Endovascular treatment for ruptured abdominal aortic aneurysm

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Review information

Review type: Intervention

Review number: 991

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Citation example: Badger S, Forster R, Blair PH, Ellis P, Kee F, Harkin DW. Endovascular treatment for ruptured abdominal aortic aneurysm. Cochrane Database of Systematic Reviews 2014 , Issue 7 . Art. No.: CD005261. DOI: 10.1002/14651858.CD005261.pub3 .

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Dates

Assessed as Up-to-date: 22 June 2016
Date of Search: 22 June 2016
Next Stage Expected: 22 June 2018
Protocol First Published: Issue 2 , 2005
Review First Published: Issue 1 , 2007
Last Citation Issue: Issue 7 , 2014

What's new

Date	Event	Description
21 September 2016	Feedback incorporated	Feedback addressed
21 September 2016	Updated	New search run. One new study included. No new studies excluded.
21 September 2016	New citation: conclusions not changed	New search run. One new study included. No new studies excluded. Text updated to reflect current Cochrane standards. 'Summary of findings' table added. No change to conclusions.

History

Date	Event	Description
21 October 2014	Feedback incorporated	Feedback received
17 April 2014	New citation: conclusions changed	Searches rerun, three new studies included, two new studies excluded. Review fully updated. Two new authors have joined review team. Conclusions changed.
17 April 2014	Updated	Searches rerun, three new studies included, two new studies excluded.
30 May 2008	Amended	Converted to new review format.

Abstract

Background

An abdominal aortic aneurysm (AAA) (pathological enlargement of the aorta) can develop in both men and women as they grow older. It is most commonly seen in men over the age of 65 years. Progressive aneurysm enlargement can lead to rupture and massive internal bleeding, a fatal event unless timely repair can be achieved. Despite improvements in perioperative care, mortality remains high (approximately 50%) after conventional open surgical repair. A minimally invasive technique, endovascular aneurysm repair (EVAR), has been shown to reduce early morbidity and mortality as compared to conventional open surgery for planned AAA repair. Emergency endovascular aneurysm repair (eEVAR) has more recently been used successfully to treat ruptured abdominal aortic aneurysm (RAAA), proving that it is feasible in selected patients. However, it is not yet known if eEVAR will lead to significant improvements in outcomes for these patients or indeed if it can replace conventional open repair as the preferred treatment for this lethal condition. This is an update of the review first published in 2006.

Objectives

To assess the advantages and disadvantages of emergency endovascular aneurysm repair (eEVAR) in comparison with conventional open surgical repair for the treatment of ruptured abdominal aortic aneurysm (RAAA). This will be determined by the effect on short-term mortality, major complication rates, aneurysm exclusion (specifically endoleaks in the eEVAR treatment group), and late complications when compared with the effects in patients who have had conventional open repair of RAAA.

Search methods

For this update the Cochrane Vascular Information Specialist (CIS) searched the Specialised Register (last searched June 2016), CENTRAL (2016, Issue 5) and trials registries. Reference lists of relevant publications were also checked.

Selection criteria

Randomised controlled trials in which patients with a clinically or radiologically diagnosed RAAA were randomly allocated to eEVAR or conventional open surgical repair.

Data collection and analysis

Studies identified for potential inclusion were independently assessed for eligibility by at least two review authors. Data extraction and quality assessment were also completed independently by two review authors. Disagreements were resolved through discussion. Meta-analysis was performed using fixed-effect models with odds ratios (ORs) and 95% confidence intervals (CIs) for dichotomous data and mean differences with 95% CIs for continuous data.

Main results

Four randomised controlled trials were included in this review. A total of 868 patients with a clinical or radiological diagnosis of RAAA were randomised to receive either eEVAR or open surgical repair. Overall risk of bias was low but one study performed randomisation in blocks by week, and paired with no allocation concealment and no blinding, this puts the study at high risk of selection bias. Another study did not adequately report random sequence generation, putting it at risk of selection bias, and two studies were underpowered. There was no clear evidence to support a difference between the two interventions on 30-day (or in-hospital) mortality, OR of 0.88 (95% CI 0.66 to 1.16; moderate quality evidence). There were a total of 44 endoleak events in 128 participants from three studies (low quality evidence). Thirty day complication outcomes (myocardial infarction, stroke, composite cardiac complications, renal complications, severe bowel ischaemia, spinal cord ischaemia, re-operation, amputation, and respiratory failure) were reported in between one and three studies and therefore no robust conclusion can currently be drawn. We downgraded the quality of the evidence for myocardial infarction, renal complications and respiratory failure due to imprecision, inconsistency and risk of bias. Odds ratios for complications outcomes were OR 2.38 (95% CI 0.34 to 16.53; 139 participants, 2 studies, low quality evidence) for myocardial infarction, OR 1.07 (95% CI 0.21 to 5.42; 255 participants, 3 studies, low quality evidence) for renal complications and OR 3.62 (95% CI 0.14 to 95.78; 32 participants, 1 study, low quality evidence) for respiratory failure. There was low quality evidence of a reduction in bowel ischaemia in the eEVAR treatment group, but very few events were reported (OR 0.37, 95% CI 0.14 to

0.94) and the evidence was downgraded due to imprecision and risk of bias. Six-month and one year outcomes were evaluated in three studies, but only results from a single study could be used for each outcome showing no clear evidence of a difference between the interventions. Six-month mortality evidence was rated at moderate quality due to imprecision (OR 0.89, 95% CI 0.40 to 1.98; 116 participants).

Authors' conclusions

The conclusions of this review are currently limited by the paucity of data. From the data available, moderate quality evidence suggests no difference in 30-day mortality between eEVAR and open repair. Not enough information was provided for complications in order to make a well informed conclusion at this time, although there is a possibility that eEVAR is associated with a reduction in bowel ischaemia. Long-term data are lacking for both survival and late complications. More high quality, randomised controlled trials comparing eEVAR and open repair for the treatment of RAAA are needed in order to better understand if one method is superior to the other, or if there is no difference between the methods on relevant outcomes.

Plain language summary

Endovascular treatment for ruptured abdominal aortic aneurysm

Background

The abdominal aorta is the main artery supplying blood to the lower part of the body. An abnormal ballooning and weakening of the wall of the aorta (aortic aneurysm) particularly affects men as they grow older. An aneurysm may progressively enlarge without obvious symptoms yet it is potentially lethal as the aneurysm can burst (rupture) causing massive internal bleeding. Death is inevitable unless the bleeding can be stopped and blood flow to the lower body restored promptly. Until recently this required an open operation (laparotomy) to clamp the abdominal aorta and replace the segment of the aorta with a synthetic artery tube-graft. Many patients do not survive this major operation due to the effects of massive bleeding or failure of vital organs, such as the heart, lungs, and kidneys, despite improvements in the surgical technique and care of the critically ill patient.

A minimally invasive technique, termed endovascular treatment, allows the surgeon to pass a stent graft through the blood vessels from the groin to the site of rupture where it is positioned and attached to healthy artery above and below the aneurysm to stop bleeding and form a new channel for blood flow. This technique is successful in suitable patients for the planned treatment of non-ruptured aneurysms and can reduce early postoperative complications and deaths.

Study characteristics and key results

The present review looked at the available evidence for endovascular repair effectiveness compared with open surgery for ruptured aneurysms. Four studies, with a total of 868 participants were included. Risk of bias was generally low but one study was at high risk of selection bias due to their block method of randomisation, one study did not adequately report randomisation methods, and two studies may not have included enough participants to answer the questions they intended. From the data currently available there appears to be no difference in death within 30 days of the procedure between endovascular repair and open repair. Endoleaks were reported in 44 participants from three studies. The data on complications (myocardial infarction, stroke, combined cardiac complications, renal complications, spinal cord ischaemia, re-operation, amputation, and respiratory failure) are not robust enough at this point to make any strong conclusions on superiority of either repair technique, but eEVAR may be associated with lower risk of bowel ischaemia. No robust conclusion can be made on outcomes at six months or one year. More studies are needed to get a better understanding of whether or not one of the aneurysm repair techniques, endovascular or open surgical, are superior based on patient outcomes.

Quality of the evidence

From the data available, moderate quality evidence suggests no difference in 30-day mortality between eEVAR and open repair. Not enough information was provided for complications in order to make a well informed conclusion at this time, although there is a possibility that eEVAR is associated with a reduction in bowel ischaemia. The quality of the evidence was downgraded as some studies did not contain enough participants, not all studies reported on all complication outcomes, and the number of complications occurring between studies varied substantially.

Background

Description of the condition

Abdominal aortic aneurysm (AAA), the pathological enlargement of the main artery in the abdomen, affects around 1.34% of men in England (Jacomelli 2016). The prevalence of AAA has been declining, which is independent of participant selection criteria and reflects better cardiovascular risk profiling and management in the overall population (Conway 2012; UK NAAASP). This is also seen elsewhere, with 2.2% prevalence in Sweden and 3.3% in Denmark (Søgaard 2012; Svensjö 2011), due to reduced risk factors, in particular the rate of smoking (Svensjö 2011). The prevalence of AAA in men is approximately three times greater than in women, and the incidence increases with advancing age (Scott 1991; Scott 1995). The cause of AAA is unknown but its development is associated with many of the cardiovascular risk factors that predispose to atherosclerosis and arterial occlusive disease, perhaps most importantly tobacco smoking (Lederle 1997; Wilmink 1999). Genetic factors are also important as the risk of aneurysm development is significantly greater in relatives of those with a diagnosed AAA (Powell 2003; van Vlijmen 2002). Unfortunately many aneurysms progressively enlarge without overt symptoms, presenting only when the aneurysm ruptures, a catastrophic event causing massive internal bleeding that results in death in the majority of those affected.

The extremely high mortality rate from ruptured AAA (RAAA) is 80%, accounting for 2% of total deaths (Gorham 2004; Nordon 2011; Veith 2003). For those at risk of RAAA the current in-hospital mortality rates in England are around 65%, and a postoperative mortality rate of 41.65% (Karthikesalingam 2014). Detailed risk analysis and scoring systems have been shown to predict non-survivors in certain groups but individual patient outcomes cannot be accurately predicted. Clinicians have been reticent to rigidly apply these scoring systems as to do so would serve to preclude most patients with RAAA from surgical repair, condemning them to certain death (Alsac 2005; Korhonen 2004; Neary 2003). It is also now clear that those patients who undergo successful open repair of RAAA enjoy a postoperative quality of life similar to the 'normal population' (Hinterseher 2004; Tambyraja 2004). Indeed, the long-term survival of RAAA patients after successful repair is the same as for elective repair patients (Mani 2009).

