Options for users of intermittent catheters

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- Evidence for single-use and multi-use catheters
- Aims of the Multi/Cath research study and how to get involved

Intermittent catheters are used to drain urine from the bladder in patients with urinary retention. In the 1980s and 1990s, using intermittent catheters was standard practice, with patients taught by nurses to clean and reuse them multiple times before discarding them. Today, sterile, single-use catheters (discarded after one use) have become the norm.

It is easy to assume that single-use catheters are better for patients and cause fewer urinary tract infections (UTI) than multi-use ones. However, this was not the reason for the change in practice. New hydrophilic-coated catheters, which become slippery in water, were introduced in the 1980s and could not be reused. In addition, regulatory changes introduced in 2006 and updated in 2013 (Medicines and Healthcare products Regulatory Agency, 2013) meant manufacturers had to provide instructions on how to restore uncoated catheters to their original state if they wanted them to be reused – it was easier to label them as single-use.

What is the evidence?

A recently updated Cochrane review (Prieto et al, 2014) concluded that: “... there remains a lack of evidence that one catheter design or technique is superior to another in terms of control of symptomatic UTI.”

Bermingham et al (2013) also stated that not only is there insufficient evidence to favour a particular type of catheter but: “Clean non-coated catheterisation is the most cost-effective method of intermittent self-catheterisation.”

Other countries have different regulations and single-use catheters have not become the norm worldwide: in Australia, New Zealand and Canada multi-use catheters are common (Leek et al, 2013; Woodbury et al, 2008), while in the US both types are used. In less-economically developed countries, intermittent catheterisation (IC) would be inaccessible to many patients if multi-use catheters were not available.

“Mixed” use might be optimum

The advantages and disadvantages of each type of catheter (Table 1) mean using both “mixed” use – might be better for some patients. For example, some might find reusing catheters at home practical but single-use catheters easier for going out. Having only single-use catheters available in the UK has reduced patient options; if multi-use catheters were shown to be safe and acceptable for patients, they could be reintroduced, giving patients more options.

Keywords: Intermittent catheters/ Single-use/Multi-use

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Abstract


Users of intermittent self-catheterisation in the UK have access only to single-use catheters. The MultICath study is under way to determine whether multi-use catheters are safe and acceptable to patients; if so, a mixed approach could improve patient choice.

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Aims of the Multi/Cath research study and how to get involved
Opportunities for innovation
Introducing mixed use may provide opportunities for innovation. For example, a catheter with a specialised coating that is slippery without water being added, repels bacteria and “self cleans” would likely cost far more than a single-use one; if it was suitable for multiple use, however, it could still be cost effective. If multi-use catheters are safe and acceptable, manufacturers could respond to the opportunity to design, and invest in, products with new technologies.

Reintroducing multi-use catheters
The evidence does not suggest multi-use catheters are likely to cause more infections than single-use ones but achieving certainty about this requires a large randomised controlled trial. This has been recommended not only by Prieto et al (2014) and Bermingham et al (2013), but also as a research priority from the James Lind Alliance (Buckley et al, 2010).

Multi-use catheters cannot be introduced without MHRA approval, which requires an evidence-based, effective cleaning method. There is also insufficient evidence to show that patient acceptability is as good for multi-use as single-use catheters, and more solid evidence is required.

The Multi/Cath programme
The MultiCath research programme – undertaken by five partner universities and NHS trusts: University of Southamton, University College London, Glasgow Caledonian University, North Bristol Trust and Newcastle University – is designed to address these issues. Funded by the National Institute for Health Research (NIHR) and with the support of the Association for Continence Advice, the Bladder and Bowel Foundation and the RCN Continence Care Forum, it began in 2013 and will last five years in two phases.

The first phase involves:
» Developing an effective and acceptable cleaning method
» Validating the tools to measure UTI symptoms and quality of life (QoL) of intermittent catheter users;
» Finding out the perspectives of key stakeholders such as continence or urology nurse specialists, community nurses, GPs and industry representatives.

The results from phase 1 are sufficiently promising that we expect to proceed to an RCT involving more than 500 patients (phase 2), in which the “mixed” catheter package will be compared with the standard method of single-use catheters.

Development of the cleaning method
Three user panels in Bristol and Southamton are helping to develop the cleaning method by testing various ways to clean catheters. Having narrowed these down to two methods that are acceptable to users, panel members reuse their catheters multiple times and return them to the microbiology laboratories for culture and analysis to determine the efficacy of the cleaning. The catheter surfaces are also being examined microscopically for any deterioration that may be caused by multiple cleaning.

Patient interviews
Patient views are being collected about reuse and single use of catheters, to determine the symptoms that are common when they have UTIs, and what they do to avoid them. Around 40 patients have been interviewed and another 10 or more will be observed during catheterisation. A new QoL tool (ISC-Q) (Pinder et al, 2012) is also being tested with users. The findings from these interviews and observations will inform and refine the tools used to measure UTI and QoL during the trial.

Views of nurses and other stakeholders
Current nursing practice in teaching IC, along with the views of nurses and other stakeholders, are being determined via an electronic survey and interviews with stakeholders. Manufacturers are also being consulted to ascertain their views and the market potential for catheter reuse. We are also exploring practices in other countries.

Randomised controlled trial
The MultiCath trial, planned for September, will determine whether the “mixed” catheter package is “no worse than” single use catheters only (non-inferiority trial with follow-up at 12 months. The primary outcome will be incidence of clinical UTI. Other outcomes will include haematuria and bleeding, pain/discomfort, and QoL and preference.

Participants will receive a home visit and the mixed-use group will get a cleaning kit and instructions in booklet and DVD form. Monthly phone calls will be used to maintain contact with participants and ensure return of data – in particular when UTIs are experienced.

The trial, run by an NIHR Clinical Trials Unit at Newcastle University, will take place across England and Scotland. Data analysis will ascertain whether mixed use is safe and acceptable to users; the findings will inform future guidance from the National Institute for Health and Care Excellence and MHRA.

References