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# Devices and dressings to secure peripheral venous catheters to prevent complications (Review)

Marsh N, Webster J, Mihala G, Rickard CM

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[Intervention Review]

### Devices and dressings to secure peripheral venous catheters to prevent complications

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### ABSTRACT

### Background

A peripheral venous catheter (PVC) is typically used for short-term delivery of intravascular fluids and medications. It is an essential element of modern medicine and the most frequent invasive procedure performed in hospitals. However, PVCs often fail before intravenous treatment is completed: this can occur because the device is not adequately attached to the skin, allowing the PVC to fall out, leading to complications such as phlebitis (irritation or inflammation to the vein wall), infiltration (fluid leaking into surrounding tissues) or occlusion (blockage). An inadequately secured PVC also increases the risk of catheter-related bloodstream infection (CRBSI), as the pistoning action (moving back and forth in the vein) of the catheter can allow migration of organisms along the catheter and into the bloodstream. Despite the many dressings and securement devices available, the impact of different securement techniques for increasing PVC dwell time is still unclear; there is a need to provide guidance for clinicians by reviewing current studies systematically.

### Objectives

To assess the effects of PVC dressings and securement devices on the incidence of PVC failure.

### Search methods

We searched the following electronic databases to identify reports of relevant randomised controlled trials (RCTs): the Cochrane Wounds Group Register (searched 08 April 2015): The Cochrane Central Register of Controlled Trials (CENTRAL; 2015, Issue 3), Ovid MEDLINE (1946 to March 7 2015); Ovid MEDLINE (In-Process & Other Non-Indexed Citations, March 7 2015); Ovid EMBASE (1974 to March 7 2015); and EBSCO CINAHL (1982 to March 8 2015).

### Selection criteria

RCTs or cluster RCTs comparing different dressings or securement devices for the stabilisation of PVCs. Cross-over trials were ineligible for inclusion, unless data for the first treatment period could be obtained.

### Data collection and analysis

Two review authors independently selected studies, assessed trial quality and extracted data. We contacted study authors for missing information. We used standard methodological procedures expected by Cochrane.

### Main results

We included six RCTs (1539 participants) in this review. Trial sizes ranged from 50 to 703 participants. These six trials made four comparisons, namely: transparent dressings versus gauze; bordered transparent dressings versus a securement device; bordered transparent dressings versus tape; and transparent dressing versus sticking plaster. There is *very low quality evidence* of fewer catheter dislodgements or accidental removals with transparent dressings compared with gauze (two studies, 278 participants, RR 0.40; 95% CI 0.17 to 0.92, P = 0.03%). The relative effects of transparent dressings and gauze on phlebitis (RR 0.89; 95% CI 0.47 to 1.68) and infiltration (RR 0.80; 95% CI 0.48 to 1.33) are unclear. The relative effects on PVC failure of a bordered transparent dressing and a securement device have been assessed in only one small study and these were unclear. There was *very low quality evidence* from the same single study of less frequent dislodgement or accidental catheter removal with bordered transparent dressings than securement devices (RR 0.14, 95% CI 0.03 to 0.63) but more phlebitis with bordered dressings (RR 8.11, 95% CI 1.03 to 64.02) (*very low quality evidence*). A small single study compared bordered transparent dressings with tape and found *very low quality evidence* of more PVC failure with the bordered dressing (RR 1.84, 95% CI 1.08 to 3.11) but the relative effects on dislodgement were not clear (*very low quality evidence*). The relative effects of transparent dressings and a sticking plaster have only been compared in one small study and are unclear. More high quality RCTs are required to determine the relative effects of alternative PVC dressings and securement devices.

### Authors' conclusions

It is not clear if any one dressing or securement device is better than any other in securing peripheral venous catheters. There is a need for further, independent high quality trials to evaluate the many traditional as well as the newer, high use products. Given the large cost differences between some different dressings and securement devices, future trials should include a robust cost-effectiveness analysis.

### PLAIN LANGUAGE SUMMARY

### Effectiveness of dressings and other devices that are used to keep a peripheral venous catheter in place

### Background

Most people admitted to an acute/emergency hospital ward require the insertion of a peripheral venous catheter/cannula (PVC), often known as a 'drip' or 'IV'. A PVC is a flexible, hollow, plastic tube that is inserted in a peripheral vein, most commonly in the hand, or lower arm. Up to half of all PVCs stop working before treatment has finished and a new one has to be inserted. This is uncomfortable for the patient and costly for the healthcare system. One of the reasons PVCs fail, is that the products used to hold them in place are not fully effective, and allow the PVC to move around. This movement causes redness, inflammation and even blood infections. The PVC can become blocked, or leak into the surrounding tissues, or even fall out as a consequence of the movement. The function of PVC dressings and/or securement devices is to keep the PVC in the vein, and to cover the insertion site so that it is kept dry and clean and protected from infection.

### **Review question**

We reviewed the evidence about the effect that different PVC dressings and securement devices have on PVC failure rates.

### Study characteristics

We searched the medical literature for studies that compared different types of products that are used to keep PVCs in place. We found six studies (involving 1539 participants) that compared four different ways of securing PVCs. These included:

1. a plain transparent film dressing compared with a gauze (woven fabric) dressing;

2. a bordered transparent dressing (clear transparent window with a reinforced fabric edge) compared with a securement device (that has anchor points or clips that hold the PVC in place over a strong adhesive base pad on the skin) that is used in conjunction with a transparent film dressing;

3. a bordered transparent dressing compared with non-sterile medical tape;

4. a plain transparent film dressing compared with sticking plaster.

The participants in the studies were both adults and children on medical and surgical wards. There were no studies based in emergency departments.

### Key results

Two studies provided very low quality evidence that PVCs were less likely to fail when a transparent dressing was used rather than gauze.

Other positive outcomes favouring one dressing over another were based on the results of very low quality, single studies. Overall there is a lack of high quality evidence and continued uncertainty regarding the best methods of securing a peripheral venous catheter remains.

More high quality research is needed in this area.

### Quality of the evidence

We assessed a number of quality indicators regarding the methods used in each study and graded the overall quality of studies as very low. Each study had a high or unclear risk of bias for some of the quality indicators. For example, it is likely that clinical staff responsible for assessing participants' outcomes knew the treatment group to which each person belonged, as the securement methods for PVCs looked different.

There were only a limited number of studies available for consideration in this review, and they did not investigate some securement products that are in common use.

### SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

### Transparent dressing versus gauze for securing peripheral venous catheters

Patient or population: Patients requiring a peripheral venous catheter Settings: Hospital or community Intervention: Transparent dressing Comparison: Gauze dressing

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Gauze	Transparent dressing				
PVC failure	This outcome was no	t reported	Not estimable	-	See comment	'PIVC failure' is a compos- ite measure
Dislodgement/	Study population		RR 0.4		000	
accidental removal	134 per 1000	<b>54 per 1000</b> (23 to 123)	- (0.17 to 0.92)	(2 studies)	<b>very low</b> <sup>1,2,3</sup>	
Phlebitis	Study population		<b>RR 0.89</b> (0.47 to 1.68)	379	000	
	87 per 1000	<b>78 per 1000</b> (41 to 146)		(3 studies)	<b>very low</b> <sup>1,2,4,5</sup>	

\*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; RR: Risk 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 an important 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.

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<sup>1</sup> Downgraded due to risk of bias (one level): Unblinded personnel and outcome assessors
 <sup>2</sup> Downgraded due to risk of bias (one level): Unclear if allocation to groups was blinded
 <sup>3</sup> Downgraded due to imprecision (one level): The 95% confidence intervals ranged from 0.17 to 0.92

<sup>4</sup> Downgraded due to risk of bias (one level): Catheters may have been in situ when participants were enrolled consequently, the outcome may have been due to the previous dressing

<sup>5</sup> Downgraded due to imprecision (one level): The 95% confidence intervals ranged from 0.47 to 1.68; indicating that the true estimate of effect lies somewhere between a reduction of 53% or an increase of 68% in the incidence of phlebitis when a transparent dressing is

used.

### BACKGROUND

### **Description of the condition**

A peripheral venous catheter (PVC), often referred to as an intravenous cannula, drip or IV, is a flexible, hollow, plastic tube that is inserted in a peripheral vein, most commonly the metacarpal vein of the hand, and alternatively, either the cephalic or basilic vein of the lower forearm (Tagalakis 2002; Dougherty 2008; O'Grady 2011). PVCs are typically used for short-term delivery of intravascular fluids and medications. PVCs are an essential element of modern medicine and their insertion is the most frequent invasive procedure performed in hospitals, with over 60% of all hospitalised patients requiring one (Wilson 2006). It has been conservatively estimated that patients have a PVC for 15% to 20% of the total time they spend in an acute care hospital (Zingg 2009). In the USA, an estimated 330 million PVCs are sold each year (Hadaway 2012).

The Infusion Nurses Society Standards of Practice recommend that PVCs be re-sited when clinically indicated, and that decisions about when to re-site should be based on an assessment of the patient's PVC site, including: skin and vein integrity, type of intravenous (IV) therapy prescribed, the treatment setting, and patency of the PVC and securing dressing or stabilisation device (INS 2011). PVCs often fail before intravenous treatment is completed. Reported failure rates, or unscheduled restarts, range from 33% to 69% (Harwood 1992; Royer 2003; Smith 2006; Bolton 2010; Rickard 2010). PVCs fail for a wide range of reasons; the most commonly identified causes of failure are partial dislodgement or accidental removal, phlebitis (irritation or inflammation to the vein wall), occlusion (blockage), infiltration (fluid moving into surrounding tissue), leakage and, rarely, infection (Webster 2008; Bolton 2010; Rickard 2010).

### **Dislodgement and accidental removal**

Inadequate catheter stabilisation or securement can lead to poor attachment of the PVC to the skin, allowing movement of the catheter in and out of, or around and within, the vein resulting in partial or complete dislodgement. PVC dislodgement rates have been reported to range from 6% of PVC insertions to as high as 20% (Wood 1997; Royer 2003; Dillon 2008; Rickard 2010).

### Phlebitis

Intravenous therapy can be disrupted by phlebitis, which is the irritation and inflammation of a vein wall caused by the presence of the PVC (Monreal 1999; Tagalakis 2002). Phlebitis can be categorised as chemical (caused by infusates or medication), bacterial (caused by contamination of the site, catheter, tubing or IV solution), or mechanical (caused by the action of the catheter in the vessel; Macklin 2003). An improperly secured PVC that allows micro-movement of the catheter within the vein can irritate the vein wall and lead to mechanical phlebitis (Sheppard 1999; Gallant 2006). Phlebitis is characterised by the presence of any combination of tenderness, pain, erythema (redness), oedema (swelling), warmth, palpable cord (hard, thickened vein), or purulent drainage (pus; Maki 1991; Tagalakis 2002; Gallant 2006). Phlebitis rates range from 2.6% to 67% depending on the authors' definition, study design, study population and the duration of follow-up period (Catney 2001; White 2001; Karadeniz 2003; Malach 2006; Webster 2008; Rickard 2010; Rickard 2012).

### Occlusion/infiltration and leakage

A poorly-stabilised PVC within a vein can kink or damage the vessel wall, instigating the release of thromboplastic substances and platelets that promote blood clotting (Gabriel 2010). This process may cause narrowing or occlusion of the catheterised vein, which then forces the backflow and potential leakage of IV fluids from the PVC insertion site, or their infiltration into the surrounding tissues, and restricts future venous access in the limb (Royer 2003; Gabriel 2010). Recent studies show PVC failure due to occlusion/ infiltration occur in 12% to 36% of patients (Homer 1998; Catney 2001; Tagalakis 2002; Webster 2008; Rickard 2010).

### Infection

Poor catheter stabilisation, particularly if it leads to unscheduled PVC re-siting, may increase a patient's risk of infection. In order to be sited, a PVC must be inserted through the patient's skin, which normally acts as a protective barrier against bacteria that might otherwise access the body. Consequently the catheter may be contaminated during initial insertion or subsequent re-sitings with a new PVC (Gabriel 2008). The most common cause of catheterrelated bloodstream infection (CRBSI) in short-term catheters occurs from bacterial entry at the skin site. Micro-organisms can cause local infection and may track along the surface of the PVC to contaminate the catheter tip, and then the bloodstream (Morris 2008; O'Grady 2011). Micro-motion while the PVC is in place may also encourage microbial entry via the PVC wound (Frey 2006). However, CRBSIs occur less frequently in PVC than in other intravascular devices such as peripherally inserted central catheters (PICC; 0.1%, 0.5 per 1000 PVC catheter-days compared with 2.4%, 2.1 per 1000 PICC catheter-days; Maki 2006). The failure of a PVC can lead to venous access difficulties, including the need for more frequent PVC re-sites or for a central venous catheter, and causing interruption to the delivery of IV therapy and medicines with a potential increase in the duration of hospital stay and healthcare costs (Monreal 1999; Tagalakis 2002; Dillon 2008).

