Incidence and Outcomes of Valve Hemodynamic Deterioration in Transcatheter Aortic Valve Replacement in U.S. Clinical Practice: A Report from the Society of Thoracic Surgery / American College of Cardiology Transcatheter Valve Therapy Registry

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On behalf of the STS/ACC TVT Registry

Disclosures, Funding and Disclaimer

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Background

- TAVR effectively treats patients with severe aortic stenosis
- There are recent reports of TAVR leaflet abnormalities and valve thrombosis (4DCT / TEE) or Valve Hemodynamic Deterioration (VHD) (increase in aortic valve mean gradient)
- Planned prospective studies to investigate this using advanced imaging will take years to complete
- STS / ACC TVT Registry: Collaboration of STS, ACC, CMS, FDA, hospitals, industry, SCAI, AATS, NIH, and consumer advocates
  - Unique opportunity to track current TAVR performance in the community
  - All commercial valve implantations in US
  - Linked to CMS database for long term follow up
  - Prespecified post-procedure, 30-day, 1-year transthoracic echo (TTE)
  - TTEs are site read

STS National Database
Using data to drive quality

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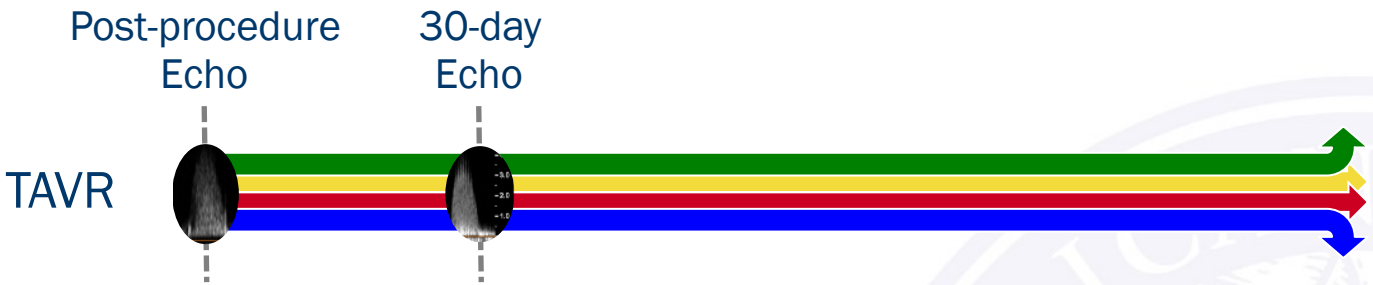
Objectives and Methods

Short Term Cohort



Aim 1: Incidence of VHD (≥ 10 mm Hg ↑ gradient)

Objectives and Methods

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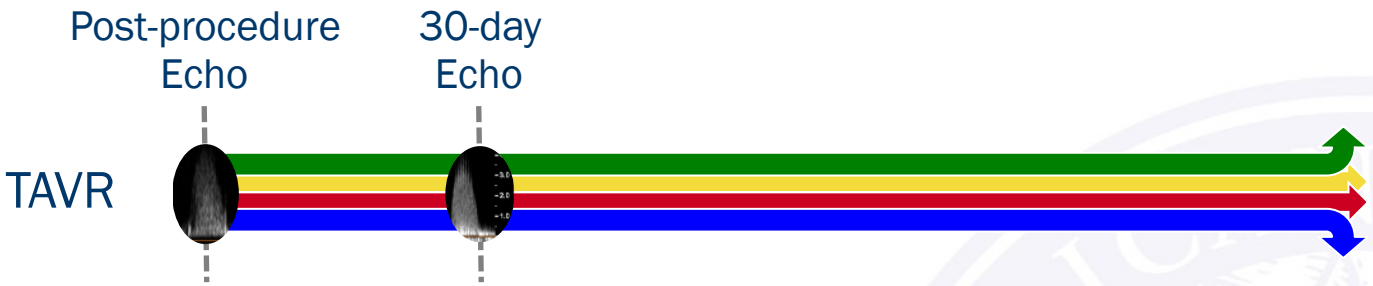

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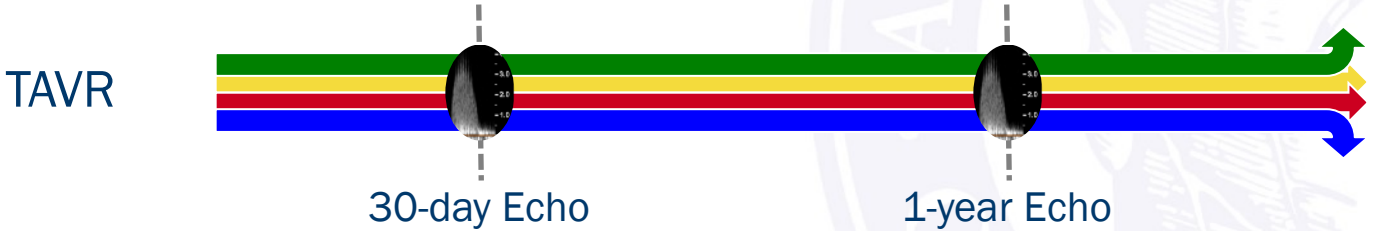
Long Term Cohort



Objectives and Methods

Short Term Cohort

Post-procedure Echo

30-day Echo

Aim 2: 18-month cardiovascular outcomes

TAVR

Aim 1: Incidence of VHD (≥ 10 mm Hg ↑ gradient)

