

Open Repair Is Still the “Gold Standard” for Good Risk Patients with Abdominal Aortic Aneurysms: Conservative Treatment Is best for Abdominal Aortic Aneurysms Less Than 5.0 cm in Diameter

NOTES

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The aim of open surgical or endovascular treatment of abdominal aortic aneurysms (AAAs) is to prevent rupture, the most frequent and lethal complication of this disease. Since the introduction of endovascular aortic aneurysm repair (EVAR) more than a decade ago, encouraging data have accumulated on thousands of patients who underwent endovascular treatment with a low early morbidity and mortality. However, the need for continuous postoperative surveillance using expensive imaging studies, high cost of the device, complications, the need for reinterventions, late ruptures and lack of evidence of improved late mortality and a better quality of life continue to question the value and specific indications of EVAR.

Results of open surgical treatment of abdominal aortic aneurysms (AAAs), on the other hand, have continuously improved during the past five decades. This can be attributed to progress in evaluation and imaging modalities, improved patient selection, better surgical techniques (retroperitoneal and mini-laparotomy exposures), and sophisticated perioperative care. Early mortality rates of elective open repairs reported from centers of excellence have been between 0 and 14%, and in 9,291 operated cases, reported by Rutherford and Krupski,¹ mortality averaged 3.2%. Mortality rates in several large centers with high number of operations were reported to be less than 2.5%. Perioperative mortality after conventional open repair for AAAs in multi-institutional, community, or statewide series still ranged from 2.6 to 13.6%.

Indications for open surgery were defined in 2003 in the guidelines of the Joint Vascular Societies.² Based on data of prospective randomized multicenter studies surgical treatment is recommended over observation for males who harbor an abdominal aortic aneurysm of 5.5 cm in diameter or greater and for females who have an aortic aneurysm of 5.0 cm or larger.^{3,4} Recent recommendation of the US Preventive Services Task Force (USPSTF) also found good evidence that surgical repair of AAAs 5.5 cm or larger in men age 65 to 75 years who have ever smoked leads to decreased AAA-specific mortality.⁵

EVAR has emerged during the past decade as an excellent alternative but less risky treatment for AAAs, and studies showed decreased early mortality and morbidity compared with open surgical repair. A recent review even questioned if EVAR was not the new “gold standard” for repair of AAAs?⁶ The sound answer of the review by Kent and colleagues was a definite no. Since then additional data were published that sheds light on further problems with EVAR. Short-term advantages of this procedure, confirmed in multiple controlled and randomized studies, did not hold up in large prospective trials, which randomized patients for EVAR and open surgical treatment.

In the EVAR-1 study, Greenhalgh and colleagues, from the United Kingdom, compared EVAR to open surgery in 1,082 patients, who had aneurysms of at least 5.5 cm in diameter.⁷ The primary end point was all-cause mortality, with secondary end points of aneurysm related mortality, health-related quality of life, postoperative complications, and hospital costs. Four years after randomization, no difference was noted in all-cause mortality (about 28%) although aneurysm-related deaths was 3% less after EVAR than after open surgery (4% versus 7%). The proportion of patients with postoperative complications within 4 years of randomization was 41% in the EVAR group and 9% in the open repair group. After 12 months, there was no difference in quality of life and mean hospital costs per patient up to 4 years were £13,257 for the EVAR group versus £9,946 for the open repair group. The authors concluded that EVAR in the long run offers no advantage with respect to all-cause mortality and health-related quality of life. In addition, EVAR is more expensive and leads to a greater number of complications and reinterventions. The issue, however, remains somewhat unanswered in this study since there was a 3% better aneurysm-related survival in the EVAR group.

The Dutch Randomized Endovascular Aneurysm Management (DREAM) Trial, published by Blankensteijn and colleagues in the *New England Journal of Medicine*,⁸ randomized 351 patients with aneurysms 5 cm or greater to EVAR and open surgical repair. The investigators found no survival difference at 2 years, with a cumulative survival rate of 89.6% for open repair and 89.7% after EVAR. Because of low perioperative mortality, survival at 2 years was better in the EVAR group. Still, with publication of results of this trial EVAR got another step further away from becoming the gold standard for AAA repair.

EVAR was presumed to be particularly effective in the treatment of high-risk patients. However, sobering data were published in *The Lancet* on results of the EVAR 2 study, which randomized 338 patients unfit for open surgery to EVAR versus observation.⁹ Greenhalgh and colleagues did not find any benefit of EVAR over observation of aneurysms in high risk patients, unfit for open surgical repair. Thirty-day mortality after EVAR was 9% and mortality at 4 years in the entire group was 64%. There was no difference in late overall mortality, nor was there a difference in aneurysm related mortality between the two groups. Hospital costs were significantly higher in the EVAR group, and there was no health-related quality of life benefit.

How should results of these trials influence our decision to treat patients with AAAs? As Cronenwett points out in his recent commentary of the UK EVAR trials, the key variables that determine the benefit of open repair versus EVAR are perioperative mortality and late aneurysm-related death.¹⁰ In our practice, open repair remains the gold standard for the treatment of AAAs and open surgery (transabdominal, retroperitoneal, or minilaparotomy) is offered as the first option to all good risk patients less than 70 years of age. Exceptions to this could be patients with excellent anatomic suitability and those informed patients who prefer to undergo endograft repair. Although high-risk patients with good anatomic suitability could benefit most from EVAR, data of the EVAR 2 study should be analyzed critically: many high-risk patients, unfit for open repair, especially those with moderate to poor anatomic suitability for EVAR, should be managed nonoperatively.

The management of small AAAs continues to be controversial. There is no doubt that some small aneurysms will rupture, and research on computerized stress analysis of the aneurysm wall is eagerly awaited to assist in selection of patients with small aneurysms who need early elective repair. Since the natural history of AAAs is that of continued expansion, intervals between surveillance imaging studies have to be adjusted appropriately: those with higher than the usual expansion rate (0.25 to 0.35 cm/yr) and smokers need the most frequent follow-up.¹¹ Since evidence from randomized trials^{12,13} indicates that early, open, elective surgery for aneurysms less than 5.5 cm in males and less than 5 cm in females does not save lives, observation rather than surgical treatment should be offered to most of these patients. Those who have small but unusual saccular aneurysm, those with an AAA of rapid expansion rate, those with a family history of ruptured aneurysms, and overly anxious patients can be considered for open or endovascular repair. Although current nonrandomized data suggest that EVAR for small aneurysms may have lower complication rates, fewer secondary interventions, fewer late ruptures and a lower rate aneurysm-related deaths than open repair, results of the PIVOTAL trial will be needed to support the conclusion that small aneurysms less than 5 cm in size should be treated with endografts. A minimum of 4 more years are required to resolve this important issue. Until then, conservative treatment remains the best for AAAs < 5.0 cm in diameter.

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