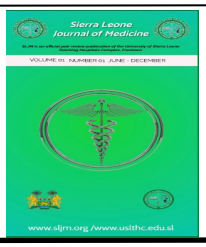
ORIGINAL ARTICLE

ISSN: 3007-4487

SIERRA LEONE JOURNAL OF MEDICINE

The Official Journal of University of Sierra Leone Teaching Hospitals Complex

Journal Homepage: www.sljm.org



Effectiveness of Chlorhexidine – Alcohol Compared with Povidone Iodine for Preventing Surgical Site Infection: A Randomized Trial

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ARTICLE INFO

Article History

Received: April 21, 2024

Accepted: August 10, 2024

Published: August 16, 2024

Corresponding Author:
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Technical Information

How to Cite: Idowu N. A. et al. Effectiveness of Chlorhexidine – Alcohol Compared with Povidone Iodine for Preventing Surgical Site Infection: A Randomized Trial: SLJM 2024;Vol 1(2) pp 75-79. https://doi.org/10.69524/sljm.v1i2.46

Editor-in-Chief: Prof. Kehinde S. Oluwadiya, University of Sierra Leone Teaching Hospitals Complex, Freetown, Sierra Leone.

Funding: No funding was received for this study.

Ethical Consideration

Conflict of interest: The authors declare they have no conflicts of interest that are directly or indirectly related to the research.

ABSTRACT

Background: Common agents for surgical site skin preparation are povidone iodine and alcohol based chlorhexidine /Cetrimide. The effectiveness of one over the other remains debatable. Our objective was to determine the effectiveness of alcohol-based chlorhexidine/cetrimide mixture compared with povidone iodine for preventing surgical site infection

Methods: All clean contaminated general and urological surgeries were recruited into the study. Patients were randomized into two groups (A & B) using GraphPad Cals. Alcohol-based chlorhexidine/cetrimide solution was assigned group A while povidone iodine solution was assigned group B. The rate of surgical site infection in each group was compared using hi-squared test. $P < 0.05$ was considered statistically significant.

Results: A total of 90 patients were allocated to each group of povidone iodine and alcohol based – chlorhexidine/cetrimide mixture/.The duration of the procedures ranged from 0.5-3hours in the povidone iodine group with a mean of 1.28 +/0.81 hours, and from 0.5 to 4 hours in the alcohol – chlorhexidine/ cetrimide mixture group, with a mean of 1.9 +/ 1.03 hours. The rate of surgical site infection among the povidone iodine and alcohol – chlorhexidine/cetrimide mixture group were 5.5% and 1.6% (relative risk RR=0.3) respectively. ($p< 0.001$).

Conclusions: This study has established that the rate of SSI was lower in patients that had alcohol–chlorhexidine/cetrimide skin preparation. This may be a pointer to the effectiveness of alcohol-based chlorhexidine/cetrimide mixture compared to povidone iodine. Lower incidence of SSI may lead to reduction in post-operative hospital stay.

Key words: Surgical Site Infection, Povidone Iodine, Chlorhexidine/Cetrimide-Alcohol.

1. INTRODUCTION

Surgical site infection (SSI) is defined as infection that occurs up to 30days after surgery or up to a year for a surgical wound with an implant. It can be an incisional or organ/space SSI[1]. The incisional SSI can either be superficial or deep depending on the depth of involvement.[2] The etiology of SSI is multifactorial.[3] It can be patient or surgery related. The development of surgical site infection imposes severe clinical and financial burden.[4] In a systematic review conducted in Nigeria it was noted that the pooled cumulative incidence of surgical site infection was 14.5%. The incidence could be as high as 40% depending on the type of the surgical wound.[5] According to the Center for Disease Control (CDC), surgical wounds are classified as clean wound which refers to any incised wound that does not involve entry into hollow viscus such as lipoma excision, clean contaminated wound which refers to surgical wound that involves visceral organ with at most minimal spillage such as appendectomy, contaminated wound which refers to wounds that involve visceral organ with spillage and the last is dirty infected wound.[6] The preventive strategy for SSI is aimed at eliminating both patients 'related factor and procedures' related factor. This is achieved by both antibiotic surgical prophylaxis and pre-operative skin preparation. Pre-operative skin preparation will decontaminate the surgical site and thereby lowering the risk of surgical site infection. These practices have led to significant reduction in the rate of surgical site infection. The commonly used antiseptic agents are povidone iodine and alcohol based chlorhexidine /cetrimide mixture[7]. Both preparations have been reported to

