2024 PCR london valves

30 Days Outcomes of Transfemoral J-VALVE for Chronic Aortic Regurgitation:
A Prospective, Multicenter Study in 127 Cases

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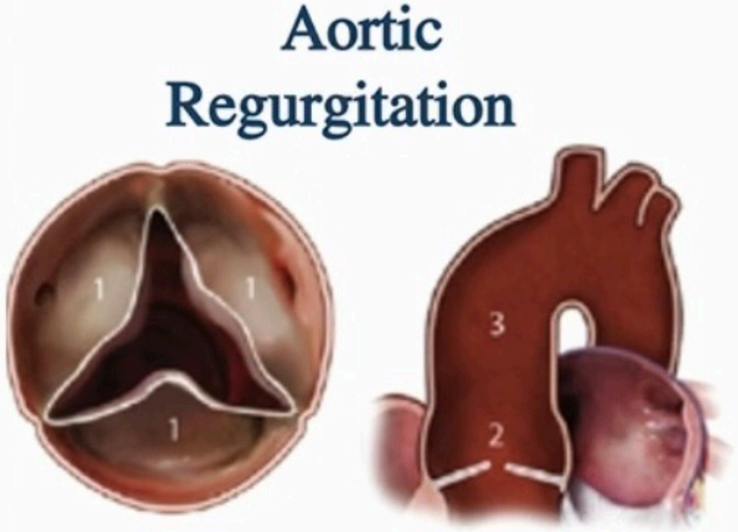
On Behalf of the J-Valve TF China Investigators

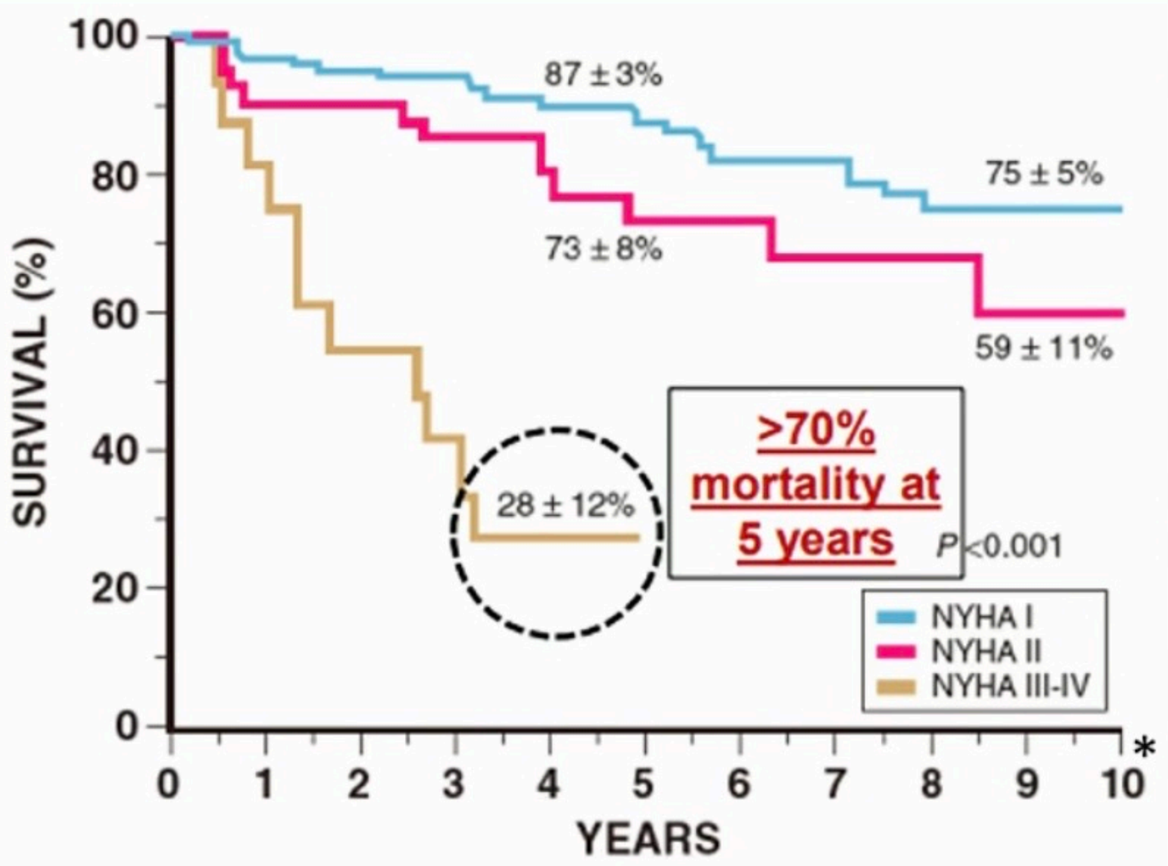
PCR EAPCI European Society of Cardiology

