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A Randomized Trial Comparing Conventional and Endovascular Repair of Abdominal Aortic Aneurysms

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ABSTRACT

BACKGROUND

Although the initial results of endovascular repair of abdominal aortic aneurysms were promising, current evidence from controlled studies does not convincingly show a reduction in 30-day mortality relative to that achieved with open repair.

METHODS

We conducted a multicenter, randomized trial comparing open repair with endovascular repair in 345 patients who had received a diagnosis of abdominal aortic aneurysm of at least 5 cm in diameter and who were considered suitable candidates for both techniques. The outcome events analyzed were operative (30-day) mortality and two composite end points of operative mortality and severe complications and operative mortality and moderate or severe complications.

RESULTS

The operative mortality rate was 4.6 percent in the open-repair group (8 of 174 patients; 95 percent confidence interval, 2.0 to 8.9 percent) and 1.2 percent in the endovascular-repair group (2 of 171 patients; 95 percent confidence interval, 0.1 to 4.2 percent), resulting in a risk ratio of 3.9 (95 percent confidence interval, 0.9 to 32.9). The combined rate of operative mortality and severe complications was 9.8 percent in the open-repair group (17 of 174 patients; 95 percent confidence interval, 5.8 to 15.2 percent) and 4.7 percent in the endovascular-repair group (8 of 171 patients; 95 percent confidence interval, 2.0 to 9.0 percent), resulting in a risk ratio of 2.1 (95 percent confidence interval, 0.9 to 5.4).

CONCLUSIONS

On the basis of the overall results of this trial, endovascular repair is preferable to open repair in patients who have an abdominal aortic aneurysm that is at least 5 cm in diameter. Long-term follow-up is needed to determine whether this advantage is sustained.

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Elective surgical repair is indicated in patients with a large abdominal aortic aneurysm. The threshold for surgery is still a subject of debate but varies between 5.0 and 5.5 cm in diameter.[1-4] Endovascular repair, pioneered by Parodi and Volodos in the early 1990s, is a less invasive alternative to conventional open repair.[5,6] Endovascular repair usually involves two small incisions made in the groin to expose the femoral arteries. With the use of guidewires, catheters, and specially designed introducer systems, a so-called endograft is assembled inside the abdominal aortic aneurysm under fluoroscopic guidance, thus excluding the aneurysm sac without opening the abdomen.

From its inception, endovascular repair has been used in patients for whom open repair poses a high risk. At the same time, patients with relatively few coexisting conditions are more likely to meet the anatomical criteria for endovascular repair, including the presence of a suitable infrarenal aortic neck and absence of severe aortoiliac tortuosity and calcification in the arterial wall.[7] These factors lead to selection in retrospective analyses and uncontrolled prospective evaluations and make an unbiased assessment of the benefits and risks of the two techniques problematic.[8-15]

Although the initial results of endovascular repair were promising and the less invasive nature of the procedure is appealing to many patients and physicians, evidence is needed that demonstrates the superiority of this approach over open repair, as are conclusive data on cost-effectiveness.[16-18] We conducted a multicenter, randomized trial — the Dutch Randomized Endovascular Aneurysm Management (DREAM) trial — to compare operative mortality and complications and other outcome events after elective open repair and endovascular repair.

METHODS

STUDY DESIGN AND PATIENTS

The design and methods of the trial have been described in detail elsewhere.[19] In brief, patients referred to surgery clinics at 24 centers in the Netherlands and 4 centers in Belgium who had received a diagnosis of an abdominal aortic aneurysm of at least 5 cm in diameter and who were considered suitable candidates for both techniques were randomly assigned to undergo open or endovascular repair, after giving written informed consent. A patient's suitability for endovascular repair was primarily determined by means of endograft-dependent anatomical criteria. A patient's suitability for open repair was determined by an internist or cardiologist. Patients who needed to undergo emergency aneurysm repair were excluded from the study, as were patients with inflammatory aneurysms, anatomical variations, connective-tissue disease, a history of organ transplantations, or a life expectancy of less than two years. The study was performed according to the principles of the Declaration of Helsinki, and the institutional review board of each participating hospital approved the protocol. Randomization was carried out centrally by means of a computer-generated permuted-block sequence and stratified according to study center in blocks of four patients.

