A randomized controlled trial of endovascular aneurysm repair versus open surgery for abdominal aortic aneurysms in low- to moderate-risk patients

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Background: **Several studies, including three randomized controlled trials (RCTs), have shown that endovascular repair (EVAR) of abdominal aortic aneurysms (AAA) offered better early results than open surgical repair (OSR) but a similar medium-term to long-term mortality and a higher incidence of reinterventions. Thus, the role of EVAR, most notably in low-risk patients, remains debated.**

Methods: **The ACE (Anevrysme de l'aorte abdominale: Chirurgie versus Endoprothese) trial compared mortality and major adverse events after EVAR and OSR in patients with AAA anatomically suitable for EVAR and at low-risk or intermediate-risk for open surgery. A total of 316 patients with >5 cm aneurysms were randomized in institutions with proven expertise for both treatments: 299 patients were available for analysis, and 149 were assigned to OSR and 150 to EVAR. Patients were monitored for 5 years after treatment. Statistical analysis was by intention to treat.**

Results: **With a median follow-up of 3 years (range, 0-4.8 years), there was no difference in the cumulative survival free of death or major events rates between OSR and EVAR: 95.9% ± 1.6% vs 93.2% ± 2.1% at 1 year and 85.1% ± 4.5% vs 82.4% ± 3.7% at 3 years, respectively ($P = .09$). In-hospital mortality (0.6% vs 1.3%; $P = 1.0$), survival, and the percentage of minor complications were not statistically different. In the EVAR group, however, the crude percentage of reintervention was higher (2.4% vs 16%, $P < .0001$), with a trend toward a higher aneurysm-related mortality (0.7% vs 4%; $P = .12$).**

Conclusions: **In patients with low to intermediate risk factors, open repair of AAA is as safe as EVAR and remains a more durable option. (J Vasc Surg 2011;53:1167-73.)**

Rupture of abdominal aortic aneurysm (AAA) is a frequent cause of cardiovascular death in industrialized countries. Prophylactic open surgical repair (OSR) is indicated for large asymptomatic AAA in patients with acceptable operative risk. However, despite improvements in surgical expertise and anesthesia, the death toll after OSR remains significant. Parodii's report raised hopes that endovascular repair of AAA (EVAR) might improve outcomes.[1] Meta-analysis of retrospective studies as well as three prospective randomized controlled studies (RCT) tended to confirm this hypothesis, at least in the early stage.[2-4]

After health care provider authorizations and stent graft reimbursements, the number of patients undergoing OSR has rapidly declined while the number undergoing EVAR has expanded.[5,6] However, rupture may still happen after EVAR, and reinterventions are not infrequent.[3,4,7] As a consequence, the long-term efficacy of EVAR is still debated.

The ACE (Anevrysme de l'aorte abdominale: Chirurgie versus Endoprothese) trial (http://ClinicalTrials.gov, #NTC00224718) was conceived in 1998. This multicenter, prospective randomized trial assessed the results of OSR vs EVAR in patients presenting with an asymptomatic AAA, deemed at low to moderate risk for surgery. We report the final results of this trial, with a median follow-up of 3 years.

METHODS

Participants. Inclusion criteria combined anatomic and clinical assessment:

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- Anatomic criteria were based on computed tomography (CT) scan findings: AAA >50 mm in men or >45 mm in women, or common iliac artery aneurysm >30 mm ***and*** upper neck free of major thrombus or calcifications ***and*** at ≥15 mm in length ***and*** an angle between the neck and the axis of the aneurysm <60° ***and*** iliac arteries compatible with the introducer sheath.
- Clinical assessment graded patients in categories 0 to 2 according to the comorbidity score of the Society for Vascular Surgery/American Association for Vascular Surgery (SVS/AAVS).[8]

Exclusion criteria were previous abdominal aortic surgery, ruptured aneurysm, mycotic aneurysm, severe iodine allergy, life expectancy deemed <6 months, or category 3 of the SVS/AAVS classification.

Centers fulfilled the recommendations issued in 2001 by the French Regulatory Agency for Medical Drug and Device Safety, which required a minimal activity of 20 AAA repairs/year and at least 8 EVAR procedures to be authorized to performed EVAR. By the time the study started, at least 30 EVAR procedures had been done in each center.

