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Original Article

An investigation of the effectiveness against bacteriuria of silver-coated catheters in short-term urinary catheter applications: A randomized controlled study☆

Fusun Zeynep Akcam [a, *], Onur Kaya [a], Esra Nurlu Temel [a], Seyit Ali Buyuktuna [b], Onur Unal [a], Vedat Ali Yurekli [c]

[a] Suleyman Demirel University, Department of Infectious Diseases and Clinical Microbiology, Isparta, Turkey
[b] Cumhuriyet University, Department of Infectious Diseases and Clinical Microbiology, Sivas, Turkey
[c] Suleyman Demirel University, Department of Neurology, Isparta, Turkey

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ABSTRACT

Aim: The aim of this study was to investigate the effectiveness of antimicrobial-coated catheters against bacteriuria and urinary tract infection in patients who have urinary catheterization.
Methods: Twenty eight and twenty six people similar in terms of demographic characteristics and primary and underlying diseases were randomly selected from patients undergoing short-time urinary catheterization in the intensive care unit. Silver-coated slicone foley catheters and normal slicone foley catheters were used for uninary catheterization in the first and second group of the patients respectively. Urine specimens were collected from patients at 2-day intervals and assessed in terms of bacteriuria.
Results: Bacteriuria was found in 12 (46.2%) of the patients using normal catheters and 13 (46.4%) of those using silver-coated catheters throughout the monitoring period. No significant relationship was determined between use of different catheter types and bacteriuria ($p = 0.98$). The most common microorganism was identified as *E. coli* in the normal catheter group while microorganism other than *E. coli* was identified in the silver-coated catheter group. The prevalence of bacteriuria was statistically significantly higher in patients with a history of hospitalization in the previous 3 months ($p = 0.028$).
Conclusion: The use of silver-coated silicone catheters was not shown to have a protective effect against bacteriuria in this study. Further well-designed studies with larger case numbers are now needed to confirm whether history of hospitalization, which emerged as a statistically significant factor in this study, increases the prevalence of catheter-related bacteriuria.

1. Introduction

Urinary tract infections (UTI) are one of the most common infectious diseases in the world. The most common type of UTI is acute cystitis, which is characterized by urinary urgency, frequency, dysuria, and pyuria [1–3]. In addition UTIs are common complications among hospitalized patients, particularly in the elderly and in patients with diabetes, bladder cancer, or indwelling catheters [4–6]. Although urinary catheters are an important component of medical practice, they also compromise host defense mechanisms and allow micro-organisms to enter and grow in a normally sterile urinary tract. Inserting an indwelling catheter is a common medical procedure, which, if often performed poorly and inappropriately, can lead to significant morbidity [7]. In addition to causing trauma and rare development of urethritis, the most important complications of urinary catheterization are bacteriuria and catheter-associated urinary tract infections. Catheter-associated urinary tract infections (CAUTI) are the most common healthcare-associated infections. The basic measures to prevent CAUTI consists of accurate assessment of catheterization indications and caution regarding aseptic conditions [8]. Efforts must be made to prevent post-catheterization bacteriuria. The most effective means

☆ All authors meet the ICMJE authorship criteria.

* Corresponding author. Suleyman Demirel University Education and Research Hospital East Campus, 32260, Cunur, Isparta, Turkey.
E-mail addresses: fusunakcam@sdu.edu.tr (F.Z. Akcam), onurkaya@sdu.edu.tr (O. Kaya), dresratemel@gmail.com (E.N. Temel), seyitbuyuktuna@gmail.com (S.A. Buyuktuna), onurunal_84@hotmail.com (O. Unal), vedatyurekli@yahoo.com (V.A. Yurekli).

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of preventing bacteriuria is still closed system catheterization and proper catheter maintenance [9]. There is still no consensus in studies to date concerning the effectiveness of antimicrobial coated catheters. In some studies, patients with antimicrobial impregnated catheters have been shown to have a small reduction in the incidence of catheter-related urinary tract infection [10]. Whether this effect is clinically significant is unclear.

The objective of this study was to investigate the effectiveness of silver-coated catheters against bacteriuria and urinary tract infection in patients undergoing short-term urinary catheterization.

