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

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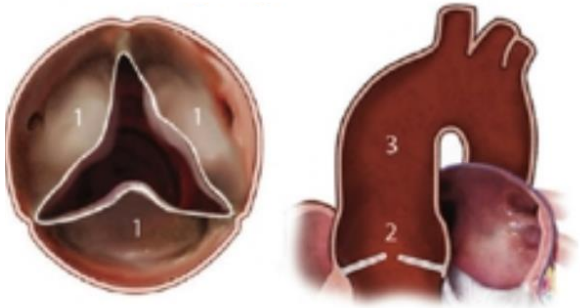
Disclosure of Relevant Financial Relationships

I, [Wang Jian’an, MD] DO NOT have any financial relationships to disclose.

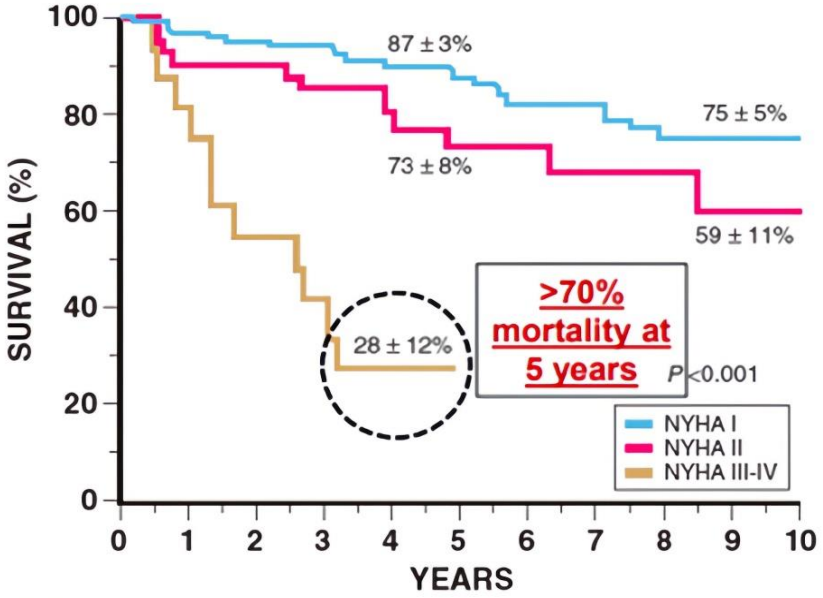
Background

Aortic Regurgitation



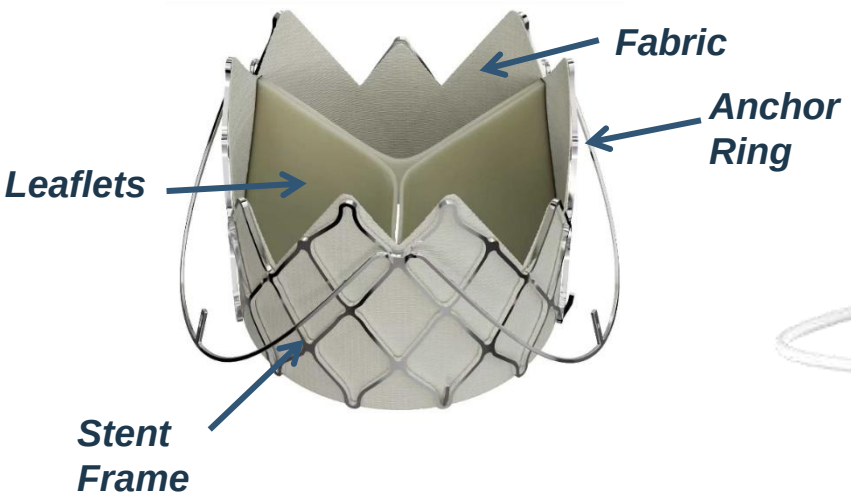
- No calcification
- Lack of anchoring area
- Annulus dilation

