CRT26
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Operator experience effect on Sirolimus Eluting Balloon (SEB) strategy for de novo coronary lesions

A sub-study of the SELUTION DeNovo trial

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for the SELUTION DeNovo Investigators

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

Study device

SELUTION SLR Drug-Eluting Balloon

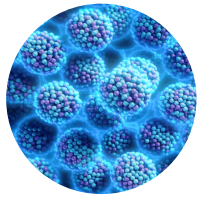


*Device not approved and available for sale in the US



MicroReservoirs

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



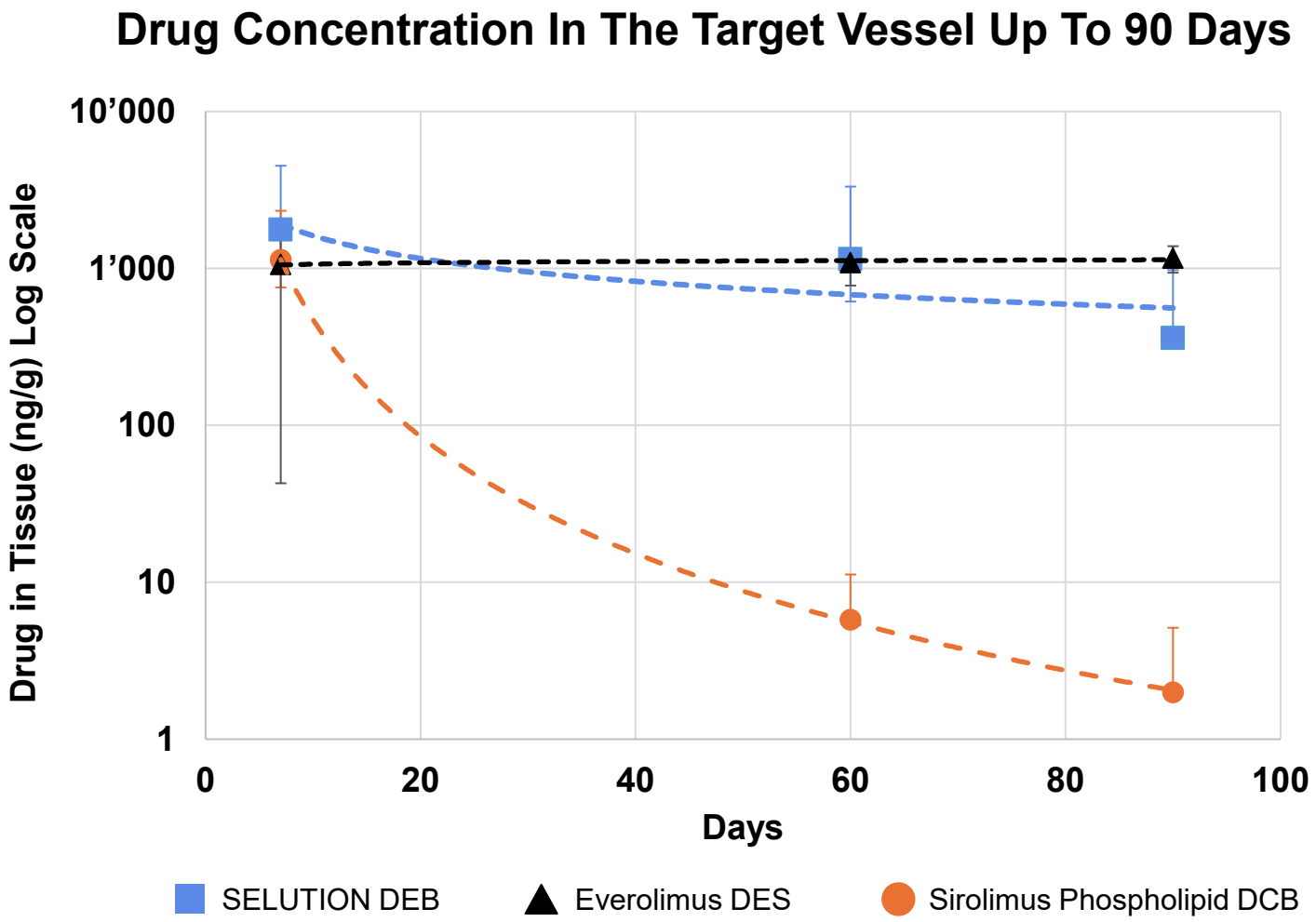
Proprietary Phospholipid Coating

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

Pharmacokinetics



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

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

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

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 lesion pre-dilatation
- 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

