



Eda Polat,
İkbal Çavdar

The Impact of Care Bundle Approach in Preventing Central Line-associated Bloodstream Infections in Surgical Intensive Care Units

Cerrahi Yoğun Bakımlarda Santral Kateter İlişkili Kan Dolaşımı Enfeksiyonunu Önlemede Bakım Paketi Yaklaşımının Etkisi

Received/Geliş Tarihi : 13.10.2020
Accepted/Kabul Tarihi : 23.08.2021

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Turkish Journal of Intensive Care published by Galenos
Publishing House.

Eda Polat
Istanbul University-Cerrahpaşa, Institute of Graduate
Studies, Surgical Diseases Nursing Ph.D. Student,
Istanbul, Turkey

İkbal Çavdar
Atlas University Faculty of Health Sciences,
Department of Nursing, Istanbul, Turkey

Eda Polat Ph.D. Student (✉),
Istanbul University-Cerrahpaşa, Institute of Graduate
Studies, Surgical Diseases Nursing Ph.D. Student,
Istanbul, Turkey

E-mail : edda_akyol@hotmail.com
Phone : +90 216 280 41 62
ORCID ID : orcid.org/0000-0002-1614-7942

This study was planned and conducted as a master's
dissertation.

ABSTRACT *Objective:* Healthcare-associated infections (HAI), which pose a significant risk to patient safety, are one of the most frequent complications that inpatients encounter. The growing concern about HAI urged the development of evidence-based guidelines for prevention. This study aimed to determine the impact of care bundle approach in preventing central line-associated bloodstream infections (CLABSI) in surgical intensive care units.

Materials and Methods: This semiexperimental controlled study included 163 subjects (83 patients and 80 controls) who were admitted to surgical intensive care units between September 2017 and October 2018, had a central venous catheter (CVC), and met the inclusion criteria. For CVC care, care bundle recommended by the US Centers for Disease Control and Prevention was applied to the study group.

Results: In 23.3% of patients, signs and symptoms of hospital infections were observed. Moreover, 25.2% of catheter tip cultures were positive, and the most frequently isolated microorganism was *Staphylococcus epidermidis* (58.5%). Patients were evaluated according to the diagnostic criteria for CLABSI. Further, CLABSI was not observed in the intervention group but was diagnosed in 10% (n=8) of the patients in the control group.

Conclusion: Care bundle approach is effective in preventing CLABSI.

Keywords: Central venous catheters, intensive care units, infections, patient care bundle

ÖZ Amaç: Hasta güvenliği için önemli bir tehdit olan sağlık hizmeti ilişkili enfeksiyon oranları hastaneye yatan hastaların en sık karşı karşıya kaldığı komplikasyonlardan biridir. Sağlık hizmetlerinde sağlık hizmeti ilişkili enfeksiyonlar için artan kaygı, kanıta dayalı rehberlerin geliştirilmesinde uyarıcı etken olmuştur. Bu çalışma cerrahi yoğun bakım ünitelerinde santral venöz kateter (SVK) ilişkili kan dolaşımı enfeksiyonlarının önlenmesinde bakım paketi yaklaşımının etkisini belirlemek amacıyla gerçekleştirildi.

Gereç ve Yöntem: Yarı deneysel kontrol gruplu bir çalışma olarak planlanan araştırma, Eylül 2017 ve Ekim 2018 tarihleri arasında cerrahi yoğun bakım ünitelerinde yatan, SVK'si bulunan ve örneklem özelliklerini karşılayan 163 hasta (83 deney, 80 kontrol) ile gerçekleştirildi. Deney grubuna SVK bakımında Hastalık Kontrol ve Önleme Merkezi tarafından önerilen bakım paketi uygulandı.

Bulgular: Hastaların %23,3'ünde hastane enfeksiyonu belirti ve bulguları gözlemlendi, kateter ucu kültürlerinin %25,2'sinde üreme olduğu, en fazla üreyen mikroorganizmanın *Staphylococcus epidermidis* (%58,5) olduğu, %4,9'unda SVK ilişkili kan dolaşımı enfeksiyonu geliştiği, enfeksiyon gelişen hastaların tamamının bakım paketi uygulanmayan hastalar olduğu belirlendi.

Sonuç: Bakım paketi yaklaşımının SVK ilişkili kan dolaşımı enfeksiyonunu önlemede etkili olduğu bulundu.

