

# Late Follow-Up from the PARTNER Aortic Valve-in-Valve Registry

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on behalf of The PARTNER II Trial Investigators

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# Disclosure Statement of Financial Interest

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
- Steering Committee
- SAB (Equity)
- Honoraria

## Company

Edwards Lifesciences  
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# Background



- Valve-in-Valve TAVR is a viable alternative for patients with failing surgical bioprosthetic valves
- Although early outcomes have been favorable, limited data is available on *longer-term* clinical outcomes, valve function, and durability

# Methods

## Study Design



- **Prospective, multicenter registry**
- **Inclusion Criteria:**
  - Symptomatic severe stenosis or regurgitation of a surgical aortic bioprosthetic valve
  - High-risk for re-operation (estimated surgical mortality or major morbidity  $\geq 50\%$ )
  - Suitable for 23mm or 26mm SAPIEN XT THV
- **Key Exclusion criteria:**
  - Surgical valve labeled size  $< 21$ mm
  - Prosthetic valve in another position
- **Angiogram, CT, Echo images and clinical data were screened on a weekly web conference call**

# The PARTNER II Trial: Aortic Valve-in-Value Registry



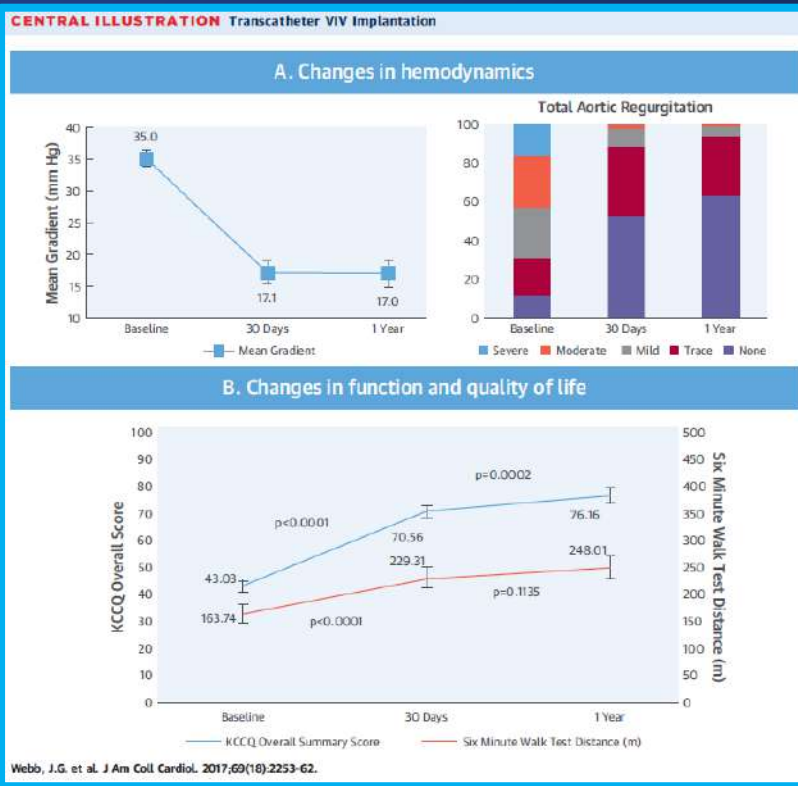
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Transcatheter  
Within  
Surgical  
PARTNER

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Howard C. Herrmann,  
Philippe Pibarot, DSc,  
Maria C. Alu, MS, PhD



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# Methods

## Statistical Analysis



- **Analysis Population**

- Nested Registry (NR3, N=96) and Continued Access Registry (CANR, N=269)
- Valve implant population (patients in whom valve implant was completed)

- **Clinical Outcomes**

- Cumulative incidence reported as Kaplan-Meier event rates
- Associations assessed by Cox proportional hazards regression models
- Comparisons performed by the log-rank test

- **Longitudinal Outcomes (echo and functional characteristics)**

- Within-subject comparisons modeled over time by linear mixed effects model to adjust for patient variability (missing data and survival bias)

# Baseline Characteristics



Characteristic (%)	All Patients N=365	Initial Registry (NR3) N=96	Continued Access (CANR) N=269	p-value
Age, years	78.9 ± 10.2	80.1 ± 9.3	78.5 ± 10.5	0.18
Male	64.1	55.2	67.3	0.03
STS Score, %	9.1 ± 4.7	9.9 ± 5.1	8.8 ± 4.6	0.06
NYHA Class 3/4	90.4	95.8	88.5	0.04
Atrial Fibrillation	46.8	50.0	45.7	0.47
CAD	75.6	76.0	75.5	0.91
COPD	30.4	29.2	30.9	0.76
Renal Insufficiency (SCr ≥2 mg/dL)	12.3	14.6	11.5	0.43

Data presented as % or mean ± SD; CAD = coronary artery disease, COPD = chronic obstructive pulmonary disease, NYHA = New York Heart Association, SCr = serum creatinine, STS = Society of Thoracic Surgeons

# Valve and Procedural Characteristics



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<b>Surgical Bioprosthesis Age</b>	<b>%</b>
< 5 years	6.8
5-10 years	27.2
> 10 years	66.0
<b>Mode of Degeneration</b>	
Stenosis	55.0
Regurgitation	23.7
Mixed	21.2
<b>Surgical Valve Type</b>	
Bioprosthetic Stented	93.1
Other	6.9

<b>Labeled Surgical Valve Size</b>	<b>%</b>
21mm	26.7
22-25mm	12.6
>25mm	59.2
<b>Implanted THV Size</b>	
23mm	69.0
26mm	31.0
<b>Access</b>	
Transfemoral	75.8
Transapical	24.2

