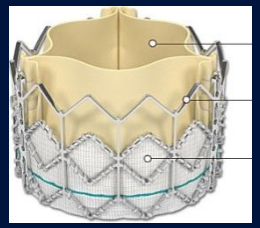
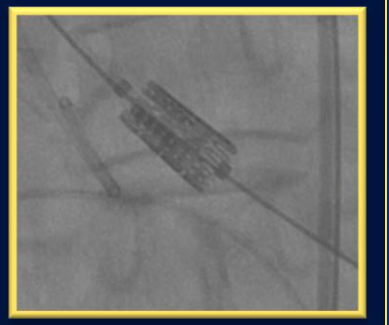
ACC Regional Meeting
October 19th, 2013



Transcatheter Aortic Valve Replacement (TAVR)

James Hermiller, MD, FACC, FSCAI
St Vincent Medical Group
St Vincent Heart Center
Indianapolis, IN



Disclosures

Affiliation/Financial Relationship	Company
• Consulting Fees/Honoraria	• Abbott, BSC, Medtronic and St Jude
• Speaker Bureau	• Medicines Company
• Research Support	• Medtronic, Abbott, BSC
• CoreValve Steering US Pivotal Trial	• Medtronic

Introduction

- **Is Severe AS Present? Does the patient have the disease?**
- **Clinical Candidate**
  - **Partner A? B? C? D?**
- **Anatomic Suitability – Annulus, Root, Coronary-Annulus Relationship, CAD, ST Junction, ASH?**
- **Access – Femoral, Subclavian, Direct Aortic, Apical?**

Initial Thought

Team Sport

Two Different Patterns of Low-Flow, Low-Gradient AS

NORMAL-LVEF
NORMAL-FLOW
HIGH-GRADIENT

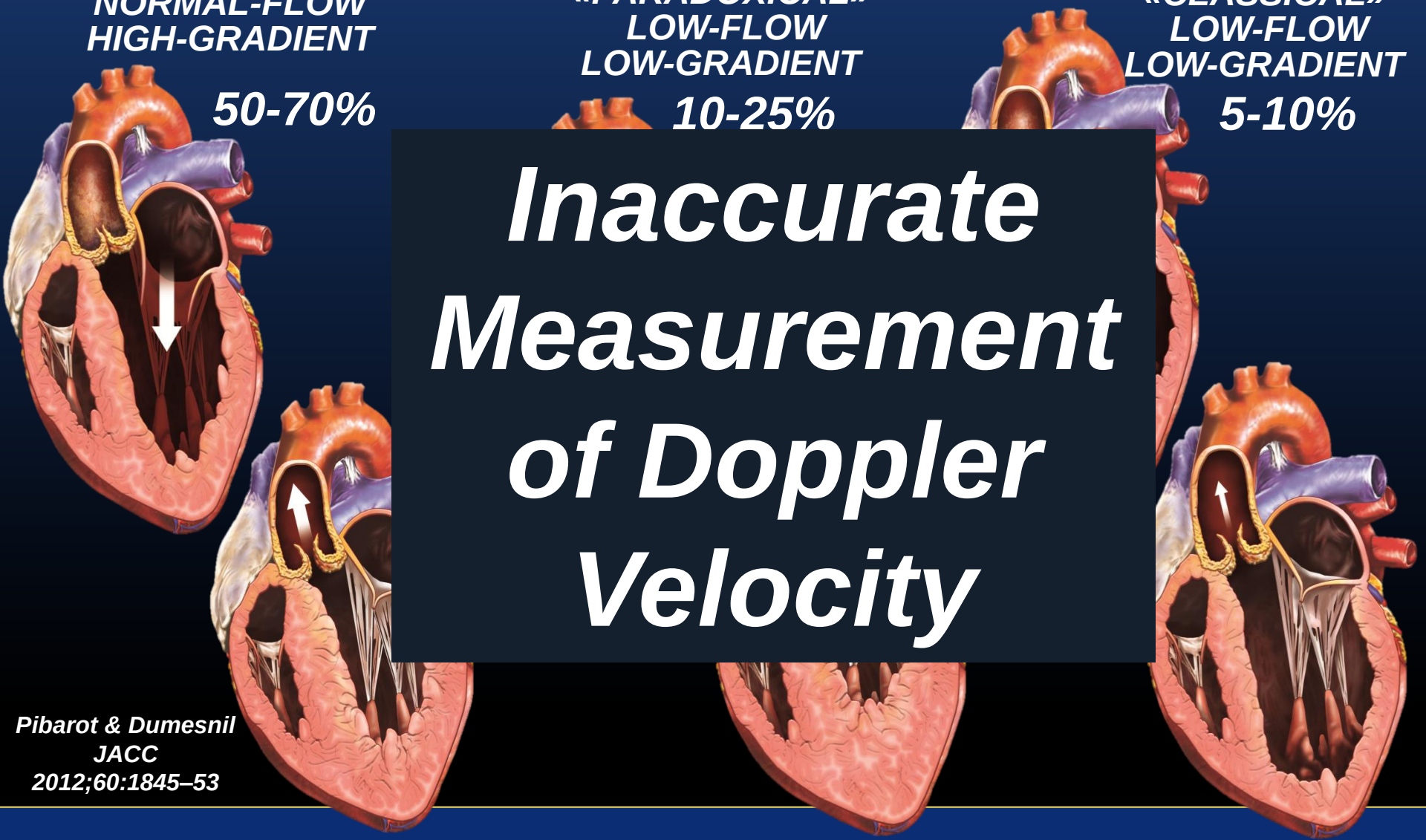
50-70%

NORMAL-LVEF
«PARADOXICAL»
LOW-FLOW
LOW-GRADIENT

10-25%

LOW-LVEF
«CLASSICAL»
LOW-FLOW
LOW-GRADIENT

5-10%



Inaccurate Measurement of Doppler Velocity

Pibarot & Dumesnil
JACC
2012;60:1845–53

Patient Selection

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The Annulus is Elliptical

The annulus is commonly oval-shaped

Reported in approximately 50% of patients evaluated for TAVR

Any single diameter cannot adequately characterize the annulus "size" due to its elliptical non-circular configuration

T **onal**
3.0

as
been previously underappreciated on 2-D imaging

Tops LF, Wood DA, Delgado V, et al. Noninvasive evaluation of the aortic root with multislice computed tomography: implications for transcatheter aortic valve replacement. JACC Cardiovasc Imaging 2008; 3:25 -32

Cross-Sectional Computed Tomographic Assessment Improves Accuracy of Aortic Annular Sizing for Transcatheter Aortic Valve Replacement and Reduces the Incidence of Paravalvular Aortic Regurgitation

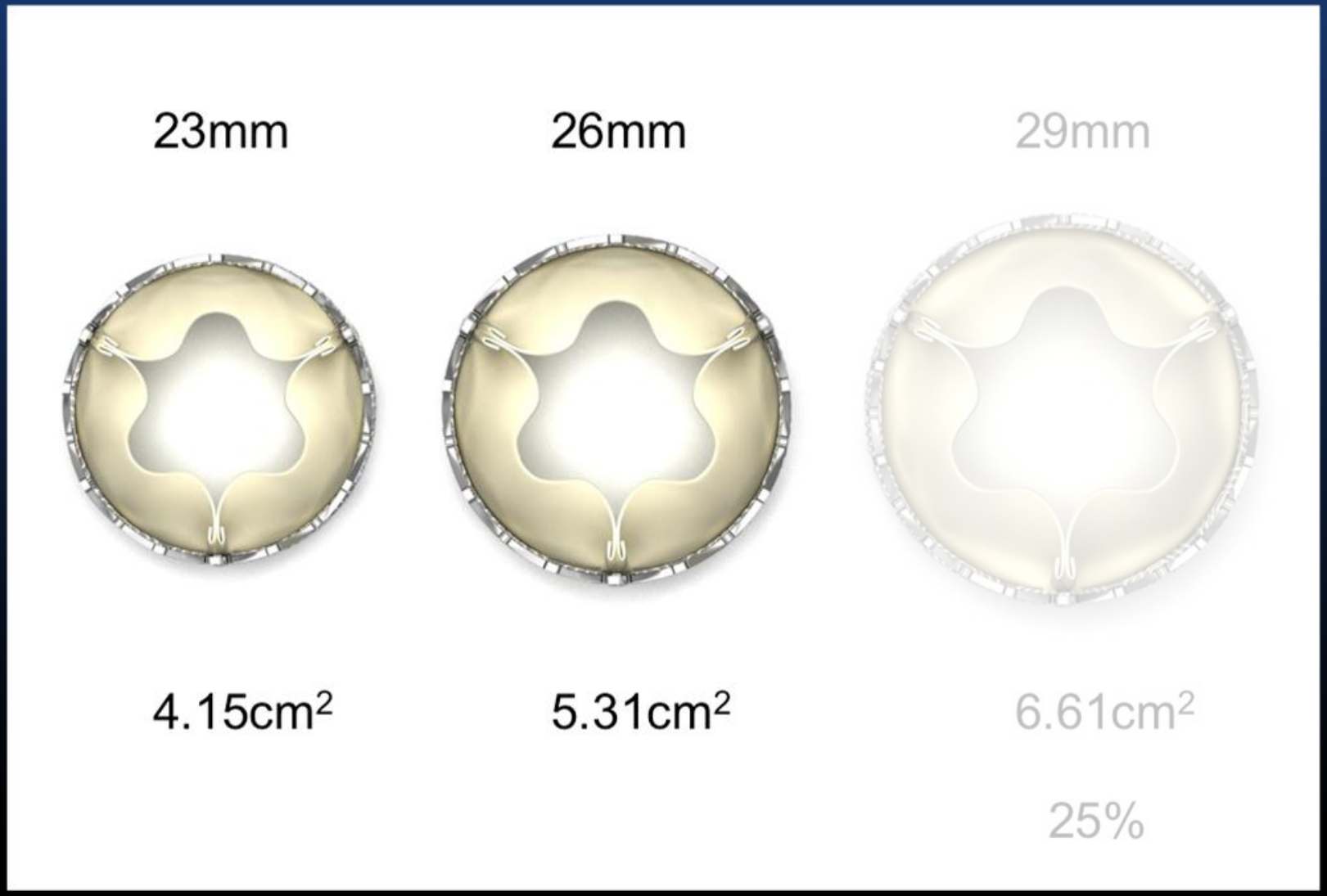
J Am Coll Cardiol 2012;59:1275–86)

Hasan Jilaihawi, BSc (Hons), MBChB,* Mohammad Kashif, MD,* Gregory Fontana, MD,† Azusa Furugen, MD, PhD,* Takahiro Shiota, MD,* Gerald Friede, BS, MS,* Rakhee Makhija, MD,* Niraj Doctor, MBBS,* Martin B. Leon, MD,‡ Raj R. Makkar, MD*

Table 5 Comparison of Outcomes Related to Prosthesis Sizing With TEE- and CT-Guided Approaches

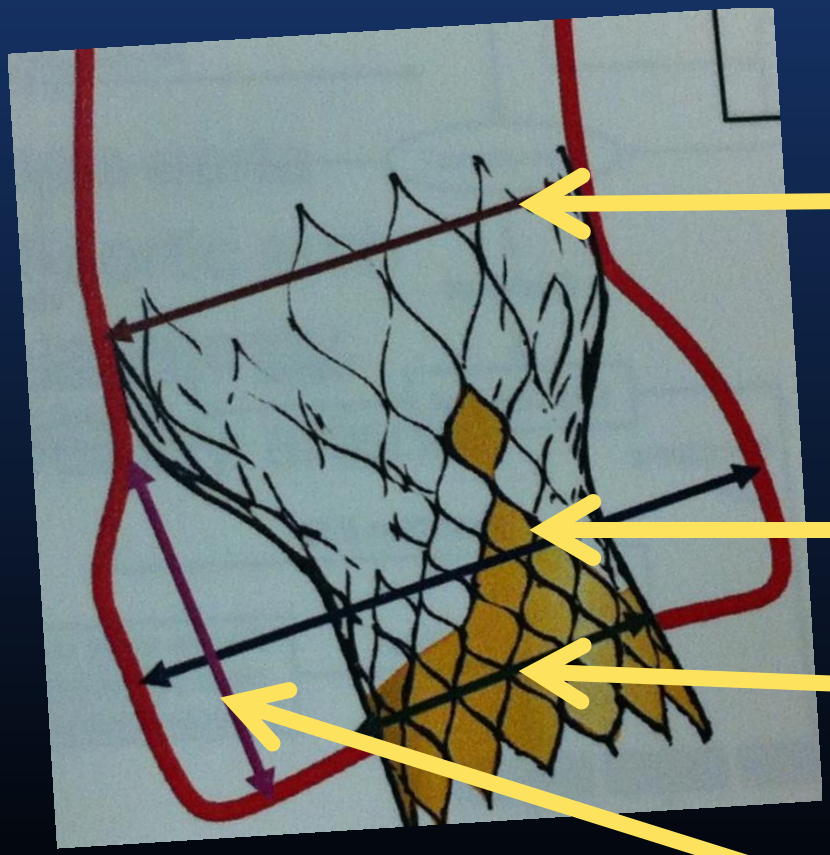
Outcomes	All Studied Patients (n = 136)	2D TEE-Guided Annular Sizing (n = 96)	Cross-Sectional CT-Guided Annular Sizing (n = 40)	p Value
PV AR				0.001
None	41 (30.1)	23 (24)	18 (45)	
Trivial or mild	71 (52.2)	52 (54.1)	19 (47.5)	
Mild-moderate	9 (6.6)	8 (8.3)	1 (2.5)	
Moderate	12 (8.8)	10 (10.4)	2 (5)	
Moderate-severe	3 (2.2)	3 (3.1)	0	
Severe		0	0	
PV AR > mild	24 (17.6)	21 (21.9)	3 (7.5)	0.045
Need for bail-out valve-in-valve	1 (0.7)	1 (1)	0	0.52
Annular rupture	1 (0.7)	1 (1)	0	0.52
Prosthesis instability (rocking)	1 (0.7)	1 (1)	0	0.52
Peri-procedural mortality	4 (3)	3 (3.2)	1 (2.5)	0.82

The St Paul's CT Sizing Scale



The St Paul's CT Sizing Scale

Annular Area (mm^2)	THV size (mm)
230 to 300	20
310 to 320	20 or 23
330 to 400	23
410	23 or 26
420 to 510	26
520	26 or 29
530 to 660	29
>660	Risk of leak/embolisation with 29



Asending Aorta (Outfow Size) Measurement

Sinus WIdth

Annulus Measurement (Perimeter)

Sinus Height > 15 mm (From the Native Leaflet to the STJ)

CoreValve Sizing Table

Valve Size	Aortic Annulus Diameter (mm)	Ascending Aortic Diameter (mm)	Sinus of Valsalva Width (mm)	Sinus Valvsalva Height (mm)	Perimeter (mm)
23	18-20	≤34	≥25	≥15	56.5 -62
26	20-23	≤40	≥27	>15	62-72
29	23-27	≤43	≥29	>15	72-84
31	26-29	≤43	≥29	>15	82-91

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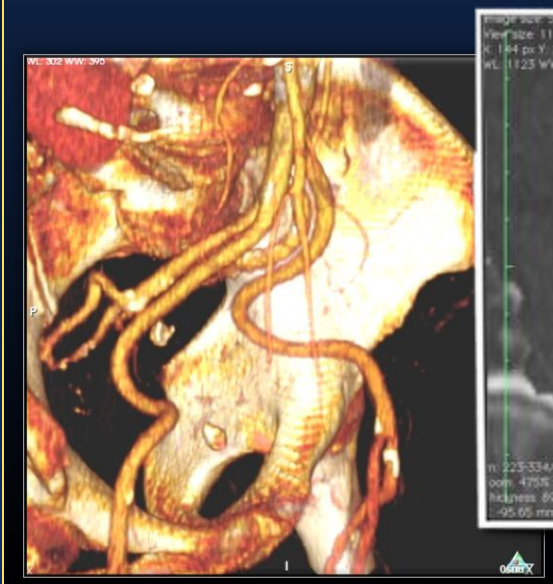
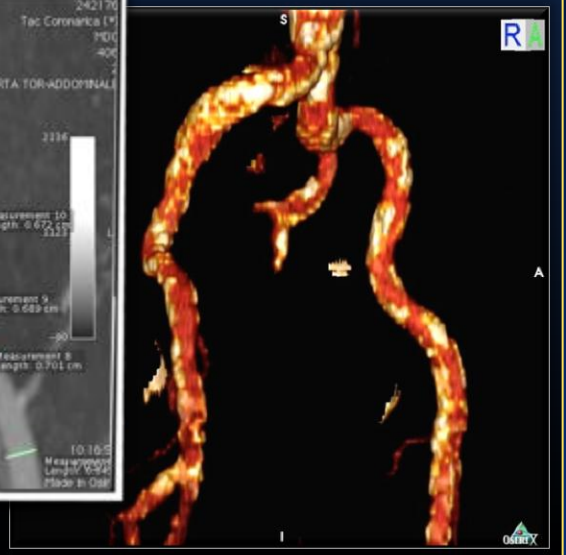
CoreValve Vascular Access

