Clean intermittent catheterization

presented by Pejman Pourshabanan

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دوشنبه، 06 نوامبر 2023

Millions of people have difficulty in emptying their urinary bladder resulting in urinary retention or clinically significant post void residue (PVR).

Urinary retention or significant urinary residue is due to lower urinary tract dysfunction, which can be caused by well-known neurological diseases like spinal cord injury (SCI) or multiple sclerosis, or in some cases it can be idiopathic.

A considerable number of individuals living with <u>neurogenic lower urinary</u> <u>tract dysfunction (NLUTD)</u> rely on <u>intermittent catheterization (IC)</u> for their bladder management. Currently, there is much debate over which type of catheter – <u>single-use</u> or <u>reusable</u> – provides the safest and most effective management solution, whilst minimizing cost and environmental impact. This article considers the current landscapes for single-use and reusable catheters.

NLUTD is a consequence of various neurological disorders, such as spinal cord injury (SCI), multiple sclerosis (MS), stroke, dementia, spina bifida (SB), and peripheral neuropathy, such as diabetes mellitus .The extent of NLUTD depends on the location (e.g., brain region or spinal cord level) and severity of neurological impairment.

Common symptoms of NLUTD include urinary incontinence, urinary retention, and/or changes in bladder and urethral sensations.

The Global Burden of Disease study (2016 data) has shown that neurological disorders are the leading cause of disease burden on a global scale, with stroke being the largest contributing factor.

With an aging population and an increase in the number of individuals affected by neurological disorders, this global burden continues to grow, posing a challenge to healthcare systems, many of which are already overstretched.

Neurological disorder	Global frequency of disorder	Frequency of urinary tract disorders*	Rate of IC use
Spinal cord injury	13 per 100,000 people (incidence) [†] (7)	82% of individuals have LUT symptoms or managed NLUTD (8)	45% of individuals with SCI are using IC (9)
Multiple sclerosis	44 per 100,000 people (prevalence) (10)	32-96% of individuals experience NLUTD symptoms depending on disease severity (1)	8% of individuals with MS use IC, if including both past and present use, it is 21% (11)
Stroke	203 per 100,000 people (incidence) [†] (7) >50% of individuals report urinary incontinence during the acute phase (1) vehabilitation phase (12)		Use of intermittent catheters is a viable option for some individuals following stroke in the early rehabilitation phase (12)
Dementias (including Alzheimer's disease)	712 per 100,000 people (prevalence) [†] (7)	11-93% of individuals with dementia experience urinary incontinence (13, 14)	Cognitive dysfunction is a major barrier to learning IC (15). Number of individuals using intermittent self-catheterization or assisted IC is unknown
Spina bifida	33.86 per 100,000 live births (prevalence) [‡] (16)	>90% experience NLUTD (1)	89–100% of individuals with spina bifida use IC (17)
Diabetes mellitus	10.5% of adult population ^{\$} (18)	62% of individuals have NLUTD ⁵ (19)	Diabetic cystopathy typically appears when the disease is in its advanced stage (19), for those who cannot empty their bladder, IC is recommended (20)

TABLE 1 Epidemiology of neurological conditions underlying urinary tract disorders.

*Data are from heterogeneous sources and, therefore, may vary across different geographical locations. [†]Age-standardized rate (2016 data). [‡]Data from geographical regions where folic aci fortification was mandatory at the time of data collection. [§]Aged 20–79 years. [§]NLUTD caused by diabetic peripheral neuropathy.

IC, intermittent catheterization; LUT, lower urinary tract; MS, multiple sclerosis; NLUTD, neurogenic lower urinary tract dysfunction; SCI, spinal cord injury.

Clean intermittent catheterization as standard of care for the management of NLUTD

Clinical guidelines recommend IC as the gold standard treatment for individuals with NLUTD with sufficient dexterity, who are unable to empty their bladder. IC is a widely available and minimally invasive technique that aims to promote an individual's independence and improve their HRQoL.

To empty the bladder, the treatment of choice is clean intermittent self-catheterisation (CISC) or, clinically less preferred, an indwelling catheter. Patients administer CISC usually 4–6 times a day, keeping the catheterised volume preferably below 400–500 mL .

