

# Lifetime Management of Aortic Valve Disease: A Surgeon's Perspective

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# Disclosures

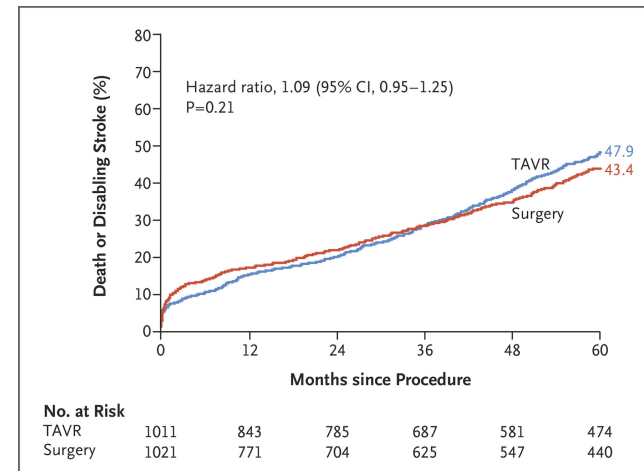
- Terumo Aortic, Medtronic & Artivion, Consultant
- Artivion PERSEVERE trial, Steering Committee

# Summary of This Presentation

1. Transcatheter aortic valve replacement (TAVR) has changed the treatment paradigm of aortic stenosis (AS) and some of other aortic valve disease
2. Minimally invasive therapy/Innovation does not necessarily lead satisfactory (long-term) outcomes
3. It is of paramount importance to understand limitations of these innovative approaches and provide the best care for our patients.

# Introduction – What We Need to Know from TAVR/SAVR RCTs

- TAVR is an established treatment for severe AS [1,2].
- Further expansion of indications includes AS with bicuspid pathology [3].
- The breakdown of implanted surgical valves were mostly NOT reported in the TAVR RCTs.
- The details for valve reinterventions were NOT reported in the previous TAVR RCTs.



5-year survival TAVR vs SAVR in patients with intermediate-risk [4]

1. Mack MJ, et al. N Engl J Med. 2019;380:1695-1705.
2. Popma JJ, et al. N Engl J Med. 2019;380:1706-1715.
3. Forrest JK,, et al. JAMA Cardiol. 2021;6:50-57.
4. Makker R, et al. N Engl J Med 2020; 382:799-809.

# What do we know about valve reinterventions from TAVR/SAVR clinical trials?

-There were some unfairness existed between groups in RCTs. Lots of SAVR valves were prostheses with externally-wrapping design. More patients received concomitant surgeries in the SAVR arm.

# TAVR/SAVR RCT Design Issues

TAVR  
(one valve type) vs SAVR valve  
(multiple different valves)

Is this fair comparison?

