ORIGINAL ARTICLE

Open versus Endovascular Repair of Abdominal Aortic Aneurysm

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ABSTRACT

BACKGROUND

Elective endovascular repair of an abdominal aortic aneurysm results in lower perioperative mortality than traditional open repair, but after 4 years this survival advantage is not seen; in addition, results of two European trials have shown worse long-term outcomes with endovascular repair than with open repair. Long-term results of a study we conducted more than a decade ago to compare endovascular repair with open repair are unknown.

METHODS

We randomly assigned patients with asymptomatic abdominal aortic aneurysms to either endovascular repair or open repair of the aneurysm. All the patients were candidates for either procedure. Patients were followed for up to 14 years.

RESULTS

A total of 881 patients underwent randomization: 444 were assigned to endovascular repair and 437 to open repair. The primary outcome was all-cause mortality. A total of 302 patients (68.0%) in the endovascular-repair group and 306 (70.0%) in the open-repair group died (hazard ratio, 0.96; 95% confidence interval [CI], 0.82 to 1.13). During the first 4 years of follow-up, overall survival appeared to be higher with endovascular repair than with open repair; from year 4 through year 8, overall survival was higher in the open-repair group; and after 8 years, overall survival was once again higher in the endovascular-repair group (hazard ratio for death, 0.94; 95% CI, 0.74 to 1.18). None of these trends were significant. There were 12 aneurysm-related deaths (2.7%) in the endovascular-repair group and 16 (3.7%) in the open-repair group (between-group difference, –1.0 percentage point; 95% CI, –3.3 to 1.4); most deaths occurred during the perioperative period. Aneurysm rupture occurred in 7 patients (1.6%) in the endovascular-repair group, and rupture of a thoracic aneurysm occurred in 1 patient (0.2%) in the open-repair group (between-group difference, 1.3 percentage points; 95% CI, 0.1 to 2.6). Death from chronic obstructive lung disease was just over 50% more common with open repair (5.4% of patients in the endovascular-repair group and 8.2% in the open-repair group died from chronic obstructive lung disease; between-group difference, –2.8 percentage points; 95% CI, –6.2 to 0.5). More patients in the endovascular-repair group underwent secondary procedures.

CONCLUSIONS

Long-term overall survival was similar among patients who underwent endovascular repair and those who underwent open repair. A difference between groups was noted in the number of patients who underwent secondary therapeutic procedures. Our results were not consistent with the findings of worse performance of endovascular repair with respect to long-term survival that was seen in the two European trials. (Funded by the Department of Veteran Affairs Office of Research and Development; OVER ClinicalTrials.gov number, NCT00094575.)

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Elective repair of an abdominal aortic aneurysm can prevent aneurysm rupture and death, as shown in randomized trials of aneurysm screening,[1] but it is responsible for more perioperative deaths than any other general or vascular surgical procedure.[2] Randomized trials have shown that endovascular repair results in lower perioperative mortality than open repair, but after a few years this advantage is no longer seen because of excess late mortality among patients who had undergone endovascular repair[3] — a pattern that has also been seen in large observational studies.[4] If this pattern were to continue over time, endovascular repair could become the inferior strategy; this possibility underscores the need for long-term follow-up information. Two European trials (the United Kingdom Endovascular Aneurysm Repair Trial 1 [EVAR-1] and the Dutch Randomised Endovascular Aneurysm Management [DREAM] trial)[5,6] have recently shown higher long-term mortality with endovascular repair than with open repair. We report here data on extended follow-up of patients in the Veterans Affairs (VA) Open versus Endovascular Repair (OVER) trial.

Methods

Trial Design and Oversight

The trial methods have been described previously.[7,8] The authors designed and conducted the trial, performed the analyses, wrote the manuscript, and vouch for the completeness and accuracy of the data and analyses and for adherence of the trial to the protocol. The trial was approved by a central human rights committee and the institutional review board at each participating center. An independent data and safety monitoring committee reviewed the data at regular intervals. The protocol is available with the full text of this article at NEJM.org. Enrollment began on October 15, 2002, and ended on April 15, 2008. Active follow-up ended on October 15, 2011, which was the cutoff date for our previous report.[8] In October 2010, the VA Cooperative Studies Program approved an additional analysis that extended follow-up to December 31, 2016; the results of this analysis are reported here. No commercial sponsor was involved in the trial.

