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Prayle AP, Hurley MN, Smyth AR.
Percutaneous lines for delivering intravenous antibiotics in people with cystic fibrosis.
Cochrane Database of Systematic Reviews 2010, Issue 11. Art. No.: CD008243.
DOI: [10.1002/14651858.CD008243.pub2](https://doi.org/10.1002/14651858.CD008243.pub2).

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[Intervention Review]

Percutaneous lines for delivering intravenous antibiotics in people with cystic fibrosis

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Editorial group: Cochrane Cystic Fibrosis and Genetic Disorders Group.

Publication status and date: Edited (no change to conclusions), published in Issue 6, 2017.

Citation: Prayle AP, Hurley MN, Smyth AR. Percutaneous lines for delivering intravenous antibiotics in people with cystic fibrosis. *Cochrane Database of Systematic Reviews* 2010, Issue 11. Art. No.: CD008243. DOI: [10.1002/14651858.CD008243.pub2](https://doi.org/10.1002/14651858.CD008243.pub2).

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ABSTRACT

Background

Percutaneous long lines (long intravenous lines) and short intravenous lines (also termed cannulae) are both used to deliver intravenous antibiotics in cystic fibrosis to treat respiratory exacerbations of the disease. The perceived advantage of a long intravenous line is a greater duration of line function, which has to be balanced against a technically more challenging insertion procedure, and the possibility of more discomfort on insertion.

Objectives

To compare long intravenous lines with short intravenous lines in people with cystic fibrosis receiving intravenous antibiotics, in terms of lifespan of the line, ease of insertion, complication rates of the line and patient satisfaction. This will help patients and clinicians choose between devices.

Search methods

We searched the Cochrane Cystic Fibrosis and Genetic Disorders Group Trials Register comprising references identified from comprehensive electronic database searches and handsearches of relevant journals and abstract books of conference proceedings.

Date of most recent search: 26 August 2010.

Selection criteria

Randomised studies comparing long intravenous lines with short intravenous lines or comparing different types of long intravenous lines.

Data collection and analysis

We identified two studies, one comparing long intravenous lines with short intravenous lines, and one comparing two different types of long intravenous lines.

Main results

Two studies (67 participants) were included in the review. Based on the published reports, both studies had potential for bias in several domains. There is some evidence that long intravenous lines are superior to short intravenous lines. One study of 20 participants found that the lifespan of a long intravenous line is longer than that of a short intravenous line, and that participants preferred the long

intravenous lines to short intravenous lines. A further study of 47 participants found no difference in lifespan, or participant preference when comparing two different long intravenous lines (the Hydrocath and Vygon EC). Neither study was powered to detect differences in serious complications of the devices.

Authors' conclusions

There is some evidence to support the use of long intravenous lines rather than short intravenous lines, in terms of lifespan of the line and patient satisfaction. There is no evidence to suggest that any one type of long intravenous line is superior, and currently choice of line should be determined by operator and patient preference. There are numerous devices available which are used in cystic fibrosis. Further research is required to identify clinically important differences between these devices.

PLAIN LANGUAGE SUMMARY

Intravenous antibiotics can be delivered through a variety of devices

In cystic fibrosis, patients require prolonged courses of intravenous antibiotics. There are several devices which can be used to administer intravenous antibiotics, including peripheral cannulae (which we have termed short intravenous lines) and percutaneous (through the skin) long intravenous lines. A percutaneous long intravenous line is a flexible narrow tube which is inserted with a needle through the skin into a vein and threaded further up the vein than a short intravenous line. We have found two trials comparing these devices and including 67 participants in total. The studies compared different devices, so we could not pool the information from the two studies. However, one study showed that long intravenous lines last for longer than short intravenous lines (thus reducing the number of procedures which a participant has to undergo for a course of antibiotics). Patient satisfaction was higher with long intravenous lines compared to short intravenous lines. The study comparing two different types of long intravenous line did not show that one type was clearly better than another. Neither study was large enough to show differences in complications for the different devices. Neither study reported on important outcomes, such as the number of attempts required to insert the device. We recommend further research to compare different types of percutaneous long intravenous line.

BACKGROUND

Description of the condition

Cystic fibrosis (CF) is the commonest life-limiting inherited disorder of the white population (O'Sullivan 2009). People with CF are usually diagnosed in childhood, either by screening, or due to symptoms such as the inability to pass stools in the first 24 hours of life, failure to grow and gain weight, or recurrent chest infections. Diagnosis of CF is by a sweat test, and high levels of sweat chloride measured on two occasions are considered diagnostic of the condition. In the UK approximately 1 in 25 people are carriers, and approximately 1 in 3000 babies of northern European descent are born with the condition, however there is variability between populations (Mateu 2002).

Many of the organ systems of the body can be affected by CF, such as the pancreas (causing problems with digestion and diabetes), the liver, bones (causing metabolic bone disease and osteoporosis) and the reproductive system (leading to reduced fertility). However, a chronic cough and recurrent lung infections (pulmonary exacerbations) are often the most disabling features of the disease, and the reason why the majority of individuals are looked after primarily in specialist respiratory clinics. There are a number of reasons why people with CF develop recurrent lung infections and the merits of these various hypotheses are debated extensively in the literature (Chmiel 2003). These lung infections require treatment, and whilst on occasion they may be treated by antibiotics taken by mouth, as the disease progresses pulmonary exacerbations require long courses (such as 10 to 14 days) of antibiotics administered into the vein (intravenous (IV) antibiotics).