# Results

## Clinical Outcomes at 3 Years



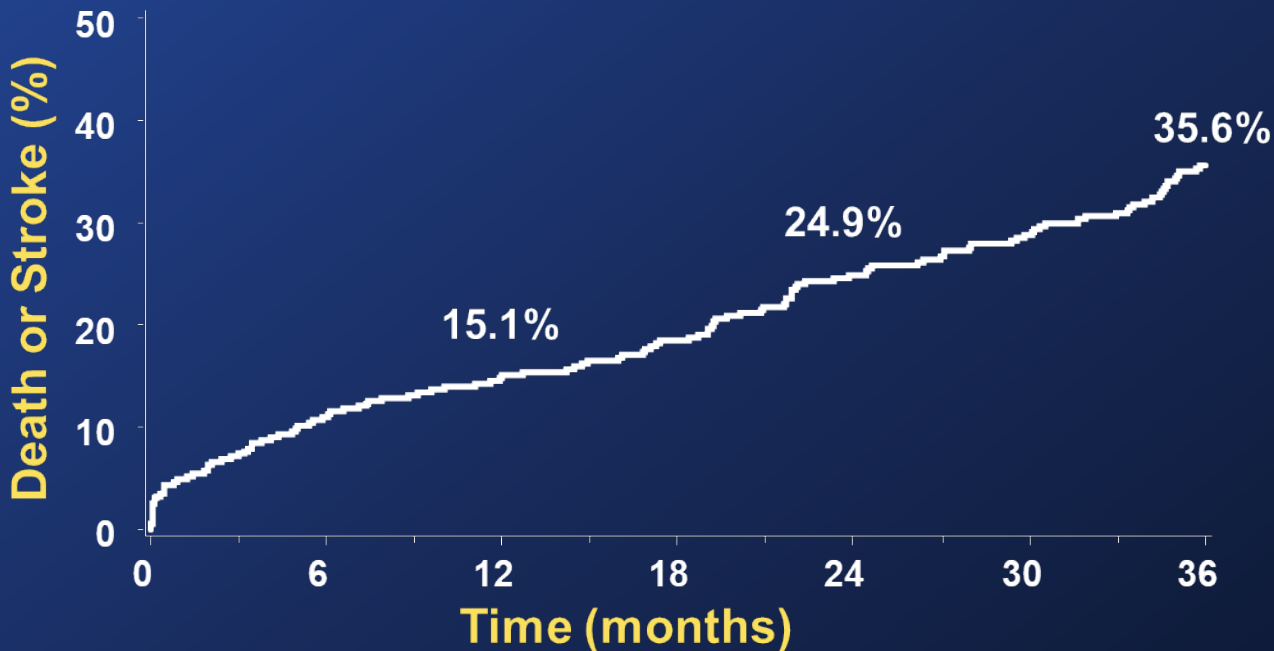
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	Events at 3 years* N=365
Composite Endpoint: All-Cause Death or Any Stroke	36.2 (127)
All-Cause Death	33.3 (116)
Cardiovascular	20.1 (68)
Non-cardiovascular	16.4 (48)
Any Neurological Event (Stroke or TIA)	7.8 (26)
Stroke	6.2 (21)
TIA	3.0 (9)
New Permanent Pacemaker	7.1 (23)
Repeat Valve Replacement	1.9 (5)

*\*All events CEC-adjudicated through 1 year and site-reported thereafter, presented as KM % (# events); TIA = transient ischemic attack*

