

Antibiotic prophylaxis in obstetric and gynaecological procedures: A comparative study between two regimens of antibiotics

Akiseku, A.K., Jagun, O.E., Kuku, H.O.A., Akinpelu, A.B., Olatunji, A.O., Sule-Odu, A.O.

¹Department of Obstetrics and Gynaecology, Olabisi Onabanjo University Teaching Hospital, Sagamu, Nigeria.

²Department of Histopathology and Morbid Anatomy, Olabisi Onabanjo University Teaching Hospital, Sagamu, Nigeria.

Article Info

Article type:
Original Article

Article history:

Received: November 10, 2022

Accepted: September 20, 2023

Published: February 16, 2024

Keywords:

Antibiotic prophylaxis, Ceftriaxone, Healthcare, Surgical site infection.

Corresponding author:

Akiseku, A.K.

ORCID-NO: <https://orcid.org/0000-0003-4530-6479>

niyikepler@yahoo.com.

The article can be accessed at:

www.rjhs.org

Abstract

Background: Postoperative wound infections have an enormous impact on the quality of life and contribute substantially to the financial cost of patient care. The study aims to compare the clinical efficacy of two perioperative/postoperative antibiotic regimens, the wound outcome and difference in cost on healthcare between these regimens.

Methods: This is an observational prospective cohort study of 290 women. Women scheduled for elective surgeries in the department were grouped to have either a combination of ampicillin/cloxacillin (Ampiclox), Gentamicin, and Metronidazole (triple regimen) or a combination of ceftriaxone and metronidazole (double regimen). Data was analysed using Statistical Package for Social Science (SPSS) Windows version 21. The wound outcome and the cost implication of the antibiotic regimen were compared by chi-square test and t-test as appropriate. A p-value less than 0.05 was considered significant.

Results: The postoperative wound infection rate in this study was 7.24%. There was no statistical significant difference in postoperative infection in the triple regimen group compared to the double regimen group. However, there was a significantly longer duration of stay in the hospital in the triple regimen group ($P < 0.05$). There was also a statistical significant difference in the cost of hospital stay and the cost of antibiotics in the triple regimen group ($P < 0.05$). There was no statistically significant difference in the pattern of organisms cultured in both groups.

Conclusions: Ceftriaxone/Metronidazole regime of antibiotics showed superiority over ampicillin/cloxacillin, Metronidazole, and Gentamicin in the prevention of postoperative wound infection, hospital stay, and reduced cost of healthcare.

Prophylaxie antibiotique dans les procédures obstétricales et gynécologiques : une étude comparative entre deux schémas thérapeutiques antibiotiques

Résumé

Contexte de l'étude: Les infections postopératoires des plaies ont un impact énorme sur la qualité de vie et contribuent considérablement au coût financier des soins aux patients. L'étude vise à comparer l'efficacité clinique de deux régimes antibiotiques péri opératoires/postopératoires, l'issue de la plaie et la différence de coût des soins de santé entre ces régimes.

Paramètres et conception : Il s'agit d'une étude de cohorte prospective observationnelle portant sur 290 femmes. Les femmes devant subir des interventions chirurgicales électives dans le département ont été regroupées pour recevoir soit une combinaison d'ampicilline/cloxacilline (Ampiclox), de gentamicine et de métronidazole (triple régime), soit une combinaison de ceftriaxone et de métronidazole (double régime).

Analyse statistique : les données ont été analysées à l'aide du progiciel statistique pour les sciences sociales (PSSS) Windows version 21. L'issue de la plaie et les implications financières du régime antibiotique ont été comparées par le test du chi carré et le test t, le cas échéant. Une valeur p inférieure à 0,05 était considérée comme significative.

