30-day Outcomes of The CENTERA Trial – a New Self-Expanding Transcatheter Heart Valve

Didier Tchétché, MD

On Behalf of the CENTERA Investigators

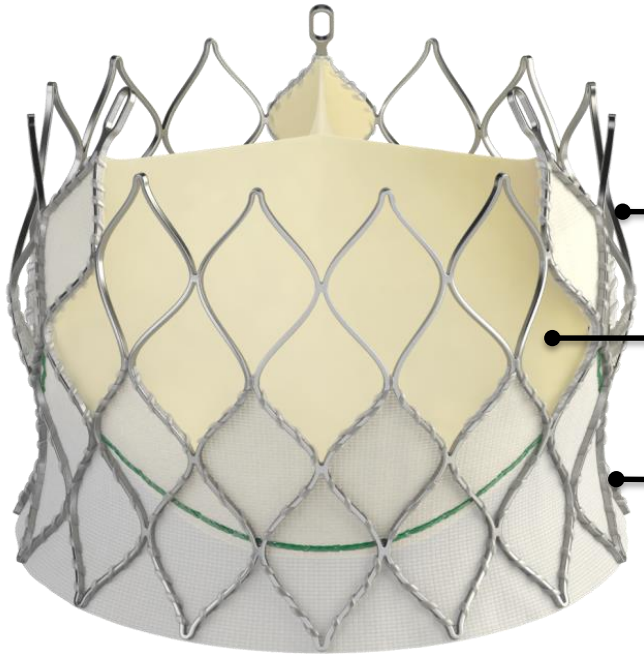
Speaker's name: Didier Tchétché, MD

- **I have the following potential conflicts of interest to report:**

Institutional grant/research support:

Consultant for Edwards Lifesciences

Edwards CENTERA Transcatheter Heart Valve System



Short valve height

Bovine pericardium

Novel contoured frame geometry

23 mm

26 mm

29 mm

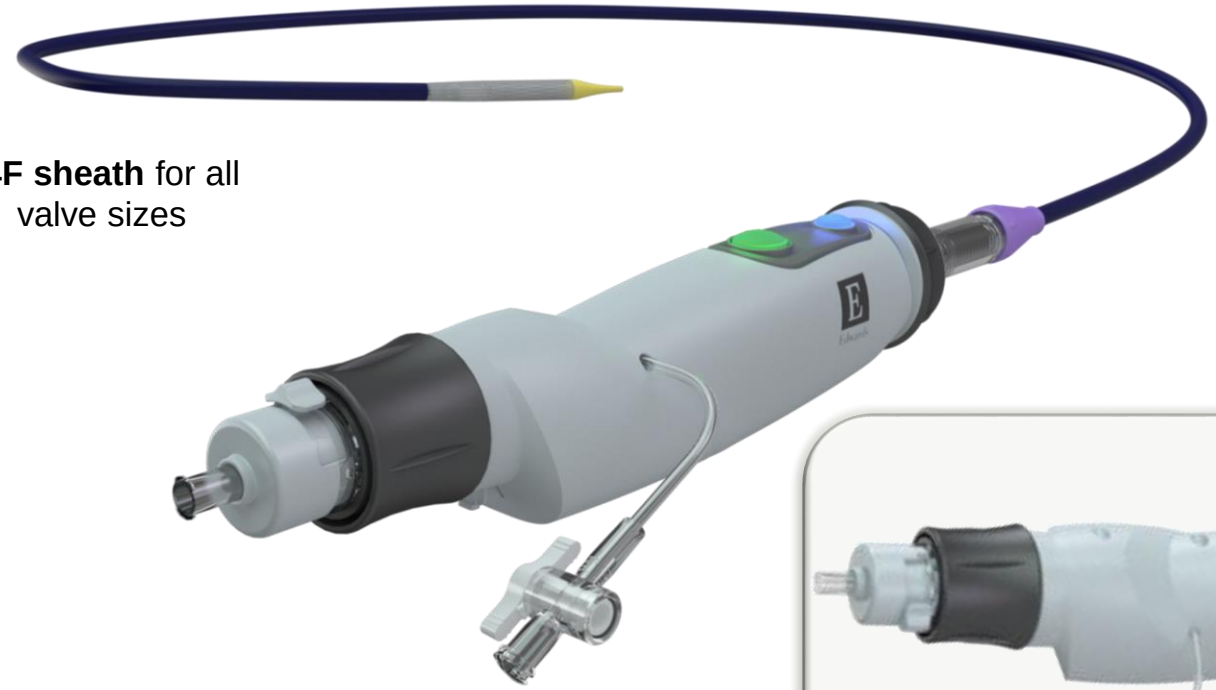
Edwards CENTERA Transcatheter Heart Valve System

