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Single-dose versus multiple-dose antibiotics prophylaxis for preventing caesarean section postpartum infections: A randomized controlled trial

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Abstract

Background: Caesarean section, a common obstetric surgical procedure, is a major predisposing factor for puerperal infections, requiring the need for antibiotic prophylaxis. Evidence suggests that single-dose antibiotic prophylaxis has comparable efficacy to multiple-dose antibiotic prophylaxis, but with a lower cost and risk of antibiotic resistance. However, single-dose antibiotic prophylaxis after caesarean section is not generally used in many centres in sub-Saharan Africa.

Objective: This study aimed to compare the effectiveness of single- versus multiple-dose antibiotic prophylaxis to prevent post-caesarean section infections.

Methodology: This open-label, randomized controlled trial involved 162 consenting patients admitted for caesarean section (elective or emergency) at the Federal Medical Centre Keffi. They were distributed randomly into treatment arm A or B. Subjects in both arms received intravenous ceftriaxone (1 g) and metronidazole (500 mg) 30–60 min before incision; subjects in arm B received additional parenteral doses for 48 h and then cefuroxime 500 mg tablets every 12 h and metronidazole 400 mg tablets every 8 h for 5 days. The patients were monitored for 2 weeks for evidence of wound infection, febrile morbidity and clinical endometritis.

Result: There was no statistical difference in the incidence of wound infection (6.6% versus 7.4%; $p = .882$) and febrile morbidity (11.8% versus 11.1%, $p = .807$). However, clinical endometritis (0.0% versus 6.1%, $p = .028$) was statistically significant with none reported in the single-dose arm.

Conclusion: Single-dose ceftriaxone and metronidazole is as effective as multiple doses for antibiotic prophylaxis to prevent post-caesarean section infections. Adoption of this approach in low-risk patients would reduce the cost of prophylactic antibiotics, workload for staff and antibiotic resistance.

Keywords

antibiotics prophylaxis, caesarean section, postoperative, wound infections

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Introduction

Caesarean section describes the delivery of a foetus through a surgical incision made in the anterior uterine wall.[1] Medical advancement has transformed this technique into one with a very low risk of maternal mortality.[1,2] It has become the most common major obstetric surgical procedure performed worldwide, constituting about 25% of all deliveries in many countries.[3,4] Delivery by

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caesarean section is associated with a 5- to 20-fold greater risk of postpartum infections, ranging from endometritis to urinary tract infection and wound infection, compared with vaginal delivery.[5] Preoperative prophylactic antibiotics are intended to reduce the size of the bacterial inoculum and to change the characteristics at the operative site during the brief time that host defences are impaired by the trauma of surgery.[6] Studies have shown that compared with placebo, prophylactic antibiotics administered alongside caesarean section significantly reduces the rate of maternal postpartum fever, wound infection, endometritis, urinary tract infections, serious infectious morbidity, death and length of hospital stay.[7] Evidence from randomized controlled trials suggests that for caesarean section, short-term antibiotic prophylaxis is comparable in efficacy to long-term antibiotic prophylaxis.[8,9] Most of these studies were done in high-income nations. Studies have shown increased cost, higher work load on medical staff and risk of antibiotic resistance with the use of long-term antibiotic prophylaxis with no additional benefit in preventing postpartum infections compared with short-term antibiotic prophylaxis.[10,11] Environmental factors, such as the source, storage and quality of the antibiotics; drug abuse and development of antibiotic resistance have made a short-term antibiotic regimen less desirable in the tropics. Most obstetricians in Nigeria seem unwilling to adapt to the evidence-based recommended single-dose regimen for surgical prophylaxis despite high awareness, perhaps from the fear of increased postoperative infection in our environment even when there is no evidence to justify this strong, long-held belief.[12] This practice negates the principle of surgical prophylaxis as an approach to prevent infections, because a therapeutic regimen is administered. We aimed to close the knowledge gap on the effectiveness of single-dose compared with multiple-dose antibiotic prophylaxis to prevent post-caesarean section infectious morbidity. We included emergency caesarean deliveries, which represent the majority of caesarean section cases in the tropics; these cases have not been widely studied in other research done in the tropics. We determined the efficacy and safety of single-dose compared with multiple-dose antibiotic prophylaxis to prevent post-caesarean section infections.

