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Original Article

Effectiveness of Pre-Incisional Amoxicillin-Clavulanic Acid in Preventing Post Caesarean Wound Infection at a Tertiary Center in North Western Nigeria

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ABSTRACT

Background: Postoperative wound infection is a recognised complication of caesarean section with a substantial burden to the health system. It may result in prolonged period of hospitalization and health implications. Prevention of such infections should be a health care priority especially in developing countries. **Objectives:** To evaluate the effectiveness of a pre-incisional administration of amoxicillin-clavulanic acid in the prevention of post caesarean wound infection in our hospital. **Material and Methods:** This was a prospective randomised controlled study of 404 women who were to have an emergency Caesarean section. Women in the study group received a single dose of 1.2 g amoxicillin-clavulanic acid preoperatively, in addition to the usual postoperative antibiotic prescription used in the department. Women in the control group received only postoperative prophylactic antibiotics. They were monitored for features of wound infection, endometritis, and the duration of hospital stay. **Results:** The rate of wound infection was 18.8% in the control group and 11.5% in the study group (RR 0.68, 95% CI 0.47-0.99, *P* 0.04). The rates of endometritis in the control and study groups were 13.5% and 5.8% respectively (RR 0.57, 95% CI 0.35-0.95, *P* 0.01). The length of hospital stay in the study group was 139.0 (± 24.81) hours while in the control group it was 151.4 (± 38.28) hours (*P* <0.01). **Conclusion:** There was a significant reduction in the rates of wound infection and endometritis and a shorter duration of hospital stay when the pre-incisional antibiotic was given to patients who were to undergo emergency Caesarean section.

Key words: caesarean section, wound infection, prophylactic amoxicillin-clavulanic acid

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INTRODUCTION

Although caesarean section (CS) has become an increasingly safe and a common surgical procedure, it is still associated with significant morbidity and mortality compared with vaginal delivery.[1] Postoperative wound infection remains a recognizable complication of caesarean section due

to its potentially contaminated nature. The incidence of puerperal infection increases by 5-20 folds with caesarean section compared with vaginal delivery.[2] Post caesarean wound infection can be attributed to a perioperative bacterial load in the tissue at the site of surgery and the diminished integrity of the host's defences.[3] Other risk factors observed for caesarean wound infections are obesity, diabetes, immunosuppressive disorders, chorioamnionitis, a previous caesarean delivery, certain medications like steroids, the lack of pre-incision antimicrobial care, lengthy labour, and multiple vaginal examinations.[4] Some of these factors are only present in patients who had emergency CS.

Infectious complications following caesarean delivery include wound infection, febrile morbidity, endometritis and urinary tract infection. Occasionally, there can be more serious complications like pelvic abscess, peritonitis, bacteraemia, septicaemia, necrotizing fasciitis, burst abdomen, and septic pelvic vein thrombophlebitis.[5] Though routine prophylactic antibiotic use has been proven to be efficacious in reducing these morbidities, there is still debate about the choice of antibiotic, time of administration, dose and duration of use.[6] The goal of antibiotic therapy is to achieve sufficient tissue levels at the time of microbial contamination.

Amoxicillin-clavulanic acid is a penicillin antibiotic consisting of amoxicillin and the beta-lactamase inhibitor clavulanate potassium (clavulanic acid). It has good activity against β-lactamase-producing strains (such as in Staphylococcus aureus, *Esterichia coli* and Haemophilus influenzae) and also against Klebsiella pneumonia and the anaerobic Bacteroides fragilis.[7] Post caesarean wound infection rates vary across localities and countries. An incidence of 2 - 7% was reported in USA, and up to 19% was reported in Africa.[8,9] However, a rate of 10% was reported in a hospital based study in South-west Nigeria and 16.2% in Ibadan.[10,11] At Aminu Kano Teaching Hospital a rate of 9.1% was reported, though the rates were much higher for emergency caesarean section.[12]

In Nigeria, haemorrhage and infection are the leading causes of maternal death after CS.[13] Furthermore, surgical site infection (SSI) results in prolonged period of hospitalization with direct cost and health implications.[14] Overwhelming genital sepsis following CS may lead to poor healing of the uterine scar and this has implications in Nigerian women who often times would wish a vaginal delivery in subsequent pregnancy and/or might not have ready access to a repeat CS.[15]

The incidence of SSI in our centre was found to be high by various studies despite the use of postoperative antibiotic therapy.[12,16,17] The purpose of this study is to examine the efficacy of an additional single dose of amoxicillin-clavulanic acid administered before skin incision in reducing the incidence of post caesarean wound infection.

