Outcomes Following Endovascular vs Open Repair of Abdominal Aortic Aneurysm

A Randomized Trial

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Context Limited data are available to assess whether endovascular repair of abdominal aortic aneurysm (AAA) improves short-term outcomes compared with traditional open repair.

Objective To compare postoperative outcomes up to 2 years after endovascular or open repair of AAA in a planned interim report of a 9-year trial.

Design, Setting, and Patients A randomized, multicenter clinical trial of 881 veterans (aged ≥49 years) from 42 Veterans Affairs Medical Centers with eligible AAA who were candidates for both elective endovascular repair and open repair of AAA. The trial is ongoing and this report describes the period between October 15, 2002, and October 15, 2008.

Intervention Elective endovascular (n=444) or open (n=437) repair of AAA.

Main Outcome Measures Procedure failure, secondary therapeutic procedures, length of stay, quality of life, erectile dysfunction, major morbidity, and mortality.

Results Mean follow-up was 1.8 years. Perioperative mortality (30 days or inpatient) was lower for endovascular repair (0.5% vs 3.0%; $P=.004$), but there was no significant difference in mortality at 2 years (7.0% vs 9.8%, $P=.13$). Patients in the endovascular repair group had reduced median procedure time (2.9 vs 3.7 hours), blood loss (200 vs 1000 mL), transfusion requirement (0 vs 1.0 units), duration of mechanical ventilation (3.6 vs 5.0 hours), hospital stay (3 vs 7 days), and intensive care unit stay (1 vs 4 days), but required substantial exposure to fluoroscopy and contrast. There were no differences between the 2 groups in major morbidity, procedure failure, secondary therapeutic procedures, aneurysm-related hospitalizations, health-related quality of life, or erectile function.

Conclusions In this report of short-term outcomes after elective AAA repair, perioperative mortality was low for both procedures and lower for endovascular than open repair. The early advantage of endovascular repair was not offset by increased morbidity or mortality in the first 2 years after repair. Longer-term outcome data are needed to fully assess the relative merits of the 2 procedures.

Trial Registration clinicaltrials.gov Identifier: NCT00094575

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Each year in the United States, 45 000 patients with unruptured abdominal aortic aneurysm (AAA) undergo elective repair, resulting in more than 1400 perioperative deaths.[1] Endovascular repair was developed to provide a less invasive method than the standard open procedure and has been reported to reduce perioperative mortality, hospital stay, and intensive care unit (ICU) stay. However, more frequent reinterventions have also been reported and the early survival advantage was lost within 2 years in previous randomized trials conducted in Europe,[2-4] leaving the preferred approach for AAA repair in doubt. Furthermore, the relative effects of the 2 procedures on quality of life and erectile function remain unclear.

Devices and techniques continue to improve and operative mortalities and morbidities were relatively high in the European trials, raising the question of how relevant their results are to current US practice. We report short-term perioperative outcomes after elective endovascular and open repair of AAA from a US multicenter randomized trial.

METHODS

Study Oversight

The study was approved by a central human rights committee and the institutional review boards at each participating center. An independent data monitoring committee reviewed the data at regular intervals.

