EVAR 2’s Level 1 Evidence no longer applies for many reasons
Why EVAR is currently indicated in many patients unfit for open repair
Which ones?

Frank Vermassen
Ghent University Hospital
Belgium

Disclosures

- I have the following potential conflicts of interest to report:
  - Receipt of grants/research support
  - Receipt of honoraria and travel support
  - Medtronic, Abbott Vascular, Philips, Boston Scientific
  - Participation in a company sponsored speakers’ bureau
  - Employment in industry
  - Shareholder in a healthcare company
  - Owner of a healthcare company
- I do not have any potential conflict of interest

There Are Flaws In Interpreting The EVAR 1 Long-Term Results To Show EVAR Is Not Superior To Open Repair: EVAR 1 15-Year Result Plus Other Data Show EVAR To Be Better Than Open Repair Short And Long-Term

Frank Vermassen
Ghent University Hospital
Belgium

EVAR 2

- RCT: EVAR vs conservative treatment in patients unfit for open repair
- 404 Patients
- 33 centres in UK
- Enrollment: 09/1999-08/2004
- AAA ≥ 55 mm
- Endpoints: overall mortality and aneurysm-related mortality, HRQOL, Cost

Who is unfit for open repair?

- Patients classified as unfit for surgery by anesthesiologist and surgeon
- **Cardiac reasons**
  - 285
  - Respiratory reasons (FEV1<1.0 L) 65
  - Renal reasons (Creatinin > 200 μmol/l) 34
- Rem: Not: hostile abdomen
- ° = past history of MI, revascularisation or angina >3mths), severe valvular disease, significant arrhythmia, congestive heart failure.

Publications on EVAR 2

- EJVES 2004
- Lancet 2005
- NEJM 2010
- Ann Surg 2017
EVAR 2: very long term results

- Estimated total survival and aneurysm related survival up to 12 years (ITT-analysis)

P=0.52

P=0.019

Ann Surg 2017

Consort diagram 2010

Delay in intervention

Mean time between randomization and EVAR: 55 days

Cross-overs

EVAR 2 Results

Intention to treat  Per protocol

EVAR 2 results

Deaths per 100 patient years

Intention to treat  Per protocol
Why are results no longer valid?

Abdominal Aortic Endografting Beyond the Trials: A 15-Year Single-Center Experience Comparing Newer to Older Generation Stent-Grants

- Freedom from reintervention @ 7 yrs: 1412 patients undergoing EVAR
  - Older stent grafts: 25.8%
  - Newer stent grafts: 16.4%
  - Risk reduction: 36%

Mortality in high risk patients

- Mortality is not conform to actual standards
- Medical treatment was not optimal
- Delay in treatment caused preventable deaths
- More than one third of patients crossed over
- Statistical analysis does not reflect actual treatment

Are EVAR 2 results still valid?

- Old study with old devices
- Mortality is not conform to actual standards
- Medical treatment was not optimal
- Delay in treatment caused preventable deaths
- More than one third of patients crossed over
- Statistical analysis does not reflect actual treatment

Long term survival

- Aspirin: 58.2%
- Statins: 41.8%

The impact of stent graft evolution on the results of endovascular abdominal aortic aneurysm repair

<table>
<thead>
<tr>
<th>Year</th>
<th>Mortality Rate</th>
</tr>
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<tbody>
<tr>
<td>2006</td>
<td>5.7%</td>
</tr>
<tr>
<td>2011</td>
<td>1.6%</td>
</tr>
<tr>
<td>2015</td>
<td>0.7%</td>
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</tbody>
</table>

Endovascular Repair of Aortic Aneurysm in Patients Physically Ineligible for Open Repair

- Designation "Unfit for Open Repair" is associated with poor outcomes after endovascular aortic aneurysm repair

Aspirin: 58.2%
Statins: 41.8%
Should we operate on all patients?

Low mortality rates after endovascular aortic repair expand use to high-risk patients

24,613 Patients in ACS NSQIP

0 1 2 3

When to perform EVAR in an “unfit” patient

The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm

CLINICAL JUDGEMENT