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[Intervention Protocol]

Dressings and securement devices to prevent complications for peripheral arterial catheters

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To compare the effectiveness of dressings and securement devices for peripheral arterial catheters.

BACKGROUND

Description of the condition

For a definition of technical terms, please see the [Appendix 1](#) in appendices.

Arterial catheters (ACs) are thin, flexible, plastic tubes that are inserted through the skin into arteries to allow easy access to the bloodstream for continuous blood pressure monitoring and regular blood sampling in emergency departments, operating theatres and intensive care units (ICUs). Peripheral ACs are typically inserted into the radial (forearm), femoral (thigh), axillary/brachial

(upper arm) and dorsalis pedis (foot) arteries ([Scheer 2002](#)). Many ACs are required to be inserted for only 24 to 48 hours, to monitor patients in the perioperative period after cardiac, liver and other major surgeries. However, patients in the ICU may require ACs for longer than 48 hours.

Catheter failure in ACs occurs if the catheter loses its function. Catheters are always removed when function is jeopardised by infectious or mechanical causes, and this triggers the need for a replacement insertion of a new AC. The risk of catheter-related bloodstream infection (CR-BSI) and other AC infections exists because the insertion of an AC breaks the skin's integrity, allowing the potential entry of micro-organisms into the body ([Hugonnet](#)

2004; Maki 2006; Safdar 2013). Micro-organisms gain access to an AC by migration externally from the skin along the exterior catheter surface or internally from the catheter hub (Donlan 2011; Zhang 2016). The incidence of CR-BSI has been reported to range from 0.59 to 1.7 per 1000 catheter days, and between 0.34% and 0.8% of intensive care patients develop an infection (Gowardman 2010; Lorente 2004; Maki 2006).

AC mechanical failure may be the result of arterial thromboses (blood clots), with the potential for occlusion (blockage of blood flow) to the distal limb, which in rare cases can lead to amputation of the limb or distal digits (fingers, thumbs or toes). Partial movement of the AC may also result in blockage of the device and resultant failure, because of a kinked catheter or the end of catheter resting on the artery wall. This requires device removal and replacement, since inaccurate blood pressure measurements have the potential for an undetected unstable patient (Scheer 2002). Dislodgement may occur due to movement or pressure on the part of the device that is external to the insertion site. In critical situations following accidental removal, shock from rapid haemorrhage can be catastrophic. Attributable costs for the care of a patient with a CR-BSI from a vascular catheter average USD 45,000 (O'Grady 2002), but can range between USD 3000 and USD 60,536 (Raad 2007; Schwebel 2012), and are likely to be significant in ACs. Other types of AC failure, such as dislodgement, typically incur lower costs than a CR-BSI; however, all require additional procedures for the insertion of a replacement device, with associated costs for disposable equipment and labour.

Description of the intervention

A variety of dressings and securement devices are available for clinicians to use with ACs, and are designed to keep the AC safely in place and free from complications. The earliest approach to keeping all intravascular devices in place was the use of simple tape or combined gauze and tape. Plastic film dressings emerged in the 1980s. Because these occlusive dressings trap skin moisture creating an ideal environment for the rapid growth of local microflora, first-generation occlusive standard polyurethane (SPU) dressings were later developed to be semipermeable to oxygen, carbon dioxide and water vapour (e.g. IV3000™, Smith and Nephew; Tegaderm™, 3M) (Frasca 2010). SPU dressings are transparent, allowing visual monitoring of the catheter insertion site. More recently, bordered polyurethane (BPU) dressings have become available that retain the central transparent polyurethane component of SPU dressings, with an additional external adhesive border to maximise catheter security (e.g. Tegaderm™ I.V. Advanced, 3M). The most common bacterial pathogens that result in hospital-acquired CR-BSIs are coagulase-negative staphylococci, in particular *Staphylococcus epidermidis* and *Staphylococcus aureus*, which are normal flora on human skin (Becker 2014; O'Grady 2002). Dressing technology has responded with antimicrobial dressings in which either the central dressing component is impregnated with

chlorhexidine gluconate (e.g. 3M™ Tegaderm™ CHG Dressing) or circular chlorhexidine gluconate-impregnated sponges are placed under the dressings (BIOPATCH®, Ethicon) and positioned around the insertion site. Alternative antimicrobial dressings, including polyhexamethylene biguanide foam discs (e.g. Kendall™ AMD Foam Disc), have been found to be safe to use at catheter insertion sites (Webster 2017).