Patients

Eligible patients had AAA for which repair was planned and had (1) a maxi-

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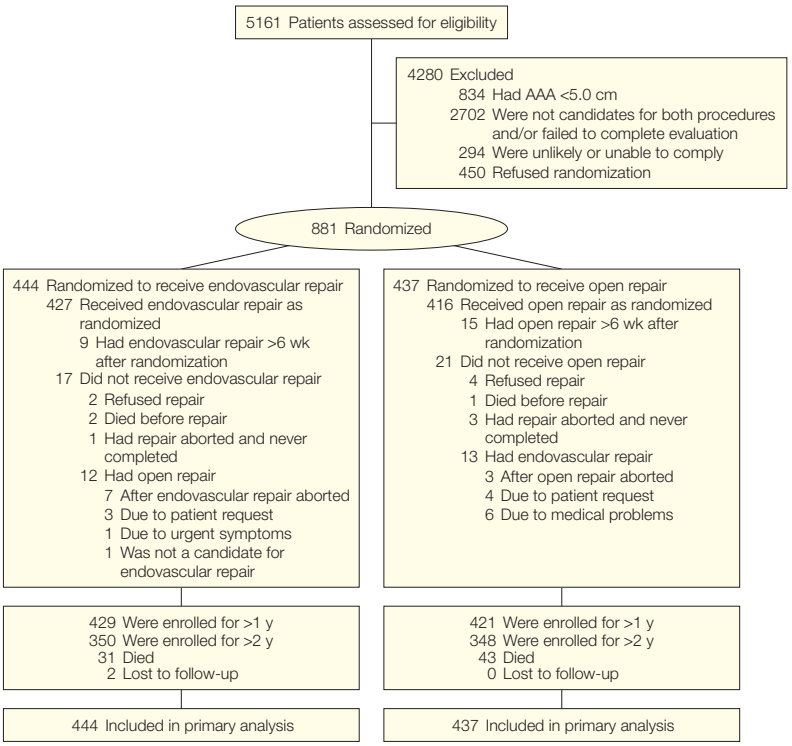
Figure 1. Flow Diagram of Study Patients



AAA indicates abdominal aortic aneurysm.

mum external diameter of at least 5.0 cm, (2) an associated iliac aneurysm with a maximum diameter of at least 3.0 cm, or (3) a maximum diameter of at least 4.5 cm plus either rapid enlargement (at least 0.7 cm in 6 months or 1.0 cm in 12 months) or saccular morphology. To be randomized, a patient had to have completed all preoperative evaluation, be considered a candidate for both procedures by the participating vascular surgeon, and meet the manufacturer's indications for the endovascular system that would be used if so assigned. Patients were excluded if they had previous abdominal aortic surgery, needed urgent repair, or were unable or unwilling to give informed consent or follow the protocol.

Procedures

Entry evaluation included demographics (race was recorded by study nurses using predefined categories of white, not of Hispanic origin; black, not of Hispanic origin; Hispanic; Asian/Oriental or Pacific Islander; American Indian or Alaskan Native; or other); comorbidities; medications; surgical risk using criteria developed by the RAND Corporation (eAppendix; available online at http://www.jama.com)[5]; measurement of height, weight, brachial, and ankle blood pressure; measurement of serum creatinine; and various parameters from preoperative aortic imaging.

Patients provided informed consent for preoperative evaluation and randomization. Randomization assigned equal probability to open or endovascular repair and was stratified by medical center using a permuted block design. Allocation was made by telephone to the coordinating center after baseline information was received and eligibility verified. Although patient assignment was of necessity unblinded, outcome data by treatment group were available during enrollment only to the biostatistician and data monitoring committee.

Open repair involves sutured anastomoses of an anatomically placed vascular graft through an abdominal or retroperitoneal incision and was performed as usual at each participating medical center. Endovascular repair involves the transluminal introduction of an expandable graft system through the femoral or iliac arteries into the aneurysmal region of the aorta and iliac arteries to exclude the aneurysm from arterial pressure. Only endovascular systems approved by the US Food and Drug Administration could be used in the study. To permit subgroup comparisons with randomized controls, the endovascular system intended for a particular patient if so assigned was reported to the coordinating center before randomization.

The protocol specified that repair should occur within 6 weeks of randomization and a study-approved vascular surgeon or interventional radiologist should perform all aneurysm repairs. Criteria for study approval were vascular surgery fellowship, certification or equivalent, or equivalent training for interventional radiologists. Individuals performing study endovascular procedures were required to have completed at least 12 procedures with adequate supervision.

Follow-up visits were scheduled 1 month after aneurysm repair, 6 and 12 months after enrollment, and then yearly. All follow-up visits after endovascular repair included computed tomography and plain radiography of the abdomen, whereas after open repair, only computed tomography at 1 year was specified, a difference intended to reflect usual clinical practice. Patients were called monthly during the first 14 months after repair and then annually midway between study visits to identify outcomes and were asked to log all health care visits. Additional follow-up information was obtained by the coordinating center using national data sets.