Interventions. The protocol did not recommend any specific preoperative treatment (eg, β-blockers or statins). Prophylactic antibiotics were injected intravenously at the beginning of the procedure. Intravenous heparin (0.5 mg/kg) was administered before clamping or sheath insertion. Aspirin (75 mg/d) was given postoperatively to all patients.

Any bifurcated or aortouniiliac stent graft with a European Conformity mark and approved by the French Health Security Agency could be used for EVAR. Access (cutdown or percutaneous) and management of hypogastric arteries (embolization, overlap by stent graft) were left to the surgeon's decision.

Surgical approach for transperitoneal or retroperitoneal OSR, type of graft (polyester of polytetrafluoroethylene), combined revascularization of inferior mesenteric artery or hypogastric artery, or both, were left to the surgeon's decision.

Outcomes. The primary end point was death of any cause and major adverse events, including myocardial infarction (defined by electrocardiogram signs, enzymes, and troponin elevation), permanent stroke, permanent hemodialysis, major amputation, paraplegia, and bowel infarction. Secondary end points included vascular reinterventions and minor complications. Sexual impairment was assessed at 1 year by asking for any alteration in sexual function after treatment. No formal established questionnaire was used. Buttock claudication was defined by the postoperative onset of a buttock pain that prevented a normal walking activity (ie, occurring for a walking distance of <300 meters). Incisional complications included all wall dehiscences and large abdominal wall palsy when the patient found it debilitating. Reinterventions for incisional repair were not recorded.

Follow-up visits were scheduled at 1, 6, and 12 months, and yearly thereafter. In the EVAR arm, plain abdominal radiography, duplex scan, and contrast CT scan were performed at each evaluation. All events were collected in the case report form.

Study organization is summarized in Appendix 1 (online only). A multidisciplinary independent committee validated all end points.

Sample size. With the hypothesis of a 2-year 30% reduction of the incidence of death and major adverse events in the EVAR group (α, 5%; β risk, 10%), 600 patients were required. Although the study was designed in 1999, it started in 2003 due to (1) conflicts between the Ministry of Health and the National Healthcare Reimbursement Organization, (2) structural changes in regulatory agencies and recommendations (temporary limitation to high-risk patients), and (3) insurance issues between Clinical Research Direction and the centers. Because of a slow inclusion rate due to previously reported reasons,[9] the scientific committee stopped enrollment in March 2008 and extended the follow-up up to 5 years. The trial ended in April 2009.

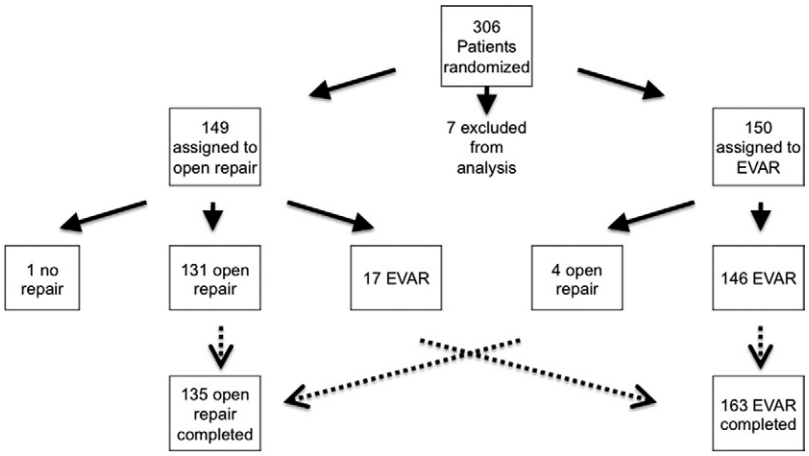
Randomization. Patient data in each center were checked by a multidisciplinary team (vascular surgeon, radiologist, and anesthesiologist). After written informed consent was obtained, the Clinical Research Unit of Henri Mondor Hospital performed randomization stratified by center. Arm allocation was notified ≤24 hours to the investigator.