In the Netherlands, virtually all patients on CISC use single use (=disposable) catheters, which is in contrast to several high income non-European countries like Japan, Canada and Australia. In those countries, single use and reusable catheters are both used for CISC. Clean intermittent self catheterisation (CISC) is performed by patient him/herself using a clean technique. It has been identified as the gold standard for the management of urinary retention/incomplete bladder emptying.

Advantages of CISC:

- CISC is a safe and effective alternative to indwelling catheter.
- CISC provides adequate drainage of the bladder, and prevents urinary incontinence and recurrent urinary tract infections in patients with diabetic neuropathy, bladder outlet obstruction5 and large bladder diverticulum.
- It can be used for regular bladder drainage for neurogenic bladder, spinal injury and multiple sclerosis, as it reduces intravesical pressure and upper urinary tract changes and kidney damage.

Indications for CISC:

- Urethral stricture narrowing of the urethra.
- Detrusor dysfunction neurological, idiopathic disorders
- Bladder outlet obstruction benign prostate hyperplasia, urethral stricture, bladder neck and meatal stenosis
- Post urinary bladder reconstruction, such as formation of neobladder and mitrofanoff procedure

Indications for CISC

• Urinary retention following surgery to restore continence can impair bladder emptying and anaesthetic technique may result in acute urinary retention.

Procedures for reducing stress urinary incontinence introduce a degree of compression to the bladder outlet, while procedures for resolving urgency urinary incontinence aim to reduce intravesical pressure and increase functional bladder capacity.

Both of these can impair the ability of the bladder to empty, possibly leading to elevated residual volume.

Contra-indications for CISC

- Same contra- indications as for urethral catheterisation (pelvic injury, urethral trauma , mentally disturbed)
- High intravesical pressure (requires continuous free drainage to protect kidneys)
- Cognitive impairment
- Poor manual dexterity
- Urinary fistula

دوشنبه، 06 نوامبر 2023

Procedure

The total fluid intake for adults doing CISC should be 1500–2000mls daily unless on fluid restriction. Fluid should be given at a rate of 25–35ml/kg/day.

If patient can void, catheterisation should be performed after voiding, to obtain the accurate post void residual urine. Encourage patient to take adequate amount of fluids and avoid constipation. Instructions to assist performing self-intermittent catheterization are as follows :

For men

Once all equipment (ie, catheter, lubricant, drainage receptacle) is assembled and the hands are washed thoroughly with soap and water, clean the urethral meatus with soap and water.

Lubricate the catheter and gently insert into the urethra with the penis positioned perpendicular to the body.

INSTRUCTIONS FOR MEN

Wash your hands thoroughly with soap and water. Sometimes it could be worthwhile to try to wee on your own before CIC (Clean Intermittent Catheterisation).





Gently pull your foreskin back (if you have one). Hold your penis up towards your stomach. In this position, yout urethra is extended and becomes U-shaped. This will make it easier to guide your catheter into your bladder.

Hint – do not squeeze your penis too hard, as this can block the opening of the urethra.

Slide your catheter slowly and smoothly into the opening of your urethra and into your bladder until the urine starts to flow.

Hint – to make it easier to insert the catheter, it may be helpful to cough or to try to pass urine.

Point your penis and the funnel end of the catheter down towards the toilet, jug or drainage bag. Hint – once the urine has started to drain, try to keep the catheter as steady as possible as it may take some time for your bladder to drain.

Empty your bladder completely. Avoid urinary infections by making sure to completely empty the

bladder each time. Once the urine flow stops, it could be because the eyes of the catheter are above the urine level in the bladder. To make sure you have emptied your bladder completely, remove the catheter slowly/stepwise and stop if more urine starts to flow.

When the bladder is empty, hold your penis up toward your stomach again and withdraw the catheter slowly.

Hint – pinch or fold the catheter so that the last few drops remains in the catheter.

End the procedure by washing your hands once more.















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For men:

As resistance is felt at the level of the prostate, relax and breathe deeply, then continue to advance the catheter. Once the urine starts to flow, continue to advance the catheter another inch. Hold the catheter in place until the urine flow stops and the bladder is empty. Remove the catheter slowly to allow complete drainage of the bladder. Instructions to assist performing self-intermittent catheterization are as follows :

For women

Assemble all equipment and wash the hands with soap and water. Clean intermittent catheterization can be performed in any comfortable position; however, many women find it easiest to stand with one foot on the toilet.

