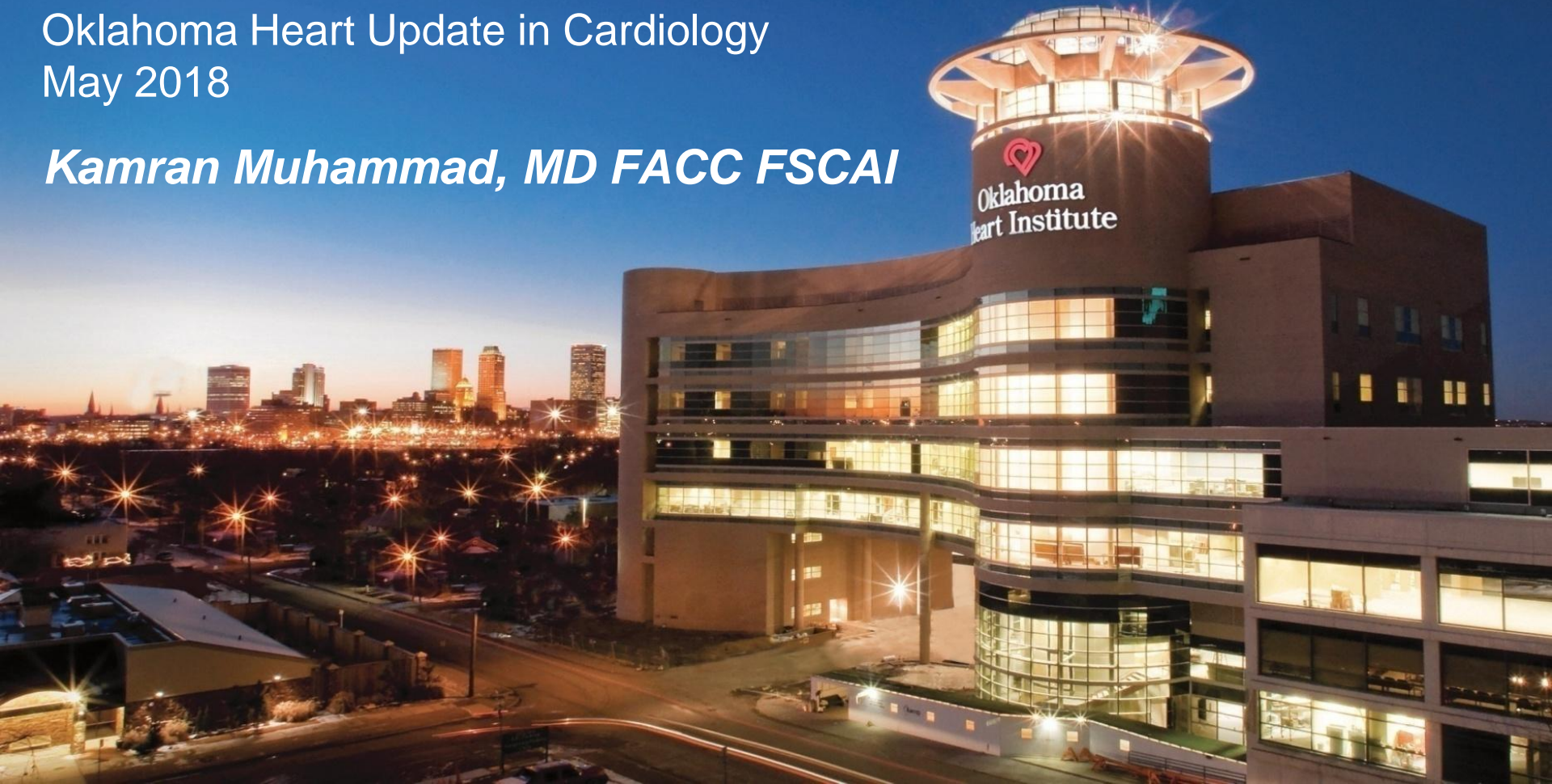


Update on Transcatheter Valve Therapies

Oklahoma Heart Update in Cardiology

May 2018

Kamran Muhammad, MD FACC FSCAI



Outline

- Transcatheter therapies for aortic stenosis
- Transcatheter therapies for mitral valve disease

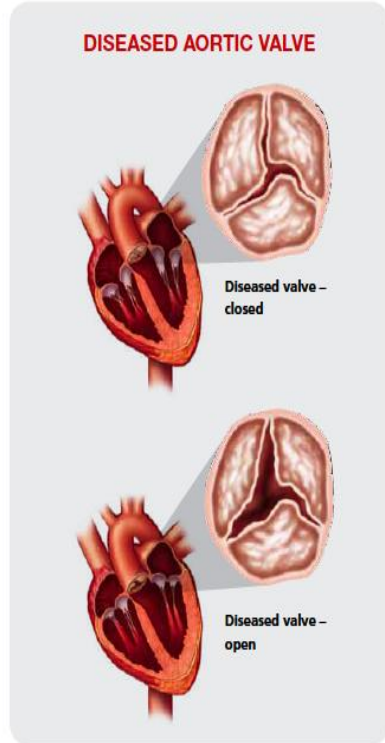
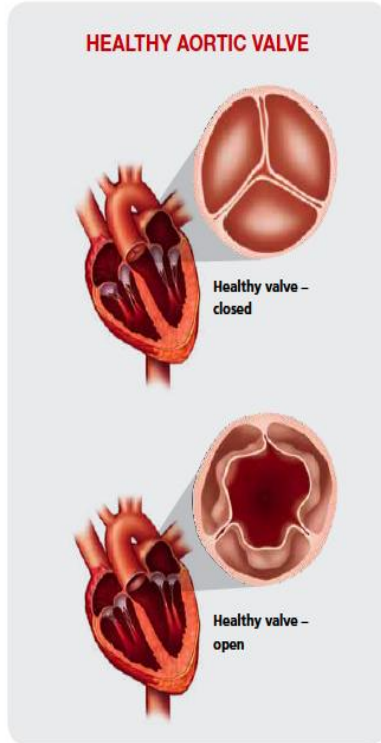
Please Log In Using Your Phone

- Login to **Hyatt_Meeting** Wi-fi
 - Password: heart
- www.slido.com
- Enter code: B720 Password: heart
- Select 'POLLS' on top

Aortic Stenosis

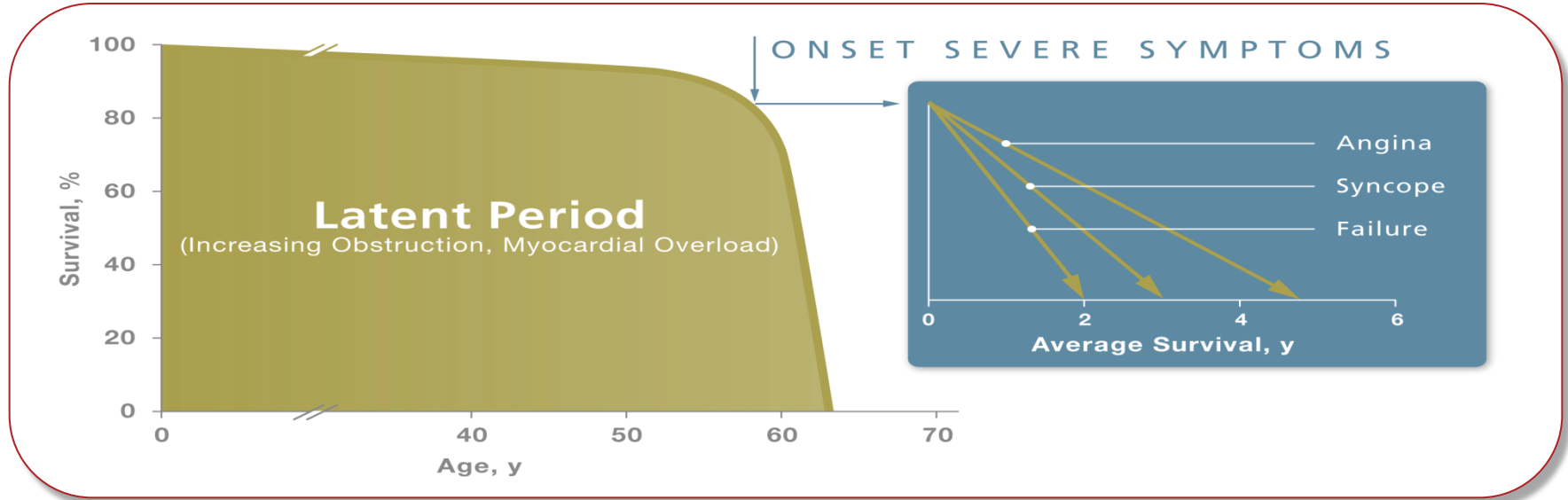
Transcatheter Aortic Valve Replacement
TAVR

Aortic Stenosis



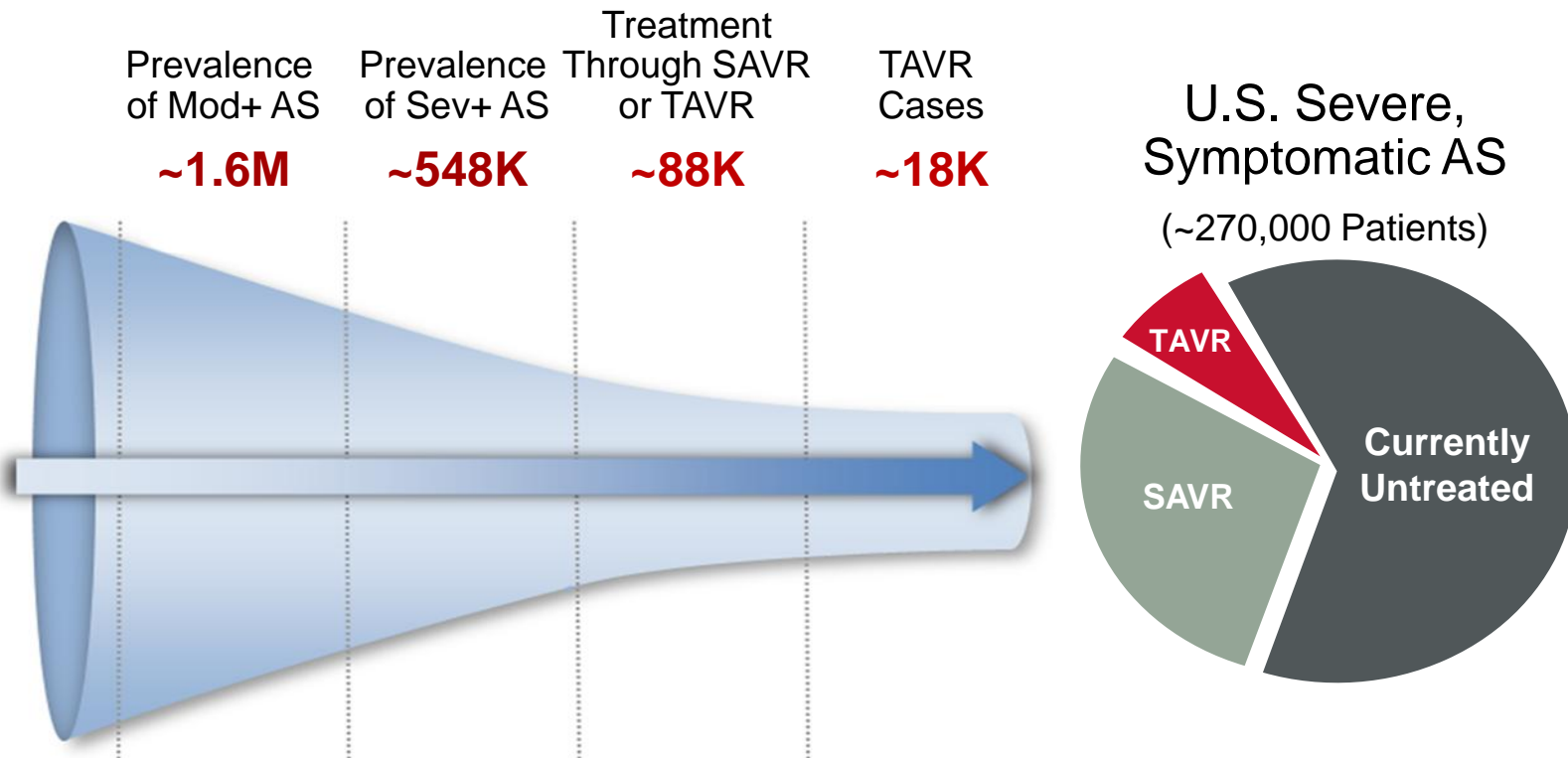
- **Aortic stenosis** is a narrowing of the **aortic** valve in the **heart**. This restricts blood flow through the valve. The **heart** then needs to squeeze (contract) harder to pump blood into the **aorta**.

Very Poor Natural History

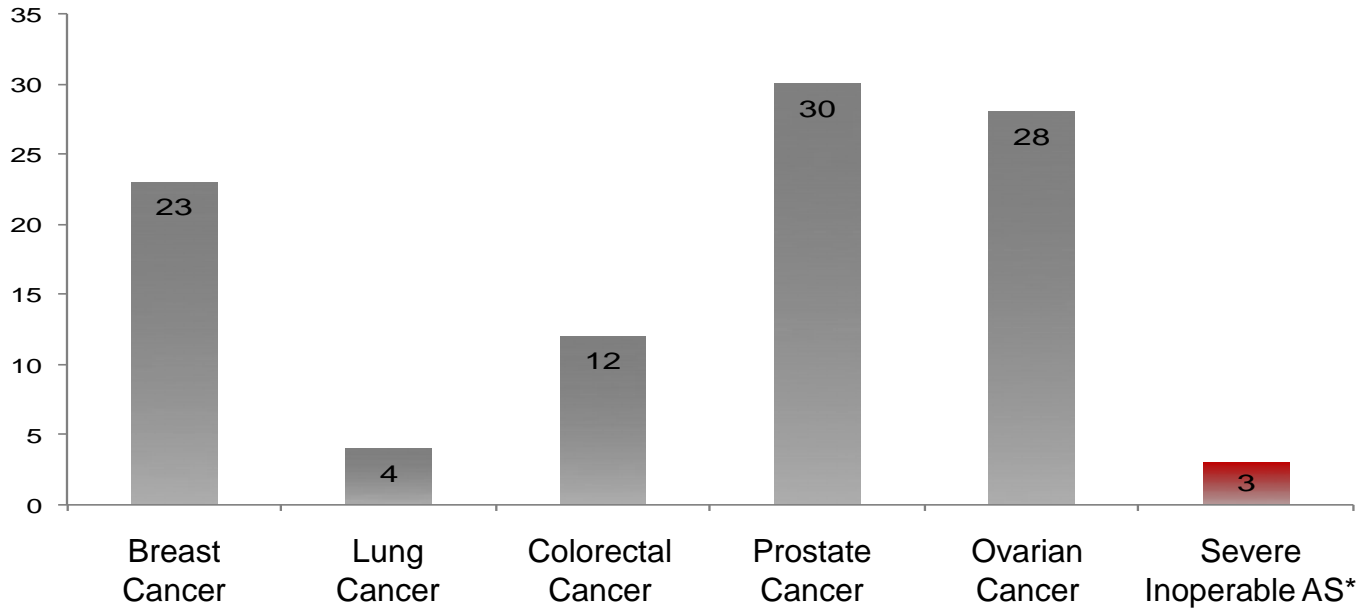


- Survival after onset of symptoms is 50% at 2 years

The Majority of AS Patients Remain Untreated

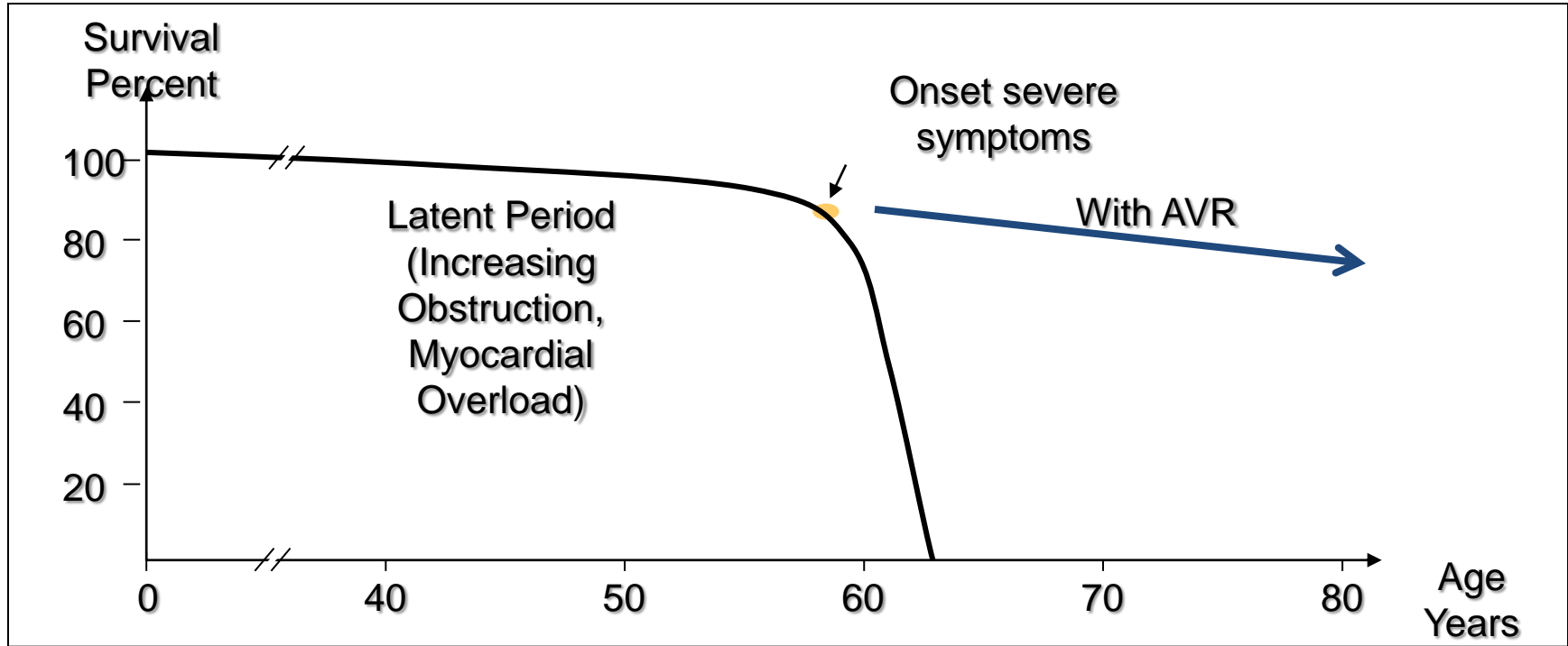


Sobering Perspective



5 year survival of breast cancer, lung cancer, prostate cancer, ovarian cancer and severe inoperable aortic stenosis

