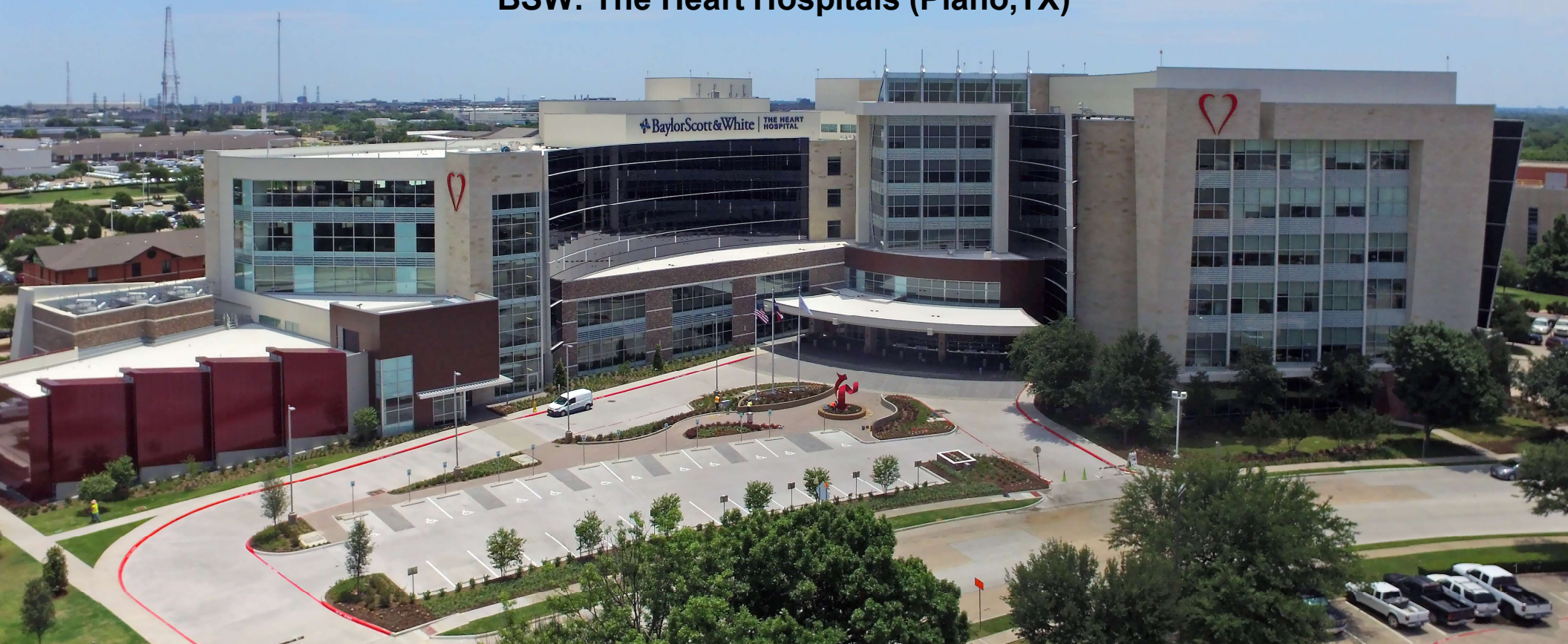


# TAVR in MAC, Current Results and Techniques

**Robert Smith, MD, MBA**  
**BSW: The Heart Hospitals (Plano, TX)**



## Disclosures (last 24 months)

Speaking/Teaching (honoraria): Medtronic, Edwards Lifesciences, enableCV

Grants/Research: (all grants/funds are run through the BSW Research Institute)

Edwards Lifesciences, Medtronic, inQB8, Cardiomech



# TAVR in MAC

Despite a growing experience, patients with MV disease complicated by MAC remain a challenging group to treat with TAVR in MAC.



# SUMMIT-MAC

103 patients with MAC

Technical success 94%

30D Mortality: 6.8%

Approximately 75% screen fail rate

(FDA approval for MR/MS complicated by MAC, 2025)



JACC Cardiovasc Interv 2023;16:2868-79.

# TAVR in MAC

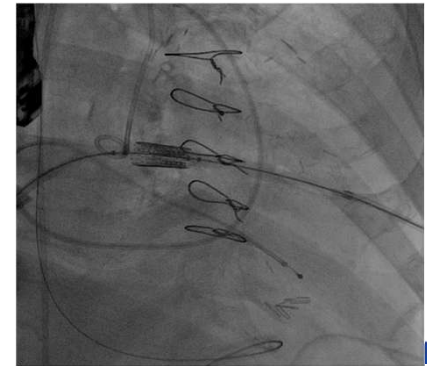
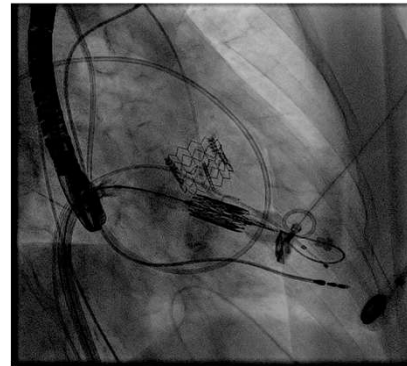
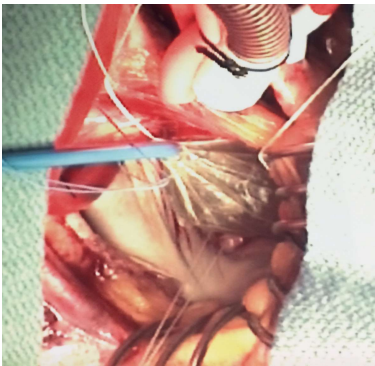
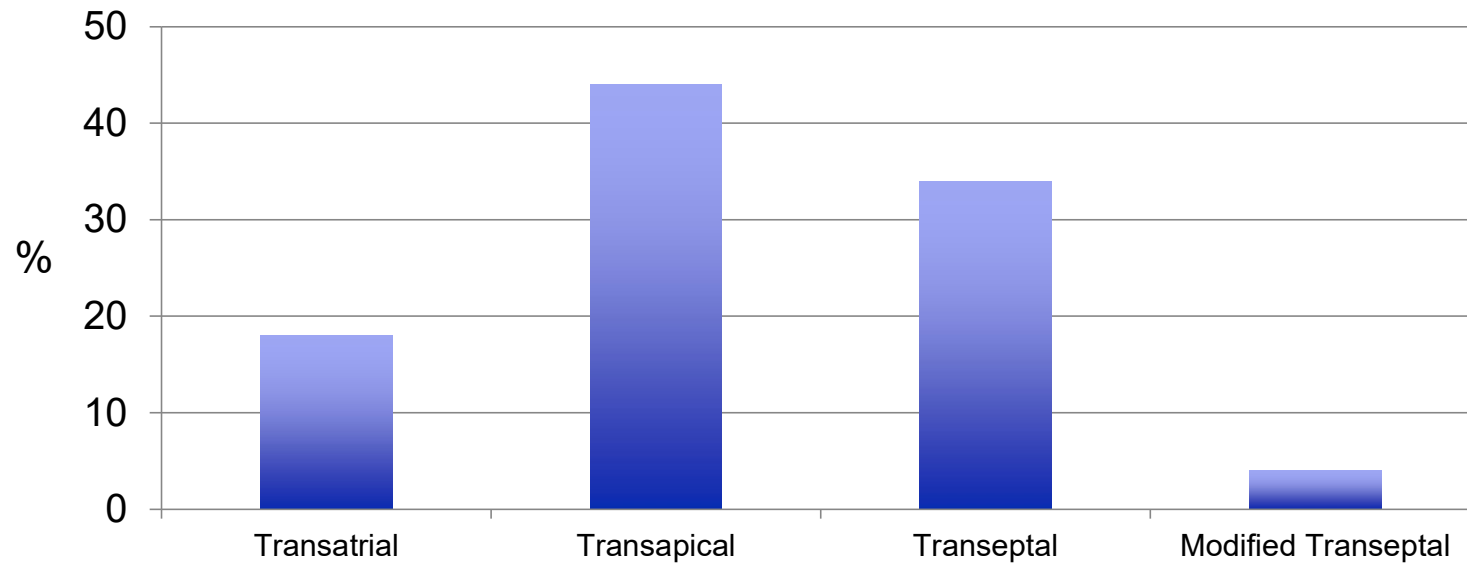
# Transcatheter Mitral Valve Replacement in Native Mitral Valve Disease with Severe Mitral Annular Calcification

