
Technical Lessons for TAVR: Expert Experience

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

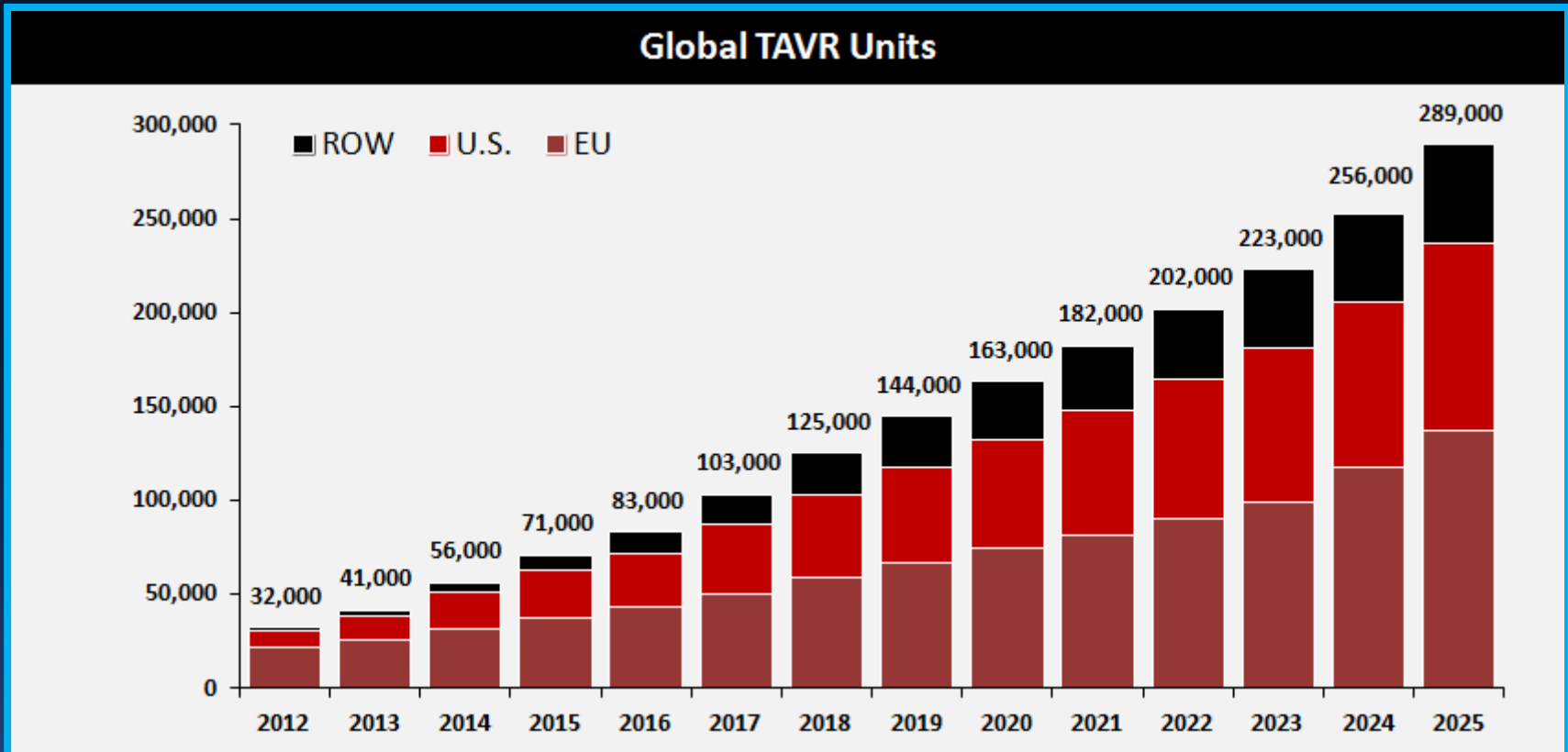
- Grant/Research Support
- Grant/Scientific Advisory Board
- Executive Physician Council

Company

- Edwards Lifesciences
- Medtronic
- Boston Scientific Corp



Estimated Global TAVR Growth



SOURCE: Credit Suisse TAVI Comment –January 8, 2015. ASP assumption for 2024 and 2025 based on analyst model. Revenue split assumption in 2025 is 45% U.S., 35% EU, 10% Japan, 10% ROW

In the next 10 years, TAVR growth will increase X4!

Stanford Experience with TAVR

Yearly Volume

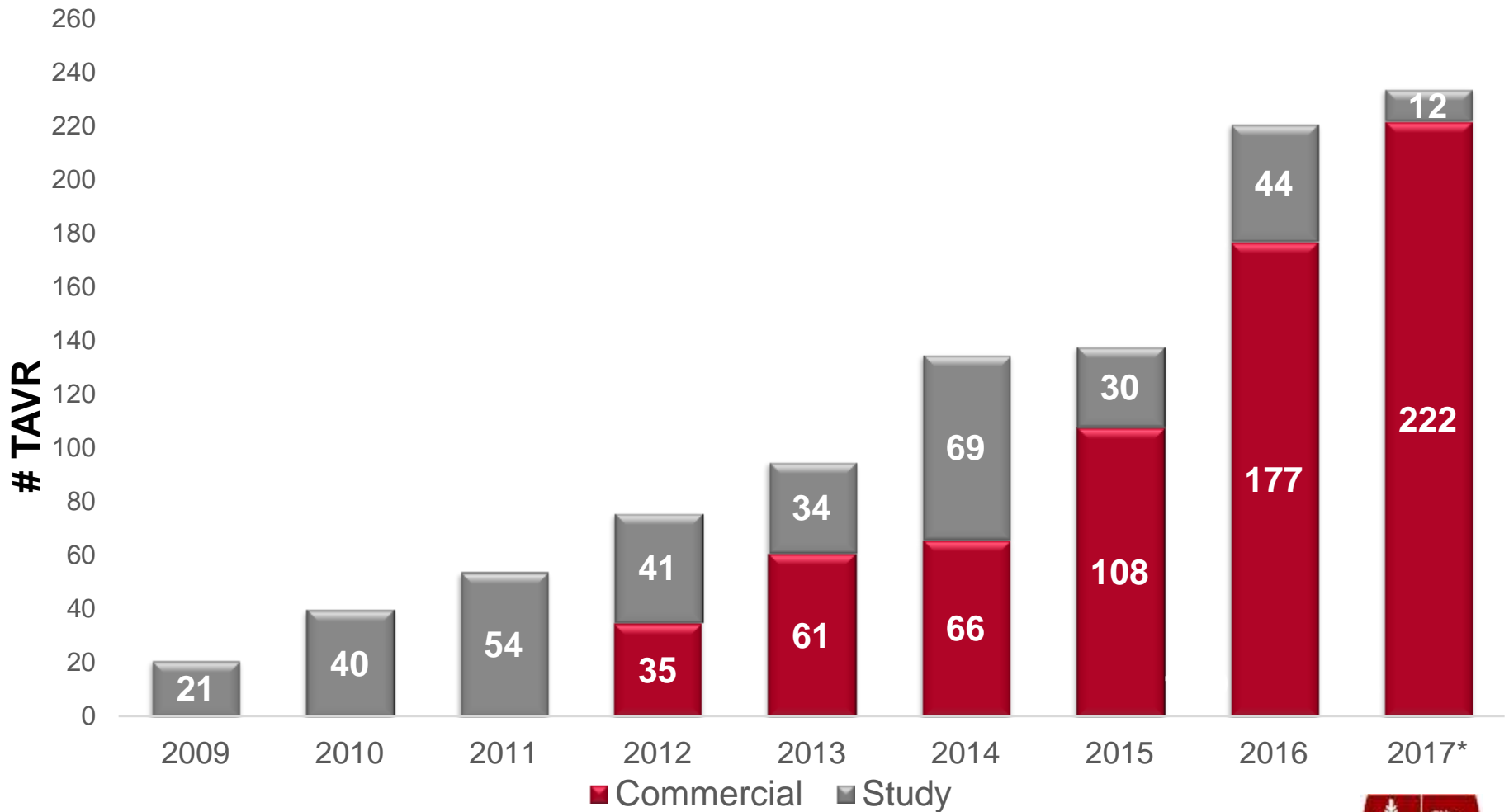


Fiscal Year

*Projected



Stanford Experience with TAVR



Expert Experience

- Building a team with structure and patient flow
- Sustaining the standard and quality of all aspects of the team
- Continue process improvement
- Technical lessons
- Recognizing special cases from routine



Stanford Leadership in TAVR

- D. Craig Miller, MD: Executive Committee, PARTNER Trials, Edwards Life Sciences
- William F. Fearon, MD: Steering Committee, PARTNER 2 Trial, Edwards Life Sciences
- Alan C. Yeung, MD: Site PI, PARTNER Trials, Edwards Life Sciences, REPRISE Trial, Boston Scientific
- Michael P. Fischbein, MD, PhD: Site PI, PORTICO Trial, St. Jude Medical



Stanford Heart Team

Interventionalists

- William Fearon, MD
- Alan Yeung, MD

THV Clinic Coordinators

- Sandy Cardoza, RN
- Zoe Magee, RN
- Cheryl McWard, RN
- Danna Salvaleon-Cua, LVN

Cardiac Surgeons

- Michael Fischbein, MD
- William Hiesinger, MD
- Anson Lee, MD
- D. Craig Miller, MD

