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Does the use of chlorhexidine gel reduce the frequency of surgical site infections?

Authors' Contribution:
A – Study Design
B – Data Collection
C – Statistical Analysis
D – Data Interpretation
E – Manuscript Preparation
F – Literature Search
G – Funds Collection

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ABSTRACT:

Introduction: Surgical site infections (SSI) involve 2–11% of all surgical procedures.

Paper assumption: The use of 6% gel with chlorhexidine as an element of preoperative skin preparation of the operated area reduces the number of surgical site infections.

Aim: The aim of the study was to assess the impact of body mass index (BMI), neutrophil to lymphocyte ratio (NLR), total protein, glucose, length of hospitalization before surgery, duration of surgery, length of drainage maintenance, transfusion of red blood concentrate on the number of SSI.

Materials and methods: 248 patients were subjected to prospective analysis. Patients were operated at the Department of General and Oncological Surgery of the Provincial Specialist Hospital in Zgierz. Patients were divided into three groups depending on the microbiological degree of cleanliness of the postoperative wound: Group I – clean wounds, Group II – clean-contaminated wounds, Group III – contaminated wounds, which also included emergency surgerical procedures. In each group two subgroups were distinguished depending on the method of preoperative preparation of the surgical field: A – gel without CHG, B – 6% gel with CHG.

Results: Surgical site infections were found in 22 patients (8.9%). The respective frequencies for groups I, II, III are: 3.0% vs 12.9% vs 12.7%. An increase in NLR by one unit resulted in a higher incidence of surgical site infections by 11%. A transfusion of RBC to the patient resulted in a 3.5-fold increase in the frequency of surgical site infections. Extending the drain maintenance time by one day increases the SSI frequency by 41%. Lowering the total protein concentration by at least 1 g/dl below normal increases the risk of surgical site infections almost three times.

Conclusions: The use of a 6% gel preparation with chlorhexidine as an element of preoperative preparation of the surgical field reduces the risk of surgical site infections, especially in clean-contaminated and contaminated wounds.

KEYWORDS: chlorhexidine, surgical site infections

ABBREVIATIONS

BMI – body mass index
CDC – Centers for Disease Control and Prevention
CHG – chlorhexidine gel
CRP – C-reactive protein
ESBL – extended-spectrum beta-lactamases
MRCNS – methicillin-resistant coagulose-negative staphylococci
NLR – neutrophil to lymphocyte ratio
SSI – surgical site infection
WBC – white blood cells

INTRODUCTION

Surgical site infection (SSI) is a complication which continues to be a real challenge despite the development of medicine. This finds confirmation in a critical report of 2008 the Supreme Audit Office regarding hospital infections, which has given rise to the idea for the study aiming to formulate a means to decrease the frequency of SSI. According to the latest studies, it is estimated at 2–11% of all surgical operations.

ASSUMPTIONS AND OBJECTIVES OF PAPER

The use of 6% chlorhexidine gel (CHG) as an element of preoperative preparation of the skin at the operated site reduces the number of infections of the operated area. The aim of the study is to assess the impact of: BMI and NLR indicators, total protein concentration, glucose concentration in the postoperative period, length of hospital stay before surgery, duration of surgery, time to remove drain, transfusion of red blood concentrate on the number of infections of the surgical site.

MATERIALS AND METHOD

A total of 248 patients undergoing scheduled and emergency surgery in the Department of General and Oncological Surgery with the Urological Unit of the Provincial Specialist Hospital in Zgierz were subjected to prospective analysis. Consent to the study was issued by the Bioethics Committee of the Medical University of Łódź of June 14, 2016 with the number RNN/186/16/KE. Patients were divided into three groups depending on the microbiological degree of cleanliness of the postoperative wound: group I-clean wounds, group II-clean-contaminated wounds, group III-contaminated wounds, which also included emergency surgery. The first group comprised 100 patients, while the second included 85 and the third 63 individuals. Two groups were distinguished in each group depending on the method of preoperative preparation of the operative field: A – gel without CHG, B – 6% gel with CHG. The types and number of treatments performed in a given group are presented in Tab. I.

Tab. I. Types and number of procedures in individual groups.

