

# After PARTNER 2A/S3i and SURTAVI: What is the Role of Surgery in Intermediate-Risk AS Patients?

Vinod H. Thourani, MD

Professor of Surgery and Medicine

Emory University

# 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

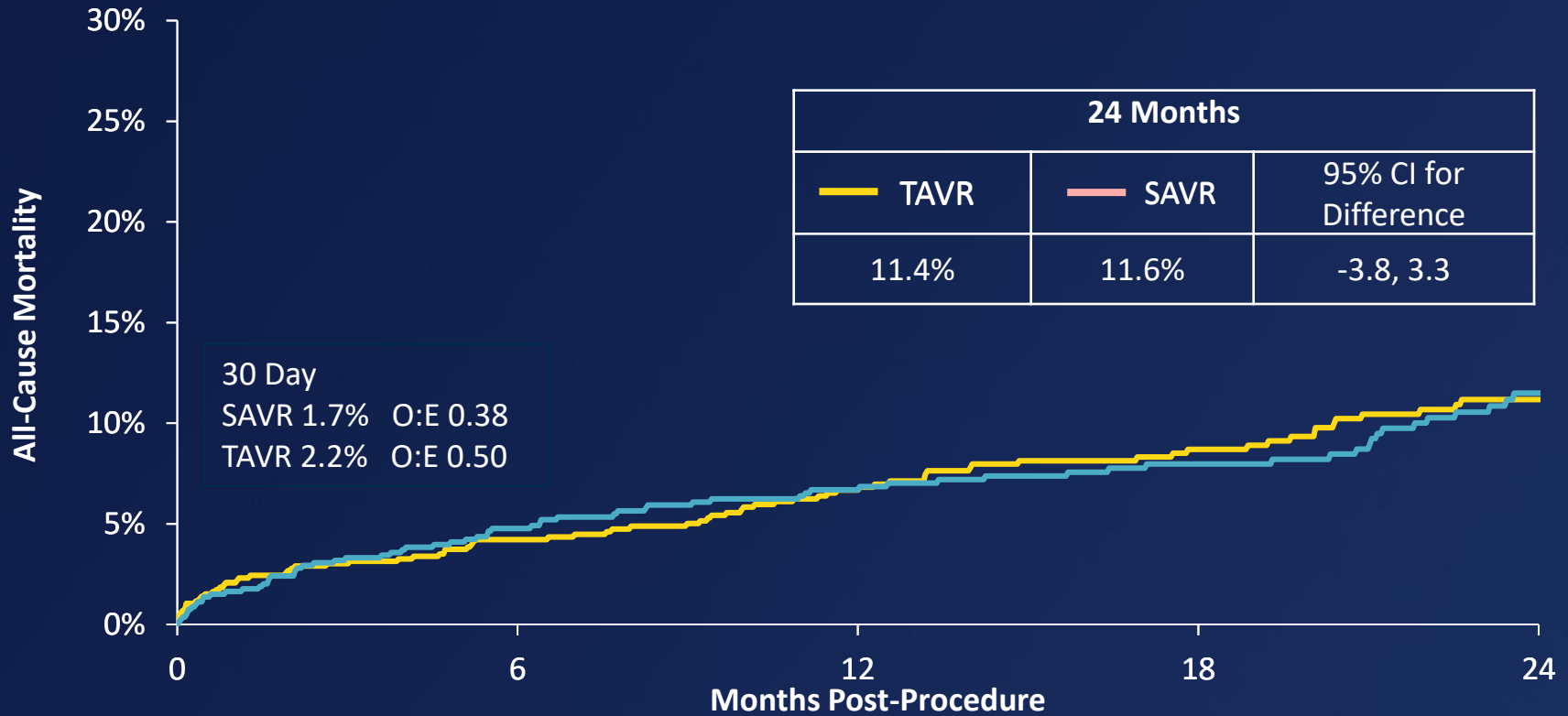
- Grant/Research Support
- Consulting Fees/Honoraria

## Company

- Edwards Lifesciences, Boston Scientific, Medtronic, Abbott Vascular
- Edwards Lifesciences, Abbott Vascular, Gore