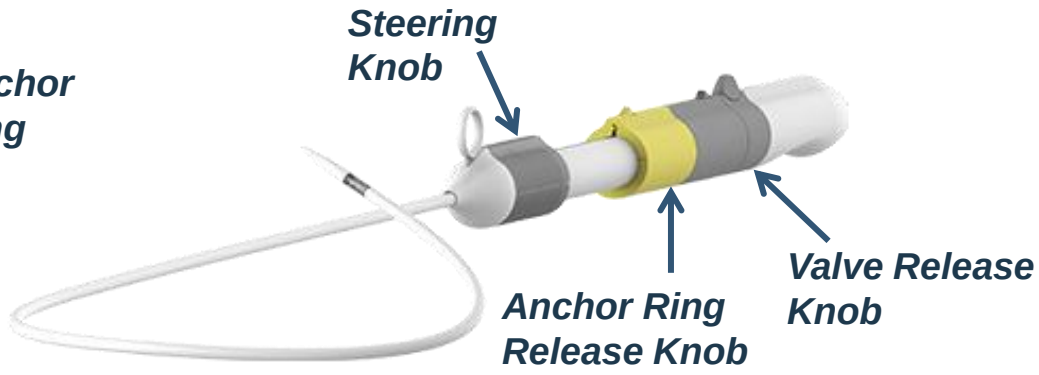
Worse prognosis



Franzone et al. JACC Cardiovasc Interv. 2016;9:2308–2317.
Dujardin et al: Circulation 1999; 99:1581-57

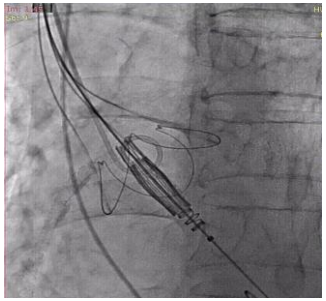
J-VALVE TF System

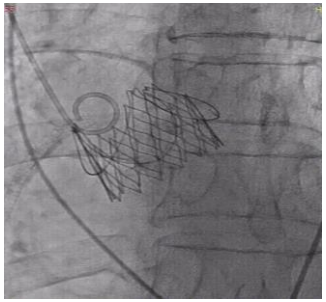




The valve sizes range from 21mm to 34 mm accommodating annular perimeters from 53 to 104 mm

