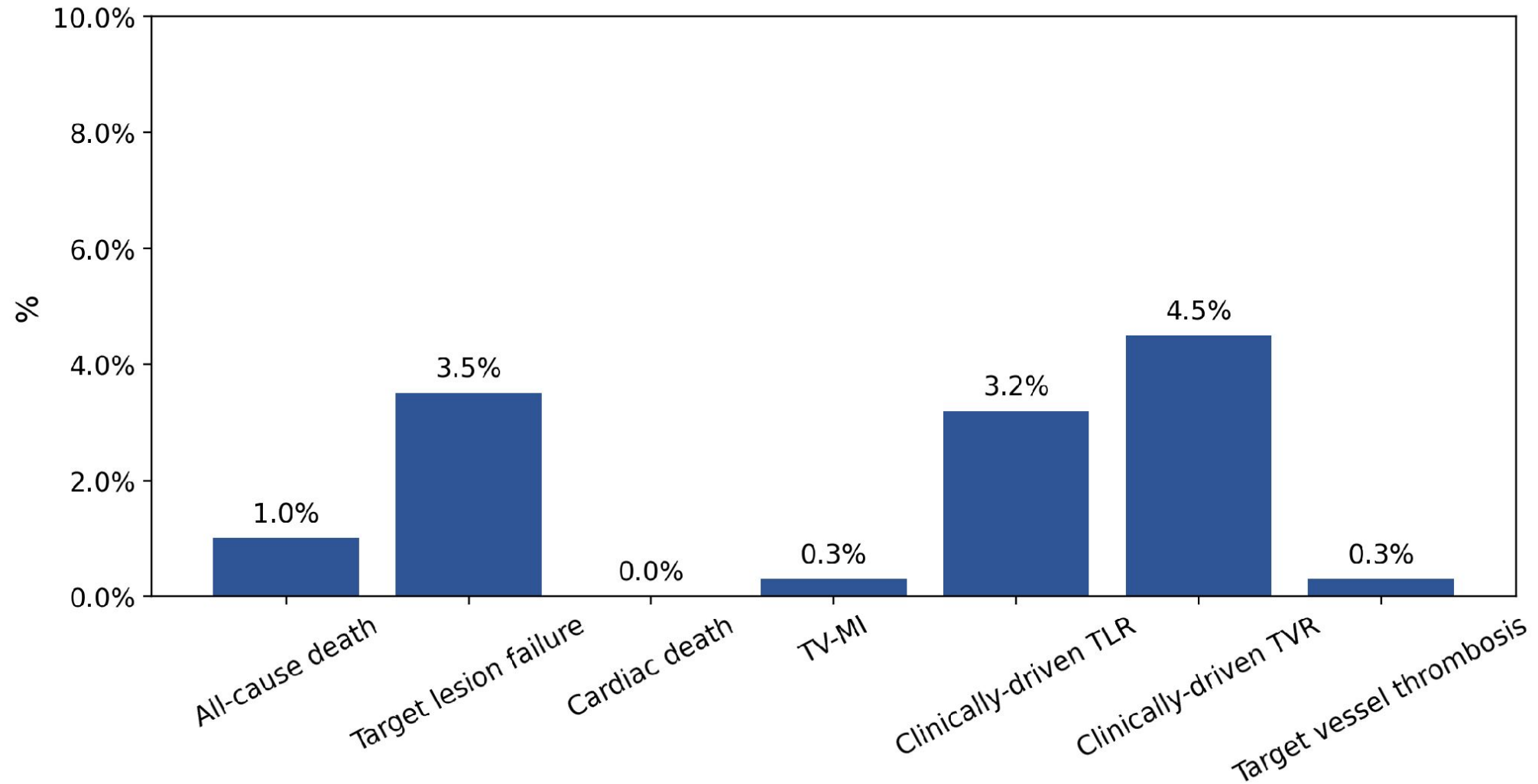
- **Secondary outcomes at 3 months control angio:**

- QCA (LLL, binary restenosis, re-occlusion) and
- IVUS metrics (MLA, plaque burden, remodelling)

Angio & Procedural Characteristics

- Target vessel: LAD 38%, RCA 36%, LCX 26%
- J-CTO 1.5±1.1 (intermediate)
- CTO lesion crossing:
 - **Antegrade/retrograde wiring 93%**
 - ADR/RDR 7%
- IVUS used in 32%
- Lesion modification:
 - NC 77%
 - Cutting/scoring 18%
 - Atherectomy 4%
- Paclitaxel-coated balloon 92%, sirolimus-coated balloon 8%
- DCB diameter 2.7±0.4 mm and length 29.7±7.7 mm
- Any angiographic dissection: 53%
- Device success 82%

