Endovascular or open repair strategy for ruptured abdominal aortic aneurysm: 30 day outcomes from IMPROVE randomised trial

IMPROVE trial investigators

EDITORIAL by Björck

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STUDY QUESTION

Should patients with clinical suspicion of ruptured abdominal aortic aneurysm be managed by an endovascular strategy (endovascular repair if anatomically suitable) or by open repair, to optimise survival and other outcomes?

SUMMARY ANSWER

30 day mortality was similar following an endovascular strategy (35%) and open surgical repair (37%), but women seemed to have lower mortality and patients were discharged home sooner with an endovascular strategy.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

For selected patients, observational studies indicate that 30 day mortality is much lower after endovascular repair than after open surgical repair, but two small randomised trials failed to show any survival advantage with endovascular repair. The large IMPROVE randomised trial starts to identify patients who may benefit from an endovascular strategy (such as women) and shows that, after 30 days, the endovascular strategy did not cost more than open repair and offers the patient earlier discharge home.

Design

This was a randomised controlled trial, stratified by centre, with computer generated allocation of patients to either an endovascular strategy (with open repair reserved for those anatomically unsuitable for conventional endovascular repair) or open repair.

Participants and setting

Eligible patients (n=613; 480 men) with a clinical diagnosis of ruptured aneurysm were recruited at 29 UK vascular centres and one Canadian centre, before evaluation of aortic anatomy, between 2009 and 2013. We randomised 316 patients to the endovascular strategy (275 confirmed ruptures and 8 acute symptomatic aneurysms (174/272 anatomically suitable for endovascular repair) and 33 other final diagnoses) and 297 patients to open repair (261 confirmed ruptures, 14 symptomatic aneurysms, and 22 other final diagnoses).

Main outcome measures

The primary outcome was 30 day mortality, with 30 day costs and time and place of discharge as secondary outcomes.

Results

Thirty day mortality was 35.4% (112/316) in the endovascular strategy group and 37.4% (111/297) in the open repair group: odds ratio 0.92 (95% confidence interval 0.66 to 1.28; P=0.62); odds ratio after adjustment for age, sex, and Hardman (morbidity) index 0.94 (0.67 to 1.33). Prespecified subgroup analyses showed that women seemed to benefit more than men from an endovascular strategy (interaction test, P=0.02) but no convincing differences with respect to Hardman index or age. For patients with confirmed rupture, 30 day mortality was 36% (100/275) in the endovascular strategy group and 41% (106/261) in the open repair group (P=0.31). More patients in the endovascular strategy group than in the open repair group were discharged directly to home (94% (189/201) *v* 77% (141/183); P<0.001). Average 30 day costs were similar between the randomised groups, with an incremental saving for the endovascular strategy versus open repair of £1186 (−625 to 2997).

Harms

The number of patients who died before aneurysm repair (endovascular strategy 6% (n=16), open repair 7% (19)) or who needed further interventions within 30 days (18% (43) *v* 20% (48)) did not differ between the randomised groups.

Bias, confounding, and other reasons for caution

All analyses were intention to treat. Overall, for 64/613 (10%) patients care did not adhere to the trial protocol. Although 30 day mortality was 38/150 (25%) for endovascular repair in the endovascular strategy group, the estimated unbiased causal odds ratio for 30 day mortality in a trial in which everyone adhered to randomised allocation still showed no significant benefit for the endovascular strategy (odds ratio 0.82, 0.51 to 1.32).

Generalisability to other populations

About two thirds of potentially eligible patients were recruited to the trial, and the proportion of women was similar in recruited and non-recruited patients.

Study funding/potential competing interests

This trial was supported by UK Health Technology Assessment award 07/37/64.

Trial registration number Current controlled trials ISRCTN48334791.

30 day mortality by randomised group, with subgroup analyses for age, sex, and Hardman index