Overview of Aortic Stenosis and Transcatheter Aortic valve Replacement/Implantation (TAVR/TAVI)

Gaurav R. Parikh, MD, MRCP(UK)

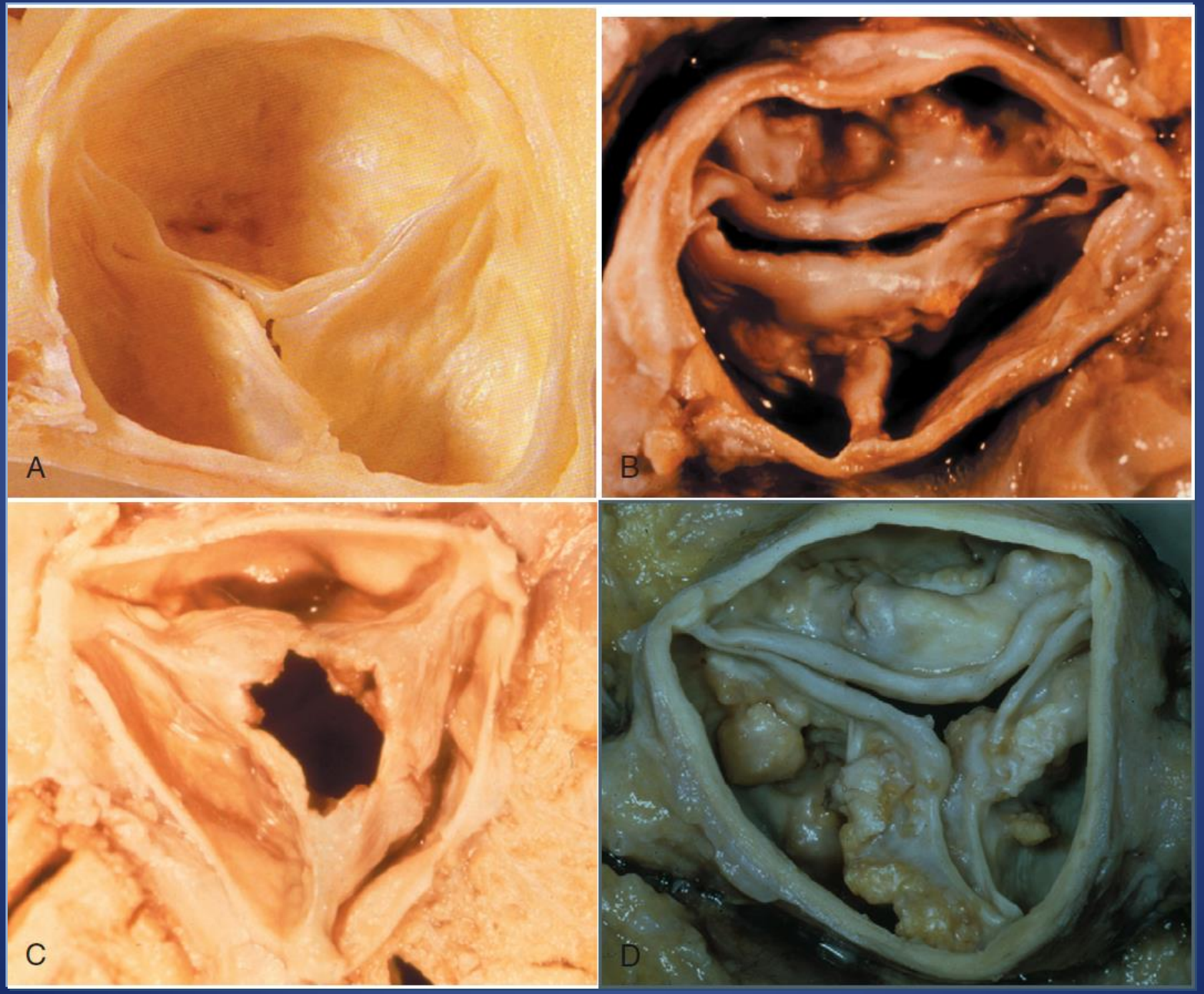
Interventional Cardiology

Aortic Stenosis

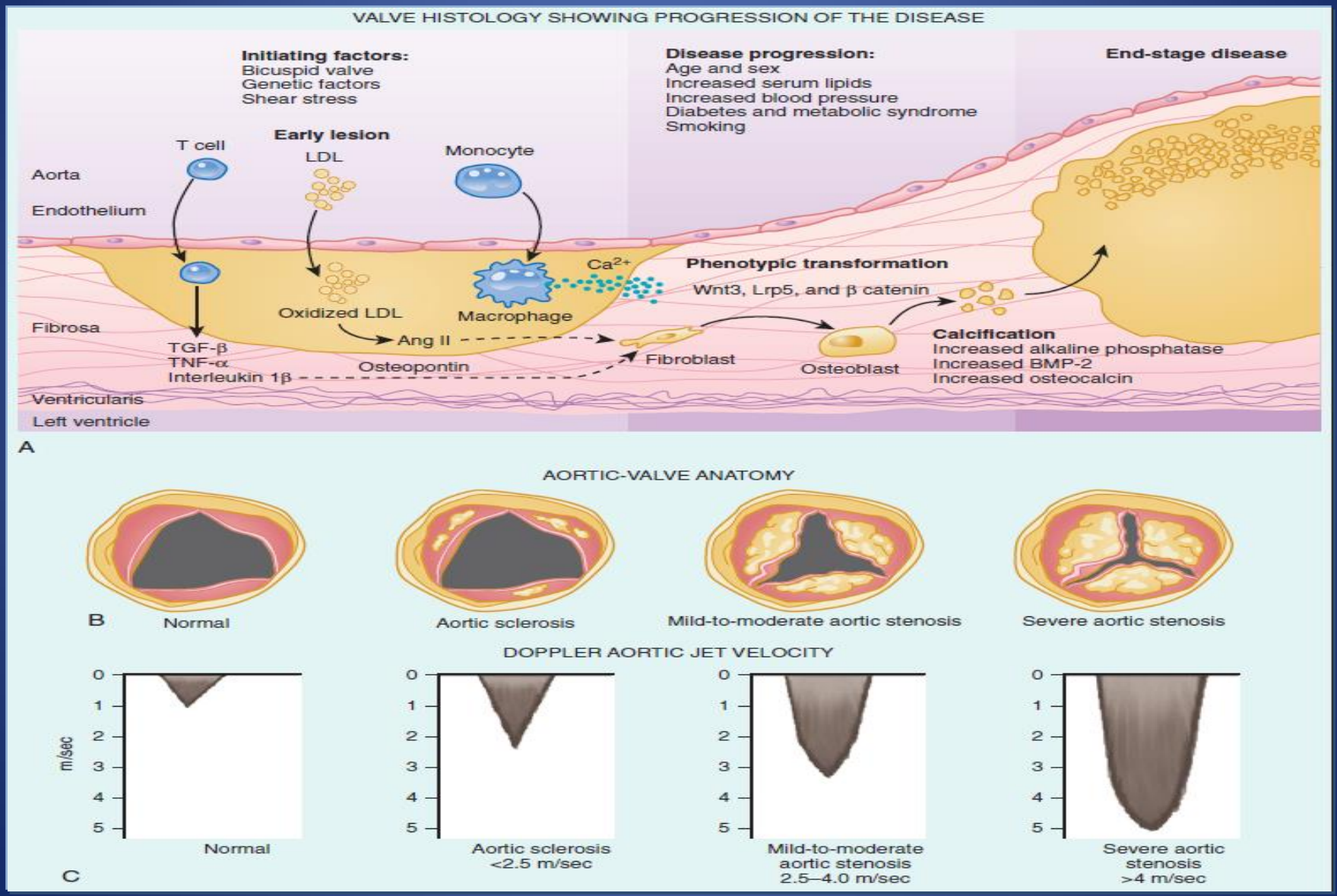
- Restricted opening of the aortic valve
  - Thickening and calcification of leaflets
  - Fusion of commissures (rheumatic)
  - Intrinsically narrowed orifice (congenital)

- **When orifice is decreased by more than 50% it becomes flow-limiting**
  - **Pressure gradient develops across valve**
  - **LV hypertrophy maintains wall stress**
  - **Eventual LV failure and coronary insufficiency result in symptomatology**