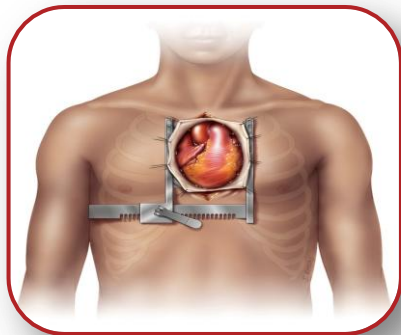
Aortic Stenosis Effect of Treatment



Options for Aortic Valve Replacement

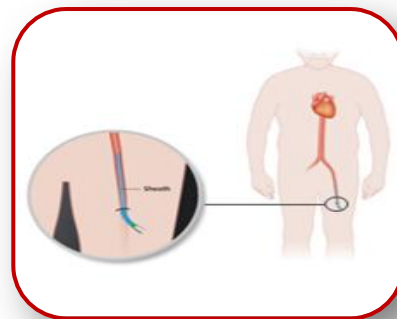
**Patients Suitable for
Open Chest Surgery**

**Surgical Aortic
Valve
Replacement
(sAVR)**



**Inoperable, High Risk &
Intermediate Risk Patients**

**Transcatheter
Aortic Valve
Replacement
(TAVR)**

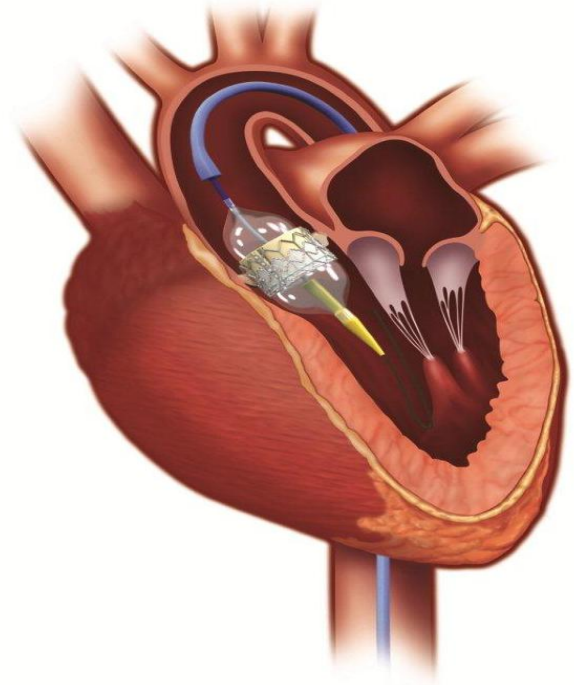


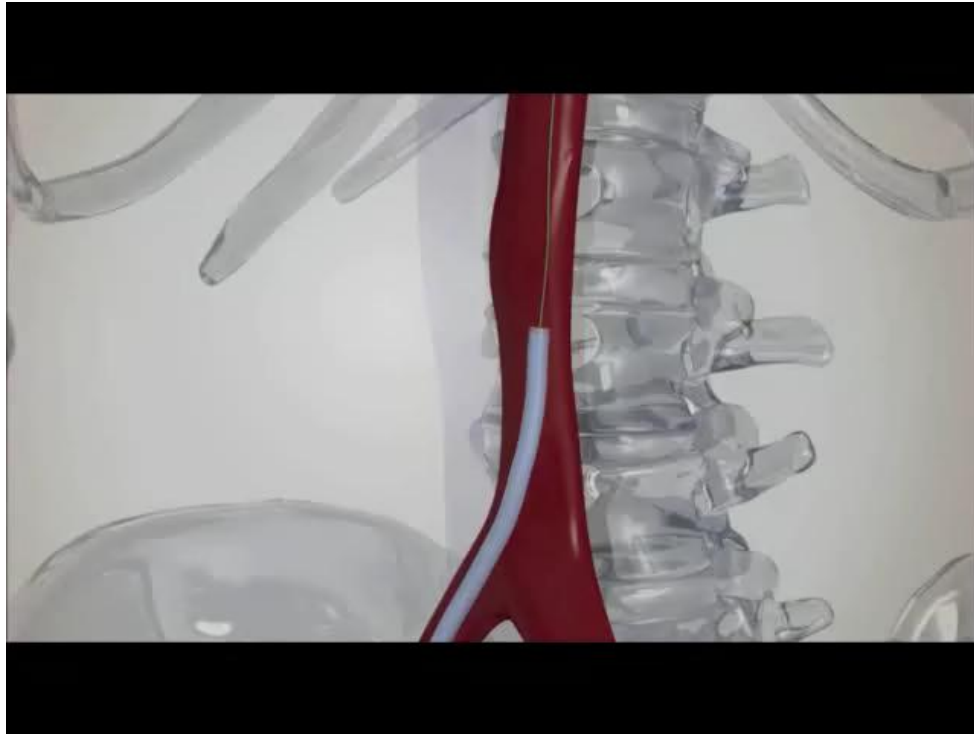
Transcatheter Aortic Valve Replacement: TAVR



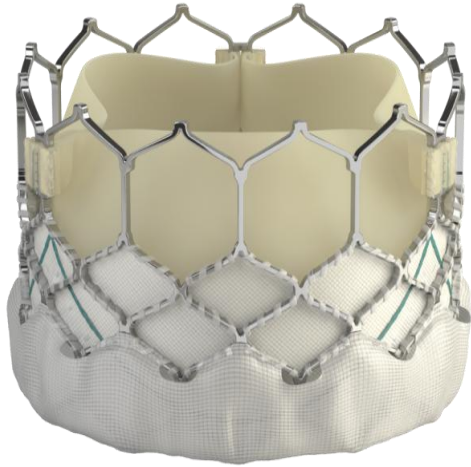
Transcatheter Aortic Valve Replacement (TAVR)

- This less invasive procedure allows the aortic valve to be replaced with a new valve while the heart is still beating
- For patients who are at intermediate risk or high-risk for open-heart surgery, TAVR may be an alternative





Edwards Sapien 3 and Medtronic CoreValve Evolut PRO

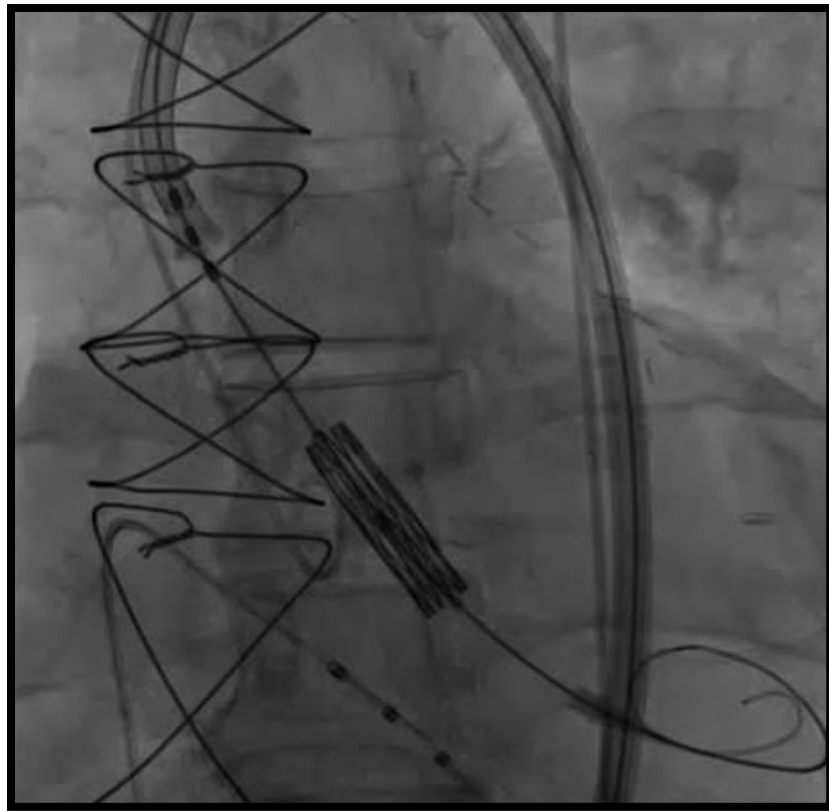


FDA-approved June 17, 2015



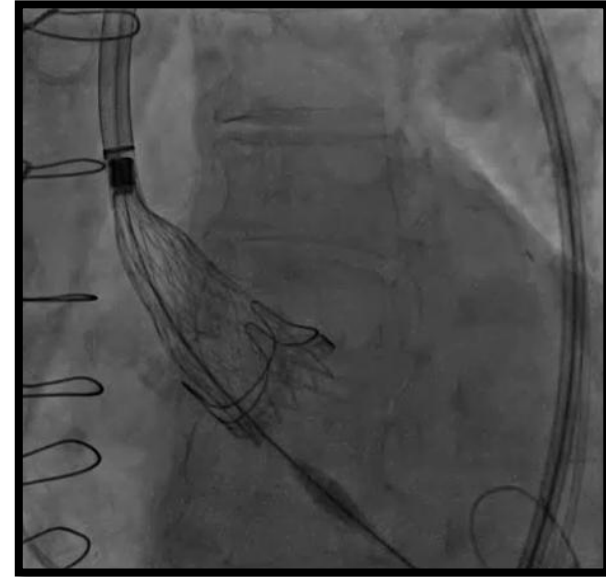
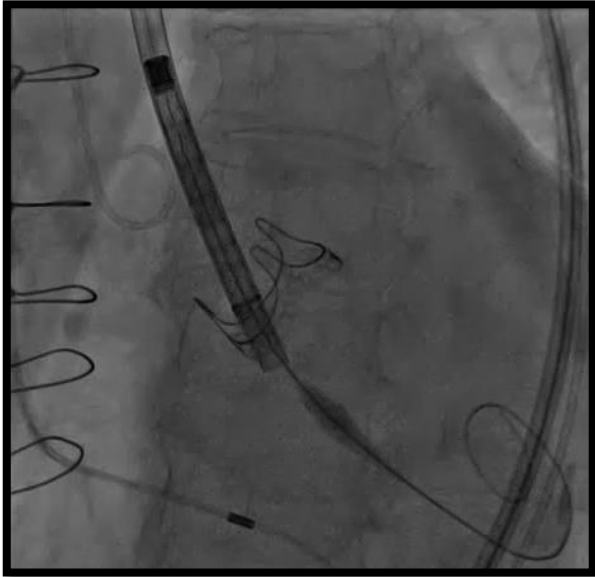
FDA-approved March 22, 2017

