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

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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I, Christian Spaulding, have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship	Ineligible Company
Grant / Research Support	French Ministry of Health, CERC
Consultant Fees / Honoraria	Medtronic Techwald, Sanofi, Novartis Sonivie, Valcare, Boston Scientific
Individual Stock(s) / Stock Options / Salary Support	Cordis (MedAlliance), Sonivie

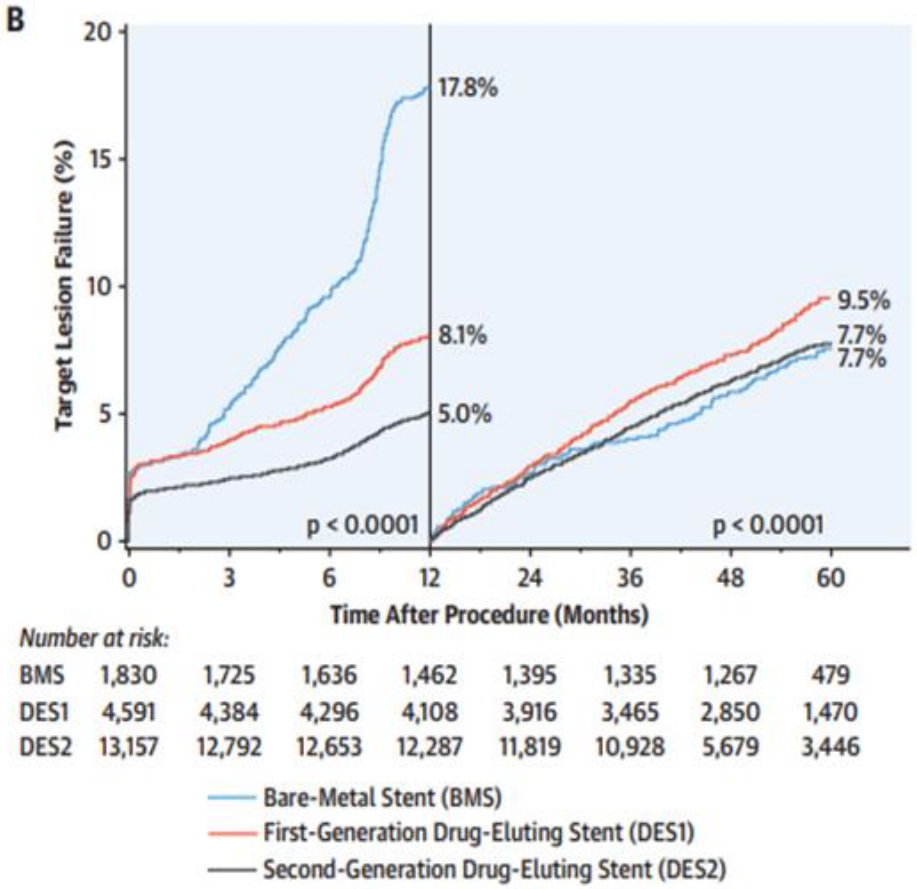
All Relevant Financial Relationships have been mitigated

Faculty disclosure information can be found on the app

Background

- Drug eluting stents (DES) are implanted in the vast majority of PCIs with well-known immediate and mid-term results
- Studies with long term clinical follow-up have shown a 2-4% annual adverse event rate[1,2]
- A drug coated balloon (DCB) approach with minimal stenting is therefore attractive
- Trials with paclitaxel DCBs have produced mixed results[3,4]
- The use of sirolimus on DCBs has been limited by technical difficulties

Very-Late Stent-Related Cardiovascular Events[1]



[1]Madhavan et al. J Am Coll Cardiol 2020 ; 75: 590–604
[2]Kufner S et al. J Am Coll Cardiol 2020;76:146-58
[3]Jeger RV et al. Lancet 2018; 392: 849–56
[4]Gao C et al. Lancet 2024; 404: 1040–50

