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[Intervention Review]

Catheter policies for management of long term voiding problems in adults with neurogenic bladder disorders

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ABSTRACT

Background

Management of the neurogenic bladder has the primary objectives of maintaining continence, ensuring low bladder pressure (to avoid renal damage) and avoiding or minimising infection. Options include intermittent urethral catheterisation, indwelling urethral or suprapubic catheterisation, timed voiding, use of external catheter (for men), drug treatment, augmentation cystoplasty and urinary diversion.

Objectives

The primary objective was to determine the effects of different methods of managing long-term voiding problems (persisting after three months) with catheters in patients with neurogenic bladder.

Specific hypotheses to be addressed included:

- 1. that intermittent catheterisation is better than indwelling catheterisation;
- 2. that indwelling urethral catheterisation is better than suprapubic catheterisation;
- 3. that external (sheath) catheters are better than indwelling or intermittent urethral catheters;
- 4. that external (sheath) catheters are better than suprapubic catheters;
- 5. that intermittent catheterisation is better than timed voiding.

Search methods

We searched the Cochrane Incontinence Group Specialised Register (searched 3 July 2013), which contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and MEDLINE in process, and handsearched journals and conference proceedings. We sought additional trials from other sources such as the reference lists of relevant articles and by contacting consultants in Spinal Cord Injury Centres throughout the United Kingdom.

Selection criteria

All randomised and quasi-randomised controlled trials comparing methods of using catheters to manage urinary voiding in people with neurogenic bladder.

Data collection and analysis

Abstracts were independently inspected by the reviewers and full papers were obtained where necessary.



Main results

Approximately 400 studies were scrutinised. No trials were found that met the inclusion criteria, and five studies were excluded from the review.

Authors' conclusions

Despite a comprehensive search no evidence from randomised or quasi-randomised controlled trials was found. It was not possible to draw any conclusions regarding the use of different types of catheter in managing the neurogenic bladder.

PLAIN LANGUAGE SUMMARY

Catheter policies for management of long-term voiding problems in adults with nerve damage affecting the bladder

People with nerve damage affecting the bladder may have incontinence (leakage of urine) or an inability to empty the bladder (voiding problem). This may cause infections or damage to the kidneys. Treatments include a permanent urinary catheter; using a catheter intermittently whenever the bladder needs to be emptied; an external sheath catheter fitted to the penis; or timed voiding, which involves regular emptying of the bladder at timed intervals. Although all these methods are used in practice, the review found that no randomised trials have been conducted to provide good evidence to suggest which is best and in which circumstances.



BACKGROUND

Neurogenic bladder comprises any dysfunctional condition of the urinary bladder caused by a spinal cord injury (SCI) or other lesion or disease of the central nervous system (CNS). The prevalence of the condition is unknown, but the estimated annual incidence of acute SCI is 40 per million population (Bracken 1981). Multiple sclerosis is a common neurological disease. A joint World Health Organization (WHO)/Multiple Sclerosis International Federation (MSIF) survey, conducted during 2005 to 2007, estimated a worldwide median prevalence of 30 per 100 000 (range 5-80) (WHO 2008).

SCI primarily affects young males, whereas young women are more likely to develop multiple sclerosis (female: male sex ratio 1:4 and 2.5:1, respectively). The permanent paralysis that often results leads to major disability and significant economic cost (Berkowitz 1992). Life expectancy may be reduced, particularly in the absence of optimal medical care. As well as respiratory and cardiovascular problems, and pressure sores, long-term consequences of damage to the CNS include urinary tract complications (loss of bladder control leading to infections and impaired renal function). Even in developed countries where those affected have access to advanced treatment and management options, social problems can arise from difficulties in maintaining bladder function.

The effects of SCI on bladder function depend on the location of the injury on the spinal cord. Two types of bladder dysfunction may occur, automatic (hyperreflexic) bladder and flaccid (areflexic) bladder.