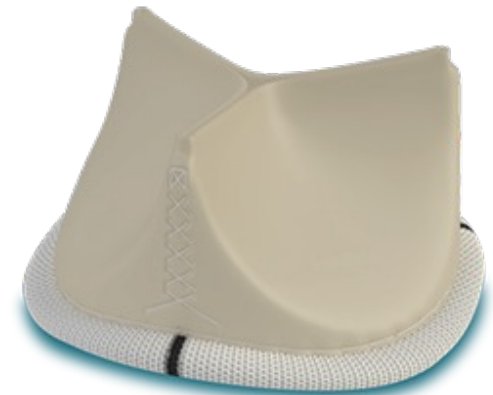
# TAVR/SAVR RCT Design Issues

Internally mounted leaflet

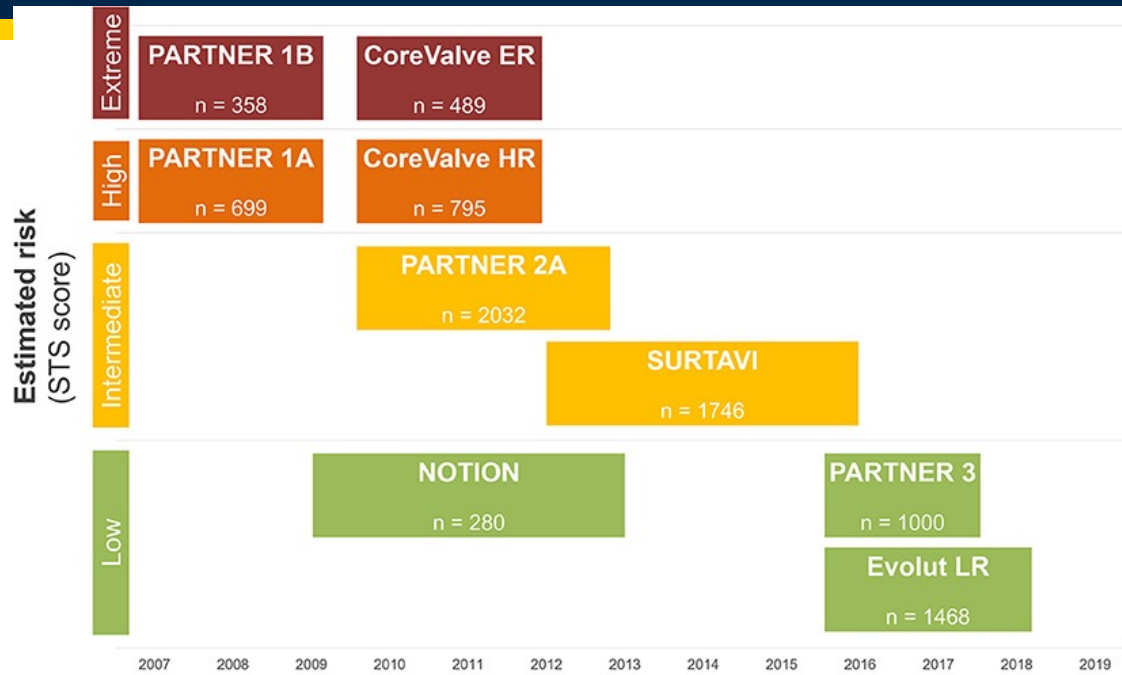


Externally mounted leaflet

VS



# SAVR Valve Make & Model Breakdown in TAVR/SAVR Clinical Trials



## Implanted SAVR valve type

NOTION: 24% Trifecta, 10% Mitroflow

PARTNER 3: 19% Trifecta

SURTAVI: 29% Trifecta

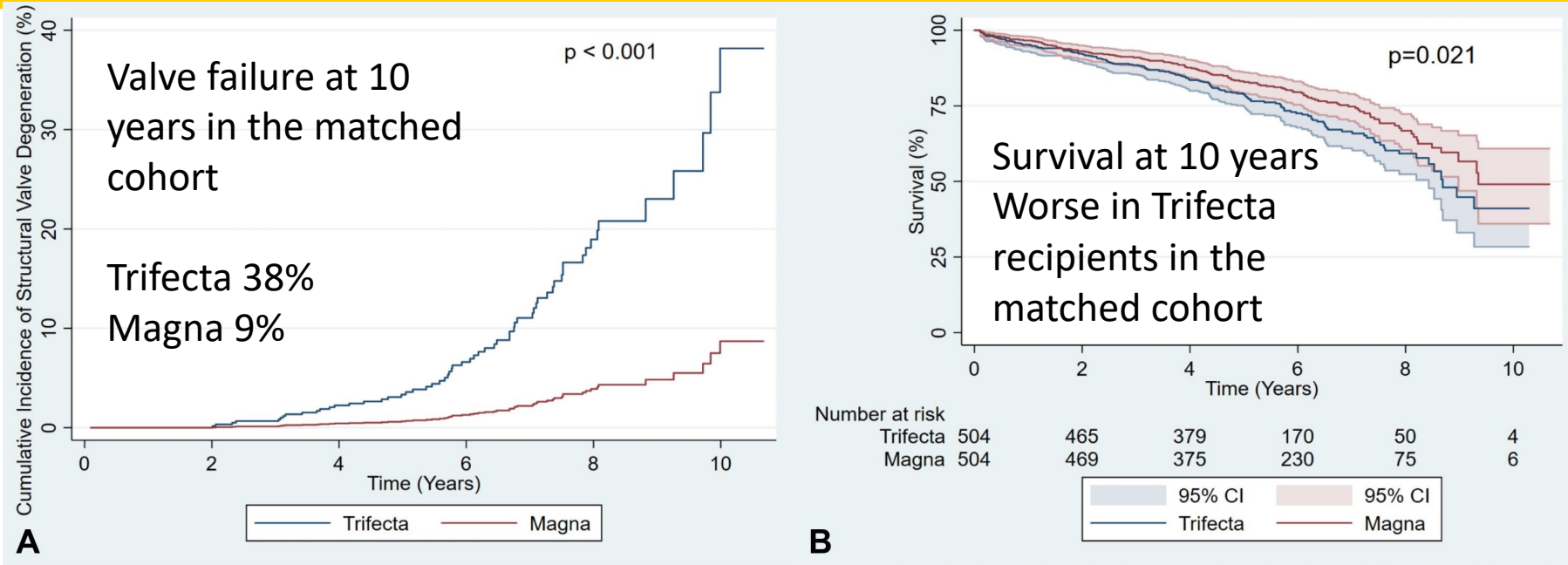
Others: Not disclosed.



W  
Car



# The potential impact of externally mounted leaflet bioprosthesis on TAVR clinical trials



Trifecta was used in 20-30% of SAVR arm patients in the landmark TAVR clinical trials.

4 times higher SVD rate

Higher 10-year mortality in the matched cohort

Fukuhara et al. Western Thoracic Surgical Association Meeting 2022

# ACC 22: 5Y Incidence, Timing & Predictors of HVD of Transcatheter & Surgical Aortic BP

Published: 04 Apr 2022

Views: 790 | Likes: 1



The slide features a dark blue background with red and white wavy borders at the top and bottom. In the top left corner is a small square icon with a green 'P' and a blue circle. The main title 'Findings from the CoreValve US Pivotal & SURTAVI Trials' is in white text. Below the title is a large white play button icon. To the left of the play button is the 'ACC 2022' logo. Below the logo, it says 'WITH Dr Michael J Reardon' and 'Houston Methodist DeBakey Heart and Vascular Center Houston, TX, US'. On the right side, there is a circular portrait of Dr. Michael J. Reardon, a man with glasses wearing a white lab coat and a red tie. A share icon is in the top right corner.

Structural valve degeneration (SVD) rate  
4.38% (SAVR) vs 2.57% (TAVR)

**SURTAVI: Trifecta implanted in 29% patients.**



Despite RCT results, it remains very unclear if **contemporary SAVR valves** have worse SVD rate compared with TAVR valves

# Concomitant Surgery?

ORIGINAL ARTICLE

## Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

Michael J. Mack, M.D., Martin B. Leon, M.D., Vinod H. Thourani, M.D., Raj Makkar, M.D., Susheel K. Kodali, M.D., Mark Russo, M.D., Samir R. Kapadia, M.D., S. Chris Malaisrie, M.D., David J. Cohen, M.D., Philippe Pibarot, D.V.M., Ph.D., Jonathon Leipsic, M.D., Rebecca T. Hahn, M.D., [et al.](#), for the PARTNER 3 Investigators\*

May 2, 2019

N Engl J Med 2019; 380:1695-1705

DOI: 10.1056/NEJMoa1814052

Chinese Translation [中文翻译](#)

**Table S2. Concomitant Procedures (TAVR & Surgery)**

TAVR	n/N (%)
PCI*	32/496 (6.5)
Pacemaker or ICD	5/496 (1.0)
Other†	2/496 (0.4)

\*includes stenting and balloon angioplasty

†includes 1 patient who was converted to surgery and received an aortic root enlargement

Surgery	n/N (%)
CABG	58/454 (12.8)
MAZE*	22/454 (4.8)
LAA ligation	43/454 (9.5)
Root enlargement	21/454 (4.6)
Ascending aorta replacement	1/454 (0.2)
Aortic endarterectomy	4/454 (0.9)
Septal myomectomy	4/454 (0.9)
MVR (replacement or repair)	6/454 (1.3)
TVR (replacement or repair)	4/454 (0.9)
Other	1/454 (0.2)

\*includes MAZE, Extended L atrial maze, Extended L + R atrial maze, Pulmonary vein isolation

# Scant Data Regarding Valve Reintervention after TAVR

## The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

FEBRUARY 27, 2020

VOL. 382 NO. 9

### Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement

R.R. Makkar, V.H. Thourani, M.J. Mack, S.K. Kodali, S. Kapadia, J.G. Webb, S.-H. Yoon, A. Trento, L.G. Svensson, H.C. Herrmann, W.Y. Szeto, D.C. Miller, L. Satler, D.J. Cohen, T.M. Dewey, V. Babaliaros, M.R. Williams, D.J. Kereiakes, A. Zajarias, K.L. Greason, B.K. Whisenant, R.W. Hodson, D.L. Brown, W.F. Fearon, M.J. Russo, P. Pibarot, R.T. Hahn, W.A. Jaber, E. Rogers, K. Xu, J. Wheeler, M.C. Alu, C.R. Smith, and M.B. Leon, for the PARTNER 2 Investigators\*

Aortic valve reintervention  
3.2% (TAVR) VS 0.8% (SAVR)  
(HR 3.28, 95% CI 1.32-8.13)

Competing events (death) were **NOT** considered.

The details **NOT** reported.

