2018 PCR london valves

One-year outcomes with the transcatheter LOTUS Edge Aortic Valve System

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On behalf of the LOTUS Edge Investigators:

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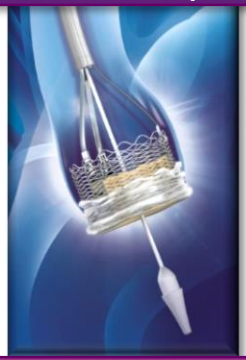
Potential conflicts of interest

Speaker's name : Matthias Götberg, MD, PhD

☑ I have the following potential conflicts of interest to report:
Receipt of honoraria or consultation fees: Boston Scientific
Grants/research support: Boston Scientific
Salary support: full-time proctor for Boston Scientific as of 01 Sept 2018

The Next Generation LOTUS *Edge*™ Valve System
Design Goals

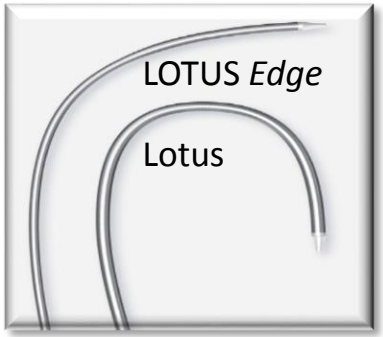
Unique features of the first-generation Lotus Valve conserved



- Adaptive seal to provide surgical-like PVL
- Mechanical expansion
  - Consistent, stable delivery
  - 100% repositionable and retrievable
- Early valve function provides haemodynamic stability

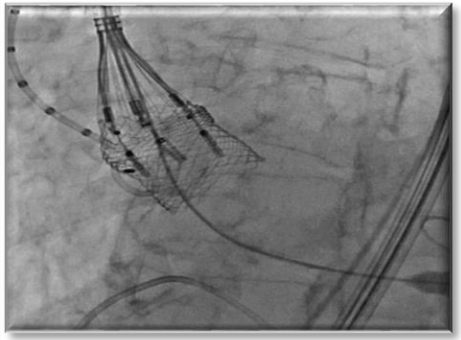
New features with LOTUS *Edge* Valve System

LOTUS *Edge* Catheter



- Increased flexibility
- Improved coaxial alignment with optimized pre-shape curve
- Proximal catheter profile reduction (3F – 4F)

LOTUS *Edge* Valve



- One-view locking with radio-opaque markers
- Limited depth of implant with Depth Guard™ technology

Study Design

Combined results from two single-arm studies with similar protocols and identical core labs designed to evaluate the safety and performance of the LOTUS Edge Valve System

	Lotus EDGE Feasibility Study	REPRISE EDGE
	21 high-surgical-risk patients with symptomatic calcific aortic stenosis enrolled at 2 centres in Australia	15 high-surgical-risk patients with symptomatic calcific aortic stenosis enrolled at 3 centres in Europe
Primary Endpoint:	Technical success*	Mean gradient at discharge/7d†
Key 2° Endpoints:	Mean gradient and AVA at discharge/7d†, paravalvular leak†, VARC-2 endpoints	Technical success*, mean AVA at 7d/discharge, paravalvular leak†, VARC-2 endpoints
Follow-up:	Baseline, peri/post-procedure, discharge/7d, 30d, 6 months, and 1 year	Baseline, peri/post-procedure, discharge/7d, 30d, 6 months, and 1 year

LOTUS *Edge* Combined Cohort (N=36)

- 1-year clinical follow-up available: 97.2% (35/36)
  (1 patient missed the 1-year visit in REPRISE EDGE)
- 1-year TTE Assessment Performed: 34

*Defined as successful vascular access, delivery, & deployment of 1 Lotus valve in the proper anatomic position with successful retrieval of the delivery system.
†As assessed by an independent core laboratory. AVA=aortic valve area; TTE=transthoracic echocardiography