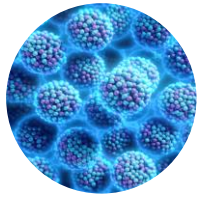
Study Device

SELUTION SLR Drug-Eluting Balloon

*Device not approved and available for sale in the US

MicroReservoirs

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



Proprietary Phospholipid Coating

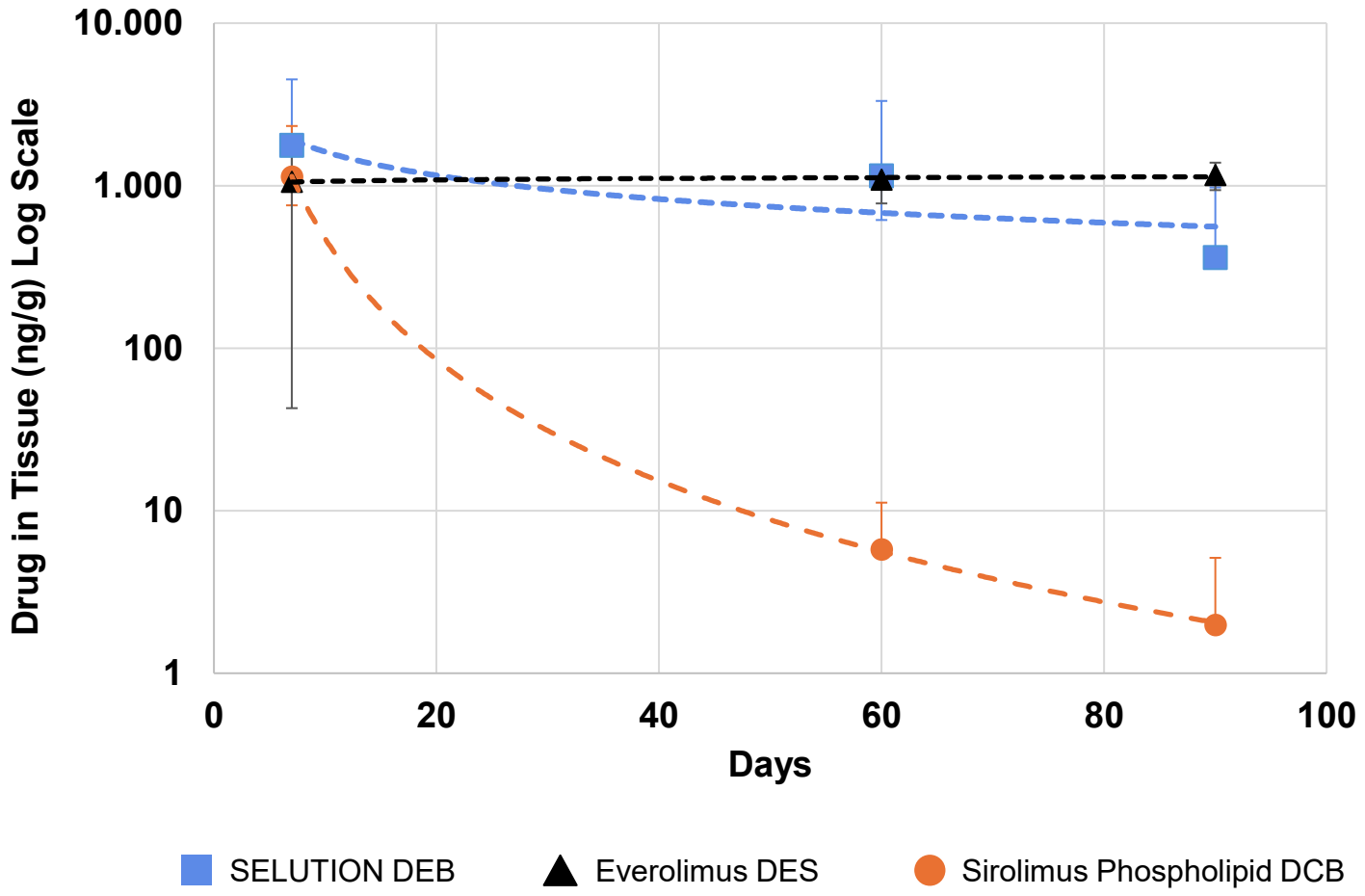
- Phospholipid blend containing and protecting MicroReservoirs at 1 µg/mm^2 sirolimus dose
- **Enhanced drug transfer efficiency**

