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Teaching for Tomorrow Together

Two-year Clinical and Hemodynamic Outcomes of the Tendyne Transcatheter Mitral Valve System in Patients with Severe Mitral Annular Calcification (MAC)

SUMMIT-MAC Pivotal Trial

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Disclosures

Vinod H. Thourani, MD

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

Grant/Research Support

PI/Steering Committee

SAB (Equity)

Honoraria

Company

Edwards Lifesciences, Abbott Vascular, JenaValve,

Edwards Lifesciences, Abbott Vascular, JenaValve, Croivalve

DASI Simulations, Trisol Medical

Arthrex, Artivion, Edwards Lifesciences, Abbott Vascular



Background

- The SUMMIT clinical pivotal trial is evaluating safety and effectiveness of the Tendyne™ Transcatheter Mitral Valve Replacement (TMVR) system in patients with mitral disease due to severe mitral annular calcification (MAC).
- Based on the 30-day and 1-year outcomes, **Tendyne TMVR became the first FDA-approved TMVR device** for the treatment of patients with severe MAC.
- Longer term analysis is needed in these high-risk patients to further understand the safety and effectiveness of the Tendyne device.



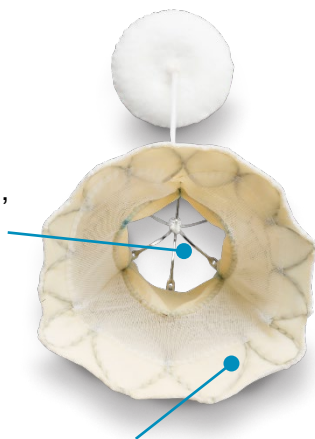
Tendyne™ TMVR System

Designed for the Mitral Anatomy to Eliminate MR

Dual-frame design provides customized anatomic fit and maintains stable hemodynamic performance

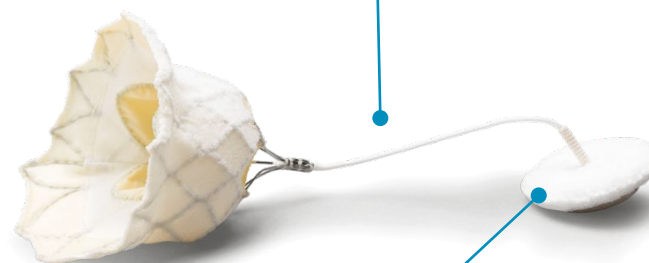
Inner Frame

Circular, self-expanding, tri-leaflet bioprosthetic valve



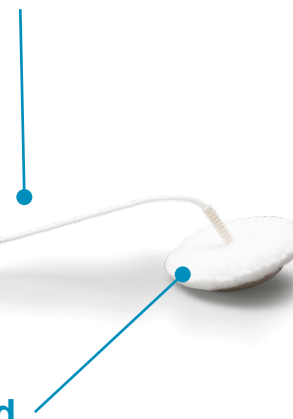
Outer Frame

Contoured design respects shape of the native mitral valve



Tether

High degree of device positioning and control, including full retrievability



Apical Pad

Placed over ventricular access site

Five size options to meet the needs of diverse anatomies

For US audience, see Important Safety Information referenced within. For audiences outside of the U.S.: always check the regulatory status of the device in your region.



SUMMIT MAC Study Design



Design:

- Single-arm, prospective, multicenter clinical study of Tendyne™ TMVR for severe MAC
- Primary Outcome: Freedom from all-cause mortality and heart failure hospitalization at 12 months post-index procedure



Key outcomes at 2 years:

- All-cause mortality, heart failure hospitalizations
- Reintervention rate, PVL, and MR severity
- Occurrence of major adverse events
- Quality-of-life and functional improvements (as assessed through KCCQ-OS score and NYHA functional class)
- Left ventricle reverse remodeling



Follow-Up:

Discharge, 30 days, 6 months, and annually through 5 years



SUMMIT Study Leadership and Participating Sites

Principal Investigators

Paul Sorajja (MAC)	Vinod Thourani (MAC)
Jason Rogers	Gorav Ailawadi

Steering Committee

Gorav Ailawadi	David
Vinay Badhwar	Heimansohn
Bassem Chehab	Jason Rogers
Jennifer Cowger	Rahul Sharma
Mayra Guerrero	Paul Sorajja
	Vinod Thourani

Patient Eligibility Committee

William Abraham	Brijeshwar Maini
Mustafa Ahmed	Emil Missov
Keith Allen	Michael Rinaldi
Judah Askew	Jason Rogers
Brian Bethea	Bassam Shukrallah
Bassem Chehab	Paul Sorajja
Robert Farivar	Gagan D. Singh
Mario Goessl	Benjamin Sun
Mayra Guerrero	Robert Stoler
Robert Hebler	James Udelson
Faraz Kerendi	John Wang

Echocardiographic and CT Core Lab

Federico Asch	Medstar Health Research Institute
Philipp Blanke	SPH/UBC Cardiac CT Core Lab





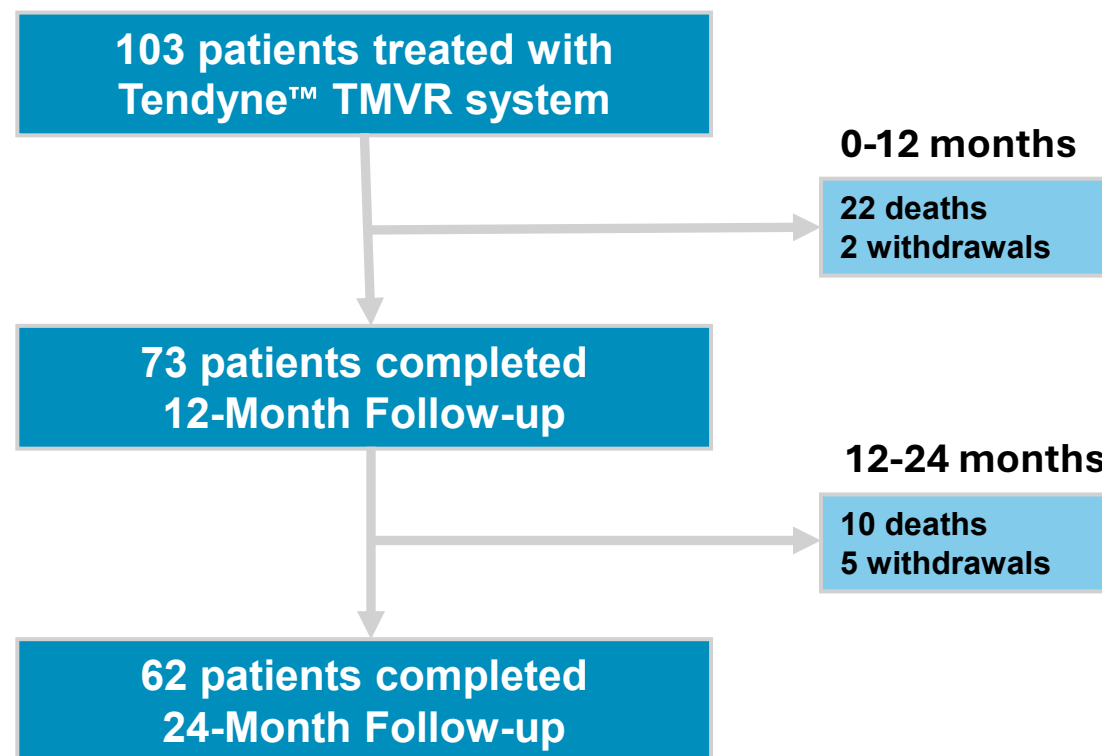
Patient Enrollment, Screening, & Follow-Up