26 mm Sapien 3 Deployment



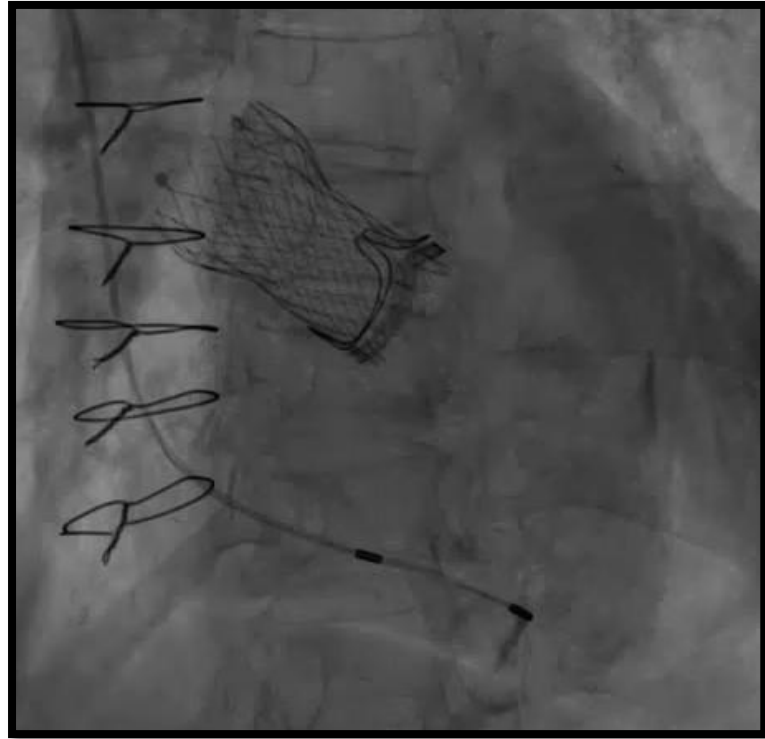
Balloon Expandable Valve

26 mm CoreValve Evolut R Deployment



Self Expanding Valve

26 mm CoreValve Evolut R Deployment

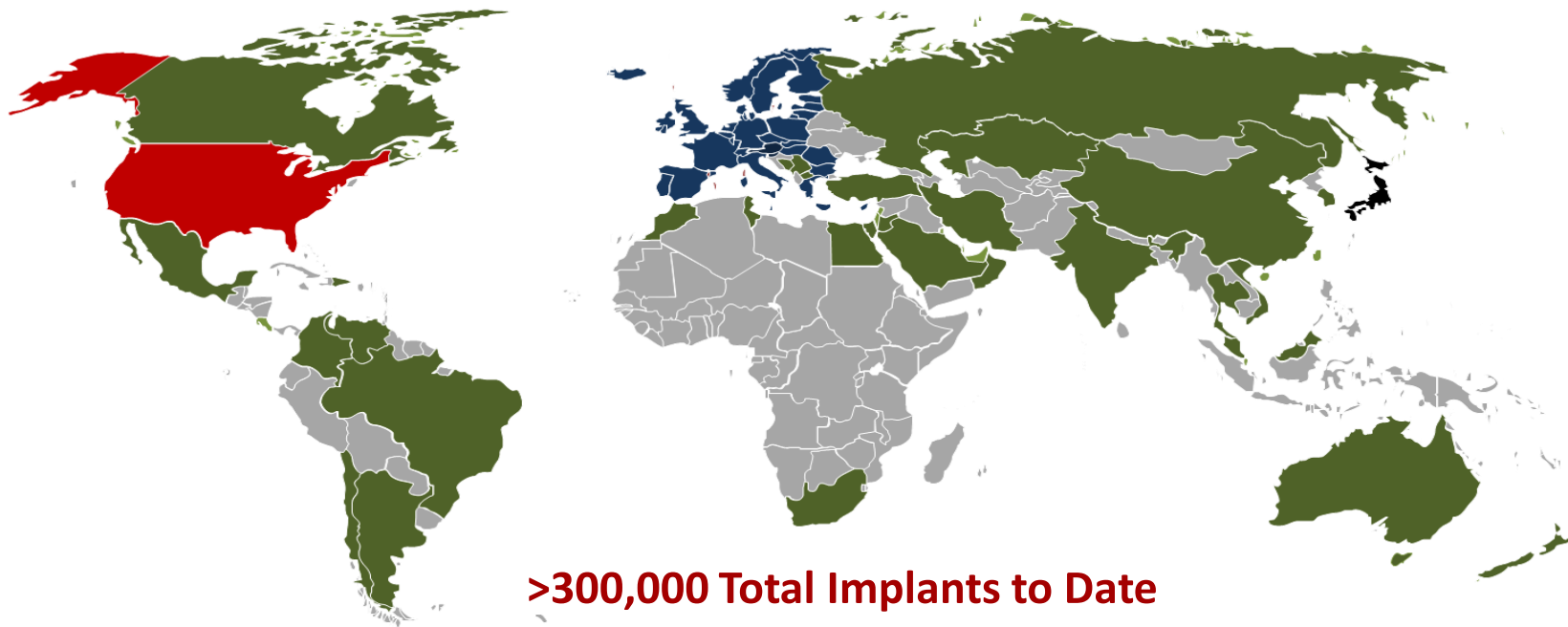


Percutaneous Femoral Access



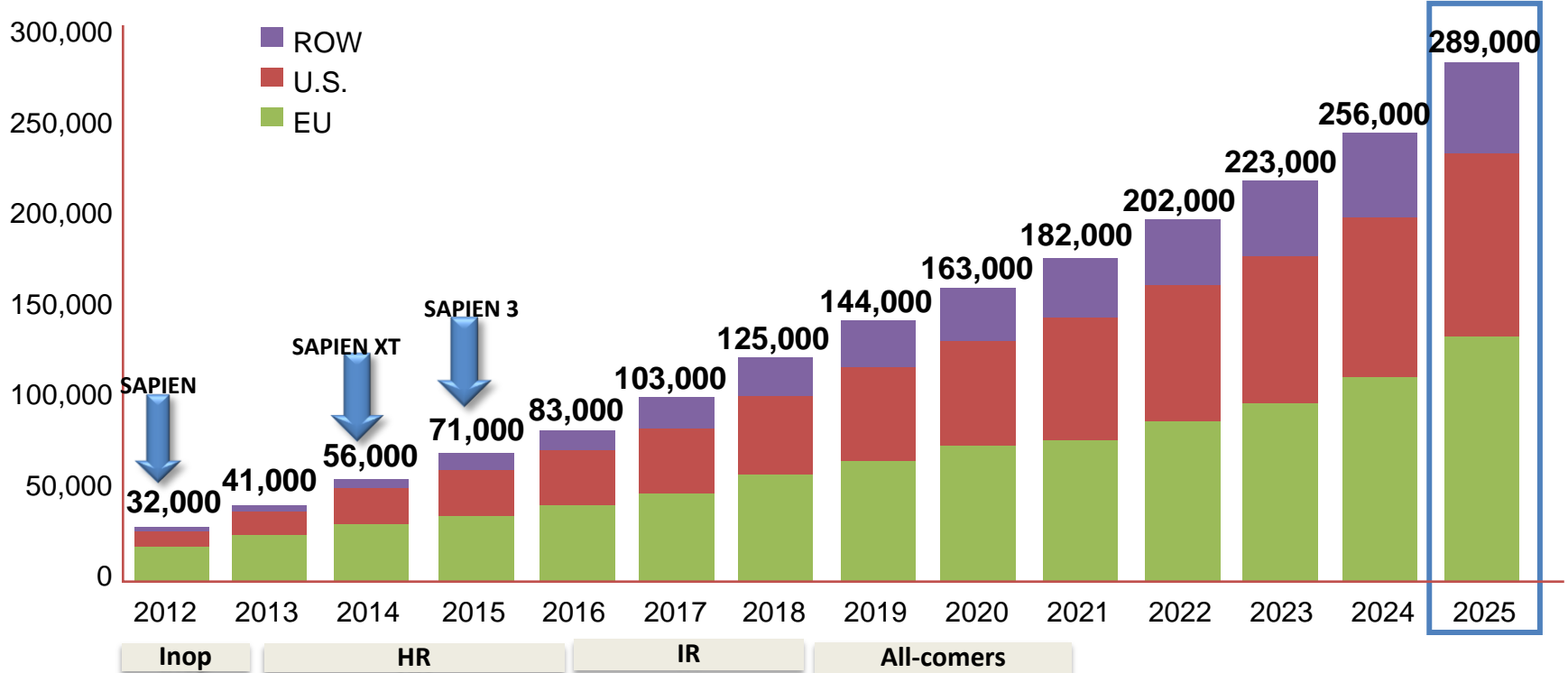
TAVR Growth Trajectory

TAVR is Available in Over 65
Countries Around the World



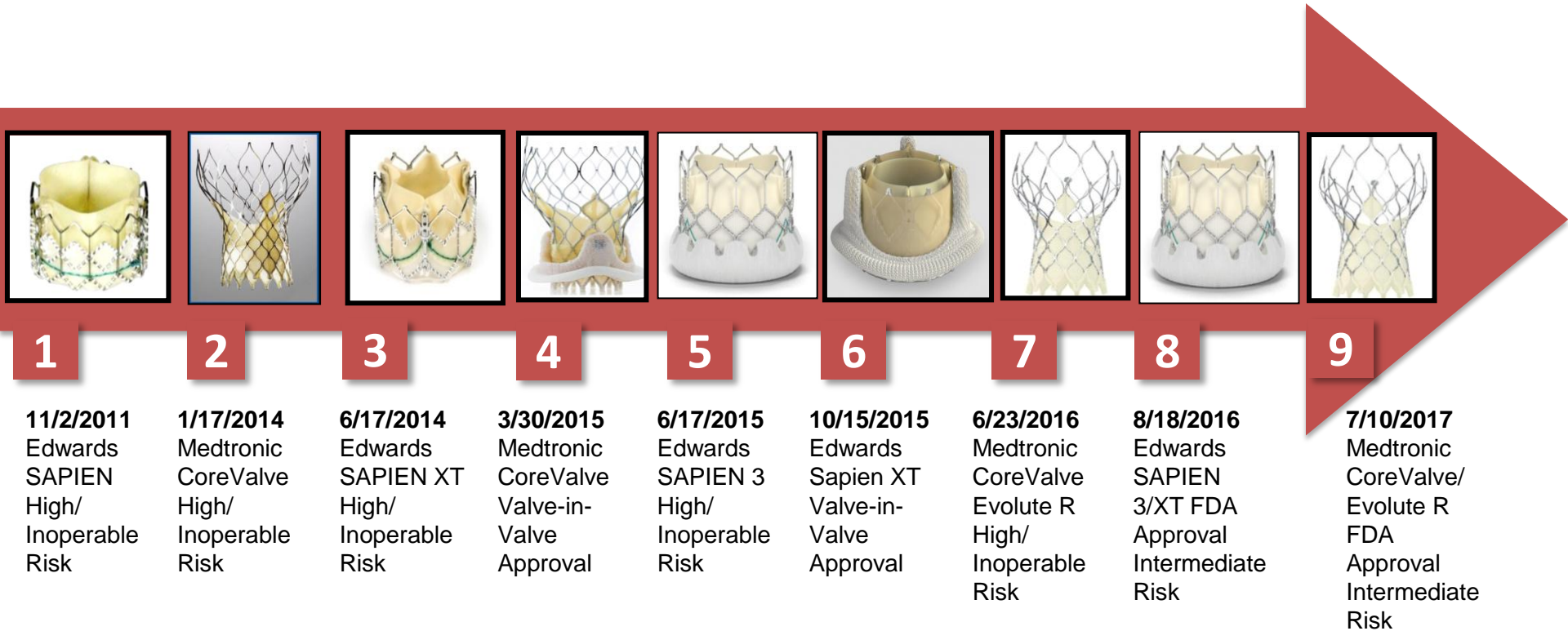
TAVR Growth Trajectory

Estimated Global TAVR Procedures



In the next 10 years, TAVR will increase 4X

Evolution of TAVR in the U.S.



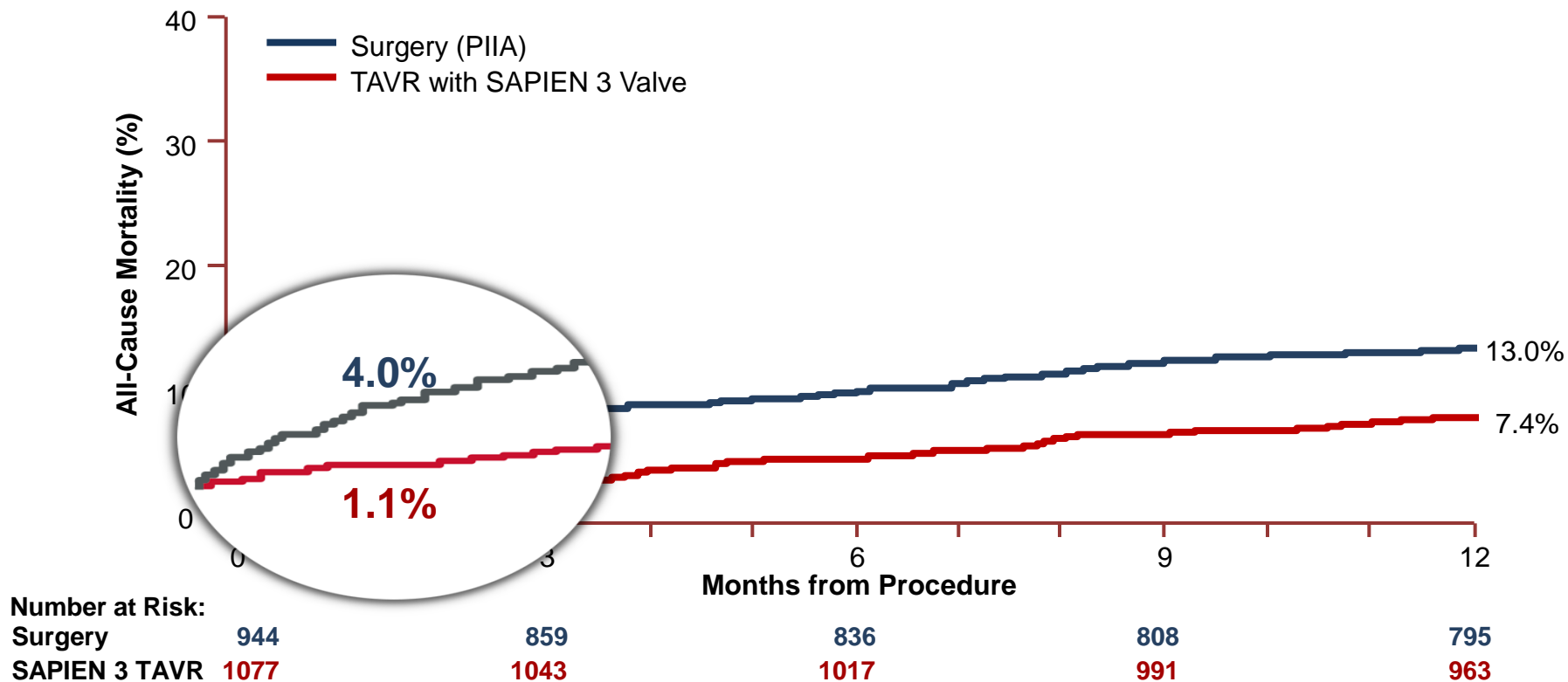
Transcatheter Aortic Valve Replacement (TAVR) with the SAPIEN 3 Valve Compared with Surgery in Intermediate-Risk Patients: A Propensity Score Analysis

Purpose:

- To evaluate the 1-year clinical and echo outcomes of TAVR with the SAPIEN 3 valve in intermediate-risk patients
- To compare these intermediate-risk patient outcomes with surgery results in similar intermediate-risk patients from the PARTNER IIA trial using a **pre-specified propensity score analysis**

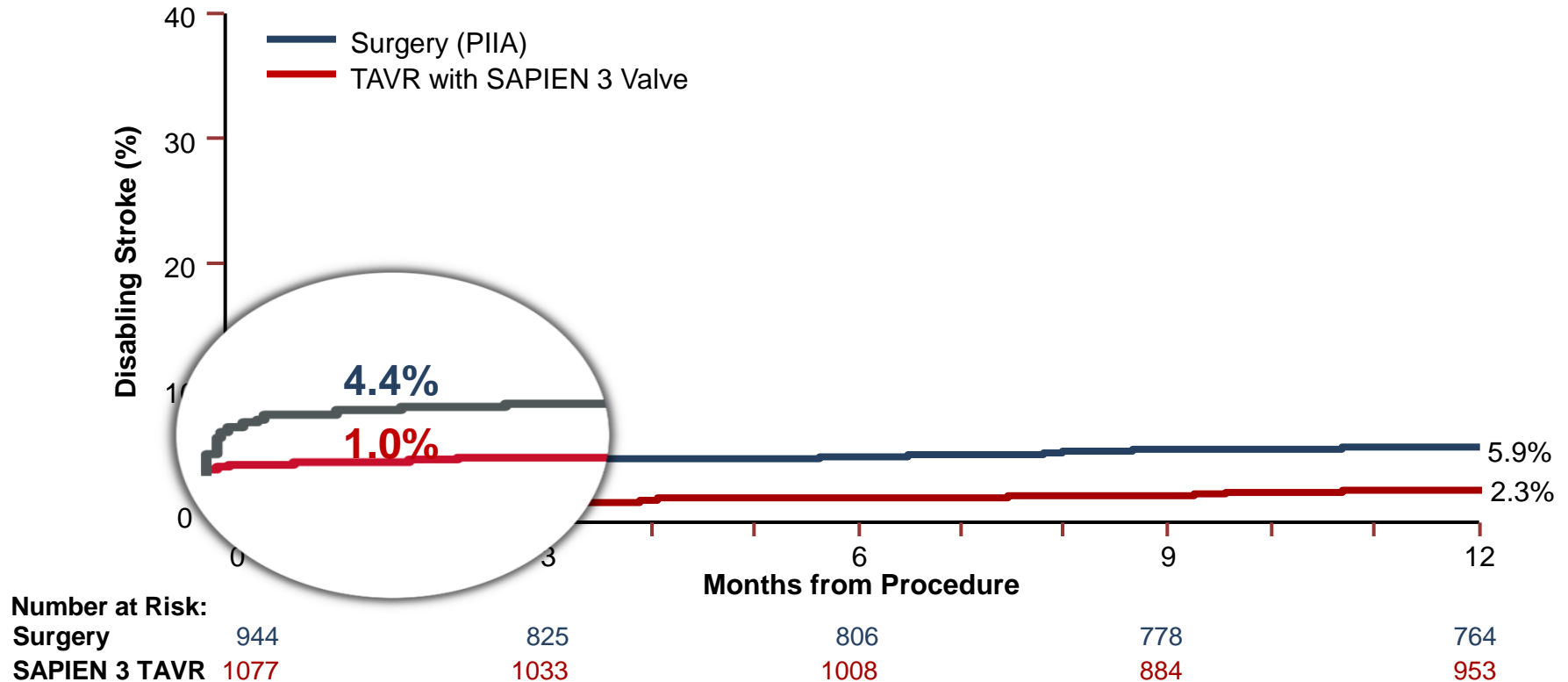


All-Cause Mortality*



*The PARTNER II trial intermediate-risk cohort unadjusted clinical event rates.

Disabling Stroke*



*The PARTNER II trial intermediate-risk cohort unadjusted clinical event rates.



Valve & Structural Heart Center
at Oklahoma Heart Institute



OHI TAVR Program - Perspective

- OHI began its TAVR program 5/2/2012
 - Among the first 70 hospitals to initiate TAVR
 - OHI TAVR physicians serve as national proctors
- Performed > 425 cases
 - 92% Transfemoral
 - Transcaval, Axillary, Transapical, Transaortic



2017-Present: Total TAVRs 177

Outcome	OHI	2015 TVT Registry
30-day Mortality	2.8%	4.6%
30-day Stroke	0.5%	1.9%
Length of Stay (days)	1.4	4
Conscious Sedation Anesthesia	92%	16.6%
Transfemoral TAVR	92%	86.6%

2018 Outcomes:
Mortality: 0%
Stroke: 0%



PARTNER 3: Low Risk TAVR Trial

- Evaluate the safety and effectiveness of the TAVR versus surgical AVR in low risk patients with aortic stenosis.
 - 1:1 randomization SAVR vs. TAVR
 - Approximately 1300 patients
 - Trial completed and results are expected next year.



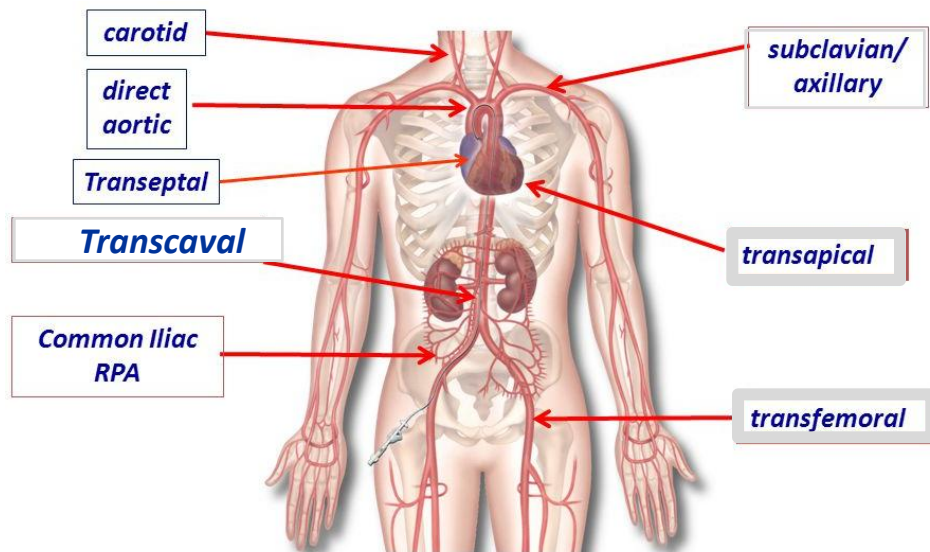
PARTNER 3: Underrepresented Population Registry

- Goal of 100 non-Caucasian patients
- Total of 5 sites:
 - Oklahoma Heart Institute only site in region
- Inclusion Criteria
 - Severe, calcific aortic stenosis
 - STS risk score < 4%



TAVR: Multiple Options for Access

- Transfemoral approach is the most common access for TAVR.
- A number of patients cannot have a TF approach due to inadequate vessel size, vessel disease, or other anatomical considerations.
- Alternate access sites have proven to be viable and safe alternatives.

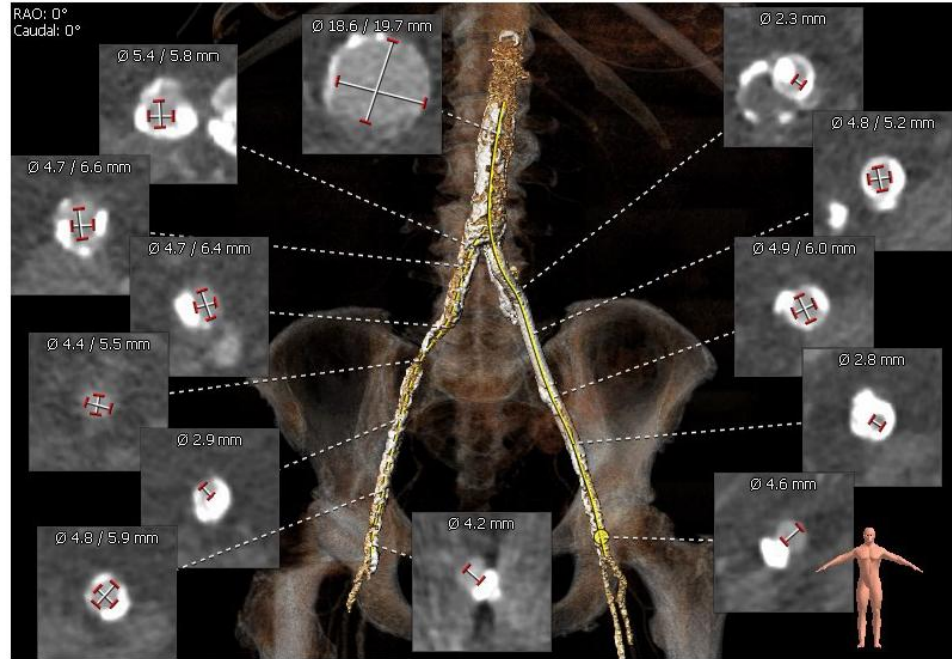


Patient History

- 82-year-old female referred from El Paso, Texas.
- History of hypothyroidism, hypertension, dyslipidemia, asthma, paroxysmal atrial fibrillation, peripheral arterial disease, stage III chronic kidney disease, 3+ mitral regurgitation, chronic diastolic heart failure (EF 60%) and severe symptomatic aortic stenosis with NYHA Class III congestive heart failure symptoms.
- STS score of 12%



TAVR Protocol CT Scan



Heavily Calcified Iliofemoral Vessels

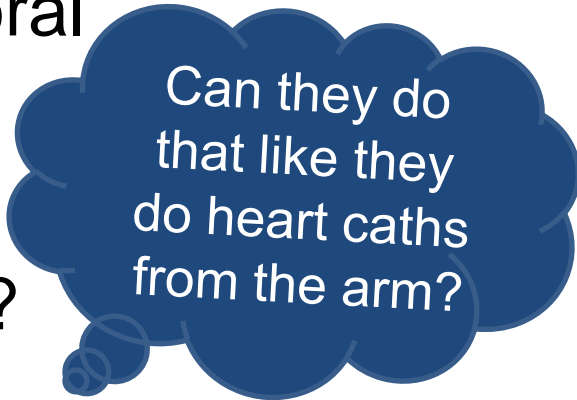
What Should We Do?

www.slido.com, enter code B720, select 'POLLS' on top

A. **Beg** the surgeons to do high risk surgery

B. Pray and do TAVR through the femoral artery

C. Perform TAVR through arm artery ??



Can they do that like they do heart caths from the arm?