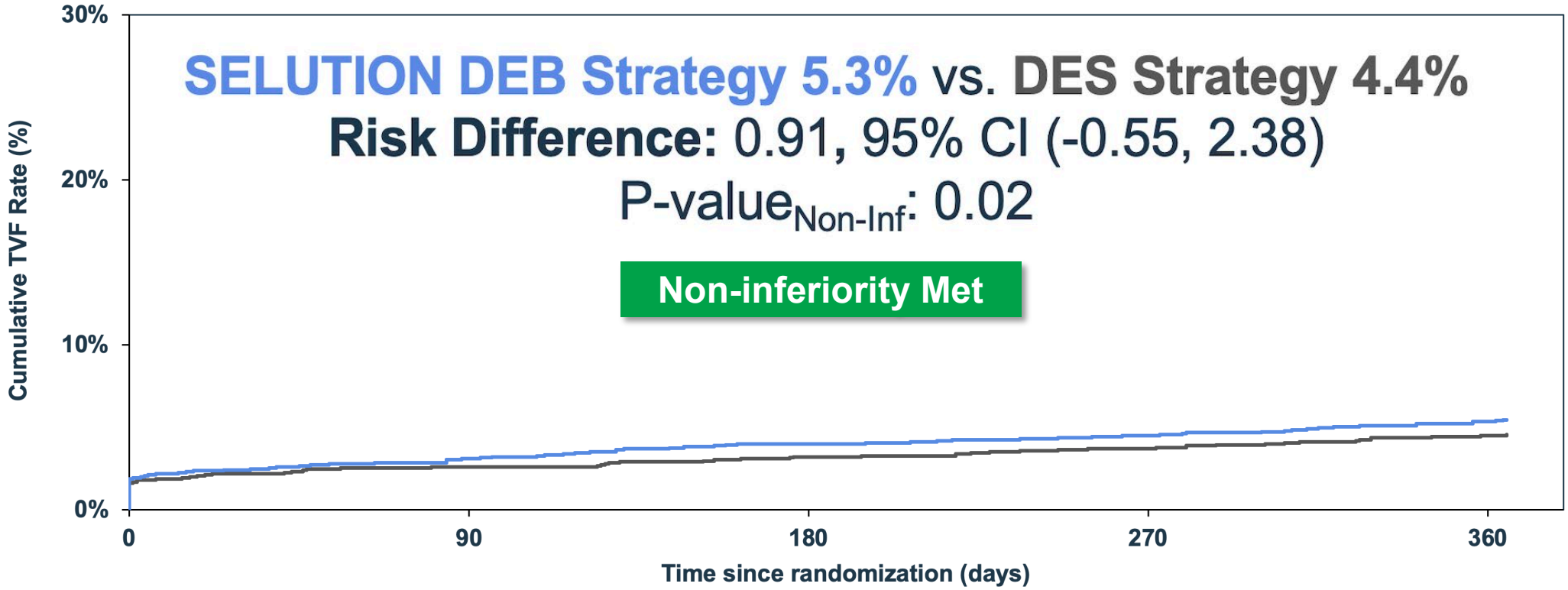
Adjunctive devices according to operator preference:

- 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

Cumulative incidence of TVF at 1-year



# 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

TVF: A composite of cardiac death, TV-MI and CD-TVR

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

Background

- When our trial began enrolling, operator experience with DCBs/DEBs for *de novo* lesions was highly variable from center to center
- Reasons for provisional stenting are related not only to flow-limiting dissections or recoil, but also a desire for an optimal (“clean”) angiographic result and the use of DES as a “safety net”.
- Many operators gained experience both inside and outside the trial, and learned to better assess the need for bail-out stenting
- This post-hoc analysis aims to assess how the SEB-based approach evolved between August 2021 and July 2024 in the 62 participating centers