Methods

Study design

This was a prospective, pragmatic, open-label randomized clinical trial.

Study population

The study comprised pregnant women who had caesarean delivery, either electively or due to an emergency.

Study duration

The study was conducted between 10 May 2020 and 10 April 2021 at the Department of Obstetrics and Gynaecology of the Federal Medical Centre, Keffi, Nigeria. The department has an average delivery rate of 1300 per year with a caesarean section rate of 35% (Federal Medical Centre Keffi, 2018).[13]

Trial registration

Before the trial commenced, it was registered (on 28 April 2020) with the Pan African Clinical Trial Registry with reference number PACTR 2020044658330781 (https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID = 10958). Reporting was done according to the CONSORT checklist (Supplemental Material).

Inclusion criterion

The inclusion criterion was pregnant women scheduled for caesarean section, either electively or due to an emergency, with no added risk for infection.

Exclusion criteria

The exclusion criteria were pregnant women with known allergy to cephalosporins or metronidazole, maternal sepsis, prolonged labour, use of antibiotics in the preceding 2 weeks, prolonged rupture of membranes ($>$24 h), preoperative haemoglobin $<$20 g/dL, weight $>$100 kg, sickle cell disease and diabetic with poor glucose control.

Interventions

Women who met the inclusion criterion were counselled and provided their consent to participate in the study. A focussed history was obtained from the participants using a structured questionnaire

The study subjects were assigned randomly to one of the two parallel study arms: A or B. Subjects in arm A received ceftriaxone 1 g (Lendacin, Novartis-Sandoz, Switzerland) and metronidazole 500 mg (Jugyl, Juhel Pharm, Nigeria) intravenously within 60 min before incision. A repeat dose was planned to be given if blood loss exceeded 1500 ml because this factor has been shown to increase infectious morbidity during surgery. Subjects in arm B received the same preoperative prophylaxis as arm A. They then received metronidazole 500 mg intravenously every 8 h for 48 h, followed by cefuroxime 500 mg (Cefax, Novartis-Sandoz) twice a day for 5 days and metronidazole 400 mg three times a day for 5 days.

The participants were examined for indicators of infection beginning 24 h post-caesarean section, then every 12 h for 72 h until discharge. Following discharge,

they were monitored and followed up via phone calls/SMS and enquiries made on presence of any symptoms of infectious morbidity by the researchers for 2 weeks. Those with possible symptoms were invited to the clinic for an evaluation.

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. Clinical endometritis was considered as the presence of fever, tachycardia, uterine tenderness or offensive lochia with or without microbiological evidence.[4] Postoperative fever was defined by temperature of greater than 38°C at least 4 h apart on two or more occasions, excluding the first 24 h after caesarean section.[2]

When infectious morbidity was suspected, history was taken and general physical examination performed to localize the potential source of infection. A full septic work up was done including full blood count and differentials, in addition to a blood film for malaria by thick and thin film preparation and urine collected for analysis, microscopy, culture and sensitivity. If endometritis was suspected, an endocervical swab was collected for microscopy, culture and sensitivity. Wound culture was done for suspected wound infection. Participants with confirmed infectious morbidity evaluated in the laboratory were treated with a full course of therapeutic antibiotics/antimalarials as needed. The primary outcome was wound infection, while the secondary outcomes were clinical endometritis and postoperative fever.

Sample size determination

The sample size was calculated using the formula for sample size determination in a randomized controlled study on the assumptions that 16.2% of the patients in the multiple-dose (control) arm would develop wound infection based on the findings of a previous study.[14] The fraction of subjects in the single-dose (test) arm expected to exhibit the primary outcome (wound infection) was set at 32.4% (double the rate in the single-dose arm), and the attrition rate was set at 10%. Based on these values, a sample size of 162 subjects would provide 80% power at the 95% confidence interval (CI).