Résultats de l'étude : Le taux d'infection des plaies postopératoires dans cette étude était de 7,24 %. Il n'y avait pas de différence statistiquement significative en termes d'infection postopératoire dans le groupe à triple régime par rapport au groupe à double régime. Cependant, la durée de séjour à l'hôpital était significativement plus longue dans le groupe triple régime ($P < 0,05$). Il y avait également une différence statistiquement significative dans le coût du séjour à l'hôpital et le coût des antibiotiques dans le groupe triple régime ($P < 0,05$). Il n'y avait pas de différence statistiquement significative dans le modèle d'organismes cultivés dans les deux groupes.

Conclusion: Le régime d'antibiotiques Ceftriaxone/métronidazole a montré une supériorité sur l'ampicilline/cloxacilline, le métronidazole et la gentamicine dans la prévention de l'infection postopératoire des plaies, du séjour à l'hôpital et de la réduction du coût des soins de santé.

INTRODUCTION

Postoperative wound infections or Surgical Site Infection (SSI) is still an important complication of surgical procedures despite advanced knowledge and technological advances in modern surgery (1). SSIs occur at the incision site and/or deeper underlying tissue spaces and organs within 30 days postoperatively. Patients with SSI has at least one of the following: a) purulent drainage from the superficial incision, b) organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision, c) at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, and superficial incision is deliberately opened by surgeon and is culture-positive or not cultured (a culture-negative finding does not meet this criterion), and d) diagnosis of superficial incisional surgical site infection by the surgeon or attending physician (2).

SSI represents a major burden for patients and healthcare systems. Patients who develop SSI usually experiences prolonged recovery times, and psychological challenges, leading to high resource use (1,2). SSIs account for about 38% of all surgically related nosocomial infections.

Postoperative wound infections have an enormous impact on quality of life and contribute substantially to the financial cost of patient care especially where hospital stay is prolonged in order to treat the infections (1). The frequency of surgical procedures complicated by surgical-site infection has been shown to be significantly higher in developing nations compared with developed countries (1,3).

Appropriate antibiotic prophylaxis is usually directed towards the likely pathogens isolated from the wound in an environment and encountered during surgery (1,4,5). Several studies have shown the beneficial effect of perioperative antimicrobial prophylaxis in preventing post-surgical infection (6-8). A recent meta-analysis of the epidemiology of surgical site infections in Nigeria revealed a cumulative incidence of 14.5% which is comparable to the overall incidence in the sub-Saharan African region of the continent (9). The incidence in this meta-analysis was found to be higher compared to those reported in developed countries (9,10). In a Previous study in this institution (5), the incidence of surgical site infections was found to be 7.78%. The prevalent bacteria isolated included *Staphylococcus aureus*, *Escherichia coli*, and *Klebsiella species* and they showed

susceptibility to ampicillin/cloxacillin (Ampiclox), metronidazole, gentamicin and cephalosporins (5). These susceptibility profiles of the commonly isolated microorganisms had formed the protocol for the perioperative antimicrobial prophylaxis in our centre to date.

The need for convenient dosing regimens, ensuring full compliance, and possible reductions in the cost of treatment, as well as reduced side effects from multiple drug use, have necessitated studies on various prophylactic regimens (11). Surgeons still have the tendency to routinely continue perioperative antibiotics up to several days after surgery because of fear of developing wound infection (2,12).

Presently the use of prophylactic antibiotics in surgical patients in our department is not standardized and is determined by the consultant in charge of each unit. Whilst taking the economic burden of wound infections into account, the attending cost implication of prolonged perioperative antibiotics usage should also be considered relative to the efficacy of the choice of the antimicrobials and the wound outcome. The objectives of this study are to determine the prevalence of surgical site infection, organisms implicated and wound outcome and to compare the clinical efficacy of the two perioperative/postoperative antibiotic regimens being used in the department and difference in cost on healthcare between these regimen.

MATERIALS AND METHODS

Study design: This is an observational prospective cohort study that was conducted at the obstetrics and gynaecology wards of Olabisi Onabanjo University Teaching Hospital institution. The study period was from August 2020 to July 2021.