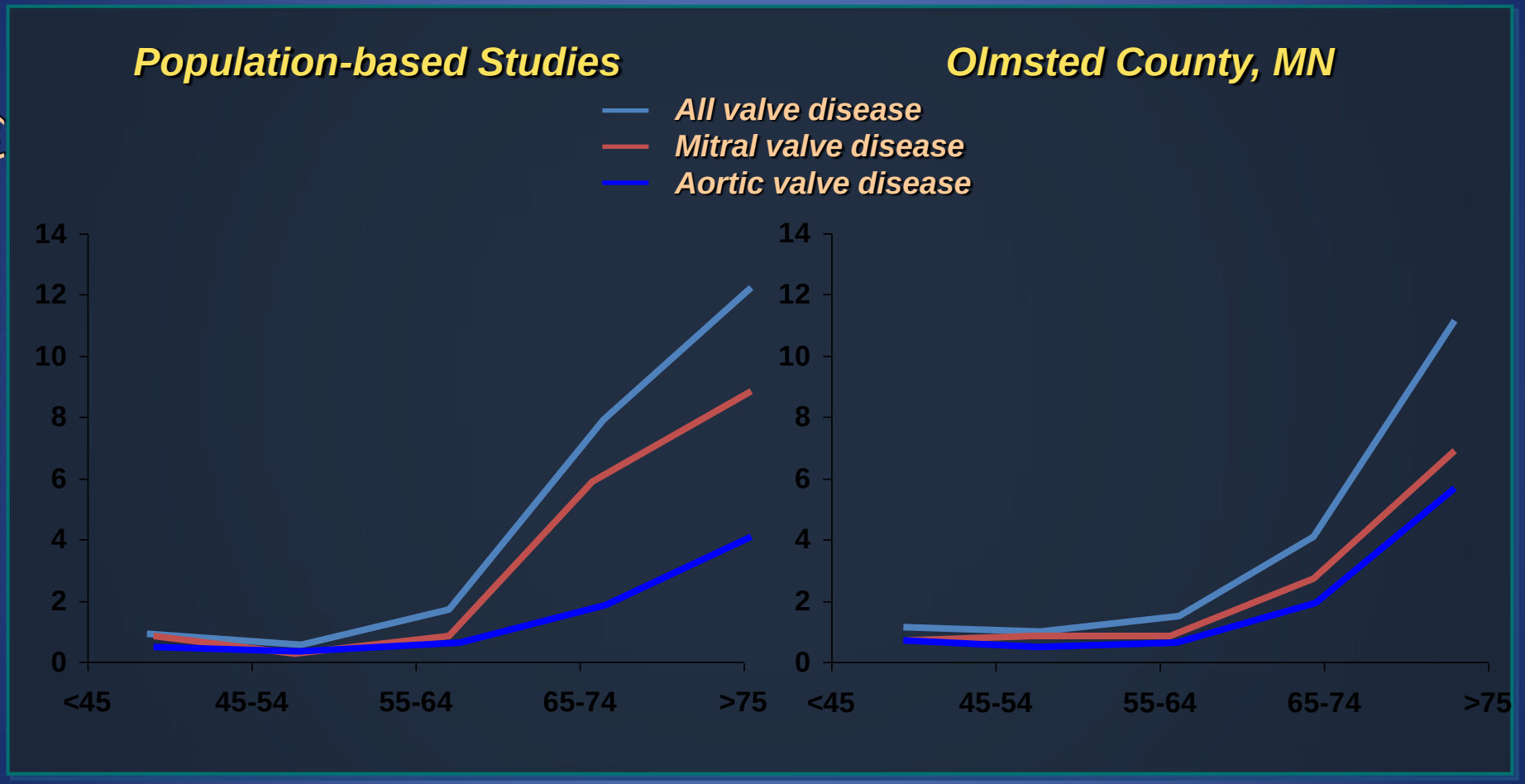
Aortic Stenosis



Pathophysiology of AS



Increasing Prevalence of Valvular Heart Disease with Age

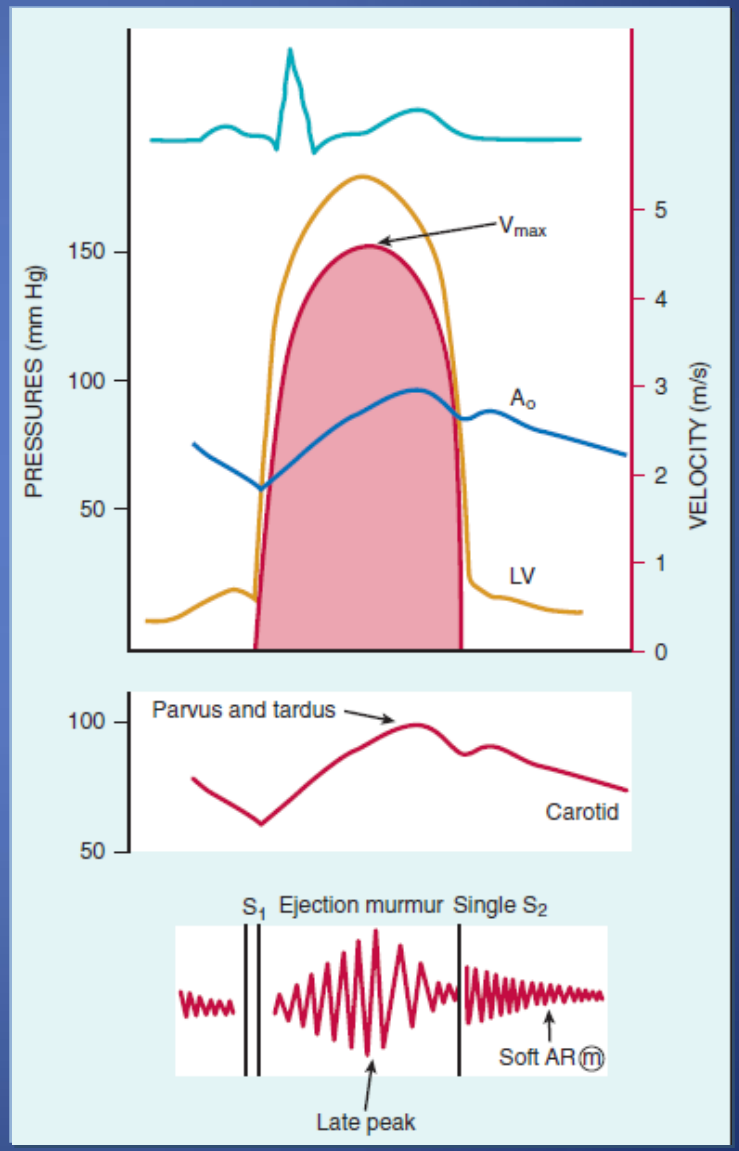


Prevalence Moderate/Severe AS 2.4 % in Those Age >75

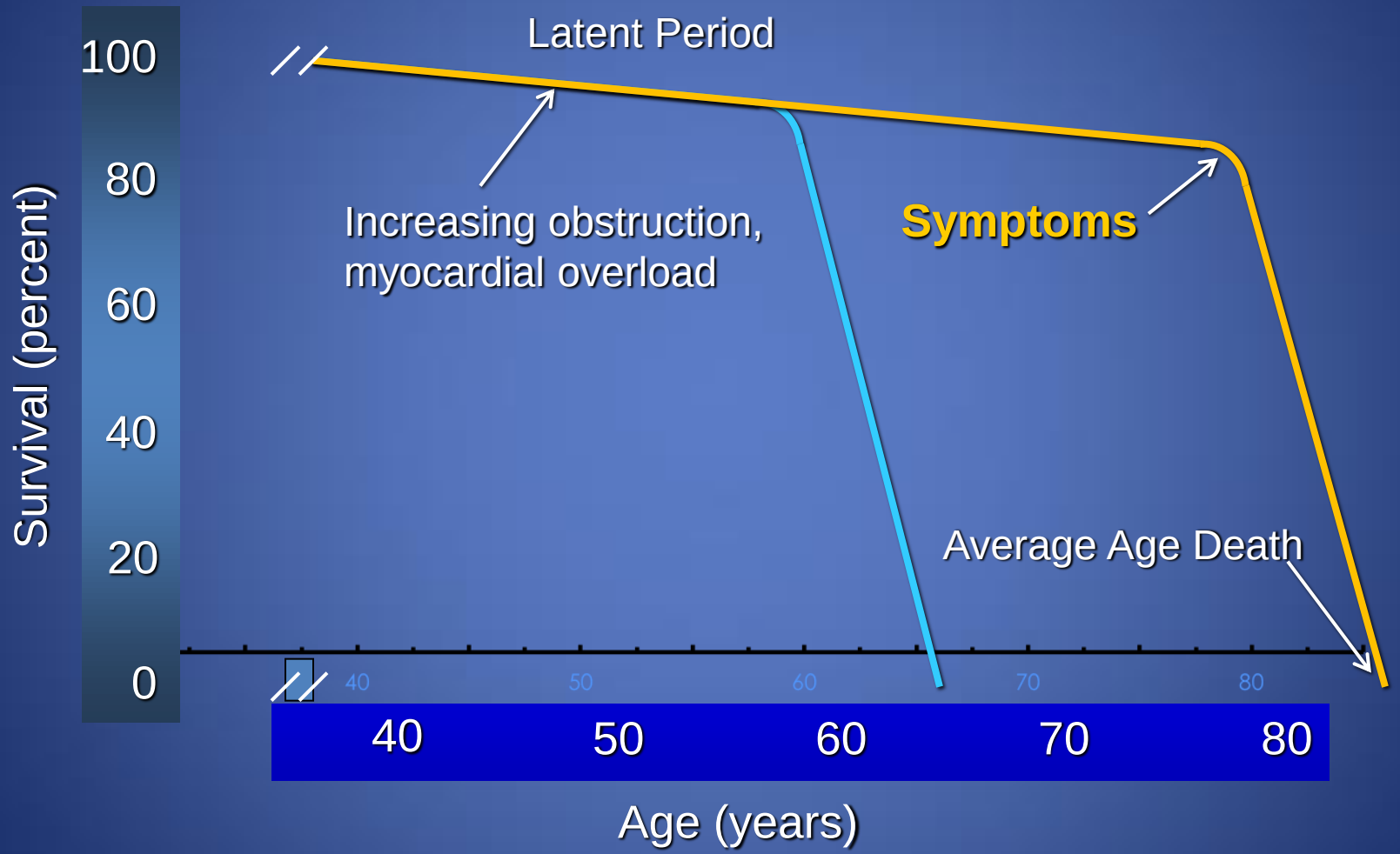
Nkomo VT at al. Lancet 2006;368:1005-1011

Clinical Presentation

- Classic symptoms:
  - Murmur
  - Dyspnea
  - Chest pain
  - Syncope
  - Heart Failure

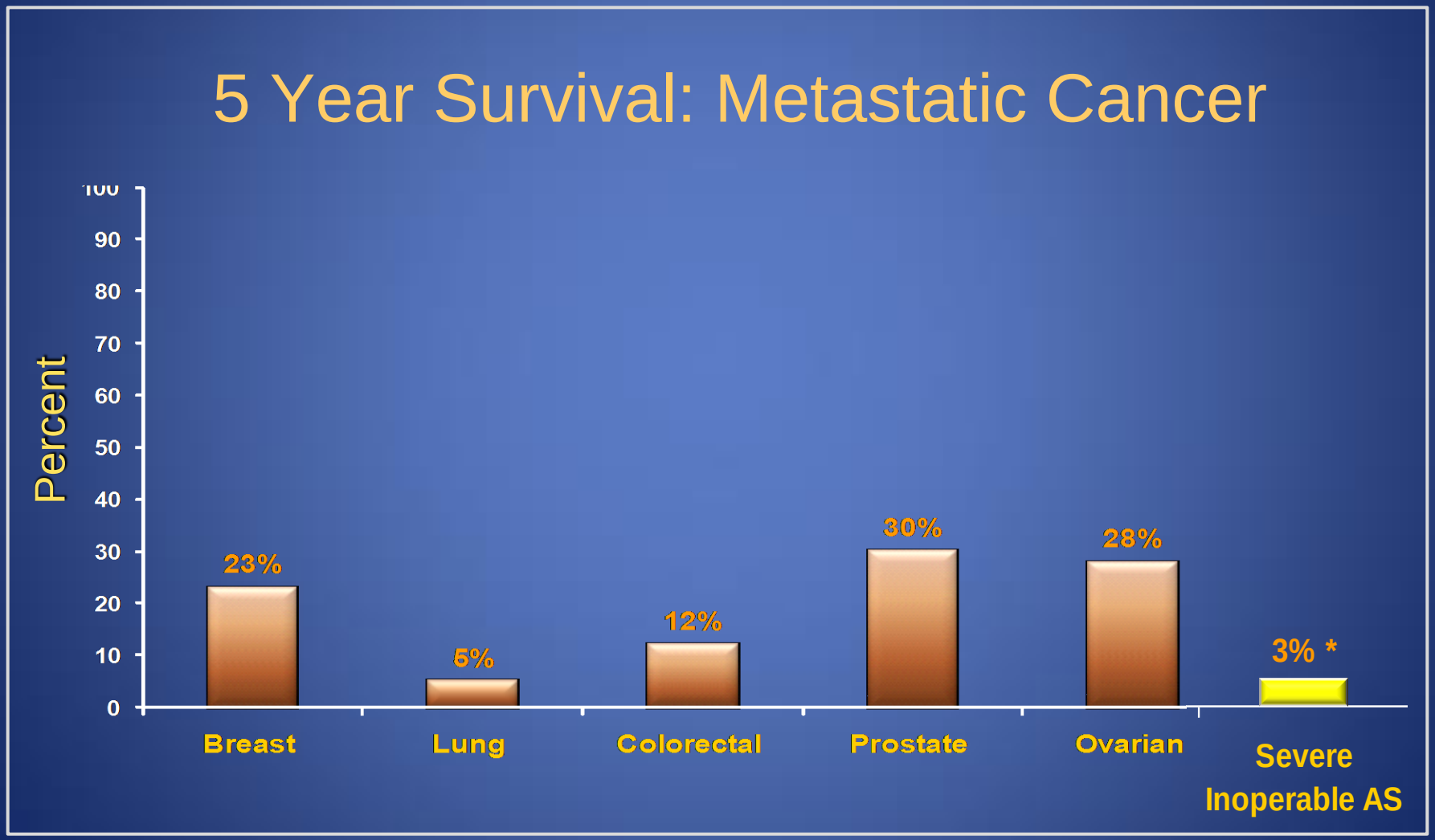


Natural History of Aortic Stenosis



Mortality with Medical Rx

Perspectives



* Constant Hazard Model

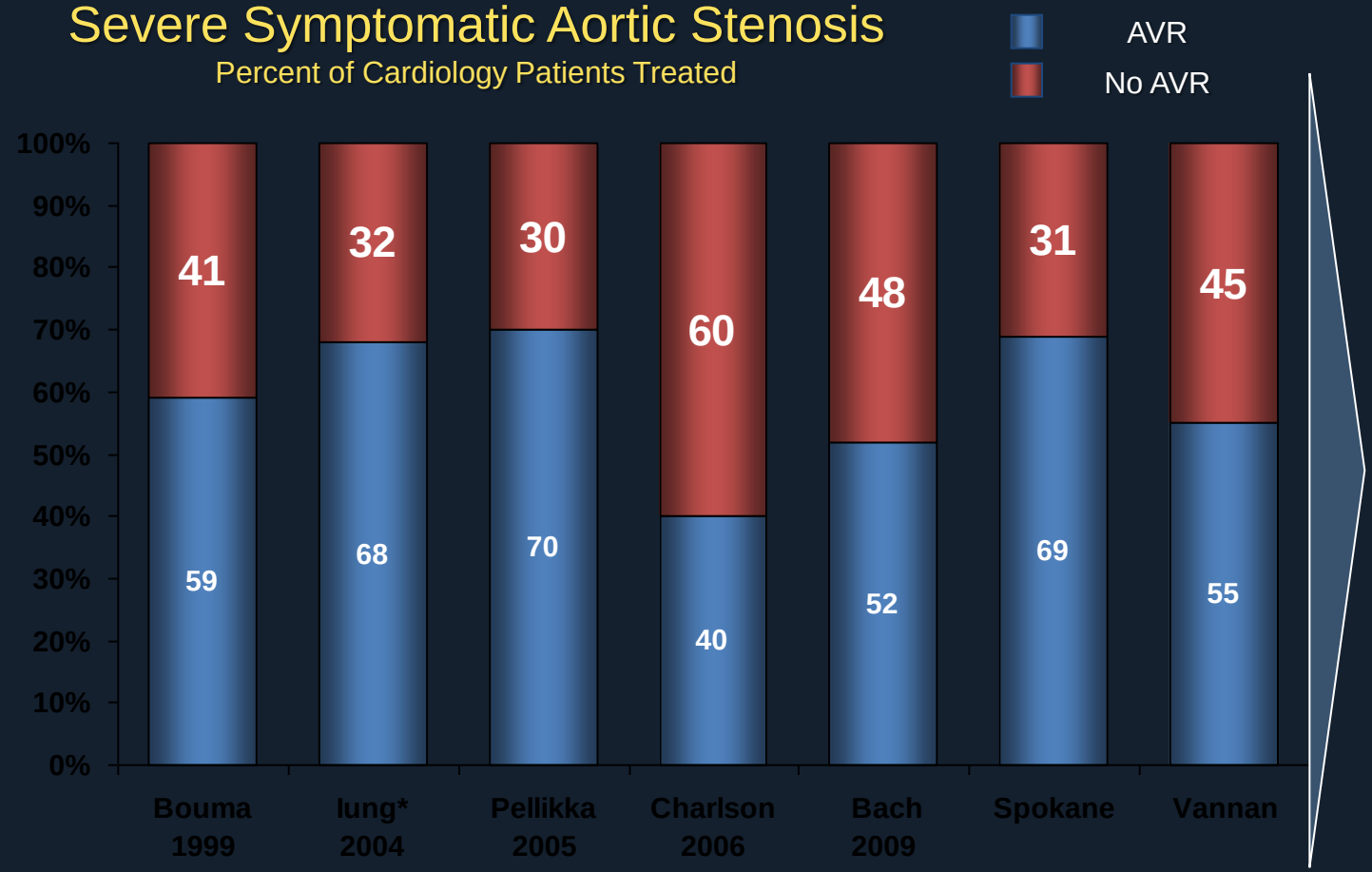
Courtesy Murat Tuzcu

Therapeutic Options

- Mechanical problem = Mechanical solution
- No medical therapy effective in delaying progression or altering outcome of AS
- Surgical AVR:
  - Mechanical vs Bioprosthetic
- Transcatheter therapy:
  - BAV and TAVR




At Least 30% of Patients with Severe Symptomatic AS are "Untreated"!



