Incidence of surgical site infection with pre-operative skin preparation using 10% polyvidone-iodine and 0.5% chlorhexidine-alcohol

Incidência de infecção do sítio cirúrgico com o preparo pré-operatório utilizando iodopolividona 10% hidroalcoólica e clorexidina alcoólica 0,5%

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ABSTRACT

Objective: To analyze the incidence of surgical site infection when the preoperative skin preparation was performed with 10% povidone-iodine and 0.5% chlorhexidine-alcohol. **Methods**: We conducted a randomized, longitudinal study based on variables obtained from patients undergoing clean and potentially contaminated operations. Those involved were divided into two groups. In group 1 (G1) we included 102 patients with skin prepared with povidone-iodine, and in group 2 (G2), 103, whose skin was prepared with chlorhexidine. In the third, seventh and 30th postoperative days we evaluated the surgical site, searching for signs of infection. **Results**: Data related to clinical profile, such as diabetes mellitus, smoking, alcoholism, haematological data (Hb, VG and leukocytes), age and gender, and the related variables, such as number of days of preoperative hospitalization, shaving, topography of incision, antibiotic prophylaxis and resident participation in the operation were not predisposing factors for surgical site infection. Two patients in G1 and eight in G2 undergoing clean operations had some type of infection (p = 0.1789), five in G1 and three in G2 undergoing potentially contaminated operations had some type of infection (p = 0.7205). **Conclusion**: The incidence of surgical site infection in operations classified as clean and as potentially contaminated for which skin preparation was done with 10% povidone-iodine and 0.5% chlorhexidine-alcohol was similar.

Key words: Incidence. Skin. Anti-infective agents, local. Infection. Surgical drapes.

INTRODUCTION

The increasing development of diagnostic and therapeutic medicine provides opportunities for healing and rehabilitation, and also brings great challenges, including infection control.

Surgical site infection (SSI) is a surgical complication that concerns health institutions, since its occurrence can mean prolonged hospitalization, increased morbidity and mortality and medical and hospital expenses. Prevention and control are considered key steps for the safety and quality of health care [1].

The sources of SSI causative micro-organisms are varied and not always possible to identify. The main source is the direct inoculation of the patient's own microflora, especially the skin and manipulated site [2].

It is known that the prophylaxis for this is based on the antisepsis of hands and forearms, sterilization of materials and preparing of the patient's skin, including hygiene with antiseptic degerming chemicals and antisepsis with alcoholic solutions.

There are several types of products available for preoperative skin preparation. However, chlorhexidine in isopropyl alcohol and povidone-iodine are the most used in clinical practice [3].

A meta-analysis comparing chlorhexidine with povidone-iodine to prepare the insertion site of vascular catheter demonstrated greater efficacy of chlorhexidine in reducing the incidence of infection[4]. Therefore, there are guidelines that recommend the use of 2% chlorhexidine in alcohol vehicle in skin preparation for this purpose [5].

Other works[3,5,6] were performed in an attempt to define the best antiseptic used in skin preparation for surgical procedures. There is controversy on which one is more efficient, though.

Because there is no consensus on the ideal solution for preoperative skin preparation in studies [7-9], the Center for Disease Control and Prevention issued no recommendation regarding the products to be used on the skin antisepsis to prevent SSI [10].

The present study aimed to analyze the incidence of SSI in procedures classified as clean and as potentially

Study conducted at the Santa Casa de Misericórdia de Ponta Grossa- Paraná –BR.
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contaminated when the preoperative skin preparation was performed with 0.5% alcoholic chlorhexidine or 10% aqueous alcohol povidone-iodine.

METHODS

This study project was approved by the Ethics in Research Committee at the State University of Ponta Grossa, Paraná State – PR, Brazil, under protocol number 03305/11 and Opinion 27/2011.

Data were collected from 208 patients undergoing clean and potentially contaminated operations in the period from April 04th to August 30th, 2011, in a charity hospital at the city of Ponta Grossa.

Those involved in the study were divided into two groups according to the order of arrival to the operating room. Those who belonged to group 1 (G1) had the skin prepared with 10% hydroalcoholic povidone-iodine and those who took part in group 2 (G2) were prepared with 0.5% alcoholic chlorhexidine.

Data relating to the clinical profile were analyzed for age, gender and presence of associated comorbidities (diabetes mellitus, smoking and alcoholism).

The variables relating to the operation were considered: number of days of hospitalization, trichotomy, topography of the incisions, resident participation, antibiotic prophylaxis and antiseptic solution used for the preparation of the surgical site.

