Why EVAR?

A review of the literature

(or… What did the EVAR trials EVER teach us?)
Because we can?
How did we get here?

- Parodi 1991\(^1\)
- Homemade devices initially \(^2,3\)
- Commercial devices 1994\(^4\)
- Registries 1996\(^5,6\)

---

Now that we can, Should we?

RCTs
DREAM, ACE, EVAR, OVER
EVAR 1 & 2

- 1999 - 2004
- Multicentre trial
- Randomised

EVAR 1: *Is EVAR better than OPEN?*
Patients fit for open repair
Open Surgical Repair or EVAR

EVAR 2: *Is EVAR better than NOTHING?*
Patients not fit for open repair
EVAR or Best Medical Therapy

The “Bottom-Line”

30 day or in-hospital all cause mortality

ACE
DREAM
EVAR 1
MEDICARE
OVER
SwedVasc

TOTAL

1.3 vs 4.7%

OR: 0.36 (0.21-0.61)

Good News, Everyone!
However...

• Is it really that simple?
What are we trying to do?

• Repair aneurysms that will otherwise shorten lives…
  – Lowest risk
  – Most economically

• NOT
  – Repair all aneurysms
  – Repair the most aneurysms
  – Enrich “big pharma”
4 Possible outcomes in patients offered elective AAA repair...

• 1: AAA was not going to be the cause of death:
  – Patient dies as a consequence of surgery – life variably shortened
  – Patient survives surgery – Surgery irrelevant

• 2: AAA was going to cause death:
  – Patient dies as a consequence of surgery – life variably shortened
  – Patient survives surgery – life variably extended

• Remember:
  – all interventions profit someone – just not necessarily the patient!!
  – 2/3 AAA intact at autopsy
1. Which aneurysms will kill?
   • UKSAT & ADAM (1996)
   • (Is death by ruptured AAA always so bad?)

2. Which patients will live longer (& for how much longer) if they have successful surgery?
   • CPX testing/Age/Co-morbidity/ 💧

3. Which is the safest, cheapest & most durable technique?
   • EVAR trials
A small, but important detail...
Randomised trials, registries and large series

Early re-intervention at/before 30 days in up to 10% of patients

- Type 1 endoleak
- Stent migration
- Graft thrombosis

Peri-operative mortality: 7.5 – 8.0%

Prinsen M et al, DREAM trial group, NEJM 2004
Rutherford RB et al. Semin Vasc Surg. 2006
Greenhalgh RM et al., EVAR trial participants Lancet 2004
Hobo R et al., EUROSTAR collaborators J Vasc Surg 2006
The EVAR Downside...

EVAR 1: Graft related complications & re-interventions
**Analysis 3.1. Comparison 3 EVAR versus OSR in the management of fit individuals: reintervention, Intermediate reintervention (up to four years).**

Review: Endovascular repair of abdominal aortic aneurysm

Comparison: 3 EVAR versus OSR in the management of fit individuals: reintervention

Outcome: Intermediate reintervention (up to four years)

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>EVAR</th>
<th>Open repair</th>
<th>Odds Ratio M-H, Random, 95% CI</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACE</td>
<td>24/150</td>
<td>4/149</td>
<td>n/a</td>
<td>25.3 %</td>
</tr>
<tr>
<td>EVARRI</td>
<td>121/626</td>
<td>46/626</td>
<td>n/a</td>
<td>37.5 %</td>
</tr>
<tr>
<td>OVER</td>
<td>61/444</td>
<td>55/437</td>
<td>n/a</td>
<td>37.1 %</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>1220</strong></td>
<td><strong>1212</strong></td>
<td><strong>n/a</strong></td>
<td><strong>100.0 %</strong></td>
</tr>
</tbody>
</table>

Total events: 206 (EVAR), 105 (Open repair)

Heterogeneity: Tau² = 0.53; Chi² = 18.93, df = 2 (P = 0.00008); I² = 89%

Test for overall effect: Z = 2.04 (P = 0.041)

Test for subgroup differences: Not applicable
EVAR vs. Open Surgical Repair

HOWEVER...
The obvious limitations

EVAR I & II - Methodology

• The null hypothesis
  – (It was way beyond 80% & 90% recruitment power – and yet extended beyond original plan)

• Technology time warp

• The comparator groups:
  – I – poor UK OPEN results
  – II – “soft” definition of unfit

• WHY?
  – (Financial/Industry/Career drivers?)
The obvious strengths

- Neither trial confirmed its prejudice!
- Both are well conducted RCT’s
Limitations of using EVAR I/II trail data in 2015...

• The trials represent early/naive experience  
  – (IFUs, learning curves)

• Technological advances

• The management of complications has evolved

• Few data on post abdominal surgery complications  
  – (laparotomies, hernia repair)

• No definition of “fitness” for EVAR 2

• Failure to adhere to randomisation for EVAR 2
Learning curves are real!
Operative Mortality & Rupture Rate

Systematic review and meta-analysis of 12 years of Endovascular Abdominal Aortic Aneurysm repair.
Franks SC et al. Eur J Vasc Endovasc Surg 2007 154-171
What the literature tells us (Elective AAA Repair)

- AAA repair confers survival benefit on patients who have otherwise long life expectancies
  - Probably 4 years+

- **UNCOMPLICATED** EVAR is associated with rapid recovery & short hospital stay

- EVAR is associated with high AAA related re-intervention rates cf. OSR
  - Requires long-term FU

- **BUT** the technology & the surgery seem to be improving
15 year results EVAR I trial:

• Reintervention:
  • High for EVAR
  • Occurred throughout the follow-up period

• Aneurysm-related mortality throughout the follow-up period
  • 0.7 ruptures per 100 person-years
  • The death rate associated rupture - 67%

• Greater risk of cancer in the EVAR group