## Results from the First Global Registry

Mayra Guerrero, MD, FACC, FSCAI  
Director of Cardiac Structural Interventions  
NorthShore University HealthSystem

*TVT 2016  
Chicago, IL  
June 17, 2016*

## Delivery Approach



## Procedural Outcomes

	n (%)
Technical success by MVARC criteria	78/104 (75%)
Need for second valve (migration=6, MR=7)	13/104 (12.5%)
LVOT obstruction with hemodynamic compromise	11/104 (10.5%)
Valve embolization	4/104 (3.8%)
Conversion to open surgery (embolization=2, LV perforation=1, LVOTO=1)	4/104 (3.8%)
LV perforation (surgery=1, conservative=1)	2/104 (1.9%)
Pulmonary Vein Perforation	1 (0.9%)

## 30 Day/Procedural Mortality

26/104 (25%)

	n (%)
Cardiovascular	11/104 (10.6 %)
LVOT Obstruction	3 (2.9%)
LV Perforation	2 (1.9%)
Complete AV block	1%
MI due to air emboli / Pulmonary vein perforation	1%
Stroke	2 (1.9%)
PEA arrest	1 %
MR	1 %
Non-Cardiac	15/104 (14.4 %)
Multi-organ failure	9 (8.6%)
Pneumonia	3 (2.9%)
Thoracentesis related bleeding complication	1%
Infection	2 (1.9%)

# Concerns for transseptal TAVR in MAC

## Device embolization

## LVOT obstruction

- From device
- From leaflet
- From ventricular septal thickness

## Difficulty in determining positioning for deployment

- 17.2% needing a second valve deployed\*

## PVL

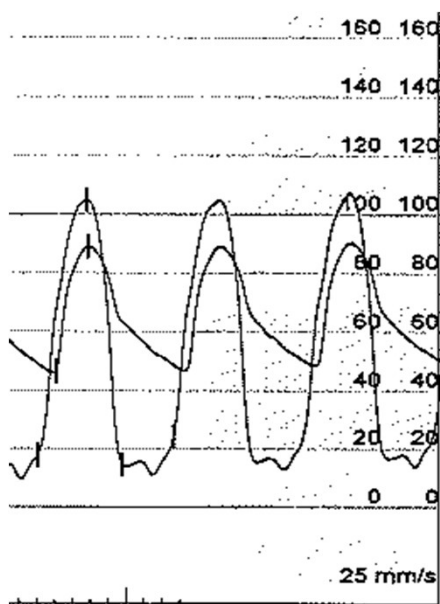
## High mortality rate reported

- All cause 30 day mortality ~30%\*

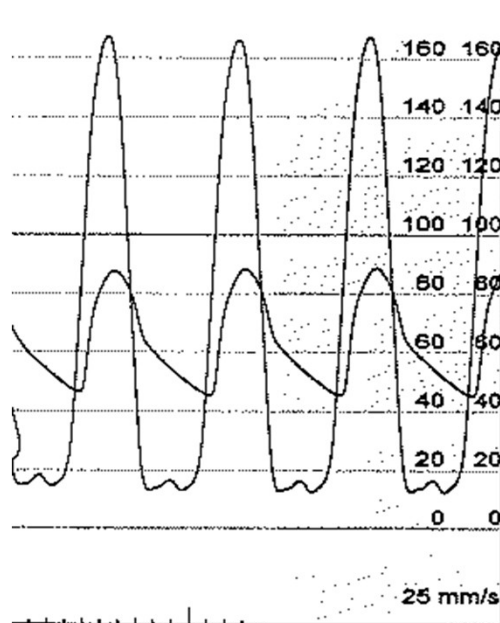
\*Guerrero, et al. *J Am Coll Cardiol Interv.* 2016;9(13):1361-1371



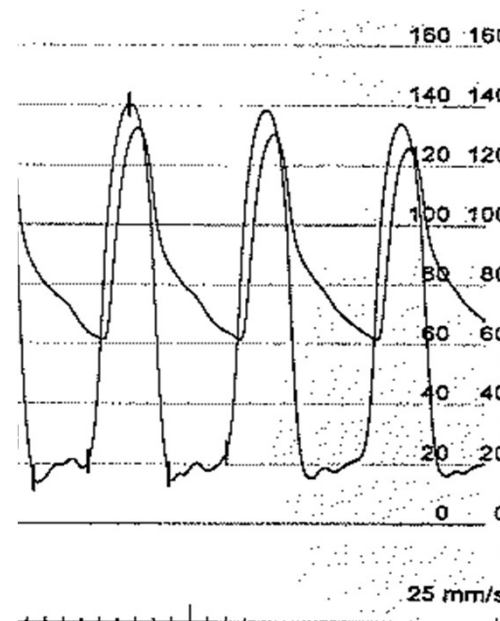
## Septal ablation to treat LVOT Obstruction after TMVR



Baseline



After TMVR



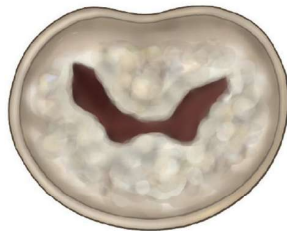
Alcohol Septal Ablation

Courtesy of Dr. William O'Neill

## **CENTRAL ILLUSTRATION: Major Factors and Solutions for Left Ventricular Outflow Tract Obstruction Following Transcatheter Mitral Valve Replacement**

### Etiologies and Treatment Options for Outflow Obstruction

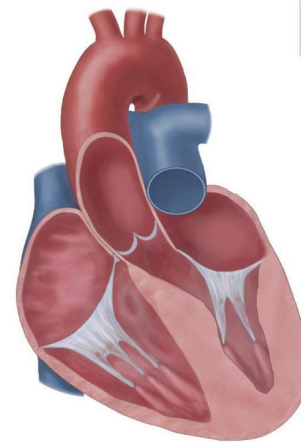
#### Anterior Mitral Leaflet Displacement



#### Solutions

- LAMPOON
- Anterior leaflet resection
- BATMAN
- TMVR device-specific designs to prevent anterior leaflet displacement

#### Basal Septal Hypertrophy



#### Solutions

- Alcohol septal ablation
- Radiofrequency ablation
- SESAME

Eleid MF, et al. J Am Coll Cardiol Interv. 2023;16(8):885-895.

**Why totally percutaneous approaches have not tackled MAC**

## The Problem is the Complexity at Baseline:

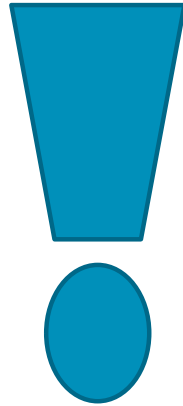
- Valves come in all sorts of sizes.
- Ventricles come in all sorts of sizes/dysfunction.
- MAC presentation is variable.
- When MAC is involved, the patient usually has bigger problems.



## The Problem is the Complexity at Baseline:

- Valves come in all sorts of sizes.

