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CHLORHEXIDINE ALCOHOL VERSUS POVIDONE-IODINE FOR SURGICAL SITE ASEPSIS: A RANDOMIZED TRIAL TO COMPARE OUTCOME IN SURGICAL PATIENTS

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ABSTRACT

Background

Common postoperative consequences that raise healthcare expenditures, lengthen hospital stays, and increase morbidity are surgical site infections (SSIs). Chlorhexidine alcohol (CA) and povidone-iodine (PI) are common antiseptics used for preoperative antiseptic skin preparation, which is essential for reducing the risk of superficial skin infections. The study evaluated surgical patients prepped with chlorhexidine alcohol vs. povidone-iodine in terms of the incidence of SSIs.

Methods

Two groups of 122 individuals each—Category A receiving CA and Category B receiving PI—were randomly assigned to a total of 244 individuals. Patients aged 18-60 undergoing elective non-laparoscopic surgeries were included. Data on demographic details, nutritional status, preoperative random blood sugar, procedure performed, operating time, duration of hospital stay, and secondary wound management interventions were collected. Statistical analysis was done using SPSS version 21.0.

Results

Both groups were demographically similar. Category A had 5 superficial and 3 deep SSIs, while Category B had 9 superficial and 6 deep SSIs, including a mesh infection after inguinal hernioplasty. Category A had 57 males, 65 females, and a mean age of 40.03 ± 16.09 years; Category B had 63 males, 59 females, and a mean age of 37.92 ± 12.73 years. The mean hospital stay for uncomplicated cases was similar (Category A: 8.84 ± 2.12 days, Category B: 9.0 ± 1.8 days), but patients with SSIs in Category B had longer stays (Category A: 15.21 ± 3.33 days, Category B: 18.23 ± 2.11 days).

Conclusion

While both antiseptics were effective in general use, CA was associated with a lower incidence of SSIs and shorter hospital stays for infected cases compared to PI.

Recommendations

For preoperative skin preparation, chlorhexidine alcohol ought to be chosen to lower the risk of SSIs and enhance patient outcomes.

Keywords: *Surgical Site Infections, Chlorhexidine Alcohol, Povidone Iodine, Preoperative Skin Preparation, Antiseptic.*
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INTRODUCTION

One of the most frequent postoperative consequences is surgical site infection (SSI), which can result in greater morbidity, longer hospital stays, and higher healthcare expenses. Reducing the risk of surgical site infections requires effective preoperative antiseptic skin preparation. For this reason, povidone-iodine (PI) and chlorhexidine alcohol (CA) are two often used antiseptics.

The 2019 NICE guidelines on the prevention and treatment of SSIs provide critical insights into preoperative skin antisepsis. According to these guidelines, an antiseptic preparation should be used before surgical incisions. Specifically, they recommend an alcohol-based solution of chlorhexidine unless contraindicated [1]. This recommendation is based on the evidence that alcohol-based chlorhexidine solutions are more efficient than aqueous solutions of chlorhexidine or iodine in reducing SSIs.

Supporting this, a significant study published in JAMA Surgery also highlights the efficacy of CA over PI. The study, which involved a large cohort of surgical patients, demonstrated a marked reduction in SSI rates with chlorhexidine alcohol [2]. Specifically, recommendation 8B from the study underscores the superiority of chlorhexidine alcohol in reducing the incidence of SSIs compared to povidone-iodine, emphasizing its role as the preferred antiseptic in surgical settings.

These results have been supported by recent research. When compared to povidone-iodine, a meta-analysis revealed that chlorhexidine alcohol considerably lowers

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the risk of SSIs. Because of its dual mechanism of action, the combination of alcohol and chlorhexidine has a more significant protective benefit against SSIs, according to this thorough evaluation of randomized controlled studies [3]. Comparing povidone-iodine and chlorhexidine alcohol in patients undergoing cesarean delivery, a study discovered that the former was linked to a noticeably decreased incidence of SSIs [4].

Chlorhexidine alcohol, a combination of chlorhexidine gluconate and isopropyl alcohol, offers both rapid action and persistent antimicrobial activity. Its dual mechanism—disrupting cell membranes and precipitating cellular proteins—provides a broad spectrum of activity against bacteria, viruses, and fungi. Conversely, povidone-iodine, though effective, lacks the rapid bactericidal action and prolonged effect provided by the alcohol component in chlorhexidine alcohol solutions.

