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Intermittent catheter techniques, strategies and designs for managing long-term bladder conditions (Review)

Prieto JA, Murphy CL, Stewart F, Fader M

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[Intervention Review]

Intermittent catheter techniques, strategies and designs for managing long-term bladder conditions

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ABSTRACT

Background

Intermittent catheterisation (IC) is a commonly recommended procedure for people with incomplete bladder emptying. Frequent complications are urinary tract infection (UTI), urethral trauma and discomfort during catheter use. Despite the many designs of intermittent catheter, including different lengths, materials and coatings, it is unclear which catheter techniques, strategies or designs affect the incidence of UTI and other complications, measures of satisfaction/quality of life and cost-effectiveness.

This is an update of a Cochrane Review first published in 2007.

Objectives

To assess the clinical and cost-effectiveness of different catheterisation techniques, strategies and catheter designs, and their impact, on UTI and other complications, and measures of satisfaction/quality of life among adults and children whose long-term bladder condition is managed by intermittent catheterisation.

Search methods

We searched the Cochrane Incontinence Specialised Register, which contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In-Process, MEDLINE Epub Ahead of Print, CINAHL, ClinicalTrials.gov, WHO ICTRP and handsearching of journals and conference proceedings (searched 12 April 2021), the reference lists of relevant articles and conference proceedings, and we attempted to contact other investigators for unpublished data or for clarification.

Selection criteria

Randomised controlled trials (RCTs) or randomised cross-over trials comparing at least two different catheterisation techniques, strategies or catheter designs.

Data collection and analysis

As per standard Cochrane methodological procedures, two review authors independently extracted data, assessed risk of bias and assessed the certainty of evidence using GRADE. Outcomes included the number of people with symptomatic urinary tract infections, complications such as urethral trauma/bleeding, comfort and ease of use of catheters, participant satisfaction and preference, quality of life measures and economic outcomes.

Main results

We included 23 trials (1339 randomised participants), including twelve RCTs and eleven cross-over trials. Most were small (fewer than 60 participants completed), although three trials had more than 100 participants. Length of follow-up ranged from one month to 12 months and there was considerable variation in definitions of UTI. Most of the data from cross-over trials were not presented in a useable form for this review.

Risk of bias was unclear in many domains due to insufficient information in the trial reports and several trials were judged to have a high risk of performance bias due to lack of blinding and a high risk of attrition bias. The certainty of evidence was downgraded for risk of bias, and imprecision due to low numbers of participants.

Aseptic versus clean technique

We are uncertain if there is any difference between aseptic and clean techniques in the risk of symptomatic UTI because the evidence is low-certainty and the 95% confidence interval (CI) is consistent with possible benefit and possible harm (RR 1.20 95% CI 0.54 to 2.66; one study; 36 participants). We identified no data relating to the risk of adverse events comparing aseptic and clean techniques or participant satisfaction or preference.

Single-use (sterile) catheter versus multiple-use (clean)

We are uncertain if there is any difference between single-use and multiple-use catheters in terms of the risk of symptomatic UTI because the certainty of evidence is low and the 95% CI is consistent with possible benefit and possible harm (RR 0.98, 95% CI 0.55, 1.74; two studies; 97 participants). One study comparing single-use catheters to multiple-use catheters reported zero adverse events in either group; no other adverse event data were reported for this comparison. We identified no data for participant satisfaction or preference.

Hydrophilic-coated catheters versus uncoated catheters

We are uncertain if there is any difference between hydrophilic and uncoated catheters in terms of the number of people with symptomatic UTI because the certainty of evidence is low and the 95% CI is consistent with possible benefit and possible harm (RR 0.89, 95% CI 0.69 to 1.14; two studies; 98 participants). Uncoated catheters probably slightly reduce the risk of urethral trauma and bleeding compared to hydrophilic-coated catheters (RR 1.37, 95% CI 1.01 to 1.87; moderate-certainty evidence). The evidence is uncertain if hydrophilic-coated catheters compared with uncoated catheters has any effect on participant satisfaction measured on a 0-10 scale (MD 0.7 higher, 95% CI 0.19 to 1.21; very low-certainty evidence; one study; 114 participants). Due to the paucity of data, we could not assess the certainty of evidence relating to participant preference (one cross-over trial of 29 participants reported greater preference for a hydrophilic-coated catheter (19/29) compared to an uncoated catheter (10/29)).

Authors' conclusions

Despite a total of 23 trials, the paucity of useable data and uncertainty of the evidence means that it remains unclear whether the incidence of UTI or other complications is affected by use of aseptic or clean technique, single (sterile) or multiple-use (clean) catheters, coated or uncoated catheters or different catheter lengths. The current research evidence is uncertain and design and reporting issues are significant. More well-designed trials are needed. Such trials should include analysis of cost-effectiveness because there are likely to be substantial differences associated with the use of different catheterisation techniques and strategies, and catheter designs.

PLAIN LANGUAGE SUMMARY

Intermittent catheter techniques, strategies and catheter designs for managing long-term bladder conditions

Review question

There are different catheterisation techniques, strategies and catheter designs which may affect symptomatic urinary tract infection (UTI; a bladder infection detected through urine testing where the person has symptoms of infection), other complications and user preference.

In this review, we focussed on these outcomes in people who used aseptic or clean catheterisation techniques, single or multiple-use catheters and different designs of catheter (e.g. coated or uncoated, standard or compact length) to determine if one approach or design is better than another.

Background

Intermittent catheterisation is a common strategy used by people who have bladder emptying problems. A hollow tube (catheter) is passed through the channel to the bladder (urethra) or through a surgically made channel to the skin surface. The catheter is emptied regularly, usually several times every day. Intermittent catheterisation can be done by a healthcare professional or by the person (or carer) themselves. There are various approaches to intermittent catheterisation which could impact on infection, other complications and user experience.

There are four main types of intervention considered in this review which might make a difference to users or to costs.

Techniques: Aseptic versus clean

An 'aseptic technique' is used in healthcare settings, with specially packaged sterile equipment (gloves, lubricant and catheter) and a technique that avoids the catheter coming into contact with anything non-sterile (including hands, equipment and surfaces) before it is inserted.

People inserting their own catheters use a 'clean' technique, where the environment is kept as clean as possible and a sterile or clean (multiple-use) catheter is used without the need for gloves.

Strategies: Single-use versus multiple-use

There are two types of catheter use: single-use and multiple-use. Re-use of catheters means that the catheter is cleaned and re-used a varying number of times (e.g. for up to 24 hours or for one week/month).

Design: Uncoated versus hydrophilic-coated

Uncoated catheters are typically clear PVC and packed individually in sterile packaging. They may be supplied pre-lubricated, or used with a separate lubricant or water to aid insertion.

Hydrophilic-coated catheters have a slippery coating and either are supplied ready to use, or require the addition of water.

Design: Shorter versus standard length

Catheters come in varying sizes and lengths to suit men, women and children, and people's different needs.

How up-to-date is this review?

We searched for evidence that had been published up to 12 April 2021.

Study characteristics

We found 23 trials (involving a total of 1339 children and adults using intermittent catheterisation for bladder emptying) comparing different catheterisation techniques and catheter designs.

Key results

Aseptic versus clean techniques

We are uncertain if there is any difference between aseptic and clean techniques in the risk of symptomatic UTI. We identified no data relating to the risk of adverse events.

Single-use (sterile) catheter versus multiple-use (clean)

We are uncertain if there is any difference between single-use and multiple-use catheters in the risk of symptomatic UTI because the certainty of evidence is low. One study comparing these interventions reported zero adverse events in either group and no other adverse event data were reported.

Hydrophilic-coated catheters versus uncoated catheters

We are uncertain if there is any difference between hydrophilic and uncoated catheters in the number of people with symptomatic UTI. Uncoated catheters probably slightly reduce the risk of urethral trauma and bleeding compared to hydrophilic-coated catheters. We are uncertain if there is any difference in patient satisfaction or preference.

One catheter length versus another catheter length

We are uncertain if there is any difference between one catheter length versus another catheter length for all included outcomes.

We identified no useable evidence relating to cost-effectiveness for any of the comparisons.

Certainty of the evidence

The current research evidence is uncertain and design and reporting issues are significant. There are many factors that could limit the generalisability of findings, for example, the study setting (e.g. hospital or home), sex of participants, variability in adherence to user instructions and whether catheterisation is undertaken by the user or another person. More well-designed trials are needed. Such trials should include analysis of cost-effectiveness because there are likely to be substantial differences associated with the use of different catheter designs, catheterisation techniques and strategies.

SUMMARY OF FINDINGS

Summary of findings 1. Aseptic technique compared to clean technique for long-term bladder management

Aseptic technique compared to clean technique for long-term bladder management

Patient or population: long-term bladder management
Setting: inpatient or community
Intervention: aseptic technique
Comparison: clean technique

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with clean technique	Risk with aseptic technique				
Number with symptomatic UTI Follow-up: 12 months	Study population 375 per 1000	450 per 1000 (203 to 998)	**RR 1.20** (0.54 to 2.66)	36 (1 RCT)	⊕⊕⊖⊖ LOW [1]	**75 more per 1000** people will have symptomatic UTI with aseptic technique (173 fewer to 623 more)
Adverse effects (urethral trauma/bleeding/haematuria)	Not reported					
Participant-assessed outcome (satisfaction)	Not reported					
Participant-assessed outcome (preference)	Not reported					
Cost-effectiveness	Not reported					

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1] Downgraded two levels for imprecision: few participants

Summary of findings 2. Single-use (sterile) catheter compared to multiple-use (clean) catheter for long-term bladder management

Single-use (sterile) catheter compared to multiple-use (clean) catheter for long-term bladder management

Patient or population: long-term bladder management
Setting: inpatient or community
Intervention: single-use (sterile) catheter
Comparison: multiple-use (clean) catheter

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with multiple-use (clean) catheter	Risk with Single-use (sterile) catheter				
Number with symptomatic UTI[1] Follow-up: range two to four months	Study population 320 per 1000	314 per 1000 (176 to 557)	**RR 0.98** (0.55 to 1.74)	97 (2 RCTs)	⊕⊕⊖⊖ LOW [2]	**6 fewer per 1000** people will have symptomatic UTI with single-use catheter (144 fewer to 237 more)
Participant-assessed outcome (satisfaction)	Not reported					
Participant-assessed outcome (preference)	Not reported					
Adverse effects (urethral trauma/bleeding/haematuria): Follow-up to 2 months	One study reported zero adverse events in both arms.					
Cost-effectiveness	Not reported					

***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1] Included one cross-over study; data used from first treatment period only (22 participants)
[2] Downgraded two levels due to serious imprecision: few participants and wide 95% CI consistent with possible benefit and possible harm

Summary of findings 3. Hydrophilic-coated catheter compared to uncoated catheter for long-term bladder management

Hydrophilic-coated catheter compared to uncoated catheter for long-term bladder management

Patient or population: long-term bladder management
Setting: inpatient or community
Intervention: hydrophilic-coated catheter
Comparison: uncoated catheter

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with uncoated	Risk with Hydrophilic-coated				
Number with symptomatic UTI Follow-up: range two to 12 months	Study population 725 per 1000	645 per 1000 (500 to 826)	**RR 0.89** (0.69 to 1.14)	98 (2 RCTs)	⊕⊕⊖⊖ LOW [1,2]	**80 fewer per 1000** people will have symptomatic UTI with hydrophilic-coated catheter (225 fewer to 101 more)
Adverse effects (urethral trauma/bleeding/haematuria) Follow-up: range two to 12 months	Study population 200 per 1000	274 per 1000 (202 to 374)	**RR 1.37** (1.01 to 1.87)	400 (3 RCTs)	⊕⊕⊕⊖ MODERATE [3]	**74 more per 1000** people will have urethral trauma, bleeding or haematuria with hydrophilic-coated catheter (2 more to 174 more)

Participant-assessed outcome (satisfaction) (higher score = greater satisfaction) Scale from: 0 to 10 Follow-up: 6 months	The mean participant-assessed score for satisfaction (higher score = greater satisfaction) was 8.6 in the uncoated catheter group	MD 0.7 higher (0.19 higher to 1.21 higher)	-	114 (1 RCT)	⊕⊖⊖⊖ VERY LOW [4 5]
Participant-assessed outcome (preference) Follow-up: 20 sets of each catheter used	One cross-over trial, reported greater preference for a hydrophilic-coated catheter (19/29) compared to an uncoated catheter (10/29).		-	29 (1 RCT)	
Cost-effectiveness	Not reported				

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1] Downgraded one level due to serious risk of bias: outcomes could have been influenced by lack of blinding.
[2] Downgraded one level due to serious imprecision: small sample sizes
[3] Downgraded one level due to serious risk of performance, detection and attrition bias
[4] Downgraded one level due to serious risk of performance and attrition bias
[5] Downgraded two levels due to very serious imprecision: few participants

BACKGROUND

See Appendix 1 for a glossary of plain language terms.

Description of the condition

Many people, including those with neurologic deficits, urethral obstruction from strictures or tumours, or bladder dysfunction post-surgery, experience chronic incomplete bladder emptying. It occurs when the muscles of the bladder do not squeeze sufficiently to empty the bladder. When this happens, an artificial means of draining the bladder is needed.

Urethral intermittent catheterisation is commonly used by people who have difficulty emptying their bladder themselves. The catheter is passed through the urethra (or occasionally another catheterisable channel such as a Mitrofanoff continent urinary diversion, a surgically constructed passage connecting the bladder with the abdominal surface) into the bladder, and urine is drained as needed. The catheter is removed immediately after urine drainage until the next void is necessary. Alternatives to intermittent catheterisation include suprapubic pressure (Credé manoeuvre) or an indwelling catheter, which is left in place for a period of time.

There are little data reporting the number of people using intermittent catheters globally, but it is estimated that there are over 300,000 users in the USA alone (Sun 2017) and, in 2016, the global intermittent catheters market was valued at US$1.6 billion (Allied Market Research 2018).

Description of the intervention

Intermittent catheterisation reflects normal filling and emptying and allows freedom from the inconvenient drainage tubing of a permanent catheter. It can be undertaken by people of all ages, including the very elderly, young children with parental supervision and carers (where this is acceptable both to the intermittent catheterisation user and carer). Disabilities such as visual impairment, lack of perineal sensation, tremor, mental disability and paraplegia should not dissuade healthcare professionals from suggesting intermittent catheterisation to individuals as they may be able to master the technique (Cottenden 2017).

Catheterisation frequency should be based on individual care plans, typically performed four to five times a day, similar to a normal adult voiding routine (EAUN 2013). Fundamental to assessing suitability for intermittent catheterisation users are impact on quality of life, frequency-volume charts, functional bladder capacity, post-void residual urine and urodynamics. Clinical decisions are also informed by urodynamic findings, detrusor pressures on filling, presence of vesico-ureteral reflux and renal function for both the adult and paediatric populations.

Although it has fewer complications than those associated with an indwelling catheter (Cottenden 2017), persistent or recurrent urinary tract infection (UTI) is a common complication of intermittent catheterisation (Wyndaele 2002). Other complications include prostatitis, epididymitis, urethritis, urethral strictures and false passage. Urethral irritation, measured by haematuria, is reported particularly when intermittent catheterisation starts but is not reported as being long-lasting (Wyndaele 2002).

How the intervention might work

There are four main types of intervention considered in this review which might make a difference to UTI or other complications, or may affect measures of user satisfaction or cost-effectiveness.

Techniques: Aseptic versus clean

An aseptic technique is used in healthcare when undertaking catheterisation procedures to minimise the risk of infection. It involves the use of sterile gloves, a sterile single-use catheter, disinfection or cleansing of the genitals and use of sterile lubricant if the catheter is not pre-lubricated. The aim of an aseptic technique is to minimise the risk of introducing pathogenic microorganisms during catheterisation and thereby reduce UTI when compared with clean techniques.

A clean technique is used for intermittent self-catheterisation, where a sterile or clean (multiple-use) catheter is inserted with clean, ungloved hands and with or without a cleansing solution (soap and water, or water alone) and clean or sterile lubricant.

Strategies: Single-use versus multiple-use

Single-use catheters are used once before disposal.

Multiple-use catheters are cleaned with detergent and water or disinfected by boiling, microwaving or immersing in chemical disinfectant between uses. They may be re-used a varying number of times (e.g. for up to 24 hours or for one week). We use the term 'multiple-use' to mean catheters that are used multiple times in the studies.

Design: Uncoated versus hydrophilic-coated

Uncoated catheters are typically clear PVC and packed individually in sterile packaging. They may be supplied pre-lubricated, used with a separate lubricant or with just water to aid insertion.

Hydrophilic-coated catheters are typically PVC, have a bonded coating and are packed individually in sterile packaging. The aim of hydrophilic-coated catheters is to reduce friction and therefore reduce trauma and infection. Most common hydrophilic-coated catheters are either supplied ready to use, or require the addition of water at the time of use to form a lubricious layer.

Design: Shorter versus standard length

Catheter lengths can vary, with longer designs as standard. Shorter catheters are designed to be more discreet and convenient to use.

Why it is important to do this review

Many people rely on intermittent catheters for bladder management. It is important to know if there are any catheter techniques, strategies or catheter designs which are likely to reduce the risks associated with regular intermittent catheterisation.

OBJECTIVES

To assess the clinical and cost-effectiveness of different catheterisation techniques, strategies and catheter designs, and their impact, on UTI and other complications, and measures of satisfaction/quality of life among adults and children whose long-term bladder condition is managed by intermittent catheterisation.

METHODS

Criteria for considering studies for this review

Types of studies

We included randomised controlled trials, including cross-over trials, comparing catheterisation techniques, strategies and catheter designs for long-term bladder management by intermittent catheterisation. Cluster-randomised trials and comparative studies where participants were allocated prospectively based on quasi-random methods, such as date of birth or case record number, were also eligible.

Types of participants

We included studies of adults or children requiring urethral intermittent catheterisation for long-term bladder management. We excluded studies where the participants used catheters inserted through routes other than through the urethra.