Annular area  
>900 mm<sup>2</sup> or  
<430 mm<sup>2</sup>



Intercommisural  
distance >31mm

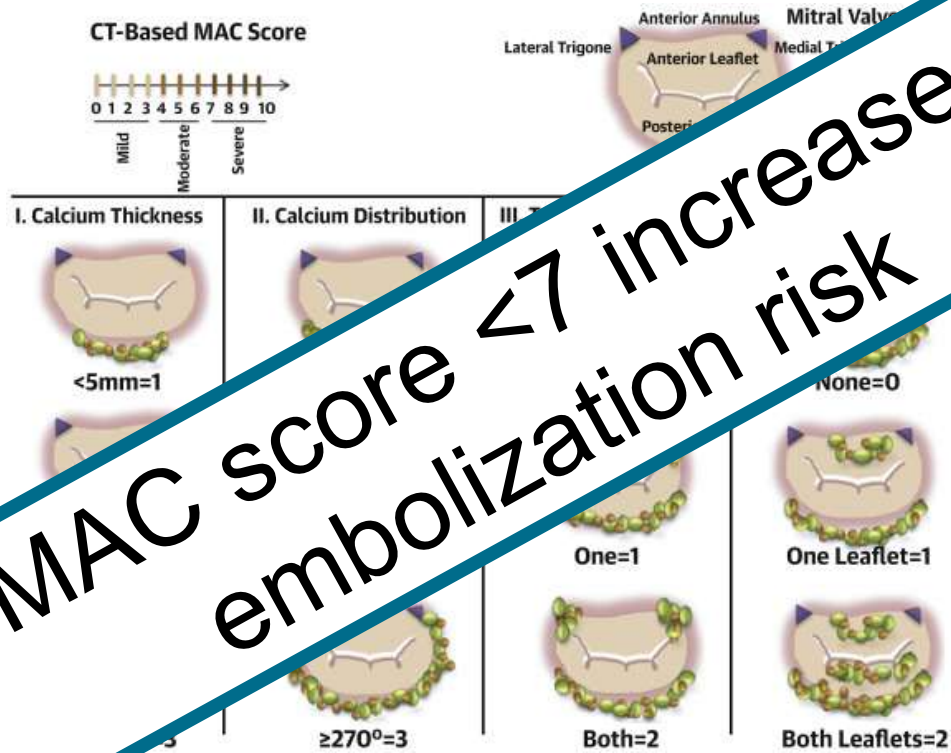




# The Problem is the Complexity:

- MAC presentation is variable.





MAC score  $< 7$  increases embolization risk



## The Problem is the Complexity at Baseline:

Multiple comorbidities (Afib),  
other valve problems, etc.

- When MAC is involved, the patient usually has bigger problems.



# Concerns for BEV in MAC

## Device embolization

### LVOT obstruction

- From device
- From leaflet
- From ventricular septal thickness

### Difficulty in determining positioning for deployment

- 17.2% needing a second valve deployed\*

### PVL

### High mortality rate reported

- All cause 30 day mortality ~30%\*

\*Guerrero, et al. *J Am Coll Cardiol Interv.* 2016;9(13):1361-1371



# MITRAL: Mitral Implantation of TRAnscatheter vaLves

Investigator initiated, prospective multi-center clinic trial

... patients with symptomatic severe MAC

• 50

92 pts presented

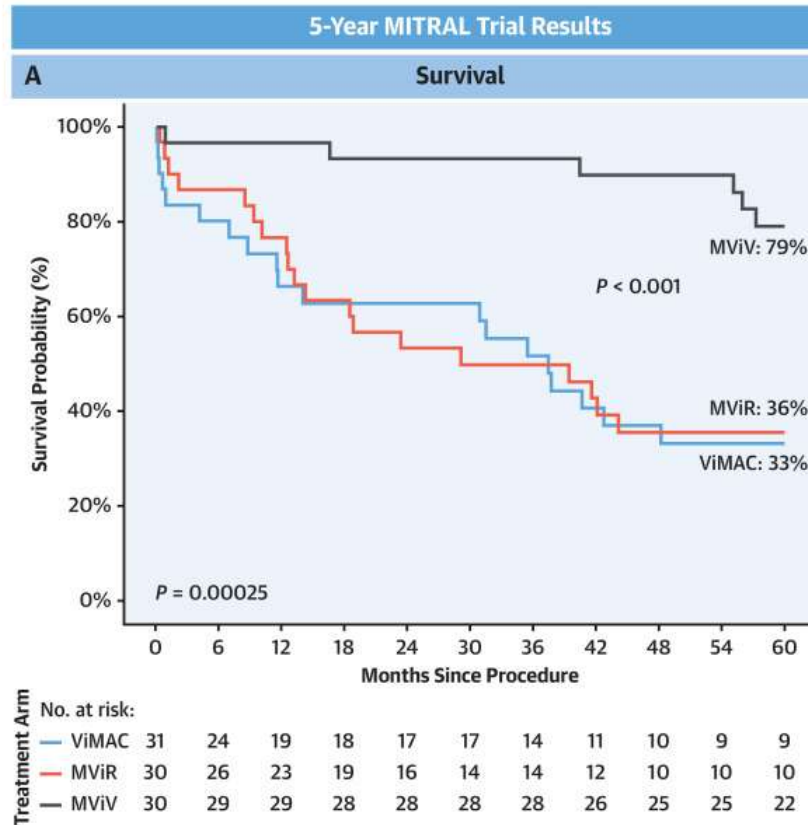
-high risk of  
-both

**Highly selected group of patients**



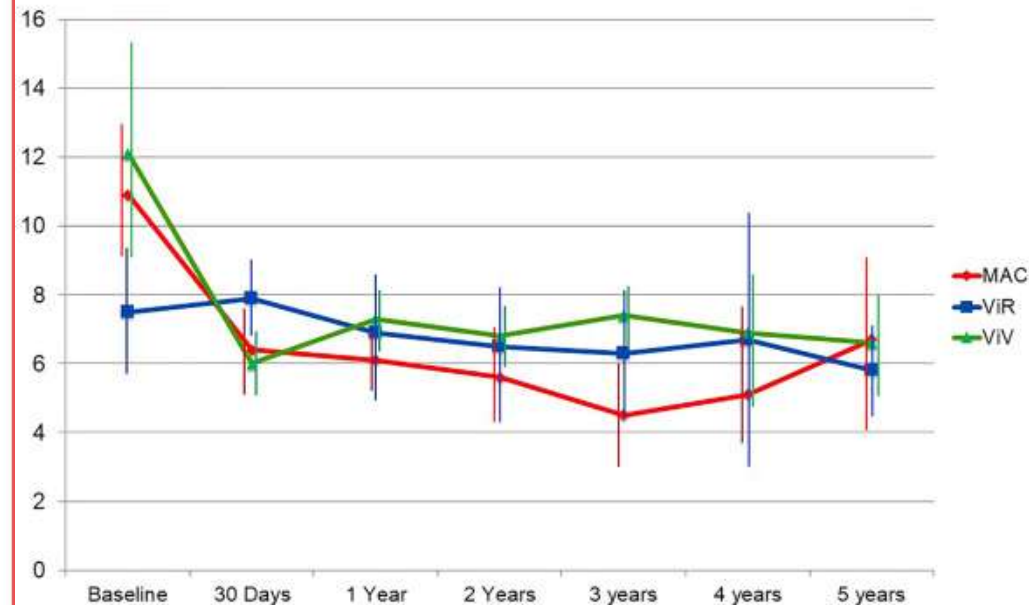
# Considerable mortality, but not from valve performance

## CENTRAL ILLUSTRATION: 5-Year Outcomes of Mitral Valve-in-Valve, Valve-in-Ring, and Valve-in-MAC



Guerrero ME, et al. J Am Coll Cardiol Intv. 2023;16(18):2211-2227.