### **Description of the intervention**

The intervention of interest is the wound dressing(s) and securement device(s) used for PVC stabilisation. Following clinical practice protocols or clinician preference, two standard dressings are generally used to secure the PVC: either sterile gauze with non sterile tape or bandage, or a transparent dressing (Gabriel 2010; O'Grady 2011). Plain non-sterile tape is often used for additional securement. However, new products, such as antimicrobial-impregnated dressings and sutureless (stitch-less) securement devices that are designed to be used with the wound dressing to improve attachment of the PVC to the skin, have recently become available.

### Gauze/tape

A combination of sterile gauze with tape or bandage has been widely used to secure PVCs. This combination can range from non-sterile tape and sterile gauze assembled by clinicians using products such as Micropore® (3M) or Hypafix® (Smith & Nephew Healthcare Ltd), to commercially-available dressings that combine a sterile tape and gauze design, for example Primapore® (Smith & Nephew Healthcare Ltd). However, gauze needs to be removed so that the insertion site can be seen and this can potentially increase the chance of catheter dislodgement or movement, resulting in complications such as phlebitis, infiltration or occlusion (Campbell 1999). Furthermore, although gauze dressings are absorbant and can prevent the pooling of moisture at the insertion site, when wet they provide an ideal environment for the proliferation of infection-producing organisms (Campbell 1999; Gabriel 2010).

### **Transparent dressings**

Transparent dressings have been in use since the early 1980s and offer clear visualisation of the PVC insertion site. The Opsite® (Smith & Nephew Healthcare Ltd) and Tegaderm® (3M) ranges of dressings are the most commonly used products (Webster 2011). An early systematic review that compared gauze dressings with transparent dressings for PVC securement found a significantly higher infection risk with transparent dressings (Hoffmann 1992). This was thought to be related to increased collection of moisture (Hoffmann 1992). As a result of these studies, modern transparent dressings were developed and it is claimed that they have greater moisture vapour permeability (MVP; Wille 1993). A study comparing standard Opsite and Opsite IV3000 for dressing central venous catheters reported MVPs of 800 g/m<sup>2</sup> and 3000 g/m<sup>2</sup>, respectively and no differences between the dressings for complications such as moisture accumulation, lifting of dressing or durability (Wille 1993). Recently, new versions of these products, with additional strongly-adhesive fabric borders, or additional sterile tapes to improve securement, have become available.

### **Antimicrobial dressings**

Antimicrobial dressings or impregnated discs have been developed to aid prevention of CRBSI, for example Biopatch® (Johnson and Johnson) and Tegaderm CHG® (3M). The most common source of infection for CRBSI is colonisation of the skin surrounding the insertion site, so antimicrobial dressings aim to reduce this colonisation, and thus decrease the incidence of CRBSI (Dainiels 2012). The Centers for Disease Control and Prevention recommend the use of a chlorhexidine-impregnated sponge for temporary shortterm catheters (typically used in intensive care units) if the central line-associated bloodstream infection rates are unacceptably high and not decreasing despite the implementation of basic preventative measures (i.e. education and training, maximal sterile barrier precautions and > 0.5% chlorhexidine in an alcoholic solution for skin antisepsis; O'Grady 2011). However, there is no mention in the guidelines of antimicrobial sponge/dressing use in conjunction with peripheral catheters.

#### Sutureless securement devices

Sutureless securement devices have incorporated anchor points, or clips, to hold the PVC in place more securely, for example Statlock® (Bard Medical), Grip-Lok® (Zefon International) or Hubguard ® (Centurion Medical Products). It is reported that these increase attachment to the skin, thus minimising catheter movement and reducing complications such as phlebitis, dislodgement, infiltration and vessel occlusion (Schears 2006). The Centers for Disease Control and Prevention have recommended the use of sutureless securement devices to decrease the risk of infection (O'Grady 2011). The Infusion Nurses Society advises that a stabilisation device should be used in preference to tape or sutures when possible, to aid in maintaining device integrity and minimisation of movement at the catheter hub (INS 2011).

### How the intervention might work

The aim of all PVC dressings and securement devices is to maintain a barrier to infection and to ensure that the device remains in the vein. This review aims to examine the different PVC protection and stabilisation methods; the impact they have on PVC dwell time and stabilisation-related complications such as dislodgement, phlebitis, occlusion/infiltration, leaking, and infection; and the costs involved with the different products. Identification of the most effective securement method may help reduce stabilisationrelated complications.

### Why it is important to do this review

PVC insertion and IV therapy is a common procedure for hospitalised patients. Prevention of failure and unscheduled restarts of PVC therapy is an important patient outcome: failure interrupts

prescribed therapy, and reinsertion can be distressing and painful. A PVC that is not securely attached to the skin has the potential to migrate externally and simply fall out, or cause complications such as phlebitis and infiltration. An inadequately secured PVC also increases the risk of CRBSI, as the pistoning action of the catheter can allow migration of organisms along the catheter and into the systemic circulation (Gabriel 2001; O'Grady 2011). These unnecessary complications can lead to delays in treatment and increases in length of hospital stay (Bolton 2010). There is also an impact on health resources, as PVC replacement is time consuming, requires skilled clinicians and disposable sterile equipment, and CRBSIs cause significant increases in treatment costs (Bolton 2010; Gabriel 2010). Despite the many dressings and securement devices available, the impact of different securement techniques for increasing PVC dwell time is still unclear; there is a need to provide guidance for clinicians by reviewing current studies systematically.

### OBJECTIVES

To assess the effects of PVC dressings and securement devices on the incidence of PVC failure.

### METHODS

### Criteria for considering studies for this review

### **Types of studies**

We included randomised controlled trials (RCTs) or cluster randomised trials (where the cluster represented randomisation at the ward or hospital level), comparing different dressings or securement devices for the stabilisation of PVCs. Cross-over trials were ineligible for inclusion, unless data for the first treatment period could be obtained.

### **Types of participants**

Any patients in any setting who require a PVC.

### **Types of interventions**

Any trial comparing dressings or securement devices with another dressing or securement device, for the protection or stabilisation of a PVC. Dressings or securement devices that are made from any type of product (e.g. polyurethane, gauze) were eligible.

### Types of outcome measures

### **Primary outcomes**

• PVC failure (a composite measure of unplanned PVC removal for any reason, such as phlebitis, infiltration accidental removal, blockage).

• Adverse events (such as allergic skin reaction; blisters) .

### Secondary outcomes

• Dislodgement and accidental removal.

 Time to catheter failure (analysed by survival methods e.g. Kaplan-Meier survival curves).

- Phlebitis, as identified by the trial investigator.
- Infiltration (the permeation of intravenous fluid or

medication into the surrounding tissue, resulting in swelling).

• Occlusion or inability to administer intravenous fluids.

• Catheter-related blood stream infection (CRBSI) with laboratory confirmation of the catheter as the source of the infection (O'Grady 2011).

- Suspected CRBSI, as identified by the trial investigator.
- Entry site local infection, as described by the trial investigator.
  - Skin damage, as described by the trial investigator.

• Cost (including cost or cost-effectiveness estimations, as well as measurements of resource use such as number of dressing/ device changes, staff time).

• Patient satisfaction (using any validated instrument, e.g. a visual analogue scale).

• Pain associated with dressing removal.

### Search methods for identification of studies

### **Electronic searches**

In April 2015 we searched the following electronic databases to identify reports of relevant RCTs:

• The Cochrane Wounds Group Specialised Register (searched 8 April 2015);

• The Cochrane Central Register of Controlled Trials (CENTRAL; 2015, Issue 3);

- Ovid MEDLINE (1946 to March 7, 2015);
- Ovid MEDLINE (In-Process & Other Non-Indexed Citations, March 7, 2015)
  - Ovid EMBASE (1974 to March 7, 2015);
  - EBSCO CINAHL (1982 to March 8, 2015).

We used the following search strategy for CENTRAL (*The Cochrane Library*):

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

#2 (peripheral venous catheter\* or PVC):ti,ab,kw #3 {or #1-#2}

#4 MeSH descriptor: [Occlusive Dressings] explode all trees

#5 (securement device\* or Statlock or Hubguard):ti,ab,kw

#6 ((occlusive or gauze or tape or polyurethane or permeable or nonpermeable or non-permeable or transparent or antimicrobial) near/3 dressing\*):ti,ab,kw

#7 (opsite or tegaderm or micropore or hypafix):ti,ab,kw

- #8 {or #4-#7}
- #9 {and #3, #8}

The search strategies for Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL can be found in Appendix 1.

We adapted this strategy to search Ovid MEDLINE, Ovid EM-BASE and EBSCO CINAHL. We combined the Ovid MED-LINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision; Lefebvre 2011). We combined the EMBASE search with the Ovid EMBASE filter developed by the UK Cochrane Centre (Lefebvre 2011). We combined the CINAHL searches with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN 2011). We did not restrict studies with respect to language, date of publication or study setting.

We searched the following clinical trials registries:

- ClinicalTrials.gov (http://www.clinicaltrials.gov/)
- WHO International Clinical Trials Registry Platform ( http://apps.who.int/trialsearch/Default.aspx)

• EU Clinical Trials Register (https://

www.clinicaltrialsregister.eu/

### Searching other resources

We searched the reference lists of all relevant publications we retrieved for other studies that had not been identified by the search methods described above. We contacted manufacturers of dressings and devices used to secure PVCs.

### Data collection and analysis

### Selection of studies

Two review authors (NM and JW) reviewed titles and abstracts located by the search process independently. After obtaining full copies of potentially relevant studies, the same two review authors assessed study eligibility independently, according to the inclusion and exclusion criteria. A third review author's (CR) opinion would have been sought had differences of opinion not been resolved by consensus.

### Data extraction and management

Two review authors (NM and JW) extracted data from all included RCTs independently, using a pre-designed pro forma. One review author (NM) entered data into Review Manager software (RevMan 2012), and a second review author (JW) checked the data for accuracy. If information regarding any part of the data was unclear, we attempted to contact the study authors of the original reports and asked them to provide further details. We included trials published as duplicate reports (parallel publications) once, using all associated trial reports to extract a maximal amount of trial information, but ensuring that the trial data were not duplicated in the review. We extracted the following information:

- participant characteristics and exclusions;
- type of dressing or securement device;
- setting;
- study dates;
- unit of investigation (participant or catheter);
- interventions;
- length of follow-up;
- information about ethics approval, consent and any
- declared conflicts of interest; and
- outcomes.

### Assessment of risk of bias in included studies

Independently, two review authors (NM and JW) assessed the included studies for risk of bias using the 'Risk of bias' tool outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

This assessment of bias tool addresses seven specific domains (see Appendix 2 for details), namely:

- sequence generation;
- allocation concealment;
- blinding of participants and personnel;
- blinding of outcome assessment;
- incomplete outcome data;
- selective outcome reporting;

• other possible problems that could put the study at risk of bias, such as unequal numbers in the study groups or early stopping of a trial.

Disagreements between the two review authors (NM and JW) were discussed and resolved by consensus, or referral to a third review author (CR). The overall assessment of the risk of bias is presented in a 'Risk of bias' summary figure, which displays all judgements in a cross-tabulation of study by entry. This display of internal validity indicates the weight the reader can give to the results of any particular study.

### Measures of treatment effect

For dichotomous outcomes, we calculated risk ratio (RR) plus 95% confidence intervals (CI). For continuous outcomes we calculated the mean difference (MD) plus 95% CI. We planned

to analyse any time-to-event data (e.g. time to development of phlebitis) using hazard ratios and did not analyse time-to-event data that were incorrectly presented as continuous data.

### Unit of analysis issues

Ideally a study would be designed with patient-level randomisation and analysis, and only one device per participant (adjustment for clustering not necessary in this case), however, we expected to find a number of studies that reported on multiple devices per participant, randomised or analysed at device level, or both, and unadjusted for clustering.

In such cases we planned to contact the study authors and attempt to obtain:

- patient-level data or results;
- data or results for one device per participant; or
- device-level data,

and then perform multilevel regression to calculate the adjusted effect. We would then combine the adjusted results in the metaanalysis with those of patient-level trials (using the generic inverse method), and perform sensitivity analyses (Higgins 2011). If we were unsuccessful in obtaining the additional data required, then we would exclude the study from the meta-analysis.