2. Materials and methods

Patients were selected from Süleyman Demirel University, (SDU) Education and Research Hospital and Isparta State Hospital Intensive Care Unit, and microbiological tests were performed at the clinical laboratory of SDU Infectious Diseases and Clinical Microbiology Department.

This randomized and double-blind clinical trial was begun in 2012 and completed within two years. As the necessary statistical significant sample size, 30 participants were required in each group [11]. Two groups with similar demographic characteristics and primary and underlying diseases were randomly selected from patients admitted to the intensive care unit and anticipated to require long-term urinary catheterization. Patients with any infectious disease on admission or with pyuria/bacteriuria in the first urine specimen collected following catheter placement were excluded from the study. Six patients were excluded from the study during the study period. In scope of the study, first group including twenty eight patients was applied silver-coated silicone foley catheters (Kendall Catheter, Dover™ Silver Urine Meter Trays by Covidien, KDLPP16XSD, England) and the second group including twenty six, was applied normal silicone foley catheters. Catheter placement was performed by trained personnel using aseptic techniques, and care was taken throughout the study fort he fact that the closed drainage systems should not be compromised. No criteria were established for which patients should receive antimicrobial-coated catheters and which should receive routine catheters, and these were distributed on a random basis as catheters were used in sequence.

Presence of bacteriuria was investigated by culture method from the urine specimens collected at 2-day intervals during one study period. The recommendations contained in the Turkish Society of Hospital Infections and Control's Prevention of Urinary Catheter Infections Guideline were applied during catheter maintenance and the collection of urine specimens [8]. Urine was collected into a sterile container and transported immediately to our microbiology research laboratory. Using a sterile calibrated loop, we streaked 1 μl of fresh, unprocessed urine onto one half each of a MacConkey agar plate and a blood agar plate and then incubated the plates at 37 °C for 2 days. Growth of 10^5 cfu/ml was regarded as representing bacteriuria. Bacteria were identified by automatic system (BD Phoeneix).

Data were entered onto SPSS 22.0 software and analyzed using the Chi-square and Fisher's exact tests. Statistical significance was set at $p \leq 0.05$.

The requisite permissions for the study were obtained from the SDU Medical Faculty Clinical Researches Ethics Committee Chair (Decision number 13, dated 07 March 2012). Written consent was obtained from patients or patient's relatives as well.

3. Results

The study involved 54 patients, 27 male and 27 female, with a mean age of 69.9 ± 15.1 years (range 28–101). Neurological disease was present in all subjects (39 cerebro vascular disease, 1 intracerebral mass, 1 Guillain-Barre, 2 amyotrophic lateral sclerosis, 3 epilepsy, 2 Parkinson's, 2 neuroepileptic malignant syndrome, 1 vasovagal syncope, 2 encephalitis, and 1 myasthenia gravis). The most prevalent common non-neurological disease was hypertension at 21/54 (38.9%). In addition, diabetes was present in 12/54 (22.2%) of the patients, chronic renal disease in 4/54 (7.4%) and chronic obstructive pulmonary disease in 3/54 (5.6%). Fourteen (25.9%) patients had a history of hospitalization and 5/54 (9.3%) of admission to the ICU in the previous 3 months. The incidence of bacteriuria was higher among patients with a history of hospitalization in the previous 3 months, and difference was statistically significant ($p = 0.028$). Details are shown in Table 1.

Bacteriuria was determined in 25/54 (46.3%) patients during the study. The most commonly detected agent, at 11/25 (44%), was *Escherichia coli*, followed by *Enterococcus* spp. 5/25 (20%), *Klebsiella pneumonia* 2/25 (8%), *Pseudomonas* spp. 2/25 (8%), *Acinetobacter* spp. 2/25 (%8), *Enterobacter cloacae* 1/25 (4%), *Proteus mirabilis* 1/25 (4%) and *Candida* spp. 1/25 (4%). Second species was grown in four of the specimens. *Enterococcus* spp. was isolated in three specimens, and *E. cloacae* in one.

During the study, twenty-four patients, 24/54 (44.4%), in whom bacteriuria was detected received antibiotics with a diagnosis of urinary tract infection. In a patient using silver catheter, colonization was diagnosed and the antibiotic was not started. No significant difference was determined in terms of different catheters used among the patients diagnosed with urinary tract infection ($p = 0.98$).