Securement of ACs was traditionally achieved by suturing the catheter in place, prior to the application of a dressing (O'Grady 2011; Yamamoto 2002). Additional non-commercial options to secure the AC include sterile or non-sterile tape in addition to a dressing. Sutureless securement devices (SSDs) have become available commercially and are used in conjunction with transparent dressings. Other dressings that incorporate a securement component are designed to avoid the need for separate securement devices, sutures or tape by combining a BPU-style dressing on the skin with an additional adhesive securement affixed to the catheter (e.g. SorbaView® SHIELD, Centurion). The use of tissue adhesive has also been reported to provide additional securement to SPU/BPU dressings (e.g. Histoacryl, B Braun) (Edwards 2014; Reynolds 2015).

How the intervention might work

AC dressings and securement products have different but overlapping roles. The role of the AC dressing incorporates the prevention of antimicrobial colonisation and CR-BSIs by providing a protective barrier to stop skin flora from migrating from the insertion site down the catheter tract, while also preventing contamination of the catheter due to contact with hands and materials (O'Grady 2011; Timsit 2011). Sutures, tapes and securement devices are designed to ensure that ACs are neither partially nor completely dislodged, to avoid losing functionality. Effective securement should prevent movement within or out of the artery (known as pistoning) by restricting movement or pressure on the external part of the device which may result in catheter failure and loss of blood pressure monitoring. It should also decrease the incidence of forced removal or 'drag' from the infusion tubing, and eliminate the risk of 'catching' on environmental structures (Durie 2002; Naimier 2004).

In summary, the ideal AC dressing or securement device, or a combination of the two, should: remain secured to the skin and provide a protective barrier to prevent environmental microbial AC contamination, colonisation and CR-BSIs; provide effective securement to prevent AC failure from accidental removal, occlusion, dislodgement and micro-motion; be comfortable for the patient; be easy to use (apply and remove); and be cost effective.

Why it is important to do this review

Prevention of AC failure is a vital objective that prevents negative impact on patient morbidity and mortality. The comparative effectiveness of dressings and securement methods remains uncertain. There is no consensus on the optimal type of dressing or method of securement to use with ACs, and this may reflect the large number of products that are now available. Cochrane systematic reviews on the dressing and securement of both central venous catheters and peripheral venous catheters have been published (Gavin 2016; Marsh 2015; Ullman 2015). In contrast, the comparative effectiveness of dressings and securement methods designed for use with ACs is not well understood, with no published Cochrane systematic reviews and few reported studies investigating AC dressing and securement (Edwards 2014; Reynolds 2015; Stephenson 2005).

OBJECTIVES

To compare the effectiveness of dressings and securement devices for peripheral arterial catheters.

METHODS

Criteria for considering studies for this review

Types of studies

We will include published and unpublished randomised controlled trials (RCTs) that evaluate the effect of different dressings and securement methods on the protection and stabilisation of peripheral ACs. We will include controlled clinical trials (CCTs) if there is an absence of RCTs. CCTs refer to quasi-randomised studies in which an intervention and control are tested with concurrent enrolment and follow-up, but without strict randomisation (Lefebvre 2011). In order to minimise potential bias, we will include cross-over trials only if they report outcome data at the conclusion of the first treatment period, and will not include cluster-randomised trials (Reeves 2013).

Types of participants

We will include any studies in which participants of any age required a peripheral AC (in the arm, leg or head) in any healthcare setting. We will include all brands/types of peripheral AC. We will exclude participants who had ACs inserted through skin burns due to their predisposition to CR-BSIs and an altered skin surface that limits the adhesiveness of dressing and securement products.

Types of interventions

We will include any trial comparing any type of dressing or securement method with another type of dressing or securement method for the protection or stabilisation of an AC. We will consider dressings and devices that are made from any type of product (e.g. polyurethane, gauze).

Dressings

- Gauze and tape
- Transparent SPU or BPU dressings
- Antimicrobial dressings
- Hydrocolloid dressings

Securement products

- External SSDs
- Subcutaneous securement devices
- Combined dressing and securement products
- Tissue adhesive
- Sutures (stitches)

Types of outcome measures

Follow-up time for all outcomes will be until AC removal, with the exception of CR-BSIs, which will be followed-up for 48 hours post AC removal, as CR-BSIs occurring in this timeframe would be considered to result from AC management if there is no other source (Mermel 2009). We will record the duration of follow-up for all outcome data.

