Accurate Endograft Placement in Angulated Aortic Necks

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Disclosures

• Spectranetics Corporation: Medical advisory board, consultant, speaker, educational grants, trainer, investigator
• Boston Scientific: Medical advisory board, speaker, fellow training faculty, educational grants, trainer, investigator
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• St Jude: investigator
• Avinger: investigator
• Gore: investigator
• Bard: Medical Advisory Board, Continuum Study Clinical Events Committee
• Ostialcorp: Medical Advisory Board; stock holder
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The Hostile Neck

- Neck Length <15 mm
- Neck angulation >60 degrees
- Reverse taper
- Calcification >50% of circumference
- Proximal neck thrombus
Considerations for the Hostile Neck

• Data and Outcomes
• Pre-procedural Planning
• Device Choice
• Tips and Tricks for Deployment
Outcomes Data

• 20% of patients with AAAs have neck morphology that is inadequate for a standard stent graft.¹

• Unfavorable neck anatomy may be responsible for up to 60% of patients who are excluded from consideration for EVAR.²

• No randomized controlled studies exist comparing outcomes between patients with hostile vs favorable neck anatomy, nor between various stent designs

### Long Term Outcomes With Hostile Necks

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Favorable</th>
<th>Hostile</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adjunctive procedure</strong></td>
<td>9%</td>
<td>22%</td>
<td>P&lt;.001</td>
</tr>
<tr>
<td><strong>Technical success</strong></td>
<td>100%</td>
<td>97%</td>
<td>P=.081</td>
</tr>
<tr>
<td><strong>30 day mortality</strong></td>
<td>2%</td>
<td>2%</td>
<td>P=.962</td>
</tr>
<tr>
<td><strong>30 day morbidity</strong></td>
<td>9%</td>
<td>15%</td>
<td>P=.065</td>
</tr>
<tr>
<td><strong>30 day re-intervention</strong></td>
<td>3%</td>
<td>0%</td>
<td>P=.949</td>
</tr>
<tr>
<td><strong>Type 1 endoleak within 30 Days</strong></td>
<td>1%</td>
<td>2%</td>
<td>P=.232</td>
</tr>
<tr>
<td><strong>Type 1 endoleak at 1 year</strong></td>
<td>1%</td>
<td>10%</td>
<td>P=.010</td>
</tr>
<tr>
<td><strong>Re-intervention at 1 year</strong></td>
<td>5%</td>
<td>5%</td>
<td>P=.974</td>
</tr>
<tr>
<td><strong>Aneurysm related mortality 1yr</strong></td>
<td>0%</td>
<td>4%</td>
<td>P=.013</td>
</tr>
</tbody>
</table>

Oversizing and Late Outcomes

• Late complications including graft migration, endoleaks, and aneurysm sac expansion may be due to remodeling of the aneurysm neck

• It is not clear if neck remodeling is related to natural progression of the AAA or due to outward forces imposed by self expanding (and oversized) stent grafts (multiple studies with conflicting conclusions exist in the literature)

• This late complication is of particular concern when deploying stent grafts in hostile neck anatomy
# IFU and the Angulated Neck Neck

<table>
<thead>
<tr>
<th>Complication</th>
<th>IFU</th>
<th>Outside IFU</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perioperative complication</td>
<td>7% (7%)</td>
<td>12% (18%)</td>
<td>P=.04</td>
</tr>
<tr>
<td>Early endo leak</td>
<td>10%</td>
<td>24%</td>
<td>P=.0002</td>
</tr>
<tr>
<td>Early Intervention</td>
<td></td>
<td></td>
<td>p=&lt;.0001</td>
</tr>
<tr>
<td>Freedom from Type 1 1 yr</td>
<td>99.5%</td>
<td>98.9%</td>
<td></td>
</tr>
<tr>
<td>2 yr</td>
<td>99.5%</td>
<td>98.1%</td>
<td></td>
</tr>
<tr>
<td>3 yr</td>
<td>98.4%</td>
<td>98.1%</td>
<td></td>
</tr>
<tr>
<td>Freedom Late Inter. 1 yr</td>
<td>99.4%</td>
<td>97.5%</td>
<td>P=0.049</td>
</tr>
<tr>
<td>2 yr</td>
<td>98%</td>
<td>96.2%</td>
<td></td>
</tr>
<tr>
<td>3 yr</td>
<td>96.8%</td>
<td>95.2%</td>
<td></td>
</tr>
<tr>
<td>Survival 1 yr</td>
<td>97%</td>
<td>93.7%</td>
<td>P=0.799</td>
</tr>
<tr>
<td>2 yr</td>
<td>93.5%</td>
<td>88.8%</td>
<td></td>
</tr>
<tr>
<td>3 yr</td>
<td>89.8%</td>
<td>86.3%</td>
<td>P=0.035</td>
</tr>
</tbody>
</table>

*Retrospective analysis of 526 patients, 52% of whom had 1 or more feature outside of the device IFU