MATERIALS AND METHODS

This was a prospective randomised controlled study of 404 pregnant women who were to have emergency caesarean section in the obstetric unit of our hospital from August 2015 to February 2016.

Sample Size Determination

This was done using the statistical formula for comparison of proportions. Po was the proportion of participants in the control group that was expected to develop wound infection. In a study by Nwankwo and colleagues in Kano, 21.1% was reported.[17] P_1 was the proportion of participants in the experimental group that was expected to exhibit the outcome of interest which is wound infection. A reduction to 10% was considered clinically significant in this study. $Z\alpha$ was 1.96 at an alpha level of 0.05. $Z\beta$ was 0.84 at a power of 80%. Ten percent was added as attrition rate. The minimum sample size that was required for each group for it to be statistically significant was 202 in each group and a total of 404 patients were recruited.

Inclusion Criteria

Pregnant women who were to have emergency CS in our hospital and had consented to participate in the study.

*Exclusion Criteria***:** Patients with the following conditions were excluded:

1. Known hypersensitivity to the drug (amoxicillin-clavulanic acid)

2. Obvious features of infection such as fever (axillary temperature of 38^0C or more), tachycardia (radial pulse of more than 100 beats per minute)
3. Gross peritonitis
4. Chorioamnionitis
5. Preterm pre-labour rupture of membranes
6. Diabetic and immunosuppressed patients (HIV positive)
7. Patients who had been on antibiotics in the last 24 hours before the operation.

A structured questionnaire was administered to obtain personal data and other relevant information about the study participants. They were then allocated by balloting into the study group (Group A) or the control group (Group B).

The control group was managed according to the present practice in the department, which was administration of antibiotics only postoperatively (intravenous amoxicillin-clavulanic acid and metronidazole for 48 hours followed by oral forms for 5 days).

However, in the study group, each patient received 1.2 g of amoxicillin-clavulanic acid intravenously within 30 minutes before commencement of the skin incision. Post operatively, this group of patients received the usual postoperative antibiotic prophylaxis prescribed in the department comprising of intravenous amoxicillin-clavulanic acid and metronidazole for 48 hours and then oral for another 5 days. The preincisional amoxicillin-clavulanic acid used throughout the study was produced by the same pharmaceutical company.

Postoperative Monitoring

Patients were monitored and assessed daily for features of endometritis like fever, tender uterus and foul-smelling lochia. Incision site was opened on day 3 and left open. It was examined daily for features of wound infection. A case of wound infection was identified using CDC USA definition that was modified in 2015.[18] A case of endometritis was identified using the clinical criteria by Olsen et al.[19]

Those patients who did not have any postoperative complication were discharged on days 5-7. Patients found to have wound infection, endometritis or other complications were kept on admission for evaluation and treatment.

Follow up After Discharge

At discharge, each patient was given a digital thermometer (CICPharm®) and instructed on how to measure and record her axillary temperature daily in the morning. They were followed up for 30 days by phone calls, text and social media (WhatsApp). Symptoms of wound infection and endometritis such as fever, discharge from the wound, swelling or pain at the wound site, abdominal pain and foul-smelling lochia were enquired.

Those with any of the above-mentioned symptoms and signs were instructed to report to the hospital for further evaluation. Those who did not have any complaint were seen at the postnatal clinic 2 weeks after discharge and then again 3 weeks later at the postnatal clinic.

Each patient was examined for the presence of purulent discharge from the wound site, tenderness, redness, swelling, and heat. For those with purulent discharge, a sample was obtained for microscopy, culture and sensitivity tests. The depth of tissue involvement was also assessed by inspection. Infection was considered superficial if it involved only the skin and subcutaneous tissues and deep if it also involved the fascial and muscle layers according to the CDC definition.[18]

Examination for fundal tenderness over the uterus was done any time the patient presented with any complaint and/or during each follow up visit.

