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Hagen S, Sinclair L, Cross S

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[Intervention Review]

Washout policies in long-term indwelling urinary catheterisation in adults

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ABSTRACT

Background

People requiring long-term bladder draining with an indwelling catheter can experience catheter blockage. Regimens involving different solutions can be used to washout catheters with the aim of preventing blockage.

Objectives

To determine if certain washout regimens are better than others in terms of effectiveness, acceptability, complications, quality of life and economics for the management of long-term indwelling urinary catheterisation in adults.

Search methods

We searched the Cochrane Incontinence Group Specialised Trials Register (searched 30 April 2009), MEDLINE (January 1966 to April 2009), MEDLINE In-Process (30 April 2009), EMBASE (January 1980 to April 2009) and CINAHL (December 1981 to April 2009). Additionally, we examined all reference lists of identified trials and contacted manufacturers and researchers in the field.

Selection criteria

All randomised and quasi-randomised trials comparing catheter washout policies (e.g. washout versus no washout, different washout solutions, frequency, duration, volume, concentration, method of administration) in adults (16 years and above) in any setting (i.e. hospital, nursing/residential home, community) with an indwelling urethral or suprapubic catheter for more than 28 days.

Data collection and analysis

Data were extracted by three reviewers independently and compared. Disagreements were resolved by discussion. Data were processed as described in the Cochrane Handbook. If the data in trials were not fully reported, clarification was sought from the authors. For categorical outcomes, the numbers reporting an outcome were related to the numbers at risk in each group to derive an risk ratio (RR). For continuous outcomes, means and standard deviations were used to derive weighted mean differences (WMD). No meta-analysis of study results was possible.

Main results

Five trials met the inclusion criteria involving 242 patients (132 completed) in two cross-over and three parallel-group randomised controlled trials. Only three of the eight pre-stated comparisons were addressed in these trials. Some trials addressed more than one comparison (e.g. washout versus no washout and one type of washout solution versus another). The analyses reported for the two cross-over trials were inappropriate as they were based on differences between groups rather than differences within individuals receiving sequential interventions. Two parallel-group trials had limited value: one combined results for suprapubic and urethral catheters and one had data on only four participants. Only one trial was free of significant methodological limitations, but its sample size was small.

Three trials compared no washout with one or more washout solution (saline or acidic solutions) and authors tended to conclude no difference in clinical outcomes between washout and no washout. In the one trial which had data of sufficient quality to allow interpretation, no difference was detected between washout and no washout groups in the rate of symptomatic urinary tract infection or time to first catheter change.

Three trials compared different types of solution: saline versus acidic solutions (two trials); saline versus acidic solution versus antibiotic solution (one trial). Authors tended to report no difference between different washout solutions but the data were too few to support their conclusions. The one trial which warranted consideration concluded no difference between saline and an acidic solution in terms of symptomatic urinary tract infections or time to first catheter change.

Authors' conclusions

The data from five trials comparing differing washout policies were sparse and trials were generally of poor quality or poorly reported. The evidence was too scanty to conclude whether or not washouts were beneficial. In the first instance we require further rigorous, high quality trials with adequate power to detect any benefit from washout being performed as opposed to none. Then trials comparing different washout solutions, washout volumes, frequencies/timings and routes of administration are needed.

PLAIN LANGUAGE SUMMARY

Policies on flushing urinary catheters which are used on a long-term basis

Many people have incontinence (leak urine) or are unable to empty their bladder properly. Some can be helped by having a catheter inserted into their bladder, through which urine is passed out of the body. When the catheter is kept in place on a long-term basis blockages may occur. Liquid solutions may be injected into the catheter to prevent or relieve a blockage. This is sometimes known as a washout. In this review we wished to assess how effective washouts were. We looked for studies which included people with long-term catheters, where they were allocated at random to have catheter washouts or not, and the effects compared. Studies which compared different types of washout solution were also searched for. Only five relevant studies were found. All five concluded that there was no evidence that washouts were helpful. However most studies were small and of poor quality, and their results could not be combined. We concluded that, at present, there is not enough good research evidence to say whether or not consumers and providers of health care should use catheter washouts.

BACKGROUND

Description of the condition

Indwelling catheterisation may be used for the management of people with intractable incontinence or chronic obstruction. People may require long-term urinary catheterisation for a number of reasons: urinary retention (incomplete emptying of the bladder) caused by benign prostatic hyperplasia (enlarged prostate) or prostate tumour, or urinary incontinence (involuntary leakage of urine) not amenable to toileting, intermittent catheterisation, or any other method of management. Individuals with conditions

such as multiple sclerosis, dementia, stroke, spina bifida, and spinal cord injury may be susceptible to these problems.

It is difficult to know precisely how many people are currently managed with long-term catheters. Estimates vary from 4% to 28% of patients in long-term care facilities (Cools 1986; Kunin 1992; Ouslander 1985; Ouslander 1987; Warren 1989) and 4% of patients living at home or in the community (Getliffe 1990; Roe 1989). Those using catheters long-term often experience complications such as blockage, leakage and infection. These complications can have significant implications for resource use and quality of life due to increased general practitioner and hospital outpatient appointments, emergency admissions and nursing time demands (Evans 2000).

Bacterial Infection

At the root of catheter-associated complications is bacteriuria which occurs when bacteria colonise the urinary tract. The risk of acquiring bacteriuria increases with increasing days of catheterisation (Garibaldi 1974; Stark 1984). High concentrations of bacteriuria were found in 98% of patients with long-term urinary catheters (Warren 1982). Increased levels of bacteriuria expose patients to an increased risk of complications, including symptomatic urinary tract infections (UTIs), secondary bacteraemia (infection in the blood) and infection at other sites, such as the joints. Up to 30% of long-term catheterised people will become symptomatic and require some intervention (Saint 1999). Catheter-associated infection is therefore a significant problem in long-term care.

In an attempt to deal with the problem of bacterial colonisation, biofilm build-up and UTI, catheter washouts or irrigations (sometimes called bladder washouts or irrigations) were introduced (Getliffe 2003). Various antibiotic and antiseptic solutions have been used as washouts over the last few decades with the aim of preventing and treating these catheter-associated problems. Evidence with regard to their effectiveness in this respect however is conflicting. There is also concern that their use can damage the bladder mucosa and increase infection rates due to opening the closed system. Current UK National Health Service guidelines specify that antibiotic solutions are not effective in treating catheter-associated UTIs (NHS QIS 2004). Use of antiseptic washouts is also believed to be of little value for the prevention and treatment of catheter-associated UTI and is therefore no longer advised in practice (Pellowe 2003).

Catheter Blockage

The most common problem of long-term indwelling catheters is the formation of encrustations on the surface of the catheter with consequent blockage and by-passing of urine resulting in urinary leakage. Nearly half of all individuals with an indwelling catheter will experience problems with catheter blockage due to encrustation (Getliffe 1992; Kohler-Ockmore 1996; Kunin 1987; Roe 1987). Blockage of an indwelling catheter is traumatic for both patients and their carers as it often causes pain and distress. Much research has been done showing that encrustation is caused by infection of the urine by bacteria which produce the enzyme urease, e.g. *Proteus mirabilis*, *Pseudomonas aeruginosa* and *Klebsiella* species. Urease breaks down urea to form ammonia which results in an increase in the alkalinity of the urine. Under these conditions, mineral salts such as calcium phosphate and magnesium ammonium phosphate (struvite) are deposited onto the catheter surface causing encrustation (Hesse 1992).

Fungal Infection

Candiduria (the presence of candida organisms in the urine) can also occur in individuals with long-term indwelling catheters, and its incidence is directly related to duration of catheterisation, hospitalisation, and antibiotic use (Hamory 1978). It is generally asymptomatic but complications can include fungal balls in the bladder or renal pelvis, renal infection and disseminated candidiasis (infection with a species of candida). Management of asymptomatic catheter-associated candiduria is unclear. Removal of the catheter results in the disappearance of candiduria in about one third of patients. For asymptomatic individuals whose candiduria persists or who must remain catheterised, several management techniques have been used, primarily involving oral medication or bladder irrigation. The solutions used, the method of administration (continuous irrigation), and the primary outcomes of interest (e.g. death, length of hospitalisation, invasive infection) in the treatment of fungal infections are very different, however, to those used to administer solutions for bacterial infection and catheter blockage, and hence are not evaluated in this review.

Description of the intervention

Current practice in the management of catheter encrustation and blockage varies but is largely dependent on the use of catheter maintenance solutions. Treatments commonly used in community-dwelling patients include washing out the catheter with saline and acidic solutions. There is much debate however about this particular practice. In vitro evidence suggests that normal saline is ineffective in diminishing encrustations whereas there is some evidence that methenamine preparations and acidic washouts reduce catheter encrustation (Getliffe 1994; Hesse 1989; King 1991). Other work however questions the efficacy of acidification of the urine for preventing catheter encrustation (Bibby 1993). In a study by Capewell and Morris none of the continence advisers questioned thought that regular washouts were useful compared to 25% of district nurses who thought they were (Capewell 1993). Despite the controversy surrounding the effectiveness of washouts for managing encrustation and blockage, a recent study has shown that they are widely used (Pomfret 2004).

Why it is important to do this review

In summary, there is no consensus regarding the indications for use of catheter washouts nor the method of administration, frequency, duration of administration and choice of solution. The wide variety of solutions available, combined with the multiplicity of possible procedures for applying these, and the potential risks they pose indicated that a systematic review of the evidence regarding washout policies may have important implications for both clinical practice and future research. This review aims to summarise the evidence from randomised controlled trials related to the use of catheter washouts for the management of long-term indwelling urinary catheterisation in adults. The results from this review will highlight gaps in the evidence base and assist in the identification of best practice.

OBJECTIVES

The purpose of this review was to determine if certain washout regimens are better than others in terms of effectiveness, acceptability, complications, quality of life and economics for the management of long-term indwelling urinary catheters in adults.

The following comparisons were made:

1) using any type of catheter washout (e.g. water, saline, antiseptic, antibiotic) versus not using one;

2) one type of catheter washout solution versus another type;

3) clinically or microbiologically indicated washout versus routine washout;

4) long intervals between catheter washouts versus short intervals;

5) one method of administration of catheter washouts (e.g. agitation, gravity, syringe) versus another method;

6) smaller volumes of washout solution versus larger volumes;

7) a stronger solution of washout versus a weaker solution;

8) a single washout instillation versus two or more sequential washout instillations of the same type.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised or quasi-randomised controlled trials, including cross-over designs, evaluating the use of urinary catheter washouts in long-term catheterised adults.