Anahtar Kelimeler: Santral venöz kateter, yoğun bakım ünitesi, enfeksiyon, hasta bakım paketi

Introduction

According to the old definition, "Healthcare-Associated Infections (HAI)" is defined as nosocomial infections, infections that do not have an infection at the time of application to the health institution or are not in the incubation period, and that occur on the third day of admission to the hospital and after. HAI, which possess a great threat for patient safety, is one of the most frequent complications that inpatients encounter. There are many invasive instruments used to treat patients and help them recover in modern healthcare. Central venous catheterization is a method used for many reasons such as drug and fluid therapy, invasive hemodynamic monitoring, parenteral nutrition, administration of blood and blood products, continuous renal replacement therapy, plasmapheresis or failure to provide peripheral vascular access. Central venous catheters (CVC) is the most important risk factor for the development of catheter-related bloodstream infections. Approximately 90% of central line-associated bloodstream infections (CLABSI) are due to CVCs. (1-3).

The US Centers for Disease Control and Prevention (CDC) reported that there are 80,000 CLABSIs diagnosed in intensive care units (ICUs) (4). İsta et al. (5) recent meta-analysis involving 2,216 adult ICUs, the median incidence of CLABSI decreased significantly from 5.7 to 2.0 per 1,000 CL-days after the bundle implementation. According to the National Nosocomial Infections Surveillance Network report by the Turkish Ministry of Health in 2013, the rate of CLABSIs vary between 1.9 to 7.1 per 1,000 catheter days depending on the type of ICU (6).

The increasing concern over HAI has been a triggering factor for developing evidence-based guidelines for prevention. The quality, equality, and efficiency of patient care is expected to increase as healthcare professionals follow these guidelines (7). Care bundle approach is a set of scientifically proven practices that when performed step-by-step, collectively, and completely rather than individually have been shown to improve patient outcomes (2).

The first application of care bundle approach is the prevention of CLABSI. Studies aimed to prevent catheter infections that implemented care bundle approach focused on training healthcare professionals, using maximum barrier measures when inserting catheters and removing the catheter as soon as possible. Also, easy and rapid access to equipment used during these practices, daily evaluation of catheter requirement and catheter use and maintenance

care according to guidelines were ensured. CLABSI is a health problem that results from CVC application, individual characteristics of patients and many elements of healthcare process causing undesirables consequences. Health institutions should aim to create institutional evidence-based protocols for CVC application and care that rely on efficient and feasible recommendations from recent guidelines, support individual education with detailed theoretical approach and reflect them onto daily practices (8).

This study aims to determine the impact of care bundle approach in preventing CLABSI in patients admitted to surgical ICUs of a university hospital.

Materials and Methods

Study Design

This study was designed as a semi-experimental controlled study.

Time and Place of the Study

This study's data were collected from January to October 2018 in neurosurgery ICU, cardiovascular surgery ICU, general surgery ICU and anesthesiology and reanimation ICUs of a 600-bed university hospital in Istanbul, Turkey.

Ethics Approval

Permission from the Haydarpaşa Numune Training and Research Hospital Ethics Committee (decision no: HNEAH-KAEK 2017/KK/143, date: 25.12.2017) and the institution were obtained prior to the start of the study. Patients and/or their first-degree relatives were informed about the study and written informed consents were obtained. The study was performed in accordance with the Declaration of Helsinki.

Universe and Sample Selection

The universe of the study was made of 2,700 patients who were admitted to surgical ICUs between 2016 and 2017. The sample of the study consisted of 163 subjects, 83 patients and 80 controls, who were selected among subjects older than 18 years, admitted to surgical ICUs 2018, had a CVC using power analysis version 3.1.7 with 95% confidence interval, 5% margin of error, 0.5 effect size and 80% power (9). Patients who had an active infection when admitted to ICU and patients without a CVC were excluded. The question whether care bundle for CLABSIs is effective in preventing CLABSIs was investigated.

Data Collecting Tools

In this study, three forms that were developed by the researcher and revised according to the opinions of 10 specialists, Patient Information Form, Central Venous Catheter Care and Follow-up Form and Nosocomial Infection Surveillance Information Form, were used for data collection.

Patient Information Form: This form included questions about the patient's age, sex, diagnosis, chronic diseases, risk factors, duration of hospital stay, and duration of ICU stay.

Central Venous Catheter Care and Follow-up Form: It consisted of information about the type of catheter inserted, date of insertion, date of dressing changes, materials used and reason for dressing changes, duration of catheter, and catheter observation.

Nosocomial Infection Surveillance Information Form: This form included signs and symptoms of infections, cultures obtained from the patient and their results, presence of any other infection, and antibiotics used and their duration.