Primary outcomes

- AC failure where the catheter has been removed due to complications
- Incidence of CR-BSI, as defined by one of the following criteria:

1. Primary bloodstream infection (BSI) (recognised pathogen in the blood) with at least one positive blood culture from a peripheral vein and no other identifiable source for the BSI other than the intravascular device (IVD), as well as either a positive semiquantitative (> 15 colony-forming units (cfu)) or quantitative ($> 10^3$ cfu) device culture, with the same organism (species and antibiogram) isolated from the device and blood (Maki 2006; Mermel 2009; O'Grady 2002).
2. Two blood cultures for a suspected CR-BSI, with paired blood samples drawn from the catheter hub and a peripheral vein, that both meet CR-BSI criteria for quantitative blood cultures (three-fold greater colony count of growth for the same organism as from the peripheral blood) or differential time to positivity (growth of the same microbe from the catheter drawn blood at least two hours before growth from the peripheral blood) (Mermel 2009); and adverse events, including allergic reactions/skin injury related to the different types of dressings and securements, local entry site infection and phlebitis as described by the trial investigator.

Secondary outcomes

- Dislodgement: partial or total dislodgement of the AC body from the artery
- Occlusion, identified by inability to draw blood, infuse flush solution or maintain an accurate trace to monitor blood pressure
- Time to catheter failure
- Adverse events reported as number of participants in each group with an event
- Participant satisfaction at study completion, using any validated instrument (e.g. a visual analogue scale).

Search methods for identification of studies

Electronic searches

We will search the following databases to retrieve reports of relevant trials:

- the Cochrane Wounds Specialised Register (to date);
- the Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library (to latest issue);
- Ovid MEDLINE (including In-Process & Other Non-Indexed Citations, MEDLINE Daily and Epub Ahead of Print) (from 1946 onwards);
- Ovid Embase (from 1974 onwards);
- EBSCO CINAHL Plus (Cumulative Index to Nursing and Allied Health Literature Plus; from 1937 onwards).

We have devised a draft search strategy for CENTRAL which is displayed in [Appendix 2](#). We will adapt this strategy to search Ovid MEDLINE, Ovid Embase and EBSCO CINAHL Plus. We will combine the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity and precision-maximising version (2008 revision) ([Lefebvre 2011](#)). We will combine the Embase search with the Ovid Embase filter terms developed by the UK Cochrane Centre ([Lefebvre 2011](#)). We will combine the CINAHL Plus search with the randomised trials filter developed by the Scottish Intercollegiate Guidelines Network ([SIGN 2017](#)). There will be no restrictions with respect to language, study setting or date of publication.

We will also search the following clinical trials registries for ongoing and unpublished studies:

- ClinicalTrials.gov (www.clinicaltrials.gov);
- World Health Organisation International Clinical Trials Registry Platform (ICTRP) (www.who.int/trialsearch);
- ISRCTN registry (www.isrctn.com/);
- Hong Kong Clinical Trials Register (www.hkclinicaltrials.com);
- Indian Clinic Trials Registry (ctri.nic.in/Clinicaltrials/login.php).

Searching other resources

We aim to identify other potentially eligible trials or ancillary publications by searching the reference lists of retrieved included trials as well as relevant systematic reviews, meta-analyses and health technology assessment reports. We will also contact experts in the field and ask for information relevant to this review, and contact dressing and securement device manufacturers, such as 3M, Smith and Nephew, and Centurion, to access possible unpublished data so as to avoid publication bias.

Data collection and analysis

Selection of studies

Two review authors (HR and AU) will independently assess the titles and abstracts of the citations retrieved from the searches for relevance. Following an initial assessment, we will retrieve full-text versions of all the potentially eligible studies and the same review authors will continue independent review, checking these papers for eligibility. We will resolve discrepancies between the review authors by discussion. If differences of opinion can not be resolved by consensus, we will consult a third independent review author (EA). We will include a list of all studies including exclusions and reasons for exclusion, in the review in order to maintain a transparent approach, using a PRISMA flowchart ([Liberati 2009](#)). If studies have been reported in multiple publications, we will extract data from all the reports to ensure we capture all available and relevant data; however, we will include such studies only once in the review.

