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[Intervention Review]

Wound drainage for lower limb arterial surgery

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ABSTRACT

Background

Drains are often used in leg wounds after vascular surgery procedures despite uncertainty regarding their benefits. Drains are placed with the aim of reducing the incidence and size of blood or fluid collections. Conversely, drains may predispose patients to infection and may prolong hospitalisation. Surgeons need robust data regarding the effects of drains on complications following lower limb arterial surgery.

Objectives

To determine whether routine placement of wound drains results in fewer complications following lower limb arterial surgery than no drains.

Search methods

In June 2016 we searched: the Cochrane Wounds Specialised Register; the Cochrane Central Register of Controlled Trials (CENTRAL; the Cochrane Library); Ovid MEDLINE; Ovid MEDLINE (In-Process & Other Non-Indexed Citations); Ovid EMBASE and EBSCO CINAHL. We also searched clinical trial registries for ongoing studies. There were no restrictions with respect to language, date of publication or study setting.

Selection criteria

We considered randomized controlled trials (RCTs) that evaluated the use of any type of drain in lower limb arterial surgery.

Data collection and analysis

Two authors independently determined study eligibility, extracted data and performed an assessment of bias. An effort was made to contact authors for missing data. The methods and results of each eligible study were summarised and we planned to pool data in meta-analyses when it was considered appropriate, based upon clinical and statistical homogeneity.

Main results

We identified three eligible trials involving a total of 222 participants with 333 groin wounds. Suction drainage was compared with no drainage in all studies. Two studies were parallel-group, randomized controlled trials, and one was a split-body, randomized controlled trial. Trial settings were not clearly described. Patients undergoing bypass and endarterectomy procedures were included, but none of the studies provided details on the severity of the underlying arterial disease.

We deemed all of the studies to be at a high risk of bias in three or more domains of the 'Risk of bias' assessment and overall the evidence was of very low quality. Two out of three studies had unit of analysis errors (with multiple wounds within patients analysed as independent) and it was not possible to judge the appropriateness of the analysis of the third. Meta-analysis was not appropriate, firstly because of

clinical heterogeneity, and secondly because we were not able to adjust for the analysis errors in the individual trials. One trial yielded data on surgical site infections (SSI; the primary outcome of the review): there was no clear difference between drained and non-drained wounds for SSI (risk ratio 1.33; 95% confidence interval 0.30 to 5.94; 50 participants with bilateral groin wounds; very low quality evidence). It was not possible to evaluate any other outcomes from this trial. The results from the other two studies are unreliable because of analysis errors and reporting omissions.

Authors' conclusions

The data upon which to base practice in this area are limited and prone to biases. Complete uncertainty remains regarding the potential benefits and harms associated with the use of wound drains in lower limb arterial surgery due to the small number of completed studies and weaknesses in their design and conduct. Higher quality evidence is needed to inform clinical decision making. To our knowledge, no trials on this topic are currently active.

PLAIN LANGUAGE SUMMARY

Drains for leg artery surgery

Review question

A surgical drain is a tube used to remove blood, pus or other fluid from a wound. We reviewed the evidence about whether inserting wound drains following leg artery surgery resulted in fewer complications compared with no drains.

Background

Patients who have severe blockages in the arteries of their legs often need to have the blockages treated. These blockages can be treated with surgery, and there are several different types of operation that can be used. Arterial bypass is an operation in which the blockage is bypassed by using a piece of vein or a synthetic tube so that the blood can go around the obstruction. An endarterectomy is an operation where the surgeon removes the fatty material that is causing the blockage, thereby improving the flow of blood. Sometimes after surgery on leg arteries, surgeons place drainage tubes in the wounds. It is thought that these drains may help to reduce infection, prevent the build-up of blood or other fluids in the wound, and avoid some other complications after operations. These benefits are not proven and nobody knows if drains are truly helpful. It is possible that drains could cause harm by allowing infection into a wound, by causing bleeding and by prolonging the time a patient spends in hospital. Nobody knows if surgeons should use drains in every wound all of the time, or only in cases where they think a drain is needed.

Study characteristics

In June 2016 we searched for randomised controlled trials (RCTs) involving the use of drains after leg artery surgery. We identified three eligible trials involving 333 wounds in 222 patients, mainly aged over 65, who had leg artery surgery. Both men and women were included and all of the wounds were in the groin area as part of bypass and endarterectomy operations to improve blood flow.

Key results

The studies involved small numbers of patients and were not clearly described. All three studies had serious weaknesses in the way they were designed and performed. The results of the individual studies do not provide reliable information because of weaknesses in study design. It is unclear whether wound drains are beneficial or harmful because we did not find any useful information. None of the studies gave information on whether drains shortened or lengthened the number of days that patients had to spend in hospital. None of the studies gave information about how drains affect patients' quality of life.

Quality of the evidence

Overall, we found that the quality of the evidence about the effects of drains after leg artery surgery was very low and we were not able to tell whether drains lead to benefits or harms for patients. Better quality research is needed if patients and healthcare providers think that this is an important topic.

This plain language summary is up to date as of 8 June 2016.

SUMMARY OF FINDINGS

Summary of findings for the main comparison.

Wound drainage compared with no drainage for lower limb arterial surgery

Patient or population: lower limb arterial surgery

Setting: hospital

Intervention: drainage

Comparison: no drainage

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants ¹ (studies)	Quality of the evidence (GRADE)	Comments
	Risk with no drainage	Risk with drainage				
Incidence of any surgical site infection	Study population		RR 1.33 (0.30 to 5.94)	50 (1 study)	very low ²	
	60 per 1000	80 per 1000 (18 to 356)				
Incidence of wound dehiscence	No meaningful data were available					
Incidence of reoperation for wound or graft-related complications	No meaningful data were available					
Changes in health-related quality of life	Not reported					

***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; **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

¹The unit of randomisation and analysis was the wound

²Downgraded one level due to a limitations in design and implementation (methodological flaws and lack of clarity) and two levels due to serious imprecision (small sample size).

BACKGROUND

Description of the condition

Peripheral arterial occlusive disease (PAOD), also known as peripheral vascular disease (PVD), refers to narrowing or blockage of the blood vessels that bring blood from the heart to distant parts of the body. PVD can occur in any blood vessel, but it most commonly affects the lower limbs. The blood supply to the leg may be restricted due to partial blockages caused by the presence of an embolus (a substance formed from either a blood clot, air, fat or tumour tissue that is carried by the bloodstream) or a thrombus (blood clot attached to the wall of the artery), or by a condition known as atherosclerosis. In atherosclerosis an abnormal mass of fat, fibrous tissue and inflammatory cells (atheroma) within the artery combines with narrowing and hardening of the vessels (arteriosclerosis) to restrict blood flow. Blood flow blockages due to emboli or thrombi tend to be sudden in onset, whereas those blockages caused by atherosclerosis tend to occur gradually. PVD is usually caused by atherosclerosis, although rare causes also exist. These rare causes include blockages caused by recurrent small emboli or arteritis (inflammation of the artery). People with PVD present with signs and symptoms that vary according to the severity of the arterial blockage and the subsequent reduction in arterial blood supply (ischaemia). Symptoms range from none, to intermittent claudication (leg pain when walking that is relieved by rest), to pain at rest, ulceration (development of open wounds) or gangrene (tissue death). Data from the National Health and Nutrition Examination Survey in the USA, reported the prevalence of PVD in the general population as being 12% to 14%, with prevalence increasing to 20% in those over 75 years of age. Amongst those affected, 70% to 80% are asymptomatic, and only a minority require revascularisation (a surgical procedure to restore blood supply) (Ostchega 2007; Selvin 2007; Shammass 2007). The incidence of symptomatic PVD increases with age, from about 3 per 1000 per year for men aged 40 to 55 years, to about 10 per 1000 per year for men aged over 75 years (Shammass 2007).