### ORIGINAL INVESTIGATIONS

### 5-Year Outcomes of Self-Expanding Transcatheter Versus Surgical Aortic Valve Replacement in High-Risk Patients



Thomas G. Gleason, MD,<sup>a</sup> Michael J. Reardon, MD,<sup>b</sup> Jeffrey J. Popma, MD,<sup>c</sup> G. Michael Deeb, MD,<sup>d</sup> Steven J. Yakubov, MD,<sup>e</sup> Joon S. Lee, MD,<sup>a</sup> Neal S. Kleiman, MD,<sup>b</sup> Stan Chetcuti, MD,<sup>d</sup> James B. Hermiller, Jr, MD,<sup>f</sup> John Heiser, MD,<sup>g</sup> William Merhi, DO,<sup>g</sup> George L. Zorn III, MD,<sup>h</sup> Peter Tadros, MD,<sup>h</sup> Newell Robinson, MD,<sup>i</sup> George Petrossian, MD,<sup>j</sup> G. Chad Hughes, MD,<sup>j</sup> J. Kevin Harrison, MD,<sup>j</sup> John V. Conte, MD,<sup>k</sup> Mubashir Mumtaz, MD,<sup>l</sup> Jae K. Oh, MD,<sup>m</sup> Jian Huang, MD, MS,<sup>n</sup> David H. Adams, MD,<sup>o</sup> for the CoreValve U.S. Pivotal High Risk Trial Clinical Investigators

Aortic valve reintervention  
3.0% (TAVR) VS 1.1% (SAVR) (p=0.04)

Competing events (death) were **NOT** considered.

The details **NOT** reported.

# Repeat TAVR Data: Omitted Patient Data without Suitable Anatomy

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AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION

VOL. 75, NO. 16, 2020



## Repeat Transcatheter Aortic Valve Replacement for Transcatheter Prosthesis Dysfunction

Landes et al. JACC 2020 Apr 28;75(16):1882-1893

212 repeat TAVR procedures  
85.1% procedure success

What happened to patients **WITHOUT** successful repeat TAVR?  
What happened to patients **WITHOUT** suitable anatomy for repeat TAVR?

→ None reported.

# What is special about reoperations after TAVR?

2018: 87 yo F with 23 mm Sapien

An intraoperative photograph showing a surgical incision in the aorta. The incision is made in the ascending aorta, approximately 2-3 cm above the aortic valve. The incision is held open with surgical retractors. The surrounding tissue is red and moist, indicating a surgical field. The text "STANDARD AORTOTOMY LOCATION FOR BALLOON EXPANDABLE VALVE EXPLANT" is overlaid on the image in white, bold, sans-serif font.

**STANDARD AORTOTOMY LOCATION FOR  
BALLOON EXPANDABLE VALVE EXPLANT**



# Why Reoperation Data After TAVR Important?

My questions after the first post-TAVR reoperation experience in 2018

1. Is it easy? → **Nobody knew**
2. Do we have the data? → **Only case reports**
3. How many people with failed TAVR received redo TAVR?  
How about reoperation? → **No data**
4. Are we using TAVRs appropriately? → **??**
5. Are we offering appropriate surgical options? → **??**

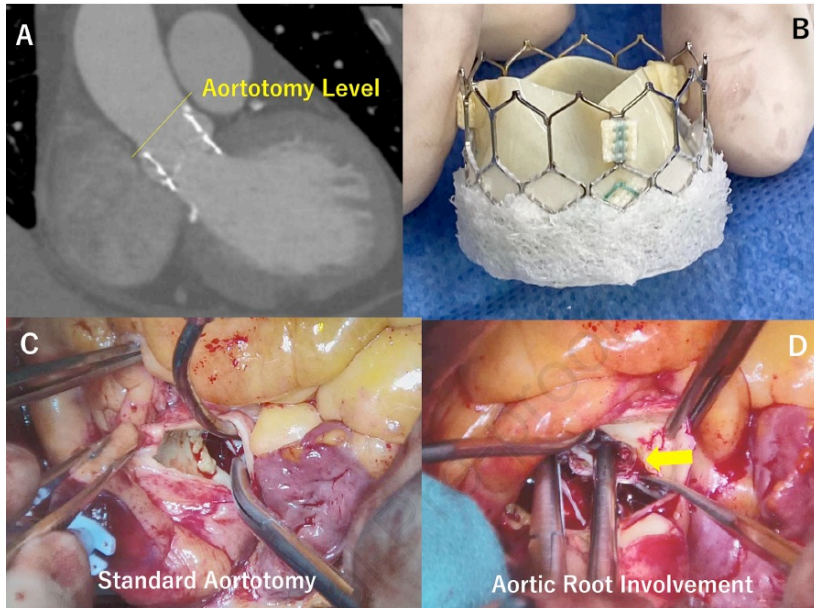
# What I learned between 2018-2019

## What is special about reoperations after TAVR?

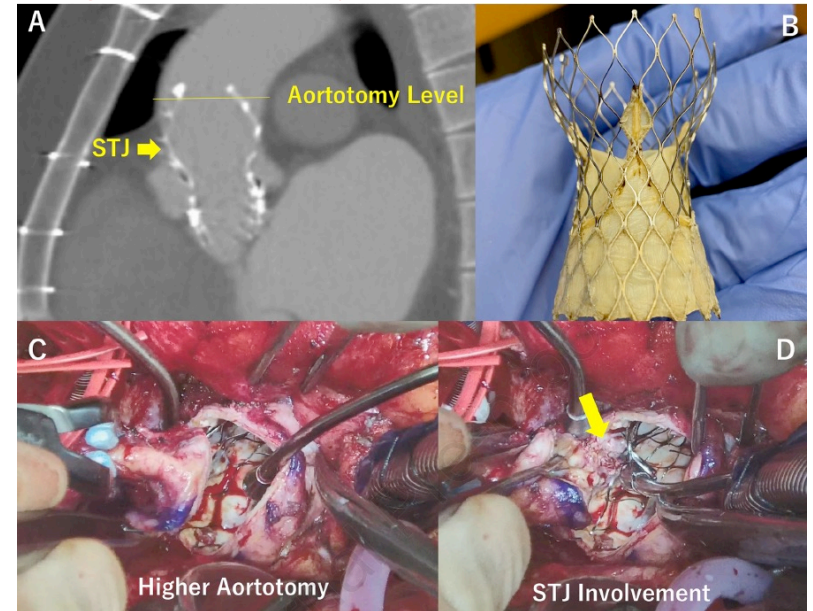
- It is not as easy as people think (a lot more difficult than redo SAVRs).
- TAVR→SAVR is a bad idea.
- Consider TAVRs carefully for lower risk younger patients.

