A prospective interventional study to examine the effect of a silver alloy and hydrogel–coated catheter on the incidence of catheter-associated urinary tract infection

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ABSTRACT

Introduction: Catheter-associated urinary tract infection is a major hospital-acquired infection. This study aimed to analyse the effect of a silver alloy and hydrogel–coated catheter on the occurrence of catheter-associated urinary tract infection.

Methods: This was a 1-year prospective study conducted at a single centre in Hong Kong. Adult patients with an indwelling urinary catheter for longer than 24 hours were recruited. The incidence of catheter-associated urinary tract infection in patients with a conventional latex Foley catheter without hydrogel was compared with that in patients with a silver alloy and hydrogel–coated catheter. The most recent definition of urinary tract infection was based on the latest surveillance definition of the National Healthcare Safety Network managed by Centers for Disease Control and Prevention.

Results: A total of 306 patients were recruited with a similar ratio between males and females. The mean (standard deviation) age was 81.1 (10.5) years. The total numbers of catheter-days were 4352 and 7474 in the silver-coated and conventional groups, respectively. The incidences of catheter-associated urinary tract infection per 1000 catheter-days were 6.4 and 9.4, respectively (P=0.095). There was a 31% reduction in the incidence of catheter-associated urinary tract infection per 1000 catheter-days in the silver-coated group. *Escherichia coli* was the most commonly involved pathogen (36.7%) of all cases. Subgroup analysis revealed that the protective effect of silver-coated catheter was more pronounced in long-term users as well as female patients with a respective 48% (P=0.027) and 42% (P=0.108) reduction in incidence of catheter-associated urinary tract infection. The mean catheterisation time per person was the longest in patients using a silver-coated catheter (17.0 days) compared with those using a conventional (10.8 days) or both types of catheter (13.6 days) [P=0.01].

Conclusions: Silver alloy and hydrogel–coated catheters appear to be effective in preventing catheter-associated urinary tract infection based on the latest surveillance definition. The effect is perhaps more prominent in long-term users and female patients.

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New knowledge added by this study

- The use of a silver alloy and hydrogel–coated (SAH) catheter has the potential to reduce catheter-associated urinary tract infection (CA-UTI), especially in certain subgroups of patients (long-term users and female patients).

Implications for clinical practice or policy

- The use of a SAH catheter potentially reduces the incidence of CA-UTI. This will lead to less morbidity and medical costs associated with CA-UTI.
- This study provides pilot data for future research.

Introduction

Catheter-associated urinary tract infection (CA-UTI) is a major cause of hospital-acquired infection, with local data showing 4.9 infections per 1000

一項前瞻性介入研究以探討銀合金水凝膠塗層導管對出現導管相關性尿道感染的影響

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引言：導管相關性尿道感染是醫院內感染中最常見的一種。本研究旨在分析銀合金水凝膠塗層導管對出現導管相關性尿道感染的影響。

方法：這前瞻性研究在香港一個單一中心內進行，為期一年。研究對象為使用留置導尿管超過24小時的成年病人。並將使用銀合金水凝膠塗層導管的病人和使用傳統沒有水凝膠的Foley（乳膠）導管的病人進行比較，找出兩組導管相關性尿道感染的發生率。病人是否有尿道感染是按美國疾病管制中心成立的國家健康照護安全網絡的最新定義來判斷。

結果：共306名病人參與本研究，他們平均年齡（標準差）為81.1（10.5）歲，男女比例相若。銀合金水凝膠塗層導管和傳統Foley導管兩組的導管使用人日分別為4352天和7474天，而每一千導管人日的導管相關性尿道感染發生率分別為6.4和9.4（P=0.095）。銀合金水凝膠塗層導管組別的每一千導管人日的導管相關性尿道感染下降了31%。大腸桿菌是所有病人中最常見的病原體（36.7%）。亞組分析顯示銀合金水凝膠塗層導管的保護作用在長期使用者以及女性病人當中更加明顯，前者的導管相關性尿道感染發生率減少了48%（P=0.027），後者減少了42%（P=0.108）。留置導管的時間方面，使用銀合金水凝膠塗層導管的病人為最長（平均17.0天），使用傳統Foley導管的病人為10.8天，曾使用兩種導管的則為13.6天（P=0.01）。

結論：根據對尿道感染的最新監測定義，銀合金水凝膠塗層導管似乎能有效預防導管相關性尿道感染。此效應在長期使用者和女性病人當中可能更明顯。

catheter-days.[1] Internationally, an estimated 900 000 nosocomial UTIs occur every year, prolonging the mean duration of hospital stay by 1 to 3.8 days. It has been estimated that approximately 80% of UTIs are related to the presence of an indwelling urinary catheter. In severe cases, these infections may lead to bacteraemia, urosepsis, and even mortality.[2,3] A case-control study also suggested that patients with CA-UTI had excess costs of US$3803 compared with patients without infection.[4] Therefore, by prevention of CA-UTI, a significant reduction in morbidity and mortality, as well as the health care economic burden, can be anticipated.

