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Original article

Chlorhexidine Alcohol versus Povidone Iodine for Prevention of Surgical Site Infection in Laparoscopic Cholecystectomy

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Abstract

Background: One of the most frequent infections associated with health care is Surgical Site Infection (SSI). Preoperative skin antisepsis is one of the important methods to minimize the prevalence of SSIs. Chlorhexidine alcohol (CHA) and povidone iodine (PI) are two of the widely active materials as a skin antiseptic. This study compared the efficacy of CHA 2.5% with PI 10% for preventing SSIs in elective laparoscopic cholecystectomies. **Methods:** This prospective controlled randomized study has been performed on 200 patients underwent elective laparoscopic cholecystectomies. Patients have been randomized into two equal groups, according to the anti-septic used for cleaning skin before surgery, group C (chlorhexidine 2.5% in 70% ethanol) or group P (PI aqueous 10%). **Results:** Superficial SSIs in group C was significantly lower (4%) in comparison to group P (13%) (P = 0.04). No cases was presented with deep SSIs in both groups. **Conclusion:** For preventing of superficial SSI, CHA is more effective than PI when applied before laparoscopic cholecystectomy.

Key words: Surgical Site Infections; Chlorhexidine-alcohol; Povidone iodine**.**

Introduction

SSIs are the most common infection and they are one of the most significant complications that can occur in patients undergoing surgery, carrying high rates of morbidity and mortality. According to reports from the Centers for Disease Control and Prevention's (CDC), SSI is the third most often diagnosed infection related to healthcare [1].

SSIs are defined as an infection that arise within 30 days of surgery and is caused by a surgical or invasive operation, or an infection that needs surgical intervention to treat [2].

There are many risk factors related to the patient, the environment, and the care given that may lead to the development of SSIs [3]. The patient's own microbial flora has been thought to be the most significant source of infection that trigger SSI, rather than the operative surgeon, equipment or environment [4].

One of the most effective measures for avoiding SSIs- is preoperative skin treatment of the surgical area with suitable antiseptic drugs. To be a suitable preoperative skin antiseptic, it should provide a rapid (i.e., within 10 minutes) and persistent (i.e., for six hours) suppression of both transient and resident microbes after application in the surgical field [5].

There are many methods to lessen the occurrence of postoperative SSIs, such as hand antiseptics and preoperative antibiotic administration. CDC [6], world health organization (WHO) [7] and the National Institute for Health and Care Excellence (NICE)- [8] have all revised their postoperative SSI preventive recommendations and stated that one of the most important determinants is the use of a preoperative skin antiseptic.

Cholerhexidine Alcohol (CHA) is a novel skin-preparation agent that is composed of 2.5% chlorhexidine gluconate and 70% isopropyl alcohol. Regardless of being more costly than PI, it has a faster onset of action when applied to the skin and remains effective even in the presence of body fluids [9].Compared with PI, it has been observed that CHA, as determined by skin microbial eradication, remains effective for hours after application [10].

A multi-centric prospective randomized controlled trial performed in 2020 in four Japanese hospitals on 587 patients that underwent clean contaminated hepatobiliary, pancreatic and gastrointestinal surgeries and it proved that olanexidine significantly reduced the chance of SSIs 19/294 (7%) in comparison with PI 39/293 (13%) with significant P value=0.002. [11].

The present study is aimed to compare the effectiveness of 2.5% CHA and 10% PI for preventing SSIs in elective abdominal operations.

Material and methods

This prospective randomized controlled study included 200 patients, between the ages of 18 to 65 years, both genders who underwent elective laparoscopic

cholecystectomy from January 2020 to January 2022. Informed written consent was obtained from each patient to be included in this study.

Randomly, participants were assigned into two groups; 100 patients in each. In group C, 2.5% CHA (chlorhexidine 2.5% in 70% ethanol) was applied for skin cleansing prior to skin incision and in group P, 10% PI aqueous was used.