Early vs. later experience with the SEB strategy

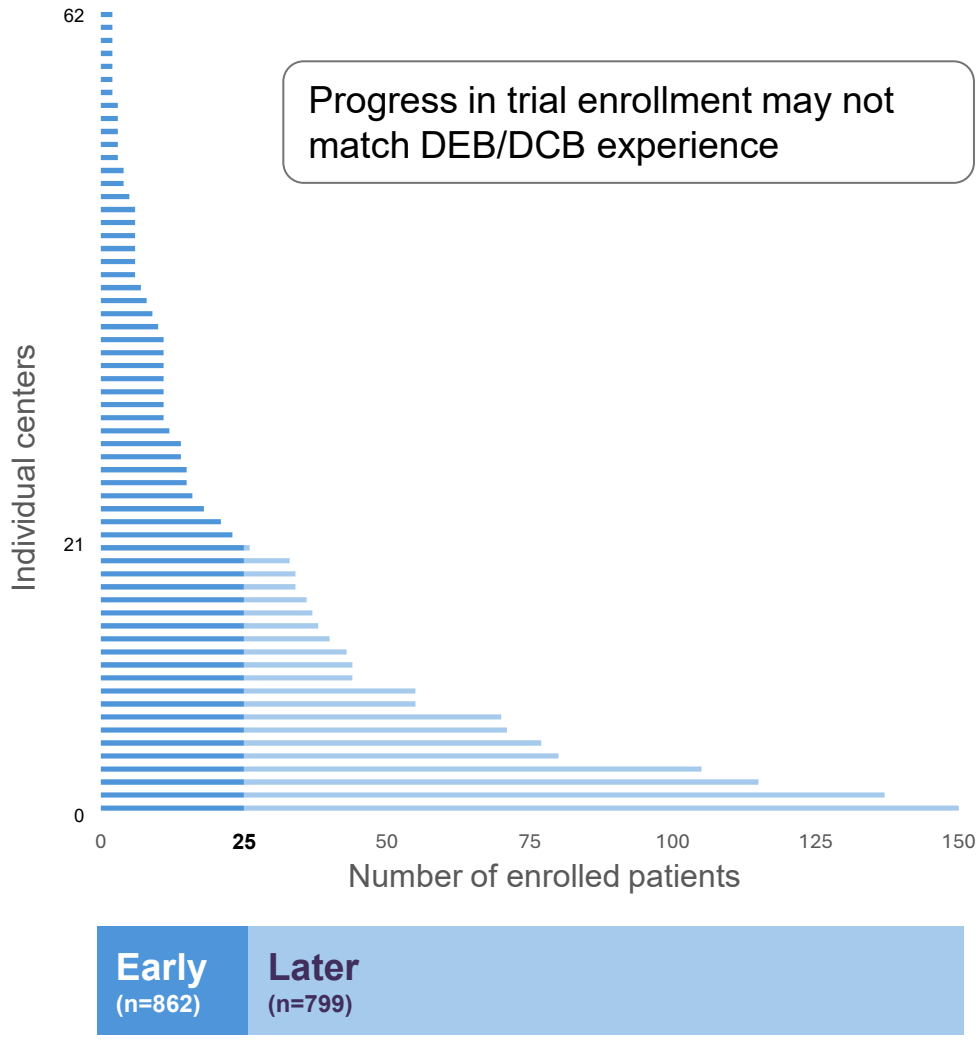
All 1661 patients in the DEB arm

For each of the 62 centers, patients were allocated to one of two groups:

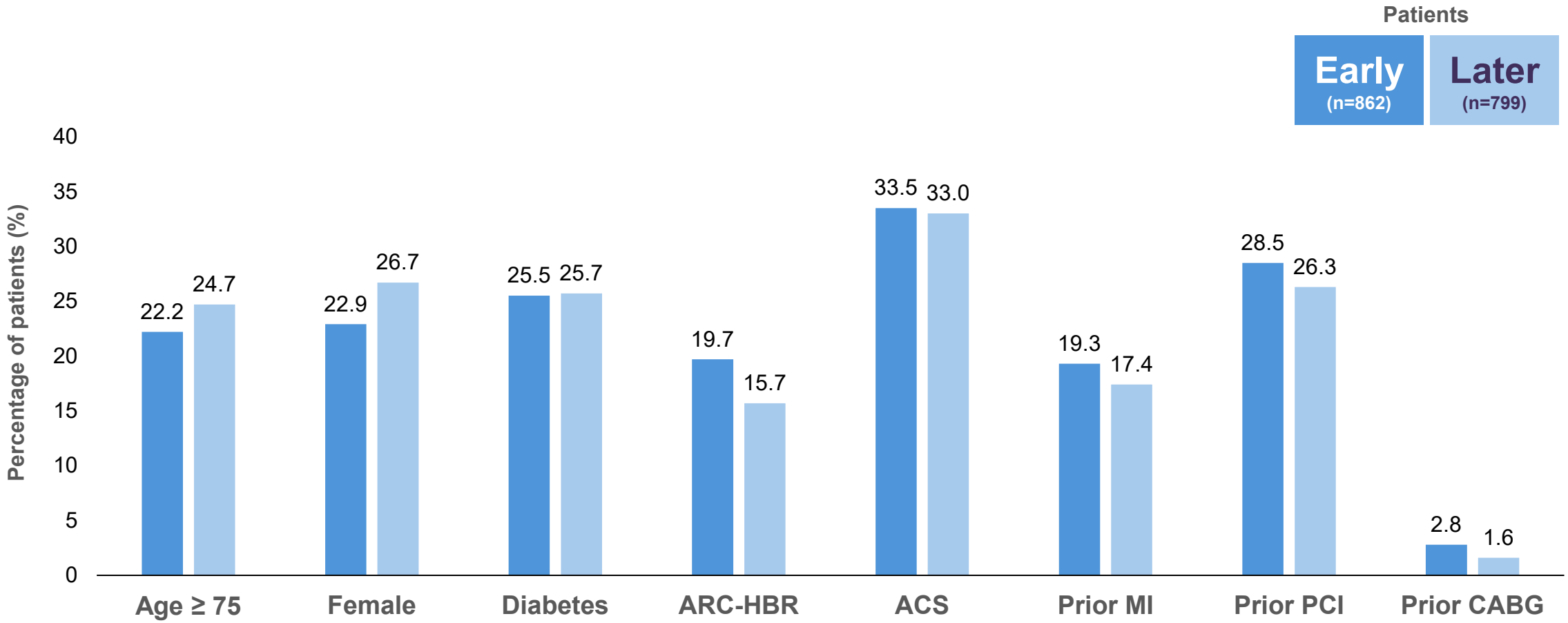
- **“Early”** = first 25 patients enrolled in the DEB arm
- **“Later”** = all subsequent patients in the DEB arm

All 62 centers contributed to the “early“ group.
21 centers with high enrollment contributed to the “later” group