Types of participants

Adults, at least sixteen years of age, in any setting (i.e. hospital, nursing/residential home, community) with an indwelling urethral, suprapubic or perineal catheter in-situ for more than 28 days. Adults who combine intermittent catheterisation with periods of indwelling catheterisation were only included if they had had an indwelling catheter in-situ for more than 28 days at the time of data collection.

Types of interventions

The interventions considered included catheter washouts with water, saline, antiseptic, acidic or antibiotic solutions or any combination of these. Studies were considered that compared (1) washouts with controls who did not receive washouts, (2) washouts with other participants who received different washouts, (3) different washout regimens at different time periods i.e. cross-over studies, and (4) different washout regimens i.e. frequency, duration, volume, concentration, method of administration.

Throughout the literature, the terminology used to refer to the 'washing-out' of catheters is somewhat confusing. The term 'washout' tends to be used in the US literature whereas in the UK, catheter washouts are often referred to as 'catheter maintenance solutions' or 'bladder washout' which can cause confusion with bladder irrigation/lavage used after surgery (Getliffe 1996). Throughout this review all trials referring to catheter or bladder washouts were considered with the exception of post-surgical bladder irrigations, therapeutic bladder instillations used, for example, in the treatment of cancer patients, and continuous irrigations with antifungal solutions.

Trials that involved irrigation of catheter drainage bags were not considered in this review. Other types of interventions to prevent or reduce encrustation or infection e.g. changes in fluid intake or use of oral prophylactic antibiotics, were also excluded.

Types of outcome measures

Primary outcomes

Catheter washouts were originally introduced to prevent or reduce the occurrence of catheter-associated infection. In recent years their use has been primarily aimed at minimising the effects of recurrent encrustation and blockage. Primary outcomes considered were therefore objective measures of catheter-associated UTI and catheter blockage. Such measures include:

- rates of asymptomatic bacteriuria,
- symptomatic UTIs,
- number of catheters used,
- length of time each catheter was in situ, and
- catheter removal rates due to blockage/ infection

(definitions of blockage/ infection will be those used in the trial reports).

Trials were considered if they reported at least one of these primary outcomes.

Secondary outcomes

Where reported, the following outcomes were also recorded:

1. Washout acceptability measures

This includes levels of patient discomfort associated with washouts; patient satisfaction with the outcome of washouts (i.e. minimisation of catheter-associated problems, reduction in pain and trauma when catheter withdrawn); and ease of use of washouts/washout regimens for patients, their carers and practitioners.

2. Health status or measures of psychological health

This includes quality of life and psychological outcome indicators as measured by generic validated instruments e.g. Short Form 36 (Ware 1993), Hospital Anxiety and Depression Score (HADS) (Zigmond 1983).

3. Measures of complications/adverse effects of washouts

This includes adverse effects that result at the time of administration of washouts, such as inability to tolerate washout solution, and irritation or trauma to urethral or bladder tissue. These effects may be indicated by bypassing or bleeding around the catheter or by volume of red blood cells returned during washout procedure. Use of prophylactic antibiotics and rescue antibiotics are also included.

4. Health economic outcomes

Economic measures considered include costs of washouts, resource implications associated with different washouts/washout regimens, and any reports of formal economic evaluations of washouts, such as cost-effectiveness or cost-utility analysis.

Any other non-pre-specified outcomes, judged to be important when performing the review, were considered.

Search methods for identification of studies

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

Electronic searches

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 of the search methods used to build the Specialised Register please see the 'Specialized Register' section of the Group's module in The Cochrane Library). The register contains incontinence-related trials identified from MEDLINE, CINAHL, the Cochrane Central Register of Controlled Trials (CENTRAL) and handsearching of journals and conference proceedings. The trials in the Incontinence Group Specialised Register are also contained in CENTRAL. The date of the most recent search of the Incontinence Group's Specialised Register for this review was 30 April 2009.

The Incontinence Group Specialised Register was searched using the Group's own keyword system. The search terms used were:

({design.cct*} OR {design.rct*})

AND

({intvent.mech.cath.washout*} OR {intvent.mech.cath.irrigation*} OR {intvent.prevent.cath*})

(All searches were of the keyword field of Reference Manager 9.5 N, ISI ResearchSoft).

For this review specific extra searches were performed by the review authors. These are detailed below:

We searched MEDLINE (January 1966 to April 2009), MEDLINE In-Process (searched on 30 April 2009), EMBASE (January 1980 to Week 17 2009) was searched on 27 April 2009, CINAHL on OVID (1982 to July Week 1 2007) was searched on 18 July 2007, CINAHL on EBSCO (December 1981 to Week 4 April 2009) was searched on 28 April 2009. These databases were searched using appropriate free text and MeSH terms/EMTREE terms/controlled vocabulary. This was done by adapting terms drawn from the existing search strategies of the Incontinence Review Group to meet the objectives of this review. The UK National Research Register, Controlled Clinical Trials and ZETOC database of conference abstracts were searched on 17 October 2006. Full details of the search strategies used are given in Appendix 1.

Searching other resources

We searched the reference lists of relevant articles for other possibly relevant trials. Key researchers in the field of catheter management, and catheter maintenance solution manufacturers (BBraun, Coloplast and Bard) were contacted to identify other possibly relevant trials.

We placed calls for information about other possibly relevant trials on the Association for Continence Advice (ACA) website (March 2007), the ACA quarterly Journal (Volume 26 Issue 2 2007), and the weekly Update of Royal College of Nursing Research &

Development Co-ordinating Centre electronic bulletin (W/C 26 March 2007). Presentations were given at the 2007 RCN International Nursing Research Conference (April 2007), the 22nd Annual Scottish Task Force Symposium on Incontinence (May 2007) and the Scottish NMAHP Research into Practice Conference (October 2007) to inform others of this review and invite information on other possibly relevant studies.

Data collection and analysis

Selection of studies

Two reviewers (LS and SC) independently assessed all titles and abstracts of studies identified from the above search strategy. Where there was any doubt regarding the potential eligibility of a study, the full paper was obtained. Any disagreements with regard to the eligibility of a study were resolved by discussion between the two reviewers. Any disagreements that could not be resolved by discussion were resolved by consultation with a third reviewer (SH). Studies were excluded from the review if they were not randomised or quasi-randomised trials of catheter washouts for adults with long-term indwelling urinary catheters, or if they made comparisons other than those pre-specified. Excluded studies are listed with reasons for their exclusion (see table of Excluded Studies).

Data extraction and management

Data extraction was performed independently by the review authors (LS, SC and SH), using a data collection form purposively designed for the review, and comparisons made to ensure accuracy. Any discrepancies were discussed until agreement was reached. Attempts were made to contact authors of trial reports if data were missing or not fully reported, or if clarification was necessary.

Assessment of risk of bias in included studies

Each of the eligible trials were critically appraised and the methodological quality assessed independently by three review authors (LS, SC and SH), without prior consideration of the results. The assessment tool for risk of bias used in The Cochrane Collaboration was implemented. This was used to assess risk of bias in four domains (sequence generation, allocation concealment, blinding (participants, personnel and outcome assessors) and incomplete outcome data), and included criteria for judging studies to be at high or low risk of bias. A risk of bias table for each study was included in the Characteristics of included studies table.

Data synthesis

Included trial data were processed as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2008). Where appropriate, meta-analysis were undertaken. For binary outcomes, the numbers reporting an outcome were related to the numbers at risk in each group to derive an risk ratio (RR). For continuous outcomes, means and standard deviations were used to derive weighted mean differences (WMD). For cross-over trials the data were analysed as recommended in section 16.4 of the handbook, subject to the availability of suitable data.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification.

Results of the search

Approximately 700 papers were identified from the above search strategy. Twenty of these reported potentially eligible studies and were therefore given particular consideration. Clarification was sought at this stage regarding study characteristics from four authors: one author responded, two authors were unable to be contacted and no response was received from one author. Fourteen of the 20 studies were subsequently excluded from the review and descriptions of these are given in the table of Characteristics of Excluded Studies (Andersson 1986; Bach 1990; Bruun 1978; Davies 1987; Elliott 1989; Elliott 1990; Furuno 1998; Gelman 1980; Kennedy 1984; Meyers 1964; Robertson 1990; Ruwaldt 1983; Vainrub 1977; Warren 1978). One study (Airaksinen 1979), written in Finnish, is awaiting fuller translation.

Therefore five studies were included in the review. Three of these were parallel-group randomised controlled trials and included a total of 173 participants (McNicoll 2003; Moore 2009; Waites 2006) and two were randomised cross-over trials that included a total of 69 participants (Kennedy 1992; Muncie 1989). Two studies were conducted in the UK (Kennedy 1992; McNicoll 2003), one in Canada (Moore 2009) and two in the USA (Muncie 1989, Waites 2006).

Included studies

Participants

Kennedy 1992 studied 25 elderly catheterised females in long-term geriatric care. No exclusion criteria were stated explicitly. The mean age of participants was 82 years (range 65 to 100 years). The type of catheter used was that already in use by the participant.

McNicoll 2003 studied 11 community patients with long-term catheters known to block with encrustation. No exclusion criteria

were stated. There was no information about the age or gender of the participants, what type of catheter they had or how long it had been in situ.

Moore 2009 studied 73 community-dwelling or long-term care adults (36 males, 37 females) with long-term indwelling catheters that required changing every three weeks or less, requiring supportive or continuing care. Excluded were those with symptomatic UTI, although individuals were eligible after 14 symptom-free days following treatment. Further exclusion criteria included: urethral erosion allowing continuous bypassing around urinary catheter; history of bladder cancer, radiation or interstitial cystitis; impaired renal function as evidenced by a serum creatinine level of 2.0 mg/dL or higher; or gross haematuria. The mean age of participants was 66.2 years (SD 17.64). A hydrophilic coated catheter (Bard) was used for all patients in this trial.

Muncie 1989 studied 44 long-term hospitalised female patients at one centre, aged 18 years or more who had indwelling urethral catheters in place for 30 consecutive days or longer, were afebrile (temperature $\leq$ 37.7 degrees) for seven days and had not received antibiotics for 14 days. Patients with malignant bladder neoplasms or those requiring continued bladder irrigation were excluded. The mean age of participants was 71 years (range 37 to 88 years). The study catheter was an 18 F, silicone-coated latex urethral catheter.

Waites 2006 randomised 89 community-residing patients (49 male, 40 female) with neurogenic bladder managed by indwelling catheter (71 Foley catheter, 18 suprapubic tube; material not stated). All were at least six months post spinal cord injury or onset of other neurological disease and had evidence of microscopic bacteriuria and pyuria at time of study enrolment. Excluded were: people with serious UTIs requiring systemic antibiotics; those with prior renal function abnormalities; those who had used an acidifying agent, bladder irrigant or systematic antibiotic in the previous seven days; and those who were pregnant or unable/unwilling to give informed consent. The mean age of participants was 45.8 years (range 19 to 82 years). The catheter material, and duration that the catheter was in situ pre-study enrolment, were not stated. There were no differences in demographic or injury-related variables by group at baseline.

