Transcatheter Treatment of Chronic Aortic Regurgitation Using the Novel J-Valve System

6-Months Results from the Transfemoral Early Feasibility Study

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on behalf of J-Valve EFS Investigators

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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship	Ineligible Company
Grant/Research Support	Edwards Lifesciences, Medtronic, BSCI, Abbott Vascular, ACC, JC Medical
Consultant Fees/Honoraria	BSCI, Abbott Vascular, Medtronic, Edwards Lifesciences
Advisory Board	Medtronic

All relevant financial relationships have been mitigated.
Faculty disclosure information can be found on the app

Background

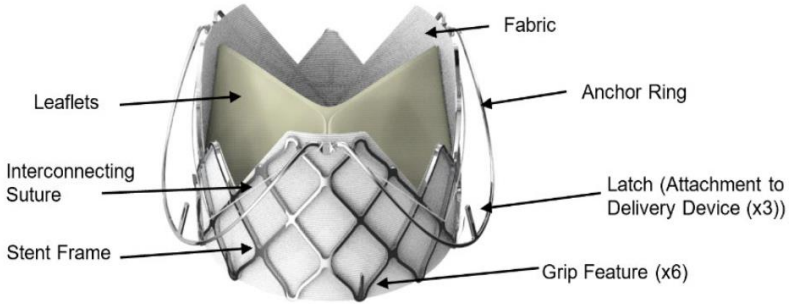
- Aortic regurgitation (AR) affects 4-5% of adults >65 years of age[1]
- **Severe AR is undertreated**, particularly in high-risk patients and is associated with increased mortality
- Off-label use of TAVR devices for AR is associated with anatomical challenges and increased complications[2]
  - **Challenges include absence of calcium, increased stroke volume, and large size of aortic annulus**
  - **Lower chance of procedural success (~82%) compared to dedicated devices (93%)**
  - **Higher rate of reintervention (10%) compared with dedicated devices (4%)**
  - **High 1-year mortality (24%) when treating AR with non-dedicated devices**

1. Lebehn M, et al. Contemporary Evaluation and Clinical Treatment Options for Aortic Regurgitation. *J Cardiovasc Dev Dis*; 10(9):364.
2. Samimi S, et al. Meta-Analysis of Dedicated vs Off-Label Transcatheter Devices for Native Aortic Regurgitation. *JACC Cardiovasc Interv*. 2025; 18(1):44-57.

J-Valve: A Novel TAVR Design to Treat AR

Comprised of bovine pericardium leaflets, nitinol frame, and a fabric skirt to mitigate PVL

- **Unique anchor rings designed to self-center the valve for optimal alignment**
- **Five valve sizes available intended to treat perimeters 57-104 mm**
- **Rounded, atraumatic rings designed to easily locate and position in the annulus**



J-Valve TF Size	Annulus Diameter (mm)	Annulus Perimeter (mm)	Annulus Area (mm^2)
22 mm	18 – 21	57 – 66	254 – 346
25 mm	21 – 24	66 – 75	346 – 452
28 mm	24 – 27	75 – 85	452 – 573
31 mm	27 – 30	85 – 94	573 – 707
34 mm	30 – 33	94 – 104	707 – 855

Low Profile

Valve Size	Height
22 mm	17 mm
25 mm	19 mm
28 mm	22 mm
31 mm	25 mm
34 mm	25 mm

Valve size recommendations are based on native valve annulus size, as measured by CT. Patient anatomical factors and imaging modality should be considered during valve selection.