The Key J-VALVE TF Implantation Steps





J-VALVE Positioning

Align with aortic annulus

Anchor Deployment

Anchor ring into native cusps

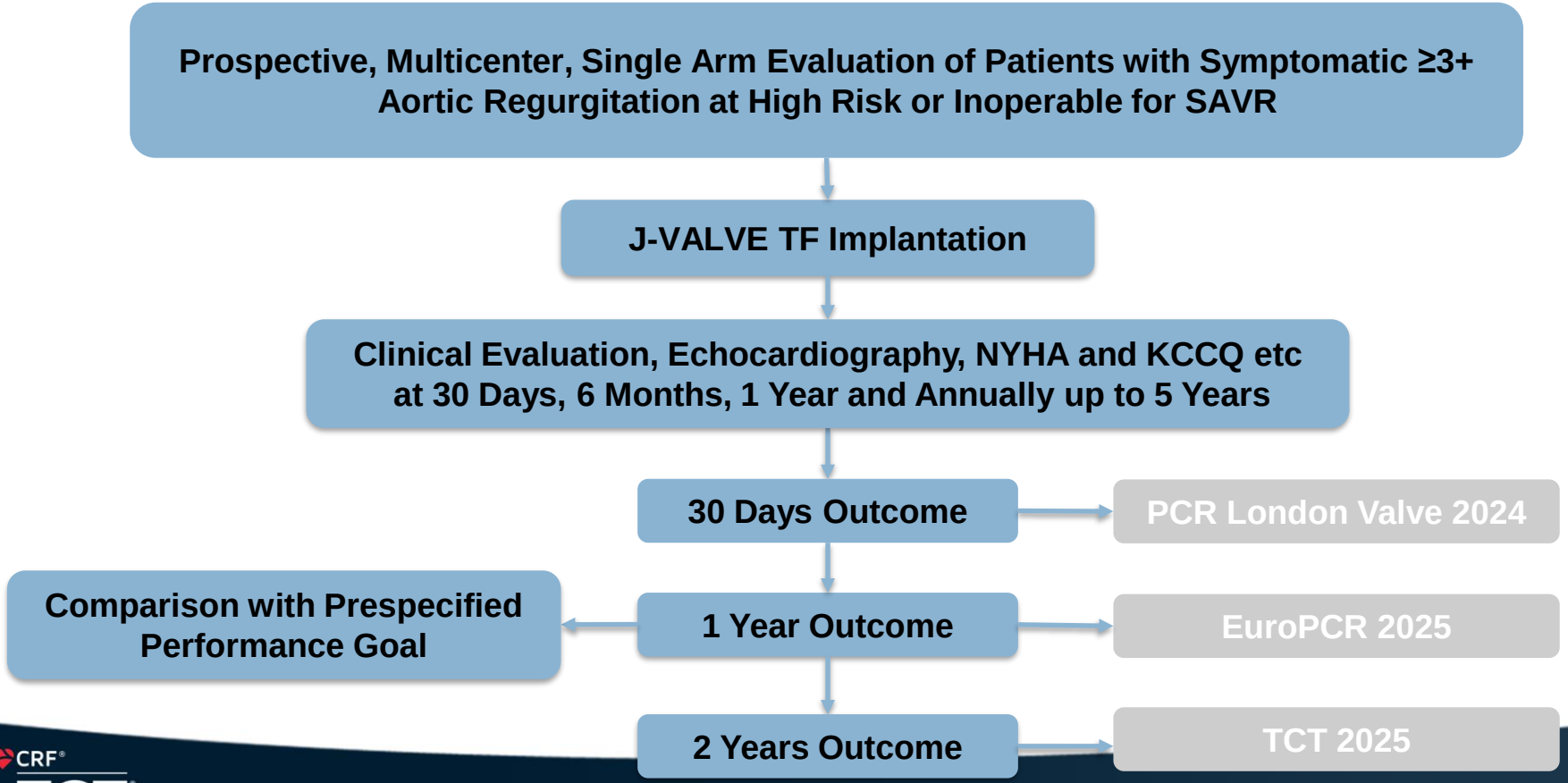
Valve Releasing

Auto-commissural alignment & open cell design benefit low coronaries

Trial Purpose

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

Trial Design



