



Continuous Passive Disinfection of Luer Access Valves to Prevent Contamination

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Abstract (revised)

Background

Catheter hub contamination is a potential cause of line-related sepsis. Hub decontamination usually relies on the user scrubbing the valve with a disinfecting agent. Compliance with this technique can vary. This study aims to evaluate the effectiveness of a luer access valve disinfection cap (DC) with 70% alcohol affixed to catheter hubs to prevent line contamination.

Methods

The case-crossover study was conducted at 3 acute care facilities and is divided into P1 (baseline) during which the standard protocol of alcohol scrub was used to disinfect hubs before accessing; P2, during which the DC was used on all patients with central venous catheters and P3, during which the DC was removed from use. Adult patients with peripherally inserted central catheters (PICC) inserted during their index hospitalization plus 5 or more consecutive PICC line days were consented and enrolled. On days 5, 6, or 7 and twice weekly thereafter during hospitalization, 1.5 ml of blood was withdrawn from each catheter lumen not actively in use and placed into an Isolator 1.5 Microbial Tube (Wampole, Cranbury, New Jersey) during first morning rounds by an intravenous therapy nurse. The aspirate was quantitatively cultured by placing 1 ml of blood aseptically onto a 150mm agar plate containing Mueller Hinton Agar with 5% Sheep Blood (Remel, Lenexa, Kansas). Outcome measures included the presence/absence of bacterial growth in the aspirate and the density of said organisms. Two-tailed

Fisher's exact and Wilcoxon Mann-Whitney U tests were used for significance testing. A fourth hospital was not involved in the study, but implemented the DC immediately and housewide central-line associated bloodstream infection (CLABSI) rates using NHSN criteria are reported here. The study was IRB approved.

Results

To date, 437 patients have been enrolled with 12.7% (31/245) contaminated during P1; 6.8% (13/192) were contaminated during P2 ($p=0.05$). The median number of colony forming units per milliliter was 4 for P1 and 1 for P2 ($p=0.03$). Coagulase negative Staphylococcus species was the predominate organism in both periods (62% vs 54% P1:P2 respectively). CLABSI rates at the fourth (intervention only) hospital declined from 1.35 per 1,000 line days (2/1,477) in the 5 months preceding implementation of the DC to 0.30 per 1,000 line days (1/3297) in the 11 months following its introduction (RR = 0.22, $p=0.23$). CLABSI rates at a second hospital declined from 2.24 (7/3126) in 4 months preceding the DC to 0.49 per 1,000 line days (2/4071) in the 5 months following its introduction (RR = 0.22, $p=0.08$). Phase 3 (P3 above) is currently underway.

Conclusions

Continuous passive disinfection via luer access cap with 70% alcohol significantly reduced the number of PICCs with intraluminal contamination, lowered the density of bacteria when such lines were contaminated and appears to have contributed to an overall reduction in infection rates.

Background

Central line associated bloodstream infections (CLABSIs) can be caused by any one or a combination of factors, including inadequate skin preparation prior to insertion, migration of skin flora at the insertion site in the days and weeks following insertion as well contamination and inadequate disinfection of catheter hubs. Recent advances in superior skin preparation at the time of insertion and supplies that provide a continual release of anti-infective solutions at the insertion site may have contributed to an overall decline in infection rates. Meanwhile, several successful CLABSI reduction initiatives have targeted "scrub the hub" campaigns to improve adherence to proper disinfection of these hubs, though the thread design of valves may make complete disinfection and consistent practice difficult to achieve and sustain. In one report, up to 31% of clinical staff accessing the lines failed to disinfect them 1. The aim of this study was to assess the frequency of contamination, organism density of contaminants and CLABSI rates following introduction of a disinfection cap (DC).

Methods

NorthShore University HealthSystem (NSUHS) is an integrated healthcare delivery system that services the northern suburbs of Chicago, IL. It consists of 4 acute care hospitals (950 beds) and more than 75 offsite physician practice groups.



Figure 1:
Disinfecting Cap Design

In 2009, NSUHS implemented the use of a chlorhexidine impregnated sponge at the insertion site for all central venous catheters (CVCs). In 2010, NSUHS began a clinical trial investigation of a novel capping device to prevent intraluminal contamination via the luer access valves. The disinfecting cap, SwabCap TM (Excelsior Medical Corporation, see Figure 1) is a plastic device with interior threading and a small sponge containing 70% isopropyl alcohol, which saturates the hub. It is affixed to catheter hubs when the valve is not actively in use and left in place to act as a physical and chemical barrier until the hub next requires use at which point the DC is removed, discarded and the line is accessed. Upon completion of tasks related to accessing the line, a new DC is affixed and left in place.