# Aortotomy

Balloon-expandable device  
Standard aortotomy



Self-expandable device  
High aortotomy for "late" explantation



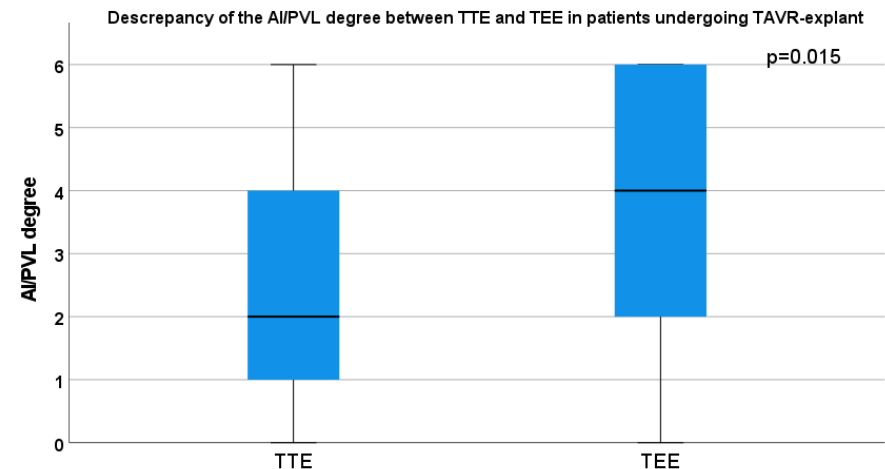
Standard aortotomy for "late" explantation → **Not recommended**



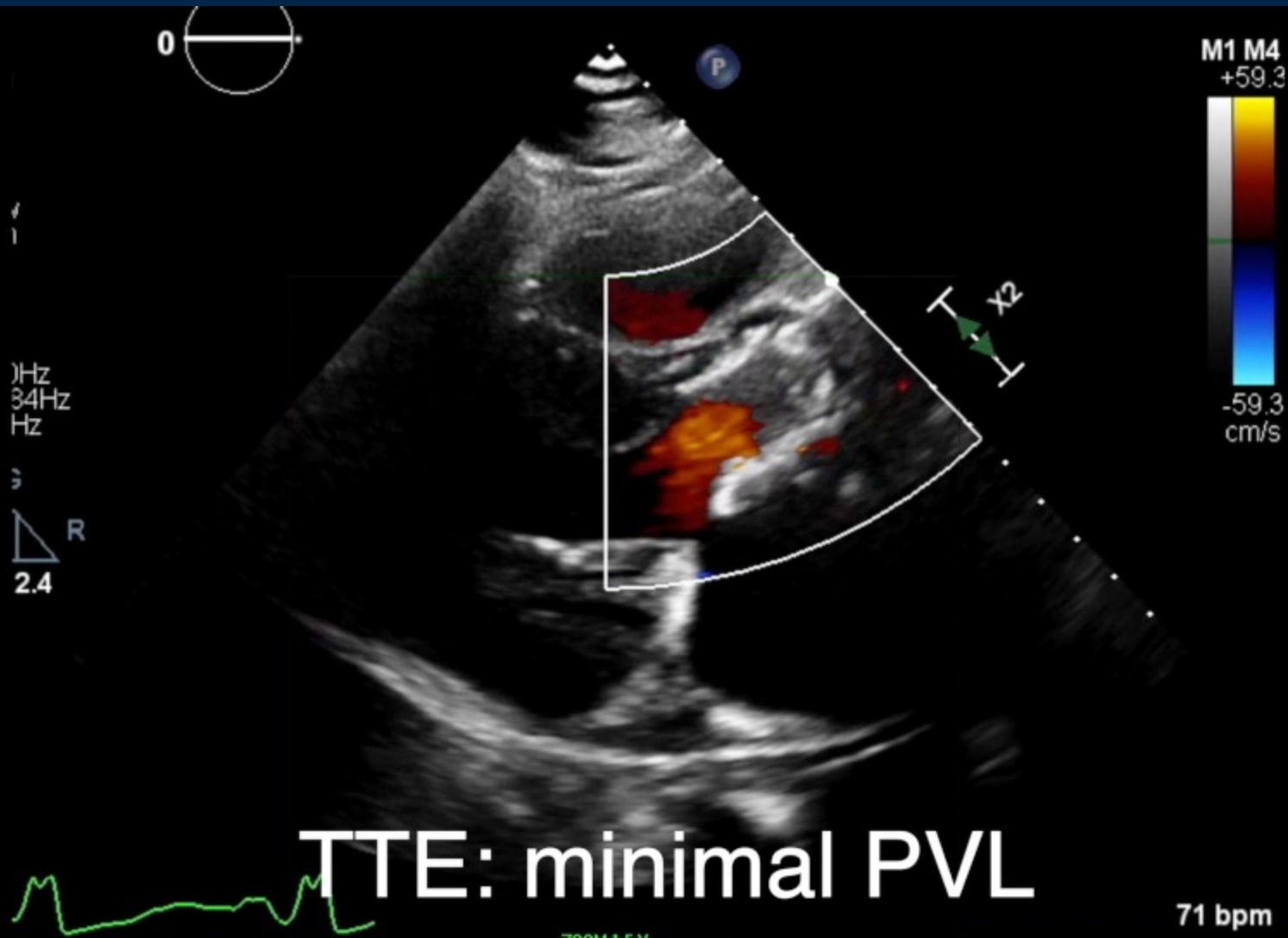
# Underestimation of PVL/AI in TAVR patients

- Antegrade cardioplegia is frequently ineffective due to PVL
- Degree of PVL is almost always **underestimated** (not well-detected on TTE)
- PVLs > mild are typically amplified after going on CPB