# Results

## Primary Endpoint – Composite of Death or Stroke



*Number at risk:*

**NR3 + CANR** 365

325

309

290

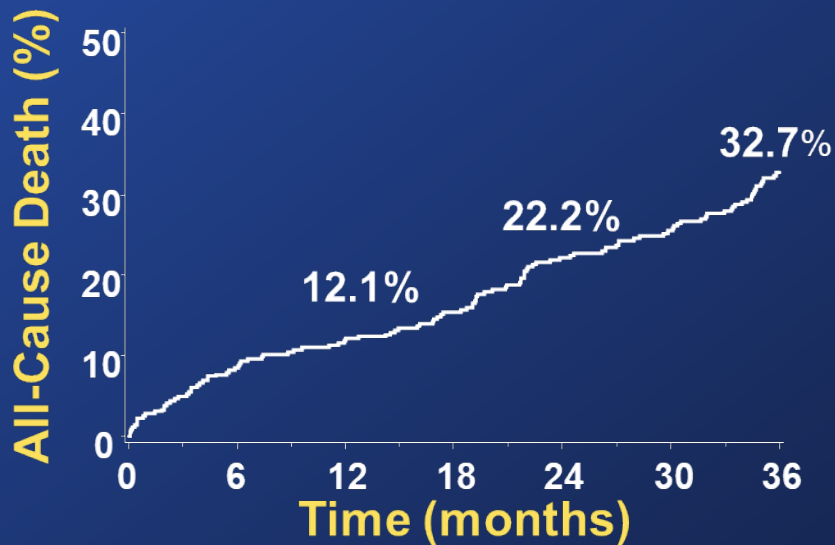
260

237

185

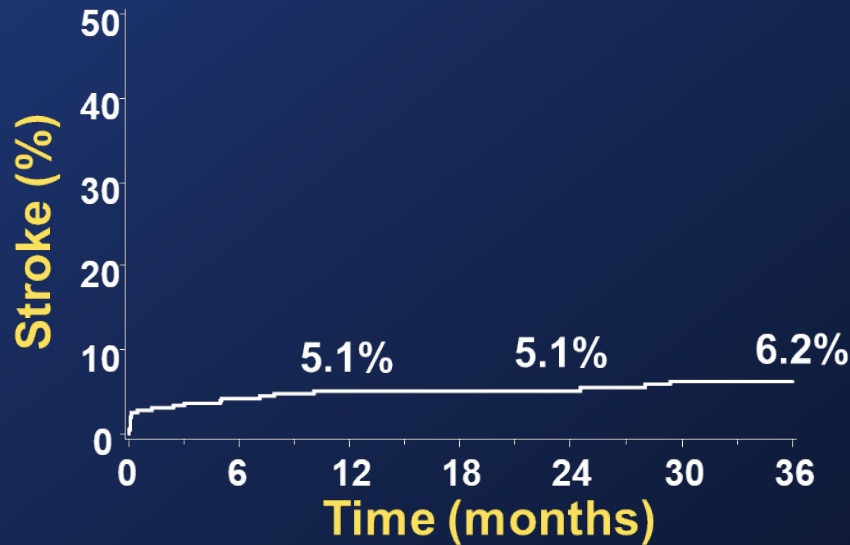
# Results

## Mortality and Stroke



*Number at risk:*

365 334 320 301 268 246 192



*Number at risk:*

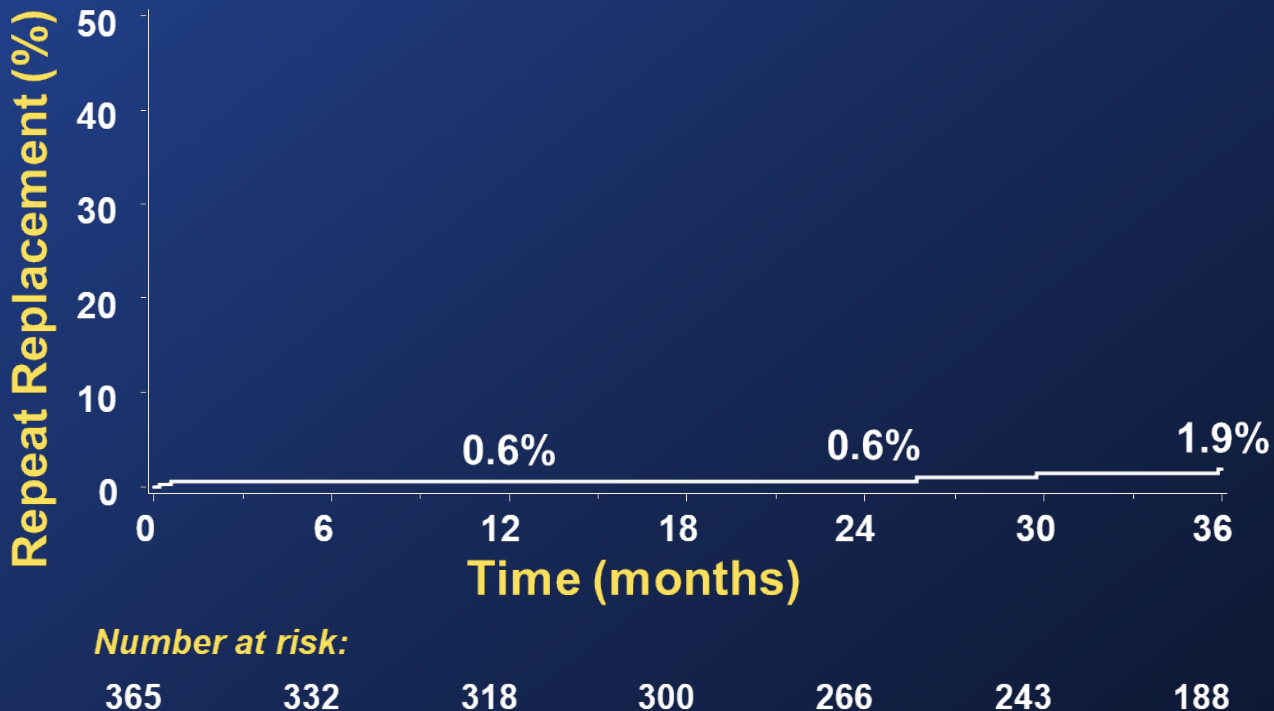
365 325 309 291 260 237 185

# Results

## Repeat Valve Replacement\*



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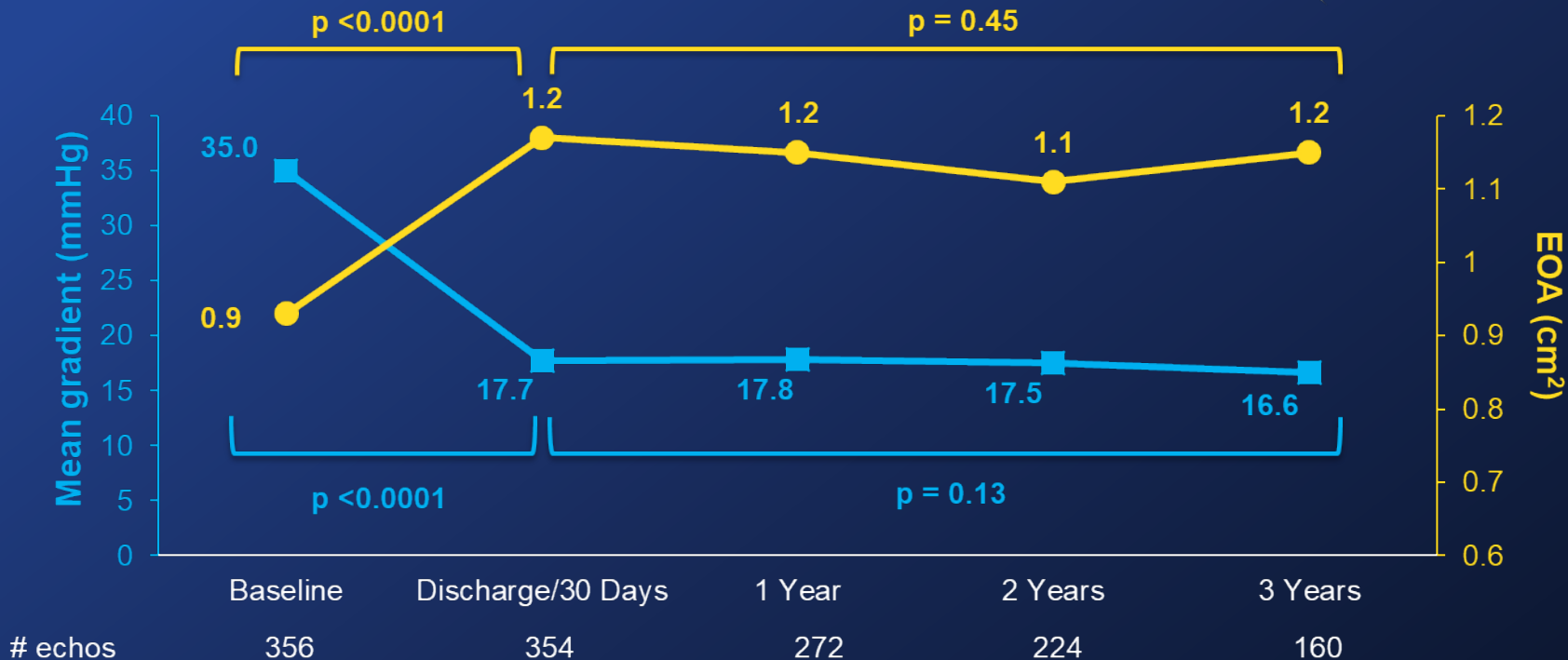
\*SAVR or ViV TAVR

