Open Repair Is As Good As EVAR for RAAA’s: The Ajax Trial Proves It

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Disclosures
- Medtronic, consultancy
- Cook, intellectual property

Why still talk about this?
- Recent meta-analysis: open rAAA mortality 48.5%
- Observational and population based studies of EVAR vs OR: outcome much better with EVAR

Original Articles
10 Years of Emergency Endovascular Aneurysm Repair for Ruptured Abdominal Aortic Aneurysms: Lessons Learned
Susan A. Kenger, MD,* Thomas S. Prior, MD,† Steven Bandy, PhD,* Linda Eichholzer, MD,*† Mark A. White, MD,* Frank J. Velez, MD,* and Marco Ljubimov, MD,*†
- 30-day mortality for EVAR was 13%
- Technical success was 99% (101/102)
- ACS in 20%

Always Endo?
- Man, 69 yo
- Excruciating abdominal pain
- BP 80/40
- Visible pulsatile mass
- No major co-morbidity
Always Endo?

EVAR available to all patients

Larger Amsterdam Area
- 3 trial centers AMC, VUMC, OLVG
- 7 regional hospitals
- 1.2 million inhabitants

AJAX trial

Hypothesis:
"EVAR compared to OR for patients with rAAA will result in a significant decrease in combined mortality and severe complications"

Primary endpoint: combined death and severe complications at 30 days
Secondary endpoints: hospital and ICU-length of stay, need for mechanical ventilation and the use of blood products

AJAX trial logistics

All required CTA

If suitable for EVAR and OR: randomization in AJAX trial
**Entire cohort**

520 patients with RAAA
- 466 evaluated in trial center
- 71 no CTA
- 395 evaluated with CTA
  - 240 anatomically unfit for EVAR
  - 16 unfit for OR
  - 11 logistics
  - 7 HD instability following CTA
  - 5 refused treatment

116 patients randomized

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**Randomized Controlled Trial**

Endovascular Repair Versus Open Repair of Ruptured Abdominal Aortic Aneurysms
A Multicenter Randomized Controlled Trial

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**AJAX TRIAL RESULTS**

**Primary endpoint**

<table>
<thead>
<tr>
<th></th>
<th>EVAR</th>
<th>OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combined death and severe complications</td>
<td>42%</td>
<td>47%</td>
</tr>
</tbody>
</table>

ARR 5.4% (95% CI -13 to +23%)

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**Secondary endpoints**

<table>
<thead>
<tr>
<th></th>
<th>EVAR</th>
<th>OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU stay</td>
<td>28 hours</td>
<td>48 hours</td>
</tr>
<tr>
<td>Hospital stay</td>
<td>9 days</td>
<td>13 days</td>
</tr>
<tr>
<td>Mechanical ventilation</td>
<td>39 patients</td>
<td>52 patients</td>
</tr>
<tr>
<td>Blood loss</td>
<td>500 ml</td>
<td>3500 ml</td>
</tr>
</tbody>
</table>

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**Components of primary endpoints**

<table>
<thead>
<tr>
<th></th>
<th>EVAR</th>
<th>OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal insufficiency</td>
<td>11%</td>
<td>30%</td>
</tr>
<tr>
<td>Mortality</td>
<td>21%</td>
<td>25%</td>
</tr>
</tbody>
</table>
Did we select the most stable patients only?

- Cohort 466 patients: 17% hemodynamically unstable
- RCT 116 patients: 20% hemodynamically unstable

What happened?

- Do we select only those patients with simple anatomy resulting in low death rates?
  - Death rate in OR patients who were not included in the RCT because of unfavorable anatomy was 26% (58/222)

AJAX: Long term survival

![Graph showing long-term survival rates for open repair and endovascular repair.]

AJAX trial

- The hypothesized difference in mortality and severe complications between EVAR and OR was not observed.
- EVAR and OR in patients with a ruptured aneurysm give equivalent results in patients whose anatomy and physical condition make them amenable for either approach.

Trial Results

- 613 patients with rAAA were randomized
- 30-day mortality: EVAR 35%, OR 37%
- EVAR patients were discharged earlier
- No cost difference

Editor's Choice – ECAR (Endovasculaire ou Chirurgie dans les Aneurysmes aorto-iliaques Rompus): A French Randomized Controlled Trial of Endovascular Versus Open Surgical Repair of Ruptured Aorto-Iliac Aneurysms

- Randomization after anatomic suitability
- Started in Jan 2008
- 107 patients
- No significant difference at 30 days and 1 year
Endovascular treatment for ruptured abdominal aortic aneurysm (Review)

Badger S, Babbs P, Blais PH, Ellis E, Kee E, Hubbs DW

Where will it go?

Value of the operation = efficacy - invasiveness

Stages of Surgical Innovation

- Limited conclusions by paucity of data
- No difference in 30-day mortality
- More randomized trials are needed

Where will it go?

Any more Trials???
Where will it go?

AJAX trial collaborators

- Amsterdam Medical Centre (39); R.Balm, M.J.W.Koelemay, M.M.Idu, C.Kox, D.A.Legemaate, C.C.Nekeman, M.C.M.Wolters, J.A.Reekers, O.M. van Delden, K.P. van Lisdonk
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Regional ambulance services: F.O. Eister