Performance of a Sirolimus-Eluting Balloon Strategy in High-Risk Profiles : Insights from the SELUTION DeNovo Randomized Trial

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Disclosures

- Speaker honoraria from Cordis
- Shareholder of CERC

SELUTION DeNovo study device

SELUTION SLR Drug-Eluting Balloon

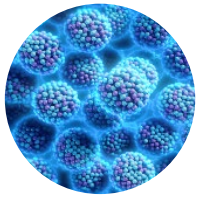


SELUTION SLR PTCA DEB is an approved product in the US for ISR indication



MicroReservoirs

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



Phospholipid Blend Coating

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

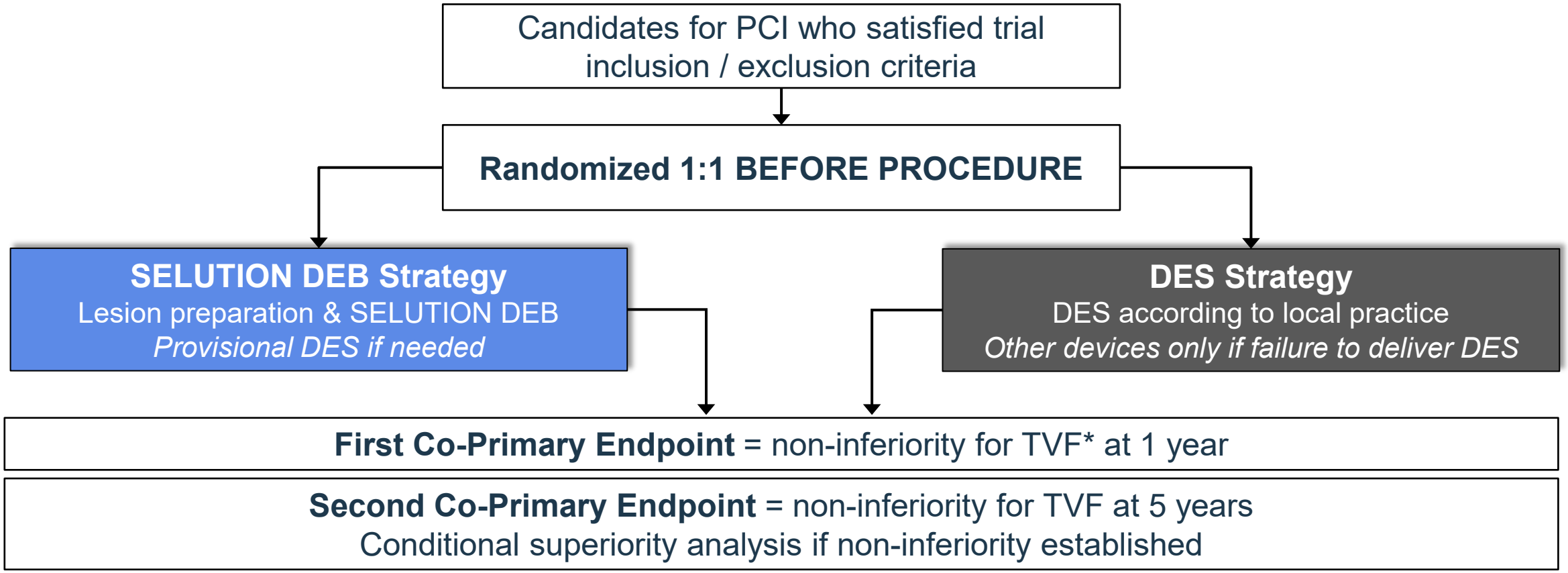
SELUTION SLR DEB provides sustained sirolimus release up to 90 days, maintaining therapeutic tissue concentrations with DES-like pharmacokinetics[1]

