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REVIEW ARTICLE

The microbiological and physical properties of catheters for intermittent catheterization: a systematic review on the impact of reuse and cleaning

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STUDY DESIGN: Systematic Review.
OBJECTIVES: To review systematically the clinical evidence of the effectiveness of various intermittent catheter cleaning methods that have been proposed as methods to prepare catheters for reuse.
METHODS: A keyword search in Medline, Excerpta Medica dataBASE, the Cumulative Index to Nursing and Allied Health Literature, Web of Science and Cochrane Central Register of Controlled Trials, was undertaken to identify all English, Russian and German language literature evaluating the effectiveness of various intermittent catheter cleaning methods. Studies selected for review included analytical experimental, prospective cohort and cross-sectional. Cleaning methods reviewed included heat-based sterilization, chemical cleaning solutions, mechanical abrasion, photocatalytic sterilization, and combined methods.
RESULTS: Overall, 12 studies were included. Heat-based sterilization and mechanical abrasion methods were either not effective or damaged the physical properties of catheters. Two studies reported evidence that their chemical cleaning methods (i.e., soaked catheters in a 70% alcohol solution for 5 min or combined approach detergent wash followed by soaking in Milton sterilizing fluid also known as the Milton method) both preserved the structural integrity of their catheters and were bactericidal.
CONCLUSIONS: Numerous cleaning methods resulted in the destruction of catheters. However, there are two reported cleaning methods, submersion for 5 min in 70% alcohol and the "Milton method", that eliminate bacterial colonization while leaving the physical properties of the catheters unchanged. While these cleaning methods are promising, each was published in just one study, therefore higher-powered / longitudinal studies confirming the safety and efficacy of these cleaning methods must be obtained before current clinical recommendations can be modified.

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INTRODUCTION

Intermittent catheterization (IC) is a method of urinary drainage commonly used by over 300,000 individuals in the United States with neurogenic lower urinary tract dysfunction (NLUTD) [1, 2], often because of a spinal cord injury (SCI). It is performed by inserting a catheter into the bladder via the urethra, allowing for the drainage of urine. Once the bladder is empty, the catheter is removed and discarded. IC was traditionally performed using an aseptic technique [3], however in 1972, Lapides et al. first demonstrated that using a clean technique, which they coined clean IC (CIC), was equally as effective at preventing an urinary tract infection (UTI) [4]. Note however that this research was based on 12 female and 2 male patients who were followed for 6–18 months, and the cleaning solution was a detergicide which was not described, so its properties are unknown. Based on this small study, a number of clinicians went on to recommend reuse of catheters and CIC became the "gold standard" for bladder emptying in individuals with NLUTD and sufficient manual dexterity; however, many clinicians are questioning the reuse CIC due to increased rates of UTI [5–7]. Presently, apart from only one manufacturer [8] that we are aware of, the majority of manufactured catheters are clearly labeled as single-use devices. As such, these catheters are distributed without instructions for cleaning, although it is well known that due to their cost and limited availability in many countries, they are commonly reused [8].

In 2014 Prieto et al. suggested that the reuse of catheters was as safe as the single use of catheters [9], although this work has since been retracted after an additional independent review of the data found crucial discrepancies of data extraction and analyses within the review [10]. At the time of writing, the Center for Disease Control and Prevention clinical recommendations [11] state that further work must be done in this area before the reuse of catheters can be safely recommended.

There are many well-known advantages (convenience, reduced economic burden for consumers, and reduced environmental

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impact) and disadvantages (cost, concern of increased UTI, burden of cleaning for users) to reusing catheters [2, 12–15]. In addition, there is recent evidence to suggest that structural damage of the catheter itself from cleaning could put users at risk of contracting an UTI by their reuse due to an increased risk of urethral and bladder trauma [16].

A variety of catheters have been marketed for IC over the years. Historically, most were constructed of materials including rubber, latex, silicone, polyvinyl chloride (PVC) and polyethylene [17]. Today, PVC catheters are the most used [18], with some having a hydrophilic outer coating for ease of use. Still, because of the continued variability in materials used, cleaning methods that are effective for some catheters may not be suitable for others. To date, there is no reported consensus on the preferred method of cleaning, nor the period of time that a single catheter may be reused [19]. Obtaining consensus is further complicated by the fact there is high variability and poor compliance when performing cleaning techniques, leading to an increased risk of bacterial colonization [19, 20] and lower urinary tract (LUT) symptoms. Consequently, it is of great interest to determine if there are effective catheter cleaning methods that do not damage the structural integrity of catheters to help ensure patient safety for those who choose to reuse them, and to potentially reduce the environmental impact and financial burden of single-use catheters onto the healthcare system.

To that end, this systematic review provides a comprehensive analysis of the effectiveness of various proposed methods of cleaning of catheters for IC to prepare them for their reuse. We were specifically interested in comparing the effectiveness of cleaning and reuse methods by evaluating the outcomes of bacterial colonization and change in physical properties. First, we examined the effectiveness of cleaning methods in terms of their ability to eliminate or diminish bacterial colonization; and second, we examined the impact of cleaning techniques on the physical properties of catheters.

METHODS

Protocol and registration

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines were used to report our systematic review [21]. A PROSPERO review protocol exists and can be accessed (registration number CRD42020176065).

Data sources and search strategy

A systematic review of all relevant literature, published from January 1, 1990 to September 14, 2021 was conducted using five databases (i.e., Medline, Excerpta Medica data BASE, Cumulative Index to Nursing and Allied Health Literature, Web of Science and the Cochrane Central Register of Controlled Trials. The initial search was done including results from January 1, 1990 to May 14 2020, and then a second search ("update") was performed September 14, 2021. Studies published prior to 1990 were not investigated as catheter material was different than the material used to make catheters today and is therefore not generalizable to current use. The population key words were: "intermittent catheter", "bladder catheter" and "urinary catheter". These were paired with the terms: "clean", "cleaning methods", "cleaning solution", "disinfect", "decontaminate", "sterilize" OR "physical", "microscopic", "mechanical" OR "reuse". See supplementary appendix (SA) 1 for the full search strategies used for each database.

Eligibility criteria

As per our PROSPERO protocol, we included all published studies thus far which investigate the properties of intermittent catheters and how they are affected by various cleaning procedures during reuse. We were specifically interested in studies focusing on either the relationship between cleaning during reuse and bacterial colonization of an intermittent catheter or the effects of cleaning and reuse on the physical properties of an intermittent catheter.

