Long-term bladder management by intermittent catheterisation in adults and children (Review)

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[Intervention Review]

Long-term bladder management by intermittent catheterisation in adults and children

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ABSTRACT

Background

Intermittent catheterisation (IC) is a commonly recommended procedure for people with incomplete bladder emptying not satisfactorily managed by other methods. The most frequent complication of IC is urinary tract infection (UTI). It is unclear which catheter types, techniques or strategies, affect the incidence of UTI. There is wide variation in practice and important cost implications for using different catheters, techniques or strategies.

Objectives

To compare sterile versus clean catheterisation technique, coated (pre-lubricated) versus uncoated (separate lubricant) catheters, single (sterile) or multiple use (clean) catheters, self-catheterisation versus catheterisation by others, and any other strategies designed to reduce UTIs in respect of incidence of symptomatic UTI, haematuria, other infections and user preference, in adults and children using intermittent catheterisation for incomplete bladder emptying.

Search methods

We searched the Cochrane Incontinence Group Specialised Trials Register (searched 19 June 2006), MEDLINE (January 1966 to June 2007), EMBASE (January 1988 to June 2007), CINAHL (January 1982 to June 2007), ERIC (January 1984 to June 2007), 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reference lists of relevant articles and conference proceedings, and we attempted to contact other investigators for unpublished data or for clarification.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 comparing at least two different catheterisation techniques, strategies or catheter types.

Data collection and analysis

Three reviewers assessed the methodological quality of trials and abstracted data. For dichotomous variables, relative risks and 95% confidence intervals (CI) were derived for each outcome where possible. For continuous variables, mean differences and 95% CI were calculated for each outcome. Because of trial heterogeneity, data were not combined to give an overall estimate of treatment effect.

Main results

Fourteen studies met the inclusion criteria; all were small (less than 60 participants). There was considerable variation in length of follow-up and definitions of UTI. Participant drop-out was a problem for several studies. Several studies were more than ten years old and outcome measures varied between studies. Where there were data, confidence intervals around estimates were wide and hence clinically important differences in UTI and other outcomes could neither be identified nor ruled out reliably.

Authors' conclusions

Intermittent catheterisation is a critical aspect of healthcare for individuals with incomplete emptying who are otherwise unable to void adequately to protect bladder and renal health. There is a lack of evidence to state that incidence of UTI is affected by use of sterile or clean technique, coated or uncoated catheters, single (sterile) or multiple use (clean) catheters, self-catheterisation or catheterisation by others, or by any other strategy. The current research evidence is weak and design issues are significant. In light of the current climate of infection control and antibiotic resistance, further, well-designed studies are strongly recommended. Based on the current data, it is not possible to state that one catheter type, technique or strategy is better than another.

PLAIN LANGUAGE SUMMARY

Prevention of urine infection in adults and children who use intermittent catheterisation (a treatment involving passing a hollow tube into the bladder regularly) to empty their bladders

Intermittent catheterisation is a common treatment used by people who have bladder emptying problems. A hollow tube (catheter) is passed through the body's channel to the bladder (urethra) or through a surgically made channel to the skin surface, to regularly empty the bladder (usually several times every day). This treatment reduces problems such as loss of bladder control (incontinence) or having to pass urine very frequently or in a hurry (urgency). But people who use this treatment are often troubled by urine infections resulting in days lost from school or work or even hospitalisations. There are many different catheter types and techniques which may affect urine infection. In this review we assessed trials which focused on incidence of urine infection in intermittent catheterisation users who used different catheterisation techniques (sterile or clean); different types of catheters (coated [pre-lubricated] or uncoated [separate lubricant]); sterile (single-use) catheters or clean (multiple use) catheters; self-catheterisation or catheterisation by others (such as parents); and other strategies designed to reduce urine infection, including catheter cleaning (for multiple use). There are no definitive studies showing that the incidence of urine infection is improved with any catheter technique, type or strategy. These studies are difficult because participants need to take part for many months and many of the reviewed studies were too small and had problems with participants dropping out. Also definitions of urine infection varied considerably. The current strength of evidence is weak and well-designed studies are strongly recommended. Based on the current evidence, it is not possible to state that any catheter type, technique or strategy is better than another.

BACKGROUND

Intermittent catheterisation (IC) is the act of passing a catheter into the bladder to drain urine via the urethra or other catheterisable channel such as a Mitrofanoff continent urinary diversion (surgically constructed passage connecting bladder with abdominal surface). The catheter is removed immediately after urine drainage is complete. It is widely advocated as an effective bladder management strategy for incomplete bladder emptying in patients with idiopathic or neurogenic bladder dysfunction. Such patients often experience urinary frequency, urgency, incontinence and repeated urine infections due to residual urine in the bladder.

IC can be undertaken by people of all ages, including the very elderly and children as young as four years old with parental supervision (Eckstein 1982). Carers can also be taught the procedure where this is acceptable to both patient and carer. Disabilities such as blindness, lack of perineal sensation, tremor, mental disability and paraplegia do not necessarily preclude mastering the technique.

Individualised care plans help identify appropriate catheterisation frequency, based on discussion of voiding dysfunction and impact on quality of life, frequency-volume charts, functional bladder ca-

pacity, and ultrasound bladder scans for residual urine. Numbers of catheterisations per day vary; in adults catheterising frequently enough to avoid residual urine greater than 500 ml is a general rule but guidance is also provided by urodynamic findings, detrusor pressures on filling, presence of reflux, and renal function. Advantages of intermittent catheterisation over indwelling catheterisation include:

- greater opportunity for individuals for self-care and independence.
- reduced risk of common indwelling catheter-associated complications.
- reduced need for equipment and appliances e.g. drainage bags.
- greater freedom for expression of sexuality.
- potential for reduced urinary symptoms (frequency, urgency, incontinence) between catheterisations.

Complications of intermittent catheterisation have been comprehensively reviewed by Wyndaele 2002. This review showed urinary tract infection (UTI) to be the most frequent complication and catheterisation frequency and the avoidance of bladder over-filling were recognised as important prevention measures. Prostatitis was an identified risk in men, but epididymitis and urethritis were relatively rare. Trauma from catheterisation, measured by haematuria, was reported but lasting effects limited. Estimates of the prevalence of urethral strictures and false passages increased with longer use of IC or with traumatic catheterisation. Similar findings were recently reported in a follow-up of children with spina bifida who had used intermittent catheterisation with an uncoated PVC catheter for at least 5 years. The incidence of urethritis, false passage, or epididymitis was very low whilst adherence to the protocol was excellent. Wyndaele and colleagues concluded that the most important preventative measures were good education of all involved in IC, adherence to the catheterisation protocol, use of an appropriate catheter material, and good catheterisation technique.

Types and characteristics of catheters used in IC vary considerably so evaluation and selection of products is complex. Plain uncoated catheters (typically clear plastic PVC) are packed singly in sterile packaging. As per industry standards, all disposable catheters are intended for one time use but PVC catheters are frequently reused because of cost or concern about the environment. Most are used with separate lubricant, although this is a matter of personal choice and some patients use no lubricant (or just use water). Cleansing varies from being washed with soap and water, boiled, soaked in disinfectants, or microwaved. Cleaned catheters are air dried and then stored in a convenient container (often plastic containers/ Zip loc bags or paper bags). Coated catheters are single-use only (they may not be cleaned and reused) and are designed to improve catheter lubrication and ease of insertion which may (according to manufacturers) reduce trauma and UTI. The most common coatings are hydrophilic (which require the addition of water to the catheter to form a lubricious layer) or pre-lubricated (whereby the catheter is supplied pre-packed with a coating of water soluble gel). There are also several pre-lubricated products with an integrated collection bag (all-in-one) which gives flexibility for the user and are efficient for hospital use. Finally, the design of catheters also varies in terms of material, length, and flexibility. These particular characteristics may be important for individual users but are not addressed in this review. The main purpose of this review was to compare incidence of symptomatic urinary tract infection (UTI) and other complications (including long-term sequelae and quality of life) in intermittent catheterisation users who are exposed to sterile or clean technique, coated or uncoated catheters or single use or multiple use catheters, catheterisation by self or others, or any other strategy (including catheter cleaning) designed to reduce UTI.

Definition of terms

For purposes of this review, the primary outcome variable is symptomatic UTI and is defined as a positive urine culture and the presence of symptoms. We had intended to use the UTI definition of the NIDRR 1992 (positive urine culture with pyuria and one or more systemic symptoms [fever, loin pain, dysuria, urgency, haematuria]) but some studies had other definitions and we chose to accept symptomatic UTI as reported in the studies reviewed. We defined positive urine culture but absence of symptoms as asymptomatic bacteriuria (rather than asymptomatic UTI).
By 'sterile technique' we mean the use of sterile gloves, sterile single use catheter, sterile drainage tray and an aseptic technique for the catheterisation procedure; and 'clean technique' as clean gloves (or no gloves in the case of a patient self-catheterising), clean but non-sterile cleansing solution, and a clean receptacle in which to drain urine. It should be noted that a sterile technique always includes a sterile (single use) catheter whereas a clean technique may include a sterile catheter or a clean (multiple use) catheter.
We define uncoated catheters as those requiring separate lubricant to aid insertion. These may be made of PVC or other material such as red rubber. When used only once they are considered as 'sterile', when reused they are considered clean and defined as multiple use. Coated catheters have a hydrophilic or other lubricated coating intended to replace the use of separate lubricant. Coated catheters are not intended for reuse and are therefore defined as sterile.
We did not define 'adult' and 'child' and accepted the definitions (if given) provided by the studies.

OBJECTIVES

To determine if certain types of intermittent catheters, catheterisation techniques, or other strategies (including catheter-clean-

ing) are better than others in terms of UTI, complications, quality of life and cost-effectiveness, for adults and children whose long-term (with no predicted endpoint) bladder management is by intermittent catheterisation.

Specific comparisons to be addressed include:

1. Sterile technique versus clean technique;

2. Coated catheter versus uncoated catheter;

3. Single use (sterile) catheter versus multiple use (clean) catheter;

4. Self-catheterisation versus catheterisation by health professional or other carer;

5. Other strategies designed to reduce infection, such as use of antibiotic gel and catheter cleaning techniques.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised clinical trials comparing catheterisation techniques, catheter types and other strategies for long-term bladder management by intermittent catheterisation.

Types of participants

Adults or children requiring intermittent catheterisation for long-term bladder management.

Types of interventions

Comparisons of intermittent catheterisation techniques (sterile versus clean), catheter types (coated versus uncoated), single (sterile) or multiple use (clean) catheter, catheterisation by self or others and other strategies designed to reduce infection including catheter cleaning techniques.