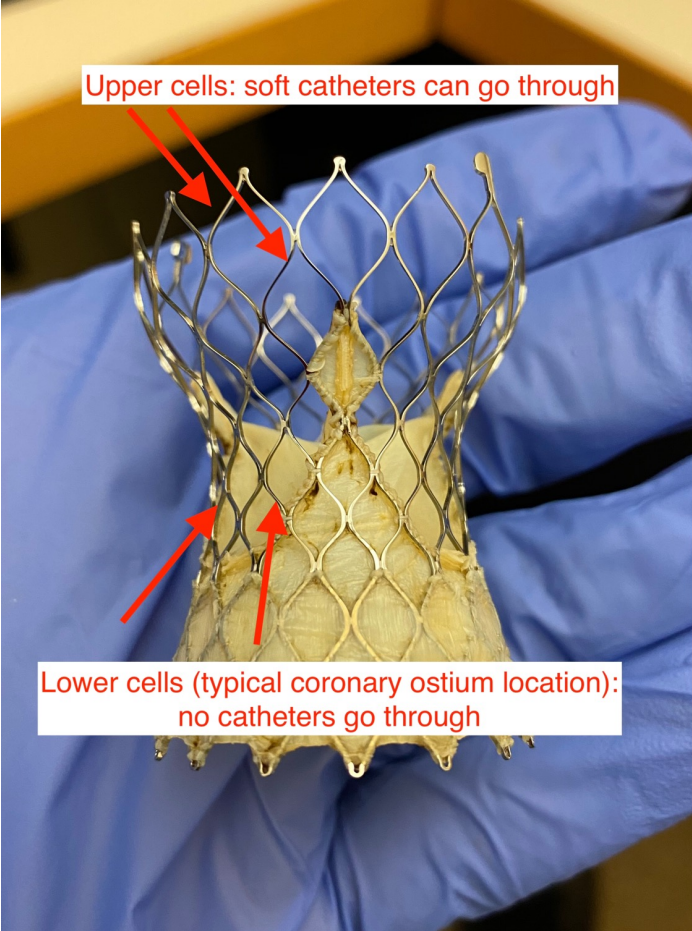
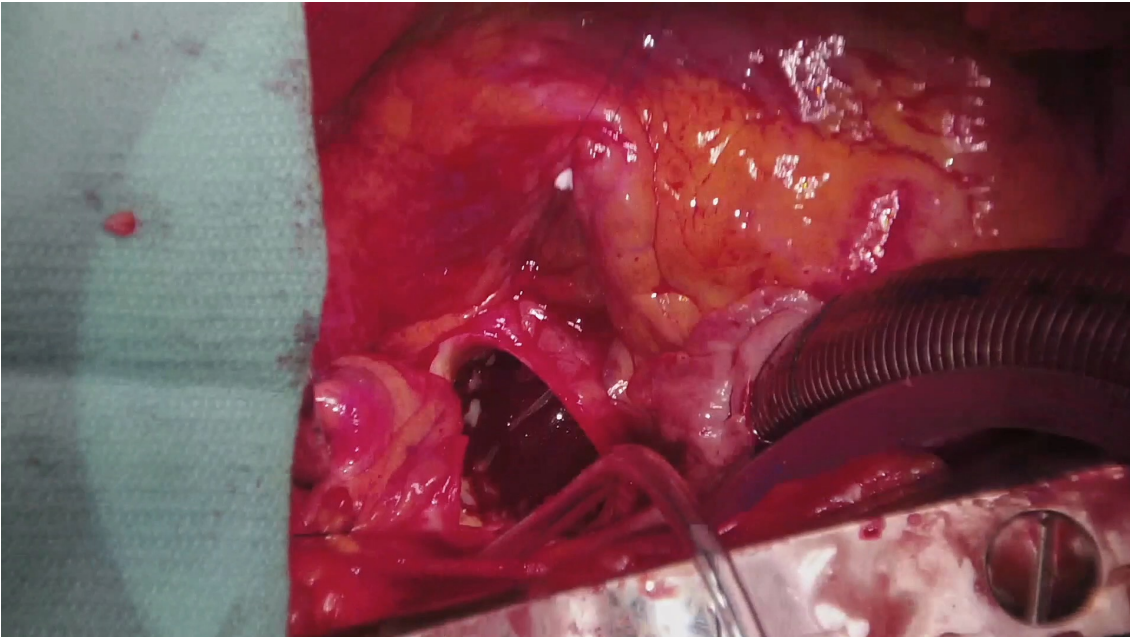
AI/PVL degree TTE vs TEE  
in TAVR-explant cases (n=37)



# 58 yo M with 29 mm SE device



# Cardioplegia Delivery during TAVR-explant

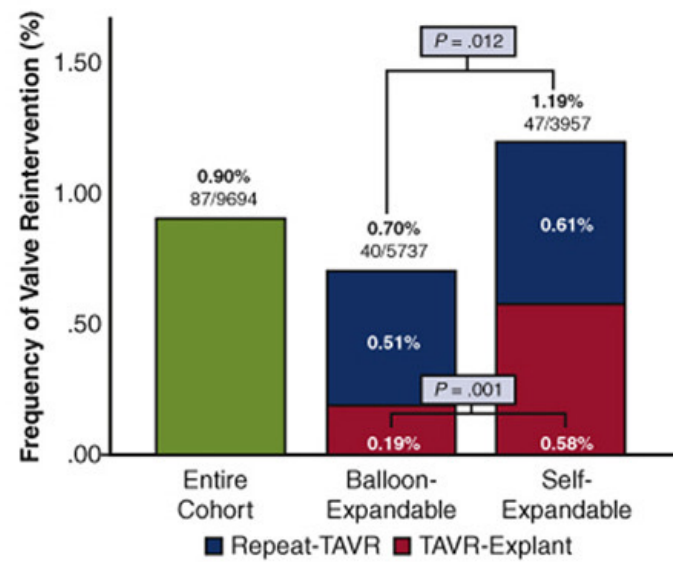
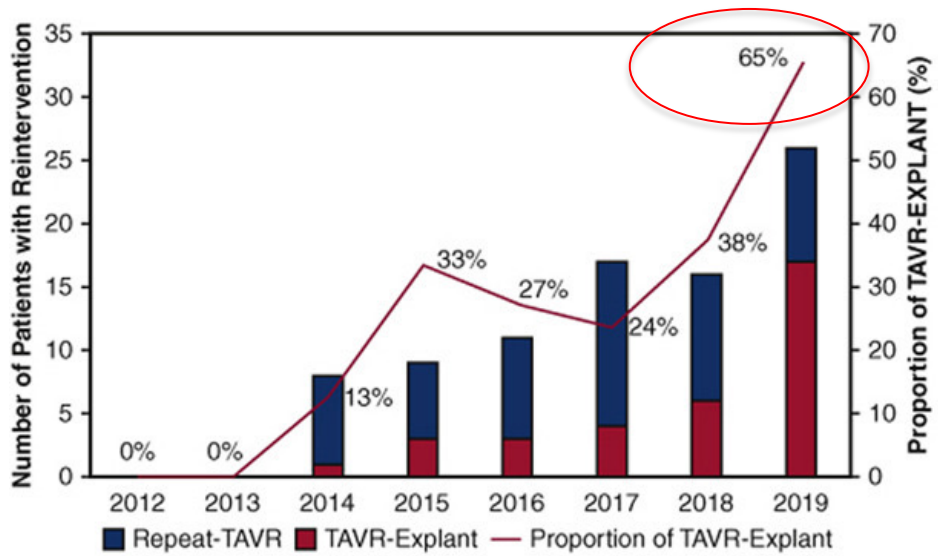
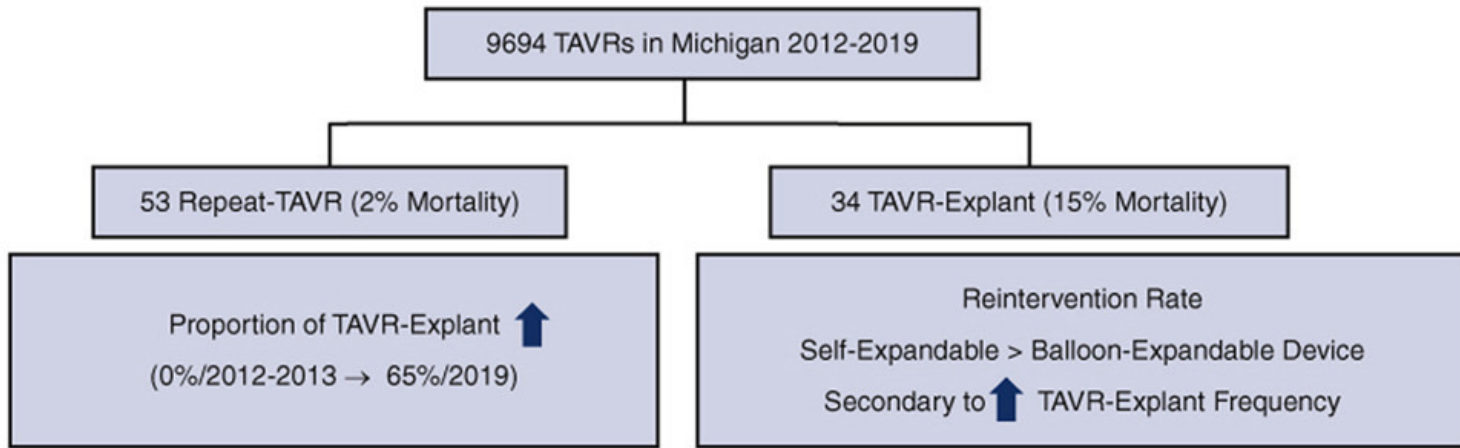