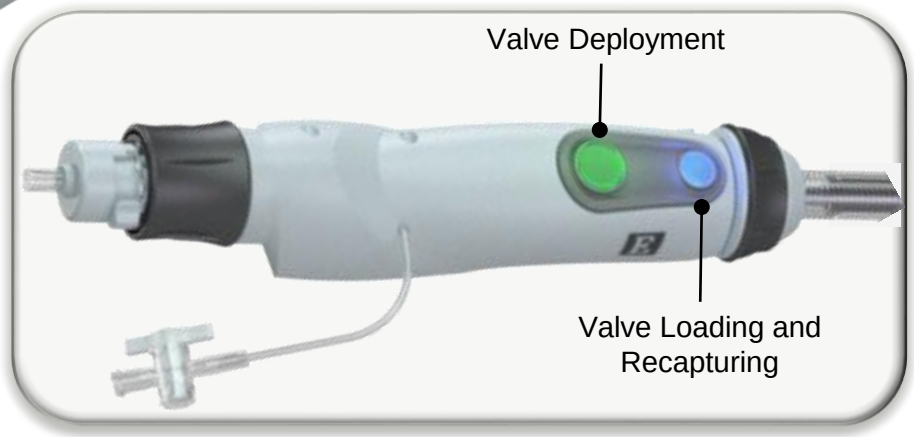
Fully pre-attached valve for rapid device preparation

14F sheath for all valve sizes

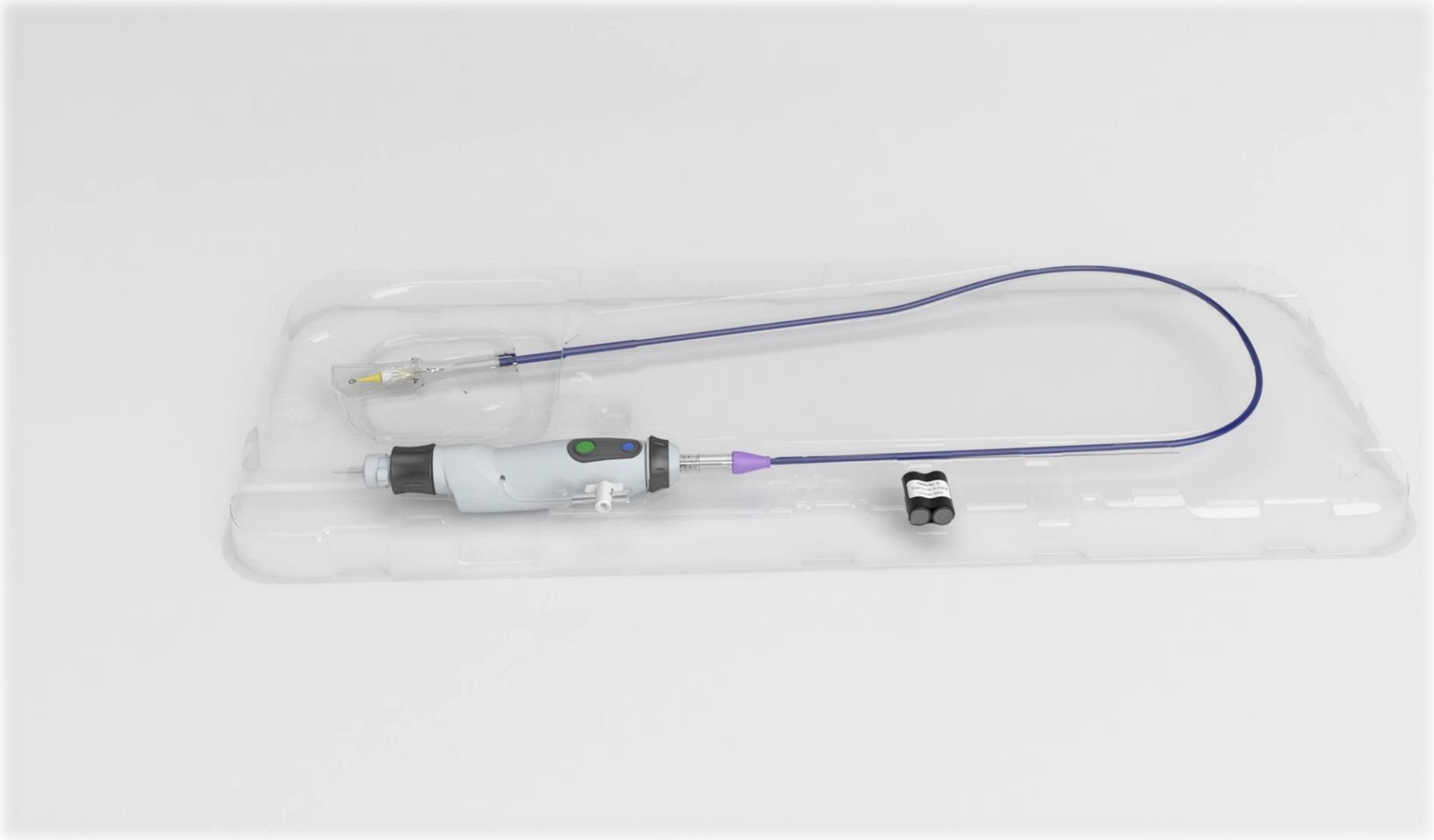
Fully motorized delivery system for stable valve deployment