D. Medical therapy and hope for the best



C. Perform TAVR through the arm

Axillary Artery Access TAVR

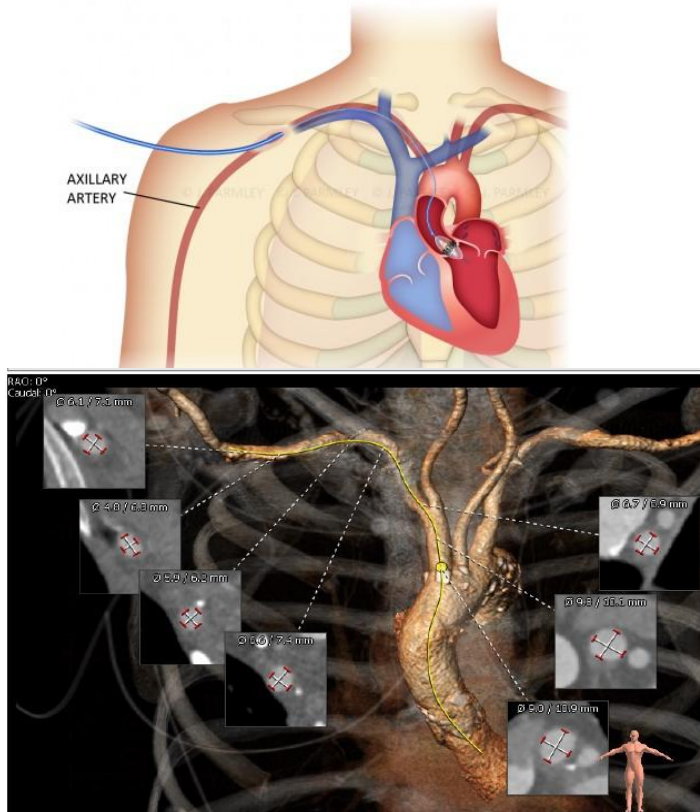


Case Plan

- TAVR protocol CT scan demonstrated that the patient was not a candidate for TF-TAVR due to severe PAD.
- Felt to be a poor candidate for alternative access approaches including transapical and transaortic TAVR given her frailty.
- **Plan:** Percutaneous right axillary artery access.



Alternative Access TAVR: Transaxillary

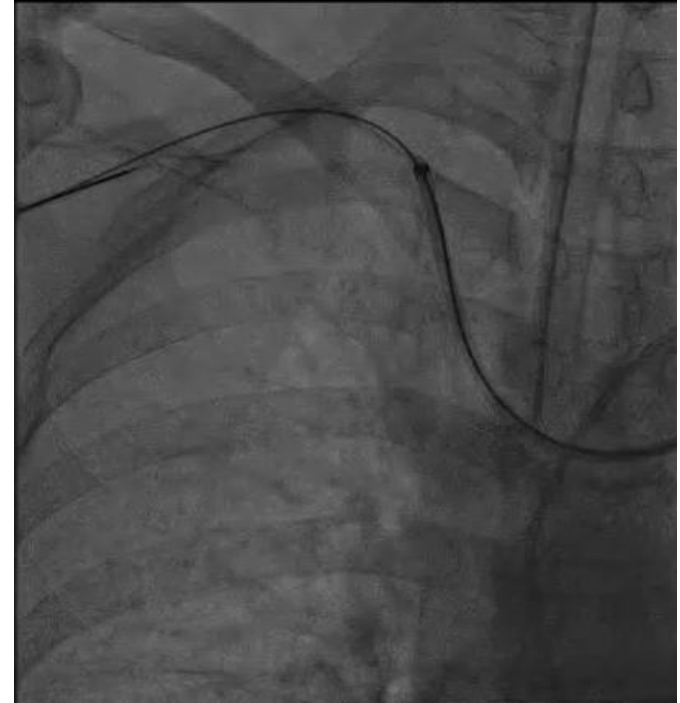


- Axillary artery appears to be far less frequently affected by atherosclerotic disease.
- Access is at the lateral margin of the first rib.
- Usually done surgically
- Percutaneous preferred at OHI

Alternative Access TAVR: Transaxillary

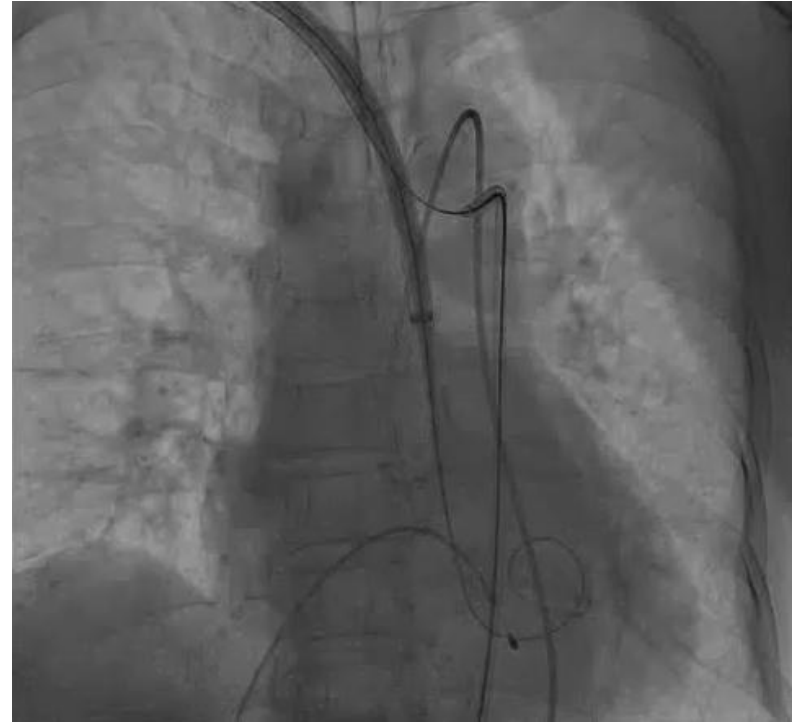
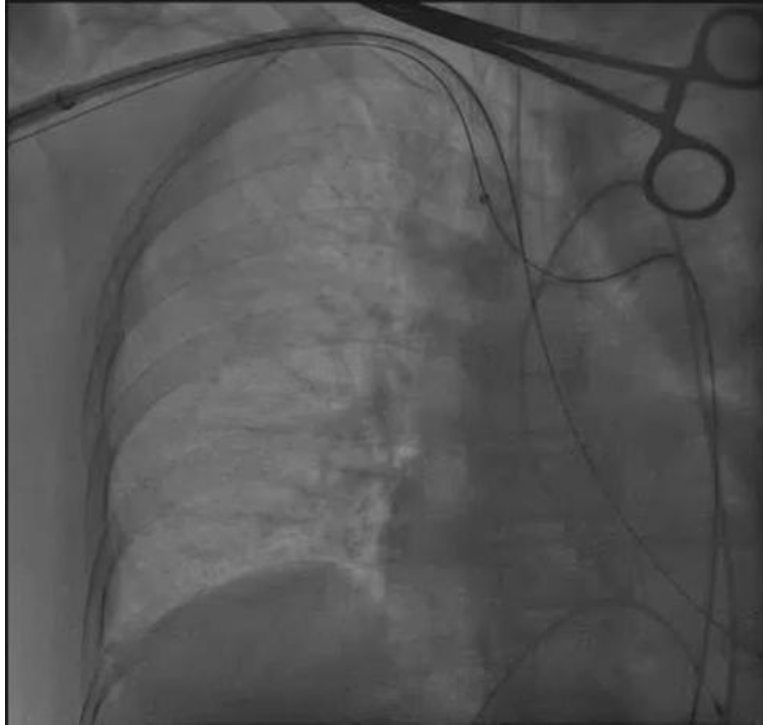


Axillary Artery Angiogram



Percutaneous access in the first portion of the right axillary artery

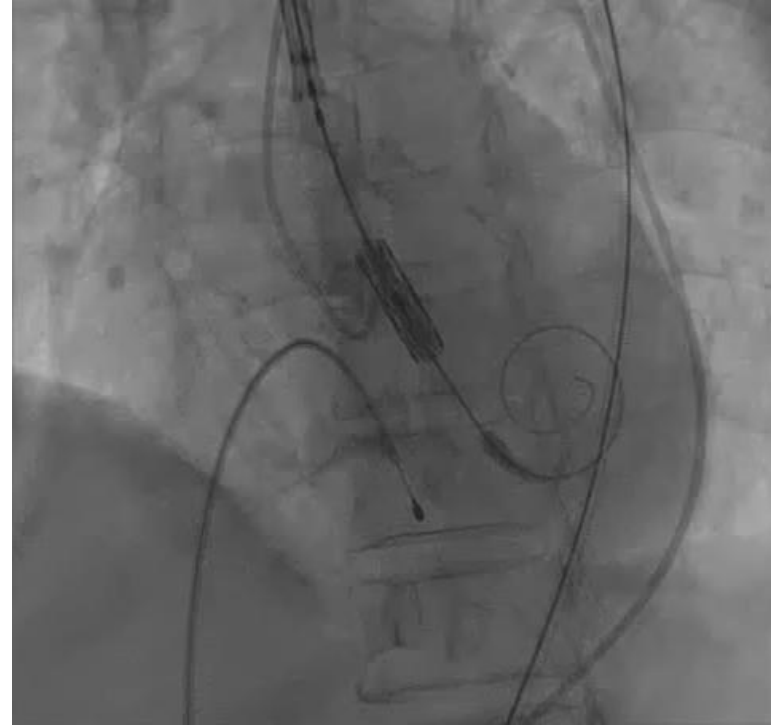
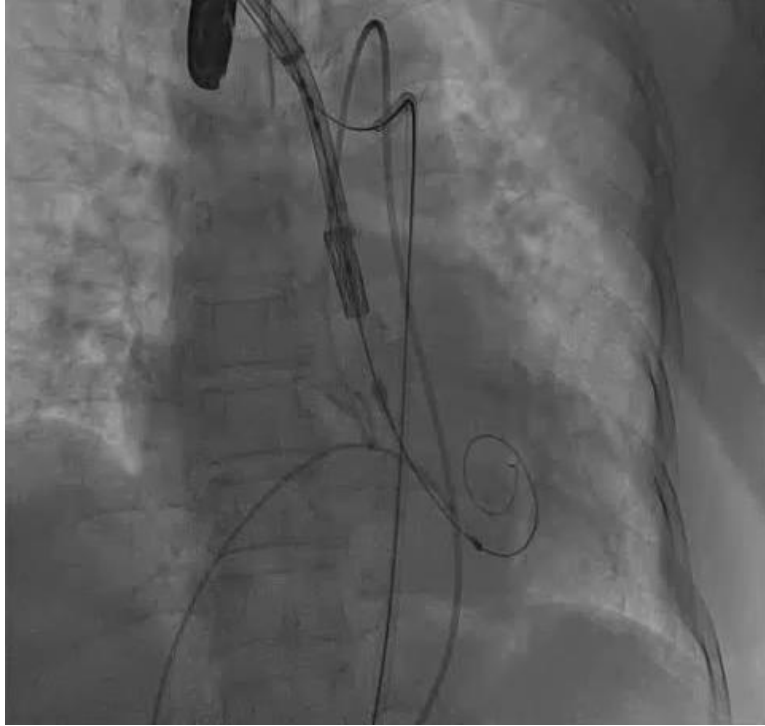
Alternative Access TAVR: Transaxillary



Inserting 16F TAVR delivery sheath percutaneously into right axillary artery
and advancing into ascending aorta

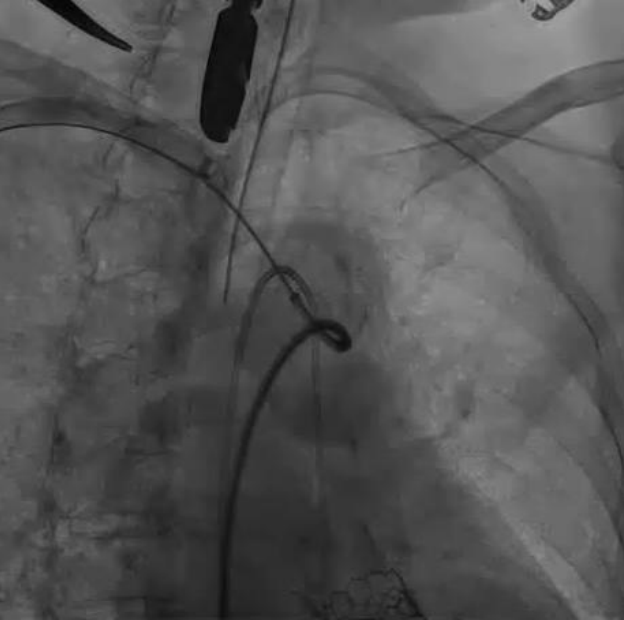


Alternative Access TAVR: Transaxillary

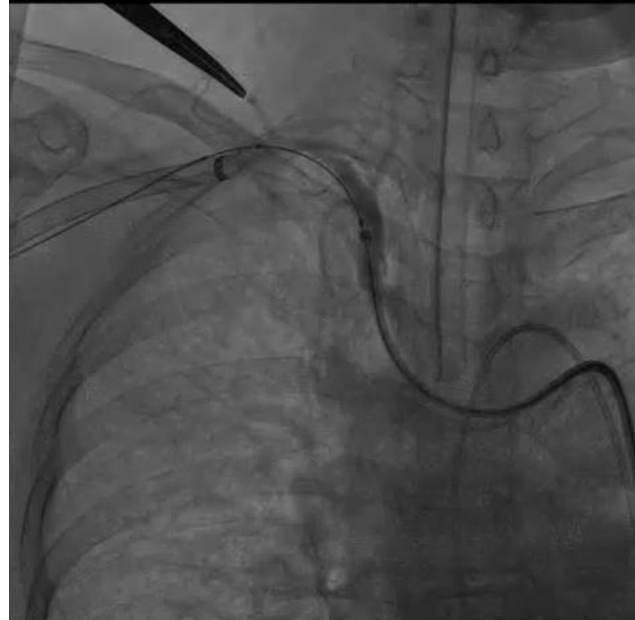


Advancing and deploying Edwards Sapien 3 valve from percutaneous right axillary artery approach

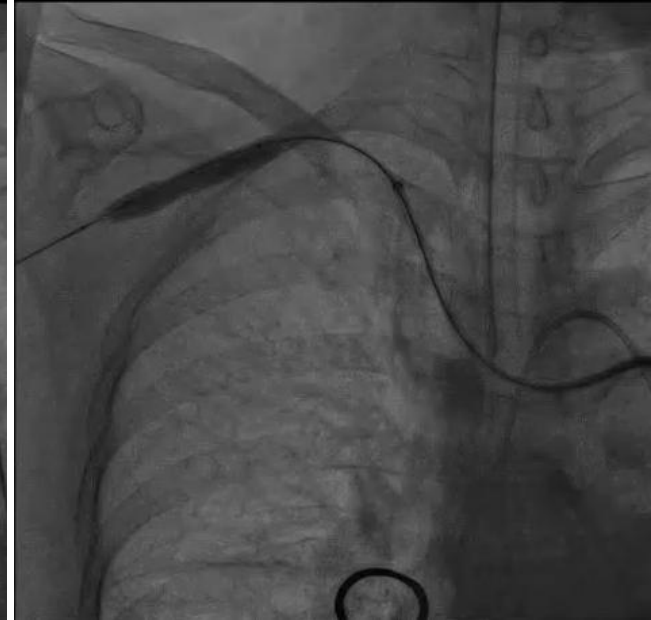
Alternative Access TAVR: Transaxillary



Brachiocephalic Angiogram with
no evidence of dissection



Removal of 16F
Edwards E-Sheath



Balloon tamponade - closure with
2 Perclose ProGlide devices

Alternative Access TAVR: Transaxillary



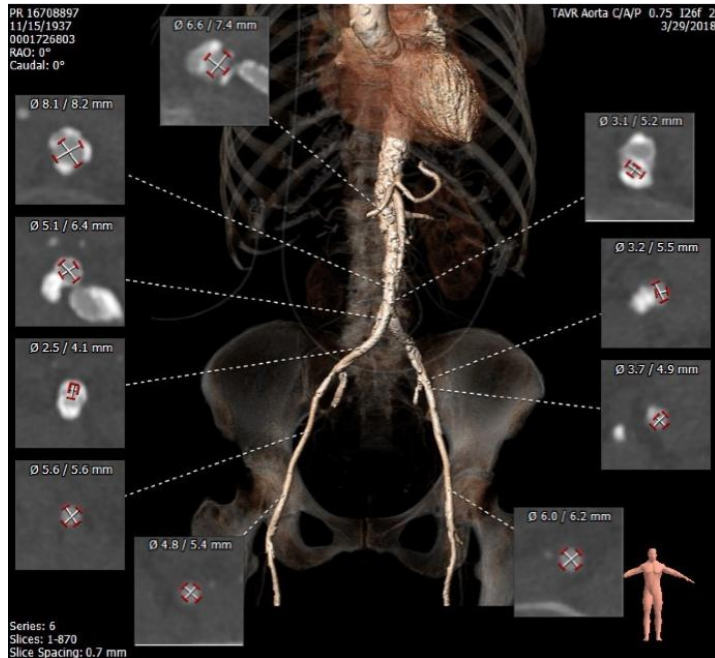
Final Axillary Artery Angiogram



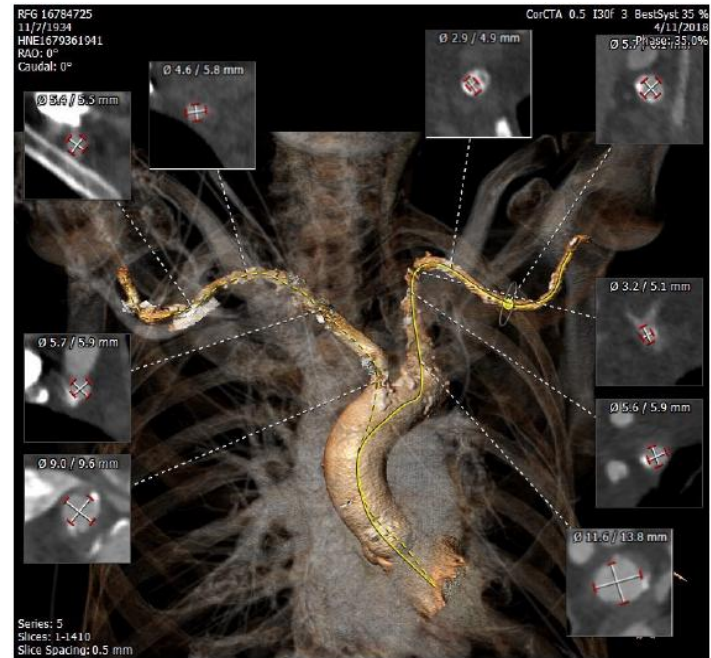
Patient History

- 80-year-old male with a history of HTN, dyslipidemia, type 2 diabetes mellitus, carotid artery disease, severe bilateral lower extremity peripheral arterial disease, mesenteric ischemia, status post superior mesenteric artery stenting, CAD with previous CABG in 2012 with subsequent PCI, history of permanent pacemaker implantation, chronic diastolic heart failure.
- Severe symptomatic aortic stenosis with New York Heart Association Class III CHF
- STS score of 13.5%.

TAVR Protocol CT Scan



Poor Transfemoral Access



Poor Subclavian Access

What Should We Do?

www.slido.com, enter code B720, select 'POLLS' on top

- A. Buy the surgeons many gifts in hopes they will do high risk surgery
- B. Perform TAVR through the arm artery
- C. Send the patient home with hospice
- D. Place the transcatheter heart valve through the femoral vein

But the venous system doesn't connect directly to the aortic valve... I think Dr. Muhammad forgot his anatomy.