Patients and Procedures

Eligible patients had abdominal aortic aneurysms for which elective repair was planned and were candidates for either endovascular or open repair.[7,8] Patients were randomly assigned to one of the two repair procedures in a 1:1 ratio.[7] The specific type of endovascular-repair device intended for a particular patient, in the event that the patient was assigned to endovascular repair, was reported to the coordinating center before randomization to permit subgroup comparisons. The protocol required that the vascular surgeons and interventional radiologists had performed a minimum of 10 previous endovascular-repair and open-repair procedures and had subspecialty training, device-specific education as approved by the Food and Drug Administration, and centralized endovascular expert training that included didactic, flow model simulation, and live-case education. Aneurysm repair was performed within 6 weeks after randomization. Trial patients were followed regularly through October 15, 2011.[7,8]

For this report of extended follow-up, we obtained no additional information from patients or participating centers since the previous report.[8] All new data on deaths, causes of death, and clinical encounters were obtained from VA and other national data sets. To identify secondary therapeutic procedures, we examined *International Classification of Diseases, 9th Revision* (ICD-9), codes and Current Procedural Terminology (CPT) codes related to aortic aneurysm procedures (ICD-9 codes 38.34, 38.36, 38.44, 38.46, 39.41, 39.49, 39.52, 39.71, and 39.79; CPT codes 33880 through 33891, 34800 through 35142, 35472, 35537 through 35540, 35637, 35638, 35721, and 35840) and ventral and incisional hernia repair (ICD-9 codes 53.5 through 53.69; CPT codes 49560 through 49568 and 49652 through 49657). These aortic procedure codes were sufficient to determine that secondary therapeutic procedures had been performed. For other codes (ICD-9 codes 39.25 and 39.26; CPT codes 75894 and 75952 through 75959), we required accompanying diagnostic codes for aortic aneurysm (ICD-9 codes 441.0 through 442.9). The cause of death was determined from the information on the death certificate, which was captured in the National Death Index. We obtained information on deaths through 2016 and on causes of death and clinical encounters through 2015.

Outcomes

The primary outcome was all-cause mortality. Secondary outcomes were all-cause mortality as assessed in prespecified subgroups[8] and secondary therapeutic procedures that resulted directly

or indirectly from the initial procedure (with each trip to the procedure suite counting as one secondary procedure), including any unplanned surgical procedures performed within 30 days after the initial procedure and any additional aortoiliac or other related procedures (such as incisional hernia repair) that were performed at any time.

The cause of death and the secondary therapeutic procedures were adjudicated by an outcomes committee (whose members were unaware of the group assignments) during active follow-up and by the authors in the case of more recent deaths. All deaths that occurred within 30 days after the repair or during the hospitalization for the repair were considered to be related to the aneurysm, as were all deaths that occurred after 30 days and were adjudicated as having resulted directly or indirectly from the aneurysm or its treatment. In the current article, we report all-cause mortality and the secondary outcomes, including those that occurred over the extended follow-up period since the previous report.

STATISTICAL ANALYSIS

The trial was designed to provide 80% power to detect 25% lower relative mortality in the endovascular-repair group than in the open-repair group, at a two-sided alpha level of 0.05, at the end of active follow-up in 2011.[7] The analysis was performed according to the intention-to-treat principle. The Kaplan–Meier method was used to calculate estimated cumulative event rates. Hazard ratios and confidence intervals were estimated with the use of Cox proportional-hazards models.[9] We evaluated possible departures from the proportional-hazards assumption by using the P value for the interaction of mortality with ($\log_{10}$) time and by plotting Schoenfeld residuals (Fig. S1 in the Supplementary Appendix, available at NEJM.org). The effect of treatment in prespecified subgroups was assessed by including treatment-by-subgroup interactions in the Cox models. Variables were compared with the use of chi-square tests and Student's t-tests. Two-sided P values of less than 0.05 were considered to indicate statistical significance. No correction for multiple comparisons was performed. Statistical analyses were performed with the use of SAS software, version 9.3 (SAS Institute). Restricted mean survival time (analogous to the area under the curve for a survival plot) was assessed with the use of the pseudo-mean values approach.[10] To facilitate comparison with EVAR-1 and the DREAM trial,[5,6] we report hazard ratios according to time periods. To avoid data-driven selection of time periods, we adopted the time periods used by EVAR-1, the larger of the European trials.[5]

RESULTS

PATIENTS

From October 2002 through April 2008, we randomly assigned 881 patients at 42 VA medical centers to undergo endovascular repair (444 patients) or open repair (437 patients). Details of exclusions before randomization and characteristics at randomization were described previously (Fig. 1, and Table S2 in the Supplementary Appendix).[7] The two groups were similar, with no significant differences except that a higher percentage of patients in the open-repair group than in the endovascular-repair group were taking aspirin (63.4% vs. 55.0%). More than 95% of patients underwent the assigned repair; in 2% of patients, the assigned repair was attempted but was not completed (Fig. 1).