We included patients aged over 18 years undergoing open-access elective procedures, with subcostal abdominal, vertical abdominal and thoracic incisions, with no history of allergy to chlorhexidine, alcohol or iodine, without immunosuppression and without infection at the incision site.

Patients were excluded if there breaches in the rules of antisepsis and asepsis, changing the classification of the surgical site, and if they abandoned follow-up.

We conducted the training of professionals who would be involved in skin antisepsis in order to standardize the process.

For preparation of the skin of G1 patients, after hand hygiene and gloving, with a compress soaked in water and 20ml povidone-iodine, we vigorously rubbed the area for five minutes. This procedure was intended to remove dirt, sebum, sweat and epithelial cells as, well as the transitional skin bacteria. The area was then cleaned with another sterile compress. The preparation was completed bu marking the operative area with 10% hydroalcoholic povidone-iodine.

In G2 patients, the skin was prepared in the same manner as it was for the G1. However, the cleaning was carried out with water and 20 ml of 2% chlorhexidine soap, and complementation with 0.5% alcoholic chlorhexidine.

Shaving, whenever necessary, was accomplished with an electric clipper, in the smallest possible area, immediately before the procedure.

The study participants were examined by a single observer in three stages: the third, seventh and thirtieth postoperative day.

The identification of SSI involved clinical and laboratory diagnosis

For the diagnosis of probable SSI was required the presence of at least one of the following signs[11]: fever, without other apparent cause, pain, heat, swelling, or confluent erythema around the incision and extrapolating the boundaries of the wound, pus in the incision site or in the deep soft tissue, or in organ/cavity handled during operation; presence of abscesses or, in the case of deep tissues, histological or radiological evidence suggestive of infection; isolated microorganism from theoretically sterile source or harvested with aseptic technique from a previously closed site, and spontaneous dehiscence of deep tissues.

When there was secretion, it was sent to identification of the germ by Gram stain and culture for aerobic microorganisms.

Results were expressed as mean, median, minimum and maximum values, and standard deviations (quantitative variables) or as frequencies and percentages (qualitative variables). To compare the two groups with respect to quantitative variables we used the Student's t for independent samples or, when appropriate, the non-parametric Mann-Whitney test. Regarding the dichotomous qualitative variables, the groups were compared using the Fisher exact test. p values < 0.05 were considered statistically significant.

RESULTS

We included 208 patients in the study. There were three exclusions, one due to death, one due to breach of the technique and one abandoned follow-up. Therefore, 205 patients remained for analysis.

In G1 39 clean operations were monitored; of those, two (5.1%) had infection. Fifty-two clean operations were in G2, and of those, eight (15.3%) had some type of infection (Table 1).

In G1 63 potentially contaminated operations were included, five (7.9%) having infection. Of the 51 potentially contaminated procedures in G2, three (5.8%) had infection (Table 2).

Of the total patients studied, 18 (8.8%) had infection, seven in G1 and 11 in G2. In G1, three cultures were positive and four negative, despite clinical signs of infection. In G2 seven cultures were positive and four patients with clinical signs of infection had negative cultures ($p = 0.460$).

The mean age of patients with infection was 50.8 ± 11.4 years, and in those without infection, 53.6 ± 14.1 years (p = 0.419).

Regarding gender, eight men and ten women had infection (p = 0.618).

The average hospital preoperatively stay was 2.4 days for the study participants who developed infections, and 2.1 days for those who had not (p = 0.790).

Those who developed infection had the following surgical accesses: three Stuwart, nine vertical abdominal, two thoracic and four subcostal abdominal (p = 0.730).

Patients who developed infection showed varying hematological results, mean hemoglobin 13.9 ± 1.5 (p = 0.177), cell volume of 42.3 ± 4.5 (p = 0.059) and average leukocytes 8.365 ± 2.849 (p = 0 247).

In this sample, only one patient who developed infection had diabetes (p = 1) and 50% of those who developed infection were smokers (p = 0.192).

Among those infected, two reported regular alcohol consumption (p = 0.627).

There were no intraoperative complications in the 18 patients who developed infection (p = 1). Mean operative time for these patients was 2.6 hours, with a maximum time of five hours (p = 0.212).

Eight of the infected individuals were shaved and in ten hair removal was not performed (p = 0.285). Residents participated in 17 operations that resulted in infection (p = 0.049).

Sixteen patients who developed infections received antibiotic prophylaxis and only two did not receive it (p = 0.249).

DISCUSSION

Proper skin preparation before surgery has a positive impact on rates of SSI and can eliminate some of the extra costs associated with this often preventable event [11].

