How sac regression at 1 year affects all-cause mortality through 5 year: key insights from the ENGAGE registry

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Disclosure

Speaker name:
Michel Reijnen

I have the following potential conflicts of interest to report:

✓ Consulting

☐ Employment in industry

☐ Stockholder of a healthcare company

☐ Owner of a healthcare company

☐ Other(s)

☐ I do not have any potential conflict of interest
Is EVAR undergoing a paradigm shift?

Sac dynamics have always been a robust indicator of EVAR durability but without distinction between stable and regressing aneurysms.
Is EVAR undergoing a paradigm shift?

New evidence links sac shrinkage to better outcomes

1-Yr Sac Dynamics Associated with 5-YR Mortality

**VSGNE, 2003 – 2011**

N=1,802 EVAR patients

Log Rank P < .0001

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

**VQI, 2003 – 2017**

N=14,827 EVAR patients

Long-Term Survival

P < .01 for all comparisons. SE < 0.1


Is EVAR undergoing a paradigm shift?

New evidence links sac shrinkage to better outcomes

17,096

total subjects in 8 studies
(8,518 patients with sac shrinkage & 8,578 patients without shrinkage)
subjected to EVAR between 1997-2018²
> 20 publications and > 100 presentations at major International/National conferences characterizing ENDURANT™ clinical outcomes
ENGAGE Registry
challenging patient cohort

- AAA >7cm: 15.2%
- Symptomatic AAA: 16.0%
- ASA IV: 10.6%
- Outside IFU: 17.8%
- Proximal Neck <15mm: 12.0%
- Infrarenal Neck >60°: 10.2%
Other baseline characteristics were not statistically different between groups

* indicates p<0.05 compared to sac decrease group, note bars charts for different variables are not drawn to the same scale
Procedural differences observed despite similar baseline characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Sac Increase</th>
<th>Sac Stable</th>
<th>Sac Decrease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Off label (%)</td>
<td>26.1</td>
<td>17.3</td>
<td>15</td>
</tr>
<tr>
<td>Implant dur. (min)</td>
<td>122.2</td>
<td>98.8</td>
<td>98.9</td>
</tr>
<tr>
<td>Contrast vol. (cc)</td>
<td>156.2</td>
<td>124.8</td>
<td>128.6</td>
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<tr>
<td>Fluoro time (min)</td>
<td>25.1</td>
<td>20.4</td>
<td>19.9</td>
</tr>
<tr>
<td>ICU stay (hours)</td>
<td>15.5</td>
<td>11.1</td>
<td>6.4</td>
</tr>
</tbody>
</table>

* indicates p<0.05 compared to sac decrease group, note bars charts for different variables are not drawn to the same scale
Clinical follow-up compliance >90% at 5 Years (>650 patients)

Imaging follow-up compliance >75% at 5 Years (>500 patients)

**SAC DYNAMICS AT 5 YEARS**

- Increase: 10.6%
- Stable: 28.0%
- Decrease: 61.4%

**SUMMARY OF RESULTS THROUGH 5 YEARS**

- **97.8%** FF Aneurysm Related Mortality
- **98.6%** FF Aneurysm Rupture
- **84.3%** FF Secondary Procedure

**61.4%** of AAA had sac diameter decrease at 5 years.
US IDE trial

**CORE LAB**

99.3% (149/150)

Successful delivery and deployment

**ENDOLEAKS**

<table>
<thead>
<tr>
<th></th>
<th>1 Year</th>
<th>2 Years</th>
<th>5 Years</th>
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<tbody>
<tr>
<td>Core Lab</td>
<td>0%</td>
<td>0.8%</td>
<td>0%</td>
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<tr>
<td>Type I/III Endoleak</td>
<td>9.1%</td>
<td>9.1%</td>
<td>4.1%</td>
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<tr>
<td>Type II Endoleak</td>
<td>52.6%</td>
<td>61.7%</td>
<td>65.5%</td>
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**AAA SAC DYNAMICS**

65.5% of AAAs decreased at 5 years

- No migrations
- No fractures
- No conversions
ENGAGE Registry

Freedom from major adverse events

<table>
<thead>
<tr>
<th>Time from Implant (Days)</th>
<th>No. at risk</th>
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<tr>
<td></td>
<td>441</td>
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<td>432</td>
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Decrease 75.7%
Stable 67.0% (p=0.007)
Increase 55.6% (p=0.004)

p-values are for comparisons to the sac decrease group
ENGAGE Registry
Freedom from secondary endovascular procedures

p-values are for comparisons to the sac decrease group
ENGAGE Registry

Freedom from all cause mortality

- Decrease 80.0%
- Stable 71.9% (p=0.007)
- Increase 62.6% (p=0.010)

p-values are for comparisons to the sac decrease group
1 year stable sacs are not benign
Of those with stable sacs at 1yr:
• 41% continue to be stable at 5yrs
• 18% have sac increase at 5yrs

1 year sac regression is indicative of 5yr sac dynamics
Of those with sac regression at 1yr:
• 86% continue to have sac regression at 5yrs
• 2% have sac increase at 5yrs

5 YEAR SAC STATUS
Summary

• 1yr stable sacs are not always benign;
  • Major adverse events
  • Secondary endovascular interventions
  • All cause mortality

• 1yr sac regression is indicative of 5yr sac dynamics

• A paradigm shift is emerging and a shrinking aneurysm should be the goal of EVAR
How sac regression at 1 year affects all-cause mortality through 5 year: key insights from the ENGAGE registry

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