Exclusion criteria included history of allergy to alcohol, chlorhexidine or PI as well as patients that have signs of infection at or near the surgical site.

Randomization:

Using closed envelop method with a 1:1 ratio, participants were randomly distributed. Prior to the operation and on skin of the surgical area, they have skin scrubbed with either 2.5% chlorhexidine gluconate and 70% isopropyl alcohol (Chlora Prep, Cardinal Health) or an aqueous solution of 10% PI (Scrub Care Skin Prep Tray, Cardinal Health).

Outcomes:

The occurrence of any SSI within 30 days of surgery was the study's primary outcome measure. The occurrence of specific forms of SSI was a secondary end point.

These were defined as a superficial infection (includes only skin and subcutaneous tissue and excludes point-related abscesses), as deep infection (including fascia and muscle), and as an inflammation of the organ space (including any organ or space rather than the incised layer of body wall that was altered during the surgery).

Statistical analysis:

Statistical analysis was done using SPSS v26 (IBM Inc., Chicago, IL, USA). Shapiro-Wilks test and histograms tested the normality of the results. The Student's t-test was used to measure the two groups' numerical variables, which were also presented as mean and standard deviation (SD). The Chi-square test or Fisher's exact test is used to analyze categorical variables that were viewed as frequency and percentage (%). A two tailed P value < 0.05 was considered significant.

Results:

In the studied groups, demographic data, age and related comorbidities- were similar. The mean age in group C was 41.94± 13.51 years while in group P mean age was 40.49± 13.51 years with no statistically significant difference between both groups (p= 0.471).The mean BMI in group C was 28.17± 4.99kg/m^2 and in group P mean BMI was 27.35± 4.42kg/$m^2$with no statistically significant difference between both groups (p= 0.220). Regarding comorbidities, 28

(28%) were diabetic and 21 (21%) were hypertensive in group C while 22 (22%) were diabetic and 26 (26%) were hypertensive in group P (**Table 1).**

The mean duration of surgery was 42.70 ± 14.79 min in group C and was 44.82 ± 19.04 min in group P with no statistically significant difference between both groups (p= 0.220). The drain were used in 31 (31%) case in group C compared to 33 (33%) case in group P with no statistically significant difference between both groups (p= 0.657) **(Table 2).**

Superficial SSI was significantly lower in group C (4%) compared to group P (13%) (P = 0.040). No cases was presented with deep SSI in both groups **(Table 3).**

Table 1. Demographic and Clinical characteristics of the study group

		Group C (n=100)		Group P (n=100)		p- value
		n	%	n	%	
Age	**mean± SD**	41.94± 13.51		40.49± 13.51		0.471
	range	19- 65		18- 63		
Gender	**Male**	52	52%	54	54%	0.887
	Female	48	48%	46	46%	
Weight	**mean± SD**	80.79± 10.89		80.27± 10.87		0.735
	range	61.0- 101.0		63.0- 98.0		
Height	**mean± SD**	170.09± 8.24		171.84± 8.55		0.142
	range	154.00 183.00		155.00 186.00		
BMI (kg/m^2)	**mean± SD**	28.17± 4.99		27.35± 4.42		0.220
	range	19.40- 40.90		19.10- 40.80		
DM		28	28%	22	22%	0. 488
Hypertension		21	21%	26	26%	0.404
Smoking		18	18%	20	20%	0.799

Table 2. Surgery characteristics of the study group

		Group C (n=100)		Group P (n=100)		p- value
		N	%	N	%	
Duration of surgery (min)	**mean± SD**	42.70 ± 14.79		44.82± 19.04		0.210
	range	21-88		18-91		
Drain usage		31	10%	33	33%	0.657

Table 3. Types of infection of the study groups

		Group C (n=100)		Group P (n=100)		p- value
Types of infections	**Superficial**	4	4%	13	13%	0.040
	Deep	0	0%	0	0%	0

Discussion:

SSI is a fearful postoperative condition affecting about 5% of all operating patients. Long-term hospital stay, extended recovery time, increased hospital rates of readmission and mortality rates are accompanied with SSI. In the vast majority of SSI, a surgical incision is contaminated with the patient's own body [12].

