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■ Original Research Article

Single Versus Multiple Doses of Amoxicillin-Clavulanic Acid for the Prevention of Surgical Site Infection Among Patients Who Had Elective Caesarean Section in Bauchi, Nigeria

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Abstract

Background: The rate of caesarean section has increased worldwide with a consequent rise in the incidence of surgical complications such as post-operative surgical site infection (SSI) and antibiotic prophylaxis has been shown to reduce this maternal morbidity. **Objective:** To assess and compare the effectiveness of single dose and multiple doses of Amoxycillin-clavulanic acid as a chemoprophylaxis for infectious morbidity at elective caesarian section in Bauchi, Nigeria. **Methodology:** This was a randomized control trial that involved 114 eligible participants, which were enrolled and randomly allocated into two study arms - Group I and Group II respectively. The fifty-seven (57) participants each in Group I and II had single dose of 1.2gm of intravenous Amoxycillin-clavulanic acid within 60minutes prior to the elective CS. Meanwhile, only the fifty-seven participants in Group II received an additional 7-day course of oral 625mg of Amoxycillin-clavulanic acid when oral feeding was established twice daily for 7days. Both groups were followed for 30days and were assessed for signs and symptoms of surgical-site infection as the primary outcome. Data were analysed using SPSS version 25.0 and $p < 0.05$ was considered statistically significant. **Results:** The mean ± SD ages of the patients in the Groups I and II were 29.3 ± 5.45 and 29.8 ± 5.35 years, respectively ($t = -0.485$, $p = 0.63$). The prevalence of wound infection in the Groups I and II were 3.6% and 1.8% respectively. The difference in surgical site infection was not statistically significant ($p > 0.99$). **Conclusion:** The effects of preoperative single dose and multiple doses of Amoxycillin-clavulanic acid on the incidence of SSI after ELCS is comparable. Thus, the former is effective with no increased risk of maternal infectious morbidity.

Key words: Incidence, Surgical site infection, Amoxycillin-clavulanic acid doses, Caesarean section, Bauchi

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INTRODUCTION

The rate of caesarean section has increased worldwide, which has also affected the rates of surgical complications including infections with a consequent rise in the incidence of surgical complications such as post-operative surgical site infection (SSI). SSI predominantly affects the skin and uterine incision.[1] Caesarean delivery makes women more prone to infection than vaginal birth. Needless to mention is that post-caesarian section surgical site infection is a crucial cause of maternal morbidity and mortality.[2]

There are other factors associated with increased risk of maternal infections. For instance, pre-existing maternal conditions such as malnutrition, diabetes, obesity, severe anaemia and bacterial vaginosis pave way of SSI. Additionally, obstetrics factors - premature rupture of membranes, prolong rupture of membranes, multiple vaginal examinations and manual removal of placenta have been linked with maternal infections following either route of birth.[3] 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.[1]

The post-caesarean infections are polymicrobial, involving aerobes, anaerobes, and ureoplasma. The major source of postpartum infection after caesarean delivery is the lower genital tract especially when the membranes are ruptured, but this still occur with an intact membrane following preterm delivery. The most isolated pathogens are anaerobes and gram-positive aerobes. The gram-negative aerobes include Klebsiella species, Escherichia coli, and Proteus specie. The anaerobes include Bacteroides specie, Clostridium specie, Fusobacterium specie and Staphylococcus aureus as gram positive.[4]

Surgical antibiotic prophylaxis is defined as the use of antibiotic to prevent infection at operation site.[5] The administration of antibiotics is not intended to sterilize tissues but to act as an adjunct for reducing intraoperative microbial load to a level which could 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.[6] Antibiotic given within an hour prior to skin incision, when compared with after cord clamping, is believed to be more beneficial in decreasing post-caesarean infectious morbidity in the mothers as well as the incidence of early on set neonatal sepsis.[4]

The current debate focuses on the optimal antibiotic agent to use, with most obstetricians preferring single agent, the types of antibiotic to be used and single versus multiple doses.[7] WHO recommended that for caesarean section, a single dose of first generation cephalosporin or penicillin should be used in preference to other antibiotics.[3] Prophylactic antibiotics should be administered, for maximal benefit, 30-60minutes before skin incision rather than intra-operatively after cord-clamping.[3]

Despite the evidence showing the single dose to be as effective as the multiple dose 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.[7] 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.[5] In low resource settings, various issues including 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.[5]

We aimed to assess and compare the preoperative single dose and multiple doses of antibiotic prophylaxis for surgical site infection in elective caesarean sections and the findings may change our policy of antibiotic prophylaxis for caesarean section.

