Reinterventions After Fenestrated and Branched Endovascular Aortic Aneurysm Repair

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DISCLOSURE

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• No relevant financial relationship reported
Endovascular aneurysm repair (EVAR)

Over last 25 years, EVAR has become the most common repair strategy for treatment of infrarenal aortic aneurysms.

Limitations:
- Life-long surveillance to monitor for complications, e.g., type 1A endoleak, graft migration, proximal neck dilation
- Need for re-interventions
Fenestrated/branched EVAR (F/BEVAR)

First described in 1990s; repair of more complex aneurysms with fenestrations and/or branches, using

- Physician-modified endografts (PMEG)
- Company manufactured devices (CMD)

Limitations:

- Similar to EVAR
- With increased complexity, potential for additional types of re-interventions
PRIMARY OBJECTIVE:
To evaluate custom made devices and physician-modified FDA-approved devices for the treatment of patients with complex abdominal or thoracoabdominal aneurysms.

External CRO, CEC, Imaging Lab.
Fenestrations

- Small (6x6mm)
- Large (8x8mm)

Branches

- Internal
- Helical

- Narrow lumen (<35mm)
- Up-going arteries

- Large lumen
- Down-going arteries
Results—Graft Type Percentage (n=202)

- Company Manufactured Graft: 155
- Physician Modified Graft: 47
## Results—Aneurysm Extent (n=202)

<table>
<thead>
<tr>
<th>Type of Aneurysm</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Iliac Aneurysm</td>
<td>5</td>
</tr>
<tr>
<td>Juxtarenal Aortic Aneurysm</td>
<td>82</td>
</tr>
<tr>
<td>Para renal Aortic Aneurysm</td>
<td>31</td>
</tr>
<tr>
<td>Thoracoabdominal Aortic Aneurysm</td>
<td>83</td>
</tr>
</tbody>
</table>
Results—Fenestrations (n=202)

Total number of target arteries included = 663

Average: 3.3 target arteries per patient
Reinterventions after fenestrated or branched endovascular aortic aneurysm repair


ABSTRACT

Objective: Reinterventions after fenestrated or branched endovascular aneurysm repair (F/B-EVAR) are sometimes necessary to maintain aneurysm exclusion or endograft and target artery patency. These reinterventions are nontrivial, potentially associated with morbidity, mortality, and resource utilization. Whereas rates, types, and outcomes of re-intervention after infrarenal EVAR have been well described, they have not been well described for F/B-EVAR. We sought to characterize the morbidity, mortality, and resource utilization due to reinterventions after F/B-EVAR.

Methods: All F/B-EVAR variables collected prospectively through a single-institution, Institutional Review Board-approved registry, which included patients enrolled in a physician-sponsored investigational device exemption trial (G130210), were reviewed (November 2010-December 2016). Reinterventions were defined as any procedure that was aneurysm related, device related, or target artery related. For patients with more than one reintervention, each intervention occurrence was treated as a discrete event. Reintervention type, indication, timing (perioperative, days 0-30; short term, days 31-180; midterm, >180 days), inpatient/outpatient, length of stay, and morbidity/mortality were recorded. Reintervention success was defined as resolution of the indication.

Results: Among 123 consecutive F/B-EVARs (mean follow-up, 25 months), 32 patients (25%) underwent 54 reinterventions (one reintervention, 20 (63%) patients; two reinterventions, 6 (19%) patients; three reinterventions, 4 (13%) patients; four reinterventions, 1 (3.1%) patient; and six reinterventions, 1 (3.1%) patient). The most frequent indications were type III endoleaks (n = 15 [28%]), target artery occlusions (n = 7 [13%]), and stenoses (n = 6 [11%]). These were performed in the perioperative, short-term, and midterm time frames 17%, 41%, and 43% of the time, respectively. Reinterventions were percutaneous (67%), inpatient procedures (61%), with median length of stay of 5 days. Of the 32 reintervention patients, 4 experienced access site complications and 4 died <30 days after reintervention (3 were adjudicated as not aneurysm related/not reintervention related). In 31 of 32 (97%) patients, reintervention success was achieved.

Conclusions: Reinterventions after F/B-EVAR were necessary in 26% of patients, most commonly for type III endoleaks and target artery complications. Whereas all but one reintervention was successful, many of these required complex procedures with significant morbidity and mortality. Development of strategies to eliminate type III endoleaks by improving component junction integrity and to ensure target artery primary patency are key next steps in the evolution of F/B-EVAR. (J Vasc Surg 2018;■:1-13.)
Aims

1. To better understand re-interventions after F/BEVAR:
   • Frequency, types, and indications
   • Hospital resources utilized

2. To determine outcomes of these re-interventions:
   • Technical success (i.e., was initial complication resolved?)
   • Morbidity/mortality
Methods: Single-Institution Retrospective Review

Prospectively-maintained database at UMass Memorial Center for Complex Aortic Disease

123 consecutive F/BEVAR (Nov 2010 – Dec 2016)

- 31 (25%) ≥1 re-intervention
- 92 (75%) No re-intervention

Mean follow-up time:
- 35 months
- 21 months
Methods: Endpoints

Primary endpoint
- Number of re-interventions
- Defined as any procedure related to:
  - Aneurysm
  - Device
  - Target artery
  - Access site

Secondary endpoints
- Type
- Indication
- Timing
- Resource utilization
- Technical success
- Morbidity
- Mortality
Results: Cohort Characteristics

• Mean age 75 years
• 69% men

• No statistical differences in:
  • Sex
  • Age
  • Comorbidities
  • Tobacco use
  • Family history

• Statistical differences in aneurysm:
  • Complexity
  • Urgency
# Results: Aneurysm Complexity & Urgency