GROUP I [100 PATIENTS]	GROUP II [85 PATIENTS]	GROUP III [63 PATIENTS]
Lichtenstein inguinal hernia repair	Elective surgery for intestinal tumor [25]	Orchidectomy for suppurative orchitis [13]
Radical orchidectomy without infection [25]	Transvesical Harris-Hryntschak prostatectomy [25]	Appendectomy for purulent appendicitis [25]
Hydrocele surgery [25]	Open radical prostatectomies [13]	Classical cholecystectomy for acute cholecystitis [25]
Nephrectomy and	Radical cystoprostatectomy with Bricker ileal conduit [25]	
Organ-preserving renal tumor excision [25]		

Exclusion criteria adopted in the study were: innate or acquired immunodeficiencies including immunosuppressive therapy, active inflammation of the skin at the operated site, positive bacteriological urine test, and severe general condition of the patient.

The age of patients included in the study and operated on in the years 2016–2019 at the the Department of General, Oncological and Urological Surgery fell within the limits of 18 and 85 years of age. The average age for the entire study group was 60.4 ± 14.9 years. The age of men ranged from 23 to 85 years, average 60.7 ± 14.3 years. However, the age of women was found to range from 18 to 83 years, and the average age was 59.1 ± 17.4 years. Among all respondents there was a dominance of men – 202 patients, who constituted as much as 81.5%. On the day of the procedure, each patient took a shower using ordinary soap. The same preparation was used in all patients. Next, the subjects were randomly assigned to one of two ways to prepare the skin at the surgical site. The first, which constituted the control group, involved application to the skin at the operated site of the base gel – without the content of chlorhexidine and other antiseptics (method A) – 60 minutes before surgery. The second, which constituted the study group, consisted in covering the operated site with a thin layer of 6% chlorhexidine gel (method B) – 60 minutes before surgery. Chlorhexidine gel was prepared by the hospital pharmacy according to the recipe: 20% chlorhexidine gluconate solution, drug base. The cost of its preparation is about PLN 15 for a 100 g pack. Skin swabs were taken twice from the operated site in all patients. The first was collected immediately after admission to the hospital to identify microorganisms on the skin, while the second was taken in the operating theater after using one of two ways of preparing the operative field to assess their effectiveness. Stuart swabs were used for collection. Microbiological tests were performed at the certified Laboratory of Bacteriology and Parasitology of the Provincial Specialist Hospital in Zgierz. All patients received perioperative antibiotic prophylaxis. In group I, cefazoline 1 g or 2 g was used for body weight over 80 kg. In the second group, cefazoline was applied analogously and furthermore, one dose of metronidazole 0.5g in gastrointestinal opening procedures. In the third group, permanent antibiotic treatment in the form of amoxicillin/clavulanic acid (2 × 1.2 g) and metronidazole (3× 0.5 g) was used for infected wounds.

In the third group, which includes contaminated wounds, permanent treatment with antibiotic was implemented, (more specifically), amoxicillin with clavulanic acid (2 × 1,2 g) as well as metronidazole (3 × 0.5 g) were used. Antibiotics were administered about 30 minutes before the first skin incision. The obtained data were subjected to statistical analysis and calculations were made in Statistica 10 software, License number: AXAP 109E735901A 10-K.

RESULTS

Skin culture at the operated site

In the course of the study, a total of 518 cultures were collected to identify pathogens on the skin at the operated site or microorganisms that cause infection of the surgical site. The results of the first culture taken at admission to the hospital are presented in Tab. II. These are microorganisms typically found on human skin – mostly staphylococci with a predominance of coagulase-negative. In nearly 34% (83 cases) of results of culture I, the flora was polybacterial (more than one pathogen was isolated). A total of 322 bacterial strains were isolated – Tab. II.

The results of the second culture (Tab. III.) are similar to those of the first culture. However, the higher frequency of isolation of intestinal bacteria – Escherichia coli and Enterococcus faecalis – is noteworthy. A conceivable explanation is that this difference is probably due to the transfer of microorganisms from the perineum during bathing with soap. Less than 21% (52 cases) of the second culture results were polybacterial. During the analysis of the results of the second culture, attention should be paid to the results in patients prepared with B-6% gel from CHG. In 96% these were negative (sterile) results; microbes were isolated only in 5 cases. This difference is visible in the total number of bacterial strains isolated in culture I and II – 322 vs 177 (Tab. II. and III.).

