Gauze and tape and transparent polyurethane dressings for central venous catheters

Author
Webster, Joan, Gillies, Donna, O' Riordan, Elizabeth, Sherriff, Karen, Rickard, Claire

Published
2011

Journal Title
Cochrane Database of Systematic Reviews

DOI
https://doi.org/10.1002/14651858.CD003827.pub2

Copyright Statement
Copyright 2011 The Cochrane Collaboration. Published by JohnWiley & Sons, Ltd. This review is published as a Cochrane Review in the Cochrane Database of Systematic Reviews 2011, Issue 11. Cochrane Reviews are regularly updated as new evidence emerges and in response to comments and criticisms, and the Cochrane Database of Systematic Reviews should be consulted for the most recent version of the Review.

Downloaded from
http://hdl.handle.net/10072/44254
Gauze and tape and transparent polyurethane dressings for central venous catheters (Review)

Webster J, Gillies D, O’Riordan E, Sherriff KL, Rickard CM

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in The Cochrane Library 2011, Issue 11

http://www.thecochranelibrary.com
# Table of Contents

- **Header** ................................................................. 1
- **Abstract** ............................................................... 1
- **Plain Language Summary** ........................................... 2
- **Summary of Findings for the Main Comparison** .................... 2
- **Background** ............................................................. 5
- **Objectives** ............................................................. 5
- **Methods** .................................................................. 5
- **Results** ................................................................. 7
- **Discussion** .............................................................. 9
- **Authors' Conclusions** ................................................ 10
- **Acknowledgements** ................................................... 11
- **References** ............................................................. 11
- **Characteristics of Studies** ............................................ 13
- **Data and Analyses** ................................................... 25
  - Analysis 1.1. Comparison 1 Transparent polyurethane dressings versus gauze and tape, Outcome 1 Catheter-related bloodstream infection. ................................................................. 25
  - Analysis 1.2. Comparison 1 Transparent polyurethane dressings versus gauze and tape, Outcome 2 Exit-site infection. ................................................................. 26
  - Analysis 1.3. Comparison 1 Transparent polyurethane dressings versus gauze and tape, Outcome 3 Skin/site colonisation. ................................................................. 26
  - Analysis 1.4. Comparison 1 Transparent polyurethane dressings versus gauze and tape, Outcome 4 Positive catheter culture. ................................................................. 27
  - Analysis 1.5. Comparison 1 Transparent polyurethane dressings versus gauze and tape, Outcome 5 Tunnel infection. ................................................................. 27
  - Analysis 2.1. Comparison 2 Transparent polyurethane dressings versus transparent polyurethane dressings, Outcome 1 Catheter-related bloodstream infection. ................................................................. 28
- **Appendices** ............................................................. 28
- **What's New** ............................................................ 33
- **History** ................................................................. 33
- **Contributions of Authors** ........................................... 34
- **Declarations of Interest** ............................................. 34
- **Sources of Support** .................................................. 34
- **Index Terms** .......................................................... 35

---

Gauze and tape and transparent polyurethane dressings for central venous catheters (Review)

Copyright © 2011 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
Gauze and tape and transparent polyurethane dressings for central venous catheters

Joan Webster1, 4, 5, Donna Gillies2, Elizabeth O’Riordan3, Karen L Sherriff4, Claire M Rickard4

1Centre for Clinical Nursing, Royal Brisbane and Women’s Hospital, Brisbane, Australia. 2Sydney West Area Mental Health Service, Parramatta, Australia. 3Faculty of Nursing and Midwifery, The University of Sydney and The Children’s Hospital at Westmead, Sydney, Australia. 4NHMRC Centre of Research Excellence in Nursing, Griffith University, Brisbane, Australia. 5School of Nursing & Midwifery, University of Queensland, Brisbane, Australia

Contact address: Joan Webster, joan_webster@health.qld.gov.au.

Editorial group: Cochrane Wounds Group.

Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 11, 2011.

Review content assessed as up-to-date: 9 May 2011.


Copyright © 2011 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

ABSTRACT

Background

Central venous catheters (CVCs) facilitate venous access, allowing the intravenous administration of complex drug treatments, blood products and nutritional support, without the trauma associated with repeated venepuncture. However, CVCs are associated with a risk of infection. Some studies have indicated that the type of dressing used with them may affect the risk of infection. Gauze and tape, transparent polyurethane film dressings such as Tegaderm® and Opsite®, and highly vapour-permeable transparent polyurethane film dressings such as Opsite IV3000®, are the most common types of dressing used to secure CVCs. Currently, it is not clear which type of dressing is the most appropriate.

Objectives

To compare gauze and tape with transparent polyurethane CVC dressing in terms of catheter-related infection, catheter security, tolerance to dressing material and dressing condition in hospitalised adults and children.

Search methods

For this third update, we searched The Cochrane Wounds Group Specialised Register (10 May 2011); The Cochrane Central Register of Controlled Trials (CENTRAL; The Cochrane Library 2011, Issue 2), Ovid MEDLINE (1950 to April Week 4 2011); Ovid MEDLINE (In-Process & Other Non-Indexed Citations, May 11, 2011); Ovid EMBASE (1980 to 2011 Week 18); and EBSCO CINAHL (1982 to 6 May 2011).

Selection criteria

All randomised controlled trials (RCTs) evaluating the effects of dressing type (e.g. gauze and tape versus transparent polyurethane dressings) on CVC-related infection, catheter security, tolerance to dressing material and dressing condition in hospitalised patients.

Data collection and analysis

Two review authors independently assessed trial quality and extracted data. We contacted study authors for missing information.
Main results

Six studies were included in earlier versions of the review. In this update two of the previously included papers have been excluded and two new trials have been added. Of these six trials, four compared gauze and tape with transparent polyurethane dressings (total participants = 337) and two compared different transparent polyurethane dressings (total participants = 126). Catheter-related bloodstream infection was higher in the transparent polyurethane group when compared with gauze and tape; OR 4.19 (95%CI 1.02 to 17.23) however these small trials were at risk of bias so this evidence is graded low quality. There was no evidence of a difference between highly permeable polyurethane dressings and other polyurethane dressings in the prevention of catheter-related bloodstream infection (low quality evidence). No other significant differences were found.

Authors’ conclusions

We found a four-fold increase in the rate of catheter related bloodstream infection when a polyurethane dressing was used to secure the central venous catheter however this research was at risk of bias and the confidence intervals were wide indicating high uncertainty around this estimate; so the true effect could be as small as 2% or as high as 17-fold. More, better quality research is needed regarding the relative effects of gauze and tape versus polyurethane dressings for central venous catheter sites.

Plain Language Summary

Different dressings used to protect the central venous catheter site with the aim of reducing the chance of developing a catheter-related infection

A central venous catheter is a small tube inserted into a major vein to allow medications and other fluids to be ‘dripped’ into the body over time without repeated injections. It is used in preference to a peripheral catheter (e.g. in the hand or arm) when access is required for long periods of time, or when the fluids being administered are damaging to the tissues. However, because central catheters are open to large veins they are associated with a risk of blood infection. Several different kinds of dressing are used for protecting the central venous catheter site, including transparent polyurethane dressings, and gauze and tape. These dressings may vary in their durability, ease of use, ability to prevent infections and skin reactions. We reviewed all relevant medical trials to identify any differences between dressings, particularly with respect to differences in infection rates. We found that there were fewer catheter-related infections in the group using gauze and tape but the evidence was low quality and larger, better quality studies are needed to confirm these findings.
### Summary of Findings for the Main Comparison

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter-related bloodstream infection (CRBI)</td>
<td>Study population</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>Transpar-ent polyurethane dress-ings or gauze and tape</td>
<td>OR 4.19 (1.02 to 17.23)</td>
<td>337 (4 studies)</td>
<td>⊕⊕⃝⃝ low¹-²</td>
</tr>
<tr>
<td></td>
<td>12 per 1000</td>
<td>47 per 1000 (12 to 169)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td></td>
<td>9 per 1000</td>
<td>37 per 1000 (9 to 135)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exit-site infection</td>
<td></td>
<td>Study population</td>
<td>OR 1.78 (0.62 to 5.08)</td>
<td>265 (3 studies)</td>
</tr>
<tr>
<td></td>
<td>Laboratory testing</td>
<td></td>
<td>45 per 1000</td>
<td>78 per 1000 (28 to 194)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td></td>
<td>38 per 1000</td>
<td>66 per 1000 (24 to 167)</td>
<td></td>
</tr>
</tbody>
</table>

**Explanation**

- **Patient or population:** patients with central venous catheters
- **Settings:** Hospital
- **Intervention:** transparent polyurethane dressings or gauze and tape

### Outcomes

- **Catheter-related bloodstream infection (CRBI):**
  - Same organism recovered from catheter tip and blood culture
  - Assumed risk: 12 per 1000
  - Corresponding risk: 47 per 1000 (12 to 169)
  - Relative risk: OR 4.19 (1.02 to 17.23)
  - No of Participants: 337 (4 studies)
  - Quality of the evidence: ⊕⊕⃝⃝ low¹-²

- **Exit-site infection:**
  - Laboratory testing
  - Assumed risk: 45 per 1000
  - Corresponding risk: 78 per 1000 (28 to 194)
  - Relative risk: OR 1.78 (0.62 to 5.08)
  - No of Participants: 265 (3 studies)
  - Quality of the evidence: ⊕⊕⃝⃝ low¹-³
## Positive catheter culture

### Laboratory testing

<table>
<thead>
<tr>
<th>Study population</th>
<th>OR 0.74 (0.27 to 2.09)</th>
<th>138 (2 studies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>139 per 1000</td>
<td>107 per 1000 (42 to 252)</td>
<td></td>
</tr>
<tr>
<td>135 per 1000</td>
<td>104 per 1000 (40 to 246)</td>
<td></td>
</tr>
</tbody>
</table>

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (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; **OR:** Odds ratio;

**GRADE Working Group grades of evidence**

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have a substantial impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** 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.