Interventions

Two trials compared washout (using saline and/or acidic solution) with no washout (Moore 2009; Muncie 1989). Two trials compared different types of washout solution (Kennedy 1992; Waites 2006), one of which included a comparison of alternative compositions of an acidic solution (Kennedy 1992). The remaining trial compared washout with planned catheter removal (McNicoll 2003). The protocol for the planned catheter removal group was not described however, and in fact varied from patient to patient. Thus it is included in this review only with trials comparing washout versus no washout.

Washout versus no washout:

In Moore 2009 participants were randomised to one of three groups: 1) a usual care group with no washout, 2) a group with weekly catheter washout with 50 ml sterile normal saline, 3) a catheter washout weekly with 50 ml sterile Contisol (also known as Suby G) (citric acid 3.23%, light magnesium oxide 0.38%, sodium bicarbonate 0.7%, and disodium edetate 0.01%). A study catheter was inserted for all individuals at the start of the study. For participants in the washout groups, prior to washout the catheter was clamped, disconnected, and both the drainage tube and the catheter end were wiped with an alcohol swab. The nozzle of the washout container was inserted into the catheter and the contents were gently squeezed by pressing on the base, providing a controlled flow over 60 seconds. The bellows of the container were then allowed to slowly reinflate, and the flushing action was repeated five times. The solution was retained in the bladder for 15 minutes and then released. The intervention duration was eight weeks.

Muncie 1989 compared 1) 10 weeks of once daily normal saline washout (30 ml via syringe) with 2) 10 weeks of no washout. New catheters were inserted at the beginning and end of each study phase, and drainage bags were changed weekly in both groups. The drainage bags used had built-in irrigation ports to enabled washout without disruption of the closed catheter system. The intervention duration was 24 weeks (two-week no washout run-in period, 10-week washout or no washout phase, and two-week no intervention period before entering alternate phase).

The McNicoll trial (McNicoll 2003) had two parallel groups: 1) daily instillation of citric acid catheter maintenance solution, and 2) planned catheter removal. The volume of solution and method of administration in the washout group were not stated. The control group were to receive "planned catheter changes " but the protocol was not described and in reality this varied from patient to patient. The intervention duration was 12 weeks.

Different types of solution:

Three types of solution were evaluated in the Kennedy trial (Kennedy 1992): 1) three weeks of twice weekly washout with 0.9% sodium chloride (saline), 2) three weeks of twice weekly washout with Suby G (as described above), 3) three weeks of twice weekly washout with Solution R (citric acid 6%, gluconolactone 0.6%, light magnesium carbonate 2.8%, disodium edetate 0.01%). All washouts were administered by attaching a 100ml sterile, pre-packed sachet to the catheter and allowing it to drain into the bladder via gravity. The catheter was clamped for 20 to 30 minutes and then the fluid was allowed to drain out. Catheters were changed at weeks 1, 5, 9 and 12. Random number tables were used to decide the order in which the three solutions were administered. The intervention duration was 12 weeks (one-week normal saline washout run-in period, plus a three-week phase with

each of the solutions, and one week normal saline washout between solutions).

Waites 2006 compared three solutions: 1) eight weeks of twice daily normal saline washout, 2) eight weeks of twice daily 0.25% acetic acid washout, 3) eight weeks of twice daily neomycin-polymyxin GU washout (containing 40mg/ml neomycin sulfate and 200,000 units/ml polymyxin B). At each time of washout 30 ml of the irrigant was instilled for 20 minutes via a syringe.

As described above, the Moore 2009 trial had three arms and provided, in addition to a washout versus no washout comparison, a comparison of saline and Contisol washout solutions.

A stronger solution of washout is better than a weaker solution:

As described above, within the Kennedy trial (Kennedy 1992), two groups received washouts with different compositions of acidic solution: one solution contained 3.23% citric acid (Suby G) and the other 6% citric acid (Solution R). However other chemical components of the two solutions differed also.

Outcomes

All trials except one (McNicoll 2003) reported data on bacteriuria or symptomatic UTI. All trials except one (Waites 2006) presented data on removal/replacement of catheters, either reporting mean number of days a catheter was in situ (Kennedy 1992; Moore 2009) or mean number of replacements (McNicoll 2003; Muncie 1989). Kennedy 1992 and Moore 2009 looked specifically at the problem of catheter encrustation. Moore 2009 and Waites 2006 measured urine pH. Three trials reported data on complications or adverse events, one in terms of red blood or urothelial cells in the washout fluid (Kennedy 1992), one in terms of incidence of microscopic haematuria and leukocytes in pre-washout dipstick urinalysis (Moore 2009), and one in terms of bladder spasms due to the washout procedure (Waites 2006). Only one trial (McNicoll 2003) considered the economic outcomes, reporting on the cost of the interventions and the time involved in administering them.

Risk of bias in included studies

All but one of the trials had at least one factor associated with risk of bias (Figure 1; Figure 2).

Figure 1. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.

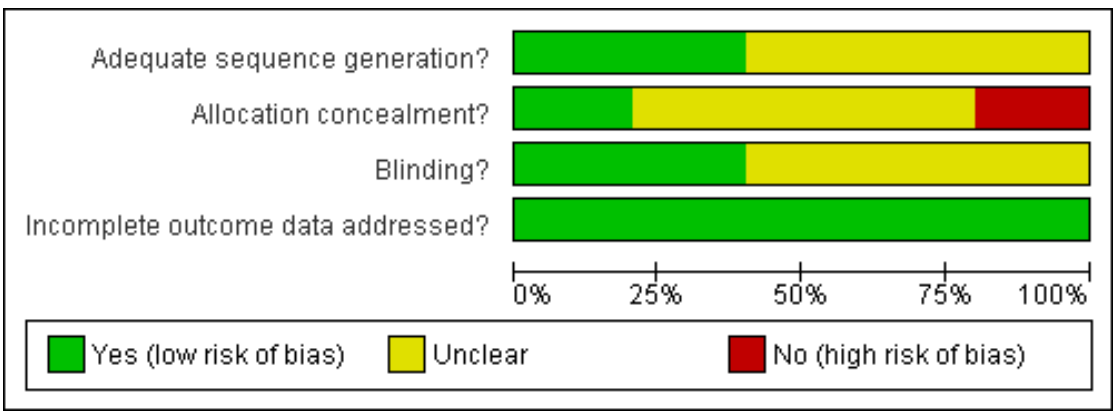
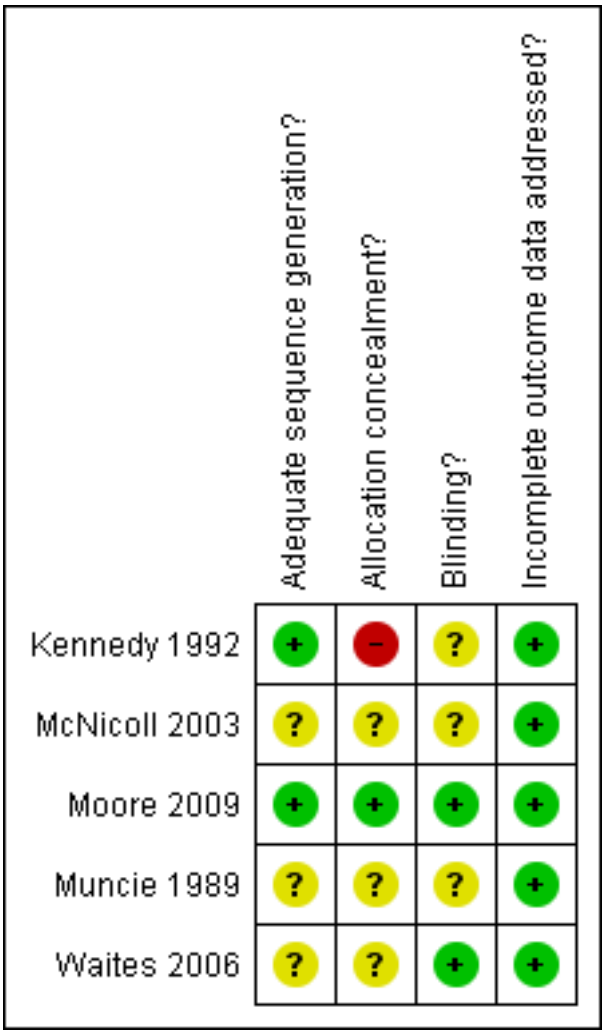


Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.



Allocation

Little information was provided regarding the process of concealment of group allocation within most of the trials. In Kennedy 1992 it was assumed the allocation process was not concealed as random number tables were used to determine the order in which patients received the three solutions. It was stated in McNicoll 2003, Muncie 1989 and Waites 2006 that there was random allocation to groups but no details were given. In Moore 2009 group assignment was determined by a computer-generated list of random numbers, placed in opaque envelopes, which were opened by the participant after consent was obtained.

Blinding

Most studies gave insufficient or no information relating to blinding. This may have been because blinding in this area of research is difficult e.g. patients and health care providers are obviously aware of bladder washout being performed, and different washout solutions may look different and so can be identified. There was no detail in Kennedy 1992, McNicoll 2003 or Muncie 1989 regarding blinding of the participants, health care providers or outcome assessors as to the intervention being given. Moore 2009 acknowledged that it was not possible to blind the research nurse to the two washout solutions due to the nature of the packaging. The outcome assessor was the nurse performing the washout who was

therefore not blinded. It was stated in Waites 2006 that participants and health care providers were blinded to treatment status but no description of this was given.

Incomplete outcome data

All included trials experienced significant withdrawals and drop-outs, resulting in incomplete outcome data, however this was well described. Two trials (Muncie 1989; Waites 2006) explored differences between completers and non-completers. The two small trials (Kennedy 1992; McNicoll 2003) suffered serious loss of participants leaving few data for analysis (n=14 and n=4 respectively), compared with larger analysis datasets of the other trials (Moore 2009 n=53, Muncie 1989 n=32, Waites 2006 n=52).

