Single-Branch Endograft Advantages for Arch Pathology Repair

Ali Azizzadeh, MD, FACS

Director, Vascular Surgery
Vice Chair, Department of Surgery
Associate Director, Heart Institute

Cedars-Sinai Medical Center
Los Angeles, CA

13th International Symposium on Endovascular Therapeutics

School of Medicine, University of Barcelona
27th to 29th MARCH 2019

Aortic Arch: Challenging Pathology

- Tortuosity
- Movement
- Non-uniform diameter
- Apposition
- Branches
- Cardiac output
- Previous open surgery
- Complications
  - Stroke
  - RTAAD

Aortic Arch Pathologies

Aneurysm
- Fusiform
- Saccular

Dissection
- Acute vs. Chronic
- Uncomp vs. Comp

Acute Aortic Syndromes
- IMH
- PAU

Traumatic
- Acute
- Chronic

Genetic/Connective
- Marfans
- Ehlers/Danlos
- Loeys-Dietz
- Familial

Infectious/Mycotic
- ABF/AEF

Coarctation

ARSCA

Tumors

Aortic Arch Treatment Options

- Open Repair
- Hybrid repair
- Chimney/Snorkel Sandwich
- In-situ fenestration
- Single-branch devices (investigational)
- Multi-branch devices (investigational)
- Physician modified endografts (IDE)

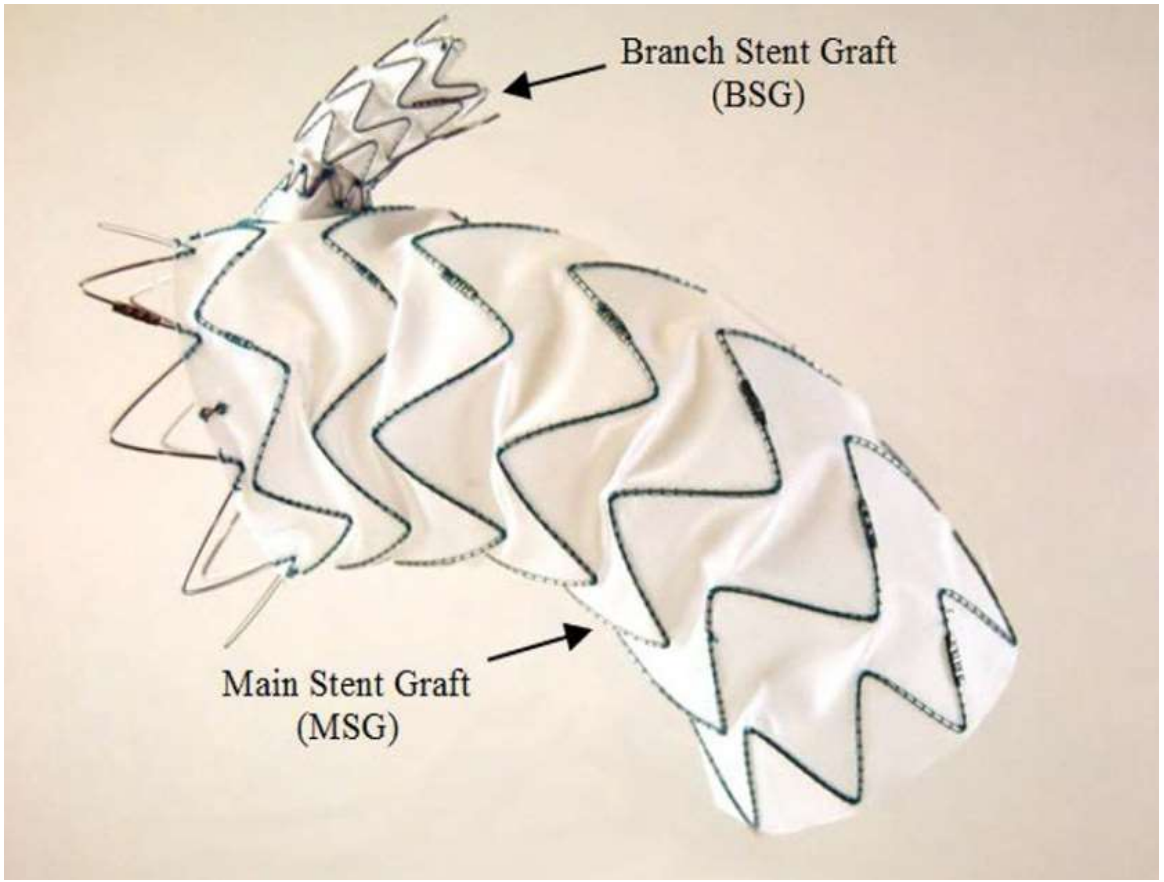
Open Repair In Moderan Era

Outcome of open total arch replacement in the modern era

Fabrizio Settepani, MD, Antioco Cappai, MD, Alessio Barzio, MD, Alessandro Berbone, MD, and Giuseppe Tarelli, MD, *Rozzano, Milan, Italy*

- Systematic Review
- 2004-2014
- 21 studies
- 2880 pts
- Operative Mortality 5.3%
- Permanent ND 3.4%
- Transient ND 5.2%

Investigational Devices: Single Branch



Device Overview

TBE Device

- Aortic Component
- Side Branch (SB) Component
- Aortic Extender (Optional)

Procedural Steps

Step 1:

- **Insert guidewires in aorta and branch vessel**

Step 2:

- **Introduce aortic component over both guidewires into position within the arch**

Step 3:

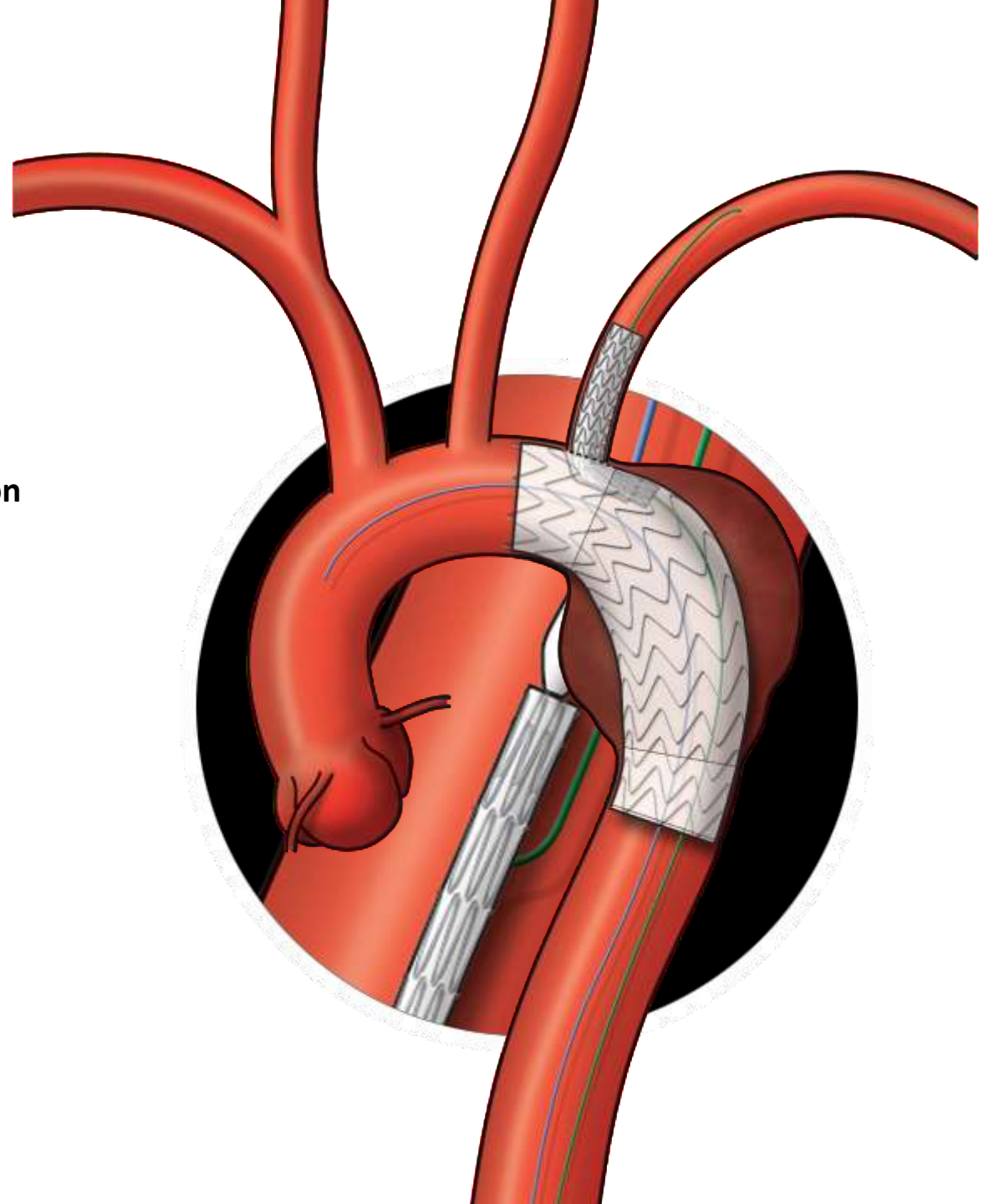
- **Deploy aortic component and withdraw catheter**

Step 4:

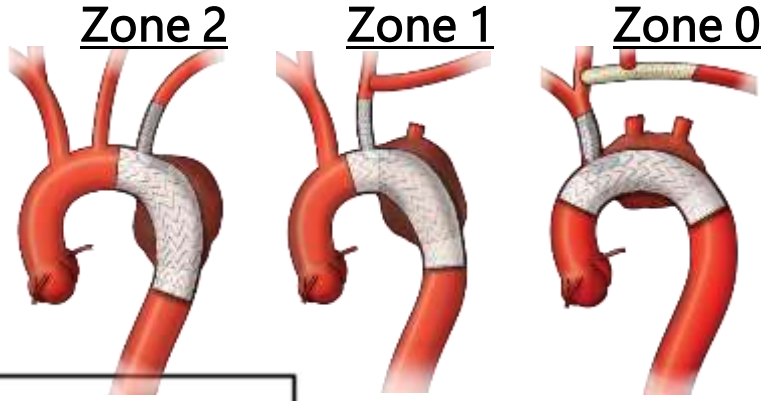
- **Advance introducer sheath and dilator**

