Sirolimus Eluting Balloons in **Complex PCI:** Evidence from the SELUTION DeNovo Trial

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for the SELUTION DeNovo Investigators

Potential conflicts of interest

- B. Braun (Receipt of grants / research supports)
- B. Braun (Receipt of honoraria or consultation fees)
- B. Braun (Participation in a company sponsored speaker's bureau)
- Cordis (Receipt of honoraria or consultation fees)
- Cordis (Participation in a company sponsored speaker's bureau)
- Medtronic (Receipt of honoraria or consultation fees)
- Medtronic (Participation in a company sponsored speaker's bureau)

Study device

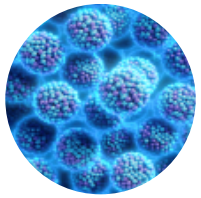
SELUTION SLR Drug-Eluting Balloon





MicroReservoirs

- ~4 µm spheres of **sirolimus** mixed with biodegradable polymer
- **Controlled release of sirolimus**



Proprietary Phospholipid Blend Coating

- Phospholipid blend coating containing and protecting MicroReservoirs at 1 µg/mm^2 sirolimus dose
- **Enhances drug transfer efficiency**

SELUTION SLR Drug-Eluting Balloon delivers sustained drug release that maintains therapeutic tissue concentration for 90 days[1]

[1] T Tanaka et al, Cardiovasc Revasc Med 2025: S1553-8389(25)00464-6

SELUTION DeNovo – study design

Prospective, randomised, open label, multicentre, non-inferiority trial

Candidates for PCI who satisfied trial inclusion / exclusion criteria

Randomised 1:1 BEFORE PROCEDURE

SELUTION DEB Strategy
Lesion preparation & SELUTION DEB
Provisional DES if needed

DES Strategy
DES according to local practice
Other devices only if failure to deliver DES

First Co-Primary Endpoint = non-inferiority for TVF* at 1 year

Second Co-Primary Endpoint = non-inferiority for TVF at 5 years
Conditional superiority analysis if non-inferiority established

*TVF: target vessel failure, a composite of cardiac death, target vessel related MI and clinically driven target vessel revascularisation

Spaulding C et al, Am Heart J 2023; 258: 77-84

Key inclusion and exclusion criteria

Key Inclusion Criteria

- ✓ All target lesions suitable for SELUTION DEB or DES treatment
- ✓ Reference Vessel Diameter ≥ 2.0 and ≤ 5.0 mm
- ✓ No limitation on number of lesions or vessels
- ✓ All target lesions are treatable with the strategy allocated by randomisation

Key Exclusion Criteria

- × Left main lesion
- × Saphenous or arterial graft lesion
- × Chronic total occlusion
- × In-stent restenosis
- × Previous PCI on a target vessel

C. Spaulding, “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”, Oral Presentation, Late Breaking Trial Session, TCT 2025

Procedure guidelines

SELUTION DEB Strategy

- Mandatory 1:1 optimal lesion preparation
- SELUTION DEB Minimum inflation time of 30”
  Use of DES in case of:
  - Residual stenosis / recoil > 30%
  - High risk dissection: Type C or greater
  - FFR < 0.8 or iFR < 0.89

DES Strategy

- Systematic DES (guidelines & local practice)
- Current generation, approved devices
- Other devices allowed if failure to deliver DES
- POBA alone allowed for side-branches

