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Catheter insertion techniques for improving catheter function and clinical outcomes in peritoneal dialysis patients (Protocol)

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TABLE OF CONTENTS

[Intervention Protocol]

Catheter insertion techniques for improving catheter function and clinical outcomes in peritoneal dialysis patients

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

This review aims to look at the benefits and harms of different PD catheter insertion techniques.

1. To establish whether a specific technique used to place catheters in adults and children, who are new to PD, result in any significant differences in clinical outcomes. Insertion techniques will be further defined as peritoneoscopic, percutaneous, fluoroscopic, laparoscopic insertion or open surgery.

2. To identify which technique offers optimal clinical outcomes and minimises post-procedure complications including postoperative haemorrhage, PD catheter dysfunction, exit site infection/peritonitis and bowel perforation.

BACKGROUND

Description of the condition

Peritoneal dialysis (PD) is a form of renal replacement therapy (RRT) used to treat end-stage kidney disease (ESKD). The management of ESKD is of increasing clinical relevance given worldwide trends for ESKD prevalence and incidence. In the United States (US) alone, the US Renal Data System (USRDS) reports an incidence of 350 per million population with over 871,000 people requiring treatment (USRDS 2015). Similarly within the United Kingdom (UK), recent UK Renal Registry data shows an increasing incidence of patients requiring RRT with over 7000 new patients dialysing in 2014 (Gilg 2016; MacNeill 2016). PD utilises the peritoneum as a semi-permeable membrane which allows the removal of waste electrolytes and water by instillation of dialysate into the abdominal cavity. This process requires the insertion of a flexible plastic tube, the PD catheter, into the peritoneal space. Optimal catheter functionality is necessary for the success of PD

as a dialysis modality.

Approximately 11% of the global dialysis population are treated with PD. Notably such utilisation varies internationally (ANZDATA 2015; Jain 2012; USRDS 2015) with apparent under-utilisation in developed countries despite equivalence to other other therapeutic modalities in terms of patient outcomes and economic efficiency (Klarenbach 2009). In the US in 2009, of the approximate 400,000 patients requiring dialysis, only 27,000 received PD (USRDS 2015). The reasons for variation are poorly understood and may relate to PD practice variation. Perl 2015 demonstrated that patients were more likely to receive PD if the catheter was inserted by a nephrologist in comparison to surgical catheter insertion. Such observations have led to the hypothesis that the pathway to catheter insertion is a critical determinant of the selection of PD as a therapeutic modality (Asif 2005; Castledine 2013). Thus, the Peritoneal Dialysis Outcomes and Practice Patterns (PDOPPS) study, an international observational cohort study, (Perl 2016) has been established to follow PD patients longitudinally with the aim of defining best practice, including techniques relating to PD catheter insertion.

In the paediatric population, among patients intended for kidney transplantation, PD is the RRT of choice due to better preservation of residual kidney function in comparison to haemodialysis (HD) which in turn allows administration of larger feeding volumes. PD is also also preferred due to avoidance of vascular access. Surprisingly utilisation of paediatric PD in the UK has fallen over the last 14 years from 55%, in the period 2000 to 2004, to 44% in 2014. Although this may be explained by a rise in preemptive kidney transplantation, variability in data collection in the paediatric ESKD population is a challenge and is likely due to adult data collection systems being arbitrarily applied to children (UKRR Report 2016a).

Description of the intervention

The primary objective of PD catheter placement is to obtain access to the peritoneal cavity to allow effective exchange of dialysate fluid. Several different techniques are used to achieve this. Many centres rely on a single surgical approach (including open surgical and laparoscopic techniques) whereas others practice a combination of insertion techniques (Rao 2015). PD catheter insertion techniques commonly in use include: fluoroscopic, percutaneous and peritoneoscopic, laparoscopic and open surgical.

Laparoscopic insertion involves abdominal insufflation and small incisions in the abdominal wall though which surgical instruments can be inserted into the abdominal cavity. The PD catheter is advanced into to the pelvic cavity and the distal end tunnelled through the abdominal wall to an exit site incision (NICE 2007). Additional procedures can be performed simultaneously (e.g. omentectomy and hernia repair). Peritoneoscopic insertion also allows direct vision of the pelvic cavity however manipulation of the tube position or other procedures cannot be performed.