Types of outcome measures

1. Catheter-associated infection (definition of infection as used in trial reports)

- Asymptomatic bacteriuria
- Symptomatic UTI (primary outcome variable)

2. Other complications/adverse effects

- Urethral trauma/haematuria
- Abnormal cytology
- Stricture formation

3. Patient-assessed outcomes

- Patient comfort, including ease of insertion and removal
- Patient satisfaction
- Patient preferences
- Quality of life measures

4. Economic outcomes

- Catheter and equipment costs
- Frequency of catheterisation
- Resource implications (personnel and other costs to services)
- Formal economic analysis (cost-effectiveness, cost utility)

5. Other outcomes

- Microbiological culture of catheter surfaces
- Additional outcomes judged to be important when performing the review

Studies were included in the review if they reported catheter-associated infection either as symptomatic UTI (primary outcome variable) or as asymptomatic bacteriuria.

Search methods for identification of studies

This review has drawn on the search strategy developed for the Cochrane Incontinence Review Group. Relevant trials were identified from the Group's Specialised Register of controlled trials which is described, along with the search strategy, under the Incontinence Group's details in *The Cochrane Library* (For more details please see the 'Specialized Register' section of the Group's module in The Cochrane Library). The register contains trials identified from MEDLINE, CINAHL, The Cochrane Central Register of Controlled Trials (CENTRAL) and hand searching of journals and conference proceedings. The Incontinence Group Specialised Trials Register was searched using the Group's own keyword system, the search terms used were:
topic.urine.incon*
AND
({design.cct*} OR {design.rct*})
AND
intvent.mech.cath*
(All searches were of the keyword field of Reference Manager 9.5 N, ISI ResearchSoft).

Date of the most recent search of the register for this review: 19 June 2006.

For this review extra specific searches were performed. These are detailed below.

Electronic bibliographic databases

We searched MEDLINE from January 1966 to June 2007, EMBASE from January 1988 to June 2007, CINAHL from January 1982 to June 2007, and ERIC from January 1984 to June 2007. All searches were performed in June 2007. The search terms included individually or combined: intermittent catheterisation/catheterization; randomised/randomized controlled trials; neurogenic bladder; incomplete emptying; catheter(s); hydrophilic coated, coated, uncoated, bacteriuria, symptomatic urinary tract infection, asymptomatic bacteriuria, asymptomatic urinary tract infection. In addition, terms to search for studies of catheter cleaning methods, the above terms were combined with microwaving, catheter cleaning, soap and water, antiseptic soak.

We searched the reference lists of relevant articles and conference proceedings for other possible relevant trials. We also attempted to contact other investigators for unpublished data or for clarification.

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

Data collection and analysis

Study selection

Three reviewers assessed the title and abstracts of trials identified by the search strategy. Full reports of all potentially relevant randomised clinical trials based on defined inclusion criteria were obtained.

Methodological quality assessment

The quality of eligible trials was assessed independently by the three review authors using a pre-defined quality assessment form which included quality of random allocation and concealment, description of drop-outs and withdrawals, analysis by intention to treat, and blinding during intervention and at outcome assessment. There were no disagreements between review authors when study quality was assessed.

Data abstraction

Relevant data regarding inclusion criteria (study design, participants, interventions, and outcomes), quality criteria (randomisation, blinding, and control) and results were extracted independently by two review authors using a data abstraction form developed specifically for this review and based on the criteria used In one case where insufficient data were reported on method of 'clean' technique, the authors were successfully contacted for further information. Excluded studies and reasons for exclusion have been detailed in the 'Characteristics of Excluded Trials' table.

Data analysis

Data was processed as described in the Cochrane handbook. For dichotomous variables, relative risks and 95% confidence intervals (CI) were derived for each outcome where possible. For continuous variables, mean differences and 95% CI were calculated for each outcome. Because of trial heterogeneity, data were not combined to give an overall estimate of treatment effect.

RESULTS

Description of studies

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

Results of the search

Thirty-eight studies were identified and 24 were excluded: seven were reviews, four were randomized but did not report catheter-associated infection, 11 were observational studies, two were studies in vitro. Reference lists from excluded studies were reviewed for potential trials. Two authors were contacted for clarification and provided further details for the reviewers. The final number of trials addressing some aspect of sterile or clean intermittent catheterization and using a measure of catheter-associated infection was 14. Study participants ranged from spinal cord injured adults to children with neurogenic bladders due to myelomeningocoele. There were considerable variations in length of follow-up, definitions of UTI, and numbers of participants. Attrition was a problem for several studies and all were underpowered. Several studies were more than 10 years old.

Included Studies

Fourteen studies met the inclusion criteria; (Day 2003; De Ridder 2005; Duffy 1995; Fera 2002; Giannantoni 2001; King 1992; Moore 1993; Moore 2006; Pachler 1999; PrietoFingerhut 1999; Quigley 1993; Schlager 2001; Sutherland 1996; Vapnek 2003).

Design

There were four two-arm crossover trials; in each arm participants were catheterized for either three weeks with coated or multiple use catheters (Pachler 1999), seven weeks (Giannantoni 2001), four months (Schlager 2001), or six months (Moore 1993).

In the ten parallel group randomised controlled trials, the duration of catheterisation ranged between 24 hours (Day 2003); four days (Quigley 1993); one month (King 1992); two months (Sutherland 1996); three months (Duffy 1995); four months (Fera 2002) up to 12 months (De Ridder 2005; Moore 2006; Vapnek 2003); or was of unclear duration (PrietoFingerhut 1999).

Sample sizes

All sample sizes were small. Two (De Ridder 2005; Moore 2006) included statistical power calculations but were unable to achieve their predicted sample sizes. At study endpoint, sample sizes ranged from 11 (Day 2003) to 58 (De Ridder 2005). A total of 565 participants were enrolled in the 14 trials but only 416 (74%) of all participants completed data collection.

Participants

Six trials involved patients with spinal cord injury (SCI) (Day 2003; De Ridder 2005; Giannantoni 2001; King 1992; Moore 2006; PrietoFingerhut 1999); one included SCI (11) and stroke (9) participants (Quigley 1993); two included participants with incomplete emptying due to prostatic obstruction from prostatic hyperplasia (Duffy 1995; Pachler 1999); two involved children with spina bifida (Moore 1993; Schlager 2001), one included participants with SCI, Hinman syndrome, or spinal dysraphism (Sutherland 1996), and one did not state etiology of the bladder dysfunction (Vapnek 2003). Age and gender ranged from boys and girls with spina bifida (Moore 1993; Schlager 2001), boys with neurogenic bladders (Sutherland 1996), adult men with prostatism (Pachler 1999), adults with SCI (Day 2003; De Ridder 2005; King 1992;Moore 2006), adult males with non-specified neurogenic bladder (Vapnek 2003). Age and gender were not described in one (Quigley 1993). Four trials included females as participants (Moore 1993 (15 boys; 15 girls); Moore 2006 (28 males; 8 females); Giannantoni 2001 (16 males; 2 females), PrietoFingerhut 1999 (16 men; 13 women), Schlager 2001 (4 boys; 6 girls); Fera 2002 (12 men; 8 women).

Setting

Acute care within an intensive care unit was the setting for one (Day 2003), a rehabilitation hospital for five (Giannantoni 2001; King 1992; Moore 2006; PrietoFingerhut 1999; Quigley 1993). continuing or long term care for one (Duffy 1995) and community for six (De Ridder 2005; Moore 1993; Pachler 1999; Schlager 2001; Sutherland 1996; Vapnek 2003).

Types of interventions

Interventions were separated into three main categories but in each of these there were variations in catheterisation technique, catheter type and multiple use versus single use. In most cases there was no clear distinction made between self and caregiver/health-care professional catheterisation. There were three trials comparing sterile versus clean technique (Duffy 1995; King 1992; Moore 2006); four comparing coated versus uncoated catheters (Day 2003; De Ridder 2005; Giannantoni 2001; Quigley 1993), two comparing coated versus multiple-use uncoated catheters (Pachler 1999, Sutherland 1996) and six comparing single to multiple use (King 1992; Moore 1993; Pachler 1999; PrietoFingerhut 1999; Schlager 2001; Vapnek 2003), none comparing self-catheterisation to catheterisation by others, one comparing catheterisation with antibiotic gel to standard gel Fera 2002 and none comparing cleaning techniques. (The numbers add up to more than 14 since some studies fit into more than one category). Within these three categories various subcategories occurred which are presented in detail in the Results section below.

Duration of intervention

In the ten parallel group randomised controlled trials, the duration of catheterisation ranged between 24 hours (Day 2003); four days (Quigley 1993); one month (King 1992); two months (Sutherland 1996); three months (Duffy 1995); four months (Fera 2002); up to 12 months (De Ridder 2005; Moore 2006; Vapnek 2003); or was of unclear duration (PrietoFingerhut 1999).

Outcome measures

13 of the studies reported symptomatic UTI, but the definition varied between studies from 'clinical infection with symptoms of UTI and for which treatment was prescribed' to 10x5 CFU/ml plus at least one of the following symptoms of fever, pyuria, haematuria, chills, increased spasms or autonomic dysreflexia (Moore 2006) One study (Day 2003) had asymptomatic bacteriuria as the primary outcome variable (See Table Characteristics of Included Studies, Notes for a complete description provided in each report).

Excluded studies

Twenty four studies were excluded: seven were reviews, four were randomized but did not report catheter-associated infection, 11 were observational studies, two were studies in vitro (See Table Characteristics of Excluded Studies).

On-going studies

Two trials are on-going. One is a parallel arm randomised controlled trial conducted in several sites in North America and comparing coated versus non-coated catheters in adults with recent SCI; the other is similar but comparing outcomes in children with neurogenic bladders. The first should be completed by 2008, the second in 2010 (see Characteristics of on-going studies for complete description of both trials).

Studies awaiting assessment

One study is in preparation for publication (Cardenas 2006) and was not included in the analysis as data in the abstract were too few for useful analysis.

Risk of bias in included studies

Details of the quality of each trial are given in the table of Characteristics of Included Studies.

The trials as a whole were methodologically weak. Sample sizes were small, outcome variables differed, particularly with respect to the definition of UTI . Positive culture in the absence of symptoms is problematic in the current healthcare climate because colonization without symptoms is typically not treated in intermittent catheterisation users. Thus the clinical relevance for current users of intermittent catheterisation is unclear. Follow up ranged from 24 hours to 12 months. Several of the trials were more than 10 years old and were typically less rigorous in design and analysis, in particular by not including pyuria as part of the diagnosis of UTI. Attrition of participants was a particular problem (see later section).

