Washout policies for the management of long-term indwelling urinary catheterisation in adults (Protocol)

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Washout policies for the management of long-term indwelling urinary catheterisation in adults

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The purpose of this review is 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.

The following hypotheses will be tested:

1) using any type of catheter washout (e.g. water, saline, antiseptic, antifungal, antibiotic) is better than not using one;
2) one type of catheter washout solution is better than another type;
3) clinically or microbiologically indicated washout is better than routine washout;
4) long intervals between catheter washouts are better than short intervals;
5) one method of administration of catheter washouts (e.g. agitation, gravity, syringe) is better than another method;
6) smaller volumes of washout solution are better than larger volumes;
7) a stronger solution of washout is better than a weaker solution;
8) a single washout instillation is better than two or more sequential washout instillations of the same type.

Some studies may address more than one hypothesis.
BACKGROUND

Catheterisation is commonly used for the management of people in long-term care settings, e.g. nursing homes or home care. Patients may require long-term urinary catheterisation for a number of reasons. These include urinary retention (incomplete emptying of the bladder), caused by benign prostatic hypertrophy (enlarged prostate) for example, and urinary incontinence (involuntary leakage of urine) which may be a problem for individuals suffering from conditions such as multiple sclerosis, dementia, stroke, spina bifida, and spinal cord injury. It may also affect those who have undergone pelvic surgery or radiotherapy, e.g. for prostate cancer.

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). Patients using catheters long-term often experience complications such as blockage, leakage and infection. These complications can have significant resource implications 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 98.4% 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. Up to 30% of long-term catheterised patients 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 this problem, catheter washouts/irrigations (sometimes called bladder washouts/irrigations) were introduced. Various antibiotic and antiseptic solutions have been used as washouts over the last few decades with the aim of preventing and treating catheter-associated infection. 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 infection and is therefore no longer advised in practice (Pellowe 2003).

Fungal Infection

Candiduria (the presence of candida organisms in the urine) can also occur in catheterised patients, 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 patients whose candiduria persists or who must remain catheterised, several management techniques have been used. Recommendations for treating candida bladder infections primarily involve oral medication although bladder irrigation may also be used.

Catheter Blockage

The most common problem however for patients with long-term indwelling catheters is the formation of encrustations on the surface of the catheter with consequent blockage and by-passing of urine. Nearly half of all patients 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).

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. Evidence seems to suggest that normal saline is ineffective in diminishing encrustations whereas there appears to be some evidence that methenamine preparations and acidic washouts may benefit patients who are prone to catheter encrustation (Getliffe 1994; Hesse 1989; King 1991; Municie 1989). 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 continent advisers questioned their 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).

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 to patients indicate that a systematic review of the evidence regarding washout policies may have important implications for both clinical practice and future research. 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 is 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.

The following hypotheses will be tested:

1) using any type of catheter washout (e.g. water, saline, antiseptic, antifungal, antibiotic) is better than not using one;
2) one type of catheter washout solution is better than another type;
3) clinically or microbiologically indicated washout is better than routine washout;
4) long intervals between catheter washouts are better than short intervals;
5) one method of administration of catheter washouts (e.g. agitation, gravity, syringe) is better than another method;
6) smaller volumes of washout solution are better than larger volumes;
7) a stronger solution of washout is better than a weaker solution;
8) a single washout instillation is better than two or more sequential washout instillations of the same type.

Some studies may address more than one hypothesis.

METHODS

Criteria for considering studies for this review

Types of studies
All randomised or quasi-randomised controlled trials 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 using only intermittent catheterisation long-term will be excluded from this review. Adults who combine intermittent catheterisation with periods of indwelling catheterisation will only be included where they have had an indwelling catheter in-situ for more than 28 days at the time of data collection.

Types of interventions
The interventions considered will include catheter washouts with water, saline, antiseptic solutions, antifungal solutions, antibiotic solutions or any combination of these. Studies that compare (1) participants who received washouts with controls who did not receive washouts, (2) participants who received washouts with other participants who received different washouts, (3) participants who received different washout regimens at different time periods i.e. crossover studies, and (3) different washout regimens i.e. frequency, duration, volume, concentration, method of administration, will be considered.

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’. Sometimes the procedure is also referred to as ‘bladder washout’ which can cause confusion with bladder irrigations/lavage used post-operatively (Getliffe 1996). Throughout this review all trials referring to catheter or bladder washouts will be considered with the exception of post-operative bladder irrigations and therapeutic bladder instillations used, for example, in the treatment of cancer patients.

Trials that involve irrigation of catheter drainage bags will not be considered in this review. Other types of study that include interventions to prevent or reduce encrustation or infection e.g. fluid intake, use of oral prophylactic antibiotics, will also be excluded from this review.

Types of outcome measures
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 will therefore be objective measures of catheter-associated infection and catheter blockage due to encrustation. Such measures will include rates of asymptomatic bacteriuria and symptomatic UTIs, number of catheters used, length of time each catheter is used, and catheter removal rates due to blockage/infection (definitions of blockage/infection will be those used in the trial reports). Trials will be considered if they report at least one of these primary outcomes.

Secondary outcomes
Where reported, the following outcomes will also be recorded:
1. Washout acceptability measures
   This will include 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 will include 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 will include 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 will also be included.