Clinical Outcomes at 6 months

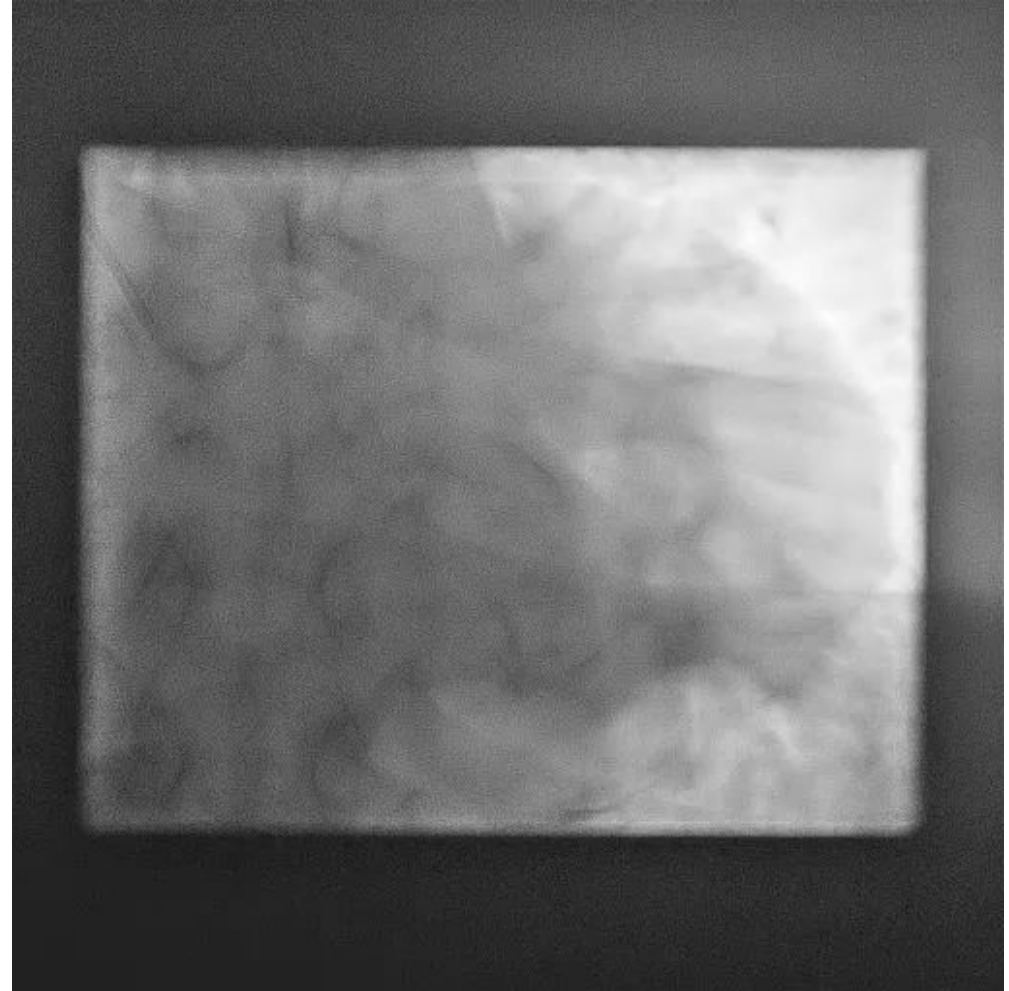
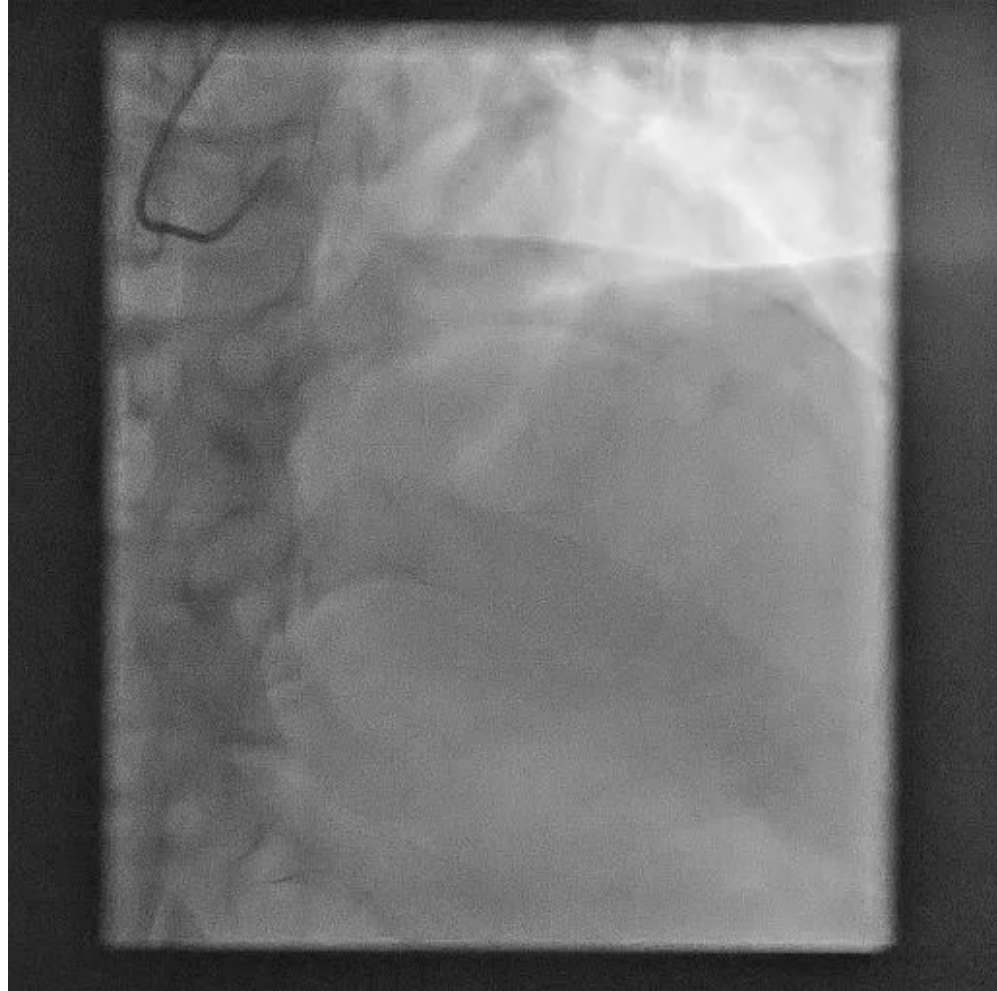


Conclusions

- The treatment of CTO with a DCB-only approach is safe with a very low number of TV-MI (0.3%) or vessel thrombosis (0.3%)
- 91% were antegrade wiring cases
- Clinical TLF at 6-month follow-up was low (3.5%)
- In selected population with angiographic follow-up, binary restenosis was 24%
 - Control angios led to repeat PCI in 14% of cases
 - Bias: control angios done at the discretion of the operator (e.g. suboptimal initial result)
- RCT comparing DCB vs DES in CTO PCI (after intraplaque wiring) is warranted preferably the net-clinical outcome as the primary endpoint

