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Original article

Single-Dose *versus* Multiple-Dose Antibiotic Prophylaxis for Preventing Post Caesarean Section Infectious Morbidity in A Cyrene Teaching Hospital

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ABSTRACT

Background and aims. *Caesarean section is a common obstetric surgery associated with an increased risk of post-partum maternal infection, enhancing the requirement for perfect antibiotic prophylaxis with fewer side effects and lower cost, the aim of this study is to evaluate the efficacy of a single- dose antibiotic regimen versus a multiple-dose antibiotic regimen in preventing post caesarean infection.* ***Methods****. The current study was prospective comparative with parallel, balanced randomization. The study was carried out on 200 patients who were divided into two groups: Group A patients received a single dose of Ceftriaxone 1g intravenously 30-40 minutes prior to caesarean section, whereas group B patients received Ceftriaxone 1 g and Metronidazole 500 mg intravenously 30-40 minutes before caesarean section, followed by Cefixime 400 mg once daily for 5 days and Metronidazole 500 mg three times daily for 5 days.* ***Results.*** *There was no significant difference between both groups in terms of post-operative infection prevention, and there was no statistically significant difference between both groups in the incidence of wound infection 2% in group A and 3% in group B (p=1.000) whereas 5% of group A and 9% of group B developed post-operative febrile morbidity (p= 0.268). 2% of group A as well as 2% of group B developed endometritis (p=1.000).* ***Conclusion.*** *Single-dose antibiotic prophylaxis is equivalent to multiple-dose antibiotics prophylaxis in infection prevention after caesarean delivery.*

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INTRODUCTION

Caesarean section refers to delivering a fetus through a surgical incision in the anterior wall of the uterus [1]. It is considered to be the most important risk factor for postnatal maternal infection. A woman undergoing a caesarean section has a 5- to 20-fold increased risk of infections and infectious diseases compared to vaginal delivery [2].

Post-cesarean infectious complications are an important and significant cause of maternal mortality and increase hospital and treatment costs. These infectious complications range from mild to severe and can be fatal. These include fever, wound infection, urinary tract infection, endometritis, pelvic abscess, septic pelvic venous thrombophlebitis, sepsis, and septic shock [3]. The infection can spread and cause life-threatening peritonitis [4]. Or, in rare cases, it may manifest as an anesthetic-infectious complication, such as meningitis or encephalitis [5]. The potential for prophylactic antibiotics has been extensively studied in both high-risk and low-risk women, showing clear benefits in reducing postpartum infection morbidity [2,6]. A single dose or a combination of broad-spectrum intravenous antibiotics given 30 to 60 minutes before caesarean delivery has been shown to reduce postoperative infections [7].

A 2010 review by The Cochrane Collaboration showed that prophylactic antibiotics reduced the incidence of

endometritis and wound infections after elective or emergency caesarean sections by two-thirds to three-quarters. The purpose of antibiotic prophylaxis in surgery is not to sterilize tissue, but rather to reduce the colonization pressure of microorganisms introduced during surgery to a level that the patient's immune system can overcome [8]. Prophylaxis does not prevent infection from postoperative contamination [9]. The purpose of this study was to compare wound infection, clinical endometritis, and febrile morbidity in mothers with single and multiple doses of antibiotic prophylaxis.

METHODS

Study design and setting

The current study was prospective comparative with parallel, balanced randomization, 1:1 randomized clinical trial (RCT) involving 200 mothers who delivered at the obstetric department of a Cyrene teaching hospital. Written informed consent was obtained from all participants. Inclusion criteria includes mothers delivering by caesarean section, either elective or emergency. While the exclusion criteria were mothers who received antibiotic treatment within two weeks before surgery, mothers with antibiotic hypersensitivity, patients showing evidence of chorioamnionitis, mothers with diabetes mellitus or autoimmune diseases, mothers who have prolonged pre-operative hospitalization, duration of labor longer than 6 hours and patients who had >3 times per-vaginal examinations.

Data collection procedure

Detailed history was taken from all patients including personal data, past medical history, obstetrical and drug history, history of endocrinal and autoimmune diseases and the indication for caesarean delivery was reported. Patients in group A received a single-dose antibiotic prophylaxis with intravenous Ceftriaxone 1 gram (g) 30-40 minutes before skin incision. Group B received intravenous Ceftriaxone 1g and Metronidazole 500mg 30-40 minutes before skin incision, followed by oral Cefixime 400 mg once daily for five days and Metronidazole 500 mg three times daily for five days. All the patients were observed during the postoperative period for the appearance of any infectious morbidity. Vital signs were recorded every six hours, and an abdominal examination was performed twice daily to note the size of the uterus and the presence of tenderness.