### Dealing with missing data

We identified the missing data for each study and attempted to contact the study authors to obtain the information necessary for analysis. Where the data could not be obtained, we performed an available-case analysis on the available data. We planned to address the potential impact of missing data in the Discussion section of the review. We also planned to explore the impact of missing data on the study results with a sensitivity analysis that compared the results from the analyses of study completers with those from best-case and worst-case scenarios. In the best-case scenario, all missing data from the treatment group were considered not to indicate PVC failure, while those missing from the control group were considered to indicate PVC failure. In the worst-case scenario missing data from the treatment group were considered to indicate PVC failure, while those missing from the control group were considered to indicate PVC failure. In the worst-case scenario

### Assessment of heterogeneity

Statistical heterogeneity was tested for by using the  $\text{Chi}^2$  test, with significance set at a P value of less than 0.10. In addition, the degree of heterogeneity was investigated by calculating the  $I^2$  statistic (Deeks 2011). This describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance). A rough guide to interpretation is as follows: 0 to 40% might not be important; 30% to 60% may represent moderate heterogeneity; 75% to 100% represents considerable heterogeneity (Deeks 2011). The importance of the observed value

of  $I^2$  depends on firstly the magnitude and direction of effects, and secondly the strength of evidence for heterogeneity (e.g. P value from the Chi<sup>2</sup> test, or a confidence interval for  $I^2$ ) (Deeks 2011).

### Assessment of reporting biases

We planned that if there were 10 or more studies included in a meta-analysis, we would assess for reporting bias by using a funnel plot. If visual inspection of the symmetry of the funnel plot showed that reporting bias was present, we planned to include a statement in our results and a note of caution in our discussion. Where possible, we also planned to access trial protocols and compare the outcome measurements planned with those reported.

### Data synthesis

We used Review Manger to perform the meta-analysis of included studies (RevMan 2012). If we had identified evidence of significant heterogeneity (i.e. greater than 50%), we planned to explore potential causes, and use a random-effects approach to the analysis.

### Subgroup analysis and investigation of heterogeneity

The following subgroup analyses were pre-specified in our protocol:

- Children (under 16 years of age) and adults.
- Continuous versus intermittent IV therapy.

• Additional bandaging versus dressing or securement device alone.

### Sensitivity analysis

We pre-specified in our protocol testing for the impact of the following study characteristics in sensitivity analyses:

- adequate vs. inadequate concealment of allocation;
- size of studies (greater or fewer than 100 patients);
- follow-up period of less or more than 48 hours;
- missing data best/worst case scenarios.

### 'Summary of findings' table

We have presented the main results of the review in 'Summary of findings' tables. Summary of findings tables present key information concerning the quality of the evidence, the magnitude of the effects of the interventions examined, and the sum of the available data for the main outcomes (Schünemann 2011a). 'Summary of findings' tables also include an overall grading of the evidence related to each of the main outcomes using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach (Schünemann 2011b). The GRADE approach defines the quality of a body of evidence with regard to the extent to which one can be confident that an estimate of effect or association is close to the quantity of specific interest. Quality of a body of evidence

involves consideration of within-trial risk of bias (methodological quality), directness of evidence, heterogeneity, precision of effect estimates and risk of publication bias (Schünemann 2011b). We planned to present the following outcomes in 'Summary of findings' tables for all comparisons:

- proportion of failed catheters;
- time to catheter failure;
- adverse events.

### RESULTS

**Description of studies** 

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

### **Results of the search**

We identified 56 references (see Figure 1). After reviewing titles and abstracts, we eliminated 47 clearly irrelevant references. We retrieved full text copies of the remaining nine potentially eligible papers. We included six of these trials (Livesley 1993; Tripepi-Bova 1997; Rodriguez 2002; Bausone-Gazda 2010; Chico-Padron 2011; Forni 2012), and excluded one trial (Machado 2005). Four further trials are awaiting classification (Maki 1987; Machado 2008; Marsh 2014; Calvino Gunther 2014). We also identified one trial on ClinicalTrials.gov but this was a prospective cohort study.

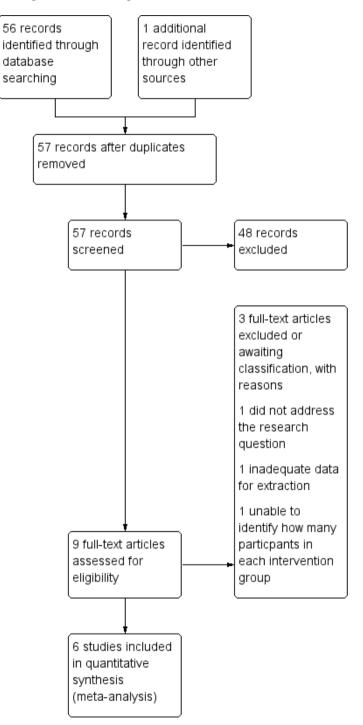


Figure 1. Flow diagram of included and excluded studies

### **Included studies**

### Types of participants

We included six trials in this review, with a total of 1539 participants, and trial sizes ranging from 50 to 703. Two trials were conducted in the USA (Tripepi-Bova 1997; Bausone-Gazda 2010), two in Spain (Rodriguez 2002; Chico-Padron 2011), one in Italy (Forni 2012), and one in England (Livesley 1993). All of the trials were conducted in a single-centre, acute inpatient setting with either paediatric only (Livesley 1993), adult and paediatric (Forni 2012) or adult only participants (Tripepi-Bova 1997; Rodriguez 2002; Bausone-Gazda 2010; Chico-Padron 2011). Among the trials recruiting adults, the mean participant age ranged between 55 and 60 years. The majority of trials were conducted within a 10-year time frame, between 2000 and 2010 (Rodriguez 2002; Bausone-Gazda 2010; Chico-Padron 2011; Forni 2012;), the Tripepi-Bova 1997 trial was undertaken between 1994 and 1995. It is unclear when the Livesley 1993 study was undertaken, but results were published in 1993. Evidence of institutional ethics approval was available for four of the trials (Tripepi-Bova 1997; Bausone-Gazda 2010; Chico-Padron 2011; Forni 2012), and participant consent in four trials (Livesley 1993; Bausone-Gazda 2010; Chico-Padron 2011; Forni 2012). Tripepi-Bova 1997 stated that consent was not required, as both dressings were considered non-experimental. One study acknowledged industry sponsorship (Bausone-Gazda 2010).

### **Types of interventions**

Four comparisons were reported in the included trials. The first comparison was of transparent dressings compared with gauze (Tripepi-Bova 1997; Rodriguez 2002; Chico-Padron 2011). The intervention dressing used by Chico-Padron 2011 was described simply as a transparent dressing, Rodriguez 2002 used a 3M<sup>TM</sup> Tegaderm<sup>™</sup> Film Dressing and the transparent dressing in the Tripepi-Bova 1997 study was Smith & Nephew's Opsite. The second comparison was of a bordered transparent dressing compared to a securement device (Bausone-Gazda 2010), and the dressing used in the intervention arm was 3M Tegaderm IV. The third comparison was of a bordered transparent dressing (Veni-Guard Breathable I.V. Dressing) assessed against tape (Livesley 1993), and, the final comparison was of a transparent dressing - described as a sterile dressing made of highly permeable polythene film, with latex-free hypoallergenic adhesive - compared with sticking plaster (Forni 2012).

### Types of outcomes

For the first comparison, none of the three trials that compared transparent dressings with gauze reported on either of our primary outcomes. Of the secondary outcomes for this comparison, Chico-Padron 2011 measured dislodgement/accidental removal, phlebitis, infiltration and cost; Rodriguez 2002 assessed phlebitis and infiltration; and Tripepi-Bova 1997 provided data for dislodgement/accidental removal, phlebitis and infiltration.

In the second comparison, the trial that compared a bordered transparent dressing to a securement device provided data for one of our primary outcomes - PVC failure, and for two secondary outcomes: dislodgement/accidental removal and phlebitis (Bausone-Gazda 2010).

In the third comparison, a bordered transparent dressing compared with tape, Livesley 1993 reported on the primary outcome of PVC failure, as well as the secondary outcome of dislodgement/ accidental removal.

In the final comparison, a transparent sterile dressing with latexfree hypoallergenic adhesive compared with sticking plaster, Forni 2012 assessed a number of our secondary outcomes: dislodgement/ accidental removal, phlebitis, infiltration and occlusion.

Data from three of the six included trials could be pooled (Tripepi-Bova 1997; Rodriguez 2002; Chico-Padron 2011). When comparing transparent dressings with gauze, all three trials reported the secondary outcomes of phlebitis and infiltration. Two of the trials reported on the secondary outcomes of dislodgement/accidental removal (Tripepi-Bova 1997; Chico-Padron 2011).

### **Excluded studies**

We excluded one study (Machado 2005) that did not address the research question (see Characteristics of excluded studies). Two further trials (Maki 1987; Machado 2008) are awaiting further information from authors (see Characteristics of studies awaiting classification).

### **Risk of bias in included studies**

### Allocation

### Sequence generation

Five of the investigators reported that they used computer generated randomisation (Livesley 1993; Tripepi-Bova 1997; Bausone-Gazda 2010; Forni 2012) or a randomly generated number list (Chico-Padron 2011). Rodriguez 2002 did not describe the method used to generate the allocation sequence in the trial.

### Allocation concealment

Both Forni 2012 and Tripepi-Bova 1997 stated that sealed envelopes were used, but only Forni 2012 stated that the envelopes were also opaque and numbered. The Bausone-Gazda 2010 trial report stated that "randomization assignment was not provided to the venous access device team nurse until the subject had been assessed and the site determination had been made" but it was unclear how the allocation details were concealed. Allocation concealment was not described in reports of the other three trials (Livesley 1993; Rodriguez 2002; Chico-Padron 2011).

### Blinding

The appearance of dressings and securement devices were dissimilar in all of the trials so it was not possible to blind participants or personnel in any of the included trials. Outcome assessors were not blinded to the intervention in any of the included trials (Livesley 1993; Tripepi-Bova 1997; Rodriguez 2002; Bausone-Gazda 2010; Chico-Padron 2011; Forni 2012;). Two investigators had outcome assessments conducted by ward nursing staff (Livesley 1993; Tripepi-Bova 1997), another two did not identify clearly who performed the outcome assessments (Rodriguez 2002; Chico-Padron 2011). Forni 2012 had assessments performed by research nurses and Bausone-Gazda 2010 had assessments performed by the hospitals Vascular Access Device team who also recruited the participants.

### Incomplete outcome data

Four trials reported complete outcome data (Tripepi-Bova 1997; Bausone-Gazda 2010; Chico-Padron 2011; Forni 2012). In the Livesley 1993 study, the number of participants originally enrolled in the trial was not stated but group numbers reported in the results were quite unequal (69:86). This disparity may suggest either post-randomisation exclusions, drop outs or a failure to report (Livesley 1993). The Rodriguez 2002 trial was translated for us from Spanish to English; it was unclear from the translation whether data were incomplete and, if they were, whether losses had been explained.

### Selective reporting

Study protocols were not available for any of the included trials (Livesley 1993; Tripepi-Bova 1997, Rodriguez 2002; Bausone-Gazda 2010; Chico-Padron 2011; Forni 2012), so it was impossible to determine if there was selective reporting bias.

### Other potential sources of bias

Two trials had unequal numbers in the intervention groups (Tripepi-Bova 1997; Chico-Padron 2011), and one trial stopped early (Bausone-Gazda 2010). In this trial, which was manufacturer sponsored, the sample size was estimated to be 400 but only

302 patients were recruited. The reason provided for stopping the trial early was "enrolment issues and the project timeline" (Bausone-Gazda 2010).

### **Effects of interventions**

See: Summary of findings for the main comparison Transparent dressing or gauze for securing peripheral venous catheters; Summary of findings 2 Bordered transparent dressing versus securement device for securing peripheral venous catheters; Summary of findings 3 Bordered transparent dressing versus tape for securing peripheral intravenous catheters; Summary of findings 4 Transparent dressing versus sticking plaster for securing peripheral venous catheters

### Transparent dressings compared with gauze (Analysis I; SoF Table I)(3 trials)

### Primary outcome: PVC failure due to IV complications

None of the trials in this comparison reported on PVC failure due to IV complications.