Quality of Allocation Concealment/Randomisation

The majority of the study reports did not describe the method of allocation nor who approached potential participants. In those that did, Moore 2006 used opaque sealed envelopes opened by a third party who informed the research nurse of the assignment. De Ridder 2005 randomised participants in blocks of four and used opaque envelopes opened by the investigator but supplied from a central research office, and Quigley 1993 used 'blind selection of a marked piece of paper from a box'. Duffy 1995 did not describe method of randomisation but did indicate participants were stratified for research site or presence/absence of UTI. Eleven did not describe the method of randomisation, stating only that participants were 'randomised'. Only Moore 2006 indicated that participants were approached by a third party for permission to meet with the research assistant.

Blinding

It was not possible to blind participants to the type of catheter being evaluated. Data entry clerk and laboratory staff were blinded in one trial (Moore 2006) and may have been in others but this was not stated.

Withdrawals/dropouts

A total of 565 participants were enrolled in the 14 trials but only 416 (74%) of all participants completed data collection. Five trials reported significant attrition (De Ridder 2005; Duffy 1995; King 1992; Quigley 1993; Vapnek 2003) related to development of UTI, no further need for intermittent catheterisation, patient request, death, restored urinary function. De Ridder 2005 randomised 123 SCI (less than 6 months since injury) to coated versus uncoated catheters, followed for a total of 12 months. At Day 15 after enrolment 114 remained; at 12 months only 57 participants had data for analysis. In the Duffy trial, 80 males in long term care in a Veteran's Administration Medical Centre were randomised to sterile or clean technique. Complete data were available up to Day 15; but only 39 had data at the 3 month end point. King 1992 randomised 46 spinal cord injured patients (SCI) to a 28 day protocol of single use versus multiple PVC catheters. By Day 11, 22 remained; by day 28 only 9 remained. In the Quigley trial, 30 SCI or stroke participants were initially randomised; at the end point (Day 4) 10 participants had been lost. Finally, Vapnek 2003 randomised 62 men to Coated versus Uncoated catheters with only 49 completing the full 12 months data collection.

Intention to Treat Analysis

No authors described intention to treat analysis. Moore 2006 noted that patients who were discharged or left the study for any reason remained in the analysis as censored observations.

Crossover trials

Four crossover trials were identified (Giannantoni 2001; Moore 1993; Pachler 1999; Schlager 2001). Moore 1993 had archived data and so was able to provide data for the first period before cross-over so it was appropriate to analyse these data as a parallel group trial. The other three did not report data in a format that took account of the cross-over designs.

Effects of interventions

Comparison 01: Sterile technique versus clean technique.

Three trials compared sterile techniques with clean techniques (Duffy 1995; King 1992; Moore 2006). In Moore 2006 sterile uncoated catheters were used in each arm. In contrast, Duffy (Duffy 1995) and King (King 1992) used single-use catheters in one arm and multiple-use in the other.

Asymptomatic bacteruria

Moore reported asymptomatic bacteruria. The results were similar in the two groups (7 out of 16 versus 9 out of 20; RR 0.97; 95% CI 0.47 to 2.03) (Comparison 01.Outcome 01).

Symptomatic UTI

All three trials reported symptomatic UTI. None showed a statistically significant result favouring either technique (Comparison 01. Outcome 02). All had wide confidence intervals and there was no apparent trend favouring either technique.

Number with urethral trauma/bleeding

No data available

Number with stricture formation.

No data available

Number with microscopic haematuria.

No data available

Number with urethritis/epididymitis, or orchitis

No data available

Weeks to onset of UTI

All three studies (Duffy 1995; King 1992; Moore 2006) measured mean time to onset of UTI. None showed statistically significant result favouring either technique (Comparison 01.Outcome 07). Mean onset ranged from 4.3 weeks (sterile group) and 4.6 weeks (clean group) (Moore 2006); 3.11 weeks (sterile group) and 3.48 weeks (clean group (Duffy 1995); and 1.25 weeks (sterile group) and 1.12 weeks (clean group) (King 1992).

Number reporting satisfaction with catheter product

No data available

Number reporting comfort and ease of insertion.

No data available

Number reporting preference.

No data available

Comparison 02: Coated catheter versus uncoated catheter

Eight trials compared some form of coated catheter with an uncoated catheter, six parallel group trials (Day 2003; De Ridder 2005; PrietoFingerhut 1999; Quigley 1993; Sutherland 1996; Vapnek 2003) and two cross over trials (Giannantoni 2001; Pachler 1999).

Asymptomatic bacteruria

Only one of the parallel group trials reported asymptomatic bacteruria, (Day 2003). This was a feasibility trial comparing a coated catheter and attached sterile drainage bag to sterile catheter tray and sterile technique. No participant in the coated system group compared with two in the uncoated groups developed a positive colony count (Comparison 02, Outcome 01). In Giannantoni's cross-over trial there were more cases of asymptomatic bacteriuria in the time period when uncoated catheters were used than when coated catheters were used i.e. results were better for coated than uncoated catheters(18 out of 54 versus 8 out of 54). This difference was statistically significant when analysed (incorrectly) as a parallel group trial.

Number with symptomatic UTI

Four parallel group trials reported symptomatic UTI (De Ridder 2005; Quigley 1993; Sutherland 1996; Vapnek 2003) (Comparison 02, Outcome 02). The Giannantoni trial has been reported as if it was a parallel group trial and information was not available to allow reanalysis as a cross-over trial. Quigley 1993 and Giannantoni 2001 used a sterile technique in both arms, De Ridder used clean technique in both arms and Sutherland and Vapnek used single use in the coated group and multiple use in the uncoated group.

In the largest of these (De Ridder 2005) the authors reported on the incidence of UTI of all enrolled participants (N=123) although only 57 participants remained in the study at the endpoint of 12 months and drop-out was greater in the coated catheter group (N= 49 compared to N=58 in uncoated catheter group at month 1). There were fewer UTIs in the coated catheter group (i.e. results were better for the coated catheters) and this was marginally statistically significant (39 out of 61 versus 51 out of 62; RR 0.78; 95% CI 0.62 to 0.97). The estimates from the three smaller trials had wide confidence intervals that straddled the no-difference line (Comparison 02.02). We chose not to derive a summary estimate because of the heterogeneity amongst the four trials, particularly in respect of the interventions.

UTI was also reported for Giannantoni's cross-over trial. As for asymptomatic bacteriuria, there were more infections in the time period when lubricant was added (12 out of 54 versus 4 out of 52).

Number with urethral trauma/bleeding

No data available

Number with Stricture Formation

One event occurred in the coated group of the de Ridder trial (De Ridder 2005) (Comparison 02.04).

Number with Microscopic Haematuria

Sutherland reported fewer cases of microscopic haematuria in the coated group (6 out of 16 versus 11 out of 14; Comparison 02.05) i.e. results were better for the coated catheters.

Number with urethritis/epididymitis, or orchitis

No available data

Number reporting satisfaction with catheter product

De Ridder 2005 reported on numbers of participants who were 'very satisfied' with their catheter (Table of Comparison 02.10). At 12 months, of the remaining participants (attrition was high) uncoated was rated favourably (7 out of 33 (21%) less than coated (9 out of 25 (36%). Sutherland used a VAS 0-10 (most to least favourable) on convenience (3.3 SD 2.8 versus 4.9 SD 2.7) and reported a higher favourable ranking for the coated catheters. Vapnek did not directly ask participants about catheter ranking but noted that there was a high degree of satisfaction with the coated catheter.

Number reporting comfort and ease of insertion

In Giannantoni's cross-over trial, participants gave better scores to the coated catheters, in respect of insertion, extraction, comfort and handling. Sutherland used a VAS 0-10 (most to least favourable) for insertion comfort (2.7 SD 2.4 vs 4.2 SD 2.6) which favoured the coated catheters.

Number reporting preference

No available data

Comparison 03: Single use (sterile) versus multiple use (clean)

Six trials included a comparison of single use catheters versus multiple use catheters (Duffy 1995; King 1992; Moore 1993 (cross-over); Pachler 1999 (cross-over); PrietoFingerhut 1999; Sutherland 1996). Duffy, King and Moore all used uncoated catheters in each arm. Duffy and King used sterile technique in single use arm and clean technique in the multiple use arm whilst Moore used clean in each arm. Pachler, Prieto-Fingerhut , and Sutherland used a coated catheter in the single use arm and an uncoated catheter in the multiple use arm of the study. Study time frames ranged from 3 weeks to 12 months. Cleaning methods varied as did time over which the catheter was used multiple times. Pachler and Vapnek both had participants use the cleaned catheter for 24 hours; Sutherland does not describe the method of cleaning or length of reuse of the non-coated catheter.

Asymptomatic bacteriuria

Moore 1993 reported asymptomatic bacteriuria and found similar rates in the two groups (17 out of 33 versus 16 out of 33; RR 1.06, 95% CI 0.66-1.72). In the Pachler 1999 cross-over trial, after three weeks, positive cultures occurred in 14 out of 27 of the sterile and 17 out of 27 in the clean groups (no data from five subjects).

Symptomatic UTI

In the Pachler 1999 cross-over trial one out of 32 in the sterile and one out of 32 in the clean groups reported symptoms of UTI. Four of the parallel group trials, Duffy, Sutherland, King and Prieto-Fingerhut, report symptomatic UTI (Comparison 03.02). For all the trials, the confidence intervals were wide and lay across the no-difference line. We decided not to derive a summary estimate because of heterogeneity; however, there was no suggestion of a trend favouring either of the approaches.

Number with urethral trauma/bleeding

In the Pachler 1999 cross-over trial transient bleeding was reported for 2 out of 32 in the sterile and 2 out of 32 in the clean groups.

Number with stricture formation

No available data

Number with microscopic haematuria

Data from one small trial (Sutherland 1996) reported fewer cases of microscopic haematuria in the group allocated single use catheters (Comparison 03.05), but this group also had coated rather than uncoated catheters.

Number with urethritis, epididymitis, or orchitis

In the Pachler 1999 cross-over trial 0 out of 32 in the sterile and 0 out of 32 in the clean groups were reported to have epididymitis or urethritis.

Weeks to onset of symptomatic UTI

Two studies (Duffy 1995; King 1992) looked at weeks to onset of UTI and found no statistically significant differences.

Number reporting satisfaction with catheter product

No available data

Number reporting comfort and ease of insertion

No available data

Number reporting preference

No available data

Preference score

Sutherland measured preference scores and found no statistical differences between the single use group and the multi use group.

Self-catheterisation versus catheterisation by health professional or other carer.

There were no trials that specifically compared catheterisation by individual versus by another person.

