MHIF FEATURED STUDY:

WARRIOR - Women's Ischemia Trial

OPEN AND ENROLLING:

EPIC message: ***Research MHIF Patient Referral***

CONDITION:	**PI:**	**RESEARCH CONTACT:**	**SPONSOR:**
Non-Obstructive CAD in Women	Retu Saxena, MD	Steph Ebnet Stephanie.ebnet@allina.com | 612-863-6286	University of FL Funded by the Department of Defense

DESCRIPTION:

The purpose of WARRIOR (Women's Ischemia Trial to Reduce Events in Non-Obstructive CAD) is to evaluate if intensive medical therapy (IMT) (**potent statin plus ACE-I or ARB**) is better than usual care in women who have s/s of suspected ischemia but no obstructive CAD (defined as <50 stenosis). The hypothesis is that IMT will reduce MACE 20% vs. usual care.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion

- Signs and symptoms of suspected ischemia prompting referral for further evaluation by coronary angiography or coronary CT angiogram within previous 3 years
- Non-obstructive CAD defined as 0-50% diameter reduction of a major epicardial vessel

Exclusion

- Hx NIHCM
- ACS within 30 days
- LVEF< 40% NYHA HF class III-IV
- Prior intolerance to ACE/ARB
- ESRD on dialysis
- Severe valvular disease requiring TVAR within 3 years
- Stroke within 180 days

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Minneapolis Heart Institute Foundation®
Creating a world without heart and vascular disease

Are you a **woman** who within the last **five years** has had chest pain severe enough to be evaluated by either:

- A CT scan of your heart
- A cardiac catheterization

And the finding indicated **no significant** coronary artery blockages?

WARRIOR

WARRIOR
Women's Ischemia Trial to Reduce Events in Non-Obstructive CAD

Women who experience chest pain and other signs of ischemia who are evaluated and found to have no significant blockages in their coronary arteries are often released from cardiac care, labeled normal, but continue to have symptoms.

WARRIOR is a clinical trial designed to determine how to best treat women with chest pain and no significant coronary artery disease.

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Adjuncts during F-BEVAR: upper extremity access and future directions

Aleem K Mirza, MD

From the Division of Vascular and Endovascular Surgery
Minneapolis Heart Institute Foundation

Minneapolis Heart Institute

Allina Health
ABBOTT NORTHWESTERN HOSPITAL

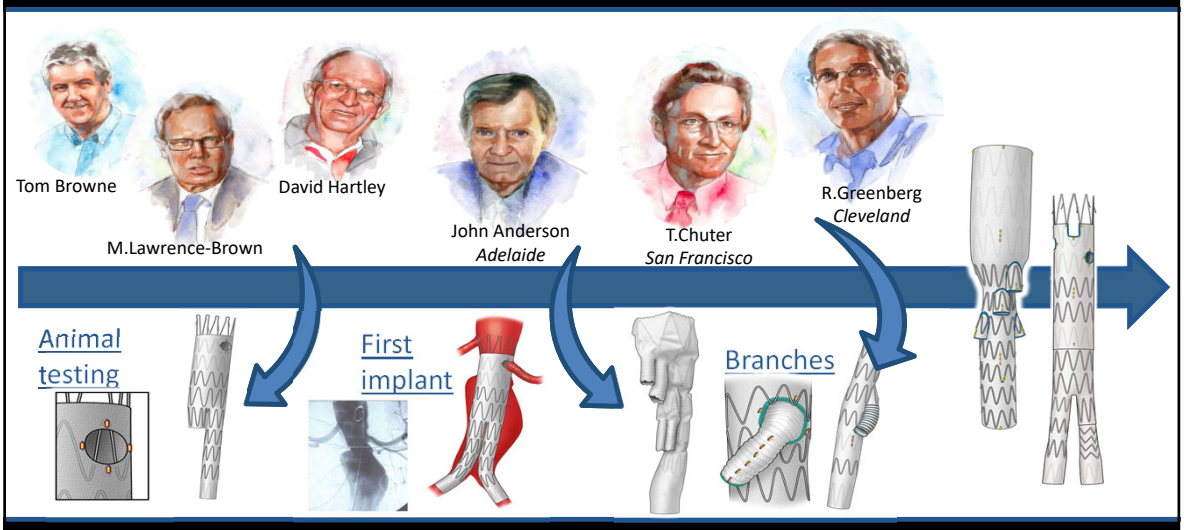
Disclosures

- No financial disclosures
- Cases and images courtesy of Gustavo Oderich, Mayo Clinic

Overview

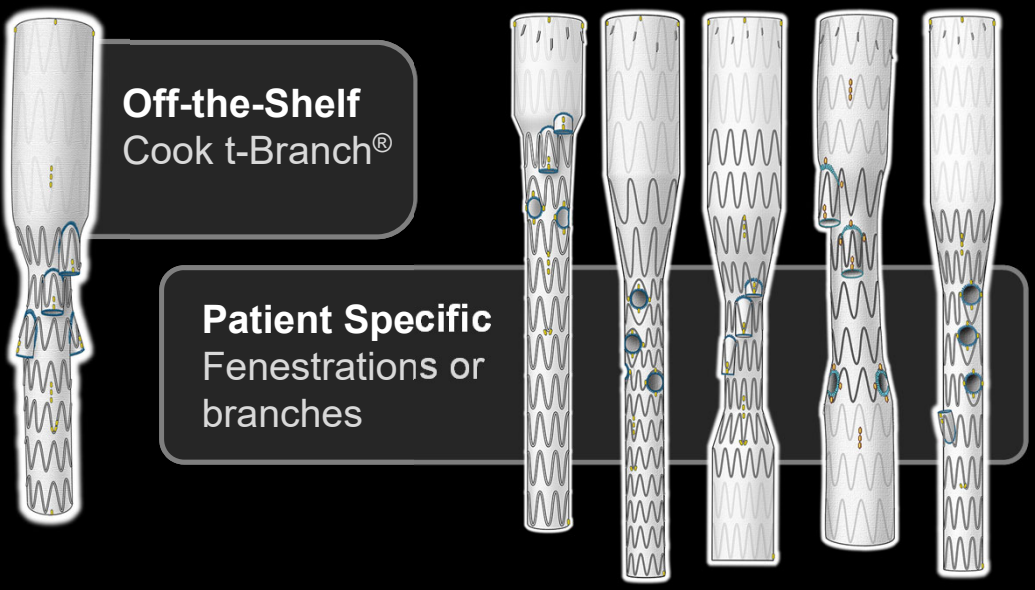
- History of fenestrated-branched technology
- Overview on adjuncts during F-BEVAR
  - Preloaded systems
  - Upper extremity access
  - Total femoral approach
- Case presentations
- Current research

Evolution of fen-branched repair

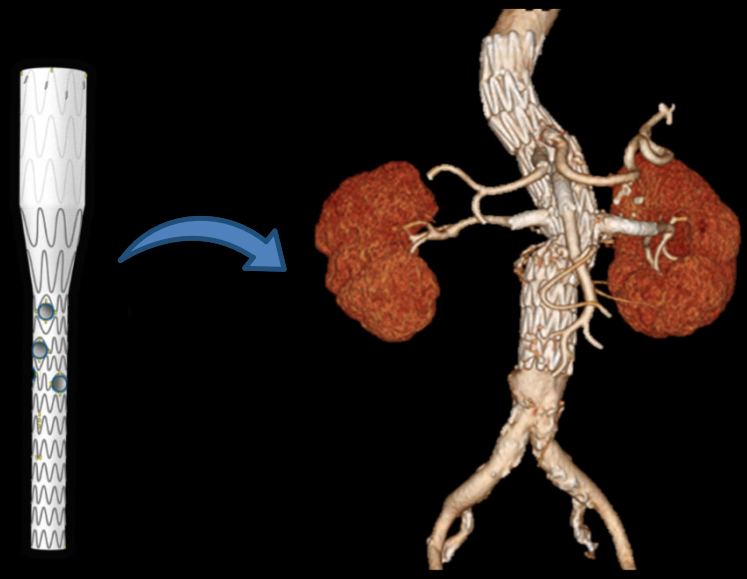


In Oderich Atlas of Fenestrated, Branched and Parallel Techniques, Springer 2016

Stent-graft design



Preloaded wires



Emergency use of physician-modified fenestrated endograft for symptomatic post-dissection thoracoabdominal aneurysm waiting for a manufactured endograft

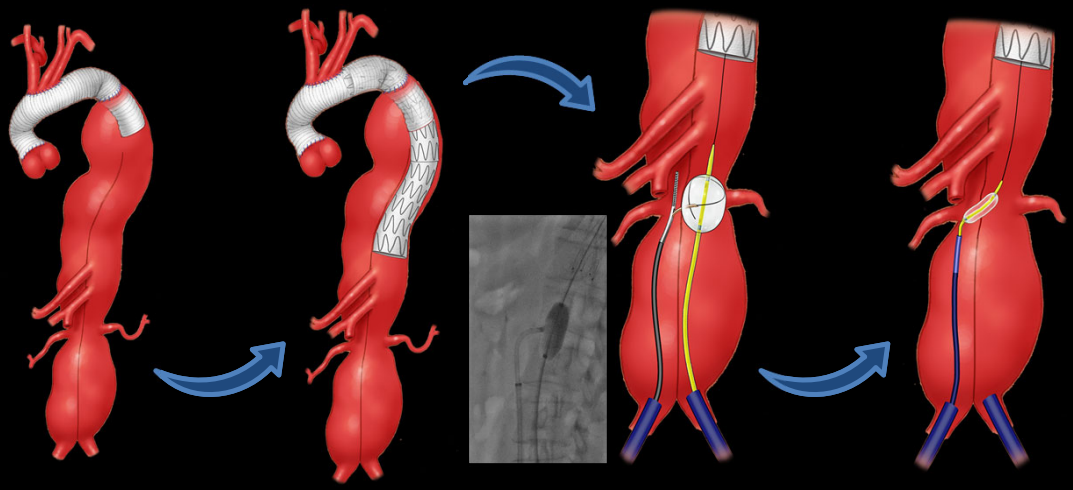
Aleem K Mirza, Jussi M Kärkkäinen, Emanuel R Tenorio, Nishant Saran, Gustavo S Oderich