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

Key Inclusion & Exclusion Criteria

Exclusion:

- Acute myocardial infarction or coronary revascularization occurred within one 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 Endpoints

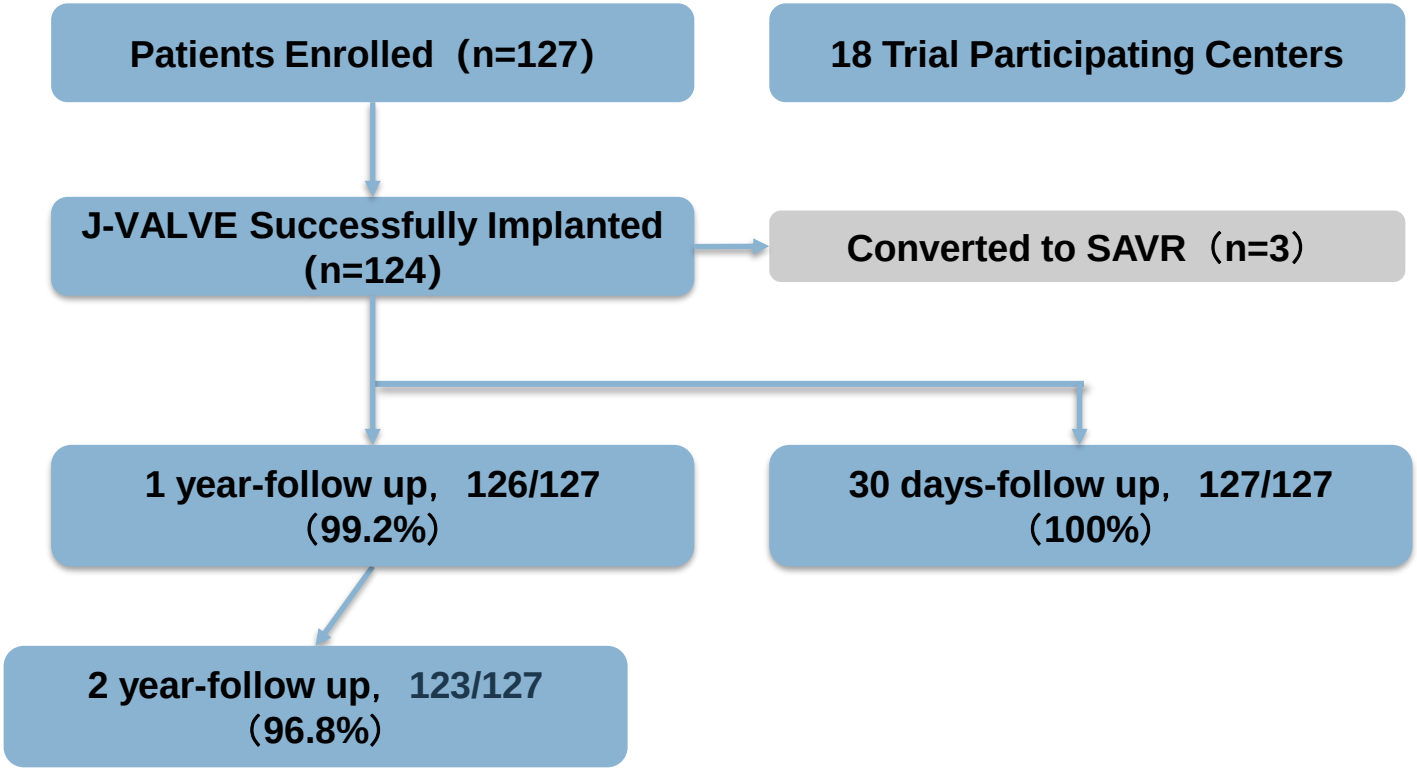
The primary endpoint was cumulative all-cause mortality at 12 months