Outcome Measures

The primary outcome is long-term (5-9 years) all-cause mortality (October 15, 2002-October 15, 2011). Secondary outcomes included (1) procedure failure, defined as failure to complete the initial repair or any secondary thera-

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peutic procedures resulting directly or indirectly from the initial procedure and requiring a separate trip to the procedure suite (each trip to the procedure suite counted as 1 secondary procedure, and these included any unplanned surgical procedures within 30 days of the initial procedure and any additional aorto-iliac procedures at any time); (2) short-term major morbidity, defined as myocardial infarction, stroke, amputation, or renal failure requiring dialysis within 1 year after the initial repair; (3) days in hospital and ICUs associated with the initial repair; (4) other procedure-related morbidities, such as incisional hernia, or new or worsened claudication; (5) health-related quality of life; and (6) erectile dysfunction. These secondary outcomes pertain primarily to the short-term perioperative period and are the main focus of this report.

Outcomes were adjudicated by an outcomes committee blinded (to the extent possible) to the randomized group. Aneurysm-related mortality was not a prespecified outcome because of the potential for ascertainment bias[4] but is presented for comparison with other trials. All deaths within 30 days after repair or during the hospitalization for repair were considered aneurysm-related, as were all late deaths adjudicated as resulting directly or indirectly from the AAA or treatment of the AAA.

Health-related quality of life was assessed by using 2 brief questionnaires, the 36-item Short Form Health Survey (SF-36) and EQ-5D (EuroQol, Rotterdam, the Netherlands), completed at baseline and follow-up visits. The SF-36 evaluates 8 health dimensions that have been aggregated into 2 summary measures, a mental component summary and a physical component summary.[6] We also computed the physical component transformed with deaths included.[7] The EQ-5D[8] consists of 5 questions used to generate an index score with US population-based preference weights, and a 20-cm visual analog scale. Erectile function was assessed by using the previously validated 5-item International Index of Erectile Func-

Table 1. Patient Characteristics at the Time of Randomization[a]

Characteristics	Endovascular Repair (n = 444)	Open Repair (n = 437)
Age, mean (SD), y	69.6 (7.8)	70.5 (7.8)
Male sex, No. (%)	441 (99.3)	435 (99.5)
White race, No. (%)	387 (87.2)	379 (86.7)
Weight, mean (SD), kg	89.9 (16.8)	89.7 (17.8)
BMI, mean (SD)	28.6 (5.2)	28.7 (5.6)
BMI ≥35, No. (%)	47 (10.6)	44 (10.1)
Smoking history, No. (%)		
Ever	428 (96.4)	413 (94.5)
Current	170 (38.3)	193 (44.2)
Blood pressure, mean (SD), mm Hg		
Systolic	133.5 (18.6)	133.0 (18.8)
Diastolic	75.8 (10.9)	74.3 (10.6)
Current history, No. (%)		
Coronary artery disease	174 (39.2)	185 (42.3)
Myocardial infarction	105 (23.6)	110 (25.2)
Coronary revascularization	159 (35.8)	153 (35.0)
Cerebrovascular disease	67 (15.1)	70 (16.0)
Hypertension	347 (78.2)	330 (75.5)
Claudication	66 (14.9)	81 (18.5)
Cancer (other than skin)	83 (18.7)	70 (16.0)
Diabetes	100 (22.5)	100 (22.9)
Chronic obstructive pulmonary disease	126 (28.4)	133 (30.4)
Medications, No. (%)		
β-Blocker	282 (63.5)	282 (64.5)
Aspirin[b]	244 (55.0)	277 (63.4)
ACE inhibitor	192 (43.2)	180 (41.2)
Anticoagulants	44 (9.9)	34 (7.8)
Ankle-brachial index on at least 1 side, No. (%)		
≤0.9	159 (35.8)	155 (35.5)
≤0.4	48 (10.8)	45 (10.3)
Maximum activity level, No. (%)		
Sedentary or mild	182 (41.0)	185 (42.4)
Moderate or vigorous	262 (59.0)	252 (57.6)
Serum creatinine, mean (SD), mg/dL	1.2 (0.5)	1.1 (0.4)
GFR <60 mL/min per 1.73 m^2, No. (%)	140 (31.5)	136 (31.1)
Surgical risk (RAND score), No. (%)		
Low	240 (54.1)	227 (51.9)
Intermediate	169 (38.1)	176 (40.3)
High	31 (7.0)	29 (6.6)
Family history of AAA, No. (%)	70 (15.8)	51 (11.7)
AAA diameter, No. (%), cm		
Mean (SD)	5.7 (0.8)	5.7 (1.0)
<5.0	23 (5.2)	18 (4.1)
<5.5	192 (43.2)	190 (43.5)
5.5-5.9	133 (30.0)	123 (28.1)
6.0-6.9	86 (19.4)	83 (19.0)
≥7.0	33 (7.4)	41 (9.4)
Intended device, No. (%)		
Cook Zenith	166 (37.4)	175 (40.0)
Gore Excluder	177 (39.6)	150 (34.3)
Medtronic AneuRx	88 (19.8)	98 (22.4)
Other	13 (2.9)	14 (3.2)