Repositionable and recapturable if needed





Edwards CENTERA Transcatheter Heart Valve System



Design and Execution

Study Design	Prospective, multi-centre safety and effectiveness clinical investigation
Access	Transfemoral
Enrollment Period	March 2015 - July 2016
Patients	203
Follow-Up Intervals	Hospital discharge, 30 days, 6 months, every year up to 5 years
Organization	Steering Committee, Clinical Events Committee, Echo & CT Corelabs
Key Inclusion Criteria	• Severe AS: Echo-derived AVA ≤ 1.0 cm^2 and mean AVG > 40 mm Hg • Cardiac symptoms: NYHA functional class ≥ II • High surgical risk
Primary Endpoint	All-cause mortality at 30 Days
Key Secondary Endpoints	• Cardiac mortality at 30 days, 6 months, and 1 year • Stroke/disabling stroke • New conduction abnormalities • New onset atrial fibrillation

Implanting Centres

23 centres in **9** participating countries

SITE	PATIENTS
Deutsches Herzzentrum Muenchen, Munich, Germany	27
Clinique Pasteur, Toulouse, France	27
Universitätskliniken Eppendorf, Hamburg, Germany	27
Royal Adelaide Hospital, Adelaide, Australia	18
Prince Charles Hospital, Brisbane, Australia	12
Herzzentrum Bad Segeberg, Bad Segeberg, Germany	10
Herzzentrum Leipzig, Leipzig, Germany	10
Rigshospitalet, Copenhagen, Denmark	10
CHU Rennes, Rennes, France	10
Royal Victoria Hospital, Belfast, United Kingdom	7
AOU Pisana-Stabilimento di Cisanello,Pisa, Italy	6
Epworth HealthCare, Richmond, Australia	5

SITE	PATIENTS
Academisch Medisch Centrum, Amsterdam, Netherlands	5
Ospedale San Raffaele, Milano, Italy	4
Institut Hospitalier Jacques Cartier, Massy, France	4
Städtisches Klinikum Karlsruhe, Karlsruhe, Germany	4
Auckland City Hospital, Auckland, New Zealand	3
Asklepios Klinik St. Georg, Hamburg, Germany	3
Charité Universitätskliniken, Berlin, Germany	3
Inselspital, Bern, Switzerland	2
Klinikum der Universitaet Muenchen – Grosshadern, Grosshadern, Germany	4
Klinikum Augsburg, Augsburg, Germany	1
Universitätskliniken, Muenster, Germany	1
Total	**203**

Baseline Characteristics

Characteristics	As Treated (N=203)
Age Years, Mean ± SD	83 ± 5.5
Female %	67.5
Log EuroSCORE Mean ± SD	17.1 ± 9.8
EuroSCORE II Mean ± SD	5.1 ± 4.0
STS Score Mean ± SD	6.1 ± 4.2
NYHA Class III/IV %	68.0
Previous Stroke %	9.4
Coronary Artery Disease %	39.4
Peripheral Vascular Disease %	14.8
Pulmonary Conditions* %	16.3
Renal Insufficiency %	33.5
Prior Pacemaker %	7.9
Porcelain Aorta %	6.4
Mean Gradient mmHg, Mean ± SD	40.6 ± 13.2
Effective Orifice Area cm^2, Mean ± SD	0.7 ± 0.2
Left Ventricular Ejection Fraction Mean ±SD	54.7 ± 9.9