- 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



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%
Hypertension	80.3%
Diabetes	11.8%

Variable	%
Prior Permanent Pacemaker	1.6%
Left Bundle Branch Block	7.1%
Right Bundle Branch Block	6.3%
Renal Insufficiency	12.6%
Pulmonary hypertension	15.7%
Peripheral Arterial Disease	58.3%
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%
Vena Contracta Width (mm)	**7.5±1.7**
Mean Gradient (mmHg)	13.8±5.0

Variable	% or mean ± SD
Ascending Aortic Diameter (mm)	40±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	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%**

Variable	% or mean ± SD
Leaflet or annular calcification	
Mild calcification	22.1%
LCA Height（mm）	12.8±3.5
RCA Height（mm）	16.7±3.9
Mean aortic annular angle（°）	55.5±10.9
> 70°（%）	10.2%
Dextrocardia（%）	0.8%

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%

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

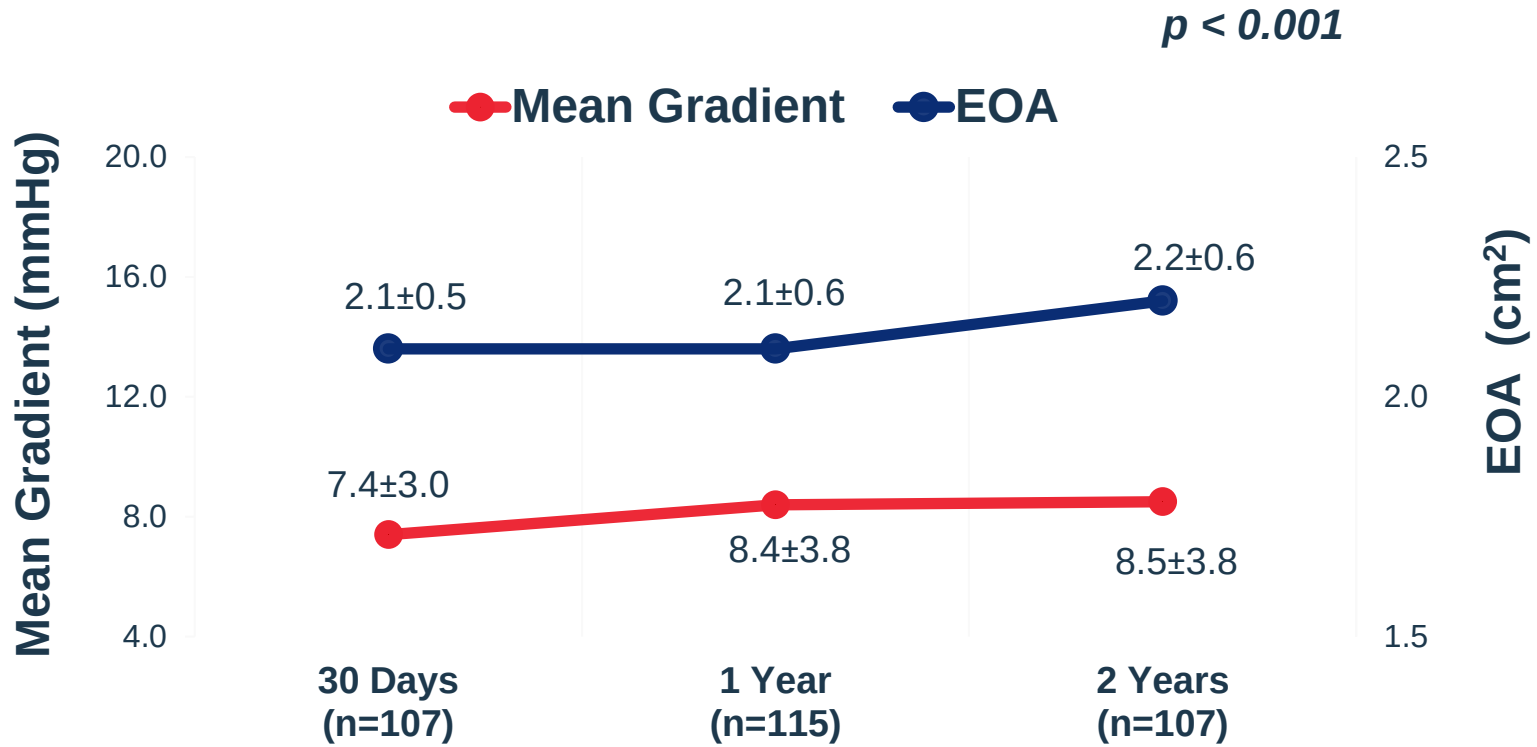
Safety Outcome	30 Days	1 Year	2 Years
All cause mortality	1.6%	3.2%	**6.3%**
Cardiovascular mortality	1.6%	2.4%	**3.9%**
New permanent pacemaker implantation	9.5%	12.6%	13.4%
III ° AV block	3.9%	5.5%	5.5%
Major Vascular Complication	0.8%	1.6%	3.2%
Myocardial infarction	0%	0%	0%
All Stroke	0%	2.4%	5.5%
Major bleeding (life-threatening or disabling)	0%	0.8%	2.4%
Acute kidney injury	0%	0.8%	1.6%