Mortality

Stroke

Heart failure

Re-intervention

Long Term Cohort

TAVR

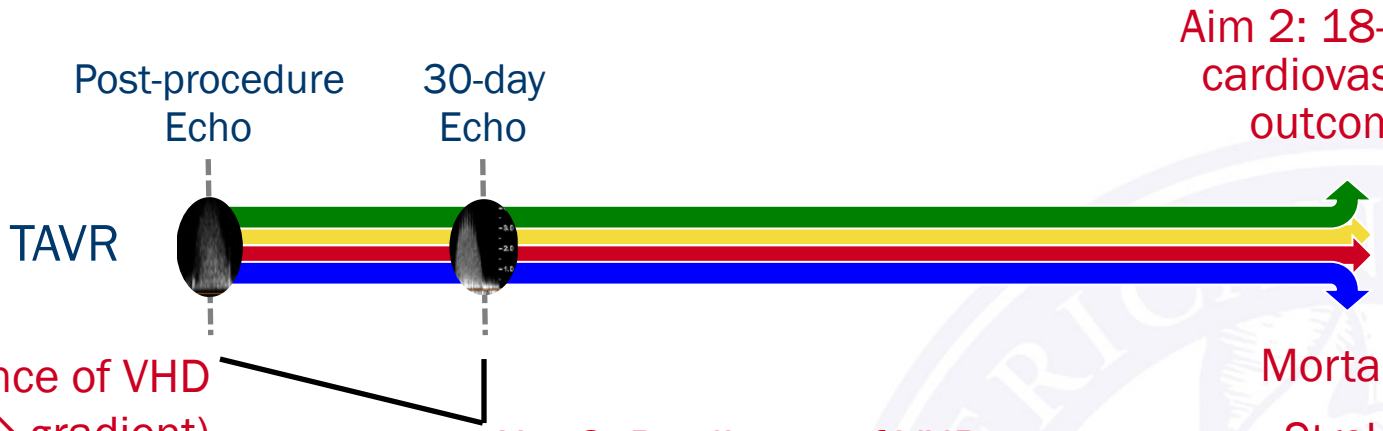
30-day Echo

1-year Echo

CMS linkage

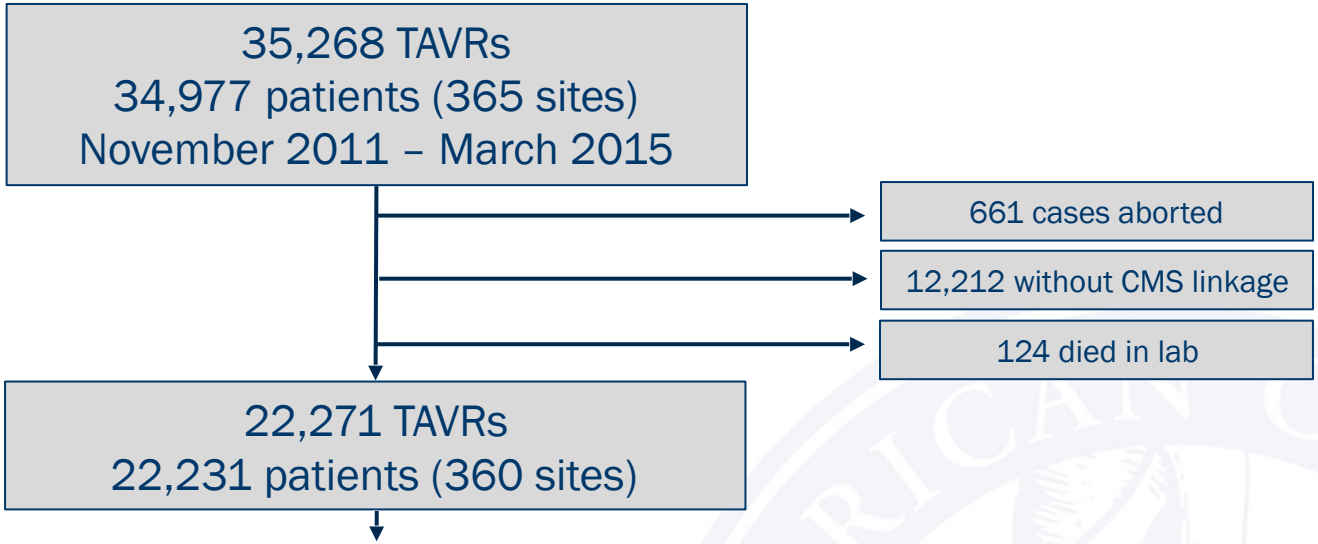
Objectives and Methods

Short Term Cohort



Long Term Cohort

Study Design



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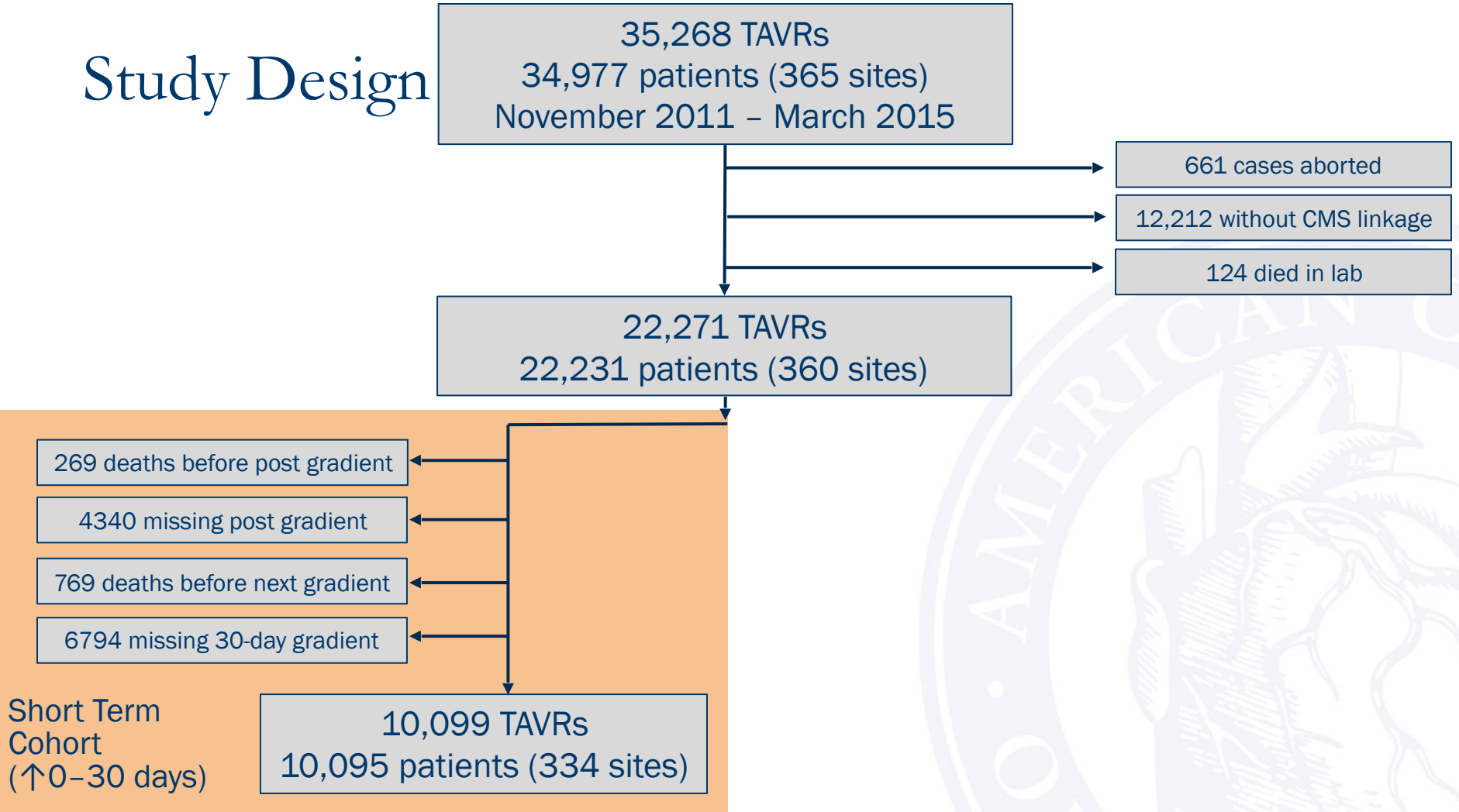