Vital status was known for all patients at the end of active follow-up on October 15, 2011. Assessment of participants was extended to December 31, 2016 (minimum follow-up, 0.02 years; maximum follow-up, 14.2 years; mean, 8.4 years; median, 9.4 years [interquartile range, 5.7 to 11.2]). We identified 316 additional deaths since the end of active follow-up, for a total of 608 deaths (69.0% of all patients who underwent randomization).

PRIMARY OUTCOME AND CAUSES OF DEATH

Our principal finding is that no significant difference in the primary outcome of all-cause mortality was noted between the endovascular-repair group and the open-repair group. A total of 302 deaths occurred in the endovascular-repair group, and 306 deaths occurred in the open-repair group (hazard ratio with endovascular repair vs. open repair, 0.96; 95% confidence interval [CI], 0.82 to 1.13; P=0.61) (Fig. 2A and Table 1).

The postoperative survival advantage with endovascular repair was significant for the first

3 years; after 3 years, the advantage disappeared, as previously reported.[8] Table 2 shows hazard ratios for death according to time since randomization. A survival advantage with endovascular repair was seen early; from years 4 through 8, a survival advantage was seen with open repair; however, after 8 years, no difference was observed (hazard ratio, 0.94; 95% CI, 0.74 to 1.18; P=0.59).

The interaction of time with treatment was not significant, which suggests the absence of a significant departure from the proportional-hazards assumption. The restricted mean survival time was also not significantly different between the groups. After 5 years, the restricted mean survival time was 4.53 years in the endovascular-repair group and 4.40 years in the open-repair group (difference, 0.13 years; 95% CI, −0.04 to 0.29), and after 14.2 years it was 9.03 years and 8.81 years, respectively (difference, 0.22 years; 95% CI, −0.34 to 0.79).

We previously reported 10 aneurysm-related deaths in the endovascular-repair group (2 occurred during the perioperative period [during the hospitalization for the repair or within 30 days after the repair], and 8 occurred late [more than 30 days after the repair]) and 16 aneurysm-related deaths in the open-repair group (13 occurred in the perioperative period and 3 occurred late).[8] In our previous report, 6 aneurysm ruptures had occurred in the endovascular-repair group (of which 3 were fatal), and none had occurred in the open-repair group. We now add 3 aneurysm-related deaths (2 in the endovascular-repair group and 1 in the open-repair group), 2 of which were caused by rupture (Table 1). One death in the endovascular-repair group had a code of "aortic aneurysm without rupture," which usually refers to a complication of a procedure performed on an unruptured aneurysm. In this case, no procedure had been performed in the patient for several years before death, the patient was known to have had severe heart disease, medical records included a code for abdominal pain 4 days before death, and the patient had a cardiac arrest in the ambulance on the day of death. We considered this to be a probable aneurysm rupture, although we were unable to rule out a cardiac cause. Another death in the endovascular-repair group was coded as "thoracic aortic aneurysm, without rupture." This patient underwent an endovascular repair of the descending thoracic aorta 7 weeks before death and an endovascular implantation of an abdominal aortic graft 2 weeks before death, which falls within the 30-day time frame for our definition of an aneurysm-related death. The third patient (who had been assigned to the open-repair group) was transported to the hospital by air ambulance, where computed tomography of the chest was performed; clinical and death codes were recorded for "thoracic aortic aneurysm, ruptured," a diagnosis we accepted (therefore, the death of this patient was not counted with

