International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Mishra V. Int J Reprod Contracept Obstet Gynecol. 2022 Dec;11(12):3332-3339
www.ijrcog.org
pISSN 2320-1770 | eISSN 2320-1789

DOI: https://dx.doi.org/10.18203/2320-1770.ijrcog20223126

Original Research Article

Comparison of single dose versus multiple doses of antibiotic prophylaxis in elective caesarean section

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Received: 01 October 2022
Accepted: 01 November 2022

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ABSTRACT

Background: Infectious complications after caesarean delivery (CD) are a substantial cause of maternal morbidity, increase in hospital stay and treatment cost. The spectrum of these complications' spreads from fever, wound infection, endometritis, urinary tract infection, and some serious complications like pelvic abscess, septic shock and septic pelvic vein thrombophlebitis. To prevent these prophylactic antibiotics have been used however the use of antibiotics should be judicious. Aim was to compare the efficacy of single dose versus multiple doses of antibiotics in elective caesarean section.
Methods: This study was conducted in a tertiary care hospital from December 2017 to May 2020. It was a prospective case control study. Sample size was 600, patients were randomly allocated in two groups A and B by card method. Pregnancy category B drug "cefuroxime" was given.
Results: Incidence of SSI was 2.7% (n=8) in single dose group and 3% (n=9) in multi-dose group, this difference was not statistically significant. Incidence of fever for more than 48 hours was 1.3% (n=4) in the single dose group and 0.6% (n=2) in multi-dose group, this difference was not statistically significant. Urine R/M for all patients on 3rd post-operative day, in single dose group 2.3% (n=7) patients and in multi-dose group 2.0 % (n=6) patients had more than 5 pus cells. Patients, who had more than 5 pus cells in urine R/M, were subjected to urine culture and sensitivity. Four (1.40%) patients in single dose group had positive cultures (*E. coli* was detected in three patients and *Klebsiella pneumoniae* in one) and three (1.0%) patients, in multi dose group, (all the three patients had *E. coli* in growth). These results were statistically not significant.
Conclusions: Single dose antibiotic prophylaxis was found to be comparable to multi-dose antibiotics in our study. Hence it is advocated that single dose antibiotic can be given in elective caesarean section as it is cost effective and as efficient as multi-dose regimen, ensures complete compliance and minimizes side effects and cut-down nursing work-load.

Keywords: Cefuroxime, Caesarean delivery, Fever, Multi-dose, Prophylactic antibiotics, Single dose, Urine culture and sensitivity, Urine routine microscopy

INTRODUCTION

Women undergoing caesarean delivery (CD) are at 5-to-20-fold greater risk of infection than women undergoing vaginal delivery. These infective impediments are a significant cause maternal morbidity, increase in hospital stay and increase in treatment expense.[1] The gamut of these complications include fever, wound infection, endometritis, urinary tract infection, and some serious complications like pelvic abscess, septic shock and septic pelvic vein thrombophlebitis.[2] The most important source of micro-organisms responsible for post CD infection is the genital tract, particularly if the membranes are ruptured. These are commonly polymicrobial and the pathogens commonly isolated are *E. coli*, other gram-negative rods, group B *Streptococcus*, *Staphylococci*, *Enterococcus fecalis*, *Gardenerella vaginalis*, anaerobes and genital mycoplasma.[3,4]

Prophylactic antibiotics are in use since decades to safeguard patient from these complications. However, the use of antibiotics should be judicial and not excessive. It has been seen that prophylactic single dose antibiotic is equally effective as compared to long term post-operative combination of antibiotics if good sterility is maintained. In this study we used SUPACEF (cefuroxime), a second-generation cephalosporin which exerts its bactericidal action against both gram positive and gram-negative bacteria, and it is a pregnancy category B drug. It is recommended that 1.5 gm should be administered intravenously not more than 30 minutes before the skin is cut as a single dose and monitor the post- operative outcomes.