Patient-focused Multidisciplinary Heart Team

THV Nurse Practitioners

- Mykl Morrissey, NP
- Martina Speight, NP

Echocardiologists

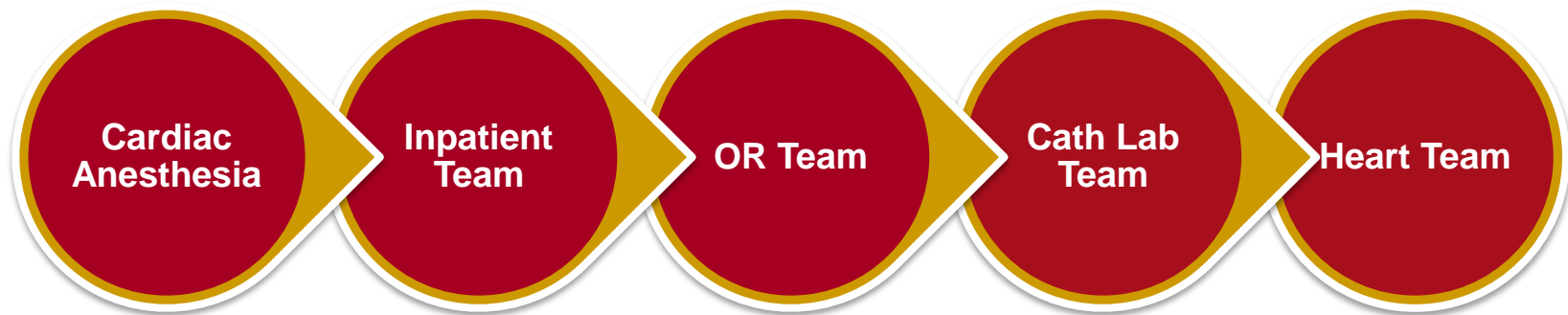
- Rajesh Dash, MD
- David Liang, MD

Radiologist (Cardiovascular)

- Dominic Fleischmann, MD



Extended Heart Team



Patient Process

Referral

- Triaged and scheduled by THV Clinic Coordinators

Evaluation

- Tests: CTA C/A/P, TTE, PFTs, & frailty metrics
- Clinic appt: Interventionalist and Cardiac Surgeon

Decision

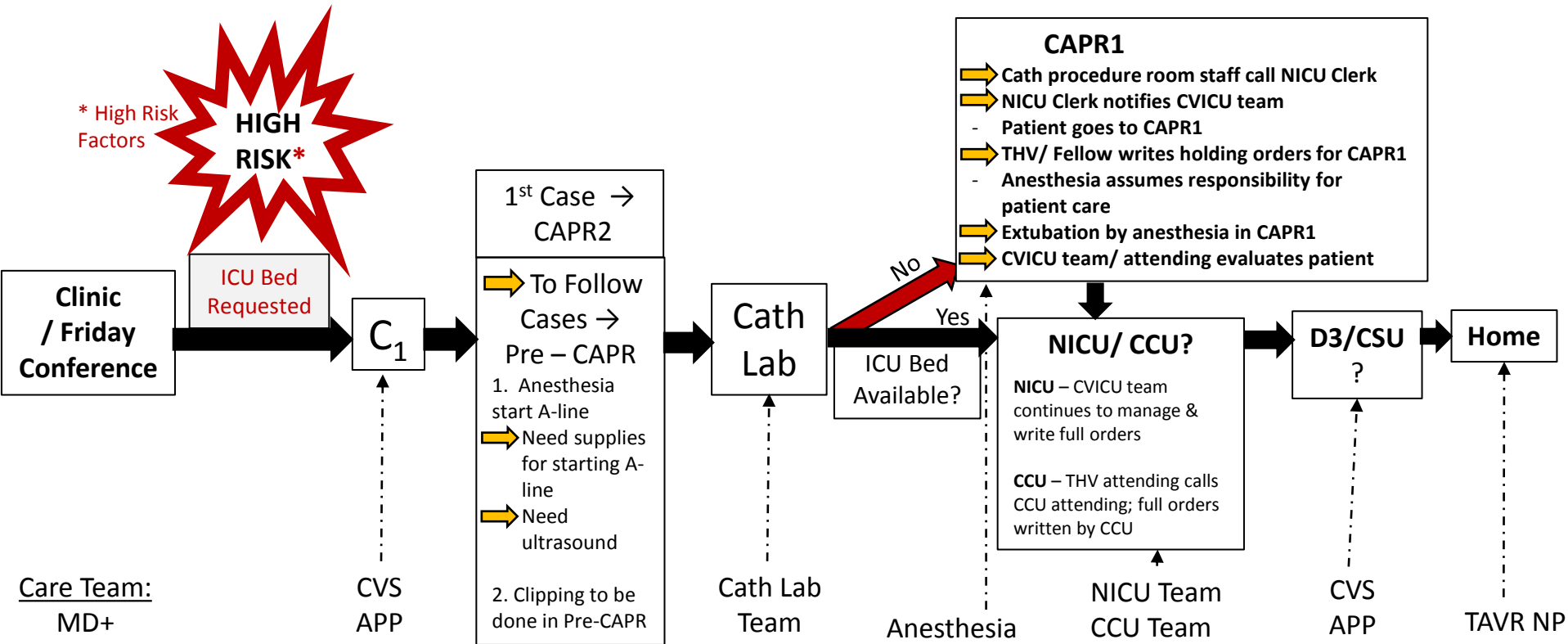
- Discussed at Multi-disciplinary Heart Team Meeting

Treatment

- Schedule TAVR
- Alternative treatments: medical management, BAV, or AVR



Patient Flow in HIGH Risk TAVR

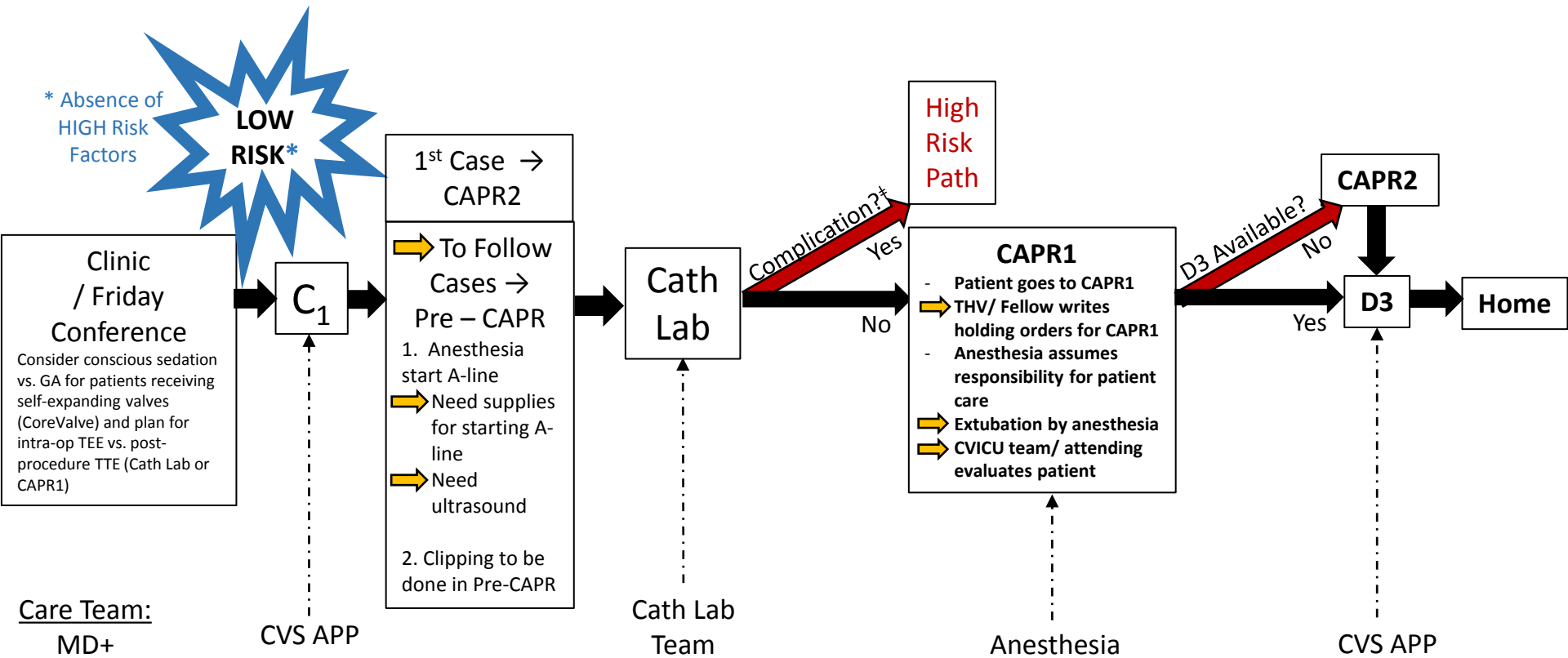


*Baseline High Risk Factors:

- | | | |
|---|--|--|
| <input type="checkbox"/> Cardiac Function | <input type="checkbox"/> -Respiratory Function | <input type="checkbox"/> Functional Status |
| • EF < 30% | • FEV1 < 60% predicted | • BMI < 18 or >35 |
| • RV dysfunction | • On home O ₂ | <input type="checkbox"/> Complex Procedure |
| • Severe TR | | • Alternative Access (TA, TAO, SC) |
| • Severe MR | <input type="checkbox"/> Renal Function | • Concomitant PCI |
| • RVSP/PAs > 60 mmHg | • Hemodialysis | • Urgent/ Inpatient procedure |
| • At risk for LVOT obstruction | | <input type="checkbox"/> Demographic Factors |
| • At risk for SAM | | • STS > 15 |

→ Action needed

Patient Flow in LOW Risk TAVR



‡ Procedural Complications:

- Rhythm Disturbances
 - Complete Heart Block/ new IVC defects
 - Rhythm requiring defibrillation intraprocedurally
- Conversion to Open/ Embolization/ More than one valve implanted

- Hemodynamic Instability
 - Requiring pressors/IABP
 - ≥ Moderate PLV/AI
 - Cardiac Tamponade

- Vascular Complication
 - Requiring cutdown
 - Requiring transfusion

→ Action needed

Commercial TAVR case

MRN 0535057-4

Referring MD: James MacLaren, MD

Proposed Treatment 6/14/2016

THV MDs: MS/AL/ACY

Fast Track Eligible: Yes

History: 59 year old male with history of HTN, HLD, hypothyroid and severe, symptomatic AS. History of seminoma with chest involvement, s/p orchiectomy and XRT to chest in 1977. Currently symptomatic of dyspnea on exertion, fatigue, and a syncopal episode resulting in a right leg fracture.

