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

The United Kingdom EVAR Trial Investigators*

ABSTRACT

BACKGROUND

Endovascular repair of abdominal aortic aneurysm was originally developed for patients who were considered to be physically ineligible for open surgical repair. Data are lacking on the question of whether endovascular repair reduces the rate of death among these patients.

METHODS

From 1999 through 2004 at 33 hospitals in the United Kingdom, we randomly assigned 404 patients with large abdominal aortic aneurysms (≥5.5 cm in diameter) who were considered to be physically ineligible for open repair to undergo either endovascular repair or no repair; 197 patients were assigned to undergo endovascular repair, and 207 were assigned to have no intervention. Patients were followed for rates of death, graft-related complications and reinterventions, and costs until the end of 2009. Cox regression was used to compare outcomes in the two groups.

RESULTS

The 30-day operative mortality was 7.3% in the endovascular-repair group. The overall rate of aneurysm rupture in the no-intervention group was 12.4 (95% confidence interval [CI], 9.6 to 16.2) per 100 person-years. Aneurysm-related mortality was lower in the endovascular-repair group (adjusted hazard ratio, 0.53; 95% CI, 0.32 to 0.89; P=0.02). This advantage did not result in any benefit in terms of total mortality (adjusted hazard ratio, 0.99; 95% CI, 0.78 to 1.27; P=0.97). A total of 48% of patients who survived endovascular repair had graft-related complications, and 27% required reintervention within the first 6 years. During 8 years of follow-up, endovascular repair was considerably more expensive than no repair (cost difference, £9,826 [U.S. $14,867]; 95% CI, 7,638 to 12,013 [11,556 to 18,176]).

CONCLUSIONS

In this randomized trial involving patients who were physically ineligible for open repair, endovascular repair of abdominal aortic aneurysm was associated with a significantly lower rate of aneurysm-related mortality than no repair. However, endovascular repair was not associated with a reduction in the rate of death from any cause. The rates of graft-related complications and reinterventions were higher with endovascular repair, and it was more costly. (Current Controlled Trials number, ISRCTN55703451.)
Endovascular Repair of Abdominal Aortic Aneurysm

Aortic aneurysm was originally developed for patients who were considered to be physically ineligible for open surgical repair, since it was thought that life expectancy would be prolonged by eliminating the risk of fatal rupture of an aneurysm. We designed the United Kingdom Endovascular Aneurysm Repair 2 (EVAR 2) trial to test this hypothesis. The midterm results of the trial, reported in 2005, showed no benefit of endovascular repair on total or aneurysm-related mortality in up to 4 years of follow-up. One factor underlying this unexpected result was an operative mortality rate that was higher than anticipated (9%). Other studies have also shown a high operative mortality rate for endovascular repair among patients considered to be physically ineligible for open repair. In addition, our midterm analysis showed high total mortality (68% at 4 years).

Another contributing factor in the unexpected outcome of EVAR 2 was a rate of rupture of large, untreated aneurysms that was lower than anticipated (9 ruptures per 100 person-years). Subsequent analysis has suggested that the rate of aneurysm rupture appears to be lower among patients with an aortic anatomy that is suitable for endovascular repair (in particular, a long aneurysm neck) and that the use of statins may have further attenuated the rate of aneurysm rupture. Nevertheless, since progressive enlargement is the natural history of large aneurysms, the benefits of endovascular repair may take longer than 4 years to become apparent. We now report the long-term follow-up of patients enrolled in the EVAR 2 trial.

**Methods**

**Trial Design**
The methods that we used in this trial have been published previously and are described in detail in the Supplementary Appendix (available with the full text of this article at NEJM.org). In summary, EVAR 2 was a randomized trial designed by the principal investigator in consultation with the grant applicants, the members of the trial-management and steering committees, and the trial manager. The trial was sponsored by the Health Technology Assessment Programme of the National Institute for Health Research in the United Kingdom. No support was provided by pharmaceutical or medical-device companies. Full approval of the trial was granted by the United Kingdom’s North West Multicentre Research Ethics Committee.

The trial was conducted at 33 hospitals that met the criteria for participation in the trial (for details, see the Supplementary Appendix). Trained local coordinators were responsible for recruitment of patients, data collection, and follow-up.

