Original Article - Infection/Inflammation

Investig Clin Urol 2022;63:334-340.
https://doi.org/10.4111/icu.20210436
pISSN 2466-0493 • eISSN 2466-054X

INVESTIGATIVE AND CLINICAL UROLOGY
ICUROLOGY

Catheter-associated urinary tract infections in patients who have undergone radical cystectomy for bladder cancer: A prospective randomized clinical study of two silicone catheters (clinical benefit of antibiotic silicone material)

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Purpose: The prevalence of catheter-associated urinary tract infections (CAUTIs) varies from 5% to 8.2%, and the risk of infection increases by 5% to 7% per day of primary indwelling. We investigated whether a novel biofilm inhibitory mechanism using an inhibitory silicone urethral catheter (a coated Foley catheter) can reduce CAUTIs compared to conventional non-coated Foley catheters.

Materials and Methods: This study prospectively analyzed the difference in the incidence of CAUTIs in patients who underwent radical cystectomy with an orthotopic neobladder for bladder cancer and received a coated or conventional non-coated catheter. Additionally, differences in bacterial colonization between the groups were analyzed using a catheter-tip bacterial culture test.

Results: Eighty-five patients were randomized into the "coated Foley catheter" group (abbreviated as "case" group; 41 patients) and a control group (44 patients). The two groups were identical except for their surgical history. The incidence of CAUTIs 2 weeks after radical cystectomy was 21.95% (case) and 27.27% (control), with no significant difference between the two groups. However, when the catheter was removed 2 weeks after surgery, the catheter tip culture test revealed significant bacterial colonies in 25 (60.98%) and 38 (86.36%) patients in the case and control group, respectively. No catheter-related postoperative side effects were observed in either group.

Conclusions: The incidence of CAUTIs in the two groups did not differ according to the catheter material. However, the catheter bacterial culture test showed that bacterial colonization was significantly suppressed on the Bi-Fi Free technology catheter, which comparatively inhibited biofilm formation.

Keywords: Bladder cancer; Urethral catheter; Urinary tract infection

Received: 10 November, 2021 • **Revised:** 20 January, 2022 • **Accepted:** 3 February, 2022 • **Published online:** 28 March, 2022
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INTRODUCTION

The prevalence of urinary tract catheter-related infections varies from 5% to 8.2%, and the risk of catheter-associated urinary tract infections (CAUTIs) is known to increase by 5% to 7% per day of indwelling during radical treatments [1]. In addition, 10% to 25% of patients have bacteriuria after only 3 days of catheter insertion [2]. The Healthcare Infection Control Practices Advisory Committee recommends that the replacement cycle of the urethral catheter should not exceed 1 month, and that patients at risk of CAUTI should have their urethral catheter replaced once or twice a week [3-5].

Accordingly, studies on urinary tract catheters made of various materials have been conducted to reduce the incidence of CAUTIs. Materials such as silver alloy and noble metals, including gold (Au), palladium (Pd), and silver (Au) (BactiguardVR Infection Protection), have been reported to reduce urinary catheter-related infections [6,7]. Meanwhile, Niepa [8] reported that 98% of bacteria were killed by treatment with 70 uA/cm^2 of direct current from carbon or metal electrodes. This finding suggests that antibiotics can prevent the inevitable damage to normal cells and provide the urinary tract catheter with electrochemical properties that can kill or inactivate persistent bacteria [8]. We hypothesized that a novel mechanism of inhibition of biofilm formation by an inhibitory silicone urethral catheter (coated Foley catheter) reduces UTIs compared with conventional non-coated Foley catheter products. Therefore, the purpose of this study was to prospectively compare and analyze the possibility of a clinically significant effect of an inhibitory silicone urethral catheter in preventing UTIs after surgery in patients who have undergone radical cystectomy for bladder cancer.

MATERIALS AND METHODS

1. Trial design and participants

We designed a multi-center, prospective, open-label, randomized controlled, non-inferiority trial (involving Seoul National University Hospital, Samsung Medical Center, and Seoul National University Bundang Hospital) to compare CAUTIs in patients who underwent radical cystectomy with a neobladder. This study was approved by the ethics committees of the participating medical centers (approval number: 1806-181-956), and all patients provided written informed consent. The trial was registered in the ClinicalTrials.gov database (NCT04152720). The 2010 CONSORT guidelines were strictly followed in the design and report of this trial [9,10].

