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Chlorhexidine Gluconate for Perioperative Skin Cleansing to Reduce Surgical Site Infection and Bacterial Colonization: A Randomized Controlled Trial

Cerrahi Alan Enfeksiyonu ve Bakteri Kolonizasyonunu Azaltmak için Perioperatif Deri Temizliğinde Klorheksidin Glukonat Kullanımı: Randomize Kontrollü Çalışma

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Abstract

Introduction: This study aimed to define the role of chlorhexidine gluconate (CG) in preoperatively skin cleansing and surgical site infection (SSI) and bacterial colonization reduction.
Materials and Methods: This study was conducted in a public hospital on 120 patients, of whom 61 consisted the intervention group and 59 in the control group. The intervention group used bath gel that contains CG and the control group used bath gels/soap without any antiseptics. Using a swab, samples from the surgical site were taken from all patients before and after bath. Surgical sites were inspected in terms of redness, edema, or fluid drainage daily during their hospital stay, as well as at the 10th and 30th days after discharge. Fever, heart rate, and blood pressure were also followed closely. This data was recorded and statistically analyzed.
Results: Infection was detected in 3.3% (n=120) of participants. In the control group, 6.8% were infected. Infection was not observed in the intervention group. Five bacteria were analyzed in terms of the effect of CG use on bacterial colonization and it was found that only Coagulase-Negative Staphylococci (CNS) growth was decreased with the use of CG. This decrease was found to be statistically significant.
Conclusion: Our results suggest that cleansing the skin with CG before thoracic surgery may be beneficial in preventing SSI and reducing CNS colonization.
Keywords: Surgical site infection, bacteria colonization, skin cleaning

Öz

Giriş: Bu çalışma ameliyat öncesi klorheksidin glukonat (KG) ile yapılan deri temizliğinin cerrahi alan enfeksiyonlarının (CAİ) ve bakteri kolonizasyonunun azaltılmasındaki rolünü belirlemek amacı ile yapıldı.
Gereç ve Yöntem: Bu çalışma bir devlet hastanesinde 61'i müdahale grubunda, 59'u kontrol grubunda olmak üzere 120 hasta üzerinde gerçekleştirildi. Müdahale grubu KG içerikli duş jeli kullanırken kontrol grubu antiseptik ürün içermeyen duş jeli/sabun kullandı. Tüm hastalardan banyo öncesi ve sonrasında ameliyat bölgesinden kültür çubuğu ile kültür alındı. Hastalar taburcu olana kadar her gün, taburcu olduktan sonra ameliyatın 10. ve 30. günlerinde lokal olarak ateş, kızarıklık, ödem ve akıntı yönünden takip edildi. Hastaların ateşi, nabzı ve kan basıncı da takip edildi. Bu veriler kaydedildi ve istatistiksel olarak analiz edildi.

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Öz

Bulgular: Çalışmaya dahil edilen 120 hastanın %3,3'ünde, kontrol grubu 59 hastanın %6,8'inde enfeksiyon tespit edildi. Müdahale grubunda hiç enfeksiyona rastlanmadı. CG kullanımının bakteri kolonizasyonuna etkisi açısından 5 bakteri analiz edildi ve sadece koagülaz negatif stafilokokların (KNS) üremesinin CG kullanımı ile azaldığı saptandı. Bu azalmanın istatistiksel olarak anlamlı olduğu bulundu.
Sonuç: Bulgular, torasik cerrahi ameliyatı öncesi KG ile deri temizliğinin, CAİ'yi önlemede ve KNS kolonizasyonunu azaltmada faydalı olabileceğini göstermektedir.
Anahtar Kelimeler: Cerrahi alan enfeksiyonu, bakteri kolonizasyonu, deri temizliği

Introduction

The term "surgical site infection" (SSI) was accepted by the Center for Disease Control and Prevention (CDC) between 1992 and 1998 and was defined as an infection detected 30-90 days after surgery[1,2]. According to World Health Organization, SSI is defined as fluid drainage, abscess, or cellulitis of the surgical site seen within a month after surgery[3].

