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ABSTRACT

Background: Catheter-associated urinary tract infection (CAUTI) can significantly affect patients' quality of life and increase healthcare costs. Aims: This study aimed to capture patients' and nurses' experience of catheter maintenance using a polyhexanide-based solution (PS) in everyday practice. Methods: Retrospective analysis of data was collected for a product evaluation. PS was used twice a week for five weeks. Findings: The study included 42 patients, 30 (71%) men and 12 women (29%). After five weeks of rinsing catheters with PS, nine patients reported no or decreased frequency of CAUTI, eight a better quality of life, eight reduced blockage, seven a decrease in odour and five fewer catheter changes. Three patients reported no benefit from PS use. Nurses reported that fewer visits were needed and consumption of disposables was lower. Conclusions: User experiences suggest that, as a novel means of catheter maintenance, PS has the potential to reduce catheter-associated complications such as CAUTI, improve quality of life and reduce healthcare costs.

Key words: Biofilm ■ Catheter maintenance ■ Indwelling catheter ■ Polyhexanide ■ Urinary tract infection

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Bacteriuria develops rapidly in catheterised patients (3–10% daily incidence rate) and the majority of patients with long-term indwelling catheters are continuously bacteriuric (Stamm, 1998; Hooton et al, 2010; Nicolle, 2014; Brusch, 2017). Even when urinalysis has positive results, the majority of these patients remain asymptomatic (Nicolle, 2014). However, up to 30% of patients with catheter-associated bacteriuria will develop symptoms; the occurrence of both positive culture and symptoms is defined as catheter-associated urinary tract infection (CAUTI) (Stamm, 1998; Nicolle, 2014).

The signs and symptoms of CAUTI, such as foul odour from the urine, fever, malaise and abdominal pain, can be embarrassing, distressing and uncomfortable for the patient (Nicolle, 2014; Dalton and Maute, 2019). If the primary infection is not effectively treated, patients may develop bacteraemia, which can be serious and lead to significant morbidity and mortality (Stamm, 1998; Nicolle, 2014). In community care settings in both residential/care homes and people's own homes, the risk of bacteraemia is much greater than it is in acute settings (Nicolle, 2014). CAUTI has been identified as the source of more than 50% of episodes of bacteraemia in long-term care facilities (Hooton et al, 2010; Fortin et al, 2012). *Escherichia coli* bacteraemia rates have increased by 24.3% between 2012 and 2016, with three-quarters defined as community onset (Bou-Antoun et al, 2016; Public Health England, 2017).

In addition to its impact on health, CAUTI may significantly affect patients' quality of life (QoL) as well as contribute substantially to healthcare use and associated costs (Wilde et al, 2013; Waskiewicz et al, 2019). In particular, patients in the community who are geographically isolated may require extra nurse visits or access to acute services when complications arise (Wilde et al, 2013; Nicolle, 2014). A study of long-term care facility residents in the US found that 19% of patients with CAUTI required extra nurse visits, 25% a visit to their physician's clinic and 35% an out-of-hours visit to the emergency department (Wilde et al, 2013). A UK study found 41% of patients with CAUTI symptoms presenting to an emergency department were admitted for systemic treatment (Ansell and Harari, 2017). Another study of adult patients admitted to UK NHS trusts between 2016 and 2017 estimated that the total

direct hospital costs associated with CAUTI were £54.4m (UI £37.3–77.8m) (Smith et al, 2019).

In CAUTI, bacteria gain access to the urinary tract either extraluminally or intraluminally and form biofilm, where bacterial colonies are embedded in a self-produced extracellular polymeric matrix that helps them to adhere to the catheter surface and drainage bag (Stamm, 1998; Nicolle, 2014; Amuthamani et al, 2017; Nguyen et al, 2017). A recent study showed that within 1 week of indwelling catheter use, biofilm is detected within the proximal (bladder-exposed) end of the catheter and, within 3–4 weeks, it is present in all segments (Nguyen et al, 2017).