Other strategies designed to reduce UTI (including catheter cleaning)

One RCT was found (Fera 2002) which compared different gels used for lubricating the catheter before insertion (Gentamycin gel versus Lidocaine gel). There were 10 subjects in each arm and patients used their allocated gel for four months. Symptomatic UTI occurred in 1 out of 20 from the Gentamycin group and 2 out of 20 from the Lidocaine group.

No randomised clinical trials that tested different cleaning methods and reported catheter-associated infection were found.

DISCUSSION

The studies reviewed indicate gaps in the evidence and some outdated studies that require re-evaluation. There were too few trials that could be entered into the meta analysis program to provide meaningful data summaries. Four studies (Giannantoni 2001; Moore 1993; Pachler 1999; Schlager 2001) were cross-over design, none had been analysed as a cross-over study and none provided the data that would allow appropriate statistical analyses. Based on the available data which could be entered for analysis, no differences were apparent between various methods of catheterisation. However, the studies suffered from low power, and from attrition and illustrate the challenges of obtaining robust data in this clinical area.

The difficulty of establishing robust outcome measures of UTI, remains problematic. Bacteriuria/positive culture is not clinically relevant unless accompanied by symptoms but the symptoms themselves may present in vague and imprecise ways, especially in spinal cord injured adults where symptoms may be masked or unclear. However, despite these limitations symptomatic UTI remains the most clinically important primary outcome variable.

The number of potential permutations and combinations of techniques and catheters has also led to problems with confounding, with several studies combining catheters and techniques such that it would not be possible to state the cause of any differences found. Large randomised controlled trials are needed to provide answers to each separate question (sterile or clean technique; coated or uncoated catheter; single or multiple use, catheterisation by self or others). But because these studies are difficult to conduct and some combinations are much more commonly used than others, prioritisation is important. We suggest that the sterile versus clean technique question is of relatively low importance because in community settings (where most IC takes place) a sterile technique is not practical. In hospital settings rising concerns about infection control indicate that a sterile technique would be needed for safety.

In community settings there are two important questions: single versus multiple use; and coated versus uncoated catheter. In practice the most commonly used single-use catheter is a coated catheter which would need to be compared to a single-use uncoated catheter, to test if the coating is of importance. If coated catheters are not found to be superior then multiple-use uncoated catheters need to be compared to single-use uncoated catheters (to test if the sterility (or single-use) of the catheter is of importance). The latter question is of highest importance because it has the most substantial cost implications; although coated catheters are more expensive than uncoated catheters (around twice the price), it is the single-use of the catheters (coated or uncoated) which makes this method so costly to individuals and health services. Multiple use of an uncoated catheter for one week will cost the price of one catheter (around £0.5/ $1 / 0.8 euros) plus the cost of any separate lubricant. The cost of using a single-use coated catheter at each catheterisation will be around £28 / $46 / 36.4 euros per week . Cost-effectiveness analysis would be an essential part of any proposed clinical trial.

There have been no RCTs comparing catheterisation by self compared to others. Moore (Moore 1993) presented descriptive data suggesting that there was no difference between the child self catheterising versus the parent. This question is of relatively low priority because catheterisation by others usually only takes place when the individual is not able to carry out the procedure themselves.

Patient satisfaction/acceptability/preference are important secondary outcome variables which need to be evaluated in future trials. Such measures should also include satisfaction/acceptability/preference under different circumstances or in different situations (e.g. at home; outside the home). These outcomes have been found to be particularly useful when evaluating cost-effectiveness of single-use/reusable products (Fader 2007) and are likely to be particularly important for if future RCTs do not demonstrate dif-

ferences in the primary outcome variable of symptomatic UTI.

No RCTs comparing different methods of catheter cleaning were found when undertaking this review. We found a number of laboratory studies testing the sterility of catheters using different methods (cleaning with soap and water, antiseptic soak, and microwave). Although most studies showed that pathogenic organisms were removed by cleaning, one study testing the microwave method and one (incidentally) the soap and water method found residual pathogenic organisms. The clinical significance of these findings are unknown. The microwave method may be less practical than other methods due to the risk of catheter melting. No randomized controlled clinical trials of cleaning methods have been published and the comparative effectiveness of cleaning methods is therefore unknown. If future research supports the use of multiple-use catheters then there will be greater need for comparing cleaning methods using an RCT with symptomatic UTI as the primary outcome variable.

Cross-over designs were used in several of the studies reviewed. Cross-over designs are attractive because intermittent catheterization is a long-term strategy for a chronic problem and preferences may be stated and sample size be reduced. However, parallel group designs have the advantage of enabling prolonged follow-up (more than 6 months is preferable) to monitor catheter-associated urinary tract infections. High attrition rates (noted in previous studies) are even more problematic for cross-over studies than parallel group because data are needed from each individual in both arms. If cross-over designs are used then data need to be analysed in a way that takes the design into account, or reported for each test period to enable reanalysis and hence meta analysis. None of the reports of the four cross-over trials recognised this.

AUTHORS' CONCLUSIONS

Implications for practice

The available data on intermittent catheterization does not provide convincing evidence that any specific technique (sterile or clean), catheter type (coated or uncoated); method (single use or multiple use) , person (self or other), or strategy is better than any other for all clinical settings. This reflects lack of reliable evidence rather than evidence of no difference. Currently clinicians will need to base decisions about which technique and type of catheter to use on clinical judgment, in conjunction with patients. Differential costs of catheters/techniques may also inform decision making.

Implications for research

There is lack of evidence demonstrating the effectiveness of any particular catheter type, technique or strategy. Variations in clinical practice and growth in the use of single-use catheters (particularly coated catheters) with associated increased costs mean that large well-designed parallel group RCTs are needed. RCTs are difficult in this area and prioritisation is necessary.

The most important pragmatic question (for both clinical and cost-effective reasons) is: Are coated (single-use) catheters superior to uncoated (multi-use) catheters? However such a two arm RCT would not determine the relative contribution of the coating or the single/reuse of the catheter.

It would be preferable firstly to conduct a large well-designed RCT of single-use (i.e. sterile) coated catheters versus (single-use) uncoated catheters, using clean technique.

If (single -use) coated catheters are not superior to (single-use) uncoated catheters then an RCT of single-use (uncoated) catheters versus multiple-use (uncoated) catheters is needed subsequently.

We recommend that the NIDRR 1992 definition of UTI is used as the primary outcome variable (positive urine culture with pyuria and one or more systemic symptoms (fever, loin pain, dysuria, urgency, haematuria).

Given the large differential costs for the methods, cost-effectiveness will need to be assessed rigorously.

To assist cost-effectiveness assessment we recommend that patient acceptability/satisfaction with procedure and a measure of health state utility are measured for different situations (e.g. home/out) as a secondary outcome variable.

If results do not demonstrate superiority of single-use catheters then it will be important to test cleaning methods (of multiple-use catheters) in an RCT using symptomatic UTI as the primary outcome variable.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Day 2003

Methods	DESIGN: Randomised controlled trial BLINDING PROCEDURES: not stated SAMPLE CALCULATION: no (feasibility study) DURATION: 24 hours FOLLOW-UP: 3 urine for C&S in 24 hours WITHDRAWALS/ DROPOUTS: no ITT: no GEOGRAPHICAL LOCATION: Canada SETTING: ICU
Participants	N=11 DIAGNOSIS: Neurogenic bladder due to recent SCI ELIGIBLE: 53 ENROLLED: 11 COMPLETED: 11 AGE: Adult GENDER: Male
Interventions	COATED VS UNCOATED: integrated catheter and bag system (all-in-one) or sterile technique with open catheter tray
Outcomes	3 urines for culture over a 24 hour period + meatal swabs
Notes	no difference between groups but sample too small and time frame too short to make any inferences

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

De Ridder 2005

Methods	DESIGN: Randomised controlled trial; ALLOCATION: done by investigator using sealed opaque envelopes. BLINDING PROCEDURES: not stated SAMPLE CALCULATION: yes DURATION: 12 months FOLLOW-UP: Baseline, Day 15 then monthly x 12 months WITHDRAWALS/ DROPOUTS: 66 ITT: yes GEOGRAPHICAL LOCATION: Europe SETTING: rehabilitation and community
Participants	N=123 DIAGNOSIS: Neurogenic bladder due to SCI < 6 months ELIGIBLE: Unknown ENROLLED: 123 COMPLETED: 57 AGE: Adult GENDER: Male
Interventions	COATED VS UNCOATED: one catheter over another; assessed at Day 15 then monthly x 12 m
Outcomes	Primary: UTI Secondary: haematuria strictures, convenience; 82% PVC had UTI; 64% Speedicath; no diff in haematuria
Notes	UTI described as "clinical infection with Sx of UTI and for which treatment was prescribed", however, lab analyses did not differ between groups. significant challenges in retaining subjects illustrating the difficulty of conducting trials in this group

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Duffy 1995

Methods	DESIGN: Randomised controlled trial ALLOCATION: not described but did stratify subjects according to presence/ absence of UTI and study site. BLINDING PROCEDURES: unclear SAMPLE CALCULATION: yes post hoc DURATION: 3 months FOLLOW-UP: days 2, 4, 6, 10, 15, 60 & 90 WITHDRAWALS/ DROPOUTS: 2 ITT: not clear GEOGRAPHICAL LOCATION: USA SETTING: 3 longterm care Veterans Administration Medical Centre Nursing Homes
Participants	N=80 DIAGNOSIS: Incomplete bladder emptying due to prostate obstruction ELIGIBLE: 203 ENROLLED: 82 COMPLETED: 80 to day 15; 39 completed to Day 90) AGE: Elderly GENDER: Male
Interventions	STERILE TECHNIQUE VS CLEAN TECHNIQUE (ALSO SINGLE VS MULTIPLE USE): sterile equipment and procedure, cleaning with betadine; Clean techique: catheter washed with soap and water and reused x 1 week
Outcomes	Number of treatment episodes for UTI + urinalysis, and cost up to 90 days
Notes	Some subjects had indwelling catheters prior to enrolment in the study (unstated how many); weeks to onset of symptomatic UTI was 3.11 (3.12) for Treatment and 3.5 (3.02) for control. Dropout rate high after Day 15 with only 39 completing data collection to Day 90