Types of interventions

We considered as eligible comparators any intervention intended to decrease urinary tract infections or other complications, or evaluate user-reported outcomes. For the purposes of this review, we grouped them into catheterisation techniques (e.g. aseptic techniques, clean techniques), catheterisation strategies (e.g. single-use catheters, multiple-use catheters), and different catheter designs. For further definition of terms, please see Appendix 1.

We did not include strategies such as antibiotic prophylaxis, antimicrobial lubricating gel or other such interventions aimed at reducing UTI.

We addressed the following comparisons:

- Aseptic technique versus clean technique;
- Single-use catheter (sterile) versus multiple-use catheter (clean);
- Hydrophilic-coated catheter versus uncoated catheter;
- One catheter length versus another catheter length.

Of these, the first three are of particular interest to clinicians and users and have, therefore, been used for Summary of findings tables.

Types of outcome measures

We assessed the following outcome measures but did not use them as a basis for including or excluding trials.

Primary outcomes

- Number of people with symptomatic UTI (within 12 months)

For trials that pre-dated or did not meet the IDSA 2009 definition of symptomatic UTI (see Appendix 1), we chose to accept the study's own definition providing it met the NIDRR 1992 criteria (presence of one or more symptoms or signs compatible with UTI, including cloudy urine with increased odour, together with quantitative urine culture (≥ 10^2 CFU/mL).

The IDSA 2009 guideline acknowledges the difficulty in distinguishing between infection and bacteriuria in a catheterised patient given most signs and symptoms are nonspecific, necessitating clinical judgement in determining whether or not to treat with antibiotics. For this reason, we considered it appropriate to accept each study's definition of symptomatic UTI providing it met the NIDRR 1992 criteria.

Secondary outcomes

- Complications/adverse effects e.g. urethral trauma/bleeding, haematuria and stricture formation
- Comfort and ease of use self-reported by participants
- Satisfaction self-reported by participants
- Preferences self-reported by participants
- Quality of life measured by validated tools, e.g. SF-36
- Economic outcomes, including:
  - Catheter and equipment costs
  - Frequency of catheterisation
  - Resource implications (personnel and other costs to services)
  - Formal economic analysis (cost-effectiveness, cost-utility)
  - Days missed from employment/school
- Mean residual urine volume (of clinical relevance when comparing standard and shorter length catheters)

Main outcomes for the summary of findings tables

- Number of people with symptomatic UTI
- Adverse effects e.g. urethral trauma/bleeding, haematuria and stricture formation
- Satisfaction
- Preference
- Formal economic analysis (cost-effectiveness, cost-utility)

Search methods for identification of studies

We did not impose any language or other limits on the searches described below.

Electronic searches

We identified relevant trials from the Cochrane Incontinence Specialised Register. For more details of the search methods used to build the Specialised Register, please see the Group's webpages where details of the Register's development (from inception) and the most recent searches performed to populate the Register can be found. To summarise, the Register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In-Process, MEDLINE Epub Ahead of Print, ClinicalTrials.gov, WHO ICTRP, and handsearching of journals and conference proceedings. Many of the trials in the Cochrane Incontinence Specialised Register are also submitted to and contained in CENTRAL.

The terms used to search the Cochrane Incontinence Specialised Register are given in Appendix 2.

Date of the most recent search of the Register for this review: 12 April 2021.

Searching other resources

We searched the reference lists of relevant articles and conference proceedings for other possible trials.

Data collection and analysis

We conducted data collection and analysis in accordance with methods specified in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019).

Selection of studies

Two review authors (JP and CM) independently assessed each title and abstract of trials identified by the search strategy and agreed a final list. Full reports were obtained of all potentially relevant randomised controlled trials based on defined inclusion criteria and two review authors screened the full-text reports of the selected titles and abstracts. We resolved any disagreements by consulting the wider review team.

Data extraction and management

Two review authors independently extracted data relating to trial design, participants, interventions and outcomes. We used a data extraction form developed specifically for this review.

Assessment of risk of bias in included studies

Two review authors (CM and FS) independently assessed risk of bias in the included studies by using the Cochrane risk of bias tool (Higgins 2011). We assessed the risk of bias in terms of random sequence generation, allocation concealment, blinding during intervention and at outcome assessment, attrition, selective reporting, and any other potential sources of bias. We resolved any disagreements by consulting the wider review team.

Measures of treatment effect

For dichotomous data, we calculated the risk ratio (RR) with a 95% confidence interval (CI). For continuous data, we planned to present the mean difference (MD) with a 95% CI. In future updates, if we identify data for continuous outcomes that are measured using different scales, we will calculate the standardised mean difference (SMD) and 95% CI with the following interpretations (Cohen 1988):

- SMD < 0.2 = trivial or no effect
- SMD ≥ 0.2 and < 0.5 = small effect
- SMD ≥ 0.5 and < 0.8 = medium effect
- SMD ≥ 0.8 = large effect

Unit of analysis issues

The unit of analysis was each participant recruited into the trials.

For cross-over trials, we looked for reporting of paired data in order to estimate within-user differences. Where no such data were provided, we used data from the first period only in the absence of washout periods to avoid the carry-over effect, since it is not possible to have a washout period for people who require intermittent catheterisation. As an exception to this, we used the end-point data for the reporting of preference as an outcome.

For studies with more than two arms, we treated each pair of arms as a separate pairwise comparison.

Dealing with missing data

As far as possible, we analysed data using intention-to-treat (ITT) analysis, whereby all participants are analysed according to the group to which they are allocated. Where participants withdrew or were excluded after randomisation, we reported in full any details provided.

Where dichotomous data were collected only from participants who completed follow-up, we used the number completed as the denominator for outcomes relating to symptomatic UTI. In other cases, we used a conservative assumption for missing data (e.g. missing data relating to preference for standard versus compact catheter: we assumed the missing data would be in favour of the standard catheter). Where trials did not state the number of participants completing the trial, we assumed that all participants completed.

We made all reasonable attempts to contact study authors to obtain missing data or to seek further clarification.

Assessment of heterogeneity

To determine whether meta-analysis was appropriate, we assessed clinical heterogeneity by examining the trial methods used. We tested for statistical heterogeneity in meta-analyses by visual inspection of forest plots and by using the I^2 statistic. We interpreted the I^2 statistic according to the following recommendations from the Cochrane Handbook (Higgins 2019):

- 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.

Where there was evidence of substantial or greater heterogeneity, we planned to use the random-effects model.

Assessment of reporting biases

Had we identified 10 or more trials with relevant data for one outcome in the same comparison, we would have assessed the risk of reporting bias by using funnel plots.

Data synthesis

We used the fixed-effect model to analyse data. In future updates, we plan to conduct both fixed and random effect analyses with an intention to present the random effects result if there is no indication of funnel plot asymmetry.

Where trials reported data on an eleven-point scale from 0-10, or from 10-0, we inverted the statistics, where necessary, in order to synthesise the data, e.g. where one trial used 0 as least favourable and 10 as most favourable, while another trial used 10 as least favourable and 0 as most favourable.

Subgroup analysis and investigation of heterogeneity

Had sufficient data been available, we planned the following subgroup analyses to explore possible sources of heterogeneity:

- definition of symptomatic UTI: IDSA 2009 and NIDRR 1992

The IDSA guidelines clarify that in the catheterised patient, the presence or absence of odorous or cloudy urine alone should not be used to differentiate catheter-associated asymptomatic bacteriuria from catheter-associated UTI or as an indication for urine culture or antimicrobial therapy. The older NIDRR 1992 definition accepted

one or more symptoms, including cloudy urine with increased odour.

Sensitivity analysis

Had sufficient data been available, we planned sensitivity analyses on the primary outcome to explore the influence of the following factors on effect size, repeating the analysis to take into account the effect of:

- excluding studies that did not meet the IDSA 2009 definition of symptomatic UTI
- excluding studies judged to be at high risk of bias in terms of random sequence generation, allocation concealment and incomplete outcome data

Summary of findings and assessment of the certainty of the evidence

We prepared summary of findings tables for the main comparisons pre-stated in Types of interventions using the GRADEpro GDT software.

We used the GRADE approach to assess the certainty of evidence related to the outcomes listed in the 'Main outcomes for the summary of findings tables' section of the Types of outcome measures (Schünemann 2019). We used the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) to assess the certainty of the body of evidence for the prespecified outcomes. We justified all decisions to downgrade the certainty of studies using footnotes.

RESULTS

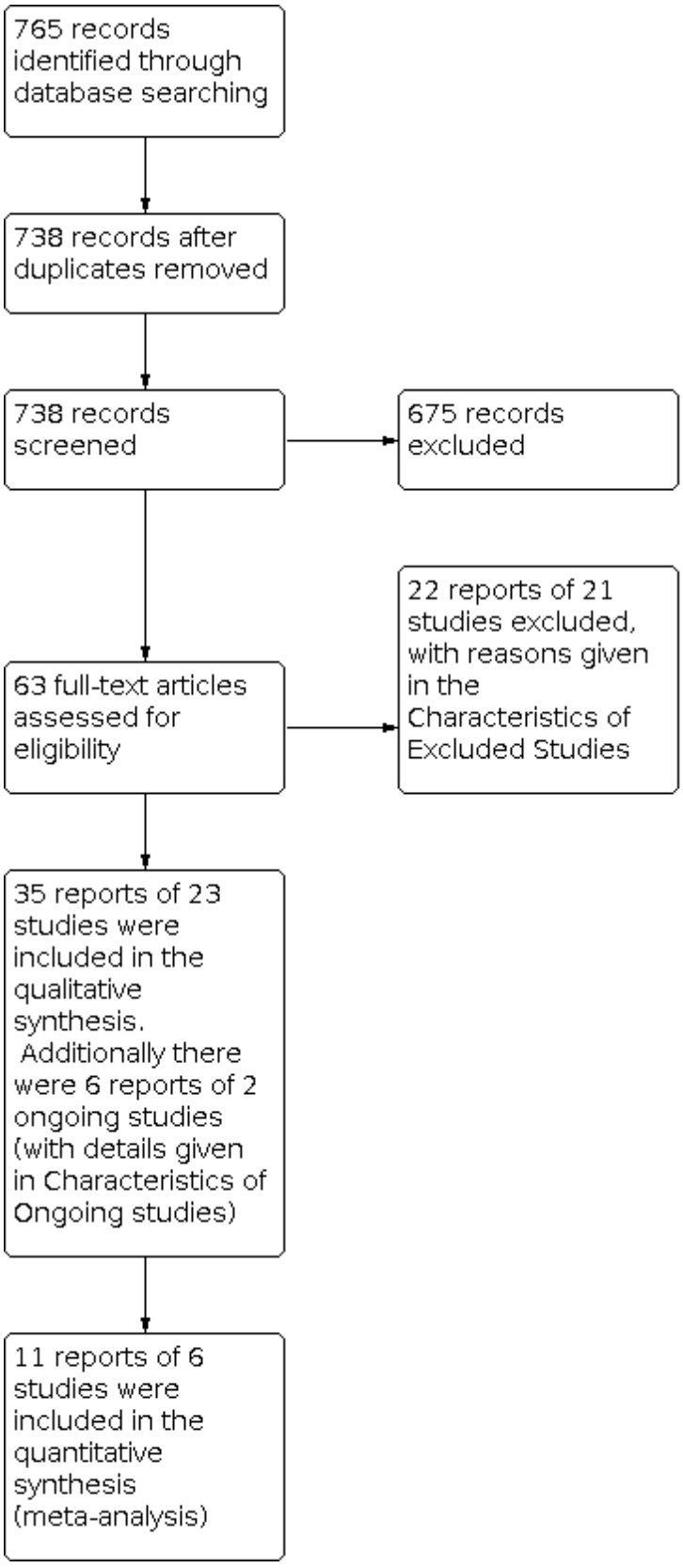
Description of studies

See Characteristics of included studies; Characteristics of excluded studies.

Results of the search

The electronic searches yielded 765 records (738 after deduplication), 63 of which we selected for full-text screening. Thirty-five reports of twenty-three studies met the eligibility criteria for inclusion in the review (the 22 reports of 21 excluded studies are listed in the Characteristics of excluded studies). There were six reports of two ongoing studies, details of which are given in Characteristics of ongoing studies. The flow of literature through the assessment process is shown in the PRISMA diagram (Figure 1).

Figure 1. PRISMA study flow diagram



Included studies

Twenty-three trials involving 1339 randomised participants met the inclusion criteria (Biering-Sorensen 2007; Cardenas 2009; Cardenas 2011; Chartier-Kastler 2011; Chartier-Kastler 2013; Costa 2013; DeFoor 2017; De Ridder 2005; Domurath 2011; Duffy 1995; King 1992; Leek 2019; Leriche 2006; Madero-Morales 2019; Moore 1993; Moore 2006; Kiddoo 2015; Prieto-Fingerhut 1997; Samal 2011; Sarica 2010; Schlager 2001; Sutherland 1996; Vapnek 2003) (see the Characteristics of included studies; Table 1).

Design

There were 12 parallel-group randomised controlled trials (Cardenas 2009; Cardenas 2011; DeFoor 2017; De Ridder 2005;Duffy 1995; King 1992; Madero-Morales 2019; Moore 2006; Prieto-Fingerhut 1997; Samal 2011; Sutherland 1996; Vapnek 2003).

The other 11 studies were cross-over randomised controlled trials:

- 10 with two arms (Biering-Sorensen 2007; Chartier-Kastler 2013; Chartier-Kastler 2011; Costa 2013; Domurath 2011; Leek 2019; Leriche 2006; Moore 1993; Kiddoo 2015; Schlager 2001); and
- one with three arms (Sarica 2010).

Sources of funding

Most studies did not report their sources of funding. Two trials stated receipt of funding from catheter manufacturers (DeFoor 2017; Schlager 2001).

Sample sizes

In most trials, the sample size was small (fewer than 60 participants). Of the 23 included trials, only three had a sample size of 100 or more (Cardenas 2011; Chartier-Kastler 2013; De Ridder 2005).

Ten trials included statistical power calculations (Biering-Sorensen 2007; Cardenas 2009; Cardenas 2011; Chartier-Kastler 2011; Chartier-Kastler 2013; De Ridder 2005; Domurath 2011; Leek 2019; Moore 2006; Kiddoo 2015). However, only one was able to achieve its predicted sample size (Chartier-Kastler 2013).

At trial end-point, the sample sizes ranged from 10 to 114 participants in total (Schlager 2001 and Cardenas 2011, respectively).

Participants

Trials included various types of people using intermittent catheterisation:

- people with spinal cord injury (Cardenas 2011; De Ridder 2005; Domurath 2011; King 1992; Moore 2006; Prieto-Fingerhut 1997; Samal 2011; Sarica 2010);
- people with spinal cord injury who had experienced more than one UTI (Cardenas 2009);
- people with spinal cord lesion (Biering-Sorensen 2007; Chartier-Kastler 2011);
- children with spina bifida (Moore 1993; Kiddoo 2015; Schlager 2001);
- children with neurogenic bladders (DeFoor 2017; Sutherland 1996);
- children and adults with neurogenic bladders (Madero-Morales 2019);
- adults with neurogenic bladder disorders (Costa 2013);
- people with a vesico-sphincteric problem of neurological origin (Leriche 2006);
- people with a variety of diagnoses (Chartier-Kastler 2013; Leek 2019); and
- people with no stated aetiology of the bladder dysfunction (Duffy 1995; Vapnek 2003).

Age and gender also varied:

- boys and girls with spina bifida (Moore 1993; Kiddoo 2015; Schlager 2001);
- children with neurogenic bladders (DeFoor 2017; Sutherland 1996);
- children and adults, male and female, with neurogenic bladders (Madero-Morales 2019);
- adult men with a vesico-sphincteric problem of neurological origin (Leriche 2006);
- adult men with no stated aetiology of the bladder dysfunction (Duffy 1995);
- adult men and women with spinal cord injury or lesion (Biering-Sorensen 2007; Cardenas 2009; Cardenas 2011; Chartier-Kastler 2011; Chartier-Kastler 2013; De Ridder 2005; Domurath 2011; King 1992; Moore 2006, Prieto-Fingerhut 1997; Samal 2011; Sarica 2010); and
- adult males and females with nonspecified neurogenic bladder (Costa 2013; Leek 2019).

Nine trials included only men as participants (Chartier-Kastler 2011; De Ridder 2005; Domurath 2011; Duffy 1995; Leriche 2006; Samal 2011; Sarica 2010; Sutherland 1996; Vapnek 2003); and one included women only (Biering-Sorensen 2007).

Setting

Settings ranged from:

- rehabilitation hospital (Biering-Sorensen 2007; Moore 2006; Prieto-Fingerhut 1997);
- spinal cord injury unit (Cardenas 2011; King 1992; Samal 2011);
- hospital outpatient clinic (Chartier-Kastler 2011; Leek 2019; Leriche 2006; Madero-Morales 2019; Sarica 2010);
- paediatric clinic (Kiddoo 2015);
- community (Cardenas 2009; Cardenas 2011; De Ridder 2005; DeFoor 2017; Schlager 2001; Sutherland 1996; Vapnek 2003); and
- residential care facility (Duffy 1995).

The setting was not described in three trials (Chartier-Kastler 2013; Costa 2013; Domurath 2011).

Interventions

Interventions were separated into four main categories.

- Aseptic technique (sterile catheter) versus clean technique (sterile catheter) (Duffy 1995; King 1992; Moore 2006; Prieto-Fingerhut 1997)

- Single-use catheter (sterile) versus multiple-use catheter (clean) (Duffy 1995; Kiddoo 2015; King 1992; Leek 2019; Madero-Morales 2019; Moore 1993; Prieto-Fingerhut 1997; Schlager 2001; Sutherland 1996; Vapnek 2003)
- Hydrophilic-coated catheter versus uncoated catheter (Cardenas 2009; Cardenas 2011; De Ridder 2005; DeFoor 2017; Leriche 2006; Kiddoo 2015; Samal 2011; Sarica 2010; Sutherland 1996; Vapnek 2003). All included studies used uncoated catheters that required separate lubrication (not pre-lubricated).
- One catheter length versus another catheter length (Biering-Sorensen 2007; Chartier-Kastler 2011; Chartier-Kastler 2013; Costa 2013; Domurath 2011)

Where there was clear potential for confounding between categories, we did not use the data. For example, in the first comparison we included only studies using a sterile catheter in both arms as the technique is the intervention. In the second comparison we aimed to compare the catheter (single versus multiple use) rather than the insertion technique and therefore only used data from studies that used the same insertion technique (either clean or sterile) in both arms.

