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DEVELOPMENT OF AN EFFECTIVE AND ACCEPTABLE CLEANING METHOD TO ALLOW SAFE RE-USE OF PLAIN, UNCOATED CATHETERS FOR INTERMITTENT CATHETERISATION

Hypothesis / aims of study

In the UK, catheters for intermittent catheterisation (IC) are used once and discarded although not necessarily the case in other countries including Canada and Australia. Those who do reuse catheters (multi-use) typically wash them with soap and water, let them air dry and then store them in a convenient portable container. Concerns raised about urinary tract infection rates with multiple use catheters are not supported by a 2014 Cochrane review (1). If individuals do reuse their catheters, it is critical that they and clinicians are confident in the cleaning method. To date, no systematic evaluation has evaluated cleaning methods. Thus the purpose of this study was to: 1) Identify and test potential cleaning methods for plain uncoated catheters and 2) Conduct clinical testing with IC users in their own homes.

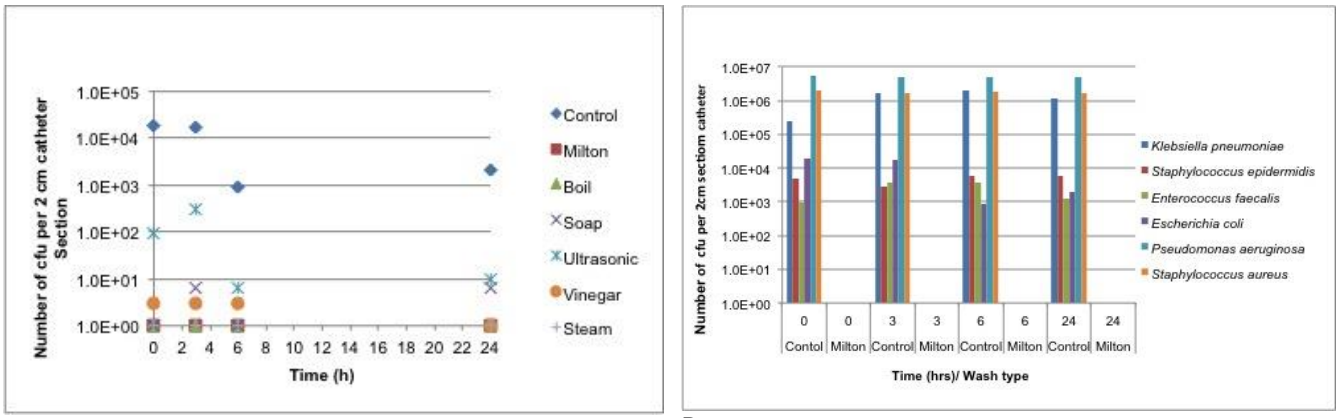
Study design, materials and methods

Step 1: Laboratory testing of cleaning methods: Six methods suitable for cleaning PVC -- steam, boiling, ultrasonic, vinegar, soap and water, Milton fluid soak (a commercial form of sodium hypochlorite) -- were compared against control treatment of tap water rinse. Sections of uncoated PVC catheters (2 cm portions of tip, shaft, funnel) were exposed to known concentrations of a range of bacterial uropathogens in artificial urine over time periods of 0, 3, 6, 24 h. Each method was assessed for effectiveness via culture. Episcopic differential interference contrast microscopy (EDIC-M) was used to show any evidence of biofilm development and to provide visual assessment of any surface changes.

Step 2: Clinical testing of the most effective cleaning methods: Post laboratory testing and in discussion with a panel of catheter users, the most effective and acceptable methods were identified. These were then tested by three IC user panels (16 m; 13 w) at home using three self-selected catheter brands. Detailed cleaning instructions and training were provided by a registered nurse expert in IC. Catheters were cleaned and re-used in a step-wise manner, from one clean and re-use up to a maximum of 28 cycles and returned to the laboratory for repeated analysis. Catheter urine specimens were taken at baseline and prior to each increment in number of cycles. Culture analysis on selective chromogenic agar provided quantification of the culturable population and species identification.

Results

Step 1 Laboratory testing showed Milton soak, steam sterilisation and boiling to be most effective at cleaning the catheter sections following exposure to uropathogens. Figure 1A shows the numbers of culturable, uropathogenic *Escherichia coli* remaining after cleaning and re-exposure over the course of 24 hrs. Figure 1B shows the effectiveness of Milton soak versus a tap water rinse (control) over the 24 hr test period with the range of uropathogens.



A. B.

Figure 1. A. effectiveness of all test methods on reduction of *E. coli;* B. comparison of treatment with Milton soak and control rinse with tap water for a range of uropathogens.

