

# DURATION OF HOSPITAL STAY: A COMPARISON OF PROPHYLACTIC SINGLE DOSE AND MULTIPLE DOSES OF AMOXICILLIN-CLAVULANIC ACID IN ELECTIVE CAESAREAN SECTION IN BAUCHI, NIGERIA

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## ABSTRACT

**Background:** The mean duration of hospital stay due to infections following caesarean deliveries are important and substantial cause of maternal morbidity and increase the cost of treatment as the rate of caesarean section increases worldwide. Antibiotic prophylaxis has been shown to reduce surgical site infections and duration of hospital stay in caesarean section.

**Objective:** To determine the duration of patients' stay in the hospital by comparing the effectiveness of single-dose and multiple-dose regimen of Augmentin for chemoprophylaxis in elective caesarean sections in Bauchi, Nigeria.

**Methods:** A randomized controlled study among 114 participants was conducted, in which participants were randomly allocated into Group I and Group II. Participants in Group I and II received a single intravenous dose of 1.2g Augmentin within 60 minutes of the procedure, then group II followed by 625mg of Augmentin twice daily for 7 days. Both groups were followed for 30 days and were assessed for duration of hospital stay as primary outcome. Data were analysed using an independent student's t-test using SPSS version 23.0 with a 5% alpha level of significance.

**Result:** The study showed that 83.9% of patients in group I and 81.8% of patients in group II had no prolonged hospital stay. However, 16.1% of patients in group I and 18.2% of patients in group II had prolonged hospital stay. There was no statistically significant difference in the mean duration of hospital stay between the two groups ( $p=0.89$ ).

**Conclusion:** This study revealed no statistically significant difference in the mean duration of hospital stay (in days) between the two groups when a preoperative single dose of amoxicillin-clavulanic acid was compared with additional 7days course of prophylactic antibiotic following elective Caesarean section in Bauchi.

**Keywords:** Duration of hospital stay, Caesarean section, Amoxycillin-clavulanic acid doses, Bauchi

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## INTRODUCTION

The mean duration of hospital stay due to infections following Caesarean deliveries is a significant contributor to maternal morbidity, substantially increasing treatment costs. This concern is heightened by the rising global rate of Caesarean sections. Notably, women undergoing Caesarean delivery are 5-20 times more likely to develop infections compared to those who have vaginal deliveries.<sup>1</sup> Women undergoing caesarean delivery are at 5-to-20-fold greater risk of infection than the women undergoes vaginal delivery. Infections following caesarean deliveries are important and substantial causes of maternal morbidity and increase in hospital stay and cost of treatment.<sup>2</sup>

The single most important risk factor for postpartum maternal infection is caesarean delivery<sup>2</sup>. The other factors associated with increased risk of maternal infection includes; pre-existing maternal conditions (e.g. malnutrition, diabetes, obesity, severe anaemia, bacterial vaginosis) and spontaneous or provider-initiated conditions during labour and childbirth (e.g premature rupture of membranes, multiple vaginal examinations, manual removal of placenta).<sup>3</sup>The incidence of post-caesarean delivery infection varies world-wide from 1.1% to 25% compared with 0.2%to 5.5% following vaginal birth.<sup>1</sup>

The post-caesarean infections are polymicrobial, involving aerobes, anaerobes, and ureaplasma. The major source of postpartum infection after caesarean delivery is the lower genital tract especially when the membranes are ruptured, but this still occurs with an intact membrane following preterm delivery. The most commonly isolated pathogens are anaerobes and gram-positive aerobes. The gram-negative aerobes include *Escherichia coli*, *Klebsiella* species, and *Proteus* species. The anaerobes include *Bacteroides* species, *Clostridium* species and *Fusobacterium* species.<sup>4</sup>

Surgical antibiotic prophylaxis is defined as the use of antibiotic to prevent infection at operation site<sup>5</sup>. A number of well-designed studies have documented the efficacy of antibiotic prophylaxis

in reducing the rates of postpartum infection in women who have undergone caesarean delivery<sup>4</sup>. The administration of antibiotics is not intended to sterilize tissues but to act as an adjunct to reduce the intraoperative microbial load to a level which can be managed by host immune responses. The goal of antibiotic therapy is to achieve sufficient tissue level at the time of microbial contamination. The optimal agent should be long-acting, inexpensive and have a low side effect profile<sup>6</sup>. Administration of antibiotic prophylaxis within an hour prior to skin incision is more effective in decreasing the post-caesarean infectious morbidity when compared to administration of the same drugs after cord-clamping and has no effect on neonatal infection<sup>4</sup>.