Randomization

A computer-generated random sequence was used to allocate eligible study participants into either group to maintain balance between each arm. Sequentially numbered opaque sealed envelope was used to ensure concealment of group allocation. The envelopes where opened after surgery because preoperative prophylaxis was the same for both arms. Subsequent administrations of antibiotics were done by the ward nurses. The pre-defined primary and secondary outcomes of interest were ascertained by the assessors, namely, the consultants/senior registrars in the managing team of each enrolled subject. This was an open-label, randomized control study because the participants, investigators and assessors were aware of the study arm to which each subject belonged.

Data analysis

The data were collected and then analysed with SPSS Statistics version 22 (IBM Corp., USA). A p-value $< .05$ was considered to be statistically significant. The outcomes were analysed with the per protocol approach, meaning that the participants were analysed in the group in which they were randomized, with exclusion for loss to follow-up. Categorical variables were analysed using the chi-square test or Fisher's exact test (where appropriate); continuous variables were analysed using Student's t-test. Baseline analysis involved comparing the baseline characteristics between the two study arms. Hypothesis testing was done to determine whether there was a significant difference in the cumulative incidence of post-caesarean infectious morbidity, with wound infection as the primary outcome of interest.

Ethical considerations

Ethical approval for the study was obtained from the Health Research Ethics Committee of the Federal Medical Centre, Keffi (reference number: FMC/KF/HREC/360/19). Written informed consent was obtained from the participants according to the Declaration of Helsinki.

Results

During the study period, there were 162 eligible women who underwent caesarean section. Four women in the single-dose arm opted out of the study while one was lost to follow-up before the 2-week postoperative follow-up. This gave an attrition rate of 3.1%. The overall mean age ($\pm$ standard deviation (SD)) of the participants was 30.59 ± 4.65 years. There was not a significant difference in the mean ages of the two groups ($p = .167$). Most of the study participants (97.5%) were married. In both arms, most of the caesarean sections were performed as elective surgery (59.2% for the single-dose arm and 53.7% for the multiple-dose arm, $p = .544$). Repeat caesarean section occurred in 94 (59.5%) participants. While spinal anaesthesia was used in all participants in the single-dose arm, there was no statistically significant difference in the choice of anaesthesia between the arms ($p = .246$). Pfannenstiel incision was the predominant choice of abdominal incision, performed in 145 (92.4%) of the caesarean sections (Figure 1).