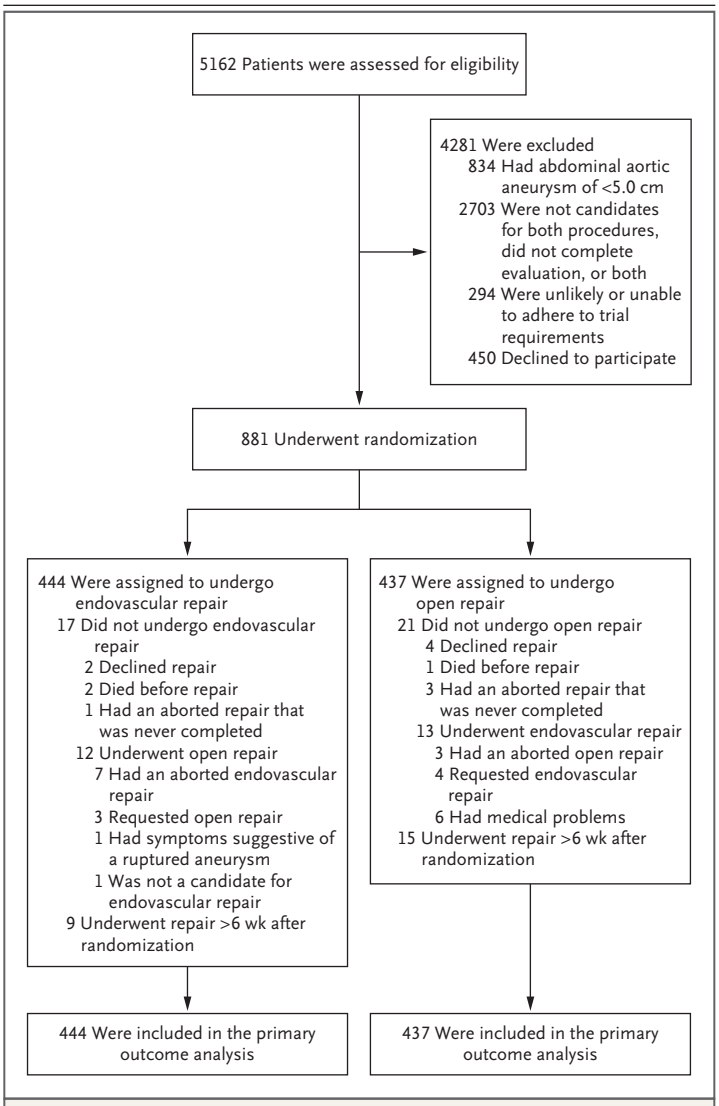

Figure 1. Randomization and Treatment.