Ethical Consideration, Recruitment of Patients and Study Population: The approval to conduct this study was given by the Health Research Ethics Committee of the hospital (00UTH/HREC/349/2020AP). After obtaining ethical approval, in line with the World Health Organisation (WHO) requirement on biomedical research, written informed consent of each patient or their guardians to willingly participate in the study was sought. Patient confidentiality was maintained throughout the study period and the participants were adequately informed of their right to withdraw from the research if they so wished without any implication.

Patients undergoing various forms of

elective abdominal surgeries in the department, such as caesarean section, myomectomy, and abdominal hysterectomy, ovarian cystectomy exploratory laparotomy, oophorectomy and vaginal hysterectomy were recruited after signed informed consent was obtained, while patients that did not consent, who had used any form of antibiotics in the last 2 weeks or had medical conditions such Diabetes, renal impairment, steroid therapy, or BMI 35kg/m^2 were excluded from the study. Patients with anaemia requiring blood transfusion prior to surgery, or had excessive blood loss at surgery were also excluded from the surgery. Also excluded are patients with contraindication to use of any of the antibiotics.

At the time of the study, there were two regimens of antibiotics used, and this was determined by the preference of the unit consultant. The choice was based on the susceptibility profiles of the commonly isolated microorganisms in the hospital. (5)

Women who met the inclusion criteria were counselled and provided their consent to participate in the study. Consecutive women who were scheduled for elective surgeries in the department and met the inclusion criteria were recruited in each group of the study until the required sample size was met.

All procedures followed the same protocol. Shaving was done 24 h before surgery using razor blade. Surgical site was prepared with alcohol-povidone iodine-alcohol sequence. The initial dressing check was done 72 hours after surgery.

All the wounds were inspected for SSI, which may include redness, discharges, tenderness disruptions on the third day of surgery. A wound swab for microbiological studies was taken if the wound showed signs of SSI. The wound was cleaned with normal saline and a sterile dressing was applied. Further wound inspection for redness, discharges, or disruptions was done on the fifth day of surgery before discharge from the hospital, which is the usual period most post operative patients are discharge. Following discharge from the hospital, a weekly follow-up on the wound was carried out looking out for signs of SSI. This was undertaken over the next 30 days. Where cases of wound infection were suspected, a wound swab for culture and sensitivity was performed, and wound management with appropriate antibiotics as recommended by the sensitivity pattern was instituted. This may delay discharge from the hospital depending on the degree of SSI or need

for parenteral antibiotics. Wound infection was defined as partial or total dehiscence or the presence of purulent discharge from the wound with localized swelling, warmth and tenderness with or without microbiological evidence.

The total cost was calculated based on the number of days each patient spent on admission, cost dressing materials, cost of antibiotics used during this period was also calculated at the prevailing rate of the hospital pharmacy and documented in the protocol form. The total cost of treatment as calculated in Naira [the local currency] was converted to US Dollars. The following demographics were obtained and assessed: age, parity, educational status, number of inpatient postoperative days and antibiotics used and additional need for antibiotics.

Sample size calculation: The minimum sample size required for the study was estimated using the formula for calculating the prevalence of a factor in a descriptive study ($N = Z^2pq/d^2$) (13). Where, N = sample size, Z = the standard normal deviation set at 1.96 (for 95% confidence interval), p = the estimate of prevalence for a previous study (19.4%) (14), $q = 1 - p$, d = desired degree of accuracy (taken as 0.05). $N = 1.96^2 \times 0.194 \times (1-0.194) / 0.05^2 = 240$. After accounting for attrition (10%), the total sample size for this study = 262.