4. Health economic outcomes
   Economic measures considered will 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.

**Search methods for identification of studies**

This review will draw on the search strategy developed for the Cochrane Incontinence Review Group. Relevant trials will be identified from the Group's specialised register of controlled trials which is described under the Incontinence Group's details in The Cochrane Library (For more details please see the 'Specialized Register' section of the Group's module in The Cochrane Library).

The register contains incontinence-related trials identified from MEDLINE, CINAHL, The Cochrane Central Register of Controlled Trials (CENTRAL) and hand searching of journals and conference proceedings. In addition, MEDLINE and CINAHL will be searched using appropriate free text and MeSH terms. This will be done by adapting terms drawn from the existing search strategies of the Incontinence Review Group to meet the objectives of this review. Additional trials will be sought from the UK National Research Register, Controlled Clinical Trials and ZETOC database of conference abstracts. The reference lists of relevant articles will be searched and key researchers in the field of catheter management will be contacted to identify other possibly relevant trials. Catheter maintenance solution manufacturers will be contacted and relevant nursing journals will be hand searched. No language or other limitations will be imposed on any of the above searches.

**Data collection and analysis**

**Selection of trials:**

The titles and abstracts of all studies identified from the above search strategy will be assessed for potential eligibility by two independent reviewers and the full paper will be obtained for all studies considered eligible. Where there is any doubt, based on title and abstract, regarding the potential eligibility of any study, the full paper will be obtained. The same two reviewers will then decide whether the trials fully meet the inclusion criteria. Any disagreements with regard to the eligibility of a study that cannot be resolved by discussion between the two reviewers will be resolved by consultation with a third reviewer. Studies will be excluded if they are not randomised or quasi-randomised trials of catheter washouts for adults with long-term indwelling urinary catheters. Excluded studies will be listed with reasons for their exclusion. Studies that have been reported in more than one publication will be included only once.

**Quality of trials:**

All eligible studies will be evaluated for methodological quality by the two reviewers without prior consideration of the results. Assessment of methodological quality will be undertaken by each reviewer using the Incontinence Group's assessment criteria which include quality of random allocation and concealment, description of dropouts and withdrawals, analysis by intention-to-treat, and 'blinding' during treatment and at outcome assessment. It is possible that in some studies confounding variables may have been introduced after randomisation (e.g. the initiation of treatment with systemic antibiotics). Studies will be assessed as to whether such significant confounding variables are introduced and will be excluded if present. Any differences of opinion will be resolved by discussion with a third reviewer.

**Data extraction:**

Data will be independently extracted by two reviewers and compared. Any disagreements will be discussed and if necessary resolved by a third reviewer. Where data are missing or not fully reported, clarification will be sought from the authors.

**Statistical analyses:**

Where trialists have not paid attention to the time that patients were at risk, incidence-density relative rates (IDRs) and/or incidence-density differences (IDDs) and number needed to treat (NNT) within a certain period will be calculated (Bouter 1995). The IDR will be calculated as follows:

- **numerator** = total number of events (e.g. bacteriuria or symptomatic UTI)
- **denominator** = total person time of follow-up minus time not at risk (total number of events multiplied by the average number of days antibiotics were given plus total number of days receiving antibiotics for other reasons than event).

Included trial data will be processed as described in the Cochrane Handbook for Systematic Reviews of Interventions (Deeks 2005).
Where appropriate, meta-analysis will be undertaken. For categorical outcomes, the numbers reporting an outcome will be related to the numbers at risk in each group to derive a relative risk (RR). For continuous outcomes, means and standard deviations will be used to derive weighted mean differences (WMD). A fixed-effect model will be used for calculations of pooled estimates and their 95% confidence intervals.

Differences between trials will be further investigated if significant heterogeneity is found (assessed via visual inspection of data together with the chi-squared test for heterogeneity at the 10% level and the I²-statistic). If there is no obvious reason for the heterogeneity, a random-effects model will be considered. If heterogeneity can be explained by differences in the characteristics of the studies, consideration will be given to the appropriateness of combining the data.

If data allow, sensitivity analysis will be performed to assess the impact of study quality (e.g. quality of randomisation at allocation). Similarly, if data allow, sub-group analyses will also be undertaken according to type of indwelling catheter (i.e. urethral/suprapubic/perineal), sex of participants, catheter material and time periods between washouts.

**Acknowledgements**

The reviewers would like to thank Dr. John Mooney for developing the previous version of the protocol on which this version is based.

**References**

**Additional references**

Bibby 1993


Bouter 1995


Capewell 1993


Cools 1986


Deeks 2005


Evans 2000


Garibaldi 1974


Getliffe 1990


Getliffe 1992


Getliffe 1994

Getliffe 1996

Hamory 1978

Hesse 1989

Hesse 1992

King 1991

Kohler-Ockmore 1996

Kunin 1987

Kunin 1992

Muncie 1989

NHS QIS 2004

Ouslander 1985

Ouslander 1987

Pellowe 2003

Pomfret 2004

Roe 1987

Roe 1989

Saint 1999

Stark 1984

Ware 1993

Warren 1982

Warren 1989

Zigmond 1983

* Indicates the major publication for the study
WHAT'S NEW

28 October 2008  Amended  Converted to new review format.

HISTORY

Protocol first published: Issue 1, 2003

CONTRIBUTIONS OF AUTHORS

All reviewers contributed to the writing of the protocol.

DECLARATIONS OF INTEREST

None known.

NOTES

John Mooney was unable to continue with this review. Lesley Sinclair took over as lead reviewer in May 2004.