Automatic (hyperreflexic) bladder (detrusor overactivity)

When injury occurs above the reflex voiding centre in the sacral portion of the spinal cord (effectively at T12 or above), hyperreflexic paralysis of the bladder (also known as 'automatic bladder') usually results. The person loses both the sensation that they need to void and their voluntary, co-ordinated control over the reflex voiding centre. When the bladder becomes sufficiently full for the stretch receptors in the detrusor muscle to be activated, uncontrolled, spontaneous bladder contraction is stimulated through the simple reflex arcs. The automatic bladder often does not empty efficiently. Spasm of the bladder outlet muscle (sphincter) can prevent the complete expulsion of urine, resulting in bladder overextension. Detrusor sphincter dyssynergia (DSD) is a combination of detrusor hyperreflexia and sphincteric hypertonicity. While the latter can be alleviated by sphincterotomy (an operation to cut the external sphincter of the bladder outlet), this can increase the risk of incontinence and compromise sexual function in males.

Flaccid (areflexic) bladder (acontractile detrusor)

Areflexic or flaccid paralysis of the bladder is usually caused by a lower motor neurone lumbosacral lesion, with damage to the reflex voiding centre in the sacral portion of the spinal cord. Reflex activity and bladder activity are diminished and overdistension of the bladder usually results.

Management of the neurogenic bladder

Problems arising from detrusor and/or sphincter dysfunction in addition to urinary incontinence can include recurrent kidney

infections and high back pressure on the kidneys. Ultimately, both of these can lead to serious renal disease.

Management of the neurogenic bladder, therefore, has the primary objectives of maintaining continence, ensuring low bladder pressure (to avoid renal damage) and avoiding or minimising infection. Management options include intermittent urethral catheterisation, indwelling urethral or suprapubic catheterisation, timed voiding, use of an external catheter (for men), augmentation cystoplasty and urinary diversion. A number of pharmacological interventions including anticholinergic drugs are also used (Vickrey 1999), particularly in people with multiple sclerosis. The type, site and extent of neurological impairment, and the type of help available, will clearly influence the choice of management option.

Some of the above options have already been or are the subject of other Cochrane reviews (Brosnahan 2004; Niel-Weise 2003a; Niel-Weise 2003b; Yong 2003). The current review was therefore confined to the use of urinary catheters and external (sheath) catheters by people with neurogenic bladder dysfunction.

The aim of our review was to compare the effectiveness of these different management options for the neurogenic bladder in terms of urinary function (in both the short and long term), but taking account of other factors such as ease of use, comfort and cost, which may influence choice of catheter policy. Provided that a sufficient number of trials of adequate quality has been conducted, the most reliable evidence is likely to come from the consideration of all well-designed randomised controlled trials.

We hoped that providing an easily accessible, periodically updated, comprehensive systematic review of such trials would help not only to identify optimal practice, but to also highlight gaps in the evidence base.

OBJECTIVES

The primary objective was to determine the effects of different methods of managing long-term voiding problems (persisting after three months) with catheters in patients with neurogenic bladder.

Specific hypotheses to be addressed included:

- 1. that intermittent catheterisation is better than indwelling catheterisation;
- 2. that indwelling urethral catheterisation is better than suprapubic catheterisation;
- 3. that external (sheath) catheters are better than indwelling or intermittent urethral catheters;
- 4. that external (sheath) catheters are better than suprapubic catheters:
- 5. that intermittent catheterisation is better than timed voiding.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised and quasi-randomised controlled trials comparing methods of using catheters to manage urinary voiding in people with neurogenic bladder.



Types of participants

Adults in hospitals, nursing homes and the community with neurogenic bladder persisting after three months for whom catheters are an option for long-term management, whether or not they have had surgery or another invasive procedure.

Types of interventions

- Indwelling urethral catheter
- · Intermittent urethral catheter
- Indwelling suprapubic catheter
- Intermittent suprapubic catheter
- · Timed voiding
- · External (sheath) catheter

Types of outcome measures

The primary outcomes were episodes of urinary incontinence, urinary retention, urinary tract infection and long-term renal function. Other outcomes were as follows.