Background



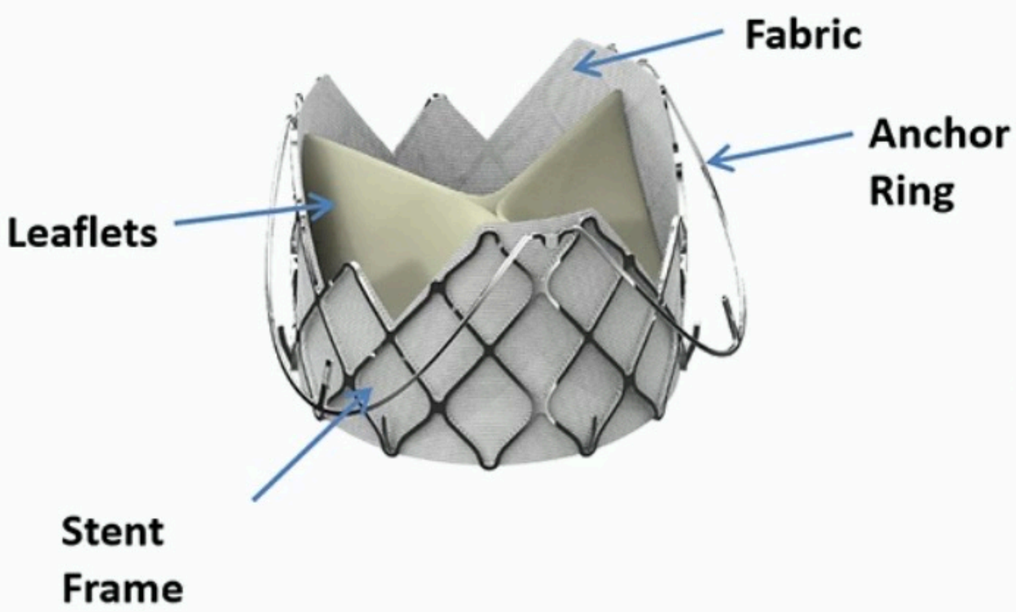
No calcification
Lack of anchoring area
Annulus dilation

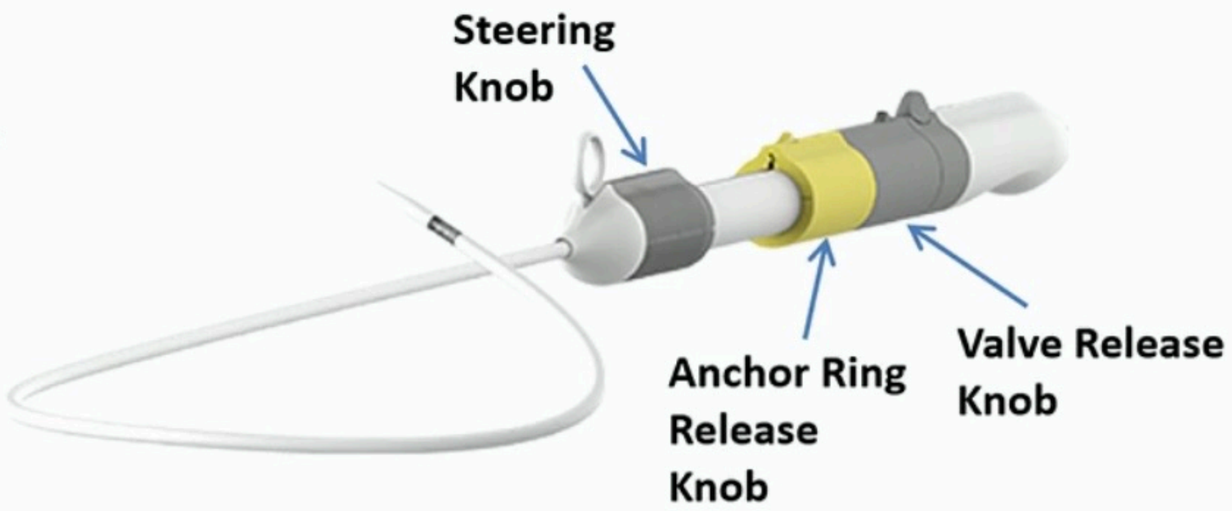
Worse prognosis



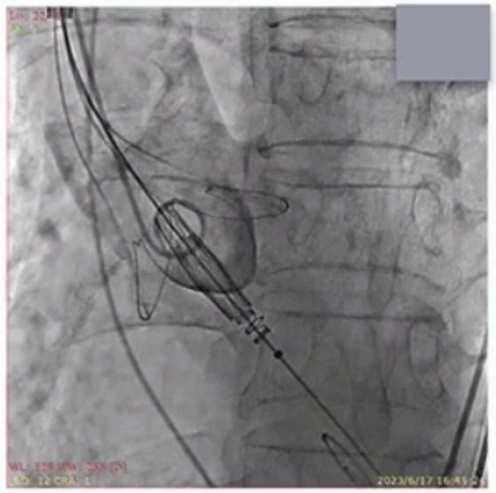
*PMID: 10199882

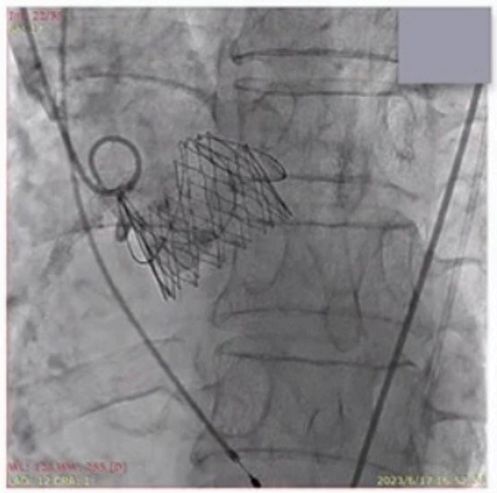
J-VALVE TF System for Aortic Regurgitation