# Primary outcome: adverse events related to dressings and securement devices

None of the trials in this comparison reported on adverse events.

### Secondary outcome: dislodgement and accidental removal

Two trials (278 participants) reported on dislodgement/accidental removal (Chico-Padron 2011; Tripepi-Bova 1997); the evidence from these trials was assessed as *very low quality*; the method used for group allocation was unclear and neither the personnel nor the outcome assessors were blinded to group allocation. When results were combined using a fixed-effect model ( $I^2$  0%), there were significantly fewer instances of dislodgement/accidental removal in the transparent dressing group (7/136) than in the gauze group (19/142) (RR 0.40; 95% CI 0.17 to 0.92; Analysis 1.1)).

### Secondary outcome: time to catheter failure

None of the trials in this comparison reported on time to catheter failure.

### Secondary outcome: phlebitis

Three trials (379 participants) at high risk of bias for at least two domains of the risk of bias tool, reported phlebitis as an outcome (Tripepi-Bova 1997; Rodriguez 2002; Chico-Padron 2011). There

was no evidence of a difference in rates of phlebitis between transparent dressings (16/184) and gauze (17/195) (RR 0.89; 95% CI 0.47 to 1.68; Analysis 1.2).

### Secondary outcome: infiltration

Infiltration was reported in all three trials for this comparison (379 participants) (Tripepi-Bova 1997; Rodriguez 2002; Chico-Padron 2011). All trials were assessed as being at high risk of bias. When results were combined, there was no evidence of a difference between groups in rates of infiltration (transparent dressing 21/184, gauze 29/195; RR 0.80; 95% CI 0.48 to 1.33; Analysis 1.3).

### Secondary outcomes:

- occlusion;
- CRBSI with laboratory confirmation of catheter as the source of infection;
  - suspected CRBSI;
  - entry site local infection;
  - skin damage;
  - cost;
  - patient satisfaction;
  - pain associated with dressing removal;

None of the trials in this comparison reported on these secondary outcomes

For this comparison, heterogeneity was not an issue with  $I^2$  values below 30% for all outcomes. However, with so few included trials confidence intervals were wide (> 70%).

## Bordered transparent dressing compared with a securement device (Analysis 2; SoF Table 2)(1 trial)

Only one trial, judged to be at high risk of performance and detection bias and at unclear risk for allocation concealment compared bordered transparent dressings with a securement device (Bausone-Gazda 2010). This trial included 302 participants, 150 in the bordered transparent dressing group and 152 in the securement device group, and reported four outcomes.

### Primary outcome: PVC failure

There was no evidence of a difference between groups (bordered transparent dressing 50/150 and securement device 59/152; RR 0.86; CI 0.64 to 1.16; Analysis 2.1) for PVC failure, where the catheter has been removed due to IV complications or fell out.

### Primary outcome: adverse events

Bausone-Gazda 2010 did not report on adverse events.

### Secondary outcome: dislodgement and accidental removal

The bordered transparent dressing group had fewer instances of dislodgement/accidental removal than the securement device group (P value 0.008; bordered transparent dressing 2/150 and securement device 14/152; RR 0.14; 95% CI 0.03 to 0.63; Analysis 2.2).

### Secondary outcome: time to catheter failure

Bausone-Gazda 2010 reported time to catheter failure as a proportion of failures occurring by 24, 48, 72 and 96 hours. There were no reported differences between the bordered transparent and the securement device groups for this measure.

### Secondary outcome: phlebitis

The securement device group had fewer cases of phlebitis compared with the bordered transparent dressing group (bordered transparent dressing 8/150 and securement device 1/152; RR 8.11; CI 1.03 to 64.02; Analysis 2.3). Very wide confidence intervals for this comparison indicate a very high level of uncertainty around the effect size.

### Secondary outcome: infiltration

Type of dressing showed no evidence of effect on the frequency of infiltration between groups (bordered transparent dressing 21/150 and securement device 27/152; RR 0.79; 95% CI 0.47 to 1.33; Analysis 2.4).

### Secondary outcome: cost

Cost was reported to favour the bordered transparent dressing (USD 5.65) when compared with the securement device (USD 7.56). No P values or standard deviations were provided (Bausone-Gazda 2010).

### Secondary outcomes:

- occlusion;
- CRBSI with laboratory confirmation of catheter as the source of infection;
  - suspected CRBSI;
  - entry site local infection;

  - skin damage;
  - cost;
  - patient satisfaction;
  - pain associated with dressing removal;

None of the trials in this comparison reported on these secondary outcomes

# Bordered transparent dressing compared with tape (Analysis 3; SoF Table 3)(I trial)

One trial, which was assessed as being at high risk of bias (the method used for group allocation was unclear and neither the personnel nor the outcome assessors were blinded to group allocation), compared a bordered transparent dressing and tape (Livesley 1993). This trial included 153 participants with a large disparity in the number of participants in each group (68 in the bordered transparent dressing group and 85 in the tape group). No explanation was provided for the 20% difference in group numbers. Two outcomes were assessed:

### Primary outcome: PVC failure due to IV complications

PVC failure occurred less frequently in the tape group than the bordered transparent dressing group (bordered transparent dressing 25/68 and tape 17/85; RR 1.84; 95% CI 1.09 to 3.11; Analysis 3.1.

# Primary outcome: adverse events related to dressings and securement devices

The Livesley 1993 trial did not report on adverse events.

### Secondary outcome: dislodgement and accidental removal

There was no evidence of a difference in rates of dislodgement/ accidental removal for either securement method (bordered transparent dressing 7/68 and tape 6/85; RR 1.46; 95% CI 0.51 to 4.14; Analysis 3.2).

### Secondary outcome: time to catheter failure

Livesley 1993 reported that, "using survival analysis and plotting the failure rate against duration, the difference between groups failed to reach significance level".

### Secondary outcomes:

- phlebitis;
- infiltration;
- occlusion;

• CRBSI with laboratory confirmation of catheter as the source of infection;

- suspected CRBSI;
- entry site local infection;
- skin damage;
- cost;
- patient satisfaction;
- pain associated with dressing removal;

### Transparent dressing compared with sticking plaster (Analysis 4)(I trial)

Forni 2012 was the only trial to compare a transparent dressing with a sticking plaster. We contacted the author who provided data for the first PVC only per patient. This trial was at high risk of performance and detection bias and included 706 participants; 346 in the transparent dressing group and 357 in the sticking plaster group.

### Primary outcome: PVC failure due to IV complications

The Forni 2012 trial did not report on PVC failure due to IV complications.

# Primary outcome: adverse events related to dressings and securement devices

Five cases of allergy were reported, three cases in the transparent dressing group and two in the sticking plaster group. However, information about how the allergic reaction presented and if further follow-up management of the allergy was required was not available.

### Secondary outcome: dislodgement and accidental removal

There was no evidence of an effect difference on dislodgement/accidental removal when transparent dressings were compared with sticking plaster (transparent dressing 22/346 and sticking plaster 17/357; RR 1.34; 95% CI 0.72 to 2.47; Analysis 4.1).

### Secondary outcome: time to catheter failure

The Forni 2012 trial did not report on time to catheter failure.

### Secondary outcome: phlebitis

There was no evidence of a difference in rates of phlebitis between transparent dressings (25/346) and sticking plaster (29/357) however this comparison is underpowered (RR 0.89; 95% CI 0.53 to 1.49; Analysis 4.2).

### Secondary outcome: infiltration

# None of the trials in this comparison reported on these secondary outcomes

There was no evidence of a difference in rates of Infiltration between transparent dressings (34/346) and sticking plaster (41/357)however this comparison is underpowered (RR 0.86; 95% CI 0.56 to 1.32; Analysis 4.3).

### Secondary outcome: occlusion

There was evidence of a difference in rates of occlusion between transparent dressings (39/346) and sticking plaster (36/357) however this comparison is underpowered (RR 1.12; 95% CI 0.73 to 1.72; Analysis 4.4).

### Secondary outcomes:

• CRBSI with laboratory confirmation of catheter as the source of infection;

- suspected CRBSI;
- entry site local infection;
- skin damage;
- cost;
- patient satisfaction;
- pain associated with dressing removal;

None of the trials in this comparison reported on these secondary outcomes.

### ADDITIONAL SUMMARY OF FINDINGS [Explanation]

Bordered transparent dressing versus securement device for securing peripheral venous catheters

**Patient or population:** Patients requiring a peripheral venous catheter **Settings:** Hospital or community

Intervention: Bordered transparent dressing

Comparison: Securement device

Outcomes	Illustrative comparative	risks* (95% CI)	Relative effect (95% Cl)	No of Participants (studies)	Quality of the evidence Comments (GRADE)	
	Assumed risk	Corresponding risk				
	Securement device	Bordered transparent dressing				
<b>PVC failure</b> Observation			RR 0.86	302 (1. stock)	€000 	
	388 per 1000	<b>334 per 1000</b> (248 to 450)	(0.64 to 1.16)	(1 study)	very low <sup>1,2,3,4,5</sup>	
Dislodgement/	Study population		RR 0.14	302	€000 	
accidental removal Observation	92 per 1000	<b>13 per 1000</b> (3 to 58)	(0.03 to 0.63)	(1 study)	very low <sup>1,2,3,4,6</sup>	
<b>Phlebitis</b> Observation	Study population		RR 8.11	302	000	
	7 per 1000	<b>53 per 1000</b> (7 to 421)	(1.03 to 64.02)	(1 study)	very low <sup>1,2,3,4,7</sup>	

\*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; **RR:** Risk 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 an important 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 Downgraded due to risk of bias (one level): Unblinded personnel and outcome assessors

<sup>2</sup> Downgraded due to risk of bias (one level): Unclear if allocation to groups was blinded

<sup>3</sup> Downgraded due to risk of bias (one level):The trial, which was manufacturer sponsored, was stopped early. In this trial, the sample

size was estimated to be 400 but only 302 patients were recruited

<sup>4</sup>Downgraded due to imprecision (one level): This outcome is reported in only one study

<sup>5</sup> Downgraded due to imprecision (one level): The confidence interval crosses no difference so an increase of up to 63% in the rate of

PVC failure is possible

<sup>6</sup> Downgraded due to imprecision (one level): The 95% confidence intervals ranged from 0.03 to 0.63

<sup>7</sup> Downgraded due to imprecision (two levels): The 95% confidence intervals ranged from 1.03 to 64.02

atient or population: ettings: Hospital or co ntervention: Bordered omparison: Tape		heral venous catheter				
Dutcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence Comments (GRADE)	
	Assumed risk Corresponding risk	Corresponding risk				
	Таре	Bordered transparent dressing				
PVC failure	Study population*		RR 1.84	153	000	
Observation	200 per 1000	<b>368 per 1000</b> (218 to 622)	(1.09 to 3.11)	(1 study)	<b>very low</b> <sup>1,2,3,4,5</sup>	
Dislodgement/	Study population		RR 1.46	153	000	
accidental removal Observation	71 per 1000	<b>103 per 1000</b> (36 to 292)	(0.51 to 4.14)	(1 study)	<b>very low</b> <sup>1,2,3,4,6</sup>	
Phlebitis	This outcome was not reported		Not estimable	_	See comment	

\* 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; **RR:** Risk 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 an important 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.

- <sup>1</sup> Downgraded due to risk of bias (one level): Unblinded personnel and outcome assessors
   <sup>2</sup> Downgraded due to risk of bias (one level): Unclear if allocation to groups was blinded
   <sup>3</sup> Downgraded due to risk of bias (one level): High risk of attrition bias

- <sup>4</sup> Downgraded due to imprecision (one level): This outcome is reported in only one study of 153
- <sup>5</sup>Downgraded due to imprecision (two levels): The 95% confidence intervals ranged from 1.09 to 3.11
- <sup>6</sup> Downgraded due to imprecision (two levels): The confidence interval crosses no difference so an increase of almost 4 times the
- incidence of dislodgement or accidental removal is possible
- \* Paediatic patients (excluding those at high risk e.g. intensive care, bone marrow transplant and metabolic unit patients)

Patient or population: Settings: Hospital or c Intervention: Transpar Comparison: Sticking	ent dressing	eral venous catheter			
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence Comments (GRADE)
	Assumed risk	Assumed risk Corresponding risk			
	Sticking plaster	Transparent dressing			
PVC failure	This outcome was no	t reported	Not estimable	-	See comment
Dislodgement/	Study population	Study population		703	000
accidental removal Observation	48 per 1000	<b>64 per 1000</b> (34 to 118)	— (0.72 to 2.47)	(1 study)	very low <sup>1,2,3</sup>
<b>Phlebitis</b> Observation	Study population	Study population		703	\$\$ \$ \$ \$
	81 per 1000	<b>72 per 1000</b> (43 to 121)	(0.53 to 1.49)	(1 study)	low <sup>1,2,4</sup>

\*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; **RR:** Risk 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 an important 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.