18 Fr sheath introduction Sheath choices include: 28 cm Gore Dry Seal, 30 cm Cook Check Flo and 30 cm St. Jude Ultimum

Arterial diameter ≥ 6mm



Tortuosity

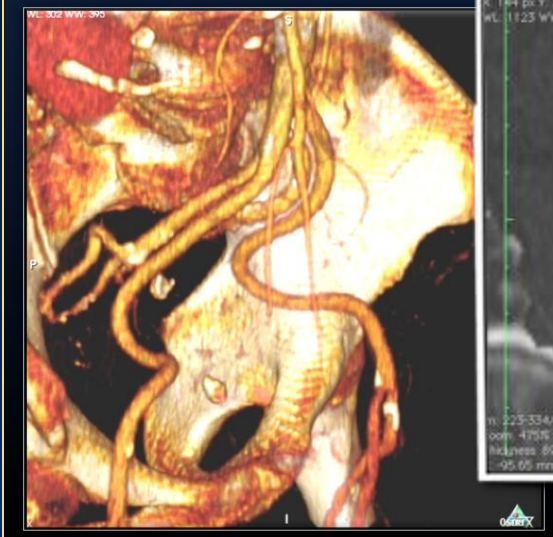


Calcium

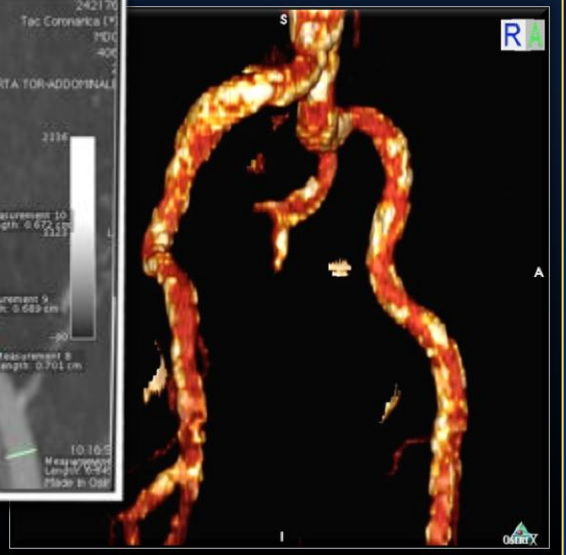
Edwards-Sapien

24 French sheath 23 Valve
26 French Sheath 26 Valve

Arterial diameter ≥ 7mm for 23
Arterial diameter ≥ 8 mm for 26

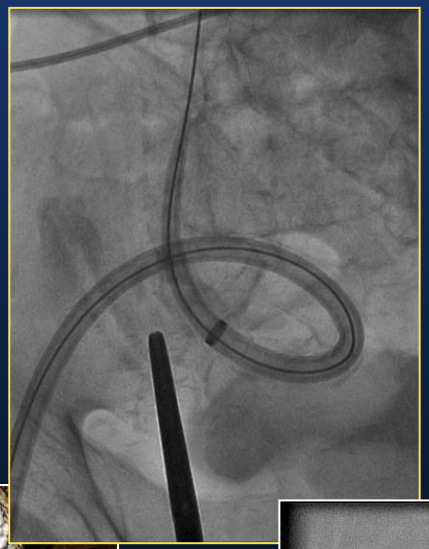


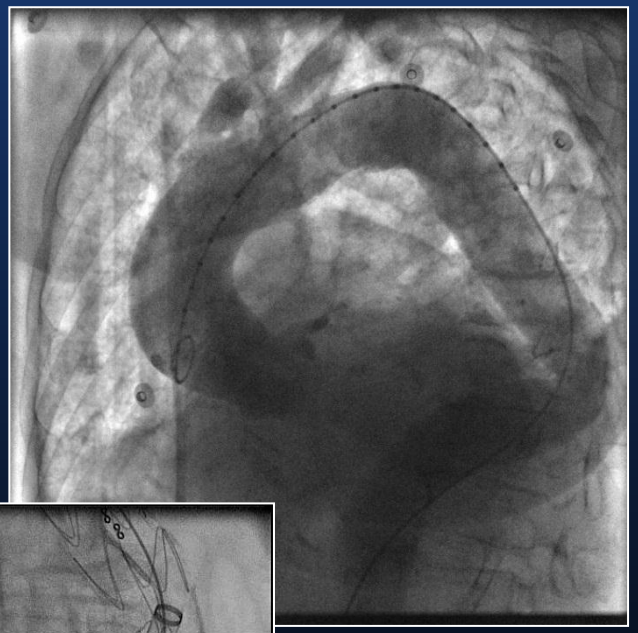
Tortuosity

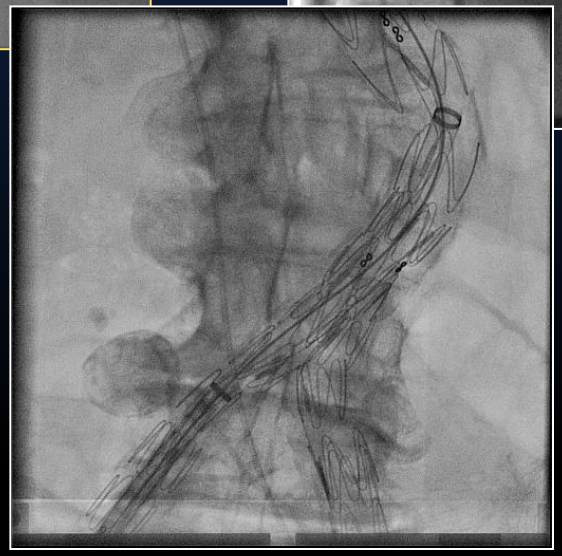


Calcium

Femoral: Unsafe/Suboptimal





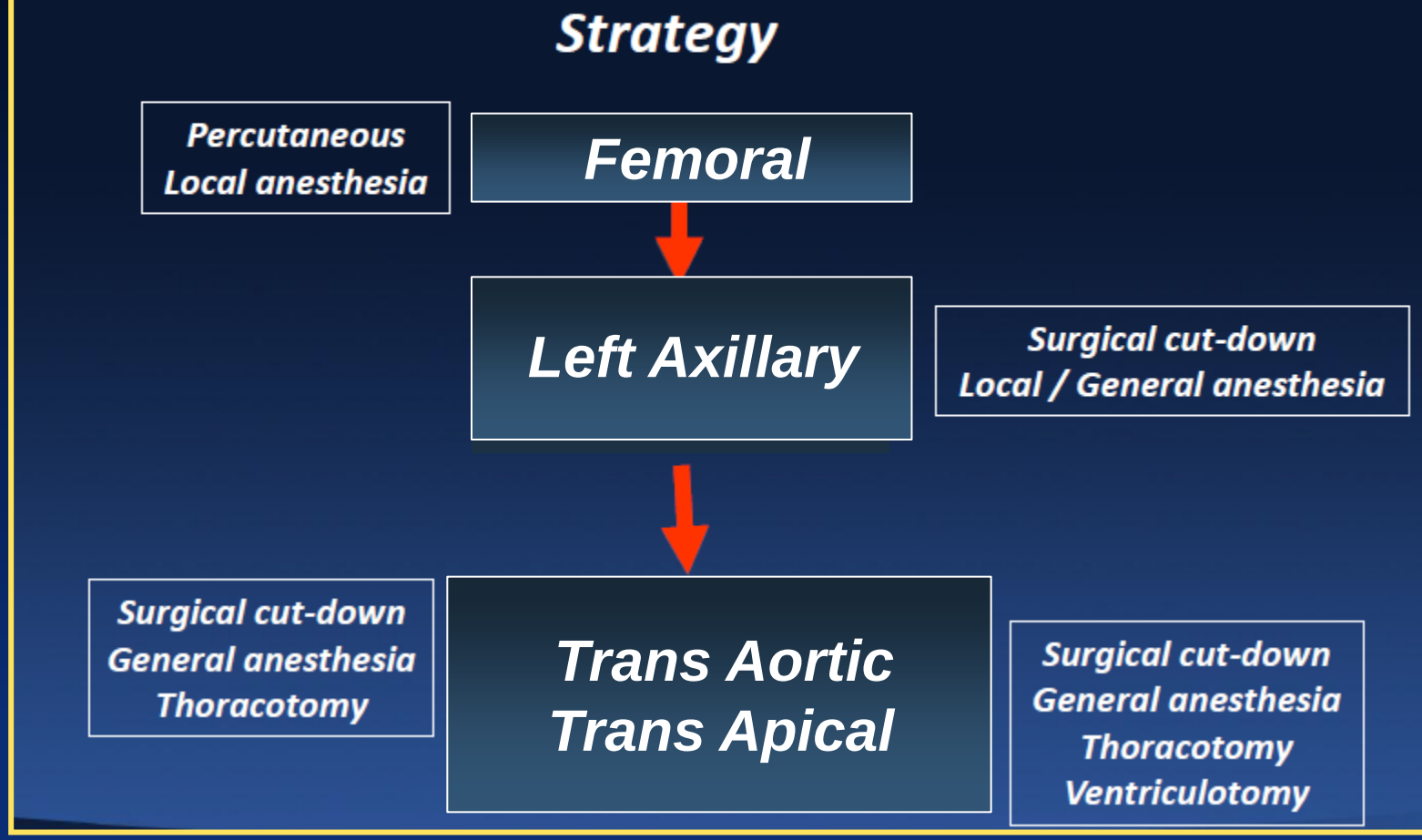


Subclavian/Axillary Selection

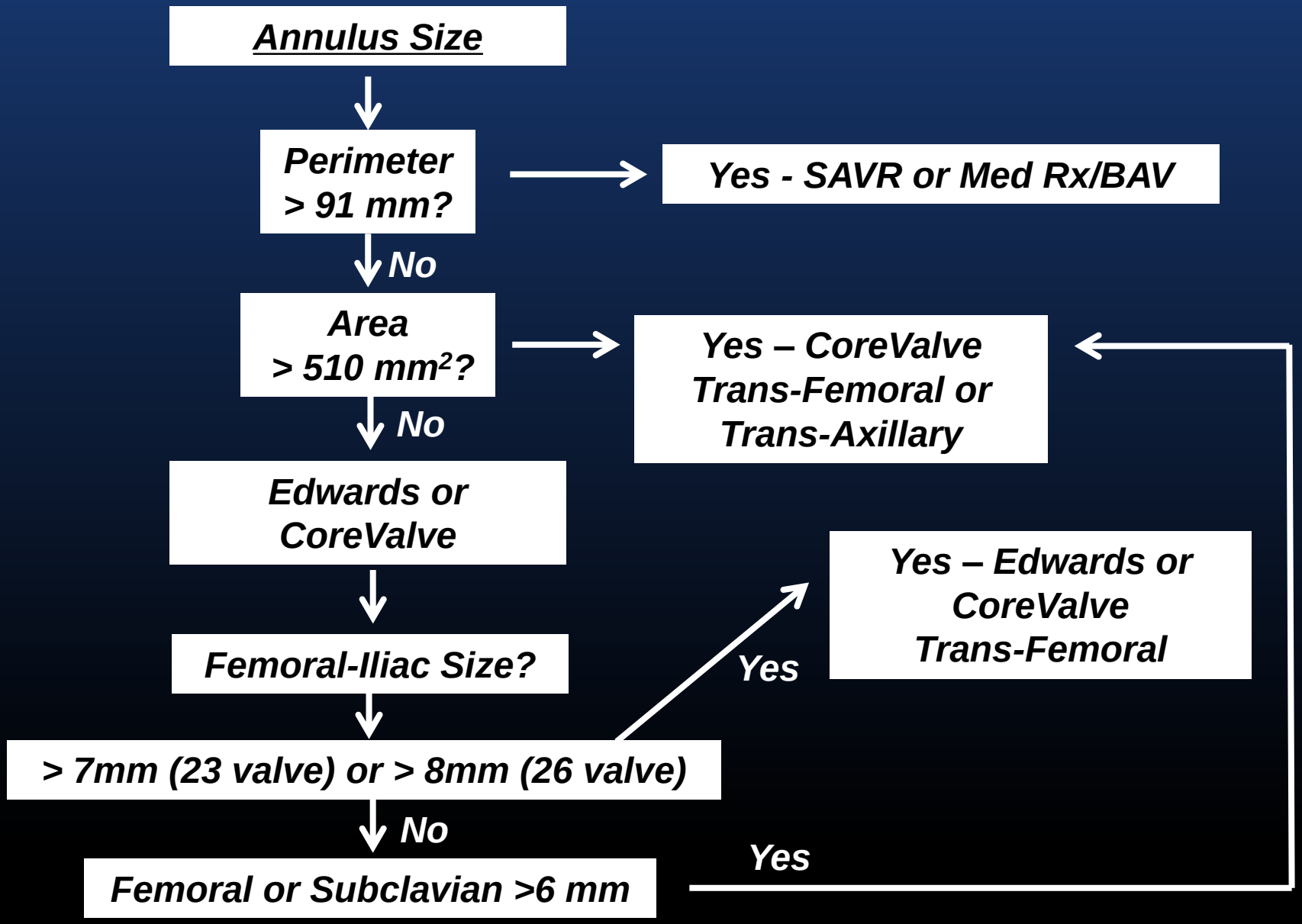
- Vessel size
  - Corevalve 23, 26, 29 and 31: 6 mm
- Atherosclerotic lesions – Calcification?
- Tortuosity – Severe?
- Patent LIMA graft
  - Relative contraindication
- PPM or AV Fistula
- Right approach usually contraindicated
  - Risk of lesion of the right carotid
  - Suboptimal aiming with CoreValve

Strategy

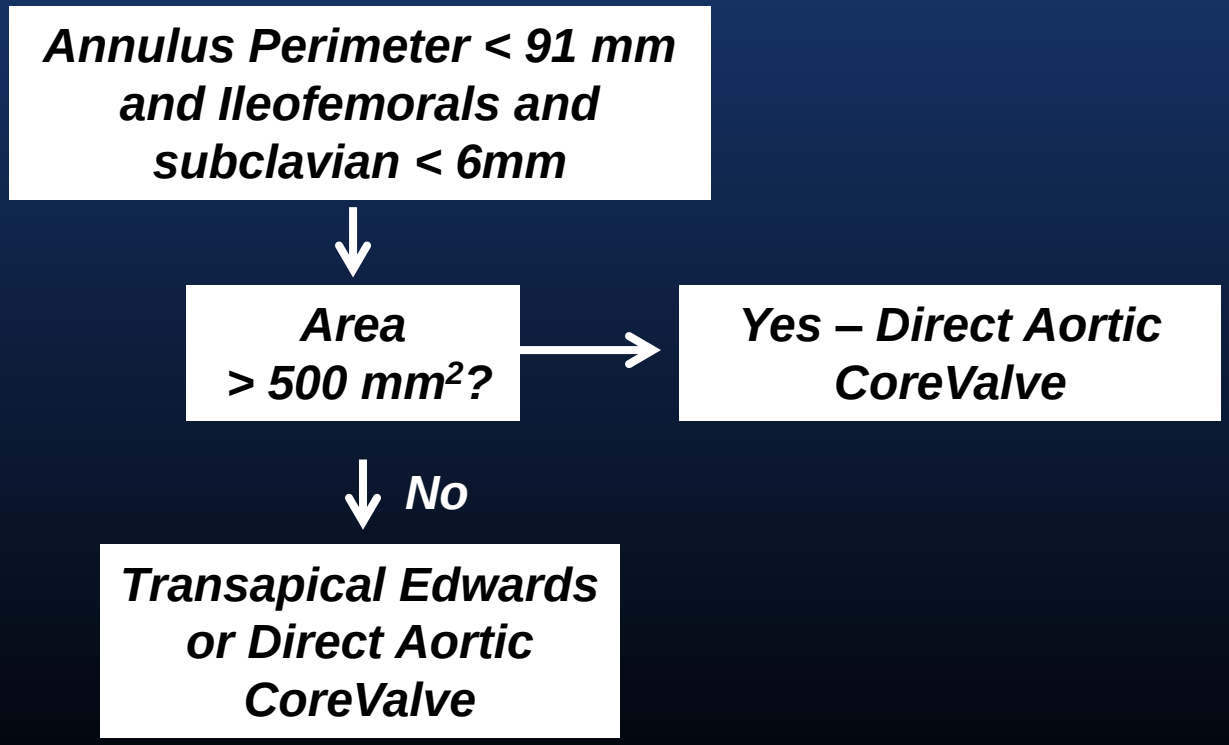
Transfemoral, Transaxillary, and Transaortic
Lessons from an International Experience



CoreValve vs Edwards-Sapien



CoreValve vs Edwards-Sapien



- 78 year old man Hx of Coarct repair, prior CABG, Cr 1.8 mg/dl, moderated COPD, myasthenia gravis (immunosuppresive therapy), DM, atrial fibrillation – STS 11.9%
- LVEF 40%
- Grafts patent
- Echo – AV velocity peak – 4.3 M/sec with valve area of 0.7 cm2

Valve Size	Aortic Annulus Diameter (mm)	Ascending Aortic Diameter (mm)	Sinus of Valsalva Width (mm)	Sinus Valvsalva Height (mm)	Perimeter (mm)
29	23-27	≤43	≥29	>15	72.3-84.8
31	26-29	≤43	≥29	>15	82-91.1

Ao Annulus mean diameter 25.7 mm

Area 530 mm2

28 x 23.3	Major x Minor aortic annulus diameter
82.3	Aortic Annulus perimeter (**26.2** x 3.14)
34.7	Max Ascending Aorta diameter
32.4-35.6	Sinus of Valsalva width
25.3-27.2	Sinus of Valsalva height (all in mm)
31.6-31.9	Sinotubular Junction width (STJ)

CT 3D Reconstructions

AP of Abdominal Aorta and iliacs

Lateral of Abdominal Aorta and iliacs

Tortuosity: None (per site)

Calcification: Mild LFA, LCI, Mod. RCI (per site)

CT Images : Peripheral Artery Measurements

Site Image of iliofemoral artery measurements – Not provided

9.0 x 9.0 RFA min. diameter

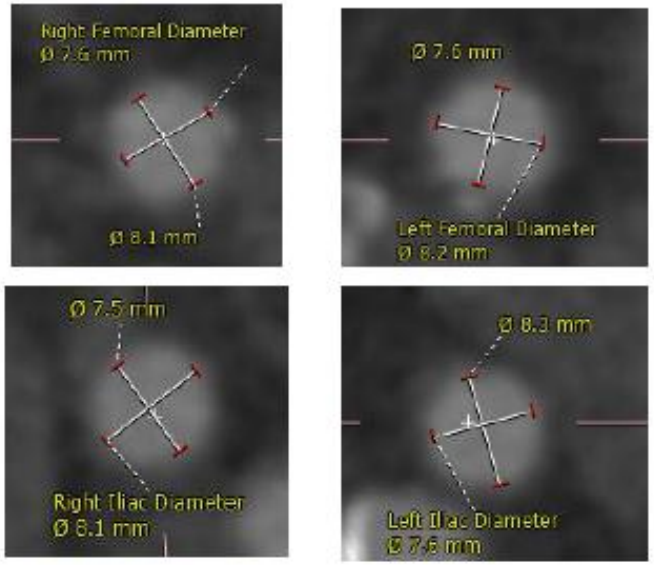
9.0 x 9.0 RIA min. diameter

8.0 x 9.0 LFA min. diameter

9.0 x 9.0 LIA min. diameter

(all in mm)