*Severe pulmonary hypertension (PA systolic pressure > 2/3 of systemic pressure), severe right ventricular dysfunction, chronic lung disease

Procedural Characteristics
AT Population

Parameters	As Treated (N=203)
Implanted THV Size %*	
23 mm	11.1
26 mm	59.1
29 mm	29.8
Anesthesia %	
Conscious Sedation	85.7
Conversion from Conscious to General Anesthesia	2.5
Procedural Characteristics mean ± SD	
Contrast Volume ml	147 ± 61.6
Fluoroscopy Time min	18 ± 9.6
Total Procedure Time (Skin to Skin) min	67 ± 33.4

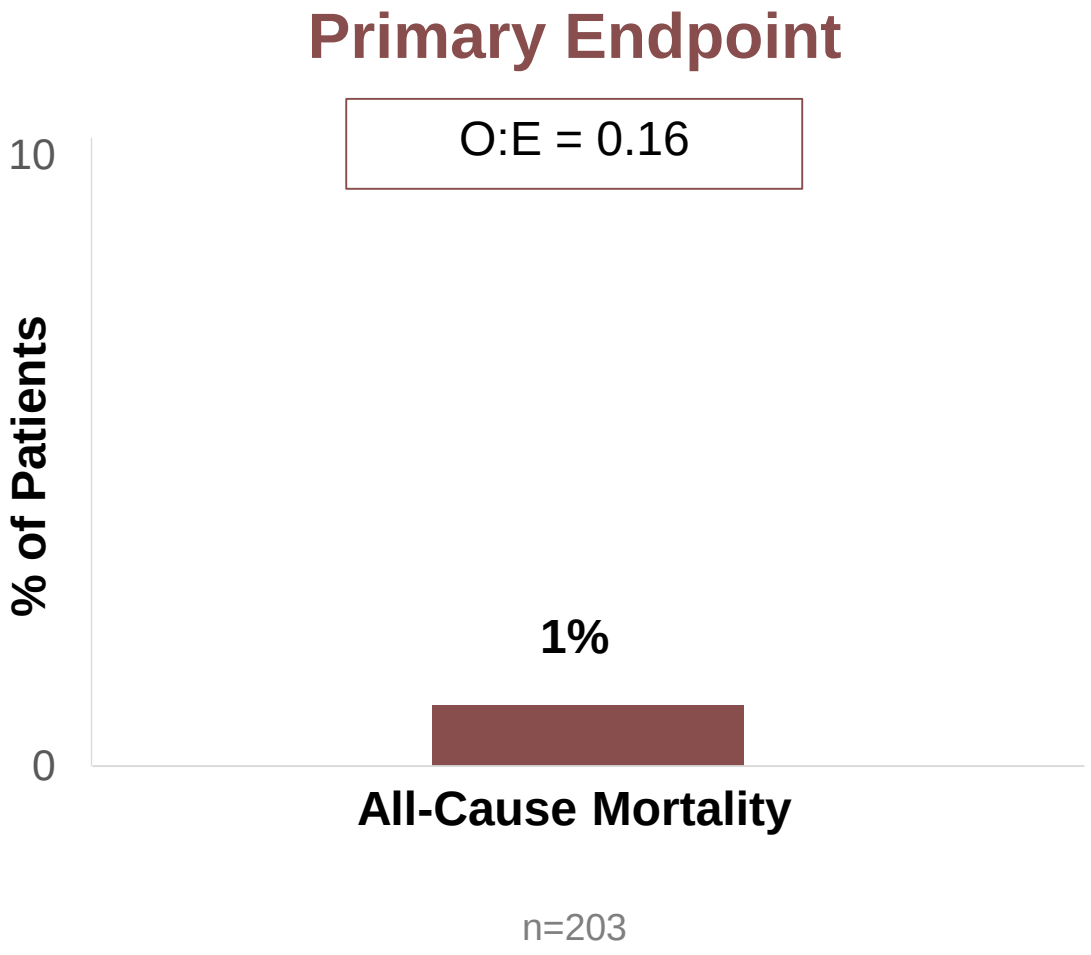
*Valve-Implanted population

Procedural Events
AT Population

Parameters	As Treated (N=203) %
Recapturing and Repositioning (yes)	3.5
With Ventricular Injury	0
With Aortic Injury	0
Valve Embolization	0.5
Post-Dilatation	33.0
Required Intra-aortic Balloon Pump	0.5
Required Cardio-pulmonary Bypass	2.0
Technical Success	97.5
Device Success*	96.4