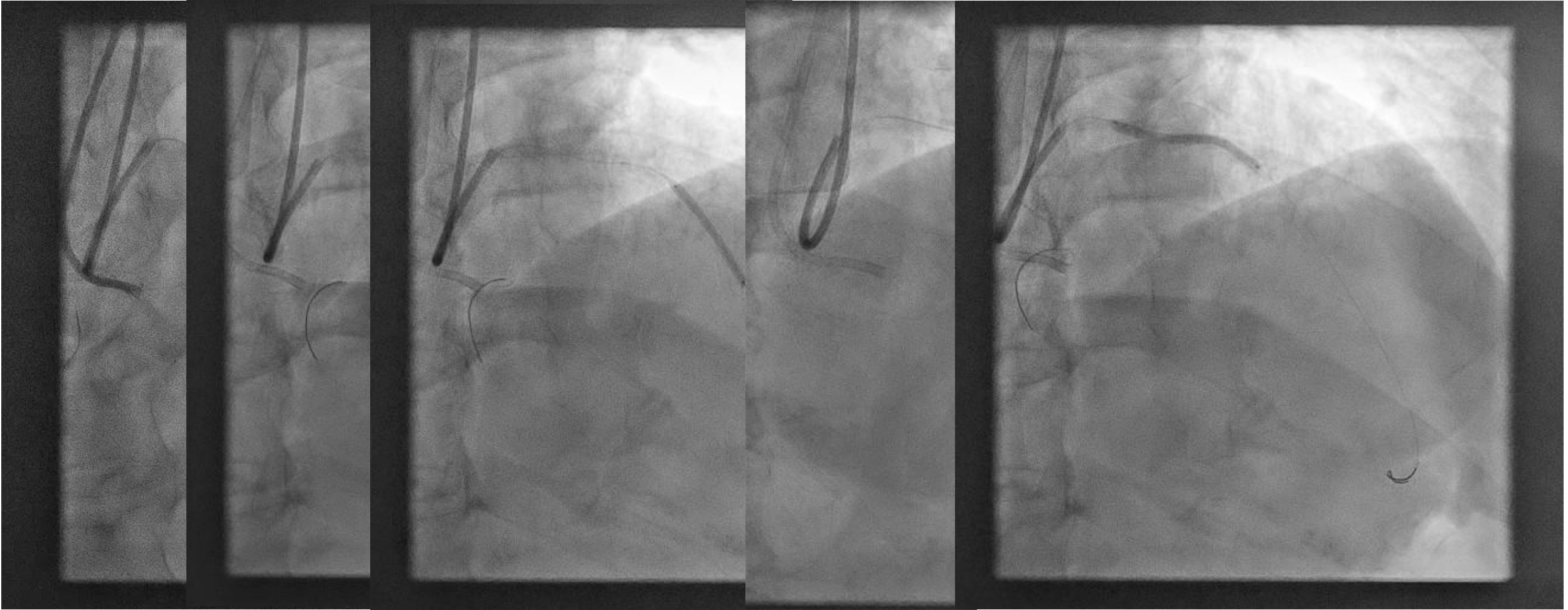
63yr male, DM2, smoker, EF 40%, CCS2

HBR: OAC, previous ulcer perforation



63yr male, DM2, smoker, EF 40%, CCS2

HBR: OAC, previous ulcer perforation

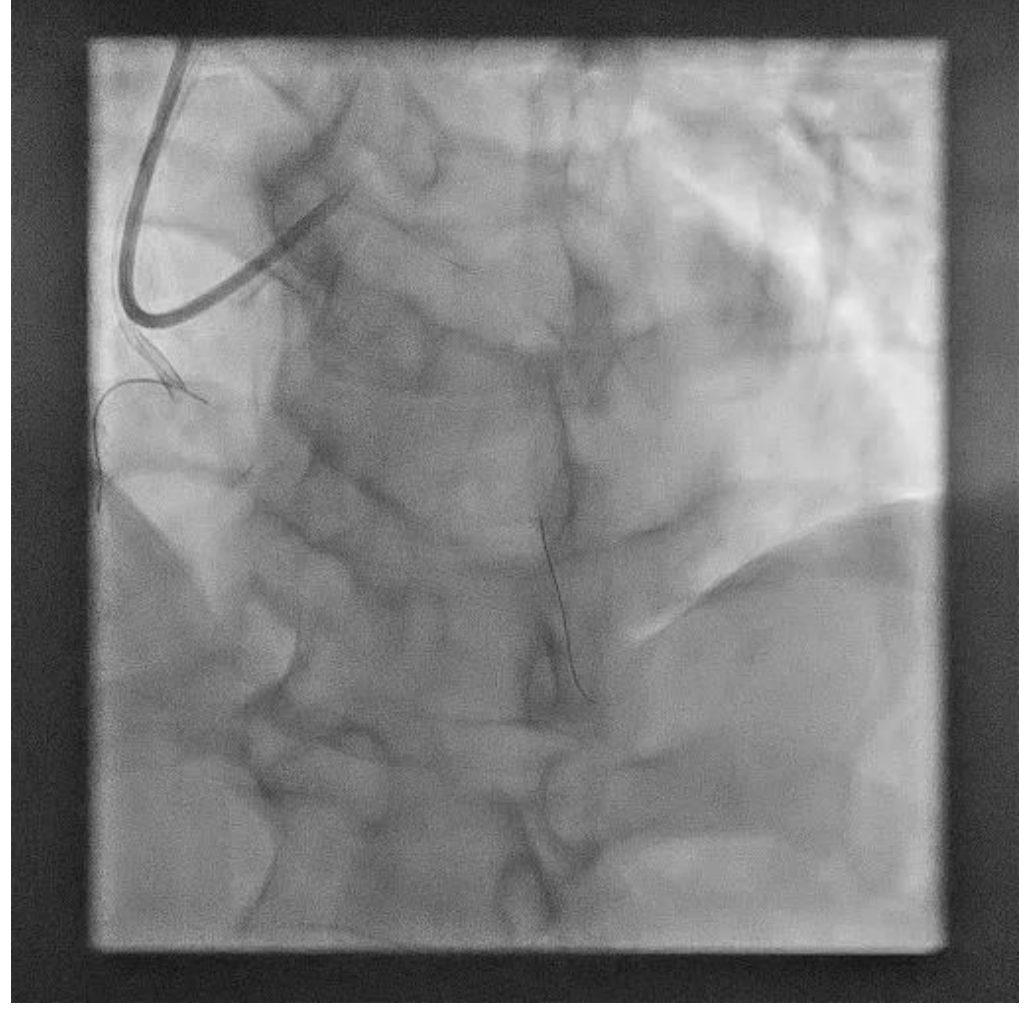
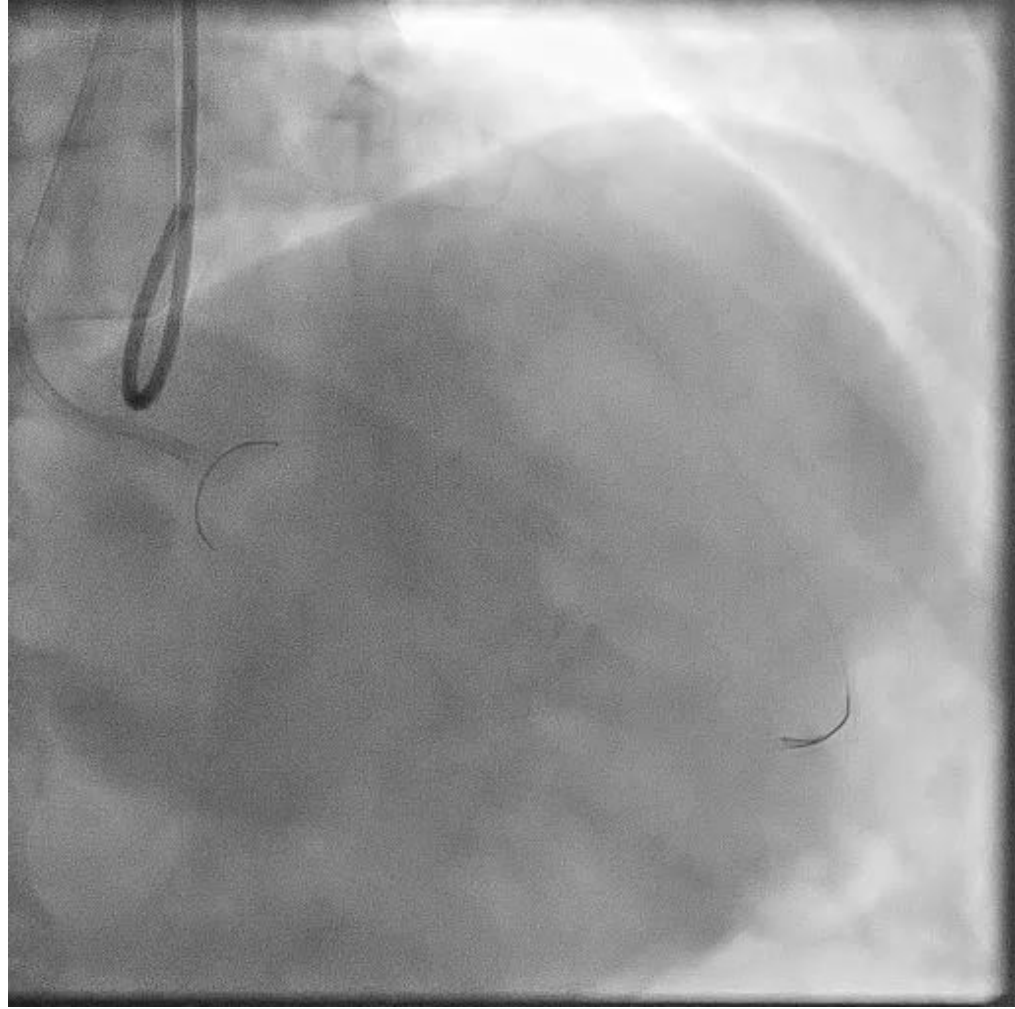


