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Alcohol Impregnated Caps and Ambulatory CLABSI: Multicenter Cluster Randomized, Crossover Trial

Aaron M. Milstone, MD, MHS [1], Carol Rosenberg, DNP, RN[2], Gayane Yenokyan, PhD[3], Danielle W. Koontz MAA[1], Marlene R. Miller, MD, MSc[4], on behalf of the CCLIP Authorship Group

[1]Department of Pediatrics, Division of Infectious Diseases, Johns Hopkins University School of Medicine, Baltimore, MD, USA; [2]Children's Hospital Association (current), Washington, DC, USA, [3]Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA, [4]Department of Pediatrics, UH Rainbow Babies and Children's Hospital, Cleveland, OH, USA

Aaron Milstone
200 North Wolfe St.
Baltimore, MD 21287
443-287-8923
amilsto1@jhmi.edu

INTRODUCTION

- Central line-associated bloodstream infections (CLABSI) cause significant morbidity and mortality and occur more commonly in the ambulatory setting in pediatric oncology patients. Whether alcohol impregnated caps placed on central venous lines can prevent CLABSI in ambulatory pediatric oncology patients is unknown.
- Our aim was to assess if use of 70% isopropyl alcohol-impregnated caps on external central lines reduce ambulatory CLABSI in pediatric hematology/oncology patients.

METHODS

- Cluster-randomized, 2 period, crossover trial at 16 pediatric hematology/oncology clinics.
- Clinics were randomly assigned to usual ambulatory central line care per each institution (control) or to 70% isopropyl alcohol-containing caps at home (intervention).
- Caps were only used in the ambulatory setting.
- The primary outcome was ambulatory CLABSI.
- Secondary outcomes included ambulatory mucosal barrier injury (MBI) CLABSI, secondary blood stream infections, single positive blood cultures (SPBC), and positive blood cultures.

RESULTS

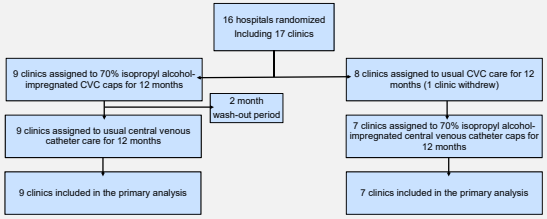

Table 1. 2015 Baseline clinic and patient population characteristics and practices of ambulatory pediatric oncology clinics and patient populations

Site Characteristic	N=16
Female, % (IQR)	46 (45-52)
Age, % (IQR)	
<2 years	15 (10-19)
2-5 years	19 (15-22)
6-11 years	26 (24-29)
≥ 12 years	41 (36-46)
Number of inpatient pediatric oncology beds, median (IQR)	25 (20-34)
Number of annual pediatric oncology admissions, median (IQR)	1,091 (727-1,354)
Number of pediatric oncology ambulatory visits, median (IQR)	8,552 (6,790-11,858)
Number of total inpatient days, median (IQR)	5,640 (4,664-8,423)
Number of total HCT patients, median (IQR)	32 (10-49)
External Central Line Practices for **Ambulatory Patients**	
Use antimicrobial/antiseptic impregnated catheters % sites (N)	0 (0)
Use antibiotic/non-antibiotic locks % sites (N)	19 (3)
Use of chlorhexidine impregnated disc % sites (N)	75 (12)
Use chlorhexidine gluconate baths % sites (N)	6 (1)
External Central Line Practices for **Inpatients**	
Percentage of patients using alcohol impregnated catheter caps prior to the trial % sites (N)	
0	38 (6)
1-49%	12 (2)
50-100%	50 (8)

RESULTS

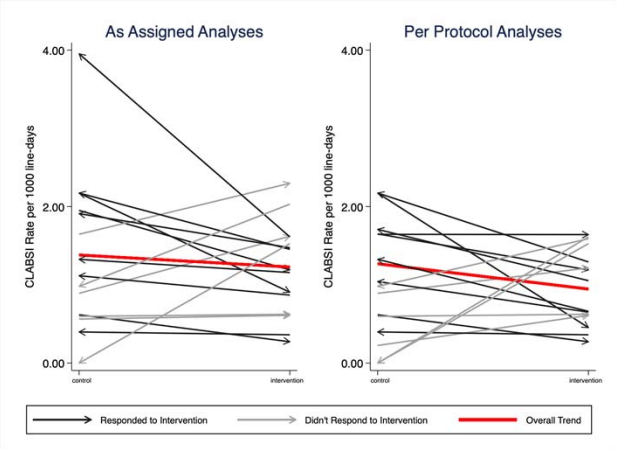

Figure 1: Crude incidence CLABSI. Each line represents one clinic. The slope shows the change in incidence of CLABSI between the intervention and control periods. The red line represents the change in overall crude incidence during intervention and control periods. Black lines represent clinics that had a decrease in CLABSI during the intervention period and grey lines represent clinics that did not have a decrease in CLABSI during intervention periods.

