Transcatheter Pulmonary Valve Implantation with the Alterra Adaptive Prestent and SAPIEN 3 Transcatheter Heart Valve: Three-year Pooled Outcomes of the ALTERRA trial

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Shabana Shahanavaz and Evan Zahn on behalf of the ALTERRA Trial Investigators

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Disclosure Information

Alejandro Torres, MD

As a faculty member for this program, I disclose the following relationships with industry:

- Investigator & Proctor: Edwards Lifesciences

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Trial Objective and Patient Population

Demonstrate safety and effectiveness of the Alterra Adaptive Prestent with the SAPIEN 3 THV system in subjects with a dysfunctional right ventricular outflow tract/pulmonary valve (RVOT/PV) for treatment of pulmonary regurgitation (PR)

Key Inclusion Criteria

- Weight ≥20 kg
- ≥ Moderate PR
- Suitable Anatomy
  - **≥ 27 mm landing zone diameter ≤ 38 mm**
  - **≥ 35 mm landing zone length**

Key Exclusion Criteria

- Inappropriate anatomy for introduction or delivery of Alterra/SAPIEN 3
- Need for concomitant procedures*
- Any intervention or surgical procedure within 30 days pre- or post-implantation (Alterra/SAPIEN 3)
- Renal insufficiency (creatinine > 3.0 mg/dL) and/or renal replacement therapy

*Exceptions: pulmonary artery or branch pulmonary artery stenting or angioplasty

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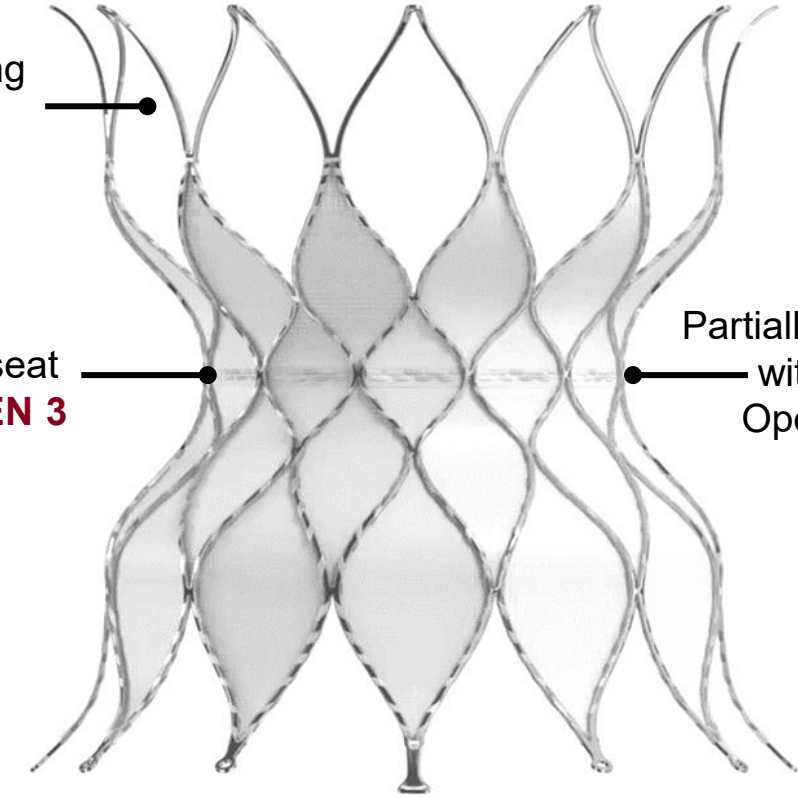
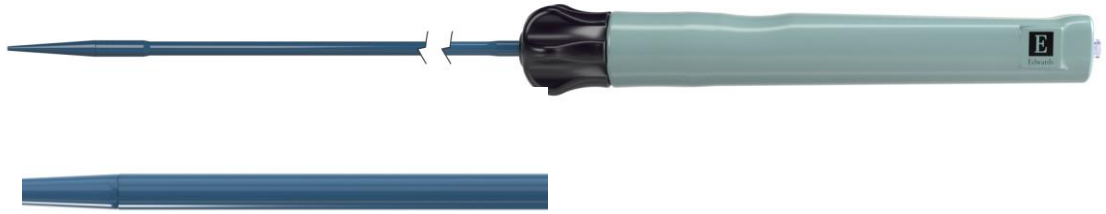
ALTERRA Trial: Devices

