

Preventing central venous catheter-associated bloodstream infections: Development of an antiseptic barrier cap for needleless connectors

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Background: Reports of outbreaks associated with the use of needle-free valve connectors suggest 2 common risk factors: (1) poor adherence to disinfection practices before use and (2) a design that allows contamination when not in use. Swabbing a membranous septum with 70% isopropyl alcohol may not eliminate septal surface contamination. Frequent access through and handling of needle-free connectors also puts patients at increased risk of central venous catheter-related bloodstream infections (CR-BSIs). A novel antiseptic barrier cap has been designed to maintain health care worker safety and eliminate the vulnerabilities of existing systems to contamination and CR-BSIs for patients at risk.

Methods: A prospective in vitro study compared the effectiveness of standard disinfection of needleless luer-activated valve connectors with 70% isopropyl alcohol and the effectiveness of an antiseptic barrier cap that, when threaded onto a luer-activated connector, rapidly sterilizes a heavily contaminated surface. Standard disinfection was done by 3- to 5-second swabbing using a sterile commercial pledget of 70% isopropyl alcohol. The antiseptic barrier cap comprises an outer cap with internal female threads and a spike inside the closed end, a capsule containing 0.25 mL of 2% chlorhexidine gluconate in 70% isopropyl alcohol, and a sponge between the septum and the capsule. When the cap is threaded onto a luer-adaptable needleless connector, the spike ruptures the capsule, saturating the sponge with the antiseptic.

Results: All 15 (100%) of the precontaminated positive control connectors not disinfected before entry showed transmission of *Enterococcus faecalis* across the membranous septum (4500-28,000 colony-forming units), and 20 (67%) of 30 connectors disinfected with 70% alcohol showed transmission (442-25,000 colony-forming units). Of 60 needle-free connectors disinfected with the antiseptic barrier cap, 1 (1.6%) showed transmission ($P < .001$).

Conclusion: An antiseptic barrier cap was highly effective in sterilizing the septum of a needle-free valve connector and preventing entry of any microorganisms, even with heavy contamination of the septum. This new technology should now be evaluated in a clinical trial with CR-BSI as the primary outcome measure. (Am J Infect Control 2008;36:S174.e1-S174.e5.)

Central venous catheters (CVCs) and needle-free systems are often used to provide treatment for oncology, immunocompromised, and other high-risk patients. Several factors make needle-free valve connectors vulnerable to contamination and increase the risk of developing CVC-related bloodstream infection (CR-BSI), including inconsistent disinfection practices,

recontamination following use, and the needleless valve's septal surface as the only barrier between the bloodstream and outside contaminants.

The results of bloodstream contamination can be tragic. In 1993 during treatment, a 4-year-old oncology patient struggled daily with appetite and weight loss, sores in her mouth, vomiting, hair loss, fear, and sadness. A year later, she was in full remission but died 3 months later from an unexpected CR-BSI. Because of the unusually rapid rate of bacterial progression, blood cultures were obtained to identify the source of the BSI. Organisms cultured from the needleless port, the intraluminal tract, and the bloodstream matched.

The oncologist had just attended a conference on CR-BSIs associated with needle-free system use and suggested that the point of entry for the pathogen might have been the septal surface of the needle-free port. If not disinfected properly, septal-surface contaminants would be forced into the patient's bloodstream. If the patient were immunocompromised, only a small amount of bacteria would trigger a BSI. This experience prompted determined efforts to provide a better safety system to protect the most vulnerable, such as

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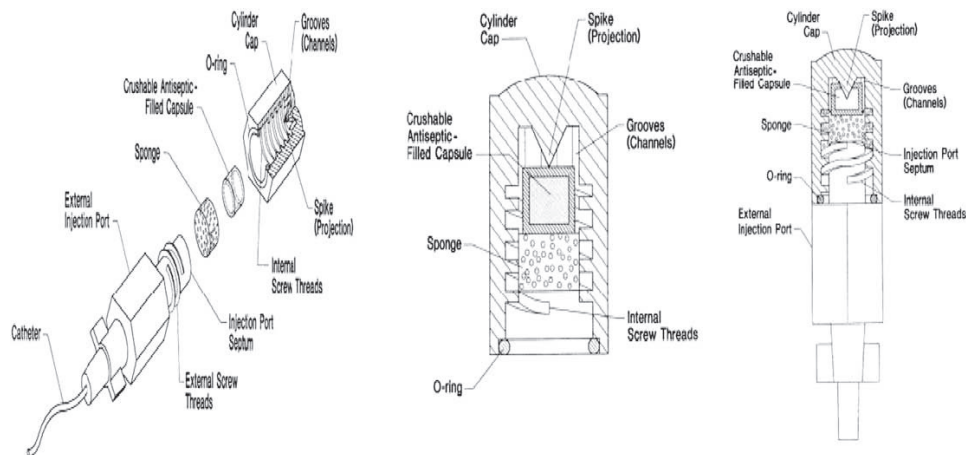