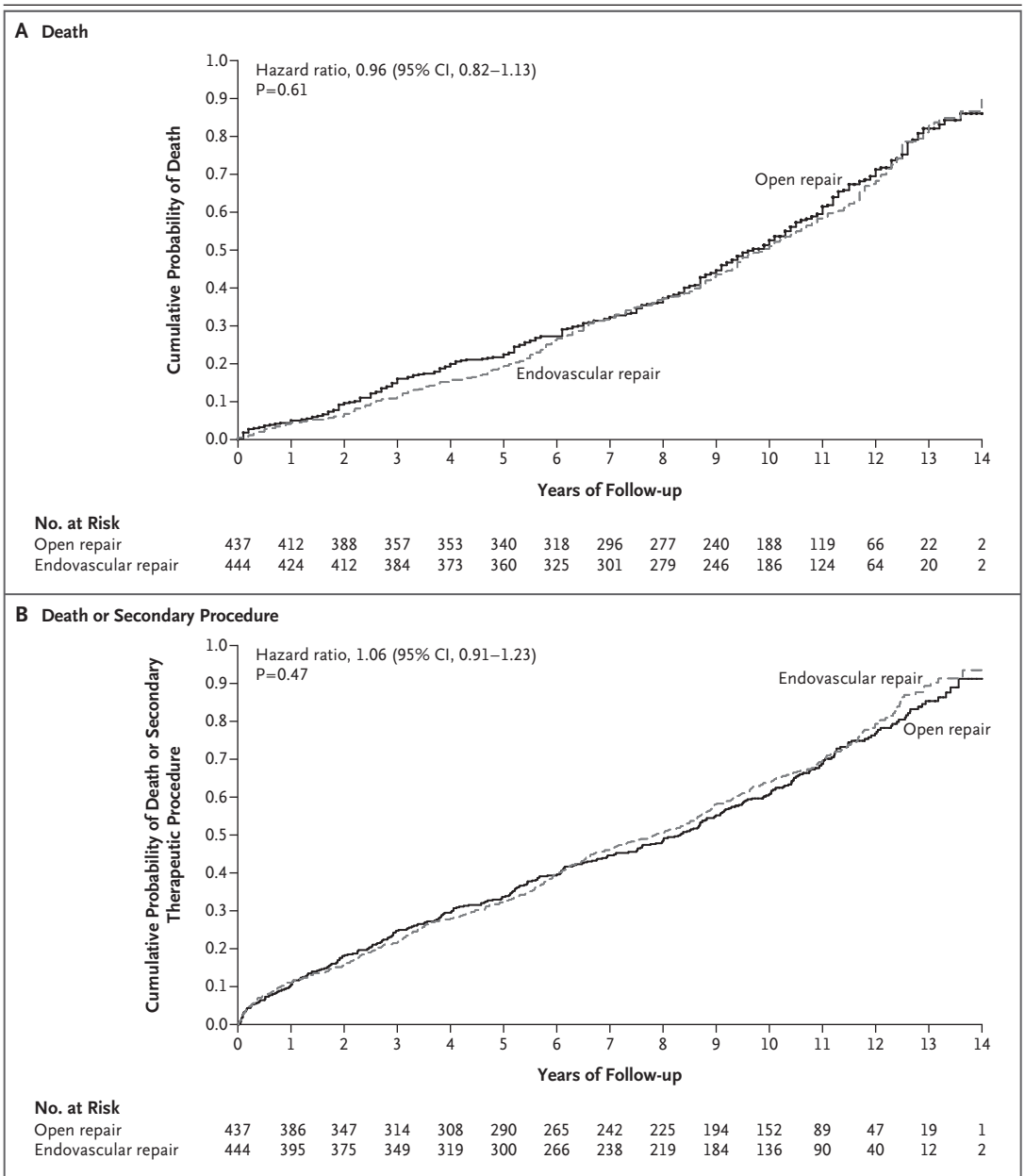

Figure 2. Kaplan–Meier Plots of the Cumulative Probability of Death and of Death or a Secondary Therapeutic Procedure.

Panel A shows the cumulative probability of death from any cause from the time of randomization among patients with an abdominal aortic aneurysm who underwent endovascular repair or open repair. Panel B shows the cumulative probability of death or a secondary therapeutic procedure. At the end of follow-up, 608 of 881 patients had died, and 675 of 881 patients had either undergone a secondary therapeutic procedure or had died.

the other aneurysm-related deaths). As a result, the totals are now 12 aneurysm-related deaths (2.7%) in the endovascular-repair group and 16 (3.7%) in the open-repair group (between-group difference, –1.0 percentage point; 95% CI, –3.3 to 1.4), and 7 ruptures (1.6%) in the endovascular-repair group and 1 (0.2%) in the open-repair group (between-group difference, 1.3 percentage

Table 1. Clinical Outcomes.*

Variable	Endovascular Repair (N=444)	Open Repair (N=437)	Between-Group Difference (95% CI)
			percentage points
All deaths — no. (%)	302 (68.0)	306 (70.0)	−2.0 (−8.1 to 4.1)
Deaths according to cause — no. (%)			
Abdominal aneurysm–related cause	12 (2.7)	16 (3.7)	−1.0 (−3.3 to 1.4)
During hospitalization or within 30 days after repair	2 (0.5)	11 (2.5)	−2.1 (−3.7 to −0.5)
Cardiovascular cause	88 (19.8)	69 (15.8)	4.0 (−1.0 to 9.1)
Cerebrovascular cause	14 (3.2)	9 (2.1)	1.1 (−1.0 to 3.2)
Cancer	80 (18.0)	85 (19.5)	−1.4 (−6.6 to 3.7)
Pneumonia or influenza	14 (3.2)	16 (3.7)	−0.5 (−2.9 to 1.9)
Other infection	9 (2.0)	6 (1.4)	0.7 (−1.1 to 2.4)
Chronic obstructive lung disease	24 (5.4)	36 (8.2)	−2.8 (−6.2 to 0.5)
Accident	12 (2.7)	6 (1.4)	1.3 (−0.5 to 3.2)
Suicide	2 (0.5)	0	0.5 (−0.2 to 1.1)
Homicide	0	2 (0.5)	−0.5 (−1.1 to 0.2)
Most likely but not confirmed to be caused by rupture of abdominal aortic aneurysm	0	1 (0.2)	−0.2 (−0.7 to 0.2)
Possibly but most likely not caused by rupture of abdominal aortic aneurysm	9 (2.0)	5 (1.1)	0.9 (−0.8 to 2.5)
Unknown or insufficient data†	38 (8.6)	55 (12.6)	
Aneurysm rupture — no. (%)	7 (1.6)	1 (0.2)‡	1.3 (0.1 to 2.6)
Secondary therapeutic procedures			
No. of secondary procedures	193	116	
Patients who underwent secondary procedures — no./total no. (%)	117/439 (26.7)	85/429 (19.8)	6.9 (2.0 to 17.5)
Patients who died or underwent secondary procedures — no. (%)	345 (77.7)	330 (75.5)	2.4 (−3.2 to 7.9)