D. Place the transcatheter heart valve through the femoral vein

Transcaval Access TAVR



Case Plan

- TAVR protocol CT scan demonstrated iliofemoral vessels to be too diseased/small for transfemoral access.
- The patient was felt to be a poor candidate for alternative access TAVR (transaortic or transapical) due to his multiple comorbidities and previous CABG.
- **Plan**: Transcaval Access

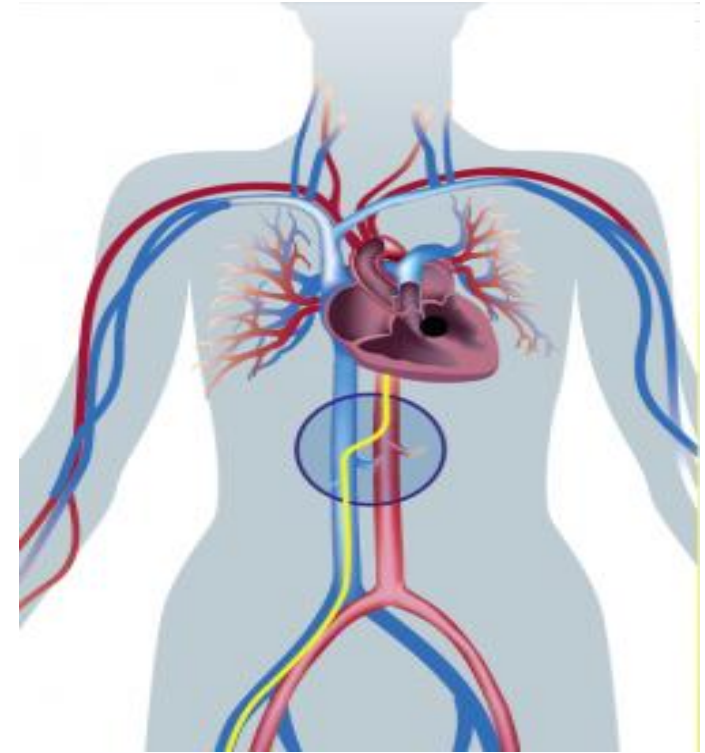


Alternative Access TAVR: Transcaval TAVR





TAVR with Caval Aortic Access

- For patients who are high or prohibitive risk for surgical aortic valve replacement
- Largest iliofemoral artery minimal lumen caliber is too small to safely pass sheaths for TAVR
- Risk of alternative access: transapical or transaortic TAVR is considered high or prohibitive risk



Transcaval Access TAVR

 **tct2016**
October 29-November 2, 2016
Walter E. Washington
Convention Center
WASHINGTON, DC

 **JACC**
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY

October 2016 >

Original Investigations | October 2016

Transcaval Access and Closure for Transcatheter Aortic Valve Replacement: A Prospective Investigation

Adam B. Greenbaum, MD^a; Vasillis C. Babaliaros, MD^b; Marcus Y. Chen, MD^c; Annette M. Stine, RN^c; Toby Rogers, PhD, BM BCh^c; William W. O'Neill, MD^a; Gaetano Paone, MD^a; Vinod H. Thourani, MD^b; Kamran I. Muhammad, MD^d; Robert A. Leonardi, MD^e; Stephen Ramee, MD^f; James F. Troendle, PhD^c; Robert J. Lederman, MD^c

[+] Author Information

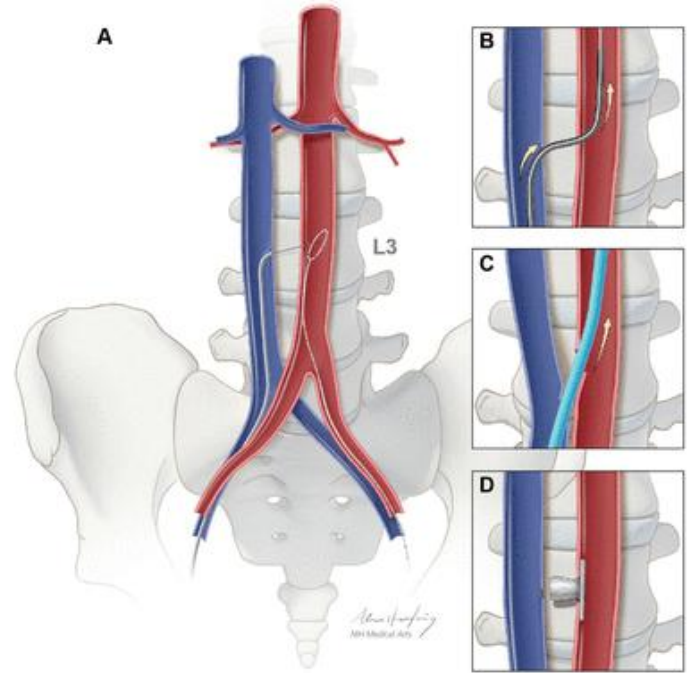
J Am Coll Cardiol. 2016;():. doi:10.1016/j.jacc.2016.10.024

Henry Ford Hospital, Detroit, Michigan; Emory University, Atlanta, Georgia; National Heart Lung and Blood Institute, National Institutes of Health, Bethesda, Maryland; Oklahoma Heart Institute, Tulsa, Oklahoma; Lexington Medical Center, West Columbia, South Carolina; Ochsner Medical Center, New Orleans, Louisiana

- The transcaval approach was systematically assessed in a small prospective study.
- Study demonstrated Transcaval access TAVR to be a safe and effective option for patients who otherwise have limited options.
- OHI was one of the top three medical centers to enroll patients.

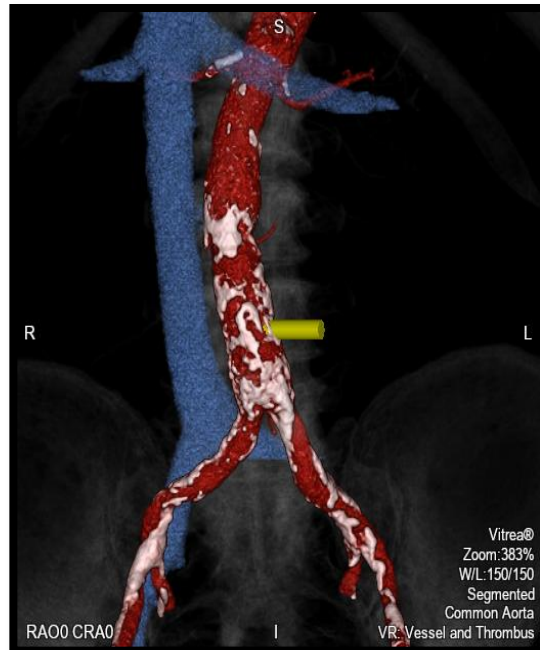
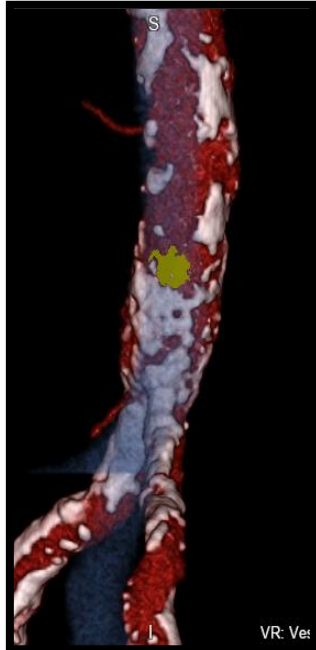
TAVR with Caval Aortic Access

- Obtain femoral venous access. Crossing catheter system is placed in IVC and crossed into abdominal aorta
- TAVR introducer sheath is positioned from femoral vein across the transcaval tract into abdominal aorta
- TAVR is performed normally
- Transcaval tract is closed using a nitinol occluder device



Alternative Access TAVR: Transcaval

- 3D CTA reconstruction of crossing point from IVC to Aorta.
- Simultaneous aorto/venogram



Alternative Access TAVR: Transcaval



Catheter in vena cava – Snare in aorta



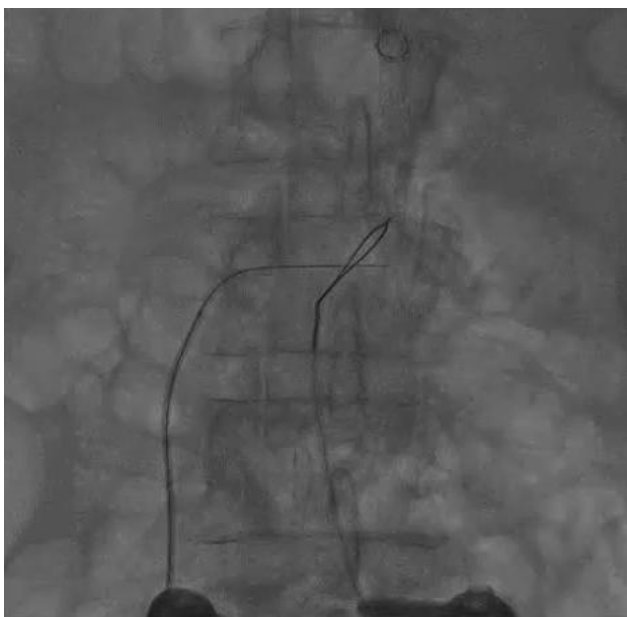
Bulls eye view of crossing site



Alternative Access TAVR: Transcaval



**Energized wire crossing
caval aortic tract**

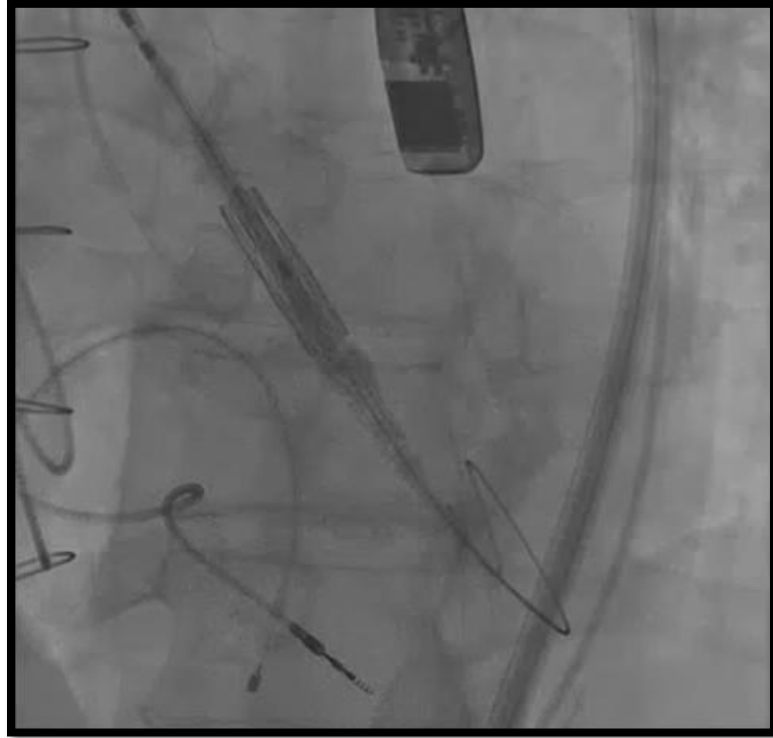


Snaring wire



**Delivery sheath crossing
caval aortic tract**

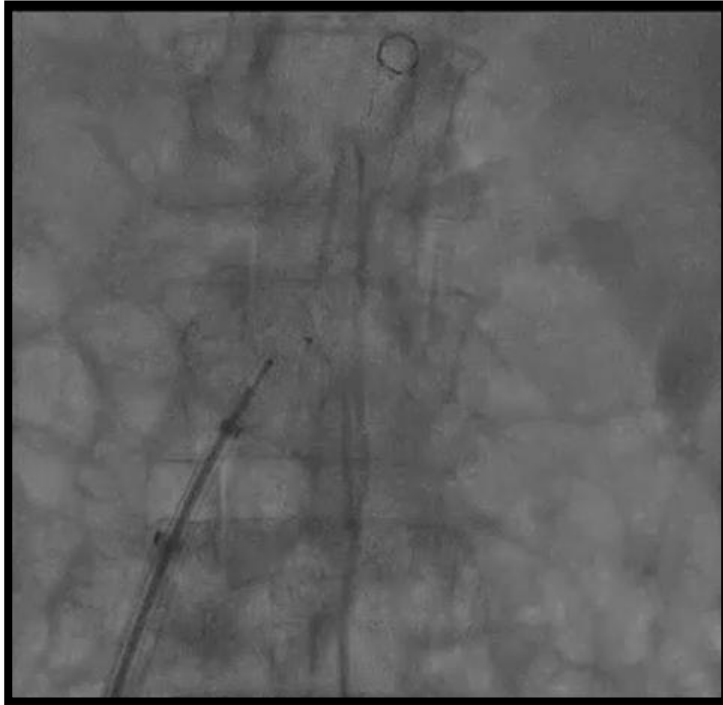
Alternative Access TAVR: Transcaval



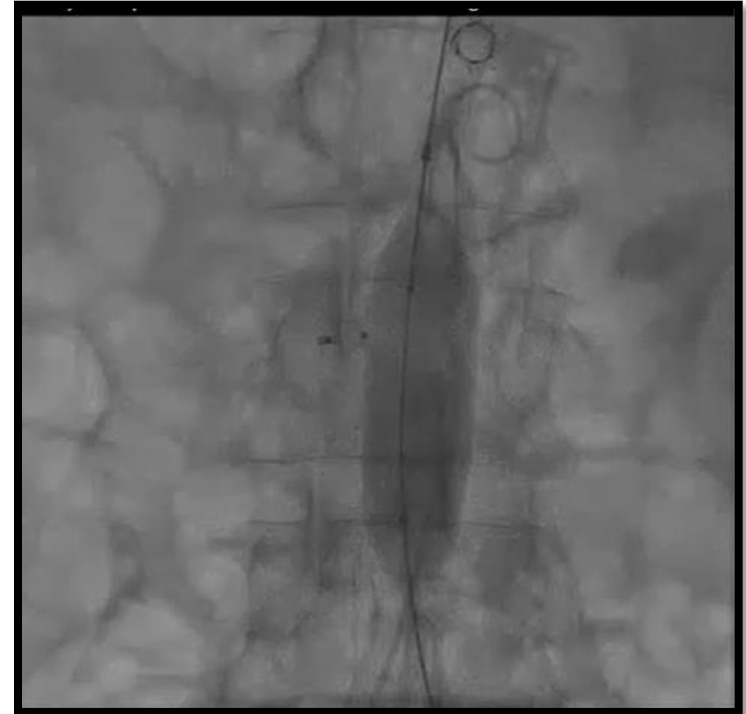
Deployment of Edwards 26mm Sapien 3 THV



Alternative Access TAVR: Transcaval

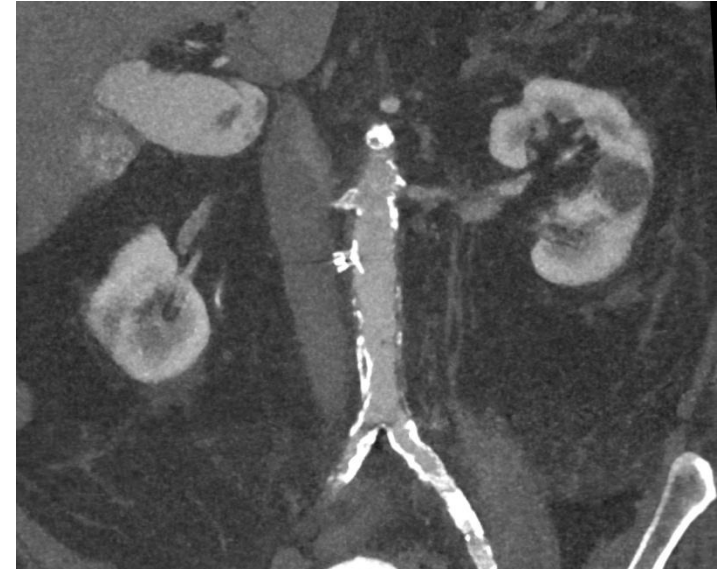
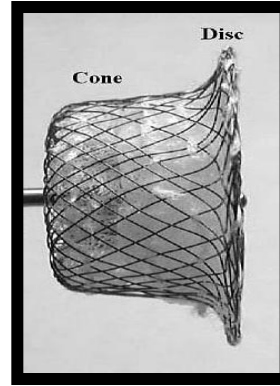


**Deployment of 10/8 mm Amplatzer
Duct Occluder 1 Device**



**20mm x 40mm Atlas Gold Balloon
for adjunctive hemostasis**

Alternative Access TAVR: Transcaval



No aortocaval flow on CTA the next day

Successful Caval-Aortic Tract Closure ADO-1 Device

Patient History

- 70-year-old female with a history of hypertension, dyslipidemia, previous stroke, paroxysmal atrial fibrillation, non-obstructive coronary artery disease.
- Underwent surgical AVR with a 21 mm Sorin Mitroflow bioprosthetic valve in 2009 , who now has severe symptomatic bioprosthetic aortic stenosis secondary to structural valve degeneration causing worsening heart failure symptoms.
- **Echo**: Normal LV and RV, LVEF 65%, Aortic valve peak velocity 5.7m/sec, mean gradient 66mmHg, trace AR.
- Patient high risk for redo surgical aortic valve replacement with an STS score of 12.8%.



