

Transcatheter Valve Replacement: Current State in 2017

Marc A. Sintek MD
Assistant Professor of Medicine
Interventional Cardiology
Cardiovascular Division
Washington University in St. Louis

Missouri ACP 2017 CME Meeting
Updates in Internal Medicine
September 17, 2017

Overview

- A Standard TAVR Case
- Evidence review and update for TAVR
- Evaluating Patients for TAVR
- Future of TAVR and unique TAVR populations
- Mitral valve therapies
- Complex TAVR Case

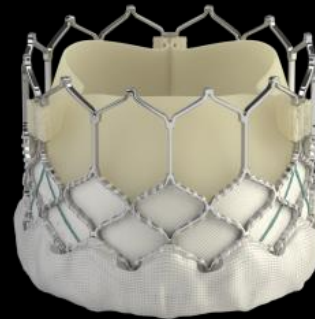
Case XX

The Evidence for TAVR

- The original data (PARTNERS)
- Intermediate Risk Patients
- Durability and Safety updates



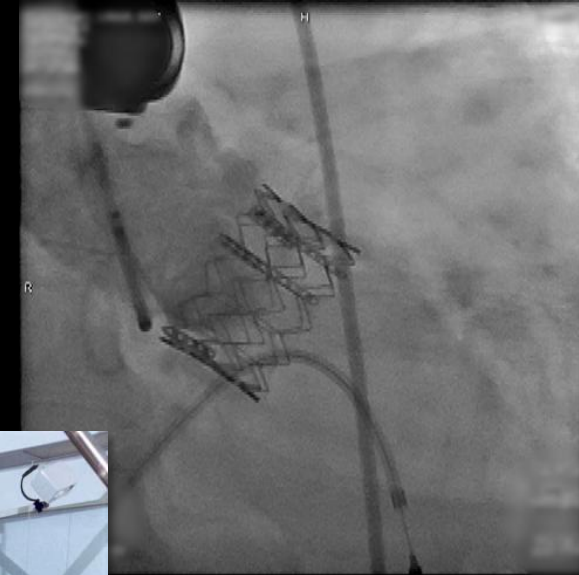
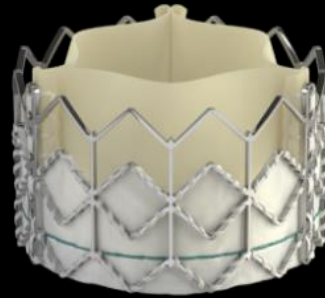
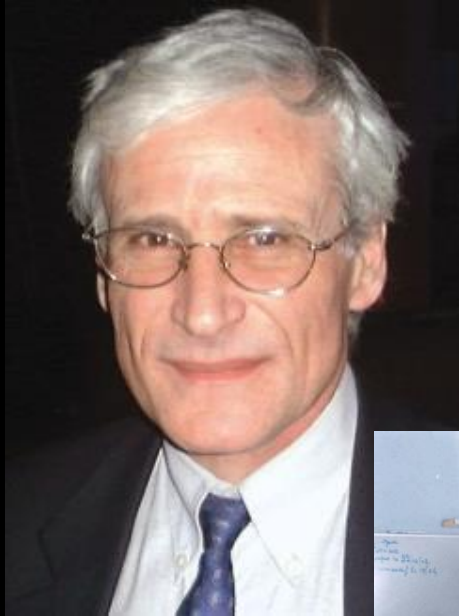
CoreValve Evolute R



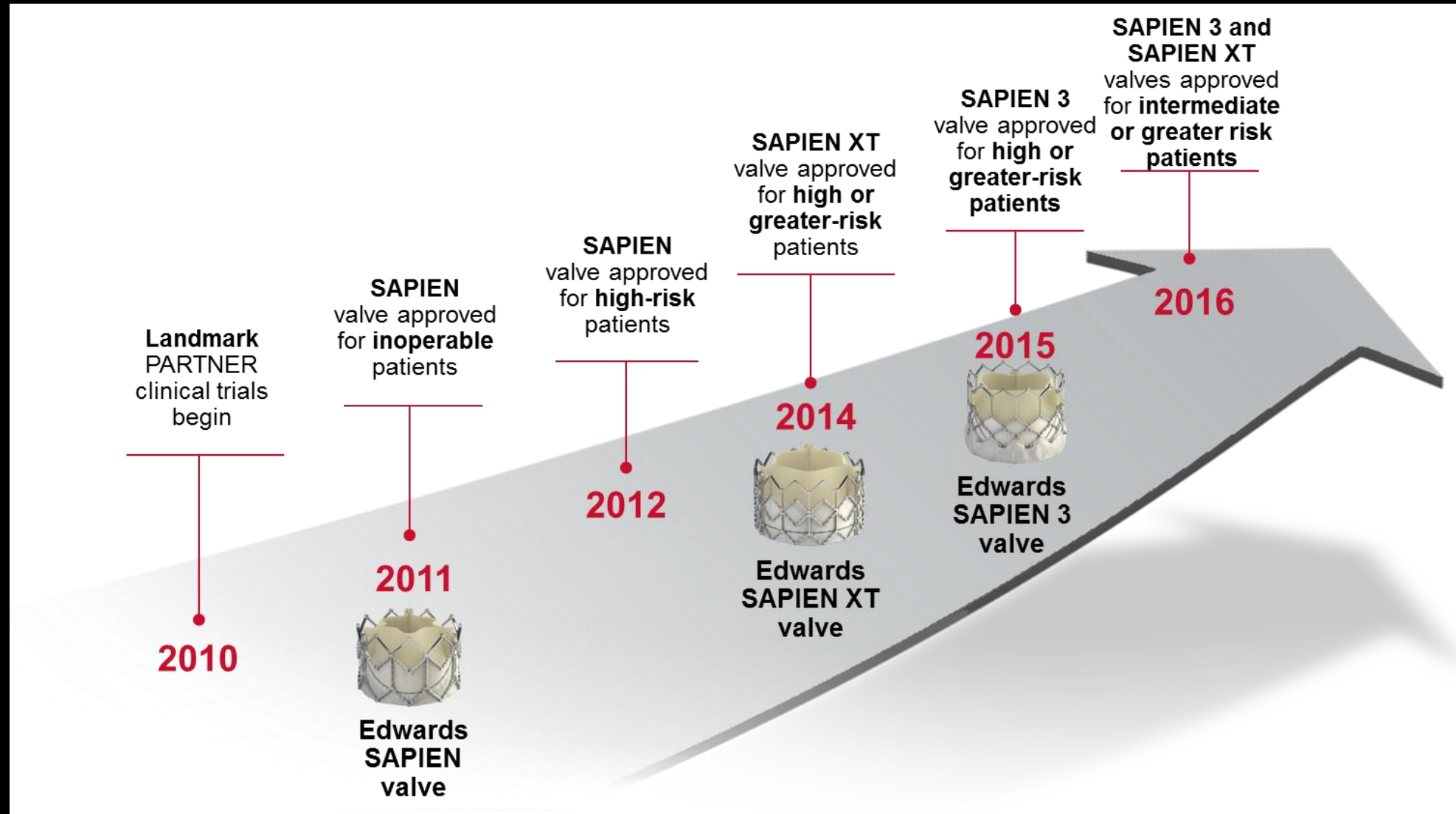
Sapien S3

Brief history of TAVR

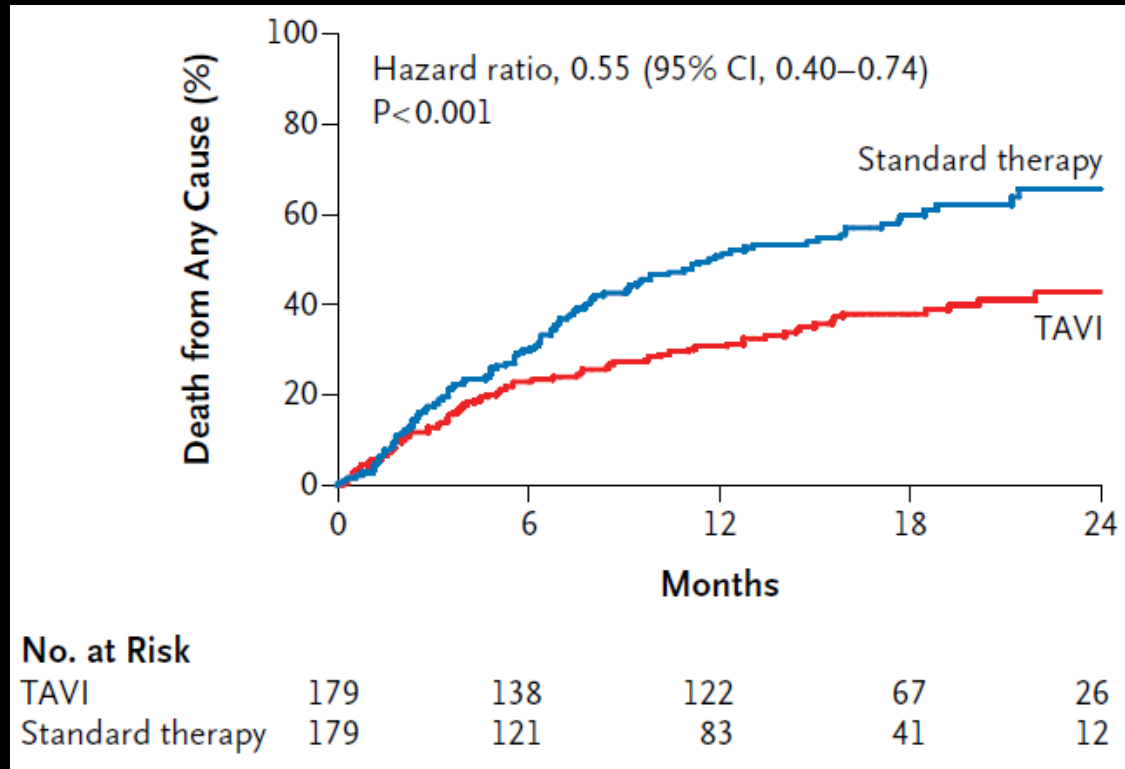
Alain Cribier:
First human transcatheter valve replacement (2002)



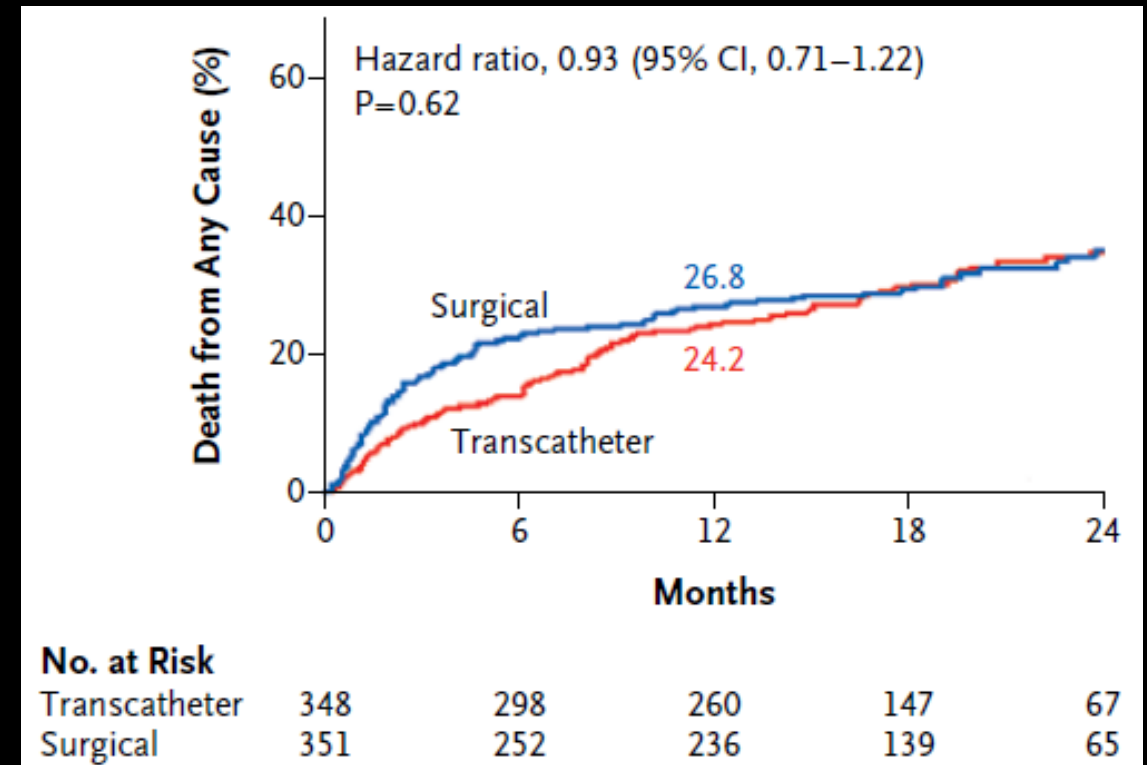
Brief history of TAVR



Brief history of TAVR

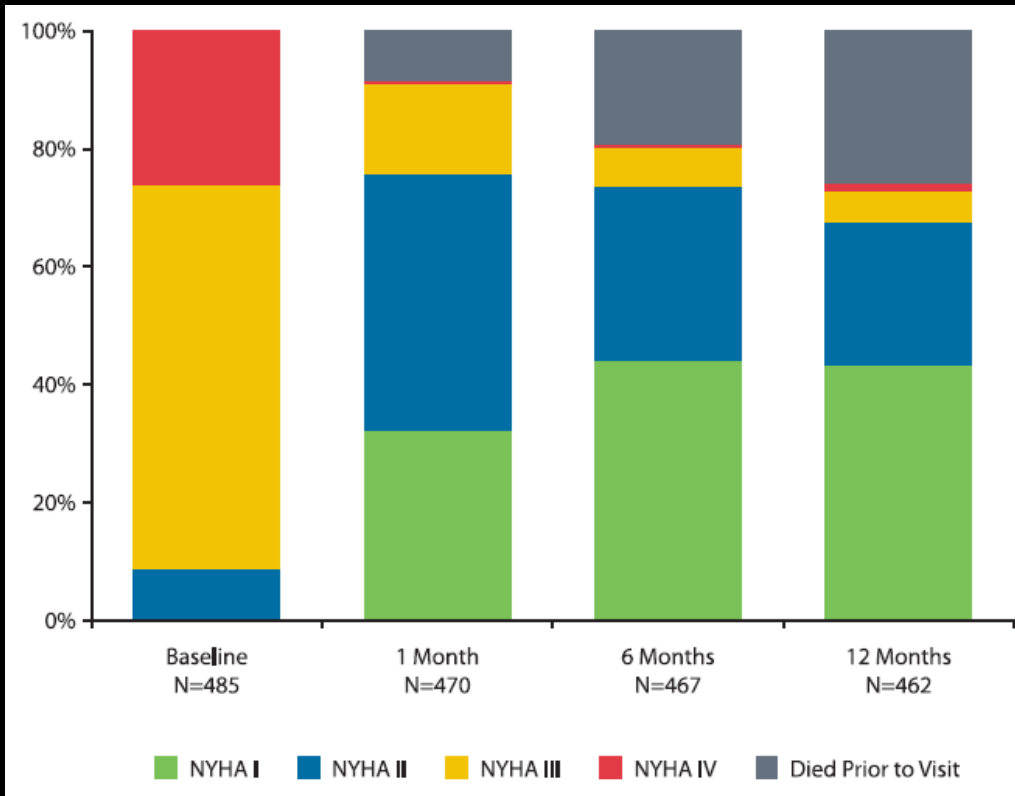


PARTNERS Cohort B
(Inoperable)