Data extraction and management

We will extract and summarise details from the eligible studies using a data extraction sheet. Two review authors (HR and AU) will perform independent data extraction using a predesigned checklist, followed by cross-checking for accuracy and agreement. We will resolve any discrepancies through discussion and arbitration by a third review author, as necessary. For any studies reported in duplicate publications, we will extract the maximum amount of data from all relevant publications. We will make attempts to contact the authors to retrieve any missing data. We will include RCTs that are reported only in abstract form provided the available data are sufficient for reasonable extraction from either the abstract or the study authors.

For studies with more than two intervention arms, we will extract only data from intervention and control groups that meet our eligibility criteria.

We intend to extract the following data:

- bibliographic data;

- participant characteristics including age, sex/gender, culture and socioeconomic status, and specified inclusion and exclusion criteria;
 - country of origin;
 - study dates;
 - setting;
 - type of AC;
 - type of dressing, securement device, or both;
 - unit of investigation (participant or dressing/securement intervention);
 - co-interventions;
 - trial design;
 - care setting;
 - number of participants randomised to each trial arm and number included in final analysis;
 - duration of treatment;
 - outcomes;
 - duration of follow-up;
 - number of withdrawals by group;
 - information regarding ethics approval, consent and declared conflicts of interest;
 - publication status; and
 - source of funding.

Assessment of risk of bias in included studies

Two review authors (HR and AU) will independently perform an assessment of quality and bias for each eligible study using the *Cochrane Handbook for Systematic Reviews of Interventions* 'Risk of bias' assessment tool (Appendix 3). We will assess seven specific domains, namely sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other issues that potentially may bias the study (Higgins 2011a). We will complete a 'Risk of bias' table for all eligible studies. Where information on risk of bias relates to unpublished data or correspondence with trialists, we will note this in the 'Risk of bias' table. We will perform separate assessments of blinding and completeness of outcome data for self-reported and objective outcome measures. We will resolve any differences or discrepancies between the review authors (HR and AU) through discussion. If consensus is not reached, we will consult a third independent review author (EA). We will present our findings and judgements in two 'Risk of bias' summary figures. One of the summary figures will be a summary of bias for each item across all studies; the second summary figure will show a cross tabulation of each study by all 'Risk of bias' items. This presentation of internal validity will indicate the weight that can be given to the results of each study. We anticipate that blinding of participants and clinical staff may not be possible in many of the comparisons; however, some blinded outcome assessments, such as CR-BSI, may still be possible.

Measures of treatment effect

We will calculate risk ratio (RR) for dichotomous outcomes and mean differences (MD) for continuous outcomes. Where final and change scores are reported for continuous outcomes, we will give the final score preference over change score. When outcomes are measured on ordinal scales, we will convert these to continuous data and analyse the data using standardised mean differences (SMD) (Anzueto-Cabrera 2011). We may encounter the use of different tools to measure the same outcome (e.g. skin damage). We will collect data only from studies that use a standard assessment tool, and will use the SMD as the summary statistic in any meta-analysis of such data. We will present treatment comparisons with 95% confidence intervals (CI). We will analyse time to event (e.g. time to the development of an occlusion). We will analyse time-to-event data as hazard ratios and we will calculate the hazard ratios where they are not reported, but calculable (Parmar 1998; Tierney 2007)

Unit of analysis issues

We do not anticipate any unit of analysis issues, expecting that the RCTs and CCTs included will have randomised participants and not ACs. For studies in which ACs and not participants have been randomised, we will include only the first AC per participant. We will include only those cross-over trials with outcome data reported at the conclusion of the first treatment period. We will not include cluster-randomised trials. In studies where two or more interventions are used in one treatment arm (e.g. tissue adhesive plus polyurethane dressing), we will analyse this as a combined intervention. If individuals undergo more than one intervention or there are multiple observations for the same outcome (e.g. repeated measurements and recurring events), we will contact the study authors for participant- and device-level data and then perform multilevel regression to calculate the adjusted effect. If additional data are unavailable we will exclude such studies from meta-analysis. In accordance with Higgins 2011b, for included studies that involve the comparison of multiple interventions using a single control, we will split the 'shared' control group to avoid additional unit of analysis issues. This is to distribute the appropriate study weight and maintain independent comparisons fairly. To prevent unit of analysis errors, participant satisfaction data will be included at the time of study completion only (i.e. not repeated observations). We will undertake time-to-event analyses for the outcome of catheter failure as hazard ratios.