Open surgical catheter insertion is perhaps the most common technique used to place a PD catheter (UKRR Report 2016b; Wallace 2016). A small open incision is made in the abdomen through the skin, subcutaneous tissue and anterior rectus sheath. A further small incision is made to the peritoneal cavity and the catheter is threaded into the pelvis (NICE 2007). The posterior rectus sheath and the peritoneum are sutured tightly around the catheter with the other end of the catheter then tunnelled subcutaneously to an exit site incision in the abdomen. A variant of the open-surgical technique is the 'mini-laparotomy', where the abdominal incision is minimised to allow the use of local rather than general anaesthetic.

Percutaneous catheter insertion requires a small incision to be made in the abdomen followed by blunt dissection of the subcutaneous tissue. A catheter guide is used to direct the catheter into the peritoneal cavity (Seldinger 1953). The other end of the catheter is tunnelled through to an exit site incision in the abdomen. Fluoroscopy is a variation on the percutaneous technique, with the use of X-rays to guide the placement of the catheter. The 'Moncrieff' approach describes burying the external end of the catheter under the skin until it is required to perform dialysis. The choice of technique is influenced predominantly by those facilities available (operating theatre access, availability of trained staff) but in centres where more than one catheter insertion technique is in use, the decision to perform a particular technique may be determined by patient factors such as suitability for general anaesthesia or the requirement for other procedures (e.g. hernia repair).

How the intervention might work

Successful PD relies on adequate function of the PD catheter. A poorly functioning catheter often leads to the abandonment of the modality completely with high levels of patient and clinician frustration. There is currently no consensus as to the best method of PD catheter insertion. In the 2012 UK national PD access audit catheters inserted percutaneously were twice as likely to fail (7% versus 14% failure at 3 months) (Briggs 2014).

A systematic review by Xie 2012 compared laparoscopic and open surgical PD catheter insertion finding no significant difference in outcomes, however Hagen 2013 found that the laparoscopic technique had significantly favourable outcomes, this was felt to be related to differing selection criteria of studies. The impact of catheter type and insertion technique on peritonitis rates in patients on PD (Strippoli 2004a; Strippoli 2004b) has also been examined - no catheter interventions were identified to have any impact on peritonitis rates. Importantly, they also identified that the current available data is significantly flawed. Hagen 2014 examined catheter type in relation to functional outcome, which favoured a straight intra peritoneal segment (influencing PD catheter survival at two years) however there was little difference in the functional outcome at one year.

Several procedural techniques are being increasingly used for PD catheter insertion in a medical rather than a surgical setting especially in the management of late presenting patients. Data from the 2014 UK Renal Registry (Briggs 2014) reports highlights that in the UK approximately 40% of late presenting patients (who had a PD tube inserted), had this done by the percutaneous route. Boujelbane 2015 examine whether catheters placed percutaneously had any benefits over those placed surgically. There was no significant benefit (or indeed detriment) to having a catheter placed percutaneously over a surgical insertion.

Data from the paediatric population is much less well defined, however the Italian Registry of Paediatric Chronic Peritoneal Dialysis reported that all PD catheters were surgically implanted and over 80% of patients underwent omentectomy (Rinaldi 2004). In the paediatric population, current guidance recommends partial omentectomy as a standard procedure in infants undergoing PD catheter insertion due to the higher rates of catheter dysfunction (Watson 2001; Zurowska 2013). Although the open surgical method of catheter insertion is recommended, there is limited available evidence. Specific factors to be taken into account in children include abdominal wall abnormalities, the presence of ostomies, and the presence of absence of nappies must also be taken into account especially in patients under the age of two years.

Why it is important to do this review

Currently no consensus exists with regards to the optimum method of PD catheter insertion and clinical guidelines are therefore lacking in clarity and consistency. The objective of this review is to examine all possible PD catheter insertion techniques, functional outcomes on PD and post-procedural complication rates thus broadening the scope of earlier reviews with the intention to maximise the uptake of PD as an RRT. Published guidelines relating to PD catheter functionality and post-insertion complication thresholds do exist, (ISPD) (Figueiredo 2010), European Best Practice Guidelines for Peritoneal Dialysis (EBPG 2005), and the Renal Association (Mactier 2011)) however their validity has not been rigorously evaluated. Current Renal Association guidelines (Mactier 2011; Wilkie 2009) state that timely surgical review to facilitate PD access however there is no recommended insertion technique as clear evidence is lacking. Surgical technique under direct vision is supported for patients with previous complex abdominal surgery however there is no direct evidence to support this approach. European guidance does not recommend a particular method of PD catheter placement stating that insertion technique is dependent on centre expertise and highlights the difficulty with generalisation (EBPG 2005).