- Of the 25 patients who entered the Kennedy 1992 trial, five died, three had their catheters removed, two withdrew at the request of nursing staff and one was discharged home and lost to follow-up, leaving 14 patients (56%) who completed the full 12 weeks of the trial.
- Of the 11 participants enrolled in the McNicoll 2003 trial, seven were lost to follow-up for reasons not stated and thus only four participants' data (34%) were analysed (citric acid group n=1, planned catheter change group n=3).
- Fifty-three out of 73 participants (73%) completed all eight weeks of the study protocol in Moore 2009 (no washout n=20, saline n=16, Contisol n=17). Sixteen subjects terminated early because of three catheter changes or self-reported UTI (non-symptomatic). The remaining subjects (n=4) terminated before completing eight weeks for other reasons: haematuria, latex sensitivity, deceased/severe illness, or personal choice.
- Of the 44 women who entered the Muncie 1989 trial, 23 (52%) completed the full 24-week intervention. Of the 21 who did not complete, nine women completed at least one phase and five weeks of the second phase of the study. Thus data were analysed on 32 participants (73%) (23 cross-overs, nine partial cross-overs). Mean hospital stay was significantly longer in those who completed the study compared to those who did not.
- Of the 89 participants enrolled in Waites 2006, 37 participants did not complete the full intervention (11 withdrew due to development of symptomatic UTI, 14 withdrew for other health-related reasons, 12 withdrew due to perceived difficulty, inconvenience or unwillingness to perform twice daily washouts) . Thus 52 participants (58%) completed the intervention (saline n=21, citric acid solution n=9, antibiotic solution n=22). Years since injury or onset of disease was significantly greater for participants who did not complete the trial protocol.

Other potential sources of bias

Only one trial (Moore 2009) stated that data were analysed using an intention-to-treat analysis. In this trial, for the purposes of analysis, for withdrawn participants the primary outcome measure (the time to first catheter change) was taken as the date they withdrew from the study. The remaining trials either did not analyse using the intention to treat principle (McNicoll 2003; Muncie 1989; Waites 2006) or it was not clear if they did so (Kennedy 1992).

Effects of interventions

The purpose of this review was to determine if certain washout regimens were better than others, and eight comparisons which potentially could be addressed within the review were pre-specified. Trials addressing three of these comparisons were found, involving 242 patients (132 completed) in two cross-over and three parallel-group randomised controlled trials. Some trials addressed more than one hypothesis. Three trials provided data on the comparison between washout and no washout (McNicoll 2003; Moore 2009; Muncie 1989) (Comparison 1). Three trials compared different types of solution (Kennedy 1992; Moore 2009; Waites 2006) (Comparison 2). In their trial comparing three washout solutions Kennedy 1992 compared one acidic solution (Solution R, contained 6% citric acid) with another of an alternative composition (Suby G, contained 3.23% citric acid) (Comparison 7). McNicoll 2003 compared a washout with planned catheter change, a hypothesis that had not been pre-specified. For the purposes of this review this trial has been grouped with the trials comparing washout with no washout.

Only limited data were available in a form that allowed entry into the tables of Comparisons and Data and corresponding meta-analysis. No data were entered from four trials (Kennedy 1992; McNicoll 2003; Muncie 1989, Waites 2006). Two of these studies (Kennedy 1992 and Muncie 1989) were cross-over trials which did not present data in a way that highlighted the paired nature of the data, thus assessment was problematic. Data from only four participants was reported in McNicoll 2003. The Waites 2006 trial combined outcome data for participants with urethral and suprapubic catheters which made clinically-relevant interpretation difficult.

The trials generally had small sample sizes, ranging from 25 to 89, although the number of participants that completed were far fewer, ranging from 4 to 53. The authors of the largest trial (Moore 2009) (n=73; n=53 completed) proposed, based on their data, that a trial with at least 400 participants per arm would be required to give adequate power to detect a 20% difference in time to first catheter change.

1) Using any type of catheter washout versus not using one

Three trials addressed this comparison (McNicoll 2003; Moore 2009; Muncie 1989).

Bacteriuria

Given that catheter obstructions may be related to particular bacterial species, Muncie 1989 reported for each group the mean number of species at >=10^5 CFU/ml per urine specimen among 23 patients completing the cross-over trial (urine specimens were obtained for culture every two weeks): for the saline washout periods the mean was 4.0, for the no washout periods the mean was 3.8. No test of statistical difference was reported. The four most prevalent organisms were *Providencia stuartii*, *Escherichia coli*, *P mirabilis* and *Enterococcus*. The percentage of specimens in which each strain was present was said to be similar in the saline washout and no washout periods of the study.

Symptomatic UTI

Muncie 1989 looked also at febrile episodes of possible urinary origin as an indicator of symptomatic UTI. Data were reported for all 32 patients (including those who did not complete the trial) for combined phases of this cross-over trial. The mean number of febrile episodes of possible urinary origin per 100 days of catheterisation for the three periods was reported: mean for the saline washout period was 1.2 (SD 1.3), and for the no washout period was 0.9 (SD 1.1). The authors reported the difference was not statistically significant, although no details were given. Moore 2009 reported no symptomatic UTIs in any of the study participants in the washout or non-washout groups (Analysis 1.1). A symptomatic UTI was defined as having at least one of five indications: fever, urgency, dysuria or suprapubic tenderness, haematuria or positive urine culture. Self-reported UTIs (which did not meet the study criteria for symptomatic UTI) were noted in each group (citric acid 5/24, saline 2/18, no washout 3/23).

Catheter replacement

The mean catheter replacement rate per 100 days of catheterisation was reported in the trial by Muncie 1989: for the saline washout periods the mean was 5.5 (n=32), for the no washout periods the mean was 4.7 (n=32). Muncie 1989 also reported for each period (saline washout/no washout) the numbers of catheters 1) replaced due to obstruction (39/32); 2) replaced due to leakage (11/21); and 3) removed outwith the study protocol (87/63). The authors concluded that daily saline washouts had no significant effect on the incidence of total number of catheter replacements. No details of statistical tests were presented. McNicoll 2003 reported on the mean number of catheter replacements during a 12 week period: the citric acid washout group mean was 9 (SD 0) (n=1), the no-washout group mean was 14.3 (SD 11.2) (n=3). Moore 2009 recorded the number of weeks until first catheter change within the trial and reported no significant differences in the mean time between the three groups: citric acid 4.57 (SD 2.61) (n=19), saline 5.18 (SD 2.90) (n=16), no washout 4.55 (SD 2.91) (n=20) (Analysis 1.2).

Complications/adverse events

No data were reported.

Resources/costs

McNicoll 2003 found, in one participant in the intervention group, that 37.25 hours were spent administering the washouts over the 12 week period. They reported that care for the "planned catheter change" group took less time, but no comparison data were presented. The cost of the intervention was £975.51 for the participant in the washout group compared to a mean of £188.70 (SD £102.90) per person for the cost of care in the control group.

2) One type of catheter washout solution versus another type

Three trials addressed this comparison (Kennedy 1992; Moore 2009; Waites 2006).

Bacteriuria

In the cross-over trial by Kennedy 1992 comparing three solutions, the percentage of patients with bacteria observed in washout fluid at the end of a washout period with one of the trial solutions was as follows: saline 100%, Suby G 75%, Solution R 76%. Only percentages were presented and it was unclear what the denominators for these percentages were. The presence of bacteria was measured also in 66 urine specimens collected from 25 patients at the time of catheter change, and only four samples showed no significant growth of bacteria (four after antibiotic treatment and one after saline washouts), thus it was concluded that none of the solutions being tested eliminated bacteria. The authors stated that the Suby G and Solution R appeared to reduce the level of bacteria but that the difference between solutions was not statistically significant (no statistical test results were presented). It was concluded that treatment with acidic solutions (i.e. Suby G and Solution R) did not prevent or reduce urease-producer bacteria.

The published data on presence of bacteria were inadequately reported. The percentages of participants harbouring *Enterococcus* species (alone or in conjunction with other types of bacteria) after completing the Waites 2006 trial were as follows: saline 13/21 (62%), acetic acid 7/9 (87%), neomycin-polymyxin 19/22 (86%). No test of significant difference between groups was presented. In the antibiotic group, from study start to finish there was a significant increase in the number of participants with *enterococci* bacteria (p=0.02). Data were reported graphically and hence exact values were not available. The authors said they detected no advantages of the antibiotic or acidic solutions over saline in reducing the urinary bacterial load.

Symptomatic UTI

The incidence of participants discontinuing the use of washouts due to the development of a symptomatic UTI was reported by Waites 2006: saline 1/29 (3%), acetic acid 6/30 (20%), neomycin-polymyxin 4/30 (13%). The difference between groups was not statistically significant. Overall a significantly greater proportion of the acetic acid group participants discontinued, but this difference was due to more individuals in this group discontinuing for "personal reasons unrelated to health". As reported earlier, Moore 2009 found no symptomatic UTIs in any group in the trial using the citric acid or saline solutions (Analysis 2.1).

Catheter blockage/encrustation

In Kennedy 1992, 100 out of the 120 study catheters were examined for encrustation. The number of catheters found to be blocked (defined as the eye or lumen completely blocked resulting in no flow of urine) when removed after each three-week solution period was reported: saline 18/44 (41%), Suby G 14/29 (48%), Solution R 7/27 (26%). The authors concluded that Solution R produced the best results and Suby G the worst, but no statistical tests were presented, and a time effect was noted such that blocked catheters would be removed early (before they could be examined) thus distorting these data. Regarding degree of visual encrustation, Kennedy 1992 reported little difference between the three solutions up to day 10, after which it was felt Solution R did not reduce encrustation. Mean encrustation scores were presented but without standard deviations. Similarly, insufficient information was presented relating to the mean number of episodes of bypassing per week (saline 1.55, Suby G 1.4, Solution R 1.9), although the authors reported that differences between groups on this outcome were not statistically significant.

Catheter replacement

Kennedy 1992 also reported mean days that the catheter was in situ: saline 16.3, Suby G 14.3, Solution R 14.2. No standard deviations were reported, however the authors reported no significant differences between groups. It was noted that only three participants retained their catheter for the full length of each trial period. Moore 2009 reported the mean time until first catheter change, and as described above there was no significant difference between the trial groups, including the two groups receiving different washout solutions (citric acid versus saline, Analysis 2.2).

Complications/adverse effects

Blood in the urine

The presence of blood in the urine may be an indication of damage caused as a result of the washout procedure. Kennedy 1992 reported for each group the percentage of participants with red blood cells in their washout fluid at the end of each treatment period (saline 21%, Suby G 17%, Solution R 14%). In addition, the authors reported a significant difference between treatment groups associated with a higher red blood count in the Suby G group compared to other groups. Moore 2009 reported results from urine dipstick testing, and found that all participants, irrespective of group, exhibited haematuria consistently.

