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# Evaluation of a triple-lumen central venous heparin-coated catheter versus a catheter coated with chlorhexidine and silver sulfadiazine in critically ill patients

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**Abstract** *Objective:* To compare the incidence of catheter colonization and catheter-related bloodstream infections between heparin-coated catheters and those coated with a synergistic combination of chlorhexidine and silver sulfadiazine. *Design:* Randomized, controlled clinical trial. *Setting:* A 20-bed medical-surgical intensive care unit. *Patients:* A total of 180 patients requiring the insertion of a trilumen central venous catheter. *Interventions:* Patients were randomized to receive either a trilumen heparin or chlorhexidine and silver sulfadiazine-coated catheter. *Measurements:* Catheter colonization was defined by a semiquantitative catheter tip culture yielding 15 or more colony-forming units or quantitative culture of 1,000 or more colony-forming units/ml. Catheter-related bloodstream infection as the isolation of the same microorganism from a peripheral blood culture and catheter tip. *Results:* A total of 260 catheters were cultured. Out of 132 heparin-coated catheters, 29 were colonized and out of 128 chlorhexidine and silver sulfadiazine- coated catheters, 13 were colonized ($p$=0.03), relative risk RR=2.16 (1.18–3.97). This represents an incidence of 23.5 and 11.5 episodes of catheter colonization per 1,000 catheter-days, respectively ($p$=0.0059), RR=2.04 (1.05–3.84). Microorganisms isolated in catheter colonization from heparin-coated catheters were gram-positive cocci 23, gram-negative bacilli 7, and *Candida* spp 4. In chlorhexidine and silver sulfadiazine-coated catheters were gram-positive cocci 6 and gram-negative bacilli 11 ($p$=0.009). The incidence of catheter-related bloodstream infections per 1,000 catheter-days was 3.24 in heparin-coated catheters and 2.6 in chlorhexidine and silver sulfadiazine-coated catheters ($p$=0.79), RR=1.22 (0.27–5.43). *Conclusions:* In critically ill patients the use of trilumen central venous catheters coated with chlorhexidine and silver sulfadiazine reduced the risk of catheter colonization due to prevention of gram-positive cocci and *Candida* spp.

**Keywords** Catheter-related blood infection · Catheter colonization · Central venous catheter · Intensive care unit · Antiseptic catheter · Heparin catheter

## Introduction

The placement of a central venous catheter (CVC) is common practice in critically ill patients and is associated with a risk of nosocomial infection [1, 2]. The incidence of catheter-related bloodstream infection (CRBSI) depends mainly on the number of days of catheterization (usually more than 2 days), the frequency of manipulation and the number of ports [3]. In the European Prevalence of Infection in Intensive Care (EPIC) study, CRBSI

represented 12% of all nosocomial infections reported in 10,038 patients [4]. The NNIS reported an average of 5.3 CRBSI per 1,000 catheter-days in a medical-surgical intensive care unit (M/SICU) [5]. The microorganisms of the skin flora around the insertion site are the main common portal of entry of infections [6, 7, 8, 9, 10]. Another pathway is through the contamination of the catheter hub [11], especially in long-term catheters [12]. Hematogenous seeding from a distal focus is less common [13, 14]. In order to prevent infections by catheters, besides the aseptic measures both for the insertion of the catheter and its maintenance, we have at present heparin-coated (HC) [15, 16] and antimicrobial and antiseptic impregnated CVCs [17]. HC catheters prevent the accumulation of fibronectin on the catheter and the subsequent facilitation of bacterial attachment to the fibronectin coating [15]. Catheters coated with the antiseptic synergistic combination of chlorhexidine and silver sulfadiazine (CSS) on the outer surface make them more resistant to bacterial colonization [18]. Some researchers have compared CVCs coated with CSS and standard catheters and found no decrease of CRBSI in patients with parenteral nutrition, [19, 20] in the long-term catheterization of immunodepressed patients, [21] in ICU patients [22] and in surgical patients [23]. However, others have found a decrease of CRBSI in critically ill patients, [24, 25], or simply a catheter colonization (CC) decrease [26, 27, 28]. These differences may be due to how CVC infections are defined and the prevalence of these infections, with variable times of catheterization, changes of the catheter over guidewire, and different patient populations. At the same time the number of CCs and CRBSIs per 1,000 catheter-days is not known in all studies, and apart from this, most studies only included a culture of the external catheter surface. Due to all of these reasons, we carried out a randomized trial to evaluate the efficacy of the CSS catheter for prevention of CC and CRBSI compared to that of the HC catheter normally used.