<sup>1</sup> Downgraded due to risk of bias (one level): Unblinded personnel and outcome assessors

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<sup>2</sup> Downgraded due to imprecision (one level): This outcome is reported in only one study
 <sup>3</sup> Downgraded due to imprecision (two levels): The confidence interval crosses no difference so an increase of almost 2 1/5 time the rate of dislodgement is possible

<sup>4</sup> Downgraded due to imprecision (one level): The 95% confidence intervals ranged from 0.53 to 1.49

### DISCUSSION

This systematic review compared the relative effectiveness of various dressings and securement devices to prevent PVC failure due to IV complications, such as dislodgement and accidental removal, phlebitis and infiltration. Six RCTs were included: three compared transparent dressings with gauze dressings (Tripepi-Bova 1997; Rodriguez 2002; Chico-Padron 2011); one compared a bordered transparent dressing with a securement device (Bausone-Gazda 2010); one compared a bordered transparent dressing with tape (Livesley 1993); and one compared transparent dressings to sticking plaster (Forni 2012).

### Summary of main results

### **Primary outcome**

Although the main purpose of PVC dressings and securement devices is to prevent PVC failure, only two trials addressed this outcome. One showed no evidence of a difference between a bordered transparent dressing and a securement device (Bausone-Gazda 2010), while in the other trial (Livesley 1993), tape alone was almost twice as effective in preventing catheter failure compared with a bordered transparent dressing (RR 1.84; 95% CI 1.09 to 3.11; Analysis 3.1). However, in this trial, we were unable to determine reasons for a disparity in the number of participants in each group (68 bordered transparent dressing group and 85 tape group), so the results are inconclusive.

### Secondary outcomes

All of the trials reported on one or more of the individual components of the composite primary outcome. Transparent dressings, with or without a border, were more effective in preventing dislodgement or accidental removal compared with gauze or a securement device (Tripepi-Bova 1997; Bausone-Gazda 2010; Chico-Padron 2011), but transparent dressings showed no evidence of benefit for any of the other secondary outcomes when compared with tape or sticking plaster (Livesley 1993; Forni 2012).

Phlebitis was eight times more likely to occur when a bordered transparent dressing was compared with a securement device (RR 8.11; 95% CI 1.03 to 64.02; Analysis 2.3). However, extremely the wide confidence intervals for this result indicate that there is a great deal of uncertainty about the effect size. No evidence of a difference in phlebitis rates were shown when any other dressings or devices were compared. Nor did any of the five trials measuring infiltration show any evidence of effect; irrespective of the dressing or device used to secure the PVC (Tripepi-Bova 1997; Rodriguez 2002; Bausone-Gazda 2010; Chico-Padron 2011; Forni 2012). Similarly, catheter occlusion rates showed no evidence of a difference when transparent dressings were compared with sticking

plaster (Forni 2012). Cost was the only other outcome measured; these results indicated that bordered transparent dressings were a cheaper securement method compared to a securement device. None of the single study comparisons was adequately powered to detect differences, so there is a possibility that type two errors could have occurred.

# Overall completeness and applicability of evidence

Dressings and securement devices for peripheral intravenous catheters continue to evolve, with new products regularly coming on to the market. A limited number of RCTs were available for this review, so most of the comparisons in the review had only one study contributing to the results. Consequently, some products in common use were not represented in this review. Another restriction on the completeness and applicability of the review, is that many of our primary and secondary outcomes were poorly reported. For example, only two trials assessed our primary outcome of PVC failure - the prevention of which is the main reason for applying a dressing or securement device. Moreover, other outcomes of interest, such as entry site local infection, CRBSI and patient satisfaction, were not reported at all. These omissions make the selection of an effective securement device difficult for healthcare providers. Finally, participants for this review were drawn largely from adult populations and were predominately from general medical/surgical wards and orthopaedic specialties. Emergency departments and general cancer care areas, which are frequent users of PVCs, were not included in this review. Additionally, the review included only those patients admitted to acute hospitals settings, consequently, the applicability of results to other settings, such as community and rehabilitation facilities remains unknown.

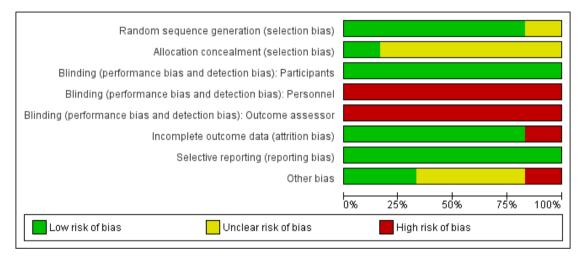
### Quality of the evidence

### Limitations in study design and implementation

The quality of the evidence was assessed as very low, using the GRADE approach (Schünemann 2011b). Risk of bias was assessed using a seven-point judgement criteria table that included: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome reporting, selective outcome reporting and other potential bias. Our assessments of risk of bias for a number of these domains in all of the included trials demonstrated limitations in study design, implementation or reporting; these have been reported elsewhere in the review (Assessment of risk of bias in included studies and summarised in Figure 2 and Figure 3). In summary, only one trial reported sufficient information for us to judge allocation concealment (Forni 2012). It was not possible to

blind personnel and participants to the intervention received, as dressings were clearly different. This can be mitigated by blinding of outcome assessment for at least some of the outcomes. In one trial the participants also received a different PVC and extension tubing according to their randomised dressing or securement device (Bausone-Gazda 2010), a co-intervention that may have had an impact on the results. Livesley 1993 reported unequal numbers in the intervention groups with more participants receiving a gauze dressing than a bordered transparent dressing, this may indicate incomplete follow-up or incomplete reporting. One of the included trials disclosed receiving manufacturer sponsorship (Bausone-Gazda 2010). In all of the trials except one (Forni 2012), the outcomes from the number of participants analysed matched the number randomised. We could not determine whether this was due to 'available case' reporting or whether there were, indeed, no losses to follow-up. In the one study where detailed recruitment and follow-up data were available (Forni 2012), losses and reasons for losses were similar across groups.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies



	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias): Participants	Blinding (performance bias and detection bias): Personnel	Blinding (performance bias and detection bias): Outcome assessor	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bausone-Gazda 2010	•	?	•	•	•	•	•	
Chico-Padron 2011	•	?	•	•	•	•	•	?
Forni 2012	•	•	•	•	•	•	•	•
Livesley 1993	•	?	•	•	•	•	•	•
Rodriguez 2002	?	?	•	•	•	•	•	?
Tripepi-Bova 1997	•	?	•	•	•	•	•	?

Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study

### Indirectness of evidence

In the only comparison where we were able to synthesise evidence from more than one trial, there was reasonable conformity between intervention products. These were all transparent dressings, that came from different manufacturers, claimed different attributes, and for which the results were published over a wide time-frame (1997 to 2011). However, the problem of indirectness occurs when head-to-head comparisons are made in different studies between one intervention (e.g. a transparent dressing) and alternative controls (e.g. in this case, a securement device, tape, gauze and sticking plaster). In such cases, it is difficult to know the relative effectiveness of say, tape against a securement device.

### Unexplained heterogeneity or inconsistency of results

In all of the pooled outcomes, heterogeneity was less than 30% indicating that, although populations and interventions varied slightly across studies, they were similar enough to combine results.

### Imprecision of results

Confidence intervals were wide in the pooled outcomes, but few studies were included and sample sizes were small. Imprecise results may reflect differences in intervention products and outcome definitions. Confidence intervals were also wide in the single studies that showed evidence of effect. In the Bausone-Gazda 2010 trial, for the 'dislodgement' outcome the CIs lay between 0.03 and 0.60, and for phlebitis between 1.04 and 67.97. When Livesley 1993 assessed PVC failure it was shown to be almost twice as high in the bordered transparent dressing group when compared with the tape group, but the CIs ranged between 1.09 and 3.11. Again, the uncertainty around the effect sizes for these outcomes suggests that further research is required to increase the level of certainty around the results.

### **Publication bias**

We feel confident that our comprehensive electronic searches identified all existing, published RCTs addressing the review question, helping to limit bias in the review process. One manufacturersponsored, observational study, comparing two different catheter stabilising systems was identified through Clinical trials.com. The trial was completed in 2013 but results have not been published. The scant contribution of the six included trials, in the face of such wide use and evolving products for PVC stabilisation, seems unusual. This may or may not indicate publication bias. There were fewer than 10 studies, so we did not construct a funnel plot.

### 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 used are transparent and reproducible. None of the review authors has reported a conflict of interest.

# Agreements and disagreements with other studies or reviews

One other systematic review has addressed a similar topic ( Hoffmann 1992). The review was published before any RCTs in this area were available, so the inclusion criteria for the review were wide (abstracts, letters, observational studies). The focus of the review was to a compare transparent polyurethane dressing with a gauze dressing for peripheral catheters. Two of the outcomes assessed in the Hoffmann 1992 review were the same as ours (phlebitis and infiltration), so we were able to compare results. Although the inclusion criteria were quite different in the Hoffman review, our results for these outcomes were in agreement and no between group differences were found for either phlebitis or infiltration. Similarly, in an earlier, quasi-RCT of 598 participants, published by the same author, no statistically significant differences were found in the rate of phlebitis between a transparent polyurethane group and a cotton gauze group (Hoffmann 1988).

### AUTHORS' CONCLUSIONS

### Implications for practice

There is no strong evidence to suggest that any one dressing or securement product for peripheral catheters is more effective than any other dressing. We found limited evidence that catheters were less likely to fail due to dislodgement or accidental removal when a transparent dressing was used, compared with gauze. Other positive outcomes, favouring one dressing over another, were based on single studies, so further trials are required to support their findings. All of the included trials were small, had either high or unclear risk of bias for one or more of the quality elements we assessed, and wide confidence intervals, indicating that further RCTs are necessary.

### Implications for research

Products included in this review were limited, as were the outcomes assessed. There is a need for suitably powered, high quality trials to evaluate the newer, high use products and novel - but

expensive - securement methods, such as surgical grade glue. Following items in the CONSORT statement when planning and reporting future trials, would provide more transparency for those assessing the quality of the studies. Important outcomes such as catheter-related bloodstream infection, entry site local infection, skin damage and the patient's satisfaction with the product were not available for assessment in this review, but should be included in future studies. Given the large cost difference between different dressings and securement devices, we believe it is important to include a planned economic analysis, including the number of dressing changes required and staff time involved. This would enable decision makers to make rational and cost effective choices when purchasing dressings and devices for peripheral catheter securement.

