Endovascular Approaches for Treatment of Valvular Disease: The Time is Now!

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Disclosures

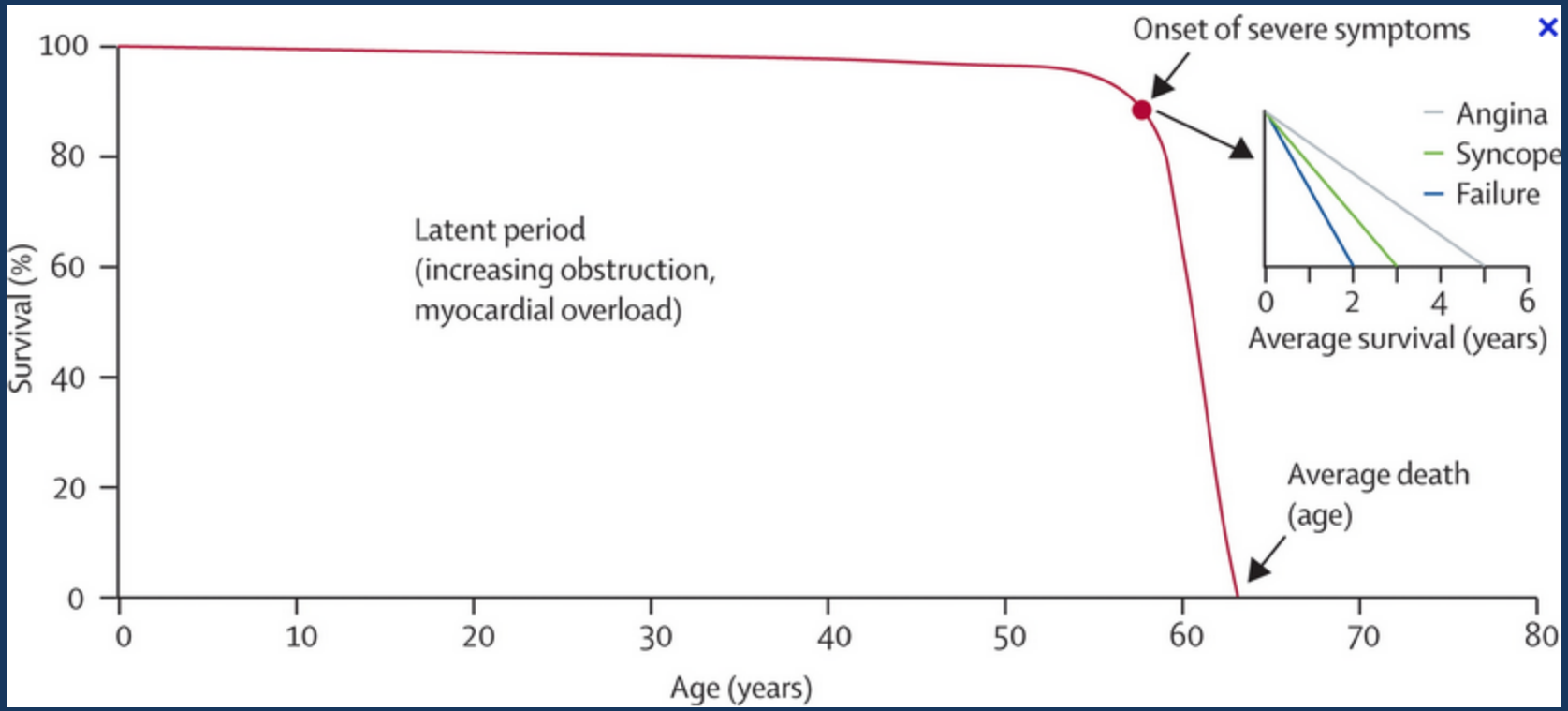
Disclosure	Company
Research	Medtronic, Edwards, Boston Scientific, Abbott/St Jude, Direct Flo Medical, Keystone Medical
Consultant/Advisory Board	Medtronic, Edwards, Boston Scientifc
Physician Proctor	Medtronic, Edwards, Boston Scientific
Stock	None
Equity	None


Greetings
from Norfolk, Virginia
64

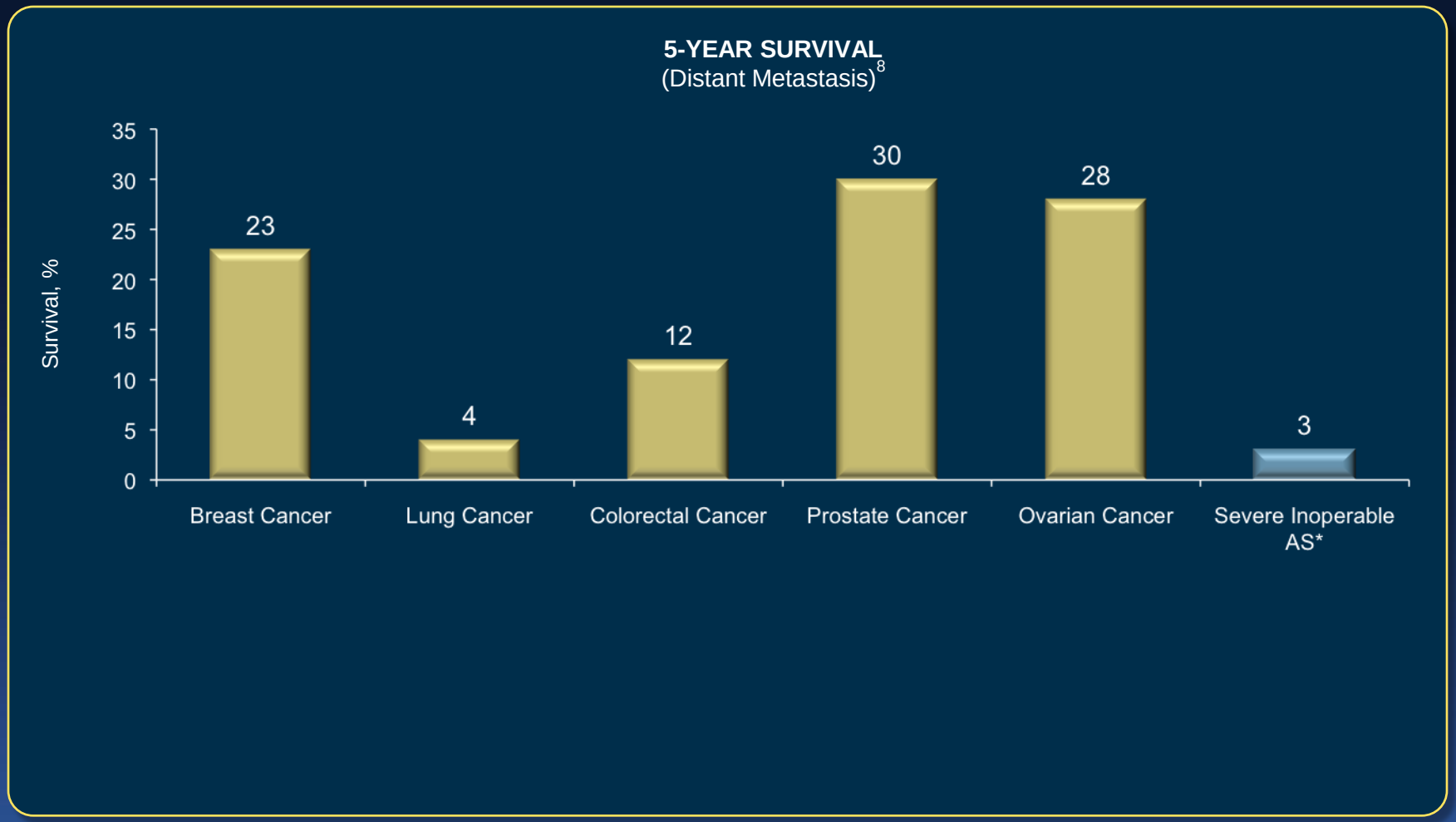
The Problem:
Aortic Stenosis

AS Survival:
High Mortality with Symptom onset

- **3 cardinal symptoms:**
  - **Angina, Syncope, Dyspnea**



Aortic Stenosis:
Worse Prognosis than Many Metastatic Cancers



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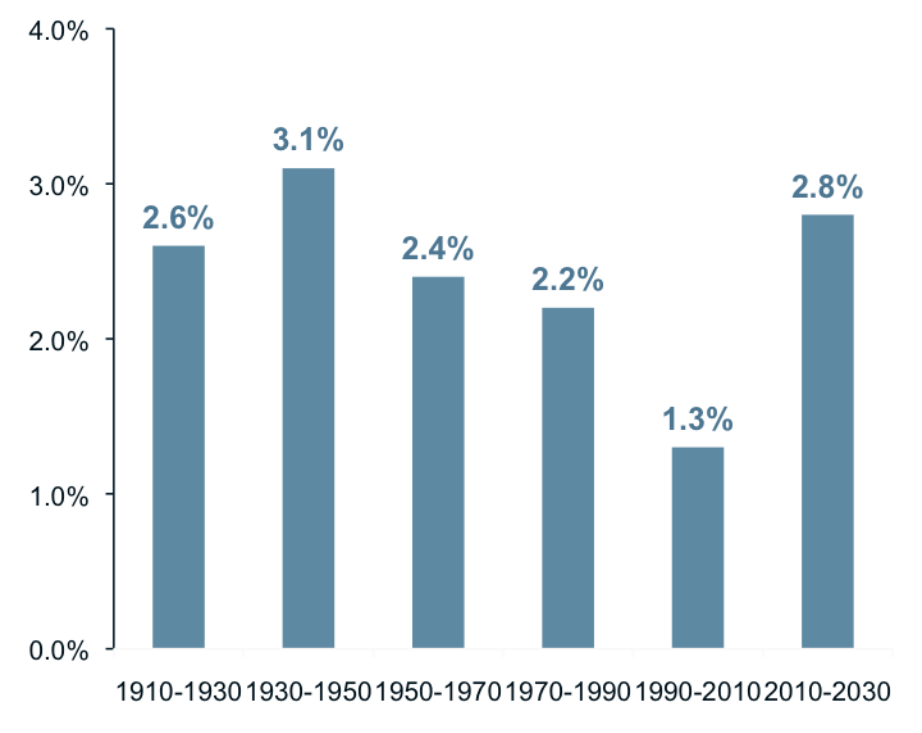
Population at Risk for Aortic Stenosis is Increasing

- Aortic Stenosis is estimated to be prevalent in **12.4% of the population over the age of 75.**[2]
- The elderly population will more than double between now and the year 2050, to 80 million.[3]

ELDERLY AVERAGE ANNUAL GROWTH RATE: 1910 to 2030



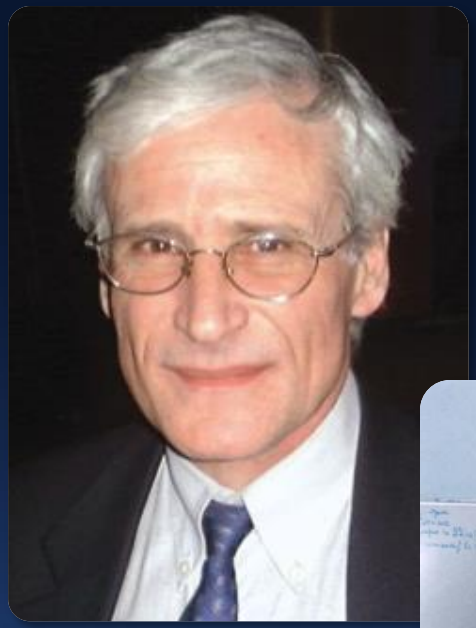
SENTARA HEART

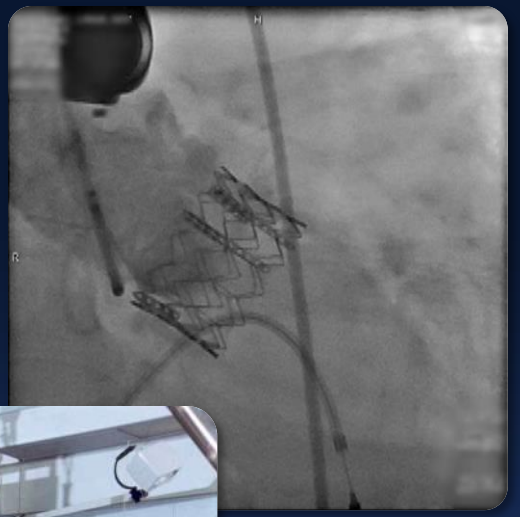
What is TAVR?

- Transcatheter Aortic Valve Replacement

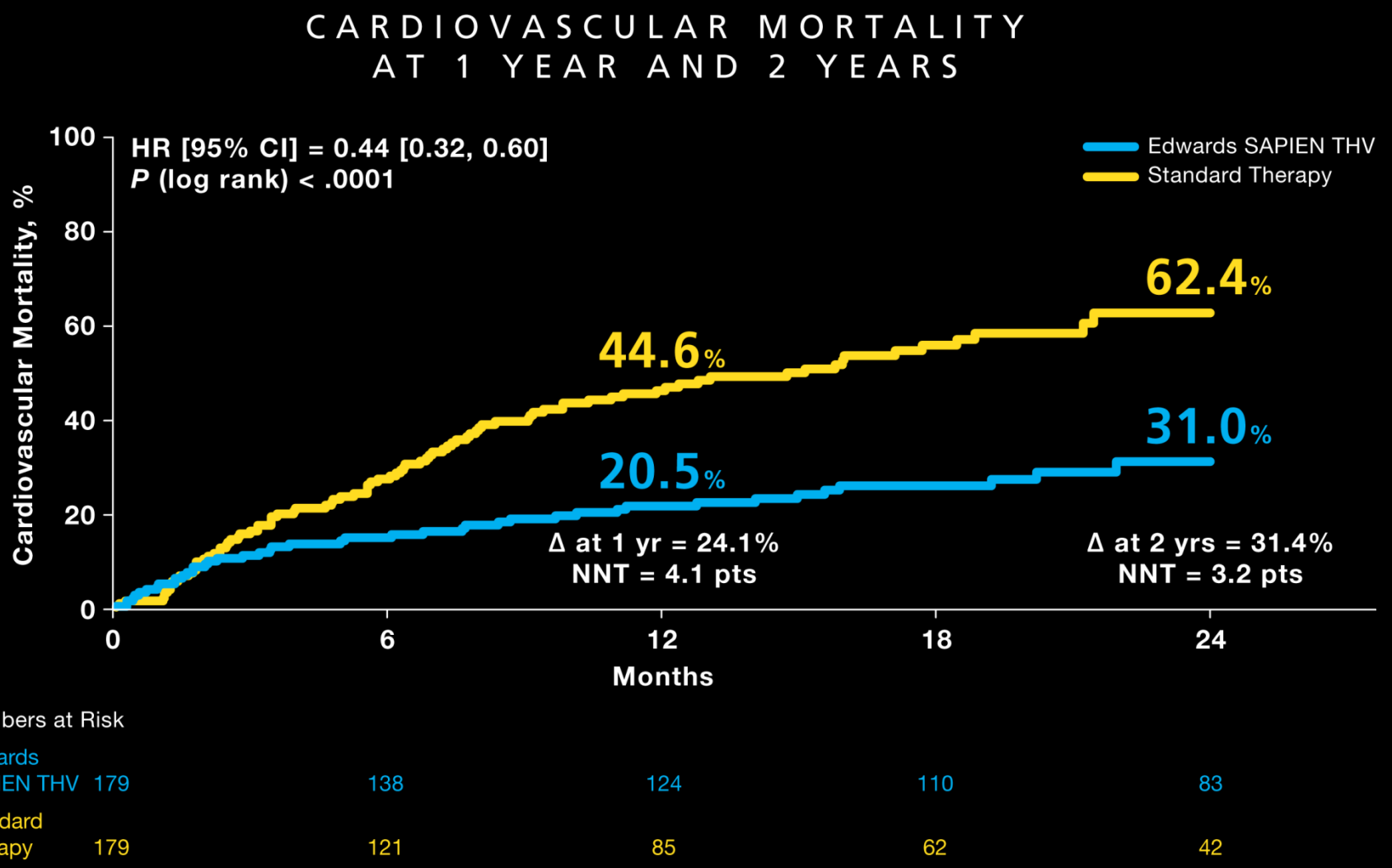
- Catheter based approach for valve replacement
- Initially: treating the untreatable
- Rapid adoption of this new technology