Duration of intervention

In each arm of the cross-over trials, participants were catheterised for one to two days (Biering-Sorensen 2007, Domurath 2011); 12 to 14 days (Chartier-Kastler 2011); six to seven weeks (Sarica 2010); 12 weeks (Chartier-Kastler 2013), four months (Leek 2019, Schlager 2001); six months (Moore 1993), 48 weeks (Kiddoo 2015); or for the time required to use 10 catheters (Costa 2013) or 20 catheters (Leriche 2006).

In the 12 parallel-group trials, the duration of the intervention varied:

- up to one month (King 1992);
- two months (Madero-Morales 2019; Samal 2011; Sutherland 1996);
- up to three months (Duffy 1995)
- up to six months (Cardenas 2011);
- up to 12 months (Cardenas 2009; DeFoor 2017; De Ridder 2005; Moore 2006; Vapnek 2003); and
- unclear duration (Prieto-Fingerhut 1997).

Outcome measures

Sixteen trials reported symptomatic UTI as an outcome measure (Cardenas 2009; Cardenas 2011; De Ridder 2005; Duffy 1995; Kiddoo 2015; King 1992; Leek 2019; Madero-Morales 2019; Moore 1993; Moore 2006; Prieto-Fingerhut 1997; Samal 2011; Sarica 2010; Schlager 2001; Sutherland 1996; Vapnek 2003).

Three trials met the ISDA 2009 definition of UTI (King 1992; Moore 2006; Sutherland 1996); eight trials met the NIDRR 1992 definition (Cardenas 2009; Cardenas 2011; Leek 2019; Madero-Morales 2019; Moore 1993; Prieto-Fingerhut 1997; Samal 2011; Sarica 2010; Schlager 2001), and four trials did not meet either definition (De Ridder 2005; Duffy 1995; Kiddoo 2015; Vapnek 2003). For the description provided in each report, please see the Characteristics of included studies.

Six trials reported on either microscopic and/or macroscopic haematuria (Cardenas 2011; De Ridder 2005; Kiddoo 2015; Leriche 2006; Sutherland 1996; Vapnek 2003).

Ten trials included user-reported outcomes (Biering-Sorensen 2007; Cardenas 2011; Chartier-Kastler 2011; Chartier-Kastler 2013; Costa 2013; De Ridder 2005; Domurath 2011; Leriche 2006; Kiddoo 2015; Sarica 2010). Some trials reported overall satisfaction, whereas others reported mean satisfaction. These results could not be combined as they provided dichotomous or continuous data. Moreover, the tools used to measure user-reported outcomes varied widely and only Chartier-Kastler 2011 used a validated tool (Pinder 2012).

Although some of the trials included calculations of the costs of one catheter versus another, none of the trials undertook a formal evaluation of cost-effectiveness.

Excluded studies

A total of 21 trials were excluded as they did not meet the review inclusion criteria, either because they were not randomised studies and/or they did not investigate one of our prespecified comparisons. For full reasons for exclusion, please see the Characteristics of excluded studies.

Ongoing studies

We identified two ongoing studies, details of which can be found in the list of Ongoing studies.

Risk of bias in included studies

Details of the risk of bias for each trial are given in the risk of bias tables in the Characteristics of included studies. The findings are summarised in Figure 2 and Figure 3.

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

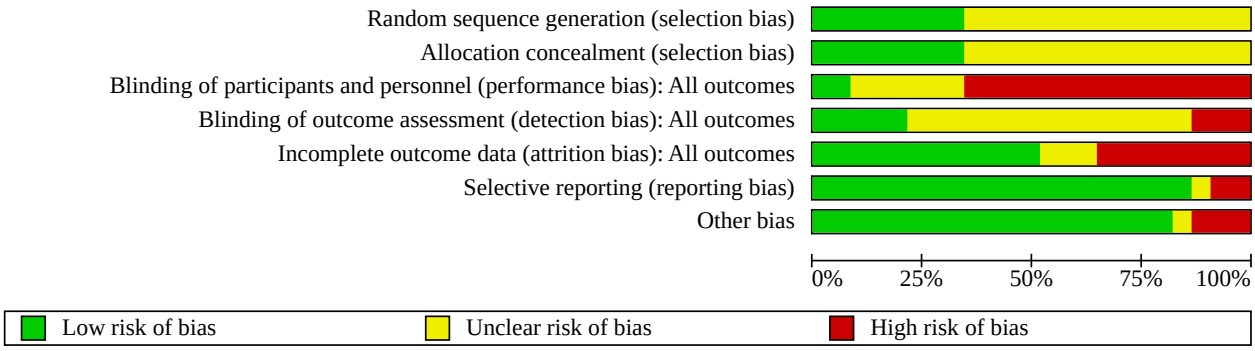


Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

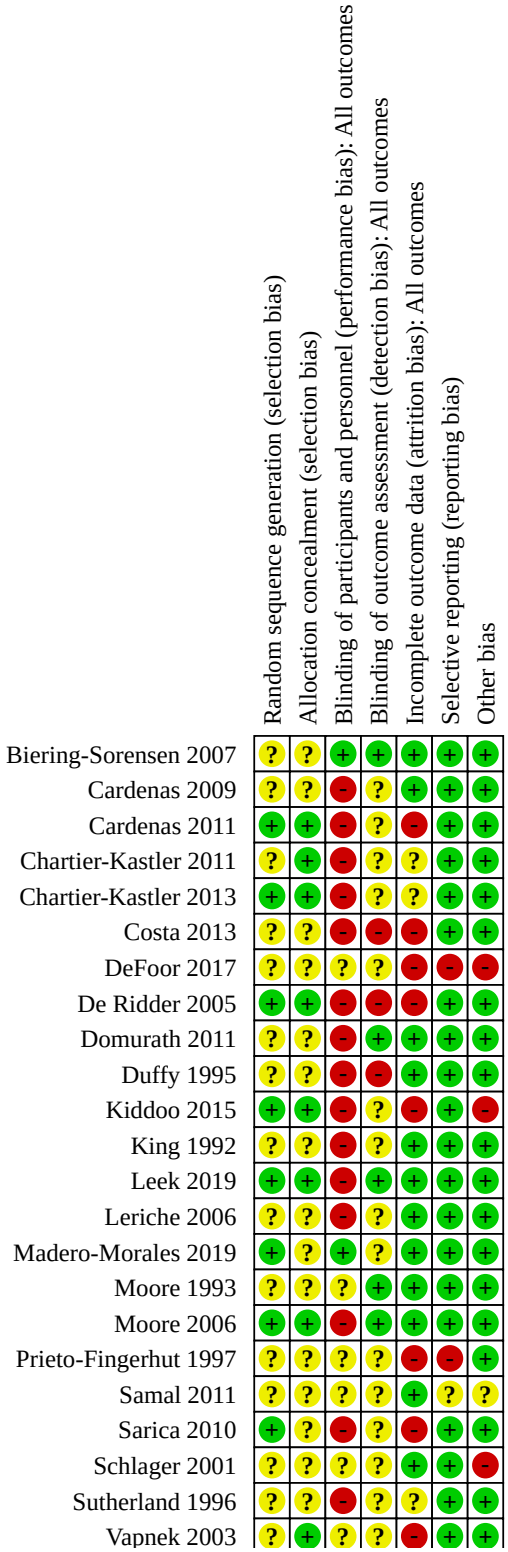
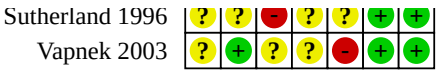


Figure 3. (Continued)



Allocation

Random sequence generation

We judged the risk of bias as low in nine studies in which an appropriate method (i.e. a random numbers table or computer software) was used to generate the random sequence (Cardenas 2011; Chartier-Kastler 2013; Costa 2013; De Ridder 2005; Kiddoo 2015; Leek 2019; Madero-Morales 2019; Moore 2006; Sarica 2010). However, in the other 14 trials, study authors did not report how participants were randomly assigned to different treatment groups. We judged the risk of bias of these trials as unclear.

Allocation concealment

Only eight trials were judged as being of low risk for allocation concealment (Cardenas 2011; Chartier-Kastler 2011; Chartier-Kastler 2013; De Ridder 2005; Kiddoo 2015; Leek 2019; Moore 2006; Vapnek 2003). The remaining trials did not provide sufficient information to permit judgement about allocation concealment.

Blinding

It was not possible to blind participants due to differences in the catheter or catheter packaging.

Blinding of participants and personnel

Risk of performance bias was judged as low in two trials (Biering-Sorensen 2007; Madero-Morales 2019), where blinding was not possible but we judged it unlikely to pose a risk of performance bias, given that the main outcomes in the study were objective.

We judged 15 trials as having high risk of performance bias because there was no blinding and it was likely that the outcome could be influenced by the participants' knowledge of their treatment allocation (Cardenas 2009; Cardenas 2011; Chartier-Kastler 2011; Chartier-Kastler 2013; Costa 2013; De Ridder 2005; Domurath 2011; Duffy 1995; Kiddoo 2015; King 1992; Leek 2019; Leriche 2006; Moore 1993; Sarica 2010; Sutherland 1996).

We judged the remaining trials as having unclear risk of performance bias because there was insufficient information in the trial reports to assess whether blinding had taken place or not and whether it could have had an effect on the outcomes.

Blinding of outcome assessment

Five trials were judged as having low risk of detection bias because study authors specified that outcome assessors were not aware of the intervention assignment (Biering-Sorensen 2007; Domurath 2011; Leek 2019; Moore 1993; Moore 2006).

Three trials were assessed as being at high risk of bias as study authors specified or indicated no blinding in the outcome assessment (Chartier-Kastler 2013; Costa 2013; De Ridder 2005). The remaining 16 trials were classed as unclear for this domain because of insufficient information needed for the judgement.

Incomplete outcome data

In six studies, attrition bias was assessed to be high risk where high numbers of participants did not complete outcome data and there was an imbalance between arms (Cardenas 2011; Costa 2013; DeFoor 2017; De Ridder 2005; Kiddoo 2015; Prieto-Fingerhut 1997). Eight studies were considered to have an unclear risk of bias and eight to have low risk where a high and balanced number of participants completed outcome data (Biering-Sorensen 2007; Cardenas 2009; Duffy 1995).

Intention-to-treat analysis

Two authors described intention-to-treat analysis (DeFoor 2017; Moore 2006).

Selective reporting

Twenty trials were assessed to have a low risk of selective reporting because they appeared to report fully their prespecified outcomes. Two were judged to be high risk because they did not report data for all their outcomes or because they did not report denominators in their data (DeFoor 2017; Prieto-Fingerhut 1997). One trial was assessed as having an unclear risk of reporting bias as an electronic translation did not provide full detail and we did not have sufficient information to make a judgement (Samal 2011). A full translation will be a priority for any future update.

Other potential sources of bias

Four trials were assessed as having high risk of other bias: one due to the possible influence of industry funding (DeFoor 2017); and three because of a lack of a washout period as part of the cross-over study design, which could have an impact on the outcomes measured. (Kiddoo 2015; Leek 2019; Schlager 2001).

Effects of interventions

See: **Summary of findings 1** Aseptic technique compared to clean technique for long-term bladder management; **Summary of findings 2** Single-use (sterile) catheter compared to multiple-use (clean) catheter for long-term bladder management; **Summary of findings 3** Hydrophilic-coated catheter compared to uncoated catheter for long-term bladder management

Aseptic technique versus clean technique

Four trials reported on aseptic versus clean technique (Duffy 1995; King 1992; Moore 2006; Prieto-Fingerhut 1997). In clinical practice, a clean insertion technique may use a sterile or a clean catheter. However, it is important to separate the effect of the insertion technique from use of single versus multiple-use catheters or sterile versus clean catheters. For this reason, we included only data from trials that used a single-use sterile catheter in both arms (Moore 2006).

Primary outcome

Number of people with symptomatic UTI

Moore 2006 reported symptomatic UTI, which met the IDSA 2009 definition of infection. We are not certain if there is any difference between aseptic and clean techniques in the risk of symptomatic UTI (low-certainty evidence; RR 1.20 95% CI 0.54 to 2.66; one study; 36 participants; Analysis 1.1; Summary of findings 1).

Secondary outcomes

None of the secondary outcomes were reported.

Single-use catheter (sterile) versus multiple-use catheter (clean)

Five parallel-group trials (Duffy 1995; King 1992; Madero-Morales 2019; Prieto-Fingerhut 1997; Vapnek 2003) and four two-arm cross-over trials (Leek 2019; Kiddoo 2015; Moore 1993; Schlager 2001) compared single-use catheters (sterile) with multiple-use catheters (clean). Only six trials which used the same insertion technique in both arms (either clean or aseptic) were included to avoid comparison of technique confounding the comparison of catheter (single- or multiple-use) (Leek 2019; Kiddoo 2015; Madero-Morales 2019; Moore 1993; Schlager 2001; Vapnek 2003). All of these trials used a clean technique in both arms.

Four trials compared single-use catheters (uncoated) with multiple-use catheters (Leek 2019; Madero-Morales 2019; Moore 1993; Schlager 2001). The other two compared single-use catheters (hydrophilic-coated) with multiple-use catheters (uncoated) (Kiddoo 2015; Vapnek 2003). Trial time frames ranged from eight weeks to one year (per arm for cross-over trials). Cleaning methods varied. In Kiddoo 2015 and Madero-Morales 2019, clean catheters were re-used for one week; in Vapnek 2003, clean catheters were re-used for one day; Leek 2019, Moore 1993 and Schlager 2001 did not describe the number of re-uses of the non-coated catheter.

Primary outcome

Number of people with symptomatic UTI

Two parallel-group trials (Madero-Morales 2019; Vapnek 2003) and three cross-over trials (Leek 2019; Moore 1993; Schlager 2001) reported on the number of participants with symptomatic UTI. However, in Vapnek 2003, the data were not usable as UTIs were self-reported by participants retrospectively and microbiological analysis of urine undertaken as part of the trial did not coincide with the time of infection. Data from Moore 1993 and Schlager 2001 were not usable in this review as they reported neither paired data nor mid- or end-point data. Mid-point data for the first eight weeks of the Leek 2019 trial was used.

Leek 2019 and Madero-Morales 2019 met the NIDRR 1992 definition, including allowing 'foul smelling urine' alone to differentiate UTI from asymptomatic bacteriuria.

We are uncertain if there is any difference between single-use and multiple-use catheters in terms of the risk of symptomatic UTI because the certainty of evidence is low and the 95% CI is consistent with possible benefit and possible harm (RR 0.98, 95% CI 0.55 to 1.74; two studies; 97 participants; Summary of findings 2).

Secondary outcomes

Complications/adverse effects

One trial reported that there were no serious adverse advents during the study period (Madero-Morales 2019).

Comfort and ease of use

One cross-over trial reported on comfort and ease of handling but it was not possible to distinguish between the effect of catheter coating (hydrophilic versus uncoated) and re-use (Kiddoo 2015). In addition, it did not report paired data or mid- and end-point data and so the data were not reported here.

Satisfaction

One trial reported on satisfaction (Kiddoo 2015). However, the data were not usable for the purpose of this review as the study reported neither paired data nor mid- and end-point data.

Preferences

Not reported.

Quality of life measures

Not reported.

Economic outcomes

Not reported.

Mean residual urine volume

Not reported.

Hydrophilic-coated catheter versus uncoated catheter

Nine trials compared a hydrophilic-coated catheter with an uncoated catheter (Cardenas 2009; Cardenas 2011; DeFoor 2017; De Ridder 2005; Kiddoo 2015; Leriche 2006; Samal 2011; Sarica 2010; Sutherland 1996). Seven trials used single-use catheters in both arms (Cardenas 2009; Cardenas 2011; DeFoor 2017; De Ridder 2005; Leriche 2006; Samal 2011; Sarica 2010). In one trial, the uncoated catheters were re-used (Kiddoo 2015).

Primary outcome

Number of people with symptomatic UTI

Three RCTs reported on the number of participants with symptomatic UTI using the NIDRR 1992 definition of infection (Cardenas 2009; DeFoor 2017; Samal 2011). In Cardenas 2009, 12 of 22 participants in the coated arm and 14 of 23 in the uncoated arm reported symptomatic UTI. In Samal 2011, 28 of 36 participants in the coated arm and 15 of 17 in the uncoated arm reported UTI. For DeFoor 2017, it was not possible to distinguish between catheters inserted urethrally and those inserted abdominally and the data were therefore not included.

We are not certain if there is any difference between hydrophilic- and uncoated catheters in terms of the number of people with symptomatic UTI because the certainty of evidence is low and the 95% CI is consistent with possible benefits and possible harms (RR 0.89, 95% CI 0.69 to 1.14; two studies; n = 98) (Analysis 3.1; Summary of findings 3).

Several trials in this comparison provided no useable data for this outcome:

- Kiddoo 2015 (cross-over trial) reported on the number of people with symptomatic UTI but did not meet either the IDSA 2009 or NIDRR 1992 definition. Also, it was not possible to distinguish between the effect of catheter coating (hydrophilic- versus uncoated) and re-use and so the data were not reported here.
- Cardenas 2011 (RCT) had no usable data for the number of people with symptomatic UTI as the incidence of UTIs per month was reported.
- Sarica 2010 (cross-over trial) had no usable data as it reported neither paired data nor mid- and end-point data.
- De Ridder 2005 (RCT) reported the number of people in each group who received antibiotics (39/61 participants in the hydrophilic group and 51/62 in the uncoated group). However, there was no trial definition of symptomatic UTI, using instead retrospective self-reported UTI for which treatment was prescribed as a proxy measure. Microbiological analysis of urine undertaken as part of the trial did not coincide with the time of self-reported treatment of infection. Therefore, the study did not meet the definition of symptomatic UTI used in this review.
- Sutherland 1996 was unclear whether the uncoated catheters were re-used or had single use and we have, therefore, not included the trial in this outcome.