OBJECTIVES

This review aims to look at the benefits and harms of different PD catheter insertion techniques.

1. To establish whether a specific technique used to place catheters in adults and children, who are new to PD, result in any significant differences in clinical outcomes. Insertion techniques will be further defined as peritoneoscopic, percutaneous, fluoroscopic, laparoscopic insertion or open surgery.

2. To identify which technique offers optimal clinical outcomes and minimises post-procedure complications including postoperative haemorrhage, PD catheter dysfunction, exit site infection/peritonitis and bowel perforation.

METHODS

Criteria for considering studies for this review

Types of studies

All RCTs and quasi-RCTs (RCTs in which allocation to treatment was obtained by alternation, use of alternate medical records, date of birth or other predictable methods) comparing PD catheter insertion techniques.

Types of participants

Inclusion criteria

Participants to be included in this review are both adults and children with kidney disease, who require dialysis treatment. This will include all patients with ESKD and acute kidney injury (AKI). Participants will have had a PD catheter inserted - this will include first PD catheter or subsequent catheters. Late presenting patients and those requiring emergency placement of a PD catheter will also be included.

Exclusion criteria

There are no exclusion criteria based on the type of participants.

Types of interventions

Studies comparing any two different PD catheter insertion techniques will be included in this review.

PD catheter insertion techniques can be broadly defined as 'medical' or 'surgical' in nature. 'Medical' techniques, for the purpose of this review, will include blind percutaneous, peritoneoscopic and fluoroscopic catheter insertion. 'Surgical' PD catheter insertion

techniques will include laparoscopic or open surgical insertion or any variation thereof.

Studies will not be excluded based on operator type. Studies comparing two medical or two surgical techniques will also be included (e.g. percutaneous versus peritoneoscopic).

Studies comparing any two catheter insertion techniques will be included - comparison of the following techniques will be included:

1. Percutaneous PD catheter insertion
2. Fluoroscopic PD catheter insertion
3. Peritoneoscopic PD catheter insertion
4. Open surgical PD catheter insertion
5. Laparoscopic PD catheter insertion

Studies comparing other catheter insertion techniques will also be considered for inclusion including hybrid techniques such as procedures incorporating 'mini-lap' PD catheter insertion.

Types of outcome measures

Primary outcomes

1. Early PD catheter function - Catheter function at the time of PD catheter insertion (primary catheter function) and up to 30 days following PD catheter insertion. If the observation period is commenced from the start of PD then this will also be collected. Early catheter failure is indicated by an event which means the catheter cannot be used to perform a PD exchange/ effective PD treatment (which may or may not require transfer to HD)
2. 'Long term' PD catheter function - This should be defined as functional PD catheter, with the ability to perform successful PD/PD exchange, post catheter insertion censored for death, transplantation or transfer to HD (for reasons other than PD catheter dysfunction) from 30 days to 2 years. PD catheter failure rate at 1 year will also be collected if reported in studies. Catheter failure may or may not result in transfer to HD.
3. Technique failure i.e. the inability to perform successful PD resulting in transfer to HD.
    - Technique failure will be defined as minimum duration of temporary period on HD as described by Lan 2016 - the patient to have been off PD and established on HD for 30 days before technique failure diagnosed. Percentage returning to returned to PD within 12 months if the duration on HD was 30 days or less was 24% but significantly lower when examining patients with a longer duration on PD (return after 180 days on PD - 3%). This is a potentially useful definition of permanent technique failure. Mechanical causes for technique failure were highest in the 30 day duration of HD cohort making it a useful definition in this situation for early technique failure with a predominantly mechanical aetiology.
    - 30 day transfer to HD and 180 day transfer to HD data will therefore be collected if reported.
    - Death will be considered technique failure however death censored technique failure will also be reported separately. Kidney recovery and transplantation will not be classified as technique failure.
4. Complications of PD catheter insertion will be examined as primary outcome measures. These will include:
    - Exit site infection (early as defined within studies)
    - Early peritonitis episode within 30 days of PD catheter insertion
    - Bowel perforation
    - Haemorrhage/haemoperitoneum
    - Catheter tip migration
    - PD catheter drainage pain
    - Exit site leak
5. Mortality
6. Catheter use - was the PD catheter ever used for PD
7. Data regarding patient characteristics (age, gender, co-morbidity, primary kidney diagnosis, previous PD catheter surgery, body mass index (BMI), diabetic status) will be collected and information about technique of PD catheter insertion including operator and number of operators per centre.
8. Details regarding the study such as sample size, study design, length of follow-up and funding source will also be collected.
9. Uncertainties identified in the publications during data extraction will be clarified with the authors where possible