Fig 1. Schematic of the “Saralex-cl” antiseptic-barrier cap, including the needle-free port. When the cap is affixed to the membranous septal surface of the needleless connector (external injection port), the spike ruptures the antiseptic-filled capsule and the sponge becomes saturated with chlorhexidine and maintains continuous contact with the entire membranous injection-port septal surface.

pediatric, oncology, intensive care unit, HIV, home care, and all immunocompromised patients.¹

BACKGROUND

Needle-free valve connectors were developed to decrease the risk of needlestick injuries to the health care workers.²⁻⁴ Outbreaks associated with the use of needleless valve connectors continued to be reported, and contamination of the needle-free valve connector has been associated with a greatly increased risk of CR-BSI.⁵⁻¹⁵ These reports have identified 2 common risk factors: (1) poor adherence to disinfection practices before use and (2) a design that allows contamination when not in use.⁵⁻¹⁵

The septal surface of the valve of needle-free valve connectors is not flush with the connector. A noticeable gap and ingress exist between the septal valve and the rim of the connector, creating vulnerability in 2 ways. First, if the septal surface is not properly disinfected before use, septal-surface contaminants will be forced into the intraluminal fluid pathway and bloodstream. Second, the septal gap ingress (internal chamber), once contaminated, is impossible to disinfect. Both vulnerabilities can lead to fluid pathway contamination and potential BSIs.

The goal was to design needleless valve connectors that would eliminate the vulnerabilities and protect the septal surface from contamination. Research over a 10-year period led to the development of the Saralex-cl antiseptic barrier cap (Saralex-cl; Menyhay Healthcare Systems, Fresno, CA) for needleless valve connectors,

which is specifically designed to protect the patient by preventing septal and intraluminal contamination.¹

Vulnerabilities of needle-free valve connector systems

An in vitro study of needle-free valve connector systems was conducted in 2006 by Menyhay and Maki.¹ The study showed the vulnerabilities of needle-free valve connector systems used throughout the health care industry.¹

In most medical centers in the United States, needleless valve connectors are disinfected by swabbing the membranous septum with 70% isopropyl alcohol; however, this technique may not eliminate septal surface contamination.¹⁶⁻²¹ Frequent access through and handling of needleless connectors put patients at increased risk of CVC-related primary BSIs.^{5,7-9,18}

The Saralex-cl antiseptic barrier cap

A prospective in vitro study of the effectiveness of standard disinfection of needle-free, luer-activated valve connectors with 70% alcohol, compared with the effectiveness of the antiseptic barrier cap “Saralex-cl” that, when threaded onto a luer-activated connector, rapidly sterilizes a heavily contaminated surface was conducted.¹

METHODS

The antiseptic barrier cap consists of 3 parts: an outer cap with internal female threads and a spike

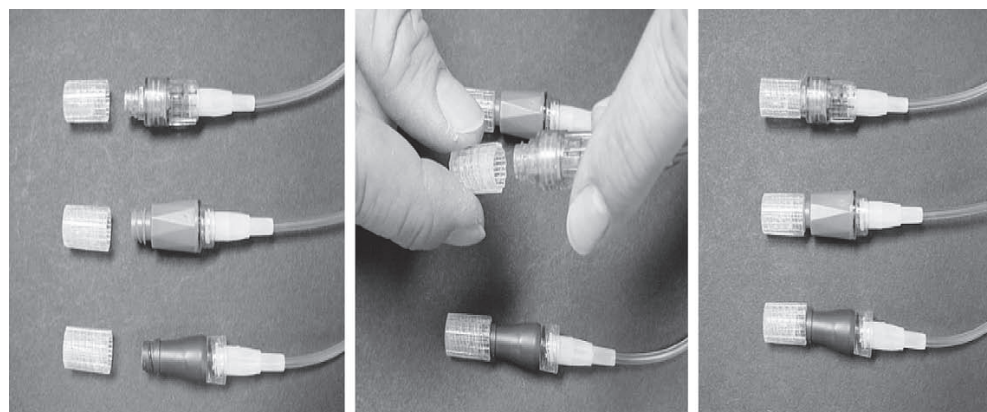


Fig 2. The Saralex-cl antiseptic-barrier cap affixed to needleless valve connectors from 3 manufacturers.