Key inclusion criteria

- Age ≥ 18 years
- NYHA $\geq$ II
- MR $\geq 3+$, or severe MS, or both moderate MR and moderate MS
- GDMT

Key exclusion criteria

- Prior mitral valve interventions
- Life expectancy < 12 months
- LVEF $< 25\%$
- LVEDD > 7.0 cm
- Severe TR
- Severe pulmonary hypertension (> 70 mmHg)
- Hemodialysis





Baseline Demographics

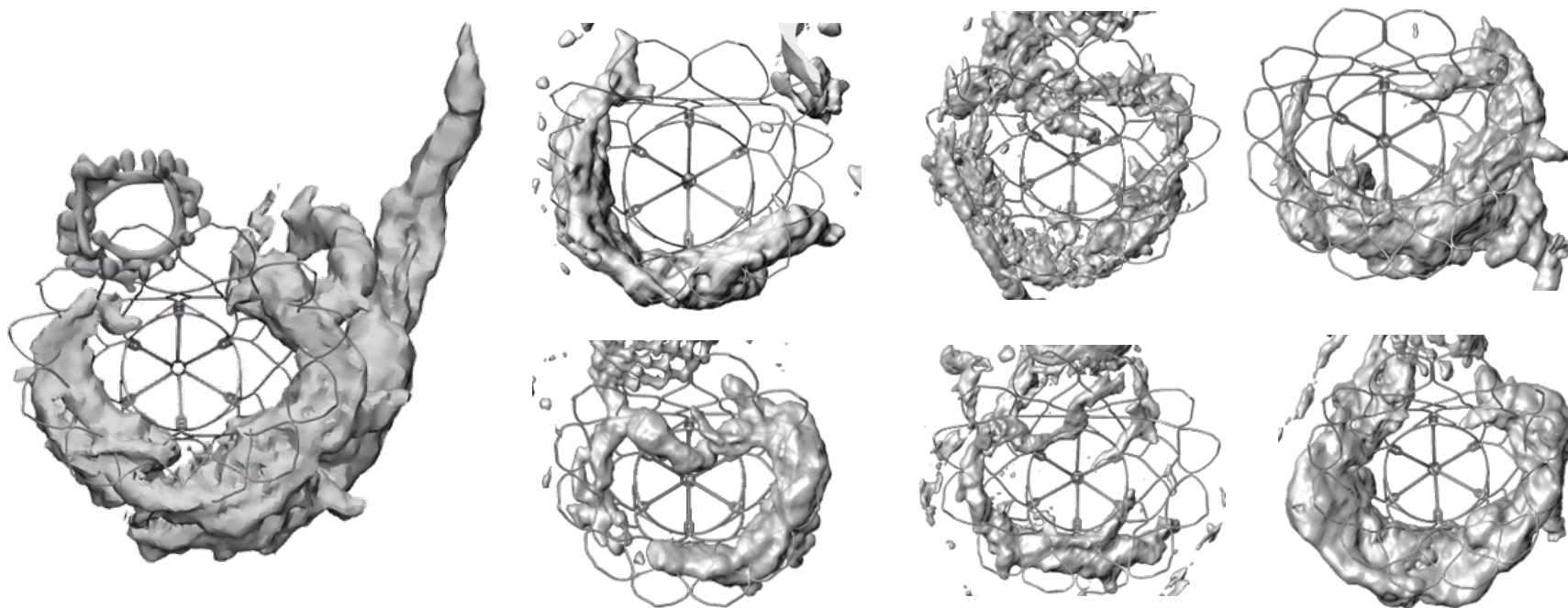
Baseline Characteristic	% or mean $\pm$ SD
Age (years)	78 $\pm$ 7
Age $\geq$ 80	49%
Female	55%
Atrial fibrillation	56%
Aortic valve replacement	52%
Coronary artery disease	62%
Diabetes	52%
HFH within prior 12 months	29%
Hypertension	89%
COPD	28%
NYHA III/IV	74%
KCCQ-OS score (points)	49 $\pm$ 23
6-minute walk test (meters)	204 $\pm$ 111

Baseline Characteristic	% or mean $\pm$ SD
MR grade	
1+	3%
2+	10%
3+	38%
4+	49%
Mitral disease	
Primary or mixed MR	93%
Secondary MR	7%
Severe mitral stenosis	12%
LVEF	56 $\pm$ 10%
Essential Frailty Toolset score, $\geq$ 2 pts	54%
STS PROM for MV replacement	7 $\pm$ 4%

Abbreviations: **COPD**, chronic obstructive pulmonary disease; **HFH**, heart failure hospitalization; **KCCQ-OS**, Kansas City Cardiomyopathy overall summary; **LVEF**, Left ventricle ejection fraction; **MV**, mitral valve; **MR**, mitral regurgitation; **NYHA**, New York Heart Association; **SD**, standard deviation ; **STS PROM**, Society of Thoracic Surgeons Predicted Risk of Mortality



Representative Images of MAC Burden



Average MAC volume: $5,679 \pm 5,670 \text{ mm}^3$

46.6% of patients with encroachment on inner frame



Procedural Outcomes in SUMMIT MAC

Variable	n=103
Procedural Success	
Procedural survival	98%
Technical success*	94%
Procedural stroke	0%
Successful deployment and correct positioning of the valve	99%
Valve implanted†	100%
Intra-Procedural Interventions	
Emergency surgery/intervention during index procedure	5%
Cardiopulmonary bypass	3%
Intra-aortic balloon pump	0%
Balloon valvuloplasty	71%
Procedure Duration	
Total procedure time (minutes) ¹	121 ± 38
Device time (minutes) ²	46 ± 20
Total fluoroscopy time (minutes)	19 ± 12
Post-Procedure Recovery	
ICU stay (days)	6 ± 7 (n = 97)
Hospital stay (days)	12 ± 23 (n = 94)

*MVARC-2 definition

¹ Time from first skin incision to final wound closure

†One valve retrieved with secondary valve implanted ² Time from apex entry to time tether tensioning ended

