



Is bactiguard infection protection catheter efficient in lowering urinary tract infections in patient with prolonged catheterization ?

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Abstract

The bactiguard infection protection technology is based on applying an extremely thin noble metal coating, consisting of gold, silver and palladium, to medical devices. The bactiguard coating is firmly bound to the surface of the device and reduces the adhesion and growth of microbes. This occurs without any pharmacological or toxic effect. The solution is unique. It is effective and, at the same time, biocompatible and tissue friendly, which increases patient safety. Bactiguard infection protection is thus an important component in the prevention of hospital acquired infection (HAI) and reduced use of antibiotics. The study will consist in an open, randomized, and parallel clinical trial with blinded assessment. The study will include 33 patients who require prolonged urethral catheterization as a method of bladder voiding who visited the polyclinic of surgical subspecialty hospital, medical city complex for the period from November 2014 to December 2015. To all 33 patients urinary catheters with antiseptic silver alloy coating were inserted (BIP Foley catheter – Silicone, bactiguard Infection Protection). All are made of full silicone. Trained health staff performs urethral catheterization procedure and select the most adequate catheter size. To ensure aseptic conditions they are asked to strictly follow the current protocol in their respective centers. Indwelling urethral catheters are periodically replaced about 14 days of use. When the catheter is replaced C/S of its tip is done too see the outcome of UTI. The result showed that the first c/s showed that from the 33 patients with catheter associated urinary tract infection 26 patients E-coli was the causative organism (78.78%), 5 patients klebsiella was the causative organism, 2 patients pseudomonas was the causative organism. The second c/s was negative in; 20 patients from 26 suffering from UTI caused by *E. coli* (76.9%), and two patients from 5 suffering from UTI caused by klebsiella (40%). Unfortunately no culture turned negative in patients suffering from UTI caused by pseudomonas. Bactiguard urinary catheters are very effective in the management of catheter associated urinary tract infection especially caused by E-coli in patients who need prolonged catheterization.

Keywords: Bactiguard catheter, Catheter associated urinary tract infection, *E. coli*, Biofilm.

Introduction

Urinary tract infections are usually the most common type of hospital acquired infection in developed countries. (Gravel *et al.*, 2007; Pellizzer *et al.*, 2008) and most of them are associated with urinary catheters (Bouza *et al.*, 2001). These catheters are generally well tolerated, although there is huge variability in patient tolerance and the causes of this are difficult to elucidate (Tambyah *et al.*, 2000). Catheter related bacteriuria is often asymptomatic but symptoms arise in some patients, of whom a few show serious complications, such as bacteremia (Steward *et al.*, 1985). The appearance of white blood cells in urine is not directly related to symptoms but it is associated with the presence of bacteria, although this association is less strong

than in non-catheter associated UTIs (Tambyah *et al.*, 2000). Catheter associated urinary tract infection is the single most common hospital acquired infection and a significant cause of nosocomial gram negative bacteremia (Warren, 1991; Saint, 2000). Several types of antimicrobial coated Foley catheter have been developed to prevent such infections. They include catheters coated with various silver compounds, which have a broad antimicrobial spectrum, or nitrofurazone, a congener of nitrofurantoin that, like nitrofurantoin, is active against most *E. coli* isolates and other common uropathogens but not *Proteus* species or *Pseudomonas aeruginosa* (Johnson *et al.*, 2006; Drekonja *et al.*, 2008). Clinical trial data suggest that silver coated and nitrofurazone coated catheters can decrease the incidence of bacteriuria/funguria

during short-term catheter use compared to uncoated control catheters (Johnson *et al.*, 2006; Drekonja *et al.*, 2008). However, whether this leads to fewer bacteriuria/funguria associated complications is unknown. To our knowledge different antimicrobial coated catheters have never been compared head-to head clinically to determine which is more effective. Furthermore, available clinical studies were done before the recent widespread emergence of gram negative bacilli resistant to extended spectrum cephalosporins, of which *E. coli* most often causes urinary tract infection (Pitout *et al.*, 2008; Pitout *et al.*, 2005). To our knowledge whether the available antimicrobial coated catheters show activity against such organisms, and their relative potency and durability of effect are unknown. However, the typically preserved susceptibility of such organisms to nitrofurantoin suggests that at least the nitrofurazone coated catheter should be active. In the absence of relevant clinical studies data from *in vitro* studies may prove helpful. In previous *In vitro* studies a nitrofurazone coated Foley catheter showed diffusible antimicrobial activity against *E. coli* clinical isolates, including multidrug resistant strains, detectable as a ZOI around catheter segments on a lawn of the test organism. In contrast, a silver coated latex catheter showed no such activity (Johnson *et al.*, 1999; Johnson *et al.*, 1993). However, in other studies silver coated catheters inhibited *E. coli* adherence to catheter surfaces, possibly through a contact dependent effect of the silver coating (Gabriel *et al.*, 1995; Gabriel *et al.*, 1996; Ahearn *et al.*, 2000).