* Some values may differ from the expected value because of rounding.
† This category includes patients with uninformative codes for cause of death (e.g., ICD-9 codes I46.9, R99) or patients whose deaths could not be attributed to a cause on the basis of available information.
‡ The aortic aneurysm in this patient was a thoracic aneurysm.

Table 2. Deaths from Any Cause According to Time since Randomization.*

Time since Randomization	Endovascular Repair	Open Repair	Hazard Ratio (95% CI)	P Value	P Value for Interaction†
	no. of deaths/total no. (%)				
Any time	302/444 (68.0)	306/437 (70.0)	0.96 (0.82–1.13)	0.61	0.25
0 to 6 mo	11/444 (2.5)	14/437 (3.2)	0.77 (0.35–1.69)	0.51	0.43
>6 mo to 4 yr	59/433 (13.6)	70/423 (16.5)	0.81 (0.57–1.14)	0.22	0.88
>4 to 8 yr	93/374 (24.9)	76/353 (21.5)	1.18 (0.87–1.60)	0.29	0.50
>8 yr	139/281 (49.5)	146/277 (52.7)	0.94 (0.74–1.18)	0.59	0.25

* Time-period categories were selected to coincide with those used in the United Kingdom Endovascular Aneurysm Repair Trial 1 (EVAR-1).[5]
† The P value is for the interaction of treatment with time.

points; 95% CI, 0.1 to 2.6 [values for percentage points may differ from the expected value because of rounding]).

Deaths from other causes were similar in the two groups, except for death from chronic obstructive lung disease, which was just over 50% more common in the open-repair group than in the endovascular-repair group (5.4% in the endovascular-repair group vs. 8.2% in the open-repair group; between-group difference, −2.8 percentage points; 95% CI, −6.2 to 0.5) (Table 1). Of note, deaths from cancer were not more common in the endovascular-repair group than in the open-repair group, despite the presumed higher exposure to ionizing radiation among patients in the endovascular-repair group.

SECONDARY PROCEDURES AND OTHER OUTCOMES

We previously reported 148 secondary therapeutic procedures in 98 patients in the endovascular-repair group and 105 secondary therapeutic procedures in 78 patients in the open-repair group.[8] To these we now add 45 procedures in 19 patients in the endovascular-repair group and 11 procedures in 7 patients in the open-repair group. The totals are now 193 secondary therapeutic procedures in 117 patients in the endovascular-repair group and 116 procedures in 85 patients in the open-repair group. The between-group difference in the numbers of procedures is significant (P=0.04), as is the between-group difference in the percentage of patients who underwent a secondary procedure (26.7% in the endovascular-repair group vs. 19.8% in the open-repair group; difference, 6.9 percentage points; 95% CI, 2.0 to 17.5) (Table 1). The total number of patients who either died or underwent a secondary therapeutic procedure was similar in the two groups (345 patients in the endovascular-repair group and 330 in the open-repair group; between-group difference, 2.2 percentage points; 95% CI, −3.4 to 7.8), which suggests that many of the excess procedures in the endovascular-repair group occurred in patients who later died. The incidence of a secondary therapeutic procedure or death, evaluated on the basis of Kaplan–Meier survival estimates, was also similar in the two groups throughout the trial (hazard ratio for death or secondary procedure, 1.06; 95% CI, 0.91 to 1.23; P=0.47) (Fig. 2B).

Figure 3 shows the risk of death in prespecified subgroups defined according to characteristics at entry. Among patients younger than 70 years of age, overall survival appeared to be higher in the endovascular-repair group than in the open-repair group, but the difference was not significant (hazard ratio for death, 0.81; 95% CI, 0.62 to 1.05; P=0.10). Among patients 70 years of age or older, there was a trend in the opposite direction (hazard ratio for death with endovascular repair vs. open repair, 1.20; 95% CI, 0.98 to 1.47; P=0.08), and the interaction of age (<70 years vs. ≥70 years of age) with treatment group was significant (P=0.02). However, no correction was made for multiple comparisons, so the data must be interpreted with caution. There was no evidence of a significant differential effect of endovascular repair or open repair on long-term mortality in other prespecified subgroups.