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Adverse Events Summary

Adverse Events	0 – 1 month (N=103)	1– 12 months (N=95)	12-24 months (N=78)
Mortality	6.8%	16.8%	11.5%
Cardiovascular	6.8%	11.6%	6.4%
Non-Cardiovascular	0%	5.2%	5.1%
Hospitalizations	20.4%	38.5%	10.3%
Heart Failure Hospitalizations	13.6%	14.6%	5.1%
Stroke or TIA	2.9%	1.1%	6.4%
Disabling Stroke	1.9%	1.1%	3.8%
Non-disabling Stroke	1.0%	0.0%	1.3%
Myocardial Infarction	1.0%	0.0%	0.0%
Bleeding (MVARC)	28.2%	16.8%	14.1%
Minor	7.8%	10.5%	5.1%
Major	5.8%	4.2%	3.8%
Extensive/Life-Threatening	12.6%	5.3%	3.8%
Fatal	2.9%	1.1%	2.6%
Acute Kidney Injury (MVARC)	11.7%	0.0%	0.0%
New Atrial Fibrillation	13.6%	1.0%	0.0%



Adverse Events (continued)

Adverse Events	0-1 month (N=103)	1 – 12 months (N=95)	12-24 months (N=78)
Mitral valve reintervention	1.9%	3.2%	1.3%
Device thrombosis	0.0%	3.2%	2.6%
Major*	0.0%	2.1%	0.0%
Minor*	0.0%	1.1%	2.6%
Structural valve dysfunction†	0.0%	0.0%	2.6%
Endocarditis	0.0%	4.2%	2.6%

*MVARC definition †Hemodynamic dysfunction (moderate or severe) in the presence of morphologic dysfunction

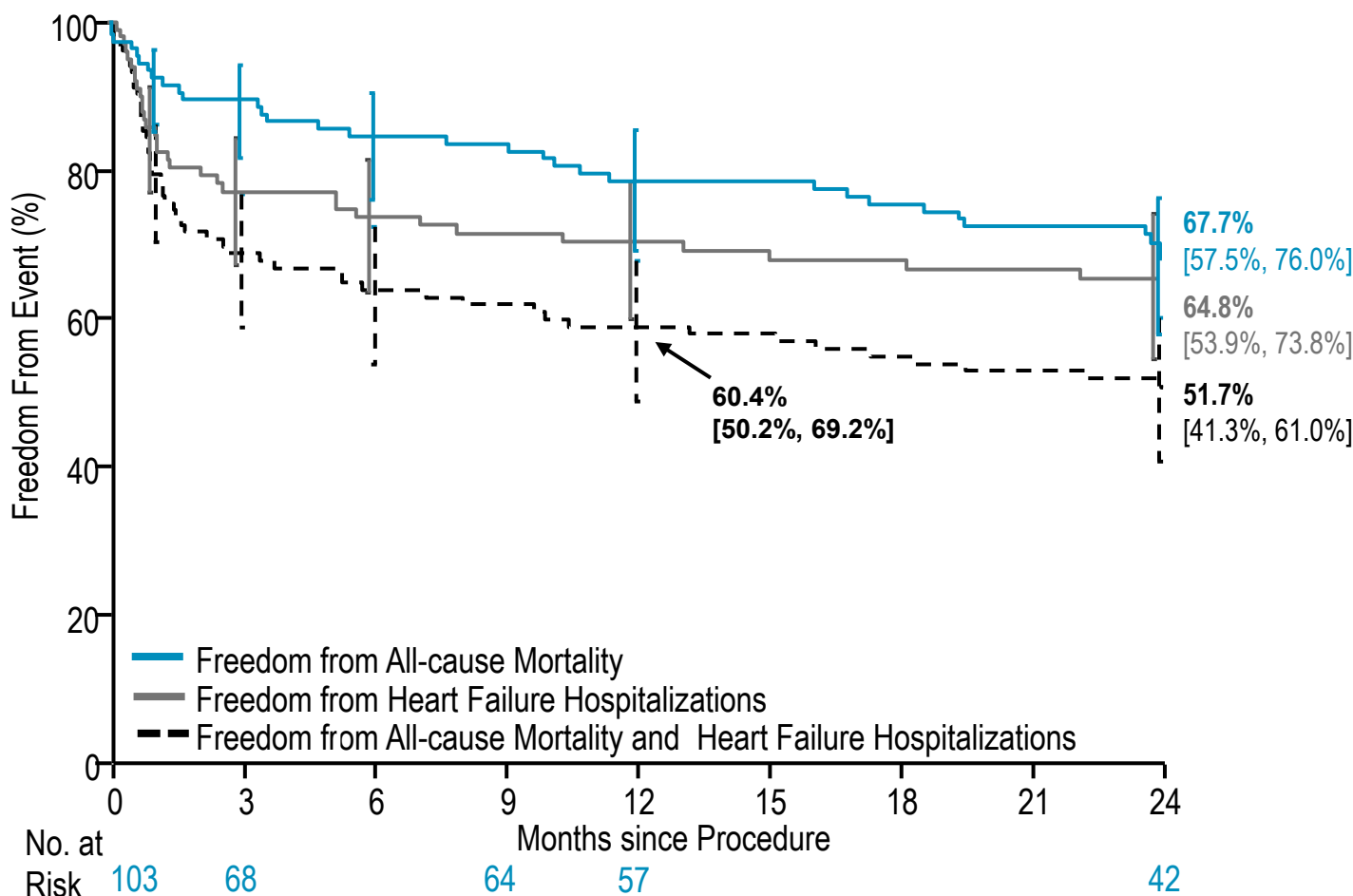


Types and Reasons for Reintervention

Adverse Events	0-1 month (N=103)	1– 12 months (N=95)	12-24 months (N=78)
Mitral valve reintervention	1.9%	3.2%	1.3%
Reintervention reason			
Paravalvular leak	1.9%	3.2%	0.0%
Structural valve dysfunction	0.0%	0.0%	1.3%
Reintervention type			
Tether length adjustment	1.0%	3.2%	0.0%
Surgical explant & replacement	1.0%	0.0%	0.0%
ViV	0.0%	0.0%	1.3%