Clinical Analyst's Image



7.6 x 8.1 RFA min. diameter

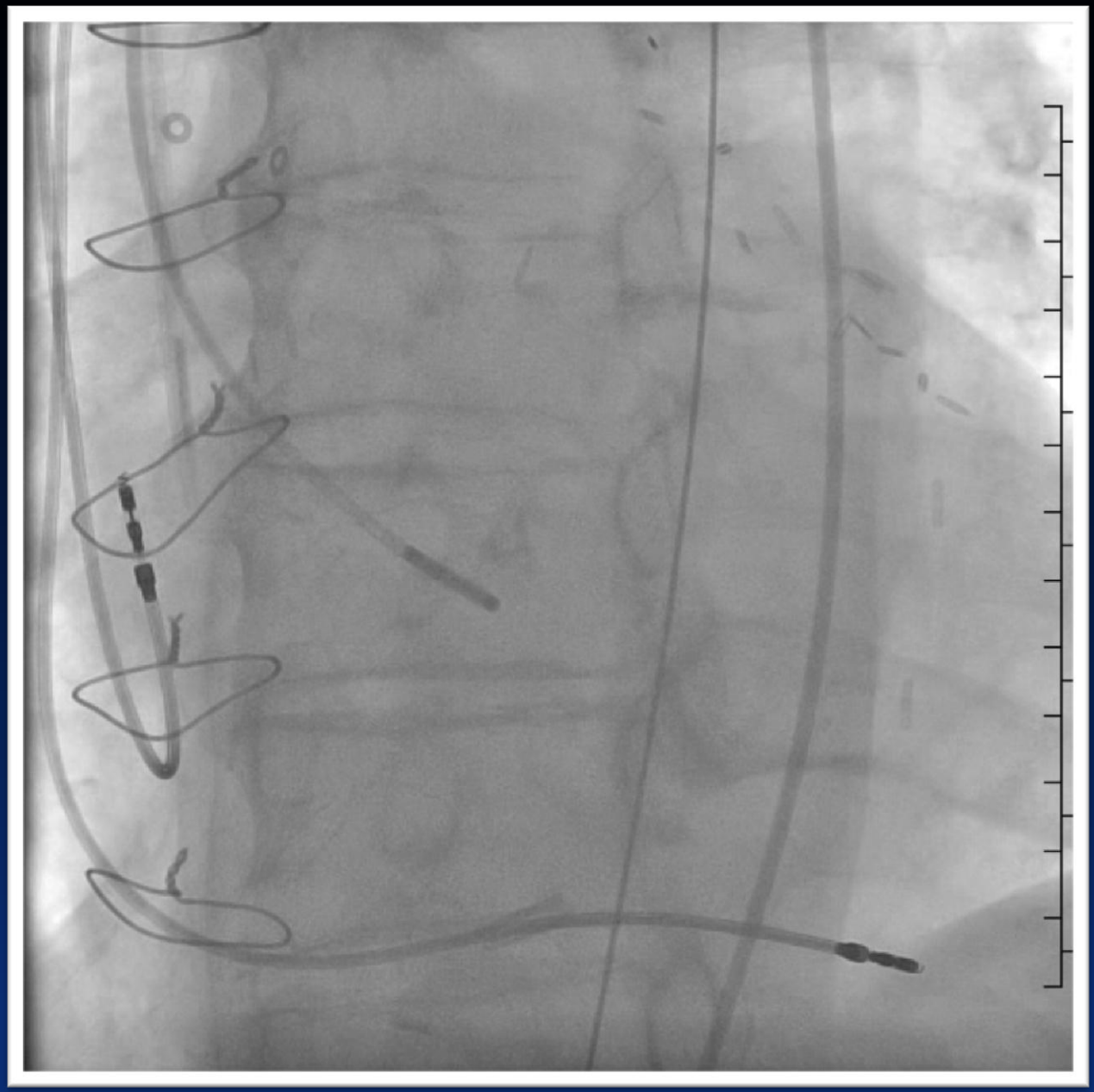
7.5 x 8.1 RIA min. diameter

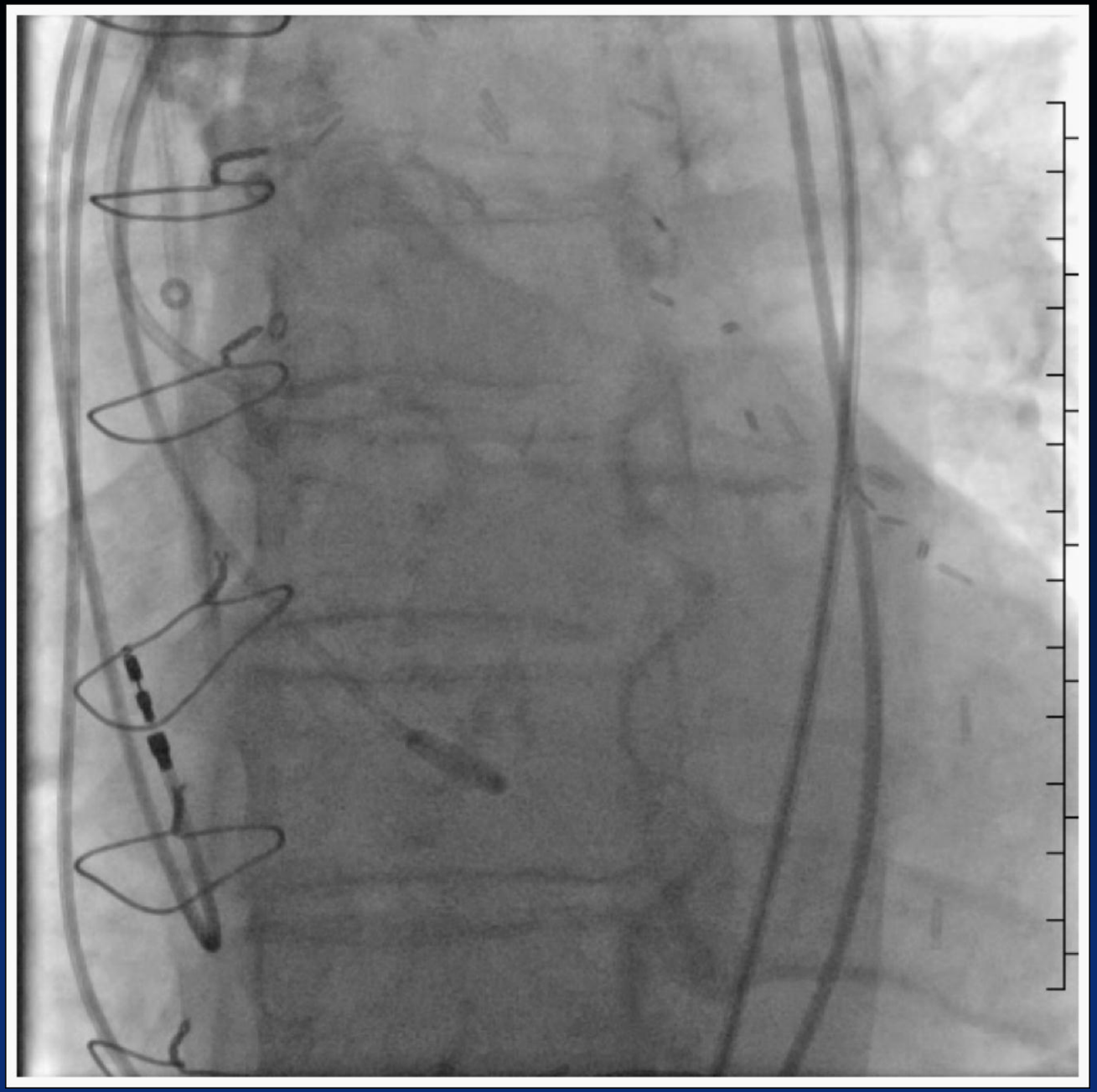
7.6 x 8.2 LFA min. diameter

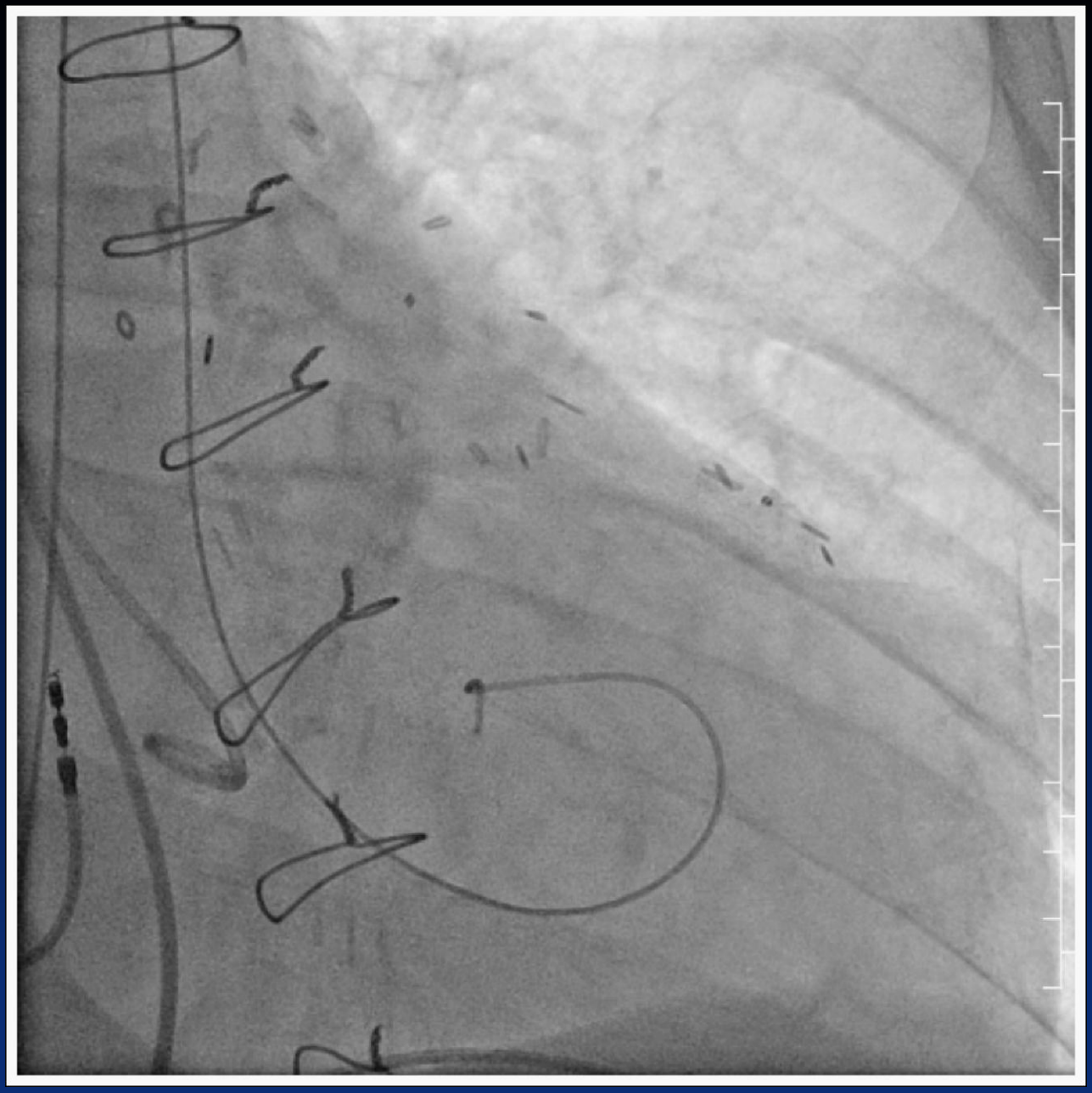
7.6 x 8.3 LIA min. diameter

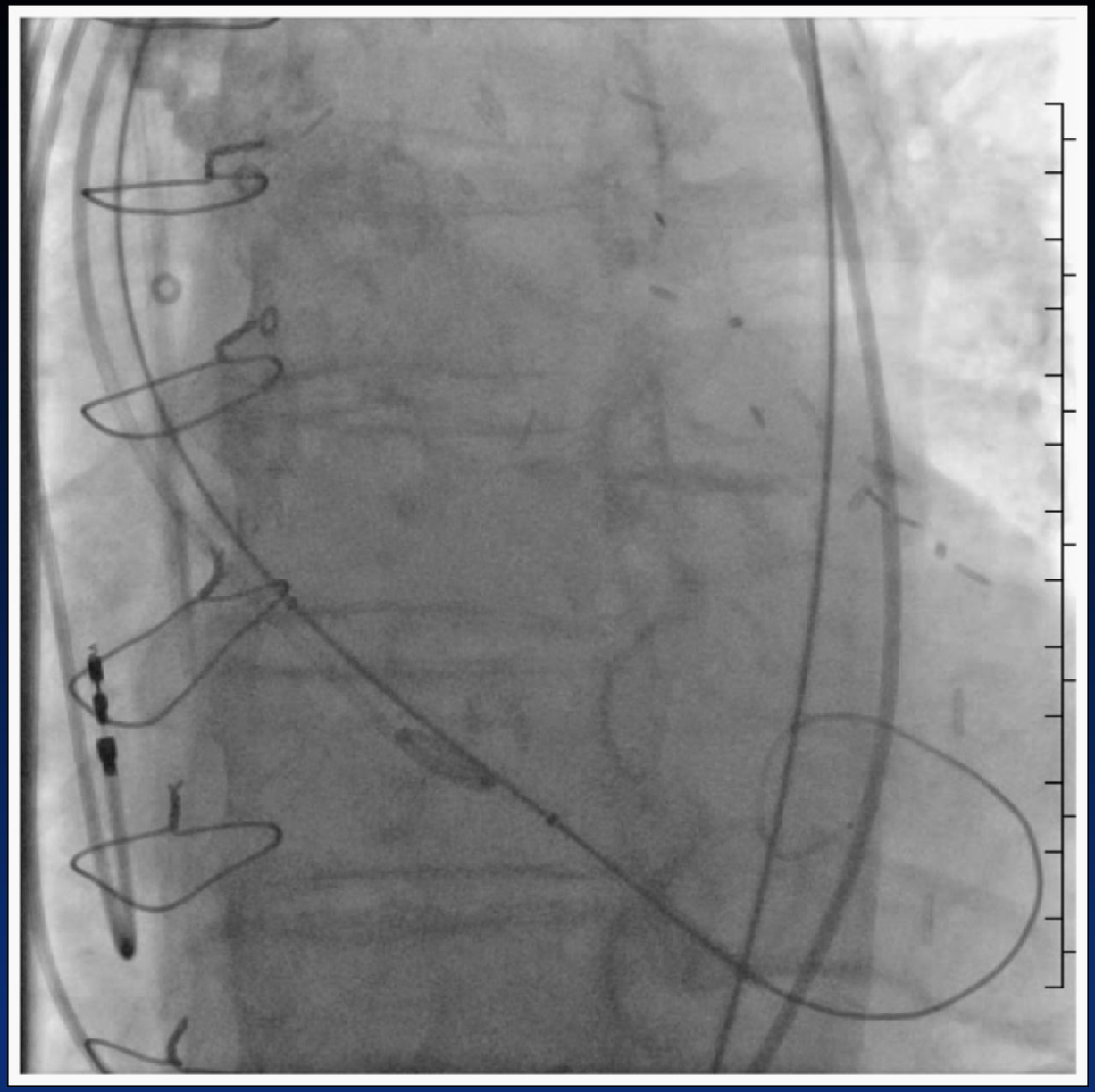
(all in mm)

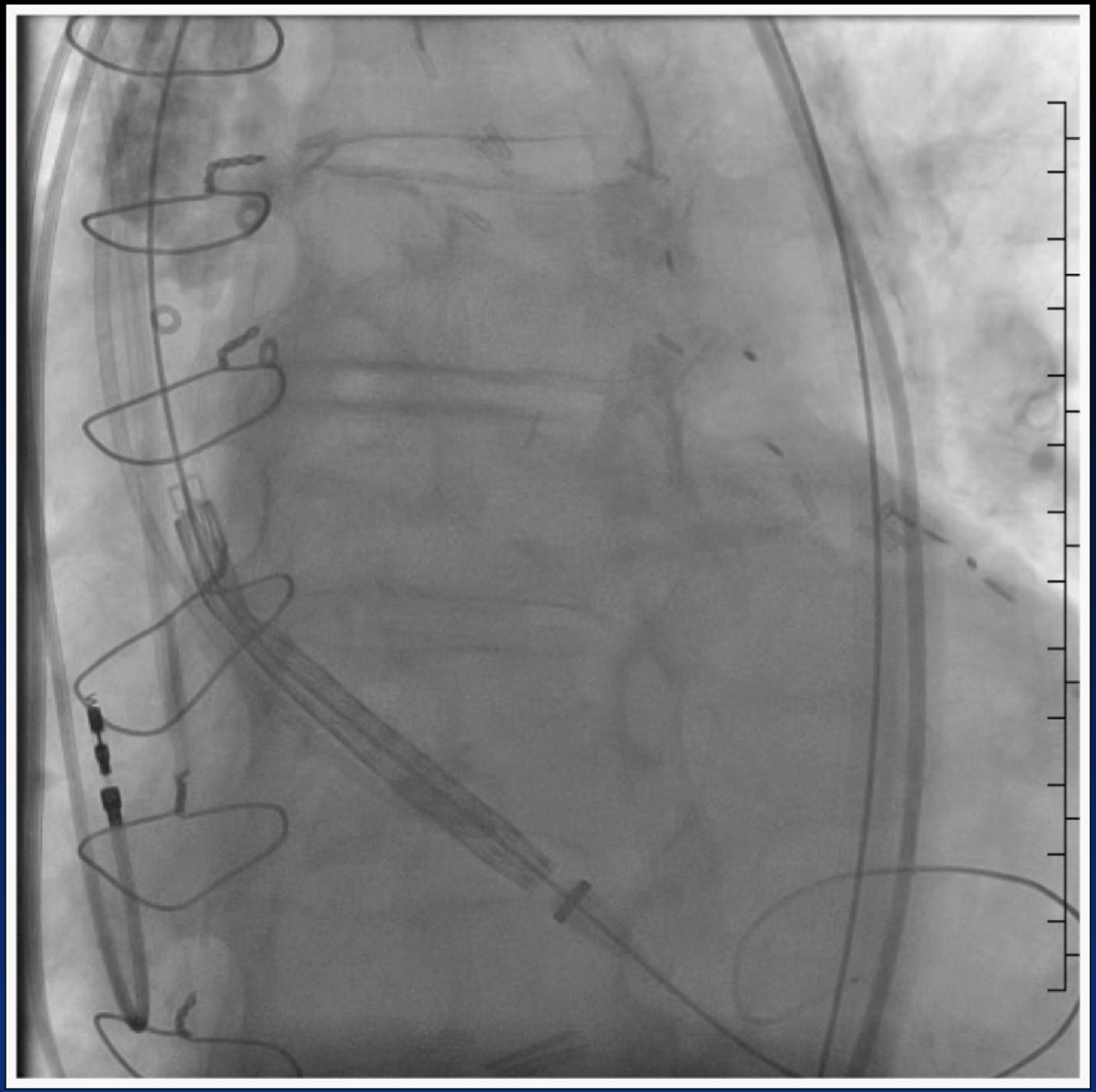
femoral artery measurements start at mid femoral head

