Cochrane
Library

Cochrane Database of Systematic Reviews

Totally percutaneous versus surgical cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair (Review)

Gimzewska M, Jackson AIR, Yeoh SE, Clarke M

Gimzewska M, Jackson AIR, Yeoh SE, Clarke M.

Totally percutaneous versus surgical cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair.

Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD010185.

DOI: [10.1002/14651858.CD010185.pub3](https://doi.org/10.1002/14651858.CD010185.pub3).

www.cochranelibrary.com

Totally percutaneous versus surgical cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair (Review)

Copyright © 2017 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

WILEY

TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
SUMMARY OF FINDINGS	4
BACKGROUND	6
OBJECTIVES	7
METHODS	7
RESULTS	8
Figure 1.	9
Figure 2.	11
Figure 3.	12
DISCUSSION	14
AUTHORS' CONCLUSIONS	15
ACKNOWLEDGEMENTS	15
REFERENCES	16
CHARACTERISTICS OF STUDIES	18
DATA AND ANALYSES	23
Analysis 1.1. Comparison 1 Percutaneous vs cut-down femoral artery access, Outcome 1 Short-term mortality rate (30-day or in-hospital).	24
Analysis 1.2. Comparison 1 Percutaneous vs cut-down femoral artery access, Outcome 2 Aneurysm exclusion.	24
Analysis 1.3. Comparison 1 Percutaneous vs cut-down femoral artery access, Outcome 3 Major complications.	24
Analysis 1.4. Comparison 1 Percutaneous vs cut-down femoral artery access, Outcome 4 Major complications (6 months).	25
Analysis 1.5. Comparison 1 Percutaneous vs cut-down femoral artery access, Outcome 5 Bleeding complications.	25
Analysis 1.6. Comparison 1 Percutaneous vs cut-down femoral artery access, Outcome 6 Operating time (minutes).	25
APPENDICES	26
WHAT'S NEW	28
CONTRIBUTIONS OF AUTHORS	28
DECLARATIONS OF INTEREST	28
SOURCES OF SUPPORT	28
DIFFERENCES BETWEEN PROTOCOL AND REVIEW	28
INDEX TERMS	29

[Intervention Review]

Totally percutaneous versus surgical cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair

Madelaine Gimzewska¹, Alexander IR Jackson^{2,3}, Su Ern Yeoh⁴, Mike Clarke⁵¹Cochrane Vascular, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh, Edinburgh, UK.²University Hospital Southampton NHS Foundation Trust, Southampton, UK. ³Clinical and Experimental Sciences Academic Unit, University of Southampton, Southampton, UK. ⁴College of Medicine and Veterinary Medicine, The University of Edinburgh, Edinburgh, UK. ⁵Northern Vascular Centre, Freeman Hospital, Newcastle upon Tyne, UK**Contact address:** Alexander IR Jackson, University Hospital Southampton NHS Foundation Trust, Southampton General Hospital, Tremona Road, Southampton, S016 6YD, UK. sandyirjackson@gmail.com, a.i.jackson@soton.ac.uk.**Editorial group:** Cochrane Vascular Group.**Publication status and date:** New search for studies and content updated (no change to conclusions), published in Issue 2, 2017.**Citation:** Gimzewska M, Jackson AIR, Yeoh SE, Clarke M. Totally percutaneous versus surgical cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair. *Cochrane Database of Systematic Reviews* 2017, Issue 2. Art. No.: CD010185. DOI: [10.1002/14651858.CD010185.pub3](https://doi.org/10.1002/14651858.CD010185.pub3).

Copyright © 2017 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

ABSTRACT

Background

Abdominal aortic aneurysms (AAAs) are a vascular condition with significant risk attached, particularly if they rupture. It is, therefore, critical to identify and repair these as an elective procedure before they rupture and require emergency surgery. Repair has traditionally been an open surgical technique that required a large incision across the abdomen. Endovascular abdominal aortic aneurysm repairs (EVARs) are now a common alternative. In this procedure, the common femoral artery is exposed via a cut-down approach and a graft introduced to the aneurysm in this way. This review examines a totally percutaneous approach to EVAR. This technique gives a minimally invasive approach to femoral artery access that may reduce groin wound complication rates and improve recovery time. The technique may, however, be less applicable in people with, for example, groin scarring or arterial calcification. This is an update of the review first published in 2014.

Objectives

This review aims to compare the clinical outcomes of percutaneous access with surgical cut-down femoral artery access in elective bifurcated abdominal endovascular aneurysm repair (EVAR).

Search methods

For this update the Cochrane Vascular Information Specialist (CIS) searched their Specialised Register (last searched October 2016) and CENTRAL (2016, Issue 9). We also searched clinical trials registries and checked the reference lists of relevant retrieved articles.

Selection criteria

We considered only randomised controlled trials. The primary intervention was a totally percutaneous endovascular repair. We considered all device types. We compared this against surgical cut-down femoral artery access endovascular repair. We only considered studies investigating elective repairs. We excluded studies reporting emergency surgery for a ruptured abdominal aortic aneurysm and those reporting aorto-uni-iliac repairs.

Data collection and analysis

Two review authors independently collected all data. Owing to the small number of trials identified we did not conduct any formal sensitivity analysis. Heterogeneity was not significant for any outcome.

Totally percutaneous versus surgical cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair (Review)**1**

Copyright © 2017 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

Main results

Two studies with a total of 181 participants met the inclusion criteria, 116 undergoing the percutaneous technique and 65 treated by cut-down femoral artery access. One study had a small sample size and did not adequately report method of randomisation, allocation concealment or pre-selected outcomes. The second study was a larger study with few sources of bias and good methodology.

We observed no significant difference in mortality between groups, with only one mortality occurring overall, in the totally percutaneous group (risk ratio (RR) 1.50; 95% confidence interval (CI) 0.06 to 36.18; 181 participants; moderate-quality evidence). Only one study reported aneurysm exclusion. In this study we observed only one failure of aneurysm exclusion in the surgical cut-down femoral artery access group (RR 0.17, 95% CI 0.01 to 4.02; 151 participants; moderate-quality evidence). No wound infections occurred in the cut-down femoral artery access group or the percutaneous group across either study (moderate-quality evidence).

There was no difference in major complication rate between cut-down femoral artery access and percutaneous groups (RR 0.91, 95% CI 0.20 to 1.68; 181 participants; moderate-quality evidence); or in bleeding complications and haematoma (RR 0.94, 95% CI 0.31 to 2.82; 181 participants; high-quality evidence).

Only one study reported long-term complication rates at six months, with no differences between the percutaneous and cut-down femoral artery access group (RR 1.03, 95% CI 0.34 to 3.15; 134 participants; moderate-quality evidence).

We detected differences in surgery time, with percutaneous approach being significantly faster than cut-down femoral artery access (mean difference (MD) -31.46 minutes; 95% CI -47.51 minutes to -15.42 minutes; 181 participants; moderate-quality evidence). Only one study reported duration of ITU (intensive treatment unit) and hospital stay, with no difference found between groups.

Authors' conclusions

This review shows moderate-quality evidence of no difference between the percutaneous approach compared with cut-down femoral artery access group for short-term mortality, aneurysm exclusion, major complications, wound infection and long-term (six month) complications, and high-quality evidence for no difference in bleeding complications and haematoma. There was a difference in operating time, with moderate-quality evidence showing that the percutaneous approach was faster than the cut-down femoral artery access technique. We downgraded the quality of the evidence to moderate as a result of the limited number of studies, low event numbers and imprecision. As the number of included studies were limited, further research into this technique would be beneficial. The search identified one ongoing study, which may provide an improved evidence base in the future.

PLAIN LANGUAGE SUMMARY

Skin puncture versus exposing the femoral artery for minimally invasive repairs of abdominal aortic aneurysms

Background

Abdominal aortic aneurysms are a ballooning of the largest blood vessel in the abdomen, the abdominal aorta, due to weakness of the vessel wall. This ballooning may lead to life-threatening rupture. Repair of the aneurysm is recommended if the risk of rupture is calculated to be greater than the risk of surgery. Most repairs involve putting in an artificial graft, a tube composed of fabric, to help reinforce the artery wall. There are two main methods for repair. One is an open technique in which the whole abdomen is opened and the graft is used to replace the diseased part of the vessel. The other technique is an endovascular aneurysm repair. With this technique the graft is fed into the abdominal aorta through an artery in the groin (the femoral artery) and avoids the large abdominal incision. This review looked at an alternative method for introducing the graft into the femoral artery, percutaneous access. Instead of making an incision in the groin to expose the femoral artery (a cut-down), a needle is inserted to the femoral artery then a flexible guide wire inserted through the needle. The needle is removed and a plastic tube introduced into the femoral artery over the guide wire (percutaneous access), with a small cut in the skin to allow the passage of the plastic tube. Once introduced, the guide wire can be removed leaving the tube in place in the artery. The graft and all other materials can then be fed into the artery via the plastic tube. Once the procedure is complete the tube can be withdrawn. The surface incision can usually be closed with one stitch.

Study characteristics and key results

This update found two studies comparing the cut-down artery access with the percutaneous technique (current to October 2016). One was a small study with 30 participants, the other a larger more robust study with 151 participants. The large study was found to be of high quality with little risk of bias. The smaller study did not report on the methods of randomisation, how the randomisation was concealed and the pre-selected outcomes of interest. Combined, the studies had 181 participants; 116 underwent the cut-down technique and 65 the percutaneous technique.

