

Efficacy of three different valve systems of needle-free closed connectors in avoiding access of microorganisms to endovascular catheters after incorrect handling*

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Objective: Disinfectable needle-free closed connectors were designed to avoid needle-stick injuries and to be easily disinfected before handling. Workloads or lack of knowledge, however, could impede the correct handling of these devices, allowing endoluminal catheter colonization. The aim of our study was to assess the barrier effect of different disinfectable needle-free closed connectors during correct and incorrect handling using an experimental model.

Design: We used a model consisting of a blood culture bottle with a peripheral venous catheter inserted under sterile conditions. Three different disinfectable needle-free closed connectors with different valve designs (microClave, Bionector, and Smartsite plus) were used to close the catheters. The external surfaces of the disinfectable needle-free closed connectors were contaminated with different concentrations of a *Staphylococcus epidermidis* culture broth. After contamination, 10 units of each con-

ector and each concentration were assigned to the correct handling group (cleaned with 70% ethylic alcohol before handling) and the same number to the incorrect handling group (handled without disinfection) with a total of 180 bottles.

Results: Increases in concentrations of external contamination and incorrect handling of the connectors resulted in an increase in connectors' permeability to the pass of microorganisms to the endoluminal way. MicroClave proved the best barrier in the experimental conditions described.

Conclusion: The barrier effect of disinfectable needle-free closed connectors is adversely affected by incorrect handling, the quantity of external valve colonization, and the valve design. (Crit Care Med 2008; 36:2558–2561)

KEY WORDS: needle-less connector; catheter infection; disinfectable connector; nosocomial infection; catheter colonization; prophylaxis

In 1992, the United States Food and Drug Administration required the adoption of safe needle-free devices by healthcare services to prevent exposure to blood-borne pathogens via nee-

dle-stick injuries (1). To avoid them, several systems of disinfectable needleless closed connectors (DNCC) were developed and included in daily practice. Knowing that hubs can be a focus on colonization of endovascular catheters (2–4), DNCC were designed to allow the external surface to be easily cleaned. Manufacturers recommended swabbing them with a dressing soaked in antiseptic before handling (iodine, 70° alcohol or chlorhexidine), the same procedure followed before subcutaneous injections. Clearly, one of the limitations of DNCC could be related to noncompliance of this recommendation. Swabbing the external surface of the connector's valve with gauze, impregnated in antiseptic, is an easy procedure but workloads or ignorance could impede the correct handling of these devices.

DNCC designs have evolved with time. First generation connectors were designed as a split septum that could be accessed with a blunt canula (Interlink, Baxter Health Care Corporation, Deerfield, IL). Despite the resulting decrease in needle-stick injuries (5), occasional increases of catheter-related infection rates were observed related to nurses' unfamiliarity with

the procedure and noncompliance of the manufacturers' recommendations regarding care practices (6, 7). Furthermore, the removal of the cannulae was associated with negative pressure allowing retrograde flow. New designs replaced the split septum connectors with closed valve systems that could be accessed by any male luer connection. The latest designs include passive positive-pressure systems that act when the luer connection is removed to avoid retrograde flow or blood clotting in the catheter. Despite reports under experimental conditions (8–10) and in clinical trials (11, 12) of the barrier effect of some of these valve connectors, increases in catheter-related bloodstream infection (CRBI) rates have been related to changes of the model of DNCC used (13). The aim of our study, which uses an experimental laboratory model, is to analyze to what extent incorrect handling affects permeability of these devices and whether differences in DNCC design can minimize the negative effect of bad handling.

MATERIALS AND METHODS

An experimental model was designed to compare the barrier effect of three DNCC of

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Figure 1. Disinfectable needle-free closed connectors are based in a valve system that seal the endoluminal way. If they are not disinfected before handling, they could allow the passing of microorganisms from the external surfaces. In some devices, inside the valve exists a fixed cylinder that enters in the infusion set (or syringe) when it presses the valve, theoretically avoiding contact with external surfaces. In this figure, we can observe the evaluated disinfectable needle-free closed connectors showing the differences of the valve designs (From top to bottom: Smart-sitePlus [Alaris Medical Systems, San Diego, CA], with an elastic silicone embolus designed to generate a passive positive pressure when returns from the wide part of the connector to the narrow; Bionector [Vygon, Valley Forge, PA], whose valve is a cylinder made from latex that allows access to an endoluminal metallic cylinder; and MicroClave [ICU Medical Inc, San Clemente, CA], with an elastic silicone embolus that allows access to a permeable cone with lateral holes that enters in the male luer system).

different design. Every unit of the experimental model consisted of a bottle of aerobic blood culture (Bact/alert, Bionerieux Inc, Durham, NC) into which an 18G peripheral venous catheter (Venflon) was inserted, following strict methods of sterility. We used DNCC from three different manufacturers to close the catheters (DNCC1 MicroClave, ICU Medical Inc, San Clemente, CA; DNCC2 Bionector, Vygon, Valley Forge, PA; DNCC3 Smartsite Plus, Alris Medical Systems, San Diego, CA)



Figure 2. The experimental model consisted of a bottle of aerobic blood culture (Bact/alert, Bionerieux Inc, Durham, NC) into which an 18G peripheral venous catheter (Venflon) was inserted. We used disinfectable needle-free closed connectors from three different manufacturers to close the catheters.