Biofilm formation is critical not only to the development but also to the persistence and recurrence of bacteriuria and CAUTI, as biofilms function both as microbe reservoirs and barriers to antimicrobial agents (Nguyen et al, 2017). Furthermore, the speed of antimicrobial resistance is enhanced in biofilms and there is a significant association between biofilm-producing bacteria and multidrug resistance as well as between long-term use of antibiotics (>5 days) and the development of infection by multidrug resistant (MDR) pathogens (Amuthamani et al, 2017). All types of catheter are vulnerable to colonisation by biofilm so changing the type of catheter will not necessarily help to reduce the risk of CAUTI (Stickler, 2008).

Current guidelines do not recommend active intervention for catheter maintenance in the majority of patients despite the impact of CAUTI in this population (Hooton et al, 2010; Geng et al, 2012). In daily practice, catheter maintenance solutions are only recommended in special circumstances, such as during the removal of blood clots after urological surgery or in palliative treatment of intractable haematuria (Geng et al, 2012). Therefore, from a management perspective, removal of the catheter may be the only option if there is recurrent infection and catheter blockage (Wilde et al, 2013). However, frequently changing an indwelling catheter may increase the risk of infection and cause discomfort and embarrassment for the patient (Milligan, 1999; Rew and Woodward, 2001; Cooper et al, 2016). Therefore, there is a rationale for a catheter maintenance strategy that will help prevent the development of catheter-associated complications (CACS) such as CAUTI and thereby improve patient well-being.

When using catheter maintenance solutions, it has to be taken into account that the instillation of any solution into a urinary catheter carries potential risks of contamination, as the drainage bag must be disconnected from the catheter for the solution to be administered. This could increase the risk of CAUTI (Cheshire & Wirral Partnership NHS Foundation Trust, 2012; National Institute for Health and Care Excellence, 2013); however, antimicrobial solutions may have the potential to reduce this risk. An in-vitro study with a novel polyhexanide-based catheter-maintenance solution (Uro-Tainer 0.02% Polyhexanide, B Braun, Sempach, Switzerland) (PS) has been shown to significantly reduce bacterial colonisation of the catheter compared to no intervention or rinsing with saline (Brill et al, 2018).

The initial purpose of this questionnaire-based case series was to carry out a product evaluation to capture both the patient and the nurse perspective on the effect of using PS for catheter maintenance in everyday clinical practice. The product evaluation was an open and uncontrolled study; however, it was thought that the resulting data might provide information of interest to nursing professionals caring for patients with long-term indwelling urinary catheters, especially those experiencing CACS such as CAUTI.

Method

Participants

Patients living long term with an indwelling urethral or suprapubic catheter from four hospital centres and five 'communities' in Denmark were included in this questionnaire-based case series. 'Communities' provide care for patients in long-term care facilities and their own homes. The continence nurses identified patients experiencing CACS (eg recurrent CAUTI and frequent catheter changes) as candidates for rinsing with PS.

A total of 11 continence nurses took part in the study; they were responsible for the care of between three and 10 patients each. The opportunity to take part in the product evaluation was offered to specialist continence nurses (eg continence advisors) in both community settings and hospitals across Denmark.

Design and data collection

This study resulted from retrospective analysis of data collected for a product evaluation. Ethics approval was judged not to be necessary by the national ethics committee as this was an interview/questionnaire-based product evaluation without human biological material or non-anonymised patient data being collected.

Before PS was administered for the first time, the nurses recorded the patient's age, sex and length of time they had been catheterised (*Table 1*). At this stage, they used the questionnaire to ask each patient what they considered to be their own subjective evaluation of all the CACS they were experiencing. The continence nurses noted the patient responses verbatim. Separately, they recorded what they considered to be the reason(s) for using PS for catheter maintenance in their patients. During the five weeks over which PS was used, the patients were managed in accordance with local practice and routine information recorded in the patient documentation.