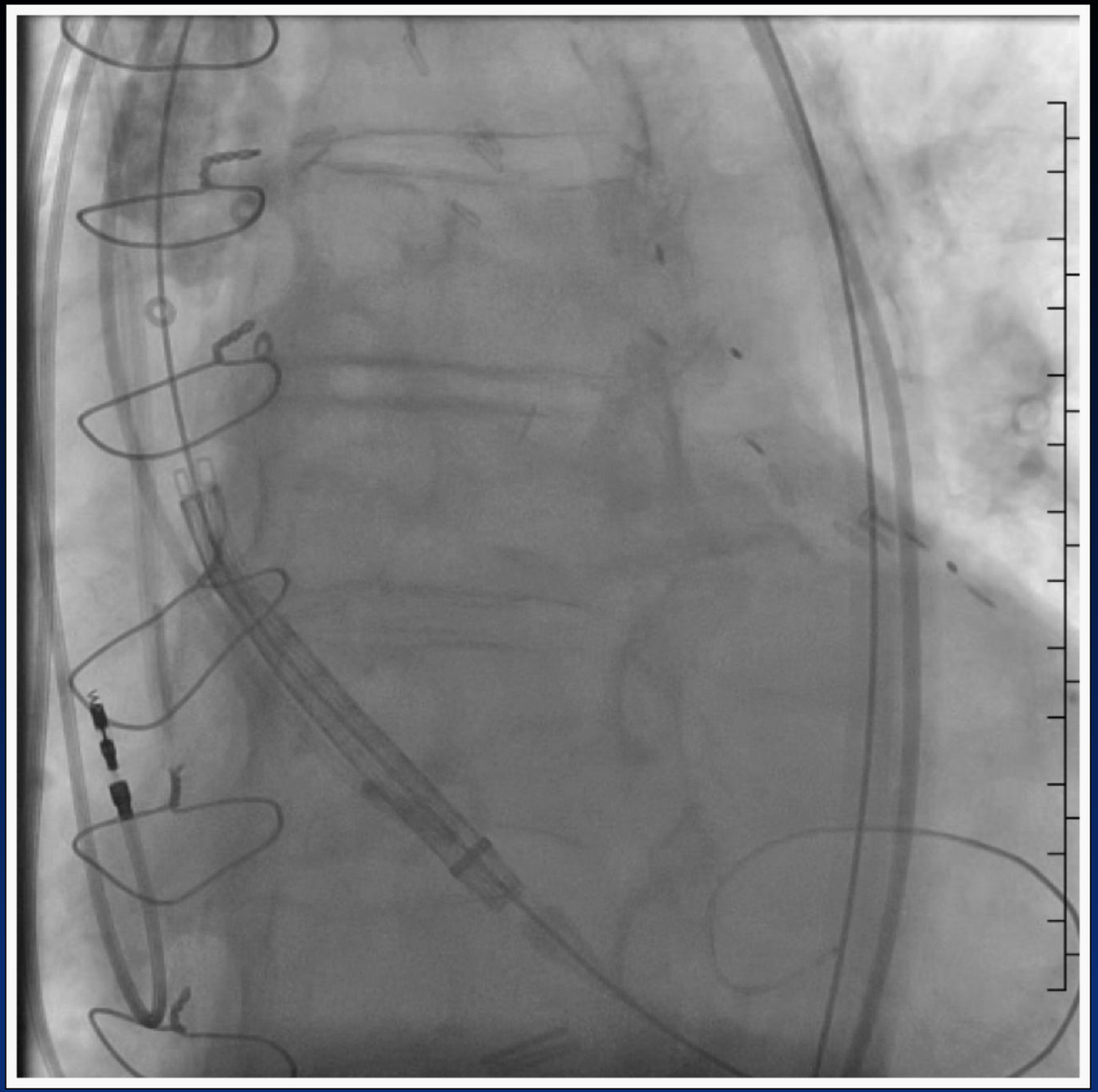


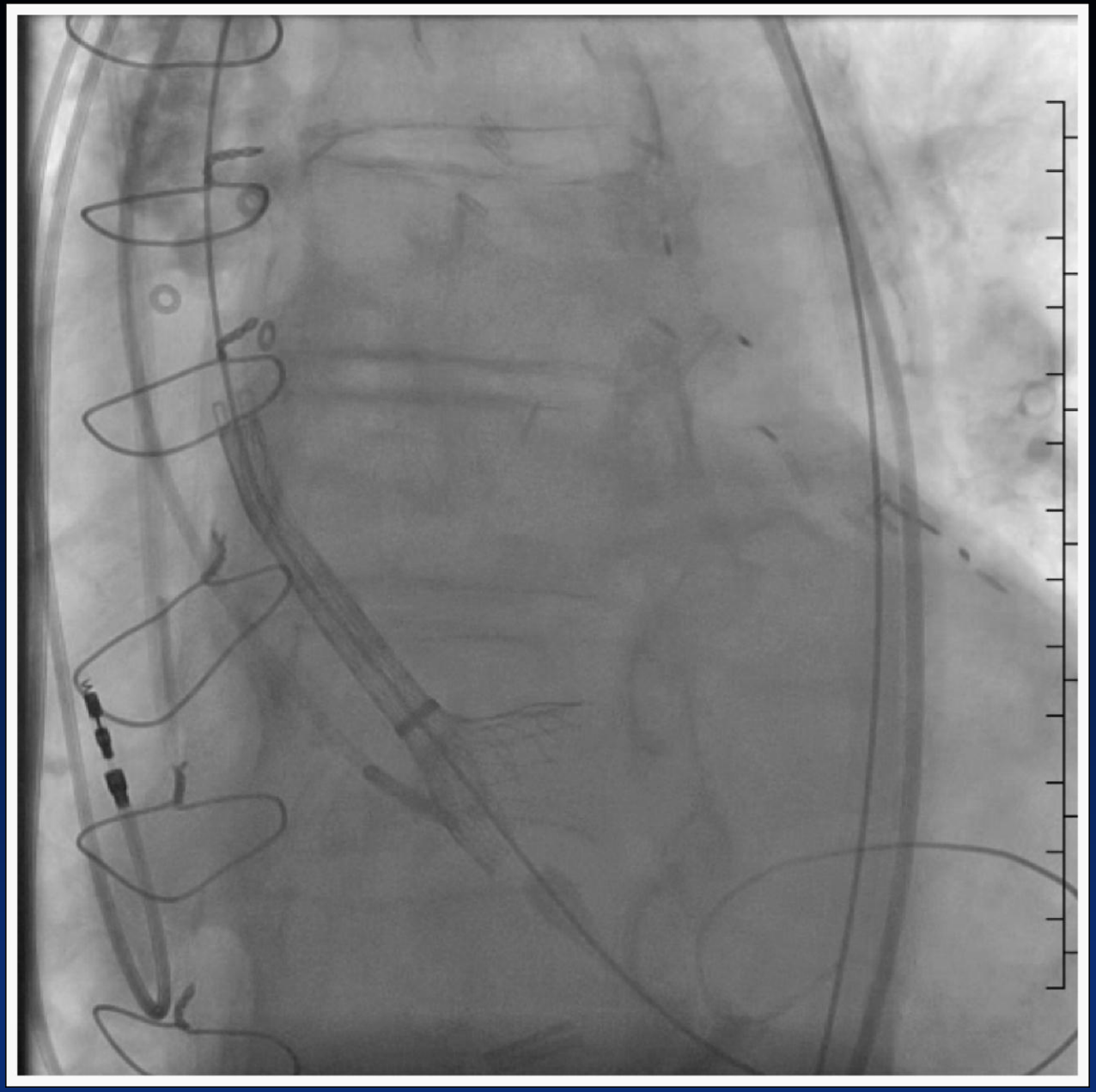


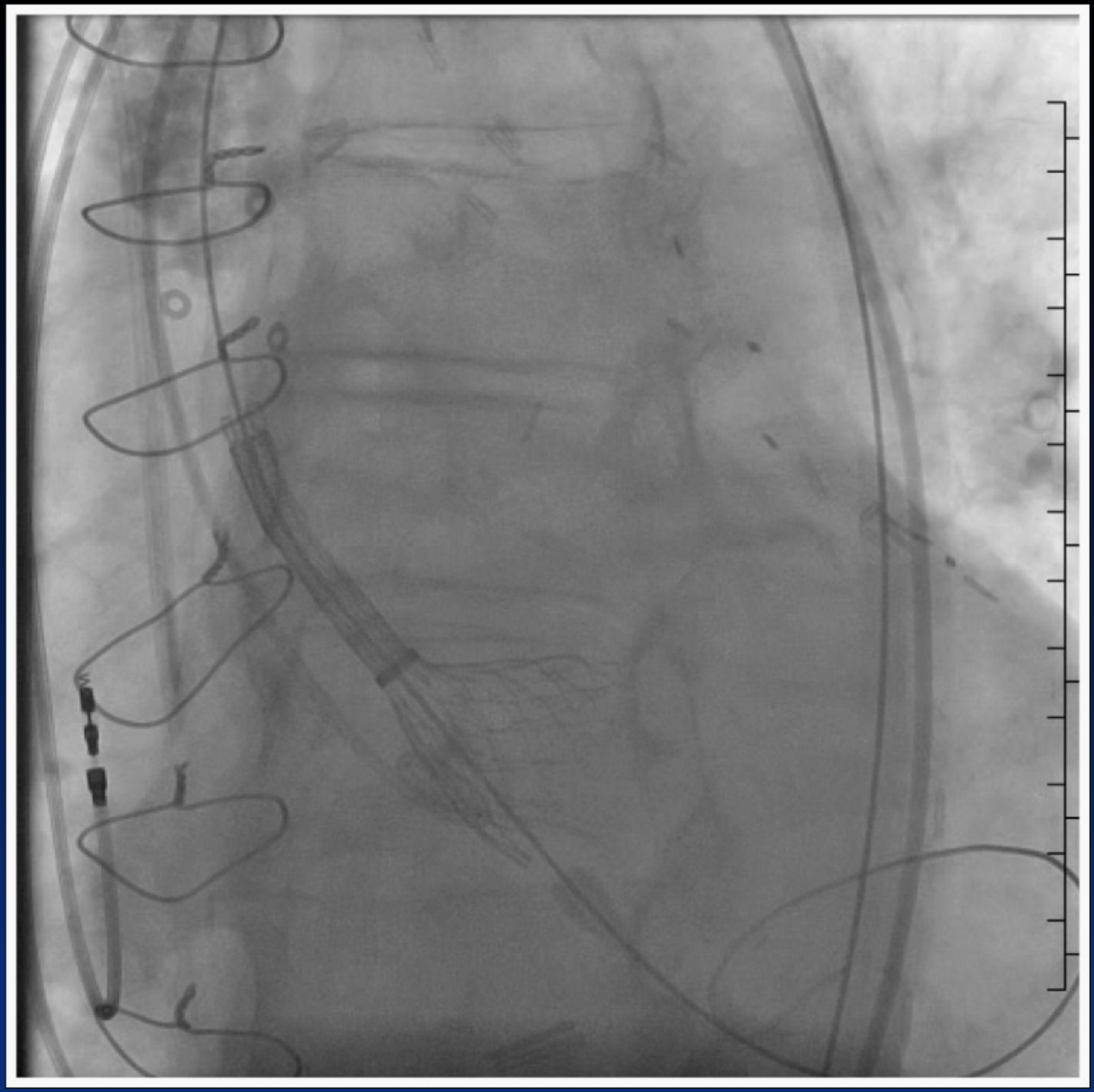


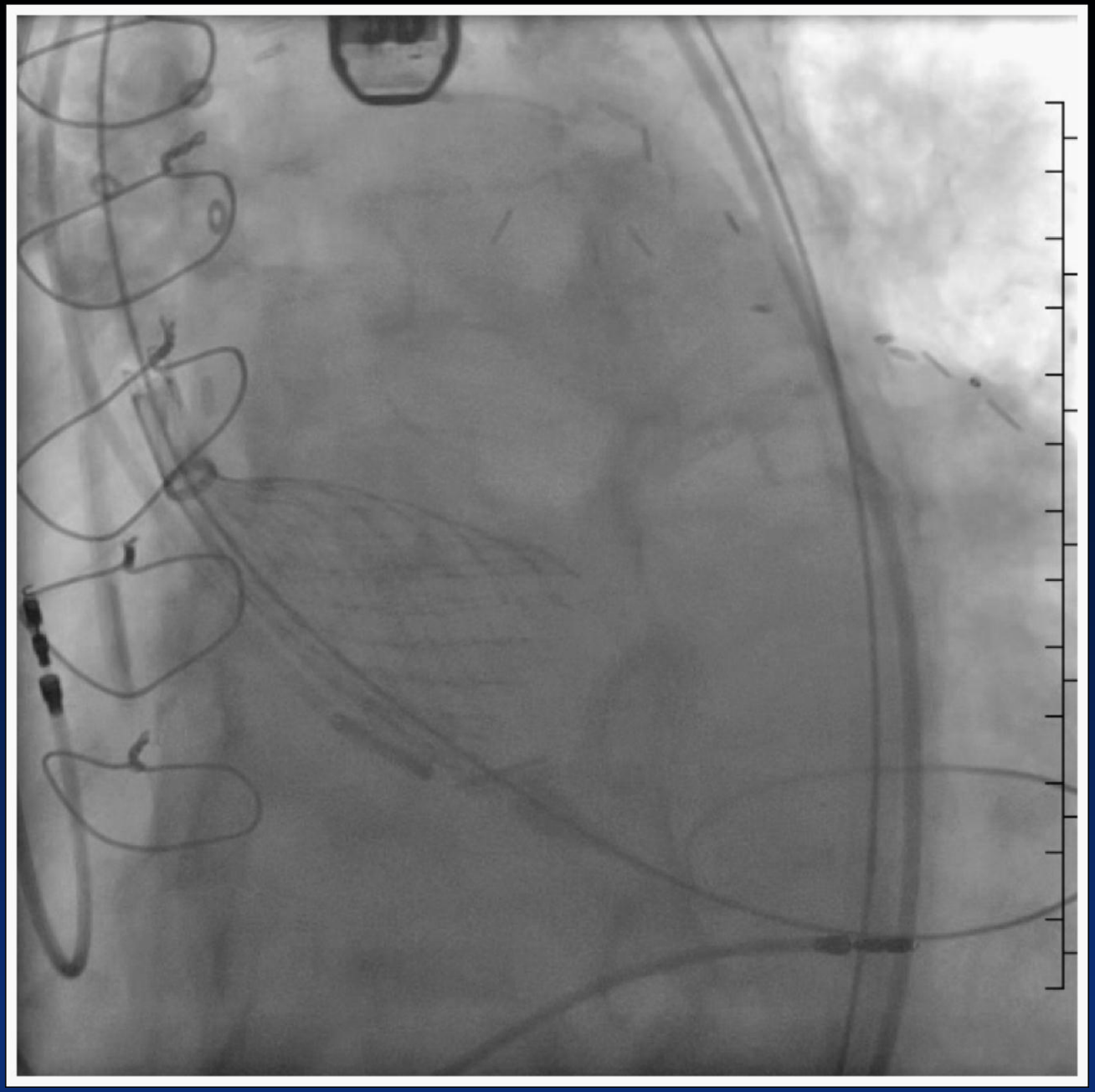


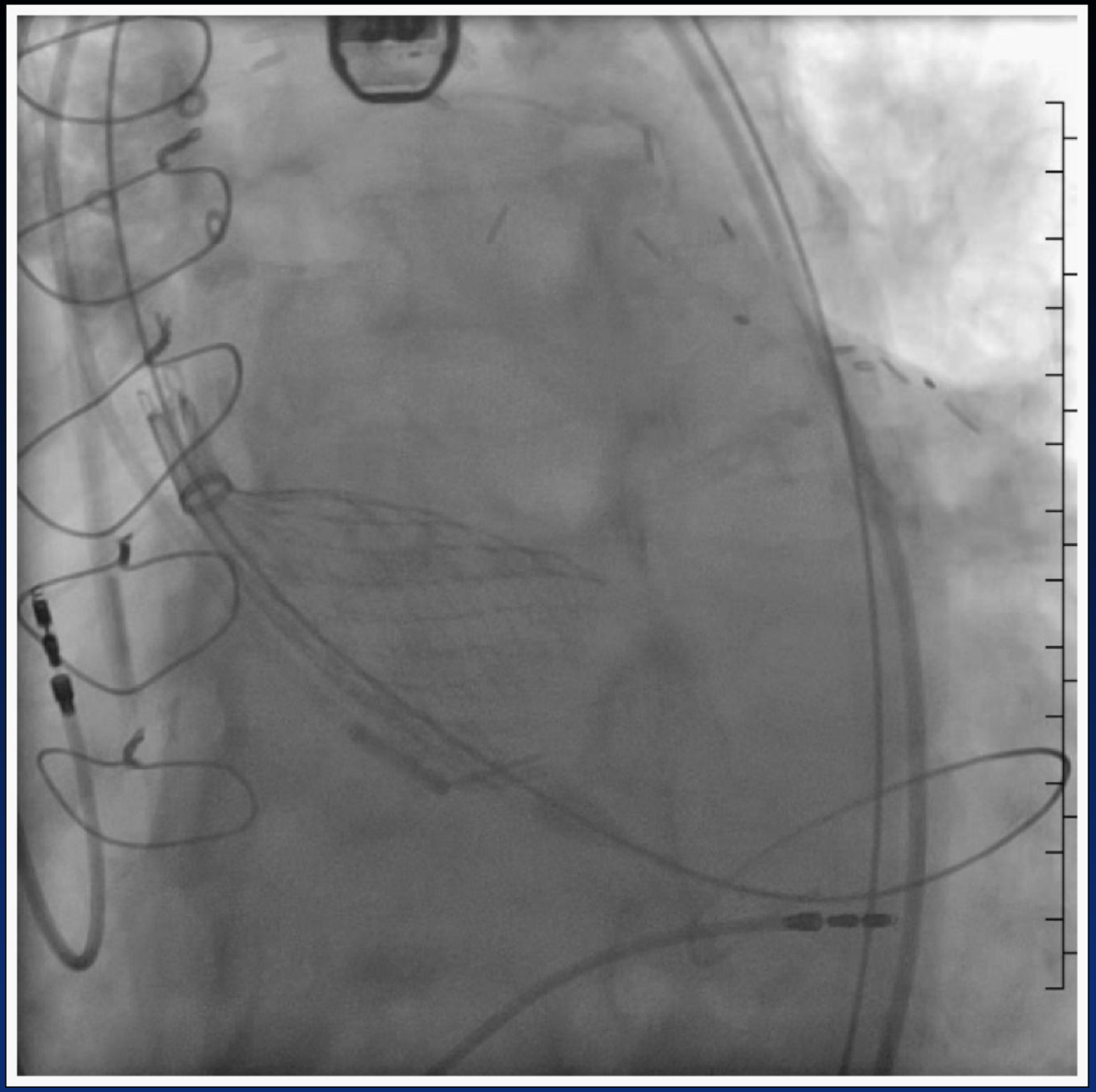




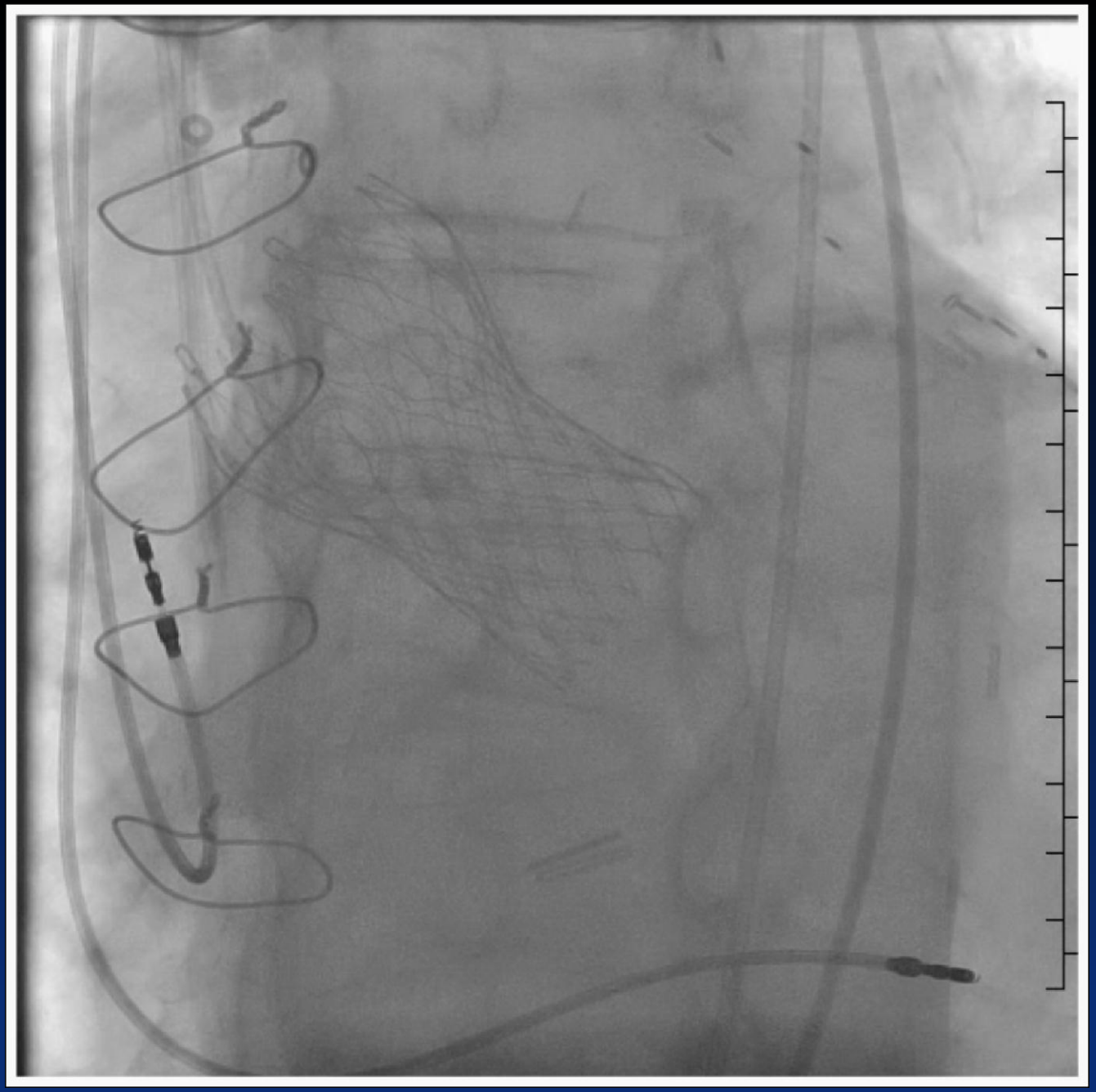




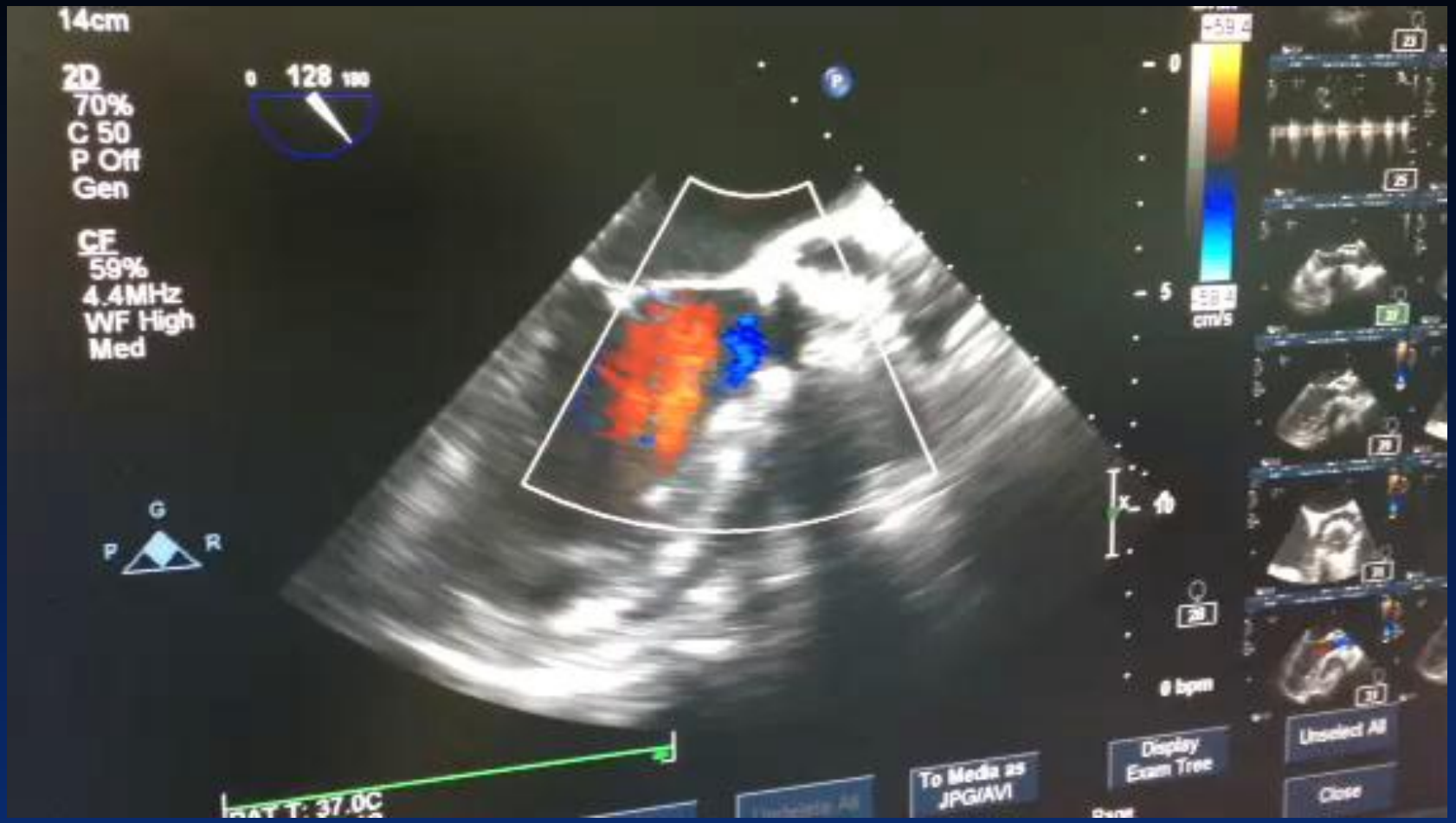




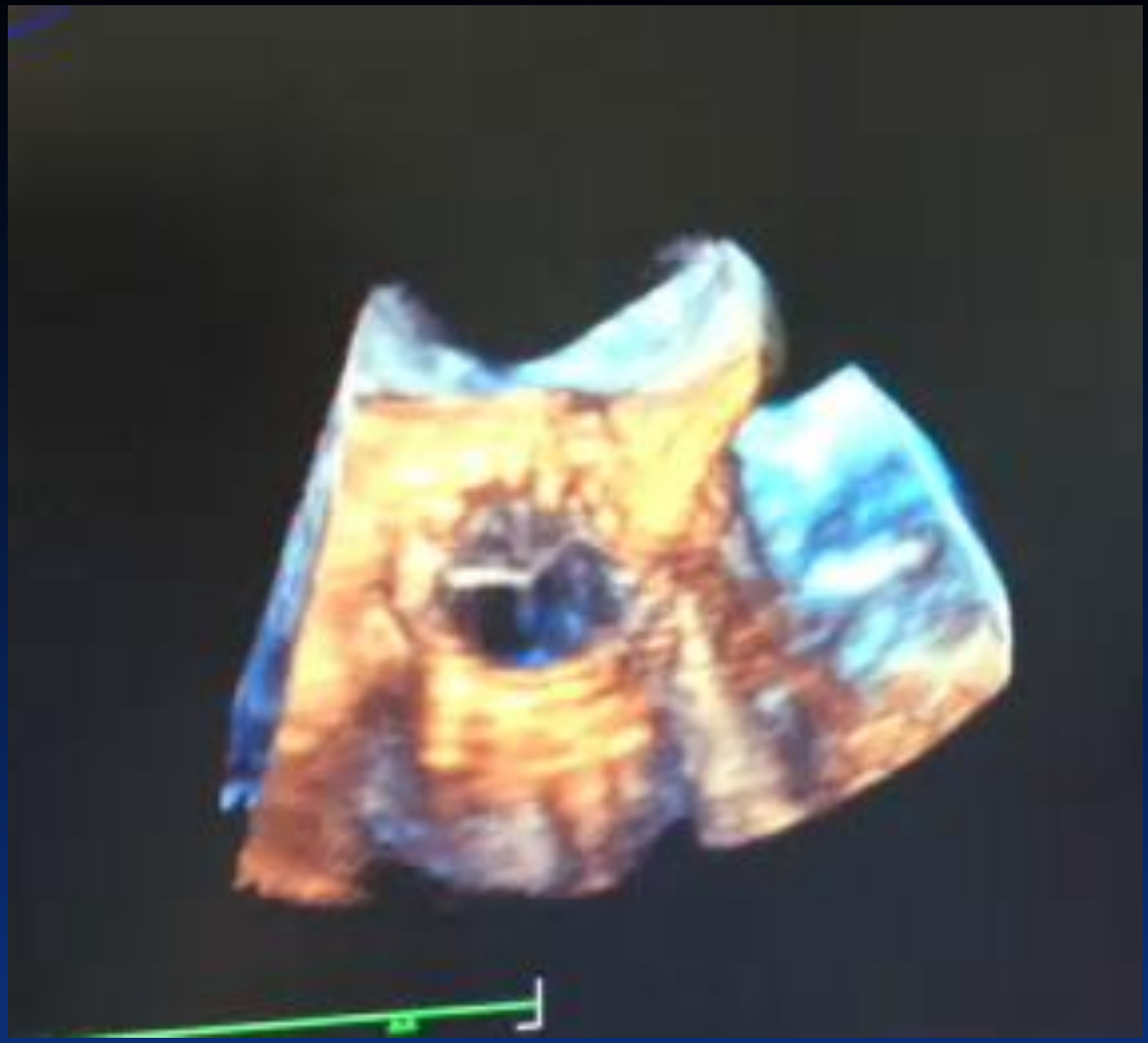

14cm
2D
68%
C 50
P Off
Gen
0
128
180
G
P
R




200
100
0
0/0
Pump I/O


14cm
2D
70%
C 50
P Off
Gen
CE
59%
4.4MHz
WF High
Med
0
128
180
G
P
R
0
-5
cm/s
0 bpm
Display Exam Tree
To Media as JPG/AVI
Unselect All
Close

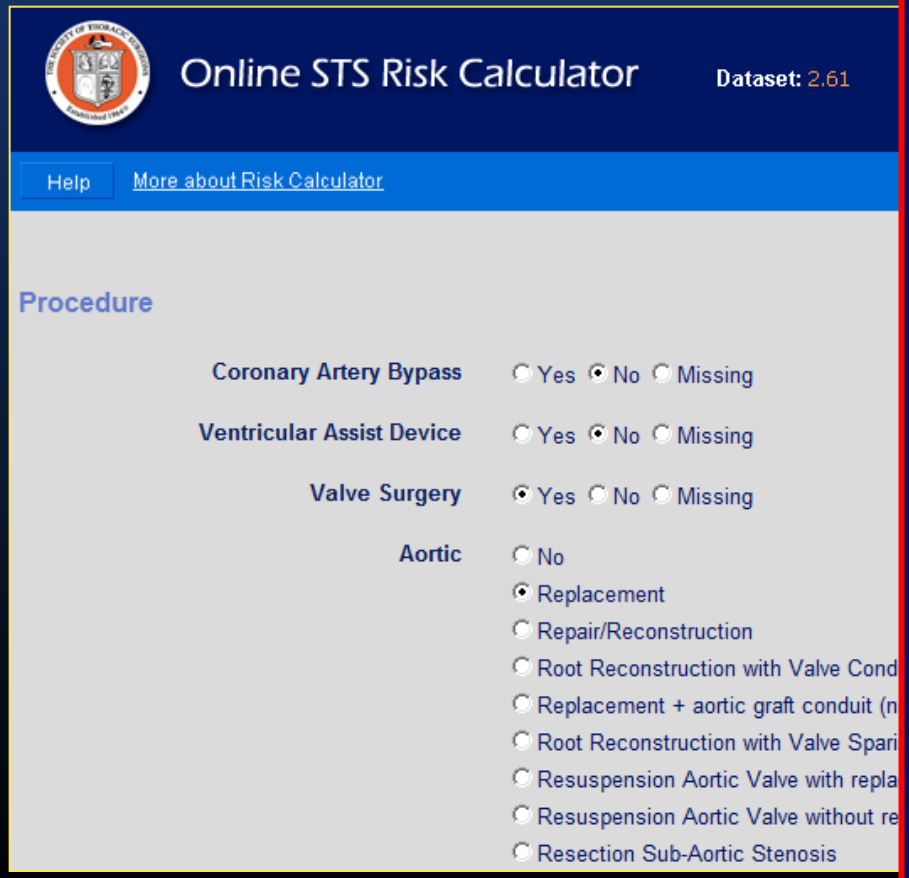

C 50
P Off
Gen
CE
50%
4.4MHz
WF High
Med



History

- 89 year old male Ht: 5’10” Wt 205 lbs