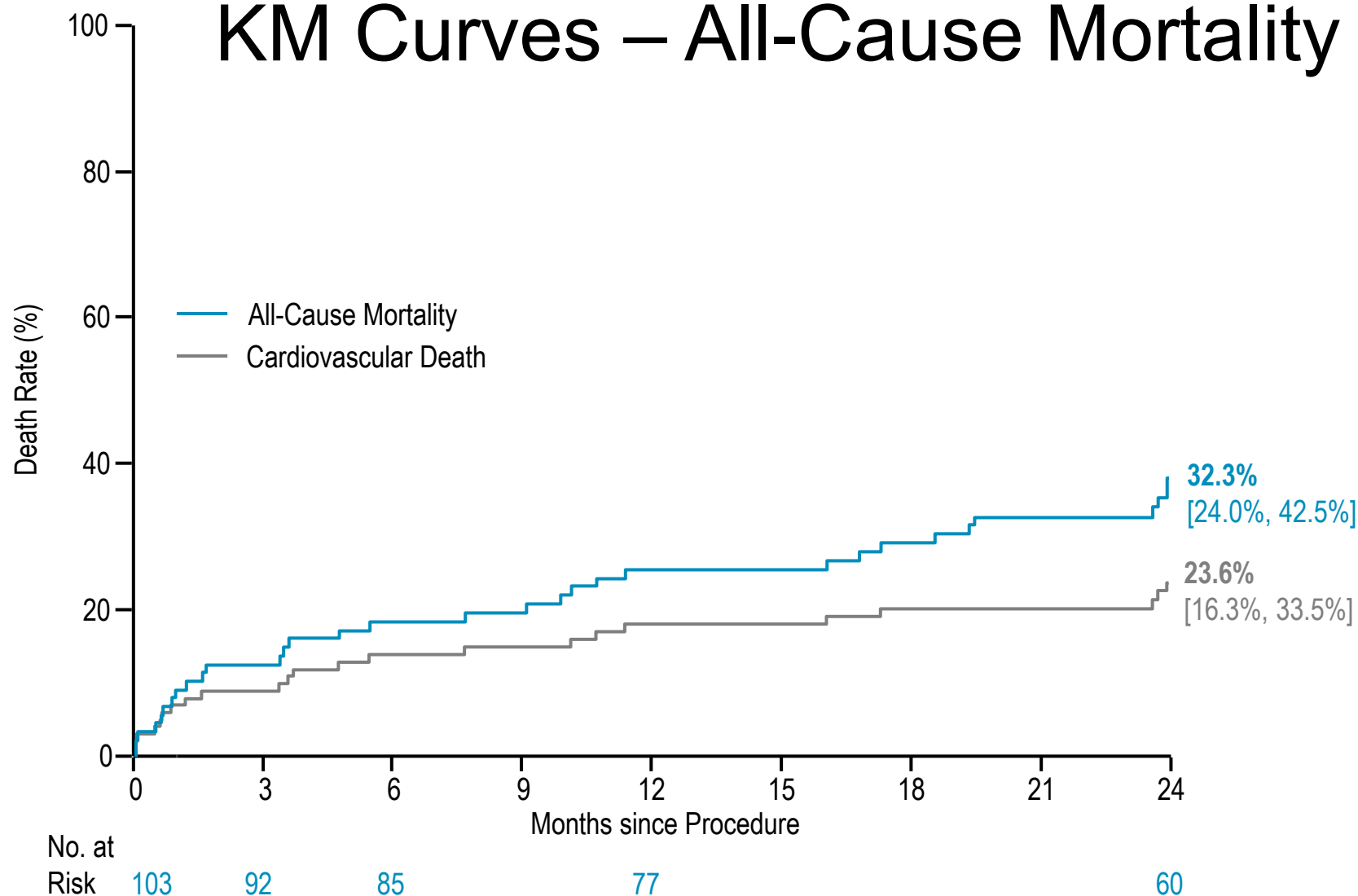
KM Curves – Primary Endpoint



Data reported as mean $\pm$ SD

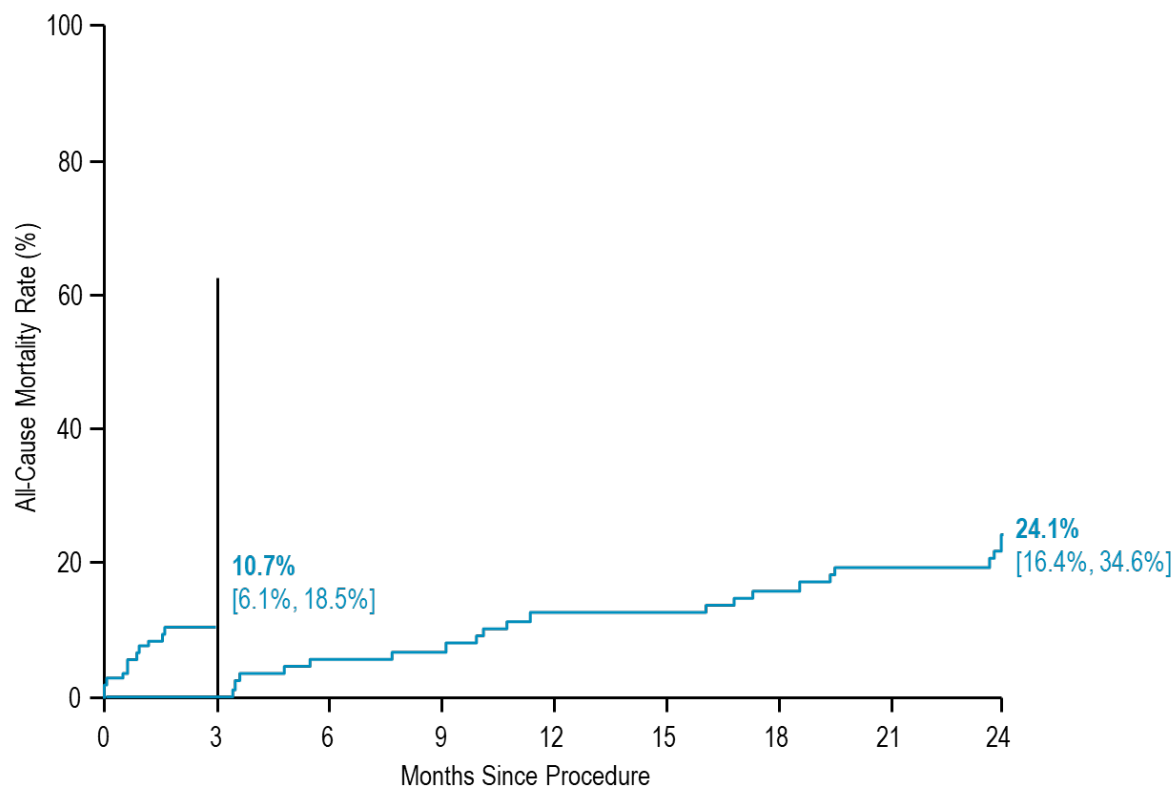
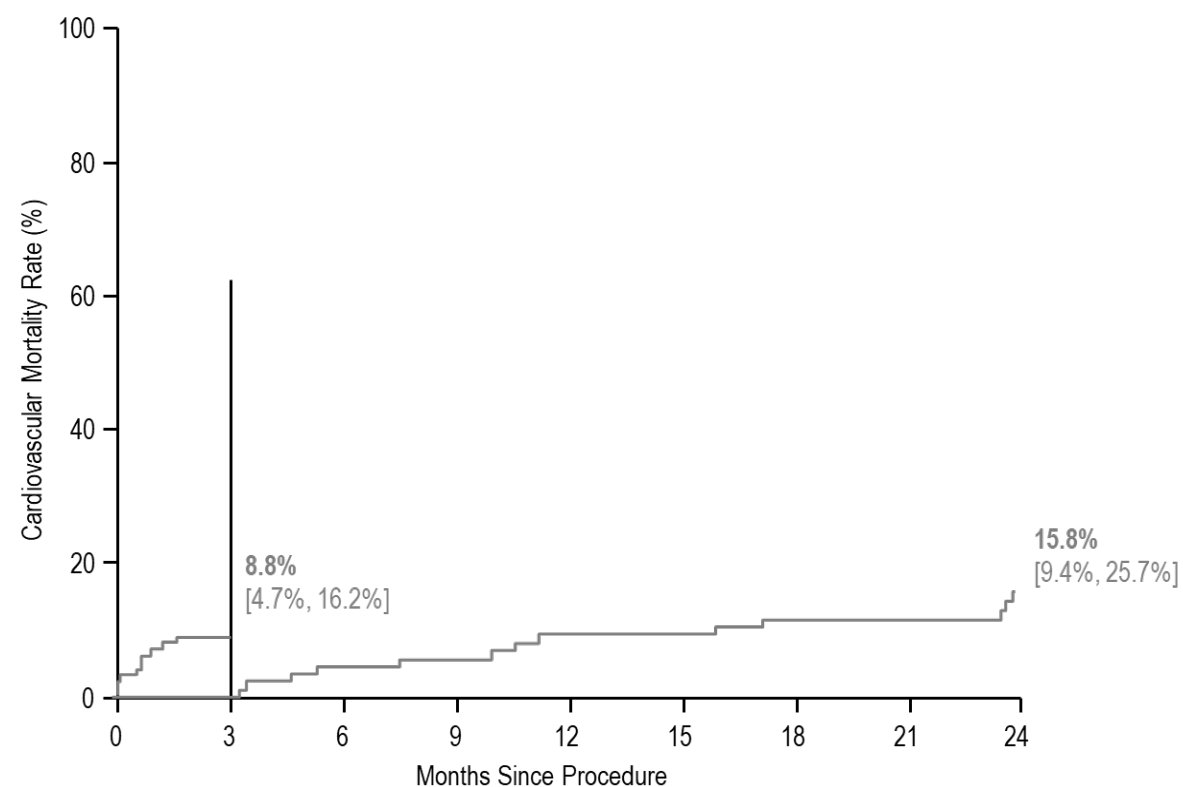