Procedure: The first regimen (triple regimen) was a combination of intravenous ampicillin/cloxacillin (Ampiclox) 500mg 6 hourly, Gentamicin 80mg 8hourly and Metronidazole 500mg 8 hourly with the first dose given 30min before the induction of anaesthesia and continued till the second postoperative day of surgery, and thereafter changed to oral form to complete a five-day course. However, the gentamicin was continued as parenteral to complete the five-day course. The second regimen (double regimen) was a combination of ceftriaxone 1g 12 hourly and metronidazole 500mg 8 hourly given 30min before induction of anaesthesia and continued till 2nd postoperative day and thereafter changed to oral cefuroxime 500mg 12 hourly and metronidazole to complete five days of use.

Data Management: Data was analysed using Statistical Package for Social Science (SPSS) Windows version 21. Continuous variables were summarized using descriptive statistics such as mean and standard deviation at a 95% confidence interval. Categorical variables were presented in

tables with frequency. The wound outcome and the cost implication of the antibiotic regimen were compared by chi-square test and t-test as appropriate. A p-value less than 0.05 was considered significant.

RESULT

A total of 290 patients were recruited and included in the study with 142 patients in the triple regimen group while 148 patients were recruited into the double regimen group.

Table 1. Showed that the groups did not differ significantly in the mean maternal age, parity, religion, and educational status. However, the duration of stay in the hospital for patients on the triple regimen was 5.79 ± 1.36 days and that of the double regimen was 5.43 ± 1.26 which was statistically significant with a $P = 0.01$. The mean cost of hospital stay and antibiotics in Dollars for the patients on the triple regimen was 92.73 ± 21.69 and that of the double regimen was 73.69 ± 16.86 , the difference was statistically significant with a $P = 0.00$.

Table 2. Demonstrated number of patients with wound infection. Postoperative wound infection was seen in 21 (7.24%). However, postoperative infection was more prevalent in the triple regimen group.

Table 3. Demonstrated the Organisms Cultured per group of patients. There was no statistically significant difference in the pattern of organisms cultured in each group. However, *Klebsiella* spp was demonstrated only in patients on the triple regimen.

Table 4. Illustrated the type of surgeries carried out in each group. Caesarean sections accounted for 81.7% of surgeries done in the triple regimen group and 79.7% in the double regimen group.

Table 5. Showed pattern of postoperative wound infection among surgeries carried out. Sixteen (76.2%) of the 21 patients with postoperative wound infection were found among patients who had a caesarean section.

DISCUSSION

Appropriate and timely use of antibiotic prophylaxis has shown to be effective in reducing the incidence of postoperative wound infection (14). An effective antibiotic prophylactic regimen is directed against the most likely organisms in the environment. Therefore, antibiotic prophylaxis should be commenced 30-60 minutes before skin incision so that optimum drug concentration is achieved (12,14). Despite the use of prophylactic antibiotics, postoperative wound infections are still a risk of surgery and it

represents a substantive burden of disease in terms of morbidity, mortality, and economic cost (12,15).

In this study, there was less incidence of wound infection 6.1% in the double regimen group when compared to the triple regimen group of 8.4% and the difference was not significant.

However, the overall postoperative wound infection rate was 7.24%, this is lower compared to a previous study (16) carried out in this institution with a postoperative wound infection of 13%. This previous study included other surgical specialties in the hospital. Other studies reported rates of 10.9% and 11%, and this is likely to be due to differences in methodology and different antibiotics combination (17,18). Other studies reported far lower postoperative infection rates (19,20). Previous works had shown that variation in postoperative wound infection rates depended on the type of procedure carried out, the standard of living, the presence of comorbidities, the use of prophylactic antibiotics combination, the grade of the surgeon, and surgical techniques (19,21,22).

The desired economic outcome in resource-limited settings such as ours where most of the patients who do not have health insurance and pay out of pocket is the reduction of healthcare costs. This can be achieved by the appropriate use of prophylactic antibiotics in postoperative wound infection prevention which results in shorter lengths of hospital stay, lower resistance rates, and ultimately the reduction of costs (6,23). Evidence showed a positive relationship between the infection rate and length of hospital stay and the reason given was that inpatients are at a high risk of infection by nosocomial and often antibiotic and multi-resistant microorganisms (6).