**Very low quality:** We are very uncertain about the estimate.

---

1 Allocation concealment was unclear in three of the four trials. It was also unclear in three of the four trials if outcome assessment was blinded. However, because this outcome involved laboratory analysis, it is likely that technicians were unaware of group allocation.

2 All of the trials were small with the largest enrolling only 101 participants. The event rate was comparatively low for CRBI with wide confidence intervals, indicating that the effect includes the possibility of higher or lower rates of CRBI.

3 Small sample size. Effect includes the possibility of higher or lower rates of exit site infection.

4 Small sample size. Effect includes the possibility of higher or lower rates of a positive catheter culture.
BACKGROUND

Central venous catheters (CVCs) are used increasingly within the hospital setting. The placement of a CVC in a central vein allows the intravenous administration of complex drug treatments, blood products and nutritional support without the trauma associated with repeated needle insertions (venepuncture). However, CVCs are associated with a higher incidence of bloodstream infection than peripheral catheters (Maki 2000). Organisms from the patient’s skin are a major source of catheter-related infection, especially in the first one to two weeks following insertion (Mermel 2011).

Traditionally, the CVC site would be dressed with dry gauze and tape, but in the early 1980s these gave way to transparent polyurethane dressings, notably OpSite® (Smith & Nephew Healthcare Ltd), Tegaderm® (3M) and, more recently, Opsite IV3000® (Smith & Nephew Healthcare Ltd). There are substantial differences between different transparent polyurethane dressings, including size, permeability and weight (Thomas 1988), and possible clinical advantages of increased durability, improved security of the catheter, visibility of the wound site, and provision of an effective barrier to micro-organisms. As some dressings may be more conducive to the growth of micro-organisms on the skin, the type of dressing applied to the catheter insertion site may influence the incidence of catheter-related infections (Callahan 1987; Maki 1992; Schwartz-Fulton 1981; Trieston-Aurand 1997). There is concern that transparent polyurethane dressings increase skin surface humidity, which may result in increased bacterial colonisation of the site, and therefore, an increased risk of catheter-related infection (Conly 1989; Dickerson 1989; Wille 1993). Therefore, dressings such as Opsite IV3000—a highly vapour permeable transparent polyurethane dressing (Wille 1993) — that increases the rate of evaporation of fluid from the CVC site may decrease the risk of infection.

Despite the possible risks associated with CVC dressings, there appear to be no clear recommendations regarding their suitability. The recommendations for the prevention of intravascular device-related infections published by the US Centers for Disease Control and Prevention direct to: “Use either sterile gauze or sterile, transparent, semipermeable dressings to cover the catheter site” (O’Grady 2011). Before embarking on the first edition of this review we searched the Cochrane Database of Systematic Reviews (CDSR) and the Database of Abstracts of Reviews of Effectiveness (DARE) to identify pre-existing reviews. No Cochrane review addressing CVC dressings was found, but a meta-analysis that compared the effects of dressing types for peripheral and central catheters was identified from DARE (Hoffmann 1992). This meta-analysis reported that the risk of catheter tip colonisation (but not catheter-related bloodstream infection) was significantly increased with transparent CVC dressings compared with gauze and tape. However, this analysis of seven studies included two studies with an additional intervention in one dressing group only (Andersen 1986; Powell 1982); one study that allocated patients on the basis of where they were nursed (not randomly) (Young 1988); and one study where the data were not from a patient sample (Conly 1989). Therefore, several factors in this meta-analysis could have biased its results. Furthermore, several new studies on this topic have been published since the Hoffmann 1992 review went to press (the search date for this review went up to mid 1991), and these data needed to be evaluated.

The lack of clear evidence regarding the most appropriate dressing for CVCs established the need to undertake this systematic review. This review was undertaken to determine whether there was any difference between gauze and tape and transparent polyurethane dressings in relation to CVC-related infection, catheter security, tolerance to dressing material and dressing condition.

OBJECTIVES

To compare gauze and tape with transparent polyurethane dressings for central venous catheters, in terms of catheter-related infection, catheter security, tolerance to dressing material and dressing condition.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials (RCTs) comparing the effects of gauze and tape with transparent polyurethane dressings, or comparing different transparent polyurethane dressings on CVC or skin colonisation, catheter-related bacteraemia (presence of bacteria in the blood), local or tunnel (following the route of the catheter) infection, catheter security, tolerance to dressing material and dressing condition in hospitalised patients. Studies with more than 50% loss to follow-up were excluded. Whilst we did not state explicitly in our protocol that studies where comparison arms had different co-interventions would be excluded, this was how we interpreted the protocol. We also excluded trials where the central line was peripherally inserted.

Types of participants

Patients, of any age, in the hospital setting, with CVCs in situ.

Types of interventions

Studies which compared gauze and tape CVC dressings with transparent polyurethane CVC dressings, or compare different transparent polyurethane CVC dressings.
Types of outcome measures

Primary outcomes

- Incidence of catheter-related bloodstream infection: isolate of the same organism from a semi-quantitative or quantitative culture of a catheter segment and from separate percutaneous blood cultures, with no other identifiable source of infection.
- Incidence of positive catheter cultures: any positive semi-quantitative or quantitative culture from a proximal or distal catheter segment.
- Incidence of skin/site colonisation (mean number of colony-forming units): any positive semi-quantitative or quantitative culture from the skin around the catheter site.

As these outcomes are measured by methods that have accepted validity and reliability these data will be collected from included studies even where reliability and validity were not shown.

Secondary outcomes

- Incidence of exit-site infection.
- Incidence of tunnel infection.
- Incidence of catheter security.
- Incidence of skin irritation.
- Dressing condition/durability (incidence or mean score).

Data for these outcomes were only collected from included studies if the measures used were shown to be valid and reliable. Any measure that had only face validity and had not been tested for reliability by methods such as inter-rater agreement was not considered to be valid and reliable.

Search methods for identification of studies

For the search methods used in the second update of this review see Appendix 1.

For this third update we searched the following electronic databases to find reports of relevant randomised controlled trials (RCTs):

- The Cochrane Wounds Group Specialised Register (searched 10 May 2011);
- The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2011, Issue 2);
- Ovid MEDLINE (1950 to April Week 4 2011);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations, May 11, 2011);
- Ovid EMBASE (1980 to 2011 Week 18);

We used the following 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*
#5 broviac NEXT catheter*
#6 cook NEXT catheter*
#7 (#1 OR #2 OR #3 OR #4 OR #5 OR #6)
#8 MeSH descriptor Occlusive Dressings explode all trees
#9 (occlusive or “gauze” or “tape” or polyurethane or permeable or non-permeable or non-permeable or transparent) NEAR/3 dressing*:ti,ab,kw
#10 (#8 OR #9)
#11 (#7 AND #10)

The search strategies for Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL can be found in Appendix 2; Appendix 3 and Appendix 4 respectively. The Ovid MEDLINE search was combined with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision) (Lefebvre 2011). The Ovid EMBASE and EBSCO CINAHL searches were combined with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN) (SIGN 2010). There were no restrictions with respect to language, date of publication or study setting.

Data collection and analysis

Selection of studies

Two review authors assessed all potentially relevant references for eligibility. Where necessary, we obtained abstracts of potentially relevant papers or full papers in order to assess further studies for inclusion. Where differences of opinion regarding eligibility occurred, they were resolved by discussion or by referral to a third member of the team.

Data extraction and management

Two members of the review group independently extracted data from each study. Differences of opinion were resolved either by consensus or by referral to a third member of the team. If data were missing from trial reports, we contacted study authors for additional information.