Cause of Death

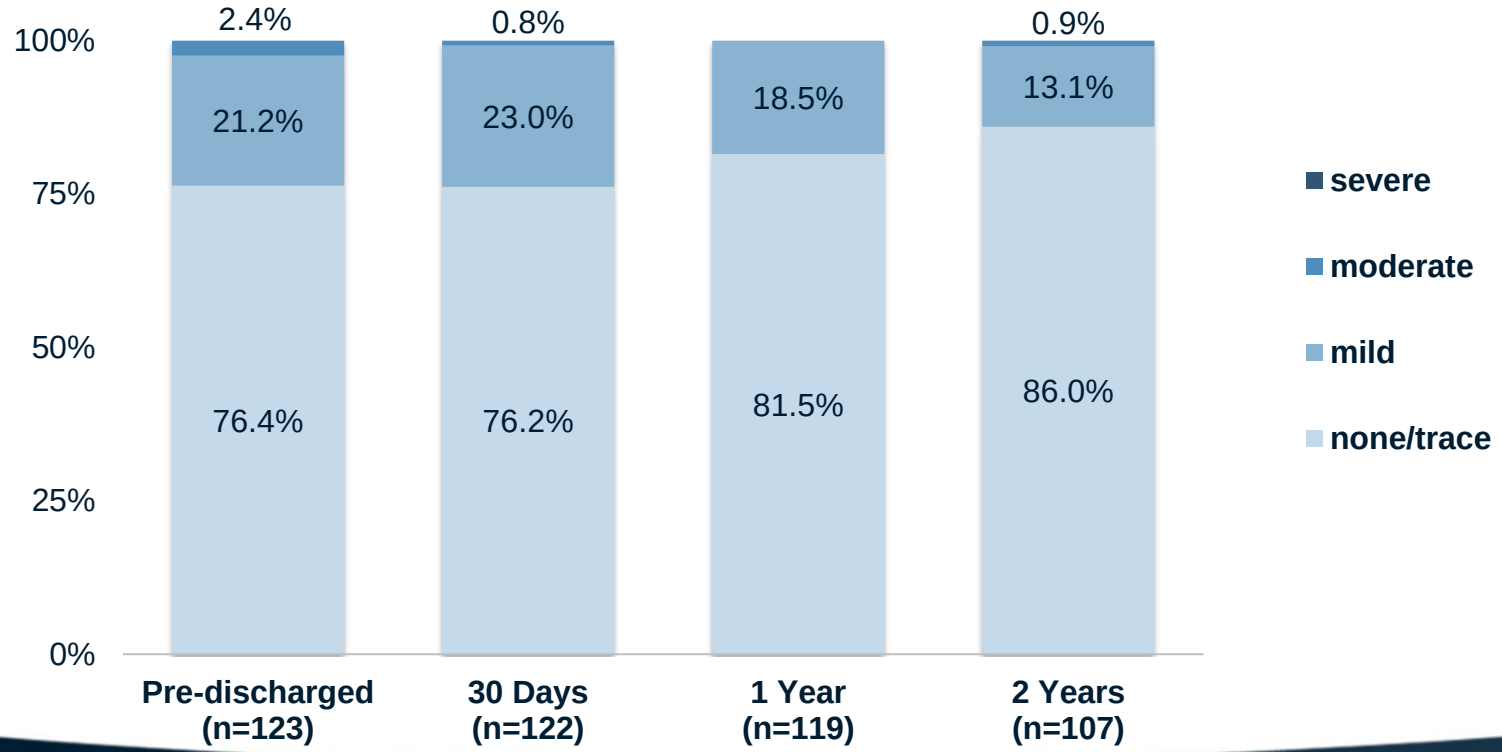
Death 1Y	Day	CEC Adjudication
Aortic Dissection	11	**Cardiovascular**
Sudden Death	17	**Cardiovascular**
Hypertension，Heart Failure	139	**Cardiovascular**
Unknown	351	Non-Cardiovascular