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

Pharmacokinetics

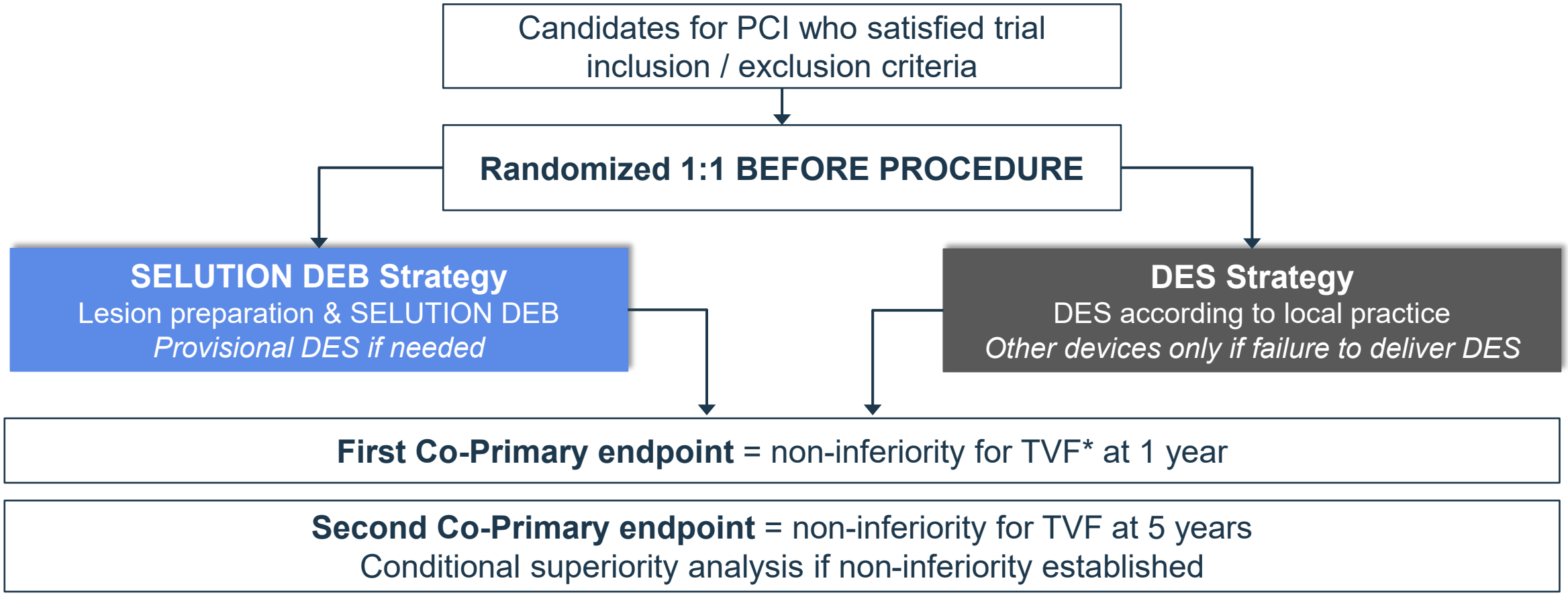
Drug Concentration In The Target Vessel Up To 90 Days



Adapted from T Tanaka et al, Cardiovasc Revasc Med 2025: S1553-8389(25)00464-6

SELUTION DeNovo – Study Design

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



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

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 randomization

Key Exclusion Criteria

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

Procedure Guidelines

SELUTION DEB Strategy

- Mandatory 1:1 lesion pre-dilatation
- SELUTION DEB
- Minimum DEB inflation time of 30 seconds
- 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

- Use of 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

Study Organization

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Simon Eccleshall, MD

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CRO & Angiography Core Laboratory
CERC, Massy, France

Angiographic Upload Platform
decidemedical by ClinFlows, Bielefeld, Germany

Funding and Study Sponsor
Cordis, through its affiliate, M.A. MedAlliance SA

SELUTION DeNovo Enrollers

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Spain	F Alfonso **M Sabaté**	V Jiminez Diaz
Czech Republic	L Pleva M Poloczek	
Singapore	F Jiang Ming **M Bin Idu Jion**	

62 sites in 12 countries across Europe and Asia

Bold text indicates country PI

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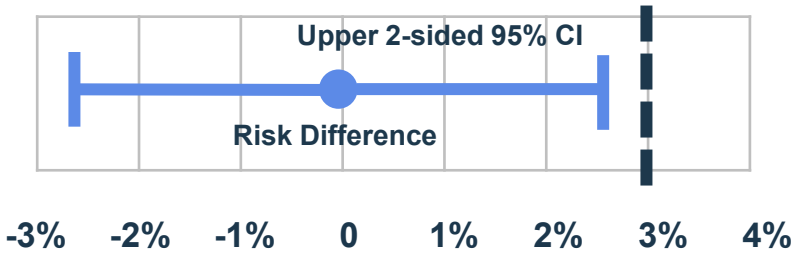
Sample Size and Statistical Analysis