AW
E

DCBs after careful lesion prep using scoring and NC balloons
1:1

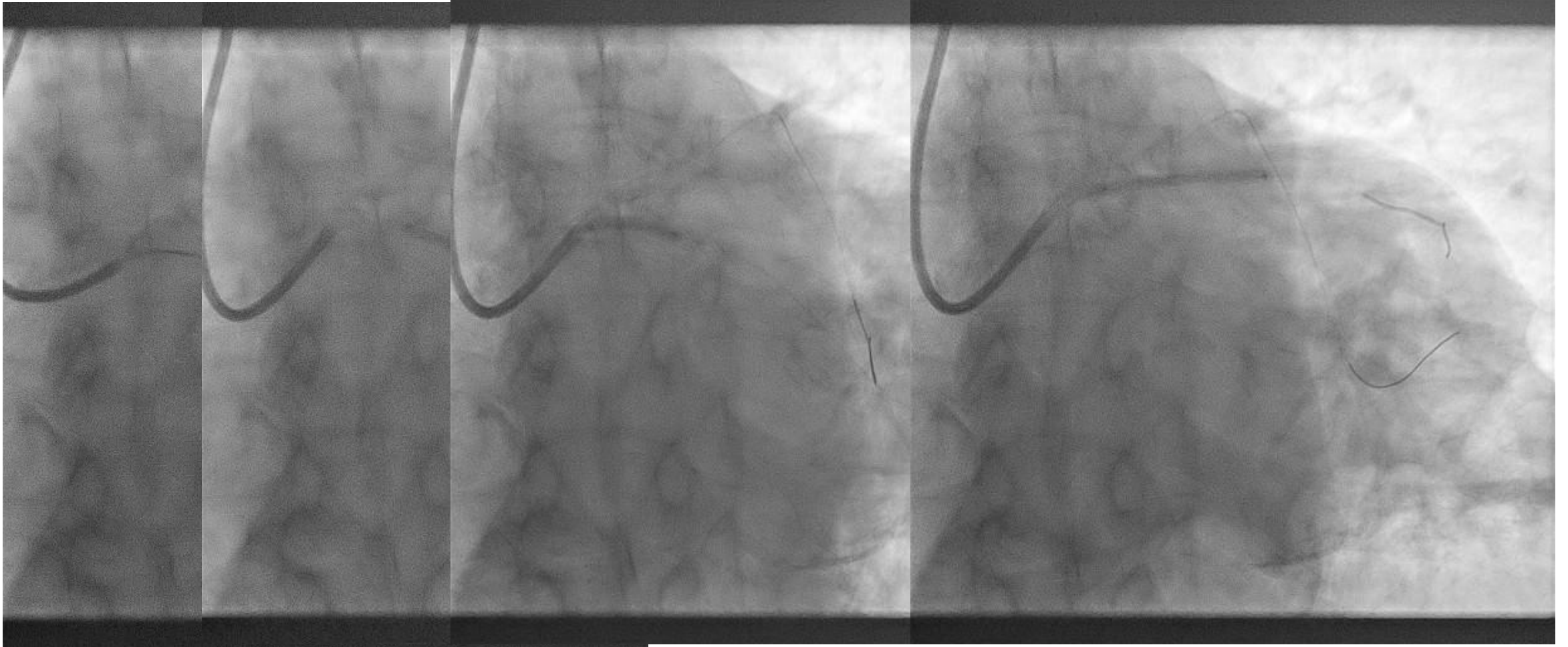
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AW
E

DCBs after careful lesion prep using cutting and NC balloons
1:1

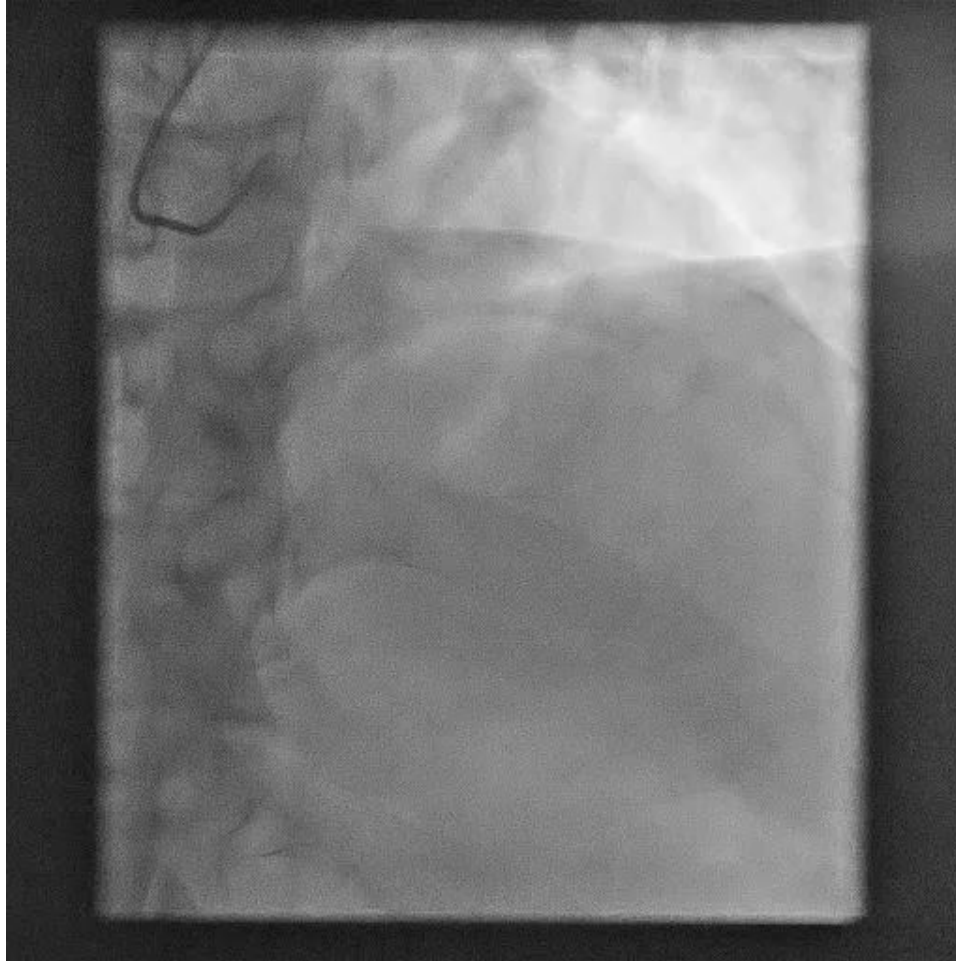
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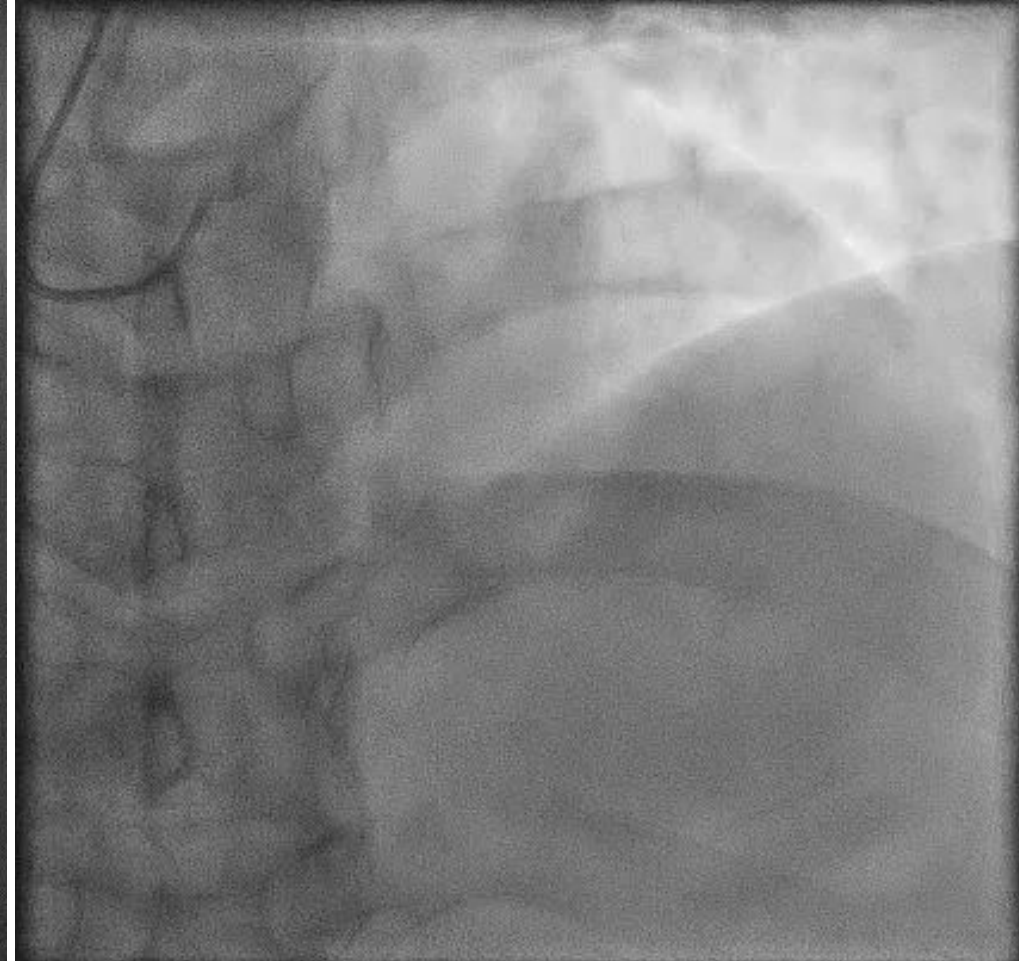