# Results

## EOA and Mean Gradient

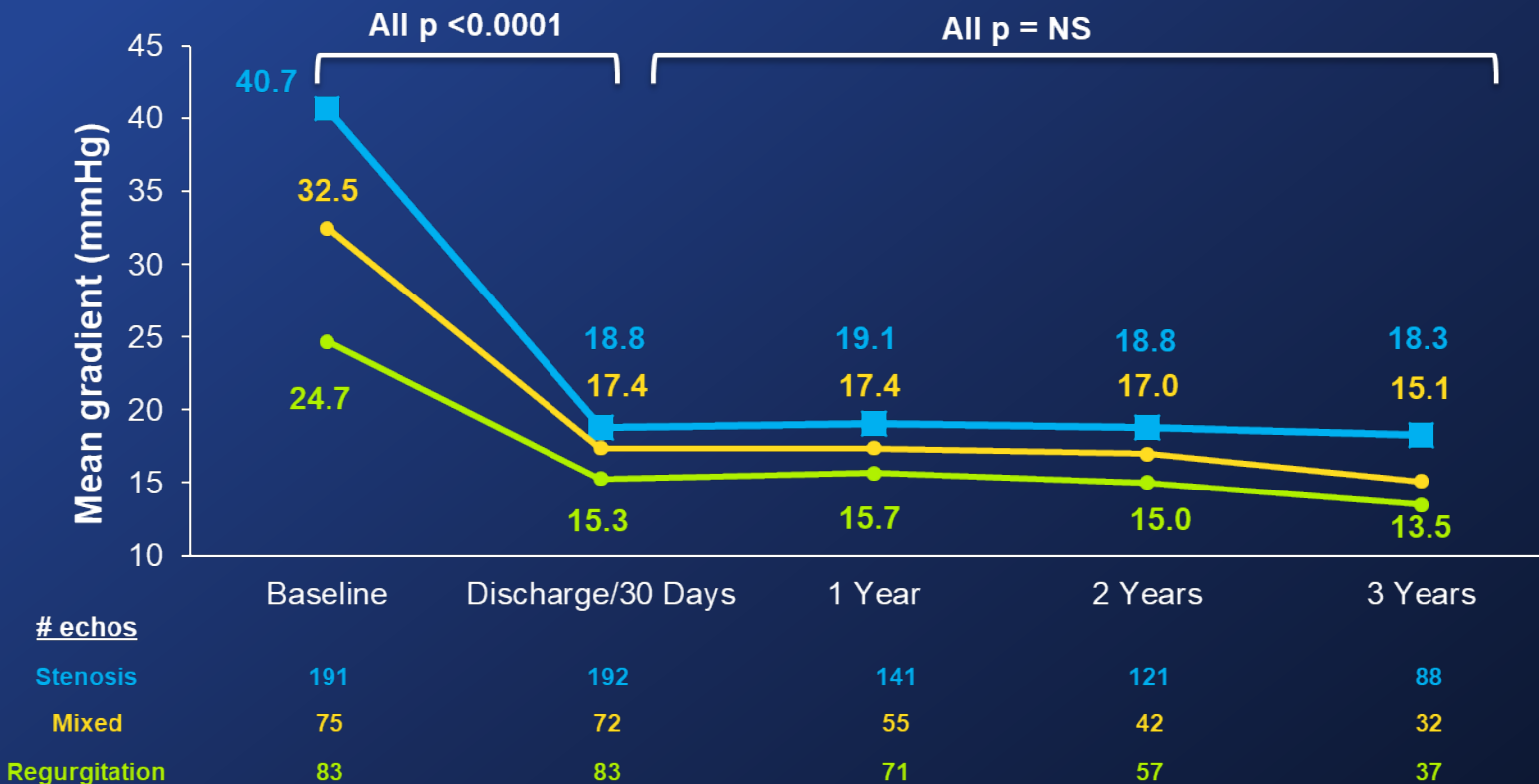


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# Results

## Mean Gradient by Failure Mode

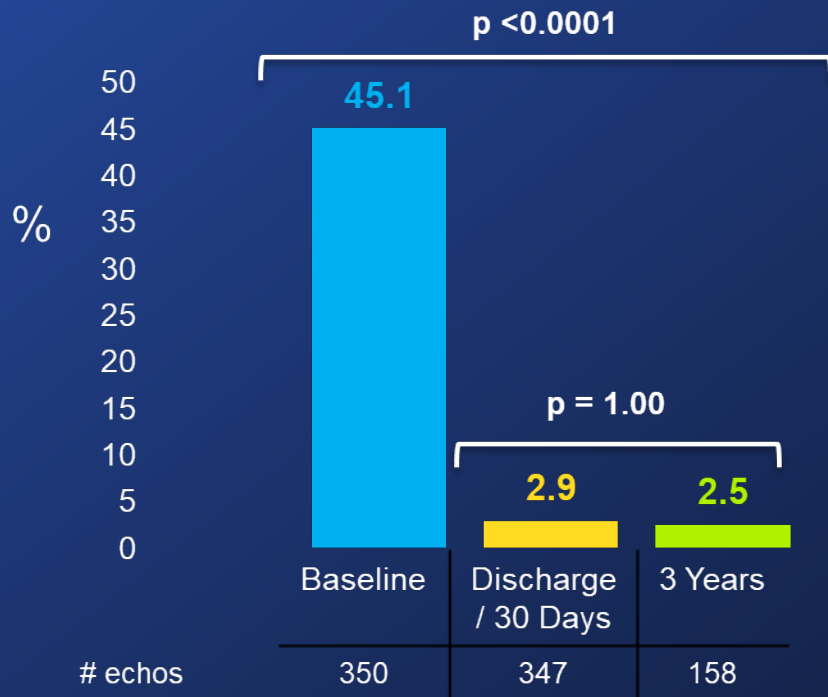


# Results

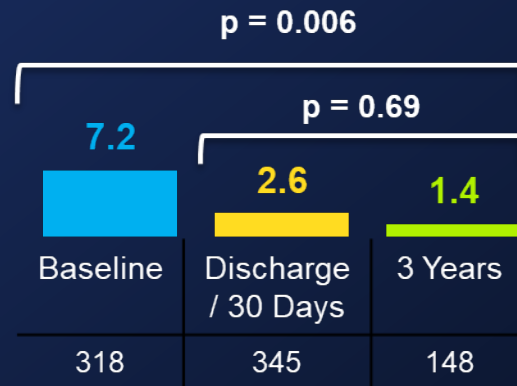