Alain Cribier: First Human Transcatheter Valve Replacement (2002)



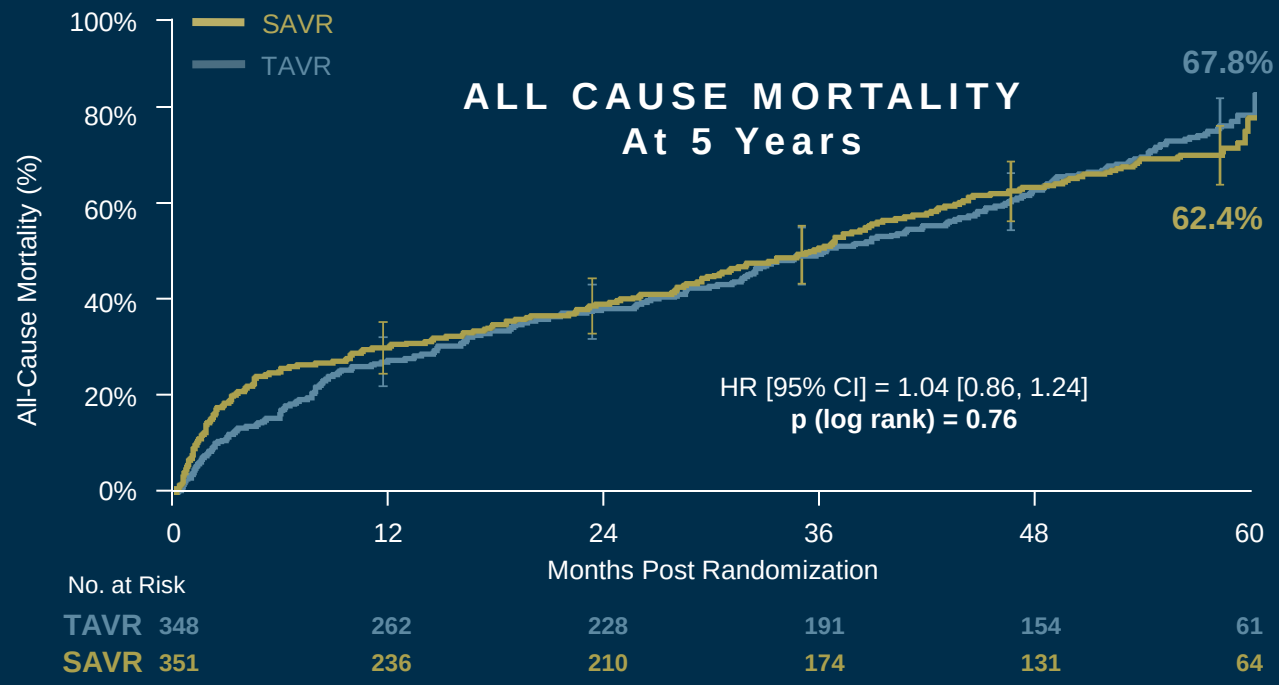


Inoperable Patients:
> 30% Absolute Reduction in CV Mortality



TAVR is Equivalent to Surgery in High-Risk Patients

Partner 1 High Risk Trial



THE PARTNER TRIAL

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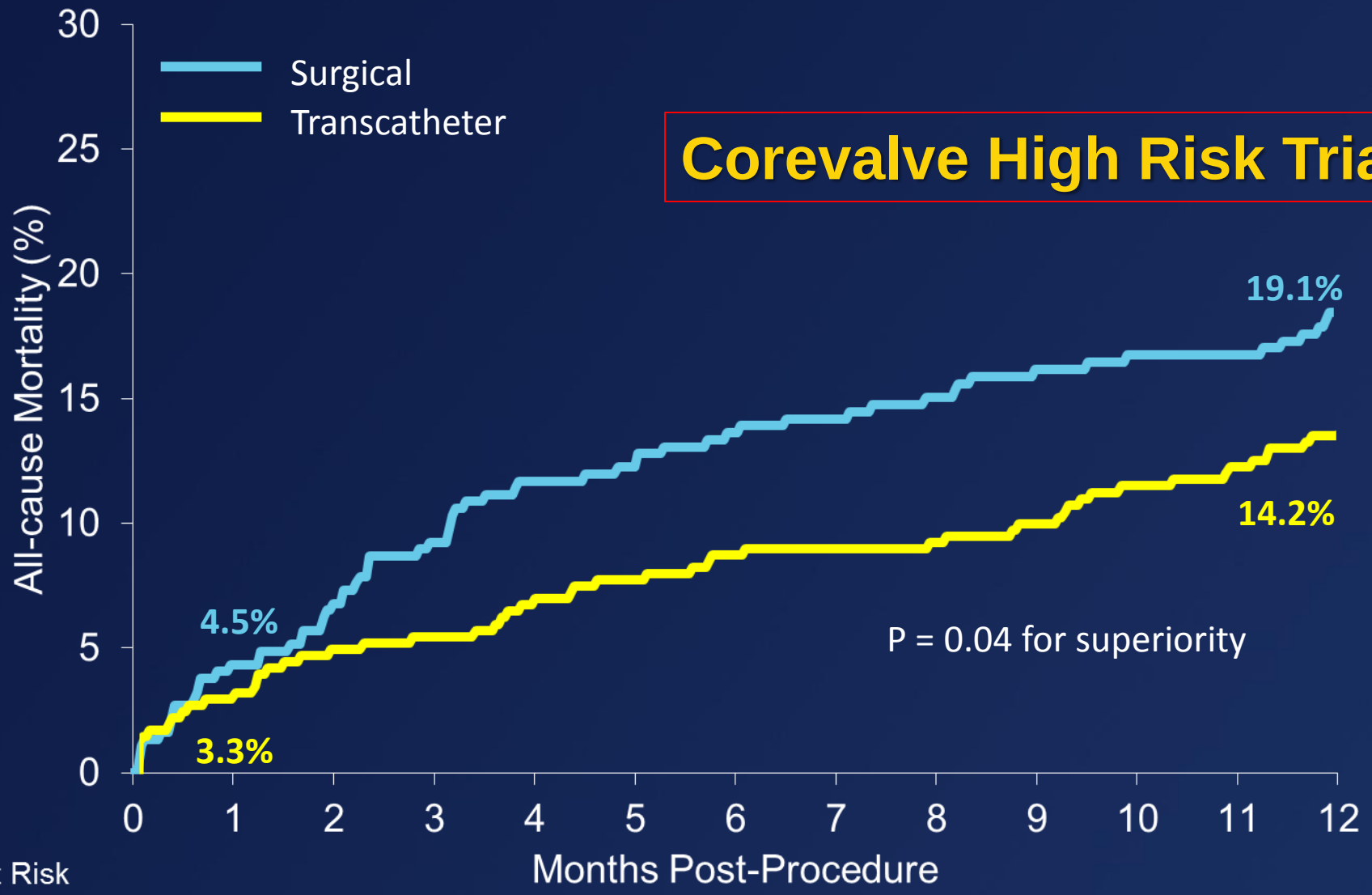
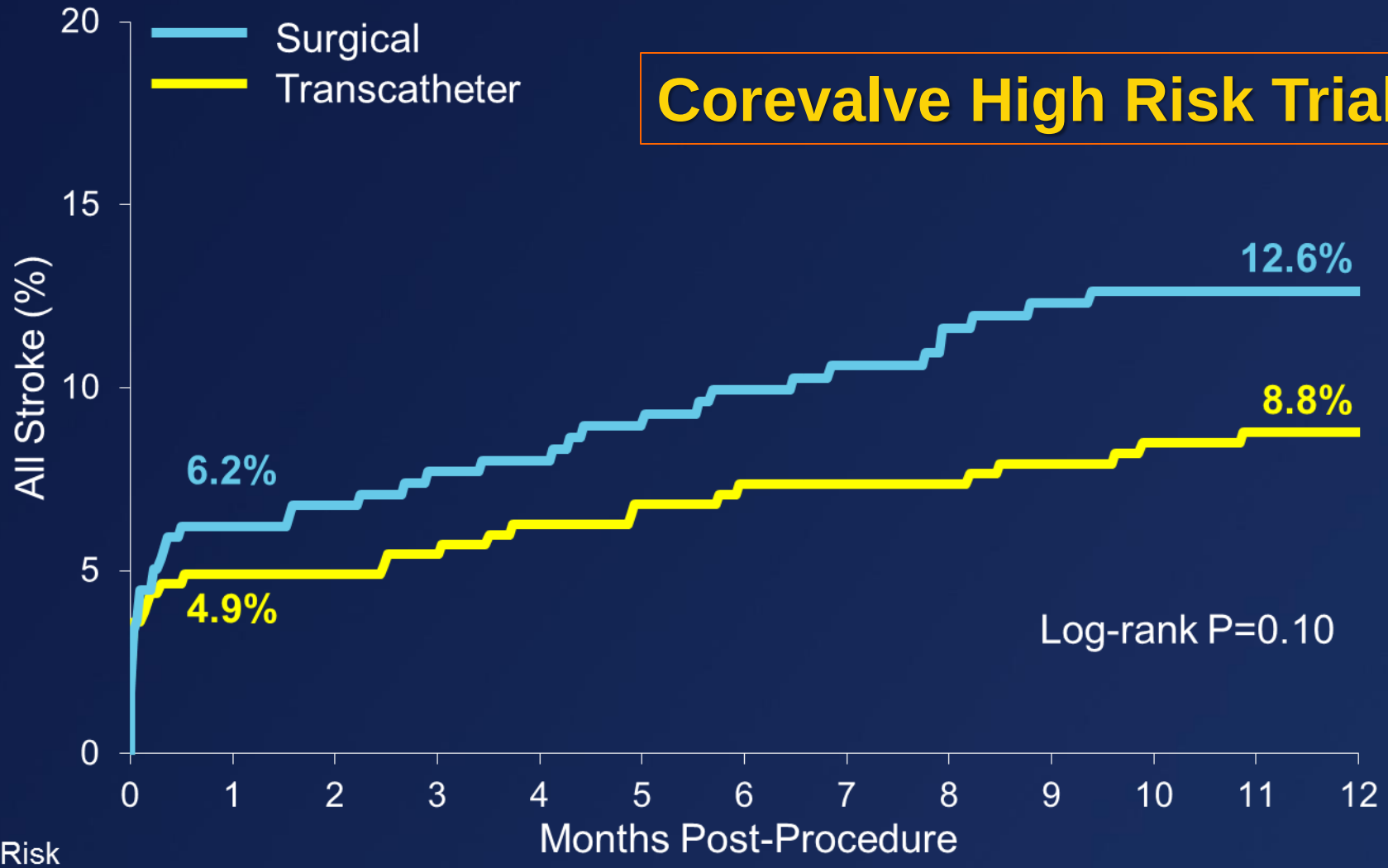
Primary Endpoint: 1 Year All-cause Mortality



All Stroke

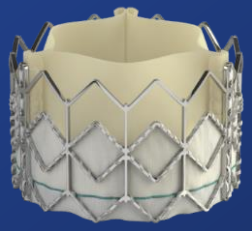
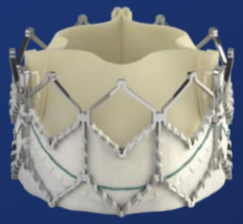
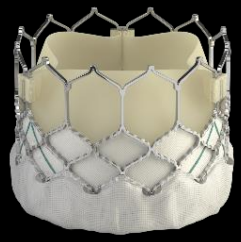
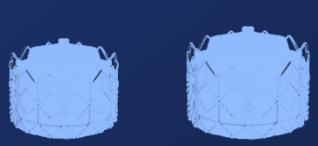
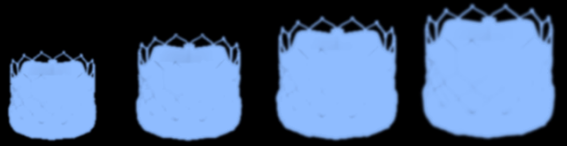


No. at Risk

Surgical	357	322	274	249
Transcatheter	390	363	334	314

SAPIEN Platforms in PARTNER
Device Evolution

THE PARTNER II TRIAL

	SAPIEN	SAPIEN XT	SAPIEN 3
Valve Technology			
Sheath Compatibility			
Available Valve Sizes	 23 mm, 26 mm	 23 mm, 26 mm, 29 mm	 20 mm, 23 mm, 26 mm, 29 mm

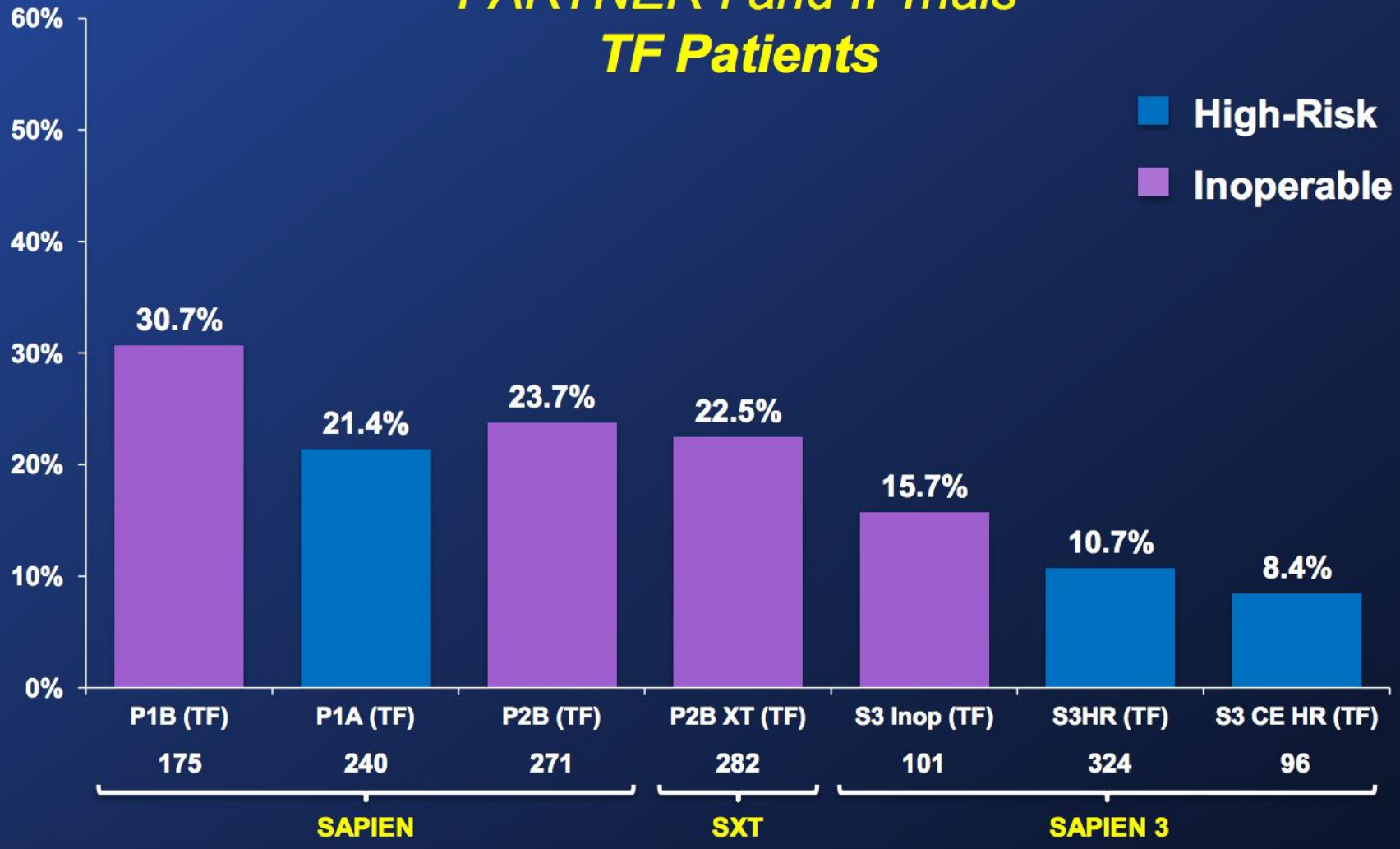
All-Cause Mortality at 1 Year

Edwards SAPIEN Valves (As Treated Patients)

THE PARTNER II TRIAL

PARTNER I and II Trials

TF Patients



2017: Deciding who gets TAVR today (and tomorrow)

- Lets look at a recent case…. It's not 2012 anymore!