An independent data-monitoring and ethics committee decided whether to continue the trial on the basis of a single interim analysis of the 30-day end points performed after half the required number of patients had been enrolled. In addition, sequential monitoring was used to monitor the incidence of death from all causes and all moderate and severe complications (not just those at 30 days) in order to safeguard against divergent outcomes beyond the perioperative period — for instance, as a result of endograft failure.[20]

SURGICAL TECHNIQUES

All repairs were carried out by surgical teams that had performed at least five endovascular procedures. Surgical teams that had performed less than 20 procedures were required to have an experienced proctor assist them during the procedure. Only endovascular devices that had been approved by the U.S. Food and Drug Administration (FDA) or that had an Investigational Device Exemption or Conformité Européen mark were allowed in the study. Endovascular repair typically involves small incisions in the groin to expose both femoral arteries, although some surgeons prefer a total percutaneous approach. The endograft is composed of fabric and metal stents and comes loaded in a specially designed delivery system. Under fluoroscopic guidance, this introducer system is fed through the iliac arteries by means of catheters and guidewires until the endograft is positioned correctly at the top and bottom of the aneurysmal segment of the aorta. Removal of the introducer system allows barbs or other fixing devices to attach to the aortic wall and hold the graft firmly in place, excluding blood flow

from the aneurysm sac and removing pressure from the aneurysmal wall. The exposure and aneurysm-repair technique used for open repair was at the surgeon's discretion.

END POINTS

Complications were classified and graded according to the reporting standards of the Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of the Society for Vascular Surgery/International Society for Cardiovascular Surgery.[21,22] Three classes of complications (systemic, local–nonvascular, and local–vascular or implant-related) and three grades of severity (mild, moderate, and severe) were used. Mild complications were not considered in this analysis.

An outcome adjudication committee, consisting of five vascular surgeons, assessed the class and severity of each complication in a blinded fashion and independently from each other. Disagreements were resolved in a plenary consensus meeting. The primary end point was a composite of operative mortality and moderate or severe complications. Operative complications were defined as those that occurred within 30 days after surgery or more than 30 days after surgery but during the same admission (in-hospital mortality and complications). Other outcome events analyzed were operative mortality and the combination of operative mortality and severe complications.

STATISTICAL ANALYSIS

The trial was designed to have 80 percent power to show a reduction of 50 percent in the primary end point at the two-sided 5 percent level with endovascular repair, as compared with open repair. The incidence of the primary end point in the open-repair group was expected to be 20 percent. Four hundred patients were required.

All analyses were based on all randomized patients who underwent aneurysm repair. Patients were classified according to the original randomized allocation in all analyses. The risk of a complication after open repair was compared with that after endovascular repair, and the results are presented as risk ratios and exact 95 percent confidence intervals, derived with the use of StatXact software (version 6.1, Cytel Software). Means (±SD) together with medians and interquartile ranges were used to describe continuous variables. Frequencies and exact 95 percent confidence intervals were calculated for categorical variables. Differences between treatment groups were evaluated with the use of the Mann–Whitney U test for continuous variables or Fisher's exact test for proportions. All reported P values are two-sided and are not adjusted for multiple testing.

The study protocol specified that recruitment would end by September 2003, with the enrollment of 400 patients, and that the study would be completed in January 2004. After negotiations with the sponsor of the study (the Health Insurance Council of the Netherlands) about a possible extension, three extra months were allowed, resulting in an eventual enrollment that was 12 percent lower than expected.

The corresponding author had full responsibility for the conduct of the trial, had full access to all the data, and controlled the decision to publish. The sponsor of the study had no role in the study design.

RESULTS

CHARACTERISTICS OF THE PATIENTS AND TREATMENT ASSIGNMENTS

Between November 2000 and December 2003, 351 patients were randomly assigned to undergo either open repair or endovascular repair (Fig. 1). Six patients did not undergo aneurysm repair after randomization: four declined treatment (three assigned to open repair and one to endovascular repair), one died from a ruptured abdominal aortic aneurysm before undergoing open repair, and one died from pneumonia before undergoing endovascular repair. The remaining 345 patients composed the treatment groups: 174 patients in the open-repair group and 171 in the endovascular-repair group.

The baseline characteristics of the patients and aneurysms are shown in Table 1.[23] Demographic characteristics, coexisting conditions, cardiovascular risk profiles, the distribution of American Society of Anesthesiologists classifications, and the characteristics of the aneurysm were similar in the two groups.

There were six crossovers: five patients who were randomly assigned to undergo open repair underwent endovascular repair, and one patient assigned to endovascular repair underwent open repair. Overall, in 96.6 percent of patients (339 of 351), the operation was started according to the randomized assignment. The median interval between randomization and surgery was 39 days in both the open-repair group (range, 4 to 260) and