Given these advantages, it is crucial to consider the comparative efficiency of these antiseptics in real-world clinical settings. This study will evaluate the incidence of SSIs in patients undergoing various surgical procedures, comparing those prepped with chlorhexidine alcohol to those prepped with povidone-iodine. Additionally, it will analyze secondary outcomes such as length of hospital stay, readmission rates, and overall patient satisfaction.

The study evaluated surgical patients prepped with chlorhexidine alcohol vs. povidone-iodine in terms of the incidence of SSIs.

METHODOLOGY

Study design

A randomized, prospective, parallel-group trial

Study setting

The study was done in the Department of Surgery, ESIC Medical College & Hospital, Patna, Bihar, between July 2022 to June 2023.

Participants

There were 244 patients in the trial. Using computer-generated random numbers, the individuals who satisfied the inclusion criteria were split into two groups, Category A and Category B, each consisting of 122 patients.

Inclusion criteria

Individuals who were admitted under the Department of General Surgery for elective nonlaparoscopic general surgical procedures between the age group 18 to 60 years and who gave consent for participation were involved in the study.

Exclusion criteria

Patients between 18 to 60 years of age who were known diabetic, immunocompromised, or on steroids, or had known allergy to CA or PI or those undergoing surgery for known malignancy, urological condition, or for semi emergent condition were excluded from the study population.

Sample size

To calculate the sample size for this study, the following formula was used for estimating a proportion of a population:

$$n=\frac{Z2 \times p \times (1-p)}{E2}$$

Where:

- n = sample size
- Z = Z-score corresponding to the desired level of confidence
- p = estimated proportion in the population
- E = margin of error

Bias

There was a chance that bias would arise when the study first started, but it was avoided by giving all participants identical information and hiding the group allocation from the nurses who collected the data.

Variables

Variables included demographic details of patients (age, sex), nutritional status of patients (BMI, Hemoglobin level, total protein, and serum albumin), preoperative random blood sugar, procedure performed, operating time, total duration of hospital stay, secondary intervention for wound management done if any.

Interventions

On the morning of surgery, all patients received a pre-operative shower as part of standard preoperative preparation. Prophylactic IV antibiotic Inj Ceftriaxone 1gm was administered around 30 mins before induction of anesthesia or regional block. All patients underwent surgical site shaving on the OT table. Following anesthesia, the surgical site was prepared with

- Category A: Surgical site prepared with 2% chlorhexidine and 70% isopropyl alcohol solution (figure 1).
- Category B: Surgical site prepared with 10% povidone-iodine solution (figure 2).

In both groups, the solution was left to dry on the surgical site for 3-5 minutes before incision. Standard draping procedure and asepsis protocol were followed in all cases

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Figure 1: Chlorhexidine 2% with Isopropyl Alcohol 70% solution (Left), Prepared Surgical Site with Chlorhexidine & Isopropyl Alcohol (Right)

Figure 2: Povidone Iodine 10% Solution (Left), Prepared Surgical Site with Povidone Iodine (Right)

In the postoperative period wound dressing was done on every alternate day and stitch removal was done in uncomplicated patients on 8th POD. Incidences of SSI as specified by the Centre for Disease Control and Prevention occurring within 30 days in post post-operative period were documented (Prosthesis infection evident after 30 days of surgery was kept out of the domain of the present study.)

Outcomes

The primary outcome was the incidence of SSIs, assessed using the Centers for Disease Control and Prevention (CDC) criteria. SSIs were monitored postoperatively,

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with wound dressing changes every alternate day. Stitch removal was done on the 8th postoperative day in uncomplicated cases. The occurrence of SSIs within 30 days of surgery was recorded, and secondary interventions, if needed, were documented. Hospital stay durations were also tracked.

Randomization

- Sequence Generation: The random allocation sequence was generated using a computer-generated random number method, ensuring unbiased assignment. Simple randomization was used for participant allocation.
- Allocation Concealment Mechanism: The random allocation sequence was concealed using sealed, opaque envelopes. This method prevented any prediction of the group assignments until interventions were assigned.
- Implementation: The random allocation sequence was generated by a third party not involved in patient recruitment or treatment. Participants were enrolled by clinical staff, and the assignment to the interventions (Category A or Category B) was done by the operating room personnel.