Randomised controlled trials and a Cochrane review have shown that mortality can be reduced by mass population ultrasound screening in men, with early detection and intervention preventing future rupture and aneurysm-related mortality (Ashton 2002; Cosford 2007; Norman 2004). The risk of aneurysm rupture has been shown to be proportional to aneurysm size, with aneurysms measuring less than 5.4 cm having an annual rupture rate of approximately 1% whereas those greater than 7.0 cm in diameter have an annual rupture rate of 32.5% (Gorham 2004). The UK Small Aneurysm Trial has shown that, in general, patients benefit from aneurysm repair when the maximum aneurysm diameter exceeds 5.5 cm, at which stage the risk of spontaneous rupture exceeds the risks of conventional open surgical repair (Greenhalgh 1998). In addition, two randomised controlled trials showed no difference in outcome in participants that received intervention of small aneurysms (< 5.5 cm) compared with participants that received surveillance at that size (CAESAR Trial; PIVOTAL Trial). With the prevalence of AAA much lower in women there is less robust data regarding the ideal size of aneurysm for treatment but it is currently recommended women receive intervention at 5 cm, 5 mm smaller than that is recommended for men (Moll 2011).

Description of the intervention

Historically, conventional open surgical repair was the only effective treatment for AAA, involving open surgical exposure of the aorta and replacement of the aneurysm with a synthetic tube-graft. This complex major operation carries a significant morbidity and mortality due to the combined effects of surgical exposure, haemorrhage, and aortic clamping with related lower body ischaemia-reperfusion injury. However, with improvements in patient selection and perioperative care, excellent results can now be achieved with open repair with some specialist centres reporting mortality rates of less than 2% and surgeons in non-specialist units achieving mortality rates of 5% to 8% (Gorham 2004; Greenhalgh 1998; Veith 2003).

In the last two decades this approach to treatment of patients with AAA has been challenged by the arrival of a minimally-invasive technique, endovascular aneurysm repair (EVAR). The EVAR technique was introduced to Western surgical practice by Parodi in 1991 (Parodi 1991). He described the placement of a home-made, material-covered metal stent across an abdominal aneurysm to exclude this from the circulation and to form a new channel for blood flow. The stent is delivered to the aorta from a remote accessible vessel such as the femoral artery at the groin. Since this seminal report, outcomes have progressively improved with significant advancements in commercial stent design, delivery, and the implantation technique (Harris 2005; Lee 2004; Thomas 2005). Since the inception of the EVAR technique many specialised vascular surgery centres have adopted its use in the elective treatment of AAA, where its use has contributed to a reduction in early postoperative morbidity and mortality (EVAR 2004; Prinssen 2004). In many countries it has now become established in most centres as the primary mode of aneurysm repair (Mani 2011). A recent Cochrane review showed improved short-term mortality for EVAR, compared with open repair, but no difference for moderate and long-term mortality (Paravastu 2014).

How the intervention might work

Modern aortic stent grafts are available in a range of sizes and can be custom designed. The addition of fenestrations and side-branches can adapt the stent to suit encountered difficult anatomical variations. These modular devices are most commonly delivered remotely by open exposure of the femoral arteries and are broadly described as the aorto-uni-iliac graft (single-lumen) and aorto-bi-iliac (bifurcated-lumen) graft. The minimally invasive nature of this technique allows it to be performed under regional or even local anaesthesia rather than general anaesthesia. In recent years minimally invasive percutaneous deployment of stent under local anaesthesia has become increasingly popular, and routine in some centres. This increases the availability of the technique to those patients with significant concomitant medical disease who may otherwise have been considered unfit for surgery (Lachat 2002; Veith 2003).

Two large prospective randomised controlled trials have compared EVAR with conventional open repair for the treatment of large AAAs and have shown significant reductions in early complications and mortality (EVAR 2004; Prinssen 2004). However, whilst endovascular repair for unruptured AAA clearly has a role in 'healthy' patients, these trials have also reinforced the knowledge that open repair is a successful technique and will remain a common form of treatment for patients presenting with a large AAA for whom EVAR is unsuitable on anatomical grounds or due to other factors (EVAR 2004; EVAR 2005). Long-term results from the EVAR 1 trial revealed later ruptures in the EVAR group and therefore short term benefit to EVAR, but no long-term difference in the all-cause mortality (Brown 2012). Furthermore, it is now clear that those patients who are unfit for open surgical repair can expect such a high mortality rate from their co-morbid disease that even successful EVAR of their aneurysm is unlikely to alter their overall prognosis and life expectancy, which remains guarded (EVAR2 2005).

Why it is important to do this review

RAAA is a catastrophic event which is occurring with increasing frequency in our increasingly elderly population.

Despite improved surgical techniques and advances in intensive care support, RAAA mortality was static for many years (Adam 1999; Huber 1995). However, it has improved in more recent years with large volume centres associated with the improvement (Karthikesalingam 2014). The high mortality associated with open repair has led many to look for alternative treatments for the management of RAAA. Several studies have confirmed that the use of EVAR, especially under local anaesthesia, reduces the physiological insult to the body as compared to conventional open surgical repair (Cuypers 2001; Peppelenbosch 2003). The EVAR technique has been successfully used in the planned treatment of non-ruptured aneurysms of the abdominal aorta and, when compared to conventional open surgical repair, has been shown to reduce early postoperative complications and death. Emergency endovascular aneurysm repair (eEVAR) has been successfully carried out using a variety of protocols and techniques and would appear to offer a feasible alternative to conventional open repair in selected patients (Peppelenbosch 2003; van Sambeek 2002). In this review we have assessed the available evidence to support the use of eEVAR to treat RAAA.

Objectives

To assess the advantages and disadvantages of emergency endovascular aneurysm repair (eEVAR) in comparison with conventional open surgical repair for the treatment of ruptured abdominal aortic aneurysm (RAAA). This will be determined by the effect on short-term mortality, major complication rates, aneurysm exclusion (specifically endoleaks in the eEVAR treatment group), and late complications when compared with the effects in patients who have had conventional open repair of RAAA.

Methods

Criteria for considering studies for this review

Types of studies

Prospective randomised controlled trials (RCTs) comparing eEVAR with emergency conventional open surgical repair.

Types of participants

All patients in whom an RAAA has been clinically diagnosed by computerised tomography (CT), angiography, magnetic resonance angiography (MRA), or objective acute symptoms suggestive of rupture of the aneurysm to warrant inclusion.

Types of interventions

All types of endovascular devices were considered in comparison with conventional open surgical treatment for patients considered fit for surgery.

Types of outcome measures

Primary outcomes

- Short-term mortality (30-day, or in-hospital mortality)

Secondary outcomes

- Endoleak (blood within the vessel but out side the stent)
- Major complications, e.g., open conversion, haemorrhage, myocardial infarction, stroke, renal failure, respiratory failure (need for postoperative mechanical ventilation), pneumonia, bowel ischaemia, lower limb ischaemia
- Minor complications, e.g., catheter site haematoma, wound infection (associated with local wound or surgical site)
- Complications and mortality at six months; re-intervention rates for problems related to the RAAA or its treatment were sought, where possible, as were cause of death with or without re-intervention, i.e., device-related
- Complications and mortality long term (longer than six months), re-intervention rates for problems related to the RAAA or its treatment were sought, where possible, as were cause of death with or without re-intervention, i.e., device-related
- Quality of life (standardised questionnaires)
- Economic analysis (cost per patient)

Search methods for identification of studies

Electronic searches

For this update the Cochrane Vascular Information Specialist (CIS) searched the following databases for relevant trials:

- The Cochrane Vascular Specialised Register (June 2016);
- The Cochrane Central Register of Controlled Trials (CENTRAL (2016, Issue 5)) via The Cochrane Register of Studies Online.

See Appendix 1 for details of the search strategy used to search CENTRAL.

The Cochrane Vascular Specialised Register is maintained by the CIS and is constructed from weekly electronic searches of MEDLINE Ovid, Embase Ovid, CINAHL, AMED, and through handsearching relevant journals. The full list of the databases, journals and conference proceedings which have been searched, as well as the search strategies used are described in the Specialised Register section of the Cochrane Vascular module in The Cochrane Library (www.cochranelibrary.com).

The following trial databases were searched by the CIS (June 2016) for details of ongoing and unpublished studies;

World Health Organization International Clinical Trials Registry http://apps.who.int/trialsearch/

ClinicalTrials.gov http://clinicaltrials.gov/

ISRCTN Register http://www.isrctn.com/

see Appendix 2 for details of the searches.

Searching other resources

References of relevant studies were reviewed for other pertinent publications.

Data collection and analysis

Selection of studies

Two review authors, SB and RF, independently reviewed the studies identified by the search for their relevance using the selection criteria. Disagreements were resolved through discussion.

For the previous version of this review, study selection and evaluation of reporting bias were performed by MD and DWH.

Data extraction and management

Two review authors, SB and RF, independently extracted the data for each included study. Details about the trial design, characteristics of participants, diagnosis of RAAA, eEVAR and open repair procedures were recorded. Data were collected on the primary outcome short-term mortality (30-day or in-hospital) and the secondary outcomes: endoleak (30-day), major and minor short-term complications, long-term mortality and complications (six months and one year), quality of life, and economic analysis.

Assessment of risk of bias in included studies

Included studies were evaluated for quality, independently by two review authors (SB and RF), using the Cochrane Collaboration's tool for assessing risk of bias (Higgins 2011). This tool provides judgments made on the domains of sequence generation, allocation concealment methods, blinding, incomplete outcome data, selective outcome reporting, and other relevant biases. Evaluations of low risk, unclear risk, and high risk were performed for each domain for each included study. Any disagreements between review authors were resolved through discussion.

Measures of treatment effect

Analysis was planned on an intention-to-treat basis and therefore all randomised patients from the included studies were to be included in the analysis. The outcomes that were dichotomous in nature were to be compiled into a meta-analysis and odds ratios (ORs) with 95% confidence intervals (CIs) were to be calculated. This excludes endoleak, which only occurs in the eEVAR treatment and is therefore inappropriate to compare in a meta-analysis and will be described through narrative synthesis. For continuous data, meta-analysis would provide mean differences with standard deviations (SDs).

