CARESITE® Luer Access Device (LAD): 7- Day Microbial Barrier Performance

Abstract

Numerous factors may contribute to the risk of bloodstream infections including design of the connection surface, internal mechanism of the device, extreme variations in healthcare worker's techniques for cleaning the device, and lack of sterility of intravenous (I.V.) administration sets used intermittently for extended periods of time.[9-11] No study has identified one factor as more important than the others in creating the risk for bloodstream infections. Following the recommendation for microbial ingress testing from the United States Food and Drug Administration (FDA) guidance, twenty-four (24) test samples of CARESITE, along with positive and negative controls were studied. This study demonstrates over the course of seven (7) days that the CARESITE LAD prevents passage of tested organisms through the needleless connector following thorough, well-defined cleaning before each use.

Background

Needleless connectors have enhanced the safety of healthcare workers by eliminating the use of needles for making numerous connections between intravenous administration sets, syringes, and the catheter hub. The BloodBorne Pathogens Standard from the Occupational Safety and Health Administration mandates the use of needleless devices and needle devices with built-in safety features.[1] While they have reduced needlestick injuries, the increasing use of needless devices has generated concern about the patient's risk of bloodstream infections.[2-8]

CARESITE is a needleless connector with a split-septum plunger surrounded by the external housing that includes a luer-locking mechanism. Fluid flows through the opening in the center of the split septum, then around the collapsible center plunger.

An independent laboratory tested the CARESITE LAD to quantify the risk of transfer of organisms through the device.

Methods

Following the recommendation for microbial ingress testing from the United States Food and Drug Administration (FDA) guidance, twenty-four (24) test samples of CARESITE, along with positive and negative controls, were studied. All needleless connector samples were twice sterilized using ethylene oxide prior to testing.

The CARESITE test devices and the positive control devices were challenged with four (4) species of organisms including *Staphylococcus aureus*, *Staphylococcus epidermidis, Pseudomonas aeruginosa, Escherichia coli.* All species were supplied by ATCC, a major provider of microorganisms for scientific testing purposes. All species were prepared using the same process. To ensure adequate viability of the organism, fresh solution was prepared daily using the same procedure. The challenge organism was incubated for 18-24 hours at 30-35 degrees C. The organism was harvested from the agar surface using sterile saline and sterile cotton swabs. The suspended organism was washed using centrifugation at 20 to 25 degrees C for no longer than 10 minutes. The organism pellet was suspended in fresh sterile saline, washed a second time, and then suspended again in fresh sterile saline. The concentration of the challenge organism was measured spectrophotometrically and diluted to yield a final concentration of 10^5 (100,000) to 10^6 (1,000,000) colony forming units per milliliter (CFU/mL) of solution.
The inlet or connection surface of the 24 test devices were inoculated with 0.01 mL of the challenge organism solution and allowed to set for 60 seconds. After inoculation and the set period, the connection surface was cleaned with a new 70% isopropyl alcohol pad using a twisting action clockwise and counterclockwise for 15 to 20 seconds. Care was taken to avoid depressing the internal piston while adequately cleaning the surface. The alcohol pad was discarded and the connection surface was allowed to dry for 30 to 60 seconds.

This cleaning procedure was performed and followed with a sterile empty syringe being connected, disconnected and discarded for each test interval Hour-0, Hour-1, Hour-2, and Hour-3. At hour-3, a sterile syringe filled with 10 mL of soybean casein digest broth (SCDB) was attached and the media flushed through each LAD and collected in a sterile test tube. This fluid was then filtered through a sterile apparatus using a 0.45-micron filter and the filter flushed with 100 mL of sterile fluid. This fluid was then plated on a soybean casein digest agar (SCBA). All agar plates were incubated at 30-35 degrees C for 2 to 3 days when colony counts were taken. After being flushed with the SCBD at hour-3, the LAD was flushed with two sterile syringes both filled with 5 mL sterile saline.

