

Sirolimus Eluting Balloon for Patients with Acute Coronary Syndrome

Evidence from the SELUTION DeNovo trial

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Society for Cardiovascular Angiography & Interventions

Disclosures

- Honoraria for speaking/consulting/proctoring from the following:

Abbott Vascular,
Boston Scientific,
Biotronik,
Brosmed,
Cordis,
Shockwave,
SMT,
Teleflex

Study device

SELUTION SLR Drug-Eluting Balloon

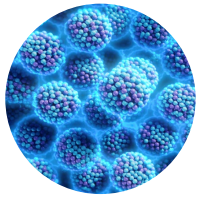


SELUTION SLR PTCA DEB is an Investigation Device Exemption and not an approved product in the US



MicroReservoirs

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



Proprietary Phospholipid Blend Coating

- Phospholipid blend 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

SELUTION DENOVO
PTCA STUDY

Prospective, randomized, open label, multicenter, non-inferiority trial

Candidates for PCI who satisfied trial inclusion / exclusion criteria

Randomized 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 revascularization

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

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DEB: *Drug-eluting Balloon*, DES: *Drug-eluting Stent*

SELUTION DeNovo trial

Key inclusion and exclusion criteria

Key Inclusion Criteria

- ✓ **Presentation with CCS or ACS**
- ✓ 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 randomization

Key Exclusion Criteria

- × **Presentation with STEMI or unstable* NSTEMI**
- × Left main lesion
- × Saphenous or arterial graft lesion
- × Chronic total occlusion
- × In-stent restenosis
- × Previous PCI on a target vessel

*** Ongoing chest pain or hemodynamic instability**

ACS: *Acute Coronary Syndrome*; CCS: *Chronic Coronary Syndrome;*
STEMI: *ST-Elevation Myocardial Infarction*; NSTEMI: *Non-ST-Elevation Myocardial Infarction*

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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

All Patients

Adjunctive devices according to operator preference:

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

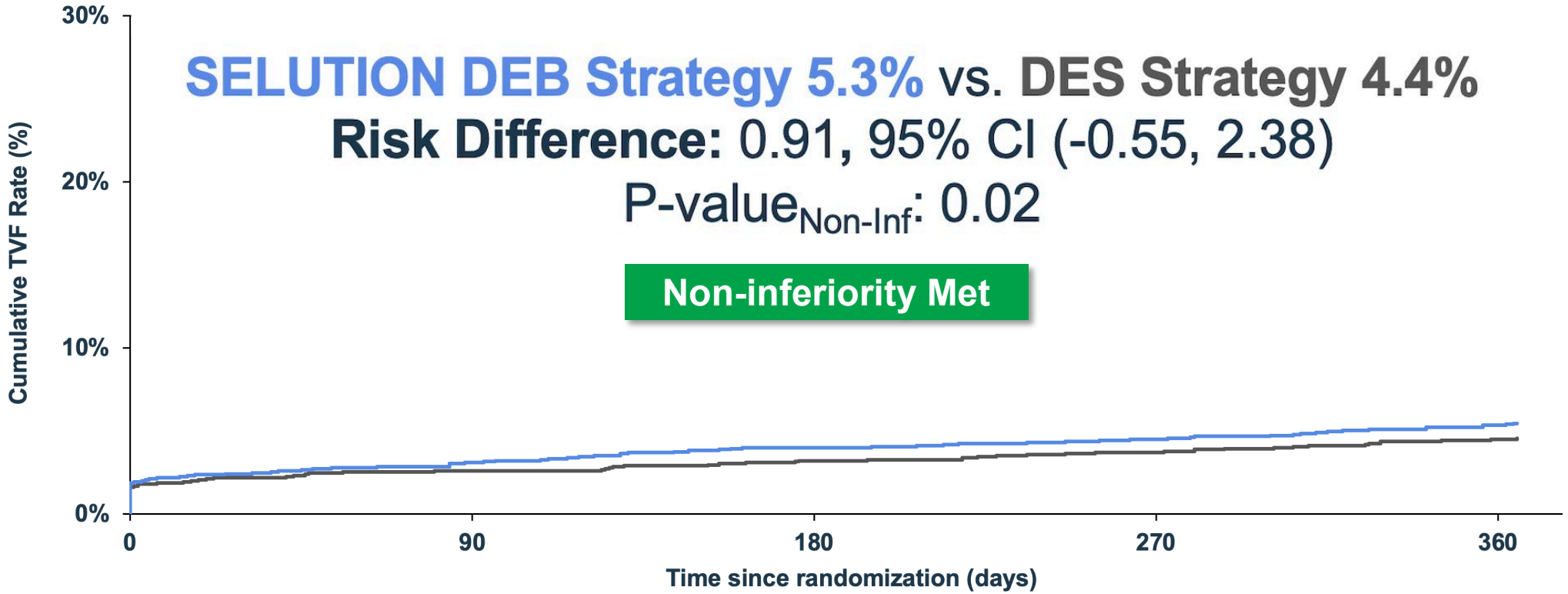
- Antithrombotic regimen based on guidelines and local practice
- Staged procedures allowed if performed ≤ 45 days after the index procedure

