Tips For Decreasing The Learning Curve For Performing F/BEVAR

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Disclosures
• Case Proctor, Cook Medical

In the United States, >80% of infrarenal elective repairs of AAA are performed utilizing EVAR

Lederle et al, NEJM, 2012

Challenges
• New technical and surgical skills
• New imaging skill set
• New knowledge of rapidly evolving endovascular graft design technologies
• Restrictive regulatory environment

Result:
Complex endovascular aortic repair embraced by relatively few centers of excellence.
Developing a complex endovascular fenestrated and branched aortic program

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In 2008, the surgical priority in our division’s 5-year strategic plan was to become an internationally recognized center of excellence for the endovascular treatment of complex aortic pathology, including those that result in the aortic dissection. The components were identified as “must-critical” to achieve this strategic priority: (1) training in areas of excellence in complex endovascular repair; (2) industry partnership to improve access to developing technologies; (3) a fully integrated team approach with one key involved in all steps of the process; (4) prospective data collection, and (5) development and implementation of the infrastructure to support our program, which included our successful participation in the Eurostar registry.

Methods

1. Identification of key programmatic elements
2. Analysis of outcomes—single center retrospective review

Results:

Key Programmatic Elements

1. On-site training at established international centers of excellence in complex endovascular aortic intervention.
   - Case review
   - Case planning
   - Device selection
   - Procedure conduct

2. Industry partnership to improve access to developing technologies.
   - Vetted different device manufacturers
   - Mutually beneficial relationship

Goals:

1. Identify key programmatic elements essential for implementation of a complex endovascular aortic program.
2. Evaluate our initial outcomes
Results:
Key Programmatic Elements

3. A fully integrated team approach with one leader involved in all steps of all cases.
   - Ensure that advanced skill set required is maximized and not diluted among many
   - Critical to ensure buy-in from entire division
     • Referring surgeon included in all planning, procedural, and follow-up events
     • Referring surgeon bills for the procedure

Results:
Key Programmatic Elements

4. Prospective data collection.
   - Demonstrating acceptable clinical outcomes is imperative to the success of any new program
   - IRB approved prospective registry
   - Physician-Sponsored Investigational Device Exemption Study

Results:
Key Programmatic Elements

5. Development and implementation of a physician-sponsored investigational device exemption (IDE) for the endovascular treatment of juxtarenal, pararenal, and thoracoabdominal aneurysms.
   - Commercially available devices extremely limited
   - Engage the FDA early and frequently

Results—Demographics

<table>
<thead>
<tr>
<th>Variable</th>
<th>N=83</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>26</td>
</tr>
<tr>
<td>Age (mean (SD) years)</td>
<td>74 (8.6)</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
</tr>
<tr>
<td>Coronary Artery Disease</td>
<td>48 (58%)</td>
</tr>
<tr>
<td>Prior Stroke</td>
<td>10 (12%)</td>
</tr>
<tr>
<td>Chronic Obstructive Pulmonary Disease</td>
<td>25 (30%)</td>
</tr>
<tr>
<td>Chronic Renal Dysfunction</td>
<td>22 (27%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>12 (15%)</td>
</tr>
<tr>
<td>Cancer</td>
<td>26 (24%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>69 (83%)</td>
</tr>
<tr>
<td>Tobacco (Current)</td>
<td>22 (27%)</td>
</tr>
<tr>
<td>Prior Abdominal Endovascular Aneurysm Repair</td>
<td>8 (10%)</td>
</tr>
<tr>
<td>Prior Thoracic Endovascular Aneurysm Repair</td>
<td>5 (6%)</td>
</tr>
<tr>
<td>First Degree Relative with Aortic Aneurysm</td>
<td>13 (16%)</td>
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</tbody>
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Presentation
- Elective Intact Aneurysm: 72 (87%)
- Urgent Symptomatic Aneurysm: 9 (11%)
- Ruptured Aneurysm: 2 (2.4%)

Results—Graft Type Percentage (n=83)

- Company Manufactured Graft: 51%
- Physician Modified Graft: 49%

Results—Aneurysm Extent (n=83)

<table>
<thead>
<tr>
<th>Type of Aneurysm</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Iliac Aneurysm</td>
<td>4</td>
</tr>
<tr>
<td>Juxtarenal Aortic Aneurysm</td>
<td>35</td>
</tr>
<tr>
<td>Pararenal Aortic Aneurysm</td>
<td>16</td>
</tr>
<tr>
<td>Thoracoabdominal Aortic Aneurysm</td>
<td>27</td>
</tr>
</tbody>
</table>
Results—Fenestrations (n=83)

- Total number of fenestrations/branches per procedure
- Number of Patients: 11, 7, 37, 28

Results—Technical Success (n=83)

- Number of Patients: 4 (4.8%), 6 (7.2%), 73 (88%)

Results—30 day (n=83)

- Number of Patients: 0, 0, 0, 1, 2, 3, 6, 8, 10

Of the 10 Type 1 or 3 endoleaks observed within 30 days, 7 resolved after a secondary intervention and 1 resolved without intervention.

Of the 3 patients who required dialysis within 30 days, 1 resolved and 2 were permanent.

Results—1 Year

- 88% success rate

Twelve-year results of fenestrated endografts for infrarenal and suprarenal abdominal aortic aneurysms: A single-center experience.


“As experience evolved, there was a trend to increase the number of fenestrations in devices treating the same anatomy…”
Conclusions

1. A team approach to program development that leverages potential resources, inside and outside of a given institution, is an effective way to build a complex endovascular aortic program.

2. In our early experience, the outcomes appear to be acceptable for the complicated patients treated.

Thank You.