KM Curves – All-Cause Mortality





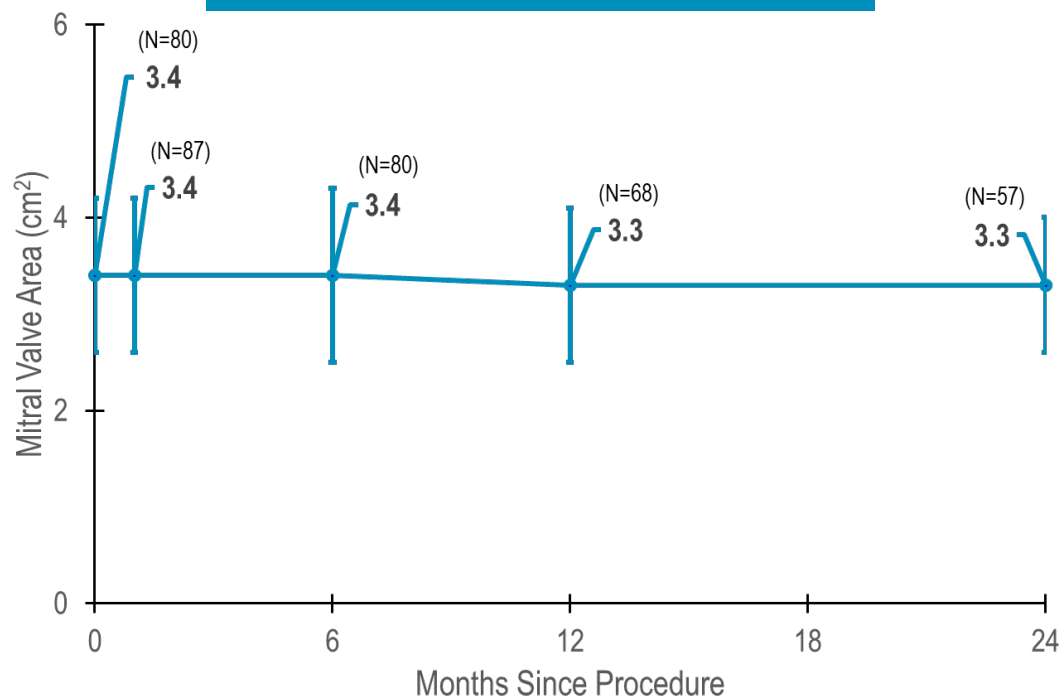
KM Curves –Landmark Analyses



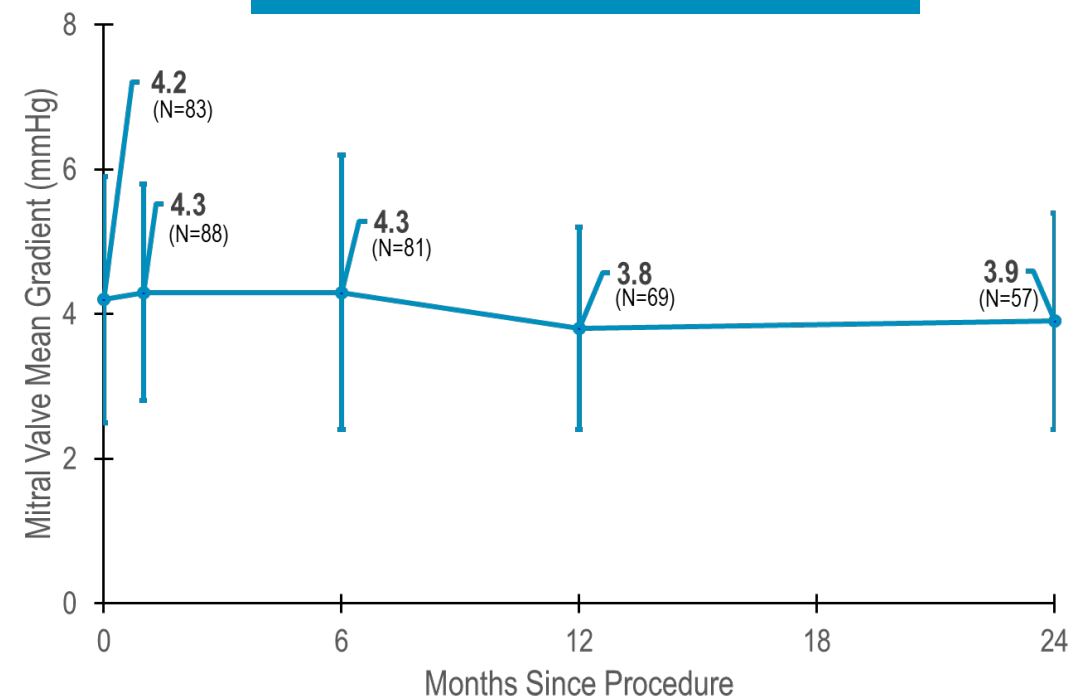


Hemodynamics Performance

Mitral Valve Area

