DECADES OF EVAR RCTs and Registries: what do they tell us?
Frank J Criado, MD, FACS, FSVM
MedStar Union Memorial Hospital
Baltimore, MD

DISCLOSURE
Medtronic: consulting, sales training

1. Abdominal aortic aneurysm of at least 5.0 cm
2. Associated iliac artery aneurysm of 5.0 cm
3. Aortic aneurysm of at least 4.5 cm with rapid growth or sacular morphology
4. Anatomically and medically eligible for either EVAR or open repair

Primary outcome
Long-term all-cause mortality
Secondary outcome
Retractability, short- and long-term mortality, quality of life, and erectile dysfunction

De novo
Zenith (Cook)
Talent (Medtronic)
Excluder (Gore)
AneuRx (Medtronic)
Quantum or Teramed (Cordis)
EVT (Guidant)

Stent-grafts used in EVAR 1 Trial

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11/15/2018

**4 Years after Randomization – EVAR vs. OPEN**

- Post-operative complications were higher in the EVAR group
- Re-intervention rate of 20% in EVAR vs. 6% in OR group
- All-cause mortality was similar (28%)
- Persistent reduction in aneurysm-related deaths in the EVAR group (4% vs. 7%)

**Aneurysm-Related Mortality through 4 years**

- > 50% of aneurysm-related mortality after 30 days due to aneurysm rupture

**Graft-related complications lead to rupture**

<p>| TABLE 2. Cox Regression Analysis of Factors Associated With Graft Rupture After EVAR Deployment |
|-----------------------------------------------|-----------------------------------------------|</p>
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Unadjusted Hazard Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Top neck diameter, mm</td>
<td>1.39 (1.05–1.86)</td>
</tr>
<tr>
<td>Stent graft</td>
<td>1.33 (0.98–1.81)</td>
</tr>
<tr>
<td>Minimum common iliac diameter, mm</td>
<td>1.20 (0.93–1.54)</td>
</tr>
</tbody>
</table>


**Charing Cross 2010**

- The EVAR 1 trial at 10 years:
  - EVAR has a lower operative mortality, But
  - at 6 years the advantage of aneurysm-related mortality is lost

**ENGAGE Global Registry**

Largest Contemporary EVAR Registry with single manufacturer’s stent graft ENDURANT

- 1263 Patients
- 30 Countries
- 6 Continents
- Real world patients - Real world practice - Standard follow-up

14 publications and > 100 presentations at major International/National conferences characterizing ENDURANT clinical outcomes
• Multicenter Prospective RCT of 1252 patients (626 patients in each arm) who had aneurysms of 5.5cm or larger
• Patient considered anaesthetically fit for an open repair
• Enrollment period: September 1999 – August 2004
• Follow-up (min-max): 5–10 yrs. (median 6 years)
• Multiple 1st Gen endografts used: 51% Zenith, 33% Talent, 7% Excluder, 4% AneuRx, 5% ‘other’

ENGAGE
• “Real-world all-comers” Registry
• 1263 patients consecutively enrolled (2009-2011)
• Follow-up: 30-day, annual visits through 10 years
• Single 4th generation device: Endurant (Medtronic)
• Extensive monitoring on-going
• 100% data review
• Independent data monitoring (100% endpoints)
• Independent Clinical Event Committee

Complications – Reinterventions (ENGAGE)
Lower complications led to fewer reinterventions in ENGAGE vs. EVAR 1
13% vs. 20%
35% Reduction

Complications for EVAR group
Complications for OSR repair group
Reinterventions for EVAR group
Reinterventions for OSR repair group
Compliations: ENGAGE
Reinterventions: for ENGAGE

EVAR 1 and ENGAGE outcomes comparison through 4 years

<table>
<thead>
<tr>
<th>Event</th>
<th>EVAR N=543</th>
<th>OPEN REPAIR N=539</th>
<th>ENGAGE N=1263</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-Cause Mortality</td>
<td>18.4% (100/543)</td>
<td>20.2% (107/539)</td>
<td>24% (301/1263)</td>
</tr>
<tr>
<td>Aneurysm-related Mortality</td>
<td>3.5% (19/543)</td>
<td>6.3% (34/539)</td>
<td>1.6% (20/1263)</td>
</tr>
</tbody>
</table>

➢ ACM similar ENGAGE included ASA IV Pts (10.6%)
➢ ARM reduction of 46%

Death from Rupture after AAA Repair

Death from Rupture after AAA Repair

Summary
• Landmark EVAR 1 trial demonstrated:
  ➢ early benefit of EVAR could be maintained through 4 yrs.
  ➢ but at the cost of higher reintervention rates
  ➢ Early benefit of EVAR was lost by 6 yrs. with >50% of late deaths due to rupture after EVAR
  ➢ Direct correlation between postop complications and reinterventions
• ENGAGE: Lower complications = lower reinterventions (35% reduction)
• ENGAGE: lower ARM, lower post EVAR rupture mortality

Conclusions
• Newer generation devices can reference data from EVAR 1 to benchmark clinical performance
• The ENGAGE registry demonstrates how EVAR evolution has contributed to improved patients outcomes
• Large real world registries (like ENGAGE) will hopefully allow us to gain insight on how to customize patient follow-up, which will increase the cost-effectiveness of EVAR.
• Longer-term data necessary to determine if durability is maintained (ENGAGE follow-up will extend to 10 years)