Case Presentation

SENTARA

[Patient LE]

Patient Evaluation
Structural Heart Program

Sentara Heart Hospital
Norfolk, VA

Interv. Cardiology:
P. Mahoney, MD
D. Talreja, MD
N. Mistry, MD

Cardiac Surgery:
J. Newton, MD
J. Philpott, MD
G. Dimeling, MD
C. Kemp, MD

TAVR Coordinators:
L. Morris, PA-C
M. Sukholutsky, PA-C
E. Willette, NP
A. Kanter, RN

Case Summary – Clinical History:

- 69 years old
- STS 2.6%
- NYHA Class II
- BSA / BMI: 1.7 / 22

- Creatinine: 0.8
- Hb: 14.3
- PLT: 178
- Team: PDM

- Ht: 165cm
- Wt: 61kg

Clinical history

Severe aortic stenosis and moderate aortic insufficiency
- Echo 2/21/17 (Riverside) -- AVA 1.0cm2, peak 104mmHg, mean 55mmHg, Vmax 501cm/s, 2+ AI
- TEE 4/14/17 – moderate AI
- Cath 4/14/17 – AVA 0.9 cm2, mean 48mmHg

Non-obstructive CAD

Normal LV function, EF 55%

COPD and Asthma -- on inhalers
- Ongoing tobacco abuse
- PFT's 4/6/17 -- FEV1 2.32, 97% predicted, DLCO 74

Multiple sclerosis - uses cane or wheelchair outside the house

Carotid PVL 4/4/17 - <50% stenosis bilaterally
Edentulous

STS Risk Score / Frailty:

- **STS risk score:**

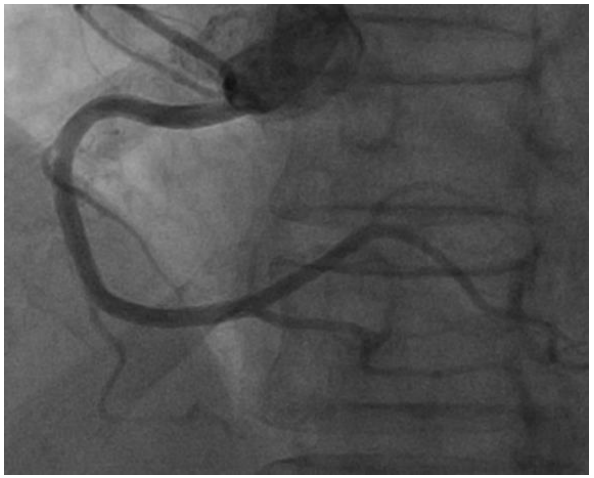
Procedure: AV Replacement
Risk of Mortality: 2.578%
Morbidity or Mortality: 15.774%
Long Length of Stay: 6.451%
Short Length of Stay: 35.949%
Permanent Stroke: 1.54%
Prolonged Ventilation: 9.522%
DSW Infection: 0.17%
Renal Failure: 2.459%
Reoperation: 7.635%

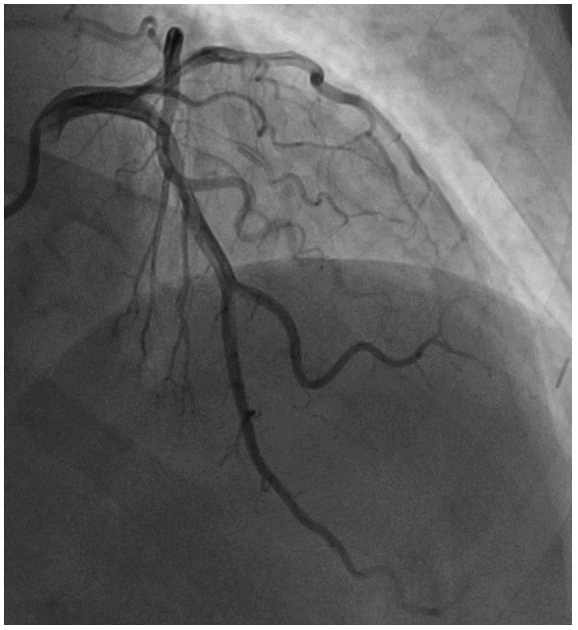
STS Risk Drivers
Mild lung disease
PAD
HTN

Frailty Assessment: 1/4

Grip strength:	[normal]
Katz ADL:	[6/6]
5 meter walk:	[abnormal]
Albumin:	[normal]

Coronary Angiography



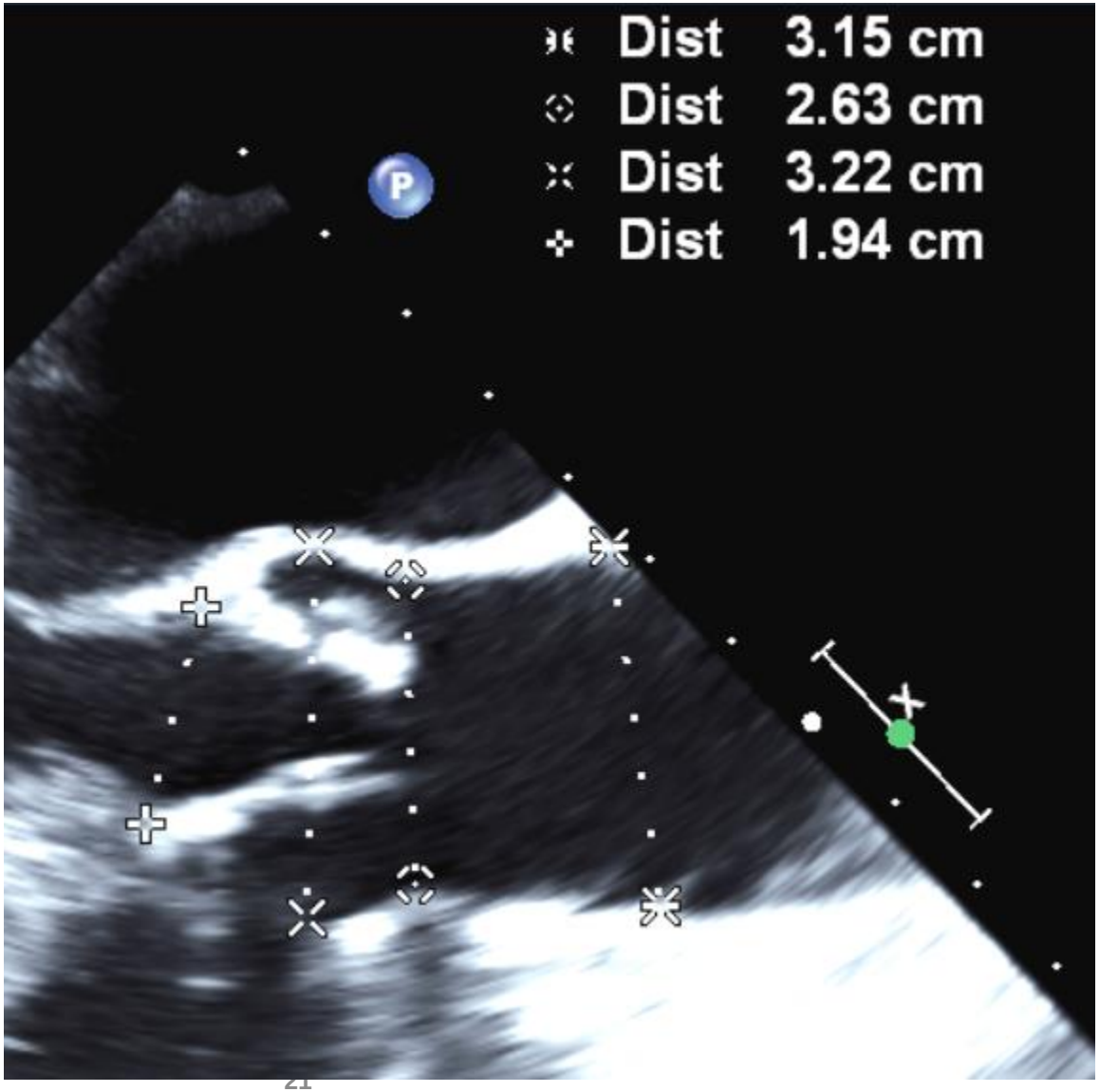


Summary: LM patent, LAD 20-30% stenosis, LCx patent, RCA patent

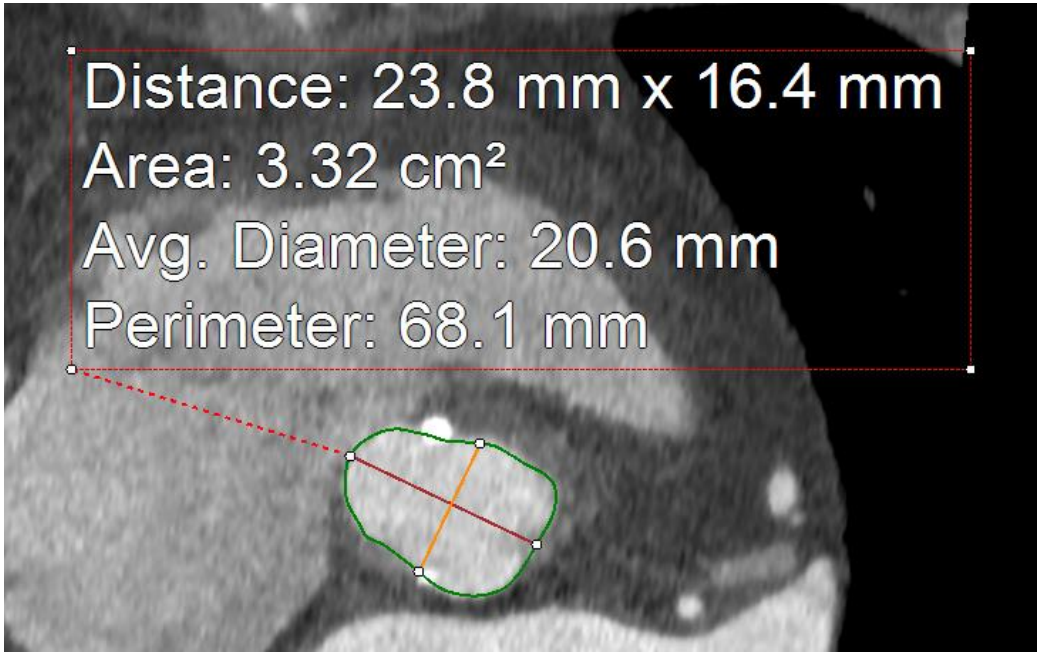
Plans for Revascularization: medical therapy