What Should We Do?

www.slido.com, enter code B720, select 'POLLs' on to

*Fracture a
surgical valve?
Has this guy
lost his mind?!*

- A. Send the patient home with Lasix
- B. Fracture the surgical valve to make more room for the new valve
- C. Place a new heart valve in the old one and hope it fits ok
- D. Offer Dr. Muhammad's car to the surgeons to do redo surgery



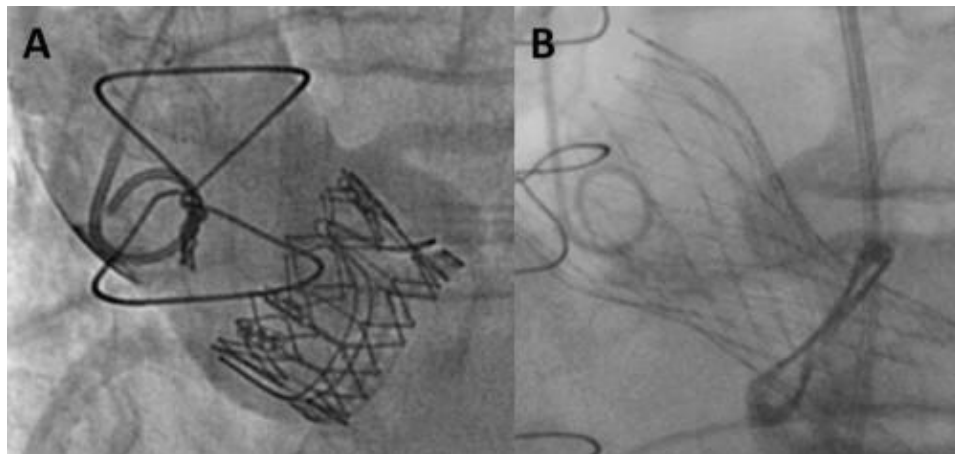
B. Fracture the surgical valve to make room for the new valve

Valve in Valve TAVR with
Bioprosthetic Valve Fracture

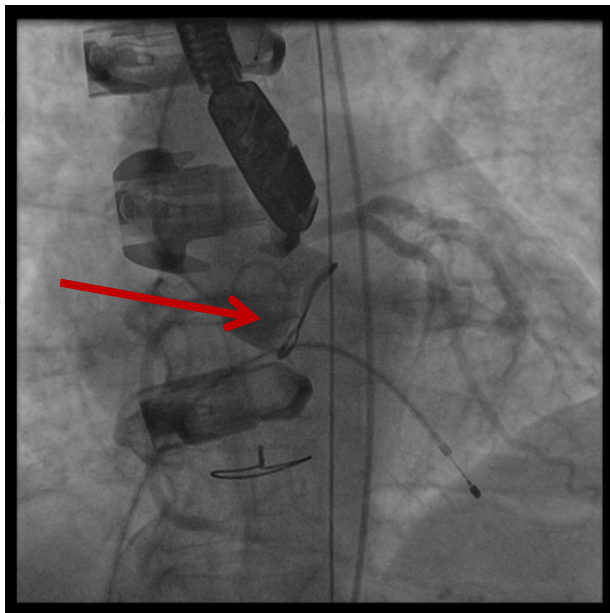
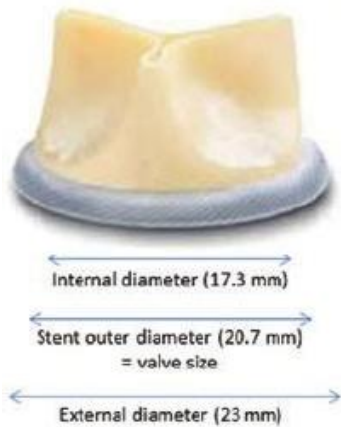


Valve-in-Valve (VIV) TAVR

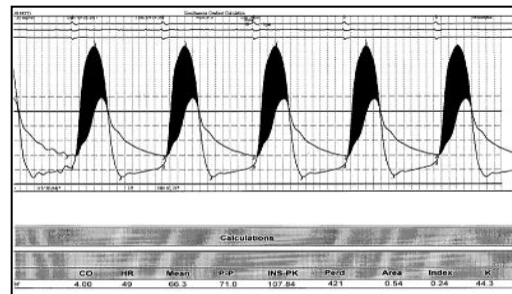
- VIV TAVR is an effective alternative to redo surgery in high risk patients with failing tissue valves.
- However, VIV TAVR can be problematic with small surgical bioprostheses (19/21mm) because of further reduction in the effective orifice leading to high residual gradients – **Patient-Prosthesis Mismatch.**



21mm Sorin Mitroflow Bioprosthetic Valve



21mm Sorin Mitroflow Valve:
Internal Diameter 17mm



Severe bioprosthetic AV stenosis:
Mean gradient: 66mmHg

20mm Sapien 3 placed in 21mm Sorin

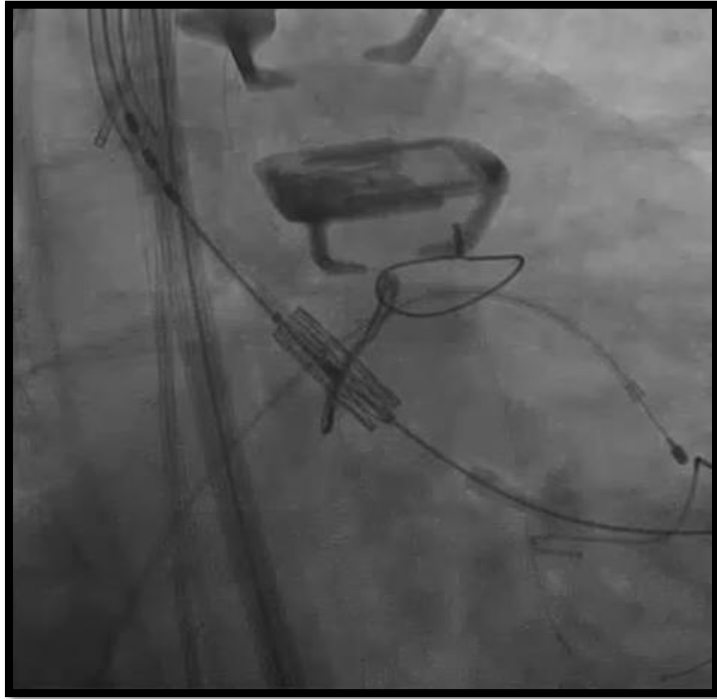


Outer Diameter 20 mm

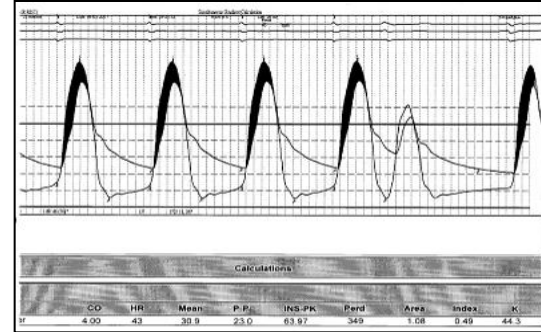


Inner Diameter 17 mm

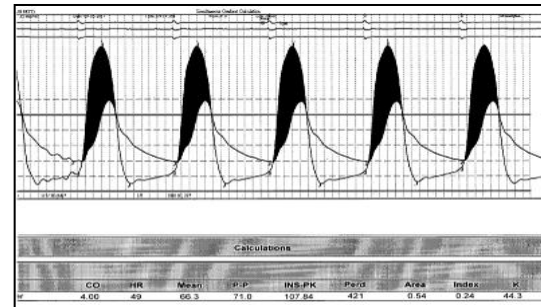
Valve-in-Valve TAVR: 20mm Sapien 3



Deployment of 20mm Sapien 3 in
21mm Sorin Mitroflow

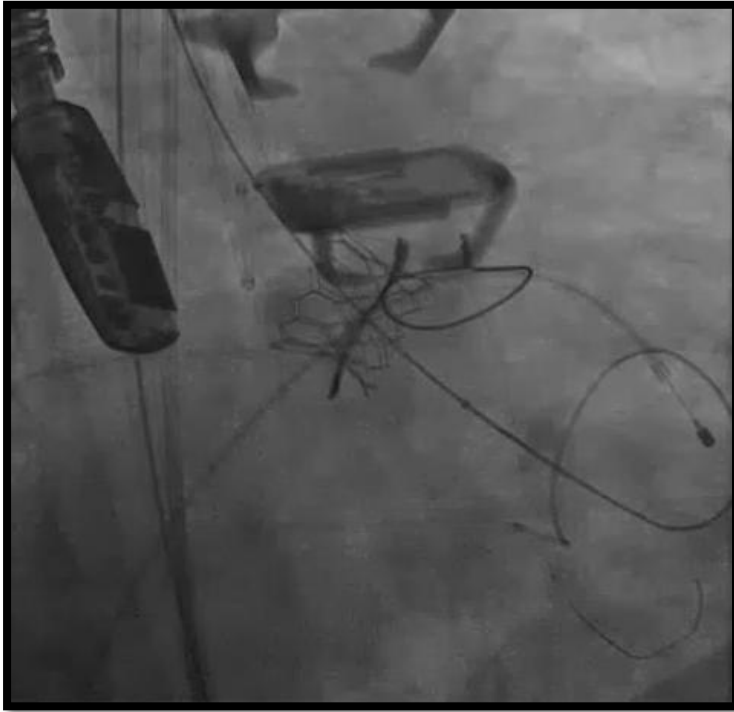


Post deployment mean AV gradient = **31 mmHg**

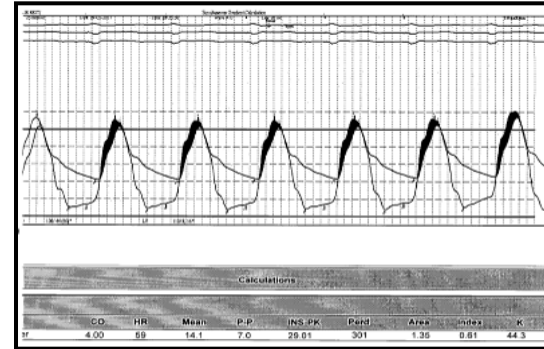


Baseline mean AV gradient = **66 mmHg**

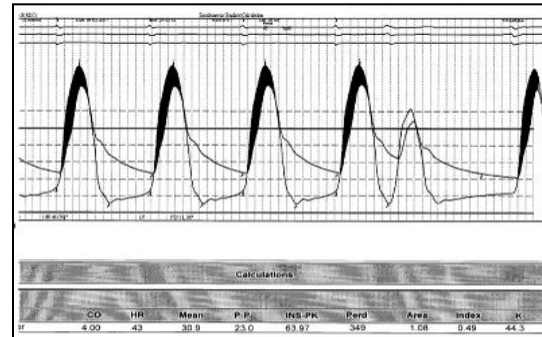
Bioprosthetic Valve Fracture (BVF)



BVF 20mm True Balloon

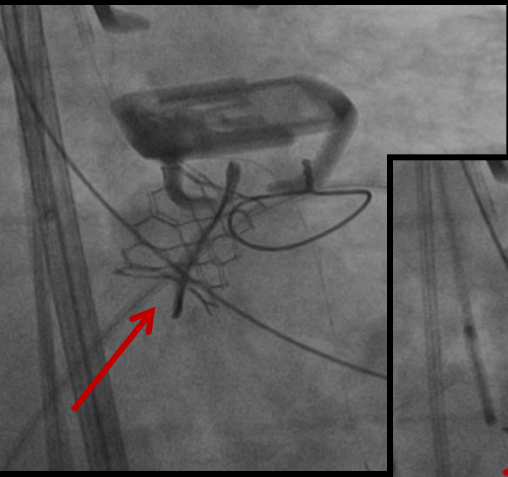


Post BVF mean gradient = **14 mmHg**

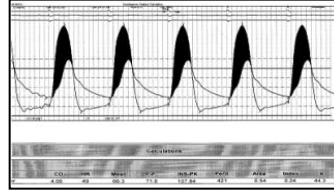


Post deployment mean AV gradient = **31mmHg**

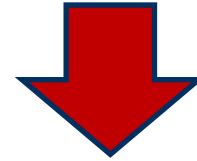
21 mm Sorin Mitroflow s/p VIV TAVR with 20 mm Sapien 3 THV



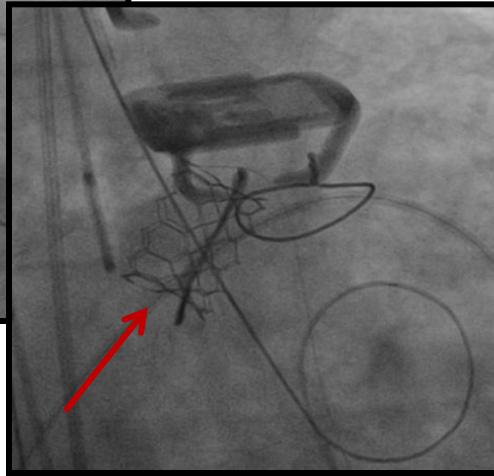
Pre BFV



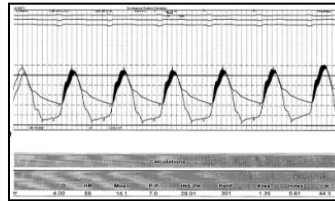
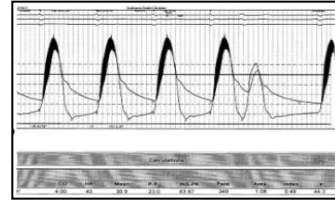
**Severe Bioprosthesis AV Stenosis: Mean
gradient = 66 mmHg**



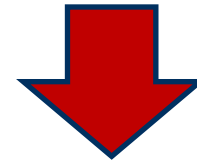
**VIV 20mm Sapien 3:
Mean gradient = 31mmHg**



Post BFV 20 S3 fully expanded

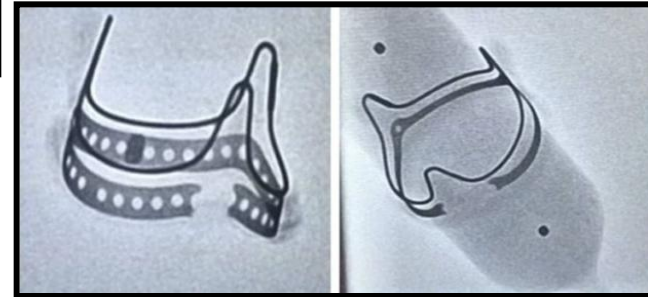
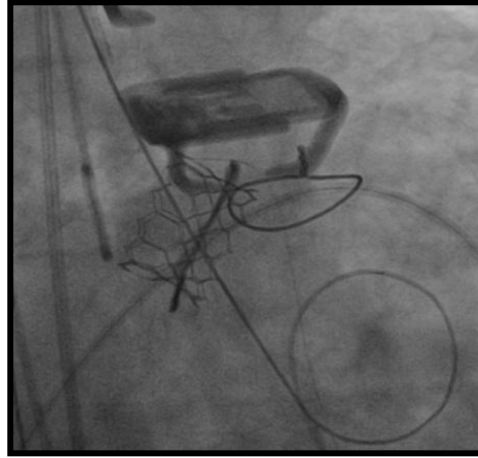


**Post BFV 20mm True Balloon:
Mean gradient = 14 mmHg**

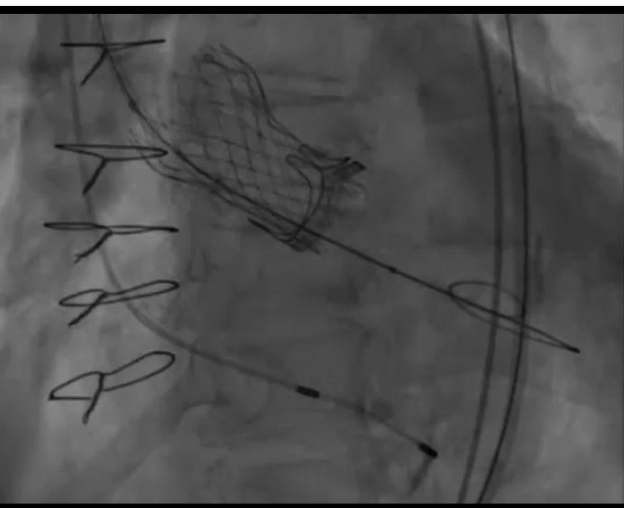


Bioprosthetic Valve Fracture to Optimize VIV TAVR

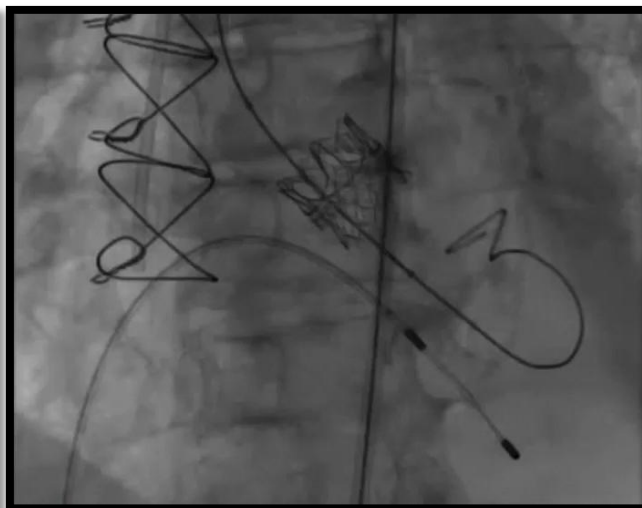
- Valve fracture may allow optimal expansion of the transcatheter heart valve, reduced post VIV residual gradients, and improve outcomes.



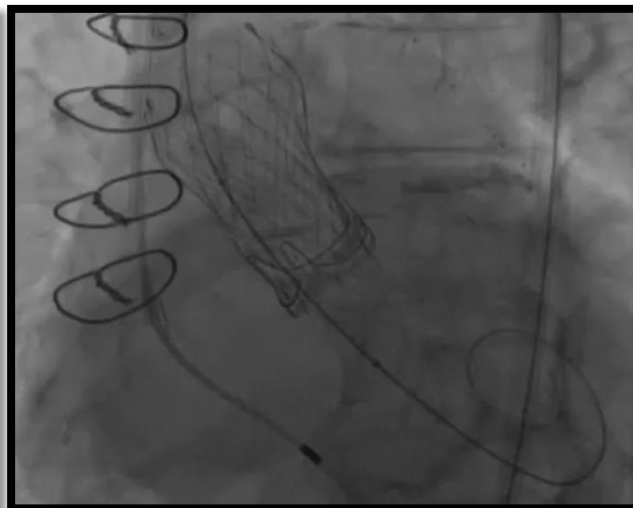
Bioprosthetic Valve Fractures



**26 mm CoreValve Evolute R
inside
23 mm Edwards PERIMOUNT**



**20 mm Sapien 3
inside
19 mm Edwards Magna**



**26 mm CoreValve Evolute R
inside
21 mm Edwards tissue valve**

Patient History

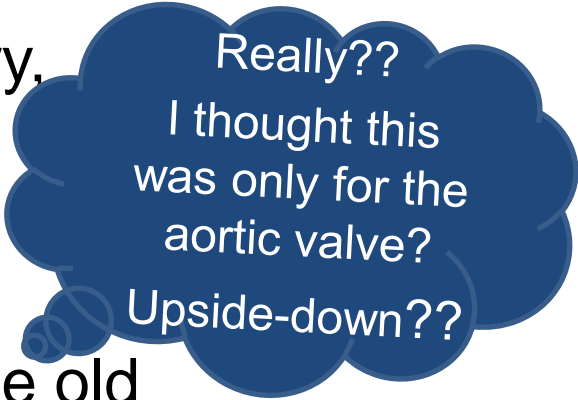
- 85-year-old female from Fayetteville, Arkansas.
- A history frailty, CKD, CAD and valvular heart disease, ischemic cardiomyopathy (LVEF 30% to 35%) who had multiple hospital admissions with acute-on-chronic combined systolic and diastolic heart failure.
- S/P combined CABG and surgical MVR (25 mm Perimount bioprosthetic valve) 2011 who developed severe bioprosthetic mitral valve stenosis due to structural valve degeneration.
- **Mean mitral valve gradient by TEE: 25mmHg**
- Extreme risk for redo sternotomy for redo surgical mitral valve replacement, STS 11.5%.