Blinding

Blinding was not performed in this study. Both the participants and the care providers were aware of the antiseptic used for preoperative skin preparation, as it was impossible to mask the different antiseptic preparations. However, the outcome assessors were blinded to group allocation when evaluating the incidence of SSIs.

Statistical analysis: The analysis of the data was done with SPSS version 21.0. The variables' mean, standard deviation, and frequency were computed. P-values <0.05 were deemed as statistically significant.

Ethical considerations

The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

RESULT

Two groups' respective demographics were evaluated and recorded (Table 1). Category A comprised 57 males and 65 females, whereas Category B had 63 men and 59 females. Category A's mean age was 40.03 ± 16.09 years, whereas Category B's mean age was 37.92 ± 12.73 years.

Table 1: Demographical Characteristics of Two Groups

Parameters	Category A	Category B	P value
Total Patient	122	122	-
Sex Distribution			
• Male	57	63	0.12
• Female	65	59	
Mean Age (in years)	40.03±16.09	37.92±12.73	0.29

The groups showed no significant differences in BMI, hematological, and biochemical indicators, suggesting equal health metrics across all groups (Table 2). More precisely, there were no significant statistical differences in the average BMI, hemoglobin levels, total protein, serum albumin, and random blood sugar levels between the two groups.

Table 2: Comparison of BMI, Hematological and Biochemical Parameters

Parameters	Category A	Category B	P value
Mean BMI (in Kg/m^2)	27.83±4.16	28.12±3.71	0.75
Mean Hemoglobulin Level (in gm/dL)	12.01±2.11	12.76±2.42	0.30
Mean Total Protein (in gm/dL)	6.42±1.37	6.68±1.02	0.58
Mean Serum Albumin (in gm/dL)	3.81±0.97	3.62±0.65	0.54
Mean Random Blood Sugar (in mg/dL)	118.56±12.65	114±13.37	0.41

Both groups had a diverse range of surgical treatments, including inguinal hernioplasty, cholecystectomy, and appendicectomy, among others (Table 3). The allocation of these procedures was very equitable among the groups, indicating no significant disparities in the types of surgeries performed.

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Table 3: Procedure Performed for Category A and B

Procedure	Category A	Category B
Inguinal Hernioplasty	19	22
Inguinal Herniorrhaphy	09	07
Cholecystectomy	31	36
Appendicectomy	11	14
Jaboulay Procedure for Hydrocele	18	24
Ventral & Incisional Hernia	11	08
Lipoma Excision under TIVA, GA	6	2
Varicose Vein Stripping/ Ligation	12	07
Others[#]	5	2

[#] *CBD Exploration, Mesenteric Cyst Excision, Gastrojejunostomy, Cystogastrostomy*

The average operating durations for different operations were likewise similar between Category A and Category B (Table 4). While there were some minor variations, none of them were statistically significant, suggesting that the length of procedures was consistent in both groups.

Table 4: Comparison of Mean Operating Time

Procedure	Mean Operating Time (in mins)		P value
	Category A	Category B	
Inguinal Hernioplasty	54.03±12.87	59.12±11.87	0.076
Inguinal Herniorrhaphy	49.22±13.45	53.76±11.98	0.134
Cholecystectomy	80.29±19.28	86±15.22	0.089
Appendicectomy	48.32±7.09	43.54±09.22	0.061
Jaboulay Procedure for Hydrocele	31.09±10.21	28.04±8.02	0.122
Ventral & Incisional Hernia	87.45±11.06	91.02±12.45	0.095
Lipoma Excision under TIVA, GA	28.08±5.87	24.50	0.058
Varicose Vein Stripping/ Ligation	49.56±08.66	54.36±8.02	0.081
Others[#]	112.66±18.02	121.0	0.074

The rate of SSI was greater in Category B as compared to Category A (Figure 3). Category B had a higher incidence of severe SSIs, including a prominent instance of mesh infection after mesh hernioplasty. The elevated infection rate indicates possible variations in postoperative treatment or patient vulnerability among the groups (Table 5).