PFTs:	FEV1 1.4 L (42%) DLCO 23 ml (86%)	Frailty:	BMI 23.74 Serum Albumin 3.9 g/dL (-) ADLs 6/6 (-) Grip Strength 37.3 kg (-) 5m WT unable to perform Score 1/4	STS	1.9%
Anticoagulation History/Regimen:	Age 59, male, Caucasian, 77.2 kg, 180.3 cm (BSA 1.97), Cr 0.93, HTN, severe lung disease, NYHA Class II, EF 60%, AS, MS, moderate AI, mild MR, mild TR, first op, elective				
Aspirin 81 mg only					

Proposed: Extreme Risk (Co-morbidities) Commercial TAVR, 26 mm Sapien 3, Transfemoral approach, Right side

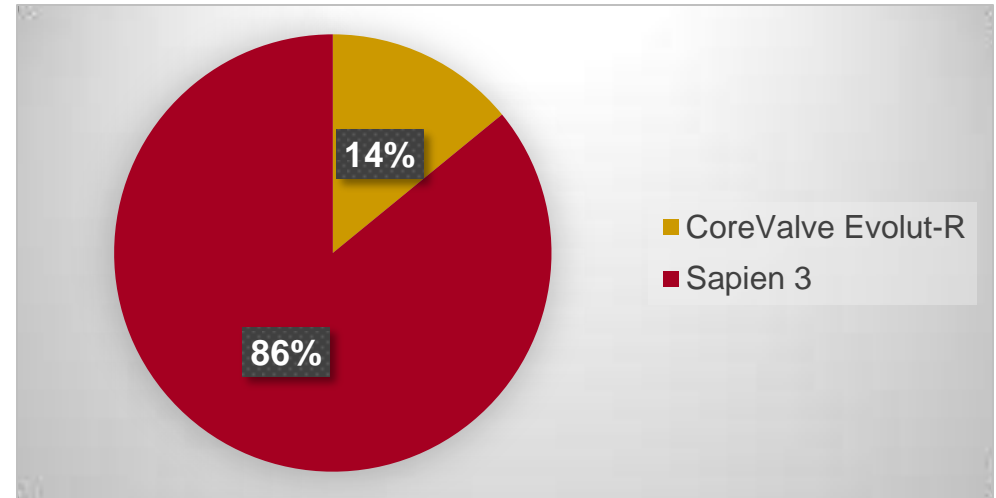
Echo:	Date 5/13/2016	RHC:	RA 8 RV 50/12 PA 50/17 PCW 20 CO 6.2 CI 3.1	Coronary heights:	LCA 17.7 mm RCA 19.3 mm	SOV Diameters:	RCC 31.8 mm LCC 33.6 mm NCC 33.6 mm
AVA 0.65 cm ²	AVAI 0.33 cm ² /m ²			Vascular access:	RCIA 11.1 x 10.3 (in mm) REIA #1 8.3 x 8.1 REIA #2 8.6 x 8.3 RCFA 9.0 x 6.4 LCIA 10.8 x 10.7 LEIA #1 9.4 x 8.4 LEIA #2 9.0 x 8.9 LCFA 10.3 x 6.2	SOV heights > 15 mm:	Yes
V2 Max 4.4 m/sec	Gradient 46 mmHg	Cors:	LM 30% 06/01/16 LAD no sig disease LCX no sig disease RCA no sig disease Grafts -			Ascending Ao diameter:	Long Axis 33.7 mm Short Axis 31.3 mm
V1/V2 -	EF 60%					Annulus:	Diameter ~24.3 mm Long Axis 28.6 mm Short Axis 20.0 mm Area 444 mm ² Perimeter 77.9 mm
RVSP 44 mmHg	AI Moderate						
MR Mild	TR Mild						

Notes: Echo: moderate MS. Hostile chest due to history of radiation

Summary:	<ul style="list-style-type: none"> • 59 year old male • STS 1.9% • Extreme Risk (Co-morbidities) TAVR • 26 mm Sapien 3 THV 	<ul style="list-style-type: none"> • Transfemoral approach • Right side • Fast Track eligible • Declined participation in Portico
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In the past 3 months...

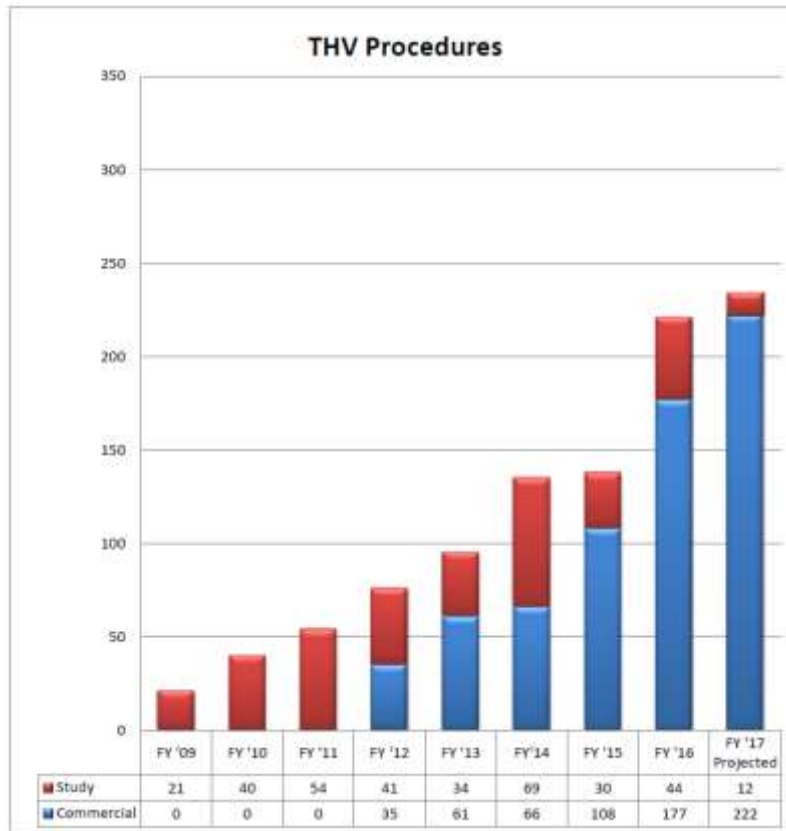
Valve	# of Cases
Sapien 3	61
CoreValve Evolut R	10



Complications	n (71)
PPM/ ICD	7%
Death (TA)	1%
Major Vasc	3%
RV Perforation	1%



In the past 3 months...



2017 Year to Date:

Description	January	February	March	Total
Number of Cases	19	22	19	60
Average PPLOS	3	3	2	2.73
No. ICU Pts	4	3	5	12
Average ICU Pt PPLOS	6	3	2.8	4.8
No. Non-ICU Pts	15	19	14	48
Average Non-ICU Pt PPLOS	2	2	2	2

- 80% Fast Track
- PPLOS down from 3 to 2.73
- Counter measure: Readmission rate ???



Technical Lessons:

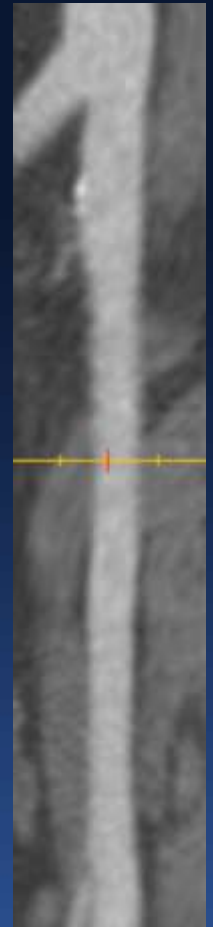
- Vascular measurements, tortuosity and calcifications
- Annulus measurement and confirmation
- *No predilatation*
- Optimization of valve function after deployment
- Know your valve-in-valve dimensions and location of deployment (esp. CoreValve)



CTA with 3D Reconstruction

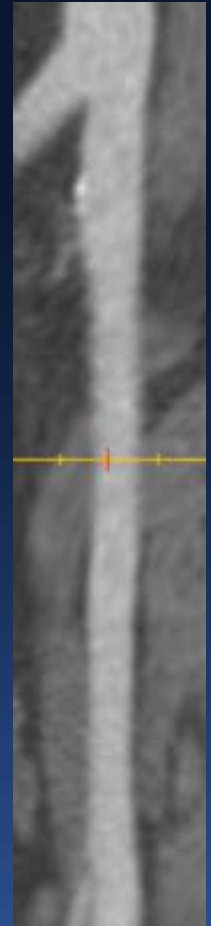
- **CTA allows *complete* 3D assessment of the iliofemoral arterial access**
 - **Minimum and mean diameter**
 - **Vessel tortuosity**
 - **Amount and pattern of calcification**
 - **Extent of atherosclerosis**
 - **Other high-risk features including dissections and complex atheromas**