METHODOLOGY

Study Area

The study was conducted at the Abubakar Tafawa Balewa University Teaching Hospital, Bauchi, Northeastern Nigeria. The facility delivers about 4000 women annually, with a caesarean section rate of 33%, out of which 6.56 % were elective.

Study design: A randomized controlled trial was employed.

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 Amoxycillin-clavulanic acid or penicillin 2 weeks prior to surgery, presence of chorioamnionitis, diabetes mellitus, obesity > 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 incidence of the surgical site infection from a previous study 7%[9] with Z_α = 1.96, the probability of type II error (β) of Power set at 80%=0.84. After Adding 10% expected attrition, a total of 57 subjects were required in each group.

Sampling technique

Pregnant women who fulfilled 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 paper 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 particular group prior to opening the envelopes (Allocation concealment).

Group I (Study group)

This group 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 comprised of 57 patients. The participant in this group received a single intravenous dose of 1.2g Amoxycillin-clavulanic acid within 60 minutes of the procedure and 625mg of oral Amoxycillin-clavulanic acid twice daily for 7days beginning immediately patients commenced orals.

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.

Outcome measures

Primary outcomes

Surgical Site Infection: The CDC defines surgical site infection (SSI) as an infection occurring within 30 days from the operative procedure, in the part of the body where the surgery took place.

It was diagnosed by presence of any of the following purulent drainage from the wound, pain or tenderness, localized swelling, redness with or without fever.

Secondary outcomes

Febrile morbidity (fever), endometritis, and serious infectious complication (such as bacteraemia, septic shock, septic thrombophlebitis, necrotizing fasciitis, pneumonia and death attributed to infection).

Postoperative follow up

The postoperative time commenced from the time of completion of skin closure. Patients in both groups were managed according to the normal postoperative protocol for caesarean section practiced in our department as earlier described except that wound was inspected on the third day for signs of infection. 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 at any time whenever they developed problems like fever, foul smelling vaginal discharge, or bleeding, discharge from the wound site margin, and breast engorgement within two weeks of discharge or to come to the hospital for follow up at two weeks. Patients were followed up for 30days. Study drug regimens were either Amoxycillin-clavulanic acid 1.2-gram single dose intravenous given within one hour before the procedure (group I) or Amoxycillin-clavulanic acid 1.2-gram single dose intravenous given within one hour before the procedure and oral Amoxycillin-clavulanic acid 625mg twice daily for 7 days (group II).

Data analysis

Data obtained was entered into an excel sheet then analyzed using the SPSS version 25.0. Quantitative variables were described using means and standard deviation while qualitative variables were described as percentages. Categorical (Qualitative) variables were analyzed using Chi-square and Fisher exact test as appropriate while 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. Variables that were statistically significant were entered into a logistics regression to adjust for confounders.

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. All patients' informed consent was obtained from the participants before enrolment while the right of withdrawal at any time after initial consent was obtained not denied. Patients who had complications were promptly evaluated and treated. Patients' information were kept in confidence and were not revealed to anyone.

RESULTS

Socio-demographic characteristics

Of the total of one hundred and fourteen (114) parturient that started the study, fifty-six patients (98.2%) in Group I and 55 patients (96.4%) in Group II success-
fully completed the study. One patient (1.8%) in Group I and two patients (3.6%) in Group II were lost to follow-up. The mean age ± SD of the patients in Group I and Group II were 29.3 ± 5.45 years and 29.8 ± 5.35 years respectively. The difference was not

Table 1: Socio-demographic characteristics of respondents'