Statistical methods. Analysis was performed by intention-to-treat. Patient characteristics, in-hospital postoperative data, and outcome measure are expressed as means with standard deviation (SD) or as counts and percentage. Qualitative variables were compared using χ^2 test or Fisher test when appropriate. Quantitative variables (mean ± SD) were compared using the t test. Overall survival was calculated from the date of inclusion until death, major adverse complication, or last follow-up. Event-free survival of minor complication was calculated from the date of inclusion until minor complication, death, major complication, or the last follow-up. Survival curves were estimated by the Kaplan-Meier method. Differences between the survival curves were tested for significance by the log-rank test. All P values reported were two-sided. Differences between the results of comparative tests were considered significant at $P < .05$. SPSS France 16.0 software (Bois Colombes, France) was used.

RESULTS

Between March 2003 and March 2008, 25 centers (Appendix 2) participated in the study. The mean number of patients per center was 12 ± 20 (range, 1-102).

A flow diagram (Fig 1) shows results of the randomization and protocol deviations. Of 306 randomized patients, 7 were excluded from analysis because of withdrawal of consent. Intention-to-treat analysis was performed in 299 patients (149 allocated to OSR and 150 to EVAR): 277 (92.6%) were treated according to randomization, 1 patient did not undergo intervention, and there were 21 crossovers, mostly due to patient's preferences. The crossover rate was significantly higher in the OSR arm (11.4% vs 2.7%; $P < .01$). Mean time from randomization to treat-



		Randomization		
		Open repair	EVAR	Total
Intervention	No treatment	1	0	1
	OpenRepair	131	4	135
	EVAR	17	146	163
	Total	149	150	299

Fig 1. Flow diagram of the study. *EVAR*, Endovascular aneurysm repair.

ment was 16.8 ± 6.6 days (range, 1-29 days). Three patients were lost to follow-up in the EVAR group (2%), and five in the OSR group (3.3%). Patients were censored at the last available follow-up.

Baseline data. There were 3 women (1.0%) and 296 men (99.0%). Mean age was 69 ± 7 years (range, 49-83 years). Preoperative risk factors, SVS/AAVS scores, American Society of Anesthesiologists classification, aneurysm classification, and diameters are reported in Table I. Both groups were similar at baseline, with the exception of a significantly higher rate of category 2 coronary disease (16.8% vs 8.0%; $P < .05$) and a more severe SVS/AAVS grading score (grade 2: 69.1% vs 54.7%; $P < .01$) in the OSR arm.

Intervention. General anesthesia was used in all operations, except for eight patients in the EVAR arm (four local and four epidural anesthesia).

In the OSR arm, surgery was performed through a midline incision in 70 patients, a transverse incision in 10, and a retroperitoneal approach in 51. A tube graft was inserted in 70 patients and a bifurcated graft in 61.

In the EVAR arm, four types of stent grafts were used: Zenith (Cook, Inc, Bloomington, Ind) in 81 patients (71 bifurcated, 10 aortouniiliac), Talent (Medtronic Vascular, Santa Rose, Calif) in 52 (41 bifurcated, 11 aortouniiliac), Excluder (W. L. Gore and Assoc, Flagstaff, Ariz) in 9 (all bifurcated), and Powerlink (Endologix, Irvine, Calif) in 4 (all bifurcated).

Operative details are summarized in Table II. EVAR was associated with a shorter duration of intervention and of ventilatory support, and less blood transfusion. As expected, X-ray exposure time and amount of contrast were higher with EVAR.

Postoperative course. Table III summarizes the postoperative outcomes. Three deaths occurred postoperatively, comprising two myocardial infarctions (one in each group) and one cardiac arrest after immediate conversion to OSR due to stent graft misdeployment. General complication and reintervention rates did not differ statistically. The mean length of stay was 5.8 ± 5.5 days after EVAR and 10.4 ± 8.3 after OSR ($P < .0001$).

Long-term results. Median follow-up was 3 years (mean 2.5 ± 1.2 years; range, 0-4.8 years). Table IV summarizes the details of deaths, major and minor adverse events, and reinterventions in the two groups.

Survival. In addition to the 3 postoperative deaths, 26 patients died during follow-up. There was no difference in the cumulative survival rates between OSR and EVAR according to the log-rank test ($P = .24$), with 96.5% ± 1.5% vs 95.2% ± 1.8% at 1 year and 86.7% ± 4.4% vs 86.3% ± 3.4% at 3 years, respectively.