CTA with 3D Reconstruction



CTA with 3D Reconstruction

- Measure perpendicular to the longitudinal axis of the vessel
- Carefully assess diameter in longitudinal and axial views
- Move cursor slowly, millimeter by millimeter through the entire artery
- If not calcified, use mean luminal diameter
- If vessel is calcified, use minimal luminal diameter



Assessment of calcification

- Non-contrast CT or CTA with appropriate windowing to minimize blooming enables quantification of calcification
- Beware circumferential or near-circumferential calcium
- Use minimum diameter measurements
- Add 1 mm to required minimum diameter for a given sheath

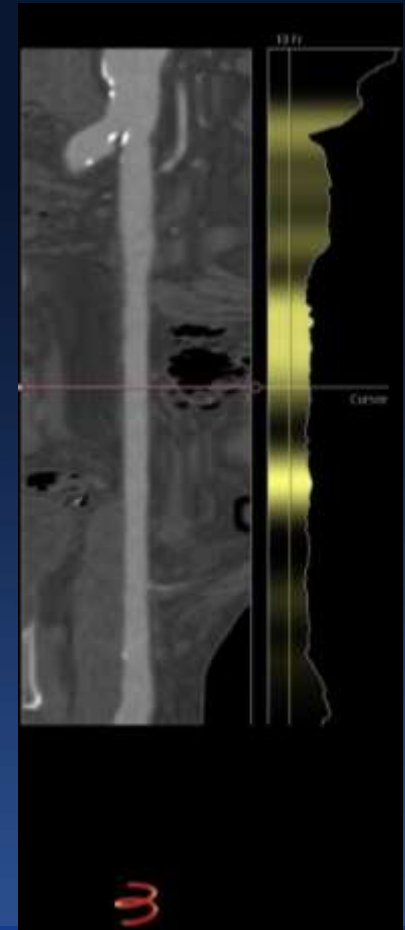
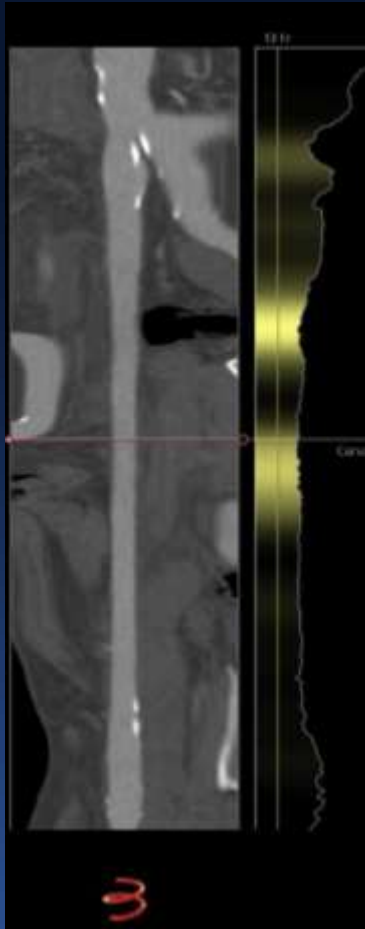


Vessel Tortuosity

- **Significant tortuosity can cause kinking of the sheath on removal of the dilator**
 - This can prevent the delivery catheter from progressing freely in the sheath
 - Increased risk if calcification present



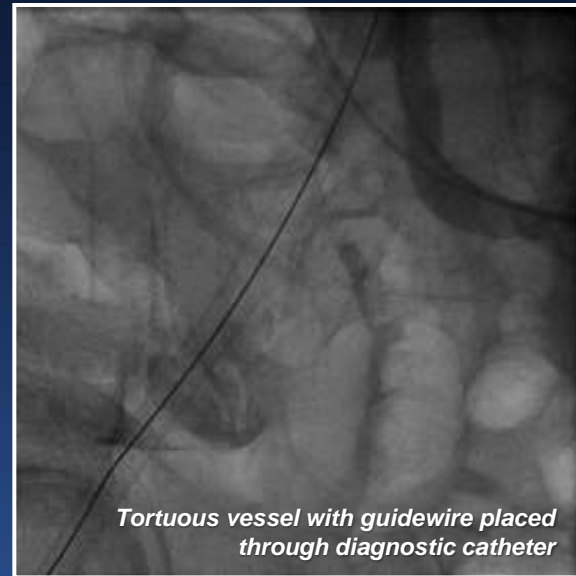
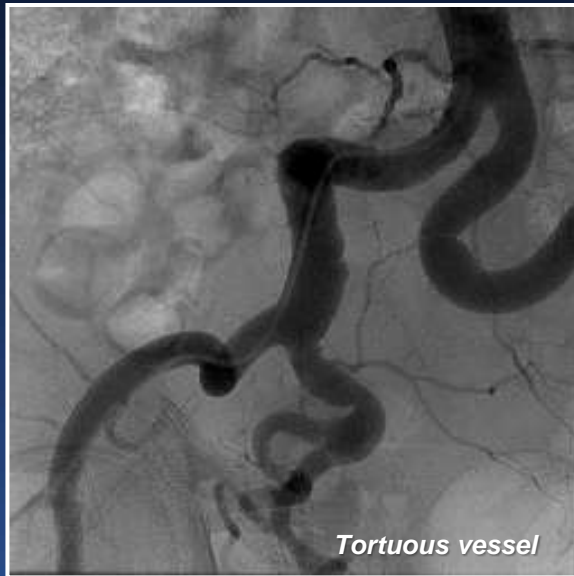
Tortuosity, but adequate diameters and minimal calcification



TAVR Likely Feasible if done carefully

Tortuosity: wire straightening

- Severely tortuous vessels with *limited calcification* may be feasible when done carefully
 - This can be verified by determining if the tortuous vessel can be straightened with a wire at diagnostic angiography

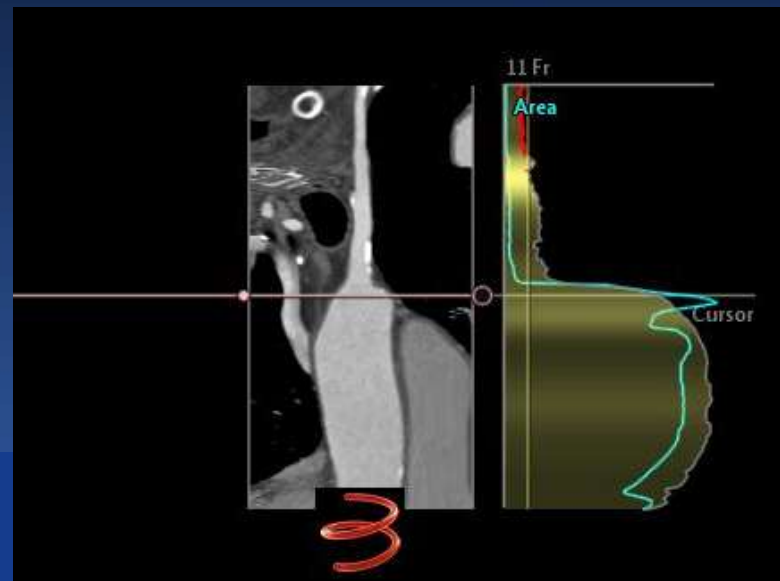
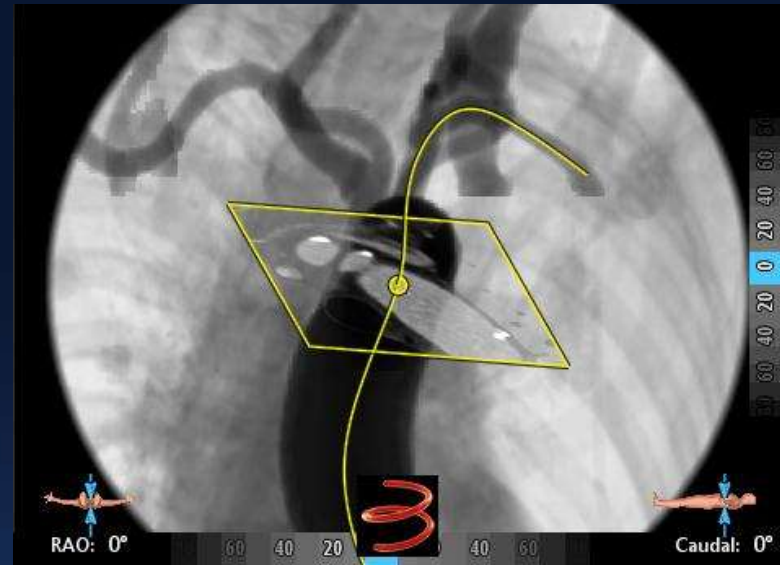