What Should We Do?

www.slido.com, enter code B720, select 'POLLs' on top

- A. Ask the surgeons to do high risk surgery, ***"pretty please"***?
- B. Do a MitraClip
- C. Place a TAVR valve ***upside-down*** in the old surgical mitral valve
- D. Give the patient medications and hope for the best



Really??
I thought this
was only for the
aortic valve?
Upside-down??

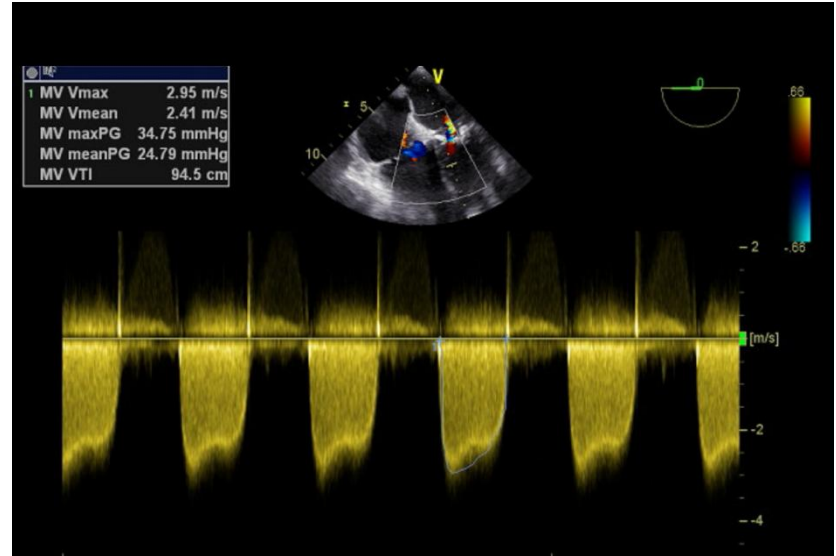
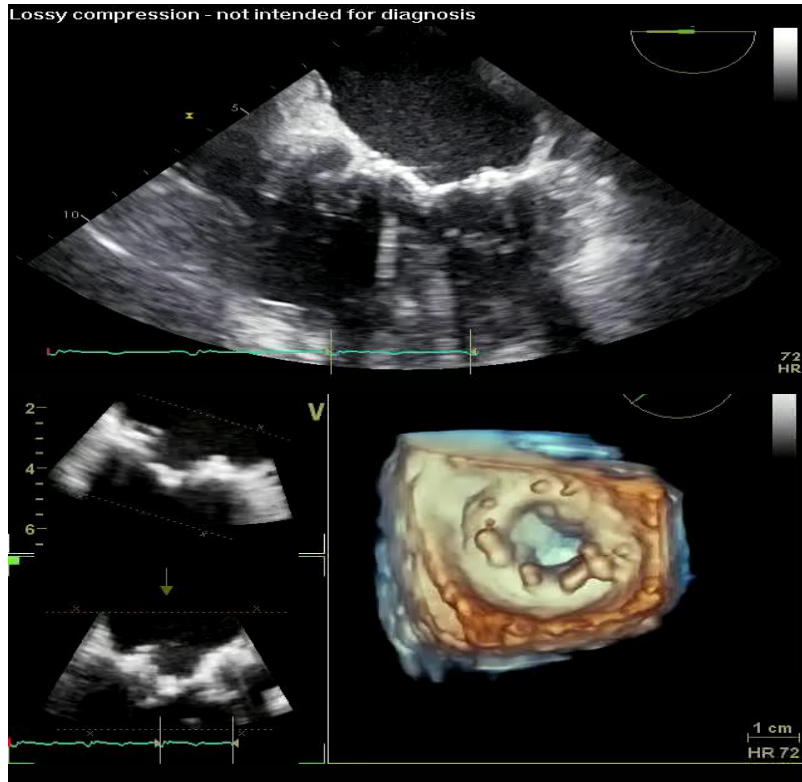


C. Place a TAVR valve upside-down in the old surgical mitral valve

Transcatheter Mitral Valve in Valve Replacement



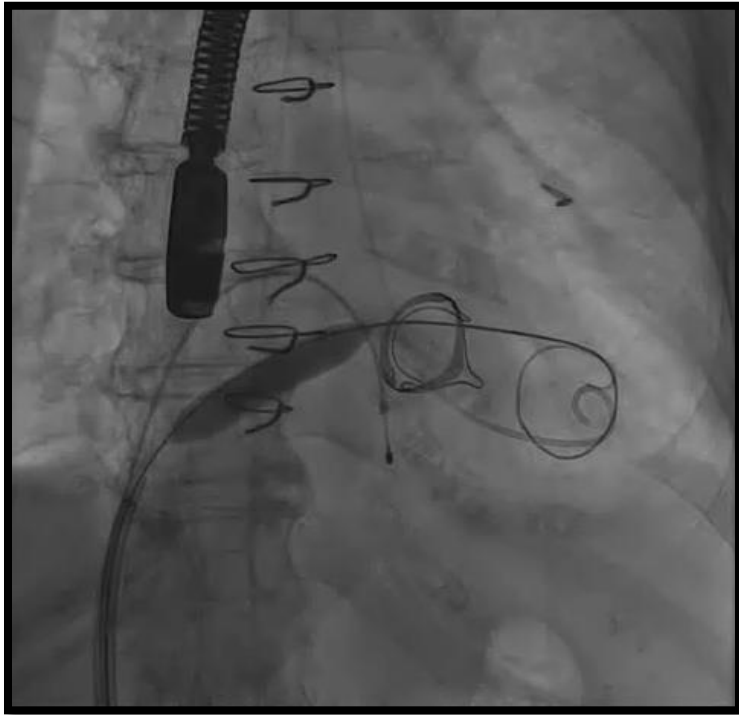
Severe Bioprosthetic Mitral Valve Stenosis 25mm Perimount Surgical Valve



Severe Mitral Stenosis Mean Gradient
= **25mmHg**



Severe Bioprosthetic Mitral Valve Stenosis 25mm Perimount Surgical Valve



Transseptal Access to Mitral Valve

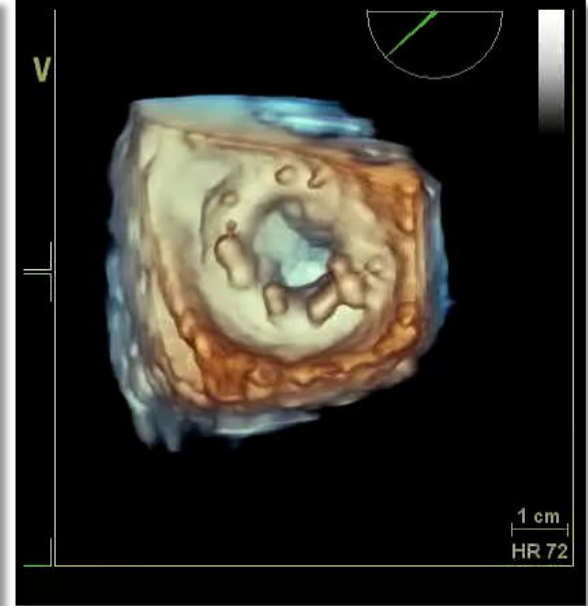


Loading 26mm Edwards Sapien 3 THV

26mm Sapien 3 THV Deployment in 25mm Perimount Surgical Valve



Mitral Valve in Valve Replacement



Post Mitral VIV mean gradient = 5mmHg

Transcatheter Mitral Valve in Ring Replacement

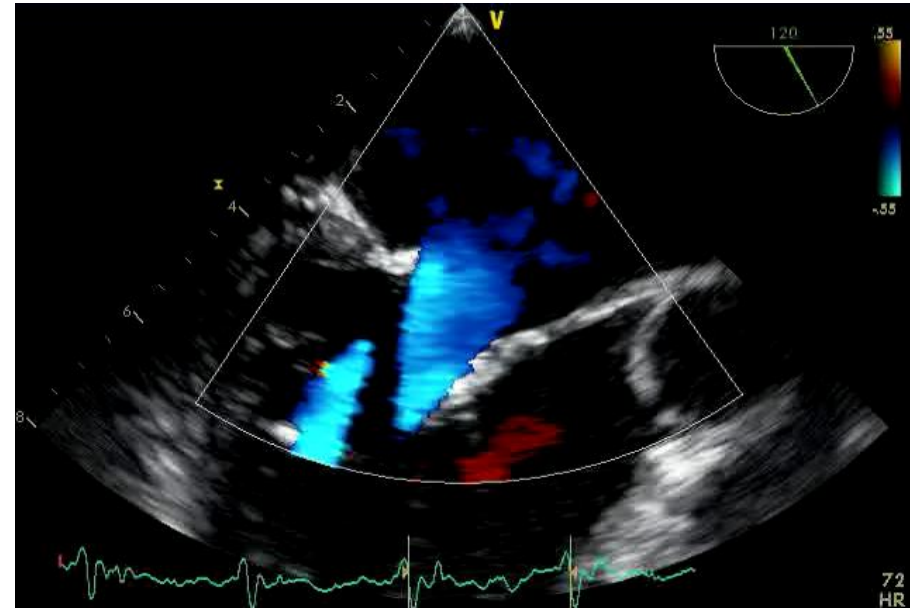
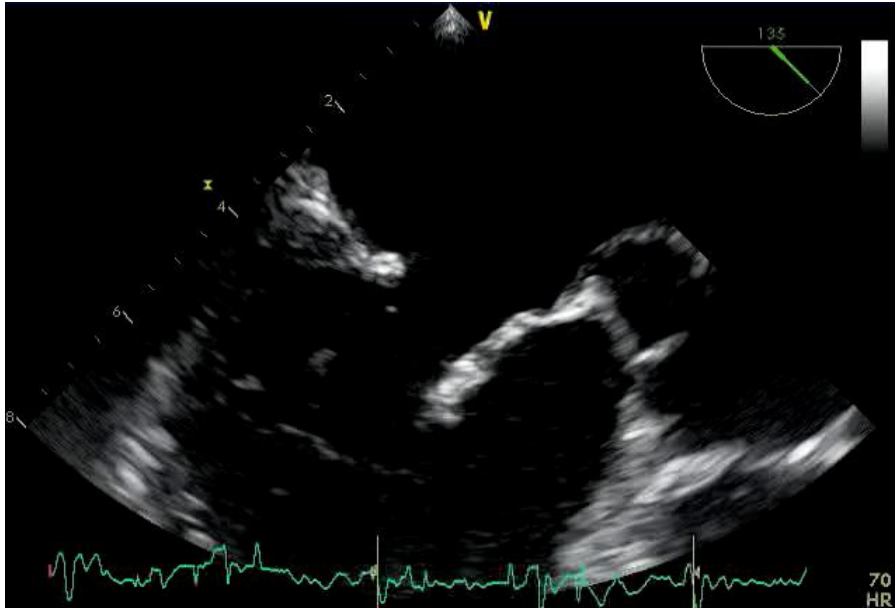


Patient History

- 81-year-old female with a history of HTN,slipidemia, type 2 DM, stage III CKD, PAF, ischemic cardiomyopathy (left ventricular ejection fraction 40%-45%)
- Coronary artery disease and valvular heart disease, status post coronary artery bypass grafting surgery and surgical mitral valve repair (**26 mm Cosgrove ring**) in **2002**
- Now with severe 4+ mitral regurgitation
- High risk for redo surgical mitral valve replacment, STS 11%
- **Plan:** percutaneous transcatheter mitral valve in valve replacement



