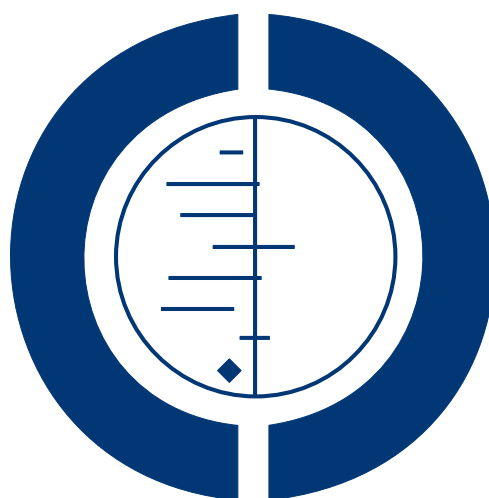# Dressings and securement devices for central venous catheters (CVC) (Protocol)

Ullman AJ, Cooke ML, Mitchell M, Lin F, New K, Long DA, Mihala G, Rickard CM

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TABLE OF CONTENTS

Dressings and securement devices for central venous catheters (CVC)

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To compare the available dressings and securement devices for CVCs, in terms of catheter-related bloodstream infection (CR-BSI), catheter colonisation, entry and exit site infection, skin colonisation, skin irritation, accidental catheter removal (complete or partial), dressing condition and mortality.

BACKGROUND

Description of the condition

Central venous catheters (CVCs) play an important role in the management of patients, serving as reliable vascular access and the site of venous pressure monitoring. They are inserted when a patient requires venous access over an extended period of time, and allow the intravenous administration of complex drug treatments, blood products and nutritional support without the trauma associated with repeated needle insertions (Webster 2011). Although mostly used in intensive-care units and oncology settings, CVCs are increasingly being used in other wards and outpatient settings.

There are multiple types of CVCs in use throughout clinical practice. A CVC can be designated by: its intended life span (e.g. temporary or short-term versus permanent or long-term); its site of insertion (e.g. subclavian, femoral, internal jugular or peripherally inserted central catheter (PICC)); its pathway from skin to vessel (e.g. tunnelled versus nominee); its physical length (e.g. long versus short) or some other special characteristic(s) (e.g. impregnation with heparin or number of lumens) (O'Grady 2011). More information regarding the variety of catheters used in clinical practice is included in Appendix 1.

Owing to the invasive procedure necessary for placing a CVC and the resulting break in the skin (integument), complications such as exit-site infections and bloodstream infections can develop (Han

2010). A serious complication of CVCs is catheter-related blood stream infections (CR-BSI), also known as 'catheter sepsis'. CR-BSI rates are influenced by patient-related factors, such as severity and type of illness (e.g. full-thickness burns versus post-cardiac surgery), by catheter-related factors (such as the condition under which the catheter was placed and catheter type), and by institutional factors (e.g. bed size, academic affiliation) (O'Grady 2011). Many studies have estimated the incidence of CR-BSI, generally reporting a range between 1 and 3.1 per 1000 patient days (Pronovost 2006; Schwebel 2012), but rates have been shown to decrease to zero after interventions (Han 2010). The attributable cost of CR-BSI varies between USD 3124 and USD60,536 per event (Raad 2007; Schwebel 2012), and is associated with an attributable mortality of 0% to 11.5% (Timsit 2011).

CVCs are foreign objects, and, as such, require their external component both to be protected adequately from microbial contamination from the surrounding environment and secured to the skin. Dressings and securements must ensure CVCs do not dislodge or fall out (or both), or move within or out of the great veins. This can occur via movement or pressure on the external component of the device, through forced removal, or 'drag' from infusion tubing or 'catching' on environmental structures (Naimer 2004). Movement of the CVC to a location outside the target placement can result in line failure or cardiovascular instability. In critical situations line failure (e.g. the interruption of inotropic support during cardiogenic shock) can have catastrophic consequences for the patient's morbidity and mortality.

Description of the intervention

There is a plethora of CVC dressings and securements from which clinicians may select. The earliest securement approach was simple tape or gauze-tape, with plastic film dressings becoming prominent in the 1980s. First-generation occlusive standard polyurethane (SPU) dressings were later developed to become semi-permeable to oxygen, carbon dioxide and water vapour (e.g. OpSite IV 3000®, Smith and Nephew; Tegaderm Plus®, 3M), as occlusive dressings trap moisture on the skin and provide an ideal environment for quick growth of local microflora (Frasca 2010). Each dressing is transparent, permitting continuous visual inspection of the catheter site. A recent approach to CVC securement is the bordered polyurethane (BPU) dressing that retains the central polyurethane component of SPU dressings with an added external adhesive border of foam or cloth fabric to maximise catheter security (e.g. Tegaderm Advanced®, 3M).