Purpose

To evaluate 6-month clinical, hemodynamic, functional, and QoL outcomes following transfemoral TAVR with J-Valve® in patients with symptomatic ≥3+ aortic regurgitation and high surgical risk

J-Valve® EFS Study Design

Prospective, single arm, multi-center interventional study of 25 patients with symptomatic ≥3+ aortic regurgitation deemed high risk for SAVR by Heart Team

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Transfemoral J-Valve® Implant Procedure

↓

Clinical Evaluation, Echocardiography, Functional and QoL Assessment at 30 Days, 6 Months, 1 Year and Annually up to 5 Years

↓

Primary Endpoint:
All cause death or disabling stroke at 30 days

Key Inclusion and Exclusion Criteria

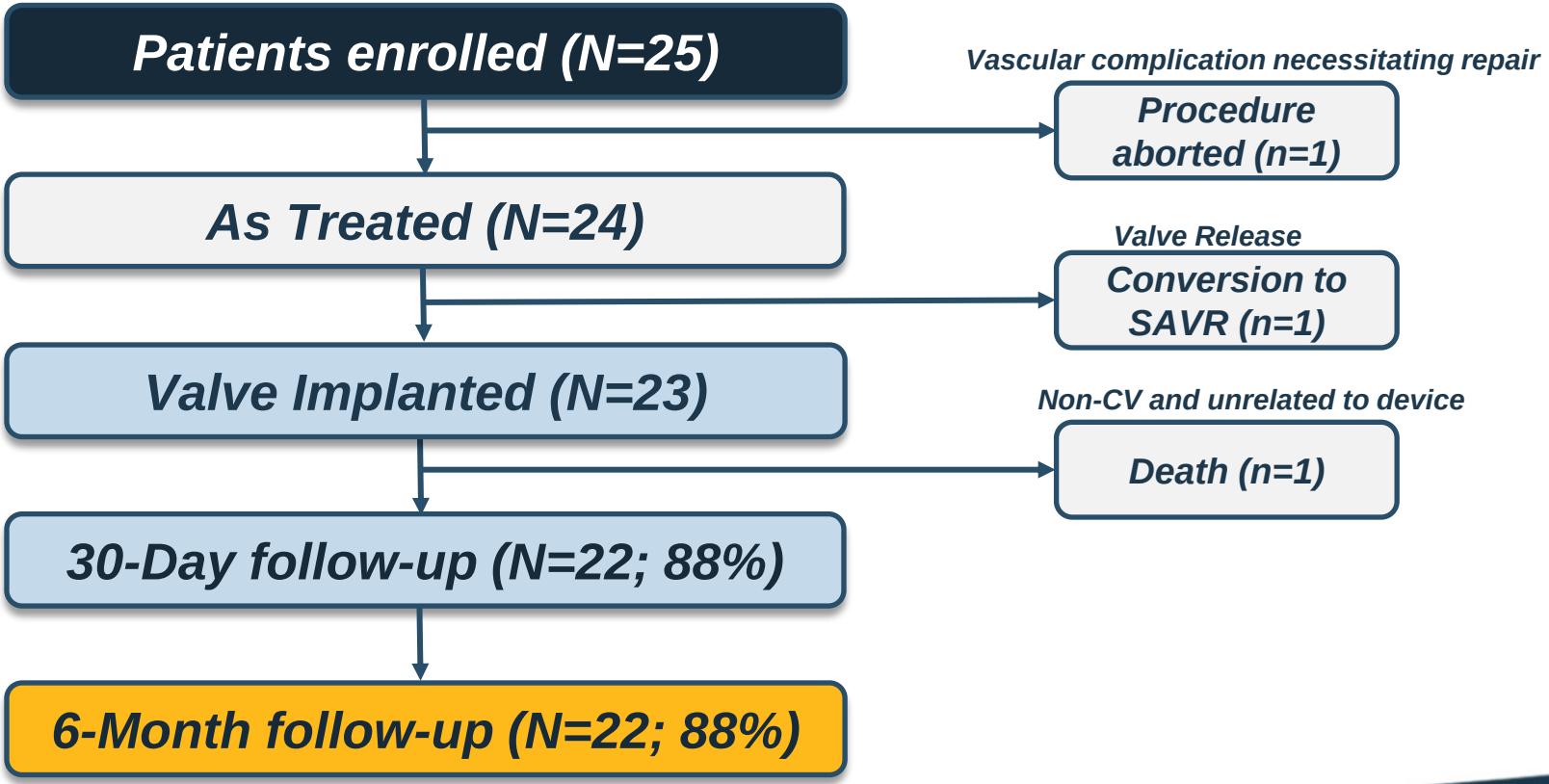
Inclusion

- Symptomatic (NYHA Class ≥ II) and severe (≥ 3+) native AR
- Patient deemed high risk for surgery
- Patient has suitable anatomy for transfemoral J-Valve implantation