VARIABLES	GROUP1 FREQ. (%)	GROUP2 FREQ. (%)	χ^2	p-value
Age group (years)				
≤ 19	3 (5.4)	0 (0.0)	Fisher's	0.62
20-24	8 (14.3)	8 (14.5)	Exact	
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)		
Mean ± SD	29.3 ± 5.45	29.8 ± 5.35	t = -0.485	0.63
Parity				
< 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)		
Estimated gestational age (weeks)				
< 37	5 (8.9)	4 (7.3)	Fisher's	>0.99
37-41	51 (91.1)	51 (92.7)	Exact	
> 41	0 (0.0)	0 (0.0)		
Total	56 (100.0)	55 (100.0)		
Mean ± SD	38 ± 1.65	38 ± 1.40	t = -1.314	0.19
Maternal weight (kg)				
< 50	1 (1.8)	1 (1.8)	Fisher's	0.22
50-59	15 (26.8)	13 (23.6)	Exact	
60-69	28 (50.0)	20 (36.4)		
70-79	12 (21.4)	21 (38.2)		
Total	56 (100.0)	55 (100.0)		
Mean ± SD	64.1 ± 7.38	65.7 ± 8.75	t = -1.04	0.30
Booking status				
Booked	55 (98.2)	53 (96.4)	Fisher's	0.62
Un-booked	1 (1.8)	2 (3.6)	Exact	
Total	56 (100.0)	55 (100.0)		
Educational status				
Primary	5 (8.9)	4 (7.3)	Fisher's	>0.99
Secondary	34 (60.7)	33 (60.0)	Exact	
Tertiary	17 (30.4)	18 (32.7)		
Total	56 (100.0)	55 (100.0)		
Previous c/s delivery				
0	16 (28.6)	19 (34.5)	Fisher's	0.33
1	9 (16.1)	13 (23.6)	Exact	
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)		
Pre-operative HB (g/dl)				
<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)		
Mean ± SD	11.2 ± 0.76	11.6 ± 1.08	t = -1.982	0.05

Table 2: Factors associated with infectious morbidity in the two groups.

statistically significant (t = −0.485, p = 0.63). Most of the enrollees were booked, with fifty-five (98.2%) and 53 (96.4%) in Group I and II respectively (p = 0.62).

The majority had secondary school education with similar proportion for both groups-(I vs II; 60.7% vs 60.0%; p = 0.99).

The mean preoperative haemoglobin concentrations of group I and group II were 11.23g/dl ± 0.76 and 11.62g/dl± 1.08 respectively (p = 0.05). Overall, there was no statistically significant difference in the socio-demographic features of the participants.

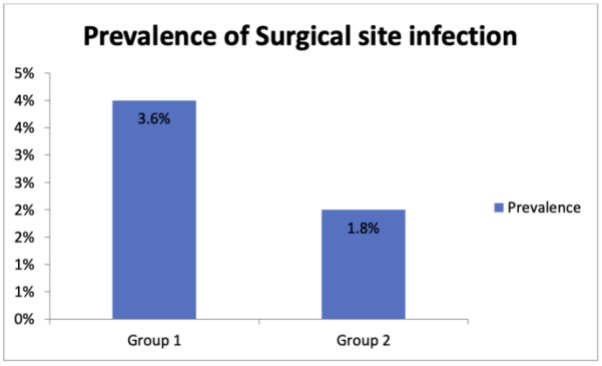
Table 2: Factors associated with infectious morbidity in the two groups.

Variables	Group1 Infectious Morbidity		Group2 Infectious Morbidity	
	Present Freq. (%)	Absent Freq. (%)	Present Freq. (%)	Absent Freq. (%)
Age group (years)				
<35	2 (4.3)	44 (95.7)	1 (2.3)	43 (97.7)
≥35	0.0 (0.0)	10 (100.0)	0 (0.0)	11 (100.0)
	p > 0.99		p > 0.99	
Parity				
< 5 (Multipara)	2 (4.2)	46 (95.8)	0 (0.0)	49 (100.0)
≥ 5 (Grand multipara)	0 (0.0)	8 (100.0)	1 (16.7)	5 (83.3)
	p > 0.99		p = 0.12	
Maternal weight (kg)				
< 70	2 (4.5)	42 (95.5)	1 (2.9)	33 (97.1)
≥ 70	0 (0.0)	12 (100.0)	0 (0.0)	21 (100.0)
	p > 0.99		p > 0.99	
Booking status				
Booked	2 (3.6)	53 (96.4)	1 (1.9)	52 (98.1)
Un-booked	0 (0.0)	1 (100.0)	0 (0.0)	2 (100.0)
	p > 0.99		p > 0.99	
Educational status				
Non-tertiary	1 (2.6)	38 (97.4)	1 (2.7)	36 (97.3)
Tertiary	1 (5.9)	16 (94.1)	0 (0.0)	18 (100.0)
	p = 0.52		p > 0.99	
Previous c/s delivery				
No previous C/S	2 (12.5)	14 (87.5)	1 (5.3)	18 (94.7)
Previous C/S	0 (0.0)	40 (100.0)	0 (0.0)	36 (100.0)
	p = 0.08		p = 0.35	
Pre-operative HB (g/dl)				
<10	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)
≥ 10	2 (3.6)	53 (96.4)	1 (1.8)	54 (98.2)
	p > 0.99		p > 0.99	-
TYPE OF SKIN INCISION				
Pfanesteil	2 (3.8)	51 (96.2)	0 (0.0)	52 (100.0)
Midline	0 (0.0)	3 (100.0)	1 (33.3)	2 (66.7)
	p > 0.99		p = 0.06	
PLACENTAL DELIVERY				
Cord traction	2 (3.6)	53 (96.4)	1 (1.9)	53 (98.1)
Manual	0 (0.0)	1 (100.0)	0 (0.0)	1 (100.0)
	p > 0.99		p > 0.99	

Figure 1 showed that the prevalence of wound infection in the Group I and the Group II were 3.6% and 1.8% respectively. There is no statistically significant difference in the prevalence of surgical site infection between the groups (p > 0.99). None of the participants developed endometritis, urinary tract infection, pelvic abscess or pelvic thrombophlebitis in both groups.

