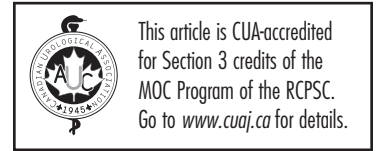


Clean intermittent catheterization: Single use vs. reuse



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Abstract

Introduction: Intermittent catheterization (IC) is one of the fundamental aspects of managing patients with chronic urinary retention. Although reuse of catheters has been allowed to be chosen as the first option for IC, the optimal method of IC and the type of catheter has been a long-standing debate. We conducted a literature review regarding risk of urinary tract infection (UTI) and the costs associated with different methods and catheters.

Methods: A MEDLINE search via PubMed, EMBASE, and EBSCO host was conducted in March 2018. The date of publication was limited to 2014 to present/current.

Results: Single use of catheters (hydrophilic-coated [HC] or uncoated [UC]) was considered to impose a lower risk of UTI in all studies, except in one study that included children, but did not test their dexterity to handle HC catheters. Cost-effectiveness of single-use catheters was confirmed by all studies during this period.

Conclusions: 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. We recommend a patient-centred 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). Larger trials investigating this matter are required.

Introduction

Intermittent catheterization (IC) is the recommended technique for bladder drainage in patients with chronic retention resulting from different causes, such as neurogenic bladder (NB).¹ Ever since the landmark paper was published by Lapidus et al² showing that clean intermittent catheterization (CIC) was possible, it has been widely used and preferred to an indwelling catheter.

For those electing to perform IC, there are two main options: either the traditional reuse of catheters with a form of cleaning between uses or single-use catheterization. Single-use catheters can be either uncoated (UC), such as those made of polyvinyl chloride (PVC), or they can be coated with hydrophilic or gel coverings.³ The main arguments in choosing between these options are risk of urinary tract infections (UTIs), uncertain cleaning methods, social issues, and finally the cost and quality of life (QoL).^{1,4}

Although single-use catheters have been introduced to decrease the risk of urethral trauma and UTI,⁵⁻⁸ comparing their outcomes with those of reusable catheters can be challenging. The difficulty in making a proper comparison between different methods of catheterization results from inconsistency of the literature regarding study population, UTI definition, type of catheter, cleaning methods, and frequency of catheterization per day. Furthermore, lack of long-term followup makes the decision-making more challenging.^{4,9-11} All these uncertainties have led many physicians and patients to reuse catheters.¹²

In 2014, a Cochrane systematic review was published by Prieto et al and supported the reuse of catheters. The authors concluded that multiple uses of a catheter does not impose a higher risk of UTI compared to single use.¹³ Since then, not only has more data become available, but also the abovementioned Cochrane review was withdrawn from publication due to an independent appraisal, which identified crucial discrepancies within this publication.^{14,15}

In order to draw a conclusion on whether reuse of catheters can still be considered the first option for CIC or not, this literature review was conducted on different IC methods regarding their risk of UTI and their associated costs.

Methods

A MEDLINE search via PubMed, EMBASE, and EBSCO host was conducted in March 2018. The following keywords were used: [{"intermittent catheterization*"} AND (reuse* OR re-use OR single-use)] or [{"intermittent catheterization*"} AND (reuse* OR re-use OR single-use)] or [{"intermittent catheter*"} AND (reuse* OR re-use)] or [{"intermittent

catheterization*) AND (coated OR uncoated)] or [(“intermittent catheterization”) AND (coated OR uncoated)] or [(“intermittent catheter”) AND (coated OR uncoated)]. The date of publication was limited to 2014 to present/current.

The results were reviewed to select the publications that addressed the relation between IC and clinical UTI or cost-effectiveness/QoL. After removing the duplicates, the non-English articles, the non-systematic reviews/commentaries, and congress presentation abstracts were excluded.

Results

Risk of UTI

Before discussing the risk of UTI, it is important to emphasize the difference between asymptomatic bacteriuria (ABU) and UTI. The former is defined as the presence of bacteria in the urine culture without any urinary tract symptoms, while the latter is a positive bacterial culture accompanied by urinary tract symptoms.¹⁶ Table 1 provides a breakdown

of the articles on the risk of UTI associated with different methods of catheterization.