Exclusion

- Bicuspid aortic valve
- Mixed aortic valve disease (> moderate AS with severe AR)
- LVEF < 25%
- Aortic Root diameter > 5.0 cm
- Mitral regurgitation > moderate
- CAD requiring revascularization
- Aortic annulus perimeter < 57 mm or > 104 mm

Patient Flow



Baseline Patient Characteristics (N=25)

Demographics and Co-Morbidities	% (n) or mean ± SD
Age	80.6 ± 4.3
Male	76.0% (19)
White	84.0% (21)
STS Score	5.6 ± 4.5
STS Score ≥ 8%	32.0% (8)
NYHA	
I	0.0% (0)
II	60.0% (15)
III	40.0% (10)
IV	0.0% (0)
Hypertension	96.0% (24)
Diabetes	12.0% (3)
Renal Insufficiency (GFR <60 ml/min)	40.0% (10)

Vascular & Other Co-Morbidities	% (n)
COPD	12.0% (3)
Peripheral Vascular Disease	4.0% (1)
Permanent Pacemaker	20.0% (5)
History of Arrhythmia	64.0% (16)
Conduction Defect	56.0% (14)
Prior MI	4.0% (1)
Prior PCI	12.0% (3)
Prior CABG	4.0% (1)
Prior TIA	16.0% (4)
Prior Stroke	8.0% (2)
Prior Mitral Valve Procedure	20.0% (5)

Baseline Echo Characteristics (N=25)

Echo Characteristic	% (n) or mean ± SD
LVEF (%)	52.6 ± 8.2
AR Severity	
Severe	44.0% (11)
Moderate to Severe	56.0% (14)
Mean Gradient (mmHg)	5.1 ± 2.2
Aortic Valve Area (cm^2)	3.1 ± 0.8
LVOT Doppler stroke volume index (mL/m^2)	52.6 ± 8.9

Echo Characteristic	% (n) or mean ± SD
LVIDs index (cm/m^2)	2.4 ± 0.4
LVEDV index (mL/m^2)	97.7 ± 19.3
LVESV index (mL/m^2)	46.9 ± 14.1
LV mass index (g/m^2)	127.2 ± 35.2
Aortic regurgitation volume (mL)	46.5 ± 13.3
Aortic regurgitation fraction (%)	46.2 ± 5.2
AR PISA EROA (cm^2)*	0.26 ± 0.1

*Reported in 13 patients.

Baseline CT Characteristics (N=25)

CT Characteristic	% (n) or mean ± SD
Aortic Root Angulation	53.4 ± 10.2
Root angle >60 mm*	24.0% (6)
AV Calcification Severity	
None	64.0% (16)
Mild	36.0% (9)
Annulus Diameter (mm)	27.7 ± 2.5
Aortic Annulus Perimeter (mm)	87.0 ± 8.9
Perimeter >90 mm	40.0% (10)
Aortic Annulus Area (mm^2)	589.6 ± 121.7

*Root angle >70 mm was present in 1 patient

Procedural Characteristics

Characteristic	% (n/N) or mean ± SD
Procedure Duration, min	79.2 ± 75.3
Contrast Volume, CCs	143.7 ± 76.3
Fluoroscopy time, min	22.4 ± 14.6
Pre-BAV performed	4.0% (1/25)
Post-BAV performed	0.0% (0/25)

Characteristic	% (n/N)
Implanted Valve Size	
22 mm	0.0% (0/23)
25 mm	4.3% (1/23)
28 mm	30.4% (7/23)
31 mm	30.4% (7/23)
34 mm	34.8% (8/23)
Sheath Size Used	
20 Fr	4.0% (1/25)
22 Fr	76.0% (19/25)
Other	20.0% (5/25)

Garcia S, et al. Treatment of Aortic Regurgitation With a Novel Device: Results of the J-Valve Early Feasibility Study. *JACC Cardiovasc Interv*. 2024; 17(17):2090-2091.