The majority of CR-BSI are caused by micro-organisms found in the patient's own commensal skin flora, such as *Staphylococcus epidermidis* and *Staphylococcus aureus* (Timsit 2011); consequently, we have seen the arrival of medication-impregnated dressings in recent years. The most common of these are the chlorhexidine gluconate-impregnated (CGI) dressings. These CGI dressings release chlorhexidine-gluconate on the cutaneous underlying surface when placed over the catheter insertion site (Arvaniti 2012). Chlorhexidine gluconate is a cationic biquanide that provides rapid antisepsis because of its broad spectrum of germicidal activity against most CR-BSI-causing pathogens (Garland 2001). The chlorhexidine gluconate impregnates the whole dressing, or is applied using an impregnated sponge (e.g. Biopatch®) and covered by a transparent polyurethane dressing. Other medication-impregnated dressings discussed in the literature include silver-impregnated and iodine-impregnated dressings (Wille 1989). The iodine-impregnated dressings release free iodine when exposed to wound exudate, while the silver-impregnated dressings expose the entrance site to silver ions, which are thought to have antimicrobial properties. Some researchers recommend the use of hydrocolloidal dressings for the dressing of CVCs. This type is traditionally used on open wound sites to promote moist healing as, as the hydrocolloid matrix absorbs excess moisture away from the skin surface, it reduces the likelihood of microbial growth (Nikoletti 1999).

Securement of the CVC is also facilitated by mechanisms other than dressings. Traditionally, CVCs were routinely sutured in place, prior to a dressing being applied (O'Grady 2011). In addition to this option, clinicians frequently reinforced the device security using non-commercial options including sterile strips or non-sterile tape. Recently, sutureless securement devices (SSD) have become available commercially. These are used in addition to transparent dressings, and use a large adhesive footplate and an underlying pad with an device-locking clasp (e.g. Statlock®, Bard). These, theoretically, reduce movement, kinking and flow impedance, maximising catheter stabilisation (Yamamoto 2002). Each of these CVC dressing and securement types has different therapeutic goals and is readily available for clinicians and patients to purchase from numerous suppliers. The diversity of dressings and securements available to clinicians (including variation within each of the types discussed above) makes evidence-based decision-making difficult in this area. With the availability of increasingly sophisticated and expensive CVC dressings and securements, practitioners need to know how effective these dressings are compared with more traditional dressings.

How the intervention might work

The ideal CVC dressing should:
1. provide a barrier protection from colonisation and infection, preventing CR-BSI;
2. provide adequate securement to prevent accidental removal, partial dislodgement and micro-motion, preventing CVC failure;
3. be comfortable and non-irritating for the patient;
4. be easy to use; and
5. be cost-effective.

Several studies have reported the effectiveness of interventions to reduce CR-BSI rates, including maximal sterile precautions during insertion, skin antisepsis, securement devices and antimicro-

bial coatings (Levy 2005; Han 2010; Timsit 2011). The role of the CVC dressing in preventing CR-BSI is to provide a barrier protection, thereby preventing migration of skin organisms at the insertion site into the cutaneous catheter tract - and subsequent colonisation of the catheter tip - and preventing direct contamination of the catheter by contact with hands and other materials (O'Grady 2011).

Why it is important to do this review

Decreasing the incidence of CR-BSI and preventing CVC failure are important objectives with a significant impact on patient morbidity and mortality, yet there is no consensus on the optimal dressing type to use with CVCs, despite more than two decades of research and debate. The recent Cochrane review "Gauze and tape and polyurethane dressings for CVC" focused on only two product types (Webster 2011), and, therefore, does not adequately address the variety of products now available in the clinical environment. A large variety of dressings and types of securement are currently available for use with CVCs, as well as reports from many research studies that used different outcomes and comparisons.

O B J E C T I V E S

To compare the available dressings and securement devices for CVCs, in terms of catheter-related bloodstream infection (CR-BSI), catheter colonisation, entry and exit site infection, skin colonisation, skin irritation, accidental catheter removal (complete or partial), dressing condition and mortality.

M E T H O D S

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs) that have evaluated the effects of CVC dressings and securements for their impact on CR-BSI, catheter colonisation, entry and exit site infection, skin colonisation, skin irritation, catheter security, dressing condition or mortality, irrespective of publication status or language. We will include controlled clinical trials (CCTs) only in the absence of RCTs. CCTs refer to quasi-randomised studies where, although the trial involves testing an intervention and control, with concurrent enrolment and follow-up of test and control-treated groups, the method of allocation is not considered to be strictly random (Lefebvre 2011). Cross-over and cluster-randomised trials will not be included.