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Before

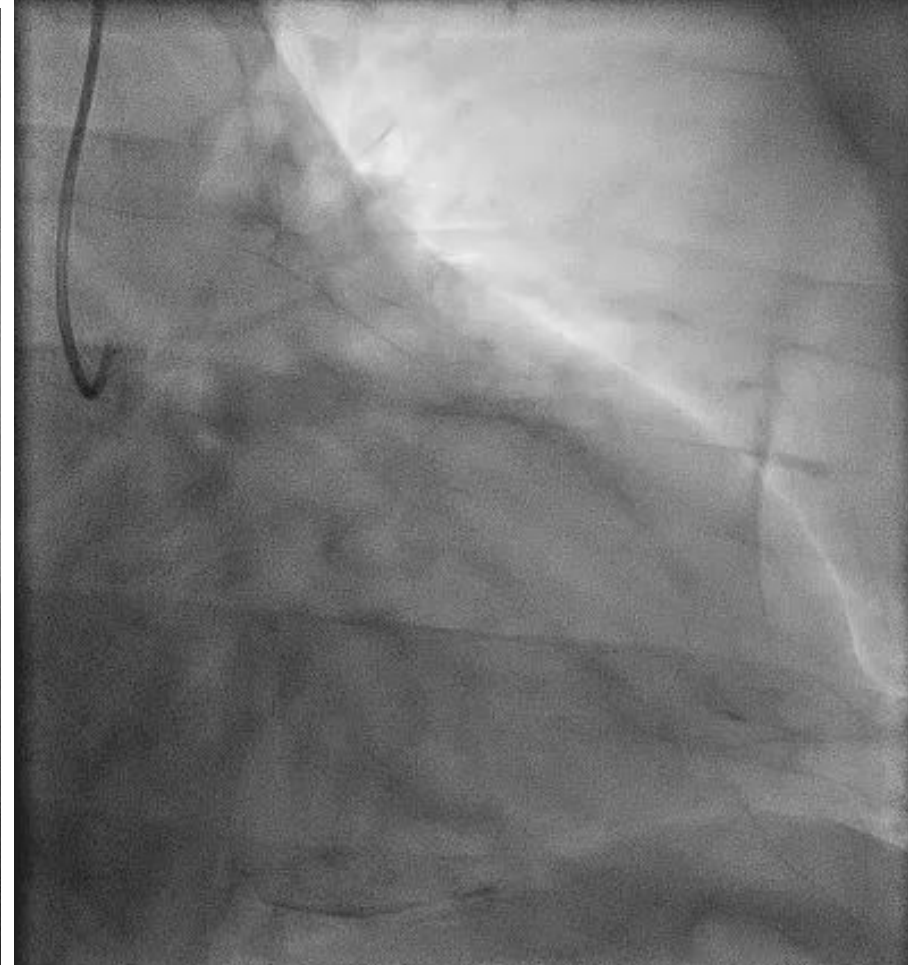


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HBR: OAC, previous ulcer perforation

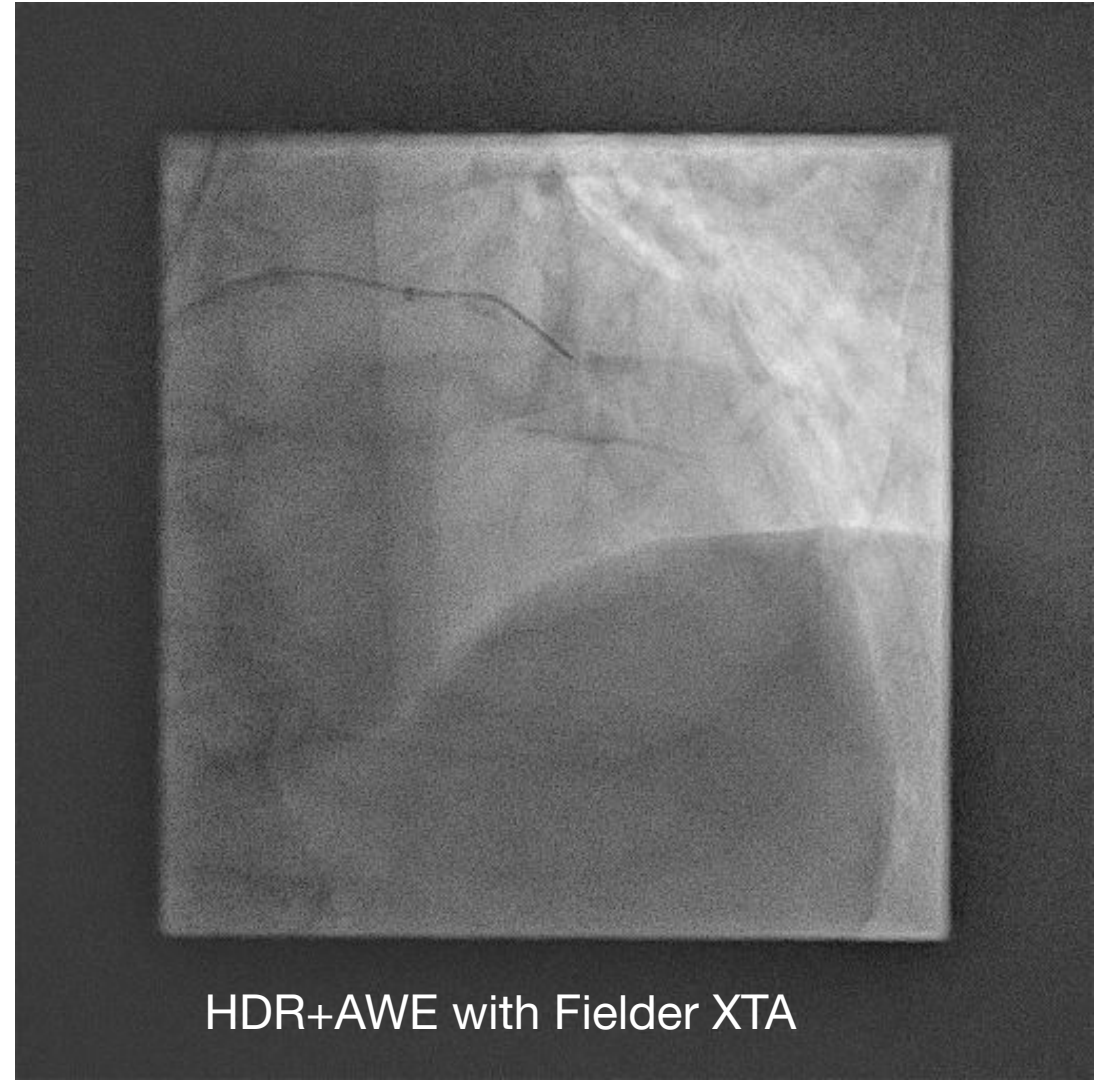
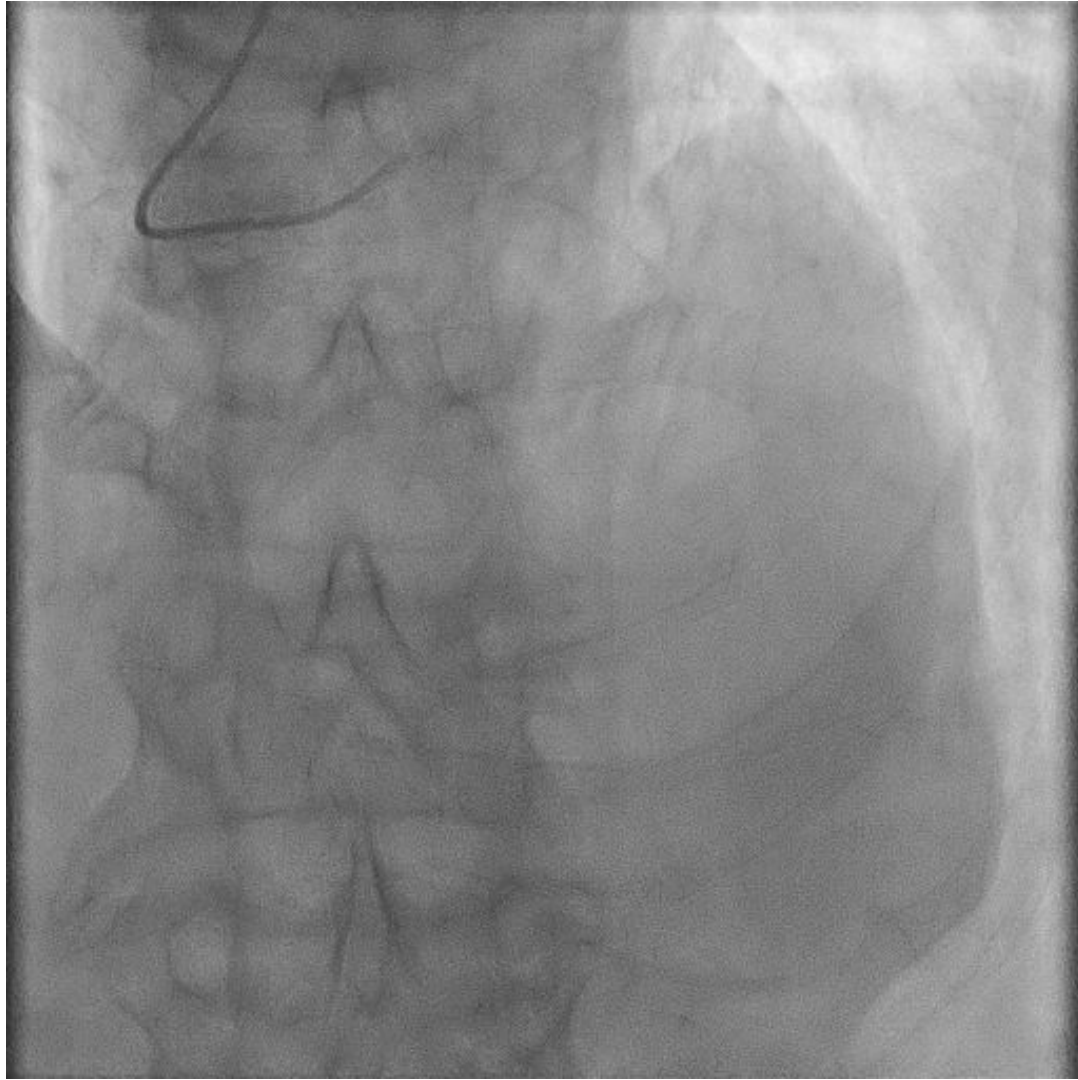