## Mean Mitral Valve Gradient at 5 Years



JACC: Cardiovascular Interventions

Volume 16, Issue 18, 25 September 2023, Pages 2211-2227



# Concept for SITRAL

**Surgical Implantation of TRAnscatheter vaLve in native mitral annular calcification**

## **Potential benefits:**

- Reduce LVOTO risks
- Reduce risk of embolization
- Reduce PVL risk

**Performed in minimally invasive approach to reduce physical recovery**



## Reduce LVOTO risk

- Remove midportion of anterior leaflet: A2
- Remove septum via myectomy
- Orient the valve into standard surgical configuration (posts at the trigones)
- Implant the valve as atrially as possible



## Reduce PVL risk

- Balloon size the valve first
- Use felt to close gaps between the irregular annulus and prosthesis.
- Added expansion post implantation to improve seal and address re-coil.
- Use a camera and look for trouble area and address them.



## Reduce Embolizaion risk

- Adding felt improves the surface area of implantation.
- **Sutures** for implanting felt or sutures in the remnant leaflet, secure the valve in position.
- Added expansion post implantation better locks valve in place.



## **Different techniques of transatrial BEV implantation**

# Transatrial implantation of a transcatheter heart valve for severe mitral annular calcification.

[Praz F<sup>1</sup>](#), [Khalique OK<sup>1</sup>](#), [Lee R<sup>2</sup>](#), [Veeragandham R<sup>3</sup>](#), [Russell H<sup>4</sup>](#), [Guerrero M<sup>4</sup>](#), [Islam AM<sup>5</sup>](#), [Deaton DW<sup>5</sup>](#), [Kaneko T<sup>6</sup>](#), [Kodali SK<sup>1</sup>](#), [Leon MB<sup>1</sup>](#), [Bapat V<sup>1</sup>](#), [Takayama H<sup>1</sup>](#), [Borger MA<sup>7</sup>](#), [George I<sup>8</sup>](#).

[J Thorac Cardiovasc Surg.](#) 2018 Jul;156(1):132-142.

## Felt on the Valve Technique

26 patients, 6 centers

92% S3 Valve

11 patients required concomitant AVR

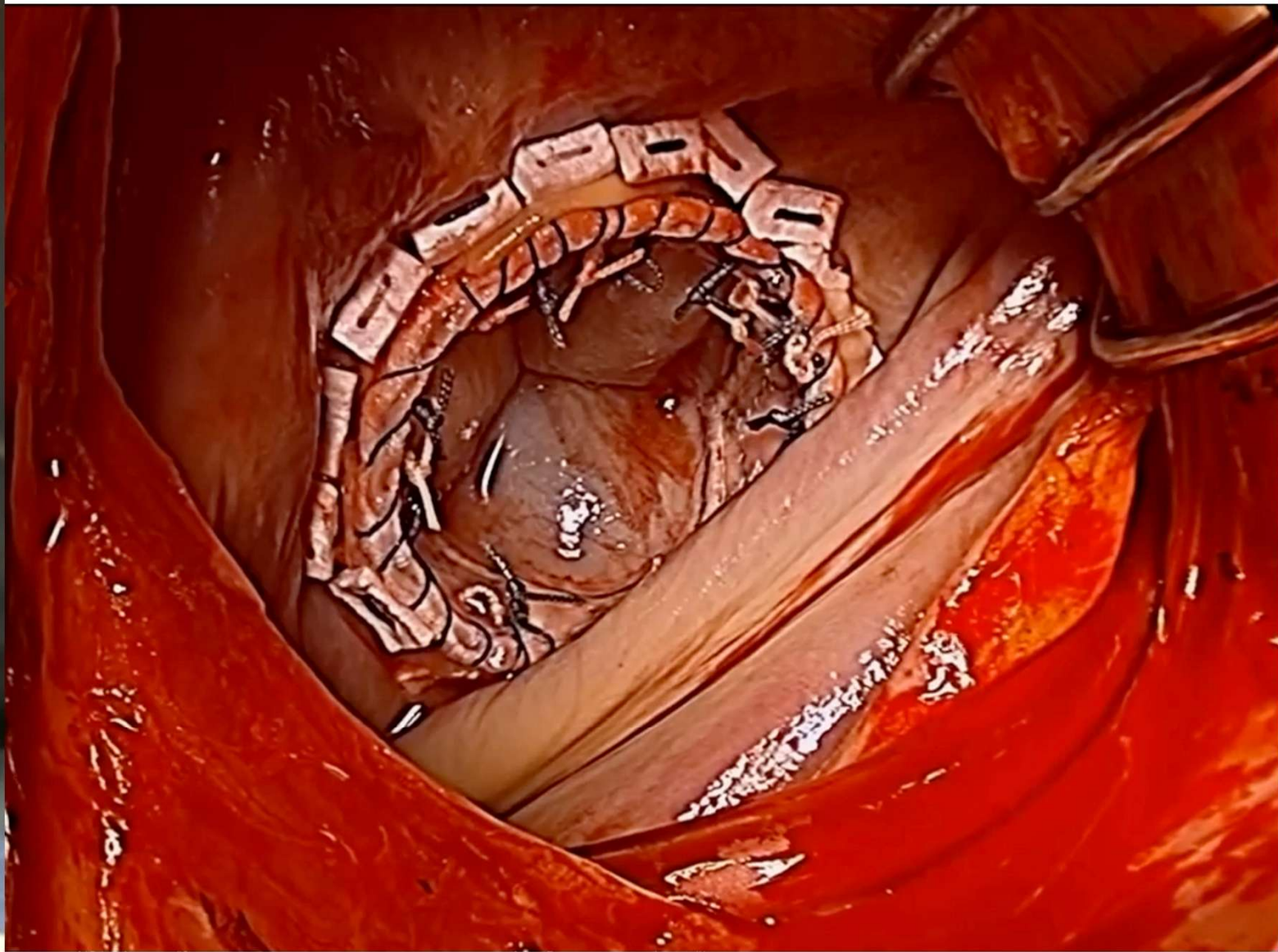
100% MVARC technical success

Gradients dropped from 10 → 4

One LVOTO

**27.5% 30D mortality**





# Surgical implantation of balloon-expandable heart valves for the treatment of mitral annular calcification

•Robert L. Smith, MD, Mohanad Hamandi, MD, Gorav Ailawadi, MD, J. Michael DiMaio, MD, William H. Ryan, MD, the BEV-in-MAC Collaborative