Bactiguard-coated Foley catheters (Bactiguard, Sweden) were approved by the US Food and Drug Administration in 1994. These catheters have a stable noble metal alloy and hydrogel coating (also referred to as silver alloy and hydrogel–coated, SAH) on the outer- and inner-luminal surfaces of the catheter, providing repellent and anti-infective properties by preventing the formation of microbial biofilm. The coating consists of gold, silver and palladium, and also preserves the urethral mucosal integrity and helps to avoid the onset of inflammation. Previous studies of CA-UTI prevention had asymptomatic bacteriuria (ASB) alone or in combination with symptomatic UTI as the endpoint so their clinical relevance was called into question. We conducted a prospective, interventional study to provide additional data on the effectiveness of the noble metal alloy urinary catheter in the prevention of CA-UTI, using the updated surveillance definition of National Healthcare Safety Network (NHSN) managed by the Centers for Disease Control and Prevention (CDC). This surveillance definition was adopted in 2009 and modified the criteria for symptomatic infection, as well as adding a category and definition for asymptomatic bacteraemic UTI together with the removal of ASB completely.[5] To study the effect on ASB, we adopted the criteria used in the Infectious Diseases Society of America practice guideline developed in 2009.[6]

Methods

This single-centre 1-year prospective study was completed in 2012 in a regional rehabilitation hospital in Hong Kong. The study population was in-patients in two medical rehabilitation wards. All patients over 18 years of age on either of the wards during the study period with an indwelling catheter for longer than 24 hours were recruited after giving informed consent. Patients who underwent suprapubic catheterisation, single in-and-out catheterisation for collection of a urine specimen, intermittent catheterisation for urine drainage, catheterisation for less than 24 hours, or who were catheterised with a silicone Foley catheter, and those who had been treated with antibiotics for a UTI were excluded from the study. Both of the study wards rotated through the two different interventions in two 6-month periods in order to act as a self-control to minimise the potential problem of variability in medical and nursing practice that might affect the outcomes. Conventional latex Foley catheters without hydrogel (sized Fr 12, 14, and 16) were used for catheterisation on both wards during the first half of the study period; SAH catheters (sized Fr 12, 14, and 16) were used during the second half of the study period. If a catheter was changed due to the presence of infection, the appropriate catheter according to the month of the study was used. Thus it was possible for patients who required a catheter for a long time and underwent catheter exchange to be exposed to both types of urinary catheter (Fig 1).

The definition of CA-UTI was adopted and modified from the CDC/NHSN definition of symptomatic UTI (Appendix[5,6]). Routine, regular screening and clinical urine samples were collected from all subjects according to the hospital protocol. Routine urine samples were taken from all subjects at four fixed time-points: on admission, on catheterisation, before removal of the catheter, and before hospital discharge. Screening samples were

taken weekly. Clinical samples were taken whenever a patient demonstrated symptoms and signs of UTI, or as part of a sepsis workup. The incidence of CA-UTI in the two groups was analysed in terms of the absolute number of CA-UTI episodes and the number of CA-UTI episodes per 1000 catheter-days. Values were expressed as mean ± standard deviation. Comparison between the two groups was performed by Pearson's Chi squared test, Student's *t* test, and one-way analysis of variance test when appropriate with a two-sided significance level of 0.05. The rate ratio of CA-ASB and CA-UTI between the two groups was compared by exact Poisson test for rate ratio. The occurrence of CA-UTI between the two groups was also analysed with Kaplan-Meier analysis. Results were analysed using the Statistical Package for the Social Sciences (Windows version 21.0; SPSS Inc, Armonk [NY], US) and R version 3.1.2.

This study was done in accordance with the principles outlined in the Declaration of Helsinki.

Results

During the 1-year study period, 306 patients were recruited. The male-to-female ratio was 1:1.13 and the mean age was 81.1 ± 10.5 years (Table 1). Overall, 187 patients used a conventional catheter only, 36 patients used a SAH catheter only, and 83 patients used both a conventional and a SAH catheter (Fig 1).