Deaths were related to the aneurysm or to the treatment (aneurysm-related mortality) in one patient after OSR (0.6%) and in six patients after EVAR (4%; $P = .14$). In the later case, two deaths were reported as in the immediate postoperative course, two died of rupture, and the remaining two deaths occurred after vascular reinterventions.

Major adverse events. As shown in Fig 2, there was no difference in the cumulative survival free of death and major adverse events rates between OSR and EVAR, with 95.9% ± 1.6% vs 93.2% ± 2.1% at 1 year, and 85.1% ± 4.5% vs 82.4% ± 3.7% at 3 years, respectively ($P = .09$). The rates of myocardial infarction, neurologic complications, and renal failure were in the same range in the two groups. There were three ruptures in the EVAR group, all >2 years

Table I. Patient characteristics

Variable[a]	*Open repair (n = 149)*	*EVAR (n = 150)*
Risk factors		
Age, years	70 ± 7.1	68.9 ± 7.7
Range	54-83	49-83
Male sex	146 (98)	151 (100)
Diabetes	29 (19.5)	20 (13.3)
Tobacco	74 (49.7)	73 (48.7)
Hypertension	95 (63.8)	99 (66.0)
Hyperlipidemia	98 (65.8)	103 (68.7)
Carotid artery disease	12 (8.1)	12 (8.0)
Coronary disease		
0	84 (56.4)	101 (67.3)
1	40 (26.8)	37 (24.3)
2	25 (16.8)	12 (8.0)
Renal insufficiency	15 (10.1)	21 (14)
Pulmonary disease	42 (28.2)	29 (19.3)
SVS/AAVS risk	1.65 ± 0.51	1.51 ± 0.53
ASA classification		
1	12	16
2	89	99
3	48	34
4	—	2
AAA classification		
Type A	48	50
Type B	52	56
Type C	16	17
Type D	21	17
Type E	4	6
Type F = saccular	1	—
Type G = iliac	6	5
AAA diameter,[b] mm	55.6 ± 6.6	55.2 ± 8.1

AAA, Abdominal aortic aneurysm; *ASA,* American Society of Anesthesiologists; *EVAR,* endovascular aneurysm repair; *SVS/AAVS,* Society for Vascular Surgery/American Association for Vascular Surgery.
[a]Categoric data are presented as number (%) and continuous data as means ± standard deviation and as noted.
[b]Excluding 11 iliac aneurysms.

Table II. Details of aneurysm repair

Variable[a]	*Open repair (n = 149)*	*EVAR (n = 150)*	P
Length of intervention, hours	2.8 ± 1.1	2.1 ± 0.9	<.0001
X-ray exposure time, minutes	1.9 ± 7.2	16.3 ± 13.5	<.0001
Contrast volume, mL	13 ± 46	131 ± 101	<.0001
Ventilatory support, hours	8 ± 13.7	3.2 ± 2.5	<.0001
Median	5.5	3.0	
RBC transfusion, U	2.1 ± 4.0	0.2 ± 0.9	<.0001
Median	2.0	0	

EVAR, Endovascular aneurysm repair; *RBC,* red blood cells.
[a]Data are presented as mean ± standard deviation, unless otherwise indicated.

after EVAR: two patients had documented endoleaks (one type I and one type II) which were awaiting treatment, and one patient ruptured 2 months after a normal CT scan due to a sudden disconnection between the distal limb of the graft and the recipient iliac artery. All three patients underwent emergency aortic repair: one patient died postoperatively, one patient died at 4 months, and one patient survived.

Table III. In-hospital postoperative data

Variable[a]	*Open repair (n = 149)*	*EVAR (n = 150)*	P
Length of stay, days	10.4 ± 8.3	5.8 ± 5.5	<.0001
Median	8.0	5.0	. . .
30-day deaths (all causes)	1 (0.6)	2 (1.3)	NS
Major adverse events, patients[b]	1 (0.6)	3 (2)	NS
Acute MI	1	1	. . .
Paraplegia	. . .	1	. . .
Renal failure	. . .	1	. . .
Stroke	. . .	1[b]	. . .
Reinterventions, patients	2 (1.3)	8 (5.3)	NS