Urothelial cells in the urine

Presence of urothelial cells in washout fluid at the end of each treatment period was similarly reported: saline 100%, Suby G 86%, Solution R 100%. Evidence of a significant difference between treatment groups in presence of urothelial cells over time was found, however the authors thought this was unlikely to be clinically significant.

Bladder spasms

Waites 2006 reported on the incidence of bladder spasms directly attributable to bladder washout, which occurred on a small number of occasions (saline 0/29, acetic acid 1/30, neomycin-polymyxin 2/30) and caused these participants to discontinue with washouts.

Moore 2009 and Waites 2006 reported on the presence of leukocytes and also urine pH. In Waites 2006 pH increased significantly in all three groups (from a mean of 6.6 at baseline to a mean ranging from 7.0 to 7.2 at eight weeks), but the data were presented graphically and therefore could not be extracted. Waites 2006 found urinary leukocytes were persistent in all groups throughout the study, but no comparison between groups was reported and graphical presentation of data precluded data extraction. Moore 2009 reported that mean pH was 6.3 (SD 1.04) and that this did not change over the study, nor did it correlate with catheter blockage. Also leukocytes were consistently present in participants' urine in the Moore 2009 study.

Resources/costs

No data were reported.

7) A stronger solution of washout versus a weaker solution

One cross-over trial (Kennedy 1992) compared two acidic solutions with different compositions. The citric acid content of one solution was higher that the other, however it is noted that the other elements of the solutions differed also, and therefore any differences may not be attributable to the strength of the citric acid. They concluded that there was no significant difference between Suby G (containing 3.23% citric acid) and Solution R (containing 6% citric acid) in terms of reducing the level of bacteria in the

urine, or in the length of time the catheter was in situ. The authors concluded that Solution R performed better than Suby G in terms of less blocked catheters (26% versus 48%). As stated previously the results presented did not utilise the cross-over nature of the trial and thus were not informative.

No data were reported on any other outcomes of interest (Bacteriuria; Symptomatic UTI; Catheter blockage/encrustation; Catheter replacement; Complications/adverse effects; Resources/costs).

DISCUSSION

The data were insufficient to provide reliable evidence about the benefit of washout polices in preventing catheter blockage or encrustation, or about the relative merits of different washout solutions. Given that it has not been possible to obtain sufficient information for further interpretation or analysis of existing published data from authors of existing trials, further high quality trials must be recommended to provide rigorous evidence relating to the use of washouts. There are several important issues raised by this review which have implications for future research in this area.

Summary of main results

This review found a poor evidence base relating to the use of washouts for long-term indwelling catheters. The evidence consisted of two randomised cross-over trials which had poor data reporting, two parallel group randomised controlled trials with very limited amounts of data, and one well-designed but potentially under-powered randomised controlled trial. The authors' conclusions tended to suggest no effect of using washouts, and no benefits of one washout solution over another, in relation to bacteria, symptomatic UTIs, catheter replacement and blocking/encrustation. However the quality of trials, their reporting and particularly their small sample sizes were so poor that it is not appropriate to draw a conclusion of no effect.

Overall completeness and applicability of evidence

Types of catheters

Different types of catheter were used across and within trials. It could be considered pragmatic to allow catheter type to vary in this way within a trial. However given the apparent difficulty experienced in recruiting and retaining participants in these trials, it may be sensible to standardise this variable in future trials to maximise the chances of detecting any differences between groups.

Volumes of solutions used for washouts

No trial looked at different volumes of the same washout solution. Studies tended to use the volume of solution provided in the manufacturers pre-prepared containers. Volumes ranged from 30 ml (Muncie 1989; Waites 2006) to 100 ml (Kennedy 1992). Waites 2006 reported that they chose 30 ml after undertaking a pilot study with 60 ml which resulted in leakage of the washout: participants in this study had neurogenic bladder and may have had reduced bladder capacity due to long-term use of indwelling catheters.

Frequencies of washouts

Neither were there trials comparing different frequencies e.g. washout once a week versus twice a week. However the frequency of washout varied across studies: twice daily (Waites 2006), daily (Muncie 1989; McNicoll 2003), twice weekly (Waites 2006), weekly (Moore 2009). The length of time the washout was retained in the bladder differed (from 15 minutes (Moore 2009) through to 20 to 30 minutes (Kennedy 1992)), as did the duration of the intervention (from 3 weeks (Kennedy 1992) to 12 weeks (McNicoll 2003)).

Treatment-free periods between two arms of crossover trials

It is important that a "washout period" is used in cross-over trials where there is potential for a carry-over effect from one treatment period to the next. Both cross-over trials in this review used this approach; Muncie 1989 used a two week period between trial periods with no intervention, whilst Kennedy 1992 used a one week period during which participants had saline washout. Both Muncie 1989 and Kennedy 1992 also used run-in periods of two weeks of no washout and one week of saline washout respectively. No reason was given for length of the run-in or "washout periods".

Person performing washout

In all except one trial (Waites 2006) the washout procedure was undertaken by a health care professional. After the first washout Waites 2006 gave pre-prepared solutions to the participant to use at home. This is an interesting, and potentially cost-saving, approach to catheter care which may be appropriate for certain patient groups, and could perhaps be the subject of future research.

Participants

The participants included in trials varied in several ways. In some trials patients had a history of blocked catheters (McNicoll 2003; Moore 2009) whilst other trials did not limit participation in this way, or did not mention any history of catheter blocking. There may be merit in looking specifically at those people with a history

of blocking since anecdotally it is thought that some individuals (referred to as "blockers") are more susceptible than others.
Kennedy 1992 and Muncie 1989 studied inpatient females in long-term or geriatric care settings who were older (mean age 82 and 71 years respectively) compared to the community-dwelling, male and female sample with neurogenic bladder studied by Waites 2006 (mean age 45.8 years). Moore 2009 studied a mix of long-term care and home care, male and female patients with a mean age 66 years. No information on age and gender was available for McNicoll 2003. The effects of a washout, if any, may differ in such diverse populations and careful thought is needed regarding whether such trials results could be usefully compared in future reviews.

Quality of the evidence

Study design

Concealment of group allocation was poor or inadequately described in all but one trial (Moore 2009). Similarly, blinding was not described or was inadequate in all trials, although the difficulties associated with blinding in this type of trial are acknowledged.

Outcomes and analysis

The trials included were somewhat heterogeneous in terms of the outcomes they measured. Most trials assessed bacteriuria, symptomatic UTIs and blockage/encrustation, although methods for doing so and definitions used varied. Standardised methods for assessing these key outcomes in catheter research are needed. There was a consistent lack of adequate reporting of statistical information e.g. denominators for percentages, summary statistics such as standard deviations and details of statistical tests. This made interpreting the study results difficult, and extracting the data for tables of Comparisons and Data impossible in many cases. The methods used by authors in analysing data from the cross-over trials were referenced and seemed appropriate, taking into account the paired nature of the data. However, the reporting of these analyses within the articles was poor and assessment of the findings and data extraction were not possible.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence from randomised controlled trials to guide clinical practice regarding all aspects of using washouts for long-term indwelling catheters. Therefore we do not know whether washouts convey any benefit or harm to patients using indwelling catheters in the long-term. Neither do we know, therefore, whether the associated costs are justified.

Implications for research

Further trials are needed with larger sample sizes and rigorous methods which will address many questions which are still unanswered. Standardisation of outcome measurement is necessary so that future trials can be compared and combined. Future trials should include a "no washout" arm as there is first a need for evidence regarding whether catheter washouts compared to no washout are beneficial. Other variables that may influence outcome, and which could be allowed for in the design of future trials, include baseline characteristics of urine (e.g. acidity), condition of patient dictating the need for indwelling catheterisation, and the patient's fluid intake.

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Warren JW, Steinberg L, Hebel JR, Tenney JH. The prevalence of urethral catheterization in Maryland nursing homes. *Archives of Internal Medicine* 1989;**149**(7):1535–7.

Zigmond 1983
Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica* 1983;**67**(6): 361–70.

* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Kennedy 1992

Methods	- 3 centre crossover RCT (no mention of blinding) - 3 interventions: A Sodium chloride washout, B Suby G washout, C Solution R washout - allocation by random number tables (i.e. to decide order in which 3 solutions administered) - intervention duration: 12 weeks (1 week normal saline washout run-in period, 3 x 3 week washout phase with each solution, and 1 week normal saline washout between interventions)
Participants	- 25 elderly females in long-term geriatric care with long-term catheter in-situ - no exclusion criteria stated - 25 women entered trial - 11 women lost to follow up (5 died, 3 catheters removed, 2 withdrawn by nursing staff, 1 discharged) - 14 women completed full 12 weeks of trial - 120 catheters inserted during study, 100 examined for encrustation - mean age 82yrs, range 65-100yrs - catheter type and material not stated (type patient already wearing used) - median duration catheter in-situ at start of study: 12 months (range 1-204 months)
Interventions	- group A: 3 weeks of twice weekly 0.9% sodium chloride washout - group B: 3 weeks of twice weekly Suby G washout (citric acid 3.23%, light magnesium oxide 0.38%, sodium bicarbonate 0.7%, and disodium edetate 0.01%) - group C: 3 weeks of twice weekly Solution R washout (citric acid 6%, gluconolactone 0.6%, light magnesium carbonate 2.8%, disodium edetate 0.01%) - each washout administered by attaching 100ml sterile pre-packed sachet to catheter and allowing to drain into bladder via gravity, clamped for 20-30mins and then allowed to drain out - catheters changed at weeks 1, 5, 9 and 12
Outcomes	- bacteriuria: patients with bacteria observed in washout fluid at end of washout period: A 100%, B 75%, C 76% (insufficient data presentation); conclusion was that treatment with acidic solutions did not prevent or reduce urease-producers - catheter blockage: blocked catheters: A 18/44, B 14/29, C 7/27, partially blocked catheters: A 14/44, B 12/29, C 10/27, non-encrusted catheters: A 12/44, B 3/29, C 10/37 (in each case denominator = no. of catheters) - degree of visual encrustation: little difference between 3 treatments up to day 10, after which Solution R did not reduce encrustation (insufficient data presentation) - mean episodes of bypassing per week: A 1.55, B 1.4, C 1.9 (insufficient data presentation); differences not statistically significant - catheter removal/replacement: mean days catheter in situ: A 16.3, B 14.3, C 14.2

Kennedy 1992 (*Continued*)