Acute Physiology and Chronic Health Evaluation-II (APACHE-II): This scoring system, which is a disease severity scoring tool used in ICUs, was used for acute physiology and chronic health evaluation. It consists of three parts: Chronic health evaluation, age, and physiology. The score of these three parts along with the surgical intervention status predicts hospital mortality.

Conducting the Study

All patients included in the study were listed from weekly lists of surgery plans. The minimum number of patients was estimated to be 163 in power analysis but 85 subjects in each group (total 170) were included, predicting there may be data losses. During data collection, 7 subjects had to be excluded due to death or transfer to another hospital and therefore the study was completed with 83 patients and 80 control subjects. Included in the care bundle;

1. Hand hygiene,
2. Maximum barrier precautions,
3. Skin antisepsis with chlorhexidine,
4. Selection of the most appropriate catheter insertion site, avoidance of the femoral vein,
5. Daily assessment of CVC requirement and removal of unnecessary lines components were fully applied to the intervention group. Checklist for preventing CLABSI as recommended by CDC defined under these 5 main components was also used (Figure 1).

All subjects in the intervention and control groups were followed for HAI. Subjects included in the study were closely monitored by Infection Control Committee (ICC) and the researcher nurse. Subjects in the intervention and control groups were daily monitored for white blood cell, tachycardia, and fever after 24 hours in the ICU. CVC observation data of subjects in both groups was evaluated daily with the data collecting form developed by the researcher. The control group received routine CVC care using sterile gauze, povidone iodine and elastic fixation tape. When the central line was removed, the catheter tip was sent to culture. Equipment present in the hospital and routine tests were used in both groups (Figure 2).

Statistical Analysis

SPSS version 21.0 (IBM SPSS Inc, Armonk, NY) software was used for statistical analyses of data obtained in the study. Sociodemographic characteristics, chronic diseases, cancer and smoking status of subjects were defined using descriptive statistics (number, percentage), mean and standard deviation. Mann-Whitney U test and Pearson chi-squared tests were used to determine the differences between the intervention and control groups. Results were assessed in 95% confidence interval and $p < 0.05$ significance.

Results

Mean age of patients in the intervention group was 57.96 ± 17.17 years. Out of these patients, 54.6% were male, 91.6% did not smoke, 68.7% had a history of chronic illness and 34.9% had a history of cancer. Mean duration of stay in the ICU was 6.38 ± 10.24 days and mean APACHE score was 10.34 ± 8.28 . On the other hand, mean age of subjects in the control group was 64.06 ± 14.92 years. Out of these subjects, 58.8% were male, 91.3% did not smoke, 63.8% had a history of chronic illness and 33.8% had a history of cancer. Mean duration of stay in the ICU was 11.91 ± 18.60 days and mean APACHE score was 13.87 ± 7.85 .

Age ≥ 65 years, smoking and cancer history were considered as intensive care risk factors. Among the intervention group, 61.4% of subjects had a risk factor, while 72.5% of subjects in the control group had an intensive care risk factor.

There was a significant difference between the intervention and control groups in terms of mean age, duration of ICU stay and APACHE-II score ($p < 0.05$), while



Figure 1. Contents of care bundle

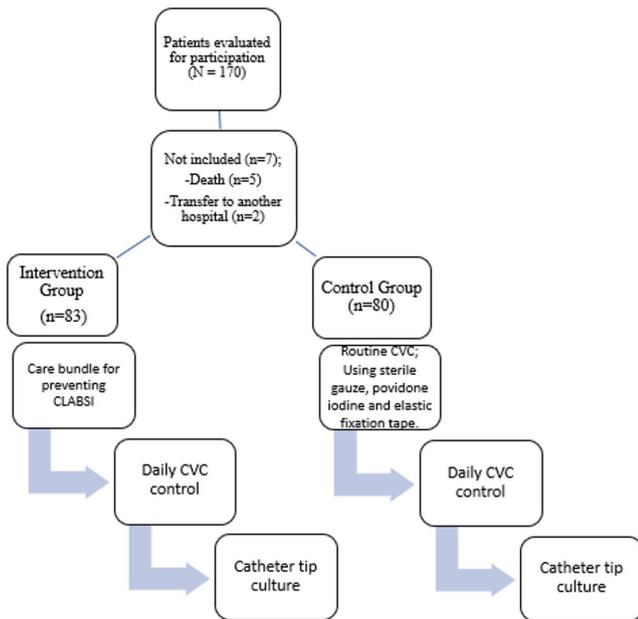


Figure 2. Patients’ randomization flowchart
CVC: Central venous catheter, CLABSI: central line-associated bloodstream infections

the duration of hospital stay did not show a statistically significant difference between two groups ($p=0.105$) (Table 1).