Data extracted included:

- Country and setting where the study was performed.
- Inclusion and exclusion criteria.
- Details of intervention.
- Outcomes measured.
- Duration of study.
- Numbers enrolled and completing in each group.
- Baseline characteristics of each group.
- Results per group.
Assessment of risk of bias in included studies

Two review authors independently assessed the quality of eligible trials (JW, KS) using the Cochrane Collaboration tool for assessing risk of bias (Higgins 2011). This tool addresses six specific domains, namely sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other issues which may potentially bias the study (see Appendix 5 for details on criteria on which the judgement was based). Blinding and completeness of outcome data were assessed for each outcome separately. A risk of bias table was completed for each eligible study. Disagreements between authors were resolved by consensus or referral to a third author. We attempted to contact investigators of included trials to resolve any ambiguities. Assessment of risk of bias is presented using a 'risk of bias summary figure', which presents all the judgements in a cross-tabulation of study by entry.

Measures of treatment effect

Event rates for binary outcomes (e.g., infection rates) are presented as odds ratios (OR) and 95% confidence intervals (CI). For continuous outcomes we calculated the difference in means with 95% confidence intervals (CI). Skewed data were not used. Skew could only be defined when a scale started from zero. If the standard deviation, multiplied by two, was greater than the mean then the distribution of data was deemed to be skewed (Altman 1996).

Assessment of heterogeneity

We tested for statistical heterogeneity by performing a chi-squared test ($\chi^2$). We assessed the extent of heterogeneity using the $I^2$ statistic (Deeks 2011). This examines the percentage of total variation across studies due to heterogeneity rather than to chance. Values of $I^2$ over 75% indicate a high level of heterogeneity. Where a high level of heterogeneity was found, a random-effects model was used for pooling. If the results of a random-effects analysis were substantially different from the fixed-effect analysis, the studies responsible for heterogeneity were not to be added to the main body of homogeneous trials, but were to be summarised and presented separately.

Assessment of reporting biases

Wherever possible, data from all included studies were to be entered into a funnel graph (trial effect against trial size) in an attempt to investigate the likelihood of overt publication bias (Egger 1997)

Subgroup analysis and investigation of heterogeneity

Planned sub-group analyses were:
- Adult and paediatric patients.
- Frequency of dressing changes.

Sensitivity analysis

Planned sensitivity analysis was based on concealment of allocation (allocation adequately concealed vs unclear / inadequate allocation concealment).

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

See: Characteristics of included studies and Characteristics of excluded studies for further details.

Of the 28 full papers and abstracts considered in previous versions of this review, six studies met the inclusion criteria and were included in the original review (Brandt 1996; Hägerström 1994a; Neufeld 1991; Petrosino 1988a; Shivnan 1991; Wille 1993). In this third update, 45 further references were screened, 41 of which were not relevant to this review. Two of the remaining four references were added to the review (de Barros 2009; Giles 2002), and two were excluded (Chico-Padron 2011; Olsøn 2008). We also excluded two of the trials included in previous versions of this review (Hägerström 1994a; Petrosino 1988a).

Included studies

Six trials, with a total of 463 participants, are included in this update. One trial was conducted in Spain (de Barros 2009), one in Turkey (Giles 2002), one in Canada (Neufeld 1991), one in the Netherlands (Wille 1993) and two in the USA (Brandt 1996; Shivnan 1991). Three acknowledged industry sponsorship (Neufeld 1991; Shivnan 1991; Wille 1993). Participants were either oncology patients (Brandt 1996; Shivnan 1991) renal patients (de Barros 2009); or general surgical patients (Giles 2002; Neufeld 1991; Wille 1993).

Two comparisons were reported in the included studies. These were gauze and tape compared with transparent polyurethane dressings (de Barros 2009; Brandt 1996; Giles 2002; Shivnan 1991) and one transparent polyurethane dressing compared with another transparent polyurethane dressing (Neufeld 1991; Wille 1993).

All the included studies reported patient data for at least one of the primary outcomes of this review (de Barros 2009; Brandt 1996; Giles 2002; Neufeld 1991; Shivnan 1991; Wille 1993), and three studies reported secondary outcomes (Brandt 1996; Neufeld 1991; Shivnan 1991). The data for dressing changes from the study by Neufeld 1991, however, were skewed and so were not added to the meta-analysis, therefore, data for secondary outcomes were available from two included studies.
Data from four of the six included studies could be pooled: Brandt 1996, de Barros 2009; Giles 2002 and Shivnan 1991 all reported data for catheter-related bloodstream infection when gauze and tape dressings were compared with transparent polyurethane dressings; catheter tip data from the de Barros 2009 and Giles 2002 trials were also pooled.

**Excluded studies**

In an earlier version of this review 22 papers and abstracts from 18 trials were excluded. In summary: three trials were not RCTs (Reynolds 1987; Wheeler 1988; Young 1988); four had a co-intervention other than the dressing type in one group only (Andersen 1986; Little 1998; Nehme 1984; Powell 1982); one used gauze in both groups (Lawson 1986); it was not possible to assess whether five studies met the eligibility criteria for this review (Dickerson 1989; Freiberger 1992; Maki 1992; Ricard 1985; Thomas 1977); two trials had not assessed the validity of their outcome measurement tools (Berggren 1995; Keenlyside 1992); two trials did not report their results by group (Conly 1989; Maki 1984); four references were either duplicate publications or later versions of the same trial (Keenlyside 1993; McCredie 1984; Powell 1984; Powell 1985), and one trial was not conducted in a hospital setting (Le Corre 2003).

For this third update, two trials identified by the new search were excluded: one because the central lines were inserted peripherally (Chico-Padron 2011), and the other, because instruments used to measure outcomes had not been assessed for validity and reliability (Olson 2008). In addition, two of the trials from earlier versions of this review were also excluded. One because it was unclear if it was a RCT (Hägerström 1994); and the other because the only outcome of interest was ‘infection’ but it was unclear what type of infection this was. Infection was defined as a composite of a number of infection indicators (such as redness, elevated temperature, erythema, pain and skin culture), ranked according to importance (Petrosino 1988).

**Risk of bias in included studies**

**Allocation**

**Sequence generation**

Only two of the six trials described an adequate method for sequence generation (Giles 2002; Shivnan 1991).

**Allocation concealment**

An adequate method of allocation concealment was reported in only one trial (de Barros 2009).

**Blinding**

**Blinding of personnel and participants**

This was not possible in trials where gauze and tape were compared with transparent polyurethane dressings (de Barros 2009; Brandt 1996; Giles 2002; Shivnan 1991). Blinding of personnel and participants was not mentioned where one transparent polyurethane dressing was compared with another transparent polyurethane dressing (Neufeld 1991; Wille 1993).

**Incomplete outcome data**

All of the included studies reported the number of patients lost to follow-up, which ranged from 0 to 40%. Four trials were graded as having a low risk of reporting bias (Brandt 1996; de Barros 2009; Giles 2002; Wille 1993). Some participants in three of these trials were excluded from the analysis following randomisation and data were analysed on an ‘as-treated’ basis by the original trialists (Brandt 1996; Giles 2002; Wille 1993). The nature of reporting in one study made it unclear whether all participants had been included in the analyses (Shivnan 1991). For the remaining trial (Neufeld 1991) reporting of data was incomplete, these studies were assessed as having a high risk of reporting bias.

**Selective reporting**

All trials provided information for all of the outcome measures pre-specified in the paper (protocols were not accessed for any of the studies). None of our primary outcome measures were reported in all reports. Catheter-related bloodstream infection was reported by Brandt 1996; de Barros 2009; Giles 2002; Shivnan 1991 and Wille 1993; catheter tip colonisation by de Barros 2009 and Giles 2002; and skin colonisation by Giles 2002; Neufeld 1991 and Shivnan 1991.

**Other potential sources of bias**

It was difficult to determine if there were ‘unit of analysis’ issues in two trials where dressings, rather than participants, were randomised (Giles 2002; Neufeld 1991). In one trial of highly vulnerable oncology patients, a range of antibiotics was administered during the study period but it was unclear if antibiotic use was evenly distributed between treatment groups (Shivnan 1991). Finally, half of the trials received partial or full manufacturer sponsorship (Neufeld 1991; Shivnan 1991; Wille 1993).
Effects of interventions

See: Summary of findings for the main comparison transparent polyurethane dressings or gauze and tape for central venous catheters

Transparent polyurethane dressings compared with gauze and tape (Analysis 01) (Summary of findings table 1)

Five outcomes were included for this comparison:
Catheter-related bloodstream infection was reported in four studies with a combined total of 337 participants (Brandt 1996; de Barros 2009; Giles 2002; Shivnan 1991). In the de Barros 2009 trial, only data for methicillin-resistant Staphylococcus aureus (MRSA) was included in this outcome. Information presented in the table for other organisms was difficult to interpret. All trials with data favoured gauze and tape and, when data were combined, there were significantly fewer infections in the gauze and tape group (p = 0.05); (transparent polyurethane dressing 9/165 and gauze and tape 2/172) (OR 4.19; 95% CI 1.02 to 17.23) Analysis 1.1

Three trials (265 participants) provided data for exit site infection (Brandt 1996; de Barros 2009; Shivnan 1991). Although fewer participants in the gauze and tape group developed an exit site infection (6/133) compared with the transparent polyurethane group (10/132), the difference was not statistically significant (OR 1.78; 95% CI 0.62 to 5.08) (Analysis 1.2).