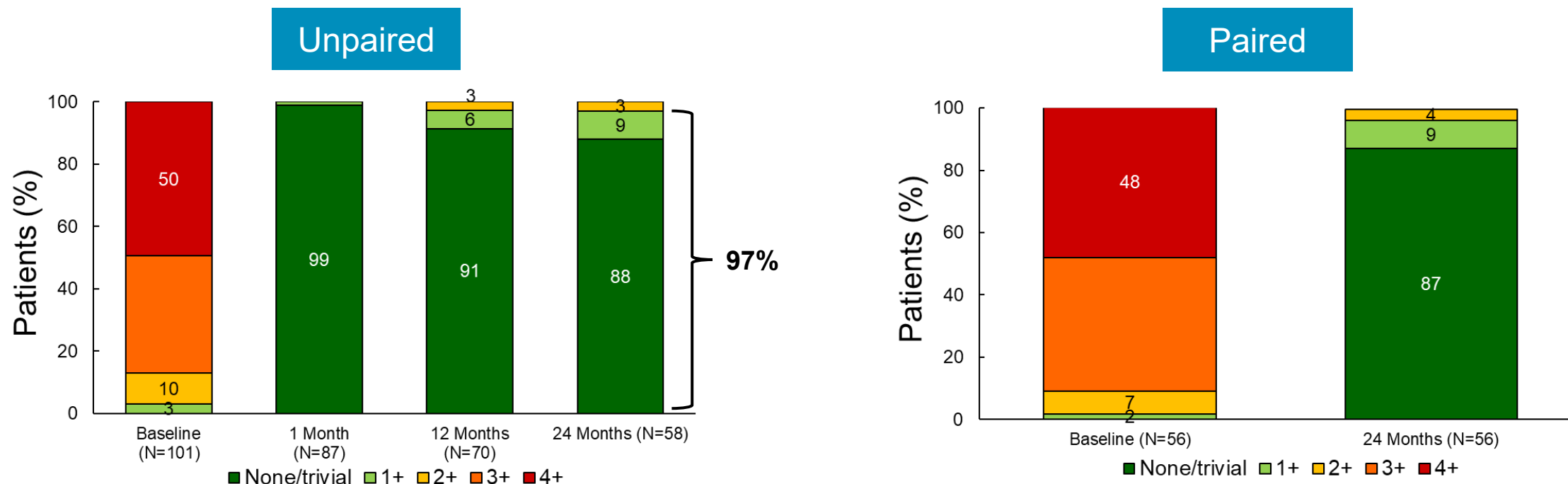


Mitral Valve Mean Gradient





MR Severity (%)

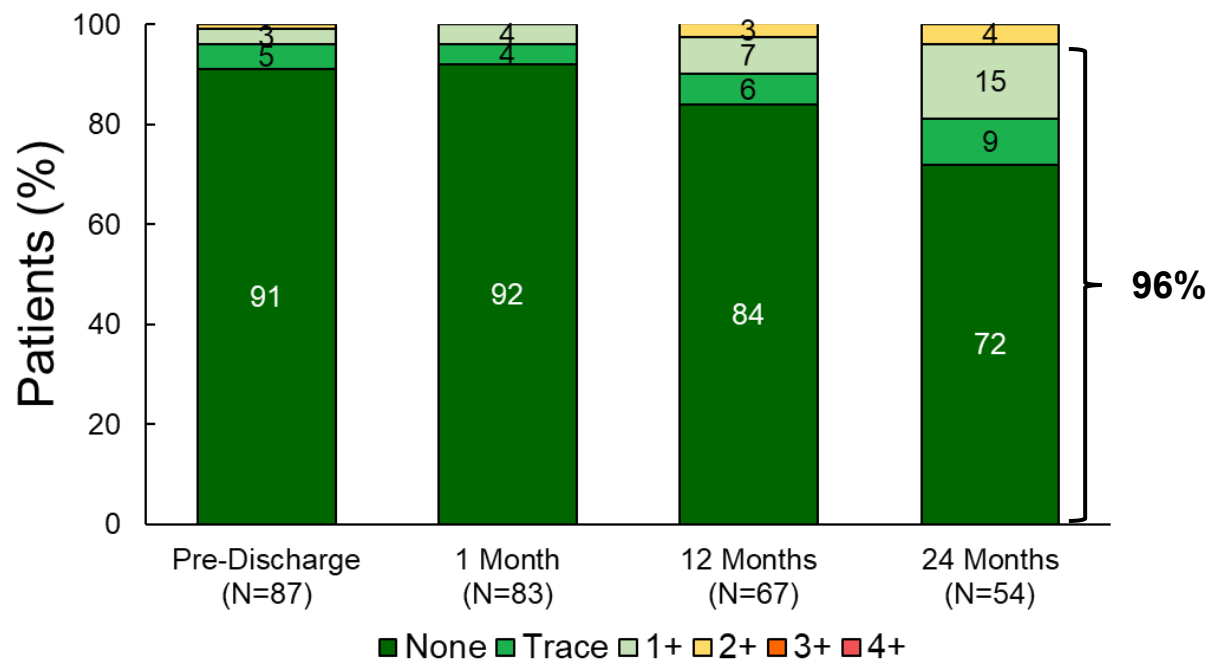


97% MR Grade ≤1+ at two years (all values core lab adjudicated)