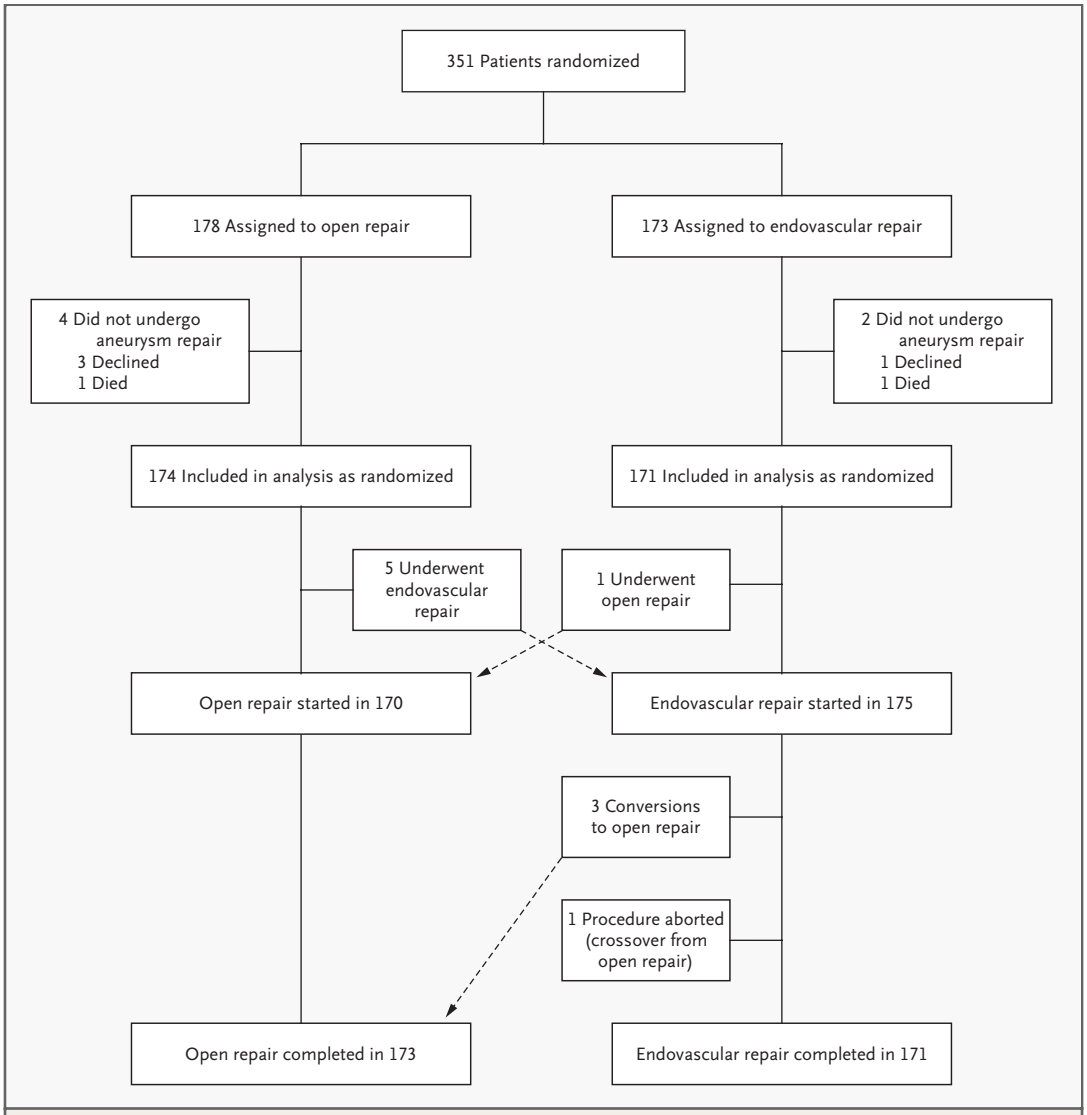

Figure 1. Randomization, Treatment, and Analysis of Outcomes.

the endovascular-repair group (range, 1 to 183; P=0.76).

SURGICAL AND POSTOPERATIVE DATA

Characteristics of the aneurysm-repair procedures are shown in Table 2. In three patients who were randomly assigned to undergo endovascular repair, the procedure was converted intraoperatively to an open procedure owing to access problems in two and failed deployment in one. In one patient, who was randomly assigned to open repair and who had crossed over to endovascular repair, the procedure was aborted owing to access problems. The aneurysm was left untreated (Fig. 1).

General anesthesia was used in 98.3 percent of patients in the open-repair group (in all except three of the five patients who crossed over to endovascular repair) and in 54.9 percent of patients in the endovascular-repair group (P<0.001). An aorto-aortic (tube) graft was used in 59.8 percent of open repairs and in 1.8 percent of endovascular repairs (P<0.001). At least one internal iliac artery was sacrificed (intentionally or unintentionally) in 4.0 percent of patients in the open-repair group,

