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Use of alcohol containing caps for preventing bloodstream infections: A randomized controlled trial

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Abstract

Background: A majority of bloodstream infections seen in intensive care units stem from intravascular catheters used on patients. Catheter hubs are the entrance for pathogenic microorganisms into the inner surfaces of the catheters. The pathogenic microorganisms colonization in the mentioned areas can cause central line-associated bloodstream infection (CLABSI).

Methods: This study was conducted as a randomized controlled trial to investigate the effect of alcohol-containing caps on the prevention of CLABSI. Total of 95 patients participated in the study. Isopropyl alcohol-containing caps were used for protecting the needle-free connectors closing the hubs of the central venous catheters in the intervention group. However, the control group patient received standard catheter caps.

Result: There was a statistically significant difference between groups in terms of infection distribution ($X2 = 13.058$; $p < 0.001$). The risk of infection in the control group was 13.7 times higher than the risk of infection in the intervention group.

Discussion: Our results suggest that alcohol-containing caps are effective or in preventing CLABSI.

Conclusion: These findings suggest that alcohol-containing caps on ports are effective in preventing CLABSI.

Keywords

Central venous catheter, randomized controlled study, isopropyl alcohol, alcohol containing caps, bloodstream infection

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Introduction

It is stated that a majority of the bloodstream infections seen at intensive care units originates from intravascular catheters used on patients.[1] Central line associated bloodstream infection (CLABSI) is one of the reasons for serious morbidity and mortality.[2]

Protective caps ensure an automatic, passive disinfection of the hubs, reducing the risk of contamination. Every cap contains 70% isopropyl alcohol and this alcohol bath cleans and disinfects catheter surface in a minute.[3] The effect of alcohol-impregnated caps on CLABSI's and contaminated blood cultures was examined on oncology patients in America and only one CLABSI was observed on 3005 central catheter days (0.3 infections / 1000 central catheter days). When the back data in the control period were examined, 16 CLABSI's were documented on 6581 central catheter days in total. This 32-bed study indicated a calculated savings of 500,000 dollars annually.[4] In another retrospective study following-up 2512 catheters from 2264 patients, it was stated that CLABSI (0.84%; 95% confidence interval, the rate of CLABSI according to 1000 instrument days; 1.62) was detected in 12 patients after alcohol-containing caps usage and the rate and number of infection decreased considerably (the rate of CLABSI; 0.5) when it was compared to past data.[5] Also, in another retrospective study, it was identified that after the use of

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disinfection caps, the rate of CLABSI decreased to 0.6461 (for 1000 catheter days) while it had been 1.682 (for 1000 catheter days).[6] While most studies related to a relevant topic have retrospective data comparison, there has not been a randomized study for this product yet in Turkey. Only one international randomized controlled study has been conducted on this subject recently.[7]

Methods

Study design: This study was conducted as a randomized controlled trial to investigate the effect of alcohol-containing caps on CLABSI. This single-blind randomized controlled trial used two parallel groups.

Setting and samples: The patients at the coronary intensive care unit of cardiology and cardiovascular surgical hospital were the target population. In the referenced article for sample size, the relative risk of the control group was reported as 14.08 (16/69 = %23.2 vs 1/47 = %2.1 for infection rate), and the required sample size for the relevant influence quantity was calculated as 95 with Type I Error (Alpha) 0.05 and 90% power.[5] Ninety-five patients who met the criteria of involvement were included in the study between July and December 2018.

Randomization: For the randomization process, over 65-year-old volunteer patients transferred from emergency department or clinics to a coronary intensive care unit, having a central venous catheter, not having diabetes mellitus, not receiving steroid and chemotherapy treatment causing immunosuppression, not receiving a transplant, not having an open sore, not having an active infection in other parts of the body, not receiving hemodialysis, not having ECMO (extracorporeal membrane oxygenation) and Intra aortic balloon pump, not having TPN (total parenteral nutrition), blood and blood products, and not having any infection symptoms before intravenous catheterization were chosen for the intervention group randomly. The patients who conformed the criteria of involvement in the figure below were used by being constituted 20 different collating to form six-fold cell. Ninety-five patients in the cell were assigned to intervention—control groups in turn after randomly-produced numbers between 1 and 20 with the random search instruction in Excel were randomized in each cell respectively (Figure 1).

