A Hybrid Surgeon's Approach to the Management of Severe Aortic Stenosis

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Evolution of Therapy

Treatment Algorithm Based Solely on Surgical Risk is Obsolete

First Principles

#1

Risk Stratification

Low-Risk Patients

STS < 4%; 0/4 Frailty; 0 MOSC

Intermediate-Risk Patients

STS 4-8%, 1/4 Frailty, 1 MOSC

High-Risk Patients

STS > 8%, 2/4 Frailty, <=2 MOSC

Extreme-Risk

Predicted risk of death or MM > 50%l; >=3 MOSC

Patient Risk for Surgical AVR

Nishimura RA. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Thorac Cardiovasc Surg. 2014 Jul;148(1):e1-e132.

Treatment Options - 2010

Low-Risk Patients

STS < 4%; 0/4 Frailty; 0 MOSC

Intermediate-Risk Patients

STS 4-8%, 1/4 Frailty, 1 MOSC

High-Risk Patients

STS > 8%, 2/4 Frailty, <=2 MOSC

Extreme-Risk

Predicted risk of death or MM > 50%l; >=3 MOSC

Patient Risk for Surgical AVR

SAVR

Nishimura RA. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Thorac Cardiovasc Surg. 2014 Jul;148(1):e1-e132.

Treatment Options - 2012

Low-Risk Patients

STS < 4%; 0/4 Frailty; 0 MOSC

Intermediate-Risk Patients

STS 4-8%, 1/4 Frailty, 1 MOSC

High-Risk Patients

STS > 8%, 2/4 Frailty, <=2 MOSC

Extreme-Risk

Predicted risk of death or MM > 50%l; >=3 MOSC

Patient Risk for Surgical AVR

SAVR

TAVR

Nishimura RA. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Thorac Cardiovasc Surg. 2014 Jul;148(1):e1-e132.

Treatment Options - 2015

Low-Risk Patients

STS < 4%; 0/4 Frailty; 0 MOSC

Intermediate-Risk Patients

STS 4-8%, 1/4 Frailty, 1 MOSC

High-Risk Patients

STS > 8%, 2/4 Frailty, <=2 MOSC

Extreme-Risk

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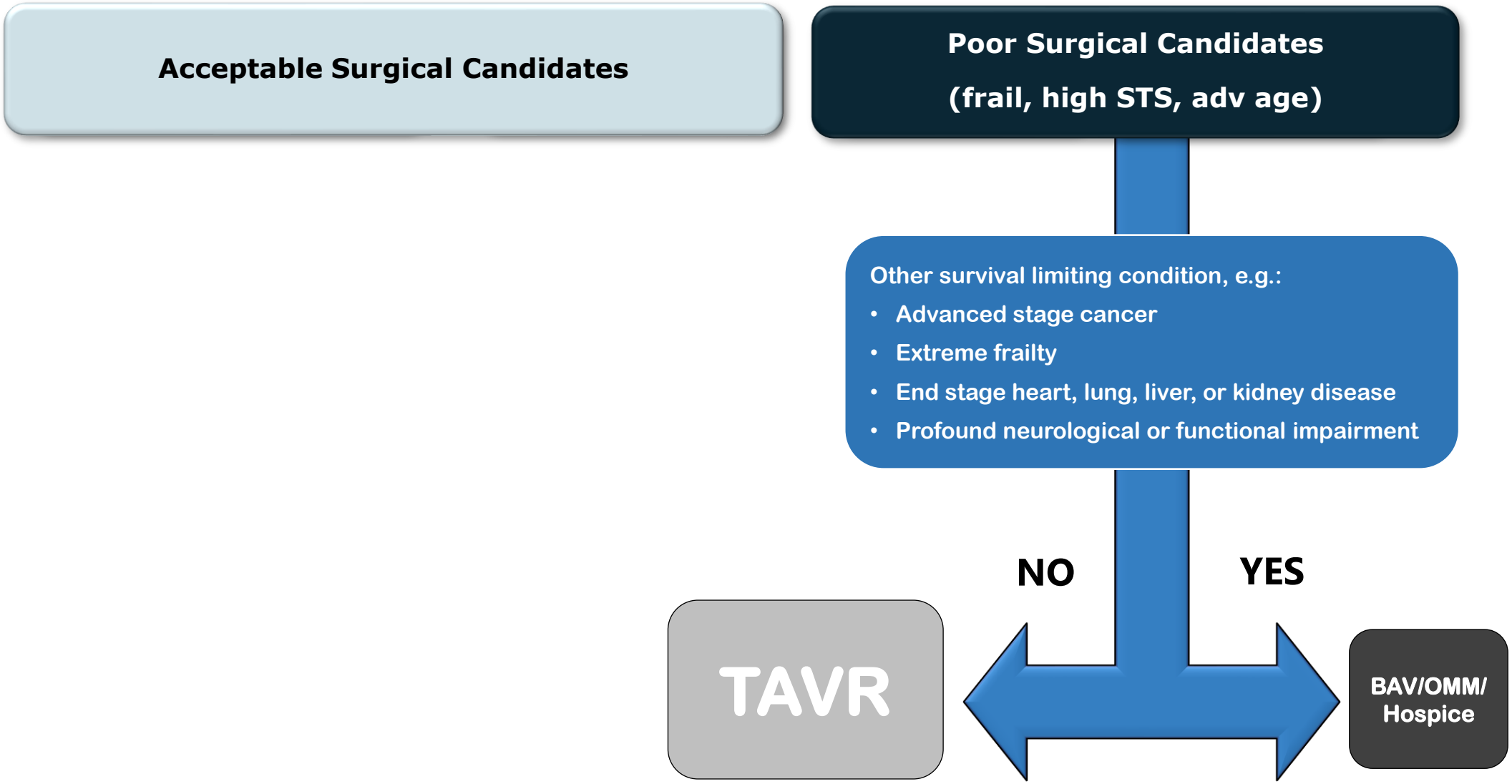
Patient Risk for Surgical AVR

SAVR

TAVR

Nishimura RA. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Thorac Cardiovasc Surg. 2014 Jul;148(1):e1-e132.

Change Paradigm for the Treatment of Severe Symptomatic Aortic Stenosis (SSAS)



Contraindications to TAVR

Expected Median Survival < 1yr

- Advanced stage cancer (Survival < 1 yr)
- Extreme Frailty (4/4) or (5/5) [1,2]
- Advanced age (>83yo) and dialysis [3]
- Child's Class C [4]
- Inpatient's with NYHA Class IV heart failure (non-acute) [5]

Profoundly Deconditioned

- Prolonged inpatient stay (> 2 wks)/Bedbound
- Profound neurological or functional impairment
- Lack of will to live

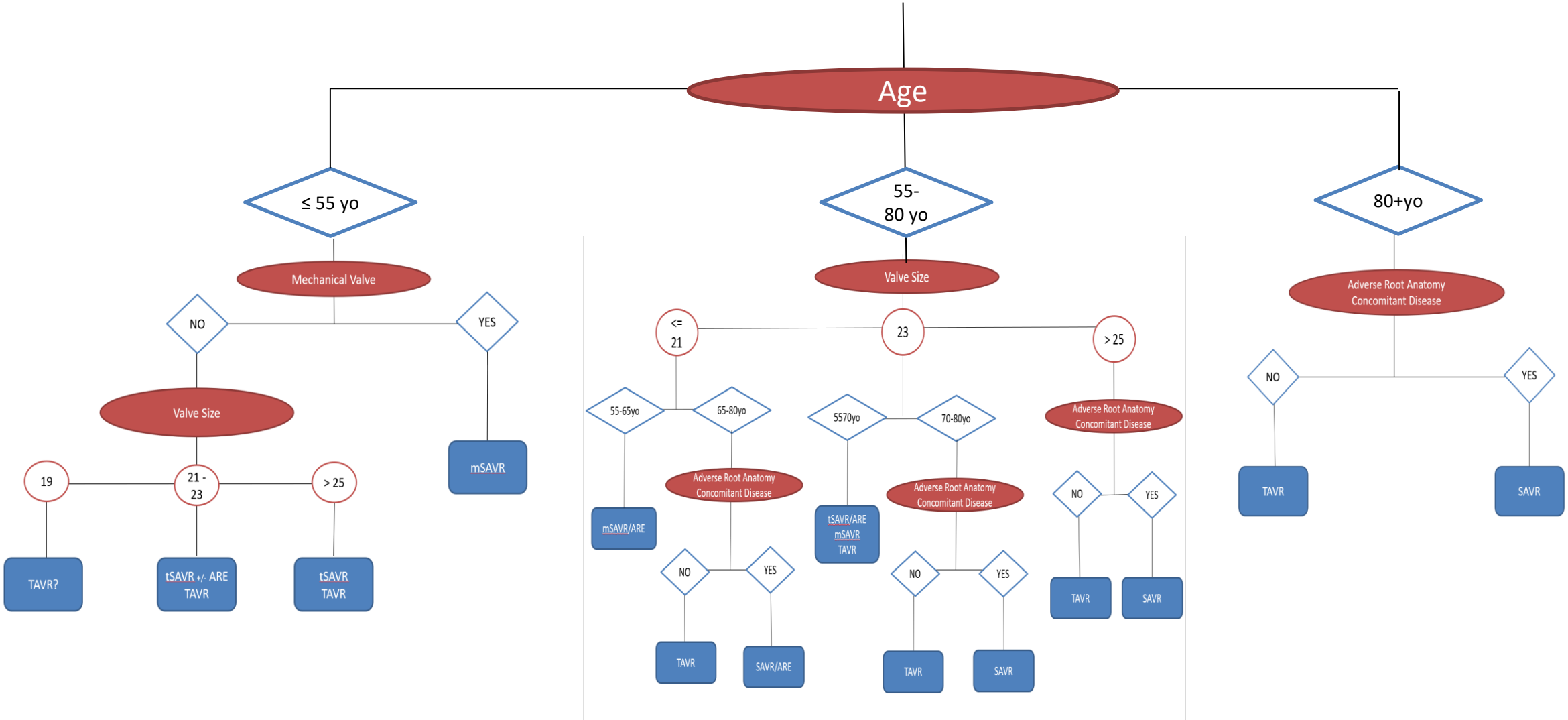
1. Chauhan D, Russo M et al. Am Heart J. 2016 Dec;182:146-154
2. Afilalo J, Lauck S et al,JACC 2017 Aug 8;70(6):689-700.
3. Tamura MK1, Kidney Int. 2012 Aug;82(3):261-9. .
4. D'Amico. J Hepatol. 2006;44:217-31.
5. Ahmed A1, Am Heart J. 2006Feb;151(2):444-50.