## Aortic Regurgitation



### Total AR $\geq$ Moderate



### Paravalvular AR $\geq$ Moderate

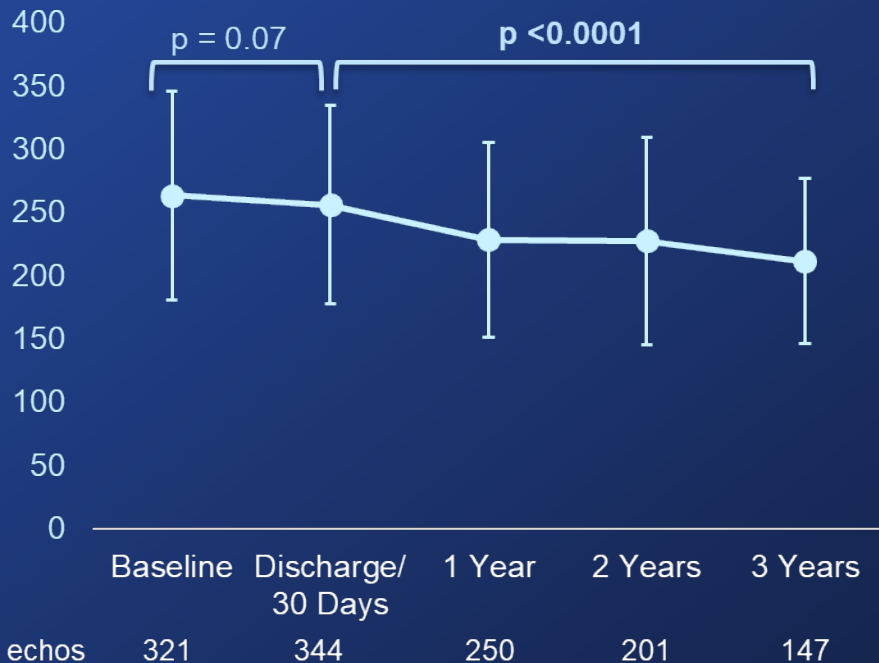


# Results

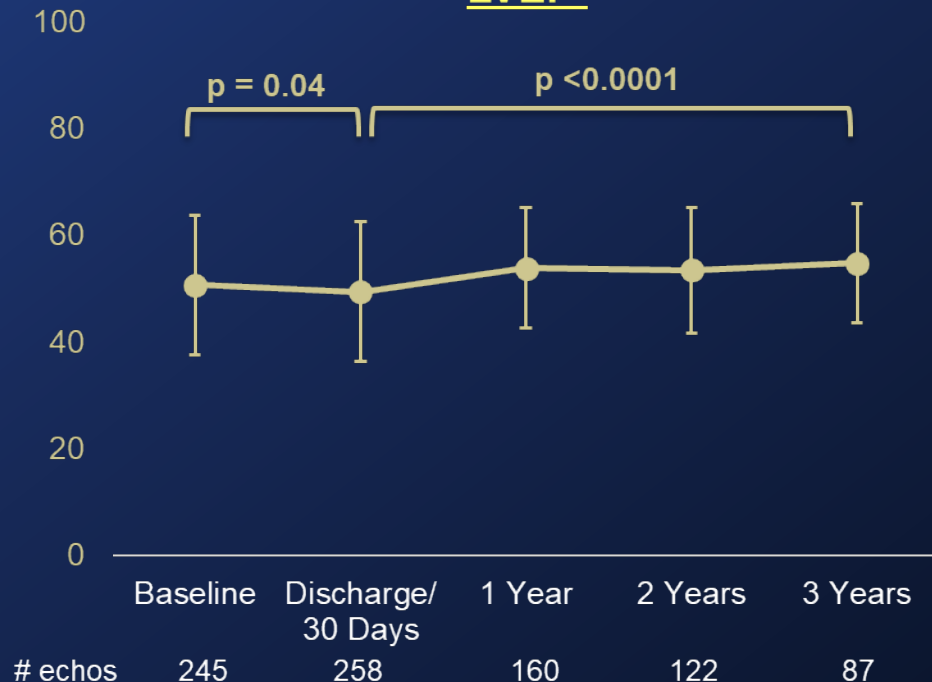
## Longitudinal Hemodynamics (LV Function)