Study Selection

Studies were included for qualitative analysis if they met the following criteria: published in English, German or Russian language that evaluated the impact that various methods of cleaning catheters have on catheter bacterial colonization and changes in catheter physical properties. We included all study designs except reviews, book chapters, opinion papers, non-peer-reviewed work, conference abstracts or papers and studies where the full text was unavailable.

Data extraction

Studies were collated and uploaded into Covidence [22]. Independent reviewers (author 1 and 3) screened titles, abstracts, and full-texts; only eligible studies were included in the qualitative analysis. A third reviewer (author 2) resolved discrepancies. Figure 1 illustrates the PRISMA flow diagram. A consensus was achieved (between all authors) on data to be extracted from studies, which included author and year of the study, study design, sample size and dropouts, inclusion/exclusion criteria, study aims, type of catheter, catheter inoculation method, catheter cleaning method, outcomes and conclusions, and funding.

Assessment of methodological quality and risk of bias assessment

A quality assessment was completed for each study by two independent reviewers (author 1 and 2). Experimental studies were examined by the Joanna Briggs Institute Critical Appraisal Checklist for quasi-experimental studies [23] to evaluate their methodological quality and therefore eligibility for inclusion. Cohort and cross-sectional studies were assessed according to the National Institute of Health quality assessment tool for observational cohort and cross-sectional studies [24]. Case series studies were assessed according to the National Institute of Health quality assessment tool for case series studies [25]. A third reviewer (author 3) resolved discrepancies. The risk of bias was assessed for eligible studies (i.e., cohort studies) in accordance with the Risk Of Bias in Non-randomized Studies - of Interventions (ROBINS-I) [26].

Statistical analysis

Extracted data was organized in tabular form using Excel (Microsoft 365, version 2103). No meta-analysis or formal statistical tests for significance were performed.

RESULTS

Search process

The literature search yielded 10,434 articles. After eliminating duplicates and reviewing the remaining titles and abstracts (Fig. 1), a total of 12 studies [8, 14, 18, 20, 27–34] that included catheter bacterial counts (e.g., CFU/L) or changes in physical properties of the catheter as their outcomes following catheter cleaning and reuse were eligible and included (Table 1).

Description of the studies

Of the 12 studies included in this systematic review, nine were analytical experimental studies [18, 27–34], one of which was also partially a cohort study [29]. The remaining were either a cohort [14] or cross-sectional [20] study and a case series [8]. Based on presently published literature, multiple cleaning methods have been tested and proposed in order to decontaminate catheters including heat (microwave [18, 20, 28, 30–32, 34], steam [18], or boiling [18]), mechanical (ultrasonic [18], detergent and rinsing [18, 27, 31, 34]), chemical (bleach [33], hydrogen peroxide [27, 33],

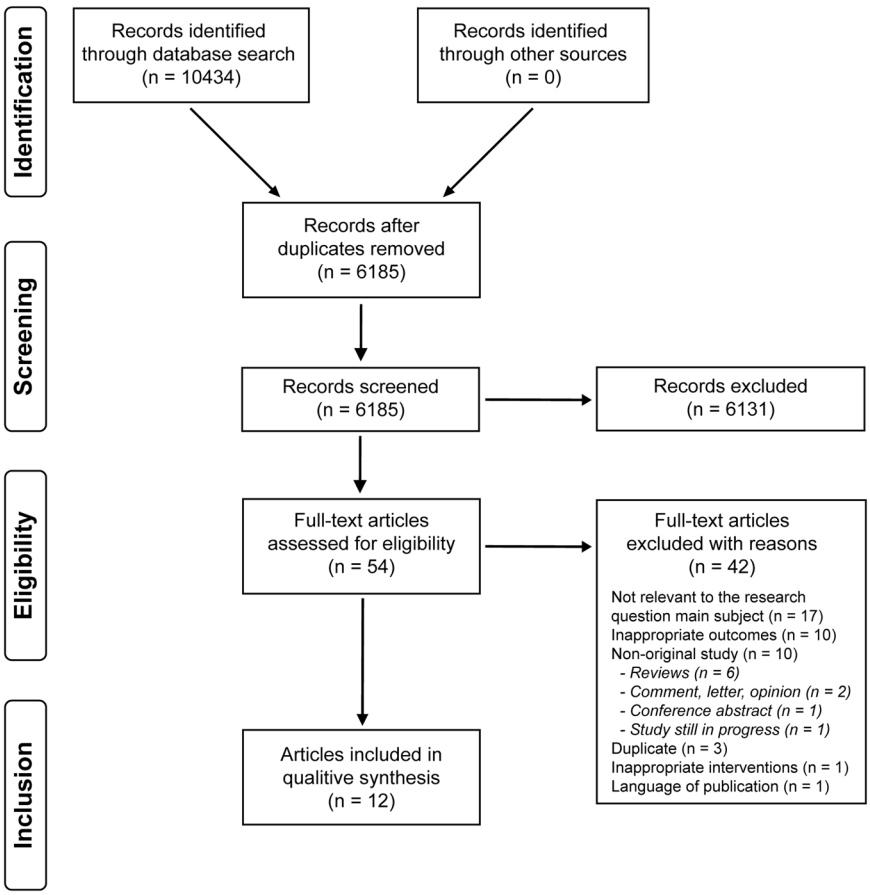

Fig. 1 PRISMA flow diagram.

betadine [33], vinegar [18, 27], diluted Milton solution (0.6% sodium hypochlorite) [18], Savlon solution (15% cetrimide and 1.5% chlorhexidine gluconate) [8], 70% alcohol [30]), and other (photocatalytic [29], mixture of methods [14] or combination of two methods [18, 34]). The majority of these studies ($n = 10$) [14, 18, 27–34] used culture analysis as a microbiological technique to assess for the presence of bacteria. Several studies ($n = 7$) [8, 14, 18, 20, 28, 30, 31] examined the impact of cleaning methods on physical properties of catheters, however only a minority ($n = 4$) [8, 14, 18, 30] examined the microscopic physical properties of the catheter. All 12 studies were grouped based on the type of cleaning methods analyzed, which included the following categories: heat-based, mechanical-based, chemical, combined and others. Next, the effectiveness of cleaning based on levels of bacterial colonization after using specific cleaning methods was determined (Table 2). In most studies, the bacterial colonization was either measured in terms of colony forming units (CFU) or log reduction depending on the quantification method reported. Changes in physical properties of catheters following various cleaning methods was then determined (Table 2). These changes were evaluated macroscopically (i.e., gross visible inspection of changes and change in stiffness) and/or microscopically (by some form of electron microscopy (EM) or differential scanning calorimetry).