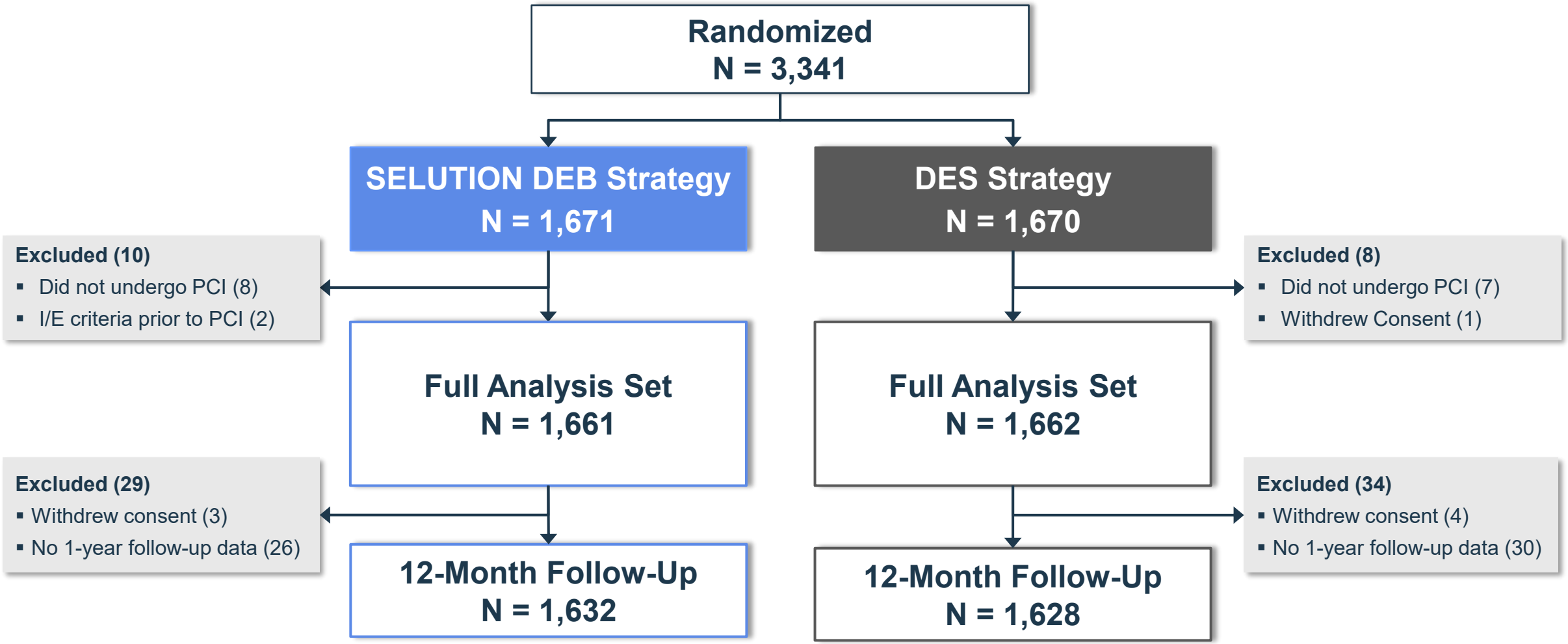
	1 Year
Endpoint	TVF (cardiac death, TV-MI or cd-TVR)
Assumed event rate	6% for both arms
Non-inferiority margin	50% of overall TVF in both arms
One-sided type I error (α)	0.025
Power	95%
Expected lost to follow-up	2%
Sample size	3,326

The primary analysis population is the full analysis set (FAS), including all randomized subjects with completed or attempted PCI, analyzed according to the intention-to-treat principle

Example: 6% event rate
Non-inferiority met



Study Flow – Consort Diagram



98% 12-month compliance

Baseline Clinical Characteristics

Characteristic	SELUTION DEB Strategy	DES Strategy
Number of patients	1661	1662
Age (years)	67.1 ± 9.7	66.7 ± 10.4
Female sex (%)	24.7	26.0
Medical history (%)		
Diabetes mellitus	25.6	26.1
Insulin-dependent diabetes	4.9	5.7
Hypertension	69.3	70.3
Hypercholesterolemia	65.8	64.7
Prior myocardial infarction	18.2	17.7
Prior stroke	4.2	4.4
Previous PCI	27.5	27.1
Previous CABG	2.2	2.6
Current smoker (%)	17.9	19.6
Renal failure (GFR < 60 ml/min) (%)	4.9	4.8
Congestive heart failure (%)	5.4	4.8
High bleeding risk[1] (%)	**17.8**	**16.3**
Acute coronary syndrome (%)	**33.3**	**31.8**
Chronic coronary syndrome (%)	66.7	68.2