The total numbers of catheter-days were 4352 and 7474 in the SAH and conventional groups, respectively. The numbers of CA-UTI episodes were 28 and 70, respectively. Thus the incidences of CA-UTI per 1000 catheter-days in the SAH and conventional groups were 6.4 and 9.4, respectively (P=0.095) with a rate ratio of 0.69 (95% confidence interval [CI], 0.42-1.08). There was a 31% reduction in CA-UTI incidence in the SAH group. Using Kaplan-Meier analysis and log-rank test, SAH catheter was associated with a significantly lower rate of CA-UTI (P=0.045; Fig 2). Regarding CA-ASB, the incidences per 1000 catheter-days in the SAH and conventional groups were 70.8 and 67.2, respectively (P=0.467) with a rate ratio of 1.05 (95% CI, 0.91-1.22). Results are summarised in Table 2. Blood cultures were taken from patients who developed CA-UTI. In both groups, none of the patients with CA-UTI developed bacteraemia. *Escherichia coli* was the most commonly involved urinary pathogen and accounted for 36.7% of all cases, followed by *Candida albicans* (17.3%) and *Proteus mirabilis* (14.3%) [Table 3]. The same pathogens were observed in both groups.

This study was not a randomised controlled trial. Thus to eliminate patient selection bias, a subgroup analysis was performed among those patients who used both types of catheter (n=83). These patients had more catheters used and more

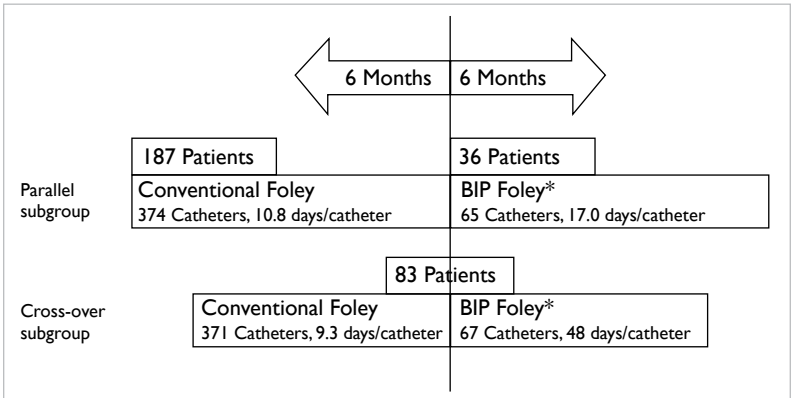

FIG 1. Flowchart showing the study design and patient distribution
* The Bactiguard Infection Protection Foley Catheter

TABLE 1. Characteristics of the study population, specimens collected, and catheter used

Characteristic	Mean ± standard deviation			Independent *t* test (female vs male)	
	All patients (n=306)	Female patients (n=162)	Male patients (n=144)	P value	Mean difference (95% confidence interval)
Age (years)	81.1 ± 10.5	82.6 ± 10.3	79.5 ± 10.5	0.01	3.1 (0.7 to 5.4)
No. of specimens collected					
Screening	7.6 ± 13.9	7.6 ± 13.0	7.5 ± 14.9	0.95	0.1 (-3.0 to 3.2)
Clinical	0.4 ± 0.7	0.4 ± 0.7	0.4 ± 0.8	0.98	0.0 (-0.2 to 0.2)
No. of catheters used					
Silver alloy and hydrogel–coated	0.8 ± 1.5	0.8 ± 1.5	0.7 ± 1.5	0.44	0.1 (-0.2 to 0.5)
Conventional	2.2 ± 2.6	2.1 ± 2.6	2.2 ± 2.8	0.81	-0.1 (-0.7 to 0.5)
All catheters	2.9 ± 3.5	3.0 ± 3.4	2.9 ± 3.7	0.88	0.1 (-0.7 to 0.9)
No. of catheter-days					
Silver alloy and hydrogel–coated	14.2 ± 35.3	14.7 ± 34.2	13.7 ± 36.6	0.79	1.1 (-6.9 to 9.0)
Conventional	24.4 ± 33.4	24.4 ± 33.0	24.5 ± 33.9	0.97	-0.2 (-7.7 to 7.4)
All catheters	38.6 ± 59.8	39.1 ± 57.2	38.2 ± 62.9	0.89	0.9 (-12.6 to 14.4)