Disclosures
GSO: consulting and research grants paid to Mayo Clinic (Cook, WL Gore, GE Healthcare)
Other authors: nothing to disclose

59-year old female with 7cm Extent II TAAA

- Prior arch repair with elephant trunk technique
- Cardiovascular risk factors
  - Hypertension, hyperlipidemia, CAD, COPD, prior smoking
- Planned staged TAAA repair
  - Stage I: TEVAR with angioplasty of small R renal reentrance
  - Stage II: patient-specific manufactured fenestrated and branched endograft

Stage I



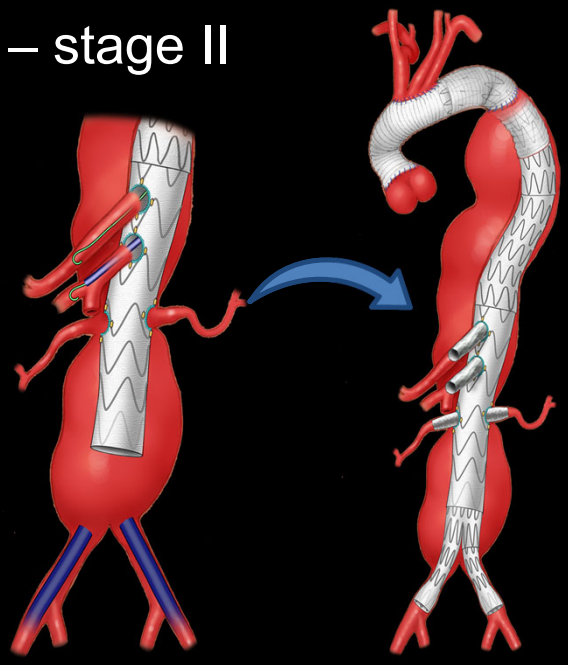
Discharged on postop day 4 with no complications

Clinical course

- Two re-admissions for chest pain and intermittent lower extremity weakness

Operative technique – stage II

- 4 – vessel fenestrated completion PMEG repair
- Preloaded wires from left brachial approach
- Distal extension with a bifurcated device



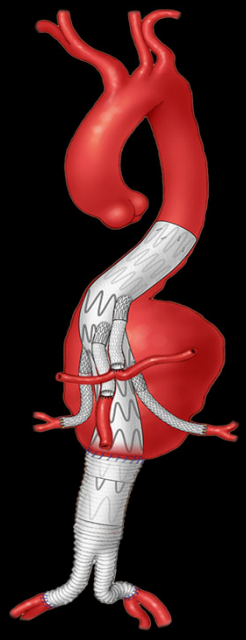
Postoperative course

- ICU cares for 4 days
- Day 1 – spinal drain removed
- Day 2 – replaced x 24 hrs for lower extremity weakness
- Day 10 – hospital discharge
- Neurologically intact
- Creatinine 1.1-mg/dL

65-year-old male with rapid aneurysm sac growth after 4-vessel branched endovascular aortic repair

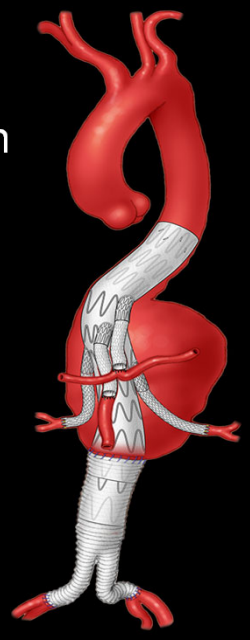
Aleem K. Mirza MD
Swati Chaparala MD
Bernardo C. Mendes MD
Gustavo S. Oderich MD

From the Aortic Endovascular Research Program
Division of Vascular and Endovascular Surgery



History of present illness

- 65M with persistent aneurysm sac growth
  - Prior 4-vessel PMEG for ruptured Extent III TAAA in 2015
  - Rapid growth of 8-mm in 7 months
  - No fevers, chills, night sweats
- New thoracic back pain
- Past medical history
  - Open infrarenal AAA repair
  - Multiple sclerosis with chronic debility
  - COPD on nocturnal O2
  - Chronic thrombocytopenia



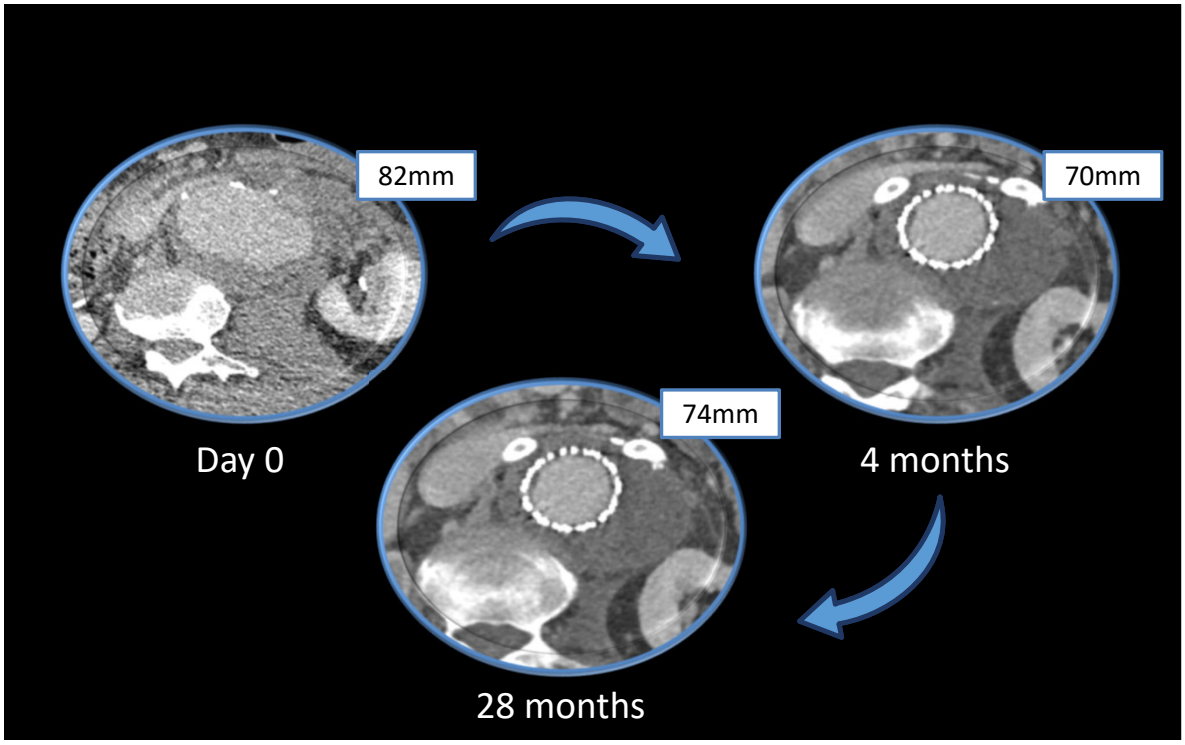
Physical exam

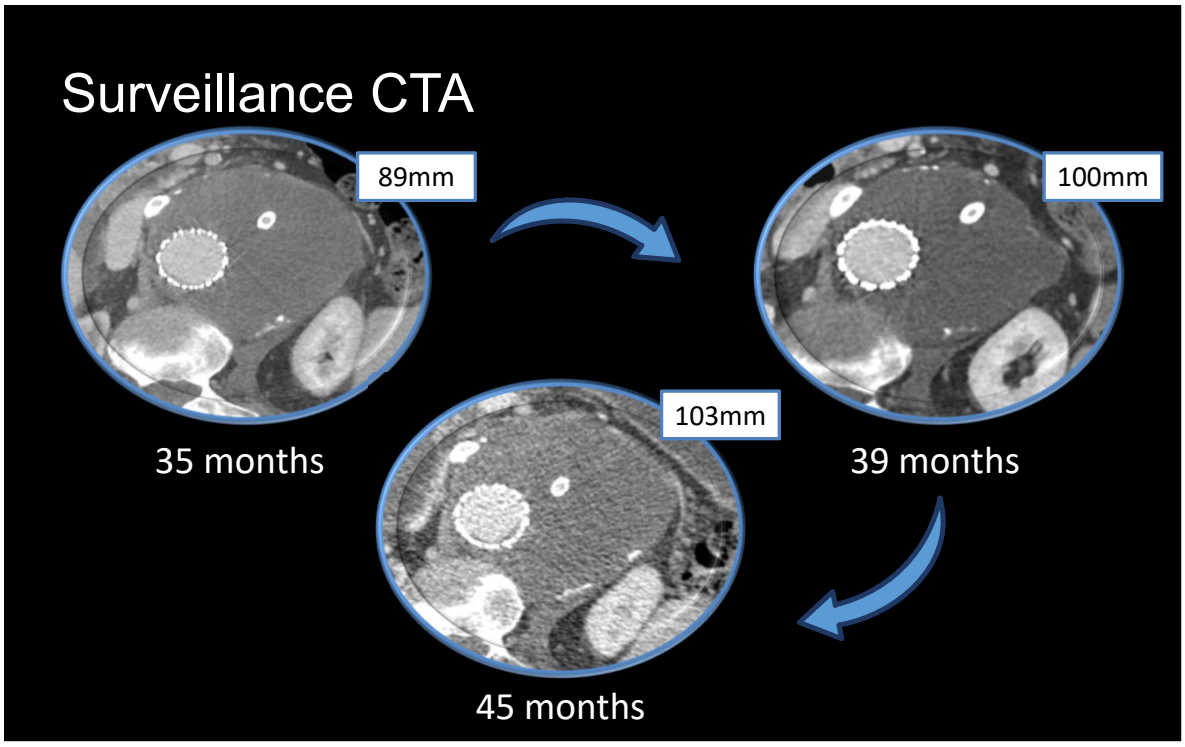
- General: **tachypnea on 4L nasal cannula**
- Cardiac: regular rate, no murmurs
- Pulmonary: **bibasilar crackles**
- Abdomen: soft, nontender, no pulsatile mass
- Extremities: **2+ pitting edema**
- Vessels:

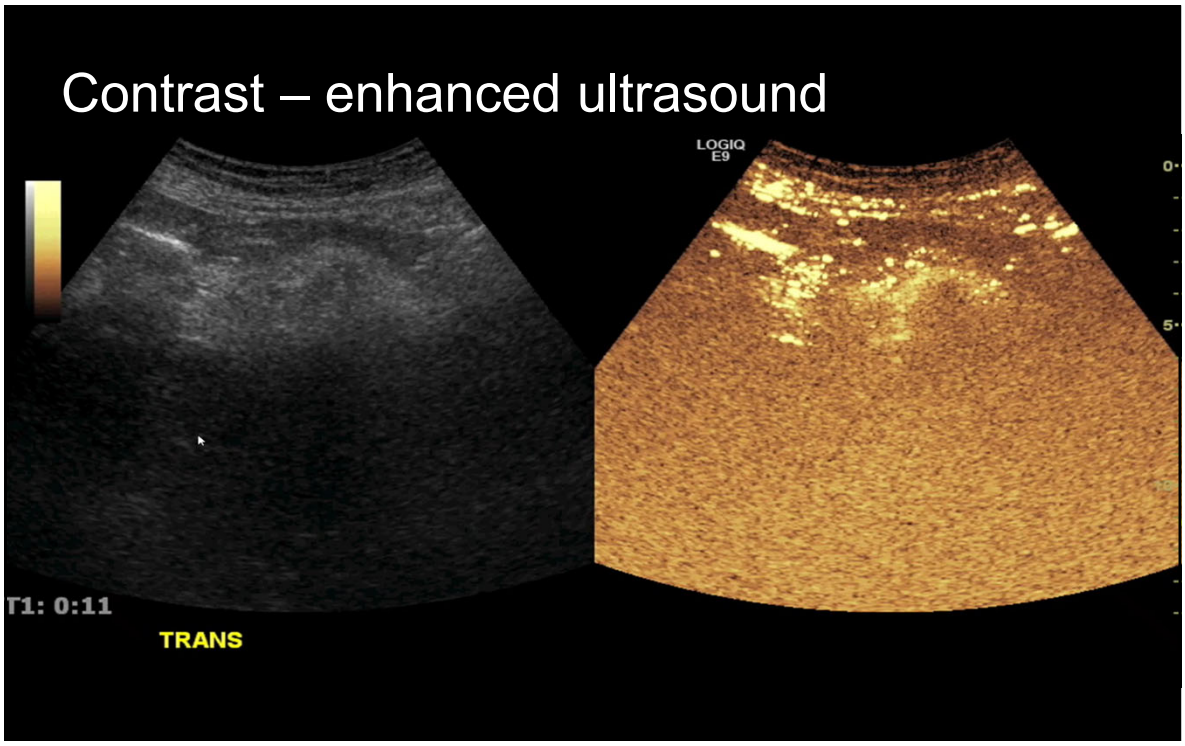
	Radial	Carotid	Femoral	DP	PT
Right:	+	+	+	(+)	(+)
Left:	+	+	+	(+)	(+)

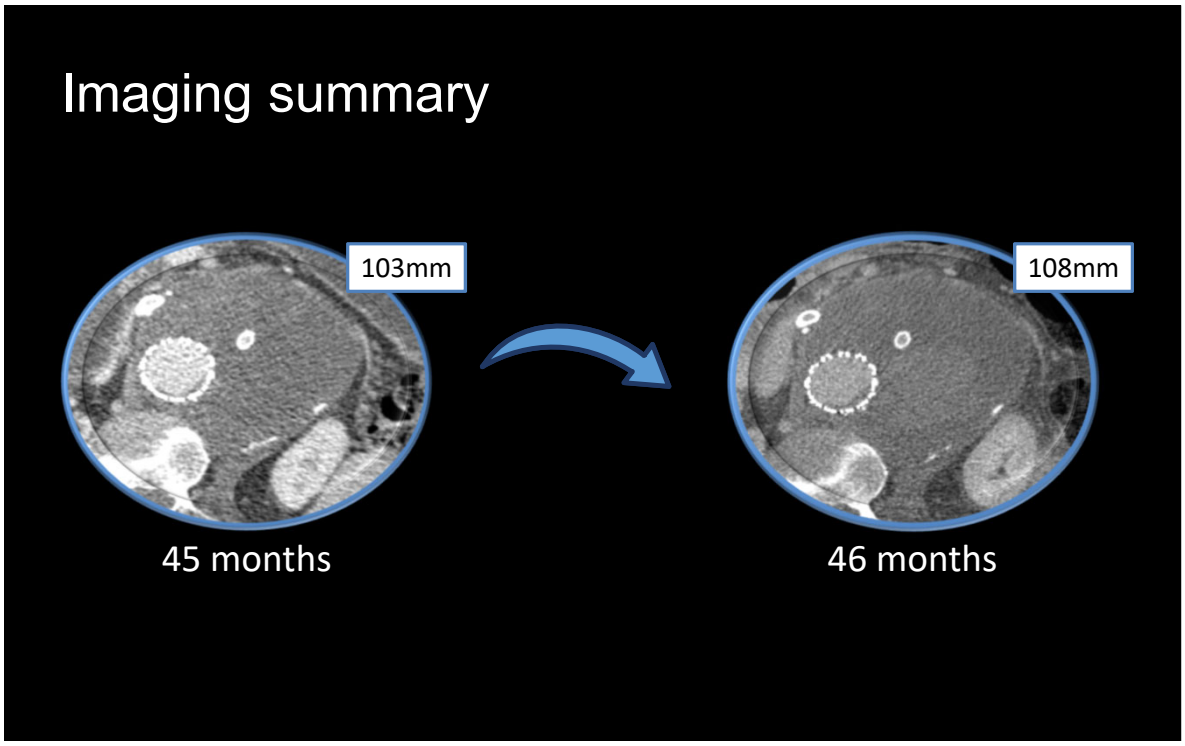
Preoperative evaluation

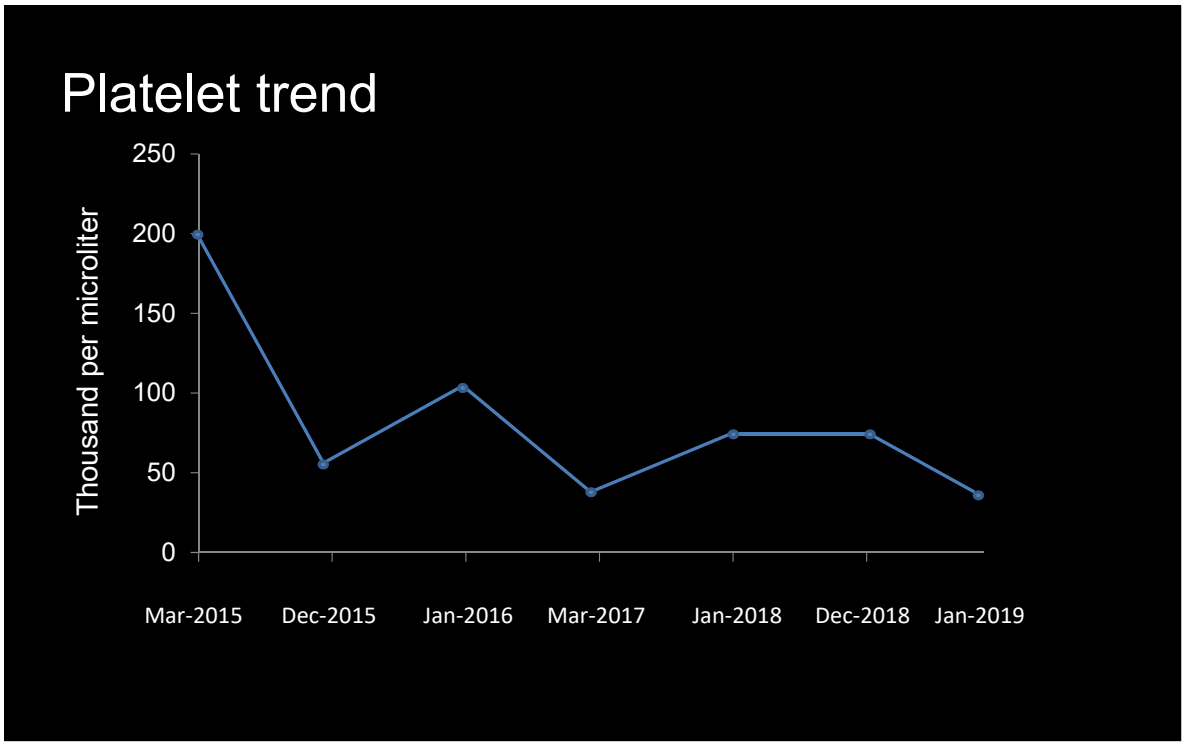
- Creatinine: 0.6 mg/dL
- Platelets: 52,000
- Echocardiogram: EF 61%
- Indium-labeled WBC scan: no infection

