Original Article

The efficacy of noble metal alloy urinary catheters in reducing catheter-associated urinary tract infection

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Abstract

Background: Catheter-associated urinary tract infection (CAUTI) is the most common device-related healthcare-acquired infection. CAUTI can be severe and lead to bacteremia, significant morbidity, prolonged hospital stay, and high antibiotic consumption.

Patients and Methods: In this study, we evaluated the CAUTI-reducing efficacy of noble metal alloy catheters in sixty patients (thirty per group) in the Intensive Care Unit (ICU) at the King Fahad Hospital in Saudi Arabia. The study was a single-blinded, randomized, single-centered, prospective investigation that included patients using urinary catheters for 3 days.

Results: A 90% relative risk reduction in the rate of CAUTI was observed with the noble metal alloy catheter compared to the standard catheter (10 vs. 1 cases, $P = 0.006$). When considering both catheter-associated asymptomatic bacteriuria and CAUTI, the relative risk reduction was 83% (12 vs. 2 cases, $P = 0.005$). In addition to CAUTI, the risk of acquiring secondary bacteremia was lower (100%) for the patients using noble metal alloy catheters (3 cases in the standard group vs. 0 case in the noble metal alloy catheter group, $P = 0.24$). No adverse events related to any of the used catheters were recorded.

Conclusion: Results from this study revealed that noble metal alloy catheters are safe to use and significantly reduce CAUTI rate in ICU patients after 3 days of use.

Key Words: Anti-infective, antimicrobial, bacteremia, bacteriuria, catheter-associated urinary tract infection, Foley catheter, hospital-acquired infection, hydrogel, infection, noble metal alloy, silver alloy, urinary catheter

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INTRODUCTION

Urinary tract infection (UTI) is the most common hospital-acquired infection worldwide and accounts for almost 30–40% of all healthcare-associated infections. Eighty percent of UTIs are attributable to indwelling urinary catheter use.[1-4] Indwelling catheters are used routinely in the Intensive Care Units (ICUs), usually for frequent and accurate monitoring of urinary output. Approximately 15–25% of hospitalized patients use a urinary catheter during their stay,[2,5] and the majority of these patients are catheterized for 2–4 days.[6,7] In the US hospitals, the incidence rate of catheter-acquired

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urinary tract infections (CAUTIs) is approximately 1 million/year (or 3.1–7.5 infections/1000 catheter days).[8] The cost of treating these infections is estimated at $400 million/year.[9,10] In Saudi Arabia, where the present study was conducted, the incidence rate is 8.18 CAUTI per 1000 catheter days for adult ICU units between 2004 and 2011.[11]

The main causal agents of CAUTIs are commensal perineal flora although microbes acquired from other sources, such as hands from healthcare personnel, can also be responsible for the infection. Most CAUTIs are monomicrobial, commonly caused by *Escherichia coli, Pseudomonas aeruginosa, Enterococci, Candida, Klebsiella,* or *Enterobacter.*[12]

In addition to pain and discomfort, CAUTIs cause prolongation of hospital stay by 1–4 extra days and increased use of antibiotics, with consequent development of resistant microbial strains.[13-17] Moreover, CAUTIs can lead to cystitis, pyelonephritis, and in severe cases, end up in bacterial invasion of the bloodstream, i.e., bacteremia.[18] Bacteremia, in turn, can result in septicemia and then septic shock, which has a relatively high mortality rate, underlining the importance of introducing treatment at an early stage of the infection[18] and employing strategies to prevent CAUTI. Examples of such preventive measures are: (i) The use of a secured, closed, drainage system that mimics normal voiding, (ii) adequate hand hygiene of hospital personnel, and (iii) the use of preinsertion checklists to avoid catheter insertion without an appropriate indication. Newer strategies have also been introduced, focusing on producing biocompatible and antimicrobial catheter materials to further reduce the risk of infection and inflammatory responses.[19] So far, catheters coated with different antiseptic and antimicrobial compounds, i.e. silver, noble metal alloy, chlorhexidine,[20] nitrofurazone, hydrogel, and polymeric coating,[21] have been tested with varying degrees of success. Existing data suggest that one promising CAUTI-reducing coating consists of a noble metal alloy and hydrogel layer. These catheters have been introduced into practice in the US and several studies support their efficacy, safety, and cost-effectiveness.[22-24] However, the CAUTI-reducing effect observed in these studies varies considerably, suggesting that the efficacy is highly dependent on patient group characteristics, hospital and/or region, catheterization time period, and which definition of CAUTI has been used.