SSI is the third most commonly seen infection among healthcare-associated infections. SSI is the cause of 20% of healthcare-related infections[4]. According to earlier studies, 2% of patients who underwent surgery suffer from SSI[5]. According to the National Health Safety Network, SSI was detected in 16,147 of 849,659 patients who underwent surgery, with an estimated general SSI incidence of 1.9% and a mortality rate of 3% (75% of deaths were directly caused by an SSI)[6]. In our country, according to the National Hospital Infections Surveillance Network (UHESA) in 2014, SSI was detected in 4,257 of 506,851 patients who underwent surgery, with an estimated general incidence of 1.0%[7]. Additionally, according to UHESA in 2016, SSI was detected in 113 of 7073 patients who underwent thoracic surgery, with an estimated incidence of 1.6%[8].

SSI is seen in patients whose immune system is too weak to fight the organism that causes the infection. Despite the advances in asepsis and antisepsis applications, sterilization methods, operating theater conditions, surgical techniques, intensive care facilities, and prophylactic antibiotic applications, SSI remains a major and serious problem of modern surgery[9].

Skin preparation can be categorized as skin cleaning and hair removal in the preoperative period and skin preparation on the operating table in the intraoperative period. Skin is a risk factor for surgical site contamination. Therefore, permanent and temporary microorganisms and dirt should be removed in the preoperative period with skin cleansing[10].

The literature review using the keywords "SSI, Bacterial Colonization, Skin Cleansing" revealed a limited number of studies that presented contradictory results[11-16]. A randomized controlled study aimed to determine the role of bathing with chlorhexidine gluconate (CG) in the preoperative period in reducing SSI and bacterial colonization.

Materials and Methods

Study Design

This study aimed to determine the role of bathing with CG in the preoperative period in reducing SSI and bacterial colonization compared to bathing with soap/shower gel. This single-blind randomized controlled trial used two parallel groups.

Setting and Samples

The population of the study consisted of patients undergoing thoracic surgery in the Süreyyapaşa Chest Diseases and Thoracic Surgery Training and Research Hospital. Sample calculation was made by considering the infection rates of 31.6% in the control group and 4.8% in the intervention group in the reference study for the sample size. Using the Fisher's exact test, the sample size required for group comparison was calculated as 80 with Type I Error (Alpha) of 0.05 and 95% strength[17]. Considering that some patients could be excluded from the study for any reason or opt themselves and their data out of the study, the study was completed with 120 patients. Patients who met the inclusion criteria (40-60 years old, operated with thoracotomy, diagnosed with cancer, with pneumonectomy, and/or planned lobectomy) were included in the study. Patients with chlorhexidine allergy, using steroids or immunosuppressive drugs, using antibiotics for an infection in the last 2 weeks (prophylactic antibiotics are used for all patients on the day before surgery, thus this prophylactic antibiotic was not an excluding criteria), with autoimmune diseases, neutropenia, open wounds, anemia, diabetes mellitus, and body mass index (BMI) of >30 (obese patients) were excluded from the study.

Randomization

This study determined gender and smoking status, which are thought to have confounding effects, as layer variables. Patients were assigned to the intervention and control groups by stratified block randomization, which ensured that the groups had similar quantitative distribution and layer variables. The method application is as follows: patients were divided into four different groups according to their gender and smoking status

and assigned to the groups by block randomization method. A total of 122 patients were randomly assigned to groups. However, two patients were excluded from the study because thoracotomy was planned but not performed (Figure 1).

Instruments

Patient Data Form

This form includes demographic information about the patient, history of chronic illness, smoking status, hospitalization and discharge dates, which group it belongs to, and information about the operation performed.

Patient Follow-up Form

This form includes the infection diagnostic criteria (fever, redness, edema, and fluid drainage), vital signs (fever, pulse, and blood pressure), the time and results of samples, and nursing notes.