Catheter associated urinary tract infections (CAUTI) account for a large proportion of healthcare associated infections (HAI) (Klevens *et al.*, 2007). These infections can result in serious complications such as urosepsis, which lead to patient suffering as well as increased mortality and healthcare costs (Kalra *et al.*, 2009). In addition, many of these infections are treated with antibiotics, which increase the risk of emergence and spread of multi-resistant microbes. WHO estimates that antimicrobial resistance is so serious that it threatens the achievements of modern medicine (Antimicrobial resistance, Global report on surveillance, WHO, 2014). The BIP Foley Catheter is a bactiguard coated indwelling urinary catheter made of latex. The bactiguard technology has been used successfully since 1995 for the prevention of HAI in the USA, UK and Japan, among other countries (Schumm *et al.*, 2008).

The bactiguard infection protection technology is based on applying an extremely thin noble metal coating, consisting of gold, silver and palladium, to

medical devices. The bactiguard coating is firmly bound to the surface of the device and reduces the adhesion and growth of microbes. This occurs without any pharmacological or toxic effect. The solution is unique. It is effective and, at the same time, biocompatible and tissue friendly, which increases patient safety. Bactiguard infection protection is thus an important component in the prevention of HAI and reduced use of antibiotics (Stenzelius *et al.*, 2009; Lederer *et al.*, 2014).

Bactiguard coated products have been used in a some 40 clinical studies and evaluations (1986–2014) involving over 100,000 patients in eight countries. BIP Foley Catheters have been shown to significantly reduce the incidence of bacteriuria and studies show that symptomatic urinary tract infections and antibiotic use can be reduced by ~50% and 60% respectively, by using bactiguard coated catheters (Schumm *et al.*, 2008; Stenzelius *et al.*, 2009; Lederer *et al.*, 2014).

The BIP Foley Catheter has been shown to effectively reduce microbial adhesion to the device by over 99 percent in microbiological *In vitro* studies with relevant clinical isolate strains (Rupp *et al.*, 2004).

Materials and Methods

Patient and method: The study will consist in an open, randomized, and parallel clinical trial. The study will include (33) patients who require prolonged urethral catheterization as a method of bladder voiding who visited the polyclinic of surgical subspecialty hospital, medical city complex for the period from November 2014 to December 2015.

- The criteria for inclusion in this study are:
 1. Male or female patients with bacterial UTI diagnose by C/S done by specialist bacteriologist.
 2. Patients who need an indwelling urinary catheter as a method of bladder drainage for at least 14 days.
 3. Patients who are willing to participate in the study and give their written informed consent (If a patient is unable to give written consent because of physical or mental disability, an affirmation of consent will be taken in his presence from his relative or legal guardian).
- The following participants will not be included in the study:
 1. Patients who can benefit from other method of bladder drainage such as intermittent catheterization, suprapubic drainage or reflex voiding; as well as those using an external collector.
 2. Current antibiotic use or use within 7 days prior to inclusion.
 3. Outpatients with sporadic medical examinations (less than one per month).

4. Known allergy to latex, silver salts or hydrogels.
5. Patients with surgical interventions in the urinary tract that may interfere, at the investigator criteria, with the study results.

The intervention arm receives urinary catheters with antiseptic silver alloy coating (BIP Foley catheter, bactiguard Infection Protection). Bactiguard Infection Protection coating consists of noble metals such as gold, palladium and silver and its mechanism of action is to avoid the adhesion of bacteria to the inner catheter surface. All are made of full silicone. Trained health staff performs urethral catheterization procedure and select the most adequate catheter size. To ensure aseptic conditions they are asked to strictly follow the current protocol in their respective centers. Indwelling urethral catheters are periodically replaced about 14 days of use. When the catheter is replaced C/S of its tip is done by the same bacteriologist in the bacteriology department of the medical city department to see the outcome of UTI.

Results and Discussion

The first culture and sensitivity showed that from the (33) patients with catheter associated urinary tract infection:

- (26) Patients had *E. coli* was the causative organism (78.78%).
- (5) Patients had *Klebsiella* was the causative organism (15.15%).
- (2) Patients had *pseudomonas areuginosa* was the causative organism (6%).