At the end of the five-week experience of using PS, the

Table 1. Demographic data

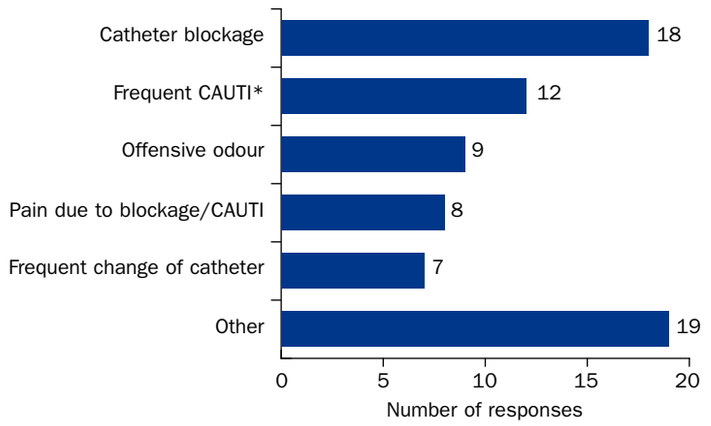
Age range (years)	**40–50** % (*n*)	**51–60** % (*n*)	**61–70** % (*n*)	**71–80** % (*n*)	**81–90** % (*n*)	**91+** % (*n*)
	7 (3)	17 (7)	17 (7)	21 (9)	28.5 (12)	9.5 (4)
Male % (n)	71% (30)					
Length of catheterisation (years)	**0–2*** % (*n*)	**3–5** % (*n*)	**6–8** % (*n*)	**9+** % (*n*)	**Not known** % (*n*)	
	48 (20)	24 (10)	12 (5)	14 (6)	2 (1)	

* The shortest period of catheterisation was 5 months

nurses asked the patients what they considered to be their own subjective evaluation of the advantages, if any, of using PS. The nurses noted the patient responses verbatim. They were also asked to note if the patient continued using PS. In addition, the nurses recorded their own subjective evaluation of the advantages, if any, of using PS.

PS administration

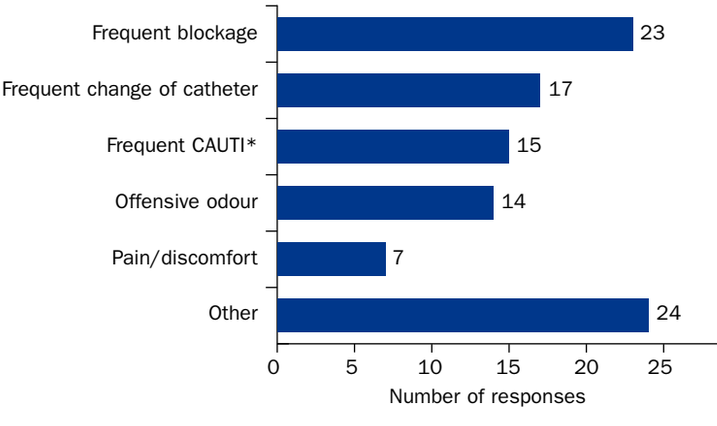
Each patient was administered PS twice a week by a nurse. The catheter was changed before the first administration of PS to provide the same starting point for each patient. Clinical management (eg use of concomitant systemic antibiotics and monitoring) of each patient was carried out in accordance with local guidance and nursing best practice.



Other: Poor sleep at night (2); the catheter changes its colour (1); pain at change of catheter (2); the catheter slips (1); insecurity over whether the catheter is working (1); leakage (2); a challenge to take penicillin (1); pain (1); mood swings (1); cystitis requiring treatment (1); hospitalisation (1); spasm (1); irritation/frustration because the indwelling bladder catheter does not work (1); reduced quality of life (1); multiresistant bacteria (1); purple urine bag syndrome (1) (*n*=19 total)

*CAUTI: catheter-associated urinary tract infection

Figure 1. Catheter-associated complications at baseline: patient response



Other: Leak at indwelling bladder catheter (2); improved quality of life (1); the catheter often slips out (1); alternatives to antibiotics (2); poor sleep at night (1); the catheter changes colour (2); bleeding at change of catheter (1); encrustation (2); rinse with NaCl and citric monohydrate acid (Suby G (B Braun)) (2); spasm (1); frequent cystitis (1); dysfunction of catheter (1); retention (2); small bladder capacity (1); sclerosis (1); benign prostatic hyperplasia (1); paraperesis after spinal stenosis surgery (1); teraplegic patient (1) (*n*=24 total) *CAUTI: catheter-associated urinary tract infection

Figure 2. Reasons for catheter maintenance at baseline: nurse response

Data analysis

The analysis included patient demographics and patient reporting of CACS, together with feedback from both patients and nurses on the effect of using PS. The data were collated and descriptive statistics used to present the results (eg range, percentage and frequency).