Table 5: Incidence of SSI as per CDC criteria among two groups

Procedure	Category A				Category B			
	Total	Superficial	Deep	Organ Space	Total	Superficial	Deep	Organ Space
Inguinal Hernioplasty	0				1		1	
Inguinal Herniorrhaphy	1	1			0			
Cholecystectomy	2	1	1		3	2	1	
Appendicectomy	0				1	1		
Jaboulay Procedure for Hydrocele	0				1	1		
Ventral & Incisional Hernia	1	1			2	1	1	
Lipoma Excision under TIVA, GA	0				0			
Varicose Vein Stripping/ Ligation	0				0			
Others[#]	1	1			1	1		

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Figure 3: SSI (Deep) in Category A Post Cholecystectomy (Left), SSI (Superficial) in Category B Ventral Hernia (Right)

The interventions for controlling SSIs were diverse, with Category B necessitating slightly more rigorous therapies, such as vacuum dressing and mesh explantation (Table 6). Notwithstanding these infections, the average duration of hospitalization for simple cases was comparable among the groups. Nevertheless, patients with SSIs experienced a notably extended duration of hospitalization in Category B, indicating the heightened challenge of managing infections in this particular group.

Table 6: Intervention for Management of SSI

Parameters	Category A	Category B
Dressing only	2	3
Secondary Suturing	2	3
Vacuum Dressing	1	2
Mesh Explantation	0	1

DISCUSSION

The study compared the demographic, clinical, and procedural characteristics of two groups, Category A and Category B, each consisting of 122 patients. Substantial variations were observed in the sex distribution and mean age, with Category A having a higher proportion of females (65 females and 57 males) and an older average age (40.03 ± 16.09 years) compared to Category B (59 females and 63 males, mean age 37.92 ± 12.73 years).

BMI, hematological, and biochemical parameters were similar among the groups, indicating no significant differences in these health metrics. Specifically, the mean BMI was 27.83 ± 4.16 kg/m² for Category A and 28.12 ± 3.71 kg/m² for Category B. Mean hemoglobin levels were 12.01 ± 2.11 g/dL (Category A) and 12.76 ± 2.42 g/dL (Category B), total protein was 6.42 ± 1.37 g/dL (Category A) and 6.68 ± 1.02 g/dL (Category B), serum albumin was 3.81 ± 0.97 g/dL (Category A) and 3.62 ± 0.65 g/dL (Category B), and random blood sugar was 118.56 ± 12.65 mg/dL (Category A) and 114 ± 13.37 mg/dL (Category B).

Regarding the types of surgical procedures performed, both groups underwent a variety of operations, including inguinal hernioplasty (Category A: 19, Category B: 22), cholecystectomy (Category A: 31, Category B: 36), and appendicectomy (Category A: 11, Category B: 14), among others. The distribution of these procedures was fairly balanced between the groups, suggesting no major discrepancies in the types of surgeries conducted.

The mean operating times for various procedures were also comparable between Category A and Category B. For example, the mean operating time for cholecystectomy was 80.29 ± 19.28 minutes in Category A and 86 ± 15.22 minutes in Category B. Although slight differences were noted, none reached statistical significance, indicating

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that the duration of surgeries was consistent across both groups.

The incidence of SSI was higher in Category B compared to Category A. In Category B, 9 cases of superficial SSIs and 6 deep infections were recorded, including a notable case of mesh infection following mesh hernioplasty. In contrast, Category A had 5 superficial SSIs and 3 deep infections. This increased infection rate suggests potential differences in postoperative care or patient susceptibility between the groups.

Interventions for managing SSIs varied, with Category B requiring slightly more intensive treatments, such as vacuum dressing (Category B: 2 cases vs. Category A: 1 case) and mesh explantation (Category B: 1 case vs. Category A: none). Despite these infections, the mean length of hospital stay for uncomplicated cases was similar between the groups (Category A: 8.84 ± 2.12 days, Category B: 9.0 ± 1.8 days). However, for patients with SSIs, Category B had a significantly longer hospital stay (18.23 ± 2.11 days) compared to Category A (15.21 ± 3.33 days), reflecting the increased burden of infection management in this group.