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\* Indicates the major publication for the study

### CHARACTERISTICS OF STUDIES

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

### Bausone-Gazda 2010

Methods	<b>Study design:</b> single-centre RCT <b>Method of randomisation:</b> computer generated <b>Concealment of allocation:</b> allocation concealed until the subject had been assessed and site determination made			
Participants	<ul> <li>Country: USA</li> <li>Number: 302 medical-surgical patients with an anticipated 96-hour need for a PVC Bordered transparent dressings were applied to 150 participants and a securement device was used for 152 participants.</li> <li>Age: bordered transparent group: mean 60 years; securement device group: mean 60.8 years</li> <li>Sex (female:male): bordered transparent group: 84:66; securement device group: 92:66 Inclusion criteria: at least 18 years of age; inpatients expected to require a PVC for 96 hours; available insertion site on the hand or arm; demonstrate cooperation with medica devices and/or treatments; able to provide consent.</li> <li>Exclusion criteria: current participants or those who have already participated in the study; PVC site located below an old infusion site or at an area of flexion; documented sensitivity to medical adhesive products; dermatitis, burns, or tattoos at or near the insertion site; diaphoretic at the time of catheter insertion; require application of topica antibiotics or ointments under the dressing; PVC site that requires a gauze pad or a tackifier; pregnant; conditions that in the opinion of the investigator of staff nurse would make the patient unsuitable for enrolment in the study</li> </ul>			
Interventions	<b>Bordered transparent group:</b> insertion of a BD Nexiva Closed IV Catheter System with a built-in stabilization platform and extension tubing with 2 split-septum access ports. The insertion site was covered with a 3M Tegaderm IV securement dressing and extension tubing secured to the skin Securement device group: insertion of a non winged B Braun Introcan Safety Catheter to which an extension tubing was attached. After placement a transparent dressing was used to cover the insertion site, and the extension tubing was secured to the skin			
Outcomes	<b>Primary outcome:</b> PVC failure - where PVC was removed due to IV complications or fell out <b>Secondary outcome:</b> dislodgement/accidental removal, phlebitis (as defined by the trial investigator)			
Notes				
Risk of bias				
Bias	Authors' judgement	Support for judgement		

### Bausone-Gazda 2010 (Continued)

Random sequence generation (selection bias)	Low risk	Quotation: "Subjects were randomised us- ing a computer-generated randomisation process"
Allocation concealment (selection bias)	Unclear risk	Quotation: "The randomisation assign- ment was not provided to the VAD nurse until the subject had been assessed and the site determination had been made"
Blinding (performance bias and detection bias) Participants	Low risk	Comment: blinding of the participants was not possible due to the type of intervention (the 2 different securement methods had different appearances). However, this was unlikely to have influenced the outcome
Blinding (performance bias and detection bias) Personnel	High risk	Comment: blinding of personnel was not possible due to the type of intervention (the 2 different securement methods had differ- ent appearances)
Blinding (performance bias and detection bias) Outcome assessor	High risk	Quotation: "When the catheter-stabiliza- tion system was removed, the VAD nurse recorded the reason for removal, ease of re- moval, any presence of adhesive residue on skin or catheter, skin redness or blisters, and the VAD nurse's overall satisfaction with the catheter and stabilization device" Comment: blinding of outcome assessor was not possible due to the type of inter- vention (the 2 different securement meth- ods had different appearances)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: number analysed matched number randomised
Selective reporting (reporting bias)	Low risk	Comment: although the protocol was not available, expected outcomes for this com- parison were reported
Other bias	High risk	Comment: the trial was stopped early. One author was an employee of the company manufacturing the intervention product

Chico-Padron 2011

Methods	Study design: single-centre RCT Method of randomisation: randomly generated number list Concealment of allocation: not stated				
Participants	Country: Spain Number: 50 patients admitted to general surgical ward and coronary intensive care unit. A transparent dressing was applied to 29 participants' PVC site and gauze to 21 participants'. Age: transparent dressing group: mean 56 years; gauze group: mean 57 years Sex: not reported Inclusion criteria: not reported Exclusion criteria: not reported				
Interventions	<b>Transparent dressing group:</b> catheter fixed to skin with sterile strip, transparent dressing applied <b>Gauze group:</b> catheter fixed to skin with sterile strip, gauze dressing applied				
Outcomes	<b>Secondary outcome:</b> dislodgement/accidental removal, phlebitis (as defined by the t investigator), infiltration, cost				
Notes					
Risk of bias					
Bias	Authors' judgement	Support for judgement			
Random sequence generation (selection bias)	Low risk	Quotation: "used a randomly generated numbers list for assignment"			
Allocation concealment (selection bias)	Unclear risk	Comment: not described			
Blinding (performance bias and detection bias) Participants	Low risk	Comment: blinding of the participants was not possible due to the type of intervention (the 2 different securement methods had different appearances). However, this was unlikely to have influenced the outcome			
Blinding (performance bias and detection bias) Personnel	High risk	Comment: blinding of personnel was not possible due to the type of intervention (the 2 different securement methods had differ- ent appearances)			
Blinding (performance bias and detection bias) Outcome assessor	High risk	Comment: blinding of outcome assessor was not possible due to the type of inter- vention (the 2 different securement meth- ods had different appearances)			
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: all recruited patients accounted for in results			

# Chico-Padron 2011 (Continued)

Selective reporting (reporting bias)	Low risk	Comment: protocol not available, but out- comes stated in design were reported
Other bias	Unclear risk	Comment: unequal number of participants allocated to groups. Participants may have had a catheter in situ when assigned to a group and consequently, some of the out- comes may have been due to the previous dressing
Forni 2012		
Methods	<b>Study design:</b> single-centre RCT <b>Method of randomisation:</b> computer gene <b>Concealment of allocation:</b> opaque enve indicated by the computer generated list	erated lopes were used according to the sequence
Participants	Country: Italy Number: 703 paediatric and adult patients with orthopedic/traumatological problems and orthopedic oncological diseases. A transparent dressing was applied to 346 partici- pants' PVC site and sticking plaster to 357 participants'. Age: transparent dressing group: mean 54.9 years; sticking plaster group: mean 55.4 years Sex (female:male): unable to extract Inclusion criteria: required PVC for at least 24 hours; informed consent Exclusion criteria: a known allergy to one of the 2 plasters/dressings; undergoing stem cell transplantation; treated in a day-surgery setting; an allergy to chlorhexidine 0.5% in alcohol (skin preparation); under intensive short-term observation; PVC placed at another hospital	
Interventions	<b>Transparent dressing group:</b> transparent sterile dressing made of highly permeable polythene film, with latex free hypoallergenic adhesive <b>Sticking plaster group:</b> non sterile, elastic, vellum-like polyester lined sticking plaster with hypoallergenic adhesive	
Outcomes	Secondary outcome: dislodgement/accidental removal, phlebitis (as defined by the trial investigator), infiltration, occlusion	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quotation: "A randomised list in blocks of ten was generated by a computer"

# Forni 2012 (Continued)

Allocation concealment (selection bias)	Low risk	Opaque envelopes were used to contain the type of securement device according to the sequence indicated by the list
Blinding (performance bias and detection bias) Participants	Low risk	Comment: blinding of the participants was not possible due to the type of intervention (the 2 different securement methods had different appearances). However, this was unlikely to have influenced the outcome
Blinding (performance bias and detection bias) Personnel	High risk	Comment: blinding of personnel was not possible due to the type of intervention (the 2 different securement methods had differ- ent appearances)
Blinding (performance bias and detection bias) Outcome assessor	High risk	Comment: blinding of outcome assessor was not possible due to the type of inter- vention (the 2 different securement meth- ods had different appearances)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: all randomised catheters were reported in the outcome tables. Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups
Selective reporting (reporting bias)	Low risk	Comment: no protocol was available how- ever expected outcomes were reported
Other bias	Low risk	

# Livesley 1993

Methods	Study design: single-centre RCT Method of randomisation: computer generated Concealment of allocation: not described
Participants	Country: England Number: 155 paediatric patients form a paediatric university teaching hospital (exclud- ing intensive care, metabolic unit and bone marrow transplant unit). A bordered trans- parent dressing was applied to 69 participants' PVC site and tape to 86 participants' Age: mean age not provided Sex: not provided Inclusion criteria: children being cannulated for the first time for the present admission; informed consent from parent or guardian Exclusion criteria: not described

# Livesley 1993 (Continued)

Interventions	<b>Bordered transparent dressing group:</b> the PVC was secured with a sterile dressing, Venigard <sup>®</sup> , and a 'T'-piece extension set with a Luer-lock was attached between the cannula hub and extension set or administration set <b>Tape:</b> non sterile tape was used to secure the cannula with an extension or administration set fixed to the hub of the cannula
Outcomes	<b>Primary outcome:</b> PVC failure - where PVC was removed due to IV complications or fell out <b>Secondary outcome:</b> dislodgement/accidental removal
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quotation: "a computer-generated num- bers list to randomise children prospec- tively"
Allocation concealment (selection bias)	Unclear risk	Comment: not stated
Blinding (performance bias and detection bias) Participants	Low risk	Comment: blinding of the participants was not possible due to the type of intervention (the 2 different securement methods had different appearances). However, this was unlikely to have influenced the outcome
Blinding (performance bias and detection bias) Personnel	High risk	Comment: blinding of personnel was not possible due to the type of intervention (the 2 different securement methods had differ- ent appearances)
Blinding (performance bias and detection bias) Outcome assessor	High risk	Comment: blinding of outcome assessor was not possible due to the type of inter- vention (the 2 different securement meth- ods had different appearances)
Incomplete outcome data (attrition bias) All outcomes	High risk	Comment: number enrolled not stated. Unequal number in groups suggests drop outs or failure to report
Selective reporting (reporting bias)	Low risk	Comment: protocol unavailable. Only catheter failure and accidental removal were mentioned in the methods section and both were reported in results

# Livesley 1993 (Continued)

Other bias	Low risk	Funding was provided in part by a manu- facturer of Intravenous Infusion machines, but these product were not included in the study	
Rodriguez 2002			
Methods	Study design: single-centre Method of randomisation Concealment of allocation	: not described	
Participants	applied to their PVC site ar Age: transparent dressing g Sex (female:male): transpa Inclusion criteria: need for Exclusion criteria: need for the hand; emergency patien	Country: Spain Number: 100 patients participated in this trial, 47 participants had a transparent dressing applied to their PVC site and 53 participants had a gauze dressing Age: transparent dressing group: mean 63.69 years; gauze group: mean 59.44 years Sex (female:male): transparent dressing group:13:34; gauze group: 20:33 Inclusion criteria: need for a PVC on the forearm or back of hand Exclusion criteria: need for a CVL; PVC in a location other than forearm or back of the hand; emergency patients; patients not part of trial at catheterization; patients with allergies requiring a different type of adhesive dressing	
Interventions	1 00	<b>Transparent dressing group:</b> 3M Tegaderm transparent <sup>TM</sup> <b>Gauze group:</b> gauze dressing	
Outcomes	Secondary outcome: phleb	itis (as defined by the trial investigator), infiltration	
Notes			

# Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Comment: not stated
Allocation concealment (selection bias)	Unclear risk	Comment: not stated
Blinding (performance bias and detection bias) Participants	Low risk	Comment: blinding of the participants was not possible due to the type of intervention (the 2 different securement methods had different appearances). However, this was unlikely to have influenced the outcome
Blinding (performance bias and detection bias) Personnel	High risk	Comment: blinding of personnel was not possible due to the type of intervention (the 2 different securement methods had differ- ent appearances)

# Rodriguez 2002 (Continued)

Blinding (performance bias and detection bias) Outcome assessor	High risk	Comment: blinding of outcome assessor was not possible due to the type of inter- vention (the 2 different securement meth- ods had different appearances)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: all recruited patient were ac- counted for in results
Selective reporting (reporting bias)	Low risk	Comment: protocol unavailable. Phlebitis and infiltration were mentioned in the methods section and both were reported in results
Other bias	Unclear risk	Comment: unable to extract this data

# Tripepi-Bova 1997

Methods	Study design: single-centre RCT Method of randomisation: computer generated Concealment of allocation: sealed envelopes	
Participants	Country: USA Number: 229 patients from 6 units (2 medical cardiology, surgical cardiology, general internal medicine, orthopedic and neurological intensive care). A transparent dressing was applied to 108 participants' PVC site and gauze to 121 participants' Age: not stated Sex: not stated Inclusion criteria: not stated Exclusion criteria: not stated	
Interventions	<b>Transparent dressing:</b> Opsite®(Smith & Nephew, Quebec, Canada) applied directly over the insertion site. Tape applied to secure the IV tubing <b>Gauze:</b> Mirasorb <sup>®</sup> sponges (5 cm x 5 cm; Johnson & Johnson Medical Inc, Arlington, Texas) applied directly over the insertion site. Tape applied to secure the IV tubing	
Outcomes	<b>Secondary outcome:</b> dislodgement/accidental removal, phlebitis (as defined by the trial investigator), infiltration	
Notes		
Risk of bias	Risk of bias	
Bias	Authors' judgement Support for judgement	
Random sequence generation (selection bias)	Low risk	Quotation: "Eligible patients were assigned randomly, by means of computer generated randomised codes in sealed envelopes"

## Tripepi-Bova 1997 (Continued)

Allocation concealment (selection bias)	Unclear risk	Comment: no mention that the envelopes were opaque. There was insufficient infor- mation about the concealment provided to make a judgement of risk of bias
Blinding (performance bias and detection bias) Participants	Low risk	Comment: blinding of the participants was not possible due to the type of intervention (the 2 different securement methods had different appearances). However, this was unlikely to have influenced the outcome
Blinding (performance bias and detection bias) Personnel	High risk	Comment: blinding of personnel was not possible due to the type of intervention (the 2 different securement methods had differ- ent appearances)
Blinding (performance bias and detection bias) Outcome assessor	High risk	Comment: blinding of outcome assessor was not possible due to the type of inter- vention (the 2 different securement meth- ods had different appearances)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Comment: all recruited patients accounted for in results
Selective reporting (reporting bias)	Low risk	Comment: no protocol was available how- ever expected outcomes were reported
Other bias	Unclear risk	Comment: unclear due to the unequal numbers in each group