be effective but the efficacy of one over the other is still a subject of debate.[8] WHO guidelines have favored chlorhexidine-alcohol antiseptic agent as an agent of choice for surgical site skin preparation antisepsis while other series have considered povidone iodine.[9] Ulasi et al reported that the most commonly used antiseptic agents in Nigeria are povidone iodine, chlorhexidine/ cetrimide mixture. And isopropyl alcohol. Alcohol based chlorhexidine/ cetrimide mixture and povidone iodine are broad spectrum agent for surgical site skin preparation. The efficacy of one over the other remains controversial. Some authors have considered the choice of chlorhexidine/cetrimide-alcohol based antiseptic agents ahead of povidone iodine as premature.[10] In a study conducted in Port Harcourt Nigeria, it was noted that alcohol-based chlorhexidine cetrimide mixture was more effective in reducing surgical site infection compared with povidone iodine while similar study in the same setting observed no difference in the effectiveness of both agents.[11] This study was therefore designed to investigate the effectiveness of chlorhexidine/cetrimide –alcohol based antisepsis vs. povidone iodine. Considering the clinical and financial burden of surgical site infection it was worthwhile to determine an effective antiseptic agent for preventing surgical site infection to ameliorate these burdens. Our objective was to determine the incidence of surgical site infection in alcohol based chlorhexidine/ cetrimide mixture group and povidone iodine group and to compare the rate of surgical site infection between the two groups.

2. PATIENTS AND METHOD

This was a prospective hospital-based comparative randomized trial that was conducted over a period of 18 months in both urology and general surgery units, Department of Surgery, Ladoke Akintola University of Technology Teaching Hospital(LTH) Ogbomoso, Oyo State, Ogbomoso is the second largest town in Oyo State. It does not only serve the people of Ogbomoso but also receives referral from the neighboring states of Osun and Kwara. The hospital was established by the government of Oyo State in 2011, has 300 in-patient beds. There are four operating theatres for major surgeries and one separate day-case theatre for minor surgeries. There is a specialized operating theatre for dirty surgical cases. About 3,600 cases are done annually.. All clean contaminated general and urological surgeries including major, minor, elective and emergency surgeries were recruited into the study (procedures such as orchidectomy and elective colorectal surgery are considered as clean contaminated in this study). Patients with diabetes mellitus, retroviral disease, those on cytotoxic drugs or chronic steroid use, as well as cases of revisited and dirty infected surgeries, were excluded from the study. A total of 180 patients were recruited into the study following informed consent, consisting of 90 patients in each group.

2.1 Ethical Approval

This was obtained from the Ethics and Research Committee of LTH Ogbomoso, with an approval number LTH/OGB/EC/2023/300

2.2 Clinical Evaluation

Patients were evaluated and investigated. The diagnosis of surgical diseases was established including the indications for surgery. This was done in both urology and gastrointestinal surgery unit

2.3 Randomization

Following an informed consent, patients were randomized into chlorhexidine/cetrimide mixture –alcohol group-A OR povidone iodine group-B by computer generated sequence on line. (Simple randomization) using Graph pad Quick cals.[12] The sequence generated was followed during allocation into either group.

2.4 Surgical Procedure, Intervention and Technique of Skin Preparation

All the patients recruited for elective procedures were asked to undergo soap and water baths on the morning of the surgery. Hairy operating sites were shaved on the morning of surgery for elective procedures and in theatre for emergency procedures. The shavings were done by the peri-operative nurses.

Single dose parenteral broad spectrum antibiotics (500mg levofloxacillin) were administered on the entire patient at the induction of anesthesia by the anesthetists. Patients will either have alcohol based chlorhexidine/cetrimide mixture at a concentration of 0.1% chlorhexidine/0.5% cetrimide -70% isopropyl alcohol or 10% povidone iodine as agents for skin preparation based on their group. The surgeons were only aware of the agents to be used in the operating theatre during operation.

Patients that that fell within povidone iodine group had scrub and paint which was allowed to dry before surgical incision while patients that fell within alcohol based chlorhexidine/cetrimide group had chlorhexidine/cetrimide based skin preparations thrice. This was followed by application of 70% isopropyl alcohol. .

Surgical sites were either cleaned with alcohol based chlorhexidine/cetrimide mixture or povidone iodine. Firm gauze dressing was subsequently applied.