Death 2Y	Day	CEC Adjudication
Aortic Dissection	391	**Cardiovascular**
Hemorrhagic stroke	423	Non-Cardiovascular
Sudden Death	468	**Cardiovascular**
Ischemic stroke	503	**Non-Cardiovascular**

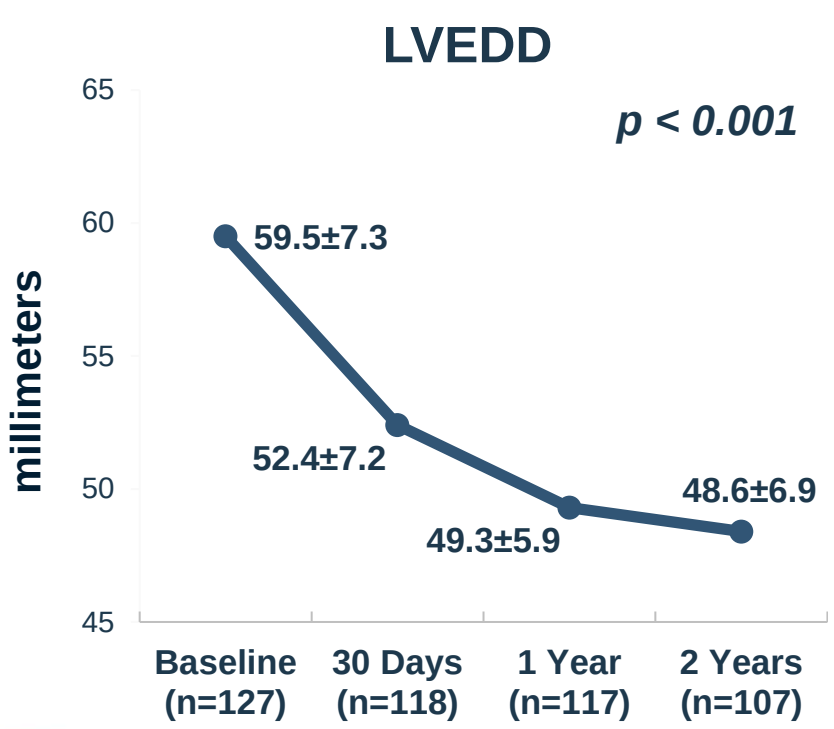
Hemodynamic Valve Performance

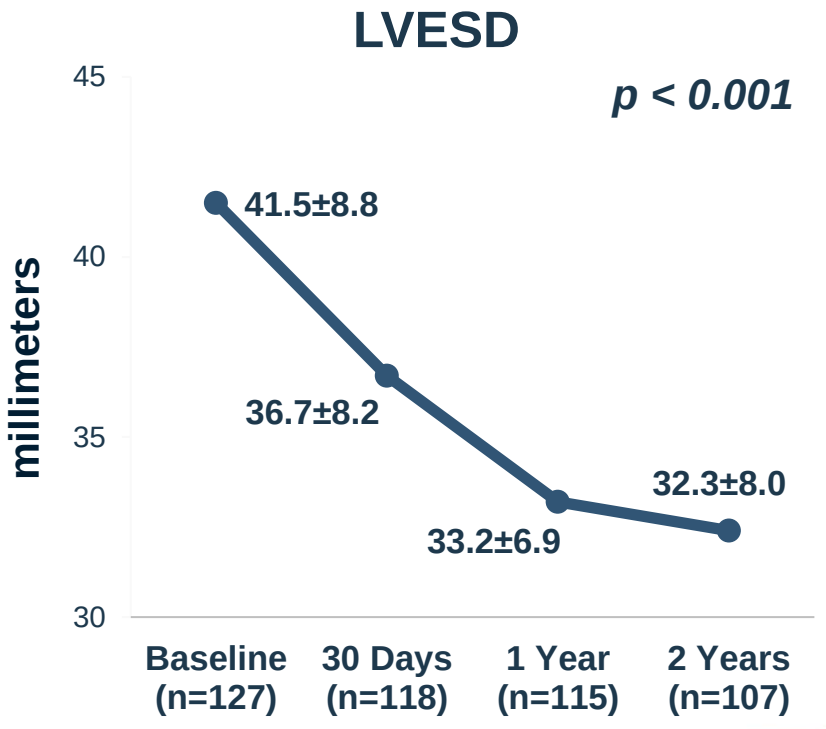


Paravalvular Regurgitation

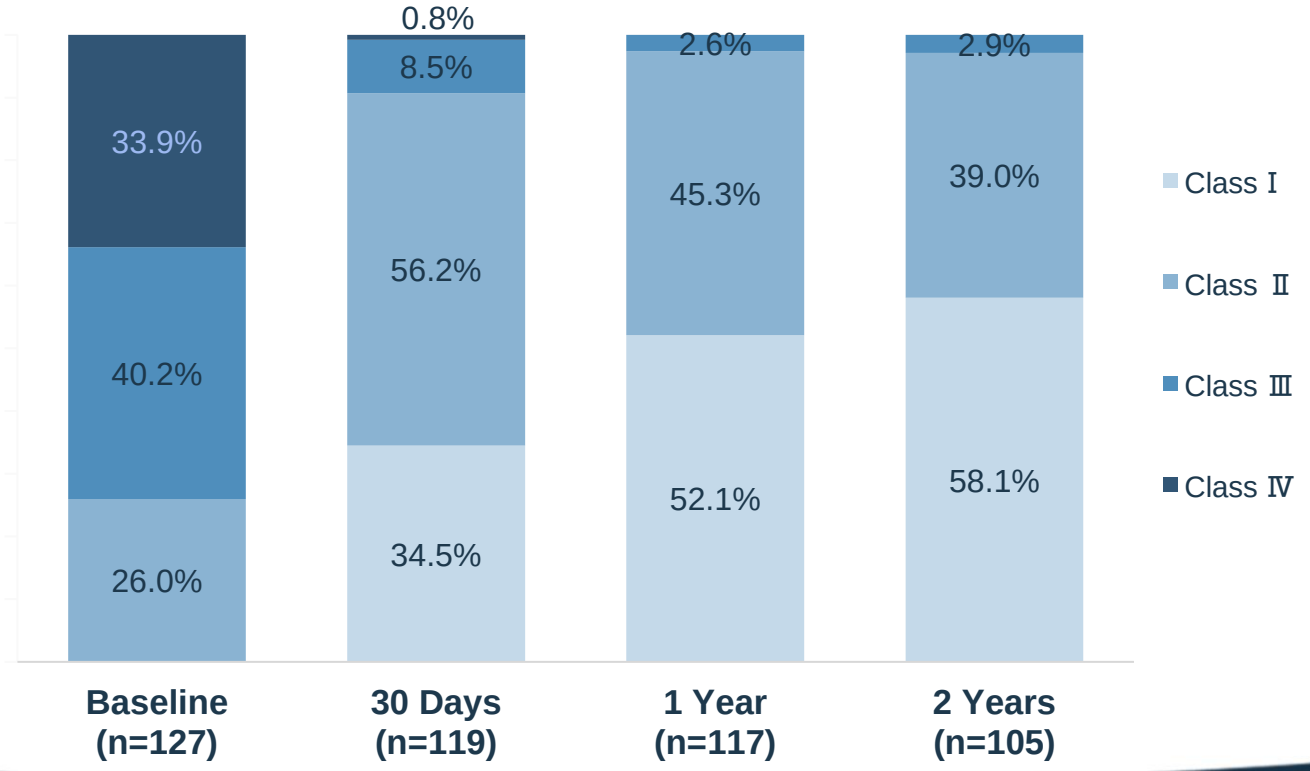


Left Ventricular Remodeling

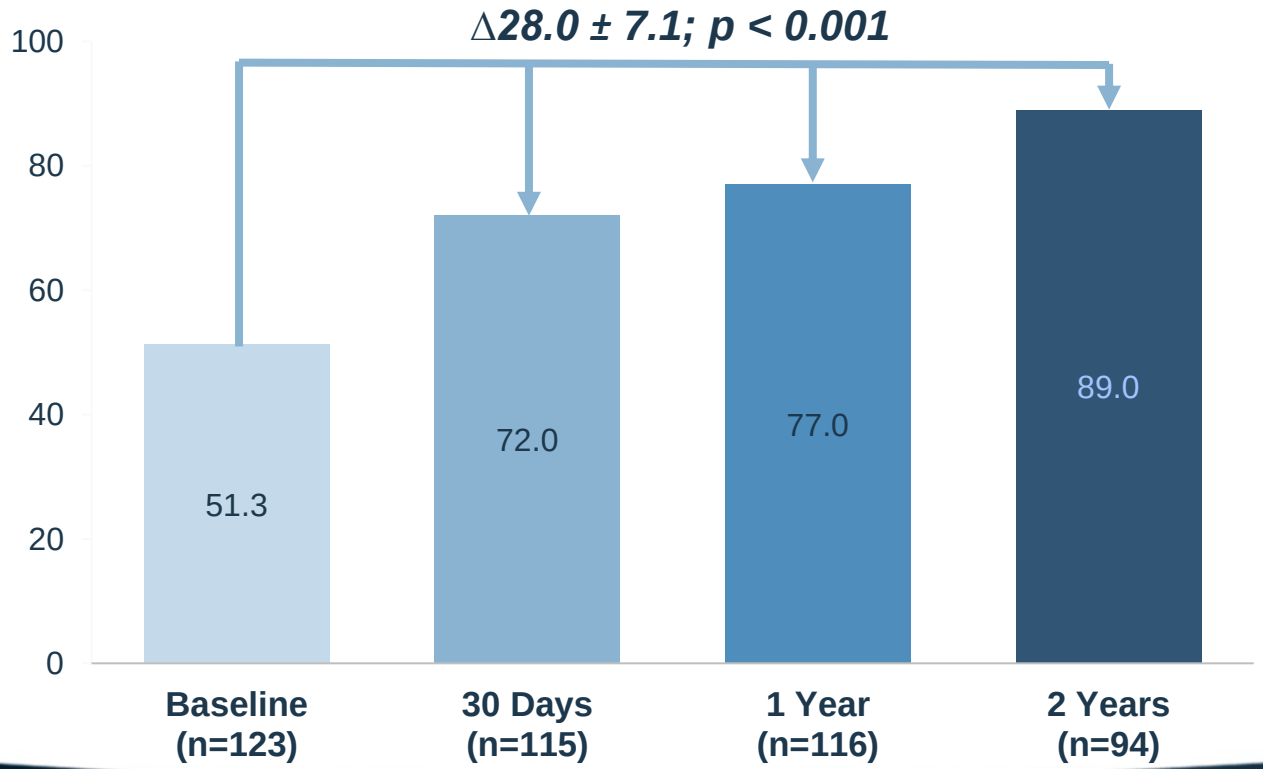




NYHA Improvement



KCCQ Improvement



Conclusion

The Transfemoral J-VALVE has demonstrated the following characters in AR patients:

- Low mortality and morbidity
- 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 are underway

Acknowledgement

The study principal investigators and sponsor express our deepest gratitude to all the clinical research assistants, clinical research coordinators, CEC members, and all the patients at J-VALVE TF Trial in China