Unit of analysis issues

The individual patient was the unit of analysis within this review.

Dealing with missing data

If data were missing from publications of the included studies, attempts were made to contact the study authors.

Assessment of heterogeneity

A test for heterogeneity examines the null hypothesis that all studies are evaluating the same effect. We obtained P values comparing the test statistic with a Chi^2 distribution. To help readers assess the consistency of results of studies in a meta-analysis RevMan 5 software includes a method (I^2 statistic) that describes the percentage of total variation across studies due to heterogeneity rather than by chance. A value of 0% indicates no observed heterogeneity and larger values show increasing heterogeneity (Higgins 2003).

Assessment of reporting biases

To assess reporting bias, it was planned to create funnel plots for meta-analyses containing 10 or more included studies. As only four studies were included in this review no assessment of reporting bias could be undertaken.

Data synthesis

Data extracted independently by two review authors (SB and RF) were compiled and entered into RevMan by one author (RF). Comparisons of data, using meta-analyses, were undertaken using fixed-effect models unless the I^2 value for heterogeneity yielded a value > 50%, in which case a random-effects model was implemented.

Subgroup analysis and investigation of heterogeneity

We planned to perform subgroup analysis to evaluate the impact of patients treated with aorto-uni-iliac devices and those treated with aorto-bi-iliac devices. Two trials (AJAX; Hinchliffe 2006) only used aorto-uni-iliac devices while the other two used both methods but the outcomes were not stratified by device used (ECAR; IMPROVE). Due to the paucity of information, subgroup analysis was not possible at this time. Also, due to the lack of outcome data stratified by other subgroups of interest, such as age and timing of the intervention, further subgroup analyses were not possible at this time.

Sensitivity analysis

Although all the participants in the IMPROVE trial had a radiological diagnoses of RAAA, upon commencement of the intervention it was found that only 536 (87%) of the 613 randomised participants had, in fact, a RAAA. The remaining 77

participants were diagnosed as follows: 10 patients had no AAA, 45 had asymptomatic AAA or other final diagnoses and 22 had symptomatic non-ruptured AAA. Sensitivity analysis was planned to evaluate the effects of this trial on the outcomes.

Summary of findings

We constructed a 'Summary of findings' table for the comparison eEVAR versus open repair using the GRADEpro GDT software (GRADEpro GDT 2015) to present the main findings of the review. We judged the outcomes mortality (30 day or in-hospital), endoleaks, complications that included myocardial infarction, renal complications, respiratory failure and bowel ischaemia, as well as mortality at six months to be most clinically relevant to healthcare professionals and patients. We calculated assumed control intervention risks from the mean number of events in the control groups of the selected studies for each outcome. The system developed by the Grading of Recommendation, Assessment, Development and Evaluation Working Group (GRADE working group) was used for grading the quality of evidence as high, moderate, low and very low, based on within-study risk of bias, directness of evidence, heterogeneity, precision of effects estimates, and risk of publication bias (Atkins 2004). Ryan 2016's document on preparing 'Summary of findings' tables was used for reference.

Results

Description of studies

Results of the search

See Figure 1.

Included studies

See Characteristics of included studies for complete information on the included studies.

For this update an additional study was added which had previously been listed as 'ongoing' (ECAR). There are now a total of four included studies with a total of 868 participants (AJAX; ECAR; Hinchliffe 2006; IMPROVE). All four studies were randomised controlled trials comparing eEVAR to emergency open surgical repair in patients with a clinical or radiological diagnosis of RAAA on outcomes that included mortality and complications. AJAX, ECAR and IMPROVE aimed to evaluate longer-term mortality and complications, at six months and one year. Also, the AJAX, ECAR and IMPROVE trials evaluated cost-effectiveness by comparing cost per patient between the two trial arms. The IMPROVE trial is currently the only study to report on quality of life outcomes. At this time none of the included studies have directly evaluated minor complications.

AJAX, ECAR and IMPROVE were all multicentre studies with AJAX taking place in Amsterdam, Netherlands, ECAR in France and IMPROVE in the UK, with one study site in Canada. Hinchliffe 2006 was a single-centre trial within England. All included participants had a clinical or radiological diagnosis of RAAA but in the IMPROVE study only 536 out of the 613 (87%) randomised participants actually had RAAA, the remaining 77 participants were diagnosed as follows: 10 patients had no AAA, 45 had asymptomatic AAA or other final diagnoses and 22 had symptomatic non-ruptured AAA. For the AJAX and ECAR studies all randomised participants were considered suitable for both eEVAR and open repair; in the Hinchliffe 2006 and IMPROVE studies suitability for eEVAR was determined after randomisation. For the Hinchliffe 2006 and AJAX studies, aorto-uni-iliac grafts were used in the endovascular trial arm; the ECAR and IMPROVE trials used both aorto-uni-iliac grafts and aorto-bi-iliac grafts.

Excluded studies

See Characteristics of excluded studies.

For this update there were no newly excluded studies, so the total number excluded remained at five studies (Peppelenbosch 2003; Resch 2003; Rödel 2012; Verhoeven 2002; Visser 2006). See Characteristics of excluded studies for more information on the excluded studies. Three studies (Peppelenbosch 2003; Resch 2003; Verhoeven 2002) were prospective trials treating patients presenting with RAAA with eEVAR. However, their comparison to open repair was made through retrospective, 'historical' controls or with open repair cohorts. One study (Rödel 2012) was a prospective comparison between eEVAR and open repair in patients with RAAA, but the study was non-randomised. A final study (Visser 2006) was a non-randomised study of 55 consecutive patients presenting with RAAA. A portion of the participants in the study were collected retrospectively and a portion prospectively.

Risk of bias in included studies

See Figure 2 and Figure 3.

Allocation (selection bias)

The ECAR study was given an evaluation of high risk for selection bias as they used a block randomisation technique by week with no allocation concealment. The authors give their reasoning for this randomisation method as it means they can prepare their surgical teams by their expertise and a team that is less proficient at a certain technique does not bias the results but performing the treatment less adequately than the other treatment. While this rationale does make sense, it still does not protect against selection bias, especially as it is paired with an unblinded trial. Both the AJAX and IMPROVE studies adequately reported random sequence generation, but the Hinchliffe 2006 study did not give a description of how the allocation sequence was produced and was therefore at unclear risk of selection bias. For AJAX, Hinchliffe 2006 and IMPROVE all three studies clearly explained adequate concealment methods.

Blinding (performance bias and detection bias)

Due to the nature of the intervention it is not possible to blind the surgeons, patients, and the research team to the treatment allocation, and this was not attempted in any of the included trials. However, we determined that a lack of blinding was unlikely to influence the outcomes of interest, and all three studies have been listed as low risk for performance and detection bias. Attempts were made by three of the studies to reduce the risk of bias: in the AJAX study an endpoint adjudication committee and independent safety committee, both blinded to treatment allocation, were utilised; the Hinchliffe 2006 study kept surgeons blinded to dimensions of the aorta until randomisation was completed; and the IMPROVE study utilised a trial core laboratory to centrally verify outcomes.

Incomplete outcome data (attrition bias)

All four included studies adequately accounted for all participants, giving thorough explanations of dropout rates and the reasons. All studies were at a low risk of attrition bias.

Selective reporting (reporting bias)

For this update all four included studies have reported all specified outcomes, so they were all at low risk of reporting bias.

Other potential sources of bias

The AJAX and IMPROVE studies appeared to be free of other sources of bias, but the ECAR and Hinchliffe 2006 studies could have been at risk of bias due to an underpowered study population. ECAR calculated a need for 80 participants in each or 160 total to reach adequate power, but only randomised 107 participants. Hinchliffe 2006 reported that the study required 100 participants to be adequately powered yet they only included 32 patients.

Effects of interventions

See the Summary of findings table 1

Short-term mortality (30-day or in-hospital)

All four studies were included in the meta-analysis for mortality (30-day or in-hospital) (AJAX; ECAR; Hinchliffe 2006; IMPROVE). For intention-to-treat purposes, all deaths that occurred after randomisation were included, which may have included deaths before intervention and peri-operative deaths. Using the fixed-effect model we found no clear evidence to support a difference in mortality between eEVAR and open repair (OR 0.88, 95% CI 0.66 to 1.16; P = 0.36; moderate quality evidence) (Analysis 1.1). When the IMPROVE study was removed for sensitivity analysis, due to randomisation of some patients, whom after commencement of treatment were found not to have RAAA, there was very little change in OR but the CI became wider as the IMPROVE study had a larger study population than the other included studies (OR 0.78, 95% CI 0.45 to 1.33; P = 0.35).

Endoleak

AJAX reported 33 endoleaks in the eEVAR treatment arm, 24 during the initial eEVAR procedure and nine during follow-up. Nine of the 33 endoleaks were type I and 10 were type II, the remaining 14 were not specified. The ECAR trial reported nine type II endoleaks diagnosed by CT scan post-operatively. Hinchliffe 2006 reported two type I endoleaks which were converted to open repair. Low quality evidence.

Major complications (30-day)

Combined major complication (as reported by studies) : three studies reported on combined major complications, but only two could be included in the meta-analysis. AJAX and ECAR had data included in this analysis which found no evidence of a difference in major complications between the treatment groups (OR 0.72, 95% CI 0.42 to 1.23; P = 0.23) (Analysis 1.2). The Hinchliffe 2006 study could not be included in the meta-analysis as only percentages were supplied. They reported 77% of participants in the eEVAR group experienced moderate or severe complications and 80% in the open repair group experienced such events. It should be noted the studies included in the analysis had different definitions and included different types of events as major complications.

Myocardial infarction : ECAR and Hinchliffe 2006 reported myocardial infarction; only four events were reported so the CI was very wide (OR 2.38, 95% CI 0.34 to 16.53; P = 0.38; low quality evidence) (Analysis 1.3).

Stroke : both the AJAX and Hinchliffe 2006 studies reported stroke events but with very few events, and opposing findings. Using the fixed-effect model, the non-significant OR had a very wide CI that was difficult to derive any meaningful conclusion from (OR 0.71, 95% CI 0.12 to 4.31; P = 0.71) (Analysis 1.4).