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

Fera 2002

Methods	DESIGN: Randomised controlled trial ALLOCATION: not described BLINDING PROCEDURES: unclear SAMPLE CALCULATION: no DURATION: 4 months FOLLOW-UP: urine culture every 3 weeks for 4 months (5 samples) WITHDRAWALS/ DROPOUTS: 0 ITT: not clear GEOGRAPHICAL LOCATION: Brazil SETTING: General School Hospital
Participants	N=20 DIAGNOSIS: Variable, mielomeningocele most common (25%) ELIGIBLE: Not stated ENROLLED: 20 COMPLETED: 20 AGE: Mixed adults and children 2-79 years (mean not stated) GENDER: 12 male and 8 female
Interventions	OTHER STRATEGIES DESIGNED TO REDUCE INFECTION: Gentamycin cream (0.1%) versus lidocaine jelly used as separate lubricant for IC
Outcomes	Number of episodes of asymptomatic bacteriuria (>= 100,000 CFU/ml) , number of patients with symptomatic UTI
Notes	Repeated measures of asymptomatic bacteriuria reported for each participant. Final measure used in table of results. Asymptomatic bacteriuria similar in both groups 8/10 in gentamycin group 6/10 in lidocaine group. 1/10 developed symptomatic UTI in gentamycin group, 2/10 in Lidocaine group

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Giannantoni 2001

Methods	DESIGN: Randomised controlled cross over trial BLINDING PROCEDURES: not clear SAMPLE CALCULATION: no DURATION: 7 weeks each arm FOLLOW-UP: urine for C&S at 2, 4, 7 weeks WITHDRAWALS/ DROPOUTS: not stated ITT: unclear GEOGRAPHICAL LOCATION: Italy SETTING: Rehabilitation Hospital
Participants	N=18 DIAGNOSIS: Neurogenic bladder due to recent SCI ELIGIBLE: Unknown ENROLLED: 18 COMPLETED: 18 AGE: Adult GENDER: 16 male & 2 female
Interventions	COATED VS UNCOATED: Single use PVC (Nelaton) catheter vs pre lubricated non-hydrophilic catheter; one catheter x 7 wks then crossover to other group
Outcomes	UTI measured by C&S at 2, 4 & 7 weeks; Urethral wall trauma by counting cells on catheter surface; VAS re: satisfaction with catheters
Notes	UTI defined as cloudy, odourous urine, onset of UI, increase autonomic dysreflexia, pyuria, bacteriuria; SS too small to draw conclusions. Attempted randomisation concealment; higher % of UTI in PVC group; no difference in urethral cell count; Unable to use data in Table of Comparisons because of cross-over design and no mid-point data

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	No	C - Inadequate

King 1992

Methods	DESIGN: Randomised controlled trial BLINDING PROCEDURES: not clear SAMPLE CALCULATION: no DURATION: 28 days FOLLOW-UP: daily urine dipslides WITHDRAWALS/ DROPOUTS: 11 ITT: unclear GEOGRAPHICAL LOCATION: USA SETTING: Rehabilitation Hospital
Participants	N=46 DIAGNOSIS: Neurogenic bladder due to recent SCI ELIGIBLE: 58 ENROLLED: 46 COMPLETED: 35 AGE: Adult GENDER: Male
Interventions	STERILE VS CLEAN TECHNIQUE (also Single Use vs Multiple Use) catheterisation kit and sterile single use catheter, meatus cleansed with povidone iodine. Clean technique: sterile catheter reused for one day after being washed with soap and water, non sterile gloves and container
Outcomes	daily urine dipslides + symptomatic UTI
Notes	No statistically significant differences between urine cultures or Sx UTI; weeks to onset of UTI was 1.1 (0.87) for treatment and 1.2 (1.0) for control. Number of days in study varied from 1 to 28 with only

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

Moore 1993

Methods	DESIGN: Randomised controlled cross-over trial with each arm 6 months BLINDING PROCEDURES: not stated SAMPLE CALCULATION: No DURATION: 6 months FOLLOW-UP: monthly WITHDRAWALS/ DROPOUTS: nil ITT: no GEOGRAPHICAL LOCATION: Canada SETTING: community
Participants	N=30 DIAGNOSIS: Neurogenic bladder due to spina bifida ELIGIBLE: Unknown ENROLLED: 30 COMPLETED: 30 AGE: Children GENDER: 15 males & 15 females
Interventions	SINGLE VS MULTI USE:sterile single use PVC or reused PVC
Outcomes	Bacteriuria > 10x3 CFU/ml obtained monthly; no difference between groups
Notes	Symptomatic UTI defined as + symptoms; catheters washed with liquid soap and water, air dried and reused (does not indicate length of reuse); several subjects took prophylactic antibiotics

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

Moore 2006

Methods	DESIGN: Randomised controlled trial ALLOCATION: by third party using sealed opaque envelopes. BLINDING PROCEDURES: Data entry blinded SAMPLE CALCULATION: yes DURATION: up to 12 months FOLLOW-UP: weekly urinalysis WITHDRAWALS/ DROPOUTS: none ITT: yes GEOGRAPHICAL LOCATION: Canada SETTING: Rehabilitation Hospital
Participants	N=36 DIAGNOSIS: Neurogenic bladder due to recent high SCI injury; neurogenic bladder. ELIGIBLE: 50 ENROLLED: 36

Moore 2006 (*Continued*)

	COMPLETED: 36 AGE: Adult GENDER: 28 male & 8 female
Interventions	STERILE TECHNIQUE VS CLEAN TECHNIQUE Sterile single use PVC catheter with sterile technique or sterile single use PVC catheter with clean technique (clean gloves, clean container, non-sterile wipes for cleansing pre catheterisation)
Outcomes	Days to onset of symptomatic UTI
Notes	UTI defined as >= 10x5 CFU/ml, pyuria + accompanying symptoms; no difference between groups

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	A - Adequate

Pachler 1999

Methods	DESIGN: Randomised controlled crossover trial BLINDING PROCEDURES: not stated SAMPLE CALCULATION: no DURATION: 3 weeks each arm FOLLOW-UP: 3 weeks WITHDRAWALS/ DROPOUTS: not stated ITT: not stated GEOGRAPHICAL LOCATION: Denmark SETTING: community
Participants	N=32 DIAGNOSIS: Retention due to BPH ELIGIBLE: not stated ENROLLED: 32 COMPLETED: 32 AGE: Adult GENDER: Male
Interventions	COATED VS UNCOATED (ALSO SINGLE USE STERILE VS MULTIUSE CLEAN) hydrophilic (Lofric) single use) or PVC (multiple use) x 3 weeks each
Outcomes	Urine for C&S at baseline and each 3 week point; haematuria; responses to catheter use questionnaire
Notes	UTI defined as > 10 x 4 CFU/ml. No differences between groups in questionnaire response, bacteriuria or haematuria but short follow up and small sample size. Unable to use data in Table of Comparisons because of cross-over design and no mid-point data

Pachler 1999 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

PrietoFingerhut 1999

Methods	DESIGN: Randomised controlled trial BLINDING PROCEDURES: not stated SAMPLE CALCULATION: no DURATION: unclear FOLLOW-UP: unclear WITHDRAWALS/ DROPOUTS: not stated ITT: no GEOGRAPHICAL LOCATION: USA SETTING: Rehabiltiation
Participants	N=29 DIAGNOSIS: Neurogenic bladder due to SCI ELIGIBLE: Unknown ENROLLED: 29 COMPLETED: unclear AGE: Adult GENDER: 16 male; 13 female
Interventions	SINGLE USE (STERILE) VS MULTIUSE (CLEAN) (also COATED VS UNCOATED) clean reused red rubber catheter (x 1 week) or integrated catheter + bag system
Outcomes	UTI Urine for C&S collected weekly x X wks -- unclear on study time frame or endpoint
Notes	UTI as defined by NIDRR (1992); higher % of UTI in closed system (42% vs 29%)

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

Quigley 1993

Methods	DESIGN: Randomised controlled trial BLINDING PROCEDURES: not stated SAMPLE CALCULATION: no DURATION: 4 days FOLLOW-UP: WITHDRAWALS/ DROPOUTS: 10 ITT: GEOGRAPHICAL LOCATION: SETTING: Rehabilitation
Participants	N=30 DIAGNOSIS: Neurogenic bladder due to recent SCI or stroke ELIGIBLE: Unknown ENROLLED: 30 COMPLETED: 20 AGE: Adult GENDER: Unclear
Interventions	COATED VS UNCOATED: Integrated catheter + bag system or open sterile system
Outcomes	UTI >10x5 CFU/ml + symptoms (fever, CV or SP tenderness)
Notes	data only collected for 4 days

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Schlager 2001

Methods	DESIGN: Randomised controlled cross over. BLINDING PROCEDURES:not stated SAMPLE CALCULATION: no DURATION: each arm was 4 months FOLLOW-UP: weekly home visit for urine for C&S, catheter count, medication use and symptoms or signs of UTI WITHDRAWALS/ DROPOUTS: none ITT: no GEOGRAPHICAL LOCATION: USA SETTING: community
Participants	N=10 DIAGNOSIS: Neurogenic bladder due to spina bifida ELIGIBLE: 12 ENROLLED:10

Schlager 2001 (*Continued*)

	COMPLETED: 10 AGE: children GENDER: 4 male; 6 female
Interventions	SINGLE VS MULTIUSE sterile 1 x use PVC or reused
Outcomes	UTI weekly urine for C&S x 4 months
Notes	UTI defined as + or > than 10x4 CFU/ml plus symptoms (fever, pain, change in continence, change in colour or odour of urine); No differences between groups (2 Sx UTI each). SS too small to draw any conclusions about effectiveness. Catheter cleaning: PVC rinsed with tap water, air dried, then boiled x 3 minutes, air dried and stored in clean bag

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Sutherland 1996

Methods	DESIGN: Randomised controlled trial BLINDING PROCEDURES: not stated SAMPLE CALCULATION: No DURATION: 8 weeks FOLLOW-UP: weekly urine C&S and microscopy x 8 weeks. WITHDRAWALS/ DROPOUTS: 3 ITT: not stated GEOGRAPHICAL LOCATION: USA SETTING: community
Participants	N=33 DIAGNOSIS: neurogenic bladder due to SCI, Hinman syndrome, spinal dysraphism; ELIGIBLE: not stated ENROLLED: 33 COMPLETED: 30 AGE: Children GENDER: Males
Interventions	SINGLE VS MULTIUSE: hydrophilic (Lofric) (single use) or PVC reused catheter. Method of cleaning catheter and length of reuse not described
Outcomes	UTI haematuria> 3 RBC per HPF; VAS for satisfaction;
Notes	UTI defined as 10x5 CFU/ml + Sx (not defined); subjects with positive cultures were treated and reentered into the trial; no diff in bacteriuria b/w groups; haematuria lower in Lofric group but SS too small to draw conclusions and groups included gastric augmentation as well