Groups are similar

[1]HBR according to the ARC-HBR Definition

Angiographic Characteristics

Characteristic	SELUTION DEB Strategy	DES Strategy
Number of treated lesions	2243	2264
Treated lesions per patient	1.4 ± 0.6	1.4 ± 0.7
Patients with multivessel procedures (%)	15.8	17.1
Location of treated lesions (%)		
Left main	0.1	0.3
Left anterior descending artery	47.7	47.3
Proximal left anterior descending artery (%)	**18.0**	**19.3**
Left circumflex artery	26.7	26.4
Right coronary artery	25.6	26.3
Any device size ≥ 3.0 mm (%)	**67.3**	**63.4**
Bifurcation lesion (%)[1]	32.1	30.8
Moderate or severe calcified lesion (%)[1]	**24.6**	**22.4**
ACC/AHA type B2 or C lesion (%)[1]	**66.8**	**62.3**

ACC/AHA: American College of Cardiology/American Heart Association

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

Procedural Characteristics

Characteristic	SELUTION DEB Strategy	DES Strategy
Number of procedures	1783	1776
Staged procedure (%)	6.6	6.3
Radial access (%)	**93.3**	**94.4**
Specialty balloon per lesion (%)[1]	**28.5**	**7.9**
Rotational atherectomy or IVL per lesion (%)	**3.6**	**2.5**
Intracoronary imaging per lesion (%)[2]	**15.8**	**18.8**
Number of devices per lesion	1.3 ± 0.6	1.2 ± 0.5
Number of devices per patient	1.7 ± 1.0	1.6 ± 0.9
Nominal device diameter (mm)	3.1 ± 0.5	3.1 ± 0.5
Mean inflation duration for SELUTION DEB (sec)	62.1 ± 28.9	NA
Total device length per lesion (mm)	31.6 ± 17.1	28.7 ± 15.1
Provisional device use per lesion (%)	**18.1**	**0.2[3]**
Provisional device use per patient (%)	**20.7**	**0.2[3]**
Procedure duration (min)	**55 ± 32**	**53 ± 35**

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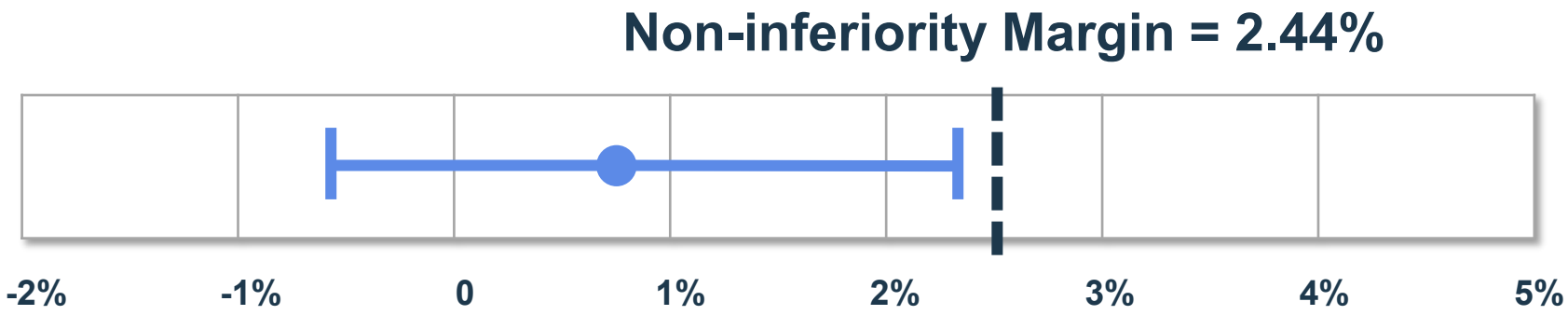
[1]Specialty balloons include scoring, cutting and high-pressure balloons
[2]Intracoronary imaging includes intravascular ultrasound and optical coherence tomography
[3]Two sirolimus and two paclitaxel DCB's