Quality of evidence and risk of bias

Overall, quality was fair for all included studies. See SA 2 for full details of quality assessment. The risk of bias was assessed in accordance with ROBINS-I for all eligible studies, i.e., the two cohort studies (see Fig. 2). Risk-of-bias assessment showed either serious or critical risk of bias. All other studies did not qualify for risk of bias analysis since only catheters and not patients were reported.

Heat-based methods

Among heat-based cleaning methods the microwave treatment ($n = 6$) [18, 20, 28, 30–32] was the most used followed by boiling ($n = 1$) [18] and steam sterilization ($n = 1$) [18]. Overall, it was generally agreed that upon increasing the length of microwaving time resulted in a reduction in colony counts. Rubber catheters were reportedly able to be sterilized by microwave treatment [28, 31, 32], but none of these studies fully analyzed the impact on the structural integrity of the catheters. When analyzing non-rubber catheters, none of the microwave treatments studied were as effective at reducing bacterial colony counts of *Escherichia (E.) coli, Pseudomonas (P.) aeruginosa and Staphylococcus (S.) aureus*, while also maintaining catheter structural integrity as were the chemical and combined methods (e.g. alcohol, "Milton method") [18, 30]. In two studies [18, 31], investigators were not able to obtain bacterial colonization data as the physical properties of the catheters changed too dramatically for the study to continue. Boiling in tap water for 2 min resulted in undetectable levels of *E. coli* but also led to the PVC catheter being damaged. Other uropathogens were not tested in this study due to evidence of catheter damage [18]. Steam cleaning also resulted in undetectable *E. coli* or *Klebsiella (K.) pneumoniae*. However, there was evidence of some viable but non-culturable bacteria (VNCB) population [18].

Mechanical-based methods

The use of detergent and water was the most common mechanical cleaning method ($n = 4$) [18, 27, 31, 34], followed by

Table 1. Overview of included studies.

Author, year; research design; sample size	Catheter type and method of contamination (human use or artificial inoculation)	Description of cleaning method	Outcome measure	
			Bacterial colonization	Physical properties
Newman et al. 2020 [14]; Cohort; $n = 39$ participants.	Catheter type: Silicone (46%), PVC (44%), latex or rubber (10%). Method of contamination: Participants used a catheter for a mean of 21 days (min-max = 1-270).	Mixed: 44% of participants used soap and water; 41% used just running water; 8% soaked in an aseptic solution; 10% stated "other" (washing machine, boiling). Control: Unused single use hydrophilic-coated catheters were used as comparators for bacterial culture analysis.	EM for microbial contamination. Bacterial culture analysis.	EM for evidence of debris on catheter surface.
Wilks et al. 2020 [18]; Analytical experimental; n = number of catheters not stated. Each catheter experiment was repeated three to five times.	Catheter type: Uncoated PVC catheters. Method of contamination: Catheter sections were placed in an artificial urine medium containing bacterial inoculum (*Escherichia coli, Pseudomonas aeruginosa, Klebsiella pneumonia, Enterococcus faecalis, Staphylococcus aureus*, and *Staphylococcus epidermis*) and incubated at 37 degrees Celsius for 5 min.	Heat: Microwave (6-min, 800 W with a 200 mL heat sink); Steam sterilizer (4-min heating and 6-min sterilizing); Boil (2 min). Mechanical: Ultrasonic cleaning using a domestic jewelry cleaner followed by water rinsing; Detergent and water (mixed and left to soak for 5 min followed by water rinsing). Chemical: White vinegar (50% solution, 30-min soak followed by water rinsing); Milton solution (15-min soak followed by water rinsing). Combination: Detergent and water (mixed, then 5-min soak) followed by Milton solution (15-min soak followed by water rinsing), also known as the Milton method. Control: Rinsed with cold tap water for bacterial culture analysis. The number of control catheters analyzed for bacterial culture analysis was not stated. One new unused catheter was used as comparator to reused catheters for EM.	Bacterial culture analysis (CFU). Direct variable count.	EM for evidence of catheter surface damage. Gross visual inspection.
Chan et al. 2009 [34]; Analytical experimental; $n = 165$ catheters.	Catheter type: Not specified. Method of contamination: Aliquots of a 24-hour broth culture of *Escherichia coli* were spread over the lumen and surface of the catheters.	Chemical: Antibacterial soap wash (5-min soak in 1.5% antibacterial soap followed by 1-min water rinsing). Combination: Combination of antibacterial soap (5-min soak in 1.5% antibacterial soap followed by 1-min water rinsing), then followed by microwave (5-min, 800 W with a 8 oz water heat sink). Control: Handling controls were uninoculated and	Bacterial culture analysis (*Escherichia coli* culture).	n/a