The objective of this study was to evaluate the efficacy of 3-day use of a noble metal alloy and hydrogel-coated catheter, compared to a standard catheter in high-risk ICU patients at the King Fahad University Hospital in Saudi Arabia. The primary end-point was the frequency of both symptomatic CAUTI and catheter-associated asymptomatic bacteriuria (CA-ASB). Additional end-points were to assess safety and occurrence of UTI-related symptoms (such as polyuria and oliguria) and secondary bacteremia. All patients were thoroughly examined just before catheterization ("day 0") to have a relevant baseline and after 3 days.

MATERIALS AND METHODS

Study design and population

This was a single-blinded, randomized, single-centered, prospective study of the safety and performance of noble metal alloy catheters in ICU patients requiring urinary catheters for at least 3 days. Data were collected at the medical and surgical critical ICU at the King Fahad Hospital of University of Dammam in Saudi Arabia. The defined inclusion criteria were (1) adult patients (≥18 years), (2) no UTI, (3) requiring a urinary catheter for at least 3 days, (4) using a closed drainage system. Accordingly, children, patients with UTIs, patients using open drainage system, urinary tract congenital abnormalities or obstetric/gynecological abnormalities, and patients with duration of urinary catheter <3 days were excluded from this study. Data were collected for 60 patients who met the inclusion and exclusion criteria. Patients were randomized to the latex noble metal alloy catheters (BIP Foley Catheter, Bactiguard AB, Stockholm, Sweden) or conventional siliconized latex Foley catheters (Jamjoom Medical Industries, Jeddah, Saudi Arabia), referred to as a standard group, in a 1:1 ratio. The BIP Foley Catheter is made of latex coated with a noble metal alloy (gold, silver, and palladium) and a hydrogel layer.

Data collection and nursing management

Demographic, medical, and clinical data for each patient were collected. The documented demographic data included age, gender, and date of urinary catheter insertion. The recorded medical data included diagnoses, such as renal tubular acidosis, pulmonary embolism, pleural effusion, status epilepticus, intracranial hemorrhage, diabetic ketoacidosis, drug overdose, and surgery (postoperated). These diagnoses were present before catheter insertion meaning they were not caused by catheterization. To reduce the risk of CAUTI, the catheters were inserted using aseptic technique and sterile equipment. The nurses performed hand hygiene before and after insertion and maintained a closed drainage system and properly secure catheters. If a problem occurred, such as disconnection or leakage, the catheter and collecting system was replaced using aseptic technique and sterile equipment. All clinical data were collected both before the catheter insertion (baseline) and on the third catheterization day, after removal of the catheter. The researcher monitored the body temperature, suprapubic tenderness, costovertebral angle pain or tenderness, and UTI-related symptoms (oliguria and polyuria). In addition, measured clinical parameters included white blood cells in blood and urine (pyuria) and bacterial culture in urine and

blood specimens. For both urine culturing and analysis, unspun urine samples were used. All laboratory analyses of urine and blood were conducted according to the standard microbiological procedures.

Definition of catheter-associated urinary tract infection, catheter-associated asymptomatic bacteriuria, asymptomatic bacteremic urinary tract infection, and symptomatic bacteremic urinary tract infection

In this study, CAUTI is clinically defined based on guidelines from the Center for Disease Control and Prevention (CDC) - National Healthcare Safety Network criteria including only symptomatic CAUTI,[25] i.e., (1) patient has, or has had, a urinary catheter within 48 h before the specimen collection, (2) a positive urine culture of $\geq 10^3$ cfu/ml or $\geq 10^5$ cfu/ml with no more than two organisms, (3) one symptom (fever, dysuria, or suprapubic tenderness), and (4) If the patient has a positive urine culture $\geq 10^3$ and $<10^5$ cfu/ml, one laboratory evidence is required (positive dipstick for leukocyte esterase and/or nitrite, pyuria, microorganism seen on Gram stain of unspun urine).