Alterra Adaptive Prestent



Symmetric design

Alterra Delivery System

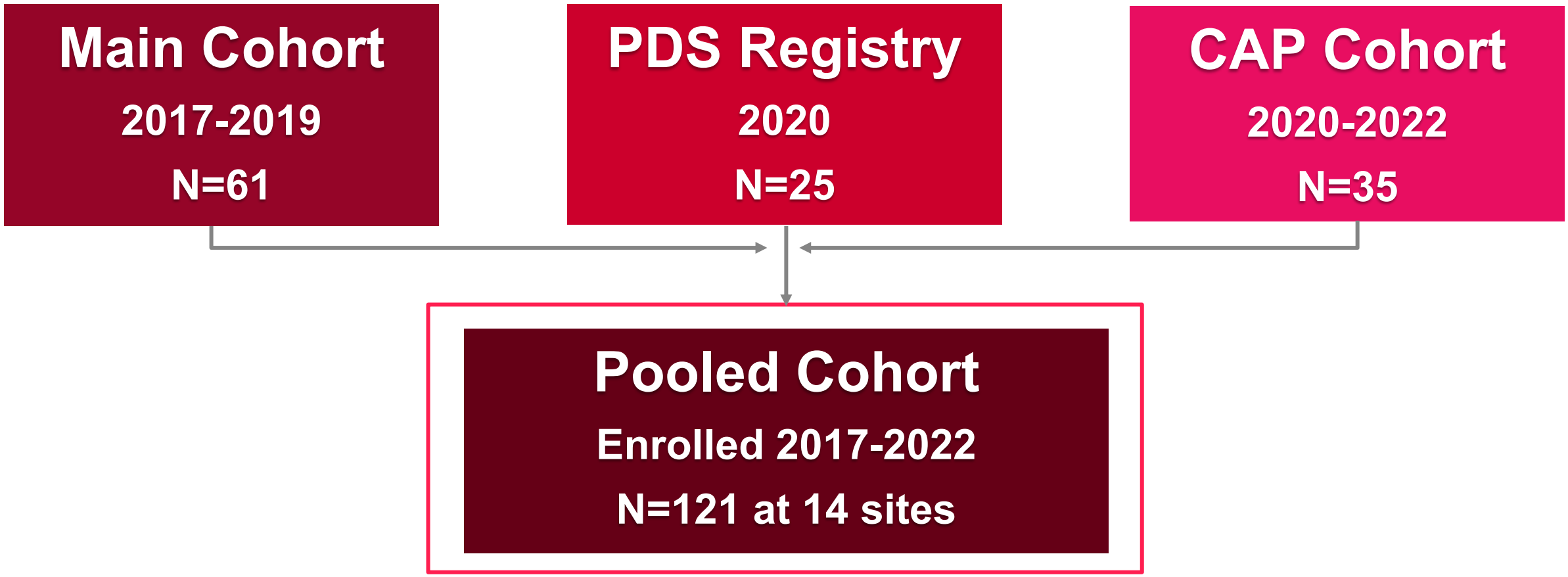


Commander Delivery System (Main Cohort)

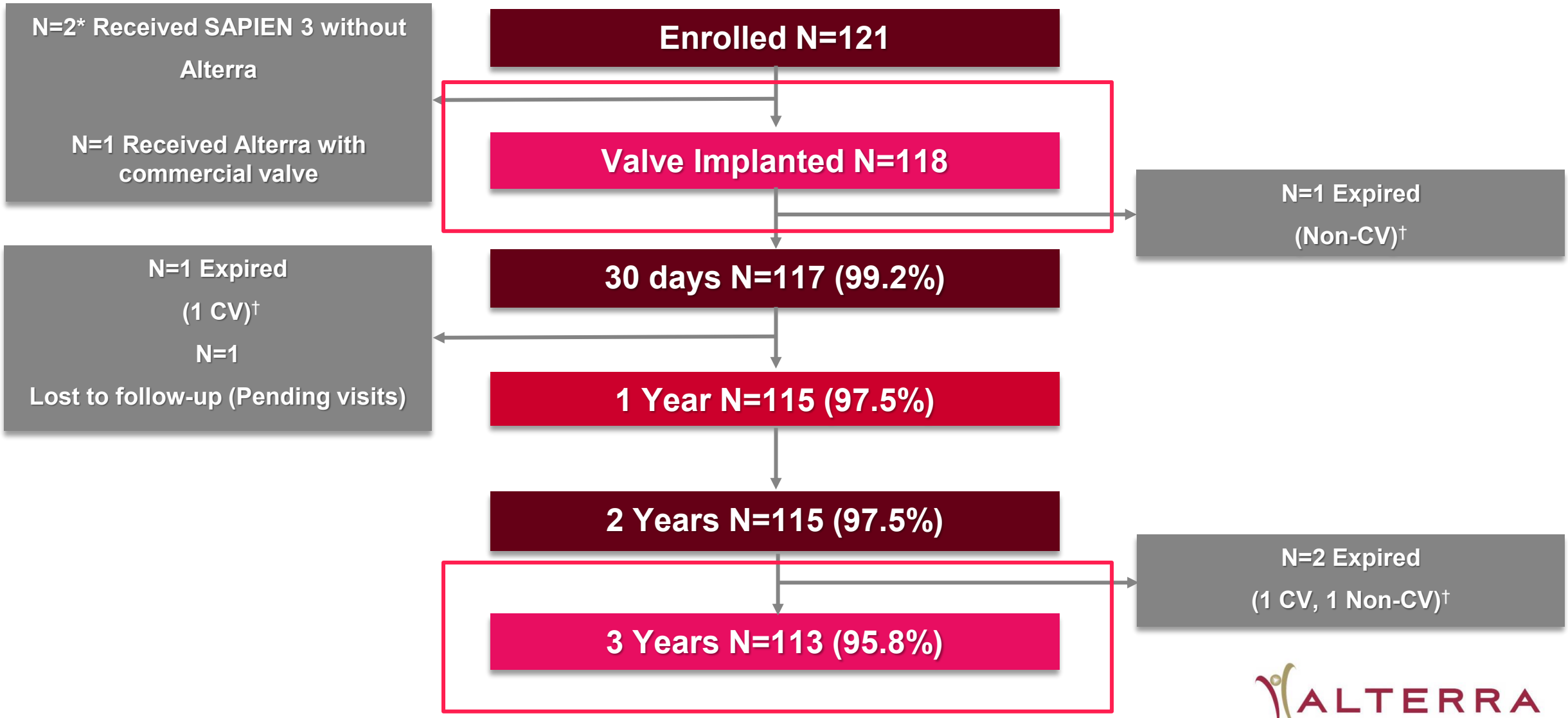
Pulmonic Delivery System (PDS+CAP)