Both studies compared rates of death, major complications, wound infections, bleeding complications, and length of the operation. Overall, we did not find any difference in the rates of death (moderate-quality evidence), major complications (moderate-quality evidence); or bleeding complications between the percutaneous and cut-down techniques (high-quality evidence). No one developed a wound infection (moderate-quality evidence). The surgery took less time (moderate-quality evidence) in the percutaneous group compared with the cut-down group.

Totally percutaneous versus surgical cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair (Review)

Only one study reported if the aneurysm wall was successfully reinforced (checked by a CT scan, moderate-quality evidence), on complications at six months, (moderate-quality evidence); and on how long participants spent in an intensive treatment unit (ITU). We did not find any difference between the cut-down and percutaneous groups.

Quality of the evidence

This review shows moderate-quality evidence of no difference between the percutaneous approach compared with cut-down femoral artery access group for short-term mortality, aneurysm exclusion (sealing of the aneurysms), major complications, wound infection and long-term (six months) complications; and high-quality evidence for no difference in bleeding complications. There was a difference in operating time, with moderate-quality evidence showing that the percutaneous approach was faster than the cut-down femoral artery access technique. We downgraded the quality of the evidence to moderate due to the small number of studies, overall event rates and imprecision (differences around the level of effect).

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Totally percutaneous compared to cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair

Totally percutaneous compared to cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair

Patient or population: people undergoing elective bifurcated abdominal endovascular aneurysm repair

Setting: hospital

Intervention: totally percutaneous

Comparison: cut-down femoral artery access

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with cut-down femoral artery access	Risk with totally percutaneous				
Short-term mortality rate (30-day or in-hospital)	See comment	See comment	RR 1.50 (0.06 to 36.18)	181 (2 RCTs)	⊕⊕⊕⊖ MODERATE 1	It was not possible to calculate risk as only one event occurred. Note that although 2 RCTs included, only one contributes to effect estimate (no events in Torsello 2003)
Failure of aneurysm exclusion (follow-up 28 days)	Study population		RR 0.17 (0.01 to 4.02)	151 (1 RCT)	⊕⊕⊕⊖ MODERATE 2	
	20 per 1000	3 per 1000 (0 to 80)				
Wound infection rate (30-day or in-hospital)	See comment	See comment	not estimable	181 (2 RCTs)	⊕⊕⊕⊖ MODERATE 3	Risk and relative effect were not estimable as no events occurred
Major complications (30-day or in-hospital)	Study population		RR 0.91 (0.50 to 1.68)	181 (2 RCTs)	⊕⊕⊕⊖ MODERATE 4	
	200 per 1000	182 per 1000 (100 to 336)				
Long term complications (follow-up 6 months)	Study population		RR 1.03 (0.34 to 3.15)	134 (1 RCT)	⊕⊕⊕⊖ MODERATE 5	

	95 per 1000	98 per 1000 (32 to 299)			
Bleeding complications and haematoma (30-day or in-hospital)	Study population		RR 0.94 (0.31 to 2.82)	181 (2 RCTs)	⊕⊕⊕⊕ HIGH
	62 per 1000	58 per 1000 (19 to 174)			
Operating time (minutes)	The mean operating time was 99 minutes	The mean operating time in the intervention group was 31.46 minutes lower (47.51 lower to 15.42 lower)	-	181 (2 RCTs)	⊕⊕⊕⊖ MODERATE ⁶

* The basis for the **assumed risk** for 'Study population' was the average risk in the comparison group (i.e. total number of participants with events divided by the total number of participants in the comparison 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) and calculated where possible from the data provided in the studies.

CI: Confidence interval; **mins:** minutes; **RCT:** randomised controlled trial; **RR:** Risk ratio;

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

¹ We downgraded by one level due to the low number of events and imprecision (wide confidence intervals include both harm and benefit)

² We downgraded by one level as event rates were low and data were available from only one study

³ We downgraded by one level due to a low number of events (no wound infections reported)

⁴ We downgraded by one level due to imprecision (wide confidence intervals include both harm and benefit)

⁵ We downgraded by one level as data were available from only one study. A loss to follow up for this outcome was detected (9% of participants; 16% of the percutaneous group and 8% of the cut-down femoral artery access group). We did not downgrade further as there was a clear breakdown of loss to follow-up and no significant difference in loss to follow-up between groups was detected

⁶ We downgraded by one level as the studies reported this outcome as a secondary outcome and were not adequately powered for this outcome.

BACKGROUND

Description of the condition

Abdominal aortic aneurysms (AAAs) are a vascular condition whereby the abdominal aorta increases in diameter. This enlargement is defined as an aneurysm of the abdominal aorta when the enlargement is 1.5 times greater than the normal diameter, or over 3 cm. The enlargement carries significant risk: if left untreated there is a high risk of rupture, which carries an approximately 80% risk of mortality (Chambers 2009). It is therefore critical to identify and repair these aneurysms as an elective procedure before they rupture and require emergency surgery.

The prevalence of AAAs in men in the UK has been estimated to range from 1.3% to 8.4% (Lucarotti 1993), depending on the criteria used to define an AAA. Meanwhile studies have consistently shown women to have a far lower prevalence (Fowkes 1989; Scott 1995). In Scott 1995 1.3% of women were found to have AAAs compared to 7.6% of men. The incidence according to hospital records in Scotland, between 1971 and 1984, was 63.6 per 100,000 people per year (Naylor 1988).

Description of the intervention

Repair has traditionally been an open surgical repair, which required a large incision across the abdomen to allow clear access to the aorta so that the damaged section could be repaired by the insertion of a prosthetic graft. However, in 1991 Parodi and colleagues reported their initial experiences with what they described as a transfemoral intraluminal graft (Parodi 1991). This rapidly developed into what we now refer to as endovascular abdominal aortic aneurysm repair (EVAR).

In this procedure the common femoral arteries are exposed via incisions in each groin, and guidewires and access sheaths are introduced. The components of the endovascular graft are then advanced over the guidewires and deployed under radiographic control. Angiography is used to confirm satisfactory deployment of the prosthesis and exclusion of the aneurysm sac, following which all catheters, sheaths and guidewires are removed. The defects in the femoral arteries are surgically repaired and the cut-down incisions closed (Rutherford 2005).

EVARs and open repairs are now the two primary forms of treatment for AAAs. EVAR has grown rapidly in popularity and in the USA, since 2003, has accounted for the majority of procedures taking place (Schwarze 2009). In the UK, the National Vascular Registry reported that EVAR is currently used in the majority (66%) of elective infra-renal AAA repairs with 2779 elective EVAR repairs conducted between 2012 and 2014 (Watson 2015). It was also used in 20% of ruptured AAA repairs in the same time period (Watson 2015).

More recently, further advances have taken place allowing for a wholly percutaneous approach. This approach was reported as early as 1999 (Papazoglou 1999) and has grown in popularity with a recent review of NSQIP (National Surgical Quality Improvement Program) data showing almost half of elective EVAR cases reviewed used a percutaneous approach (Kauvar 2016).

The approach has developed with the use of several different suture-mediated closure devices being reported in the literature including the Prostar XL (Abbott) (Malkawi 2010) and Proglide system (Abbott) for closure (Dosluoglu 2007). The adoption may

also have been influenced by the rise of low-profile stent grafts, which are more malleable, easier to introduce and navigate, and have been shown to compare favourably in the mid-term in those with challenging anatomy (Sobocinski 2015).

The most common technique employed is the pre-close technique. Access is gained to the common femoral artery and the initial sheath is then replaced by a percutaneous closure device over a guidewire. The major difference in this technique from percutaneous techniques used in other procedures is the deployment of a suture-mediated closure device at the start of the procedure. This allows the arteriotomy to be enlarged, enabling the insertion of sheaths of a larger size and allowing the EVAR to be conducted normally. At the conclusion of the repair the sheath is then removed with the use of a knot pusher, aiding closure. The final wound is closed using a single suture or tape. Some variations of this technique exist at different centres and with the use of different devices (Lee 2008; Malkawi 2010; Watelet 2006).

How the intervention might work

The stent-grafts used and the manner in which they achieve aneurysm exclusion are identical to the already widely used EVAR techniques. As such, many of the long-term complications are similar.

The key differences are the initial arterial access, wound closure and the use of a percutaneous suture-mediated closure device during surgery. One concern that has been identified with EVAR procedures is the continued problem of wound closure, which a number of studies have examined (Dalainas 2004; Faries 2002). As the percutaneous approach is less invasive, and results in a smaller final wound closure, it may help to address this problem. Wound infection rates with the use of percutaneous closure devices have been reported to be as low as 0.2% (Watelet 2006), compared with 2% in cut-down femoral artery access (Slappy 2003).

Some patients may be at risk of problems with arterial access using this intervention. These include people with calcification of the femoral artery, groin scarring or an inguinal arterial prosthesis, morbid obesity and small or tortuous arterial iliac arteries (Traul 2000; Watelet 2006). This makes patient selection key to the initial success of the procedure. In addition, the percutaneous technique may not always achieve adequate haemostasis (Torsello 2003), and there may be increased risk of bleeding and haematoma formation with a need to convert to a conventional cut-down approach.

Why it is important to do this review

It has been suggested that a totally percutaneous approach to EVAR offers a less invasive treatment with faster recovery and reduced wound infection rates than with cut-down femoral artery access. This hypothesis must be tested by a robust systematic review as this would make percutaneous access a preferable choice for many surgical interventions. In the review we aim to demonstrate the efficacy and safety of percutaneous access as an alternative procedure and highlight any shortcomings in the technique. This review is important to allow clinicians to make a more informed decision when deciding on the appropriate technique for each individual patient.

This review was originally conducted in 2014, with one included and one ongoing trial identified that met the inclusion criteria. It is

good practice to formally update the review to include any newly available data.