Lower limb arterial surgery is performed to restore blood flow to legs that are affected by acute or chronic ischaemia when non-operative treatment has been unsuccessful (Grace 1996). Surgical procedures to restore blood supply to the leg involve removing or bypassing the blockage. A thrombus or embolus can be removed by a thrombectomy or embolectomy procedure. If the blockage is caused by the slow build up of atheroma to a critical level, an endarterectomy may be performed. This is an operation in which a short deposit of atheroma is removed, thus improving blood flow. If removing the blockage is not a suitable option, the blockage may be bypassed using a graft. Grafts can be made of synthetic material or can be autologous (i.e. a portion of the patient's own vein). In some cases peripheral angioplasty - a technique in which narrowed or obstructed arteries are widened mechanically - is used in conjunction with surgical treatment. In this procedure, a collapsed balloon, known as a balloon catheter, is passed with X-ray guidance into the artery along a guide wire to the site of the obstruction. The balloon is inflated to open up the blood vessel for improved flow, then the balloon is deflated and withdrawn (Grace 1996). Arterial surgical procedures are often complicated by infections, groin haematomas (localised collection of blood outside blood vessels, within the tissue), lymphoceles (collection of lymphatic fluid that can result from damage to lymph vessels during surgery), or seromas (a pocket of clear serous fluid that

develops after surgery) (Karthikesalingam 2008; Youssef 2005). Any of these complications can cause failure of the operation, and therefore they should be avoided if possible (Karthikesalingam 2008; Youssef 2005).

Description of the intervention

Drains remove blood, lymph, serum and other fluids that can accumulate in the wound bed after an operation. If allowed to collect, these fluids can form haematomas, seromas and lymphoceles that can put pressure on the surgical site and adjacent organs, vessels, and nerves. This increased pressure can cause additional pain and reduce the delivery of blood to the micro vessels (reducing perfusion) which may impair healing. Accumulated fluid may also increase the risk of infection. The practice of placing drains routinely to safeguard against complications in surgical wound management following lower limb arterial surgery remains widespread (Grobmyer 2002). Some units employ a selective policy of using drains if there have been concerns over haemostasis (stopping bleeding) intraoperatively, while others use drains routinely (Karthikesalingam 2008). Drains can rely on pressure and gravity to help drainage (passive drainage), or can be helped by a suction mechanism (active drainage). Fluids can be removed from a wound using either open or closed systems. An open drain depends on gravity to remove fluid from a wound site into a wound dressing placed over the end of the drain; examples include corrugated, Penrose and Yeates drains. A closed drainage system consists of a tube left in the wound that drains fluids from the body into a closed container. Closed drains may be assisted by suction or a vacuum, as in the Redon or Jackson-Pratt drains. The type of drain that a surgeon chooses to use in a given operation depends upon the location of the operative site and the amount of fluid drainage expected. In certain procedures the use of drains has been shown to be of no benefit, and it has been suggested they may cause harm to the patient (for instance providing a portal for invasion by bacteria) (Barie 2002). Open drains may be associated with an increased risk of infection because they provide a portal for bacteria and the potential for drained fluid to come into contact with the incision site. Debate regarding the use of drains following lower limb arterial surgery is ongoing and this review aims to clarify the benefits and harms of this intervention in this group of patients.

How the intervention might work

The potential benefits of drainage are many, and include prevention of fluid accumulation, reduction of infection and earlier identification of bleeding (Youssef 2005). Conversely, drains may actually cause infection and may prolong hospital stay (Karthikesalingam 2008).

Why it is important to do this review

Although use of wound drains appears logical, some studies in various different types of surgery, suggest that routine drainage is not beneficial to patients (Charoenkwan 2014; Clifton 2008; Diener 2011; Gurusamy 2007a; Gurusamy 2007b; Gurusamy 2013a; Gurusamy 2013b; Hellums 2007; Karliczek 2006; Parker 2007; Samraj 2007; Wang 2015; Zhang 2011). It is unclear whether routine placement of surgical drains is of benefit in lower limb arterial surgery. Currently, there are no formal guidelines for usage of drains following arterial surgery. A systematic review on this topic was published in 2008 (Karthikesalingam 2008), and concluded there was no clear evidence that closed-suction drainage reduced

complications following lower limb revascularisation. The review included data from just four small trials which, combined with an absence of information on data extraction and validity assessment, limited the reliability of the findings. Our Cochrane review aimed to provide a definitive appraisal of the evidence on drainage in lower limb arterial surgery. We aimed to provide vascular surgeons with robust data, from a thorough evaluation of the literature, upon which to base their drain-usage policy. In addition we hoped that this review might provide policy makers with the evidence to support or limit this practice.

OBJECTIVES

To determine whether routine placement of wound drains after lower limb arterial surgery results in fewer complications compared with not using drains.

METHODS

Criteria for considering studies for this review

Types of studies

We considered randomized controlled trials (RCTs) that evaluated the use of any type of drain in lower limb arterial surgery. Cross-over trials were deemed ineligible due to the short-term nature of the intervention under investigation. Quasi-randomised controlled trials were also ineligible. Cluster trials were eligible for inclusion and, if encountered, we planned to undertake a sensitivity analysis to evaluate the effect of the cluster trial(s) on the final results. A study follow-up period of one year or less was applied for the purpose of the review to allow for the reporting of longer-term outcomes such as reoperation.

Types of participants

We considered trials that recruited people undergoing elective or emergency lower limb arterial surgery (bypass with synthetic or autologous graft; endarterectomy with or without angioplasty; embolectomy; thrombectomy) eligible for inclusion.

Types of interventions

We aimed to compare the effects of placement of any surgical drain following lower limb arterial surgery with routine closure and no surgical drain. We planned to include trials that compared different types of drains (e.g. closed versus open drains; suction versus non-suction drains) as separate subgroups within the review. There was no restriction regarding the location of wounds.

Types of outcome measures

Primary outcomes

- Incidence of any surgical site infection (superficial or deep, or both); incidence of all types of surgical site infection (if type not specified). Surgical site infection: as defined by the Centers for Disease Prevention and Control (CDC) (Mangram 1999), is an infection that occurs within 30 days after surgery in the part of the body where the surgery took place. Surgical site infections can be superficial, involving the skin only, or they can be deep, involving tissues under the skin, organs, or implanted material (Mangram 1999).