Description of the intervention

There are several methods for delivering IV antibiotics. A short IV line (also termed a cannula) is a short flexible plastic tube inserted over a hollow needle which protrudes just beyond the tip of the plastic tube. This is normally inserted into a peripheral vein such as one in the hand or forearm. After insertion of the needle and IV line into the vein, the needle is removed, the IV line is taped in position, and IV medications can be administered via the IV line. A long IV line is a variant of this, in which the vein is punctured with a needle, and a longer (several centimetres) flexible hollow tube is inserted through the needle into the vein, following which the needle is removed. These are also inserted into peripheral veins. There are several differing designs of these. Some designs involve inserting a thin flexible wire through the needle into the vein and then the needle is removed, following which the long line is inserted into the vein over the wire, and then the wire is removed (the "Seldinger Technique", used for shorter long lines). In other designs the long line is threaded directly through the needle, and then the needle is removed. Insertion of short and long IV lines are typically done at the participant's bedside. Long IV lines can be of varying lengths - the longest terminate in a central vein (these are often termed Peripherally Inserted Central Catheters or PICCs). Long IV lines are used in several other patient populations (for example cancer chemotherapy), and observational studies suggest that these are a safe option for long-term IV access (Abedin 2008). Both long IV lines and short IV lines are inserted percutaneously (through the skin).

A third commonly used method in CF is via totally implantable vascular access devices, which are inserted in the operating theatre.

These have been the subject of another Cochrane review (A-Rahman 2003) and therefore are not considered in this review.

Definitions used in this review

There are no consensus definitions within the literature. We will define a short IV line as a short percutaneous IV device of less than 5 cm length. This group would include cannulae. We will define a long IV line as a percutaneous catheter which is inserted beyond 5 cm. As this definition of long line will include lines of differing lengths, when comparing different types of long lines in this review we will state the length of the line.

How the intervention might work

Any bedside IV procedure is accompanied by discomfort, and often distress. Therefore, an intervention which is required less often is beneficial for the individual. Antibiotic courses in people with CF are usually over a week in duration. However, short IV lines usually last for several days before they cease to work; this usually happens when a short IV line tip migrates out of the vein into surrounding tissue. Long IV lines are said to last longer. However, balanced against this, long IV lines are technically more challenging and take longer to insert, thus potentially increasing the discomfort for the individual.

Why it is important to do this review

Long IV lines are perceived to decrease the need for repeated peripheral cannulation which can occur with short IV lines; however, they are associated with complications, including increased difficulty of placement with associated pain and distress. There are several different products available. This review will aim to find out if long IV lines are more effective than short IV lines and to resolve which are the best types of long IV lines.

OBJECTIVES

To compare long IV lines with short IV lines in people with CF receiving IV antibiotics, in terms of lifespan of the line, ease of insertion, complication rates of the line and patient satisfaction.

To compare different types of long IV lines. Lines can be subtyped by method of insertion (e.g. Seldinger versus 'through the needle'), length and gauge of the line, and material properties of the line (e.g. silastic versus plastic).

To assess if aids to insertion (i.e. with or without ultrasound guidance) impact upon the successful insertion rate.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised (including any appropriately randomised model e.g. cluster randomised studies) and quasi-randomised studies. Both blinded and unblinded studies were considered.

Types of participants

People with CF of any age who have a course of IV antibiotics administered by a percutaneous device (excluding studies in which individuals have a totally subcutaneous indwelling IV access device e.g. a portacath).

Cystic fibrosis was defined as ([Rosenstein 1998](#)):

"One or more characteristic phenotypic features

- or a history of CF in a sibling
- or a positive newborn screening test result

AND an increased sweat chloride concentration by pilocarpine iontophoresis on two or more occasions

- or identification of two CF mutations
- or demonstration of abnormal nasal epithelial ion transport".

Individuals of any age were included. However, given the differences between paediatric and adult practice, we planned to subgroup participants by age.

Types of interventions

We compared:

1. Any type of long IV line versus short IV line;
2. Different types of long IV line.

We considered any setting (e.g. bedside, radiology suite, theatre) and include both the use of ultrasound guidance for placing the device or no use of ultrasound.

Types of outcome measures

Primary outcomes

1. Lifespan of the line (number of days)
2. Number of procedures required for the duration of a 14-day course of antibiotics
3. Complications of the device (phlebitis, occlusion, thrombosis, allergic reaction to device, other 'malfunction')

Secondary outcomes

1. Number of attempts required to insert device
 - a. with ultrasound guidance
 - b. without ultrasound guidance
2. Time taken to insert device
3. Participant satisfaction with the device (e.g. validated or not validated questionnaire, if this is reported)
4. Incidence of bacteraemia - an episode of bacteraemia will be defined as a positive blood culture, including coagulase negative *Staphylococcus* species as these are the most common cause of sepsis associated with IV lines
5. Completion of 14 days of planned antibiotic course
6. Number of doses of antibiotic missed

Search methods for identification of studies

Electronic searches

Relevant studies were identified from the Group's Cystic Fibrosis Trials Register using the term: catheter.

The Cystic Fibrosis Trials Register is compiled from electronic searches of the Cochrane Central Register of Controlled Trials (Clinical Trials) (updated each new issue of *The Cochrane Library*), quarterly searches of MEDLINE, a search of EMBASE to 1995 and the prospective hand searching of two journals - *Pediatric*

Pulmonology and the *Journal of Cystic Fibrosis*. Unpublished work is identified by searching the abstract books of three major cystic fibrosis conferences: the International Cystic Fibrosis Conference; the European Cystic Fibrosis Conference and the North American Cystic Fibrosis Conference. For full details of all searching activities for the register, please see the relevant sections of the [Cystic Fibrosis and Genetic Disorders Group Module](#).

Date of latest search: 26 August 2010.