(Fig. 1). The DNCCs were composed of a rigid body, with a valve system, that becomes permeable when compressed by any luer-type connector. In all DNCC, the valve returns to its previous position when the syringe or the infusion equipment is removed, the system being hermetically sealed to the exterior without the need of a cap. Differences between DNCC mainly involve valve design (Fig. 2). The microClave valve is an elastic silicone embolus that allows access to a permeable cone, which enters in the male luer system when the valve is compressed. The Bionector valve is a cylinder made from latex that allows access to an endoluminal metallic cylinder. The Smartsite valve is an elastic silicone embolus that opens the fluid path when compressed. SmartsitePlus is a development of Smartsite designed to generate a passive positive pressure when the luer connection is removed to avoid retrograde flow and blood clotting in the catheter.

We used 60 units in each DNCC group. Because there is no evidence about the amount of colony-forming unit (CFU) that can colonize the external surfaces of DNCC in clinical practice, each group was divided into three subgroups of 20 models the external surfaces of which were contaminated with 25 lambdas (0.025 mL) of *Staphylococcus epidermidis* culture broth at different concentrations, (concentration A, 100 CFU/mL; concentration B, 500 CFU/mL; and concentration C, 1000 CFU/mL). Inoculum was selected based on the number of microorganisms that colo-

nize the dry region of the skin of patients and healthcare workers, which contains about 1000 CFU/cm², mainly of Gram-positive cocci (14). Ten units of each subgroup were included in a “correct handling group” (connectors were cleaned with 70% ethylic alcohol before handling) and 10 models to an “incorrect handling group” (handled without disinfection), with a total of 180 models. Eight hours after contamination, the external surfaces of the connectors were cleaned by swabbing with a dressing soaked in 70° alcohol in the correct handling group, or not cleaned in the incorrect handling group, and 1 mL of saline solution was infused. This procedure was repeated three times in 24 hrs. Then, the catheters were removed and, to avoid external contamination, the bottles were directly incubated in the Bact/alert system for 5 days or until positive. Bact/alert automatically monitors bacterial growth using a colorimetric system. A sensor inserted in the bottom of the bottle changes color on detecting the CO₂ produced by the growth of the bacteria. Once positive, the liquid in the bottle is examined to identify the microorganism. At the end of the study, the sterility of the liquid in the negative bottles was tested. The chi-square test was used to compare rates of positivity between groups.

This experimental design does not include human subjects and do not use human tissue or samples, so it was exempt from approval of the local ethics committee.

RESULTS

The barrier effect of all DNCCs, when they were cleaned before handling, maintained the sterility of all the models when they were tested with broth culture at 100 CFU/mL and 500 CFU/mL concentrations. When concentrations were increased to 1000 CFU/mL, however, only microClave connectors maintained 100% sterility, although Bionector and SmartsitePlus showed a decrease in the barrier effect, bottle sterility being maintaining in only 80% and 70% of the models, respectively. When DNCC were handled without previous disinfection, 100% sterility of models sealed with microClave was maintained after three handlings in group A (100 CFU/mL), in group B (500 CFU/mL), and 50% in group C (1000 CFU/mL). Although Bionector and Smartsite plus maintained model sterility in group A, the barrier effect was impaired with the increase in contamination of the external inoculum sterility being reduced to 80% and 40%, respectively, at group B concentrations and 20% and 10%, respectively, at group C concentrations. Analyzing the

complete range of models, incorrect handling of the DNCC resulted in a reduction of 94.4%–66.7% of sterile bottles, $p < 0.001$.

Statistically significant differences between connectors were also observed on comparing sterility for all conditions of contamination and handling (91% of sterility in microClave group, 80% in Bionector, and 70% in Smartsite Plus, $p = 0.011$).

The concentration of the contaminating inoculum was also clearly related to the level of barrier effect of the DNCC. The increase in concentration was related to a reduction in the proportion of sterile bottles (100% of sterility after DNCC were contaminated with concentration A, 87% with concentration B and 55% with concentration C, $p < 0.001$).

DISCUSSION

The results of the present study reveal some differences between the permeability of the DNCC evaluated. Two factors are involved in their barrier efficacy, valve design and correct handling. Furthermore, if we analyze every connector independently, we can observe that the bacterial permeability of the DNCC is also related to the extent of external colonization. Higher degrees of external contamination were related to higher rates of permeability for all connectors. However, caution must be used before extrapolating these findings from laboratory to clinical practice, our results emphasize the relevance of incorrect handling to avoid undesirable effects and suggest that each DNCC could be associated with varying rates of CRBI in clinical practice.