### LV Mass



### LVEF\*



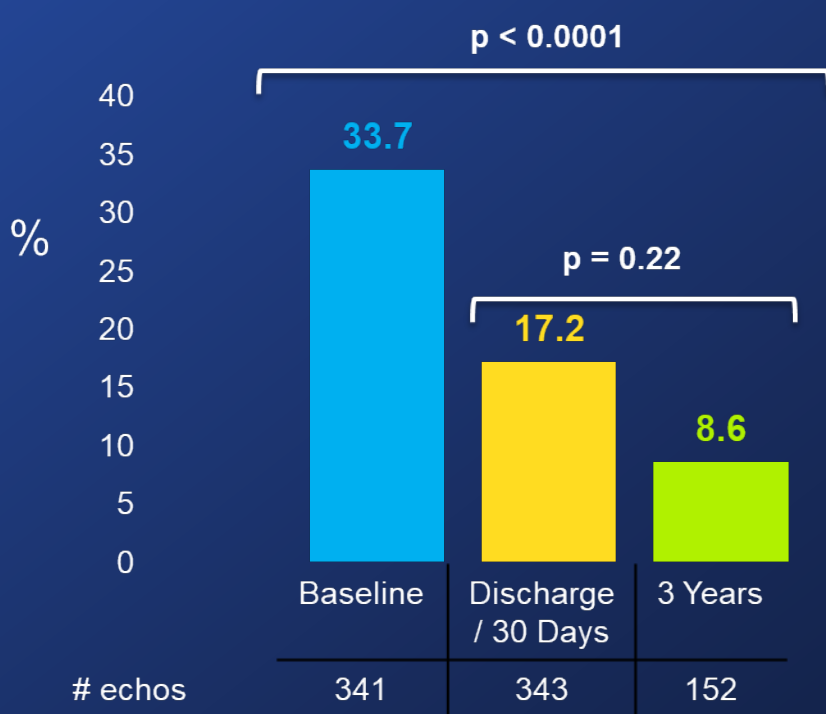
\*LVEF by Simpson's

# Results

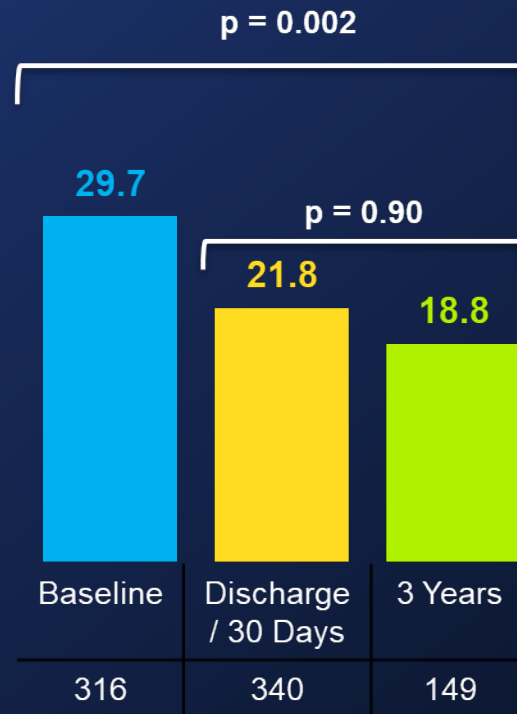
## Mitral and Tricuspid Regurgitation



### Mitral Regurgitation $\geq$ Moderate



### Tricuspid Regurgitation $\geq$ Moderate

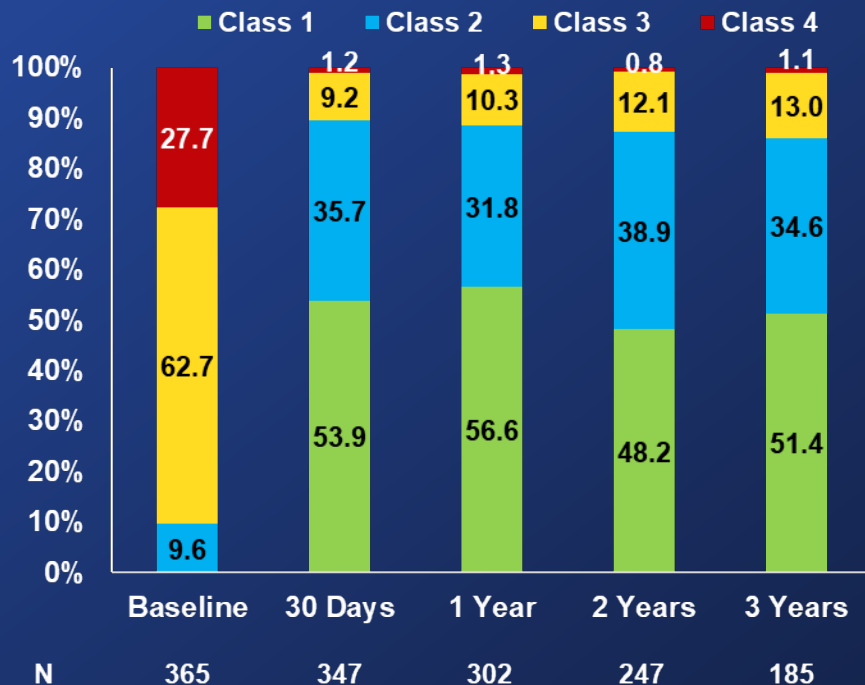