The current debate focuses on the optimal antibiotic agent to use, with most obstetricians preferring single agent, the type of antibiotic to be used and single versus multiple doses<sup>7</sup>. WHO recommended that for the caesarean section, a single dose of first generation cephalosporin or penicillin should be used in preference to other antibiotics. Prophylactic antibiotics should be administered, for maximal benefit, 30-60minutes before skin incision rather than intra-operatively after cord-clamping. Antibiotics are still beneficial when used outside the suggested time frame and should be applied when the available time to administer a prophylactic antibiotic might be limited (e.g. emergency caesarean section).<sup>3</sup>

Despite the evidence showing the single dose to be as effective as the multiple doses's regimens, recent trials suggested multiple doses of an extended spectrum antibiotic regimen may reduce infectious complications. Furthermore, recent surveys report are inconsistent and showed variable application of antibiotic prophylaxis in caesarean section world-wide<sup>7</sup>. Similarly, in Nigeria, anecdotal evidence suggest that there is no uniformity in adherence to evidence-based practice among obstetricians performing caesarean section in terms of timing and duration of prophylaxis.<sup>5</sup> In low resource settings, various aspects include lack of sufficient infrastructure in operating rooms, lack of optimal asepsis, absence of clear aseptic technique, re-use of disposable materials, challenges in postoperative follow up after discharge from hospital, patient level of

education to maintain their hygiene, dictate the use of extended antibiotic prophylaxis after emergency and even elective caesarean section by many health professionals. Prolonged and inappropriate use of antibiotics for prevention of surgical site infection has been shown to be associated with emergence of antibiotic resistance and increased health care cost.<sup>5</sup>

Consequently, we lack evidence-based standardized protocols to guide the duration of antibiotic prophylaxis after caesarean section in low resource settings. Considering the consequences of inappropriate use of antibiotics and lack of evidence-based consensus about a clear protocol in low resource setting, comparing single and multiple dose antibiotic prophylaxis in uncomplicated caesarean section is worthy to be done<sup>1</sup>.

The purpose of this study is to determine the duration of patients stay in the hospital by comparing the effectiveness of single dose and multiple doses of Augmentin for chemoprophylaxis in elective caesarean section in Bauchi, Nigeria. The hope is that the findings may change our policy of antibiotic prophylaxis for the caesarean section, with attendant cost reduction and savings in nursing time.

## METHODS

### Study area

The study was conducted at Bauchi in Abubakar Tafawa Balewa University Teaching Hospital in north eastern Nigeria. The hospital delivers about 4000 women annually, with a caesarean section rate of 33.04% and about 6.56 % of caesarean sections are elective operations.

### Study design

A randomized controlled trial was used.

### Study population

Pregnant women admitted in the Antenatal ward of the Hospital, for elective caesarean section for various indications were included and those with known hypersensitivity to Amoxicillin-clavulanic acid or penicillin 2 weeks prior to

surgery, presence of chorioamnionitis, diabetes mellitus, obesity and women >85 kgs, HIV in pregnancy, prolonged pre-operative hospitalization and established labor were excluded.

### Sample size calculation

The minimum sample size was determined using the formula for comparison of proportions using the mean duration of hospital stay from a previous study 7%<sup>9</sup> with  $Z_{\alpha} = 1.96$ , the probability of type II error ( $\beta$ ) of Power set at 80%=0.84. After Adding 10% expected attrition, a total of 57 subjects were required in each group with the total sample size of 114.

### Sampling technique

Pregnant women who satisfied the eligibility criteria and consented to participate in the study were randomized into two groups: Group I and Group II.

Fifty-seven small pieces of paper were marked group I and another 57 were marked group II. These pieces of papers were then mixed thoroughly and each placed in serially numbered 114 opaque envelopes (Randomization) which were kept in a box. Allocation was done by opening a sealed opaque envelope. The sealed envelopes were secured and kept in the antenatal ward. The matron in the ward who was otherwise not involved in the study opened the envelopes serially as the patients were brought in until the completion of the study. Neither the surgeon nor the participants were aware of the allocation of participants to any group prior to opening the envelopes (Allocation concealment).

### Group I (Study group)

This group is comprised of 57 patients. Each patient received a single dose of 1.2g of amoxicillin-clavulanic acid intravenously. The dose was administered by the anesthetist within 60 minutes before the skin incision. To reconstitute, 20mls of sterile water for injection was added to a vial of 1.2g of amoxicillin-clavulanic acid, then this was administered intravenously over 3-4 minutes within 20minutes of reconstitution. No additional antibiotics were

given. Those who developed infectious morbidity were evaluated and managed.