We searched www.clinicaltrials.gov and [International Standard Randomised Controlled Trial Number Register](#) (ISRCTN) for ongoing studies, please see appendices ([Appendix 1](#); [Appendix 2](#)).

Date of latest searches: 06 September 2010.

Searching other resources

We reviewed the reference lists of the included studies to search for additional studies. We contacted manufacturers who supply the UK National Health Service (NHS) with IV devices to request unpublished data. We contacted the following manufacturers: BD medical (Oxford, UK); Kimal PLC (Droitwich, UK); Smith Medical International (Kent, UK); Teleflex Medical (High Wycombe, UK); and Vygon UK Ltd (Gloucestershire, UK).

The personal collections of the authors were hand searched.

Data collection and analysis

Selection of studies

In order to select studies for inclusion, the first and second authors (AP and MH) independently reviewed relevant studies. We did not blind review authors to the authors of the studies. We resolved any disagreement regarding inclusion of a study by discussion.

Data extraction and management

Two authors (AP and MH) used a standard data extraction form to acquire data for analysis from each study. Where there are multiple reports of the same study, we linked them together and evaluated them as a single study. We judged that outcome data were missing from the report of several studies, and as planned, attempted to contact the author of the study reports to request further information. We attempted to contact the authors of both the included studies ([Lacy 1996](#); [Williams 1988](#)) and one study awaiting classification ([Pradeepkumar 1992](#)). However, we were not able to make contact.

Two authors (AP and MH) collected results for the outcomes specified as of interest in the protocol. Where it was unclear whether the study report states the standard deviation (SD) or the standard error (SE), the review authors attempted to contact the author of the study report for clarification and to request the SD. However, we were unable to make contact to clarify these issues. We converted any SEs to SDs ($SD = SE \times \text{square root of } n$).

Prior to undertaking the review, we planned to extract data for time points within the two-week course of antibiotics. A two-week period is the usual duration of a course of IV antibiotics ([UK Cystic Fibrosis Trust Antibiotic Working Group](#)). With the data available to us from the published reports, we were not able to do this. We therefore reported on all the pre-specified outcomes for the total duration of the course of antibiotics.

Prior to the review, we planned to note the types of analgesia and anaesthesia used to aid line insertion where possible (topical cream, spray, subcutaneous local anaesthetic, entonox inhalation, oral or IV sedation, general anaesthetic) and the setting where the line was inserted (bedside, theatre, radiology), and whether ultrasound guidance was used. None of these were reported.

Prior to undertaking the review, we reasoned that studies may analyse data in different ways. Some may randomise patients to the first IV line during a course of antibiotics, and report only on this episode. Others may randomise the patient for a type of line for the total duration of the study. If participants remained within the same arm for the total duration of the 14-day course of antibiotics, we analysed the rate of required insertions per participant, and the number of procedures required per participant (to take account of the correlation for each participant). If participants were randomised for only the first device in a course of antibiotics, we analysed the lifespan of the first inserted line per participant, and the complications for that line.

We analysed the number of attempts required to insert the device as rate per participant, to take account of the correlation for each participant, given that participants may have several lines. We only considered attempts in which the type of device was randomised.

Assessment of risk of bias in included studies

We assessed the risk of bias as described in Chapter 8 of *The Cochrane Handbook for Reviews of Interventions* (Higgins 2008a). This included consideration of sequence generation, allocation concealment, and incomplete outcome data. In particular the authors did not assume that data were missing at random, and considered whether this was due to selective outcome reporting. No published protocols were available for the included studies; therefore we could not compare protocol with reported methods.

Given the nature of the treatments compared (a large long IV line versus a small short IV line) and the fact that these are usually recognisable by both the participant and the investigator on visual inspection, blinding of participants and personnel is recognized to be difficult to achieve. However, it may be possible in the study design to blind outcome assessors to some of the outcomes, and therefore the authors considered this in their assessment of the study.

Measures of treatment effect

We analysed dichotomous data, such as complications of the device, by calculating the risk ratio (RR) with its 95% confidence intervals (CIs). We categorized episodes of bacteraemia as dichotomous data, with two groups of either "no episodes of bacteraemia" or "one or more episodes of bacteraemia". We recorded the means and SDs for continuous variables and analysed these data, such as the number of procedures required during the course of antibiotics, by calculating the mean difference (MD) with its 95% CIs.

For the outcome 'Participant satisfaction with the device' our analysis depended upon the tool used by the study investigators to measure participant satisfaction. We anticipated that a narrative description of participant satisfaction would be possible, but that further comparison statistics would not be appropriate if differing tools were used in each included study. A linear analogue score was used to assess participant satisfaction in a number of studies.

We analysed these data as continuous. If, in future, different measurements of participant satisfaction are used to assess the same comparisons, we plan to calculate the standardised mean difference.

Unit of analysis issues

We planned to include cluster randomised studies in our analysis. We intended to take care when incorporating their results to check that the reported analysis was not performed as if the randomisation had been undertaken at the level of the individual rather than the cluster (i.e. that there is no 'unit of analysis' error). If future revisions include cluster randomised studies, we will attempt to correct for this as described in Chapter 16 of *The Cochrane Handbook for Reviews of Interventions* (Higgins 2008b).

In the future, if studies with multiple treatment groups are included, (for example comparing a short IV line versus one type of long IV line and another type of long IV line), we plan to combine the groups which use a long IV line and compare these to the short IV line group.

Dealing with missing data

Where possible and if necessary, we attempted to contact the original authors to request missing data; to date we have received no replies. We assessed the impact which these missing data have upon the risk of bias (such as due to selective reporting of outcomes).

Having assessed the risk of bias, we analysed only the available data, in an available-case analysis.