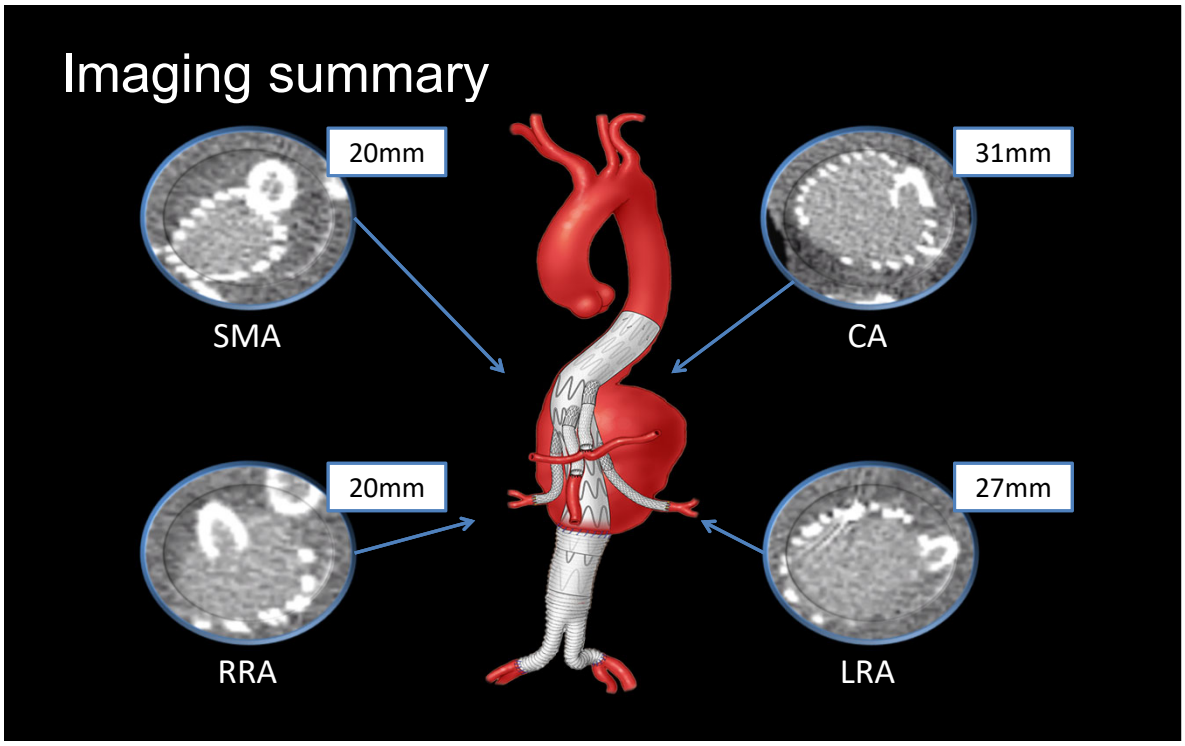



Surveillance CTA
89mm
35 months
100mm
39 months
103mm
45 months

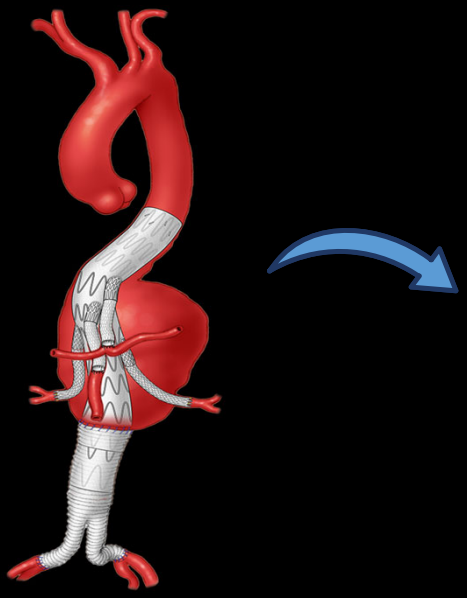

Contrast – enhanced ultrasound
LOGIQ
E9
T1: 0:11
TRANS


Imaging summary
103mm
108mm
45 months
46 months


Platelet trend
Thousand per microliter
250
200
150
100
50
0
Mar-2015
Dec-2015
Jan-2016
Mar-2017
Jan-2018
Dec-2018
Jan-2019

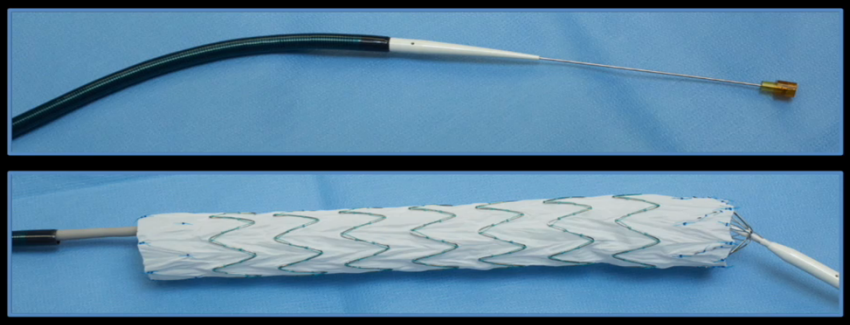

Imaging summary
20mm
SMA
31mm
CA
20mm
RRA
27mm
LRA

Operative – plan



4-vessel PMEG
- 3 inner branches
- 1 fenestration

ALPHA THORACIC LP (18-20Fr)

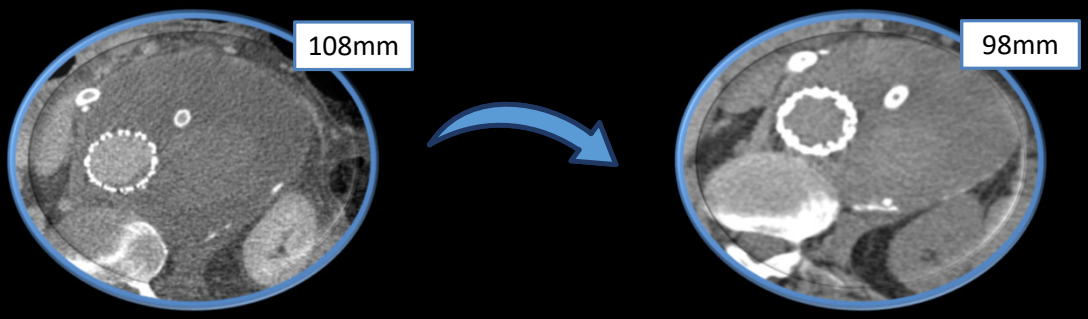


- Select smaller tapered stent in larger sheath
- Un-sheath entire stent but keep metallic cannula

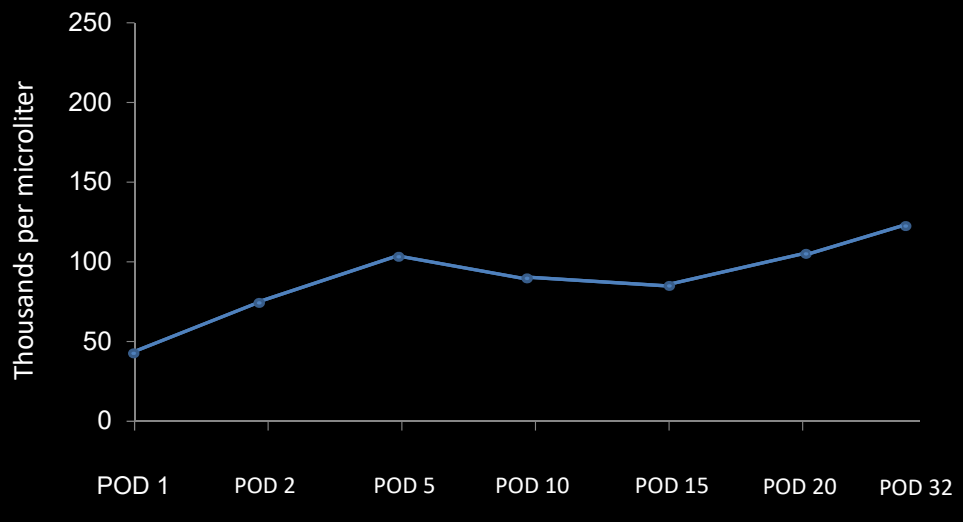
Postoperative course

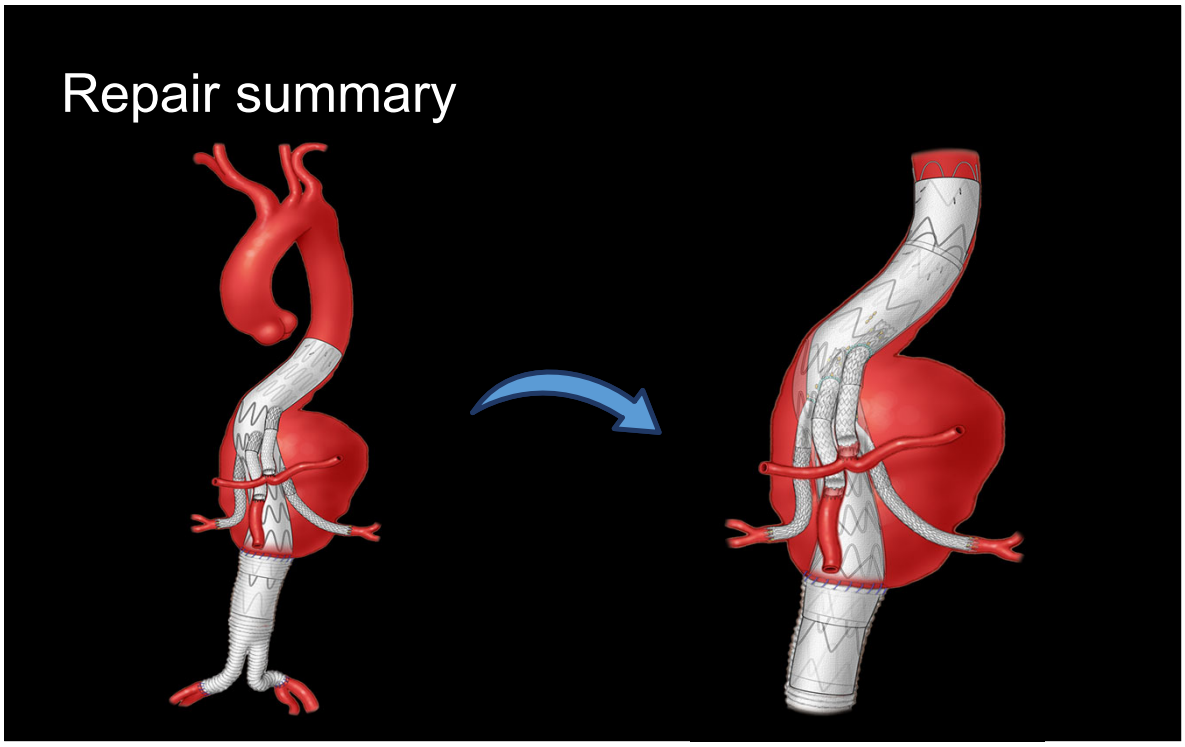
- ICU cares x 16 days
  - Respiratory support
  - Tracheostomy on POD 17
- No new neurologic deficits
- Dismissed on POD 31
- ASA 81mg, Plavix 75mg