Secondary outcomes

- Incidence of wound dehiscence: defined as rupture of the wound suture line after surgery.
- Incidence of fluid collections: defined as a collection of either serous or lymphatic fluid within the tissue (seroma and lymphocoele respectively).
- Incidence of haematoma formation: defined as a localised collection of blood outside the blood vessels, within the tissue.
- Incidence of graft occlusion: defined as a blockage of the bypass graft that limits blood flow.
- Incidence of reoperation for wound or graft-related complications.
- Length of hospital stay.
- Change in health-related quality of life between pre-operative baseline and within 30 days post-operatively. Data generated using validated generic instruments (e.g. EQ-5D, SF-36, SF-12 or SF-6D) or validated wound-specific instruments would have been used.
- Mortality (all cause).

Definitions of outcome in individual eligible studies were extracted from study reports and included in the review.

Search methods for identification of studies

Electronic searches

The following electronic databases were searched to identify reports of relevant randomized clinical trials:

- The Cochrane Wounds Specialised Register (8 June 2016);
- The Cochrane Central Register of Controlled Trials (CENTRAL; the Cochrane Library, 2016 Issue 6);
- Ovid MEDLINE (1946 to 8 June 2016);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations; 8 June 2016);
- Ovid EMBASE (1974 to 8 June 2016);
- EBSCO CINAHL (1982 to 8 June 2016).

Our search strategies are outlined in [Appendix 1](#). Firstly, we searched the Cochrane Central Register of Controlled Trials (CENTRAL) and then we adapted this strategy to search Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL ([Appendix 1](#)). We combined the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision) (Lefebvre 2011). We combined the EMBASE search with the Ovid EMBASE filter developed by the UK Cochrane Centre (Lefebvre 2011). We combined the CINAHL search with the trial filter developed by the Scottish Intercollegiate Guidelines Network (SIGN 2015). We did not restrict studies with respect to language or date of publication or study setting.

We also searched the following online clinical trial registries on 11 June 2016:

- ClinicalTrials.gov (www.clinicaltrials.gov);
- The EU Clinical Trials Register (www.clinicaltrialsregister.eu);
- Current Controlled Trials Register (www.controlled-trials.com);
- The World Health Organization International Trial Registry Platform (www.who.int/ictrp/en).

A detailed description of our search of online clinical trial registries can be found in [Appendix 1](#).

Searching other resources

We attempted to contact trialists to obtain unpublished data and information as required. We also searched the reference lists of other systematic reviews and the reference lists of included trial reports.

Data collection and analysis

Selection of studies

Independently, two review authors (DH and MCM) assessed the titles and abstracts of papers retrieved by the searches and reviewed their relevance. After this initial assessment, we obtained full texts of those trials thought to be potentially relevant. Independently, two review authors (DH and MCM) checked the full papers for eligibility, with disagreements resolved by discussion and, where required, referral to a third author (SRW). We recorded our reasons for exclusions.

Data extraction and management

Independently, two review authors (DH and MCM) extracted and summarised details of the eligible trials and entered the details into a review-specific spreadsheet template, after which both data extractions were compared for agreement. We resolved disagreements by discussion. We attempted to contact trial authors to obtain potentially relevant missing data. We included trials published as duplicate reports (parallel publications) once, using all associated trial reports to extract the maximum amount of trial information, but ensuring that the trial data were not duplicated in the review. We extracted the following information in addition to the specific outcomes already listed.

- Trial authors
- Year of publication
- Country in which trial was undertaken
- Setting of care
- Participant characteristics (selection criteria and baseline characteristics)
- Trial design (e.g. pragmatic RCT, cluster RCT)
- Overall sample size and methods used to estimate statistical power
- Unit of investigation
- Number of participants allocated per group
- Intervention regimens and comparators (characteristics of drains used, duration of drainage, co-interventions such as antibiotics)
- Outcomes (assessment methods and data per group)
- Withdrawal (numbers per group and reasons)
- Risk of bias criteria.

Assessment of risk of bias in included studies

Independently, two review authors (DH and MCM) applied the Cochrane tool for assessing risk of bias to each included study ([Higgins 2011](#)). This tool addresses six specific domains: sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting, and other issues. The criteria

used to define levels of bias as high risk, low risk or unclear risk of bias are detailed in [Appendix 2](#).

We used a 'Risk of bias' summary figure to present our assessment of risk of bias. This presents all of the judgements in a cross-tabulation of trials. This display of internal validity indicates the weight the reader may give the results of each trial.

Measures of treatment effect

For dichotomous variables, we planned to calculate risk ratios (RR) with 95% confidence intervals (CI). For continuous variables, we planned to calculate the mean difference (MD) with 95% CIs.

Unit of analysis issues

Lower limb revascularisation procedures often result in clustered data with multiple wounds per patient. At the time of writing our protocol, we thought that some trials might use the number of wounds as the group denominator, rather than the number of participants randomized into the group. A possible unit of analysis issue arises if individual participants with multiple wounds are randomized, the allocated treatment used on the multiple wounds per participant (or on a subset of participants) and then the results presented by wound and not person. Where studies contained some or all clustered data, we reported this alongside whether the data had been incorrectly analyzed as independent. We recorded this as part of the 'Risk of bias' assessment under the incomplete outcome data subheading. We also recorded when the wound was used as the unit of randomisation and allocation, and whether the correct paired analysis had been carried out in participants with multiple wounds. We prespecified that our main analysis would be limited to trials that reported outcomes using participants rather than wounds as the unit of analysis. We did not plan to undertake further calculation to adjust for clustering.

Dealing with missing data

We contacted primary trial authors to obtain relevant missing data. Where missing data remained unavailable, we used information that was available from the trial report (i.e. complete case data).

Assessment of heterogeneity

We planned to consider clinical and statistical heterogeneity. Statistical pooling was only considered for groups of RCTs with similar participant, intervention and outcome characteristics in order to minimise the effect of clinical heterogeneity on meta-analyses. We planned to use the Chi² test (P value < 0.1) and I² and H² values with 95% confidence intervals to test for the presence of significant statistical heterogeneity between effect sizes of included studies. We planned to interpret the I² statistic values as follows:

- 0% to 40%: might not be important;
- 30% to 60%: might represent moderate heterogeneity;
- 50% to 90%: might represent substantial heterogeneity;
- 75% to 100%: represents considerable heterogeneity.

Where there was evidence of substantial or considerable statistical heterogeneity, we planned to explore the reasons for this.

Assessment of reporting biases

We planned to construct funnel plots to estimate publication bias if at least ten studies could be included in a meta-analysis.

Data synthesis

We provide a narrative overview of all included RCTs, with results grouped according to the type of drain used (open or closed) and the comparator characteristics. We considered clinical and statistical heterogeneity and we planned to pool data only when trials were similar.

We planned to compare any drain versus no drain for the main analysis and we planned comparisons between different types of drains as secondary analyses. We planned to use random-effects models rather than fixed-effect because fixed-effect underperform in the presence of any heterogeneity and random-effects models are more conservative ([Brockwell 2001](#)). We planned to present results with 95% confidence intervals (CI). Estimates for dichotomous outcomes (e.g. wound infection - yes or no) were to be reported as a pooled risk ratio (RR) ([Deeks 2011](#)), and we planned to present continuous data (e.g. length of hospital stay) as pooled mean difference (MD). We planned to use the standardised mean difference (SMD) for pooling continuous data when RCTs used a variety of instruments to assess a common underlying concept (e.g. change in health-related quality of life).