Surgical site infections

In the group of all examined patients, surgical site infections occurred in 8.9% (22 patients). A statistically significant difference was found in the incidence of surgical site infections in the analyzed groups I, II and III ($p < 0.05$). Infections were the least frequent in group I, and apparently more often in groups II and III. Suitable frequencies are: 3.0% vs 12.9% and 12.7%. As can be seen, the incidence of surgical site infections in groups II and III was similar. The incidence of surgical site infection was compared in each group considering the method of preparation of the operative field: subgroup A – gel without CHG, subgroup B – 6% gel with CHG. In subgroup IA, the incidence of infection was 6.1%, and in subgroup IB there was no infection (0%). This difference was not statistically significant ($p > 0.05$). In group II, there was a statistically significant difference between subjects in whom the operative field was not prepared using a chlorhexidine gel and patients in which the operative field was prepared with the gel ($p < 0.05$). It turned out that in patients with a gel without CHG, the incidence of infection was significantly higher than in patients using a chlorhexidine gel. Relevant infection rates were: 20.9% vs. 4.8%. Similarly, in group III, there was also a statistically significant difference between subjects in whom the operative field was not prepared using a chlorhexidine gel and patients in whom the operative field was prepared with a 6% gel with CHG ($p < 0.05$). The incidence of infection was substantially higher in patients without a gel with CHG than in patients with a gel with chlorhexidine. Relevant infection rates were: 21.9% vs 3.2% (Ryc. 1.).

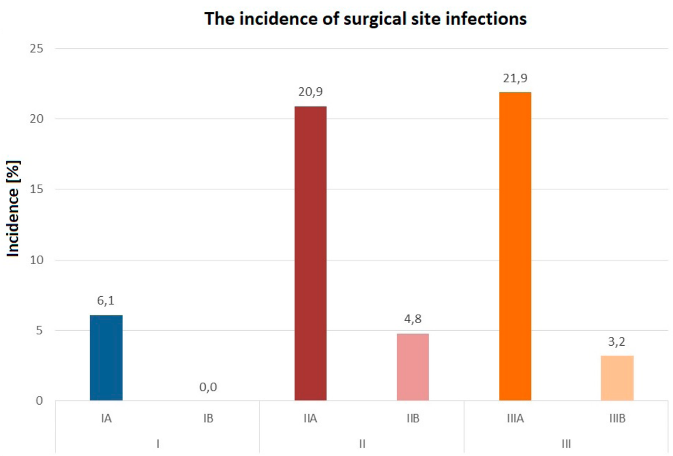

Fig. 1. The incidence of surgical site infections in individual subgroups.

Tab. IV. presents types of microorganisms isolated in the event of surgical site infection. Nine cases of SSI (41%) were polybacterial. Gram-positive staphylococci were most commonly isolated in 64.5% of cases, and among them the bacterium mainly responsible for SSI is Staphylococcus epidermidis. Strains of MRCNS, i.e. methicillin-resistant coagulase-negative staphylococci, as well as ESBL (extended-spectrum beta-lactamases) strains, considered as alert pathogens, were also cultured.

Assessment of risk factors for surgical site infection – SSI

Concluding from the analysis in Tab. V., the subjects who did not use the 6% chlorhexidine gel are affected by an infection of the surgical site more than seven times more often than people who used the gel (OR = 7.30; $p < 0.01$). Also, the statistically significant impact on the occurrence of infection was seen in the NLR index; it turned out that the increase in its size by one unit raised the frequency of SSI by 11% (OR = 1.11; $p < 0.05$). In turn, a reduction in total protein concentration of 1g/dl causes an almost threefold increase in the incidence of SSI (OR = 0.34; $p < 0.01$). A significant statistical influence on the occurrence of postoperative wound infection was seen in transfusion of a preparation of red blood cell concentrates. In patients who were transfused RPBCs, surgical site infection occurred more than 3.5 times more frequently than in those who were not treated for RPBCs (OR = 3.59; $p < 0.01$). The time to hold the drain also had a statistically significant impact on the occurrence of infection; prolonging the time by one day increased the chance of infection of the operative field by 41% (OR = 1.41; $p < 0.05$). In contrast, no statistically significant effect was found on the incidence of infection of the operative field of the following variables: gender, age, BMI, duration of hospital stay before surgery, postoperative blood glucose levels and type of surgery (general surgery or urology).