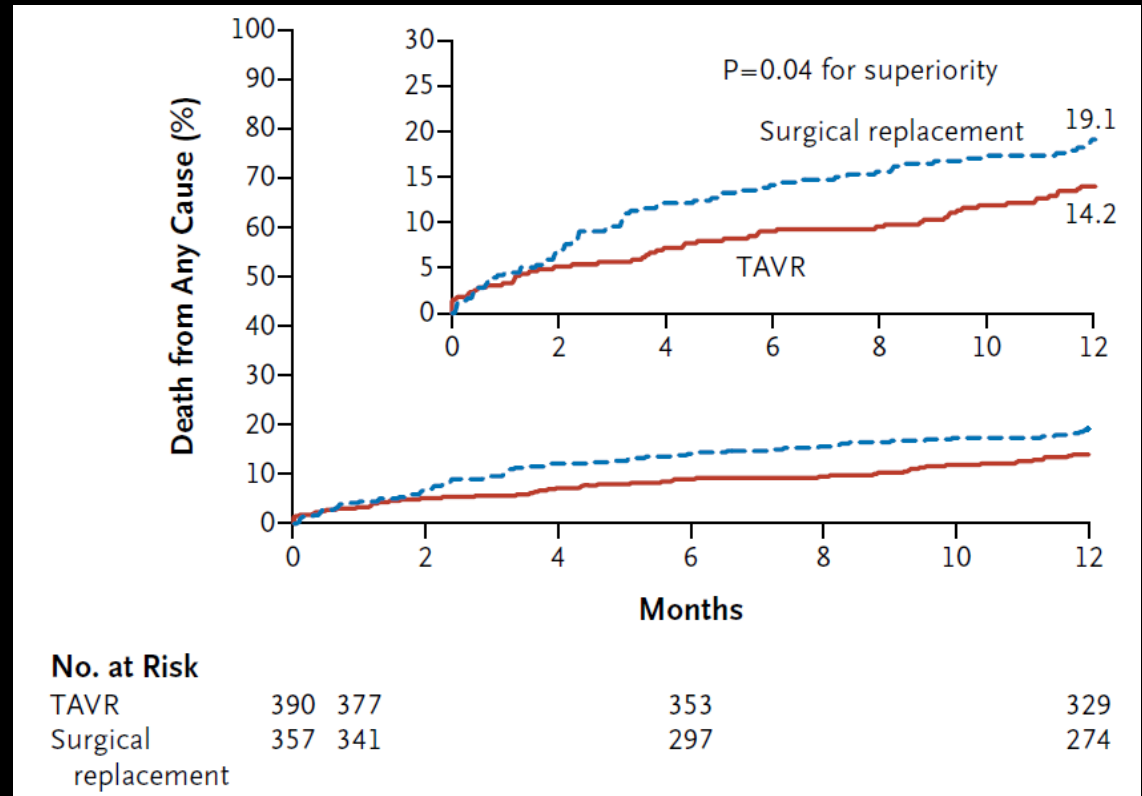


PARTNERS Cohort A
(High Risk)

Brief history of TAVR



CoreValve Extreme Risk Trial
(Inoperable)



CoreValve Pivotal Trial
(High Surgical Risk)

Brief history of TAVR

Low mortality and stroke rates

Patient selection, procedural techniques,
device evolution



RetroFlex 3
delivery system



NovaFlex+
delivery system



Edwards Commander
delivery system

Improved vascular access

Lower profile devices expands
treatment possibilities



RetroFlex 3
introducer sheath



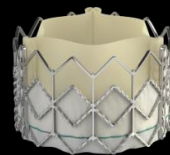
Edwards eSheath
introducer set



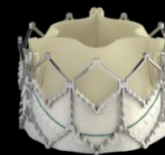
Edwards eSheath
introducer set*

Increased treatment range

Larger and smaller valves



SAPIEN valve
23 mm and 26 mm



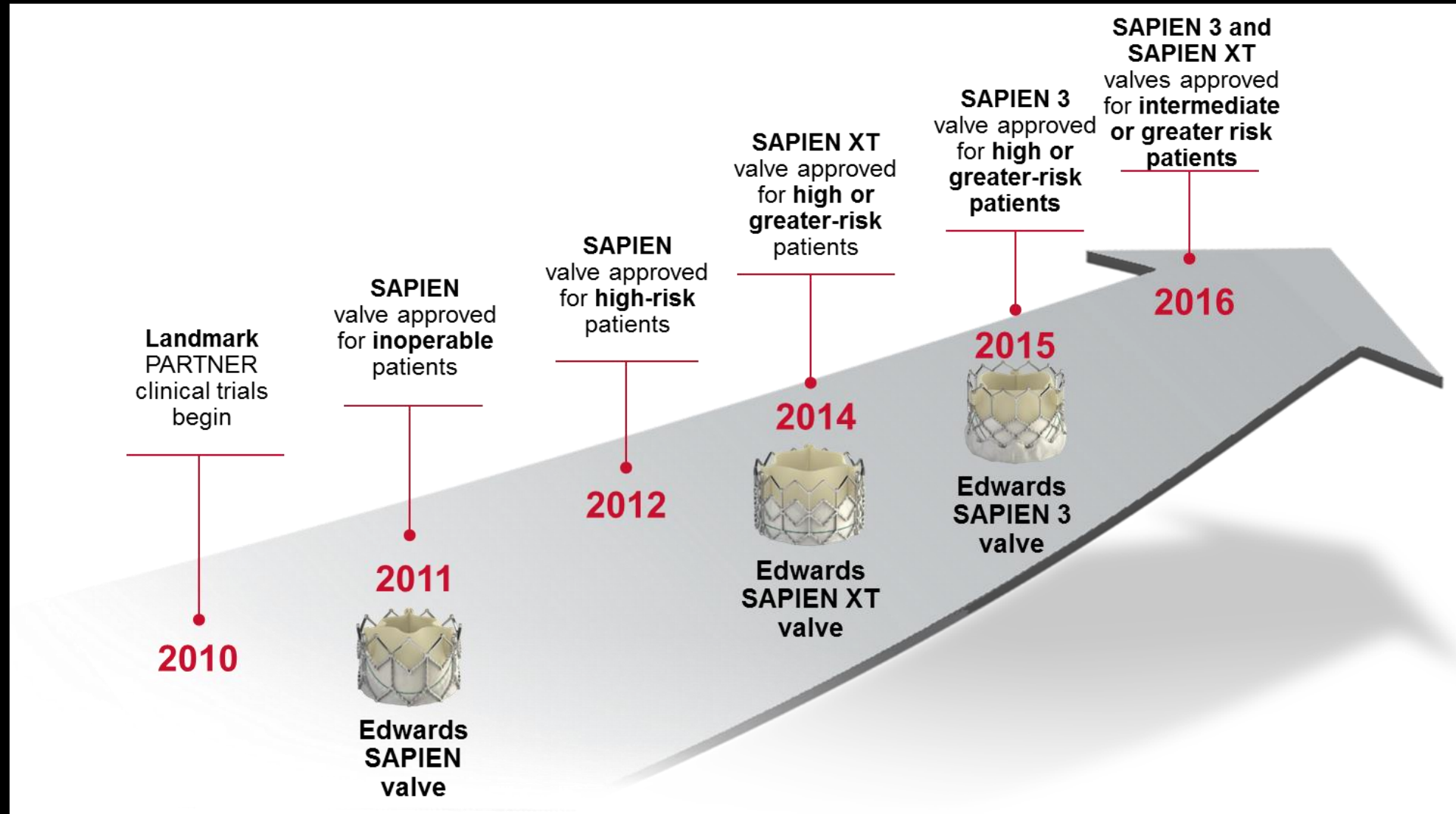
SAPIEN XT valve
23 mm, 26 mm, 29 mm



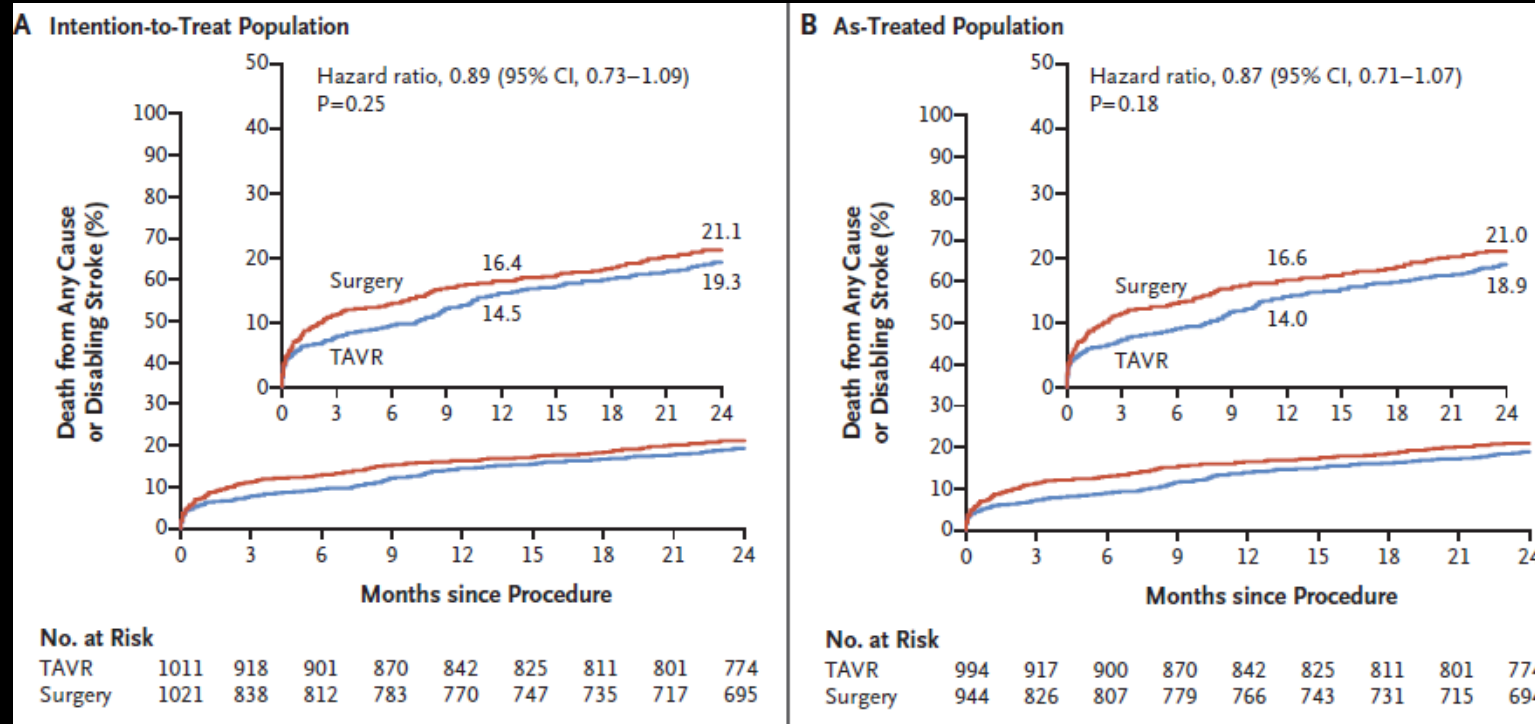
SAPIEN 3 valve
20 mm, 23 mm, 26 mm, 29 mm

*Only used with 20 mm, 23 mm, 26 mm valve sizes

Brief history of TAVR



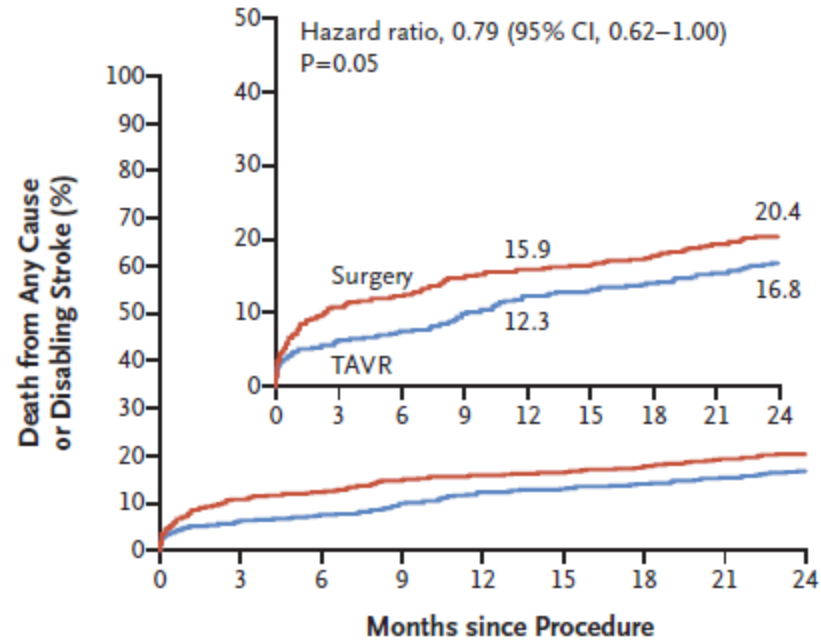
PARTNER II



- 2032 patients with STS score between 4-8%.
- PCI/CABG allowed
- Sapein XT valve

PARTNER II

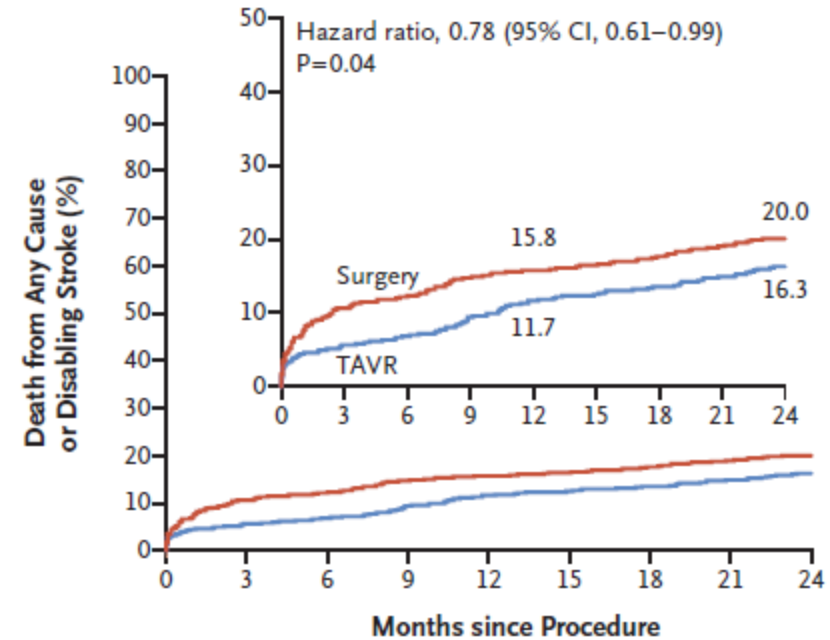
C Transfemoral-Access Cohort, Intention-to-Treat Analysis