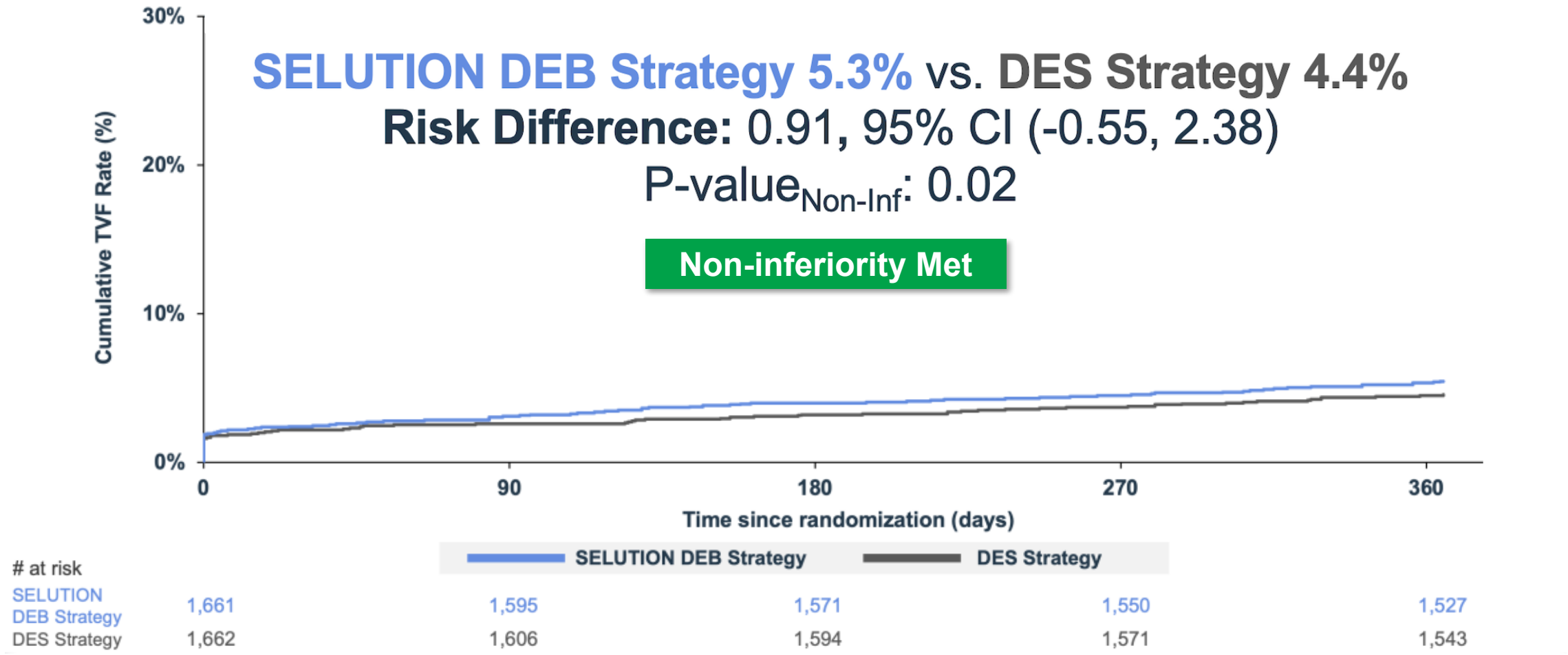
All Patients

Adjunctive devices according to operator preference:

- Cutting, scoring, high-pressure balloons
- Atherectomy, IVL
- IVUS, OCT
- FFR, iFR

- Antithrombotic regimen based on guidelines and local practice
- Staged procedures allowed if performed ≤ 45 days after the index procedure

Target Vessel Failure at 1-year (overall cohort)



Target Vessel Failure: A composite of Cardiac Death, Target Vessel-Myocardial Infarction and Clinically-Driven Target Vessel Revascularisation

C. Spaulding, “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”, Oral Presentation, Late Breaking Trial Session, TCT 2025

Rationale for the complex PCI subgroup analysis

- Use of Drug-Eluting Stents (DES) for treating patients who require complex Percutaneous Coronary Intervention (PCI) is associated with high event rates, both acutely and during follow-up
- Drug-coated balloons offer a potential alternative by delivering antiproliferative therapy without implantation of multiple foreign bodies, yet evidence supporting their use for complex procedures remains limited
- This analysis focuses on the performance of a Drug-Eluting Balloon (DEB) based strategy in a predefined subgroup of patients with complex PCI from the SELUTION DeNovo trial