Types of participants

Any participant requiring a CVC in any healthcare or community setting. Age will not be an excluding factor. All CVCs will be included, i.e. short- and long-term CVCs, tunnelled and non-tunnelled, port-a-caths, haemodialysis catheters, and peripherally-inserted central catheters (PICCs).

Types of interventions

Trials comparing any CVC dressings or securements including (but not limited to):

Dressings

- Gauze and tape.
- Standard polyurethane (SPU) dressings.
- Bordered polyurethane (BPU) dressings.
- Chlorhexidine gluconate-impregnated (CGI) dressings.
- Other medication-impregnated dressings.
- Hydrocolloid dressings.
- No dressing.

Securements

- Sutureless securement devices (SSD).

Types of outcome measures

Primary outcomes

- Incidence of catheter-related blood stream infection (BSI): as defined by one of the following three criteria:

    i) Primary bacteraemia/fungaemia with at least one positive blood culture from a peripheral vein with no other identifiable source for the BSI other than the intravascular device (IVD), plus, one of: 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 (O'Grady 2002; Maki 2006).

    ii) Two blood cultures (one from an IVD hub and one from a peripheral vein), that both meet the 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 (DTP) (growth of the same microbe from hub drawn blood at least two hours before growth from the peripheral blood).

    iii) Two quantitative blood cultures of samples obtained through two catheter lumens in which the colony count for the blood sample drawn through one lumen is at least three-fold greater than the colony count for the blood sample from the second lumen (Mermel 2009).

Secondary outcomes

- Frequency of CR-BSI per 1000 patient days: CR-BSI as previously defined.
- Incidence of catheter tip colonisation: positive semi-quantitative (> 15 cfu/catheter segment) or quantitative (> 10^3 cfu/catheter segment) culture from a proximal or distal catheter segment (O'Grady 2002).
- Incidence of entry and exit site infection: as described by the trial investigator.
- Incidence of skin/site colonisation: positive semi-quantitative (> 15 cfu) or quantitative (>10^3 cfu) culture from the skin around the catheter site (O'Grady 2002).
- Incidence of skin irritation or damage: as described by the study investigator using a formal assessment tool.
- Incidence of failed catheter securement: frequency of accidental or forced removal or dislocation resulting in CVC failure.
- Dressing condition/durability: incidence or mean score using a formal assessment tool.
- Mortality from any cause.

We will construct a summary of findings table using Grade-PRO to display the main overall results of the primary outcome (Schunemann 2011), including relative effects and quality of the evidence.

Search methods for identification of studies

Electronic searches

We will search the following electronic databases to identify reports of relevant randomised clinical trials:

- The Cochrane Wounds Group Specialised Register;
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*) (Latest issue);
- Ovid MEDLINE (1946 to present);
- Ovid EMBASE (1974 to present);
- EBSCO CINAHL (1982 to present)

We will use the following provisional search strategy in The Cochrane Central Register of Controlled Trials (CENTRAL):

#1 MeSH descriptor: [Catheterization, Central Venous] explode all trees
#2 (venous near/3 (catheter* or line*)):ti,ab,kw
#3 (central near/3 (catheter* or line*)):ti,ab,kw
#4 (hickman next catheter*):ti,ab,kw
#5 (broviac next catheter*):ti,ab,kw
#6 (cook next catheter*):ti,ab,kw
#7 MeSH descriptor: [Catheters, Indwelling] explode all trees
#8 ("implantable vascular access device" or IAVD or PortACath):ti,ab,kw
#9 ("peripherally inserted central catheter" or PICC):ti,ab,kw

#10 (h*emodialysis next catheter*):ti,ab,kw
#11 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10
#12 MeSH descriptor: [Occlusive Dressings] explode all trees
#13 MeSH descriptor: [Bandages, Hydrocolloid] explode all trees
#14 MeSH descriptor: [Silver] explode all trees
#15 MeSH descriptor: [Silver Sulfadiazine] explode all trees
#16 MeSH descriptor: [Polyurethanes] explode all trees
#17 MeSH descriptor: [Iodine] explode all trees
#18 MeSH descriptor: [Chlorhexidine] explode all trees
#19 ((occlusive* or hydrocolloid* or silver* or polyurethane* or permeable or nonpermeable or non-permeable or transparent or chlorhexidine or iodine* or gauze or tape) near/3 (dressing* or sponge*)):ti,ab,kw
#20 #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19
#21 #11 and #20

We will adapt this strategy to search Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL. 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 developed by the UK Cochrane Centre (Lefebvre 2011). We will combine the CINAHL searches with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN 2012). We will not restrict studies with respect to language, date of publication or study setting.