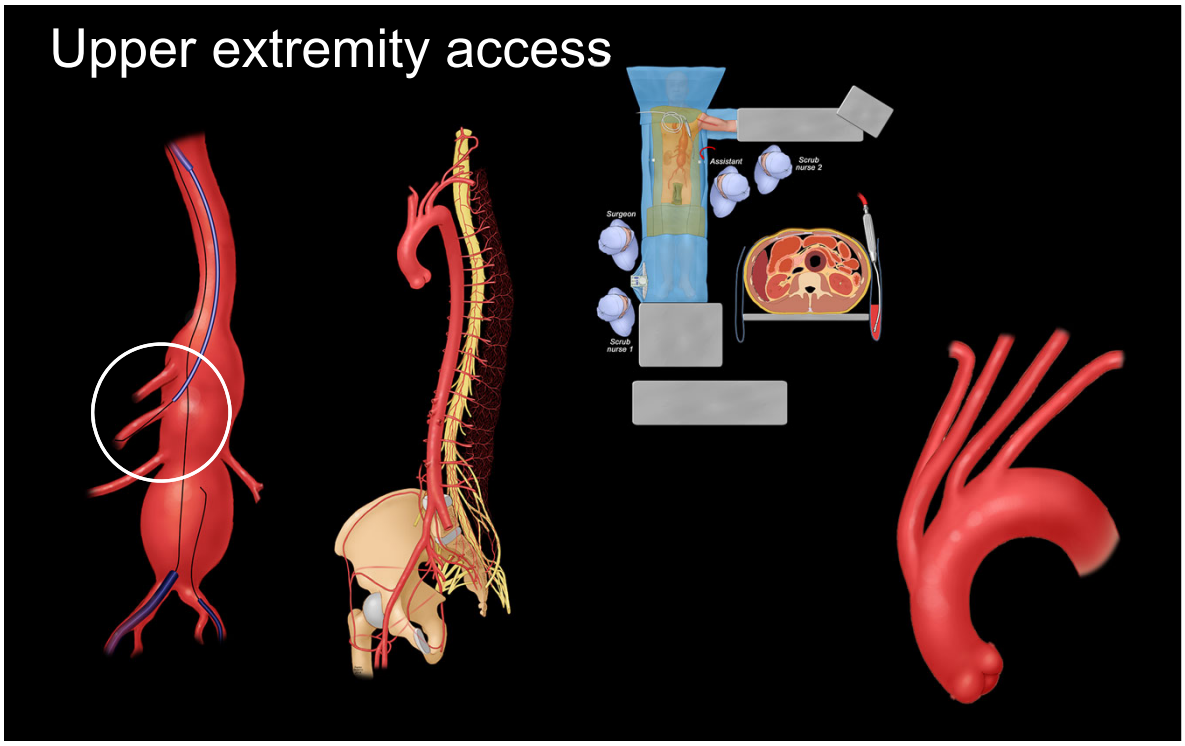
Imaging summary

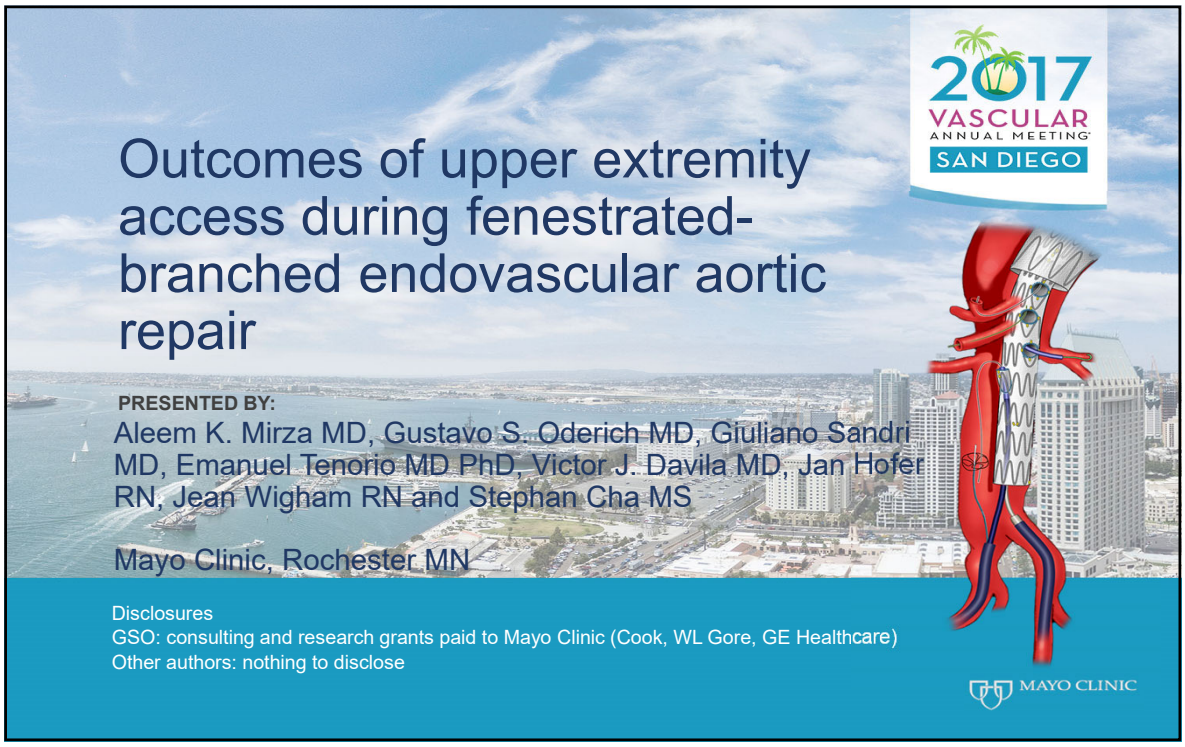


Platelet trend




Repair summary


Upper extremity access
Assistant
Scrub nurse 2
Surgeon
Scrub nurse 1

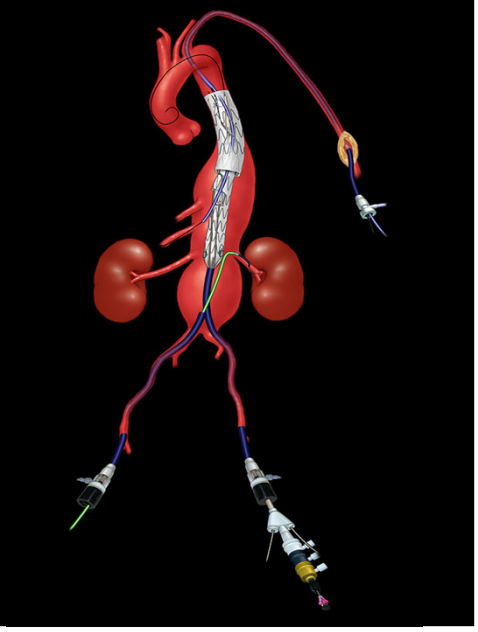


Background

- Fenestrated-branched endovascular aortic repair (F-BEVAR) has been widely used for complex aneurysm repair
- Upper extremity (UE) access is often needed for catheterization of caudally-oriented vessels or directional branches
- Limitations are the risks of cerebral embolization, upper extremity arterial and peripheral nerve injury

Purpose

- The aim of this study was to evaluate the outcomes of F-BEVAR using UE access with small and large sheaths



Methods

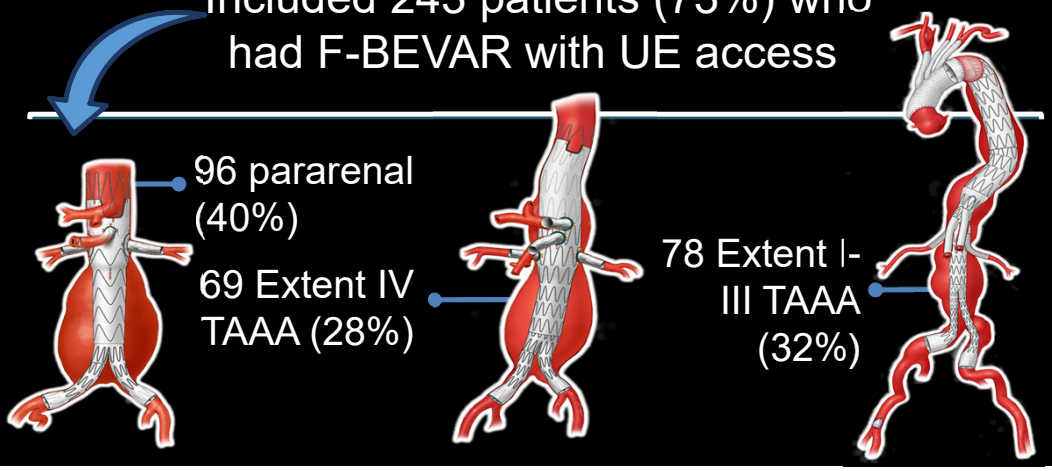
- Retrospective review of a prospectively collected database
- Included patients treated by F-BEVAR for thoracoabdominal (TAAA) or pararenal aortic aneurysms (PAA) using UE access
- Endpoints:
  - Mortality and Major Adverse Events (MAEs)
  - Access-related complications