Cardiac complications (moderate or severe) : cardiac complications were evaluated in the AJAX, ECAR and Hinchliffe 2006 studies. The fixed-effect meta-analysis found a no difference between the treatment groups (OR 0.84, 95% CI 0.32 to 2.23); P = 0.73) (Analysis 1.5).

Renal complications (moderate or severe) : the AJAX, ECAR and Hinchliffe 2006 studies reported renal complications and the random-effects model was used to analyse the association with no clear difference between the interventions (OR 1.07, 95% CI 0.21 to 5.42; P = 0.93; I^2 = 77%; low quality evidence) (Analysis 1.6).

Respiratory failure : respiratory failure was evaluated in the Hinchliffe 2006 study alone. With only a single event in the eEVAR arm the CI was very wide (OR 3.62, 95% CI 0.14 to 95.78; low quality evidence) with no overall association (Analysis 1.7).

Bowel ischaemia : two studies evaluated bowel ischaemia (AJAX and ECAR), and found a reduction in odds of bowel ischaemia in the eEVAR treatment group with an OR of 0.37 (95% CI 0.14 to 0.94; P = 0.04; low quality evidence) (Analysis 1.8).

Spinal cord ischaemia : spinal cord ischaemia was only evaluated in the AJAX study, which had only one event. With an OR of 3.16 and a very wide confidence interval (95% CI 0.13 to 79.17) very little could be concluded regarding this outcome (Analysis 1.9).

Re-operation : the occurrence of re-operation specific to the aneurysm repair was reported in two studies (AJAX; Hinchliffe 2006). Using the fixed-effect model we did not find clear evidence to support a difference between the interventions (OR 0.89, 95% CI 0.39 to 2.01; P = 0.78) (Analysis 1.10).

Amputation : the AJAX and ECAR trials were the only studies to evaluate amputation. There were only five total events, all in the open repair intervention group (OR 0.16, 95% CI 0.02 to 1.32; P = 0.09) (Analysis 1.11).

Open conversion : as open conversion could only be evaluated in the eEVAR treatment group, meta-analysis was not an appropriate way to compare this outcome between the three studies. The AJAX trial reported 10 cases of open conversion in the 57 (17.5%) participants randomised to eEVAR. Hinchliffe 2006 had one open conversion out of the 15 (6.7%) participants randomised to eEVAR, and the IMPROVE study reported four out of the 316 (1.3%) randomised, which was far lower than the other two trials. This could also be the result of the 13% of randomised participants in the IMPROVE study that did not have RAAA but rather 10 patients had no AAA, 45 had asymptomatic AAA or other final diagnoses and 22 had symptomatic non-ruptured AAA, and also 84 participant randomised to eEVAR were determined unsuitable for the procedure and moved to open repair but were not considered as open conversion patients.

Minor complications

Currently none of the included studies have directly evaluated minor complications.

Mortality and complications at six months or longer

In the AJAX trial there was no clear evidence to support a difference between the interventions for mortality (OR 0.89, 95% CI 0.40 to 1.98) combined major complications (OR 0.84, 95% CI 0.39 to 1.80) or re-operation (OR 1.28, 95% CI 0.53 to 3.06) (Analysis 1.12; Analysis 1.14) at six months.

Mortality at one year was reported by the IMPROVE trial (OR 0.85, 95% CI 0.62 to 1.17) Analysis 1.15. No conclusions could be drawn from the single study.

ECAR has also evaluated mortality at six months and one year, finding no difference in the treatment groups, but they do not report the values needed to include the data in our meta-analysis. Authors have been contacted to obtain the necessary data.

Economic analysis (cost per patient)

Cost per patient was evaluated in three studies: AJAX, ECAR and IMPROVE, but only IMPROVE could be included in our meta-analysis as the other two studies did not supply sufficient data for comparison (authors have been contacted with no response). IMPROVE found the mean cost slightly less in the eEVAR treated arm after 30 days: GBP 13,433 compared to GBP 14,619 in the open repair group. The mean difference worked out to be GBP 1186 favouring eEVAR, but as both trial arms had large SDs the 95% CI was very wide spanning GBP -2996.24 to GBP 624.24. As only a single study could be included in the cost analysis no overall association could be determined (Analysis 1.16).

The AJAX trial reported, over 30 days post-operatively the costs for eEVAR were €32,742 and €27,436 for open repair. ECAR reported €7,087.5 for eEVAR and €9,329.4 for open repair for the cost of their hospital stay.

Quality of Life

The AJAX study included quality of life data from two questionnaires, the Short Form 36 (SF-36®) and the EuroQol Group, Rotterdam, The Netherlands (EQ-5D^{TM}). At 6 months there was no difference in the either the physical component or mental component of the SF-36® measure: eEVAR 44.33 and 44.68, and open repair 40.77 and 49.93, respectively. There were also no differences between the treatment groups for the EQ-5D^{TM} measure: eEVAR 32 and open repair 31.

Table 1 contains peri- and postoperative patient characteristics that were not considered as outcomes in this review but are of interest when comparing eEVAR with open repair, and also for comparisons between the trials. The table addresses time spent waiting for surgical intervention, time in operating theatre, blood loss during operation, and length of time spent in hospital. As two studies used median and interquartile range and one study reported using mean and SD, the findings could not be compared quantitatively but were used for anecdotal analysis.

Discussion

Summary of main results

Four studies were included in this review with a total of 868 participants randomised to receive eEVAR or open repair to treat an RAAA. All four studies reported on short-term mortality, defined as either 30-day or in-hospital, and the meta-analysis found no significant difference between eEVAR and open repair. Thirty-day complications were only reported in three studies (low quality of evidence), and many of the individual 30-day complication outcomes were only reported in a single study. As evaluated by the GRADE tool the evidence for myocardial infarction, renal complications and respiratory failure was rated as low quality. Bowel ischaemia was the only complication with a statistically significant association, favouring eEVAR (low quality evidence). Longer-term outcomes, mortality and complications at six months and one year were reported in three studies, but only evaluated by meta-analysis in two (one at six months and one at one year). A conclusion regarding either of the long-term outcomes could not be determined with such a paucity of data. Evidence for 6-month mortality was evaluated as moderate quality. Quality of Life was evaluated in a single study and no conclusions can currently be drawn from it. Cost

per patient was evaluated in three studies, but currently only a single study could be evaluated for meta-analysis, with a slight decrease in cost for the patients randomised to eEVAR.

Currently we cannot draw any significant conclusions regarding the superiority of either of the interventions on mortality and complication outcomes. Hopefully further high quality studies being undertaken evaluating eEVAR versus open repair for RAAA help us to understand if there is truly no difference between these two interventions regarding the outcomes evaluated in this review or if currently we simply do not have enough data to determine any differences.

Overall completeness and applicability of evidence

The four studies included in the review are of good quality, with the exception of a high risk of selection bias for a single study. The evidence gathered using the three studies can be considered relevant, however insufficient data make any conclusions spurious at this time. Of the outcomes addressed in the review there were little data to support an association, and other outcomes of interest were not acknowledged within the studies, such as minor complications.

All four included studies required a clinical or radiological diagnosis of RAAA for inclusion in the study, yet the IMPROVE study, upon commencement of intervention, found that 13% of their included randomised participants did not have RAAA but rather 10 had no AAA, 45 had asymptomatic AAA or other final diagnoses and 22 had symptomatic non-ruptured AAA, which they claimed was a more 'real world' approach to the issue. While this may not affect the overall outcomes it is of concern and should be kept in mind. Also, the IMPROVE trial did not assess eEVAR suitability prior to randomisation, which resulted in 84 participants randomised to eEVAR not being suitable for the procedure and they were transferred to open repair. Hinchliffe 2006 also did not select participants for their suitability for both eEVAR and open repair prior to randomisation and one patient randomised to eEVAR was transferred to open repair. The AJAX and ECAR trials evaluated a more selected study population of participants suitable for both eEVAR and open repair. There are, therefore, two separate questions being addressed in the trials, namely if an EVAR strategy for all RAAAs would work (IMPROVE) or if EVAR suitable patients are better treated thus or by open surgery (AJAX; ECAR). Such issues are emphasized by the IMPROVE trial's findings that aortic morphology, specifically neck length, have an effect on patient outcome. For our review analysis we found a paucity of data regarding subgroup data which meant none of the planned subgroup analyses could be carried out at this time and it was therefore not possible to assess in detail whether certain patient groups may benefit more from either EVAR or open surgery. With future updates of this review we hope more detailed subgroup data will be made available so we can provide a more robust analysis.

Quality of the evidence

In the update of this review 868 participants from four trials of good quality have been included for analysis. Risk of bias of the included studies was generally low but one study used a block randomisation technique by week, which had no allocation concealment and was unblinded leading to a high risk of selection bias (ECAR). Another study did not adequately report random sequence generation (Hinchliffe 2006), putting it at risk of selection bias. The same two studies were underpowered (ECAR; Hinchliffe 2006) as per their own calculations reported by the study authors, leading to an unclear risk of other bias. The data gathered from these four studies are currently not thorough enough to draw any robust conclusions about the outcomes evaluated in this review regarding the comparison of eEVAR and open repair for the treatment of RAAA.

The quality of the evidence according to GRADE varied by outcome and was assessed as moderate to low. Several outcomes had issues with heterogeneity, leading to inconsistency, and most outcomes included few participants or events, leading to imprecision. The outcome of endoleaks could not be analysed using meta-analysis as it only occurs in the eEVAR treatment group, but we found large heterogeneity in the reported events in each of the three reporting trials. This outcome remains an important factor for success for eEVAR and should be evaluated in future trials. For the outcomes that had a majority of participants from the ECAR study we downgraded for risk of bias as the study did not have adequate random sequence generation and allocation concealment techniques. See Summary of findings table 1.

In the Hinchliffe 2006 study, the outcomes used in our review were gathered from descriptions within the text of the publication and were not presented in a table. The authors were contacted to confirm these outcomes but no response was received. Also, in the Hinchliffe 2006 study the single myocardial infarction, stroke, and respiratory failure events were all from the same individual.

Potential biases in the review process

Study selection, data extraction, and quality assessment were performed independently by two review authors in order to reduce bias and subjectivity. We are confident that all potential sources of data to be included in this review were carefully vetted. It still remains that there is the possibility of relevant data that we did not include in this review, which were not published or were not found in the search.