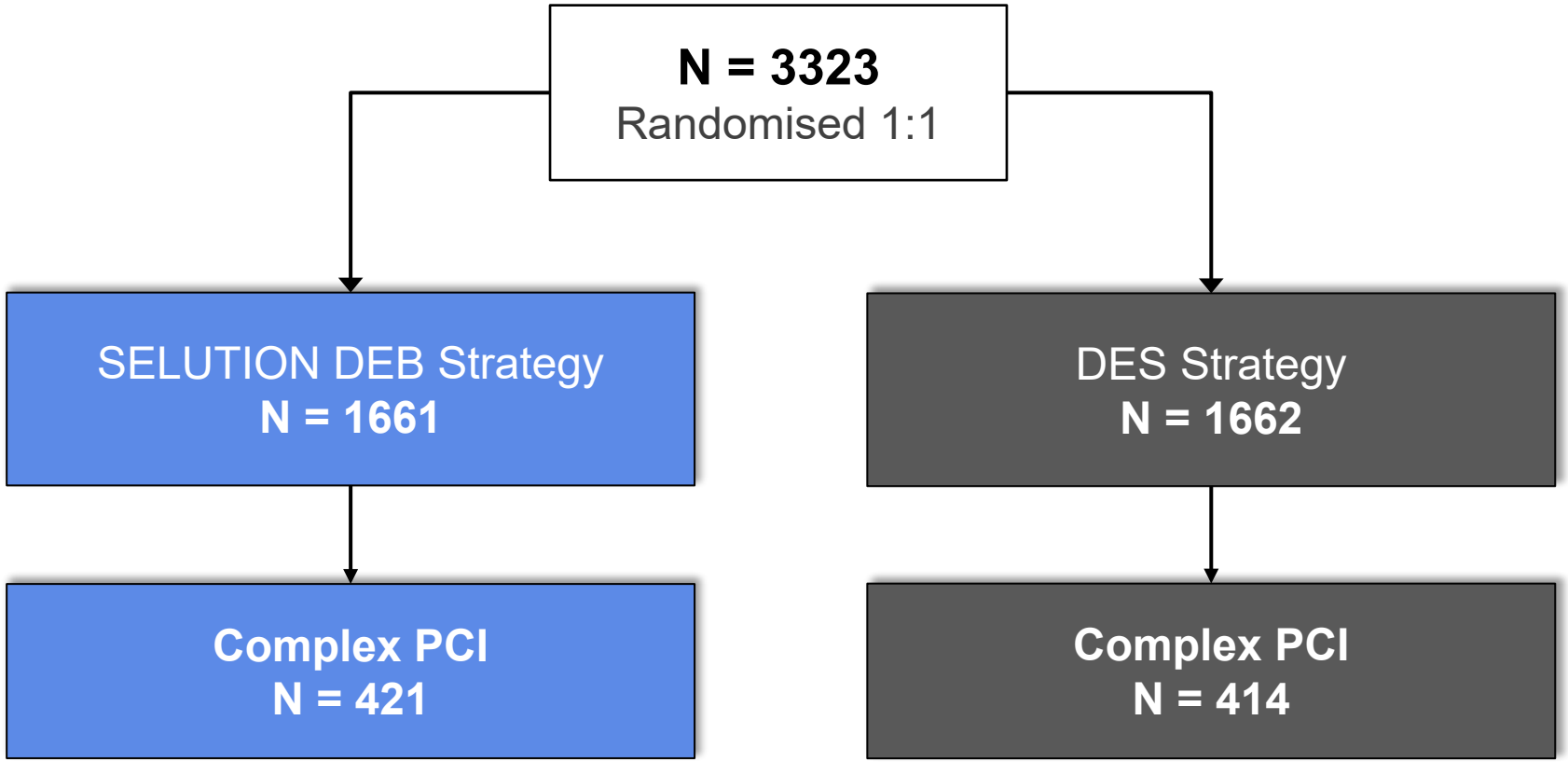
Definition of complex PCI*

Procedures in which patients met **at least one of the following criteria**:

- treatment of all three coronary vessels
- treatment of three or more lesions
- three or more drug-eluting balloons or stents
- bifurcation lesion with both main branch and side branch treated
- chronic total occlusion
- total device length exceeding 60 mm

*Adapted from: Giustino G, et al. JACC 2016; 68: 1851-1864

Patient flow chart



Baseline clinical characteristics

Characteristic	Complex PCI **DEB Strategy**	Complex PCI **DES Strategy**
Number of patients	421	414
Age (years)	67.1 ± 9.6	67.4 ± 9.9
Male sex (%)	79.6	78.5
Diabetes mellitus (%)	25.7	23.7
Insulin-dependent diabetes (%)	5.2	5.3
Hypertension (%)	71.3	67.9
Hypercholesterolemia (%)	64.6	64.3
Current smoker (%)	15.9	18.1
Renal failure (GFR < 60 ml/min) (%)	4.8	4.3
Congestive heart failure (%)	6.2	7.3
Prior myocardial infarction (%)	11.9	18.1
Prior stroke (%)	4.8	5.3
Previous PCI (%)	21.6	26.3
Previous CABG (%)	2.6	1.9
High bleeding risk[1] (%)	17.7	14.7
ACS (%)	36.1	33.6