# CoreValve Explant

## 2.2-year-old 23 mm Evolut R

- 77 yo M with history of SAVR (21 mm Magna Ease) and CABG x 3 in 2009 followed by valve-in-valve TAVR (23 mm Evolut R) in 2017
- Moderate-severe PVL + left main intermittent occlusion due to distal TAVR valve migration

# Reintervention in Michigan State



39% needed reoperation rather than redo TAVR

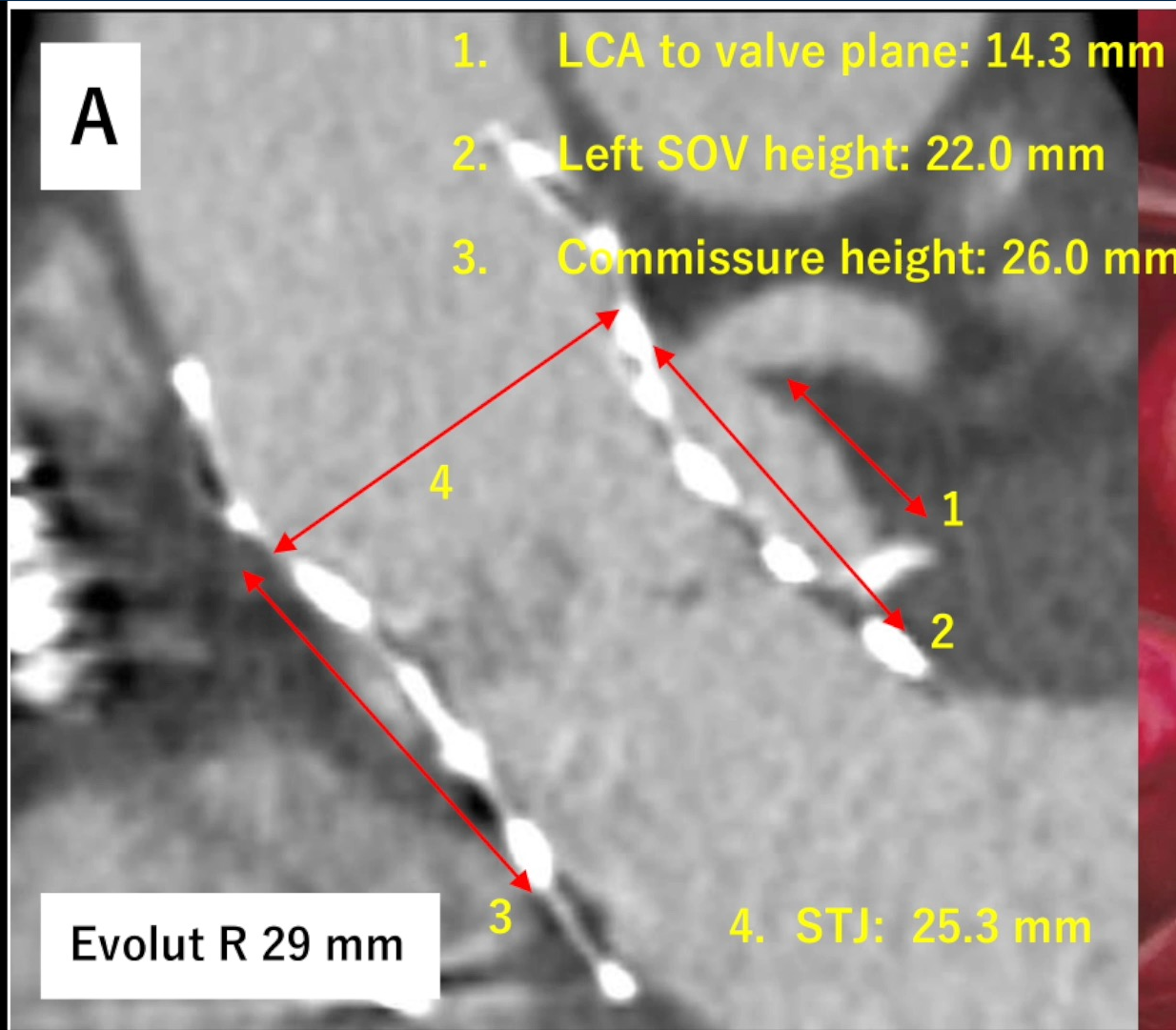
Self-expandable valves more frequently needed reoperation (49%)

Fukuhara et al. J Thorac Cardiovasc Surg. 2021



# Unfavorable Repeat TAVR anatomy

## Sequestered sinus of Valsalva



STJ diameter & Sinus of Valsalva height are more important than valve size or coronary heights for repeat TAVR feasibility