The criteria for CA-ASB are: (1) Patient has, or has had, a urinary catheter within 48 h before the specimen collection, (2) a positive urine culture of $\geq 10^3$ cfu/ml or $\geq 10^5$ cfu/ml with no more than two organisms, (3) If the patient has a positive urine culture of $\geq 10^3$ and $<10^5$ cfu/ml, one laboratory evidence is required (positive dipstick for leukocyte esterase and/or nitrite, pyuria, microorganism seen on Gram stain of unspun urine).

For asymptomatic bacteremic UTI (ABUTI), the patient must meet all the following criteria for diagnosis (based on the CDC criteria):[25] (1) Patient has no signs or symptoms of CAUTI, (2) patient has a urine culture with no more than two species of organisms, at least one of which is a bacteria of $\geq 10^5$ cfu/ml, and (3) patient has a positive blood culture with at least one matching bacteria to the urine culture. ABUTI is not categorized as a CAUTI in this study.

Symptomatic bacteremic UTI (SBUTI) is defined as: (1) Patient has fulfilled the criteria for CAUTI and (2) has a positive blood culture with at least one matching bacteria to the urine culture.

Secondary bacteremia includes both ABUTI and SBUTI.

Ethical permission

Ethical permission was obtained from the Research Ethical Committee at the University of Dammam, (committee for surgical and medical ethics) Saudi Arabia, and ministry of higher education. Furthermore, an official permission was obtained from hospital administration and the director of the ICU. Informed consent was obtained from all individual participants included in the study.

Statistical analysis

For numerical and normally distributed data, differences between groups (noble metal alloy vs. standard catheters) were tested for significance with two-tailed *t*-test. However, for numerical data that were not normally distributed, the Mann–Whitney test was instead used. Categorical data (demographic/medical data) were analyzed using Fisher's exact test. Minitab, version 17 (State College, Pennsylvania, USA) was used for statistical analyses.

RESULTS

Demographic and medical data

The present study includes totally sixty patients where thirty patients were randomized to the noble metal alloy urinary catheter group and thirty patients to the standard catheter group. The demographic data did not differ significantly between the two categories [Table 1], except for age. Despite randomization, the mean ages of the two groups receiving a standard and noble metal alloy catheters were 58 and 44, respectively, and were statistically different ($P = 0.01$).

Catheter-associated asymptomatic bacteriuria and catheter-associated urinary tract infection

After the catheterization period of 3 days, ten cases of CAUTI were recorded in the standard catheter group while only one case

Table 1: Patient demographic characteristics

Item	Standard catheter (*n*=30)	Noble metal alloy catheter (*n*=30)	*P*
Age (%)			
19-25	3 (10)	8 (27)	
26-50	7 (23)	12 (40)	
51-75	14 (47)	6 (20)	
76-99	6 (20)	4 (13)	
Mean (±SD)	58.4 (±19.5)	43.9 (±21.7)	0.01[T]
Gender (%)			
Males	14 (47)	16 (53)	0.8[F]
Females	16 (53)	14 (47)	
Diagnosis (%)			
Shock	7 (23)	2 (6.7)	0.2[F]
RTA	4 (13)	8 (27)	0.3[F]
Pulmonary embolism	3 (10)	2 (6.7)	1.0[F]
Plural effusion	1 (3.3)	0 (0)	1.0[F]
Aspiration pneumonia	2 (7)	1 (3)	1.0[F]
Status epilepticus	1 (3)	1 (3)	1.0[F]
ICH	1 (3)	1 (3)	1.0[F]
DKA	0 (.0)	1 (3)	1.0[F]
Drug overdose	0 (0)	1 (3)	1.0[F]
Total	21	21	1.0[F]
Surgery (%)			
Postoperation	9 (30.0)	9 (30.0)	1.0[F]

[T]Student's *t*-test, [F]Fisher's exact test. SD: Standard deviation, RTA: Renal tubular acidosis, ICH: Intracranial hemorrhage, DKA: Diabetic ketoacidosis

of CAUTI occurred in the noble metal alloy catheter group. Thus, the relative risk was 0.1 (95% confidence interval [CI]; 0.014–0.733, $P = 0.006$) and the risk reduction was 90% (33% vs. 3.3% per catheter days) [Figure 1 and Table 2]. The etiologies of these cases were *Enterobacter cloacae, Acinetobacter baumannii/haemolyticus, Escherichia coli, Candida tropicalis/albicans, Morganella morganii,* and *P. aeruginosa* [Table 3].