Challenging Case 1: Extreme Tortuosity of the Abdominal Aorta

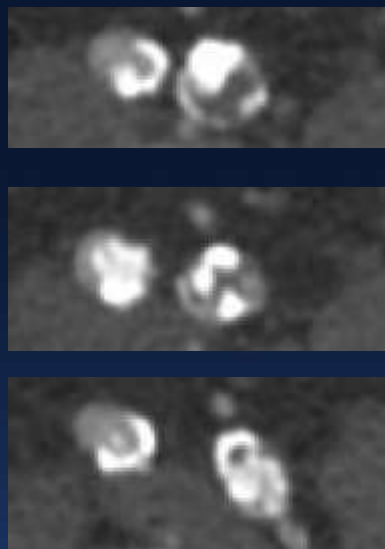
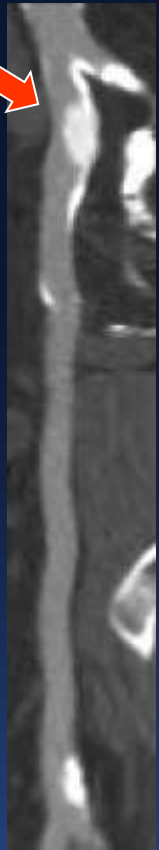


Transfemoral TAVR not feasible

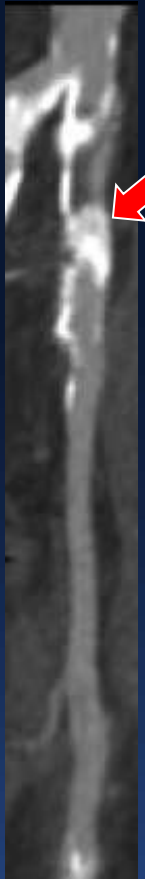
Evaluate for Transaortic or Subclavian



Challenging Case 2: Inadequate Iliofemoral Arterial Access



Severe bilateral calcified iliac disease

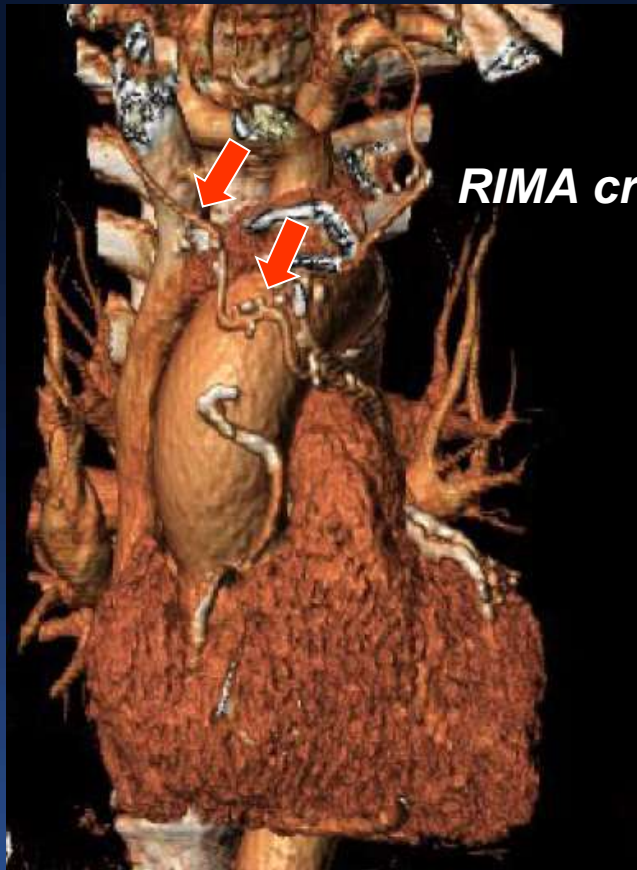


Severe stenosis Right Common Iliac

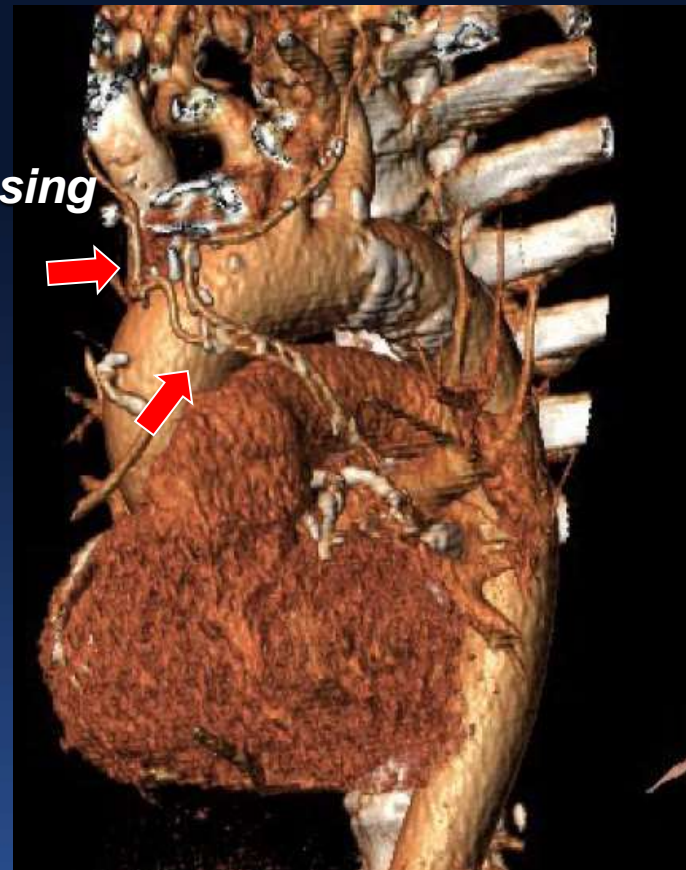


Occluded Left Common Iliac

Direct Aortic Access limited by RIMA, Grafts Subclavian with stenosis, patent LIMA



RIMA crossing



Challenging Case 3: Prior AAA Repair

- TAVR can be performed through prior AAA repair if:
 - Vessel diameter is adequate
 - Add 2 mm to the usually required diameter
 - Minimal tortuosity
 - Risk of sheath kinking if more than mild tortuosity
 - Native vessels distal adequate
 - Not fresh grafts (≥ 6 months)



Technical Lessons:

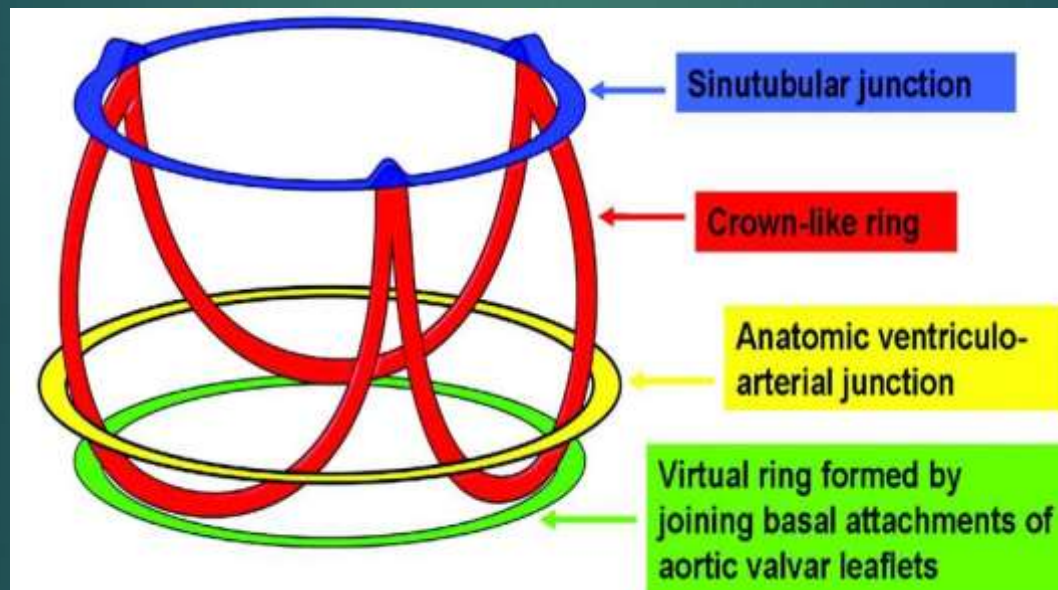
- Vascular access:
 - ❑ Choice of TAVR systems
 - ❑ Lindequist wire for tortuosity
 - ❑ Edward dilator sets for femoral iliac/aortic dilatation
 - ❑ Dry Seal sheath vs Cordis sheath
 - ❑ Ultrasound guidance for vascular access (avoid anterior calcium as well as side puncture)



Why do we need these aortic measurements?