Clean the vulva with soap and water. With the nondominant hand, spread the labia with the second and fourth finger, using the middle finger to locate the urethral opening, which is below the clitoris and above the vagina.

INSTRUCTIONS FOR WOMEN

Wash your hands thoroughly with soap and water. Sometimes it could be worthwhile to try to wee on your own before CIC (Clean Intermittent Catheterisation).

Chose a position that is most comfortable. During the learning period it is important to find the one that suits you best. You can sit on a toilet, on the side of a bed or on a chair. Try pushing your pelvis forward as much as possible to get a better view. Hint - to start with, it can be helpful to use a mirror to find the opening of your urethra. However over the long-term, it will be better for you to feel your way to allow for greater flexibility.







Take the catheter out of the package. With the index and middle finger of one hand, spread the labia apart and lift it gently upwards.

You should now be able to see the opening of your urethra.

Hint - do not worry if you cannot find your urethra the first time. Try to relax and take a break if you need to.

With your other hand, slowly push your catheter into your urethra until the urine starts to flow. Make sure the funnel end is pointing into a toilet, jug or drainage bag.

When the urine starts to flow, push the catheter a further one or two cm to make sure that it is fully inside the bladder. You can now let go of your labia to free up your other hand.

Once the urine flow stops, it could be because the eves of the catheter are above the urine level in the

bladder. To make sure you have emptied your bladder completely, remove the catheter slowly/ stepwise and stop if more urine starts to flow.

Hint - it can sometimes be easier to hold like you would a pen. This can make it easier to insert. Once the urine has started

to drain, try to keep the catheter as steady as possible as it may take some time for your bladder to drain.

When the bladder is empty withdraw the catheter slowly.

Hint - pinch or fold the catheter so that the last drops remains in the catheter.

End the procedure by washing your hands once more.















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For women

Gently insert the catheter into the opening with the dominant hand. Guide the catheter toward the umbilicus (ie, belly button). Urine will begin to flow when the catheter has been inserted two to three inches. Advance the catheter another inch and hold it in place until the urine flow stops and the bladder is empty. Remove the catheter slowly to allow complete drainage of the bladder.

Frequency of CISC

The frequency of CISC is documented in a medical order.

For a patient with urinary retention, a bladder diary is an invaluable tool for review of frequency of procedure.

Frequency of CISC should be based on the bladder diary, which records the urine voided and post- void residuals (PVRs) via the catheter (catheter residuals).

Frequency of CISC

The frequency of CISC is based on the impact to the person's quality of life, bladder diary (frequency –volume chart); functional bladder capacity and post void residual; to avoid a bladder urine volume greater than 500ml.

• If the patient is unable to void at all, CISC should be performed 4–6 times per day with urine volume 300–500ml.

Frequency of CISC

 If the patient is voiding, the frequency of CISC should be based on maintaining post- void residual of less than 500ml (Vahr et al, 2013). The American Urologic Association recommends that patients should keep bladder volumes less than 500ml in order to present Kidney function and prevent UTIS.

• For self- urethral dilation, the frequency depends on voiding function (e.g. initiation, stream, hesitancy). The procedure is titrated accordingly from daily to monthly.

Possible complications

Catheter associated urinary tract infections (CAUTI)

Bacteriuria is estimated at 1–3% per catheterisation. For people with spinal cord injury or disorders, asymptomatic bacteriuria is as high as 60% in CISC users, with an average 2.5 episodes of CAUTI per year.

Dipstix urinalysis to detect infection has limited value, due to uncertainty in the performance of procedure. If the patient is symptomatic, urine culture is required.

Possible complications

Catheter associated urinary tract infections (CAUTI)

Commonly prophylactic antibiotic is not recommended, only symptomatic CAUTI requires treatment. (Symptomatic UTI: urine with 10x 5 CFU/ mL + at least one of the following symptoms: fever, chills, pyuria, haematuria, increased spasm or autonomic dysreflexia.

Other infections

Other infections included epididymo - orchitis, urethritis and prostatitis.

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Possible complications Trauma

- bleeding
- urethral false passage
- urethral stricture
- bladder perforation
- meatal stenosis.