'Summary of findings' tables

We planned to include a 'Summary of findings' table, presenting key information relating to the quality of evidence, the size of the effects of the interventions examined, the sum of the available data for the main outcomes ([Schünemann 2011a](#)) and a grading of the quality of evidence using the GRADE assessment (Grading of Recommendations Assessment, Development and Evaluation) approach ([Schünemann 2011b](#)). The GRADE approach defines the strength of a body of evidence as the extent to which one can be confident that an estimate of effect or association is close to the true value. GRADE involves consideration of within-trial risk of bias (methodological quality), directness of evidence, heterogeneity, precision of effect estimates and risk of publication bias ([Schünemann 2011b](#)). We planned to present the following outcomes in our 'Summary of findings' table:

- wound infection;
- wound dehiscence;

- reoperation for wound or graft-related complications;
- changes in health-related quality of life.

Subgroup analysis and investigation of heterogeneity

We planned to undertake a subgroup analysis evaluating the effect of drains specifically in revision surgery (surgery requiring reopening of a healed wound). We also planned a subgroup analysis to compare different types of drains.

Sensitivity analysis

Treatment effects may differ between cluster-randomised and individual-randomised trials. In some instances, large positive or negative treatment effects in cluster-randomised trials may outweigh the results of individual-randomised trials. To account for this, we planned to perform a sensitivity analysis to evaluate the impact of cluster trials on the pooled treatment effect estimates. We planned to conduct a further sensitivity analysis to include those studies that adhered to the strict CDC definition of wound infection within 30 days of surgery ([Mangram 1999](#)). We planned to undertake a third sensitivity analysis to evaluate the influence of the risk of bias on effect sizes; we planned to assess the influence of removing studies classed as being at high and unclear risk of bias from meta-analyses. We planned to only include studies that were assessed as having a low risk of bias in all key domains. Clarification of the definitions in these contexts is provided in [Appendix 2](#). As mentioned earlier, we specified that the main analysis would be limited to trials that used participants as the unit of analysis. We planned an additional sensitivity analysis that would include studies that used wounds as the unit of analysis.

RESULTS

Description of studies

See: [Characteristics of included studies](#).

Results of the search

The results of the search are summarised in the flow diagram ([Figure 1](#)). The search yielded 148 citations and one citation was found from other sources. We deemed 146 citations to be ineligible on the basis of examination of their titles and abstracts.

Figure 1. Study flow diagram.

We included three studies in this review (Dunlop 1990; Healy 1989; Youssef 2005). Some of the data relating to Youssef 2005 were also published in a conference abstract (Dawson 1994).

Included studies

Three randomized controlled trials were eligible for inclusion in this review, involving a total of 222 people with 333 wounds (Dunlop 1990; Healy 1989; Youssef 2005). All of the wounds were groin wounds for femoral artery access. Two studies were conducted in the UK (Dunlop 1990; Youssef 2005), and one was conducted in the USA (Healy 1989). One of the trials took place in two centres (Healy 1989), and the other two trials were probably single-centre trials (Dunlop 1990; Youssef 2005), although this was not specified. The dates of conduct of all three trials were not specified. One trial used a split-body design and included patients who underwent bilateral groin incisions with one of the wounds in each patient being randomly allocated to drainage and the other to non-drainage (Healy 1989). The other two trials used parallel group designs (Dunlop 1990; Youssef 2005). Dunlop 1990 randomized wounds to drainage or non-drainage and in cases of bilateral procedures only one wound was randomized and included. However, 127 wounds in 99 patients were finally included; thus some participants

must have been included in the study more than once, although this was not explicitly stated in the report. Youssef 2005 also randomized wounds to drainage or non-drainage, but in cases with bilateral groin incisions one of the groins was randomly allocated to drainage and the other to no drainage. Both men and women were included in the studies. Youssef 2005 involved patients with a median age of 72 years, while the drainage and non-drainage groups of Dunlop 1990 had mean ages of 66 and 68 years respectively. The age profile of patients in Healy 1989 was not reported. Trial reports lacked details about other patient characteristics including comorbidities. None of the trials provided details on indications for surgery, or the severity of patients' arterial disease. The trials included bypass and endarterectomy operations and, in all three, drainage was achieved with closed suction systems only.

Excluded studies

There were no excluded studies.

Risk of bias in included studies

See Figure 2.

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
Dunlop 1990	?	?	-	+	-	-	-
Healy 1989	?	?	-	?	-	+	-
Youssef 2005	?	?	-	-	-	-	-

Allocation

No study provided details on how the random sequence was generated. One study, [Youssef 2005](#), reported that sealed envelopes were used, but no details were provided on who had access to the envelopes, whether they were sequentially opened or whether they were opaque. The other two studies ([Dunlop 1990](#); [Healy 1989](#)) did not provide sufficient detail to judge allocation concealment.

Blinding

Participants were not blinded in any of the studies. [Healy 1989](#) did not provide details on who assessed outcomes or how outcomes were assessed, and there was no mention of blinded outcome assessment. [Dunlop 1990](#) reported that outcomes were assessed by a blinded independent observer more than 48 hours postoperatively when drains would have been removed. Outcome assessors in [Youssef 2005](#) were not blinded.

Incomplete outcome data

No study reported any attrition.

All studies were at high risk of bias due to unit of analysis issues. [Healy 1989](#) used a split-body design, but it was not clear whether an appropriate paired analysis was used. [Dunlop 1990](#) randomized one wound in each patient, but some patients were included twice because 127 wounds were reported in 99 patients. The extra 28 wounds were likely to relate to revision procedures or further primary procedures. The statistical tests used did not account for repeated measurements of the same wound from the same patient. [Youssef 2005](#) sometimes included two groin wounds simultaneously, with one groin receiving drainage and the other being a control, but a paired analysis was not used for this group. In these three different situations, outcomes from one wound in a particular patient would not be independent of outcomes in other wounds in the patient. There was no adjustment for this in the trial analyses.

Selective reporting

No protocols were available for evaluation; thus it is unclear whether outcomes were prespecified. [Youssef 2005](#) did not describe the incidence of wound infections according to treatment allocation, although they collected data on wound infections. [Dunlop 1990](#) did not report the incidence of wound infections, although incidence of wound erythema and discharge were reported, which suggests that the authors may have had data on infections. [Healy 1989](#) was the only study deemed to be at low risk of reporting bias because all outcomes mentioned in the methods section were reported.

Other potential sources of bias

No study provided data regarding the numbers of revision procedures that were performed. This is a potential source of bias, as revision procedures are associated with worse outcomes.

Effects of interventions

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

We prespecified that our main analysis would be limited to trials that reported outcomes using participants as the unit of investigation. It was not clear whether [Healy 1989](#) used the appropriate paired analysis, but nonetheless the report yielded enough data to calculate risk ratios for individual outcomes at participant level using the technique described in [Hirji 2011](#). No participant-level data were available from [Dunlop 1990](#) and [Youssef 2005](#). Unfortunately, despite efforts to contact authors, it was not possible to obtain any additional data beyond what was published in the reports of the three trials.