Table 1. Baseline Characteristics of the Patients.*

Characteristic	Open Repair (N=174)	Endovascular Repair (N=171)	P Value
Age — yr	69.5±6.8	70.7±6.6	0.11
Male sex — no. (%)	157 (90.2)	159 (93.0)	0.44
Moderate or severe SVS/ISCVS risk-factor score — %†			
Diabetes mellitus	9.8	9.9	0.97
Tobacco use	54.0	64.9	0.07
Hypertension	54.0	57.9	0.92
Hyperlipidemia	53.6	47.0	0.22
Carotid-artery disease	15.1	13.5	0.71
Cardiac disease	46.6	40.9	0.30
Renal disease	7.5	7.6	0.98
Pulmonary disease	17.8	27.5	0.04
Sum of SVS/ISCVS risk-factor scores†	4.4±2.5	4.4±2.5	0.70
FEV_1 — liters/sec	2.6±0.7	2.5±0.7	0.24
Body-mass index	26.6±4.1	26.2±3.4	0.42
ASA class — no. (%)			
I (healthy status)	44 (25.3)	37 (21.6)	0.45
II (mild systemic disease)	106 (60.9)	119 (69.6)	0.09
III (severe systemic disease)	24 (13.8)	14 (8.2)	0.12
Data missing	0	1 (0.6)	
Previous abdominal surgery — no. (%)	56 (32)	43 (25.1)	0.15
Maximal diameter of aneurysm — mm			0.68
Mean	60.0±8.5	60.6±9.0	
Median	58	58	
Interquartile range	54–65	55–65	
Eurostar aneurysm morphology class — no. (%)‡			
A (confined to aorta, distal aortic neck available)	20 (11.5)	12 (7.0)	0.15
B (involves aortic bifurcation, normal iliac arteries)	101 (58.0)	114 (66.7)	0.12
C (involves both proximal common iliac arteries)	20 (11.5)	16 (9.4)	0.30
D (extends into one iliac bifurcation)	15 (8.6)	14 (8.2)	0.90
E (extends into both iliac bifurcations)	18 (10.3)	15 (8.8)	0.62
Cylindrical shape of infrarenal aortic neck — no. (%)	127 (73.0)	107 (62.6)	0.05
Unfavorable features of infrarenal aortic neck — no. (%)§	74 (42.5)	92 (53.8)	0.05
Iliac calcification <25% of the iliac segment — no. (%)	125 (71.8)	118 (69.0)	0.40
Unfavorable features of iliac arteries — no. (%)¶	51 (29.3)	53 (31.0)	0.81

* Plus–minus values are means ±SD. FEV_1 denotes forced expiratory volume in one second, and ASA American Society of Anesthesiologists. The body-mass index is the weight in kilograms divided by the square of the height in meters. Because of rounding, not all percentages total 100.

† The Society for Vascular Surgery/International Society for Cardiovascular Surgery (SVS/ISCVS) risk-factor score for each of eight domains ranges from 0 (no risk factors) to 3 (severe risk factors).[21] Total scores can range from 0 to 24, with higher scores indicating more risk factors.

‡ The Eurostar classification of aneurysm morphology has been described in detail by Harris et al.[23]

§ The following were unfavorable neck features: reverse tapering, a diameter of more than 28 mm, angulation of more than 30 degrees, length of less than 15 mm, a mural thrombus of more than 2 mm, and irregular wall or bulge.

¶ The following were unfavorable iliac features: angulation of more than 90 degrees, a diameter of more than 18 mm, and a diameter of less than 6 mm or more than 50 percent stenosis.

Table 2. Characteristics of the Aneurysm-Repair Procedures.*

Characteristic	Open Repair (N=174)	Endovascular Repair (N=171)
	no. of patients (%)	
Type of anesthesia		
General	120 (69.0)	89 (52.0)
General and regional	51 (29.3)	5 (2.9)
Regional	2 (1.1)†	68 (39.8)
Local	1 (0.6)†	9 (5.3)
Configuration at completion		
Conventional tube graft	104 (59.8)	2 (1.2)‡
Conventional bifurcated graft	65 (37.4)	2 (1.2)§
Endovascular tube graft	—	1 (0.6)
Endovascular monoiliac graft	—	6 (3.5)
Endovascular bifurcated graft	4 (2.3)†	160 (94.0)
Procedure aborted	1 (0.6)†	—
Distal anastomosis		
Aortoaortic graft	104 (59.8)	3 (1.8)
Other	69 (39.7)	165 (96.5)
Aortobiiliac	58 (33.3)	159 (93.0)
Aortoiliac or aortofemoral	8 (4.6)	6 (3.5)
Aortobifemoral	3 (1.7)	—
Procedure aborted or converted	1 (0.6)†	3 (1.8)
Postoperative status of internal iliac artery relative to preoperative patency¶		
Unchanged	167 (96.0)	142 (83.0)
One of two patent internal iliac arteries lost or sacrificed	6 (3.5)	25 (14.6)
One of one patent internal iliac artery lost or sacrificed		1 (0.6)
Both internal iliac arteries lost or sacrificed	1 (0.6)	3 (1.8)
Type of endograft used		3 (1.8)
Zenith (Cook)	2 (1.1)†	57 (33.3)
Talent (World Medical/Medtronic)	3 (1.7)†	46 (26.9)
Excluder (W.L. Gore and Associates)	0	37 (21.6)
Other‖	0	30 (17.5)