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

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SELUTION DeNovo trial

Target Vessel Failure at 1-year (overall cohort)



# at risk					
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

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

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

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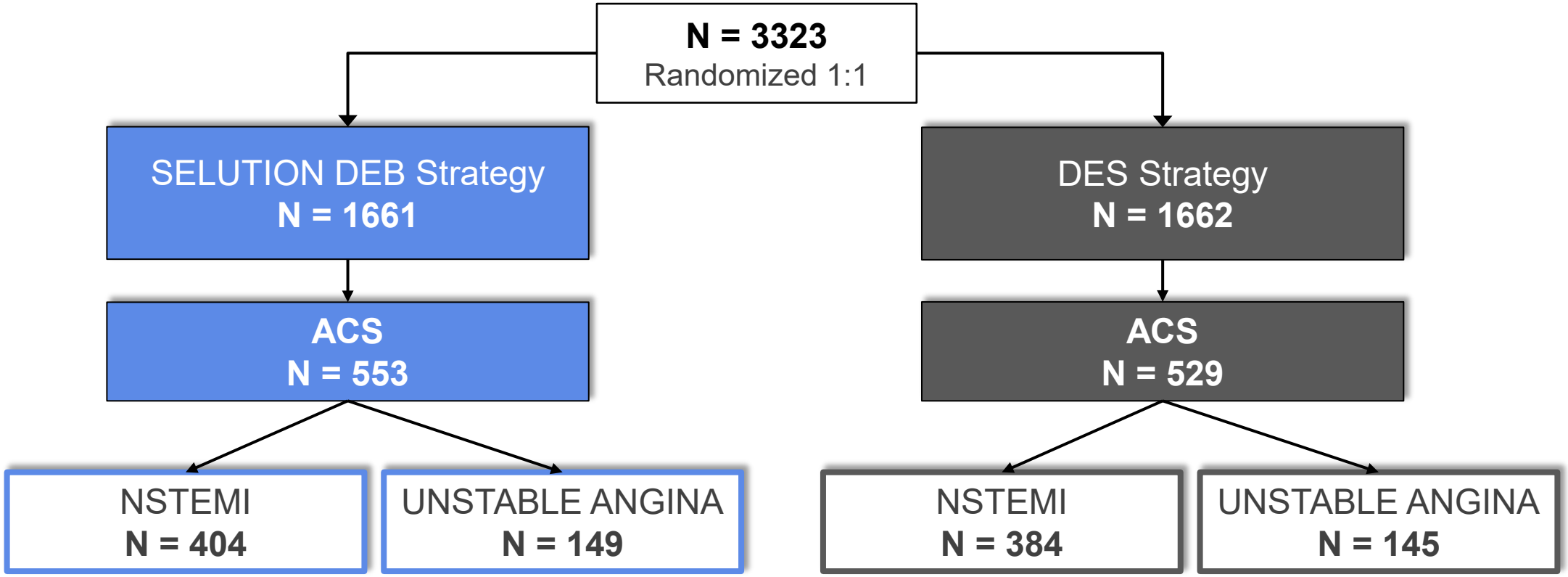
Rationale for the ACS subgroup analysis

