Endovascular Repair or Surveillance of Patients with Small AAA


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Objective. To compare the outcome of patients with small abdominal aortic aneurysms (AAA) treated in a prospective trial of endovascular aneurysm repair (EVAR) to patients randomized to the surveillance arm of the UK Small Aneurysm Trial.

Method. All patients with small AAA (<5.5 cm diameter) treated with a stent graft (EVARsmall) in the multicenter AneuRx clinical trial from 1997 to 1999 were reviewed with follow up through 2003. A subgroup of patients (EVARmatch) who met the age (60–76 years) and aneurysm size (4.0–5.5 cm diameter) inclusion criteria of the UK Small Aneurysm Trial were compared to the published results of the surveillance patient cohort (UKsurveil) of the UK Small Aneurysm Trial (NEJM 346:1445, 2002). Endpoints of comparison were aneurysm rupture, fatal aneurysm rupture, operative mortality, aneurysm related death and overall mortality. The total patient years of follow-up for EVAR patients was 1369 years and for UK patients was 3048 years. Statistical comparisons of EVARmatch and UKsurveil patients were made for rates per 100 patient years of follow up (/100 years) to adjust for differences in follow-up time.

Results. The EVARsmall group of 478 patients comprised 40% of the total number of patients treated during the course of the AneuRx clinical trial. The EVARmatch group of 312 patients excluded 151 patients for age >60 or <76 years and 15 patients for AAA diameter <4 cm. With the exception of age, there were no significant differences between EVARsmall and EVARmatch in pre-operative factors or post-operative outcomes. In comparison to the UKsurveil group of 527 patients, the EVARmatch group was slightly older (70 ± 4 vs. 69 ± 4 years, p = 0.009), had larger aneurysms (5.0 ± 0.3 vs. 4.6 ± 0.4 cm, p <0.001), fewer women (7 vs. 18%, p <0.001), and had a higher prevalence of diabetes and hypertension and a lower prevalence of smoking at baseline. Ruptures occurred in 1.6% of EVARmatch patients and 5.1% of UKsurveil patients; this difference was not significant when adjusted for the difference in length of follow up. Fatal aneurysm rupture rate, adjusted for follow up time, was four times higher in UKsurveil (0.8/100 patient years) than in EVARmatch (0.2/100 patient years, p <0.001); this difference remained significant when adjusted for difference in gender mix. Elective operative mortality rate was significantly lower in EVARmatch (1.9%) than in UKsurveil (5.9%, p <0.01). Aneurysm-related death rate was two times higher in UKsurveil (1.6/100 patient years) than in EVARmatch (0.8/100 patient years, p = 0.03). All-cause mortality rate was significantly higher in USsurveil (3.8/100 patient years) than in EVARmatch (2.4/100 patient years, p = 0.02).

Conclusions. It appears that endovascular repair of small abdominal aortic aneurysms (4.0–5.5 cm) significantly reduces the risk of fatal aneurysm rupture and aneurysm-related death and improves overall patient survival compared to an ultrasound surveillance strategy with selective open surgical repair.

Keywords: Endovascular; Surveillance; Abdominal aortic aneurysm; Surgery.

Introduction

The risk of rupture of abdominal aortic aneurysms is related to aneurysm size.1 While there is little disagreement on the need to repair large aortic aneurysms, the best treatment strategy for patients with small aneurysms is unclear. Two prospective randomized clinical trials of good risk patients with small (<5.5 cm) aortic aneurysms found no difference in overall survival rates between patients treated with early elective surgical repair compared to those followed with ultrasound surveillance.2,3 While the effectiveness of early surgery or surveillance in preventing aneurysm rupture was not an end-point in these trials, they are cited as evidence that aneurysms smaller than 5.5 cm have a very low risk


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of rupture. Since, the operative mortality for elective open surgical repair of abdominal aneurysms is 3–6%, it is commonly recommended that small aneurysms should not be treated unless they enlarge or become symptomatic.