Tapered tip to facilitate crossing right-heart structures

ALTERRA Trial: Study Design



Subject Accountability: Pooled Cohort



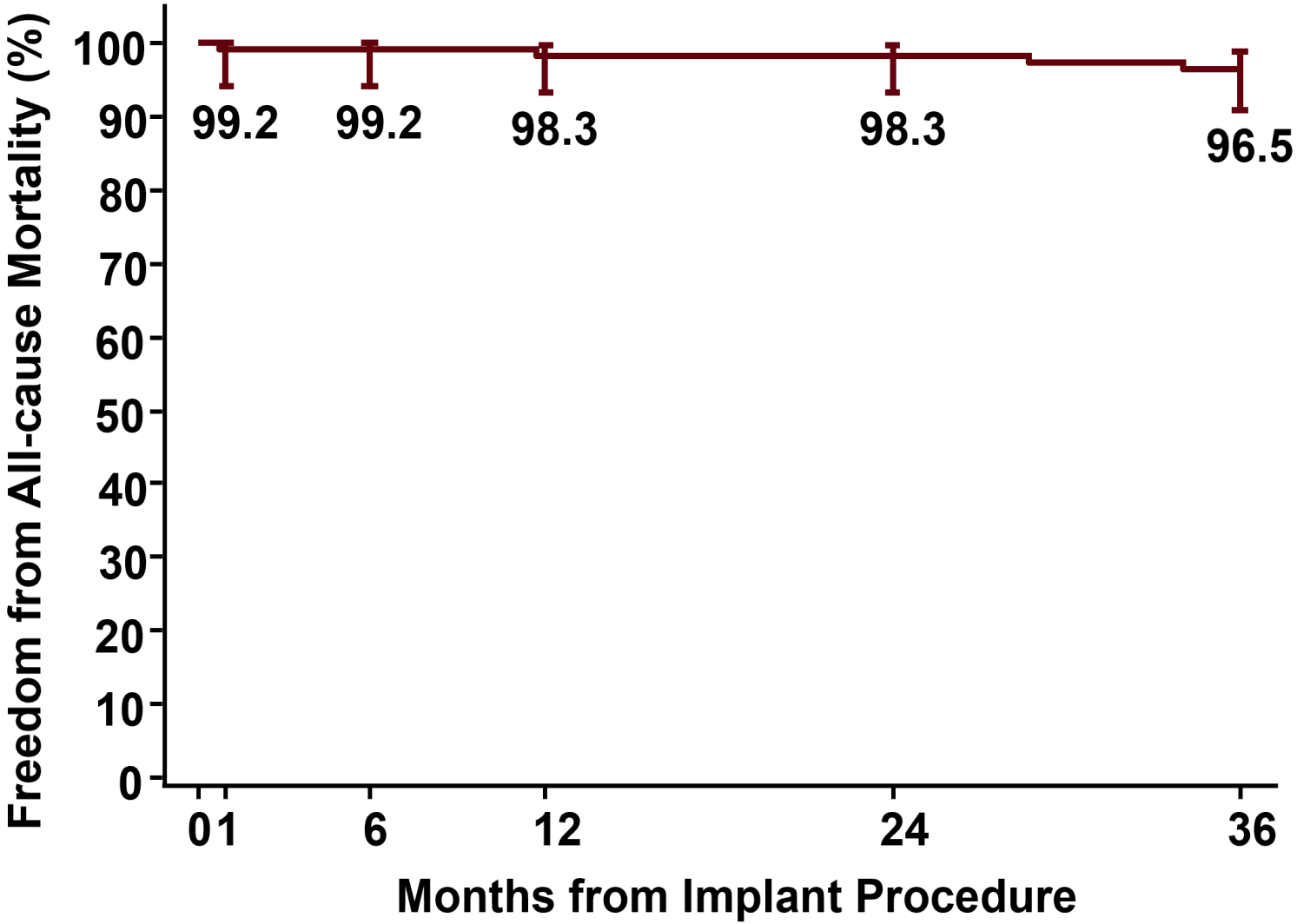
*Unsuitable/borderline anatomy. †All deaths adjudicated by the CEC

Baseline Characteristics: Pooled Cohort

Variable	Enrolled N=121
Age (years)	28.6 ± 15.9
>21 years (%)	51.2%
Weight (kg)	72.5 ± 21.7
Primary CHD Diagnosis	
Tetralogy of Fallot	66.1 % (80/121)
Pulmonary valve stenosis	**27.3 % (33/121)**
Pulmonary atresia	3.3% (4/121)
Other	3.3% (4/121)

Categorical measures – %; Continuous measures - mean ± SD

Freedom from Mortality



VI population (N=118)

