Catheter washout solutions for long-term urinary catheterisation in adults:
A Cochrane Review Summary

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Abstract

Objectives: To determine if certain urinary catheter washout regimens are better than others in terms of effectiveness, acceptability, complications, quality of life and critically appraise and summarise economic evidence for the management of long-term indwelling urinary catheterisation in adults.

Methods: We searched the Cochrane Incontinence Group Specialised Trials Register, which contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In-Process, MEDLINE Epub Ahead of Print, CINAHL, ClinicalTrials.gov, WHO ICTRP and hand-searching of journals and conference proceedings to 23 May 2016.

Results: We included seven trials involving a total of 349 participants, 217 of whom completed the studies. Three were cross-over and four were parallel-group randomised controlled trials (RCTs). Analyses of three cross-over trials yielded suboptimal results because they were based on between-group differences rather than individual participants' differences for sequential interventions. Two parallel-group trials had limited clinical value. Only one trial was free of significant methodological limitations, but there were difficulties with recruitment and maintaining participants in this study. None of the trials addressed: number of catheters used, washout acceptability measures (including patient satisfaction, patient discomfort, pain and ease of use), or health status/measures of psychological health; very limited data were collected for health economic outcomes. Trials assessed; a washout with no washout, different types of washout versus no washout, and stronger washout solutions versus a weaker solution.

Conclusions: Data from seven trials that compared different washout policies were limited, and generally, of poor methodological quality or were poorly reported. The evidence was not adequate to conclude if washouts were beneficial or harmful. Further rigorous, high quality trials that are adequately powered to detect benefits from washout being performed as opposed to no washout are needed. Trials comparing different washout solutions, washout volumes, and frequencies or timings are also needed.

Key words: urinary incontinence, catheter care, catheter blockages, quality of life
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Background

People may require long-term urinary catheterisation for a number of reasons, such as: urinary retention (incomplete emptying of the bladder) caused by benign prostatic hyperplasia (enlarged prostate) or prostate tumour; reduced bladder contractility; or urinary incontinence (involuntary leakage of urine) not amenable to toileting or other method of management. People with conditions such as multiple sclerosis, dementia, stroke, spina bifida, and spinal cord injury may be susceptible to these problems.

The number of people with a long-term catheter is difficult to estimate. Between April and May 2013, 1,181 long-term care facilities in Europe participated in a point prevalence survey of healthcare-associated infection and related risk factors. The median percentage of long-term care facility residents with a urinary catheter was 6.3%; the highest percentage of urinary catheterisation was reported in the Czech Republic (33.3%) (ECDC 2014). The percentage of people receiving care at home with a urinary catheter was estimated to be 5.4% in another European study (range 0% to 23%) (Sørbye et al 2005). Those using catheters long-term often experience complications such as blockage, leakage and infection. These complications can have significant implications for quality of life and resource use due to increased general practitioner and hospital outpatient appointments, emergency admissions and nursing resource demands (Evans and Godfrey 2000).
Relevance for Nursing

The most common problem for long-term indwelling catheter users is the formation of encrustations on the luminal and outer surfaces of the catheter with consequent blockage and by-passing of urine resulting in urinary leakage. Nearly half of all people with an indwelling catheter experience problems with catheter blockage due to encrustation (Getliffe 1992; Kohler-Ockmore and Feneley 1996; Kunin et al 1987; Roe and Brocklehurst 1987). Blockage of an indwelling catheter is traumatic, causing pain and distress. The most commonly isolated bacteria in blockages is *Proteus mirabilis* (Stickler and Feneley 2010), which may cause crystalline deposits (such as calcium phosphate and magnesium ammonium phosphate (struvite) to build up through a rise in pH caused by the metabolism of urea to ammonia and bicarbonate (Hesse et al 1992; Wilks et al 2015). Current practice for the management of catheter encrustation and blockage lies largely with nursing staff and it is clear that this practice varies greatly but is largely dependent on the use of catheter maintenance (“washout”) solutions, yet the evidence to support this practice is weak. Maintenance solutions may be saline, acidic or both. However there is currently no consensus amongst nursing staff regarding the indications for use of catheter washouts nor the method of administration, frequency, duration of administration or choice of solution. The wide variety of solutions available, combined with the multiplicity of possible procedures for their application, and potential risks posed, indicated the need for this systematic review. We aimed to summarise the evidence from randomised controlled trials on the use of catheter washout solutions for the management of adults with long-term indwelling urinary catheters.

Objectives

In this paper we present an abridged version of our Cochrane review in which we investigated if certain washout regimens were better than others in terms of effectiveness,

We aimed to compare:

1. use of 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 use of washout versus routine washout;
4. longer intervals between catheter washouts versus shorter 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; and
8. a single washout instillation versus two or more sequential washout instillations of the same type.

Methods

All randomised or quasi-randomised controlled trials, including cross-over designs, evaluating the use of urinary catheter washouts in long-term catheterised adults were included. Participants were adults, aged at least 16 years, in any setting (i.e. hospital, nursing or residential home, community) with an indwelling urethral, suprapubic or perineal catheter in situ for more than 28 days. Adults whose treatment combined intermittent catheterisation with periods of indwelling catheterisation were included only if the indwelling catheter had been in situ for more than 28 days at the time of data collection. Data collection and analysis were conducted in accordance to the Cochrane Review Methods.
Two review authors (AS, SH) independently screened titles and abstracts for inclusion of all the potential studies identified as a result of the search. We retrieved the full-text study reports and the same two review authors independently screened the full-text to identify studies for inclusion. We extracted the following study characteristics.