Moreover, two cases of CA-ASB caused by, e.g. *E. cloacae* and *C. tropicalis*, were observed in the standard group while only one case of CA-ASB in the noble metal alloy catheter group was observed (microbial species identity not determined in this case) [Figure 1 and Table 2].

When considering both CAUTI and CA-ASB, the relative risk was 0.167 (95% CI; 0.041–0.682, $P = 0.005$), and the risk reduction of acquiring CAUTI was 83% in the group using noble metal alloy catheters compared to the standard catheter (40% vs. 6.7% per catheter days) [Figure 1 and Table 2].

Table 2: Catheter-associated urinary tract infection, catheter-associated asymptomatic bacteriuria, polyuria, and oliguria cases

	Standard catheter (cases)	Noble metal catheter (cases)	*P*
CAUTI	10	1	0.006[F]
CA-ASB	2	1	1.0[F]
CAUTI + CA-ASB	12	2	0.005[F]
ABUTI	1	0	1.0[F]
SBUTI	2	0	0.49[F]
Total secondary bacteremia (SBUTI + ABUTI)	3	0	0.24[F]
Other bacteremia (not associated to UTI)	6	5	1.0[F]
Polyuria (%)	6 of 17 (35.3)	3 of 24 (12.5)	0.13[F]
Oliguria (%)	5 of 17 (29.4)	6 of 24 (25.0)	1.0[F]

[F]Fisher's exact test. UTI: Urinary tract infection, ABUTI: Asymptomatic bacteremic UTI, SBUTI: Symptomatic bacteremic UTI, CAUTI: Catheter-associated UTI, CA-ASB: Catheter-associated asymptomatic bacteriuria

Table 3: Microbiology data after 3 days of catheterization

	Standard catheter (number of positive cultures)		Noble metal alloy catheter (number of positive cultures)	
	Urine	Blood*	Urine	Blood*
Species not identified	4	0	2	0
E. cloacae	2	1	0	0
E. coli	1	0	0	0
A. baumannii/haemolyticus	1	1	0	0
S. epidermidis	0	0	0	0
S. aureus	0	0	0	0
E. faecalis	0	0	0	0
K. pneumonia	1	0	0	0
S. haemolyticus	0	0	0	0
Candida spp.	2	0	0	0
B. cepacia	0	0	0	0
P. aeruginosa	1	0	0	0
E. coli	1	1	0	0
A. baumannii/haemolyticus	0	0	0	0
E. cloacae	0	0	0	0
M. morganii	1	0	0	0

*For microbiology in blood, we have only specified the microbes of the secondary bacteremia (ABUTI and SBUTI cases), not for the other bacteremia cases that are not associated with UTI. *E. cloacae: Enterobacter cloacae, E. coli: Escherichia coli, A. baumannii: Acinetobacter baumannii, S. epidermidis: Staphylococcus epidermidis, S. aureus: Staphylococcus aureus, E. faecalis: Enterococcus faecalis, K. pneumonia: Klebsiella pneumonia, S. haemolyticus: Staphylococcus haemolyticus, B. cepacia: Burkholderia cepacia, P. aeruginosa: Pseudomonas aeruginosa, M. morganii: Morganella morganii*, UTI: Urinary tract infection, ABUTI: Asymptomatic bacteremic UTI, SBUTI: Symptomatic bacteremic UTI

Bacteremia

Some cases of bacteremia (microbe(s) detected in blood) were observed already before the start of the catheterization period at day 0. Bacteremia cases were present in both groups: Seven patients in the standard catheter group and five patients in the noble metal alloy catheter group. Most likely, the microbial source(s) of these cases was other than a urinary tract since none of the microbes causing the bacteremia were detected in the urine of these patients. All the microbial strains of all bacteremia cases in both groups are however typical for causing nosocomial infections.[26]

After 3 days of catheterization, a total of 9 cases of bacteremia were observed in the standard group, but no additional cases were observed in the noble metal alloy catheter group. Three of the 9 bacteremia cases were considered to be secondary bacteremic UTI since they were positive for the same strains of microorganism in both blood and urine, suggesting that this microbe(s) originated from the urinary tract. Of these three secondary bacteremia cases, one case fulfilled the criteria for ABUTI (see criteria described in the method section)