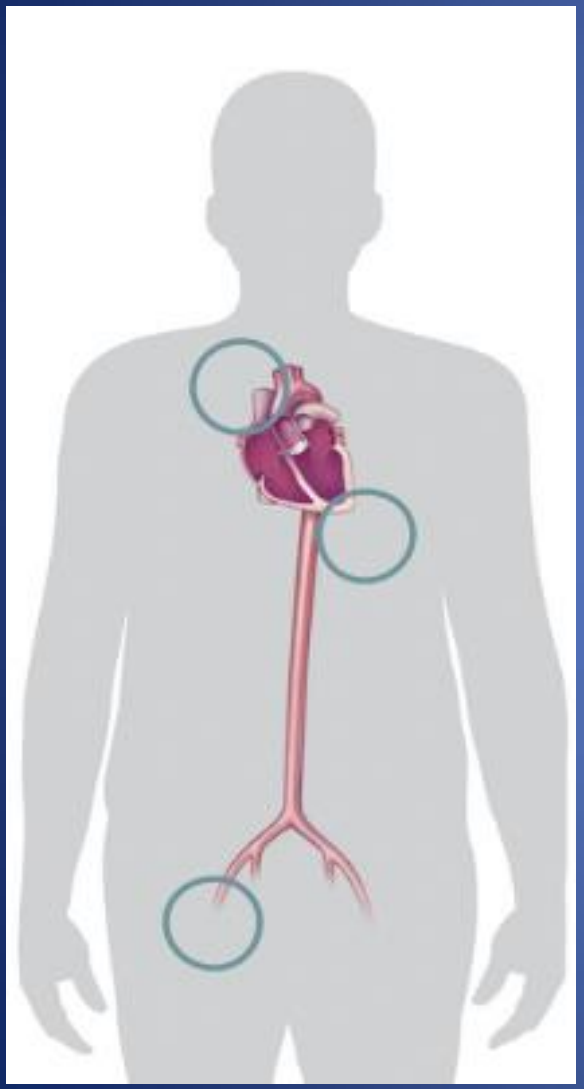
Unmet Clinical Need

1. Bouma B J et al. To operate or not on elderly patients with aortic stenosis: the decision and its consequences. Heart 1999;82:143-148
2. Iung B et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. European Heart Journal 2003;24:1231-1243 (*includes both Aortic Stenosis and Mitral Regurgitation patients)
3. Pellikka, Sarano et al. Outcome of 622 Adults with Asymptomatic, Hemodynamically Significant Aortic Stenosis During Prolonged Follow-Up. Circulation 2005
4. Charlson E et al. Decision-making and outcomes in severe symptomatic aortic stenosis. J Heart Valve Dis2006;15:312-321

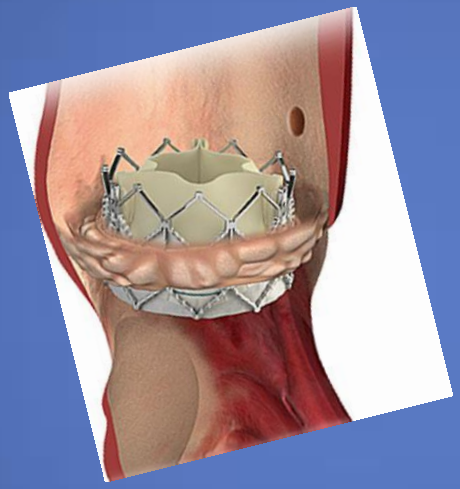
NO ONE Likes Surgery (of any kind)!

Alain Cribier:
First human transcatheter valve replacement (2002)

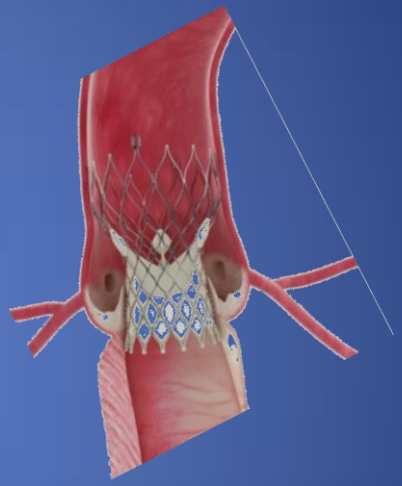
TAVR – Current Landscape



Edwards SAPIEN 3
Balloon Expandable



Medtronic CoreValve Evolut
Self Expanding



- Intermediate-, high- and extreme-risk
- Valve-in-valve

The TAVR Revolution

First Generation Devices

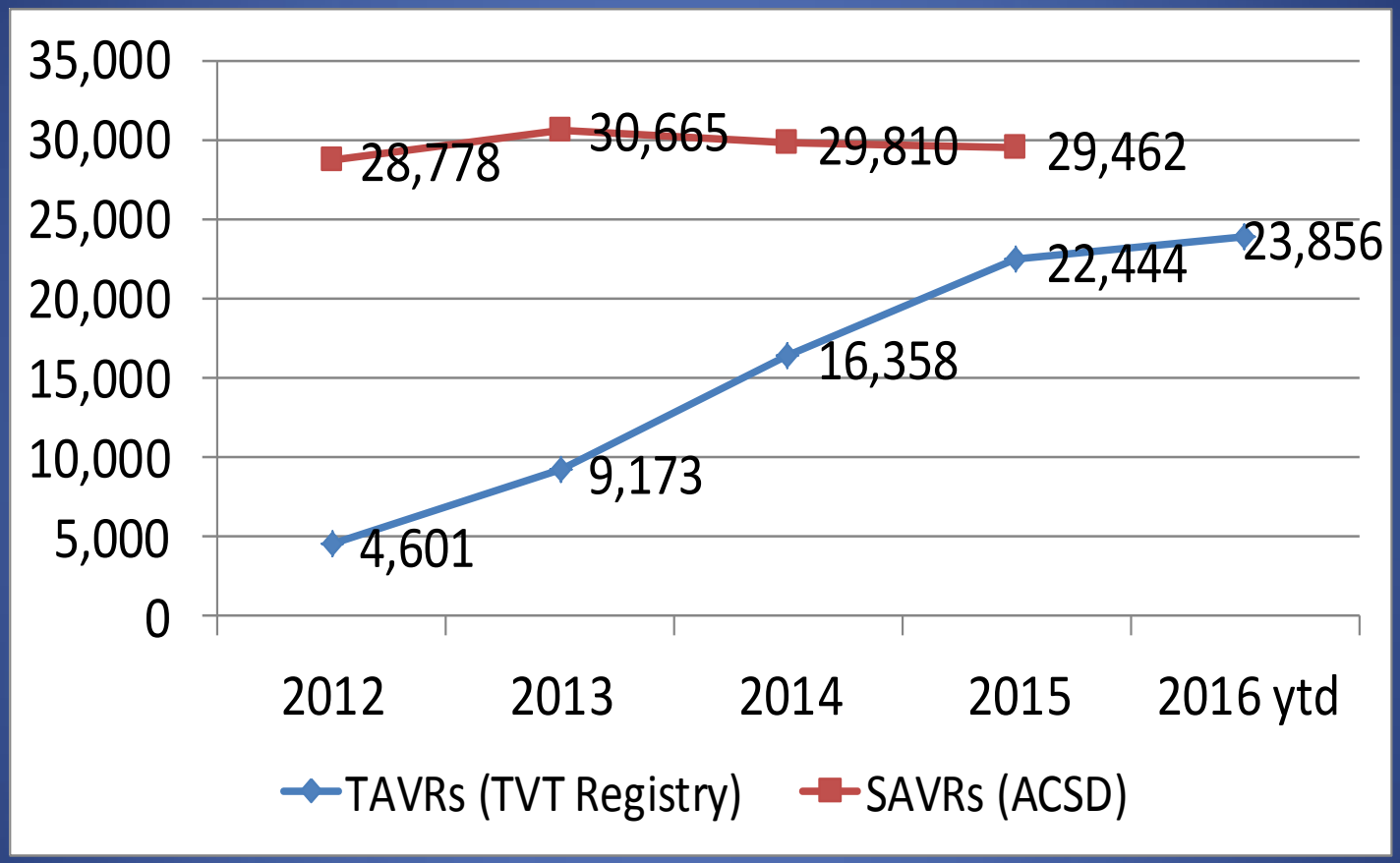
Edwards Lifesciences

Approved Nov 2011

Medtronic CoreValve

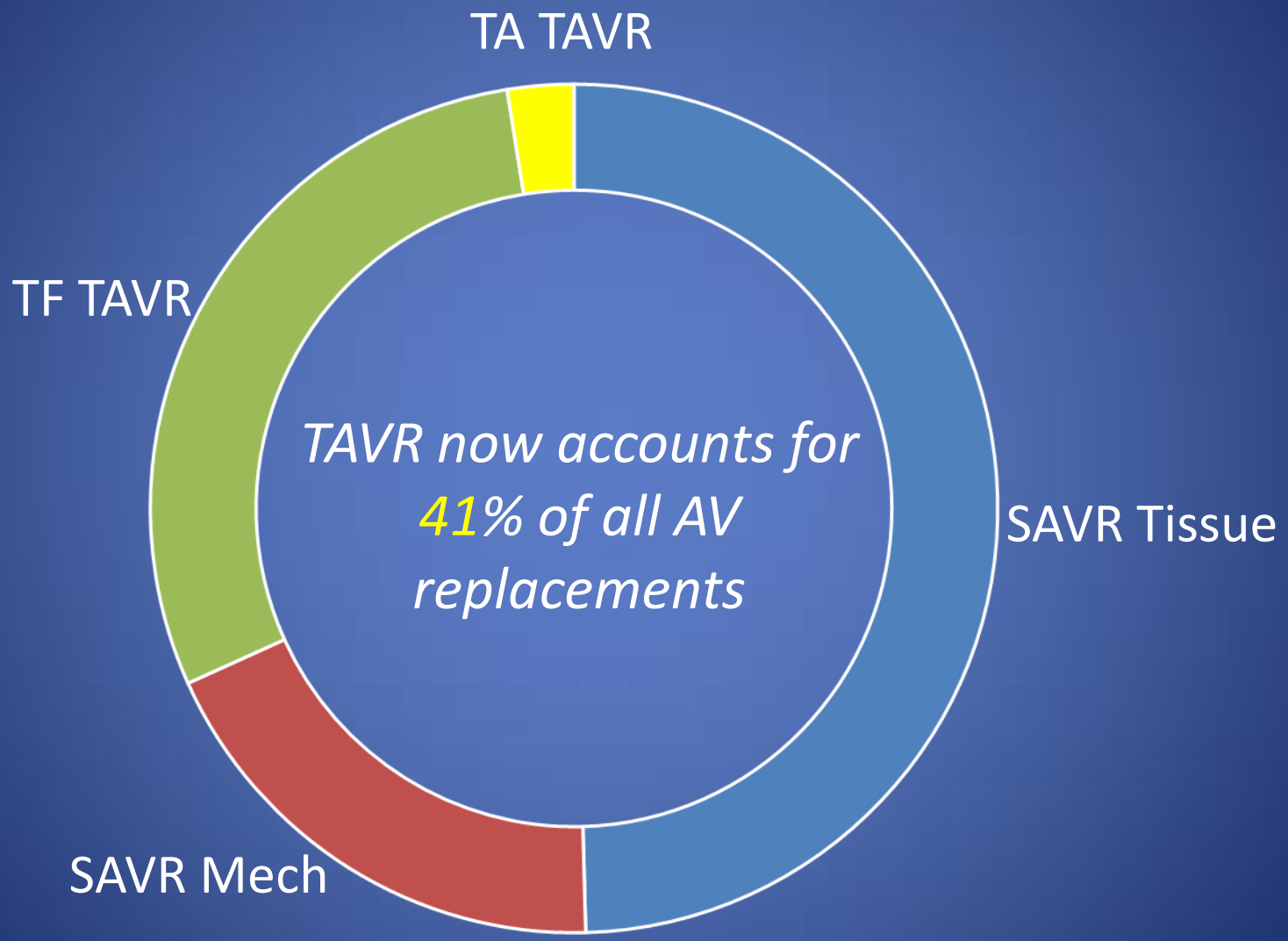
Approved Jan 2014

TAVR and SAVR* Procedures In the TVT Registry and STS ACSD*



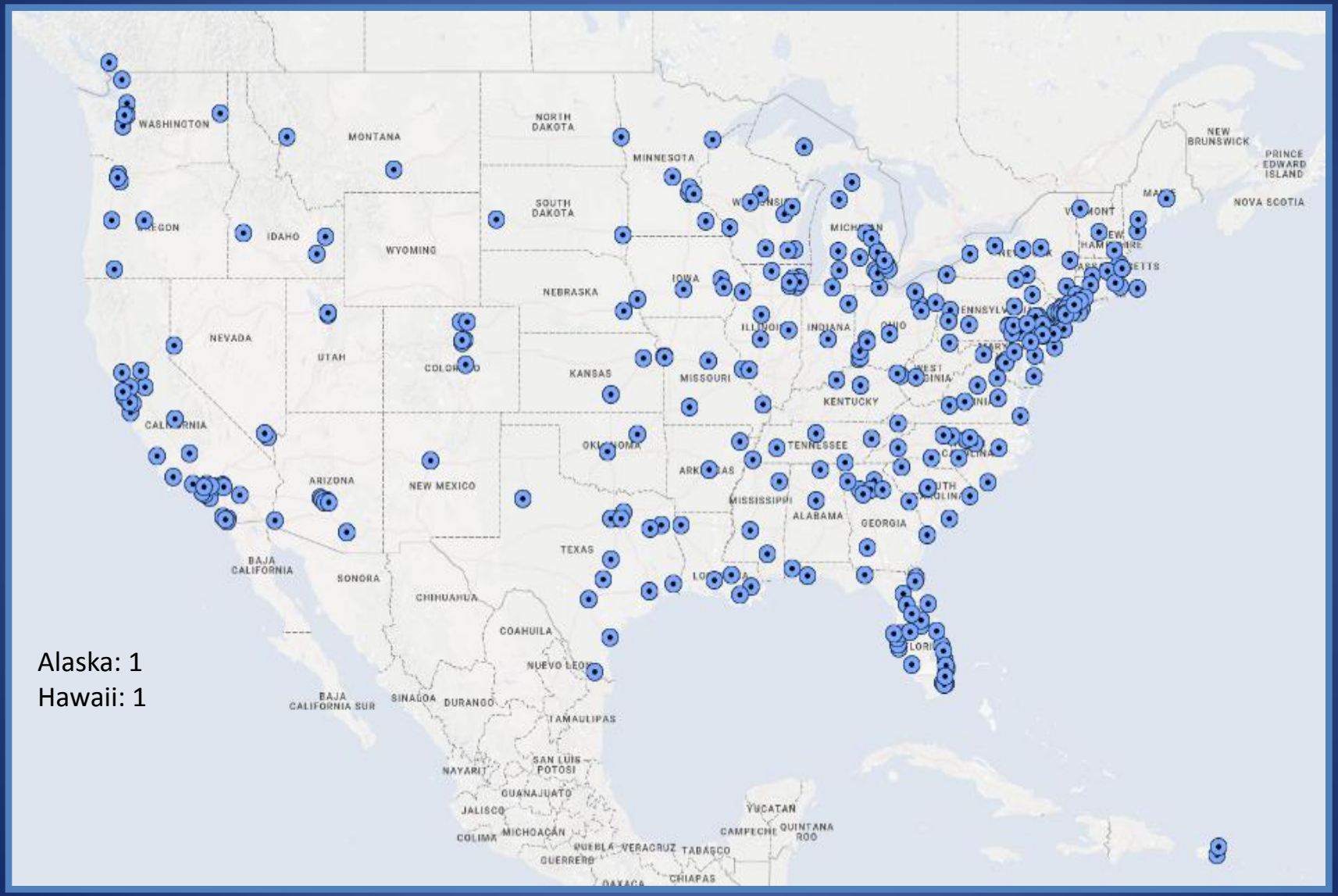
*** SAVR= isolated surgical aortic valve replacement; ACSD=Adult Cardiac Surgery Database**
Source: STS/ACC TVT Registry Database as of Oct 18, 2016; STS ACSD 2015 Annual Report