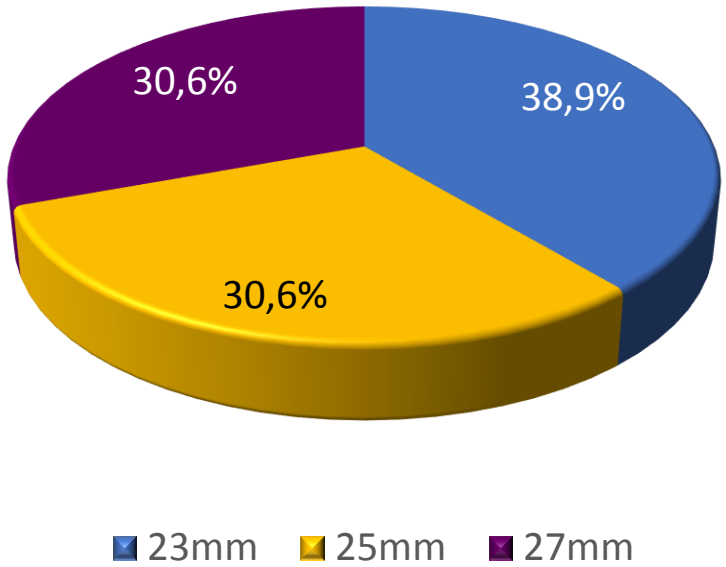
Baseline Characteristics

Characteristic	Feasibility Study N=21	REPRISE EDGE N=15	Overall N=36
Female	61.9%	66.7%	63.9%
Age, years	84.0 ± 5.1	83.2 ± 6.1	83.7 ± 5.4
STS Score, %	4.3 ± 1.5	4.5 ± 2.5	4.4 ± 1.9
EuroSCORE 2011, %	4.1 ± 3.3	5.4 ± 3.8	4.7 ± 3.6
History of stroke, %	4.8%	13.3%	8.3%
NYHA Functional Class III or IV	57.1%	66.7%	61.1%
Mean aortic valve area, $cm^{2\dagger}$	0.63 ± 0.19	0.64 ± 0.19	0.63 ± 0.19
Mean aortic valve gradient, mmHg†	51.3 ± 9.5	49.5 ± 16.0	50.6 ± 12.2
Calcification, moderate/severe, %†	85.7%	100%	91.2%
Left ventricular ejection fraction, %†	57.5 ± 7.6 (21)	59.1 ± 4.5 (10)	58.0 ± 6.7 (31)
Permanent pacemaker at baseline	14.3% (3/21)	0% (0/15)	8.3% (3/36)

All patients had agreement by the Heart Team that they were at high risk for surgery based on STS Score and/or comorbidities.
†As assessed by an independent core laboratory