OBJECTIVES

This review aims to compare the clinical outcomes of percutaneous access with cut-down femoral artery access in elective bifurcated abdominal endovascular aneurysm repair (EVAR).

METHODS

Criteria for considering studies for this review

Types of studies

We considered only randomised controlled trials (RCTs) for evaluation. We would have included cross-over trials, with only the first phase results considered, but we did not identify any.

Types of participants

We included all patients diagnosed with an abdominal aortic aneurysm (AAA), which had been visualised using either computed tomography (CT) or ultrasonography, in the review.

We considered only people undergoing elective repairs. People undergoing emergency surgery for a ruptured abdominal aortic aneurysm (rAAA) and those undergoing aorto-uni-iliac (also known as aorto-mono-iliac) repairs were excluded.

Types of interventions

The primary intervention was a totally percutaneous endovascular repair. We considered all device types. We compared this against cut-down femoral artery access for endovascular repair.

Types of outcome measures

Primary outcomes

- Short-term mortality rates (30-day or in-hospital, i.e. procedure related)
- Aneurysm exclusion (no flow into the abdominal aortic aneurysm (AAA) sac on follow-up imaging) 30 days after the procedure
- Wound infection rate (30-day or in-hospital)

Secondary outcomes

- Major complications, for example, myocardial infarction, stroke, renal failure, respiratory failure, lower limb ischaemia, pneumonia, technical failure, or conversion to alternative technique (30-day or in-hospital)
- Long-term (12 months) complications and mortality (re-intervention rates, device-related complications, cause of death)
- Bleeding complications and haematoma
- Operating time, duration of intensive treatment unit (ITU) and hospital stay

With regard to the primary outcomes mortality and aneurysm exclusion, at least equivalence but not necessarily superiority over surgical cut-down had to be demonstrated to allow a recommendation as percutaneous interventions may still be preferable if there are fewer wound problems and length of hospital stay is reduced.

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 (October 2016);
- The Cochrane Central Register of Controlled Trials (CENTRAL; 2016, Issue 9) 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 CIS searched the following trials registries (October 2016) for details of ongoing and unpublished studies using the terms percutaneous and aneurysm:

- World Health Organization International Clinical Trials Registry (apps.who.int/trialsearch/);
- ClinicalTrials.gov (clinicaltrials.gov/);
- ISRCTN Register (www.isrctn.com/).

See [Appendix 2](#) for details of the search strategies.

Searching other resources

We did not impose any restriction on language of publication or publication status. We checked reference lists of retrieved articles.

Data collection and analysis

We conducted data collection and analysis in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011a](#)).

Selection of studies

One review author (MG) scanned the titles and abstracts of retrieved articles, excluding irrelevant studies. Those studies deemed relevant were retrieved in full. Two review authors (MG, AJ), then independently assessed the full-text articles for suitability for inclusion. All disagreements were successfully resolved by consensus.

Data extraction and management

Two review authors (MG, AJ) extracted data from the included studies independently using a data extraction form. We found no discrepancies but had there been any, we would have resolved them by consensus. If necessary, we would have contacted study authors for clarification.

Assessment of risk of bias in included studies

We assessed included studies for risk of bias using Cochrane's 'Risk of bias' tool ([Higgins 2011b](#)). This tool covers sequence generation, allocation concealment, blinding of participants and

personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other sources of bias. We assessed each of these domains as either high, low or unclear risk of bias and we provided support for each judgement. We presented our conclusions in a 'Risk of bias' table.

Measures of treatment effect

We measured the treatment effect according to the statistical guidelines recommended by Cochrane Vascular. For dichotomous data, we calculated risk ratios (RRs) with 95% confidence intervals (CI) as the measure of effect. We analysed continuous data in a continuous form by mean difference (MD). If similar outcomes were reported on different scales, we planned to calculate standardised mean difference (SMD).

Unit of analysis issues

The primary analysis was per individual randomised. Our search did not identify any cross-over trials but if it had, we would only have included the first phase data.

Dealing with missing data

No data relating to primary outcomes were found to be missing. However, had data been missing we would have contacted the study authors to request missing data as the first step. If this was unsuccessful we would assess whether the data were missing at random. If this was found to be the case we would have excluded the missing data from the review. If the data were found not to be missing at random then we would have undertaken imputation of individual values and explored its impact in the final discussion.

Assessment of heterogeneity

Heterogeneity was measured by the I^2 statistic (Higgins 2003). Moderate heterogeneity, defined as over 30%, would have been discussed and reasons identified (Deeks 2011).

Assessment of reporting biases

The single best step undertaken to minimise reporting bias was a full and comprehensive search encompassing both published and grey literature, whilst being aware of duplication of data. Had more than 10 studies been included within the final analysis we would have used a funnel plot to explore small study effects.

Data synthesis

We synthesised available data using Review Manager 5 (RevMan) (RevMan 2014). We investigated pooled estimates of the effects of

treatment using a fixed-effect model to calculate RR with 95% CIs for dichotomous outcomes and MD for continuous outcomes. If it was not possible to pool data we described the results reported by the studies in the text.

Subgroup analysis and investigation of heterogeneity

We did not plan or perform any subgroup analyses owing to the small number of studies included. We did not identify any significant heterogeneity (above 30%, moderate), therefore we conducted no further investigation into heterogeneity. If significant heterogeneity had been identified, we would have identified the clinical causes and conducted a sensitivity analysis.

Sensitivity analysis

We intended to carry out sensitivity analyses to explore the robustness of the conclusions reached. These would have examined a number of factors, including study quality and risk of bias, data source (published or unpublished), and any other analyses which might have appeared significant upon completion of the review. Given the low number of trials (two) and low risk of bias, a sensitivity analysis was not deemed necessary.

Summary of findings

We produced a 'Summary of findings' table (Schünemann 2011a) for the comparison of totally percutaneous access versus cut-down artery access for people undergoing elective bifurcated abdominal endovascular aneurysm repair; using the GRADEpro GDT software (grade.pro.org/). We used the GRADE approach to assess the quality of the evidence for the review outcomes as described in [Types of outcome measures](#). We downgraded the evidence from 'high quality' for serious or very serious study limitations (risk of bias, indirectness and inconsistency of evidence, imprecision of effect estimates or potential publication bias) according to the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011b) and the GRADE Working Group (GRADE Working Group 2004).

RESULTS

Description of studies

See [Characteristics of included studies](#); [Characteristics of excluded studies](#).

Results of the search

See [Figure 1](#).

Figure 1. Study flow diagram

Included studies

One new study (two reports) was included for this update (Nelson 2014). Two independent studies therefore met the inclusion criteria: Torsello 2003 and Nelson 2014.

The Torsello 2003 study was conducted in Germany and was a small randomised pilot study. It consisted of 30 participants (29 male, one female) aged 51 to 90 years (mean 72.9 ± 9.9 years). Anyone presenting with an aortic aneurysm was considered, including those with calcification of the femoral artery, scars in the groin or obesity. The exclusion criteria included people with psychiatric

conditions, those undergoing the implantation of an aorto-mono-iliac graft, and people with an aneurysm of the femoral artery. Aneurysms were repaired using either the Zenith graft (Cook, Bloomington, Indiana) (n = 16) or using the Talent endovascular graft (Medtronic, Sunrise, Florida) (n = 14), although the paper did not describe how these different grafts were distributed among the treatment arms.

In participants undergoing the percutaneous procedure (n = 15), a 10F Prostar XL percutaneous vascular surgery device (Perclose, Redwood City, California) was used in the 'pre-close' technique for closure of the access site. For participants undergoing cut-down femoral artery access (n = 15), a transverse groin incision was made to expose the common femoral artery for direct needle puncture. All participants received 5000 IU of heparin after sheath insertion. Duplex ultrasound scanning was performed before and after the procedure. The paper did not explicitly state which outcomes had been selected but reported a wide range of outcomes, including time of surgery, mortality and major complications.

The [Nelson 2014](#) study presented the PEVAR (totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair) trial. This was a multicentre randomised controlled trial conducted in 18 centres in the USA. All centres had prior experience in EVAR using both cut-down femoral artery access and percutaneous techniques. All investigators (surgeons and interventionalists) were required to provide evidence of experience in the use of closure devices, complete the Endologix EVAR training programme and perform 20 PEVAR preclose cases before commencing the trial.

The trial consisted of 151 participants (136 male, 15 female). Anyone over the age of 18 presenting with an AAA that was 5 cm or more, or rapidly expanding was considered. Participants had to understand and sign an informed consent form, and agree to all follow-up visits. Anatomical eligibility was determined by computed tomography of the thoracic and abdominal aorta. Additional assessments of common femoral artery characteristics were conducted by an experienced, independent vascular surgeon. Participants were only included if they had an absence of the following: prior groin incision, haematoma or significant scarring at the ipsilateral arterial access site, clip-based vascular closure device placement ever, collagen-based vascular closure device placement in either arterial access site within 90 days, femoral artery needle puncture in either arterial access site within 30 days, active groin infection, traumatic vascular injury, femoral artery aneurysm or pseudoaneurysm, or arteriovenous fistula.

Participants had to have a life expectancy of more than one year, serum creatinine 1.7 mg/dL or less, BMI less than 40 kg/m², have no planned major interventions or surgery within 30 days after the study procedure, and be free from myocardial infarction and cerebrovascular accident within three months of enrolment.