Data Collection/Procedure

Patients were randomly included in the study according to the exclusion and inclusion criteria. The extent of the surgical incision will be considered in the study, thus only patients who will be operated on via the thorax (thoracotomy) were included in the study. Patients in the intervention and control groups were interviewed the day before the surgery and were informed about the study, and their written consent was obtained.

One day before the surgery, the first culture was taken from the surgical area using a swab without applying any other procedure (wiping, shaving, etc.). The culture was taken from the lumbar region near the chest and 10 cm below the axilla. Then, those in the intervention group showered with CG at the same time on the morning of the surgery day (06:00-07:00 am). Those in the control group took a shower with antiseptic-free soap or shower gel simultaneously with the intervention group. The second culture/specimen was taken from all participants at 08:00 am on the day of the surgery (within the period after the bath, which the product maintains its effectiveness). Patients' vital signs were followed up every day during the hospital stay and on the 10th and 30th day after being discharged. The patients undergoing surgery were followed up every day for the signs and symptoms of infection (fever, redness, pain, and edema) during the hospital stay and the findings were recorded on the patient's follow-up form. The Stuart transport medium used in the study was sterile and capable of protecting the sample for 24 h. A uniform intensive care monitor, sphygmomanometer, thermometer, and portable pulse oximeter, which were regularly calibrated by the authorized company, were used to monitor the vital signs. The surgical duration was important for our study,