Secondary outcomes

- Additional procedures performed at time of catheter insertion (e.g. omentopexy/hernia repair)
- Catheter type (Swan neck versus straight catheter, number of cuffs)
- Whether patients were able to receive their chosen modality - i.e. automated PD (APD) versus continuous ambulatory PD (CAPD)
- Length of hospital stay
- Estimated glomerular filtration rate (eGFR) at time of PD catheter insertion
- Re-admission to hospital and further intervention/ procedures
- Patient reported outcomes e.g. patient satisfaction, health related quality of life measures
- Cost analysis of PD catheter insertion

Search methods for identification of studies

Electronic searches

We will search the Cochrane Kidney and Transplant Specialised Register through contact with the Information Specialist using

search terms relevant to this review. The Specialised Register contains studies identified from the following sources.

1. Monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL)
2. Weekly searches of MEDLINE OVID SP
3. Handsearching of kidney-related journals and the proceedings of major kidney conferences
4. Searching of the current year of EMBASE OVID SP
5. Weekly current awareness alerts for selected kidney and transplant journals
6. Searches of the International Clinical Trials Register (ICTRP) Search Portal and ClinicalTrials.gov.

Studies contained in the Specialised Register are identified through search strategies for CENTRAL, MEDLINE, and EMBASE based on the scope of Cochrane Kidney and Transplant. Details of these strategies, as well as a list of handsearched journals, conference proceedings and current awareness alerts, are available in the Specialised Register section of information about Cochrane Kidney and Transplant.

See Appendix 1 for search terms used in strategies for this review.

Searching other resources

1. Reference lists of review articles, relevant studies and clinical practice guidelines.
2. Letters seeking information about unpublished or incomplete studies to investigators known to be involved in previous studies.

Data collection and analysis

Selection of studies

The search strategy described will be used to obtain titles and abstracts of studies that may be relevant to the review. The titles and abstracts will be screened independently by two authors, who will discard studies that are not applicable; however studies and reviews that might include relevant data or information on studies will be retained initially. Two authors will independently assess retrieved abstracts and, if necessary the full text, of these studies to determine which studies satisfy the inclusion criteria.

Data extraction and management

Data extraction will be carried out independently by two authors using standard data extraction forms. Studies reported in non-English language journals will be translated before assessment. Where more than one publication of one study exists, reports will be grouped together and the publication with the most complete data will be used in the analyses. Where relevant outcomes are only published in earlier versions these data will be used. Any discrepancy between published versions will be highlighted.

Assessment of risk of bias in included studies

The following items will be independently assessed by two authors using the risk of bias assessment tool (Higgins 2011) (see Appendix 2).

- Was there adequate sequence generation (selection bias)?
- Was allocation adequately concealed (selection bias)?
- Was knowledge of the allocated interventions adequately prevented during the study?
    - Participants and personnel (performance bias)
    - Outcome assessors (detection bias)
- Were incomplete outcome data adequately addressed (attrition bias)?
- Are reports of the study free of suggestion of selective outcome reporting (reporting bias)?
- Was the study apparently free of other problems that could put it at a risk of bias?

Measures of treatment effect

For dichotomous outcomes (peritonitis rate at two weeks, exit site infection rate, postoperative haemorrhage rate, catheter migration) results will be expressed as risk ratio (RR) with 95% confidence intervals (CI).

Where continuous scales of measurement are used to assess the effects of treatment (catheter survival) methods of survival analysis will be used including hazard ratios, If change from baseline scores are reported in studies, these will be included if appropriate. Missing standard deviations will be dealt with via imputation techniques.

Skewed data and non-quantitative data will be presented descriptively.

Unit of analysis issues

Studies with non-standard designs such as multiple intervention groups and cluster RCTs will be included depending on study design. For cluster RCTs, the unit of analysis will be the individual patient however if the unit of randomisation in the study does not match the unit of analysis, these will be subject to statistical modelling as outlined in the Cochrane Handbook of Systematic Reviews (Higgins 2011).

Dealing with missing data

Any further information required from the original author will be requested by written correspondence (e.g. emailing corresponding author/s) and any relevant information obtained in this manner will be included in the review. Evaluation of important numerical data such as screened, randomised patients as well as intention-to-

treat, as-treated and per-protocol population will be carefully performed. Attrition rates, for example drop-outs, losses to follow-up and withdrawals will be investigated and sensitivity analysis used to assess the impact of inclusion of these studies. Issues of missing data and imputation methods (for example, last-observation-carried-forward) will be critically appraised (Higgins 2011) and the most appropriate method selected.