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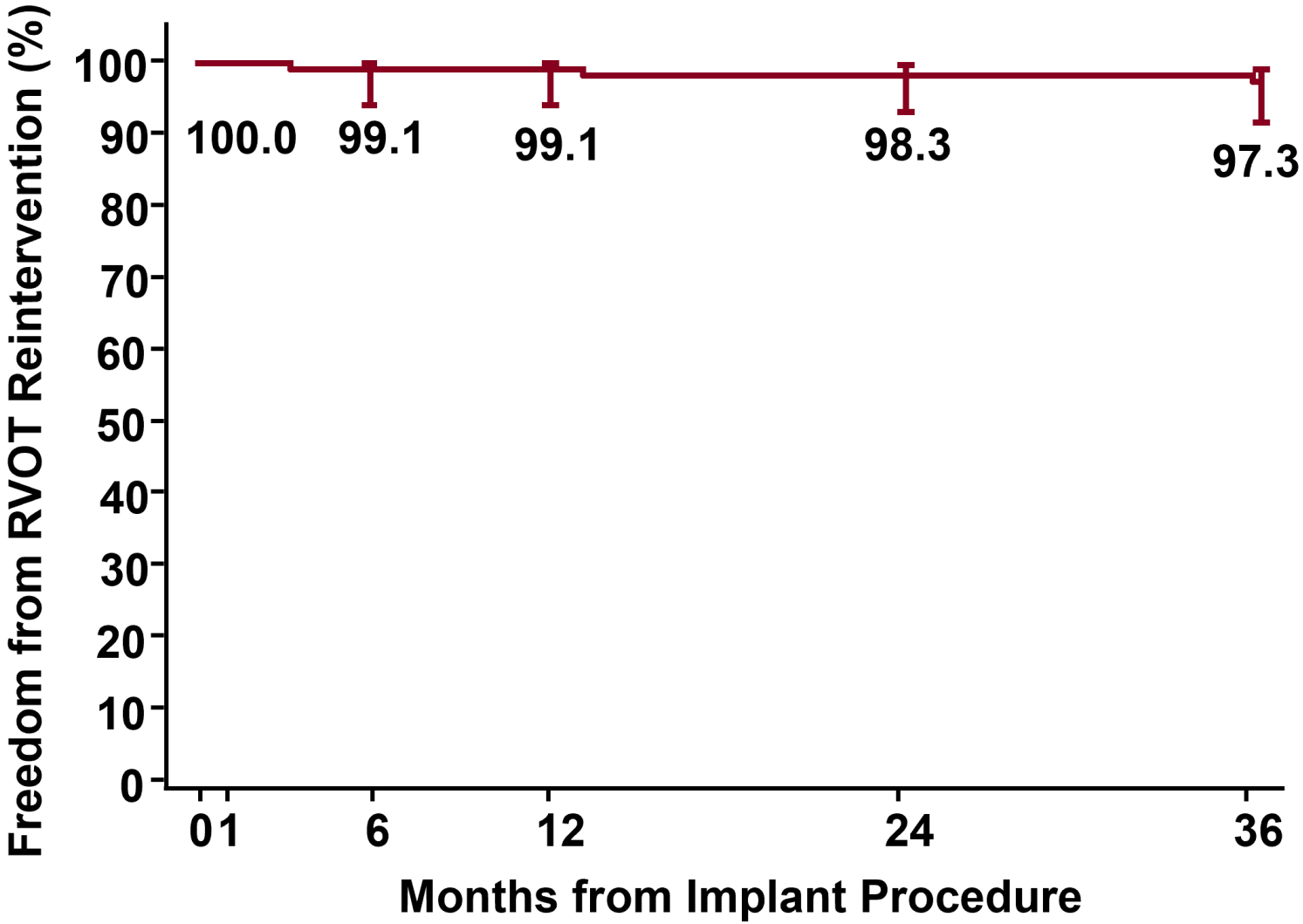
Freedom from Reintervention



VI population (N=118)

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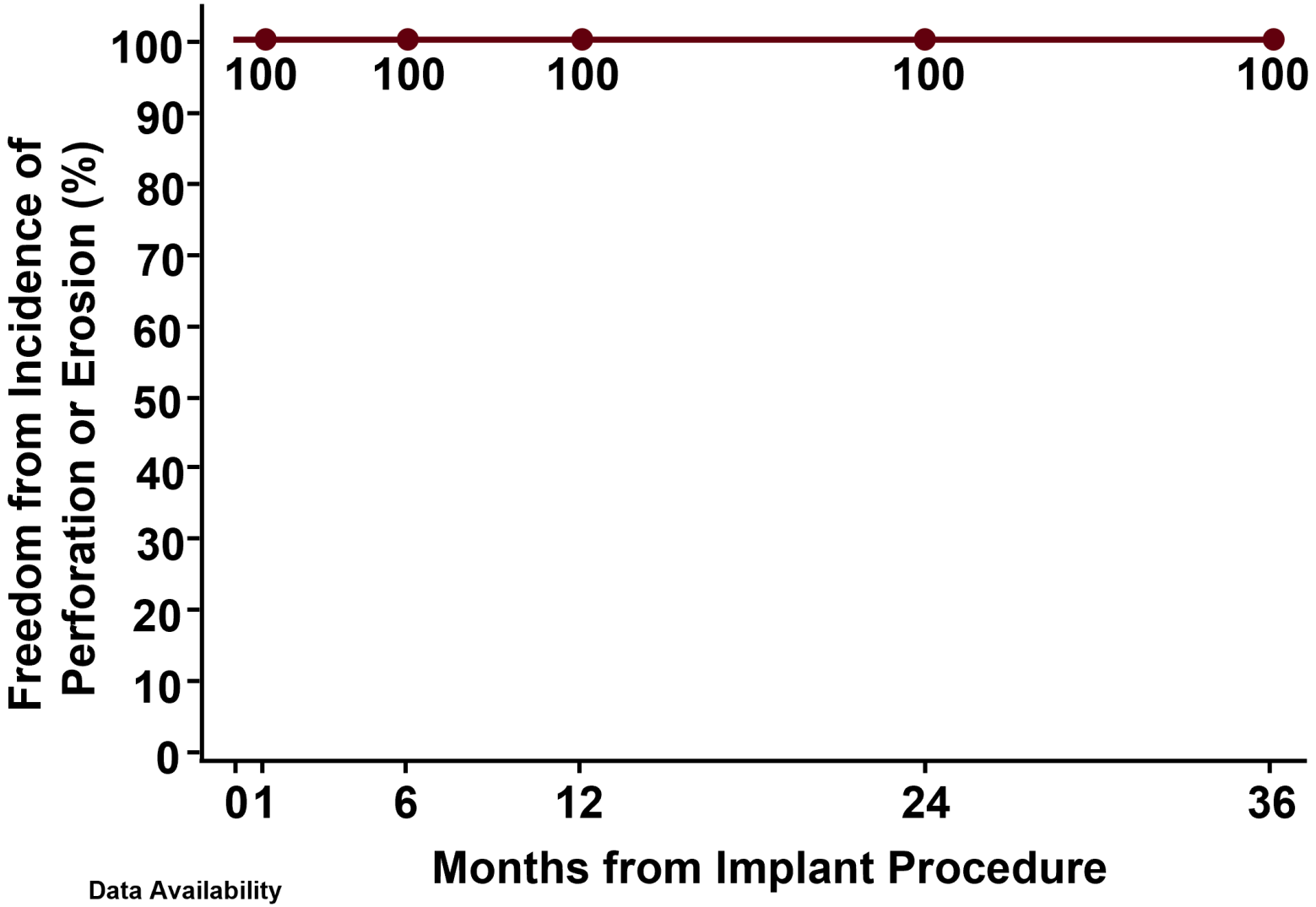
Freedom from Incidence of Perforation or Erosion



