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Endovascular versus Open Repair of Abdominal Aortic Aneurysm

The United Kingdom EVAR Trial Investigators*

ABSTRACT

BACKGROUND

Few data are available on the long-term outcome of endovascular repair of abdominal aortic aneurysm as compared with open repair.

METHODS

From 1999 through 2004 at 37 hospitals in the United Kingdom, we randomly assigned 1252 patients with large abdominal aortic aneurysms (≥5.5 cm in diameter) to undergo either endovascular or open repair; 626 patients were assigned to each group. Patients were followed for rates of death, graft-related complications, reinterventions, and resource use until the end of 2009. Logistic regression and Cox regression were used to compare outcomes in the two groups.

RESULTS

The 30-day operative mortality was 1.8% in the endovascular-repair group and 4.3% in the open-repair group (adjusted odds ratio for endovascular repair as compared with open repair, 0.39; 95% confidence interval [CI], 0.18 to 0.87; P=0.02). The endovascular-repair group had an early benefit with respect to aneurysm-related mortality, but the benefit was lost by the end of the study, at least partially because of fatal endograft ruptures (adjusted hazard ratio, 0.92; 95% CI, 0.57 to 1.49; P=0.73). By the end of follow-up, there was no significant difference between the two groups in the rate of death from any cause (adjusted hazard ratio, 1.03; 95% CI, 0.86 to 1.23; P=0.72). The rates of graft-related complications and reinterventions were higher with endovascular repair, and new complications occurred up to 8 years after randomization, contributing to higher overall costs.

CONCLUSIONS

In this large, randomized trial, endovascular repair of abdominal aortic aneurysm was associated with a significantly lower operative mortality than open surgical repair. However, no differences were seen in total mortality or aneurysm-related mortality in the long term. Endovascular repair was associated with increased rates of graft-related complications and reinterventions and was more costly. (Current Controlled Trials number, ISRCTN55703451.)

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Abdominal aortic aneurysm is a common condition of increasing prevalence, particularly among older men. As the size of the aneurysm increases, so does the risk of rupture. Therefore, prophylactic repair with insertion of a prosthetic graft is offered. Since 1951, open surgical repair has been practiced.[1] Minimally invasive endovascular aneurysm repair was first reported in 1986.[2] The three principal randomized trials comparing endovascular and open repair of abdominal aortic aneurysm have all shown a marked benefit of endovascular repair with respect to 30-day operative mortality,[3-5] and these results have been supported by data from large registries.[6] Therefore, endovascular repair has become a common treatment option.

There is strong evidence that open repair is durable,[7,8] but there has been little careful long-term follow-up of endovascular repair. The European Collaborators on Stent/Graft Techniques for Aortic Aneurysm Repair (EUROSTAR) Registry, which is the largest registry of patients undergoing endovascular repair, provides data for a mean follow-up of only 3 years on patients who received first-generation endografts, which had relatively poor performance as compared with endografts that are currently in use.[9] In the three major randomized trials, the follow-up period was also fairly short (mean, 2 to 3 years).[5,10,11] Good-quality data regarding the longer-term durability, costs, and effects of endovascular repair are limited. In the current trial, called the United Kingdom Endovascular Aneurysm Repair 1 (EVAR 1) trial, we compared the long-term results of endovascular versus open repair of large aneurysms.

Methods

Trial Design

The methods that we use in this trial have been described previously[3,11,12] and are discussed in detail in the Supplementary Appendix (available with the full text of this article at NEJM.org). In summary, EVAR 1 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 37 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 anatomically and clinically suitable candidates for either open surgical repair or endovascular repair were offered enrollment in the EVAR 1 trial (see the Supplementary Appendix for details regarding candidate evaluation). Patients who were not considered to be candidates for open surgical repair but who were considered to be candidates for endovascular repair were offered enrollment in the Endovascular Aneurysm Repair 2 (EVAR 2) trial, reported elsewhere in this issue of the *Journal*.[13] All patients provided written informed consent.