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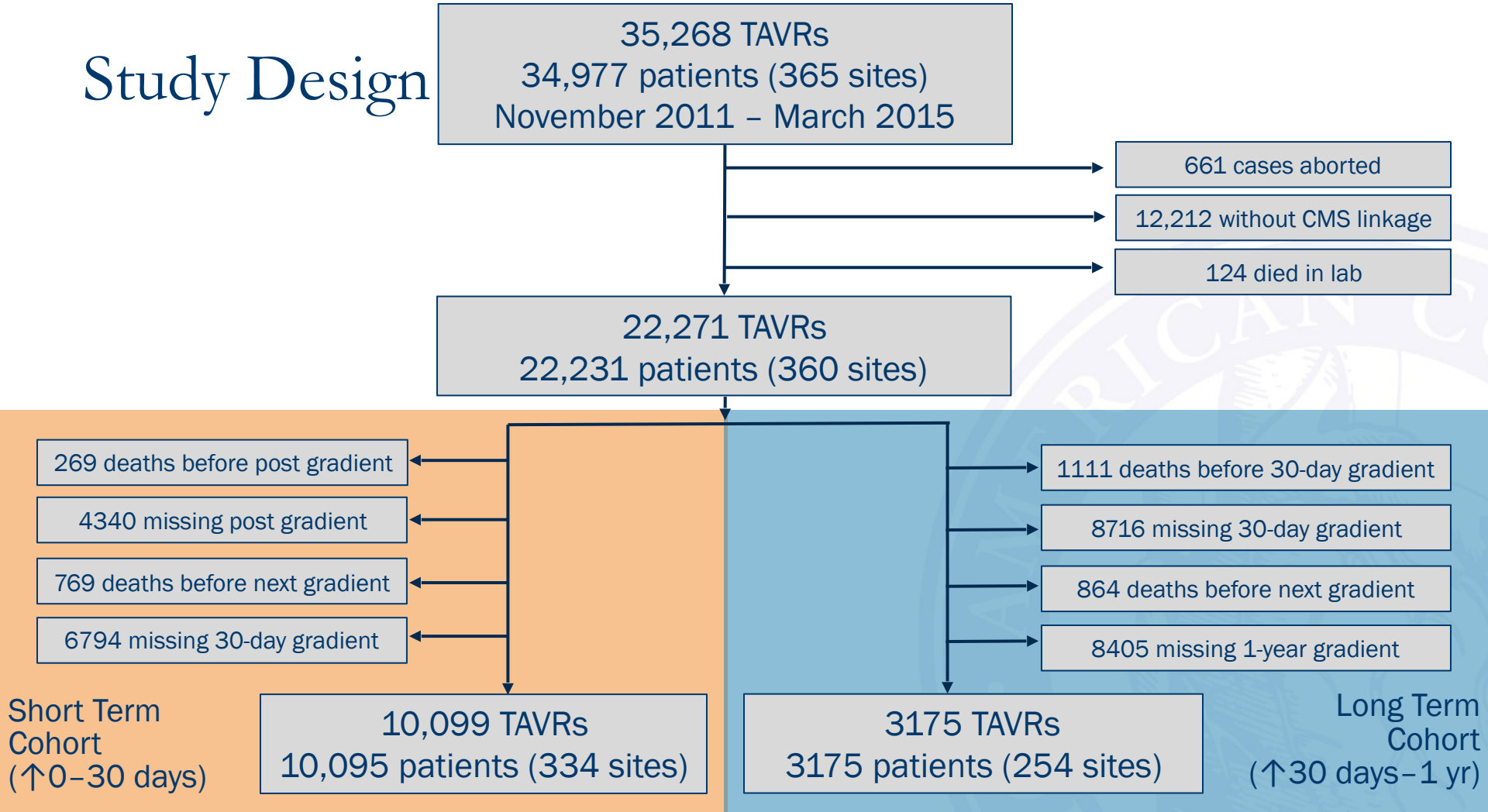


Baseline Patient Characteristics

	Short Term Cohort (N=10,099)	Long Term Cohort (N=3175)
Age (years), median (IQR)	84.0 (78.0,88.0)	84.0 (78.0,88.0)
Male sex	5182 (51.3)	1487 (46.8)
Hypertension	9003 (89.1)	2801 (88.2)
Diabetes Mellitus	3593 (35.6)	1109 (34.9)
Prior MI	2405 (23.8)	774 (24.4)
Prior stroke or TIA	1891 (18.7)	582 (18.3)
Atrial fibrillation/flutter	4146 (41.1)	1222 (38.5)
Dialysis dependent	379 (3.8)	84 (2.6)
STS PROM Score, median (IQR)	6.7 (4.5,10.0)	6.4 (4.5,9.6)
Aspirin (Discharge)	8798 (87.1)	2816 (88.7)
Warfarin (Discharge)	2510 (24.9)	780 (24.6)
Dabigatran (Discharge)	2602 (25.8)	832 (26.2)
P2Y12 inhibitor (Discharge)	6586 (65.2)	2106 (66.3)
Factor Xa inhibitor (Discharge)	373 (3.7)	59 (1.9)