Of 179 screened participants, 153 were identified as suitable, and 151 were enrolled in the trial. Participants were randomised by a 2:1 design to percutaneous access/closure (n = 101) or cut-down femoral artery access (termed open femoral exposure) (n = 50). The percutaneous access/closure procedure group was divided equally between two suture-mediated pre-closure device types: the 8F Perclose ProGlide (PG, n = 50) and the 10F Prostar XL (PS, n = 51) (both Abbott Vasc, Inc, Redwood City, California). All endovascular AAA repairs were performed using the Endologix 21F profile sheath-based system (Endologix, Inc, Irvine, California). Post deployment graft position/aneurysm exclusion was confirmed on angiography.

The primary endpoint was identified as 'treatment success', a composite endpoint comprising 1) procedural technical success and 2) absence of major adverse events and vascular complications at 30 days. Six-month follow-up was also conducted. Subgroup analysis of major ipsilateral access-related complications (vascular injury, lower extremity ischaemia, bleeding/transfusion, nerve injury) of PS and PG versus femoral exposure at 30 days was conducted. The following secondary procedural and in-hospital outcomes were recorded: activated clotting time, contrast volume, fluoroscopy time, estimated blood loss, blood transfusion, procedure time, ipsilateral time to haemostasis, time to ambulation, time to normal diet, ICU length of stay, medication for groin pain and time to hospital discharge.

Excluded studies

One new study was excluded in this update ([Ichihashi 2016](#)). In total we excluded five studies. One trial did not include the primary intervention ([Hattab 2012](#)). Four trials were non-randomised ([Ichihashi 2016](#); [Jean-Baptiste 2008](#); [Krajcer 2010](#); [Xiong 2012](#)).

Ongoing studies

We identified two ongoing studies ([NCT02822560](#); [Vierhout 2015](#)). See [Characteristics of ongoing studies](#) for details. Future updates of this review will include any data available at that time.

Risk of bias in included studies

See [Figure 2](#) and [Figure 3](#).

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Nelson 2014
Torsello 2003

Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

Allocation

[Nelson 2014](#) reported randomisation by study site, using two block sizes (3 or 6) with random choice of block size order. The study used 2:1 randomisation (PEVAR:FE), with equal allocation to the two PEVAR groups (PG, PS). [Nelson 2014](#) provided centres with a set of sealed randomised envelopes. Upon a participant meeting eligibility screening criteria, the next sequential envelope was opened and the assignment immediately allocated. [Nelson 2014](#) was therefore assessed to be at low risk of selection bias. [Torsello 2003](#) did not report on either random sequence allocation or allocation concealment. This made it impossible to make a formal judgement on the risk of bias generated and was judged to be at unclear risk of selection bias.

Blinding

Both [Nelson 2014](#) and [Torsello 2003](#) did not report on blinding of trial participants and outcome assessments, and it is impossible to blind personnel performing the procedure. We judged both studies to be at an unclear risk of performance bias. This is unlikely to affect the risk of bias as the outcomes selected by the authors of both papers, and those analysed by this review, were not susceptible to bias from a lack of blinding, so both studies were assessed as being at low risk of detection bias.

Incomplete outcome data

Both [Nelson 2014](#) and [Torsello 2003](#) had complete follow-up of all participants at 30 days or in-hospital, and were at low risk of attrition bias. [Nelson 2014](#) had 9% loss to follow-up at six months, which introduced attrition bias for this isolated outcome. Loss to follow-up was higher in the cut-down femoral artery access group (7/50, 14%) than the totally percutaneous group (8/100, 8%), however we did not find this difference to be statistically significant ($P = 0.53$). Reasons for loss to follow up were given for each group. In the totally percutaneous group six participants withdrew, and two participants were missed. In the cut-down femoral artery access group, three participants withdrew, two participants were missed, and two refused six-month follow-up. The same proportion of participants in each group were withdrawn (6%). Twice as many

participants were missed in the cut-down femoral artery access group (2/50, 4%) compared with the totally percutaneous group (2/100, 2%) and a further two participants (4%) of the cut-down femoral artery access group refused six-month follow-up.

Selective reporting

[Nelson 2014](#) clearly stated its primary and secondary outcomes and reported on these fully with raw data presented, and was assessed as being at low risk of selective reporting bias. [Torsello 2003](#) did not outline its selected outcomes and therefore it was prone to a higher risk of bias due to selective reporting of the results. However, major outcomes identified by this review appeared to have been reported so we have assessed it as being at an unclear risk of reporting bias.

Other potential sources of bias

No other sources of bias were identified within [Nelson 2014](#) or [Torsello 2003](#).

Effects of interventions

See: [Summary of findings for the main comparison Totally percutaneous compared to cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair](#)

See [Summary of findings for the main comparison](#)

Primary outcomes

Short-term mortality rates (30-day or in-hospital, i.e. procedure-related)

[Torsello 2003](#) recorded no short-term or operative mortality in either group. [Nelson 2014](#) reported one cardiac death on day 28 in the percutaneous group. See [Analysis 1.1](#) (RR 1.50, 95% CI 0.06 to 36.18; participants = 181; studies = 2; $P = 0.8$). Note that although [Analysis 1.1](#) considered two studies, [Torsello 2003](#) reported no mortality and therefore did not contribute to the effect estimate in this analysis.

Aneurysm exclusion (no flow into the abdominal aortic aneurysm (AAA) sac on follow-up imaging) 30 days after the procedure

[Torsello 2003](#) did not provide data on aneurysm exclusion post procedure.

[Nelson 2014](#) conducted follow up CT scans at 28 days, with one participant in the cut-down femoral artery access group (n = 50) requiring a type 1a endoleak repair within one month post-procedure.

Wound infection rate (30-day or in-hospital)

Both [Torsello 2003](#) and [Nelson 2014](#) reported that there were no wound infections in either group.

Secondary outcomes

Major complications (30 day or in-hospital)

[Torsello 2003](#) reported two major complications in the cut-down femoral artery access group and four major complications in the percutaneous group. In one case in the percutaneous group, the Prostar device was unsuccessful in closing the arterial entry site, and conversion to an open groin incision was necessary. In a further two cases surgical repair of the access artery was necessary due to bleeding in one, and arterial thrombosis in the other. Two participants (one in each group) developed post-operative femoral artery occlusion requiring surgical thrombectomy. One participant in the cut-down femoral artery access group required surgical repair of the access artery due to arterial thrombosis.

[Nelson 2014](#) reported "unsuccessful treatment" due to procedural technical failure, a major adverse event or a vascular complication in 17 endovascular participants and 11 cut-down femoral artery access participants. The number of major complications exceeded the number of participants suffering major complications, indicating some participants suffered more than one major complication.

In the cut-down femoral artery access group 14 major complications occurred (11 participants): neurological complication (3), renal failure (1), respiratory complication (1), secondary procedure (2), femoral neuropathy (1), thrombosis (3), vascular injury (2). There was one endovascular device failure which required switching to a lower-profile Endologix system for EVAR and external iliac artery stenting. In the percutaneous group 26 major complications occurred (17 participants): cardiac morbidity (2), renal failure (3), respiratory complication (3), secondary procedure (1), thrombosis (4), vascular injury (4). Nine procedural technical failures were reported; eight ipsilateral pre-close failures requiring surgical cut down/return to operating theatre and one thrombectomy/iliac stenting for thrombosis.

When the numbers of participants experiencing adverse events were combined, there was no difference in major complications between the percutaneous and cut-down femoral artery access groups (RR 0.91, 95% CI 0.5 to 1.68; participants = 181; studies = 2; P = 0.77; see [Analysis 1.3](#)). Little heterogeneity was detected between the studies ($I^2 = 20\%$).

Long term complications (12 months) and mortality

[Torsello 2003](#) only included in-hospital data and did not report any long-term complications or mortality.

[Nelson 2014](#) did not report 12 month data, however did report trial data at 6 months. Between 31 and 210 days, nine major adverse events or vascular complications were reported in percutaneous participants, and four events were reported in cut-down femoral artery access participants. In the endovascular group the following occurred: renal failure (1), ABI decrease (not requiring intervention) (3), cancer death (1), critical renal artery stenosis requiring stenting (1), and endoleak requiring secondary procedure (3). In the cut-down femoral artery access group the following occurred: cancer death (1), endoleak requiring secondary procedure (2), lymphocele (1). This was assessed as not statistically significant by the study authors (the P value was not reported by the study authors but was calculated by the review authors as P = 0.96. See [Analysis 1.4](#) (RR 1.03, 95% CI 0.34 to 3.15; participants = 134; studies = 1)).

In [Nelson 2014](#) loss to follow-up at six months was 9%. Loss to follow-up was higher in the cut-down femoral artery access group (7/50, 14%) than the totally percutaneous group (8/100, 8% - note only 100 participants as one participant died in hospital and was therefore not included in the six-month follow-up). Loss to follow-up was broken down into the following reasons in the totally percutaneous group: participant withdrawn (6), participant missed (2). In the cut-down femoral artery access group loss to follow up was due to: participant withdrawn (3), participant missed (2), participant refused follow-up (2). The same proportion of participants in each group were withdrawn (6%). Twice as many participants were missed in the cut-down femoral artery access group (2/50, 4%) compared with the totally percutaneous group (2/100, 2%) and a further two participants (4%) of the cut-down femoral artery access group refused six-month follow-up.

Bleeding complications and haematoma

[Torsello 2003](#) reported one bleeding-related complication requiring surgical repair of the access artery in the percutaneous group. There was no significant difference between groups regarding blood loss (haemoglobin or haematocrit). [Nelson 2014](#) reported no haematomas in either group. Six cases of bleeding were reported in the percutaneous group, and four cases of bleeding were reported in the cut-down femoral artery access group. There was no significant difference in estimated blood loss or blood transfusion requirements between groups.