JCTVS

Published: August 24, 2021

DOI: <https://doi.org/10.1016/j.jtcvs.2021.08.047>

## Felt on the Annulus Technique

51 patients

90% Sapien 3

84.3% Size 29

12 AVRs, 21 Myectomies, 15 TVRr

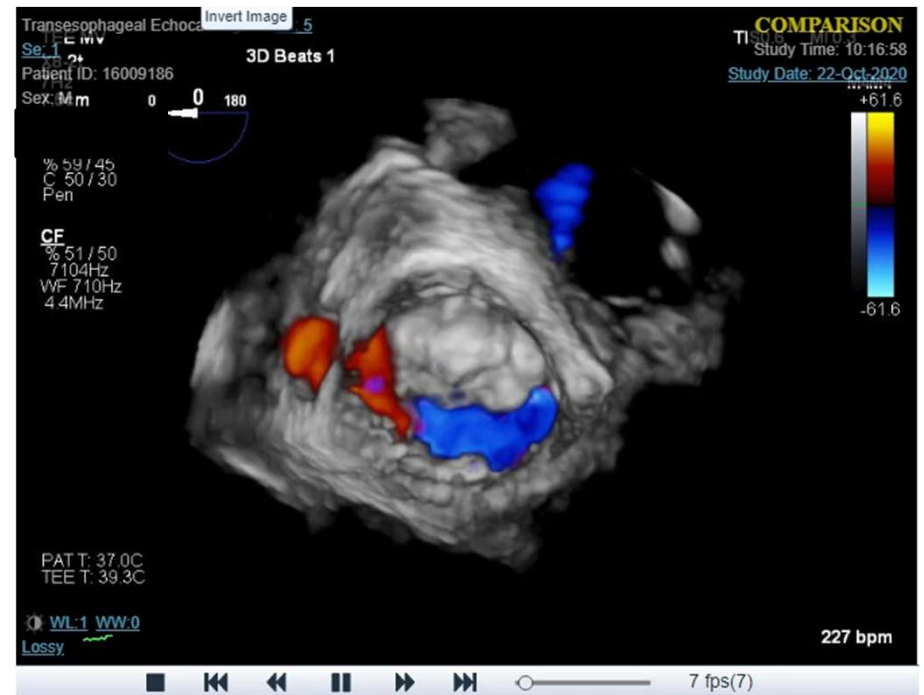
75% Minimally invasive

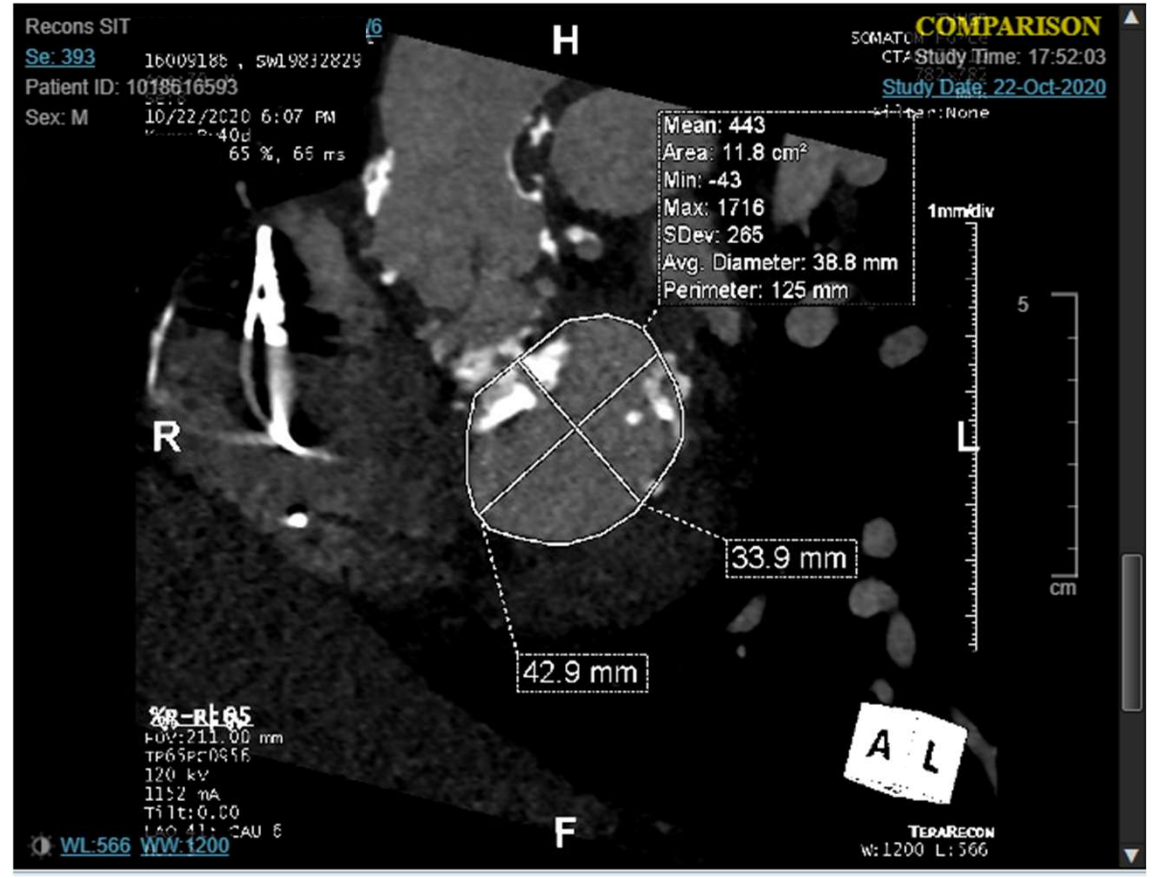
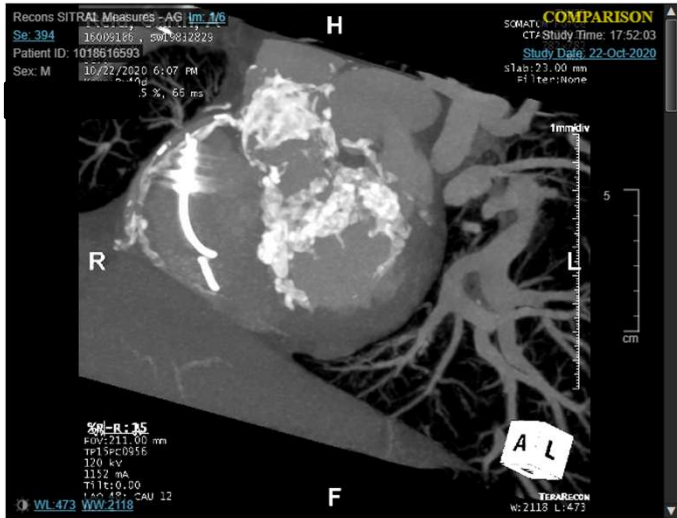
**13.7% 30-Day Mortality**

**33.3% 1-Year Mortality**



**64 yo male with h/o mantle radiation for Hodgkin's Lymphoma  
H/O CABG, AVR (Toronto root replacement), and PPM with LVEF 45%  
Severe calcific MS with MR**