VI population (N=118)
CEC adjudicated per VARC-2 definitions

Data Availability (No. of patients)				
89	21	7	3	

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Clinical Outcomes

Incidence Rate, % (N patients) Valve Implanted Population	0 - 3 Years (N=118)
All-cause mortality	**3.3% (4)**
Cardiovascular deaths	**1.7% (2)**
RVOT reintervention	**2.5% (3)**
Major CV bleed (transient pericardial effusion)*	**0.8% (1)**
Coronary artery compression†	**0%**
Endocarditis	**0%**
Prestent thrombus‡	**4.1% (5)**
SAPIEN 3 valve thrombus‡§	**5.0% (6)**

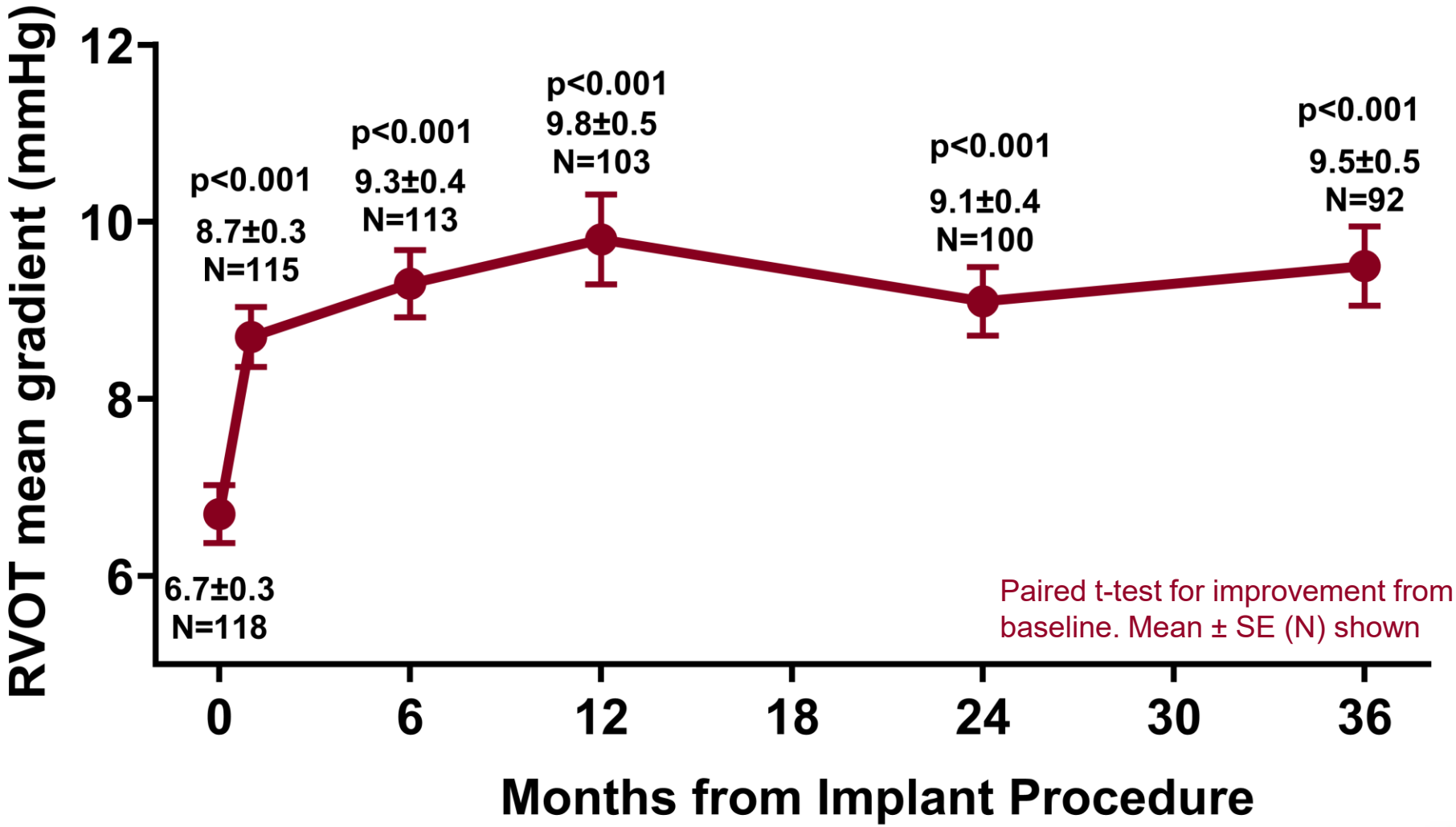
*Self resolved without drainage, believed to be reactive effusion. †CEC adjudicated out to 30 days, site-reported thereafter. ‡Site-reported only. §5/6 resolved with treatment. 1/6 onset at POD 560 is considered resolving at 3y