Table 2 showed the factors associated with surgical site infection in both groups. Maternal age, parity, weight, booking status, educational status, previous C/S, pre-operative haemoglobin, type of skin incision and the method of placental delivery were all shown not to be associated with infectious morbidity in both Group I and Group II respectively. {(p >0.99 vs p >0.99); (p >0.99 vs p >0.12); (p > 0.99 vs p > 0.99); (p>0.99 vs p>0.09); (p>0.52 vs p>0.99); (p>0.08 vs p=0.35); (p>0.99 vs p>0.99); (p>0.99 vs p>0.06) & (p>0.99 vs p> 0.99).

Table 3 showed that on logistic regression analysis, variables were not significant predictors of infectious morbidity in the two groups.



p > 0.99

Figure 1: Prevalence of Surgical site infection

Table 3: Logistic regression analysis of socio-demographic factors associated with infectious morbidity in the two groups.

Predictors	GROUP1 AOR (95% CI)	p-value	GROUP2 AOR (95% CI)	p-value
Parity	0.0	0.99	3.5	>0.99
Previous CS	0.0	0.99	0.0	0.99
Type of skin incision	0.8	>0.99	1.9	0.99

DISCUSSION

This randomized clinical trial was conducted among eligible parturients in Federal Teaching Hospital, Bauchi, Nigeria; to assess and compare the preoperative single dose and multiple doses of antibiotic prophylaxis for surgical site infection at Elective Caesarian Sections. In this study, there was no statistically significant difference in the general characteristics, indication for CS and operative

characteristic 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.

The prevalence of post caesarean wound infection was 3.6% and 1.8% in group I and group II respectively and there was no statistically significant difference between the two groups ($p > 0.99$). This is far less than the prevalence reported in Maiduguri where an incidence of 31.3% was reported.[8] It is also less than the post-caesarian SSI rates of 8.9% and 7.8% quoted in Kano and Abuja respectively.[10] Another study conducted in Mozambique on comparison of single dose combined preoperative antibiotics with a 7 days postoperative regimen reported similar findings (5.2% vs. 6.4%).[11]

It was noticed that the group that received antibiotics postoperatively for 7 days had lower cases of wound infection, but this difference is not statistically significant. Both groups received preoperative Augmentin within 1hour of skin incision. This shows that critical to antibiotic prophylaxis is the timing of administration, not how long it was given, as demonstrated by several randomized controlled trials, systematic reviews, meta-analyses, and Cochrane review of 2014.[12] All these supported administration of antibiotics prior to skin incision. Microbial contamination of the surgical site is a necessary precursor of SSI. Antimicrobial prophylaxis is not an attempt to sterilize tissues, but a critically timed adjunct used to reduce the microbial burden of intraoperative contamination to a level that cannot overwhelm host defenses.[13] Therefore, prophylactic antibiotic administration is most effective before microbial contamination.

This study showed lower incidence of wound infection compared to all the studies quoted probably because in this study only elective cases were included, and emergencies were excluded.

In this study, the preoperative factors of age, parity, maternal weight, booking status, educational status, previous caesarean delivery, preoperative haemoglobin, type of skin incision and mode of placental delivery were not significantly associated with surgical site infection. This was further corroborated by the findings of logistic regression analysis of these variables which showed that they were not significant predictors of surgical site infection.

Risk factors well documented in the literature include emergency caesarean section, duration of ruptured membranes, duration of surgery, excessive vaginal manipulation, and obesity.

Limitations of the Study

Drug resistance and site effects were noticed in some patients, but the advantages of single dose amoxicillin-clavulanic acid include convenience, compliance and reduction in the cost of treatment.

CONCLUSION

The effects of preoperative single dose and multiple doses of Amoxicillin-clavulanic acid on the incidence of SSI after ELCS is comparable. Thus, the former is an effective chemoprophylaxis with no increased risk of maternal infectious morbidity.

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