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Preventive measures

• Fluid intake – adequate fluid should be consumed to produce 1200 ml urine/day unless contraindicated. Patients should avoid excessive fluid intake that may cause bladder overdistension.

• Maintain the recommended frequency of CISC to prevent urine stagnation and bladder distension.

Preventive measures

- Perform proper hand hygiene
- Gentamycin washout may be used to reduce UTI in CISC patients in a U.S. study, a six-month follow up of 22 neurogenic bladder patients who were practising IC after introducing daily gentamycin instillation, showed fewer UTIs, fewer oral antibiotic prophylaxis and treatment. Note nursing staff should adhere to NSW Health and local antibiotic stewardship policies.

Catheters and other equipment⁶

Size	Retention	female: size 12–14 Fg male: size 12–14 Fg can use both size 12 or 14 Fg for retention (the smaller the catheter, the less risk of trauma)	
	Strictures	female: size 14–16 Fg male: size 16–18 Fg	
Length		Female: approximately 7–22cm Male: approximately 40cm In meatal dilation, a female length can be used	
Material types		PVC, silicone, glass	
Catheter set		Catheter and lubricant/activator (e.g. water to activate hydrophilic function) with drainage bag	
Types		Single use catheters: Nelaton, pre-lubricated, no-touch, hydrophilic Reusable catheters: Cliny, Glass	
Other (aids, etc)		clothing holder, leg mirror, urine container	

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Reuse of catheters for the purpose of IC has been popular and widely used. Although this has been more common in developing countries, it has been reported to be practiced by more than 35% of patients in North America.

Despite this common use, the evidence on the prevalence of UTIs associated with repeated use of a catheter is conflicting.

Aside from questionable cleaning methods, it is unclear how long a multiple-use catheter can be reused. With the level of variation observed across clinical trials, it is likely that similar, if not more variation can be expected in public use.

Reusable catheters as a solution for the management of NLUTD

Whether the incidence of UTIs is affected by the type of catheter remains a matter of debate. Some studies suggest that the use of hydrophilic-coated catheters considerably lowers the risk of UTIs versus other catheters.

Hydrophilic-coated catheters have also been reported to be cost-effective compared with uncoated catheters .

In contrast, a retrospective study of individuals with SCI in the US found that a shift from reusable to single-use catheters did not decrease hospitalizations for genitourinary symptoms, including UTIs .

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Cleaning methods

If reusable urinary catheters are to be used for IC, the method of sanitation becomes particularly important.

Several methods have been reported in the literature, including: cleaning with antibacterial soap and water; alcohol sterilization; using aseptic solutions, such as chlorhexidine 1.5% and cetrimide 15%, microwave sterilization; or simply rinsing with water and combinations of these methods.

Cleaning methods

A literature review in 2014 could not recommend a standardized method for cleaning reusable catheters and to our knowledge, no randomized controlled trials have compared the efficacy of different cleaning methods since then.

Although a systematic review published in 2017 referred to two articles that recommended a sterile (aseptic) technique, neither this review nor the Cochrane review provided any statistically significant recommendation on cleaning standards.

IC can be done using different techniques:

- Sterile technique the bladder is emptied via an in & out catheter during surgery in an operating room.
- Aseptic technique an in & out catheter is inserted in the hospital setting. To minimise cross infection, all equipment used are sterile. This includes a sterile catheter, sterile lubricant and sterile gloves. The meatal/genital area is cleansed using disinfectant and dressing forceps

• No-touch technique – an aseptic procedure is used with a ready-to-use catheter. A pull-in- aid or finger- grip device is used to hold the catheter.

• Clean technique – the patient or caregiver performs this in the home or community setting using standard meatal/genital hygiene. A disposable or cleansed reusable catheter is exposed to homogenous bacteria, which do not routinely cause symptomatic urinary tract infection.

Preventive measures

- Consumption of cranberry capsules/juices to prevent bacteria growth in the urethra and bladder
- Lactobacillus (yoghurt) to prevent E . Coli growth in the urethra
- Hiprex and Vitamin C to acidify urine and prevent bacterial growth
- Change the catheter type to single use, no- touch, hydrophilic.
The lack of evidence-based recommendations is sure to confuse the general public and alter their adherence to cleaning methods.