*All TVT 2017 faculty disclosures are listed online and on the app.*

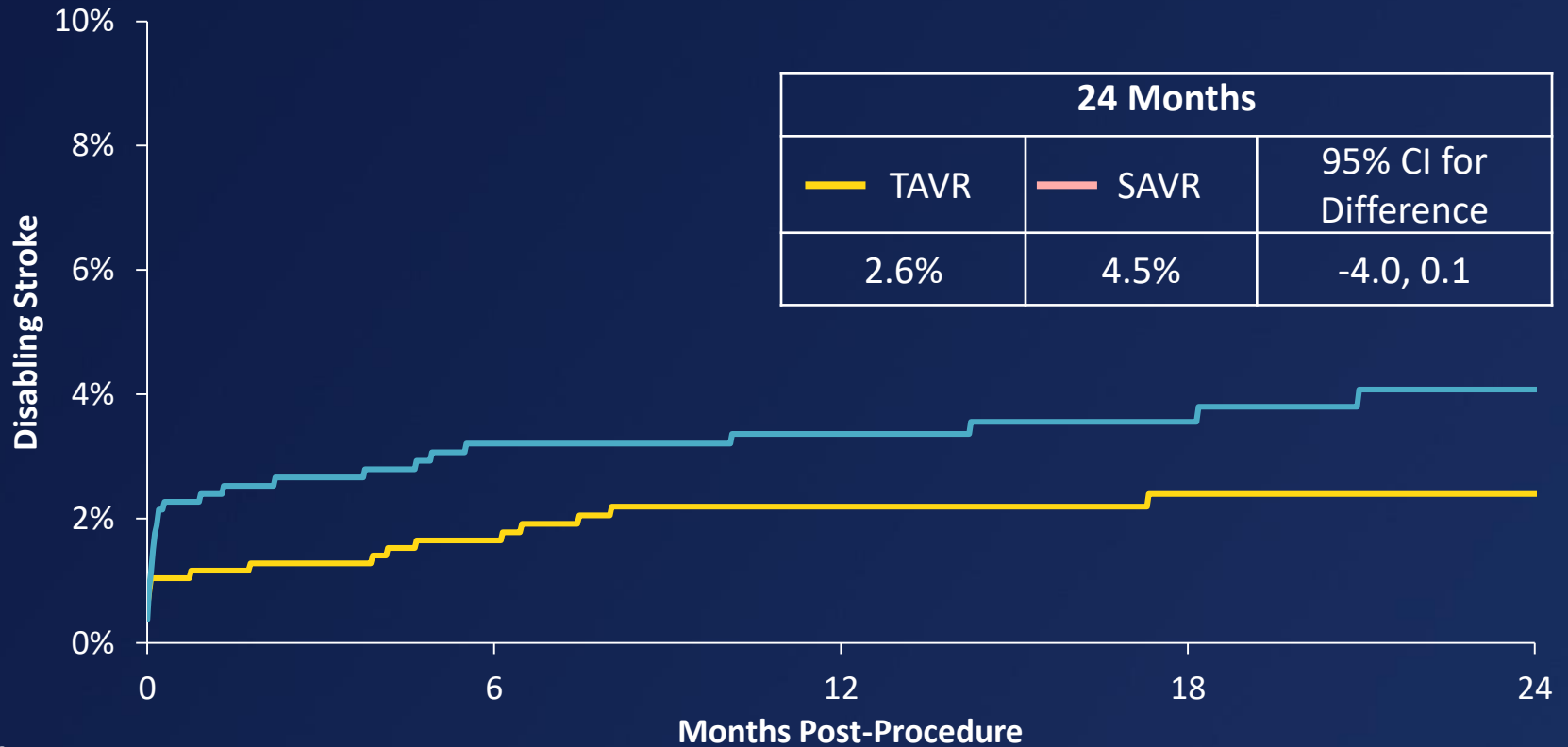
# SURTAVI: All-Cause Mortality



30 Day  
 SAVR 1.7% O:E 0.38  
 TAVR 2.2% O:E 0.50

No. at Risk	0	6	12	18	24
SAVR	796	690	569	414	249
TAVR	864	762	621	465	280

# SURTAVI: Disabling Stroke



No. at Risk

SAVR	796	674	555	407	241
TAVR	864	755	612	456	272

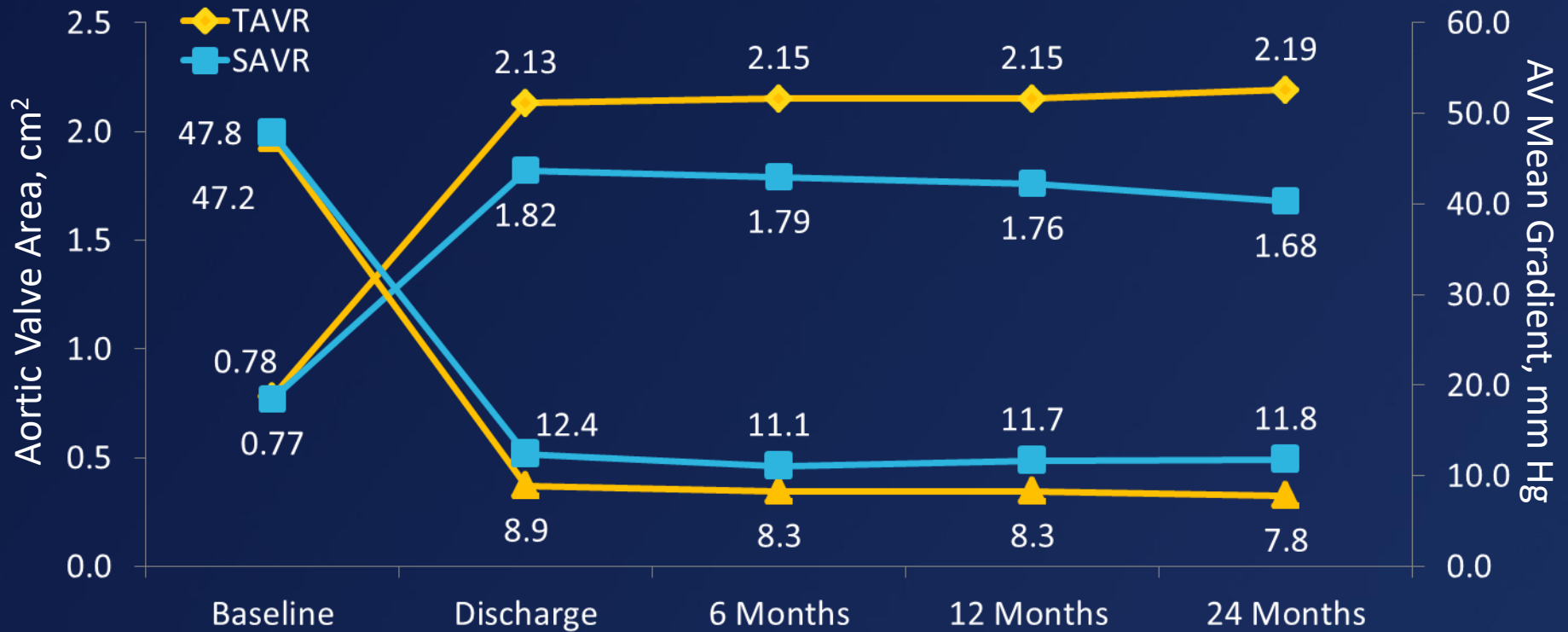
## 30-Day Safety and Procedure-related Complications

	TAVR (N=864)	SAVR (N=796)	95% CI for Difference
All-cause mortality or disabling stroke	2.8	3.9	-2.8, 0.7
All-cause mortality	2.2	1.7	-0.9, 1.8
Disabling stroke	1.2	2.5	-2.6, 0.1
All stroke	3.4	5.6	-4.2, -0.2
Overt life-threatening or major bleeding	12.2	9.3	-0.1, 5.9
Transfusion of PRBCs* - n (%)			
0 units	756 (87.5)	469 (58.9)	24.4, 32.5
2 – 4 units	48 (5.6)	136 (17.1)	-14.5, -8.5
≥ 4 units	31 (3.6)	101 (12.7)	-11.7, -6.5
Acute kidney injury, stage 2-3	1.7	4.4	-4.4, -1.0
Major vascular complication	6.0	1.1	3.2, 6.7
Cardiac perforation	1.7	0.9	-0.2, 2.0
Cardiogenic shock	1.1	3.8	-4.2, -1.1
Permanent pacemaker implant	25.9	6.6	15.9, 22.7
Atrial fibrillation	12.9	43.4	-34.7, -26.4

\*Percentage rates, all others are Bayesian rates

# Hemodynamics\*

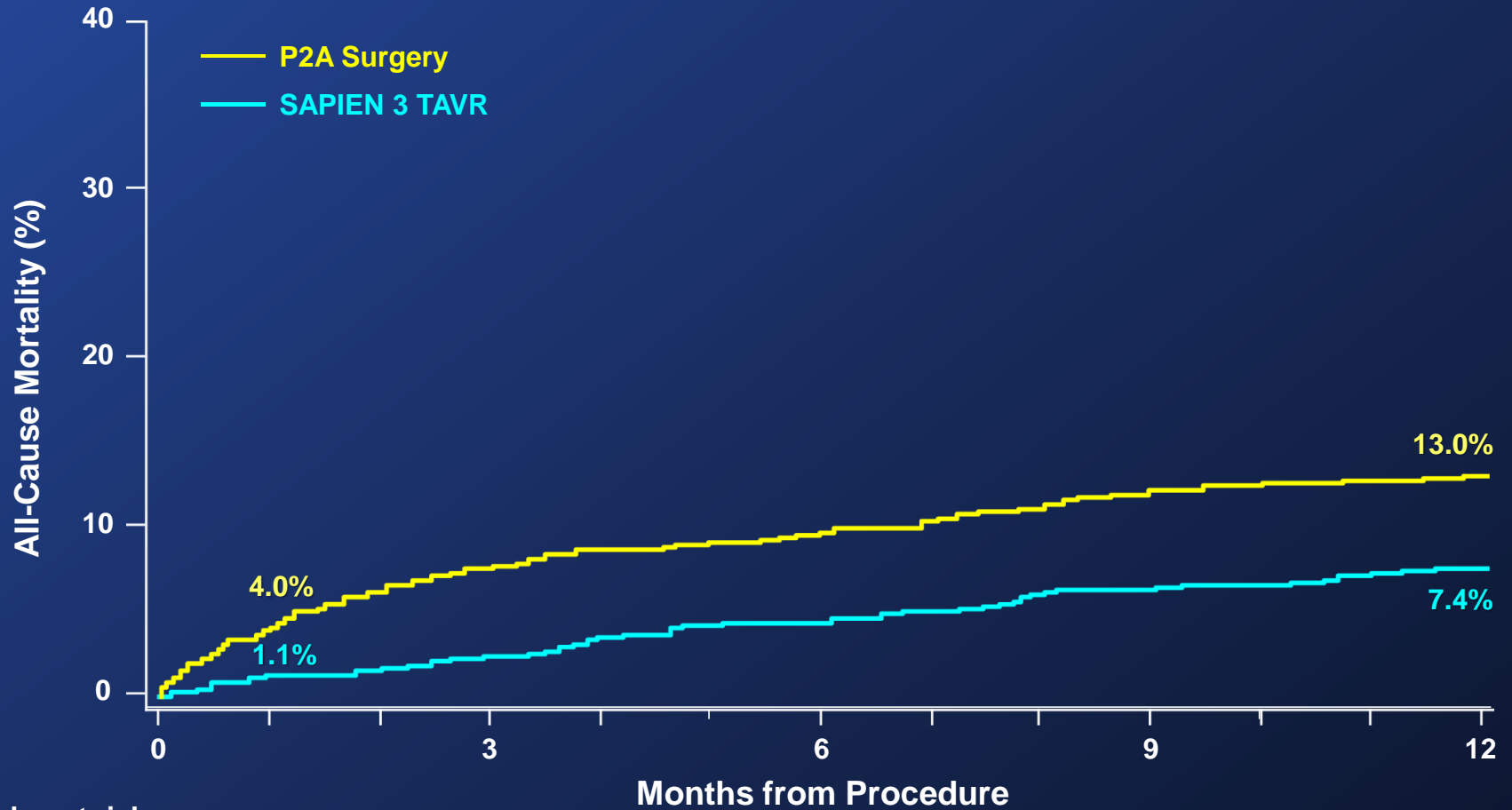
TAVR had significantly better valve performance over SAVR at all follow-up visits



\*Core lab adjudicated

# Unadjusted Time-to-Event Analysis

## All-Cause Mortality (AT)



Number at risk:

**P2A Surgery** 944

**S3 TAVR** 1077

**859**

**1043**

**836**

**1017**

**808**

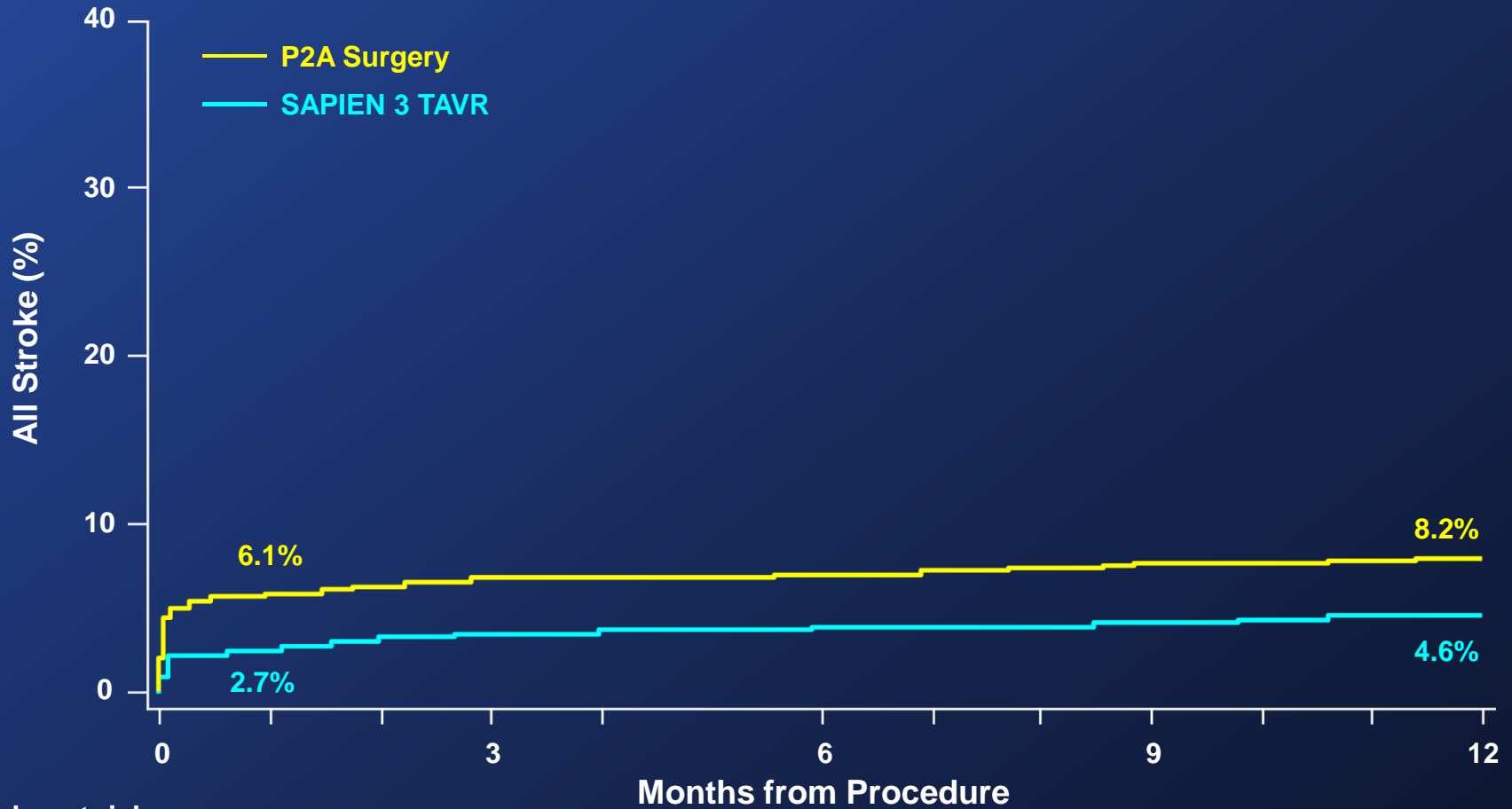
**991**

**795**

**963**

# Unadjusted Time-to-Event Analysis

## All Stroke (AT)



Number at risk:

**P2A Surgery** 944  
**S3 TAVR** 1077

**805**  
**1012**

**786**  
**987**

**757**  
**962**

**743**  
**930**



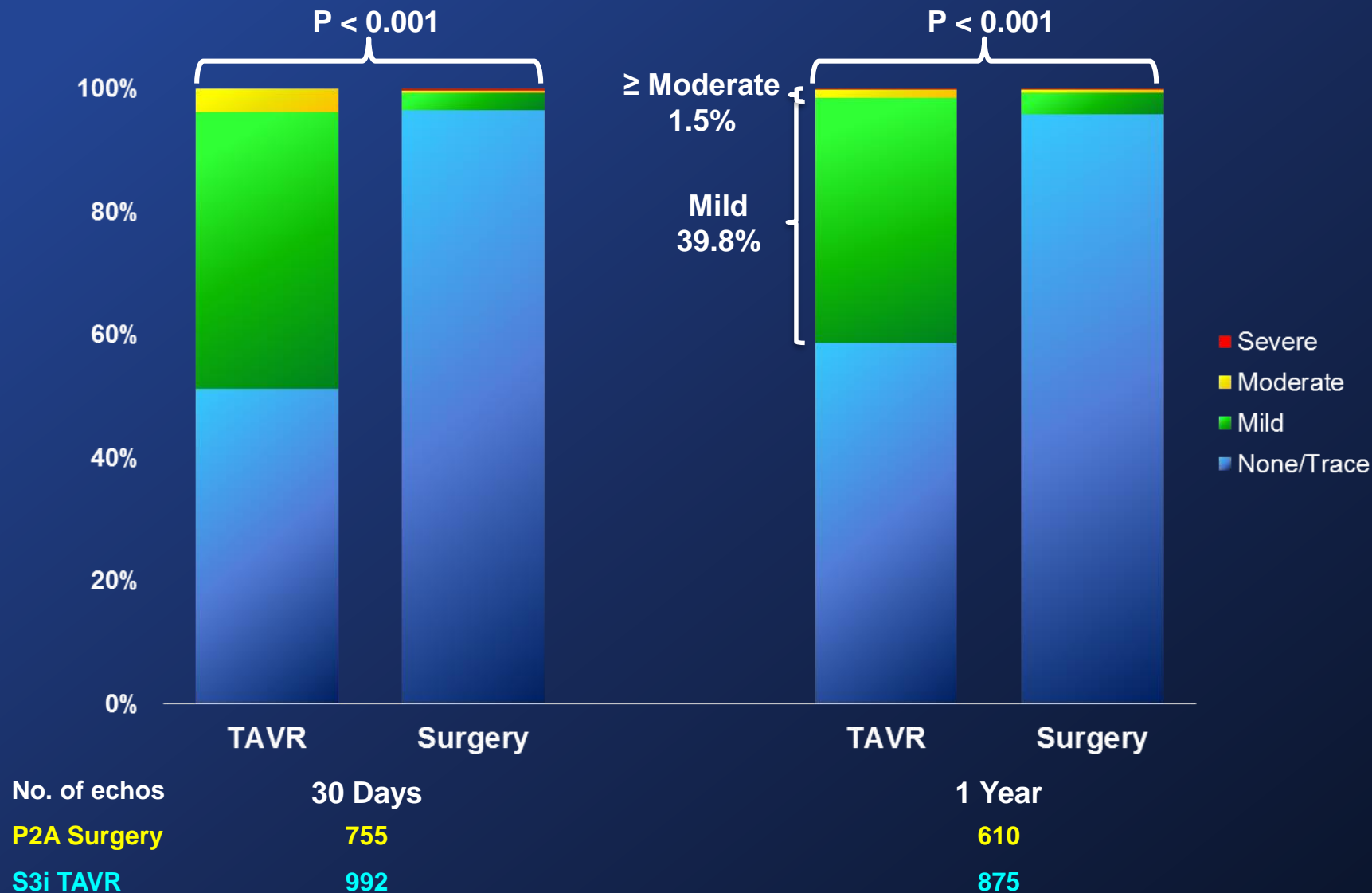
# Other Unadjusted Clinical Outcomes

## At 30 Days and 1 Year (AT)



Events (%)	30 Days		1 Year	
	TAVR (n = 1077)	Surgery (n = 944)	TAVR (n = 1077)	Surgery (n = 944)
Re-hospitalization	4.6	6.8	11.4	15.1
MI	0.3	1.9	1.8	3.1
Major Vascular Complication	6.1	5.4	---	---
AKI (Stage III)	0.5	3.3	---	---
Life-Threatening/Disabling Bleeding	4.6	46.7	---	---
New Atrial Fibrillation	5.0	28.3	5.9	29.2
New Permanent Pacemaker	10.2	7.3	12.4	9.4
Re-intervention	0.1	0.0	0.6	0.5
Endocarditis	0.2	0.0	0.8	0.7

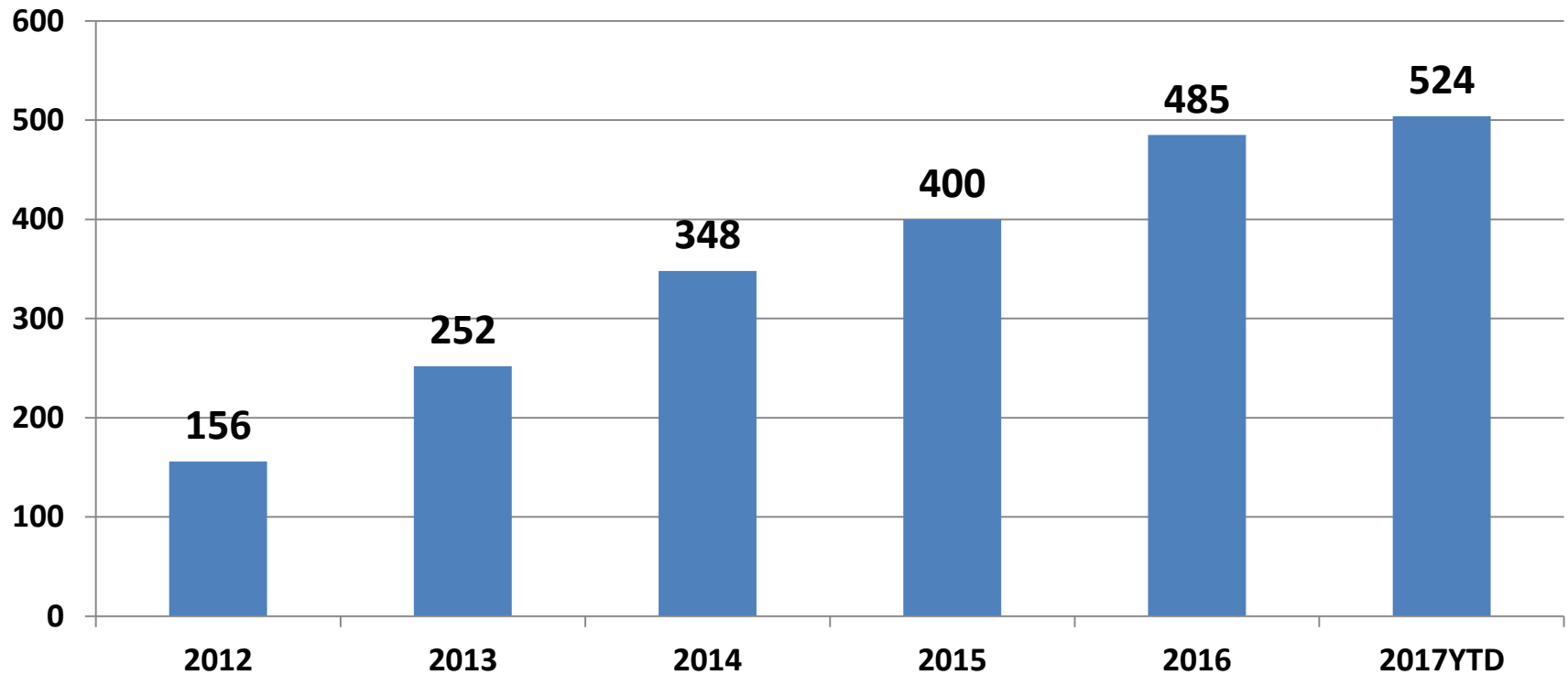
# Paravalvular Regurgitation 3-Class Grading Scheme (VI)