Kanaheswari et al¹⁷ conducted a prospective crossover study among children with neurogenic bladder (n=40) and concluded that a longer duration of catheter reuse resulted in an increased prevalence of ABU, without changing the incidence of UTI. In this study, a comparison was made between weekly and triweekly catheter replacement over nine-week intervals. The 65% ABU noted at baseline increased to 74.2% during the triweekly CIC. This percentage plummeted to 34.2% when the catheter was changed on a weekly basis. There were no symptomatic UTIs over the 18 weeks of study in either group. However, the authors suggested that adherence to the cleaning technique might have been unusually high among the participants, impacting their findings. No comparison to single-use of catheters was made.¹⁷

A retrospective study by Krassioukov et al¹⁸ surveyed athletes with spinal cord injuries (n=61); they found that those who reused catheters experienced 4±3 UTIs per year, while the figures for single-users stood at only 1±1 UTI(s) per year. This association between catheter reuse and UTI

Table 1. Different methods of intermittent catheterization and associated UTI risk

Method of catheterization (comparator)	Author, date	Age (years)	Outcome	Type/ duration of study	Duration of use before disposal	Frequency of CIC
Duration of use (with multiple use of catheters)	Kanaheswari et al, 2014	1–18	Lower risk of ABU with shorter duration of use (Z-score 6.218; p<0.001)	Prospective 18 weeks	1 week (9 cycles) vs. 3 weeks (3 cycles)	At least 3 times per day
Single use vs. multiple use of catheters	Krassioukov et al, 2015	Paralympic athletes: 16–60	Lower risk of UTI with single use of catheter (p<0.001)	Retrospective (1year data)	2–200 times per catheter	6±2 times per day
Single use vs. multiple use of catheters	Christison et al, 2017*	Not specified	No significant difference	Appraisal of a Cochrane review	Variable	Variable
HC catheters vs. other catheters	Christison et al, 2017*	Not specified	Lower risk of UTI with HC catheters** (p=0.043)	Appraisal of a Cochrane review	Variable	Variable
Single use of HC vs. multiple use of other catheters	Håkansson, 2014	Not specified	Lower risk of UTI with single use HC catheter (20–30%)	Systematic review	Variable	Variable
Single use of HC (SpeediCath) vs. multiple use of PVC catheters	Kiddoo et al, 2015	6–18	Lower risk of UTI with multiple use of PVC catheters (p<0.001)	Prospective cross-over 24-week: HC catheter 24-week: standard PVC	1 day–1 week	3 or more times per day
Single use of HC vs. multiple use of PVC catheters	Rognoni and Tarricone, 2017*	Adult/ adolescent	Lower risk of UTI with single use of HC catheters (p=0.003)	Systematic review	Variable	4–5 times per day
Single use of HC (Lofric) vs. single use of UC	DeFoor et al, 2017	Children with dexterity	Lower risk of UTI with HC catheters (p=0.003)	Prospective RCT (1year)	Advised to use only once	3 or more times per day
Single use HC vs. single use non-HC	Rognoni and Tarricone, 2017*	Adult/ adolescent	Lower risk of UTI with single use of HC catheters (p=0.003)	Systematic review	Single	4–5 times per day
Prelubricated catheters (Instantcath) or those with AMC or those with introducer	Shamout et al, 2017	Adult	Lower incidence compared to standard catheters	Systematic review: 1 study on each topic was found	Variable	Variable

*This study provided two subanalyses and, therefore, has been repeated twice. **After UTI definition was adjusted, the difference between HC catheters and other catheters was no longer significant. ABU: asymptomatic bacteriuria; AMC: anti-microbial coating; CIC: clean intermittent catheterization; HC: hydrophilic-coated; PVC: polyvinyl chloride; RCT: randomized controlled trial; UTI: urinary tract infection.

was statistically significant ($p < 0.001$). Athletes from developing countries experienced higher UTI frequency compared to athletes from other countries ($p = 0.027$). This was explained by the fact that 73% of those from developing countries reused their catheter, while this was the method in only 17% of those from developed countries. The study also showed that catheterization frequency per day did not impact the UTI frequency. Compared to the previous study by Kanaheswari et al,¹⁷ this study might better account for the actual adherence to cleaning practices, simply due to its retrospective design.¹⁸