Data Analysis

Information obtained at the end of the study was processed using the SPSS 20.0 statistical programme. Categorical data was analyzed by chi-square test and continuous data was analyzed using independent sample T test, and the results were presented in tables. P value of less than 0.05 was determined to be statistically significant.

Ethical Consideration

Ethical clearance was obtained for the study from the Research and Ethics committee of our hospital. All participants were fully counseled about the study and an informed consent was obtained.

RESULT

There were 2856 deliveries from August 2015 to February 2016. Of these, 514 were through Caesarean section, giving a caesarean section rate of 18.0%. Out of these, 439 (85.4%) had emergency CS while 75 (14.6%) had elective CS. Four hundred and four patients who had emergency CS were recruited and randomized into the control group and the study group. Ten patients in the control group and 11 patients in the study group were lost during follow up. One hundred and ninety-two patients (95.1%) and 191 patients (94.6%) were successfully followed in the control and study groups respectively, and the data was analyzed.

Table 1: General characteristics of patients

Variable	Group A n=192	Group B n=191	Test	P-value
Mean Age ± SD **(years)**	26.0 ± 5.12	26.7 ± 5.70	t = -1.16	0.25
Mean parity ± SD	2.0 ± 2.37	2.1 ± 2.57	t = -0.56	0.58
Mean GA at Delivery (weeks) ± SD	38.7 ± 1.88	38.7 ± 1.92	t = -0.45	0.65
Mean number of previous CS ± SD	0.1 ± 0.38	0.1 ± 0.33	t = 0.84	0.40
Mean weight (kg) ± SD	73.5 ± 10.01	74.3 ± 9.65	t = -0.76	0.45
Booking status				
Booked	99 (51.6%)	98 (51.3%)	X^2 = 0.01	0.96
Unbooked	93 (48.4%)	93 (48.7%)		
Education				
Quranic	11 (5.7%)	12 (6.2%)		
Education	17 (8.9%)	13 (6.8%)	X^2 = 1.82	0.61
Primary Education	92 (47.9%)	83 (43.5%)		
Secondary Education	72 (37.5%)	83 (43.5%)		
Tertiary Education				

Table 2: Labour characteristics of the patients

Variable	Group A n=192	Group B N=191	t Test	P-value
Mean labour duration (minutes) ± SD	276.4 ± 276.45	276.2 ± 271.65	0.01	0.99
Mean duration of membrane rupture (minutes) ± SD	295.2 ± 272.14	300.6 ± 278.25	-0.19	0.85
Mean number of pelvic examinations	3.2 ± 2.30	3.3 ± 2.45	-0.26	0.79

Table 3: Operative characteristics

Variable	Group A n=192 (%)	Group B n=191 (%)	Test	P-value
Indication for operation				
CPD/Failed VBAC	78 (40.6)	74 (38.7)		
Hypertensive disorders	51 (26.6)	48 (25.1)		
Malpresentation	26 (13.5)	27 (14.1)		
Antepartum haemorrhage	12 (6.2)	16 (8.4)	X^2 = 2.18	0.97
Failed IOL/ Postdate	8 (4.2)	9 (4.7)		
Fetal distress	8 (4.2)	11 (5.8)		
≥2 previous CS in labour	3 (1.6)	2 (1.0)		
Twin gestation	4 (2.1)	2 (1.0)		
Cord prolapse	2 (1.0)	2 (1.0)		
Type of anaesthesia				
General anaesthesia	21 (10.9)	19 (9.9)	X^2 = 0.10	0.75
Spinal	171 (89.1)	172 (90.1)		
Type of skin incision				
Midline sub-umblical	4 (2.1)	3 (1.6)	X^2 = 1.14	0.71
Pfannenstiel	188 (97.9)	188 (98.4)		
Placental delivery				
Manual	3 (1.6)	5 (2.6)	X^2 = 0.52	0.47
Controlled cord traction	189 (98.4)	186 (97.4)		
Mean duration of Surgery ± SD **(minutes)**	57.2 ± 7.56	56.4 ± 7.01 492.7 ± 134.75	t = 1.06 t = -0.87	0.29
Mean EBL ± SD **(mls)**	481.0 ± 127.26			0.38