No. at Risk

TAVR	775	718	709	685	663	652	644	634	612
Surgery	775	643	628	604	595	577	569	557	538

D Transfemoral-Access Cohort, As-Treated Analysis

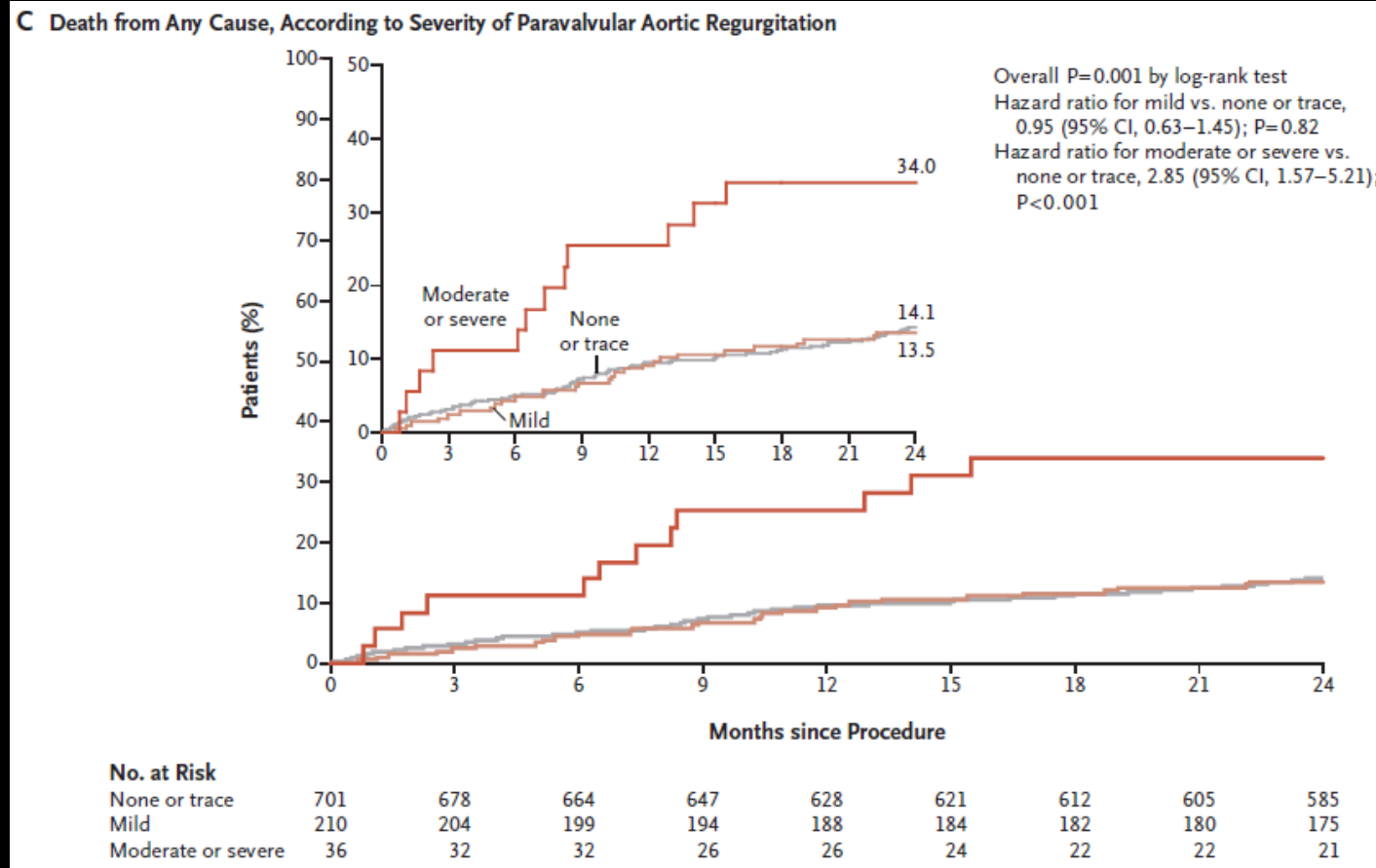


No. at Risk

TAVR	762	717	708	685	663	652	644	634	612
Surgery	722	636	624	600	591	573	565	555	537

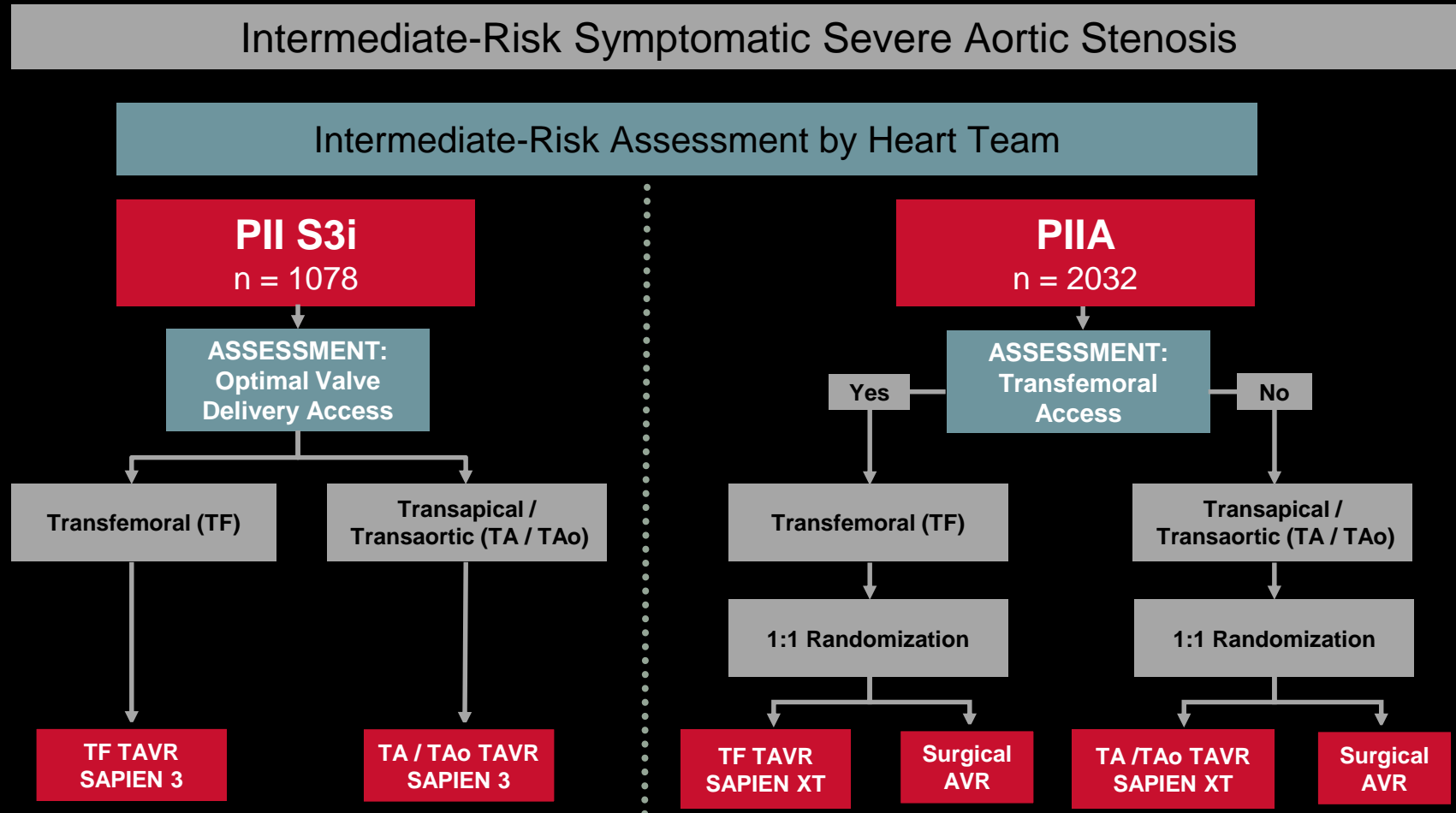
236 patients (11%) were transthoracic TAVR.

PARTNER II

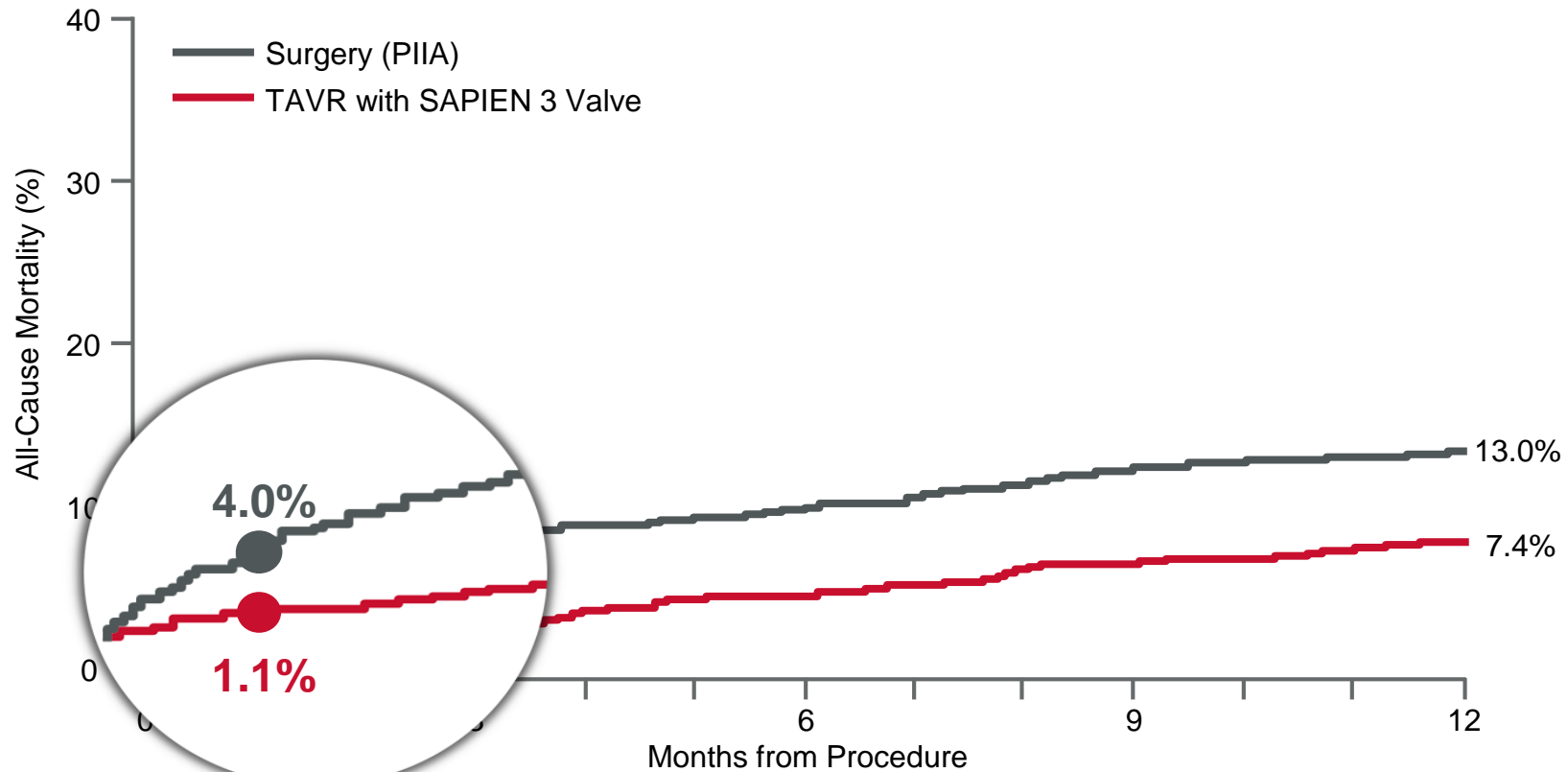


LEAK is BAD

The PARTNER IIA and S3i Trial Study Design



PARTNER II S3i



Number at Risk:

Surgery 944

SAPIEN 3 TAVR 1077

859

1043

836

1017

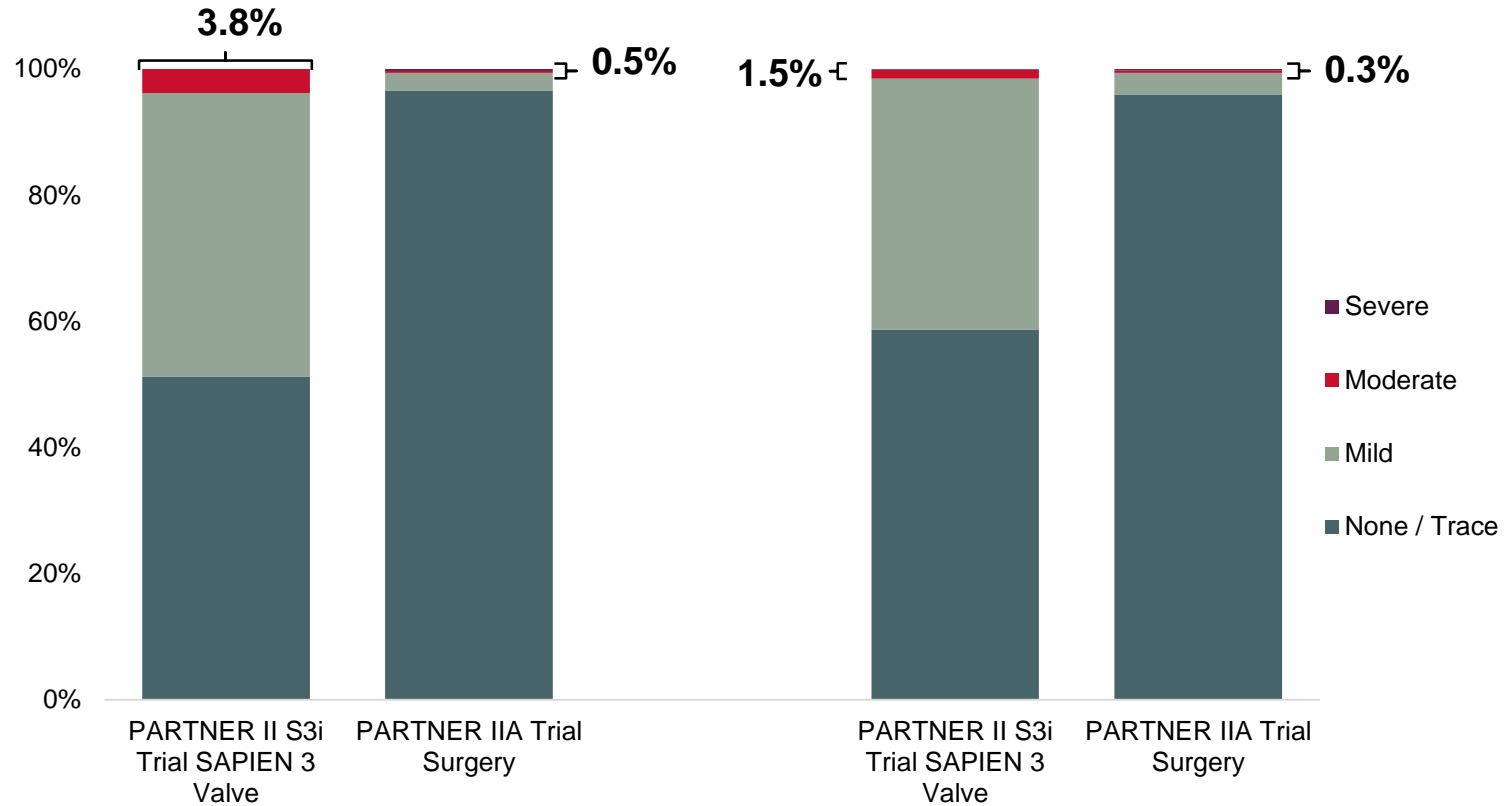
808

991

795

963

PARTNER II S3i Leak



Number of Echos:

Surgery 755

SAPIEN 3 TAVR 992

1 Year

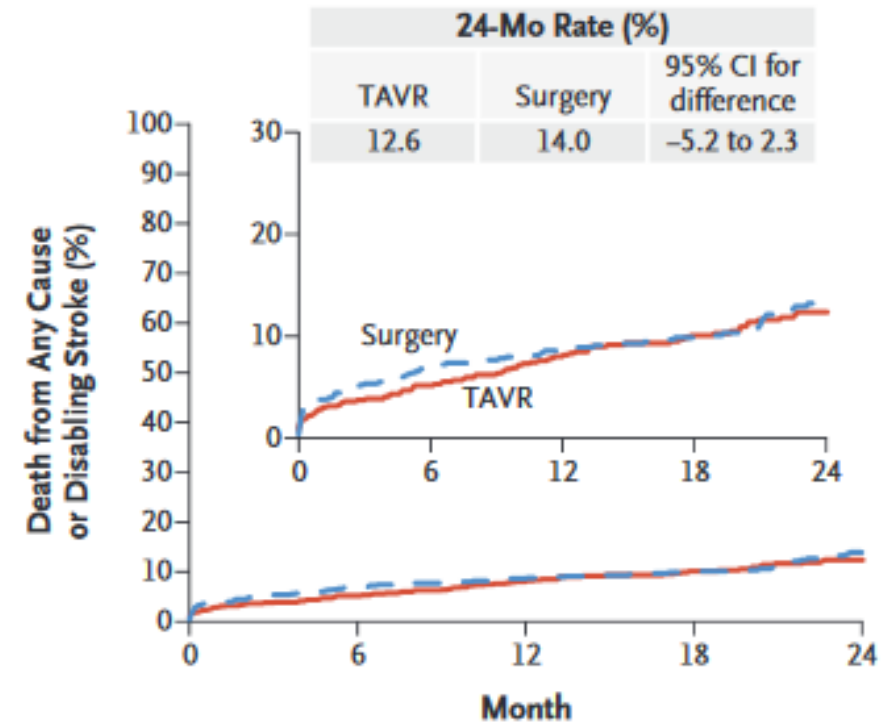
610

875

SURTAVI

- 1746 patients
- STS score 3-15% but heart team agreed intermediate risk (mean STS score was 4%).
- Corevalve 84% (Evolute R 16%).

B Primary Outcome

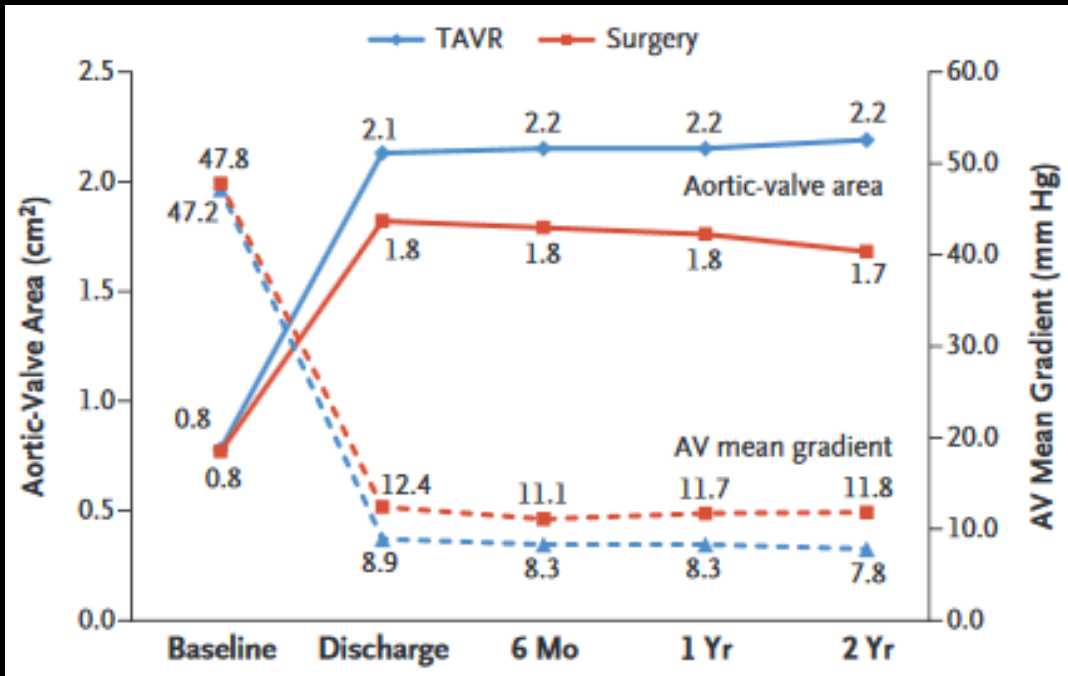


No. at Risk

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

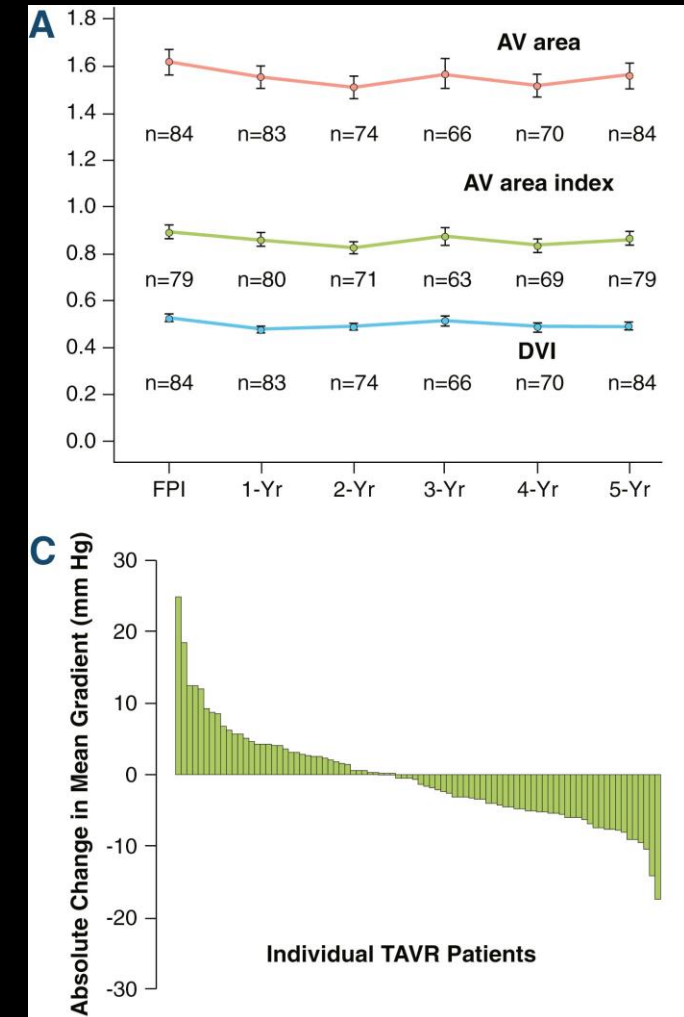
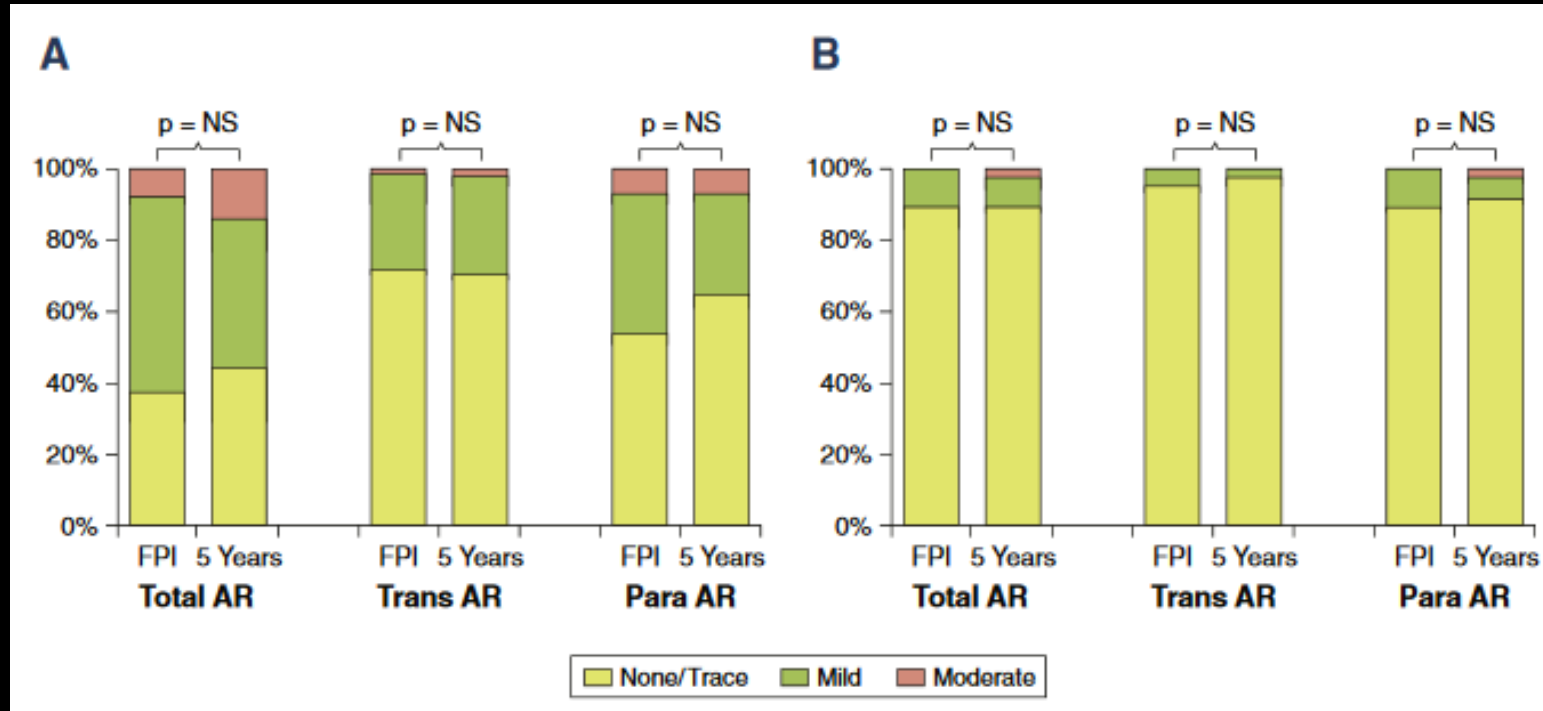
SURTAVI

SURTAVI 30 day Outcomes

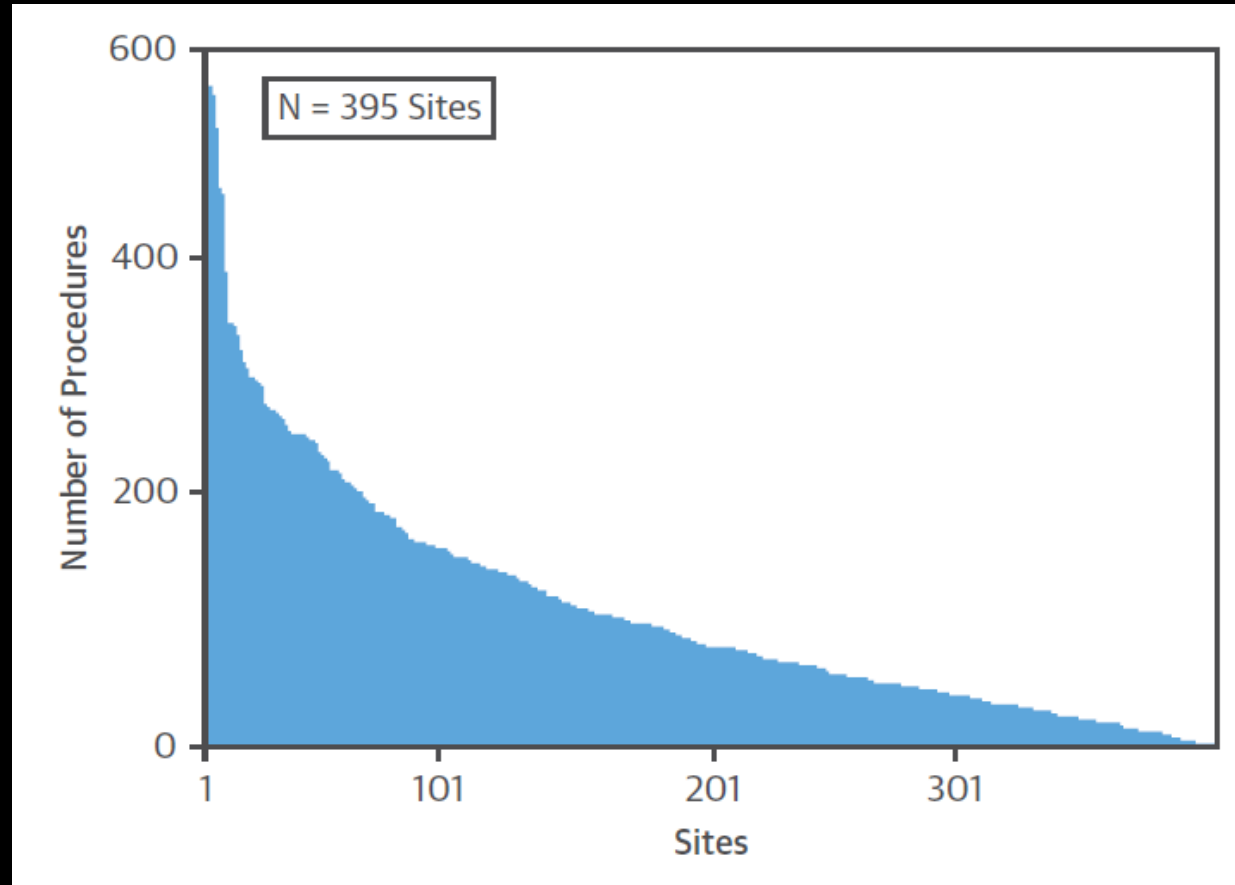


	TAVR	SAVR	Significant
All cause death	2.2%	1.7%	No
Any Stroke	3.4%	5.6%	No
Pacemaker	25.9%	6.6%	Yes
Vascular Complication	6.0%	1.1%	Yes