Agreements and disagreements with other studies or reviews

To our knowledge this is the first systematic review, evaluating only studies which are prospective RCTs, comparing eEVAR with open repair in patients with RAAA. There have been other studies, including several systematic reviews, that have addressed eEVAR versus open repair in patients with RAAA but these have been mostly observational, non-randomised studies, many of which were retrospective. These types of studies are more likely to be subject to bias compared with RCTs.

A systematic review from 2007 included 10 studies, all observational studies, using the inclusion criteria that there was a comparison between patients who underwent eEVAR and patients who underwent open surgery, a minimum of five patients in each treatment group, data available on patients' haemodynamic condition at presentation, and availability

of 30-day mortality data (Visser 2007). The Visser 2007 review did not include any of the studies in our systematic review. A crude random-effects model for 30-day mortality, comparing eEVAR with open repair, found an OR of 0.45 (95% CI 0.28 to 0.72) and when the patient haemodynamic condition at presentation, which varied between studies, was included in the model the adjusted OR was 0.67 (95% CI 0.31 to 1.44; P = 0.37). These results indicate that both eEVAR and open repair are suitable for treatment of patients with RAAA, and that eEVAR may possibly have a higher 30-day survival. The crude and adjusted ORs showed a stronger relationship between eEVAR and lower mortality than our results for the 30-day mortality outcome, which showed no difference between the two interventions. The Visser 2007 review also evaluated a composite systemic complications outcome, which found a lower point estimate within the eEVAR group (28%, 95% CI 17% to 48%) compared with open repair (56%, 95% CI 37% to 85%) indicating fewer complications within the eEVAR group. Our review did not have sufficient data on complications to compare with these results and we did not include a composite systemic complications outcome.

The Takagi 2011 meta-analysis included 11 RCTs or risk-adjusted observational studies with a total of 42,888 patients. Inclusion criteria required studies to be RCTs or risk-adjusted observational comparative studies with acceptable risk-adjustment methods (propensity score analyses or multivariate logistic regression), that the study population must be patients with RAAA, patients were assigned to eEVAR or open repair, and outcomes must include in-hospital or 30-day mortality. This review included one RCT, which was also included in our review, and 10 observational studies. The random-effects model found a statistically significantly OR of 0.49 (95% CI 0.35 to 0.69; P < 0.0001). While our mortality results showed little difference in mortality between eEVAR and open repair the Takagi 2011 study showed a strong relationship between eEVAR and lower mortality.

These results also reflect the result of another meta-analysis (Qin 2014). A total of 18 studies were included of which 12 were retrospective, four were prospective but with observational or retrospective components, and two were RCTs, which were also included in our review. The review demonstrated a lower mortality (OR 0.62, 95% CI 0.58 to 0.67; P < 0.001) and shorter length of stay in the eEVAR group (mean difference -5.25 days, 95% CI -9.23 to -1.26; P = 0.010), differing from our own conclusion of no difference between the intervention types. However, the heterogeneity of study designs in the meta-analysis significantly detracts from the quality of the results and conclusions.

A meta-analysis performed by van Beek 2014 also aimed at evaluating 30-day or in-hospital mortality when comparing eEVAR and open surgery for RAAA. This review included RCTs as well as observational studies and administrative registries. The three RCTs included by van Beek 2014 were the same RCTs we included in this Cochrane review, therefore their OR was nearly identical to ours for 30-day or in-hospital mortality (OR 0.90, 95% CI 0.65 to 1.24; P = 0.966). The 21 observational studies and eight administrative registries included by van Beek 2014 showed reduced mortality within the eEVAR group, which reflects the meta-analyses described above that also included observational studies.

A recent literature review and meta-analysis included 41 studies, of which two were RCTs and the remaining studies were observational, population-based studies, with a total of 59,941 participants (Antoniou 2013). The two RCTs were also included in our review. The review authors evaluated studies for inclusion if they compared perioperative outcomes of eEVAR and open repair of ruptured infrarenal or juxta-renal AAA. All types of comparative studies were included. The review authors found, using a random-effects model, a statistically significant lower mortality for the participants who underwent eEVAR compared with open repair (OR 0.56, 95% CI 0.50 to 0.64; P < 0.00001). The mortality outcome of the Antoniou 2013 review shows a strong mortality odds reduction for the eEVAR group whereas our review found little difference between the eEVAR and open repair groups. Many of the complications evaluated in the Antoniou 2013 study also showed a lower risk in those who underwent eEVAR, such as respiratory complications (OR 0.59, 95% CI 0.49 to 0.69; P < 0.00001) and acute renal failure (OR 0.65, 95% CI 0.55 to 0.78; P < 0.00001), as well as trends towards lower risk in the eEVAR group, however statistically insignificant, of lower limb ischaemia (OR 0.63, 95% CI 0.37 to 1.07; P = 0.09) and mesenteric ischaemia (OR 0.66, 95% CI 0.44 to 1.00; P = 0.05). The authors also evaluated cardiac complications but mistakenly measured risk difference instead of OR and showed a borderline statistically significant risk difference (RD) favouring eEVAR (RD -0.02, 95% CI -0.03 to 0.00; P = 0.05). The findings for the complications outcomes in our review cannot currently be compared as there were not enough data to make any definitive conclusions.

A recent individual patient data meta-analysis was conducted from three randomised controlled trials evaluating mortality at 30 days, 90 days and one year after receiving either eEVAR or open repair for RAAA (Sweeting 2015; Sweeting 2015a). The three studies included in this meta-analysis were also included in our review (AJAX; ECAR; IMPROVE). Sweeting 2015 calculated very similar results to our own, with no difference in mortality at 30 days (OR 0.88 95% CI 0.66 to 1.18), and also they found no difference at 90 days (OR 0.85 95% CI 0.64 to 1.13). At one year there was still no difference in mortality between the treatment groups (OR 0.84 95% CI 0.63 to 1.11) (Sweeting 2015a), similar to our own findings, but we were only able to include the data from a single study (IMPROVE).

Authors' conclusions

Implications for practice

The conclusions of this review are currently limited by the paucity of data. From the data available there is moderate quality evidence of no difference in the primary outcome evaluated in this review between eEVAR and open repair, 30 day or in-hospital mortality. Not enough information was provided for complications in order to make well informed conclusions at this time, although there was some evidence of reduced bowel ischaemia in the eEVAR treatment group. Long-term data are lacking for both survival and late complications.

Implications for research

Further trials are required to evaluate the role of eEVAR in the treatment of RAAA. These trials should be methodologically adequate in terms of sample sizes, treatment standardisation, and duration of follow up. Clinically-relevant outcomes such as rate of major complications, open conversion, aneurysm exclusion, endoleak, rupture, and mortality should be addressed. Long-term results on survival and secondary interventions will also be an important aspect of future results. However, accumulating evidence from non-randomised studies, which show significant reductions in mortality in selected patients deemed suitable for endovascular repair, may raise ethical concerns in relation to randomising these patients to open repair. Large prospective studies are required to validate the acceptable anatomical criteria for eEVAR in RAAA. Furthermore, longitudinal studies are required to assess the long-term durability of this form of treatment in terms of re-intervention rate, open-conversion rate, and rupture-free survival. There are indications that eEVAR patients have a higher rate of discharge to home with associated enhanced quality of life and also that aortic morphology could be important for outcomes. For our review, due to a paucity of data we were unable to undertake any subgroup analysis that may illuminate if certain patient groups may benefit from either intervention more. This is of vital interest to patients and deserves more attention in future research. Finally, as technology improves the EVAR devices outcome differences may emerge in future research.

Acknowledgements

The authors would like to thank the members of the Cochrane Vascular editorial board for their guidance and support and Marianne Dillon and Chris Cardwell for their work on the previous version of the review.

Contributions of authors

For the current update of this review, study selection, quality assessment, and data extraction were performed by Stephen Badger and Rachel Forster. Drafting of the review was performed by Rachel Forster with input from Stephen Badger and Denis W Harkin.

For previous versions of this review Marianne Dillon and Denis W Harkin performed the literature searches, identified all possible trials, considered them for inclusion, and assessed trial quality. Paul Blair, Peter Ellis, Chris Cardwell, and Frank Kee acted as arbitrators where disagreements over inclusion and quality of studies occurred during the review process.

Declarations of interest

SB: none known
RF: none known
PB: editorial base will complete on submission of COI form
PE: none known
FK: none known
DH: none known

Differences between protocol and review

In order to reflect the nature of the diagnosis of RAAA, 'clinical diagnosis of ruptured abdominal aortic aneurysm' was rephrased to 'clinical and radiological diagnosis of ruptured abdominal aortic aneurysm'. Also, 'Types of participants' was clarified.
A new outcome 'complications and mortality long term (longer than six months), re-intervention rates for problems related to the RAAA or its treatment will be sought, where possible, as will cause of death, with or without re-intervention, that is, device-related' was added as it is expected that these data will become available in the future.

The outcome 'aneurysm exclusion' has been clarified to 'endoleak' as this previously used term was very vague and found to be misleading.