Abbreviations: AAA, abdominal aortic aneurysm; ACE, angiotensin-converting enzyme; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); GFR, glomerular filtration rate.
SI conversion factor: To convert serum creatinine to μmol/L, multiply by 88.4.
[a] Ever smoking history is smoking more than 100 cigarettes over lifetime. The GFR was estimated using the 4-variable Modification of Diet in Renal Disease Study equation.[14] For surgical risk (RAND score), see online eAppendix at http://www.jama.com.[5] Intended device indicates if assigned to endovascular repair.
[b] $P = .01$.

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tion.[9] Questionnaires were completed by the patient and reviewed for completeness by study personnel.

Statistical Analysis

We originally assumed a mortality rate of 5.6% per year following open repair[10-12] and 5% loss to follow-up, and planned a 4.5-year enrollment period and a minimum follow-up of 3.5 years. Three years after enrollment began in October 2002, the study was reconfigured by the investigators with the approval of the data and safety monitoring board without knowledge of results by randomized group to reflect lower than planned enrollment rate, higher mortality rate (6.6% per year), and lower losses to follow-up (1%). By increasing enrollment to 5 years and follow-up to 4 years, 872 patients would provide 80% power to detect a 25% relative reduction in mortality with 2-sided $\alpha = .05$. To reach this number of patients, enrollment was continued an additional 6 months at 3 centers.

The analysis was by intention-to-treat. Estimates of cumulative event rates were calculated by the Kaplan-Meier method, and hazard ratios (HRs) with confidence intervals (CIs) were estimated by Cox proportional hazards regression models.[13] The effect of treatment in prespecified subgroups was assessed by treatment-subgroup interactions in the Cox proportional hazards regression model. Variables were compared by using χ^2 and t tests. P values were 2-sided and $P < .05$ was considered statistically significant. Statistical analyses were performed by using SAS version 9.1 (SAS Institute Inc, Cary, North Carolina).

The protocol originally specified publication of 1-year results when available on all patients to ensure that short-term postoperative outcomes would be disseminated while still maximally relevant. Because of the important changes in the effect size for survival noted during the second year of follow-up in previously published trials,[2-4] this plan was amended by the investigators with the approval of the data and safety monitoring board without knowledge of the results in February 2007 to include all follow-up data to 2 years after randomization as of the same date of October 15, 2008.

Table 2. Details of Aneurysm Repair by Randomly Assigned Group[a]

	Median (Interquartile Range)	
	Endovascular Repair (n = 439)	Open Repair (n = 429)
Patients with aorta as distal attachment site (vs iliac/femoral), No. (%)	23 (5.2)	190 (44.3)
Time from randomization to repair, d	18.0 (10.0-28.0)	17.0 (9.0-26.0)
Duration of procedure, h	2.9 (2.3-3.7)	3.7 (2.9-4.7)
Duration of mechanical ventilation, h	3.6 (3.0-4.5)	5.0 (4.0-9.1)
Duration of fluoroscopy, min	23.0 (17.0-31.0)	0
Volume of contrast used, mL	132.5 (96.5-176.0)	0
Estimated blood loss, mL	200 (150-400)	1000 (650-2000)
Banked red cell transfusion within 24 h, unit	0	1.0 (0-3.0)
Duration of hospital stay for initial repair, d	3.0 (2.0-5.0)	7.0 (6.0-10.0)
Time in intensive care unit, d	1.0 (1.0-2.0)	4.0 (3.0-6.0)

[a] Patients who had no repair (refused, aborted and never completed, or died before repair as shown in Figure 1) are not included. $P < .001$ for all comparisons of means, except time from randomization to repair ($P = .36$).