The discredited Cochrane systematic review, published in 2014, stated, "There is still no convincing evidence that the incidence of UTI is affected by use of aseptic or clean technique, coated or uncoated catheters, single (sterile) or multiple-use (clean) catheters, self-catheterization or catheterization by others, or by any other strategy."^{13,15} The ability of this publication to influence clinical practice raised many concerns, leading to an independent appraisal of this Cochrane review. This re-analysis revealed many flaws and as a result of all the raised concerns, the Cochrane review was withdrawn from publication.^{14,15} The reanalysis illustrated that if HC catheters are not considered separately, a small but non-significant trend in favour of single usage vs. reuse of catheters could be found (risk ratio [RR] 0.91; $p = 0.593$). When focusing on HC catheters, the appraisal showed a significant reduction in the incidence of UTI compared to other catheters (RR 0.81; 95% confidence interval [CI] 0.65–0.99; $p = 0.043$).¹⁵ An important consideration to mention is that if UTI definition was to be adjusted for, only two trials (from 1996 and 1999) could be considered for comparing HC catheters with other types and no significant difference was found regarding the incidence of UTI.^{14,15}

In the same year (2014), a narrative review of the complications associated with single- or multiple-use catheters was published. This review revealed that single-use HC catheters can reduce the risk of UTI by about 20–30%.³ Based on the observational studies, this review estimated the risk of UTI to be about 70–80% in those who reused their catheter, while the estimated risk with single-use catheters was about 40–60%, based on review of randomized controlled trials.³

Recently, more data has become available comparing HC catheters to other catheters. A prospective crossover trial conducted by Kiddoo et al compared single-use HC catheters and multiple-use PVC catheters in a pediatric and young adult population with NBs.¹⁹ Each treatment period was 24 weeks, for a total duration of 48 weeks. The study showed that the risk of UTI was higher with the single-use HC catheters as opposed to multiple-use PVC catheters (person-weeks of UTI were 3.42 ± 4.67 and 2.20 ± 3.23 , respectively; $p < 0.001$). The fact that 52% of the children in this study were self-catheterizing, along with challenges in learning how to use HC catheters might explain the increased person-weeks

of UTIs in the HC group and indicates the importance of catheter handling. Another explanation might be that the primary outcome of this study was not based on a standard definition of UTI; UTI was defined as positive leukocytes plus UTI symptoms (instead of positive bacterial culture).¹⁹

Comparing single usage of HC catheters with reuse of PVC catheters was also addressed in a recently published systematic review by Rognoni and Tarricone in adult and adolescent populations.²⁰ The frequency of UTI was shown to be lower with HC catheters (RR 0.84; 95% CI 0.75–0.94; $p = 0.003$ for both analyses) and the estimated risk reduction with HC catheters was found to be 16%.²⁰ The mean age in all of the studies included in this review was above 37 years, which can justify the different results observed by Kiddoo et al (mean age 10.6 ± 6.2 years).¹⁹

A prospective, randomized control trial published in 2017 compared the advantage of HC catheters against single use of UC catheters for one year.²¹ Interestingly, children were chosen as the target population, but the differences between this cohort and the population in the Kiddoo et al study¹⁹ is that dexterity testing of both hands was performed in this trial (if the child was self-catheterizing). It was illustrated that HC catheters were associated with a lower risk of UTI, even if the UC catheter was used only once and then discarded (9.1% vs. 51.5% UTIs per person-year; $p = 0.003$). Comparing the UTI rates during the year prior to the study with the rates during the study year showed that the HC group saw a drop from 16% to 5%, although this was not statistically significant. While the number of times that a UC catheter was used before being discarded is not clear in this study, the authors stated, "In our practice, uncoated catheters are 'one-time' use only and patients are never advised to wash and reuse their catheters."²¹

Further comparison of single-use HC and single-use non-HC catheters was addressed in a separate subanalysis of the previously mentioned systematic review by Rognoni and Tarricone. Once again, the frequency of UTI was lower with single-use of HC catheters (RR 0.84; 95% CI 0.75–0.94; $p = 0.003$ for both analyses), with the estimated risk reduction found to be 16%.²⁰

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.^{22–25}

A literature review in 2014 could not recommend a standardized method for cleaning reusable catheters³ 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,²⁶ neither this review nor the Cochrane review provided any statistically significant recommendation on cleaning standards.^{13,15}

Cost

The cost of single-use catheters has been one of their main drawbacks for a long time. From the perspective of the public payer, the out-of-pocket cost for these catheters can only be justified if it can offer good value regarding complications, expected life-years, and QoL. It should be emphasized that the QoL is affected by several health-related and non-health-related factors, such as UTI, pain, discomfort, time spent on catheterization, and social factors associated with catheterization. As cost-effectiveness and cost-utility are among the fundamental aspects of health economics, several authors have looked into this matter to assist both patients and policy-makers with their decisions.²⁷⁻³³