Overall, while the groups were largely similar in terms of BMI, hematological, and biochemical parameters, Category B had a higher incidence of SSIs and required more extensive interventions. These results highlight the importance of targeted strategies to reduce infection rates and manage complications effectively, particularly for patients who may be at higher risk.

A study assessed the effectiveness of CHG versus PVI in preoperative skin antisepsis for dogs. The study found no substantial variation in bacterial logarithmic reduction between the two groups (CHG: 6.46 ± 2.62 log10, PVI: 6.51 ± 1.94 log10) [5]. Another study evaluated preoperative skin preparation with aqueous PVI alone versus a combination of PVI and CHG at a tertiary care hospital. The combination was found to significantly reduce colonization rates at the incision site compared to PVI alone, leading to lower postoperative wound infection rates [6].

For preoperative antisepsis in cesarean births, CHG-alcohol and PVI were evaluated in a randomized control experiment. While not statistically significant, the SSI rate was lower in the CHG-alcohol group (5.4%) than in the PVI group (8.6%) [7]. The effectiveness of CHG-alcohol against PVI for cesarean birth was the subject of a meta-analysis. In comparison to PVI, the study found that CHG-alcohol considerably decreased the probability of SSI [8]. For cutaneous antisepsis during cardiac surgery, a multicenter randomized experiment contrasted 2% CHG-70% isopropanol with 5% PVI-69% ethanol. Reoperations resulting from SSI were the main outcome, and CHG-alcohol indicated a tendency towards decreased reoperation rates [9]. The effectiveness of CHG alcohol versus PVI alcohol in lowering SSI after cesarean procedures was examined in a study. According to the study, the PVI group had a substantially higher SSI rate (14.28%; P=0.005) than the CHG group (6.95%) [10].

A study compared PVI and CHG-alcohol for skin antisepsis in gynecologic surgeries. The study noted a lower frequency of SSI in the PVI group when warmed to 37°C, but no significant difference between PVI and CHG-alcohol overall [11]. A review was conducted on preoperative skin antisepsis in veterinary surgery. The study found comparable efficacy between CHG and PVI in preventing postoperative SSI [12].

The effectiveness of PVI and aqueous lofexidine in gastrointestinal procedures was examined in a study. In comparison to PVI, lofexidine dramatically decreased SSI, according to the study [13]. PVI and CHG were compared in a meta-analysis for preoperative cutaneous antisepsis. In particular, for clean-contaminated procedures, the analysis showed that CHG was more effective than PVI in preventing postoperative SSI [14].

Generalizability

The findings of this trial apply primarily to patients aged 18-60 undergoing elective, non-laparoscopic general surgeries. However, the exclusion of diabetic, immunocompromised, and steroid-treated patients limits the generalizability to those populations. Additionally, the study was conducted in a single hospital setting, which may affect the external validity across different healthcare environments and surgical specialties. Therefore, while the results suggest that chlorhexidine alcohol is superior to povidone-iodine in reducing SSIs, further studies in diverse populations and surgical contexts are needed to confirm these findings.

CONCLUSION

In conclusion, while Category A and Category B were demographically and clinically similar in terms of BMI, hematological, and biochemical parameters, Category B exhibited a higher incidence of surgical site infections and required more extensive postoperative interventions. This led to a significantly longer hospital stay for patients with SSIs in Category B. These findings underscore the need for enhanced infection control measures and postoperative care to mitigate complications and improve patient outcomes.

Limitations

The limitations of this study include a small sample population who were included in this study. Furthermore, the lack of a comparison group also poses a limitation for this study's findings.

Recommendation

For preoperative skin preparation, chlorhexidine alcohol ought to be chosen to lower the risk of SSIs and enhance patient outcomes.

Acknowledgment

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supporting staff of our hospital who were involved in the patient care of the study group.

List of abbreviations

SSI - Surgical Site Infection
CA - Chlorhexidine Alcohol
PI - Povidone Iodine
NICE - National Institute for Health and Care Excellence
JAMA - Journal of the American Medical Association
BMI - Body Mass Index
IV - Intravenous
Inj - Injection
TIVA - Total Intravenous Anesthesia
GA - General Anesthesia
OT - Operating Table
POD - Postoperative Day
CDC - Centers for Disease Control and Prevention

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Conflict of interest

The authors have no competing interests to declare.

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