Although statistical difference existed regarding age, it is not real, since they were in the same physiological age. The mean age in G1 was 49 ± 14.3 years, and in G2, 54 ± 13.1. One can understand that the groups were within the same range of risk. Additionally, age is not a factor that influences the incidence of SSI (p = 0.419).

The largest number of cases in women should also not be considered, since the number of women in the sample was higher, justified by the inclusion of gynecological abdominal operations and breast oncology ones. There was no established link between gender and development of SSI. Gelape study followed patients undergoing heart surgery and found a higher incidence of SSI in men, which, according to the author, may have been due to the higher tension on the sternal wound [12].

It is known that the longer the period of preoperative hospitalization, the greater the risk of the patient to be colonized with hospital microbiota, thus contributing to increased rates of infection [10,13].

Petrosillo *et al*. conducted a prospective multicenter surveillance study in general and gynecological units in 48 Italian hospitals involving 4665 patients and considered preoperative hospitalization as a risk factor for SSI (p < 0.001)[14].

Interestingly, Ercole et al. studied the risk for SSI in orthopedic operations and found no relationship between length of preoperative hospitalization with the incidence of SSI (p = 0.3) [15]. One possible explanation for this finding is the clean nature of orthopedic surgical procedures that, although involving more destruction of the soft tissues, rarely enter into potentially contaminated areas[16].

With regard to the patients in this sample, there was no relationship between duration of preoperative hospitalization and the presence of SSI (p = 0.790). It was

Table 1 - Surgical site infection in clean operations.

Group	Infection					p*
	Present		Absent		Total	
G 1	2	(5.1%)	37	(94.9%)	39	
G 2	8	(15.3%)	44	(84.6%)	52	0.1789
Total	10		81		91	

Table 2 - Surgical site infection in potentially contaminated operations.

Group	Infection					p*
	Present		Absent		Total	
G 1	5	(7.9%)	58	(92.1%)	63	
G 2	3	(5.8%)	48	(94.2%)	51	0.7205
Total	08		106		114	

observed that the one patient who remained under the longest preoperative hospitalization was among those who did not develop infection. It has to be taken into account that not only the risk classification of the wound, but also contacts, the hospital area occupied these patients and the sustained manipulation are factors of more or less facilitation for colonization with hospital bacteria.

The type of incision was not related to the incidence of either. the rate of hemoglobin (p = 0.177). Changes in the healing process can happen if blood circulation is poor on the site, hampering the synthesis of collagen and the formation of epithelial cells[17]. According to Fernandes *et al*, patients with anemia have a relative risk of infection two times higher than non-anemic [18].

Diabetes mellitus – especially insulin-dependent – is an important factor in the occurrence of SSI, as it may be accompanied by poor healing due to vascular lesions and changes in phagocytic cells that favor the onset of infections [19,20].

It is known that smoking can lead to wound healing deficiencies, but controlled trials have not been performed [21]. Tobacco use inhibits fibroblast proliferation by direct action of nicotine, as well as decreases collagen production and angiogenesis, delaying the healing time [22].

The routine use of alcohol is an important risk factor for SSI and must be taken into consideration when determining the individual susceptibility of the patient [23]. The exact mechanism by which this factor increases the risk is unknown, but it is known that alcohol affects numerous physiological functions including hemostasis, immune, cardiovascular and central nervous systems [23].

In the present study, there was a relationship between SSI and diabetes mellitus, smoking and alcoholism. Although there has been complications during surgery – including cardiopulmonary arrest, gallbladder perforation and injury to the pulmonary artery – SSI did not develop in these patients. However, this variable must be considered when studying infection because of increased surgical and anesthetic times, the increased movement of people in the room, the entry of teams from different specialties and more manipulation of the surgical site.

Hairs possess microbiota that should not be considered as an important source of pathogens. Their removal by shaving is a known predisposing factor for SSI [10,12,13]. Similar to the research of Poveda *et al.*, who found no association between shaving and SSI [13], in this study this association was not identified.

A study conducted by Sistla *et al.* did not observe influence of the participation of surgeons in specialization phase with the appearance of SSI [8]. In this study, residents participated in 94% of surgical procedures, leaving the sample without their attendance too small to allow conclusion.

Another important aspect relates to the use of prophylactic antibiotics performed during anesthesia, as directed by the hospital infection control department. Only one patient who developed infection did not receive such medication.

The microbiology of SSI varies depending on the type procedure performed [11]. *Staphylococcus aureus* was the predominant isolated microorganism, followed by *Klebisiella pneumoniae*, *Escherichia coli* and *Klebsiella ozonae*.