Intraprocedural Outcomes

Characteristic	% (n/N) or n
Successful Valve Implant*	**92.0% (23/25)**
Intraprocedural Complications	**12.0% (3/25)**
Major/Life-Threatening or Fatal Bleeding†	2
Major Vascular Complication†	2
Cardiac Structural Complication	0

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*1 patient had vascular access and life-threatening bleeding complications upon sheath insertion, case was aborted; 1 patient converted to SAVR.
†1 patient had both life-threatening bleeding and vascular complications; case was aborted.

6-Month Clinical Outcomes (N=25)

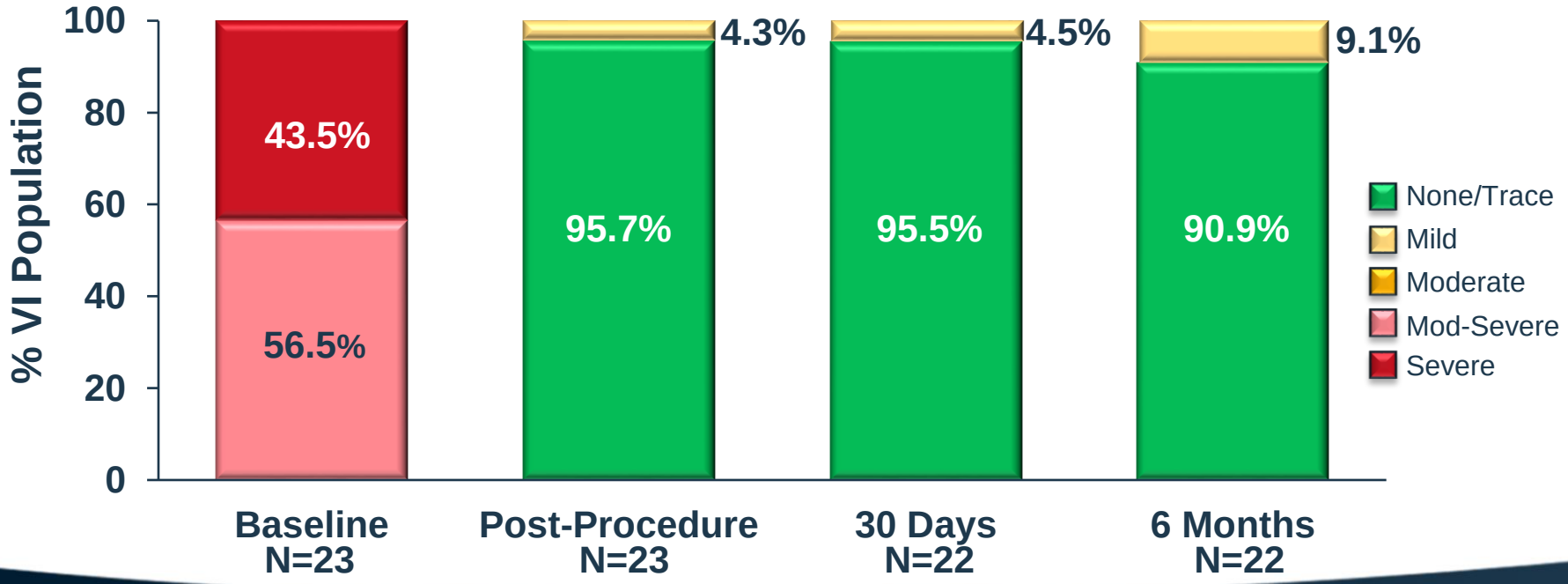
Outcome	30 Days % (n)	6 Months % (n)
All-Cause Death or Disabling Stroke	**8.0% (2)**	**8.0% (2)**
All-Cause Mortality*	**4.0% (1)**	**4.0% (1)**
Cardiovascular Mortality	0.0% (0)	0.0% (0)
Non-Cardiovascular Mortality*	4.0% (1)	4.0% (1)
Stroke	**8.2% (2)**	**8.2% (2)**
Disabling Stroke	4.0% (1)	4.0% (1)
Non-Disabling Stroke	4.2% (1)	4.2% (1)
New Permanent Pacemaker	10.0% (2)	15.0% (3)†
Major/Life-Threatening or Fatal Bleeding	8.0% (2)	8.0% (2)
Major Vascular Complication	8.0% (2)	8.0% (2)