Secondary outcomes

Complications/adverse effects

Urethral trauma/bleeding

Six trials reported on urethral trauma or visible bleeding (Cardenas 2011; DeFoor 2017; De Ridder 2005; Leriche 2006; Samal 2011; Sutherland 1996). However, data from DeFoor 2017 and Leriche 2006 were not usable. Leriche 2006 reported neither paired data nor mid- and end-point data. In DeFoor 2017, it was not possible to distinguish between catheters inserted urethrally and those inserted abdominally.

There is moderate certainty of evidence that risk of urethral trauma and bleeding from uncoated catheters is similar or lower compared to hydrophilic-coated catheters (RR 1.37, 95% CI 1.01 to 1.87; Analysis 3.2; moderate-certainty evidence; Summary of findings 3).

Haematuria

Two trials reported on this outcome. Kiddoo 2015 reported on microscopic haematuria. However, the results were not usable as neither paired data nor mid- and end-point data were reported. De Ridder 2005 reported haematuria between the two groups, except at the initial study visit, where a higher number of patients had microscopic haematuria in the SpeediCath group compared to the PVC group (P = 0.02). This difference was eliminated at day 15.

Stricture formation

Not reported.

Comfort and ease of use

Three trials reported on comfort or ease of use (Cardenas 2011; Kiddoo 2015; Leriche 2006). However, data from Kiddoo 2015 and Leriche 2006 were not usable as they reported neither paired data nor mid- and end-point data.

With regard to ease of insertion and comfort, Cardenas 2011 reported patient-assessed scores on a 0 to 10 scale, where higher scores indicate greater ease and greater comfort. For ease of insertion, comfort during insertion and comfort during withdrawal, the hydrophilic-coated catheters scored better on average than the uncoated catheters (although this difference was not examined statistically).

Outcome	Hydrophilic-coated (n = 45) (mean score [SD])	Uncoated (n = 69) (mean score [SD])
Ease of insertion	9.2 (1.6)	8.6 (1.6)
Comfort during insertion	9.3 (1.2)	8.9 (1.4)
Comfort during withdrawal	9.4 (1.1)	9.0 (1.5)

Satisfaction

Five trials reported on satisfaction (Cardenas 2011; De Ridder 2005; Kiddoo 2015; Leriche 2006; Sarica 2010). However, three of these reported data in a way that was not suitable for analysis (De Ridder 2005; Leriche 2006; Sarica 2010). Kiddoo 2015 reported on satisfaction but it was not possible to distinguish between the effect of catheter coating (hydrophilic versus uncoated) and re-use and so the data were not reported here.

Cardenas 2011 reported on mean satisfaction scores on a 0-10 scale (where a higher number equals greater satisfaction). We are very uncertain if there is any difference in satisfaction between coated and uncoated catheters because the certainty of evidence is very low (MD 0.70, 95% CI 0.19 to 1.21; 114 participants 114; one study; Analysis 3.3; Summary of findings 3).

Preference

One cross-over trial reported preference for a hydrophilic-coated catheter set (19/29) or an uncoated catheter set (10/29) (both with integral collection bags) (Leriche 2006). We are very uncertain if there is any difference between hydrophilic-coated catheters and uncoated catheters in terms of preference because the certainty of evidence is very low (Summary of findings 3).

Quality of life measures

Not reported.

Economic outcomes

Not reported.

Mean residual urine volume

Not reported.

One catheter length versus another catheter length

Five two-arm cross-over trials compared a shorter catheter length with a standard catheter (Biering-Sorensen 2007; Chartier-Kastler 2011; Chartier-Kastler 2013; Costa 2013; Domurath 2011). Chartier-Kastler 2011 and Domurath 2011 compared hydrophilic-coated catheters in both arms. In Biering-Sorensen 2007 and Chartier-Kastler 2013, the shorter catheter was hydrophilic-coated and the standard catheters were various designs. Costa 2013 evaluated uncoated catheters in both arms, the only difference being standard (40 cm) versus shorter (30 cm) length. All but one trial tested the catheters on male participants; Biering-Sorensen 2007 had female only participants. Participants in Biering-Sorensen 2007, Chartier-Kastler 2011; Chartier-Kastler 2013 and Domurath 2011 had either spinal cord injuries or lesions, while those in Costa 2013 were paraplegics requiring wheelchairs for mobility.

Primary outcome

Number of people with symptomatic UTI

Not reported.

Secondary outcomes

Complications/adverse effects

Domurath 2011 reported the number of participants with visible bleeding but did not provide paired or mid- and end-point data.

Comfort and ease of use

Two cross-over trials reported on discomfort (Chartier-Kastler 2011; Domurath 2011), while four cross-over trials reported aspects of ease of use (Biering-Sorensen 2007; Chartier-Kastler 2011; Costa 2013; Domurath 2011). However, these data were not usable as the studies reported neither paired data nor mid- and end-point data.

Satisfaction

One cross-over trial reported on satisfaction (Biering-Sorensen 2007). However, the data were not usable as the study reported neither paired data nor mid- and end-point data.

Preferences

Cross-over trials allow for evaluation of preference. Three trials reported on user preference (Chartier-Kastler 2013; Costa 2013; Domurath 2011).

Domurath 2011 and Chartier-Kastler 2013 compared standard length hydrophilic-coated catheters with a shorter length compact design catheter in men and found in favour of the shorter catheter (101/162 preferred the shorter length). However, Costa 2013 compared uncoated catheters in both arms and found that few participants (male) preferred the shorter catheter (7 out of 81). Differences in the products used in each of the trials means that comparison between trials could be confounded by other product characteristics (e.g. coating).

Quality of life measures

One cross-over trial used a validated quality of life tool (Chartier-Kastler 2013). However, the data were not usable as the study reported neither paired data nor mid- and end-point data.

Economic outcomes

Not reported.

Mean residual urine volume

Two cross-over trials reported residual volume (Biering-Sorensen 2007; Domurath 2011). However, Biering-Sorensen 2007 reported median rather than mean volume and therefore data have not been included. Domurath 2011 reported a mean residual volume for the shorter length catheter of 12.44 mL compared to 9.35 mL for the standard length catheter.

DISCUSSION

Summary of main results

The purpose of the current review was to determine if certain catheterisation technique, strategies (including re-use) or designs of catheter are better than others in terms of UTI, complications, user satisfaction, preference, ease of use and/or cost-effectiveness for adults and/or children whose long-term (with no predicted end-point) bladder management is by urethral IC. There remains an absence of robust evidence to support any given technique, strategy or design over another with respect to control of clinical symptoms, particularly symptomatic UTI. None of the trials included an economic evaluation.

We are uncertain if aseptic technique compared with clean technique has any effect on the risk of symptomatic UTI because the wide 95% CI is consistent with possible benefit and possible harm (low-certainty evidence; Summary of findings 1). No other evidence was available comparing aseptic technique with clean technique for our other prespecified GRADE outcomes.

We are uncertain if single-use catheter compared with multiple-use catheter has any effect on the risk of symptomatic UTI because the wide 95% CI is consistent with possible benefit and possible harm (low-certainty evidence; Summary of findings 2). Due to the paucity of data, we could not assess the certainty of evidence relating to adverse events (one study reported zero events in both arms). No other evidence was available comparing single-use catheter with multiple-use (clean) catheter for our other prespecified GRADE outcomes.

We are uncertain if hydrophilic-coated catheter compared with uncoated catheter has any effect on the risk of symptomatic UTI because the wide 95% CI is consistent with possible benefit and possible harm (low-certainty evidence; Summary of findings 3). There is moderate certainty of evidence that risk of urethral trauma and bleeding from uncoated catheters is similar or lower compared to hydrophilic-coated catheters (Summary of findings 3). We are uncertain if hydrophilic-coated catheter compared with uncoated catheter has any effect on participant satisfaction (very low-certainty evidence; Summary of findings 3). Due to the paucity of data, we could not assess the certainty of evidence relating to participant preference (one cross-over study reported greater preference for hydrophilic-coated compared with uncoated catheter).

We are uncertain whether the length of the catheter has any effect on the outcomes of interest, including patient-reported outcomes and complications.

Overall completeness and applicability of evidence

There is insufficient evidence supporting one catheter technique, strategy or design over another. Given the wide variety of catheter designs available and the various factors that affect use of intermittent catheterisation, not all aspects of catheter design or usability were addressed in the available studies. Moreover, our ability to compare studies was limited by the wide range of participants, varying in age, sex, health conditions and settings, in the included studies.

A key clinical question remains about the influence of catheter technique, strategy or design on incidence of symptomatic UTI. The difficulty of establishing robust outcome measures of UTI remains problematic. A positive urine culture is not clinically relevant unless accompanied by symptoms but the symptoms themselves may present in vague and imprecise ways, especially in adults with spinal cord injury (IDSA 2009). However, symptomatic UTI remains the most clinically important outcome variable and was the primary focus of this review.

A further complication are the differing definitions of symptomatic UTI, which can potentially lead to inconsistencies between trials. As UTI definitions are based on consensus statements (IDSA 2009; NIDRR 1992; see full definitions in the Types of outcome measures), Cochrane leaves the interpretation to the review authors. Differences in these UTI definitions posed a potential issue with data interpretation - for example, cloudy/odorous urine and pyuria were included as symptoms in NIDRR 1992 but were excluded in IDSA 2009. In this Cochrane Review, trialists' definitions ranged from self-reported symptoms and the need for antibiotics, to the more specific descriptions by NIDRR 1992 and IDSA 2009.

To test whether heterogeneous or homogenous definitions made a difference, we planned to analyse the data in two ways according to the definitions presented in the trial (IDSA 2009; NIDRR 1992). However, sufficient data were not available. It must be noted that the narrower the definition, the fewer the trials that can be included. We remain uncertain if there is any difference in incidence of UTI between catheter technique, strategy or design.

We did not identify any economic evaluations conducted alongside any of the included trials, so we cannot draw any conclusions relating to the prespecified economic outcomes. Evidence from model-based economic evaluations exists but we did not include this in the review (Bermingham 2013; Clark 2016; Hakansson 2016; Rognoni 2017a; Truzzi 2018; Watanabe 2017; Welk 2018).

Quality of the evidence

There remains an absence of robust evidence to support any given catheterisation technique, strategy or catheter design over another with respect to control of clinical symptoms, particularly symptomatic UTI. Generally, the risk of bias in terms of randomisation, allocation concealment and blinding of outcome assessment was unclear due to insufficient reporting. Lack of blinding of participants and personnel in a substantial number of the trials was judged to introduce a high risk of bias but it is recognised that this is unavoidable in some circumstances. Around a third of the trials were at high risk of bias due to incomplete outcome data. The certainty of the evidence was low to very low. We downgraded for risk of bias and for imprecision due to low numbers of participants in the trials.

Assessment of user-reported outcomes: A total of 10 trials had user-reported outcomes, nine of which used questions that had not undergone standard psychometric testing and validation. Chartier-Kastler 2013 was the first trial to apply a newly developed and validated 24-item Intermittent Self-Catheterisation Questionnaire (ISC-Q), which evaluates aspects of quality of life specific to the needs of individuals performing ISC (Pinder 2012). The tool has four domains (ease of use, discreetness, convenience and psychological well-being) and a total score, although Chartier-Kastler 2013 only reported the total score. In this review, the most frequently reported outcome measures related to ease of use, with nine studies reporting ease of insertion and seven reporting ease of handling. Fewer studies reported outcomes relating to discreetness and convenience. Future studies would benefit from adopting a more consistent approach to the measurement of user-reported outcomes in assessing the benefit of one intermittent catheterisation product over another.

Reporting standards: standards varied and not all trials followed the Consort guidelines, making it difficult to extract data. In those that followed good reporting standards, adverse events such as haematuria were clearly attributed to one of the trial arms.

Potential biases in the review process

Notwithstanding the comprehensive literature searches, it is possible there is unpublished evidence pertinent to our review question that we have not identified. Furthermore, suboptimal reporting of trial methods limits our ability to make meaningful comparisons using the relevant data. In our analysis of cross-over studies, we acknowledge that by including data from only the first treatment period there is a potential source of bias in that we have discarded some outcome data that could theoretically contribute to answering our research question. However, we judged this approach to be appropriate in the context of the cross-over studies that we identified, which did not include a washout period and in which carry-over could be a problem.

Cross-over trials: Cross-over trials are attractive to researchers as they can reduce confounding covariates and have the participant act as their own control. One important point to note is that cross-over studies can be much smaller than parallel-group RCTs whilst still being adequately powered. For example, if a cross-over trial is designed to detect a 20% reduction from three UTIs per year, and assuming within-participant variance was no more than half that of the between-participant variance (which is typical), then a trial of only 20 per arm would have 80% power. However, the methods for analysing cross-over studies for meta-analysis are complex. In the 11 cross-over trials reviewed, there seems to have been two approaches considered.

The first method, where all intervention data is compared with all control data, fails to take into account the paired nature of cross-over trial data and, as such, results lack precision. The second method, which just uses data from the first period only, is now recognised to be biased as first-period data is more commonly available when there is significant carryover and this underestimates the true treatment effect. Although these methods are suboptimal, they are, however, conservative approaches: both

are more likely to yield Type II rather than Type I errors. The Cochrane Handbook recommends a third method, i.e. to use all the data and also take the paired nature of the data into account. This avoids the imprecision and bias which can occur when other methods are used, and we attempted to use this approach when possible. The problem with this method, however, is that it is dependent on sufficient results (e.g. a paired t-test) being published in the included trials in order to estimate the within-patient differences. It may be that lack of reporting (or the inability to contact authors) might mean that one of the other methods needs to be employed, but we suggest that at least an attempt at approximating a paired analysis should be undertaken.

Another issue with cross-over trials is the need for a washout period. The analysis always assumes that there is no carryover effect, and studies should be designed to include a washout period of a suitable duration if carryover is possible, otherwise the treatment effect can be underestimated. We considered that a UTI which begins in the first period might not be detected until the second period. If this is plausible, then a washout period would be required in a well-designed cross-over study where UTI is an outcome. A washout period could therefore be justifiable as one of the inclusion criteria for analysis of UTI outcomes. It might be that the first two weeks of data in both arms is not included in the analysis.

Agreements and disagreements with other studies or reviews

Four systematic reviews with meta-analysis have been published on the occurrence of UTI in IC users (Bermingham 2013; Health Quality Ontario 2019; Li 2013; Rognoni 2017b).

Bermingham 2013 reviewed trials to determine the most clinically effective and cost-effective approach for patients performing self IC with either hydrophilic-coated, single-use uncoated, gel reservoir or clean uncoated catheters. Data were obtained from eight trials (Cardenas 2009; De Ridder 2005; Duffy 1995; Giannantoni 2001; King 1992; Pachler 1999; Sutherland 1996; Vapnek 2003). Data from two trials indicate IC users were significantly less likely to report one or more UTIs compared with sterile non-coated catheters (De Ridder 2005; Giannantoni 2001). Their conclusions that were related to gel reservoir catheters were based on one cross-over study (Giannantoni 2001). In our review, this study was ineligible as we classified gel reservoir catheters as uncoated. They found no differences in mean monthly or total annual UTI between hydrophilic-coated and single-use uncoated and little difference between clean versus sterile IC (P = 0.06). Overall, multiple use was reported to be the most cost-effective type of IC. Of note is their point that there are limitations and gaps in the evidence base and non-coated PVC catheters are designated as single-use devices in the UK. Therefore, they recommend a precautionary principle should be adopted and that patients should be offered a choice between hydrophilic and gel reservoir catheters. We agree with Bermingham 2013 that there is inadequate evidence to state that incidence of symptomatic UTI is affected by any one catheter design.

Health Quality Ontario 2019 reviewed 14 RCTs: single-use vs multi-use (Chick 2013; Duffy 1995; Kiddoo 2015; Pachler 1999; Prieto-Fingerhut 1997; Vapnek 2003); hydrophilic single-use versus non-coated single-use (Cardenas 2009; Cardenas 2011; DeFoor 2017; De Ridder 2005; Sarica 2010) or gel reservoir single-use versus non-coated single-use (Giannantoni 2001; Quigley 1993; Sarica 2010). In line with our review, they concluded that given the overall low certainty of evidence in available studies, there is uncertainty on whether any specific type of IC (coated or non-coated, single- or multiple-use) significantly reduces symptomatic UTI, haematuria, or other serious adverse clinical events, or whether a specific type improves patient satisfaction. They additionally concluded that, in the absence of any certainty, the lowest-cost catheter is likely the most cost-effective.

Rognoni 2017b conducted a systematic review of seven papers exploring the same questions as Bermingham 2013 and reviewed essentially the same trials regarding coated versus uncoated and uncoated, re-used or single-use catheters (Cardenas 2009; Cardenas 2011; De Ridder 2005; Pachler 1999; Sarica 2010; Sutherland 1996). UTI and haematuria were the primary outcomes. However, the authors concluded that hydrophilic-coated catheters are associated with a reduced risk of UTI among patients using IC. Rognoni 2017b's findings concur with our own that hydrophilic catheters may affect the incidence of UTI but that the certainty of the evidence is weak and that further studies are crucial to provide more direct evidence of the comparisons. Similar to our review, the authors noted that the ability to draw meaningful conclusions is compromised by methodological limitations, including heterogeneity of outcomes and definitions, absence of high-quality trials and a higher dropout rate in the arms related to hydrophilic catheters.

Li 2013 also sought to examine the benefit of one catheter design (hydrophilic versus non-hydrophilic) in the occurrence of UTI and haematuria. Reviewing five papers (Cardenas 2009; Cardenas 2011; De Ridder 2005; Sutherland 1996; Vapnek 2003), the authors concluded that both UTI and haematuria occurred less frequently with the use of hydrophilic-coated catheters. The review findings were based on two errors: mistaking proportions for raw data in the Cardenas 2011 trial where raw data were not reported; and errors in reporting attrition. These two errors skewed interpretation of the data in favour of hydrophilic-coated. We do not agree with the conclusion based on the analysis.