Severe Bioprosthetic Mitral Regurgitation 26mm Cosgrove Ring

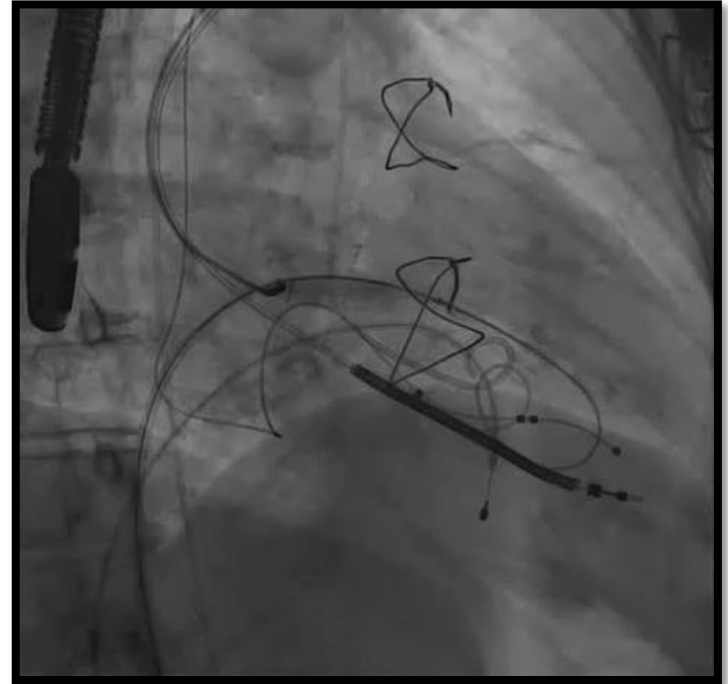


Severe 4+ Mitral Regurgitation

Severe Bioprosthetic Mitral Regurgitation 26mm Cosgrove Ring

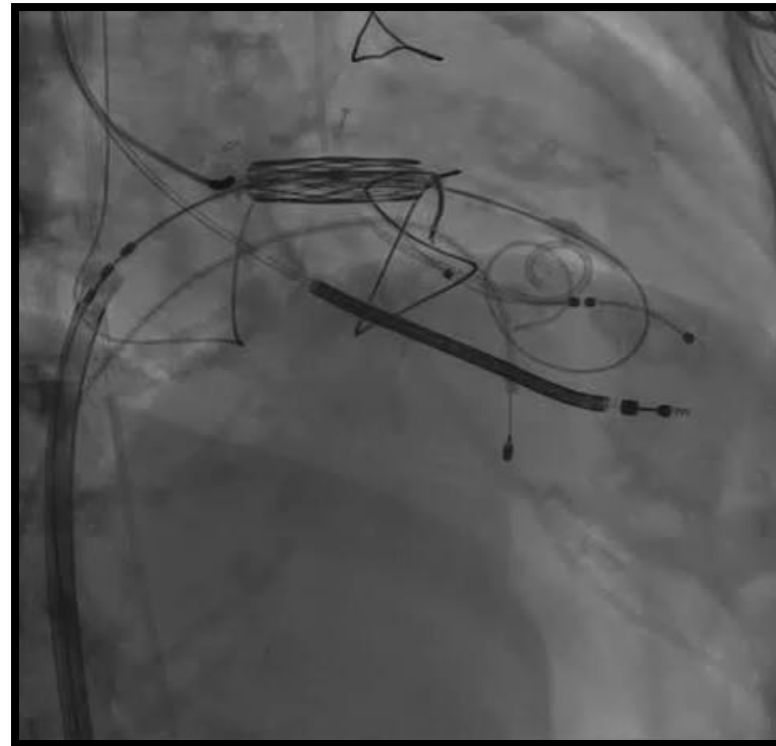


Transseptal Access to Mitral Valve

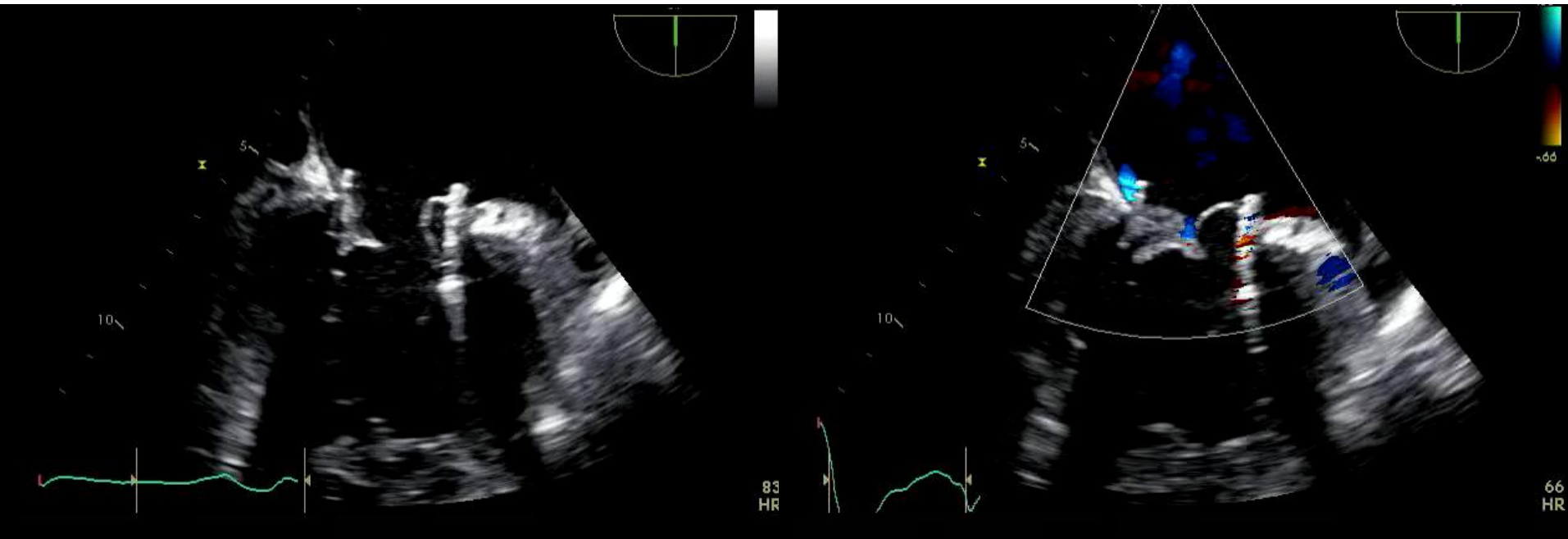


Balloon sizing with 25mm x 4cm balloon

Deployment of 29mm Sapein 3 THV in 26mm Cosgrove Ring

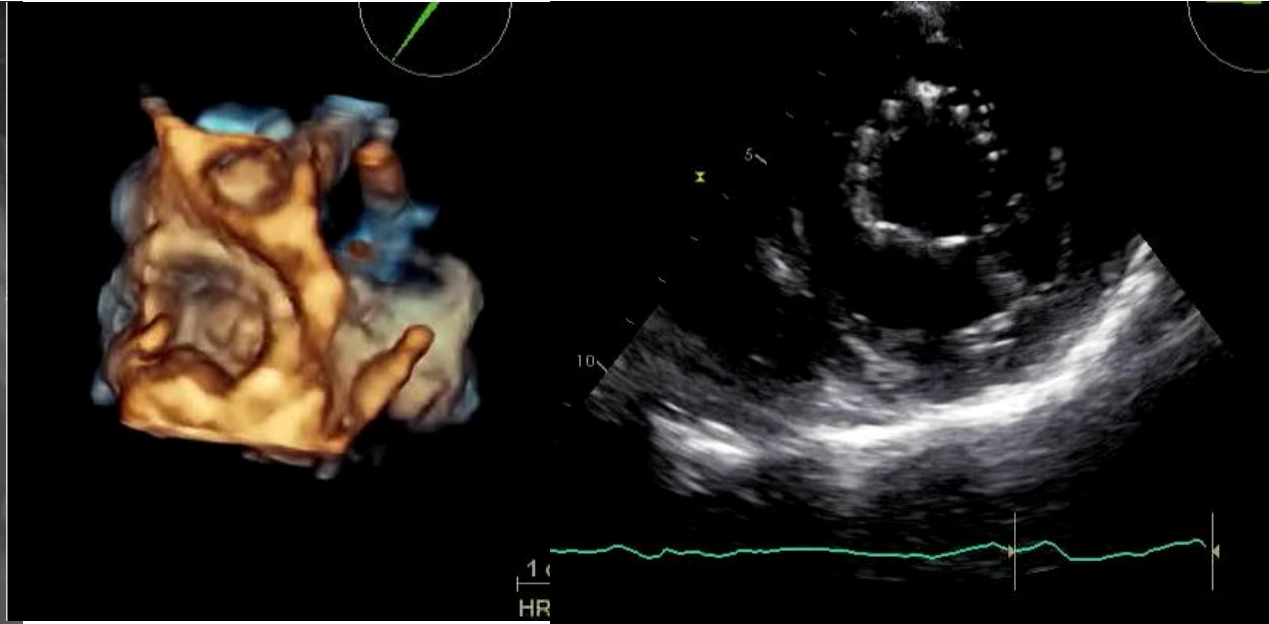


Deployment of 29mm Sapein 3 THV in 26mm Cosgrove Ring



Trace paravalvular regurgitation

Transcatheter Mitral Valve-in-Ring Replacement



Mean MV gradient 1.9 mmHg; Trace MR



Transcatheter Mitral Valve Repair MitraClip

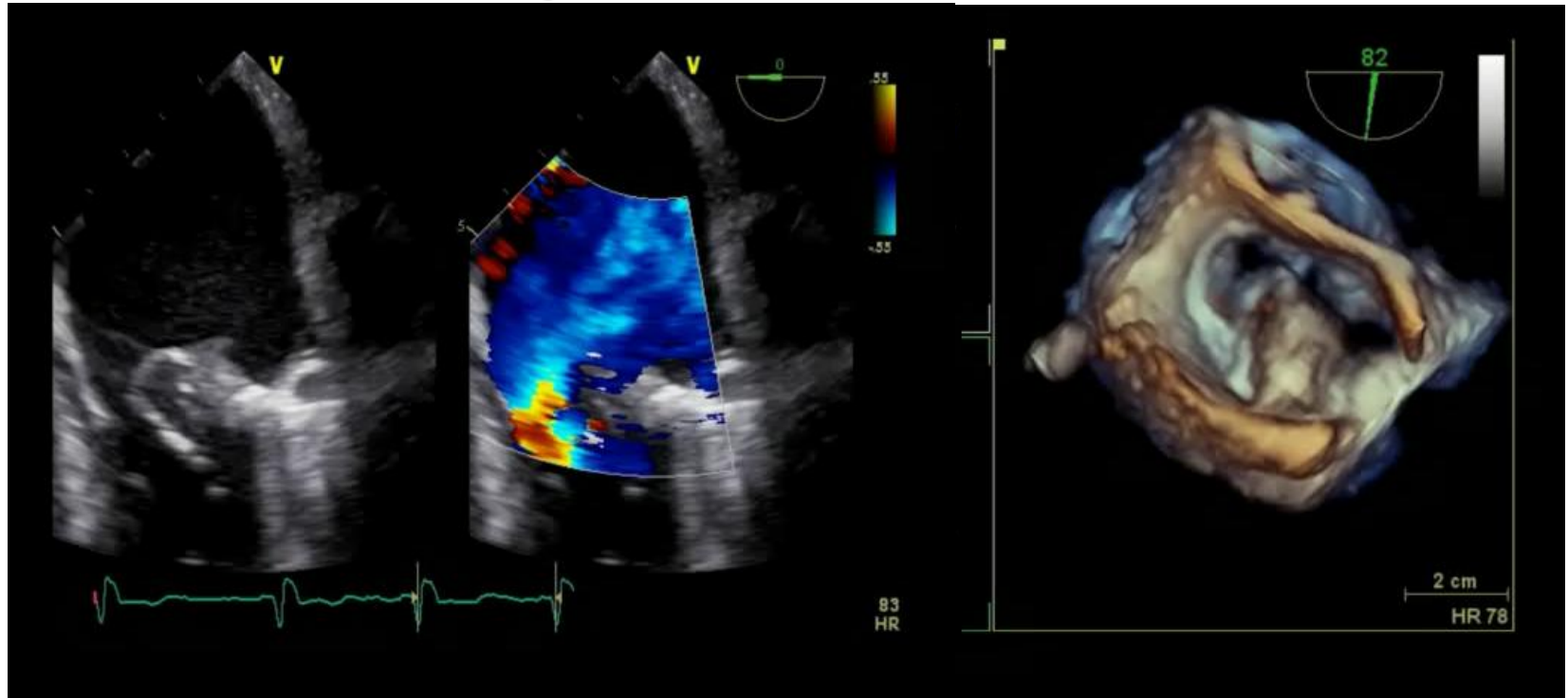


Patient History

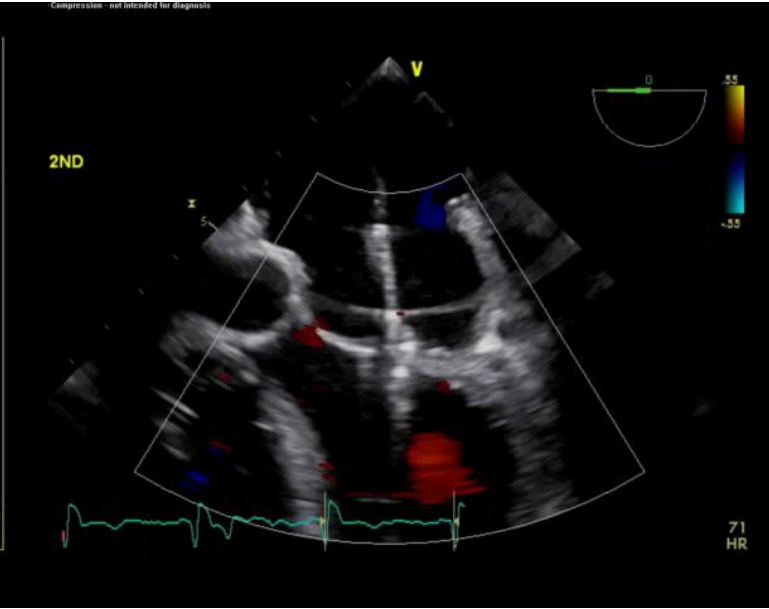
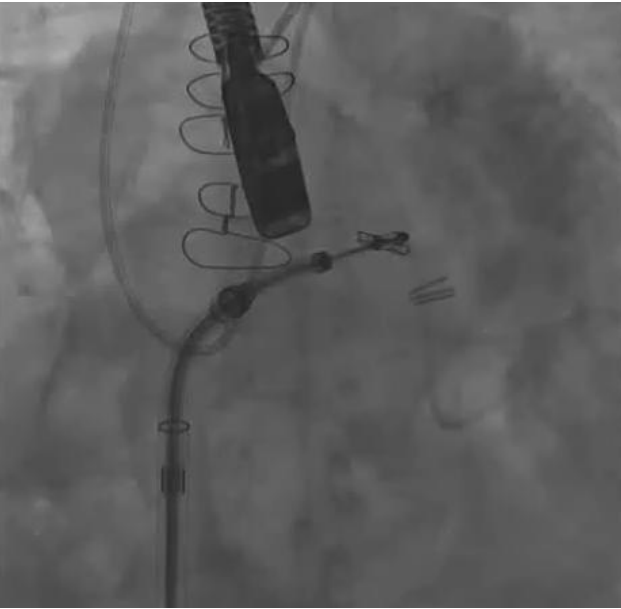
- 85 yo male
- History of HTN, dyslipidemia, COPD, persistent atrial fibrillation, CAD previous CABG, chronic kidney disease, who was hospitalized due to acute on chronic diastolic heart failure and cardiogenic shock related severe mitral regurgitation.
- The patient was previously admitted four times in the previous 2 month for acute heart failure.
- The patient was high risk for surgical mitral valve replacement/repair (STS 13%).
- Plan: Transcatheter Mitral Valve Repair with MitraClip

Severe Mitral Regurgitation by TEE

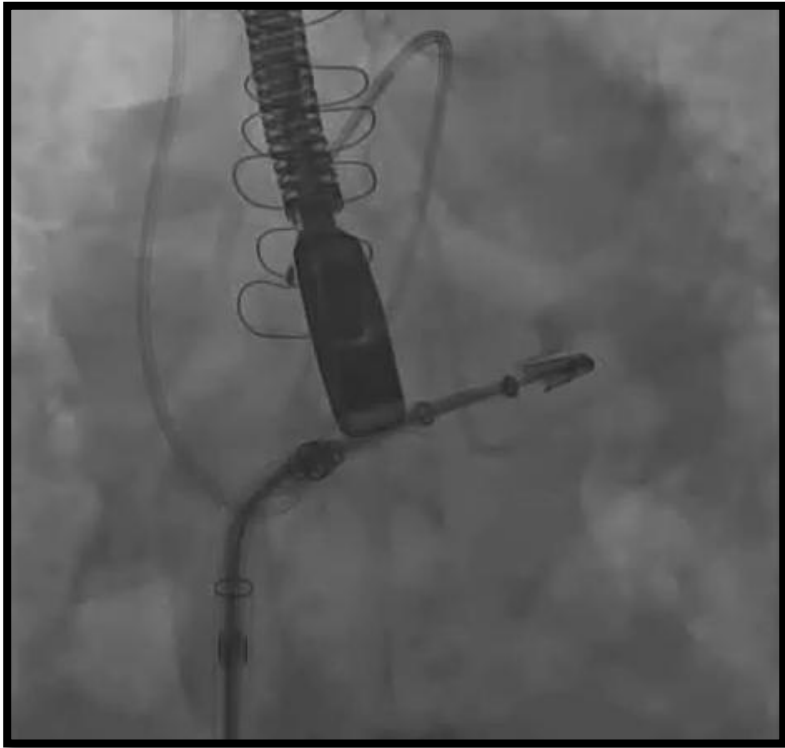
Severe Prolapse of Anterior MV Leaflet



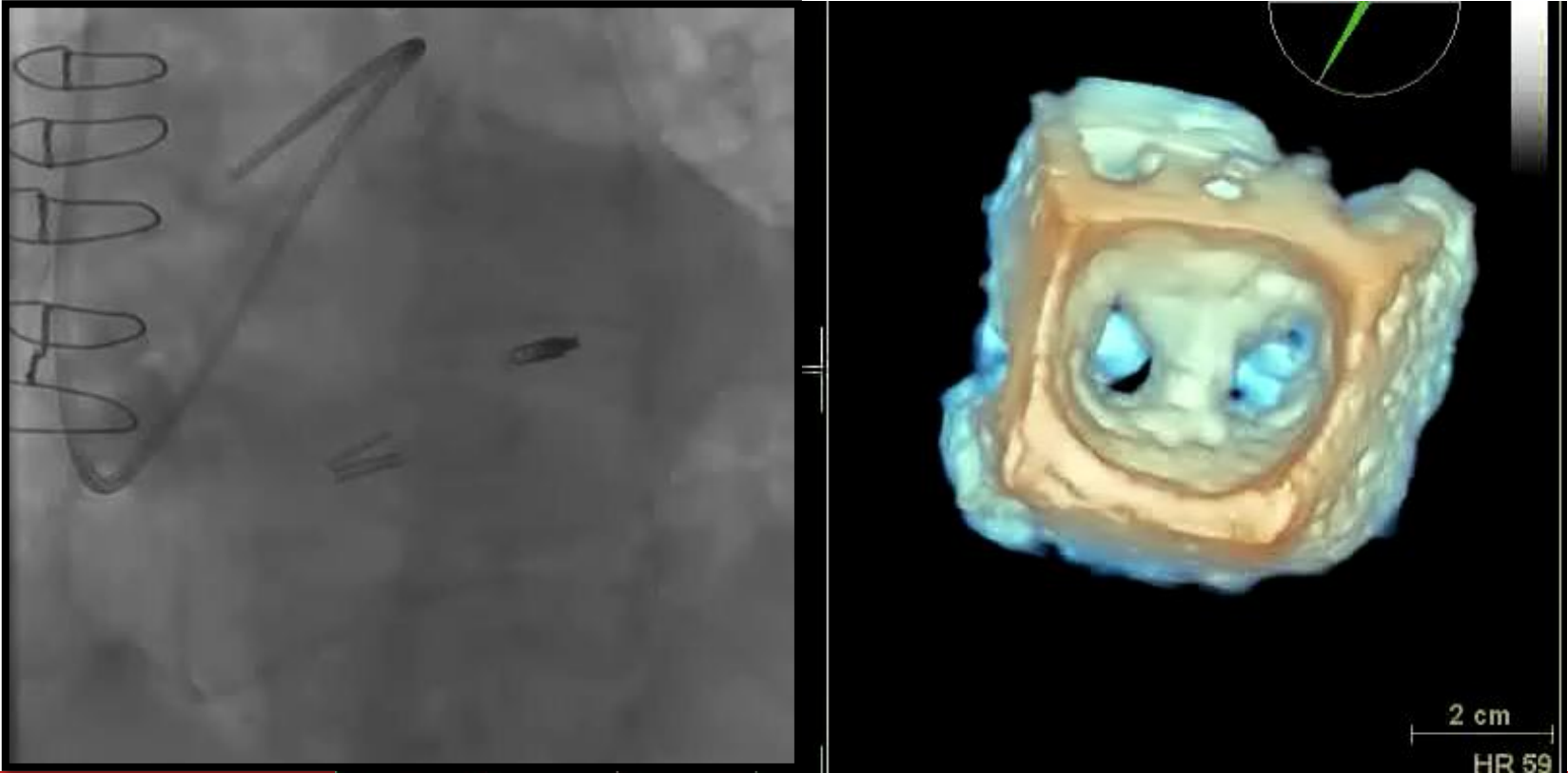
Clip Positioning



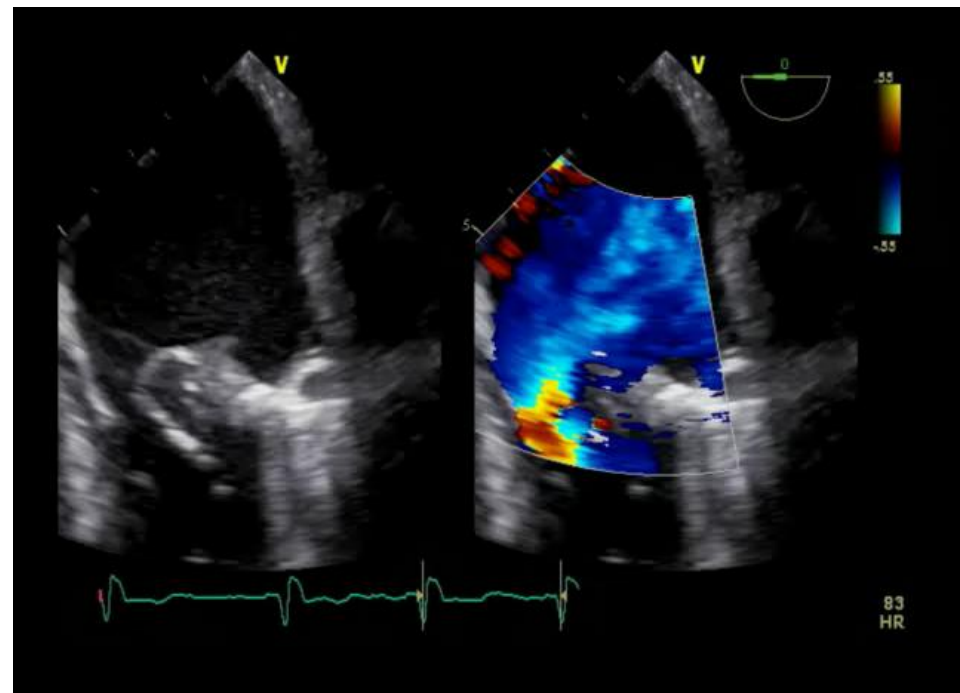
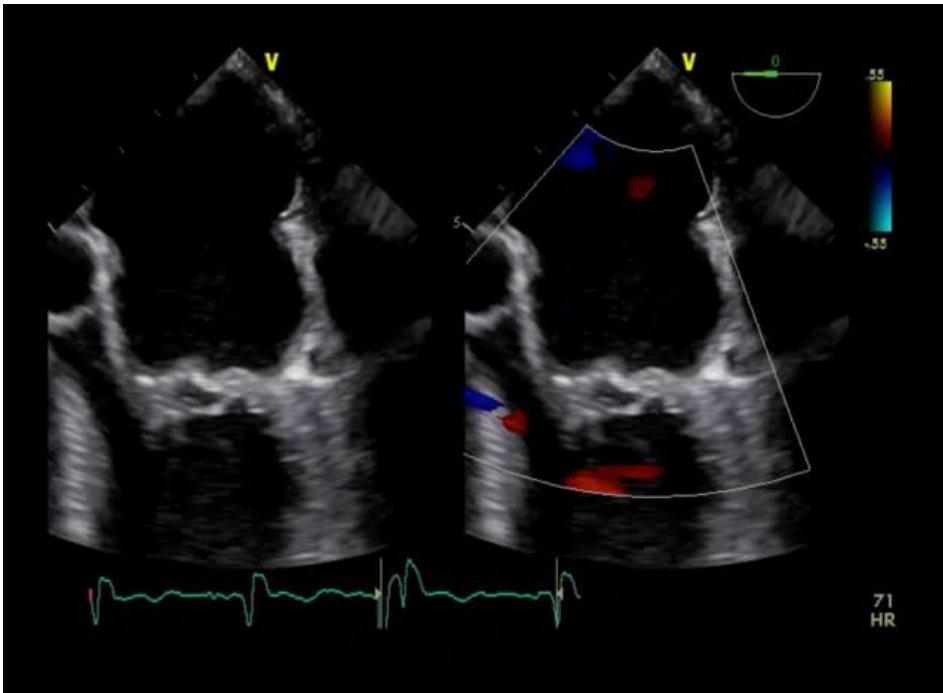
Leaflet Grasp



Final Clip Deployment



Trace – 1+ MR post Single Clip



Stay Tuned

- TAVR for low-risk patients
- Transcatheter mitral valve repair replacement
- Transcatheter tricuspid valve repair





THANK YOU !

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