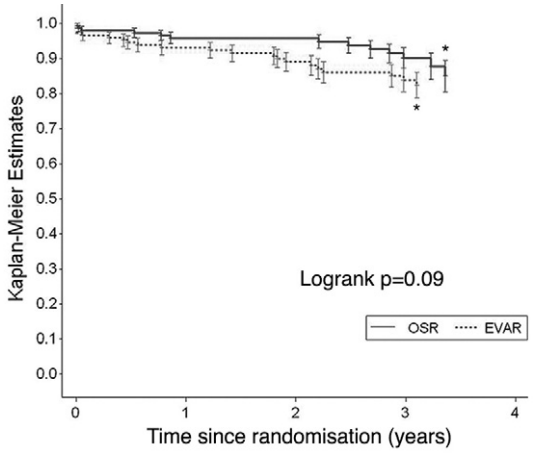
EVAR, Endovascular aneurysm repair; *MI,* myocardial infarction.
[a]Continuous data are shown as mean ± standard deviation and median; categoric data are number (%).
[b]Five complications occurred in 4 patients in the EVAR arm, and this patient also had renal failure.

Table IV. All outcome measures in study patients

Variable	*Open repair (n = 149) No. (%)*	*EVAR (n = 150) No. (%)*	P
Deaths	12 (8)	17 (11.3)	NS
Major adverse events	6 (4)	10 (6.7)	NS
Stroke	1 (0.7)	1 (0.7)	NS
Myocardial infarction	4 (2.7)	6 (4)	NS
Paraplegia	. . .	1 (0.7)	NS
Renal failure	1 (0.7)	3 (2)	NS
AAA rupture	. . .	3 (2.0)	NS
Reinterventions	4 (2.7)	24 (16)	<.0001
Minor adverse events	73 (48.7)	62 (41.3)	NS
Hemorrhage	7 (4.7)	4 (2.7)	NS
Infection	11 (7.4)	14 (9.3)	NS
Minor cardiac complications	19 (12.8)	9 (6)	<.05
Respiratory complications	8 (5.4)	5 (3.3)	NS
Atheroembolism	1 (0.7)	3 (2)	NS
Graft infection	1 (0.7)	. . .	NS
Lymphorrhea/lymphocele	. . .	4 (2.7)	NS
Incisional complications	38 (25.5)	1 (0.7)	<.0001
Buttock claudication	3 (2)	21 (14)	<.001
Sexual dysfunction	11 (7.4)	7 (4.7)	NS

Reinterventions. Fig 3 shows that there was a significant difference in the cumulative survival free of death and vascular reintervention rates—including graft replacement and endovascular or open repair of endoleaks, occlusions or stenoses—between OSR and EVAR, with 96.5% ± 1.5% vs 91.3% ± 2.3% at 1 year and 85.8% ± 4.5% vs 76.1% ± 4.6% at 3 years, respectively ($P = .01$). In the EVAR group, the crude percentage of vascular reintervention rate was higher (2.7% vs 16%, $P < .0001$) with a trend toward a higher aneurysm-related mortality (0.7% vs 4%; $P = .12$).

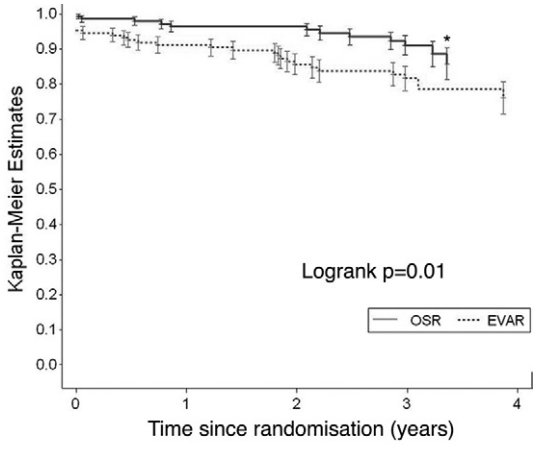
Minor complications. There was no significant difference in minor complications between OSR and EVAR.



Numbert at risk					
OSR	149	132	116	68	19
EVAR	150	129	103	71	26

* SED exceeds 10%

Fig 2. Kaplan-Meier curve of survival free of death or major events after open surgical repair (*OSR*) or endovascular aneurysm repair (*EVAR*).