* Because of rounding, not all percentages total 100.
† Values reflect patients who crossed over from open to endovascular repair.
‡ One of these patients crossed over from endovascular to open repair, and one underwent an immediate conversion owing to difficulty accessing an endovascular bifurcated graft.
§ One of these patients underwent an immediate conversion owing to difficulty accessing an endovascular monoiliac graft, and one did so owing to failed deployment of an endovascular bifurcated graft.
¶ Two patients (one in each group) were not at risk for change in status, since both had bilateral occlusion of the internal iliac arteries preoperatively.
‖ The following other endografts were used: AneuRx (Medtronic) in 12 patients, Quantum LP (Cordis) in 8, Ancure (Guidant–EVT) in 5, Lifepath (Baxter Healthcare) in 4, and Endologix (Bard/Impra) in 1.

as compared with 17.0 percent of patients in the endovascular-repair group (P<0.001).

Table 3 shows the main surgical and postoperative data. As compared with open repair, endovascular repair resulted in a significantly shorter duration of surgery (P<0.001), less blood loss (P<0.001) and blood replacement (P<0.001), a lower rate of use of postoperative mechanical ventilation (P<0.001), less of a change in the hematocrit (P<0.001), a shorter stay in the medium care unit and intensive care unit (P<0.001), and a shorter hospital stay (P<0.001).

END POINTS AND ADVERSE EVENTS

The operative mortality rate was 4.6 percent in the open-repair group (8 of 174 patients; 95 percent confidence interval, 2.0 to 8.9 percent) and 1.2 percent in the endovascular-repair group (2 of 171 patients; 95 percent confidence interval, 0.1 to 4.2 percent), resulting in a risk ratio of 3.9 (95 percent confidence interval, 0.9 to 32.9; P=0.10) (Table 4). The combined rate of operative mortality and severe complications was 9.8 percent in the open-repair group (17 of 174 patients; 95 percent confidence interval, 5.8 to 15.2 percent) and 4.7 percent in the endovascular-repair group (8 of 171 patients; 95 percent confidence interval, 2.0 to 9.0 percent), resulting in a risk ratio of 2.1 (95 percent confidence interval, 0.9 to 5.4; P=0.10). The combined rate of operative mortality and moderate or severe complications was 23.6 percent in the open-repair group (41 of 174 patients; 95 percent confidence interval, 17.5 to 30.6 percent) and 18.1 percent in the endovascular-repair group (31 of 171 patients; 95 percent confidence interval, 12.7 to 24.7 percent), resulting in a risk ratio of 1.3 (95 percent confidence interval, 0.9 to 2.0; P=0.23).

Table 4 shows the rates of operative complications according to class and grade for the two groups. As compared with endovascular repair, open repair resulted in a higher rate of moderate and severe systemic complications as well as a higher rate of severe complications. The majority of the difference was due to a higher rate of pulmonary complications in the open-repair group (10.9 percent vs. 2.9 percent). Local–vascular and implant-related complications tended to be more frequent after endovascular repair than after open repair, but the difference was significant only for moderate or severe complications. There were no significant differences between the groups in the rate of local–nonvascular complications.

DISCUSSION

When taken together, the findings of this randomized trial comparing open and endovascular aneurysm repair suggest that in patients who qualify for either procedure, endovascular repair is preferable to open repair over the first 30 days after the procedure. To clarify these findings, some issues need to be addressed. The size of the study group was chosen so that we could demonstrate at least a 10 percent absolute difference in the primary outcome. Owing to time restrictions imposed by the sponsor, the ultimate size of the patient group was 12 percent lower than anticipated. In addition, although our estimate of a 20 percent rate of the primary end point after open repair was accurate (23.6 percent had such an end point), the rate after endovascular repair turned out to be higher than expected (18.1 percent, rather than 10 percent).

When designing the trial, we anticipated that the rate of moderate complications after open repair would be considerable. To avoid overlooking a significant difference in the outcome accounted for by differences in the rate of moderate complications, we incorporated these into the combined primary end point. Many of the complications included in the Society for Vascular Surgery/International Society for Cardiovascular Surgery definition of moderate complications are important for the postoperative care of patients with abdominal aortic aneurysm and for the assessment of cost-effectiveness. However, after an analysis of all moderate complications, the outcome adjudication committee concluded that these complications were unlikely to have an appreciable effect on clinical decision making.

As compared with open repair, endovascular repair resulted in significantly better perioperative outcomes, such as a lower rate of systemic complications (mainly pulmonary), less blood loss, a briefer duration of surgery, a lower rate of use of postoperative mechanical ventilation, and shorter hospital stays, all reflecting the less invasive nature of the endovascular approach. These results are consistent with those of previously reported series and systematic reviews.[8-15] This advantage, in combination with a near-significant advantage of endovascular repair over open repair in terms of operative mortality and combined operative mortality and severe complications, makes a compelling case for endovascular repair. The risk ratio for operative mortality was 3.9 for open repair as compared with endovascular repair, with a 95 percent confidence interval of 0.9 to 32.9.