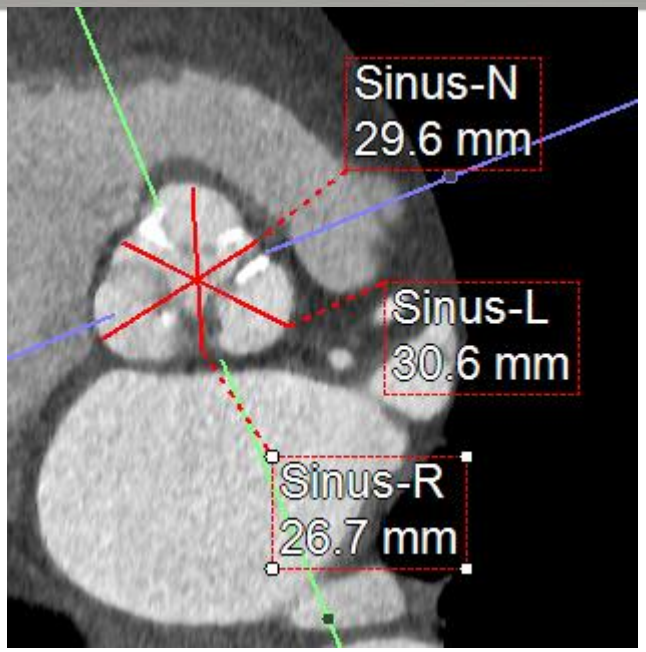
Echocardiography

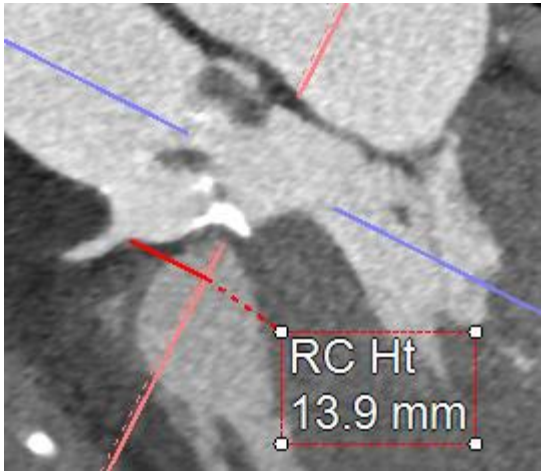
Annulus = 19mm

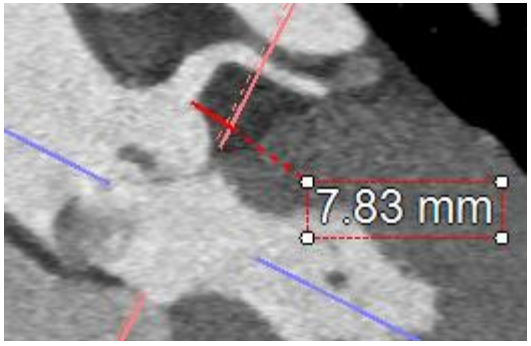


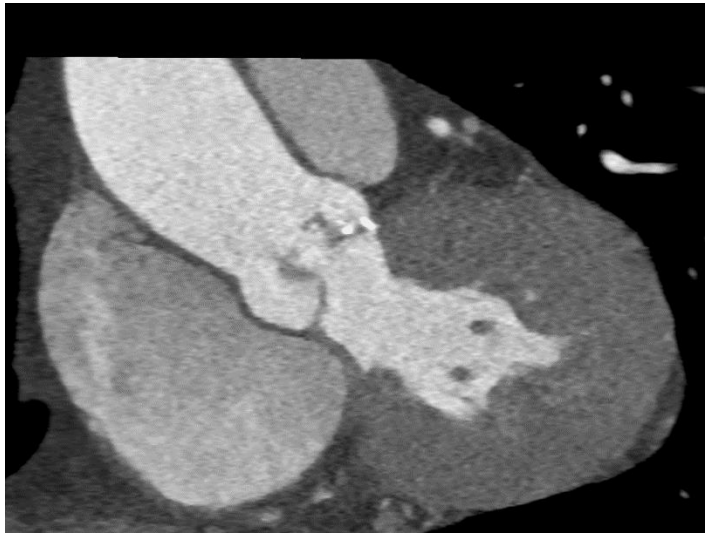
Aortic valve assessment by CT



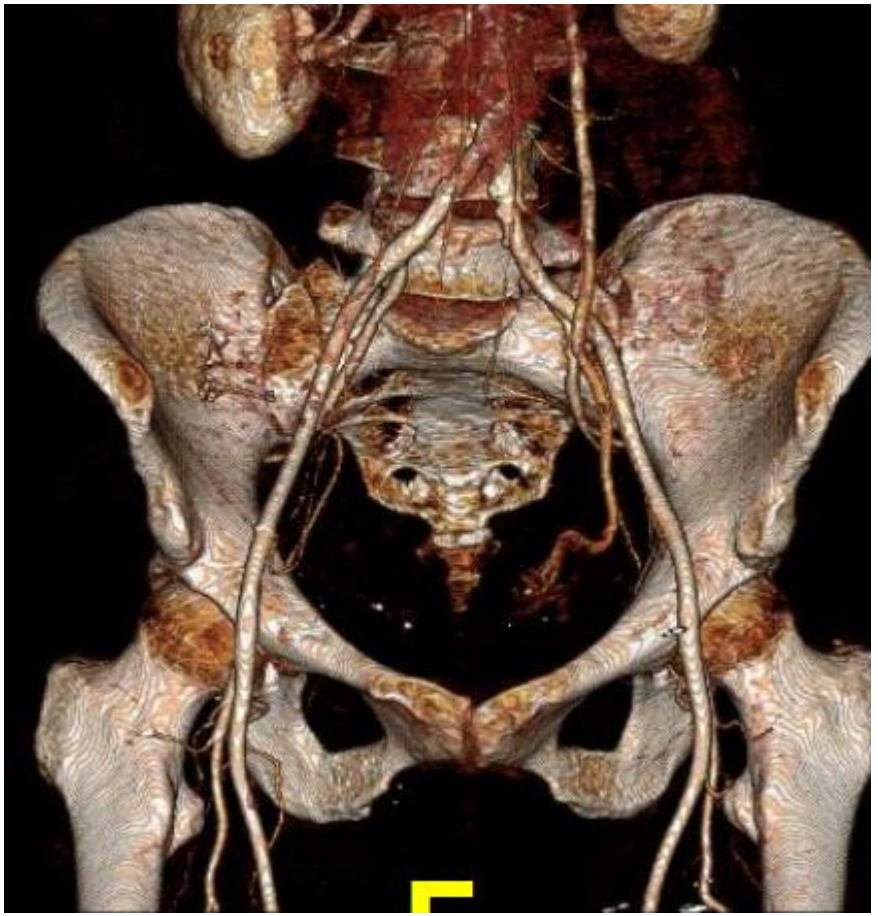






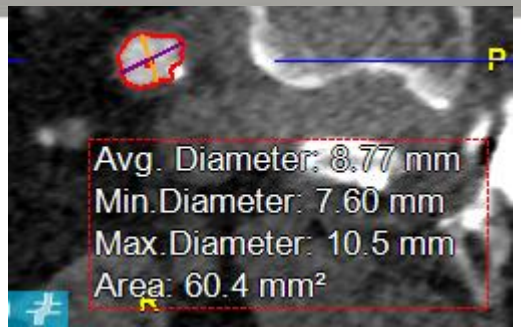


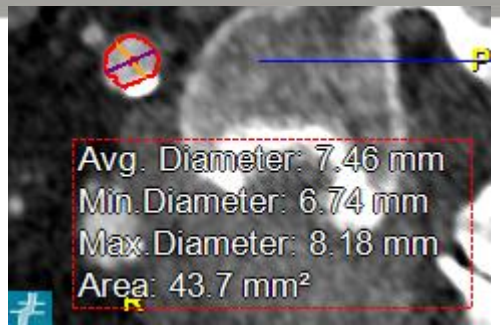
Peripheral assessment



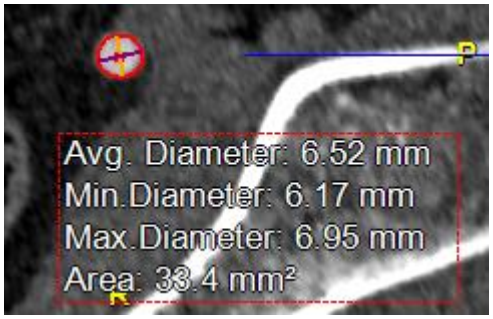
CT

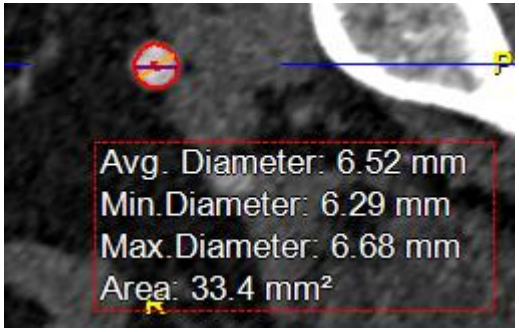
Common iliacs



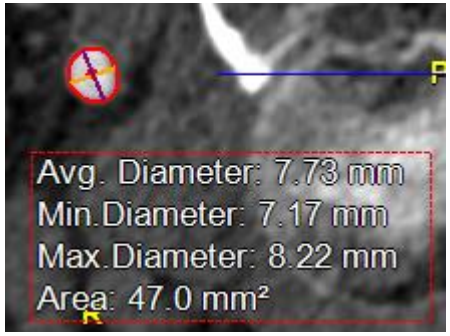


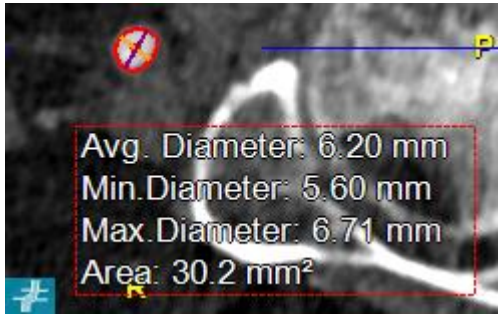
External iliacs





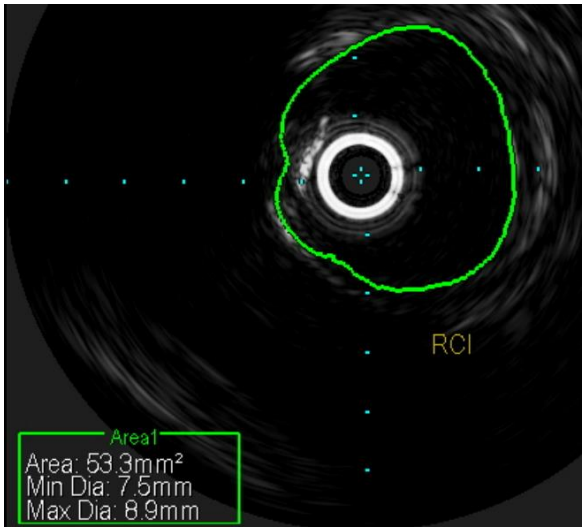
Common femorals

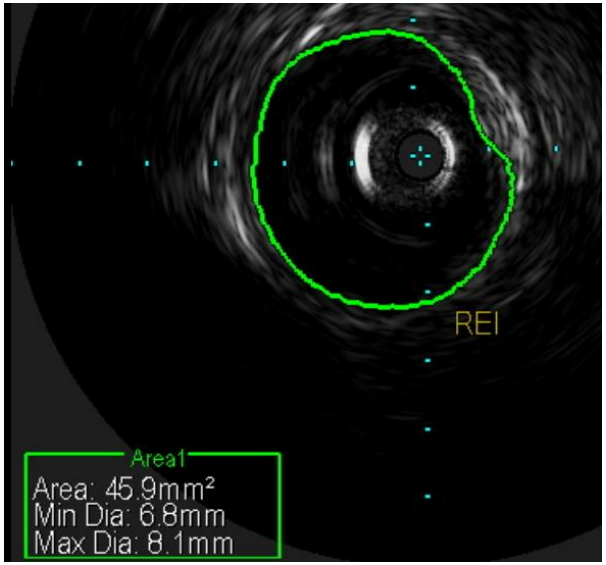


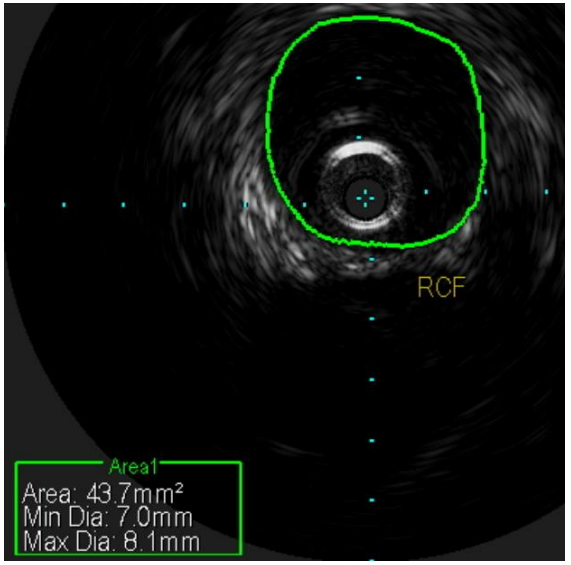


IVUS

	Right	Left
Common Iliac	8.2mm	xxx
External Iliac	7.5mm	xxx
Common Femoral	7.5mm	xxx







Procedural Plan:

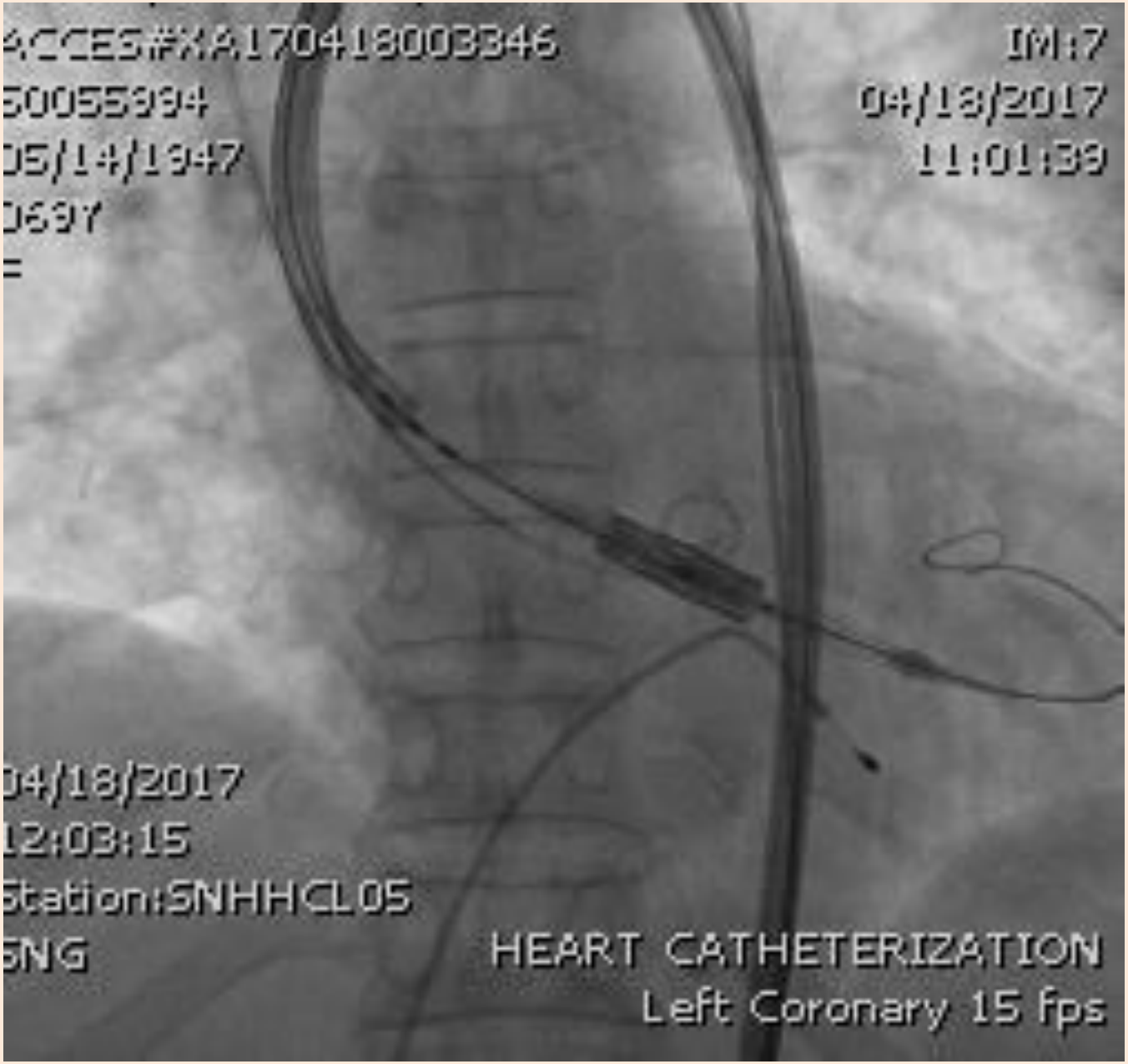
- Judgement of Heart Team:
  - **Patient is at INTERMEDIATE risk for planned AVR given STS score and comorbidities.**

- Bailout → OPEN

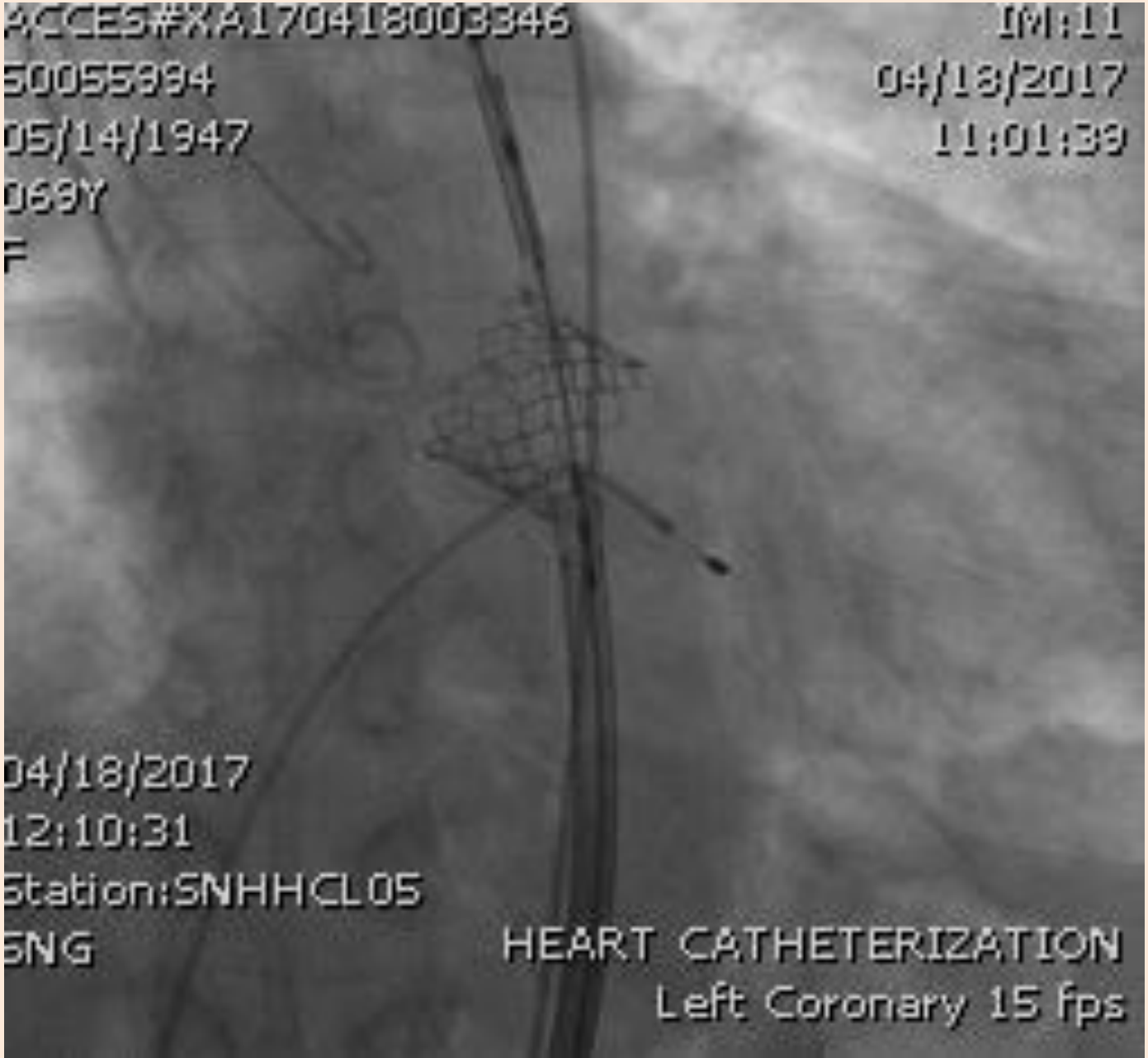
- Fast Track Protocol

Annulus Diameter and Area Measurements	THV Valve Size Proposed	Access	Smallest Vessel Diameter Measurement in accessed vessel
Annulus = 19mm Area = 332mm Perimeter = 68.1mm	**[23] S3**	**RFA** (high bifurcation)	7.5mm Right EI and CF