Numbert at risk					
OSR	149	132	116	68	19
EVAR	150	128	103	71	25

* SED exceeds 10%

Fig 3. Kaplan-Meier curve of survival free of death or reintervention after open surgical repair (*OSR*) or endovascular aneurysm repair (*EVAR*).

However, the OSR group experienced more minor cardiac and incisional complications, whereas buttock claudication was more frequent in the EVAR group. Of the incisional complications in the OSR group, 36.3% (29 of 80) occurred after a transperitoneal approach and 17.6% (9 of 51) after a retroperitoneal approach. Buttock claudication was mostly observed in patients with types C, D, E, or G aneurysms, in whom the hypogastric artery was coil embolized or lost (14 of 45 [31%]).

Endoleaks. CT scan found endoleaks in 41 of 150 patients (27%) in the EVAR arm. Among 10 type I endoleaks, 2 were treated by open surgery and graft replacement, 5 were successfully treated by an endoluminal procedure, and 3 were awaiting treatment at the time of this analysis. Of 31 type II endoleaks, 8 were treated by coil embolization, and 23 were left untreated.

Sexual function. Sexual assessment 1 year after treatment showed no difference between the two treatments (Table IV), although there was a trend toward more sexual dysfunction in the OSR group.

Given the crossover rate, a per-protocol analysis was performed but did not change the conclusions.

DISCUSSION

The ACE trial shows that EVAR or OSR in low-risk to moderate-risk patients carries a similar risk of early-term and medium-term (up to 4.8 years) death, major adverse events, and minor complications. However, EVAR was associated with more vascular reinterventions and a trend toward higher aneurysm-related mortality.

Three RCTs[2-4] have reported lower 1-month postoperative mortality rates after EVAR compared with OSR (difference range, 2.5%-4.1%). Accordingly, the propensity score-matched analysis of a 45,660 cohort of Medicare patients confirmed a reduction in the postoperative mortality after EVAR (1.2% vs 4.8%).[10] In ACE, we did not find such a reduction after EVAR: the postoperative mortality rate was very low in the OSR group, whereas mortality after EVAR was in the same range as the three previous RCTs (0.5% to 2.1%). After OSR, a similar low mortality rate of 3% was found in Veterans Affairs Open versus Endovascular Repair (OVER) trial,[2] in control groups of the U.S. Food and Drug Administration phase 2 trials (range, 0%-2.7%),[11-13] and in centers of excellence,[14,15] but the rate was 4.1% in Dutch Randomised Endovascular Aneurysm Management (DREAM)[4] trial and 6.2% in the Comparison of Endovascular Aneurysm Repair with Open Repair in Patients with Abdominal Aortic Aneurysm (EVAR 1) trial.[3]

Among numerous factors potentially accounting for differences in mortality rates, study design, population studied, selection of centers, national standards of care, and date of publication may be relevant. Although most patients in the three previous RCTs were fit for surgery, baseline characteristics may not be fully identical, and a similar distribution of risk factors does not fully take into account the association of risks. The OVER trial used the RAND surgical risk score, with only 53% patients categorized as at low risk for surgery. Patients in EVAR 1 or DREAM may have been at higher risk for OSR because risk assessment was left to each center team's appreciation.

We chose the SVS/AAVS grading system. Although it may be less accurate than scoring systems such as the Physiological and Operative Severity Score for enUmeration of Mortality and Morbidity (POSSUM) score,[16] Glasgow Aneurysm Score,[17] or the fitness score proposed by the EVAR-1 trial-

ists,[18] it may have excluded severe risk factors such as renal, cardiac, or pulmonary insufficiencies more efficiently than previous trials. As in the OVER trial, and by hazard of enrollment, fewer women were enrolled which may affect the generalization of the results. More favorable results after OSR may also be explained by the size of aneurysms in the ACE trial, smaller than EVAR 1, but similar to OVER and DREAM. However, results of the OVER trial suggest a very limited role of AAA diameter on the early outcome in the population studied in those RCTs. Finally, the favorable anatomy for EVAR of all randomized patients also means an easier and more straightforward open surgical repair.