Data collection/procedure: The patients who received jugular and subclavian central venous catheterization in the intensive care unit (ICU) were informed and consented to participate in the study and randomly assigned into the groups

The steps of central catheter insertion and management were as follows:

The procedure is performed by the cardiologist in the coronary intensive care unit. The ultrasound guidance wasn't used per institution policy. Patients were given the appropriate position for the procedure. Aseptic technique is practiced at hand washing, donning and doffing bouffant caps, masks, sterile gowns, and gloves. The skin is prepped with an antiseptic solution (2% chlorhexidine %70 Alcohol) and allowed to dry for 30 s. The site is covered with a sterile fenestrated drape. A 7 Fr polyurethane catheter with two lumens was used and secured with a suture. Two types of dressing were used in this study: gauze dressing and chlorhexidine-impregnated dressing (transparent dressing with chlorhexidine-releasing gel foam). The date of insertion is documented on the dressing.

Immediately after catheterization, needle-free connectors were covered with isopropyl alcohol-containing caps in the intervention group, but not in the control group. The disinfecting cap was replaced after each use of each infusion line.

We used disinfecting caps containing a sponge with 70% isopropyl alcohol (Curos, 3M); 1 min after they are applied over the connecting surface of the needle-free connectors, they ensure proper disinfection of the hub.

Catheter dressing type is one of the risk factors for bloodstream infection. The frequency of dressing change differs according to the products used. The dressing over the exit site of the catheter must be changed every 2 days if using a sterile gauze dressing, or every 7 days if using transparent dressing.[8,9] Two types of dressing were used in this study: gauze dressing and chlorhexidine-impregnated dressing (transparent dressing with chlorhexidine-releasing gel foam). Through the study, patients' catheter dressings were immediately changed when they become wet, disintegrated, or soiled. The catheter dressings with chlorhexidine content were changed once 7 days when the dressing was not soiled or disintegrated. The skin was followed up antiseptic solution (2% chlorhexidine %70 Alcohol) in all patients. The patients in both groups were followed up with isopropyl alcohol-containing caps and non-alcoholic caps as long as they were in the intensive care unit, and if they were transferred into another department, the same treatment was followed for two more days according to 2011 guidelines of Centers for Diseases Control (CDC). The patients transferred into service from the coronary intensive care unit were unfollowed at the end of two calendar days because the infections emerging two calendar days after the patient is transferred are attributed to the new department.[10] The patients whose central venous catheterization was explanted for any reason were unfollowed two calendar days after they had without central venous catheterization.

During follow-up, two bottles of aerob and two bottles of anaerob cultures were taken from the patients either having the symptoms of less than 36°C or higher than 38°C body temperature or having chills. Those cultures were analyzed at the microbiological laboratory. The cultures were analyzed at the microbiological laboratory. The laboratory staff were unaware of which intervention group the cultures belonged to.

Data collection tools: Data was collected through the CLABSI tracking form, the researcher had prepared it by