Earlier studies suggested that DNCC can resist some degree of external colonization without increasing the risk of CRBI. Casey et al. (15) analyzed the best antiseptic to disinfect the PosiFlow DNCC and observed some residual colonization of external valve surfaces, even after correct disinfection of the DNCC (30.8% of residual contamination after chlorhexidine alcohol, 69% after alcohol, and 41.6% after iodine povidone). Despite this residual colonization, however, they observed greater endoluminal protection with DNCC than with conventional caps. Only 6.6% of hubs, protected with DNCC, were colonized when compared with 18% of hubs closed with caps ($p < 0.0001$). Using another DNCC in clinical practice, Seymour et al. (16) observed 9% of iso-

Table 1. Sterility of experimental models after infusion of 1 mL of saline every 8 hrs through disinfectable needle-free closed connectors (DNCC) previously contaminated with different concentrations of broth and handled after manufacturers' recommendations or without disinfection, expressed in number of sterile bottles/total number of bottles (%)

	100 CFU/mL	500 CFU/mL	1000 CFU/mL	Total
Correct handling (%)				
MicroClave	10/10 (100)	10/10 (100)	10/10 (100)	30/30 (100)
Bionector	10/10 (100)	10/10 (100)	8/10 (80)	28/30 (93.3)
Smartsite Plus	10/10 (100)	10/10 (100)	7/10 (70)	27/30 (90)
DNCC correctly handled	30/30 (100)	30/30 (100)	25/30 (83.3)	85/90 (94.4)
Incorrect handling (%)				
MicroClave	10/10 (100)	10/10 (100)	5/10 (50)	25/30 (83.3)
Bionector	10/10 (100)	8/10 (80)	2/10 (20)	20/30 (66.7)
Smartsite Plus	10/10 (100)	4/10 (40)	1/10 (10)	15/30 (50)
DNCC incorrectly handled	30/30 (100)	22/30 (73.3)	8/30 (26.6)	60/90 (66.7)
All handling (%)				
MicroClave	20/20 (100)	20/20 (100)	15/20 (75)	55/60 (86.6)
Bionector	20/20 (100)	18/20 (90)	10/20 (50)	48/60 (80)
Smartsite Plus	20/20 (100)	14/20 (70)	8/20 (40)	42/60 (70)
DNCC after all handling	60/60 (100)	52/60 (86.6)	33/60 (55)	145/180 (80.5)

Differences between correct and incorrect handling: 94.4% vs. 66.7% ($p < 0.001$).

Differences between DNCC after all handling: 86.6% vs. 80.0% vs. 70% ($p = 0.011$).

Differences between different bacterial load after all handling: 100% vs. 86.6% vs. 55% ($p < 0.001$), CFU, colony-forming units.

lations of microorganisms in the Clave Connector after disinfection, but not that it resulted in an increase of CRBI. The protective effect of other DNCC (Smartsite and Bionector) with respect to conventional caps was also described under experimental conditions with ideal handling (9, 10).

The usefulness of DNCC in the prevention of CRBI with respect to conventional caps has also been reported in prospective clinical trials, where handling might not always have been preceded by disinfection. Yébenes et al. (11) reported 0.7 CRBI/1000 risk days using Smartsite, with a 84% reduction of CRBI, with respect to conventional open systems in central venous catheter in critically ill patients ($p = 0.034$), and Bouza et al. (12) using Clave Connector, observed a reduction in the rate of catheter colonization in a nonselected population of catheters from a postcardiac surgical intensive care unit (12).

The clinical impact of the varying permeability observed in the DNCC has been analyzed recently. In a retrospective analysis of critically ill patients, Maragakis et al. (13) observed an increase in CRBI rates after the change of DNCC from Clave Connector to SmartsitePlus. Although CRBI rates were below Centers for Disease Control benchmarks (17) in both cohorts, differences were statistically significant and could reflect the role

of the connector design on the effectiveness of CRBI prevention. In the present study, after exposing several DNCC to similar external bacterial contamination, we observed a higher resistance to the pass of microorganisms when the DNCC included a second barrier method (Table 1). The connector with the best results was microClave, the valve design of which includes a double access system (a silicon valve that allows access to an endoluminal blunt cone that enters the male luer lumen). The protection of the blunt cone by the silicon valve probably provides better isolation from external surfaces than the metal-latex interaction in the Bionector, allowing total isolation of the endoluminal way even without disinfection after contamination with a broth culture of 500 CFU/mL. The absence of a second endoluminal-protected access in Smartsite Plus could explain its higher permeability with respect to microClave. Results with Bionector were mid-range, possible because of the design of the protection system of the endoluminal access of the connector.

In conclusion, the barrier effect of DNCC is adversely affected by increasing concentration of bacterial external valve contamination. Disinfecting the DNCC before handling reduces the external bacterial colonization and improves the barrier effect of the DNCC. Of the connectors evaluated,

the microClave design provided the best protection in these experimental conditions.

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