Dealing with missing data

The existence of missing data may be due to the exclusion of participants from analysis post-randomisation or participants lost to follow-up. This potentially introduces bias into the trial. When the evidence shows that data are missing, we will make every attempt to contact the study authors to request the missing information. If

the required data are not supplied after multiple attempts, we will analyse only the available data. Where measures of variance are missing, we will calculate these where possible (Higgins 2011a). If we are not able to calculate measures of variance, we will document this, but exclude from the meta-analysis. We will consider the impact of the missing data on the findings of the review in the discussion. If there are sufficient data, we will investigate the impact of missing data using a sensitivity analysis, excluding the studies with missing data to assess how this will affect the results.

Assessment of heterogeneity

We will undertake an assessment of comparability of the studies with regard to clinical, methodological and statistical heterogeneity prior to meta-analysis. We will visually inspect the meta-analytic model, and consider the Chi^2 and I^2 statistics in order to assess the likelihood that the variance across the studies is due to heterogeneity rather than chance (Higgins 2003). If we find significant heterogeneity using these criteria, we will explore heterogeneity through subgroup and sensitivity analyses (including and excluding outlying studies). An I^2 statistic of more than 50% may represent moderate heterogeneity, and a value of 0 to 40% may suggest that heterogeneity is not important (Kontopantelis 2012; Kontopantelis 2013; Ryan 2016). If the level of these statistics cannot be improved through subgroup or sensitivity analyses, with the P value of the Chi^2 test being less than 0.1 or the I^2 statistic greater than 50%, we will consider not performing a meta-analysis (Higgins 2011a; Higgins 2011b). The importance of the observed value of the I^2 statistic depends on the magnitude and direction of effects and the strength of evidence for heterogeneity (e.g. the P value from the Chi^2 test, or a confidence interval for the I^2 statistic).

Assessment of reporting biases

We will use funnel plots to assess reporting bias using Review Manager 5 (RevMan 5) (Review Manager 2014) if sufficient studies (at least 10 RCTs) are included in a meta-analysis. We will visually inspect a funnel plot for asymmetry, and will test funnel plot asymmetry statistically using a linear regression test (Egger 1997). A P value of less than 0.1 could be an indication of publication bias or small study effects.

Data synthesis

We will combine details of included studies in a narrative review according to the type of comparator, possibly by location/type of wound and then by outcomes. We will consider the clinical and methodological heterogeneity and undertake pooling when studies appear appropriately similar in terms of wound type, intervention type, duration of follow-up and outcome type.

In terms of meta-analytical approach, we are unable to pre specify the amount of clinical, methodological and statistical heterogeneity in the included studies, but it might be extensive. Thus, we anticipate using a random-effects approach for meta-analysis. Conducting meta-analysis with a fixed-effect model in the presence of even minor heterogeneity may provide overly narrow confidence intervals. We will use a fixed-effect approach only when we assess clinical and methodological heterogeneity to be minimal, and the assumption that a single underlying treatment effect is being estimated holds. We will use the Chi^2 and I^2 statistics to quantify heterogeneity but we will not use them to guide the choice of model for meta-analysis. We will exercise caution when meta-analysed data are at risk of small study effects, because a random-effects model may be unsuitable. In this case, or where there are other reasons to question the selection of a fixed-effect or random-effects model, we will assess the impact of the approach using sensitivity analyses to compare results from the alternate models. We will report any evidence that suggests that the use of a particular model might not be robust. We may conduct meta-analyses even when we think there is extensive heterogeneity. We will attempt to explore the causes behind any heterogeneity using meta-regression, if possible (Thompson 1999).

We will present data using forest plots, where possible. For dichotomous outcomes we will present summary estimates as risk ratio (RR) with 95% confidence intervals (CIs). Where continuous outcomes are measured in the same way across studies, we plan to present pooled mean difference (MDs) with 95% CIs; we plan to pool standardised mean difference (SMD) estimates where studies measure the same outcome using different methods. For time-to-event data, we plan to plot (and, if appropriate, pool) estimates of hazard ratios and 95% CIs as presented in the study reports using the generic inverse variance method in RevMan (Review Manager 2014). Where time to healing is analysed as a continuous measure but it is not clear whether all wounds healed, we will document the use of the outcome in the study but we will not summarise data and not subject it to meta-analysis.