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

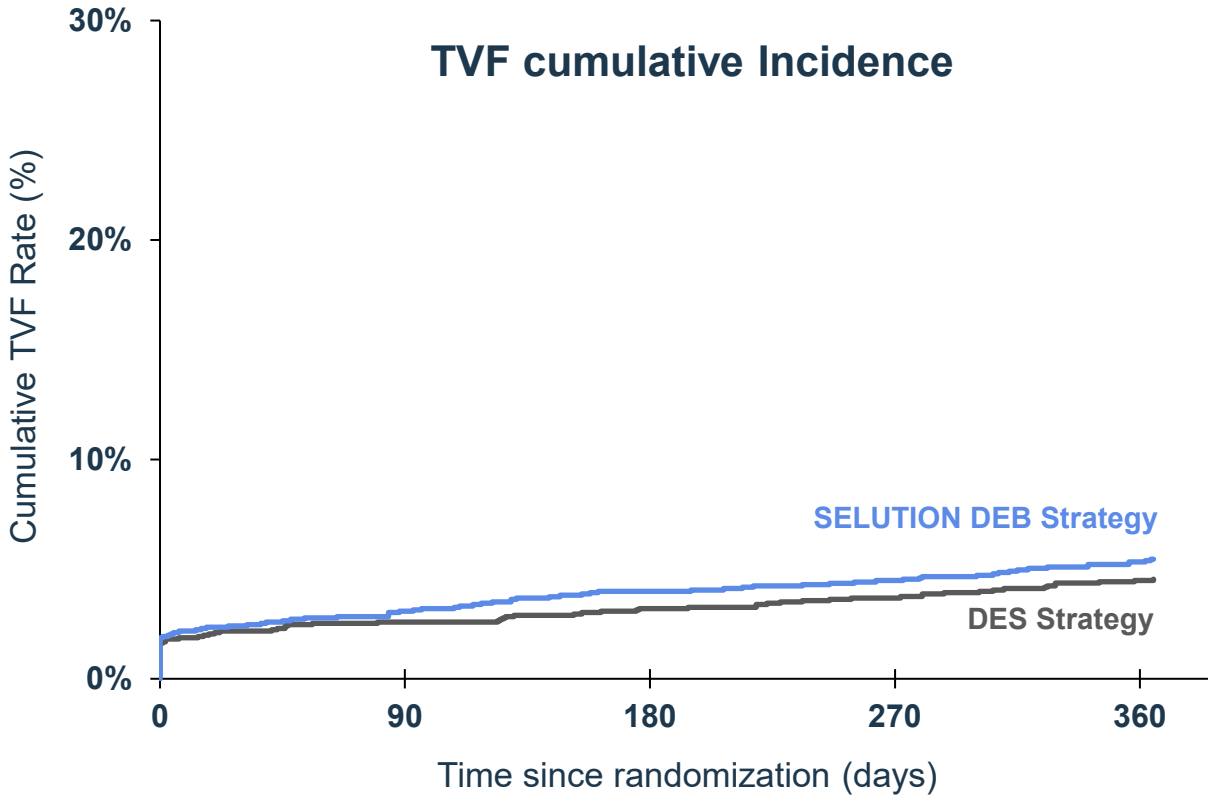


*TVF: target vessel failure, a composite of cardiac death, target vessel related MI and clinically driven target vessel revascularization

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

SELUTION DeNovo Trial:

SELUTION DEB strategy vs. DES strategy in 3323 patients



Primary Endpoint Results: TVF* at 1-Year

DES Strategy (N=1,662)
4.4%

SELUTION DEB Strategy (N=1,661)
5.3%

Risk Difference: 0.91%
Upper 2-sided 95% CI: 2.38%

***P*-value non-inferiority**
0.02

Non-inferiority Primary Endpoint Met

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

C. Spaulding et al., *Circulation*. 2026;154:185–97

Rationale

- Despite advances in contemporary DES technology, important limitations remain, particularly in patients with high-risk clinical, anatomical, or procedural characteristics
- A DEB strategy may be particularly attractive in selected high-risk settings, where avoiding a permanent implant may offer potential procedural and clinical advantages
- The SELUTION DeNovo trial provides a unique opportunity to explore whether a SELUTION DEB strategy may overcome some of the limitations of DES in high-risk profiles and provide greater clinical benefits
- Rather than looking at one factor at a time, we conducted a target vessel failure multivariable analysis to assess the effect of each factor while accounting for potential confounders