We planned to undertake a sensitivity analysis involving trials that used wounds as the unit of investigation. [Dunlop 1990](#) and [Youssef 2005](#) yielded no meaningful data because they failed to adjust their analyses for the situations where participants had more than one wound, and we could not access data beyond the reports. In any case, we did not consider that we could pool outcome data from the trials because there were many reporting inadequacies, and we were not sure that studies were sufficiently similar. Even if the trials were comparable, complete data sets from each trial would have been needed to amend the errors in analysis that are highlighted above.

The remainder of this section presents the available data for each outcome in the review. The results from [Dunlop 1990](#) and [Youssef 2005](#) are unreliable, and [Healy 1989](#) has major limitations, although it was still possible to generate a RR for one outcome from the [Healy 1989](#) trial. It was not possible to perform our prespecified sensitivity analyses or secondary analyses.

Incidence of any surgical site infection

One trial provided data on the incidence of any surgical site infection in drained versus non-drained wounds ([Healy 1989](#)). There was no clear difference in the incidence of infections (4/50 in drained wounds versus 3/50 in non-drained wounds: RR 1.33 (95% CI 0.30 to 5.94) (analyzed using the technique described in [Hirji 2011](#)). Notably, the definition for what constituted a wound infection was not described in the trial report. [Dunlop 1990](#) did not report explicitly on wound infection rates, rather, the trialists reported on numbers of wounds that developed erythema and discharge, which were 49/65 and 11/65, respectively,

in the drainage group and 48/62 and 12/62, respectively, in the no drainage group. Finally, [Youssef 2005](#) did not report on the incidence of wound infection according to treatment allocation.

GRADE assessment: very low quality evidence. We downgraded the evidence by one level due to limitations in design and implementation (methodological flaws and lack of clarity) and by two levels due to imprecision (sample size of 50 participants).

Incidence of wound dehiscence

Only one trial provided data on the incidence of wound dehiscence ([Youssef 2005](#)): 0/49 wounds in the drainage group and in 1/57 in the no-drainage group dehisced. No meaningful analysis was possible due to the unit of analysis issues that we mentioned earlier. Data were unclearly reported regarding this outcome in [Healy 1989](#), and not reported in [Dunlop 1990](#).

GRADE assessment: no meaningful data were available.

Incidence of fluid collections

[Healy 1989](#) and [Dunlop 1990](#) provided data on the incidence of fluid collections. No collections were noted in [Healy 1989](#), and therefore it was not possible to determine risk ratios. [Dunlop 1990](#) reported that lymph cysts were found in 5/65 wounds in the drainage group versus 6/48 in the no drainage group. In this trial lymph cysts were diagnosed when a wound swelling was found from which clear fluid could be aspirated. Notably, [Youssef 2005](#) reported that ultrasound-detected fluid collections were found in 7/49 in the drainage group versus 14/57 in the no drainage group. However, the nature of these fluid collections was not evaluated, and in the trial report these collections were labelled as haematomas. Overall, no meaningful analysis was possible.

Incidence of haematoma formation

Two trials reported on the incidence of wound haematomas. [Healy 1989](#) reported that no wound haematomas occurred in either treatment group (50 wounds in each group), and so it was not possible to determine risk ratios. [Youssef 2005](#) reported that 7/49 wounds developed an ultrasound-detected collection (which were labelled as haematomas) in the drainage group versus 14/57 in the no drainage group. Overall, no meaningful analysis was possible.

Incidence of graft occlusion

None of the trials provided data on graft occlusion rates according to the treatment groups.

Incidence of reoperation for wound or graft-related complications

Two studies reported on the incidence of reoperation for wound or graft-related complications. [Healy 1989](#) reported that 2/50 grafts had to be removed due to infection in the drainage group and no grafts had to be removed in the no drainage group. It was not possible to calculate RR because one group had no events. Data on other types of reoperation were not reported. [Youssef 2005](#) reported that one graft in the no drainage group became infected requiring revision surgery with subsequent amputation, and that no graft in the drainage group required reoperation. Overall, no meaningful analysis was possible.

GRADE assessment: no meaningful data were available.

Length of hospital stay

No trial provided data on length of hospital stay.

Change in health-related quality of life

No trial provided data on change in health-related quality of life.

Mortality

No trial provided data on mortality according to treatment allocation. [Healy 1989](#) reported that one patient died after a graft infection in a drained wound but this was a split-body trial.

DISCUSSION

Summary of main results

This review includes three eligible trials involving 333 wounds in 222 patients. All of the wounds were groin incisions for femoral artery access as part of revascularisation procedures and the procedures comprised both bypasses and endarterectomies. None of the trials reported adequately on baseline characteristics of the patients or on the indications for surgery. All trials used closed suction drainage systems. Individual studies reported on surgical site infections, wound dehiscence, fluid collections, wound haematomas and incidence of reoperation for wound or graft-related complications. Importantly, there were major errors in analysis in two of the studies ([Dunlop 1990](#); [Youssef 2005](#)), and a lack of clarity about the analysis in the third study ([Healy 1989](#)): each study included some participants who had multiple wounds without describing analyses that would take this into account. Wound outcomes should not be considered independent when a single patient has multiple wounds. Unfortunately, we were not able to obtain any data beyond the three published reports and, as a result, we could not adjust for these errors in this review. Consequently, we found few meaningful data in the studies. We advise against making any interpretations from the individual study results.

All studies were considered to be of very low quality due to limitations in design and implementation, so, as GRADE puts it, "further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate".

Overall completeness and applicability of evidence

The chief factors that limit the completeness and applicability of evidence are limitations in design and implementation, and the indirectness of the studies. The trials had major methodological flaws, and wounds were the unit of analysis rather than participants. From the perspective of decision makers, it is much more desirable to have effect size estimates for patients rather than wounds.

We highlight that all of the studies focused on groin wounds and that no data were available on wounds in other parts of the leg. It is possible that wounds in other locations would have a reduced tendency to develop lymph leakage. A further concern is that none of the included studies provided data on patients' characteristics and the severity and nature of their arterial disease. A prespecified aim of our review was to evaluate the utility of drains specifically in revision procedures; no study provided data on outcomes following

revision surgery. We also aimed to compare different types of drain (such as suction or non-suction drains) but we found no such data.

Overall, we think that there is a lack of completeness and applicability of the evidence and that, therefore, it is not possible to make any generalisations based upon the studies contained in this review.

Quality of the evidence

We could only generate a risk ratio for one outcome (incidence of any surgical site infection) from one trial ([Healy 1989](#)). The GRADE assessment for this outcome determined that the quality of evidence was very low (downgraded for risk of bias and twice for imprecision). We could not assess inconsistency or publication bias due to insufficient number of studies. Risk of bias was denoted as unclear or high for most domains in the 'Risk of bias' assessment tool. This results from flawed or unclear methodology and reporting in the three trials. Despite efforts to contact authors, we found no additional information. Our bias assessment tables and [Figure 2](#) outline our concerns regarding the methodology of the included trials.

Potential biases in the review process

Our search strategy was extensive, but nonetheless it is possible that potentially relevant studies were missed. We minimised bias in the review process by adhering to our strict predefined methodology. Independently, two authors determined study eligibility and extracted the data. Assessment of bias was also carried out independently and discrepancies were resolved by discussion.