The patients in EVAR 1 were randomly assigned to undergo either open repair or endovascular repair. Patients were encouraged to undergo repair within 1 month after randomization, although such 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.) For patients who died, we obtained death certificates from the Office for National Statistics and classified the deaths using codes from the *International Classification of Diseases, 10th Revision*. An independent end-points committee whose members were unaware of study-group assignments reviewed all deaths. 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 and were based

Table 1. Baseline Characteristics of the Patients.*

Characteristic	Endovascular Repair (N=626)	Open Repair (N=626)
Age — yr	74.1±6.1	74.0±6.1
Male sex — no. (%)	565 (90.3)	570 (91.1)
Diameter of abdominal aortic aneurysm (626 and 625 patients) — cm	6.4±0.9	6.5±1.0
Body-mass index (625 and 620 patients)†	26.5±4.6	26.5±4.3
Diabetes (624 and 620 patients) — no. (%)	61 (9.8)	68 (11.0)
Smoking status (625 and 625 patients) — no. (%)		
Current smoker	134 (21.4)	136 (21.8)
Former smoker	419 (67.0)	444 (71.0)
Never smoked	72 (11.5)	45 (7.2)
History of cardiac disease — no. (%)‡	269 (43.0)	261 (41.8)
Blood pressure — mm Hg		
Systolic (621 and 624 patients)	148±22	147±21
Diastolic (619 and 623 patients)	82±12	82±13
Ankle–brachial pressure index (613 and 599 patients)§	1.01±0.18	1.03±0.18
Forced expiratory volume in 1 second (618 and 622 patients) — liters	2.1±0.7	2.2±0.7
Serum creatinine (625 and 622 patients) — μmol/liter		
Median	102	102
Interquartile range	91–118	90–120
Serum cholesterol (608 and 601 patients) — μmol/liter	5.1±1.2	5.1±1.1
Statin use (619 and 623 patients) — no. (%)	216 (34.9)	224 (36.0)
Aspirin use — no. (%)	338 (54.0)	325 (51.9)

* Data were available for all patients except for characteristics where numbers in the endovascular-repair group and the open-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.

on the intention-to-treat principle, with outcomes assessed from the time of randomization. Logistic regression was used to compare operative and in-hospital mortality among patients who had undergone aneurysm repair, and Cox regression was used to compare total mortality, aneurysm-related mortality, and rates of graft-related complications and reinterventions. Kaplan–Meier estimates were used to present results for 8 years, when just over 200 patients remained in follow-up. Crude regression estimates are presented, as well as estimates adjusted for baseline covariates (see the Supplementary Appendix).

Hazard ratios were calculated for total follow-up and for three predefined periods: randomization to 6 months, more than 6 months to 4 years, and after 4 years. A per-protocol analysis was performed on data from patients who had undergone their randomly assigned treatment. This analysis excluded patients who did not undergo aneurysm repair, those who underwent emergency repair, those in whom the repair was abandoned during surgery (i.e., the aorta was left unrepaired), and those who did not undergo the randomly assigned procedure. All reported P values are two-sided. All analyses were performed with the use of Stata statistical software, version 10. (Additional information on the statistical methods that were used, including detailed methods for assessment of costs, is provided in the Supplementary Appendix.)

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

Outcome	Endovascular Repair (N=626)	Open Repair (N=626)	Hazard Ratio (95% CI)		P Value†
			Unadjusted	Adjusted*	
	no./total no. (rate/100 person-yr)				
Any death					
All patients	260/626 (7.5)	264/626 (7.7)	0.98 (0.82–1.16)	1.03 (0.86–1.23)	0.72
Time since randomization					
0–6 mo	26/626 (8.5)	45/626 (15.0)	0.57 (0.35–0.92)	0.61 (0.37–1.02)	0.06
>6 mo–4 yr	125/599 (6.7)	116/581 (6.3)	1.06 (0.82–1.37)	1.12 (0.86–1.45)	0.39
>4 yr	109/472 (8.4)	103/461 (7.9)	1.04 (0.80–1.37)	1.09 (0.82–1.44)	0.57
Aneurysm-related death					
All patients	36/626 (1.0)	40/626 (1.2)	0.89 (0.57–1.39)	0.92 (0.57–1.49)	0.73
Time since randomization					
0–6 mo	14/626 (4.6)	30/626 (10.0)	0.46 (0.24–0.87)	0.47 (0.23–0.93)	0.03
>6 mo–4 yr	12/599 (0.6)	8/581 (0.4)	1.48 (0.60–3.61)	1.46 (0.56–3.82)	0.44
>4 yr	10/472 (0.8)	2/461 (0.2)	4.96 (1.09–22.65)	4.85 (1.04–22.72)	0.05

* 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 77 patients were excluded from the follow-up analysis because of missing data.