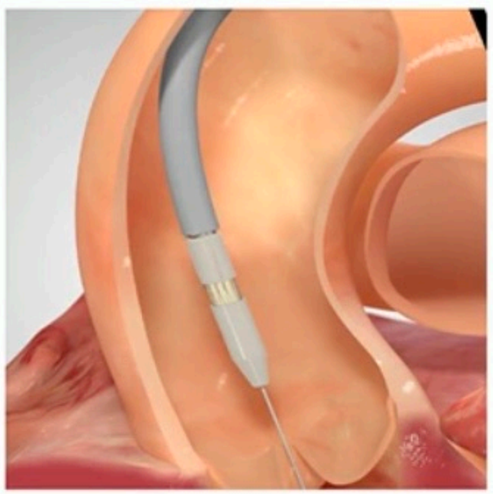


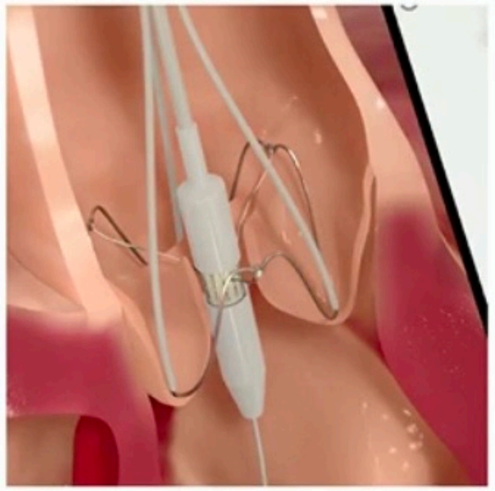


J-VALVE TF Implantation

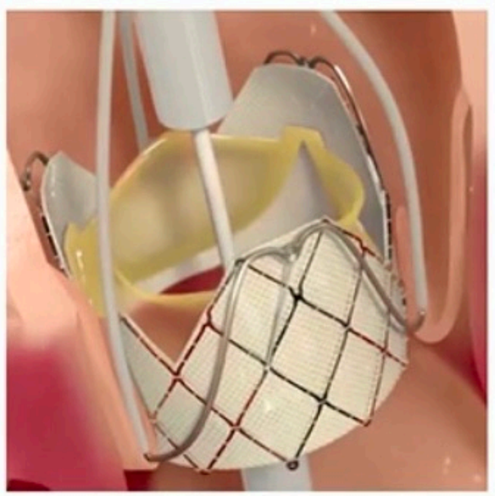




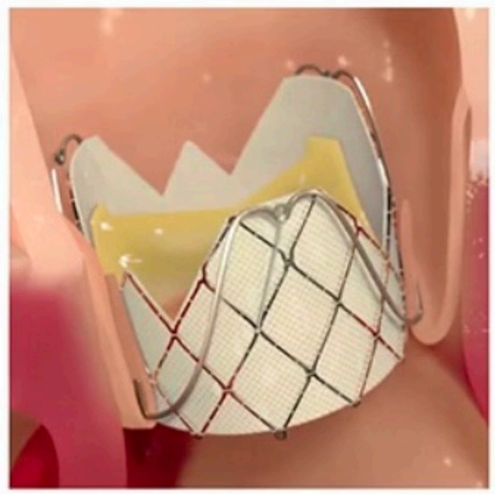




Anchor Ring Deployed



Valve Deployed



Final Result

Trial Purpose

To evaluate the effectiveness and safety of the J-VALVE transcatheter aortic valve system amongst patients with symptomatic severe aortic regurgitation who are high-risk or inoperable for SAVR.

Trial Design

Prospective, Multicenter, Single Arm Evaluation of Patients with Symptomatic ≥3+ Aortic Regurgitation at High Risk or Inoperable for SAVR

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J-Valve TF Implantation

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Clinical Evaluation, Echocardiography, NYHA and KCCQ etc at 30 Days, 6 Months, 1 Year and Annually up to 5 Years

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30 Days Outcome → Presented at 2024 London Valve

↓

1 Year Outcome → Comparison with Prespecified Performance Goal

NCT05580952

Key Inclusion & Exclusion Criteria

Inclusion:

- Age ≥ 65 years;
- Patients with symptomatic moderate to severe or severe aortic valve regurgitation, and NYHA ≥ II
- High risk or inoperable for SAVR evaluated by the surgical team
- Aortic valve anatomy is suitable for TAVR evaluated by the investigators
- Sign informed consent form, and are willing to accept relevant examinations and clinical follow-ups

Exclusion:

- Acute myocardial infarction or coronary revascularization occurred within 1 month before procedure
- Cerebrovascular accident (CVA) occurred within 30 days before procedure
- Other valve diseases that need interventions;
- Previous aortic valve implantation (mechanical or biological)
- Left ventricular ejection fraction < 20%