Progress in trial enrollment may not match DEB/DCB experience

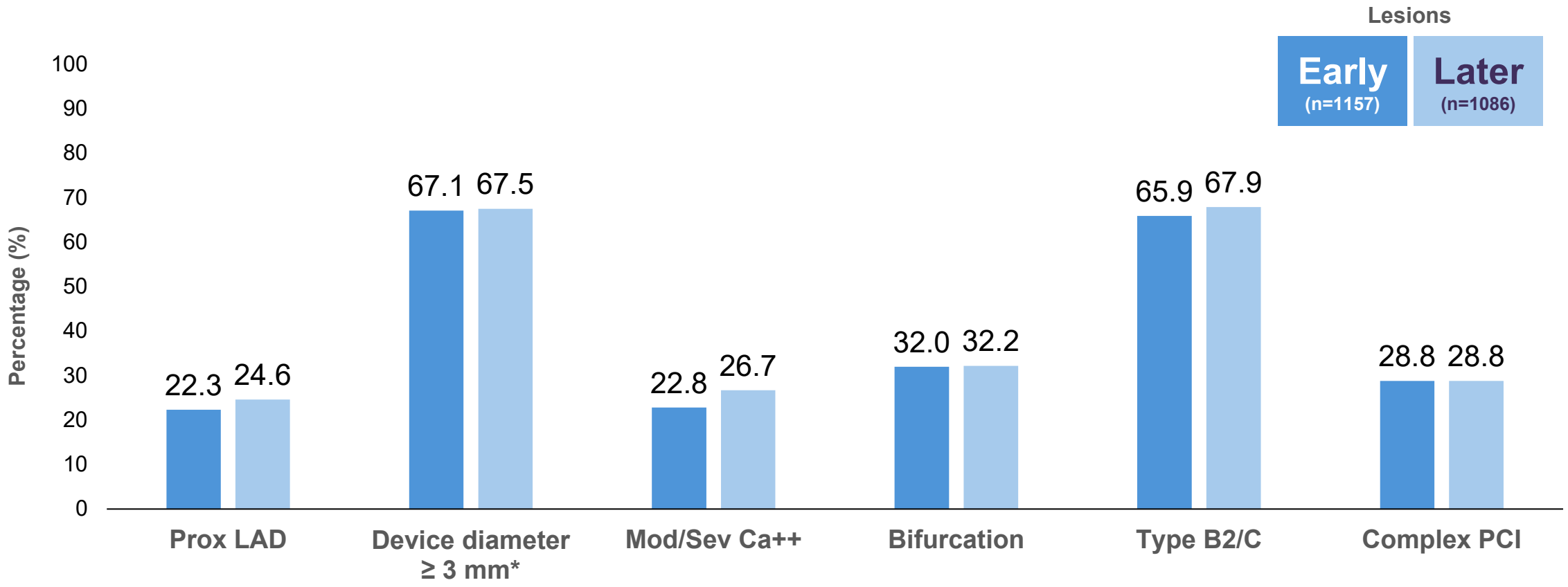


Baseline clinical characteristics



Groups are similar

Baseline angiographic characteristics

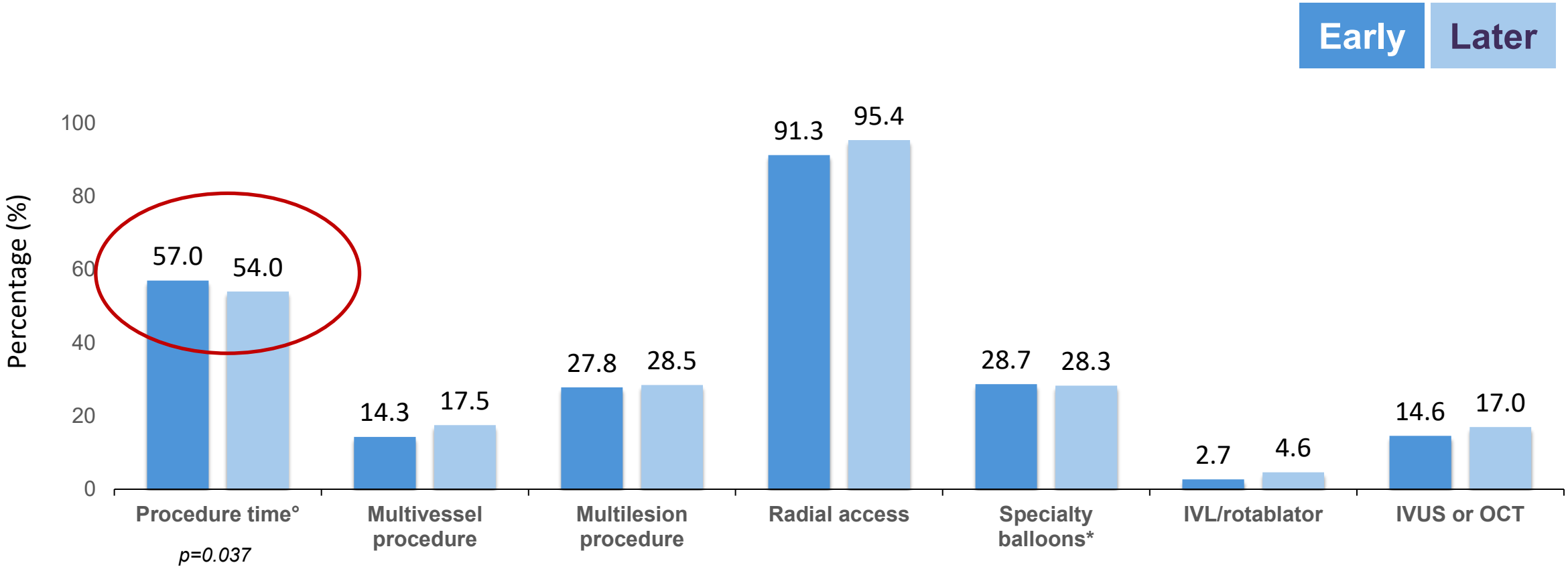


* Based on largest used nominal device diameter

Average number of lesions per patient 1.4 + 0.6 in early experience and 1.3 ± 0.6 In later experience