- NYHC IV CHF and DOE
- HTN, DM, CAD
- Atrial Fibrillation on Chronic Warfarin
- Prior CVA with Nearly Complete Recovery
- Former Smoker - Quit in 2000
- FEV1 of 59% Predicted
- Creatinine 1.8 mg/dl
- Hb 10.2 gm/dl and Hct 32.1
- Lives with wife independently; 5M walk – 4 sec

History

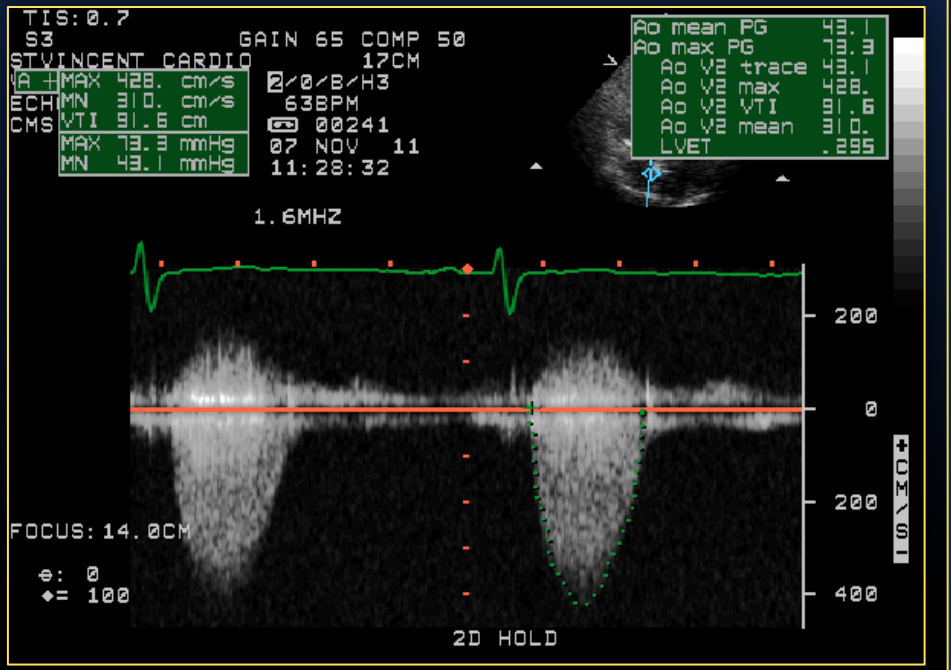


Calculations

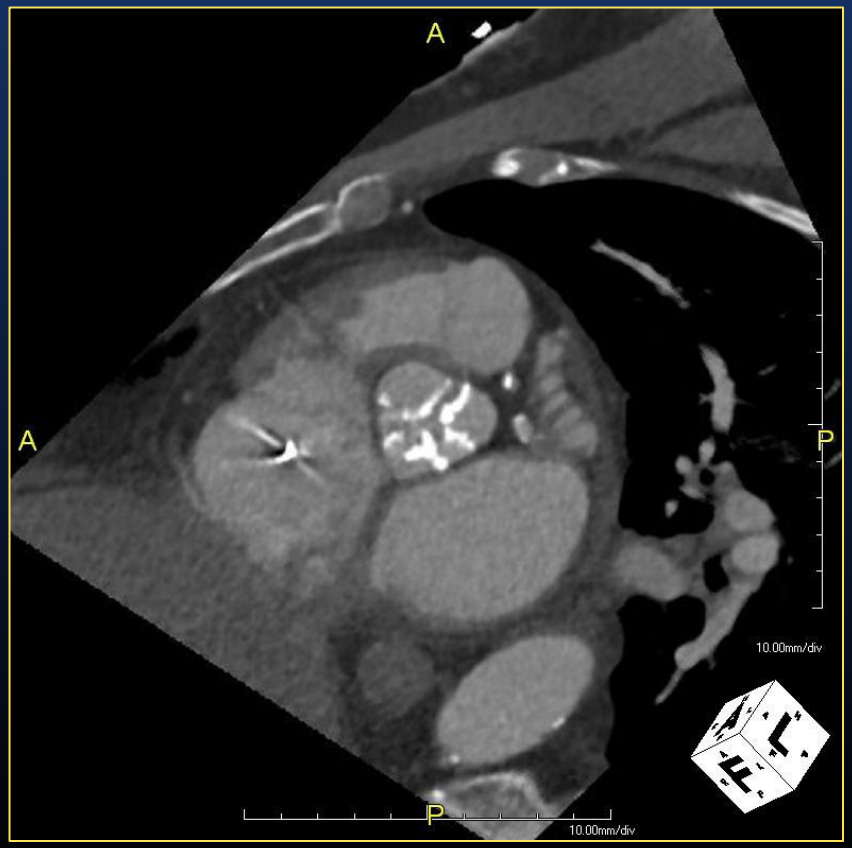
Procedure Name	**Isolated AVRepl**
Risk of Mortality	**17.1%**
Morbidity or Mortality	**53.4%**
Long Length of Stay	**39.8%**
Short Length of Stay	**4.7%**
Permanent Stroke	**4.4%**
Prolonged Ventilation	**43.8%**
DSW Infection	**0.7%**
Renal Failure	**31.3%**
Reoperation	**18.3%**

