Vantex Central Venous Catheter with Oligon Material: Results of a Clinical Trial

Introduction

CVCs have been associated with catheter-related bloodstream infection (CRBSI), a serious complication that is costly to treat.[1] To reduce the incidence of CRBSI, CVCs have been developed using materials impregnated with or coated by antimicrobial agents. Ranucci et al. (2003) performed a prospective, randomized clinical trial that evaluated the effectiveness of a new antimicrobial CVC. The findings were published in *Critical Care Medicine*.

Definitions

CVC: Central venous catheter

CFUs: Colony-forming units (found in cultures)

Colonization: cultures of catheter segments resulting in

- Growth of ≥ 15 CFUs by the roll-plate method
- Growth of ≥ 1000 CFUs by the sonication method

CRBSI: (Catheter-related bloodstream infection):

- Cultures of the catheter and peripheral blood samples result in isolation of the same organism
- Patient must also have clinical signs of BSI.[1]

Materials and Methods

Patients

Ten Italian institutions enrolled medical and surgical adults expected to need a CVC for more than three days. Patients were randomly assigned to the test or control group. Patients with systemic infections and those allergic to CVC components were excluded.

CVCs

- Test Group: Vantex Central Venous Catheter with Oligon material (Edwards Lifesciences), a polyurethane CVC that incorporates silver, platinum, and carbon. According to Ranucci et al., "This combination should release silver ions from both the inner and outer device surfaces, limiting the possibility of bacterial colonization on the catheter and the surrounding environment."[1]
- Control Group: Multi-Med Central Venous Catheter (Edwards Lifesciences), a polyurethane CVC treated with the antimicrobial agent benzalkonium chloride.

All CVCs were inserted via new venipunctures under sterile conditions. Insertion sites included the subclavian, internal jugular, and femoral veins. Dressing changes occurred at least every 48 hours. Infusion catheters were changed every 72 hours and after infusion of lipids or blood products.[1]

Cultures

After aseptic removal, CVC tips and subcutaneous segments were placed in sterile containers. All sites used the roll-plate method, and two sites also used sonication. Peripheral blood samples were cultured in patients with clinical signs of BSI. Organisms were identified using standard microbiological methods.

Results

Patient Characteristics

Of 607 enrolled patients, 545 had complete data. There were 308 surgical cases and 237 medical cases. Approximately 85% of all patients were cared for in the ICU. Antibiotic therapy was administered to 28% of control patients and 26% of test patients.

Catheter Colonization

Colonization occurred with 24% of CVCs (82 control and 50 test). The colonization rate was significantly higher for control catheters (Fig. 1).

Colonization Rate Per 1000 Catheter Days
(95% confidence Interval)

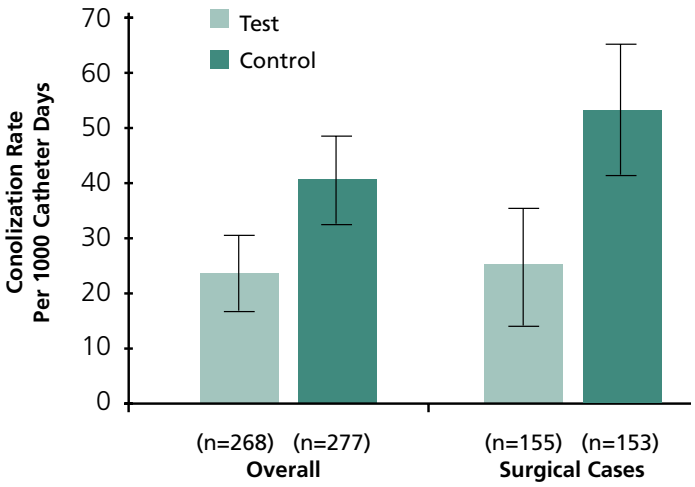

Figure 1

Colonization with coagulase-negative staphylococci and gram-negative bacilli occurred more frequently in the control group than in the test group (Fig. 2).

Overall Catheter Colonization
(By the main organisms responsible for CRBSI)

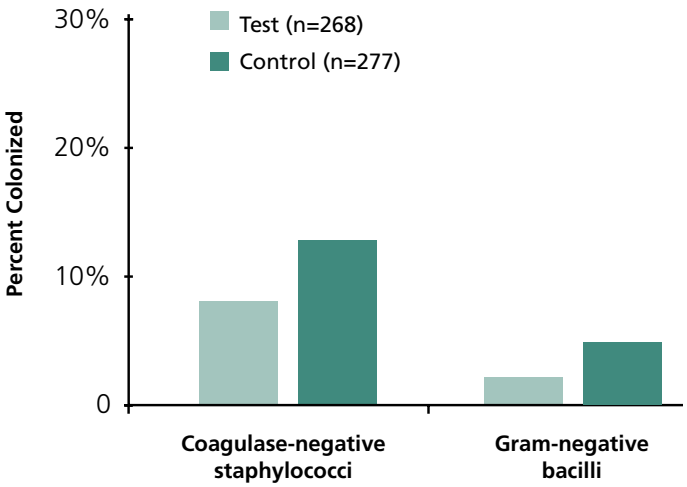

Figure 2

Surgical Subgroup Catheter Colonization
(n=308)