For Poor Surgical Candidates with SSAS, TAVR indicated regardless

- Multivessel CAD
- Low EF
- Severe Mitral Regurgitation

Acceptable Surgical Candidates

Acceptable Surgical Candidates



AVR in Patients ≤ 55yo

In Patients < 55yo, Mechanical Prosthesis is Associated with Survival Benefit

First Principles

#3

The NEW ENGLAND JOURNAL of MEDICINE

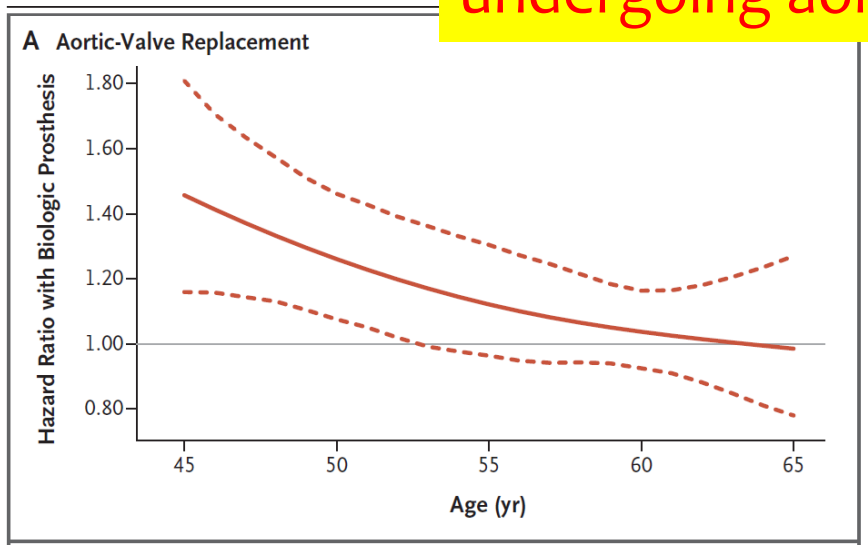
ORIGINAL ARTICLE

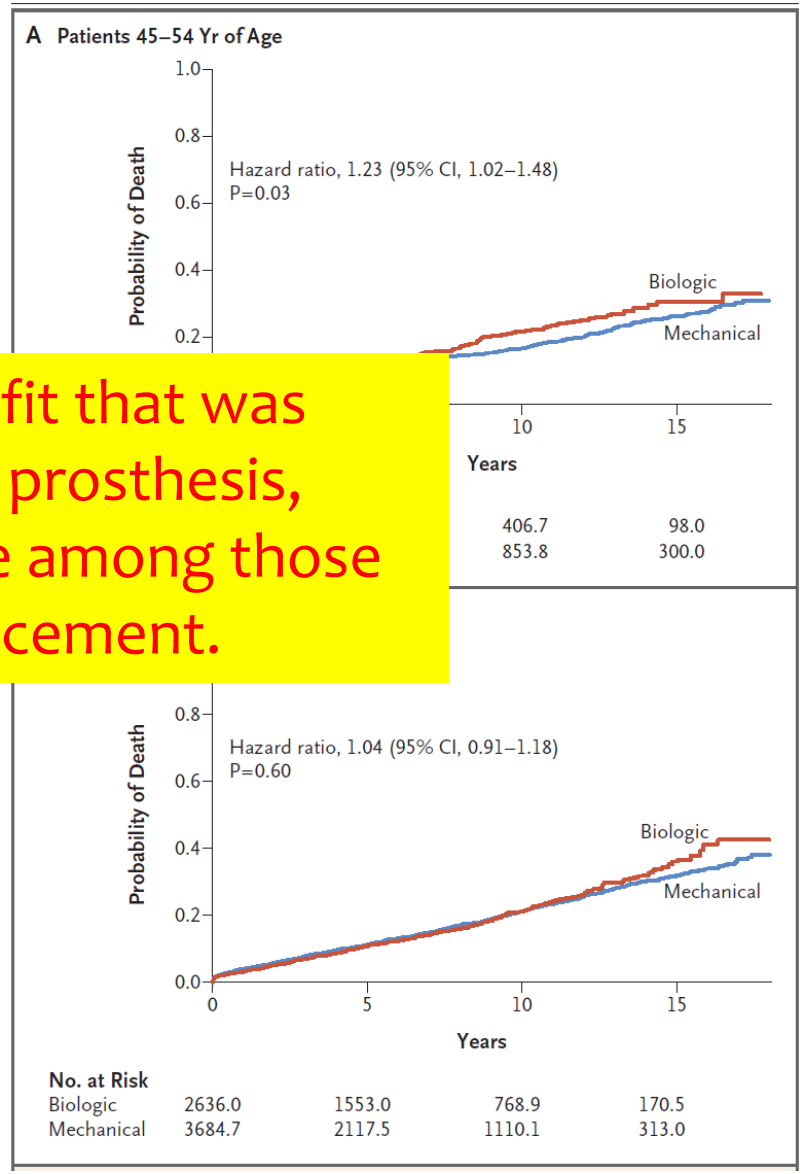
Mechanical or Biologic Prostheses for Aortic-Valve and Mitral-Valve Replacement

Andrew B. Goldstone, M.D., Ph.D., Pete
Bharathi Lingala, Ph.D., William L. Patrick,
and Y. Joseph

9942 patients undergoing SAVR i

The long-term mortality benefit that was associated with a mechanical prosthesis, persisted until 55 years of age among those undergoing aortic-valve replacement.





AVR in Patients ≥80yo

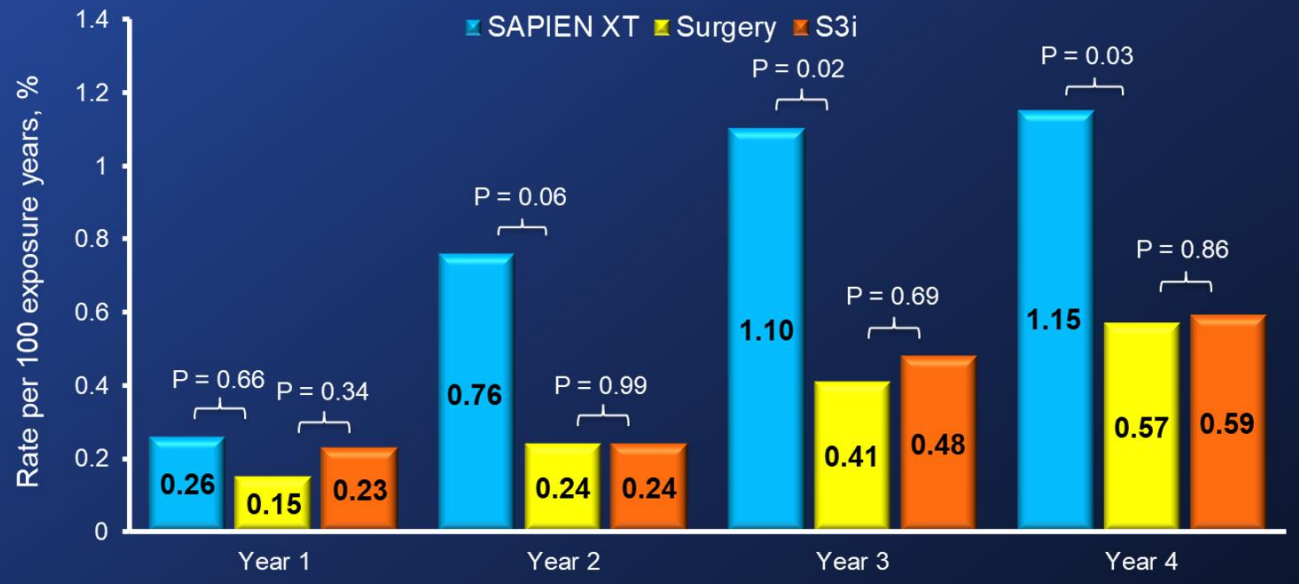
AVR in 80+yo

TAVR

Exception

- **patients with angina like symptoms and severe LM/prox LAD disease not amenable to PCI**
- **Symptomatic MR**