We are aware of three other randomized trials comparing open repair with endovascular repair: the Endovascular Aneurysm Repair (EVAR-1) trial in the United Kingdom, the Anévrisme de l'aorte abdominale: Chirurgie versus Endoprothèse (ACE) trial in France, and the Open versus Endovascular Repair (OVER) trial in the United States. Whereas the last two trials are ongoing, the results of the EVAR-1 trial have been published recently and are similar to our results.[24] Our trial and the EVAR-1 trial are almost equivalent in terms of patient selection (patients with low surgical risk) and outcome criteria. Combining the results of the two trials yields the most accurate approximation of the risk ratio for in-hospital death to date: an operative mortality of 5.8 percent in the open-repair group (40 of 690 patients; 95 percent confidence interval, 4.2 to 7.8) and of 1.9 percent in the endovascular-repair group (13 of 702 patients; 95 percent confidence interval, 1.0 to 3.2), resulting in a risk ratio of 3.1 (95 percent confidence interval, 1.7 to 6.2).

Although our results for endovascular repair compare well with those in the literature, there is some variation in reported operative mortality rates after open repair among our randomized trial and the randomized EVAR-1 trial, historical and recent population-based studies,[9,10,25] and the FDA phase 2, pivotal, concurrent, controlled endograft trials.[12-15] Before the endovascular era, population-based series reported operative mortality rates of approximately 8 percent,[25] whereas recent nationwide or statewide series have reported rates of approximately 4 percent.[9,10] This difference can be explained by the acceptance of a larger proportion of high-risk patients for open repair as the only available option in the older series. Operative mortality rates in the open-repair (control) groups in the FDA phase 2 trials ranged from 0 to 2.7 percent, but these were highly selected patients. The recent population-based series with an operative mortality of approximately 4 percent can be considered a valid representation of the true operative mortality rate for open repair and compares well with the results of our randomized trial of patients with low surgical risk. It is hard to predict whether the overall population-based mortality associated with aneurysm repair would decrease with the widespread use of endovascular repair, since its use in a broader range of patients might diminish some of the benefits that we and others have identified.[9,26]

Table 3. Surgical and Postoperative Data.*

Variable	Open Repair (N=174)	Endovascular Repair (N=171)	P Value
Duration of surgery — min			<0.001
Mean	151	135	
Median	150	120	
Interquartile range	120 to 170	105 to 150	
Estimated blood loss — ml			<0.001
Mean	1654	394	
Median	1500	250	
Interquartile range	900 to 2300	100 to 500	
Autologous blood returned — ml			
Mean	486±482	—†	
Median	420	—	
Interquartile range	0 to 726	—	
Homologous blood transfused — units			<0.001
Mean	0.44	0.09	
Median	0	0	
Interquartile range	0 to 0	0 to 0	
Intraoperative blood transfusion — % (95% CI)	72 (64 to 78)	6 (3 to 11)	<0.001
Homologous blood products used — % (95% CI)‡	21 (15 to 28)	4 (2 to 9)	<0.001
Intravenous contrast — ml			
Mean	—§	167±63	
Median	—	150	
Interquartile range	—	120 to 200	
Total fluoroscopy time — min			
Mean	—§	25±18	
Median	—	21	
Interquartile range	—	14 to 28	

Patients in our trial had to be eligible for either operation in order to undergo randomization. Consequently, our findings may not be generalizable to patients who are not suitable candidates for open repair. These patients frequently have multiple manifestations of advanced atherosclerotic disease and are at increased operative risk. Neither can our data be generalized to patients who are not suitable for endovascular repair, since these patients are likely to have more challenging anatomy.[7] Moreover, a patient's eligibility for endovascular repair is dependent on the state of device technology. The introduction of fenestrated and branched endografts is expected to increase the proportion of patients with abdominal aortic aneurysm who can be treated by endovascular repair in the near future.[27]

Age is a well-known predictor of mortality after repair of abdominal aortic aneurysm. Open and endovascular repair may yield similar results in relatively young patients at low surgical risk, whereas the latter approach may be particularly advantageous in older and high-risk patients.[28] The size of our trial is not sufficient to permit a meaningful subgroup analysis of the effect of age or coexisting conditions on the difference in outcome between open repair and endovascular repair. Other larger and longer-term trials are needed to explore this issue further. The sponsor of the current trial has

Table 3. (Continued.)