Access-related complications

- Any stroke or TIA
- UE arterial complication resulting in symptoms, disability or reintervention: hematoma, pseudoaneurysm, dissection, stenosis, thrombosis or distal embolization
- Peripheral nerve injury
- UE wound-related complication: seroma, lymphatic leak or infection

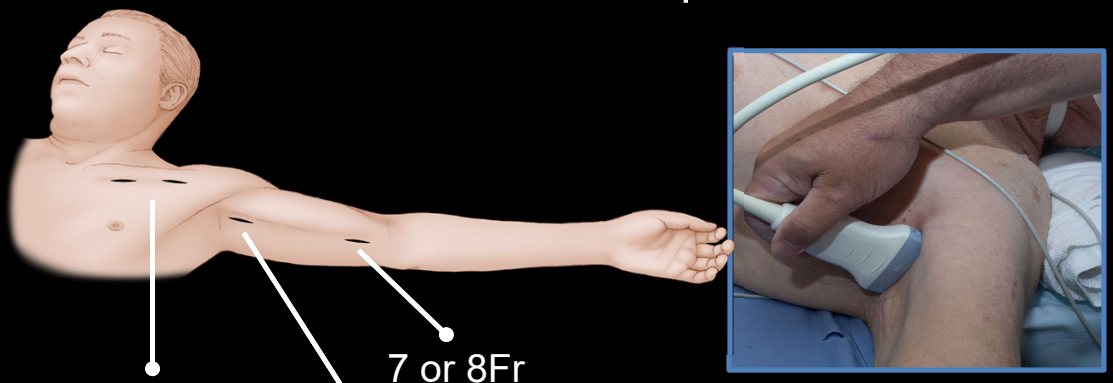
Patients

334 patients treated by F-BEVAR (2007-2016)



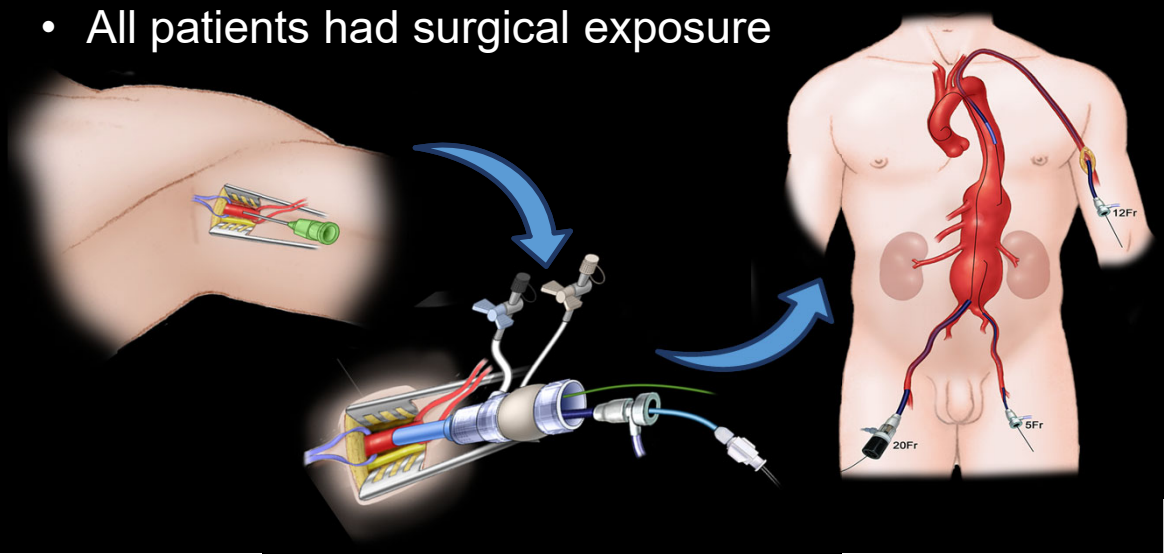
Selection of access site

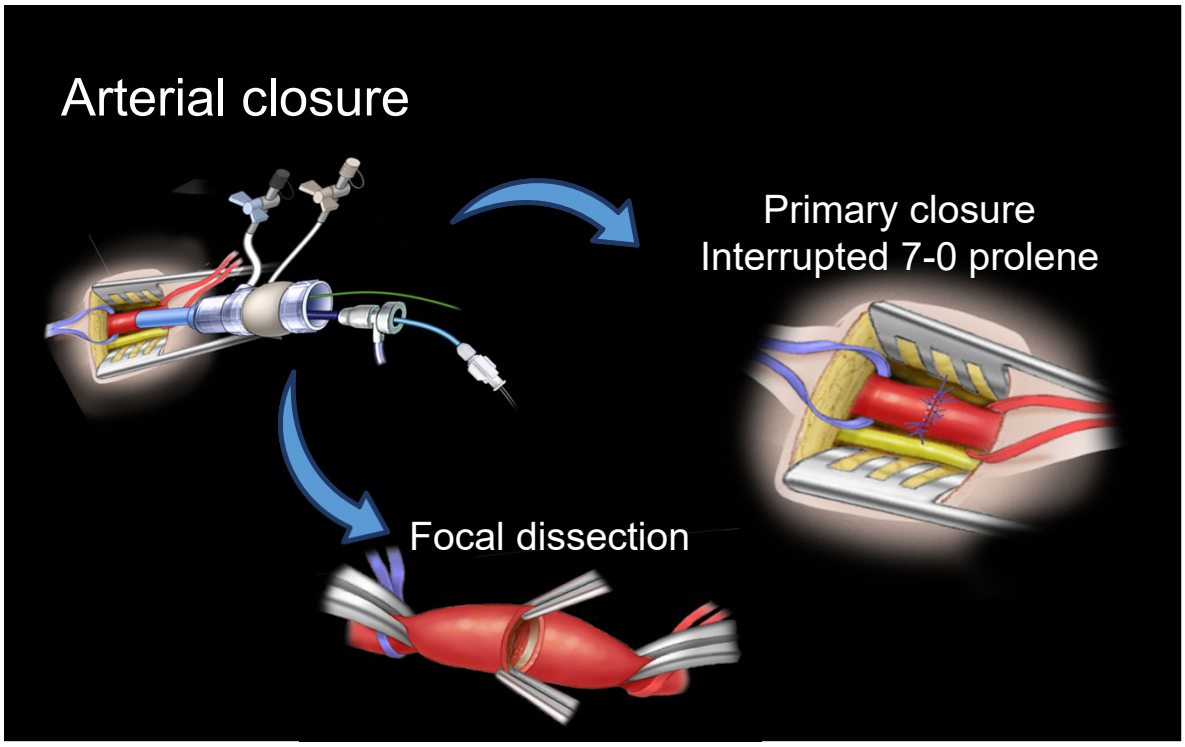
- Left side selected whenever possible

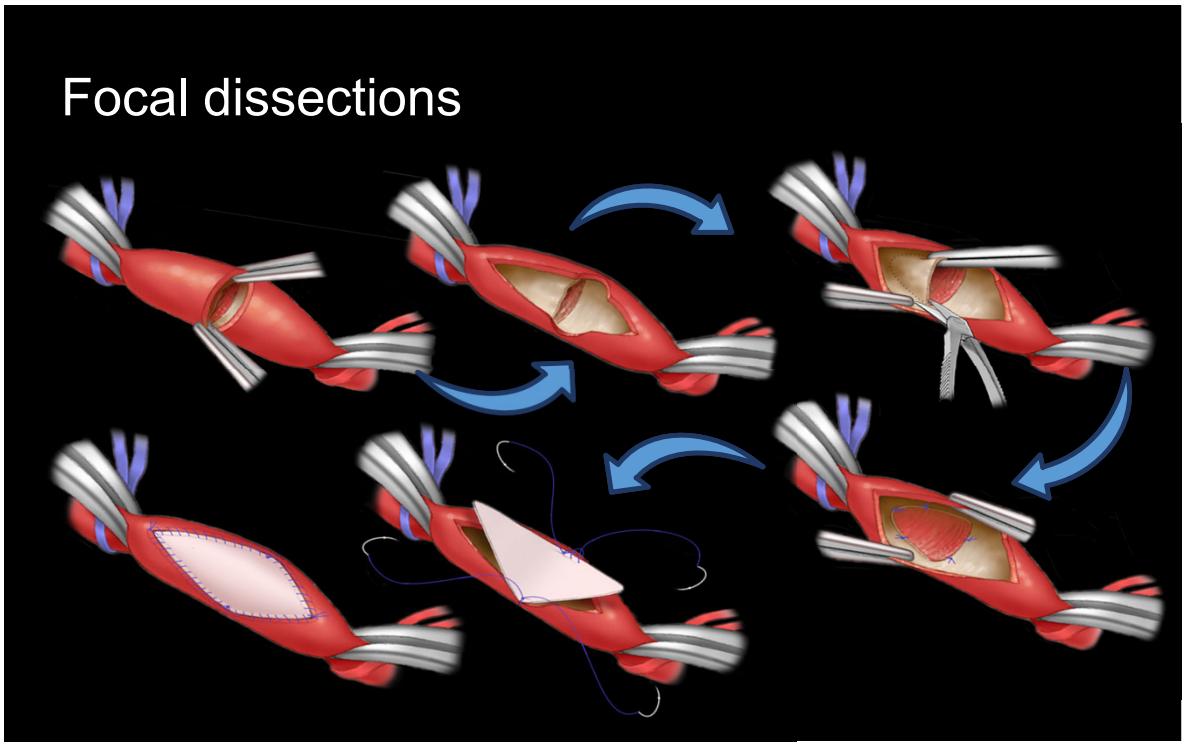


Access technique

- All patients had surgical exposure




Arterial closure
Primary closure
Interrupted 7-0 prolene
Focal dissection


Focal dissections

UE **arterial closure**

- 212 patients (87%) had primary closure
- 30 patients (12%) had Bovine patch angioplasty
- 1 patient (0.4%) had vein interposition graft

