Clinically indicated replacement versus routine replacement of peripheral venous catheters (Protocol)

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This is a reprint of a Cochrane protocol, prepared and maintained by The Cochrane Collaboration and published in The Cochrane Library 2009, Issue 2

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Clinically indicated replacement versus routine replacement of peripheral venous catheters

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Editorial group: Cochrane Peripheral Vascular Diseases Group.


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ABSTRACT

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

To assess the effects of removing peripheral IV catheters when clinically indicated compared with removing and re-siting the catheter routinely.
BACKGROUND

Among hospitalised patients, intravenous therapy is the most common invasive procedure. It is associated with a phlebitis rate of between 2.3% and 60% (White 2001; Gupta 2007) and an intravenous catheter-related bacteraemia rate of approximately 0.8% (Maki 1991). Current guidelines recommend that peripheral intravenous catheters should be re-sized every 72 to 96 hours to restrict infection potential (O’Grady 2002), and most hospitals follow this recommendation. The most recent guidelines state “replace peripheral venous catheters at least every 72 to 96 hours in adults to prevent phlebitis” (p.762) and carries a category rating of 1B (strongly recommended for implementation and supported by some experimental, clinical or epidemiological studies). However, the guideline cites only one study to support the recommendation. This was a paper published in 1998 and based on data collected in 1998 (Lai 1998). Since then, there have been improvements in catheter design and composition and more recent studies indicate that the recommendation may need to be revised.

Description of the condition

Peripheral vein infusion thrombophlebitis is characterized by pain, erythema (reddening, swelling, and palpable thrombosis of the cannulated vein (Monreal 1999)). Diagnosis remains controversial and a number of grading systems have been proposed, including the Maddox scale (Maddox 1977) and the Baxter scale (Panadero 2002), which rank infusion thrombophlebitis according to the severity of clinical signs and symptoms. The scales are limited because not all symptoms may be present or they may not always be present in the clusters described in the scales. Consequently, many investigators define peripheral vein infusion thrombophlebitis based on two or more of the following: pain, tenderness, warmth, erythema (redness of the skin), swelling, and a palpable cord (Maki 1991; Monreal 1999). Although the precise pathogenesis of thrombus formation remains unclear it is thought to be related to inflammation of the vein wall. Studies have been unable to demonstrate a high correlation between phlebitis and catheter infection and Maki has suggested that phlebitis may be primarily a physical response (Maki 1991). This was supported by Catney and colleagues when investigating the aetiology of phlebitis; they found that drug irritation, size of catheter and the person inserting the catheter were all predictors (Catney 2001). Ultrasonographic imaging has demonstrated thrombus formation in two thirds of catheterised veins studied and it has been suggested that catheter design may be implicated (Evertie 1997). Thus, possible causes of phlebitis are mechanical irritation from the catheter and the properties of the infusate or intravenous (IV) administered medications.

Description of the intervention

The intervention under consideration is replacing an intravenous peripheral catheter only if there are clinical indications to do so. Clinical indications include blockage, pain, redness, infiltration, swelling, leakage and phlebitis.

How the intervention might work

Each time skin integrity is breached, a potential portal for pathogens is provided. For example, Uslusoy (2008) found a significant relationship between the number of times infusions were started and phlebitis (Uslusoy 2008). There is also some support for this relationship from observational studies that have compared outcomes between cannulas remaining in situ for varying periods. In an adequately powered observational study, which included patients from medical wards and intensive care units, the investigators were unable to demonstrate any increased risk for phlebitis beyond the second day (Bregenzer 1998). Similarly, in a retrospective study of 784 IV starts, the rate of phlebitis on days one and two was 11.5% dropping to 3.9% by day four (Homer 1998). The authors concluded that “there appeared to be less risk in continuing therapy beyond the third day than re-starting the therapy” (pp304). Catney 2001 also failed to demonstrate any increase in phlebitis rates with the passage of time with failure rates being less at 144 hours (1.9%) than at 72 hours (2.5%) Catney 2001. Similarly, in a prospective investigation of 305 peripheral catheters there were 10 cases of infusion phlebitis amongst patients who had their catheter in situ for less than 72 hours, whereas none were reported in patients where the dwell time was longer (White 2001). In the same study, there were three cases of post-infusion phlebitis; these all occurred amongst patients whose peripheral vein infusion catheter had been in place for less than 72 hours. Even among a high risk population of oncology and infectious diseases patients, phlebitis rates were no different when length of cannulation was dichotomised to three days or less and more than three days (Cornely 2002).

