

Surgical Site Infection Following Laparotomy, Is There A Role For Surgical Incise Drapes?

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ABSTRACT

Background

Surgical site infection (SSI) occurs in about 25 to 26% of patients after elective laparotomy. SSI is a significant cause of morbidity, increased length of hospital stay, increased cost of treatment and in some cases even mortality.

Reduction of SSI will reduce the above complications. The use of antiseptic incise drapes in the prevention of SSI in resource-poor countries such as Nigeria is relatively limited. This study aims to evaluate the use of antiseptic drapes in the prevention of SSI compared to the routine method of skin preparation.

Materials and methods

The study is a prospective, single blind, randomized interventional study carried out in University of Port Harcourt Teaching Hospital in a year. A data sheet was used to collect post-operative progress reports of the subjects, especially on wound healing and likely SSI.

Data collected was entered in Microsoft Excel version 10, and analyzed using the Statistical Package for Social Sciences (SPSS). Results were presented in graph and tables.

Results

There was a reduction in surgical site infection with the use of antiseptic incise drapes from 28.3% to 0.8%. This was more apparent in class III wounds and this was statistically significant. Although, superficial and deep SSI were more without the use of antiseptic incise drapes, it was not statistically significant.

Conclusion

This study reveals that the use of antiseptic incise drapes significantly reduces bacterial recolonization during surgery and Surgical Site Infection (SSIs).

Keywords: surgical site infection (SSI), antiseptic incise drape, wound, contamination.

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I. Introduction

Surgical site infection (SSI) occurs in about 25 to 26% of patients after elective laparotomy.^{1,2} SSI is a significant cause of morbidity, increased length of hospital stay and increased cost of treatment.^{2,3,4}

The burden associated with SSI has led to the development of measures in preventing SSI, such as use of antiseptic skin preparation,⁵ antibiotic prophylaxis,⁶ wound irrigation,⁷ silver impregnated dressing,⁸ changing instruments before wound closure,⁹ preoperative hair removal,¹⁰ intra-cavitary lavage,¹¹ and antiseptic incise drapes.¹²

Although there is theoretical advantage for the use of antiseptic incise drapes, conflicting reports have been published regarding their usefulness in limiting bacteria contamination around the surgical site and preventing SSI.¹³ Moreover, re-colonization of the skin following antiseptic preparation is also more rapid under antiseptic incise drapes compared with skin preparation alone.¹⁴ The use of antiseptic incise drapes in the prevention of SSI in resource-poor countries such as Nigeria is relatively limited.

A study evaluating the knowledge, attitude and infection control practices of two tertiary hospital in Port Harcourt has been carried out by Brisibe et al.¹⁵ Another study on the implementation of infection control

policy in Port Harcourt has also been carried out.¹⁶ This study aims to evaluate the effectiveness of antiseptic incise drapes in the prevention of SSI compared to the routine method of skin disinfection with antiseptics.

II. Materials And Methods

The study is a prospective, double-blind, randomized interventional study carried out at the Surgery Department of the University of Port Harcourt Teaching Hospital, Rivers state Nigeria from January 1st 2019 to December 31 2019.

Ethical approval to conduct the study was obtained from the Ethics Committee of the institution before commencement of the study. Informed consent was obtained from the prospective subjects before recruitment into the study.

The study population consisted of adult patients presenting at the surgical department of the University of Port Harcourt Teaching Hospital scheduled for laparotomy with no established infections on the skin over which incision will be made or established infection who gave consent to be included in the study.

Exclusion criteria included patients with immunosuppression, chronic smokers, malnourished patients, patients with renal failure, diabetes mellitus, surgery beyond three hours, obese patients, elderly patients above 65 years, and patients with established sepsis.

Sample size calculation is based on the formula for interventional study.¹⁷

$$n = \frac{(Z\alpha + Z\beta)^2 p (1 - p)}{(p1 - p2)^2}$$

n = minimum sample size per group

Z α = standard normal deviate of 95% significant level, corresponds to a value of 1.96.

Z β = power of study of 80%, corresponds to a value of 0.84

p1 = proportion of outcome in study group from similar study; proportion of SSI among combination of antiseptic incise drape and perioperative skin care was 3.1% (0.031) based on a previous study by Yoshimura et al.¹⁸

p2 = proportion of outcome in study group in control study from similar study; proportion of SSI among perioperative skin care only was 14.1% (0.141) based on a previous study by Yoshimura et al.¹⁸

p = average proportion; $p1 + p2 = 0.031 + 0.141 = 0.086$

$$n = \frac{(1.96 + 0.84)^2 \times 0.086 (1 - 0.086)}{(0.031 - 0.141)^2} = 0.6163 = 50.9 \sim 51$$

Allowance for 10% attrition

$$= \frac{n}{1 - \text{Attrition rate}}$$

where n is minimum sample size (51), attrition is 10% (0.1)

$$= \frac{51}{1 - 0.1} = 56.66 \text{ rounded off to } 60$$

Hence, this study will comprise of 60 patients per group making a total sample size of 120.