U. S. Medicare AV Cases in 2016



FY2015 MedPAR, all cases on file regardless of IPPS status

TAVR Sites in US = 477 and counting



Alaska: 1
Hawaii: 1

FIND A TAVR CENTER

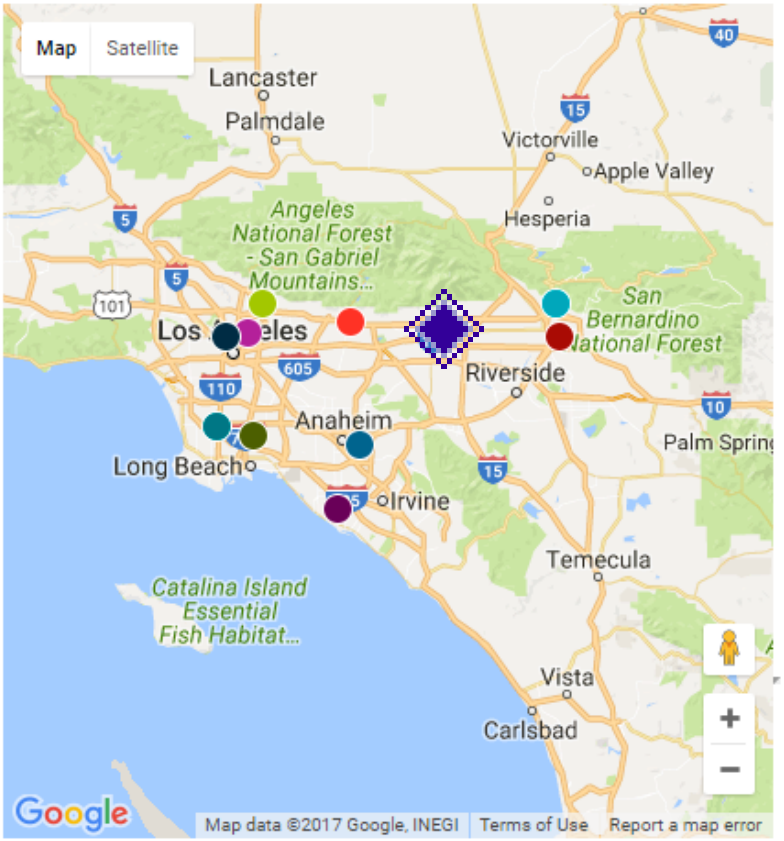
Use this tool to find a multi-disciplinary Heart Team that can determine whether transcatheter aortic valve replacement (TAVR) is an option for you or someone you care for. Search to find TAVR Centers and view details about each listing.

*ENTER CITY AND/OR STATE, ZIP CODE, OR HOSPITAL NAME AND SELECT FROM THE LIST.

91767 X

Show the closest 10 TAVR Centers

SEARCH



Showing 10 closest TAVR Centers Download | Print

CITRUS VALLEY INTERCOMMUNITY HOSPITAL
210 W. San Bernardino Road
Covina, CA 91723
Distance: 8mi

ST. JOSEPH HOSPITAL
1100 W. Steward Drive
Orange, CA 92868
Distance: 21mi

HUNTINGTON HOSPITAL
100 West California Boulevard
Pasadena, CA 91105
Distance: 23mi

KECK MEDICAL CENTER OF USC
1500 San Pablo
Los Angeles, CA 90033
Distance: 26mi

DIGNITY HEALTH ST. BERNARDINE MEDICAL CENTER
2101 North Waterman Ave.
San Bernardino, CA 92404
Distance: 26mi

LOMA LINDA UNIVERSITY HEALTH
11234 Anderson St.
Loma Linda, CA 92354

2014 AHA/ACC Guideline

Table 5. Risk Assessment Combining STS Risk Estimate, Frailty, Major Organ System Dysfunction, and Procedure-Specific Impediments

	Low Risk (Must Meet ALL Criteria in This Column)	Intermediate Risk (Any 1 Criterion in This Column)	High Risk (Any 1 Criterion in This Column)	Prohibitive Risk (Any 1 Criterion in This Column)
STS PROM*	<4% **AND**	4% to 8% **OR**	>8% **OR**	Predicted risk with surgery of death or major morbidity (all-cause) >50% at 1 y **OR**
Frailty†	None **AND**	1 Index (mild) **OR**	≥2 Indices (moderate to severe) **OR**	
Major organ system compromise not to be improved postoperatively‡	None **AND**	1 Organ system **OR**	No more than 2 organ systems **OR**	≥3 Organ systems **OR**
Procedure-specific impediment§	None	Possible procedure-specific impediment	Possible procedure-specific impediment	Severe procedure-specific impediment

Class 1 recommendation: Patients with severe VHD should be evaluated by a multidisciplinary Heart Valve Team when intervention is considered.

Risk Assessment: Beyond The Risk Scores

- STS risk score provides a reasonable preliminary estimate of risk for the majority of patients

- The STS score fails to account for many important factors affecting surgical risk
  - Porcelain aorta
  - Chest wall radiation or deformity (hostile chest)
  - Previous sternotomy with adhesion of IMAs to chest wall
  - Severely compromised respiratory function
  - Severe liver disease
  - Severe pulmonary hypertension
  - Dementia and/or severe cerebrovascular disease
  - Frailty: “eyeball” test vs objective assessment

- Clinical judgment of experienced operators plays a key role in assessment of surgical risk status

Classic TAVR Patient #1

- 68 y.o. male
- Recurrent CHF admissions

Clinical History	
Systolic Heart Failure	Severe low gradient low flow AS
CABG x 4 - 2005	HTN
Stent to RCA graft x2 (1/4/17)	ICD
Ischemic cardiomyopathy	Hyperlipidemia
EF 20 – 25%	

Risk determination:

- Intermediate risk based on STS score of 6%
- Severe Pulmonary hypertension – 77/32 (48)mmHg
- Severe biventricular dysfunction
- Redo sternotomy

Classic TAVR Patient #2

90 year old female

Severe AS with reduced EF of 35% now with CHF symptoms

History:

- Severe AS
- PPM 6/14
- CHF
- Hyperlipidemia
- Left hip fx with fixation
- Extremely HOH

Patient factors :

*Independent for ADLs
*Lives with daughter and son-in-law
*Enjoys going out to dinner, casino, knitting, and frequent trips to the river.
* Has been dx with AS for several years, but was asymptomatic until recently, and would now like treatment.
* 1/31/17 Admitted from ER with SOB, trop 0.52, 0.59.

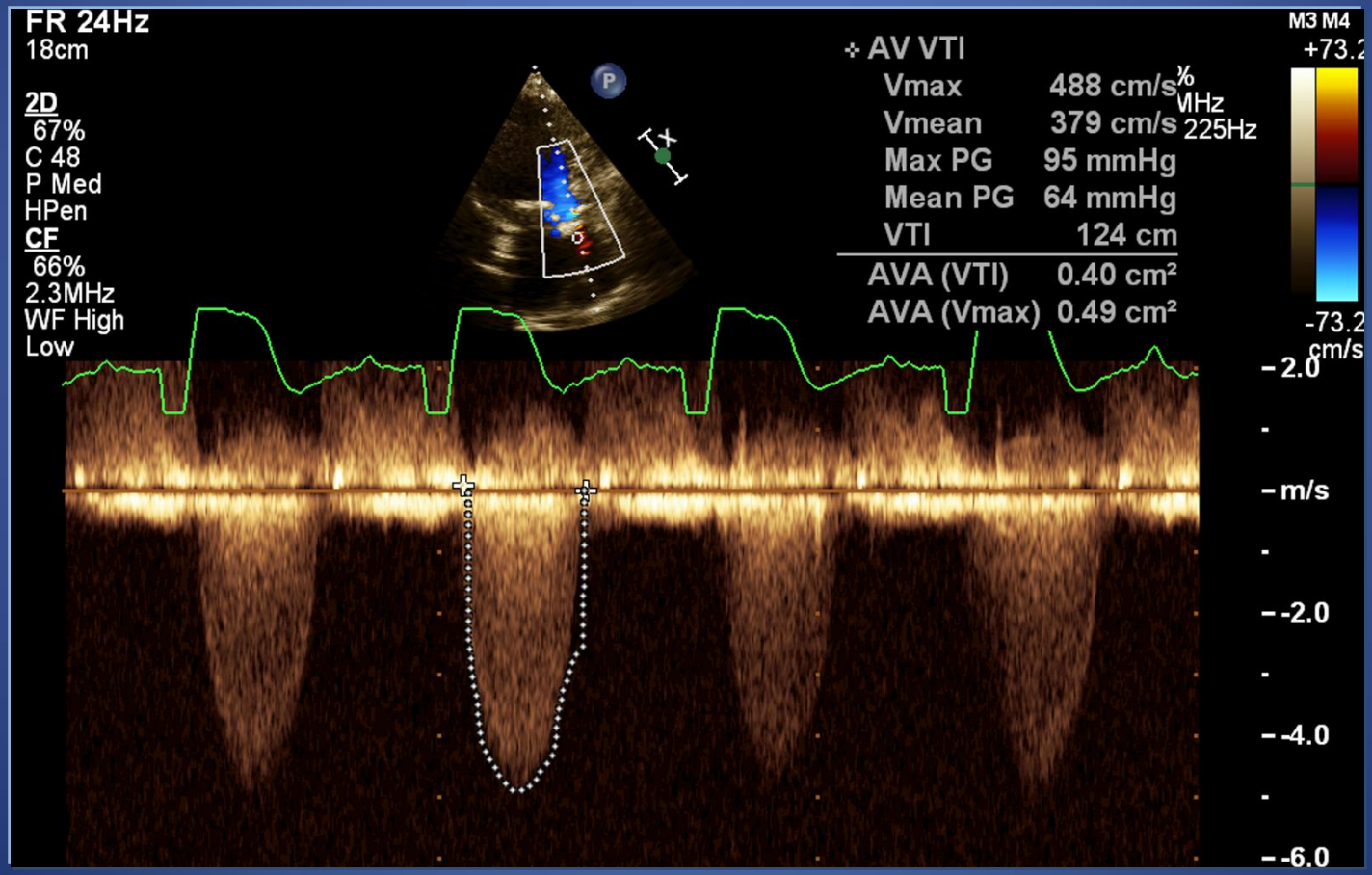
TAVR Candidate Risk Determination:

*High Risk Candidate based on STS score of 13
*Frailty

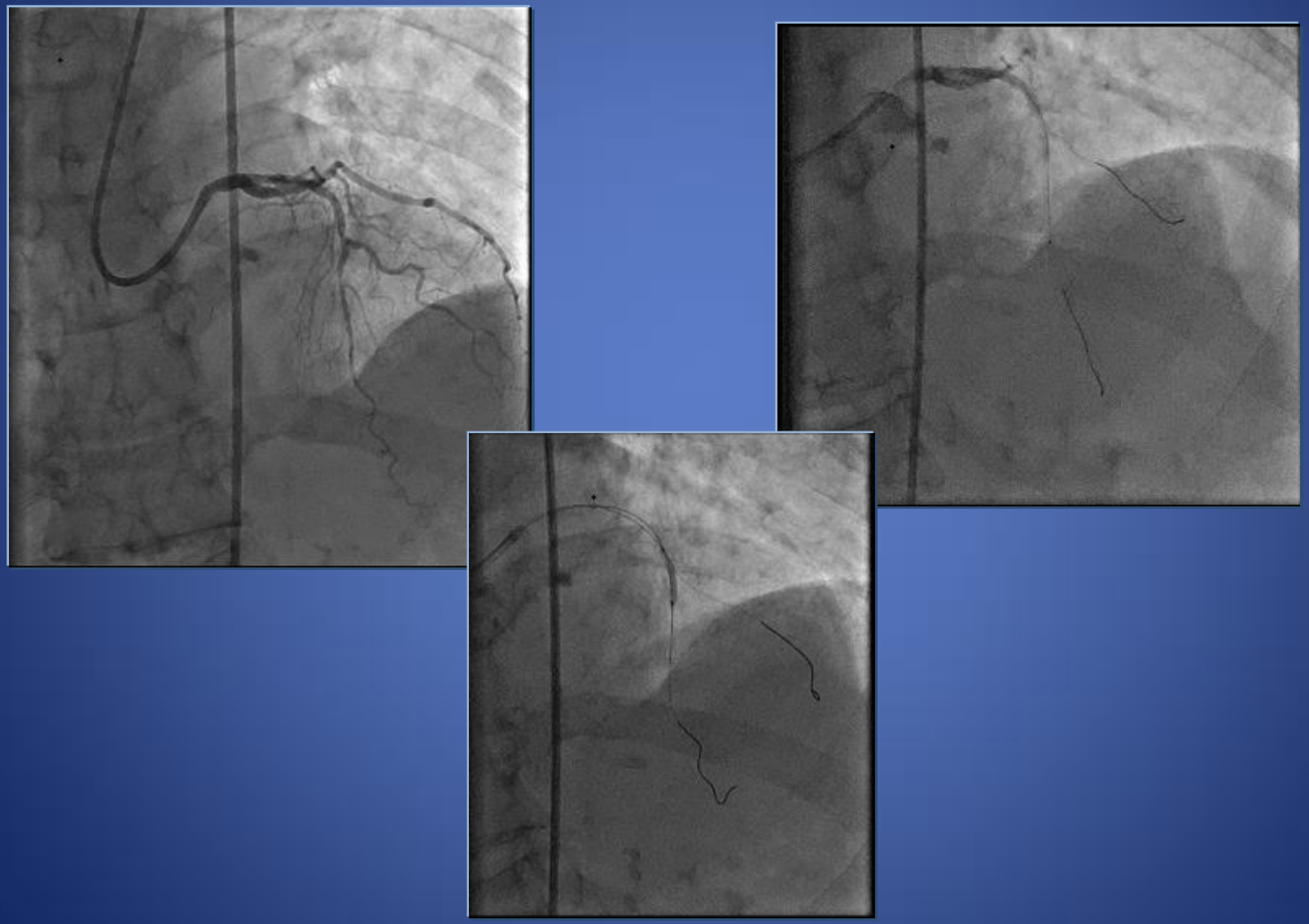
Workup for TAVR

- Transthoracic echocardiogram
- Cardiac catheterization
- MDCT gated CT scan of heart, abd pelvis
- Risk assessment (STS score, technical issues)
- Frailty assessment
- Heart Team meeting