Indication	Total (n = 243)	Pararenal (n = 96)	Extent IV (n = 69)	Extent I-III (n = 78)	P value
	n (%)				
Total	31 (13)	9 (9)	7 (10)	15 (19)	0.13
Dissection	29 (12)	9 (9)	7 (10)	13 (17)	0.28
Thrombosis	1 (0.4)	0	0	1 (1)	0.32
Transection	1 (0.4)	0	0	1 (1)	0.32

Access-related complications

8 patients (3%) had access-related complications

Complication	Total (n = 243)	Pararenal (n = 96)	Extent IV (n = 69)	Extent I-III (n = 78)	P value
	n (%)				
Stroke	5 (2)	2 (2)	2 (3)	1(1)	0.8
Neuropraxia	2 (1)	2 (2)	0	0	0.24
Hematoma*	1 (0.4)	1 (0)	0	0	1

- No pseudoaneurysm, stenosis, thrombosis, distal embolization or UE wound infection
- No loss of UE arterial patency after mean follow up of 38±15 months

** Hematoma requiring surgical evacuation*

Cerebral events

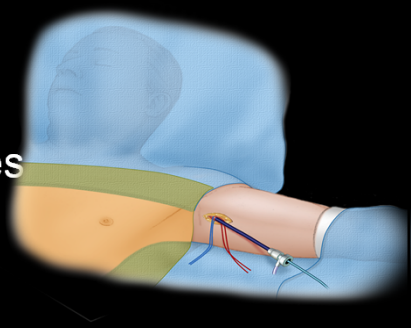
5 patients (2%) had stroke

Complication	Total (n = 243)	Pararenal (n = 96)	Extent IV (n = 69)	Extent I-III (n = 78)	P value
	n (%)				
Minor stroke	3 (1)	0	1 (1)	2 (3)	0.27
Major stroke	2 (1)	1 (1)	0	1 (1)	0.65

- 2 patients (1%) had asymptomatic cerebral emboli incidentally diagnosed by imaging studies
- Right UE access was associated with more strokes compared to left UE access (13% vs 1%, P=0.03)

Conclusions

- Upper extremity arterial access using surgical exposure and large diameter sheaths was associated with low rates of complications, stroke and peripheral nerve injuries in patients treated by F-BEVAR
- Left-sided UE access was associated with lower stroke rates



Radiation physics

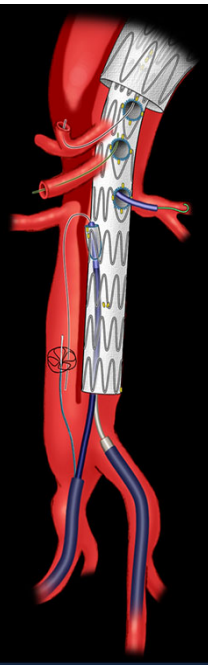
Minimizing radiation exposure to the vascular surgeon

Surgeon radiation dose during complex endovascular procedures

Radiation exposure to operating room personnel and patients during endovascular procedures

Abhisekh Mohapatra, BA,[a] Roy K. Greenberg, MD,[b] Tara M. Mastracci, MD,[b] Matthew J. Eagleton, MD,[b] and Brett Thornsberry, RT(R),[b] *Cleveland, Ohio*

CEREBROEMBOLIC OUTCOMES OF RIGHT VS LEFT UPPER EXTREMITY ACCESS DURING F-BEVAR



Aleem K. Mirza, Emanuel R. Tenorio, Jussi M. Kärkkäinen, and Gustavo S. Oderich

Advanced Endovascular Aortic Program
Mayo Clinic Aortic Center, *Rochester Minnesota*

International Symposium CHARING CROSS 15–18 APRIL 2019 MONDAY–THURSDAY OLYMPIA LONDON • UNITED KINGDOM

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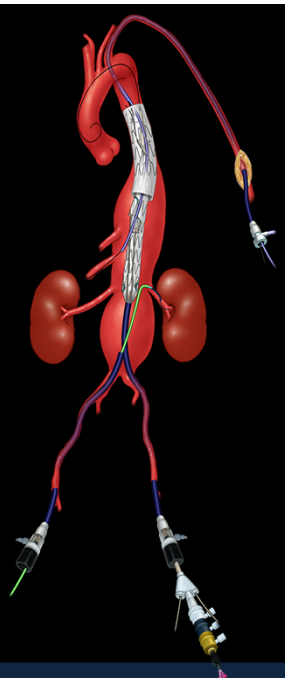
Purpose

- The aim of this study was to evaluate cerebroembolic outcomes of right (RUE) versus left (LUE) upper extremity access for F-BEVAR



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Methods

- Retrospective review of a prospectively collected database, under a physician-sponsored investigational device exemption
- All consecutive patients treated by F-BEVAR for thoracoabdominal (TAAA) and pararenal aneurysms (PRA) between 2013 and 2018
  - Included patients with UE with 12F sheaths
- Primary endpoints:
  - Major adverse events, mortality, technical success

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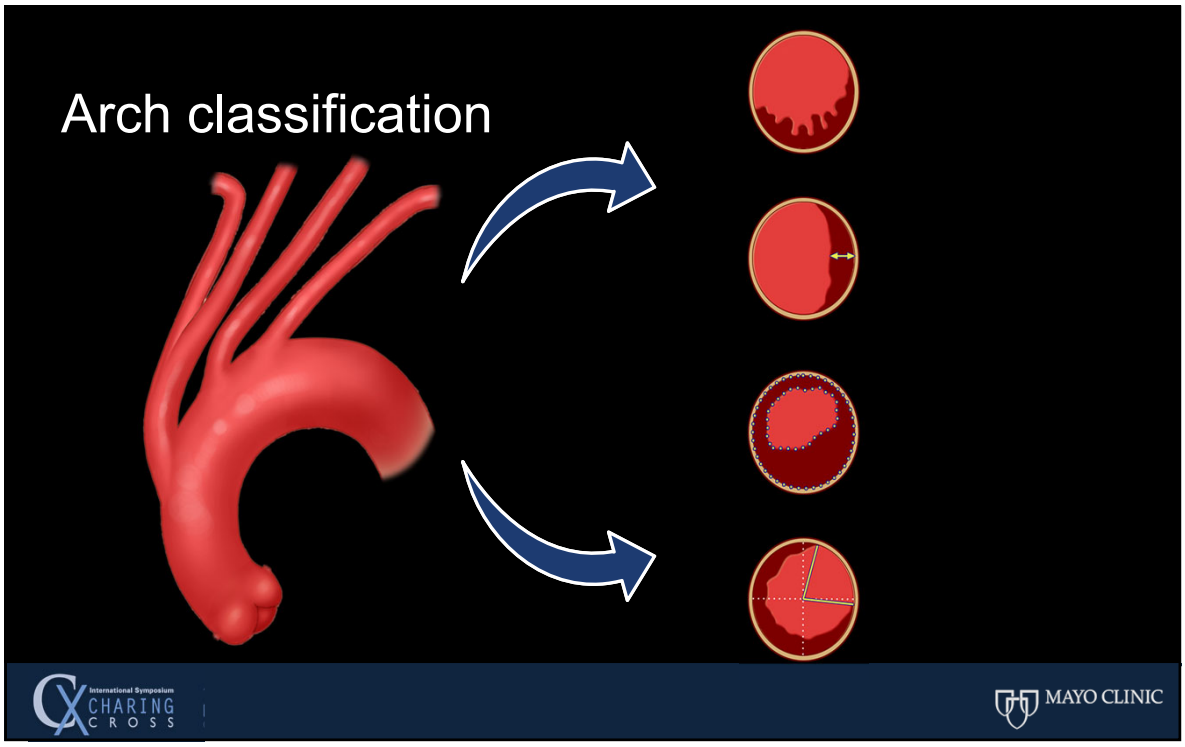
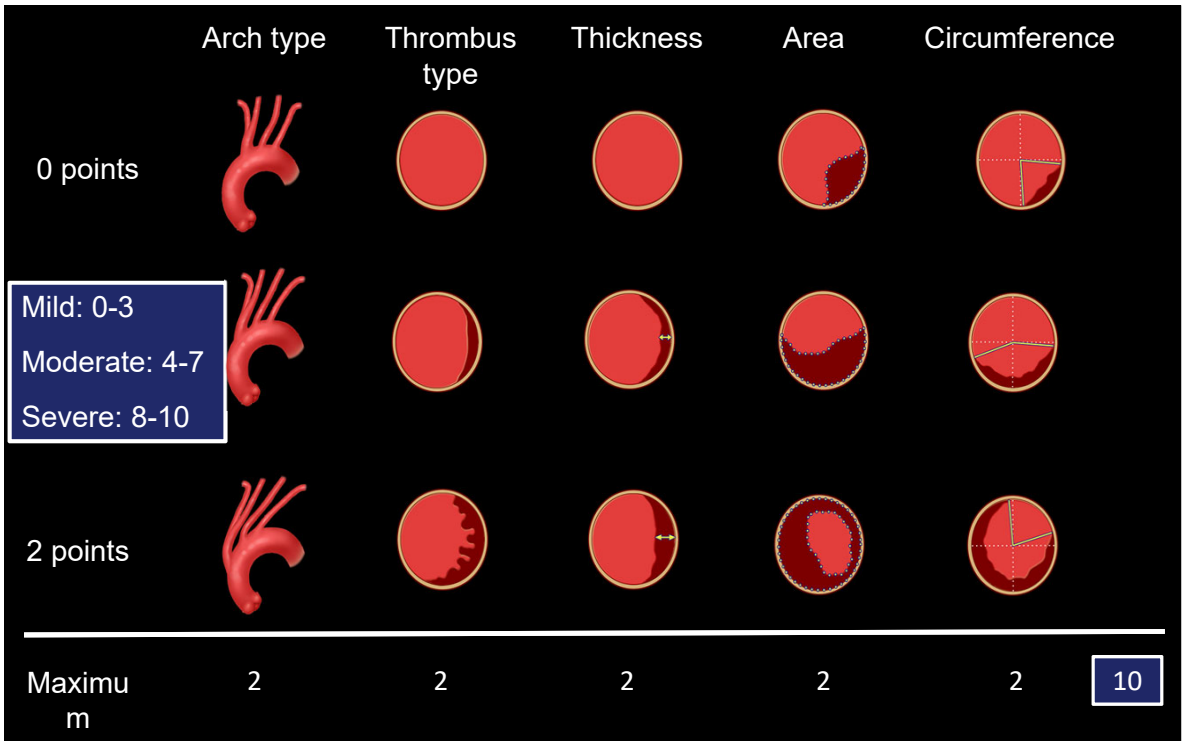