Table 1. Results of an in vitro study comparing the efficacy of conventional disinfection of heavily precontaminated commercial needleless connectors with the efficacy of the Saralex-cl antiseptic barrier cap

Variable	No disinfection	Disinfection with 70% alcohol	Disinfection with Saralex-cl antiseptic barrier cap
No. connectors showing microbial transmission across the membrane/ total No. of connectors studied (%)	15/15 (100)	20/30 (67)	1/60 (1.6)
Approximate No. of colony-forming units traversing the membrane	4500-28,000	442-25,000	0-350

inside the closed end, a capsule containing 0.25 mL 2% chlorhexidine gluconate in 70% isopropyl alcohol, and a sponge between the septum and the capsule (Fig 1). When the cap is threaded onto a luer-adaptable, needle-free connector, the spike ruptures the capsule, saturating the sponge with antiseptic. When the cap is tightened, the antiseptic-impregnated sponge is brought into continuous contact with the membranous septal surface of the needle-free connector until the cap is removed (Figs 1 and 2). After removal of the cap, there is no need to disinfect the membranous septal surface before access. After removal of the male needle-free connector, the antiseptic cap can be reattached to the needle-free connector.

Study design

Needle-free, luer-activated valve connectors from 3 manufacturers (Clearlink [Baxter Healthcare, Deerfield, IL], PosiFlow [Becton-Dickinson, Franklin Lakes, NJ], and Micro CLAVE [ICU Medical, San Clemente, CA]) were studied. All of the connectors have a membranous septal surface that is designed to be accessed by a blunt luer-lock male connector.

Thirty-six connectors from each manufacturer were tested concurrently in the trial. One device of

each type was used as a negative control (ie, accessed without precontamination). The remaining 35 devices from each manufacturer were precontaminated by immersing the membranous septal surface in a suspension of *Enterococcus faecalis* containing $>10^8$ colony-forming units (cfu)/mL, after which the septum was allowed to dry in a protected aseptic container for 24 hours (final inoculum on the septum, approximately 105 cfu).

Negative controls

One noncontaminated device taken directly from its protective package was not disinfected. The membrane was entered 5 times before being flushed with the broth and then collected for culture.

Positive controls

Five precontaminated connectors of each type were removed from the protective containers, dried overnight, accessed with a sterile syringe containing 3 mL of sterile trypticase soy broth (BBL; Becton Dickinson) and flushed with the broth. The injected broth was collected on the downstream side of the intraluminal fluid pathway in a sterile container, and the number of

organisms traversing the septum was counted by quantitative culture.

Conventional disinfection with 70% alcohol

Ten precontaminated connectors from each manufacturer were disinfected with a vigorous 3- to 5-second swabbing, using a sterile commercial pledget of 70% isopropyl alcohol. A fresh pledget was used for each device tested. After disinfection, the connectors were accessed as described above, and the broth was collected on the intraluminal downstream side and cultured quantitatively.

Antiseptic barrier cap

Twenty precontaminated needleless connectors from each manufacturer had the antiseptic cap threaded onto the hub and left in place for 10 minutes. The cap was then removed; and, after the septum was allowed to dry, the hub was accessed and flushed as previously described above, and the broth was captured and cultured.

RESULTS

All 15 (100%) of the precontaminated positive control connectors that were not disinfected before entry showed transmission of *E. faecalis* across the membranous septum (4,500-28,000 cfu) (Table 1). Of the 30 connectors that were disinfected with 70% alcohol, 20 (67%) showed transmission of *E. faecalis* (442-25,000 cfu). In contrast, of 60 precontaminated connectors entered after application of an antiseptic barrier cap for 10 minutes, only 1 (1.6%) showed any transmission of *E. faecalis* ($P < .001$). None of the 3 negative control connectors showed any transmission of microorganisms. The results were very similar for connectors from each of the 3 manufacturers (data not shown).

DISCUSSION

In a growing number of BSI outbreaks, CVC needle-free valve connectors appear to have become extrinsically contaminated by microorganisms that traversed the septal membrane to colonize the internal valve structure of the connector.⁵⁻⁹ A growing body of evidence suggests that there are increased rates of intravenous device-BSIs that appear to be related to the contamination of the needleless valve during use.¹⁰⁻¹⁵

Our findings suggest that, if the septum of the needleless valve connector is heavily contaminated, conventional disinfection with 70% alcohol does not reliably prevent entry of microorganisms, which can multiply in the connector's intraluminal fluid column or colonize the internal surface of the valved device.

Either instance creates a high risk of a patient's developing intravenous device-related BSIs. The findings show that disinfecting the septum of the needleless connector is clearly beneficial; however, outcome studies that evaluate the effect of different protocols on rates of CVC-related BSIs are needed to determine the regimens most effective in preventing microbial transmission.

In summary, a prospective in vitro study showed that the innovative Saralex-cl antiseptic barrier cap was highly effective in sterilizing the septum of a needle-free connector and preventing entry of any microorganisms, even with heavy contamination of the septum. The Saralex-cl antiseptic barrier cap should now be evaluated in a clinical trial with catheter-related BSIs as the primary outcome measure.

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