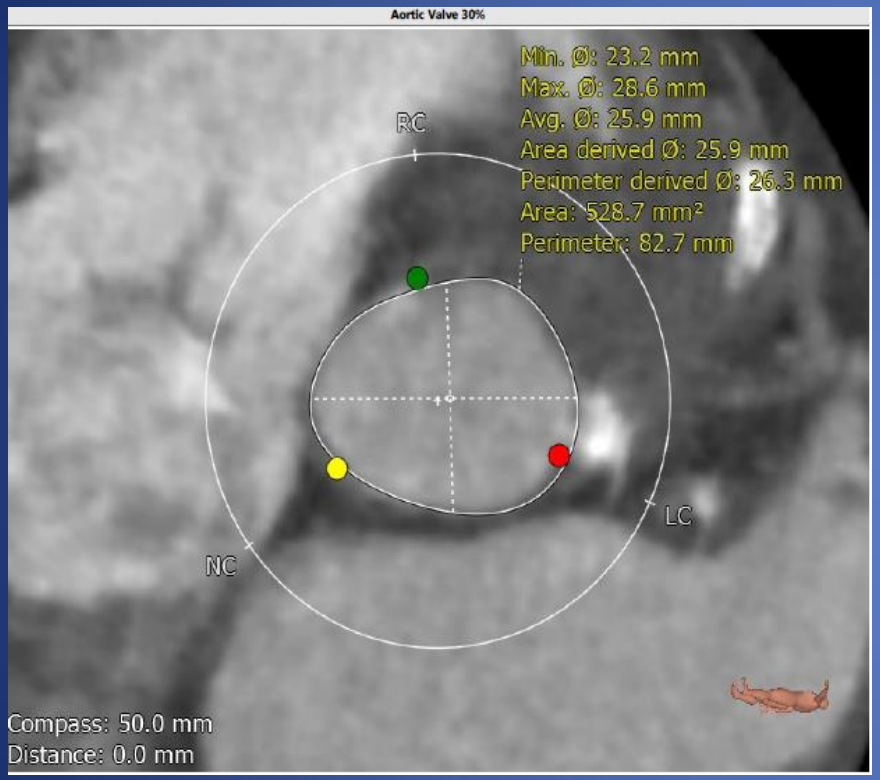
Workup - Echocardiogram



Workup- Cardiac catheterization



Retrospective Gated MDCT– Annulus Sizing



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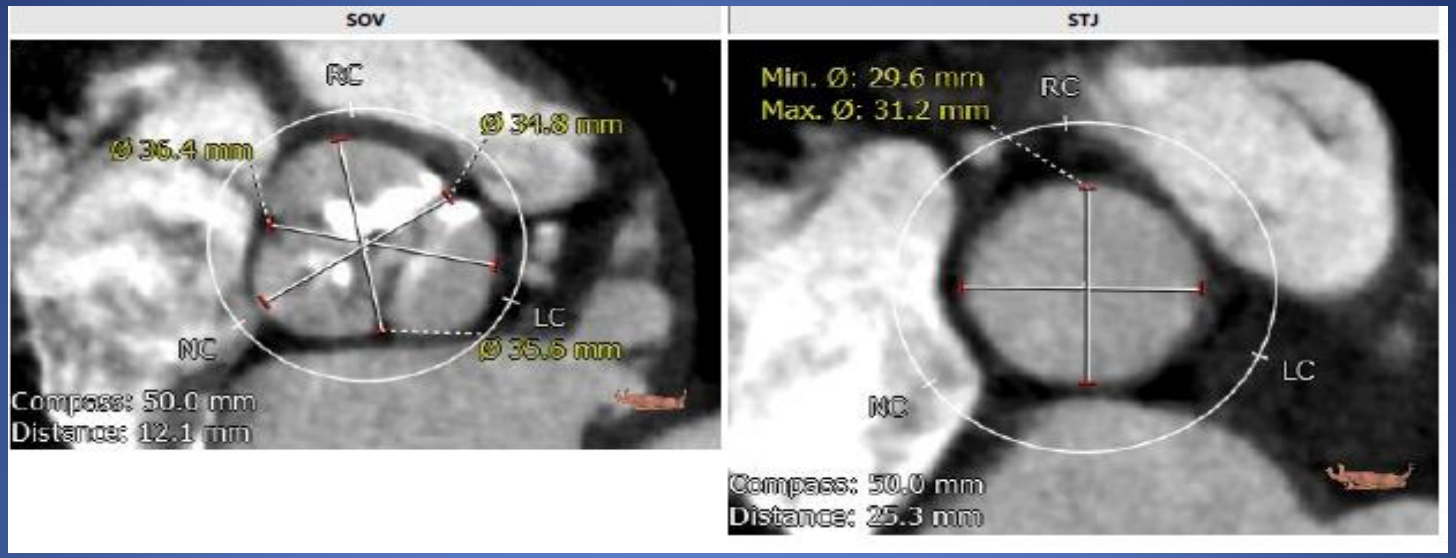

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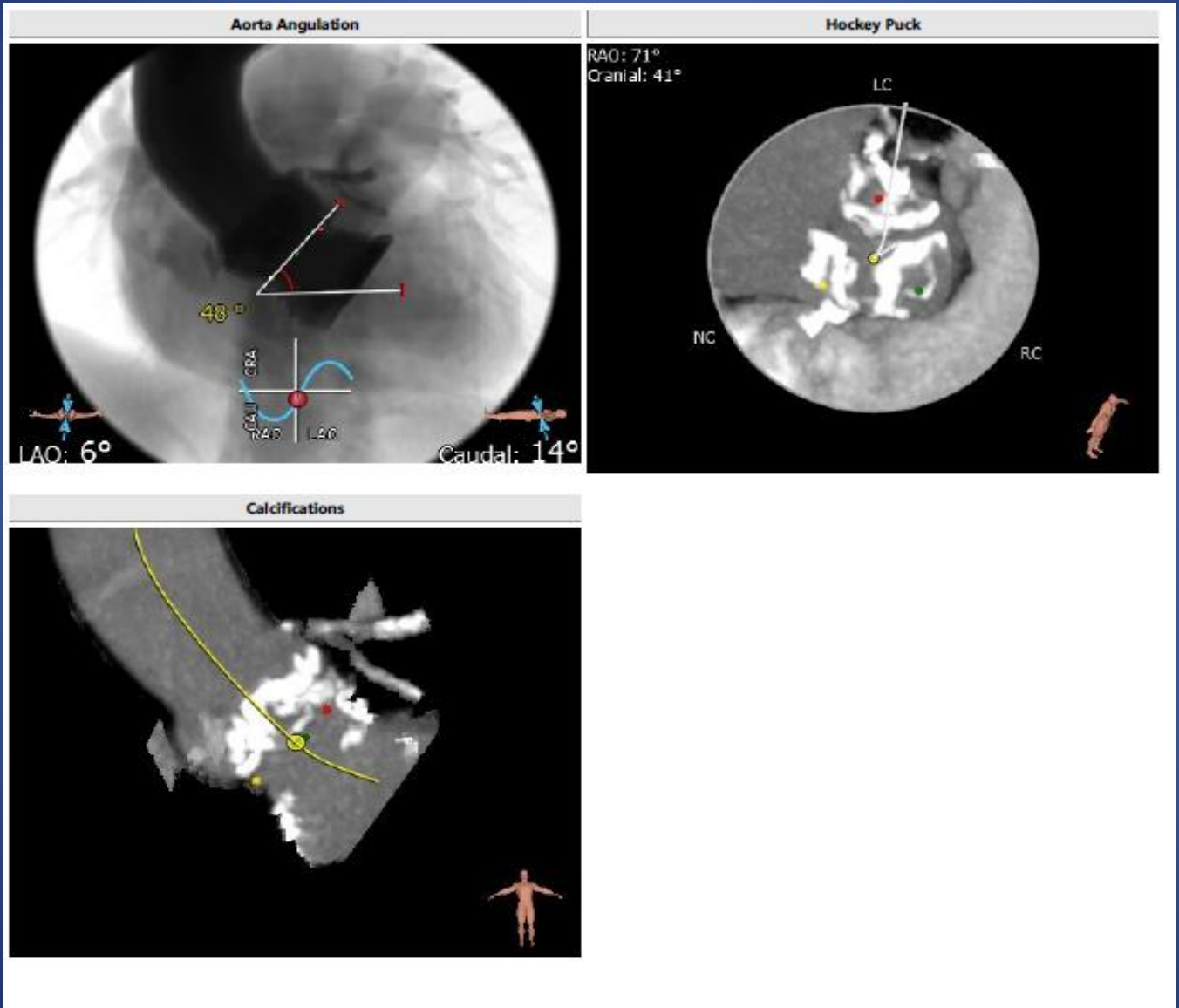
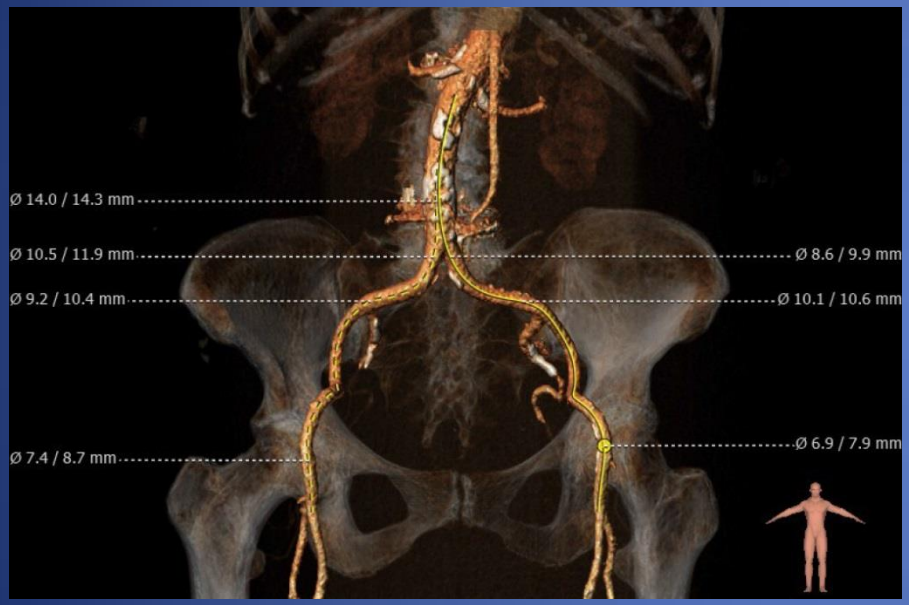
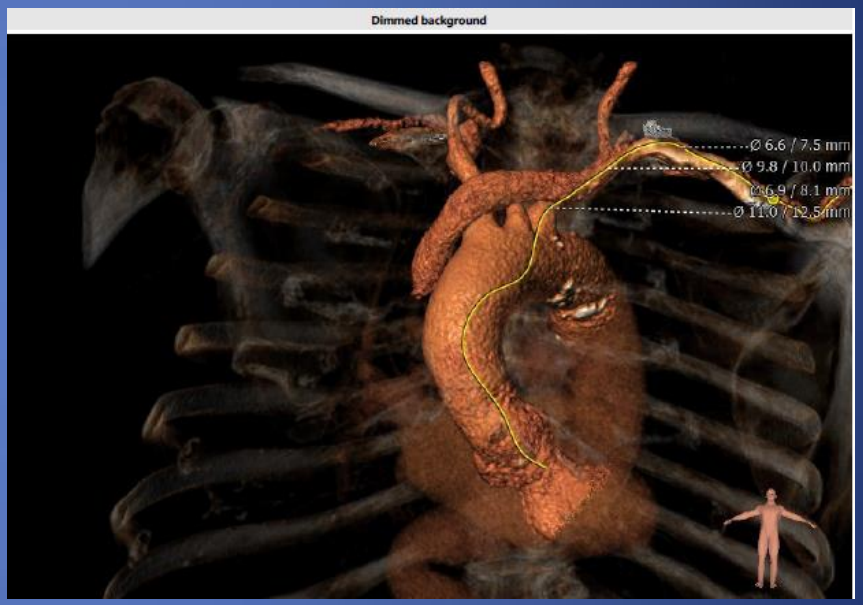
Retrospective Gated MDCT