[1]HBR according to the ARC-HBR Definition

Angiographic characteristics

Characteristic	Complex PCI **DEB Strategy**	Complex PCI **DES Strategy**
Number of treated lesions	817	851
Treated lesions per patient	2.0 ± 0.9	2.1 ± 0.9
Patients with multivessel procedures (%)	42.3	45.7
Location of treated lesions (%)[1]		
Left main	0.0	0.0
Left anterior descending artery	45.9	45.5
Proximal left anterior descending artery	26.7	28.6
Left circumflex artery	26.3	26.5
Right coronary artery	28.0	28.0
At least 1 device size ≥ 3.0 mm (%)	66.4	67.0
Bifurcation lesion (%)[1]	**37.8**	**43.3**
Moderate or severe calcified lesion (%)[1]	**27.4**	**28.3**
ACC/AHA type B2 or C lesion (%)[1]	79.4	76.8

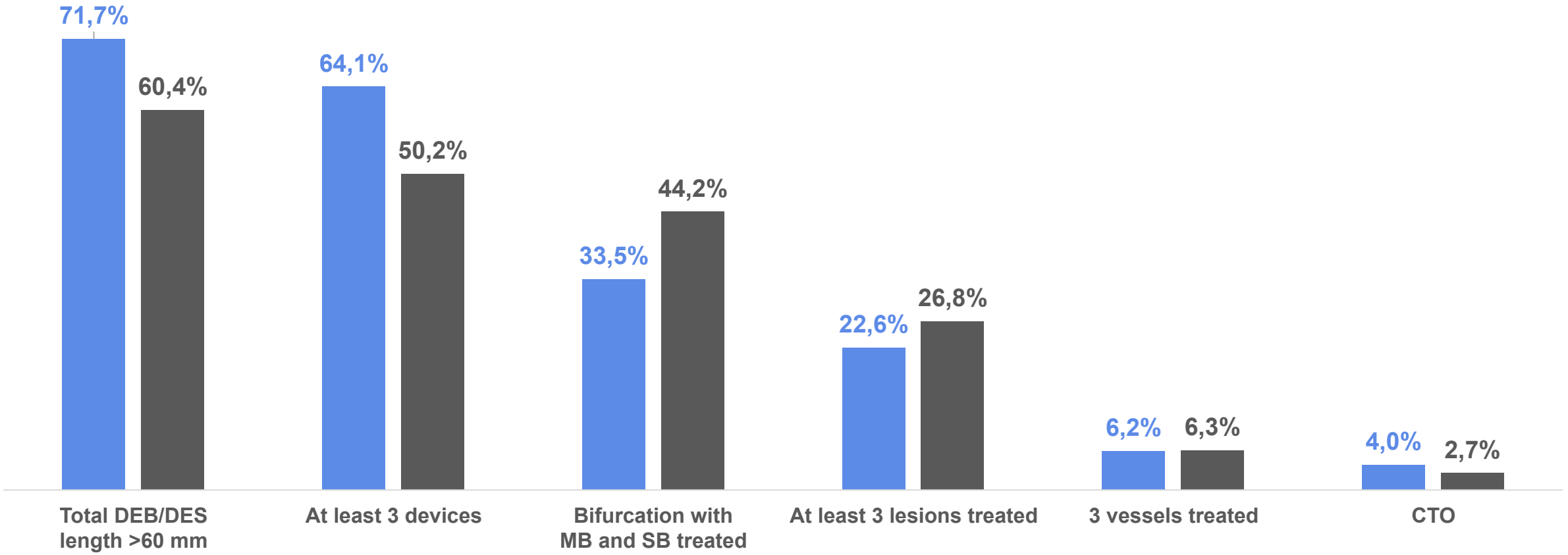
[1]Based on a qualitative analysis of available angiograms by the CoreLab