These facts suggest single use of catheters as a potential remedy. It is also important to consider the effects that cleaning and repetitive uses can have on catheters. The American Urological Association (AUA) white paper on catheter-associated UTIs provides no recommendation on cleaning the reusable catheters, stating that HC catheters may be preferable to standard UC catheters; nevertheless, as of April 2008, both Medicare and Medicaid fully reimburse for single-use catheters, in the U.S. in quantities that allow for use of a new catheter several times per day.

This is consistent with the results of many health-economic studies indicating the cost-effectiveness and improved QoL associated with single-use catheters.

The European Association of Urology (EAU) recommends aseptic IC for patients with NB. Their definition of aseptic IC refers to genital disinfection and using <u>sterile</u> catheters, instruments, and gloves.

Given the difficulty of completely sterilizing catheters at home, and considering the challenge of keeping the sterility with reusable catheters, specifically for neurologically impaired patients, single-use catheters remain the only realistic option. The Society of Urologic Nurses and Associates (SUNA) specifically recommends that a new catheter be used for each Catheterization.

The European Association of Urology Nurses (EAUN) states that the gold standard remains a single-use sterile catheter and highlights concerns about the cleaning efficacy and compliance associated with multiple-use catheters. The current Canadian Urological Association (CUA) recommendations for male and female CIC are to use a catheter for a week or until physical damage is noticed.

The wording specifically used for female CIC specifies that "a catheter can be reused and cleaned for about a week or so." This language is vague and leaves much to patient interpretation, the result of which can be unsafe practices.

The recommended CUA cleaning protocol is to clean the catheter immediately after use with hand or dish soap and air dry.

The CUA stands out with recommendations that specifically support the multiple use of intermittent catheters in direct contradiction with what is supported by other North American and European organizations.

The recommendation for reuse of single-use catheters also contravenes the Health Canada labelling for single use of these catheters.

Considering the emergence of new evidence supporting single-use catheters, the CUA stands alone with the position on multiple catheter use.

Due to exponential population growth, there is an ongoing increase in healthcare use, and the consequential rising costs and environmental waste are a widespread concern.

The global urinary catheter market size was valued at US\$4.65 billion in 2020, with gradual growth in future perspective. The majority of this market is formed by intermittent single use catheters, which are accountable for around 60% of the market.

The use of disposable catheters in the Netherlands increased substantially in the past two decades from 15 000 users to 46 000 users, resulting in an expenditure of 74 million euros in 2018.

The rising costs and environmental pollution are reasons to reduce the use of disposable catheters. Reusable catheters could be a potential cost and waste reduction opportunity.

Other possible advantages of the reusable catheters include increased patient choice and reducing fear of running out of catheters. Several healthcare insurances, provide up to four catheters a day, which is often not sufficient for the needs of all patients. This potentially introduces stress for the patients due to fear of not having enough catheters and does not stimulate the quality of life (QoL) of patients. Additionally, it is clear that storage of large amounts of catheters, or travelling with a stock of catheters, is not ideal for patients. The current guideline of the European Association of Urology Nurses on intermittent catheterisation discusses the possible advantage in favour of the single use catheters based on low (grade 4) level of evidence, mainly concerning the efficacy of cleaning catheters by different methods.

Other guidelines from the European Urology Association (EAU) and the Dutch society for geriatric specialists (Verenso) do not discuss differences between single use and reusable catheters for CISC.

The available literature on the differences in safety and efficacy between single use and reusable catheters is conflicting and of low level of evidence. On the one hand, it has been suggested that reuse of catheters introduces unwanted bacterial contamination and therefore increases the risk of symptomatic urinary tract infections (sUTIs) and other complications, like stone formation and urethral strictures. On the other hand, evidence in patients on CISC suggest that reusable catheters are as safe and effective as single use catheters. Prieto *et al reported in their Cochrane analysis of 2021 that they* are uncertain whether there is any difference between single use and multiple-use catheters in the risk of sUTIs because the certainty of the evidence is low.

Consultant physicians are willing to prescribe reusable catheters or a mixture of single use and reusable, if the use is substantiated by evidence. In view of the lack of this evidence, clinical research is recommended to investigate if the use of reusable catheters are not less safe than single use catheters. We designed this randomised controlled non-inferiority trial to answer this question.