Table 1 – Testing Procedure (repeated for 7 days)

Hour	Action
Hour 0	Clean connection surface of LAD Allow to air dry 30-60 sec Inoculated LAD connection surface Allow to set for 60 sec Clean connection surface of LAD Allow to air dry 30-60 sec Attach and detach empty sterile syringe
Hour 1	Clean connection surface of LAD Allow to air dry 30-60 sec Attach and detach empty sterile syringe
Hour 2	Clean connection surface of LAD Allow to air dry 30-60 sec Attach and detach empty sterile syringe
Hour 3	Clean connection surface of LAD Allow to air dry 30-60 sec Attach SCDB-filled syringe and flush through the LAD into a test tube Disconnect empty syringe Attach a saline filled syringe and flush with 5 mL saline. Disconnect syringe Attach a second saline filled syringe and flush with 5 mL saline

The positive controls were run concurrently with the test samples in each cohort. Three LADs were inoculated each day using the same solution and process described above. No cleaning was performed on these devices. The SCDB-filled syringe was attached and flushed through the device, however one (1) mL of the solution was filtered to obtain a countable range of organisms.

The negative controls were also run concurrently with the test and positive controls. These devices did not receive the inoculum step. At hour-3, the final SCDB flush solution was collected in the same manner as the test devices.

This procedure was repeated in the same manner for seven (7) days.

Results

Table 2 lists the results of the tested CARESITE LAD for all seven (7) days. Devices growing greater than 15 colony forming units (cfu) are reported as this is a primary criterion for diagnosing catheter colonization.[12] Each CARESITE device met these criteria for all bacteria challenges over the seven (7)-day test period.

Table 2 – Test Results for CARESITE cohort

Devices growing greater than 15 cfu							
Organism	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**
Staphylococcus aureaus	0	0	0	0	0	0	0
Staphylococcus epidermidis	0	0	0	0	0	0	0
Pseudomonas aeruginosa	0	0	0	0	0	0	0
Escherichia coli	0	0	0	0	0	0	0

The positive control devices, those inoculated but not cleaned, produced colony counts ranging from 1.1×10^2 to 2.0×10^3 for staphylococcus aureus. The positive controls for all other organisms were consistently less than 1×10^3 cfu per device although the applied organisms were well above this level. The negative control devices, those that did not receive the inoculation, showed no growth.

Conclusion

This study demonstrates that the CARESITE LAD prevents passage of tested organisms through the needleless connector following thorough, well-defined cleaning before each use over the course of a seven (7)-day simulated access protocol.

Discussion

Introduction of organisms is possible with each manipulation of the catheter hub including administration of fluids and medications, changing I.V. administration sets and needleless connectors, flushing catheters to assess functionality and reduce lumen occlusion, and drawing blood samples. These procedures can result in excessive numbers of catheter lumen and hub manipulations, with some procedures requiring multiple connections and disconnections to the needleless connector.

The cleaning and disinfection methods performed in this study are the manufacturer's recommendation for best practice to ensure proper surface maintenance of the luer access device. Detailed evidence-based procedures for cleaning luer connection surfaces have not been established as industry standards. The details of such a procedure should include the best agent to use, the length of cleaning time, the cleaning technique, and the length of drying time.

It is important that hospitals emphasize the need for aseptic technique when performing these luer connection hub manipulations. One survey of the critical care units in 10 US hospitals found that 80% addressed hand hygiene in the policy and procedures for catheter insertion, however only 36% included the same hand hygiene requirements in policies and procedures for accessing the catheter.[13] One small in vitro study demonstrated that a 15-second scrub with either isopropyl alcohol or a combination of chlorhexidine gluconate and isopropyl alcohol was sufficient to clean the surfaces of many needleless connectors. While this length of time may seem difficult to enforce in clinical practice, it has been demonstrated *in vitro* that this is effective at killing the bacteria that may be present on the luer connection surfaces.

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