DISCUSSION OF RESULTS

Chlorhexidine digluconate as an antiseptic for topical use has been available for over 50 years [2]. It has a broad scope of application in the entire healthcare system and is the most commonly used in preoperative preparation of the operative field. It is used in various forms: 2–4% bath soap, wipes impregnated with a 2% solution of chlorhexidine or powder for armpits and groin. Recently, the range of preparations containing CHG has expanded significantly. CHG can be used in the form of a gel (for the placement of intravesical catheters), mouthwash or lozenges for throat infections [3, 4].

Tab. II. Results of culture I – all groups – 322 bacterial strains in total.

MICROBE	NUMBER OF STRAINS [N]	PERCENTAGE OF STRAINS [%]
S. epidermidis MSCNS	78	24.2
S. epidermidis MRCNS	44	13.6
S. haemolyticus MSCNS	40	12.4
S. hominis MSCNS	39	12.1
S. capitis MSCNS	28	8.7
S. aureus MSSA	26	8.1
E. faecalis	19	5.9
S. haemolyticus MRCNS	15	4.7
E. coli	13	4.1
S. aureus MRSA	5	1.6
S. wareni	5	1.6
E. faecalis HLAR	4	1.2
Acinetobacter spp.	3	0.9
K. pneumoniae ESBL	1	0.3
Burkholderia cepacia	1	0.3
Proteus mirabilis ESBL	1	0.3

Tab. III. Results of culture II – all groups – 177 bacterial strains in total.

MICROBE	NUMBER OF STRAINS [N]	PERCENTAGE OF STRAINS [%]
S. epidermidis MSCNS	42	23.6
S. epidermidis MRCNS	24	13.5
E. faecalis	18	10.2
S. capitis MSCNS	17	9.6
E. coli	16	9.0
S. hominis mscns	15	8.5
S. haemolyticus MSCNS	15	8.5
S. aureus MSSA	14	7.9
S. haemolyticus MRCNS	10	5.6
S. aureus MRSA	3	1.8
K. pneumoniae ESBL	2	1.2
E. faecalis HLAR	1	0.6

In the recent decade, the PubMed database has seen the publishing of 115 papers assessing the impact of CHG on infections, including surgical site infections. In the paper of Karki et al. it was proven that the number of SSI was reduced after using tissues with 2% chlorhexidine, but mainly in orthopedic procedures [5]. In the meta-analysis of Franco et al. which included over ten thousand patients, the effectiveness of preoperative bath with 4% soap with chlorhexidine was assessed. A reduction in the number of skin-colonizing bacteria was demonstrated, but no statistically significant difference was observed in reducing the number of surgical site infections. The authors pointed to the lack of standardization of the procedure regarding the number of baths, bath duration, and the amount of used preparation. The reason for the lack of effectiveness of a bath with 4% chlorhexidine soap can be the short contact time of it with the skin, as well as the subsequent necessity to rinse it with water and wipe the skin [6]. It is suggested by Pereira et al. that contact of 4% CHG preparation with skin for 3 to 5 minutes ensures an optimal antibacterial effect [7]. Thus, the

Tab. IV. Microorganisms isolated in SSI.

MICROBE	NUMBER OF STRAINS [N]	PERCENTAGE OF STRAINS [%]
S. epidermidis MSCNS	7	22.6
S. aureus MSSA	5	16.0
E. faecalis	4	12.9
E. coli	4	12.9
S. haemolyticus MRCNS	3	9.7
S. hominis MSCNS	3	9.7
S. epidermidis MRCNS	2	6.5
K. pneumoniae ESBL	2	6.5
E. coli ESBL	1	3.2

Tab. V. Univariate logistic regression analysis – dependent variable: occurrence of surgical site infections.