Before

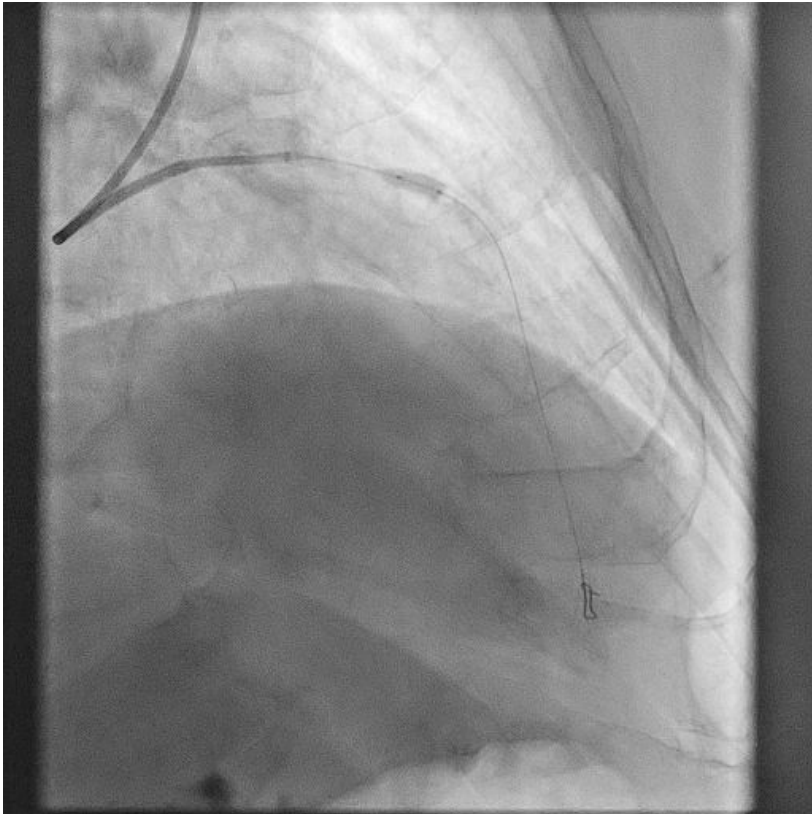


3 months control angio after "leaving nothing behind"