The central line was inserted through the right jugular vein (RJV) in 77.1% and the left subclavian vein in 19.3% of patients in the intervention group. For the control group, RJV was preferred in 75% and left subclavian vein was preferred in 15% (Table 2).

All subjects included in the study was closely monitored for signs and symptoms of HAIs by the ICC and the researcher. Nine patients in the intervention group (10.8%) exhibited signs and symptoms of infection. Among those, all nine had fever ($>38.5\text{ }^{\circ}\text{C}$), 44.4% had leukocytosis and 55.6% had tachycardia ($>120\text{ bpm}$). The remaining 89.2% had no signs or symptoms of infection. In the control group, 36.2% exhibited signs and symptoms of infection, which were leukocytosis, fever, and tachycardia (93.1%, 96.6% and 44.8%, respectively). The remaining 51 control subjects (63.8%) did not develop any related signs of symptoms. The difference in signs and symptoms of infection between the intervention and control groups was statistically significant ($p<0.05$) (Table 3).

Table 1. Comparison of descriptive and medical characteristics of patients who received and did not receive care bundle

		Intervention group n=83	Control group n=80		
		n (%)	n (%)	x ²	p-value
Gender	Female	36 (43.4%)	33 (41.3%)	0.075	0.874
	Male	47 (54.6%)	47 (58.8%)		
History of smoke	Yes	7 (8.4%)	7 (8.8%)	0.05	0.943
	No	76 (91.6%)	73 (91.3%)		
History of chronic illness	Yes	57 (68.7%)	51 (63.8%)	0.442	0.506
	No	26 (31.3%)	29 (36.3%)		
History of cancer	Yes	29 (34.9%)	27 (33.8%)	0.026	0.873
	No	54 (65.1%)	53 (66.3%)		
Risk factors	Yes	51 (61.4%)	58 (72.5%)	2.247	0.134
	No	32 (38.6%)	22 (22.5%)		
		Mean ± SD	Mean ± SD	Z_{MWU}	p-value
Age		57.96±17.17	64.06±14.92	-2.333	0.020
Stay in the hospital		13.03±10.53	18.9±20.85	-1.619	0.105
Stay in the ICU		6.38±10.24	11.91±18.60	-2.450	0.014
APACHE-II score		10.34±8.28	13.87±7.85	-3.906	0.000

x²: Chi-square test, SD: standard deviation, ICU: intensive care unit, APACHE-II: Acute Physiology and Chronic Health Evaluation-II, Z_{MWU}: Mann-Whitney U test; p<0.05

Table 2. Distribution of CVC sites

	Intervention group	Control group
	n (%)	n (%)
Right jugular vein	64 (77.1%)	60 (75%)
Right subclavian vein	16 (19.3%)	12 (15%)
Left subclavian vein	2 (2.4%)	1 (1.3%)
Right femoral vein	1 (1.2%)	3 (3.8%)
Left jugular vein	-	3 (3.8%)
Left femoral vein	-	1 (1.3%)

CVC: Central venous catheter

The catheter tip cultures obtained from subjects included in the study were positive in 8.4% of the intervention group and in 40.5% of the control group. The most frequently isolated microorganism was *Staphylococcus epidermidis* (4 vs. 20) and the difference was statistically significant.

All central lines of patients included in the study were observed for redness, swelling and discharge by the researcher and the findings were recorded to the Central Venous Catheter Care and Follow-up Form developed by the researcher. Signs of local inflammation in the catheter entry site were observed in 7.2% of patients in the intervention group. All 6 patients had redness, 16.6% had swelling and none had discharge. On the other hand, 41.3% of patients

Table 3. Comparison of infection signs in patients who received and did not receive care bundle

Symptom of infection*	n (%)	x ²	p-value		
Intervention group					
Signs (yes)	9 (10.8%)	14.708	0.000		
Leukocytosis	4 (44.4%)				
Fever	9 (100%)				
Tachycardia	5 (55.6%)				
Signs (no)	74 (89.2%)				
Control group					
Signs (yes)	29 (36.2%)				
Leukocytosis	27 (93.1%)				
Fever	28 (96.6%)				
Tachycardia	13 (44.8%)				
Signs (no)	51 (63.8%)				

*More than one symptoms, x²: chi-square test; p<0.05

in the control group exhibited signs of local inflammation in the catheter entry site. All of those had redness, 21.2% had discharge and 6.0% had swelling. The difference between the intervention and control groups in terms of redness and discharge in the catheter entry site was statistically significant (p<0.05) (Table 4).