Why it is important to do this review

These observational studies create uncertainty around the CDC guidelines relating to peripheral intravenous catheter management. This has led some hospitals to adopt the practice of re-siting only where there is evidence of inflammation or infiltration (personal communication). Making the guidelines even more difficult to rationalise is the recommendation for peripheral catheter replacement in children, which states “do not replace peripheral catheters unless clinically indicated” (CDC,15; pp761). This recommendation was based on several studies using dwell times of intravenous catheters of greater than 72 hours (Catney 2001; Cornely 2002; Shimandle 1999). Insertion of a peripheral intravenous catheter can be a painful and traumatic process and, if unnecessary, adds not only to patient’s discomfort but also has
significant cost implications for the institution. There is a clear need to provide direction for clinicians through systematically reviewing existing studies.

**OBJECTIVES**

To assess the effects of removing peripheral IV catheters when clinically indicated compared with removing and re-siting the catheter routinely.

**METHODS**

**Criteria for considering studies for this review**

**Types of studies**

All randomised controlled trials comparing routine removal of peripheral IV catheters with removal only when clinically indicated will be considered.

**Types of participants**

Any patient requiring a peripheral IV catheter to be in situ for at least three days for the administration of intermittent or continuous therapy (this may include patients in hospitals, nursing homes or in community settings).

**Types of interventions**

Any duration of routine replacement versus clinically indicated replacement will be included.

**Types of outcome measures**

**Primary outcomes**

- Thrombophlebitis (using any definition identified by the trial author).
- Cost (in terms of materials and labour associated with IV catheter-related insertion). This may be unavailable in some reports so cost is not an inclusion criteria.

**Secondary outcomes**

- Infiltration (defined as permeation of IV fluid into the interstitial compartment, causing swelling of the tissue around the site of the catheter).
- Catheter occlusion (identified by the inability to infuse fluids).
- Number of catheter re-sites.
- IV-related sepsis (localised or systemic).
- Mortality.
- Pain.
- Satisfaction.

**Search methods for identification of studies**

**Electronic searches**

The Cochrane Peripheral Vascular Diseases (PVD) Group will search their Trials Register and the Cochrane Central Register of Controlled Trials (CENTRAL) in *The Cochrane Library* for publications describing randomised controlled trials of routine peripheral IV replacement compared with replacement based on clinical indications. The PVD Group's Trials Register is compiled from electronic searches of MEDLINE (1950 to date), EMBASE (1980 to date), and CINAHL (1982 to date), and through handsearching relevant journals. The full list of journals that have been handsearched, as well as the search strategies used to search databases are described in the editorial information about the Cochrane PVD Group in *The Cochrane Library* http://www.mrw.interscience.wiley.com/cochrane/clabout/articles/PVD/frame.html.

The review authors will search the Cochrane Central Register of Controlled Trials (CENTRAL), (*The Cochrane Library*, latest issue) using the strategy described in Appendix 1 and MEDLINE (1950 to current) using the search strategy described in Appendix 2.

**Searching other resources**

We will contact researchers and manufacturers in order to obtain any unpublished data. Reference lists of potentially useful articles will also be searched. We will also use ‘Google’ to search the world wide web for other relevant articles. There will be no restriction on language.

**Data collection and analysis**

**Selection of studies**
Titles and abstracts identified through the search process will be independently reviewed by JW and SO. Full reports of all potentially relevant trials will be retrieved for further assessment of eligibility based on the inclusion criteria. Differences of opinion will be settled by consensus or referral to a third reviewer. There will be no blinding of authorship.

**Data extraction and management**

Two review authors will independently assessed the quality of eligible trials, using the PVD quality assessment criteria outlined below. Disagreements between review authors will be resolved by consensus or referral to a third reviewer. We will contact investigators of included trials to resolve any ambiguities.