Fig. 1 depicts a flowchart of patient enrollment, allocation, and follow-up. A total of 121 patients were screened, and 111 patients (aged 19–80 y) were enrolled and randomly assigned to the "case" group that received an embedded Foley catheter (APOLLON, Seoul, Korea) (n=54) or the control group (conventional catheter; Uro Technology Sdn Bhd, Johor, Malaysia) (n=57) in a 1:1 ratio according to type of surgery (robotic or open surgery) as a stratification factor. The inclusion criteria were age 19 to 80 years, muscle-invasive bladder cancer scheduled for radical cystectomy with a neobladder, and voluntary sign-up for our clinical trial agreement. The exclusion criteria were a suspected malnutrition status, an active infection status or acquired immunodeficiency syndrome, allergy or hypersensitivity to chlorhexidine, and any notable active medical illness that, in the opinion of the investigator, could preclude protocol treatment. The primary endpoint was the rate of CAUTIs following radical cystectomy, and the secondary endpoint was the rate of positive bacterial cultures from the catheter tip test at 2 weeks after surgery. Second-generation cephalosporins were administered for 72 to 96 hours after surgery as prophylaxis to prevent postoperative infection, according to the

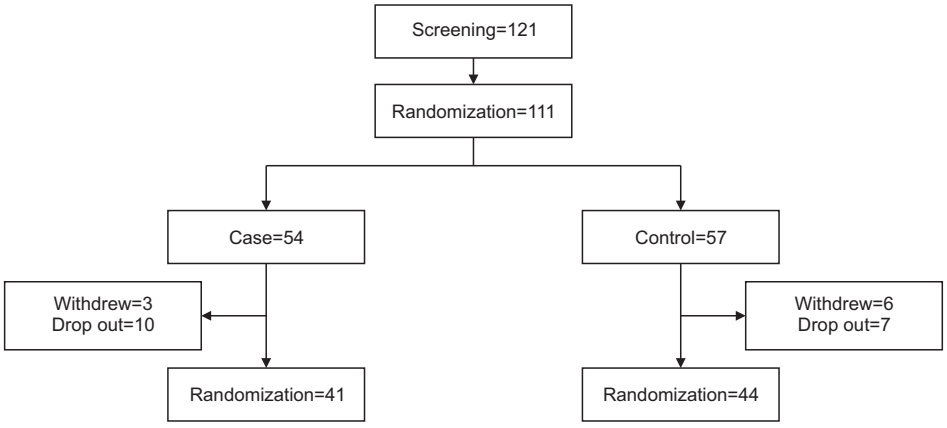

Fig. 1. CONSORT diagram of this study.

Table 1. Baseline patient characteristics

Characteristic	Case (n=41)	Control (n=44)	p-value
Age (y)	65.22±10.25	65.36±8.56	0.8499
Sex (male)	35 (85.37)	37 (84.09)	0.8704
Body mass index (kg/m^2)	24.79±3.62	24.45±3.57	0.6567
Previous-operation history	21 (51.22)	32 (72.73)	0.0408
Hemoglobin (g/dL)	12.64±1.88	12.56±1.75	0.8441
Serum creatinine (mg/dL)	0.94±0.29	1.01±0.29	0.1406
Indwelling duration of a urethral catheter (day)	13.00±1.08	13.07±1.20	0.6532

Values are presented as mean±standard deviation or number (%).

guidelines of the European Association of Urology (EAU).

2. Study protocol

The definition of a CAUTI in this study used the criteria for symptomatic UTI proposed by the National Healthcare Safety Network for CAUTIs [11]. The criteria for CAUTIs are as follows: (1) at least one of the following signs or symptoms with no other recognized cause: fever (>38°C), suprapubic tenderness, costovertebral angle pain or tenderness, or, for patients ≤1 year of age, fever (>38°C core), hypothermia (<36°C core), apnea, bradycardia, dysuria, lethargy, or vomiting; (2) urine culture with ≥10^5 CFU/mL with no more than two species of microorganisms or urine culture with ≥10^3 and <10^5 CFU/mL with no more than two species and positive urinalysis (one positive dipstick for leukocyte esterase or nitrite; pyuria [≥10 WBC/mm^3 or >5 WBC/HPF unspun urine]; microorganisms seen in Gram staining of unspun urine).