Procedure characteristics

Characteristic	Complex PCI **DEB Strategy**	Complex PCI **DES Strategy**
Number of procedures	510	503
Staged procedure (%)	16.7	17.1
Radial access (%)	92.8	94.6
Specialty balloons per lesion (%)[1]	**29.7**	**10.3**
Atherectomy or IVL per lesion (%)	4.5	2.8
Intracoronary imaging per lesion (%)[2]	**18.0**	**26.1**
Number of devices per lesion	1.5 ± 0.8	1.3 ± 0.6
Number of devices per patient	3.0 ± 1.2	2.6 ± 1.2
Nominal device diameter (mm) Median (Q1; Q3)	3.0 (2.5; 3.5)	3.0 (2.5; 3.5)
Inflation duration for SELUTION DEB (sec)	60.6 ± 20.4	/
Total device length per lesion (mm)	40.7 ± 22.2	34.3 ± 19.1
Provisional DES use per lesion (%)	32.5	/
Procedure duration (min)	70 ± 42	68 ± 39

[1]Specialty balloons include scoring, cutting and very high-pressure balloons
[2]Intracoronary imaging includes intravascular ultrasound and optical coherence tomography

Complexity criteria

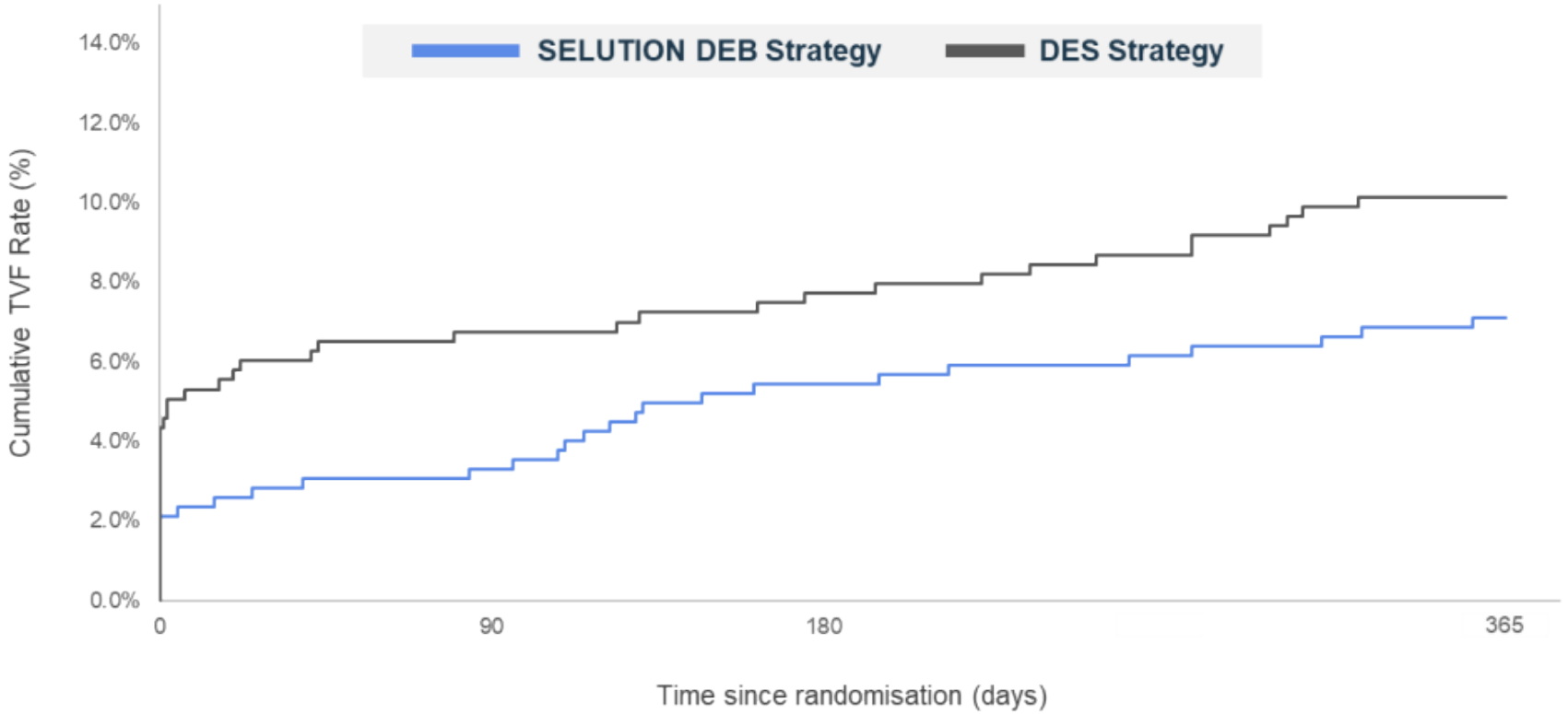


A patient may meet multiple criteria for classification as a complex PCI patient

TVF at 1 year in the complex PCI subgroup

SELUTION DEB Strategy 7.2% vs. DES Strategy 10.2%

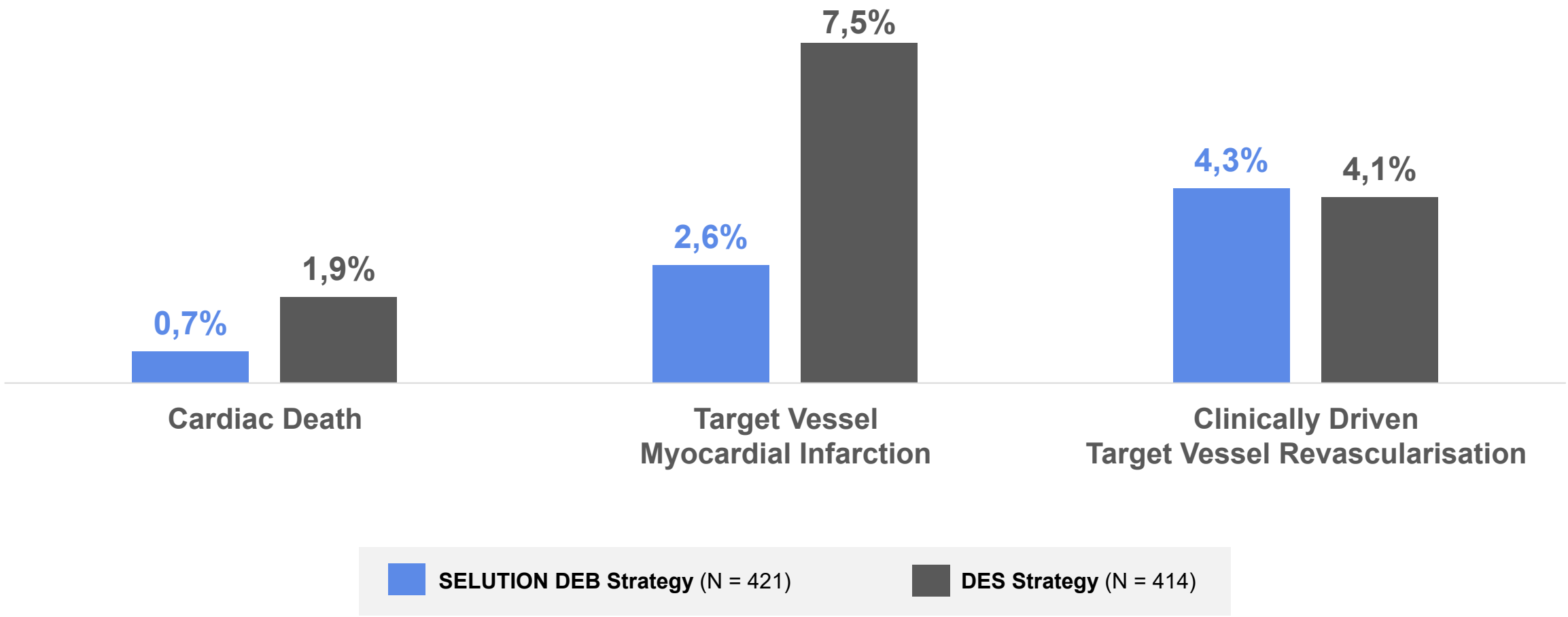
Risk Difference: -3.00, 95% CI (-6.82, 0.82)