Primary Endpoint

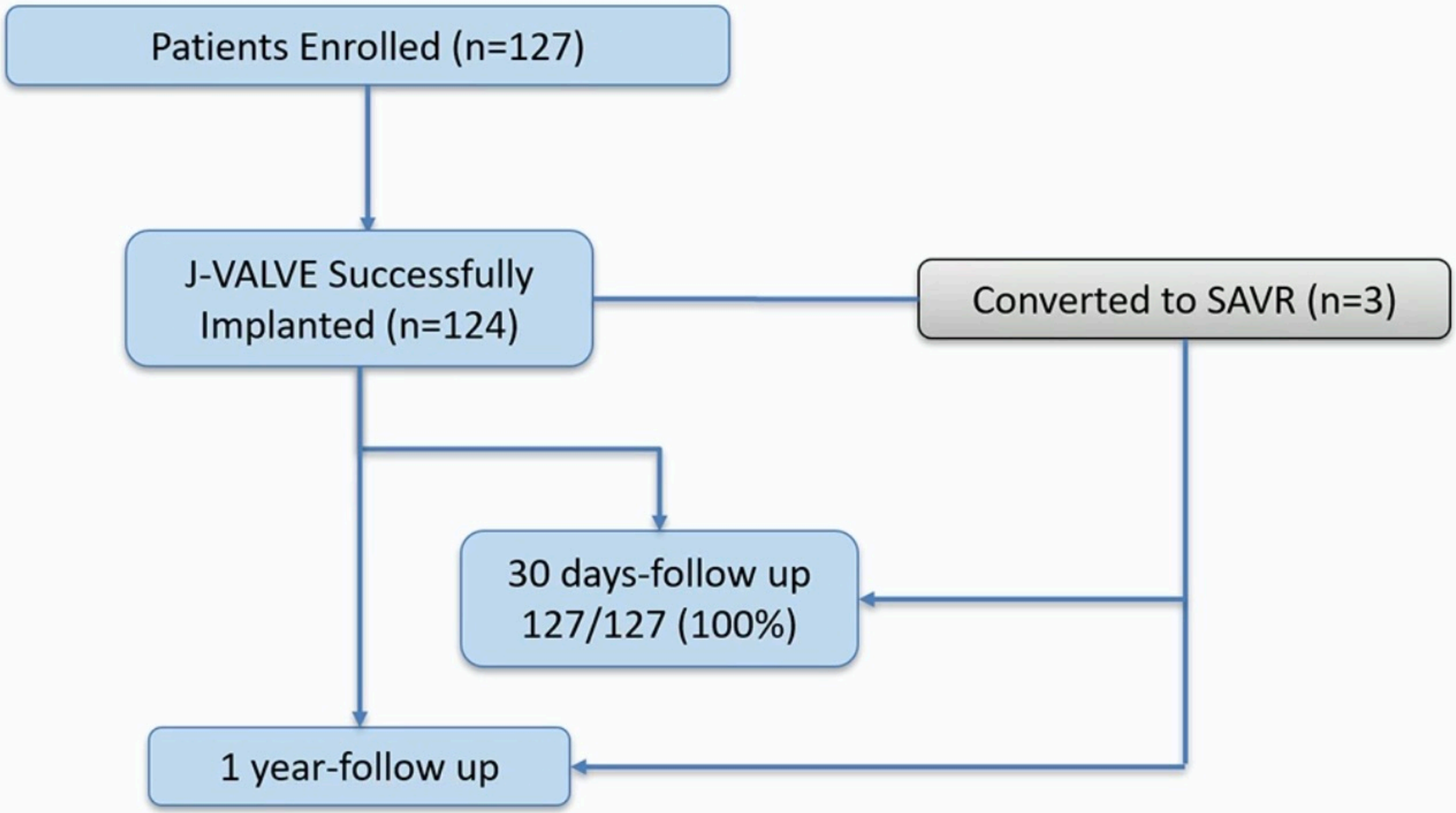
The primary endpoint was cumulative all-cause mortality at 12 months

- All-cause mortality included cardiovascular mortality and non-cardiovascular mortality

Key Secondary Endpoints

- Cardiovascular mortality
- Permanent pacemaker implantation
- Hemodynamic valve performance
- LV remodeling measured by echocardiography
- Functional Improvement of heart (NYHA)
- Quality of life (KCCQ)

Screening and Patient Disposition (As Treated)



Baseline Patient Characteristics

Variable	% or mean ± SD
Age (years)	73.9±5.9
Female	36.2%
Mean STS Score	6.1±4.5
NYHA Class III or IV	74.0%
Coronary artery Disease	45.7%
Frailty	74.0%
Bundle Branch Block	13.4%

Variable	%
Prior Permanent Pacemaker	1.6%
Renal Insufficiency	12.6%
Pulmonary hypertension	15.7%
Hypertension	80.3%
Diabetes	11.8%
Atrial fibrillation	18.9%
Prior CVA or TIA	15.7%

Baseline Echo Characteristics

Variable	% or mean ± SD
AR Severity	
Severe	78.7%
Moderate to Severe	21.3%
Pure AR	89.0%
AR with mild AS	11.0%
Vena Contracta Width （mm)	7.5±1.7
Mean Gradient (mmHg)	13.8±5.0

Variable	% or mean ± SD
Ascending aortic diameter (mm)	40.6±4.2
Mitral regurgitation (mild)	44.9%
Mitral regurgitation (≥ moderate)	20.5%
LVESD （mm)	41.5±8.8
LVEDD （mm)	59.5±7.3
LVEF （%± SD)	56.6±11.3
PASP （mmHg)	32.8±9.8

Baseline CT Characteristics

Variable	% or mean ± SD
Leaflet	
Tricuspid	96.1%
Bicuspid/Quadricuspid	3.9%
Annular perimeter (mm)	81.3±6.9
> 80mm	62.2%
Leaflet or annular calcification	
No calcification	76.4%
Mild calcification	22.1%

Variable	% or mean ± SD
LCA height (mm)	12.8±3.5
LCA-min(mm)	4.3
LCA < 10mm(%)	18.9%
RCA height (mm)	16.7±3.9
RCA-min(mm)	8.9
RCA < 10mm(%)	0.8%
Mean annulus angle (°)	55.5±10.9
> 70° (%)	10.2%

Procedural Details

Variable	% or mean ± SD
Valve Size Implanted	
Large (29,31,34)	**15.0%**
Medium (25,27,28)	**81.9%**
Small (21,22,23)	**3.1%**
General Anesthesia	**99.2%**
Device time (sheath introduce to removal from patient), min	**16.8±12.7**

Procedural Outcomes

Outcome	%
In-procedural Death	0%
Stroke	0%
Acute myocardial infarction	0%
Bleeding	0%
Acute kidney injury	0%
Converted to SAVR	2.4%
Valve in Valve	3.9%
Coronary Obstruction	0%
Femoral Access Site Intervention	0.8%