Table 3. All Outcome Measures

	No. (%) of Patients		
Outcomes	Endovascular Repair (n = 444)	Open Repair (n = 437)	*P* Value
All-cause mortality	31 (7.0)	43 (9.8)	.13
Before AAA repair	2 (0.5)	1 (0.2)	>.99
Within 30 d after repair	1 (0.2)	10 (2.3)	.006
Within 30 d after repair or during hospitalization	2 (0.5)	13 (3.0)	.004
AAA diameter <5.5 cm	1 (0.5)	5 (2.6)	.10
AAA diameter ≥5.5 cm	1 (0.4)	8 (3.2)	.02
After 30 d or hospitalization	27 (6.1)	29 (6.6)	.74
Cause of death	(n = 31)	(n = 43)	
AAA-related[a]	6 (1.4)	13 (3.0)	.10
Cardiovascular	9 (2.0)	4 (0.9)	.26
Cancer	10 (2.3)	15 (3.4)	>.99
Other[b]	5 (1.1)	7 (1.6)	.54
Unknown	1 (0.2)	4 (0.9)	.21
Patients with procedure failure	58 (13.1)	51 (11.7)	.53
Patients with no repair attempted	4 (0.9)	5 (1.1)	.75
Patients with aborted initial procedure	8 (1.8)	6 (1.4)	.61
Patients having secondary therapeutic procedures	46 (10.4)	40 (9.2)	.73
All secondary therapeutic procedures, No. of events	61	55	
Patients with any 1-year major morbidity	18 (4.1)	20 (4.6)	.70
Myocardial infarction	6 (1.4)	12 (2.7)	.14
Stroke	7 (1.6)	4 (0.9)	.38
Amputation	1 (0.2)	3 (0.7)	.37
Renal failure requiring dialysis	5 (1.1)	3 (0.7)	.73
Patients with new or worsened claudication	37 (8.3)	20 (4.6)	.02
All postrepair aneurysm-related hospitalizations, No. of events	108	86	

Abbreviation: AAA, abdominal aortic aneurysm.
[a] Includes all deaths within 30 days after repair or during hospitalization.
[b] Includes cerebrovascular disease, injury, pneumonia, other infections, and unexplained sudden deaths not considered AAA-related.

RESULTS

We randomized 881 patients (aged ≥49 years) at 42 medical centers (FIGURE 1).

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The 2 groups were similar at baseline (TABLE 1), with no significant differences except for a greater proportion using aspirin in the open repair group. Of the 41 patients randomized with AAA of less than 5.0 cm, reasons for eligibility were iliac aneurysm in 34 patients, rapid enlargement in 4 patients, and saccular morphology in 3 patients. Fifteen patients (8 endovascular repair and 7 open repair) had abdominal or back pain noted before repair, but no aneurysm ruptures were identified at any time during the study period. More than 95% of randomized patients had the assigned repair (n=843) and in another 2% (n=14), the assigned repair was attempted but aborted (Figure 1).

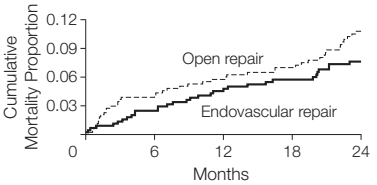
All 109 lead proceduralists for aneurysm repair were vascular surgeons. An endovascular system other than the one prespecified as intended was used in 43 patients in the endovascular group. Endovascular repair resulted in significantly reduced procedure time, duration of mechanical ventilation, hospital and ICU stays, blood loss, and transfusion requirement, but required substantial exposure to fluoroscopy and contrast (TABLE 2).