Periprocedural Outcomes

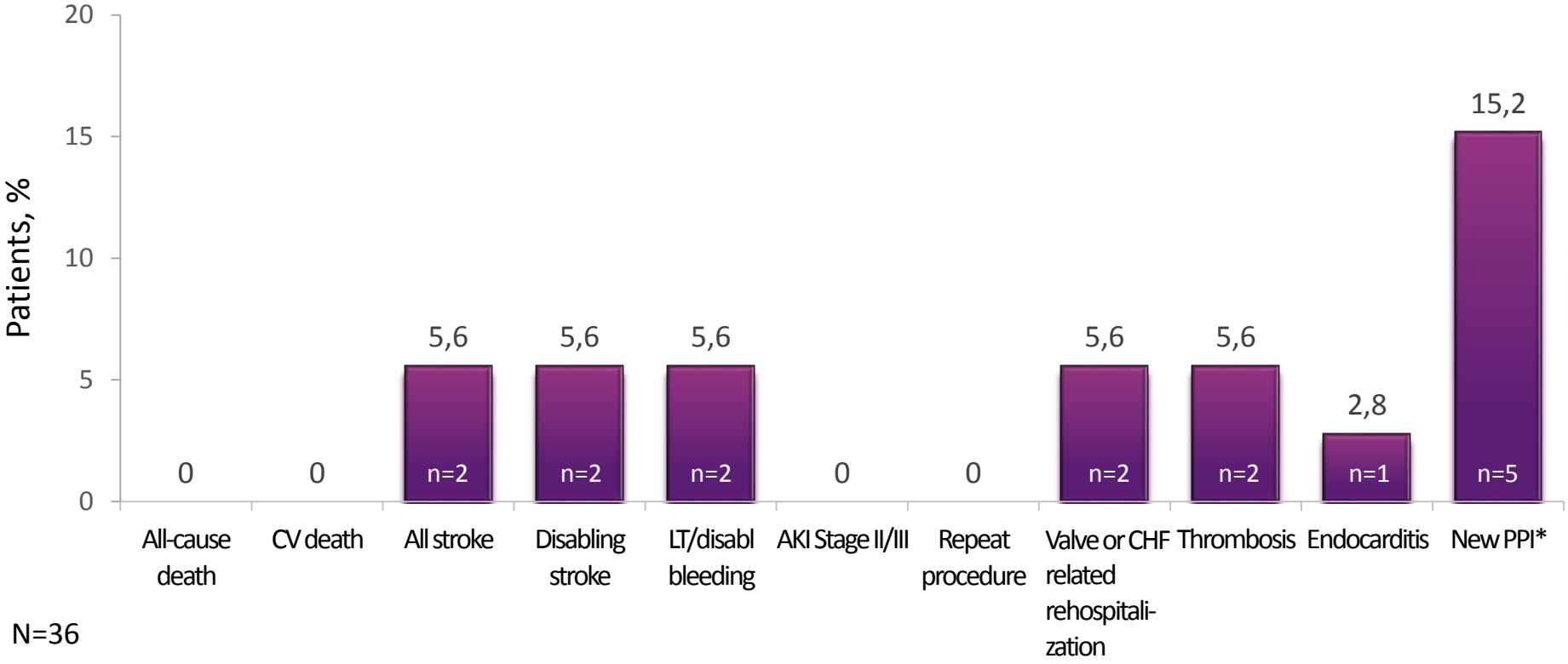
Valve Size Implanted



Characteristic	Overall N=36
Technical success, %*	100%
Mean depth of implantation, mm (n)	4.6 ± 2.2 (35)
Valve repositioned	67%
Valve fully retrieved	6%
Major vascular complications, %	13.9%
Coronary obstruction, %	0%
Cardiac tamponade, %	0%
Ventricular septal perforation, %	0%
Valve migration, %	0%
Valve embolization, %	0%
TAV-in-TAV performed, %	0%

*Defined as successful vascular access, delivery, & deployment of 1 Lotus valve in the proper anatomic position with successful retrieval of the delivery system.