- A DEB-first strategy has been shown to be non-inferior at one year when compared with a DES strategy
- However, the pathophysiology of culprit ACS lesions frequently differs from those treated for CCS with a preponderance of plaque rupture and erosion
- The response of acute lesions and the efficacy of a DEB-first strategy may differ from those treated for CCS
- Growing data suggests a DEB-first strategy may be feasible in selected ACS patients
- This pre-specified subgroup analysis aims to assess the performance of a SELUTION DEB strategy in **patients with ACS enrolled in the SELUTION DeNovo trial**

DEB: *Drug-eluting Balloon*, DES: *Drug-eluting Stent*, ACS: *Acute Coronary Syndrome*; CCS: *Chronic Coronary Syndrome*

SELUTION DeNovo trial – ACS subgroup analysis

Patient flow chart



Presentation with STEMI or unstable NSTEMI constituted an exclusion criterion

ACS: *Acute Coronary Syndrome*; STEMI: *ST-Elevation Myocardial Infarction*; NSTEMI: *Non-ST-Elevation Myocardial Infarction*

SELUTION DeNovo trial – ACS subgroup analysis

Baseline clinical characteristics

Characteristic	ACS SELUTION DEB Strategy	ACS DES Strategy
Number of patients	553	529
Age (years)	65.9 ± 10.3	65.4 ± 11.4
Male sex (%)	72.3	74.3
Diabetes mellitus (%)	21.7	22.1
Insulin-dependent diabetes (%)	4.3	5.3
Hypertension (%)	61.5	60.3
Hypercholesterolemia (%)	52.4	53.3
Current smoker (%)	21.7	22.7
Renal failure (GFR < 60 ml/min) (%)	5.3	3.8
Congestive heart failure (%)	4.5	3.6
Prior myocardial infarction (%)	13.0	12.7
Prior stroke (%)	3.6	4.0
Previous PCI (%)	13.2	13.0
Previous CABG (%)	1.1	2.3
High bleeding risk[1] (%)	**16.5**	**15.0**

[1]HBR according to the ARC-HBR Definition

Groups are similar

SELUTION DeNovo trial – ACS subgroup analysis

Baseline lesion characteristics

Characteristic	ACS SELUTION DEB Strategy	ACS DES Strategy
Number of treated lesions	750	723
Treated lesions per patient	1.4 ± 0.6	1.4 ± 0.7
Patients with multi-vessel procedures (%)	16.8	18.7
Location of treated lesions (%) [1]		
Left main	0.0	0.0
Left anterior descending artery	49.5	48.2
Proximal left anterior descending artery	25.9	30.9
Left circumflex artery	23.8	26.7
Right coronary artery	26.7	25.2
At least 1 device size ≥ 3.0 mm (%)	**72.0**	**71.2**
Bifurcation lesion (%)[1]	29.0	33.5
Moderate or severe calcified lesion (%)[1]	**18.5**	**19.4**
ACC/AHA type B2 or C lesion (%)[1]	**66.1**	**67.1**