Arch classification
International Symposium
CHARING CROSS
MAYO CLINIC


Arch type
Thrombus type
Thickness
Area
Circumference
0 points
Mild: 0-3
Moderate: 4-7
Severe: 8-10
2 points
Maximum
2
2
2
2
2
10

Target-vessel incorporation

Technical success was 99% (202/205) for LUE and 92% (60/65) for RUE access, P=0.02

	Total (n = 270)	LUE access (n = 205)	RUE access (n = 65)	P value
	Percent or Mean ± Standard Deviation			
Total vessels incorporated	1054	804	250	NA
No. vessels per patient	3.9±0.6	3.9±0.5	3.8±0.7	0.21
Total vessels via UE access	689 (65)	523 (65)	166 (66)	0.75
No. vessels via UE per patient	2.6±1.0	2.6±0.9	2.6±1.0	0.88
Preloaded system	195 (72)	147 (72)	48 (74)	0.87

Major adverse events

	Total (n = 270)	LUE access (n = 205)	RUE access (n = 65)	P value
	Percent or Mean ± Standard Deviation			
Death	2 (1)	1 (1)	1 (1)	0.42
Any MAE	82 (30)	65 (32)	17 (26)	0.44
Acute kidney injury	39 (14)	28 (14)	11 (17)	0.54
Estimated blood loss >1L	30 (11)	24 (12)	6 (9)	0.66
Myocardial infarction	10 (4)	8 (4)	2 (3)	1.00
SCI grade 3a – c	8 (3)	6 (3)	2 (3)	1.00
Stroke	7 (3)	6 (3)	1 (2)	1.00
Respiratory failure	6 (2)	4 (2)	2 (3)	0.63
Bowel ischemia	24 (9)	18 (9)	6 (9)	1.00

- Mean follow-up was 19 ± 14 months

Embolic stroke

	Total (n = 270)	LUE access (n = 205)	RUE access (n = 65)	P value
	Percent or Mean ± Standard Deviation			
Embolic stroke	5 (2)	4 (2)	1 (1.5)	0.65
Ipsilateral stroke	4 (2)	3 (1.5)	1 (1.5)	0.67
Minor stroke	3 (1)	3 (2)	0	0.43
Major stroke	2 (0.5)	1 (0.5)	1 (1.5)	0.42
Posterior circulation	3 (1)	2 (1)	1 (1.5)	0.56
Anterior circulation	1 (0.5)	1 (0.5)	0	0.76
Combined ant. & post.	1 (0.5)	1 (0.5)	0	0.76

- Five patients had embolic strokes
- Four patients had strokes ipsilateral access to UE access

Embolic stroke

Points	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Total score	4	4	5	5	7
Arch type	2	2	2	1	2
Thrombus type	1	1	1	1	2
Thrombus thickness	1	1	1	1	2
Thrombus area	0	0	0	0	0
Thrombus circumference	0	0	1	2	1

- Four strokes (80%) had type III arches
- One stroke (20%) had a type II arch

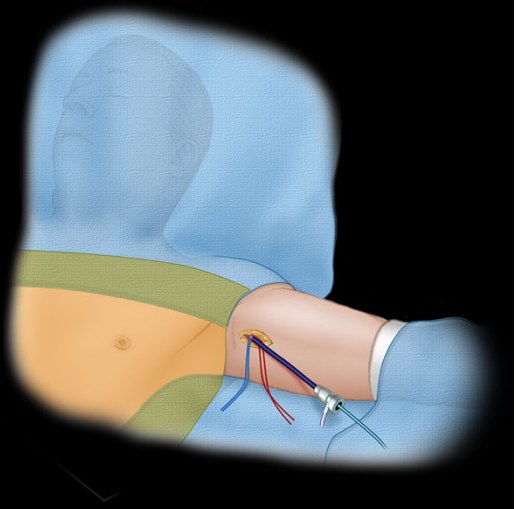
Mild: 0-3

Moderate: 4-7

Severe: 8-10

Conclusions

- Right and left UE access during F-BEVAR have similar rate of cerebroembolic complications and procedural metrics
  - Radiation dose was lower with right UE access
- The majority of strokes occurred with unfavorable type III aortic arches



International Symposium CHARING CROSS

MAYO CLINIC

78-year-old man with enlarging Extent II TAAA after DeBakey Type I aortic dissection, prior ascending aortic repair and EVAR

Aleem Mirza MD and Gustavo S. Oderich MD

From the Aortic Endovascular Research Program
Division of Vascular and Endovascular Surgery

VASCULAR ANNUAL MEETING SAN DIEGO

MAYO CLINIC

Current research

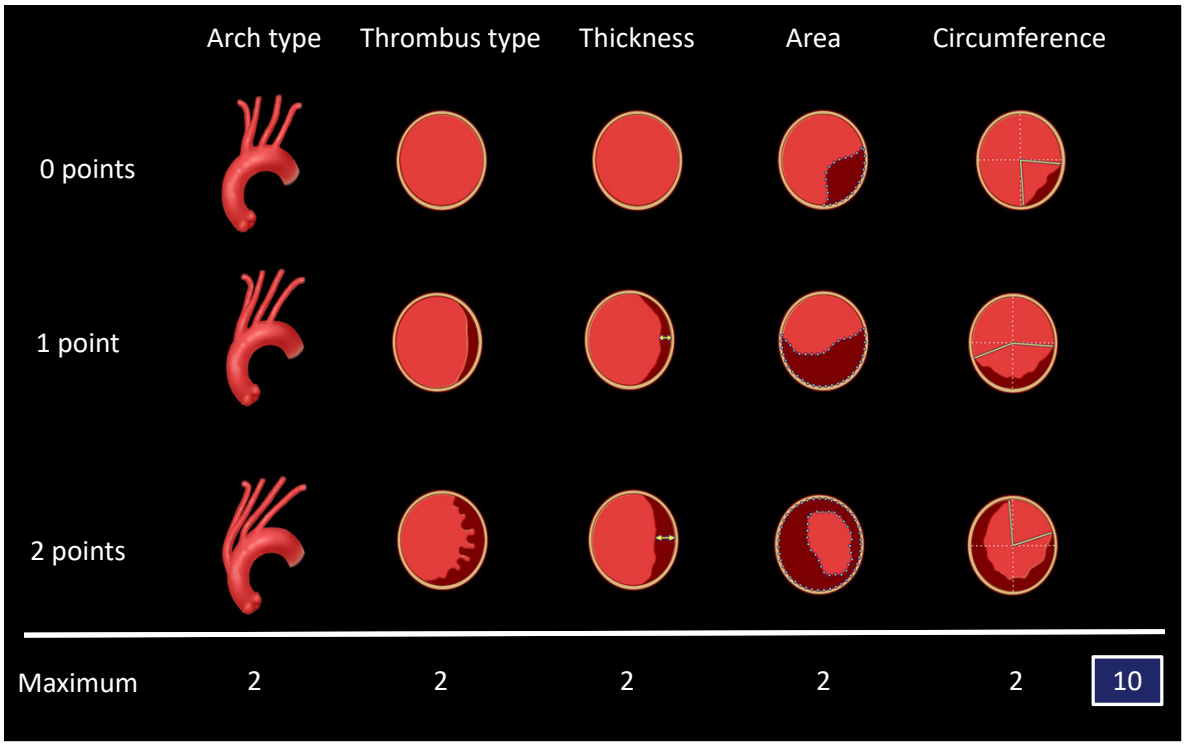
Anatomic characteristics of the aortic arch associated with cerebroembolism

- Aims:
  - evaluate the incidence of stroke after TEVAR and TAVR
  - Determine anatomic characteristics of the aortic arch that predispose to stroke

Current research

Anatomic characteristics of the aortic arch associated with cerebroembolism

- Patients:
  - >1000 patients who underwent TEVAR/TAVR
  - Exclude those with cerebral protection
- Preoperative CTA
  - Centerline-flow imaging



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