ENDOGRAFTS
ARE WE DOING A GOOD JOB
WITH THEM?
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Chairman, Department of Surgery

CONFLICTS
• Consultant
  • Boston Scientific
  • Endologix
  • Medtronic
  • Shockwave Medical
• Safety Monitoring Board
  • Bard

STANDARD ENDOGRAFTS
• Decreased peri-operative
  • Mortality
  • ICU need
  • MI
  • Respiratory complications
  • Blood transfusion requirements
  • LDS
• But there are issues with proximal neck anatomy which can make treatment challenging
• There are type II endoleaks
• There are distal anatomic issues

RAPID CONTINUED INCREASE IN EVAR

EVAR 1 Trial: Late Outcomes

EVAR 1 Trial: Late Outcomes
ACE Trial: “Low-Mod Risk” Patients

Survival Free of Death or Major Events

10,228 patients
59% <55mm diameter
31% didn’t meet 'the most liberal IFU'
41% sac enlargement at 5 years

Predictors:
- Age
- Endoleak
- Adverse neck/iliac anatomy


Mean 3 Yr F/U

Ten-year results of endovascular abdominal aortic aneurysm repair from a large multicenter registry

Robert W. Chang, MD1, Philip Goodney, MD2, Li-Yen Tucker, BA1, Steven Okutchnik, MD1, Hong Hua, MD2, Ann Rhoades, RN3, Nayan Sivaswamy, MD2, and Bradley Hill, MD2

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Mean 3 Yr F/U

Major adverse outcomes were seen in 7.9% of patients and decreased significantly from 12.3% in 2000 to 2005 to 5.6% in 2006 to 2010 (P<.001). There were 22 open conversions, 9 graft infections requiring graft removal, 7 major embolic events, 36 graft occlusions requiring treatment, 22 ruptures, and 48 cases of graft migration requiring intervention

EVAR Outside of IFU

10,228 patients
9% of cases
41% didn’t meet “most liberal IFU”
47% used endograft at 3 year

Predictors:
- Age
- Embolized
- Adverse neck/iliac anatomy
Any nonadherence to instructions for use predicts graft-related adverse events in patients undergoing elective endovascular aneurysm repair

- Close to 40% are treated outside of the IFU
- Hypothesis for worse outcomes in later years: increasingly aggressive treatment of complex necks
  - Larger neck diameters
  - Conical necks
  - Highly angulated necks
- Adapted from A. Schanzer et al., Circulation 2011; 23: 2848-55

Sac Growth As a Risk-Marker for AAA-related Mortality

- Long-term prevalence of sac growth:
  - 2% @ 1 year
  - 17% @ 3 years
  - 41% @ 5 years
- Effect of off-IFU implants:
  - Close to 40% of patients
- Adapted from Schanzer et al., Circulation 2011; 23: 2848

Covariates Prevalence, % HR P-value
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Age >80 y.o. 20.0 - 26.3 1.32 0.05
Neck diameter 28-32mm 4.7 - 7.3 1.80 <0.0001
Neck diameter >32mm 1.4 - 2.3 2.07 <0.0001
Neck angle >60 deg 6.2 - 9.5 1.96 <0.0001
One aneurysmal CIA 7.8 – 9.5 1.46 <0.0001
Any endoleak 32 2.70 <0.0001

Outcome-based anatomic criteria for defining the hostile aortic neck

- William D. Jostin Jr., MD,a Kanush Chotb, MD,b Mazin Mobin, MD, MPH,c David Verheugen, MD,b,c,d William M. Moore Jr., MD,a Frank R. Arko, MD,a James Joyce, DO,a and Juan F. P. M. de Vries, MD,a

**LARGE NECK DIAMETER**

- Conclusion: infrarenal neck diameter >30 mm
  - Threefold increased risk of EL1A
  - Fivefold risk of aneurysm rupture after EVAR
  - Worse overall survival.
LARGE NECK DIAMETER

Conclusion: EVAR in AAAs with large necks significant infrarenal aortic neck enlargement at 24 months increased risk of proximal type I endoleak increased risk of proximal neck reinterventions

In this subgroup of patients, main body oversizing >15% or suprarenal sealing after aortic morphology assessment should be considered.

ANGULATED NECK OUTCOMES

Increased neck angulation associated with increased Type Ia EL at 24 months increased need for reintervention for neck problems No overall mortality differences 24 month follow-up in small number of patients (45 AN vs 65 SN)

Midterm Success and Long-term Results

- Only long-term observations clarify effects on AAA-related complications and re-interventions

<table>
<thead>
<tr>
<th>Neck Length</th>
<th>10-15</th>
<th>&lt;10</th>
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<tbody>
<tr>
<td>Periop complications</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>Type I Endoleak (early)</td>
<td>42</td>
<td>40</td>
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<tr>
<td>Proximal cuff</td>
<td>56</td>
<td>58</td>
</tr>
<tr>
<td>Mean f/u 24.7 mos</td>
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</tbody>
</table>

SHORT NECK

- 60 patients
- Mean neck length 8.5mm
- Mean neck diameter 23.5mm
- Mean f/u 51 mo
- 3 ruptures (all with increased angulation)
- MV analysis – length<7mm associated with HR 2.8 (Type Ia endoleak and reintervention)

NECK LENGTH AND OUTCOMES

- 238 pts over 7 yrs
- 3 groups
  - >15
  - 10-15
  - <10
- Mean f/u 24.7 mos

The correlation of aortic neck length to early and late outcomes in endovascular aneurysm repair patients

Abdul Rahman, MD, John Campbell, MD, Patrick A. Stone, MD, Arvind Nanjundappa, MD, Akhlesh Jain, MD, L. Scott Dean, PhD, MBA, Joseph Habib, MD, Tannsi Reiss, RN, and Mary Eckenrode, PhD, Charleston, W. F.
CONCLUSIONS

• EVAR
  • Reduces peri-operative morbidity and mortality but mortality reduction not sustained
  • Increased risk in larger aneurysms, complex neck anatomy
  • Failure rate approximately 5 times that of open repair with current devices and approach
  • Healthy patients with “poor anatomy” should be educated about the benefits they receive from open aneurysm
  • All low risk patients deserve realistic education about the potential increased risk they have with EVAR