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 symptoms 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
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?

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.

PI:
Retu Saxena, MD

RESEARCH CONTACT:
Steph Ebnet, RN
Stephanie.ebnet@allina.com | 612-863-6286
Adjuncts during F-BEVAR: upper extremity access and future directions

Aleem K Mirza, MD

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-branch repair

In Oderich Atlas of Fenestrated, Branched and Parallel Techniques, Springer 2016
Stent-graft design

- Off-the-Shelf
  - Cook t-Branch®

- Patient Specific
  - Fenestrations or branches

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:

<table>
<thead>
<tr>
<th>Radial</th>
<th>Carotid</th>
<th>Femoral</th>
<th>DP</th>
<th>PT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right:</td>
<td>+</td>
<td>+</td>
<td>(+)</td>
<td>(+)</td>
</tr>
<tr>
<td>Left:</td>
<td>+</td>
<td>+</td>
<td>(+)</td>
<td>(+)</td>
</tr>
</tbody>
</table>
Preoperative evaluation

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

35 months
89mm

45 months
103mm

39 months
100mm

Contrast – enhanced ultrasound
Imaging summary

45 months

46 months
Platelet trend

![Graph showing platelet trend over time, with data points for March 2015 to January 2019.]

Imaging summary

![Imaging summary with images of SMA, RRA, CA, and LRA, showing measurements in millimeters.]

- SMA: 20mm
- RRA: 20mm
- CA: 31mm
- LRA: 27mm
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

Thousands per microliter

POD 1 | POD 2 | POD 5 | POD 10 | POD 15 | POD 20 | POD 32
Outcomes of upper extremity access during fenestrated-branched endovascular aortic repair

PRESENTED BY:
Aleem K. Mirza MD, Gustavo S. Oderich MD, Giuliano Sandri MD, Emanuel Tenorio MD PhD, Victor J. Davila MD, Jan Hofer RN, Jean Wigham RN and Stephan Cha MS

Mayo Clinic, Rochester MN

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

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)

Included 243 patients (73%) who had F-BEVAR with UE access

- 96 pararenal (40%)
- 69 Extent IV TAAA (28%)
- 78 Extent I-III TAAA (32%)
Selection of access site

• Left side selected whenever possible

Access technique

• All patients had surgical exposure
Arterial closure

Focal dissection

Primary closure
Interrupted 7-0 prolene

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

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

**Access-related complications**

8 patients (3%) had access-related complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>Total (n = 243)</th>
<th>Pararenal (n = 96)</th>
<th>Extent IV (n = 69)</th>
<th>Extent I-III (n = 78)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>5 (2)</td>
<td>2 (2)</td>
<td>2 (3)</td>
<td>1 (1)</td>
<td>0.8</td>
</tr>
<tr>
<td>Neuropraxia</td>
<td>2 (1)</td>
<td>2 (2)</td>
<td>0</td>
<td>0</td>
<td>0.24</td>
</tr>
<tr>
<td>Hematoma*</td>
<td>1 (0.4)</td>
<td>1 (0)</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

- 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

<table>
<thead>
<tr>
<th>Complication</th>
<th>Total (n = 243)</th>
<th>Pararenal (n = 96)</th>
<th>Extent IV (n = 69)</th>
<th>Extent I-III (n = 78)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor stroke</td>
<td>3 (1)</td>
<td>0</td>
<td>1 (1)</td>
<td>2 (3)</td>
<td>0.27</td>
</tr>
<tr>
<td>Major stroke</td>
<td>2 (1)</td>
<td>1 (1)</td>
<td>0</td>
<td>1 (1)</td>
<td>0.65</td>
</tr>
</tbody>
</table>

- 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

Abhishek 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
Purpose

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

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
Arch classification

Arch type

0 points

Mild: 0-3
Moderate: 4-7
Severe: 8-10

2 points

Maximum

2 2 2 2 2 2 10

Thrombus type

Thickness

Area

Circumference
# Target-vessel incorporation

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

<table>
<thead>
<tr>
<th></th>
<th>Total (n = 270)</th>
<th>LUE access (n = 205)</th>
<th>RUE access (n = 65)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total vessels</td>
<td>1054</td>
<td>804</td>
<td>250</td>
<td>NA</td>
</tr>
<tr>
<td>incorporated</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. vessels per</td>
<td>3.9±0.6</td>
<td>3.9±0.5</td>
<td>3.8±0.7</td>
<td>0.21</td>
</tr>
<tr>
<td>patient</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total vessels via</td>
<td>689 (65)</td>
<td>523 (65)</td>
<td>166 (66)</td>
<td>0.75</td>
</tr>
<tr>
<td>UE access</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. vessels via UE</td>
<td>2.6±1.0</td>
<td>2.6±0.9</td>
<td>2.6±1.0</td>
<td>0.88</td>
</tr>
<tr>
<td>per patient</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preloaded system</td>
<td>195 (72)</td>
<td>147 (72)</td>
<td>48 (74)</td>
<td>0.87</td>
</tr>
</tbody>
</table>