The interventionally embedded silicone catheters were manufactured and directly delivered by APOLLON. The Bi-Fi Free technology that is the distinguishing feature of these catheters is a combination of silicon and zinc oxide (ZnO) polymers that implements the dispersion technology used in semiconductor electromagnetic wave shielding and inhibits biofilm formation. The size of all catheters was unified to 20 Fr. All urethral catheters were allowed to indwell for 14 days (±1 d) and removed 14 days after surgery. Urine culture tests were also performed on the 14th day after surgery, and a bacterial culture test for the urethral catheter tip was performed immediately after catheter removal. A researcher in our department screened and enrolled the study participants, who were assigned to either the case or the control group, using an online computer-generated randomization sequence with a permuted-block procedure using varying block sizes.

3. Statistical methods and sample size

The analysis was based on a per-protocol analysis and restricted to participants who fulfilled the protocol in terms of eligibility, interventions, and outcome assessments. The sample size calculation was based on the following sequence: to demonstrate non-inferiority, the upper limit of the 95% confidence interval of the difference between the two groups should not exceed 20%. As our study was an exploratory clinical trial, and the primary endpoint was not related to patient survival, we decided to set the non-inferiority margin of 20% based on clinical judgment. Considering 80% power and a one-sided type 1 error of 5%, 120 patients (60 in each group) were required to allow for a dropout rate of 20%. Differences in wound assessment and adverse events between the two groups were analyzed using Fisher's exact test (two-sided). All statistical analyses were conducted using SPSS 21.0 (IBM Corp., Armonk, NY, USA). Differences were considered statistically significant at p<0.025.

RESULTS

1. Patient population

A total of 121 patients were enrolled and screened, and 111 were randomized into the two groups. Nine patients (case, three; control, six) withdrew their consent immediately after surgery, and 17 patients dropped out because of a management plan after surgery, leaving 41 patients in the case group and 44 patients in the control group (Fig. 1). Baseline data, safety assessments, the primary endpoint of CAUTIs, and secondary endpoints of the tip culture-positive rate were thus examined in 85 patients. The baseline characteristics were similar between the two groups (Table 1).

2. Primary and secondary endpoint

The incidence of bacteriuria after radical cystectomy was 46.34% (n=19) in the case group and 50.00% (n=22) in the conventional silicone catheter group (p=0.736) (Table 2). The incidence of CAUTIs was lower in the case group: in nine (21.95%) and 12 (27.27%) patients in the case and control groups, respectively (p=0.377). Although the lower limit of

https://doi.org/10.4111/icu.20210436

Table 2. Incidence of bacteria growth in urine culture and tip culture after radical cystectomy (2 wk)

Variable	Case (n=41)	Control (n=44)	p-value
Bacteriuria			0.736
Yes	19 (46.34)	22 (50.00)	
No	22 (53.66)	22 (50.00)	
CAUTI			0.377
Yes	9 (21.95)	12 (27.27)	
No	32 (78.05)	32 (72.73)	
Tip culture			0.008
Positive	25 (60.98)	38 (86.36)	
Negative	16 (39.02)	6 (13.64)	
Positive catheter tip cultures had CAUTI till catheter removal	9 (21.95)	12 (27.27)	0.377

Values are presented as number (%).
CAUTI, catheter-associated urinary tract infection.

Table 3. Types of organisms in urine and urethral catheter tip cultures

Variable	Case	Control
Urine	19	22
Enterococcus faecalis	8	11
Pseudomonas aeruginosa	4	4
Yeast	3	2
Streptococcus species	2	2
Klebsiella pneumoniae	1	2
MRSA	1	1
Catheter tip	25	38
Enterococcus faecalis	11	17
Pseudomonas aeruginosa	4	9
Yeast	2	2
Streptococcus species	2	2
Klebsiella pneumoniae	1	2
MRSA	1	2
Proteus mirabilis	1	2
Acinetobacter junii	1	1
Corynebacterium species	2	1

Values are presented as number only.
MRSA, methicillin-resistant *Staphylococcus aureus*.

the one-sided 97.5% confidence interval (p=0.2316) was larger than the significance margin, no statistically significant difference between the groups was observed. All catheters were removed on postoperative day 14 (±1 d), and a catheter-tip culture test was performed to determine the bacterial colonization on the catheter surface. The positivity rate of the tip culture was 60.98% (n=25) in the case group and 86.36% (n=38) in the conventional silicone catheter group (p=0.008). The most frequent pathogen in the tip cultures of both groups was *Enterococcus faecalis* (Table 3).