Procedural Outcomes

Outcome	%
Valve thrombosis	0%
Mitral valve damage or dysfunction	0%
Cardiac tamponade	0%
Endocarditis	0%
Ventricular Perforation	0%
Aortic Dissection	0%
Annular Rupture	0%
Technical Success*	93.7%

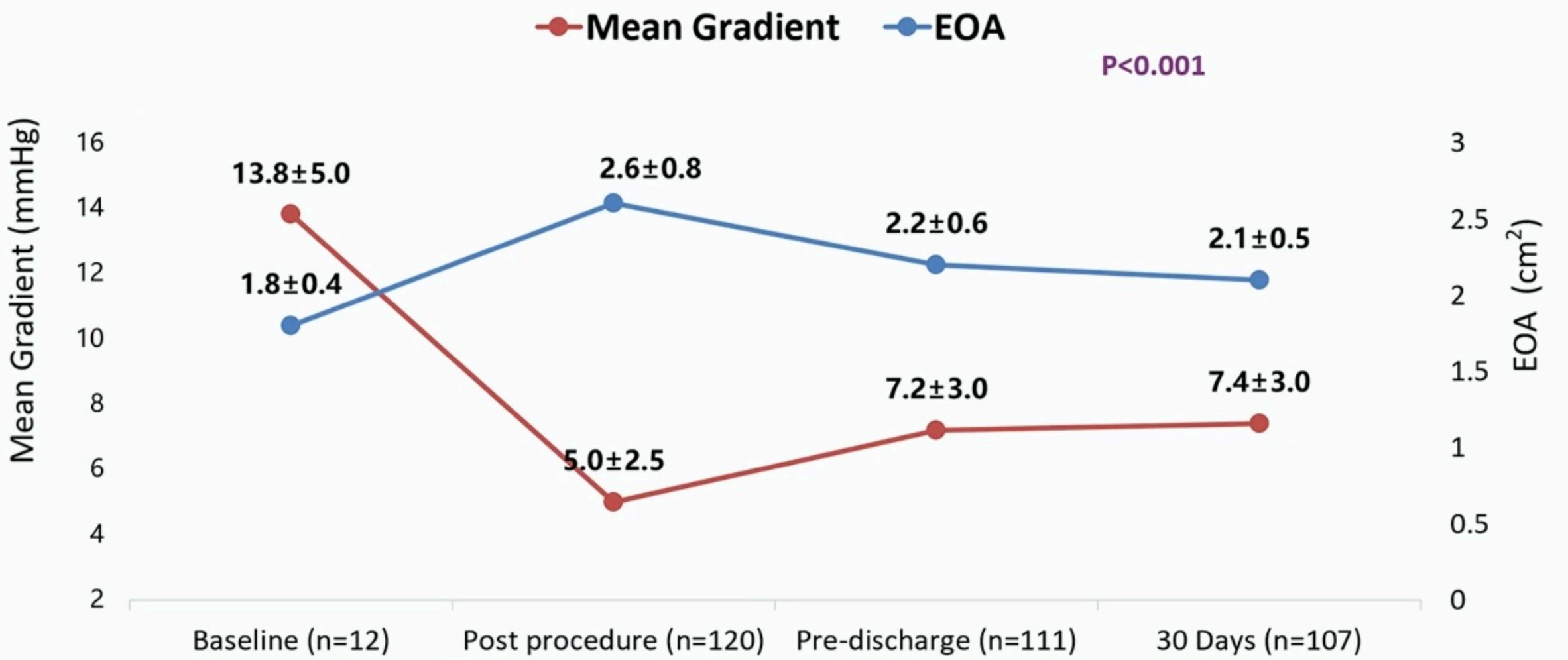
* Is calculated according the definition of VACR 3

