Large Diameter EVAR Devices (up to 36mm) Can Be Effective And Are Associated With Acceptable Risks: Tips For Treatment

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Disclosures:
• None

President Trump has stated many times, "preventing leaks is easy..." 

Endovascular Aneurysm Repair (EVAR)
• EVAR has become the preferred treatment for AAA repair
• Indications for use have expanded with progressive improvements:
  – active fixation
  – technology & imaging
  – delivery systems
  – physician experience
• Despite this, arguments for and against EVAR in unfavorable anatomy have been ongoing for 2 decades

Anatomic Limitations for EVAR
• Endograft advancements include the development of large diameter devices
  – US devices:
    – 36 mm: Cook Zenith
    – 36 mm: Medtronic Endurant
    – 35 mm: Gore Excluder
• Since obtaining FDA approval, large devices have been increasingly used to treat hostile aortic necks (not just wide)

Achilles’ Heel of EVAR- Infrarenal Aortic Neck
• ≈ 35% patients undergoing EVAR have adverse anatomic neck characteristics:
  – Length <10-15 mm
  – Diameter >25 mm
  – Angle > 60°
  – ≥50% thrombus or calcification
  – Reverse taper
• Skepticism exists about the use of large and/or oversized devices placed in hostile necks (out side of the IFU)
Critical Issue: Diameter & Proximal Neck Morphology are predictive of adverse events

- Flared
- Parallel
- Barrel
- Cone
- Irregular
- Hourglass

Clinical outcomes for hostile versus favorable aortic neck anatomy in endovascular aortic aneurysm repair using modular devices

- 258 patients with EVAR, 19 (8%) large diameter >28 mm
- Compared favorable v. hostile neck anatomy
- Treatment was based on IFU
- Additional hostile neck features were present in all large necks (defined as hostile necks)
- Overall type Ia endoleak rate was no different 8% v. 11% (P=.9218)

None of the neck aortic features were significant predictors for midterm type I endoleaks or intervention

Isolated large necks were excluded from the study, no late type I endoleaks with >28 diameter

Cook Zenith Flex 36 mm Aortic Endovascular Graft

- 2006, FDA approved Cook Zenith 36 mm device
- Data from Australian clinical study and Cleveland Clinic IDE
- 41 device implants (neck diameters 29-32 mm)
- 12 month results:
  - No aortic related deaths
  - No type I endoleaks
  - No device migration (>10mm)
- 36 mm device results are comparable to the US Clinical trial for 22-32 mm devices

Introduction

A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy

- Ample evidence exists linking hostile aortic necks to unfavorable EVAR outcomes
- However, increased physician experience and improved device technology have challenged these results

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Data from 3 high volume centers in Netherlands 2008-12
Comparison infrarenal necks <30 mm(n=353) v. ≥30 mm(n=74)
1° endpoint freedom neck-related adverse events
- (endoleak, migration, 2° intervention)
Median follow-up 4.1 and 3.1 years
4 year freedom from neck related adverse events were 95% and 75% (P<.001)
Limitation of large neck cohort:
- 31 reversed tapered necks 41.9% v. 25% (P=.003)
- 26 ≤10% stent graft oversizing 35.6% v.16% (P ≤.001)

Oliveira NF J Vasc Surg 2016
Oliveira NF J Vasc Surg 2016
AbuRahma J Vasc Surg 2018

Can large neck aneurysms be effectively and durably treated by EVAR?
Probably, but I have my reservations…

Tips and Techniques
EVAR in Large Neck Cases
1) Tip: avoid it when possible
   - degeneration of the infrarenal neck does occur
   - Follow IFU
2) Techniques for emergent cases:
   - Maximize landing zone and utilize suprarenal fixation
   - Close follow-up
3) Techniques for elective cases:
   - fenestrated or branched EVAR
   - conventional open repair

Tips and Techniques
Adjunctive Techniques in Large Neck Cases
1) EVAR and parallel grafts:
   - PERICLES registry: comparable outcomes to FEVAR
   - valid off the shelf option, immediately available alternative for complex EVAR
2) EVAR and Heli-FX endoanchors:
   - ANCHOR registry: freedom from type Ia endoleaks 95% at 1 year
   - Endurant II with Heli-FX endoanchors approved for short necks and angulated (not large necks)
   - anchors are an effective adjunct in prophylaxis against proximal neck complications
Conclusion

- Large aortic necks probably reflect an advancing state of aortic wall degeneration
- Early follow-up supports that larger devices are safe and effective, mid-term evidence is less favorable
- Consider using standard EVAR to treat large aortic necks in urgent or emergent cases
- Adjunctive techniques endotacking or CHIMPS may reduce neck related adverse events

Tips and Techniques (outside IFU)
Emergent EVAR in Large Neck Cases

- Maximize landing zone
- Relatively normal pararenal aorta
- EVAR with active suprarenal fixation
- Close follow-up

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