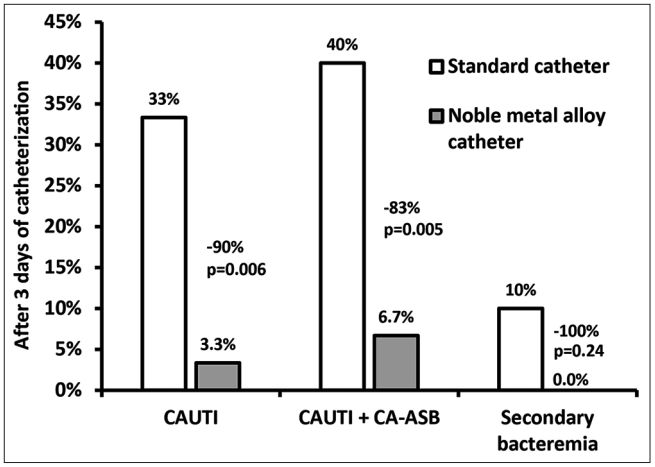

Figure 1: Observed CAUTI, CA-ASB, and secondary bacteremia rates. The relative risk reduction of CAUTI, CAUTI + CA-ASB, and secondary bacteremia when using the noble metal alloy catheters compared to standard catheters. The CAUTI/CA-ASB and secondary bacteremia (ABUTI + SBUTI) rates are presented as percentage. CAUTI: Catheter-associated urinary tract infection, CA-ASB: Catheter-associated asymptomatic bacteriuria, ABUTI: Asymptomatic bacteremic urinary tract infection, SBUTI: Symptomatic bacteremic urinary tract infection

since this patient did not have any CAUTI symptoms while the other 2 cases were SBUTI. Note that the ABUTI case is also considered as a CA-ASB case (and not CAUTI) since this patient had bacteriuria without symptoms. The etiologies of the secondary bacteremia cases were *E. cloacae, A. baumannii/haemolyticus,* and *E. coli* [Table 3]. In the noble metal alloy catheter group, none of the patients were positive for the same microbial strain both in blood and urine after catheter use. The difference of secondary bacteremia cases between the two groups was thus 3 cases versus 0 case ($P = 0.24$).

Additional urinary tract infection-related symptoms; polyuria and oliguria

The CAUTI-related symptoms, polyuria or oliguria, were recorded after 3 days of catheterization [Figure 2]. Some of the patients had symptoms already at catheter insertion and were found to have the same symptoms also after 3 days of catheterization independent of intervention. These patients were hence excluded from the calculations regarding polyuria/oliguria since their symptoms were not related to catheterization and only the symptom-free patients at catheterization initiation were included [Figure 2], which were 17 and 24 patients in the standard and noble metal alloy catheter groups, respectively, both set as 100% for its group. After the catheter period of 3 days, 63% of patients using the noble metal alloy catheters remained free from any signs of UTI symptoms compared to 35% in the standard catheter group. Polyuria at the 3rd day of catheterization [Figure 2] occurred in 6 of 17 patients (35%) in the standard group versus 3 of 24 patients (13%) in the noble metal alloy catheter group (relative risk 0.35, 95% CI; 0.10–1.22) $P = 0.13$). A similar percentage of the patients with oliguria was observed in both groups, 5 of 17 (29%) and 6 of 24 (25%) in the standard group (relative risk 0.85, 95% CI; 0.31–2.34, $P = 1.0$) and noble metal alloy group, respectively.