*VARC-2 Definition

All-cause Mortality at 30 Days
AT Population



*KM (%) Estimate

Clinical Outcomes at 30 Days

AT Population

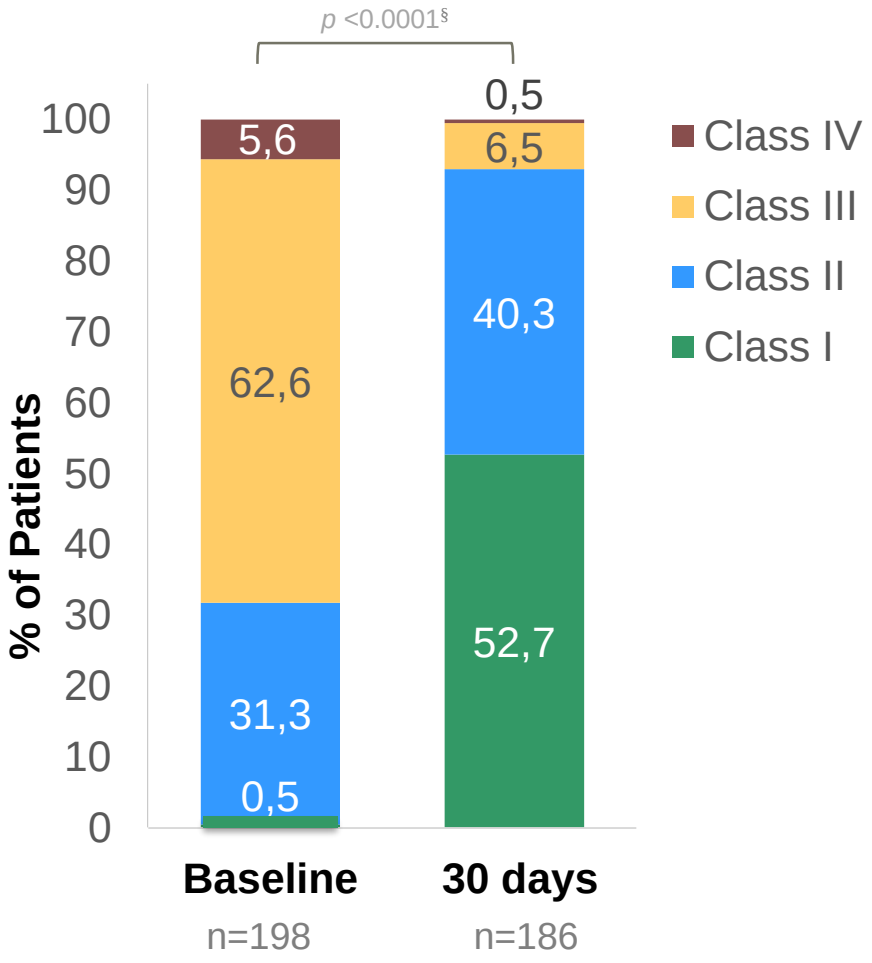
Safety Endpoints	As Treated (N=203) %
Mortality	1.0
Cardiovascular Mortality	1.0
Stroke	4.0
Disabling Stroke	2.5
Myocardial Infarction	1.5
Coronary Artery Obstruction Requiring Intervention	0.5
Major Vascular Complications	6.4
Life-Threatening or Disabling Bleeding	4.9
Acute Kidney Injury (Stage 2 or 3)	1.0
New Onset Atrial Fibrillation	8.0
New Permanent Pacemaker	4.9
THV-related Dysfunction Requiring a Repeat Procedure	0