Assessment of heterogeneity

For future updates, if we include more studies, we plan to assess heterogeneity visually on a forest plot. We also plan to use the I^2 statistic to assess heterogeneity between studies (Higgins 2003). We will categorise heterogeneity as low, moderate, substantial and considerable by the I^2 values: 0% to 40%; 30% to 60%; and 50% to 90%; and 75% to 100% respectively.

Assessment of reporting biases

For future updates, if we include more studies (at least 10 studies reported) we plan to assess for publication bias with a funnel plot. However, if less than 30 studies are included, we plan to interpret the funnel plot with caution (Lau 2006). If we find asymmetry of the funnel plot, we plan to consider alternative explanations as described in chapter 10 of *The Cochrane Handbook for Reviews of Interventions* (Higgins 2008c).

If study protocols had been available, we planned to compare these to the final study reports to investigate selective reporting of results within studies. However, we were unable to find published protocols of the included studies.

Data synthesis

We used a fixed-effect model to analyse the data. If we had found a moderate or higher level of heterogeneity (such as an I^2 of over 30%) between studies, we planned to use a random-effects model.

Subgroup analysis and investigation of heterogeneity

If we identified heterogeneity between studies (see [Assessment of heterogeneity](#)), we planned to investigate this by performing subgroup analyses. There are differences between the size of veins in children and adults. Children have smaller veins which might be more suited to different designs of devices. We therefore considered a subgroup analysis of children, if the data published from identified studies allowed this. We planned to perform a subgroup analysis of different methods for analgesia and anaesthesia (topical, sedation, general anaesthesia). However, all the identified studies were undertaken in children, and methods of analgesia were not reported. Therefore we did not perform these subgroup analyses.

Sensitivity analysis

For future updates, when we include more studies, we plan to perform a sensitivity analysis based on the overall risk of bias of the study, including analyses of all studies and also analyses of studies including unclear and high risk of bias ([Higgins 2008a](#)). We also plan to investigate the impact of using a fixed-effect model versus a random-effects model.

We recorded any arbitrary decisions (e.g. whether to categorise a type of device as a short or long IV line) made during the implementation of the protocol in the study file. In the future, we plan to assess the effect of these at the data analysis stage with a series of sensitivity analyses.

If in the future, we incorporate cluster randomised studies into a meta-analysis, we plan to perform a sensitivity analysis to analyse the impact of this upon the result.

RESULTS

Description of studies

Results of the search

Three studies were identified by the Group's Trials Search Co-ordinator ([Lacy 1996](#); [Williams 1988](#); [Pradeepkumar 1992](#)). Two of these are included ([Lacy 1996](#); [Williams 1988](#)); and one is currently awaiting assessment ([Pradeepkumar 1992](#)).

We contacted manufacturers of long IV lines (BD Medical, Kimal PLC, Smith Medical International, Teleflex Medical and Vygon). No further studies were identified from the manufacturers. Searches of www.clinicaltrials.gov and [ISRCTN](#) revealed no ongoing studies.

Included studies

Study characteristics

Two single-centre unblinded randomised studies were eligible for inclusion (including 67 participants) ([Lacy 1996](#); [Williams 1988](#)).

Both are from the same UK regional children's CF centre. Williams described a randomised comparison of a silastic long IV line versus a short IV line ([Williams 1988](#)). The participants were 20 children with CF who required IV antibiotics; median age was 13 years (range 5 to 16 years). Lacy described a randomised comparison of two different designs of long IV lines, a Hydrocath (a hydrophilic coated polyurethane catheter) inserted using the Seldinger technique and a Vygon EC (a silastic catheter) inserted using the 'through the needle' technique ([Lacy 1996](#)). There were 47 paediatric participants; median age was 11 years (range 1.5 to 17.5 years).

For each study, though not specifically described, device insertion was probably performed on a hospital ward, either at the bedside or in a treatment room. Ultrasound guidance was not used. Lines were inserted by "one of three doctors experienced in the techniques" ([Williams 1988](#)) or "one of three doctors experienced in the technique of inserting the silastic catheter but with no previous clinical experience with the Hydrocath" ([Lacy 1996](#)).

Outcomes measured

Primary outcomes

Both studies reported on two of the primary outcomes of the review - lifespan of the line and complications of the device. Neither reported on the number of procedures required for the duration of a 14-day course of antibiotics.

Secondary outcomes

Neither study reported on the number of attempts required to insert the device. Lacy reported on the time taken to insert the device ([Lacy 1996](#)). Both studies report on participant satisfaction using an arbitrary visual analogue scale. Both studies report on bacteraemia. Neither report on the completion of a 14-days course of antibiotics, but Lacy reported on the proportion of completed courses of antibiotics with a single line ([Lacy 1996](#)). Neither reported on the number of doses of antibiotics missed.

In routine clinical practice most of these outcomes would probably be recorded, however, without the study protocols we are unable to ascertain whether they were either not collected as part of the study, or collected but not reported on.

Excluded studies

No identified studies were excluded. It is unclear whether one study was randomised (see [Studies awaiting classification](#)).

Risk of bias in included studies

See [Figure 1](#)

Figure 1. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Adequate sequence generation?	Allocation concealment?	Blinding?	Incomplete outcome data addressed?	Free of selective reporting?
Lacy 1996	?	?	-	+	?
Williams 1988	+	?	-	+	?

Allocation

Generation of allocation sequence

Williams reported that in their study participants were "allocated by random numbers" ([Williams 1988](#)), and we therefore judge this as having a low risk of bias. Lacy stated that "the patient was randomly allocated" but does not give further details ([Lacy 1996](#)).