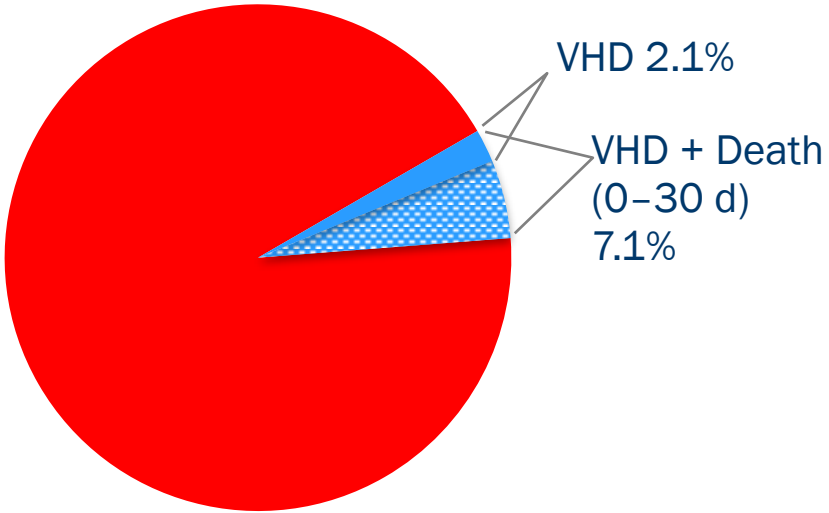
Procedure and Echo Variables

	Short Term Cohort (N=10,099)	Long Term Cohort (N=3175)
Baseline echo variables		
LVEF median (IQR)	58.0 (45.0,64.0)	58.0 (48.0,63.5)
Procedure variables		
Balloon expanding valve	8029 (79.5)	2981 (93.9)
Self-expanding valve	2068 (20.5)	194 (6.1)
Valve size = 23 mm	3273 (32.4)	1376 (43.3)
Valve size = 26 mm	4502 (44.6)	1647 (51.9)
Valve size = 29 mm	1612 (16.0)	91 (2.9)
Valve size = 31 mm	710 (7.0)	61 (1.9)
Valve in valve	486 (4.8)	137 (4.3)
Postprocedure echo variables		
Valve oversizing	1.2 (1.1,1.4)	1.3 (1.1,1.4)
Mean AV gradient mm Hg, median (IQR)	9.0 (6.0,12.0)	10.0 (7.0,13.0)
EOA index cm^2, median (IQR)	1.0 (0.8,1.2)	0.9 (0.7,1.2)
PPM present (moderate/severe)	2957 (29.3%)	847 (26.7%)

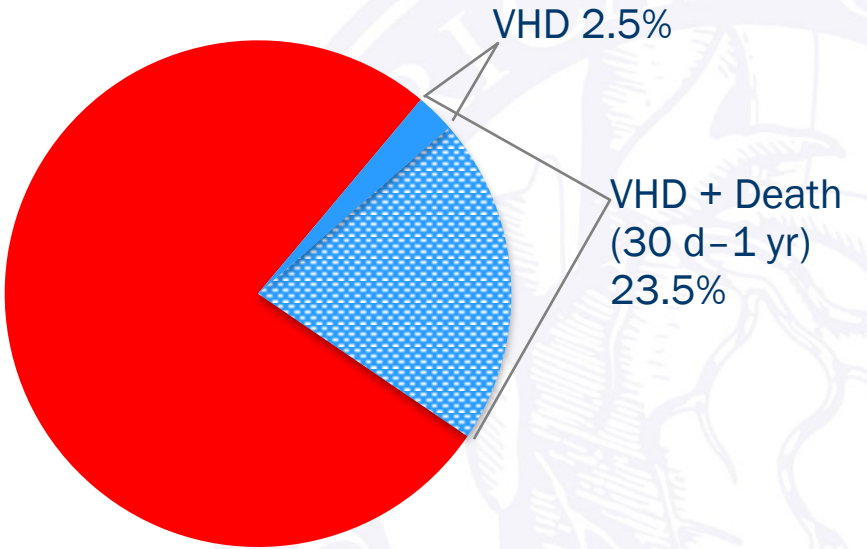
Incidence of VHD

VHD defined as ↑ AS mean gradient ≥ 10 mm Hg

Short Term Cohort (↑ gradient 0–30 days)

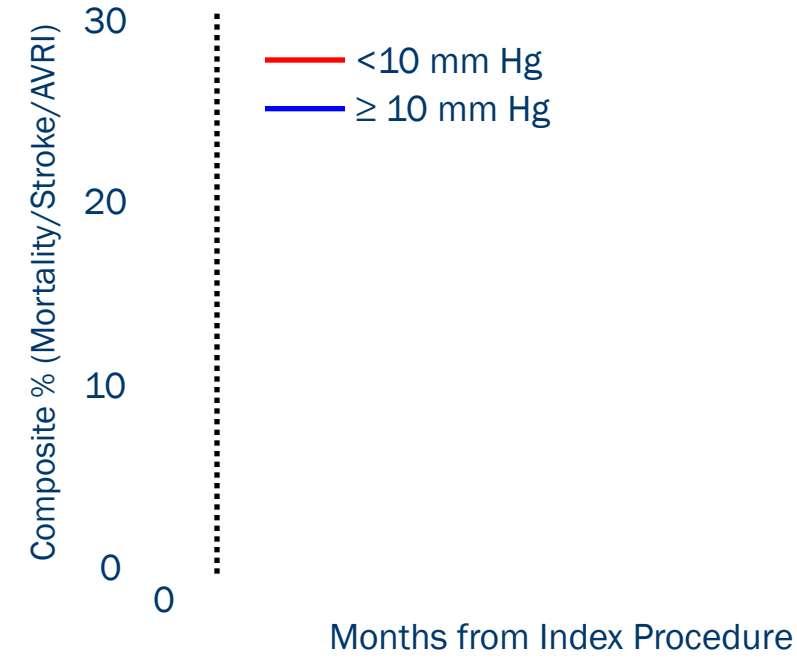


Long Term Cohort (↑ gradient 30 day–1 yr)



Landmark Cumulative Incidence of Mortality/Stroke /Aortic Valve Reintervention

Short Term Cohort (↑ gradient 0–30 days)



