EVAR vs no intervention for patients in whom open surgery is not considered appropriate

Full citation	**EVAR 2 trial (results reported in multiple publications outlined in the Cochrane systematic review)** **NB: a new publication was identified from update searches** **Sweeting M J, Patel R, Powell J T, and Greenhalgh R M (2017) Endovascular Repair of Abdominal Aortic Aneurysm in Patients Physically Ineligible for Open Repair: Very Long-term Follow-up in the EVAR-2 Randomized Controlled Trial. Annals of Surgery. 24**
Study details	Study type: multicentre, non-blinded, randomised controlled trial Location: UK Aim: compare long-term total and aneurysm-related mortality in physically frail patients with AAA who were randomised to either early EVAR or no intervention Study dates: patients were recruited from September 1999 to August 2004 Follow-up: mean of 12 years Sources of funding: this study was funded by the National Institute for Health Research Health Technology Assessment programme

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Participants	Population: patients with large aneurysms in whom open surgical repair was considered inappropriate Sample size: 404; sex-specific proportions were not reported Inclusion criteria: patients over 60 years old with AAAs at least 5.5 cm in diameter (confirmed by computed tomography) who were considered physically ineligible for open repair, and anatomically suitable for EVAR, were included. The appropriateness of surgery was determined locally by the treating surgeon, radiologist, anaesthetist and cardiologist. Exclusion criteria: not reported Baseline characteristics: Mean age: EVAR group, 77.2 years; No repair group, 76.4 years Sex: EVAR group, 85.3% male; No repair group, 86.5% male Mean aneurysm diameter: EVAR group, 68.0 mm; No repair group, 67.0 mm Diabetes: EVAR group, 15.4%; No repair group, 14.1% History of cardiac disease: EVAR group, 67.0%; No repair group, 73.9%
Intervention	EVAR
Comparison	No intervention
Outcomes measures	All-cause mortality, aneurysm-related mortality, graft-related complications and graft-related re-interventions.
Risk of bias assessment (using Cochrane)	1. Random sequence generation (selection bias): Low risk – Randomisation was performed appropriately, using randomly permuted block sizes. 2. Allocation concealment (selection bias): Low risk – Allocation was done only after all baseline data were recorded 3. Blinding of participants and personnel (performance bias): Unclear – Due to the nature of the interventions, it was not possible to blind participants and personnel 4. Blinding of outcome assessment (detection bias): Unclear risk – insufficient information was available 5. Incomplete outcome data (attrition bias): Low risk – reasonable rates of loss to follow-up, and reasons for losses were explained 6. Selective reporting (reporting bias): Low risk – Study reported on all predefined outcomes

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	7. Other bias: High risk – there was a considerably high rate of crossover between groups: 33.8% (70/207) patients in the no intervention were ended up being treated by EVAR during the trial. Authors analysed 4- and 8-year follow-up data using a intention-to-treat approach, which would not have taken crossover into account. Overall risk of bias: high risk for analyses performed at 4-and 8-year follow-up; low risk for analyses performed at 12-year follow-up because appropriate measures were taken to minimise bias due to crossover. Directness: directly applicable