DISCUSSION

In this multicenter, randomized trial with an extended follow-up period, no difference was observed between endovascular and open repair in the primary outcome of all-cause mortality. Among younger patients, endovascular repair resulted in somewhat higher long-term overall survival than open repair, but among older patients, endovascular repair resulted in somewhat lower long-term overall survival than open repair. More deaths from chronic obstructive lung disease occurred in the open-repair group than in the endovascular-repair group. We found between-group differences in the number of secondary therapeutic procedures that were performed and in the number of patients who underwent secondary procedures.

Much of the early enthusiasm for endovascular repair focused on an expected advantage in old or frail patients who were not good candidates for open repair. Our finding that endovascular repair resulted in more benefit than open repair in younger patients and less benefit in older patients was therefore surprising. This conclusion is not statistically robust. The clinical implications of this age effect must be reconciled with our finding that all ruptures of infrarenal aneurysms occurred in the endovascular-repair group, which makes this procedure seemingly less desirable for use in younger patients. However, the percentage of ruptures in

Subgroup	Endovascular Repair	Open Repair	Hazard Ratio for Death (95% CI)	P Value for Interaction
	no. of patients who died/total no. of patients (%)			
Randomization period				0.81
Up to April 15, 2005	156/212 (73.6)	155/201 (77.1)	0.98 (0.79–1.23)	
After April 15, 2005	146/232 (62.9)	151/236 (64.0)	0.95 (0.76–1.20)	
Age				0.02
<70 yr	120/218 (55.0)	111/188 (59.0)	0.81 (0.62–1.05)	
≥70 yr	182/226 (80.5)	195/249 (78.3)	1.20 (0.98–1.47)	
AAA diameter				0.99
<5.5 cm	132/192 (68.8)	127/190 (66.8)	0.96 (0.75–1.23)	
≥5.5 cm	170/252 (67.5)	179/247 (72.5)	0.96 (0.78–1.19)	
Surgical risk				0.19
Low	145/240 (60.4)	152/228 (66.7)	0.87 (0.69–1.10)	
Intermediate or high	154/200 (77.0)	149/204 (73.0)	1.09 (0.87–1.37)	
Coronary artery disease				0.54
No	184/270 (68.1)	175/252 (69.4)	1.00 (0.81–1.23)	
Yes	118/174 (67.8)	131/185 (70.8)	0.91 (0.71–1.17)	
Intended endovascular-repair device				
Cook Zenith	108/166 (65.1)	117/175 (66.9)	0.97 (0.74–1.26)	
Gore Excluder	117/177 (66.1)	105/150 (70.0)	0.91 (0.70–1.19)	0.65
Medtronic AneuRx	67/88 (76.1)	72/98 (73.5)	1.06 (0.76–1.48)	0.56
All patients	302/444 (68.0)	306/437 (70.0)	0.96 (0.82–1.13)	

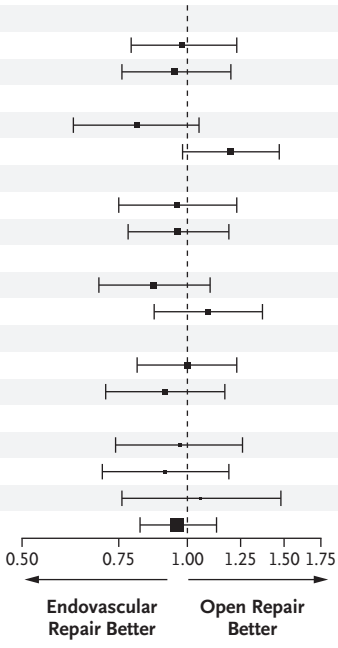

Figure 3. Hazard Ratios for Death According to Baseline Characteristics.

The size of the box is proportional to the total number of deaths in each subgroup. The P value for the interaction of age with treatment group has not been corrected for multiple comparisons and therefore should not be considered robust. Surgical risk was determined on the basis of RAND criteria (Table S1 in the Supplementary Appendix).[11] RAND scores were not reported for 8 patients who died (3 patients in the endovascular-repair group and 5 patients in the open-repair group). P values for the Gore Excluder and the Medtronic AneuRx devices are for the comparisons with the other two intended endovascular-repair devices. A total of 22 patients who died (10 patients in the endovascular-repair group and 12 patients in the open-repair group) had an intended endovascular-repair device that was different from the three listed devices. AAA denotes abdominal aortic aneurysm.

our trial was low (0.9%). Five of the eight ruptures, including three of the five fatal ruptures, occurred in patients older than 70 years of age at entry; at least three of the eight ruptures occurred in patients who did not receive the recommended intervention, and two were ruptures of thoracic aneurysms. Extended survival after repair of an infrarenal aneurysm may permit detection of aortic aneurysms at other sites.