However, the effectiveness of surveillance in preventing aneurysm rupture has not been established. Despite close monitoring and early surgery when indicated, rupture occurred in the surveillance group of both prospective clinical trials. Brown and Powell found that in a cohort of 2257 patients with small aneurysms, including 1090 patients from UK Small Aneurysm Trial, there were 2.7 aneurysm ruptures per 100 person years of follow up. In other words, in 1.7 years, 4.6% of patients (69 of 1509 patients) with small aneurysms, 4.0–5.5 cm in diameter, sustained rupture. In addition, ineligible patients followed outside the UK trial had a higher risk of aneurysm rupture than randomized patients. This suggests the need for better strategies to prevent aneurysm rupture in patients with small aneurysms.

Since, completion of the prospective small aneurysm trials, endovascular aneurysm repair (EVAR) has gained acceptance in the treatment of suitable patients with infrarenal aortic aneurysms. Endovascular repair compares favorably to open surgical repair in short and mid-term analysis and may have long-term benefits with reduced aneurysm related death. Two recent prospective randomized clinical trials comparing EVAR to open surgical repair found a three- to four-fold reduction in 30 day operative mortality in patients undergoing endovascular aneurysm repair.

Favorable results with EVAR have also been demonstrated in patients with small aneurysms. However, extending the use of EVAR to patients with small aneurysms has been questioned.

The purpose of this study is to determine whether endovascular repair (EVAR) is more effective than ultrasound surveillance in preventing aneurysm rupture and death in patients with small AAA. In order to address this question, we compared patients with small AAA treated with EVAR in a prospective, controlled clinical trial to patients with small AAA randomized to ultrasound surveillance in the prospective UK Small Aneurysm Trial.

**Methods**

We reviewed the pre-operative maximal aortic aneurysm diameter of all 1193 patients treated during the course of the multicenter AneuRx clinical trial from 1996 to 1999. Patients treated with the commercially available version of the AneuRx stent graft who had a pre-operative aortic aneurysm diameter of 5.5 cm or less were selected for study. Patients treated with the stiff prototype device and those treated off-protocol in the high-risk patient cohort were excluded from this analysis. The group of 478 patients (EVARsmall) included 151 patients who would not have been candidates for the UK Small Aneurysm Trial on the basis of age less than 60 years or age greater than 76 years and 15 patients who would not have been candidates for the UK trial because aneurysm diameter was smaller than 4.0 cm. Exclusion of these 166 patients resulted in a cohort of 312 patients (EVARmatch) which was used for comparison to the UK Small Aneurysm Trial. Follow-up information was complete for the EVARsmall and EVARmatch groups through August 2003 and results for the entire group of 1193 patients has been published. The results of patients entered into the UK Small Aneurysm Trial from 1991 to 1995 were published in 1998 and in 2002. This multicenter, prospective clinical trial of 60–76 year old patients with small aneurysms (diameter = 4.0–5.5 cm) who were fit for elective open surgical repair, randomly assigned 527 patients to ultrasound surveillance and compared them to 563 patients randomly assigned to early elective open surgery.

The patients in the UK surveillance group, according to protocol, were offered open surgical repair if the aneurysm enlarged to a diameter greater than 5.5 cm, enlarged by more than 1 cm per year, became tender or became symptomatic. In this report, we compared the published results of the 527 patients in the UK surveillance group (UKsurveil) to the results of the matched subgroup of patients treated with endovascular repair (EVARmatch).

The primary endpoints of comparison were (a) rupture, (b) fatal rupture, (c) elective operative mortality (d) aneurysm related death rate and (e) overall survival. In order to standardize comparisons, endpoints were calculated as a rate per 100 patient years of follow-up, in accordance with the methodology used in the UK Small Aneurysm Trial. Aneurysm related death was defined as the sum of 30-day mortality and secondary procedure mortality, including surgical conversion mortality, rupture and/or aneurysm-repair related mortality.