Published notes

Characteristics of studies

Characteristics of included studies

AJAX

Methods	Study type: multicentre, randomised controlled trial, intention-to-treat Study aim: compare EVAR and open repair in treating RAAA on mortality and severe complications Country: Netherlands Setting: 3 large hospital vascular centres in Amsterdam
Participants	Number randomised: total n = 116 (eEVAR n = 57; open repair n = 59) Age (mean years, 95% CI): eEVAR = 74.5 (72.3-77.5); open repair = 74.5 (72.2-76.8) Gender (M/F): eEVAR = 49/8; open repair = 50/9 Inclusion criteria: male and females over 18 years; clinical diagnosis of RAAA; aneurysm accompanied by acute haemorrhage outside of the aortic wall of CTA; suitable for eEVAR and open repair Exclusion criteria: extension of the aneurysm to juxta- or suprarenal aorta; kidney transplant; horseshoe kidney; allergy to intravenous contrast; connective tissue disease; severe haemodynamic instability prohibiting CT eEVAR anatomical suitability requirements: suitable infrarenal anchoring segment, minimum length of the infrarenal segment of at least 10 - 15 mm, infrarenal diameter of 20 - 32 mm, no obstructing calcifications, tortuosity of thrombosis, suitable iliac anchoring segment, ipsilateral iliac diameter of 8 - 18 mm, contralateral iliac diameter of 10 - 20 mm, at least one iliac artery should be able to accommodate an endograft CVD risk factors (n (%)): diabetes (EVAR n = 2 (4%), open repair n = 1 (2%)); hypertension (EVAR n = 13 (23%), open repair n = 10 (17%)); smoker (EVAR n = 23 (40%), open repair n = 20 (34%)); hyperlipidaemia (EVAR n = 13 (23%), open repair n = 19 (32%)); renal disease (EVAR n = 1 (2%), open repair n = 2 (3%)); pulmonary disease (EVAR n = 7 (12%), open repair n = 3 (5%)); carotid disease (EVAR n = 16 (28%), open repair n = 10 (17%)); cardiac disease (EVAR n = 16 (28%), open repair n = 14 (24%)) Type of RAAA: infrarenal
Interventions	eEVAR description: aorto-uni-iliac endograft and contralateral iliac occluding device, followed by a femoro-femoral crossover bypass graft Open repair description: midline laparotomy and exclusion of rupture aneurysm by either polyester tube or bifurcated graft; conducted under general anaesthesia
Outcomes	Composite death and severe complications at 30 days post intervention; long-term mortality rates (6 months after randomisation); length of hospital and ICU stay; duration of intubation/ventilation; use of blood products; for EVAR, occurrence of endoleaks
Notes	Study period: April 2004 to February 2011; 3 main trial centres, all other (7) regional hospitals transferred participants to one of the trial centres

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The randomization sequence was generated by an independent clinical research unit using ALEA software for randomization in clinical trials with a 1:1 allocation using random block sizes of 4 or 6, stratified for each participating centre."
Allocation concealment (selection bias)	Low risk	"Allocation was concealed using sequentially numbered opaque sealed envelopes."
Blinding of participants and personnel (performance bias)	Low risk	Surgical team not possible to blind, but unlikely to influence outcomes
Blinding of outcome assessment (detection bias)	Low risk	Double database entry; endpoint adjudication committee blinded; independent safety committee blinded
Incomplete outcome data (attrition bias)	Low risk	All patients accounted for in CONSORT diagram; both treatment groups had similar dropout rates and reasons
Selective reporting (reporting bias)	Low risk	All outcomes reported on
Other bias	Low risk	None

ECAR

Methods	Study type: multicentre, randomised controlled trial, open label, intention-to-treat Study aim: to compare post-operative mortality between open surgical repair and endovascular repair for aorto-iliac abdominal aortic aneurysms in a homogeneous group of patients Country: France Setting: 14 locations
Participants	Number randomised: total n = 107 (eEVAR n = 56; open repair n = 51) Age (mean years (range)): eEVAR = 75.0 (56.0-96.0); open repair = 73.8 (54.0-93.0) Gender (M%): eEVAR = 91%; open repair = 90% Inclusion criteria: patients had to be haemodynamically stable (systolic blood pressure on arrival > 80 mmHg unassisted by high dose catacholamines; pre-operative CT angiography had to prove aortic rupture and document anatomic suitability for OR or EVAR, aneurysm rupture was defined by the existence of blood outside the aorto-iliac aneurysm wall: retroperitoneal haematoma with peri-aortic blood in the peri-renal space and/or the para-renal space or intraperitoneal haematoma; availability of a qualified surgeon (minimum prerequisite of having carried out 15 EVAR procedures for asymptomatic/symptomatic AAA) and availability of devices and facilities for performing EVAR Exclusion criteria: see inclusion criteria Type of RAAA: aorto-iliac
Interventions	eEVAR: aorto-uni-iliac or bifurcated aorto-bi-iliac stent graft; multiple devices used Open repair: standard operation;
Outcomes	30 day mortality; post-op morbidity (cardiac, pulmonary, digestive, renal and neurological), length of stay in ICU, amount of blood transfused, 6 month and 1 year mortality and morbidity, complications
Notes	Study period: patients enrolled between January 2008 to January 2013

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"Randomization was done by week, synchronously in all centers"; "patients were treated by OSR during the first week and subsequent odd numbered weeks, and by EVAR during the second week and subsequent even numbered weeks"; authors cite this method as suitable as imposing one method on a surgical team whom may be used to performing the other method would bias the study. This is not a form of randomisation but rather alternation and is insufficient to prevent selection bias
Allocation concealment (selection bias)	High risk	Treatment assignment was based on weeks of the study
Blinding of participants and personnel (performance bias)	Low risk	No blinding but unlikely to affect outcomes
Blinding of outcome assessment (detection bias)	Low risk	No blinding but unlikely to affect outcomes
Incomplete outcome data (attrition bias)	Low risk	All participants accounted for; no patients lost to follow-up
Selective reporting (reporting bias)	Low risk	All pre-defined outcomes were reported on
Other bias	Unclear risk	Underpowered: to achieve a power > 80% with an alpha risk of 5%, 80 patients were required in each treatment group

Hinchliffe 2006

Methods	Study type: single-centre, randomised controlled trial, open label, intention-to-treat Study aim: to test the hypothesis that EVAR can reduce the perioperative mortality of ruptured AAA, compared with open repair Country: England Setting: hospital
Participants	Number randomised: total n = 32 (eEVAR n = 15; open repair n = 17) Age (median years (IQR)): eEVAR = 74 years (68.8 to 79.5); open repair = 80 years (73.8 to 83.8) Gender (M/F): eEVAR = 11/4; open repair = 13/4 Inclusion criteria: all patients admitted with clinically suspected or radiologically confirmed rupture of an infrarenal abdominal aortic aneurysm that, in the opinion of the duty consultant vascular surgeon would normally be treated with open repair Exclusion criteria: no endovascular team available; full selection of emergency stent-grafts not available; age < 50 years; inability to give verbal or written consent; unconscious patient; allergy to radiological contrast, stainless steel or polyester; severe co-morbidity that would preclude intensive care treatment following open repair; previous endovascular AAA repair; women of child bearing potential not taking contraception; pregnant and lactating women eEVAR anatomical suitability (exclusion criteria): absolute contraindications: no evidence on aneurysm rupture, juxtarenal aneurysm, neck diameter > 32 mm, external iliac artery diameter > 6 mm; relative contraindications: proximal neck length < 10 mm, excessive thrombus in the proximal neck, common iliac artery length < 25 mm, heavily calcified iliac arteries CVD risk factors (n (%)): ischaemic heart disease (eEVAR = 3 (20%), open repair = 5 (29%)); chronic obstructive airways disease (eEVAR = 0 (0%), open repair = 3 (18%)); peripheral vascular disease (eEVAR = 1 (7%), open repair = 2 (12%)); renal disease (eEVAR = 1 (7%), open repair = 2 (12%)); hypertension (eEVAR = 5 (29%), open repair = 8 (47%)); active smoker (eEVAR = 4 (27%), open repair = 6 (35%)); ex-smoker (eEVAR = 8 (53%), open repair = 3 (18%)); known AAA (eEVAR = 3 (20%), open repair = 7 (41%)) Type of RAAA: infrarenal
Interventions	eEVAR description: Those with a diagnostic CT were transferred directly to operating theatre, and those without first had a CT scan to determine aortic measurement; performed in dedicated vascular operating theatre using a Siremobil 2000 image intensifier, with digital subtraction angiography facilities; most patients heparinised; two-piece aorto-uni-iliac stent-graft made with Gianturco stents with uncovered suprarenal component; occluding device used in contralateral common iliac artery; after deployment of stent-graft, a femoro-femoral crossover graft was performed Open repair description: After randomisation to open repair, patients were transferred directly to the operating theatre, according to local practice; performed transperitoneally either by midline or transverse incisions; aorta clamped below renal arteries; patients no heparinised; inlay technique was used and grafts were gelatin-coated polyester
Outcomes	Perioperative mortality (defined as 30-day or in-hospital), complications
Notes	"Patients were deemed suitable for EVAR if, in the opinion of the operating surgeon, they could perform the repair"; participants recruited September 2002 to December 2004; 5 surgeons on unit, required that surgeon and team available had sufficient expertise to offer EVAR, if not, conventional open repair was offered; unstable patients that might be disadvantaged by delay incurred by CT scan could, at the surgeon's discretion, not be randomised and taken directly for open repair

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Randomisation was then performed from sealed opaque envelopes kept in the Accident and Emergency Department". Unclear how randomisation sequence was generated
Allocation concealment (selection bias)	Low risk	"Randomisation was then performed from sealed opaque envelopes kept in the Accident and Emergency Department"
Blinding of participants and personnel (performance bias)	Low risk	Study was unblinded, due to nature of intervention but unlikely to influence outcomes. "The surgeons were blinded to the dimensions of patient's aorta until randomisation had taken place" to avoid bias
Blinding of outcome assessment (detection bias)	Low risk	Not possible to blind team regarding allocation group, but unlikely to influence outcome measures
Incomplete outcome data (attrition bias)	Low risk	All patients accounted for; crossover patients accounted for; similar dropout rates and reasons between treatment groups
Selective reporting (reporting bias)	Low risk	Most of protocol outlined in the text; all relevant outcomes reported; with the exception of mortality, outcomes are not well described in the methods
Other bias	Unclear risk	Underpowered study: 32 of the required 100 patients recruited

IMPROVE

Methods	Study type: multicentre, randomised controlled trial, open label, intention-to-treat Study aim: To assess whether EVAR versus open repair reduces early mortality for patients with suspected RAAA Country: UK and Canada Setting: 30 hospital vascular units and specialist centres
Participants	Number randomised: Total n = 613 (eEVAR n = 316; open repair n = 297) Age (mean years (± SD)): eEVAR = 76.7 (7.4); open repair = 76.7 (7.8) Gender (M/F): eEVAR = 246/70; open repair = 234/63 Inclusion criteria: men and women over the age of 50 years; clinical diagnosis of RAAA or ruptured aorto-iliac aneurysm, made by a senior trial hospital clinician Exclusion criteria: previous aneurysm repair; rupture of an isolated internal iliac aneurysm, aorto-caval or aorto-enteric fistulae; recent anatomical assessment of the aorta; connective tissue disorder; if intervention was considered futile eEVAR anatomical suitability requirements: no absolute requirements will be set for the study, but proximal neck morphology with a diameter exceeding 32 mm or a length less than 10 mm may be considered unfavourable, and iliac artery diameters should be in the range of 8 - 22 mm CVD risk factors (n (%)): not given Type of RAAA: "ruptured AAA or ruptured aortoiliac aneurysm"
Interventions	eEVAR description: endovascular supracoeliac aortic balloon occlusion will be used to support less stable patients; most interventions performed with aorto-uni-iliac graft, but some patients received bifurcated grafts, with subsequent femoro-femoral crossover graft with contralateral iliac occlusion; control of aorta achieved using local/region anaesthesia, with general anaesthesia used later in procedure if necessary Open repair description: CT scan is optional; aneurysms repaired by cross-clamping the proximal aorta and inserting a prosthetic inlay graft; performed under general anaesthesia
Outcomes	30-day mortality, 24 hour and in-hospital mortality, costs, re-interventions at primary admission time and place of discharge, cost effectiveness and mortality at 12 months
Notes	Participants recruited September 2009 to July 2013; flow diagram shows 623 randomised, but 10 were excluded after Data Monitoring Commitee reviewed participants, 613 used in analysis; only 275 (87%) of EVAR and 261 (88%) of open repair had confirmed RAAA