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

SELUTION DeNovo trial – ACS subgroup analysis

Baseline procedural characteristics

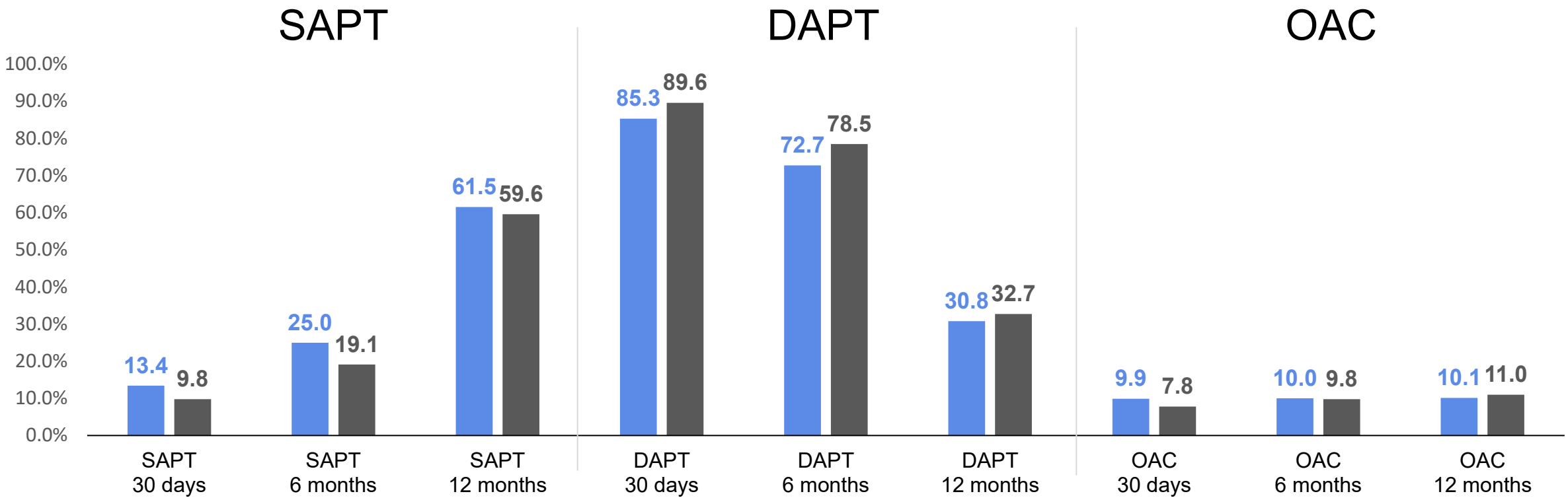
Characteristic	ACS SELUTION DEB Strategy	ACS DES Strategy
Number of procedures	602	575
Staged procedure (%)	7.5	7.7
Radial access (%)	93.0	94.1
Specialty balloon per lesion (%)[1]	34.8	7.8
Rotational atherectomy or IVL per lesion (%)	3.5	3.7
Intracoronary imaging per lesion (%)[2]	**25.33**	**29.6**
Number of devices per lesion	1.3 ± 0.6	1.2 ± 0.5
Number of devices per patient	1.8 ± 1.1	1.6 ± 1.0
Nominal device diameter (mm) Median (Q1; Q3)	3.0 (2.75; 3.5)	3.0 (2.75; 3.5)
Inflation duration for SELUTION DEB (sec)	60.1 ± 19.0	/
Total device length per lesion (mm)	33.0 ± 18.2	30.5 ± 16.2
Provisional device use per lesion (%)	18.4	/
Provisional device use per patient (%)	21.0	/
Procedure duration (min)	59 ± 30	58 ± 36

[1]Specialty balloons include scoring, cutting and high-pressure balloons

[2]Intracoronary imaging includes intravascular ultrasound and optical coherence tomography

SELUTION DeNovo trial – ACS subgroup analysis

Antithrombotic regimens in the ACS subgroup



Patient-reported data collected at each follow-up time point within the follow-up window, reflecting medication use at the time of assessment.