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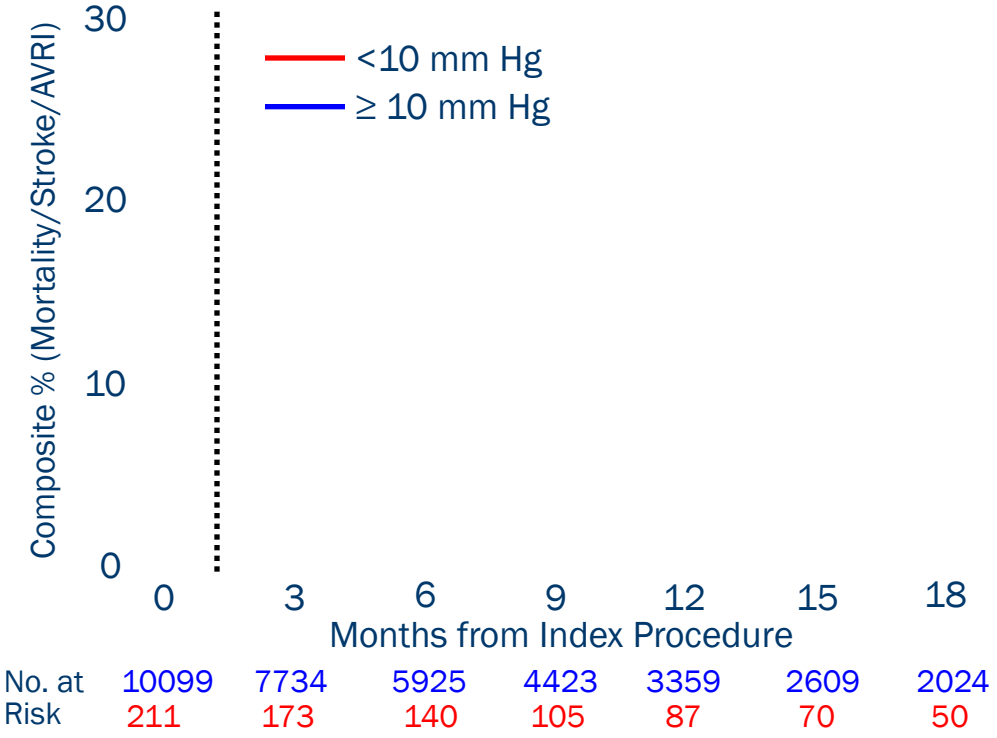

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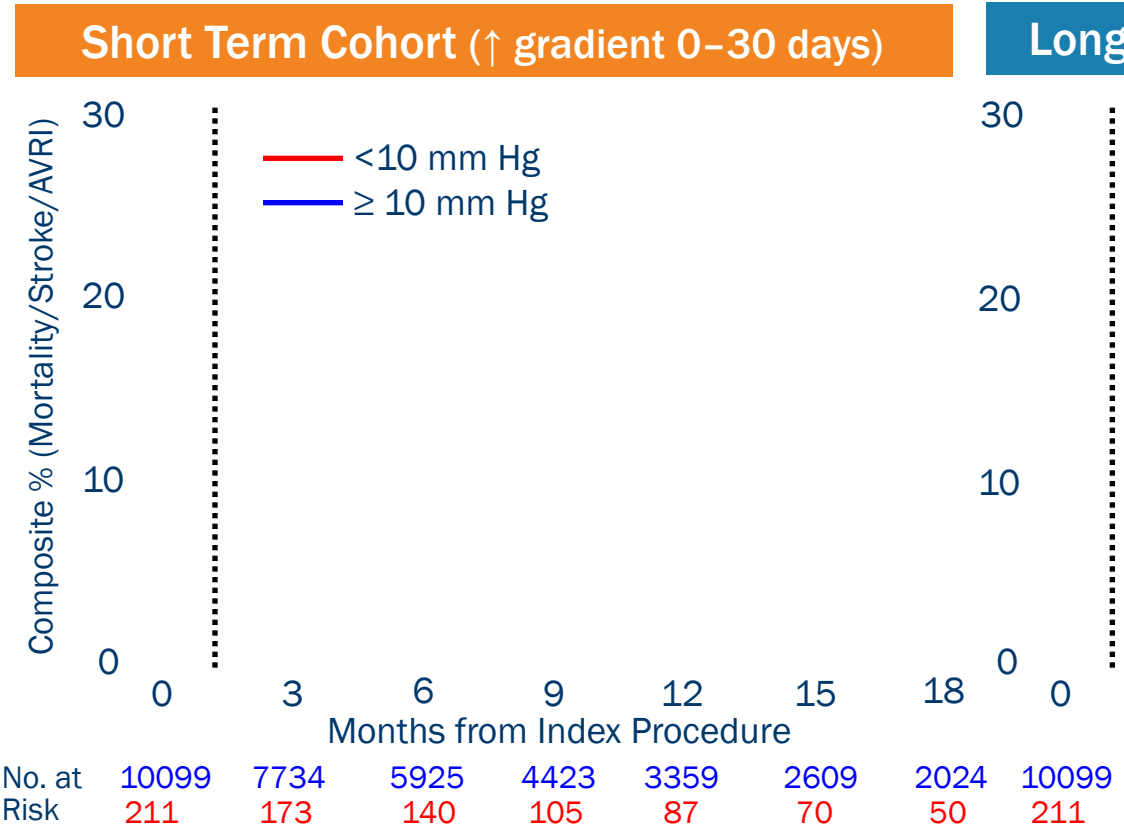