*All Values are CEC adjudicated; KM (%) Estimate;
According to VARC-2 Guidelines

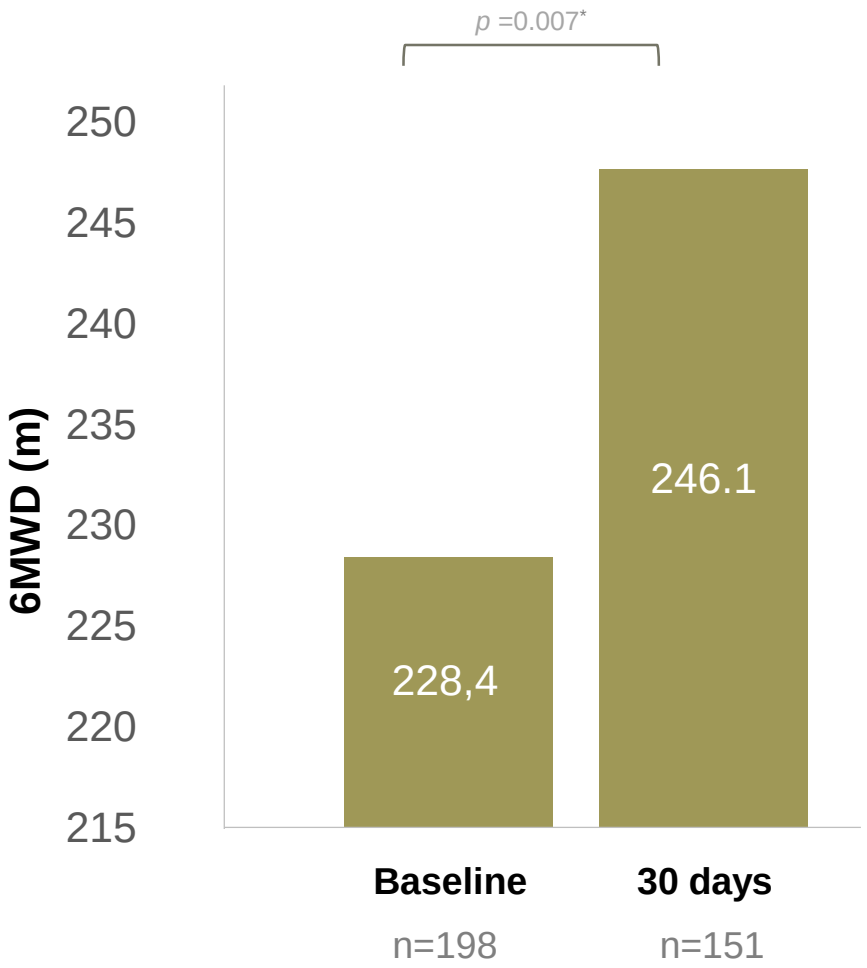
Functional Improvement at 30 Days

VI Population

New York Heart Association