## Patients and methods

### Patient population and catheters types

This study was conducted prospectively in a 20 bed M/SICU with adult patients, in a university hospital of 600 beds. During a 9-month period, 196 consecutive patients admitted to the M/SICU and who needed a triple-lumen CVC were first randomized to receive either a triple-lumen polyurethane HC (Abbott) catheter or one coated with CSS on the outer surface (Arrow). If a patient was included several times, the first catheter and each subsequent catheter were in the same arm.

The study was approved by the ethical comission of clinical investigation of our hospital and consent was obtained from each patient on admittance to the M/SICU (written for the insertion of CVC, and verbal according to the type of catheter).

### Methods

All catheters were inserted in the M/SICU into a new site by the attending physician who used full barrier precautions (large sterile drapes, long-sleeved sterile gown, sterile gloves, cap, surgical mask). The puncture site was cleaned with soap and disinfected with 10% povidone-iodine (allowed to dry before insertion). After insertion, catheters were dressed with non-transparent sterile gauze. The sterile gauze was removed every 48 h and whenever the dressing was dirty or moist, and the site of puncture inspected by a nurse for local signs of infection and disinfected with povidone-iodine. Connections were manipulated with washed hands and gloves. Administration sets were replaced every 72 h under aseptic conditions, except for blood products (these lines were immediately removed after use) and parenteral nutrition (replacement every 24 h). No routine catheter removal based on duration alone was done. The catheter was removed aseptically on indication by the physician and the 5 -cm distal segment was placed in a sterile tube and sent to the microbiology laboratory. Three pairs of blood samples for culture were drawn percutaneously from all patients before catheter removal, if the patient had had no blood culture in the previous 24 h.

All catheters were cultured by semiquantitative [29] and quantitative methods [30]. We did not use media containing inhibitors of the compounds used in the CSS catheter. The microbiologist who processed all cultures was blinded to each catheter group. Data collected for each catheter insertion included the patient's diagnosis, APACHE II at M/SICU admission, age, sex, reason of catheter removal, the use of parenteral nutrition, anatomical site (i.e. subclavian, femoral, internal jugular vein), the number of days the catheter had been in place, other sites of infections and if the patients had been on antibiotic treatment in the preceding 48 h.

### Measurement

The incidence of catheter colonization and catheter-related bloodstream infection.

### Definitions

Catheter colonization was defined by a semiquantitative catheter tip culture yielding 15 or more colony-forming units (cfu) or quantitative culture of 1,000 or more cfu/ml. Catheter-related bloodstream infection as isolation of the same microorganism from a peripheral venuos blood culture and catheter tip (identical antimicrobial susceptibility). For coagulase-negative *staphylococci* (CNS) two positive blood cultures were required.

### Statistical analysis

The study sample size was estimated according to 22% of cumulated incidences of CC from our ICU [31]. We also took into account the results obtained by Maki et al. [25]. Based on this data we expected a reduction of one-third (out of 22%) in the CSS catheters, for which 102 catheters were required in each group. Additional catheters were randomized in each group for possible postrandomization exclusion. We used catheters rather than individual patients for the statistical analysis. We have studied two independent variables, catheter colonization and the microorganism involved, the $\chi^2$-test was used to assess the significance of the relationship between the type of catheter and different microorganisms/colonization. The risk ratio was used as a measure of association. All tests were perfomed at the 0.05 level of significance and were two-tailed.