Volume and qualification of centers are important to successfully deal with postoperative complications.[19] The volume threshold is about 30 cases/year.[20,21] A review of 3912 patients undergoing AAA repair[22] found postoperative mortality was 2.2% for vascular surgeons, 4% for cardiac surgeons, and 5.5% for general surgeons ($P < .001$). In the frame of RCTs, it is difficult to compare centers: in ACE, as in OVER, OSR was performed by full-time vascular surgeons, but in the EVAR 1 trial, although a few highly trained centers performed EVAR, OSR was also performed by general surgeons.

DREAM and EVAR-1 trialists enrolled patients between 1999 and 2003, OVER started in 2002, and ACE in 2003: we cannot exclude that improvement in patients' preoperative, intraoperative, and postoperative management affected mortality reduction.

As reported in previous RCTs and defined in practice guidelines,[23] blood loss, need for transfusion, duration of postoperative mechanical ventilation, and hospital length of stay were significantly lower in the EVAR group. However, we did not find a significant reduction of postoperative general complication rates between the two treatments. Of note, the length of stay after both techniques was longer than usually reported in the United States. This had more to do with the difference in the health care system and behaviors of patients and physicians than with the occurrence of complications. The length of stay was much shorter with EVAR.

Survival, with a median follow-up of 3 years (up to 4.8 years) did not differ between the two treatments options. These results, consistent with the 2-year results of the DREAM[4] and OVER[2] trials and the 4-year results of EVAR-1,[3] are confirmed by recent reports of, respectively, 6 and 8 years of follow-up for DREAM[24] and EVAR-1.[25] The expected less invasiveness of EVAR did not translate into a significant reduction of death or of major adverse events, which is also in agreement with the OVER trial findings. In other words, low-risk and intermediate-risk patients sustain well the more aggressive treatment of OSR.

AAA ruptures remain the Achilles' heel of EVAR. Despite a thorough follow-up, three ruptures (2%) occurred in the EVAR arm, leading to two deaths despite emergency intervention. Two ruptures may have been prevented by more expedient treatment of identified endoleaks and in the third patient by a longer limb overlap in the common iliac artery. The OVER trial did not report any rupture, but follow-up was shorter (1.8 years). The DREAM[24] trial reported one rupture before treatment, and the possibility of rupture in two patients who died after EVAR was considered but not proven. EVAR-1 reported 13 ruptures: 10 before treatment, and 3 after treatment (2 after EVAR, 1 after OSR).

The distribution of recorded complications differed according to treatment: more buttock claudication occurred after EVAR and more incisional complications after OSR. Buttock claudication is a well-known complication of overlapping hypogastric arteries by the limb of a stent graft when the aneurysm extends close to or involves the hypogastric bifurcation. Although spontaneous improvement can be expected over time, we previously reported that 15% of patients remain disabled despite rehabilitation.[26] The patency of the hypogastric artery should be maintained, whenever feasible, in healthy patients, especially those who have normal walking activity, such as most of the patients in this trial. At present, this may be achieved by inserting currently available large distal limbs in the common iliac artery or by using branched stent grafts in selected cases.[27]

Incisional complications are frequent after OSR and seem more frequent in patients with AAA than in patients with occlusive disease.[28] In the OVER trial, 5% of patients in the OSR group underwent incision hernia repair. Similarly to EVAR-1 and DREAM, we did not record specifically all abdominal wall repairs or the incidence of bowel obstruction. That 24% of the patients in our OSR group presented incisional complications underlines one drawback of the open approach. Finally, the higher rate of minor cardiac complications in the OSR group may be related to a higher rate of coronary disease in this group or to the more invasive procedure, or both.

Similar to the OVER trial, where 12% of EVAR patients underwent a vascular reintervention vs 1.6% in the OSR group, in the ACE trial, vascular reinterventions occurred in 16% of the EVAR group vs 2.7% in the OSR group. In EVAR-1, the overall rates of graft-related complications and reinterventions were higher by a factor of three to four in the endovascular group. However, indications for reintervention were highly variable: rupture, thrombosis, or type I endoleak were indications for reintervention, whereas the need for reintervention in type II endoleaks was still debated. The DREAM[24] investigators rightly stated that reintervention is a "soft" end point because the decision is at the surgeon's discretion.

Finally the lack of significant difference in sexual function impairment between OSR and EVAR in ACE trial is consistent with the OVER[2] and DREAM[29] findings.