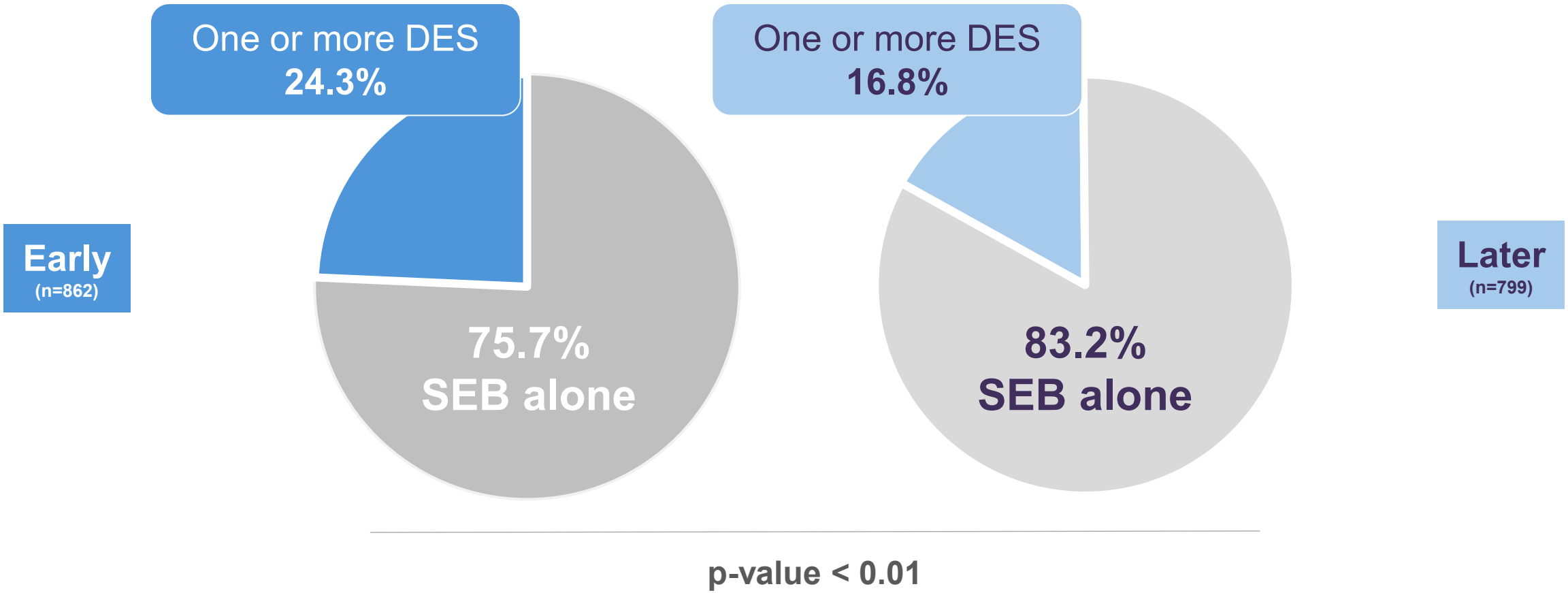
Complex PCI: when patients were treated with at least one of the following criteria: treatment of all three coronary vessels, treatment of three or more lesions, bifurcation lesions requiring two devices, chronic total occlusion target lesion, implantation of three or more drug-eluting balloons or stents, or total device length exceeding 60 mm.