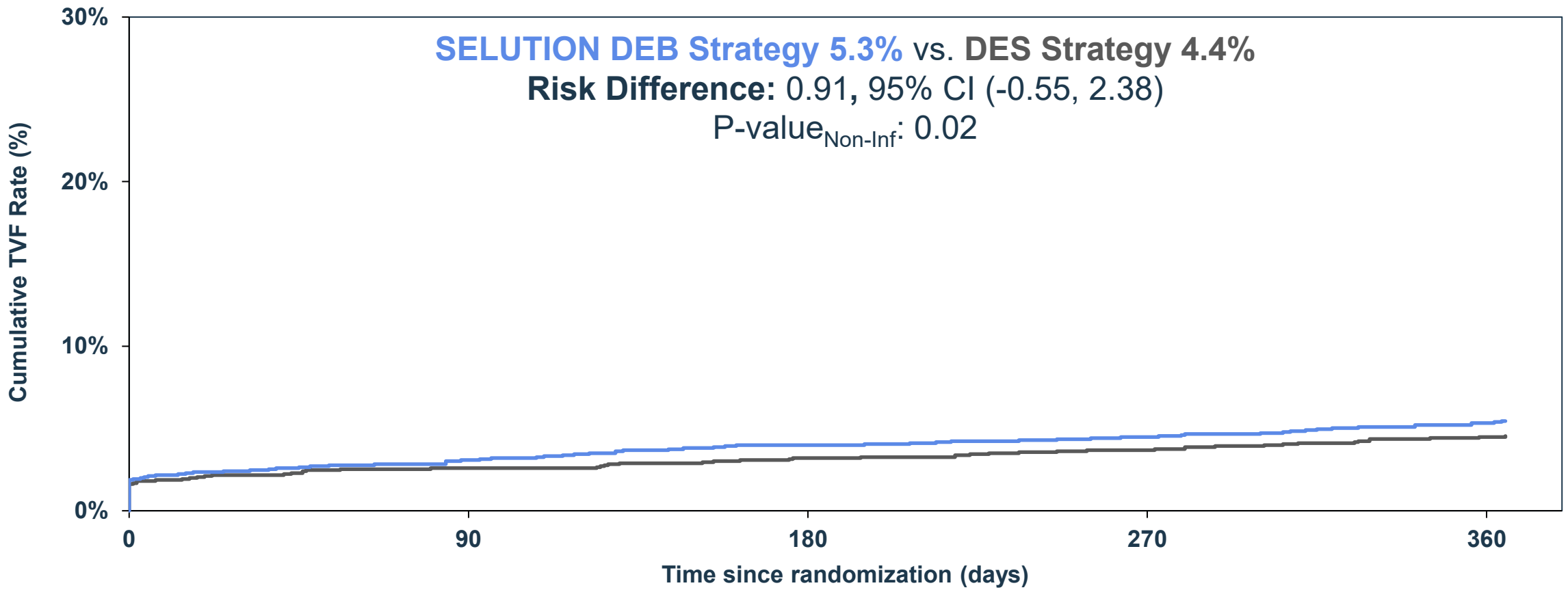
Primary Endpoint Results: TVF at 1-Year

DES Strategy (N = 1,662)	SELUTION DEB Strategy (N = 1,661)	Risk Difference: 0.91%	*P*-value non-inferiority
4.4%	5.3%	Upper 2-sided 95% CI: 2.38%	0.02