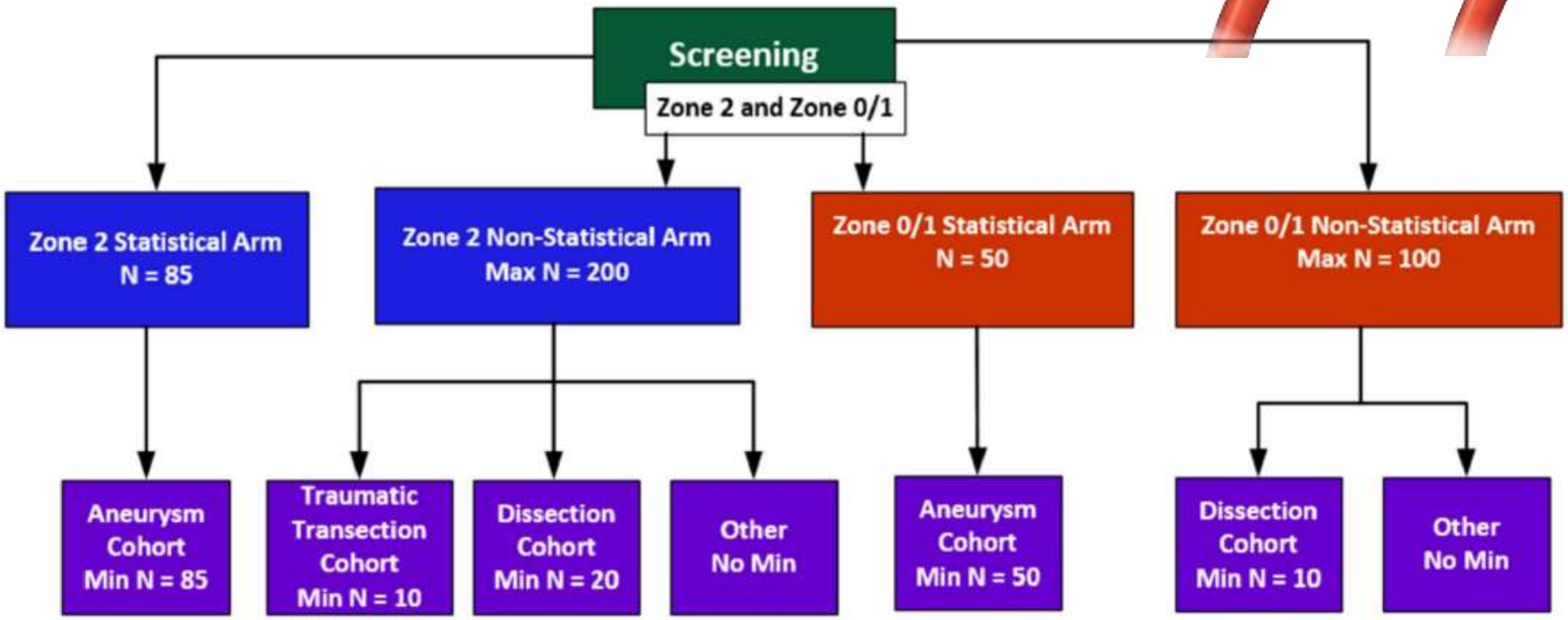
Step 5:

- **Advance and deploy branch component**



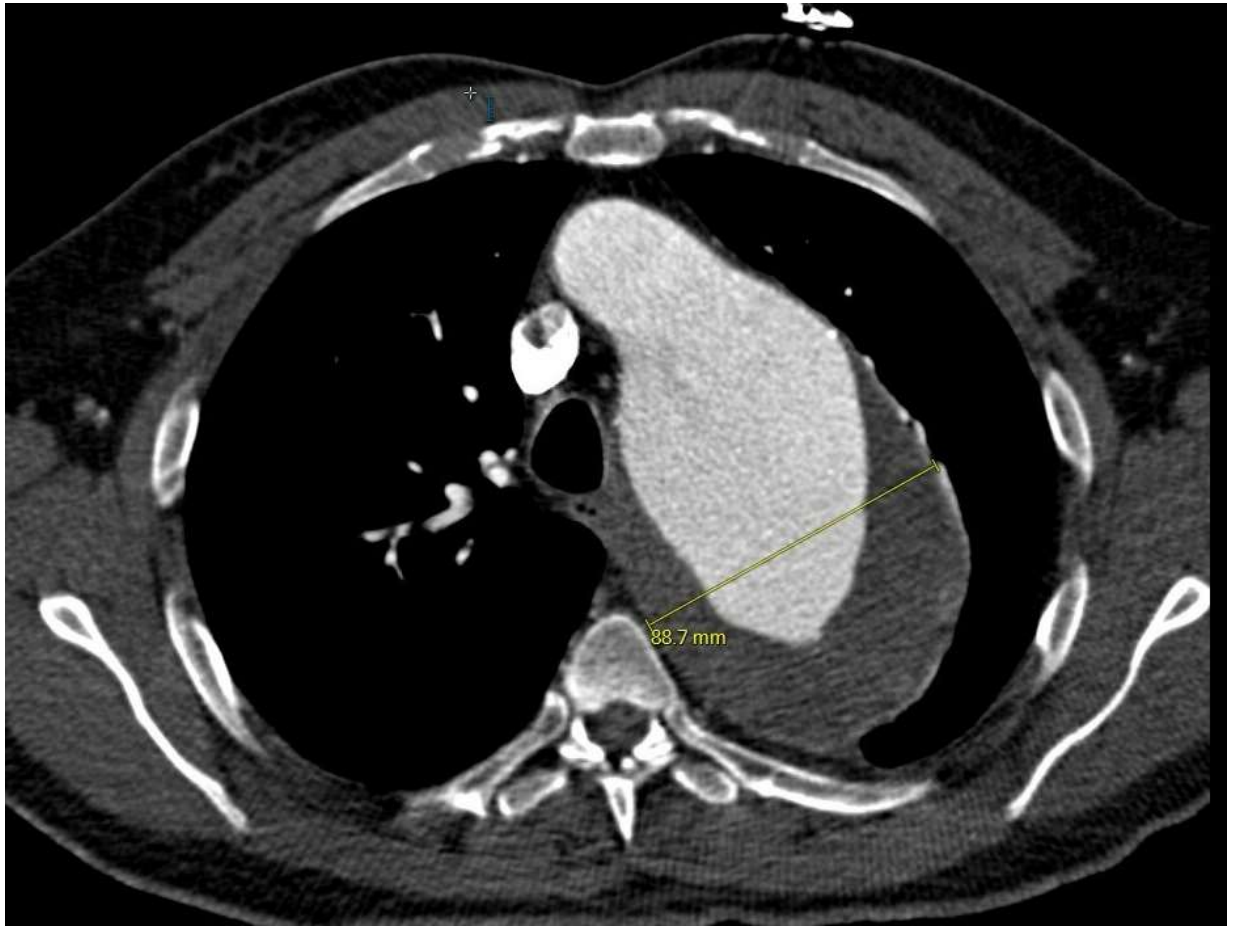
Pivotal Trial Design

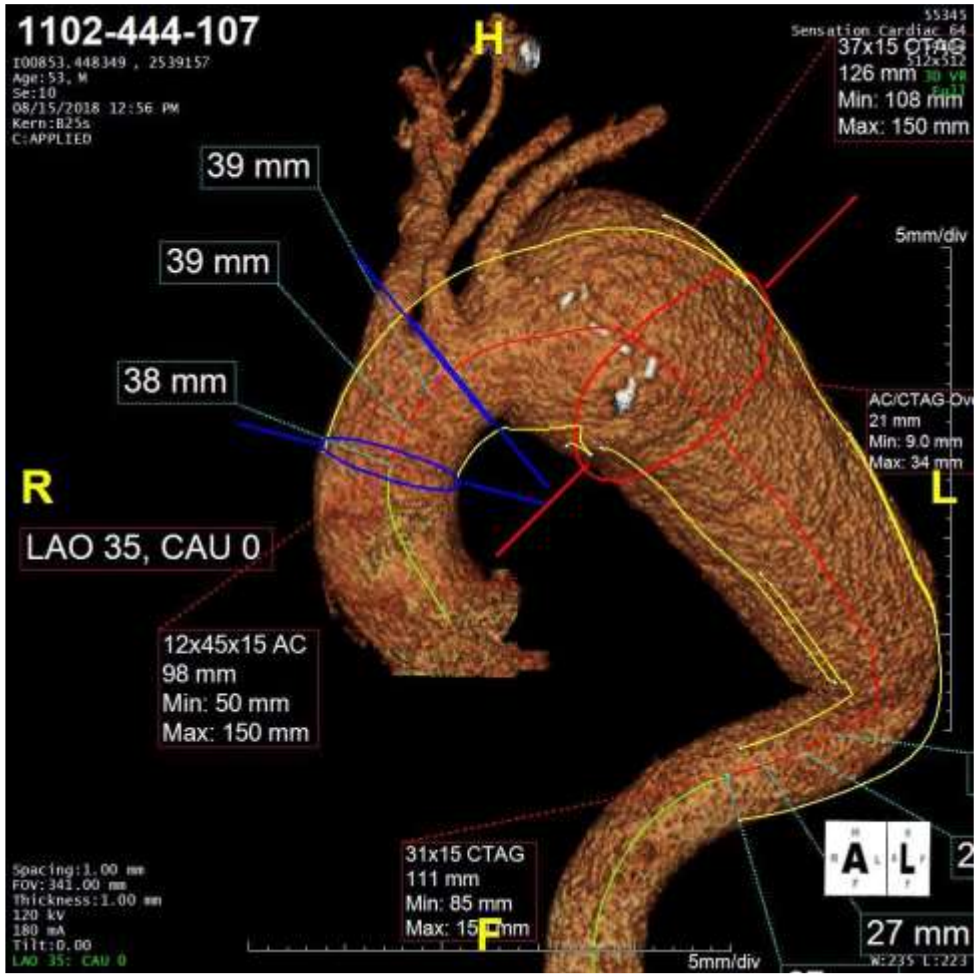




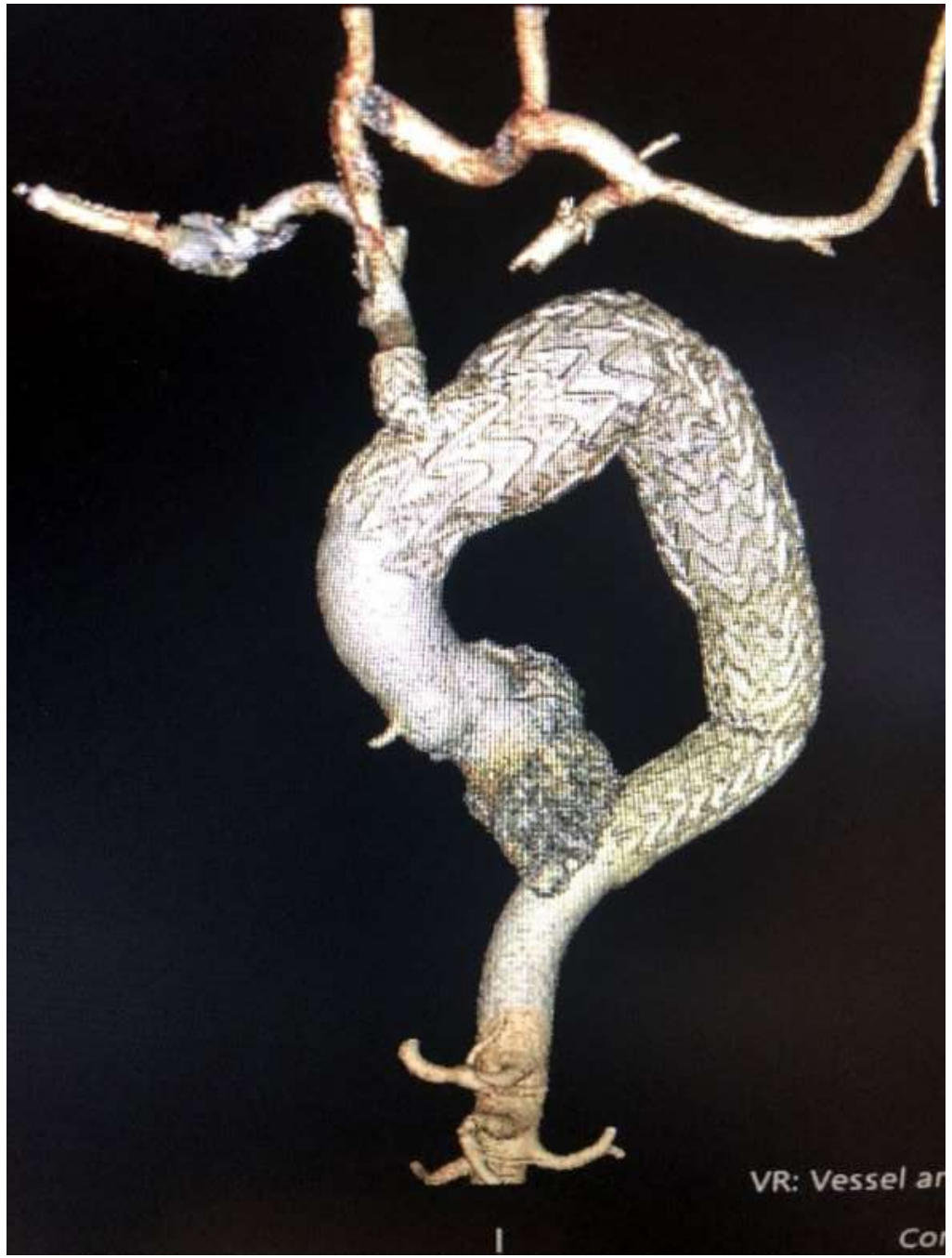
Enrollments	**85**	**7**	**107**	**9**	**20**	**12**	**2**