1. Methods: study design, total duration of study, details of any run-in period, number of study centres and location, study setting, withdrawals, random allocation sequence, outcome assessment blinding and date of study.
2. Participants: number, mean age, age range, gender, inclusion criteria, and exclusion criteria.
3. Interventions: type of washout intervention, comparison, method of administration.
4. Outcomes: primary and secondary outcomes specified and collected, and time points reported.
5. Notes: funding for trial, and notable conflicts of interest of trial authors.

The primary outcomes considered were objective measures of catheter-associated urinary tract infection (CAUTI), which ranged in definitions among trials, and catheter blockage. Such measures include:

1. symptomatic urinary tract infections (UTIs) (as defined by the trialists);
2. number of catheters used;
3. length of time each catheter was in situ;
4. catheter removal rates due to blockage or infection (definitions of blockage or infection were those used in the trial reports); and
5. rates of asymptomatic bacteriuria.
We also considered the following secondary outcomes:

1. Washout acceptability measures.
2. Health status or measures of psychological health.
3. Measures of complications or adverse effects of washouts.
4. Health economic outcomes.

**Results**

The search identified 686 records (Figure 1) of which 23 reported potentially eligible studies. On screening, seven studies met the inclusion criteria with 349 participants randomised. Four studies were parallel-group randomised controlled trials (RCTs) (Airaksinen et al 1979; McNicoll 2003; Moore et al 2009; Waites et al 2006) and three were randomised cross-over trials (Kennedy et al 1992; Linsenmeyer et al 2014; Muncie et al 1989). Three studies were conducted in the USA (Linsenmeyer et al 2014; Muncie et al 1989; Waites et al 2006), two in the UK (Kennedy et al 1992; McNicoll 2003), and one each in Canada (Moore et al 2009) and Finland (Airaksinen et al 1979).
Characteristics of the evidence

We identified seven trials eligible for inclusion in this review relating to the use of washouts for people with long-term indwelling catheters. Most trials were small and statistically underpowered with inadequate reporting to permit judgement of quality. The studies reviewed consisted of three randomised cross-over trials which had poor data reporting, three parallel group RCTs with very limited data, and one well-designed, but potentially under-powered, RCT. Of the nine primary and secondary outcome measures sought, data
were available for six. Trials assessed only three of the eight intervention comparisons specified in the review. Due to the imprecision of the results of the included trials we are uncertain if washouts have an important effect on the primary outcomes of numbers of participants with symptomatic UTIs and length of time each catheter was in situ.

**Overall completeness and applicability of evidence**

None of the included trials addressed: number of catheters used, washout acceptability (including patient satisfaction, patient discomfort, pain and ease of use), or health status/measures of psychological health. Very limited health economic data were available. Any new policy regarding the management of long-term urinary catheters with or without the use of washout solutions must be shown to be favourable for these important outcomes. As for the eight pre-identified washout comparisons, the included trials provided data relating to only three (any catheter washout solution versus no catheter washout; one type of catheter washout solution versus another type; and a stronger washout solution versus a weaker washout solution). No trials looked at different volumes of the same washout solution. Studies tended to use the volume of solution provided in the manufacturer's pre-prepared containers. Volumes ranged from 10 ml (Airaksinen et al 1979) to 100 ml (Kennedy et al 1992). None of the trials compared different washout frequencies. However, washout frequency varied between studies: twice daily (Waites et al 2006), daily (McNicoll 2003; Muncie et al 1989), twice weekly (Linsenmeyer et al 2014; Waites et al 2006), weekly (Moore et al 2009), and every two weeks (Airaksinen et al 1979). The length of time the washout was retained in the bladder ranged from 15 minutes (Linsenmeyer et al 2014; Moore et al 2009) to 20 to 30 minutes (Kennedy et al 1992), as did the duration of the intervention from 3 weeks (Kennedy et al 1992) to 26 weeks (Airaksinen et al 1979).
Implications for practice

There is currently insufficient evidence from RCTs to guide nursing practice regarding all aspects of using washouts for long-term indwelling catheters. It is unknown if washouts convey any benefits or harms for patients using indwelling catheters in the long-term. We found very little evidence on economic outcomes associated with managing long-term indwelling catheter use.

Implications for research

There is a need for a large rigorously designed RCT which will determine the optimal policies to prevent or relieve catheter blockage. This trial would initially include a 'no washout' arm as there is first a need for evidence regarding whether catheter washouts compared to no washout are beneficial. Objective measures of CAUTI and blockage including length of time catheter in situ, catheter removal rates, and number of catheters used would be key outcome measures. Washout acceptability (patient discomfort, satisfaction, pain), psychological health and quality of life, measured using validated tools, must also be considered. Health economic analysis associated with different washout regimens must also be reported. Other variables that may influence outcome, and which should be allowed for in the design of a future trial, include baseline characteristics of urine (e.g. acidity), condition of patient dictating the need for indwelling catheterisation, and the patient's fluid intake. We would also suggest that long-term follow up is needed. Given the difficulty experienced in previous trials in recruiting and retaining participants, it may be sensible to standardise the different types of catheters in future trials to maximise the chances of detecting any differences between groups.

With one exception (Waites et al 2006), the washout procedure was undertaken by a
healthcare professional, usually a nurse, in the included studies. After the first washout, Waites et al (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 a future trial.

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 urgently needed. Indeed, we currently lack robust evidence-based diagnostic criteria for CAUTI, which means that cases may be missed – especially in the elderly. 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 impossible in many cases. The methods used by study authors to analyse 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 in the publications was poor and assessment of the findings and data extraction were not possible.

**Conclusions**

There is currently insufficient evidence from RCTs to guide nursing practice regarding all aspects of using washouts for long-term indwelling catheters. It is unknown if washouts convey any benefits or harms for patients using indwelling catheters in the long-term.
Key words
Catheter blockages, catheter care, community care, quality of life, urinary incontinence

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