	(insufficient data presentation); no significant differences between groups; only 3 patients retained catheter for full length of each trial period - patients with red blood cells in washout fluid at end of washout period: A 21%, B 17%, C 14% (insufficient data presentation), higher counts during treatment B - patients with urothelial cells in washout fluid at end of washout period: A 100%, B 86%, C 100% (insufficient data presentation), some evidence of a significant difference in the changes over time within the 3 treatments (chi-squared (14) = 22.5, P=0.068) but proportions all consistently high thus unlikely to be clinically significant - 1 patient developed haematuria following treatment with solution C - other outcomes reported (not analysed within this review): type and volume of crystals observed in washout fluid: significantly more crystals found during saline washouts than during acidic solutions (chi-square (2) = 29.06, p<0.001); struvite appeared significantly more often in the saline washouts than in the Suby G and Solution R washouts (chi-square (2) = 22.075, p<0.001); uric acid crystals appeared with Suby G and Solution R; calcium oxalate was slightly more common in saline washouts than during the acidic treatments; urates were seen only during saline washouts; no difference between the 3 regimes at the end of each 3-week washout period - white blood cells present in washout fluid: A 100%, B 87%, C 14% (insufficient data presentation); no significant differences between the 3 treatments
Notes	- definition of blocked catheter: eyes or lumen completely blocked, resulting in no flow of urine - definition of partially blocked catheter: still able to allow urine drainage - analysis based on end-point data available - insufficient data to analyse any possible interactions involving treatment order - authors' conclusion: acidic washouts administered twice weekly for 3 weeks had no effect on preventing crystal formation or catheter encrustation, and the frequency of red cells in the urine suggests an adverse effect on the bladder endothelium

Risk of bias ***Risk of bias***

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Adequate (random number tables used to determine the order of the solutions)
Allocation concealment?	No	Inadequate (procedure not described)
Blinding? All outcomes	Unclear	No mention of blinding
Incomplete outcome data addressed? All outcomes	Yes	States numbers and reasons

McNicoll 2003

Methods	- single centre parallel group RCT (no mention of blinding) - 2 groups: A citric acid catheter maintenance solutions (CMS'), B planned catheter changes - method of group allocation not stated
Participants	- 11 community patients with long term catheters known to block with encrustation - no exclusion criteria stated - 11 participants enrolled in trial (number allocated to each group not stated) - 7 participants lost to follow-up (reasons not stated) - 4 patients analysed (A 1, B 3) - age and sex of participants not stated - urethral catheters, material not stated - duration catheter in situ at start of study not stated
Interventions	- group A: daily instillation of citric acid CMS', volume used and method of administration not stated (108 patient contacts) - group B: planned catheter removal (approx. 55 patient contacts) - duration of intervention was 12 weeks
Outcomes	- catheter replacements: group A mean 9 (SD 0) (n=1), group B mean14.3 (SD 11.2) (n=3) - resources: time to implement intervention, group A mean 37.25 hours (SD 0) (n=1), group B not reported (insufficient data presentation) - cost of intervention: group A mean £975.51 (SD 0) (n=0), group B mean £188.70 (SD £102.90) (n=3)
Notes	- planned catheter change intervention varied: 1 patient had catheter changed twice a week, 1 patient had catheter changed when it showed signs of blocking, 1 patient had weekly pH tests and had catheter changed at beginning and end of the study - nursing care provided by district nurses - analysis based on end point data available - author's conclusion: method B utilised less in terms of time, cost and reduced risk of infection compared with method A however complete data on time and risk of infection not reported

Risk of bias ***Risk of bias***

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Unclear
Allocation concealment?	Unclear	Unclear
Blinding? All outcomes	Unclear	No mention of blinding
Incomplete outcome data addressed? All outcomes	Yes	States numbers only (no reason given)

Moore 2009

Methods	- parallel group RCT - 3 groups: catheter flush with saline vs acidic solution vs standard care (no washout) - attempts to blind patients, research nurses were not blinded to solution
Participants	- community dwelling or longterm care - English speaking individuals - MMSE >=23 - indwelling catheter in situ longer than 30 days and who require catheter changes because of blockage more than once a month - exclusion criteria included: symptomatic UTI (individuals were eligible for the study following successful treatment of the UTI after a symptom-free period of 14 days); urethral erosion allowing continuous bypassing (leakage) around urinary catheter; history of bladder cancer, or radiation or interstitial cystitis; impaired renal function as evidenced by a serum creatinine level of 2.0 mg/dL or higher; gross hematuria; or indwelling catheter that was changed less frequently than every 8 weeks
Interventions	- group A: 8 weeks of usual care, no washout (control) - group B: 8 weeks of weekly washout with 50 ml sterile normal saline washout - group C: 8 weeks of weekly washout with 50 ml sterile Contisol solution (containing citric acid 3.23%, light magnesium oxide 0.38%, sodium bicarbonate 0.7%, and disodium edetate 0.01%)
Outcomes	- mean time to first catheter change: Contisol 4.57 (SD 2.61) (n=19), saline 5.18 (SD 2.90) (n=16), no washout 4.55 (SD 2.91) (n=20) - incidence of symptomatic UTI (defined as at least one of five indications with no other recognised cause: fever >=38 degrees C, urgency, dysuria or suprapubic tenderness, haematuria or positive urine culture (>=100,000 microorganisms per cc of urine with no more than two species of microorganisms). None were detected in any group: Contisol 0/17, saline 0/16, control 0/20. - incidence of microscopic haematuria. All participants had haematuria consistently (no data provided). - incidence of microscopic leukocytes. All participants had haematuria consistently (no data provided). - urine pH: mean pH 6.3 (SD 1.04) (range 5-8.5), not reported for groups - measurement of cross sectional catheter lumen. slicing of first 50 catheters supported the theory that biofilm or encrustations begins at the catheter tip, first at the eyes, proceeding down the shaft. % of catheters with encrustation was low and the majority were obstructed with thick biofilm
Notes	- cross sectional measurement of catheter was abandoned as the method did not prove useful for comparing effectiveness of washouts - data on all available patients was included in the Kaplan Meier analysis of time to first catheter change (with censoring when an individual withdrew, died, had a UTI treated with antibiotics, etc), however results on mean time to first catheter change are based on data for those who completed the trial only - authors gave reviewers access to data for further analysis
Risk of bias	***Risk of bias***

Moore 2009 (*Continued*)

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Adequate (computer generated random numbers)
Allocation concealment?	Yes	Adequate (group allocation placed in opaque envelope, opened by participant)
Blinding? All outcomes	Yes	Blinding stated but no description given (blinding of the participants to washout type attempted, not possible to blind the research nurse due to nature of the intervention and the packaging of washouts)
Incomplete outcome data addressed? All outcomes	Yes	States numbers and reasons

Muncie 1989

Methods	- single centre crossover RCT (no mention of blinding) - 2 interventions: group A normal saline irrigation, group B no irrigation - method of group allocation not stated - intervention duration: 24 weeks (2-week no irrigation run-in period, 2 x 10 week irrigation/no irrigation phase, and 2 week no-irrigation washout period before entering alternate phase)
Participants	- 44 long-term hospitalised female patients - aged 18 years or more, mean age 71 years, range 37 to 88 years, 33 women were aged 65 or over - with indwelling urethral catheters in place for 30 consecutive days or longer - were afebrile (temperature <= 37.7 degrees) for 7 days - had not received antibiotics for 14 days - excluded: patients with malignant bladder neoplasms or patients whose physician insisted on continued bladder irrigation - 44 women entered the trial, 21 women did not complete the full intervention (10 died, 4 discharged, 3 catheter removed, 4 physician request), 23 women completed the full 24 week intervention (A first 10, B first 13), 9 women completed at least one phase and five weeks of the second phase of the study - 32 women analysed: 23 crossovers, 9 partial crossovers - catheter type: double lumen, 18 F, silicone-coated latex urethral catheters - mean hospital stay longer for those who completed the study (810 days) than for those who did not (455 days) ($p<0.05$) - neither age nor activities of living distinguished between those who completed the study and those who did not
Interventions	- group A: 10 weeks of once daily normal saline irrigation (30mls via bladder syringe) - group B: 10 weeks of no irrigation - new catheters inserted at beginning and end of each study phase, drainage bags changed

	weekly in both groups - drainage bags with built-in irrigation ports used that enabled irrigation without disruption of the closed catheter system
Outcomes	Patients who completed (n=23) - bacteriuria: mean number of species (at >=10 to power 5) per urine specimen: group A 4.0, group B 3.8. No standard deviations reported. 4 most prevalent organisms in each phase: Providencia stuartii, Escherichia coli, P mirabilis and enterococcus; percentage of specimens in which each present was similar in each phase. - febrile episodes: mean number of febrile episodes of possible urinary origin 1st period: irrigation 1.6 (SD 1.7) (n=10), non-irrigation 0.9 (SD 1.1) (n=13) 2nd period: irrigation 1.0 (SD 1.6) (n=13), non-irrigation 0.6 (SD 0.7) (n=10) All participants (n=32) - febrile episodes of possible urinary origin per 100 days of catheterisation: group A mean1.2 (SD 1.3) (n=32), group B mean 0.9 (SD 1.1) (n=32) - catheter replacements per 100 days of catheterisation: group A mean 5.5 (SD not reported) (n=32), group B mean 4.7 (SD not reported) (n=32) - no. of catheter replacements due to obstruction (n=32): A 39, B 32; no. of catheter replacements due to leakage (n=32): A 11, B 21; no. of non-prescribed catheter removals (n=32): A 87, B 63 - other outcomes reported (not analysed within this review): all febrile episodes per 100 days of catheterisation: group A mean 1.7 (SD 1.9) (n=32), group B mean 1.1 (SD 1.6) (n=32)
Notes	- definition of febrile episode: consecutive days of fever (temperature more than 37.7 degrees) classified using predefined criteria of 44 diagnosis of infection and other causes of fever. If not thought to be from any of these then classed as of possible urinary origin. - definition of catheter leakage: patient's bed being wet with urine with the catheter still connected to the connection tube - definition of catheter obstruction: absence of urine flow from the catheter that irrigation could not restore - daily irrigations administered by trained nurse - routine catheter care included daily perineal cleansing with soap and water - number of non-protocol irrigations were similar during irrigation and non-irrigation periods - analysis based on end point data available - 2 sets of analysis carried out: patients completing all 24 weeks of the study, patients who completed one period and at least 5 weeks of the next period - authors' conclusion: Routine, once daily normal saline irrigation of long-term indwelling urethral catheters does not reduce the incidence of catheter obstructions or episodes of fever

Risk of bias ***Risk of bias***

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Unclear
Allocation concealment?	Unclear	Unclear

Muncie 1989 (*Continued*)

Blinding? All outcomes	Unclear	No mention of blinding
Incomplete outcome data addressed? All outcomes	Yes	States numbers and reasons