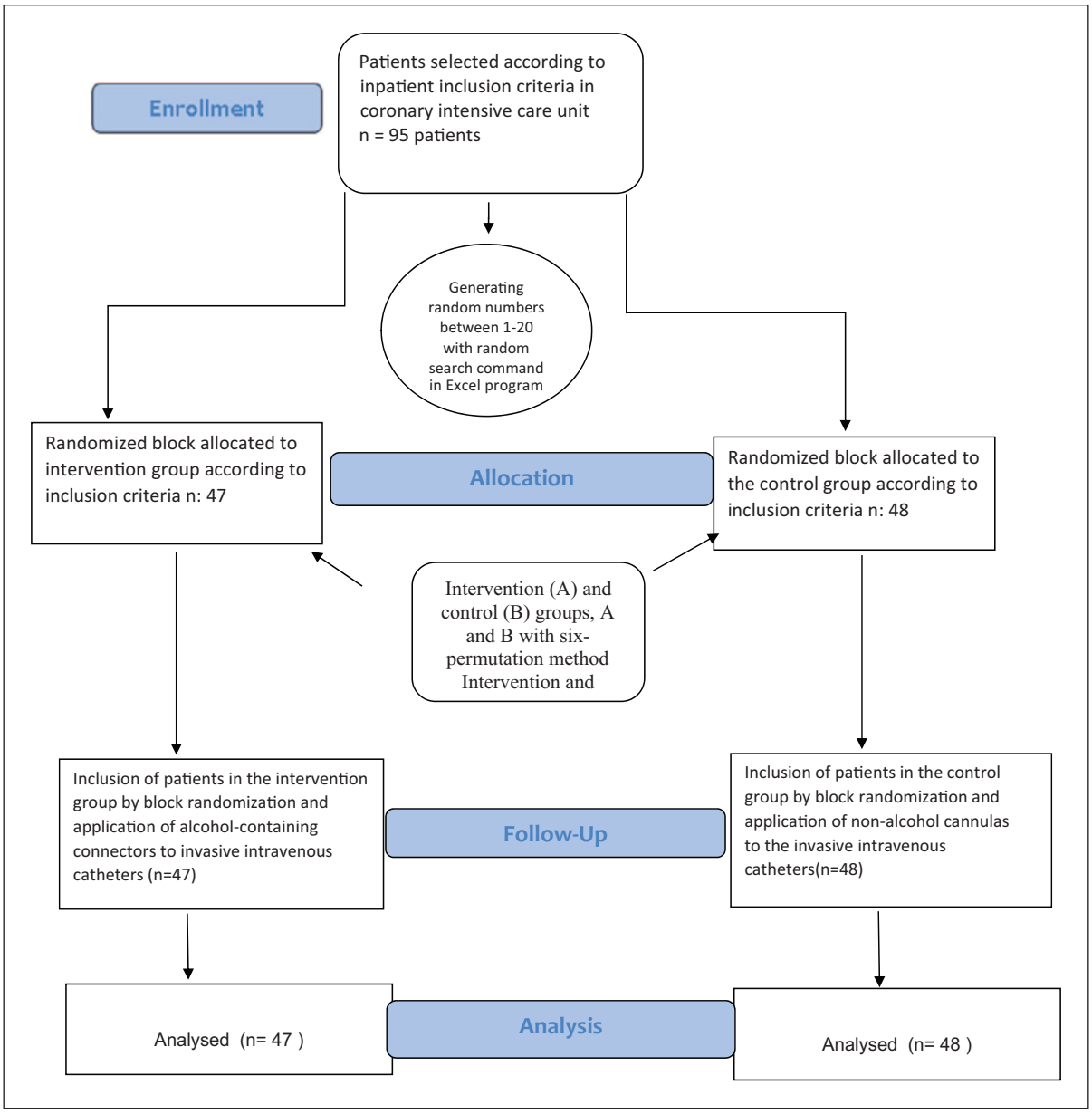

Figure 1. Flow diagram.

reviewing the related literature. The patients' demographic information, the duration of hospitalization and discharge, groups, central catheter location, the dates of catheter fixation and extraction, vital signs, the follow-up blood culture results, and the length of follow-up can be found on the CLABSI tracking form. The information on temperature, chills, and culture was recorded on the CLABSI tracking form. When there was a proliferation in blood culture, the name of the microorganism was also written down on the form.

Data analysis: SPSS 25 program was used for statistical analysis. While qualitative variables of the groups were summarized as number and percentage, quantitative data were summarized as mean and standard deviation. The comparison of means of two independent groups was made with independent samples *t*-test. Chi-square test was done to compare the percentage between the groups and Relative risk (RR) statistic was calculated as the risk measure being appropriate for prospective studies and its significance was tested.