**Trial Procedures**
Patients of both sexes who were at least 60 years of age with an abdominal aortic aneurysm measuring at least 5.5 cm in diameter on computed tomography (CT) were evaluated for trial participation. Patients who were considered to be physically ineligible for open repair but who were candidates for endovascular repair were offered enrollment in the EVAR 2 trial (see the Supplementary Appendix for details regarding the evaluation of candidates). Patients who were considered to be suitable candidates for either procedure were offered enrollment in the Endovascular Aneurysm Repair 1 (EVAR 1) trial, reported elsewhere in this issue of the Journal. All patients provided written informed consent.

The patients in EVAR 2 were randomly assigned to undergo endovascular aneurysm repair or to have no intervention. Patients in the endovascular-repair group were encouraged to undergo repair within 1 month after randomization, though this scheduling was not always possible for logistic or other reasons. CT was performed at 1 and 3 months in patients undergoing endovascular repair and annually in all patients in the two study groups. The primary outcome was death from any cause, but aneurysm-related death was also assessed, as were graft-related complications and graft-related reinterventions. (Full definitions of the trial end points are available in the Supplementary Appendix.) An independent end-points committee whose members were unaware of study-group assignments reviewed all mortality outcome events. The methods that we used to assess the completeness of data for all outcomes and to account for loss to follow-up are described in the Supplementary Appendix.

**Statistical Analysis**
All analyses were performed according to a predefined statistical-analysis plan with the use of Stata statistical software, version 10. All analyses were based on the intention-to-treat principle, with outcomes assessed from the time of ran-
domination. Cox-regression analysis was used to compare total mortality and aneurysm-related mortality (with data censored for deaths due to causes other than aneurysm) between the study groups in the EVAR 2 trial and to compare the rates of graft-related complications and reinterventions (in both cases with data censored for deaths) between the endovascular-repair groups in EVAR 2 and EVAR 1. Unadjusted hazard ratios were calculated as well as hazard ratios adjusted for baseline covariates (see the Supplementary Appendix). Hazard ratios were calculated for total follow-up and for three predefined time periods: randomization to 6 months, more than 6 months to 4 years, and after 4 years.

Kaplan–Meier estimates were used to present results for 8 years of follow-up, but 6-year estimates are reported because of the high attrition after this time. An overall rate of aneurysm rupture was estimated in the no-intervention group after the censoring of data for patients who died from a cause other than aneurysm rupture or who underwent elective aneurysm repair. A per-protocol analysis excluded patients at the time of protocol deviation. (Additional information on the statistical methods that we used, including details of the per-protocol classification, assessment of the proportional-hazards assumption, interaction testing, and assessment of costs, is provided in the Supplementary Appendix.)

## RESULTS

### PATIENTS

Between September 1, 1999, and August 31, 2004, we recruited 404 patients to participate in EVAR 2. This overall group consisted of the 338 patients included in the planned midterm analysis that was reported in 2005 and an additional 66 patients who were enrolled between January 2004 and August 2004, who were not included in the midterm analysis (Fig. 1 in the Supplementary Appendix). A total of 197 patients were randomly assigned to the endovascular-repair group, and 207 were assigned to the no-intervention group. There were no significant differences between the two study groups with respect to baseline characteristics (Table 1). The mean (±SD) age was 76.8±6.5 years, and 347 of the patients (86%) were men. The mean aneurysm diameter was 6.7±1.0 cm.

Patients were followed until September 1, 2009 (minimum, 5 years; maximum, 10 years). The median follow-up until death or the end of the study was 3.1 years (interquartile range, 1.3 to 5.4), and less than 1% of patients were lost to follow-up in terms of mortality. During the study period, 249 aneurysm-repair procedures were actually performed, including 10 emergency procedures (Fig. 1 in the Supplementary Appendix). For the 179 patients in the endovascular-repair group who underwent aneurysm repair, the median time from randomization to surgery was 55 days (interquartile range, 38 to 77), and for the 70 patients in the no-intervention group who underwent repair, the median time from randomization to surgery was 244 days (interquartile range, 83 to 643).