Baseline characteristics of the different patient cohorts include the mean and standard deviation for quantitative variables and percentages for binary variables. Statistical comparisons between the EVARmatch and UKsurveil cohorts for the four outcomes: ruptures, fatal ruptures, AAA related death and all-cause mortality were based on the number of events per 100 patient years of follow-up. Since, the EVARmatch and UKsurveil groups were significantly...
different in gender mix, gender-specific rates per 100 patient years of follow-up were calculated for both patient cohorts when possible. When the event rates were stratified by gender for the UKsurveil group, these rates were directly standardized to the EVARmatch gender-specific years of follow-up. This allowed comparison of the UKsurveil cohort to the EVARmatch group with adjustment for gender differences. The comparison of operative mortality rates did not need to be adjusted for differences in length of follow-up since these events are captured acutely (within 30 days of treatment). The normal approximation to the binomial was used to test for differences between these endpoints.25

Results

Endovascular small aneurysm groups

The 478 patients with aneurysms 5.5 cm or smaller (EVARsmall) comprised 40% of the total number of 1193 patients treated during the course of the AneuRx clinical trial. A total of 166 patients (35%) small aneurysm patients in the AneuRx trial did not meet the inclusion criteria of the UK Small Aneurysm Trial surveillance group. Comparisons of the baseline characteristics of the EVARmatch group to the UKsurveil group are shown on Table 1. The EVARmatch group was 1 year older than EVARmatch (70±4 vs. 70±4 years). Otherwise, there were no significant differences between the EVAR groups as shown on Table 1. Mean preoperative aneurysm diameter was 5.0 cm in both groups. Mean duration of follow up was 2.9±1.2 years (range 0–5 years) with no difference in follow up time between the two endovascular groups (Table 2). The number of patient years of follow up in the EVARmatch group was 898 patient years and in the EVARsmall group was 1369 patient years. This difference is due to the greater number of patients in the EVARsmall group.

Table 1. Baseline characteristics in the study groups

<table>
<thead>
<tr>
<th></th>
<th>EVARsmall1 (n=478)</th>
<th>EVARmatch1 (n=312)</th>
<th>UKsurveil2 (n=527)</th>
<th>p-value3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years)</td>
<td>73 (SD 7)</td>
<td>70 (SD 4)</td>
<td>69 (SD 4)</td>
<td>0.009</td>
</tr>
<tr>
<td>Gender (male:female)</td>
<td>90%/10%</td>
<td>93%/7%</td>
<td>82%/18%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>AAA diameter (cm)</td>
<td>5.0 (SD 0.4)</td>
<td>5.0 (SD 0.3)</td>
<td>4.6 (SD 0.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ever smoked</td>
<td>82%</td>
<td>87%</td>
<td>94%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes</td>
<td>12%</td>
<td>13%</td>
<td>3%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>66%</td>
<td>63%</td>
<td>40%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>COPD</td>
<td>27%</td>
<td>28%</td>
<td>n.a.</td>
<td></td>
</tr>
</tbody>
</table>

* Endovascular repair patients with small aneurysms in AneuRx clinical trial (≤5.5 cm).
† Subset of endovascular small aneurysm patients who met the age and aneurysm diameter inclusion criteria of the UK Small Aneurysm Trial surveillance group.
§ Comparison between EVARmatch and UKsurveil groups.

Table 2. Study results after EVAR and ultrasound surveillance of small aneurysms

<table>
<thead>
<tr>
<th></th>
<th>EVARsmall</th>
<th>EVARmatch</th>
<th>UKsurveil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patient-years of follow-up</td>
<td>1369</td>
<td>898</td>
<td>3048</td>
</tr>
<tr>
<td>Mean years of follow-up (SD, range)</td>
<td>2.9 (1.2, 0–5)</td>
<td>2.9 (1.2, 0–5)</td>
<td>5.8 (n/a, 0–10)</td>
</tr>
<tr>
<td>Total ruptures</td>
<td>1.3%</td>
<td>1.6%</td>
<td>5.1%</td>
</tr>
<tr>
<td>Fatal ruptures</td>
<td>0.4%</td>
<td>0.6%</td>
<td>4.6%</td>
</tr>
<tr>
<td>Elective operative mortality*</td>
<td>1.3%</td>
<td>1.9%</td>
<td>5.9%</td>
</tr>
<tr>
<td>Total AAA related death</td>
<td>1.7%</td>
<td>2.2%</td>
<td>9.5%</td>
</tr>
<tr>
<td>Total mortality</td>
<td>19%</td>
<td>18%</td>
<td>48%</td>
</tr>
</tbody>
</table>