Table 1. continued

Author, year; research design; sample size	Catheter type and method of contamination (human use or artificial inoculation)	Description of cleaning method	Outcome measure	
			Bacterial colonization	Physical properties
		not cleaned. Wash controls were uninoculated and cleaned by washing. Wash + microwave controls were uninoculated and cleaning by washing + microwave. Positive controls were inoculated and not cleaned.		
Sekiguchi et al. 2007 [29]; Part 1 = Analytical experimental; n = number of catheters not stated. Part 4 = Cohort; n = 18 participants and 25 catheters.	Catheter type: TiO_2 coated silicone catheters. Method of contamination: Part 1: 3–4 cm sections of the catheter were filled with a 100-μL aliquot of either an *Escherichia coli, Staphylococcus aureus, Pseudomonas aeruginosa, Serratia marcescens*, and *methicillin-resistant Staphylococcus aureus* suspension (2×10^5 cells/mL). Part 4: Participants used catheter for 4 weeks.	Other (Photocatalytic): Illuminated with a 15 W black lamp (low-intensity ultraviolet light: 352 nm, light intensity of 1000μW/cm^2) for 10-60 min on 10-min intervals. Control: Part 1: Uncoated silicone catheter with no UV radiation, and TiO_2 coated silicone catheter with no radiation. Silicone catheter with 1 h of UV radiation. Part 4: Silicone catheter rinsed with clean water and preserved in 0.025 mol benzalkonium chloride with glycerol.	Part 1: Bacterial culture analysis (Bacterial survival rate). Part 4: Bacterial culture analysis (Rate of positive cultures).	n/a
Bogaert et al. 2004 [30]; Analytical experimental; n = not stated.	Catheter type: Three types of PVC catheters: standard, atraumatic with flexible Ergothan tip, and hydrogel coated. Method of contamination: Lumens of the catheters were contaminated by contact with a culture of pathogenic *Escherichia coli, Pseudomonas aeruginosa* and *Staphylococcus aureus* strains for 1 h at 37 degrees Celsius.	Heat: Microwave (12-min, 750 W - 1000 W microwaves with a 200 mL water heat sink). Chemical: Alcohol (5-min submersion in 70% alcohol; 45-min submersion in 70% alcohol). Controls: Positive control was inoculated but not cleaned for comparison of bacterial culture analysis. Reference glass transition values of the catheters were given for calorimetric analysis and deviation from this was inferred to be caused by structural changes of the catheters.	Bacterial culture analysis (log reduction in number of germs).	Calorimetric analysis of structural changes. Gross visual inspection.
Kovindha et al. 2004 [8]; Case series; n = 3 catheters.	Catheter type: Silicone. Method of contamination: Human use. One catheter was reused for period of 1.5 years and another for a period of 2 years.	Chemical: 1:100 Savlon solution (1.5% chlorhexidine gluconate and 15% cetrimide). Control: One new unused catheter was used as comparator to reused catheters for EM.	n/a	EM for evidence of catheter surface damage, lumen encrustation and stiffness.
Sherbondy et al. 2002 [20]; Cross-sectional; n = 129 surveys were mailed and 84 were completed and returned. A follow-up questionnaire was mailed to the 47 respondents who reported using a microwave oven to sterilize catheters, and 40 returned the questionnaire.	Catheter type: Vinyl (48%), rubber (24%), PVC (18%) and other (10%). These percentages refer to all 129 participants that returned the survey. Method of contamination: Human use.	Heat: Microwave (variable length but 73% reported 6 min. 39% reported using 500 to 1000 W microwave, 37% reported using > 1000 W microwave and remaining 24% did not know wattage. All reported using a heat sink between 125 mL to 1 L water). This refers to the 40 participants from the follow-up survey. Controls: None.	n/a	Gross visual inspection.

Table 1. continued

Author, year; research design; sample size	Catheter type and method of contamination (human use or artificial inoculation)	Description of cleaning method	Outcome measure	
			Bacterial colonization	Physical properties
Mervine et al. 1997 [31]; Analytical experimental; $n = 10$ catheters.	Catheter type: Rubber ($n = 5$) and clear plastic ($n = 5$). Method of contamination: Catheters were placed in a tryptic soy broth solution contaminated with 100,000 bacteria/mL and shaken for 30 s. A separate container was used for each different type of stock bacteria tested: *Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus pneumoniae, Candida albicans, Proteus mirabilis*, and *coagulase negative Staphylococcus* and contaminated human urine (> 100,000 CFU/mL).	Heat: Microwave (5-min 800 W with a 250 mL water heat sink). Mechanical: Detergent and water (washed for 15 s and then rinsed off with water). Controls: None.	Bacterial culture analysis (bacterial colony count).	Gross visual inspection.
Lavallee et al. 1995 [27]; Analytical experimental; $n = 312$ catheters.	Catheter type: Plastic. Method of contamination: Catheter tips were submerged in contaminated urine (10^7 cells/mL *Pseudomonas aeruginosa* and 10^7 cells/mL *Escherichia coli*) for 5 min.	All catheters were rinsed and dried before cleaning. Chemical: 3% hydrogen peroxide (5-min soak); Vinegar (5-min soak). Mechanical: Detergent (10-s wash with detergent followed by 10-s rinse with tap water). Controls: Washing with water (for 10 s) and rinsing (for 10 s).	Bacteria culture analysis (bacterial colony count).	n/a
Kurtz et al. 1995 [33]; Analytical experimental; $n = 48$ catheters.	Catheter type: Non-latex catheters. Method of contamination: Catheters were inoculated in 3 different *Escherichia coli* isolates at concentrations ranging from 4.8×10^5–1.0×10^8 CFU at 37 degrees Celsius for 2 h.	Chemical: Catheters were rinsed for 1 min with tap water and then soaked in one of three cleaning solutions for 30 min: 0.6% hydrogen peroxide; Bleach in a 1:4 solution with tap-water; Betadine in a 1:2 solution with tap water. Controls: One catheter tap water rinsed.	Bacteria culture analysis (*Escherichia coli* growth via CFU).	n/a
Griffith et al. 1993 [28]; Analytical experimental; $n = 30$ catheters.	Catheter type: Polyethylene. Method of contamination: Catheters were immersed in a solution of *Proteus mirabilis*, bacteria (10^6 - 10^7 CFU/mL) for 30 s. In addition, the bacterial solution was drawn through the lumen of the catheter with a sterile syringe.	Heat method: Microwave (Either for 2, 4, 6, or 8 min (each six catheters), 650 W microwave with a 300 mL water heat sink). Controls: Six non-microwaved catheters (for 0 min).	Bacterial culture analysis (CFU).	Gross visual inspection.
Douglas et al. 1990 [32]; Analytical experimental; $n = 6$ catheters.	Catheter type: Rubber. Method of contamination: Catheters were incubated in the solution of microorganisms (*Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Enterobacter cloacae, Pseudomonas*	Heating Method: Microwave (12-min, 10,650 W microwave with a 250 mL heat sink). Controls: One non-microwaved catheter.	Bacterial culture analysis (number of viable microorganisms).	n/a

Table 1. continued

Author, year; research design; sample size	Catheter type and method of contamination (human use or artificial inoculation)	Description of cleaning method	Outcome measure	
			Bacterial colonization	Physical properties
	aeruginosa, Streptococcus pneumoniae, Staphylococcus aureus, and *Candida albicans*) of a concentration of 10^4- 10^6 cells /mL for 60 min at a temperature of 37 degrees Celsius.			

CFU colony forming unit, *EM* electron microscopy, *PVC* polyvinyl chloride, TiO_2 titanium dioxide, *VNBC* viable but non-culturable.

ultrasonic jewelry cleaner ($n = 1$) [18]. Although these methods have demonstrated some reduction in bacterial counts, neither of these methods were effective for sterilisation. For example, Chan et al. showed that 44% of PVC catheters still had a positive culture following soaking in a 1.5% solution of antibacterial soap for 5 min followed by a 1-min water wash [34]. Wilks et al. reported that the use of a domestic jewelry cleaner was also not an effective cleaning method as the action of the cleaner was not bactericidal and damaged the catheter surface [18].