Agreements and disagreements with other studies or reviews

One previous review has been performed on the topic ([Karthikesalingam 2008](#)). This review involved four studies, but the authors erroneously duplicated data from the cohort of patients in [Youssef 2005](#) by including data that were obtained in abstract form ([Dawson 1994](#)). Their primary outcomes were wound infection, seroma/lymphocoele formation and haematoma formation, and they chose to pool all available data for each outcome, yielding no significant results. They concluded that drains were associated with no benefits and therefore should be not be used routinely. We found no meaningful data and therefore we disagree with that conclusion.

AUTHORS' CONCLUSIONS

Implications for practice

The data upon which to base practice are extremely limited. Larger studies which strive to avoid bias are needed before conclusions can be drawn.

Implications for research

Further studies on this topic are needed if this is deemed to be an important topic by patients and healthcare providers. Future studies should use patients as the unit of investigation and should have robust methodology.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Dunlop 1990

Methods	Parallel group, randomized controlled trial, performed in the UK. Dates of conduct of the trial were not specified. No sample size calculation was described.
Participants	The study included consecutive patients undergoing femoral artery exploration via a longitudinal incision as part of a vascular surgery procedure. No exclusion criteria were described.

Wound drainage for lower limb arterial surgery (Review)

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Dunlop 1990 (Continued)

Wounds were randomized rather than participants. 127 wounds in 99 participants were included. 96/99 participants were men. The drainage group comprised 65 wounds in an unclear number of participants. The non drainage group comprised 62 wounds in an unclear number of participants. Mean age was similar between the groups (66 and 68 years) and the procedures were similar. The drainage group comprised 14 vein graft bypasses, 39 prosthetic graft bypasses and 12 local procedures where no graft was used. The no drainage group comprised 15 vein graft bypasses, 37 prosthetic graft bypasses and 10 local procedures where no graft was used. There were no details regarding disease severity, comorbidities or revision procedures. In cases of bilateral wounds, only one wound was randomized, therefore, some participants were included twice. The number of participants who withdrew from the study was unspecified.

Interventions	Drainage group: drainage consisted of a narrow bore Redivac suction drain being placed in the wound with removal at 48 h after surgery. No drainage group: received no drainage intervention.
Outcomes	Outcomes were numbers of lymph fistulas (defined as a continued leak of clear fluid from the wound for more than 48 h), lymph cysts (defined as a swelling under the wound developing ≥ 2 days after surgery from which clear fluid was obtained via needle aspiration) and wound infections (defined clinically based upon the presence of cellulitis or pus discharge). A blinded independent observer assessed wounds daily from 48 h until full healing or discharge from hospital.
Notes	Groins wounds were the unit of investigation rather than participants. An attempt was made to contact authors for additional data, but this was unsuccessful.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details were provided on how the random sequence was generated.
Allocation concealment (selection bias)	Unclear risk	Sealed envelopes were used to allocate treatments. No details were provided on who had access to them, whether they were sequentially opened or whether they were opaque.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Outcomes were assessed by an independent assessor after 48 h, when drains would have been already removed.
Incomplete outcome data (attrition bias) All outcomes	High risk	No losses to follow-up were reported. A total of 127 groin wounds in 99 participants were randomized to drainage or no drainage. The unit of randomisation was the wound. Only one wound was randomized in participants undergoing bilateral procedures, so the additional 28 groin wounds must relate to further procedures (either revision procedures or primary procedures) on participants who were already included. The statistical tests used did not account for repeated measurements from the same participant. The number of participants with wound complications was not reported, only the number of wound complications in each group.
Selective reporting (reporting bias)	High risk	Incidence of wound infections was not described although incidence of wound erythema and discharge were reported, which suggests that the authors may have had data on infections.

Dunlop 1990 (Continued)

Other bias	High risk	No details were provided regarding numbers of revision procedures that were performed.
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Healy 1989

Methods	Split-body, randomized controlled trial performed in 2 hospitals in the USA. Dates of conduct of the trial were not specified. No sample size calculation was described.
Participants	Eligible patients were undergoing lower limb revascularisation surgical procedures that required bilateral groin incisions. No exclusion criteria were described. 50 participants with 100 groin wounds were included. Numbers of men and women were not reported. The included participants underwent aortobifemoral bypass (n = 38), axillofemoral bypass (n = 3), femorofemoral bypass (n = 9). No details were provided on characteristics of the participants. Numbers of participants who withdrew from the study were not specified.
Interventions	Drainage group: drainage consisted of a Hemovac suction drain that was placed in the wound outside the femoral sheath and was brought out through a separate skin incision. There were no set criteria for drain removal, but generally this took place when drainage was less than 8 mL for 2 consecutive 8-h periods. No drainage group: received no drainage intervention.
Outcomes	Outcomes were numbers of haematomas, seromas, lymphoceles, infections, and mortality. No definitions for outcomes were provided. Infections were subclassified into superficial, subcutaneous or graft infections. Outcomes were assessed during in-patient stay and then at 3 weeks after operation.
Notes	Groin wounds were the unit of investigation rather than participants. As this was a split-body trial, each patient served as his/her own control. An attempt was made to contact the trial author for additional data, but this was unsuccessful.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details were provided about how the random sequence was generated.
Allocation concealment (selection bias)	Unclear risk	No details were provided about how treatments were allocated.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants were not blinded.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details were provided on who assessed outcomes and how outcomes were assessed.
Incomplete outcome data (attrition bias)	High risk	No losses to follow-up were reported.

Wound drainage for lower limb arterial surgery (Review)

Healy 1989 (Continued)

All outcomes

All 50 participants were undergoing bilateral procedures with the right or left side randomly allocated to drainage, requiring a paired analysis. No information was provided on the statistical tests used, though it was reported that differences were not statistically significant between the drainage and no drainage groups. Descriptive statistics for types of complications were reported using the wound as the unit of analysis. The overall wound complication rate for the 50 participants was also reported.

Selective reporting (reporting bias)	Low risk	All outcomes mentioned in the methods were reported, although we could not access the protocol
Other bias	High risk	No details were provided regarding the number of revision procedures that were performed.