In institutions where facilities exist for proper sterile techniques the use of antibiotics should be a minimal however in practice this is not the case. This study was carried out in a well-equipped tertiary care hospital with all facilities for asepsis to find whether use of multiple doses is indeed justified.

Although such studies have been done earlier, we found that reinforcement of this was very essential as people tend to overshoot this aspect especially in good resource setting where the wellbeing of the patient is of prime importance and the treating doctors do not want to take any wound infections.

Aim was to compare the efficacy of single dose prophylaxis versus multiple doses of antibiotics in elective caesarean section.

Objectives

To compare the incidence of surgical site infection (SSI). To compare the incidence of febrile illness. To compare the incidence of urinary tract infection (UTI).

METHODS

After the approval of Institutional Ethical Committee and Scientific Committee, written informed consent was obtained from all patients who had participated in the study.

Study site

This study was conducted at Department of Obstetrics and Gynecology of a tertiary care teaching hospital.

Study design

It was a prospective, case control study.

Study duration

The duration of the study was from December 2017 to May 2019.

Sample size

The primary purpose of the study is to find out difference between 2 groups in Surgical site infection rate (SSI). In a study reported by Dlamini et al, these rates were 85.1% in group A and 65.9% in group B.[5] To be able to detect a difference of 10 % in this rate with a power of 80% and significance level 5% the sample size comes to 286. Using the following formula-

$$\frac{\left[z_{\frac{\alpha}{2}}\sqrt{2\underline{\pi}(1-\underline{\pi})}+z_{\beta}\sqrt{\pi_1(1-\pi_1)+\pi_2(1-\pi_2)}\right]^2}{\delta^2}$$

Where: $z_{\frac{\alpha}{2}} = 1.96$ corresponding to 95% confidence

$\pi_1 = 0.851, \pi_2 = 0.659$

$$\underline{\pi} = \frac{\pi_1 + \pi_2}{2}$$

δ = 0.10 (difference to be detected), $z_{\beta} = 0.84$ corresponding to 80% power.

Therefore, 300 patients were included in each group making a total of 600 cases over a period of 2 years.

Febrile morbidity

Fever >37ºC developing or persisting for 48 hours after surgery was regarded as febrile morbidity.[6]

Surgical site infections (SSIs)

Surgical site infections (SSIs) occur near or at the incision site and/or deeper underlying tissue spaces and organs within 30 days of a surgical procedure (CDC Guidelines for SSI, 2017).[7]

Inclusion criteria

Patient undergoing elective caesarean section. Patients willing to participate in the study and giving written informed consent.

Exclusion criteria

Patient in labor/PROM for emergency caesarean section. Patient with placenta previa, placenta accreta. Patient having pregnancy associated medical disorders. Patient having any infection prior to elective caesarean section (UTI, URI, vaginitis, dental infection). Patient with HIV/AIDS.

Procedure

All patients admitted for elective caesarean section through OPD were included in the study, while the patients admitted for emergency caesarean section and the patient

admitted for elective caesarean section with medical disorders were excluded from the study. A sample size of 600 patients was randomly allocated in two groups A and B by card method. Informed consent was taken for surgery and anesthesia. Similar pre-operative preparation was done for both groups. Skin preparation was done by hair clipping as opposed to shaving, abdominal scrubbing was done with povidone iodine (10%) surgical scrub followed by parts painting with povidone iodine (10%) solution. Surgery was performed by specialists by standard technique. Suture material was vicryl number 1 (polyglycolic acid) for closing the uterus. Skin closure was done by sub cutaneous suturing using monocryl 2-0. Postoperative wound was cleaned by povidone solution and antiseptic dressing was applied in OT. Routine standard post-op care was given to all patients. Surgical site was examined on day 3, dressing was changed using aseptic precautions and patient discharged if fit with advice to follow up on 7th post -operative day.

In group A, 1.5 gm of cefuroxime (Supacef) single dose was given intravenously half an hour before incision and patients in group B, 1.5 gm cefuroxime intravenously was given half an hour before skin incision and continued 12 hourly for next 48 hours, followed by 500 mg of cefuroxime (Ceftum) oral dose twice daily for next 5 days. Each patient was observed in post- operative ward. Four hourly temperature was taken and patient was kept for 3 days in the hospital.