We will also search the following clinical trial registers:

- Clinical Trial www.clinicaltrial.gov;
- Current Controlled Trials www.controlled-trials.com/mrct;
- Hong Kong clinical trials register www.hkclinicaltrials.com;
- Indian clinical trials registry www.ctri.in;
- UK Clinical Trials Gateway www.controlled-trials.com/ukctr/ and,
- the World Health Organization (WHO) search portal www.who.int/trialsearch.

Searching other resources

We will handsearch bibliographies of all retrieved and relevant publications identified by these strategies for further relevant studies. We will contact experts in the field to ask for information relevant to this review. We will also contact dressing and securement device manufacturers, including companies such as 3M, and Smith and Nephew, for possible unpublished data in order to counteract publication bias.

Data collection and analysis

Selection of studies

Independently, two review authors (AU and MM) will assess titles and abstracts of retrieved studies for relevance. After this initial assessment, full versions of all potentially eligible studies will be retrieved. Independently, the same two review authors will then check the full papers for eligibility. Discrepancies between reviewers will be resolved through discussion and, where required, a third independent review author (CR) will be consulted. A list of all studies, including excluded studies and reasons for their exclusion will be published for transparency using the PRISMA flowchart (Liberati 2009).

Data extraction and management

Details from eligible studies will be extracted and summarised using a data extraction sheet. Due to the large number of studies it is predicted will be included in this review, teams of two review authors will review specific interventions including: CGI dressing studies, gauze studies, SSD studies, paediatric and neonatal studies, and remaining studies. These teams will extract data independently and then cross check them for accuracy and agreement. Any discrepancies will be resolved though discussion and arbitration by a third review author, if necessary. For studies that have been published in duplicate, we will extract maximal data from all relevant publications, but we will not duplicate data in analyses. If there are any data missing from the papers, then attempts will be made to contact the authors to retrieve the missing information. A data extraction sheet will be used to extract summary data from each trial. The data extraction sheet will contain baseline characteristics of the study, including control group participants: their number; age; gender; disease; treatment; type of CVC; number of catheter lumens; time in situ (dwell time) of the CVC, dressing and/or securement; number of dressing changes during the dwell time of the CVC; known allergies to dressings; skin complexion; known history of, or current, positive blood cultures; and healthcare setting in which the intervention occurred. We will list each trial's criteria for patient inclusion and exclusion, a description of the intervention(s), the number of patients randomised to each intervention and primary and secondary outcome measures.

Assessment of risk of bias in included studies

Each eligible study will be independently assessed for quality and bias using the Cochrane Collaboration 'Risk of bias assessment tool'. This tool addresses six specific domains, namely, sequence generation, allocation and concealment, blinding, incomplete outcome data, selective outcome reporting, and other issues that potentially may bias the study (Higgins 2011a). A 'Risk of bias' table will be completed for each eligible study. A separate assessment of blinding and completeness of outcome data will be conducted for each outcome. Discrepancies between reviewers will be resolved through discussion. Findings will be presented using the 'Risk of bias' summary figure that will present all judgements in a cross-tabulation of study by entry.

Measures of treatment effect

Our primary analysis will involve pair-wise comparisons of treatment effect between dressing and securement types, using all the described outcomes. For dichotomous outcomes, we will calculate risk ratio (RR) plus 95% confidence intervals (CI). For continuous outcomes, we will calculate mean difference (MD) plus 95% CIs. For outcomes best presented as a rate per time period, we will use hazard ratios (HR) and standard errors (SE) to inform inverse-variance analysis. In addition, some of our secondary outcomes may be measured using ordinal scales. For simplicity, we will assume that these are continuous, and analyse data with the standardised mean difference (SMD). It is also possible that different tools may be used to measure the same outcome (e.g. skin damage). We will collect data only from those studies that used a formalised assessment tool. We will use the SMD as the summary statistic in any meta-analysis of such data.

In addition to the main pair-wise analysis described above, in order to inform clinical decision-making we will undertake pair-wise comparisons using the 'clustering' of interventions on the basis of patient treatment goals and outcomes. This will involve comparison of:

CR-BSI

- Medication-impregnated dressings (CGI, povidone-iodine and silver-impregnated) versus non-impregnated dressings (SPU, BPU, gauze and tape, hydrocolloidal).
- CGI-impregnated dressings versus all other medication-impregnated dressings (povidone-iodine, silver).
- Silver-impregnated dressings versus all other medication-impregnated dressings (povidone-iodine, CGI).
- Povidine-iodine impregnated dressings versus all other medication-impregnated dressings.
- Gauze and tape versus SPU and BPU.