Objective and methods

OBJECTIVE:

- To identify patient, lesion and procedural profiles associated with differential impact on TVF according to the assigned treatment strategy

METHODS:

- A post hoc exploratory patient level Cox regression analysis was performed related to TVF
- Pre-specified clinical, anatomical, and procedural variables were selected based on established prognostic clinical relevance after PCI and were evaluated as potential treatment-effect modifiers:
  - age, gender, diabetes, ACS[1], HBR[2], complex procedure[3], bifurcation[4], vessel size[5], lesion length[6], calcification[7], multivessel disease, imaging use

1. *NSTEMI and unstable angina;* ***2.*** *Urban P et al. European Heart Journal 2019; 40: 2632–2653;* ***3.*** *Adapted from: Giustino G, et al. JACC 2016; 68: 1851-1864: treatment of all three coronary vessels, treatment of 3 or more lesions, 3 or more DEB or DES, bifurcation lesion with both MB and SB treated, CTO, total device length exceeding 60 mm; S. Eccleshall, EuroPCR 2026;* ***4.*** *At least one bifurcation lesion with MB & SB treated;* ***5.*** *Only small vessels (<=2.75 mm), only large vessels (>2.75 mm), mixed size with small and large vessels included.* ***6.*** *At least 1 long lesion (≥25mm);* ***7.*** *At least 1 lesion with moderate/severe calcified lesion*

PCI risk factors differentially affect TVF according to treatment strategy

Patient level analysis

Cox regression model Included variables	**Simple Model** (variable + treatment)		**Multivariable Model** (adjusted for all listed variables)
	HR (95% CI)	**Treatment Interaction p-value**	**Treatment Interaction p-value**
Age	**1.02 (1.01, 1.04)**	0.24	0.11
Gender	**0.86 (0.62, 1.19)**	0.05	0.18
Diabetes	**1.54 (1.13, 2.09)**	1.00	1.00
ACS	**1.01 (0.74, 1.38)**	0.38	0.44
Bifurcation	**1.68 (1.26, 2.25)**	0.96	0.81
Imaging Use	**1.12 (0.77, 1.62)**	0.39	0.82
HBR	1.37 (0.95, 1.96)	**0.04**	**0.04**
Complex procedure	2.31 (1.72, 3.10)	**0.01**	**0.01**
Vessel size	1.82 (1.22, 2.78)	**0.04**	**0.03**
	1.67 (1.07, 2.59)		
Long Lesion	1.61 (1.16, 2.21)	**0.07**	**0.08**
Calcification	1.55 (1.14, 2.10)	**0.04**	**0.06**
Multivessel Disease	1.83 (1.31, 2.54)	**0.03**	**0.03**

Significant variables have interaction p-values that retain signal across simple and multivariable models. Stronger evidence of treatment-effect modification

p-values<0.15 exploratory/suggestive*

**Given the exploratory nature of the analyses and limited power for interaction testing, interaction p-value < 0.15 was used to identify potential treatment-effect modifiers for further evaluation.*