* EVARmatch rate is significantly lower than UKsurveil (p=0.001).
Aneurysm rupture

Aneurysm ruptures occurred in both the EVAR small aneurysm and UK surveillance groups. A total of six of 478 patients (1.3%) in the EVARsmall group sustained aneurysm rupture. Two of these ruptures were early ruptures and occurred during the implant procedure. There were four late ruptures, occurring between 20 and 48 months. One of the two early ruptures is included in the EVARmatch group (1 year rupture rate of 0.3%) and all four late ruptures occurred among EVARmatch patients. Thus, a total of five of 312 patients (1.6%) in the EVARmatch group sustained aneurysm rupture (Table 2).

During the course of the UK clinical trial (ending in June 1998), 25 aneurysms ruptured with an average risk of rupture of 1.6% per year, including small aneurysms that had enlarged to > 5.5 cm or become symptomatic. Of these ruptures were in aneurysms 4.0-5.5 cm in diameter at last measurement with a mean risk of rupture of 1.0% per year. Since, rupture was not a primary endpoint of the UK trial, the timing and distribution of ruptures between the surveillance and early surgery groups was not reported, so that 1-year rupture rates could not be compared. A total of 27 of 527 UK surveillance patients (5.1%) sustained rupture by the end of UK patient follow up (August 2001). Adjusted for the difference in length of follow up, the rupture rate was slightly higher, but not statistically significantly different, in the UK surveillance patients (0.9/100 patient years) compared to the EVARmatch patients (0.6/100 patient years, ns) (Table 2).

Fatal ruptures

Fatal ruptures, including patients who sustained rupture and underwent emergent surgical repair occurred in two of 478 patients (0.4%) in the EVARsmall group. Both patients were in the EVARmatch group, which had a fatal rupture rate of 0.6% (two of 312 patients). Fatal ruptures occurred in 24 of 527 patients (4.6%) in the UK surveillance group during the follow up period (Table 2). Of these, 21 were un repaired aneurysms undergoing surveillance and three were aneurysms that had undergone open repair. Overall, 8% of all deaths in the surveillance group were due to rupture of un repaired aneurysms and 1% of deaths were due to rupture of repaired aneurysms. In the EVAR group, 4% of all deaths were due to ruptured aneurysms (Table 4). The fatal rupture rate/100 patient years of follow up was four times higher among UK surveillance patients (0.8/100 patient years) than among EVARmatch patients (0.2/100 patient years, \( p < 0.001 \)) (Table 3). In view of the fact that the risk of fatal rupture was four times higher in women than in men in the UK trial, we adjusted the UKsurveil rate to correct for differences in lengths of follow-up for each gender. Using direct standardization to adjust the UK length of follow-up to the EVARmatch length of follow-up, the UK rate decreased to 0.7/100 patient years but remained significantly higher than the EVARmatch group (\( p = 0.05 \)).

Elective operative mortality

Elective 30 day operative mortality rate for the EVARmatch group was 1.9%, significantly lower (\( p < 0.01 \)) than the 5.9% operative mortality rate for the 355 patients in the UK surveillance group who underwent elective open surgical repair. There was no significant difference in operative mortality between women (0%, 0/23) and men (2.1%, 6/289) in the EVARmatch group. Gender specific operative mortality data was not published for the UK Small Aneurysm Trial, therefore, these rates could not be further adjusted to account for gender differences.

Aneurysm related death rate

The total aneurysm-related death rate for EVARmatch patients was 2.2%. The total aneurysm related death rate among UKsurveil patients was 9.5%. Adjusted for the difference in length of follow up, AAA related death was two times higher in UK surveillance patients (1.6/100 patient years) than in EVARmatch patients (0.8/100 patient years, \( p = 0.03 \)) (Table 3). There was no significant difference in the AAA related death rates between women (0%, 0/23) and men (0%, 0/23).