### AbuRahma et al (cont)

<table>
<thead>
<tr>
<th>Feature</th>
<th>Complication</th>
<th>Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck angle &gt;60 degrees</td>
<td>Death</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Sac expansion</td>
<td>2.6</td>
</tr>
<tr>
<td></td>
<td>Early Intervention</td>
<td>3.3</td>
</tr>
<tr>
<td></td>
<td>Late type 1 endoleak</td>
<td>2.8</td>
</tr>
<tr>
<td>Neck Length &lt; 10mm</td>
<td>Early Intervention</td>
<td>3.4</td>
</tr>
<tr>
<td></td>
<td>Late Intervention</td>
<td>4.6</td>
</tr>
<tr>
<td></td>
<td>Late type 1 endoleak</td>
<td>4.3</td>
</tr>
</tbody>
</table>
Pre-Procedural Planning

• Dynamic CTA
• (Non-enhanced MR Angiography—equivalent to CTA; useful in renal dysfunction¹)
• Aortic Angulation vs Aortic Curvature
• 3D Imaging

1. Goshima et al; Radiology, June 2013:267(3)948-952
Dynamic CTA

• Aortic neck area increases 8.4% +/- 4.1% at the supra-renal level and 5.9% +/- 4.2% at the infra-renal level during systole

• Comparing static and dynamic images resulted in a 30% change in the size of endograft chosen

1. Van Keulen et al; Eur J Vasc Endovasc Surg 2010; 39:193-199
2. Iezzi et al; Radiology 2011; 260:591-598
Neck Angulation vs Neck Curvature

- Angulation is the angle created by the center lines of flow (supra-renal artery to the neck; neck to the aneurysm body, etc)
- Curvature describes the distance over which that angulation occurs
- Stent graft design will determine the ability of that graft to accommodate the curvature
- Larger (more abrupt) curvature results in greater displacement forces

1. Figueroa et al; J Endovasc Ther 2009;16(3):284-94
2. Schuurman et al; Eur J Endovasc Surg 2016;51:216-224
Center Lumen Line Analysis

- 3D Center lumen line (CLL) analysis provides far more accurate choosing of endograft sizing.
- 3D CLL vs 2D CLL sizing resulted in similar endograft size choice only 17% of the time\(^1\).
- Stretched 2D CLL analysis may result in overestimation of the neck length especially in severely angulated necks\(^2\).

1. Pitoulias et al; Acta Radiol 2011;52:317-323
True 3D Imaging (Echopixel™)

- 3D work station
- 3D Glasses
- Light pen that works in the 3D space
- Allows manipulation and measurements around any axis and from any view
Tips For Accurate Angulated Neck Deployment

• Device Choice: Understand the IFU and choose a device that will conform to the anatomy and not make the anatomy conform to the device

• Understand the differences between various manufacturers and stent graft design (some newer generation devices conform to severe AAA neck angulation better than others)

• Case planning: understand the anatomy clearly and in all 3 dimensions before even starting the case.

• Use the inner curvature of an angulated neck as the measurement of the functional sealing zone
Diameter at deployment in an angulated neck will likely be larger than the diameter of the neck

- In a steeply angulated neck, it is more likely that the stent graft will sit slightly angulated relative to the center line of the aorta.
- As such, the aortic diameter “seen” by the stent graft is more typically reflected by diameter $AC$ rather than diameter $AB$
- As diameter $AC$ is $>\,$diameter $AB$, graft sizing should be adjusted to accommodate diameter $AC$
Use the Inner curvature of the neck as the functional sealing zone

- The inner curve is shorter than the outer curve.
- The inner curve therefore represents the true functional seal zone.
Tips For Accurate Angulated Neck Deployment (cont)

• Oversizing (of a self expanding graft) of 10-20% is optimal.

• Deliver with a stiff wire but pull back to the soft portion or exchange for a soft wire for deployment to allow the device to conform to the aorta.

• Lengthen the functional neck: Supra-renal coverage with snorkels or fenestrations.

• Future: Deflectable tips.
Case Examples: Extending the neck
Case Example 1

<10 mm angulated neck
Case Example 1

Both renal arteries wired
Case Example 1

Covered stents in both renal arteries

Main body of graft
Case Example 1

Stents deployed simultaneously with graft main body
Case Example 1

Stent balloons also inflated with graft post-dilatation
Case Example 1

Final Result
Case Example 2 JAAA (Juxta-renal AAA / reverse taper)

Aneurysm extends to renal arteries

Wall of Aneurysm

Wall of Aneurysm
Localizing Renal Arteries

- Wire/guide in left renal
- Pigtail in Aorta
Both Renals Wired (Bilateral Brachial artery Puncture)
Renal Stents Positioned Before Advancing the Graft

- Covered stent in left renal
- AAA stent graft
- Covered stent in right renal
Covered Renal Stents Inflated While Graft is Deployed
Deployment of Remainder of Main Body
Post-dilatation of Main Body (With balloons up in renals)
Endo-leak Actually from Right Renal
Extension of Right Renal With 2nd Covered Stent
Final Result/Leak Resolved

No Leak
Conclusions:

• Accurate endograft placement in angulated and other hostile neck anatomies begins with careful case planning.

• Comfort with and understanding of 3 D imaging and aortic structure is essential.

• Account for the dynamic nature of the anatomy (beat to beat expansion and contraction; straightening of the aorta due to the device or wire; and chronic remodeling).

• Understand the differences between the construction and conformability of the various devices, and stay within the IFU!

• Employ wire and device positioning tricks that allow the device to conform to the shape of the aorta rather than the aorta being forced into conforming to the shape of the device.

• If all else fails, remove the angle from consideration by lengthening the neck (snorkels and fenestrations).
Thank You
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