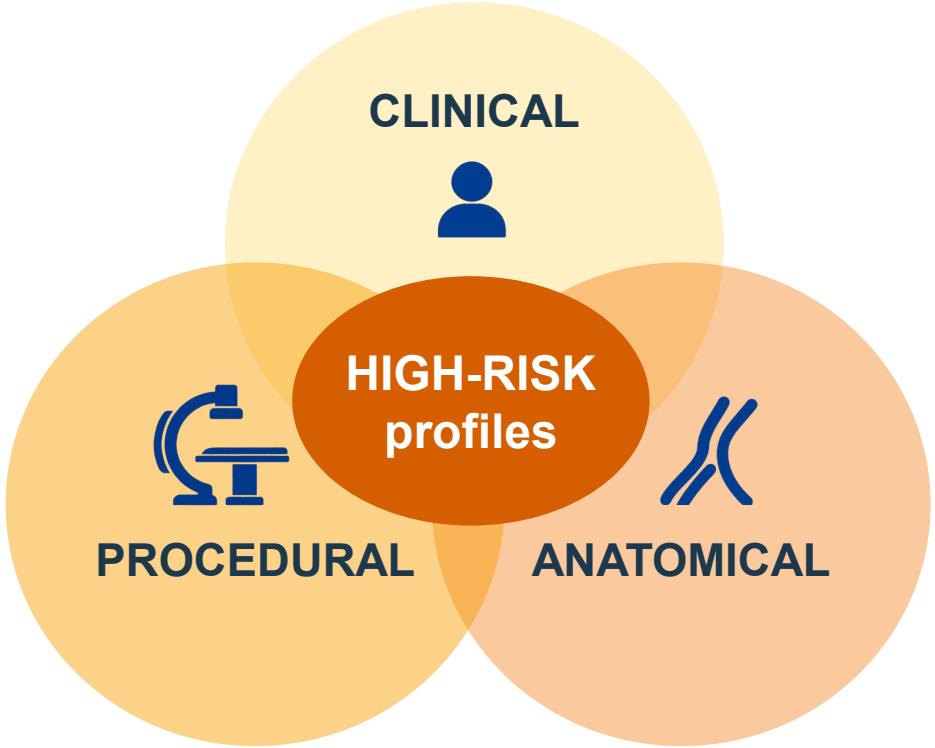
From the interaction signals to high-risk profiles

COX significant interaction variables largely corresponds
to profiles typically associated with high-risk profiles, where DES have known limitations[1]

SIGNIFICANT INTERACTIONS

- HBR
- Complex procedure*
- Vessel size
- Lesion length
- Calcification
- Multivessel Disease