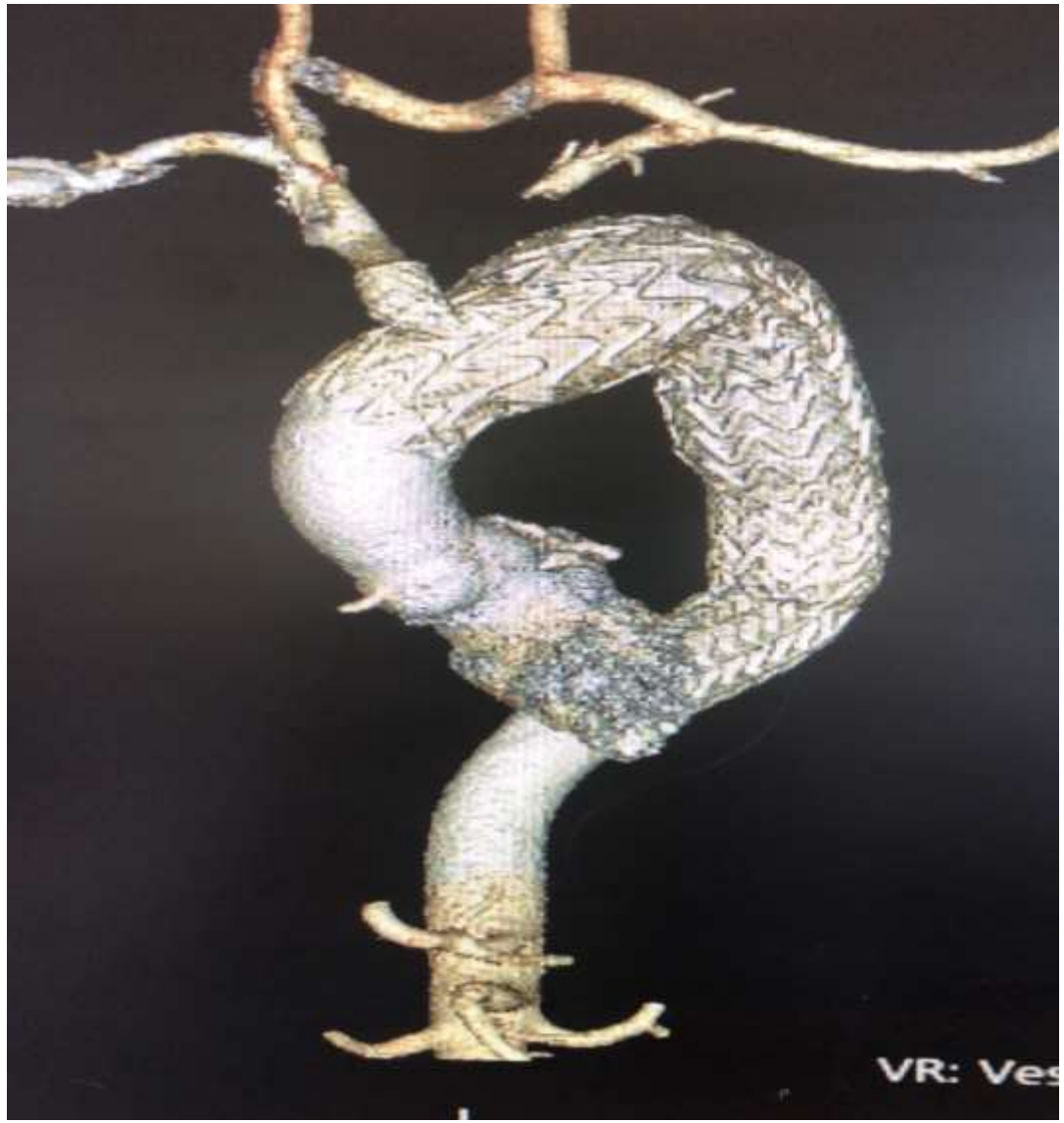
53 yo man with CP found to have a 9 cm DTAA