Safety Outcomes at 30 Days

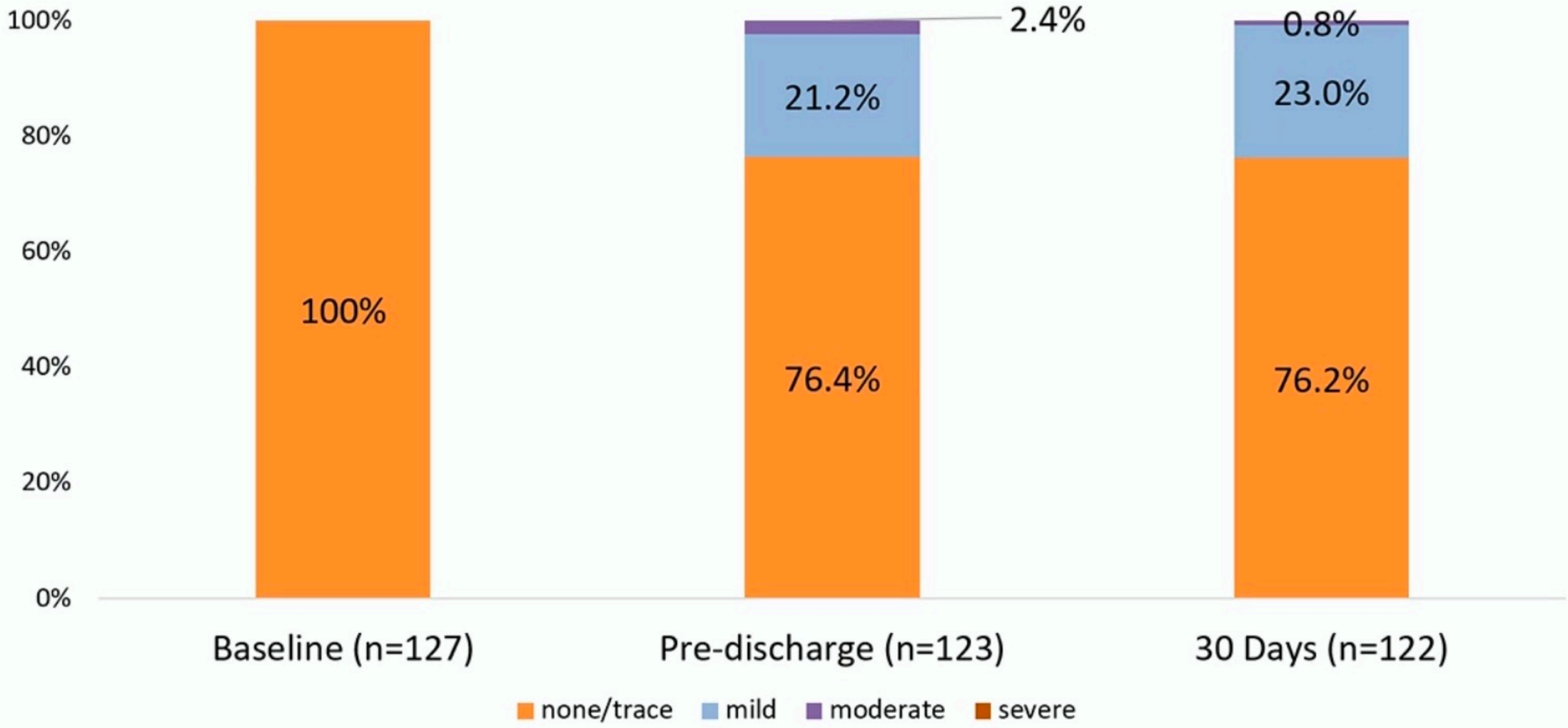
Safety Outcome	%
All cause mortality	1.6%
Cardiovascular mortality	1.6%
New permanent pacemaker implantation Pre-existing PPM	9.5% 1.6%
Major Vascular Complication	0.8%
Myocardial infarction	0%
All Stroke	0%
Major bleeding (life-threatening or disabling)	0%
Acute kidney injury	0%
Safety Composite endpoint*	16.5%

*Include: all-cause mortality, any stroke, major vascular complication, life threatening or major bleeding, new pacemaker, acute kidney injury, valve dysfunction and surgery or intervention related to the device.