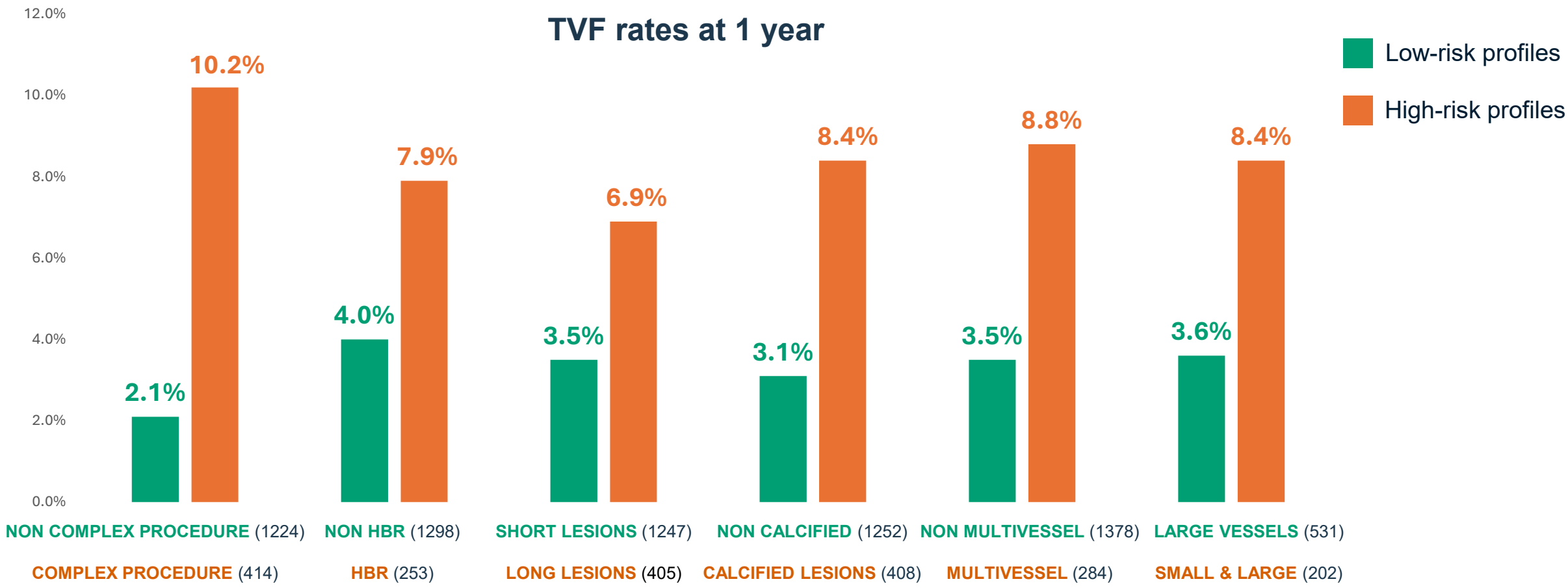
HIGH-RISK PROFILES



M Konigstein, et al. *American heart journal* 213 (2019): 105-111.
* *Adapted from: Giustino G, et al. JACC 2016; 68: 1851-1864; S. Eccleshall, EuroPCR 2026;*

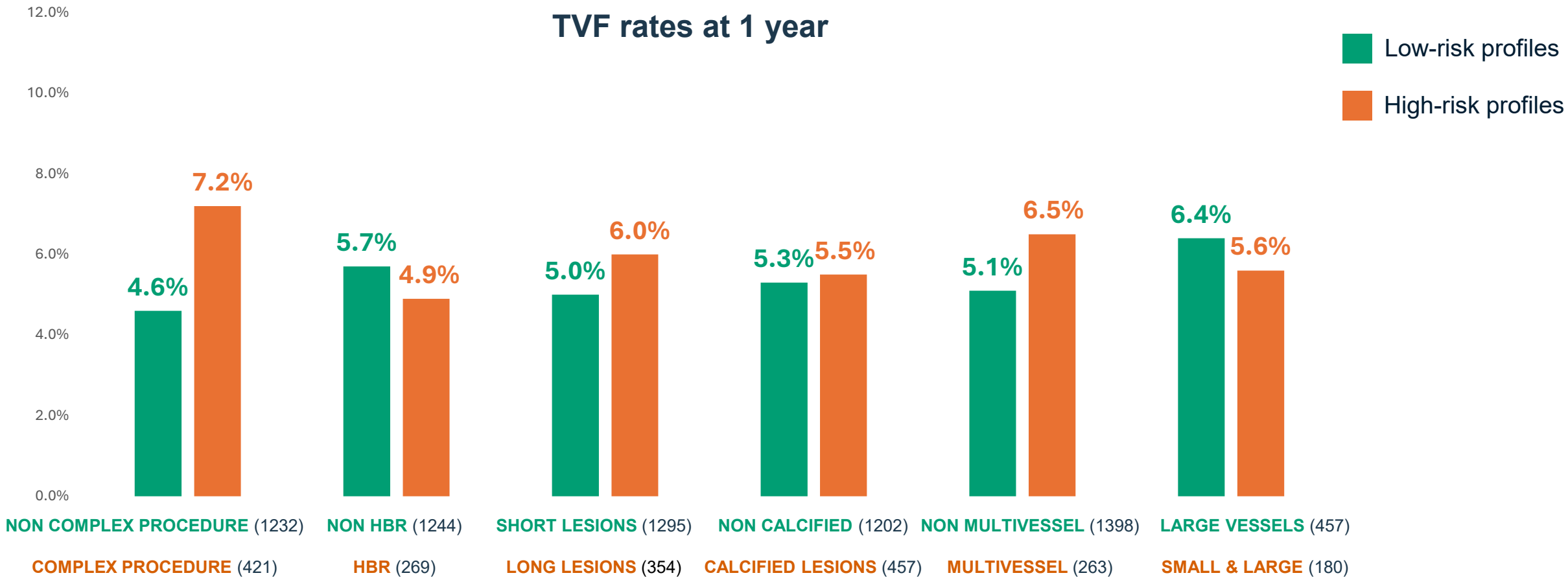
Patient level analysis - TVF in the DES strategy