Percentages represent Kaplan-Meier estimates at 30 days and 6 months.

*1 death at POD 3 due to food asphyxiation, autopsy revealed J-Valve® was in proper position.
† New PPMi after 30 days occurred in the patient who converted to surgery and did not receive the study valve.

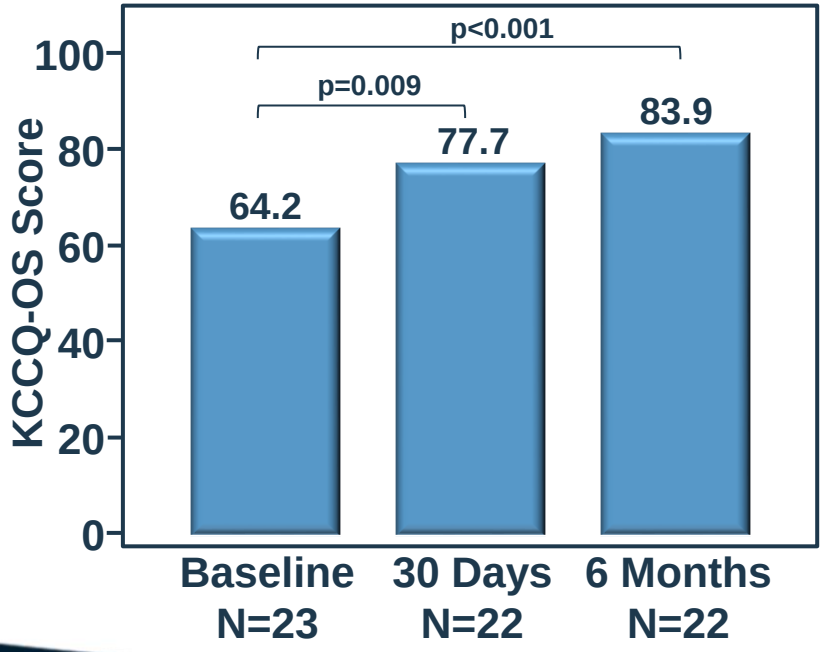
Total Aortic Regurgitation Through 6 Months