Mean follow-up was 1.8 years, and 80% of patients (n=710) had either completed 2 years of follow-up or died before 2 years (follow-up was truncated at 2 years for both study groups). Perioperative mortality was significantly higher for open repair at 30 days (0.2% vs 2.3%; $P=.006$), and at 30 days or during hospitalization (0.5% vs 3.0%; $P=.004$) (TABLE 3), a difference that did not appear to vary with AAA diameter (P for interaction=.25). Vital status after 2 years or by October 15, 2008, was confirmed for all but 2 patients, and national data sets contained no death reports on these 2 patients. There was no significant difference in all-cause mortality at 2 years (7.0% vs 9.8%; HR, 0.7; 95% CI, 0.4-1.1; $P=.13$) (FIGURE 2). Mortality after the perioperative period was similar in the 2 groups (6.1% vs 6.6%) (Table 3), but 4 of the late deaths in the endovascular group were aneurysm-related compared with none in the open repair group. No significant differences in mortality were observed for any of the prespecified subgroups shown in FIGURE 3, including patients with coronary artery disease ($P=.06$). No significant interactions were found between treatment effect and any subgroup characteristic.

No differences were observed between the 2 groups in procedure failures, secondary therapeutic procedures, aneurysm-related hospitalizations, or 1-year major morbidity (Table 3). The 61 secondary therapeutic procedures in the endovascular repair group included 42 endovascular procedures, 3 explantations of the graft with conversion to open repair, 9 other arterial procedures with an open component, 5 groin wound procedures, and 2 amputations (both legs of 1 patient). The 55 secondary therapeutic procedures in the open-repair group included 24 incisional hernia repairs, 7 aortic graft procedures, 4 procedures for wound complications, 4 amputations (1 toe, 1 leg, and below and above knee on same leg), 4 laparotomies for bowel obstruction, 2 laparotomies for hematoma, 2 procedures to relieve claudication, and 8 miscellaneous minor procedures.

Incisional hernia was reported in 30 patients who had open repair, resulting in secondary therapeutic procedures in 21 patients (4.9%), all of whom had undergone an anterior surgical approach in the original open repair. In the endovascular repair group, there were 134 endoleaks (blood flow between the graft and the aneurysm wall) in 110 patients (25%), resulting in 21 secondary therapeutic procedures in 18 patients (4.1%).

Figure 2. Kaplan-Meier Curve of Cumulative Probabilities of Death From Time of Randomization

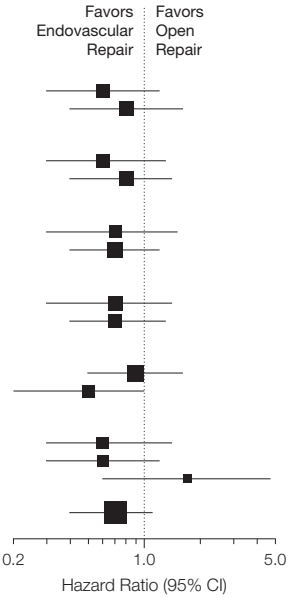


No. at risk					
Open repair	437	420	396	363	310
Endovascular repair	444	433	411	371	326

There was no significant difference in cumulative mortality for open vs endovascular repair (hazard ratio, 0.7; 95% confidence interval, 0.4-1.1; log-rank $P=.13$).

Figure 3. Hazard Ratios for Death According to Baseline Characteristics

Subgroup	No. Patients	No. Deaths	Hazard Ratio (95% CI)
Randomization period			
Before April 15, 2005	413	40	0.6 (0.3-1.2)
After April 15, 2005	468	34	0.8 (0.4-1.6)
Age, y			
<70	406	26	0.6 (0.3-1.3)
≥70	475	48	0.8 (0.4-1.4)
AAA diameter, cm			
<5.5	382	27	0.7 (0.3-1.5)
≥5.5	499	47	0.7 (0.4-1.2)
Surgical risk (RAND score)			
Low	467	29	0.7 (0.3-1.4)
Intermediate or high	405	42	0.7 (0.4-1.3)
Coronary artery disease			
No	522	43	0.9 (0.5-1.6)
Yes	359	31	0.5 (0.2-1.0)
Intended endovascular system			
Cook Zenith	341	26	0.6 (0.3-1.4)
Gore Excluder	327	28	0.6 (0.3-1.2)
Medtronic AneuRx	186	15	1.7 (0.6-4.7)
Overall	881	74	0.7 (0.4-1.1)