† P values have been adjusted for baseline covariates.

RESULTS

PATIENTS

From September 1, 1999, through August 31, 2004, we recruited 1252 patients to participate in EVAR 1, with patients equally and randomly divided into the two surgical groups. This overall group consisted of the 1082 patients included in a planned midterm analysis that was reported in 2005[11] and an additional 170 patients who were enrolled between January 2004 and August 2004, who were not included in the midterm analysis (Fig. 1 in the Supplementary Appendix). There were no significant differences between the two treatment groups with respect to baseline characteristics (Table 1). The mean (±SD) age was 74.1±6.1 years, and 1135 of the patients (90.7%) were men. The mean aneurysm diameter was 6.4±0.9 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 6.0 years (interquartile range, 3.9 to 7.3), and only 1% of patients were lost to follow-up in terms of mortality. During the study period, 1216 aneurysm-repair procedures were actually performed, including 8 emergency procedures (Fig. 1 in the Supplementary Appendix). For patients undergoing aneurysm repair, the median time from randomization to surgery was 44 days (interquartile range, 29 to 70) in the endovascular-repair group and 35 days (interquartile range, 20 to 57) in the open-repair group.

Of the 12 patients in the endovascular-repair group who did not undergo aneurysm repair, 7 died within 6 months after randomization (3 as a result of rupture), 3 became physically ineligible, 1 declined surgery, and 1 became anatomically unsuitable because of a change in the shape of the aorta. Of the 24 patients in the open-repair group who did not undergo aneurysm repair, 7 died within 6 months after randomization (3 as a result of rupture), 7 became physically ineligible, 8 declined surgery (of whom 3 died), and 2 had an unknown reason (of whom 2 died).

OPERATIVE MORTALITY

At 30 days after surgery, the numbers of patients who had died were 11 of 614 patients (1.8%) in the endovascular-repair group (including 1 patient who underwent emergency repair) and 26 of 602 patients (4.3%) in the open-repair group (including 1 patient who underwent emergency re-

pair) (adjusted odds ratio in the endovascular-repair group, 0.39; 95% confidence interval [CI], 0.18 to 0.87; P=0.02). The total numbers of patients who died during hospitalization for aneurysm repair were 14 of 614 patients (2.3%) in the endovascular-repair group (including 2 patients who underwent emergency repair) and 36 of 602 patients (6.0%) in the open-repair group (including 3 patients who underwent emergency repair) (adjusted odds ratio, 0.39; 95% CI, 0.20 to 0.76; P=0.006).

TOTAL AND ANEURYSM-RELATED MORTALITY

During 6904 person-years of follow-up, 524 deaths occurred, 76 of which were aneurysm-related. Table 2 presents total mortality and aneurysm-related mortality on the basis of Cox regression analysis. The overall total mortality was 7.5 deaths per 100 person-years in the endovascular-repair group and 7.7 deaths per 100 person-years in the open-repair group (adjusted hazard ratio in the endovascular-repair group, 1.03; 95% CI, 0.86 to 1.23; P=0.72). The overall aneurysm-related mortality was 1.0 deaths per 100 person-years in the endovascular-repair group and 1.2 deaths per 100 person-years in the open-repair group (adjusted hazard ratio, 0.92; 95% CI, 0.57 to 1.49; P=0.73).