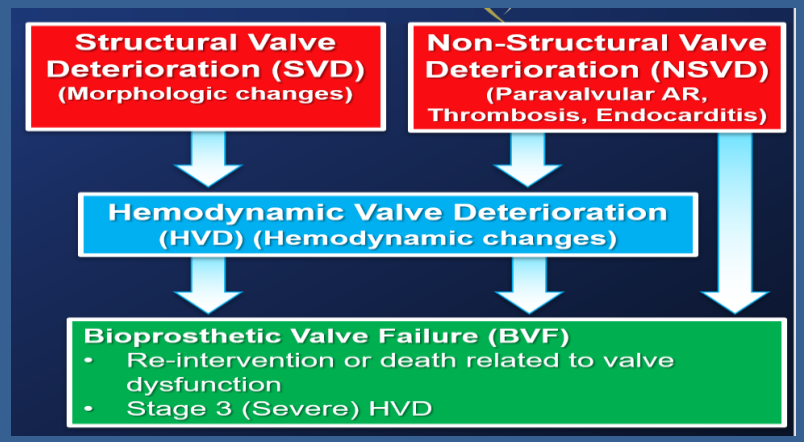
SVD-related HVD
P2A Surgery, P2A SAPIEN XT, & P2 S3i



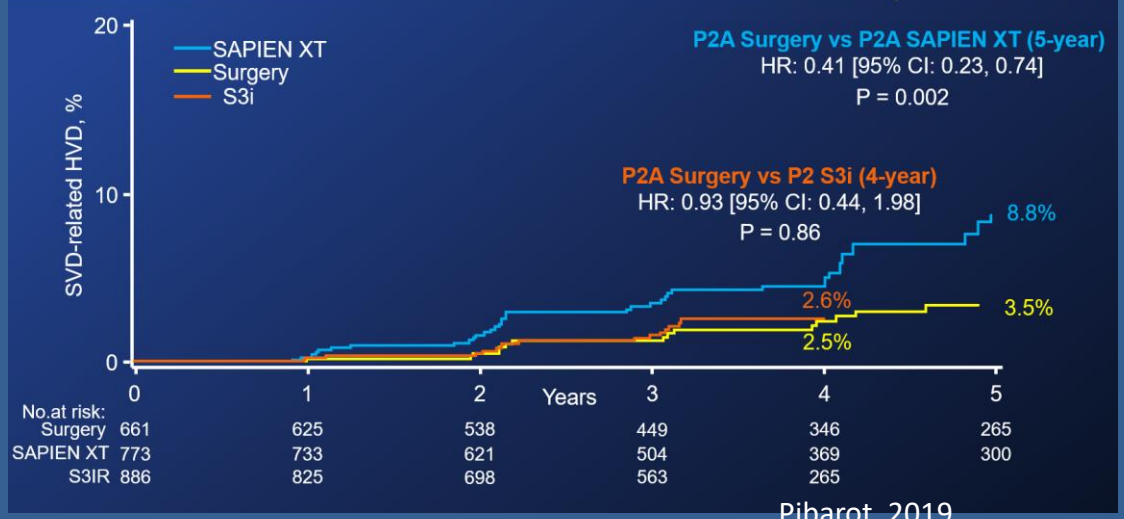
Incidence, Predictors, and Outcome of Structural Valve Deterioration in Transcatheter versus Surgical Aortic Valve Replacement: 5 Year Follow-up from the PARTNER 2 Trials – Intermediate risk

Philippe Pibarot, DMV, PhD & Rebecca Hahn, MD
on behalf of The PARTNER Trial Investigators

London Valves | London | November 18, 2019



SVD-related HVD
P2A Surgery, P2A SAPIEN XT, & P2 S3i

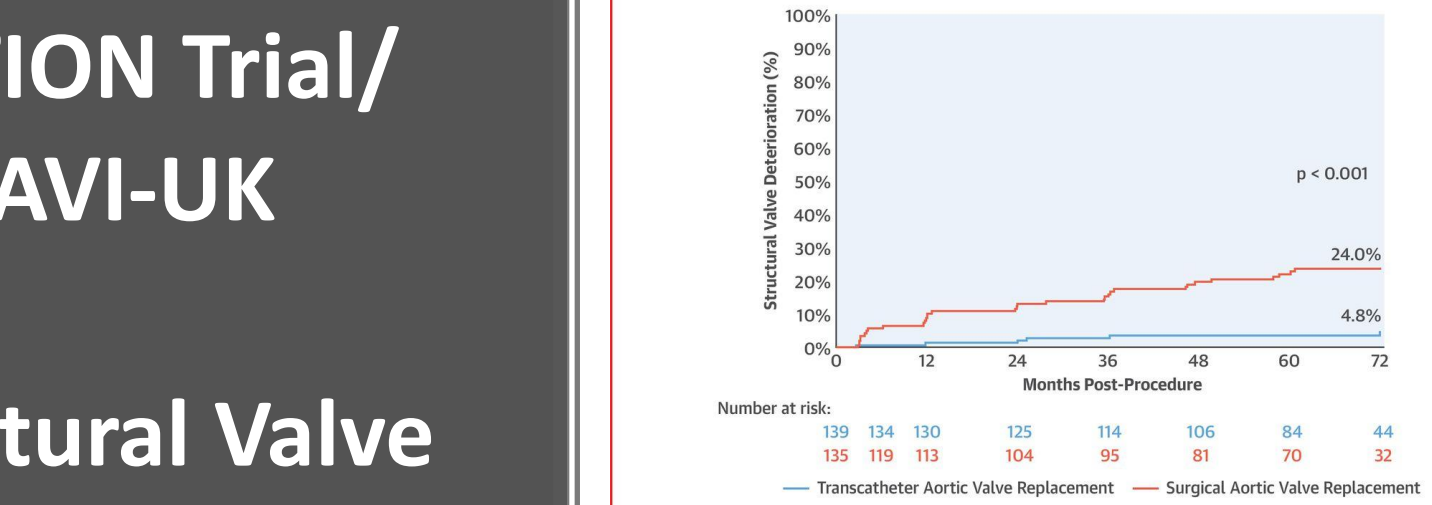


Pibarot, 2019

NOTION Trial/ TAVI-UK

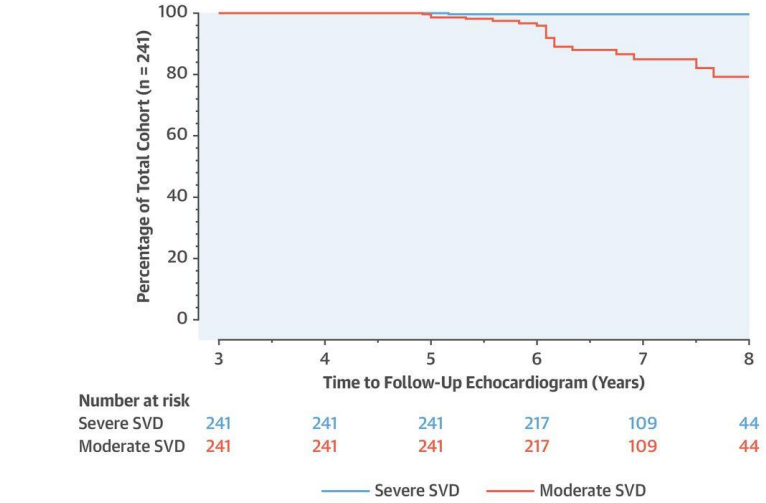
Structural Valve Deterioration

CENTRAL ILLUSTRATION: Cumulative Incidence of Structural Valve Deterioration Through 6 Years



Søndergaard, L. et al. J Am Coll Cardiol. 2019;73(5):546-53.