Chemical methods

There were a variety of cleaning solutions examined ($n = 9$) [8, 18, 27, 30, 33]. Submerging PVC catheters in a 70% alcohol solution for 5 min ($n = 1$) [30] was the most effective as there was both bacterial sterilization (6-log colony count reduction) and showed no catheter damage. Another study determined that soaking plastic catheters for 5 min in 3% peroxide solution ($n = 1$) [27] was not fully bactericidal but reduced the bacterial colony count by nearly 3 log. Similarly, it was found that soaking non-latex catheters in 0.6% hydrogen peroxide (n = 1), 1:4 solution of bleach in tap water ($n = 1$), or a 1:2 solution of betadine in tap water ($n = 1$) for 30 min were all effective at preventing *E. coli* growth 48 h post cleaning, but there was no analysis for structural damage [33]. Soaking in vinegar ($n = 2$) [18, 27] was not effective at eliminating most uropathogens, although it did not affect the physical properties of the catheters. In addition, it was found that the use of Milton solution (diluted Milton concentrate with tap water as per manufacturer's instructions to a 0.6% sodium hypochlorite final concentration) ($n = 1$) [18] resulted in no detectable culturable bacteria after repeated contamination and decontamination events over 24 h when tested with a full range of uropathogens; however, there was evidence of some VNCB population remaining. A cross-sectional study by Kovindha et al. followed participants who kept their reusable silicone catheters in a Savlon solution between uses over the course of 1–2 years. These reused catheters showed encrustation of the lumen and an increase in stiffness of 20% relative to a new catheter [8]. Finally, it should be noted that in general cleaning was not as effective without rinsing and drying the catheter prior to submersion in the cleaning solution [27].

Combined, mixed and other methods

There were two combined methods reported. The first combined an antibacterial soap wash for 5 min followed by microwaving in an 800 W microwave for 5 min ($n = 1$) [34]. This was found to be more effective than washing with antibacterial soap alone, but still found that 24% of catheters had a positive *E. coli* culture. The other, coined the "Milton method" by Wilks et al, was found to be more effective and was performed by soaking a catheter in hot soapy water for 5 min, rinsed with water, left to soak in Milton solution for 15 min and then rinsed off with tap water again ($n = 1$) [18]. This resulted in undetectable *E. coli* levels, no evidence of a VNCB population and showed no structure damage to the uncoated PVC catheters. Sekiguchi et al. have developed a titanium oxide (TiO_2) coated silicone catheter which has a photocatalytic antimicrobial effect using only ultraviolet-A illumination [29]. After 60 min of black light illumination using a 15 W 352 nm black lamp with intensity of 1000μW/cm^2, it was demonstrated that the photocatalytic effect of the TiO_2 catheters reduced the survival of all bacteria tested (*Serratia marcescens, methicillin-sensitive S. aureus, methicillin-resistant S. aureus, P. aeruginosa*) to a negligible level. These catheters reportedly maintained their antibacterial effect after 200 uses. There was no data collected about how the sterilization affected the structure of the catheters. Another recent study by Newman et al. did not control for cleaning methods (participants choice and a mix of methods were reportedly used) but found that after a mean reuse of 21 days, 74% of catheters had microbial contamination and 20 different bacterial species were found in

Table 2. Outcomes of cleaning methods.

Author, year; research design; sample size	Cleaning method	Outcomes	
		Bacterial colonization	**Physical properties**
Newman et al. 2020 [14]; Cohort; $n = 39$ participants.	Control	Unused catheter had no bacterial contamination.	No EM control catheter.
	Mixed	74% of reused catheters had microbial contamination: 20 different bacterial species were found in total. A biofilm was found in 20% of the reused catheters. Viable microorganisms could be cultured in 67% of the samples.	Debris contamination was found on all reused catheters. EM showed the debris to be a mixture of residuals from urine, lubricant, soap, detergents and cells.
Wilks et al. 2020 [18]; Analytical experimental; n = number of catheters not stated. Each catheter experiment was repeated three to five times.	Control	Consistently high values of culturable bacteria as well as VNCB present following tap water rinse.	Highly disordered but no damage or evidence of bacterial attachment.
	Microwave	Was not fully tested due change in physical properties.	Catheters melted and there were changes in flexibility.
	Steam sterilizer	No culturable *Escherichia coli at any time point*. No culturable *Klebsiella pneumoniae* at 6 and 24 h, but > 10^2 CFU/cm at 0 and 3 h. Presence of elongated bacteria (10^1/cm) in the DVC analysis which indicates development of VBNC bacteria (i.e., 20% fields of view). Large areas of bacterial deposition were observed on the surface of the catheter.	Microscopic surface damage and changes in flexibility.
	Boiling	No culturable *Escherichia coli* but noticeable changes in flexibility so no further testing was performed.	Microscopic surface damage and changes in flexibility.
	Ultrasonic cleaning using a domestic jewelry cleaner	Only a minor reduction in culturable bacteria. *Escherichia coli* was detected at > 10^1 CFU/cm at 0 h, > 10^2 CFU/cm after 3 h, and < 10^1 CFU/cm after 6 and 24 h. *Klebsiella pneumoniae* was detected at > 10^5 CFU/cm at 0 h, at > 10^4 CFU/cm after 3 h, at 10^4 CFU/cm at 6 h, and at 10^5 CFU/cm at 24 h. Presence of elongated bacteria (> 10^5/cm). VBNC were sub-lethally damaged/stressed and but observed in ~ 90% fields of view. Areas of bacterial deposition were observed on the surface of the catheter.	Microscopic surface damage present.
	Detergent and water	Culturable *Escherichia coli* was detected in < 10^1 CFU/cm across all time points. *Klebsiella pneumoniae* was not detected at 0 h but seen between 10^2 and 10^1 CFU/cm after 3, 6, or 24 h. Presence of elongated bacteria (< 10^1/cm). There was evidence of VBNC bacteria remaining, i.e., in < 20% fields of view.	EM showed no microscopic damage.
	Vinegar	Less than 10^1 CFU/cm of culturable *Escherichia coli* was detected at 0, 3, 6, or 24 h after exposure and there was no detectable culturable *Klebsiella pneumoniae* at all time point. Presence of elongated bacteria (> 10^1/cm). There was evidence of VBNC population remaining (i.e. ~ 20% fields of view).	No change.
	Milton solution	No culturable *Escherichia coli* detected at any time point. *Klebsiella pneumoniae* was detected at 10^3 CFU/cm at 0 and 3 h, 10^2 CFU/cm at 6 h but not culturable at 24 h. When tested with full range of uropathogens, no culturable bacteria was observed after 24 h of repeated exposure. Presence of elongated bacteria (< 10^1/cm). There was evidence of VBNC population remaining (i.e. < 20% fields of view).	EM showed no microscopic damage.
	Combined: Detergent and water + Milton solution also known as "Milton method"	Total bactericidal effect on all tested uropathogens, hence no elongated bacteria per 1 cm catheter section and 0% fields of view with elongated bacteria.	No change.