- ▶ Predictors of paravalvular leak, BE/SE: undersizing, calcification, implant depth
 - Athappan et al, JACC 2013
- ▶ Predictors of root rupture BE: oversizing > 20%, LVOT calcification
 - Barbanti et al, Circ 2013
- ▶ Predictors of LM occlusion BE/SE: SOV < 30 mm + LMCA distance < 12 mm
 - Ribeiro et al, JACC 2013

“Virtual” Aortic Annulus – where the transcatheter valve anchors



Piazza N et al. *Circ Cardiovasc Interv*
2008;1:74-81

S3

EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE

Annulus Sizing		20 mm	23 mm	26 mm	29 mm
Native Valve Annulus Size (CT)	Area	273 - 345 mm ²	338 - 430 mm ²	430 - 546 mm ²	540 - 683 mm ²
	Area Derived Diameter	18.6 - 21 mm	20.7 - 23.4 mm	23.4 - 26.4 mm	26.2 - 29.5 mm
Native Valve Annulus Size TEE		16 - 19 mm	18 - 22 mm	21 - 25 mm	24 - 28 mm

Corevalve/Evolut

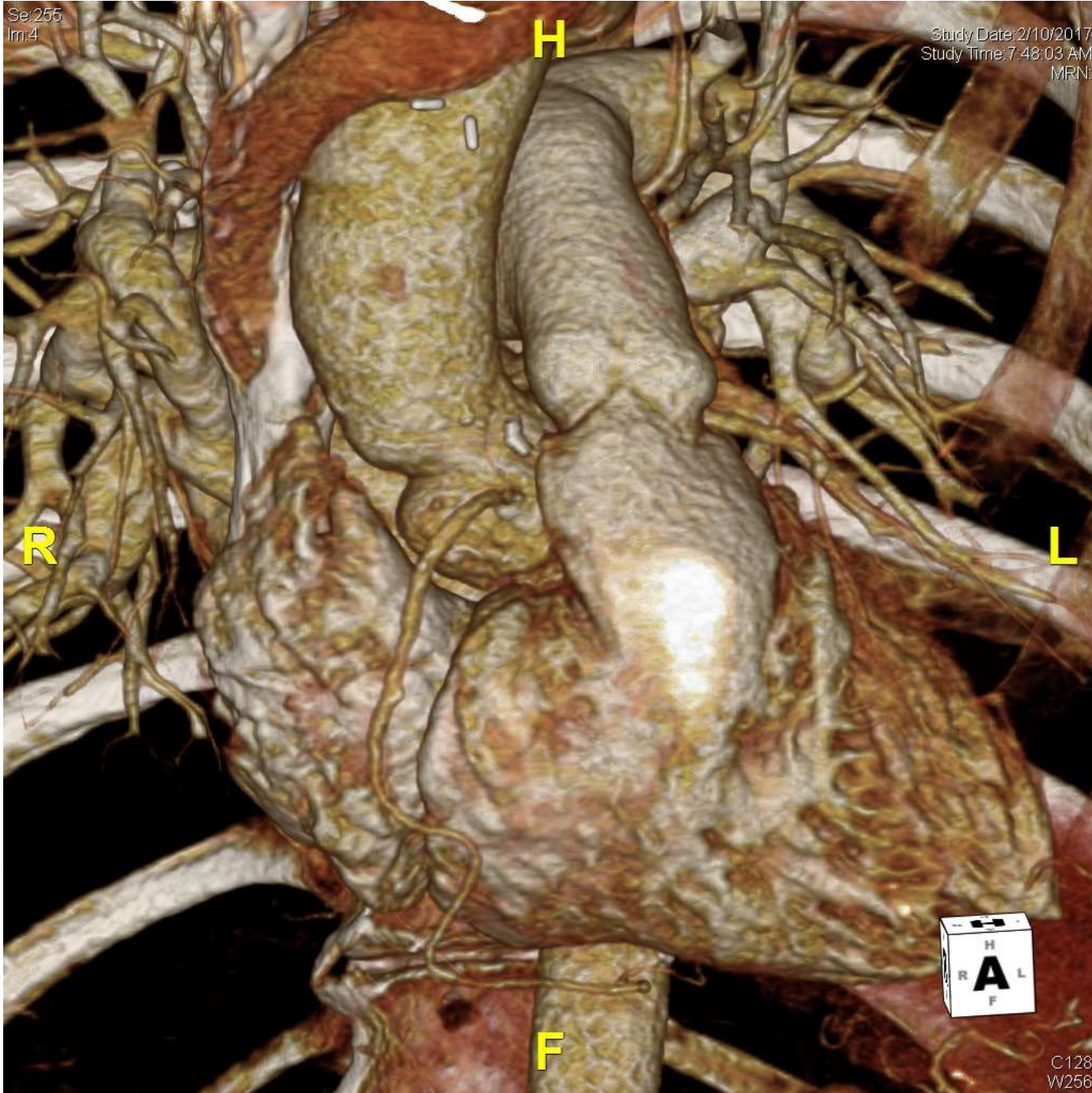
Device and Patient Selection Measurements per MSCT

Valve Size	Aortic Annulus Measurements			Sinus of Valsalva Diameter	Native Leaflet to Sinutubular Junction Length	Ascending Aorta Diameter*
	Diameter	Perimeter	Area Range			
23	18 mm – 20 mm	56.5 mm – 62.8 mm	254.5-314.2 mm	≥ 25 mm	≥ 15mm	≤ 34 mm
26	20 mm – 23 mm	62.8 mm – 72.3 mm	314.2-415.5 mm	≥ 27 mm	≥ 15mm	≤ 40 mm
29	23 mm – 27 mm	72.3 mm – 84.8 mm	415.5-572.6 mm	≥ 29 mm	≥ 15mm	≤ 43 mm
31	26 mm – 29 mm	81.6 mm – 91.1 mm	530.9-660.5 mm	≥ 29 mm	≥ 15mm	≤ 43 mm

*Ascending Aorta measurements are taken at 30 mm from the aortic annulus for the 23 mm device and at 40 mm from the aortic annulus for the 26, 29, and 31 mm devices.

Se: 255
Im: 4

Study Date: 2/10/2017
Study Time: 7:48:03 AM
MRN:



C128
W256



Ascending Aorta



Adult Echo

X7-2t

53Hz

12cm

2D

49%

C 50

P Off

Gen

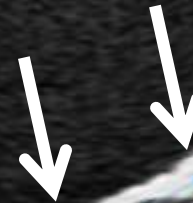


TIS 0.1 MI 0.4

Length - 1.9 cm

M4

1.9 cm



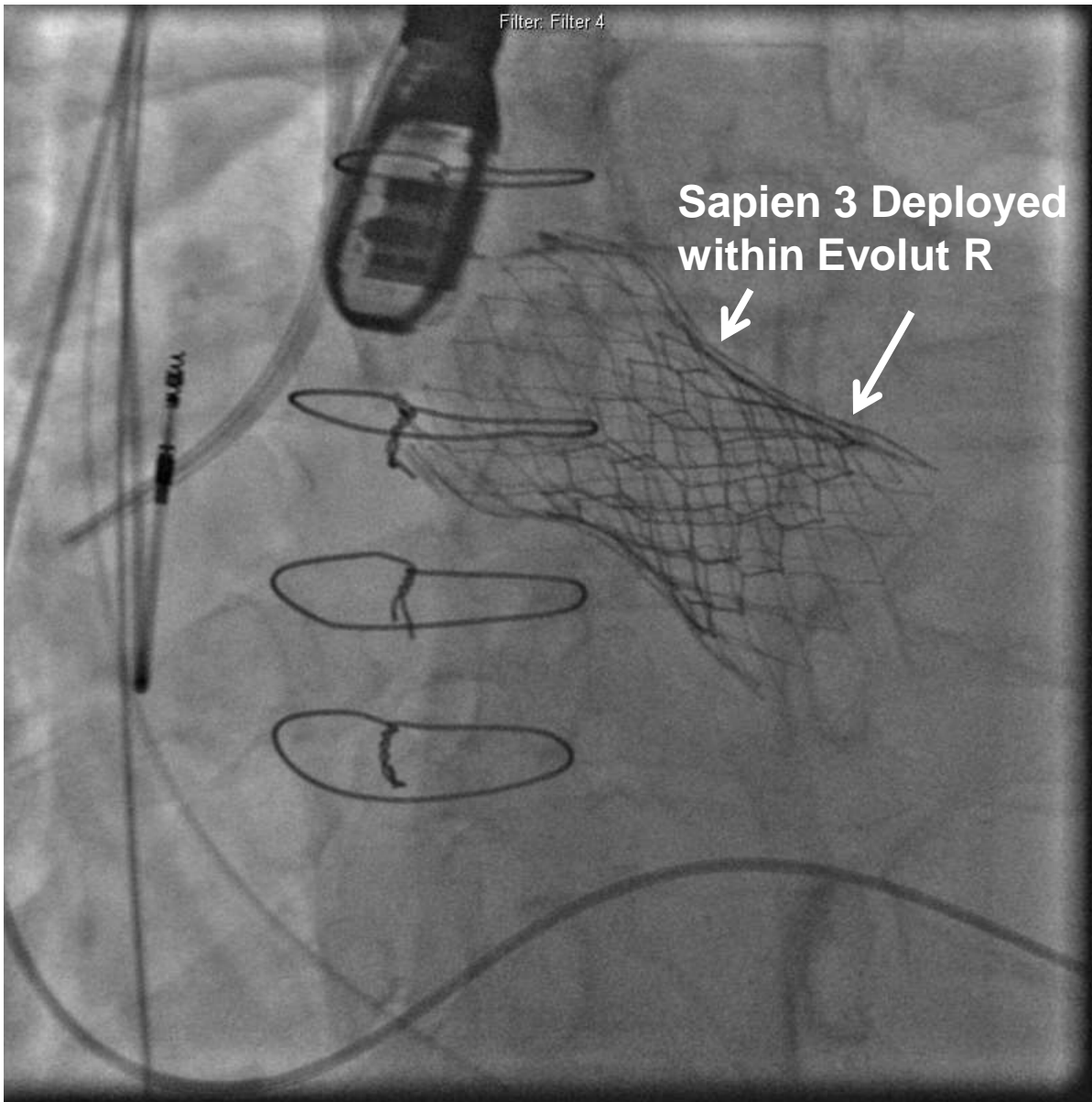
PAT T: 37.0C
TEE T: 38.2C

*** bpm
15 of 107



Filter: Filter 4

**Sapien 3 Deployed
within Evolut R**



Technical Lessons:

- Annular measurements:
 - ❑ There should be quality control of area measurements
 - ❑ If in between size, larger valve with volume subtraction or smaller valve with additional volume. Depends on calcification of outflow, valve, age....
 - ❑ If not clear, verify with TEE



Extreme Risk Commercial TAVR case

MRN 1564317-4

Proposed Treatment 4/21/2017

Fast Track Eligible: No

Referring MD: Antonio Chan, MD

THV MDs: ACY/AL

RN: CM

History: 94 year old female with history of HTN, HLD, DM2, CAD, PVD, CVD, TIA, and severe, symptomatic AS. s/p PCI/BMS to LAD/D1 in May 2002. s/p left CEA in November 2002. Hospitalizations in February 2017 with PNA and CHF. Currently symptomatic of dyspnea on exertion.