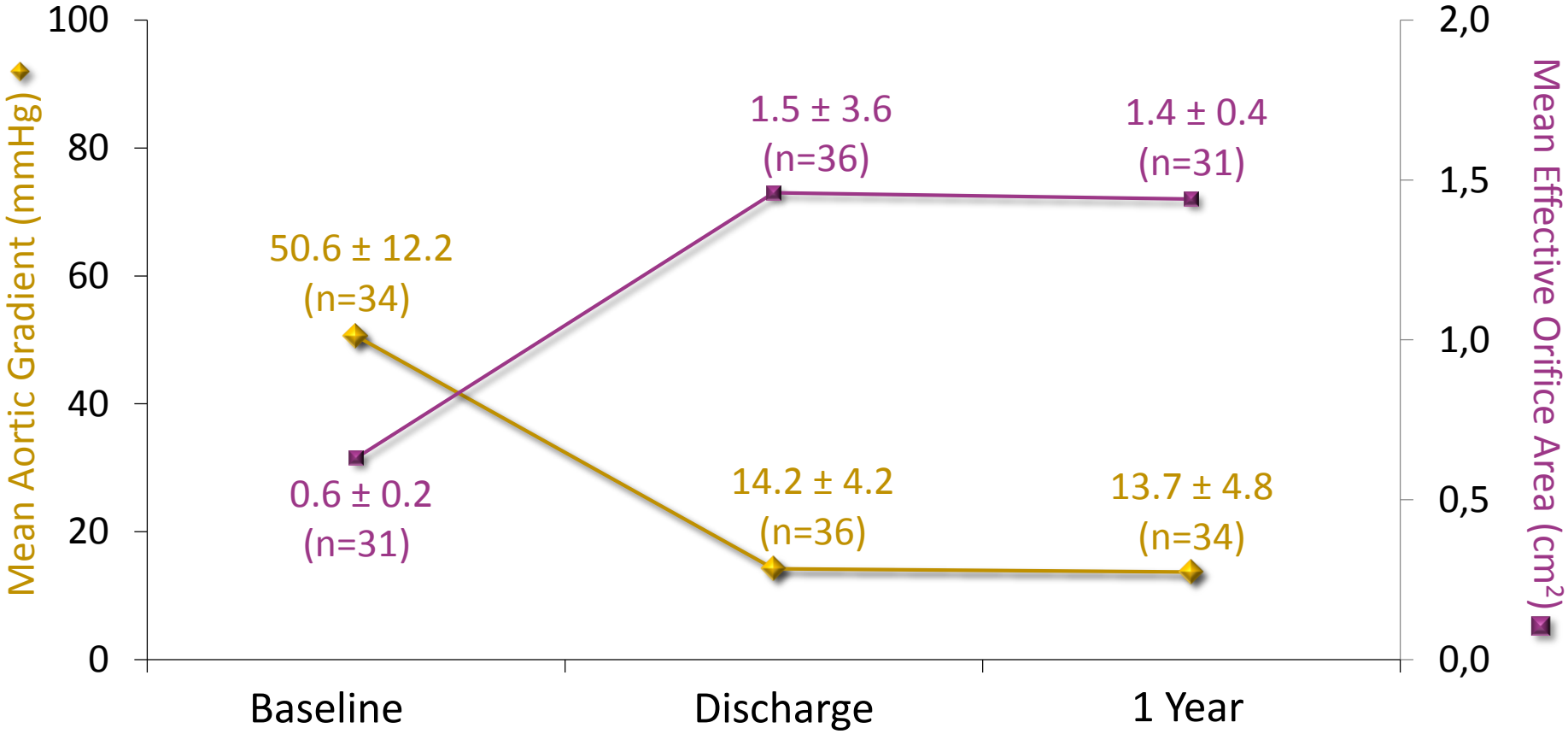
Clinical Outcomes Through 1 Year



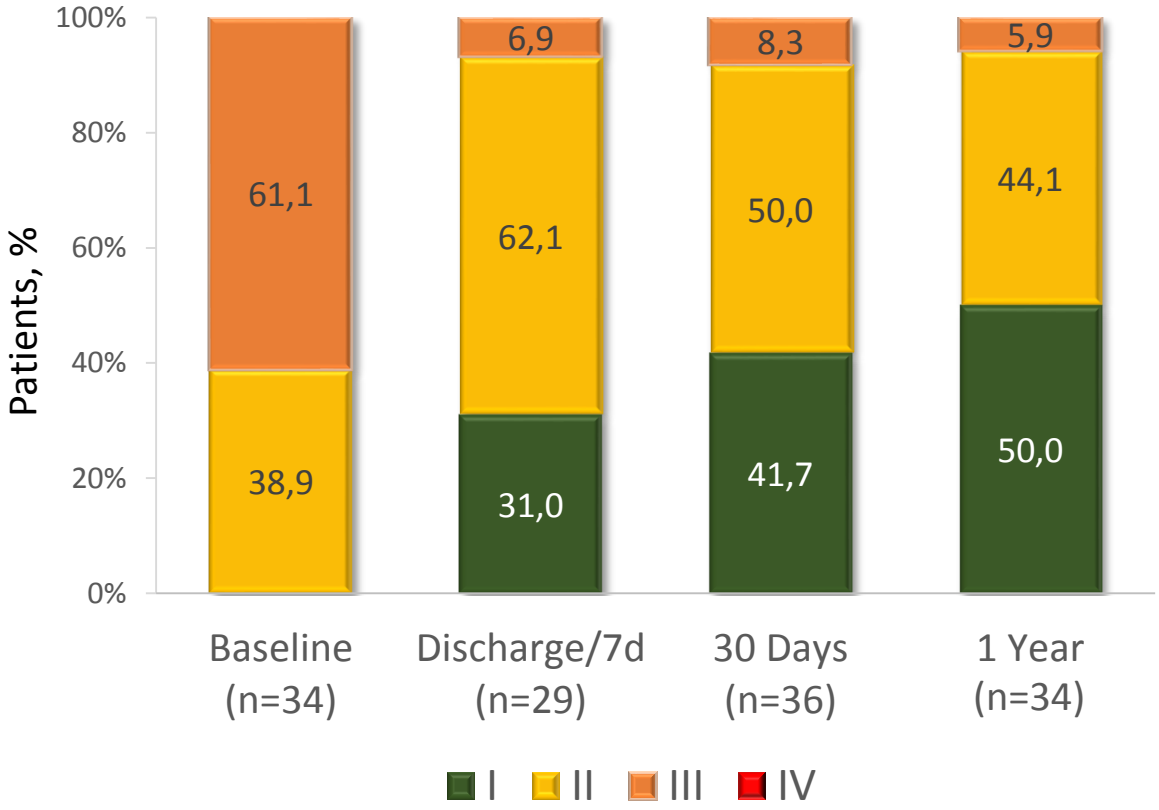
N=36

*Rate excludes patients with permanent pacemaker at baseline (n=3). CV=cardiovascular. LT=life-threatening. AKI=acute kidney injury. PPI=permanent pacemaker implantation.