Findings

Demographics

Forty-two patients with long-term indwelling catheters were followed, 17 from four hospitals and 25 from five communities. Demographic information was available for all 42 participants. The majority of the patients were men (*n*=30; 71%) and more than half were >71 years of age (*Table 1*). All patients had been catheterised in the long term (>30 days), half had been catheterised for 3 years or more.

Baseline catheter-associated complications

Patients reported a range of CACS including QoL concerns (*Figure 1*). Before using PS, the five most common CACS experienced by the patients were catheter blockage (*n*=18), frequent CAUTI (*n*=12), offensive odour (*n*=9), pain because of a blockage or CAUTI (*n*=8) and frequent change of catheter (*n*=7). A further 16 individual CACS were mentioned by one or two patients each and categorised as 'Other' (see foot of *Figure 1* for details).

The five key reasons given by nurses for the need for catheter maintenance were similar to those reported by the patients and included frequent catheter blockage (*n*=23), frequent change of catheter (*n*=17), CAUTI (*n*=15), offensive odour (*n*=14) and pain/discomfort (*n*=7) (*Figure 2*). A further 18 reasons were mentioned for one to two patients each and categorised as 'Other' (see foot of *Figure 2* for details).

Effects of PS: patient feedback

After five weeks of use, the patients considered the most common benefits of rinsing with PS to be none or decreased frequency of CAUTI (*n*=9), none or reduced catheter blockage (*n*=8), improved wellbeing (*n*=8), reduced offensive odour (*n*=7), fewer catheter changes (*n*=5), less inconvenience (*n*=4) and being less bothered because of wet clothing (*n*=4) (*Figure 3*).

A further 10 benefits of using PS were reported by one or two patients each and classified as 'Other' (see foot of *Figure 3* for the details). Three of the patients reported no benefit of using PS.

Twenty-five (60%) of the 39 patients who completed the 5-week treatment period continued to use PS after the evaluation phase ended, 10 (24%) did not and a further four (9%) were still to confirm their willingness to continue. Three patients (7%) stopped treatment before the end of the observation period so did not answer this question.

Effect of PS: nurse feedback

In addition to improvement in patient wellbeing (n=16) the nurses reported the main advantages of using PS to be connected to their own practice and better use of resources, including fewer nursing visits and catheter changes (n=16), and a reduction in consumption and therefore expenditure on disposables (n=8) (*Figure 4*). A further eight advantages of PS were mentioned for one or two patients each and classified as 'Other' (see foot of *Figure 4* for details). The nurses reported no advantages from using PS in two patients.

Adverse events

Two patients (5%) experienced stinging in the bladder during the observation period with PS and, as a result, ceased using the product. Another patient dropped out of the study for a reason unrelated to use of PS (bladder stones).

Discussion

Summary of key findings

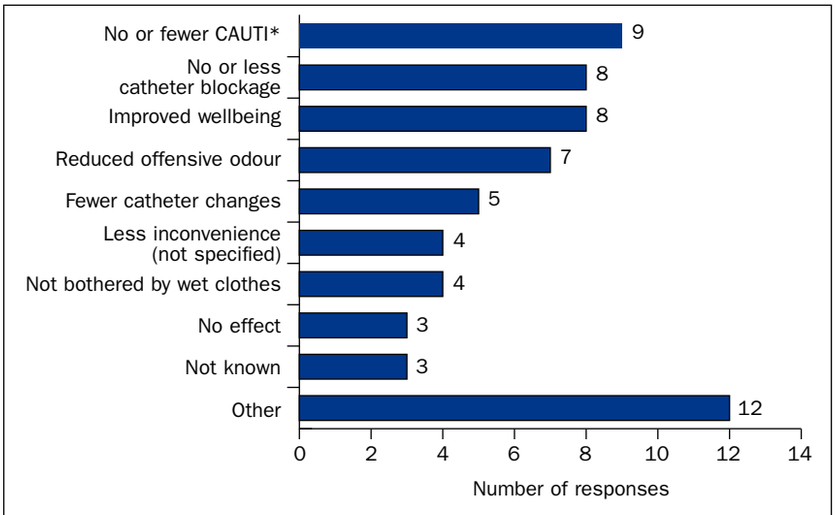
This case-series analysis indicates positive effects of catheter maintenance with PS in adult patients living long term with an indwelling urinary catheter and experiencing CACS (eg CAUTI). Following 5 weeks of using PS twice weekly, the majority of patients benefited from improvements in both CACS and QoL (eg reduced urine odour) (*Figure 3*). PS was also well tolerated by the patients. The positive impact of PS is demonstrated in the 60% of patients who expressed their willingness to continue using it after the five-week period ended. The feedback from the nurses also suggests that catheter maintenance with PS improved patients' wellbeing and QoL and had a positive impact on their own practice and use of healthcare resources (eg fewer nursing visits and reductions in the use and cost of disposables) (*Figure 4*).