Variable	Open Repair (N=174)	Endovascular Repair (N=171)	P Value
Duration of MCU or ICU stay — hr¶			<0.001
Mean	72	16	
Median	23	3	
Interquartile range	21 to 47	0 to 20	
Postoperative mechanical ventilation — % (95% CI)	51 (43 to 58)	6 (3 to 10)	<0.001
Duration of postoperative mechanical ventilation — hr			<0.001
Mean	34	5	
Median	1	0	
Interquartile range	0 to 6	0 to 0	
Duration of hospitalization — days			<0.001
Mean	13	6	
Median	10	4	
Interquartile range	8 to 15	3 to 6	
Change in hematocrit‖			<0.001
Mean	0.09	0.07	
Median	0.09	0.07	
Interquartile range	0.05 to 0.12	0.04 to 0.10	
≤20% Decrease in hematocrit — % (95% CI)	53 (44 to 61)	35 (27 to 43)	0.002
Change in creatinine — μmol/liter**			0.93
Mean	–0.5	–5.4	
Median	7	7	
Interquartile range	–6 to 17	–6.3 to 10	
≥20% Increase in creatinine — % (95% CI)	13 (8 to 19)	13 (8 to 20)	1.00

* Plus–minus values are means ±SD. CI denotes confidence interval.
† Autologous blood was returned in three patients whose surgery was converted from endovascular repair to open repair (412, 700, and 1000 ml).
‡ Homologous blood products consisted of packed cells, fresh-frozen plasma, cryoprecipitate, and platelets.
§ In five patients who crossed over from open to endovascular repair, the volume of intravenous contrast used was not available for one and was 120, 129, 200, and 200 ml in the other four, and the total fluoroscopy time was not available for one and was 13, 37, 39, and 40 minutes in the other four.
¶ The stay in the medium care unit (MCU) and the intensive care unit (ICU) included the time spent in the recovery room.
‖ For the change in hematocrit, expressed as a fraction (preoperative value minus postoperative [day 1] value), 140 (80.5 percent) pairs were available for the open-repair group and 136 (79.5 percent) pairs were available for the endovascular-repair group.
** For the change in creatinine level (preoperative value minus postoperative [day 2] value), 161 (92.5 percent) pairs were available for the open-repair group and 134 (78.4 percent) pairs were available for the endovascular-repair group. To convert values for creatinine to milligrams per deciliter, divide by 88.4.

funded an extension of the follow-up period for a total of seven years after surgery; thus, our data address only the perioperative issues.

The ultimate decision regarding which type of repair should be used in a given patient with an abdominal aortic aneurysm is based on a number of factors, including the quality of life expected postoperatively, cost-effectiveness, risk of sexual dysfunction, risk of aneurysm rupture, and reintervention rate.[29] These factors must be considered before a final decision is reached. Our results indicate that in patients who are candidates for both techniques, endovascular repair is preferable to open repair, given its lower rates of operative mor-

Table 4. End Points and Operative Complications.*

Variable	Open Repair (N=174)	Endovascular Repair (N=171)	Risk Ratio (95% CI)	P Value
	no. of patients (%)			
End point†				
Operative mortality	8 (4.6)	2 (1.2)	3.9 (0.9–32.9)	0.10
Operative mortality and severe complications	17 (9.8)	8 (4.7)	2.1 (0.9–5.4)	0.10
Operative mortality and moderate or severe complications	41 (23.6)	31 (18.1)	1.3 (0.9–2.0)	0.23
Systemic complications‡				
Moderate and severe	46 (26.4)	20 (11.7)	2.3 (1.4–3.8)	<0.001
Severe	19 (10.9)	6 (3.5)	3.1 (1.3–9.1)	0.01
Cardiac complications	10 (5.7)	9 (5.3)		
Severe	2 (1.1)	3 (1.8)		
Pulmonary complications	19 (10.9)	5 (2.9)	3.7 (1.5–11.9)	0.005
Severe	8 (4.6)	2 (1.2)	3.9 (0.9–32.9)	0.10
Renal complications	2 (1.1)	2 (1.2)		
Severe	1 (0.6)	0		
Cerebrovascular or spinal cord	2 (1.1)	1 (0.6)		
Severe	2 (1.1)	1 (0.6)		
Bowel ischemia	2 (1.1)	1 (0.6)		
Severe	2 (1.1)	0		
Other	11 (6.3)	2 (1.2)	5.4 (1.4–53.5)	0.02
Severe	4 (2.3)	0		
Local–vascular or implant-related complications‡				
Moderate and severe	15 (8.6)	28 (16.4)	0.5 (0.3–0.9)	0.03
Severe	9 (5.2)	7 (4.1)	1.3 (0.5–4.0)	0.80
Hemorrhage	6 (3.4)	3 (1.8)		
Severe	6 (3.4)	1 (0.6)		
Graft complications	0	6 (3.5)		
Severe	0	1 (0.6)		
Graft infection	2 (1.1)	1 (0.6)		
Severe	0	0		
Endovascular-leak intervention	0	2 (1.2)		
Severe	0	1 (0.6)		
Thromboembolic complications	2 (1.1)	2 (1.2)		
Severe	1 (0.6)	0		
Obstruction of main renal artery	0	3 (1.8)		
Severe	0	1 (0.6)		
Arterial or graft obstruction	5 (2.9)	11 (6.4)	0.5 (0.1–1.2)	0.13
Severe	2 (1.1)	3 (1.8)		
Local–nonvascular complications‡				
Wound complications	6 (3.4)	6 (3.5)		
Severe	2 (1.1)	1 (0.6)		
Iatrogenic bowel perforation	1 (0.6)	0		
Severe	1 (0.6)	0		

