Operating below AAA threshold of 5.5 cm saves lives!!

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Disclosure

Speaker name: Matt Thompson, MD

I have the following potential conflicts of interest to report:

☐ Consulting
☒ Employment in industry – Endologix, Inc., Chief Medical Officer
☒ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Mortality results for randomised controlled trial of early elective surgery or ultrasonographic surveillance for small abdominal aortic aneurysms

The UK Small Aneurysm Trial Participants*

Introduction

Abdominal aortic aneurysms commonly require intervention when they expand to a certain size. Aneurysms are an important cause of death and form a large part of the vascular surgical caseload. Non-surgical studies and clinical trials have suggested that the risk of rupture increases with increasing aortic diameter. Therefore, generally urgent prophylactic repair of aneurysms of more than 6.0 cm in diameter (which is about three times larger than the normal aortic diameter) is recommended. There is, however, uncertainty about whether prophylactic repair is the best management for smaller asymptomatic aneurysms of 4.0-5.9 cm diameter. Ultrasonographic screening studies of the general population in the UK show that 1.5-3.4% of men older than 60 years have small aneurysms in this size range.

There is currently no randomized trial that can provide evidence about whether prophylactic repair can prevent aneurysm growth and decrease the risk of rupture. The only available treatment for smaller abdominal aortic aneurysms is the insertion of a prosthetic aortic graft. Traditionally, surgery has been an elective open procedure with a 5-6% operative mortality risk of 6-15. Endovascular repair has been introduced, but this technique is still under development and also has a high risk of procedure-associated mortality.

Elective surgery is, however, safer than emergency repair of a ruptured aortic aneurysm, for which the 30-day mortality is 30-50%.

It is not clear whether a policy of open surgical repair of small abdominal aortic aneurysms is preferable to a policy of surveillance, which has a higher risk of aneurysm rupture and death. Vascular surgeons in the UK, Canada, and the USA have been participating in three separate randomised trials (to include the hypothesis that early prophylactic elective surgery decreases the long-term mortality for patients with small abdominal aortic aneurysms (4.0-5.5 cm). This diameter range was selected by vascular surgeons in the UK, whom the first trial started. The Canadian trial ended early because of inadequate recruitment (C. William Craig, personal communication and the US trial is continuing (Frank Leitlmeier, personal communication).

In the UK Small Aneurysm Trial, 1090 patients were randomised between 1991 and 1995 to undergo either open surgical repair or regular ultrasonographic surveillance of aortic diameter. We report on the all-cause mortality results of the UK trial.

Methods

The methods have been described elsewhere. In 1090 UK hospitals between September 1991 and October 1993, 1270 patients aged 65-75 years who were alive at the time of study were identified having aneurysms 40 mm in diameter.
The results from the four trials to date demonstrate no advantage to immediate repair for small AAA (4.0 cm to 5.5 cm), regardless of whether open or endovascular repair is used and, at least for open repair, regardless of patient age and AAA diameter.

Thus, neither immediate open nor immediate endovascular repair of small AAAs is supported by currently available evidence.
KEEP CALM AND CHALLENGE THE STATUS QUO
Re-evaluate the Diameter Threshold for AAA Repair – Intervene Earlier

- Threshold >5.5cm not appropriate in females

- Trials have been generally misinterpreted: no benefit does not equate to harm

- Threshold <5.5cm already established practice

- Evidence that community threshold diameter for AAA repair associated with outcome
“While there remains a paucity of data to definitively support earlier intervention in females, that which does exist would point towards a policy of surgery at a maximum aortic diameter, measured by ultrasonography, of closer to 5.2 cm, rather than the 5.5 cm threshold used for men.”
Small Aneurysm Trial - 12 Year Results

- 75% patients in surveillance arm underwent surgery
- Primary outcome – all cause mortality
- Twice as many deaths from rAAA in surveillance cohort
- No benefit to early surgery – also no harm (preference)

BJS 2007; 94: 702
Sub 5.5cm Threshold

Already Established Practice

Proportion of patients undergoing AAA surgery below threshold

<table>
<thead>
<tr>
<th></th>
<th>Male (&lt;=5.5cm)</th>
<th>Female (&lt;=5.5cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>26.6</td>
<td>17.1</td>
</tr>
<tr>
<td>Finland</td>
<td>18.5</td>
<td>40.0</td>
</tr>
<tr>
<td>Hungary</td>
<td>25.7</td>
<td>48.4</td>
</tr>
<tr>
<td>Norway</td>
<td>13.6</td>
<td>30.7</td>
</tr>
<tr>
<td>Sweden</td>
<td>17.5</td>
<td>38.2</td>
</tr>
<tr>
<td>UK</td>
<td>6.0</td>
<td>9.0</td>
</tr>
</tbody>
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*Mani et al EJVES 2015; 49: 646*
Variation in Transatlantic Practice – AAA Related Death (300,000 Patients)

- Investigate influence of threshold for AAA repair on mortality from AAA
- USA and UK Practice – threshold, prevalence and outcome
## AAA Diameter and Repair Below Threshold (2013-14)

<table>
<thead>
<tr>
<th></th>
<th>England</th>
<th>USA</th>
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<tbody>
<tr>
<td>AAA diameter cm (male)</td>
<td>6.41 (1.29)</td>
<td>5.86 (1.34)</td>
</tr>
<tr>
<td>AAA diameter cm (female)</td>
<td>6.17 (1.08)</td>
<td>5.63 (1.20)</td>
</tr>
<tr>
<td>Male &lt;5.5cm</td>
<td>8.87%</td>
<td>39.21%</td>
</tr>
<tr>
<td>Female &lt; 5.0 cm</td>
<td>4.91%</td>
<td>17.19%</td>
</tr>
</tbody>
</table>
48 men per 100,000 above the mean diameter for AAA repair in England, compared to 76 men per 100,000 above the mean diameter for AAA repair in the USA.
Rate of Intact AAA Repair 2005-2012

England 27.11 – 31.85 per 100,000

USA 57.85 – 64.17 per 100,000

Adjusted OR 2.058 (95% CI 2.033 to 2.083)
Rate of Hospitalization and Aneurysm Related Death

England 53.55 – 34.43 per 100,000

USA 16.24 – 9.03 per 100,000

Adjusted OR 3.596
(95% CI 3.549 to 3.644)
Operating Below Threshold Saves Lives

- Threshold >5.5cm not appropriate in females

- Surveillance and early surgery (4.0-5.5cm) similar results

- 5.5cm threshold in UK leads to surgery at inappropriate mean AAA diameter

- Higher AAA intervention rate associated with better outcomes
Operating below AAA threshold of 5.5 cm saves lives!!

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