### Group II (Control group)

This group is comprised of 57 patients. Participants in this group received a single intravenous dose of 1.2g Amoxicillin-clavulanic acid within 60 minutes prior to the procedure, followed by 625mg of oral Amoxicillin-clavulanic acid twice daily for 7 days, commencing as soon as oral intake was tolerated.

### Data collection method

Data was collected using structured pre-tested interviewer questionnaires by trained research assistants after obtaining an informed consent from the pregnant women.

### Postoperative follow up

Patients in both groups received standard postoperative care for Caesarean section, following our department's established protocol, with the exception that wound inspection for signs of infection occurred on the third postoperative day. Patients were assessed daily for the above outcomes. Those patients who were well on day three or day seven (depending on the type of skin incision used) were discharged. Patients found to have wound infection were kept on admission for evaluation and treatment.

After discharge every patient was instructed to report to the hospital if they develop symptoms like fever, foul smelling vaginal discharge, bleeding per vaginum, discharge from the surgical site, and breast engorgement within two weeks of discharge or to come to the hospital for follow up at two weeks. Patients were followed for 30days.

### Data analysis

Data obtained was entered into an excel sheet then analyzed using SPSS version 25.0.

Quantitative variables were described using means and standard deviation while qualitative variables were described as percentages. Continuous (Quantitative) variables were analyzed using independent sample t test, and the results were presented in tables and charts. P value < 0.05 was considered statistically significant.

### Ethical consideration

An approval for the study was obtained from the Health Research Ethics Committee of the Hospital and registered with Pan African clinical trial registry before commencement of the study. Patients were fully informed by the investigators about the aims and procedures of the study and its potential risks and benefits. Following this, written informed consents were obtained from the patients that participated in the study.

### RESULTS

The response rate was (98.2%) in Group I and (96.4%) in Group II with attrition of (1.8%) in Group I and (3.6%) in Group II respectively among 114 participants, 57 in each group.. The mean age  $\pm$  SD of the patients in Group I and Group II were  $29.3 \pm 5.45$  and  $29.8 \pm 5.35$  years respectively. ( $t = -0.485$ ,  $p = 0.63$ ). The mean gestational age in weeks  $\pm$  SD at the time of CS was  $38 \pm 1.65$  and  $38 \pm 1.4$  in Group I and Group II respectively ( $t = -1.314$ ,  $p = 0.19$ ). Fifty-five (98.2%) and 53 (96.4%) patients were booked in Group I and Group II respectively ( $p = 0.62$ ). Majority of patients in both groups had secondary level of education which was 60.7% and 60.0% for group I and II respectively ( $p = 0.99$ ), there was no statistically significant difference in the socio-demographic characteristics of the patients.

The mean preoperative hemoglobin in group I was  $11.23\text{g/dl} \pm 0.76$ , while it was  $11.62\text{g/dl} \pm 1.08$  in group II ( $p = 0.05$ ).

Table 1: General Characteristics of the respondents

VARIABLES	GROUP1 FREQ. (%)	GROUP2 FREQ. (%)	$\chi^2$	p-value
<b>Age group (years)</b>				
≤ 19	3 (5.4)	0 (0.0)	Fisher's Exact	0.62
20-24	8 (14.3)	8 (14.5)		
25-29	14 (25.0)	16 (29.1)		
30-34	21 (37.5)	20 (36.4)		
≥ 35	10 (17.9)	11 (20.0)		
Total	56 (100.0)	55 (100.0)		
<b>Mean ± SD</b>	29.3 ± 5.45	29.8 ± 5.35	t = -0.485	0.63
<b>Parity</b>				
< 1	8 (14.3)	4 (7.3)	1.90	0.37
1-4	40 (71.4)	45 (81.8)		
> 4	8 (14.3)	6 (10.9)		
Total	56 (100.0)	55 (100.0)		
Median (IQR)	2(1.75)	2(2)		
<b>Estimated gestational age (weeks)</b>				
< 37	5 (8.9)	4 (7.3)	Fisher's Exact	>0.99
37-41	51 (91.1)	51 (92.7)		
> 41	0 (0.0)	0 (0.0)		
Total	56 (100.0)	55 (100.0)		
<b>Mean ± SD</b>	38 ± 1.65	38 ± 1.40	t = -1.314	0.19
<b>Maternal weight (kg)</b>				
< 50	1 (1.8)	1 (1.8)	Fisher's Exact	0.22
50-59	15 (26.8)	13 (23.6)		
60-69	28 (50.0)	20 (36.4)		
70-79	12 (21.4)	21 (38.2)		
Total	56 (100.0)	55 (100.0)		
<b>Mean ± SD</b>	64.1 ± 7.38	65.7 ± 8.75	t = -1.04	0.30