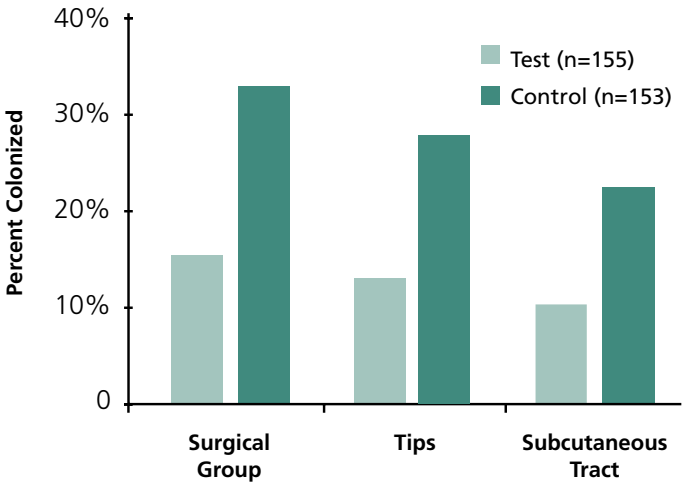

Figure 3

The differences in colonization rates between test and control CVCs were even more significant for surgical patients. In the surgical subgroup, there were 77 colonized catheters (51 control and 26 test). Test catheters had less colonization at the tip and along the subcutaneous segment (Fig. 3).

Ranucci et al. reported a relationship between indwell time and colonization. As indwell time increased, colonization occurred more frequently in the control catheters than in the test catheters.

CRBSI

In this study, 21 patients were found to have CRBSI (see Definitions, page 1). Although there were fewer cases of CRBSI among test patients, the difference was not statistically significant (Fig. 4).

CRBSI by Study Group
(Catheter-Related Blood Stream Infection)

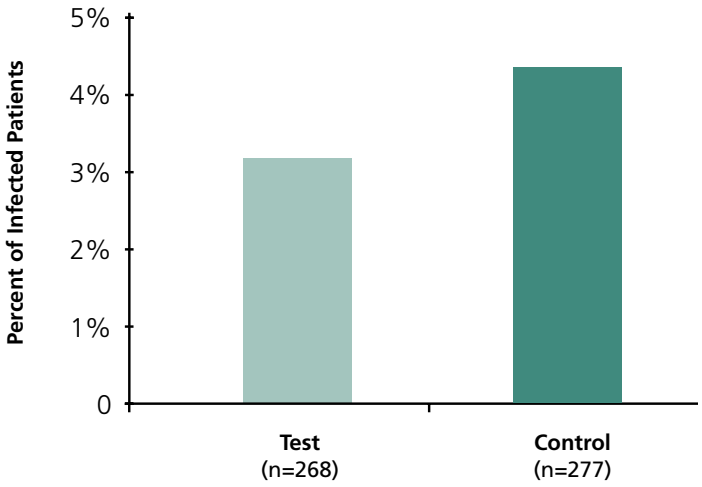

Figure 4

"The catheter colonization rate is, of course, higher than the catheter-related bloodstream infection, the first being a necessary but not sufficient condition for the diagnosis of the second."[1] (p. 56)

Ranucci et al. reported a time-dependent relationship between colonization and CRBSI. The rate increased significantly with increasing indwell time (Table 1).

Indwell time (# of days)	Colonized catheters resulting in CRBSI (%)
< 5 days	0 %
6 to 10 days	15 %
11 to 15 days	19 %
> 15 days	37 %

Table 1. CRBSI Rates Over Time

Discussion and Conclusion

Ranucci et al. reported that Oligon material catheters significantly reduced colonization with coagulase-negative staphylococci and gram-negative bacilli. In surgical patients, there was a 16% reduction in colonization (relative risk of 0.5 – a decrease of 50%).

The authors indicated they did not enroll a sufficient number of patients to detect significant differences in CRBSI rates between groups. Analysis showed that 1,500 surgical patients would have been needed to detect differences between the test and control groups.

They also developed a multivariate model to identify risk factors for colonization and CRBSI. Risk factors included indwell time, tracheostomy, operation time, ICU stay, and antibiotic therapy. They recommended that preventive strategies be utilized to decrease colonization and CRBSI (e.g., maximal sterile barriers, effective antimicrobial agents, antiseptic hubs, subcutaneous silver cuffs, and chlorhexidine and benzalkonium skin preparation).

According to Ranucci et al., "Our results indicate that Oligon™-treated catheters significantly reduce the catheter colonization rate by about 11%, with a relative risk decrease of 37%."[1] (p. 57)

References
1. Ranucci M, Isgro G, Giomarelli PP, et al. Impact of Oligon™ central venous catheters on catheter colonization and catheter-related bloodstream infection. Crit Care Med. Jan 2003;31(1):52-59.
2. Mermel LA, Farr BM, Sherertz RJ, et al. Guidelines for the management of intravascular catheter-related infections. J Intraven Nurs. 2001;24(3):180-205.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information.

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