AUTHORS' CONCLUSIONS

Implications for practice

We are uncertain whether UTI is affected by the use of aseptic or clean technique, single- (sterile) or multiple-use (clean) catheters or hydrophilic-coated or uncoated catheters. The variability in user-reported outcomes suggests patient choice could be important. Because the evidence is of low certainty, healthcare professionals who are advising individuals on intermittent catheterisation will need to base their decisions on clinical judgement in conjunction with users. Differential costs of catheters or techniques may also inform decision-making but without robust data on cost-effectiveness, definitive conclusions cannot be reached.

Implications for research

There is a lack of evidence demonstrating the effectiveness of any particular catheter technique, strategy or design. Variations in clinical practice and growth in costs mean that large, well-designed parallel-group RCTs are needed. The most important pragmatic question (both for clinical and cost-effectiveness reasons) is: are multiple-use catheters equivalent to single-use catheters? Two

trials (MultiCath ISRCTN42028483 and COMPaRE NL8296) aimed at addressing this question are currently underway.

There are many other aspects of catheter design and use that are important, for example, sustainability or convenience of use of different designs. Future trialists should consider using the IDSA 2009 definition of UTI as the primary outcome variable. However, there is a need to validate these symptoms on IC users. A validated tool (e.g. Pinder 2012) to measure user acceptability should also be considered. Given the large differential costs for the methods, cost-effectiveness will need to be assessed rigorously.

Cross-over trials can be used to evaluate patient preference, particularly for one catheter design over another. However, for evaluating UTI and adverse events, RCT designs should be used.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Biering-Sorensen 2007

Study characteristics	
Methods	**Study design**: cross-over RCT **Dates study conducted:** not reported
Participants	**Number**: 24 **Setting:** outpatient clinic **Country:** Denmark **Age**: adults, mean age 44 (range 19 to 64) **Sex:** female **Diagnosis**: spinal cord lesion **Inclusion criteria**: not stated **Exclusion criteria:** pregnancy, participation in other clinical tests and any signs or symptoms of ongoing urinary tract infection
Interventions	**Intervention:** SpeediCath Compact catheter. Short-length female catheter (hydrophilic-coated), 14.3 cm in total (coated part 7 cm) **Control:** standard length (various designs) female catheter All 24 participants used one catheter followed by the other. "The test of each catheter type lasted 1 day per person over a period of 1 month." Unclear if there was any washout period
Outcomes	Residual urine measured by ultrasound, satisfaction, handling, suitability of length
Funding sources	"The study was funded by Coloplast A/S".
Study conflicts of interest	Not reported
Notes	Mixture of experienced and naive users
Risk of bias	

Biering-Sorensen 2007 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Participants were randomised in blocks of four".
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "Single-blind" Comment: not possible to blind participants, but outcome assessment was blinded and the non-blinding of participants was considered unlikely to introduce bias.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "Study nurse (who carried out the ultrasound) was not present during the catheterization in order to remain blinded regarding the type of catheter used". Comment: participant-reported handling and satisfaction of catheter and was unblinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

Cardenas 2009

Study characteristics	
Methods	**Study design**: RCT **Dates study conducted:** not reported
Participants	**Number**: 56 **Setting**: community **Countries**: North America **Age**: adults **Sex**: 29 male, 16 female **Diagnosis**: spinal cord injury for > 6 months with > 1 UTI **Inclusion criteria:** (1) SCI 6 months or more ago, (2) self-reported history of 2 or more UTIs during the past year, (3) use of IC with a non-coated catheter and an open system, (4) no plan to change the method of bladder drainage during the study period, (5) naive to hydrophilic catheters, and (6) at least 18 years of age **Exclusion criteria**: Subjects were excluded if they had evidence of upper urinary tract abnormalities or renal or bladder calculi in a screening renal ultrasound.
Interventions	**Group I (n = 28):** hydrophilic-coated catheter (single-use)

Cardenas 2009 *(Continued)*

	Group II (n = 28): uncoated catheter (single-use)
Outcomes	Symptomatic UTI, treatment with antibiotics
Funding sources	"supported by the National Institute on Disability and Rehabilitation Research, Office of Special Education and Rehabilitation Services, United States Department of Education, Washington, DC (grant no. H133N000003). No commercial party having a direct financial interest in the results of the research supporting this article has or will confer a benefit on the authors or on any organisation with which the authors are associated".
Study conflicts of interest	Not reported
Notes	**Blinding procedures:** non-blinded **Sample size calculation:** yes **Withdrawals/dropouts:** 11 **Completed**: 45 **ITT analysis performed:** not stated Definition of symptomatic UTI pre-dated and did not meet IDSA 2009 guideline, but aligned with NIDRR 1992 criteria

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated. More women in the control group; significantly more tetraplegic participants in the control group
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not possible; participant-reported outcomes may have been influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unblinded. Monthly self-report of UTI symptoms together with urine sampling used to determine presence of UTI. Use of antibiotics determined by participant's clinician (independent of research trial)
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data balanced in numbers between intervention group (n = 6) and control group (n = 5), with similar reasons for missing data across groups
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

Cardenas 2011

Study characteristics	
Methods	**Study design**: RCT **Dates study conducted:** not reported
Participants	**Eligible:** not stated **Enrolled**: 224 **Completed**: 114 **Countries**: North America **Setting**: hospital and community **Age**: adults (mean age: group I 35.1 (SD 13.2); group II 37.2 (SD 14.4) **Sex**: 161 male, 39 female (enrolled - did not state gender of numbers completing) **Diagnosis**: spinal cord injury no longer than 3 months **Inclusion criteria:** SCI less than 3 months before inclusion, neurogenic bladder dysfunction due to the SCI, and IC required at least 3 times a day to maintain bladder emptying **Exclusion criteria**: symptoms of UTI or treatment with prophylactic antibiotics to prevent UTI, history of unresolved vesico-ureteral reflux and/or urolithiasis, IC for more than 10 days before study inclusion, pregnancy, or plans to become pregnant during the study period. Finally, the participants were not permitted to participate in other clinical pharmaceutical or urology studies.
Interventions	**Group I (n = 108):** hydrophilic-coated catheter (single-use) **Group II (n = 116):** uncoated catheter (single-use)
Outcomes	Time to 1st UTI; UTI incidence; microhaematuria measured at weeks 3 and 4; satisfaction measured at 45 days
Funding sources	"The study was supported by Coloplast A/S".
Study conflicts of interest	Disclosure Key can be found in the Table of Contents at www.pmrjournal.org.
Notes	**Sample size calculation:** yes **Duration**: up to 6 months **Withdrawals/dropouts:** 110 **ITT analyses performed:** not stated Definition of symptomatic UTI did not meet IDSA 2009 guideline, but aligned with NIDRR 1992 criteria.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "A centralized computer-generated randomization list was generated".
Allocation concealment (selection bias)	Low risk	Quote: "Sealed envelopes were provided".

Cardenas 2011 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "The inability to blind participants and clinicians to the catheter type is a potential limitation of the trial". Comment: Participant-reported outcomes may have been influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "The inability to blind participants and clinicians to the catheter type is a potential limitation of the trial". Comment: Outcome of UTI was participant- and clinician-determined. Not clear if outcome assessors were blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "In the hydrophilic catheter group... many of the investigational sites did not routinely use hydrophilic catheters. The trial protocol did not include a number of training catheterizations". Comment: A greater number of participants dropped out in the hydrophilic-coated group, resulting in incomplete outcome data both for UTI, and participant satisfaction, which did not appear to have been measured in these participants.
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

Chartier-Kastler 2011

Study characteristics	
Methods	**Study design**: cross-over RCT **Dates study conducted:** not reported
Participants	**Eligible**: 36 **Enrolled**: 36 **Completed**: 27 **Countries**: France/Denmark **Setting**: hospital outpatient clinic **Age**: adults over 18 years old **Sex**: male **Diagnosis**: spinal cord lesion and normal/impaired urethral sensation **Inclusion criteria:** males over 18 years with spinal cord lesion and neurogenic bladder dysfunction. Use of clean, intermittent self-catheterisation for at least 14 days at enrolment and the ability to open and prepare the catheters for catheterisation **Exclusion criteria:** had a symptomatic urinary tract infection, as assessed by the investigator, or if they were mentally unstable and unable to comply with study procedures. Participants could be reassessed for enrolment 5 days after termination of treatment for a symptomatic urinary tract infection.
Interventions	**Group I (n = 17):** short-length male hydrophilic-coated catheter

Chartier-Kastler 2011 *(Continued)*

	Group II (n = 19): standard-length male hydrophilic-coated catheter
Outcomes	Participant satisfaction and ease of use
Funding sources	"We would also like to acknowledge Carsten Henrik Wachmann for assistance with the statistical analysis, supported by Coloplast and Anna Karina Busch, PhD of Coloplast A/S for technical review and assistance with editing the manuscript. Medical writing assistance, including co-ordination of drafting the manuscript and consolidation of comments, was provided by Tom Newton of Elements Communications Ltd, UK, supported by Coloplast. Clinical trial registration number (ClinicalTrials.gov): NCT00990093"
Study conflicts of interest	Not reported
Notes	**Sample size calculation**: yes **Duration**: 14 days **Withdrawals/dropouts**: 9 (5 in control arm, 4 in other arm) **ITT analysis performed**: not applicable Participants had no prior experience of test catheter.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomised to one of two treatment groups by computer"
Allocation concealment (selection bias)	Low risk	Quote: "Sealed randomization envelopes were provided".
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding, the outcomes could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Participant-reported outcome - risk of detection bias unclear
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Flowchart to report participant dropout presented, but no information to report how data handled in the analysis, particularly regarding imputation
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

Chartier-Kastler 2013

Study characteristics

Methods	**Study design**: cross-over RCT

Chartier-Kastler 2013 *(Continued)*

	Dates study conducted: not reported
Participants	**Eligible**: 125 **Enrolled**: 125 **Completed**: 106 **Countries**: France, Germany, Norway, Sweden, Denmark **Setting**: hospitals, clinics, research centres **Age**: adults with a mean age of 53.8 years **Sex**: male and female **Diagnosis**: neurogenic bladder dysfunction, various **Inclusion criteria:** Eligible patients for the study were over 18 years old and suffering from a neurogenic bladder dysfunction. Spinal cord injury had to be more than 12 months prior to inclusion. The patients had used coated catheters for ISC as the primary bladder emptying method for at least 6 months, had no previous experience with the compact catheter, and were not primarily using catheter sets. At inclusion, patients were asked to try one compact catheter. **Exclusion criteria:** At inclusion, patients were asked to try one compact catheter; if unable to use the compact catheter, the patient was not included in the study. Patients, who were admitted to a rehabilitation centre, were pregnant or breastfeeding were excluded from participation in the study as well.
Interventions	**Group I (n = 63):** shorter hydrophilic catheter **Group II (n = 62):** longer hydrophilic catheter
Outcomes	ISC-Q score and user preference
Funding sources	"The study was sponsored by Coloplast A/S".
Study conflicts of interest	Not reported
Notes	**Sample size calculation**: yes **Duration**: 12 weeks **Withdrawals/dropouts**: 6 **ITT analysis performed:** not applicable Domain scores for ISC-Q not reported Participants had no prior experience of test catheter.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "patients were allocated to the treatment sequence by randomization of numbers in sealed identical and non-transparent envelopes".
Allocation concealment (selection bias)	Low risk	Quote: "patients were allocated to the treatment sequence by randomization of numbers in sealed identical and non-transparent envelopes".

Chartier-Kastler 2013 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Participants and caregivers could not be blinded which could have an influence on outcomes.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	19 enrolled participants did not complete all data collection.
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

Costa 2013

Study characteristics	
Methods	**Study design:** cross-over RCT **Dates study conducted:** October 2010 - July 2011
Participants	**Eligible**: not stated **Enrolled**: 91 **Completed**: 81, although 23 of these did not fully complete test arm **Country**: US **Setting**: 7 sites **Age**: adults mean age 38.4 years 11.8 SD **Sex**: male **Diagnosis**: paraplegic with neuropathic voiding dysfunction **Inclusion criteria:** adult males who currently self-catheterise at least three times daily and use a wheelchair. Subjects had to be able to use a size 12 or 14 French catheter and self-catheterise for at least 2 months at the time of enrolment. **Exclusion criteria:** not reported
Interventions	**Intervention:** shorter-length catheter (uncoated, pre-lubricated closed system with integrated collection bag) **Control:** standard-length catheter (uncoated, pre-lubricated closed system with integrated collection bag) 91 participants began the trial, each using first one catheter then the other. Data from 81 were used in analysis; it was unclear how many participants used both catheters.
Outcomes	User preference for catheter length (standard versus shorter-length), ease of use, sensation of emptying

Costa 2013 *(Continued)*

Funding sources	"Hollister research investigators contributed to the writing of this manuscript. This study was funded by Hollister Incorporated (ClinicalTrials.gov Identifier No. NCT01284361). Drs Costa, Kohler and Mr. Doran, as well as other participating centers were part of this investigation and received research funding. This study was funded by Hollister Incorporated".
Study conflicts of interest	"Dr Costa is a consultant for Coloplast Inc. Ms Menier is a statistician employed by Hollister Incorporated. Mr Doran has no disclosures. Dr Kohler is a consultant for American Medical Systems and Coloplast Inc. He is also on the speaker's bureau for Allergan, Auxilium and Actient".
Notes	**Blinding procedures:** none **Sample size calculation:** no **Duration**: use of 10 catheter sets for each arm of trial **Withdrawals/dropouts:** 9 **ITT analyses performed**: not applicable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: “Subjects were randomized to order of catheter use”. No other details reported
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding; outcomes may be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "unblinded study" Comment: outcome measurement may be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	High risk	23 of 82 participants were unable to complete use of all 10 test catheters (shorter-length) due to inadequate bladder drainage. Data only reported for completers. “Ten subjects were removed from the data set for various protocol violations”.
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

DeFoor 2017

Study characteristics

Methods	**Study design**: RCT **Dates study conducted:** not reported
Participants	**Eligible**: not stated

DeFoor 2017 *(Continued)*

	Enrolled: 78 (48 urethral, 30 stoma) **Completed**: 55 (urethral and stoma combined) **Country**: USA **Setting**: paediatric urological clinic and spina bifida clinic **Age**: children with a mean age of 12. 9 (hydrophilic group) and 13.6 (uncoated group). **Sex**: male 38; female 40 **Diagnosis**: neurogenic bladder **Inclusion criteria:** children ages 2 -17 years with neurogenic bladder on CIC. Patients were required to be on a regular schedule of at least three catheterisations daily. Block randomisation was performed in groups of 10 to keep the groups relatively even in the event of slow accrual **Exclusion criteria:** stomal stenosis, urethral stricture disease, or active UTI. Other exclusion criteria included patients deemed clinically unstable or who were imminently scheduled for continent lower urinary tract reconstruction. Patients with abdominal wall catheterisable channels were not excluded.
Interventions	**Group I (n = 37):** hydrophilic catheters with an attached bag **Group II (n = 41):** uncoated
Outcomes	UTI per person-years Gross haematuria User-reported outcomes
Funding sources	"Hydrophilic catheters were supplied to the study subjects by the manufacturer (Wellspect Healthcare). Research nursing support was provided by an unrestricted grant from Wellspect Healthcare".
Study conflicts of interest	"None"
Notes	**Blinding procedures**: none **Sample size calculation:** yes **Duration**: 1 year **Withdrawals/dropouts**: 15 from treatment arm (5 due to the test catheter), 8 from control arm **ITT analyses performed**: yes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "block randomization was performed in groups of 10". Comment: no other details given
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported

DeFoor 2017 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "withdrawn patients were analysed up to the time of withdrawal". Comment: no ITT. 8/41 and 15/37 withdrawals. Reasons for withdrawal not explained per group.
Selective reporting (reporting bias)	High risk	Some outcomes not reported in full. User-reported outcomes were not reported for the uncoated catheter and only partially reported for the hydrophilic catheter.
Other bias	High risk	Funded by hydrophilic catheter manufacturer

De Ridder 2005

Study characteristics	
Methods	**Study design:** RCT **Dates study conducted:** not reported
Participants	**Eligible**: unknown **Enrolled**: 123 **Completed**: 57 **Countries**: Europe **Setting**: rehabilitation and community **Age**: adults (mean age: group I 37.5 (SD 14.6); group II 36.7 (SD 14.6) **Sex**: male **Diagnosis**: neurogenic bladder due to spinal cord injury < 6 months **Inclusion criteria:** male spinal cord injured patients, who were 16 or more years old and had been injured less than 6 months **Exclusion criteria:** patients with symptomatic UTI and patients with urethral stenosis or fibrosis were excluded, as were mentally unstable patients and those participating in another clinical trial.
Interventions	**Group I (n = 61):** hydrophilic-coated catheter (single-use) (Speedicath catheter) **Group II (n = 62):** uncoated catheter (single-use) (PVC catheter) Assessed at day 15 then monthly x 12 m
Outcomes	**Primary outcomes:** retrospective self-report of UTI for which treatment was prescribed **Secondary outcomes**: haematuria strictures, convenience
Funding sources	Not reported
Study conflicts of interest	Not reported
Notes	**Blinding procedures:** not stated

De Ridder 2005 *(Continued)*

Sample size calculation: yes

Duration: 12 months

Withdrawal/dropouts: 66

No trial definition of symptomatic UTI. Used retrospective reporting of clinical infection for which treatment was prescribed as a proxy measure

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Patients were randomised in blocks of 4 using a randomisation list produced automatically using Medstat software version 2.1.
Allocation concealment (selection bias)	Low risk	"The randomisation was performed by the investigator using sealed coded envelopes provided by the study sponsor and containing the identity of the assigned treatment".
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding; outcomes are likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding; outcome measurement may be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	High risk	Outcome data accounted for descriptively. High attrition in both groups: group I 25/61 and group II 33/62 completed the study. This has not been accounted for in the analysis.
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

Domurath 2011

Study characteristics

Methods	**Study design:** cross-over RCT **Dates study conducted:** not reported
Participants	**Eligible**: 37 **Enrolled**: 37 **Completed**: 36 **Country**: Germany **Setting**: 3 trial sites **Age**: adults with a mean age of 40 years. **Sex**: male