Access Vessels on CT Angiogram





Workup for TAVR

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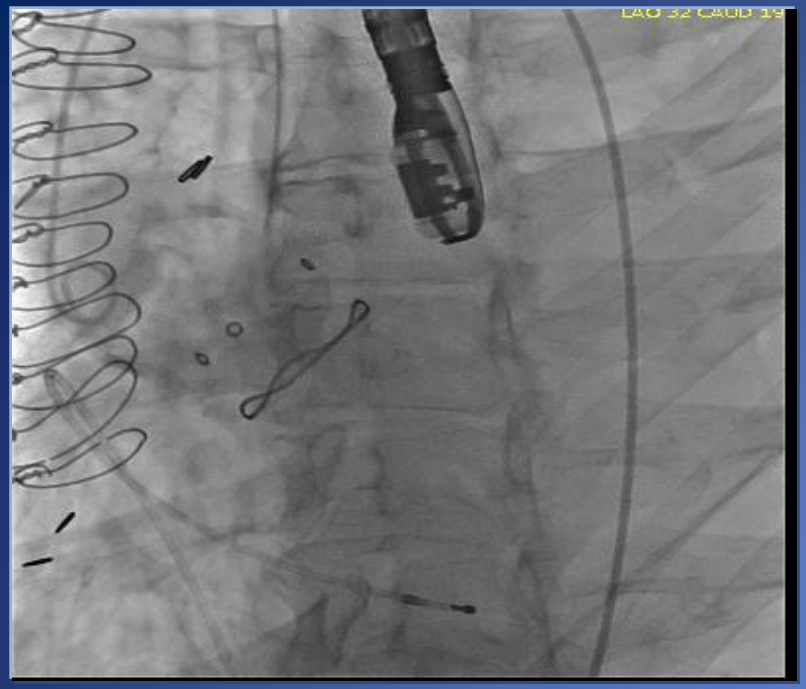
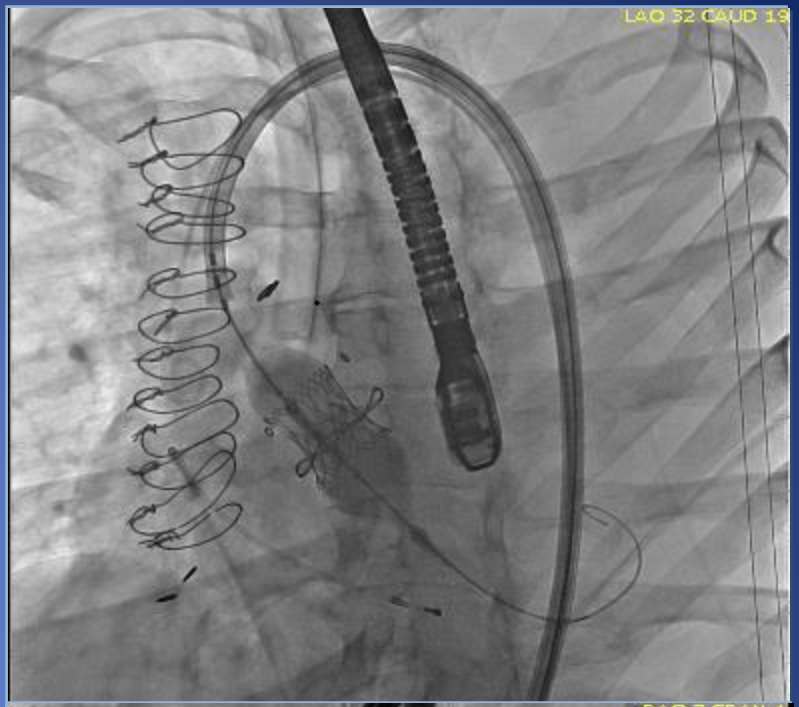
- Cardiac catheterization
- MDCT gated CT scan of heart, abd pelvis
- Risk assessment (STS score, technical issues)
- Frailty assessment
- Heart Team meeting

TAVR Procedure & Hospital Course

- Done in Cardiac Catheterization Lab / Hybrid OR
- General Anesthesia/moderate sedation
- Both Interventional Cardiologist and Cardiac surgery in the room
- Both groins accessed
  - 14 - 16 French for catheter for valve (arterial)
  - Temporary pacer (venous) & Pigtail (arterial)
- Percutaneous arterial access and closure
- Patient extubated in cathlab on table
- Patient to CICU for < 12-24 hrs
- LOS: 2 or 3 days


LAO 32 CAUD 19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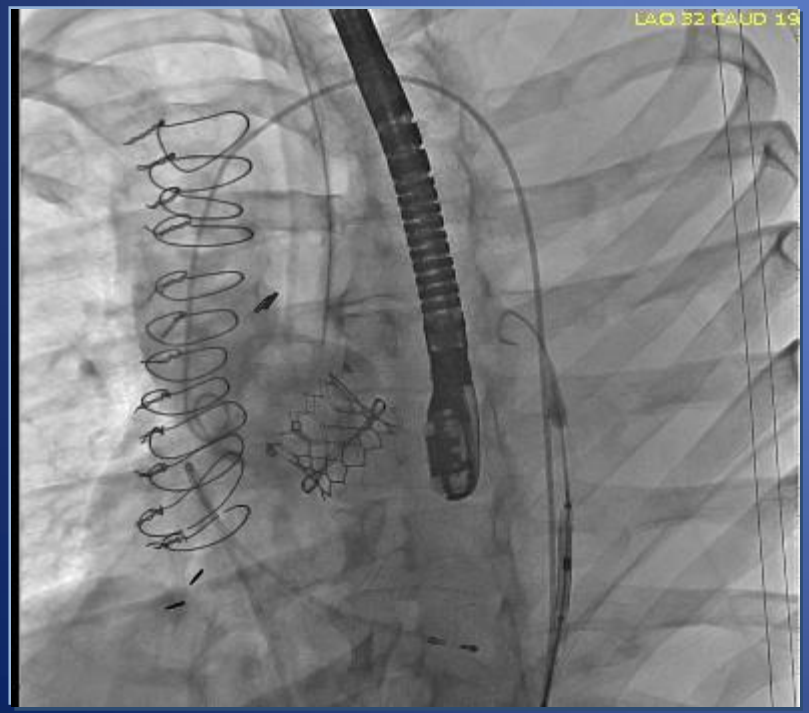

LAO 32 CAUD 19


RAO 3 CRAN 4

S/p Successful Trans-femoral TAVR Sapien 3 Valve

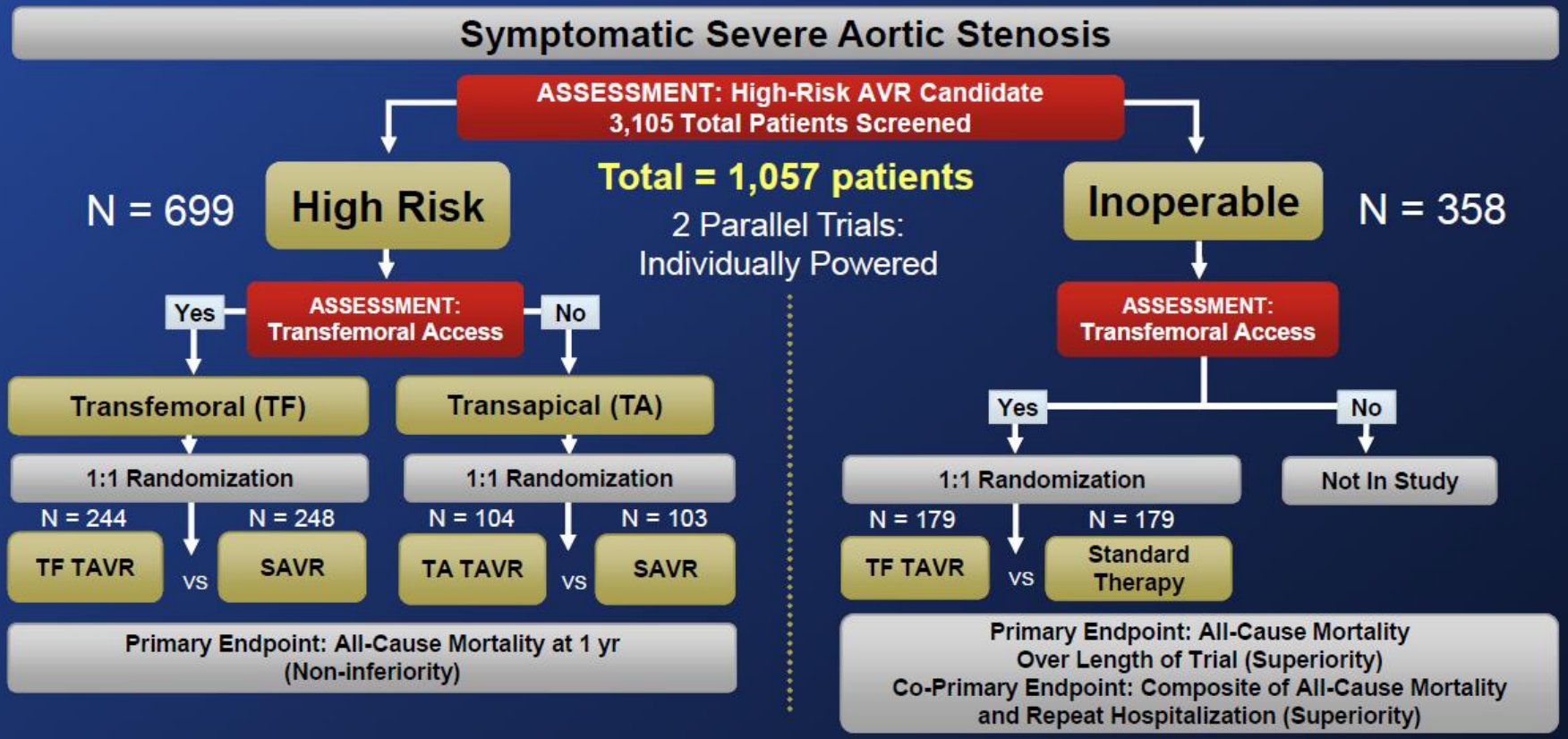
#1

- Tolerated procedure well
- Extubated next day
- Was able to get diuresed and now tolerate HF meds
- Discharged Home after 7 days
- Has not had any more CHF admission
- Able to walk > 30 min upon DC

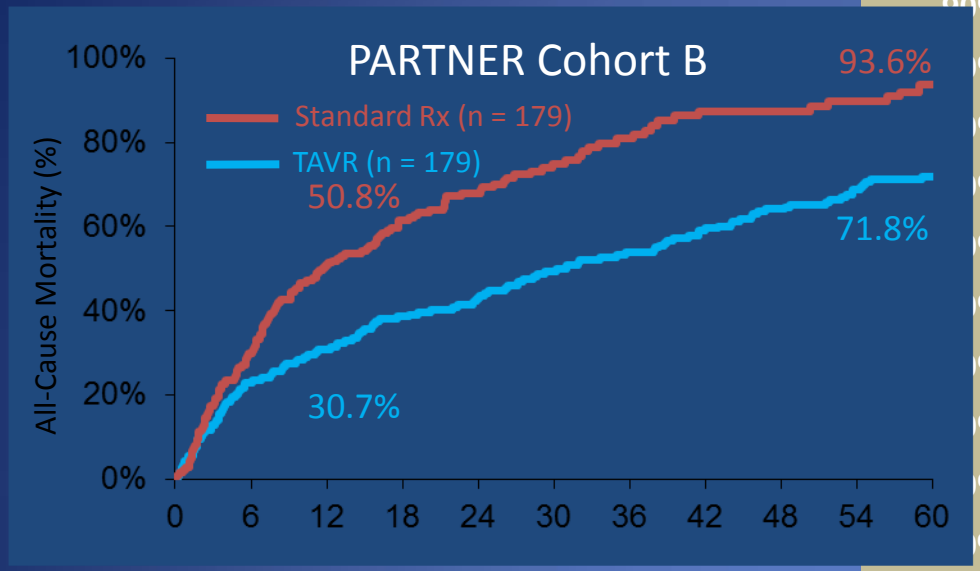
#2

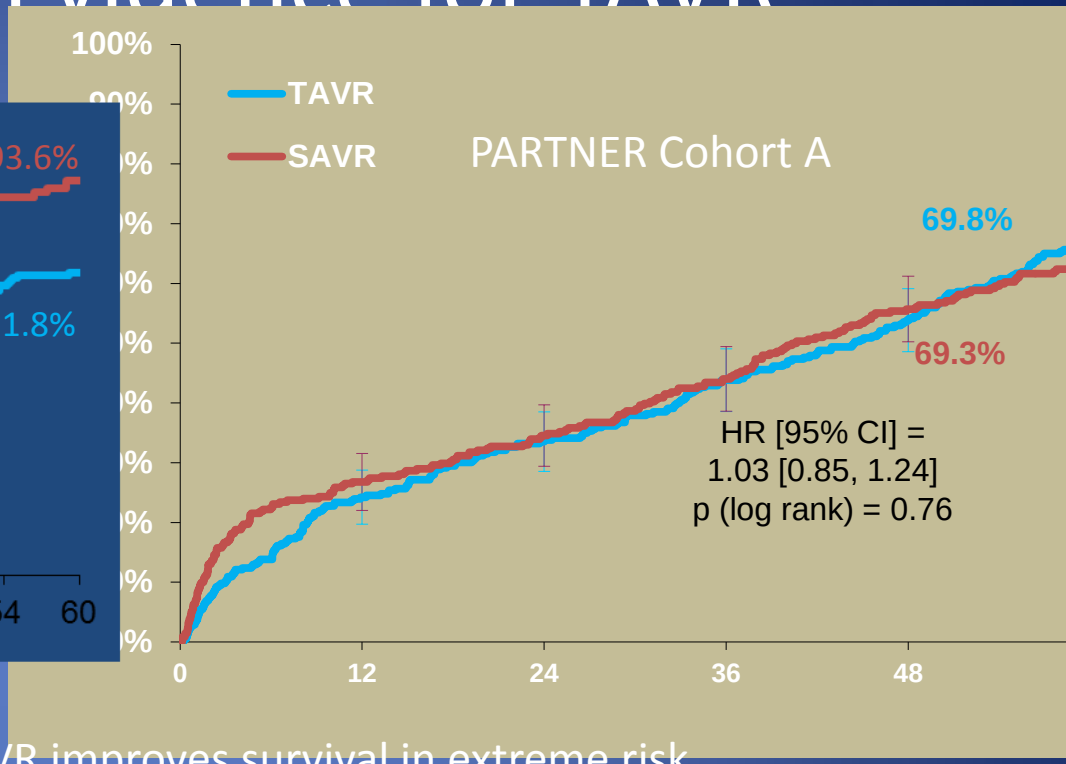
- Tolerated procedure well
- Extubated on table
- Ambulating next day
- Discharged home within 48 hours
- Continues to do well