Table 4: Postoperative complications

Complications	Group A n=192	Group B n=191	RR	95% CI	P-value
Wound infection	36 (18.8%)	22 (11.5%)	0.68	0.47-0.98	0.04*
Superficial	29 (80.6%)	20 (90.9%)			
deep	7 (19.4%)	2 (9.1%)			
Endometritis	26 (13.5%)	11 (5.8%)	0.57	0.35-0.95	0.01*
Fever	29 (15.1%)	13 (6.8%)	0.59	0.37-0.94	0.01*
UTI	7 (3.7%)	5 (2.6%)	0.83	0.42-1.64	0.56

*significant

Table 1 shows the general characteristics of the patients in the two groups. There were no statistically
significant differences between the two groups in their mean age (t = -1.16, *P* = 0.25), parity (t = -0.56, *P = 0.58*), gestational age at delivery (t = -0.45, *P = 0.65*), number of previous caesarian section (t = 0.84, *P* = 0.40) and weight on admission (t = -0.76, *P* = 0.45). Table 2 shows that there were no statistically significant differences between the two groups in their labor characteristics in terms of the mean duration of labor (t = 0.01, *P* = 0.99), duration of membrane rupture (t = -0.19, *P* = 0.85) and number of pelvic examination (t = -0.26, *P* = 0.79).

Table 5: Mean time of development of wound infection and endometritis (number of days postoperative)

	Group A n = 36	Group B n = 22	Test	P value
Wound Infection				
Mean number of days postoperatively at diagnosis	6.4 ± 2.34	7.2 ± 3.63	t = -0.85	0.40
Diagnosed on admission		16 (72.7%)	X^2 = 0.48	0.49
Diagnosed after discharge	29 (80.6%) 7 (19.4%)	6 (27.3%)		
	Group A n = 23	Group B n = 11	Test	P value
Endometritis				
Mean number of days postoperatively at diagnosis	5.7 ± 3.03	5.3 ± 3.13	t = 0.41	0.69
Diagnosed on admission	18 (78.4%)	9 (81.8%)	X^2 = 0.06	0.81
Diagnosed after discharge	5 (21.6%)	2 (18.2%)		

Table 6: Microbiological pattern of post caesarean wound infection

Organisms	Group (A) n=36	Group (B) n=22
‡*Staphylococcus aureus*	16 (44.4%)	9 (40.9%)
§*Eschericia coli*	13 (36.1%)	7 (31.8%)
¶*Klebsiella species*	7 (19.4%)	5 (22.8%)
†*Pseudomonas*	3 (8.3%)	1 (4.5%)
††*Proteus species*	2 (2.6%)	0 (0.0%)

Five patients in group A had polymicrobial infections with both *Staphylococcus aureus* and *Escherichia coli* cultured. None of the patients in group B had polymicrobial infection.

Sensitivity pattern

‡ Ceftrixone^{+++}, Levofloxacin^{+++}, Augmentin^{++}

§ Ceftriaxone^{+++}, Levofloxacin^{+++}, Augmentin^{++}, Gentamycin^{++}

¶ Ceftrixone^{+++}, Levofloxacin^{++}, Gentamycin^{++}

† Ceftrixone^{+++}, Levofloxacin^{++}, Gentamycin^{+++}, Augmentin^{++}

†† Ceftrixone^{+++}, Augmentin^{++}, Levofloxacin^{++}, Gentamycin^{++}

Table 3 shows the operative characteristics of the patients in the two groups. The main indications for CS in the two groups were cephalopelvic disproportion (40.6% and 38.7% in the control and study groups respectively), followed by hypertensive disorders in pregnancy (26.6% and 25.9% in the control and study groups respectively). There was no statistically significant difference in the indications for the operation between the two groups (X^2 = 2.18, *P* = 0.97). Most of the patients in the control (97.9%) and study group (98.4%) had a Pfannenstiel incision. Details of other operative characteristics are shown in the same table 3. Generally, there were no statistically significant differences in the operative characteristics between the two groups.

