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Original Research Paper

Single dose antibiotic with pre-operative vaginal preparation versus multiple doses of prophylactic antibiotics in respect to surgical site infection in elective caesarean section

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ABSTRACT:

Introduction: Surgical site infection (SSI) is one of the infectious complications that follow caesarean section(C/S). Perioperative prophylactic antibiotics and preoperative vaginal preparation with povidone-iodine solution are perioperative strategies for reducing its risk following C/S. Therefore, this research aimed to compare the incidence of surgical site infection following the use of a single dose of antibiotic with preoperative vaginal preparation versus multiple doses of antibiotics in elective C/S. **Study design**: A blinded randomized controlled trial. **Methods:** Two hundred eligible participants were randomized into two arms (100 each). Arm A (a single dose of intravenous antibiotics with preoperative vaginal preparation and placebo). Arm B (multiple doses of antibiotics). Data entry was done using statistical package of social sciences version 23. The fisher's exact and independent t- tests were used as tests of significance where applicable. A P< 0.005 is considered significant. **Results:** Incidence of surgical site infection in elective C/S in Ekiti State University Teaching Hospital was 2.5%. There was no significant statistical difference in the incidence of SSI between the two Arms (2% versus 3%, p-value is 0.651). The mean cost of antibiotics and hospital admission are lower in Arm A (#3,398.09) and (#75,820.00) respectively compared to (#4,836.60) and (#77,445.70) respectively in Arm B. There was a significant statistical difference in the mean cost of antibiotic treatment (*P* =value 0.0001) and admission (*P*=value 0.001) respectively. **Conclusion:** Single dose of intravenous antibiotic in combination with preoperative vaginal preparation is comparable with multiple doses in preventing SSIs in elective C/S.

Keywords: surgical site infections, prophylactic antibiotics, placebo, preoperative vaginal preparation, elective caesarean section.

INTRODUCTION:

SSI can be defined as an infection related to an operative procedure that occurs at or near the surgical incision within 30 days of the procedure or 90 days if prosthetic material is implanted at surgery.[1,2] Studies done in various centres in Nigeria revealed surgical site infection rates of 9.1 to 16.2%.[3] The three types of SSIs that are currently recognised are superficial (involving the skin and subcutaneous layer), deep (involving fascia and muscle), and organ/space (involving any part of the anatomy of the organs and spaces other than the incision,

which is opened or manipulated during operation, including endometritis).[4, 5]

Even with the use of preventative antibiotics, the rate of post-cesarean infections, such as SSIs, is still an issue today.[6] As a single antibiotic agent, Ceftriaxone 1g + Sulbactam 500mg is regarded as the drug of choice in this study because the World Health Organisation (WHO) recommends Ceftriaxone (bactericidal) as a prophylactic antibiotic and Sulbactam, a β lactaminase inhibitor, enhances the effectiveness of Ceftriaxone.[7] Povidone iodine is an iodinated polyvinyl polymer with broad antimicrobial activity against bacteria, and reommnded by WHO for preoperative vaginal washing.[7,8]

Vaginal cleansing right before caesarean delivery in women in labour and those with ruptured membranes lowers the risk of postoperative endometritis.[9] Alekwe et al.[10] discovered that a single intravenous dose of ceftriaxone 1g stat is equivalent to several doses of ampiclox, gentamicin, and metronidazole given over a seven-day period. This did not change the unacceptable rate of endometritis and wound infection, which was 23% for repeated doses and 21% for single doses on both arms. Another study conducted in southwest Nigeria also concluded that there was no difference in the incidence of endometritis (3% versus 2%) and wound infections (4%versus3%) when short term prophylactic antibiotics for 24 hours was compared to long term prophylactic antibiotics for 7days following elective caesarean section.[11] The results of the two aforementioned trials may have been impacted since the SSI diagnosis was not made within 30 days after surgery, as required by the CDC. According to WHO guidelines, prophylactic antibiotics shouldn't be given more than 24 hours after surgery.[12,13]

The incidence of surgical site infections (SSIs) following elective caesarean section in our center was unknown, and the potential benefit of single dose prophylactic antibiotic coupled with preoperative vagina preparation had not been explored prior to this study. This research seeks to compare incidence of surgical site infection following the use of a single dose of antibiotic with preoperative vaginal preparation versus multiple doses of antibiotics in elective C/S.