Clean intermittent urethral catheterisation in adults

GUIDE

SEPTEMBER 2019

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Intermittent catheterisation (IC), also known as 'in & out' catheterisation, is the insertion and removal of a urinary catheter to empty the bladder via the urethra or other catheterisable channel (such as a stoma or Mitrofanoff continent urinary diversion).



TYPE Perspective PUBLISHED 28 March 2023 DOI 10 3389/fruro 2023 1158260

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OPEN ACCESS

EDITED BY Charles Hubscher, University of Louisville, United States

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Intermittent catheterization: A patient-centric approach is key to optimal management of neurogenic lower urinary tract dysfunction

دوشنبه، 06 نوامبر 2023

- NLUTD has been shown to have a significant socio-economic burden, while also having a considerable negative impact on an individual's health-related quality of life (HRQoL).
- A Danish registry study has demonstrated a significantly greater number of total hospitalizations, outpatient visits and primary healthcare contacts, and longer inpatient stays during the first year after a diagnosis of NLUTD in individuals with SCI or MS versus controls from the general population (matched by age, gender, marital status, municipality, and education; all p<0.05).

The burden specifically due to lower urinary tract (LUT) and bowel complications was also significantly increased .These complications often required hospitalization and antibiotic therapy .

Furthermore, earned income was reduced by up to threefold versus matched controls, which was countered by an increase in income transfer payments, mainly in the form of disability pension and sick pay .

Neurological disorders and associated NLUTD can restrict many aspects of an affected individual's life .

For example, individuals with MS, SCI, or stroke who are experiencing NLUTD compared with neurologically intact individuals with normal independent bladder function, reported poorer HRQoL in terms of their physical, mental, and sexual health, and in other important aspects of life, such as socializing and travel.

Improvements in HRQoL in these individuals can be achieved through effective management of NLUTD, with the goals of continence, voluntary bladder emptying (often with IC), preserved renal function, and a low risk of urinary tract infections (UTIs).

If not addressed, UTIs can escalate to **urosepsis**, a severe medical condition that can be life-threatening and can have considerable negative impacts on individuals and healthcare . Crucially, for many individuals with NLUTD, effective management helps them to retain an element of independence in their everyday lives .

Since the 1970s, IC has been performed using a 'clean' technique, which involves hand washing, regular genital hygiene, and catheter cleaning before reuse .

Over the years, the practice of IC has evolved from reusable to single-use catheters, due, in part, to a lack of evidence on appropriate storage and cleaning procedures, a perceived increased risk of UTIs for reusable catheters, and a lack of certified and available reusable catheters in many countries.

Currently, there is no conclusive evidence that reusable catheters are as safe as single-use .

Given the complexity of underlying conditions of individuals who require management for NLUTD, there is no single type of IC that is suitable for all. Based on the current evidence available, hydrophilic single-use catheters are considered to be the optimal choice for management of NLUTD due to a reduced risk of UTIs, improved HRQoL, and individual preference.

Individual preference is likely to improve compliance with IC which, in turn, ensures long-term successful management of NLUTD .

However, depending on geographical location, access to specific types of catheters is limited by reimbursement policies, under-resourcing, and issues with funding . In the US, restrictions on the type of catheter available and on the quantities provided to users are important factors challenging the health and well-being of individuals with NLUTD .

Many private insurers do not provide enough catheters per month to cover the number of catheterizations needed each day and, consequently, people resort to reusing single-use catheters, even though this is considered 'off-label' use.

In Europe, only disposable single-use catheters are reimbursed .The situation is very different in developing countries where resources and funding are limited, which means that reusable or reuse of disposable catheters may be the only option available .

Recently published reports highlight a growing concern over the environmental impact of nonbiodegradable plastic waste resulting from the use of disposable, single-use catheters, including the products, packaging, manufacturing processes, and transportation. It has been suggested that this environmental impact may be alleviated by using reusable catheters.

Reusable catheters have also been advocated as a means of reducing the cost of managing NLUTD .

In an era where sustainability is a key focus for developed countries, and limited funding/access to healthcare resources remains a problem for developing countries, the value of disposable, single-use catheters is firmly under the spotlight .