The patients were assigned into the groups in the study by randomization via allocation concealment before skin preparation. This was achieved using opaque envelope comprising of pieces of paper labeled as A or B. The opaque envelope contained 60 pieces of paper labeled as A and another 60 pieces of paper labeled as B. A piece of paper from the opaque envelope was selected for each of the eligible patient in the study by an independent observer and the patient was then assigned to the group on the paper.

Group A: Patients in this group underwent the usual perioperative preparation of the surgical area.

Group B: Antiseptic incise drapes was used for patients in this group perioperative in addition to perioperative skin preparation.

Single blinding was employed in this study. The patients were unaware of the particular group they would belong to. The researcher assessing the outcome variables was aware of the group as well as the intervention received by the patient. The single blinding employed in the study ensured some level of validity of findings.

All patients were wheeled into the operating room at the assigned time of the surgery. In Group A subject, the surgical area was decontaminated with savlon thrice, then dried and then 90% alcohol base solution (methylated spirit) applied and laparotomy carried out accordingly after appropriate draping. An antiseptic incise drape (Ioban™) was placed on the surgical area of the Group B patients after routine skin preparation as above and laparotomy was carried out accordingly. Skin incision was midline longitudinal.

All patients had intravenous second-generation cephalosporin (cefuroxime) at induction of anaesthesia.

The subjects were assessed for surgical site infections daily before discharge from the hospital, which included daily clinical history of operative site pain/tenderness, fever and sero-purulent stain of operative site

dressing. Wound inspection was done on day 4 or day 5. The primary outcome variable was SSI. Secondary outcome variables included wound healing.

A PROFORMA data form (Appendix I) was used to collect information such as age, gender and other relevant clinical information including risk factors. A data sheet was used to collect post-operative progress reports of the subjects, especially on wound healing and likely SSI.

Data collected via study proforma and data sheet were entered in Microsoft Excel version 10, and analyzed using the Statistical Package for Social Sciences (SPSS) version 22 software. Descriptive statistics of categorical variables were presented appropriately using frequencies and percentages in tables and charts, while descriptive statistics of numerical/continuous variables were presented in means and standard deviation. The differences in the proportions of SSIs between groups in the study was compared using Chi-Square (X^2) statistics. Bivariate logistic regression using Odds Ratios (ORs) analyses was employed to identify the risk level of SSI between the study groups. Odds ratios corresponding to 95% Confidence Interval was determined as measures of association. A p-value of less than or equal to 0.05 ($p \leq 0.05$) was considered statistically significant.

III. Results

Table 1: Socio-Demographic Data

Characteristics	Frequency n=120	Percentage (%)
Sex		
Male	64	53.3
Female	56	46.7
<i>M/F Ratio</i>		<i>1.43:1</i>
Marital Status		
Married	70	58.3
Single	43	35.8
Widow	5	4.2
Divorced	2	1.7
Educational Level		
No Formal Education	10	8.3
Primary	8	6.7
Secondary	48	40.0
Tertiary	54	45.0
Religion		
Christian	114	95.0
Islam	6	5.0
Occupation		
Civil Servant	37	30.8
Trading	34	28.3
Farming	19	15.8
Professional	9	7.5
House Wife	7	5.8
Students	6	5.0
Unemployed	8	6.7