Research ethics: For the research to be done, after getting the required approval with the permission dated 06.09.18 and numbered 2018/05 from Maltepe University Ethics Committee, through Health Promotion Department, Provincial Health Directorate institution the permit numbered 168667222 to 604.01.01 was obtained from Health Sciences University Koşuyolu High Speciality Educational and Research Hospital where the scientific study was

Table 1. Comparison of age, gender, central venous catheter type, hospitalization, fever-chills findings.

		Intervention	Control	*p*	X^2
Age	*n*	47	48		
	Average	72.98	73.4		
Gender	Women	23 (48.9)	21 (43.8)	0.612	0.257
	Men	24 (51.1)	27 (56.3)		
CVC Type	Jugular	17 (36.2)	12 (25)	0.237	1.397
	Subclavian	30 (63.8)	36 (75)		

done. After the patients were given the necessary information about the study, their written permission was received with Patient Information and Consent Form.

Results

There is no statistically significant difference in terms of gender distribution between groups ($X^2 = 0.257$; $p = 0.612$). When all the patients in two groups were taken into consideration, 46.3% of them were women while 53.6% of them were men. There was no statistically significant difference between groups in terms of central venous catheter access preference distributions ($X^2 = 1.397$; $p = 0.237$) (Table 1).

There was a statistically significant difference between groups with regards to fever distribution ($X^2 = 15.739$; $p < 0.001$). There was a statistically significant difference between groups with regards to chills distribution ($X^2 = 5.853$; $p = 0.016$) (Table 2).

There was a statistically significant difference between groups in terms of infection distribution ($X^2 = 13.058$; $p < 0.001$). Infection risk in the control group was 13.7 times higher than the infection risk in the intervention group (Table 3).

When the distribution of pathogenic microorganisms is examined, gram-negative bacteria, gram-positive bacteria, and fungal infections are seen. In the intervention group, only one patient had CLABSI correlated with *MRSA*. (one infection / 35 central catheter-days) 14 CLABSI's correlated with various pathogenic microorganisms were identified in the control group (Table 4).

Discussion

In this study, over 65-year-old patients are chosen to equalize both groups in terms of age variable which is thought that it affects infection. There are some studies about the relationship between the risks of age and infection in the literature.[11,12] During research sampling, the patients with chronic disease and/or immunodeficiency were not included in the sample considering the risk of infection. Dumyati et al.[13] stated that chronic diseases such as diabetes mellitus and renal failure and immunodeficiency were risk factors in bloodstream infections.[13] According to the results of our study, there is no statistically significant difference between groups with regards to gender distribution. Kaur et al.[14] conducted a prospective study in which risk factors were evaluated for CLABSI in a tertiary hospital. According to the results of the study, a statistically significant difference between gender and CLABSI could not be found.[14] In our study, in both the control group and intervention group, subclavian venous access was used more than jugular venous access. Ünlü[15] found that infections caused by CVCs in the intensive care unit were caused by femoral, jugular and subclavian catheters, respectively.

In this study, patients were followed-up in terms of the symptoms of hypothermia, hyperthermia, and chills. According to the symptoms, the risk of hypothermia or hyperthermia in the control group is higher than the intervention group. The risk of having chills in the control group is higher than the intervention group. Less fever and chills were observed in the patients using alcohol-containing caps. Kitagawa et al.[16] emphasized that increases or decreases in body temperature are the most common cause to take blood cultures, and blood culture samples should also be taken in clinical situations suggesting sepsis-like chills.[16]

In our study, the infection risk in the control group is 13.7 times higher than the infection risk in the intervention group. In a non-randomized study, the effect of alcohol-containing caps on the rates of CLABSI was examined and it was ascertained that the 1.9 rate of v in 2010 was decreased to 0.5 at the end of the one-year trial of the caps in all patients.[17] Ramirez et al. found out that caps were effective to prevent CLABSI and it had parallels with the results of our randomized controlled trial.[17] In another quasi-experimental study, when alcohol-containing caps were used in the USA, it was found out that the rate of CLABSI fell from 1.43 to 0.69 for 1000 line days.[18] Inchingolo et al. report that the use of educational measures combined to the application of Curos® Disinfecting

Table 2. Comparison of response and control group in terms of fever-chills findings.