There was evidence of deviation from the proportional-hazards assumption for aneurysm-related mortality (P=0.004), with an early benefit of endovascular repair during the first 6 months (adjusted hazard ratio, 0.47; 95% CI, 0.23 to 0.93; P=0.03) being counteracted by an increase in aneurysm-related mortality after 4 years (adjusted hazard ratio, 4.85; 95% CI, 1.04 to 22.72; P=0.05). There was no significant evidence of deviation from the proportional-hazards assumption for total mortality (P=0.11). Kaplan–Meier curves for total mortality and aneurysm-related mortality are shown in Figure 1, with rates of death from any cause in the two groups converging at 2 years and rates of aneurysm-related death converging at 6 years.

Causes of death are listed in Table 2 in the Supplementary Appendix, stratified according to the time of death in relation to the time of aneurysm repair. 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 randomly assigned treatment and age, sex, or aneurysm diameter for either total mortality or aneurysm-related mortality (P>0.10 for all comparisons). Per-protocol analysis was performed for the 1165 patients who had undergone their randomly assigned treatment (Fig. 1 in the Supplementary Appendix). A total of 469 deaths occurred (56 of which were aneurysm-related) in the per-protocol group. The overall total mortality was 7.2 deaths per 100 person-years in the endovascular-repair group and 7.1 deaths per 100 person-years in the open-repair group (adjusted hazard ratio in the endovascular-repair group, 1.05; 95% CI, 0.87 to 1.27; P=0.61). The overall aneurysm-related mortality was 0.9 deaths per 100 person-years in the endovascular-repair group and 0.8 deaths per 100 person-years in the open-repair group (adjusted hazard ratio, 1.06; 95% CI, 0.60 to 1.88; P=0.85).

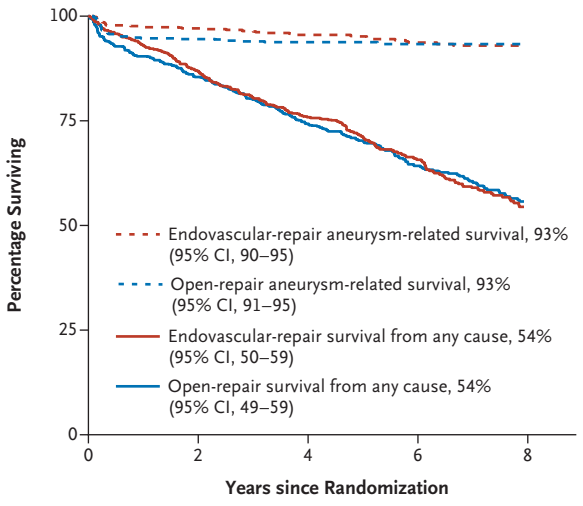

Figure 1. Kaplan–Meier Estimates for Total Survival and Aneurysm-Related Survival during 8 Years of Follow-up.

Among patients randomly assigned to either endovascular repair or open repair of an abdominal aortic aneurysm, an early benefit with respect to aneurysm-related mortality in the endovascular-repair group was lost by the end of the study, at least partially because of fatal endograft ruptures (adjusted hazard ratio with endovascular repair, 0.92; 95% CI, 0.57 to 1.49; P=0.73). By the end of 8 years of follow-up, there was no significant difference between the two groups in the risk of death from any cause (adjusted hazard ratio, 1.03; 95% CI, 0.86 to 1.23; P=0.72).

GRAFT-RELATED COMPLICATIONS AND REINTERVENTIONS

During 5309 person-years of follow-up, 567 graft complications were reported in 360 patients, with

Table 3. First Graft-Related Complication or Reintervention, According to Time since Randomization.