# Abbreviations

CVL = central venous line PVC = peripheral venous catheter RCT = randomised controlled trial

# Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Machado 2005	Did not address the research question

# Characteristics of studies awaiting assessment [ordered by study ID]

## Calvino Gunther 2014

Methods	Single centre, 2-arm RCT
Participants	Patients > 18 years admitted to an intensive care unit
Interventions	3M <sup>tm</sup> IV Advanced (intervention), 3M <sup>tm</sup> HP (control for 9 months) or Smith and Nephew IV3000 <sup>tm</sup> (control for seven months)
Outcomes	Post-insertion complications, mean number of complication per patient, time of occurrence, life span of catheters, number of disrupted dressings, and tolerance
Notes	Awaiting assessment

## Machado 2008

Methods	RCT
Participants	Children aged 0-12 years
Interventions	Sterile gauze (intervention), transparent dressing (intervention) and adhesive tape (control)
Outcomes	Unclear
Notes	Awaiting response from author

#### Maki 1987

Methods	RCT
Participants	Adults over 18 years
Interventions	Eight ply fine mesh sterile gauze and tape (intervention), polyurethane transparent adhesive dressing (intervention), transparent dressing with a poly- <i>N</i> -vinyl-pyrolidone-acrylated adhesive that contained 2% titratable iodine iodophor antiseptic (intervention) and sterile gauze replaced every 48 hours (control)
Outcomes	Unclear
Notes	Awaiting response from author

#### Marsh 2014

Methods	Single centre, 4-arm RCT
Participants	Patients in an acute hospital who required a peripheral venous catheter

# Marsh 2014 (Continued)

Interventions	Intervention 1: Hystoacryl glue and a standard polyurethane dressing (SPU); Intervention 2: a bordered polyurethane dressing; Intervention 3: a sutureless securement device and SPU; Control: SPU
Outcomes	Peripheral intravenous catheter failure.
Notes	Awaiting assessment

# Abbreviation

RCT = randomised controlled trial

# DATA AND ANALYSES

## Comparison 1. Transparent dressing versus gauze

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Dislodgement/accidental	2	278	Risk Ratio (M-H, Fixed, 95% CI)	0.40 [0.17, 0.92]
removal				
2 Phlebitis	3	379	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.47, 1.68]
3 Infliltration	3	379	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.48, 1.33]

# Comparison 2. Bordered transparent dressing versus securement device

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 PVC failure	1	302	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.64, 1.16]
2 Dislodgement/accidental removal	1	302	Risk Ratio (M-H, Fixed, 95% CI)	0.14 [0.03, 0.63]
3 Phlebitis	1	302	Risk Ratio (M-H, Fixed, 95% CI)	8.11 [1.03, 64.02]
4 Infiltration	1	302	Risk Ratio (M-H, Fixed, 95% CI)	0.79 [0.47, 1.33]

# Comparison 3. Bordered transparent dressing versus tape

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 PVC failure	1	153	Risk Ratio (M-H, Fixed, 95% CI)	1.84 [1.09, 3.11]
2 Dislodgement/accidental removal	1	153	Risk Ratio (M-H, Fixed, 95% CI)	1.46 [0.51, 4.14]

# Comparison 4. Transparent dressing versus sticking plaster

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Dislodgement/accidental removal	1	703	Risk Ratio (M-H, Fixed, 95% CI)	1.34 [0.72, 2.47]
2 Phlebitis	1	703	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.53, 1.49]
3 Infliltration	1	703	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.56, 1.32]
4 Occlusion	1	703	Risk Ratio (M-H, Fixed, 95% CI)	1.12 [0.73, 1.72]

Devices and dressings to secure peripheral venous catheters to prevent complications (Review)

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# Analysis I.I. Comparison I Transparent dressing versus gauze, Outcome I Dislodgement/accidental removal.

Review: Devices and dressings to secure peripheral venous catheters to prevent complications

Comparison: I Transparent dressing versus gauze

Outcome: I Dislodgement/accidental removal

Study or subgroup	Transparent	Gauze	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H,Fixed,95% Cl		M-H,Fixed,95% CI
Chico-Padron 2011	1/29	1/21		6.4 %	0.72 [ 0.05, 10.93 ]
Tripepi-Bova 1997	6/107	18/121		93.6 %	0.38 [ 0.16, 0.91 ]
Total (95% CI)	136	142	•	100.0 %	0.40 [ 0.17, 0.92 ]
Total events: 7 (Transparent	:), 19 (Gauze)				
Heterogeneity: Chi <sup>2</sup> = 0.20,	, df = 1 (P = 0.65); $I^2 = 0$	0.0%			
Test for overall effect: $Z = 2$	2.14 (P = 0.032)				
Test for subgroup difference	es: Not applicable				
			0.01 0.1 1 10 100		
			Favours transparent Favours gauze		

## Analysis I.2. Comparison I Transparent dressing versus gauze, Outcome 2 Phlebitis.

Review: Devices and dressings to secure peripheral venous catheters to prevent complications

Comparison: I Transparent dressing versus gauze

#### Outcome: 2 Phlebitis

Study or subgroup	Transparent	Gauze	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H,Fixed,95% Cl		M-H,Fixed,95% CI
Chico-Padron 2011	8/29	5/21	-	33.9 %	1.16 [ 0.44, 3.04 ]
Rodriguez 2002	6/47	8/53		44.0 %	0.85 [ 0.32, 2.26 ]
Tripepi-Bova 1997	2/108	4/121		22.1 %	0.56 [ 0.10, 3.00 ]
Total (95% CI)	184	195	+	100.0 %	0.89 [ 0.47, 1.68 ]
Total events: 16 (Transparent), 1	7 (Gauze)				
Heterogeneity: Chi <sup>2</sup> = 0.59, df =	= 2 (P = 0.74); I <sup>2</sup> =0	.0%			
Test for overall effect: $Z = 0.36$ (	(P = 0.72)				
Test for subgroup differences: No	ot applicable				

0.01 0.1 1 10 100 Favours transparent Favours gauze

## Analysis I.3. Comparison I Transparent dressing versus gauze, Outcome 3 Infliltration.

Review: Devices and dressings to secure peripheral venous catheters to prevent complications

Comparison: I Transparent dressing versus gauze

Outcome: 3 Infliltration

Study or subgroup	Transparent n/N	Gauze n/N	Risk Ratio M-H,Fixed,95% Cl	Weight	Risk Ratio M-H,Fixed,95% Cl
Chico-Padron 2011	2/29	0/21		2.0 %	3.67 [ 0.19, 72.63 ]
Rodriguez 2002	0/47	4/53		14.9 %	0.13 [ 0.01, 2.26 ]
Tripepi-Bova 1997	19/108	25/121	<b>–</b>	83.1 %	0.85 [ 0.50, 1.46 ]
Total (95% CI)	184	195	•	100.0 %	0.80 [ 0.48, 1.33 ]
Total events: 21 (Transparer Heterogeneity: Chi <sup>2</sup> = 2.63, Test for overall effect: Z = 0 Test for subgroup difference	$df = 2 (P = 0.27); I^2 = 2$ 0.86 (P = 0.39)	24%			
			0.01 0.1 1 10 100 Favours transparent Favours gauze		

# Analysis 2.1. Comparison 2 Bordered transparent dressing versus securement device, Outcome 1 PVC failure.

Review: Devices and dressings to secure peripheral venous catheters to prevent complications

Comparison: 2 Bordered transparent dressing versus securement device

Outcome: I PVC failure

Study or subgroup	Bordered transparent n/N	Securement device n/N	Risk Ratio M-H,Fixed,95% Cl		Weight	Risk Ratio M-H,Fixed,95% Cl	
Bausone-Gazda 2010	50/150	59/152	-	d,7570 Cl	100.0 %	0.86 [ 0.64, 1.16 ]	
Total (95% CI)	150	152	•		100.0 %	0.86 [ 0.64, 1.16 ]	
Total events: 50 (Bordered	transparent), 59 (Securement	device)					
Heterogeneity: not applica	ble						
Test for overall effect: Z =	0.99 (P = 0.32)						
Test for subgroup difference	es: Not applicable						
			0.01 0.1 1	10 100	)		
		Favou	urs b-transparent	Favours secure	ement device		

## Analysis 2.2. Comparison 2 Bordered transparent dressing versus securement device, Outcome 2 Dislodgement/accidental removal.

Review: Devices and dressings to secure peripheral venous catheters to prevent complications

Comparison: 2 Bordered transparent dressing versus securement device

Outcome: 2 Dislodgement/accidental removal

Study or subgroup	Bordered transparent	Securement device	F	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H,Fix	ed,95% Cl		M-H,Fixed,95% CI
Bausone-Gazda 2010	2/150	14/152	<mark></mark>		100.0 %	0.14 [ 0.03, 0.63 ]
Total (95% CI)	150	152	-		100.0 %	0.14 [ 0.03, 0.63 ]
Total events: 2 (Bordered t	transparent), 14 (Securement	device)				
Heterogeneity: not applica	ble					
Test for overall effect: Z =	2.59 (P = 0.0097)					
Test for subgroup difference	es: Not applicable					
			0.01 0.1	I IO IOO		
		Fav	ours b-transparent	Favours secure	ment device	

#### Analysis 2.3. Comparison 2 Bordered transparent dressing versus securement device, Outcome 3 Phlebitis.

Review: Devices and dressings to secure peripheral venous catheters to prevent complications

Comparison: 2 Bordered transparent dressing versus securement device

Outcome: 3 Phlebitis

-

-

Study or subgroup	Bordered transparent	Securement device		Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H,F	ixed,95% Cl		M-H,Fixed,95% Cl
Bausone-Gazda 2010	8/150	1/152			100.0 %	8.11 [ 1.03, 64.02 ]
Total (95% CI)	150	152			100.0 %	8.11 [ 1.03, 64.02 ]
Total events: 8 (Bordered t	transparent), I (Securement c	device)				
Heterogeneity: not applica	ble					
Test for overall effect: $Z =$	I.98 (P = 0.047)					
Test for subgroup difference	es: Not applicable					
			0.01 0.1	I IO IOO		
		Favo	ours b-transparent	Favours secure	ment device	

# Analysis 2.4. Comparison 2 Bordered transparent dressing versus securement device, Outcome 4 Infiltration.

Review: Devices and dressings to secure peripheral venous catheters to prevent complications

Comparison: 2 Bordered transparent dressing versus securement device

Outcome: 4 Infiltration

Study or subgroup	Bordered transparent	Securement device		Risk Ratio		Weight	Risk Ratio
	n/N	n/N		M-H,Fixed,95% C	1		M-H,Fixed,95% CI
Bausone-Gazda 2010	21/150	27/152				100.0 %	0.79 [ 0.47, 1.33 ]
Total (95% CI)	150	152		•		100.0 %	0.79 [ 0.47, 1.33 ]
Total events: 21 (Bordered	transparent), 27 (Securement	t device)					
Heterogeneity: not applical	ble						
Test for overall effect: Z =	0.89 (P = 0.37)						
Test for subgroup difference	es: Not applicable						
			0.01 (	D.I I IO	100		

Favours b-transparent Favours securement device

#### Analysis 3.1. Comparison 3 Bordered transparent dressing versus tape, Outcome I PVC failure.

Review: Devices and dressings to secure peripheral venous catheters to prevent complications

Comparison: 3 Bordered transparent dressing versus tape

Outcome: I PVC failure

Study or subgroup	Bordered transparent n/N	Tape n/N	Risk Ratio M-H,Fixed,95% Cl	Weight	Risk Ratio M-H,Fixed,95% CI
Livesley 1993	25/68	17/85		100.0 %	.84 [  .09, 3.   ]
Total (95% CI)	68	85	•	100.0 %	1.84 [ 1.09, 3.11 ]
Total events: 25 (Bordere	ed transparent), 17 (Tape)				
Heterogeneity: not appli	cable				
Test for overall effect: Z	= 2.26 (P = 0.024)				
Test for subgroup differe	nces: Not applicable				
			0.01 0.1 1 10 100	0	
		Favou	rs b-transparent Favours tape		

## Analysis 3.2. Comparison 3 Bordered transparent dressing versus tape, Outcome 2 Dislodgement/accidental removal.

Review: Devices and dressings to secure peripheral venous catheters to prevent complications