3. Adverse events

Adverse events were investigated in all participants, including those who withdrew consent and dropped out immediately after the surgery. Cumulative adverse events were reported in 24.07% of the patients in the case group and 28.07% of the patients in the control group (Table 4). Serious adverse events occurred in one patient in the case group, who died after developing sepsis due to acute cholecystitis after the surgery. Overall, four cases of device-related adverse events were observed, due to catheter ballooning rupture (two cases [3.70%] in the control group and two cases [3.51%] in the case group); no difference in terms of adverse events was noted between the groups (p=0.630).

DISCUSSION

The primary aim of this study was to evaluate whether the use of a Bi-Fi Free technology catheter would reduce the frequency of CAUTIs in patients who had undergone radical cystectomy for invasive bladder cancer. Both catheter models used in this study were registered products that can be used in hospitals in South Korea, and patients who underwent a similar surgery for equalization of possible patient groups were targeted. In this study, the difference in the incidence of CAUTIs between patients in the two study groups was not significant. However, biofilm formation, which is the main cause of CAUTIs, differed between the two groups.

There have been various attempts at coating silicone catheters with different materials to reduce CAUTIs [6,7,12]. In a meta-analysis of randomized controlled trials, silver alloy-coated catheters reduced the risk of asymptomatic bacteriuria compared with standard latex catheters (control latex catheters were either uncoated or coated with hydrogel, Teflon, or silicon), although compared with the standard all-silicone catheters, the risk was not different [13]. Most of

Table 4. Adverse event during study period

Variable	Case (n=54)	Control (n=57)	p-value
Overall adverse events			0.712
Yes	13 (24.07)	16 (28.07)	
No	41 (75.93)	41 (71.93)	
Severe adverse events			0.496
Yes	1 (1.85)	0 (0.00)	
No	53 (98.15)	57 (100.00)	
Dropped out due to device-related adverse events			0.630
Yes	2 (3.70)	2 (3.51)	
No	52 (96.30)	55 (96.49)	

Values are presented as number (%).

these attempts to coat the surface of a catheter with an antibiotic or substance lead to an initial expression of an antibiotic effect; however, biofilm formation cannot be controlled over time. Therefore, complications such as UTIs occur, and the hospitalization period is prolonged owing to additional treatment.

The catheter used in this study deviated from the concept of a coated catheter to prevent biofilm formation and comprised a material in which a carbon nanotube (CNT) and a ZnO-bonded CNT polymer were mixed with silicon. In particular, it was designed to expand the fluid flowing from the outside, thereby creating the same environment as the Foley catheter. Therefore, it can suppress biofilm formation, which causes bacterial infection, without an additional antibiotic.

CNTs are cylindrical crystals made of carbon atoms, with a diameter of 2 to 20 nm (1 nm is 1/1,000,000 m) and a length of hundreds to thousands of nanometers. The CNT polymer is one in which CNTs and ZnO are combined, and CNTs and ZnO are either polymerized in the same ratio or ZnO may be polymerized at a higher rate than CNTs; vice versa is also possible if required. The CNT polymer used in this catheter reacts to the native physiological potential and has a constant capacitance that is harmless to the patient but has a lethal galvanic effect on bacteria and biofilms, thereby preventing biofilm formation. This capacitance can be minimized, and because of the high thermal conductivity that is characteristic of CNTs, it is possible to minimize rejection during catheter insertion. This was demonstrated in the patients in this study; almost no discomfort or allergic reaction was observed due to the catheter.

Radical cystectomy with orthotopic neobladder urinary diversion involving the bowel has a higher rate of postoperative infection than many other surgeries, partly because of the severity of the stress caused by the procedure [11]. Microscopic examination has detected leukocytes (85.4%), erythrocytes (83.8%), and bacteria (96.8%) after radical cystectomy with neobladder reconstruction after 2 weeks [14]. Therefore, many previous studies have used different antibiotics to reduce postoperative infections after radical cystectomy [15,16]. Additionally, previous studies have reported detailed analyses of the causative agent in cases of surgical site infections after radical cystectomy and found that *E. faecalis* is the most commonly isolated bacterium in Asian countries, although *Escherichia coli* is the most frequently isolated bacterium worldwide [17,18]. In a retrospective study, Shigemura et al. [19] reported that *Enterococcus* was the most frequently isolated bacterium in urine cultures.