- Subjective/objective factors
 - · Patient comfort
 - · Patient satisfaction
 - Ease of use for patient
 - · Ease of use for carer
 - Sexual function
 - Incontinence/bypass leakage
 - Need to use supplementary pads/bed pads
 - Ease of use for practitioner
 - · Need to change catheter/sheath
 - · Number of catheters/sheaths used
 - · Length of time each catheter/sheath used
 - Compliance
- Quality of life
 - Generic QoL measures (eg MOS 36-item Short Form Health Survey (Ware 1992))
 - Psychological outcome measures (eg Hospital Anxiety and Depression Scale (Zigmond 1983))
- · Complications/adverse effects
 - Asymptomatic bacteriuria
 - Symptomatic urinary tract infections
 - Use of prophylactic antibiotics
 - Use of rescue antibiotics
 - Urethral strictures
 - Bladder or kidney stones
 - · Urgency/bladder spasms/detrusor overactivity
 - · Creation of false passages in urethra
 - Trauma to skin or urethra
 - Other (other than urinary tract infection)
- Economic outcomes
 - Costs of intervention(s)
 - Resource implications of differences in outcomes
 - Formal economic analysis (cost effectiveness, cost utility)
- Other outcomes

• Non-prespecified outcomes judged important when performing the review

Search methods for identification of studies

We imposed no language or other limits on the searches.

Electronic searches

This review has drawn on the search strategy developed for the Cochrane Incontinence 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 module in *The Cochrane Library*. The register contains trials identified from the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, MEDLINE In-Process, CINAHL and the handsearching of journals and conference proceedings. The Cochrane Incontinence Group's trials register was searched using the Group's own keyword system. The search terms used were: ({design.cct*} OR {design.rct*})

AND

({intvent.mech.cath*} OR	{intvent.mech.device*} OF	₹
{intvent.mech.sheaths.} OR	{intvent.prevent.antibiotics*}	OR
{intvent.prevent.antifect.*}		OR
{intvent.prevent.antiinfect.per	riurethralcare.}	OR
{intvent.prevent.AntiInfect.Ure	ethralMeatusCare.}	OR
{intvent.prevent.antiInfection.	.}	OR
{intvent.prevent.cath.stricture	e.} OR {intvent.prevent.clea	ning
fluids*})		
(All searches were of the keyw	vord field of Reference Manager	12,

The date of the most recent search of the Register for this review: 3 July 2013.

The trials in the Cochrane Incontinence Group Specialised Register are also partially contained in CENTRAL.

Searching other resources

Thomson Reuters).

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

- The reference lists of relevant articles were searched for other possible relevant trials.
- Consultants in Spinal Cord Injury Centres throughout the United Kingdom were contacted to ask for information about other possible relevant trials, published or unpublished.

In addition, it was intended that the files of the National Acute Spinal Cord Injury Study (NASCIS) in the USA would be searched for trials, along with any neurology-related abstracts presented at urology conferences (eg AUA, EAU, ICS). In the event, we discovered that the NASCIS covers only research into the treatment of spinal cord injury *per se.* We were advised by experts in the field that searching the neurological abstracts was therefore unlikely to uncover trials fulfilling our inclusion criteria.

Data collection and analysis

The lead reviewer (JJ) and one of the coreviewers (JMcC) independently assessed all titles and abstracts identified by the search. Where there was any possibility that the study might be included, the full paper was obtained.



It was planned that these two reviewers would independently assess each report for inclusion and methodological quality using the Cochrane Incontinence Group's quality assessment tool.

Data were to be extracted by two reviewers and cross-checked. If the data in trials had not been fully reported, clarification was to be sought directly from the trialists.

It was planned that included trial data would be processed as described in the *Cochrane Reviewers' Handbook* (Clarke 2003). When appropriate, meta-analysis was to have been undertaken. For categorical outcomes, we were to relate the numbers reporting an outcome to the numbers at risk in each group to derive a relative risk (RR). For continuous variables, we were to use means and standard deviations to derive a mean difference (MD). A fixed-effect model was to have been used for calculations of pooled estimates and their 95% confidence intervals. If the data allowed, sensitivity analyses were to have been performed to assess the impact of study quality (eg quality of randomisation at allocation). Analyses of subgroups (eg males/females, different medical diagnostic groups

or individuals who had/had not undergone previous surgery or other invasive procedures for bladder outlet obstruction) were also to have been undertaken, if appropriate.

It was planned that trials would be compared to assess and investigate the likelihood of important clinical heterogeneity. This would also take into account the results of the Chi² test for heterogeneity at the 10% level and the I² statistic (Higgins 2003). Consideration was to have been given to using a random-effects model where there were concerns that heterogeneity might be complicating an analysis.