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THE HEART HOSPITAL  
PLANO

Joint ownership with physicians

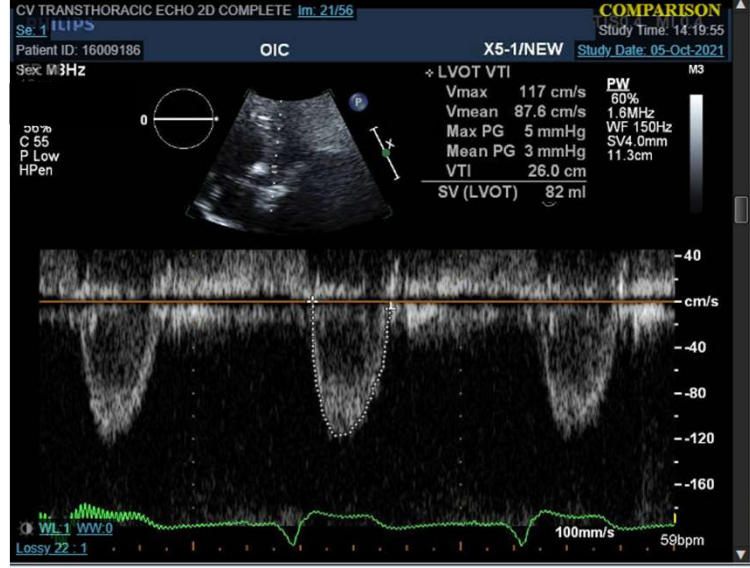
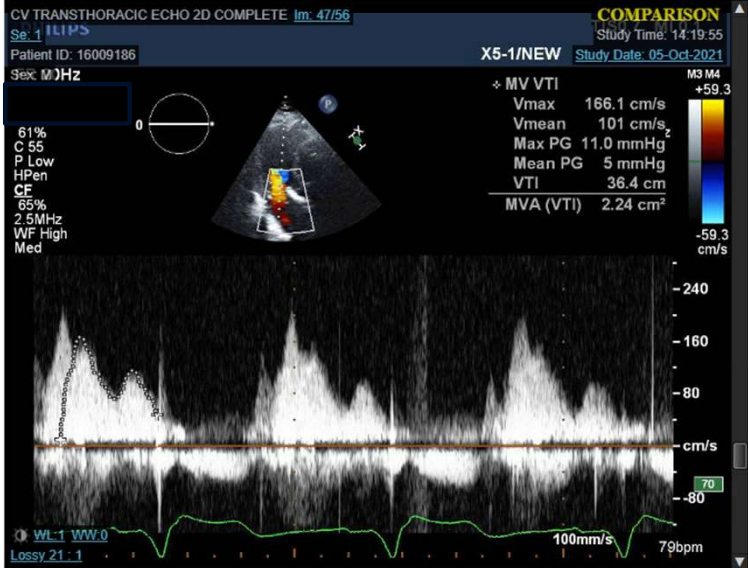
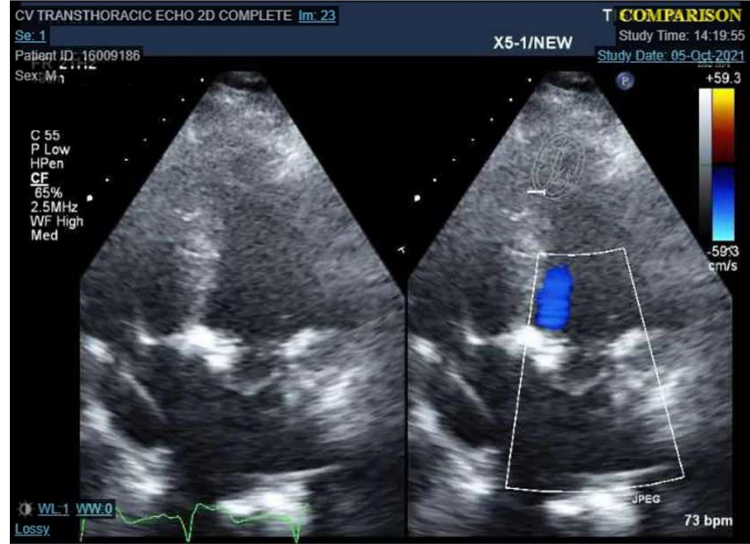
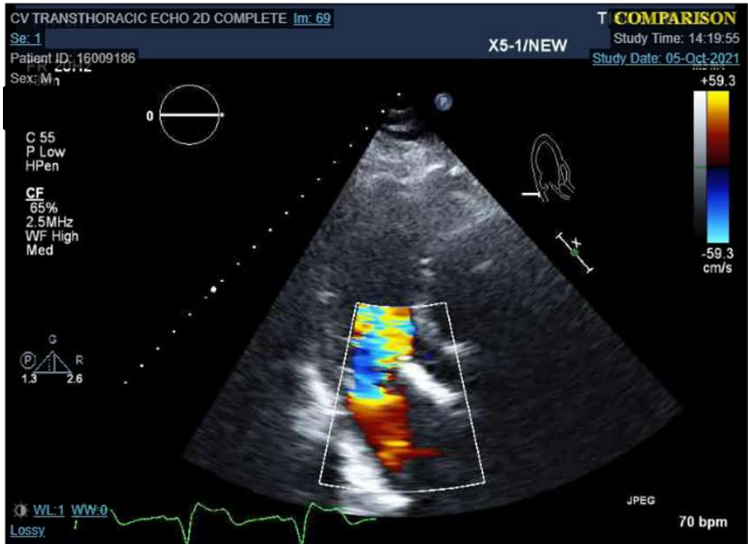


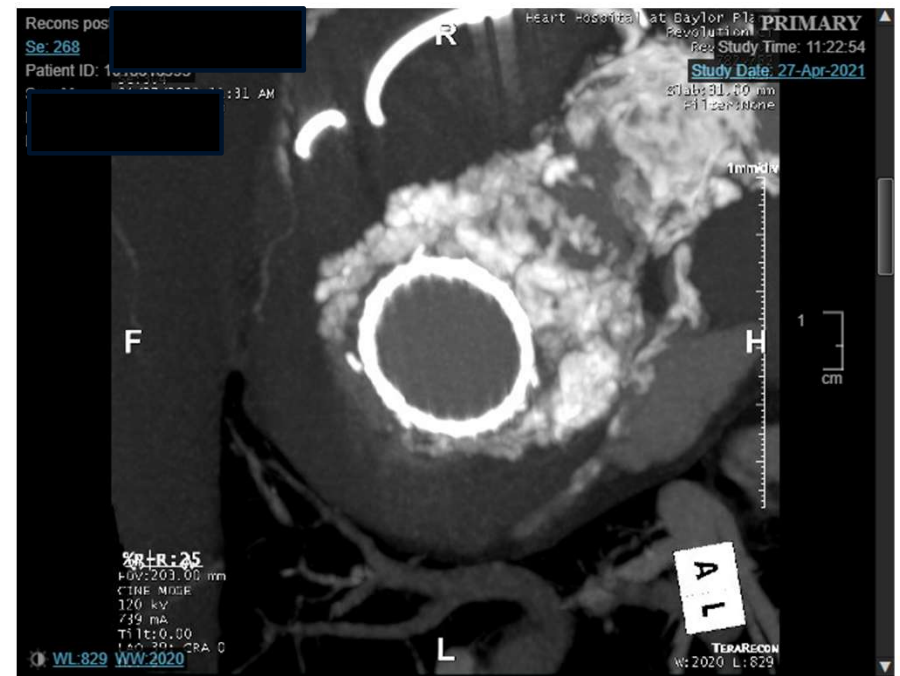
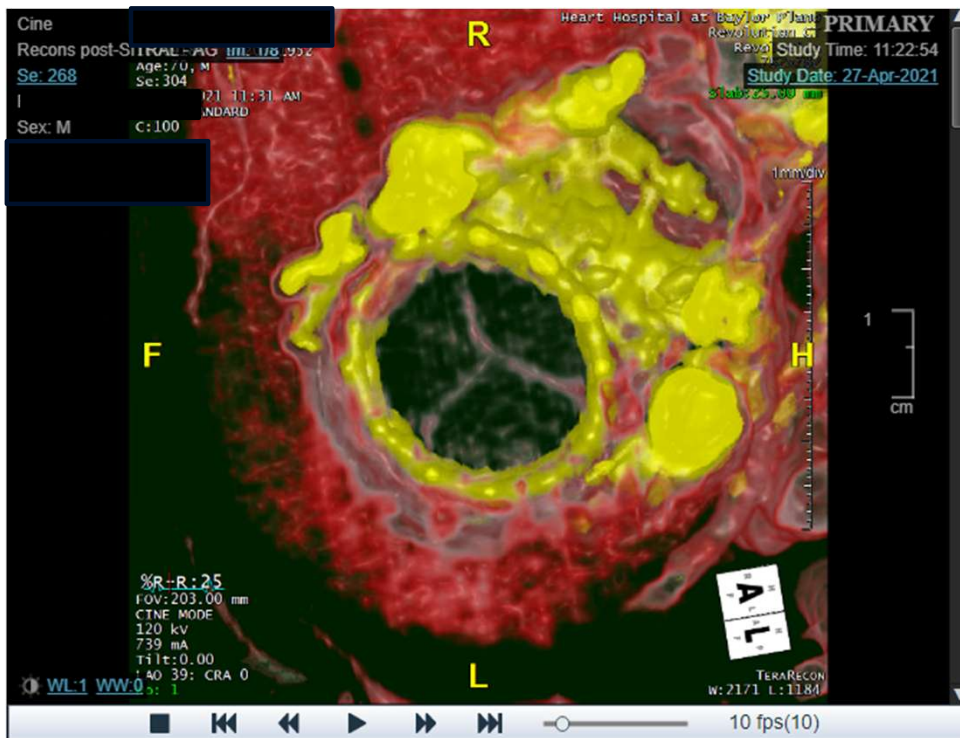
## Case Summary:

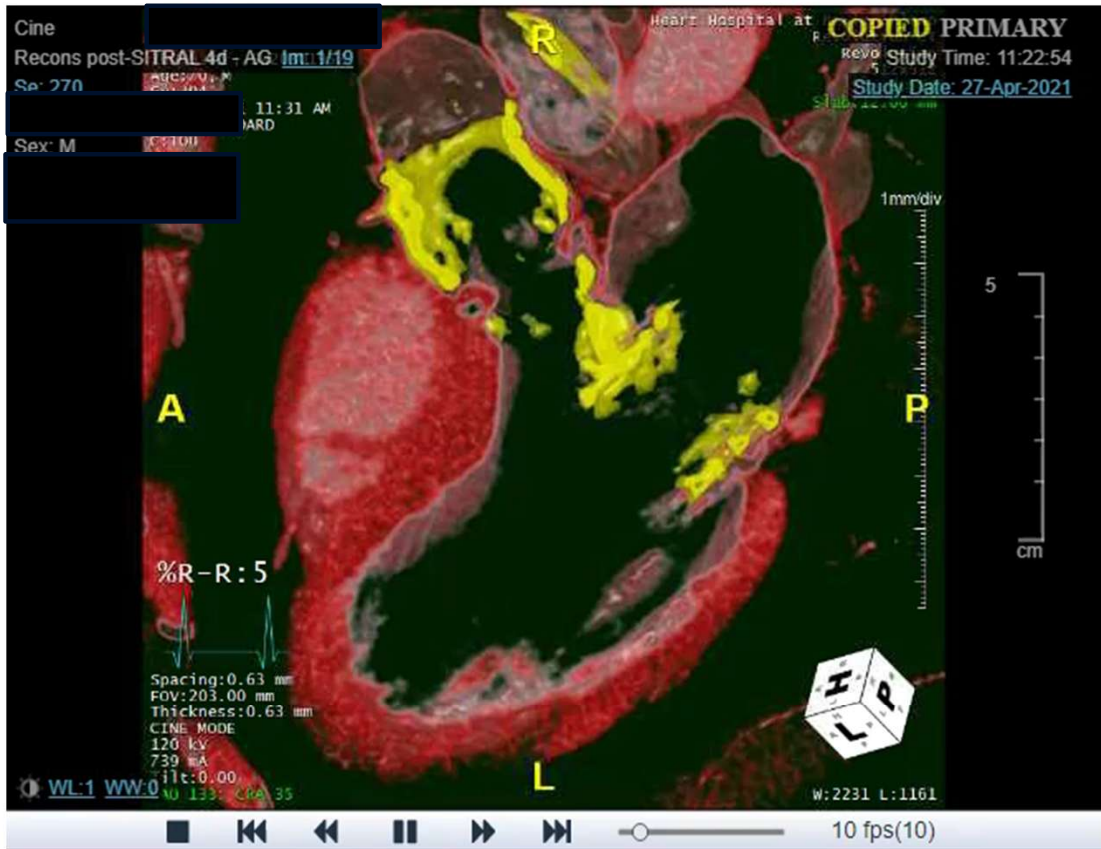
**69 year-old man**

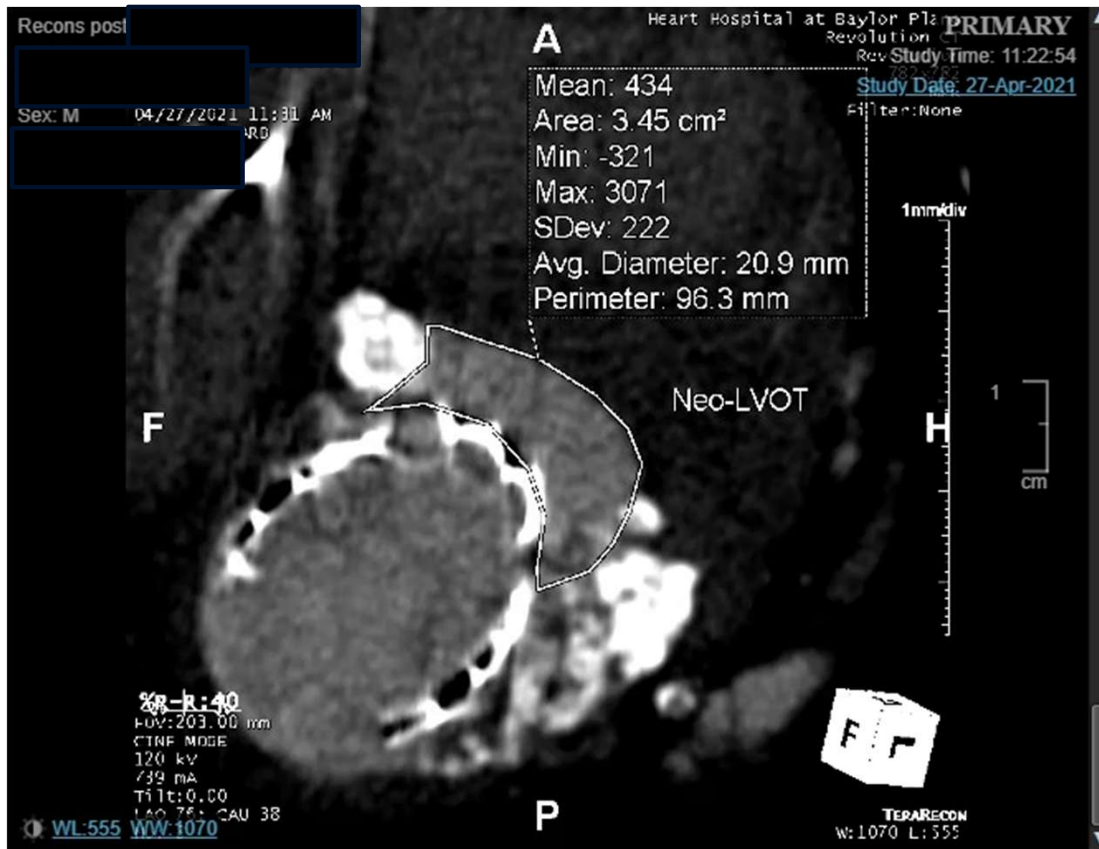
PMH:

- **Severe MS**
- **H/o AVR**
- **H/o CABG**
- **PPM**
- **EF = 45%**









Neo LVOT 3.45 cm<sup>2</sup>



## Use of balloon-expandable valves for the surgical treatment of mitral valve disease in the setting of severe mitral annular calcification

N=82 (2015-2023)

Septal myectomy	34 (41.5)
Other concomitant procedures	52 (63.4)
TVrR	22 (26.8)
CABG	11 (13.4)
AVR	29 (35.4)
Root procedure	5 (6.1)
Ablation	5 (6.1)
LAA exclusion	5 (6.1)
Impella	2 (2.4)
Wedge resection	2 (2.4)
PFO closure	2 (2.4)
PPM	1 (1.2)

Postoperative stroke	4 (4.9)
Mortality	
30-d mortality	11 (13.4)
1-y mortality	19 (23.2)