Domurath 2011 *(Continued)*

	Diagnosis: spinal cord injury **Inclusion criteria:** not reported **Exclusion criteria:** symptoms of urinary tract infection and known abnormalities in the lower urinary tract
Interventions	**Intervention:** short-length male hydrophilic-coated catheter **Control:** standard-length male hydrophilic-coated catheter 36 participants used both catheters.
Outcomes	Residual urine and user satisfaction
Funding sources	"Premier Research Group Limited contributed to the writing of this manuscript. This study was funded by Coloplast A/S. Drs B Domurath, J Kutzenberger, I Kurze and A Kaufmann (Kliniken Maria Hilf, Mo¨nchengladbach, Germany) were investigators in the study and received research funding from Coloplast A/S; ClinicalTrials.gov registry number: NCT 01048541".
Study conflicts of interest	"The authors declare no conflict of interest".
Notes	**Blinding procedures:** single-blind (trial nurse) **Sample size calculation:** yes **Duration**: 1 day **Withdrawals/dropouts:** 1 **ITT analyses performed**: not applicable

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Crossover design, randomized in permuted blocks"
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding of participants, but participant-reported outcomes could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinding of trial nurse throughout all measurement procedures
Incomplete outcome data (attrition bias) All outcomes	Low risk	1 withdrawal reported because the participant "did not consider the 'test' catheter material flexible enough"
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

Duffy 1995

Study characteristics	
Methods	**Study design:** RCT **Dates study conducted:** not reported
Participants	**Eligible**: 203 **Enrolled**: 82 **Completed**: 80 to day 15, 39 to day 90 **Country**: USA **Setting**: 3 long-term care Veterans Administration Medical Centre Nursing Homes **Age**: adults (mean age 72) **Sex**: male **Diagnosis**: Incomplete bladder emptying due to prostate obstruction **Inclusion criteria:** patients with indwelling catheters for relief of residual urine, currently managed by intermittent catheterisation, or had significant residual urine and an anticipated stay of at least 110 days **Exclusion criteria:** medical diagnosis of urethral stricture, presence of combativeness or other behavioural problems
Interventions	**Group I (n = 42):** aseptic technique **Group II (n = 38):** clean technique Also single versus multiple use
Outcomes	Number of treatment episodes of UTI plus urinalysis
Funding sources	Not reported
Study conflicts of interest	Not reported
Notes	**Blinding procedures:** not clear **Sample size calculation:** yes, post hoc **Duration**: 3 months **Withdrawls/dropouts:** 2 **ITT analyses performed**: not stated Definition of symptomatic UTI pre-dated and did not meet IDSA 2009 guideline. It did not align with NIDRR 1992 criteria as it allowed white blood cell count per high power field as an alternative to quantitative microbiology.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Duffy 1995 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Quote: "subjects were randomly assigned […] Randomisation was controlled for research site and presence or absence of UTI history".
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not blinded; participant-reported outcomes could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "scheduled, routine, non blinded laboratory examination of blood and urine was obtained from each subject".
Incomplete outcome data (attrition bias) All outcomes	Low risk	High attrition but not differential. Numbers completing the 90-day study: group I 19/42 and group II 20/38. All participants provided data for the UTI outcome at 15 days' follow-up.
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

Kiddoo 2015

Study characteristics	
Methods	**Study design:** cross-over RCT **Dates study conducted:** not reported
Participants	**Eligible**: not stated **Enrolled**: 70 **Completed**: 46 **Country**: Western Canada **Setting**: paediatric clinic (4 sites) **Age**: children (mean age 10.6 years) **Sex**: 21 male, 25 female **Diagnosis**: spina bifida **Inclusion criteria:** 6 months to 18 years old, had spina bifida, were community-dwelling, were able to read and understand English or had a parent who could read and understand English, and underwent intermittent self-catheterisation or intermittent catheterisation administered by a consistent person (more than 6 months of experience) more than twice daily using a PVC catheter that was cleaned and re-used from 1 day to 1 week. **Exclusion criteria:** children with urethral deformities (i.e. stricture, false passage), allergy to PVC, diabetes mellitus, history of bladder pathology (e.g. calculus) or history of surgical bladder reconstruction (augmentation cystoplasty, catheterisable channel)

Kiddoo 2015 *(Continued)*

Interventions	**Group I:** first period hydrophilic-coated single-use catheter (34); second period uncoated multiple-use PVC (23) **Group II:** uncoated multiple-use PVC catheter (32); second period hydrophilic-coated single-use catheter (25)
Outcomes	Symptomatic UTI, antimicrobial use, haematuria, days of missed activities, user-reported satisfaction
Funding sources	"Funded by Spina Bifida and Hydrocephalus Associations of Northern Alberta and Southern Alberta, Glenrose Rehabilitation Hospital, Edmonton Lions Club and Northern Alberta Urology Foundation"
Study conflicts of interest	"Colleen Allen, Megan Allison, Yvonne Appah, Genevieve Carrier, Bev Irwin, Mike Kerr, Teresa Kerridge, Sally Martin, Roxanne Miller, Ellen Ford, and Dr. William Hyndman, Alberta Children's Hospital, contributed to the study. Dr. Donald Schopflocher, Center for Health Promotion Studies, University of Alberta, provided statistical advice. Coloplast Denmark supplied the hydrophilic catheters".
Notes	**Blinding procedures:** not possible to blind participants **Sample size calculation:** yes **Duration**: 48 weeks (24 weeks each arm) **Withdrawals/dropouts:** 24 **ITT analyses performed:** not applicable Definition of symptomatic UTI did not align with IDSA 2009 guideline or NIDRR 1992 criteria as it relied on the dipstick method of urinalysis in place of microbiological culture. **Communication with trialists**: paired data or mid- and end-point data were sought from the trialists. Trialists replied that they were not able to provide data in this format (Moore 2021).

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Computer generated list into random blocks of 8"
Allocation concealment (selection bias)	Low risk	Quote: "Sealed opaque envelopes"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Not possible to blind subjects to product" Comment: participant-reported outcomes could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not blinded; unclear if outcome assessment could be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	High risk	24 participants dropped out. Only completers were included in the analysis, and there was unbalanced attrition in the first treatment period (32 and 34 began first period of study, 23 and 25 began second period). Reasons for withdrawal largely related to intervention: 10 withdrew because hydrophilic catheter was too slippery, 3 because of preference for hydrophilic catheter, 2 because of undergoing continent diversion, 6 for other reasons not stated in trial report

Kiddoo 2015 *(Continued)*

Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	High risk	No washout period, which could impact the outcomes

King 1992

Study characteristics	
Methods	**Study design:** RCT **Dates study conducted:** not reported
Participants	**Eligible**: 58 **Enrolled**: 46 **Completed**: 35 **Country**: USA **Setting**: rehabilitation hospital **Age**: adults (mean age 29.9 (SD 12.4)) **Sex**: male **Diagnosis**: neurogenic bladder due to recent spinal cord injury **Inclusion criteria:** patients with SCI, admitted to inpatient rehabilitation programme at any time post-injury, performing catheterisation at least every six hours, normal serum creatine, BUN and urinalysis, no prophylactic antibiotics, absence of drug-resistant organism on urine culture, bacteriuria less than 10,000 colonies per mL. **Exclusion criteria:** not reported
Interventions	**Group I (n = 23):** sterile technique **Group II (n = 23):** clean technique (Also single-use versus multiple-use)
Outcomes	Daily urine dipslides; symptomatic UTI
Funding sources	"This study was supported by a grant from The American Association of Spinal Cord Injury Nurses and was supplemented by The Rehabilitation Institute Foundation". "No commercial party having a direct or indirect interest in the subject matter of this article has conferred or will confer a benefit upon the authors or upon and organisation with which the authors are associated".
Study conflicts of interest	Not reported
Notes	**Blinding procedures**: not clear **Sample size calculation:** no **Duration**: 28 days **Withdrawals/dropouts:** 11 **ITT analyses performed**: not stated

King 1992 *(Continued)*

	Definition of symptomatic UTI pre-dated IDSA 2009 guideline, but aligned with it. Number of days in trial varied from 1 to 28.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomly assigned"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not possible. Participant-reported outcomes could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not blinded; unclear if outcome assessment could be influenced by lack of blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full data for our main outcome of interest (symptomatic UTI)
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

Leek 2019

Study characteristics

Methods	**Study design**: cross-over RCT **Dates study conducted: Not reported**
Participants	**Eligible**: 41 **Enrolled**: 23 **Completed**: 20 **Country**: Australia **Setting**: hospital outpatient pelvic floor clinic **Age**: adults **Sex**: 6 male, 17 female **Diagnosis**: varied **Inclusion criteria:** male and female patients over 18 years of age, had previously been performing CISC, or had a new diagnosis requiring CISC at least twice-daily, willing and able to attend for six clin-

Leek 2019 *(Continued)*

	ic visits during the 16-week trial period, and to be willing to change catheter use method at the eight-week point **Exclusion criteria:** Excluded if they were unable to perform CISC, or unable to wash their catheters due to eyesight or dexterity problems
Interventions	Uncoated catheter and clean technique, both arms
Outcomes	Asymptomatic and symptomatic UTI with microbiological confirmation
Funding sources	"Funding for the SURE trial was provided by a research grant from the St George Medical Research Foundation. Other study costs were provided by the Pelvic Floor Unit Research Trust Fund, St George Hospital".
Study conflicts of interest	"The authors declare that there is no conflict of interest".
Notes	**Blinding procedures:** "Full blinding not possible, but microbiological data were entered by blinded staff". **Sample size calculation**: yes **Duration**: 16 weeks (8 weeks per arm) **Withdrawals/dropouts**: 3 participants dropped out. **ITT analyses performed:** not applicable Definition of symptomatic UTI did not meet IDSA 2009 guideline, but aligned with NIDRR 1992 criteria. Abstract only, no full-text article found. Not clear how often re-used catheters were changed

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Computer-generated randomisation code"
Allocation concealment (selection bias)	Low risk	Quote: "Opaque sequentially numbered sealed envelopes"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Quote: "Full blinding not possible, but microbiological data entered by blinded staff" Comment: lack of blinding could influence participants' perception of symptoms.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Main outcome assessment done by blinded staff "microbiological data entered by blinded staff"
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data reported for all enrolled participants
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	No washout period but unlikely to affect outcome as we only used data from the first treatment period

Leriche 2006

Study characteristics	
Methods	**Study design:** cross-over RCT **Dates study conducted:** November 2004 to February 2005
Participants	**Eligible**: not stated **Enrolled**: 31 **Completed**: 29 **Country**: France **Setting**: hospital **Age**: adults **Sex**: male **Diagnosis**: vesico-sphincteric problem of neurological origin **Inclusion criteria:** adults with neurological bladder sphincter disorders, who perform self-catheterisation and catheterise at least twice a day using Charriere 12 or 14 catheters, and are able to complete the questionnaire. Patients already using Actreen® Set were not included for this study. **Exclusion criteria:** not reported
Interventions	**Group I:** hydrophilic-coated catheter with integrated bag (aseptic technique, single-use) **Group II:** uncoated catheter with integrated bag (aseptic technique, single-use) All 31 participants were assigned to use first one catheter then the other; it was not reported how many had hydrophilic followed by uncoated or vice versa.
Outcomes	Product evaluation questionnaire and overall preference questionnaire
Funding sources	Laboratoires Coloplast sponsored the trial.
Study conflicts of interest	Authors' declarations of interest not reported
Notes	**Blinding procedures**: none **Sample calculation:** not reported **Duration**: use of 20 sets of each product **Withdrawals/dropouts:** 2 **ITT analyses performed:** not applicable Evaluation of catheter sets in naive users (all but one had not used a set prior to the study)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	The order of treatment was randomised for each participant but no details were reported regarding how the randomisation sequence was generated.

Leriche 2006 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding; outcomes were likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "open study" Comment: unclear if outcome assessment was blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing outcome data from 2 participants - withdrawals described as not being related to the trial
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

Madero-Morales 2019

Study characteristics	
Methods	**Study design:** RCT **Dates study conducted:** August 2015 to August 2016
Participants	**Number of participants:** 83 **Country**: Mexico **Setting**: Dr. José Eleuterio Gonzalez University Hospital, Monterrey **Mean age:** 12.7 (9.5) years; (range 2-56 years) **Inclusion criteria:** age 2 years or greater, a diagnosis of spina bifida, self-IC or IC performed by a trained person, 3 months or more use of a re-used PVC catheter (1 per week) with clean technique and ability to read and understand informed consent **Exclusion criteria:** other causes of NB, symptomatic UTI at the time of the initial evaluation (defined as a positive urine culture with pyuria and odorous urine, flank pain, malaise or fever), inconsistent IC, an indwelling catheter, PVC allergy, urethral pathology (e.g. stricture, false passage or hypospadias) and refusal to participate in the trial. Receipt of a prophylactic antibiotic was not an exclusion criterion provided that the participant continued with the usual therapy for the study duration.
Interventions	**Group I (n = 37):** single-use PVC catheter **Group II (n = 38):** re-usable PVC catheter, programmed to last a week. The PVC catheter was washed with water and soap, and stored in a container with 0.5% benzalkonium chloride. “Patients and parents were instructed to use clean technique”: assumed this referred to participants in both groups **Duration of treatment:** 8 weeks **Duration of follow-up:** 8 weeks

Madero-Morales 2019 *(Continued)*

Outcomes	Mean person-urine sample UTI, febrile and nonfebrile UTI, bacteriuria and antibiotic use
Funding sources	"No funding organization influenced study design, analysis or conclusions. No direct or indirect commercial, personal, academic, political, religious or ethical incentive is associated with publishing this article".
Study conflicts of interest	"No direct or indirect commercial, personal, academic, political, religious or ethical incentive is associated with publishing this article".
Notes	**Abstract only:** no **Number of dropouts**: A: 4; B: 4. **Definition of symptomatic urinary tract infection:** positive urine culture (growth of more than 100,000 CFU) with pyuria and odorous urine, flank pain, malaise or fever **Definition of asymptomatic bacteriuria (ASB) (or asymptomatic UTI):** positive urine culture (growth of more than 100,000 CFU), with no symptoms

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: “Subjects were randomized into block sizes of 6 using a computer generated list”.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: “A blinding process was impossible due to the nature of the intervention”. Comment: lack of blinding unlikely to affect the outcome
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	4/41 and 4/42 withdrew for reasons not related to the study.
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

Moore 1993

Study characteristics

Methods	**Study design:** cross-over RCT **Dates study conducted:** not reported
Participants	**Eligible**: unknown

Moore 1993 *(Continued)*

	Enrolled: 30 **Completed**: 30 **Country**: Canada **Setting**: community **Age**: children (age range 3 to 16 years) **Sex**: 15 male, 15 female **Diagnosis**: neurogenic bladder due to spina bifida **Inclusion criteria:** not reported **Exclusion criteria:** not reported
Interventions	**Group I:** sterile single-use PVC then re-used PVC catheter **Group II:** re-used PVC catheter then sterile single-use PVC 30 children in total; numbers allocated to each group not reported
Outcomes	Bacteriuria > 10^3 CFU/mL obtained monthly
Funding sources	"For financial assistance appreciation is extended to Baxter Corporation, Canadian Hospital Suppliers. Congdon's Aids to Daily Living, Glenrose Rehabilitation Hospital, Lever Brothers, Mentor Corporation, the Northern Alberta Urology Foundation, the Spina Bifida Association (SBA) of Southern Alberta".
Study conflicts of interest	Not reported
Notes	**Blinding procedures:** not stated **Sample size calculation:** no **Duration**: each arm 6 months **Withdrawals/dropouts:** nil **ITT analyses performed:** not applicable Definition of symptomatic UTI pre-dated and did not meet IDSA 2009 guideline, but aligned with NIDRR 1992 criteria.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomly assigned"
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported
Blinding of outcome assessment (detection bias)	Low risk	Quote: "technologists used standard laboratory methods for interpretation of results and were blind to the arm of the crossover design".