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"And independent contractor provided telephone randomisation, with computer generated assignation of patients in a 1:1 ratio, using variable block size and stratified by centre."
Allocation concealment (selection bias)	Low risk	"And independent contractor provided telephone randomisation, with computer generated assignation of patients..."
Blinding of participants and personnel (performance bias)	Low risk	Surgical team not possible to blind, but unlikely to influence outcomes
Blinding of outcome assessment (detection bias)	Low risk	Data verification performed centrally at the trial core laboratory, unclear if blinding, but unlikely to influence outcomes
Incomplete outcome data (attrition bias)	Low risk	All patients accounted for, with both treatment groups having similar dropout rates/reasoning
Selective reporting (reporting bias)	Low risk	All pre-described outcomes reported on
Other bias	Low risk	None

Footnotes

AAA: abdominal aortic aneurysm
CT: computed tomography
CTA: computed tomography angiography
CVD: cardiovascular disease
eEVAR: emergency endovascular aneurysm repair
EVAR: endovascular aneurysm repair
ICU: intensive care unit
RAAA: ruptured abdominal aortic aneurysm
SD: standard deviation

Characteristics of excluded studies

Peppelenbosch 2003

Reason for exclusion	Prospective study of 40 consecutive patients with symptomatic or RAAA in whom eEVAR was the preferential management compared with 28 historical controls who underwent open repair for symptomatic or RAAA

Resch 2003

Reason for exclusion	Prospective study of 21 patients with RAAA undergoing eEVAR (1997 to 2002). Retrospective analysis to evaluate why 23 patients underwent open repair compared to 14 contemporaneous patients who underwent eEVAR for RAA (2001 to 2002)

Rödel 2012

Reason for exclusion	Prospective, non-randomised study of 117 consecutive patients presenting with RAAA; 35 treated with eEVAR the remainder with open repair; 2006 to 2010

Verhoeven 2002

Reason for exclusion	Prospective study of 47 patients with acute AAA (RAAA and symptomatic); 16 underwent eEVAR compared to open surgical cohort

Visser 2006

Reason for exclusion	Part prospective, part retrospective, non-randomised study of 55 consecutive RAAA patients; 26 underwent eEVAR and 29 underwent open repair; 2001 to 2005

Footnotes

eEVAR: emergency endovascular aneurysm repair
RAAA: ruptured abdominal aortic aneurysm

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

Summary of findings tables

1 Is there an advantage of emergency endovascular aneurysm repair (eEVAR) compared to conventional open repair for ruptured abdominal aortic aneurysm?

eEVAR compared to conventional open repair for ruptured abdominal aortic aneurysm

Patient or population: patients diagnosed with RAAA
Setting: hospital

Intervention: eEVAR
Comparison: conventional open repair

Outcomes	№ of participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with conventional open repair	Risk difference with eEVAR
Short-term mortality (30 day or in-hospital)	868 (4 RCTs)	⊕⊕⊕⊖ MODERATE[1]	OR 0.88 (0.66 to 1.16)	Study population	
				366 per 1,000	29 fewer per 1,000 (90 fewer to 35 more)
Endoleak (30 day)	128 (3 RCTs)	⊕⊕⊖⊖ LOW[2]	-	A total of 44 endoleak events occurred in 128 participants that were randomised to eEVAR treatment. As endoleaks are only a result of endovascular repair it is inappropriate to make a comparison using meta-analysis	
Complication: myocardial infarction (30 day)	139 (2 RCTs)	⊕⊕⊖⊖ LOW[3,4]	OR 2.38 (0.34 to 16.53)	Study population	
				15 per 1,000	20 more per 1,000 (10 fewer to 183 more)
Complication: renal complications (moderate or severe) (30 day)	255 (3 RCTs)	⊕⊕⊖⊖ LOW[3,5]	OR 1.07 (0.21 to 5.42)	Study population	
				197 per 1,000	11 more per 1,000 (148 fewer to 374 more)
Complication: respiratory failure (30 day)	32 (1 RCT)	⊕⊕⊖⊖ LOW[6]	OR 3.62 (0.14 to 95.78)	Study population	
				One respiratory failure event occurred in 15 participants that were randomised to eEVAR treatment. No respiratory failure events were reports in the open repair group	
Complication: bowel ischaemia (30 day)	223 (2 RCTs)	⊕⊕⊖⊖ LOW[3,4]	OR 0.37 (0.14 to 0.94)	Study population	
				145 per 1,000	86 fewer per 1,000 (122 fewer to 8 fewer)
Mortality (6 months)	116 (1 RCT)	⊕⊕⊕⊖ MODERATE[3]	OR 0.89 (0.40 to 1.98)	Study population	
				305 per 1,000	24 fewer per 1,000 (156 fewer to 160 more)

* We calculated the assumed risk of the conventional open repair group from the average risk in the conventional open repair group (i.e. the number of participants with events divided by total number of participants of the conventional open repair group included in the meta-analysis). **The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **eEVAR**: emergency endovascular aneurysm repair; **OR:** odds ratio; **RAAA:** ruptured abdominal aortic aneurysm

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Footnotes

[1]Downgraded by 1 level due to imprecision: two of the three studies included in this outcome were underpowered to report on this outcome, as calculated by the study authors
[2]Downgraded by 2 levels due to inconsistency: event values varied greatly between studies resulting in heterogeneity
[3]Downgraded by 1 level due to imprecision: few participants or events, or both were included in the outcome analysis
[4]Downgraded by 1 level due to risk of bias due to inadequate random sequence generation and allocation concealment within the ECAR study which contributes a majority of participants within this outcome
[5]Downgraded by 1 level due to inconsistency: event values varied between studies

[6]Downgraded by 2 levels due to very serious imprecision: only a single event was reported in the eEVAR group

Additional tables

1 Perioperative and postoperative patient characteristics

		AJAX (median, IQR)	ECAR (mean, SD)	Hinchliffe 2006 (median, IQR)	IMPROVE (mean, SD)
Time waiting for procedure	eEVAR	74 min (39 - 126 min)	2.9 hours		93 min (± 370)
	Open repair	45 min (35 - 70 min)	1.3 hours		73 min (± 157)
Time in operating theatre	eEVAR	185 min (160 - 236 min)		160 min (150 - 234 min)	156 min (± 100)
	Open repair	157 min (136 - 194 min)		150 min (141 - 204 min)	180 min (± 107)
Blood loss during operation	eEVAR	500 mL (200 - 1375 mL)	Units for transfusion: 6.8 (range 0 - 25.0)	200 mL (163 - 450 mL)	
	Open repair	3500 mL (1000 - 4600 mL)	Units for transfusion: 10.9 (range 0 - 53.0)	2100 mL (1150 - 3985 mL)	
Length of hospital stay	eEVAR	9 days (4 - 21 days)	14.3 days (6.0 to 99.0)	10 days (6 - 28 days)	9.8 days (± 9.0)
	Open repair	13 days (5 - 21 days)	17.1 days (9.1 to 81.1)	12 days (4 - 52 days)	12.2 days (± 10.2)

Footnotes

eEVAR: emergency endovascular aneurysm repair
IQR: interquartile range
SD: standard deviation

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Included studies

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[CRSSTD: 3400115; ISRCTN: 66212637]

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Classification pending references