PARTNER Study Design



Building the Evidence for TAVR

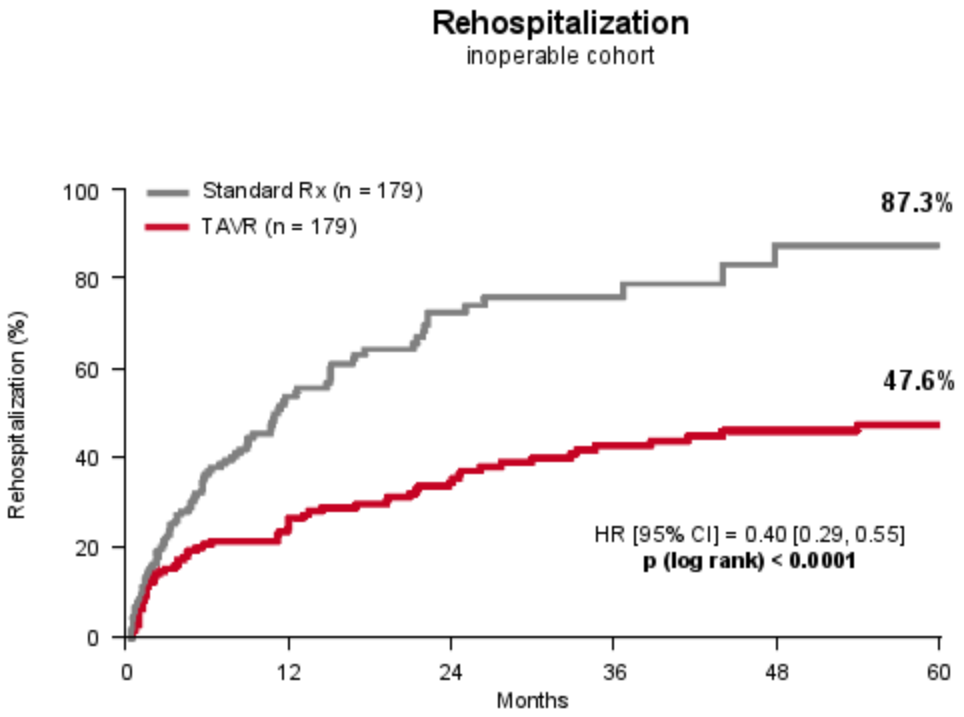




- PARTNER trial established that TAVR improves survival in extreme risk patients with AS and is an alternative to surgery in high risk patients
- Key points to remember
  - Enrollment started in 2007 - <100 TAVRs performed in US and only 6 sites had experience prior to trial
  - First generation device used (24F sheath, no nosecone on delivery catheter and original SAPIEN device used)

PARTNER: Inoperable Cohort

Patients treated with standard therapy were rehospitalized twice as often as TAVR patients



Of the **358** patients **87.3% of patients with standard therapy** were rehospitalized for cardiac issues

39.7% absolute reduction of rehospitilization at 5 years

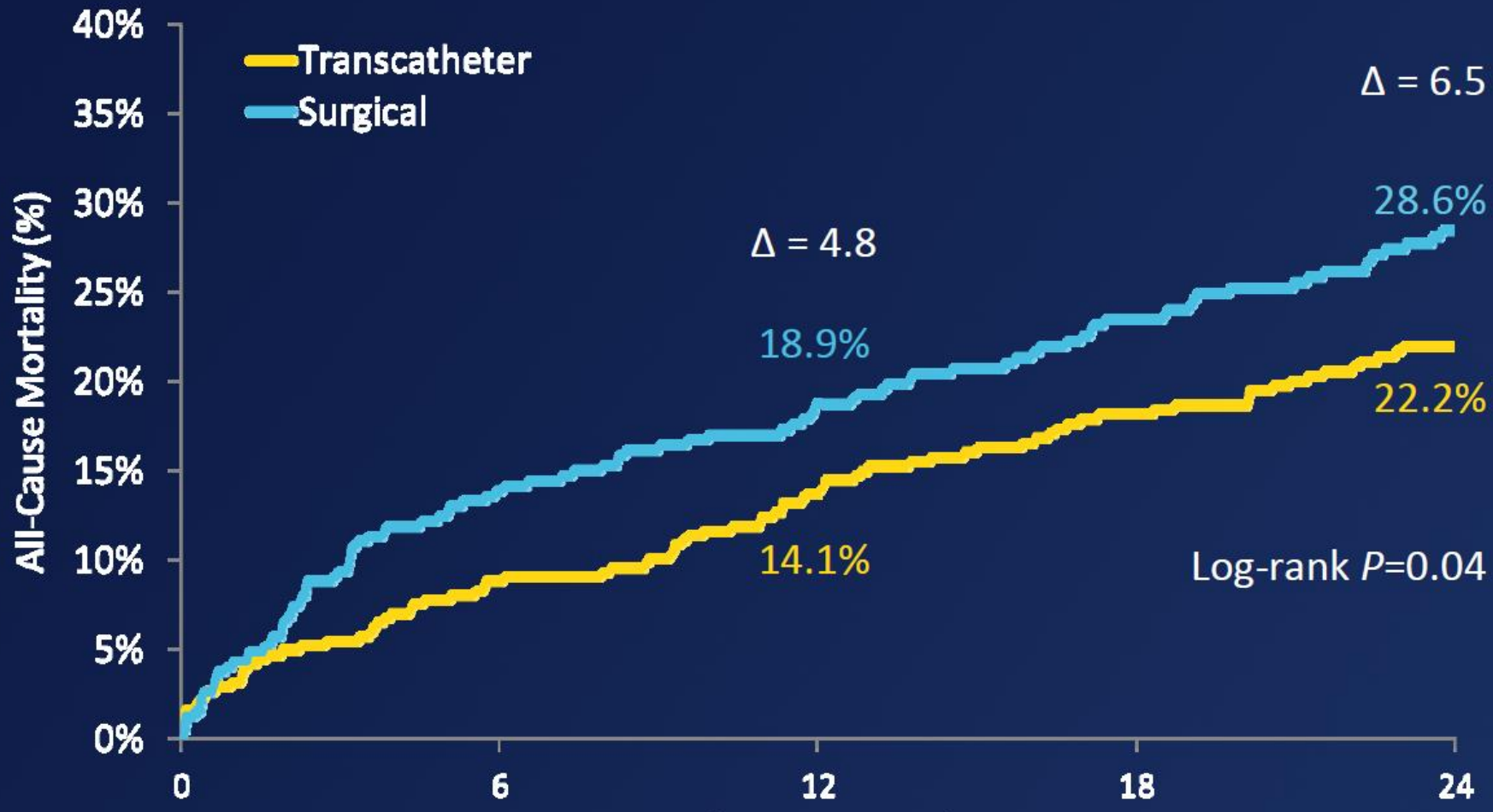
Pivotal Trial Design

* Randomization stratified by intended access site

All-Cause Mortality

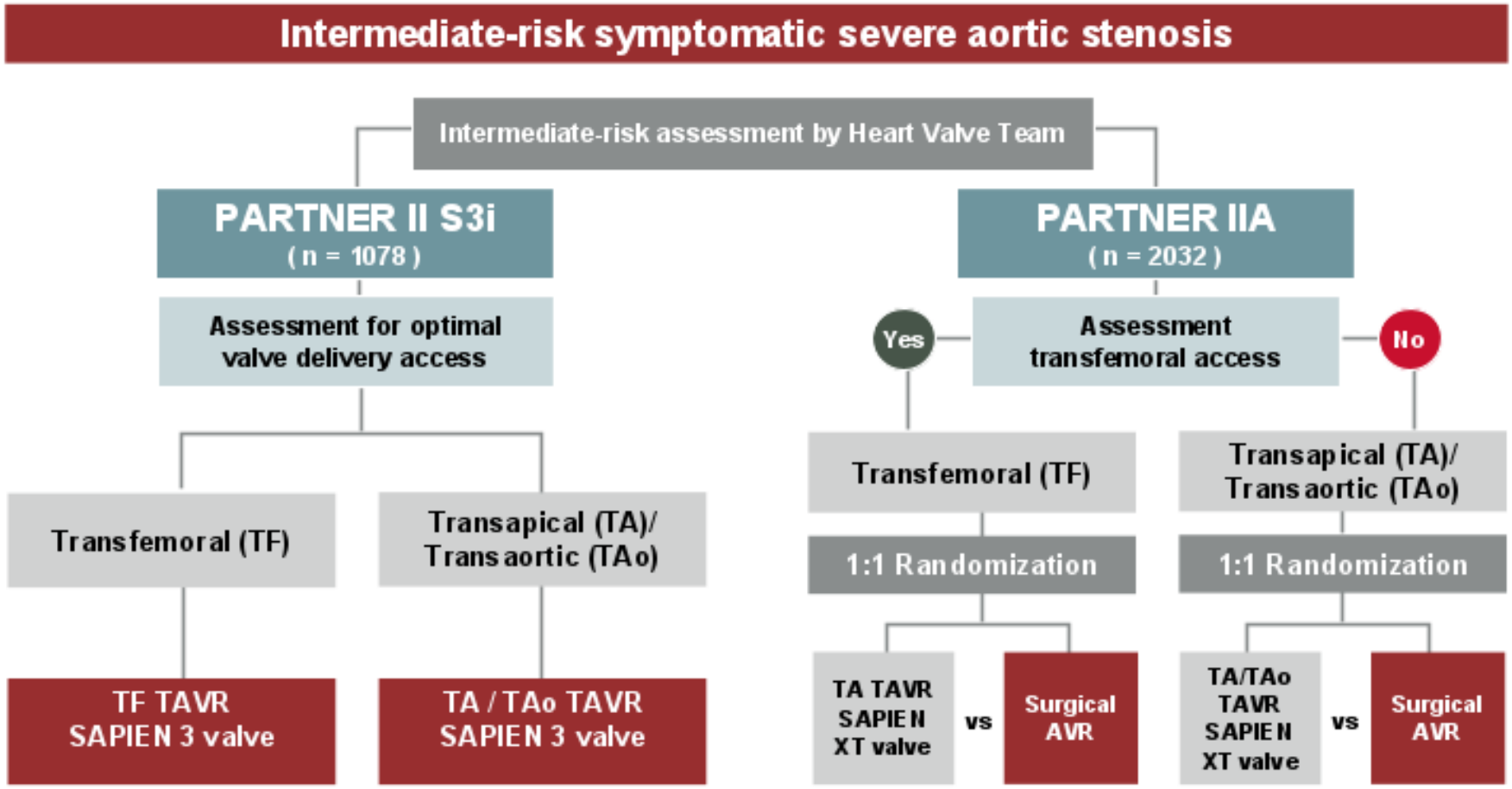
CoreValve US Clinical Trials

ACC 2015



No. at Risk					
Transcatheter	391	378	354	334	219
Surgical	359	343	304	282	191

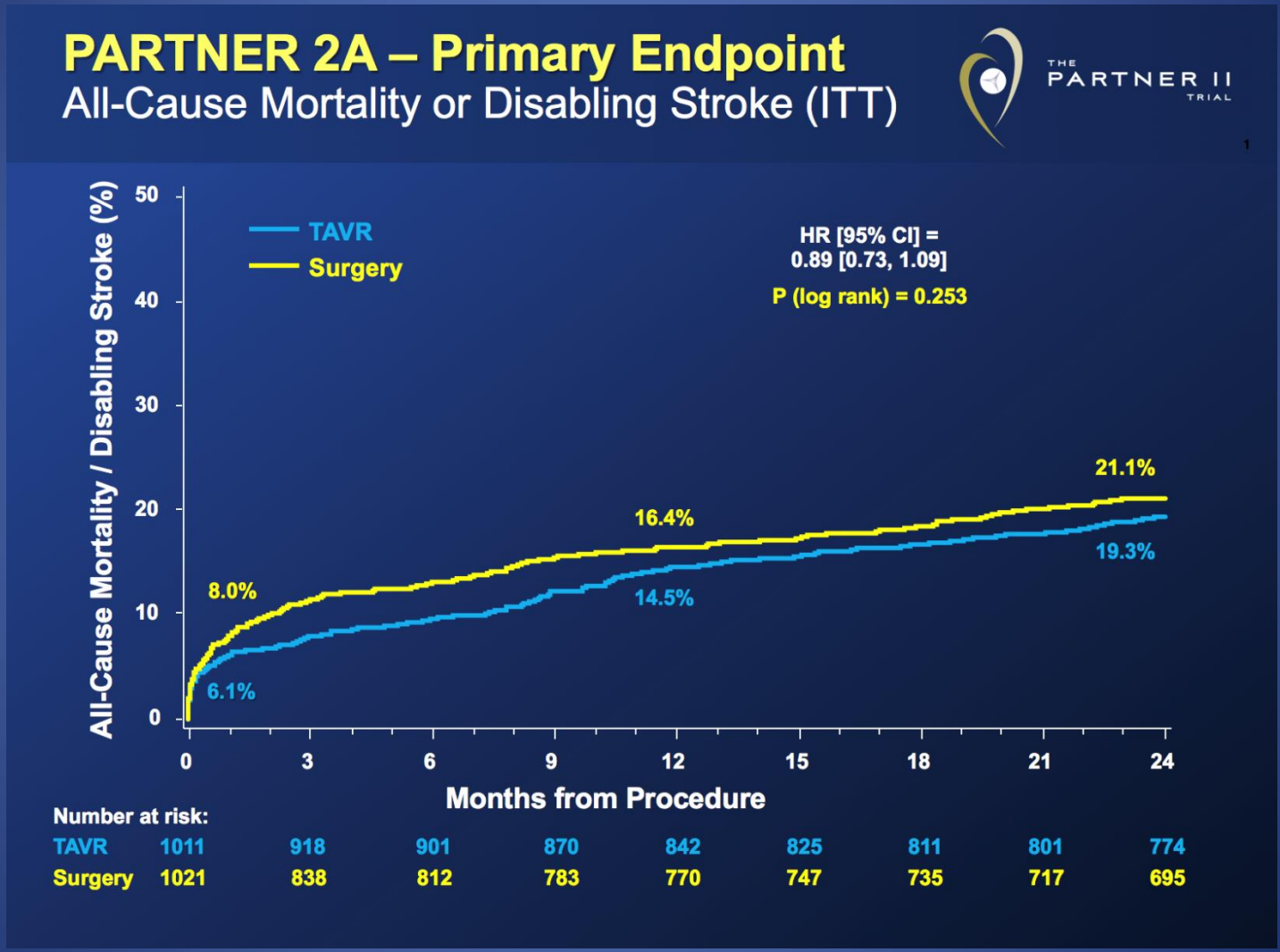
The PARTNER II Trial: Intermediate-risk cohort



The most robust, rigorous study in **more than 3,000 intermediate-risk patients**

Is TAVR Superior to Surgery?