The rate of bacteriuria in the first 24 h was higher in the silver-coated catheter group, although the difference was also not statistically significant ($p = 0.67$). No significant difference was also observed between the groups at other periodic examinations. The results are shown in Table 2. Bacteriuria developed in 12/26 (46.2%) of the patients using normal catheters and 13/28 (46.4%) of those using silver-coated catheters throughout the monitoring period. No significant relation was determined between the use of different catheter types and rates of bacteriuria ($p = 0.98$). *E. coli* grew in 7/26 (26.9%) and microorganisms other than *E. coli* in 5/26 (19.3%) of the subjects using normal catheters, while *E. coli* grew in 4/28 (14.3%) and other microorganisms in 9/28 (32.1%) of the patients using silver-coated catheters. No significant relation was determined between type of device used and the rate of *E. coli* growth ($p = 0.38$).

4. Discussion

The duration of catheterization is the main risk factor for CAUTI [12–15]. Other factors that increase the risk of CAUTI include rapidly fatal underlying illness, more than 50 years of age, hospitalization in orthopedic or urology department, insertion of catheter outside the operating room, diabetes mellitus and serum creatinine greater than 2 mg/dL at the time of catheterization. Additionally, the major risk factors for catheter associated bacteriuria was reported as obesity as well as duration of catheterization, female gender, and diabetes mellitus [16]. In this study, the incidence of bacteriuria was higher among subjects with diabetes although this was also not statistically significant ($p = 0.343$). Fourteen (25.9%) patients had a history of hospitalization in the previous 3 months, and 5 (9.3%) had a history of admission to intensive care in the preceding 3 months. The incidence of bacteriuria was higher among patients with a history of hospitalization in the previous 3 months, even though this is not a defined factor increasing catheter-related bacteriuria, and this difference was statistically significant ($p = 0.028$). The incidence of growth was also higher among subjects with a history of admission to the

Table 1
Comparison of group demographics and urinary infection development.

	Silver-coated catheter	Foley catheter
Age	31–101 (70.61)	28–89 (69.23)
Gender		
Female	12	15
Male	16	11
Neurological disease		
Cerebro vascular disease	18	21
Intracerebral mass	1	0
Gullian Barre	1	0
Amyotrophic lateral sclerosis	1	1
Epilepsy	2	1
Parkinson's disease	1	1
Neuroepileptic malignant syndrome	1	1
Vasovagal sencop	1	0
Encephalitis	1	1
Myasthenia Gravis	1	0
Additional disease		
Hypertension	10	11
Diabetes mellitus[a]	6	6
Chronic renal disease	2	1
Chronic pulmonary disease	3	1
Hospitalization in the last three months[b]	8	6
Admission to the intensive care unit[c]	2	2
Urinary system infection[d]	12	12

[a] Bacteriuria were present in 7 out of 12 patients who were diabetic and 18 out of 42 who were non-diabetic. The incidence of bacteriuria was higher diabetic patients although this was not statistically significant ($p = 0.343$).
[b] The higher incidence of bacteriuria among patients with a history of hospitalization in the previous 3 months was not statistically significant in each group (silver-coated catheter $p = 0.055$; foley catheter $p = 0.250$).
[c] In 4 out of 5 patients who were inpatients in ICU's and in 21 out of 49 who didn't have ICU records in the last 3 months had bacteriuria. The difference between these two did not carry a statistically valuable meaning ($p = 0.170$).
[d] The incidence of bacteriuria was higher among patients group with a history of hospitalization in the previous 3 months, and the difference was statistically significant when all of the patients were evaluated together ($p = 0.028$). Since 24 of 25 patients with bacteriuria was diagnosed of urinary tract infections. And half of these patients had silver-covered catheters and the rest were in the group of normal foley catheter.

Table 2
Comparison of the groups in terms of bacteriuria.