The second culture and sensitivity was negative in:

- (20) Patients from (26) suffering from CA-UTI caused by *E. coli* (76.9%).
- (2) Patients from (5) suffering from CA-UTI caused by *Klebsiella* (40%).
- Unfortunately no culture turned negative in patients suffering from CA-UTI caused by *pseudomonas areuginosa* (0%).

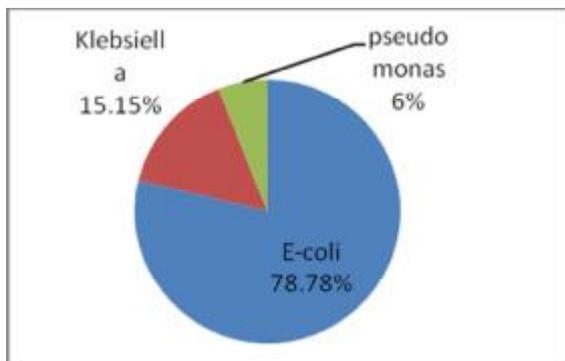


Figure (1): Percentage of Patients with first culture & sensitivity positive results before using BIP

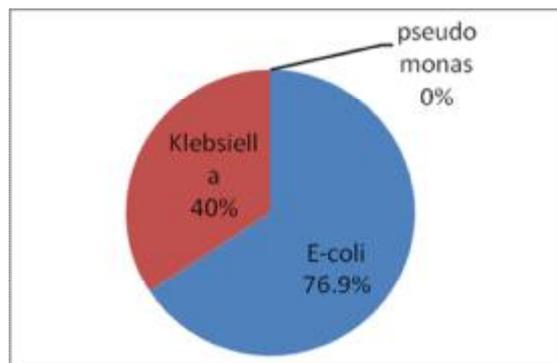


Figure (2): Percentage of Patients with second culture & sensitivity negative results after using BIP catheters

Table(3): Percentage test (z- test)

Organisms	Sample size	Percent % of (-ve) c/s	P- value	Z- test
<i>E. coli</i>	26	76.9	0.001 (HS)	6.83
<i>Klebsiella</i>	5	40.0	0.05 (S)	
<i>pseudomonas</i>	2	0.0	(NS)	

As show above in Table (3), by using Z-test, there is highly significant results for *E. coli* bacteria (P-value 0.001), for *Klebsiella* bacteria significant results (P-value 0.05) and not significant for *pseudomonas areuginosa* bacteria.

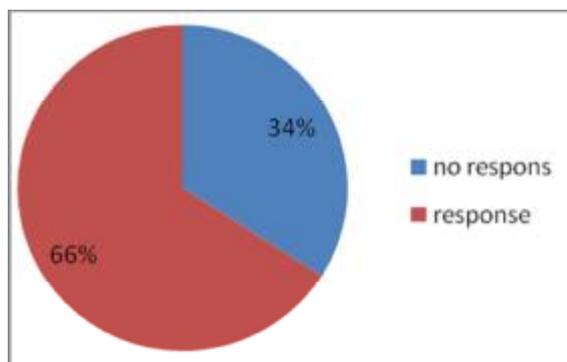


Figure (3): Total response rate with using BIP

The risk of CA-UTI increases by an estimate of 5%-10% for each day the catheter remaining in place. Among patients catheterized for 10 days, the chance of developing bacteriuria increases to 50%. By day 30 after catheter insertion, the risk of CA-UTI nearly doubles (Bruminhent *et al.*, 2010; Rhodes *et al.*, 2009; Daillyet *al.*, 2012; Andreessen *et al.*, 2012).

UTIs account for approximately 40% of all HA infections annually, with 80% of these HA UTIs attributable to indwelling urethral catheters. It is

well established that the duration of catheterization is directly related to risk for developing a UTI. With a catheter in place, the daily risk of developing a UTI ranges from 3% to 7% (Edmond *et al.*, 1999).

CA-UTI occurs when urethral catheters inoculate organisms in the bladder and cause colonization due to providing a medium for bacterial adhesion and mucosal irritation. Urinary catheter is the most important risk factor for bacteriuria (Leone *et al.*, 2004).

Since biofilm on the urinary catheter is the central factor in pathogenesis of CAUTI, many scientists seek to alter the catheter surface in order to inhibit biofilm formation. No surface can resist biofilm formation indefinitely in the urinary tract, but impeding biofilm formation may suffice if the catheter is intended for short term use (Beiko *et al.*, 2004).