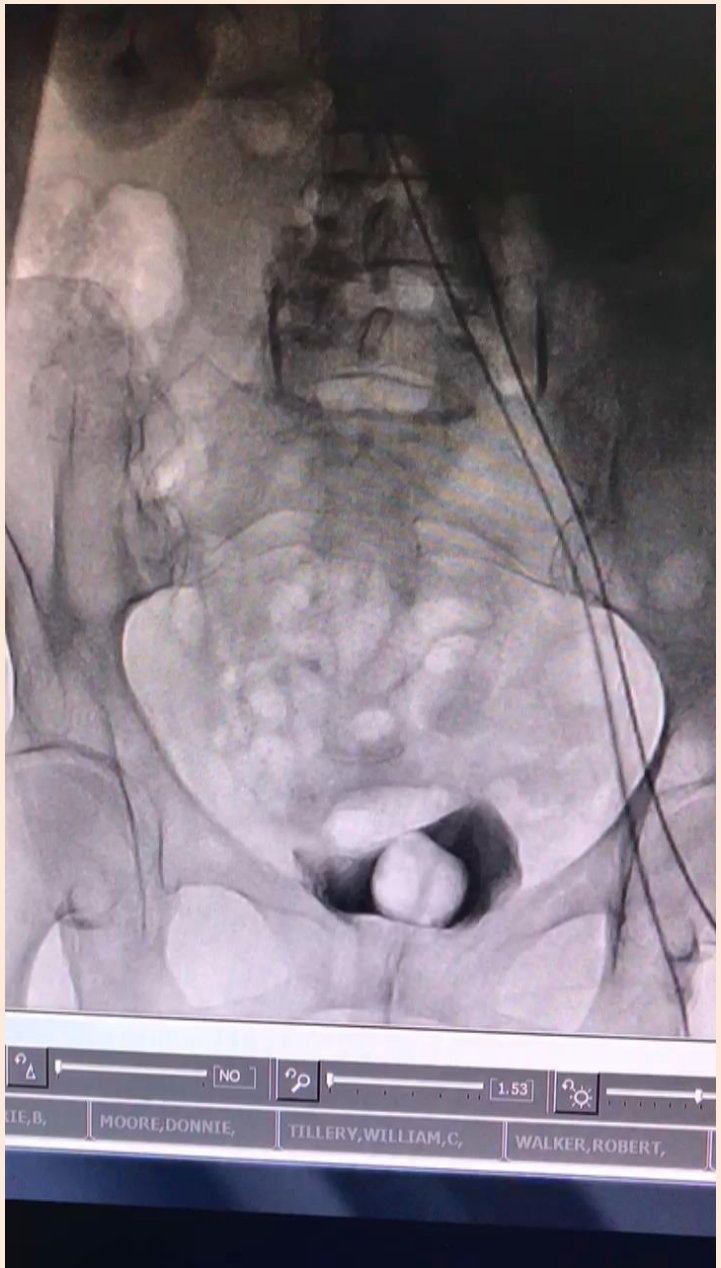
TAVR Procedure



Post deployment

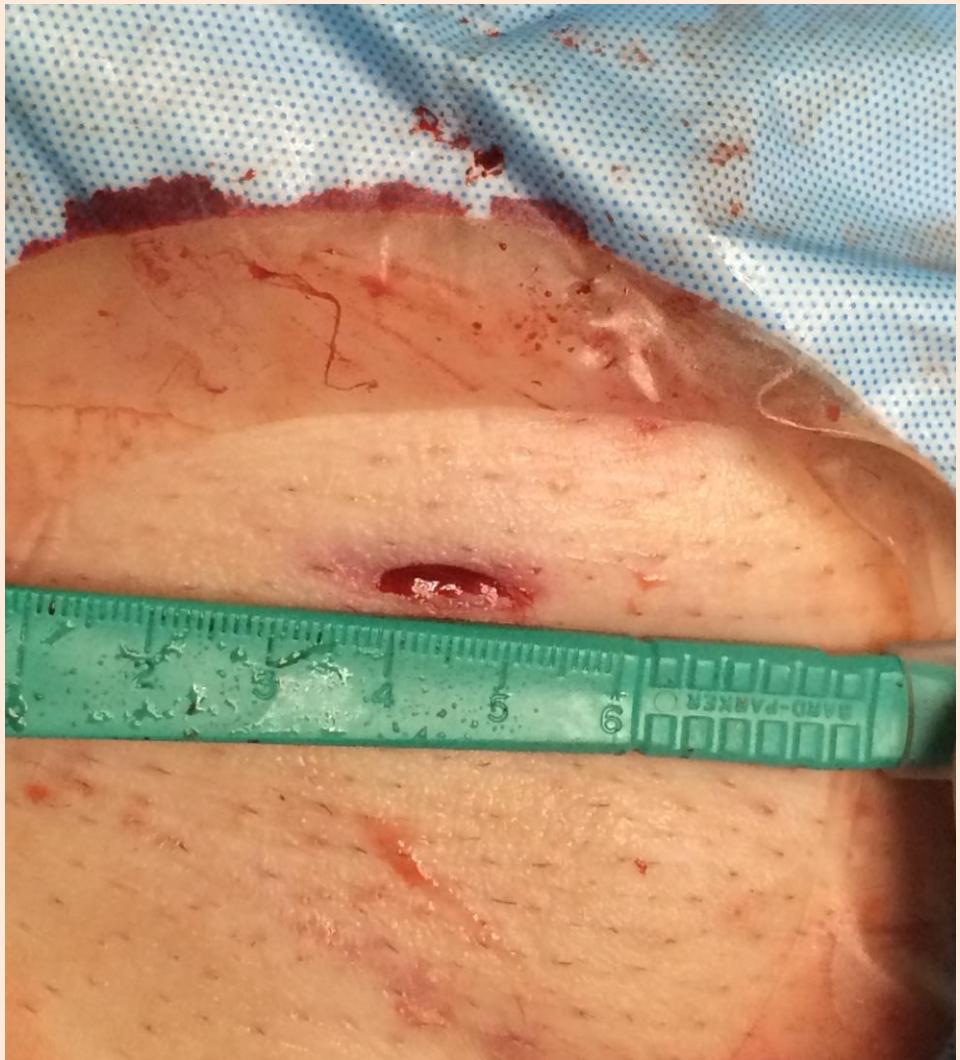


Vascular Access- Completion angiography



Vascular Access: Percutaneous Approach

- 14 Fr Arterial Sheath
- Perclose sutures placed percutaneously



Hospital Course

- Uncomplicated TAVR
- Procedure time: 31 minutes, skin to skin

- Minimalist approach, fast track
  - Conscious sedation
  - No TEE, No PA catheter
  - 4 hour ICU stay; ambulating at 4 hours
  - POD #1: Discharged to home

TAVR Trials : Intermediate Risk Patients

- 2 surgeons agree on risk
- 2 year follow up
- Major endpoints: Death, stroke

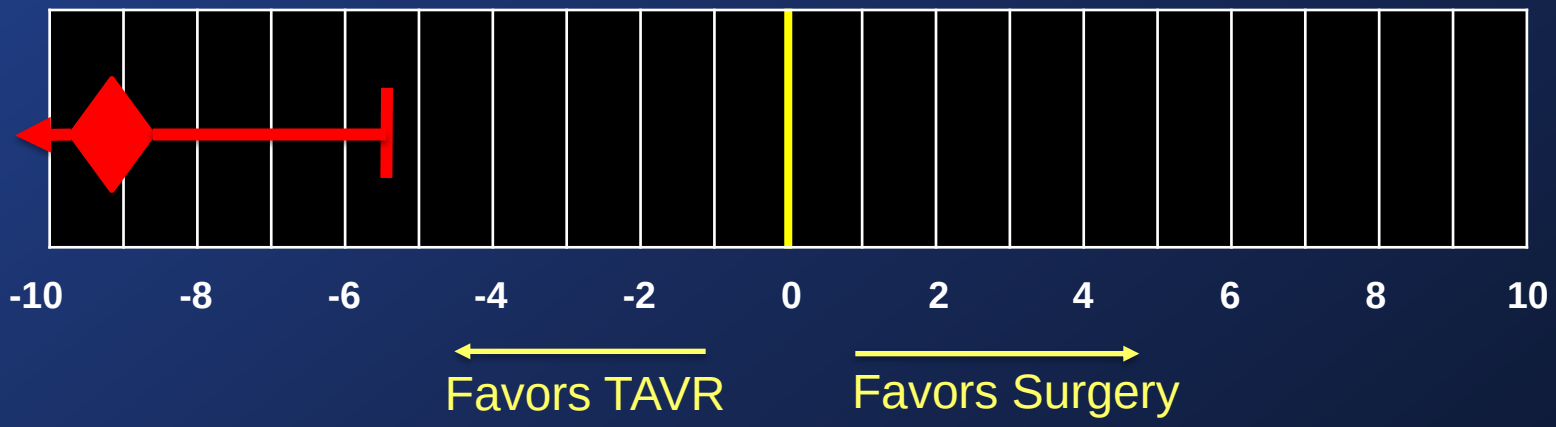
Primary Endpoint - Superiority

Death, Stroke, or AR ≥ Mod at 1 Year (VI)

THE PARTNER II TRIAL

Weighted Difference	**-9.2%**
Upper 2-sided 95.0% CI	**-5.4%**

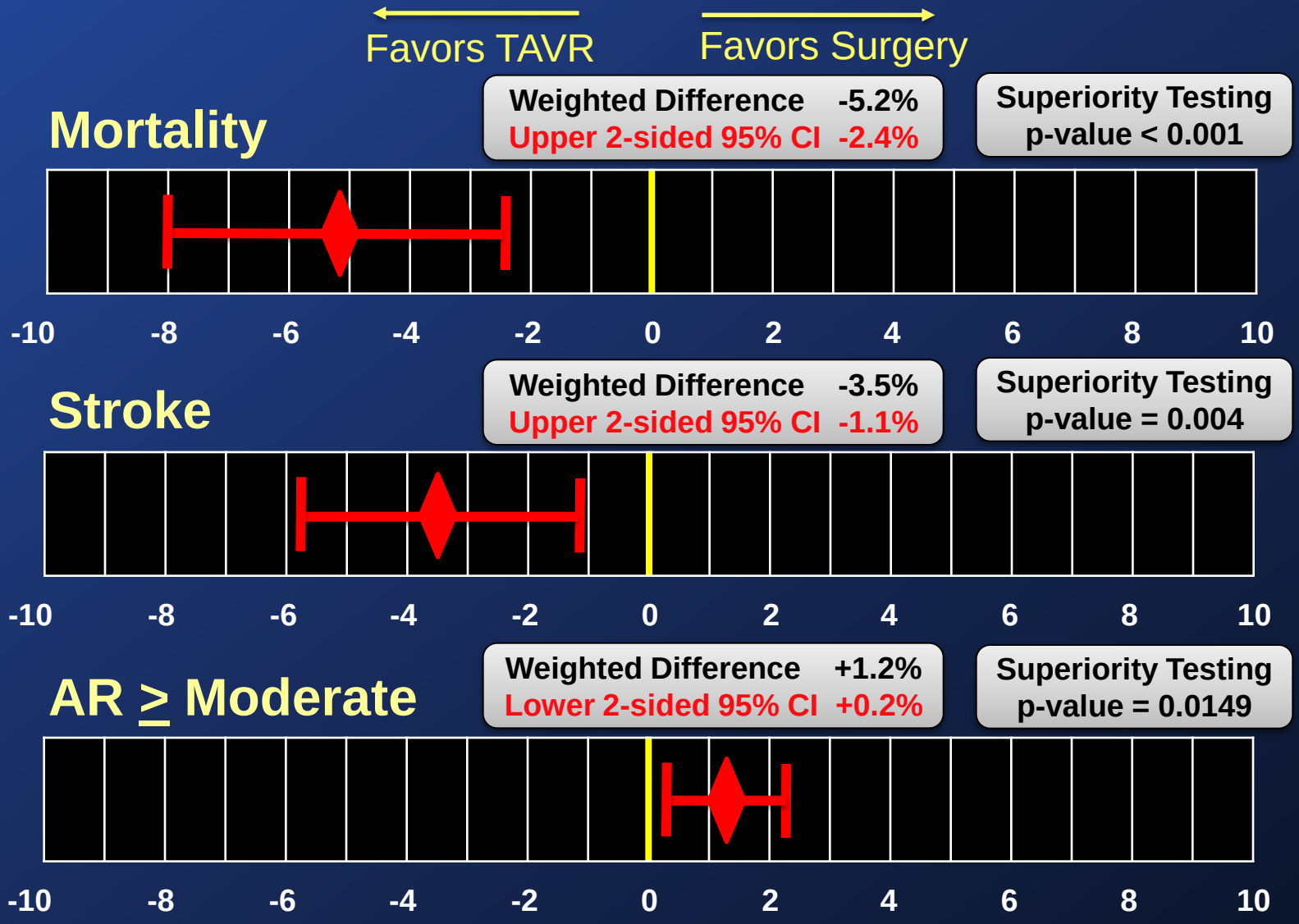
Superiority Testing
p-value < 0.001



Superiority Achieved

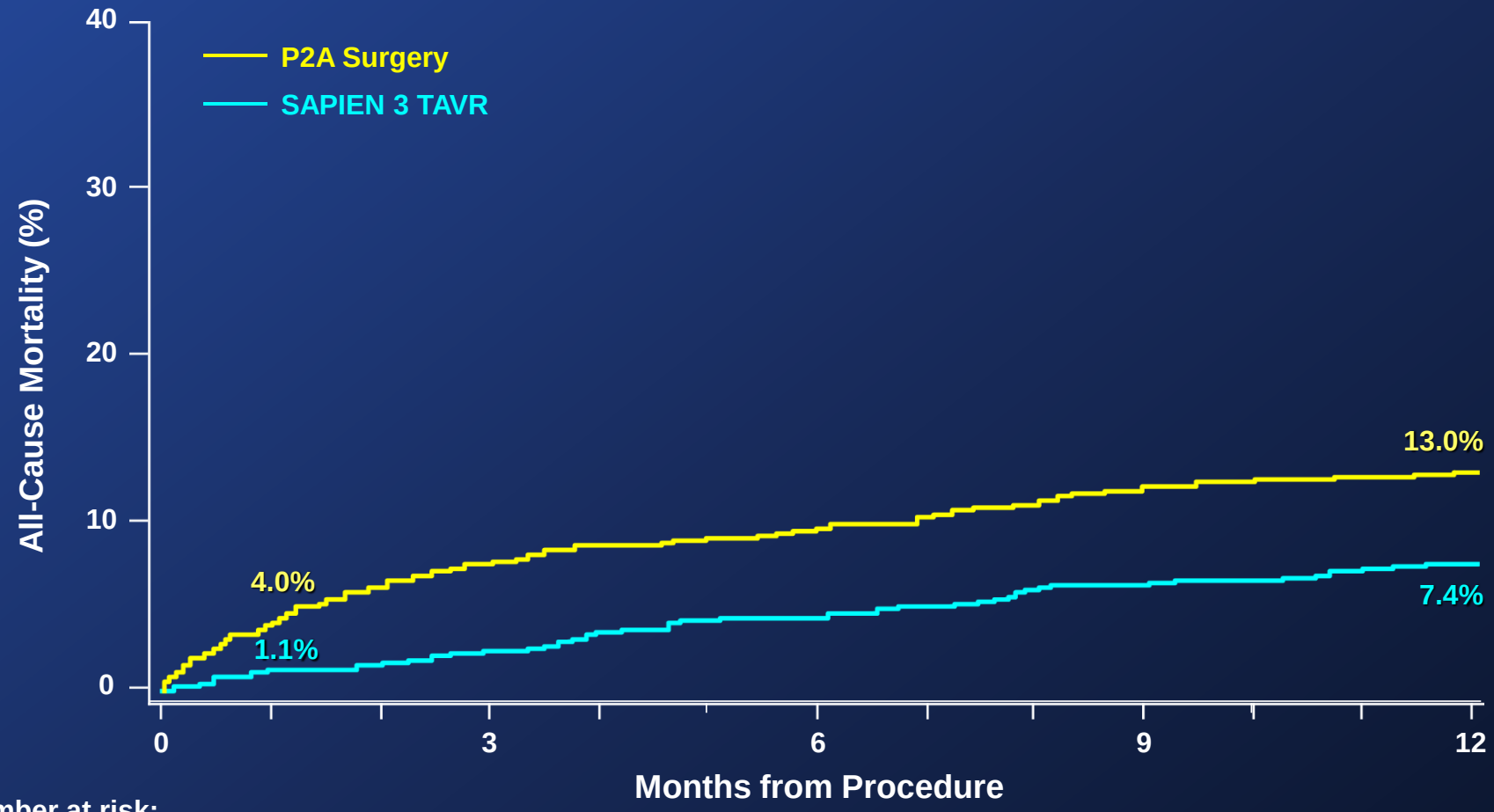
Superiority Analysis
Components of Primary Endpoint (VI)