CEC Adjudicated Arrhythmias

Incidence Rate, % (n, N) or n events Valve Implanted Population	0 - 30 Days N=118	31 Days – 2 Years N=117	2 - 3 Years N=112
Arrhythmias	**38.0% (52, 46)**	**1.8% (2, 2)**	**0.9% (1, 1)**
Ventricular tachycardia	22	0	0
NSVT	21	0	0
PVCs	21	1	0
Atrial fibrillation/flutter	2	0	0
Ventricular fibrillation	0	1*	1†
Other‡	7	0	0

*Patient that had history of congenital complete heart block and ectopies had VFib at 355 d and expired.
†Patient had sudden episode while playing basketball, AED placed and normal sinus rhythm after shock. Negative work up followed by ICD implantation. No other associated AEs.
‡Other: Junctional rhythm (3), Right Bundle Branch Block (1), Left Posterior Fascicular Block (1), Prolonged QTc Interval (1), Wenckeback Block (1)

Mean RVOT Gradient



VI population (N=118)
Echo Core Lab TTE

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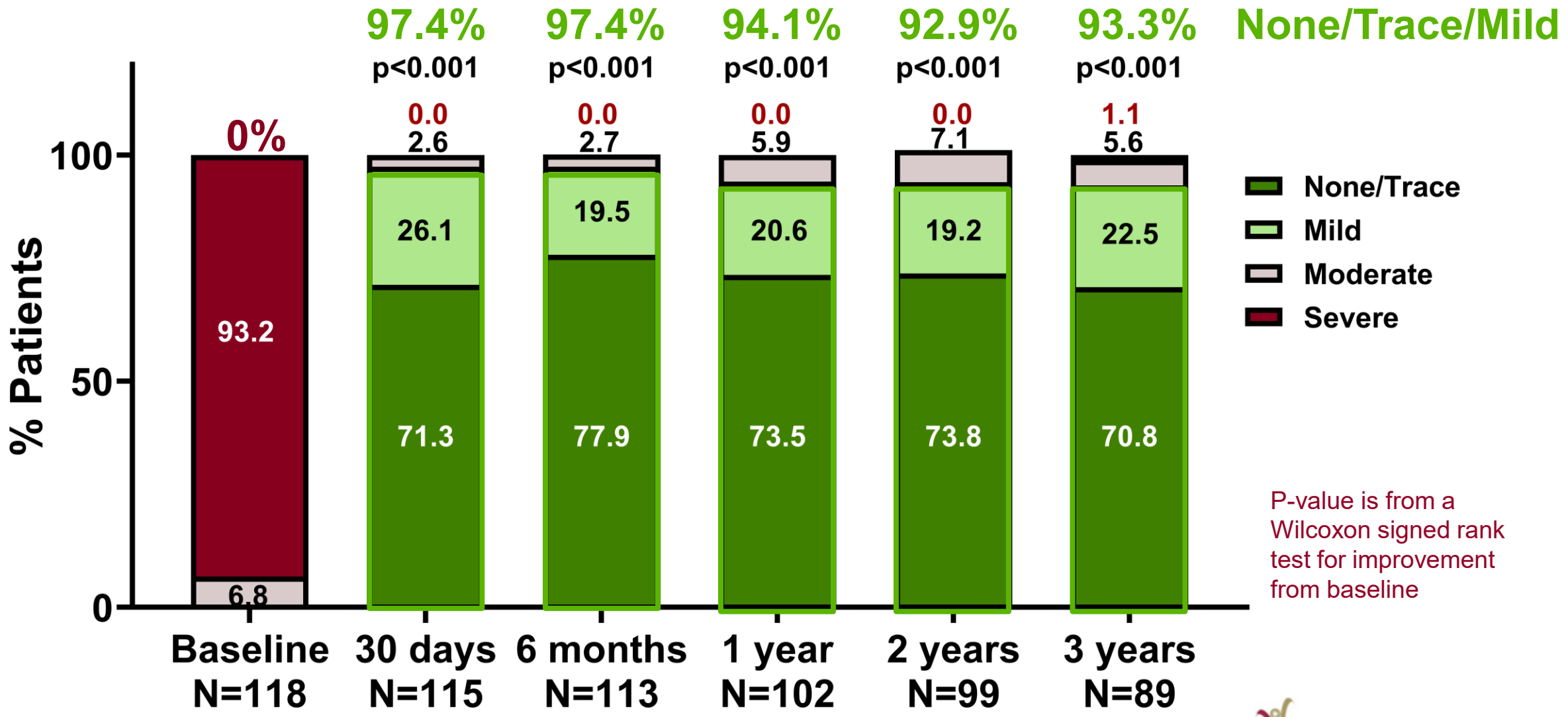
Total Pulmonic Regurgitation