One weakness of this study was the slow pace of enrollment and the failure to reach the expected number of patients. This may have affected the power of the analysis, as may have been the case in the DREAM trial, which was of a similar magnitude. Except for the early mortality rates, however, our findings were in agreement with the three previous RCTs. A meta-analysis of these four trials may help to clarify the relative indication of EVAR and open surgery in AAA patients.

Finally, these results, as those of previous trials, reflect current stent graft technology. With continuous advances in stent graft design, it may be possible, as shown by the Euro-

pean Collaborators on Stent-Graft Techniques for AAA and Thoracic Aortic Aneurysm and Dissection Repair (EUROSTAR) results,[30] that the durability of EVAR will improve in the future.

CONCLUSIONS

In a selected group of patients with low to intermediate risk factors, OSR and EVAR offer no difference in survival or in major and minor complications. The choice between OSR and EVAR should rely on the balance of different risks: more postoperative transfusions, a longer hospital stay, and incisional complications with OSR vs the need of follow-up with repeat CT scans, a higher rate of vascular reinterventions, and a small but persistent risk of rupture with EVAR.

AUTHOR CONTRIBUTIONS

Conception and design: JPB, MS
Analysis and interpretation: JPB JM
Data collection: JPB JM, JCP, FL, YG, PL, ES
Writing the article: JPB JM
Critical revision of the article: JPB JM
Final approval of the article: JPB, JM, MS, JCP, FL, YG, PL, ES
Statistical analysis: JPB, JM
Obtained funding: JPB MS
Overall responsibility: JPB

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APPENDIX 1 (ONLINE ONLY).

ACE study committees and organization

Writing committee: Jean-Pierre Becquemin (corresponding author), Jean Marzelle

Principal investigators: Jean-Pierre Becquemin, Marc Sapoval

Scientific committee: Jean-Pierre Becquemin, Jean-Pierre Favre, Jacques Watelet, Patrick Lermusiaux, Marc Sapoval

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Surveillance committee: Peter Harris, Luc Stockx, Gilles Chatellier

Safety issues committee: Claude Mialhe, Jean-Noel Fiessinger, Luc Pagny, Hicham Kobeiter

End points and adverse events validation committee: Christian Boissier, Philippe Lacroix, François Ledru, Jean-Jacques Pinot Jean-François Deux, Boyan Tzvetkov, Philippe Duvaldestin, Jacques Watelet

Data management: Cécile Jourdain, Virginie David, Delphine Enouf, Namou Ady, Amor Krimi, Noël Boudjema

APPENDIX 2 (ONLINE ONLY).

ACE trial participating centers and physicians with corresponding number of cases.

CHU Angers– Hôtel Dieu, Angers: Yann Jousset, Bernard Enon, Vincent Blin, Jean Picquet, Philippe L'Hoste, Francine Thouveny (n = 3);

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Hôpital Henri Mondor, Creteil: Jean-Pierre Becquemin, Pascal Desgranges, Eric Allaire, Jean Marzelle, Hicham Kobeiter (n = 102);

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Hôpital Européen Georges Pompidou, Paris: Pierre Juliae, Jean Noël Fabiani, Patrick Chevalier, Myriam Combes, Agathe Seguin, Denis Belhomme, Marc Sapoval, Jean Baque, Olivier Pellerin (n = 3);

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Clinique Saint-Augustin, Nantes: François Lescalie, Gérard Tilly (n = 25);

Hôpital du Bocage, Dijon: Eric Steinmetz, Claire Favier, Roger Brenot, Denis Krause, Jean Pierre Cercueil (n = 15);

Clinique Pasteur, Toulouse: Olivier Vahdat, Michel Sauer, Philippe Soula, Aristide Querian, Olivier Garcia, Michel Levade, Daniel Colombier (n = 2);

Clinique des Franciscaines, Nimes: Jean-Marie Cardon, André Joyeux, Pierre Borrelly, Georges Dogas (n = 10);

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Hôpital La Cavale Blanche, Brest: Pierre Gouny, Ali Badra, Jacques Braesco, Michel Nonent (n = 2);

Hôpital Sud, Rennes: Antoine Lucas, Alain Cardon, Yvon Kerdiles, Yann Rolland (n = 3);

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