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**Table 3. Study endpoints after EVER and ultrasound surveillance of small aneurysms (per 100 patient years of follow-up)**

<table>
<thead>
<tr>
<th></th>
<th>EVARsmall</th>
<th>EVARmatch</th>
<th>UKsurveil</th>
<th>p-value (EVARmatch vs. UK)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total ruptures/100 patients years</td>
<td>0.4</td>
<td>0.6</td>
<td>0.9</td>
<td>ns</td>
</tr>
<tr>
<td>Fatal ruptures/100 person years</td>
<td>0.1</td>
<td>0.2</td>
<td>0.8</td>
<td>0.001</td>
</tr>
<tr>
<td>AAA related deaths/100 person years</td>
<td>0.6</td>
<td>0.8</td>
<td>1.6</td>
<td>0.03</td>
</tr>
<tr>
<td>All-cause death/100 person years</td>
<td>6.6</td>
<td>6.4</td>
<td>8.3</td>
<td>0.02</td>
</tr>
</tbody>
</table>

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All-cause mortality

All-cause mortality rate among EVARmatch patients was 18% while all-cause mortality among UKsurveil patients was 48%. The causes of death for the two groups are similar as shown in Table 4. Deaths due to thoracic aneurysm rupture were the same in both groups (4% in each). However, deaths due to abdominal aortic rupture were higher in UKsurveil (9.4%) than in EVARmatch (3.5%). Adjusted for the difference in length of follow up, the all-cause mortality rate was lower among EVARmatch patients (6.4/100 patient years) than among UKsurveil patients (8.3/100 patient years, \( p = 0.02 \)). These rates/100 patient years of follow-up did not change upon adjusting for gender differences.

Discussion

The primary objective of elective aneurysm repair is to prevent aneurysm rupture and death. However, the results of surgical repair of aortic aneurysms are rarely reported in terms of effectiveness in preventing rupture but rather only in terms of operative mortality rates and overall patient survival.\(^5\)-\(^8\) It is usually assumed that the risk of rupture has been eliminated following open surgical repair, although late aneurysm ruptures and deaths have been reported to occur following open repair with a frequency of 1% or more.\(^7\),\(^26\) In the UK Small Aneurysm Trial, 1% of all deaths in the surveillance group were due to aneurysm rupture in patients who had been successfully treated with open repair.\(^9\) Endovascular aneurysm repair, on the other hand, is usually evaluated in terms of its effectiveness in preventing aneurysm rupture and aneurysm related death and includes a number of indirect measures which are thought to reflect the risk of rupture, such as endoleak, device migration and aneurysm enlargement.\(^27\) These differences in primary endpoint focus have made comparisons between open and endovascular repair more complex. While there is little controversy with regard to the need to repair large aortic aneurysms by open or endovascular techniques, these differences have contributed to uncertainty on the best way to treat small aneurysms.

Both the UK Small Aneurysm Trial and ADAM study randomly assigned patients to ultrasound surveillance or elective open surgery and used all-cause mortality (overall survival) as the primary endpoint to conclude that long term survival was not improved by early surgery compared to ultrasound surveillance. Despite including only young, good risk patients who were fit for surgery, overall mortality rate for these small aneurysm patients was high with a mean duration of survival of only 6.5 years. By the end of the follow up period, 48% of UK surveillance patients had died, as had 43% of early surgery patients.\(^9\) This is consistent with the well known fact that patients with aortic aneurysms frequently have multiple comorbidities and have a reduced life expectancy compared to an age-matched normal population.\(^28\) Thus, overall survival can be expected to be a poor discriminator of different treatment strategies to prevent aneurysm rupture. This is illustrated by the fact that despite finding a long term survival advantage (after 8 years) for early surgery patients in the UK trial, this benefit was attributed to smoking cessation and lifestyle changes rather than to the aneurysm treatment strategy.\(^9\)