We therefore judge this to have an unclear risk of bias. However, we note that the studies share the same senior author, so it is quite possible that the allocation sequence used by Lacy had a low risk ([Lacy 1996](#)).

Allocation concealment

The method of allocation concealment is not stated in either study (Lacy 1996; Williams 1988). Therefore, we judge both studies to have an unclear risk of bias.

Blinding

It is impossible to blind the operator tasked with inserting an IV device to the allocated device. In most cases, it would be either very troublesome or impossible to blind a participant. If blinding after insertion was performed by using an opaque occlusive dressing, judgments on whether a complication of the device had occurred would usually necessitate removing this dressing (and hence unblinding). Thus blinding of outcome assessors is also problematic. Therefore, it is not surprising that neither the Williams nor the Lacy study were blinded, though clearly lack of blinding does give rise to an unavoidable source of bias (Lacy 1996; Williams 1988).

Incomplete outcome data

No participants were withdrawn from the Williams study, which reported on all participants who were randomised, and therefore we judged this study to have a low risk of bias (Williams 1988). One participant was withdrawn after randomisation from the Lacy study (Lacy 1996). Results appear to have been analysed on a per protocol basis. However, it is not clear from the report whether the participant (who was withdrawn after three attempts of insertion of a silastic long line) had a subsequent long line. If he or she did not, the primary outcomes of this review (lifespan of a long line etc) would be unaffected. We therefore judge this to be at a low risk of bias.

Selective reporting

Comparing the 'Methods' and 'Results' sections of the reports gives no evidence of selective reporting (Lacy 1996; Williams 1988). Both studies were reported in a period when publication of protocols and study registration were unusual.

In routine clinical practice most of the outcomes listed in this review would probably be recorded, however, without the study protocols we are unable to ascertain whether they were either not collected as part of the study, or collected but not reported on.

We therefore have limited evidence to judge whether selective reporting has taken place, and therefore conclude that there is unclear risk of bias.

Other potential sources of bias

We have not identified any further potential sources of bias.

Effects of interventions

Long IV line versus short IV line

This comparison included one study with 20 participants which compared a Dow Corning long line (length 15 cm; internal diameter 0.3 mm) with a size 20 or 22 gauge Venflon (Williams 1988).

Primary outcome measures

1. Lifespan of the line (number of days)

The mean lifespan of the line was 8.4 (SD 4.5) days in the long IV line group and 4.0 (SD 2.1) days in the short IV line group. Williams used the Wilcoxon Signed Rank Sum test, and calculated a P value

of 0.001. Given the data were originally analysed using a non-parametric method, we have chosen not enter these data into the analyses. It appears that the long IV line lasted longer than the short IV line.

2. Number of procedures required for the duration of a 14-day course of antibiotics

The included study did not report on this outcome.

3. Complications of the device

There were eight complications in the long IV line group (seven episodes of occlusions and one thrombophlebitis). There were 24 complications in the short IV line group (21 episodes of leak of fluid into the tissues, and three of thrombophlebitis). It is not possible to separate out the complications on a per patient basis.

Secondary outcome measures

1. Number of attempts required to insert device

Lines were inserted without ultrasound guidance. Number of attempts was not reported.

2. Time taken to insert device

This was not reported.

3. Participant satisfaction with the device

This was assessed with a visual analogue scale, with 0 = "awful" and 10 = "excellent". There was a significant difference between groups, favouring the long IV line group, MD 3.10 (95% CI 1.28 to 4.92), assuming a normal distribution (see Analysis 1.1).

4. Incidence of bacteraemia

Bacteraemia was not specifically reported, however the authors stated that "there were no episodes of major sepsis".

5. Completion of 14 days of planned antibiotic course

This was not reported.

6. Number of doses of antibiotic missed

This was not reported.

Comparison of long IV lines

This comparison included one study with 58 courses of IV antibiotics administered to 47 participants. For each course a participant was randomly allocated to either a Hydrocath long IV line or Vygon EC long IV line (Lacy 1996). The report does not give SDs for its results, preventing us from independently estimating effect size. We have been unable to make contact with the authors to allow us to make further analysis.

Primary outcome measures

1. Lifespan of the line (number of days)

The mean life (days) was 12.1 in the Hydrocath group, and 11.4 in the Vygon EC group. Standard deviations for these are not given in the report. The generic inverse variance method was used to construct a forest plot (see Analysis 2.4). The reported MD was 0.75 days (95% CI -1.21 to 2.71). This difference was not statistically significant.

2. Number of procedures required for the duration of a 14-day course of antibiotics

This was not reported.

3. Complications of the device

The following analysis is in terms of complications for the first line inserted in the course of antibiotics, and an assumption is made that each line is associated with a maximum of one complication. There were five (17.8%) complications in the Hydrocath group (three episodes of thrombophlebitis and two of pain on infusion of the antibiotic). There were 11 (36.7%) complications in the Vygon EC group (seven episodes of occlusion, four of line leakage). There was no significant difference between groups, the RR for complications was 0.49 (95% CI 0.19 to 1.23) (see [Analysis 2.1](#)).

There were three (10.7%) complications in the Hydrocath group which required removal of the line, and six (20.0%) complications requiring removal of the line in the Vygon EC group. The RR for complications requiring removal of the line was 0.54 (95% CI 0.15 to 1.94) (see [Analysis 2.2](#)).

Secondary outcome measures

1. Number of attempts required to insert device

Lines were inserted without ultrasound guidance. Number of attempts required to insert the device was not reported.

2. Time taken to insert device

The study authors reported a statistically significant difference regarding insertion time. This was 12.3 minutes in the Hydrocath group, and 7.9 minutes in the Vygon EC group. The reported mean difference is 4.4 min (95% CI 0.4 to 8.4), $P = 0.032$.