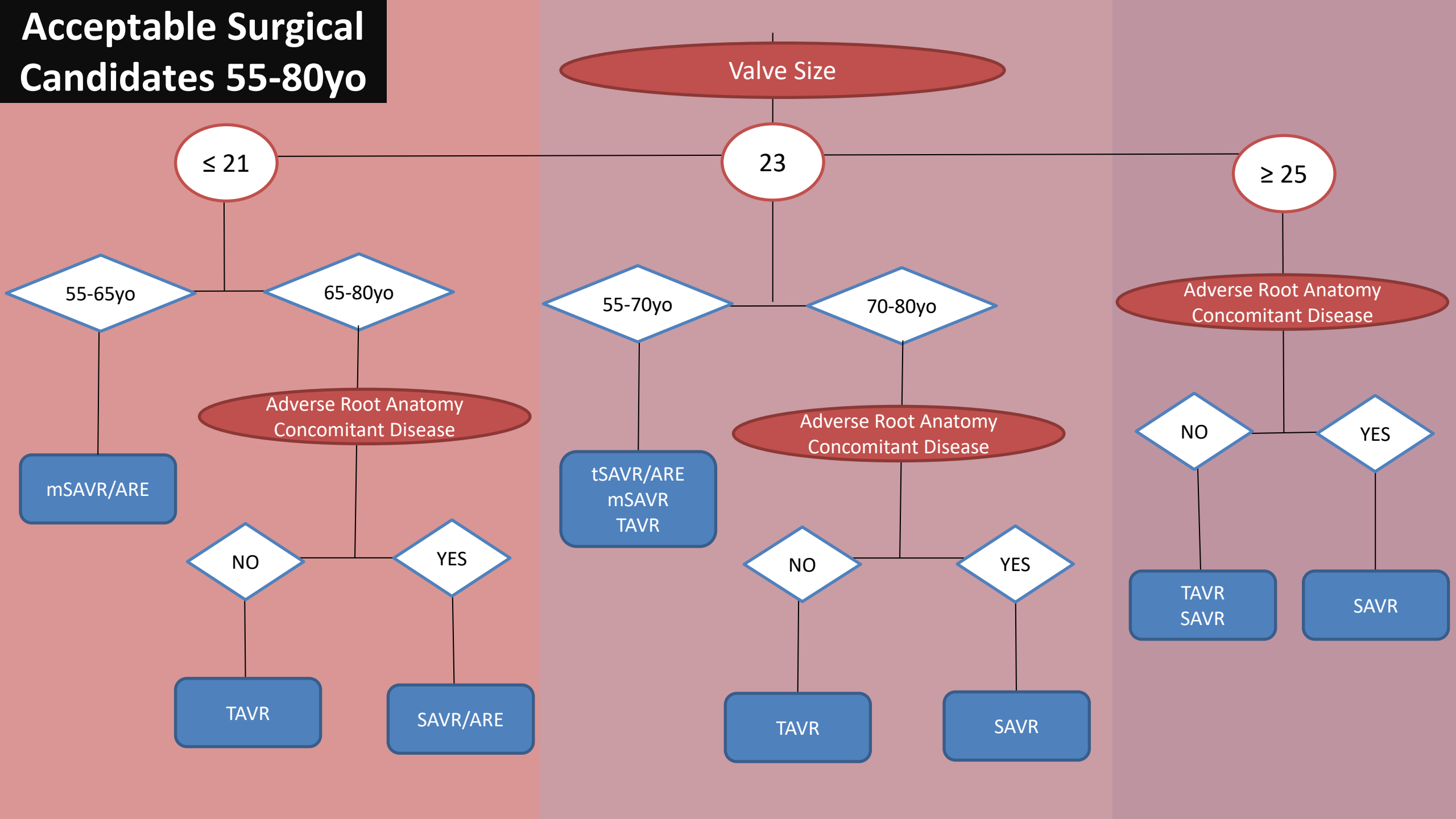
CENTRAL ILLUSTRATION: Freedom From Structural Valve Deterioration Over Time: Kaplan-Meier Curve



Blackman, D.J. et al. J Am Coll Cardiol. 2019;73(5):537-45.

AVR in Patients 55yo – 80yo

Acceptable Surgical Candidates 55-80yo



Variables for Acceptable Surgical Candidates

- Patient Preference

What is the Patient Trying to Achieve?

- Avoid anticoagulation
- Minimize # of Procedures

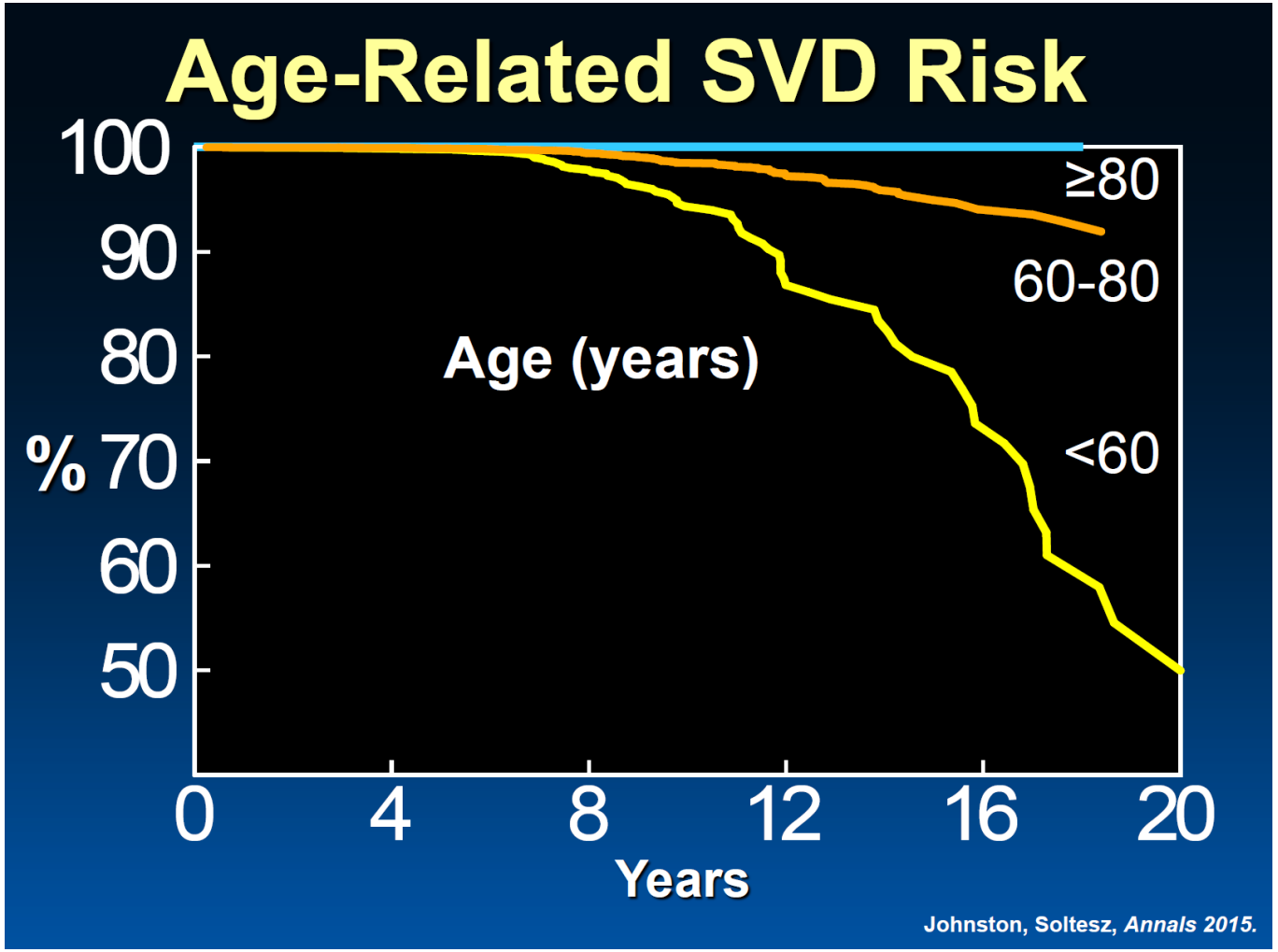
Variables for Acceptable Surgical Candidates

- Patient Preference
- Other Cardiac Disease
  - LM/LAD dz w (-) PCI
  - Severe MR
  - Ao Aneurysm
  - Severe TR, Maze/LAA

Variables for Acceptable Surgical Candidates

- Patient Preference
- Other Cardiac Disease
- Longevity (Age)

Age and probability of explant due to SHD at 20 years



Johnston DR, Soltesz EG. Long-term durability of bioprosthetic aortic valves: implications from 12,569 implants. Ann Thorac Surg. 2015 Apr;99(4):1239-47.

Variables for Acceptable Surgical Candidates

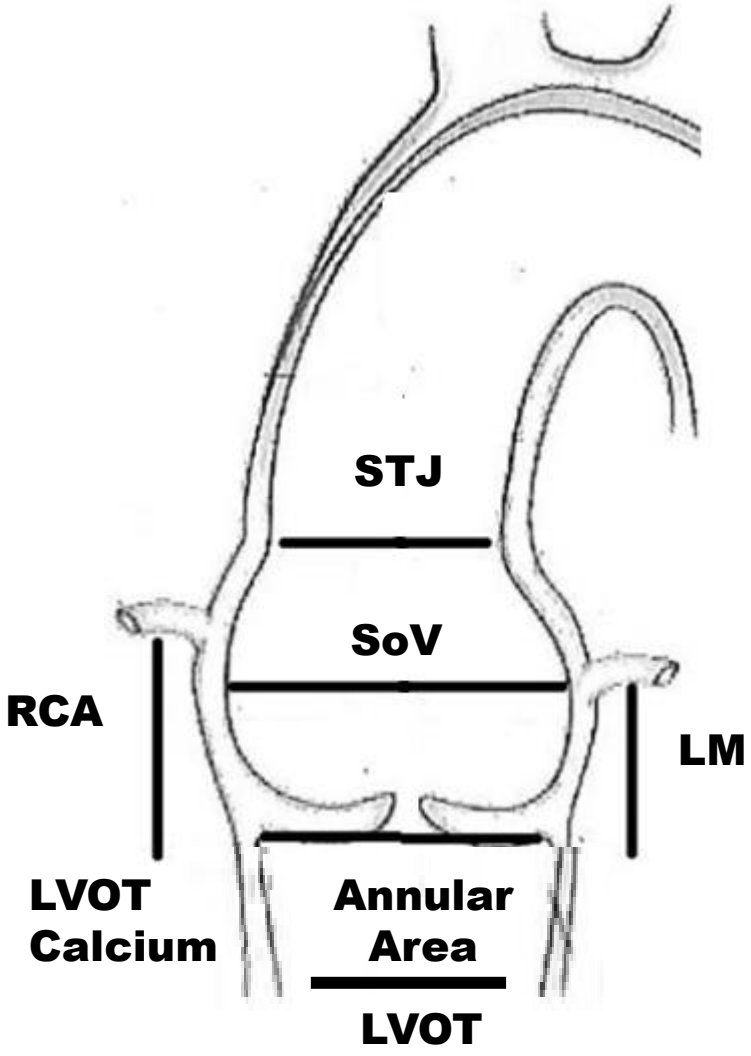
- Patient Preference
- Other Cardiac Disease
- Longevity (Age)
- Root Anatomy
  - Valve Size