We will obtain pooled estimates of treatment effects using RevMan (Review Manager 2014).

'Summary of findings' tables

We will present the main results of the review in 'Summary of findings' tables. These tables present key information concerning the quality, clinical importance and context of the evidence, the magnitude of the effects of the interventions examined and the sum of available data for the main outcomes (Schünemann 2011a). 'Summary of findings' tables also include an overall grading of the evidence relating to each of the main outcomes using the GRADE approach. This approach defines the quality of a body of evidence regarding the extent to which one can be confident that an estimate of effect or association is close to the true quantity of specific interest. The quality of a body of evidence 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 will present the following outcomes in the 'Summary of findings' tables:

- AC failure
- incidence of CR-BSI
- adverse events

Subgroup analysis and investigation of heterogeneity

We will assess heterogeneity across the subgroups listed below and conduct subgroup analyses to investigate differences between the subgroups. We will perform a standard test for heterogeneity across subgroup results rather than across individual study results. We will use a fixed-effect inverse-variance weighted average approach for meta-analysis, which is equivalent to the test described by Deeks 2001. We will also compute the I^2 statistic for subgroup differences:

- adult participants versus paediatric participants versus neonatal participants;
- AC dwelling (less than 48 hours versus 48 hours or longer): if participants require ACs for more than 48 hours, this suggests higher acuity, with increased needs for securing devices in relation to physical status (e.g. increased perspiration making dressing adhesion difficult); there also may be a greater infection risk over time;
- ACs inserted in the operating theatre as part of a surgical procedure versus those inserted in intensive care. Operating theatre-inserted ACs may be subject to different forces requiring different methods of securement to those inserted in an ICU (e.g. people undergoing surgery are initially immobile, are then transferred within the hospital and have ACs removed within 1

to 2 days, whereas those in the ICU remain immobile and usually require an AC for longer);

- winged versus non-winged AC designs. Some ACs have plastic tabs/wings extending from the sides of the catheter and this may impact on the effectiveness of securement method

Sensitivity analysis

We will test our protocol for the impact of the following study characteristics in sensitivity analyses:

- study size (less than or greater than 100 participants); small studies of less than 100 participants will be removed to assess the contribution to overall effect size.
- studies classified as having 'high' risk of selection bias, reported as 'high' bias within either randomisation or allocation concealment, will be removed to assess the influence on the results;
- missing data, with consideration of best (all missing cases failed in control group and not failed in intervention group) and worst (all missing cases failed in intervention group and not failed in control group) case scenarios;
- use of a fixed-effect versus a random-effects model.

Elements of this Methods section are modelled on the standard Cochrane Wounds Protocol Template.

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* Indicates the major publication for the study

APPENDICES

Appendix 1. Glossary of terms

Antimicrobial: destroying or inhibiting the growth of microorganisms.

Arterial catheter: a thin flexible plastic tube that is inserted into an artery for easy access to the bloodstream for medical uses.

Arterial thrombosis: blood clot that forms in an artery.

Axillary artery: a major artery of the upper arm.

Brachial artery: a major artery of the upper arm.

Central venous catheter: a long, thin, flexible tube used to give medicines, fluids, nutrients, or blood products inserted in the arm or chest into a large vein for use in critical care or for long term therapy.

Distal digits: fingers, thumbs and toes.

Dorsalis pedis artery: the artery which provides the main blood supply to the foot.

Femoral artery: a major artery of the thigh.

Occlusion: blockage of a blood vessel or device.

Peripheral: distal parts of the limbs where venous and arterial catheters may be inserted.

Microorganisms: small living organisms such as bacteria, fungi and viruses that are only visible under a microscope.

Radial artery: the main artery in the lateral aspect of the forearm.

Securement: a device to keep intravascular catheters in place, preventing accidental removal.

Vascular: relating to blood vessels.

Venous catheter: a thin flexible plastic tube that is inserted into a vein for therapy such as medications and fluids.