The wound and the uterine tenderness were evaluated on the 4th and 7th postoperative days. Febrile morbidity was defined as an oral temperature >38 °c in the first 10 days postpartum excluding the first 24 h. We searched for and noted any evidence of any other infections that might have developed in the postoperative period. Endometritis was described as the presence of noticeable uterine tenderness and/or offensive vaginal discharge accompanied by fever.

Wound infection was defined as the presence of palpable induration and local tenderness with either serous or purulent wound discharge. Urinary tract infection is defined as a positive urine culture, either accompanied or not by dysuria and fever.

Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp.). Categorical data were represented as numbers and percentages. The Chi-square test was applied to compare two groups. For continuous data, they were tested for normality by the Kolmogorov-Smirnov test. Quantitative data were expressed as range (minimum and maximum), mean, standard deviation and median. Student t-test was used to compare two groups for normally distributed quantitative variables, while Mann Whitney test was used to compare two groups for not normally distributed quantitative variables. The significance of the obtained results was judged at the 5% level.

RESULTS

A total of 200 patients participated in this study, 100 patients in group A received a single antibiotic dose and were compared with 100 patients in group B who received multiple antibiotic doses, both groups were comparable in terms of demographic status and clinical features. The mean age was 32.87 ± 5.60 years in group A, and 32.89 ± 5.66 years in group B; the mean Gestational age (weeks) was 38.85 ± 1.59 in group A and 38.61 ± 1.24 in group B. The mean number of parity was 2.50 ± 1.90 in group A and 2.94 ± 2.03 in group B. The mean weight in Kg was 72.86 ± 12.21 in group A and 75.64 ± 10.89 in group B. The indications of caesarian section were comparable in both groups except for a significant difference between the two groups in the indication of C/S among PET patients and patients with a previous history of infertility. The most common indication of caesarian delivery among both groups was a previous history of caesarean section, followed by fetal distress as the second most common indication.

Spinal anesthesia was used in the vast majority of the patients (96% of group A patient, and 98% of group B patients). Most operations were performed in emergency situations (55% of group A and 66% of group B). (Table 1)

Table 1. Comparison between the two studied groups according to demographic and clinical parameters

Demographic and clinical parameters	Group A (Single dose) (n=100)	Group B (Multiple doses) (n=100)	Test of sig.	*P*
Age (years)				
Mean ± SD.	32.87 ± 5.60	32.89 ± 5.66	t= 0.025	0.980
Median (Min. – Max.)	34 (21 – 44)	33 (22 – 47)		
Weight (kg)				
Mean ± SD.	72.86 ± 12.21	75.64 ± 10.89	t= 1.699	0.091
Median (Min. – Max.)	73 (45 – 97)	76.5 (43 – 98)		
Parity in numbers				
Mean ± SD.	2.50 ± 1.90	2.94 ± 2.03	U= 4418.500	0.151
Median (Min. – Max.)	2.5 (0 – 7)	3 (0 – 9)		
Gestational age (weeks)				
Mean ± SD.	38.85 ± 1.59	38.61 ± 1.24	U= 4654.500	0.382
Median (Min. – Max.)	39 (37 – 49)	39 (37 – 41)		
No. of vaginal examination				
0	44(44%)	39(39%)	χ^2= 10.155*	^{MC}p= 0.026*
1	4 (4%)	9 (9%)		
2	21 (21%)	35 (35%)		
3	30 (30%)	17 (17%)		
4	1 (1%)	0 (0%)		
Indication of CS				
Fetal distress	16 (16%)	15 (15%)	χ^2=0.038	0.845
One or more previous scars	23 (23%)	25 (25%)	χ^2=0.110	0.741
Bi size	8 (8%)	10 (10%)	χ^2=0.244	0.621
Old PG	2 (2%)	0 (0%)	χ^2=2.020	^{FE}p=0.497
Breech	8 (8%)	8 (8%)	χ^2=0.0	1.000
PET	1 (1%)	8 (8%)	χ^2=5.701*	^{FE}p=0.035*
Obstructed labour	11 (11%)	12 (12%)	χ^2=0.049	0.825
CPD	8 (8%)	7 (7%)	χ^2=0.072	0.788
Twin	3 (3%)	0 (0%)	χ^2=3.046	^{FE}p=0.246
Infertility	10 (10%)	3 (3%)	χ^2=4.031*	0.045*
Abruption	2 (2%)	1 (1%)	χ^2=0.338	^{FE}p=1.000
Polyhydramnios	1 (1%)	0 (0%)	χ^2=1.005	^{FE}p=1.000
PROM	5 (5%)	3 (3%)	χ^2=0.521	^{FE}p=0.721
Low placenta	2 (2%)	6 (6%)	χ^2=2.083	^{FE}p=0.279
Cord prolapse	0 (0%)	1 (1%)	χ^2=1.005	^{FE}p=1.000
ICSI	0 (0%)	1 (1%)	χ^2=1.005	^{FE}p=1.000
Emergency	55 (55%)	66 (66%)	χ^2=2.532	0.112
Elective	45 (45%)	33 (33%)	χ^2=3.026	0.082
Anesthesia				
Spinal	96 (96%)	98 (98%)	χ^2= 0.687	^{FE}p= 0.683
General	4 (4%)	2 (2%)		