PFTs:	FEV1 1.1 L (87%) DLCO -	Frailty:	BMI 20.96 Serum Albumin 4.4 g/dL (-) ADLs 3/6 (+) Grip Strength 0 kg (+) 5m WT 11.2 sec (+) Score 3/4	STS 14.4%	Age 94, female, Asian, 55.4 kg, 162.6 cm (BSA 1.59), IDDM, Cr 1.47, HTN, PVD, CVD, TIA, s/p PCI, NYHA Class III, 1v CAD, EF 60%, AS, mild AI, trace MR, trace TR, first op, elective
Anticoagulation History/Regimen:	ASA only				

Proposed: Extreme Risk Commercial TAVR, 29 mm CoreValve Evolut R, Transfemoral approach, Right side

Echo:	Date 2/17/2017 AVA 0.81 cm ² AVA/AVAI 0.50 cm ² /m ² V2 Max 3.8 m/sec Gradient 35 mmHg V1/V2 0.23 EF 60% RVSP - AI Mild MR Trace TR Trace	RHC:	RA - RV - PA - PCW - CO - CI -	Coronary heights:	LCA 10.5 mm RCA 14.3 mm	SOV Diameters:	RCC 27.1 mm LCC 29.4 mm NCC 28.9 mm
		Cors:	LM - LAD - LCX - RCA Grafts NA	Vascular access: (in mm)	RCIA 5.7 x 3.8 REIA #1 6.3 x 6.2 REIA #2 6.1 x 5.6 RCFA 6.3 x 5.7 LCIA 4.8 x 4.2++ LEIA #1 6.1 x 5.7 LEIA #2 6.9 x 5.7 LCFA 6.3 x 5.4	SOV heights > 15 mm: Yes	Ascending Ao diameter: Long Axis 30.8 mm Short Axis 30.1 mm
						Annulus:	Diameter ~24.5 mm Long Axis 27.8 mm Short Axis 21.2 mm Area 472 mm ² Perimeter 78.6 mm

Notes: CT: focal intimal tear with ulcerated plaque in infrarenal abdominal aorta and markedly reduced aortic diameter to 4 mm - unchanged from exam in 2015; right hilar lymph nodes enlarged since prior exam; 70% stenosis of left renal artery.

Summary:	<ul style="list-style-type: none"> • 94 year old female • STS 14.4% • Extreme Risk Commercial TAVR, 29 mm CoreValve Evolut R • Transfemoral approach, Right side 	<ul style="list-style-type: none"> • Lunderquist wire • Fast Track exclusion: CoreValve • ### • Coronary angiogram at time of TAVR
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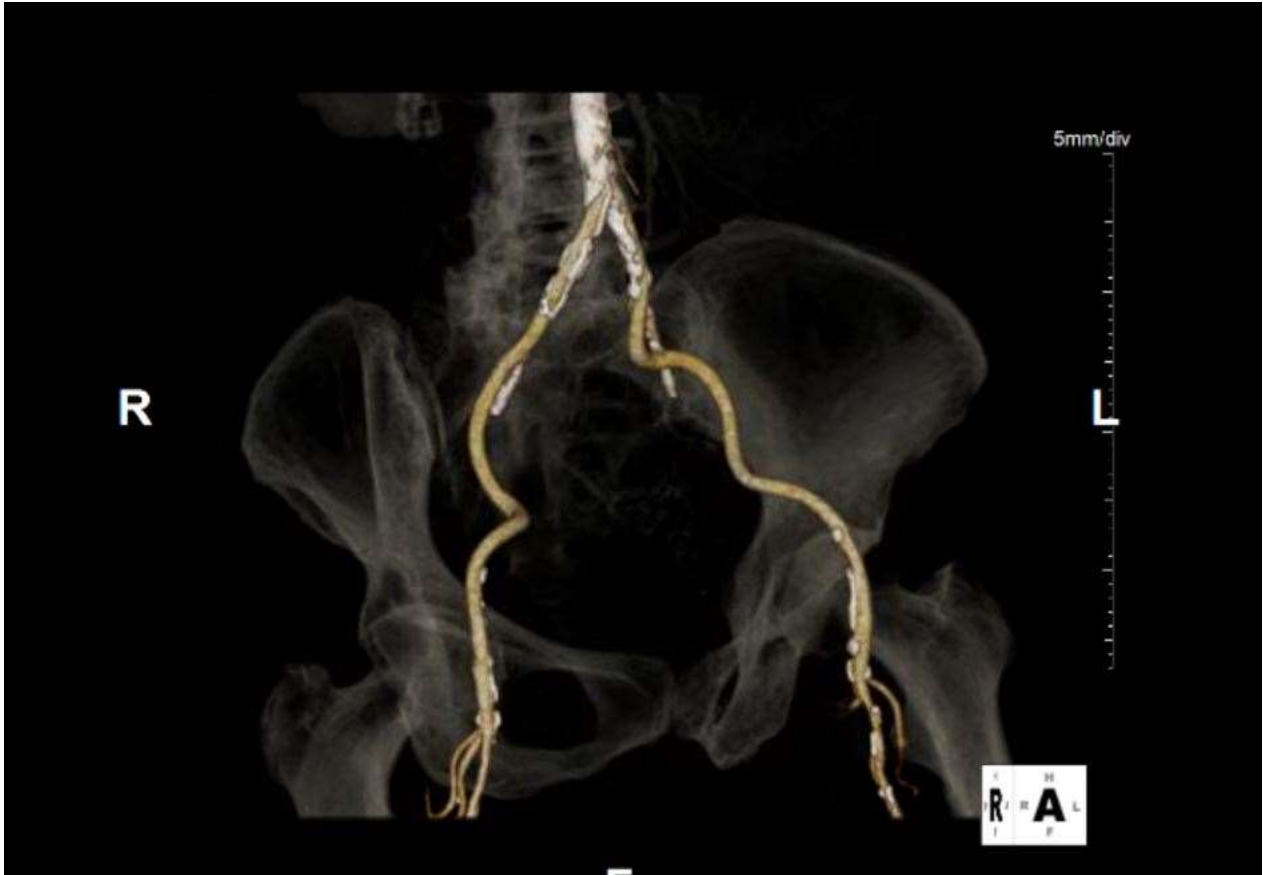
Echo:	Date 2/17/2017 AVA 0.81 cm ² AVAI 0.50 cm ² /m ² V2 Max 3.8 m/sec Gradient 35 mmHg V1/V2 0.23 EF 60% RVSP - AI Mild MR Trace TR Trace	RHC:	RA - RV - PA - PCW - CO - CI -	Coronary heights:	LCA 10.5 mm RCA 14.3 mm	SOV Diameters:	RCC 27.1 mm LCC 29.4 mm NCC 28.9 mm
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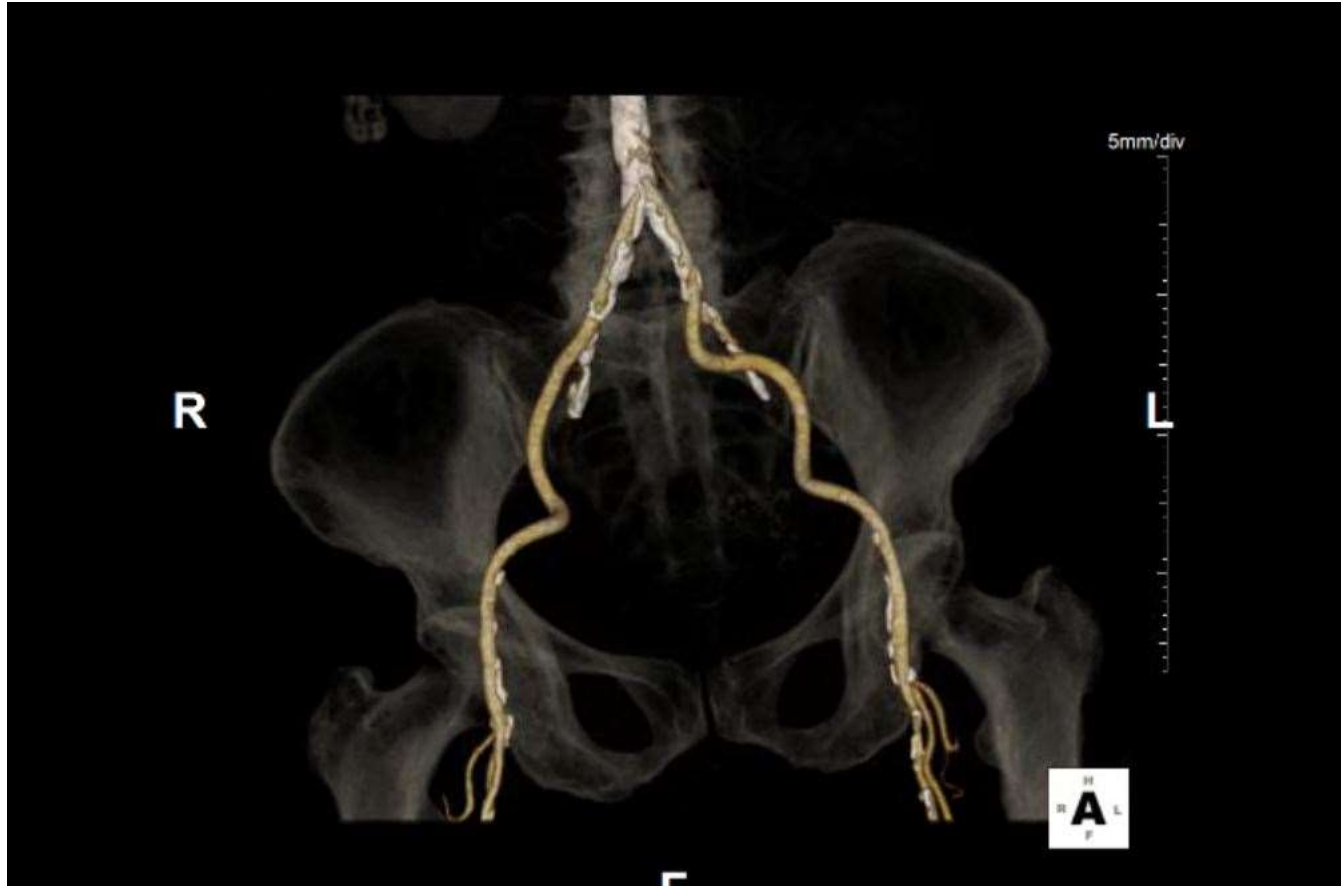
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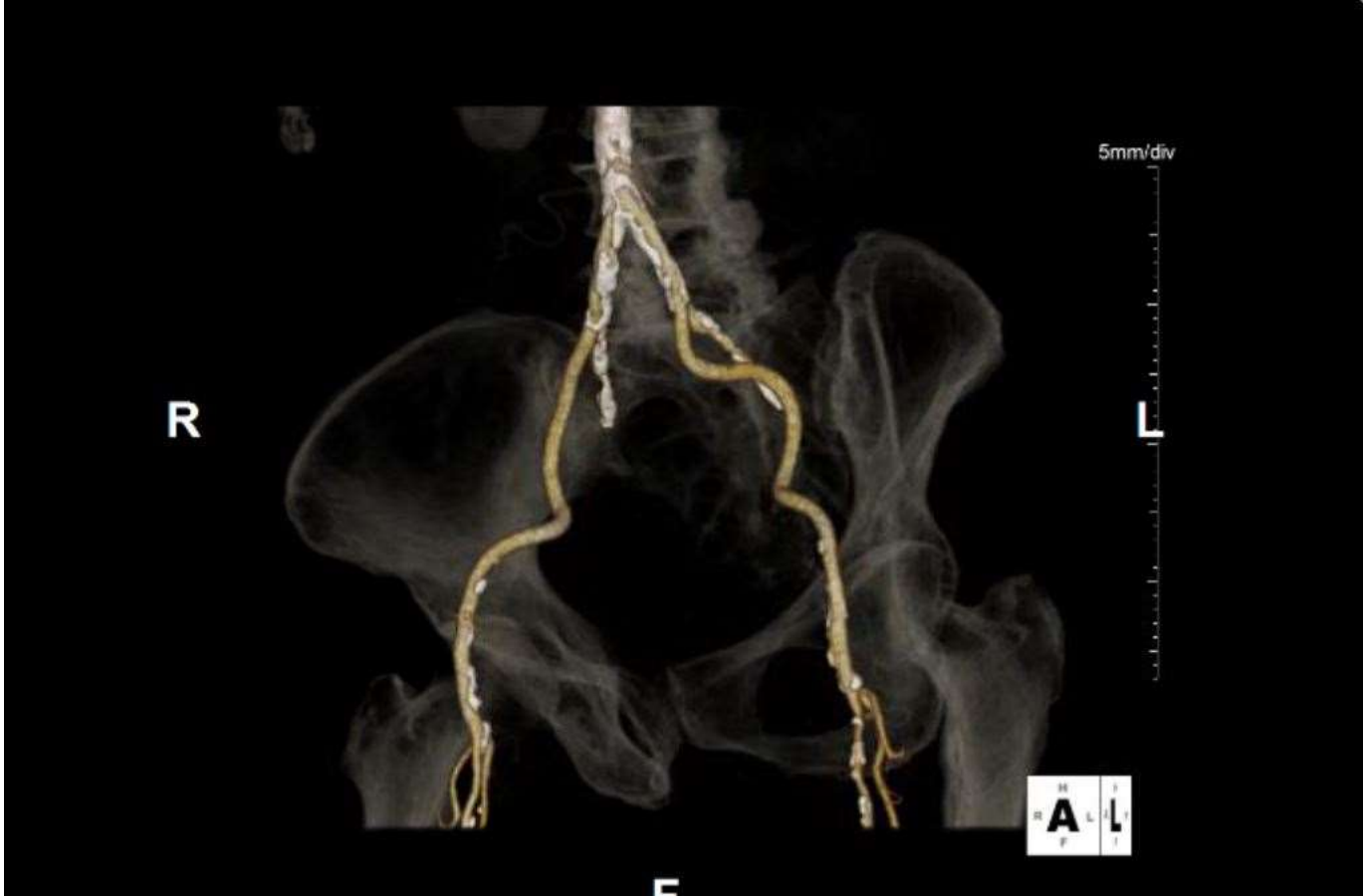
Summary:

- 94 year old female
- STS 14.4%
- Extreme Risk Commercial TAVR, 29 mm CoreValve Evolut R
- Transfemoral approach, Right side
- Lunderquist wire
- Fast Track exclusion: CoreValve
- ###
- Coronary angiogram at time of TAVR







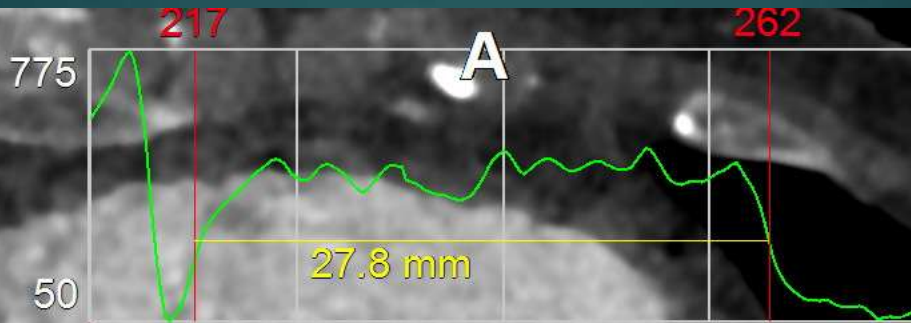






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Im:1

Study Date:3/17/2017
Study Time:2:04:16 PM
MRN:

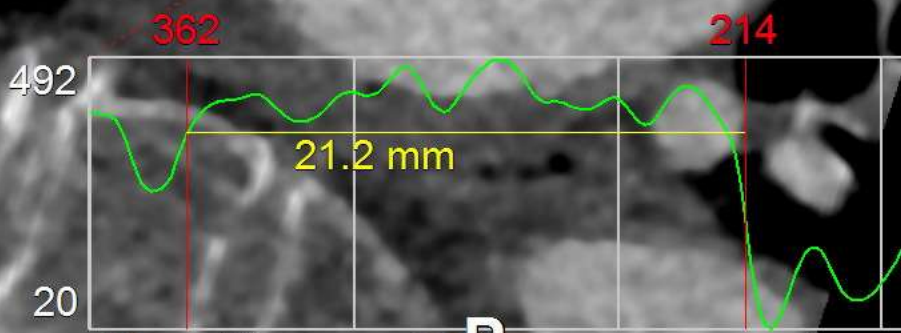


Mean: 200
Area: 4.78 cm²
Min: -68
Max: 604
SDev: 169

Mean: 420
Area: 4.72 cm²
Min: 43
Max: 602
SDev: 73.1
Avg. Diameter: 24.5 mm
Perimeter: 78.6 mm

F

H



Technical Details:

- 95 year women, small femoral-iliac system that can accommodate a “bare-back” Evolut R?
- Aortic is narrowed to 4mm, can the device pass?
- Annular circumference seems too large for her size. Don't want to oversize her



Technical Plan:

- Re-measure her annulus: corrected to 26 Evolut R
- Confida wire in LV through 7F sheath
 - Should we use a Lunderquest? Like Confida better
- Progressive dilation using Edwards dilators system to 18F
 - What if dilators would not pass? Unlikely valve will pass? Switch to valvuloplasty as temp and explore other access
- Deployment of 26mm Evolut R
 - If valve would not pass aorta, dilate with 20F dilator



BANAAG, CATALINA
1554317-4
YEUNG, A
SHC

Derived

4/21/2017 1:40:37 PM

521537767

5

1

1/52



4.30 P/AO
29.70 CAU



Technical Results:

- 26mm Evolut R.....mild AR
- Wait....mild AR
- Post dilate with 22 mm Zmed balloon
- 16mm internal to 20mm internal
- Final: trace AR
- Home in 48hrs, no pacer



Technical Lessons:

- TAVR procedures are getting pretty routine
- Technical challenges in routine cases are low
- However, “devils are in the details”
- Vascular “safety”
- Annular “efficacy”
- Care “uniformity”