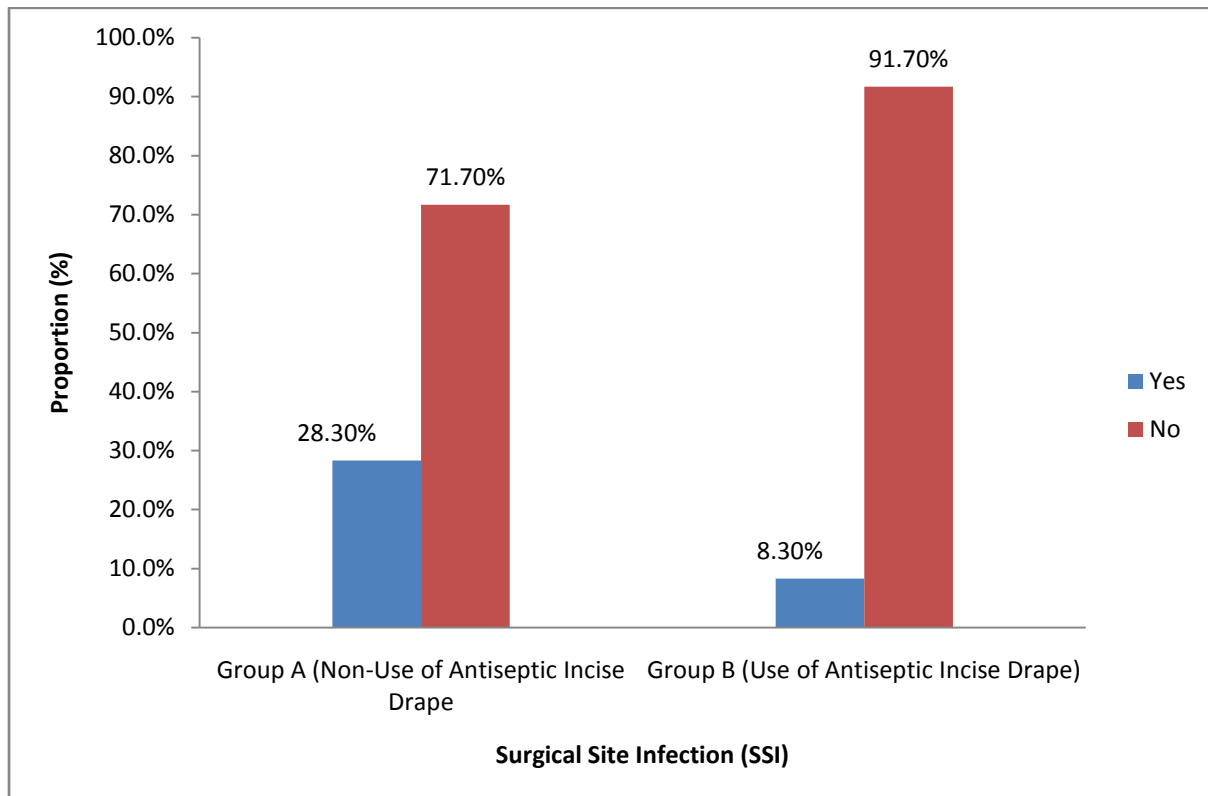


Figure 1: Showing incidence of Surgical Site Infections (SSI) after laparotomies with perioperative skin preparation alone and with skin preparation and use of antiseptic incise drapes.

Participants who had perioperative skin preparation only, 28.3% had surgical site infection (SSI) after laparotomies, compared to 8.3% who had skin preparation and used antiseptic incised drape had surgical site infection (SSI) after laparotomy.

Table 2: Wound Classification

Characteristics	Group		Fishers exact p
	A (PSD) n=60 Freq (%)	B (PSD+AD) n=60 Freq (%)	
Class I (Clean)			
Yes	2 (11.76)	1 (4.76)	0.5768
No	15 (8.24)	20 (95.24)	
Class II (Clean Contaminated)			
Yes	7 (25.0)	1 (5.0)	0.1159
No	21 (75.0)	19 (95.0)	
Class III (Contaminated)			
Yes	8 (53.33)	3(15.79)	0.0030*
No	7 (46.67)	16 (84.21)	

*Statistically significant ($p < 0.05$)

There was a higher prevalence of SSI amongst participants with perioperative skin preparation alone compared to those with perioperative skin preparation and used antiseptic incise drapes as shown in Table 2. No statistical significance difference was observed in Class I and II but a statistically significant difference was observed in Class III ($p=0.003$).

Table 3: Comparison of the occurrence of surgical site infection between the use of perioperative skin disinfection alone and perioperative skin disinfection with the use of antiseptic incise drapes.

Surgical Site Infection	Group		Total	df	Chi-Square (χ^2) (p-value)	Odds Ratio (OR) (95% CI)
	A (PSD) Freq (%)	B (PSD+AD) Freq (%)				
Yes	17 (28.3)	5 (8.3)	22 (18.3)	1	6.73 (0.01)*	4.35 (1.36-14.76)
No	43 (71.7)	55 (91.7)	98 (81.7)			
Total	60	60	120			

CI=Confidence Interval **df**=degree of freedom **statistically significant (p<0.05)*

The findings observed a statistically significant higher proportion of SSI amongst participants with perioperative skin disinfection alone compared to those with perioperative skin disinfection with the use of antiseptic incise drapes, (28.3% vs. 8.3%; p=0.01) as shown in Table 2.

The bivariate logistic regression analysis showed that participants with perioperative skin disinfection alone were 4.35 times more likely to experience SSI compared to those with perioperative skin disinfection with the use of antiseptic incise drapes (OR=4.35; p=0.001; 95%CI: 1.36-14.76).