Comparison: 3 Bordered transparent dressing versus tape

Outcome: 2 Dislodgement/accidental removal

Study or subgroup	Bordered transparent	Tape	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H,Fixed,95% Cl		M-H,Fixed,95% Cl
Livesley 1993	7/68	6/85		100.0 %	1.46 [ 0.51, 4.14 ]
Total (95% CI)	68	85	-	100.0 %	1.46 [ 0.51, 4.14 ]
Total events: 7 (Bordered	d transparent), 6 (Tape)				
Heterogeneity: not appli	cable				
Test for overall effect: Z	= 0.71 (P = 0.48)				
Test for subgroup differe	nces: Not applicable				
			0.01 0.1 1 10 100		
		Favour	rs b-transparent Favours tape		

### Analysis 4.1. Comparison 4 Transparent dressing versus sticking plaster, Outcome I Dislodgement/accidental removal.

Review: Devices and dressings to secure peripheral venous catheters to prevent complications

Comparison: 4 Transparent dressing versus sticking plaster

Outcome: I Dislodgement/accidental removal

Study or subgroup	Transparent n/N	Sticking plaster n/N	Risk Ratio M-H,Fixed,95% Cl	Weight	Risk Ratio M-H,Fixed,95% Cl
Forni 2012	22/346	17/357		100.0 %	1.34 [ 0.72, 2.47 ]
Total (95% CI)	346	357	•	100.0 %	1.34 [ 0.72, 2.47 ]
Total events: 22 (Transpar	rent), 17 (Sticking plaste	er)			
Heterogeneity: not applic	able				
Test for overall effect: Z =	= 0.92 (P = 0.36)				
Test for subgroup differen	ices: Not applicable				
				1	
			0.01 0.1 1 10	100	
			Favours transparent Favours stic	king plaster	

### Analysis 4.2. Comparison 4 Transparent dressing versus sticking plaster, Outcome 2 Phlebitis.

Review: Devices and dressings to secure peripheral venous catheters to prevent complications

Comparison: 4 Transparent dressing versus sticking plaster

Outcome: 2 Phlebitis

Study or subgroup	Transparent n/N	Sticking plaster n/N	1	Risk Ratio 1-H,Fixed,95% C		Weight	Risk Ratio M-H,Fixed,95% Cl
Forni 2012	25/346	29/357			I	00.0 %	0.89 [ 0.53, 1.49 ]
Total (95% CI)	346	357		•	100	).0 %	0.89 [ 0.53, 1.49 ]
Total events: 25 (Transpa	rent), 29 (Sticking plaste	er)					
Heterogeneity: not applic	able						
Test for overall effect: Z =	= 0.45 (P = 0.66)						
Test for subgroup differer	nces: Not applicable						
			0.01 0.	I I I0	100		
			Favours transpa	rent Favour	s sticking plaster		

# Analysis 4.3. Comparison 4 Transparent dressing versus sticking plaster, Outcome 3 Infliltration.

Review: Devices and dressings to secure peripheral venous catheters to prevent complications

Comparison: 4 Transparent dressing versus sticking plaster

Outcome: 3 Infliltration

Study or subgroup	Transparent n/N	Sticking plaster n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% Cl
Forni 2012	34/346	41/357		100.0 %	0.86 [ 0.56, 1.32 ]
Total (95% CI)	346	357	•	100.0 %	0.86 [ 0.56, 1.32 ]
Total events: 34 (Transpa	rent), 41 (Sticking plaste	er)			
Heterogeneity: not applic	able				
Test for overall effect: Z =	= 0.71 (P = 0.48)				
Test for subgroup differer	nces: Not applicable				
			0.01 0.1 1 10 10	0	
			Favours transparent Favours sticking	ng plaster	

## Analysis 4.4. Comparison 4 Transparent dressing versus sticking plaster, Outcome 4 Occlusion.

Review: Devices and dressings to secure peripheral venous catheters to prevent complications

Comparison: 4 Transparent dressing versus sticking plaster

Outcome: 4 Occlusion

Study or subgroup	Transparent n/N	Sticking plaster n/N	Risk Ratio M-H,Fixed,95% Cl	Weight	Risk Ratio M-H,Fixed,95% Cl
Forni 2012	39/346	36/357		100.0 %	1.12 [ 0.73, 1.72 ]
Total (95% CI)	346	357	+	100.0 %	1.12 [ 0.73, 1.72 ]
Total events: 39 (Transpa	rent), 36 (Sticking plast	er)			
Heterogeneity: not applic	able				
Test for overall effect: Z =	= 0.51 (P = 0.61)				
Test for subgroup differer	nces: Not applicable				
				L	
			0.01 0.1 1 10 10	00	

Favours transparent Favours sticking plaster

# APPENDICES

## Appendix I. Search strategies

#### **MEDLINE:**

1 exp Catheterization, Peripheral/ (8005) 2 (peripheral venous catheter\* or PVC).tw. (3869) 3 1 or 2 (11753) 4 exp Occlusive Dressings/ (3380) 5 (securement device\* or Statlock or Hubguard).tw. (27) 6 ((occlusive or gauze or tape or polyurethane or permeable or nonpermeable or non-permeable or transparent or antimicrobial) adj3 dressing\$).ti,ab. (1506) 7 (opsite or tegaderm or micropore or hypafix).tw. (1015) 8 or/4-7 (5250) 9 3 and 8 (59) **EMBASE:** 1 exp Catheterization, Peripheral/ (132218) 2 (peripheral venous catheter\* or PVC).tw. (6567) 3 1 or 2 (138442) 4 exp Occlusive Dressings/ (506) 5 (securement device\* or Statlock or Hubguard).tw. (54) 6 ((occlusive or gauze or tape or polyurethane or permeable or nonpermeable or non-permeable or transparent or antimicrobial) adj3 dressing\$).ti,ab. (2149) 7 (opsite or tegaderm or micropore or hypafix).tw. (1738) 8 or/4-7 (4134)

9 3 and 8 (144) 10 Randomized controlled trials/ (44267) 11 Single-Blind Method/ (18729) 12 Double-Blind Method/ (121977) 13 Crossover Procedure/ (39367) 14 (random\$ or factorial\$ or crossover\$ or cross over\$ or cross-over\$ or placebo\$ or assign\$ or allocat\$ or volunteer\$).ti,ab. (1333989) 15 (doubl\$ adj blind\$).ti,ab. (149615) 16 (singl\$ adj blind\$).ti,ab. (14549) 17 or/10-16 (1399725) 18 exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/ (20843564) 19 human/ or human cell/ (15195392) 20 and/18-19 (15148733) 21 18 not 20 (5694831) 22 17 not 21 (1209068) 23 9 and 22 (50) **CINAHL:** S22S9 AND S21 S21S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 S20TX allocat\* random\* S19(MH "Quantitative Studies") S18(MH "Placebos") S17TX placebo\* S16TX random\* allocat\* S15(MH "Random Assignment") S14TX randomi\* control\* trial\* S13TX ( (singl\* n1 blind\*) or (singl\* n1 mask\*) ) or TX ( (doubl\* n1 blind\*) or (doubl\* n1 mask\*) ) or TX ( (tripl\* n1 blind\*) or (tripl\* n1 mask\*) ) or TX ( (trebl\* n1 blind\*) or (trebl\* n1 mask\*) ) S12TX clinic\* n1 trial\* S11PT Clinical trial S10(MH "Clinical Trials+") S9(S4 OR S5 OR S6 OR S7) AND (S3 AND S8) S8S4 OR S5 OR S6 OR S7 S7TI ( (opsite or tegaderm or micropore or hypafix) ) OR AB ( (opsite or tegaderm or micropore or hypafix) ) S6TI ( ((occlusive or gauze or tape or polyurethane or permeable or non permeable or non-permeable or transparent or antimicrobial) n3 dressing\*) ) OR AB ( ((occlusive or gauze or tape or polyurethane or permeable or non-permeable or non-permeable or transparent or antimicrobial) n3 dressing\*)) S5TI ( (securement device\* or Statlock or Hubguard) ) OR AB ( (securement device\* or Statlock or Hubguard) ) S4(MH "Occlusive Dressings") S3S1 OR S2 S2TI ( (peripheral venous catheter\* or PVC) ) OR AB ( (peripheral venous catheter\* or PVC) ) S1(MH "Catheterization, Peripheral+")

#### Appendix 2. 'Risk of bias' table judgement criteria

#### I. Was the allocation sequence generated adequately?

• Low risk of bias - adequate sequence generation is described in sufficient detail for example, using a computer random number generator, random number tables, coin tossing or shuffling envelopes

• High risk of bias - non random component in sequence generation is described by the author. This description usually involves a systematic non-random approach, for example, sequence generated by odd or even date of birth; by a rule based on date of admission or on hospital or clinic record number.

• Unclear - Insufficient information about the sequence generation provided to make a judgement of risk of bias.

#### 2. Was the allocation sequence adequately concealed?

• Low risk of bias - participants and investigators enrolling participants could not forsee allocation assignment because one of the following methods was used for allocation concealment: central allocation, for example, via 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: an open random allocation schedule; assignment without appropriate safeguards, for example non-opaque envelopes or envelopes that were not sequentially-numbered; alternation of rotation; date of birth; case record number; or any other unconcealed procedure.

• Unclear - Insufficient information about the concealment provided to make a judgement of risk of bias.

# 3. Blinding of participants and personnel - was knowledge about the allocation of interventions adequately prevented during the study?

• Low risk of bias - either of the following: no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by the lack of blinding; or blinding of participants and the study personnel ensured, and unlikely that the blinding could have been broken

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

• Unclear - either of the following: insufficient information provided to permit judgement of risk of bias; or the study did not address the outcome.

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

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

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

• Unclear - either of the following: insufficient information provided to permit judgement of risk of bias; or the study did not address this outcome.

#### 5. Were incomplete outcome data adequately addressed?

• Low risk of bias - any one of the following: no missing outcome data; reasons for missing outcome data are unlikely to be related to true outcome (for survival data, censoring is 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 is 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 is 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 is 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 is 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 is enough to induce clinically relevant bias in observed effect size; 'as-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation; potentially inappropriate application of simple imputation.

• Unclear - either of the following: insufficient reporting of attrition/exclusions to permit 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.

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

• Low risk of bias - either of the following: the study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; or 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 provided to permit judgement of risk bias.

#### 7. 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.

#### Appendix 3. Glossary

Colonisation: the presence of bacteria or other micro-organisms in a specific body part or a device in the body

Dwell time: number of hours/days that a device remains in a patient

Erythema: redness or inflammation of the skin

Intravascular device: a catheter or device that is placed within a vessel (vein or artery) and used for intravascular access

Intravascular fluids: liquid that is delivered intravascularly, usually from a fluid bag, via a line or administration set and through an intravascular device

Peripheral venous catheter (PVC): a flexible, hollow, plastic tube that is inserted into a peripheral vein

Phlebitis: irritation to a vein wall caused by the presence of an intravascular device

Skin integrity: a description of a patient's skin, whether it is intact or not

## CONTRIBUTIONS OF AUTHORS

Nicole Marsh: conceived and developed the protocol and co-ordinated its development, completed the first draft of the review, coordinated edits of subsequent drafts, made an intellectual contribution, approved the final version of the review prior to submission.

Joan Webster: conceived and developed the protocol and co-ordinated its development, contributed to the review and subsequent drafts, made an intellectual contribution, approved the final version of the review prior to submission.

Gabor Mihala: performed statistical analyses using RevMan and, in addition, made an intellectual contribution, approved the final version of the review prior to submission.

Claire Rickard: conceived and developed the protocol and co-ordinated its development, completed the first draft of the review, made an intellectual contribution, approved the final version of the review prior to submission.

#### **Contributions of editorial base**

Nicky Cullum: edited the review; advised on methodology, interpretation and review content. Approved the review for submission. Liz McInnes, Editor: approved the final protocol prior to submission.

Sally Bell-Syer: co-ordinated the editorial process. Advised on methodology, interpretation and content. Edited the review. Ruth Foxlee and Amanda Briant: designed the search strategy and edited the search methods section.

Rachel Richardson: checked and edited the protocol.

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Gabor Mihala and Joan Webster: nothing to declare

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# INDEX TERMS

## Medical Subject Headings (MeSH)

\*Bandages; \*Calcium Sulfate; \*Surgical Tape; Adhesives; Catheter Obstruction; Catheter-Related Infections [prevention & control]; Catheterization, Peripheral [adverse effects; instrumentation; \*methods]; Catheters [\*adverse effects]; Extravasation of Diagnostic and Therapeutic Materials [prevention & control]; Oligopeptides; Phlebitis [prevention & control]; Randomized Controlled Trials as Topic

## MeSH check words

Humans