Arguably, reusable catheters alleviate the environmental and economic pressures of catheterization, whereas single-use catheters address user comfort and the risk of UTIs; all of which are important considerations for individuals using IC. Presently the vast majority of IC are produced with single-use indication.

Reusing catheters requires appropriate, effective cleaning to reduce the risk of bacteria entering the bladder, and to avoid damaging the structural integrity of the catheter.

Various catheter cleaning methods have been evaluated but, as yet, no uniform clinical recommendations on how to clean and reuse catheters exist. Evidence on the safety and efficacy of different cleaning methods must be established to help guide future clinical guidelines.

Furthermore, the cleaning processes involved in using reusable catheters may not be achievable for all individuals with NLUTD, for example, individuals with cognitive impairment, restricted hand dexterity, or limited access to clean water, and may represent an additional burden for caregivers.

Importantly, 'off-label' reuse of catheters that are intended and approved for single-use can, potentially, lead to unsafe practice, health risks, and other complications . It would also be prudent to consider the environmental impact of the cleaning fluids used in catheter reuse processes.

Until there is scientific evidence that reusable catheters are not inferior to singleuse with respect to long-term complications as mentioned previously, healthcare providers (HCPs) should continue to take a patient-centric approach to catheterization; choosing single-use or reusable catheters (once certified reusable catheters are available), or a combination of both, considering the specific requirements of each individual and their preferences for management of NLUTD.

Different groups may require different recommendations, but they all require a simple and easy solution that is not associated with any major risks (safety or otherwise). It is the role of the HCP to ensure that individuals are well-informed of the benefits and risks before starting IC. Furthermore, the choice of catheter should not be based on financial aspects at the detriment of safety.

CLEAN INTERMITTENT URETHRAL CATHETERIZATION IN ADULTS

CANADIAN BEST PRACTICE RECOMMENDATIONS FOR NURSES





Developed By Nurses Specialized in Wound, Ostomy and Continence Canada, Canadian Nurse Continence Advisors, Urology Nurses of Canada, and Infection Prevention and Control Canada.



دوشنبه، 06 نوامبر 2023

Clean (nonsterile) technique for intermittent catheterization is safe with lower complication rates compared with indwelling urethral or suprapubic catheterization

No differences in the incidence of asymptomatic bacteriuria or catheter-associated urinary tract infection have been found between sterile versus clean technique for intermittent catheterization, coated versus uncoated catheters, or single-use versus multi-use catheters. Compact catheters are available for use and may increase patient quality of life .

The technique for CIC is generally the same as for indwelling catheter placement except for the option for clean technique and the removal of the catheter following bladder drainage.

If the catheter is disposable, it is discarded immediately after use. Reusable catheters are also available and can be used for up to <u>four weeks</u>. Following catheterization, the reusable catheter is washed with soap, rinsed with water, dried, and stored in a clean, dry location.

Outpatient chronic CIC can be challenging for the patient. The patient must have appropriate cognitive and physical abilities to self-catheterize or an appropriately trained caregiver.
Single use versus reusable catheters in intermittent catheterisation for treatment of urinary retention: a protocol for a multicentre, prospective , randomised controlled, non-inferiority trial (COMPaRE)

دوشنبه، 06 نوامبر 2023

Chronic urinary retention is a common lower urinary tract disorder, mostly neurogenic or idiopathic in origin. The preferred treatment is clean intermittent urinary self-catheterisation (CISC) four to six times a day.

In most European countries, virtually all patients use single use catheters, which is in contrast to several countries where the use of reusable catheters is more common.

The available literature on the use of reusable catheters is conflicting and until now, no randomised controlled trial with sufficient power has been performed to investigate if reusable catheters for CISC is as safe as single use catheters.

Open access

Protocol

دو شنبه، 06 نو امبر 2023

BMJ Open Single use versus reusable catheters in intermittent catheterisation for treatment of urinary retention: a protocol for a multicentre, prospective, randomised controlled, non-inferiority trial (COMPaRE)

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To cite: van Doorn T,

Berendsen SA, Scheepe JR, et al. Single use versus reusable catheters in intermittent catheterisation for treatment of urinary retention: a protocol for a multicentre, prospective, randomised controlled, non-inferiority trial (COMPaRE). *BMJ Open* 2022;12:e056649. doi:10.1136/ bmjopen-2021-058849

 Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/ bmjopen-2021-058649).