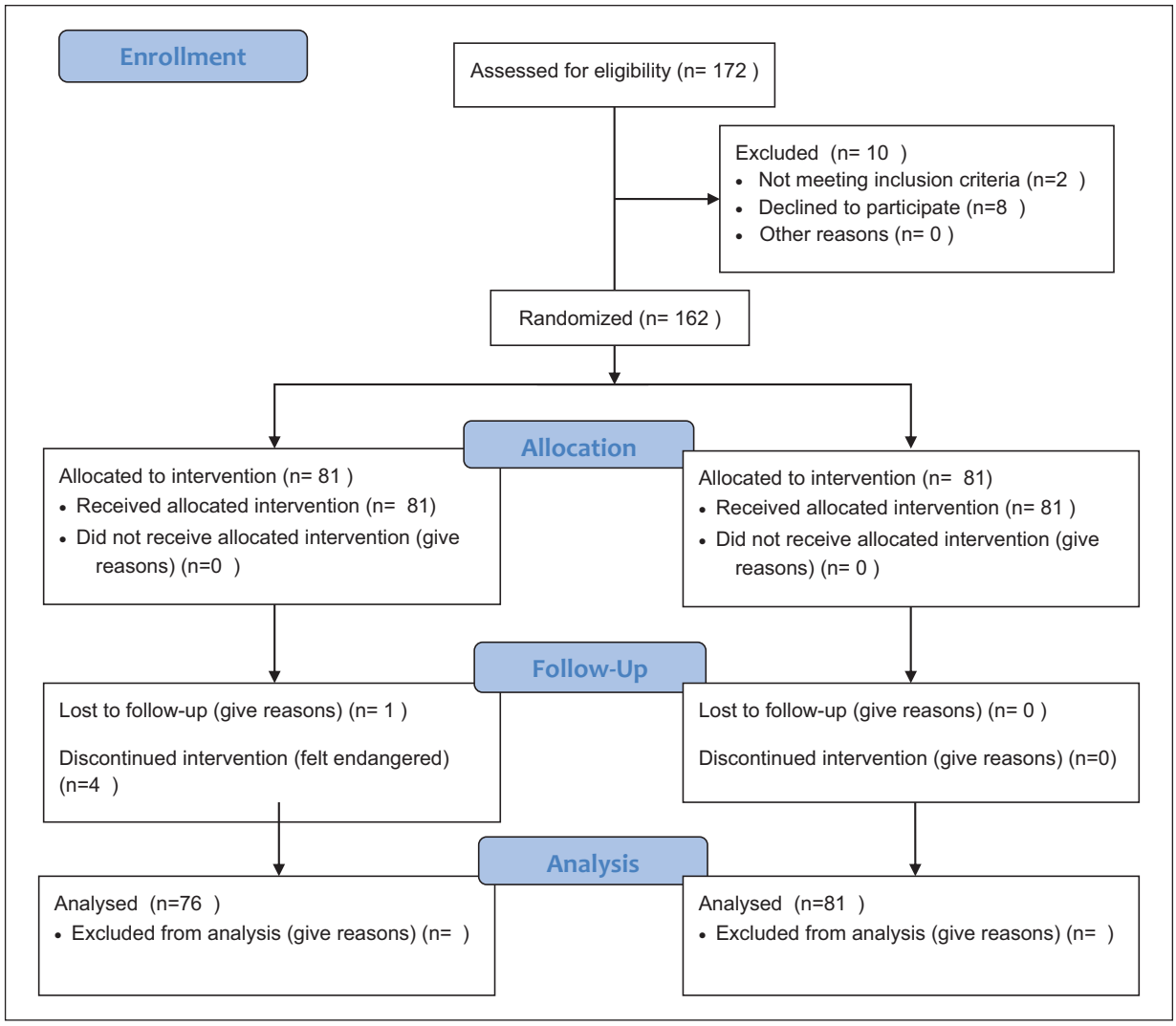

Figure 1. Consort flow diagram.

Table 1 shows the general characteristics of the participants. The overall mean age of the participants was 30.59 ± 4.65. There is no significant difference in the sociodemographic characteristics between participants in both arms.

Table 2 shows the postoperative outcomes in the two study arms. The overall incidence of wound infection was 7%, and there was not a significant difference between the groups ($p = .822$). The occurrence of postoperative febrile morbidity was also not significantly different between the groups ($p = .807$), with a prevalence of 11.5% in the total study population. The incidence of clinical endometritis post-caesarean section was 3.2%, with no cases in the single-dose arm; there was a significant difference between the study arms ($p = .028$). The additional need for therapeutic antibiotics was also not significantly different between the study arms ($p = .092$).

A bivariate regression analysis (Table 3) revealed that none of the dependent variables – category of caesarean section, type of caesarean section, type of skin incision and cadre of surgeons – had a significant effect on wound infection, the primary outcome. Only two dependent variables had a significant effect on febrile morbidity: category of caesarean section ($p = .030$) and type of caesarean section ($p = .029$). Furthermore, none of the dependent variables had a significant effect on clinical endometritis.

Discussion

This study was a randomized clinical trial in which single dose of ceftriaxone and metronidazole given within 60 min before skin incision was compared with an additional 5 days of prophylactic antibiotics for women undergoing caesarean section (either electively or due to an emergency). The single- and multiple-dose study arms were similar in terms of demographics and operative characteristics, with no significant differences between the arms. There were no significant differences in the rates of

Table 1. Sociodemographic characteristics of the study participants.