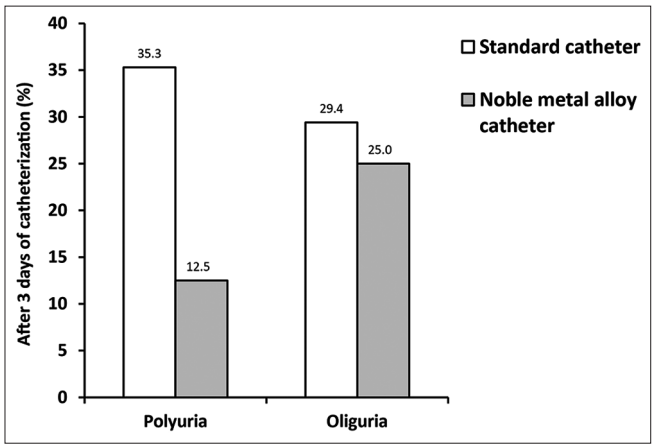

Figure 2: Polyuria and oliguria incidences in the standard and the noble metal alloy catheter groups after the 3 day-catheterization period. Some patients had polyuria/oliguria already before catheterization and were hence excluded from the calculations. 6/17 (35%) and 3/24 patients (12.5%) had polyuria, and 5/17 (29.4%) and 6/24 patients (25%) had oliguria in the standard and noble metal alloy catheter groups, respectively

DISCUSSION

In this study, we evaluated the safety and CAUTI-reducing efficacy of short-term (3 days) noble metal alloy urinary catheter use in patients in the ICU at the King Fahad Hospital in Saudi Arabia. Our results demonstrate a 90% ($P = 0.006$) relative reduction in the noble metal alloy catheter group of the CAUTI rate. When considering both CAUTI and CA-ASB, an 83% relative reduction was observed ($P = 0.005$). In addition, polyuria and secondary bacteremia cases were reduced with relative reductions of 65% ($P = 0.13$) and 100% ($P = 0.24$), respectively, in the group using noble metal alloy catheters while oliguria was similar (relative reduction 15%, $P = 1.0$).

The noble metal coating (Bactiguard®-coating) consists of an extremely thin noble metal alloy of gold, silver, and palladium that is firmly attached to the surface of the catheter. During the last three decades, the clinical efficacy of noble metal alloy catheters has been evaluated in a number of clinical trials, cohorts, and surveillance studies.[23,24,27-29]

Data from these studies show that the coating is nontoxic. There have been no adverse events related to the coating and the vast majority of these studies consistently show that CAUTI is reduced. For example, in a recent multisite cohort by Lederer *et al*.,[22] including 853 patients, a 58% reduction was observed in the metal alloy catheter group (referred to as "silver-alloy and hydrogel-coated urinary catheter" in this report) when considering the revised CDC-defined symptomatic CAUTI[25,30] (excluding asymptomatic bacteriuria) and a 47% reduction when including also clinical CAUTI definitions. Moreover, in another large study including 27,878 patients,[17] the risk of CAUTI declined by 21% among study wards that were randomized to noble metal alloy-coated urinary catheters (referred to as "silver coated catheters" in this report) and by 32% among patients in whom noble metal alloy-coated catheters were used on the wards. In this study, it was also demonstrated that the use of the noble metal alloy-coated catheters offered cost savings by preventing excess hospital stay costs caused by CAUTI.

Nevertheless, many of the published studies on catheters with noble metal coating are not randomized and most of them have CAUTI definitions that include only asymptomatic bacteriuria or aggregated numbers for both symptomatic CAUTI and asymptomatic bacteriuria (since bacteriuria was included in the CAUTI definition before 2009). Moreover, many of

the studies include broad spectra of patients, which makes it difficult to identify patient groups at most benefit for the noble metal-coated catheters.

In this study, we overcome many of these weaknesses. Our study is randomized and uses the current criteria of symptomatic CAUTI (including also data on secondary bacteremia, such as ABUTI and SBUTI). The reason why we observed a pronounced relative reduction of CAUTI, already after 3 days of catheterization, may be due to a homogeneous patient group with high infection rates. Furthermore, the same nurses treated the patients and collected the data. Another recent study by Pickard *et al*.[31] revealed that short-term catheterized, low-risk surgery patients (1–2 catheterization days) were not benefited by noble metal alloy-coated catheters in reducing symptomatic CAUTI.

However, there are several limitations in the present report. First, there is a limited number of participants ($n = 60$) implying that every CAUTI case has a large impact on the relative reduction rate. Second, there was a difference in age distribution between the groups. No difference was observed between the groups with regards to the gender or diagnoses.

CONCLUSION

CAUTI rates and secondary outcomes such as polyuria and secondary bacteremia were found to be in lower frequency rate in the noble metal alloy group compared to the standard group.

To obtain further clinical evidence of the anti-infective effects and to assess cost efficiency of these catheters, the next step would be to conduct randomized clinical studies in a larger study population, in different patient types including cost-driving parameters.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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