Data and analyses

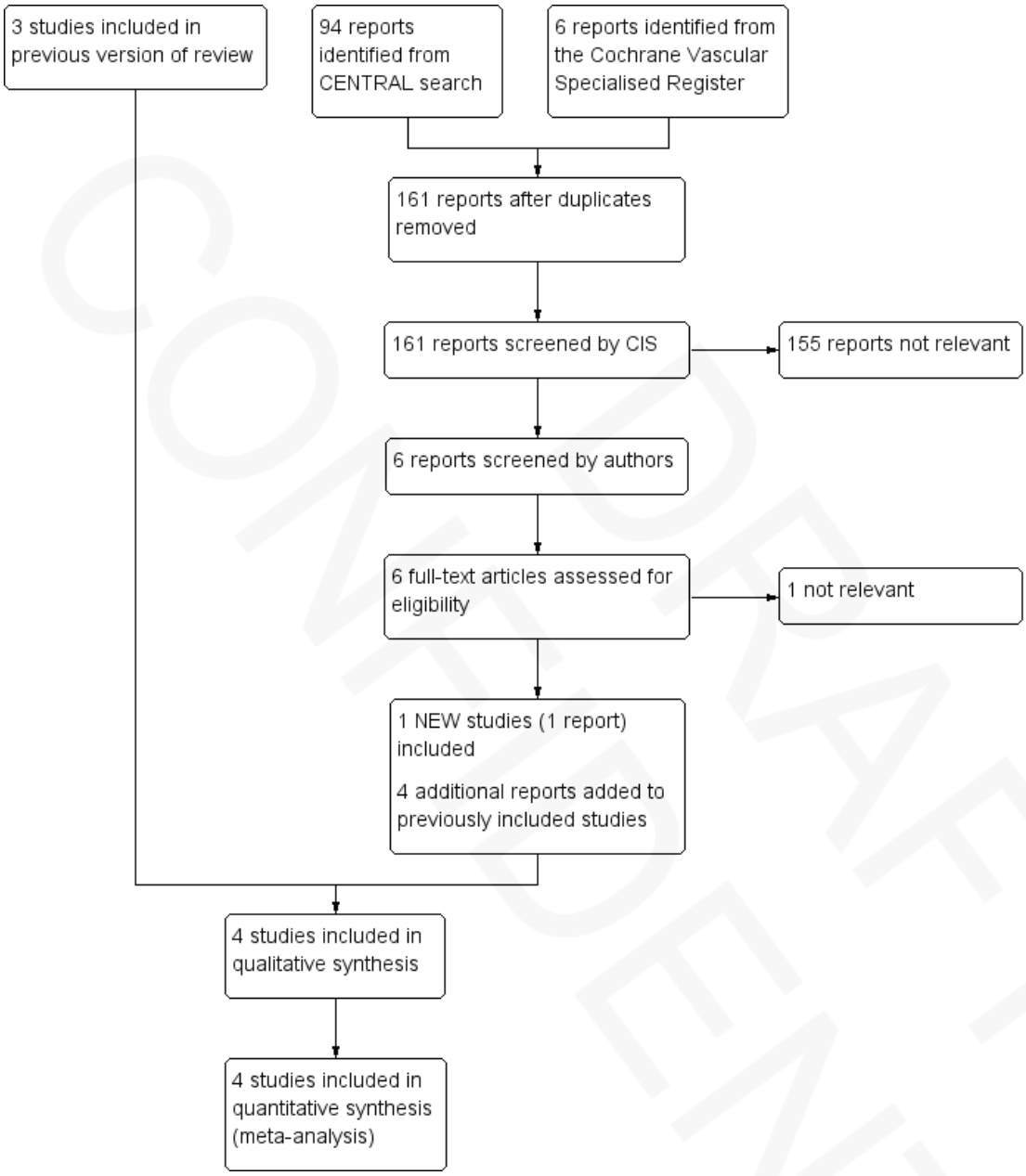
1 eEVAR versus open repair

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Short-term mortality (30 day or in-hospital)	4	868	Odds Ratio(M-H, Fixed, 95% CI)	0.88 [0.66, 1.16]

1.2 Major Complications- 30 day	2	223	Odds Ratio(M-H, Fixed, 95% CI)	0.72 [0.42, 1.23]
1.3 Complication- Myocardial infarction	2	139	Odds Ratio(M-H, Fixed, 95% CI)	2.38 [0.34, 16.53]
1.4 Complication- Stroke	2	148	Odds Ratio(M-H, Fixed, 95% CI)	0.71 [0.12, 4.31]
1.5 Complication- Cardiac complications (moderate or severe)	3	253	Odds Ratio(M-H, Fixed, 95% CI)	0.84 [0.32, 2.23]
1.6 Complication- Renal complications (moderate or severe)	3	255	Odds Ratio(M-H, Random, 95% CI)	1.07 [0.21, 5.42]
1.7 Complication- Respiratory failure	1		Odds Ratio(M-H, Fixed, 95% CI)	No totals
1.8 Complication- Bowel ischaemia	2	223	Odds Ratio(M-H, Fixed, 95% CI)	0.37 [0.14, 0.94]
1.9 Complication- Spinal cord ischaemia	1		Odds Ratio(M-H, Fixed, 95% CI)	No totals
1.10 Complication- Re-operation	2	148	Odds Ratio(M-H, Fixed, 95% CI)	0.89 [0.39, 2.01]
1.11 Complication- Amputation	2	223	Odds Ratio(M-H, Fixed, 95% CI)	0.16 [0.02, 1.32]
1.12 Mortality- 6 months	1		Odds Ratio(M-H, Fixed, 95% CI)	No totals
1.13 Major Complications- 6 months	1		Odds Ratio(M-H, Fixed, 95% CI)	No totals
1.14 Complication- Re-operation 6 months	1		Odds Ratio(M-H, Fixed, 95% CI)	No totals
1.15 Mortality- 1 year	1		Odds Ratio(M-H, Fixed, 95% CI)	No totals
1.16 Cost per patient- 30 day	1		Mean Difference(IV, Fixed, 95% CI)	No totals

Figures

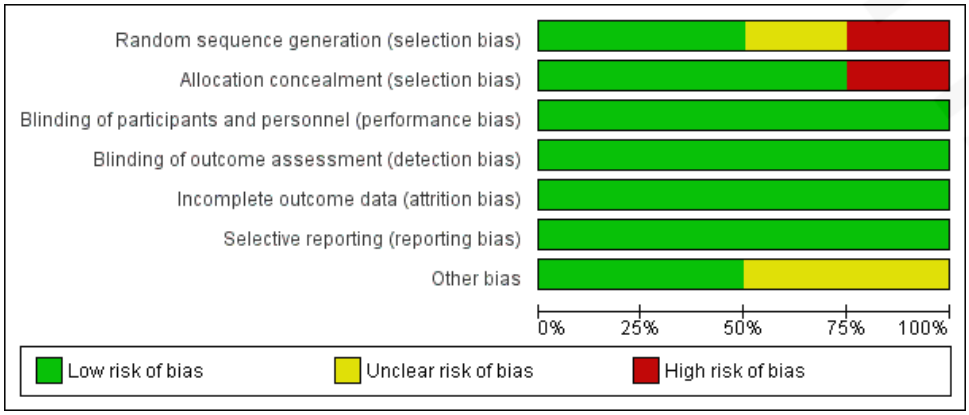
Figure 1



Caption

Study flow diagram.

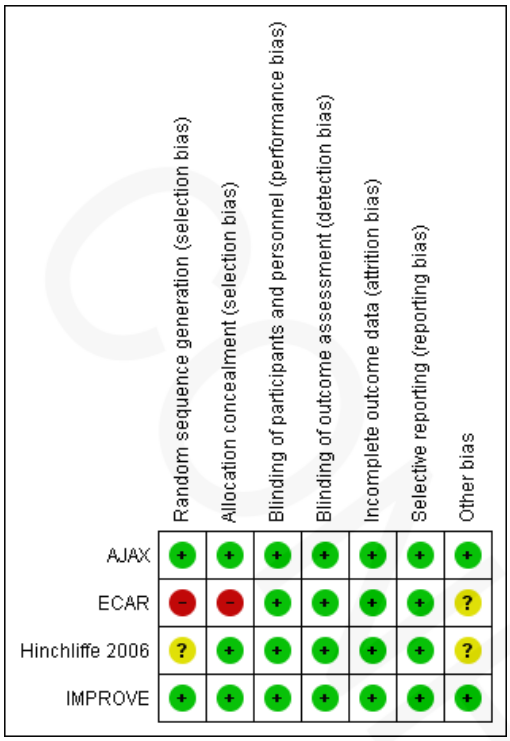
Figure 2



Caption

Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Figure 3



Caption

Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

Sources of support

Internal sources

- No sources of support provided

External sources

- Chief Scientist Office, Scottish Government Health Directorates, The Scottish Government, UK
  The Cochrane Vascular editorial base is supported by the Chief Scientist Office.
- National Institute for Health Research (NIHR), UK
  This project was supported by the NIHR, via Cochrane Incentive Award funding (16/72/05) to Cochrane Vascular. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Systematic Reviews Programme, NIHR, NHS or the Department of Health.

Feedback

1 IMPROVE trial, 21 October 2014

Summary

The authors have misinterpreted the diagnoses of patients in the IMPROVE trial.
613 patients had a clinical diagnosis of ruptured AAA before CT scanning
10 patients had no AAA
45 patients had asymptomatic AAA & other final diagnoses
22 patients had symptomatic non-ruptured AAA
(not 77 as cited in review)
536 patients had proven diagnosis of AAA rupture, of whom 35 died before AAA repair was started.

Reply

We agree we have misinterpreted the 77 participants that were randomised but did not actually have a ruptured abdominal aortic aneurysm, which was discovered at commencement of the intervention. We have amended the text in the locations where we discuss this aspect of the IMPROVE trial using the data supplied by Professor Janet Powell.

Contributors

Feedback: Prof Janet Powell, Chief Investigator IMPROVE trial, Imperial College London, UK

Reply: Mr Stephen Badger, Department of Vascular Surgery, Mater Misericordiae University Hospital, Dublin, Ireland
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Appendices

1 CENTRAL search strategy

#1	MESH DESCRIPTOR Aneurysm, Ruptured EXPLODE ALL TREES	154
#2	MESH DESCRIPTOR Aneurysm, Dissecting	64
#3	MESH DESCRIPTOR Aorta EXPLODE ALL TREES WITH QUALIFIERS SU	310
#4	((aneurysm* or abdom* or thoracoabdom* or thoraco-abdom* or aort*) near (ruptur* or tear or bleed* or trauma)):TI,AB,KY	790
#5	RAAA:TI,AB,KY	8
#6	#1 OR #2 OR #3 OR #4 OR #5	1137
#7	MESH DESCRIPTOR Endovascular Procedures EXPLODE ALL TREES	6264
#8	MESH DESCRIPTOR Stents EXPLODE ALL TREES	3132
#9	MESH DESCRIPTOR Vascular Surgical Procedures	523
#10	MESH DESCRIPTOR Blood Vessel Prosthesis EXPLODE ALL TREES	406
#11	MESH DESCRIPTOR Blood Vessel Prosthesis Implantation EXPLODE ALL TREES	389
#12	endovasc*:TI,AB,KY	1224
#13	endostent*:TI,AB,KY	1
#14	endoluminal:TI,AB,KY	125
#15	endoprosthe*:TI,AB,KY	236
#16	(graft or endograft*):TI,AB,KY	12927
#17	percutaneous*:TI,AB,KY	9399
#18	stent*:TI,AB,KY	6994
#19	(Palmaz or Zenith or Dynalink or Hemobahn or Luminex* or Memotherm or Wallstent):TI,AB,KY	332
#20	(Viabahn or Nitinol or Intracoil or Tantalum):TI,AB,KY	242
#21	EVAR:TI,AB,KY	100
#22	EVRAR:TI,AB,KY	0
#23	TEVAR:TI,AB,KY	24
#24	#7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23	29429
#25	#6 AND #24	348
#26	* NOT SR-PVD:CC AND 31/03/2014 TO 31/07/2016:DL	186054
#27	#25 AND #26	94

2 Trial registries search strategies

World Health Organization International Clinical Trials Registry

9 records for 7 trials found for: ruptured and abdominal and aneurysm

ClinicalTrials.gov

67 studies found for: ruptured and aneurysm and abdominal

ISRCTN Register

14 results ruptured and abdominal and aneurysm