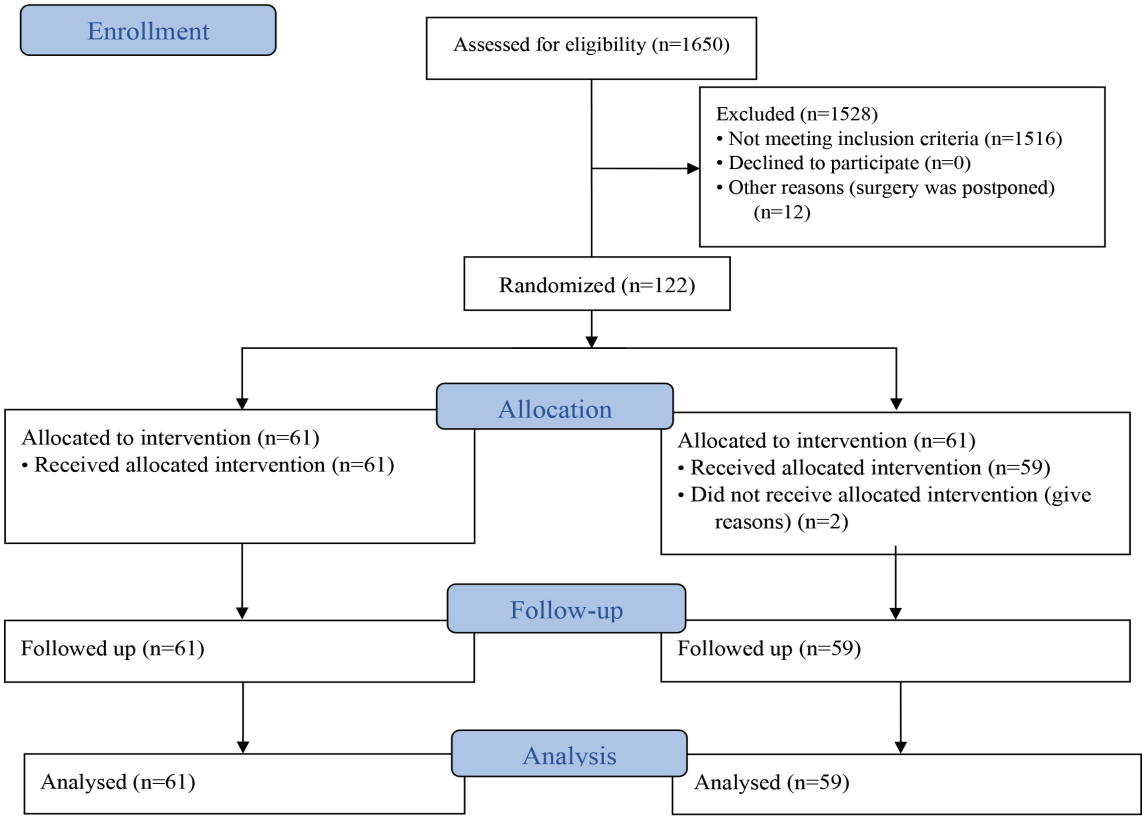

Figure 1. CONSORT flow diagram

thus all patients to be operated on with thoracotomy in the hospital were generally taken to the operating theater between 08:00 and 12:00 o'clock. According to the research data, the effect time of the product used is 30 sec and lasts 6-8 h. Thus, considering all these conditions, all participants showered at the same time, and immediately afterward, the sample was taken to provide a standard. The Microbiological Laboratory team did not know to which group of patients the sample belonged, as well as the nurses. The single-use shower gel containing CG and the transport medium was provided by a microbiologist. There is no preoperative bath application in the preoperative preparation procedure applied in the institution where the study is conducted. Within the context of preoperative preparation, only information about the hospital, the disease, and the process is provided.

The ethical committee approval dated 06/09/2018 and numbered 2018-05 from the Maltepe University Ethics Committee and the permission of the institution where the study was conducted was obtained. After providing the necessary study information, written informed consent was obtained from all participants.

Statistical Analysis

The Statistical Package for the Social Sciences version 25 and R software nparLD packages were used for statistical analysis. Qualitative variables of the groups were summarized as numbers and percentages and tested with the chi-square test. Quantitative data were summarized as mean and standard deviation and tested in independent samples by t-test. The distributions of culture reproduction numbers were skewed, thus the non-parametric Wald test was tested with R software nparLD package to simultaneously analyze both before-after and intervention-control groups. Data analysis was evaluated at a 95% confidence interval and p-values of <0.05 were considered significant.

Results

The obtained data revealed no significant difference between the groups in terms of the mean age, gender, BMI, smoking history, and operation type (Table 1). The difference between the groups in terms of infection distributions was not statistically significant (X^2=4,278; p=0.0554). Infection was seen in 6.8% of the control group and none in the intervention group. Infection was seen in 3.3% of all patients (Table 2). The change in coagulase-negative staphylococci (CNS) reproductive amounts in pre- and post-shower measurements between the groups was significantly different (Wald=3,907; p=0.048). The group * time interaction effects were not significant in terms of culture growth of *Neisseria*, *Corynebacterium*, *Micrococcus*, and *Alpha Streptococcus* bacteria (respectively; Wald=3,503, p=0.061; Wald=0.150, p=0.699; Wald=0.150, p=0.699; and Wald=0.150, p=0.699) (Table 3).

Table 1. Comparison of age, sex, smoking history, BMI, and type of operation

		Experimental group	Control group	t	SD	p	X^2
Age	n	61	59	-0.378	118000	0.706	
	Mean	53.52	53.17				
	Standard deviation	5.06	5.24				
Sex	Woman	13 (21.3)	13 (22)			1.000	0.009
	Man	48 (78.7)	46 (78)				
Smoking history	Smoking	26 (42.6)	24 (40.7)			0.855	0.047
	No smoking	35 (57.4)	35 (59.3)				
BMI	n	61	59	0.018	118000	0.986	
	Mean	24.69	24.69				
	Standard deviation	1.79	2.06				
Operation type	Lobectomy	47 (77)	44 (74.6)			0.832	0.100
	Pneumonectomy	14 (23)	15 (25.4)				