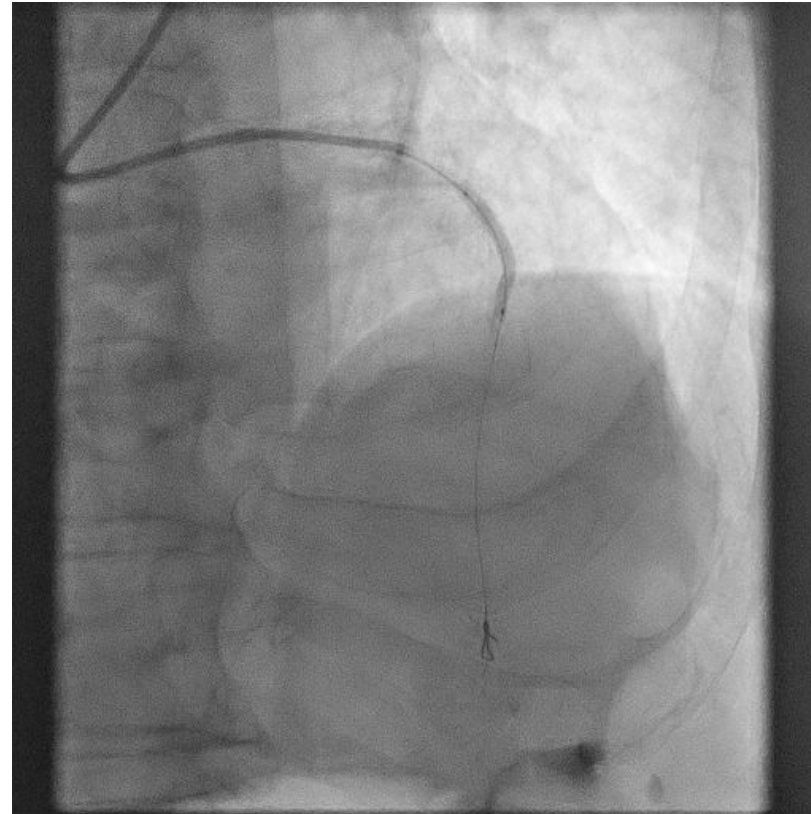
DCB+DES hybrid PCI in CTO



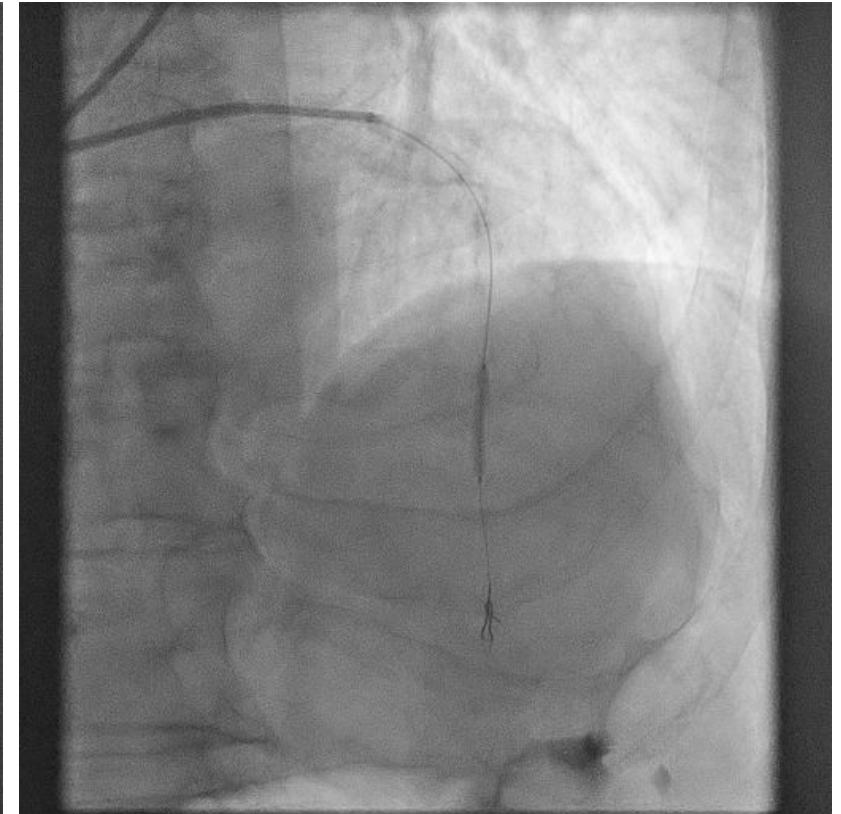
DCB+DES hybrid PCI in CTO



DES 3.5 x 8 mm
proximal to bifurcation
due to recoil > 30%



DCB 3.0 x 30 mm
to avoid complex
bifurcation PCI



DCB 2.5 x 20 mm
for distal small vessel
disease

DCB+DES hybrid PCI in CTO



Final

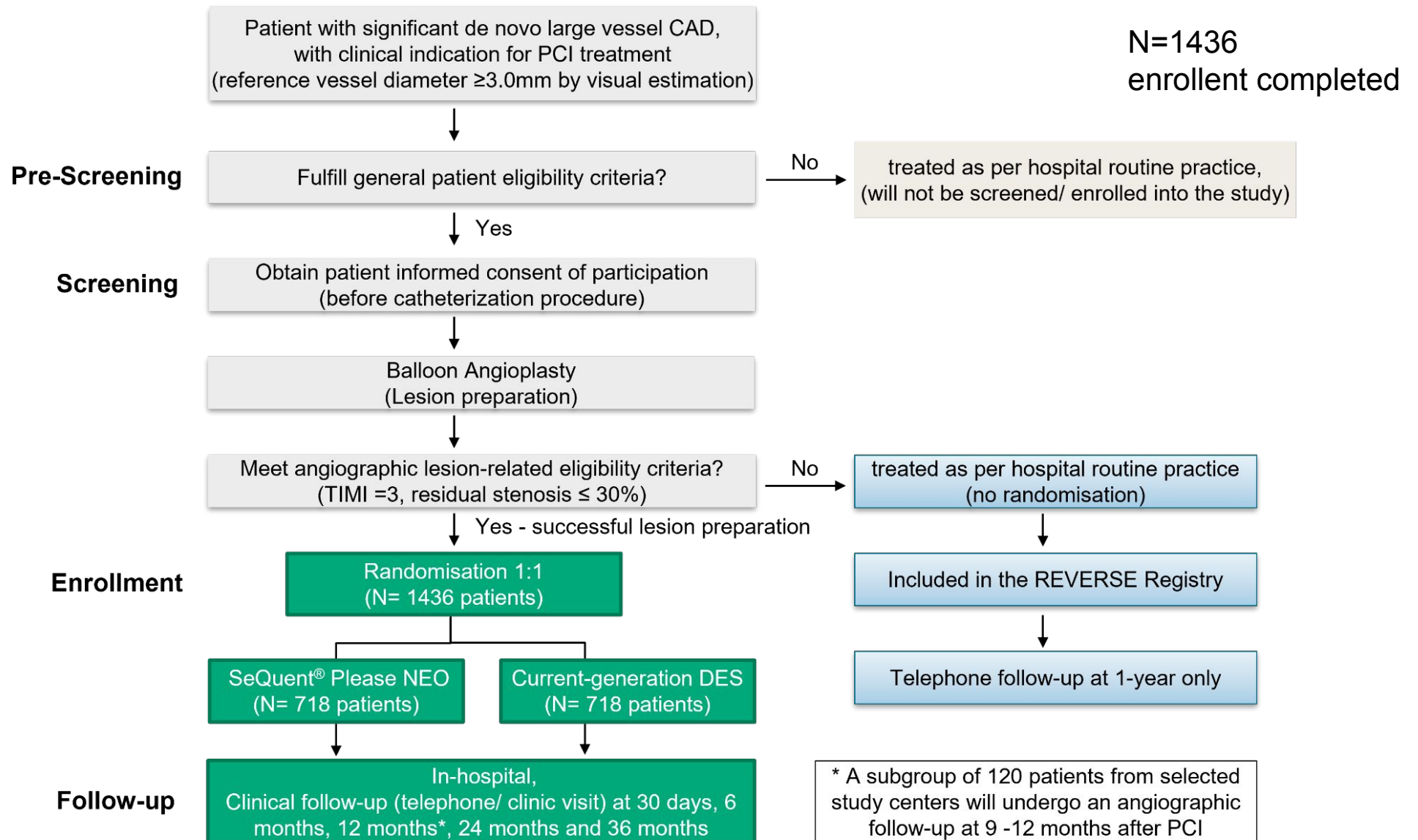
Overall DES length 8 mm

TIMI3 flow

Diagonal open

We need RCTs!