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Received 01 September 2021 Accepted 22 March 2022

(F) Check for updates

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Introduction Orronic urinary retention is a common lower urinary tract disorder, mostly neurogenic or idiopathic in origin. The preferred treatment is clean intermittent urinary self-catheterisation (CISC) four to six times a day. In most European countries, virtually all patients use single use catheters, which is in contrast to several countries where the use of reusable catheters is more common. The available literature on the use of reusable catheters is conflicting and until now, no randomised controlled trial with sufficient power has been performed to investigate if reusable catheters for CISC is as safe as single use catheters.

ABSTRACT

Methods and analysis We described this protocol for a prospective, randomised controlled non-inferiority trial to investigate if the use of reusable catheters is as safe as single use catheters for CISC patients, measured by symptomatic urinary tract infections (sUTIs). Secondary objectives are adverse events due to a sUTI, urethral damage, stone formation, quality of life and patient satisfaction. A cost-effectiveness analysis will also be performed. 456 Participants will be randomised into two groups stratified for age, gender, menopausal status and (non-)neurogenic underlying disorder. The intervention group will replace the reusable catheter set every 2 weeks for a new set and replace the cleaning solution every 24 hours. The control group continues to use its own catheters. The primary outcome (amount of sUTIs from baseline to 1 year) will be tested for non-inferiority. Categorical outcome measures will be analysed using x² tests and quantitative outcome variables by t-tests or Mann-Whitney U tests. Two-sided p values will be calculated.

Ethics and dissemination This protocol was reviewed and approved by the Medical Ethics Committee of the Erasmus MC (MEC 2019-0134) and will be performed according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist for non-inferiority trials. The results of this randomised controlled non-inferiority trial will be published in a peer-reviewed journal and will be publicly available. Trial registration number NL8296.

Strengths and limitations of this study

- This protocol describes a prospective, randomised controlled, non-inferiority study and will provide information regarding the safety, effectiveness, patient satisfaction and costs-effectiveness of musable catheters in comparison to single use catheters in patients on clean intermittent urinary self-catheterisation (CISC) of the urinary bladder.
- It is the first study protocol with a sufficient sample size calculation able to detect non-inferiority for the reusable catheter measured by symptomatic urinary tract infections (sUTis).
- The definition of an sUTI is fully and clearly defined in this protocol.
- The steps involved in using the reusable catheter set are more time consuming. This might result in a higher dropout rate in the intervention arm.
- Non-interiority of the reusable catheter for sUT is has the following implications: increased patients choice and reducing fear of running out of catheters, a reduction in healthcare costs and plastic medical waste and the opportunity for patients in low income countries to perform CISC with a reusable catheter as the single use catheter at present is much too expensive for the healthcare systems in low-income countries.

BACKGROUND

Millions of people have difficulty in emptying their urinary bladder resulting in urinary retention or clinically significant post void residue (PVR).¹ Urinary retention or significant urinary residue is due to lower urinary tract dysfunction, which can be caused by well-known neurological diseases like spinal cord injury (SCI) or multiple sclerosis, or in some cases it can be idiopathic. To empty the bladder, the treatment of choice is clean intermittent self-catheterisation (CISC) or,

van Doom T, et al. BMJ Open 2022;12:x056649. doi:10.1136/bmjopen-2021-056649

Clean intermittent catheterization: Single use vs.reuse

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دوشنبه، 06 نوامبر 2023

Conclusion

Reuse of catheters exposes the patient to a plethora of possible cleaning techniques and duration of catheter use.

Patient adherence to cleaning method cannot be predicted and this further amplifies the risk of complications and their burden on the healthcare system.

Given the benefits of single-use catheters and all the uncertainties with reuse, we believe that repeated use of catheters should not be the preferred method for long-term bladder management.

Conclusion

Until more data becomes available, we <u>recommend a patient-centred</u> approach to consider HC catheters as the first option, while considering the patient's/caregiver's ability to accommodate the usage technique.

Single-use UC catheters, and finally reuse of catheters are considered as next options if HC catheters are found difficult to handle (especially in children doing self-catheterization).

Many Thanks For Your Attention

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دوشنبه، 06 نوامبر 2023