3. Participant satisfaction with the device

This was measured using a visual analogue scale with 0 = "very dissatisfied" to 100 = "very satisfied". The mean score was 87.8 for the Hydrocath group versus 71.5 for the Vygon EC group. The reported mean difference was 19.7 (95% CI -0.8 to 25.5), $P = 0.064$, favouring the Hydrocath group.

4. Incidence of bacteraemia

This was not reported in the study

5. Completion of 14 days of planned antibiotic course

This was not reported in the study. However, the line lasted the full duration of the planned course of antibiotics for 25 out of 28 (89%) participants in the Hydrocath group, and 24 out of 30 (80%) participants in the Vygon EC group, RR 1.12 (95% CI 0.9 to 1.39) (see [Analysis 2.3](#)).

6. Number of doses of antibiotic missed

This was not reported.

DISCUSSION

Our review includes two studies: one which compared short IV lines to long IV lines ([Williams 1988](#)), and one comparing two different designs of long IV lines ([Lacy 1996](#)). Both were single-centre randomised non-blinded studies conducted in the same UK regional children's hospital. Reports from both studies were brief, in keeping with a typical report from the period. Evaluation

of sources of bias within the studies was difficult, in particular regarding generation of the allocation sequence and concealment of the allocation sequence. Of note, a particular problem specific to studies comparing procedures and devices is the issue of blinding of participants, clinicians and outcome assessors (see [Blinding](#)).

Both these studies are from some years ago, and at present we have been unable to successfully make contact with the authors of either study. We hope to be able to address this in future revisions of this review.

Our chosen primary endpoints were the lifespan of the line, complication rate of the line, and number of procedures required. We reasoned that the main advantage of a long IV line would be the longer lifespan, thus decreasing the need for repeated IV procedures. Our other primary outcome was to determine if long IV lines are more or less safe than short IV lines. Most line complications are minor (line blockage, leakage, pain and thrombophlebitis etc), but may necessitate removal of the line. We decided to group complications which would probably require removal of the line together, rather than analyse them separately. This was because we felt the most important aspect of a complication of the line for the patient and clinician would be whether this would lead to the line being removed. We chose to analyse bacteraemia as a separate outcome, as this would probably merit further treatment and be an important outcome for clinicians and patients in its own right.

Choosing appropriate statistical methods was difficult in this review, as the distribution of the data from the studies was not always clear. Although means and SDs of lifespan of the line were reported in the short versus long IV line study suggesting a normal distribution, the statistical test reported was non-parametric ([Williams 1988](#)). A specific distribution of the lifespan of the line was not discussed in the Lacy study, but a t-test was used, implying a normal distribution ([Lacy 1996](#)). Most long IV lines in clinical practice are removed after a 14-day course of antibiotics (if they last this long), thus the lifespan of the line may not be normally distributed, as there will be few lines retained beyond this cut off point. We have presented the data as reported in the studies, and where possible summarized the data.

Both the studies included in this review were small. A large observational series of 192 lines in CF has been published in abstract form ([Jones 2000](#)). Serious side effects occurred rarely in this study. Therefore, neither study was powered to detect differences between the risk of serious complications.

Insertion of long IV lines is more challenging (and may be more painful) than insertion of short IV lines, and therefore participant opinion over whether long IV lines are superior to short IV lines is an important secondary endpoint. The other secondary endpoints were designed to examine the number of attempts required to insert the line, time taken to insert it, completion of a 14-day course of antibiotics and number of antibiotic doses missed. This last endpoint was included, as we reasoned that insertion of a long IV line is a skilled procedure which may not be available as a 24-hour service. Thus, if a long IV line failed overnight, a patient may miss antibiotic doses until the next day. We were also keen to establish if there is an increased risk of bacteraemia with a long IV line, and we defined this as a positive blood culture.

Our first analysis considers whether long IV lines are superior to short IV lines ([Williams 1988](#)). Evaluation of the data from

the Williams study comparing a long IV line with short IV lines was hampered because it was not clear whether the reported continuous variables were normally distributed. That said, the published data suggests that the lifespan of a long IV line is twice that of a short IV line. There was no evidence of a difference in complication rate between the two devices, although the numbers of participants in each arm (10) was small. Participants were more satisfied with the long IV lines. In a later publication by the same group (Lacy 1996), the authors state that the number of venepunctures required for IV access was halved in the long IV line group; however, this result is not specifically stated in the study report (Williams 1988).

A larger study of short versus long IV lines in people with CF has been reported by Pradeepkumar (Pradeepkumar 1992). This study is also a single centre study which reported on line life and complications. It is unclear from the report whether this study was randomised. We have attempted to make contact with the authors, but have not yet been successful. We plan to conduct a meta-analysis of the Williams and Pradeepkumar studies if we are able to obtain more information from the authors.

Our second analysis considers whether there is evidence of superiority of one long IV line over another (Lacy 1996). This study compared two different types of long IV line: one with a hydrophilic coating (the Hydrocath) and a silastic line (the Vygon EC). A number of factors could be related to a difference between the line, as there were several differences between the two devices (see Table 1), including the material the line is manufactured from, the length, internal and external diameter, gauge of introducing venepuncture and method of insertion. Our planned analysis of the data from this study was not possible, as the SDs of the continuously distributed data were not published (95% CIs of the difference between means were published). We have used the generic invariance method to complete a forest plot.

Lacy did not detect a difference in the line survival between the two different types of catheter (Lacy 1996). There was no evidence of a difference in complication rates between the two devices, although numbers are small. The mean participant satisfaction score for the Hydrocath group was higher than the Vygon EC group, but the 95% CI of a difference includes zero (-0.8 to 25.5). With a larger sample size the study may have detected a difference in participant opinion between the two groups.