The evidence builds…



Smith, ACC 2016

Other unadjusted clinical events

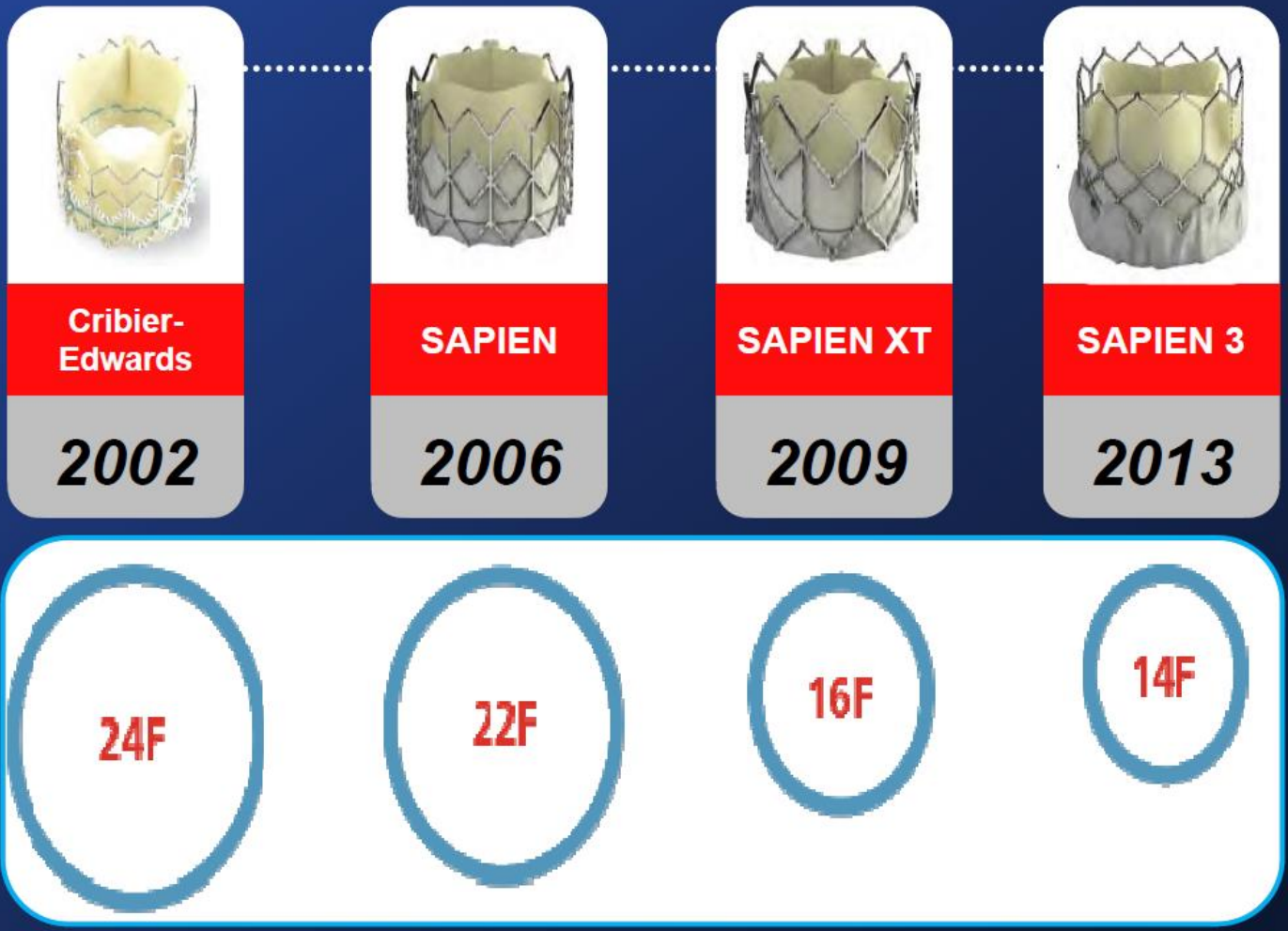
At 30 days and 1 year (AT)

Events (%)	30 Days		1 Year	
	PARTNER II S3i trial SAPIEN 3 valve (n =1,077)	PARTNER IIA trial surgery (n =944)	PARTNER II S3i trial SAPIEN 3 valve (n =1,077)	PARTNER IIA trial surgery (n =944)
Re-hospitalization	4.6	6.8	11.4	15.1
Myocardial infarction	0.3	1.9	0.3	3.1
Major vascular complication	6.1	5.4	---	---
Life-threatening / disabling bleeding	4.6	46.7	---	---
New atrial fibrillation	5.0	28.3	5.9	29.2
New permanent pacemaker	10.2	7.3	12.4	9.4
Re-intervention	0.1	0.0	0.6	0.5
Endocarditis	0.2	0.0	0.8	0.7

	PARTNER II S3i trial SAPIEN 3 valve (n =1,077)	PARTNER IIA trial surgery (n =944)
Mean total hospitalization LOS (days)	5.6	11.9
Mean ICU stay (days)	2.7	5.6

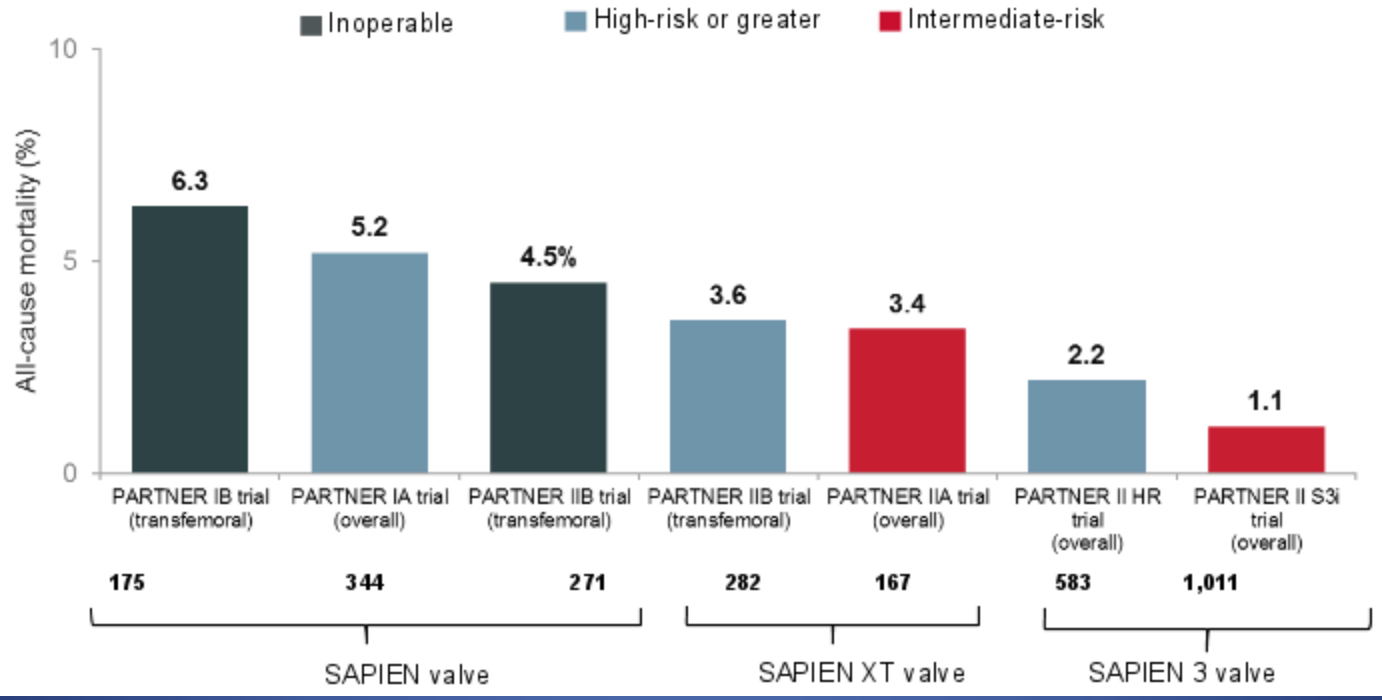
Evolution of the Edwards Balloon-Expandable Transcatheter Valves

THE PARTNER II TRIAL

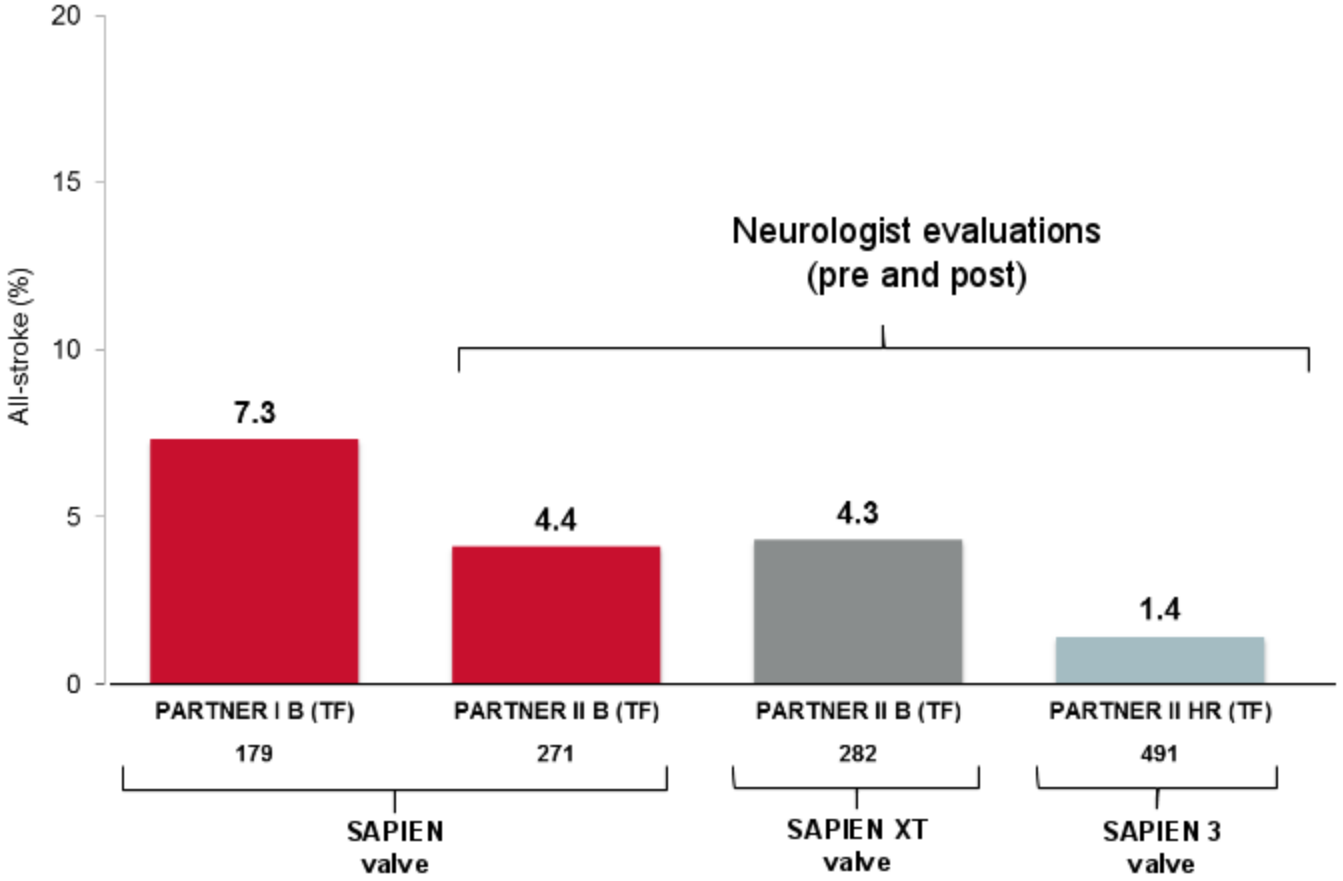


* Sheath compatibility for a 23 mm valve

Mortality rates continue to decline



Stroke rates continue to decline



TAVR in 2018

New performance benchmarks for high-risk AS patients (@ 30 days)

- All-cause mortality < 3%
- Major (disabling) strokes < 3%
- Major vascular complications < 5%
- Major bleeding complications <5%
- Mod-severe para-valvular regurgitation < 5%
- New pacemaker requirement <10%

Discharge Instructions Highlights

- Cardiology follow-up 4 – 5 days, 30 days, 1 year
- Aspirin 81 mg daily and Plavix 75 mg daily x 3-6 months
- Standard Post Cath precautions
- **Antibiotics prophylaxis prior to dental work**

The Future of TAVR?

- Multiple valve choices
  - How many do we need?
  - Different learning curves
  - How do we choose?
- Expanding indications
  - Bicuspid valves
  - Valve in valve
  - Lower risk patients
  - Moderate AS
  - Asymptomatic patients