MATERIALS AND METHODS:

Design:

It is a randomized controlled trial done over a period of 12 months, between February 2021 and January 2022. This study was carried out at the obstetric unit in the Department Obstetrics and Gynaecology of Ekiti State University Teaching Hospital Ado Ekiti (EKSUTH), Ekiti State Nigeria. The number of the delivery per year in our center is presently 2180, and the caesarean section rates according to Olofinbiyi et al in 2015 audit is 35.5%[14].

Inclusion and exclusion criteria:

All pregnant women planned for elective C/S for various indications were recruited. The following patients were excluded from the study: Pregnant women who received antibiotics within 2 weeks before the operation, evidence of infection before the operation, previous midline scar or C/S with an intrapartum midline incision, anemia in pregnancy (PCV < 30%), Diabetic pregnant women, Patient with Human Immunodeficiency Virus positive in pregnancy, Patient with an allergy to povidone-iodine or any of the antimicrobials, and Patients who did not wish to participate in the study. Samples were taken for some basic investigations such as packed cell volume and urinalysis and were all within normal range.

Sample and randomization:

The participants were randomized into two arms of the study using blocked randomization table from computer-generated random numbers. Each random number corresponded to either Arm A (a single dose of intravenous antibiotics with preoperative vaginal preparation and placebo or Arm B (multiple doses of antibiotics). Each group contained 100 patients. The randomized patients for Arm A had vaginal cleansing done with 4×4cm gauze in a sponge holding forceps soaked in 10% povidone iodine solution, each gauze sponge was rotated 360- degree in all parts of the vagina, especially in the fornices, and the cleansing process lasting for 30 seconds. (Procedure was repeated twice). This was done following spinal anesthesia and urethral catheterization by the doctor who passed the catheter with two assistance who abducted the hip and flexed the knee joints of the lower limb. Arm A participants also received single dose of intravenous antibiotic (1.5g of Tandak: a Combination of Ceftriaxone 1g + sulbactam 500mg as a single antibiotic agent) immediately after the administration of anesthesia prior to skin incision, and placebos instead of active agent of antibiotics were given to the patient from 2nd to 7th day post operation. Arm B received same intravenous antibiotics daily plus metronidazole 500mg 8hrly for 48hours, and subsequently oral cefuroxime 500mg 12hourly and metronidazole 400mg 8hourly for 5 days.

The first dose of antibiotics was administered by the anesthetists immediately after the administration of

anesthesia prior to skin incision in the theatre, and subsequent doses by the nurses who were not aware of the allotment from the randomized package for each patient till patients were discharged. Thereafter, patients completed the oral doses at home. All caesarean sections were performed by at least a senior registrar. In both groups, the urinary catheter was removed post operatively after 24 hours. Post-operative packed cell volume was done on the 2nd post-operative day. The occlusive skin dressing was removed after 72 hours and the patients was taught wound care with methylated spirit cleansing until complete healing took place. Assessment of SSIs was made by the investigator or at least by the senior registrar of the unit who was not involved in the surgery or drug administration on days 3, 14 and 30 post-operatively based on follow up visit schedule and recommendation of CDC.[15]

Data analysis:

Data entry was done using the SPSS 23 version and presented in tables and pie charts. Continuous variables were presented as mean ± standard deviation and categorical variables in frequency tables and percentages. The Fisher's exact and independent t-tests were used as tests of significance where applicable.

Ethical considerations:

This research was approved by the ethics committee of the Ekiti State University Teaching Hospital Ado Ekiti (EKSUTH/A67/2019/10/010). Patients paid for the surgeries and the routine investigations prior to the surgery while the investigator paid for the drugs and the investigations after the surgery. Incentives were given to the patients to encourage them in the area of transportation.