Gated Cardiac CT Should Be Standard for All Preop Aortic Stenosis Patients

#4

Aortic Root Assessment

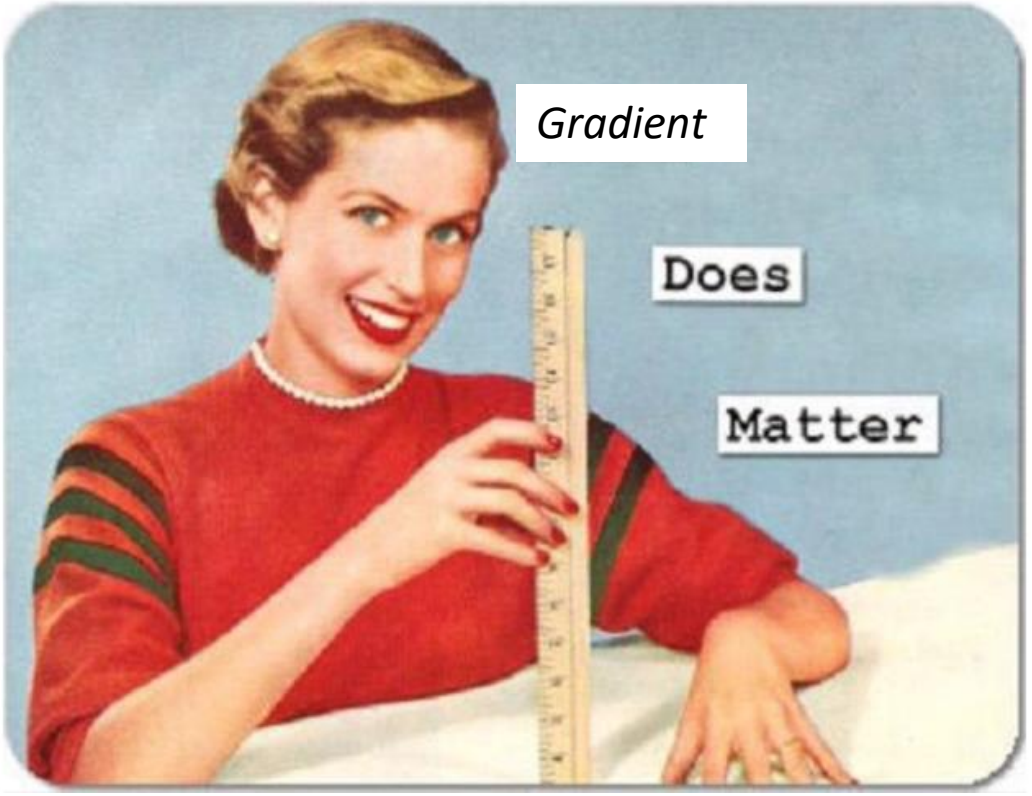
- Annular area
  - LVOT area
- Root Features
  - SOV and STJ Dimensions
  - Coronary heights (LM/RCA)
  - Leaflet Calcification
  - Leaflet lengths
  - LVOT Calcification



Valve Selection – Initial AVR

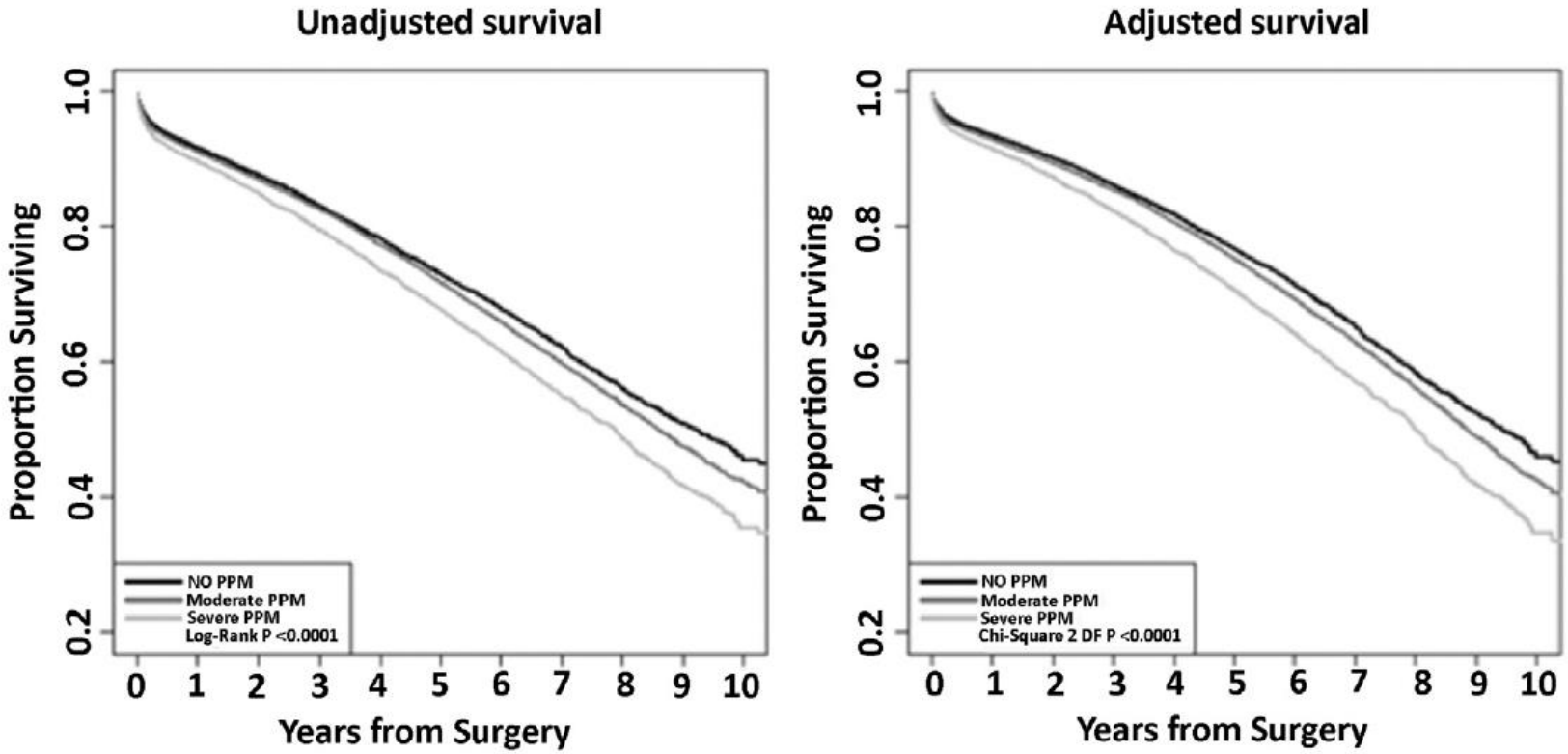
- *AS patients who are appropriate surgical candidates are likely to be lower risk and therefore have significant longevity*
- Must seek the **larger valve sizes** and **lowest gradients**
    - Avoid PPM
    - Provide reasonable AVIV option