Incidence of skin irritation or damage

- Hydrocolloidal dressing versus all other.
- Gauze and tape versus SPU and BPU.
- CGI-impregnated versus SPU and BPU.

Failed catheter securement

- BPU versus all non-bordered dressings (SPU, hydrocolloidal).
- SSD versus all other dressing types.
- No dressing versus all other dressing types.

These clustering comparisons will be done because of the heterogeneity of populations that use CVCs, and the way their goals for treatment differ. In order to minimise bias, these clustering

comparisons have been identified prior to undertaking the analyses. Additionally, at the conclusion of the review we will consider undertaking a 'multiple-treatments meta-analysis' in order to summarise the results further, and so to assist clinicians in making meaningful-decisions (Salanti 2008; Higgins 2011b).

Unit of analysis issues

We do not anticipate any unit of analysis issues. It is expected that the RCTs/CCTs will randomise participants and not their CVCs. For studies where CVCs are randomised, rather than participants, we will only include the first CVC per participant. Cross-over and cluster-randomised trials will not be included.

Dealing with missing data

If there is evidence of missing data, attempts will be made to contact the study authors to request the missing information. If, after several attempts to contact the author, the missing data have not been provided, we will analyse the available data only. We will also address the potential impact of the missing data on the findings of the review in the discussion.

Assessment of heterogeneity

We will consider clinical, methodological and statistical heterogeneity and will undertake an assessment of comparability of the studies prior to meta-analysis. We will investigate the degree of statistical of heterogeneity, that is, variation between the true intervention effects underlying the different studies, by a combination of methods. This will involve visual inspection of the meta-analytic model and interpretation of the Chi^2 and I^2 statistics that examine the total variance across studies due to heterogeneity rather than chance (Higgins 2003). If significant levels of heterogeneity are identified using these criteria, we will explore the heterogeneity through subgroup analyses and a sensitivity analysis (with and without the exclusion of outlying studies), and, if a Chi^2 P value of less than 0.10 remains, and an I^2 of greater than 50% (Higgins 2011a), we will consider not undertaking a meta-analysis.

Assessment of reporting biases

We will report each outcome separately. We will use funnel plots to assess reporting biases, if sufficient studies are included in the review. We will undertake an observation of small-study effects if required.

Data synthesis

Initially we will conduct a structured narrative summary of the studies included in the review. We will enter quantitative data into RevMan 5.1 and analyse them using RevMan analysis software. If appropriate, data will be pooled for meta-analysis using RevMan 5.1. We will use a random-effects model because of the predicted clinical heterogeneity.

Subgroup analysis and investigation of heterogeneity

If sufficient data are available we will undertake the following subgroup analysis for the primary outcomes:
- Adult participants versus paediatric participants versus neonatal participants.
- Participants diagnosed with haematology/oncology conditions versus other participants.
- CVC type (tunnelled versus non-tunnelled, short-term versus long-term, dialysis versus non-dialysis, PICC versus centrally-inserted CVC).
- Participants receiving the intervention in an acute versus a community setting.
- Participants receiving lipid and parenteral nutrition (PN) versus patients not receiving lipid and PN.

Sensitivity analysis

We will perform a sensitivity analysis by excluding studies as indicated by the results of the final meta-analysis. This will probably involve the exclusion of the studies of the lowest quality. In this sensitivity analysis, we will only include studies that are assessed as having a low risk of bias in all key domains, namely adequate generation of the randomisation sequence, adequate allocation concealment, and blinding of outcome assessor, for the estimates of treatment effect.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Types of central venous catheters (CVCs) used

Catheter type	Entry site	Length
Non-tunnelled central venous catheters	Percutaneously inserted into central veins (subclavian, internal jugular or femoral)	≥ 8 cm depending on patient size
Peripherally inserted central venous catheters (PICC)	Inserted into basilic, cephalic or brachial veins and enter the superior vena cava	≥ 20 cm depending on patient size
Tunneled central venous catheters	Implanted into subclavian, internal jugular, or femoral veins	≥ 8 cm depending on patient size
Totally implantable	Tunnelled beneath skin and have subcutaneous port accessed with a needle; implanted in subclavian or internal jugular vein	≥ 8 cm depending on patient size

O'Grady 2011 p 22

≥ = greater than or equal to

WHAT'S NEW

Date	Event	Description
24 February 2015	Amended	Contact details updated.

HISTORY

Protocol first published: Issue 2, 2013

Date	Event	Description
13 November 2013	Amended	Acknowledgement added to the funders

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No declarations of interests to state.

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