THE PARTNER II TRIAL



Unadjusted Time-to-Event Analysis
All-Cause Mortality (AT)

THE PARTNER II TRIAL

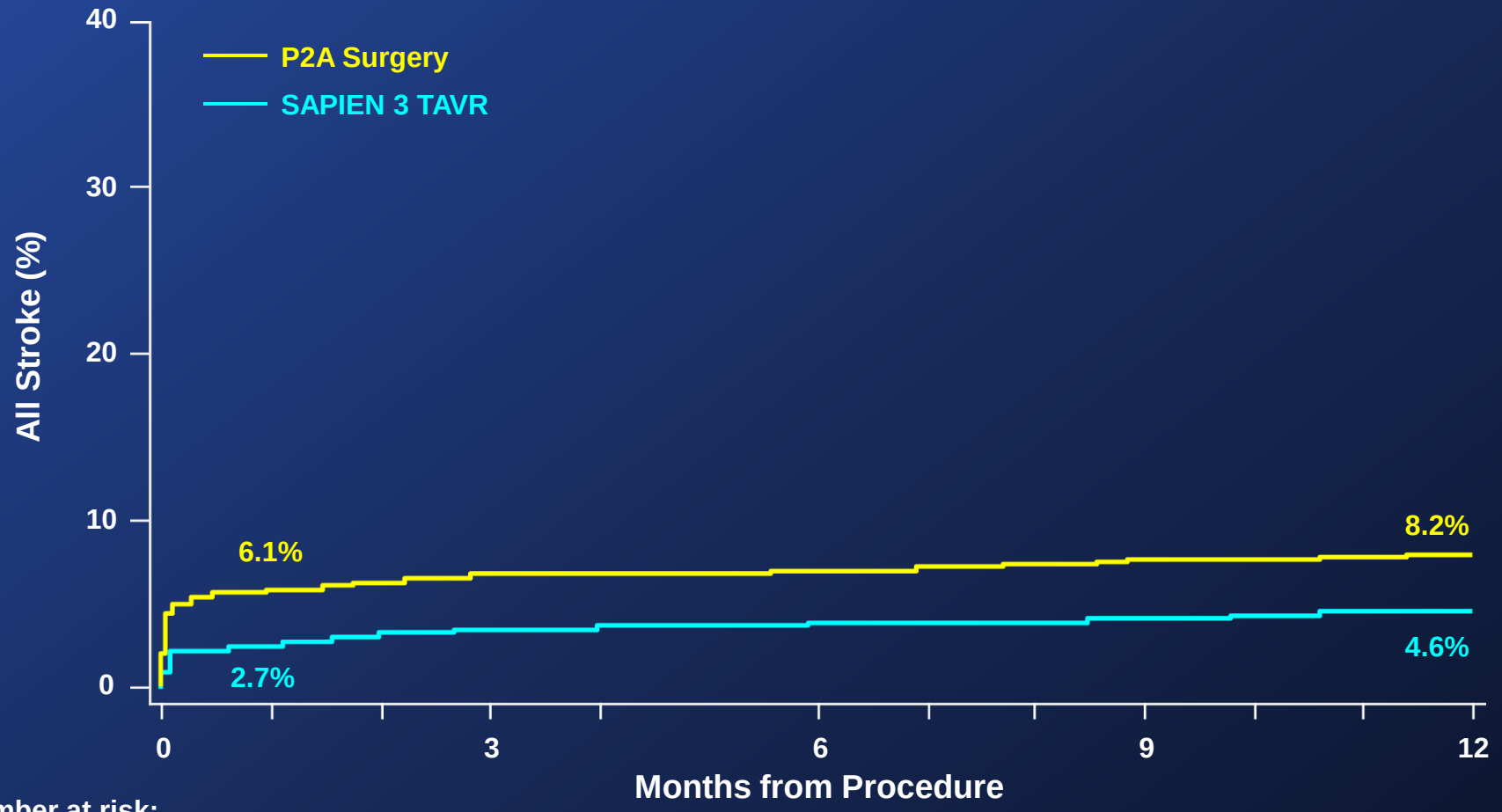


Number at risk:

P2A Surgery	944	859	836	808	795
S3 TAVR	1077	1043	1017	991	963

Unadjusted Time-to-Event Analysis
All Stroke (AT)

THE PARTNER II TRIAL

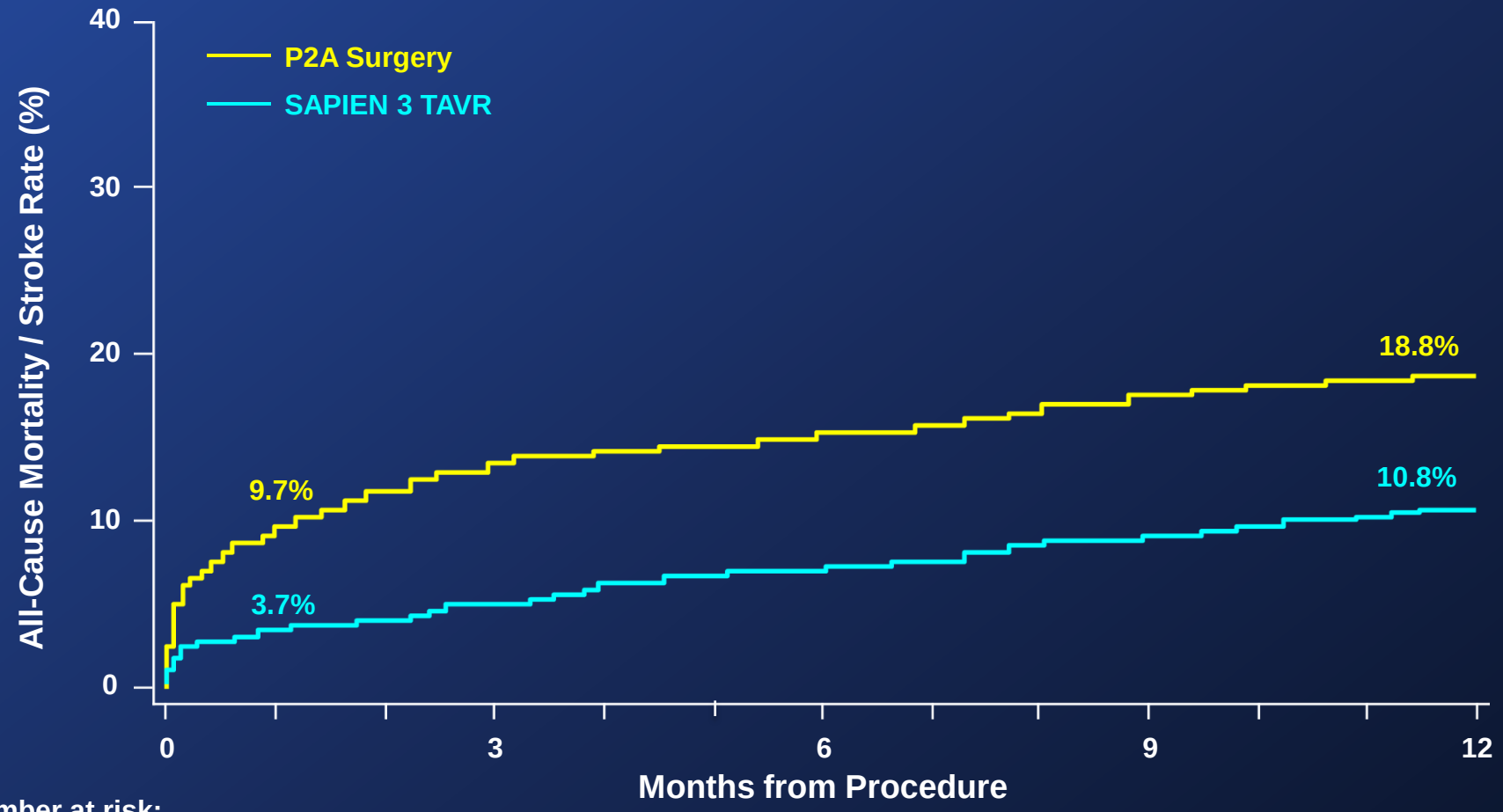


Number at risk:

P2A Surgery	944	805	786	757	743
S3 TAVR	1077	1012	987	962	930

Unadjusted Time-to-Event Analysis
All-Cause Mortality and All Stroke (AT)

THE PARTNER II TRIAL



Number at risk:

P2A Surgery	944	805	786	757	743
S3 TAVR	1077	1012	987	962	930

Other Unadjusted Clinical Outcomes
At 30 Days and 1 Year (AT)

THE PARTNER II TRIAL

Events (%)	30 Days		1 Year	
	TAVR (n = 1077)	Surgery (n = 944)	TAVR (n = 1077)	Surgery (n = 944)
Re-hospitalization	4.6	6.8	11.4	15.1
MI	0.3	1.9	1.8	3.1
Major Vascular Complication	6.1	5.4	---	---
AKI (Stage III)	0.5	3.3	---	---
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

The PARTNER 2A and S3i Trial
Clinical Implications

THE PARTNER II TRIAL

- *The conclusions from the PARTNER 2A randomized trial and this propensity score analysis provide strong evidence that in intermediate-risk patients with severe aortic stenosis, SAPIEN 3 TAVR compared with surgery improves clinical outcomes and is the preferred therapy.*

75% reduction in death vs surgery
75% reduction in stroke vs surgery

Options for Aortic Valve Replacement per Guidelines[9]

Indications for Severe Symptomatic Aortic Stenosis

Transcatheter Heart Valve

Surgical Heart Valve

Therapy	Low- to Moderate-Risk	High Risk	Greater Risk
Transcatheter Aortic Valve Replacement (TAVR)	X (interm)	X	X
Open-Heart Surgery (AVR)	X	X	

Expanding TAVR Clinical Indications

- Low risk patients (all comers?)
- Severe asymptomatic AS

- Low flow, low gradient AS
- Bicuspid AV disease
- AS + concomitant disease (CAD, MR, AF)
- Bioprosthetic valve failure (aortic and mitral)
- Moderate AS + CHF
- High risk AR

The PARTNER 3 Trial
Study Design

Symptomatic Severe Calcific Aortic Stenosis

Low Risk ASSESSMENT by Heart Team
(STS < 4%, TF only)

1:1 Randomization
(n=1,228)

TF - TAVR
(SAPIEN 3)

- CT Imaging Sub-Study (n=200)
- Actigraphy/QoL Sub-Study

Surgery
(Bioprosthetic Valve)

- CT Imaging Sub-Study (n=200)
- Actigraphy/QoL Sub-Study

PARTNER 3 Registries

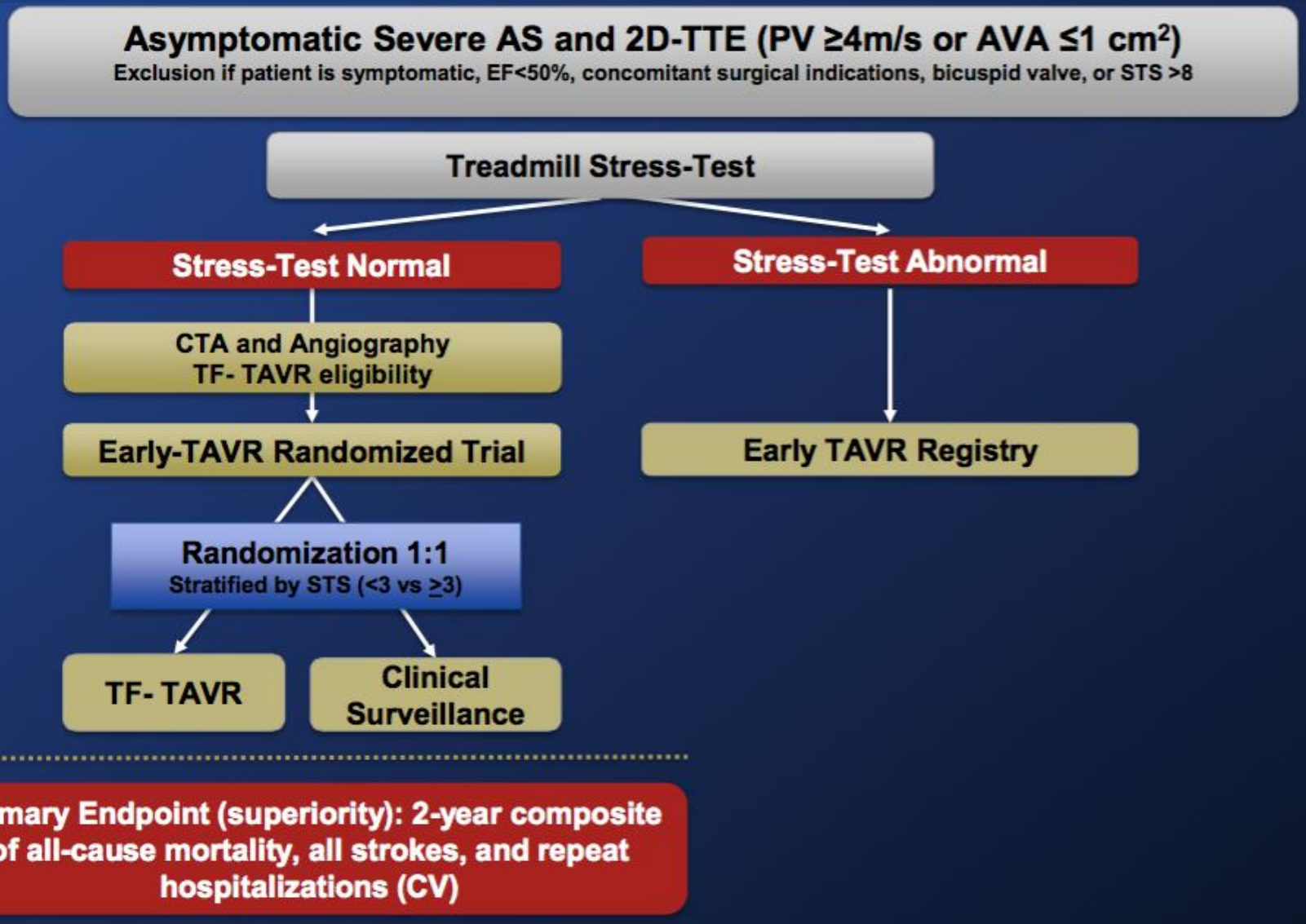
- Alternative Access (n=100) (TA/TAo/Subclavian)
- Bicuspid Valves (n=50)
- SAVR orTAVR ViV (n=100/25)
- Mitral ViV or ViR (n=50/50)