This analysis also highlights the negative impact of CACS on patients living long term with indwelling urethral and suprapubic catheters (*Figure 1*). At the outset, both patients and nurses reported a range of CACS, including recurrent CAUTI, pain and blockage, which often lead to frequent catheter removal and a poorer QoL. These results confirm other findings on the disease burden of CACS such as CAUTI on both patients and healthcare providers (Nicolle, 2009; 2014).

Evaluation of the patient population

The clinical background (ie length of catheterisation and presenting signs and symptoms) of the patients in this analysis appears comparable to that of other populations of patients living long-term with an indwelling urethral or suprapubic catheter (Wilde et al, 2013).

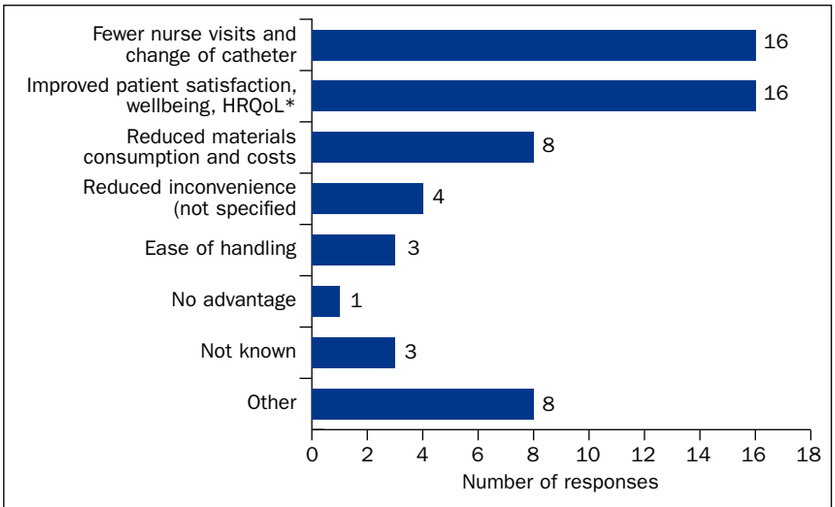
However, the mean age of patients in this analysis is higher than in other studies (Wilde et al, 2013). In a US survey of patients with long-term catheters living in a long-term care facility, the mean age was 61 years compared to 71 years in the present study (Wilde et al, 2013). Likewise, the male: female ratio in our analysis differs markedly (Wilde et al, 2013). In the US survey, 51% of the population was male, compared to 71% in our analysis. These differences must be taken into account when interpreting this analysis.



Other: Self-reliant (1); has not been confused/hallucinating (1); less inflated abdomen (1); fewer worries about catheter blockage (2); reduced use of resources for personal hygiene (1); reduced pain (2); less discolouration of the catheter (1); no hospitalisation (1); rest the bladder (1); no indication of cystitis (1) (total n=12)

*CAUTI: catheter-associated urinary tract infection

Figure 3. Effects of using polyhexanide-based solution: patient experience



Other: Prevention of or no urinary tract infections (2); fewer catheter blockages (1); lower workload (1); extension of catheter lifetime (2); better planning for nursing staff (1); attention is paid to how well the catheter is working (1); fewer leaks (2); no hospitalisations (1) (total n=11)