Notable intra-operative findings were comparable between both groups except for the fact that difficult head extraction was higher in group A at 11% than in group B at 2%, while significant adhesions were more noticeable in group B at 10% than in group at A 2%. (Table 2 & figure 1).

Table 2. Comparison between the two studied groups according to the notable intraoperative finding

Notable intraoperative finding	Group A (Single dose) (n=100)	Group B (Multiple doses) (n=100)	χ^2	p
Difficult head extraction	11 (11%)	2 (2%)	6.664*	0.010*
Extension of uterine incision	5 (5%)	5 (5%)	0.0	1.000
Scare dehiscence	4 (4%)	7 (7%)	0.866	0.352
Scare rupture	0 (0%)	0 (0%)	–	–
Low placenta	1 (1%)	1 (1%)	0.0	FEp=1.000
Significant adhesion	2 (2%)	10 (10%)	5.674*	0.017*
Meconium	6 (6%)	8 (8%)	0.307	0.579

χ^2: **Chi square test** FE**: Fisher Exact**
p: p value for comparing between **the two studied groups**
*: Statistically significant at $p \leq 0.05$

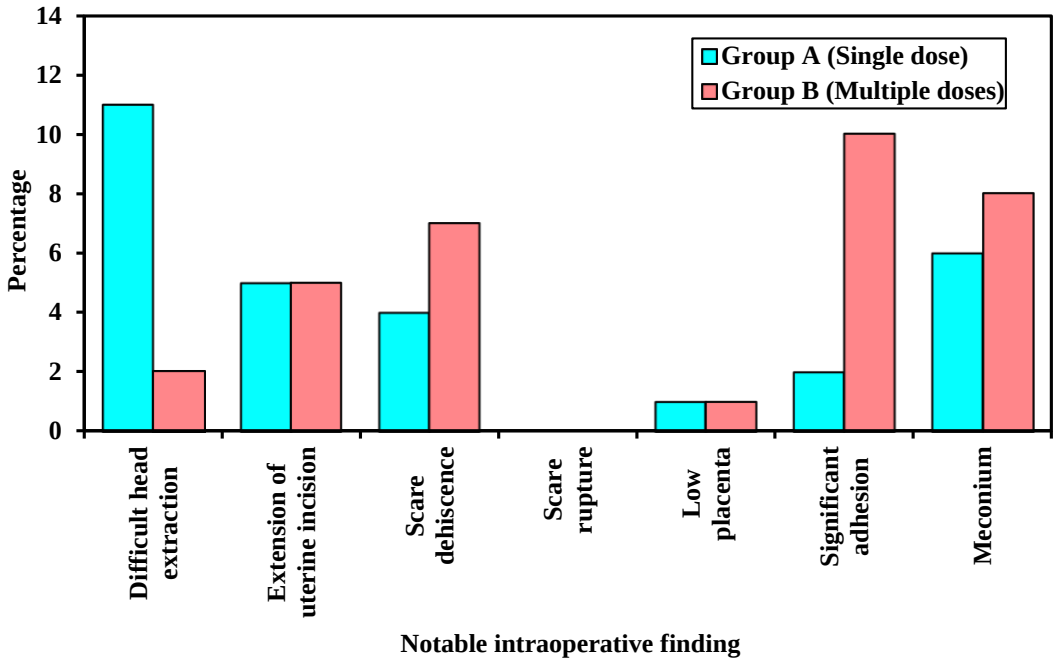

Figure 1. Comparison between the two studied groups according to the notable intraoperative findings

Comparison between the two studied groups according to post-operative morbidity following antibiotic administration does not show any significant difference between both groups. No statistically significant difference was found between both groups in the incidence of both wound infection and febrile morbidity; only 2% of group A and 3% of group B developed wound infection post-operatively, whereas 5% of group A and 9% of group B developed post-operative febrile morbidity. 2% of group A and 2% of group B developed endometritis (Table 3 & figure 2).