# Repeat TAVR Data: What Happened to Patients without Suitable Anatomy?

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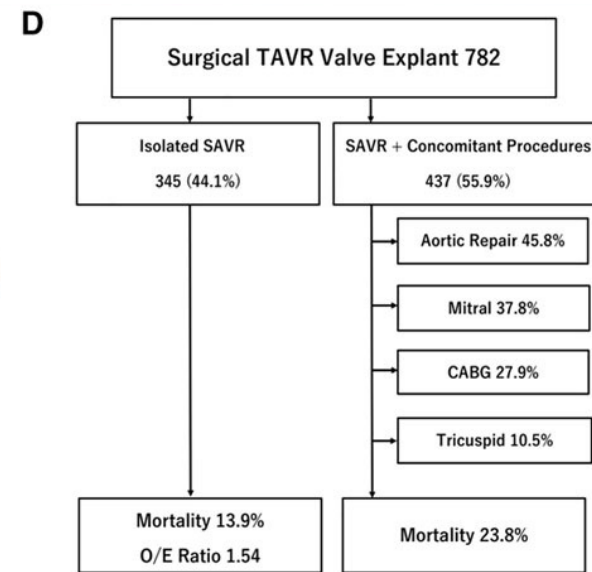
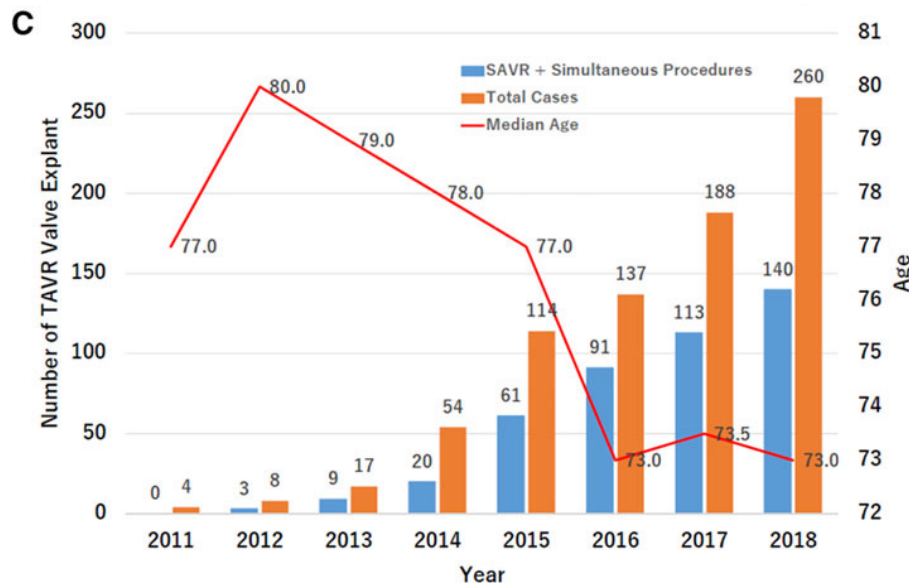


Landes et al. JACC 2020 Apr 28;75(16):1882-1893

212 repeat TAVR procedures

200 reoperations??

# TAVR-explant from the STS database



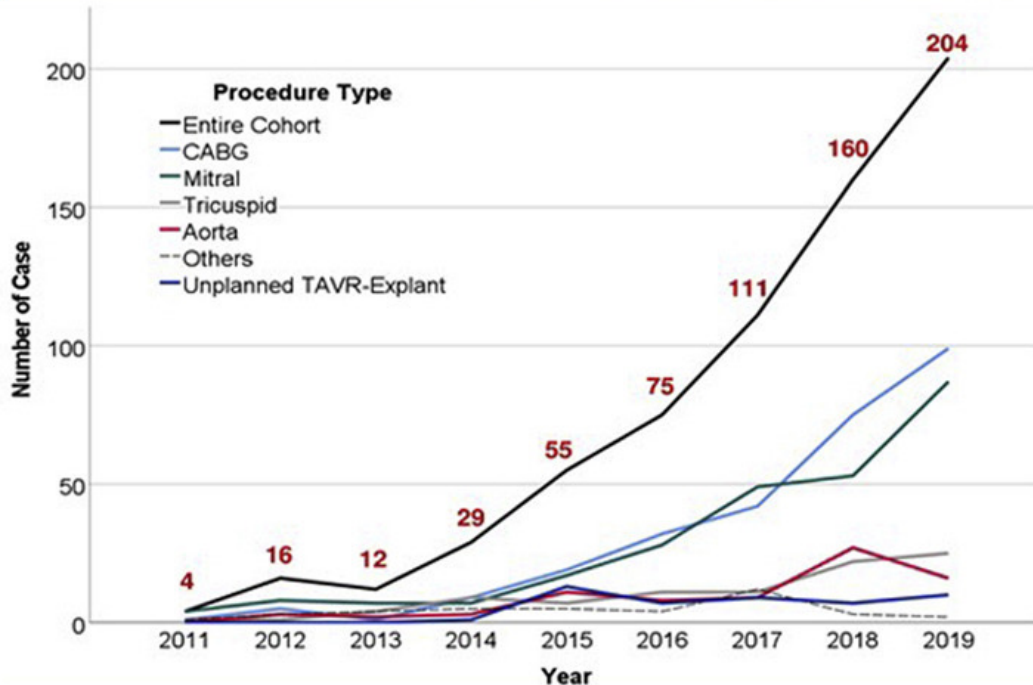
Fukuhara S, et al. Circulation. 2020 Dec 8;142(23):2285-2287.

**Isolated SAVR mortality 13.9%, SAVR with concurrent procedures mortality 23.8%, O/E ratio 1.6**

*Mortality higher than acute type A aortic dissection repair*

# Non-aortic valve reoperations from the STS database

## 666 patients between 2011-2019



❖ **Most common: CABG and Mitral Procedures**

- Case number ↑ over time

❖ **30-day Mortality: 17%**

❖ **Consistently high O/E ratio**

TAVR, transcatheter aortic valve replacement  
CABG, coronary artery bypass grafting  
O/E ratio, observed-to-expected mortality ratio

**Non-aortic valve operation after TAVR is associated with high mortality and O/E ratio. Assessment of concurrent cardiac pathology and multi-disciplinary TAVR team approach remain crucial.**

THE ANNALS OF  
THORACIC SURGERY

Official Journal of The Society of Thoracic Surgeons and the Southern Thoracic Surgical Association