PRIMARY ENDPOINT:
Composite of all-cause mortality, all strokes, or re-hospitalization at 1 year post-procedure

Follow-up: 30 days, 6 mos, 1 year and annually through 10 years

EARLY TAVR Trial
Study Flow

THE PARTNER 3 TRIAL

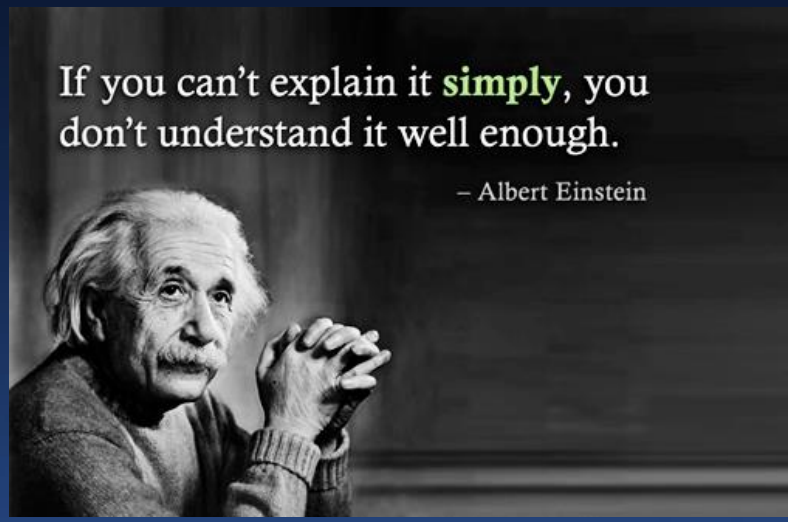


TAVR: Transition to standard of care

- Increasing volume
- Decreasing acuity of illness of patients
- Expanding indications (intermediate risk, valve in valve)
- Improving outcomes
- Transition to mostly transfemoral
- Better patient selection
  - Frailty
  - Better identification of Risk (beyond STS) by CT surgeons
- Improved post operative protocols

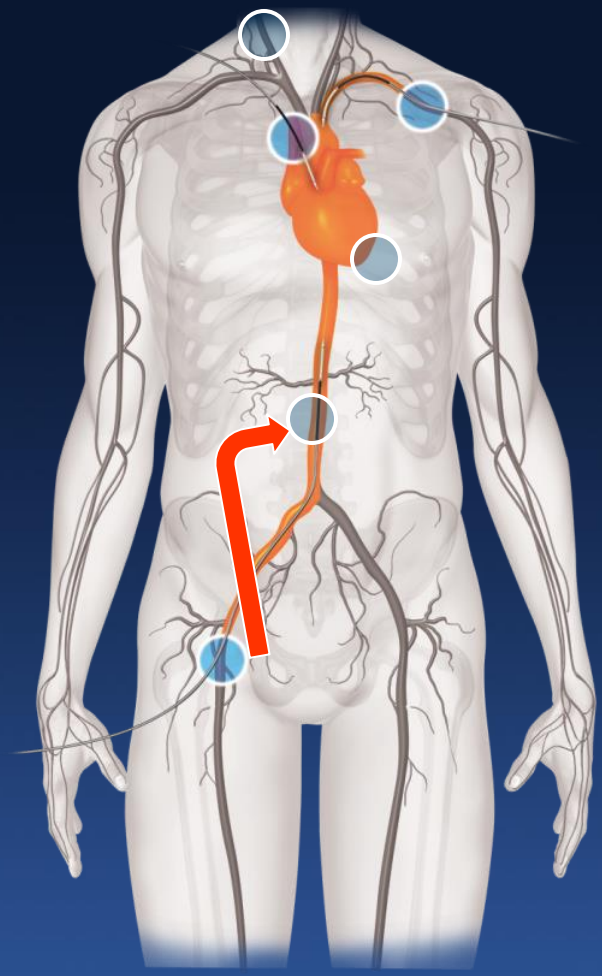
TAVR: As volume rises, "minimalist" approach helpful

- **Why a minimalist approach?**
  - Reduce complexity, cost, improve outcome and programmatic efficiencies
- **KISS model**
  - Percutaneous Access
  - No Foley catheters (men)
  - No routine PA catheter
  - No TEE
  - Conscious sedation protocols
    - Reduce ICU and overall LOS
    - Fast track ICU protocols: goal 4-6 hours in ICU

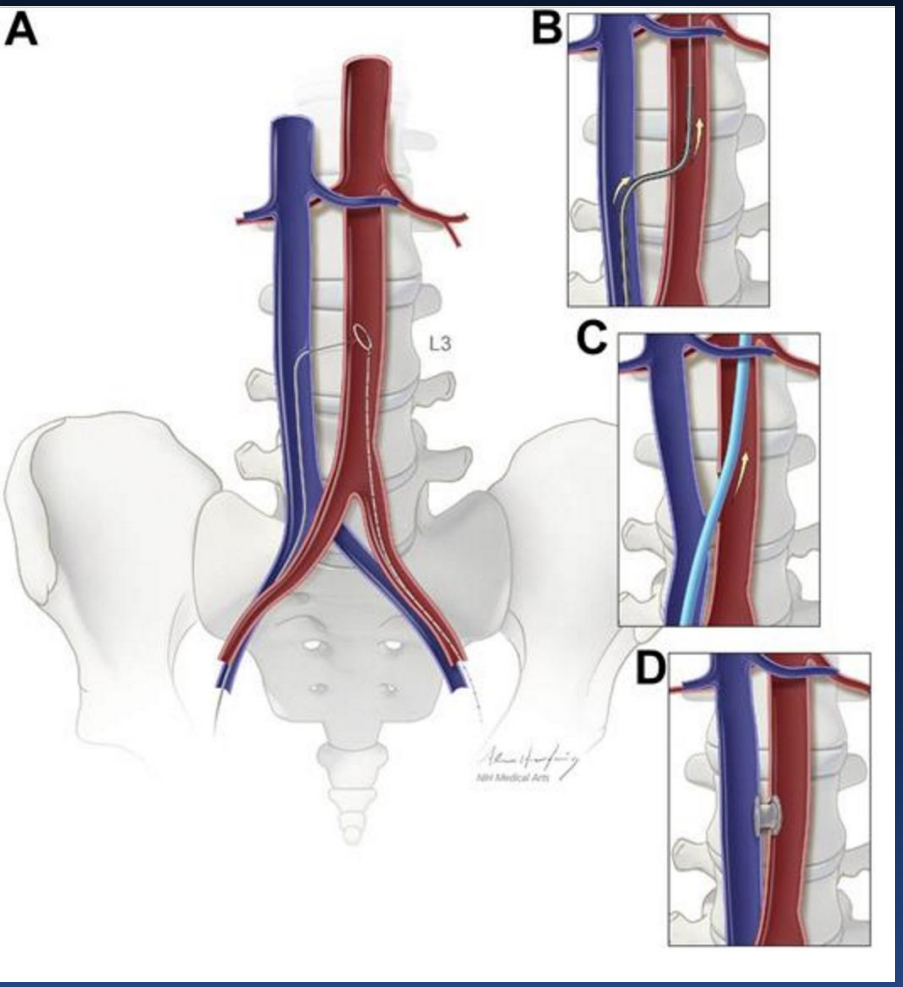


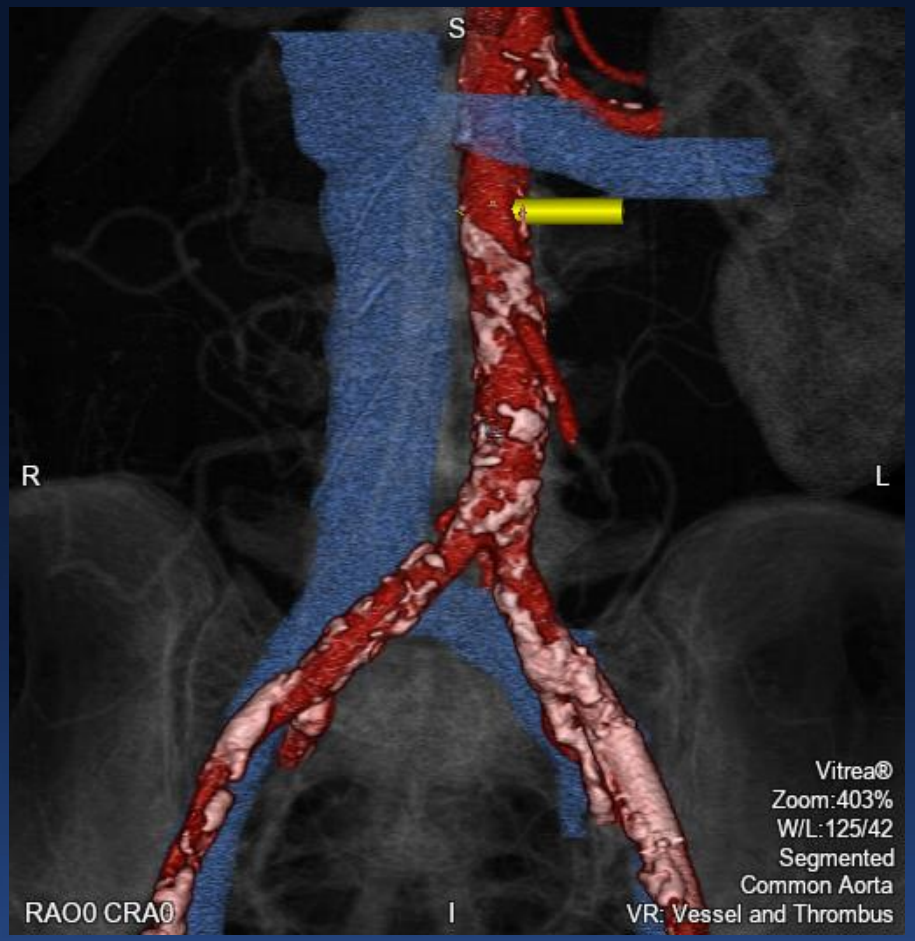
Same time, expanding high risk capabilities

- Alternate access
  - Subclavian/Axillary
  - Direct aortic
  - Transcarotid
  - Transcaval
  - transapical

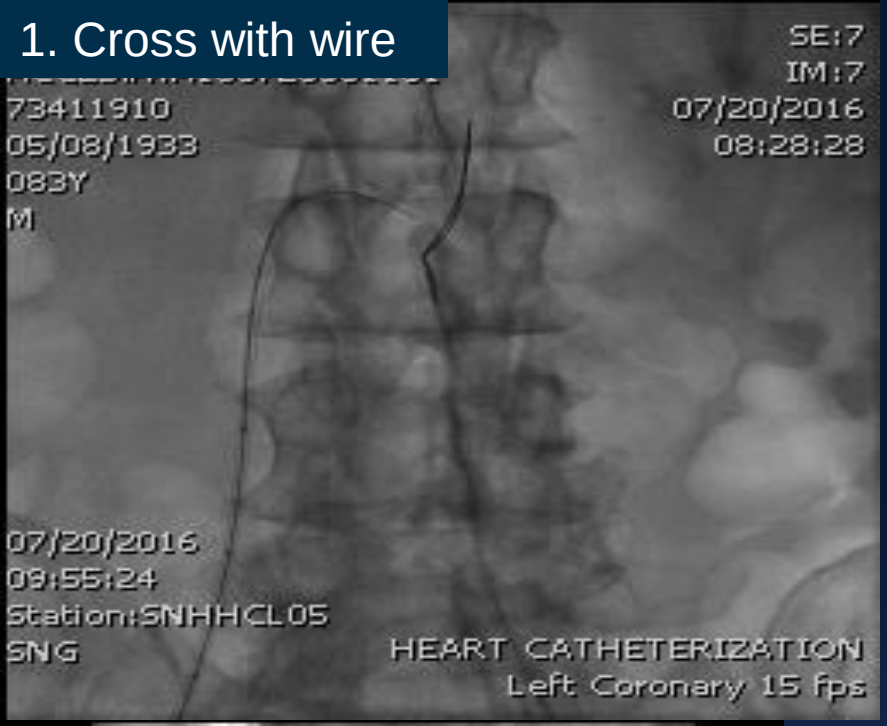


Transcaval

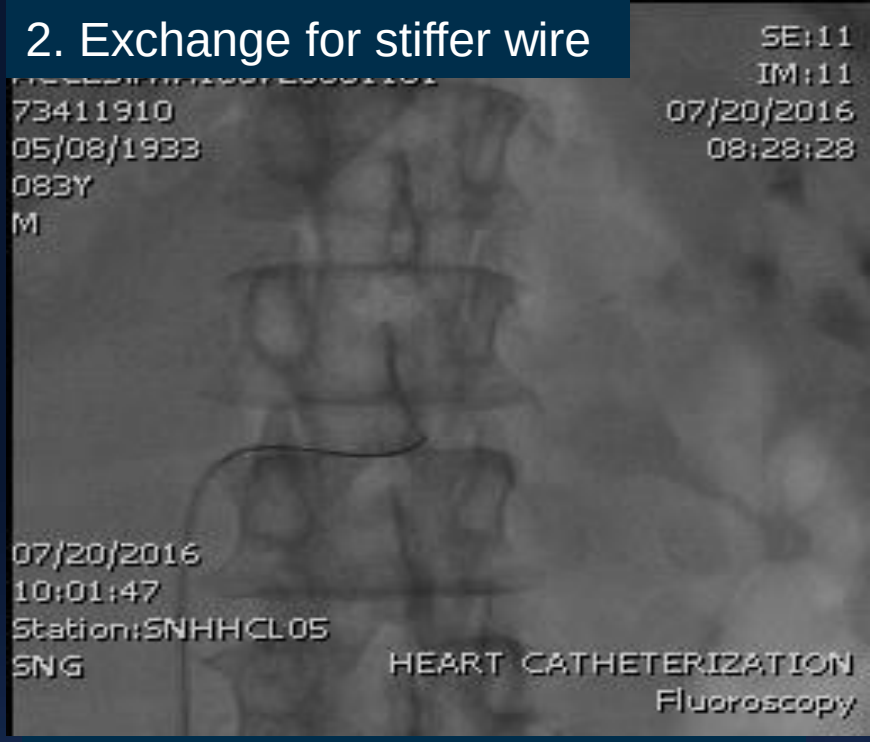

A
B
C
D
L3


S
R
L
I
RAO0 CRA0
Vitrea®
Zoom:403%
W/L:125/42
Segmented
Common Aorta
VR: Vessel and Thrombus

