Might EVAS be associated with a difference in mortality compared to EVAR?

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- Bentley InnoMed GmbH
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- Endologix Inc.
- W.L. Gore and associates
- Vascular Insights LLC
5y Survival of Patients with AAA

67% freedom from mortality vs. 81% Matched Control

86% Freedom from CV Events vs. 93% Matched Control

AAA, N=19,505 / Control, N=75,260

Karthikesalingam et al EJVES 2014; 46: 533
Factors Affecting Survival

Aneurysm Size
Statin and Antiplatelet Therapy

5y survival and AAA diameter

O’Donnell et al JVS 2018
Bahia et al BJS 2016; 103: 1626
Mortality following EVAR and Open Repair

- EVAR confers no long-term mortality advantage over open repair
- 50% of EVAR patients are alive at 8 years

Schermerhorn et al. NEJM 2015
Endovascular versus open repair of abdominal aortic aneurysm in 15-years’ follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial

Rajesh Patel, Michael J Sweeting, Janet T Powell, Roger M Greenhalgh, for the EVAR trial investigators

• 1252 patients between 1999 and 2004
• Mean FU of 12.7±1.5 years
• At 6 months EVAR had a lower mortality
• Beyond 8 years open-repair had a significantly lower mortality

“EVAR has an early survival benefit but an inferior late survival compared with open repair, which needs to be addressed by lifelong surveillance of EVAR and prompt re-intervention if necessary.”

Lancet. 2016 Nov 12;388(10058):2366-2374
Endovascular Aneurysm Repair
Association of Aneurysm Sac Behavior with Long-Term Survival Following EVAR

- Sac behavior associated with new endoleaks, reintervention, and long-term mortality.
- Even stable sacs are associated with lower survival.
- Association between sac behavior and long-term mortality persisted in patients without endoleaks, and was not modified by reintervention.

All patients (n=14,827) undergoing EVAR the Vascular Quality Initiative (VQI), 2003 - 2017

O’Donnell et al. Accepted to JVS 2018
Endovascular Aneurysm Sealing

Might EVAS be Associated with a Difference in Mortality Compared to EVAR?
Endovascular Aneurysm Sealing

- Steep initial learning curve on the procedure to 2016
- Promising 1-year clinical results in challenging patient cohorts with low endoleak rates
- Failure modes apparent at 2y (migration and sac expansion)
- Root cause analysis and refinement of IFU
- Excellent expected clinical outcomes but reduced applicability
- Confirmatory IDE study underway
2Y Mortality Signals with EVAS: All-Cause and CV

EVAS FORWARD IDE (US)

EVAS FORWARD Global Registry (OUS)

Test Group: 333 EVAS IDE patients treated in 2014-2016

Control: 15,431 EVAR patients from the U.S. Vascular Quality Initiative (VQI) treated in 2014-2016

Applied IDE exclusion criteria: hemodialysis, creatinine > 2.0 mg/dL, or rupture

Calculated propensity scores, weighted for AAA size and CV risk factors

Primary outcome: overall survival in propensity-weighted cohort

Secondary analysis: overall survival stratified by aneurysm diameter

Schemerhorn M, presented at Charing Cross 2018
After weighting; EVAS patients experienced higher 3y survival than EVAR.

- Corresponds to 41% lower risk of mortality for EVAS (HR 0.59 [0.38 – 0.92], P = .02)

Schemerhorn M, presented at Charing Cross 2018
No difference in survival between patients with aneurysms < 5.5cm treated with EVAS vs EVAR (P = 0.25)

94% EVAS
91% EVAR

Schemerhorn M, presented at Charing Cross 2018
EVAR patients with aneurysms ≥ 5.5 cm experienced twice the rate of mortality as those treated with EVAS (HR 2.01, P = .01)

Schemerhorn M, presented at Charing Cross 2018
Why would EVAS carry a lower mortality than EVAR?

- **EVAR**: Passive Sac Management
  - Thrombosis of aneurysm sac
  - Type 2 endoleak and sac growth
  - Aneurysm sac remains biologically active

- **EVAS**: Active Sac Management
  - Eradicate space in aneurysm sac – minimal thrombosis
  - Prevent Type 2 endoleak
  - Change biological response
Sac filling reduces post-implant syndrome

<table>
<thead>
<tr>
<th></th>
<th>EVAS (63)</th>
<th>EVAR (41)</th>
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<tbody>
<tr>
<td>PIS (%)</td>
<td>4.9</td>
<td>20.6</td>
</tr>
<tr>
<td>CRP (mg/l)</td>
<td>6.6</td>
<td>15.4</td>
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<tr>
<td>WCC</td>
<td>9.7</td>
<td>13.4</td>
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<tr>
<td>MAE (%)</td>
<td>12.2</td>
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<td>Cardiac MAE</td>
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<td>11</td>
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<tr>
<td>Endoleaks</td>
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<td>12.7</td>
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</table>

Berg et al. JEV 2017; 24: 670

Stenson et al Veith 2017
Summary

• EVAS is associated with lower mid-term all-cause mortality compared to traditional EVAR.

• The survival benefit was the strongest in patients with aneurysms > 5.5 cm.

• Biology of AAA post EVAS may play a role, but confirmatory studies are needed.
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