Appendix 2. The Cochrane Central Register of Controlled Trials (CENTRAL) draft search strategy

#1 MeSH descriptor: [Catheterization, Peripheral] explode all trees

#2 MeSH descriptor: [Catheters] explode all trees

#3 (arteri* near/3 catheter*):ti,ab,kw

#4 (arteri* next line*):ti,ab,kw

#5 (vascular next access next device*):ti,ab,kw

#6 (vascular near/3 catheter*):ti,ab,kw

#7 (“vascular access”):ti,ab,kw

#8 {or #1-#7}

#9 MeSH descriptor: [Bandages] explode all trees

#10 MeSH descriptor: [Hydrogels] explode all trees

- #11 MeSH descriptor: [Alginates] explode all trees
- #12 MeSH descriptor: [Silver] explode all trees
- #13 MeSH descriptor: [Silver Sulfadiazine] explode all trees
- #14 MeSH descriptor: [Honey] explode all trees
- #15 MeSH descriptor: [Polyurethanes] explode all trees
- #16 MeSH descriptor: [Tissue Adhesives] explode all trees
- #17 MeSH descriptor: [Chlorhexidine] explode all trees
- #18 MeSH descriptor: [Sutures] explode all trees
- #19 (dressing* or hydrocolloid* or alginate* or hydrogel* or “foam” or “bead” or “film” or “films” or tulle or gauze or non-adherent or “non adherent” or silver or honey or matrix):ti,ab,kw
- #20 (securement next device*):ti,ab,kw
- #21 (securement next method*):ti,ab,kw
- #22 ((standard or border*) near/2 (polyurethane*)):ti,ab,kw
- #23 (chlorhexidine or CHG) near/4 dressing*:ti,ab,kw
- #24 (SSD or SPU or BPU or CGI):ti,ab,kw
- #25 (Tegaderm or Opsite or Statlock or “Grip-Lok” or Histacryl or “I.V. Advanced” or SorbaView or Centurion or BIOPATCH):ti,ab,kw
- #26 ((tissue* or skin) next (adhesive* or glue)):ti,ab,kw
- #27 ((suture* or stitch* or closure or close or closing*) near/3 (securement*)):ti,ab,kw
- #28 {or #9-#27}
- #29 {and #8, #28} in Trials

Appendix 3. Assessment of risk of bias

1. Was the 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

Insufficient information about the sequence generation process provided to permit a judgement of low or high risk of bias.

2. Was the 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, web-based and pharmacy-controlled randomisation); sequentially numbered drug containers of identical appearance; 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: use of an open random allocation schedule (e.g. a list of random numbers); assignment envelopes used without appropriate safeguards (e.g. envelopes were unsealed, non-opaque or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure.

Unclear

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

3. Blinding - was knowledge of the allocated interventions adequately prevented during the study?

Low risk of bias

Any one of the following.

- No blinding, but the review authors judge that the outcome and the outcome measurement were not likely to have been influenced by lack of blinding.
- Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others was unlikely to introduce bias.

High risk of bias

Any one of the following.

- No blinding or incomplete blinding, and the outcome or outcome measurement was likely to have been influenced by lack of blinding.
- Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken and the outcome or outcome measurement was likely to have been influenced by lack of blinding.
- Either participants or some key study personnel were not blinded, and the non-blinding was likely to introduce bias.

Unclear

Either of the following.

- Insufficient information provided to permit a judgement of low or high risk of bias.
- The study did not address this outcome.

4. Were incomplete outcome data adequately addressed?

Low risk of bias

Any one of the following.

- No missing outcome data.
- Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias).
- Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
- For dichotomous 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.
- 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.
- Missing data have been imputed using appropriate methods.

High risk of bias

Any one of the following.

- Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk was enough to induce clinically relevant bias in intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes was enough to induce clinically relevant bias in observed effect size.
- 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation.
- Potentially inappropriate application of simple imputation.

Unclear

Either of the following.

- Insufficient reporting of attrition/exclusions to permit a judgement of low or high risk of bias (e.g. number randomised not stated, no reasons for missing data provided).
- The study did not address this outcome.

5. Are reports of the study free of suggestion of selective outcome reporting?

Low risk of bias

Either of the following.

- The study protocol is available and all of the study's prespecified (primary and secondary) outcomes that are of interest in the review have been reported in the prespecified way.
- The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were prespecified (convincing text of this nature may be uncommon).

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 are reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not prespecified.
- One or more reported primary outcomes of the study 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

Insufficient information provided to permit judgement of low or high risk of bias. It is likely that the majority of studies will fall into this category.