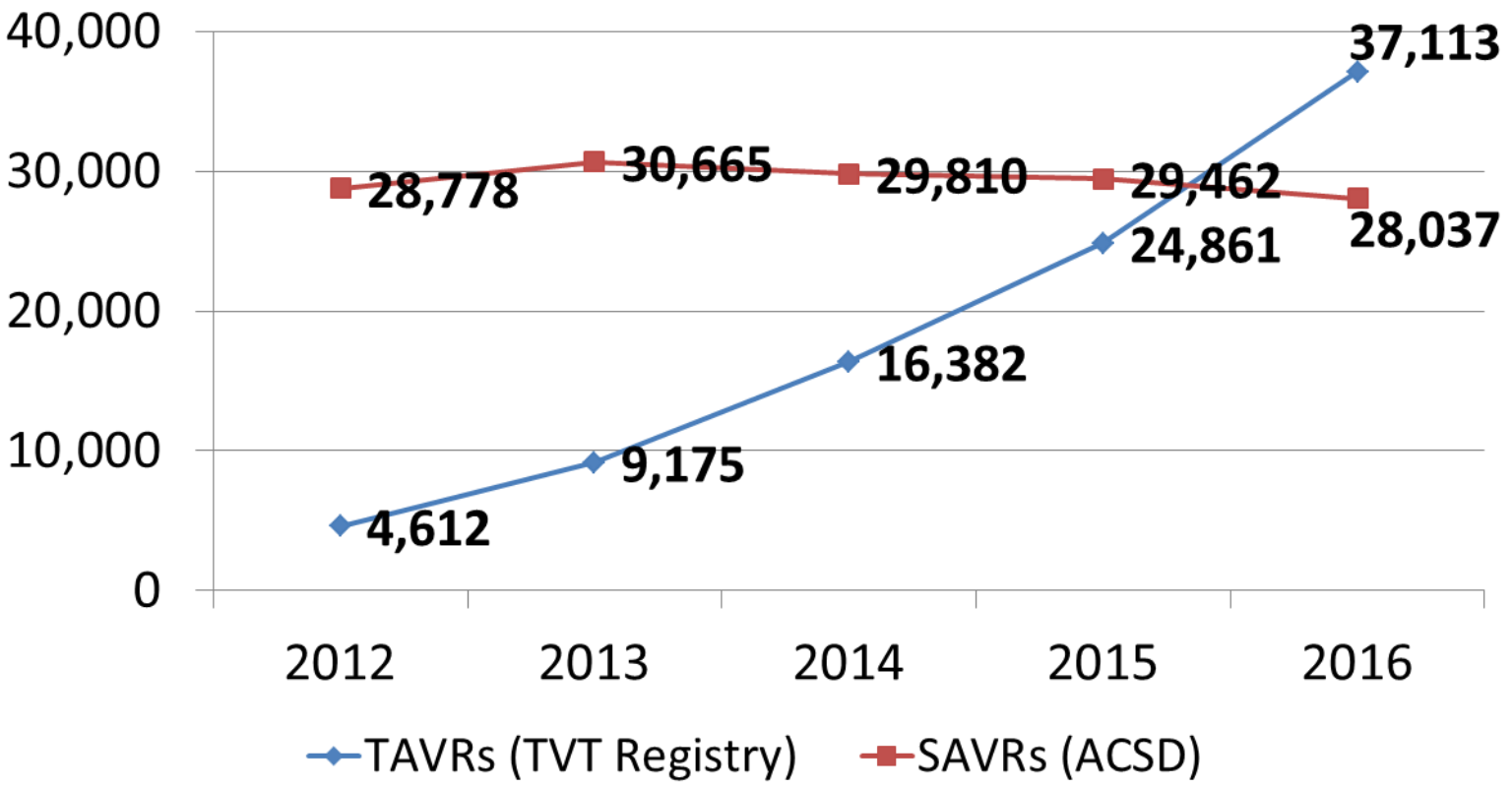
As of April 2017

*Over 101,264, Patients in US Have  
Received FDA Approved TAVR Therapy*

# Sites Enrolled in TVT Registry as of June 13, 2017

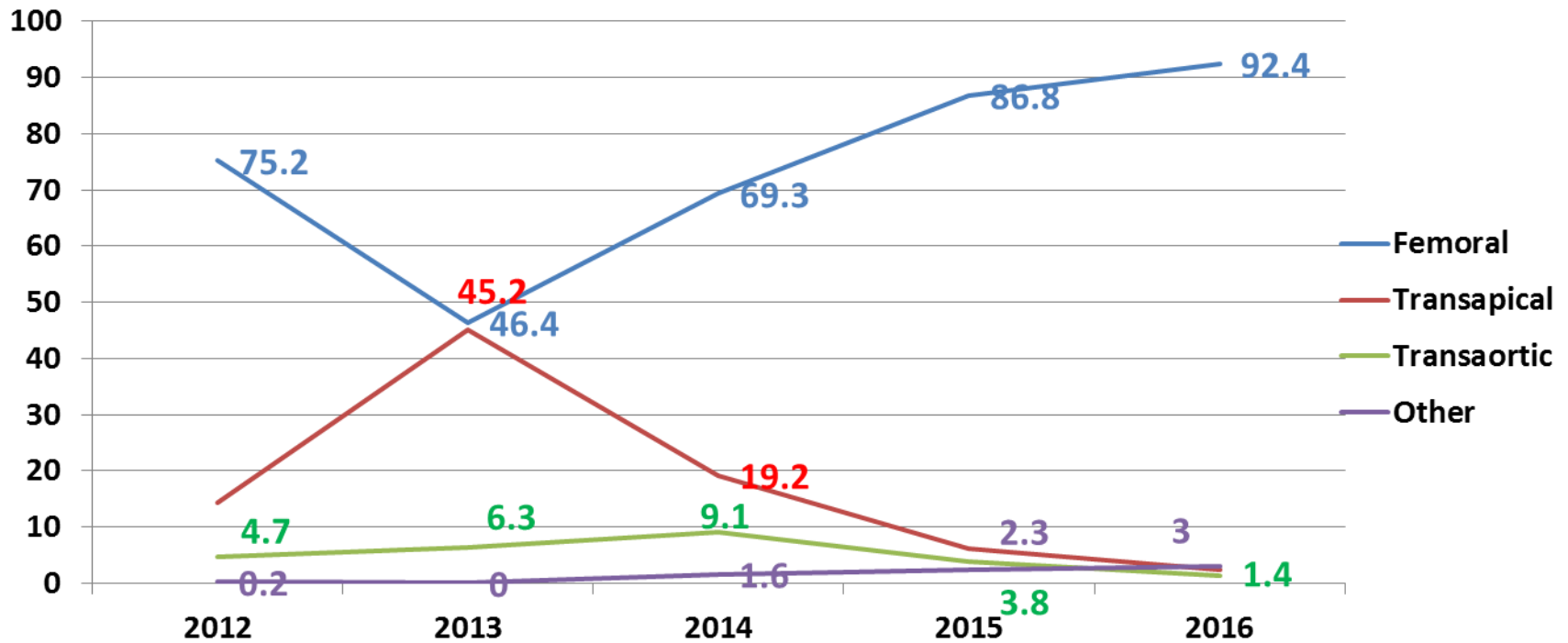


# TAVR and SAVR\* Procedures In the TVT Registry and STS ACSD\*



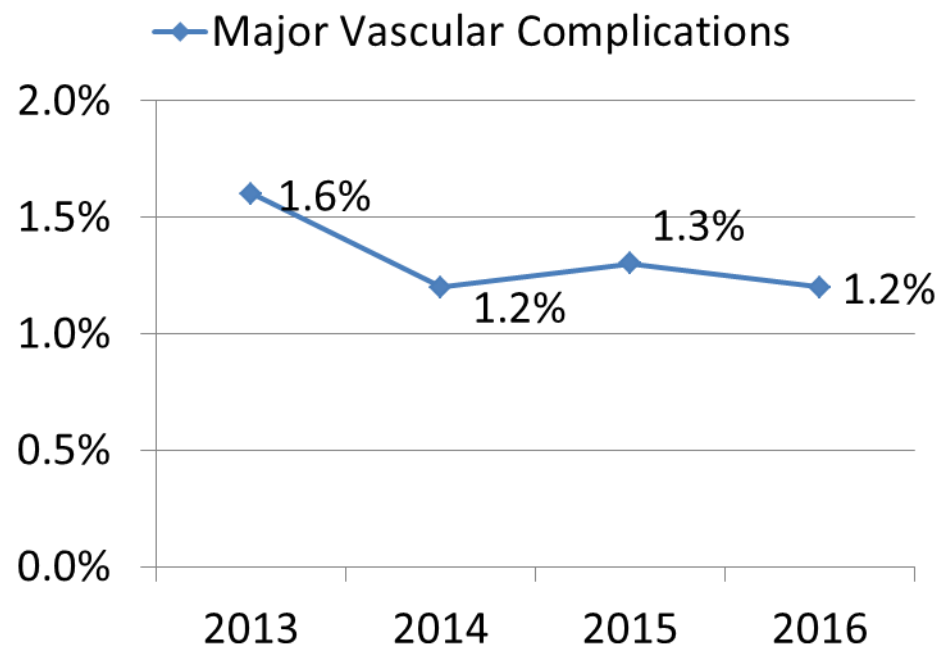
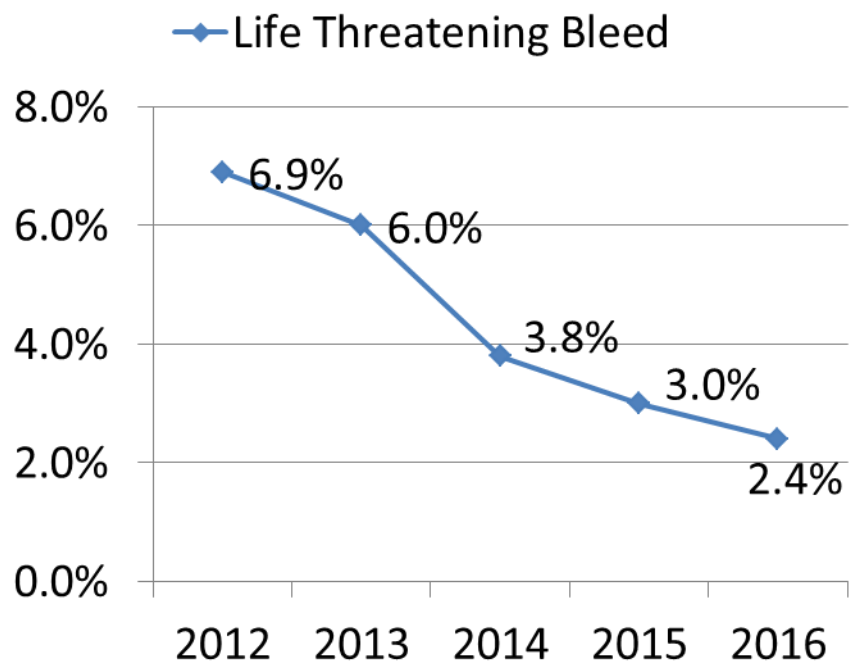
Source: STS/ACC TVT Registry Database and STS Database  
2017  
as of April 10, 2017

# TAVR Access Site %



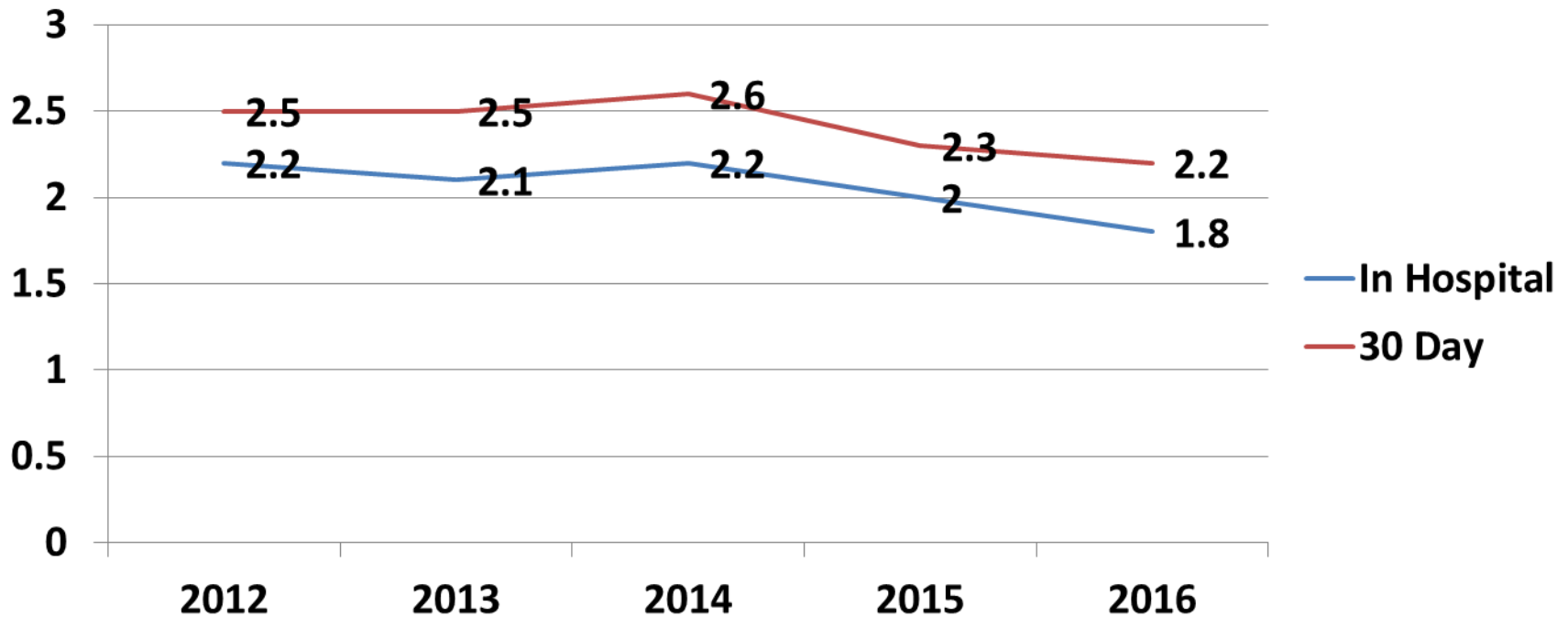
Source: STS/ACC TVT Registry Database.  
as of April 10, 2017