<b>Booking status</b>				
Booked	55 (98.2)	53 (96.4)	Fisher's Exact	0.62
Un-booked	1 (1.8)	2 (3.6)		
Total	56 (100.0)	55 (100.0)		
<b>Educational status</b>				
Primary	5 (8.9)	4 (7.3)	Fisher's Exact	>0.99
Secondary	34 (60.7)	33 (60.0)		
Tertiary	17 (30.4)	18 (32.7)		
Total	56 (100.0)	55 (100.0)		
<b>Previous c/s delivery</b>				
0	16 (28.6)	19 (34.5)	Fisher's Exact	0.33
1	9 (16.1)	13 (23.6)		
2	21 (37.5)	14 (25.5)		
3	10 (17.9)	7 (12.7)		
4	0 (0.0)	2 (3.6)		
Total	56 (100.0)	55 (100.0)		
<b>Pre-operative HB (g/dl)</b>				
<10	1 (1.8)	0 (0.0)	Fisher's	>0.99
≥10	55 (98.2)	55 (100.0)	Exact	
Total	56 (100.0)	55 (100.0)		
<b>Mean ± SD</b>	11.2 ± 0.76	11.6 ± 1.08	t = -1.982	0.05

Figure 1 showed the duration of hospital stay. Eighty-three percent of patient in group I and 81.8% of patient in group II had no prolonged hospital stay. Only 16.1 % of patient in group I and 18.2% of patient in group II had prolonged hospital stay. There was no statistically significant difference in the mean duration of hospital stay in days between the two groups (4.6 and 4.5,  $t = 0.143$ ,  $p = 0.89$ ).



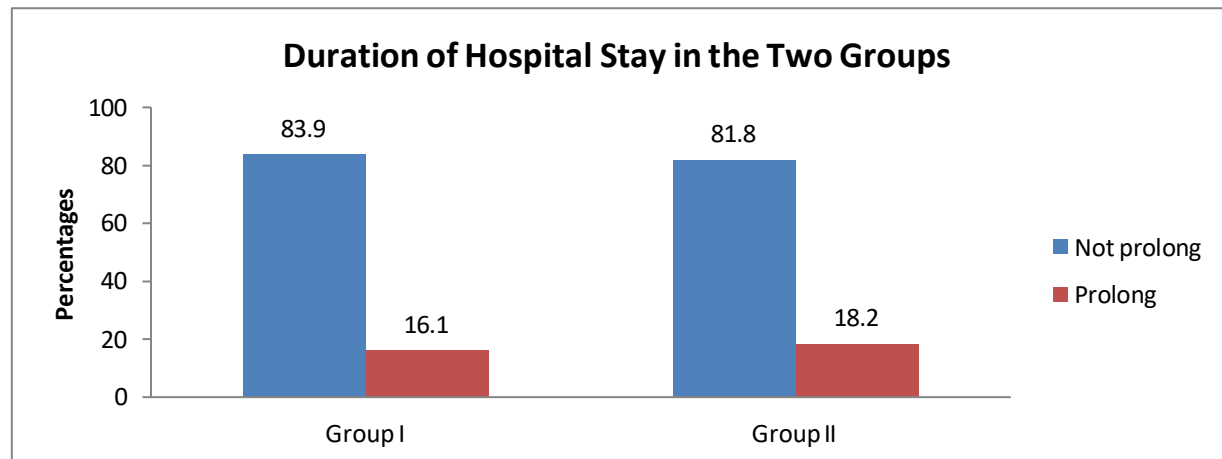


Figure 1: Duration of Hospital stay in the two groups

Table 2 showed the reason for prolonged hospital stay among the patients in the two groups. One patient in Group I that had wound infection had a prolonged hospital stay of 17days and the other patient that had wound infection was discharged on day 4. However, the patient developed wound infection after discharge. The one patient that developed wound infection in Group II had prolonged hospital stay of 19days. The other reasons for the prolonged hospital stay were hypertension, anaemia and others. However, there was no statistically significant difference between the two groups ( $p = 0.10$ )

Table 2: Reasons for prolonged hospital stay

Variables	Group I	Group II
Wound infection	2 (3.6)	1 (1.7)
Hypertension	0 (0.0)	5 (9.1)
Anaemia	3 (5.4)	3 (5.4)
Others	5 (9.0)	3 (5.4)