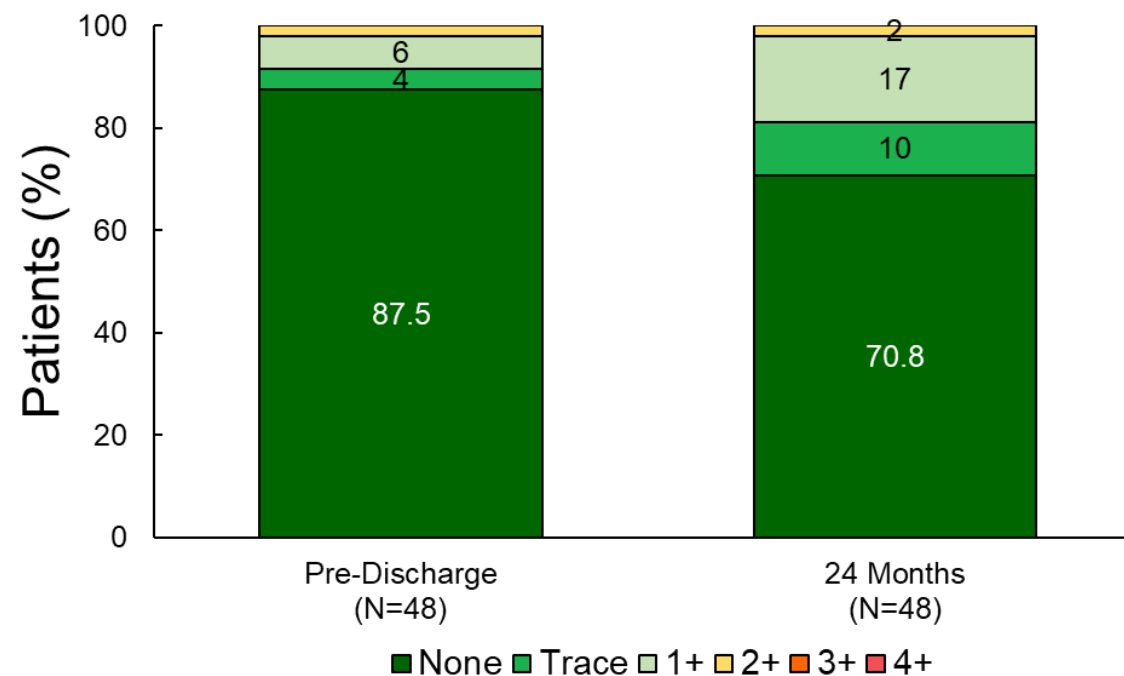


Paravalvular Leak (%)

Unpaired



Paired

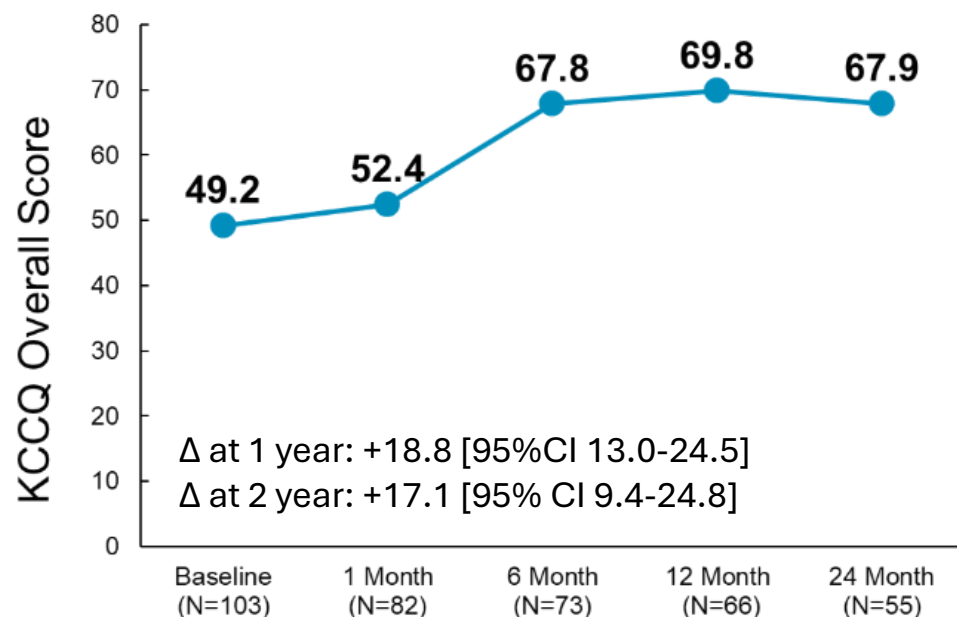


96% PVL Grade ≤1+ at two years (all values core lab adjudicated)



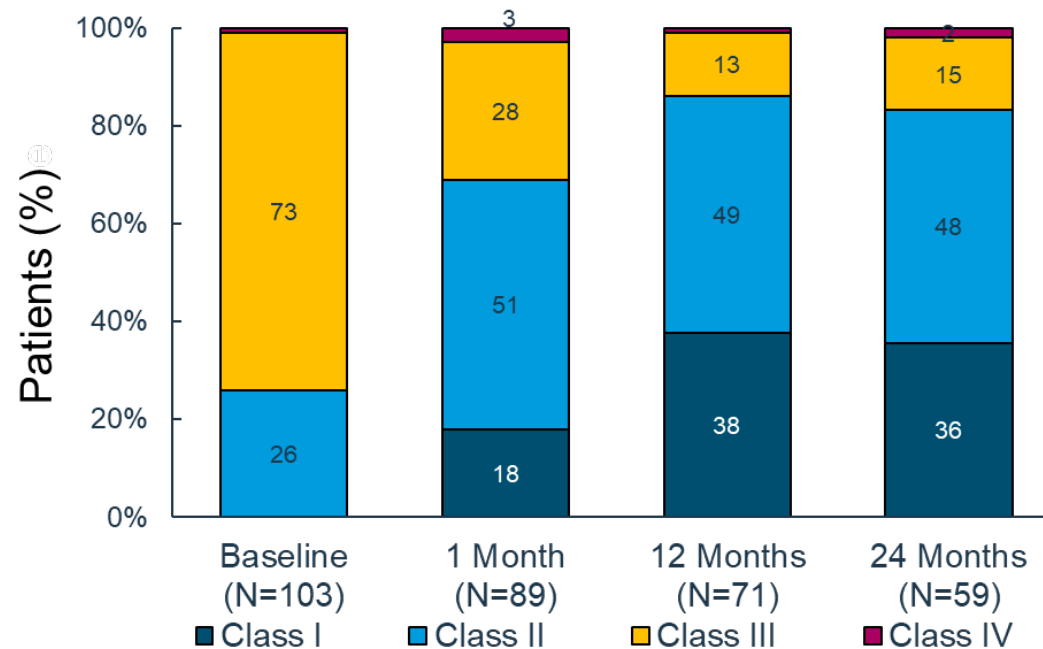
Quality-of-Life and Functional Improvements

KCCQ-OS



67% with improvement ≥ 10 at two years

NHYA Functional Class (Unpaired)