RCCA-LCCA-LSCA Bypass, Zone 0 TBE


VR: Vessel


VR: Ves

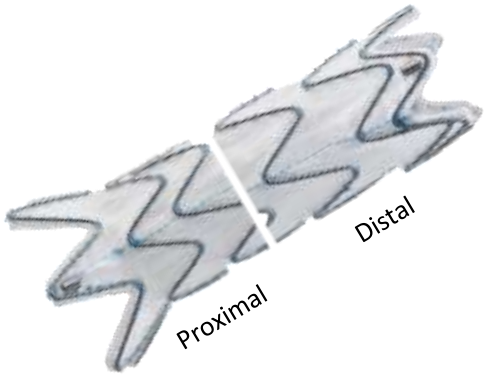
Valiant Mona LSA: Device Overview

Main Stent Graft (MSG)

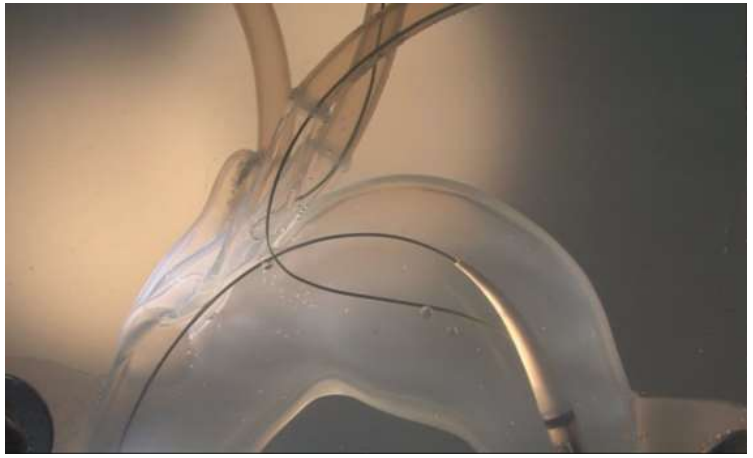
- Flexible, conical-shaped cuff for BSG
- Diameters: 30 – 46mm
- Nominal length: 15cm

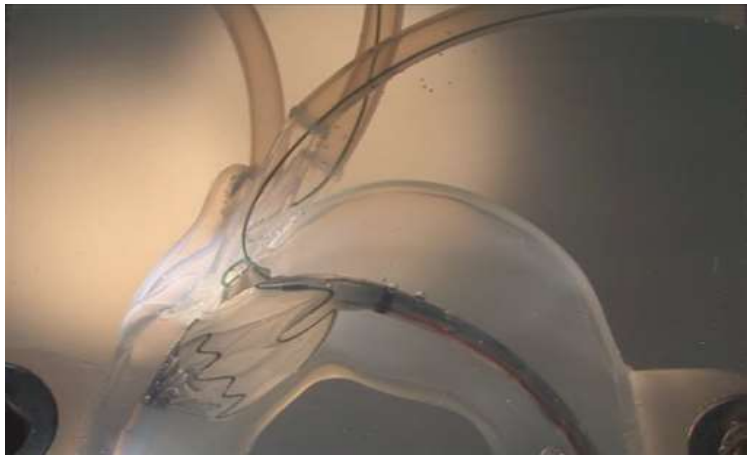
Branch Stent Graft (BSG)

- Nitinol helical stent with high radial force
- PE material with proximal flare
- Diameters: 10, 12, 14mm
- Length: 40mm