One study of 72 participants assessed skin/site colonisation (Giles 2002; Analysis 1.3); there was no statistically significant difference between groups (transparent polyurethane dressing 2/33 and gauze and tape 1/39); OR 0.58; 95% CI 0.05 to 6.68.

Both de Barros 2009 and Giles 2002 (138 participants) reported on the incidence of positive catheter cultures (Analysis 1.4). There was no statistically significant difference between groups on this measure (transparent polyurethane dressing 7/66 and gauze and tape 10/72) (OR 0.74; 95% CI 0.27 to 2.09).

A total of 101 participants were assessed for tunnel infection in the (Brandt 1996) trial. The number of infections was similar between groups (transparent polyurethane dressing 3/48 and gauze and tape 5/53) (OR 0.64; 95% CI 0.14 to 2.83) (Analysis 1.5).

The small number of included studies precluded the proposed subgroup analyses for adult and paediatric patients and frequency of dressing changes. Nor did we consider it necessary to conduct a sensitivity analysis. Only one investigator (de Barros 2009) reported information about allocation concealment; results for this trial were consistent with results from other trials (heterogeneity I2 between 0% to 2%).

Transparent polyurethane dressings compared with other transparent polyurethane dressings (Analysis 02)

Wille 1993 was the only investigator to report rates of catheter-related bloodstream infection for this comparison. The incidence of catheter-related bloodstream infection was similar when one transparent polyurethane dressings (Opsite) (3/50) was compared with another transparent polyurethane dressings (Opsite 3000) (1/51) (OR 0.31; 95% CI 0.03 to 3.12) Analysis 2.1.

No site colonisation occupied in either group when one transparent polyurethane dressings (Opsite) was compared with a different transparent polyurethane dressing (Opsite 3000) (OR not estimable). All data for this analysis came from the study by Neufeld 1991 which had a total sample size of 25. Although it was proposed that data from all included studies were to be entered into a funnel graph (trial effect against trial size) in an attempt to investigate the likelihood of overt publication bias (Egger 1997), this was not possible due to the small number of included studies.

Discussion

Summary of main results

This systematic review compared gauze and tape with any type of polyurethane dressing designed to secure a central venous catheter. Outcomes analysed were catheter-related bloodstream infection, catheter colonisation, skin/site colonisation, exit site infection and tunnel infection. Despite the relatively high number of studies identified as relevant to this review, few could be included. The major reasons for exclusion were the number of studies without adequate information, and studies where there was an intervention - apart from dressing type - that could have accounted for any differences between groups.

We found a four-fold increase in the rate of catheter related blood stream infection when a polyurethane dressing was used to secure the central venous catheter. However, the confidence intervals were wide, indicating high uncertainty around this estimate; the true effect could be as small as 2% or as high as 17-fold. More research is needed to reduce the uncertainty around the size of the difference. Rates of catheter-related blood steam infections (between 0% and 6%) were similar to those reported in prior research (Maki 2006), irrespective of the type of product used.

There have been suggestions that highly vapour permeable transparent polyurethane dressing may be superior to other types of transparent dressings (Wille 1993). However, a complete lack of heterogeneity in our analyses indicates that, at this stage, there is no evidence of difference between these types of dressings for the prevention of catheter-related blood stream infection.

In terms of other primary outcomes, it is impossible to draw any conclusions about the effectiveness of each of the dressing types from the included studies. This is because data for each of the analyses came from a limited number of studies, the largest of which reported data from 101 participants. Therefore, all of the

Copyright © 2011 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
included studies were underpowered to detect clinically important differences, should they exist. In particular, the sample sizes in the individual studies would have been too small to identify any difference in the incidence of catheter-related bloodstream infection, as statistically significant. Given the incidence of approximately 3.3% of catheter-related bloodstream infection in this review, data from approximately 2260 patients would be required to show a halving in the incidence of catheter-related bloodstream infection, and much larger numbers required to show a smaller effect size.

Overall completeness and applicability of evidence
Most of the trials included in this systematic review addressed the review's most important outcome, catheter-related bloodstream infection, albeit with very small samples. Other outcomes of clinical interest, however, such as exit site infection, positive catheter cultures, skin reaction and catheter security were poorly reported, and many could not be extracted for this review.

In terms of applicability of evidence, although the participants were drawn from oncology, haematology and general surgical cohorts, intensive care patients - who are high users of central lines - were not represented in any of the trials included in the review. In addition, all outcomes were underpowered for demonstration of differences between groups, so support for external validity is low.

Quality of the evidence
Risk of bias was difficult to assess in most of the studies due to poor reporting. Only one trial supplied sufficient information for us to judge allocation concealment (de Barros 2009), and it was unclear in most of the trials whether those assessing the outcome were blinded to intervention group. It was not possible to blind the participants or personnel to the gauze and tape intervention as dressings were dissimilar. In one trial (Shivnan 1991), more patients in the gauze group than the polyurethane group received prophylactic vancomycin when the catheter was inserted, which may have had an impact on results. Other issues involved inability to confirm evidence from authors. The Summary of findings for the main comparison therefore identifies that the evidence for the effects of these alternative dressings on catheter-related bloodstream infection, exit-site infection and positive catheter culture, is low quality. Finally, half of the trials received partial or full manufacturer sponsorship. It was not clear in these trials whether any publication restrictions had been placed upon authors.

Potential biases in the review process
Clearly described procedures were followed to prevent potential bias in the review process. A careful literature search was conducted and the methods we used are transparent and reproducible. None of the authors has any conflict of interest.

Agreement or disagreement with other studies or reviews
In their review of eight controlled clinical trials examining interventions for preventing infectious complications in haemodialysis patients with CVCs, McCann 2010 found no difference in exit site infection or catheter-related bacteraemia when polyurethane dressings were compared with gauze dressings. By contrast, Hoffmann 1992 found that use of transparent dressings to secure CVCs was associated with a higher risk of catheter tip infection (risk ratio (RR) 1.38; 95% CI 1.69 to 2.95). She also found a non-significantly higher rate of catheter-related bloodstream infection and bacteraemia in the polyurethane group. Nonetheless, the Hoffmann review was not limited to RCTs, and included data from letters, abstracts and other reports (Hoffmann 1992).

AUTHORS' CONCLUSIONS
Implications for practice
The review found that gauze and tape as a dressing to secure central venous catheters was associated with lower rates of catheter-related bloodstream infection than transparent polyurethane dressings. However, individual studies included in the review were small and at risk of bias. We found no evidence of effect for either gauze and tape or polyurethane dressings in the prevention of any of the other outcomes included in this review.

Implications for research
Information about important factors such as cost, patient and clinician preference, and ease of use were not available for assessment in this review. These factors may influence choice of dressing, especially, where differences in clinical outcomes are small or unable to be demonstrated. Future primary research of CVC dressings should continue to measure catheter-related bloodstream infection and exit site infection, but should also include a formal, planned economic analysis, as well as an assessment of patient preference. Information about whether or not catheters are cuffed, and the location of catheter insertion are important, and should be included in future trials. In addition, other clinical data should be collected using standardised measures to facilitate comparisons and the application of evidence. Finally, the role of other dressings and technologies currently used to secure CVCs requires exploration. The quality of most of the evidence in this review was low and the trials were poorly reported. Following the CONSORT guidelines would add significantly to the usefulness of future trials (Schulz 2010).
ACKNOWLEDGEMENTS

The review authors would like to thank: Cochrane Review Wounds Group referees (Marie Westwood, Finn Gottrup, Karen Cowley, Madeleine Flanagan, Allyson Lipp), Editors (Nicky Cul lum, Andrea Nelson, Mieke Flour), and Statistical Advisor (Vicky Ashton) for their comments to improve the review, and Elizabeth Royle for copy editing the most recent update.

The authors would also like to acknowledge the contribution of D Carr, J Frost, R Gunning and I O’Brien who were review authors and contributed to the original review and subsequent updates, they are no longer active authors of this review.