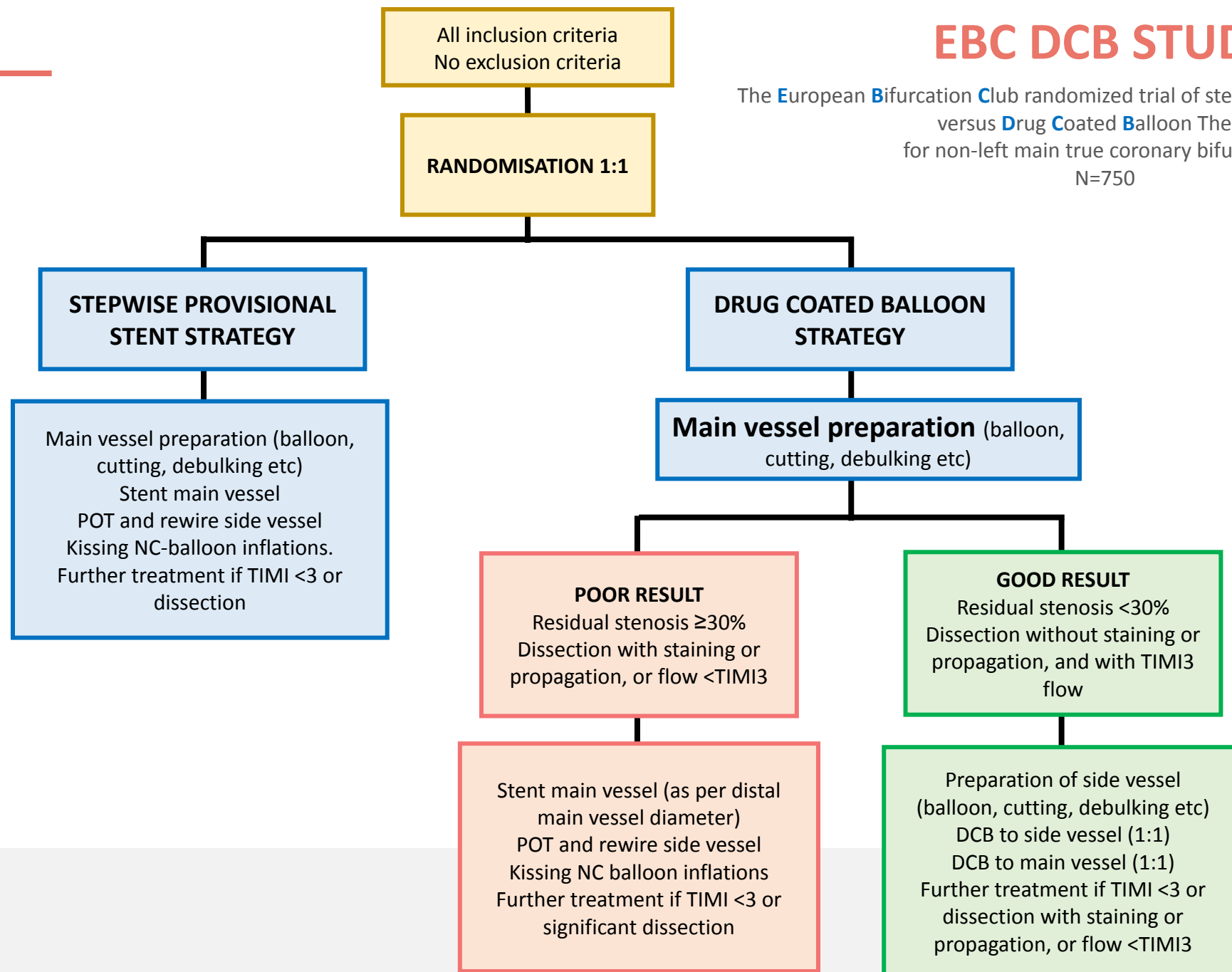
REVERSE trial of DCB for large vessel disease



The primary endpoint of **net adverse clinical event (NACE) 12 months:** a composite of all-cause death, non-fatal myocardial infarction, clinically driven target vessel revascularization, or major bleeding (BARC type 3 to 5).

EBC DCB STUDY

The European Bifurcation Club randomized trial of stepwise provisional stenting versus Drug Coated Balloon Therapy for non-left main true coronary bifurcations
N=750



Stents versus PAclitaxel Coated Balloons for Revascularization of Complex and Small Coronary Vessels (SPARX) Trial

The first patient
randomized
on 22nd April!

Main inclusion criteria

- Small vessel
- Long lesion
- Calcified lesion
- Bifurcation
- CTO
- ISR
- ...

Main exclusion criteria

- STEMI, CS
- Left main
- Suboptimal lesion preparation (DS $\geq$ 30%, TIMI $<$ 3, flow limiting dissection)
- ...

Patient oriented composite endpoint (POCE) within 2 years.

- All-cause death
- Any Stroke
- All new MI (TV and non-TV related)
- Ischemia-driven repeat revascularization

1

:

1

:

1

Protégé DCB

Agent DCB (FDA)

DES

at least noninferiority

noninferiority

FU 2 yrs

BASKET-B-ALL



Patient Population n = 2184

Inclusion Criteria:

Coronary Artery Disease with Indication for PCI and

High Clinical Risk (Diabetes, ≥ 75 Years, $\text{eGFR} < 60 \text{ ml/min/1.73m}^2$, ACS, HBR) or

High Anatomical Risk (Multivessel, True Bifurcation, Long Lesions, Calcium Modification)

Sequent Please SCB®

R
1 : 1

Current DES

Clinical Follow-up at 30 Days and 1, 2 and 3 Years

Primary Endpoints:

Composite endpoint of target-vessel failure (TVF) and bleeding BARC 3-5 at 12 and 36 months

Specifics:

- Randomized, multicenter, international, open-label non-inferiority trial
- Up to 60 centers in up to 15 countries
- Strategy trial of sirolimus-coated balloon vs. conventional DES in high-risk de-novo lesions
- Primary endpoint "net clinical benefit" (ischemic + bleeding)
- Angiographic follow-up in 6% of patients

Principal Investigator: Raban Jeger, Switzerland

Sponsor: B. Braun Melsungen AG, Germany

Study Management & Core Laboratory: CERC (Cardiovascular European Research Center), France

The DEBATE trial for DCB in HBR

Patients with stable **CAD** or **ACS** with *de novo* lesion(s) in native coronary arteries or bypass grafts
AND high bleeding risk (ARC criteria)

Exclusion criteria:
ISR, CTO, STEMI,
unsuccessful
predilation

Predilation 1:1 (SC, NC, cutting, scoring, rota, IVL etc.)

Recoil $\geq 30\%$ or TIMI flow < 3

Yes

Excluded (DES)

No

Paclitaxel-coated DCB (SeQuent Please Neo)
n=250

Stable CAD:
SAPT-only
(OAC: periop. SAPT)

ACS:
1 month DAPT
(OAC: 1 mo SAPT)

DES (Any with CE mark for 1 mo DAPT)
n=250

Stable CAD:
1 month DAPT
(OAC: 6 mo SAPT)

ACS:
3 months DAPT
(OAC: 6 mo SAPT)

Non-inferiority in the **net clinical outcome**:
MACE (CV death, nonfatal-MI and ischemia driven-TVR) AND **BARC 2-5** bleeding at 12 months

PI: Tuomas Rissanen, Finland. Study centers from Finland, France, Spain and Australia pending

Conclusions

- There are good evidence of **DCB-use** in some complex subsets:
 - Small vessels and diffuse disease
 - Bifurcations (especially in SB)
 - High-bleeding risk patients
 - ISR
- **DCB-only or the hybrid DES+DCB approach to** reduce stent burden in complex PCI appears rational and is supported by observational data
- **RCTs are ongoing** in complex patients and complex anatomies
- Data is needed on the use of **intravascular imaging in DCB PCI**
- DCB and DES are not competing but **complimentary tools in the cathlab**

Application of Drug-Coated Balloons in Complex High Risk and Indicated Percutaneous Coronary Interventions

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Keywords: advanced coronary artery disease | complex high risk PCI | drug-coated balloon | percutaneous coronary intervention

ABSTRACT

There is a growing trend of patients with significant comorbidities among those referred for percutaneous coronary intervention (PCI). Consequently, the number of patients undergoing complex high risk indicated PCI (CHIP) is rising. CHIP patients frequently present with factors predisposing to extensive drug-eluting stent (DES) implantation, such as bifurcation and/or heavily calcified coronary lesions, which exposes them to the risks associated with an increased stent burden. The drug-coated balloon (DCB) may overcome some of the limitations of DES, either through a hybrid strategy (DCB and DES combined) or as a leave-nothing-behind strategy (DCB-only). As such, there is a growing interest in extending the application of DCB to the CHIP population. The present review provides an outline of the available evidence on DCB use in CHIP patients, which comprise the elderly, comorbid, and patients with complex coronary anatomy. Although the majority of available data are observational, most studies support a lower threshold for the use of DCBs, particularly when multiple CHIP factors coexist within a single patient. In patients with comorbidities which predispose to bleeding events (such as increasing age, diabetes mellitus, and hemodialysis) DCBs may encourage shorter dual antiplatelet therapy duration—although randomized trials are currently lacking. Further, DCBs may simplify PCI in bifurcation lesions and chronic total coronary occlusions by reducing total stent length, and allow for late lumen enlargement when used in a hybrid fashion. In conclusion, DCBs pose a viable therapeutic option in CHIP patients, either as a complement to DES or as stand-alone therapy in selected cases.