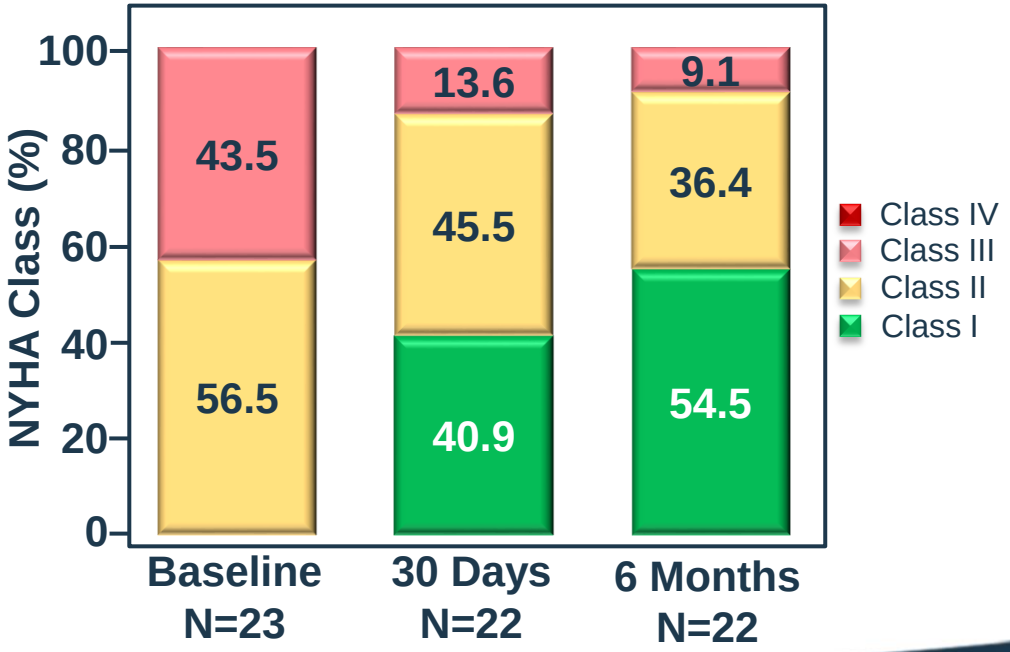
> 90% patients had None/Trace Total AR at 6 Months



Functional and QoL Outcomes Through 6 Months*

Significant and sustained improvement in symptoms and quality of life





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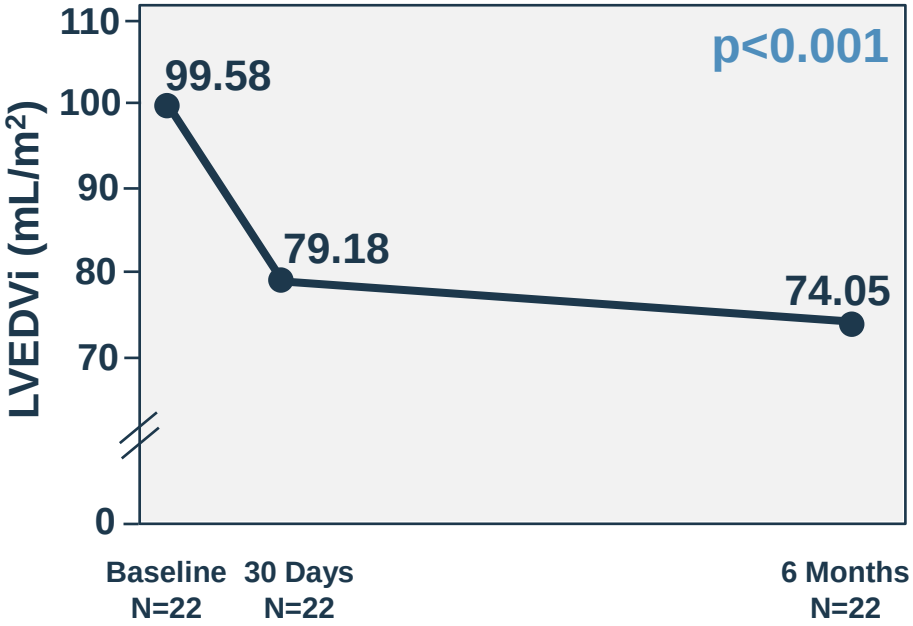
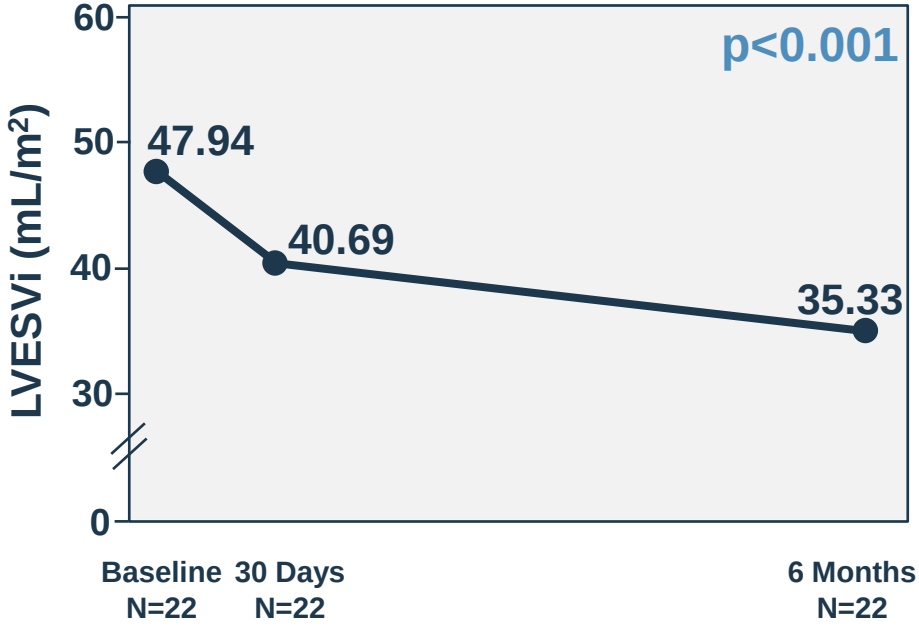
*Based on VI population
P-value from paired comparison by using Wilcoxon signed rank test.