Sutherland 1996 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

Vapnek 2003

Methods	DESIGN: Randomised controlled trial BLINDING PROCEDURES: not stated SAMPLE CALCULATION: no DURATION: 12 months FOLLOW-UP: urine C&S every 3 months WITHDRAWALS/ DROPOUTS: 13 ITT: not stated GEOGRAPHICAL LOCATION: 3 sites in USA SETTING: Community
Participants	N=62 DIAGNOSIS: neurogenic bladder (cause not stated) ELIGIBLE: not stated ENROLLED: 62 COMPLETED: 49 AGE: Adult GENDER: Male
Interventions	COATED VS UNCOATED; ALSO SINGLE VS MULTIUSE: hydrophilic coated catheter (Lofric) (single use) vs PVC clean reused times 24 hours
Outcomes	UTI; pyuria; haematuria; satisfaction.
Notes	UTI defined as 10x5 CFU/ml + at least one clinical symptom (fever, chills, malodorous urine, increased spasticity, malaise). Catheter cleaning not described; used 1 reused catheter per day. no statistically significant group differences were noted; unclear how long subjects were using IC before entering study; pre study UTI based on subject recall

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

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

Study	Reason for exclusion
Charbonneau 1993	Retrospective chart review of incidence of UTI in patients using standard practice IC in rehabilitation from 1985-1988 then evaluation of UTI in 18 subjects of a closed catheter/bag system. Not an RCT
Diokno 1995	Patient satisfaction evaluated only; not randomized; does not evaluate UTI
Fader 2001b	Report on study published in British Journal of Urology 2001 comparing user impressions of different hydrophilic coated catheters available on the market at the time; does not compare PVC to hydrophilic or incidence of UTI ADRIAN: ? NOT RANDOMISED?
Grigoleit 2006	Article in German; appears to be a review of catheterisation methods (based on short English Abstract)
Hedlund	Review of the literature
Hudson 2005	Laboratory study evaluating the likelihood of catheter contamination based on catheter design; did not compare incidence of UTI. Not an RCT
Kovindha 2004	Survey of catheter users who reused a silicone catheter - does not compare different products or provide quantitative measure of UTI. Not an RCT
Lemke	Review article discussing various catheterisation methods.
Normelli 1993	Indwelling catheterisation vs no indwelling catheter but IC in patients undergoing spina fusion. Not a suitable comparison
Pascoe 2001	Not an RCT
Pickard 1996	Hand washing comparison (30 s + double gloving) or 3 minutes hand to elbow + sterile gown on incidence of UTI in patients receiving indwelling catheterisation. IC not used
Sherbondy 2002	Survey of individuals using intermittent catheterisation and reusing the catheter. Not an RCT
Sims 1993	Chart review of two difference cleaning methods and comparison of UTI (wash with soap and water then soak in povidone iodine or allow to air dry) . Not an RCT
Stensballe 2005	Laboratory evaluation of friction force of 2 hydrophilic catheters and one non-hydrophilic catheter. Not an RCT
Terpenning 1989	Observational study of the incidence and time to onset of UTI in elderly in a Veterans Administration Centre (USA). Not an RCT
van Kuppevelt 2004	Abstract in ICS 2004 unpublished proceedings. Unable to reach author for further information on the study. No usable data
Wu 1981	Case report of one type of catheter proposed by the authors “Wu Reusable Catheter”. Not an RCT

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

Coloplast A/S

Trial name or title	Multicentre trial comparing occurrence of UTI in patients with SCI using either coated or uncoated intermittent catheterisation
Methods	
Participants	newly SCI adults requiring self or health care provider intermittent cahteterisation
Interventions	randomized to sterile single use PVC or sterile single use hydrophilic catheters (Speedicath)
Outcomes	incidence of symptomatic UTI, haematuria, satisfaction with products by subject and staff; antibiotic use; appointments missed
Starting date	July 2006
Contact information	Darin Hurninan Coloplast Canada
Notes	

Moore KN 2007

Trial name or title	Incidence of UTI in children with spina bifida using clean reused PVC or sterile single use hydrophilic catheters
Methods	
Participants	children with spina bifida requiring intermittent catheterisation
Interventions	sterile single use hydrophilic or standard care (clean reused PVC catheter)
Outcomes	incidence of symptomatic UTI; haematuria; antibiotic use, days missed from school, physician appointments, subject satisfaction
Starting date	January 2007
Contact information	Katherine Moore University of Alberta, Canada
Notes	

DATA AND ANALYSES

Comparison 1. Sterile technique versus clean technique

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number with asymptomatic bacteriuria	1	36	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.47, 2.03]
1.1 uncoated (sterile catheter) both arms	1	36	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.47, 2.03]
1.2 single use (uncoated, sterile catheter) versus multiple use (uncoated, clean catheter)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2 Number with symptomatic UTI	3		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.1 uncoated (sterile catheter) both arms	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.2 single use (uncoated, sterile catheter) versus multiple use (uncoated, clean catheter)	2		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3 Number with urethral trauma/ bleeding	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.1 uncoated (sterile catheter) both arms	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4 Number with stricture formation	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.1 uncoated (sterile catheter) both arms	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5 Number with microscopic haematuria	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5.1 uncoated (sterile catheter) both arms	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6 Number with urethritis, epididymitis, or orchitis	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6.1 uncoated (sterile catheter) both arms	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
7 Weeks to onset of symptomatic UTI	3		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
7.1 uncoated (sterile catheter) both arms	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
7.2 single use (uncoated) versus multiple use (uncoated)	2		Mean Difference (IV, Fixed, 95% CI)	Not estimable
8 Number reporting satisfaction with catheter product	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
8.1 uncoated (sterile catheter) both arms	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9 Number reporting comfort and ease of insertion	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9.1 uncoated (sterile catheter) both arms	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

10 Number reporting preference	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
10.1 uncoated (sterile catheter) both arms	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 2. Coated versus uncoated catheter

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number with asymptomatic bacteriuria	1	11	Risk Ratio (M-H, Fixed, 95% CI)	0.17 [0.01, 2.92]
1.1 sterile technique and catheter (both arms)	1	11	Risk Ratio (M-H, Fixed, 95% CI)	0.17 [0.01, 2.92]
1.2 clean technique (sterile catheter) both arms	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 single use (sterile catheter) clean technique versus multiple use (clean catheter) clean technique	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2 Number with symptomatic UTI	4		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.1 sterile technique and catheter (both arms)	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.2 sterile catheter (clean technique) both arms	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.3 single use (sterile catheter) clean technique versus multiple use (clean catheter) clean technique	2		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3 Number with urethral trauma/ bleeding	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.1 sterile technique and catheter (both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.2 sterile catheter (clean technique) both arms	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.3 single use (sterile catheter) clean technique versus multiple use (clean catheter) clean technique	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4 Number with stricture formation	1	58	Risk Ratio (M-H, Fixed, 95% CI)	3.92 [0.17, 92.43]
4.1 sterile technique and catheter (both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.2 sterile catheter (clean technique) both arms	1	58	Risk Ratio (M-H, Fixed, 95% CI)	3.92 [0.17, 92.43]
4.3 single use (sterile catheter) clean technique versus multiple use (clean catheter) clean technique	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5 Number with microscopic haematuria	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

5.1 sterile technique and catheter (both arms)	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5.2 sterile catheter (clean technique) both arms	0		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5.3 single use (sterile catheter) clean technique versus multiple use (clean catheter) clean technique	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6 Number with urethritis, epididymitis, or orchitis	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6.1 sterile technique and catheter (both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6.2 sterile catheter (clean technique) both arms	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6.3 single use (sterile catheter) clean technique versus multiple use (clean catheter) clean technique	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
7 Weeks to onset of symptomatic UTI	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
7.1 sterile technique and catheter (both arms)	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
7.2 sterile catheter (clean technique) both arms	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
7.3 single use (sterile catheter) clean technique versus multiple use (clean catheter) clean technique	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
8 Number reporting satisfaction with catheter product	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
8.1 sterile technique and catheter (both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
8.2 sterile catheter (clean technique) both arms	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
8.3 single use (sterile catheter) clean technique versus multiple use (clean catheter) clean technique	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9 Number reporting comfort and ease of insertion	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9.1 sterile technique and catheter (both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9.2 sterile catheter (clean technique) both arms	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9.3 single use (sterile catheter) clean technique versus multiple use (clean catheter) clean technique	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
10 Number reporting preference	1	58	Risk Ratio (M-H, Fixed, 95% CI)	1.70 [0.73, 3.93]
10.1 sterile technique and catheter (both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

10.2 sterile catheter (clean technique) both arms	1	58	Risk Ratio (M-H, Fixed, 95% CI)	1.70 [0.73, 3.93]
10.3 single use (sterile catheter) clean technique versus multiple use (clean catheter) clean technique	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 3. Single use (sterile) versus multiple use (clean) catheter

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number with asymptomatic bacteriuria	1	66	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.66, 1.72]
1.1 uncoated catheter, clean technique (both arms)	1	66	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.66, 1.72]
1.2 coated versus uncoated (clean technique both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 sterile technique versus clean technique (uncoated catheter both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2 Number with symptomatic UTI	4		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2.1 uncoated catheter, clean technique (both arms)	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.2 coated versus uncoated (clean technique both arms)	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.3 sterile technique versus clean technique (uncoated catheter both arms)	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.4 coated (sterile technique) versus uncoated (clean technique)	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3 Number with urethral trauma/ bleeding	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.1 uncoated catheter, clean technique (both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.2 coated versus uncoated (clean technique both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
3.3 sterile technique versus clean technique (uncoated catheter both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4 Number with stricture formation	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.1 uncoated catheter, clean technique (both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.2 coated versus uncoated (clean technique both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.3 sterile technique versus clean technique (uncoated catheter both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

5 Number with microscopic haematuria	1	30	Risk Ratio (M-H, Fixed, 95% CI)	0.48 [0.24, 0.95]
5.1 uncoated catheter, clean technique (both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5.2 coated versus uncoated (clean technique both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5.3 sterile technique versus clean technique (uncoated catheter both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
5.4 coated versus uncoated	1	30	Risk Ratio (M-H, Fixed, 95% CI)	0.48 [0.24, 0.95]
6 Number with urethritis, epididymitis, or orchitis	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6.1 uncoated catheter, clean technique (both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6.2 coated versus uncoated (clean technique both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
6.3 sterile technique versus clean technique (uncoated catheter both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
7 Weeks to onset of symptomatic UTI	2	85	Mean Difference (IV, Fixed, 95% CI)	-0.11 [-0.64, 0.43]
7.1 uncoated catheter, clean technique (both arms)	1	39	Mean Difference (IV, Fixed, 95% CI)	0.38 [-1.55, 2.31]
7.2 coated versus uncoated (clean technique both arms)	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
7.3 sterile technique versus clean technique (uncoated catheter both arms)	1	46	Mean Difference (IV, Fixed, 95% CI)	-0.15 [-0.71, 0.41]
8 Number reporting satisfaction with catheter product	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
8.1 uncoated catheter, clean technique (both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
8.2 coated versus uncoated (clean technique both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
8.3 sterile technique versus clean technique (uncoated catheter both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9 Number reporting comfort and ease of insertion	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9.1 uncoated catheter, clean technique (both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9.2 coated versus uncoated (clean technique both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
9.3 sterile technique versus clean technique (uncoated catheter both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
10 Number reporting preference	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
10.1 uncoated catheter, clean technique (both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
10.2 coated versus uncoated (clean technique both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

10.3 sterile technique versus clean technique (uncoated catheter both arms)	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
10.4 coated versus uncoated	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
11 Preference score	1	30	Mean Difference (IV, Fixed, 95% CI)	-1.60 [-3.57, 0.37]
11.1 uncoated catheter, clean technique (both arms)	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
11.2 coated versus uncoated (clean technique both arms)	1	30	Mean Difference (IV, Fixed, 95% CI)	-1.60 [-3.57, 0.37]

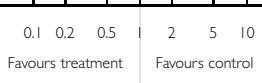
Analysis 1.1. Comparison 1 Sterile technique versus clean technique, Outcome 1 Number with asymptomatic bacteriuria.