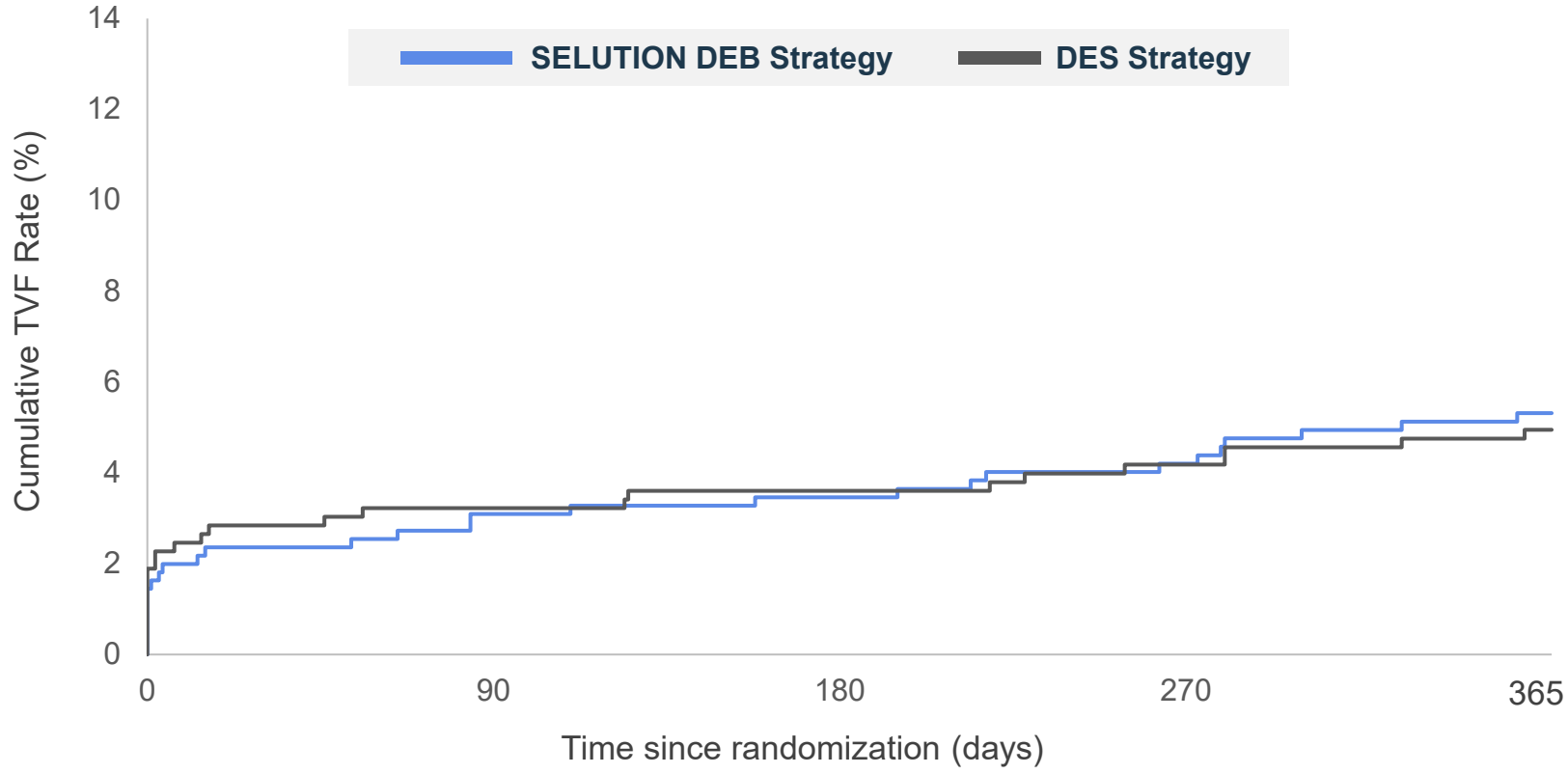
SAPT: *Single Antiplatelet Therapy*; DAPT: *Dual Antiplatelet Therapy*; OAC: *Oral Anticoagulation*

SELUTION DeNovo trial – ACS subgroup analysis

Target Vessel Failure at 1 year in the ACS subgroup

SELUTION DEB Strategy 5.3% vs. DES Strategy 4.9%

Risk Difference: 0.37, 95% CI (-2.28, 3.01)