Moore 1993 *(Continued)*

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

Moore 2006

Study characteristics	
Methods	**Study design:** RCT **Dates study conducted:** not reported
Participants	**Eligible**: 50 **Enrolled**: 36 **Completed**: 36 **Country**: Canada **Setting**: rehabilitation hospital **Age**: adults (mean age 40 SD 16.7) **Sex**: 28 male, 8 female **Diagnosis**: neurogenic bladder due to recent high spinal cord injury; neurogenic bladder **Inclusion criteria:** the inclusion criteria were previously healthy adults with stated pre-injury normal bladder function and no history of urinary tract infections who, as a result of the injury, now required intermittent catheterisation by nursing staff every 4-6 h, and were able to speak and read English. **Exclusion criteria:** subjects were excluded if they were taking prophylactic antibiotics for recurrent symptomatic urinary tract infection or for any other reason or were self-catheterising or had a caregiver catheterising them.
Interventions	**Group I (n = 20):** sterile single-use PVC catheter with sterile technique; uncoated **Group II (n = 16):** sterile single-use PVC catheter with clean technique (clean gloves, clean container, non-sterile wipes for cleansing pre-catheterisation); uncoated
Outcomes	Days to onset of symptomatic UTI; UTI defined as ≥ 10 x 5 CFU/mL, pyuria + accompanying symptoms
Funding sources	"The study was funded by the Glenrose Rehabilitation Hospital Research Fund and Small Faculties Grant at the University of Alberta. These grants do not carry any restrictions as to publication of the study or use of the data and none of the authors had a financial or product interest in the study. Appropriate ethical clearances were obtained".
Study conflicts of interest	Not reported
Notes	**Allocation**: by third party using sealed opaque envelopes

Moore 2006 *(Continued)*

	Blinding procedures: data entry blinded
	Sample size calculation: yes
	Duration: up to 12 months
	Withdrawals/dropouts: none
	ITT analyses performed: yes
	Definition of symptomatic UTI pre-dated IDSA 2009 guideline but aligned with it.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Computer generated random numbers"
Allocation concealment (selection bias)	Low risk	Quote: "Sealed brown envelopes"
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible; outcomes could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "laboratory was blinded to subject allocation".
Incomplete outcome data (attrition bias) All outcomes	Low risk	No incomplete data
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

Prieto-Fingerhut 1997

Study characteristics

Methods	**Study design:** RCT
	Dates study conducted: not reported (data collected over a three-month period)
Participants	**Eligible**: unknown
	Enrolled: 29
	Completed: not stated
	Country: USA
	Setting: rehabilitation
	Age: adults (Non-sterile group: mean 38 (SD 22). Sterile group: mean 34 SD 14)

Prieto-Fingerhut 1997 *(Continued)*

	Sex: 16 male, 13 female **Diagnosis**: neurogenic bladder due to spinal cord injury **Inclusion criteria:** not reported **Exclusion criteria:** not reported
Interventions	**Group I (n = 14):** single-use uncoated catheter with an integrated bag (sterile) **Group II (n = 15):** multiple-use uncoated catheter (clean)
Outcomes	UTI urine for C&S collected weekly - unclear on trial time frame or end-point
Funding sources	"This study was supported by Medical Marketing Group Inc., Decatur, GA".
Study conflicts of interest	Not reported
Notes	**Blinding procedures:** not stated **Sample size calculation:** no **Duration**: unclear **Withdrawals/dropouts:** not stated **ITT analyses conducted:** not applicable Definition of symptomatic UTI pre-dated and did not meet IDSA 2009 guideline, but aligned with NIDRR 1992 criteria.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding; it was unclear if outcomes were likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	High risk	No information about withdrawals. Outcome data presented using number of urine cultures as denominator instead of number of participants
Selective reporting (reporting bias)	High risk	Outcomes not reported completely (no denominators)
Other bias	Low risk	Nothing to indicate any other source of bias

Samal 2011

Study characteristics	
Methods	**Study design:** RCT **Dates study conducted:** not reported
Participants	**Eligible**: not clear **Enrolled**: 53 **Completed**: 53 **Country**: Czech Republic **Setting**: spinal unit **Age**: adults **Sex**: male **Diagnosis**: spinal cord injury Inclusion criteria and exclusion criteria were unclear due to translation difficulties.
Interventions	**Group I (n = 36):** hydrophilic catheter **Group II (n = 17):** PVC catheter
Outcomes	Asymptomatic bacteriuria, symptomatic UTI, urethral trauma/haematuria
Funding sources	Translated quote: "The work was created with the financial support of the Scientific of the Regional Hospital of Liberec, as Coloplast A / S has long been cooperating is with the Regional Hospital Liberec, as, within the "Partnership" project free of charge rofil catheters for spinal unit patients Regional Hospital Liberec, as The authors thank the whole team of doctors and nurses of the spinal unit for pro-realistic cooperation in data collection. Without theirs careful and sacrificial work would not work originate" [sic].
Study conflicts of interest	Not reported
Notes	**Blinding procedures:** not clear **Sample size calculation:** no **Duration**: 9.07 ± 1.80 weeks **Withdrawals/dropouts:** 0 **ITT analyses performed:** no Translated from Czech to English using Google Translate Definition of symptomatic UTI did not meet IDSA 2009 guideline, but aligned with NIDRR 1992 criteria.

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: “randomized, open label, prospective"

Samal 2011 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Insufficient information - full translation not available
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information - full translation not available
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information - full translation not available
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data presented in tables (in English) for all participants
Selective reporting (reporting bias)	Unclear risk	Insufficient information - full translation not available
Other bias	Unclear risk	Insufficient information - full translation not available

Sarica 2010

Study characteristics	
Methods	**Study design:** cross-over RCT **Dates study conducted:** not reported
Participants	**Eligible**: 25 **Enrolled**: 21 **Completed**: 10 (all three arms) **Country**: Turkey **Setting**: hospital clinic **Age**: adults (mean age 37.04 SD 11.86 years) **Sex**: male **Diagnosis**: spinal cord injury **Inclusion criteria:** male patients with spinal cord injuries, 18 years or older, injured less than 6 months, able to perform intermittent self-catheterisation at least 5 times a day (4-6 times/day) **Exclusion criteria:** UTI, unexplained haematuria, bladder calculi, urethral stenosis or fibrosis, mentally unstable patients or patients participating in any other trial
Interventions	**Intervention:** uncoated **Intervention:** hydrophilic-coated **Intervention:** uncoated, pre-lubricated with integrated bag Evaluated at weeks 6, 12 and 18

Sarica 2010 *(Continued)*

	21 participants completed use of 1 catheter, 20 completed use of 2 catheters, 10 completed use of 1.
Outcomes	Urethral cytology, urine culture, user satisfaction
Funding sources	"We have no support for this study".
Study conflicts of interest	Not reported
Notes	**Blinding procedures:** no **Sample size calculation**: no **Duration**: 6 weeks **Withdrawals/dropouts**: 11 **ITT analyses performed**: not applicable Definition of symptomatic UTI did not meet IDSA 2009 guideline, but aligned with NIDRR 1992 criteria.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Sequence generated by table of random numbers"
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding; user satisfaction could be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Quote: "Urethral cytology samples were taken by a blinded doctor". Comment: Unclear if assessors of other outcomes were blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	Data were missing from 11/21 participants who did not complete the study; 1 because of having urological surgery, 1 who had < 4 intermittent catheterisations per day and 9 because of non-approval of the catheter (2 gel-lubricated catheters, 5 PVC catheters, 2 hydrophilic catheters)
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

Schlager 2001

Study characteristics

Methods	**Study design:** cross-over RCT **Dates study conducted:** not reported
Participants	**Eligible**: 12

Schlager 2001 *(Continued)*

	Enrolled:10 **Completed**: 10 **Country**: USA **Setting**: community **Age**: children (range 10 - 20 years) **Sex**: 4 male, 6 female **Diagnosis**: neurogenic bladder due to spina bifida **Inclusion criteria:** not reported **Exclusion criteria:** not reported
Interventions	**Group I (n = 5):** single catheter (clean technique) **Group II (n = 5):** multi-use uncoated catheter (clean technique)
Outcomes	UTI weekly urine for C&S x 4 months
Funding sources	"This study was supported in part by Mentor Corporation (Santa Barbara, CA)".
Study conflicts of interest	Not reported
Notes	**Blinding procedures:** not stated **Sample size calculation:** no **Duration**: each arm was 4 months **Withdrawals/dropouts:** none **ITT analyses performed:** not applicable Definition of symptomatic UTI pre-dated and did not meet IDSA 2009 guideline, but aligned with NIDRR 1992 criteria. Catheters re-used 5 times as the standard method, compared with single use as the test method

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomised"
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding; it was unclear if outcomes were likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated whether laboratory technician was blinded to catheter

Schlager 2001 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Minimal missing data
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	High risk	No washout period, which could influence the outcomes. Funding provided by manufacturer of one of the catheters

Sutherland 1996

Study characteristics	
Methods	**Study design:** RCT **Dates study conducted:** not reported
Participants	**Eligible**: not stated **Enrolled**: 33 **Completed**: 30 **Country**: USA **Setting**: community **Age**: children (mean age: group I 11.7 (SD 3.8); group II 12.1 (SD 5.7) **Sex**: male **Diagnosis**: neurogenic bladder due to spinal cord injury, Hinman syndrome, spinal dysraphism **Inclusion criteria:** boys who were adept at performing clean intermittent catheterisation with voiding dysfunction due to spinal dysraphism, spinal cord injury or Hinman syndrome **Exclusion criteria:** history of urethral pathology
Interventions	**Group I (n = 17):** hydrophilic-coated, single-use catheter (LoFric) **Group II (n = 16):** uncoated multiple-use catheter (Mentor) Method of cleaning catheter and length of re-use not described
Outcomes	UTI Haematuria > 3 RBC per HPF VAS for satisfaction
Funding sources	Not reported
Study conflicts of interest	Not reported
Notes	**Blinding procedures:** not stated **Sample size calculation:** no **Duration**: 8 weeks

Sutherland 1996 *(Continued)*

	Withdrawals/dropouts: 3 **ITT analyses performed:** not stated Definition of symptomatic UTI pre-dated IDSA 2009 guideline but aligned with it. Participants with positive urine cultures were treated and re-entered into the trial. Assumed to be single- versus multiple-use catheters, although this was not explicitly stated. It was not clear how often re-used catheters were changed.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "we performed a randomised trial".
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding; outcomes were likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated whether laboratory technician was blinded to catheter
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	1/17 and 2/16 did not complete the trial. It was not clear if the reasons for missing data were related to outcome or treatment.
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

Vapnek 2003

Study characteristics

Methods	**Study design:** RCT **Dates study conducted:** not reported
Participants	**Eligible**: not stated **Enrolled**: 62 **Completed**: 49 **Country**: USA **Setting**: community (3 sites) **Age**: adults; mean age in hydrophilic-coated group: 39.8 SD 12.9, polyvinyl chloride group: 39.6 SD 16.0

Vapnek 2003 *(Continued)*

	Sex: male **Diagnosis**: neurogenic bladder (cause not stated) **Inclusion criteria:** not reported **Exclusion criteria:** those requiring prophylactic antibiotics and those considered incapable of following the study schedule were excluded from analysis.
Interventions	**Group I (n = 31):** hydrophilic-coated, single-use catheter **Group II (n = 31):** uncoated multiple-use catheter. re-use time 24 hours
Outcomes	UTI; pyuria; haematuria
Funding sources	Supported by Astra Tech AB
Study conflicts of interest	Frederick M, Maynard has "Financial interest and/or other relationship with Pharmacia and Merc".
Notes	**Blinding procedures:** not stated **Sample size calculation:** no **Duration**: 12 months **Withdrawals/dropouts:** 13 **ITT analyses performed:** not stated Definition of symptomatic UTI pre-dated IDSA 2009 guideline but aligned with NIDRR 1992 criteria. However, microbiological analysis of urine was undertaken at fixed time intervals and not at the time when UTI symptoms were self-reported by participants and so the diagnosis of UTI was made based on clinical symptoms alone. Catheter cleaning was not described; used 1 re-useable catheter per day Unclear how long participants were using IC before entering trial; pre-trial UTI based on participant recall

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomised fashion"
Allocation concealment (selection bias)	Low risk	Quote: “sealed list: The group assignment was revealed only after the patient signed the consent form and was officially enrolled in the study”.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No blinding; it was unclear if the outcomes were likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated whether laboratory technician was blinded to catheter
Incomplete outcome data (attrition bias) All outcomes	High risk	Withdrawal rate greater in the experimental arm (8/31 vs 5/31). Data not included for participants who withdrew. Some of the reasons for withdrawal were related to outcome and/or intervention (group I: 2 did not return for follow-up, 1 hospitalised for bladder surgery, 1 unhappy with catheter, 1 poor

Vapnek 2003 *(Continued)*

		drainage, 1 moved away, 1 died of gastric cancer, 1 resumed normal voiding; group II: 2 did not return for follow-up, 1 had difficulty passing catheter, 1 hematuria, 1 UTI).
Selective reporting (reporting bias)	Low risk	Outcomes seemed to be reported in full.
Other bias	Low risk	Nothing to indicate any other source of bias

ASB: asymptomatic bacteriuria
BPH: benign prostatic hyperplasia
BUN: blood urea nitrogen
CFU/mL: colony-forming unit per millilitre
CIC: clean intermittent catheterisation
CISC: clean intermittent self-catheterisation
C&S: culture and sensitivity
IC: intermittent catheterisation
ICU: intensive care unit
ISC-Q: Intermittent Self-Catheterisation Questionnaire
ITT: intention-to-treat
PVC: polyvinyl chloride
NB: neurogenic bladder
NIDRR: National Institute on Disability and Rehabilitation Research
RBC per HPF: red blood cell per high power field
RCT: randomised controlled trial
SCI: spinal cord injury
SD: standard deviation
UI: urinary infection
UTI: urinary tract infection
VAS: visual analogue scale

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

Study	Reason for exclusion
Charbonneau 1993	Not a RCT.
Day 2003	Comparison of use of standard versus closed (integrated bag) catheter, aseptic technique in both arms. Excluded as aseptic technique used in both arms.
Denys 2012	Comparison of novel hydrophilic catheter versus participant's own hydrophilic catheter. Excluded as not comparing hydrophilic with uncoated catheter.
Diokno 1995	Not a RCT.
Edokpolo 2012	Not a RCT.
Fader 2001	Four way cross-over of hydrophilic coated catheters. No eligible comparisons.
Fera 2002	Comparison of antibiotic cream versus lidocaine jelly as a lubricant for IC.
Giannantoni 2001	No eligible comparisons, compares uncoated with gel reservoir. Additionally a cross-over study that does not include data in a usable format.

Study	Reason for exclusion
Grigoleit 2006	Article in German, appears to be a review of catheterisation methods (based on short English abstract).
Hudson 2005	Not a RCT.
Litherland 2007	RCT comparing effect of two hydrophilic-coated catheters. Excluded as did not compare hydrophilic with uncoated catheters.
Martins 2009	Cross-over trial (non-randomised) comparing hydrophilic-coated catheter versus an uncoated catheter. Excluded because of non-randomised design.
Mauroy 2001	No eligible comparisons.
Nalinthip 1996	Article in Thai, abstract translated. Comparison of UTI rate when IC performed by participant or nurse.
Pachler 1999	Comparison of hydrophilic and uncoated catheters. Excluded as the trial report did not indicate that the participants were randomised
Pascoe 2001	No eligible comparisons
Quigley 1993	Comparison of two uncoated catheters (with and without integrated bag). No eligible comparisons
Sallami 2011	RCT comparing the effect of clean IC using a hydrophilic catheter versus a standard PVC nelaton catheter on participant satisfaction, complications and recurrence of urethral stricture following endoscopic urethrotomy. Excluded as not for long-term bladder management
Stensballe 2005	Laboratory evaluation (RCT) of friction force of 2 hydrophilic catheters and one non-hydrophilic catheter. Healthy volunteers used
Terpenning 1989	Not an RCT
Witjes 2009	Comparison of two hydrophilic-coated catheters. Excluded as did not compare hydrophilic with uncoated catheters

IC: intermittent catheterisation
PVC: polyvinyl chloride
RCT: randomised controlled trial
UTI: urinary tract infection

Characteristics of ongoing studies *[ordered by study ID]*

ISRCTN42028483

Study name	ISRCTN42028483 (MultiCath)
Methods	Non-inferiority RCT
Participants	IC users
Interventions	Single-use vs mixed-use (single and re-usable)
Outcomes	UTI, antibiotic use, urethral bleeding, quality of life, costs, user experience
Starting date	2021

ISRCTN42028483 *(Continued)*

Contact information	Mandy Fader
Notes	

NL8296

Study name	COMPaRE
Methods	Non-inferiority RCT
Participants	IC users
Interventions	Single-use vs re-usable intermittent catheter
Outcomes	Symptomatic UTI, safety
Starting date	2020
Contact information	Bertil Blok
Notes	

IC: intermittent catheterisation
RCT: randomised controlled trial
UTI: urinary tract infection

DATA AND ANALYSES

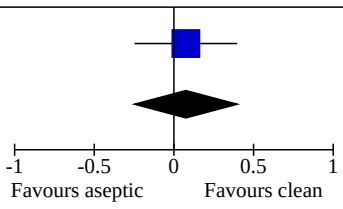
Comparison 1. Aseptic versus clean technique

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Symptomatic UTI	1	36	Risk Difference (M-H, Fixed, 95% CI)	0.08 [-0.25, 0.40]

Analysis 1.1. Comparison 1: Aseptic versus clean technique, Outcome 1: Symptomatic UTI

Study or Subgroup	Aseptic Events	Aseptic Total	Clean Events	Clean Total	Weight	Risk Difference M-H, Fixed, 95% CI
Moore 2006	9	20	6	16	100.0%	0.08 [-0.25 , 0.40]
Total (95% CI)		**20**		**16**	**100.0%**	**0.08 [-0.25 , 0.40]**
Total events:	9		6			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.46 (P = 0.65)
Test for subgroup differences: Not applicable



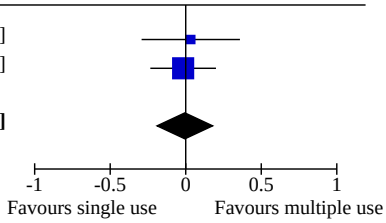
Comparison 2. Single-use catheter (sterile) versus multiple-use catheter (clean)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Symptomatic UTI	2	97	Risk Difference (M-H, Fixed, 95% CI)	-0.01 [-0.19, 0.18]

Analysis 2.1. Comparison 2: Single-use catheter (sterile) versus multiple-use catheter (clean), Outcome 1: Symptomatic UTI

Study or Subgroup	Single use Events	Total	Multiple use Events	Total	Weight	Risk Difference M-H, Fixed, 95% CI
Leek 2019	2	10	2	12	22.5%	0.03 [-0.29 , 0.36]
Madero-Morales 2019	13	37	14	38	77.5%	-0.02 [-0.23 , 0.20]
Total (95% CI)		**47**		**50**	**100.0%**	**-0.01 [-0.19 , 0.18]**
Total events:	15		16			

Heterogeneity: Chi² = 0.07, df = 1 (P = 0.80); I² = 0%
Test for overall effect: Z = 0.06 (P = 0.95)
Test for subgroup differences: Not applicable



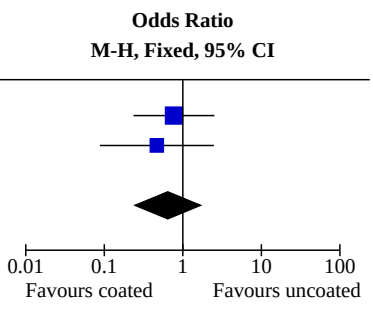
Comparison 3. Hydrophilic-coated catheter (single-use) versus uncoated catheter (single use)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Symptomatic UTI	2	98	Odds Ratio (M-H, Fixed, 95% CI)	0.64 [0.25, 1.67]
3.2 Adverse effects: number with urethral trauma/bleeding	4	430	Risk Ratio (M-H, Fixed, 95% CI)	1.37 [1.01, 1.87]
3.3 Satisfaction	1	114	Mean Difference (IV, Fixed, 95% CI)	0.70 [0.19, 1.21]