# TAVR: Bleeding and Major Vascular Complications



Source: STS/ACC TVT Registry Database  
as of April 10, 2017

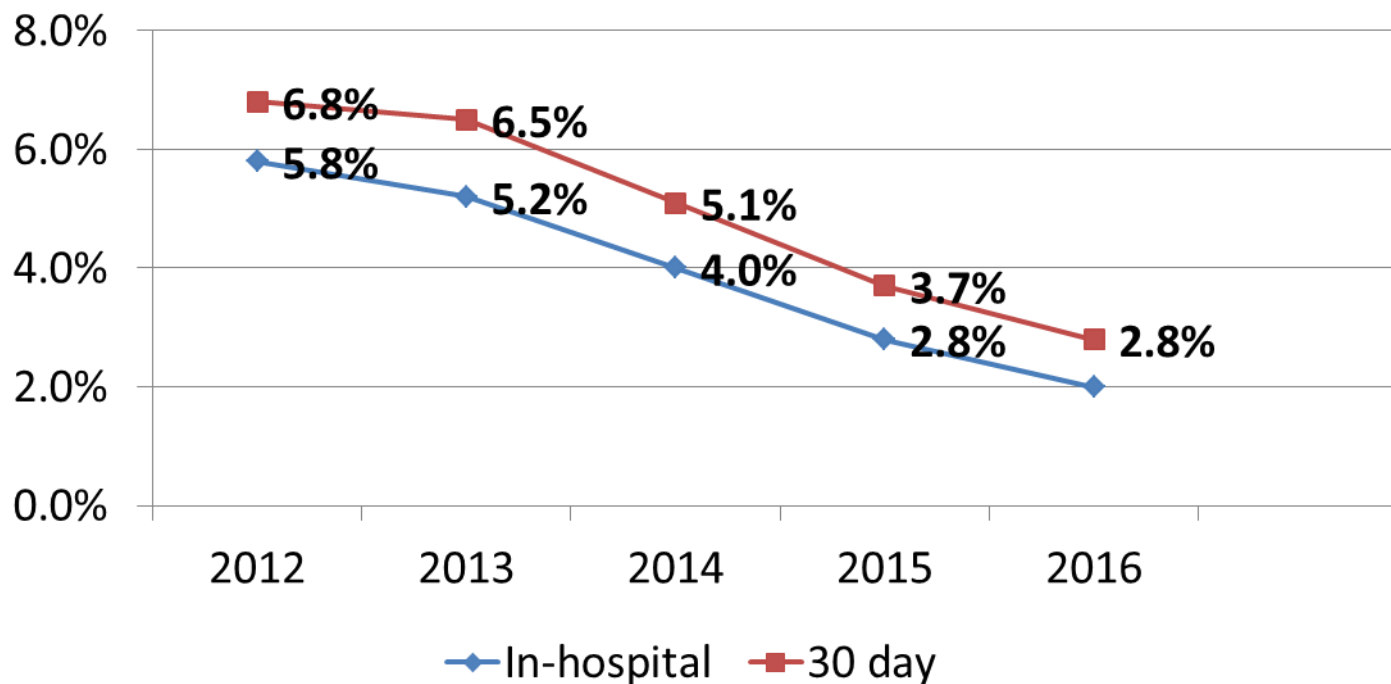
# TAVR Stroke %



Source: STS/ACC TVT Registry Database.  
as of April 10, 2017



# TAVR Mortality



Source: STS/ACC TVT Registry Database  
as of April 10, 2017

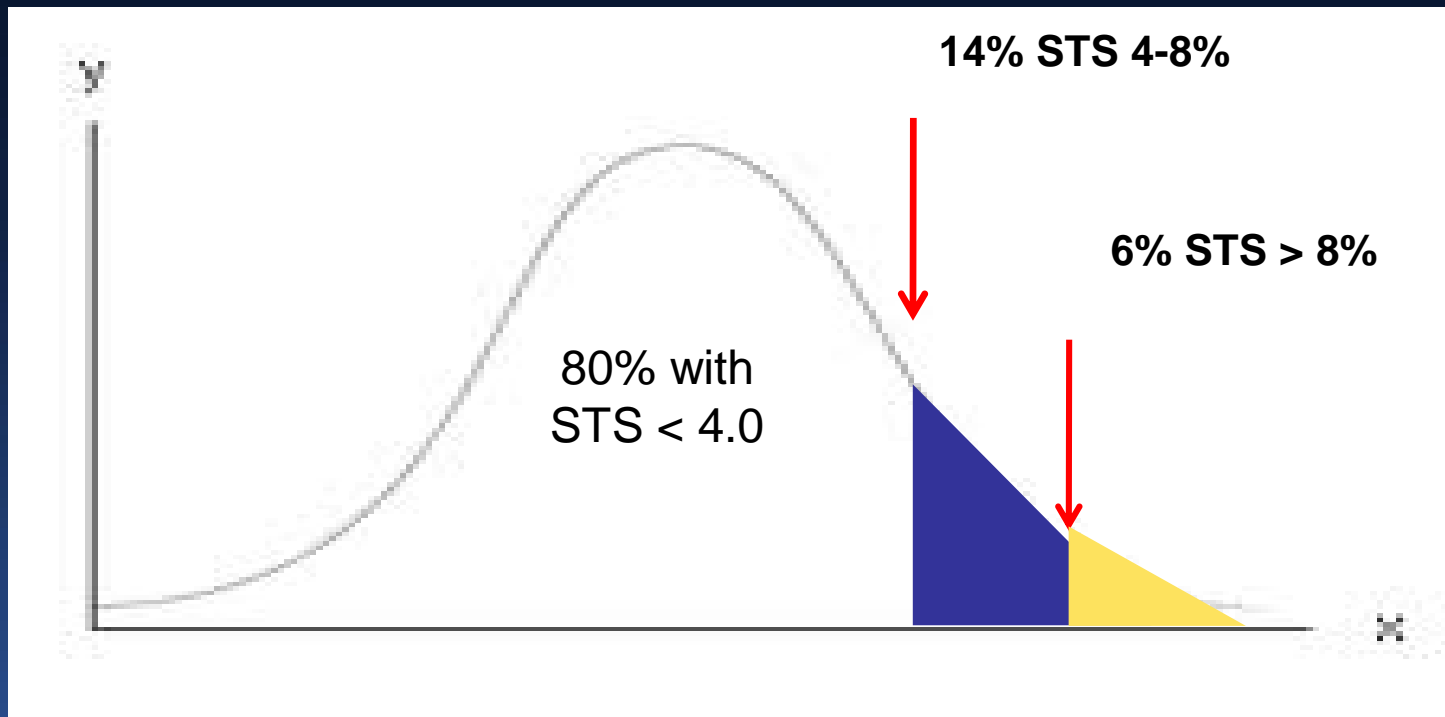
# Expanding TAVR Clinical Indications

## *A Transformative Technology at the Crossroads?*

- Bioprosthetic valve failure (aortic and mitral), thrombosis is an issue
- Low-risk patients: PARTNER 3, CoreValve LR trial
- Low-flow, low-gradient AS
- Bicuspid AV disease
- AS + concomitant disease (CAD, MR, AF)
- Severe asymptomatic AS: EARLY trial
- Moderate AS + CHF: UNLOAD trial
- High-risk AR