The choice of the most suitable antiseptic agent is a necessary step in the preparation of preoperative skin. PI is used as a multi-valent, local, broad-spectrum antiseptic with sporicidal, bactericidal and fungicidal properties [13]. Molecular iodine has a long and successful track record as a disinfectant and the most commonly used antiseptic in the operating procedure and has not been linked to the growth of bacterial resistance. Even though, bactericidal action of PI on healthy skin on bacteria is powerful and persistent. Blood, necrotic tissue, and pus can make PI less successful [14].

In hospitalized patients undergoing operation, SSI cause major morbidity and mortality. Postoperative SSI leads to rise in hospitalization duration and related costs [15]. Despite mounting evidence for newer skin antiseptic agents, uncertainty persists as to which agent is linked to a lower risk of postoperative SSI. This study compared the effectiveness of 2.5 % CHA versus 10% PI in preventing SSI in elective abdominal surgeries.

A recent meta-analysis done by Peel et al. [16] revealed that CHA use reduced risk of SSIs compared with PI (RR 0.79; 95% CI 0.669, 0.932).

Levin et al. [17] found that the rates of SSI in elective gynecological laparotomies were significantly lower with CHA (4.5 %) than with PI (14.5 %), P = 0.011.

According to Noorani et al. [18], in patients undergoing clean-contaminated surgery, preoperative skin washing with CHA was found to be superior to PI in avoiding SSIs.

When CHA is applied to the skin's surface, it has been shown to reduce microbial logs more effectively than PI. Furthermore, as compared to PI, the antimicrobial activity of CHA was observed to last several hours after application, as determined by the skin surface microbial log reduction.

Darouiche et al., [19] concluded that the rate of SSIs was considerably lower in patients performing clean-contaminated surgeries with CHA39/409 (9.5 %) than PI71/440 (16.1 %) (P = 0.004).

Identical to our result, a Chinese group in 2020 published a systemic review and meta-analysis on thirty studies including nearly 29.000 patients. This study proved that CHA had superiority on PI in avoidance of SSI not only in clean- contaminated surgeries with P value > 0.00001 but also in clean surgeries with P value = 0.03 [3]

In contrast to our results, Srinivas et al., [4] reported that the rate of SSIs after clean contaminated upper abdominal surgeries was 10.8 % with CHA and 17.9 % with PI but the difference was insignificant (P = 0.061). This may due the unequal groups, excluded cases and different types of operations.

Also, Swenson et al., [20]compared the efficacy three different skin preparations (iodine povacrylex in alcohol, CHA 2 % in 70 % alcohol and PI 10 %) in preventing SSI. No outcome differences was found between patients that used PI as skin disinfectant and those scrubbed with iodine povacrylex in isopropyl alcohol while in comparison with rate of SSIs in patients sterilized with CHA, they found the difference was significant (4.8% vs. 8.2% ; P = 0.001). Nonetheless, the study did not use a randomized clinical trial and involved all types of surgical patients.

Opposite to the current study, a Pakistani study from two hospitals in 2015 showed that SSI in PI group was 22/220 (10%) in comparison with CHA group 12/168 (7.1%) with insignificant p value=0.324 and they conclude that PI and CHA are similarly had the same effect as an antiseptic preoperatively. [21]

In 2017, a South Korean group published a randomized clinical trial on 534 participants with upper abdominal surgeries with rate of SSI 5.8% (31/534) with no difference between CHA group 15/267 (5.6%) and PI group 16/267 (6%). [22]

Conclusion

Incidence of superficial SSI was lower with the application of CHA skin preparation than with PI in elective laparoscopic cholecystectomy with no effect on deep SSIs.

Limitation of this study

As limitations of this study we could list the small number of patients, this study was not a multi-centric one as it was limited to our department without any consideration in the economical aspect as the price difference between both products.

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