Haemodynamic Outcomes Through 1 Year

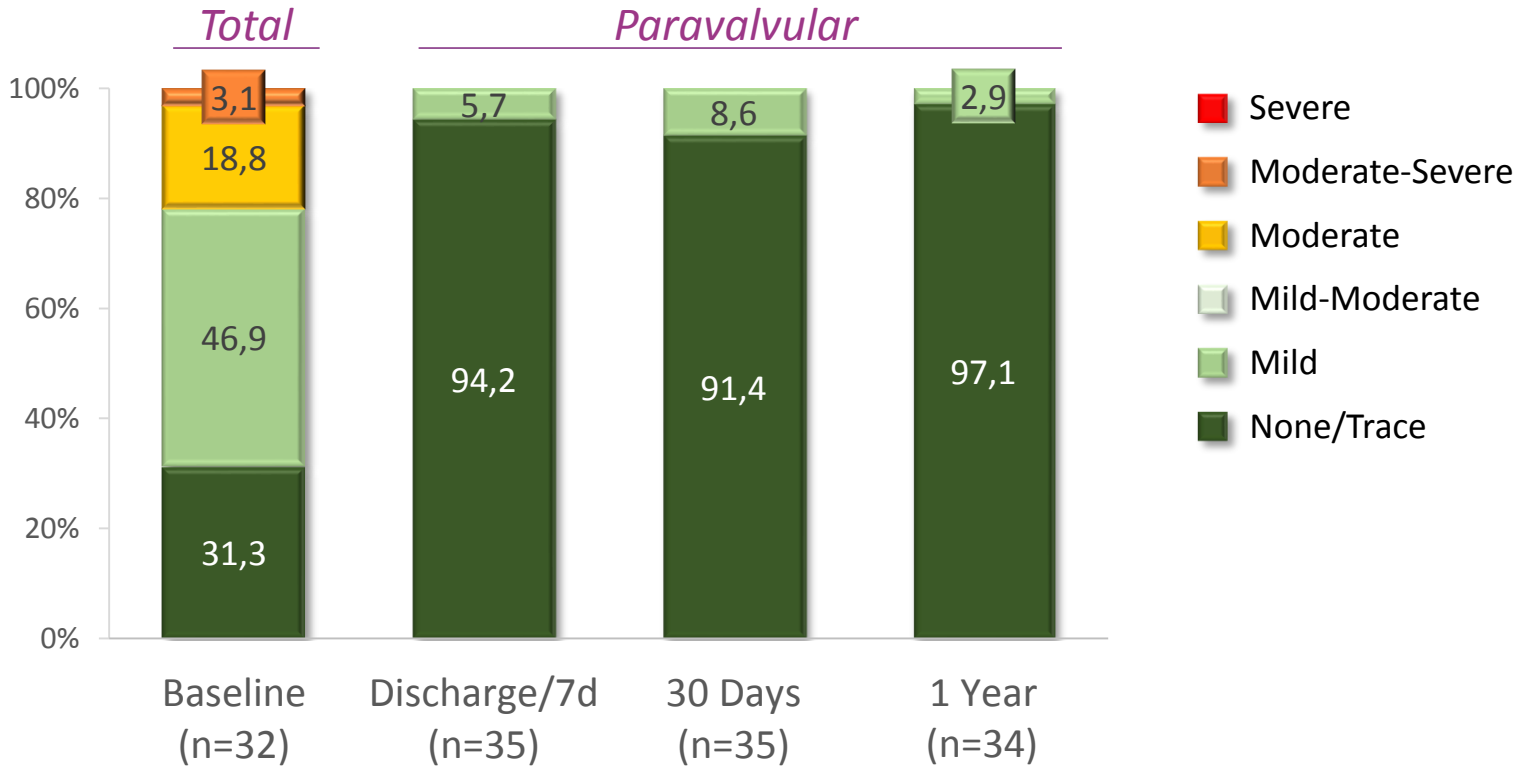


NYHA Class Through 1 Year



Improvement From Baseline to 1 year	Patients N=34
At least 1 NYHA class	76.5%
At least 2 NYHA classes	29.4%

Aortic Regurgitation Through 1 Year



Among patients with evaluable echocardiograms. As assessed by an independent core laboratory.

Summary & Conclusions

- One-year results with the next-generation LOTUS *Edge* transcatheter aortic valve demonstrate
  - Low rates of death and stroke
  - Sustained haemodynamics and functional improvement
  - 97.1% none/trace paravalvular leak
  - 15.2% rate of new permanent pacemaker vs ~30% with first-generation Lotus
- Limitation: small feasibility study; results need to be confirmed in a larger trial
- The REPRISE IV trial will evaluate outcomes with LOTUS *Edge* in intermediate risk and bicuspid patients. Enrollment is anticipated to begin Q4 2018.

Thank you to the LOTUS Edge Investigators

Study	Enrolling Centre	Enrolled, n
Feasibility Study	Monash Medical Centre, Clayton, VICTORIA, Australia *PI: Robert Gooley, MBBS, PhD*	14
Feasibility Study	The Prince Charles Hospital, Brisbane, Queensland, Australia *PI: 0. Christopher Raffel MB, ChB*	7
REPRISE EDGE	University Hospital of Lund, Lund, Sweden *PI: Matthias Götberg, MD, PhD*	6
REPRISE EDGE	Rigshospitalet Copenhagen, Copenhagen, Denmark *PI: Lars Søndergaard, MD*	5
REPRISE Edge	Clinique Pasteur, Toulouse, France *PI: Nicolas Dumonteil, MD*	4

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Angiography Core Lab

Jeffrey Popma, MD - BIDMC

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