<table>
<thead>
<tr>
<th></th>
<th>≥1 Re-intervention N=31</th>
<th>No Re-intervention N=92</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aneurysm extent</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thoracoabdominal &amp; pararenal</td>
<td>21 (68%)</td>
<td>44 (48%)</td>
<td>0.05</td>
</tr>
<tr>
<td><strong>Presentation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urgent symptomatic aneurysm</td>
<td>5 (16%)</td>
<td>4 (4.4%)</td>
<td>0.04</td>
</tr>
</tbody>
</table>
### Results: Device Type & Configuration

<table>
<thead>
<tr>
<th>Graft type, n (%)</th>
<th>≥1 Re-intervention (n=31)</th>
<th>No Re-intervention (n=92)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician-modified endograft (PMEG)</td>
<td>21 (68%)</td>
<td>21 (23%)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Company manufactured device (CMD)</td>
<td>10 (32%)</td>
<td>71 (77%)</td>
<td></td>
</tr>
</tbody>
</table>

| Number of target arteries incorporated in repair $^a$ | 3.3 (0.79) | 3.2 (0.92) | 0.53 |
| Number of stented fenestrations or branches $^a$   | 2.7 (0.94) | 2.7 (1.02) | 0.93 |
| Total number of bridging stents $^a$              | 2.6 (1.3)  | 2.8 (1.2)  | 0.51 |

$^a$ mean (SD)
### Results: Length of Stay

<table>
<thead>
<tr>
<th></th>
<th>≥1 Re-intervention (n=31)</th>
<th>No Re-intervention (n=92)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU length of stay (b)</td>
<td>0 (0, 2)</td>
<td>0 (0, 1)</td>
<td>0.43</td>
</tr>
<tr>
<td>Hospital length of stay (b)</td>
<td>3 (1, 4)</td>
<td>3 (1, 4)</td>
<td>0.66</td>
</tr>
</tbody>
</table>

(b) median (IQR)
Results: Re-intervention Indication

- **Endoleak**: 51%
- **Target artery stenosis/occlusion**: 30%
- **Access site related**: 10%
- **Other**: 9%
- **Type 3 endoleak**: 28%
Results: Re-intervention Timing

Perioperative, Days 0-30: 8 (15%)
Early, Days 31-180: 22 (42%)
Mid-term, >180 days: 23 (43%)
## Results: Re-intervention Type

N=31 patients

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent placement</td>
<td>22</td>
</tr>
<tr>
<td>Angioplasty only</td>
<td>7</td>
</tr>
<tr>
<td>Translumbar coil or glue embolization</td>
<td>4</td>
</tr>
<tr>
<td>Access site artery thrombectomy</td>
<td>3</td>
</tr>
<tr>
<td>Aptus EndoAnchor placement</td>
<td>3</td>
</tr>
<tr>
<td>Endograft extension of proximal/distal seal</td>
<td>3</td>
</tr>
<tr>
<td>Thrombin injection of pseudoaneurysm</td>
<td>2</td>
</tr>
<tr>
<td>Aortic arch replacement</td>
<td>1</td>
</tr>
<tr>
<td>Aortic cuff bridge placement</td>
<td>1</td>
</tr>
<tr>
<td><strong>Bypass surgery:</strong></td>
<td></td>
</tr>
<tr>
<td>SMA bypass</td>
<td>1</td>
</tr>
<tr>
<td>Axillobifemoral bypass</td>
<td>1</td>
</tr>
<tr>
<td>EIA to PFA bypass</td>
<td>1</td>
</tr>
<tr>
<td>Femoral to femoral bypass</td>
<td>1</td>
</tr>
<tr>
<td>Embolization of fenestration</td>
<td>1</td>
</tr>
<tr>
<td>Palmaz stent placement</td>
<td>1</td>
</tr>
<tr>
<td>Thrombectomy of iliac artery and distal bypass</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>53</strong></td>
</tr>
</tbody>
</table>
Results: Re-intervention Resource Utilization

• Procedure type
  - Endovascular, percutaneous: 68%
  - Open: 17%
  - Endovascular, open exposure: 15%

• Hospital course
  - 27 (51%) required hospital admission
  - 21 (40%) were outpatient
  - 5 (9.4%) occurred during primary hospitalization attributed to F/BEVAR
Results: Re-intervention Outcome & Mortality

• **Outcomes**
  – Technical success achieved in 30 of 31 (97%) patients
  – One case was not resolved:
    • SMA occlusion (n=1)

• **Mortality**
  – **0-30 days**: 4 (13%) deaths
    • Aneurysm-related: SMA bypass (n=1)
  – **>30 days**: 5 (16%) deaths
    • All were non-aneurysm-related/non-re-intervention-related
Study Limitations

- Prospective cohort study, but some additional re-intervention details were collected retrospectively.

- Series includes all consecutive F/BEVAR cases performed since the inception of our endovascular complex aortic program → “Learning curve”

- Limited generalizability
In Summary

Among 123 consecutive F/BEVAR, 25% of patients required at least one re-intervention over two years.

The most common indications were type 3 endoleaks and target artery complications.

While most re-interventions were successful and treated endovascularly, high-risk open procedures were required with associated morbidity and mortality.
Conclusion

F/BEVAR allows us to treat complex aortic aneurysm disease with a less invasive approach than open repair.

However, F/BEVAR requires life-long surveillance and potential re-interventions, similar to the management of a chronic disease.
Future Research

Future studies should be aimed at strategies to:

• Reduce type 3 endoleak
• Improve target artery patency
• Determine optimal device configuration of fenestrations and branches

These are crucial next steps in the evolution of F/BEVAR.
Thank You