EDIC-M clearly showed attachment of bacteria in the control (tap water rinse) samples (Figure 2B). However, the heat-based cleaning treatments caused surface damage and could lead to increased bacterial attachment on the PVC catheters (see Figure 2C). In addition, these were less acceptable methods to catheter users and were therefore excluded. Two methods – i) soap and water, and ii) soap and water plus Milton soak (Milton Method) were therefore selected as the most effective and acceptable methods for clinical testing in #2.

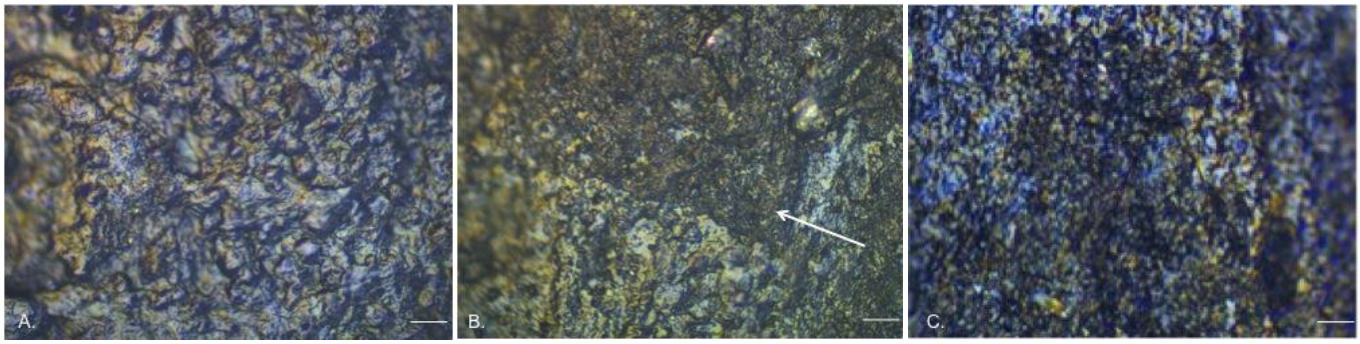


Figure 2. EDIC images of PVC (Pennine) catheter sections. A. Sterile, unused catheter showing highly disordered surface structure, typical of a sterile PVC catheter. B. Surface of control catheter section, exposed to *E. coli* four times (0, 3, 6, 24 h), arrow indicates darker region showing bacterial colonisation. C. Surface following steam sterilisation showing bacterial colonisation (darker region indicated by arrow). (Magnification x 500, bar = 20 µm)

Step 2: User panel testing (home cleaning of catheters) showed that simple cleaning with soap and water alone was less effective than when followed by a Milton Method. The Milton Method was therefore adopted for subsequent testing (Table 1). User panel urine specimens indicated a high degree of bacterial contamination. Culturable bacteria following cleaning were found on < 10% of samples but, where present, tended to be the same species found in the urine and included *E. coli*, *Enterococcus faecalis*, *Klebsiella pneumoniae* and *Staphylococcus aureus*. Using the Milton Method, surface analysis with EDIC-M showed no visible damage to uncoated PVC catheters and no evidence of biofilm formation. The effectiveness of the Milton Method continued with up to 28 re-uses (Table 1).

No. times catheter reprocessed	Cleaning method tested	Total samples tested* (from men and women)	No. (%) samples with culturable bacteria
1 - 7	Soap & water only	225 (m =117; w =108)	58 (26)
	Milton Method	678 (m = 306; w = 378)	21 (3)
8 - 14	Milton Method	84 (m = 36; w = 48)	0 (0)
15 - 27	Milton Method	24 (m = 6; w = 2)	1 (4)
28+	Milton Method	63 (m = 27; w = 36)	0 (0)
*A total of three samples were taken from each catheter.			

Table 1. No. of culturable bacteria on 2 cm lengths of catheters following different reprocessing frequencies.

Interpretation of results

Laboratory testing demonstrated the relative effectiveness of cleaning methods and provided data for the most suitable clinical testing methods. Cleaned catheter samples from IC users confirmed that soap & water followed by a 15 minute Milton soak was effective for catheters reused up to 28 times; users also reported that the method was acceptable (practical, easy to use at home and away). They agreed that catheter reuse was a possible option for IC users in the future with advantages which complemented those of single use catheters. The safety and acceptability must now be tested on large participant groups.

Concluding message

Laboratory and user testing has shown that the 'Milton Method' is effective at removing a range of commonly occurring uro-pathogens from PVC catheters without damaging the catheter surface and with 0 - minimal culturable bacteria. Milton is an acceptable method for IC users at home with the potential to facilitate re-use of catheters as part of a mixed package of multi and single use. It is now being tested in a large multi-centre RCT in the UK.

References

1. Prieto J, Murphy CL, Moore KN, Fader M. Intermittent catheterisation for long-term bladder management. Cochrane Database of Systematic Reviews 2014, Issue 9. Art. No.: CD006008. DOI: 10.1002/14651858.

Disclosures

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