The Hydrocath took longer to insert than the Vygon EC (12.3 minutes compared to 7.9 minutes); however, the doctors inserting the lines were said to be more experienced with the Vygon EC prior to the study taking place. Interestingly, the Hydrocath survived for 97.5% of the total length of the IV course, compared to 85.9% in the Vygon EC group, but again the 95% CI of the difference includes zero (-0.3 to 23.4). Lacy reported several variables not included in our endpoints, including pain on insertion (which was worse in the Hydrocath group) and ease of drug administration (which was easier in the Hydrocath group). Overall, the Hydrocath is equivalent to the Vygon EC, and in several domains there is a trend towards superiority. These have to be balanced against pain on insertion. There is a trend to increased participant satisfaction with the Hydrocath.

AUTHORS' CONCLUSIONS

Implications for practice

We have found no studies which can guide practice in patients over the age of 18 years. Long IV lines for administering IV antibiotics in CF appear superior to short IV lines in terms of lifespan of the line and patient satisfaction. Long IV lines are therefore a useful and effective intervention to deliver antibiotic therapy. Due to the small number of participants in studies to date, this review does not have statistical power to detect a difference in the rates of serious complications such as bacteraemia.

Many institutions have a policy of removing short IV lines after a defined interval (e.g. 72 hours) in order to reduce the incidence of nosocomial infection. Neither of the two studies was designed to address this aspect of clinical practice, but we note that the mean survival of the short IV lines was four days, and no episodes of bacteraemia were reported. Given that short IV lines are frequently used for longer than three days in some CF centres, the incidence of bacteraemia could readily be studied in the CF population with a well-designed observational study.

We found that different types of long IV lines have seldom been compared in head-to-head studies. Only the Hydrocath and Vygon EC lines have been compared, and there is no clear evidence of superiority of one line over the other in terms of lifespan of the line, patient satisfaction or complication rate. Given the absence of evidence of superiority of one long line over another, the choice of long line is largely determined by operator and patient preference.

Implications for research

There are numerous percutaneous long IV lines currently marketed for IV access in children and adults. There is a need to compare such devices in order to establish superiority of one device over another. As with any intervention which is in part operator-dependent, care will be needed when designing such studies, as it is difficult to make a fair comparison between two interventions when the operators tend to have more prior experience with one device before a study commences. Important outcome measures which have not been reported in the reviewed studies include proportion of courses of IV antibiotics completed with a single line, number of attempts, number of doses of antibiotic missed per patient and number of procedures per patient.

We note that the lifespan of a line was not normally distributed in one of the two included studies. We suggest that the primary outcome measure for future studies and systematic reviews could be proportion of lines which last 14 days or more (the usual length of an IV course). Power calculations for such a study could be based on this proportion. These studies will need to be sufficiently powered to detect a difference in complication rate between two devices, and should ideally include patient satisfaction as a primary outcome measure.

ACKNOWLEDGEMENTS

AP is supported by an National Institute for Health Research (NIHR) Fellowship. MH is currently supported by a Wellcome Trust Fellowship (and was previously supported by a Nottingham Respiratory Biomedical Research Unit Fellowship).

The authors would like to thank the Cochrane CF and Genetic Disorders Group for their support, and their peer reviewers and Contact Editor (Dr Gerard Ryan) for their comments.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Lacy 1996

Methods	Single-centre randomised comparison of 2 different long IV lines.
Participants	47 children with CF attending a UK regional CF centre.

Lacy 1996 (Continued)

Age range provided by treatment group only. Hydrocath group (median 11 years, range 1.5 to 17.5 years); silastic group (median 11 years, range 0.5 to 17.5 years).

Interventions	Hydrocath 22-gauge (Viggo-Spectramed) a hydrophilic coated polyurethane catheter compared with a 23-gauge (Vygon EC) silastic catheter.
Outcomes	Lifespan of the long IV line (days). Time taken to insert device (min). Patient satisfaction (arbitrary visual analogue scale, 100 = very satisfied, 0 = very dissatisfied). Complications of the device. Completion of the course of antibiotics with a single line.
Notes	One participant dropped out, a silastic catheter could not be inserted.

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	A previous study with the same senior author used random numbers to generate the sequence. The method of sequence generation is not discussed in the report of this study.
Allocation concealment?	Unclear risk	Unclear from the published report how allocation was concealed.
Blinding? All outcomes	High risk	Unblinded study.
Incomplete outcome data addressed? All outcomes	Low risk	One participant dropped out prior to successful insertion of a line (silastic group). Data from this participant were not included in the results. However, given that the primary endpoint is lifespan of the catheter, number of procedures required over a 14-day course of antibiotics and complications of the catheter, this is unlikely to have affected the results.
Free of selective reporting?	Unclear risk	Insufficient information to permit judgement.

Williams 1988

Methods	Single-centre randomised comparison of silastic long IV line and short IV line
Participants	20 children with CF attending a UK regional CF centre. Median age 13 years (range 5 to 16 years).
Interventions	Silastic long IV line (0.3 mm internal diameter, Dow Corning) inserted into the brachial vein versus short IV line (20 or 22 Gauge, Venflon). All lines had a constant infusion of 1 unit / mL of heparin running at one mL/h.
Outcomes	Lifespan of the line (days). Number of procedures. Patient satisfaction: arbitrary visual analogue scale (0 = awful; 10 = excellent).

Williams 1988 (Continued)

Complications of the device.

