Choosing the Right Device for Your Patients: When Aorfix Meets the Challenge

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Disclosure

Speaker name:
Associate Professor Andrew Holden

I have the following potential conflicts of interest to report:
- [x] Consulting – Clinical Investigator for Lombard Medical
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
# Current IFUs

<table>
<thead>
<tr>
<th>Company</th>
<th>Device</th>
<th>Neck Angulation</th>
<th>Neck Length</th>
<th>Neck Diameter</th>
<th>Iliac Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endologix</td>
<td>AFX</td>
<td>&lt; 60°</td>
<td>15mm</td>
<td>32mm</td>
<td>23mm</td>
</tr>
<tr>
<td>Medtronic</td>
<td>Endurant</td>
<td>&lt; 60°</td>
<td>10mm</td>
<td>32mm</td>
<td>25mm</td>
</tr>
<tr>
<td>Cook</td>
<td>Zenith LP</td>
<td>&lt; 60°</td>
<td>15mm</td>
<td>32mm</td>
<td>20mm</td>
</tr>
<tr>
<td>Gore</td>
<td>C3</td>
<td>&lt; 60°</td>
<td>15mm</td>
<td>29mm</td>
<td>18.5mm</td>
</tr>
<tr>
<td>Trivascular</td>
<td>Ovation</td>
<td>&lt; 60°</td>
<td>7mm</td>
<td>30mm</td>
<td>20mm</td>
</tr>
<tr>
<td>Endologix</td>
<td>Nellix*</td>
<td>&lt; 60°</td>
<td>10mm</td>
<td>34mm</td>
<td>35mm</td>
</tr>
<tr>
<td>JNJ</td>
<td>Incraft</td>
<td>&lt; 60°</td>
<td>15mm</td>
<td>31mm</td>
<td>22mm</td>
</tr>
<tr>
<td>Terumo</td>
<td>Anaconda</td>
<td>&lt; 60°</td>
<td>15mm</td>
<td>31mm</td>
<td>21mm</td>
</tr>
</tbody>
</table>
Hostile Neck Anatomy

- Neck length < 15mm
- Neck diameter > 32mm
- Neck angulation > 60 degrees
- Necks with significant mural calcium or thrombus
- Conical necks
EVAR Outside of Company IFUs

- FDA database analysis of 10,228 patients treated with approved EVAR devices between 1999 and 2008
- 31-58% of patients fell outside IFU compliance
- Most due to hostile neck anatomy
The number of cases attempted with hostile neck anatomy is substantial and increasing.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Occurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck &gt;15mm</td>
<td>57.8%</td>
</tr>
<tr>
<td>Neck 10-15mm</td>
<td>17.9%</td>
</tr>
<tr>
<td>Neck &lt;10mm</td>
<td>24.4%</td>
</tr>
<tr>
<td>Female</td>
<td>15.9%</td>
</tr>
</tbody>
</table>

Source: Schanzer et al. (2011)
• Significant increase \( (p=0.02) \) in late type 1 endoleaks in hostile neck anatomy \( (9.5\%) \) compared to favourable neck anatomy \( (4.5\%) \)

• **Significant increase \( (p<0.01) \) in total interventions in HNA \( (22.8\%) \) compared to FNA \( (11.0\%) \)

*Stather et al, EJVES 2012:44:556-561*
A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy

George A. Antoniou, MD, PhD, a George S. Georgiadis, MD, b Stavros A. Antoniou, MD, c Ganesh Kuhar, MD, FRCS, a and David Murray, MD, FRCS, a Manchester, United Kingdom; Alexandroupolis, Greece; and Marburg, Germany

• Meta-analysis of 7 observational studies involving 1559 patients
• HNA patients had a fourfold increased risk of developing a late type 1 endoleak (OR 4.563) compared to FNA
• HNA patients had a ninefold increased risk of ARM within 1 year of treatment (OR 9.378)

Antoniou et al, JVS 2013:57:527-538
EVR Approach to Neck Angulation > 60°

- Commercially available devices all outside IFU
- Breaking IFU rules on proximal neck angulation carries a risk of serious complications (type 1A endoleak, migration)
EVR Approach to Neck Angulation > 60°

- I have preferred to use a tube graft to treat the angulated infra-renal neck
- This minimizes the risk of kinking in the angulated segment
- A proximal cuff/Palmaz stent may be needed to achieve seal
- A conventional bifurcated graft is then deployed into the tube graft within the aneurysm to exclude it
- Supra-renal stents may be counter-productive, especially with there is angulation between the supra and infra-renal segment
Post ESG, and Post insertion of:
Palmaz 4014, ballooned to 25mm
RIGHT
Post ESG, and
Post Insertion of:
Palmaz 4014, ballooned to 25mm
EVR Approach to Neck Angulation $> 60^\circ$

- The ability to treat severely angulated neck anatomy within company IFU with Aorfix is appealing
- Changed my approach to this anatomy
Aorfix™ Case in New Zealand
RIGHT
LAO 10° CRAN 18
Aorfix Flexible Stent Graft 27.95-80-18 Insitu
RIGHT
LAO 10/ CRAN 18
Aorfix Flexible Stent Graft 27-96-30-13 Insitu
EVR Approach to Iliac Angulation

- Conventional endograft limbs based on Z-stent designs have performed sub-optimally in cases with severe iliac artery angulation or tortuosity.
- In these cases, I have opted to use a composite graft solution, utilizing ring or helical stent support in the limbs.
EVR Approach to Iliac Angulation
EVR Approach to Iliac Angulation
EVR Approach to Iliac Angulation

Tips for severe iliac angulation
EVR Approach to Iliac Angulation

Images courtesy Dr John Hardman
5.9% circumferential thrombus
75% mild calcification
5.1% moderate to severe calcification
Aorfix™ Pythagoras IDE Trial Iliac Characteristics

Minimum Access Diameters
All Patients

- >6mm: 72%
- ≤6mm: 28%

Maximum Common Iliac Angle

- ≤150°: 62%
- >150°: 38%
Female patients have a much higher prevalence in severely angulated neck anatomy than they do in less angulated necks.

Angle Distribution By Gender

- M Count
- F Count

### Aorfix™ Pythagoras IDE Trial Inclusion

- Female patients have a much higher prevalence in severely angulated neck anatomy than they do in less angulated necks.
Pythagoras Results at 2-yr Follow-Up

Freedom from Sac Diameter Increase

97.7% All
98.5% >=60
98.9% 60-90
96.1% <60
Pythagoras Results at 2-yr Follow-Up

Freedom from Graft Occlusion

97.6%  All
97.2%  >=60
97.2%  60-90
98.5%  <60

Freedom from Migration

97.9%  All
97.8%  >=60
99.0%  60-90
98.2%  <60
Pythagoras Results at 2-yr Follow-Up

Freedom from AAA-Related Morality

97.9%  All
97.8%  >=60
99.0%  60-90
98.2%  <60
Conclusions

- Treatment of patients with complex anatomy for EVAR remains challenging
- Severely angulated infra-renal necks and tortuous iliac arteries are outside the IFU of most current EVR devices
- Aorfix is a useful tool to expand the range of treatable patients and allows more to be treated on-label
- The Aorfix™ Pythagoras IDE trial demonstrates encouraging results in angled necks and challenging anatomy
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