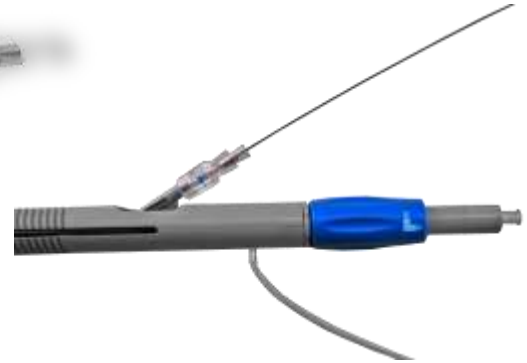
Valiant Mona LSA: Delivery System



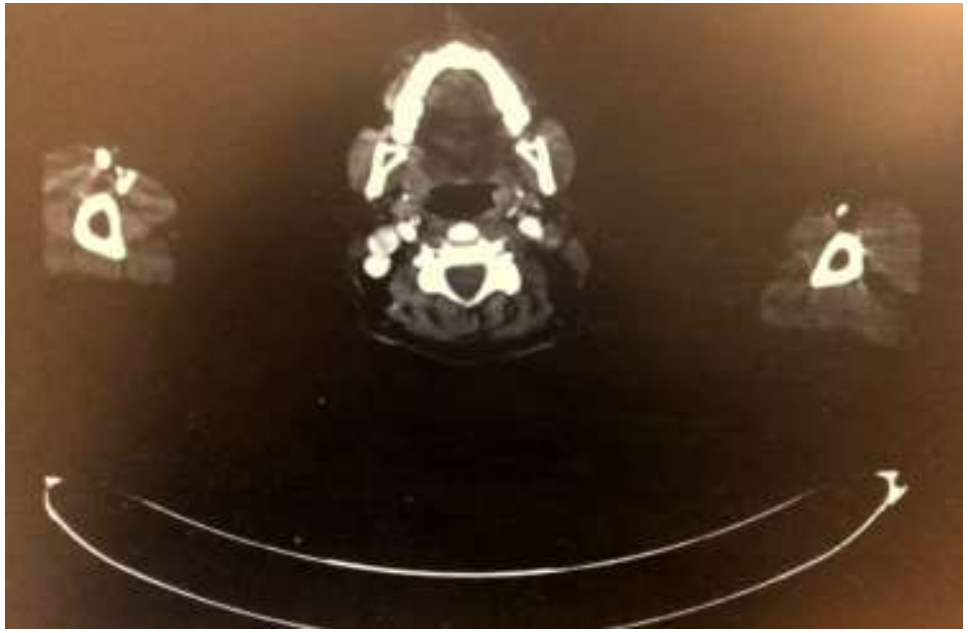


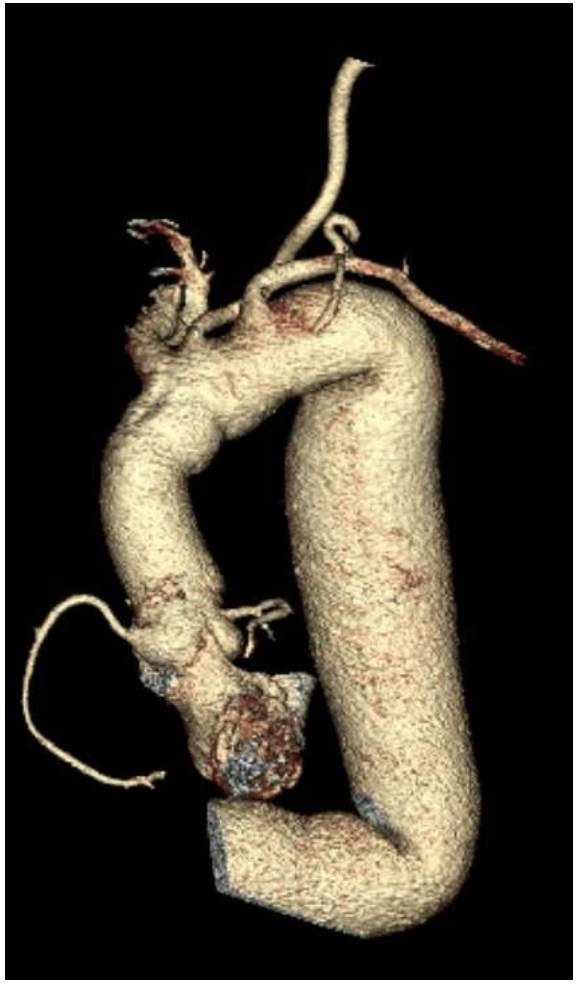
Delivery System

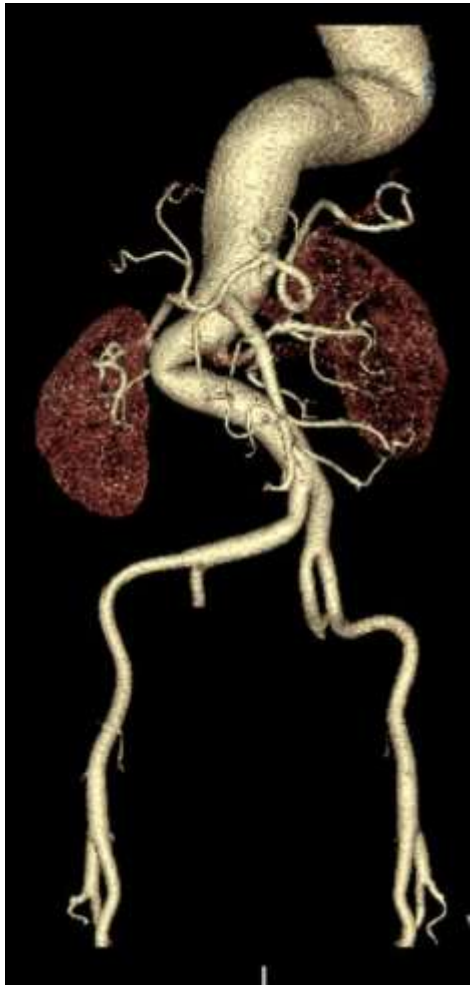
- Two wire system
  - Main/primary aortic tracking wire
  - LSA cannulation wire
- Pre-cannulated LSA cuff
- Tip capture for precise MSG delivery