Presence of bacteriuria		Total	Catheter type		χ^2	p
		N	Normal (n = 26) n (%)	Silver-coated (n = 28) n (%)		
Within 24 h	yes	6	2 (7.7)	4 (14.3)	0.59	0.67
	no	48	24 (92.3)	24 (85.7)		
Within 48 h	yes	13	7 (26.9)	6 (21.4)	0.22	0.64
	no	41	19 (73.1)	22 (78.6)		
Within 96 h	yes	16	7 (26.9)	9 (32.1)	0.18	0.68
	no	38	19 (73.1)	19 (67.9)		
Within 6 days	yes	19	8 (30.8)	11 (39.3)	0.43	0.51
	no	35	18 (69.2)	17 (60.7)		
Within 8 days	yes	22	11 (42.3)	11 (39.3)	0.05	0.82
	no	32	15 (57.7)	17 (60.7)		
Within 10 days	yes	23	12 (46.2)	11 (39.3)	0.26	0.61
	no	9	2 (53.8)	7 (60.7)		
Within 12 days	yes	23	12 (46.2)	11 (39.3)	0.26	0.61
	no	31	14 (53.8)	17 (60.7)		
Within 14 days	yes	24	12 (46.2)	12 (42.9)	0.06	0.81
	no	30	14 (53.8)	16 (57.1)		
Within 16 days	yes	24	12 (46.2)	12 (42.9)	0.06	0.81
	no	30	14 (53.8)	16 (57.1)		
Within 18 days	yes	24	12 (46.2)	12 (42.9)	0.06	0.81
	no	30	14 (53.8)	16 (57.1)		
Within 20 days	yes	24	12 (46.2)	12 (42.9)	0.06	0.81
	no	30	14 (53.8)	16 (57.1)		
Within 22 days	yes	25	12 (46.2)	13 (46.4)	0.00	0.98
	no	29	14 (53.8)	15 (53.6)		

intensive care in the previous months although this difference was not statistically significant ($p = 0.170$). The higher incidence of bacteriuria among patients with a history of hospitalization in the previous 3 months, was not statistically significant when the groups were assessed separately. The results are shown in Table 1.

Biofilm formation on the urinary catheter is known to play a significant role in CAUTI development [4]. There has therefore been considerable research into means of preventing the formation of such biofilms. Antimicrobial-releasing catheters are first samples of this. Maki et al. have reported a significant lower level of CAUTI in

subjects receiving catheters containing nitrofurantoin compared to a control group ($p \leq 0.01$) [17]. Many studies have been reported showing the protection of antibiotics or metal alloy coated catheters over the years [17,18]. On the other hand no consensus has been achieved on the subject. There is no recommendation for the routine use of anti-microbial urinary catheters to prevent CAUTIs [15,19–21]. The present study identified no protective characteristic against bacteriuria of silver-coated silicone catheters.

No bacteriuria was determined during monitoring in 53.8% of the patients using normal catheters, while *E. coli* was identified in 26.9% and other microorganisms in 19.3%. In the silver-coated catheter group, no bacteriuria was determined during monitoring in 53.6%, while *E. coli* was identified in 14.3% and other bacterial agents in 32.1%. The high rate of the microorganisms other than *E. coli* in the silver coated catheter group suggested that *E. coli* may have greater sensitivity to silver ions. There is a need for further studies to confirm this claim that we cannot support with the current literature.

Clinical diagnosis of a CAUTI is challenging, because pyuria and bacteriuria are almost uniformly present, but neither are reliable indicators of symptomatic UTI in the setting of catheterization [9,15,20]. The majority of catheter-related bacteriuria are asymptomatic. However, urinary tract infection findings including fever and other symptoms occur in 10–39% of patients with bacteriuria [22]. Twenty-four patients in this study (24/54; 44.4%) received antibiotic treatment with a diagnosis of urinary tract infection. Fever may be, only the clinical indication, of UTI in patients who are critically ill such as intensive care patients. However, except these patients populations, additional urinary tract specific signs and symptoms should be sought for the diagnosis of UTI [9,20]. Limitation of this study is that the presence of bacteremia in patients was not investigated, and the presence of bacteriuria-related urinary tract infection could not be sufficiently examined. Differences emerging as statistically insignificant may be attributed to the low sample numbers. Our results may warrant further well-designed studies with larger case numbers to confirm.

In conclusion, the use of silver-coated silicone catheters was not shown to have a protective effect against bacteriuria in this study, and these do not seem to be superior to routinely used urinary catheters.

Conflicts of interest

The authors declare no conflict of interest.

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