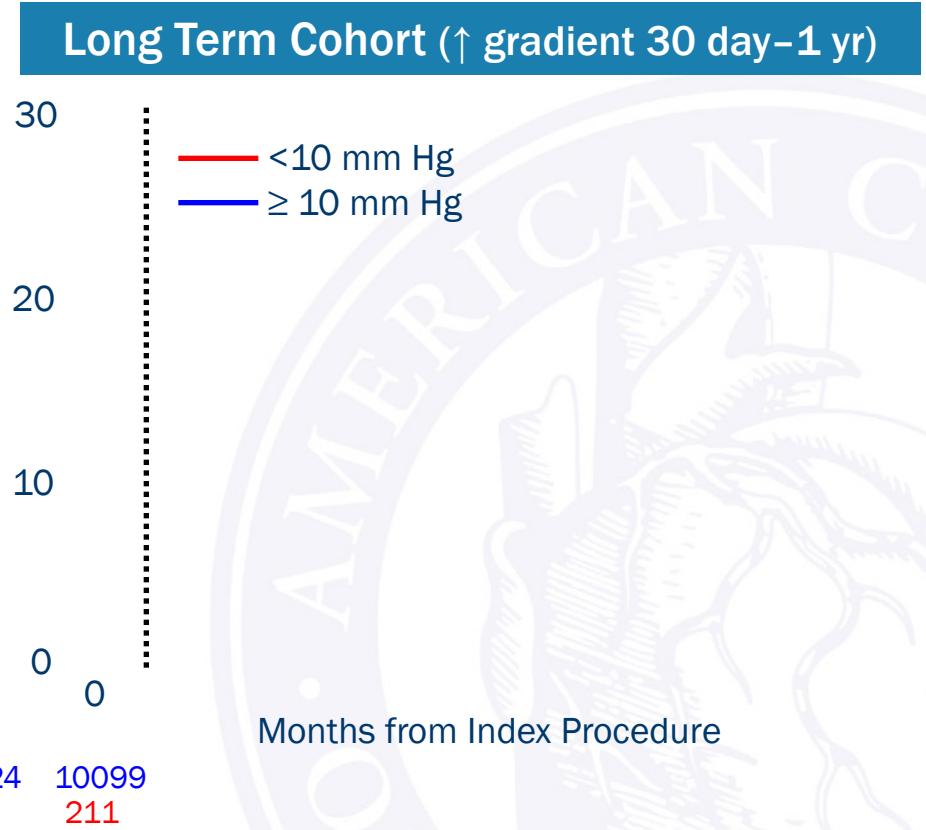

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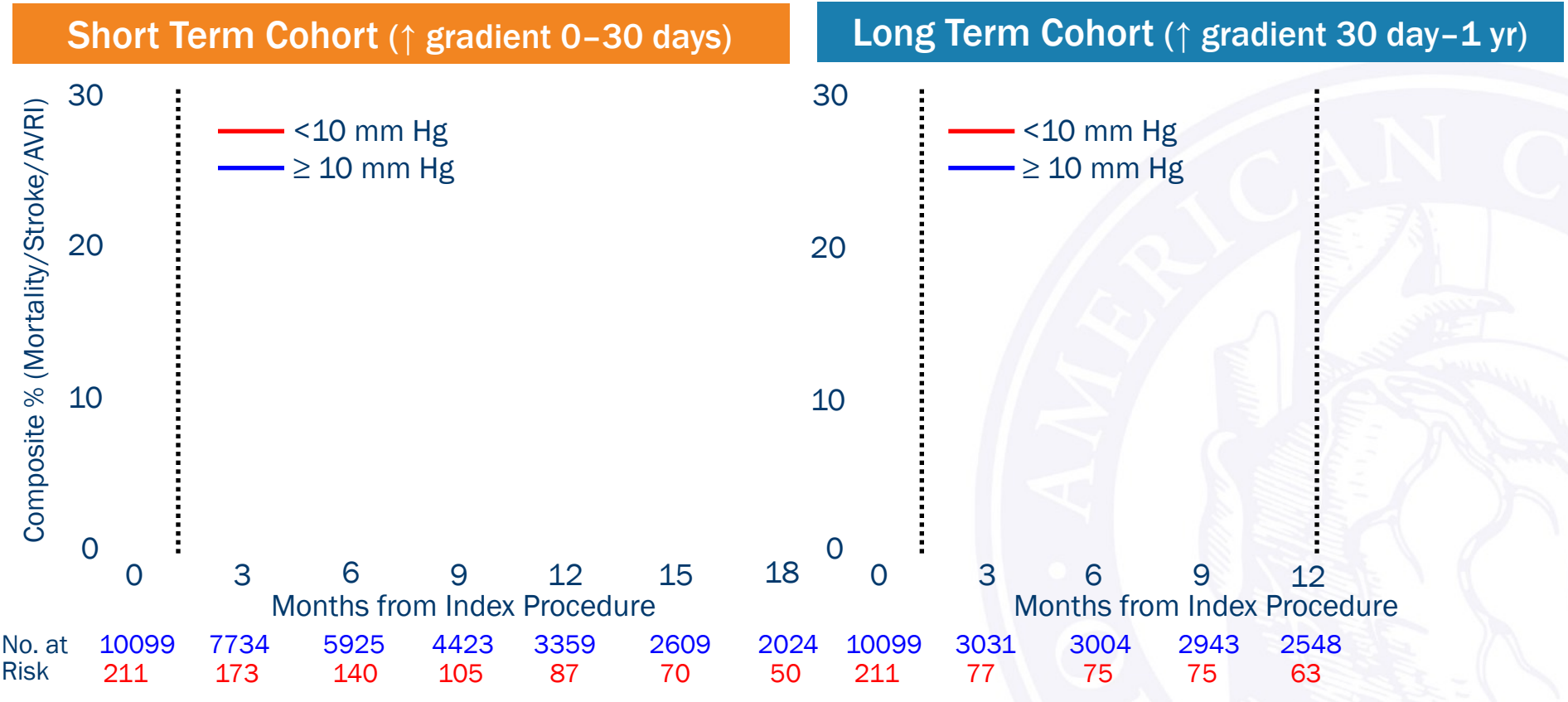