Assessment of heterogeneity

We will first assess the heterogeneity by visual inspection of the forest plot. We will quantify statistical heterogeneity using the I^2 statistic, which describes the percentage of total variation across studies that is due to heterogeneity rather than sampling error (Higgins 2003). A guide to the interpretation of I^2 values will be as follows.

- 0% to 40%: might not be important
- 30% to 60%: may represent moderate heterogeneity
- 50% to 90%: may represent substantial heterogeneity
- 75% to 100%: considerable heterogeneity.

The importance of the observed value of I^2 depends on the magnitude and direction of treatment effects and the strength of evidence for heterogeneity (e.g. P-value from the Chi^2 test, or a confidence interval for I^2) (Higgins 2011).

Assessment of reporting biases

If possible, funnel plots will be used to assess for the potential existence of small study bias (Higgins 2011).

Data synthesis

Data will be pooled using the random-effects model but the fixed-effect model will also be used to ensure robustness of the model chosen and susceptibility to outliers.

Subgroup analysis and investigation of heterogeneity

Subgroup analysis will be used to explore possible sources of heterogeneity (e.g. participants, interventions and study quality). Heterogeneity among participants could be related to age, sex, kidney pathology, diabetic status, body mass index (BMI) or prior surgical intervention. Heterogeneity in intervention (procedure) could relate to operator type or number of operators. Adverse effects will be tabulated and assessed with descriptive techniques, as they are likely to be different for the various insertion techniques used. Where possible, the risk difference with 95% CI will be calculated for each adverse effect, either compared to no treatment or to another procedure type.

Sensitivity analysis

We will perform sensitivity analyses in order to explore the influence of the following factors on effect size.

- Repeating the analysis excluding unpublished studies
- Repeating the analysis taking account of risk of bias, as specified
- Repeating the analysis excluding any very long or large studies to establish how much they dominate the results
- Repeating the analysis excluding studies using the following filters: diagnostic criteria, language of publication, source of funding (industry versus other), and country.

'Summary of findings' tables

We will present the main results of the review in 'Summary of findings' tables. These 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). The 'Summary of findings' tables also include an overall grading of the evidence related to each of the main outcomes using the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) approach (GRADE 2008). The GRADE approach defines the quality of a body of evidence as the extent to which one can be confident that an estimate of effect or association is close to the true quantity of specific interest. The 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 plan to present the following outcomes in the 'Summary of findings' tables.

1. Catheter survival: divided according to time window available from the data
2. Technique failure: divided according to time window from the available data
3. Surgical complications: hernias, leaks, haemorrhage
4. Infection: peritonitis, exit site infection, tunnel infection
5. Patient reported outcome measures: if reported (e.g. catheter related pain)
6. Catheter flow: if documented
7. Catheter tip migration: if documented.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Electronic search strategies

Database	Search terms
CENTRAL	1. MeSH descriptor: [Renal Replacement Therapy] this term only 2. MeSH descriptor: [Peritoneal Dialysis] explode all trees 3. peritoneal dialysis:ti,ab,kw (Word variations have been searched) 4. PD or CAPD or CCPD or APD:ti,ab,kw (Word variations have been searched) 5. {or #1-#4} 6. MeSH descriptor: [Catheters, Indwelling] this term only 7. MeSH descriptor: [Catheters] this term only 8. MeSH descriptor: [Catheterization] this term only 9. catheter insert* or catheter implant*:ti,ab,kw (Word variations have been searched) 10. (peritoneal dialysis or PD) and catheter*:ti,ab,kw (Word variations have been searched) 11. "blind percutaneous" or peritoneoscopic or fluoroscopic or laparoscopic:ti,ab,kw (Word variations have been searched) 12. MeSH descriptor: [Fluoroscopy] this term only 13. MeSH descriptor: [Laparoscopy] explode all trees 14. {or #6-#13} 15. {and #5, #14}
MEDLINE	1. Renal Replacement Therapy/ 2. exp Peritoneal Dialysis/ 3. peritoneal dialysis.tw. 4. (PD or CAPD or CCPD or APD).tw. 5. or/1-4 6. Catheters, Indwelling/ 7. Catheters/ 8. Catheterization/ 9. (catheter insertion or catheter implant$).tw. 10. ((peritoneal dialysis or PD) and catheter$).tw. 11. (blind percutaneous or peritoneoscopic or fluoroscopic or laparoscopic).tw. 12. Fluoroscopy/ 13. Laparoscopy/ 14. or/6-13 15. and/5,14
EMBASE	1. Peritoneal Dialysis/ 2. Continuous Ambulatory Peritoneal Dialysis/ 3. peritoneal dialysis.tw. 4. (PD or CAPD or CCPD or APD).tw. 5. renal replacement therapy-dependent renal disease/ 6. or/1-5 7. peritoneal dialysis catheter/ 8. catheterization/ 9. peritoneal dialysis catheter$.tw. 10. (catheter insertion or catheter implant$).tw.