Review: Long-term bladder management by intermittent catheterisation in adults and children

Comparison: 1 Sterile technique versus clean technique

Outcome: 1 Number with asymptomatic bacteriuria

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 uncoated (sterile catheter) both arms					
Moore 2006	7/16	9/20		100.0 %	0.97 [0.47, 2.03]
Subtotal (95% CI)	**16**	**20**		**100.0 %**	**0.97 [0.47, 2.03]**
Total events: 7 (Treatment), 9 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.07 (P = 0.94)					
2 single use (uncoated, sterile catheter) versus multiple use (uncoated, clean catheter)					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**16**	**20**		**100.0 %**	**0.97 [0.47, 2.03]**
Total events: 7 (Treatment), 9 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.07 (P = 0.94)					



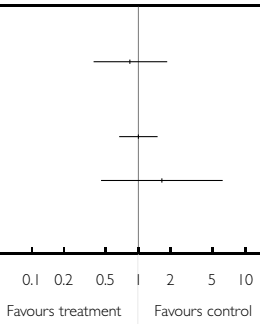
Analysis 1.2. Comparison 1 Sterile technique versus clean technique, Outcome 2 Number with symptomatic UTI.

Review: Long-term bladder management by intermittent catheterisation in adults and children

Comparison: 1 Sterile technique versus clean technique

Outcome: 2 Number with symptomatic UTI

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 uncoated (sterile catheter) both arms				
Moore 2006	6/16	9/20		0.83 [0.38, 1.85]
2 single use (uncoated, sterile catheter) versus multiple use (uncoated, clean catheter)				
Duffy 1995	20/38	22/42		1.00 [0.66, 1.53]
King 1992	5/23	3/23		1.67 [0.45, 6.17]



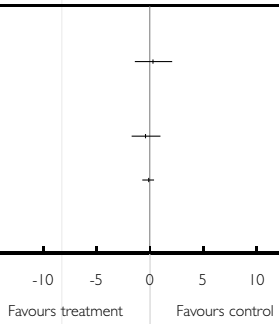
Analysis 1.7. Comparison 1 Sterile technique versus clean technique, Outcome 7 Weeks to onset of symptomatic UTI.

Review: Long-term bladder management by intermittent catheterisation in adults and children

Comparison: 1 Sterile technique versus clean technique

Outcome: 7 Weeks to onset of symptomatic UTI

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 uncoated (sterile catheter) both arms						
Moore 2006	16	4.6 (3.3)	20	4.3 (1.5)		0.30 [-1.45, 2.05]
2 single use (uncoated) versus multiple use (uncoated)						
Duffy 1995	42	3.11 (3.12)	38	3.5 (3.02)		-0.39 [-1.74, 0.96]
King 1992	23	1.1 (0.87)	23	1.25 (1.05)		-0.15 [-0.71, 0.41]



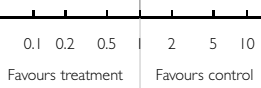
Analysis 2.1. Comparison 2 Coated versus uncoated catheter, Outcome 1 Number with asymptomatic bacteriuria.

Review: Long-term bladder management by intermittent catheterisation in adults and children

Comparison: 2 Coated versus uncoated catheter

Outcome: 1 Number with asymptomatic bacteriuria

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 sterile technique and catheter (both arms)					
Day 2003	0/6	2/5		100.0 %	0.17 [0.01, 2.92]
Subtotal (95% CI)	**6**	**5**		**100.0 %**	**0.17 [0.01, 2.92]**
Total events: 0 (Treatment), 2 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.22 (P = 0.22)					
2 clean technique (sterile catheter) both arms					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
3 single use (sterile catheter) clean technique versus multiple use (clean catheter) clean technique					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**6**	**5**		**100.0 %**	**0.17 [0.01, 2.92]**
Total events: 0 (Treatment), 2 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.22 (P = 0.22)					

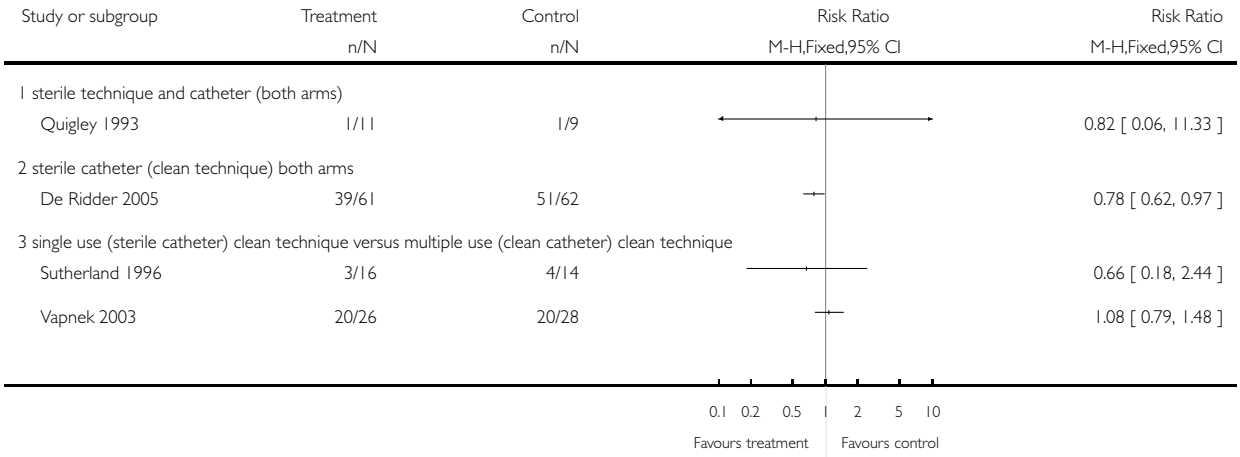


Analysis 2.2. Comparison 2 Coated versus uncoated catheter, Outcome 2 Number with symptomatic UTI.

Review: Long-term bladder management by intermittent catheterisation in adults and children

Comparison: 2 Coated versus uncoated catheter

Outcome: 2 Number with symptomatic UTI



Analysis 2.4. Comparison 2 Coated versus uncoated catheter, Outcome 4 Number with stricture formation.

Review: Long-term bladder management by intermittent catheterisation in adults and children

Comparison: 2 Coated versus uncoated catheter

Outcome: 4 Number with stricture formation

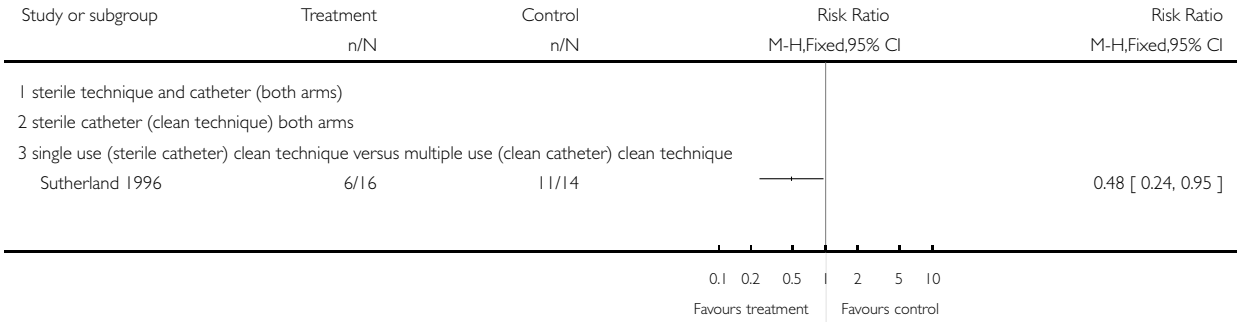
Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 sterile technique and catheter (both arms)					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
2 sterile catheter (clean technique) both arms					
De Ridder 2005	1/25	0/33		100.0 %	3.92 [0.17, 92.43]
Subtotal (95% CI)	**25**	**33**		**100.0 %**	**3.92 [0.17, 92.43]**
Total events: 1 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.85 (P = 0.40)					
3 single use (sterile catheter) clean technique versus multiple use (clean catheter) clean technique					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**25**	**33**		**100.0 %**	**3.92 [0.17, 92.43]**
Total events: 1 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.85 (P = 0.40)					

Analysis 2.5. Comparison 2 Coated versus uncoated catheter, Outcome 5 Number with microscopic haematuria.