->No role for small bioprosthetic valves (eg 19mm) in the current era



STS Database (2018) Analysis of 60,000 SAVR Patients with 10-Year Follow-up

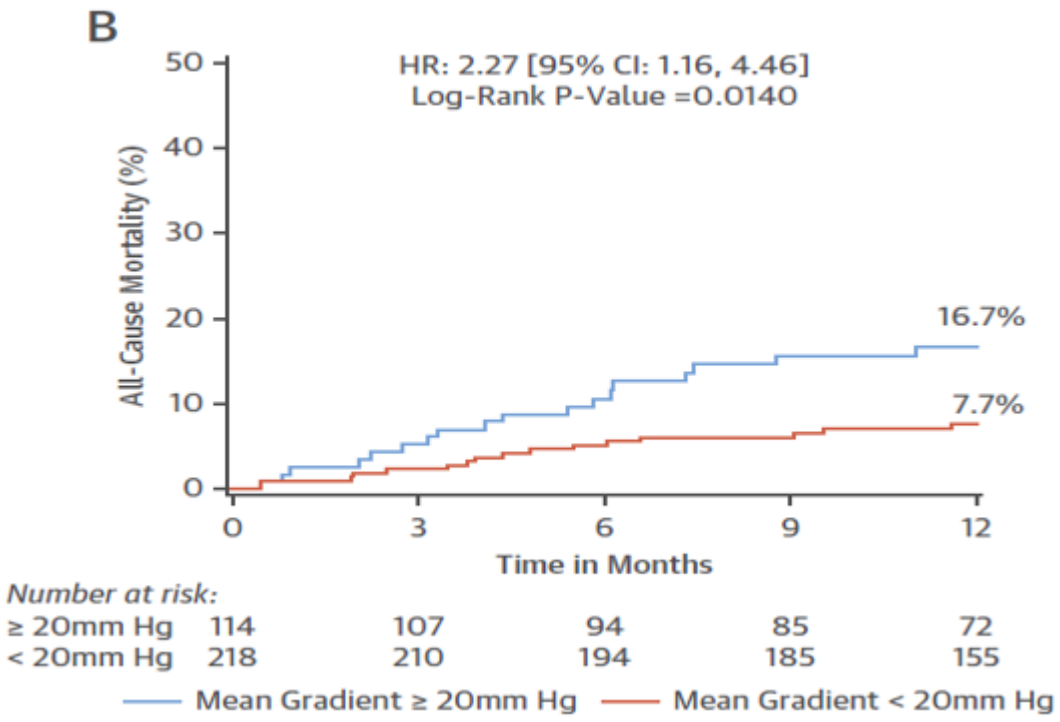
Severe PPM was Associated with Higher Mortality

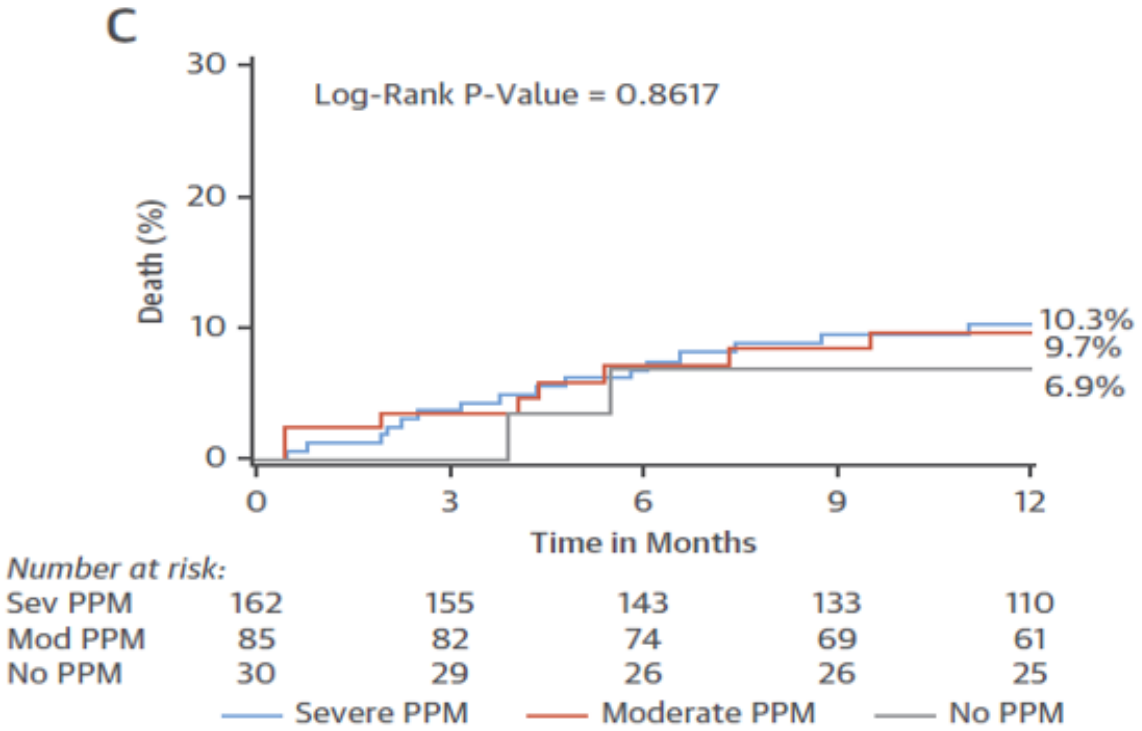


Time (yr)	Number at risk		
	None	Moderate	Severe
1yr	17,626	27,725	5,599
3yr	10,027	18,540	4,064
5yr	5,252	10,698	2,429
10yr	155	345	67

Fallon JM, et al . The Incidence and Consequence of Prosthesis-Patient Mismatch After Surgical Aortic Valve Replacement. Ann Thorac Surg. 2018 Jul;106(1):14-22.

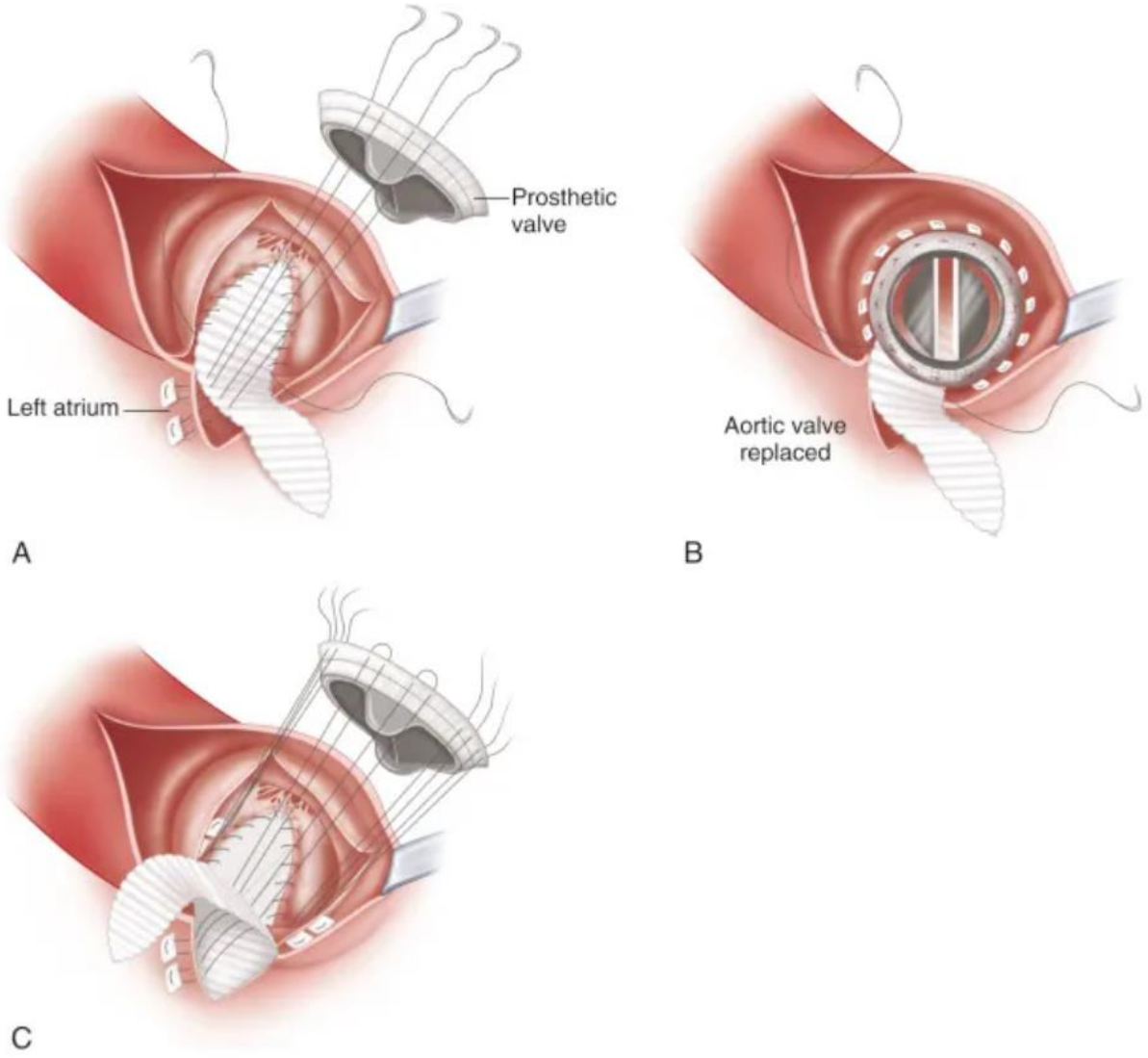
The PARTNER 2 Registry/SXT: Significantly increased mortality with higher gradients and a trends toward increased mortality in patients w PPM and smaller valve size