RESULTS

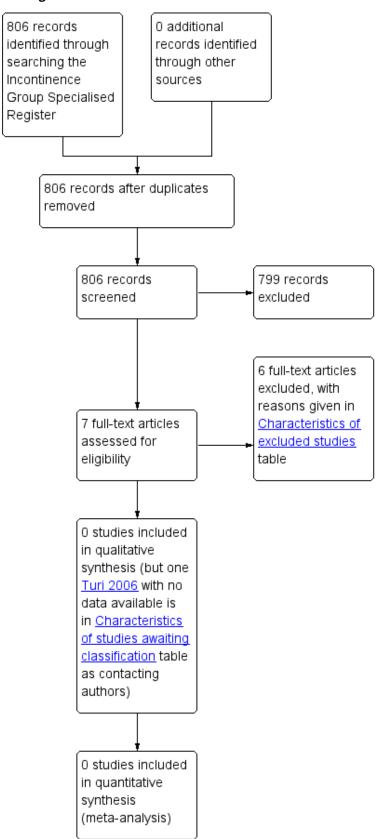
Description of studies

Results of the search

In total, 806 records were assessed for eligibility for this review. The flow of the literature through the assessment process is shown in Figure 1.



Figure 1. PRISMA study flow diagram.





1. Excluded studies

Six studies appeared to fulfil the eligibility criteria and the full-text articles were retrieved and given particular consideration. However, they failed to meet the inclusion criteria and were excluded (Faure 1980; Grundy 1983; Khan 2010; Piergiovanni 1991; Sethia 1987; Vandoni 1994). Descriptions of these studies with reasons for exclusion are given in the Characteristics of excluded studies table.

2. Studies awaiting assessment

One study (Turi 2006) is awaiting assessment. The details of the study are unclear and the authors have been contacted for further information.

3. Ongoing studies

No ongoing studies were identified.

4. Included studies

No studies meeting the a priori inclusion criteria were identified.

Risk of bias in included studies

No randomised or quasi-randomised controlled trials were found and therefore no studies were assessed for methodological quality.

Effects of interventions

No randomised or quasi-randomised controlled trials were found and therefore no analyses were carried out.

DISCUSSION

This review has highlighted a lack of research in the area of catheter policies for people with neurogenic bladder. We found no randomised or quasi-randomised controlled trials comparing catheter methods for managing voiding problems experienced by such people. There were a number of trials comparing intermittent and urethral catheterisation in patients who had undergone surgery or who were in the acute phase following SCI. There were also trials comparing clean and sterile means of undertaking urethral catheterisation. However, none of these trials provided any evidence in relation to the topic of this review.

We found a systematic review of risk factors for urinary tract infection in adults with spinal cord dysfunction (Shekelle 1999). This review included controlled clinical trials, and cohort and cross-sectional studies, and included method of drainage as a risk factor. Three controlled clinical trials (including two randomised

controlled trials) were found relating to method of drainage. However, these were comparisons of types of intermittent catheter or of clean versus sterile catheterisation.

The Shekelle 1999 review found eight prospective cohort studies comparing catheter policies in adults with spinal cord dysfunction (eg bladder retraining versus intermittent catheterisation, indwelling versus intermittent catheterisation, use of condom catheter versus intermittent catheterisation). The review noted that seven of these studies found that persons using intermittent catheterisation had fewer urinary tract infections than those with indwelling catheters. However, none of these studies had adjusted for differences in baseline characteristics.

We found a small number of trials comparing surgical and other invasive interventions (eg sphincterotomy) for DSD in people with neurogenic bladder. The choice of drainage method in such people is heavily dependent on whether any previous intervention has been undertaken, and this indicates that a systematic review of evidence relating to these interventions and associated catheter use should be carried out.

AUTHORS' CONCLUSIONS

Implications for practice

Despite a thorough search for evidence relating to the effectiveness of different catheter policies in adults with neurogenic bladder no evidence was found. This review cannot therefore offer any evidence-based guidelines for practice.

Implications for research

Catheter use in persons with neurogenic bladder is heavily influenced by prior surgical or other invasive intervention, by factors such as the dynamic nature of the pathophysiology of the neurogenic bladder, the degree of loss of neurological function, the availability of carers and above all by individual preference. Before proposing that randomised controlled trials be carried out in this area, we recommend that a further systematic review be conducted that would cover surgical and pharmacological interventions in the management of neurogenic bladder.