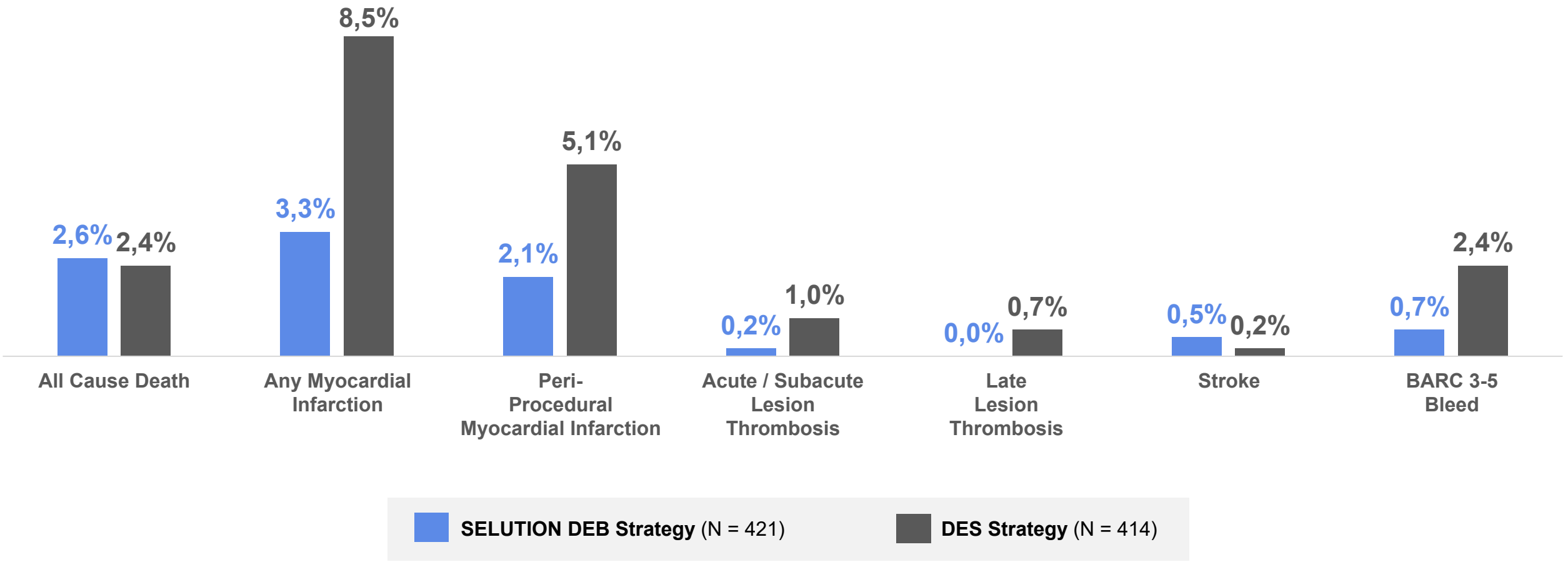
Number at risk

SELUTION DEB Strategy	421	401	389	375
DES Strategy	414	383	379	368

Components of TVF in the complex PCI subgroup



Secondary safety endpoints in the complex PCI subgroup



Limitations

- Our protocol definition for complex PCI is widely used but alternative definitions could have been chosen
- A low use of specialty balloons and intra-coronary imaging may have impacted results in both groups
- The definition of “complex” includes operator-driven procedure characteristics, partially losing the benefit of randomisation
- This analysis is based on a subgroup of 835 patients (25.1% of the overall study population) and should therefore be considered hypothesis-generating

Conclusions

- The use of a SELUTION DEB strategy with minimal stenting appears to be a safe and effective alternative to systematic DES implantation for patients with complex PCI
- The difference in TVF was mainly driven by the TV-MI and cardiac death, while revascularisation rates were similar
- No acute or late safety concerns were observed, and the DEB strategy had lower rates of MI, lesion thrombosis, and BARC 3-5 bleeding
- The potential long-term benefits of a minimal stenting strategy for complex PCI will be further evaluated through follow-up extending to 5 years

The essentials to remember

- **WHY?**
  DES for complex PCI is associated with high rates of early and late adverse events

- **WHAT?**
  Use of a SELUTION sirolimus DEB strategy for complex PCI

- **HOW?**
  Comparison of a DEB + provisional DES strategy vs. DES only in a predefined subgroup of patients with complex PCI from the SELUTION DeNovo trial

- **WHAT ARE THE RESULTS?**
  At 1 year, TVF event rates were lower for the DEB vs. the DES strategy

- **WHY IS THIS IMPORTANT?**
  Reducing stent use by 2/3 for complex PCI is both safe and effective at 1 year and may translate into a lower rate of stent-associated long-term adverse events



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BACK-UP

CD-TVR comparison

