

MINDFUL PRACTICE

EVAR vs. Open Repair of AAA

BY JON O. EBBERT, M.D., AND ERIC G. TANGALOS, M.D.

The Problem

A 68-year-old man with a history of diabetes and hypertension presents to your clinic for follow-up of multiple medical issues. His diabetes and hypertension are under adequate control, and he has a known abdominal aortic aneurysm (AAA) that you have been following. On his most recent examination, the diameter of his AAA had increased to 5.6 cm. You previously obtained a vascular surgery consult, and they suggested that he undergo an endovascular aneurysm repair (EVAR) when the aneurysm was larger than 5.5 cm or was rapidly expanding. You have another patient who underwent EVAR, had an endoleak, required a reintervention, and has periodic CT scans for follow-up. You wonder if EVAR is worth the benefit of not undergoing an open repair with its attendant risks.

The Question

In patients undergoing elective AAA repair, does EVAR improve mortality and quality of life and reduce expenditures, compared with open repair?

The Search

You log on to PubMed (www.pubmed.gov), enter search term "endovascular aneurysm repair," and limit results to randomized controlled trials. You find a relevant study. (See box at right.)

Our Critique

As the authors of this important study highlight, complications are more common and costs are higher with EVAR. Long-term surveillance does not appear to be needed for open repair but is required for EVAR. Differences in the aneurysm-related mortality at 4 years (4% with EVAR vs. 7% with open repair) corresponds to the 3% difference in operative mortality at 30 days favoring EVAR. The number of EVAR procedures has surpassed the number of open repairs at some institutions. The higher costs of EVAR should give us some pause. Perhaps as interventionists develop new skills and techniques, costs will drop, but this study suggests that upfront costs of open repair can be quickly matched by costs generated by complications, reinterventions, and surveillance required with EVAR. Importantly, emerging data from a 9-year study in the U.S. Veterans Affairs system (see story at right) suggests the possibility that lower early morbidity and mortality can be achieved with newer EVAR techniques that could change its cost-benefit analysis.

Clinical Decision

You suggest to the patient that an open repair will require less follow-up and he will be less likely to have a complication. However, EVAR will be associated with less perioperative risk. He elects to undergo EVAR. The patient has had no complications, and you follow up with CT scans.

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**EVAR Trial Participants.**

Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1). Lancet 2005;365:2179-86.

► **Design and Setting:** Randomized clinical trial done at multiple hospitals in the United Kingdom.

► **Patients:** Patients were eligible for enrollment if they were 60 years or older, had an aneurysm measuring at least 5.5 cm diameter in any plane on CT, and were medically well enough to undergo anesthesia for elective, nonemergent open repair.

► **Intervention:** Patients were randomized to EVAR or open repair.

► **Outcomes:** The primary outcome was all-cause mortality. Deaths were adjudicated by a blinded end-point committee that assigned the cause of death. Secondary outcomes included aneurysm-related mortality, incidence of postoperative complications of aneurysm repair and secondary interventions, health-related quality of life, and hospital costs. Aneurysm-related mortality was defined as deaths within 30 days of AAA surgery unless overruled by post-mortem findings or if a separate procedure unrelated to the aneurysm took place between aneurysm repair and death and was attributed as the cause of death.

► **Results:** Of 1,423 eligible patients, 1,082 were randomized (543 EVAR, 539 open repair). Groups were similar at baseline, with a mean age of 74 years; 91% were men, and median aneurysm diameter was 6.2 cm (interquartile range 5.8-7.0). All patients were followed for 1 year, 70% for 2 years, 47% for 3 years, and 24% for 4 years. During follow-up, 209 deaths were observed, with 100 deaths in the EVAR group and 109 in the open repair group. All-cause mortality at 4 years after randomization was similar between the two groups (hazard ratio 0.90; 95% CI 0.69-1.18). However, a significant difference in aneurysm-related deaths was observed favoring EVAR (HR 0.55; 95% CI 0.31-0.96). Post hoc analyses analyzing time since randomization found that for the first 6 months after surgery, the hazard ratio for aneurysm-related mortality was 0.42 (95% CI 0.21-0.82) favoring EVAR and 1.15 (95% CI 0.39-3.41) for the period after 6 months. By 4 years, the proportion of patients with at least one complication after AAA repair was 41% in the EVAR group, compared with 9% in open repair. Rates of complications were 17.6 per 100 person-years in the EVAR group and 3.3 per 100 person-years in open repair. The rate of at least one reintervention was 6.9 per 100 person-years in the EVAR group and 2.4 per 100 person-years in the open repair group. Health-related quality of life did not differ by group at 12-24 months after randomization, although it was lower at 0-3 months in the open repair group. The overall costs per patient were higher in the EVAR group than in the open repair group.

EVAR Advantages Still Apparent at 2 Years

BY MARY ANN MOON

Endovascular repair of abdominal aortic aneurysms led to lower perioperative mortality than open surgical repair in a large randomized trial, as expected.

However, unlike in earlier studies, this early advantage was not offset by higher rates of late morbidity and mortality during 2 years of follow-up (JAMA 2009;302:1535-42). Two previous European studies showed that reintervention was more frequent with the endovascular approach, so that the early survival advantage it conferred was lost within 2 years of follow-up, said Dr. Frank A. Lederle and his associates in the Open Versus Endovascular Repair (OVER) study group.

The OVER study was undertaken because surgical techniques and devices have improved since the European trials were reported.

Dr. Lederle and his colleagues are performing an ongoing study comparing endovascular against open AAA repair, with the primary outcome of long-term all-cause mortality to be determined in 2011. The current report presents the interim results after 2 years of follow-up.

The 881 patients, aged 49 and older, were treated electively at 42 medical centers by 109 experienced vascular surgeons. A total of 444 patients were randomly assigned to endovascular repair in which an expandable graft system was introduced transluminally. The other 437 patients were assigned to open repair in which a vascular graft was placed anatomically via an abdominal or retroperitoneal incision. Eligible patients had a maximum external AAA diameter of at least 5.0 cm, an associated iliac aneurysm with a maximum diameter of at least 3.0 cm, or a maximum AAA diameter of 4.5 cm plus either rapid enlargement or sacular morphology.

The study subjects were followed in person at 1, 6, and 12 months, and yearly thereafter. They also were followed by phone every month for the first 14 months after the procedure, then annually between study visits, said Dr. Lederle of the Veterans Affairs Medical Center, Minneapolis, and his associates.

Endovascular repair required significantly less procedure time, duration of mechanical ventilation, ICU stay, and hospital stay, and it resulted in less blood loss and fewer transfusion requirements. However, it required substantial exposure to fluoroscopy.

Perioperative mortality was significantly higher with open repair (2.3%) than with endovascular repair (0.2%), as expected. However, unlike in previous studies, all-cause mortality did not increase to a greater degree with endovascular repair over time. There was no significant difference in all-cause mortality between open repair (9.8%) and endovascular repair (7.0%) at 2 years, the investigators said.

There also were no significant



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DR. LEDERLE

differences in procedure failure rates, the need for secondary procedures, aneurysm-related hospitalizations, or major morbidity. These findings remained consistent regardless of patient age and surgical risk status, the diameter of the aneurysm, the presence or absence of coronary artery disease, and the type of graft device used.

In addition, there were no significant differences between the two groups in health-related quality of life or in erectile function. "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," Dr. Lederle and his associates said.

However, all four late deaths that were related to aneurysm in this study occurred in the endovascular group, they noted.

"Longer-term studies are needed to fully assess the relative merits of the two procedures," the researchers said.

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