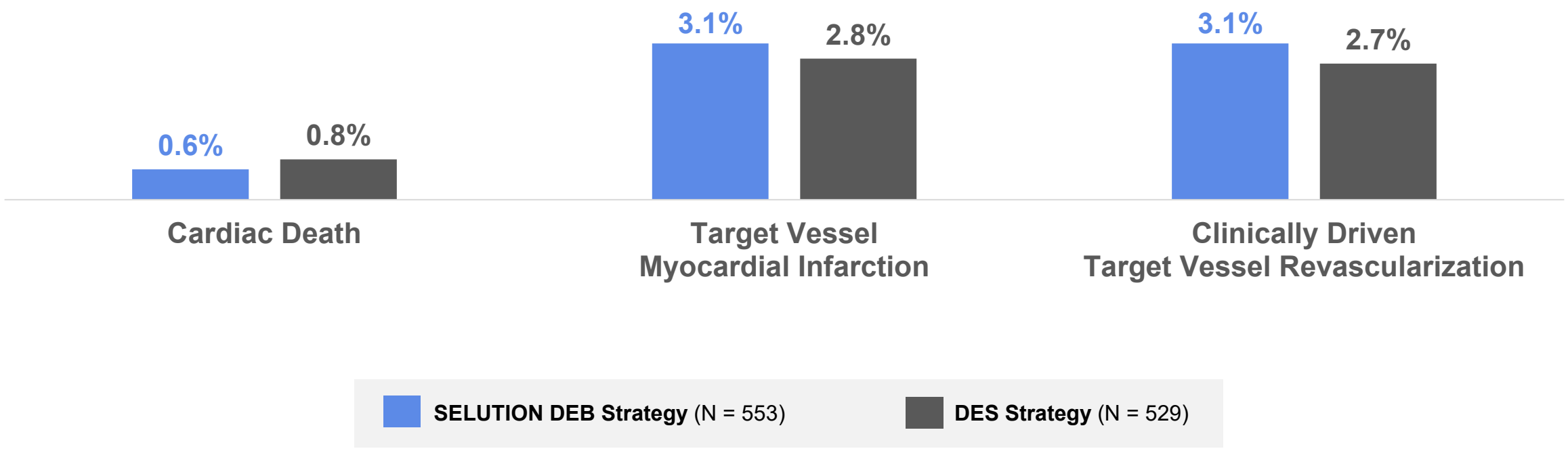


Number at risk

SELUTION DEB Strategy	553	527	521	513	505
DES Strategy	529	508	506	499	490

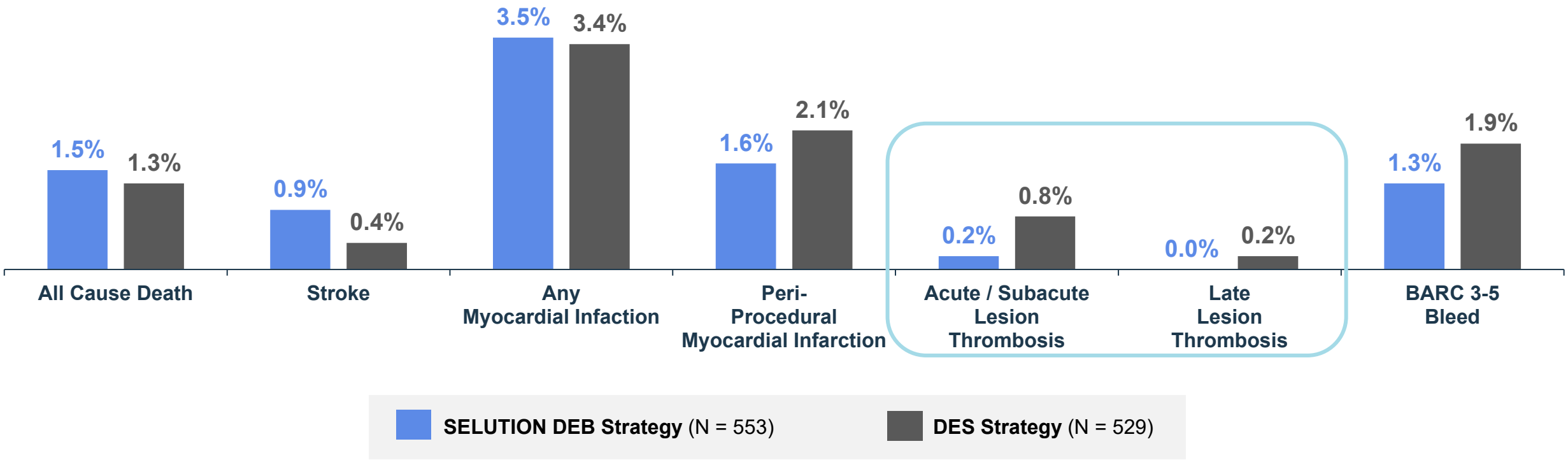
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Components of Target Vessel Failure in the ACS subgroup