Table 4. Comparison of CVC observations of patients who received and did not receive care bundle

	Intervention group	Control group		
	n (%)	n (%)	χ^2	p-value
Symptom of infection*	6 (7.2%)	33 (41.3%)	25.904	0.000
Redness	6 (100%)	33 (100%)	25.904	0.000
Discharge	0 (0%)	7 (21.2%)	7588	0.000
Swelling	1 (16.6)	2 (6%)	0.378	0.530

*More than one symptoms, CVC: Central venous catheter, χ^2 : chi-square test; $p < 0.05$

All subjects included in the study were evaluated according to the diagnostic criteria of CLABSI. No patients in the intervention group had CLABSI while 10% of the patients in the control group were diagnosed with CLABSI.

Discussion

HAIs are observed more often in ICUs due to patient-healthcare worker relationship, common use of mechanic ventilators and invasive equipment, common use of broad-spectrum antibiotics and more frequent colonization of resistant microorganisms. The incidence of HAI in the world varies between 7% and 10%. An estimated 1.4 million people worldwide are thought to have nosocomial infections every day. It is reported that nosocomial infections develop in 5% to 10% of hospitalized patients in a year in the USA, while this rate is between 6-9% in Europe, and this rate varies between 1-3% and 16% in Turkey. Although 5-10% of hospitalized patients are primarily treated in the ICU, 20-25% of all HAIs are seen in ICUs. Patients hospitalized in the ICU are at higher risk of developing infection compared to patients treated in other units, due to the severity of their condition and exposure to highly invasive procedures. It is stated that 53.6% of HAIs seen in ICUs result in death, and considering this rate, the prevention and control of HCAIs is of great importance (10-12).

Although the care bundle is a new concept, its strongest feature is that it includes evidence-based care interventions. The fact that science is behind it and the method of intervention requires continuity gives it national and international standards. It is generally recommended that the number of maintenance-related items (maintenance intervention) in the bundle be between 3 and 5. It is stated that each intervention should be the most accepted (the

most effective care for the patient) intervention in its field. The care bundle is often confused with checklists. A checklist is a mix of useful practices or processes (important and useful, but not evidence-based changes), while a bundle is a mix of imperative processes (proven by randomized controlled experiments) (13). It can also be used with the 5 basic component checklists included in the care bundle. Organizations such as the Institute for Healthcare Improvement and The Joint Commission have created lists of CLABSI prevention interventions. In the study, the CDC checklist, which includes the subtitles of the main components in the care bundle and has been proven by studies in the literature, was used.

The use of care bundle for placement and maintenance of CVCs is an important strategy for CLABSI prevention. Care bundle consist of structured evidence-based practices that aim to improve the care process and patient outcomes when followed collectively and reliably. Care bundle have proven effective in reducing CLABSIs in ICU patients (14).

As the longer duration of hospital and ICU stay increases the need for a CVC, it also increases the risk of CLABSI (15-17). On the other hand, Bohart et al. (18) reported no significant association between the duration of ICU stay and CLABSI risk. In the current study, we found that the risk of CLABSI was higher in patients with longer ICU stay. However, the mean duration of hospital stay had no statistically significant difference.

The studies about the association of age and HAIs have reported conflicting results. While some authors state then age is associated with infection (19,20), there is other report that found no association between age and risk of HAI (21). In our study, the mean age of the intervention and control groups were significantly different.

APACHE-II, which predicts disease severity by incorporating changes in physiological measurements, is the most common scoring system used in ICUs. It consists of three parts: chronic health evaluation, age and acute physiology score. The total score of these three parts along with whether the patient is planned to undergo a surgical intervention predicts hospital mortality. In our study, the difference between the mean APACHE-II scores was statistically significant, which was consistent with Pawar et al. (22) but contradictory to Hsin et al. (23).