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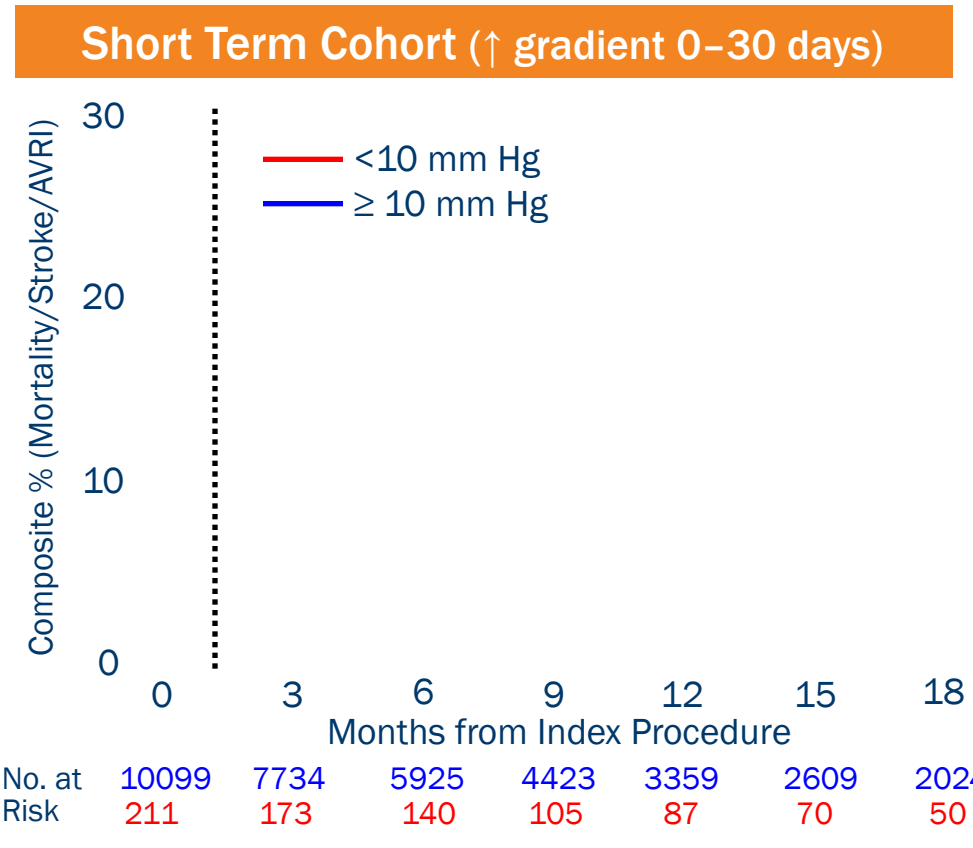
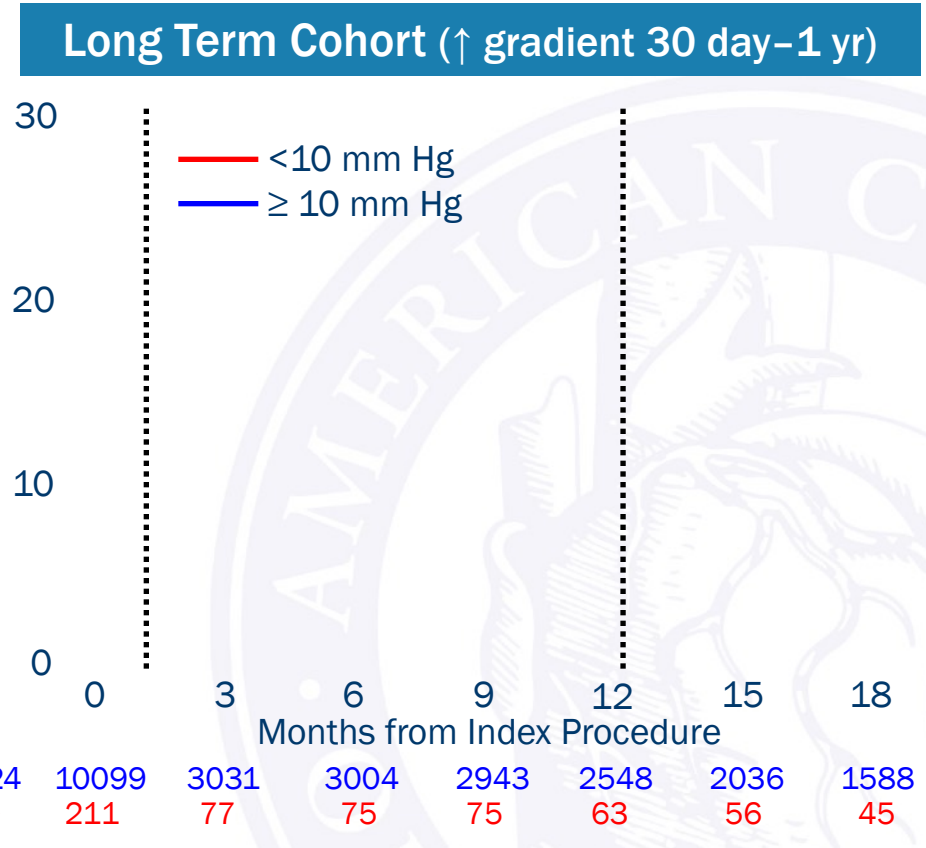
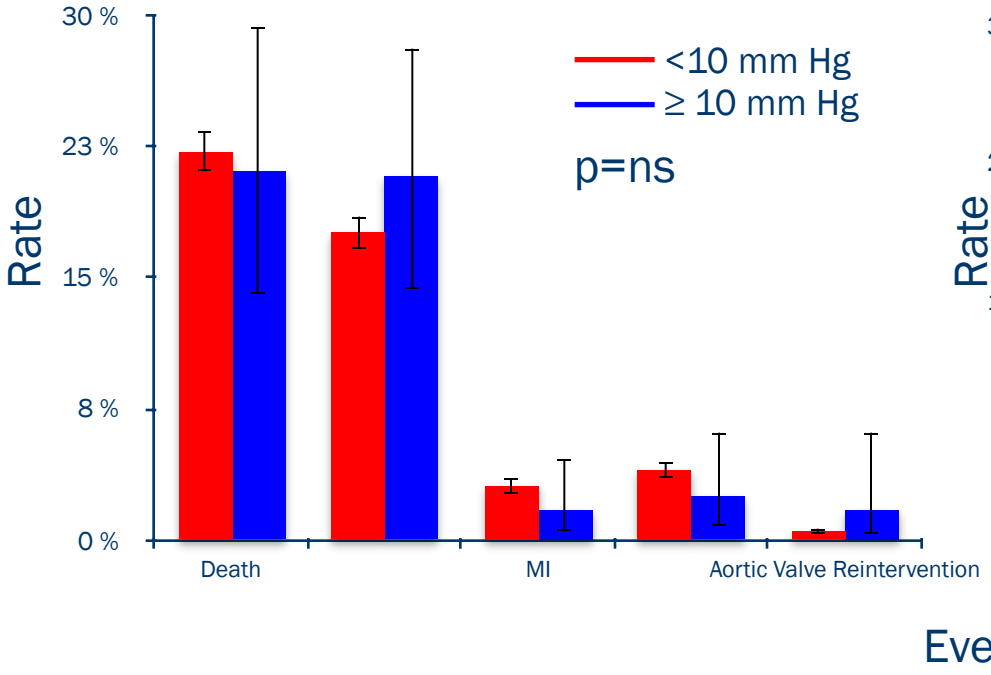




18-Month Outcomes

Short Term Cohort (↑ gradient 0–30 days)