# Results

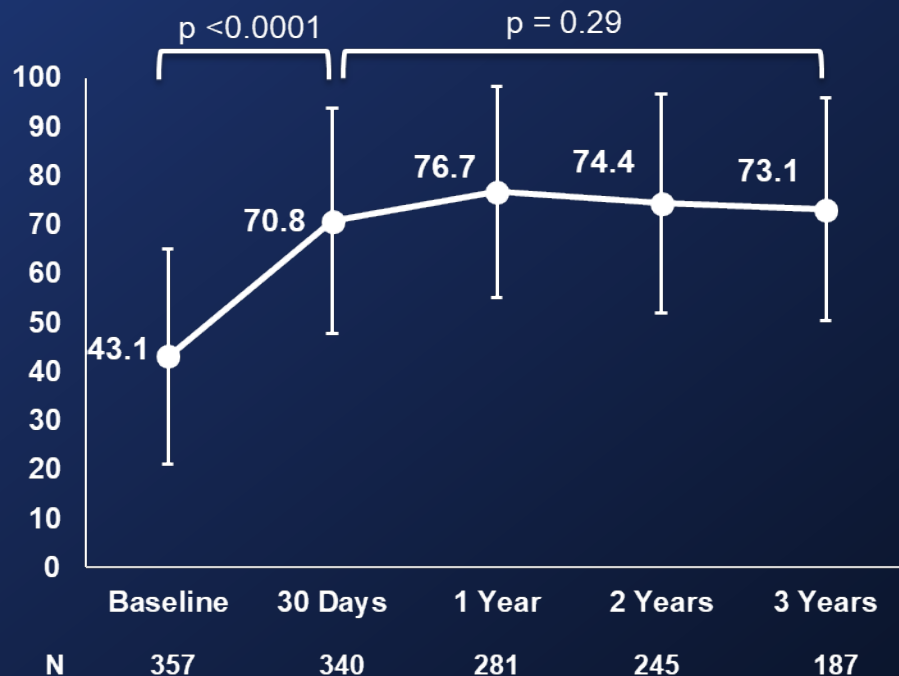
## Changes in Function and Quality of Life



### NYHA



### KCCQ Overall Summary Score



# Results

## HR for Mortality

### Surgical Valve Size (Labeled):

21mm vs 22-25mm

21mm vs >25mm

22-25mm vs >25mm

### Surgical Valve True ID: ≤21mm vs >21mm

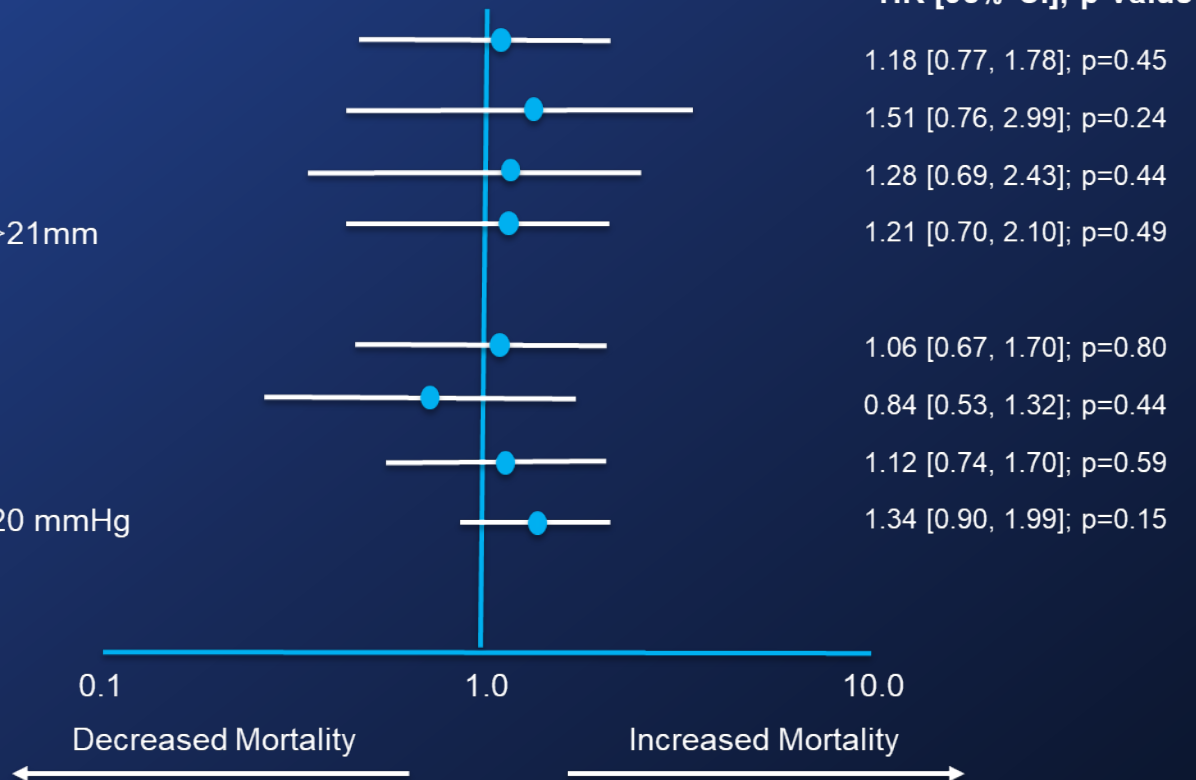
### Failure Mode:

Stenosis vs Regurgitation

Stenosis vs Mixed

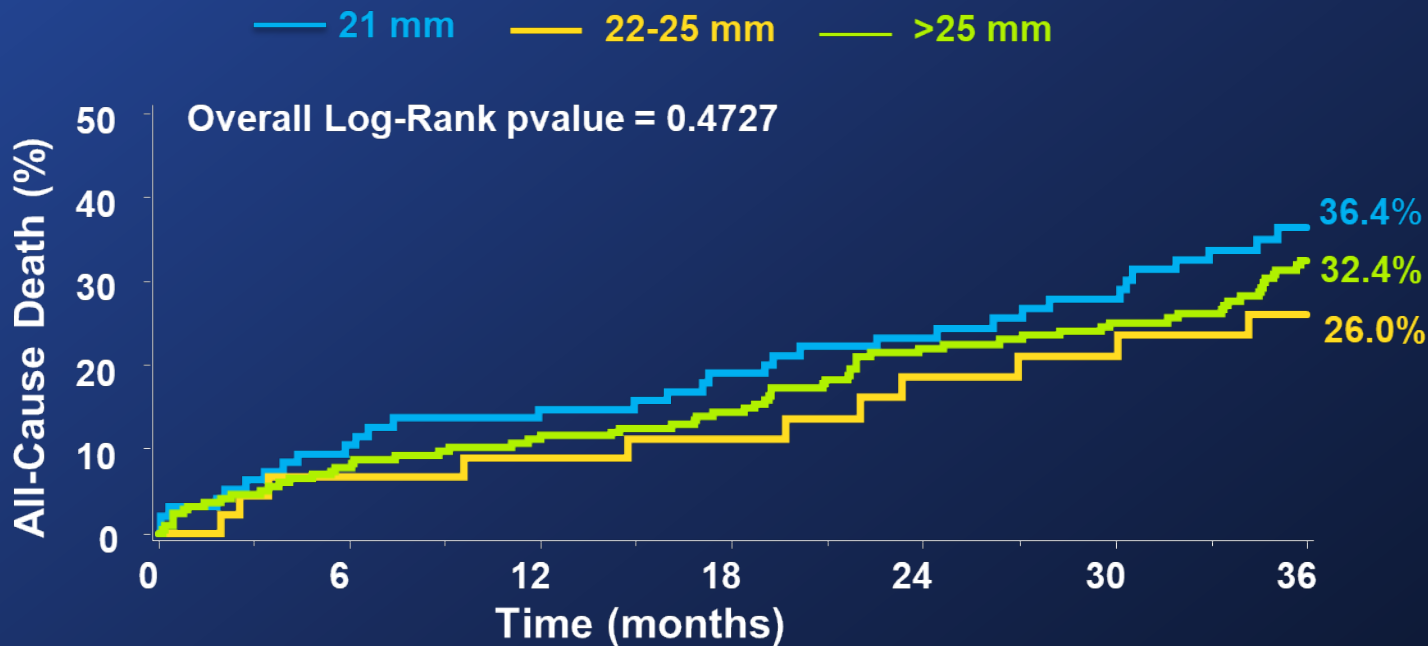
### Approach: TT vs TF

### Residual gradient: ≥20 mmHg vs <20 mmHg



# Results

## Mortality by surgical valve size (labeled)

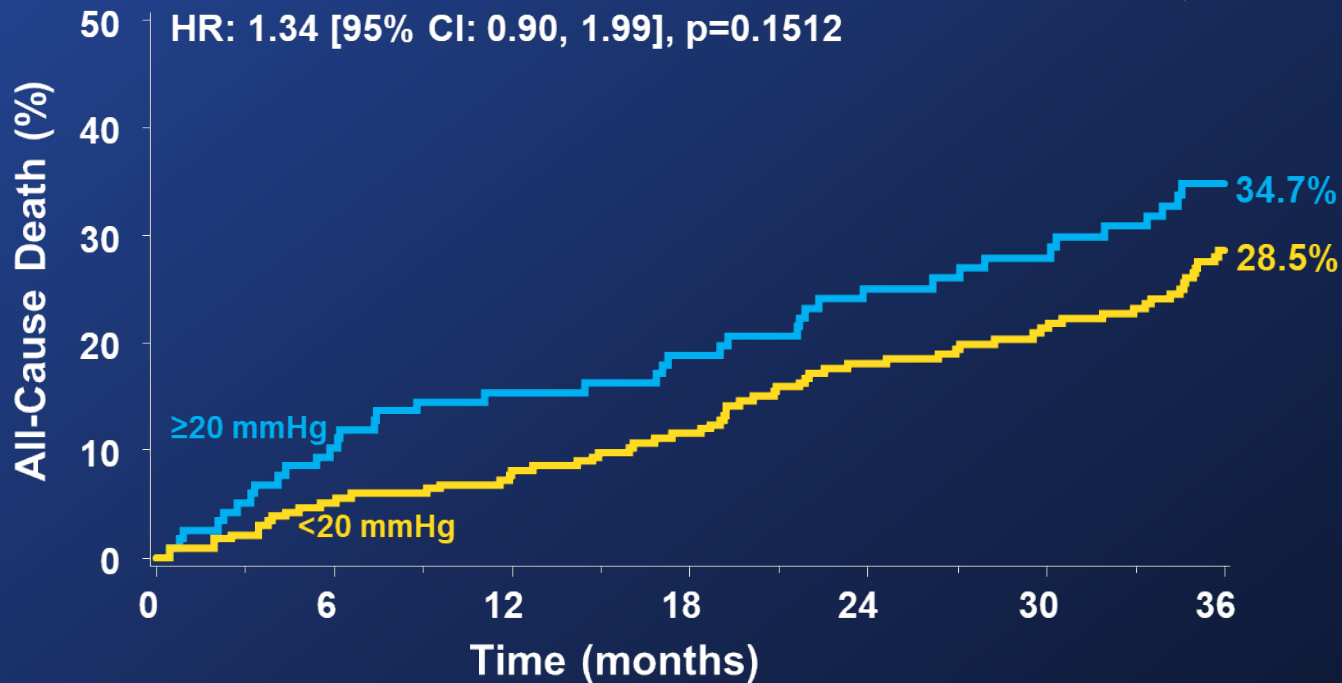


### Number at risk:

	0	6	12	18	24	30	36
21mm	95	85	81	76	68	62	43
22-25 mm	45	42	40	37	33	32	25
>25 mm	216	199	191	181	161	146	118

# Results

## Mortality by post-implant gradient



### Number at risk:

≥20 mmHg	118	106	99	93	82	75	56
<20 mmHg	236	224	217	204	184	170	136

# Conclusions



- The mortality of 33.3% at 3 years reflects multiple co-morbidities in this high-risk patient population (mean STS 9.1%).
- In survivors, early improvements in functional status and quality of life indices are maintained through 3-years.
- Valve performance is also sustained through 3 years with rare signs of structural valve deterioration requiring repeat procedures.

# Conclusions



- *The early improvements associated with ViV TAVR are maintained through 3 years, supporting the value of ViV TAVR as an important alternative therapy in appropriate patients with aortic bioprosthetic valve failure.*