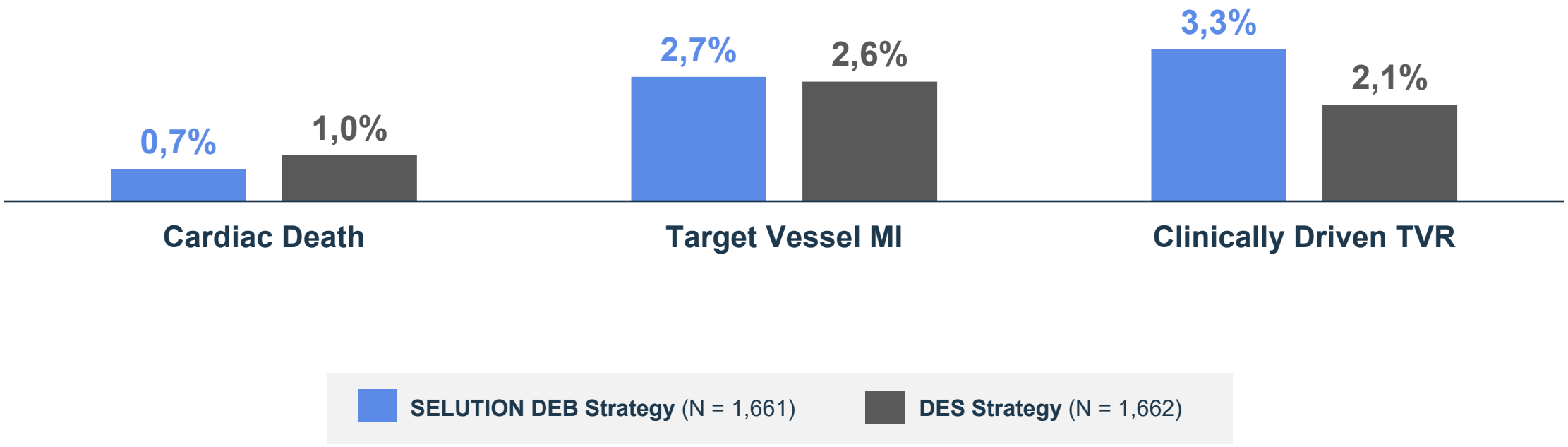
Non-inferiority Met

Cumulative Incidence: TVF

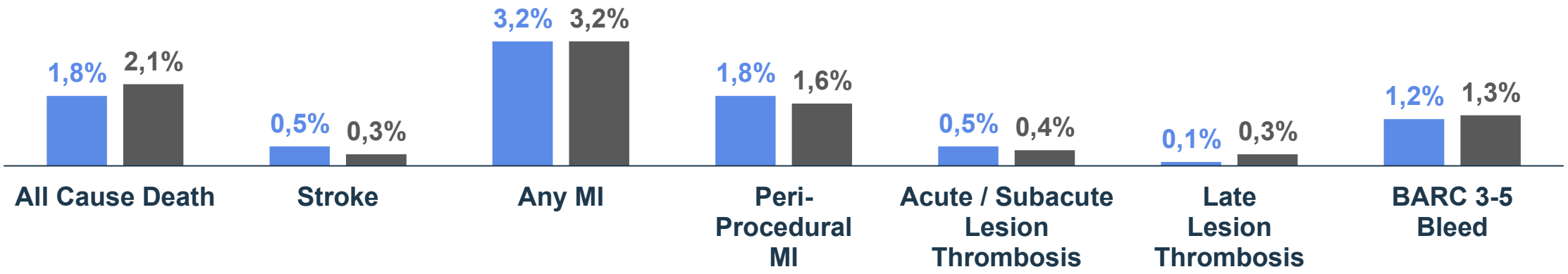


# at risk					
SELUTION DEB Strategy	1,661	1,595	1,571	1,550	1,527
DES Strategy	1,662	1,606	1,594	1,571	1,543

Components of Primary Endpoint (TVF)