Table 7: Mean duration of hospital stay (hours)

	Mean duration	t test	p-value
Group (A) ± SD	151.4 ± 38.28	3.78	< 0.01*
Group (B) ± SD	139.0 ± 24.81		

*Significant

Table 4 shows the postoperative complications that the patients developed. Wound infection was diagnosed in 36 (18.8%) patients in the control group and 22 patients (11.5%) in the study group. The wound infection rate was significantly lower in the study group. Pre-incisional administration of the antibiotic was associated with a significant reduction in the rate of wound infection by 32% (RR = 0.68, 95% CI = 0.47-0.98, *P* = 0.04). Most of the patients in both groups had superficial wound infections (80.6% and 90.9% in the control and study groups respectively), while few had deep wound infection (19.4% and 9.1% respectively). There was no statistically significant difference in the type of wound infection in the two groups (X^2 = 4.45, *P* = 0.08). Endometritis was diagnosed in 26 (13.5%) patients in the control group and 11 (5.8%) patients in the study group. The difference was statistically significant, and the rate of endometritis was significantly lower in the study group. Pre-incisional administration of the antibiotic was associated with a significant reduction in the rate of endometritis by 43% (RR = 0.57, 95% CI = 0.35-0.95, *P* = 0.01). Fever occurred in 29 patients (15.1%) in the control group and 13 patients (6.8%) in the study group, and the difference was

statistically significant. Preincisional administration of the antibiotic was associated with a significant reduction in the rate of postoperative fever by 41% (RR = 0.59, 95% CI = 0.37-0.94, *P* = 0.01).

Table 8: Reasons for prolonged hospital stay

Reason	Group A n=31	Group B n=13	X^2	P-value
Wound infection	13 (41.9%)	2 (15.4%)		
Endometritis	14 (45.2%)	6 (46.2%)	12.55	0.02*
Poor BP control	3 (9.7%)	3 (23.0%)		
Anaemia	1 (3.2%)	2 (15.4%)		

Table 5 shows the differences in the meantime of development of wound infection in the two groups which was not statistically significant (t = -0.85, p = 0.40). The mean time of development of endometritis postoperative was 5.7 (±3.03) days in the control group and 5.3 (±3.13) days in the study group. The difference was also not statistically significant (t = 0.41, p = 0.69). Endometritis was diagnosed while on admission in 18 (78.4%) patients and 9 (81.8%) patients in the control and study groups respectively. It was diagnosed after discharge from the hospital in 5 patients (21.6%) in the control group and 2 patients (18.2%) in the study group, the difference was also not statistically significant (X^2 = 0.06, p = 0.81). All these patients were readmitted for management. Eighteen patients of the 36 patients with wound infection in the control group (50.0%) and 10 of the 22 patients with wound infection in the study group (54.6%) developed both wound infection and endometritis.

Table 6 shows the microbiological pattern of the postoperative wound infections. The most common organism isolated in both groups was *Staphylococcus aureus* in 44.4% and 40.9% of the wound infections in the control and study groups respectively. Details of other organisms isolated were shown in table 6. Five patients in the control group have polymicrobial infections with both *Staphylococcus aureus* and *Escherichia coli* cultured. The sensitivity pattern showed all the cultured organisms were most sensitive to Ceftriaxone and Levofloxacin.

Table 7 shows that the mean duration of hospital stay in the control group was 151.4 (±38.28) hours (approximately 6 days and 7 hours), and in the study group, it was 139.0 (±24.81) hours (approximately 5 days and 19 hours). The mean duration of hospital stay was significantly lower in the study group (t = 78, p <0.01).

Table 8 shows the main reasons for the prolongation in hospital stay. Hospital stay was prolonged in 31 (16.2%) patients in the control group and 13 (6.8%) patients in the study group. In the control group, the reasons for prolonged hospital stay were wound infection (41.9%), endometritis (45.2%), poor blood pressure control (9.7%) and anaemia (3.2%). The reasons for prolonged hospital stay in the study group were wound infection (15.4%), endometritis (46.2%), poor blood pressure control (23.0%) and anaemia (15.4%).