PARTNER I- 5 year

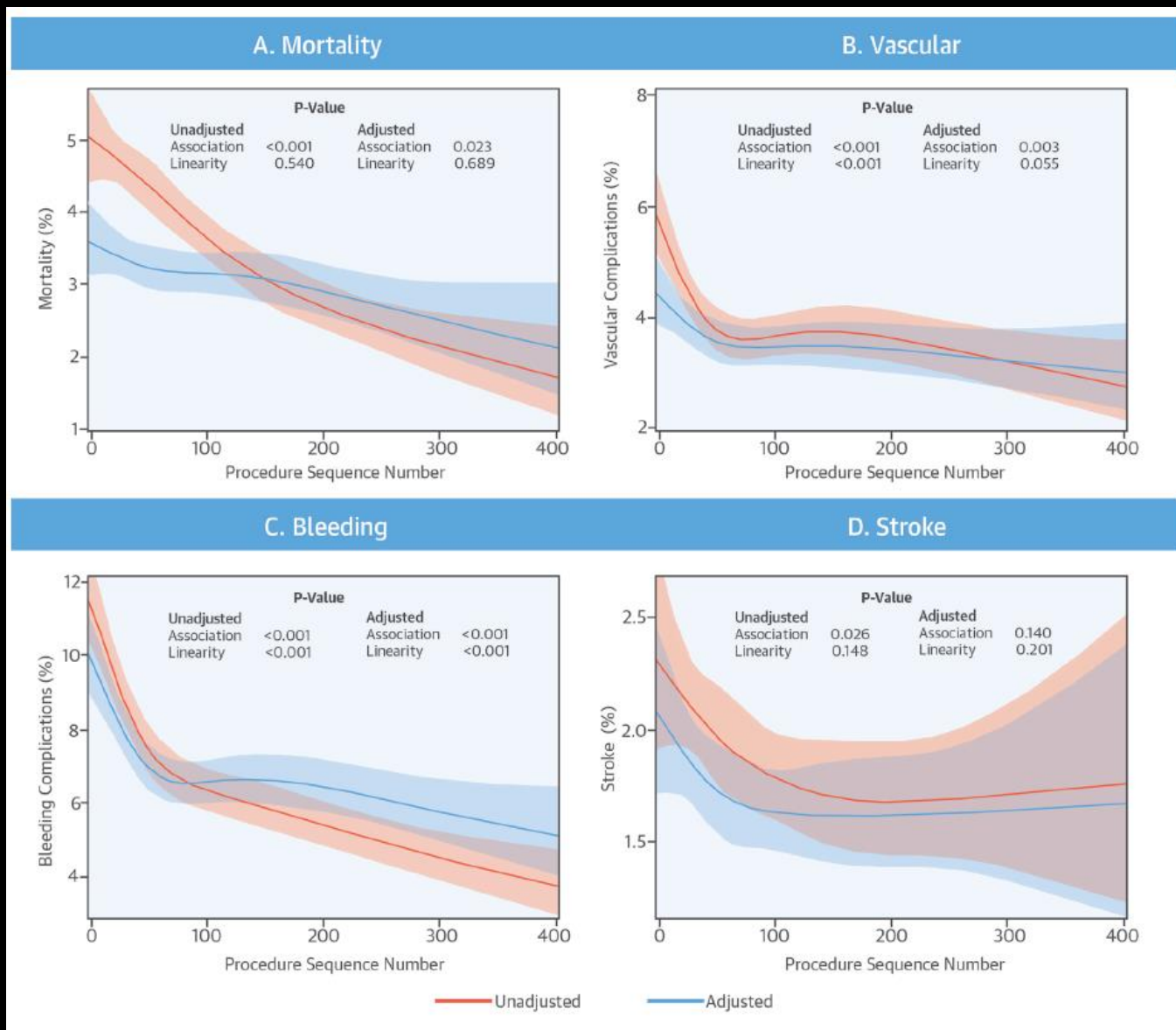


TVT Registry

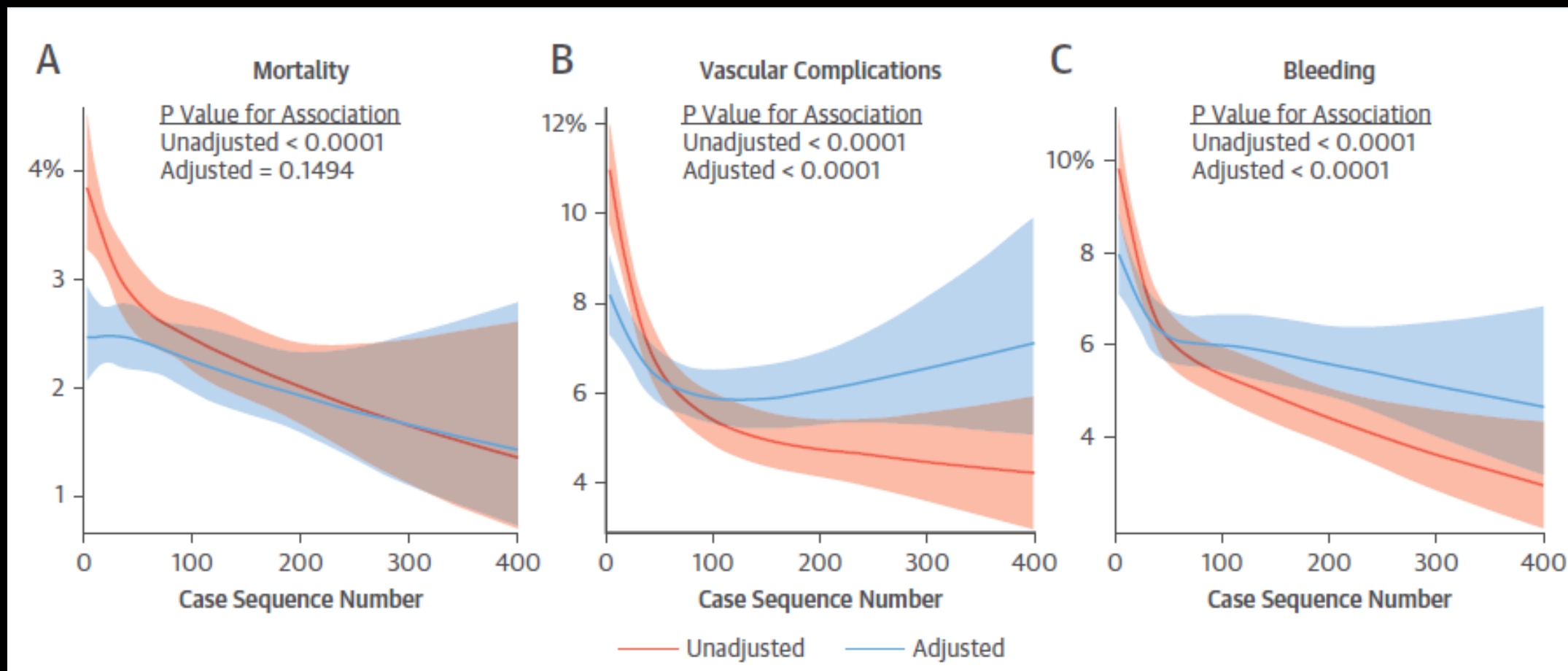


42,998 implants from 2011-2015
62% had STS <8% (intermediate)

TVT Registry



TVT Registry



The TAVR Evaluation

- Understanding risk and STS score
- TAVR diagnostic testing
- “Cohort C”
- The heart team

The TAVR Evaluation

1. Does the patient have Severe AS?
2. Is the patient having symptoms of severe aortic stenosis?
3. What is the best treatment?

The TAVR Evaluation

riskcalc.sts.org/stswebriskcalc/#/calculate

Home Calculate Support

Procedure Type

CAB Only

AV Replacement

MV Replacement Only

MV Repair

AV Replacement + CAB

MV Replacement + CAB

MV Repair + CAB

Risk Model and Variables - STS Adult Cardiac Surgery Database
Version 2.81

RISK SCORES
[About the STS Risk Calculator](#)

Procedure: N/A

Risk of Mortality: N/A

Morbidity or Mortality: N/A

Long Length of Stay: N/A

Short Length of Stay: N/A

Permanent Stroke: N/A

Prolonged Ventilation: N/A

DSW Infection: N/A

Renal Failure: N/A

Reoperation: N/A

PRINT CLEAR

Non-ST Elevation MI (Non-STEMI) ST Elevation MI (STEMI)

Home Calculate Support

No Symptoms

Prior MI

Yes No Unknown

Cardiac Arrhythmia

Yes No Unknown

RF-Chronic Lung Disease

Mild Moderate

Severe Lung disease documented, severity unknown

No Unknown

RF-Cerebrovascular Dis

Yes No Unknown

RF-Peripheral Arterial Disease

Yes No Unknown

RF-Diabetes

Yes No Unknown

Risk Model and Variables - STS Adult Cardiac Surgery Database
Version 2.81

RISK SCORES
[About the STS Risk Calculator](#)

Procedure: AV Replacement

Risk of Mortality: 3.398%

Morbidity or Mortality: 18.976%

Long Length of Stay: 7.245%

Short Length of Stay: 29.85%

Permanent Stroke: 1.821%

Prolonged Ventilation: 10.535%

DSW Infection: 0.213%

Renal Failure: 5.029%

Reoperation: 8.657%

PRINT CLEAR

<http://riskcalc.sts.org>

The TAVR Evaluation

RF-Chronic Lung Disease

Indicate whether the patient has chronic lung disease, and the severity level according to the following classification: No; Mild: FEV1 60% to 75% of predicted, and/or on chronic inhaled or oral bronchodilator therapy. Moderate: FEV1 50% to 59% of predicted, and/or on chronic steroid therapy aimed at lung disease. Severe: FEV1 < 50 or Room Air pCO2 > 50. CLD present, severity not documented Unknown A history of chronic inhalation reactive disease (asbestosis, mesothelioma, black lung disease or pneumoconiosis) may qualify as chronic lung disease. Radiation induced pneumonitis or radiation fibrosis also qualifies as chronic lung disease. (if above criteria is met) A history of atelectasis is a transient condition and does not qualify. Chronic lung disease can include patients with chronic obstructive pulmonary disease, chronic bronchitis, or emphysema. It can also include a patient who is currently being chronically treated with inhaled or oral pharmacological therapy (e.g., beta-adrenergic agonist, anti-inflammatory agent, leukotriene receptor antagonist, or steroid). Patients with asthma or seasonal allergies are not considered to have chronic lung disease.

RF-Cerebrovascular Dis

RF-Peripheral Arterial Disease

RF-Diabetes

Permanent Stroke: 1.821%
Prolonged Ventilation: 10.535%
DSW Infection: 0.213%
Renal Failure: 5.029%
Reoperation: 8.657%

RISK LEVEL

STS Risk of Mortality

Low

<3%

Intermediate

4-8%*

High

>8%

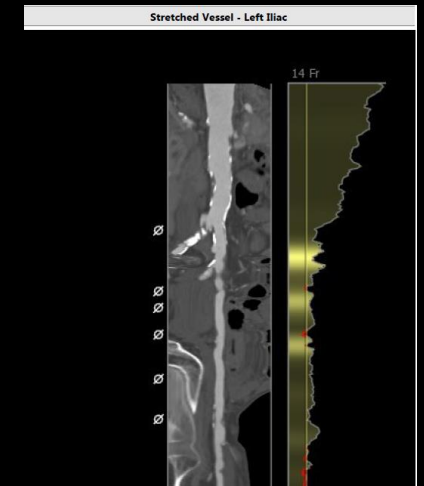
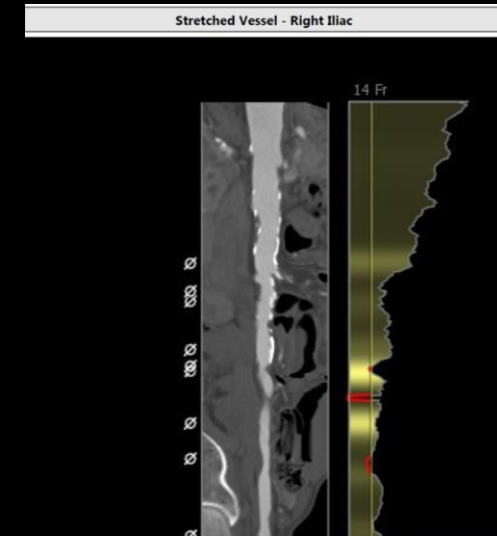
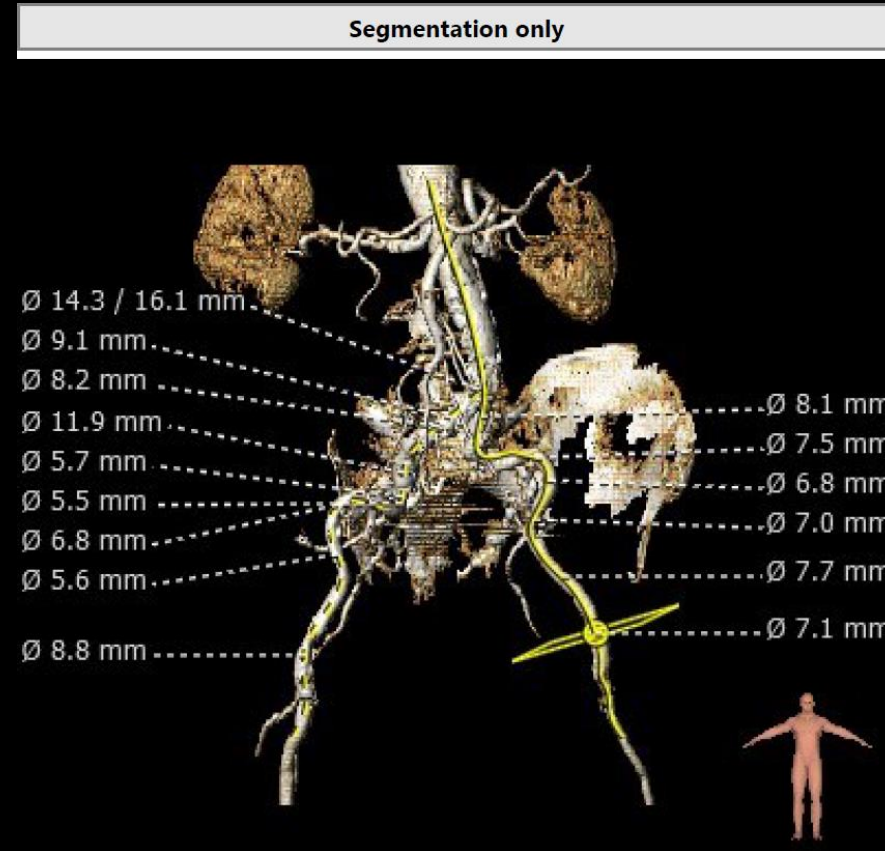
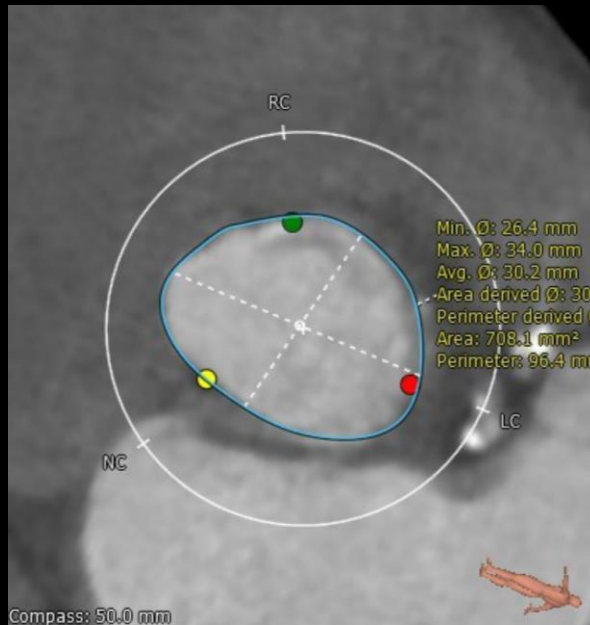
Extreme