RESULTS:

Table 1: Maternal characteristics of the participants in the two groups

	ARM A		ARM B	
Variables	**A single dose of antibiotic and preoperative vaginal preparation+ placebo**		**Multiple doses of prophylactic antibiotics**	
	N	**(%)**	**N**	**(%)**
Age group				
<20	1	(1.0)	0	(0.0)
20-29	18	(18.0)	29	(29.0)
30-39	72	(72.0)	69	(69.0)
40-49	9	(9.0)	2	(2.0)
Gestational age (weeks)				
<37	3	(3.0)	5	(5.0)
37-42	97	(97.0)	95	(95.0)
Parity				
Nulliparous	19	(19.0)	21	(21.0)
Primiparous	36	(36.0)	37	(37.0)
Multiparous	45	(45.0)	42	(42.0)
Number of previous abdominal surgeries				
0	35	(35.0)	38	(38.0)
1	38	(38.0)	41	(41.0)
2	26	(26.0)	21	(21.0)
3	1	(1.0)	0	(0.0)
Number of previous CS				
0	35	(35.0)	41	(41.4)
1	41	(41.0)	37	(37.4)
2	24	(24.0)	21	(21.2)
Total	**100**	**(100.0)**	**100**	**(100.0)**

Majority of the participants in each group were age group of 30-39yrs with total number of 141 equivalents to 70.5% of all the participant. One hundred and ninety-two (96%) of the caesarean sections were done at term (37- 42weeks), while

only 8(4%) were preterm. Multiparous women had the highest elective caesarean sections 87(43.5%) while the nulliparous had the least 40(20%).

Table 2: Presence of SSI in each Arm

Presence of surgical site infection	Group			
	Single dose of antibiotic and preoperative vaginal preparation+ placebo		Multiple doses of prophylactic antibiotics	
	N	(%)	N	(%)
No	98	(98.0)	97	(97.0)
Yes	2	(2.0)	3	(3.0)
Total	**100**	**(100.0)**	**100**	**(100.0)**

Fisher's exact test = 0.205, p-value = 0.651

Table 2 shows the presence of SSI in each Arm. Two elective C/S (2%) cases had SSI in Arm A compared to three (3%) in Arm B. There is no significant statistical difference in the incidence of surgical site infection between the two Arms (2% versus 3%, P value= 0.651). It was observed in this study that there was no case of urinary tract infection in both Arms.

Figure 1: Pie chart showing the incidence of surgical site infection (SSI)

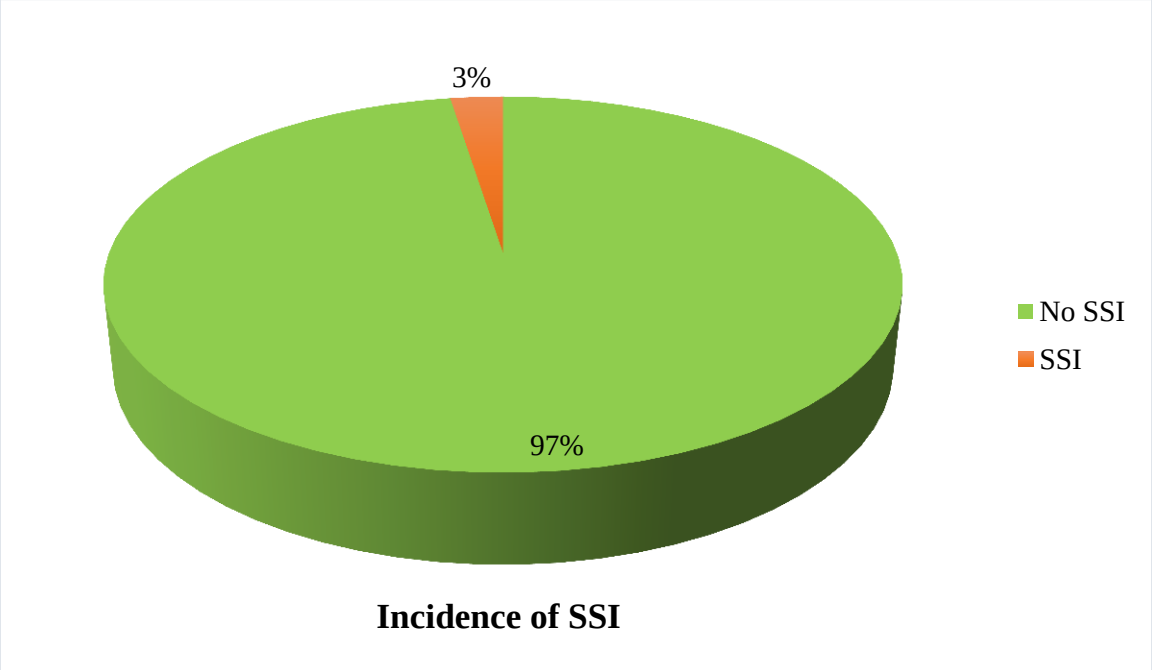

Figure 1 shows the incidence of SSI among participants. It shows that only 5 (2.5%) had SSI and 195 (97.5%) had no SSI.