Procedural characteristics

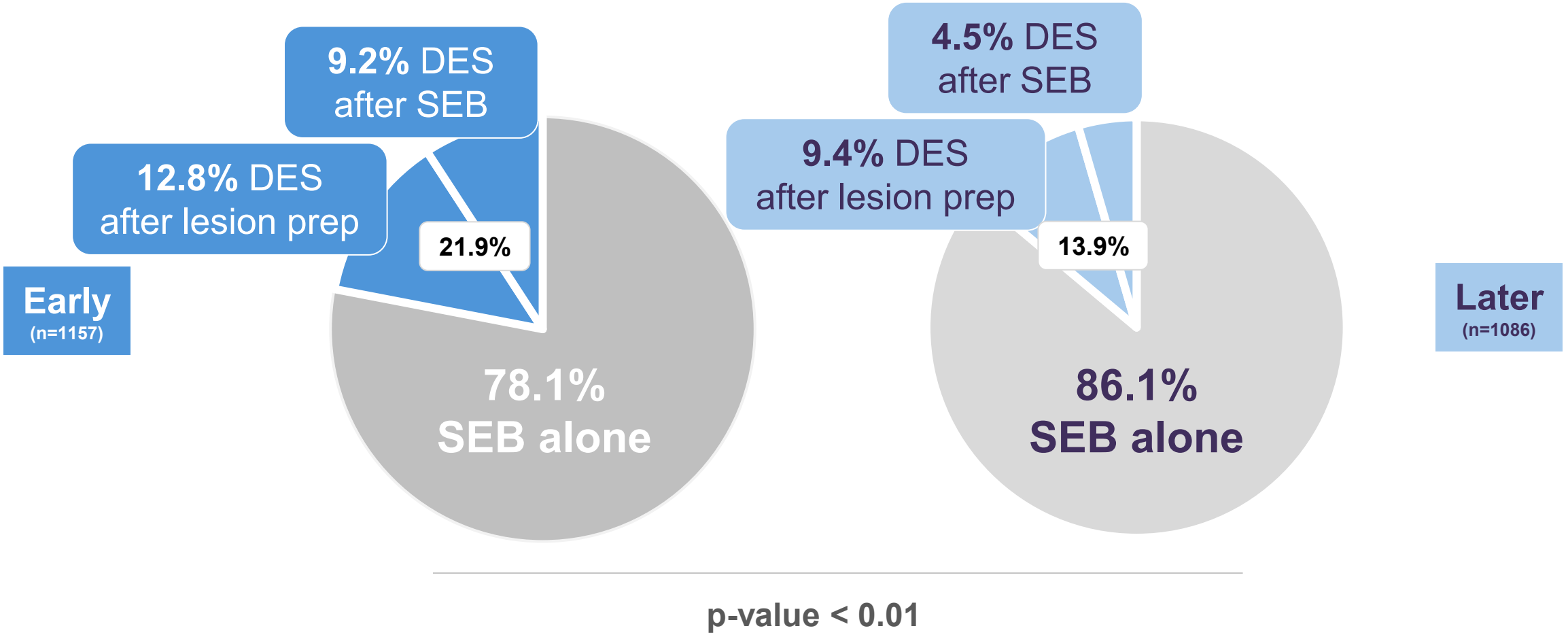


° Procedure time expressed in minutes
*Specialty balloons include scoring, cutting and high-pressure balloons
Percentages are derived from the total number of procedures or lesions, as applicable