Of the 18 patients in the endovascular-repair group who did not undergo aneurysm repair, 7 died within 6 months after randomization (2 as a result of rupture), 8 became physically ineligible or anatomically unsuitable for endovascular repair, 1 declined aneurysm repair, and 2 had an unknown reason. Of the 70 patients in the no-intervention group who underwent repair, 64 underwent elective procedures for the following reasons: 14 had aneurysms that became tender on examination, 8 had aneurysms that grew quickly, 1 had symptoms, 1 was incorrectly enrolled in trial 2 rather than trial 1, 24 declined surveillance, and 16 had an unknown reason. By September 2009, a total of 99 patients remained alive; 14 of these patients had not undergone aneurysm repair.

### OPERATIVE MORTALITY

Among the 179 patients in the endovascular-repair group who underwent aneurysm repair, 13 patients (7.3%) died within 30 days after the procedure, and 15 patients died in the hospital (8.4%); among the 175 patients who underwent elective repair, 10 (5.7%) died within 30 days after the procedure, and 11 (6.3%) died in the hospital. In the no-intervention group, among the 70 patients who underwent aneurysm repair, 2 patients (3%) died within 30 days after the procedure, and 3 patients died in the hospital (4.3%); among the 64 patients who underwent elective repair, 1 patient (2%) died within 30 days after the procedure, and 2 patients (3%) died in the hospital.

### TOTAL AND ANEURYSM-RELATED MORTALITY

During 1413 person-years of follow-up, 305 deaths occurred, 78 of which were aneurysm-related (Table 2). The overall total mortality was 21.0 deaths
Endovascular Repair of Aortic Aneurysm

Table 1. Baseline Characteristics of the Patients.*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Endovascular Repair (N = 197)</th>
<th>No Repair (N = 207)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age — yr</td>
<td>77.2±6.3</td>
<td>76.4±6.7</td>
</tr>
<tr>
<td>Male sex — no. (%)</td>
<td>168 (85.3)</td>
<td>179 (86.5)</td>
</tr>
<tr>
<td>Diameter of abdominal aortic aneurysm — cm</td>
<td>6.8±1.0</td>
<td>6.7±1.0</td>
</tr>
<tr>
<td>Body-mass index (196 and 206 patients)†</td>
<td>26.4±5.0</td>
<td>26.5±4.4</td>
</tr>
<tr>
<td>Diabetes (195 and 205 patients) — no. (%)</td>
<td>30 (15.4)</td>
<td>29 (14.1)</td>
</tr>
<tr>
<td>Smoking status — no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>33 (16.8)</td>
<td>37 (17.9)</td>
</tr>
<tr>
<td>Former smoker</td>
<td>152 (77.2)</td>
<td>156 (75.4)</td>
</tr>
<tr>
<td>Never smoked</td>
<td>12 (6.1)</td>
<td>14 (6.8)</td>
</tr>
<tr>
<td>History of cardiac disease — no. (%)‡</td>
<td>132 (67.0)</td>
<td>153 (73.9)</td>
</tr>
<tr>
<td>Blood pressure — mm Hg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>140±20</td>
<td>139±23</td>
</tr>
<tr>
<td>Diastolic (197 and 204 patients)</td>
<td>79±12</td>
<td>79±12</td>
</tr>
<tr>
<td>Ankle–brachial pressure index (187 and 199 patients)§</td>
<td>0.99±0.20</td>
<td>0.98±0.19</td>
</tr>
<tr>
<td>Forced expiratory volume in 1 second (190 and 203 patients) — liters</td>
<td>1.6±0.6</td>
<td>1.7±0.7</td>
</tr>
<tr>
<td>Serum creatinine (197 and 205 patients) — µmol/liter</td>
<td>Median</td>
<td>107</td>
</tr>
<tr>
<td>Interquartile range</td>
<td>90–134</td>
<td>94–140</td>
</tr>
<tr>
<td>Serum cholesterol (184 and 200 patients) — mmol/liter</td>
<td>4.8±1.2</td>
<td>4.8±1.1</td>
</tr>
<tr>
<td>Statin use (196 and 207 patients) — no. (%)</td>
<td>82 (41.8)</td>
<td>86 (41.5)</td>
</tr>
<tr>
<td>Aspirin use (196 and 207 patients) — no. (%)</td>
<td>114 (58.2)</td>
<td>114 (55.1)</td>
</tr>
</tbody>
</table>

* Data were available for all patients except for characteristics where numbers in the endovascular-repair group and the no-repair group, respectively, are shown. Plus–minus values are means ±SD. To convert the values for creatinine to milligrams per deciliter, divide by 88.4. To convert the values for cholesterol to milligrams per deciliter, divide by 0.02586.