VARIABLE	LUB	95%CI	P
Preparation of preoperative field			
6% chlorhexidine gel – method B	1.00	Ref.	
Gel without chlorhexidine – method A	**7.30**	2.09–25.5	**0.0018**
NLR			
Increase by unit	**1.11**	(1.01–1.21)	**0.0300**
Total protein before surgery			
Decrease by unit (01g/dl)	**0.34**	(0.18–0.65)	**0.0011**
Red blood cell transfusion			
No	1.00	Ref.	**0.0082**
Yes	**3.59**	(1.39–9.32)	
Time to remove drain			
Increase by one day	**1.41**	(1.08–1.84)	**0.0122**

authors underline the importance of "patient compliance" as a factor significantly impacting the effectiveness of selected treatment methods [7]. Cooperation on the part of the patient and his compliance with recommendations are the key to the success of the therapeutic process. One publication assessed "patient compliance" in the use of CHG during bathing at 78%. The authors of this work also referred to the low level of education among patients about the benefits of using chlorhexidine. The role of medical personnel is broadly understood education and mobilization of patients [8].

In a systematic review of the literature from 2013, Chlebicki et al. evaluated 16 randomized trials (from 1979 to 2011) involving a total of 17,923 patients. Of this group, 7,952 took a shower with CHG, while others were assigned to different groups: bath with ordinary soap or no bath. SSI in the CHG group was found in 6.8% and in the remaining groups it was 7.2% ($p > 0.05$). Despite a smaller percentage of surgical site infections in the CHG group, the authors did not show significant benefits of using CHG for preoperative bathing. They recommend conducting tests with a strictly defined protocol for the use of chlorhexidine to determine the final conclusions [9].

Several publications questioning the effectiveness of preoperative use of chlorhexidine preparations have led to a change in the CDC guidelines in 2017. The use of CHG in the form of soap or wipes is not currently recommended [10]. However, a bath with the use of ordinary soap on the day of surgery has the status of a strong recommendation and is advised as a simple hygienic operation.

Therefore, a question arises: Is the use of antiseptics in the preoperative period still justified? In what form and how long prior to the procedure should preparations with chlorhexidine be used?

In the course of developing the study plan, the abovementioned comments of authors regarding the standardization of the procedure of using chlorhexidine in the protocol of preoperative preparation of the operative field were considered. Efforts were made to minimize the impact of patient compliance on the result. Therefore, the patients themselves only took a bath with ordinary soap on the day of the procedure. This was followed by the application of a layer of 6% gel with CHG or gel without antiseptic (placebo) to the operated site with a sterile gauze 60 minutes before the procedure. It was decided to use a higher concentration of chlorhexidine and extend the time of CHG contact with the patient's skin. Both procedures proved to be safe for the patients; complications characteristic of chlorhexidine described in the literature were not observed [11, 12]. The development of a relevant procedure for the use of CHG and its personal application allowed to eliminate the errors mentioned in the work of Franco et al. and Prabhu et al. [6, 13]. The division of patients according to the microbiological risk of wound infection and the use of perioperative antibiotic therapy in all individuals allowed all patients within a given group to maintain the same initial risk of wound infection, regardless of how the surgical field was prepared. It is worth mentioning that comparing patient subgroups (IA-IB, IIA-IIB, IIIA-IIIB) in terms of: age, gender, BMI, ASA score, preoperative test results (WBC, CRP, NLR, total protein concentration), perioperative factors (glucose concentration after surgery, length of hospital stay before surgery, time to remove drain, duration of surgery, transfusion of red blood cells), did not reveal any statistically significant differences.