While this study shares similarities with previous studies, some remarkable differences need to be noted. First, according to the urine analysis performed 2 weeks after surgery, the incidence of bacteriuria was 96% in the previous study, whereas in the current study, it was 46.3% in the case group and 50% in the control group; the occurrence of bacteriuria in this study was thus low overall. However, not many studies have reported on fever or UTIs that occur after radical cystectomy, and some of the reported differences in incidence rates may be due to differences in reference points according to the specific research protocol used. Nevertheless, this study is the first randomized controlled trial in an Asian patient sample to investigate the incidence of UTIs and bacteriuria after radical cystectomy. Additionally, this is the first study on patients with bladder cancer who underwent radical cystectomy, and the first study that reports on Foley catheter tip cultures.

It is difficult to determine whether a lower bacterial positivity rate on the Foley catheter tip can reduce UTIs. However, in *in vitro* models, CAUTIs were found to be relevant when analyzing bacterial growth inside the catheter and in urine or artificial urine [20,21]. A previous study that examined the association between the catheter culture test and UTI suggested that the same strains of bacteria, as determined by ≥98% similarity of the 16S ribosomal DNA

https://doi.org/10.4111/icu.20210436

sequence, were found on the outside and inside of catheters and in urine [22]. Additionally, our study confirmed that 95% of the bacteria that the tip culture was positive for were present in urine culture. These results suggest that the biofilm generated at the catheter tip can eventually cause UTIs, and that the Bi-Fi Free technology used in this study can reduce this risk.

Compared to similar previous studies, the specific contributions of this study are as follows: a UTI is one of the most common complications after radical cystectomy and orthotopic neobladder surgery. Kim et al. [23] demonstrated that the incidence of febrile UTIs was 17.6% and 19.8% at 6 months and 24 months after radical cystectomy with a neobladder, respectively, and Suriano et al. [24] found that approximately 57% of patients who underwent radical cystectomy had bacteriuria on urine culture at 3 months after surgery. However, there have been few studies on CAUTIs or febrile conditions after radical cystectomy in the acute phase. Therefore, the current study is valuable as a well-controlled prospective study that presents data on the incidence of CAUTIs occurring after radical cystectomy. Additionally, while the catheter using Bi-Fi Free technology did not reduce the incidence of CAUTIs compared with conventional products in patients who underwent radical cystectomy with long-term catheter indwelling, biofilm formation was reduced. This suggests that Bi-Fi Free technology incorporated into various medical devices that require catheter insertion into the human body may reduce catheter-induced infections.

Despite the aforementioned highlights, this study has some limitations. First, the orthotopic bladder is a neobladder without a normal bladder environment and, because it is contaminated, its physiology is different from that of a normal bladder. However, the environment is favorable for biofilm formation in the orthotopic neobladder; this indicates that the Bi-Fi Free catheter has the potential to prevent biofilm formation. Additionally, the test group did not show a reduced CAUTI incidence compared to the control group. This may be due to the shorter indwelling period of the catheter (approximately 2 weeks) and various preventive interventions, for example for postoperative wound infections and CAUTIs. Therefore, to determine the absolute effect of the catheter, it should be tested on patients who receive a suprapubic cystostomy catheter in future studies.

CONCLUSIONS

In this randomized controlled trial, the use of a Bi-Fi Free technology catheter did not reduce the frequency of CAUTIs compared with that with a standard silicone catheter in patients undergoing radical cystectomy with an orthotopic neobladder. However, the Bi-Fi Free technology catheter reduced microbial deposition on the catheter tip compared to the conventional catheter.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

FUNDING

This research was supported by Basic Science Research Program through the National Research Foundation of Korea (NRF) funded by the Ministry of Education (grant number: 2021R1I1A1A01051050) and APOLLON Co., Ltd. No funders had any role in study concept and design, experiments, analysis of data, writing of the manuscript, or the decision for publication.

AUTHORS' CONTRIBUTIONS

Research conception and design: Bum Sik Tae and Ja Hyeon Ku. Data acquisition: Ja Hyeon Ku, Jong Jin Oh, and Byong Chang Jeong. Statistical analysis: Bum Sik Tae. Data analysis and interpretation: Bum Sik Tae and Ja Hyeon Ku. Drafting of the manuscript: Bum Sik Tae. Critical revision of the manuscript: Ja Hyeon Ku, Jong Jin Oh, and Byong Chang Jeong. Obtaining funding: Ja Hyeon Ku. Administrative, technical, or material support: Bum Sik Tae and Ja Hyeon Ku. Supervision: Ja Hyeon Ku. Approval of the final manuscript: Bum Sik Tae and Ja Hyeon Ku.

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https://doi.org/10.4111/icu.20210436