Factors	Group		Total	χ^2	*p*
	Single dose (*n* = 76)	Multiple doses (*n* = 81)			
	n (%)	*n* (%)			
Age (years)				7.432	.167
15–19	0 (0.0)	2 (2.5)	2 (1.3)		
20–24	9 (11.8)	3 (3.7)	12 (7.6)		
25–29	23 (30.3)	32 (39.5)	55 (35.0)		
30–34	22 (28.9)	25 (30.8)	47 (29.9)		
35–39	17 (22.4)	17 (21.0)	34 (21.7)		
40–44	5 (6.6)	2 (2.5)	7 (4.5)		
Mean age ± SD	30.50 ± 4.82	30.62 ± 4.63	30.59 ± 4.65		
Marital status				4.317	.054
Single	4 (5.3)	0 (0.0)	4 (2.5)		
Married	72 (94.7)	81 (100.0)	153 (97.5)		
Level of education				30.266	<.001
No formal education	0 (0.0)	6 (7.4)	6 (3.8)		
Primary	9 (11.8)	8 (9.9)	17 (10.8)		
Secondary	14 (18.4)	41 (50.6)	55 (35.0)		
Tertiary	53 (69.8)	26 (32.1)	79 (50.4)		
Occupation				7.363	.025
Skilled	32 (42.1)	23 (28.4)	55 (35.0)		
Unskilled	14 (18.4)	50 (61.7)	64 (40.8)		
Professional	30 (39.5)	8 (9.9)	38 (24.2)		
Ethnicity				12.333	.020
Igbo	23 (30.3)	15 (18.5)	38 (24.2)		
Yoruba	0 (0.0)	6 (7.4)	6 (3.8)		
Hausa	9 (11.8)	15 (18.5)	24 (15.3)		
Eggon	0 (0.0)	3 (3.7)	3 (1.9)		
Mada	4 (5.3)	2 (2.5)	6 (3.8)		
Others	40 (52.6)	40 (49.4)	80 (51.0)		

Table 2. Outcomes of antibiotic use among the study participants.

Factors	Single dose (*n* = 76)	Multiple doses (*n* = 81)	Total	χ^2	*p*
	n (%)	*n* (%)			
Postoperative wound infection				0.051	.822
Yes	5 (6.6)	6 (7.4)	11 (7.0)		
No	71 (93.4)	75 (92.6)	146 (93.0)		
Postoperative febrile morbidity				0.013	.807
Yes	9 (11.8)	9 (11.1)	18 (11.5)		
No	67 (88.2)	72 (88.9)	139 (88.5)		
Postoperative clinical endometritis				4.848	.028
Yes	0 (0.0)	5 (6.1)	5 (3.2)		
No	76 (100.0)	76 (93.9)	152 (96.8)		
Postoperative need for therapeutic antibiotics				2.847	.092
Yes	5 (6.6)	12 (14.8)	17 (10.8)		
No	71 (93.4)	69 (85.2)	140 (89.2)		

postoperative infections (wound infections, febrile morbidity and clinical endometritis) between the study arms. The findings in this study are consistent with the evidence-based recommended single-dose regimen and should help to allay the fears that have been expressed by obstetricians in the tropics.[12]

Table 3. Bivariate analysis of dependent variables on the outcomes of interest.