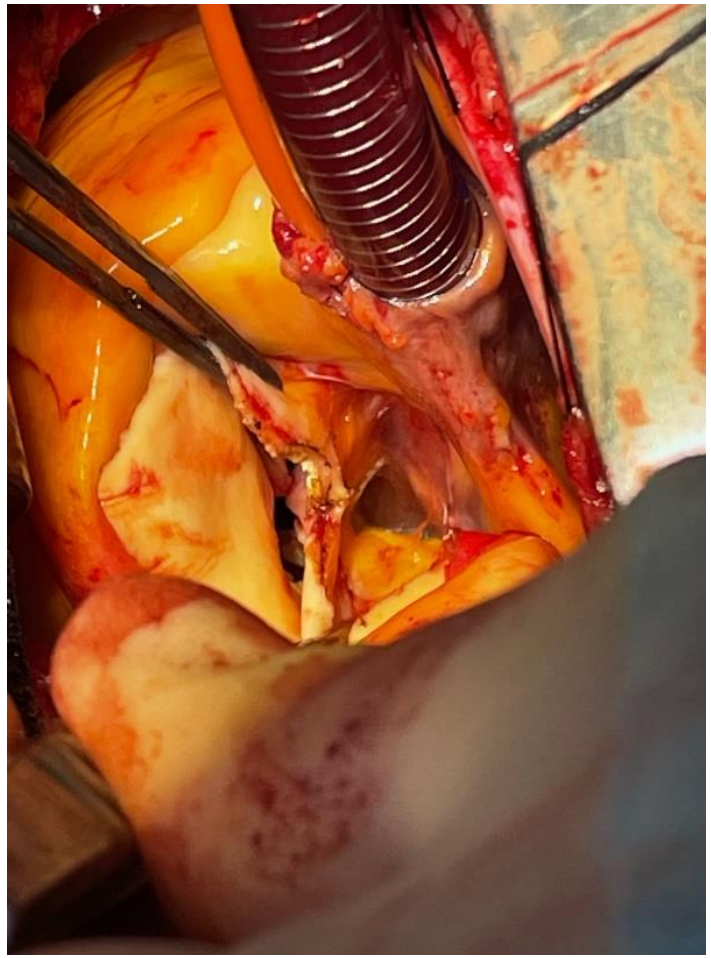


Webb JG, et al. Transcatheter Aortic Valve Implantation Within Degenerated Aortic Surgical Bioprostheses: PARTNER 2 Valve-in-Valve Registry. J Am Coll Cardiol. 2017;69(18):2253-2262.