* The standards of the Society for Vascular Surgery/International Society for Cardiovascular Surgery were used.[21]
† For end points, only the most severe event in each patient was counted.
‡ For complications, all events that occurred in each patient were counted.

tality and complications and the significant reduction in the rates of systemic complications.

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APPENDIX

The members of the DREAM Trial Group were as follows: *Steering Committee* — D.E. Grobbee, J.D. Blankensteijn, J. Buth, P.M. Pattynama, E.L.G. Verhoeven, A.E. van Voorthuisen, A.A.A. Bak; *Executive and Writing Committee* — J.D. Blankensteijn, M. Prinssen, M.R.H.M. van Sambeek, E.L.G. Verhoeven, J. Buth, P.W.M. Cuypers, R. Balm, E. Buskens, D.E. Grobbee; *Data Monitoring and Ethics Committee* — M.G. Hunink, J.M. van Engelshoven, M.J.H.M. Jacobs, B.A.J.M. de Mol; *Site and Device Selection Committee* — J.H. van Bockel, R. Balm, J. Reekers, X. Tielbeek, E.L.G. Verhoeven, W. Wisselink; *Data Management* — N. Boekema, I. Sikking; *Outcome Adjudication Committee* — M. Prinssen, R. Balm, J. Buth, M.R.H.M. van Sambeek, E.L.G. Verhoeven, J.D. Blankensteijn; *Data Analysis* — J.D. Blankensteijn, M. Prinssen, E. Buskens; *Clinical Centers (number of patients randomized are listed in parentheses)* — **the Netherlands**: Catharina Hospital, Eindhoven (94): J. Buth, A.V. Tielbeek; University Medical Center, Utrecht (35): J.D. Blankensteijn; Academic Medical Center, Amsterdam (32): R. Balm, J.A. Reekers; Erasmus Medical Center, Rotterdam (30): M.R.H.M. van Sambeek, P. Pattynama; University Hospital, Groningen (27): E.L.G. Verhoeven, T. Prins; St. Franciscus Gasthuis, Rotterdam (27): A.C. van der Ham, J.J.I.M. van der Velden; Rijnstate Hospital, Arnhem (14): S.M.M. van Sterkenburg, G.B. ten Haken; Leyenburg Hospital, 's-Gravenhage (9): C.M.A. Bruijninckx, H. van Overhagen; Albert Schweitzer Hospital, Dordrecht (8): R.P. Tutein Nolthenius, T.R. Hendriksz; Atrium Medical Center, Heerlen (8): J.A.W. Teijink, H.F. Odink; Medical Center Rijnmond Zuid, Rotterdam (7): A.A.E.A. de Smet, D. Vroegindeweij; Jeroen Bosch Hospital, den Bosch (7): R.M.M. van Loenhout, M.J. Rutten; St. Elisabeth Hospital, Tilburg (5): J.F. Hamming, L.E.H. Lampmann; Maxima Medical Center, Veldhoven (5): M.H.M. Bender, H. Pasmans; Onze Lieve Vrouwe Gasthuis, Amsterdam (5): A.C. Vahl, C. de Vries; Meander Medical Center, Amersfoort (4): A.J.C. Mackaay; Vlietland Hospital, Schiedam (4): L.M.C. van Dortmont; University Medical Center, Nijmegen (4): D. van der Vliet; L. Schultze Kool; Martini Hospital, Groningen (3): J.H.B. Boomsma, H.R. van Dop; Medical Center Haaglanden, 's-Gravenhage (3): J.C.A. de Mol van Otterloo, T.P.W. de Rooij; Hospital Bernhoven, Oss (3): T.M. Smits; Oosterschelde Hospital, Goes (3): E.N. Yilmaz; Vrije Universiteit Medical Center, Amsterdam (2): W. Wisselink, F.G. van den Berg; Leiden University Medical Center, Leiden (1): M.J.T. Visser, E. van der Linden; University Medical Center, Maastricht (1): G.W.H. Schurink, M. de Haan; Bronovo Hospital, 's-Gravenhage (1): H.J. Smeets; **Belgium:** St. Jozef Hospital, Turnhout (4): P. Stabel; Vermassen St. Trudo Hospital, St. Truiden (3): F. van Elst; University Hospital, Antwerp (1): J. Poniewierski; and University Medical Center, Ghent (1): F.E.G. Vermassen.

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