Factors	Wound infection, *n* (%)		χ^2	Odds ratio	95% confidence interval	*p*
	Yes (*n* = 11)	No (*n* = 146)				
Category of caesarean section			1.239	2.140	0.546–8.391	.267
Elective	8 (9.0)	81 (91.0)				
Emergency	3 (4.4)	65 (95.6)				
Type of caesarean section			1.771	2.813	0.788–10.040	.184
Primary	7 (10.1)	56 (88.9)				
Secondary	4 (4.3)	90 (95.7)				
Type of skin incision			0.972	2.122	0.118–38.170	.978
Pfannenstiel	11 (7.3)	134 (92.4)				
Midline	0 (0.0)	12 (100.0)				
Cadre of surgeon			0.228	1.061	0.126–8.907	.633
Registrar	10 (7.0)	132 (93.0)				
Consultant	1 (6.7)	14 (93.3)				
	Febrile morbidity					
	Yes (*n* = 18)	No (*n* = 139)				
Category of caesarean section			4.717	4.392	1.217–15.850	.030
Elective	15 (16.9)	74 (83.1)				
Emergency	3 (4.4)	65 (95.6)				
Type of caesarean section			4.778	3.451	1.221–9.752	.029
Primary	12 (19.0)	51 (81.0)				
Secondary	6 (6.4)	88 (93.6)				
Type of skin incision			0.244	3.627	0.206–63.870	.621
Pfannenstiel	18 (12.4)	127 (87.6)				
Midline	0 (0.0)	12 (100.0)				
Cadre of surgeon			0.035	0.825	0.171–3.995	.852
Registrar	16 (11.3)	126 (88.7)				
Consultant	2 (13.3)	13 (86.7)				
	Clinical endometritis					
	Yes (5)	No (152)				
Category of caesarean section			0.094	0.498	0.081–3.067	.759
Elective	2 (12.2)	87 (97.8)				
Emergency	3 (4.4)	65 (95.6)				
Type of caesarean section			0.210	0.995	0.161–6.127	.647
Primary	2 (3.2)	61 (96.8)				
Secondary	3 (3.2)	91 (96.8)				
Type of skin incision			0.555	0.979	0.051–18.740	.456
Pfannenstiel	5 (3.4)	140 (96.6)				
Midline	0 (0.0)	12 (100.0)				
Cadre of surgeon			0.301	1.240	0.065–23.510	.584
Registrar	5 (3.5)	137 (96.5)				
Consultant	0 (0.0)	15 (100.0)				

The overall incidence of wound infection (primary outcome) was 7% (6.6% in the single-dose arm and 7.4% in the multiple-dose arm). This is similar to the findings reported by Alekwe et al.[15] in Ife, Nigeria (7% versus 8%); these authors compared a single dose of ceftriaxone with multiple doses of ampiclox, gentamicin and metronidazole to prevent infectious morbidity following elective caesarean section. Our study findings are also similar to a report from Kano, Nigeria.[16] The authors compared treatment with just two doses of antibiotics with antibiotics administered for 7 days, with an overall wound infection rate of 8.4% (6.4% for two doses versus 10.5% for 7-day treatment). However, our wound infection rate was higher than the 4.5% overall wound infection rate in a similar study done in Abuja, Nigeria comparing short-term versus long-term antibiotic prophylaxis for caesarean section.[17] The

lower wound infection rate could be related to environmental factors because infection control protocols differ across facilities. This was also the case with a similar study done in Uganda[18] with a wound infection rate of 1.3% in the single-dose arm and 2.4% in the multiple-dose arm (relative risk = 1.895, 95% CI = 0.2–21.4). However, those authors only examined elective caesarean sections, a difference that may explain the lower wound infection rate because emergency caesarean section has been reported as a risk factor for wound infection.[19]

The overall incidence of postoperative febrile morbidity, defined as temperature > 38°C measured twice at least 4 h apart on two occasions excluding the first 24 h post-caesarean section, was 11.5%, with no difference between the arms. This was the most common of the three infectious morbidity outcome measured. This overall incidence of 11.5% is higher compared with the findings reported by Alekwe et al.[15] in Ife, Nigeria (7% for the single-dose group and 6% for the multiple-dose group, $p = .774$). However, the rate in this study was lower compared with the study by Ijarotimi et al.[20] who reported a febrile morbidity rate of 17% in the short-term prophylaxis group and 18% in the long-term prophylaxis group ($p = .852$). This may be attributed to the use of ceftriaxone in the present study; it has a wider spectrum compared with ampiclox that was used by Ijarotimi et al.