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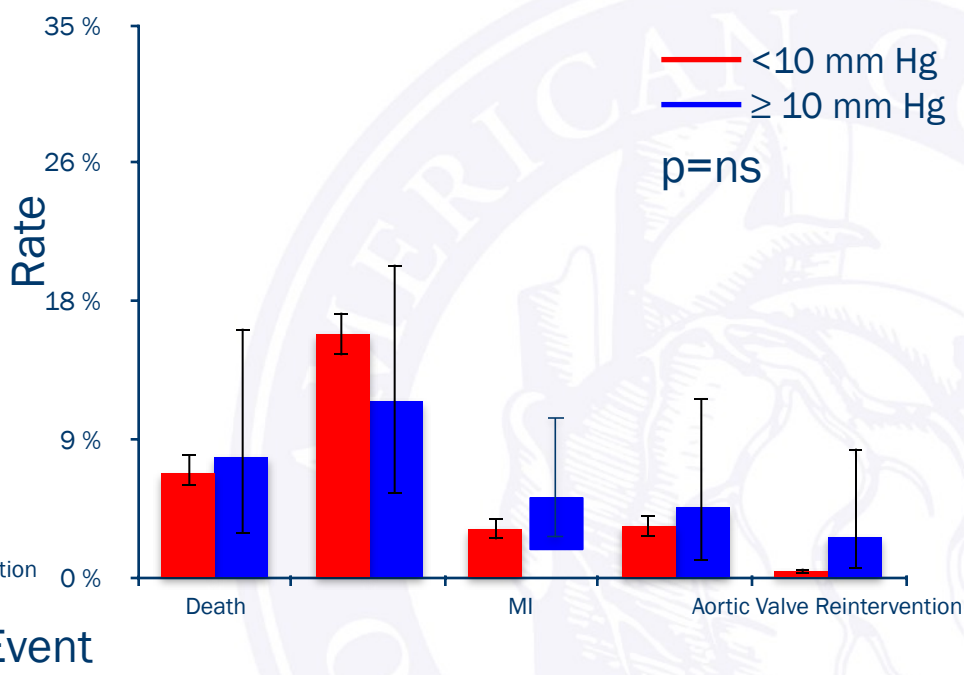
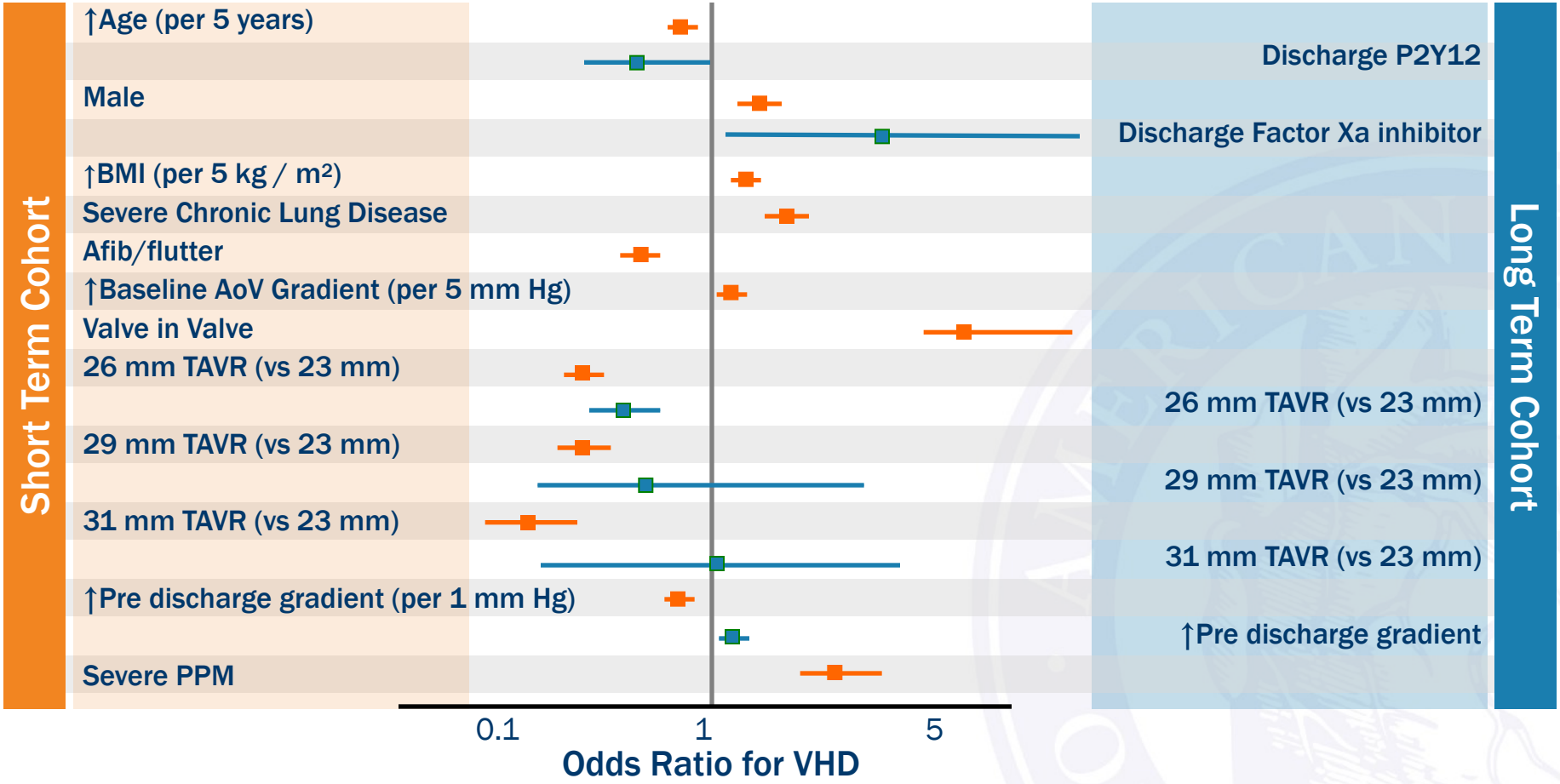


Factors Associated with VHD



Summary

- There is a small but present incidence of Valvular Hemodynamic Deterioration after TAVR (defined by ↑ AV gradient ≥ 10 mmHg)
  - 2.1% in the post-procedure to 30 day timeframe
  - 2.5% in the 30 day to 1-year timeframe
- VHD does not appear to be not associated with excess events
  - Cumulative incidence of a composite of death, stroke, and aortic valve re-intervention and of its components are similar between those with and without VHD
- Predictors of VHD include both patient and procedural factors
  - Patient: Male, ↑BMI severe lung disease,
  - Procedural: 23 mm TAVR valve, valve-in-valve, ↑Baseline AoV gradient, severe PPM

Limitations

- Retrospective analysis using site reported, surveillance echo data obtained at pre-specified time points
  - Uncertain relationship to clinical events, if any
  - May also detect asymptomatic or clinically unapparent VHD
- Definition of VHD (↑ 10 mm Hg mean gradient) is not validated
- Incidence of VHD may be underestimated due to death/reoperation before follow-up gradient measurement
  - The incidence of VHD when including death is 2–4x the rate of VHD
- Significant echo data missingness; Clinical follow-up only in CMS pts
- Absence of 4DCT/TEE to determine etiology of VHD or leaflet abnormalities

Conclusions

- Incidence of VHD as reported in clinical practice is low; ~2%
- VHD is not clearly associated with adverse CV events
- These findings, especially patient and procedural predictors, may help to inform TAVR care including patient selection, surveillance and preventive strategies
- Large, prospective studies using advanced imaging (4DCT/TEE) are necessary to fully elucidate the incidence, mechanisms and consequences of VHD

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