BMI: Body mass index, SD: Standard deviation

Table 2. The comparison of groups in terms of infection distribution

	SSI			
	Infection (–)	Infection (+)	X^2	p
Control group	55 (93.2)	4 (6.8)	4,278	0.055
Experimental group	61 (100)	0 (0)		

*Fisher's Exact test **Exact p-value

SSI: Surgical site infection

Table 3. The evaluation of bacterial growth in terms of group * time interaction

Bacteria type	Group-time	Raw average.	n	Relative effect size	Wald ist.	SD	p
CNS	Control group	137.17	118	0.569			
	Experimental group	104.37	122	0.433			
	Before	137.91	120	0.573			
	After	103.64	120	0.430			
	Control group: before	149.00	59	0.619			
	Control group: after	125.35	59	0.520			
	Experimental group: before	126.81	61	0.526			
	Experimental group: before	81.93	61	0.339			
	Group				14,070	1	P<0.001
	Time				40,729	1	P<0.001
	Group: time				3,907	1	0.048
Neisseria	Control group	122.28	118	0.507			
	Experimental group	118.77	122	0.493			
	Before	126.09	120	0.523			
	After	114.97	120	0.477			
	Control group: before	124.63	59	0.517			
	Control group: after	119.94	59	0.498			
	Experimental group: before	127.55	61	0.529			
	Experimental group: after	110.00	61	0.456			
	Group				0.473	1	0.491
	Time				10,469	1	0.001
	Group: time				3,503	1	0.061
Corynebacterium	Control group	123.28	118	0.512			
	Experimental group	117.82	122	0.489			
	Before	123.94	120	0.514			
	After	117.15	120	0.486			
	Control group: before	126.12	59	0.523			
	Control group: after	120.43	59	0.500			
	Experimental group: before	121.76	61	0.505			
	Experimental group: after	113.87	61	0.472			
	Group				0.974	1	0.324
	Time				5.666	1	0.017
	Group: time				0.150	1	0.699
Micrococcus	Control group	120.53	118	0.500			
	Experimental group	120.47	122	0.500			
	Before	121.49	120	0.504			
	After	119.51	120	0.496			
	Control group: before	120.54	59	0.500			
	Control group: after	120.52	59	0.500			
	Experimental group: before	122.44	61	0.508			
	Experimental group: after	118.50	61	0.492			
	Group				0.001	1	0.981
	Time				2.060	1	0.151
	Group: time				2.007	1	0.157

Table 3. Continued

Bacteria type	Group-time	Raw average.	n	Relative effect size	Wald ist.	SD	p
Alpha *Streptococcus*	Control group	119.50	118	0.496			
	Experimental group	121.47	122	0.504			
	Before	121.47	120	0.504			
	After	119.50	120	0.496			
	Control group: before	119.50	59	0.496			
	Control group: after	119.50	59	0.496			
	Experimental group: before	123.43	61	0.512			
	Experimental group: after	119.50	61	0.496			
	Group				2,034	1	0.154
	Time				2,034	1	0.154
	Group: time				2,034	1	0.154

SD: Standard deviation, CNS: Coagulase-negative staphylococci

Additionally, for the same bacteria, the distribution between the groups regardless of the time, was not significant (respectively; Wald=0.473, p=0.491; Wald=0.974, p=0.324; Wald=0.974, p=0.324; and Wald=0.974, p=0.324). In *Neisseria* and *Corynebacterium*, regardless of the groups, the distributions between the first and the last measurement were statistically significant, the mean order of the last measurements was lower than the first measurements (respectively; Wald=10,469, p=0.001; Wald=5,666, p=0.017). In *Micrococcus* and *Alpha Streptococcus* bacteria, regardless of the groups, the distributions between the first and the last measurement were not statistically significant (respectively; Wald=5,666, p=0.017; Wald=5,666, p=0.017) (Table 3).