Baseline Echocardiography

- Peak AV Velocity - 4.3 M/sec
- Peak AV Gradient - 73 mmHg
- Mean Gradient - 43 mmHg
- EF – 55%
- Estimated PAP - 55/26 mmHg
- LVOT – 22 mm
- MR 2+
- TR 1+



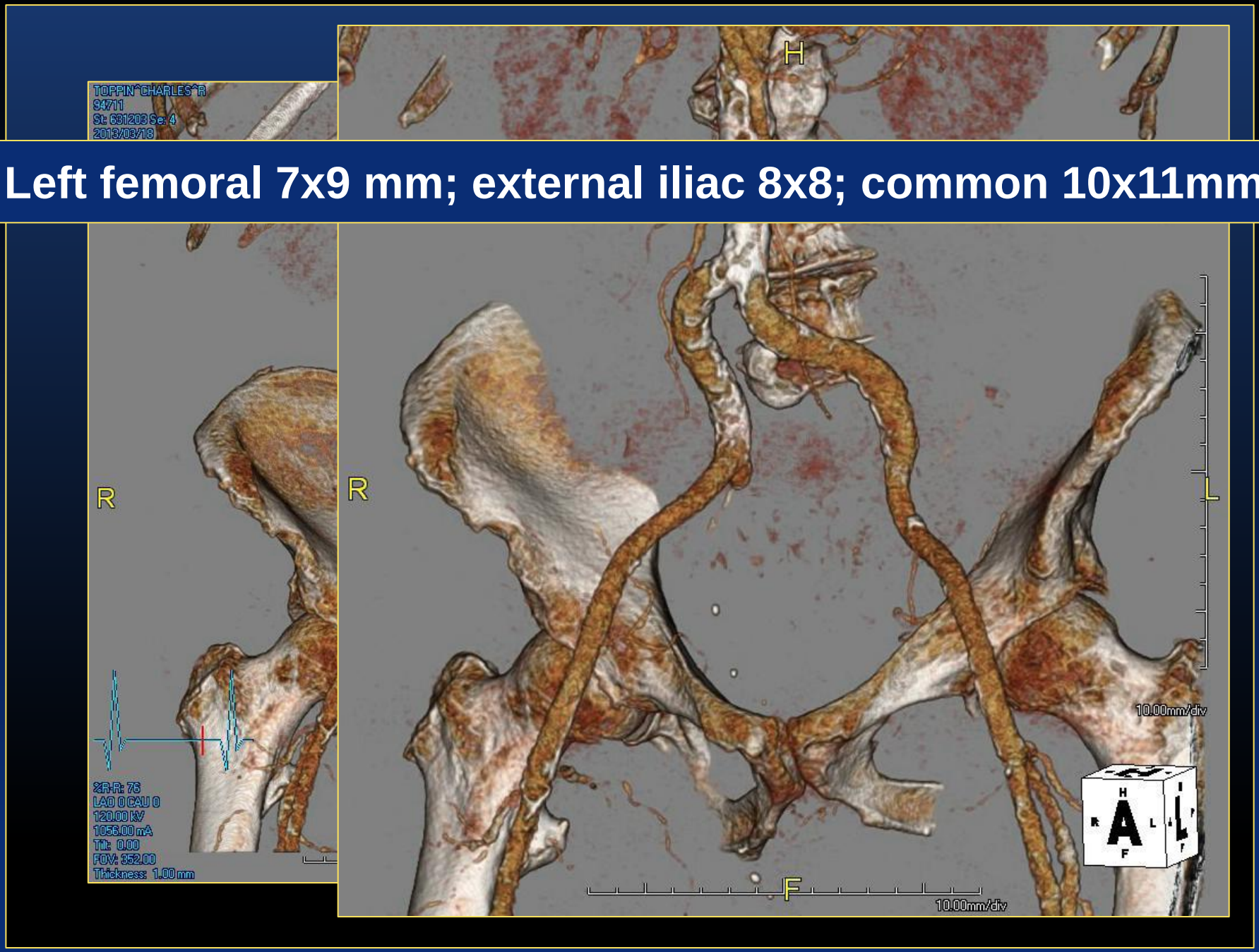
Annulus/Root Assessment



Heavily Calcified Tri-leaflet Valve

Annulus/Root Assessment

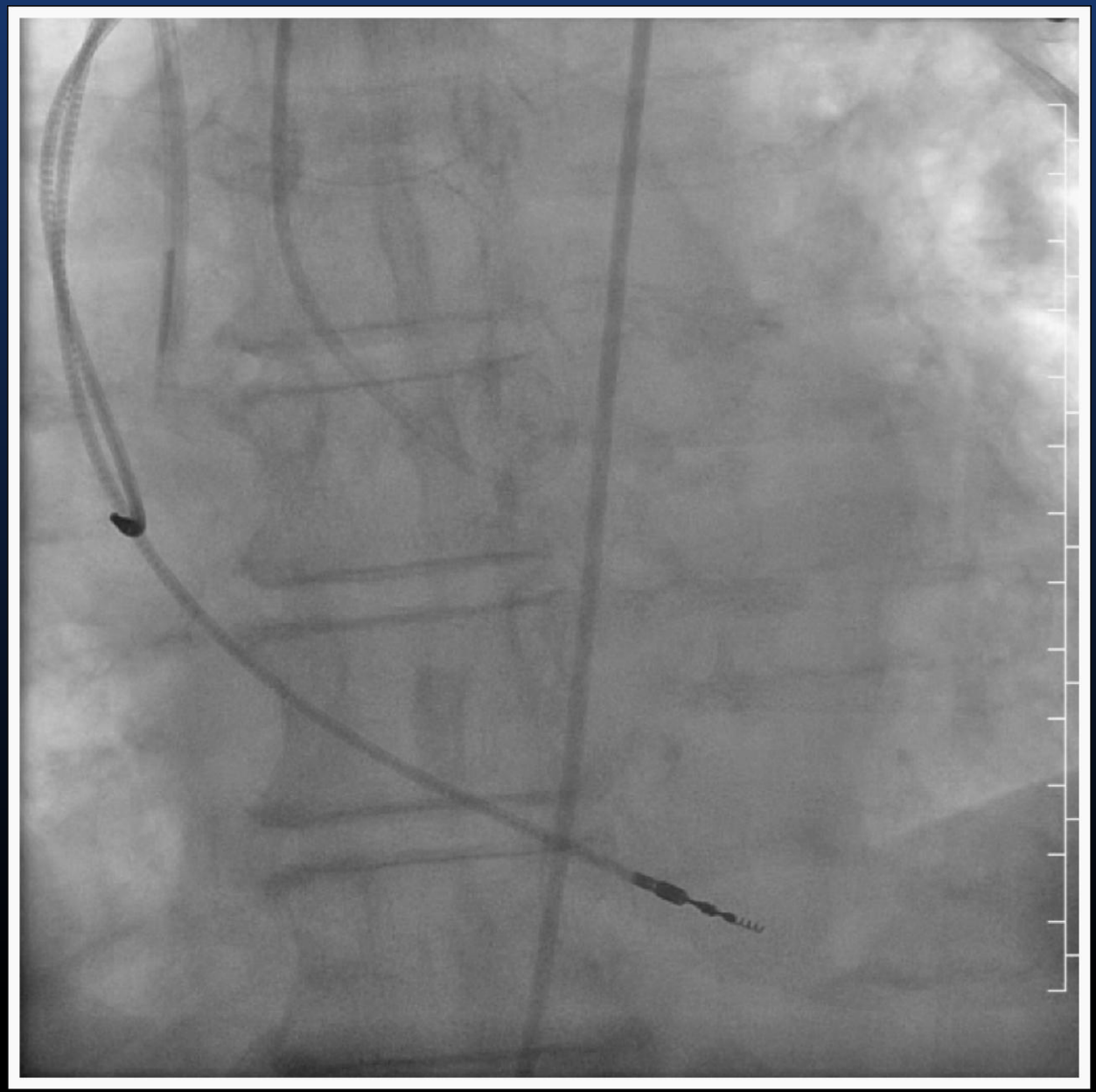
Coronary Height 17 and 19 mm; Ascending Ao 31 mm

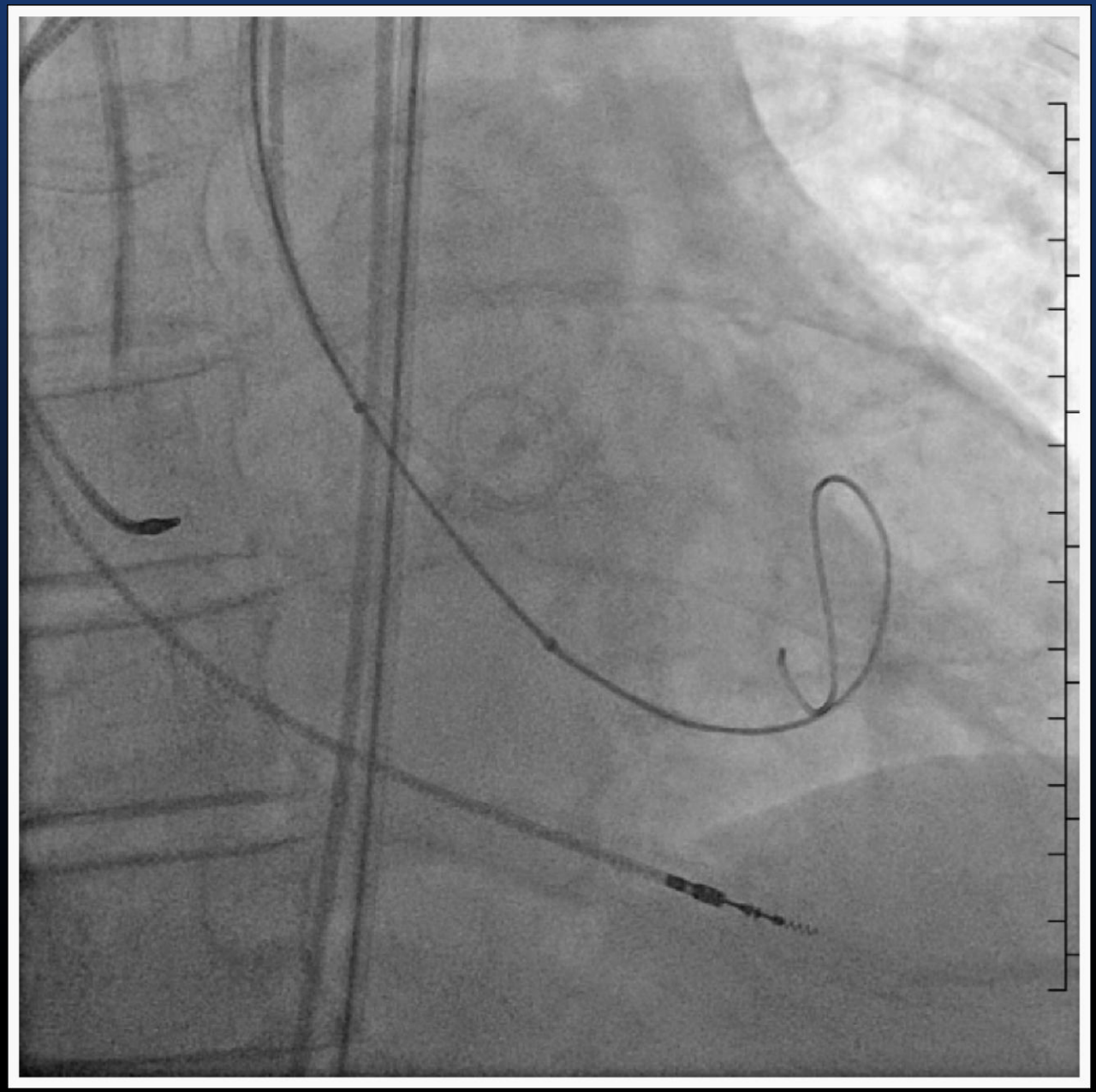


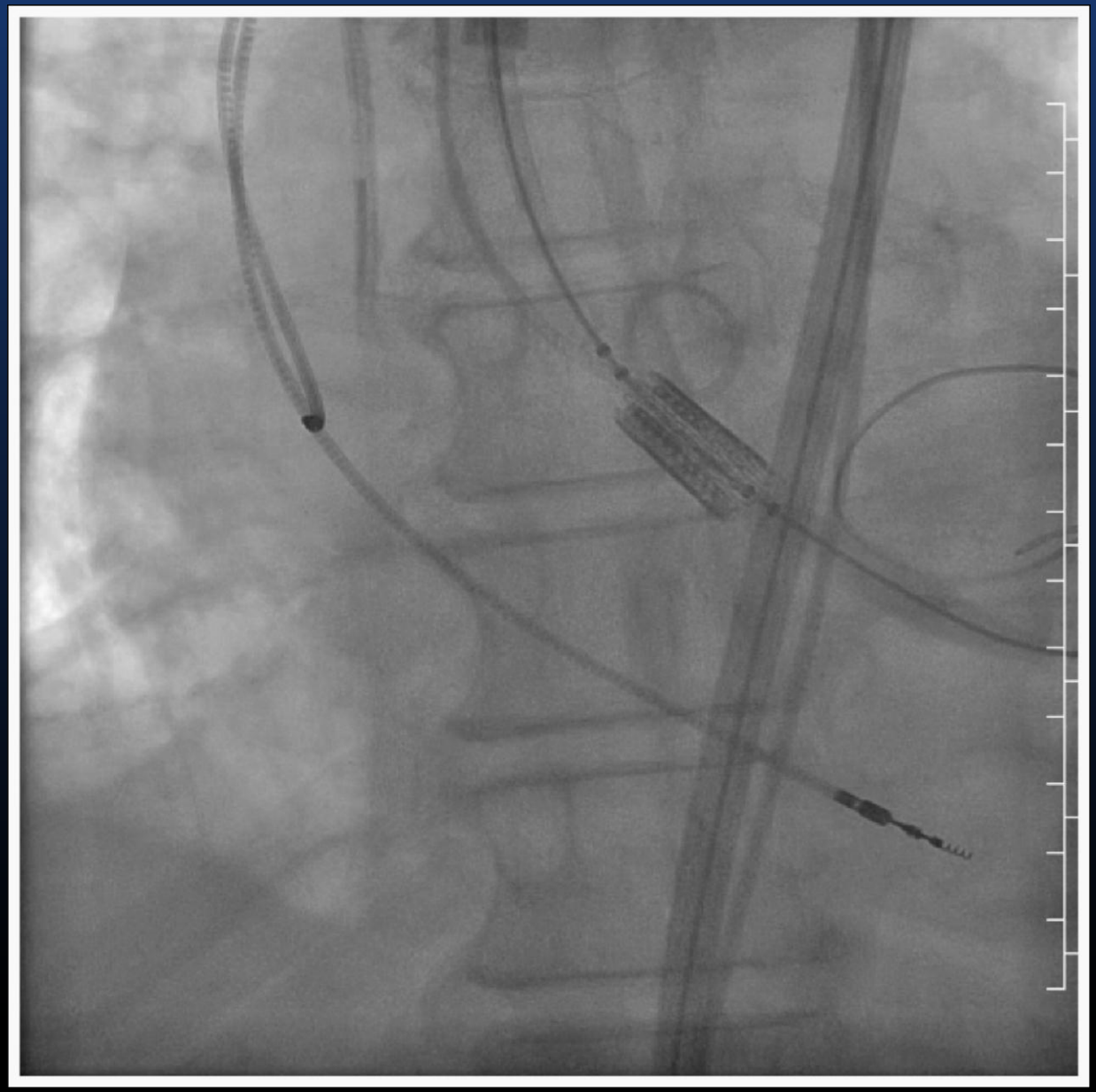
Left femoral 7x9 mm; external iliac 8x8; common 10x11mm