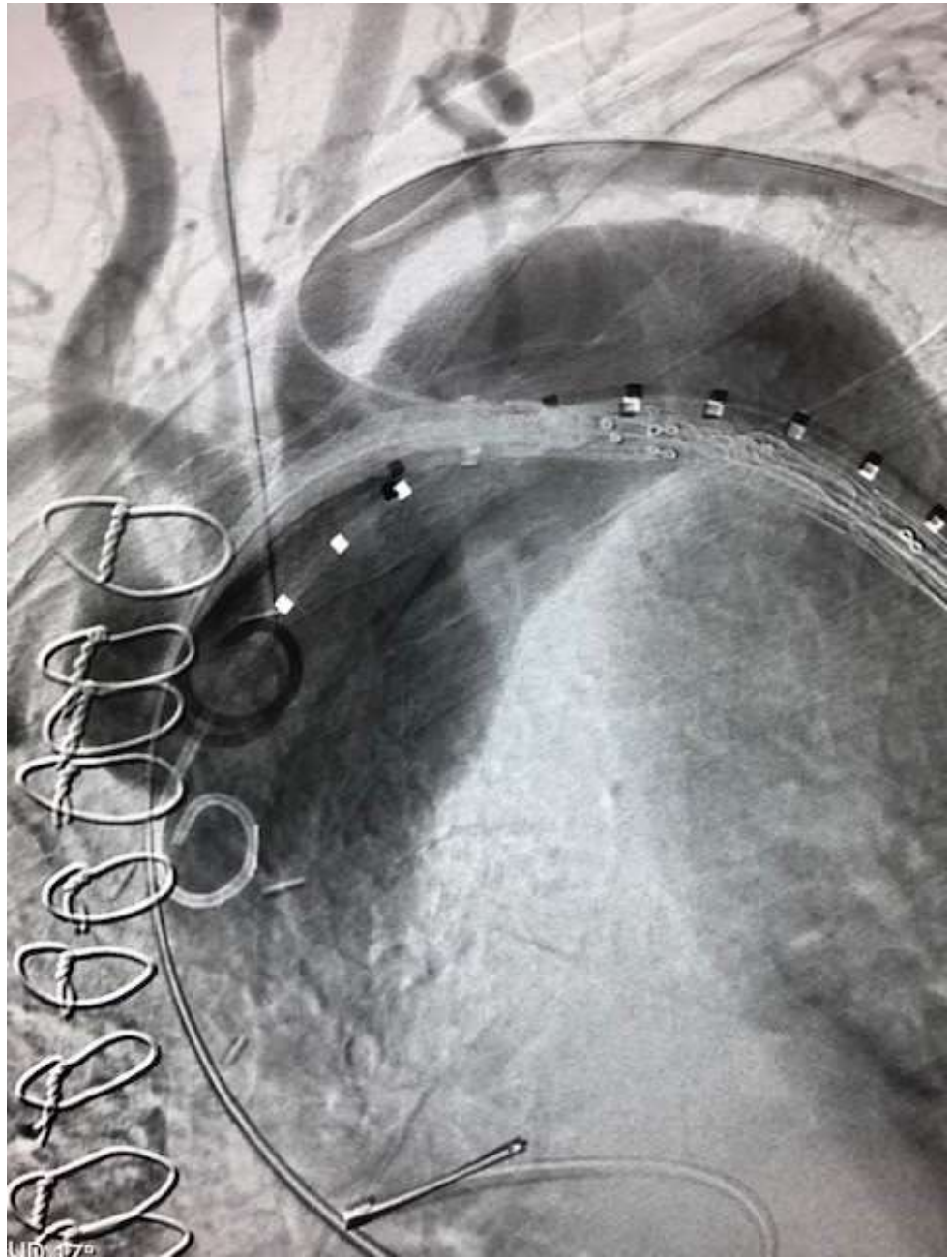


61 yo woman with 5 cm DTAA







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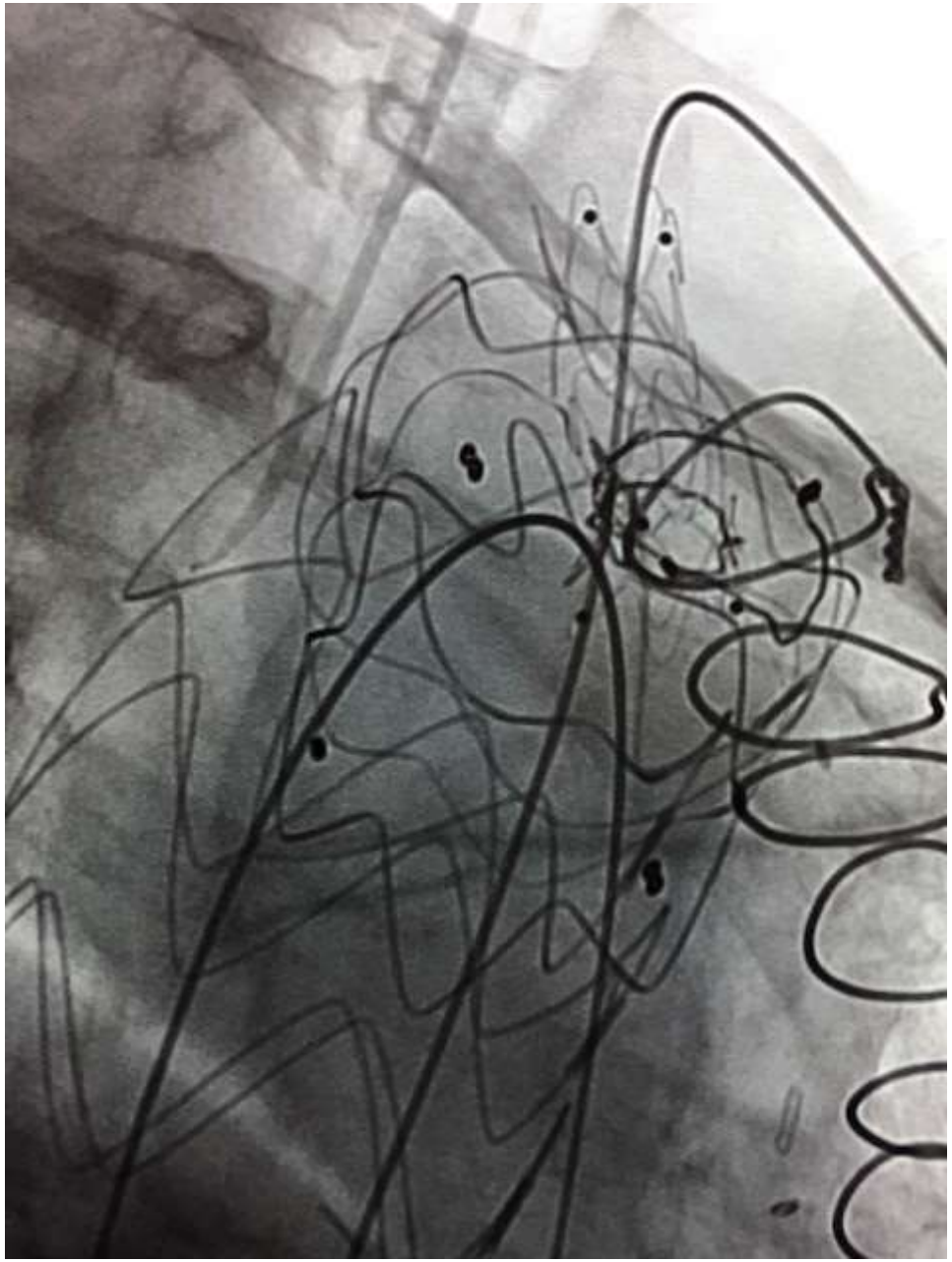

Conclusion

- Treatment of arch pathology remains a challenge
- Multiple treatment options
  - Open, Hybrid, Endovascular
- Single-Branch option is an attractive alternative
- Tailor the therapy to the patient risk profile, anatomy, local expertise, and device availability
- Technology rapidly evolving