This is a case-crossover study in which adult patients with peripherally inserted central catheters (PICCs) inserted during their index hospitalization at one of 3 hospitals (Facilities B-D) with 5 or more consecutive PICC line days were consented and enrolled. On days 5, 6, or 7 and twice weekly thereafter during hospitalization, 1.5 ml of blood was drawn from each catheter lumen not actively in use and placed into

an Isolator 1.5 Microbial Tube (Wampole, Cranbury, New Jersey) during first morning rounds by an vascular access team nurse. The aspirate was quantitatively cultured by placing 1 ml of blood aseptically onto a 150mm agar plate containing Mueller Hinton Agar with 5% Sheep Blood (Remel, Lenexa, Kansas). The study was designed into three phases: 1. Baseline assessment of current (scrub the hub) practice. 2. Implementation of the DC and continued sampling 3. Discontinued use of the DC followed by continued sampling. One hospital (facility A) was not included in the formal study design, but designated to undergo implementation of the DC immediately. Although the enrollment of patients was limited to those with PICCs, the implementation of the device was universal for all patients with any type of CVC. Therefore, CLABSI rates are not limited to patients with PICCs only and results are reported for all 4 facilities. Phase 3 began at one of the facilities on April 1, 2011. The results reported here are for Phases 1 and 2.

Analysis included measuring contamination of the intraluminal space dichotomously by patient and as a proportion of total lumens cultured (yes/no, significance testing by a two-tailed Fisher's exact test) as well as organism density measured as colony forming units (CFUs) per milliliter (ml) of fluid among enrolled subjects (Wilcoxon Mann-Whitney U test). CLABSI rates were measured per 1,000 CVC days (Mantel-Haentzel estimate of the common rate ratio with 95% confidence intervals estimates and a Fisher's exact p-value for the rate ratio).

Results

See Table 1. Between April 2010 and February 2011, 437 patients were enrolled with 12.65% (31/245) of patients having one or more contaminated lumens P1 and 6.8% (13/192) contaminated following the P2 intervention (p=0.05). Similarly, the proportion of contaminated lumens declined between P1 and P2 (31/314 or 9.87% vs 13/279 or 4.66% p=0.02). The median number of colony forming units per milliliter was 4 for P1 and 1 for P2 (p=0.03). Coagulase negative Staphylococcus species was the predominate organism in both periods (62% vs 54% P1:P2 respectively). CLABSI rates in Hospital A (intervention only) declined from 1.35 per 1,000 line days (2/1,477) in the 5 months preceding implementation of the DC to 0.30 per 1,000 line days (1/3297) in the 11 months following its introduction (RR = 0.22, p=0.23). CLABSI rates at Hospital B declined from 2.24 (7/3126) in the first 4 months preceding implementation of the DC to 0.49 per 1,000 line

days (2/4071) in the 5 months following its introduction (RR = 0.22, p=0.08). When outcome measures for Hospital A-B are combined, the reduction appears to be statistically significant (p=0.02).

Conclusions

Patients with PICC lines using the DC were nearly half as likely to have intraluminal contamination than patients with standard scrub-the-hub care and this improvement was statistically significant. When there was contamination, the organism density was markedly reduced. Similar success in reducing contamination has been shown in a controlled in vitro study whose DC utilized a combination of 70% isopropyl alcohol and chlorhexidine gluconate (CHG). 2

This study is ongoing. Two hospitals have just implemented the DC and the third hospital just entered phase 3 (withdrawal) of the trial and returned to baseline practice by removing the DC from the facility.

Continuous passive disinfection via luer access cap with 70% alcohol significantly reduced the number of patients whose PICCs became contaminated in the intraluminal space. When contamination did occur, the organism density was significantly reduced in patients with the DC. Lastly, infections, as measured by CLABSIs, appear to have had a significant reduction following implementation of the DC. The third phase of this study will evaluate whether such a reduction can be contributed to the DC alone.

References

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Disclosure

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	HOSPITAL A	HOSPITAL B	HOSPITAL C	HOSPITAL D	OVERALL
Phase 1 (P1) Start Date		Apr-10	May-10	Aug-10	
Phase 2 (P2) Start Date	Mar-10	Aug-10	Mar-11	Mar-11	
Phase 3 (P3) Start Date		Apr-11			
P1 Patients Sampled		89	113	43	245
P1 Patients Positive		11	14	6	31
P2 Patients Sampled		192			192
P2 Patients Positive		13			13
P1 PERCENT POSITIVE		12.36%	12.39%	13.95%	12.65%
P2 PERCENT POSITIVE		6.77%			6.77%
p-value		0.17			0.05
P1 # OF LUMENS SAMPLED		120	128	66	314
P1 # OF POSITIVE LUMENS		11	14	6	31
P2 # OF LUMENS SAMPLED		279			279
P2 # OF POSITIVE LUMENS		13			13
P1 PERCENT POSITIVE		9.17%	10.94%	9.09%	9.87%
P2 PERCENT POSITIVE		4.66%			4.66%
p-value		0.11			0.02
P1 MEDIAN CFU/ML		2	8	4	4
P2 MEDIAN CFU/ML		1			1
p-value		0.22			0.03
BASELINE DATES	10/09-2/10	4/10-7/10	7/10-1/2011	7/10-1/2011	
P2 DATES	4/10-1/2011	9/10-1/2011			
BASELINE CLABSIs/LINE DAYS	2/1477	7/3126	2/2873	4/2814	9/4603
P2 CLABSIs/LINE DAYS	1/3297	2/4071			3/7368
Rate Ratio (95% CI)		0.22(0.03,1.71)			0.21 (0.06,0.71)
Fisher's exact p-value		0.23	0.08		0.02

Table 1: Contamination rates, organism density and infection rates following introduction of a disinfecting cap on central venous catheters.