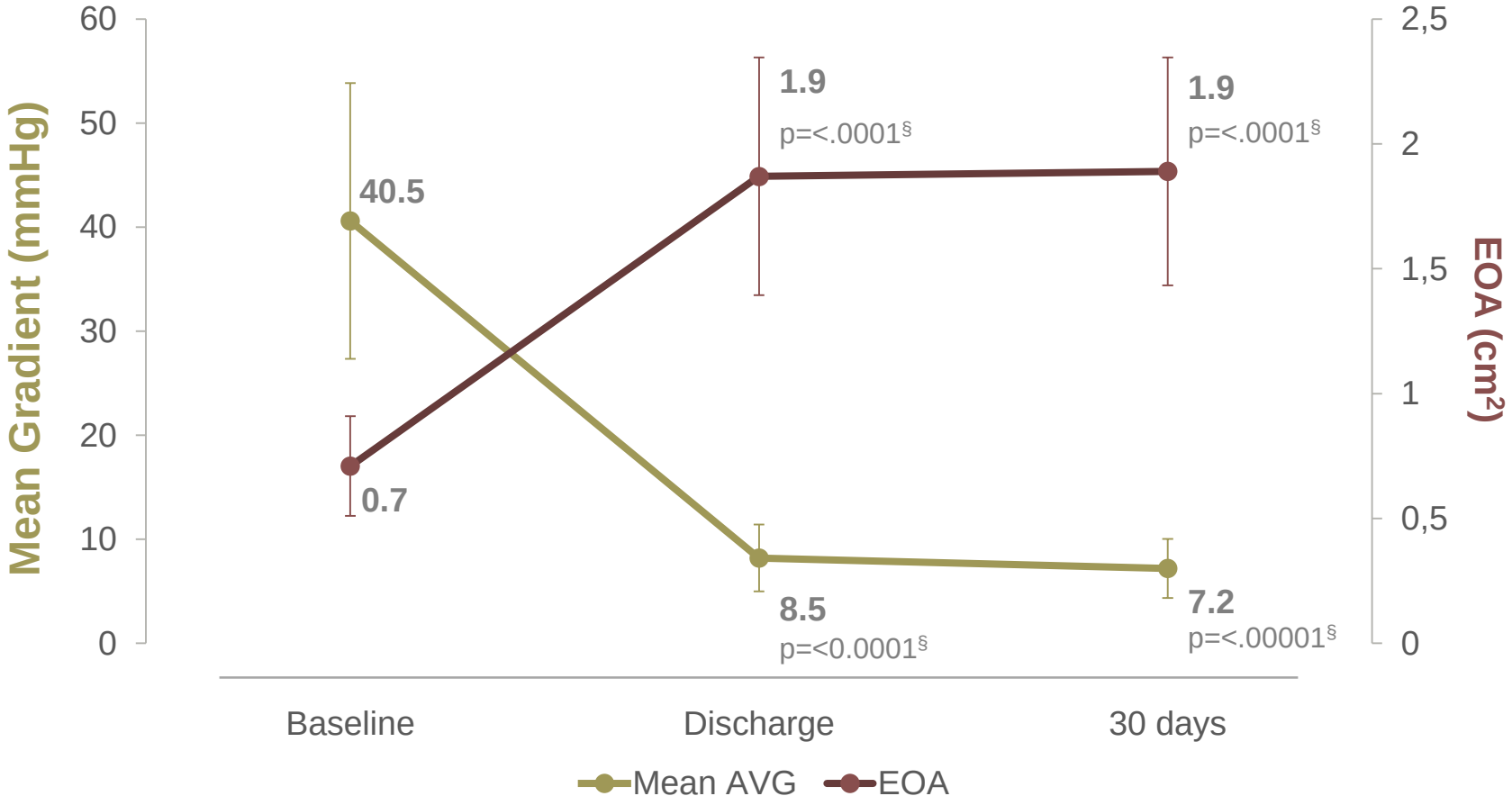
Six Minute Walk Distance



§Two-sided paired t-test and *Fisher's Exact Test;
with the null hypothesis that there is **no change from baseline**;