P-value is from a Wilcoxon signed rank test for improvement from baseline

VI population (N=118)
Echo Core Lab TTE

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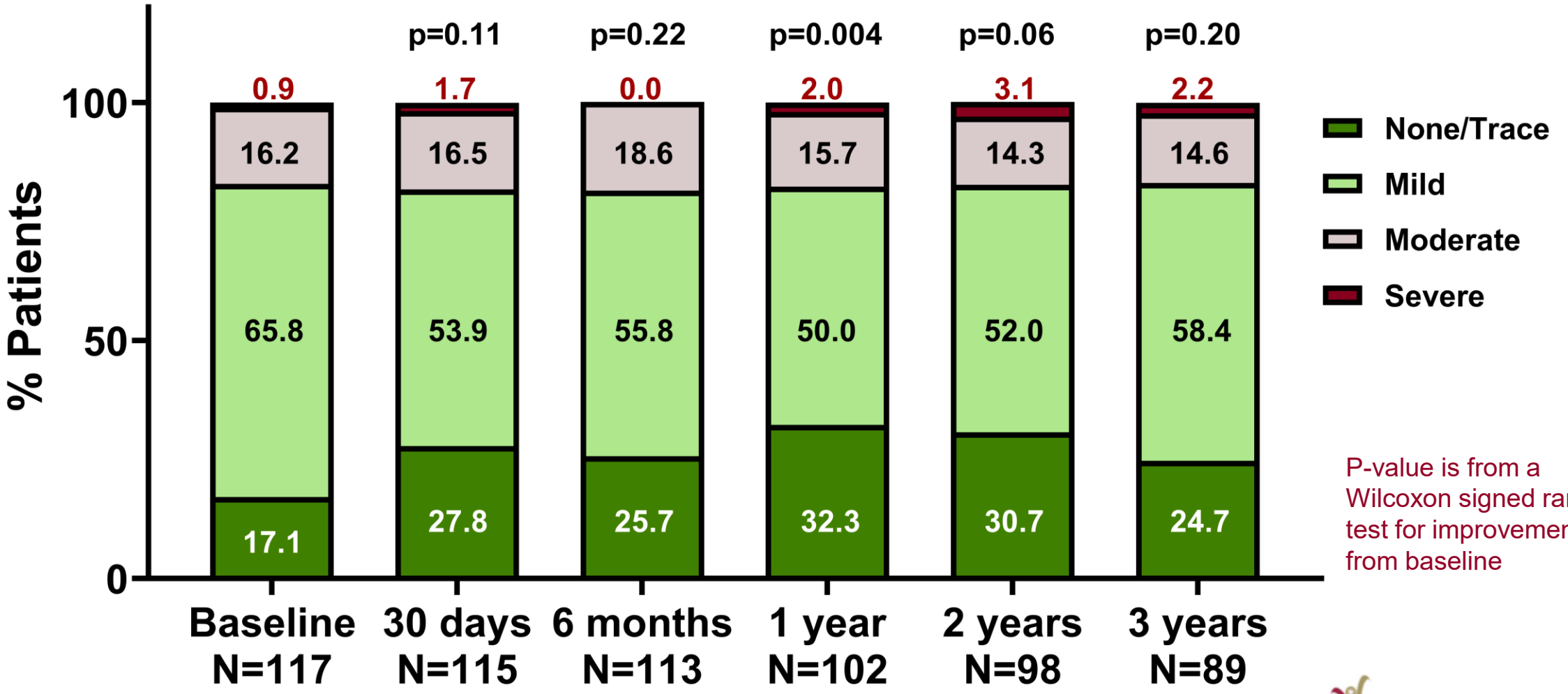
Tricuspid Regurgitation



P-value is from a Wilcoxon signed rank test for improvement from baseline

VI population (N=118)
Echo Core Lab TTE

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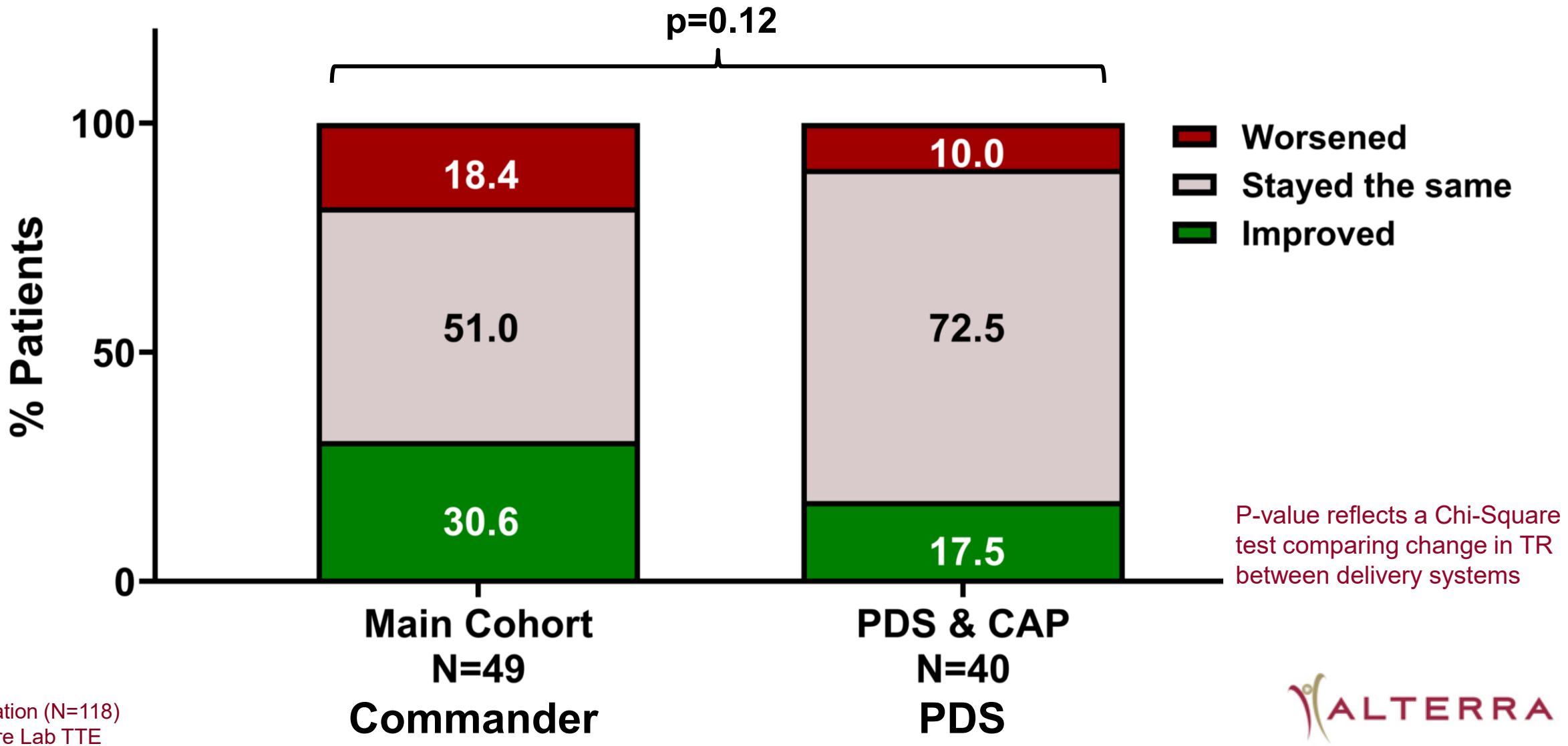
Change in Tricuspid Regurgitation at 3 years