Table 4: Depth of Infection

Type of Infection	Group A (PSD) n=60	Group B (PSD+AD) n=60	Fishers exact p
	Frequency (%)	Frequency (%)	
Superficial	12 (20.0)	4 (6.67)	
Deep	5 (8.3)	1 (1.67)	0.58
Organ Space	0 (0.0)	0 (0.0)	
Total	17	5	

Table 4:Depth of infection

Although Superficial and Deep types of infection were higher in Group A (non-use of antiseptic incise drapes) compared to Group B (use of antiseptic incise drapes) (20.0% vs. 6.67% and 8.3% vs. 1.67%), these findings were not statistically significant (p=0.58).

IV. Discussion

Surgical site infections (SSIs) are defined as infections occurring up to 30 days after surgery (or up to one year after surgery in patients receiving implants) and affecting either the incision or deep tissue at the operation site. Despite preoperative skin preparation, complete sterilization of the skin is not possible and gradual recolonization may occur and lead to SSI.^{19,20}

The present study had more male respondents (53.3%), those who are married were 58.3%, those with tertiary education were 45.0%. Overall Mean age and BMI were 34.38±1.51 and 33.35 ± 1.26.

Our study revealed a reduction in SSI with the use of antiseptic incise drapes after laparotomy as shown in Figure 1. This seems to be in agreement with studies conducted by other authors.^{19,20} A single centre unblinded prospective cohort study conducted in Saudi Arabia found no difference between use of these drapes and not using the drapes in the prevention of SSI.²¹ However, this current study was single blinded and had a higher sample size. In the Saudi Arabian study, the patients who used the drapes seemed to be worse than those without the drapes, these factors could explain the discordant result compared to this study.

According to a study conducted by Sarath and Umamaheswari,²² surgical site infections were the most common post-operative complications which occurred in 27% of the all clean-contaminated surgeries; these findings were also similar to the present study with an overall prevalence of surgical site infection of 28.3%. Although a much lower prevalence of between 13.58% to 15.6% was recorded in a Nigerian study conducted by Olowo-Okere et al.²³ and 8.95% observed in a study conducted by Lilani et al.²⁴

The present study showed a statistically significant higher rate of SSI in the group with non-use of antiseptic incise drape compared to group with the use of antiseptic incise drapes (p=0.01). The bivariate logistic regression analysis also showed that respondents without antiseptic incise drapes were 4.35 times more likely to experience SSI compared to those with antiseptic incise drapes. Findings of this study were similar to a study conducted by Karapınar and Kocatürk²⁰ and Bejko et al.²⁵

In the present study, the prevalence of SSI amongst participants for clean wound (Class I) was 3.3%, clean contaminated wound (Class II) 15.0% and contaminated wound (Class III), 21.66%, which is in line with findings from the studies conducted by Zinn and Swofford,²⁶ and VanWicklin and Brubaker.²⁷ Although in a study conducted by Lilani et al.,²⁴ the prevalence of SSI for clean wound was similar to our study (3.03%), the prevalence for clean contaminated wound was much higher (22.41%).

The present study showed a reduced prevalence of Class I to III surgical wound contamination in the group where antiseptic incise drape was used compared to the group with no antiseptic incise drape as shown in Table 3. However, there was no statistically significant difference in surgical wound contamination for Class I (p=0.50) and Class II (p=0.128). Moreover, Class III showed a statistical significantly lower surgical wound contamination in the use of antiseptic incisedrape compared to non-use (6.67% vs. 21.66%) thus indicating its effectiveness (p=0.04). This finding was similar to a study conducted by Moylan et al.²⁸ involving 2181 clean and clean-contaminated general surgical procedures performed to evaluate the effectiveness of an antiseptic

incise drape system versus use of a cotton system in reducing wound infection. Use of antiseptic incise drape had a significantly lower overall infection rate (2.83% vs. 6.5%) as well as better rates in clean (1.8% vs. 3.8%) and clean-contaminated (4.8% vs. 11.4%) procedures. According to a study by Milandt et al.,²⁹ it is possible that recolonizing organisms adhere to the antiseptic of the drape when the drape is taken off, thereby removing organisms from the skin.

This study reveals that the use of antiseptic incise drape significantly reduces bacterial recolonization during surgery and Surgical Site Infection (SSIs). The results from this study provide an important knowledge on the benefits of using an antiseptic incise drapes, and hopefully will prompt further discussion in our environment regarding its effectiveness and use. The use of antiseptic incise drape can be recommended to decrease SSIs in Port Harcourt.

Limitations of study

This study is limited by its low sample size.

Conflict of interest

The authors declare there was no conflict of interest in the study

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This study was self-sponsored by the authors

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Surgical Site Infection Following Laparotomy, Is There A Role For Surgical Incise Drapes?

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