## Robotic subset

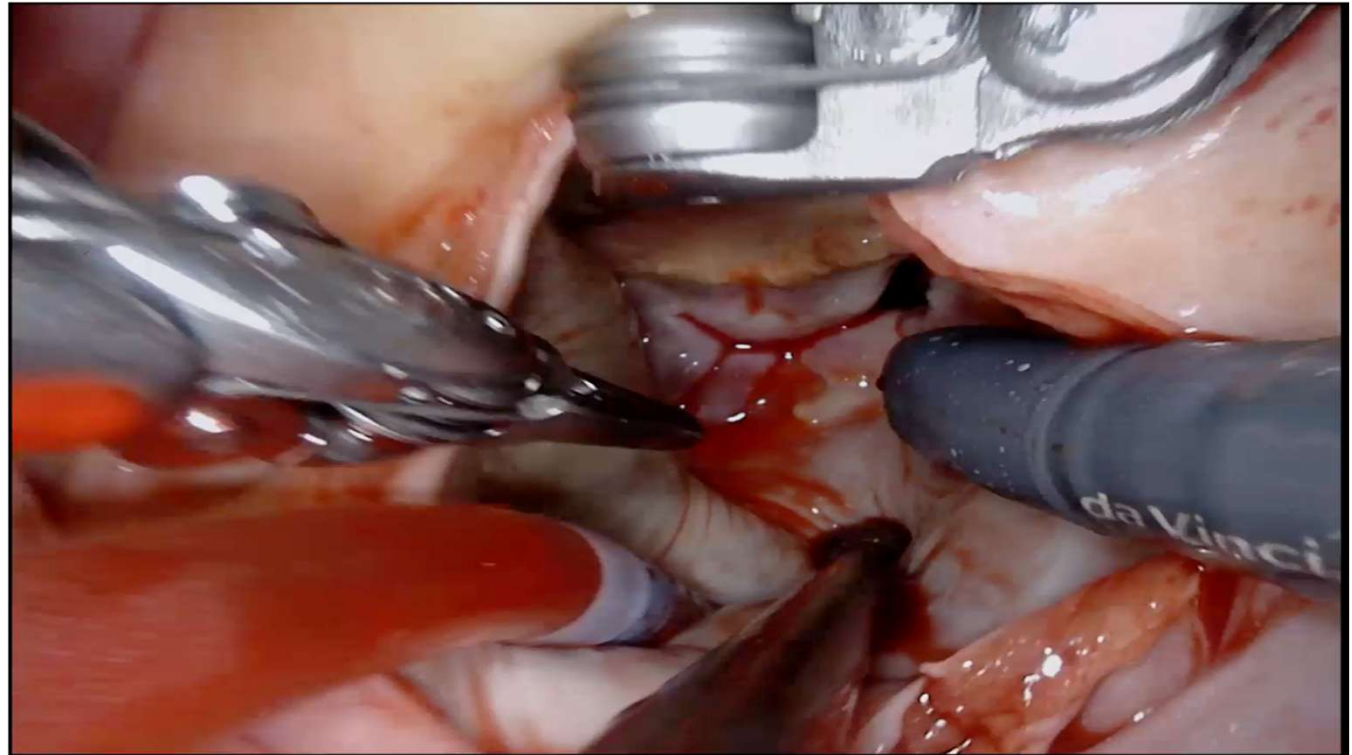
**TABLE E2. Operative data and outcomes among the robotically assisted cohort**

Category	Value (N = 29)
Device	
Sapien 3	29 (100)
Device size (mm)	
26	3 (10.3)
29	26 (89.7)
Septal myectomy	13 (44.8)
Other concomitant procedures	13 (44.8)
TVr	6 (20.7)
TAVR	3 (10.3)
PV ablation	1 (3.4)
LAA exclusion	2 (8.3)
Pleurodesis	1 (3.4)
CPB time (min)	177.5 [165.3-213.8]
Crossclamp time	108 [90-120]
Perivalvular leak	2 (8.3)
30-d outcomes	
All-cause mortality	3 (10.3)
Any documented stroke	2 (6.9)
1-y outcomes	
All-cause mortality	6 (20.7)
Pacemaker	7 (24.1)

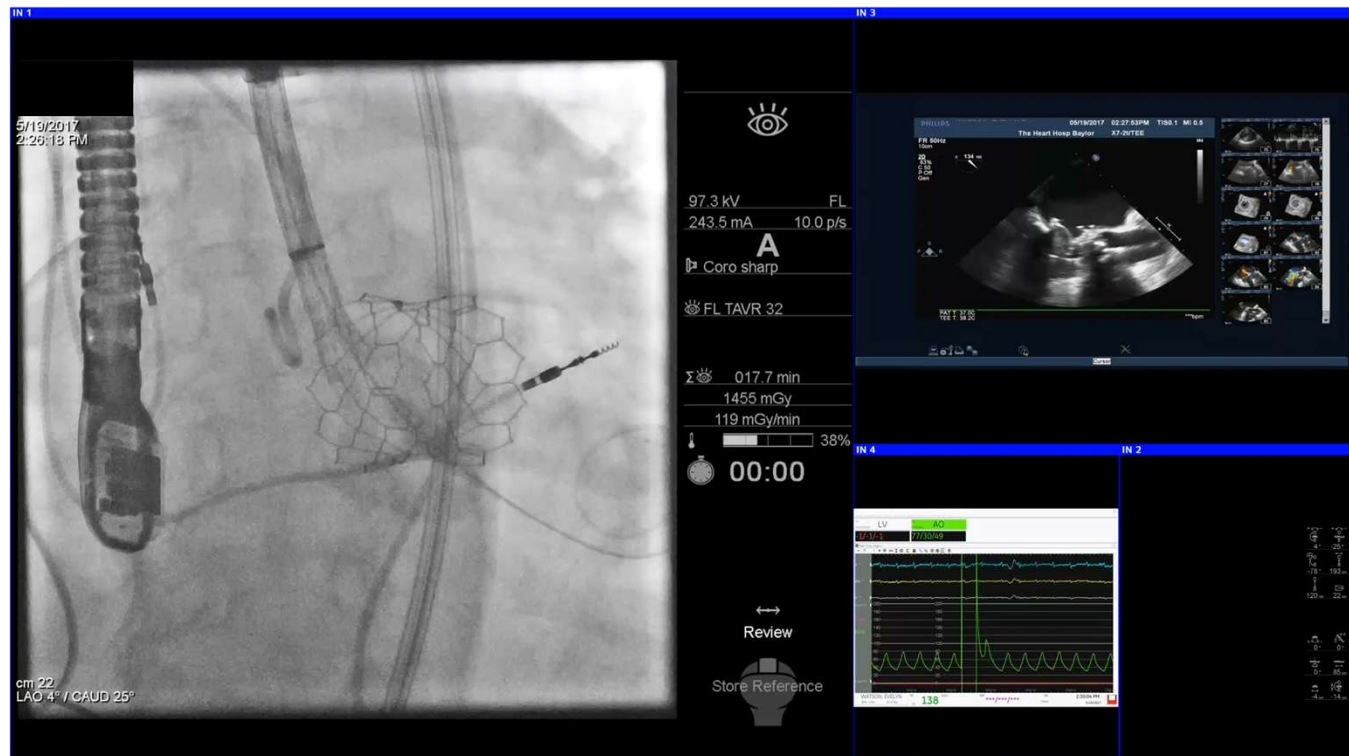


**What about complex multivalve disease**

## 90 yo Female Severe AS/ MS



# Even can add a TAVR same day



The image features a solid background divided diagonally from the bottom-left to the top-right. The upper-left portion is a light blue, and the lower-right portion is a dark blue. The word "Summary" is centered in white, bold, sans-serif font.

# Summary

# Intervening on the MV dysfunction complicated by MAC

- **SITRAL attempts to impact the risk of LVOTO, PVL and embolization risk that can accompany transseptal BEV in MAC.**
- **Largely should be viewed as complimentary approach, not competing with transseptal approaches**
- **Continues to highlight the importance of the HEART TEAM approach and shared decision making with the patient.**
- **We have a lot more that we need to learn... far from the end of the chapter.**



# Thank you!

Robert.Smith1@BSWHealth.org

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PLANO  
Joint ownership with physicians