P-value reflects a Chi-Square test comparing change in TR between delivery systems

VI population (N=118)
Echo Core Lab TTE

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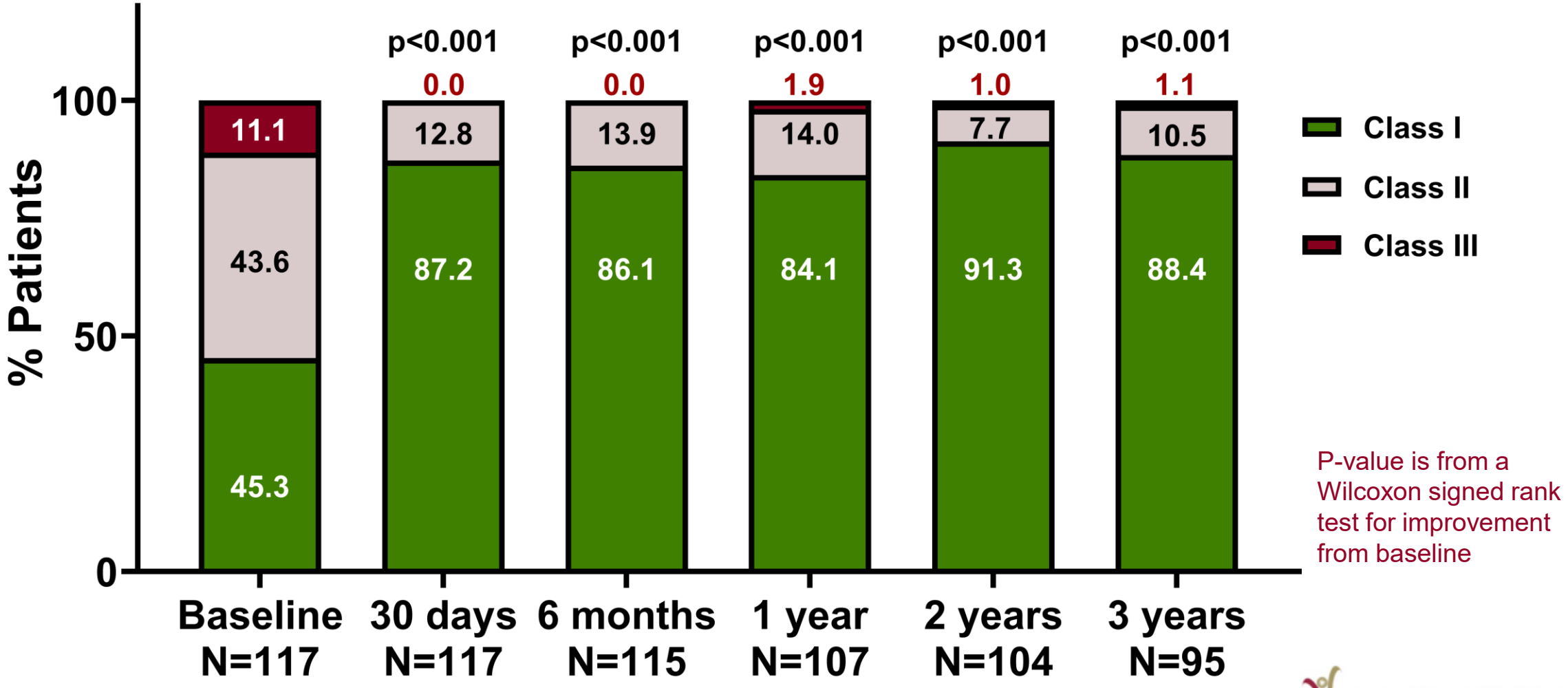
NYHA Functional Class



P-value is from a Wilcoxon signed rank test for improvement from baseline

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Conclusions

The Alterra Adaptive Prestent/SAPIEN 3 THV system demonstrated safety and effectiveness out to 3 years:

- Excellent valve performance
  - 98.9% patients had improved PR from baseline (93.3% with ≤ mild PR)
  - Mean gradient remains low and stable
- Low rate of reintervention (2.5%)
- No acute perforations or chronic erosions
- Ventricular arrhythmias were predominantly periprocedural and resolved
- Sustained improvement in NYHA class

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Thanks and Recognition

Participating Sites

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Evan Zahn, Ruchira Garg

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Texas Children's Hospital
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Cardiovascular Research Foundation, New York, NY

Clinical Events Committee

Cardiovascular Research Foundation, New York, NY

CT Core Laboratory

St. Paul's Hospital, Vancouver, Canada
Directors: Jonathon Leipsic, Philipp Blanke

Echocardiographic Core Laboratory

Children's Mercy, Kansas City, MO
Directors: Girish Shirali, Anitha Parthiban§

Sponsor

Edwards Lifesciences, Irvine, CA

*Dr. Shahanavaz is now with Cincinnati Children's Hospital, OH
†Dr. Dimas and Dr Stapleton are now with Medical City Children's Hospital Heart Center, TX
‡ Dr Lim is now at the University of British Columbia, Vancouver, Canada.
§Dr. Parthiban is now with Texas Children's Hospital, Baylor College of Medicine, TX

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