Since, the primary objective of aneurysm treatment is to prevent rupture and death, more meaningful endpoints to evaluate effectiveness of treatment are aneurysm rupture rate and aneurysm-related mortality.\(^16\) Although aneurysm rupture was not a primary endpoint in the UK and ADAM trials, both studies reported a low rupture rate (1.0 and 0.6% per year, respectively) for small aneurysms and suggested that small aneurysms could be safely followed with ultrasound surveillance.\(^2\),\(^3\) Nonetheless, abdominal aortic aneurysm ruptures were responsible for 9% of the deaths in the UK surveillance group and 4% of the patients in the UK early surgery group, indicating that aortic aneurysm rupture and death is a significant problem for patients with small aneurysms. In

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Table 4. Cause of death EVARmatch vs. UKsurveil

<table>
<thead>
<tr>
<th>Cause of Death</th>
<th>EVARmatch</th>
<th>UKsurveil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total deaths</td>
<td>57</td>
<td>254</td>
</tr>
<tr>
<td>Cardiovascular—total</td>
<td>30 (53%)</td>
<td>172 (68%)</td>
</tr>
<tr>
<td>MI</td>
<td>11 (19%)</td>
<td>48 (19%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>3 (5%)</td>
<td>12 (5%)</td>
</tr>
<tr>
<td>Ruptured TAA</td>
<td>2 (4%)</td>
<td>11 (4%)</td>
</tr>
<tr>
<td>Ruptured AAA</td>
<td>2 (4%)</td>
<td>24 (9%)</td>
</tr>
<tr>
<td>Other cardiovascular</td>
<td>12 (21%)</td>
<td>52 (20%)</td>
</tr>
<tr>
<td>Cancer—total</td>
<td>10 (18%)</td>
<td>44 (17%)</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>5 (9%)</td>
<td>13 (5%)</td>
</tr>
<tr>
<td>Other cancer</td>
<td>5 (9%)</td>
<td>31 (12%)</td>
</tr>
<tr>
<td>Other</td>
<td>16 † (28%)</td>
<td>37 (15%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>1 (2%)</td>
<td>1 (&lt;1%)</td>
</tr>
</tbody>
</table>

\(^{*}\) Twenty-one ruptures occurred while patients were undergoing surveillance, and three occurred after open repair.

\(^{†}\) Ten of the 16 were pulmonary including: COPD, pneumonia, emphysema and respiratory.
In this study, we sought to determine whether early endovascular repair of small aortic aneurysms offered an advantage over ultrasound surveillance strategy by comparing patients with small aneurysms in the AneuRx clinical trial to those in the UK Small Aneurysm Trial. In doing so, it should be noted that there are significant differences between the two trials. The prospective, non-randomized, multicenter AneuRx clinical trial was conducted from 1996 to 1999, after patient entry into the prospective, randomized UK Small Aneurysm Trial had been completed in 1995. Patient selection criteria were different and endpoints and objectives of the two trials were different. Nonetheless, both studies have comprehensive and long term follow up of well-characterized patients with infrarenal abdominal aortic aneurysms. In the AneuRx clinical trial, 40% of the patients treated had small aneurysms (5.5 cm or smaller). We made every effort to match the AneuRx small aneurysm patient population to the inclusion criteria of the UK Small Aneurysm Trial by excluding 151 patients for age less than 60 years or age greater than 76 years as well as 15 patients for aneurysm diameter less than 4.0 cm. Despite this, there were important differences between the matched EVAR and UK surveillance groups with respect to age, comorbidities and gender distribution. Patients in the AneuRx trial were slightly older, had more comorbidities and had larger aneurysms than patients in the UK trial. This difference would tend to balance the analysis in favor of surveillance. On the other hand, the UK clinical trial enrolled proportionally twice as many women as the AneuRx trial. Since, rupture and death from rupture was four-fold higher among women than among men in the UK trial, the difference in gender distribution may partially account for the different outcomes. We adjusted our analysis for gender difference and found that differences in outcomes remained statistically significant. In addition, there was a significant difference in the duration of follow up between the groups with a mean follow up of 5.8 years in the UK surveillance group and mean follow up of only 2.9 years in the matched EVAR group. In order to correct for this difference, statistical comparisons of endpoints were made in terms of 100 patient years of follow up. While this allows valid comparisons to be made with the available data, longer follow up may show an increasing rate of late complications for endovascular repair, which could invalidate the conclusions. However, thus far there is no evidence for such an increase in late complications with flat Kaplan–Meier curves for freedom from aneurysm rupture, aneurysm related death and surgical conversion from 3 to 5 years among the 1193 AneuRx clinical trial patients.