Review: Long-term bladder management by intermittent catheterisation in adults and children

Comparison: 2 Coated versus uncoated catheter

Outcome: 5 Number with microscopic haematuria

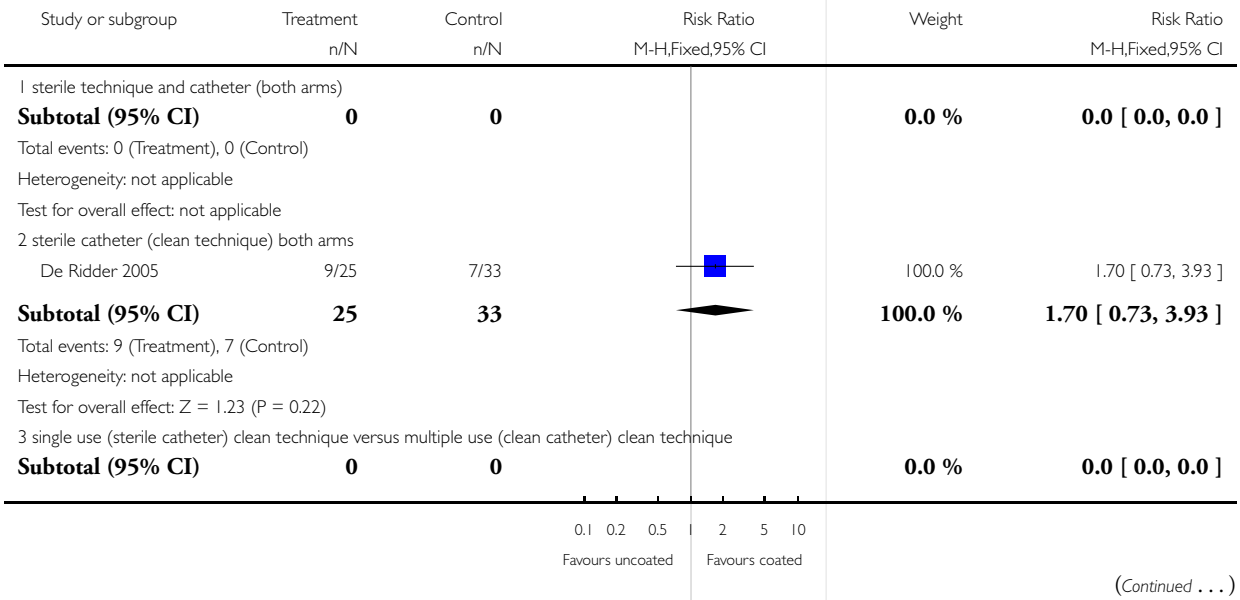


Analysis 2.10. Comparison 2 Coated versus uncoated catheter, Outcome 10 Number reporting preference.

Review: Long-term bladder management by intermittent catheterisation in adults and children

Comparison: 2 Coated versus uncoated catheter

Outcome: 10 Number reporting preference



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Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**25**	**33**		**100.0 %**	**1.70 [0.73, 3.93]**
Total events: 9 (Treatment), 7 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.23 (P = 0.22)					

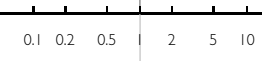
Analysis 3.1. Comparison 3 Single use (sterile) versus multiple use (clean) catheter, Outcome 1 Number with asymptomatic bacteriuria.

Review: Long-term bladder management by intermittent catheterisation in adults and children

Comparison: 3 Single use (sterile) versus multiple use (clean) catheter

Outcome: 1 Number with asymptomatic bacteriuria

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 uncoated catheter, clean technique (both arms)					
Moore 1993	17/33	16/33		100.0 %	1.06 [0.66, 1.72]
Subtotal (95% CI)	**33**	**33**		**100.0 %**	**1.06 [0.66, 1.72]**
Total events: 17 (Treatment), 16 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.25 (P = 0.81)					
2 coated versus uncoated (clean technique both arms)					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
3 sterile technique versus clean technique (uncoated catheter both arms)					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					



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Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Total (95% CI)	**33**	**33**		**100.0 %**	**1.06 [0.66, 1.72]**
Total events: 17 (Treatment), 16 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.25 (P = 0.81)					

Analysis 3.2. Comparison 3 Single use (sterile) versus multiple use (clean) catheter, Outcome 2 Number with symptomatic UTI.

Review: Long-term bladder management by intermittent catheterisation in adults and children

Comparison: 3 Single use (sterile) versus multiple use (clean) catheter

Outcome: 2 Number with symptomatic UTI

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 uncoated catheter, clean technique (both arms)				
Duffy 1995	20/38	22/42		1.00 [0.66, 1.53]
2 coated versus uncoated (clean technique both arms)				
Sutherland 1996	3/16	4/14		0.66 [0.18, 2.44]
3 sterile technique versus clean technique (uncoated catheter both arms)				
King 1992	5/23	3/23		1.67 [0.45, 6.17]
4 coated (sterile technique) versus uncoated (clean technique)				
PrietoFingerhut 1999	9/14	8/15		1.21 [0.65, 2.23]

Analysis 3.5. Comparison 3 Single use (sterile) versus multiple use (clean) catheter, Outcome 5 Number with microscopic haematuria.

Review: Long-term bladder management by intermittent catheterisation in adults and children

Comparison: 3 Single use (sterile) versus multiple use (clean) catheter

Outcome: 5 Number with microscopic haematuria

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 uncoated catheter, clean technique (both arms)					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
2 coated versus uncoated (clean technique both arms)					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
3 sterile technique versus clean technique (uncoated catheter both arms)					
Subtotal (95% CI)	**0**	**0**		**0.0 %**	**0.0 [0.0, 0.0]**
Total events: 0 (Treatment), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
4 coated versus uncoated					
Sutherland 1996	6/16	11/14		100.0 %	0.48 [0.24, 0.95]
Subtotal (95% CI)	**16**	**14**		**100.0 %**	**0.48 [0.24, 0.95]**
Total events: 6 (Treatment), 11 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.10 (P = 0.035)					
Total (95% CI)	**16**	**14**		**100.0 %**	**0.48 [0.24, 0.95]**
Total events: 6 (Treatment), 11 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.10 (P = 0.035)					

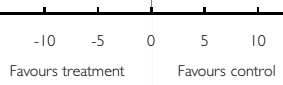
Analysis 3.7. Comparison 3 Single use (sterile) versus multiple use (clean) catheter, Outcome 7 Weeks to onset of symptomatic UTI.

Review: Long-term bladder management by intermittent catheterisation in adults and children

Comparison: 3 Single use (sterile) versus multiple use (clean) catheter

Outcome: 7 Weeks to onset of symptomatic UTI

Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 uncoated catheter, clean technique (both arms)							
Duffy 1995	20	3.48 (3.02)	19	3.1 (3.12)		7.7 %	0.38 [-1.55, 2.31]
Subtotal (95% CI)	**20**		**19**			**7.7 %**	**0.38 [-1.55, 2.31]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.39 (P = 0.70)							
2 coated versus uncoated (clean technique both arms)							
Subtotal (95% CI)	**0**		**0**			**0.0 %**	**0.0 [0.0, 0.0]**
Heterogeneity: not applicable							
Test for overall effect: not applicable							
3 sterile technique versus clean technique (uncoated catheter both arms)							
King 1992	23	1.1 (0.87)	23	1.25 (1.05)		92.3 %	-0.15 [-0.71, 0.41]
Subtotal (95% CI)	**23**		**23**			**92.3 %**	**-0.15 [-0.71, 0.41]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.53 (P = 0.60)							
Total (95% CI)	**43**		**42**			**100.0 %**	**-0.11 [-0.64, 0.43]**
Heterogeneity: Chi^2 = 0.27, df = 1 (P = 0.60); I^2 =0.0%							
Test for overall effect: Z = 0.40 (P = 0.69)							
Test for subgroup differences: Chi^2 = 0.27, df = 1 (P = 0.60), I^2 =0.0%							

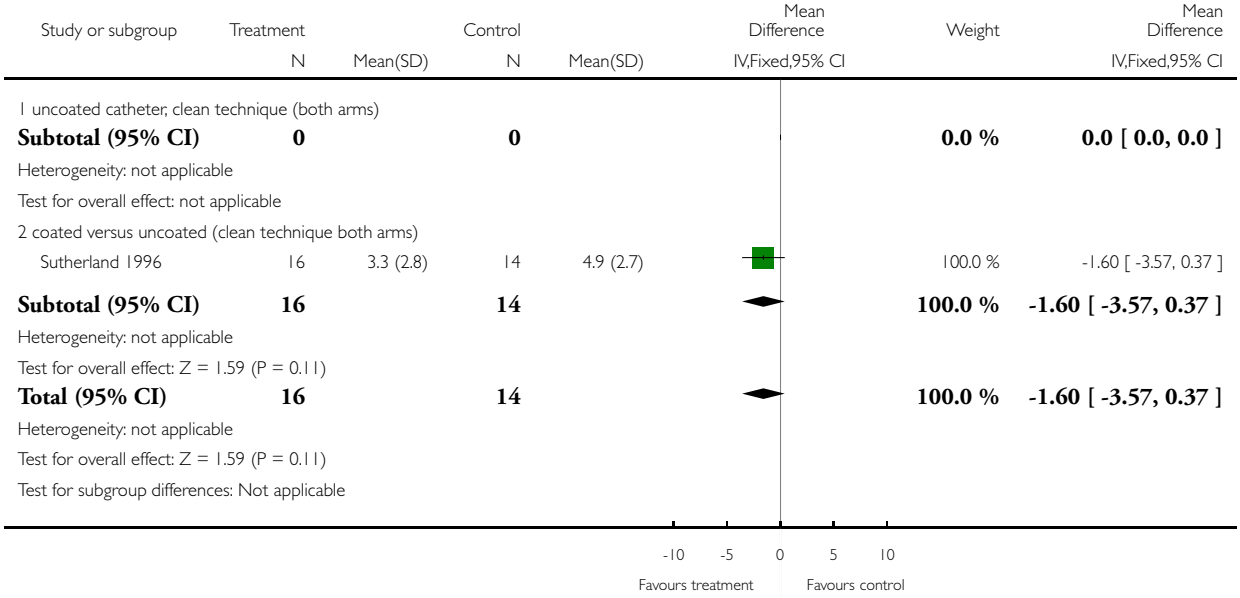


Analysis 3.11. Comparison 3 Single use (sterile) versus multiple use (clean) catheter, Outcome 11 Preference score.

Review: Long-term bladder management by intermittent catheterisation in adults and children

Comparison: 3 Single use (sterile) versus multiple use (clean) catheter

Outcome: 11 Preference score



WHAT'S NEW

Last assessed as up-to-date: 21 August 2007.

Date	Event	Description
9 October 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 2, 2006

Review first published: Issue 4, 2007

Date	Event	Description
22 August 2007	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

KNM took the lead in article retrieval and summary of initial findings which were then reviewed and edited as necessary by KG and MF. All three review authors contributed towards the writing of the review.

DECLARATIONS OF INTEREST

Katherine Moore is a co-investigator on an intermittent catheterisation trial sponsored by Coloplast A/S

Mandy Fader has received intermittent catheter products for research purposes from Astra Tech AB

Kathryn Getliffe has received research funding from Bard Ltd and BBraun Ltd for work on indwelling catheters

INDEX TERMS

Medical Subject Headings (MeSH)

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

MeSH check words

Adult; Child; Female; Humans; Male