When the studies were combined, there was no difference in bleeding-related complications between the percutaneous and cut-down femoral artery access groups (RR 0.94, 95% CI 0.31 to 2.82; participants = 181; studies = 2; P = 0.91; see [Analysis 1.5](#)). No heterogeneity was detected between the studies ($I^2 = 0\%$).

Operating time

[Torsello 2003](#) reported significant differences in operating time (percutaneous 86.7 ± 27 minutes versus cut-down femoral artery access 107.8 ± 38.5 minutes; P < 0.05). [Nelson 2014](#) reported a significant difference in operating time (percutaneous group PG 107 ± 45 minutes versus cut-down femoral artery access 141 ± 73 minutes, P < 0.01, and percutaneous group PS 95 ± 35 minutes versus cut-down femoral artery access 141 ± 73 minutes, P < 0.01).

To facilitate meta-analysis, the results of the two different percutaneous groups (PS, PG) were combined using the methods described in the Cochrane Handbook (Deeks 2011).

When the two studies were combined, there was a difference in operating time between the percutaneous and cut-down femoral artery access groups (MD -31.46 minutes; 95% CI -47.51 to -15.42 minutes; participants = 181; studies = 2; $P = 0.0001$; see Analysis 1.6) favouring percutaneous access. No significant heterogeneity was detected between the studies ($I^2 = 25\%$).

Duration of ITU stay

Torsello 2003 did not report on duration of ITU stay.

Nelson 2014 reported no difference in length of ITU stay (hours) between groups (cut-down femoral artery access 35 ± 38 , percutaneous PG 26 ± 9 , percutaneous PS 31 ± 15 ; percutaneous PG versus cut-down femoral artery access $P = 0.269$, percutaneous PS versus cut-down femoral artery access $P = 0.61$).

Duration of hospital stay.

Torsello 2003 did not report on duration of hospital stay.

Nelson 2014 reported no difference in time to hospital discharge (days) between groups (cut-down femoral artery access 1.8 ± 2.4 , percutaneous PG 1.3 ± 0.7 , percutaneous PS 1.4 ± 0.9 ; percutaneous PG versus cut-down femoral artery access $P = 0.135$, percutaneous PS versus cut-down femoral artery access $P = 0.213$).

DISCUSSION

Summary of main results

This review aimed to compare the clinical outcomes of percutaneous access with cut-down femoral artery access in elective bifurcated abdominal endovascular aneurysm repair (EVAR). With regard to the primary outcomes mortality and aneurysm exclusion, at least equivalence, but not necessarily superiority, over cut-down EVAR had to be demonstrated to allow a recommendation, as percutaneous interventions may still be preferable if there are fewer wound problems and reduced length of hospital stay.

The two included studies, Torsello 2003 and Nelson 2014, recorded only one operative mortality and one endoleak requiring repair in the 30-day follow-up. Wound infection rates were zero across both studies. The results of the meta-analysis indicated no significant difference in 30-day major complication rate or bleeding across the studies. Six-month data from one study (Nelson 2014), continued to show no significant difference in major complications and mortality between percutaneous and cut-down femoral artery access groups.

We detected a difference in operating time, with percutaneous access taking less time than cut-down femoral artery access, with a significantly shorter operating time representing a potential benefit.

The Nelson 2014 study reported no significant difference in ITU stay between groups. Nelson 2014 also reported time from procedure to hospital discharge (days). The study authors found no difference between percutaneous and cut-down femoral artery access groups (percutaneous PG vs cut-down femoral artery access $P = 0.135$, percutaneous PS vs cut-down femoral artery access $P = 0.213$).

This was not one of the outcomes selected by this review and we cannot confirm its validity given the age of the study. However, this is in contrast to previous hypotheses that percutaneous access may reduce length of hospital stay by proxy of fewer wound complications.

Torsello 2003 also reported on the costs of the percutaneous and cut-down femoral artery access interventions. The study investigators identified a higher cost of percutaneous interventions (percutaneous EUR 474.7 ± 109.7) versus cut-down femoral artery access (EUR 375.5 ± 153.3 ; $P < 0.01$), which was, in their view, related to the cost of closure devices.

Overall completeness and applicability of evidence

The single biggest limitation of this review is that only two studies, one study with a small sample size, were included. This gave a pool of 181 participants to examine, 151 from one study and 30 from the other. Clearly for a systematic review this is a low number of studies and limited pool of participants, and limits the widespread applicability of the results. There was a significant difference in the participant inclusion criteria between the studies. The Torsello 2003 study included participants with calcification of the femoral artery, scars in the groin or obesity, which are considered risk factors for wound complications. By contrast, the Nelson 2014 study was more selective of its participants, specifically excluding the morbidly obese and those with significant scarring at the arterial access site. Not enough data regarding the co-morbidities of the Torsello 2003 participants were reported to examine this further. This may have an influence on the outcomes included, however overall this was not deemed significant as all other aspects of the trial conduction were comparable. Also of note were the differing sheath diameters used in the studies. Torsello 2003 reported using multiple sheath sizes, while Nelson 2014 reported use of only 21F sheaths. This again may influence outcomes and may not be reflective of modern practice, where lower profile sheaths can be found.

This review did not identify any studies, meeting inclusion criteria, considering the fascia suture technique, which has been reported as a potential alternative to closure devices for percutaneous access (Larzon 2006; Larzon 2015).

The review has identified two ongoing studies (NCT02822560; Vierhout 2015), which may be suitable for inclusion in future reviews and could greatly increase the pool of data available for analysis.

Quality of the evidence

Of the two studies, the Nelson 2014 study was methodologically stronger, had a large sample size, good follow-up and reported pre-defined outcome data with minimal risk of bias. The Torsello 2003 study had more limitations, namely a failure to adequately report the method of randomisation, allocation concealment and the pre-selected outcomes. Although in general it was a study of moderate quality with complete follow-up of all included participants, it remains hampered by its small sample size as mentioned above.

We used the GRADEpro GDT software (<http://gradepr.org/>) to assess the overall quality of evidence in relation to each review outcome. We graded bleeding complications and haematoma, and operating time, as high-quality evidence. Bleeding complications and haematoma, were well documented in both studies, with no

significant bias or confounding. Operating time was documented in both studies with no significant bias identified. Short-term mortality, failure of aneurysm exclusion, wound infection rate, and major complications were graded as moderate in quality. We downgraded short-term mortality by one evidence level due to a low number of events and wide confidence interval. We downgraded failure of aneurysm exclusion by one evidence level due to having data from one study and a low event rate (Nelson 2014). We downgraded wound infection rate by one evidence level as no wound infections were reported. We graded long-term complications as moderate quality as it involved only the Nelson 2014 study. Although losses to follow-up were present at six months, these were well described and there was no significant difference in the rate of loss between the percutaneous and cut-down access groups. We downgraded operating time to moderate quality, as the included studies reported this as a secondary outcome and were not adequately powered for this outcome.

Potential biases in the review process

The bias within the review process was minimised as far as possible. The most important aspect of this was a comprehensive literature search, encompassing grey literature as well as published sources. The review is limited by the number of studies included and as such no firm conclusions can be drawn. In the future, a further review should be conducted when a bigger pool of data from multiple larger studies can be identified. Hospital duration should be included alongside ITU stay, as this is a major determinant of overall procedure cost. Neither included study reported one-year outcomes. It may be beneficial to examine medium-term outcomes at less than one year, for example six months, if suitable outcomes are reported at the same time across studies.

Agreements and disagreements with other studies or reviews

A previous review (Malkawi 2010) examined 22 papers (one randomised, 10 non-randomised and 11 retrospective studies). The review concluded that the percutaneous approach appeared safe and effective with low access-related complications, but that further research was required to identify suitable candidates for the percutaneous approach. This broadly matches with the findings of the present review with regard to safety and efficacy. However, due

to the nature of this review (only RCTs were included) the pool of data for this review was substantially smaller and, as such, no firm conclusions were reached. No significant changes in the conclusion have been drawn since the first version of this review.

AUTHORS' CONCLUSIONS

Implications for practice

This review shows moderate-quality evidence of no difference between the percutaneous approach compared with cut-down femoral artery access group for short-term mortality, aneurysm exclusion, wound infection, major complications and long-term (six-month) complications. We have shown high-quality evidence for no difference in bleeding complications. There was moderate-quality evidence that the operating time for percutaneous approach was shorter than the cut-down femoral artery access group between the percutaneous approach compared with cut-down femoral artery access.

Implications for research

This review has identified a need for further research into a potentially beneficial technique. The ongoing study identified in the search may provide an improved evidence base in the future and should be considered for inclusion in all future reviews. Further independent and sufficiently powered trials would also be helpful. The authors of future research and reviews may wish to examine a number of the areas identified within this review, namely differences in cost, operating time, hospital stay, wound infection rates, potential bleeding and haematoma complications, and operative success. Measuring these, along with core issues such as mortality, could give a more complete picture of the possible benefits and drawbacks of the differing approaches to endovascular aneurysm repair and more fully inform future surgical decisions. In addition, if the technique is found to be effective in elective aneurysm repairs it may be considered in the future for the treatment of ruptured abdominal aortic aneurysms.

ACKNOWLEDGEMENTS

The authors would like to thank all the staff at Cochrane Vascular for all their help, support and patience throughout this review process.

REFERENCES

References to studies included in this review

Nelson 2014 {published data only}

Krajcer Z, Matos JM. Totally percutaneous endovascular abdominal aortic aneurysm repair: 30-day results from the independent access-site closure study of the PEVAR trial. *Texas Heart Institute Journal* 2013;**40**(5):560-1.

Nelson PR, Krajcer Z, Kansal N, Rao V, Bianchi C, Hashemi H, et al. A multicenter, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial). *Journal of Vascular Surgery* May 2014;**59**(5):1181-93.