		Intervention	Control	RR (%95GA)	*p*	X^2
Comparison of fever distributions of groups	*n*	47	48	15.667 (2.163–113.452)	<0.001	15.739
	Hyperthermia or Hypothermia	1 (2.1)	16 (33.3)			
	No hyperthermia or hypothermia	46 (97.9)	32 (66.7)			
Comparison of chills distributions of groups	n	47	48	7.833 (1.019–60.218)	0.016	5.853
	chills	1 (2.1)	8 (16.7)			
	No chills	46 (97.9)	40 (83.3)			

Table 3. Groups bloodstream ınfections with central venous catheter comparison of distributions.

		Intervention	Control	RR (%95GA)	*p*	X^2
Bloodstream ınfections with central venous catheter (CLABSI) distributions	*n*	47	48	13.708 (1.877–100.132)	<0.001	13.058
	CLABSI developed	1 (2.1)	14 (29.2)			
	No CLABSI developed	46 (97.9)	34 (70.8)			

Table 4. Pathogen microorganism distribution.

	Microorganism	Blood culture day	Intervention (I), control (C)	How many patients are seen	Distribution percentage of factor
Gram positive microorganisms	*MRSA*	13. day	C	4	%26.6
		32. day	C		
		23. day	C		
		35. day	I		
Gram negatif microorganisms	*Pseudomonas Aeruginosa*	10. day	C	1	%6.6
	Klebsiella Pneumoniae	24. day	C	5	%33.3
		15. day	C		
		60. day	C		
		30. day	C		
		50. day	C		
	Acinetobacter Baumannii	48. day	C	2	%13.3
		51. day	C		
	Escherichia Coli	57. day	C	1	%6.6
	Proteus Mirabilis	50. day	C	1	%6.6
Fungal	*Candida Spp.*	40. day	C	1	%6.6
Total				15	%100

Port Protector led to zero cases of contaminated blood cultures and reduce the risk of CLABSI's in a Respiratory semi-Intensive Care Unit.[7] In an in vitro study, firstly the membranous septum of the test instrument was contaminated with *Enterococcus faecalis* forming about 10 (5) colonies and then, it was dried for 24 h. While 30 of them were disinfected with wipes containing 70% alcohol, 60 of them were screwed with alcohol-containing caps, and the liquid obtained from the lower part of the flow of intraluminal fluid path of membranous septums of the test instrument was added to broth medium 10 min later. All 15 control connectors (100%) showed a vast amount of microorganism transmission through the membranous septum (4.500 to 10.000 colony forming units). Out of 30 connectors attained after conventional disinfection with 70% alcohol, 20 (67%) showed that microorganisms (442–25.000 colony-forming units) were transported. However, only 1 (1.6%) of the 60 cultured connectors showed microorganism transmission after alcohol-containing caps were used ($p < 0.001$).[19] In another in vitro study, it was found that the disinfection caps containing 70% isopropyl alcohol cause a significant decline in *Staphylococcus aureus* in injection ports in comparison with the use of wipes containing 70% isopropyl alcohol and chlorhexidine.[20]

According to the result of this study, the most common microorganism causing CLABSI is *Klebsiella Pneumoniae*. In the study by Tatsuna et al., coagulase-negative staphylococci were detected as frequently isolated microorganisms in CLABSIs.[21] In another study, the most frequently isolated microorganism among all of them was *Klebsiella Pneumoniae* with 224 (12.4%) growth.[22] While gram-positive bacteria like MRSA have been isolated more in our country since 1980,[23] gram-negative bacteria have been encountered more in recent years .[24]

In this study, patients that are used both gauze dressing and chlorhexidine-impregnated dressing were counted in intervention and control groups. In order not to affect the results of the study, the number of patients used both of the dressings were equal. Even though the groups are equal, it is the limitation of this study.

Conclusion

Our results show that caps containing alcohol is beneficial in preventing CLABSI. Based on these results, it is recommended to use alcohol-containing caps to keep the unused central venous lines closed.

Declaration of Conflicting Interests

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