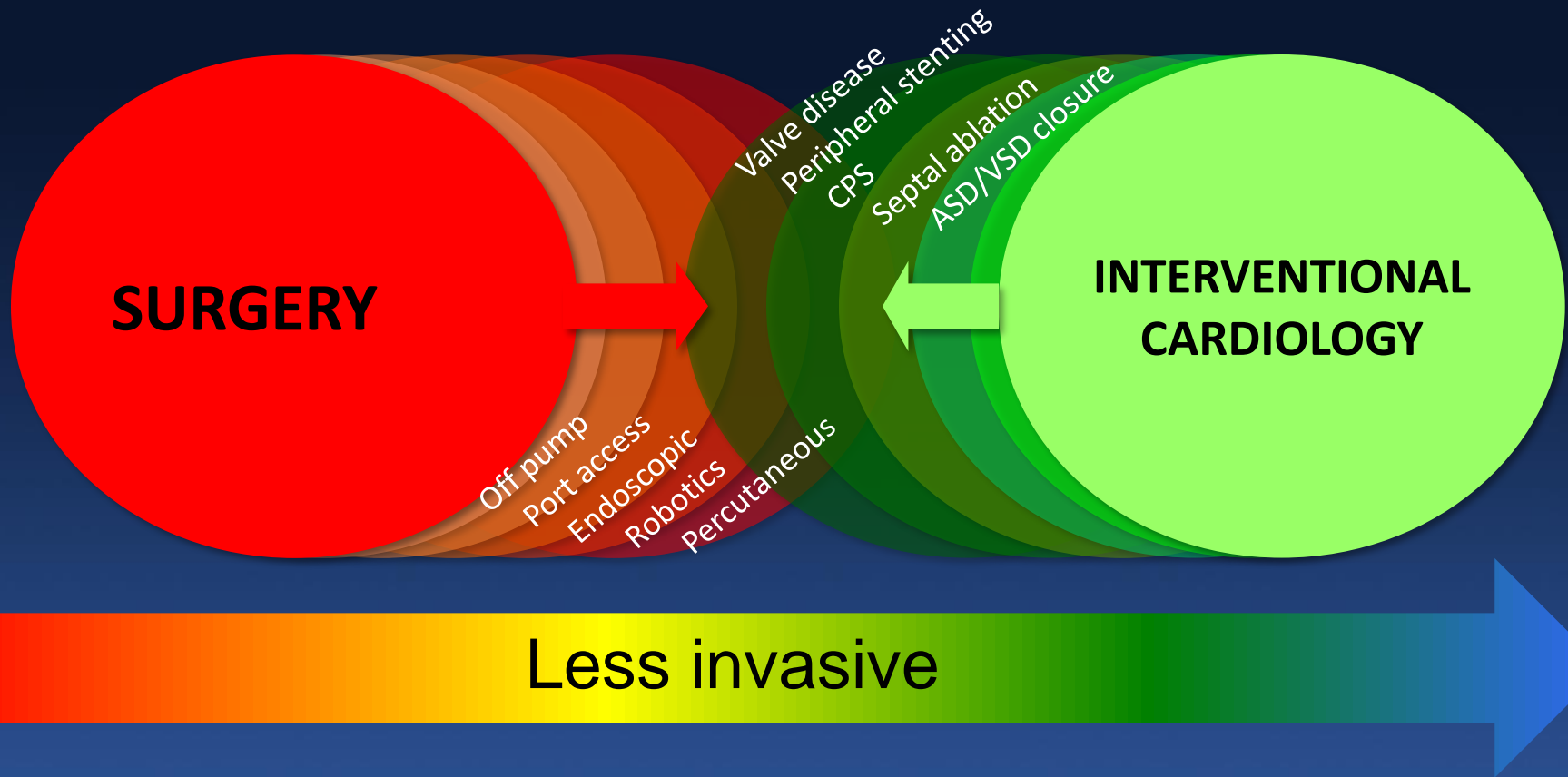
# SAVR in the US

Isolated AVR: STS Database  
141,905 patients  
2002 - 2010

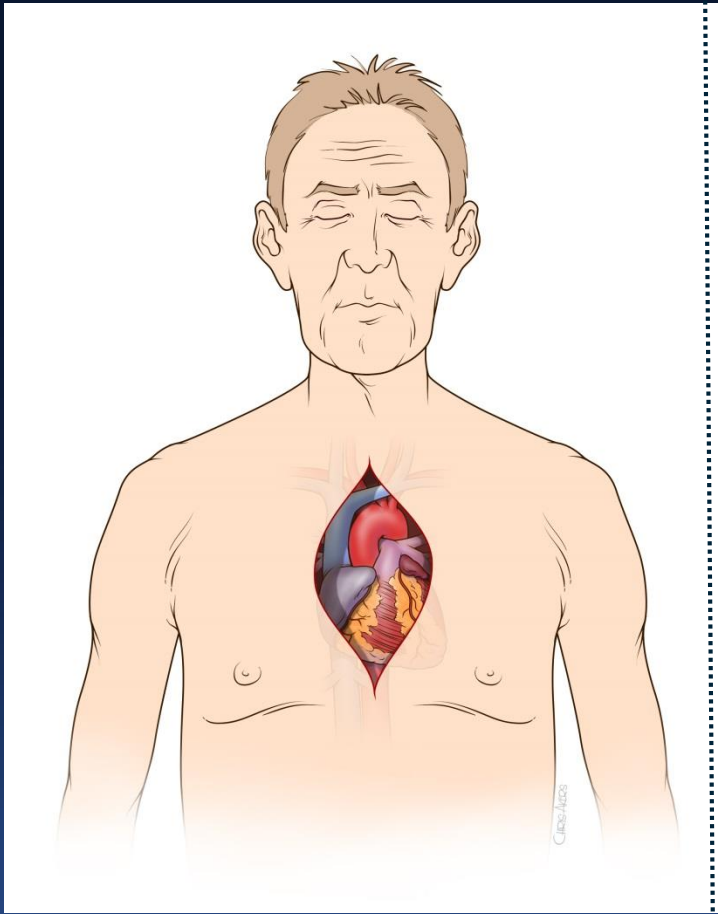


Thourani et al. ATS, 2015

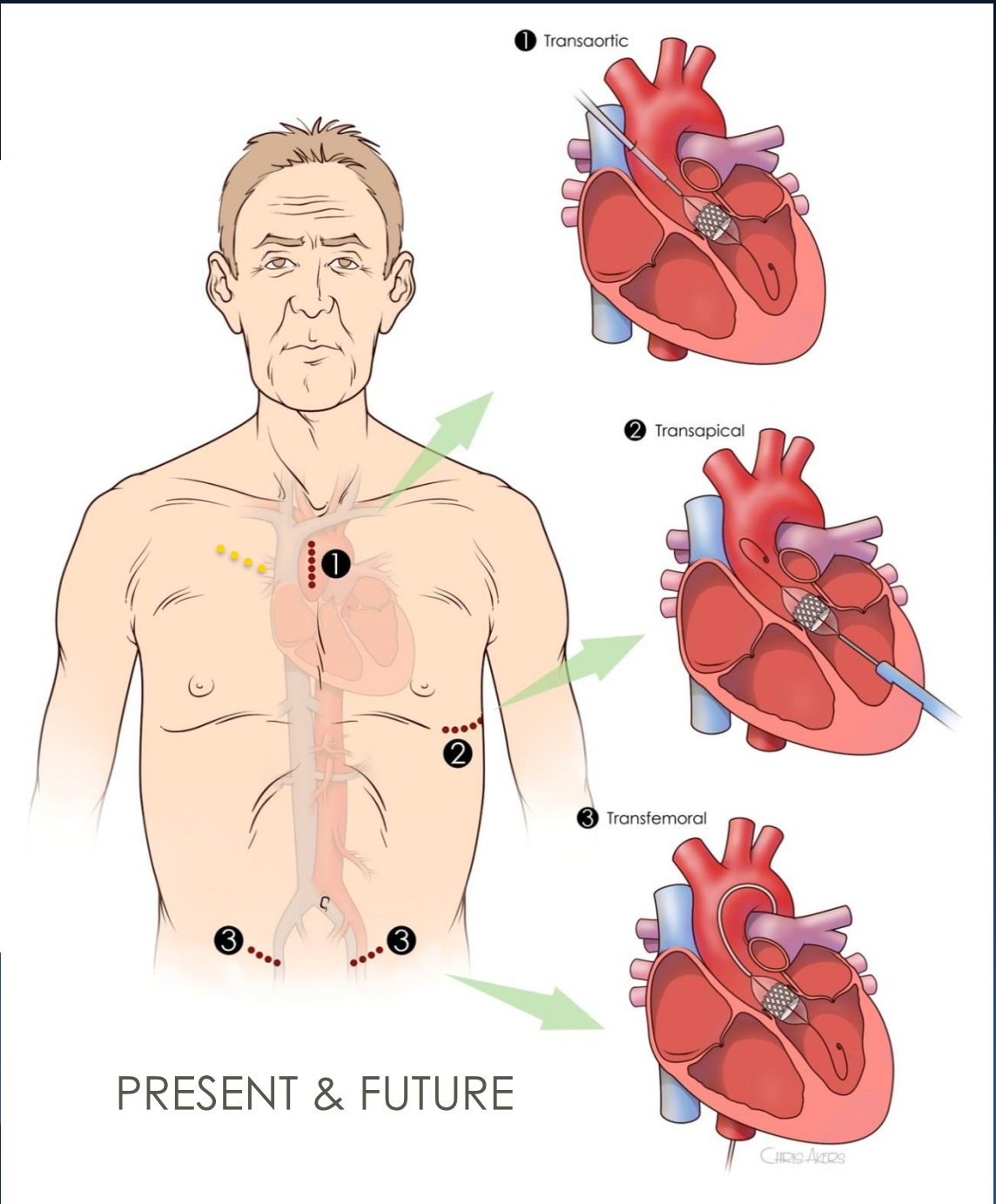
# Overlapping Targets, Overlapping professions



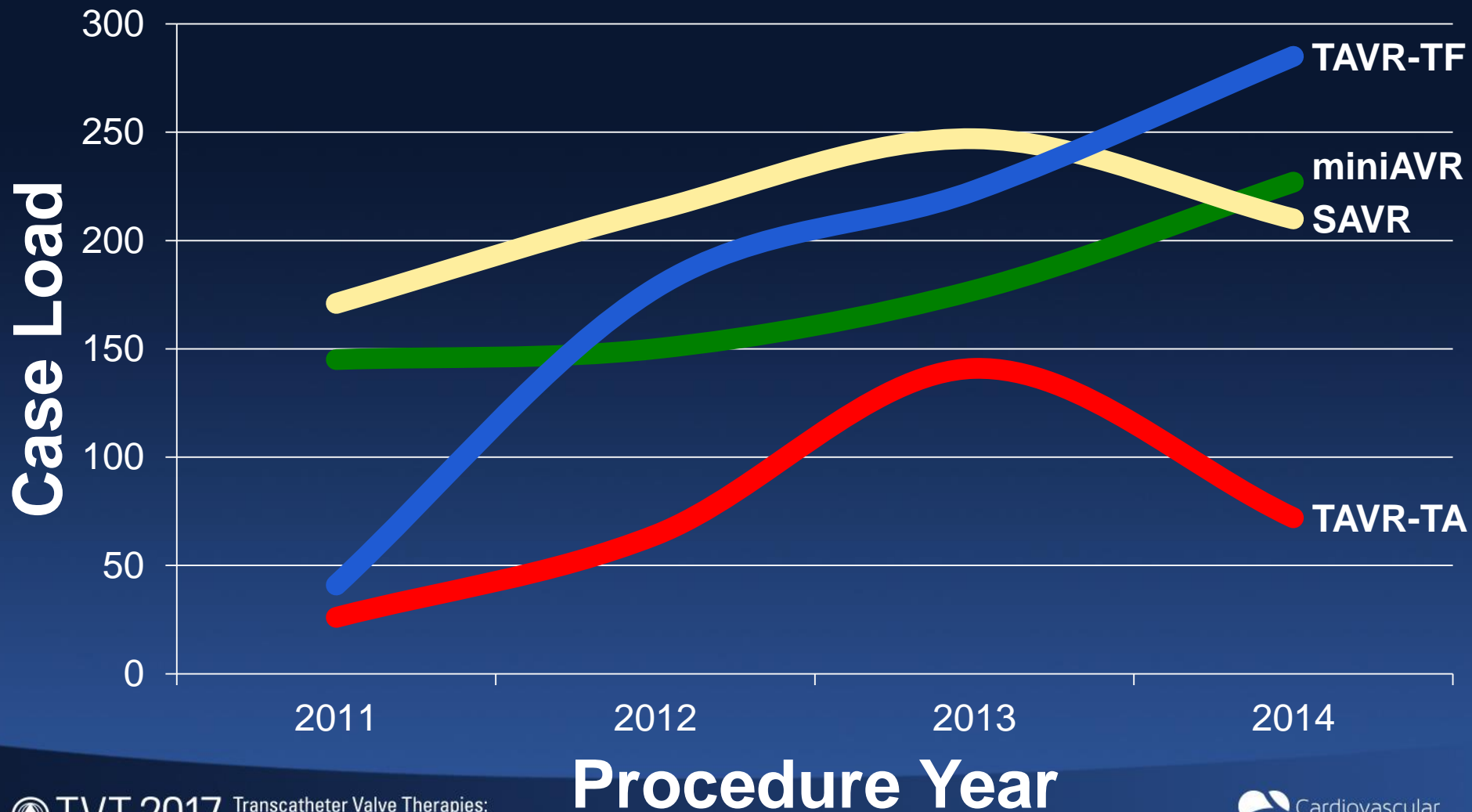
Courtesy of Dr. Masiano



PAST



# AVR by Procedure



# In 2007, Prior to TAVR: Conversation With My Patient

- “Hi Mr. Smith for your aortic valve disease I can offer you **3 operations**”:
  - Open aortic valve replacement
    - Minimally invasive AVR
    - Sternotomy AVR
    - Apical Aortic Conduit

# In 2017:

## Conversation With My Patient

- “Hi Mr. Smith for your aortic valve disease I can offer you **8 operations**:

- Open aortic valve replacement
  - Minimally invasive AVR
  - Sternotomy AVR

**I am 1<sup>st</sup> operator for all procedures so I have equipoise for all techniques**

- Transfemoral
  - Trans-arterial
  - Transcaval
- Transapical
- Transaortic
- Transcarotid
- Trans-subclavian



# Evolution of the Treatment of Aortic Stenosis

**Surgery is the only treatment**

**Surgery is the gold standard treatment**

**Surgery is the preferred treatment for low and intermediate risk patients**

**Transcatheter interventions are performed in intermediate risk patients**

**Surgery is performed in patients with contraindication to transcatheter approach**

# Pt. Initials: CLM

Patient Information	
Age	85
Gender	Male
<b>STS Score</b>	<b>5.01</b>
NYHA Class	II
Height	178
Weight	101.8
BMI	32.1
GFR	1.19
CR	55
HGB	15.7
Consent Date	
Planned TAVR Procedure Date	6/22