Outcome	Endovascular Repair (N=626)	Open Repair (N=626)	Hazard Ratio (95% CI)		P Value†
			Unadjusted	Adjusted*	
	no./total no. (rate/100 person-yr)				
Complication					
All patients	282/626 (12.6)	78/626 (2.5)	4.38 (3.41–5.63)	4.39 (3.38–5.70)	<0.001
Time since randomization					
0–6 mo	132/626 (48.7)	45/626 (15.6)	3.08 (2.20–4.33)	3.18 (2.23–4.52)	<0.001
>6 mo–4 yr	114/473 (9.0)	18/550 (1.1)	8.37 (5.09–13.76)	7.92 (4.80–13.09)	<0.001
>4 yr	36/280 (5.1)	15/413 (1.4)	3.65 (2.00–6.67)	3.33 (1.76–6.29)	<0.001
Reintervention					
All patients	145/626 (5.1)	55/626 (1.7)	2.78 (2.04–3.80)	2.86 (2.08–3.94)	<0.001
Time since randomization					
0–6 mo	66/626 (22.9)	40/626 (13.8)	1.65 (1.12–2.44)	1.75 (1.16–2.63)	0.007
>6 mo–4 yr	55/537 (3.4)	6/555 (0.3)	9.97 (4.29–23.15)	9.12 (3.90–21.3)	<0.001
>4 yr	24/377 (2.4)	9/428 (0.8)	3.12 (1.47–6.80)	3.24 (1.48–7.11)	0.003

* 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, serum cholesterol level, top neck diameter (aortic diameter at the lowest renal artery), neck length (distance from the lowest renal artery to the start of the aneurysm expansion), and common iliac diameter (log maximum for both legs). A total of 91 patients were excluded from the follow-up analysis because of missing data.

† P values have been adjusted for baseline covariates.

1 complication in 238 patients, 2 complications in 67 patients, 3 complications in 33 patients, 4 complications in 17 patients, 5 complications in 2 patients, and 6 complications in 3 patients (Table 3 in the Supplementary Appendix). Graft rupture occurred in 25 patients after the placement of the endograft, with conversion to open repair attempted in 7 patients, 5 of whom survived. Conversion to open repair occurred for other reasons in an additional 18 patients, 15 of whom survived. Mortality was high after graft rupture, with 17 of 25 patients (68.0%) dying within 30 days and 1 patient dying after 30 days (Table 2 in the Supplementary Appendix). A total of 257 graft-related reinterventions were performed in 200 patients, with 1 reintervention in 161 patients, 2 reinterventions in 26 patients, and 3 to 5 reinterventions in 13 patients.

The overall rates of graft-related complications and reinterventions were higher by a factor of three to four in the endovascular-repair group than in the open-repair group (Table 3 and Fig. 2). There was evidence of deviation from the proportional-hazards assumption for both complications (P=0.01) and reinterventions (P=0.001), with most of the deviation attributable to a high relative increase in graft-related events in the endovascular-repair group from 6 months to 4 years after surgery.

COSTS

Detailed costs are provided in Table 4 in the Supplementary Appendix. The mean cost of the primary aneurysm repair was £13,019 (U.S. $19,698) in the endovascular-repair group and £11,842 ($17,917) in the open-repair group (mean difference, £1,177 [$1,781]; 95% CI, −374 to 2,728 [−566 to 4,127]). The mean cost of aneurysm-related readmissions was £2,283 ($3,454) in the endovascular-repair group and £442 ($669) in the open-repair group (mean difference, £1,841 [$2,785]; 95% CI, 913 to 2,770 [1,381 to 4,191]). During 8 years of follow-up, the total average cost of aneurysm-related procedures in the endovascular-repair group was £3,019 ($4,568) more than in the open-repair group (mean costs, £15,303 [$23,153] and £12,284 [$18,586], respectively). The primary admission and the later admissions for graft-related reinterventions contributed almost equally to the cost difference.

DISCUSSION

The results over a median follow-up period of 6 years confirm our previously published midterm findings that operative mortality associated with endovascular repair of abdominal aortic aneurysm was only a third of that associated with the open-repair procedure and that aneurysm-related mortality was reduced during the early years after endovascular repair.[11] However, the early benefit was completely lost in the longer term, with substantially higher aneurysm-related mortality after 4 years in the endovascular-repair group than in the open-repair group. We found no significant difference in total mortality between the two study groups. The rate of graft-related complications after endovascular repair remained substantial after 4 years, as did the need for reinterventions. Secondary rupture after aneurysm repair was reported only after endovascular repair and appeared to explain the long-term increase in aneurysm-related mortality. In contrast, open repair was very durable but was associated with higher operative mortality. These findings have implications for the selection of patients for endovascular repair, the choices for patients, surveillance after repair, and cost-effectiveness. The results also confirm that careful long-term follow-up of surgical innovations is essential, as highlighted in recent research recommendations.[14]