This study demonstrated a significant increase in the length of hospital stay in the patients on triple regimens with a corresponding increase in the cost of healthcare. This difference may be due to the slight increase in postoperative wound infection seen in the triple regimen group. This outcome was corroborated by Sule-Odu et al (24) where patients on Ampiclox, Metronidazole, and Gentamicin compared to patients on Ceftriaxone had longer hospital stay and eventually ended up paying more for healthcare. Alekwe et al (11) noted in their study that patients with an antibiotic combination of Ampiclox, Metronidazole, and Gentamicin paid more for healthcare, though there was no corresponding increase in hospital stay.

Generally, postoperative infections in Obstetrics and Gynaecology are polymicrobial (25). This was not the situation in this study

where polymicrobial (*Staphylococcus aureus* and *Klebsiella species*) infection was found only in the group of patients on the triple regimen, accounting for 1.4% of the population.

Staphylococcus aureus has been described as the most common organism responsible for *postoperative wound infection* in abdominal procedures (19,22). *Staphylococcus aureus* resides on skin surfaces and it is estimated that *Staphylococcus aureus* colonizes the anterior nares in approximately 31% (range 6–56%) of the general population at any given time (26,27). It is not surprising to find *Staphylococcus aureus* to be the most common organism cultured in both groups of patients but there was no statistically significant difference. This was not consistent with previous studies carried out in this institution (5,24) where *Klebsiella species* was the predominant organism cultured in patients with postoperative wound infection. This difference is presumed to be due to improved surgical skills of the surgeons, infection control within the hospital, and the use of appropriate prophylactic antibiotics.

Staphylococcus aureus was cultured in 81% (16/21) of the patients with postoperative wound infection and a bulk of this was seen among patients who had Caesarean Section compared to those who had Gynaecological surgeries. This outcome cannot be generalized as there are conflicting reports. Some studies have shown that postoperative wound infection is more common in patients with Caesarean Section because of the increased risk of blood loss and most procedures are carried out by residents under supervision in the teaching hospitals, thus resulting in longer operative times due to intraoperative teaching and instruction (28,29). However, some have experienced more postoperative wound infections in gynaecological procedures because they believe age played a factor and others are associated with comorbidities, inadequate dosing of prophylactic antibiotics, tissue trauma due to instrumentation, manipulation, exposure to environmental pathogens, and risk for breach of sterile technique (29,30). In this study, the increased postoperative wound infection experienced in patients with Caesarean section compared to other procedures was because of the greater number of Caesarean sections carried out during the period of study.

Several classes of antibiotics are effective against the majority of the relevant microorganisms (25). The various strains of pathogenic microorganisms cultured in this study were sensitive against Ceftriaxone, Ceftazidime, Cefixime, Ampicillin, Amoxicillin, Augmentin, Gentamycin, Ciprofloxacin, Imipenem. This

pattern did not show much difference in the antibiotic's sensitivity compared to the previous study carried out by Sule et al (5).

CONCLUSION

In conclusion, this study has given insight into the current causative organisms of postoperative wound infection and their sensitivity pattern in the hospital. The study further revealed the superiority of the Ceftriaxone/Metronidazole regime of antibiotics over ampicillin/cloxacillin, Metronidazole, and Gentamicin in the prevention of postoperative wound infection, shorter hospital stay, and reduced cost of healthcare.

Conflict of interest: None declared

Acknowledgment: The authors wish to thank all our participants and resident doctors in the Department of Obstetrics and Gynaecology, Olabisi Onabanjo University Teaching Hospital, Sagamu, Nigeria.

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Table 1: Demographic Characteristics.

