

# Do Results of the EVAR 1 Trial Justify Endovascular Repair of All Abdominal Aortic Aneurysms in Patients with Suitable Anatomy?

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## Purpose

Endovascular aneurysm repair (EVAR) to exclude abdominal aortic aneurysm (AAA) was introduced in the early 1990s for patients of poor health status considered unfit for major surgery. As the technology has progressed, EVAR has become an alternative choice of treatment for patients considered fit for open repair as it is minimally invasive and generally involves a shorter hospital stay. The two EndoVascular Aneurysm Repair (EVAR) Trials were instigated to assess the safety and efficacy of endovascular aneurysm repair in the treatment of AAA in terms of mortality, quality-of-life, durability, and cost-effectiveness for patients considered fit (EVAR Trial 1) or unfit (EVAR Trial 2) for open repair.

## Methods

Full methods have been published previously.<sup>1</sup> Between September 1999 and December 2003, male and female patients aged at least 60 years with an AAA diameter measuring at least 5.5 cm on a computed tomography (CT) scan were assessed for anatomical suitability for EVAR across 41 eligible UK centers. Suitable patients were offered entry either into the EVAR Trial 1, if they were considered fit for conventional open repair, or the EVAR Trial 2 if they were considered unfit. EVAR 1 randomly allocated patients to EVAR or open repair and EVAR 2 randomly allocated patients to EVAR with medical treatment or medical treatment alone. Target recruitment for EVAR Trials 1 and 2 was 900 and 280 patients, respectively. Patients were followed up for a minimum of 1 year to December 31, 2004, and were all flagged for mortality at the Office for National Statistics with death certificates reviewed by an independent end points committee for cause of death. Patients were also followed in terms of health-related quality-of-life (HRQL), costs and cost-effectiveness, graft complications, and secondary interventions.

## Results

Full results have been published previously.<sup>2,3</sup> By the end of planned recruitment on December 31, 2003, 1,082 had been entered into EVAR Trial 1, with 543 allocated to EVAR and 539 allocated to open repair. Patients (983 men, 99 women) had a mean age of 74 years (SD 6 years), a mean aneurysm diameter of 6.5 cm (SD 1.0). Ninety-four percent of patients complied with their allocated treatment and by the end of mid-term follow-up in December 2004, 209 patients had died, 53 from aneurysm-related causes. Early 30-day postoperative mortality was significantly lower in the EVAR group 1.7% versus 4.7%, logistic regression hazard ratio 0.35 (95% CI 0.16–0.77,  $p = .009$ ). Four years after randomization, all-cause mortality was similar (about 28%) comparing the EVAR to the open repair group, hazard ratio 0.90 (95% CI 0.69–1.18), although there was a persistent reduction in aneurysm-related deaths in the EVAR group (4% vs 7%), hazard ratio

0.55 (95% CI 0.31–0.96,  $p = .04$ ). The proportion of patients with postoperative complications within 4 years of randomization was 41% in the EVAR group, compared with 9% in the open repair group, hazard ratio 4.9 (95% CI 3.5–6.8,  $p < .0001$ ). After 12 months, there was negligible difference in HRQL between the two groups. The mean hospital costs per patient up to 4 years were £13,257 for the EVAR group versus £9,946 for the open repair group, mean difference £3,311 (SE 690).

## Current Interpretation for EVAR Trial 1

EVAR in fit patients had an ongoing 3% better aneurysm-related survival than open repair but no demonstrable all-cause mortality or HRQL benefit. The continuing need for interventions mandates ongoing surveillance and this leads to marginally increased costs. Longer term follow-up for detailed cost-effectiveness evaluation is underway.

## References

1. Brown LC, Epstein D, Manca A, et al. The UK EndoVascular Aneurysm Repair (EVAR) Trials: design, methodology and progress. *Eur J Vasc Endovasc Surg* 2004;27:372–81.
2. The EVAR Trial Participants. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR Trial 1), 30-day operative mortality results: randomised controlled trial. *Lancet* 2004;364:843–8.
3. The EVAR Trial Participants. Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR Trial 1): randomized controlled trial. *Lancet* 2005;365:2179–86.