catheter-days than those patients who used only one type of catheter (Table 4a). This was due to study design where longer-term users had a higher chance of exposure to both types of urinary catheter. Among them, the total numbers of catheter-days were 3210 and 3457 in the SAH and conventional groups, respectively. The numbers of CA-UTI episodes were 17 and 35, respectively. This resulted in the incidences of CA-UTI per 1000 catheter-days in the SAH and conventional groups being 5.3 and 10.1, respectively (P=0.027) with a rate ratio of 0.52 (95% CI, 0.27-0.96). There was a statistically significant reduction of 48% in CA-UTI incidence in the SAH group (Table 4b). Because the catheters were exchanged when an infection occurred, the CA-UTI reducing effect resulted in less need to exchange a SAH catheter—the mean catheterisation time per person was 17.0 days for a SAH catheter compared with 10.8 days for a conventional catheter and 13.6 days for patients using both catheters (Table 4a).

To examine the presence of outcome difference in relation to gender in the entire study population, we also performed a subgroup analysis based on gender differences (Table 4c). In male patients (n=144), the number of CA-UTI episodes was 15 in the SAH group (total catheter-days, 1966) and 33 in the conventional group (total catheter-days, 3529). The incidences of CA-UTI per 1000 catheter-days in the SAH and conventional groups were 7.6 and 9.4, respectively (P=0.551) with a rate ratio of 0.82 (95% CI, 0.41-1.54). For female patients (n=162), the number of CA-UTI episodes was 13 in the SAH group (total catheter-days, 2386) and 37 in the conventional group (total catheter-days, 3945). The incidences of CA-UTI per 1000 catheter-days in the SAH and conventional groups were 5.4 and 9.4, respectively (P=0.108), with a rate ratio of 0.58 (95% CI, 0.28-1.12).

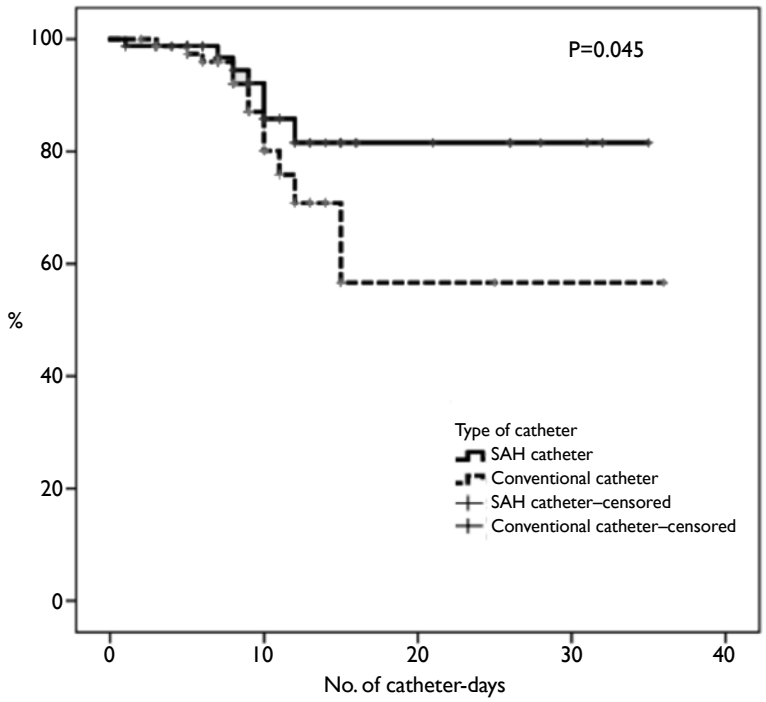

FIG 2. Comparison of CA-UTI occurrence between SAH and conventional catheters in the entire study population using Kaplan-Meier analysis
Abbreviations: CA-UTI = catheter-associated urinary tract infection; SAH = silver alloy and hydrogel–coated

Discussion

Urinary tract infection is one of the most commonly encountered infections in daily clinical practice and the majority of cases are catheter-related. Although a number of clinical practices such as aseptic technique for catheter insertion, closed drainage systems, and shorter duration of catheterisation have been introduced in an attempt to reduce the onset of CA-UTI, the incidence remains high.[3,7] Therefore, research for strategies or new technologies to prevent CA-UTI is still needed. Since the early 1990s, research has focused on different anti-infective catheter-coating materials but results have

TABLE 2. Overall comparison of CA-UTI and CA-ASB episodes between SAH catheters and conventional catheters