*HRQoL: health-related quality of life

Figure 4. Effects of using polyhexanide-based solution: nurse experience

Comparative literature review

The current literature on treatment of CAUTI is largely restricted to the use of a range of systemic antibiotic agents (Buehlmann et al, 2011). There are a number of reasons that these agents may not be the most effective means of managing CAUTI in the long term. Standard therapeutic doses of antibiotics may have little or no effect on bacteria in biofilm (Phillips et al, 2010; Sabir et al, 2017). Furthermore, Amuthamani et al (2017) demonstrated that there is a correlation between

length of antibiotic use and development of MDR pathogen infection, which may provide a stronger reason to minimise use of long-term systemic antibiotics in this population. Because of such concerns, systemic antibiotic treatment is not recommended for CAUTI unless there is a specific indication (eg after urological surgery) for patients requiring short or long-term catheterisation (Gould et al, 2010).

As an alternative to systemic approaches, there has been a growing body of research into coating or impregnating catheters with compounds with the aim of reducing surface adhesion of bacteria or with antibacterial properties (eg silver) (Singha et al, 2017; Oleksy-Wawrzyniak et al, 2018). However, none of these coatings have been shown to resist biofilm formation in the clinical setting effectively (Singha et al, 2017). Because of short half-life of some of the compounds tested, the risk of the microbes developing resistance may be increased (Oleksy-Wawrzyniak et al, 2018). In addition, their efficacy may be limited as some of the compounds tested may not be effective against the wide variety of Gram-negative and positive bacteria that commonly colonise catheter surfaces (Słojewska-Poznan'ska et al, 2017; Oleksy-Wawrzyniak et al, 2018).

Several factors make polyhexanide an interesting option for the mechanical rinsing and bacterial decolonisation of urinary catheters. There is evidence to suggest that physical removal, ie mechanical rinsing, is the best method of biofilm removal (Phillips et al, 2010). Ongoing, regular cleansing is also required to prevent biofilm regrowth (Phillips et al, 2010). Topical broad-spectrum antimicrobial agents that kill rather than inhibit microorganisms are thought to be the most appropriate agents to use for mechanical rinsing (Phillips et al, 2010). Polyhexanide (polyhexamethylene biguanide) is a broad-spectrum microbicidal antimicrobial, which was developed as an improved, second generation compound, with distinct advantages over chlorhexidine as tissue tolerates it much better and is not so easily degraded (Moore and Gray, 2007). Polyhexanide has demonstrated good clinical safety and minimal toxicity and is used in a wide range of products in the medical and dental fields such as contact lens cleansers and mouthwashes as well as in wound management (Bradbury and Fletcher, 2011; Oleksy-Wawrzyniak et al, 2018).

As well as having a significantly better antimicrobial effect in vitro than rinsing with saline (Brill et al, 2018), polyhexanide has been shown to have anti-adhesive properties, which may help to prevent bacterial colonisation of the catheter surface (Afinogenova et al, 2011; Kamaruzzaman et al, 2017). Furthermore, polyhexanide has been shown to be effective against a range of Gram-negative bacteria, which are common causes of CAUTI (Oleksy-Wawrzyniak, 2018). Importantly, no cross-resistance with other antibiotics or resistance to the antiseptic agent itself have been observed (Bradbury and Fletcher, 2011; Renzoni et al, 2017; Oleksy-Wawrzyniak et al, 2018). The lack of any reported interaction between polyhexanide and other antibiotic groups indicates that the combination of mechanical rinsing with polyhexanide alongside systemically administered antibiotics may be a clinical option (Oleksy-Wawrzyniak, 2018).

In addition to the in vitro data, the effect of PS has been tested in vivo in a small series of acutely hospitalised patients with significant comorbidities and proven urine infection with species of MDR bacteria including *Pseudomonas aeruginosa* (sensitive only to gentamicin [MIC4] with a minimum inhibitory concentration 4µg/ml), *Acinetobacter baumannii* and *Escherichia coli* (Oleksy-Wawrzyniak et al, 2018). In this series of four cases, PS was used for catheter maintenance in addition to the standard approach (eg 3.23% citric acid) twice a day for between 2 and 7 days. Following the use of PS, in three out of the four cases the urine cultures were negative for MDR bacteria.