6. Other sources of potential bias

Low risk of bias

The study appears to be free of other sources of bias.

High risk of bias

There is at least one important additional risk of bias. For example, the study:

- had a potential source of bias related to the specific study design used; or
- has been claimed to have been fraudulent; or
- had some other problem.

Unclear

There may be a risk of bias, but there is either:

- insufficient information to assess whether an important risk of bias exists; or
- insufficient rationale or evidence that an identified problem will introduce bias.

CONTRIBUTIONS OF AUTHORS

Heather Reynolds: conceived the review question, developed the protocol, coordinated the protocol development, completed the first draft of the protocol, contributed to writing or editing the protocol, made an intellectual contribution to the protocol, approved the final version prior to submission and is guarantor of the protocol.

Amanda Ullman: contributed to writing or editing the protocol, made an intellectual contribution to the protocol and approved the final version prior to submission.

Martin Culwick: contributed to writing or editing the protocol, made an intellectual contribution to the protocol and approved the final version prior to submission.

Gabor Mihala: contributed to writing or editing the protocol, made an intellectual contribution to the protocol and approved the final version prior to submission.

Evan Alexandrou: contributed to writing or editing the protocol, made an intellectual contribution to the protocol and approved the final version prior to submission.

Jessica Schults: contributed to editing the protocol and approved the final version of the protocol prior to submission.

Claire Rickard: conceived the review question, contributed to writing or editing the protocol, made an intellectual contribution to the protocol, advised on the protocol and approved the final version prior to submission.

Contributions of the Editorial Base

Gill Norman (Editor): edited the protocol, advised on methodology, interpretation and protocol content, and approved the final protocol prior to submission.

Gill Rizzello (Managing Editor): coordinated the editorial process, advised on content and edited the protocol.

Reetu Child and Naomi Shaw (Information Specialists): designed the search strategy and edited the search methods section.

Zipporah Ihezor-Ejiofor (Methodologist): advised on methodology.

Ursula Gonthier (Editorial Assistant): edited the reference section.

DECLARATIONS OF INTEREST

Heather Reynolds: none known.

Amanda Ullman: is a Board Member of the Association for Vascular Access Foundation. She is an academic researcher and her employer (Griffith University) has received grants from government and not-for-profit bodies as well as unrestricted research/educational grants-in-aid and consultancy payments for conference attendance, lectures and expert opinion from manufacturers/distributors of intravenous dressings, vascular access devices and add-on equipment (3M, Adhezion, Angiodynamics, Bard, Baxter, BBraun, Becton Dickinson, Carefusion, Centurion Medical Products, Covalon, FloMedical and Teleflex). The manufacturer companies did not undertake study design, procedures, data analysis or preparation of results for publication on any of her projects.

Martin Culwick: is employed by, and receives travel, accommodation and meeting expenses from, Queensland Health and the Australian and New Zealand College of Anaesthetists. He also performs unpaid work for the University of Queensland. He has received meeting and travel expenses as an invited speaker at an educational meeting conducted by Merck Sharp & Dohme (Australia) Pty. The presentation did not involve promotion of any particular product. He holds shares in CSL Australia Pty Ltd in a superannuation portfolio. He acts as a medical expert witness for Avant Ltd, which is an Australian medical indemnity insurance company.

Gabor Mihala: none known.

Evan Alexandrou: has undertaken product review for BBraun and provided education services for Carefusion Australia, Teleflex Australia and USA, Cook Medical Australia, 3M Australia, Becton and Dickinson Australia and Flo Medical Australia, as well as receiving unrestricted research grants-in-aid from Becton and Dickinson USA, 3M USA, Flo Medical Australia and Cook Medical Australia. All education has been generic and not related to or promoting specific products.

Jessica Schults: none known.

Claire Rickard: is a Board Member of the Intensive Care Foundation. She is an academic researcher and her employer has received grants from government and not-for-profit bodies as well as unrestricted research/educational grants-in-aid and consultancy payments for conference attendance, lectures and expert opinion from manufacturers/distributors of intravenous dressing/securements (3M, Adhezion, Becton Dickinson, Centurion Medical Products, Entrotech, Medtronic, ResQDevices and Teleflex). The manufacturer companies did not undertake study design, procedures, data analysis, have access to data, prepare results or have involvement in writing the manuscript for any of her publications.

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