Fukuhara et al, 2021



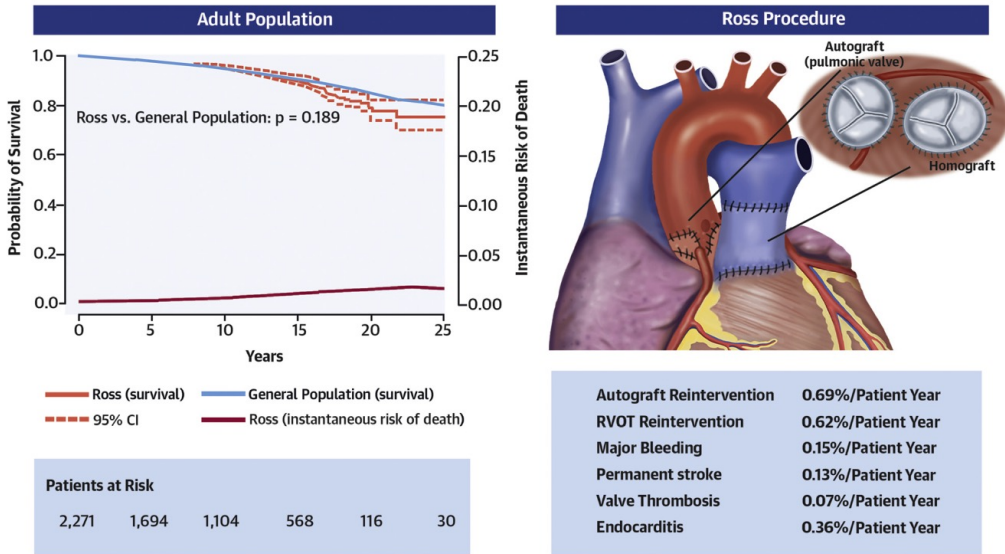
@ShinFukuharaMD #TSSMN  
#VisualAbstract #AnnalsImages

We MUST take care of patients **surgically** if patients have

- 1) Unfavorable redo TAVR anatomy
- 2) Concurrent cardiac pathologies (mitral, complex CAD)

# Why Not Ross?

## CENTRAL ILLUSTRATION Overall Survival of Patients After Ross Procedures



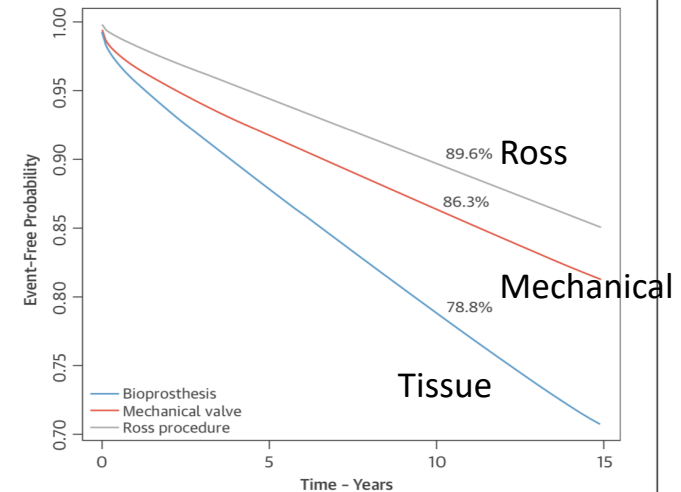
Aboud, A. et al. J Am Coll Cardiol. 2021;77(11):1412-22.

Survival estimates and the instantaneous risk of death for the study population (red) were calculated using Kaplan-Meier methods. The age- and gender-matched general population is depicted in blue.

The only operation closely mirroring hemodynamic performance and life expectancy of healthy individuals.

About A, et al. Long-Term Outcomes of Patients Undergoing the Ross Procedure. J Am Coll Cardiol. 2021 Mar 23;77(11):1412-1422.

**FIGURE 3** Comparison of Long-Term Outcomes Among the Ross Operation, Mechanical Aortic Valve Replacement, and Bioprosthesis for Young Adults (16 to 40 Years of Age)



Confidence bands are not included to avoid clutter. These are unadjusted event curves after matching using a 3-way composite algorithm (described in Methods section).

J Am Coll Cardiol 2016;67:2858-70

# Why Not Mechanical?

## Proact Xa Trial



**Patients with On-X aortic valve replacement > 3 months prior  
(n=1000)**



**Apixaban 5 mg BID**  
Apixaban 2.5 mg BID in selected patients

Open  
Label

**Continued warfarin**  
INR goal 2.0 – 3.0

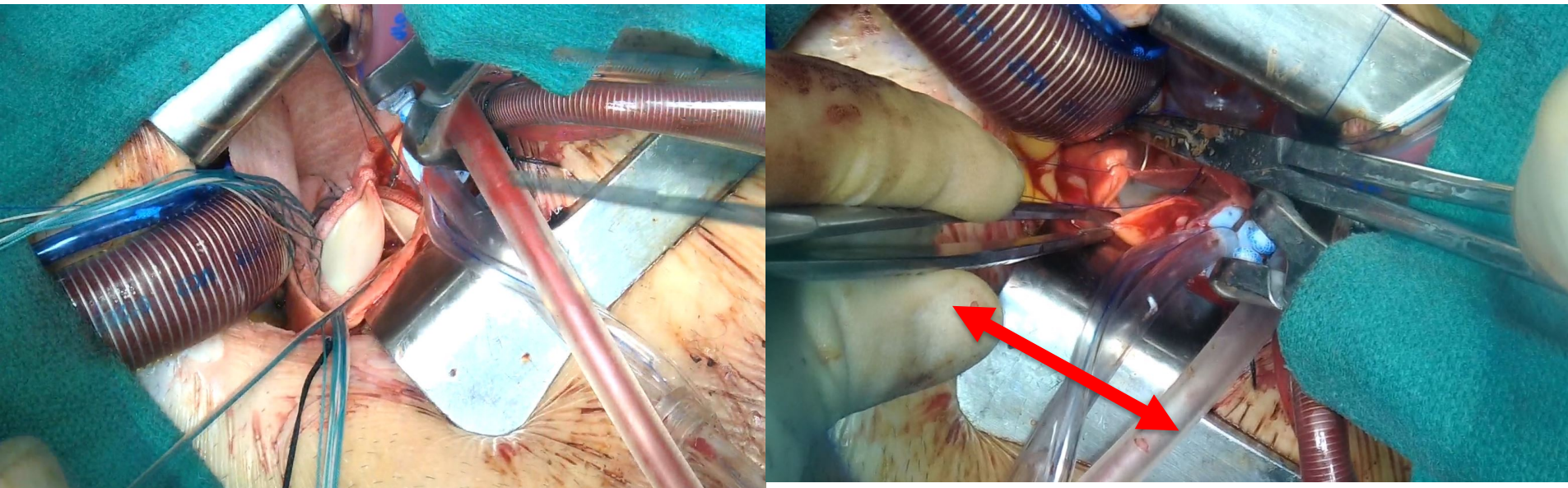
2-year follow-up

**Primary endpoint:** composite of valve thrombosis and valve-related thromboembolism

**Secondary endpoints:** components of primary composite endpoint, major bleeding

# Mini AVR with Aggressive Root Enlargement

Aggressive root enlargement through 5-6 cm incision



6 cm



# Lifetime Management of Aortic Valve Disease in 2022

What is the best route?

SAVR → TAVR → TAVR ?

SAVR → TAVR → SAVR ?

TAVR → SAVR → TAVR ?

SAVR with root enlargement → TAVR → redo TAVR

# Take Home Message

Paradoxical co-existence of less invasive TAVR and possible risky future reoperation after TAVR

**Future reoperation risk should be part of informed consent for TAVR recipients**