Low-risk vs high-risk profiles



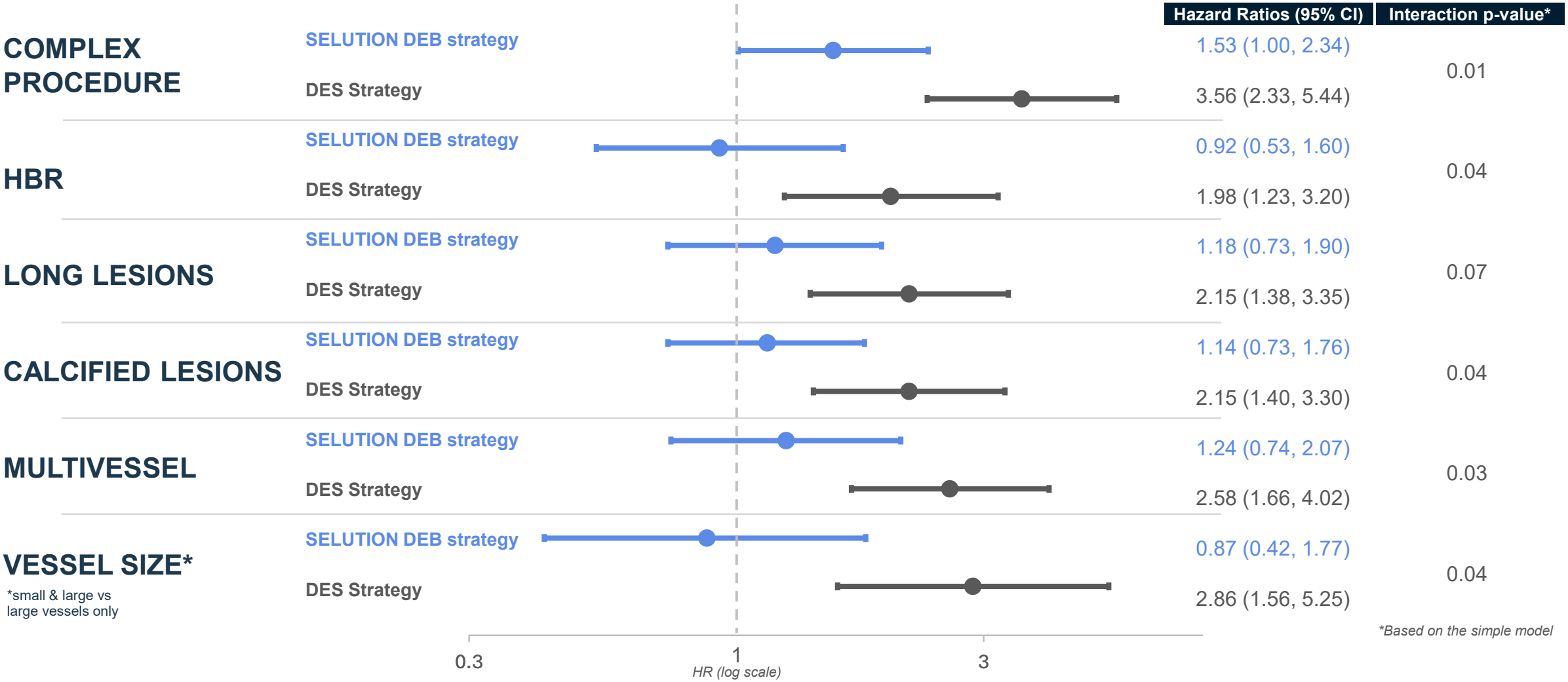
Patient level analysis - TVF in the SELUTION DEB strategy