Variables		Triple regimen n=142(%)	Double regimen n=148(%)	Statistics test value	p-value
AGE±SD		32.91±7.70	33.19±8.66	t= 0.327	0.568
Ethnicity	Yoruba	121(85.2)	126(85.1)	x2= 3.078	0.380
	Igbo	9(6.3)	15(10.1)		
	Hausa	3(2.2)	1(0.7)		
	Others	9(6.3)	6(4.1)		
Religion	Christianity	102(71.8)	114(77.0)	x2= 2.215	0.330
	Islam	40(28.2)	33(22.3)		
	Others	0(0.0)	1(0.7)		
Educational status	Informal	3(2.1)	5(3.4)	x2= 2.418	0.490
	Primary	13(9.2)	9(6.1)		
	Secondary	54(38.0)	66(44.6)		
	Tertiary	72(50.7)	68(45.9)		
Parity±SD		1.98±1.52	2.05±1.54	t= 0.657	0.418
	The mean duration of Hospital Stay (day)+SD	5.79±1.36	5.43±1.26	t= 2.368	0.019
The mean cost of antibiotics and hospital stay(dollars)+SD		92.73±21.69	73.69±16.86	t= 8.363	0.000

Table 2 Number of Wound Infections in Each Group

Antibiotic use	Wound		Chi-square value	p-value
	Not infected n(%)	Infected n(%)		
Triple regimen	130(91.6)	12(8.4)	0.606	0.436
Double regimen	139(93.9)	9(6.1)		

Table 3 Organisms Cultured in Each Group

Organism Cultured	Antibiotic Use		Total
	Triple Regimen n(%)	Double Regimen n(%)	
Klebsiella spp	2(1.4)	0(0.0)	2
Staphylococcus aureus	8(5.6)	9(6.1)	17
Staphylococcus aureus & Klebsiella spp	2(1.4)	0(0.0)	2

x2= 4.238 P = 0.237

Table 4 Distribution of Surgeries Performed and Antibiotic Use

Type of Surgeries	Antibiotic Use		Total
	Triple regimen n(%)	Double regimen n(%)	
Caesarean section	116(81.7)	118(79.7)	234
Ovarian cystectomy	0(0.0)	2(1.4)	2
Exploratory laparotomy	10(7.0)	12(8.1)	22
Myomectomy	6(4.2)	8(5.4)	14
Oophorectomy	0(0.0)	1(0.6)	1
Total abdominal hysterectomy	9(6.3)	5(3.4)	14
Vaginal hysterectomy	1(0.7)	2(1.4)	3
Total	142	148	290

$\chi^2 = 4.839$ P = 0.565

Table 5. Organism Cultured in Relation to Surgeries.

Variables	Organism Cultured				Total
	Non n(%)	Klebsiella spp n(%)	Staphylococcus Aureus n(%)	Staphylococcus Aureus, Klebsiella Spp n(%)	
Caesarean Section	218(75.2)	2(0.7)	12(4.1)	2(0.7)	234(80.7)
Cystectomy	2(0.7)	0(0.0)	0(0.0)	0(0.0)	2(0.7)
Exploratory Laparotomy	20(6.9)	0(0.0)	2(0.7)	0(0.0)	22(7.6)
Myomectomy	12(4.1)	0(0.0)	2(0.7)	0(0.0)	14(4.8)
Oophorectomy	1(0.4)	0(0.0)	0(0.0)	0(0.0)	1(0.4)
TAH BSO	13(4.4)	0(0.0)	1(0.4)	0(0.0)	14(4.8)
Vaginal Hysterectomy	3(1.0)	0(0.0)	0(0.0)	0(0.0)	3(1.0)
Total	269(92.8)	2(0.7)	17(5.8)	2 (0.7)	290(100)

$\chi^2 = 3.770$ P = 1.000

►Please cite this article as:

Akiseku, A.K., Jagun, O.E., Kuku, H.O.A., Akinpelu, A.B., Olatunji, A.O., Sule-Odu, A.O. Antibiotic prophylaxis in obstetric and gynaecological procedures: A comparative study between two regimens of antibiotics. Research Journal of Health Sciences, 2024; 12(1): 34-41

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<http://dx.doi.org/10.4314/rejhs.v12i1.5>