REFERENCES

References to studies included in this review

Brandt 1996 [published data only]

de Barros 2009 [published data only]

Giles 2002 [published data only]

Neufeld 1991 [unpublished data only]

Shivman 1991 [published data only]

Wille 1993 [published data only]

References to studies excluded from this review

Andersen 1986 [published and unpublished data]

Berggren 1995 [published data only]

Chico-Padrón 2011 [published data only]

Conly 1989 [published data only]

Dickerson 1989 [published data only]

Freiburger 1992 [published data only]

Hägerström 1994 [published data only]
Keenlyside 1992 [published data only]

Keenlyside 1993 [published data only]

Lawson 1986 [published data only]

Le Corre 2003 [published data only]

Little 1998 [published data only]

Maki 1984 [published data only]

Maki 1992 [published data only]

McCreddie 1984 [published data only]

Nehme 1984 [published data only]

Olson 2008 [published data only]

Petrosino 1988 [published data only]

Powell 1982 [published data only]

Powell 1984 [published data only]

Powell 1985 [published data only]

Reynolds 1987 [published data only]

Ricard 1985 [published data only]

Thomas 1977 [published data only]

Wheeler 1988 [published data only]

Young 1988 [published data only]

Additional references
Altman 1996

Callahan 1987

Deeks 2011
CHARACTERISTICS OF STUDIES

Characteristics of included studies  (ordered by study ID)

Brandt 1996

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT of gauze and tape vs highly-permeable transparent polyurethane dressing (Opsite IV3000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Included: 101 patients at least 18 years old; having a tunneled CVC inserted after admission for an autologous BMT. BMT unit of a regional oncology centre, USA. Excluded: patients who had catheter-related bloodstream infection within 14 days of study entry or patients with short term CVCs Time in study: approximately 22 days.</td>
</tr>
<tr>
<td>Interventions</td>
<td>Group 1: gauze and tape (daily change); Group 2: Opsite IV3000 (weekly change).</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Catheter-related bloodstream infection, exit site infection, tunnel infection</td>
</tr>
<tr>
<td>Notes</td>
<td></td>
</tr>
</tbody>
</table>

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>&quot;subjects randomly were assigned to one of the following CVC dressing protocols: ...” Comment: randomisation procedure not reported.</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Not reported. Comment: it was unclear from the study report if allocation was concealed</td>
</tr>
<tr>
<td>Blinding (performance bias and detection bias) All outcomes</td>
<td>High risk</td>
<td>Evidence for participants: not stated. Comment: not possible due to the nature of the intervention (two dressings with different appearances) Evidence for personnel: not stated. Comment: not possible due to the nature of the intervention (two dressings with different appearances)</td>
</tr>
<tr>
<td>Blinding (performance bias and detection bias) All outcomes</td>
<td>Unclear risk</td>
<td>Evidence for outcomes: nursing staff obtained cultures; &quot;investigators recorded the organisms isolated in all cultures obtained while patients remained on study” Comment: it was unclear from the study report if the outcome assessor was blinded</td>
</tr>
</tbody>
</table>
### Incomplete outcome data (attrition bias)

| All outcomes | Low risk | “Four patients (two Gauze and tape, two Opsite IV3000) with histories of pre-BMT skin sensitivity (e.g., secondary to drug rash, radiation skin reaction, abrasion) required an alternative dressing early after accrual and were taken off study.” Comment: Four participants (2 from each group who had skin reactions to the trial product) were removed from the study after randomisation. Analysis was per-protocol rather than intention to treat (ITT). We subsequently conducted an ITT analysis, and results remained essentially the same |

### Selective reporting (reporting bias)

| Low risk | All of the paper’s pre-specified outcomes were reported (protocol not accessed) |

### Other bias

| High risk | More frequent dressings than specified in protocol in Opsite IV3000 group; 2 additional dressing changes in the Opsite IV3000 group in week one (21%), and in week two (31%). Additional dressing changes in dry sterile gauze dressing group n = 15 “The high incidence of subjects in the experimental dressing protocol requiring more frequent dressing changes than specified in the protocol limits the conclusions about exclusive effect of the assigned dressing on the development of CVC infection” |

---

### de Barros 2009

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT of gauze and tape vs transparent polyurethane dressing (Tegaderm IV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Included: 66 patients with end-stage renal disease, undergoing haemodialysis (33 in each group), in dialysis unit in a hospital in Sao Paulo, Brazil Excluded: patients with acute renal failure undergoing femoral venous catheterization</td>
</tr>
<tr>
<td>Interventions</td>
<td>Group 1: sterile gauze and micropore changed each dialysis session Group 2: sterile transparent film 8.5 cm x 10.5 cm (Tegaderm IV) changed every 7 days, or as needed Both groups: catheter insertion site disinfected with 10% alcoholic povidone-iodine solution</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Catheter-related bloodstream infection, positive catheter culture, exit site infection</td>
</tr>
</tbody>
</table>
In the outcomes table, we have assumed that ‘infection’ is exit site infection. Bacteraemia and catheter tip infection were listed separately and exit site infection was one of the defined study outcomes. Attempts to clarify this point with the study author were unsuccessful.

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Random sequence generation (selection bias)</strong></td>
<td>Unclear risk</td>
<td>&quot;A random list of dressings was used to divide 66 patients in two groups (33 in group 1 and 33 in group 2)&quot;. Comment: it was unclear from the study report what method had been used to generate the randomisation sequence</td>
</tr>
</tbody>
</table>
| **Allocation concealment (selection bias)**  | Low risk           | "The sequences of dressings were kept in a locked envelope. If the patient was eligible for the study, the envelope containing dressing sequences was open and the following indicated intervention was performed:"
| **Blinding (performance bias and detection bias)** | High risk          | Evidence for participants: not stated. Comment: not possible due to the nature of the intervention (two dressings with different appearances) Evidence for personnel: not stated. Comment: not possible due to the nature of the intervention (two dressings with different appearances) |
| **Blinding (performance bias and detection bias)** All outcomes | Unclear risk       | Evidence for outcomes: not stated. Comment: it was unclear from the study report if the outcome assessor was blinded |
| **Incomplete outcome data (attrition bias)** All outcomes | Low risk           | "There were no losses to follow up." Comment: attrition and missing data reported as nil. ITT analysis can be assumed |
| **Selective reporting (reporting bias)** All outcomes | Low risk           | All of the paper’s pre-specified outcomes were reported (protocol not accessed) |
| **Other bias** All outcomes | Low risk           | No other potential threats to validity identified |
Methods

RCT of gauze and tape vs transparent polyurethane dressing (brand not disclosed)

Participants

Included: 70 patients undergoing surgical procedures for various benign or malignant gastrointestinal disorders
Excluded: not stated.

Interventions

Group 1: sterile gauze and tape changed every day and the insertion site cleaned with 10% povidone-iodine solution
Group 2: sterile, transparent occlusive dressing. Catheter site inspected daily but dressing not changed for 7 days unless there were signs of local inflammation
Both groups: catheter insertion site disinfected with 10% povidone-iodine solution

Outcomes

Catheter-related bloodstream infection, positive skin culture, positive tip culture

Notes

At the start of the study, 70 patients with 72 CVCs were included - possible ‘unit of analysis’ issue

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>“...catheter insertion site care was done following two different methods according to the number patient on the random table”</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>“according to the number patient on the random table”. Comment: possibly not concealed.</td>
</tr>
<tr>
<td>Blinding (performance bias and detection bias)</td>
<td>High risk</td>
<td>Evidence for participants: not stated. Comment: not possible due to the nature of the intervention (two dressings with different appearances) Evidence for personnel: not stated. Comment: not possible due to the nature of the intervention (two dressings with different appearances)</td>
</tr>
<tr>
<td>Blinding (performance bias and detection bias)</td>
<td>Low risk</td>
<td>Evidence for outcomes: laboratory based. Comment: assumption made they were probably blinded.</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>“Of 76 CVCs inserted in 74 patients, four were excluded from the study: one patient died on the second postoperative day, tip culture was not available in one and the remaining two catheters were occluded shortly after insertion.” Comment: Analysis was per-protocol</td>
</tr>
</tbody>
</table>
### Giles 2002  (Continued)

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All of the paper’s pre-specified outcomes were reported (protocol not accessed)</td>
</tr>
<tr>
<td>Other bias</td>
<td>High risk</td>
<td>A co-intervention was used in the gauze and tape group (daily cleansing with 10% povidone iodine), making it difficult to determine which intervention was effective. The unit of analysis in this study was the catheter (70 patients with 72 CVCs were included) - probable ‘unit of analysis’ issue</td>
</tr>
</tbody>
</table>

### Neufeld 1991

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT of transparent polyurethane dressing (Opsite) vs highly-permeable transparent polyurethane dressing (Opsite IV3000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Included: 25 adult medical/surgical inpatients with percutaneous or tunnelled central lines in place for &gt; 48 h. Excluded: oncology and haematology patients. Time in study: at least 48 h.</td>
</tr>
<tr>
<td>Interventions</td>
<td>Group 1: Opsite (changed weekly or PRN); Group 2: Opsite IV3000 (changed weekly or PRN).</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Site colonisation, no of dressings changed per week. Dressing data were skewed, so not used for meta-analysis. Catheter-related bloodstream infection.</td>
</tr>
<tr>
<td>Notes</td>
<td>Randomisation was by ‘line’, not person. Unit analysis issue for most outcomes</td>
</tr>
</tbody>
</table>

### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>“Consecutive eligible patients were randomised using a previously established randomisation technique to receive either Op-Site Wound and dressing change protocol...or I.V.3000 and dressing change protocol...” Comment: it was unclear from the study report what method had been used to generate the randomisation sequence</td>
</tr>
</tbody>
</table>
Neufeld 1991  
(Continued)