† The body-mass index is the weight in kilograms divided by the square of the height in meters.

‡ Cardiac disease was defined as any of the following: myocardial infarction, angina, cardiac revascularization, cardiac-valve disease, clinically significant arrhythmia, and uncontrolled congestive heart failure.

§ The ankle–brachial pressure index is the ratio of the blood pressure in the lower legs to the blood pressure in the arms; the mean for both legs is shown.

per 100 person-years in the endovascular-repair group and 22.1 deaths per 100 person-years in the no-intervention group (adjusted hazard ratio with endovascular repair, 0.99; 95% confidence interval [CI], 0.78 to 1.27; P = 0.97). The overall aneurysm-related mortality was 3.6 deaths per 100 person-years in the endovascular-repair group and 7.3 deaths per 100 person-years in the no-intervention group (adjusted hazard ratio, 0.53; 95% CI, 0.32 to 0.89; P < 0.02).

There was evidence of deviation from the proportional-hazards assumption for aneurysm-related mortality (P < 0.001), with a nonsignificant increase in aneurysm-related deaths in the endovascular-repair group during the first 6 months (adjusted hazard ratio, 1.78), reflecting operative deaths. This increase was counterbalanced by a decrease in aneurysm-related deaths in the same group after 6 months (adjusted hazard ratio for the period from randomization to 4 years, 0.26) (Table 2). There was no significant evidence of deviation from the proportional-hazards assumption for total mortality (P = 0.07). Kaplan–Meier curves for total and aneurysm-related mortality are shown in Figure 1.

Causes of death, stratified according to the time of death relative to the time of randomization, are listed in Table 2 in the Supplementary.
P values have been adjusted for baseline covariates. A total of 34 patients were excluded from the follow-up analysis because of missing baseline data. NC denotes data that could not be calculated.

Hazard ratios have been adjusted for baseline age, sex, diameter of abdominal aortic aneurysm, forced expiratory volume in 1 second, serum creatinine level (log transformed), use or nonuse of statins, body-mass index, smoking status, systolic blood pressure, and serum cholesterol level.

Appendix. A total of 68 ruptures, 63 of which were fatal, occurred in both study groups. A total of 55 ruptures occurred in the no-intervention group, for an unadjusted rupture rate of 12.4 ruptures (95% CI, 9.6 to 16.2) per 100 person-years.

Sensitivity analyses that included patients with missing baseline adjustment covariates produced results that were almost identical to the results of analyses that included only patients with complete data. There was no evidence of significant interactions between the study group and age, sex, or aneurysm diameter for either aneurysm-related mortality or total mortality (P > 0.10 for all comparisons). In the per-protocol analyses (Fig. 2), overall rates of death from any cause were 21.1 deaths per 100 person-years in the endovascular-repair group and 27.6 deaths per 100 person-years in the no-intervention group (adjusted hazard ratio, 0.82; 95% CI, 0.63 to 1.07; P = 0.14). The overall aneurysm-related mortality was 3.7 deaths per 100 person-years in the endovascular-repair group and 10.9 deaths per 100 person-years in the no-intervention group (adjusted hazard ratio, 0.41; 95% CI, 0.24 to 0.69; P = 0.001).