Torsello 2003 {published data only}

Torsello GB, Kasprzak B, Klenk E, Tessarek J, Osada N, Torsello GF. Endovascular suture versus cutdown for endovascular aneurysm repair: a prospective randomized pilot study. *Journal of Vascular Surgery* 2003;**38**(1):78-82.

References to studies excluded from this review

Hattab 2012 {published data only}

Hattab M, Hakim M, Carreira VB, Elhadad S. TCT-393 A randomized trial comparing two vascular closure devices: PROGLIDE and the novel EXOSEAL after percutaneous femoral procedures. *Journal of the American College of Cardiology* 2012;**60**(17_S):B112.

Ichihashi 2016 {published data only}

Ichihashi T, Ito T, Kinoshita Y, Suzuki T, Ohte N. Safety and utility of total percutaneous endovascular aortic repair with a single Perclose ProGlide closure device. *Journal of Vascular Surgery* 2016;**63**(3):585-8.

Jean-Baptiste 2008 {published data only}

Jean-Baptiste E, Hassen-Khodja R, Haudebourg P, Bouillanne PJ, Declémy S, Batt M. Percutaneous closure devices for endovascular repair of infrarenal abdominal aortic aneurysms: a prospective, non-randomized comparative study. *European Journal of Vascular and Endovascular Surgery* 2008;**35**(4):422-8.

Krajcer 2010 {published data only}

Krajcer Z, Gregoric I. Totally percutaneous aortic aneurysm repair: methods and outcomes using the fully integrated IntuiTrak endovascular system. *Journal of Cardiovascular Surgery* 2010;**51**(4):493-501.

Xiong 2012 {published data only}

Xiong J, Wei R, Guo W, Liu X, Jia X, Ma X, et al. Comparison of early effectiveness between total percutaneous endovascular aneurysm repair and surgical femoral cutdown endovascular aneurysm repair for asymptomatic abdominal aortic aneurysm. *Chinese Journal of Reparative and Reconstructive Surgery* 2012;**26**(11):1348-51.

References to ongoing studies

NCT02822560 {published data only}

NCT02822560. Economic comparison of percutaneous (PEVAR) vs. open access in EVAR. (EVAcess). ClinicalTrials.gov 2016. [https://clinicaltrials.gov/ct2/show/NCT02822560 (accessed 26 October 2016)]

Vierhout 2015 {published data only}

Vierhout BP, Saleem BR, Ott A, Van Dijn JM, Van Andringa de Kempenaer TD, Pierie MEN, et al. A comparison of Percutaneous femoral access in Endovascular Repair versus Open femoral access (PiERO): study protocol for a randomized controlled trial. *Trials* September 2015;**16**:408.

Additional references

Chambers 2009

Chambers D, Epstein D, Walker S, Fayter D, Paton F, Wright K, et al. Endovascular stents for abdominal aortic aneurysms: a systematic review and economic model. *Health Technology Assessment* 2009;**13**(48):1-189, 215-318, iii.

Dalainas 2004

Dalainas I, Nano G, Casana R, Tealdi Dg D. Mid-term results after endovascular repair of abdominal aortic aneurysms: a four-year experience. *European Journal of Vascular and Endovascular Surgery* 2004;**27**(3):319-23.

Deeks 2011

Deeks JJ, Higgins JPT, Altman DG (editors). Chapter 9: Analysing data and undertaking meta-analyses. In: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from handbook.cochrane.org.

Dosluoglu 2007

Dosluoglu HH, Cherr GS, Harris LM, Dryjski ML. Total percutaneous endovascular repair of abdominal aortic aneurysms using Perclose ProGlide closure devices. *Journal of Endovascular Therapy* 2007;**14**(2):184-8.

Faries 2002

Faries PL, Brener BJ, Connelly TL, Katzen BT, Briggs VL, Burks JA Jr, et al. A multicenter experience with the Talent endovascular graft for the treatment of abdominal aortic aneurysms. *Journal of Vascular Surgery* 2002;**35**(6):1123-8.

Fowkes 1989

Fowkes FG, Macintyre CC, Ruckley CV. Increasing incidence of aortic aneurysms in England and Wales. *BMJ* 1989;**298**(6665):33-5.

Higgins 2003

Higgins JPT, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003;**327**:557-60.

Higgins 2011a

Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from handbook.cochrane.org.

Higgins 2011b

Higgins JPT, Altman DG, Sterne JAC (editors). Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from handbook.cochrane.org.

Kauvar 2016

Kauvar DS, Martin ED, Givens MD. Thirty-day outcomes after elective percutaneous or open endovascular repair of abdominal aortic aneurysms. *Annals of Vascular Surgery* 2016;**31**:46-51.

Krajcer 2013

Krajcer Z, Matos JM. Totally percutaneous endovascular abdominal aortic aneurysm repair: 30-day results from the independent access-site closure study of the PEVAR trial. *Texas Heart Institute Journal* 2013;**40**(5):560-1.

Larzon 2006

Larzon T, Geijer H, Gruber G, Popek R, Norgren L. Fascia suturing of large access sites after endovascular treatment of aortic aneurysms and dissections. *Journal of Endovascular Therapy* 2006;**13**(2):152-7.

Larzon 2015

Larzon T, Roos H, Gruber G, Henrikson O, Magnuson A, Falkenberg M, et al. A randomized controlled trial of the fascia suture technique compared with a suture-mediated closure device for femoral arterial closure after endovascular aortic repair. *European Journal of Vascular and Endovascular Surgery* 2015;**49**(2):166-73.

Lee 2008

Lee WA, Brown MP, Nelson PR, Huber TS, Seeger JM. Midterm outcomes of femoral arteries after percutaneous endovascular aortic repair using the Preclose technique. *Journal of Vascular Surgery* 2008;**47**(5):919-23.

Lucarotti 1993

Lucarotti M, Shaw E, Poskitt K, Heather B. The Gloucestershire aneurysm screening programme: the first 2 years' experience. *European Journal of Vascular Surgery* 1993;**7**(4):397-401.

Malkawi 2010

Malkawi AH, Hinchliffe RJ, Holt PJ, Loftus IM, Thompson MM. Percutaneous access for endovascular aneurysm repair: a systematic review. *European Journal of Vascular and Endovascular Surgery* 2010;**39**(6):676-82.

Naylor 1988

Naylor AR, Webb J, Fowkes FG, Ruckley CV. Trends in abdominal aortic aneurysm surgery in Scotland (1971-1984). *European Journal of Vascular Surgery* 1988;**2**(4):217-21.

Papazoglou 1999

Papazoglou K, Christu K, Iordanides T, Balitas A, Giakoystides D, Giakoystides E, et al. Endovascular abdominal aortic aneurysm repair with percutaneous transfemoral prostheses deployment under local anaesthesia. Initial experience with a new, simple-to-use tubular and bifurcated device in the first 27 cases. *European Journal of Vascular and Endovascular Surgery* 1999;**17**(3):202-7.

Parodi 1991

Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. *Annals of Vascular Surgery* 1991;**5**(6):491-9.

RevMan 2014 [Computer program]

The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). Version Version 5.3. The Nordic Cochrane Centre, The Cochrane Collaboration, 2014.

Rutherford 2005

Rutherford RB (editor). Vascular Surgery. 6th Edition. Philadelphia: Elsevier Saunders, 2005.

Schwarze 2009

Schwarze ML, Shen Y, Hemmerich J, Dale W. Age-related trends in utilization and outcome of open and endovascular repair for abdominal aortic aneurysm in the United States, 2001-2006. *Journal of Vascular Surgery* 2009;**50**(4):722-9.e2.

Schünemann 2011a

Schünemann HJ, Oxman AD, Higgins JPT, Vist GE, Glasziou P, Guyatt GH. Chapter 11: Presenting results and 'Summary of findings' tables. In: Higgins JPT, Green S (editors), Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from handbook.cochrane.org.

Schünemann 2011b

Schünemann HJ, Oxman AD, Vist GE, Higgins JPT, Deeks JJ, Glasziou P, et al. Chapter 12: Interpreting results and drawing conclusions. In: Higgins JPT, Green S (editors), Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 (updated March 2011). The Cochrane Collaboration, 2011. Available from handbook.cochrane.org.

Scott 1995

Scott RAP, Wilson NM, Ashton HA, Kay DN. Influence of screening on the incidence of ruptured abdominal aortic aneurysm: 5-year results of a randomized controlled study. *British Journal of Surgery* 1995;**82**(8):1066-70.

Slappy 2003

Slappy AL, Hakaim AG, Oldenburg WA, Paz-Fumagalli R, McKinney JM. Femoral incision morbidity following endovascular aortic aneurysm repair. *Vascular and Endovascular Surgery* 2003;**37**(2):105-9.

Sobocinski 2015

Sobocinski J, Briffa F, Holt PJ, Martin Gonzalez T, Spear R, Azzaoui R, et al. Evaluation of the Zenith low-profile abdominal

aortic aneurysm stent graft. *Journal of Vascular Surgery* 2015;**62**(4):841-7.

Surgeons of England November 2015. [www.vsqip.org.uk/reports/2015-nvr-annual-report/]

Traul 2000

Traul DK, Clair DG, Gray B, O'Hara PJ, Ouriel K. Percutaneous endovascular repair of infrarenal abdominal aortic aneurysms: a feasibility study. *Journal of Vascular Surgery* 2000;**32**(4):770-6.

Watelet 2006

Watelet J, Gallot JC, Thomas P, Douvrin F, Plissonnier D. Percutaneous repair of aortic aneurysms: a prospective study of suture-mediated closure devices. *European Journal of Vascular and Endovascular Surgery* 2006;**32**(3):261-5.