In total, 22 (8.9%) SSI cases were observed in the entire study population, of which 19 were superficial and 3 deep. There were no infections of the operated site or organ. The percentage of surgical site infections partly overlaps with the results of studies presented in two works by Lilani et al. and Carvalho et al. [14, 15], both of which report the frequency of infections in clean wounds at a level close to 3%, which is consistent with my results. On the other hand, there are differences in the case of clean-contaminated wounds. In the first of the cited papers, clean-contaminated wounds were infected in 22.4%, and in the second only in 3.2%. Such a large disproportion in the case of clean-contaminated wounds stems from, in my opinion, various surgical procedures included in the study in both papers, as well as from a much larger study population in the work of Carvalho et al. – 16,882 patients vs 190 patients in the work of Lilani et al. The obtained results were 12.9% surgical site infections in the case of clean contaminated wounds, within the range specified by the abovementioned publications. The frequency of surgical site infections in individual subgroups identified in groups I, II or III was also compared, based on the method of preoperative preparation of the operative field: A – gel without CHG, B – 6% gel with CHG. In subgroups IA and IB (clean wounds), there was no statistically significant difference in the occurrence of SSI. Lynch et al. observed a similar correlation in a paper which included 3,482 patients operated mainly in the scope of vascular surgery – clean wounds; there was no difference in the incidence of SSI observed between patients who underwent preoperative chlorhexidine shower and the group of patients with placebo. The ineffectiveness of using the CHG gel for clean wounds is probably due to the low percentage of surgical site infections for this group of wounds or other factors that I have not identified [16]. However, in subgroups IIA, IIB (clean-contaminated wounds) and IIIA and IIIB (contaminated wounds) I found statistically significantly more frequent occurrence of SSI in cases of preoperative gel preparation without chlorhexidine. The group where the 6% CHG gel was not used had SSI more than seven times more frequent than in the group with the CHG gel – Tab. V. Most often, surgical site infections were observed after radical cystectomy – 24%, then after surgery for intestinal tumor, classical cholecystectomy and following the removal of the suppurative appendix – 12% SSI, respectively. *Staphylococcus epidermidis* turned out to be the pathogen mainly isolated in the case of surgical site infection – 29% of cases, followed by *Staphylococcus aureus* MSSA – 16.1% – none of the strains were methicillin resistant, *E. coli* and E. *faecalis* – respectively after 12.9% of cases – Tab. IV. The obtained results presenting the etiology of SSI differ slightly from the literature data. The difference is in the type of microorganism that most often causes SSI. In the paper, I found that *S. epidermidis* was the most frequently isolated bacterium. On the other hand, in the literature, the case of SSI involves the isolation of *S. aureus*, followed by coagulase-negative staphylococci, and *E. coli* and *E. faecalis* [17].

Univariate and multifactorial logistic regression analysis formed the grounds to identify several risk factors for surgical site infections, which were statistically significantly more likely to have contributed to SSI: NLR index, preoperative total protein concentration, transfusion of blood-based preparations (RPBCs) and time to remove drain. The neutrophil to lymphocyte ratio (NLR) is a simple and cheap biomarker for assessing the inflammatory response. Its increase in the preoperative period is associated with a greater number of infectious complications. I demonstrated that an increase in NLR by one unit caused more frequent occurrence of surgical site infections by 11% – Tab. V. Similarly, in the work of Kubo et al., preoperative elevated NLR was associated with a higher percentage of infections, including SSI, in colorectal surgery [18]. NLR above 3.3 resulted in a higher frequency of surgical site infections in transabdominal hysterectomy [19]. Another statistically significant risk factor for surgical site infection was transfusion of red blood cell preparations. I demonstrated that administration of RPBCs to patients resulted in a 3.5-fold increase in the frequency of surgical site infections. In a study of patients undergoing surgery for pancreatic, liver, biliary tract and colorectal surgery, perioperative blood transfusion resulted in an over 2-fold increase in the incidence of SSI [20]. Another factor that substantially affects the surgical site is the time to remove drain. I demonstrated that extending the time to remove drain time by one day increases the frequency of SSI by up to 41%. A meta-analysis of Woods et al. compared 25 randomized studies assessing the validity of drainage in thyroid surgery. It has been proven that the lack of drainage does not affect the formation of hematoma in the postoperative space site, but reduces the risk of infection of the surgical site more than twice [21]. Lowering the total protein concentration by at least 1 g/dl below standard turned out to be a statistically significant factor increasing the risk of surgical site infections almost three times. In a paper by Jugadne et al., it was proven that hypoproteinemia caused an increase in the frequency of surgical site infection from 14% to 25% in abdominal procedures [22].

The use of a 6% chlorhexidine gel preparation on the operated site brings measurable benefits in the form of reducing the risk of surgical site infections, especially in clean-contaminated and contaminated wounds. A decrease in total protein concentration, transfusion of red cell concentrates, longer time to remove drain, and an increase in the NLR index substantially increase the risk of surgical site infection. In the conducted studies, I did not demonstrate statistical significance for some risk factors for surgical site infections described in the literature: preoperative hospitalization, postoperative hyperglycemia, obesity, and advanced age of patients.

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