>15%

The TAVR Evaluation

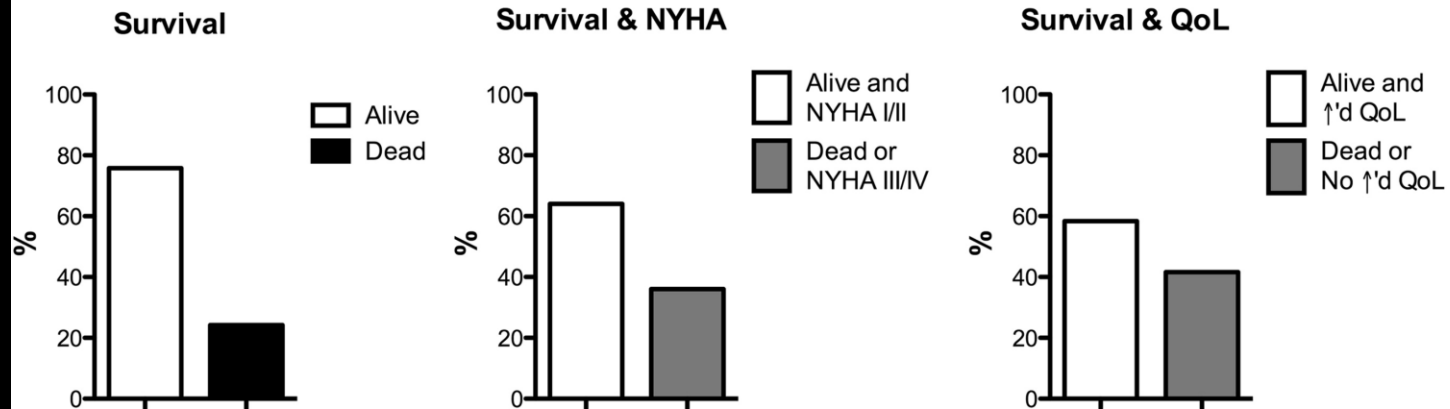
- Consultation with 1 cardiologist and 2 cardiac surgeons
- Echocardiogram
- Coronary angiogram
- Pulmonary function testing
- Carotid Dopplers
- TAVR protocol CT (gated CT with 1mm slices of the heart, chest, abdomen and pelvis)
- Frailty Evaluation

The CT is King

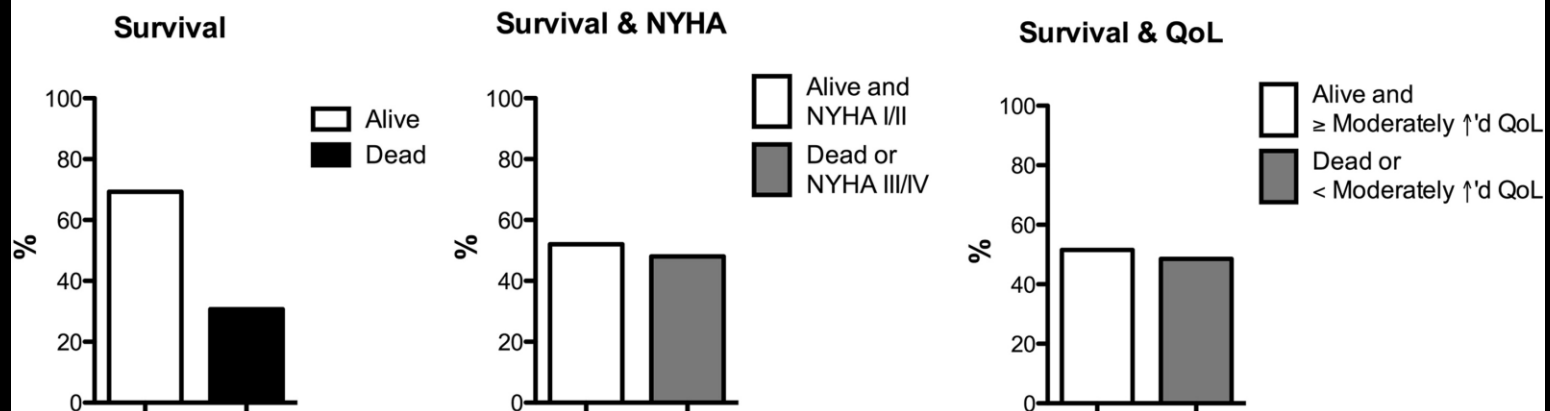


“Cohort C”

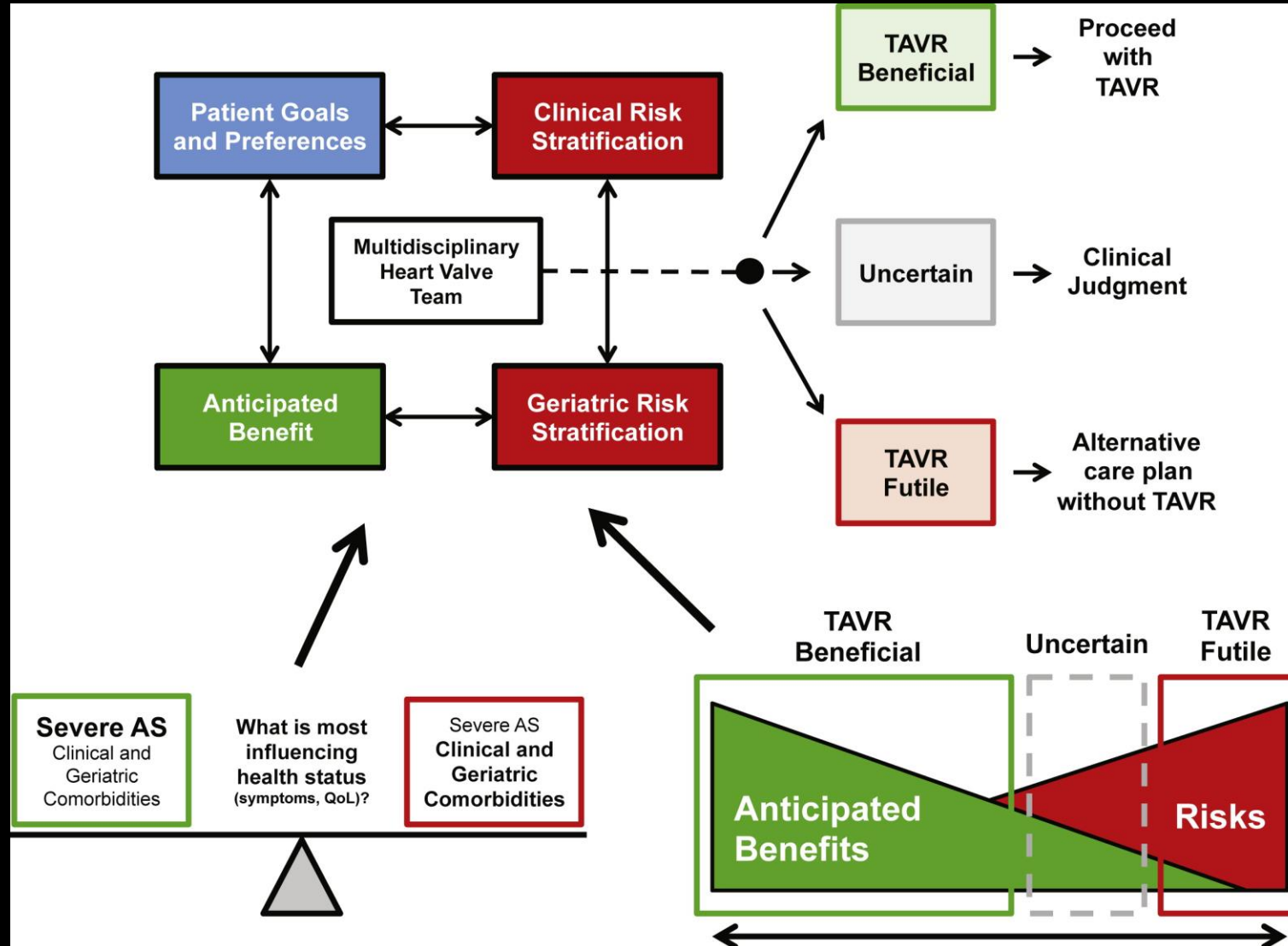
High Risk Patients in the PARTNER Trial - 1 Year Outcomes



Prohibitive Risk Patients in the PARTNER Trial - 1 Year Outcomes

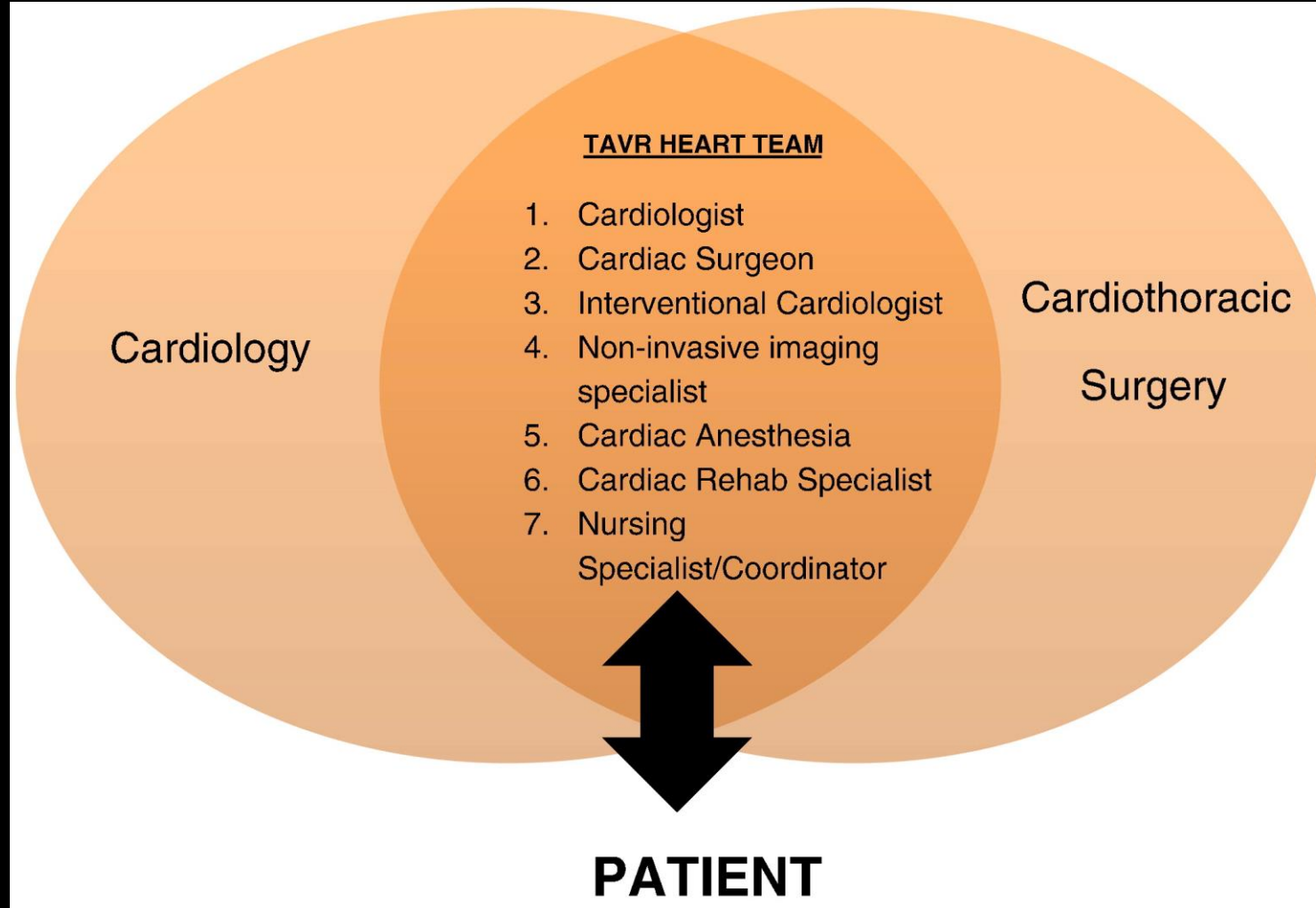


“Cohort C”