Table 3: Types of SSI in each Arm

Types of surgical site infection	Group			
	Single dose of antibiotic and preoperative vaginal preparation+ placebo		Multiple doses of prophylactic antibiotics	
	N	(%)	N	(%)
Superficial SSI	2	(2.0)	1	(1.0)
Deep SSI	0	(0.0)	0	(0.0)
Organ space SSI (E)	0	(0.0)	2	(2.0)
No SSI	98	(98.0)	97	(97.0)
Total	**100**	**(100.0)**	**100**	**(100.0)**

Fisher's exact test = 2.34, p-value = 0.311, (E)= Endomtritis)

Table 3 shows the types of SSI in each Arm. Two (2%) elective C/S cases had superficial SSI and none (0%) had organ space SSI in Arm A compared to one (1%) superficial and two(2%) organ space (endometritis) SSI in Arm B. None of the Arm (A or B) had a case of deep SSI. There is no significant statistical difference in the incidence of type of surgical site infection between the two Arms .The p-value is 0.311.

Table 4: The total cost of antibiotics (naira), total cost of admission (naira), and the length of hospital stay (days) in each Arm

Variables	Group		T-test	P-value
	Single dose of antibiotic and preoperative vaginal preparation+placebo	Multiple doses of prophylactic antibiotics		
	Mean± SD	Mean±SD		
Total cost of antibiotics (Naira)	3398.09±2380.70	4836.60±3265.29	-3.560	<0.0001*
Total cost of admission (Naira)	75820.00±2388.05	77445.70±4393.10	-3.251	0.001*
Length of hospital stay (days)	4.00±0.00	4.04±0.28	-1.421	0.157

*Statistically significant

From table 4, the cost of antibiotic and hospital admission are statistically lower in Arm A when compared with those in Arm B, and it is statistically significant (#3,398.09 versus 4,836.60, p value- 0.0001) (#75,820.00 versus 77,445.70, P value - 0.001) respectively. There is however no significant statistical difference in the mean duration of hospital stay between the two groups. P- value is 0.157

DISCUSSION:

Surgical site infection (SSI) is one of the infectious complications that follow caesarean section(C/S), and is associated with high morbidity and mortality.[18] Several studies have been done both locally and internationally, with the conclusion that single and multiple doses of prophylactic antibiotics following elective C/S are comparable. Despite this fact, many centres like ours; EKSUTH still administer multiple doses of antibiotics following elective C/S, this may be due to the high incidence of SSI in these previous studies[10].

The incidence of surgical site infections (SSI) in this study is 2.5%. This result is comparable to the studies done by Madhavi Latha and Madhavi[19] where the incidence was 2.0%, and Walaa et.al[20] which was 3% (Cephalosporin Arm). The similarity could be the Cephalosporin group of drugs that were used in the two studies. The incidence of SSIs in this study is also comparable with the global range of 2.5% - 41.9%[21] and that of the United States of America 2- 7 %.[21] The incidence is however lower than the incidence of 9.1% in Kano[3], 16.2% in Ibadan[22]and 12.5% in Nnewi[21] Enugu state, all in Nigeria. It is also lower than the two studies that were done in Obafemi Awolowo Teaching Hospital Ile Ife, south west of Nigeria by Alekwe et al (22%)[10], and Ijarotimi et al (6%).[11] The significant decrease in the incidence of SSI in this study may be due to preoperative vaginal preparation with povidone iodine, which has broad antimicrobial activity with little or no pathogens resistance.[8] The combination of sulbactum with ceftriaxone, a β lactaminase inhibitor strengthens the efficacy of ceftriaxone, may also contribute to the reduction of incidence of SSIs in this study. The incidence is however higher than the incidence of wound infection (1%) in study that was done in Women's Hospital Kathmanda, Nepal by Bhattachan et al.[23] The lower incidence could be due to lower sample size (100), 14 days following up, and the diagnosis of SSIs was not made based on CDC's criteria.