The preferred anatomical site of CVC insertion is determined by the applying physician. The care bundle states that when selecting the site of CVC use of femoral vein

should be avoided when possible and emergency femoral vein interventions should be switched to a more appropriate site when the patient is hemodynamically stable (2). It was thought that the location of the catheter also affected the development of infection, and the infection rate would be higher due to the risk of urinary and fecal contamination, especially in the femoral vein, but it was reported that there was no difference in infection between the femoral vein and the subclavian vein in studies (24). In our study, most of the central lines of patients in the intervention group were inserted through the RJV. Femoral vein was used in only one patient in the intervention group and the site of CVC was changed as soon as possible in this patient. RJV was also the most preferred entry site in the control group. RJV was a commonly preferred route in the study hospital due to its easy access and availability of rapid intervention in the risk of complications. Aygun et al. (25) also did not find a significant relationship between the location of the catheter and the risk of infection.

Preparation the area where the catheter will be inserted is another matter to be considered. Chlorhexidine, povidine iodine and 70% alcohol are antiseptic products used. In recent years, due to the strong binding of chlorhexidine to skin proteins and its antimicrobial effect on the skin for 48 hours, it is recommended to perform skin antisepsis with 2% chlorhexidine gluconate among the components of the care bundle. In this study, 10% povidine iodine was used in the control group. Although transparent polyurethane or chlorhexidine-impregnated closure covers are among the preferred methods for the prevention of CLABSI in ICU, it is also known that the use of these products does not reduce the infection rate (26,27). Hatler et al. (28) compared transparent polyurethane and chlorhexidine-impregnated closure dressings, and no significant difference was reported in terms of the risk of infection development. In this study, all the catheters were inserted with aseptic technique, they were maintained with the same care and the entry points were checked. The dressings applied to the control group with sterile gauze were changed daily. Transparent dressings impregnated with chlorhexidine were used in the experimental group, and catheter care was performed weekly as long as the integrity of the dressing was not impaired.

Certain studies, however, report that there is no significant difference between the intervention and control groups in terms of signs of local inflammation (29-31). In

our study, signs and symptoms of local inflammation were significantly lower in the intervention group ($p < 0.05$). Among the control group, patients with signs and symptoms of local inflammation were found to have a higher risk of developing CLABSI. Our significant findings indicate that all stages of care bundle should be performed step-by-step.

In the current study various microorganisms causing CLABSI were isolated. Of these microorganisms, 50% were Gram-positive while the other 50% were Gram-negative. Gram-positive (Coagulase-negative *staphylococci*, *Staphylococcus aureus*) are the most frequently detected microbiological agents in CLABSI's. It is known that *staphylococci* are protected from antibiotics by wrapping the catheter thanks to their biofilm feature made of exopolysaccharides. Gram-negative agents and fungi are also common infectious agents (25). Lin et al. (19) showed that the most commonly isolated pathogens were Gram-negative bacteria with 38%, Gram-positive bacteria with 34.7%, *Candida* spp. with 24.0%, and anaerobic bacteria with 4.7%. İnan et al. (32) reported that 47.6% of microorganisms causing CLABSIs were Gram-negative bacteria, 44.8% Gram-positive, 6.1% *Candida* spp. and 1.5% other pathogens. Yoshida et al. (33) reported that Gram-negative bacteria were the most common pathogens with 61.8%, among which *Pseudomonas aeruginosa* was seen at a rate of 28.2%. Jaggi et al. (34) reported that 25% *Klebsiella* and 16% *Pseudomonas aeruginosa* 15% *Candida* are the pathogens causing CLABSI in their study. In our study, the most common microorganism causing CLABSI was *Staphylococcus epidermidis* with 37.5%.

Conclusion

Care bundle approach is found to be effective in preventing CLABSI. Interdisciplinary interactions should not be disregarded when implementing care bundle approach. It is important that nurses should take an active role in universalizing the care bundle and making sure each step is performed. Care bundle approach should be integrated into nursing care and nurses should be effective in its implementation. Applying the care bundle for preventing CLABSIs for all patients with a central line will increase the quality of care, patient satisfaction, improve nurses' job satisfaction and have a positive impact on economy.

Acknowledgement: Authors thank all participations.

Ethics

Ethics Committee Approval: Permission from the Haydarpaşa Numune Training and Research Hospital Ethics Committee (decision no: HNEAH-KAEK 2017/KK/143, date: 25.12.2017) and the institution were obtained prior to the start of the study.

Informed Consent: Patients and/or their first-degree relatives were informed about the study and written informed consents were obtained.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: E.P, İ.Ç., Concept: E.P, İ.Ç., Design: E.P, İ.Ç., Data Collection and Process: E.P, İ.Ç., Analysis or Interpretation: E.P, İ.Ç., Literature Search: E.P, İ.Ç., Writing: E.P, İ.Ç.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

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