ACKNOWLEDGEMENTS

Assistance from the Editorial Base of the Cochrane Incontinence Group is gratefully acknowledged. Dr Jamison's participation in this review was funded through a Cochrane Fellowship from the Health Research Board, Ireland.



REFERENCES

References to studies excluded from this review

Faure 1980 {published data only}

Faure JJ, Retief PJM, Key AG. Urological management of the patient with spinal cord injury. *South African Medical Journal* 1980;**58**(17):682-6.

Grundy 1983 (published data only)

Grundy DJ, Fellows GJ, Gillett AP, Nuseibeh I, Silver JR. A comparison of fine-bore suprapubic and an intermittent urethral catheterisation regime after spinal cord injury. *Paraplegia* 1983;**21**(4):227-32.

Khan 2010 {published data only}

Khan F, Pallant JF, Pallant JI, Brand C, Kilpatrick TJ. A randomised controlled trial: outcomes of bladder rehabilitation in persons with multiple sclerosis. *Journal of Neurology, Neurosurgery and Psychiatry* 2010;**81**(9):1033-8. [SR-INCONT40030]

Piergiovanni 1991 {published data only}

Piergiovanni M, Tschantz P. Urinary catheterization: transurethral or suprapubic approach? [Sondage urinaire: voie transurétrale ou suspubienne?]. *Helvetica Chirurgica Acta* 1991;**58 (1-2)**:201-5.

Sethia 1987 {published data only}

Sethia KK, Selkon JB, Berry AR, Turner CM, Kettlewell MG, Gough MH. Prospective randomized controlled trial of urethral versus suprapubic catheterization. *British Journal of Surgery* 1987;**74**(7):624-5.

Vandoni 1994 {published data only}

Vandoni RE, Lironi A, Tschantz P. Bacteriuria during urinary tract catheterization: suprapubic versus urethral route: a prospective randomized trial. *Acta Chirurgica Belgica* 1994;**94**(1):12-6.

References to studies awaiting assessment

Turi 2006 {published data only}

Turi MH, Hanif S, Fasih Q, Shaikh MA. Proportion of complications in patients practicing clean intermittent self-catheterization (CISC) vs indwelling catheter. *JPMA - Journal of the Pakistan Medical Association* 2006;**56**(9):401-4. [SR-INCONT22267]

Additional references

Berkowitz 1992

Berkowitz M, Harvey C, Greene CG, Wilson SE. The Economic Consequences of Traumatic Spinal Cord Injury. New York: Demos Medical Publishing, 1992.

Bracken 1981

Bracken MB, Freeman DH, Hellenbrand K. Incidence of acute traumatic spinal cord injury in the United States. *American Journal of Epidemiology* 1981;**133**:615-22.

Brosnahan 2004

Brosnahan J, Jull A, Tracy C. Types of urethral catheters for management of short-term voiding problems in hospitalized adults. *Cochrane Database of Systematic Reviews* 2003, Issue 4. [DOI: 10.1002/14651858.CD004013]

Clarke 2003

Clarke M, Oxman AD. Analysing and presenting results. Cochrane Reviewers Handbook 4.2.0, Section 8 [updated March 2003] 2003 URL: http://www.cochrane.org/cochrane/hbook.htm.

Higgins 2003

Higgins JPT, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *British Medical Journal* 2003;**327**:557-60.

Niel-Weise 2003a

Niel-Weise BS, van den Broek PJ. Urinary catheter policies for short-term management of voiding in hospitalised adults. *Cochrane Database of Systematic Reviews* 2003, Issue 2. [DOI: 10.1002/14651858.CD004203]

Niel-Weise 2003b

Niel-Weise BS, van den Broek PJ. Urinary catheter policies for long-term management of voiding in adults. *Cochrane Database of Systematic Reviews* 2003, Issue 2. [DOI: 10.1002/14651858.CD004201]

Shekelle 1999

Shekelle PG, Morton SC, Clark KA, Pathak M, Vickrey BG. Systematic review of risk factors for urinary tract Infection in adults with spinal cord dysfunction. *Journal of Spinal Cord Medicine* 1999;**22**(4):258-72.