Waites 2006

Methods	- parallel group RCT (double blind but no description given) - 3 groups: group A normal saline irrigation, B acetic acid irrigation, C neomycin-polymyxin GU irrigation - groups stratified by sex - method of group allocation not stated - intervention duration: 8 weeks
Participants	- 89 community residing patients with neurogenic bladder managed by indwelling catheter - at least 6 months post spinal cord injury or onset of other neurological disease - evidence of microscopic bacteriuria and pyuria at time of study enrolment - excluded: patients with serious UTIs requiring systemic antibiotics or with prior renal function abnormalities, patients who had used an acidifying agent, bladder irrigant or systematic antibiotic in previous 7 days, and patients who were pregnant or unable/unwilling to give informed consent - 89 participants entered the trial (group A 29, group B 30, group C 30) - 37 participants did not complete the full intervention (11 withdrew due to development of symptomatic UTI, 14 withdrew due to other health related reasons, 12 withdrew due to perceived difficulty, inconvenience or unwillingness to perform twice daily irrigations) - 52 participants completed the intervention and were analysed (group A 21, group B 9, group C 22) - no differences in demographic and injury related variables by group at baseline - years since injury or onset of disease significantly greater for participants who did not complete the study protocol - mean age 45.8 years, range 19 to 82 years - 49 men, 40 women - catheter type 71 foley catheter, 18 suprapubic tube, catheter material not stated - duration catheter in situ pre-study enrolment not stated
Interventions	- group A: 8 weeks of twice daily normal saline irrigation - group B: 8 weeks of twice daily 0.25% acetic acid irrigation - group C: 8 weeks of twice daily neomycin-polymyxin GU irrigation containing 40mg/ml neomycin sulfate and 200,000 units/ml polymyxin B - 30 mls of each irrigant instilled for 20mins via bladder syringe
Outcomes	- bacteriuria or pyuria in urine: no data reported at group level except for Enterococcus species (see below) - participants harbouring Enterococcus species alone or in conjunction with other types of bacteria after completing study: group A: 13/21, group B: 7/9, group C: 19/22 - increased occurrence of enterococci over time significant for group C (p=0.02) (data

	reported graphically hence unable to determine exact values by group) - participants discontinuing use of irrigation due to development of symptomatic UTI: group A: 1/29, group B: 6/30, group C: 4/30 - acceptability: bladder irrigation well tolerated with the exception of 3 participants (see adverse effects) - adverse effects: bladder spasms attributed directly to participation in bladder irrigation: group A 0/29, group B 1/30, group C 2/30 - other outcomes reported (not analysed within this review): generation of antimicrobial-resistant organisms, urinary pH, urinary leukocytes
Notes	- first irrigation shown to patient in clinic setting, remaining irrigations administered at home by participant or carer - participants advised to continue usual practices for perineal hygiene and catheter care - drop out rate in group B significantly higher than other two groups - analysis based on end point data available - data analysis combines patients with urethral and suprapubic catheters (author contacted to request results separately for these groups however with no success) - authors' conclusion: no basis on which to recommend the use of bladder irrigation as a routine method for treating asymptomatic bacteriuria in catheterised people with neurogenic bladder

Risk of bias ***Risk of bias***

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Unclear
Allocation concealment?	Unclear	Unclear
Blinding? All outcomes	Yes	Blinding stated but no description given (participants and healthcare providers blinded, no mention of blinding of outcome assessor)
Incomplete outcome data addressed? All outcomes	Yes	States numbers and reasons

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

Study	Reason for exclusion
Andersson 1986	Primary outcomes of interest to review (i.e. catheter-associated infection and encrustation) not addressed. RCT of Varidase versus saline to compare effects and side effects in patients with catheter problems. Outcomes studied related to cleansing of bladder from pus, fibrin, necrotic tissue and blood clots

(*Continued*)

Bach 1990	Not long term catheterisation. RCT of citric acid versus saline to prevent catheter encrustation
Bruun 1978	Unable to determine duration of catheterisation. RCT (crossover design) of four irrigating solutions: saline, 0.25% acetic acid, 0.02% chlorhexidine, 0.25% silver nitrate
Davies 1987	Not all patients catheterised for more than 28 days. RCT of chlorhexidine versus saline on urinary bacterial count. 48 patients catheterised for 3 weeks or more
Elliott 1989	Study methods insufficiently described and insufficient data reported on the effect on bacteruria in treatment and control groups. Thus the study was excluded as it did not contribute information on any of the reviews primary outcome measures, rather it focused on urothelial exfoliations rates and presented these data only graphically RCT (crossover design) of effect of washouts (2.5% noxythiolin or saline) on the urothelium
Elliott 1990	Unable to determine if patients randomised. Study methods insufficiently described. Insufficient data reported for calculating the effect on bacteruria in treatment and control groups
Furuno 1998	Not an RCT. Comparison of irrigation with super oxidation water and normal saline in 21 paraplegics (conference abstract at 33rd Annual Meeting of Japan Medical Society of Paraplgia 1998)
Gelman 1980	Unable to determine if patients randomised. Duration of catheterisation at start of study less than 28 days for some patients. Comparison of three methods of irrigation with 0.25% acetic acid (no irrigation, one irrigation a week, two irrigations per day)
Kennedy 1984	Not an RCT. Crossover study of saline versus two Uro-tainer solutions.
Meyers 1964	Not all patients catheterised for more than 28 days. Analysis of long-term catheterised patients not reported. RCT of nitrofurazone and neomycin/polymyxin for prevention of bacteriuria
Robertson 1990	Not an RCT. Comparison of effect of mandelic acid on two different types of species. There was only a single group of subjects who received a single regimen of 1% mandelic acid
Ruwaldt 1983	Unable to determine if RCT. Crossover comparison of twice daily irrigations with Suby G versus no irrigations
Vainrub 1977	Comparison with intermittent catheterised patients not relevant to review. Comparison of effect of methanamine mandelate and ascorbic acid on bacteriuria between indwelling and intermittent catheterised patients
Warren 1978	Not long term catheterisation. RCT of neomycin-polymyxin irrigation versus no irrigation for prevention of UTIs

Characteristics of studies awaiting assessment *[ordered by study ID]*

Airaksinen 1979

Methods	- RCT with 4 groups. The study set out to compare 2 different types of catheter and also two different washouts. Also aimed to assess the effect of the balloon size
Participants	- 40 participants (10 per group) who were 18 years or older. 5 were home-dwelling, the remainder were in hospital
Interventions	- Saline washout versus no washout
Outcomes	- Effect of irrigation on catheter function and UTIs.
Notes	

DATA AND ANALYSES

Comparison 1. Any washout vs no washout

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 no. of people with symptomatic UTI	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 any washout versus no washout	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 saline washout versus no washout	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 citric acid washout versus no washout	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2 weeks to first catheter change	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 any washout versus no washout	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.2 saline washout versus no washout	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable
2.3 citric acid washout versus no washout	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable

Comparison 2. One washout solution versus another

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 no. of people with symptomatic UTI	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 citric acid verus saline	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2 weeks to first catheter change	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 citric acid verus saline	1		Mean Difference (IV, Fixed, 95% CI)	Not estimable

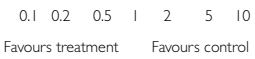
Analysis 1.1. Comparison 1 Any washout vs no washout, Outcome 1 no. of people with symptomatic UTI.

Review: Washout policies in long-term indwelling urinary catheterisation in adults

Comparison: 1 Any washout vs no washout

Outcome: 1 no. of people 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 any washout versus no washout				
Moore 2009	0/33	0/20		Not estimable
2 saline washout versus no washout				
Moore 2009	0/16	0/20		Not estimable
3 citric acid washout versus no washout				
Moore 2009	0/17	0/20		Not estimable



Analysis 1.2. Comparison 1 Any washout vs no washout, Outcome 2 weeks to first catheter change.

Review: Washout policies in long-term indwelling urinary catheterisation in adults

Comparison: 1 Any washout vs no washout

Outcome: 2 weeks to first catheter change

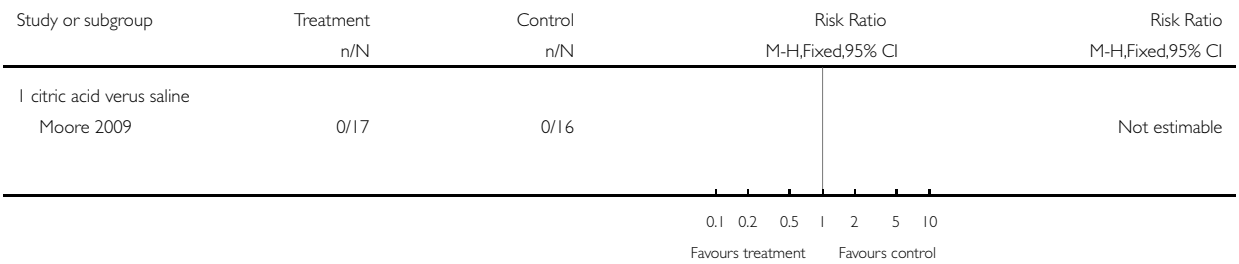
Study or subgroup	Treatment N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 any washout versus no washout						
Moore 2009	35	4.86 (2.72)	20	4.55 (2.91)		0.31 [-1.25, 1.87]
2 saline washout versus no washout						
Moore 2009	16	5.18 (2.9)	20	4.55 (2.91)		0.63 [-1.28, 2.54]
3 citric acid washout versus no washout						
Moore 2009	19	4.57 (2.61)	20	4.55 (2.91)		0.02 [-1.71, 1.75]

Analysis 2.1. Comparison 2 One washout solution versus another, Outcome 1 no. of people with symptomatic UTI.

Review: Washout policies in long-term indwelling urinary catheterisation in adults

Comparison: 2 One washout solution versus another

Outcome: 1 no. of people with symptomatic UTI

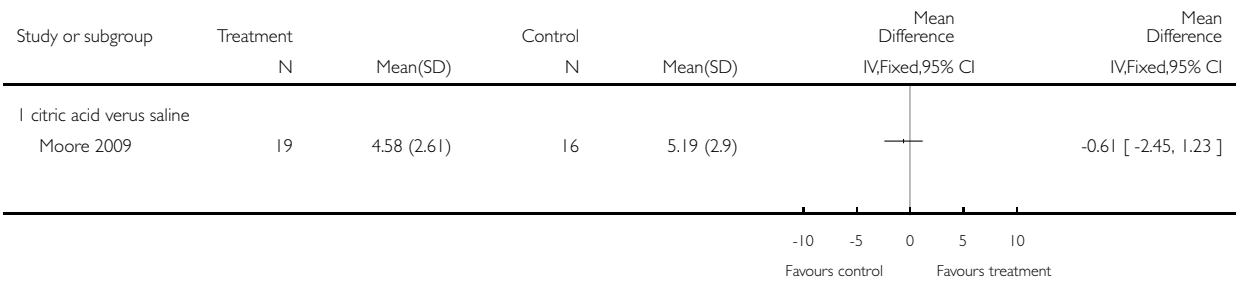


Analysis 2.2. Comparison 2 One washout solution versus another, Outcome 2 weeks to first catheter change.