2.5 Post-Operative Care

Th. Patients were monitored for surgical site infection according to CDC guidelines which broadly involve local and systemic clinical features of wound sepsis. from post –operative day 3 for up to 30 days after surgery.[13] Wound evaluation during clinic appointment was done by the resident doctors and consultants who were unaware of the agent used on the patients. Patients with sign and symptoms of surgical site infection such as fever, pain, tenderness, discharge and swelling had wound swab microscopy, culture and sensitivity. This surveillance was done by the residents doctors and the microbiologists. Infection that involved the skin and subcutaneous tissue of the incision in the presence of either purulent drainage from the superficial incision, or cultured organism and patient had at least one of the following localized pain or tenderness, localized swelling or erythema was evaluated as superficial incision SSI. Infection that involved the fascia or muscle layers with the above signs and symptoms as stated above was considered as deep incisional SSI while the infection that involved any part of the body that was deeper than the fascia or muscle layers was considered as organ/space SSI. Patients that developed SSI were managed with the sensitive antibiotics and adequate wound dressing. The degree of surgical site infection as well as microorganism cultured in either group was recorded in a designed proforma.

2.6 Statistical Analysis

The data obtained were entered into IBM SPSS version 22. Calculation of mean, median and mode were estimated as required. Independent samples t-test was used to compare means among variables. The incidence of SSI in each group was calculated and the difference was analyzed with the chi-square test. The relative risk was estimated. $P<0.05$ was considered statistically significant.

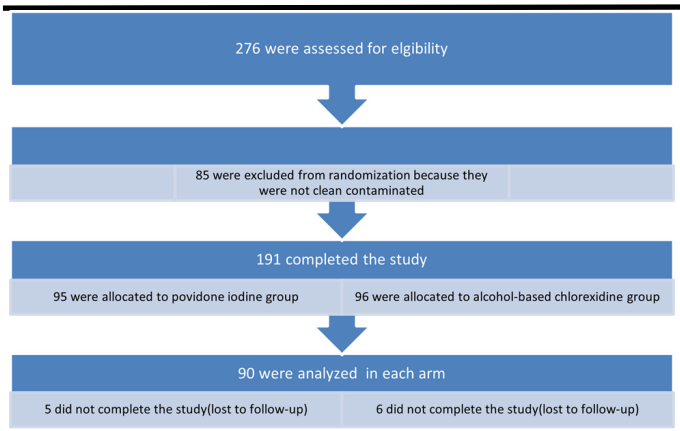

Figure1: Flow Diagram for Clinical Assessment, Randomization, Allocation, Follow-up and Analysis

2.7 Data Availability

The data will be made available upon request from the corresponding author with permission from Research and Ethics Committee of Ladoke Akintola University of Technology Teaching Hospital.

3. RESULT

A total of 276 patients were assessed for eligibility during the study period. Eighty five of them were excluded from the study because they did not fall within clean contaminated surgeries. However, 180 patients eventually completed the study. Eleven other patients were lost to follow-up. A total of 90 patients each were allocated to each group of povidone iodine and alcohol-based chlorhexidine/cetrimide. This is shown in figure 1.

The surgical operations performed on the studied population primarily involved gastrointestinal and genitourinary procedures. Genitourinary surgeries accounted for 102 procedures (56.6%), while gastrointestinal surgeries constituted 43.3% (78 patients), as shown in Table 1. The duration of procedures in the povidone iodine group ranged from 0.5 to 3 hours, with a mean of 1.28 hours (±0.80 SD). In contrast, the alcohol-based chlorhexidine group had procedures ranging from 0.5 to 4 hours, with a mean of 1.90 hours (±1.03 SD). The difference between groups was statistically significant ($p < 0.001$).

The overall incidence of surgical site infection in this study was 7.2%, (5% vs. 2.2% for gastrointestinal and genitourinary surgery respectively) while it was 5.5% (relative risk [RR], 0.1) in the povidone-iodine group and 1.6% (RR, 0.03) in the alcohol-based chlorhexidine/cetrimide mixture group. This difference was observed to be statistically significant ($P < 0.001$). All patients with SSI in either group developed superficial incisional SSI, except for one with organ space infection, which was noted in the povidone-iodine group. This was discovered following pelvis sonogram, which showed pelvic collection in a patient who had undergone open prostatectomy. Other patients who developed SSI included those who had bilateral total orchidectomy, hemicolectomy and appendectomy, Table 2.

Table 1: Rate of Surgical Site Infection in Each Study Group

Surgical Site Infection	Yes	No	Total
Povidone Iodine group	10 (5.5%)	80(44.4%)	90
Alcohol – Chlorhexidine/ Cetrimide Group	3 (1.6%)	87(48.3%)	90
Total	13 (7.2%)	167(92.7%)	180
P<0.001			