# Major adverse events

<table>
<thead>
<tr>
<th></th>
<th>Total (n = 270)</th>
<th>LUE access (n = 205)</th>
<th>RUE access (n = 65)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>2 (1)</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>0.42</td>
</tr>
<tr>
<td>Any MAE</td>
<td>82 (30)</td>
<td>65 (32)</td>
<td>17 (26)</td>
<td>0.44</td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>39 (14)</td>
<td>28 (14)</td>
<td>11 (17)</td>
<td>0.54</td>
</tr>
<tr>
<td>Estimated blood loss</td>
<td>30 (11)</td>
<td>24 (12)</td>
<td>6 (9)</td>
<td>0.66</td>
</tr>
<tr>
<td>&gt;1L</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>10 (4)</td>
<td>8 (4)</td>
<td>2 (3)</td>
<td>1.00</td>
</tr>
<tr>
<td>SCI grade 3a – c</td>
<td>8 (3)</td>
<td>6 (3)</td>
<td>2 (3)</td>
<td>1.00</td>
</tr>
<tr>
<td>Stroke</td>
<td>7 (3)</td>
<td>6 (3)</td>
<td>1 (2)</td>
<td>1.00</td>
</tr>
<tr>
<td>Respiratory failure</td>
<td>6 (2)</td>
<td>4 (2)</td>
<td>2 (3)</td>
<td>0.63</td>
</tr>
<tr>
<td>Bowel ischemia</td>
<td>24 (9)</td>
<td>18 (9)</td>
<td>6 (9)</td>
<td>1.00</td>
</tr>
</tbody>
</table>

- Mean follow-up was 19 ± 14 months
### Embolic stroke

<table>
<thead>
<tr>
<th></th>
<th>Total (n = 270)</th>
<th>LUE access (n = 205)</th>
<th>RUE access (n = 65)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embolic stroke</td>
<td>5 (2)</td>
<td>4 (2)</td>
<td>1 (1.5)</td>
<td>0.65</td>
</tr>
<tr>
<td>Ipsilateral stroke</td>
<td>4 (2)</td>
<td>3 (1.5)</td>
<td>1 (1.5)</td>
<td>0.67</td>
</tr>
<tr>
<td>Minor stroke</td>
<td>3 (1)</td>
<td>3 (2)</td>
<td>0</td>
<td>0.43</td>
</tr>
<tr>
<td>Major stroke</td>
<td>2 (0.5)</td>
<td>1 (0.5)</td>
<td>1 (1.5)</td>
<td>0.42</td>
</tr>
<tr>
<td>Posterior circulation</td>
<td>3 (1)</td>
<td>2 (1)</td>
<td>1 (1.5)</td>
<td>0.56</td>
</tr>
<tr>
<td>Anterior circulation</td>
<td>1 (0.5)</td>
<td>1 (0.5)</td>
<td>0</td>
<td>0.76</td>
</tr>
<tr>
<td>Combined ant. &amp; post.</td>
<td>1 (0.5)</td>
<td>1 (0.5)</td>
<td>0</td>
<td>0.76</td>
</tr>
</tbody>
</table>

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

### Embolic stroke

<table>
<thead>
<tr>
<th>Points</th>
<th>Patient 1</th>
<th>Patient 2</th>
<th>Patient 3</th>
<th>Patient 4</th>
<th>Patient 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total score</td>
<td>4</td>
<td>4</td>
<td>5</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Arch type</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Thrombus type</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Thrombus thickness</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Thrombus area</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Thrombus circumference</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

- 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
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
Arch type | Thrombus type | Thickness | Area | Circumference
---|---|---|---|---
0 points | | | | 
1 point | | | | 
2 points | | | | 
Maximum | 2 | 2 | 2 | 2 | 2 | 10

References