<table>
<thead>
<tr>
<th>Bias Type</th>
<th>Risk Level</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear</td>
<td>Not reported. Comment: it was unclear from the study report if allocation was concealed</td>
</tr>
<tr>
<td>Blinding (performance bias and detection bias) All outcomes</td>
<td>High risk</td>
<td>Evidence for participants: not stated. Evidence for personnel: not stated. Comment: not possible due to the nature of the intervention (two dressings with different appearances)</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias) All outcomes</td>
<td>High risk</td>
<td>44 lines randomised; 25 lines included in analysis. ITT analysis not used. Forty-four lines were randomised. Twenty five lines were included in the study. Nineteen lines were excluded. Reasons for exclusion were: nine lines were removed prior to the 48 hours post insertion initial site inspection. Five patients (6 lines) expired prior to the 48 hour initial site inspection; two lines were dropped from the study because the wrong dressing protocol was used; and one patient who had two central lines was transferred to another hospital prior to the initial site inspection</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All of the paper’s pre-specified outcomes were reported. (Masters thesis protocol not accessed.)</td>
</tr>
</tbody>
</table>
| Other bias                             | High risk  | Evidence: “variety of skill and number of nurses performing central line dressings... nurses were not tested to ensure protocol compliance” Comment: consider possible effect due to variances in dressing techniques Evidence: “absence of a pigtail on the single lumen central line required twice the

Gauze and tape and transparent polyurethane dressings for central venous catheters (Review)  
Copyright © 2011 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
number of dressing changes than the two and three pigtail central lines combined. Although lines were randomised to the control or experimental group, the type of line was not stratified to either the control or experimental group. The numbers for the type of line used were therefore not equally distributed and the numbers were too small to ascertain specific factors related to number of times dressings were changed in the no pigtail lines.”

Comment: unequal distribution amongst groups may have affected results
The unit of analysis in this study was the catheter (unclear how many participants were included) - probable ‘unit of analysis’ issue
Industry-sponsored, unclear if any constraints imposed on results

Shivnan 1991

Methods
RCT of gauze and tape vs transparent polyurethane dressing (Tegaderm)

Participants
Included: 71 patients aged 5-56 years with a pre-existing CVC undergoing BMT for malignant or immunological disorders.
Excluded: patients who preferred gauze dressings or had reaction to Tegaderm or tape.
Time in study: 26-30 days.

Interventions
Group 1: gauze and tape (replaced daily).
Group 2: Tegaderm (replaced every 4 days).

Outcomes
Catheter-related bloodstream infection, site colonisation, exit site infection

Notes

Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Low risk</td>
<td>Block randomisation within each stratum. Comment: language used in the methods section suggests that the allocation sequence was most likely computer generated</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Not reported. Use of block sequencing may have enabled some prediction of group allocation if personnel aware of block arrange-</td>
</tr>
</tbody>
</table>
**Shivnan 1991**  
(Continued)

<table>
<thead>
<tr>
<th>Bias</th>
<th>Risk</th>
<th>Evidence</th>
<th>Comment</th>
</tr>
</thead>
</table>
| Blinding (performance bias and detection bias) | High risk | Evidence for participants: not stated.  
Comment: not possible due to the nature of the intervention (two dressings with different appearances)  
Evidence for personnel: not stated.  
Comment: not possible due to the nature of the intervention (two dressings with different appearances) |
| Blinding (performance bias and detection bias) | Unclear risk | Not reported.  
Comment: it was unclear from the study report if the outcome assessor was blinded |
| Incomplete outcome data (attrition bias) | Unclear risk | “Five individuals did not complete the study because of unexpected discharge or transfer from the unit (n = 3) or because of dissatisfaction with the assigned dressing (n = 2).”  
Unclear whether drop outs were accounted for in analysis; “although skin cultures were collected from all of the subjects, difficulties in laboratory quality control allowed analysis of only the first 75 subjects” |
| Selective reporting (reporting bias) | Low risk | All of the paper’s pre-specified outcomes were reported (protocol not accessed) |
| Other bias | High risk | n = 27 patients changed from assigned dressing.  
“prophylactic course of vancomycin administered to some patients at the time of catheter insertion”  
Industry-sponsored in part, unclear if any constraints imposed on results |

**Wille 1993**

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT of transparent polyurethane dressing (Opsite) vs highly-permeable transparent polyurethane dressing (Opsite IV3000)</th>
</tr>
</thead>
</table>
| Participants | Included: 101 patients > 16 years, hospitalised for major elective surgery and scheduled to have a single lumen CVC in a newly created site. A district general hospital, Netherlands.  
Excluded: not stated.  
Time in study: up to 21 days. |
### Interventions

| Group 1: Opsite (changed weekly); |
| Group 2: Opsite IV3000 (changed weekly). |

### Outcomes

Catheter-related bloodstream infection.

### Notes

#### Risk of bias

<table>
<thead>
<tr>
<th>Bias</th>
<th>Authors’ judgement</th>
<th>Support for judgement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Random sequence generation (selection bias)</td>
<td>Unclear risk</td>
<td>“The patients were randomised to one of the two dressing treatment groups”. Comment: it was unclear from the study report what method had been used to generate the randomisation sequence</td>
</tr>
<tr>
<td>Allocation concealment (selection bias)</td>
<td>Unclear risk</td>
<td>Not reported. Comment: it was unclear from the study report if allocation was concealed</td>
</tr>
<tr>
<td>Blinding (performance bias and detection bias)</td>
<td>High risk</td>
<td>Evidence for participants: not stated. Comment: not possible due to the nature of the intervention (two dressings with different appearances) Evidence for personnel: not stated. Comment: not possible due to the nature of the intervention (two dressings with different appearances)</td>
</tr>
<tr>
<td>Blinding (performance bias and detection bias)</td>
<td>Unclear risk</td>
<td>Not reported. Comment: it was unclear from the study report if the outcome assessor was blinded</td>
</tr>
<tr>
<td>Incomplete outcome data (attrition bias)</td>
<td>Low risk</td>
<td>“The 13 patients not included in the analysis were evenly distributed between the two dressing groups ... and were excluded for the following reasons ....” Analysis was per-protocol rather than intention to treat. Although 11 percent of participants were excluded, we subsequently conducted an ITT analysis and results remained essentially the same</td>
</tr>
<tr>
<td>Selective reporting (reporting bias)</td>
<td>Low risk</td>
<td>All of the paper's pre-specified outcomes were reported (protocol not accessed)</td>
</tr>
</tbody>
</table>
### Wille 1993 (Continued)

<table>
<thead>
<tr>
<th>Other bias</th>
<th>Unclear risk</th>
<th>Industry-sponsored, unclear if any constraints imposed on results</th>
</tr>
</thead>
</table>

### Abbreviations

- $>$ = more/greater than
- BMT = Bone marrow transplant
- CVC = central venous catheter
- h = hour(s)
- ITT = intention to treat (analysis)
- IV = intravenous
- no = number
- PRN = When necessary
- RCT = randomised controlled trial
- vs = versus

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

<table>
<thead>
<tr>
<th>Study</th>
<th>Reason for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andersen 1986</td>
<td>Only the gauze and tape group had Nobecutan (verified with authors). One arm of the study had a co-intervention with the dressing, as a result it was not possible to assess the effects of the dressing from those of Nobecutan, the co-intervention</td>
</tr>
<tr>
<td>Berggren 1995</td>
<td>Reliability was not shown for outcomes. No further data regarding validity and reliability could be obtained</td>
</tr>
<tr>
<td>Chico-Padron 2011</td>
<td>CVCs were peripherally inserted and did not include outcomes of interest</td>
</tr>
<tr>
<td>Conly 1989</td>
<td>Outcome data not reported per patient group. No further data could be obtained</td>
</tr>
<tr>
<td>Dickerson 1989</td>
<td>There was inadequate information to evaluate whether the study met the eligibility criteria, i.e. definition of outcomes unclear. No further data could be obtained</td>
</tr>
<tr>
<td>Freiberger 1992</td>
<td>No data available. No further data could be obtained.</td>
</tr>
<tr>
<td>Hägerström 1994</td>
<td>There was inadequate information to evaluate whether the study was a randomised controlled trial</td>
</tr>
<tr>
<td>Keenlyside 1992</td>
<td>Outcomes not valid and reliable.</td>
</tr>
<tr>
<td>Lawson 1986</td>
<td>Gauze and tape was compared with gauze and Tegaderm. Duplicate publication of excluded study McCredie 1984.</td>
</tr>
<tr>
<td>Le Corre 2003</td>
<td>Patients were not hospitalised.</td>
</tr>
</tbody>
</table>
Little 1998  
“Standard” was not defined. Only the dry sterile dressing group had povidone-iodine ointment

Maki 1984  
Outcome data not reported per patient group. No further data could be obtained

Maki 1992  
Methodology unclear. No further data could be obtained.

McCredie 1984  
Gauze and tape was compared with gauze and Tegeaderm. Duplicate publication of Lawson 1986.

Nehme 1984  
Only the gauze and tape group had povidone-iodine ointment.

Olson 2008  
Outcomes not valid and reliable.

Petrosino 1988  
Outcome not valid and reliable.

Powell 1982  
Only the gauze and tape group had povidone-iodine ointment.