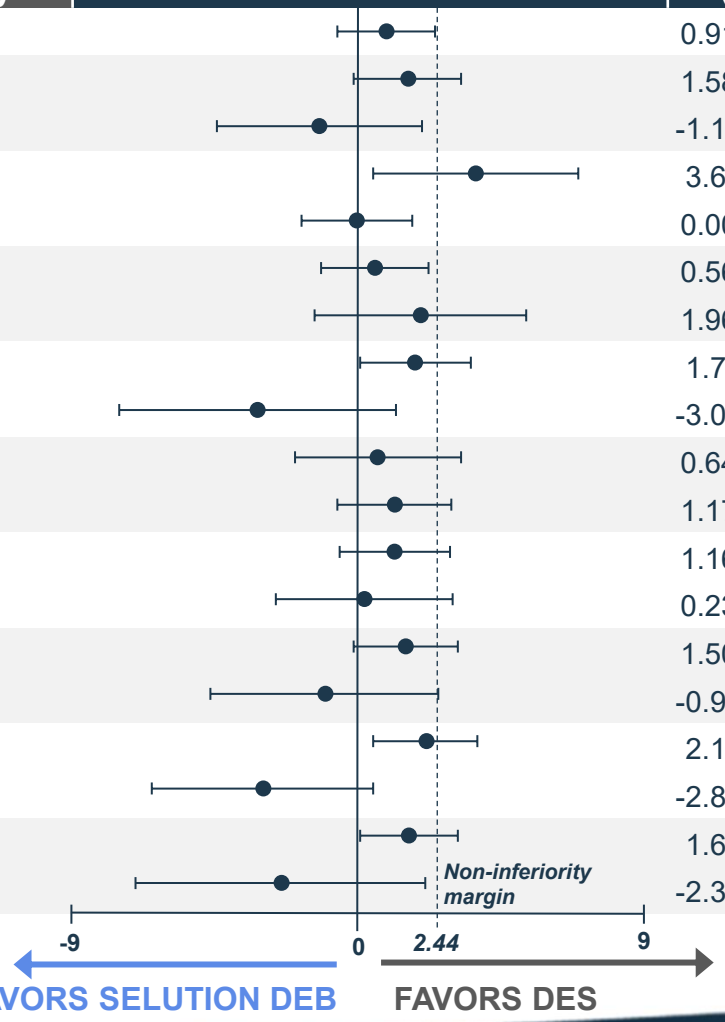


Secondary Safety Endpoints



Subgroup Analysis of TVF

Subgroup		SELUTION DEB Strategy	DES Strategy	Absolute Risk Difference	AR (95% CI)	Interaction p-value
Overall		5.3%	4.4%		0.91 (-0.55, 2.38)	
Age ≥ 75 yrs	No (N = 2,525)	5.4%	3.9%		1.58 (-0.06, 3.23)	**0.13**
	Yes (N = 798)	5.0%	6.1%		-1.15 (-4.33, 2.03)	
Sex	Female (N = 842)	7.4%	3.7%		3.65 (0.54, 6.75)	**0.04**
	Male (N = 2,481)	4.7%	4.7%		0.00 (-1.66, 1.67)	
Diabetes	No (N = 2,464)	4.6%	4.1%		0.56 (-1.06, 2.18)	**0.45**
	Yes (N = 859)	7.3%	5.3%		1.96 (-1.30, 5.23)	
High bleeding risk	No (N = 2,542)	5.7%	4.0%		1.79 (0.12, 3.47)	**0.04**
	Yes (N = 522)	4.9%	7.9%		-3.05 (-7.27, 1.17)	
Any device size ≥ 3.0mm	No (N = 897)	4.2%	3.5%		0.64 (-1.90, 3.19)	**0.74**
	Yes (N = 2,403)	5.6%	4.4%		1.17 (-0.58, 2.91)	
Any bifurcation lesions	No (N = 2,064)	4.5%	3.4%		1.16 (-0.53, 2.86)	**0.57**
	Yes (N = 1,246)	6.5%	6.2%		0.23 (-2.49, 2.94)	
Any long lesion (≥ 25mm)	No (N = 2,542)	5.0%	3.5%		1.50 (-0.07, 3.06)	**0.21**
	Yes (N = 759)	6.0%	6.9%		-0.97 (-4.47, 2.53)	
Any severe or moderate calcification	No (N = 2,454)	5.3%	3.1%		2.14 (0.54, 3.73)	**0.01**
	Yes (N = 865)	5.5%	8.4%		-2.87 (-6.29, 0.54)	
Multivessel procedure	No (N = 2,776)	5.1%	3.5%		1.60 (0.09, 3.12)	**0.10**
	Yes (N = 547)	6.5%	8.8%		-2.31 (-6.76, 2.14)	



Limitations

- Broad inclusion criteria, but excluded STEMI, CTO, ISR, left main, and surgical grafts – dedicated trials required
- Lesion preparation reflected current European practice – limited use of specialty balloons and calcification modification
- QCA analysis is ongoing
- Study performed with SELUTION DEB – the results cannot be applied to other DEB / DCBs (no class effect)

Summary

- SELUTION DeNovo was a large, investigator-driven, pragmatic strategy study that randomized patients before lesion preparation
- There were no acute or late safety concerns – the SELUTION DEB strategy had low rates of cardiac death, lesion thrombosis, and TV-MI, similar to DES
- 80% of participants treated with the SELUTION DEB did not require a stent
- These results, with broad inclusion criteria, apply to a significant segment of PCI procedures including high-risk patients and complex lesions
- Five-year follow-up is planned to assess long-term non-inferiority and potential superiority of a SELUTION DEB strategy with minimal stenting

Conclusion

At one year, a strategy of PCI with SELUTION DEB and provisional DES was non-inferior to the systematic use of DES for the primary endpoint of TVF