Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial

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BACKGROUND
Short-term survival benefits of endovascular aneurysm repair (EVAR) versus open repair of intact abdominal aortic aneurysms have been shown in randomised trials, but this early survival benefit is lost after a few years. We investigated whether EVAR had a long-term survival benefit compared with open repair.

METHODS
We used data from the EVAR randomised controlled trial (EVAR trial 1), which enrolled 1252 patients from 37 centres in the UK between Sept 1, 1999, and Aug 31, 2004. Patients had to be aged 60 years or older, have aneurysms of at least 5·5 cm in diameter, and deemed suitable and fit for either EVAR or open repair. Eligible patients were randomly assigned (1:1) using computer-generated sequences of randomly permuted blocks stratified by centre to receive either EVAR (n=626) or open repair (n=626). Patients and treating clinicians were aware of group assignments, no masking was used. The primary analysis compared total and aneurysm-related deaths in groups until mid-2015 in the intention-to-treat population. This trial is registered at ISRCTN (ISRCTN55703451).

FINDINGS
We recruited 1252 patients between Sept 1, 1999, and Aug 31, 2004. 25 patients (four for mortality outcome) were lost to follow-up by June 30, 2015. Over a mean of 12·7 years (SD 1·5; maximum 15·8 years) of follow-up, we recorded 9·3 deaths per 100 person-years in the EVAR group and 8·9 deaths per 100 person-years in the open-repair group (adjusted hazard ratio [HR] 1·11, 95% CI 0·97-1·27, p=0·14). At 0-6 months after randomisation, patients in the EVAR group had a lower mortality (adjusted HR 0·61, 95% CI 0·37-1·02 for total mortality; and 0·47, 0·23-0·93 for aneurysm-related mortality, p=0·031), but beyond 8 years of follow-up open-repair had a significantly lower mortality (adjusted HR 1·25, 95% CI 1·00-1·56, p=0·048 for total mortality; and 5·82, 1·64-20·65, p=0·0064 for aneurysm-related mortality).
The increased aneurysm-related mortality in the EVAR group after 8 years was mainly attributable to secondary aneurysm sac rupture (13 deaths [7%] in EVAR vs two [1%] in open repair), with increased cancer mortality also observed in the EVAR group.

INTERPRETATION
EVAR has an early survival benefit but an inferior late survival compared with open repair, which needs to be addressed by lifelong surveillance of EVAR and re-intervention if necessary.

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