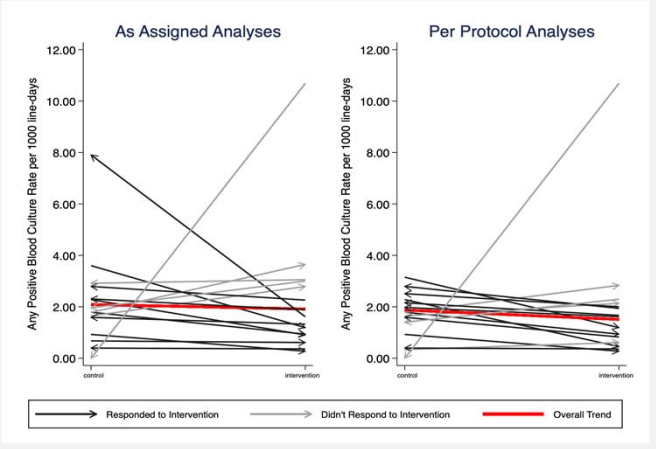

Figure 2: Crude incidence of any positive blood culture. Each line represents one clinic. The slope shows the change in incidence of any positive blood culture between the intervention and control periods. The red line represents the change in overall crude incidence during treatment and control periods. Black lines represent clinics that had a decrease in any positive blood culture during the intervention period and blue lines represent clinics that did not have a decrease in any positive blood culture during intervention periods.

Table 2. Summary of Primary and Secondary (MBI-CLABSI, SBSI, SPBC, Any positive blood culture) Outcomes

	Events in Control Clinics	Events in Intervention Clinics	Crude Control IR per 1000 at-risk Days	Crude Intervention IR per 1000 at-risk Days	Adjusted IRR[a] (95% CI)	p-value
ITT Analyses						
CLABSI, as assigned (primary outcome)	123	109	1.38	1.23	0.83 (0.63, 1.11)	0.22
MBI-CLABSI, as assigned	16	10	0.18	0.11	0.54 (0.17, 1.75)	0.30
Secondary BSI, as assigned	11	0	0.12	0	-	-
Single positive blood culture, as assigned	36	51	0.40	0.57	1.38[b] (0.76, 2.48)	0.29
Any positive blood culture, as assigned (CLABSI, MBI-CLABSI, SBSI, SPBC)	186	170	2.09	1.91	0.81 (0.61, 1.07)	0.14
Per Protocol Analysis						
CLABSI, as assigned	113	84	1.27	0.95	0.71 (0.48, 1.04)	0.08
MBI-CLABSI, as assigned	14	8	0.16	0.09	0.48 (0.15, 1.60)	0.23
Secondary BSI, as assigned	11	0	0.12	0	-	-
Single positive blood culture, as assigned	29	42	0.33	0.47	1.35 (0.73, 2.49)	0.34
Any positive blood culture, as assigned (CLABSI, MBI-CLABSI, SBSI, SPBC)	167	134	1.88	1.51	0.72 (0.52, 0.99)	0.045

CLABSI - central line-associated bloodstream infection; MBI-CLABSI – mucosal barrier injury central line-associated bloodstream infection; SBSI – secondary bloodstream infection; SPBC - single positive blood culture; IR – Incidence rate; IRR – Incidence rate ratio
[a] adjusted for the year-specific total number of HCT patients and the use of chlorhexidine impregnated disc
[b] the planned model did not converge, a generalized linear model with unit-correlated robust variance was used instead

CONCLUSIONS

- Intention to treat analysis: isopropyl alcohol-impregnated central line caps did not lead to a statistically significant reduction in CLABSI rates in ambulatory hematology/oncology patients.
- Per protocol analysis: there was a statistically significant decrease in any positive blood cultures.
- Larger trials are needed to elucidate the impact of 70% isopropyl alcohol-impregnated caps in the ambulatory setting.

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