AAA indicates abdominal aortic aneurysm; CI, confidence interval. Size of the data markers is relative to the number of deaths in that subgroup. All $P>.10$ for interaction with treatment effect. For surgical risk (RAND score), see online eAppendix at http://www.jama.com.[5]

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Table 4. Quality of Life and Erectile Dysfunction[a]

	Mean (SD)					
	Baseline		1 Year Minus Baseline		2 Years Minus Baseline	
Measures	Endovascular Repair	Open Repair	Endovascular Repair	Open Repair	Endovascular Repair	Open Repair
SF-36						
MCS	50.6 (10.9)	51.7 (10.4)	–0.77 (10.2)	–0 (10.0)	–0.01 (10.0)	–0.93 (9.8)
PCS	40.5 (10.4)	40.1 (10.5)	–1.2 (9.8)	–1.2 (10.1)	–2.2 (10.2)	–2.0 (10.8)
PCTD	62.5 (22.8)	61.6 (22.8)	–3.0 (22.0)	–2.8 (22.3)	–5.0 (23.3)	–4.29 (23.4)
EQ-5D						
Index score	0.79 (0.16)	0.79 (0.16)	–0.02 (0.16)	–0 (0.17)	–0.01 (0.19)	–0.02 (0.16)
Visual analog scale	71.5 (19.1)	70.3 (18.6)	–1.3 (18.9)	0.88 (17.8)	–2.2 (22.3)	–1.4 (20.3)
IIEF-5	11.4 (8.7)	10.3 (8.8)	–2.5 (8.3)	–2.3 (7.8)	–3.0 (8.5)	–2.9 (8.5)

Abbreviations: EQ-5D, EuroQol; IIEF-5, 5-item International Index of Erectile Function; MCS, mental component summary; PCS, physical component summary; PCTD, physical component transformed with deaths included; SF-36, 36-item Short Form Health Survey.

[a] For endovascular vs open repair, all $P > .05$. The MCS, PCS, and PCTD scores are 0 to 100, with 100 representing better health. The EQ-5D (EuroQol, Rotterdam, the Netherlands) index scores range from 0 (death) to 1.0 (perfect health) and visual analog scale scores from 0 ("worst imaginable health state") to 100 ("best imaginable health state"). The IIEF-5 scores range from 5 to 25, with 25 representing better function.

As shown in TABLE 4, there were no significant differences between the 2 groups in health-related quality of life or erectile function over the 2 years of follow-up.

COMMENT

In this interim report of 2-year outcomes after elective AAA repair, endovascular repair resulted in lower perioperative mortality than open repair without evidence of excess late mortality. Hospital and ICU stays were shorter with endovascular repair and need for transfusion was decreased. No significant differences were observed in major morbidities, secondary procedures, or aneurysm-related hospitalizations.

Two European trials, the United Kingdom Endovascular Aneurysm Repair Trial 1 (EVAR-1)[15] and the Dutch Randomized Endovascular Aneurysm Management (DREAM) trial,[16] previously reported lower operative mortality with endovascular vs open repairs. Perioperative mortality in our study was lower than in the European trials for both treatments. Mortality within 30 days or during hospitalization for endovascular repair was 2.1% in the EVAR-1 trial, 1.2% in the DREAM trial, and 0.5% in our study, and for open repair, mortality was 6.2% in the EVAR-1 trial, 4.6% in the DREAM trial, and 3.0% in our study.[15,16] We did not observe the increased mid-term mortality after endovascular repair that resulted in the loss of its early survival advantage in those trials,[2,3] but all 4 late aneurysm-related deaths in our study occurred in the endovascular group.

The lower perioperative mortality in our study compared with the previous trials could result from several possible factors. First, our procedures were performed more recently, from 2002-2007 compared with 1999-2003 in the EVAR-1 and DREAM trials. Of the 15 deaths within 30 days after repair or during hospitalization in our study, 10 occurred in the first 412 patients, enrolled before April 15, 2005, including the 2 deaths in the endovascular group.