Vickrey 1999

Vickrey BG, Shekelle P, Morton S, Clark K, Pathak M, Kamberg C. Prevention and Management of Urinary Tract Infections in Paralysed Persons. Evidence Report / Technology Assessment No. 6 (AHCPR 99-E008). Rockville, MD: Agency for Healthcare Research and Quality, 1999.

Ware 1992

Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Medical Care* 1992;**30**(6):473-83.

WHO 2008

World Health Organization, Multiple Sclerosis International Federation. Atlas: Multiple Sclerosis Resources in the World: 2008. Geneva: World Health Organization (WHO), 2008.

Yong 2003

Yong SM, Dublin N, Pickard R, Cody J, Neal DE, N'Dow J. Urinary diversion and bladder reconstruction / placement using intestinal segments for intractable incontinence or following cystectomy. *Cochrane Database of Systematic Reviews* 2003, Issue 1. [DOI: 10.1002/14651858.CD003306]



Zigmond 1983

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

CHARACTERISTICS OF STUDIES

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion	
Faure 1980	Not an RCT. 515 patients with spinal cord injuries admitted to a specialist centre over a 3-year period were studied. Intermittent catheterisation was used in those assessed as having incomplete lesions (n = 296), and indwelling catheterisation in those with complete lesions (n = 219). "A random group" of 24 male patients with complete lesions had suprapubic catheterisation. No comparisons between those with suprapubic and urethral catheterisation were reported.	
Grundy 1983	RCT, but patients studied were in the acute stage following spinal cord injury.	
Khan 2010	RCT, but randomisation was performed on 101 patients with multiple sclerosis of whom only a subset (n = 74) had bladder symptoms.	
Piergiovanni 1991	RCT, but patients requiring catheter drainage did not have neurogenic bladder. French language.	
Sethia 1987	RCT, but patients requiring catheter drainage did not have neurogenic bladder.	
Vandoni 1994	RCT, but patients requiring catheter drainage did not have neurogenic bladder.	

RCT = randomised controlled trial.

Characteristics of studies awaiting assessment [ordered by study ID]

Turi 2006

Methods	Use the term "randomised study" but also states that "forty consecutive patients were included in each group", so not entirely clear.	
Participants	80 participants (40 in each arm), aged 15 to 80 years, 73 male and 7 female with symptoms of bladder outlet obstruction. In Group A, 25 participants had neurogenic bladder and 15 participants had benign prostatic hyperplasia (BPH) "but were not operated due to high surgical risk". In Group B, 35 participants had neurogenic bladder and 5 had BPH "not operated due to high surgical risk". Recruited from November 2003 to April 2004, in Karachi, Pakistan.	
Interventions	Clean intermittent self-catheterisation (Group A) versus indwelling catheters (Group B).	
Outcomes	Symptomatic infections and complications.	
Notes	Have attempted to email and write to authors but no reply so far.	

WHAT'S NEW



Date	Event	Description
3 July 2013	New citation required but conclusions have not changed	Search updated. No new trial identified.
3 July 2013	New search has been performed	Search updated. No new trial identified.

HISTORY

Protocol first published: Issue 3, 2003 Review first published: Issue 2, 2004

Date	Event	Description
1 November 2011	New search has been performed	Search updated up to 1st November 2011
1 November 2011	New citation required but conclusions have not changed	Search updated up to 1st November 2011
16 September 2008	Amended	Converted to new review format.
28 March 2007	New search has been performed	minor update
25 February 2004	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

All reviewers contributed to writing the text of the review. JJ and JMcC independently assessed all titles and abstracts.

DECLARATIONS OF INTEREST

None known

SOURCES OF SUPPORT

Internal sources

• No sources of support supplied

External sources

- Health Research Board, Ireland.
- The National Institute for Health Research (NIHR), UK.

 $The \ National \ Institute \ for \ Health \ Research \ (NIHR) \ is \ the \ largest \ single \ funder \ of \ the \ Cochrane \ Incontinence \ Group.$

INDEX TERMS

Medical Subject Headings (MeSH)

Urinary Bladder, Neurogenic [*therapy]; Urinary Catheterization [instrumentation] [*methods]

MeSH check words

Adult; Humans