**Assessment of risk of bias in included studies**

**Adequacy of the randomisation process**
A - Adequate sequence generation is reported for example, using random number tables, computer random number generator, coin tossing or card shuffling.
B - did not specify on the adequate reported methods in (A) but mentioned randomisation method.
C - Other method of allocation that may not be random.

**Adequacy of allocation concealment**
A - Adequate: allocation concealment described that would not allow investigators /participants to know or influence intervention group before eligible participant entered in the study, for example central randomisation, serially numbered, opaque, sealed envelopes.
B - Unclear: unclearly concealed trials in which the author either did not report allocation concealment approach at all, or reported an approach that was not clearly adequate.
C - Inadequate: inadequately concealed trials in which the method of allocation is not concealed, such as alternation methods or unsealed envelopes; any information in the study that indicated that investigators or participants could influence intervention group.

**Blinding**
A - Blinding of treatment providers: Yes/No/Unclear.
B - Blinding of participants: Yes/No/Unclear.
C - Blinding of outcome assessor: Yes/No/Unclear.
D - Blinding of data analysis: Yes/No/Unclear.

**Intention-to-treat analysis (ITT)**
A - Yes: Specifically reported by authors that ITT was undertaken and this was confirmed on study assessment, or not stated but evident form study assessment that ITT was undertaken.
B - Unclear: Described as ITT analysis but unable to confirm on study assessment, or not reported and unable to confirm by study assessment.
C - No: Lack of ITT analysis confirmed on study assessment, for example patients who were randomised were not included in the analysis because they did not receive the study intervention, or they withdrew from the study, or were not included because of protocol violation, regardless of whether ITT reported or not.

**Completeness of follow up**
Percentage of participants for whom data was completed at defined study end-point.

**Measures of treatment effect**
For individual trials, effect measures for categorical outcomes will include relative risk (RR) with its 95% confidence interval (CI). For statistically significant effects, number needed to treat (NNT), or number needed to harm (NNH), will be calculated. For continuous outcomes, the effect measure will be mean difference (MD) or, if the scale of measurement differs across trials, standardized mean difference (SMD), each with its 95% CI. For any meta-analyses (see below), for categorical outcomes the typical estimates of RR with their 95% CI will be calculated; and for continuous outcomes the weighted mean difference (WMD) or a summary estimate for SMD, each with its 95% CI, will be calculated.

Data will be analysed using The Cochrane Collaboration's Review Manager (RevMan) 5 software.

**Unit of analysis issues**
We do not anticipate any unit of analysis issues. Cross-over trials are not eligible. Cluster randomised trials are not expected in this field. It is possible that one patient may experience more than one episode of thrombophlebitis (or other outcome) during the period of study. We plan to analyse the data as the proportion of participants having one or more episodes.

**Dealing with missing data**
If some outcome data remain missing despite our attempts to obtain complete outcome data from authors, we will perform an available-case analysis, based on the numbers of patients for whom outcome data are known. If standard deviations are missing, we will impute them them from other studies or, where possible, compute them from standard errors using the formula SD = SE X √N , where these are available Higgins 2008.
Assessment of heterogeneity
Heterogeneity will be assessed visually and by using the chi-squared statistic with significance being set at P < 0.10. In addition, the degree of heterogeneity will be investigated by calculating the I² statistic Higgins 2008. If evidence of significant heterogeneity is identified (> 50%), we will explore potential causes and a random-effects approach to the analysis will be used.

Assessment of reporting biases
Reporting bias will be assessed using guidelines in Cochrane Hand- book for Systematic Reviews of Interventions Higgins 2008.

Data synthesis
Where appropriate, results of comparable trials will be pooled using a fixed-effect model and the pooled estimate together with its 95% CI will be reported. We will conduct a narrative review of eligible studies where statistical synthesis of data from more than one study is not possible or considered not appropriate.