The overall incidence of clinical endometritis, defined as the presence of fever, tachycardia, uterine tenderness or offensive lochia with or without microbiological evidence,[4] was 3.2% (0.0% for the single-dose arm and 6.1% for the multiple-dose arm, $p = .028$). The lack of cases recorded in the single-dose arm underscores the effectiveness of this regimen and supports the need for larger studies. Our finding is comparable to a similar study in Abuja, Nigeria, where the overall incidence was 2.1% (0.4% in the single-dose group and 1.6% in the multiple-dose group, $p = .213$).[17] Our finding is much lower than that reported by Alekwe et al.[15] with 14% in the single-dose group and 15% in the multiple-dose group. This may be due to the microbiological criteria used to define endometritis in the study: an endocervical swab was taken routinely from all participants on postoperative days 3 and 5 for microscopy and culture. The exclusion of participants with increased risk, such as prolonged rupture of membrane in this study and preclinical endometritis, may also be responsible for the low rate found in this study. The incidence in this study, however, is within the range reported in a study done in the United States.[21]

In this study, 10.8% of the study participants (6.6% for the single-dose arm versus 14.8% for the multiple-dose arm, $p = .09$) had a need for additional antibiotics, and this was considered a sign of infection. However, the difference between the arms was not significant.

Bivariate regression analysis showed that none of the dependent variables had an effect on the primary outcome and wound infection rate. Importantly, emergency caesarean sections did not increase the rate of wound infection. This outcome has also been demonstrated in previous studies in Ibadan, Nigeria[15] and in New Zealand[22] (odds ratio = 0.976, 95% CI = 0.663–1.438, $p = .987$). The exclusion of emergency cases, which have an additional risk of infection, may have been the reason for no significant difference in this study.

The strength of this study is that unlike other studies that excluded emergency caesarean sections, which comprise a notable fraction of caesarean sections in resource-limited settings, we incorporated them, and found that there was no additional risk of infectious morbidity. The limitations include the inability to blind the study participants and obstetric caregivers. Moreover, we could not record the clinical signs and symptoms that may have occurred at home prior to the 2-week follow-up visit.

The implication of these findings to future research is for multicentric research with larger sample sizes in low-resource settings comparing single- with multiple-dose regimens to help validate or disprove the findings for clinical recommendations.

Conclusion

We have shown that pre-incision single-dose ceftriaxone and metronidazole is as effective as multiple-dose antibiotic prophylaxis to prevent post-caesarean section infectious morbidity. The single-dose approach represents a cost-effective option, reduces workload for hospital staff and may reduce the risk of antibiotic resistance.

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Gerald Tochukwu Igwemadu: Conceptualization; Investigation; Methodology; Writing – original draft; Writing – review & editing.

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Enang Enang Eno: Conceptualization; Formal analysis; Investigation; Methodology; Validation; Writing – review & editing.

Uche Augustine Akunaeziri: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Supervision; Writing – original draft.

Folashade Adeola Afolabi: Conceptualization; Investigation; Methodology; Supervision; Validation; Writing – review & editing.

Abayomi Ibukun Alao: Conceptualization; Formal analysis; Investigation; Methodology; Writing – original draft; Writing – review & editing.

Onazi Ochima: Formal analysis; Methodology; Supervision; Writing – review & editing.

Consent for publication

All participants provided written informed consent for publication.

Data availability

The data used to support the findings of this study are available from the site publicly.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Disclosure statement for publication

All authors have made substantial contributions to: conception and design, acquisition of data or analysis and interpretation of data; drafting of the article or revising it critically for important intellectual content; and final approval of the version submitted. This article has not been submitted for publication in another journal.

Ethical approval and consent to participate

The study was approved by the Ethics Review Board of the federal medical centre, Keffi with reference number FMC/KEF/HREC/360/19. Pan African Clinical Trial Registry with reference number PACTR 2020044658330781. https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID=10958

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Supplemental material

Supplemental material for this article is available online.

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