Youssef 2005

Methods	<p>Parallel group, randomized controlled trial, performed in the UK.</p> <p>Dates of conduct of the trial were not specified.</p> <p>No sample size calculation was described, but the authors stated that they expected a 25% reduction in fluid collection volume between drained and non-drained wounds.</p>
Participants	<p>Inclusion and exclusion criteria were not explicitly stated. Included participants underwent groin arterial surgery in the form of bypass or endarterectomy.</p> <p>Characteristics were provided for the entire cohort only and not described by treatment groups. 73 participants who underwent 106 groin incisions were included. 40/73 were men. Median age was 72 years (range 44 to 90 years). 86 groin incisions were for bypass procedures and 20 were for endarterectomy procedures. Details regarding comorbidities, disease severity and revision procedures were not provided. Numbers of participants per group were not specified. Only the number of groins per group was specified - 57 groins had no drainage, 49 groins had drainage. Numbers of participants who withdrew from the study were not specified.</p>
Interventions	<p>Drainage group: drainage consisted of a 10 French suction Redivac drain placed alongside the femoral vessels in the groin and brought out through a separate stab incision below and medial to the wound. Drains were removed when they collected less than 30 mL of fluid in 24 h.</p> <p>No drainage group: received no drainage intervention.</p>
Outcomes	<p>Outcomes were the number of ultrasound-detected groin haematomas of any size, and ultrasound-detected groin haematomas of > 10 mL in volume; and wound infection diagnosed clinically and on microbiological testing. Ultrasound was performed by an unblinded radiologist or accredited vascular technologist at 5 days postoperatively. There was no specified methodology for the assessment of wounds for infections. Microbiological testing was performed as clinically indicated.</p>
Notes	<p>Groins wounds were the unit of investigation rather than participants. We successfully contacted the authors who confirmed that the Dawson 1994 abstract represented the same study, but no additional data were available from the authors.</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details were provided about how the random sequence was generated

Youssef 2005 (Continued)

Allocation concealment (selection bias)	Unclear risk	Sealed envelopes were used to allocate treatments. No details were provided about who had access to them, whether they were sequentially opened or whether they were opaque.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants were not blinded. Methods of determining outcomes other than ultrasound-detected fluid collections were not described.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessors were not blinded. Methods of determining outcomes other than ultrasound-detected fluid collections were not described.
Incomplete outcome data (attrition bias) All outcomes	High risk	There were no apparent losses to follow-up. A total of 106 groins in 73 participants were randomized to drainage or to no drainage. Participants undergoing a unilateral procedure were randomized to drainage or to no drainage. Participants undergoing a bilateral procedure had one groin randomized to drainage and the other to no drainage, which requires a paired analysis. The statistical tests used did not account for the subset of participants with 2 wounds randomized. The number of participants with wound complications was not reported, only the number of wound complications in each group, though treatment with antibiotics was reported at the participant level.
Selective reporting (reporting bias)	High risk	Incidence of wound infections was not described according to treatment allocation, although the authors collected data on wound infections.
Other bias	High risk	No details were provided about the number of revision procedures that were performed.

APPENDICES

Appendix 1. Search Strategies

Cochrane Central Register of Controlled Trials (CENTRAL)

```
#1 MeSH descriptor: [Vascular Surgical Procedures] explode all trees
#2 MeSH descriptor: [Lower Extremity] explode all trees
#3 #1 and #2
#4 MeSH descriptor: [Leg] explode all trees
#5 #1 and #4
#6 MeSH descriptor: [Groin] explode all trees
#7 (lower limb* near/5 (arterial surgery or artery surgery or revasculari?ation)):ti,ab,kw
#8 (lower extremi* near/5 (arterial surgery or artery surgery or revasculari?ation)):ti,ab,kw
#9 (leg* near/5 arterial surgery):ti,ab,kw
#10 MeSH descriptor: [Femoral Artery] explode all trees
#11 femoral arter* surgery:ti,ab,kw
#12 (endarterectomy near/5 (leg* or lower extremi*)):ti,ab,kw
#13 (thrombectomy or embolectomy or peripheral arterial bypass):ti,ab,kw
#14 {or #3, #5-#13}
#15 MeSH descriptor: [Drainage] explode all trees
#16 MeSH descriptor: [Suction] explode all trees
#17 drain*:ti,ab,kw
#18 {or #15-#17}
#19 #14 and #18
```

Wound drainage for lower limb arterial surgery (Review)

Ovid MEDLINE and MEDLINE (In-Process & Other Non-Indexed Citations)

1 exp Vascular Surgical Procedures/
 2 exp Lower Extremity/
 3 1 and 2
 4 exp Leg/
 5 1 and 4
 6 exp Groin/
 7 (lower limb* adj5 (arterial surgery or artery surgery or revasculari?ation)).tw.
 8 (lower extremit* adj5 (arterial surgery or artery surgery or revasculari?ation)).tw.
 9 (leg* adj5 (arterial surgery or artery surgery)).tw.
 10 Femoral Artery/su [Surgery]
 11 femoral arter* surgery.tw.
 12 (endarterectomy adj5 (leg* or lower extremit*)).tw.
 13 (thrombectomy or embolectomy or peripheral arterial bypass).tw.
 14 or/3,5-13
 15 exp Drainage/
 16 exp Suction/
 17 drain*.tw.
 18 or/15-17
 19 14 and 18
 20 randomized controlled trial.pt.
 21 controlled clinical trial.pt.
 22 randomi?ed.ab.
 23 placebo.ab.
 24 clinical trials as topic.sh.
 25 randomly.ab.
 26 trial.ti.
 27 or/20-26
 28 exp animals/ not humans.sh.
 29 27 not 28
 30 19 and 29

Ovid EMBASE

1 exp vascular surgery/
 2 exp leg/
 3 and/1-2
 4 exp inguinal region/
 5 (lower limb* adj5 (arterial surgery or artery surgery or revasculari?ation)).tw.
 6 (lower extremit* adj5 (arterial surgery or artery surgery or revasculari?ation)).tw.
 7 (leg* adj5 (arterial surgery or artery surgery)).tw.
 8 exp femoral artery/su [Surgery]
 9 femoral arter* surgery.tw.
 10 or/3-9
 11 exp wound drainage/
 12 exp surgical drainage/
 13 exp suction/
 14 drain*.tw.
 15 or/11-14
 16 10 and 15
 17 Randomized controlled trials/
 18 Single-Blind Method/
 19 Double-Blind Method/
 20 Crossover Procedure/
 21 (random* or factorial* or crossover* or cross over* or cross-over* or placebo* or assign* or allocat* or volunteer*).ti,ab.
 22 (doubl* adj blind*).ti,ab.
 23 (singl* adj blind*).ti,ab.
 24 or/17-23
 25 exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/
 26 human/ or human cell/
 27 and/25-26

Wound drainage for lower limb arterial surgery (Review)

28 25 not 27

29 24 not 28

30 16 and 29

EBSCO CINAHL

S32 S19 AND S31

S31 S20 or S21 or S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30

S30 MH "Quantitative Studies"

S29 TI placebo* or AB placebo*

S28 MH "Placebos"

S27 TI random* allocat* or AB random* allocat*

S26 MH "Random Assignment"

S25 TI randomi?ed control* trial* or AB randomi?ed control* trial*

S24 AB (singl* or doubl* or trebl* or tripl*) and AB (blind* or mask*)

S23 TI (singl* or doubl* or trebl* or tripl*) and TI (blind* or mask*)

S22 TI clinic* N1 trial* or AB clinic* N1 trial*

S21 PT Clinical trial

S20 MH "Clinical Trials+"

S19 S14 AND S18

S18 S15 OR S16 OR S17

S17 TI drain* OR AB drain*

S16 (MH "Suction+")

S15 (MH "Drainage+")

S14 (S3 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13

S13 TI ((thrombectomy or embolectomy or peripheral arterial bypass)) OR AB ((thrombectomy or embolectomy or peripheral arterial bypass))

S12 TI ((endarterectomy N5 (leg* or lower extremi*))) OR AB ((endarterectomy N5 (leg* or lower extremi*)))

S11 TI femoral arter* surgery OR AB femoral arter* surgery

S10 (MH "Femoral Artery/SU")