We found that the risk of fatal aneurysm rupture and aneurysm related death as well as elective operative mortality and all-cause mortality were all significantly lower in patients treated with endovascular repair compared to patients followed in an ultrasound surveillance program. These data suggest that early endovascular repair may be preferable to surveillance and delay of aneurysm treatment until the aneurysm enlarges or becomes symptomatic. It should be noted that the great majority of UK patients with small aneurysms who were randomized to undergo ultrasound surveillance required surgical treatment of their aneurysm at some later date. By the end of the UK clinical trial in 1998, 327 of 527 surveillance patients (62%) had undergone open surgical repair and 19 patients (3.6%) had experienced aneurysm rupture with a 1 year rupture rate of 1.6%. After three more years of follow up, an additional 62 patients had undergone open surgery and there were eight additional ruptures with a rupture rate of 3.2% per year. By August 2001, a total of 389 patients (74%) had undergone surgical repair and only 33 patients (6% of the surveillance cohort) were alive without having had surgery and without aneurysm rupture. Thus, surveillance did not effectively protect patients from the risk of rupture and did not eliminate the need for aneurysm treatment for most patients.

The prospective, randomized ADAM trial was similar in design to the UK Small Aneurysm Trial and reached similar conclusions regarding lack of long term survival benefit for early open surgical repair of small aneurysms. Among 567 patients with aneurysms 4.0–5.4 cm in diameter who were randomized to ultrasound surveillance, there were 11 aneurysm ruptures (1.9%), seven fatal ruptures (1.2%) and 15 aneurysm related deaths (2.6%). Operative mortality in the surveillance group was 2.1%. Almost all patients in the surveillance group were men (99.6%) and the age entry criteria for the trial was 50–79 years. Average follow up time for all patients in the trial was 4.9 years, significantly longer than the mean follow up time of 2.9 years for EVAR small aneurysm patients. However, follow up time and total patient follow-up years for the surveillance group was not reported and, therefore, endpoints could not be expressed in terms of 100 patient years. Thus, although we were able to select an EVAR subgroup matched to ADAM inclusion criteria, it was not possible to adjust for differences in length of follow up and published data was insufficient for valid...
comparisons of the endpoints of aneurysm rupture, fatal rupture, aneurysm related death and survival.

The most reliable method to compare two treatment strategies is a prospective randomized clinical trial. Two such trials comparing endovascular aneurysm repair to open surgical repair of large aneurysms have recently been published.\(^{17,18}\) Both showed a significant reduction in 30 day mortality with endovascular repair. Our study suggests that patients with small aneurysms who are treated with EVAR have a significant reduction in the risk of fatal aneurysm rupture and have improved survival compared to ultrasound surveillance. However, these findings should be confirmed with a prospective randomized clinical trial. Our study further suggests that late all-cause mortality, such as used in the UK and ADAM trials, may not be a discriminating end-point when comparing different treatment strategies for elderly patients with aortic aneurysms. Aneurysm specific endpoints such as aneurysm rupture, fatal rupture and aneurysm related death may be better suited for this purpose and should be used in future prospective trials.

Conclusion

Early endovascular repair of small abdominal aortic aneurysms appears to significantly reduce the risk of fatal rupture and aneurysm-related death and improves overall patient survival compared to a strategy of ultrasound surveillance of small aneurysms. On the basis of information available at this point in time, it appears that endovascular repair can be supported as a safe and effective treatment for selected patients with small aortic aneurysms.

References


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