Echo LV Volume Indices Through 6 Months*

Significant and sustained reduction in LV volumes





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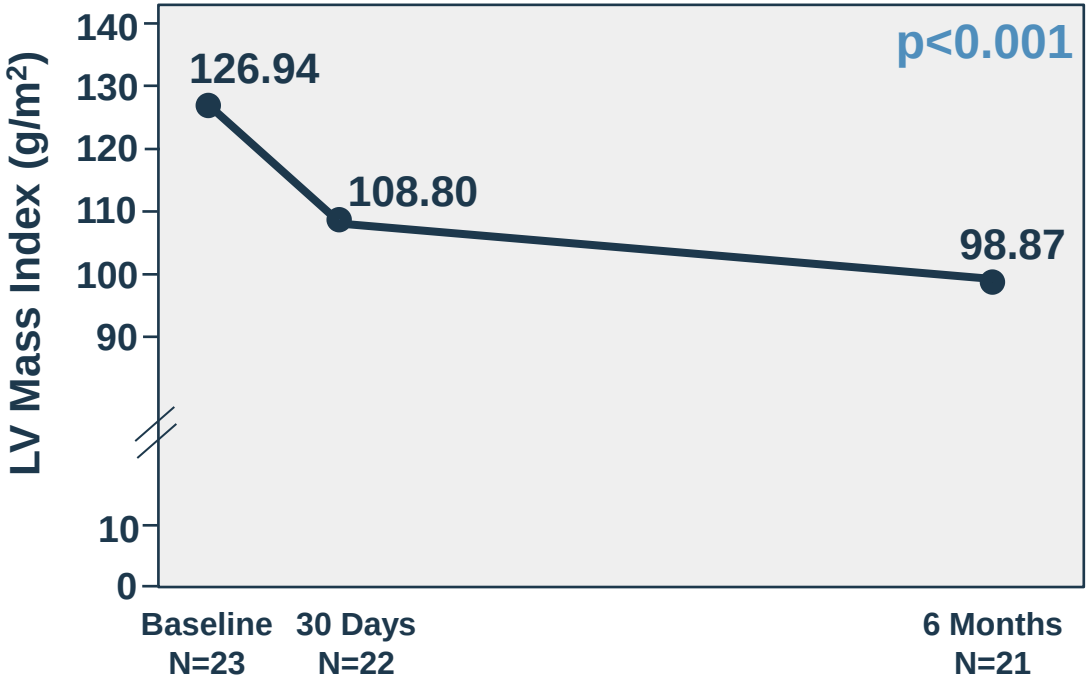
*Based on VI population
P-value from Wilcoxon signed-rank test for paired comparison between baseline and 6 months