The type of urinary catheter modification that has undergone the most extensive clinical testing is impregnating the catheter with antimicrobial agents, most commonly with silver. In 2004 the Cochrane Database of Systemic Reviews published a comprehensive assessment of impregnated catheters intended for short-term use in hospitalized adults. Eight differently-designed trials compared silver alloy catheters with standard catheters. Pooled results indicated that the risk of asymptomatic bacteriuria was significantly reduced in the silver alloy group at less than 1 week of catheterization (RR 0.36; 95% CI 0.25–0.52) and, to a lesser degree, at greater than 1 week (RR 0.67; 95% CI 0.50–0.90). The risk of symptomatic UTI was also lower in the groups with silver alloy catheters (RR 0.60; 95% CI 0.50–0.73), although the symptoms used to define UTI were not specified (Brosnahan *et al.*, 2004).

Because biofilm formation is central to the pathogenesis of CAUTI, novel methods to hinder or alter biofilm formation on the surface of urinary catheters might assist in prevention of CAUTI. BIP Foley catheters are designed to reduce and delay morbidities related to CAUTI (bacteriuria, symptomatic infections, bacteremia, urosepsis).

Long catheterization time requires special attention since long time catheterization means highest risk for patient from infection perspective and at the same time is most challenging from clinical trial perspective. Therefore, an effort has been put here to evaluate all patients with catheterization time of 14 days or more.

Mazzoli *et al.* (2009) showed that there is; Strong reduction of biofilm on BIP catheters compared to uncoated catheters (-78%) has been reported for 37 patients being catheterized for 30 days or more (Mazzoli *et al.*, 2009).

Estores *et al.* (2008) showed that there is; one permanently catheterized patient reported in a case report. He was exchanging catheters every 30-days and was completely cured from frequent symptomatic urinary tract infections during 6 months period of follow up (6 x 30 days), when he used bactiguard coated bardex IC instead of uncoated catheter. Although he still had bacteria in urine after these 6 months, the MDR (Multi Drug Resistant) strains disappeared (Estores *et al.*, 2008).

In the study of Tsang *et al.* (2012) -800 patients with need of long term catheterization, catheters were replaced when the problems like infections occurred. The results indicate that BIP Foley catheter was "problem-free" for about double as long time as for standard Foley (mean: 18 days and 10 days, respectively; up to 28 days and 14 days, respectively). Further, CAUTI infections were reduced by 25% during this period (Tsang *et al.*, 2012).

The study of Seymore *et al.* (2006) with 117 patients shows strong reduction of symptomatic CAUTI, 71%, by use of bactiguard coated Foleys (Bardex IC) compared to standard catheter. The mean catheterization time is 18-19 days, and the longest catheterization is 28 days (Seymore *et al.*, 2006). Liedberget *et al.* (1993) and Madeo *et al.* (2004) Two studies evaluated delay and reduction of bacteriuria in long term catheterization (Liedberg *et al.*, 1993, Madeo *et al.*, 2004). In the Liedberg study with 168 patients, all of them were catheterized for at least 21 days. Reduction of CAUTI (Bacteriuria) for patients catheterized with bactiguard coated Foleys compared to standard Foley, was ~25% at 21 days of catheterization (Liedberget *et al.*, 1993). In Madeo study with 188 patients, mean catheterization time was 15-17 days, and a portion of patients were catheterized for 30 or more days. The results of study show delay of bacteriuria onset by 12 days in average, and a general decrease of bacteriuria by 11%, and specifically of gram-positive bacteria – by 78% (Madeo *et al.*, 2004). Karchmer 2008, Thomas 2002 and Rupp 2004; Three largest surveillance studies in the US (~60 000 patients) have covered medium long and long catheterization time (Karchmer *et al.*, 2008, Thomas *et al.*, 2002 and Rupp *et al.*, 2004). Karchmer has not specified the catheterization time, but the author gives information that catheters were changed every 30 days, unless problems occurred. So – many patients were catheterized for 30 days, and the average effect was CAUTI reduction of 32% (Karchmer *et al.*, 2008). Similarly, Thomas study, showing CAUTI reduction of ~35 – 45%, and reduction of antibiotic use and multi drug resistant strains, has mean catheterization time of ~15 days – and longest

catheterization patients of ~30 days (Thomas *et al.*, 2002). Finally, Rupp, showing CAUTI reduction of ~45-55%, has most probably long term catheterized patients since it includes patients units with normal long term rehabilitation like burn units, transplantation units (Rupp *et al.*, 2004). In summary studies show that BIP Foley catheters/bactiguard coated catheters are effective in reduction of biofilm and CAUTI for at least 30 days. Further strong support for that is found in the other studies, which show CAUTI reduction long term catheterization for 14 days or more, which do include high proportion of patients catheterized for approximately 30 days.

Conclusion

Bactiguard urinary catheters are very effective in the management of catheter associated urinary tract infection caused by *E. coli* in patients who need prolonged catheterization.

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