DISCUSSION

There were no significant differences between the two groups in terms of their general characteristics, labour characteristics and operative characteristics in this study. This shows that these variables, which could affect the rate of postoperative complications, were similar in the two groups and the observed differences in the postoperative infectious complications rates was mainly due to the administration of the preoperative antibiotic in one group since all the patients in both groups received the same course of postoperative antibiotics.

In this study, the incidence of post-caesarean wound infection was found to be high when preoperative antibiotic was not administered (18.75%). This is similar to the findings from another study in Kano where the incidence of wound infection after emergency CS was found to be 20.1%, preoperative antibiotics were also not given in that study.[17] One study in Ibadan also reported a high rate of wound infection after CS with an incidence of 16.2%.[11] In the absence of preoperative antibiotics, high rates of wound infection have also been reported in studies from Kenya (19.0%) and Ethiopia (27.1%).[9,20] The rate is much lower than the rates reported from developed countries, where rates of 2.7% and 4.7% have been reported.[8,21] The high incidence of wound infection in the control group was probably because our centre serves as a tertiary and referral centre to which patients with various pregnancy and labour complications present or are referred to for emergency CS. Also, preparations

and patient optimization may be inadequate in an emergency setting compared to an elective procedure.[17] The incidence of wound infection was found to be lower when preoperative antibiotic was given (11.52%). In one study in Abakalaki, in which intravenous amoxicillin-clavulanic acid 1200 mg and intravenous metronidazole 500 mg were given to every patient preoperatively with an additional 7 day course postoperatively, the incidence of postoperative wound infection was found to be 7.0%.[22]

In this study, the incidence of post-caesarean wound infection was found to be significantly lower when preoperative amoxicillin-clavulanic acid was given.

Wound infection was diagnosed after discharge in a higher proportion of patients in the study group (27.27%) than in the control group (19.44%). This may suggest that the infecting organisms could have gained access to the wound perioperatively, causing the infection to manifest earlier in the control group who did not receive perioperative antibiotics. In the study group, the source of infection was probably related to the patient or her environment postoperatively, causing the infection to manifest later. Most of the wound infections in both groups were diagnosed on admission or readmission. This is different from the findings from a study in the US, where 80% of wound infections were diagnosed after discharge, with a peak incidence at the fourth to fifth day postoperatively. [23] The longer hospital stay in our center allows for detection of more cases of wound infection while the patients are still on admission, as patients spend 5-7 days in our center compared to US where they spend 3-4 days.

The wound swab culture result revealed that the most common organism causing the infections was *Staphylococcus aureus*, followed by *Escherichia coli* and *Klebsiella species* in both groups. This is similar to findings from an earlier study in our centre, and also similar to findings from other studies.[12,24] All the organisms showed very good sensitivity to Ceftriaxone and Levofloxacin. This is similar to the findings from an earlier study in our centre.[12]

In this study, the incidence of endometritis was found to be 13.54% and 5.76% in the control and study groups respectively. There was a significant reduction in the incidence of endometritis when preincisional amoxicillin-clavulanic acid was given. Other studies found similar results.[25,26] As a tertiary and referral centre, our centre receives patients with prolonged labour, prolonged membrane rupture, and patients who have had multiple vaginal examinations at the referral centre from which they have been referred. All these are known risk factors for chorioamnionitis and post-caesarean endometritis.[27]

The incidence of postoperative fever was also found to be significantly reduced, by 41% with the use of preincisional antibiotic. This is similar to the findings from other studies.[25,28] None of the patients in the two groups in this study developed fascial dehiscence or pelvic abscess.

The length of hospital stay was found to be significantly shorter when preoperative antibiotic was administered. This is similar to findings from other studies.[12,25] The shorter duration of hospital stay was as a result of the decrease in the rates of wound infection and endometritis.

CONCLUSION

There was a significant reduction in the rates of wound infection and endometritis and a shorter duration of hospital stay when the pre-incisional antibiotic was given to patients who were to undergo emergency Caesarean section.

Recommendation

A single intravenous dose of 1.2 g of amoxicillin-clavulanic acid should be given within 30 minutes of the skin incision during emergency caesarean section in order to reduce the rates of post-caesarean wound infection, endometritis and fever in our hospital.

Conflict of Interest

The authors have no conflict of interest to declare.

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