Systematic review: repair of unruptured abdominal aortic aneurysm
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CRD summary
This review evaluated active surveillance and open or endovascular repair for unruptured abdominal aortic aneurysms. The authors concluded that treatment of small aneurysms did not improve survival. The endovascular approach seemed to reduce operative mortality in comparison with open repair. The review was generally well-conducted although there are potential constraints to the applicability of the conclusions.

Authors’ objectives
To compare the effectiveness of treatment options for unruptured abdominal aortic aneurysms (AAAs).

Searching
MEDLINE (1966 to December 2006), the Cochrane Library and ClinicalTrials.gov were searched; brief search terms were reported. No language restrictions were applied. Reference lists of relevant articles were searched and experts in the field were contacted to identify additional studies.

Study selection
Study designs of evaluations included in the review
Randomised clinical trials (RCTs) were eligible for inclusion in the review.

Specific interventions included in the review
Studies comparing open repair versus endovascular repair, or either of these procedures versus active surveillance, were eligible for inclusion in the review. Studies that included variations in method for any procedure were excluded.

Participants included in the review
Studies of patients with unruptured AAAs were eligible. In the included studies the mean AAA diameter ranged from 4.6 to 6.5 cm. The mean age of the participants ranged from 68.1 to 76.4 years and 0.7 to 17% were women.

Outcomes assessed in the review
There were no specified outcome criteria. The primary outcome measured in the review was all-cause mortality. Secondary outcomes included operative mortality (up to 30 days in patients undergoing repair), AAA-related mortality, quality of life, adverse events, and complications such as treatment-related mortality and morbidity and the need for re-interventions. The mean follow-up ranged from 0.8 to 8 years.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
Study quality was assessed using a published checklist for method of randomisation, allocation concealment, blinding and intention-to-treat. Data on study quality were extracted by trained personnel and subsequently confirmed by the principal author. Any discrepancies were resolved through discussion.

Data extraction
Data were extracted by trained personnel on standardised forms and cross-checked by another reviewer. Any discrepancies were resolved through discussion. When necessary, authors were contacted for additional data. Data on the outcome all-cause mortality were collected and analysed based on an intention-to-treat principle.
Methods of synthesis

How were the studies combined?
A random-effects model was used to calculate relative risks (RRs) or hazard ratios (HRs) and their relative 95% confidence intervals (CIs).

How were differences between studies investigated?
Statistical heterogeneity was evaluated by the chi-squared test and the I-squared statistic. Variations were also discussed in terms of age, gender, AAA diameter and renal function.

Results of the review

Seven RCTs (n=4,116) were included in the review.

None of the included studies were blinded; randomisation and allocation concealment were considered adequate in 6 out of the 7 studies. All studies analysed data on an intention-to-treat basis.

Open repair versus active surveillance.

Two RCTs (n=2,226) compared open repair of AAAs with active imaging surveillance in patients with asymptomatic AAAs of less than 5.5 cm diameter. No significant differences in all-cause mortality or AAA-related mortality were found between the study groups, or when trial effects were combined. There was evidence of statistical heterogeneity between the trials measuring all-cause mortality (p=0.03; I-squared >78.5%).

Open repair versus endovascular repair.

Open repair was compared with endovascular repair in 4 RCTs (n=1,532).

Endovascular treatment was associated with lower 30-day post-operative all-cause mortality (RR 0.33, 95% CI: 0.17, 0.64) and mid-term (up to 4 years) AAA-related mortality (RR 0.53, 95% CI: 0.31, 0.92), while the mid-term all-cause mortality was comparable (RR 0.95, 95% CI: 0.76, 1.19). There was no statistical heterogeneity for any of these outcomes. These findings were unchanged after correcting for age, AAA diameter, renal function and gender. Endovascular repair seemed to shorten the period of hospitalisation (pooled weighted median 6.2 days versus 11.5 days), but increases in the rate of re-interventions and adverse events were reported. The endovascular approach also seemed to improve short-term quality of life whereas no differences were found after 1 to 3 months.

Endovascular repair versus surveillance.

Endovascular repair was compared with active surveillance in one trial (n=338) which included patients with AAA of at least 5.5 cm diameter who could not undergo open repair. Similar all-cause mortality (HR 1.21, 95% CI: 0.87, 1.69) and AAA-related mortality (HR 1.01, 95% CI: 0.55, 1.84) were found in the study groups. The results were not significantly different according to age, gender, AAA diameter or renal function.

Authors’ conclusions

Open repair of small AAAs did not seem to prolong survival. Endovascular treatment was associated with lower operative all-cause mortality and lower mid-term AAA-related mortality, but with a comparable mid-term all-cause mortality, and was also associated with a higher frequency of re-interventions. In patients unable to undergo open repair, no survival benefits seemed to derive from the endovascular approach.

CRD commentary

This review had clearly stated inclusion criteria with respect to the study design, interventions and participants. It was not clear if the study outcomes were specified a priori. The authors searched two relevant databases and made efforts to find further trials by reviewing reference lists and contacting experts in the field. The potential influence of publication bias was not evaluated. No language restrictions were applied. The authors attempted to minimise bias and errors during the majority of the review process, although this could not be verified for the study selection procedure. The absence of
statistical heterogeneity for the main outcome supports the authors' decision to pool the studies in a meta-analysis. The review was generally well-conducted although failure to report some aspects of the review process and, as the authors acknowledged, the small number and size of included trials present potential constraints to the reliability and generalisability of the authors' conclusions.

**Implications of the review for practice and research**

**Practice:** The authors did not state any implications for practice.

**Research:** The authors stated that the efficacy of endovascular versus open repair should be evaluated in long-term randomised trials. More studies are warranted to assess the safety and efficacy of endovascular repair versus surveillance in high-risk patients.

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.