In the analysis of related clinical profile (age, gender, diabetes mellitus, smoking, alcohol) and related variables (number of days of preoperative hospitalization, shaving, topography of the incision, resident participation and antibiotic prophylaxis), no association with the development of SSI was evidenced.

It can be noticed that SSI prevention strategies have focused mainly on other variables such as prophylactic antibiotics, whereas the role of antiseptics in the decontamination of the skin have not attracted much attention [17].

The results of this study showed that most patients who participated in the research progressed without SSI in G1 (93.14%) and in G2(89.32%). Seven from G1 had infection, five superficial incisional, one deep incisional and one of organ/cavity. Of the 11 G2 patients who developed infections, nine were classified as superficial incisional and two deep incisional.

This finding corroborates studies that describe the superficial incisional infection as the most common SSI [24,25]. Thus, skin antisepsis before surgery can result in clinical benefit.

SSI rates found in clean operations exceeded values considered acceptable by the literature (5%), and rates presented in potentially contaminated procedures were within the acceptable range (3-11%).

There was no superiority of one antiseptic solution over the other.

In the course of this study, we could observe that SSI is a common event, which results in more recovery time, higher hospital costs and other undesirable factors.

Knowledge of the pathways of contamination, types of microorganisms involved and the predisposing risk factors for SSI allow the development of daily practices in order to reduce the occurrence and severity of these infections.

The identification of an SSI involves clinical and laboratory interpretation, and it is essential that the definitions used in surveillance programs are coherent and uniform, otherwise incorrect rates will be calculated and published.

A meta-analysis conducted by Noorani et al. aimed at recognizing the efficacy of chlorhexidine compared with povidone-iodine for wounds classified as clean-contaminated and observed an increased efficiency of chlorhexidine (p = 0.019) 16. This statement was confirmed by Levin *et al.*, who compared alcoholic solutions of chlorhexidine and povidone in gynecological laparotomies (p = 0.011) [26].

However, Swenson et al. followed 3,209 general surgical procedures and concluded that the iodophor compounds are superior to chlorhexidine in preventing SSI ($p = 0.001$) [6].

It is seen that, although there is a tendency of authors to indicate chlorhexidine, there is no consensus on the superiority of this antiseptic for skin preparation.

In the study we found that the groups were similar and that the risk factors did not influence the incidence of SSI. Further studies, in which we can include a single type of intervention without the variables of access routes and separating clean from potentially contaminated operations, can improve the analysis.

In conclusion, the incidence of SSI in operations classified as clean and potentially contaminated whose skin preparation was done with 10% hydroalcoholic povidone-iodine and 0.5% alcoholic chlorhexidine was similar.

R E S U M O

Objetivo*: analisar a incidência de infecção do sítio cirúrgico, quando o preparo pré-operatório da pele foi realizado com iodopolividona 10% em solução hidroalcoólica e clorexidina 0,5% alcoólica,* ***Métodos:*** *estudo longitudinal randomizado, a partir de variáveis obtidas de pacientes submetidos à operações limpas e potencialmente contaminadas. Os envolvidos foram alocados em dois grupos. No grupo 1 (G1) participaram 102 pacientes com pele preparada com iodopolividona e do grupo 2 (G2) 103 que utilizaram clorexidina. No terceiro, sétimo e 30º dia de pós-operatório avaliou-se o sítio cirúrgico, buscando-se sinais de infecção.* ***Resultados:*** *os dados relacionados ao perfil clínico como: diabete melito, tabagismo, alcoolismo, dados hematológicos (Hb, VG e leucócitos), idade e sexo, e as variáveis relativas como: número de dias de internamento pré-operatório, tricotomia, topografia da incisão, antibioticoprofilaxia e a participação de residentes na operação, não foram evidenciadas como fatores predisponentes a infecção do sítio cirúrgico. Dois pacientes do G1 e oito do G2 submetidos à operações limpas apresentaram algum tipo de infecção (p=0,1789), cinco do G1 e três do G2 submetidos à operações potencialmente contaminadas apresentaram algum tipo de infecção (p=0,7205).* ***Conclusão:*** *a incidência de infecção do sítio cirúrgico em operações classificadas como limpas e potencialmente contaminadas, cujo preparo da pele foi feito com iodopolividona 10% em solução hidroalcoólica e clorexidina alcoólica 0,5%, foi semelhante.*

Descritores: *Pele. Antissépticos. Infecção. Cirurgia.*

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