### Table 2. Deaths from Any Cause and from Aneurysm-Related Causes, According to Time since Randomization.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Endovascular Repair (N = 197)</th>
<th>No Repair (N = 207)</th>
<th>Hazard Ratio (95% CI)</th>
<th>P Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Death from any cause</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time since randomization</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>0–6 mo</td>
<td>145/197 (21.0)</td>
<td>160/207 (22.1)</td>
<td>0.95 (0.76–1.19)</td>
<td>0.99 (0.78–1.27)</td>
</tr>
<tr>
<td>0–6 mo</td>
<td>24/197 (26.0)</td>
<td>19/207 (19.0)</td>
<td>1.38 (0.76–2.52)</td>
<td>1.32 (0.68–2.54)</td>
</tr>
<tr>
<td>&gt;6 mo–4 yr</td>
<td>92/173 (21.4)</td>
<td>108/188 (23.6)</td>
<td>0.90 (0.69–1.20)</td>
<td>1.02 (0.75–1.37)</td>
</tr>
<tr>
<td>&gt;4 yr</td>
<td>29/81 (17.3)</td>
<td>33/80 (20.0)</td>
<td>0.86 (0.52–1.42)</td>
<td>0.72 (0.42–1.24)</td>
</tr>
<tr>
<td><em>Aneurysm-related death</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time since randomization</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–6 mo</td>
<td>25/197 (3.6)</td>
<td>53/207 (7.3)</td>
<td>0.50 (0.31–0.81)</td>
<td>0.53 (0.32–0.89)</td>
</tr>
<tr>
<td>0–6 mo</td>
<td>15/197 (16.3)</td>
<td>9/207 (9.0)</td>
<td>1.82 (0.80–4.16)</td>
<td>1.78 (0.75–4.21)</td>
</tr>
<tr>
<td>&gt;6 mo–4 yr</td>
<td>10/173 (2.3)</td>
<td>35/188 (17.6)</td>
<td>0.31 (0.15–0.62)</td>
<td>0.34 (0.16–0.72)</td>
</tr>
<tr>
<td>&gt;4 yr</td>
<td>0/81</td>
<td>9/80 (5.5)</td>
<td>0</td>
<td>NC</td>
</tr>
</tbody>
</table>

* Hazard ratios have been adjusted for baseline age, sex, diameter of abdominal aortic aneurysm, forced expiratory volume in 1 second, serum creatinine level (log transformed), use or nonuse of statins, body-mass index, smoking status, systolic blood pressure, and serum cholesterol level. A total of 34 patients were excluded from the follow-up analysis because of missing baseline data. NC denotes data that could not be calculated.

† P values have been adjusted for baseline covariates.

### Graft-Related Complications and Reinterventions

During 1084 person-years of follow-up, 158 graft complications were reported in 97 patients, with 1 complication in 52 patients, 2 complications in 33 patients, 3 complications in 8 patients, and 4 complications in 4 patients (Table 3 in the Supplementary Appendix). Graft rupture occurred in two patients after the placement of an endograft (one patient underwent insertion of a stent on an emergency basis and survived, and the other underwent attempted conversion to open repair but died). Conversions to open repair occurred for other reasons in an additional two patients, and both survived. A total of 66 graft-related reinterventions were performed in 55 patients, with 1 reintervention in 48 patients, 2 reinterventions in 3 patients, and 3 reinterventions in 4 patients.

The rates of graft-related events did not differ significantly between the endovascular-repair groups in EVAR 1 and EVAR 2, despite the considerable disparity in fitness between the two trial cohorts (Fig. 3A). The unadjusted hazard ratio for complications (with endovascular repair in trial 2 as compared with endovascular repair in trial 1) was 1.02 (95% CI, 0.79 to 1.32; P = 0.87). The unad-
adjusted hazard ratio for reinterventions was 1.20 (95% CI, 0.85 to 1.70; P=0.31).

**COSTS**

Detailed costs for aneurysm-related procedures are provided in Table 4 in the Supplementary Appendix. The mean cost of the primary aneurysm repair was £13,301 (U.S. $20,124) in the endovascular-repair group. In the no-intervention group, fewer patients actually underwent repair; the mean cost in this group was thus lower, at £4,467 ($6,759) (mean difference, £8,834 [$13,366]; 95% CI, 7,068 to 10,599 [10,802 to 16,127]). The mean cost of aneurysm-related readmissions was £1,694 ($2,563) in the endovascular-repair group and £702 ($1,062) in the no-intervention group. During 8 years of follow-up, the total average cost of aneurysm-related procedures was £14,995 ($22,687) in the endovascular-repair group and £5,169 ($7,821) in the no-intervention group (cost difference, £9,826 [$14,867]; 95% CI, 7,638 to 12,013 [10,802 to 18,176]). Most of the cost difference was attributed to the primary aneurysm-repair procedure itself.

**DISCUSSION**

In 2005, when the midterm results of the EVAR 2 trial were reported, they offered little support for endovascular repair of abdominal aortic aneurysms in patients considered to be physically ineligible for open surgical repair. With longer follow-up, we found a benefit of endovascular repair in terms of aneurysm-related mortality. However, these patients had a limited life expectancy, regardless of whether the aneurysm was repaired or no intervention was performed, with few surviving after 8 years.