Review: Washout policies in long-term indwelling urinary catheterisation in adults

Comparison: 2 One washout solution versus another

Outcome: 2 weeks to first catheter change



APPENDICES

Appendix 1. Search strategies used for this review

We searched:

- MEDLINE (January 1966 to April 2009),
- MEDLINE In-Process (searched on 30 April 2009),
- EMBASE (January 1980 to Week 17 2009) was searched on 27 April 2009,
- CINAHL on OVID (1982 to July Week 1 2007) was searched on 18 July 2007,
- CINAHL on EBSCO (December 1981 to Week 4 April 2009) was searched on 28 April 2009.

These databases were searched by the review authors using appropriate free text and MeSH terms/EMTREE terms/controlled vocabulary. This was done by adapting terms drawn from the existing search strategies of the Incontinence Review Group to meet the objectives of this review. Full details of the search terms used are given below:

MEDLINE and MEDLINE In-Process & Other Non-Indexed Citations on OVID

1. Irrigation/
2. (bladder adj5 irrigat$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
3. bladder washout$.mp.
4. (catheter$ adj5 irrigat$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
5. (catheter$ adj3 maintenanc$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
6. catheter blockage$.mp.
7. Crystallization/
8. encrustation$.mp.
9. Anti-Bacterial Agents/ad, tu [Administration & Dosage, Therapeutic Use]
10. Anti-Infective Agents/ad, tu [Administration & Dosage, Therapeutic Use]
11. Antifungal Agents/ad, tu [Administration & Dosage, Therapeutic Use]
12. Candidiasis/dt [Drug Therapy]
13. Bacteriuria/dt [Drug Therapy]
14. Bacteriuria/pc [Prevention & Control]
15. or/1-14
16. catheters, Indwelling/
17. urinary catheter$.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
18. Urinary Catheterization/
19. ((long-term or long-term or longterm) adj2 catheter$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
20. ((indwelling or in-dwelling) adj2 catheter$).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
21. bladder catheter$.mp.
22. urethral catheter$.mp.
23. or/16-22
24. Catheterization, Central Venous/
25. Postoperative Care/
26. Vascular Patency/
27. 24 or 25 or 26
28. 15 and 23
29. 28 not 27

This set of terms was combined with the first two parts of the Cochrane Highly Sensitive Search Strategy for identifying reports of randomised controlled trials in MEDLINE (Appendix 5b.2, Cochrane Reviewers Handbook, version 4.2, March 2003) using the Boolean operator 'AND'.

CINAHL (on OVID)

1. "URINARY CATHETER IRRIGATION (SABA CCC)"/ or CATHETER IRRIGATION, URINARY/ or URINARY BLADDER IRRIGATION/ or irrigation.mp. or IRRIGATION/

2. (catheter$ adj3 maintenanc$).mp. [mp=title, subject heading word, abstract, instrumentation]
3. catheter blockage$.mp.
4. encrustation$.mp. or Catheter Occlusion/
5. Antiinfective Agents/ad, tu [Administration and Dosage, Therapeutic use]
6. Antifungal Agents/ad, tu [Administration and Dosage, Therapeutic use]
7. CANDIDIASIS/dt [Drug Therapy]
8. BACTERIURIA/pc, dt [Prevention and Control, Drug Therapy]
9. Catheter-Related Infections/pc, dt [Prevention and Control, Drug Therapy]
10. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9
11. urinary catheterization.mp.
12. urinary catheterisation.mp. or Urinary Catheterization/
13. urinary catheter$.mp. or Catheters, Urinary/
14. Catheter Care, Urinary/
15. (long-term adj2 catheter$).mp.
16. bladder catheter$.mp.
17. urethral catheter$.mp.
18. 11 or 12 or 13 or 14 or 15 or 16 or 17
19. 10 and 18

This set of terms was combined with the sensitive search strategy for identifying reports of trials in CINAHL (developed by the Cochrane Stroke Group, available via OVID on the NHS eLibrary) using the Boolean operator 'AND'.

CINAHL (on EBSCO)

Query
S53 S52 and em 200707-
S52 S27 and S51
S51 S40 and S50
S50 S41 or S42 or S43 or S44 or S45 or S46 or S47 or S48 or S49
S49 urethral catheter*
S48 bladder catheter*
S47 (long-term or longterm) N2 catheter*
S46 (MH "Catheter Care, Urinary")
S45 (MH "Catheters, Urinary")
S44 urinary catheter*
S43 (MH "Urinary Catheterization")
S42 urinary catheterisation
S41 urinary catheterization
S40 S28 or S29 or S30 or S31 or S32 or S33 or S34 or S35 or S36 or S37 or S38 or S39
S39 (MH "Catheter-Related Infections/DT/PC")
S38 (MH "Bacteriuria/DT/PC")
S37 (MH "Candidiasis/DT")
S36 (MH "Antifungal Agents/AD/TU")
S35 (MH "Antiinfective Agents/AD/TU")
S34 encrustation*
S33 catheter* N3 blockage*
S32 catheter* N3 maintenanc*
S31 TI irrigation or AB irrigation
S30 (MH "Catheter Occlusion")
S29 (MH "Irrigation") or (MH "Urinary Bladder Irrigation")
S28 (MH "Catheter Irrigation, Urinary") or (MH "Urinary Catheter Irrigation (Saba CCC)")
S27 S26 or S25
S26 (MH "Comparative Studies")
S25 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22 or S23 or S24
S24 (MH "Clinical Research+")

S23 (MH “Static Group Comparison”)
S22 (MH “Quantitative Studies”)
S21 (MH “Crossover Design”) or (MH “Solomon Four-Group Design”)
S20 (MH “Factorial Design”)
S19 (MH “Community Trials”)
S18 (MH “Random Sample”)
S17 (MH “Random Assignment”)
S16 TI balance* N2 block* or AB balance* N2 block*
S15 TI “latin square” or AB “latin square”
S14 TI cross-over or AB cross-over
S13 TI crossover or AB crossover
S12 TI factorial or AB factorial
S11 TI (tripl* N25 (blind* or mask*)) or AB (tripl* N25 (blind* or mask*))
S10 TI (trebl* N25 (blind* or mask*)) or AB (trebl* N25 (blind* or mask*))
S9 TI (doubl* N25 (blind* or mask*)) or AB (doubl* N25 (blind* or mask*))
S8 TI (singl* N25 (blind* or mask*)) or AB (singl* N25 (blind* or mask*))
S7 TI clin* N25 trial* or AB clin* N25 trial*
S6 (MH “Study Design”)
S5 (AB random*) OR (TI random*)
S4 (AB placebo*) OR (TI placebo*)
S3 (MH “Placebos”)
S2 PT Clinical Trial
S1 (MH “Clinical Trials+”)

EMBASE on OVID

1. irrigation.mp. or BLADDER IRRIGATION/
2. (catheter$ adj3 maintenanc$).mp. [mp=title, subject heading word, abstract, instrumentation]
3. bladder washout$.mp.
4. catheter blockage$.mp.
5. encrustation$.mp. or Catheter Occlusion/
6. Crystallization/
7. Antiinfective Agent/ad, do, dt [Drug Administration, Drug Dose, Drug Therapy]
8. Antifungal Agent/ad, do, dt [Drug Administration, Drug Dose, Drug Therapy]
9. antibacterial agent$.mp.
10. CANDIDIASIS/dm, dt, th [Disease Management, Drug Therapy, Therapy]
11. BACTERIURIA/pc, dm, dt, th [Prevention, Disease Management, Drug Therapy, Therapy]
12. Catheter Infection/pc, dm, dt, th [Prevention, Disease Management, Drug Therapy, Therapy]
13. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12
14. Indwelling Catheter/
15. indwelling catheter$.mp.
16. Urine Catheter/
17. urine catheter$.mp.
18. urinary catheter$.mp.
19. Suprapubic Catheter/
20. suprapubic catheter$.mp.
21. suprapubic bladder catheterization/
22. (long-term adj2 catheter$).mp.
23. Bladder Catheterization/
24. bladder catheter$.mp.
25. urethral catheter$.mp.
26. 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
27. 13 and 26
28. Postoperative Care/
29. Vascular Patency/

30. Central Venous Catheterization/
31. 28 or 29 or 30
32. 27 not 31

This set of terms was combined with the Cochrane suggested search strategy for identifying reports of randomised controlled trials in EMBASE (available via OVID on the NHS eLibrary) using the Boolean operator 'AND'. An optimal strategy for EMBASE has not yet been tested and formally approved. However, the suggested strategy has been employed in searches for the Cochrane collaboration. The UK National Research Register, Controlled Clinical Trials and ZETOC database of conference abstracts were searched on 17 October 2006 using various combinations of the following search terms: catheter, bladder, washout, maintenance, solution, irrigation, instillation, care, infection, bacteriuria, encrustation, blockage, occlusion, crystallisation, anti-infective agents, anti-bacterial agents.

WHAT'S NEW

Last assessed as up-to-date: 3 December 2009.

Date	Event	Description
26 February 2010	Amended	TSC comments amended

HISTORY

Protocol first published: Issue 1, 2003

Review first published: Issue 3, 2010

CONTRIBUTIONS OF AUTHORS

All reviewers contributed to the writing of the protocol, with LS taking the lead in its development. LS developed the search strategy and conducted all original searching and specific extra searches of various electronic databases. LS and SC independently assessed all titles and abstracts identified by the search strategy. LS, SC and SH completed the data extraction and quality assessment of all included trials. LS and SH contacted authors of papers, and gathered additional data. SH was responsible for data entry, analysis and interpretation. SC provided clinical perspective and interpretation. SH will be the guarantor for the review.

DECLARATIONS OF INTEREST

None known.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

No major alterations were made to the protocol during the completion of the review.

INDEX TERMS

Medical Subject Headings (MeSH)

*Catheters, Indwelling; Device Removal; Equipment Failure; Randomized Controlled Trials as Topic; Solutions [*administration & dosage; chemistry]; Therapeutic Irrigation [adverse effects; *methods]; Time Factors; Urinary Bladder Neck Obstruction [therapy]; Urinary Catheterization [*instrumentation]; Urinary Incontinence [therapy]

MeSH check words

Adult; Aged; Aged, 80 and over; Female; Humans; Male; Middle Aged