(*Continued*)

	11. ((peritoneal dialysis or PD) and catheter$).tw. 12. (blind percutaneous or peritoneoscopic or fluoroscopic or laparoscopic).tw. 13. fluoroscopy/ 14. laparoscopy/ 15. or/7-14 16. and/6,15

Appendix 2. Risk of bias assessment tool

Potential source of bias	Assessment criteria
Random sequence generation Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence	*Low risk of bias:* Random number table; computer random number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots; minimisation (minimisation may be implemented without a random element, and this is considered to be equivalent to being random)
	High risk of bias: Sequence generated by odd or even date of birth; date (or day) of admission; sequence generated by hospital or clinic record number; allocation by judgement of the clinician; by preference of the participant; based on the results of a laboratory test or a series of tests; by availability of the intervention
	Unclear: Insufficient information about the sequence generation process to permit judgement
Allocation concealment Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment	*Low risk of bias:* Randomisation method described that would not allow investigator/participant to know or influence intervention group before eligible participant entered in the study (e.g. central allocation, including telephone, web-based, and pharmacy-controlled, randomisation; sequentially numbered drug containers of identical appearance; sequentially numbered, opaque, sealed envelopes)
	High risk of bias: Using an open random allocation schedule (e.g. a list of random numbers); assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure
	Unclear: Randomisation stated but no information on method used is available

(*Continued*)

Blinding of participants and personnel Performance bias due to knowledge of the allocated interventions by participants and personnel during the study	*Low risk of bias*: No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken
	High risk of bias: No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding
	Unclear: Insufficient information to permit judgement
Blinding of outcome assessment Detection bias due to knowledge of the allocated interventions by outcome assessors	*Low risk of bias:* No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; blinding of outcome assessment ensured, and unlikely that the blinding could have been broken
	High risk of bias: No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding
	Unclear: Insufficient information to permit judgement
Incomplete outcome data Attrition bias due to amount, nature or handling of incomplete outcome data	*Low risk of bias:* No missing outcome data; reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; for continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; missing data have been imputed using appropriate methods
	High risk of bias: Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; for continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically rel-

(*Continued*)

	evant 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: Insufficient information to permit judgement
Selective reporting Reporting bias due to selective outcome reporting	*Low risk of bias:* The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon)
	High risk of bias: 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. sub-scales) that were not pre-specified; one or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); one or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; the study report fails to include results for a key outcome that would be expected to have been reported for such a study
	Unclear: Insufficient information to permit judgement
Other bias Bias due to problems not covered elsewhere in the table	*Low risk of bias:* The study appears to be free of other sources of bias.
	High risk of bias: Had a potential source of bias related to the specific study design used; stopped early due to some data-dependent process (including a formal-stopping rule); had extreme baseline imbalance; has been claimed to have been fraudulent; had some other problem
	Unclear: Insufficient information to assess whether an important risk of bias exists; insufficient rationale or evidence that an identified problem will introduce bias

CONTRIBUTIONS OF AUTHORS

1. Draft the protocol: VB, MW, JF, AA
2. Study selection: MW, JF, KR, AA, VB
3. Extract data from studies: VB, AA, MW, JF, KR
4. Enter data into RevMan: VB, AA
5. Carry out the analysis: VB, RJ, JF, AA
6. Interpret the analysis: VB, RJ, JF
7. Draft the final review: VB, AA, JF, MW, KR
8. Disagreement resolution: MW, MC
9. Update the review: VB

DECLARATIONS OF INTEREST

Dr Victoria Briggs has been awarded a Baxter Clinical Effectiveness Council (CEC) to support a separate project developing the data collection tools as part of the development of the UK PD catheter study (UKcath) and using UK Renal Registry (UKRR) data to examine catheter insertion practices in the United Kingdom (in early stages). This award does not support the work done as part of this systematic review.

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