Watson 2015

Watson S, Johal A, Heikkila K, Cromwell D, Loftus I. National Vascular Registry: 2015 Annual report. The Royal College of

References to other published versions of this review

Jackson 2012

Jackson A, Yeoh SE, Clarke. Totally percutaneous versus standard femoral artery access for elective bifurcated abdominal endovascular aneurysm repair. *Cochrane Database of Systematic Reviews* 2012, Issue 11. [DOI: [10.1002/14651858.CD010185](https://doi.org/10.1002/14651858.CD010185)]

Jackson 2014

Jackson A, Yeoh SE, Clarke M. Totally percutaneous versus standard femoral artery access for elective bifurcated abdominal endovascular aneurysm repair. *Cochrane Database of Systematic Reviews* 2014, Issue 2. [DOI: [10.1002/14651858.CD010185.pub2](https://doi.org/10.1002/14651858.CD010185.pub2)]

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Nelson 2014

Methods	Study design: RCT Method of randomisation: block Concealment of allocation: unblinded
Participants	Country: USA No: 151 Ages: 70 ± 6.6, 74 ± 11, 73 ± 8.8 for PG, PS and femoral cut down (cut-down femoral artery access) groups respectively Sex: 136 male, 15 female Inclusion criteria: <ul style="list-style-type: none"> • presenting with AAA with maximal diameter ≥ 5 cm or rapidly expanding • over the age of 18 • informed consent form understood and signed, and agreement to all follow-up visits • suitable ipsilateral common femoral artery for percutaneous access with preclose technique - with criteria for this specified • anatomical eligibility for Endologix System (EVAR stent) • life expectancy > 1 yr (judged by investigator) • serum creatinine level ≤ 1.7 mg/dL • no planned major intervention or surgery within 30 days after study procedure • not morbidly obese (BMI < 40 kg/m²) Exclusion criteria: <ul style="list-style-type: none"> • prior groin incision, haematoma or significant scarring at ipsilateral arterial access site, clip based vascular closure device placement ever, collagen-based vascular closure device placement in either arterial access site within prior 90 days, femoral artery needle puncture in either arterial access site within prior 30 days • localised groin infection, traumatic vascular injury, femoral artery aneurysm, arteriovenous fistula, pseudoaneurysm

Nelson 2014 (Continued)

- allergy to any device component, coagulopathy or uncontrolled bleeding disorder, active systemic infection, connective tissue disease, prior renal transplant
- cerebrovascular event or myocardial infarction within 3 months of enrolment

Interventions	<p>All aneurysms were repaired using the Endologix 21F profile based sheath system (Endologix, Inc, Irvine, California).</p> <p>Open femoral exposure, n = 50. In these participants a small oblique incision was made, with direct exposure and control of the femoral artery. Access site closure was achieved with direct artery repair and layered wound closure</p> <p>Perclose ProGlide, n = 50. In these participants a 8F Perclose ProGlide (PG) device (Abbott Vascular, Inc, Redwood City, California) was used in the pre-close technique for closure of the access site</p> <p>Prostar XL, n = 51. In these participants a 10F Prostar (PS) XL device (Abbott Vascular, Inc, Redwood City, California) was used in the pre-close technique for closure of the access site.</p> <p>Postdeployment graft position/aneurysm exclusion was confirmed angiographically in all cases.</p>
Outcomes	<p>Primary endpoint: 'treatment success'; a composite endpoint comprising procedural technical success and absence of major adverse events or vascular complications at 30 days.</p> <p>Secondary endpoints: activated clotting time, contrast volume, fluoroscopy time, estimated blood loss, blood transfusion, procedure time, ipsilateral time to haemostasis, time to ambulation, time to normal diet, ICU length of stay, medication for groin pain and time to hospital discharge.</p> <p>Subgroup analysis: major ipsilateral access-related complications (vascular injury, lower extremity ischaemia, bleeding/transfusion, nerve injury) of PS and PG versus femoral exposure at 30 days.</p>
Notes	<p>It should be noted that one study author served on the Scientific Advisory Board for Endologix, Inc, and three authors are on the Endologix, Inc speaker's bureau. In addition, the trial was funded by Endologix, Inc, with financial contribution by Abbott Vascular, Inc. and all Abbott Vascular, Inc ipsilateral closure devices provided free of charge. This is unlikely to have influenced the primary outcomes as there was good follow up to 30 days and the protocol was adhered to. However had the results shown inferiority of percutaneous access publication bias may have been introduced.</p> <p>One further manuscript (Krajcer 2013), presented the 30-day results of the same trial. The data extracted from Krajcer 2013 was the same as Nelson 2014, and was not considered as a separate data set; data were cross checked to ensure reporting consistency.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation by study site, using two block sizes (3 or 6) with random choice of block size order. Sealed randomisation envelopes were used. 2:1 randomisation (PEVAR:FE) was used, with equal allocation to the two PEVAR groups (PG, PS).
Allocation concealment (selection bias)	Low risk	Sealed randomisation envelopes were used: on screening eligibility confirmation the next sequential randomisation envelope was opened and assignment immediately allocated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding was not possible due to due nature of surgical interventions
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unlikely relating to the primary endpoint and subgroup analysis as they are objective in nature
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants reported with no loss to follow-up at 30 days. There was 9% loss to follow-up at 6 months. This only affects 1 secondary outcome within

Nelson 2014 (Continued)

		the review (long-term complications). Reasons for loss to follow-up were given for each group.
Selective reporting (reporting bias)	Low risk	Primary endpoint, secondary outcomes and subgroup analysis clearly defined and reported
Other bias	Low risk	See 'notes' section in table above

Torsello 2003

Methods	Study design: RCT Method of randomisation: not reported Concealment of allocation: unblinded
Participants	Country: Germany No: 30 Age: 51-90 years (mean 72.9 ± 9.9 years) Sex: 29 male, 1 female Inclusion criteria: <ul style="list-style-type: none"> anyone presenting with an AAA considered, including those with calcification of femoral artery, scars in the groin or obesity Exclusion criteria: <ul style="list-style-type: none"> people with psychiatric conditions those undergoing the implantation of an aorto-mono-iliac graft people with an aneurysm of the femoral artery
Interventions	Aneurysms were repaired using either the Zenith graft (Cook, Bloomington, Ind), n = 16, or using the Talent endovascular graft (Medtronic, Sunrise, Fla), n = 14 Percutaneous access, n = 15. In these participants a 10F Prostar XL percutaneous vascular surgery device (Perclose, Redwood City, Calif) was used in the pre-close technique for closure of the access site. Surgical cut-down (femoral artery access), n = 15. In these participants a transverse groin incision was made to expose the common femoral artery for direct needle puncture. All participants received 5000 IU of heparin after sheath insertion. Duplex ultrasound scanning was performed before and after the procedure.
Outcomes	Outcomes: operative success (the successful closure of the femoral artery following insertion of graft); in-hospital mortality and major complications; wound complications; re-intervention rate; blood loss; operative time and time to ambulation; total operative cost.
Notes	No conflicts of interest reported. Attempt made to contact authors via e-mail on 21/12/2015 with no reply received.

Risk of bias

Bias	Authors' judgement	Support for judgement
------	--------------------	-----------------------

Torsello 2003 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Method of randomisation not reported
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not reported and no details given
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Blinding not possible due to nature of surgical interventions
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Unlikely given the outcome measures used being objective in nature
Incomplete outcome data (attrition bias) All outcomes	Low risk	All patients fully reported with no loss to follow-up due to small numbers and short time scale
Selective reporting (reporting bias)	Unclear risk	Selected outcomes not outlined making the paper more prone to selective reporting, however most major outcomes appear to have been reported
Other bias	Low risk	None identified

AAA: abdominal aortic aneurysm

BMI: body mass index

EVAR: endovascular aneurysm repair

FE: femoral access

ICU: intensive care unit

PEVAR percutaneous endovascular aneurysm repair

PG: 8F Perclose ProGlide device

PS: 10F Prostar XL device

RCT: randomised controlled trial

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Hattab 2012	Did not include primary intervention. Study only examined percutaneous closure devices not aneurysm repairs
Ichihashi 2016	Non-randomised
Jean-Baptiste 2008	Non-randomised
Krajcer 2010	Non-randomised
Xiong 2012	Non-randomised

Characteristics of ongoing studies *[ordered by study ID]*
NCT02822560

Trial name or title	Economic comparison of percutaneous (pEVAR) vs. open access in EVAR (EVAcess)
---------------------	---

Totally percutaneous versus surgical cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair (Review)
21

NCT02822560 (Continued)

Methods	<p>Study design: RCT</p> <p>Method of randomisation: randomisation is performed by lot (participants draw an envelope which contains either left or right side is done by pEVAR)</p> <p>Concealment of allocation: envelope</p>
Participants	<p>Country: Austria</p> <p>Ages eligible for study: 18-90 years</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • Indication for endovascular aortic repair <p>Exclusion criteria:</p> <ul style="list-style-type: none"> • femoral aneurysm, severe femoral artery calcification, keloided inguinal region, obesity, people diagnosed with Alzheimer's disease, people with occlusive aortic disease
Interventions	<p>pEVAR: percutaneous femoral access using a suture-mediated closure system</p> <p>open femoral access: cut down to femoral artery and surgical closure</p>
Outcomes	<p>Primary outcome measures: overall costs of each different access</p> <p>Overall costs of each different access way including used material and duration of the procedure (shorter duration = less costs of running operation theatre)</p> <p>Secondary outcome measures: access duration</p> <p>Separately measured duration of each access way itself (from start until first sheath is applied and from removal of sheath until wound is closed). The duration of endovascular repair is not included</p> <p>Other outcome measures: wound complications</p> <p>Descriptive analysis of wound healing and complications after open vs percutaneous access in the same individual</p>
Starting date	April 2016
Contact information	<p>Miriam Uhlmann, MD +43 49150 4107 miriam.uhlmann@wienkav.at</p> <p>Fadi Taher, MD +43 49150 4107 fadi.taher@wienkav.at</p>
Notes	Estimated study completion date: April 2017