A cost-comparison analysis by Neovius et al showed that the catheter cost for single-use types was more than that of reusable types (€2188 vs. €817 per year and per patient). However, the annual cost imposed by catheter complications was lower in the single-use group. With the single-use catheters, complications such as UTI, antibiotic-resistant UTI, bacteremia, strictures, and bladder stones resulted in an annual cost of €1243, while the figures for reusable catheters stood at €2067 per patient. In other words, 60% of the extra cost of single-use catheters was compensated.³³

Watanabe et al²⁹ studied the cost-effectiveness of HC catheters for bladder management in spinal cord injury (SCI) patients in Japan. They used a modified Markov decision model and addressed direct medical costs, quality-adjusted life years (QALYs) and life years gained (LYG). In contrast to UC catheters, HC catheters resulted in 0.334 QALYs and 0.781 LYG at an incremental cost of ¥1 279 886 (\$10 578 USD at an exchange rate of \$1 USD=¥121) for HC catheters per SCI patient. The incremental cost-effectiveness ratio (ICER) of HC catheters vs. UC catheters was \$31 623 USD/QALY gained and \$13550 USD/LYG.

Clark et al published a paper comparing the cost-effectiveness of long-term IC with single-use HC catheters vs. single-use UC catheters.³² They developed a model based on the results published regarding IC in adults with SCI. UTIs and renal function were considered model health states. Their model predicted the life expectancy of a 36-year-old SCI patient who used HC catheters to be 1.4 years longer compared to those using UC single-use catheters (on average, another 23.9 years with HC catheters and 22.5 years with UC types). When the increased cost of HC catheters was factored in, the ICER was a gain of £6100 for each QALY. This cost is well within the thresh-

old for the National Institute of Clinical Excellence (NICE) in the U.K.³²

Using a modified version of the model developed in the previous study,³² cost-effectiveness of HC catheters was addressed in Canada.²⁷ This model predicted that in a 50-year-old patient with SCI, using HC catheters would lead to living 0.78 years longer and to the gain of an additional 0.72 QALYs compared to using UC. The incremental cost and ICER for this gain was \$48 016 CAD and \$66 634 CAD/QALY, respectively. Moreover, the lifetime risk of developing UTI in these patients was estimated to be 11% less with HC catheters compared to UC types. The authors concluded that reimbursement of HCIC catheters should be considered in these settings.

A similar study was conducted in Brazil and results were presented as cost per LYG, cost per QALY, and cost per number of avoided UTIs. The results revealed cost-effectiveness of HC catheters compared to UC PVC catheters per LYG (57 432 Brazilian Reais [BRL] equal to \$17 773 USD, at an exchange rate of 0.31) and per QALY (122 330 BRL, equal to \$37 857 USD). HC catheters showed the potential to reduce the lifetime number of UTIs by 6% at the cost of 31 240 BRL (\$9817 USD).³⁰

Cost-effectiveness of HC catheters has also been evaluated from the perspective of Italian Healthcare Service system. The base-case incremental cost-effectiveness and cost-utility ratios (ICER and ICUR) associated with HC catheters were €20 761 and €24 405, respectively. This implies that HC catheters are likely to be cost-effective in comparison to uncoated ones, as the proposed Italian threshold values range is between €25 000 and €66 400.³¹

Discussion

Reuse of catheters for the purpose of IC has been popular and widely used. Although this has been more common in developing countries,¹⁸ it has been reported to be practiced by more than 35% of patients in North America.³ Despite this common use, the evidence on the prevalence of UTIs associated with repeated use of a catheter is conflicting.^{9,10,12,34} 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. The lack of evidence-based recommendations is sure to confuse the general public and alter their adherence to cleaning methods.^{23,24} 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.^{18,22-25}

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;⁴ 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.³⁰⁻³³

The European Association of Urology (EAU) recommends aseptic IC for patients with NB. Their definition of aseptic IC refers to genital disinfection and using sterile catheters, instruments, and gloves.¹ 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.³⁵ The European Association of Urology Nurses (EAUN) states that the gold standard remains a single-use sterile catheter and highlights concerns about the cleaning efficiency and compliance associated with multiple-use catheters.³⁶

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.^{37,38} 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.

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.

Until more data becomes available, we recommend a patient-centred approach to consider HC catheters as the first option, while considering the patient’s/caregiver’s abil-

ity 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).

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This paper has been peer-reviewed.

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