Second, our results could have been improved by enrollment of patients with small AAA. Forty-three percent of our patients (n=382) had aneurysms smaller than 5.5 cm in diameter and therefore would not have been eligible for enrollment in the EVAR-1 trial. However, perioperative mortality rates (Table 3) and treatment effects (Figure 3) were similar between patients with AAA of less than 5.5 cm and those with larger AAA, suggesting that AAA diameter was not an important factor.

Third, there could be differences in surgical technique and postoperative care between our trial and the European trials. Procedures in our trial were performed by experienced university-affiliated vascular surgeons. Although the participation of more than 100 surgeons in our trial supports generalizability within this group, and procedures in the European trials were also performed by experienced vascular surgeons, differences between trials in surgical technique and postoperative care cannot be completely excluded. Inpatient mortality following nonruptured open AAA repair in the United States during our enrollment period was 4.5%,[1] roughly half that in the United Kingdom during the EVAR-1 enrollment period,[17,18] a difference that reflects the differences in operative mortalities between trials. Furthermore, previous studies have reported low perioperative mortality for AAA repair in the Veterans Affairs health system compared with other US health care organizations.[19,20]

Fourth, there were differences in the endovascular systems used. The EVAR-1 trial used the Medtronic Talent (which was not approved for use in the United States until after our enrollment ended) in a third of the patients and used the Gore Excluder and Medtronic AneuRx much less frequently than in our study. We did not find significant interactions between device selection and treatment effect in our study, although there was a nonsignificantly less favorable outcome after endovascular repair with AneuRx compared with other endovascular systems (Figure 3), and the 2 perioperative deaths and 2 of the 4 late aneurysm-related deaths in our endo-

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vascular group were in the AneuRx subgroup, suggesting that greater use of this device probably did not improve survival in our study relative to the European trials. In 2008, the US Food and Drug Administration issued a public health notification regarding higher than expected late aneurysm–related mortality with AneuRx.[21] Longer follow-up is needed to monitor performance of the various graft systems.

Our findings of no difference in major morbidities or secondary therapeutic procedures contrast with the EVAR-1 findings of highly significant differences favoring open repair in complications and reinterventions.[2] At least some of these differences between the 2 trials may result from how the categories were defined. For example, the EVAR-1 trial appears to have counted as reinterventions only procedures directly related to graft placement, whereas our study included any secondary therapeutic procedures resulting from the original procedure, such as incisional hernia repairs. Incisional hernia repairs were the most common secondary therapeutic procedures in the open-repair group in our study, occurring in 4.9% of patients at 2 years. This is comparable with the 5.8% rate reported in a Medicare population within 4 years after open repair.[22] A recent meta-analysis found that open AAA repair carries a 5-fold greater risk of incisional hernia than does surgery for aortoiliac occlusive disease, possibly reflecting an underlying collagen defect in patients with AAA.[23]

Health-related quality of life decreased in the early postoperative period in the European trials, particularly following open repair, but these changes resolved before 6 months.[4] In the DREAM trial,[24] quality of life at 6 months and 1 year was lower in the endovascular group. Our study focused on later postoperative quality of life and found no differences between the 2 groups at 1 and 2 years.

Open AAA repair results in erectile dysfunction in some patients, although most of the dysfunction observed after repair in 1 large trial was not new.[25] Erectile dysfunction has been reported to be reduced after endovascular repair compared with open repair, but these data are from nonrandomized retrospective surveys and are subject to recall and response bias.[26,27] Our finding of no difference between open and endovascular repair in erectile dysfunction at 1 and 2 years is in agreement with randomized prospective data from the DREAM trial, which reported no difference between open and endovascular repair in erectile dysfunction at 3, 6, and 12 months.[28]

CONCLUSION

In this randomized trial, endovascular repair resulted in fewer perioperative deaths than open repair, even though open repair was performed with low mortality. This early advantage was not offset by increased morbidity or mortality in the endovascular group in the first 2 years after repair. Longer-term data are needed to fully assess the relative merits of the 2 procedures.

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