SELUTION DeNovo trial – ACS subgroup analysis

Secondary safety endpoints in the ACS subgroup

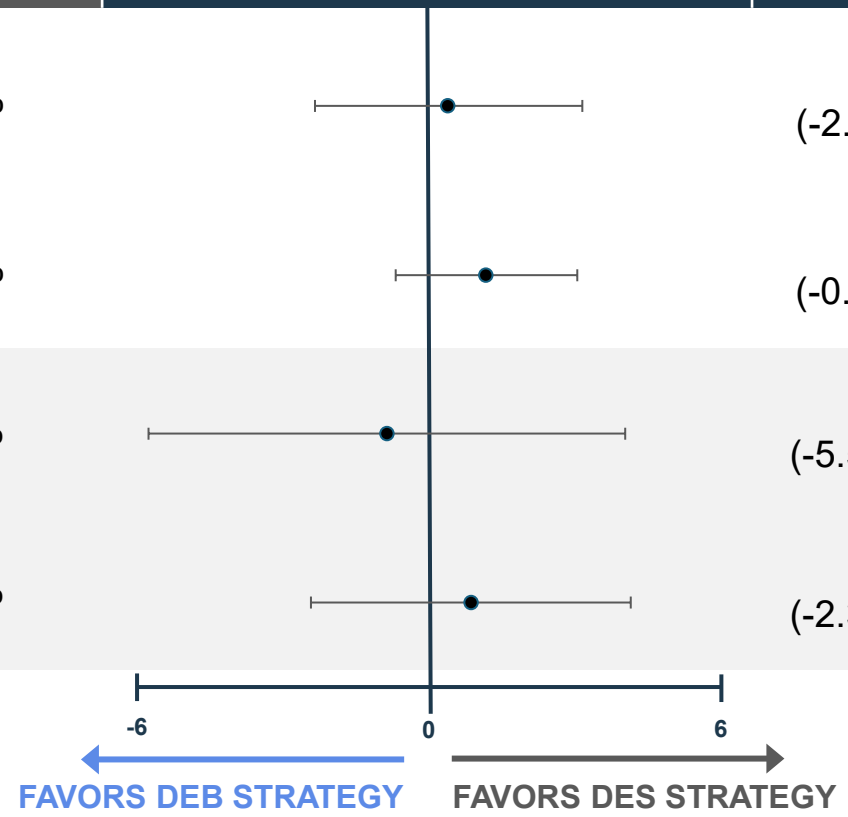


BARC: Bleeding Academic Research Consortium

SELUTION DeNovo trial – ACS subgroup analysis

Subgroup interactions

Subgroup		TVF		Absolute Risk Difference	AR (95% CI)	Interaction p-value
		SELUTION DEB Strategy	DES Strategy			
Clinical Presentation	ACS (n=1082)	5.3%	4.9%		0.37 (-2.28; 3.01)	**0.65**
	CCS (n=2148)	5.4%	4.3%		1.12 (-0.70; 2.94)	
ACS	Unstable Angina (n=294)	4.0%	4.9%		-0.84 (-5.56, 3.89)	**0.57**
	NSTEMI (n=788)	5.8%	5.0%		0.83 (-2.34, 4.00)	



ACS: *Acute Coronary Syndrome*; CCS: *Chronic Coronary Syndrome;*
TVF: *Target Vessel Failure;* NSTEMI: *Non-ST-Elevation Myocardial Infarction*

Limitations

- Patients presenting with STEMI or unstable NSTEMI were excluded; consequently, certain ACS subsets are not represented
- NSTEMI diagnoses were site-reported, with no systematic collection of baseline biomarkers and no core-lab ECG assessment
- This analysis is based on a subgroup of 1,082 patients (32.6% of the overall study population) and should therefore be considered hypothesis-generating

ACS: *Acute Coronary Syndrome*; STEMI: *ST-Elevation Myocardial Infarction*; NSTEMI: *Non-ST-Elevation Myocardial Infarction*

Conclusions

- The use of a SELUTION DEB strategy with minimal stenting appears to be a safe and effective alternative to systematic DES implantation for ACS patients presenting with NSTEMI or unstable angina
- At 1 year, TVF event rates were low and similar in both groups, consistent with outcomes observed in patients with CCS (p-value for interaction = 0.65)
- There were no acute or late safety concerns – the DEB strategy had low rates of cardiac death, acute/subacute and late lesion thrombosis, and TV-MI, similar to DES
- The potential long-term benefits of a minimal stenting approach will be further evaluated with follow-up extending out to 5 years

TVF: *Target Vessel Failure;* DEB: *Drug-eluting Balloon;* DES: *Drug-eluting Stent;* ACS: *Acute Coronary Syndrome;*
CCS: *Chronic Coronary Syndrome;* NSTEMI: *Non-ST-Elevation Myocardial Infarction,* TV-MI: *Target Vessel Myocardial Infarction*

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