Figure 2 showed the microbiological pattern of the infections in the two groups. The pattern of wound infection revealed *Staphylococcus aureus* as the commonest organism responsible for wound infection accounting for 2 wound infections (66.7%) and *Klebsiella oxytoca* accounting for 1 (33.3%) of the wound infection. *Staphylococcus aureus* is responsible for the two wound infections, one in each group, while *Klebsiella* was the organism implicated in the second patient with wound infection in Group I. *Staphylococcus aureus* had sensitivity to Ampiclox and Ciprofloxacin in both patients while *Klebsiella* showed sensitivity to Methicillin, Levofloxacin, Ofloxacin and Gentamicin.



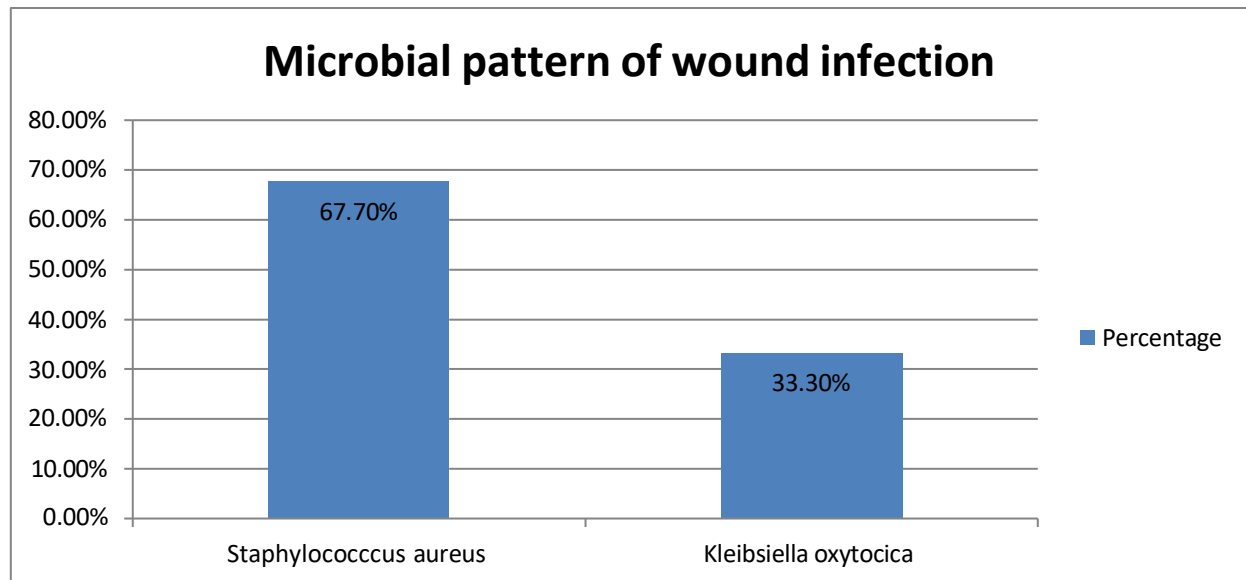


Figure 2: Microbial pattern of wound infection

## DISCUSSION

In this study, there was no statistically significant difference in the general characteristics, indications for CS and operative characteristics between the study and the control groups. This shows that the two groups were comparable and variations in outcome measures would be because of difference in antibiotics administered.

This study demonstrated no statistically significant difference in the mean duration of hospital stay in days between the two groups. This is similar to the findings in Mozambique and Pakistan.<sup>11,12</sup> The duration of hospital stay is prolonged in 17.3% of patient in Group I and 19.6% of patient in Group II. The patient in Group I with infectious morbidity had longer duration of hospital stay which is statistically different from those that didn't have wound infection ( $p = 0.003$ ). Patient in Group II with infectious morbidity had longer duration of hospital stay which is statistically ( $p = 0.16$ )

compared to those without wound infection. It is considered that the onset of SSI doubles the normal stay in hospital and costs for that operation. Study in the United State showed that SSI prolonged hospital stay by 7.3 days with additional cost of 3200 dollars thereby significantly impacting healthcare costs and resource utilization.<sup>13</sup>

## CONCLUSION

This study revealed no statistically significant difference in the mean duration of hospital stay in days between the two groups when preoperative single dose amoxicillin-clavulanic acid was compared with additional 7 days course of prophylactic antibiotic following elective caesarean section at ATBUTH.

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## Conflict of interest

No conflict of interest

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