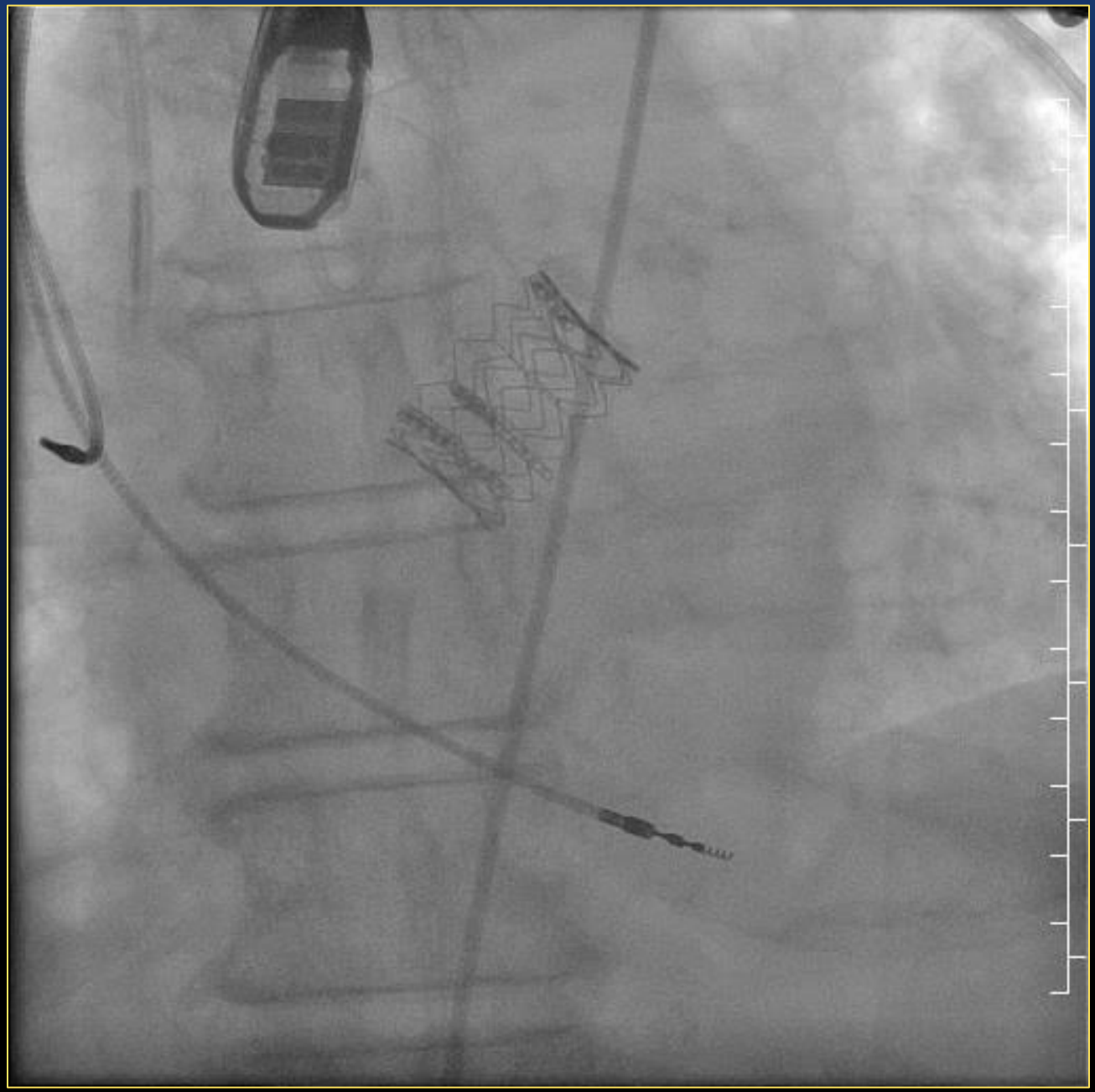
What was Done

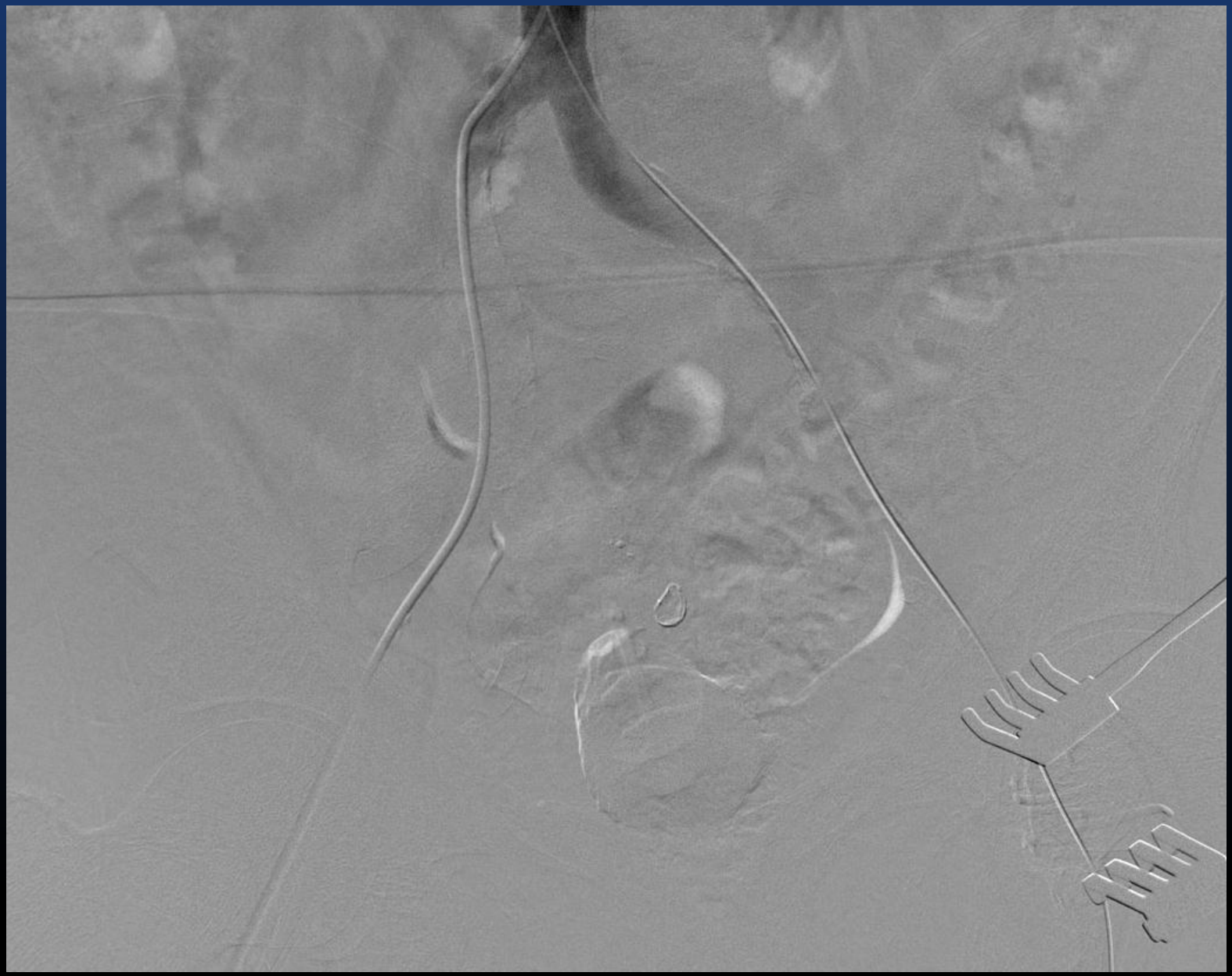
- Trans-Femoral TAVR
- 26 mm Edwards-Sapien
- General Anesthesia/TEE
- Left Femoral







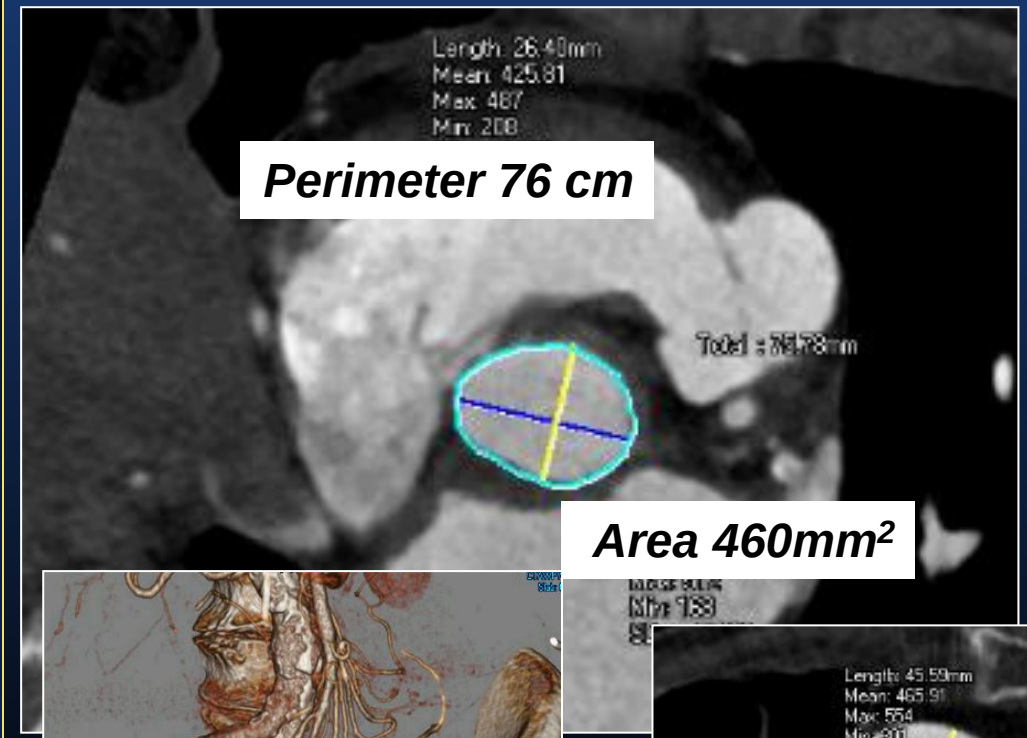


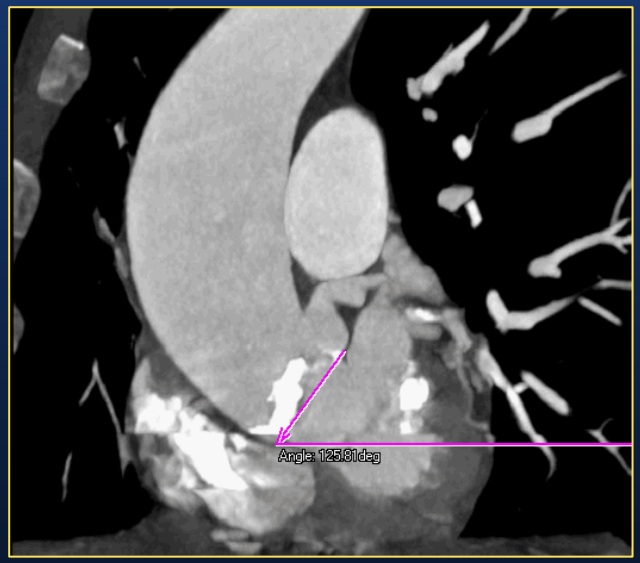


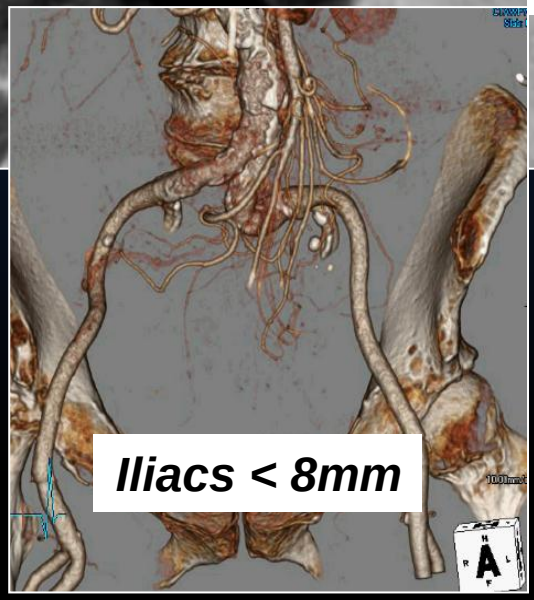
Post Procedure

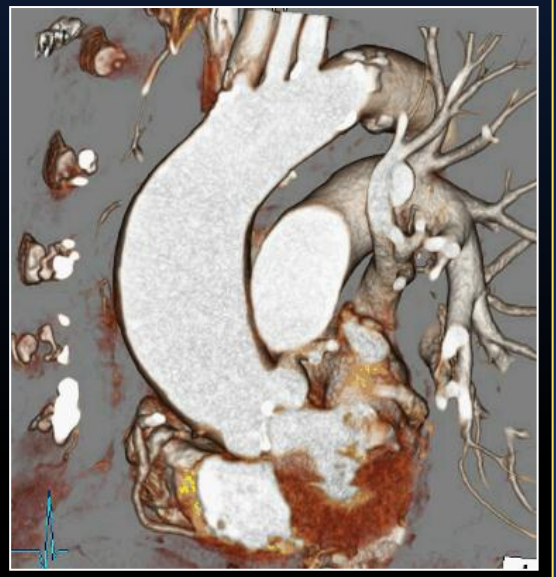
- Procedure time – 35 minutes
- TEE – No AI with appropriate valve positioning
- Extubated on table
- Ambulating that evening
- Creatinine peaked to 2.0 mg/dl and at discharge 1.6 mg/dl
- Home day 3

91 year old severe AS







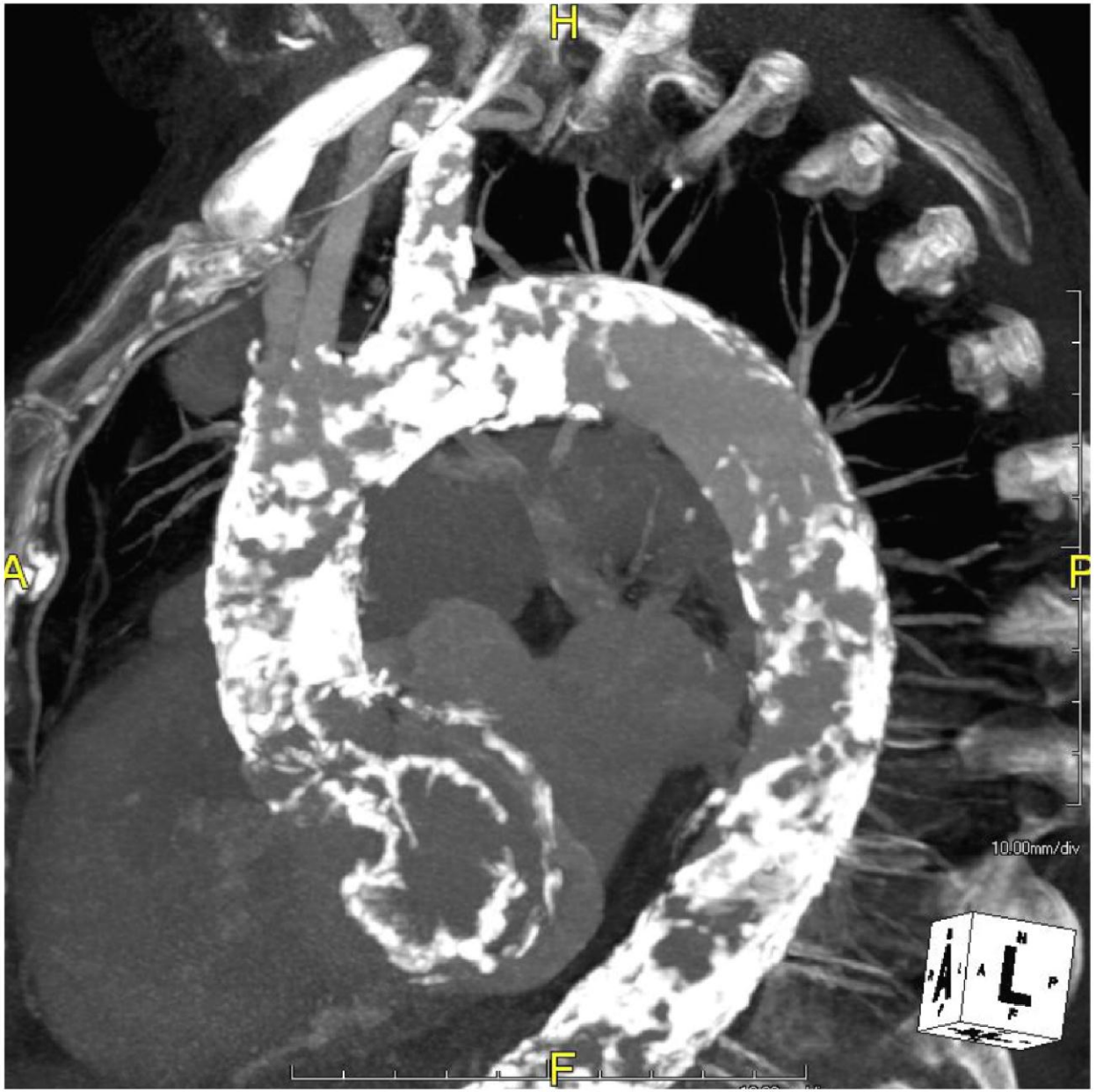


History

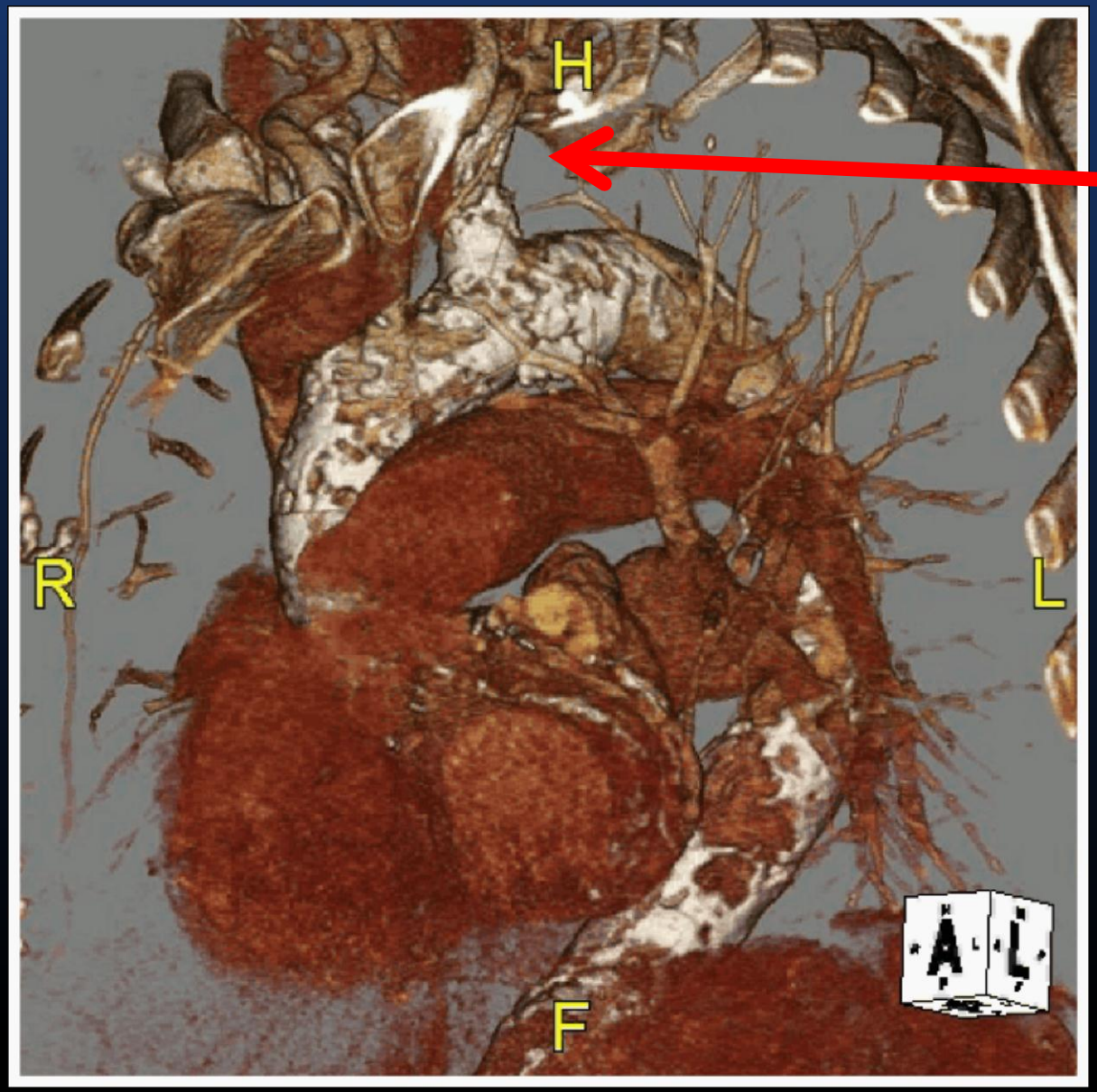
- *84 year old*
- *Severe AS with FC IV CHF, atrial Fib*
- *COPD on home O2*
- *Hx Non-Hodgkins Lymphoma*
- *Pulmonary HTN – 70mm Hg & Mild-Mod TR*
- *Peak aortic valve velocity 4.6 M/sec*
- *Mean Aortic Vale Gradient 54 mmg Hg with valve area of 0.7 cm2*
- *Severely Calcified Porcelain Aorta & Frail*
- *Femoral-Iliacs - <5 mm in diameter & calcified*