Discussion

In this study, in the preoperative stage, 61 patients were bathed with CG and 59 with antiseptic-free shower gel or soap. Study results revealed no infection in the intervention group, whereas 4 in the control group. This result was not statistically significant (p=0.055). While 6.8% of the control group gets infected, none was seen in the intervention group, suggesting that the product reduced the risk of SSI. This finding is not statistically significant; however, it suggests its clinical importance (Table 2). This study revealed that infection developed at a lower rate than the reference study used for the sample size, which indicates the success of the clinic. However, this seems to have caused the sample size of the study to remain low for the specific conditions. Some studies in the literature reported that the use of CG can reduce SSIs[12,15,18-20]; however, some studies reported that the use of CG is not effective on SSIs[11,13,14].

Kaiser et al.[15] included more than 700 patients who preoperatively used CG, povidone-iodine, and triclocarban soaps baths. They revealed that the solutions and soaps reduced the number of microbial colonies in the skin but no data were available about SSI decreases[15].

Holder and Zellinger[20] emphasized that preoperative skin cleaning with 2% or 4% CG is a good procedure to prevent infections. Another study revealed that cleansing with 2% CG-impregnated cloth during preoperative skin preparation is effective in reducing SSI[12]. A statement published in 1999 reported that taking a bath with an antiseptic soap or shower gel the day before surgery decreases the SSI rates[18]. Tayran[19] argues that insufficient skin preparation and contaminated antiseptics will increase the risk of SSI.

Additionally, some other studies have argued that the use of CG has no significant effect on reducing SSI. Webster and Osborne[11] investigated the effects of preoperative baths with antiseptics in preventing SSI and revealed that bathing with 4% CG was effective in reducing SSI compared to no bathing at all. It was determined that 4% CG, is more effective than povidone-iodine and soap, but without clear evidence that CG baths are superior to other bathing products used in the preoperative period[11]. Another study on this subject revealed that the use of chlorhexidine did not cause a significant decrease in the incidence of SSI compared to soap, placebo, or no shower[13]. Savage and Anderson[14] reported that the use of a chlorhexidine bath gland before surgery may reduce the risk of SSI, but without clear clinical evidence that an antiseptic-containing solution effectively reduces the rate of postoperative infection. The same study revealed that chlorhexidine did not decrease SSIs[14].

In this study, the most frequently seen five bacteria were statistically analyzed according to culture results. According to the analysis, the use of CG decreased CNS growth, which was statistically significant (p=0.048). *Neisseria*, *Corynebacterium*,

Micrococcus, and *Alpha Streptococcus* growth were statistically insignificant (Table 3). A literature review shows studies about the effect of preoperative skin cleansing with antiseptic-containing shower gel on the reduction of bacterial colonization. Jakobsson et al.[21], Karki and Cheng[22], Malazgirt[23], and Dönmez[10] argue that bathing with antiseptic shower gels before surgery reduces bacterial colonization in the skin.

According to these findings, CG is more effective than soap or shower gel in terms of skin cleansing, infection prevention, and bacterial colonization reduction.

This research is limited to patients who have undergone thoracic surgery. In the intraoperative period, the surgical team was assumed to comply with all asepsis and antisepsis rules and the patients followed the instructions for chlorhexidine product usage.

Conclusion

Our study results revealed that the shower taken in the preoperative stage by applying CG was not statistically significant in terms of decreasing SSI between the groups. However, the use of CG was effective in reducing CNS growth and suggests that preoperative skin cleansing with CG may be effective in reducing bacterial colonization.

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Ethics

Ethics Committee Approval: The ethical committee approval dated 06/09/2018 and numbered 2018-05 from the Maltepe University Ethics Committee.

Informed Consent: Consent form was filled out by all participants.

Peer-review: Externally and internally peer-reviewed.

Authorship Contributions

Concept: A.Y., S.A., A.K., Design: A.Y., S.A., A.K., Data Collection or Processing: A.Y., S.A., A.K., Analysis or Interpretation: A.Y., S.A., A.K., Literature Search: A.Y., S.A., A.K., Writing: A.Y., S.A., A.K.

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