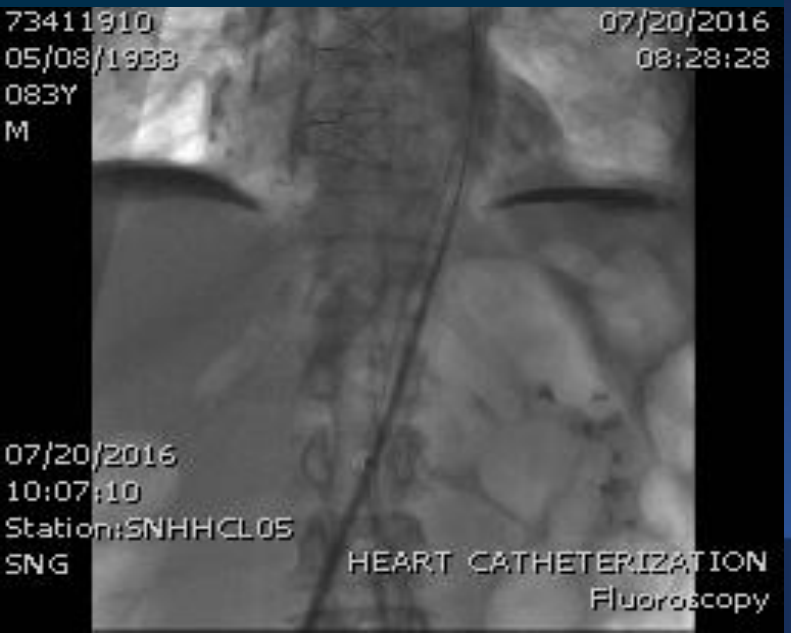
1. Cross with wire



2. Exchange for stiffer wire



3. Bring sheath from RFV to aorta

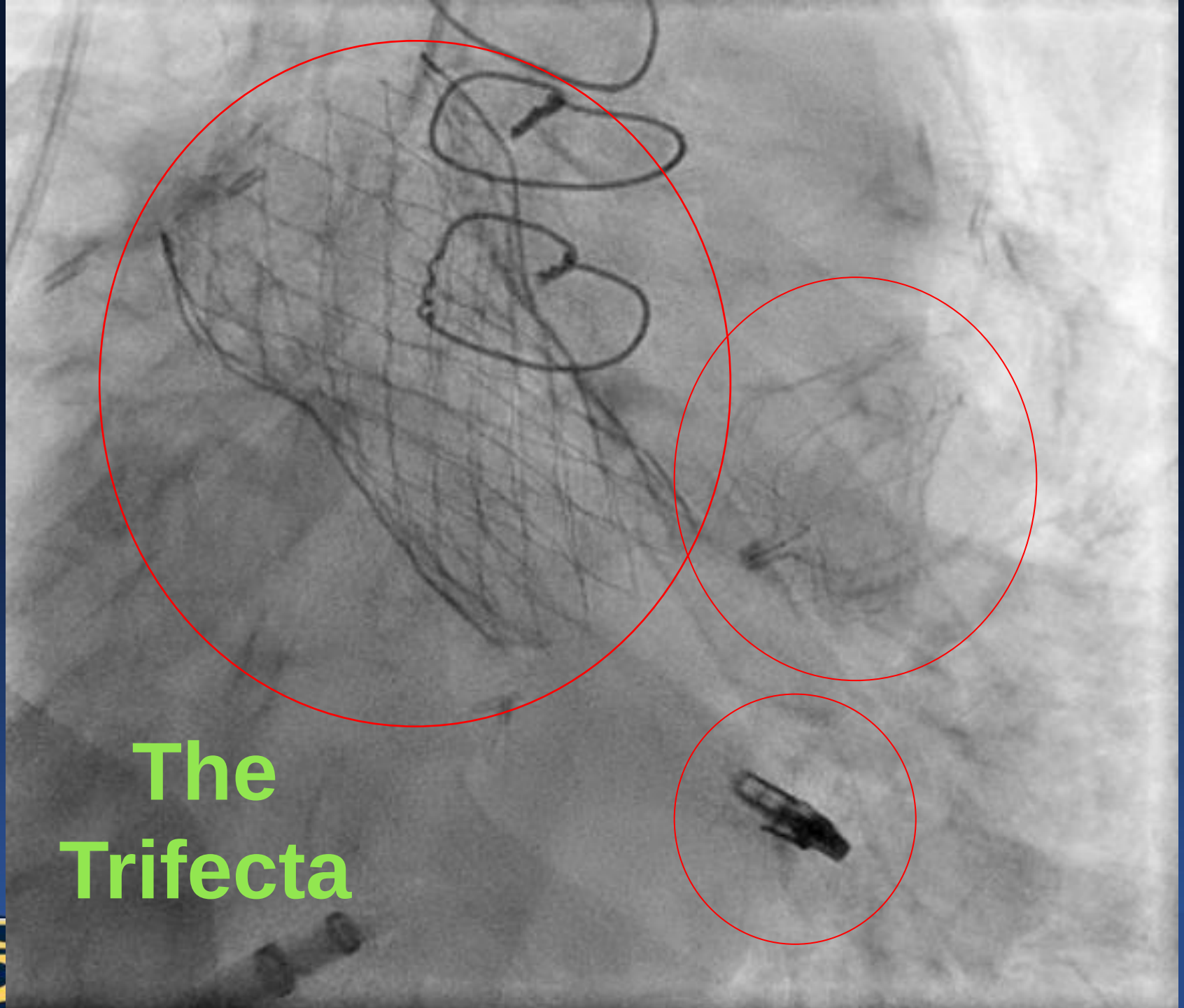


4. Close aorta with Amplatz device

Limitations of TAVR

- **Durability**
  - ***No real "in vivo" data past 10 years***
  - ***8-10 years - minimal valve failure***
  - ***Rx for failed TAVR is… repeat TAVR***

- **AS plus other anatomy**
  - **Aortic pathology**
  - **CAD**
  - **Polyvalvular disease**


The
Trifecta

Case Presentation

SENTARA

[Patient CC]

Patient Evaluation
Structural Heart Program

Sentara Heart Hospital
Norfolk, VA

Interv. Cardiology:
P. Mahoney, MD
D. Talreja, MD
N. Mistry, MD

Cardiac Surgery:
J. Newton, MD
J. Philpott, MD
G. Dimeling, MD
C. Kemp, MD

TAVR Coordinators:
L. Morris, PA-C
M. Sukholutsky, PA-C
E. Willette, NP

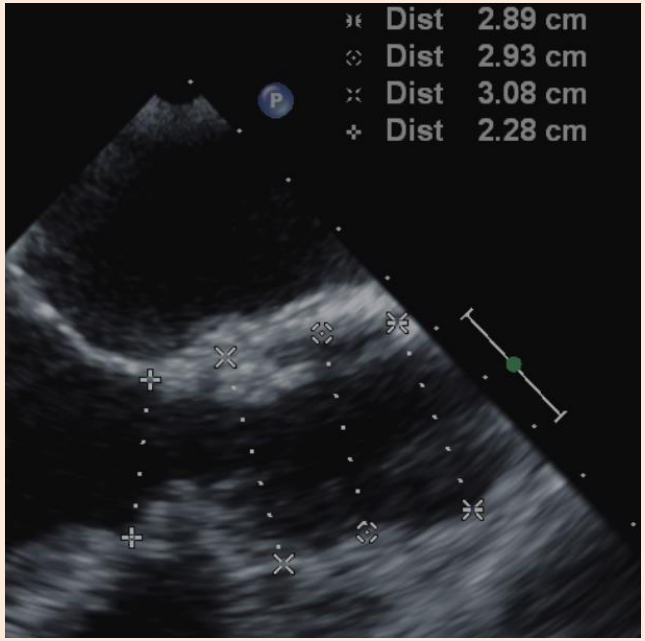
Summary – Clinical History:

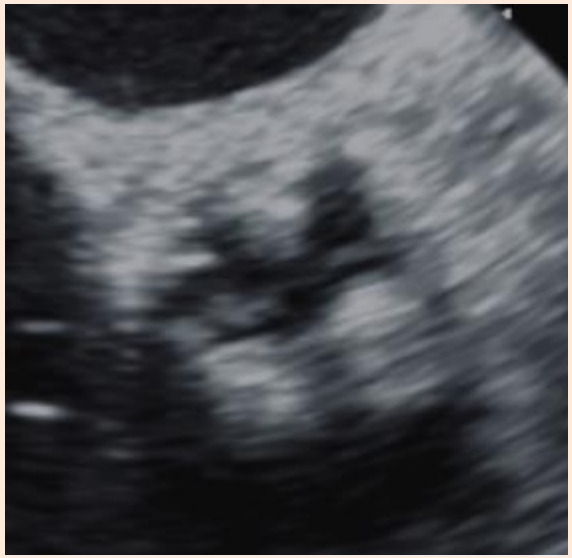
- 68 years old
- STS 2.1% AVR
- NYHA Class II
- BSA / BMI: 1.93 / 26
- Creatinine: 0.6
- Hb: 13.7
- PLT: 182
- Team: PDM
- Ht: 173 cm
- Wt: 78 kg

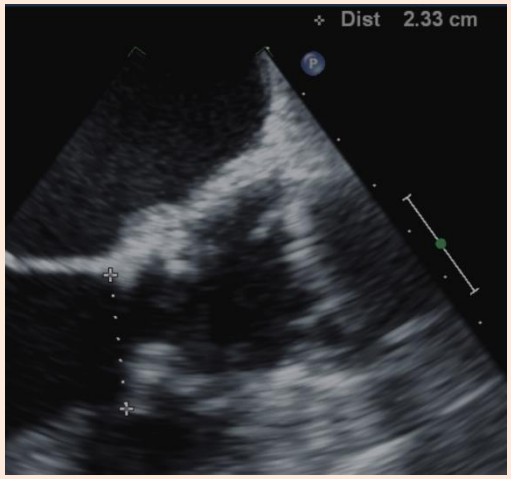
Clinical history
Bioprosthetic aortic valve stenosis and AI • H/o severe AS with root enlargement s/p aortic root replacement with #23 Medronic freestyle graft, and #26 Gelweave graft as ascending aortic interposition graft by Dr. B on 6/17/2004 • 2D Echo 11/10/16 -- AVA 1cm2, peak gradient 44mmHG, mean gradient 22mmHG, Vmax 330cm/s with moderate AI • LHC 3/9/17 – AVA 0.96cm2, mean gradient 17 mmHg, severe AI by aortography
2D Echo 11/10/16 -- EF 60% TEE 3/9/17 – moderate MR
Normal Coronary arteries by LHC 3/9/17
CTA 3/7/17 – as shown
Hyperlipidemia , Hypothyroidism , Urinary frequency
Panorex – cleared by Primary dentist (in EPIC) Carotid PVL 3/3/17 - < 50% stenosis bilaterally PFT's 3/3/17 – FEV1 2.19, 81% predicted, DLCO 67

Annulus = 23mm

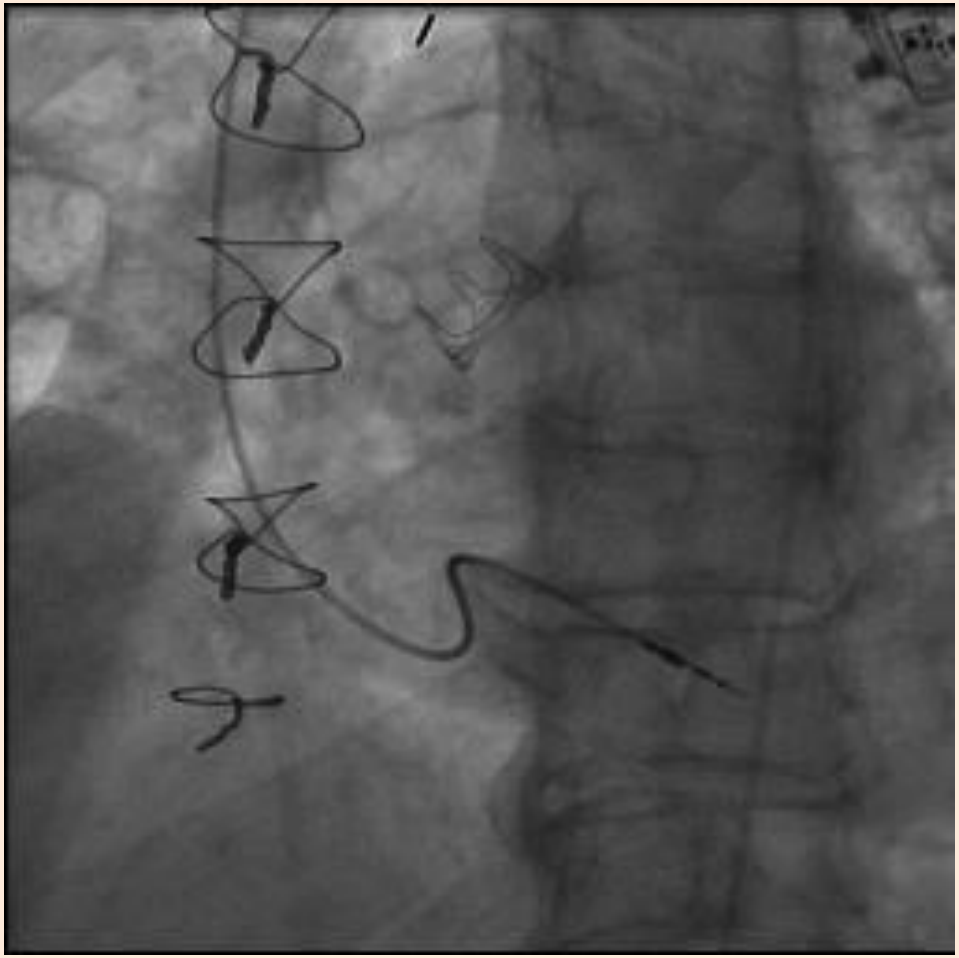
Echocardiography







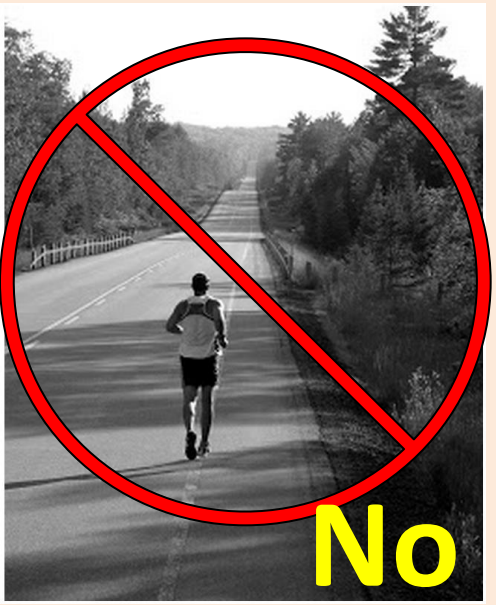
Sentara Heart Hospital



Plan: SURGERY – REDO AVR with root and ascending aorta repair

What does a Valve clinic look like in 2017?

- The Heart Team



Developing TAVR Program at Sentara Heart

- First implant: Dec 2011
  - >800 TAVR procedures to date; > 300 pred in 2017
  - > 100 MitraClip
  - > 200 Watchman
  - >200 CHIP cases
- Structural Heart Service
  - IC, CTS, Imaging
  - 4 PA's, 2 RN's, 1 MA
  - Busy in-patient service
  - daily full office schedule

SENTARA HEART

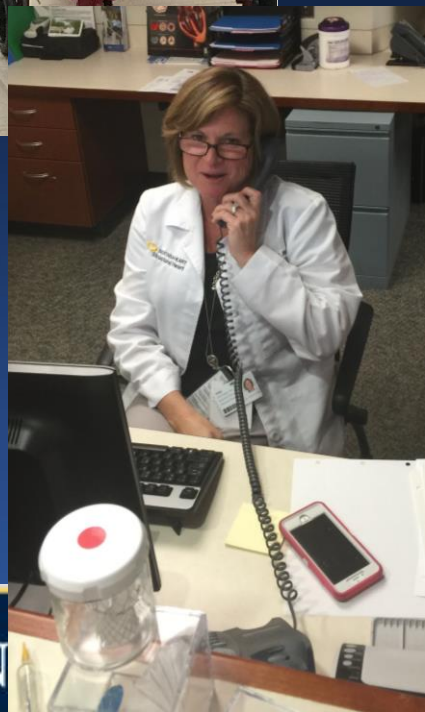
Research

- PORTICO – High risk TAVR, novel valve
- SURTAVI – Intermediate Risk, Evolut
- Partner 3 – Low risk TAVR 1:1 surgery
- Early TAVR - Asymptomatic AS

- Transcatheter Mitral Valve Replacement Trials – coming this summer!


2015
NOTES
TAHITI
CYPRUS
Pamela
Mia


SENTARA HEART HOSPITAL



SENTARA HEART