Echocardiographic Haemodynamics Results at 30 Days

VI Population



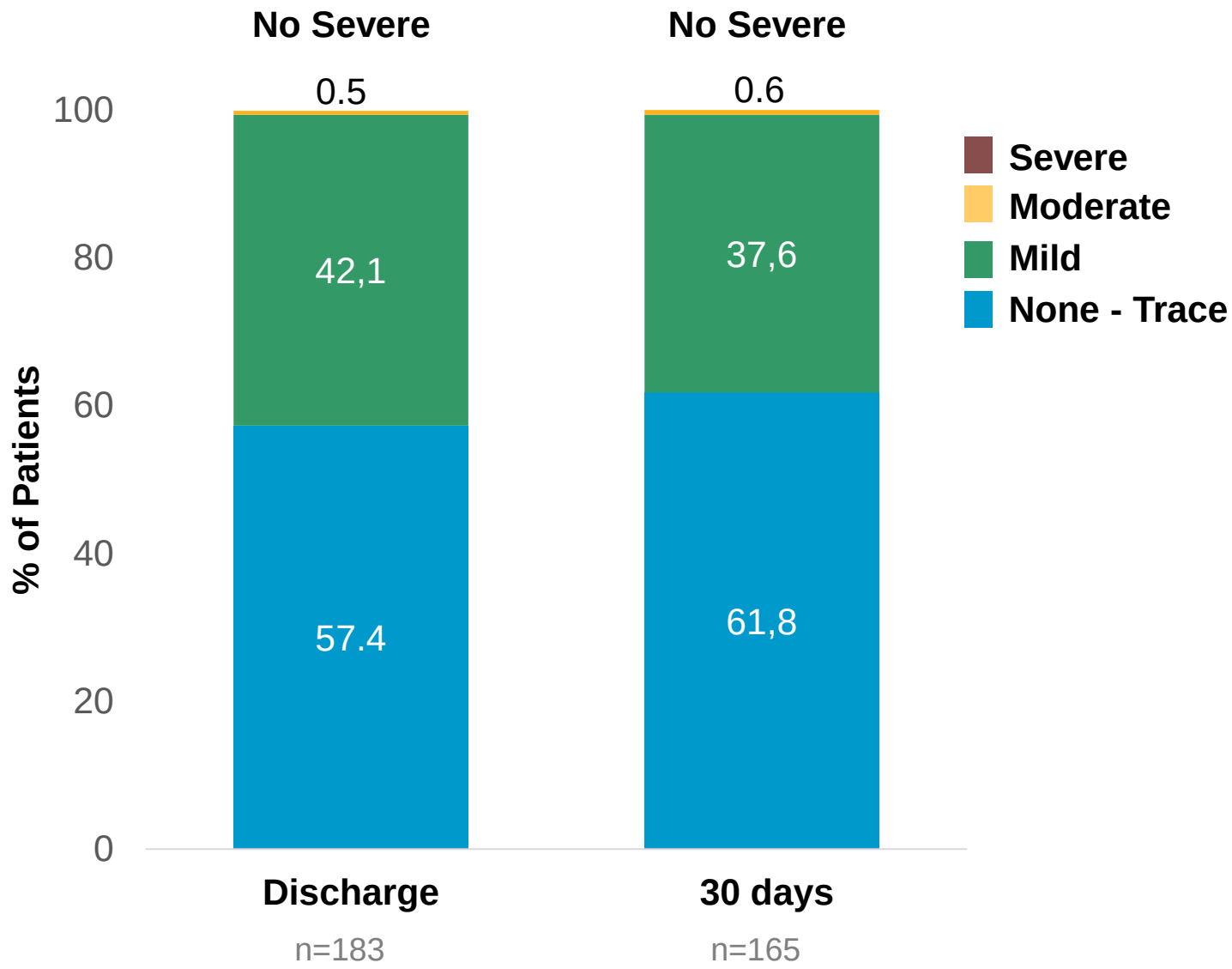
Number of Observations

Mean Gradient (n)	**187**	**186**	**166**
EOA (n)	**148**	**143**	**145**

*Modified Valve Implant Population; All Values are Corelab adjudicated;
§Two-sided paired t-test and with the null hypothesis that there is **no change from baseline**

Total Aortic Regurgitation at 30 Days

VI Population



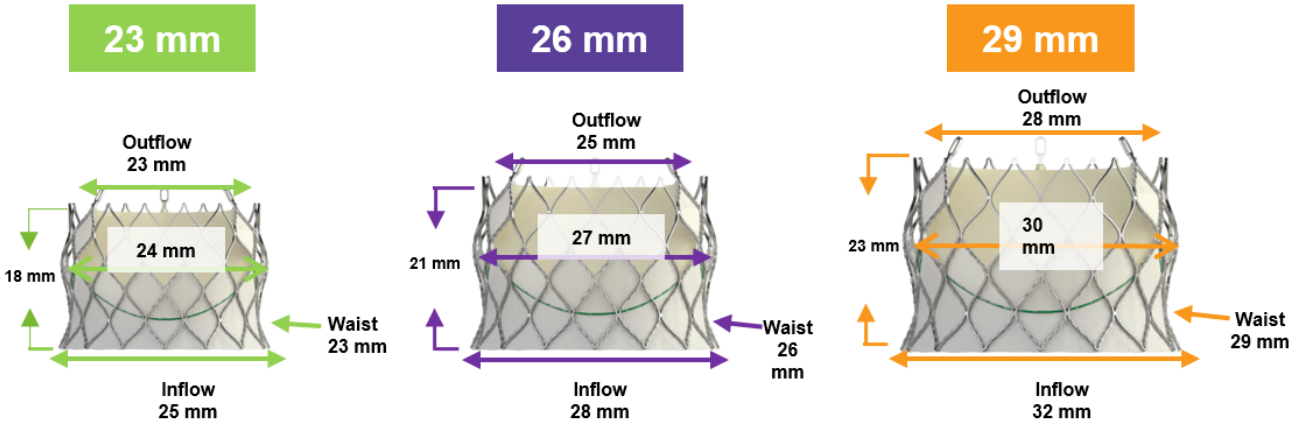
Conclusions

- **The CENTERA valve with a unique design has been shown to be safe and effective at 30 days.**
  - Low incidence of all-cause mortality (1%; O:E=0.16)
  - Low incidence of permanent pacemakers (4.9%)
  - Significant hemodynamic improvements with very low moderate and no severe paravalvular regurgitation
  - Significant improvement in functional assessments.

- **The novel nitinol transcatheter CENTERA valve has stable deployment, high technical success and a low need for recapture and repositioning.**

THANK YOU

NOTE:
Approximately half of the height of the THV is covered by PET Skirt



*Dimensions above are after single THV load, recapture and deployment

Nominal frame height is 17.5mm, 20mm, and 22.1mm for size 23, 26, and 29, respectively