Table 2. continued

Author, year; research design; sample size	Cleaning method	Outcomes	
		Bacterial colonization	**Physical properties**
Chan et al. 2009 [34]; Analytical experimental; $n = 165$ catheters.	Control	Handling and washing controls were negative for growth of the indicator organisms, but had growth from contaminants which the authors concluded were from the packaging materials. 89% of positive controls had *Escherichia coli* growth at 7 days.	n/a
	Antibacterial soap wash	44% of catheters remained contaminated with *Escherichia coli*.	n/a
	Combined: Antibacterial wash + microwave	26% of catheters washed with antibacterial soap remained contaminated with *Escherichia coli.*	n/a
Sekiguchi et al. 2007 [29]; Part 1 = Analytical experimental; n = number of catheters not stated. Part 4 = Cohort; $n = 18$ participants and 25 catheters.	Control	Part 1: Inoculated Silicone and TiO_2 coated silicone catheters that were not exposed to UV radiation had 70% and 80% *Escherichia coli* survival rate after 1 h. Silicone catheter exposed to 1 h of UV radiation had about 50% survival rate of *Escherichia coli* after 1 h. Part 4: 60% (6/10) catheters had positive cultures.	n/a
	Photocatalytic	Part 1: The photocatalytic effect of the TiO_2 catheters reduced the survival rate of all bacteria to a negligible level within 60 min of black light illumination. The antibacterial effect was stable after 200 uses. Part 4: 20% positive culture rate.	n/a
Bogaert et al. 2004 [30]; Analytical experimental; n = not stated.	Control	Inoculated uncleaned catheters had at minimum 2 log greater of *Escherichia coli*, *Pseudomonas aeruginosa* and *Staphylococcus aureus* in comparison to microwave and alcohol cleaned catheters.	n/a
	Microwave	There was an antimicrobial effect on *Escherichia coli* but was not effective at eliminating *Pseudomonas aeruginosa* or *Staphylococcus aureus*.	Minimal microscopic changes in all 3 catheters types studied.
	70% alcohol	Submersion for 5 min resulted in a complete antimicrobial effect on *Escherichia coli, Pseudomonas aeruginosa* and *Staphylococcus aureus* in all catheters. There was no additional benefit to soaking the catheters for 45 min.	Soaking catheters for 5 min did not affect the physical properties of the catheters. Soaking catheters for > 45 min in the 70% alcohol solution caused considerable microscopic changes in the physical properties of all catheters as demonstrated as increased glass transition values during calorimetric analysis. It should be advised to not store catheters for reuse chronically in an alcohol solution as it causes significant structural damage of PVC catheters.
Kovindha et al. 2004 [8]; Case series; $n = 3$ catheters.	Control	n/a	Unused catheter had no evidence of surface damage.
	Savlon solution	n/a	EM showed encrustation in lumen. The reused catheters showed a 20% increase in stiffness compared to a new catheter.
Sherbondy et al. 2002 [20] Cross-sectional; $n = 129$ surveys were mailed and 84 were completed and returned. A follow-up questionnaire was mailed to the 47 respondents who reported using a microwave oven to sterilize catheters, and 40 returned the questionnaire.	No control	n/a	n/a
	Microwave	n/a	63% participants reported having experienced catheter melting. Melting during microwaving was significantly correlated with users who did not use a rotating table ($p = 0.016$) and with vinyl catheters compared to other types ($p = 0.049$).

Table 2. continued

Author, year; research design; sample size	Cleaning method	Outcomes	
		Bacterial colonization	Physical properties
Mervine et al. 1997 [31]; Analytical experimental; $n = 10$ catheters.	No control	n/a	n/a
	Microwave	Bacteria was eliminated on the red rubber catheters. Clear plastic catheters melted in the microwave so the antibacterial could not be determined.	The red rubber catheters were microwaved over 100 times in 5-min intervals and there was no gross visible change in pliability or patency. The clear plastic catheters melted while microwaved.
Lavallee et al. 1995 [27]; Analytical experimental; $n = 312$ catheters.	Control	Significantly higher amounts of *Pseudomonas aeruginosa* and *Escherichia coli* then peroxide, vinegar. There was no significant difference between the water rinsing control and detergent rinse.	n/a
	Detergent and water	Log reduction of total bacteria was significantly ($p < 0.001$) worse than a 5-min soak in 3% hydrogen peroxide. Log reduction of *Escherichia coli* was significantly ($p < 0.05$) worse than a 5-min soak in vinegar. Rinsing and drying catheters before cleaning had the biggest impact on reducing bacteria. Cleaning was not effective without rinsing and drying the catheter prior to submersion in the cleaning solution.	n/a
	3% hydrogen peroxide	Log reduction of total bacteria was significantly ($p < 0.001$) better than washing with detergent and water. Log reduction of *Escherichia coli* was significantly ($p < 0.05$) better than using vinegar. Log reduction of *Pseudomonas aeruginosa* was significantly ($p < 0.05$) worse than using vinegar. Rinsing and drying catheters before cleaning had the biggest impact on reducing bacteria. Cleaning was not effective without rinsing and drying the catheter prior to submersion in the cleaning solution.	n/a
	Vinegar	Log reduction of *Escherichia coli* was significantly ($p < 0.05$) worse than using 3% hydrogen peroxide. Log reduction of *Pseudomonas aeruginosa* was significantly ($p < 0.05$) better than using 3% hydrogen peroxide. Rinsing and drying catheters before cleaning had the biggest impact on reducing bacteria. Cleaning was not effective without rinsing and drying the catheter prior to submersion in the cleaning solution.	n/a
Kurtz et al. 1995 [33]; Analytical experimental; $n = 48$ catheters.	Control	Positive cultures in tap water rinse control (5.2×10^2 CFU/mL).	n/a
	0.6% hydrogen peroxide	All three procedures were equal and effective, completely preventing *Escherichia coli* growth when measured 48 h post cleaning.	n/a
	Bleach solution		
	Betadine solution		
Griffith et al. 1993 [28]; Analytical experimental; $n = 30$ catheters.	Control	The non-microwaved control catheter produced a mean of 7.8×10^4 CFU per catheter.	n/a
	Microwave	Increasing the length of time microwaving was associated with a reduced colony count. Complete sterilization was achieved after microwaving for 6 min.	Microwaving did not cause any gross visual evidence of fracturing, brittleness, melting or discoloration of the catheters. The catheter lumen was still able to be flushed easy.
Douglas et al. 1990 [32]; Analytical experimental; $n = 6$ catheters.	Control	Control catheters had 10^4-10^6 organisms per catheter.	n/a
	Microwave	Complete sterilization.	n/a