S9 TI ((leg* N5 (arterial surgery or artery surgery))) OR AB ((leg* N5 (arterial surgery or artery surgery)))

S8 TI ((lower extremi* N5 (arterial surgery or artery surgery or revasculari?ation))) OR AB ((lower extremi* N5 (arterial surgery or artery surgery or revasculari?ation)))

S7 TI ((lower limb* N5 (arterial surgery or artery surgery or revasculari?ation))) OR AB ((lower limb* N5 (arterial surgery or artery surgery or revasculari?ation)))

S6 (MH "Groin")

S5 S1 AND S4

S4 (MH "Leg")

S3 S1 AND S2

S2 (MH "Lower Extremity+")

S1 (MH "Vascular Surgery+")

Clinical Trial Registries

ClinicalTrials.gov

We performed an initial search on www.clinicaltrials.gov using the terms "peripheral vascular disease" AND "drain(age)". Then we used the advanced search option to perform a targeted search using "peripheral vascular disease" as the condition and "drain" OR "drainage" as the intervention. We performed another advanced search using "arterial surgery" as the condition with "drain" OR "drainage" as interventions.

EU Clinical Trials Register

We used the search tool at <https://www.clinicaltrialsregister.eu/ctr-search/search>. The searches were: (("peripheral vascular disease" OR "arterial surgery") AND ("drain" OR "drains" OR "drainage")), "peripheral arterial disease", "peripheral vascular disease".

Current Controlled Trials Register

We used the search tool at <http://www.controlled-trials.com/>. The searches were "peripheral vascular disease" and "peripheral arterial disease".

The World Health Organization International Trial Registry Platform

We used the search portal. The searches were "peripheral vascular disease" and "peripheral arterial disease".

Appendix 2. 'Risk of bias' criteria

1. Was allocation sequence randomly generated?

Low risk of bias: the investigators describe a random component in the sequence generation process such as: referring to a random-number table; using a computer random-number generator; coin-tossing; shuffling cards or envelopes; throwing dice; drawing of lots.

High risk of bias: the investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: sequence generated by odd or even date of birth; sequence generated by some rule based on date (or day) of admission; sequence generated by some rule based on hospital or clinic record number.

Unclear risk of bias: insufficient information about the sequence generation process to permit a judgement of low or high risk of bias to be made.

2. Was treatment allocation adequately concealed?

Low risk of bias: participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone and web-based randomisation); sequentially-numbered, opaque, sealed envelopes.

High risk of bias: participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: using an open random allocation schedule (e.g. a list of random numbers); assignment envelopes without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially-numbered); alternation or rotation; date of birth; case record number; or any other explicitly unconcealed procedure.

Unclear risk of bias: insufficient information to permit a judgement of low or high risk of bias to be made. This is usually the case if the method of concealment is not described, or not described in sufficient detail to allow a definite judgement to be made, for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially-numbered, opaque and sealed.

3. Blinding of participants and personnel - was knowledge of allocated interventions adequately prevented during the study period?

Low risk of bias: no blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding or blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.

High risk of bias: no blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding, or blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.

Unclear risk of bias: insufficient information to permit a judgement of low risk or high risk to be made, or the study did not address this outcome.

4. Blinding of outcome assessment - was knowledge of allocated interventions adequately prevented during the study period?

Low risk of bias: no blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding or blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.

High risk of bias: no blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding or blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding.

Unclear risk of bias: insufficient information to permit a judgement of low risk or high risk to be made, or the study did not address this outcome.

5. Were incomplete outcome data adequately addressed?

Low risk of bias: no missing outcome data, or reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias), or missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; or (for dichotomous (categorical) outcome data), the proportion of missing outcomes compared with observed event risk was not enough to have a clinically relevant impact on the intervention effect estimate; or (for continuous outcome data), plausible effect size (difference in means or standardised difference in means) among missing outcomes was not enough to have a clinically relevant impact on observed effect size; or missing data have been imputed using appropriate methods

High risk of bias: any one of the following; not all of the study's prespecified primary outcomes have been reported; one or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not prespecified; one or more reported primary outcomes were not prespecified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); one or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; the study report fails to include results for a key outcome that would be expected to have been reported for such a study.

Unclear risk of bias: insufficient information to permit a judgement of low or high risk of bias to be made.

6. Other

We anticipated that studies might include participants who underwent revision arterial surgery and that this might lead to a bias because people undergoing revision arterial surgery may be at higher risk of wound complications.

Low risk of bias: trials that excluded people undergoing revision surgery, or that included them but used stratified randomisation to distribute them across the trial groups.

High risk of bias: trials that included revision patients, but did not stratify or provide a subgroup analysis for the revision surgery group.

Unclear risk of bias: insufficient information to permit a judgement of low risk or high risk to be made.

CONTRIBUTIONS OF AUTHORS

Stewart Walsh: conceived the review question, co-ordinated the development, performed part of the writing and editing, made an intellectual contribution to, advised on, acted as guarantor for and approved final version of the review prior to submission.

Donagh Healy: developed and made an intellectual contribution to the protocol, screened studies, extracted data, wrote the first draft and approved the final draft of the review.

Mary Clarke-Moloney: developed, edited, made an intellectual contribution to the protocol, screened studies, extracted data, revised and approved the final draft.

Ailish Hannigan: interpreted data, analyzed and interpreted data, made a contribution to the final draft and approved the final draft.

Contributions of editorial base

Susan O'Meara, (Editor): edited the protocol; advised on methodology, interpretation and protocol content. Approved the final protocol prior to submission.

Nicky Cullum (Editor): edited the review; advised on methodology, interpretation and review content. Approved the final review prior to submission.

Sally Bell-Syer (Managing Editor): co-ordinated the editorial process for the protocol. Advised on methodology, interpretation and content. Edited the protocol.

Gill Rizzello (Managing Editor): co-ordinated the editorial process for the review. Advised on interpretation and content. Edited the review.

Ursula Gonthier: helped to co-ordinate the editorial process for the review.

Ruth Foxlee and Rocio Rodriguez-Lopez (Information Specialists): designed and ran the search and edited the search methods sections for the protocol.

Reetu Child (Information Specialist): edited the search strategy and search methods section and ran the search for the review.

DECLARATIONS OF INTEREST

Donagh Healy: none known.

Mary Clarke-Moloney: none known.

Ailish Hannigan: none known.

Stewart Walsh: received an honorarium from KCI Medical for speaking at a company-organised event

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Internal sources

- No sources of support supplied

External sources

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Our prespecified primary analysis was not possible as no trial provided data using participants as the unit of analysis. We were not able to perform any of our prespecified subgroup analysis due to the absence of data.

We included unit of analysis issues in the assessment of bias.

INDEX TERMS

Medical Subject Headings (MeSH)

*Vascular Surgical Procedures; Drainage [instrumentation] [*methods]; Groin; Hematoma [epidemiology]; Lower Extremity [*blood supply]; Peripheral Arterial Disease [*surgery]; Randomized Controlled Trials as Topic; Reoperation [statistics & numerical data]; Suction; Surgical Wound Infection

MeSH check words

Aged; Female; Humans; Male