The Heart Team Concept

RISK

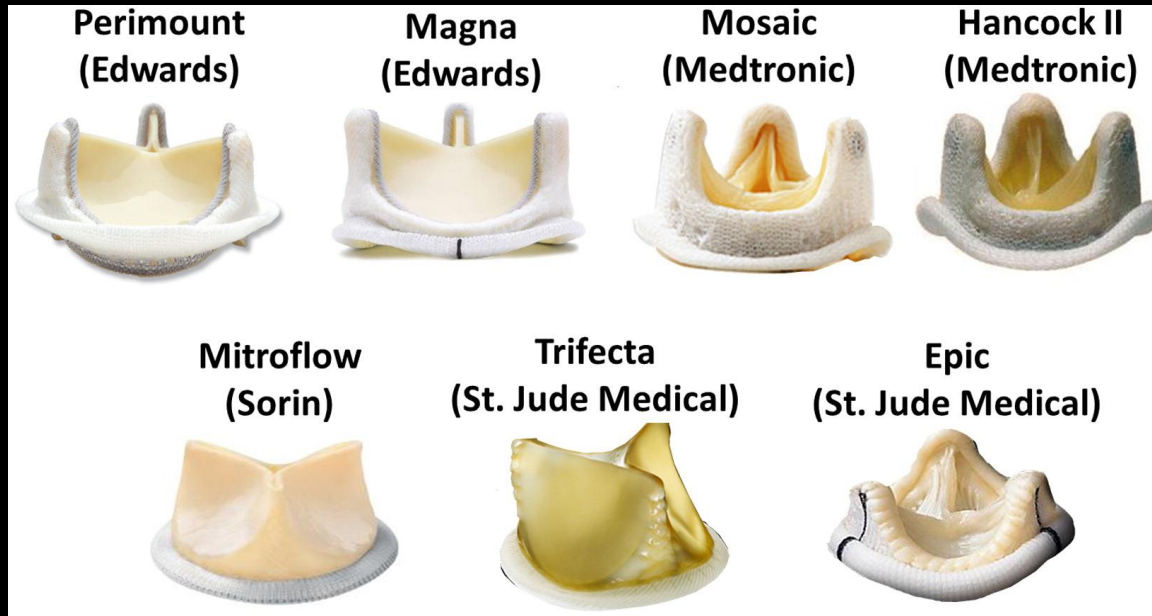


ANATOMY

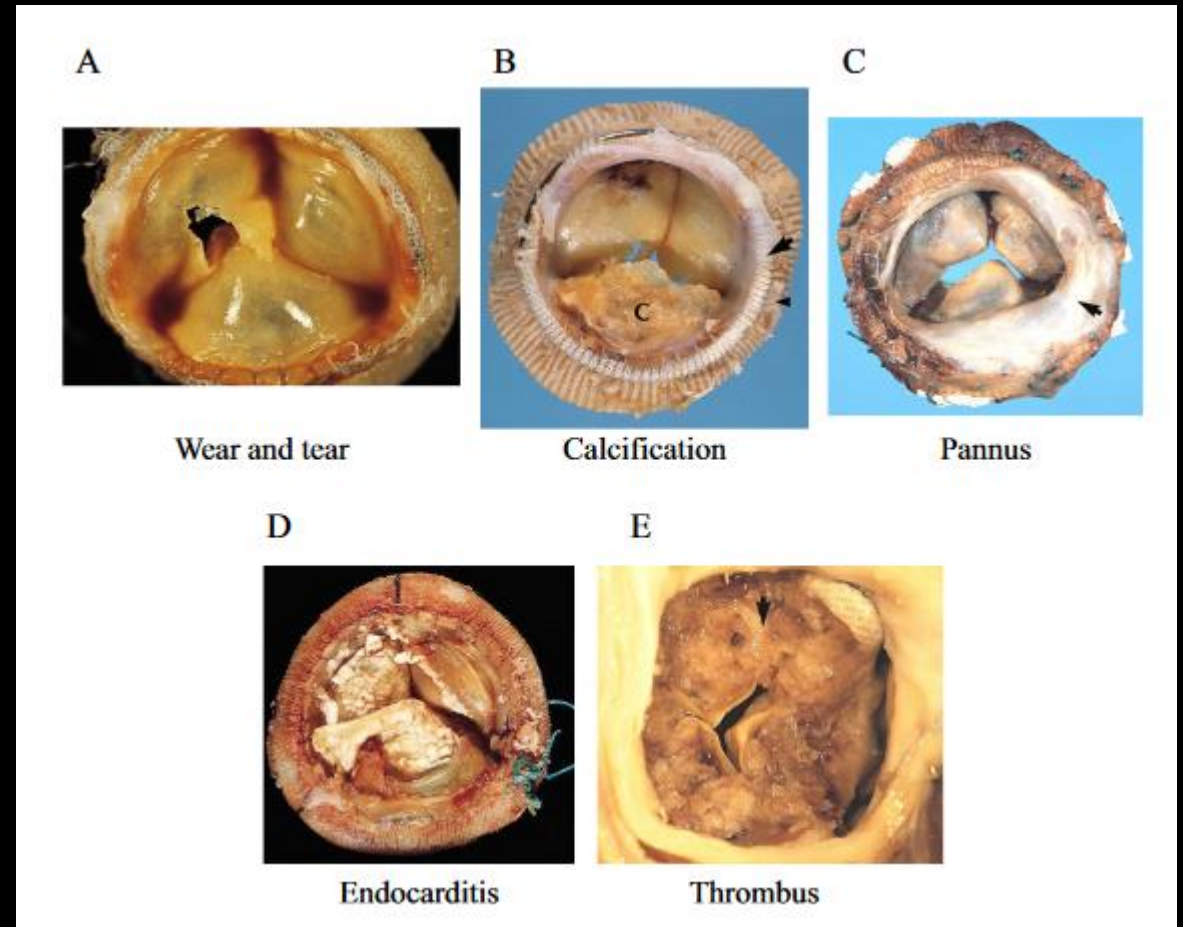
The Unique “TAVR”

- Valve in Valve
- Pulmonic valve

Valve in Valve

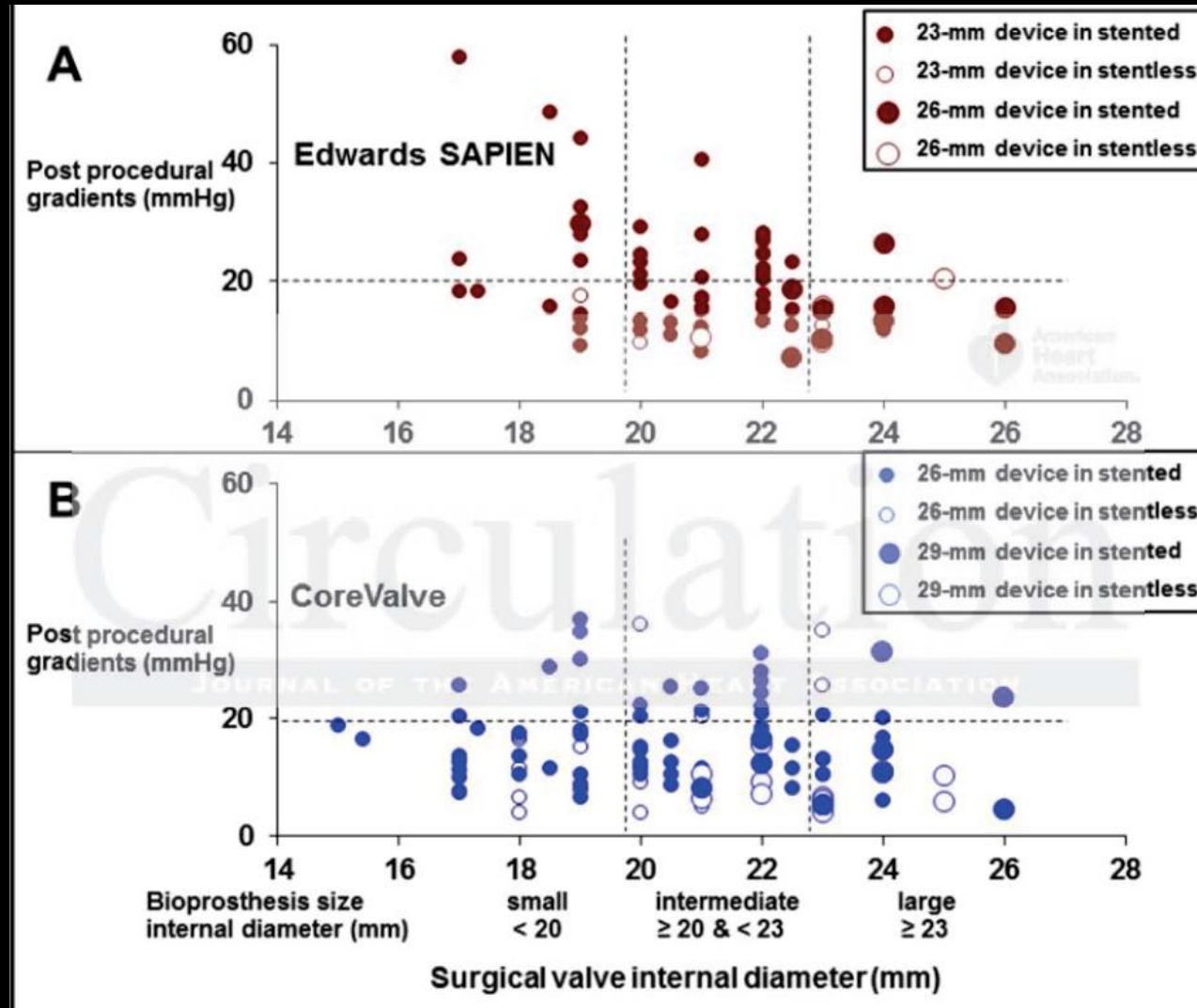


Common Surgical Valves



Valve Failure

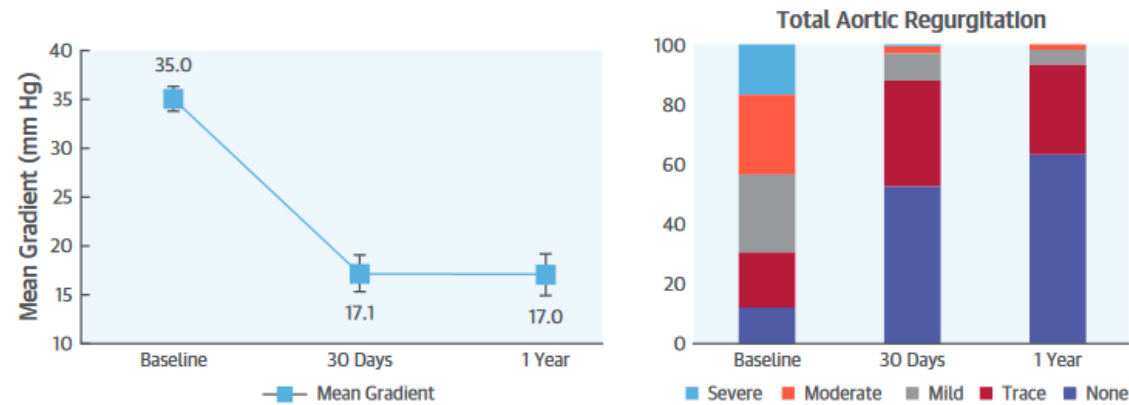
Valve in Valve



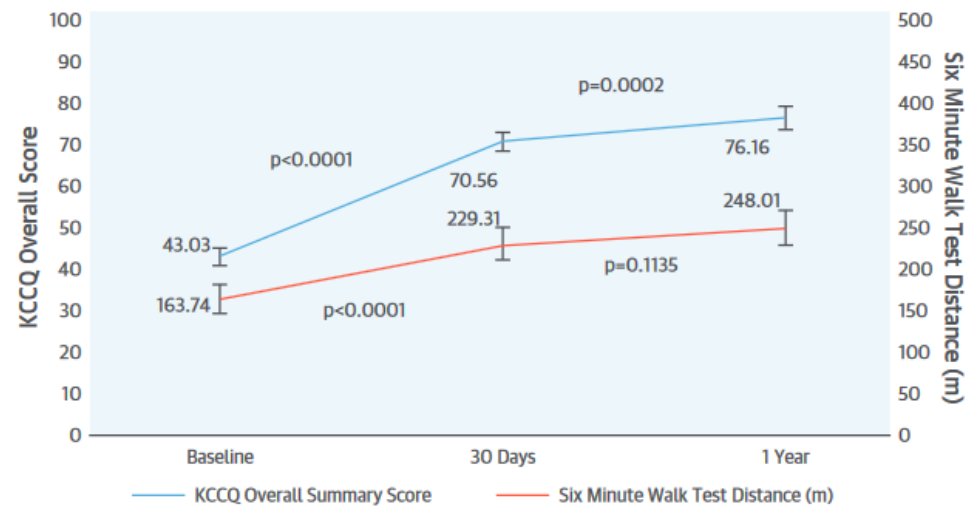
Global ViV registry
202 patients
93% Success rate

Valve in Valve

A. Changes in hemodynamics



B. Changes in function and quality of life



Webb, J.G. et al. J Am Coll Cardiol. 2017;69(18):2253-62.

Valve in Mitral

CASE

Pulmonic Valve Replacement

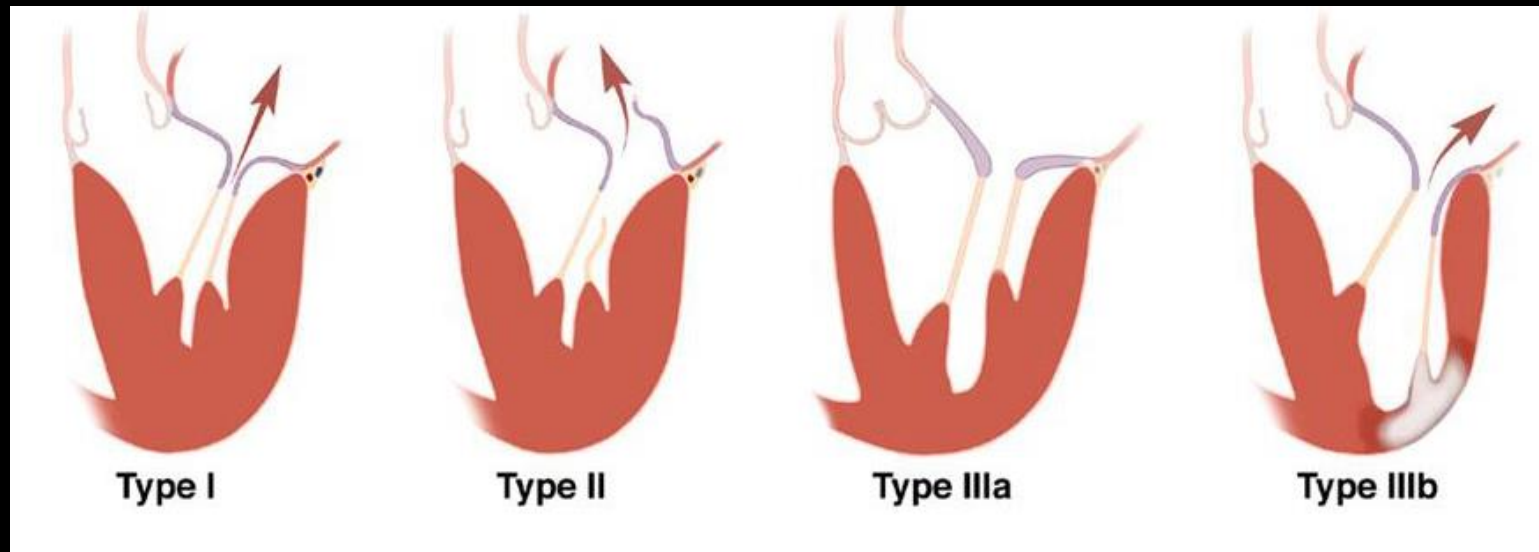
CASE

Future of TAVR

- Low Risk Trial PARTNER 3 (Corevalve low Risk) currently enrolling.
- Bicuspid Valve disease.
- PCI/TAVR versus AVR/CABG.
- Moderate AS in setting of LV dysfunction (TAVR-UNLOAD).