After the postoperative period, just under half of all deaths were attributed to cardiovascular disease (including aneurysm), a slightly lower proportion than that reported for the 4-year results,[11] which may reflect improvements in medical therapy.[15] Just over one quarter of deaths were attributed to cancer. A total of 20 patients in the endovascular-repair group and 6 patients in the open-repair group died from aneurysm-related causes after the postoperative period; 2 of the late deaths in the open-repair group were from graft ruptures in patients who had been assigned to open repair but had undergone endovascular repair. In total, 25 secondary aneurysm ruptures were reported, and of those 18 (72.0%) were fatal. Therefore, the loss of the aneurysm-related survival benefit in the endovascular-repair group would appear to be attributable principally to endograft rupture. Many of the patients in whom such an event occurred had graft-related complications that were detected before rupture.

Very few of the patients in our study either did not undergo the assigned treatment or were lost to follow-up, and there were few missing data. Per-protocol analysis yielded results that were very similar to those of the intention-to-treat analysis. However, this study had some limitations that could affect the interpretation of our findings. First, although the trial used principally second- and third-generation endografts, subsequent iterations of the grafts would now be the more common choices of device. The long-term durability of these later iterations of endografts has not

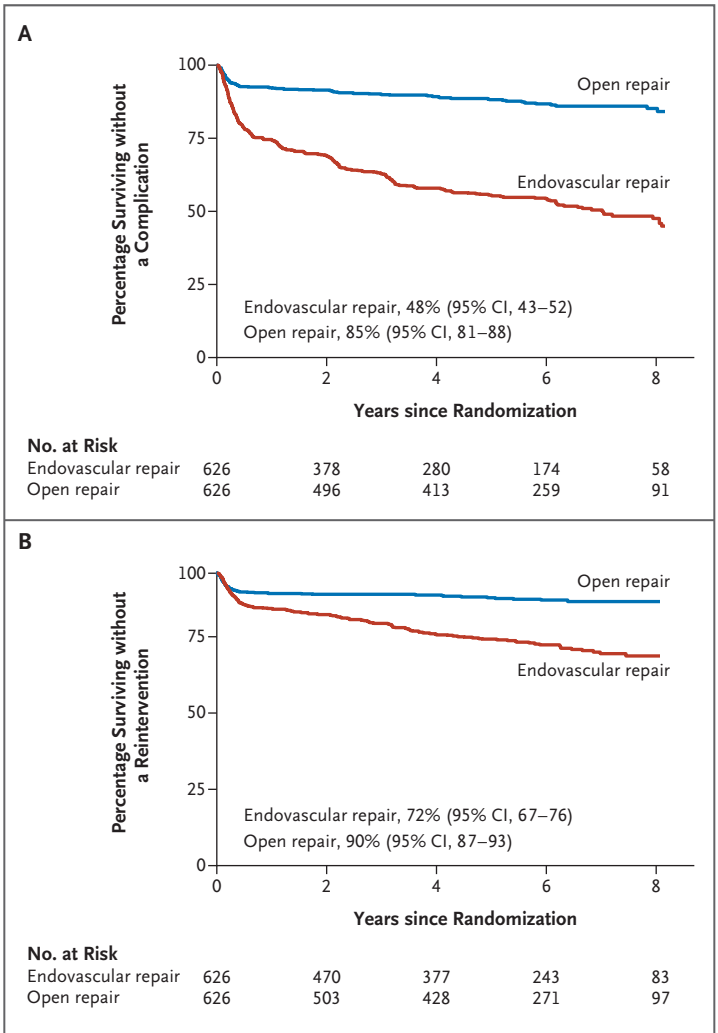

Figure 2. Kaplan–Meier Estimates for the Time to the First Graft-Related Complication or Reintervention during 8 Years of Follow-up.