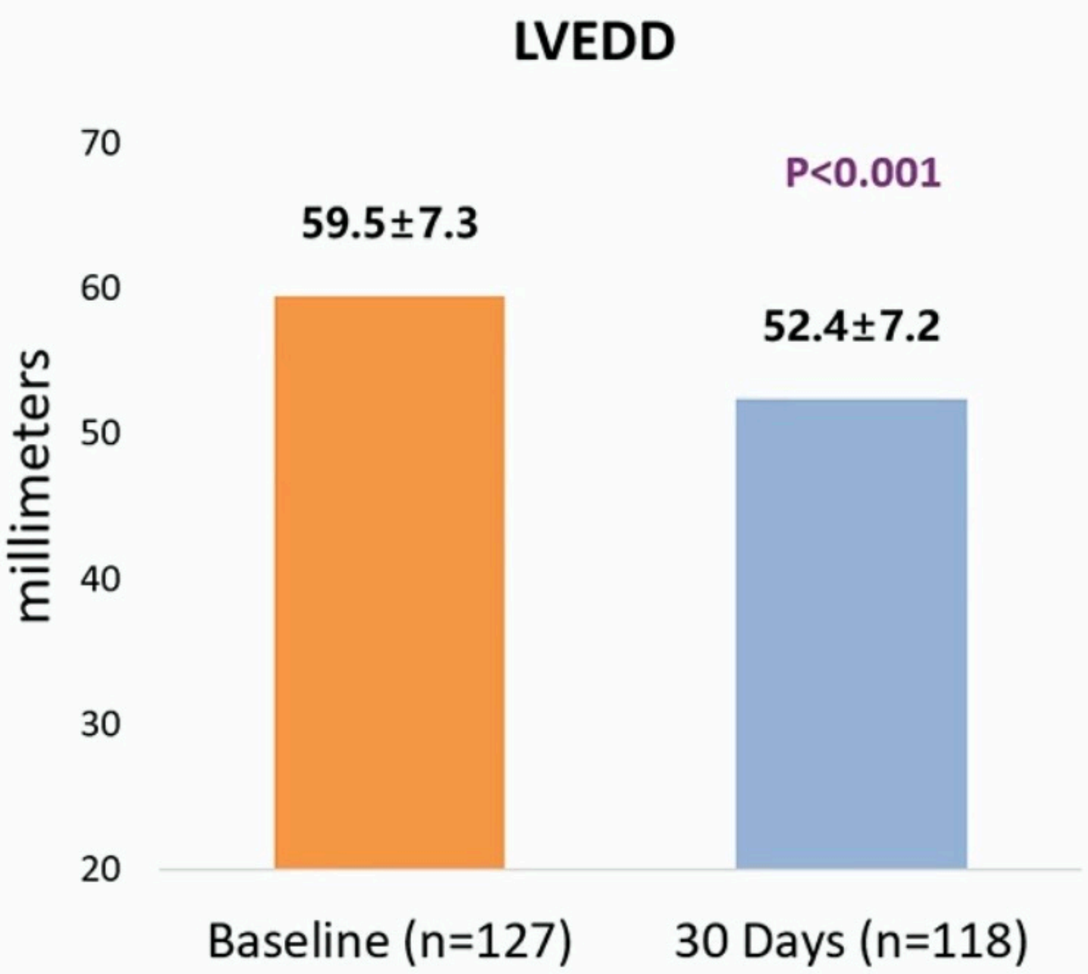
Hemodynamics Valve Performance

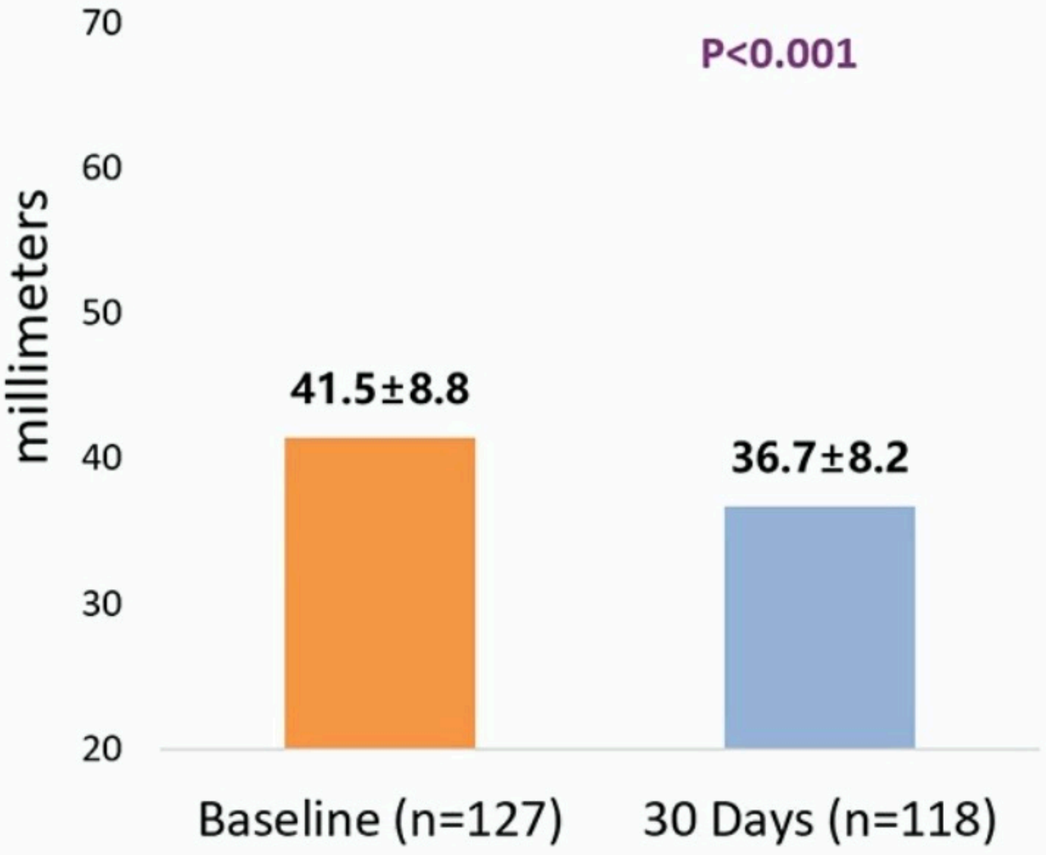


Paravalvular Regurgitation

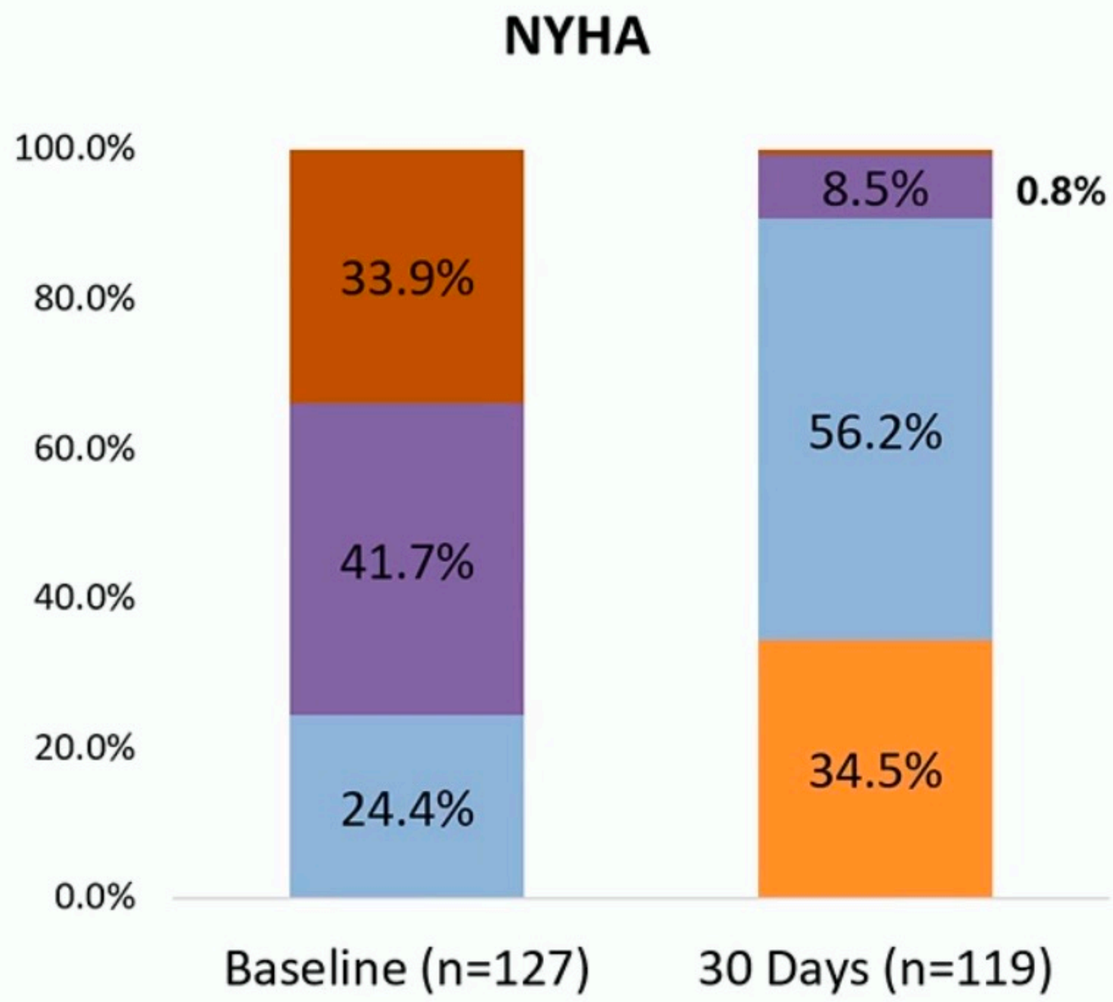


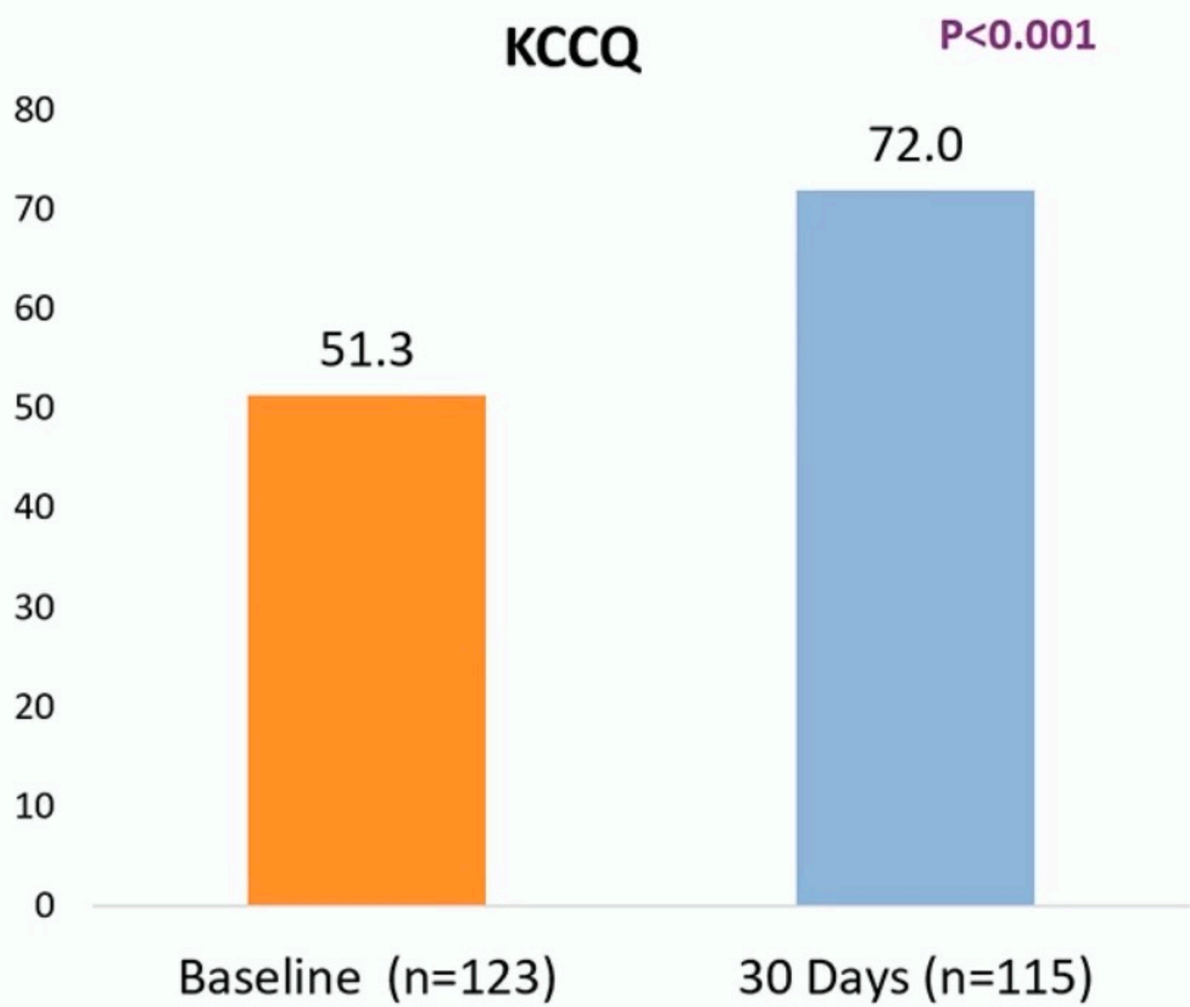
Left Ventricular Remodeling





NYHA & KCCQ Improvement





Conclusion

The J-VALVE Transfemoral (TF) System has demonstrated the following characters in AR patients:

- **Low mortality and morbidity at 30-days**
- **Low new permanent pacemaker implantation rate**
- **Excellent hemodynamics valve performance**
- **Echocardiography demonstrated significant improvement in LV remodeling**
- **Significant clinical functional improvement**

Longer term evaluation of clinical outcomes and valve performance are underway