This present study demonstrated that the incidence SSI was 2% for the single dose antibiotic + preoperative vaginal preparation (povidine iodine) group and 3% for the multiple doses, and there was no significant statistical difference between the 2 groups. P-value = 0.651. This is comparable to a study that was done by Mugisa et al[24] where the incidence of single dose of ceftriaxone and metronidazole versus multiple doses for antibiotic prophylaxis at elective caesarean section in Mulago hospital was 1.3% versus 2.4%. This incidence is however lower than the incidence of wound infection in a study that was done by Fadhili et al[17] in Tanzania with the incidence of 4.8% (single) versus 6.4%(multiple doses). Higher incidence may be due higher sample size (500). It may also be due to the antibiotic regimen (gentamicin in combination with metronidazole) unlike in this study where combination of sulbactum with ceftriaxone, was administered. The preoperative vaginal preparation with povidine iodine that was done in this study may also contribute to the lower incidence of SSIs. It is however contrary to the study that was done by Nitrushwa et al[25] where the incidence is higher in single dose than multiple doses 5.5% versus 2.6%. This may be because preoperative vaginal preparation with povidone iodine was not combined with the single dose.

The total prevalence of superficial (3), deep (0) and organ space (2) (endometritis) in this present study are

1.5%, 0% and 1% respectively. Absence of deep SSI in the study is similar to a study done by Kumari et al[26] in India. The similarity may be due to the usage of ceftriaxone in the two studies. The incidence of superficial and organ space (endometritis) SSIs in this study is lower than the study done by Babeeta & Kulhari[27] with 18(9%) and (5)2.5% superficial and organ space respectively. It was also observed in this present study that no case of organ space (endometritis) in the Arm A; but 2(2%) in the Arm B(multiple doses) has organ space SSI. This may be due to the application of preoperative vaginal preparation with povidone iodine in the Arm A, which has broad antimicrobial activity with little or no pathogens resistance.[8]

Most of the SSIs were diagnosed between 4 – 15days 4(80%) while 1(20%) between 16 – 30days. None was diagnosed on admission 0 – 3days. The diagnosis of SSIs made between 4 – 15 are comparable to a finding by Nitrushwa et al[25].in Rwanda where most diagnosis were made on day. The similarity may be due to the diagnosis based on CDC's criteria in the two groups.

During this present study there was no case of urinary tract infection, comparable to the incidence (1) 1.1% and (0) 0% in the studies done by Western et al[28] and Mohan et al[29] respectively. The mean cost of antibiotics (#3,398.09 versus #4,836.60) and admission (#75,820.00 versus #77,445.70) Arm A versus Arm B were statistical significantly different, with P –values of 0.001 and 0.001 antibiotics respectively. The significant difference of the total cost of antibiotics in this study is similar to several previous studies that were done by Fadhili et al[17], Ijarotimi et al[11] and Bhattachan el al.[23] It is not surprising that the cost for antibiotics and admission were higher in multiple doses regimen than the single dose because of multiple antibiotics, more cases of SSIs mainly endometritis, and these required higher cost of antibiotics and hospital stay. Arm B had higher incidence of endometritis than A, probably because preoperative vaginal preparation with povidone iodine was not considered.

CONCLUSION:

Combination of Ceftriaxone 1g + sulbactam 500mg as a single antibiotic agent with preoperative vaginal preparation (povidone- iodine) is as effective as a multiple doses of prophylactic antibiotics: ceftriaxone 1g + sulbactam 500mg) 1.5g daily plus metronidazole 500mg 8hrly for 48hours, and subsequently oral cefuroxime 500mg 12hourly and metronidazole 400mg 8hourly for 5 days in preventing SSIs in elective caesarean section. It is cheaper, easier to administer, save nursing time, may minimizes drug resistance and the financial burden on the patients.

RECOMMENDATION:

Based on the findings in this study, we recommend a combination of Ceftriaxone 1g + sulbactam 500mg as a single intravenous antibiotic agent and preoperative vaginal preparation with povidone-iodine for prevention of surgical site infection in all elective caesarean section. This is because of the various benefits such as minimizing drug resistance and the financial burden that the patients stand to gain. We recommend that more studies with larger sample size in multiple centers to buttress the facts in this study should be done in Nigeria, West Africa, and Africa; even globally so that more meta-analysis can be done.

Competing Interests:

The authors declare no conflict of interest. All authors have read and agreed to the published version of the manuscript.

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