Vierhout 2015

Trial name or title	A comparison of Percutaneous femoral access in Endovascular Repair versus Open femoral access (PiERO)
Methods	<p>Study design: RCT</p> <p>Method of randomisation: not reported</p> <p>Concealment of allocation: unblinded</p>
Participants	<p>Country: Netherlands</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> • > 18 years old • informed consent • physically and mentally capable of giving consent for participation and data storage

Vierhout 2015 (Continued)

- diagnosed with an aneurysm of the abdominal aorta with a diameter of at least 55 mm (or growth of 5 mm or more in 6 months) suitable for bifurcated endovascular repair through 2 femoral access sites, without additional access needed

Exclusion criteria:

- severe atherosclerosis at the access site (> 50% of the circumference of the common femoral artery)
- previous common femoral artery surgery
- documented infection at the time of operation
- treated with an aorto-mono-iliacal device implanted, followed by a femoro-femoral crossover
- aneurysm necessitating more than two accesses (brachial or carotid) for repair

Interventions	Aneurysm repair (graft type not stated) with bilateral groin access obtained in all participants by open femoral access (surgical access) in one groin, and a percutaneous device (either the Prostar XL or Proglide, both Abbott Vasc, Inc, Redwood City, California) in the contralateral groin. Participants will serve as their own controls. Group A: surgical access for main body of endoprosthesis. Group B: percutaneous access (Prostar XL or Proglide) for main body of endoprosthesis.
Outcomes	Primary: number of surgical site infections in the groin 30 days and at 1 year postoperatively, evaluated by the Southampton Wound Assessment Score and with wound culture confirming diagnosis. Wound control will be performed at 1 day, 2 weeks, 6 weeks postoperatively, with final evaluation at 1 year. Secondary: haematoma, femoral neuropathy, dehiscence, fluid discharge, stenotic/occlusive complications in the CFA Other outcomes: all participants will score wound comfort or pain using a VAS score 1 day and 2 weeks postoperatively
Starting date	Registered 10 th November 2013
Contact information	Principal Investigator BP Vierhout bas.vierhout@wza.nl
Notes	Contacted 21/12/2015, responded with trial still recruiting participants in Dec 2015

CFA: common femoral artery

EVAR: endovascular aneurysm repair

pEVAR: percutaneous endovascular aneurysm repair

RCT: randomised controlled trial

DATA AND ANALYSES

Comparison 1. Percutaneous vs cut-down femoral artery access

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Short-term mortality rate (30-day or in-hospital)	2	181	Risk Ratio (M-H, Fixed, 95% CI)	1.5 [0.06, 36.18]
2 Aneurysm exclusion	1	151	Risk Ratio (M-H, Fixed, 95% CI)	0.17 [0.01, 4.02]
3 Major complications	2	181	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.50, 1.68]

Totally percutaneous versus surgical cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair (Review)

23

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4 Major complications (6 months)	1	134	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.34, 3.15]
5 Bleeding complications	2	181	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.31, 2.82]
6 Operating time (minutes)	2	181	Mean Difference (IV, Fixed, 95% CI)	-31.46 [-47.51, -15.42]

Analysis 1.1. Comparison 1 Percutaneous vs cut-down femoral artery access, Outcome 1 Short-term mortality rate (30-day or in-hospital).

Analysis 1.2. Comparison 1 Percutaneous vs cut-down femoral artery access, Outcome 2 Aneurysm exclusion.

Analysis 1.3. Comparison 1 Percutaneous vs cut-down femoral artery access, Outcome 3 Major complications.

Analysis 1.4. Comparison 1 Percutaneous vs cut-down femoral artery access, Outcome 4 Major complications (6 months).

Analysis 1.5. Comparison 1 Percutaneous vs cut-down femoral artery access, Outcome 5 Bleeding complications.

Analysis 1.6. Comparison 1 Percutaneous vs cut-down femoral artery access, Outcome 6 Operating time (minutes).

APPENDICES

Appendix 1. CENTRAL search strategy

Search run on Wed Oct 26 2016		
#1	MESH DESCRIPTOR Aortic Aneurysm	101
#2	MESH DESCRIPTOR Aortic Aneurysm, Abdominal	428
#3	aort*:TI,AB,KY	6820
#4	(juxta renal):TI,AB,KY	0
#5	juxtarenal:TI,AB,KY	4
#6	(juxta renal or juxtarenal):TI,AB,KY	4
#7	(pararenal or para renal):TI,AB,KY	4
#8	(suprarenal or supra renal):TI,AB,KY	23
#9	(short neck* or shortneck*):TI,AB,KY	9
#10	(visceral aortic segment):TI,AB,KY	0
#11	thorac*:TI,AB,KY	9042
#12	abdominal:TI,AB,KY	20479
#13	#3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12	33929
#14	aneur*:TI,AB,KY	2658
#15	#13 AND #14	1078
#16	(AAA OR JRAAA or JRAAAs or PAAA or PAAAs or TAAA or TAAAs or JPAA or JPAAs or SRA or SRAs or SRAA or SRAAs):TI,AB,KY	417
#17	((aort* near3 (ballon* or dilat* or bulg* or expan*))) :TI,AB,KY	80
#18	#1 OR #2 OR #15 OR #16 OR #17	1249
#19	MESH DESCRIPTOR Endovascular Procedures EXPLODE ALL TREES	6473
#20	MESH DESCRIPTOR Stents EXPLODE ALL TREES	3215
#21	MESH DESCRIPTOR Vascular Surgical Procedures	540
#22	MESH DESCRIPTOR Blood Vessel Prosthesis	408

(Continued)

#23	MESH DESCRIPTOR Blood Vessel Prosthesis Implantation EXPLODE ALL TREES	400
#24	endovasc*:TI,AB,KY	1420
#25	endostent*:TI,AB,KY	1
#26	stent*:TI,AB,KY	7405
#27	EVAR:TI,AB,KY	107
#28	EVRAR:TI,AB,KY	0
#29	TEVAR:TI,AB,KY	26
#30	(endoprosthe* or endograft*):TI,AB,KY	298
#31	Palmaz:TI,AB,KY	91
#32	(Zenith or Dynalink or Hemobahn or Luminex* or Memotherm or Wallsten- t):TI,AB,KY	267
#33	(Viabahn or Nitinol or Hemobahn or Intracoil or Tantalum):TI,AB,KY	258
#34	#19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33	13790
#35	percutaneous*:TI,AB,KY	9915
#36	prostar:TI,AB,KY	11
#37	proglide:TI,AB,KY	7
#38	percuse:TI,AB,KY	15
#39	precuse:TI,AB,KY	1
#40	intuitrak:TI,AB,KY	1
#41	MESH DESCRIPTOR Femoral Artery EXPLODE ALL TREES	807
#42	femoral:TI,AB,KY	7024
#43	#35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42	16496
#44	#18 AND #34 AND #43	60

Appendix 2. Trial registries searches

World Health Organization International Clinical Trials Registry

5 records for 5 trials found for:percutaneous and aneurysm

ClinicalTrials.gov

15 studies found for percutaneous AND aneurysm

ISRCTN Register

Totally percutaneous versus surgical cut-down femoral artery access for elective bifurcated abdominal endovascular aneurysm repair (Review)

Copyright © 2017 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

12 results for percutaneous AND aneurysm

WHAT'S NEW

Date	Event	Description
26 October 2016	New citation required but conclusions have not changed	New search run. One new included study, one new excluded study and two new ongoing studies were identified. New author joined team. Text amended to reflect Cochrane standards. 'Summary of findings' table added. Conclusions not changed.
26 October 2016	New search has been performed	New search run. One new included study, one new excluded study and two new ongoing studies were identified.

CONTRIBUTIONS OF AUTHORS

MG: was responsible for trial selection, data extraction, data analysis, and writing the review update

AJ: was responsible for drafting the protocol, trial selection, data extraction, and data analysis in the previous review, and for trial selection and data extraction in this review

SEY: was responsible for trial selection and data extraction in the previous review

MC: was responsible for reviewing the draft protocol and draft review

DECLARATIONS OF INTEREST

MG: none known

AJ: has declared that he received travel and accommodation expenses for attendance of the Technologies in Endovascular Aortic Repair conference, December 2015. Funding was directly from the conference organisers and enabled an oral presentation of a previous iteration of this review. No other declarations of interest are known

SEY: none known

MC: none known

SOURCES OF SUPPORT

Internal sources

- University of Southampton National Institute of Health Research Academic Foundation Programme, UK.

AIRJ was supported by the University of Southampton National Institute of Health Research Academic Foundation Programme.

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 Programme Grant funding to Cochrane Vascular (13/89/23). 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.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The outcome 'Bleeding complications and haematoma' was added to the original review.

The outcome 'Duration of hospital stay' was added to this version of the review.

INDEX TERMS

Medical Subject Headings (MeSH)

Aneurysm, Ruptured [*prevention & control]; Aortic Aneurysm, Abdominal [*surgery]; Elective Surgical Procedures [methods]; Endovascular Procedures [*methods]; Femoral Artery [*surgery]; Randomized Controlled Trials as Topic; Rupture, Spontaneous [prevention & control]

MeSH check words

Humans