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	Participants were allocated by random numbers.
Allocation concealment?	Unclear risk	Unclear from the published report how allocation was concealed.
Blinding? All outcomes	High risk	Unblinded study.
Incomplete outcome data addressed? All outcomes	Low risk	No participants missing from either group.
Free of selective reporting?	Unclear risk	Insufficient information to permit judgement.

CF: cystic fibrosis

IV: intravenous

Characteristics of studies awaiting assessment [ordered by study ID]

Pradeepkumar 1992

Methods	Controlled study of silastic long IV line compared with short IV line.
Participants	34 participants with CF (2 positive sweat tests) an acute pulmonary exacerbation requiring IV therapy. Age range 4 years to 20 years.
Interventions	Half of the participants were allocated to the silastic long line group.
Outcomes	Mean line life in the long IV line group was 16.76 days (SD 4.44) versus 2.66 (0.62) days in the short IV line group. 6 long IV lines had complications. The number of complications in the short IV lines group was not reported. No episodes of bacteraemia.
Notes	Unclear from the published report whether the participants were randomised.

CF: cystic fibrosis

IV: intravenous

SD: standard deviation

DATA AND ANALYSES

Comparison 1. Long IV line versus short IV line

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Patient satisfaction	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected

Analysis 1.1. Comparison 1 Long IV line versus short IV line, Outcome 1 Patient satisfaction.

Study or subgroup	Long iv line		Short iv line		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Fixed, 95% CI
Williams 1988	10	8.8 (1.7)	10	5.7 (2.4)		3.1[1.28,4.92]
					Favours short iv line	Favours long iv line

Comparison 2. Long IV lines compared

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Complications of the long line	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2 Complication necessitating removal of the line	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
3 Completion of a course of antibiotics with a single long iv line	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
4 Lifespan of the long iv line	1		Mean Difference (Fixed, 95% CI)	Totals not selected

Analysis 2.1. Comparison 2 Long IV lines compared, Outcome 1 Complications of the long line.

Study or subgroup	Hydrocath n/N	Vygon n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Lacy 1996	5/28	11/30		0.49[0.19,1.23]
			Favours Hydrocath	Favours Vygon

Analysis 2.2. Comparison 2 Long IV lines compared, Outcome 2 Complication necessitating removal of the line.

Study or subgroup	Hydrocath n/N	Vygon n/N	Risk Ratio M-H, Fixed, 95% CI	Risk Ratio M-H, Fixed, 95% CI
Lacy 1996	3/28	6/30		0.54[0.15,1.94]
			Favours Hydrocath	Favours Vygon

**Analysis 2.3. Comparison 2 Long IV lines compared, Outcome 3
Completion of a course of antibiotics with a single long iv line.**

Study or subgroup	Hydrocath n/N	Vygon n/N	Risk Ratio		Risk Ratio M-H, Fixed, 95% CI
			M-H, Fixed, 95% CI		
Lacy 1996	25/28	24/30			1.12[0.9,1.39]
Favours Hydrocath 0.5 0.7 1 1.5 2 Favours Vygon					

Analysis 2.4. Comparison 2 Long IV lines compared, Outcome 4 Lifespan of the long iv line.

Study or subgroup	Hydrocath N	Vygon N	Mean Dif- ference (SE)	Mean Difference	
				IV, Fixed, 95% CI	IV, Fixed, 95% CI
Lacy 1996	0	0	0.8 (1)		0.75[-1.21,2.71]
Hydrocath -10 -5 0 5 10 Vygon					

ADDITIONAL TABLES**Table 1. Characteristics of the lines studied by Lacy**

	Hydrocath	Vygon EC
Material	Hydrophilic coated polyurethane	Silastic
Length (cm)	20	30
Internal diameter (mm)	0.6	0.3
Initial venepuncture (gauge)	22	19
Insertion technique	'Through the needle'	'Seldinger'

Taken from a table in [Lacy 1996](#).

APPENDICES**Appendix 1. Clinicaltrials.gov search strategy**

We searched www.clinicaltrials.gov for:

"cystic fibrosis AND long line"

"cystic fibrosis AND cannula"

"cystic fibrosis AND cannulae"

"cystic fibrosis AND catheter"

"cystic fibrosis AND percutaneous"

"cystic fibrosis AND intravenous"

"cystic fibrosis AND access"

Search last performed on 06-09-2010

Appendix 2. ISRCTN search strategy

We searched ISRCTN for:

"cystic fibrosis AND long line"

"cystic fibrosis AND cannula"

"cystic fibrosis AND cannulae"

"cystic fibrosis AND catheter"

"cystic fibrosis AND percutaneous"

"cystic fibrosis AND intravenous"

"cystic fibrosis AND access"

Search last performed on 06-09-2010

WHAT'S NEW

Date	Event	Description
29 June 2017	Amended	Contact details updated.

HISTORY

Protocol first published: Issue 1, 2010

Review first published: Issue 11, 2010

Date	Event	Description
22 May 2012	Amended	Contact details updated.

CONTRIBUTIONS OF AUTHORS

AP wrote the protocol with contributions from MH and AS. AP and MH collected the data, and AS arbitrated. AP, MH and AS wrote the review.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- Wellcome Trust Fellowship, UK.

Matthew Hurley is the recipient of this fellowship.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

No differences between the protocol and review.

INDEX TERMS

Medical Subject Headings (MeSH)

*Catheters, Indwelling; Anti-Bacterial Agents [*administration & dosage]; Bacterial Infections [*drug therapy] [etiology]; Cystic Fibrosis [*complications]; Infusions, Intravenous [instrumentation] [psychology]; Lung Diseases [*drug therapy] [etiology]; Randomized Controlled Trials as Topic

MeSH check words

Humans