## Results

During the study period a total of 276 catheters from 196 patients were randomized. However, 16 catheters from 16 patients were excluded from the study because they were not cultivated (7 HC catheters and 9 CSS catheters), the majority of these catheters with a short time of catheterization (24–48 h in polytrauma patients). We therefore studied 260 catheters from 180 patients. Characteristics of the two groups of patients and catheters are shown in Table 1. Out of 132 HC catheters, 29 were associated with colonization and out of 128 CSS catheters, 13 were colonized ($p$=0.03), RR=2.16 (1.18–3.97). The incidence of CC in HC catheters was 23.9 episodes per 1,000 catheter-days, and in the group CSS 11.5 episodes per 1,000 catheter-days ($p$=0.0059), RR=2.04 (1.05–3.84). Characteristics of CC are shown in Table 2. The uncolonized catheters had been in situ for a median time of 7 days in the CSS group and also in the HC group. Microorganisms involved in CC and CRBSI are shown in Table 3. Gram-positive cocci and fungi were more likely to colonize HC than CSS catheters ($p$=0.009). *S.aureus* in CSS catheters and six strains of *S.aureus* in HC catheters were methicillin-resistant, as were all CNSs in both groups. The incidence of CRBSI was 3.24 and 2.6 episodes per 1,000 catheter-days in HC and in CSS catheters, respectively ($p$=0.79), RR=1.22 (0.27–5.43). Of the 3 catheters which gave CRBSI in the CSS group, 2 had been in place for 6 days and 1 for 17 days. In the HC group there were 4 catheters which had been in place for 5, 6, 12 and 22 days, respectively. All catheters were in patients with mechanical ventilation and with antibiotic therapy. In each group there was one catheter with parenteral nutrition. No adverse effects from antiseptic catheters were observed.

## Discussion

This is the first study to compare the HC catheter with the CSS catheter. Our two groups were similar in demographic characteristics, there were no differences in underlying pathological conditions, or the use of systemic antibiotics. The study was only blinded for the microbiologist, and caused no apparent bias between the two groups, due that to the fact that the knowledge of the type of catheter (HC or CSS) did not affect the care given to the patient or the catheter. Both surfaces of catheters were cultured, as when

**Table 1** Characteristics of patients and catheters

| Characteristics of patients | Heparin-coated | Chlorhexidine and silver-sulfadiazine |
|---|---|---|
| Number of patients | 91 | 89 |
| Median Apache II score at admission | 20.5 | 20 |
| Mechanical ventilation | 78 | 70 |
| Age (years, mean±SD) | 55±18.6 | 57±16.9 |
| Male/female | 61/30 | 54/35 |
| Major diagnosis of patients | | |
| Medical | 50 | 55 |
| Surgical | 23 | 21 |
| Traumatic | 18 | 13 |
| Number of catheters | 132 | 128 |
| Location | | |
| Internal jugular vein | 51 | 41 |
| Subclavian vein | 26 | 26 |
| Femoral vein | 55 | 61 |
| Total number of catheter days | 1,234 | 1,127 |
| Catheters with parenteral nutrition | 26 | 24 |
| Catheters with systemic antibiotic therapy | 107 | 109 |
| Catheter colonization | 29 | 13 |
| Catheter-related bloodstream infections | 4 | 3 |

**Table 2** Characteristics of catheter colonization

| Characteristics of catheters | Heparin-coated | Chlorhexidine and silver-sulfadiazine |
|---|---|---|
| Number of catheters | 29 | 13 |
| Median insertion days | 9.5 | 9 |
| Catheters with parenteral nutrition | 7 | 6 |
| Catheters with systemic antibiotic therapy | 26 | 12 |
| Catheters with mechanical ventilation | 29 | 13 |

**Table 3** Microorganisms of catheter colonization and catheter-related bloodstream infection

| Microorganisms | Heparin-coated[a] (*n*=132) | Chorhexidine and silver-sulfadiazine[b] (*n*=128) |
|---|---|---|
| Catheter colonization | 29 | 13 |
| Gram-positive cocci | 23 | 6 |
| *Staphylococcus* coagulase-negative | 16 | 3 |
| *Staphylococcus aureus* | 7 | 1 |
| *Enterococcus faecalis* | 0 | 2 |
| Gram-negative bacilli | 7 | 11 |
| *Acinetobacter baumannii* | 4 | 3 |
| *Pseudomonas aeruginosa* | 0 | 1 |
| *Enterobacter aerogenes* | 0 | 1 |
| *Serratia marcescens* | 0 | 1 |
| *Klebsiella pneumoniae* | 0 | 1 |
| *Escherichia coli* | 0 | 1 |
| *Morganella morganii* | 1 | 0 |
| *Proteus mirabilis* | 2 | 3 |
| Yeasts | 4 | 0 |
| *C.albicans* | 2 | 0 |
| *C. parapsilosis* | 2 | 0 |
| Catheter-related bloodstream infection | 4 | 3 |
| *Staphylococcus aureus* | 2 | 1 |
| *Proteus mirabilis* | 1 | 0 |
| *Pseudomonas aeruginosa* | 0 | 1 |
| *Serratia marcescens* | 0 | 1 |
| *Candida albicans* | 1 | 0 |

[a] 5 catheters polymicrobial.
[b] 4 catheters polymicrobial.