Low-risk vs high-risk profiles

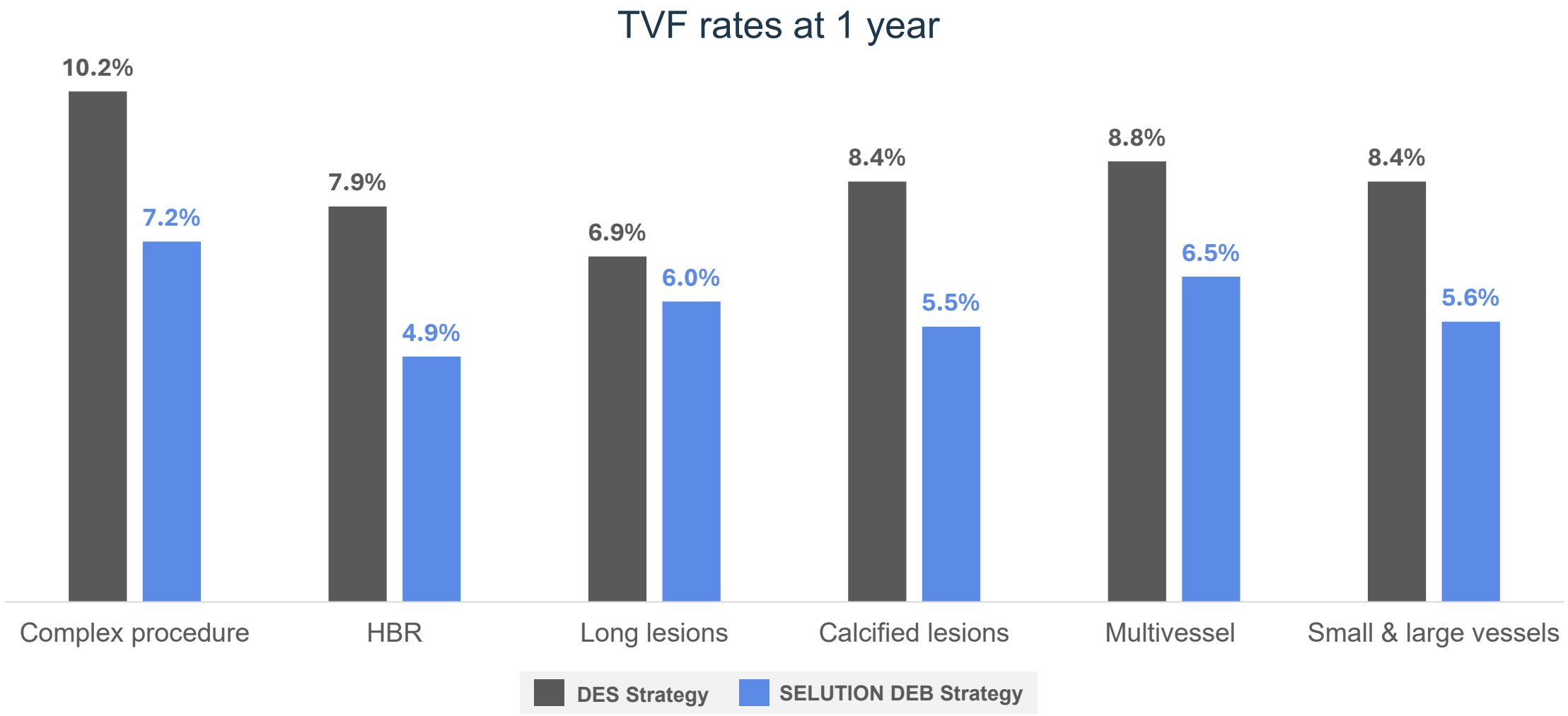


Consistency of TVF risk across variables

Increased risk of TVF in the DES strategy group and consistent outcomes in the SELUTION DEB strategy group



Potential clinical benefit of SELUTION DEB strategy in high-risk profiles



Limitations

- The results of this post-hoc exploratory analysis are hypothesis generating
- The risk factors for PCI are not standardized; alternative variables could have been chosen
- Mechanistic and procedural aspects not considered in this analysis could influence the results
- The variables identified in this analysis are established predictors of stent failure; factors associated with DEB failure remain less well characterized

Conclusions

- In the DES strategy group, high-risk profiles were associated with increased rates of TVF compared with low-risk profiles
- In contrast, TVF rates in the SELUTION DEB strategy were more consistent across PCI risk profiles, with lower event rates observed in high-risk profiles compared with the DES strategy
- The findings suggest a potential treatment-by-risk-profile interaction, with a possible relative advantage of the DEB strategy in selected high-risk profiles subgroups
- These findings warrant further evaluation through the trial's 5-year follow-up and adequately powered randomized trials on high-risk profiles are needed