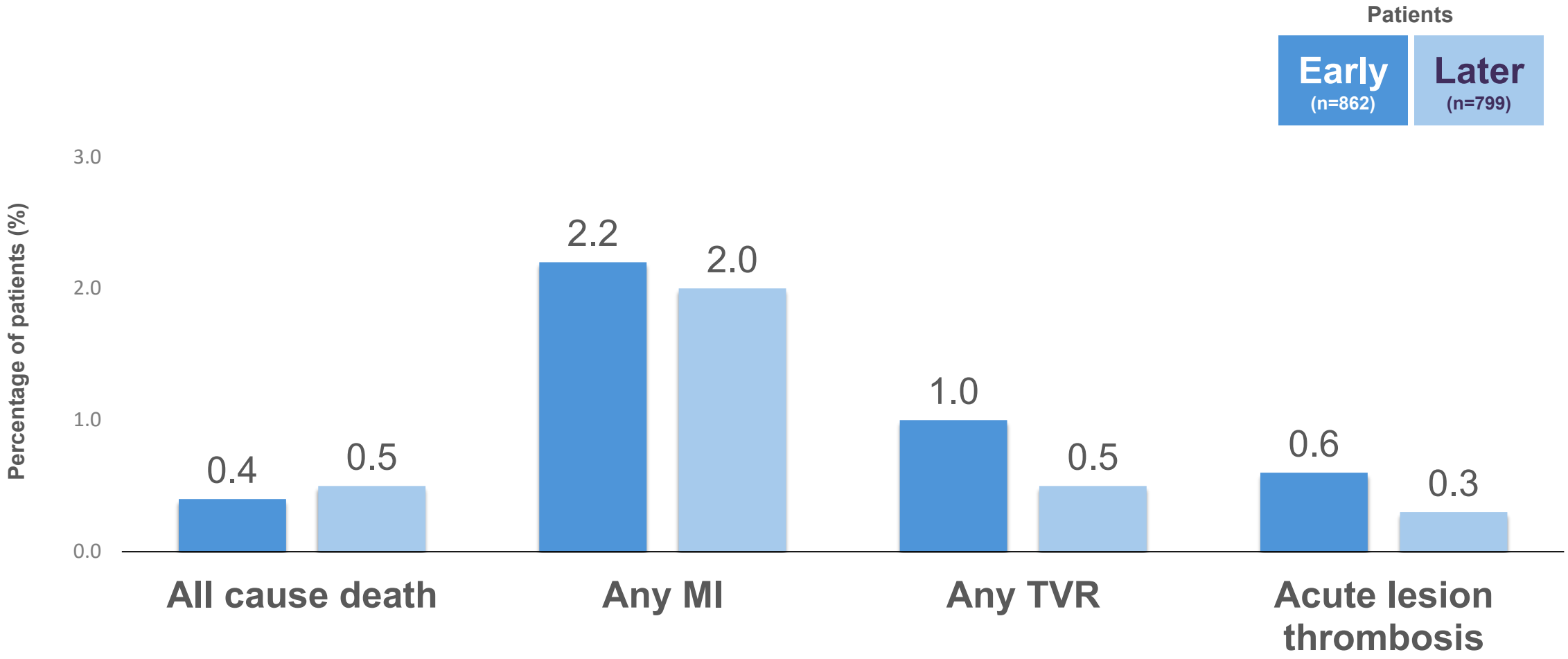
Provisional stenting per patient



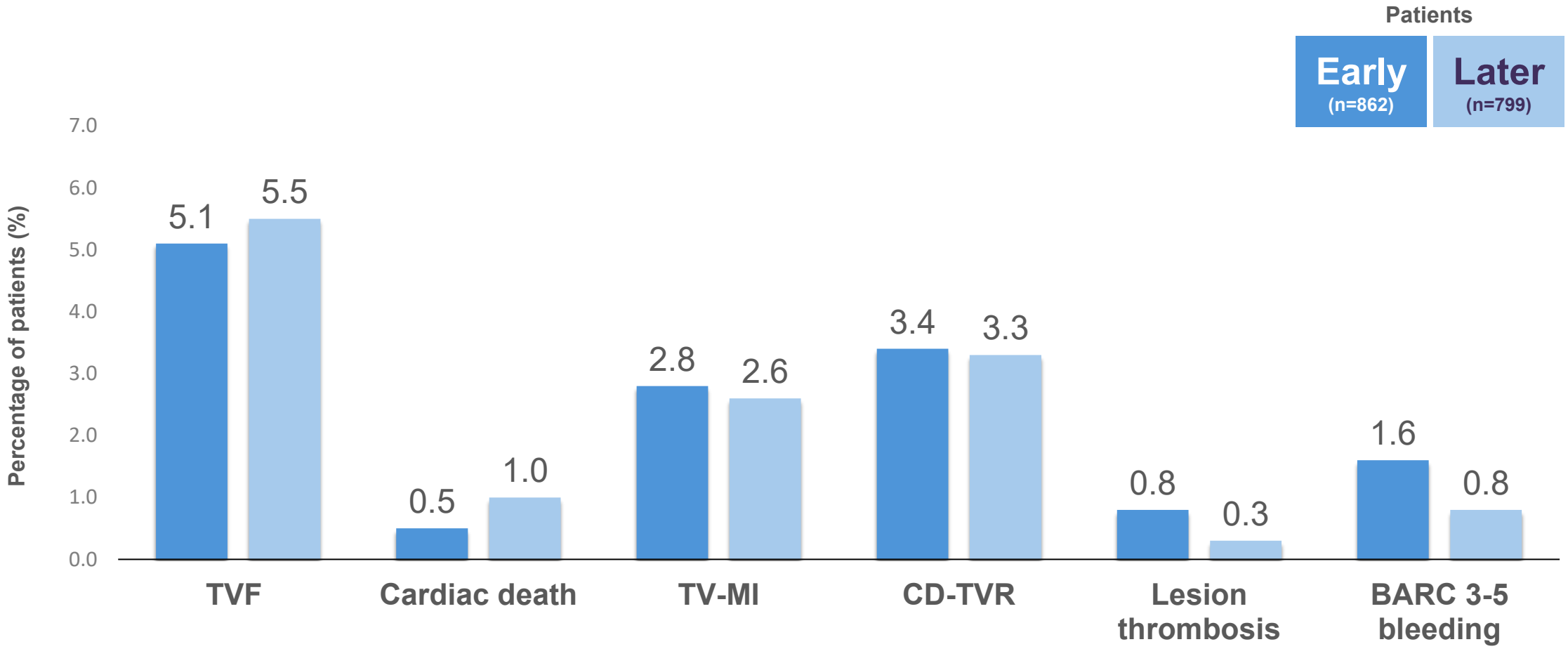
Provisional stenting per lesion



Safety at 30 days



Outcomes at 1-year



TVF: A composite of cardiac death, TV-MI and CD-TVR

Limitations

- As a post-hoc evaluation, the findings should be considered exploratory and hypothesis-generating
- The analysis was performed at the center level and does not account for individual operator experience
- Progress in trial enrollment doesn’t necessarily correlate to DEB/DCB experience
- The threshold of 25 cases may not reflect a clinically validated or statistically optimized volume threshold
- The analysis looks at 62 centers, but only 21 centers have early and later patients

Conclusions

- Patient, lesion and procedure characteristics remained largely unchanged as centers gained experience
- As individual centers gained experience, operator confidence increased, leading to a >30% reduction in the use of provisional stenting without adversely affecting early safety or one-year outcomes
- The potential benefits of reducing the number of implanted stents will be further evaluated at five years