Chronic obstructive lung disease caused just over 50% more deaths in the open-repair group than in the endovascular-repair group. This difference was significant, and it is supported by strong trends in the two European trials. In EVAR-1, a total of 55 patients (8.8%) in the endovascular-repair group and 73 (11.7%) in the open-repair group died from respiratory disease (P=0.09).[5] In the DREAM trial, 8 patients (4.6%) in the endovascular-repair group and 14 (7.9%) in the open-repair group died from pulmonary causes (P=0.26).[6] These differences cannot be explained by baseline rates of smoking or respiratory disease. Data on changes in tobacco use after randomization were not reported for the current trial or for the European trials.

In all three long-term randomized trials and in a large Medicare study, endovascular repair conferred a perioperative survival advantage that continued for several years and then disappeared because of increased deaths in the endovascular-repair groups.[4-6,8] The important questions are, what caused these later deaths in the endovascular-repair groups, and would the trend continue, with the result that endovascular repair would become the inferior strategy? The first question remains unanswered, but the most widely ac-

cepted explanation is that the perioperative deaths after open repair most likely occurred in the frailest patients, so the curves converged as later deaths occurred in the frailest patients in the endovascular-repair groups.[8]

The second question can be addressed empirically, now that long-term results have been reported for all three trials. In EVAR-1,[5] aneurysm-related mortality and adjusted total mortality were higher in the endovascular-repair group than in the open-repair group after 8 years; in the DREAM trial,[6] more late secondary procedures were performed in the endovascular-repair group than in the open-repair group. In contrast, we found numerically fewer deaths after 8 years in the endovascular-repair group than in the open-repair group (hazard ratio, 0.94; 95% CI, 0.74 to 1.18; P=0.59), very few late aneurysm-related deaths in either group, and little evidence for a late increase in secondary therapeutic procedures in the endovascular-repair group (Fig. 2B). Even though the result of the primary analysis (the hazard ratio) suggests that there is no significant difference in the outcome between the two groups, an assessment of the hazard ratio at various time periods suggests that this estimated overall hazard ratio might not be a good summary statistic for long-term follow-up.

Why might our results differ from those of the two European trials? First, the European trials began several years before our trial, during a time when endovascular-repair devices, techniques, and strategies were changing rapidly. The OVER trial required investigators performing the procedures to have specific skills as well as device training and trial-associated training to avoid potential increased mortality resulting from inexperience.[12] In addition, evaluation strategies in the early years of endovascular repair involved high doses of radiation, which may have been responsible for the significantly higher number of deaths from cancer in the endovascular-repair group than in the open-repair group in EVAR-1[5]; there was a similar trend in the DREAM trial.[6] In contrast, in our trial, the total number of deaths from cancer was lower in the endovascular-repair group than in the open-repair group. There were 37 deaths from cancer in the open-repair group and 41 in the endovascular-repair group since our last report,[8] for a total of 165 deaths (80 in the endovascular-repair group and 85 in the open-repair group).

Second, postoperative mortality was lower in our trial than in the European trials. The percentages of patients who died within 30 days after undergoing endovascular repair or during hospitalization were 1.2% in the DREAM trial, 2.1% in EVAR-1, and 0.5% in our trial; among patients who underwent open repair, the percentages were 4.6%, 6.2%, and 2.5%, respectively.[13,14] We discussed possible reasons for these differences extensively in a previous article.[7] Besides the difference in timing noted above, operative mortality has been shown to be lower in the United States than in Europe, and this was reflected in the data from the three trials discussed here. The quality of the surgical procedure may affect the long-term durability of the device as well as perioperative clinical outcomes. It is less clear that higher surgical quality would result in better long-term outcomes after endovascular repair, but it is possible that the steep learning curve for endovascular repair resulted in differences in surgical quality that were reflected in later results.

Finally, although the procedures for which we report long-term results were performed more than a decade ago, the operative mortality in our trial was lower than that currently reported nationally in the United States.[15] This suggests that our results can have ongoing relevance.

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