Subgroup analysis and investigation of heterogeneity
We plan to analyse potential sources of heterogeneity using the following subgroup analyses:

1. Type of randomisation (truly randomised versus not reported).
2. Concealment of allocation (adequate versus not reported).
3. Blinding (patients and clinicians blinded versus open-label).
4. Statement of withdrawals and losses to follow up in each group (stated versus not stated).
5. Intermittent versus continuous infusion.

Sensitivity analysis
We will perform sensitivity analyses to explore the effect of the following criteria:

1. Concealment of allocation.
2. Size of studies (< 100 patients versus at least 100 patients).
3. Duration of follow up.
4. Unpublished studies (if any).

ACKNOWLEDGEMENTS
We are grateful to Heather Maxwell, PVD Review Group Co-ordinator, for her support and speedy responses, and to the editors Mr Paul Tisi and Dr Jackie Price for their useful comments.

REFERENCES

Additional references

Bregenzer 1998

Catney 2001

Cornely 2002

Everitt 1997

Gupta 2007

Higgins 2008

Homer 1998

Lai 1998
Lai KK. Safety of prolonging peripheral cannula and i.v. tubing use from 72 hours to 96 hours. American Journal of Infection Control 1998:26:66–70.

Maddox 1977

Maki 1991

Monreal 1999
O'Grady 2002

Panadero 2002

Shimandle 1999

Uslusoy 2008

White 2001

* Indicates the major publication for the study

### Appendixes

#### Appendix 1. Central search strategy

#1 MeSH descriptor PHLEBITIS exp. trees 1, 2 and 3
#2 phlebitis in All Text
#3 thrombophlebitis in All Text
#4 (#1 OR #2 OR #3)
#5 MeSH descriptor INFUSIONS, intravenous
#6 intravenous infusion* in All Text
#7 peripheral vein infusion* in All Text
#8 peripheral intravenous catheter* OR PICs in All Text
#9 peripheral IVs in All Text
#10 catheterization indwelling in All Text
#11 intravenous peripheral cannula* in All Text
#12 peripheral venous canula* in All Text
#13 (#5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #12)
#14 (#4 AND #13)
Appendix 2. MEDLINE search strategy

#1 MeSH PHLEBITIS exp.
#2 MeSH THROMBOPHLEBITIS
#3 phlebitis in All Fields
#4 periphlebitis in All Fields
#5 thrombophlebitis in All Fields
#6 (#1 OR #2 OR #3 OR #4 OR #5)
#7 MeSH INFUSIONS, intravenous
#8 MeSH CATHETERIZATION, peripheral
#9 intravenous infusion* in All Fields
#10 peripheral venous catheter* in All Fields
#11 peripheral intravenous catheter* OR PIC
#12 peripheral IVs in All Fields
#13 intravenous peripheral cannula* in All Fields
#14 peripheral venous canula* in All Fields
#15 peripheral vein infusion* in All Fields
#16 (#7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15)
#17 MeSH RANDOMIZED CONTROLLED TRIAL.pt.
#18 MeSH RANDOMIZED CONTROLLED TRIALS.topic
#19 MeSH CONTROLLED CLINICAL TRIAL .pt.
#20 MeSH RANDOM ALLOCATION
#21 MeSH DOUBLE-BLIND METHOD
#22 MeSH SINGLE-BLIND METHOD
#23 MeSH PLACEBOS
#24 MeSH CLINICAL TRIALS exp
#25 random* ti,ab
#26 placebo* ti,ab
#27 MeSH COMPARATIVE STUDY
#28 (#17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #26 OR #27)
#29 (#6 AND #16 AND #28)

HISTORY

Protocol first published: Issue 2, 2009

CONTRIBUTIONS OF AUTHORS

JW conceived the idea for the review. JW and SO wrote the protocol and JH wrote the search strategy.

JW will search for and select trials, assess methodological quality of trials, extract and enter data, analyse the results and draft the final review.

SO will search for trials, arbitrate on the selection of trials, interpret the analysis and draft the final review.

JH will comment on the draft review.

CR will select trials for inclusion, extract data, check data entry, interpret the analysis and comment on the draft review.
DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

• No sources of support supplied

External sources

• Chief Scientist Office, Scottish Government Health Directorates, The Scottish Government, UK.