Table 3. Comparison between the two studied groups according to post-operative morbidity

Post-operative morbidity	Group A (Single dose) (n=100)	Group B (Multiple doses) (n=100)	χ^2	p
Febrile morbidity	5 (5%)	9 (9%)	1.229	0.268
Endometritis	2 (2%)	2 (2%)	0.0	^{FE}p=1.000
UTI	3 (3%)	6 (6%)	1.047	^{FE}p=0.498
RTI	5 (5%)	7 (7%)	0.355	0.552
Paralytic ilius	1 (1%)	2 (2%)	0.338	^{FE}p=1.000
Wound infection	2 (2%)	3 (3%)	0.205	^{FE}p=1.000

χ^2: **Chi square test** FE**: Fisher Exact**
p: p value for comparing between the two studied groups

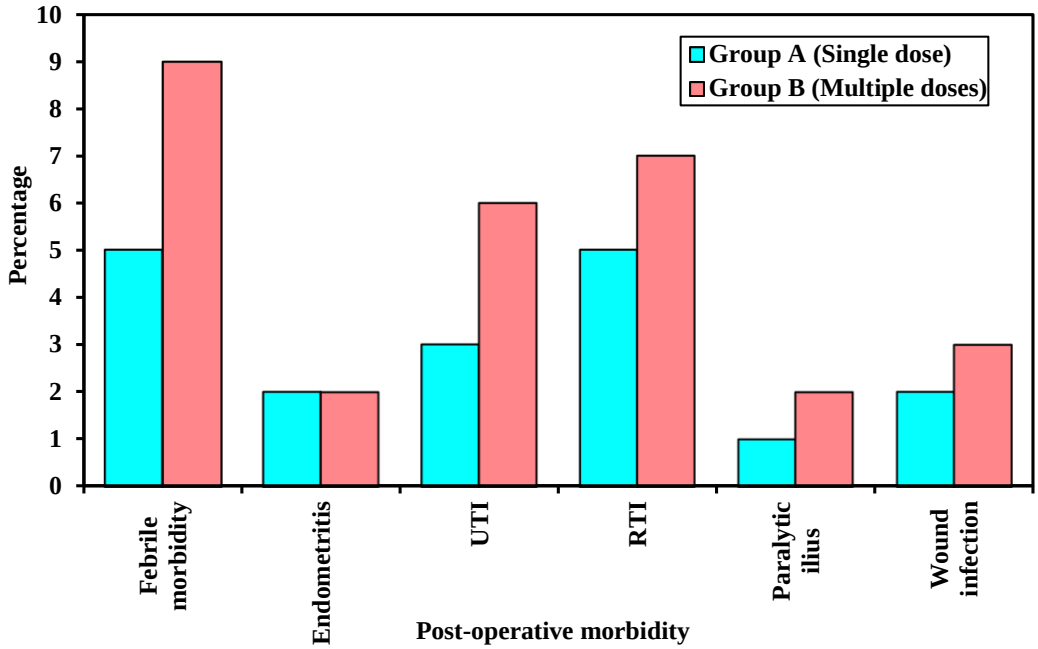

Figure 2. Comparison between the two studied groups according to post-operative morbidity

DISCUSSION

Delivery by Cesarean section is associated with a greater risk of postpartum infection, with a 5-20 times increased infection incidence as compared to normal vaginal delivery [10]. In fact, the most common risk factor for postpartum infection is Cesarean delivery. The importance of pre-operative antibiotic prophylaxis in patients undergoing Cesarean section has been proven [6,10] and recommended for all patients undergoing caesarean section according to the international current guidelines [11], the issue now is to determine the best way of antibiotic administration that fulfills the goals with fewer side effects and cost, The current study is a prospective comparative study, conducted to assess the efficacy of a single-dose antibiotic compared to multiple-doses in infection prevention in mothers who give birth by Cesarean section, a preoperative single-dose of IV Ceftriaxone alone was compared to a preoperative IV dose of Ceftriaxone and Metronidazole followed by multiple doses of Cefixime and Metronidazole for 5 days. This study shows that single-dose antibiotic prophylaxis is as effective as a multiple-dose antibiotic regimen in preventing infection among study participants, this is in agreement with a previous study performed by Kayihura et al., showed that a single dose of Gentamycin and Metronidazole preoperatively is equivalent to a multidrug regime consisting of crystalline Penicillin, Erythromycin and Metronidazole[12].

our study is also in agreement with Alekwe et al., study which showed that single pre-procedure dose of Ceftriaxone has the same protective effect as a regimen composed of three drugs Ampiclox, Metronidazole and Gentamycin[13]. Shakya et al., compared the efficacy of a single dose of Cefazolin and Metronidazole to the same regimen for several days and found no significant difference between them in preventing infection post operatively[14]. Another study

conducted by Westen et al., showed that a single prophylactic dose of Ampicillin and Metronidazole is as effective as a regimen of multiple day doses of Amoxicillin and Metronidazole [15]. Similarly Parthima et al., concluded that a single dose of narrow-spectrum Cefotaxime is as effective as a triple drug regimen composed of Ceftriaxone, Metrogyl and Gentamycin for 5 days postoperatively [16].