The rates of graft-related complications (Panel A) and reinterventions (Panel B) were higher among patients in the endovascular-repair group than among those in the open-repair group. New complications occurred throughout the 8-year follow-up period, contributing to the higher overall costs of the endovascular procedure.

been evaluated, but it is hoped that they would be associated with lower complication rates. Second, the trial started 3 years before the standardized reporting of graft-related complications.[16] Thus, the reporting of complications reflected the assessments made by radiologists in the participating centers, and these reports were not evaluated in a core laboratory. Third, we did not record outpatient procedures, which would have included minor procedures, such as diagnostic angiography, that are often performed after endovascular repair to obtain more detailed information on any potential complications. A corresponding underestimation of reintervention rates and costs may also have occurred for the open-repair group, since readmission data were not collected for abdominal hernias or other complications related to open repair.

New graft-related complications and reinterventions continued to be reported for as long as 8 years after endovascular procedures were performed. Future work should determine whether specific complications, or combinations of complications, of endovascular repair may signal an increased risk of endograft rupture or death. The continuing occurrence of graft-related complications and reinterventions underscores the need for continued surveillance, and these clinical episodes contribute to the increase in the lifetime cost of aneurysm-related events after endovascular repair as compared with open repair. A streamlined post-repair surveillance algorithm designed to minimize the exposure of patients to radiation without limiting the future detection and management of potentially dangerous complications of graft failure is likely to enhance cost-effectiveness. More detailed modeling is under way to assess whether endovascular repair is cost-effective for all patients or only for selected subgroups. Currently, patients strongly prefer endovascular repair to open repair.[17,18] However, these preferences were declared on the basis of early and midterm evidence alone. Although there is still an early mortality reduction with endovascular repair, which is less invasive than open repair, it is difficult to predict what effect these late results will have on patients' preferences or on the implications for cost-effectiveness, factors that will influence future clinical-management decisions and policy recommendations.

In conclusion, among patients who were considered to be suitable candidates for either endovascular repair or open repair of abdominal aortic aneurysm, the endovascular procedure was associated with a significantly lower operative mortality. However, no significant differences were seen in total mortality or aneurysm-related mortality in the long term. Endovascular repair was associated with increased rates of complications and reinterventions and was more costly.

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Dr. Greenhalgh reports serving as a salaried medical director of BIBA Medical and having an equity interest in the company, serving as a director of and having an equity interest in Spaceform Holdings, and serving as an expert witness on behalf of patients with vascular disease; Mr. Epstein, receiving fellowship support from Medtronic; and Dr. Sculpher, receiving consulting fees from Medtronic. No other potential conflict of interest relevant to this article was reported. Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

The views expressed in this article are those of the authors and do not necessarily represent those of the United Kingdom National Health Service.

APPENDIX

The United Kingdom EVAR trial investigators include the following: *Grant Applicants:* R.M. Greenhalgh (principal investigator), D.J. Allison, P.R.F. Bell, M.J. Buxton, P.L. Harris, B.R. Hopkinson, J.T. Powell, I.T. Russell, S.G. Thompson. *Data and Trial Management*: L.C. Brown (trial manager). *Statistical and Costs Analyses*: L.C. Brown, D. Epstein, M.J. Sculpher, S.G. Thompson. *Trial Management Committee*: R.M. Greenhalgh (chair), J.D. Beard, M.J. Buxton, P.L. Harris, J.T. Powell, J.D.G. Rose, I.T. Russell, M.J. Sculpher, S.G. Thompson. *Trial Steering Committee*: R.J. Lilford (chair), P.R.F. Bell, R.M. Greenhalgh, S.C. Whitaker. *Data Monitoring and Ethics Committee*: P.A. Poole-Wilson (chair), C.V. Ruckley, W.B. Campbell, M.R.E. Dean, M.S.T. Ruttley, E.C. Coles. *End-Points Committee*: J.T. Powell (chair), A. Halliday, S. Gibbs. *Data Audit*: H.D. Dorricott.

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CLINICAL TRIAL REGISTRATION

The *Journal* requires investigators to register their clinical trials in a public trials registry. The members of the International Committee of Medical Journal Editors (ICMJE) will consider most clinical trials for publication only if they have been registered (see N Engl J Med 2004;351:1250-1). Current information on requirements and appropriate registries is available at www.icmje.org/faq.pdf.