Variable	SAH group (a)	Conventional group (b)	Rate ratio a/b (95% confidence interval)	P value (exact Poisson test for rate ratio)
No. of patients	119	270	-	-
No. of catheters	159	635	-	-
No. of catheter-days	4352	7474	-	-
CA-ASB episodes	308	502	-	-
CA-ASB episodes/1000 catheter-days	70.8	67.2	1.05 (0.91-1.22)	0.467
CA-UTI episodes	28	70	-	-
CA-UTI episodes/1000 catheter-days	6.4	9.4	0.69 (0.42-1.08)	0.095

Abbreviations: CA-ASB = catheter-associated asymptomatic bacteriuria; CA-UTI = catheter-associated urinary tract infection; SAH = silver alloy and hydrogel–coated

TABLE 3. Organisms identified from CA-UTI specimens (some specimens showed mixed flora)

Organisms	SAH group	Conventional group	Total
Gram-negative organisms	26	92	
(All ESBL producers)	8	23	
Enterobacteriaceae			
Escherichia coli	12	24	36
(ESBL producers)	(8)	(15)	
Proteus mirabilis	5	9	14
(ESBL producers)	(0)	(4)	
Klebsiella pneumoniae / species	4	6	10
(ESBL producers)	(0)	(1)	
Other Enterobacteriaceae	2	8	10
(ESBL producers)	(0)	(3)	
Pseudomonas aeruginosa / species	1	12	13
Acinetobacter species	2	1	3
Gram-positive organisms	7	11	
Enterococcus species	5	7	12
Methicillin-resistant *Staphylococcus aureus*	2	3	5
Coagulase-negative *Staphylococcus*	0	1	1
Fungi	5	22	
Candida albicans	3	14	17
Candida species	2	8	10
Total No. of positive samples	**28**	**70**	**98**

Abbreviations: CA-UTI = catheter-associated urinary tract infection; ESBL = extended spectrum beta lactamase; SAH = silver alloy and hydrogel−coated

been generally inconclusive. Bactiguard-coated Foley catheters, an essential noble metal (gold, silver, and palladium) alloy and hydrogel–coated catheter, have been introduced to slow bacterial colonisation.

In the early 2000s, a randomised cross-over study by Karchmer et al[8] demonstrated that the risk of UTI could be decreased by 21% on wards and by 32% among patients when a noble metal alloy catheter was used instead of a conventional catheter. Since then, more studies to compare anti-infective urinary catheters with conventional urinary catheters have been carried out. The noble metal alloy indwelling catheter has been shown in multiple large clinical trials and smaller case studies to reduce the incidence of CA-UTI, when compared with conventional catheters.[9-15] These studies have examined endpoints such as bacteriuria and symptomatic CA-UTI, or surveillance-defined UTI.[8,16,17] In a study by Pickard et al,[17] noble metal alloy catheters were found to be ineffective in reducing the incidence of symptomatic surveillance-defined UTI when used in short-term (mean, 2 days) surgical patients and they did not support the routine use of these catheters in this patient group. Lack of effect is not surprising due to the short catheterisation time and low-risk patient group. In a more recent multicentre cohort study in 2014, Lederer et al[4] examined the impact of noble metal alloy catheters on symptomatic CA-UTI and antibiotic use based on the NHSN surveillance and concluded that a 58% relative reduction (P<0.0001) in NHSN-defined CA-UTI rate was observed and 60% fewer antibiotics were used when compared with conventional catheters.

In the present study, we were able to demonstrate a 31% reduction in the incidence of CA-UTI episodes per 1000 catheter-days in the SAH group although it did not reach statistical significance, likely due to too small study groups. We believe that the incidence rate per catheter-days is a more appropriate comparison to reflect the risk of infection associated with different types of catheter as it also takes into account the duration of catheterisation, which is known to be an important factor associated with the incidence of CA-UTI. This is also reflected by the fact that the noble metal alloy catheter can be left in situ for the longest period of time. Although the cost of each SAH catheter (approximately HK$100) is higher than that of a conventional catheter (approximately HK$15), we believe the benefit of longer duration and potential reduction in CA-UTI justify its use.