CFU colony forming units, *DVC* direct variable count, *EM* electron microscopy, *PVC* polyvinyl chloride, *VNBC* viable but non-culturable.

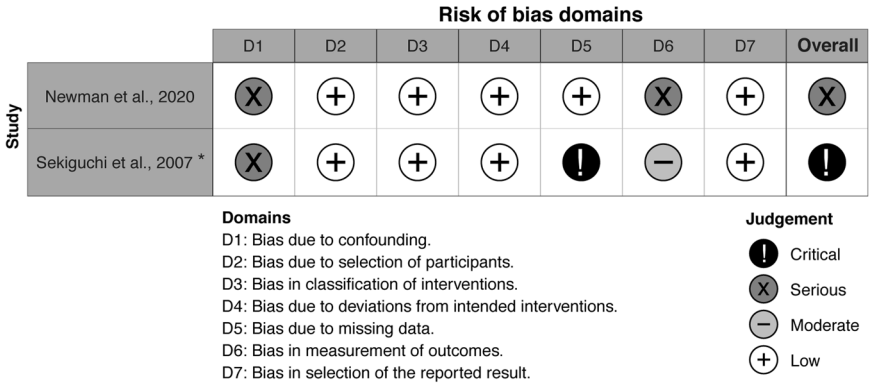

Fig. 2 Risk of bias. * This publication consists of multiple parts, i.e., analytical experimental part and cohort. The risk of bias analysis only addresses the cohort part of this publication.

total. A biofilm was found in 20% of the reused catheters and viable microorganisms could be cultured in 67% of the samples. There was debris contamination found on all catheters which EM showed to be a mixture of residuals from urine, lubricant, soap, detergents and cells [14].

Controls

Unused catheters were found to have no microbial contamination ($n = 2$) [14, 34], except in one study where growth of contaminants was found due to the packaging materials of the catheters [34]. Likewise unused catheters had no surface damage as determined by EM ($n = 2$) [8, 18]. Catheters that were inoculated and not cleaned, or inoculated and rinsed with tap water only, had consistently higher bacterial colonization than catheters that had been cleaned by heat, mechanical, chemical, combined, or other methods ($n = 7$) [18, 28–30, 32–34]. In a cohort trial by Sekiguchi et al. the control silicone catheters ($n = 10$), which were rinsed with clean water and preserved in 0.025 mol benzalkonium chloride with glycerol, had a 60% positive culture rate versus a 20% positive culture rate from the TiO_2 coated catheters ($n = 15$) which were sterilized by the photocatalytic effect [29].

DISCUSSION

This systematic review provides an up to date and comprehensive summary of the clinical evidence of the effectiveness of various cleaning methods of IC that have been proposed to prepare catheters for reuse. This analysis will help guide future clinical recommendations and is applicable to both health care providers and individuals requiring the use of catheters for IC.

The available evidence suggests that the effectiveness of microwave sterilization greatly depends on the material of the catheter. Rubber catheters seem to be able to withstand repeated microwave sterilizations with a common household microwave without incurring macroscopic changes [28, 31, 32]. It should be noted that to date, no assessment of microscopic structural damage has been published after microwaving rubber catheters. Reported time to sterilize seems to be a minimum of 5 min and depends on the wattage of the microwave used, however there was an inverse relationship between the duration of microwave sterilization and the amount of viable bacterial colonies present on the catheter [28]. It should be noted that rubber catheters pose additional allergy risk as latex allergies are common and may be acquired with long-term exposure to rubber catheters which can be latex-based [35]. Polyethylene catheters were shown to also be completely sterilized by a microwave sterilization method; however, this material of catheter was only evaluated in one study and no data regarding the physical properties of the catheter was present [28]. In addition, it has been determined that plastic catheters melted in the microwave [27]. Microwave sterilization is also not a recommended cleaning method for other catheter material such as latex or PVC as there is evidence of melting and incomplete sterilization [18, 27]. Although gross changes in physical properties of catheters were documented in a few studies, less is known regarding the microscopic changes and changes in stiffness of catheters. It is crucial to acknowledge that based on expert consensus opinion, the physical properties of catheters are a crucial risk factor for urethral microtrauma and development of UTIs [16]. Other heat-based methods (steaming and boiling) were not effective and damaged PVC catheters [18].

The quality of evidence for the efficacy of chemical cleaning is limited because the effectiveness of most methods has not been duplicated by more than one study, and many do not have corresponding data regarding their effects on catheter physical properties. To date, it seems that the most promising chemical cleaning methods are 70% alcohol solution and Milton solution. It was demonstrated by one study that soaking a PVC catheter in the 70% alcohol solution for 5 min reduced bacterial colony counts by 6 log and did not affect the physical properties of PVC catheters. Soaking for a longer period in alcohol solution is not recommended, as damage was seen in the catheters soaked for 45 min [30]. Milton solution also did not affect the properties of PVC catheters, but did show some evidence of VNCB present [18]. Other cleaning solutions such as 0.6% peroxide, a 1:4 solution of bleach with tap-water or a 1:2 solution of betadine in tap water were shown to be bactericidal against for *E. coli* but no structural analysis was performed [33]. Another study supported the suggestion that peroxide could be a potential cleaning solution as it reported that a 3% peroxide solution reduced the bacterial colony count by 3 log; however, the same study also noted that it was less effective than rinsing with water and drying alone, which reduced the bacteria colony count by 5 log [27]. Vinegar, while it appears to not affect the physical properties of the catheters, does not seem to be a suitable bactericidal cleaning solution [18, 27]. Kovindha et al. examined the effects of long term reuse with a Savlon cleaning solution as a case series by imaging catheters with EM [8]. They found that there was encrustation on the lumen, and that the catheters had a 20% increase in stiffness. It should be noted that the two non-control catheters used in this case series were used for 1.5 and 2 years. Given the extent of time of reuse, one cannot make a conclusion on the short-term burden of reuse from this study. Future studies, such as randomized-controlled trials that incorporate larger sample sizes and long-term follow-up, should be conducted before these chemical cleaning solutions can be recommended for the reuse of catheters.