PS is indicated as a solution for the maintenance of indwelling urethral and suprapubic catheters to aid removal of deposits, tissue waste, clots and mucus. Supported by the preservative property of polyhexanide, PS helps to reduce bacterial colonisation of the catheter and maintain hygienic conditions during urinary catheter manipulations.

A recently published safety and tolerability analysis in 32 patients indicated that multiple instillations with PS over five days were safe and well tolerated (Pannek et al, 2020). Although there were few cases of discomfort and adverse events, these were temporary and did not persist throughout the course of the study. None of the patients experienced allergic reactions to the contents of the medical device.

Strengths and limitations

Qualitative data is increasingly recognised as having an important role in informing clinical practice, especially in areas of long-term medicine such as this where the persistent nature of the problem may severely affect a patient's QoL (Thorne et al, 2004; Nicolle, 2014). Therefore, a key strength of this questionnaire-based case series is that it has provided data on everyday use of PS in patients living long-term with a urinary catheter and affected by CAUTI or other CACS. Such real-life data suggest that patients may benefit from this novel means of catheter maintenance, which has the potential to improve their wellbeing and QoL. Likewise, nursing professionals who care for these patients have indicated that PS has the potential to improve their own practice.

The main limitation of this questionnaire-based case series is that it was initially intended as a product evaluation, not a rigorous systemic analysis. Therefore, it had no control group or formal inclusion and exclusion criteria, which may have led to bias. As far as other factors that may have influenced the outcome are concerned, the authors recognise it would have been valuable to know which patients received systemic antibiotics during the 5-week period of PS use as well as the severity of the adverse events reported by the two patients who stopped treatment before the end of the treatment period.

The study was carried out over a relatively short period of time compared to the normal lifespan of a catheter, which may be expected to be 12 weeks in patients without CACS (Nicolle, 2014). However, the fact that the feedback was consistently positive and 60% of patients were keen to carry on with the administration of PS after five weeks would suggest that it delivered benefits over and above those of previous interventions.

All the potential limiting factors outlined above could be addressed in a prospective, controlled study with a formal

protocol and well-defined inclusion and exclusion criteria. Such a study could also provide data of interest to nursing professionals and healthcare providers to help improve practice; this could involve an objective evaluation of the severity of CAUTI symptoms, the drivers of QoL, objective rating of response (including length of catheter life) and the effect of PS on patient QoL (using a validated QoL instrument) as well as a cost-benefit analysis focusing on nursing time, use of disposables and doctor and out-of-hours hospital visits.

Furthermore, in this study, PS was administered twice per week but the manufacturer's instructions allow for more frequent use (up to twice per day). It would also be interesting to evaluate the effect of tailored administration of PS based on patient response.

Conclusions

These findings indicate that use of PS in everyday clinical practice provides a novel means of catheter maintenance, which has the potential to address CACS such as CAUTI and improve patients' QoL as well as having positive effects on nursing practice and healthcare costs. Further research is required to confirm these findings and to refine the use of PS in terms of patient selection and frequency of administration. **BJN**

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KEY POINTS

- Catheter-associated complications (CACS) such as catheter-associated urinary tract infection (CAUTI) may significantly affect patients' quality of life as well as contribute substantially to healthcare use and costs
- Bacteria can form biofilms, which help them to adhere to the catheter surface and drainage bag and act as barriers to antimicrobial agents
- Current guidelines do not recommend active intervention for catheter maintenance in the majority of patients; however, recommendations are based on a lack of high-quality evidence, rather than that maintenance is not effective
- Catheter maintenance solutions can be used as part of a management plan to optimise catheter life by decolonisation, resulting in fewer catheter changes and reducing trauma on catheter removal
- Catheter maintenance with a polyhexanide-based solution (PS) can improve the quality of life of patients with a long-term indwelling urinary catheter

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CPD reflective questions

- How do you normally approach the management of patients with catheter-associated complications (CACS) such as urinary tract infections? Do you think this is adequate?
- How do you think that CACS may affect the quality of life and wellbeing of your patients?
- How do you think the findings of this study would affect the care of your patients with long-term indwelling catheters?

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