With subgroup analysis, the effect of a noble

TABLE 4. (a) Characteristics of patients who used both types of catheter, SAH catheter only, or conventional catheter only. (b) Comparison of CA-UTI and CA-ASB incidences between SAH and conventional catheters in 83 patients who used both types of catheter (cross-over group). (c) Comparison of CA-UTI and CA-ASB incidences between SAH and conventional catheters in male and female patients

(a)

	No. of patients or mean ± SD			P value
	Both types of catheter (n=83)	SAH catheter only (n=36)	Conventional catheter only (n=187)	
Sex				0.41*
Female	49	19	94	
Male	34	17	93	
Diabetes mellitus				0.97*
Yes	17	8	38	
No	66	28	149	
Age (years)	79.2 ± 12.5	82.8 ± 10.2	81.7 ± 9.5	0.12†
No. of catheters per patient (all catheters)	5.5 ± 5.6	1.9 ± 1.6	2.0 ± 1.4	<0.001†
No. of catheter-days per patient (all catheters)	80.3 ± 97.2	31.7 ± 38.7	21.5 ± 18.4	<0.001†
Average days per catheter per person	13.6 ± 4.8	17.0 ± 9.8	10.8 ± 4.9	0.01†

* Chi squared test
† One-way analysis of variance

(b)

	SAH catheter (a)	Conventional catheter (b)	Rate ratio a/b (95% confidence interval)	P value (exact Poisson test for rate ratio)
No. of catheters	67	371		
No. of catheter-days	3210	3457		
No. of days per catheter	48	9.3		
CA-ASB episodes	206	201		
CA-ASB episodes/1000 catheter-days	64.2	58.1	1.10 (0.90-1.34)	0.322
CA-UTI episodes	17	35		
CA-UTI episodes/1000 catheter-days	5.3	10.1	0.52 (0.27-0.96)	0.027

(c)

	SAH catheter (a)	Conventional catheter (b)	Rate ratio a/b (95% confidence interval)	P value (exact Poisson test for rate ratio)
Male patients (n=144)				
No. of patients	51	127		
No. of catheters	98	318		
No. of catheter-days	1966	3529		
CA-ASB episodes	134	211		
CA-ASB episodes/1000 catheter-days	68.2	59.8	1.14 (0.91-1.42)	0.239
CA-UTI episodes	15	33		
CA-UTI episodes/1000 catheter-days	7.6	9.4	0.82 (0.41-1.54)	0.551
Female patients (n=162)				
No. of patients	68	143		
No. of catheters	132	346		
No. of catheter-days	2386	3945		
CA-ASB episodes	174	291		
CA-ASB episodes/1000 catheter-days	72.9	73.8	0.99 (0.81-1.20)	0.924
CA-UTI episodes	13	37		
CA-UTI episodes/1000 catheter-days	5.4	9.4	0.58 (0.28-1.12)	0.108

Abbreviations: CA-ASB = catheter-associated asymptomatic bacteriuria; CA-UTI = catheter-associated urinary tract infection; SAH = silver alloy and hydrogel–coated; SD = standard deviation

metal alloy catheter on reduction of CA-UTI was more prominent in long-term users and female patients. In patients who used both catheters and who served as their own control, a significant reduction (48%, P=0.027) was observed in the SAH group. The same reduction was not observed in those who used only one type of urinary catheter whose number of catheters used and catheter-days were significantly fewer (Table 4a and 4b). We cannot give an exact explanation for this observation but we believe the protective effect of Bactiguard catheters is best seen in patients who require long-term urinary catheterisation. Nonetheless, it must be emphasised that the effect due to mixed use of catheters is unknown. The reduction in CA-UTI was also slightly more prominent in female patients (rate ratio of CA-UTI episodes per 1000 catheter-days, 0.58; Table 4c). Whether these are genuine and significant findings will warrant future randomised controlled studies to confirm.

This study has several limitations. First, this was a non-randomised study with a lack of blinding of outcome observers. Second, some patients might have used both catheters and the effects of each catheter type might have confounded the results. Third, as patients were recruited from a regional rehabilitation hospital, their underlying different medical conditions and risk factors might have affected the outcomes. As patients admitted during the two 6-month periods were incomparable, confounding by underlying risk factors for CA-UTI could not be excluded.

Conclusions

Our findings suggest that SAH-coated catheters may be effective in reducing CA-UTI based on CDC's NHSN surveillance definition. The effect seems to be more pronounced in high-risk patients such as long-term users and female patients. Future randomised controlled studies on this subject should be carried out based on these pilot data.

Appendix

Additional material related to this article can be found on the HKMJ website. Please go to <http://www.hkmj.org>, and search for the article.

Declaration

All authors have disclosed no conflicts of interest.

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