Mechanical cleaning methods such as washing with detergent or using a domestic jewelry cleaner left much to be desired when used on their own. When washing with detergent, one study reported that 44% of catheters still resulted in a positive culture [34], while another showed that there was still 100,000 bacteria/

mL present [31]. A combined approach of washing with detergent and microwaving was better, but still resulted in 22% of catheters having a positive culture swab, and it was limited by the fact that microwaving greatly damages some catheter materials. A third study reported that just rinsing with tap water and drying alone resulted in a greater reduction in bacteria on catheters than washing with detergent alone [27]. Just soaking in detergent also lowered counts of *E. coli* and *K. pneumonia* and did not damage PVC catheters, although it was reported to leave behind some residue in the lumen of the catheters [14]. Soaking in detergent followed by soaking in Milton solution ("Milton method") was reported as totally bactericidal and left no evidence of damage on PVC catheters [18]. While shown to be effective in this study, this cleaning method may not be practical for all users as this cleaning method requires 20 min of the user's time after each IC. The other mechanical cleaning method analyzed, domestic jewelry cleaner, was not an effective as it was not bactericidal and caused surface damage to the catheters [18].

Photocatalytic sterilization was reportedly bactericidal for all bacteria tested but no structural analysis was performed [29]. A major limitation to this method is that a special TiO_2 coated silicone catheter and ideally a black lamp is required, although it was reported that sunlight could be used as an alternative to the black lamp. In addition, we had to grade the study done by Sekiguchi et al. in terms of risk of bias as critical because there was missing data. Overall, 15 TiO_2 catheters were analysed but only 10 control catheters when there should have been 15 control catheters (i.e., one each per the 15 participants).

Newman et al. performed a cohort study where they did not control for the method of cleaning [14]. Forty-one per cent of participants stated they just rinsed with water and 44% reported they use both soap and water to clean their catheters before reuse. These catheters were collected, and it was found that 74% of them had microbial contamination and 20% had biofilm formation. Debris from residuals of urine, soap, detergent, and cells were seen on EM. It should be noted that the mean number of days these catheters were reused prior to analysis was 21 days, but reuse ranged from one day to 270 days. Because of this wide range, there was some bias of generalizing the results of the impact of bacterial load.

Limitations of this systematic review

A major limitation of this systematic review was that every experimental study used a different approach for analyzing the effectiveness of cleaning methods. For example, the catheter material, method of cleaning, indicator organisms, and outcome measures were not constant among studies, making quality assessment and meaningful comparisons a challenge. The non-experimental studies also did not standardize the type of catheter or cleaning method used. Many of the studies also only performed the cleaning method once before analysis, which generated outcomes that were not practical for real-life application [36] as those who reuse catheters often do so more than once. In addition, there is no consensus or data on the length of time that a catheter should be reused and that in actual practice, the length of time that catheters are reused varies greatly between users [14]. Many studies also did not completely analyze the impact of cleaning on the physical properties of the catheters, which also decreased the practicality of their outcomes.

The amount of published data on the topic is also a limitation on our results. While there were 12 studies that met our inclusion criteria, many of them were examining different cleaning methods on different catheter types, so in many cases cleaning methods were only examined in one study. For example, the two most promising cleaning methods reported, 70% alcohol immersion and "Milton method" were only examined in one in vitro study which decreased our confidence. As a result, we were not able to perform any meaningful meta-analysis. At the present time, we do not have adequate evidence to draw any conclusion on which of the both cleaning methods (i.e., Milton method or 70% alcohol) is more effective.

Future work

Due to limited evidence, there are still many unknowns when it comes to the safety of cleaning and reusing catheters. It should be determined if there is an "acceptable" limit of catheter bacterial colonization that does not cause the risk of UTI to increase significantly as well as the frequency in which incompletely sterilized catheters result in clinical infection. Studies must also be conducted in order to make recommendations for proper catheter storage conditions following sterilization. In addition, it would be useful to have a better understanding as to what degree catheter damage contributes to infection or injury.

CONCLUSION

There were two cleaning methods reported that reduced all bacteria tested to negligible levels while confirming that the structural integrity of the catheter was maintained: soaking catheters in 70% ethanol solution for 5 min, and the combined approach of soaking catheters for 5 min in hot detergent water followed by soaking for 15 min in Milton solution. The structural integrity of catheters after these methods were confirmed by calorimetric analysis and EM respectively. The remainder of the cleaning methods either did not completely sterilize the catheters, damaged the structural integrity of the catheters, or did not analyze for the cleaning method's ability to sterilize or its impact on structural integrity of the catheter.

Major limitations to these two cleaning methods were that they have not been confirmed effective by more than one study, only PVC catheters were examined, the results were obtained from in vitro data, and outcomes were measured after only a single reuse. While these two cleaning methods are promising, additional data, specifically clinical evidences or in vivo data must be obtained before we would feel comfortable challenging current clinical recommendations. The authors believe that this topic requires further consideration and additional research that could provide better insight on cleaning methods, reuse of catheters, and potential benefits versus harm to individuals who use of catheters for IC.

DATA AVAILABILITY

The datasets generated and / or analysed during the current study are available from the corresponding author.

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AUTHOR CONTRIBUTIONS

MG: Study conception and design, acquisition of data, analysis and interpretation of data, drafting of the manuscript and critical revisions. MW: Study conception and design, acquisition of data, analysis and interpretation of data, critical revisions of the manuscript, and supervision. AVK: Study conception and design, acquisition of data, analysis and interpretation of data, critical revisions of the manuscript, and supervision. All authors approve the final version to be published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

COMPETING INTERESTS

Andrei V. Krassioukov is an advisory board member for Coloplast and Wellspect. All other authors declare that they have no conflict of interest.

ADDITIONAL INFORMATION

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