Powell 1984  
Definition of catheter-related bloodstream infection and catheter colonisation differed from the review protocol. Duplicate publication of excluded study Powell 1985.

Powell 1985  
Definition of catheter-related bloodstream infection and catheter colonisation differed from the review protocol. Duplicate publication of excluded study Powell 1984.

Reynolds 1987  
Patients were alternately allocated to groups.

Ricard 1985  
Results appear to have included data from patients with peripheral catheters. Also, outcome data were not reported per patient. No further data could be obtained.

Thomas 1977  
Not clear how patients were allocated to groups. No further information could be obtained.

Wheeler 1988  
Historical controls.

Young 1988  
Convenience allocation used.

**Abbreviations**

CVC = central venous catheter
### DATA AND ANALYSES

**Comparison 1. Transparent polyurethane dressings versus gauze and tape**

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Catheter-related blood stream infection</td>
<td>4</td>
<td>337</td>
<td>Odds Ratio (M-H, Fixed, 95% CI)</td>
<td>4.19 [1.02, 17.23]</td>
</tr>
<tr>
<td>2 Exit-site infection</td>
<td>3</td>
<td>265</td>
<td>Odds Ratio (M-H, Fixed, 95% CI)</td>
<td>1.78 [0.62, 5.08]</td>
</tr>
<tr>
<td>3 Skin/site colonisation</td>
<td>1</td>
<td>265</td>
<td>Odds Ratio (M-H, Fixed, 95% CI)</td>
<td>Totals not selected</td>
</tr>
<tr>
<td>4 Positive catheter culture</td>
<td>2</td>
<td>138</td>
<td>Odds Ratio (M-H, Fixed, 95% CI)</td>
<td>0.74 [0.27, 2.09]</td>
</tr>
<tr>
<td>5 Tunnel infection</td>
<td>1</td>
<td>101</td>
<td>Odds Ratio (M-H, Fixed, 95% CI)</td>
<td>0.64 [0.14, 2.83]</td>
</tr>
</tbody>
</table>

**Comparison 2. Transparent polyurethane dressings versus transparent polyurethane dressings**

<table>
<thead>
<tr>
<th>Outcome or subgroup title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Catheter-related blood stream infection</td>
<td>1</td>
<td>101</td>
<td>Odds Ratio (M-H, Fixed, 95% CI)</td>
<td>0.31 [0.03, 3.12]</td>
</tr>
</tbody>
</table>

**Analysis 1.1. Comparison 1 Transparent polyurethane dressings versus gauze and tape, Outcome 1 Catheter-related blood stream infection.**

Review: Gauze and tape and transparent polyurethane dressings for central venous catheters

Comparison: 1 Transparent polyurethane dressings versus gauze and tape

Outcome: 1 Catheter-related blood stream infection

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Trans poly dressing n/N</th>
<th>Gauze % tape n/N</th>
<th>Odds Ratio M-H,Fixed,95% CI</th>
<th>Odds Ratio M-H,Fixed,95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brandt 1996</td>
<td>5/48</td>
<td>1/53</td>
<td>6.05 [0.68, 53.74]</td>
<td></td>
</tr>
<tr>
<td>de Barros 2009</td>
<td>3/33</td>
<td>1/33</td>
<td>3.20 [0.32, 32.48]</td>
<td></td>
</tr>
<tr>
<td>Giles 2002</td>
<td>0/33</td>
<td>0/39</td>
<td>0.0 [0.00, 0.0]</td>
<td></td>
</tr>
<tr>
<td>Shivnan 1991</td>
<td>1/51</td>
<td>0/47</td>
<td>2.82 [0.11, 70.98]</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>165</td>
<td>172</td>
<td>4.19 [1.02, 17.23]</td>
<td></td>
</tr>
</tbody>
</table>

Total events: 9 (Trans poly dressing), 2 (Gauze % tape)

Heterogeneity: Chi^2 = 0.22, df = 2 (P = 0.90); I^2 = 0.0%

Test for overall effect: Z = 1.98 (P = 0.047)

Test for subgroup differences: Not applicable
Analysis 1.2. Comparison 1 Transparent polyurethane dressings versus gauze and tape, Outcome 2 Exit-site infection.

Review: Gauze and tape and transparent polyurethane dressings for central venous catheters

Comparison: 1 Transparent polyurethane dressings versus gauze and tape

Outcome: 2 Exit-site infection

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Trans poly dressing n/N</th>
<th>Gauze % tape n/N</th>
<th>Odds Ratio M-H,Fixed,95% CI</th>
<th>Weight M-H,Fixed,95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brandt 1996</td>
<td>4/48</td>
<td>2/53</td>
<td>32.4% 2.32 [0.41, 13.27]</td>
<td></td>
</tr>
<tr>
<td>de Barros 2009</td>
<td>4/33</td>
<td>3/33</td>
<td>49.0% 1.38 [0.28, 6.71]</td>
<td></td>
</tr>
<tr>
<td>Shivnan 1991</td>
<td>2/51</td>
<td>1/47</td>
<td>18.6% 1.88 [0.16, 21.41]</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>132</strong></td>
<td><strong>133</strong></td>
<td><strong>100.0% 1.78 [0.62, 5.08]</strong></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 10 (Trans poly dressing), 6 (Gauze % tape)
Heterogeneity: Chisq = 0.19, df = 2 (P = 0.91); I^2 =0.0%
Test for overall effect: Z = 1.07 (P = 0.28)
Test for subgroup differences: Not applicable

Analysis 1.3. Comparison 1 Transparent polyurethane dressings versus gauze and tape, Outcome 3 Skin/site colonisation.

Review: Gauze and tape and transparent polyurethane dressings for central venous catheters

Comparison: 1 Transparent polyurethane dressings versus gauze and tape

Outcome: 3 Skin/site colonisation

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Trans poly dressing n/N</th>
<th>Gauze % tape n/N</th>
<th>Odds Ratio M-H,Fixed,95% CI</th>
<th>Odds Ratio M-H,Fixed,95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Giles 2002</td>
<td>1/33</td>
<td>2/39</td>
<td>0.58 [0.05, 6.68]</td>
<td></td>
</tr>
</tbody>
</table>

Gauze and tape and transparent polyurethane dressings for central venous catheters (Review)  
Copyright © 2011 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.
### Analysis 1.4. Comparison 1 Transparent polyurethane dressings versus gauze and tape, Outcome 4 Positive catheter culture.

Review: Gauze and tape and transparent polyurethane dressings for central venous catheters

Comparison: 1 Transparent polyurethane dressings versus gauze and tape

Outcome: 4 Positive catheter culture

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Trans poly dressing n/N</th>
<th>Gauze % tape n/N</th>
<th>Odds Ratio M-H,Fixed(95% CI)</th>
<th>Weight</th>
<th>Odds Ratio M-H,Fixed(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>de Barros 2009</td>
<td>4/33</td>
<td>3/33</td>
<td>1.38 [ 0.28, 6.71 ]</td>
<td>31.1 %</td>
<td></td>
</tr>
<tr>
<td>Giles 2002</td>
<td>3/33</td>
<td>7/39</td>
<td>0.46 [ 0.11, 1.93 ]</td>
<td>68.9 %</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>66</strong></td>
<td><strong>72</strong></td>
<td></td>
<td><strong>100.0 %</strong></td>
<td><strong>0.74 [ 0.27, 2.09 ]</strong></td>
</tr>
</tbody>
</table>

Total events: 7 (Trans poly dressing), 10 (Gauze % tape)
Heterogeneity: Chi^2 = 1.02, df = 1 (P = 0.31); I^2 = 2%
Test for overall effect: Z = 0.56 (P = 0.57)
Test for subgroup differences: Not applicable

### Analysis 1.5. Comparison 1 Transparent polyurethane dressings versus gauze and tape, Outcome 5 Tunnel infection.

Review: Gauze and tape and transparent polyurethane dressings for central venous catheters

Comparison: 1 Transparent polyurethane dressings versus gauze and tape

Outcome: 5 Tunnel infection

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Trans poly dressing n/N</th>
<th>Gauze % tape n/N</th>
<th>Odds Ratio M-H,Fixed(95% CI)</th>
<th>Weight</th>
<th>Odds Ratio M-H,Fixed(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brandt 1996</td>
<td>3/48</td>
<td>5/53</td>
<td>0.64 [ 0.14, 2.83 ]</td>
<td>100.0 %</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>48</strong></td>
<td><strong>53</strong></td>
<td></td>
<td><strong>100.0 %</strong></td>
<td><strong>0.64 [ 0.14, 2.83 ]</strong></td>
</tr>
</tbody>
</table>

Total events: 3 (Trans poly dressing), 5 (Gauze % tape)
Heterogeneity: not applicable
Test for overall effect: Z = 0.59 (P = 0.56)
Test for subgroup differences: Not applicable
Analysis 2.1. Comparison 2 Transparent polyurethane dressings versus transparent polyurethane dressings, Outcome 1 Catheter-related blood stream infection.