The operative mortality after endovascular repair in EVAR 2 (7.3%) was considerably higher than that reported among the patients in EVAR 1 (1.8%). The midterm results of EVAR 2 showed a slightly higher operative mortality, at 8.7%, which appears to have been attenuated with the recruitment of an additional 66 patients. The rate of statin use increased during the course of the EVAR 2 trial (from 39.5% before December 2003 to 53.0% afterward); this may have reduced the operative rate of death. Other improvements in clinical practice and efforts to optimize fitness may have been implemented. Another analysis of EVAR 2 data suggested that the rate...
of cardiovascular events (myocardial infarctions and strokes) was higher in the endovascular-repair group than in the no-intervention group, although this difference was not statistically significant. Thus, the previous recommendation that optimization of fitness for intervention should be given priority over placement of an endovascular graft remains valid.

In this longer-term study, placement of an endovascular graft led to a significant reduction in aneurysm-related mortality, primarily through prevention of late aneurysm rupture. The rupture rate of 12.4 per 100 person-years in the no-intervention group is somewhat lower than the rates in other cohorts of patients with large aneurysms who were considered to be physically ineligible for open surgical repair, but it remains high, and the danger of large aneurysms should not be downplayed. Previous studies have suggested that anatomical suitability may impart some protection against rupture. Also, the aneurysm repairs that were performed against protocol may have led to a reduced number of ruptures; thus, the rupture rate in our study may not reflect the true natural history of large aneurysms if they are left untreated in the long term.

Although endovascular repair reduced the rate of aneurysm rupture, it did not lead to an improvement in overall survival. The factors leading to the judgment that these patients were physically ineligible for open repair (primarily because of cardiovascular disease, as noted in Table 1 in the Supplementary Appendix) seem likely to have contributed to a high subsequent rate of death from any cause; this rate was not influenced by assignment to endovascular repair. Thus, on the basis of these data, a decision to perform endovascular repair when open surgical repair is deemed inadvisable should presumably balance the risk of the intervention itself against the risk of aneurysm rupture, with the expectation that survival would probably be unaffected.

During the course of the trial, a substantial minority of patients in the no-intervention group and their physicians opted in favor of repair, resulting in a loss of equipoise. A post hoc analysis comparing baseline fitness in the patients who crossed over to endovascular repair with patients assigned to endovascular repair who underwent repair showed that the patients who crossed over were significantly more fit (details are available in the Supplementary Appendix). Per-protocol analyses showed a greater benefit of endovascular repair in terms of aneurysm-related mortality. A nonsignificant benefit with respect to total mortality was also shown. However, the interpretation of these data is problematic, since the analyses were not performed according to study group and therefore were potentially biased. Regardless of these considerations, the rate of crossover in the trial suggests that it may prove difficult to withhold endovascular repair in the future.
Graft-related complications and reinterventions were common after endovascular repair, but they were not associated with increased mortality. Very few procedure-related deaths occurred 6 or more months after the primary procedure. Despite gross differences in the fitness of patients and overall mortality between the EVAR 1 and EVAR 2 cohorts, the rates of complications and reinterventions were remarkably similar; suitability for open repair, as determined by an anesthesiologist, appears to be of little relevance in the development of subsequent graft-related events. Other studies investigating baseline factors that might be associated with serious graft-related complications and reinterventions after endovascular aneurysm repair have shown that older age and a larger aneurysm diameter appear to be strongly influential. However, differences in these factors between EVAR 1 and EVAR 2 did not lead to different rates of graft-related events. This finding may be explained in part by the attrition due to high mortality in EVAR 2, leaving less time for graft-related complications to develop. This attrition may also explain why only two endovascular-graft ruptures occurred in EVAR 2, as compared with 25 ruptures in EVAR 1.

In conclusion, the EVAR 2 trial showed that in patients with abdominal aortic aneurysm who were considered to be physically ineligible for open surgical repair, endovascular repair, as compared with no intervention, was associated with a significantly lower rate of aneurysm-related mortality in the long term, but with no reduction in total mortality. Endovascular repair was considerably more expensive than no intervention.

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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APPENDIX

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