Why Sac Regression Matters: 5yr Experience with Endurant

Hence JM Verhagen, MD PhD
Professor and Chief of Vascular Surgery
Erasmus University Medical Center
Rotterdam, The Netherlands
Disclosures

- Medtronic
- WL Gore
- Abbott
- Terumo
- Endologix
- Arsenal AAA
Key determinants of EVAR success

- No/low incidence of endoleaks
  No endoleaks is a marker of success

- Positive AAA sac dynamics
  Shrinking AAA sac = good clinical scenario
Early sac shrinkage

• Is shrinkage of the AAA sac a proxy for success?

• Can we predict complications based on early sac dynamics?
Methods

- Patients with at least 2 similar exams (CTA or DUS), postoperative and at 1 year
- Stratify based on early sac dynamics

Early sac shrinkage predicts a low risk of late complications after endovascular aortic aneurysm repair

F. Bastos Gonçalves¹,², H. Baderkhan³, H. J. M. Verhagen¹, A. Wanhainen⁴, M. Björck⁴, R. J. Stolker², S. E. Hoeks² and K. Mann¹

BJSR 2014; 101: 802–810
Multicenter study

2000-2011
840 EVARs

Excluded because of death within 1 year: 68
28/103 ruptured AAA
40/737 intact AAA

Excluded because no 2 consecutive exams
175/772

Included: 597 (71%)
## Multicenter study

<table>
<thead>
<tr>
<th>NO SHRINKAGE</th>
<th>MODERATE SHRINKAGE</th>
<th>MAJOR SHRINKAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;5mm</td>
<td>5-9mm</td>
<td>≥10mm</td>
</tr>
<tr>
<td>N=284</td>
<td>N=142</td>
<td>N=171</td>
</tr>
</tbody>
</table>
Freedom from complications

94.4% Extensive shrinkage
88.1% Moderate shrinkage
84.3% No shrinkage
Sac dynamic and post-operative course

- Pts with no shrinkage had significantly more secondary interventions than those with moderate and major shrinkage.
- Persistent or late-onset type II endoleaks were more frequent in the no shrinkage group (19.4%) when compared to moderate and major shrinkage, 6.3% and 5.3%, respectively.

Early sac shrinkage predicts a low risk of late complications after endovascular aortic aneurysm repair

F. Bastos Gonçalves¹,², H. Baderkhan²,³, H. J. M. Verhagen¹, A. Wanhainen², M. Björck², R. J. Stolker², S. E. Hoeks³ and K. Mami³

BJS 2014; 101: 802–810
Conclusions

- Early sac shrinkage is a strong predictor of complications after EVAR

- This parameter may be used to tailor subsequent postoperative surveillance, allowing for a more rational and evidence-based strategy

_Early sac shrinkage predicts a low risk of late complications after endovascular aortic aneurysm repair_


_BJS_ 2014; 101: 802–810
Recent interest in AAA sac dynamics beyond the aorta

1-year Sac Dynamics Associated with 5-year Mortality

VSGNE, 2003–2011
N=2,437 EVAR patients

Recent interest in AAA sac dynamics beyond the aorta

1-year Sac Dynamics Associated with 5–year Mortality

VSGNE, 2003–2011
N=2,437 EVAR patients

1-year Sac Dynamics Associated with 5- and 10-year Mortality

VQI, 2003–2017
N=14,827 EVAR patients

Latest clinical signals indicate that sac regression is associated with better long-term outcomes

Long-term Survival

P < 0.01 for all comparisons. SE<0.1

n = 14,817 in VQI study

Medtronic stent graft evolution
ANEURX™, TALENT™ AND ENDURANT™ STENT GRAFT SYSTEMS

5YR IDE Trial Results

Endurant design features that influence therapy success

Accurately and reliably align the proximal edge of the stent-graft
Max seal length and low need for intra-op adjuncts

Maximize the support within the seal
Low type Ia endoleak rates

Woven High Density multifilament polyester graft fabric
Positive AAA remodeling

Tip Capture

M Sealing Stent

Endurant™ Fabric

Consistent sac regression rates with Endurant

### 5 YR SAC REGRESSION RATES

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>US IDE + PAS</td>
<td>66%</td>
<td>114/173</td>
</tr>
<tr>
<td>Full Cohort</td>
<td>61%</td>
<td>302/492</td>
</tr>
<tr>
<td>Women</td>
<td>67%</td>
<td>32/48</td>
</tr>
<tr>
<td>Men</td>
<td>61%</td>
<td>270/444</td>
</tr>
<tr>
<td>On-Label</td>
<td>63%</td>
<td>267/422</td>
</tr>
<tr>
<td>No Endoleaks</td>
<td>72%</td>
<td>246/341</td>
</tr>
</tbody>
</table>

**ENGAGE**

**per IFU**

**Real World**
### Summary

**AAA Sac Dynamics matter and device design plays a major role**

| ✔️ | Through 5-yr follow-up across ~1600 pts, ~ 98% of Endurant pts were free from rupture and aneurysm-related mortality |
| ✔️ | Large EVAR registries are showing associations between sac dynamics and long-term mortality, with sac regression correlated to improved survival overall *(further investigation warranted)* |
| ✔️ | Endurant™ design features drive low endoleak and high sac regression rates while expanding on-label patient applicability |
Thank you
Why Sac Regression Matters: 5yr Experience with Endurant

Hence JM Verhagen, MD PhD
Professor and Chief of Vascular Surgery
Erasmus University Medical Center
Rotterdam, The Netherlands