Review: Gauze and tape and transparent polyurethane dressings for central venous catheters

Comparison: 2 Transparent polyurethane dressings versus transparent polyurethane dressings

Outcome: 1 Catheter-related blood stream infection

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Opsite IV3000 n/N</th>
<th>Opsite n/N</th>
<th>Odds Ratio M-H,Fixed,95% CI</th>
<th>Weight %</th>
<th>Odds Ratio M-H,Fixed,95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wille 1993</td>
<td>1/51</td>
<td>3/50</td>
<td>100.0 %</td>
<td>0.31 [ 0.03, 3.12 ]</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>51</strong></td>
<td><strong>50</strong></td>
<td></td>
<td><strong>100.0 %</strong></td>
<td><strong>0.31 [ 0.03, 3.12 ]</strong></td>
</tr>
</tbody>
</table>

Total events: 1 (Opsite IV3000), 3 (Opsite)

Heterogeneity: not applicable

Test for overall effect: Z = 0.99 (P = 0.32)

Test for subgroup differences: Not applicable

APPENDICES

Appendix 1. Search strategies for the second update 2008

Search methods for identification of studies

For the first update of this review in 2006, we searched The Cochrane Wounds Group Specialised Register (January 2006) and The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2006, Issue 1).

For this second update in 2008 we searched the:

Cochrane Wounds Group Specialised Register (Searched 7 March 2008);
The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library 2008, Issue 1);
Ovid MEDLINE (1950 to February Week 4 2008);
Ovid EMBASE (1980 to 2008 Week 09);
Ovid CINAHL (1982 to February Week 4 2008).

Cochrane Wounds Group Specialised Register search strategy

((catheter* and venous) or (catheter* and central) or (central and venous and line*)) or (hickman and catheter) or (broviac and catheter) or (cook and catheter)) and ((occlusive and dressing*) or (gauze and dressing*) or (tape and dressing*) or (polyurethane and dressing*) or (permeable and dressing*) or (transparent and dressing*) or (nonpermeable and dressing*) or tegaderm or opsie)
CENTRAL search strategy

1. CATHETERIZATION CENTRAL VENOUS single term (MeSH)
2. (catheter* and venous)
3. (catheter* near central)
4. (central and venous and line*)
5. (hickman and catheter)
6. (broviac and catheter)
7. (cook and catheter)
8. (#1 or #2 or #3 or #4 or #5 or #6 or #7)
9. OCCLUSIVE DRESSINGS single term (MeSH)
10. (occlusive and dressing*)
11. (gauze and dressing*)
12. (tape and dressing*)
13. (polyurethane and dressing*)
14. (permeable and dressing*)
15. (transparent and dressing*)
16. (nonpermeable and dressing*)
17. tegaderm
18. opsite
19. (#9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18)
20. (#8 and #19)
No restrictions were made on the basis of date, language or publication status.

Appendix 2. Ovid MEDLINE search strategy

1 exp Catheterization, Central Venous/
2 (venous adj3 (catheter$ or line$)).ti,ab.
3 (central adj3 (catheter$ or line$)).ti,ab.
4 hickman catheter$.ti,ab.
5 broviac catheter$.ti,ab.
6 cook catheter$.ti,ab.
7 or/1-6
8 exp Oclusive Dressings/
9 ((occlusive or gauze or tape or polyurethane or permeable or nonpermeable or non-permeable or transparent) adj3 dressing$).ti,ab.
10 or/8-9

Appendix 3. Ovid EMBASE search strategy

1 exp Central Venous Catheter/
2 (venous adj3 (catheter$ or line$)).ti,ab.
3 (central adj3 (catheter$ or line$)).ti,ab.
4 hickman catheter$.ti,ab.
5 broviac catheter$.ti,ab.
6 cook catheter$.ti,ab.
7 or/1-6
8 exp occlusive dressing/
9 ((occlusive or gauze or tape or polyurethane or permeable or nonpermeable or non-permeable or transparent) adj3 dressing$).ti,ab.
10 or/8-9
11 7 and 10
Appendix 4. EBSCO CINAHL search strategy

S13 S8 and S12
S12 S9 or S10 or S11
S11 AB occlusive N3 dressing* or gauze N3 dressing* or tape or polyurethane N3 dressing* or permeable N3 dressing* or non-permeable or non-permeable N3 dressing* or transparent N3 dressing*
S10 TI occlusive N3 dressing* or gauze N3 dressing* or tape or polyurethane N3 dressing* or permeable N3 dressing* or non-permeable or non-permeable N3 dressing* or transparent N3 dressing*
S9 (MH "Oclusive Dressings")
S8 S1 or S2 or S3 or S4 or S5 or S6 or S7
S7 TI cook catheter* or AB cook catheter*
S6 TI broviac catheter* or AB broviac catheter*
S5 TI hickman catheter* or AB hickman catheter*
S4 TI ( central N3 catheter* or central N3 line* ) or AB ( central N3 catheter* or central N3 line* )
S3 TI ( venous N3 catheter* or venous N3 line* ) or AB ( venous N3 catheter* or venous N3 line* )
S2 (MH "Central Venous Catheters+")
S1 (MH "Catheterization, Central Venous+")

Appendix 5. Risk of bias criteria

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 to permit 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: using an open random allocation schedule (e.g. a list of random numbers); assignment envelopes were used 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; any other explicitly un concealed procedure.
Unclear
Insufficient information to permit 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 are not likely to be 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 unlikely to introduce bias.

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

Unclear
Any one of the following.
- Insufficient information to permit 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 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 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 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 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**

Any one of the following.

- Insufficient reporting of attrition/exclusions to permit 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**

Any of the following.

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

**High risk of bias**

Any one of the following.

- Not all of the study’s pre-specified 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 pre-specified.
- One or more reported primary outcomes were not pre-specified (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 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 risk of bias. For example, the study:

- had a potential source of bias related to the specific study design used; or
- had extreme baseline imbalance; 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.

WHAT’S NEW

Last assessed as up-to-date: 9 May 2011.

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 May 2011</td>
<td>New search has been performed</td>
<td>Third update, two new studies included (de Barros 2009; Giles 2002) and two studies excluded (Chico-Padron 2011; Olson 2008). In addition two previously included studies were excluded, Hägerström 1994 because it was judged not to be a RCT and Petrosino 1988 because the outcome of 'infection' was not clearly defined or attributed. The conclusions remain unchanged. Summary of findings table completed</td>
</tr>
<tr>
<td>10 May 2011</td>
<td>New citation required but conclusions have not changed</td>
<td>New authors added to the review team</td>
</tr>
</tbody>
</table>

HISTORY


Review first published: Issue 4, 2003

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>14 April 2010</td>
<td>Amended</td>
<td>Contact details updated.</td>
</tr>
<tr>
<td>11 November 2008</td>
<td>Amended</td>
<td>Contact details updated.</td>
</tr>
<tr>
<td>17 March 2008</td>
<td>New search has been performed</td>
<td>For this second update, new searches were carried out in March 2008. Twenty-four citations were screened but no new studies were identified for inclusion. The review authors' conclusions remain unchanged</td>
</tr>
<tr>
<td>17 March 2008</td>
<td>Amended</td>
<td>Converted to new review format.</td>
</tr>
<tr>
<td>22 January 2006</td>
<td>New search has been performed</td>
<td>First update. The first update of this review was published in the Cochrane Library, Issue 2, 2006. For the first update, new searches were carried out in January 2006. Three new studies were excluded</td>
</tr>
</tbody>
</table>
from the review. The authors' conclusions remain unchanged

23 May 2003  New citation required and conclusions have changed  Substantive amendment. Review first published.

CONTRIBUTIONS OF AUTHORS
Joan Webster: risk of bias tables, data extraction, analysis, writing of 2011 update.
Donna Gillies: protocol development, data extraction, analysis, writing of original review and of all updates.
Claire Rickard: data extraction, writing of 2011 update.
Libba O’Riordan: protocol development, data extraction, analysis, writing of original review and of updates in 2006 and 2008.
Karen Sherriff: risk of bias tables, data extraction for 2011 update.

Contributions of editorial base:
Nicky Cullum: edited the review, advised on methodology, interpretation and review content. Approved the final review and review update prior to submission.
Sally Bell-Syer: coordinated the editorial process. Advised on methodology, interpretation and content. Edited and copy edited the review and the updated review.
Ruth Foxlee: designed the search strategy, ran the searches and edited the search methods section for the update.

DECLARATIONS OF INTEREST
None known.

SOURCES OF SUPPORT

Internal sources
• The Children’s Hospital at Westmead, Sydney, Australia.
• The University of Sydney, Australia.
• Sydney West Area Health Service, Australia.
External sources

- NIHR/Department of Health (England), (Cochrane Wounds Group), UK.

INDEX TERMS

Medical Subject Headings (MeSH)

*Occlusive Dressings; *Polyurethanes; Bacterial Infections [*prevention & control]; Catheterization, Central Venous [*adverse effects]; Randomized Controlled Trials as Topic

MeSH check words

Humans