An extended use microbial challenge of SwabArt® Disinfecting Cap

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Purpose:

Central-venous-catheter-related bloodstream infections (CRBSIs) are an important cause of hospital-acquired infection associated with morbidity, mortality, and cost. Amongst, different measures implemented to reduce the risk for CRBSI, preventive strategies based on inhibiting micro-organisms originating from the skin or catheter hub from adhering to the catheter involve utilization of needle-free valves (also called needleless connectors). Numerous elements have been ascribed to the level of infection risk associated with needle-free connectors and incorporates the adequacy of sanitization of the infusion ports. It has additionally been proposed that surface disinfection of needle-free connectors is not intuitive which may lead to non-compliance. In this study, effectiveness of continuous passive disinfection cap, which contains 70% (v/v) IPA, as standard cleaning for the microbial decontamination of injection port of needle-free valves was evaluated.

Materials and Methods:

Table 1. Number of devices used vs organisms

Microorganism	Number of devices used						
	Test 1 min	Test 2 min	Test 7d	Positive control 1 min	Negative control 1 min	Negative control 2 min	Negative control 7d
Staphylococcus aureus ATCC 29213	6	6	6	2			
Klebsiella pneumoniae ATCC 10031	6	6	6	2			
Pseudomonas aeruginosa ATCC 27853	6	6	6	2			
Escherichia coli ATCC 25923	6	6	6	2			
Candida albicans ATCC 10231	6	6	6	2			
-	-	-	-	-	6	6	6
TOTAL	**30**	**30**	**30**	**10**	**6**	**6**	**6**

The FlowArt© device, luer-activated mechanical valve needle-free connector manufactured by Asset Medikal (Istanbul, TR) was used in this study. The SwabArt® device, 70% IPA (v/v) containing cap manufactured by Asset Medikal (Istanbul, TR) was used for decontamination of the needle-free connectors.

Cultures of challenge organisms (Table 1.) obtained from American Type Culture Collection ATCC, Manassas, Virginia, United States were stored at -71°C, and a fresh subculture, grown overnight on tryptic soy agar (TSA) at 35°C was used for each experiment to prepare a 1×10^5 CFU/mL suspension in tryptone sodium chloride (1 g/L tryptone, 8.5 g/L NaCl in distilled water).

An unused NFV was removed from its packaging using sterile methods. Each device was activated once using a sterile syringe. Sterile Phosphate Saline was used as flush solution for the activation to simulate clinical use. Following one activation of each connector, the external injection port of each sterile needle-free connector were inoculated with a 10 µL suspension containing at least 1.0 x 10^3 CFU of the challenge organisms and allowed to air dry for 1 min at room temperature.

Following air drying, the inoculated NFV was disinfected using SwabArt® disinfection caps attached to the injection port of NFV for a length of 1, 2 minutes and 7 days at room temperature in air and were compared with non-inocculated sterile NFVs. A total of 30 NFV were studied per time point following each disinfection procedure. 2 control NFVs which were contaminated as above and which were not disinfected were similarly studied and acted as positive controls and 6 control NFVs which were not contaminated at all were also similarly studied and acted as negative controls for each sampling (Table 1.). Negative controls were also used for sterility control of the methods. The positive controls were flushed with 10 ml of a nominal 1.0 x 10^3 CFU/mL volume of challenge suspension after injection of 10 ml of sterile saline.

A 10 cc sterile syringe containing soybean casein digest broth containing 5% bovine serum albumin (Gibco Dublin, Ireland) was attached to the injection port end of each treated NFV. A polycarbonate filter holder (Sartorius, Göttingen, Germany) equipped with a sterile 0.45 µm nitrocellulose filter (Isolab, Germany) was attached to the other end of the device, and 10 ml of broth was passed through the device. Filters were then placed on Mueller Hinton agar (Labvital, Istanbul, Turkey). All plates were incubated at 37°C overnight and counted.

The positive controls were not disinfected with the cap. 10mL of soybean casein digest broth containing 5% bovine serum albumin was flushed through the valves after injection of 10 ml of sterile saline.

After incubation number of organisms on the membranes for each treatment length and challenge organism was measured by viable count.

The minimum CFU count on the controls (the NFVs which were not decontaminated after inoculation with challenge microorganisms) during the study was 3 log10 CFU, therefore total kill (TK) represented a ≥ 3 log10 CFU reduction. (Table 2)

Table 2. Effect of disinfection length on reduction of viable organisms on NFV internal surfaces effluent following valve activation. (**-** : no CFU growth was detected, TK; **+**: growth)

length	sample	challenge microorganism				
		S. aureus	E. coli	K. pneumoniae	P. aeruginosa	C. albicans
-	P. Control	+	+	+	+	+
1 min	N. Control	-	-	-	-	-
	Test	-	+	-	-	-
2 min	N. Control	-	-	-	-	-
	Test	-	-	-	-	-
7 d	N. Control	-	-	-	-	-
	Test	-	-	-	-	-

Results and Discussion

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The total mean log10 CFU per untreated NFV (positive control) internal surface effluent for all experiments was 3. These results provided evidence that a single activation of the NFV valve is sufficient to transfer viable cells from the external septum surface of the NFV into the lumen of the device.

6 uninoculated, sterile NFVs (negative control) were processed to recover and quantify any organisms on NFV effluent, using the standard recovery protocol. No CFU/NFV was detected in these samples (Table 2).

The effect of cap disinfection on NFV septum surfaces using each disinfection length is shown in Table 2. For 1 minute treatment length category, it was found that IPA was significantly less effective against all organisms except E. coli when treated for 1 minute. However, no CFUs could be undetected on filters from NFVs inoculated with any of the challenge organisms at 2 min treated length category.

All positive controls had positive assays confirming the viability of the challenge organisms for the duration of each test period. All negative controls had negative assays confirming the absence of the organism in samples not inoculated with challenge organism. This also proved the sterility of the methodology.

After 7 days of continuous attachment of the cap, none of the test samples treated with either of the challenge organisms showed detectable colony formation upon inoculation of the filters.

Conclusion:

This study demonstrated the effectiveness of an alcohol impregnated cap for catheter hubs in preventing intraluminal contamination and infection. It was concluded that SwabArt® disinfecting caps could provide effective decontamination against E. Coli within 1 min, while > 1 min but < 2 min of capping is effective for decontamination from Staphylococcus aureus, Klebsiella pneumoniae, Pseudomonas aeruginosa and Candida albicans. It was also showed that the cap not only disinfects the NFV injection port but also protects it from any microorganism contamination and growth safely up to 7 days.

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