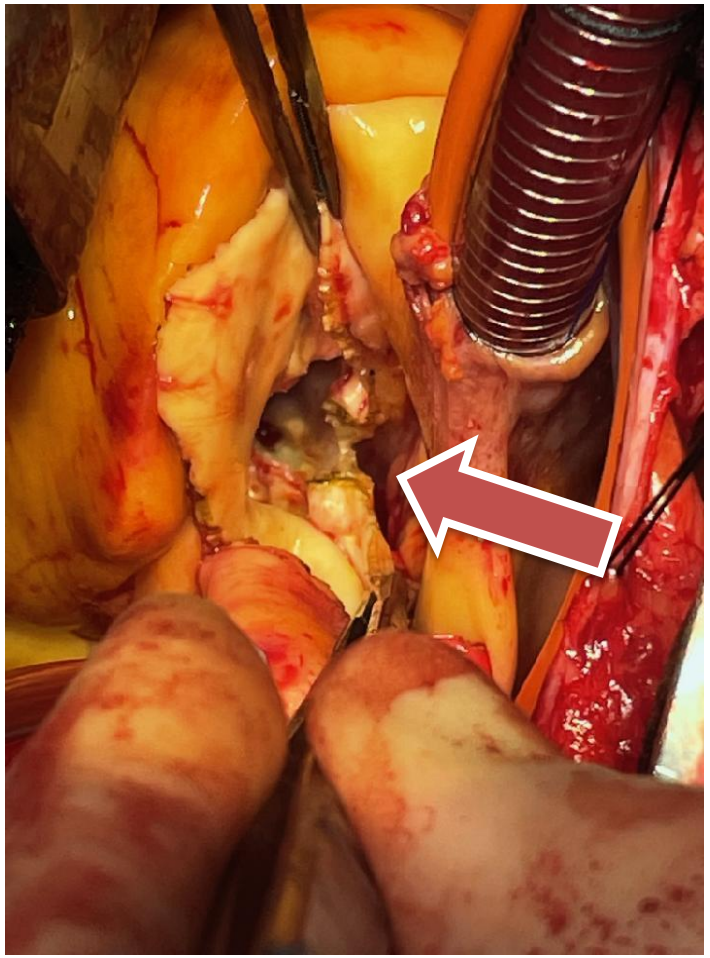
Annular Enlargement



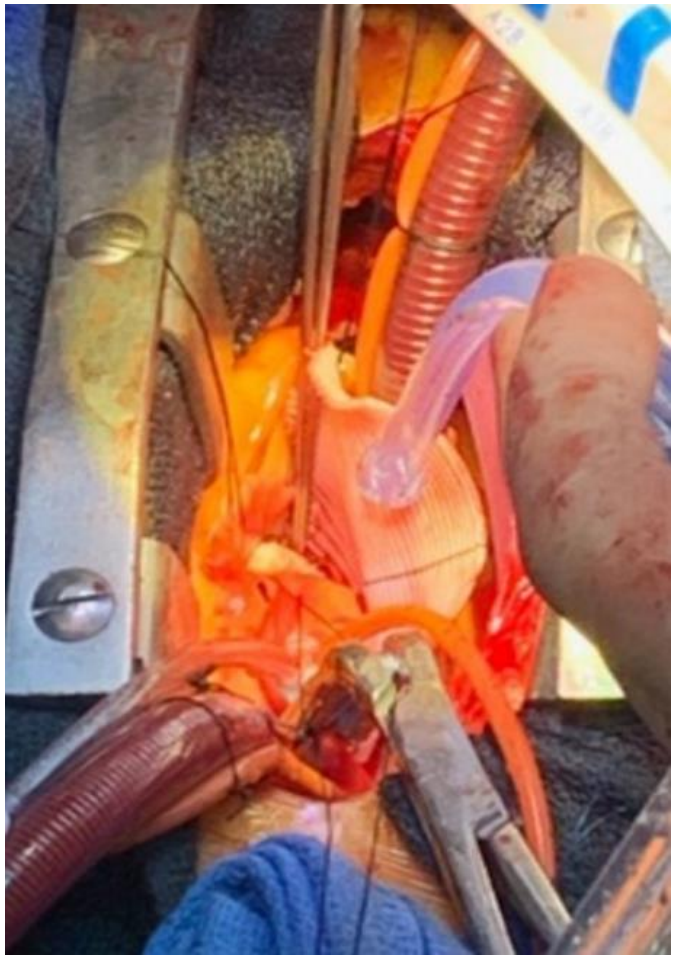
Aortic Annular Enlargement



Open the Aorta;
dissect the NC off the RA

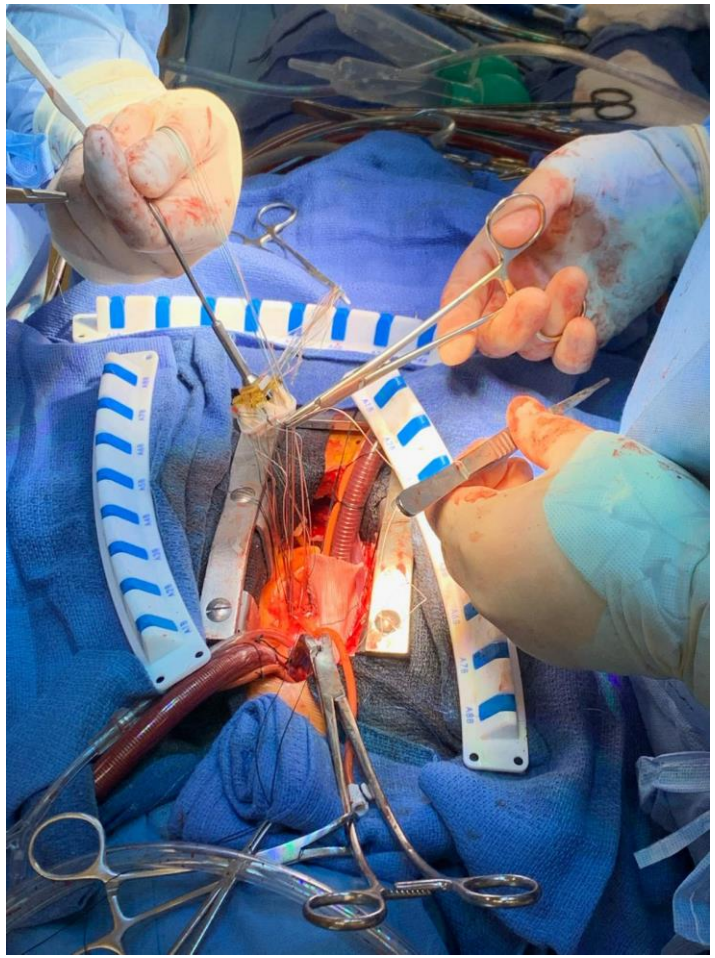


Extend the Aortotomy thru the NC
of Aortic Annulus onto the MV

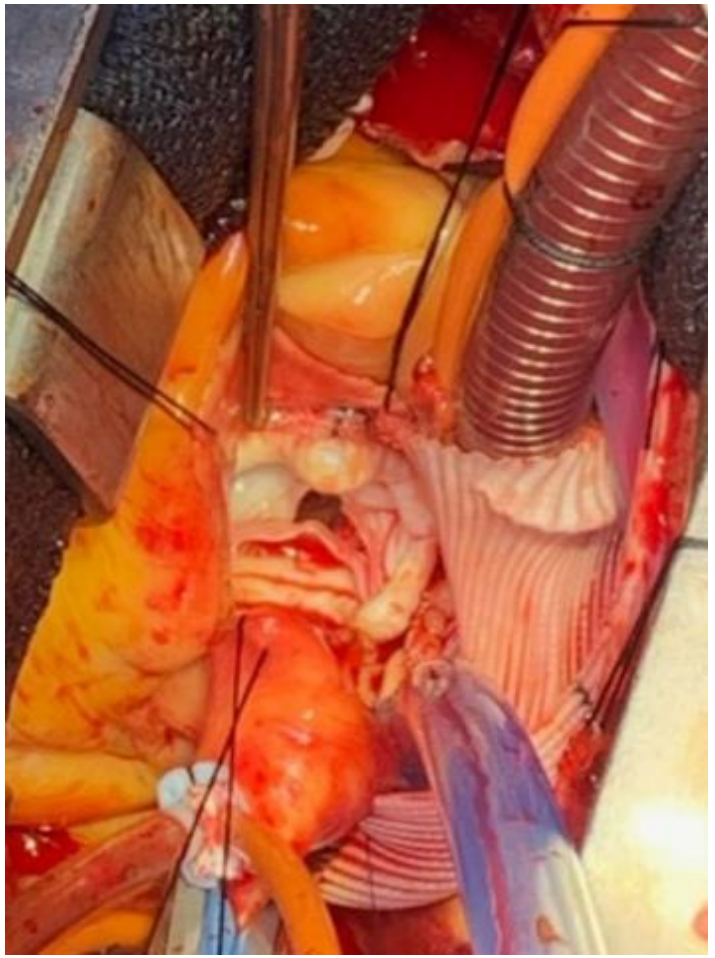


Patch MV, Ao Annulus, and
Aorta w Dacron graft

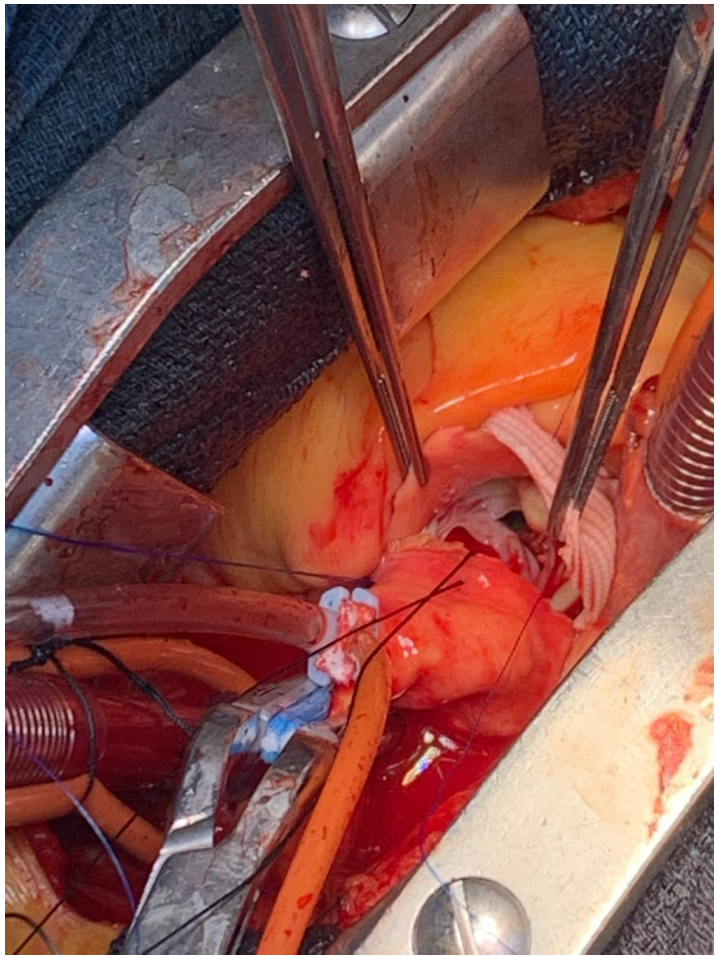
Aortic Annular Enlargement



Implant Aortic Valve

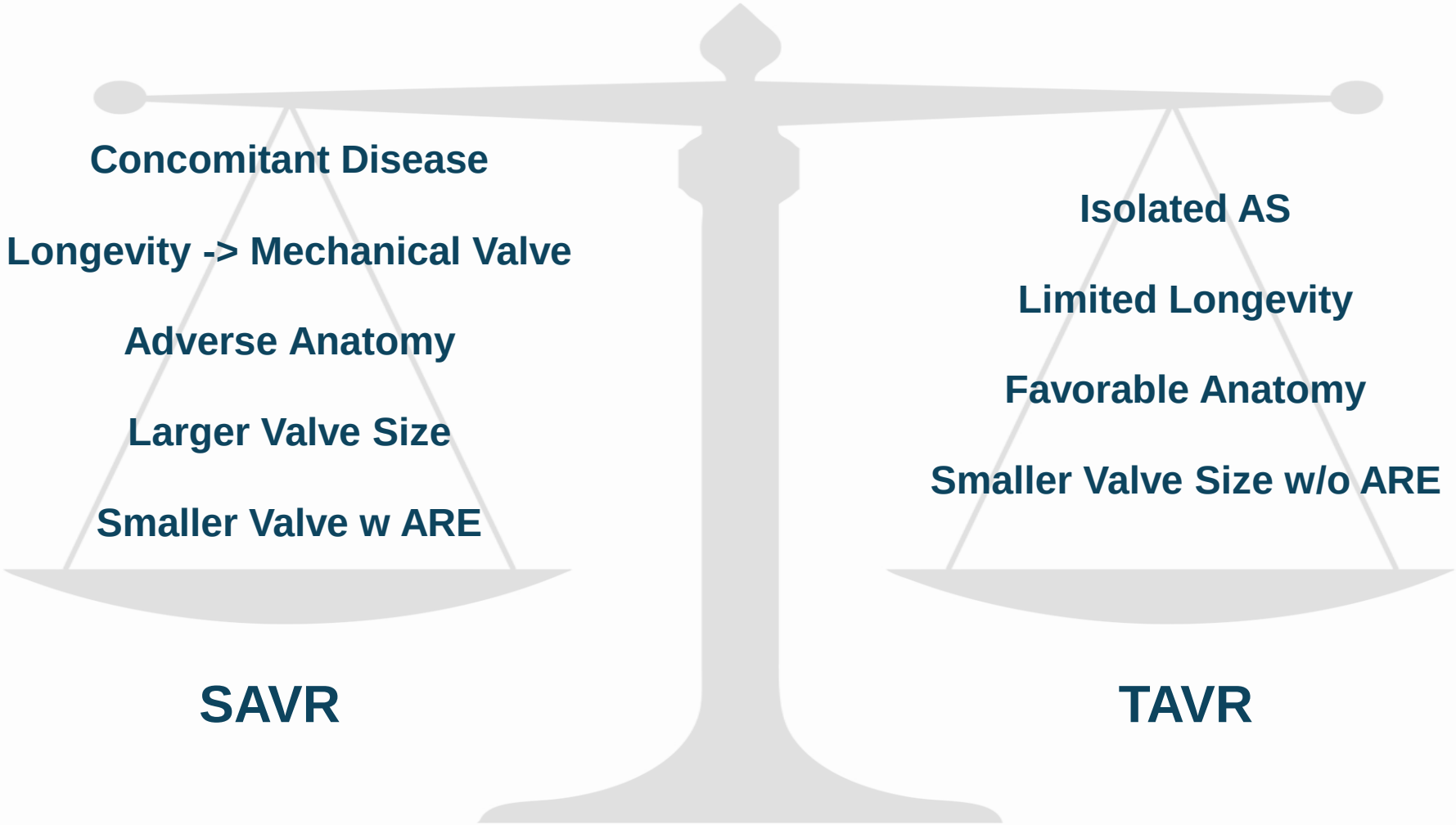


Tie Valve in place



Complete Patch
w Dacron graft

Factors to Consider SAVR vs TAVR in Patients 55yo - 80yo



Conclusions

- <55yo - SAVR w Mechanical Valve
- 80+yo - TAVR
  - Unacceptable Surgical Candidates w 1+ year of survival regardless of other cardiac disease
- 55-80yo - Acceptable Surgical Candidates
  - Algorithm must consider Longevity, Other Cardiac Disease, Root Anatomy
- *Gated Cardiac CT should be standard for All Preop Aortic Stenosis Patients*

Scenarios