RESEARCH HIGHLIGHTS

Endovascular repair of abdominal aortic aneurysm —the importance of long-term follow-up data

ndovascular repair of abdominal aortic aneurysms has been associated with lower short-term mortality than open surgical repair. The results of multicenter trials published in the *New England Journal of Medicine* now provide long-term follow-up data that will help better evaluate the relative merits of the two approaches.

The first of these studies, the EVAR 1 (United Kingdom Endovascular Aneurysm Repair 1) trial, involved 1,252 patients with abdominal aortic aneurysms \geq 5.5 cm in diameter. The study started in 1999 and patients were followed up for a minimum of 5 years and a maximum of 10 years (median 6 years). The second trial, the DREAM (Dutch Randomized Endovascular Aneurysm Repair) study, started in 2000 and involved 351 patients with abdominal aortic aneurysms ≥ 5 cm in diameter, who were followed up between 5.1 and 8.2 years (median 6.4 years). In both studies, patients were randomly assigned to receive either endovascular or open repair.

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The differences in 30-day mortality (1.8% among patients who received endovascular repair and 4.3% in the openrepair group) and 6-month aneurysmrelated mortality that were observed in the EVAR 1 trial corroborate earlier findings that endovascular repair is superior to open surgery in the short term. The EVAR and DREAM investigators, however, show that this benefit is lost in the long term: in both trials, the allcause mortality of the two intervention groups was not significantly different by the end of the study period. This finding seems at least partially the result of an increase in aneurysm-related mortality in the endovascular-repair group, owing to endograph rupture. "Patients will now have to be briefed carefully of the relative strength of the two methods," summarizes EVAR lead investigator Roger Greenhalgh.

Importantly, patients who were treated by endovascular repair had a significantly higher need of reintervention during follow-up than patients who had open repair surgery (adjusted hazard ratio 2.86 in the EVAR 1 trial and an 11.5 percentage point difference in the DREAM trial). The EVAR investigators also observed that the rate of graft-related complications was significantly higher in the endovascularrepair group than in the open-repair group (adjusted hazard ratio 4.39), and that endovascular repair was more costly. Dr Greenhalgh and colleagues plan to report on their analysis of late ruptures associated with endovascular aortic aneurysm repair devices, and their associated factors, in November 2010. "This will indicate which follow-up factors are important," he says.

The modifications on endovascular repair devices that have taken place since the beginning of these trials might change the rate of complications and/or mortality associated with endovascular repair. Nevertheless, "patients will now know the risks of endovascular and open repair, and be better able to enter into a dialogue with their doctor," says Dr Greenhalgh.

For patients who are very ill from comorbidities, however, the choice between endovascular and open repair is not an option. Patients who are too physically frail to undergo open repair can receive either no intervention or endovascular repair (provided that they are anatomically suitable). "The question here is if endovascular repair prevents rupture and, if so, if this translates to better all-cause mortality," explains Dr Greenhalgh. In the EVAR 2 randomized study, he and his colleagues



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compared the outcomes of endovascular repair with no intervention in a population of 404 patients with abdominal aortic aneurysms ≥5.5 cm in diameter.

In EVAR 2, endovascular repair prevented aneurysm rupture in this patient population, which was associated with a decrease in mortality after intervention: the rate of aneurysm-related death among patients who underwent endovascular repair was 3.6 deaths per 100 person-years, but was 7.3 per 100 person-years among patients who did not undergo intervention. "At least the fear of sudden aneurysm rupture is removed," Dr Greenhalgh points out. As so many patients died during follow-up in EVAR 2, however, all-cause mortality did not significantly differ between the two groups, although a perprotocol analysis indicated that endovascular repair is superior to no repair. Commenting on the comparison made in EVAR 2, Dr Greenhalgh says that "it is a shame that this trial is unique".

Overall, as Dr Greenhalgh concludes, these results emphasize the benefits of careful and long follow-up in randomized controlled trials.

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Original articles The United Kingdom EVAR Trial Investigators. Endovascular versus open repair of abdominal aortic aneurysm. *N. Engl. J. Med.* **362**, 1863–1871 (2010) | De Bruin, J. L. *et al.* Long-term outcome of open or endovascular repair of abdominal aortic aneurysm. *N. Engl. J. Med.* **362**, 1881–1889 (2010) | The United Kingdom EVAR Trial Investigators. Endovascular repair of aortic aneurysm in patients physically ineligible for open repair. *N. Engl. J. Med.* **362**, 1872–1880 (2010)