Table 2: Surgical Procedures

Gastrointestinal Surgery	Frequency n(%)	Developed SSI n(%)	Group A	Group B
Diversionary colostomy	13 (7.2)	0	0	0
Appendectomy	40 (22.2)	2 (15.4)	1	1
Hemicolectomy and anastomosis	10 (5.5)	2 (15.4)	0	2
Cholescystectomy	5 (2.7)	0	0	0
Genitourinary Surgery				
Open suprapubic cystostomy	12 (6.6)	1 (7.7)	1	0
Partial cystectomy	2 (1.1)	0	0	0
Ureteroneocystostomy	20(11.1)	2 (15.4)	0	2
Open cystolithotomy	11(6.1)	0	0	0
Nephrectomy	5 (2.7)	0	0	0
Pyeloplasty	4 (2.2)	1 (7.7)	0	1
Nephrolithotomy	4 2.2)	0	0	0
Open prostatectomy	26 (14.4)	3 (23.1)	1	2
Bilateral total orchidectomy	28 (15.5)	2 (15.4)	0	2
Total	180 (100)	13 (100)	3	10

The microorganisms cultured from these wounds were Staphylococcus aureus, Pseudomonas aeruginosa, and Escherichia coli. Staphylococcus aureus was responsible for the majority of infections (61.5%, 8 cases), followed by Escherichia coli, (30.7%, 4 cases).

4. DISCUSSION

This study investigated the effectiveness of an alcohol-based chlorhexidine/cetrimide mixture compared with povidone-iodine for preventing SSI. The global pooled incidence of SSI has been reported to be 2.5%, with the highest incidence of 7.2% reported in the African region. The overall incidence of SSI observed in this study was similar to the finding in the African region, which may be due to the same study location.

The rate of SSI depends on several factors. One of these is the class of the surgical wound. According to the Center for Disease Control surgical wound classification, the rate of surgical site infection in clean contaminated wounds is about 3- 10%[14] .This agrees with the finding from this study. A similar study reported a higher incidence of 22.4% in clean contaminated surgeries,[1] which contrasts with our findings.

The rate of surgical site infection in povidone-iodine group was significantly higher than in alcohol-based chlorhexidine cetrimide group (5.5% vs. 1.6%), with a relative risk of 0.3 This study further supports similar previous studies that have confirmed the effectiveness of alcohol based chlorhexidine cetrimide mixture compared with single agent povidone-iodine. Darouiche et al reported an SSI rate of 16.1% and 9.5% for povidone-iodine group and alcohol based chlorhexidine/cetrimide group, respectively.[15] In a similar study conducted by Luwang AL et al, the SSI rate in both povidone-iodine group and alcohol based chlorhexidine was 8.6% and 5.4%, respectively.[16] This rates were higher compared to the findings from this study.

Other factors that may affect the incidence of SSI, apart from the type of surgical wound, is the duration of surgery. It has generally being reported that prolonged operative duration increases the risk of surgical site infection.[17] This is in contrast to what was noted in this study. Prolonged operative duration was noted in alcohol-based chlorhexidine/ cetrimide mixture group with lower incidence of SSI. This finding may not be unconnected with the heterogeneity of the surgical procedures investigated.

The most commonly reported degree of post-operative wound infection is superficial incisional SSI.[1] This study was no exception, as all the groups with SSI developed superficial incisional SSI, except for one case of organ space SSI. This was noted in a patient that had open simple prostatectomy among the povidone-iodine group. This has further established the effectiveness of alcohol – chlorhexidine/cetrimide mixture compared with povidone iodine for surgical site prophylaxis.

The micro-organisms isolated from the infected surgical wounds from this study which included Staphylococcus aureus, Escherichia coli, Pseudomonas were the most commonly reported culprits in surgical site infection.[14] This study is consistent with a similar series by AA Kalayu et al who reported Staphylococcus aureus as most organism identified.[18] This may be linked to the large presence of Staphylococcus aureus among the skin flora.

4.1 Conclusion

This study has established that the rate of SSI was lower in patients who had alcohol-chlorhexidine for surgical site skin preparation compared to povidone iodine. This has shown alcohol - chlorhexidine solution to be more effective in preventing SSI.

Considering both the clinical and financial burdens of surgical site infection, surgeons should adopt more effective anti-sepsis for surgical site skin preparation and avoid extended antibiotic surgical prophylaxis when not indicated

4.2 Limitation

This study did not consider factors such as time of surgery, American Society of Anesthesiologists (ASA) category of the patients, pre-operative circulatory status and specific timing of antibiotics prophylaxis among others which may affect the risk of SSI and could subsequently affect the outcome of this study.

Conflicts of Interest

The authors declare no conflicts of interest

Funding

The study was funded solely by the authors

Contributor Roles Taxonomy Statement

Idowu N A: Conceptualization, formal analysis, original draft, formal analysis, writing review & editing
Akanbi OO: Writing, validation, review & editing methodology
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Rasheed WM: Writing, review & editing, resources, investigation

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