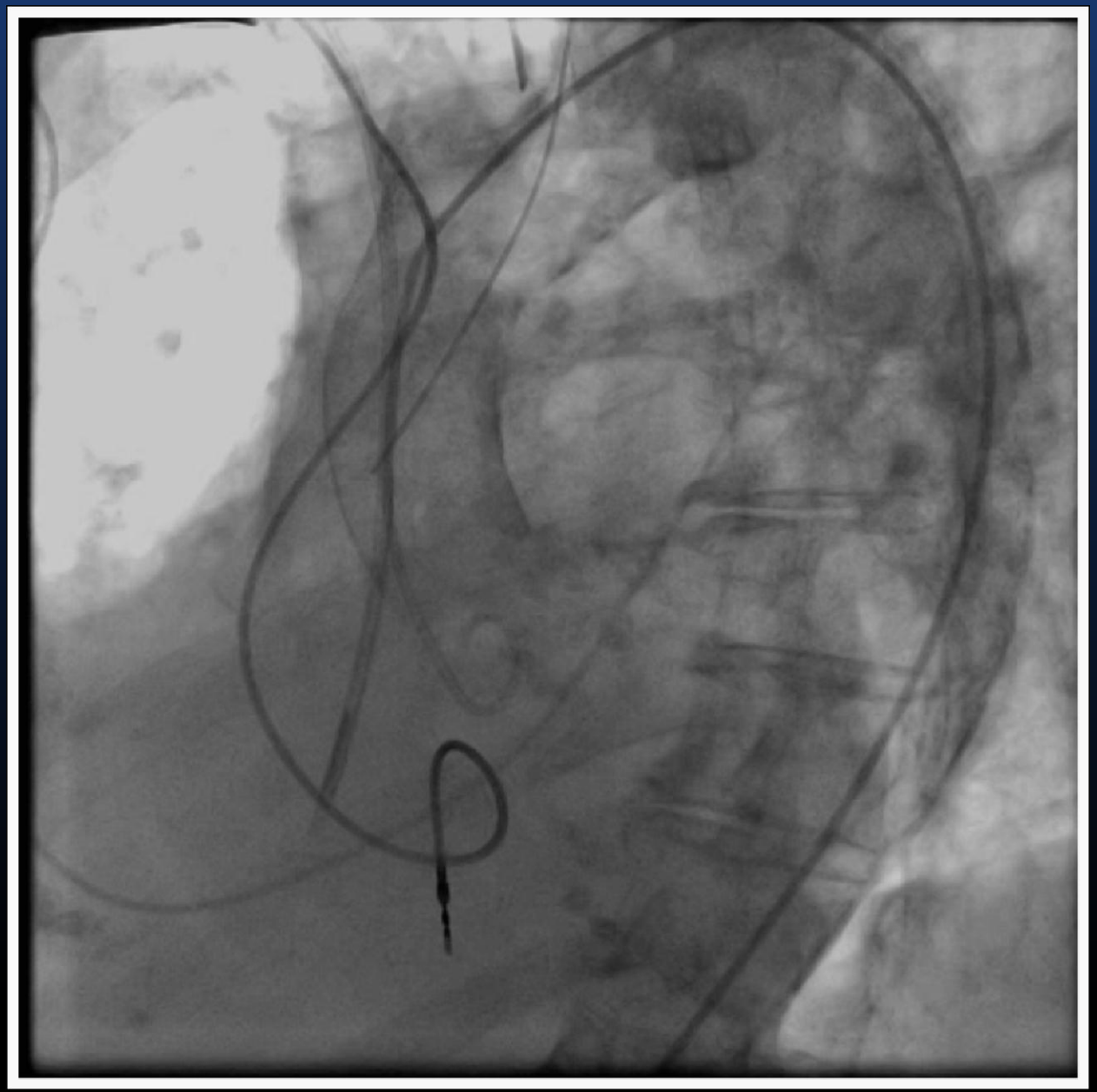
Vascular Measurements

- 22 mm Aortic annular size with perimeter of 75 mm
- SOV 27mm
- 40.5 mm ASC aorta diameter
- Severe concentric femoral/iliac calcification and tortuosity
- Max diameters of femorals 5 mm


H
A
P
F
10.00mm/div
L

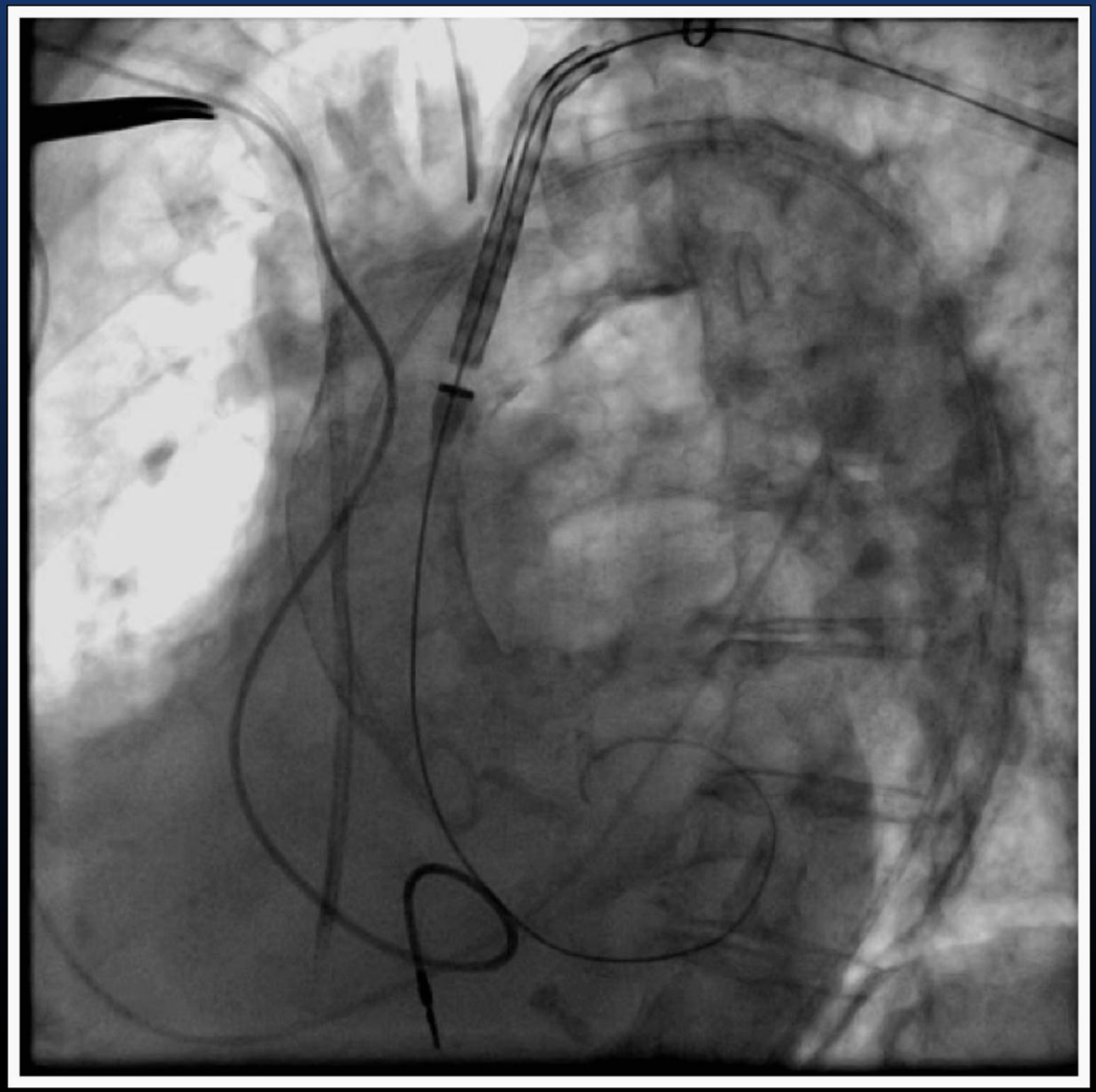
- *Right subclavian 4mm min size*
- *Left subclavian smallest diameter 5.8 x 7.2 mm*



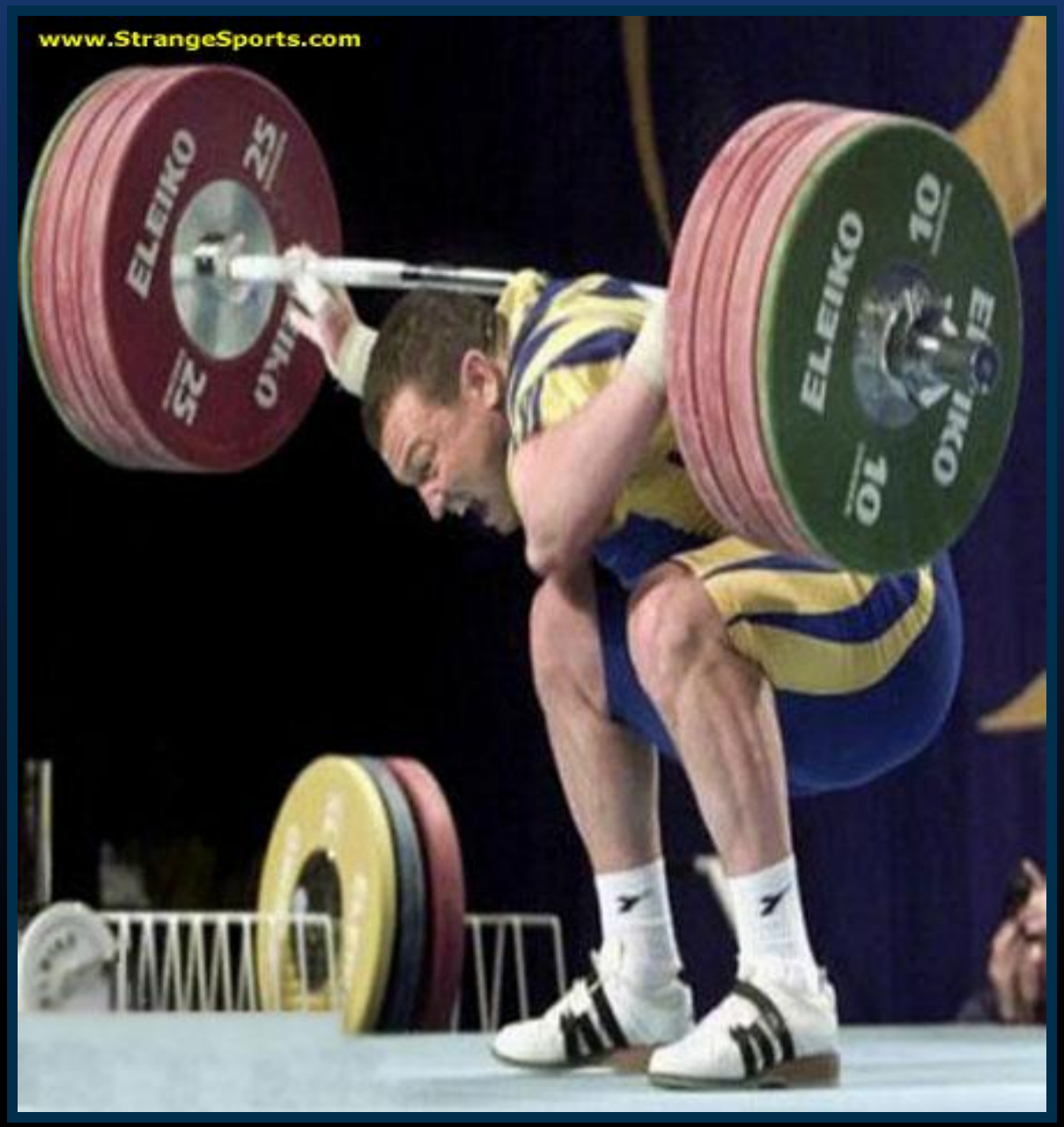


- *St Jude sheath just past vertebral – would not turn into aorta*

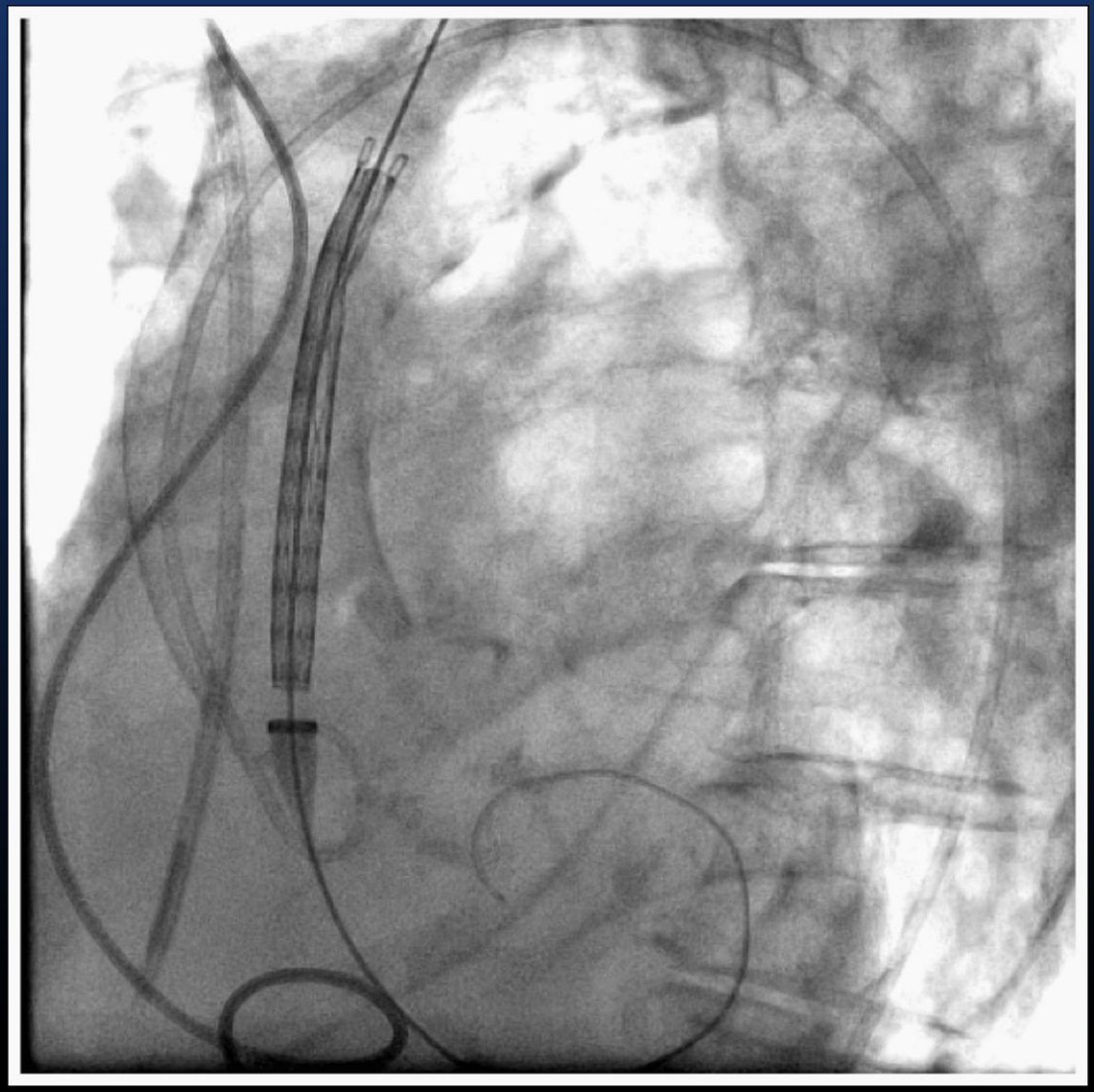
- *Following valvuloplasty with 20 mm balloon*
- *Deliver CoreValve*



A little push



- *Deliver CoreValve*



Post Procedure and F/U

- *Uneventful post procedure course – equal BP's both arms*
- *1 month follow up – normal LV function, trivial AI, and estimated RV pressure 42 mm Hg preserved LV function; equal BP's in both arms*