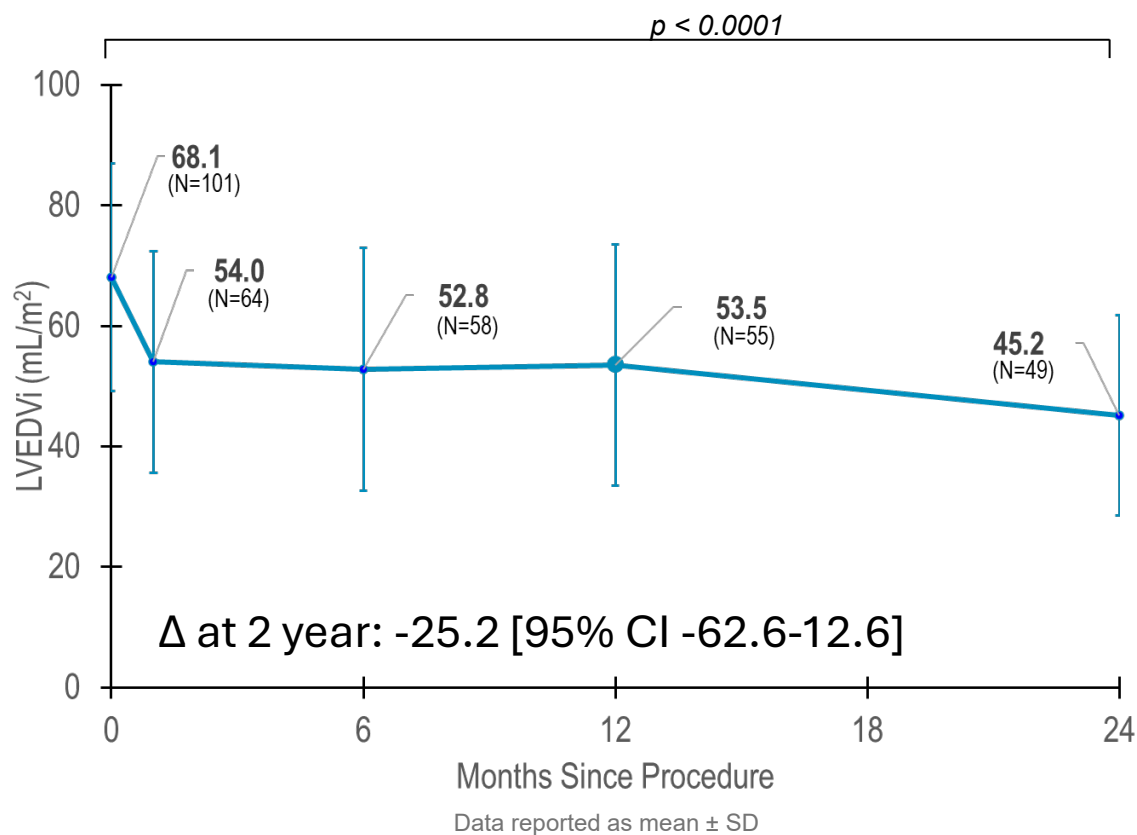


84% NYHA Class I/II at two years



Left Ventricular Remodeling

LVEDVi



Echocardiography Outcomes (Paired)

	Baseline	24 months	p-value
LVEDD (cm)	5.2 $\pm$ 0.5	5.1 $\pm$ 0.7	0.42
LVEDV (mL)	135.1 $\pm$ 39.9	87.2 $\pm$ 36.6	<0.0001
LVEDVi (mL/m ²)	70.2 $\pm$ 17.1	45.1 $\pm$ 16.6	<0.0001
LVESD (cm)	3.5 $\pm$ 0.6	3.7 $\pm$ 0.7	0.006
LVESV (mL)	61.7 $\pm$ 27.0	41.5 $\pm$ 21.9	<0.0001
LAV (mL)	114.8 $\pm$ 44.9	96.8 $\pm$ 33.6	<0.0001
LVEF (%)	56.6 $\pm$ 8.6	49.5 $\pm$ 10.3	<0.0001

92% with improvement in LVEDVi at 2 years



Conclusions

- This 2-year analysis of the Tendyne™ TMVR system in high-risk patients with severe MAC and significant mitral valve dysfunction represents the longest follow-up to date for this indication.
- Meaningful improvements in clinical outcomes and reductions in MR severity were sustained through 2 years.
 - **MR Severity:** 97% ≤ 1+
 - **Quality-of-Life:** +17.1 in KCCQ-OS score
 - **Functional Status:** 84% NYHA Class I/II
 - **Left Ventricular Remodeling:** 92% LVEDVi improvement
 - **Mitral Valve Reintervention:** 1.3%
- Tendyne was the first **FDA approved TMVR device** and addresses an unmet clinical need for patients with mitral value disease and severe MAC.



Thank You!

- We would like to extend our deepest gratitude to the patients and their families.
- We would like to thank the SUMMIT investigators and personnel from our participating sites.
- Questions: vinod.thourani@piedmont.org

For US audience only

Rx Only

Important Safety Information

Tendyne™ Transcatheter Mitral Valve System

Indications for Use

The Tendyne™ Transcatheter Mitral Valve System is indicated for the treatment of symptomatic severe mitral valve dysfunction (moderate-to-severe or severe mitral regurgitation (MR), severe mitral stenosis (MS), or moderate MR with moderate or greater MS) associated with severe mitral annular calcification (MAC) in patients who are deemed unsuitable for mitral valve surgery or transcatheter edge-to-edge repair by a multidisciplinary heart team.

Contraindications

The Tendyne™ Transcatheter Mitral Valve System is contraindicated in patients with:

- anticoagulation/antiplatelet intolerance;
- sepsis or active endocarditis;
- evidence of left ventricular or left atrial thrombus at risk of embolization;
- a thin or fragile apex rendering the subject unsuitable for a transapical procedure; or
- untreatable hypersensitivity to nickel or titanium

Patients not deemed a candidate by the local heart team based on clinical or anatomical factors should not have the Tendyne™ Transcatheter Mitral Valve procedure

Potential Complications and Adverse Events

Adverse events potentially associated with use of the Tendyne™ Transcatheter Mitral Valve System may include, but are not limited to, the following: Death, Adverse foreign body response, Adverse reaction to anesthesia, Allergic reaction, Anemia, Annular dissection, Aortic insufficiency, Atrial or ventricular injury, Atrial Septal Defect (resulting from transseptal mitral valvuloplasty, if performed), Bioprosthetic valve dysfunction, Bleeding complications, Blood loss which may require transfusion, Cardiac arrest, Cardiac perforation, Conduction defect with or without need for pacemaker, Cardiac arrhythmia, atrial or ventricular, Damage to cardiac tissue and/or structures, Decreased LV function and/or cardiac output, Device embolism, Device erosion, migration or malposition, Device thrombosis, Embolism (air, blood clot, calcium, tissue, etc.), Endocarditis, Esophageal irritation, stricture, or perforation, Fever, Foreign body response, Heart Failure, new or worsening, Hematoma, Hemolysis, Hypotension, Infection / Sepsis, Leaflet, chordal, papillary or ventricular rupture (resulting from mitral valvuloplasty, if performed), Liver failure, Mitral valve injury, Mitral valve prolapse / stenosis, Myocardial infarction, Obstruction, Pain, Pleural effusion, Pulmonary embolism, Pulmonary hypertension, Paravalvular leak, Pericardial effusion / tamponade, Renal insufficiency or failure, Respiratory difficulty, insufficiency or failure, Stroke or transient ischemic attack, Tear or damage to device, Vascular and access-related complications, Worsening of mitral regurgitation.

Source: STS Jan 2026

For US audience, see Important Safety Information referenced within. For audiences outside of the U.S.: always check the regulatory status of the device in your region.

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