LV Mass Index Through 6 Months*

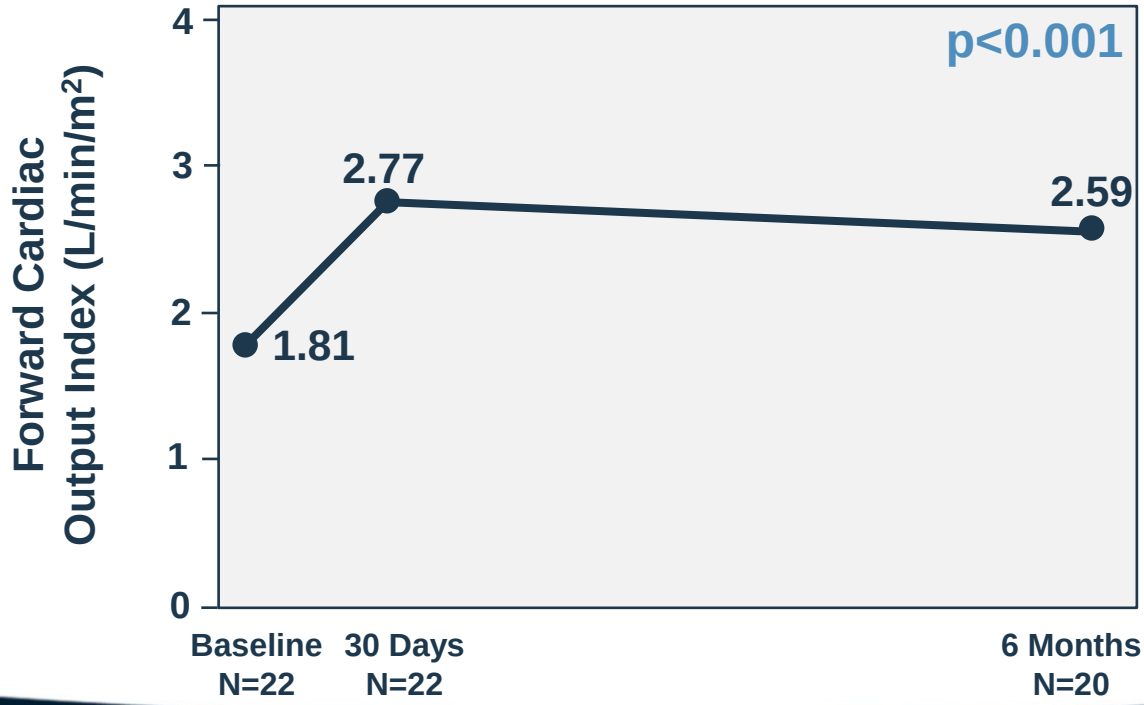
Significant and sustained reduction in LVMi



*Based on VI population
P-value from Wilcoxon signed-rank test for paired comparison between baseline and 6 months

Forward Cardiac Output Index Through 6 Months*

Significant and sustained improvement in forward cardiac output



EOA Index: 1.4 ± 0.3 cm^2/m^2
Mean Gradient: 5.7 mmHg

*Based on VI population
P-value from Wilcoxon signed-rank test for paired comparison between baseline and 6 months

Conclusions

At 6 months, treatment with the J-Valve implant in symptomatic patients with ≥ 3+ aortic regurgitation at high surgical risk resulted in:

- **Expanded treatable AR population** due to availability of larger valve sizes
- **Low rates of major adverse events**
- **Effective reduction of aortic regurgitation** (none/trace AR > 90%)
- **Significant reduction in LV volumes and regression of LV mass**
- **Significantly improved forward flow and cardiac output**
- **Significant improvement in symptoms and quality of life**

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