Plan	
Cohort	IR
Planned Valve Size	29
Access	TF- Right

## Relevant History:

- **CHF**
- **HTN**
- **Afib/Aflutter s/p cardioversion x2 on Coumadin**

Risk of Mortality: 5.01%

Morbidity or Mortality: 26.305%

Long Length of Stay: 12.851%

Short Length of Stay: 15.546%

Permanent Stroke: 1.766%

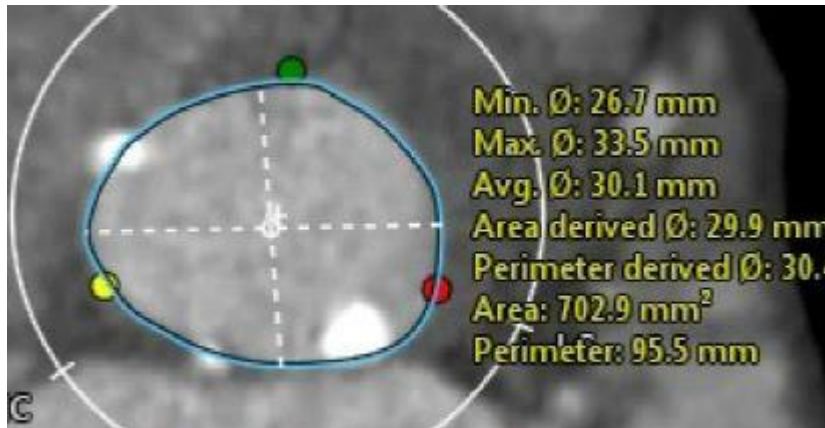
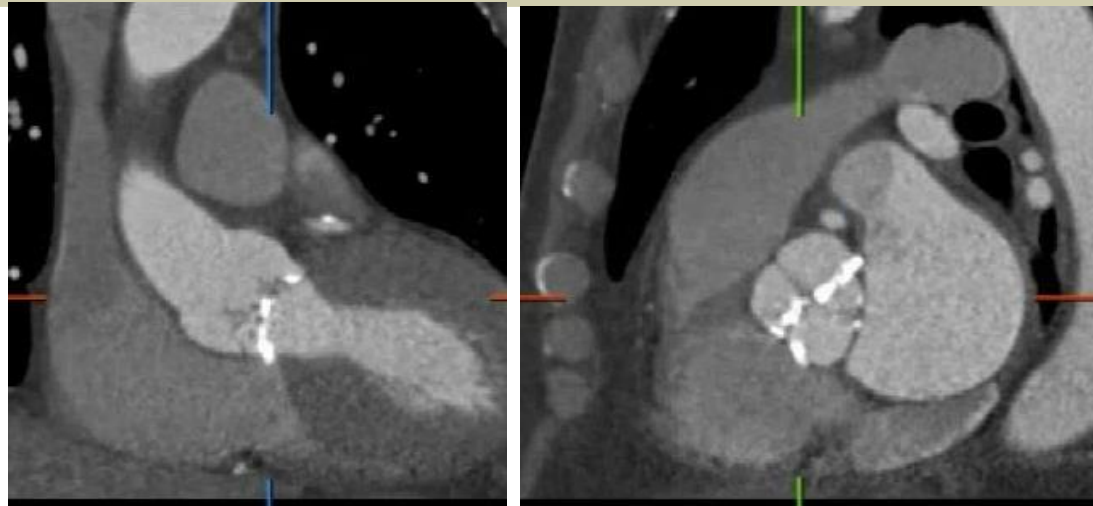
Prolonged Ventilation: 17.384%

DSW Infection: 0.686%

Renal Failure: 7.055%

Reoperation: 10.395%

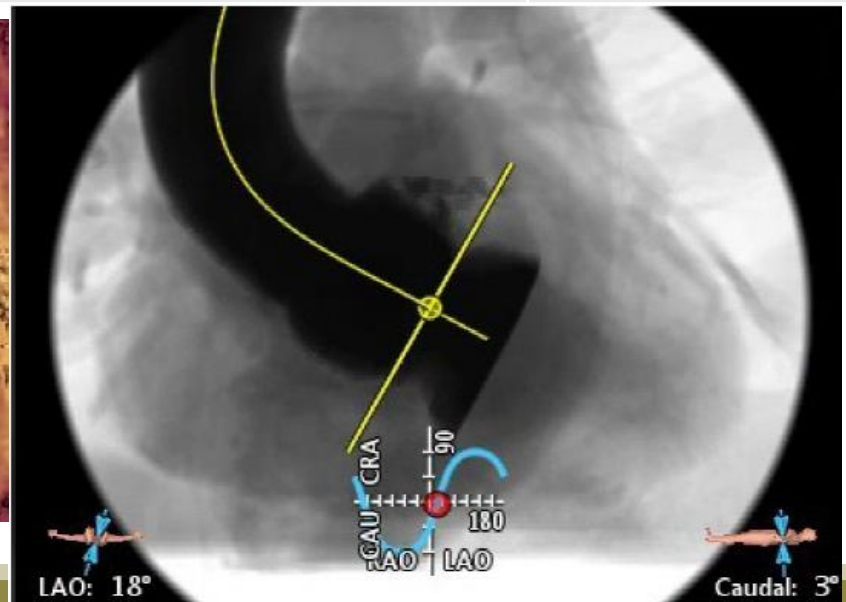
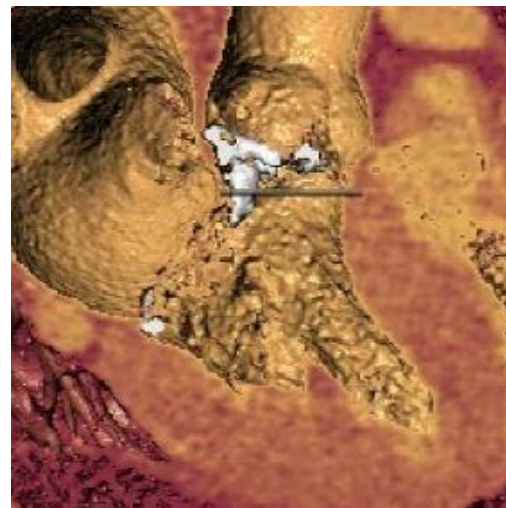
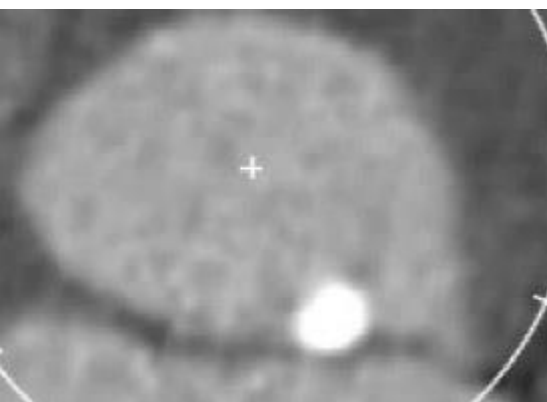
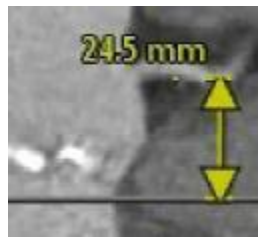
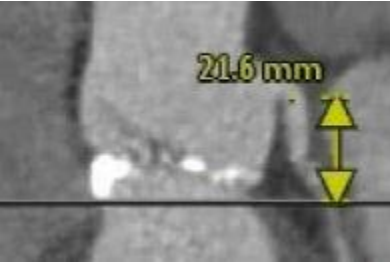
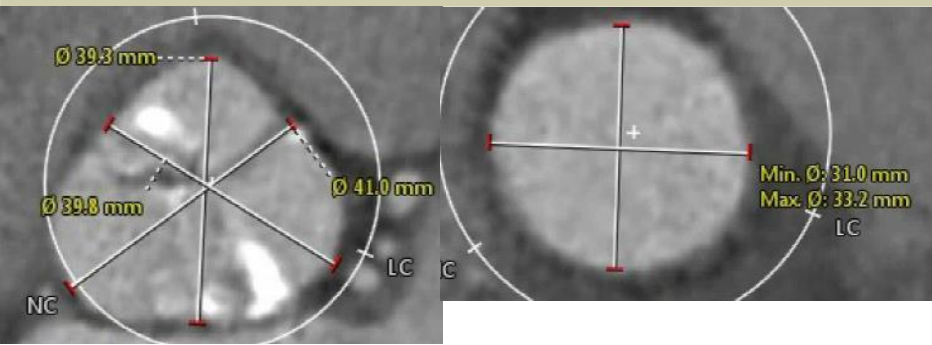
# CT Analysis (Emory): Large annular calcium load



Aortic Annulus	Measure
Short Annulus Diameter	26.7
Long Annulus Diameter	33.5
Annular Area	702.9
% Oversizing	-7.3
Planned Valve Size	29
Sizing Comments	Large calcium in annulus adj to LA in Left Cusp

# CT Analysis (Emory)

Aortic Root	Measure
Tricuspid Aortic Valve?	Y
Congenital Bicuspid?	N
Sinus of Valsalva	39.8x39.3x41
Sinotubular Junction	31 x 33
Left Coronary Height	21.6
Right Coronary Height	24.5
LVOT Calcification	Mod, same piece from LC extends down
Mitral Annular Calcification	Mild



# Scenarios That May Require SAVR

- High risk for PVR (calcium in LVOT) or root rupture
- Bicuspid valve and low risk with or without enlarged aortic root
- Very young pts who want mechanical valves
- Aortic annulus area > 750mm
- Enlarged root requiring replacement
- Predominantly AI and very little AS
- Short annulus to STJ and worried about root rupture
- Low coronaries although usually ok if root large enough

# Conclusions

- The future of cardiac surgery is at an important crossroads
  - I hope that cardiac surgeons will have an increasing presence in the cath lab.
- Role of the cardiac surgeon has changed forever
  - We are required to perfect our open techniques in intermediate-risk patients with the utmost concentration with high quality outcomes
- We must continue to innovative WITH our cardiologist to provide the
  - This collaboration is very fulfilling and can be successful