only semiquantitative cultures are performed nearly 15% of the CRBSI could go undetected when the source originates from contaminated catheter hubs [32]. This study showed that there was a significantly lower rate of CC in CSS catheters compared to HC catheters. This decrease was due to a lower colonization by fungi and gram-positive cocci where CNS represented the largest subgroup decrease. However, CSS catheters did not seem to prevent the risk of colonization by gram-negative bacilli when compared with HC catheters. We did not investigate the in vitro antimicrobial activity of CSS against bacteria. Yorganci et al. [33] demonstrated the in vitro efficacy of CSS catheters against gram-positive bacterial adherence and colonization. Sheng et al. [28] found that gram-positive cocci and fungi colonized standard catheters more frequently than CSS catheters. The activity of CSS catheters against gram-negative bacteria is not well known. Yorganci et al. [34] have shown good activity against *K. pneumoniae*, but this data could not be extended to other gram-negative microorganisms.

Our study is underpowered to show a significant difference in CRBSI. The CRBSI in both groups of catheters was low (3.24 vs 2.6 CRBSI per 1,000 catheter-days), therefore the difference in CRBSI between the 2 groups was low. Maki et al. [25] randomized 195 standard catheters and 208 CSS catheters in 158 patients and found a decrease in CRBSI from 7.6 to 1.6 per 1,000 catheter-days, but the patients were less critically ill (median APACHE II score 14) than our patients and these catheters remained in situ for a shorter time (average of 6 days in each group). Hanley et al. [24] comparing the standard cathether with the CSS catheter, also found a decrease in CRBSI in ICU patients, but the prevalence of CRBSI was high. The decrease was from 11.3 to 5.4 per 1,000 catheter-days.

The CSS on the outer surface of the catheter should have protected it from CC and CRBSI by an extraluminal route (the main route of infection for catheters in place less than 10–14 days [12]). A potential limitation of this study is that we did not investigate the source of microorganisms causing CC and CRBSI, although the colonized catheters in both groups had been in situ for a longer period of time than uncolonized catheters. We cannot rule out that this CC could be due to the fact that the antimicrobial effects of CSS catheters wane within several days of placement [33, 35] and not due to the contamination of the hub. The CRBSI in CSS catheters probably occurred via an extraluminal source. Two CRBSI occurred in the first week (*P.aeruginosa* and *S.marcescens*). One of the catheters had a clinical infection at the insertion site and in the case of the other one, only the semiquantitative culture had the criteria CC. The third catheter was in place for a longer period of time (up to 14 days) and the bacteremia was caused by *S.aureus* which colonized the skin.

Another limitation of this study was that we did not use media containing inhibitors to CSS when culturing these catheters. Schmitt et al. [35] demonstrated in an in vitro

study that antiinfective compounds elute from the antiseptic catheter during culturing processes. This effect could give falsely give low or negative culture results. Based on this information we considered in our study the possibility of CRBSI with negative catheter tip or a colony count lower than the definition of CC. For this reason, we revised 14 positive hemocultives in CSS catheters where the relationship with the catheter tip could not be identified.

This study was carried out in critically ill patients with a high risk of infection and there was a low rate of CRBSI, attributed to the adherence to aseptic techniques in insertion and maintenance of CVCs, as has been demonstrated in two recent studies [36, 37]. It is also probable that the use of HC catheters was decisive, as these catheters have demonstrated the prevention of infections [15, 38, 39]. This could be another reason why CSS catheters failed to show a significant reduction of CRBSI.

In relation to the cost-effectiveness and considering an amount of 30.6 €uro for the CSS catheter compared to HC catheter, in the present study the used of CSS catheters does not seem to be cost efficient.

In conclusion, in our study CSS catheters did not decrease CRBS compared to HC catheters, and in this case it is not advisable to use CSS catheters. However, doubt remains about possible clinical repercussions produced by a decrease in CC in CSS catheters. This effect is related to a more efficacious prevention especially of gram positive-cocci and among them CNS. We did not find CRBSI by CNS, but the reduction in bacterial colonization is the basis for preventing CRBSI, and these bacteria are one of the important microorganisms in nosocomial infections [40]. Although the FDA has approved the use of catheters impregnated intraluminally with chlorhexidine, in addition to CSS extraluminal impregnation [41], studies are needed to demonstrate the clear impact of reduction of colonization by gram-positive cocci compared with HC catheters, in similar groups of patients.

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