Analysis 3.1. Comparison 3: Hydrophilic-coated catheter (single-use) versus uncoated catheter (single use), Outcome 1: Symptomatic UTI

Study or Subgroup	Coated Events	Total	Uncoated Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Cardenas 2009	12	22	14	23	57.9%	0.77 [0.24 , 2.52]
Samal 2011	28	36	15	17	42.1%	0.47 [0.09 , 2.48]
Total (95% CI)		**58**		**40**	**100.0%**	**0.64 [0.25 , 1.67]**
Total events:	40		29			

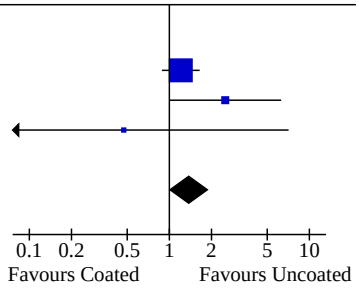
Heterogeneity: Chi² = 0.23, df = 1 (P = 0.63); I² = 0%
Test for overall effect: Z = 0.91 (P = 0.37)
Test for subgroup differences: Not applicable



Analysis 3.2. Comparison 3: Hydrophilic-coated catheter (single-use) versus uncoated catheter (single use), Outcome 2: Adverse effects: number with urethral trauma/bleeding

Study or Subgroup	Coated Events	Coated Total	Uncoated Events	Uncoated Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Sutherland 1996	0	16	0	14		Not estimable
De Ridder 2005	38	61	32	62	81.6%	1.21 [0.89 , 1.65]
Cardenas 2011	14	108	6	116	14.9%	2.51 [1.00 , 6.29]
Samal 2011	1	36	1	17	3.5%	0.47 [0.03 , 7.11]
Total (95% CI)		**221**		**209**	**100.0%**	**1.37 [1.01 , 1.87]**
Total events:	53		39			

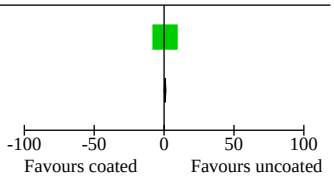
Heterogeneity: Chi² = 2.91, df = 2 (P = 0.23); I² = 31%
Test for overall effect: Z = 2.04 (P = 0.04)
Test for subgroup differences: Not applicable



Analysis 3.3. Comparison 3: Hydrophilic-coated catheter (single-use) versus uncoated catheter (single use), Outcome 3: Satisfaction

Study or Subgroup	Coated Mean	Coated SD	Coated Total	Uncoated Mean	Uncoated SD	Uncoated Total	Weight	Mean Difference IV, Fixed, 95% CI
Cardenas 2011	9.3	1.4	45	8.6	1.3	69	100.0%	0.70 [0.19 , 1.21]
Total (95% CI)			**45**			**69**	**100.0%**	**0.70 [0.19 , 1.21]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.68 (P = 0.007)
Test for subgroup differences: Not applicable



ADDITIONAL TABLES

Table 1. Description of interventions

Study	Intervention	Comparator
Comparison one: aseptic technique versus clean technique		
Duffy 1995	Sterile: single-use catheter	Clean: multiple-use catheter
King 1992	Sterile: single-use catheter	Clean: multiple-use catheter
Moore 2006	Sterile: single-use catheter	Clean: single-use catheter
Prieto-Fingerhut 1997	Sterile: Single-use catheter with an integrated bag	Clean: multiple-use catheter
Comparison two: single-use catheter (sterile) versus multiple-use catheter (clean)		
Kiddoo 2015	Single-use (hydrophilic-coated)	Multiple-use (uncoated) Clean catheters re-used for one week
Leek 2019	Single-use (uncoated)	Multiple-use

Table 1. Description of interventions *(Continued)*

		Number of re-uses not described
Moore 1993	Single-use (uncoated)	Multiple-use Number of re-uses not described
Schlager 2001	Single-use (uncoated)	Multiple-use Number of re-uses not described
Vapnek 2003	Single-use (hydrophilic-coated)	Multiple-use (uncoated) Clean catheters re-used for one day
Comparison three: hydrophilic-coated catheter versus uncoated catheter		
Cardenas 2009	Single-use coated	Single-use uncoated
Cardenas 2011	Single-use coated	Single-use uncoated
DeFoor 2017	Single-use coated	Single-use uncoated
De Ridder 2005	Single-use coated	Single-use uncoated
Kiddoo 2015	Single-use coated	Multiple-use uncoated
Leriche 2006	Single-use coated	Single-use uncoated
Samal 2011	Single-use coated	Single-use uncoated
Sarica 2010	Single-use coated	Single-use uncoated
Sutherland 1996	Single-use coated	Multiple-use uncoated
Comparison four: one catheter length versus another catheter length		
Biering-Sorensen 2007	Short-engtth hydrophilic-coated catheter	Standard-length (various designs)
Chartier-Kastler 2011	Short-length hydrophilic-coated catheter	Standard-length hydrophilic-coated catheter
Chartier-Kastler 2013	Short-length hydrophilic-coated catheter	Standard-length (various designs)
Costa 2013	Short-length (30 cm) uncoated, pre-lubricated closed system with integrated collection bag	Standard-length (40 cm) uncoated, pre-lubricated closed system with integrated collection bag
Domurath 2011	Short-length hydrophilic-coated catheter	Standard-length hydrophilic-coated catheter

APPENDICES

Appendix 1. Glossary of terms

Aseptic technique	In healthcare, an aseptic technique is a set of specific practices and procedures used to ensure that susceptible sites (e.g. open wounds or insertion sites of invasive devices) or sterile equipment/devices (e.g. catheters) are not contaminated with microorganisms during a procedure (Loveday 2014). It is used in healthcare when undertaking bladder catheterisation procedures.
Catheter design	Different sizes, lengths, tips, presentation (e.g. protective sleeve, pre-lubrication, integrated collection bag) and coatings
Catheter materials	The base material of the catheter (e.g. PVC, PVC-free, latex), and the presence or not of a bonded coating (e.g. hydrophilic)
Multiple-use catheter	A sterile or clean uncoated catheter, which may be re-used after decontaminating
Clean technique	A clean technique is used for intermittent self-catheterisation, where a sterile or clean (multiple-use) catheter is inserted with clean, ungloved hands and with or without a cleansing solution (soap and water, or water alone) and clean or sterile lubricant.
Hydrophilic- coated catheter	A type of catheter with a slippery coating designed to ease catheter insertion and may (according to the manufacturers) reduce urethral trauma and UTI. The most common hydrophilic coating is either supplied ready to use, or requires the addition of water at the time of use to form a lubricious layer.
Sterile catheter	Sterile single-use catheter
Symptomatic UTI	The presence of symptoms or signs compatible with UTI (not including odorous or cloudy urine alone) with no other identified source of infection along with $\geq 10^3$ CFU/mL of 1 bacterial species in a single catheter urine specimen (IDSA 2009)
Uncoated catheter	Typically clear PVC, uncoated catheters are packed singly in sterile packaging. They may be supplied pre-lubricated, used with a separate lubricant or with just water to aid insertion.

Appendix 2. Search of the Cochrane Incontinence Specialised Register

The Cochrane Incontinence Specialised Register was searched using the Group's own keyword system. The search terms used are given below:

topic.urine.incon*
AND
(design.cct* OR design.rct*)
AND
intvent.mech.cath*

All searches were of the keyword field of EndNote 2018.

F E E D B A C K

Feedback from Professor Dr Andrei Krassioukov and colleagues, August 2017

Summary

Our team that includes clinicians and scientists from Belgium, Canada, United States and Switzerland involved in rehabilitation and medical management of individuals with spinal cord injury (SCI) would like to ask your opinion and help to address the following issue. During the last few years, the international community engaged in strong debates on issues related to urinary tract infection and re-use of catheters during the management of neurogenic bladder among individuals with SCI.

In this respect, this review became one of the leading documents that captured the mind and attention of clinicians around the world. Although numerous countries completely switched to single-use catheters as guidelines for management of individuals with SCI, the opinion that was expressed in the above-mentioned review has the potential to make a significant negative impact on the future management of individuals with SCI.

Upon closer inspection of this review, we have become concerned about data that has been presented as well as conclusions drawn by the authors. We are reaching out to you to make you aware of our findings and interpretation of the studies that authors of the 'Intermittent catheterisation for long-term bladder management" Prieto and colleagues 2014 included and discussed in their review. We are seeking your advice and guidance on how we can proceed with this information.

We have identified three main concerns with this Cochrane review that was conducted by Prieto and co-investigators (Prieto 2014):

First, upon close inspection it appears that there are discrepancies in data extraction. For example, in 'Analysis 2.1 Comparison 2 Single-use (sterile) catheter versus multiple-use (clean) catheter, Outcome 2 Number with symptomatic UTI' of eight data sets, six (Sutherland 1996, Leek 2019, Kiddoo 2015, Duffy 1995a, King 1992a and Prieto-Fingerhut 1997) are inconsistent with data reported by the original authors. Similar discrepancies are noted throughout analyses in the review. At times, it appears data have simply been displaced (for example King 1992a: data for single-use catheter and data for multiple-use catheter must be swapped) and at times it appears data have been extracted differently than we would expect (for example, Leek 2019: one arm of the cross-over trial was reported instead of both arms). Additionally, an abstract referenced (Kiddoo 2015) provided data in a form that could not be extracted (person-weeks).

Secondly, although the review was published in 2014, the definition of symptomatic UTI was taken from the NIDRR 1992 statement in 'The Prevention and Management of Urinary Tract Infections Among People with Spinal Cord Injuries'. At that time, there were other more current definitions available such as the Infectious Diseases Society of America (IDSA) 2009 Guidelines which comprehensively covers definitions of catheter-associated urinary tract infections and is significantly different from the NIDRR 1992 definition. In addition, the authors of this Cochrane review chose to accept each study's definition of symptomatic UTI, despite none of the studies using a definition consistent with current standards. As a result, heterogeneous and inappropriate definitions of symptomatic UTI were included in analysis.

Finally, we feel clarification regarding the Analyses 1.1 through 4.4 (30 in total) may be required. Twenty of the 39 analyses consist of only 1 study, which is inconsistent with the Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 which states "Meta-analysis is the statistical combination of results from two or more separate studies". There are also inconsistencies with providing subtotals and totals for a number of analyses. An example of such can be seen for 'Analysis 3.1 Comparison 3 Hydrophilic-coated or a pre-lubricated catheter versus other catheter (pre-lubricated, coated or uncoated)'. The authors "chose not to derive a summary of estimate because of heterogeneity amongst the trials and the problem of attrition bias" despite having similar issues in other analyses and continuing to derive a summary in those instances. Alternatively, for 'Analysis 2.1 Comparison 2 Single-use (sterile) catheter versus multiple-use (clean) catheter, Outcome 2 Number with symptomatic UTI' the authors state "We decided not to derive a summary estimate because of heterogeneity; however, there was no suggestion of a trend favoring either of the approaches." (p. 13). They in fact derived both subtotal and total summaries and provided them (p. 73-74). A number of other analyses that did not include subtotals or totals did not provide a reason why they were not completed.

Following careful re-evaluation of the studies that were included in the review we have re-analysed the data and compared results between our analyses and previously published data by Prieto and co-investigators. When discrepancies in data were revised, we found that, in contrast to the 2014 review, Analysis 2.1 exhibits a trend (albeit small) toward the single-use (sterile) catheter, and Analysis 3.1 significantly favours hydrophilic catheters.

When a current definition of UTI (the IDSA 2009 Guidelines – Diagnosis, Prevention, and Treatment of Catheter-Associated Urinary Tract Infection in Adults: 2009 International Clinical Practice Guidelines from the Infectious Diseases Society of America) is applied and data are examined through this lens, further changes to outcomes are visible. As it is not possible to attach or submit figures/tables with this comment, we can only offer to share our results in detail with you.

As Cochrane reviews are highly influential in the medical community, we believe it is important others become aware of possible changes to the review. Would you be supportive of our group submitting a different perspective on the data published in the 2014 Cochrane review that was conducted by Prieto and co-investigators to The Cochrane Collaboration, or should we consider other venues for this publication?

We look forward to hearing from you on this matter and welcome input for moving forward. If you have any questions or need further clarification, please feel free to contact us.

Reference:

IDSA 2009

Infectious Diseases Society of America (IDSA). Diagnosis, prevention, and treatment of catheter associated urinary tract infection in adults: 2009 international clinical practice guidelines from the Infectious Diseases Society of America. Information available here: http://www.idsociety.org/Guidelines/Patient_Care/IDSA_Practice_Guidelines/Infections_by_Organ_System/Genitourinary/Catheter-Associated_Urinary_Tract_Infection/

Reply

This reply has been prepared jointly by the Cochrane Incontinence Group editorial office and the Cochrane Editorial Unit (CEU).

The Cochrane Incontinence editorial office and the CEU are grateful for the submission of the feedback from Professor Krassioukov and colleagues. Following an independent assessment of the review by a statistician and an editor from the CEU, the decision to withdraw the review was agreed between the acting Editor in Chief, Karla Soares Weiser, and Co-ordinating Editor of the group, Luke Vale. The issues identified have been shared with the authors and the review will be republished following revision and update.

Contributors

Andrei V. Krassioukov, Kathleen Christison, Matthias Walter, Jean-Jacques J.M. Wyndaele, Thomas M. Kessler, Michael Kennelly

WHAT'S NEW

Date	Event	Description
23 July 2021	New search has been performed	In this version of the review, published in 2021, the following changes were made: 1. The search was updated to April 2021 and now includes 23 trials. 2. For trials that pre-dated or did not meet the IDSA 2010 definition of symptomatic UTI (see Appendix 1), we chose to accept the study's own definition providing it met the NIDRR 1992 criteria (presence of one or more symptoms or signs compatible with UTI, including cloudy urine with increased odour, together with quantitative urine culture (≥ 10^2 CFU/mL)). For more details, please see the Differences between protocol and review. 3. We reconsidered the clinical relevance of the comparisons and made changes accordingly. For more details, please see the Differences between protocol and review. 4. We substantively revised, updated and reformatted the review, including assessing the certainty of evidence using the GRADE approach and developing summary of findings tables, in accordance with current Cochrane standards. 5. Data entry errors from the previous version of the review were corrected.
23 July 2021	New citation required but conclusions have not changed	The paucity of useable data and uncertainty of evidence means that it remains unclear whether the incidence of UTI or other complications is affected by use of aseptic or clean technique, coated or uncoated, single (sterile) or multiple-use (clean) catheters, or different catheter lengths.

HISTORY

Protocol first published: Issue 2, 2006
Review first published: Issue 4, 2007

Date	Event	Description
10 August 2017	Amended	This review has been withdrawn following feedback from a group of readers who have identified possible errors in the analysis of data in the review. These concern handling of cross-over and multi-arm trials as well as corrections and clarifications of data used. This review has been withdrawn whilst these issues are addressed. Changes are also required to reflect current

Date	Event	Description
		methodological standards. The review will be re-published following updating, revision and peer review.
10 September 2014	New citation required but conclusions have not changed	Risk of bias was re-assessed for all the included trlas as per current recommendation.
10 September 2014	New search has been performed	Added 17 new studies in this update.
22 August 2007	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

JP: screened search results and selected studies for inclusion; extracted data; assessed risk of bias; provided clinical interpretation of data and jointly co-ordinated the review.
CM: screened search results and selected studies for inclusion; extracted data; assessed risk of bias; conducted GRADE assessment and jointly co-ordinated the review.
FS: extracted data, assessed risk of bias, conducted GRADE assessment, drafted summary of findings tables.
MF: provided oversight review and clinical interpretation of data.

All review authors contributed towards the writing of the review.

DECLARATIONS OF INTEREST

JP: none known
CM: none known
FS: none known
MF: has received funding from the UK National Institute of Health Research for a trial on intermittent catheters (MULTICATH Trial registration ISRCTN42028483).

SOURCES OF SUPPORT

Internal sources

- No sources of support provided

External sources

- National Institute for Health Research, UK

  This project was supported by the National Institute for Health Research, via Cochrane Infrastructure funding to Cochrane Incontinence. The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Evidence Synthesis Programme, the NIHR, NHS or the Department of Health and Social Care.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

For this version of the review, published in 2021, the following changes were made.

1. For trials that pre-dated or did not meet the IDSA 2010 definition of symptomatic UTI (see Appendix 1), we chose to accept the study's own definition providing it met the NIDRR 1992 criteria (presence of one or more symptoms or signs compatible with UTI, including cloudy urine with increased odour, together with quantitative urine culture (≥ 10^2 CFU/mL)). We considered this appropriate because the IDSA 2010 guideline acknowledges the difficulty distinguishing between infection and bacteriuria in a catheterised patient given most signs and symptoms are nonspecific, necessitating clinical judgement in determining whether or not to treat with antibiotics.

2. We redefined comparison number one to focus on aseptic versus clean technique (which is the important clinical question) rather than including one aseptic technique versus another aseptic technique. Similarly, we redefined comparison number three to focus on hydrophilic catheters versus uncoated catheters rather than including a wide range of comparisons of different types of hydrophilic or pre-lubricated/gel reservoir catheters, as was done in the previous review. This meant that a number of trials that were included in the previous version of the review were excluded. We have moved them to the Characteristics of excluded studies and have given reasons for their exclusion.

3. We substantively revised, updated and reformatted the review, including assessing the certainty of evidence using the GRADE approach and developing summary of findings tables, in accordance with current Cochrane standards.

4. Data entry errors from the previous version of the review were corrected following feedback (see Feedback 1).

INDEX TERMS

Medical Subject Headings (MeSH)

Equipment Reuse; Patient Dropouts; Urinary Catheterization [adverse effects] [instrumentation] [*methods]; *Urinary Catheters [adverse effects]; Urinary Retention [*therapy]; Urinary Tract Infections [etiology] [prevention & control]

MeSH check words

Adult; Child; Female; Humans; Male