Transcatheter Mitral Valve Therapies

- Mitral Clip
- New valve replacement technologies
- New valve “repair” technologies



Carpentier Classification of mitral regurgitation

Mitraclip



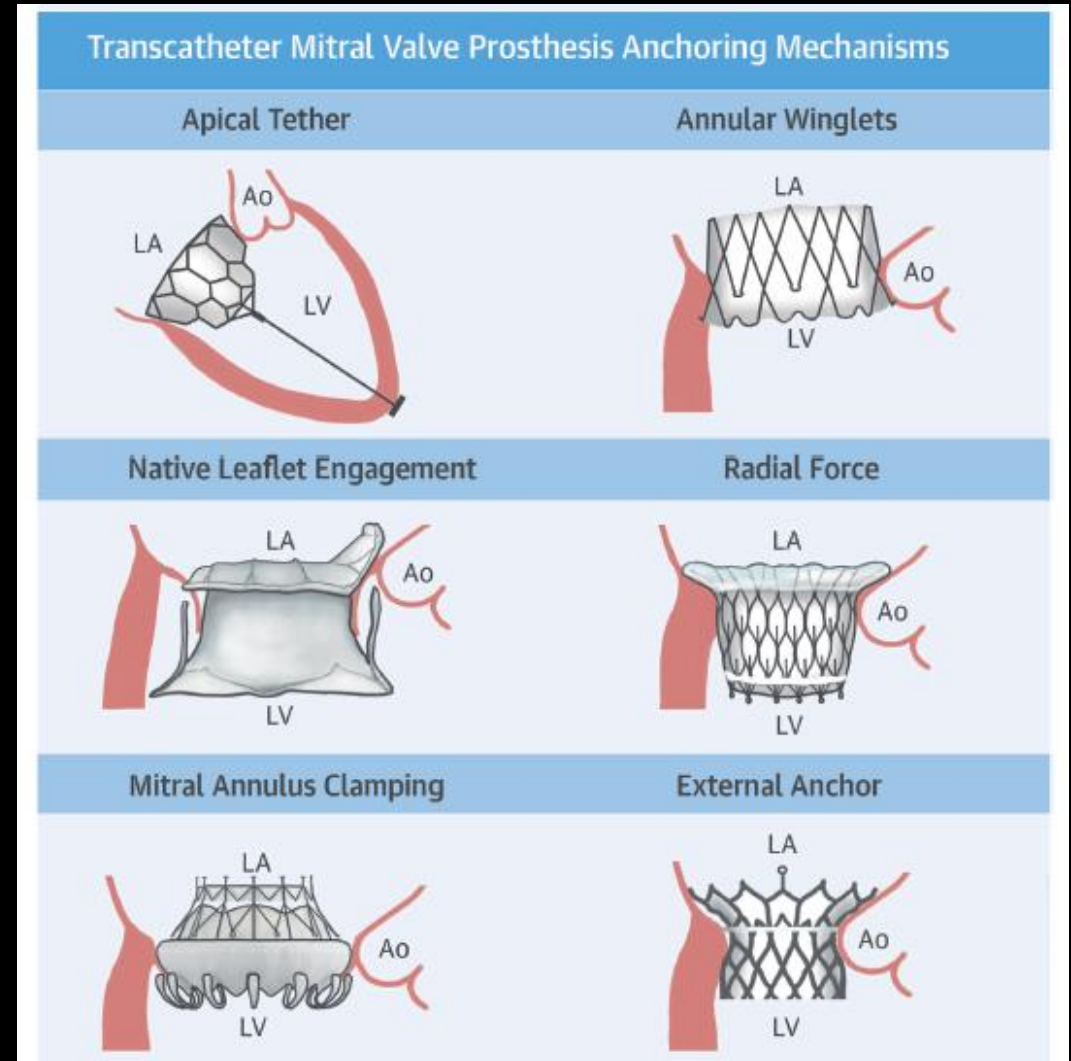
- FDA approved for treatment of “degenerative” mitral valve disease in those at high surgical risk
- High risk: >6% mitral valve repair or >8% for replacement
- COAPT trial: treatment of functional MR in patients with LV dysfunction
- Continued Access COAPT registry

Mitraclip

CASE

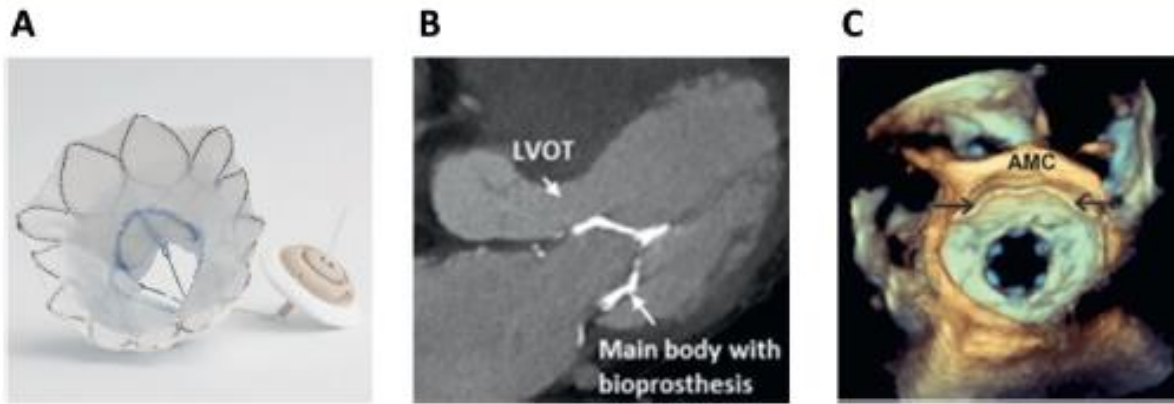
TMVR

- Mitral valve position
- Valve sealing
- Obstruction of the LV outflow tract
- Delivery system
- Anchoring and retention
- Complex mitral valve anatomy



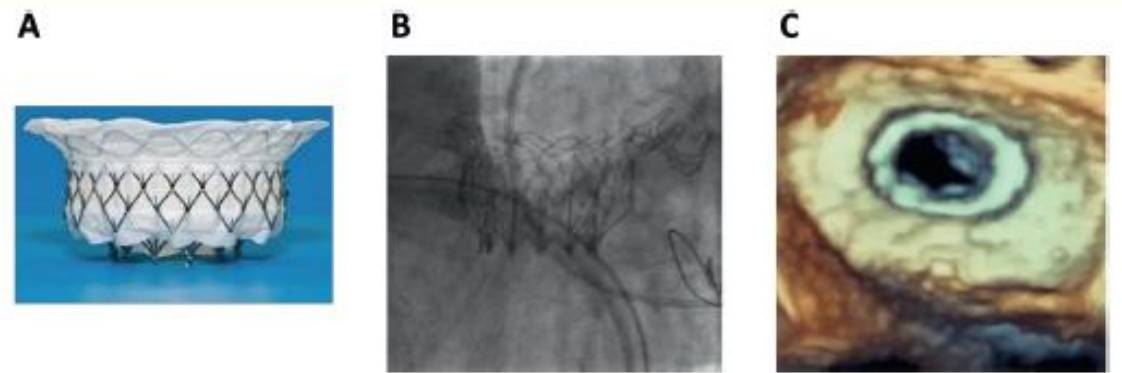
TMVR

FIGURE 4 Tendyne Valve



(A) Valve prosthesis. (B) Fluoroscopy. (C) Three-dimensional transesophageal echocardiography from the surgeon's point of view. Reprinted with permission from Muller et al. (43).

FIGURE 5 Intrepid TMVR



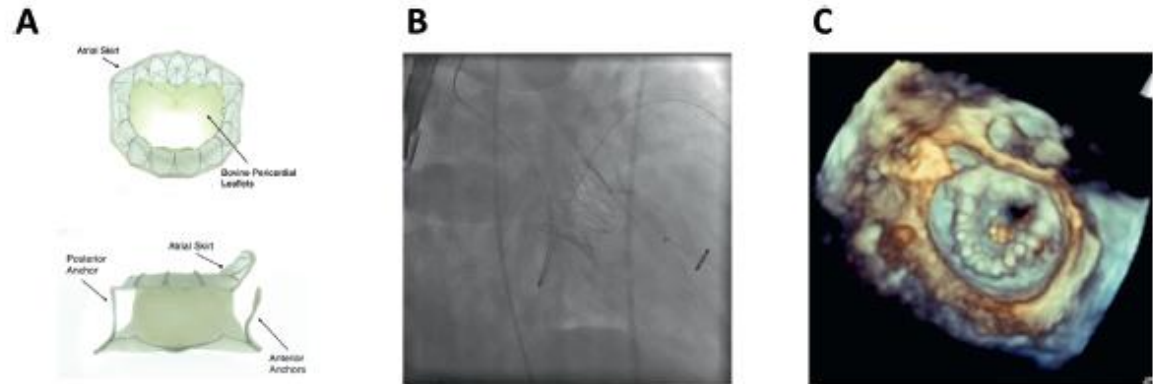
(A) Valve prosthesis. (B) Fluoroscopy. (C) Three-dimensional transesophageal echocardiography from the surgeon's point of view. TMVR = transcatheter mitral valve replacement. A was reprinted from Meredith et al. (44), printed with permission from Europa Digital & Publishing. B and C are courtesy of Dr. Vinayak Bapat, Guy's and St. Thomas' NHS Foundation Trust, London, United Kingdom.

Tendyne

Intrepid

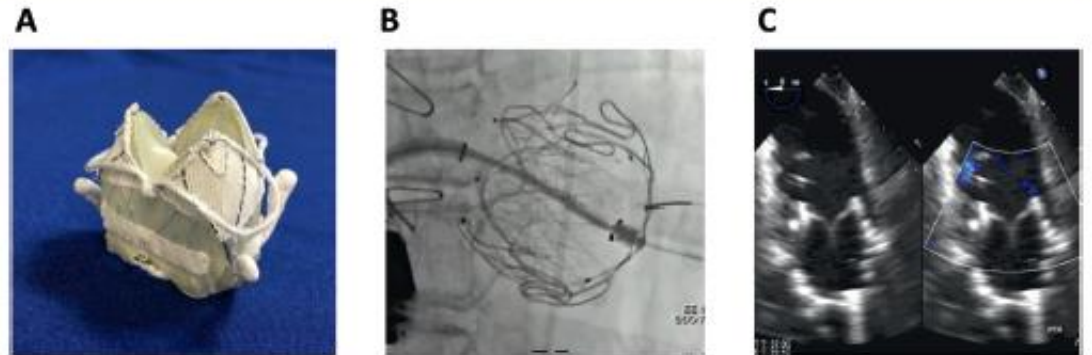
TMVR

FIGURE 3 Tiara Valve



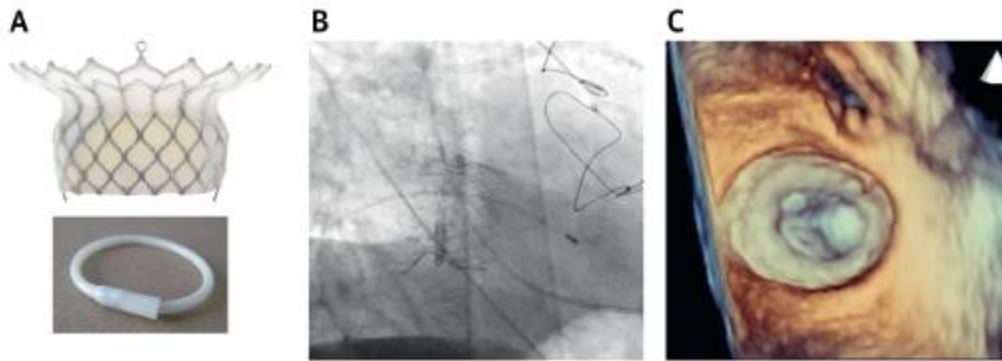
(A) Valve prosthesis. (B) Fluoroscopy. (C) Three-dimensional transesophageal echocardiography from the surgeon's point of view. Reprinted with permission from Cheung et al. (38).

FIGURE 6 Caisson Valve



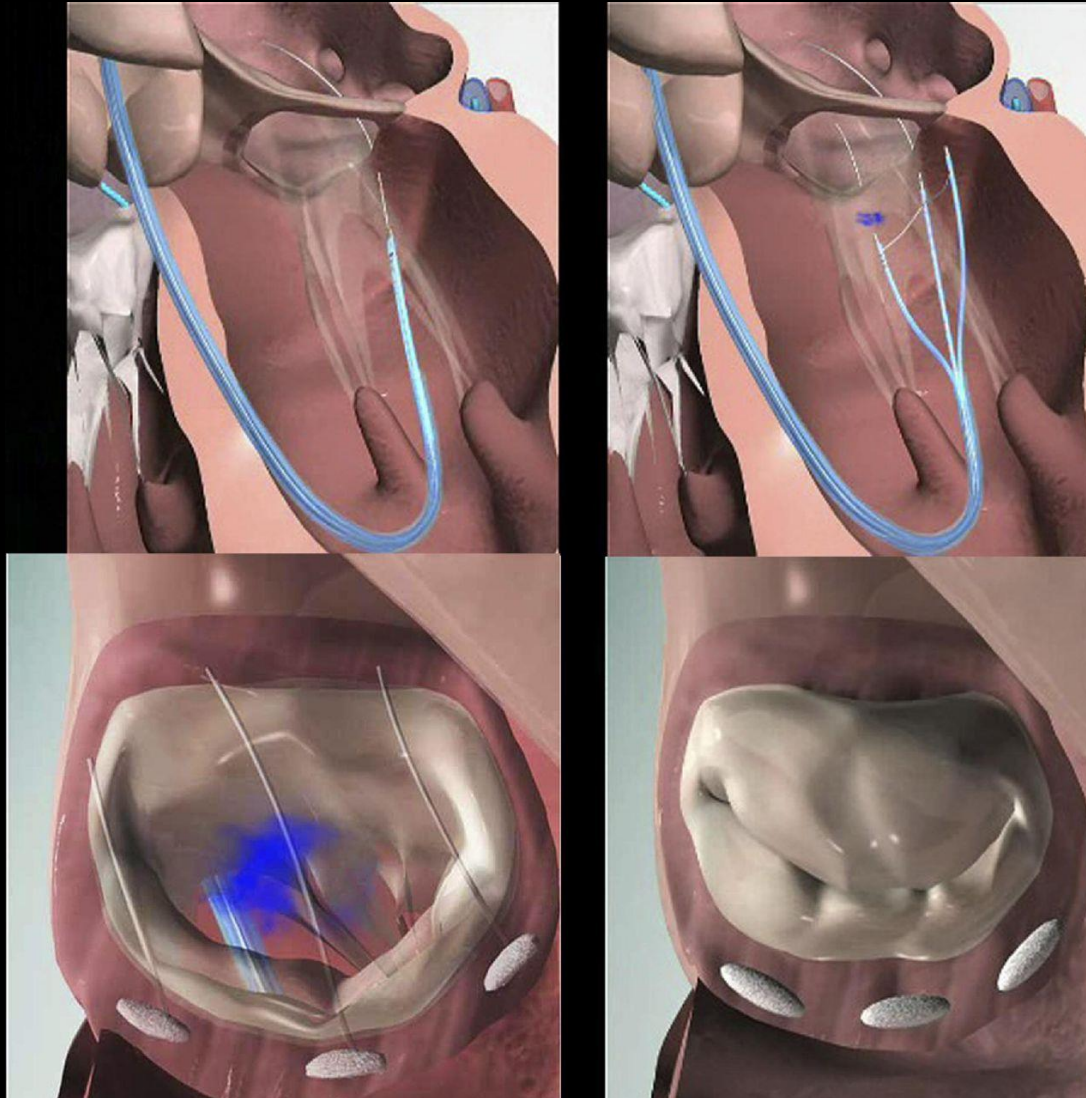
(A) Valve prosthesis. (B) Fluoroscopy. (C) Two-dimensional transesophageal echocardiography. A was provided by Caisson Interventional. B and C are courtesy of Dr. Mathew Williams, NYU Langone Medical Center, New York, New York.

FIGURE 7 HighLife Valve



(A) Valve prosthesis. (B) Fluoroscopy. (C) Transesophageal echocardiography from the surgeon's point of view. Courtesy of Dr. Rüdiger Lange, German Heart Center Munich, Munich, Germany.

ANCORA/ACCUCINCH



Case XX

Conclusion

- Transcatheter aortic valve replacement has been transformative for the care of patients with Severe AS.
- Refinements in technology has improved care.
- Mitral Valve disease is the new frontier in structural heart disease.

Questions

Marc A. Sintek MD

Assistant Professor of Medicine

Interventional Cardiology

Cardiovascular Division

Washington University in St. Louis

msintek@wustl.edu

314-747-3617