Recently Mohammed So et al. studied the prophylactic effects of two doses of Amoxicillin-Clavulanic acid versus a 7-day course of Amoxicillin-Clavulanic acid and Metronidazole and found no statistically significant difference [17].

Another recent study conducted by Adaji et al., compared a short term prophylaxis with Cefuroxime and Metronidazole for 48 h to a long term prophylaxis with the same drugs for 5 days and found no difference between both regimens [18].

More recently, Igwemadu et al., conducted a study that shows that a Single dose of Ceftriaxone and Metronidazole is as effective as multiple doses in post-caesarean section infection prevention [19].

In contrast with our study, Andrews et al., studied the effect of extended spectrum antibiotic prophylaxis in the prevention of post caesarean endometritis and found a higher infection incidence among the patients who received a single dose of Cefotetan [20], this could be attributed to the timing of antibiotic administration because the antibiotic was administered after clamping the cord. In order to achieve the maximum benefits of prophylaxis the antibiotic is better administered 30-60 minutes prior to the surgical incision, and the chosen antibiotic should be long acting with fewer side effects and a low cost [7, 21, 22].

CONCLUSION

Our study shows that preoperative prophylaxis with a single-dose antibiotic regimen is equivalent to multiple antibiotic regimens, single dose antibiotic regimen could contribute in decreasing the risk of emerging bacterial antibiotic resistance, lowering the treatment cost, and improving patient compliance.

Conflict of Interest

There are no financial, personal, or professional conflicts of interest to declare.

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جرعة واحدة مقابل جرعات متعددة من المضادات الحيوية للوقاية من الأمراض المعدية بعد الولادة القيصرية في مستشفى سيرين التعليمي

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المستخلص

الخلفية والأهداف. العملية القيصرية هي جراحة التوليد الشائعة المرتبطة بزيادة خطر الإصابة بعدوى الأم بعد الولادة ، مما يعزز الحاجة إلى الوقاية المثالية بالمضادات الحيوية مع آثار جانبية أقل وتكلفة أقل ، والهدف من هذه الدراسة هو تقييم فعالية نظام جرعة واحدة من المضادات الحيوية مقابل نظام مضاد حيوي متعدد الجرعات في الوقاية من عدوى ما بعد الولادة القيصرية. **طُرق الدراسة**. الدراسة الحالية هي مقارنة مستقبلية مع عشوائية متوازية ومتوازنة. أجريت الدراسة على 200 مريض تم تقسيمهم إلى مجموعتين: المجموعة الأولى تلقوا جرعة واحدة من سيفترياكسون 1 جم عن طريق الوريد 30-40 دقيقة قبل العملية القيصرية ، بينما تلقى مرضى المجموعة ب سيفترياكسون 1 جم وميترونيدازول 500 مجم عن طريق الوريد 30-40 دقيقة قبل العملية القيصرية ، تليها سيفيكسيم 400 مجم مرة واحدة يوميًا لمدة 5 أيام وميترون. **النتائج**. لم يكن هناك فرق احصائي بين المجموعتين من حيث الوقاية من العدوى بعد الجراحة ، ولم يكن هناك فرق معتد به إحصائيًا بين المجموعتين في حدوث عدوى الجرح 2٪ في المجموعة A و 3٪ في المجموعة B (p = 1.000) بينما 5٪ من المجموعة A و 9٪ من المجموعة B تعرضو الي حمى بعد الجراحة .(p = 0.268)أصيب 2٪ من المجموعة (أ) وكذلك 2٪ من المجموعة (ب) بالتهاب بطانة الرحم (ع = 1.000). **الخاتمة**. العلاج الوقائي بالمضادات الحيوية بجرعة واحدة مكافئ للوقاية من المضادات الحيوية بجرعات متعددة في الوقاية من العدوى بعد الولادة القيصرية.

الكلمات الدالة. عملية قيصرية ، عدوى ما بعد الجراحة ، الوقاية من المضادات الحيوية ، جرعة واحدة ، جرعات متعددة.