Outcome measures

Wound was examined on 3rd and 7th day and after 30 days for any evidence of superficial and deep infection, pus discharge, abscess formation, wound dehiscence. Patients were also assessed for UTI. Urine routine examination was done on 3rd post-operative day for all patients. Urine culture was done in patients having fever or urinary symptoms or those who developed fever or where urine routine microscopy showed pus cells more then 5/HPF.

Statistical methods

Data was analysed and statistically evaluated using SPSS-PC-20 version. Quantitative data was expressed in mean, standard deviation and difference between two comparable groups was tested by student's t-test (unpaired) or Mann Whitney 'U' test while qualitative data was expressed in percentage. Statistical differences between the proportions were tested by chi square test or Fisher's exact test. 'P' value less than 0.05 was considered statistically significant.

RESULTS

Based on inclusion and exclusion criteria total of 600 patients who underwent elective caesarean section were included in the study. Three hundred patients were randomized to receive a single dose of prophylactic antibiotics (cefuroxime) pre-operatively whereas 300 patients received a standard seven days course (multiple doses) of cefuroxime antibiotics.

The maximum numbers of patients in both the groups in our study were in age group of 31-40 years, which was a reflection of the trend of women having children at later age specially educated and working women belonging to a higher socio-economic status (Table 1). The age distribution in the two groups was not statistically significant.

Table 1: Age distribution in study subjects.

Age group	<20 years		21-30 years		31-40 years		>40 years		P value
	No.	%	No.	%	No.	%	No	%	
Single dose	5	1.7	139	46.3	152	50.7	4.	1.3	0.23
Multiple dose	1	0.3	130	43.3	167	55.7	2	0.7	
Total	6	1.0	269	44.8	319	53.2	6	1.0	

Table 2: Distribution by parity.

Gravida	Primi-gravida		Para two or more		Total		P value
	No.	%	No.	%	No.	%	
Single dose	136	45.3	164	54.7	300	100.0	
Multiple dose	120	40	180	60.0	300	100.0	0.18
Total	256	42.7	344	57.3	600	100.0	

Most of the cases were second gravidas or more 344 (57.3%), primi-gravida were 256 (42.7%), however this difference was not statistically significant (p=0.18) (Table 2). In the single dose group, 232/300 (77.3%) patients were primi, 61 (20.3%) had previous one LSCS and 7 (2.3%) had two or more caesareans. In the multiple dose group, 193/300 (64.3%) were primi-gravidas, 86 (28.60%) had previous one caesarean, and 21 (7%) had previous two or more caesareans.

Table 3: Indications for elective caesarean section in single and multiple dose groups.

Indication of cesarean section	Single dose		Multiple dose		Total	
	No.	%	No.	%	No.	%
Previous LSCS	85	28.3	84	28	169	28.1
Previous 2 or more LSCS	75	25	76	25.3	151	25.1
CPD	47	15.6	43	14.3	90	15
CDMR	60	20	62	20.6	122	20.3
Breech	31	10.3	32	10.6	63	10.5
Others	2	0.6	3	1.0	5	0.83

Table 4: Incidence of fever.

Puerperal outcome	Febrile		Afebrile		Total		P value
	No.	%	No.	%	No.	%	
Single dose	4	1.3%	296	98.7	300	1.0	
Multiple dose	2	0.60%	298	99.40	300	99.0	0.68
Total	6	1.9%	584	97.3	600	100.0	

Table 5: UTI in study subjects.

UTI	Present		Absent		Total		P value
	No.	%	No.	%	No.	%	
Single dose	4	1.4	296	98.6	300	100.0	
Multiple dose	3	1.00	297	99.0	300	100.0	0.28
Total	8	1.3	592	98.7	600	100.0	

Table 6: Surgical site infections in study subjects at day 3 post-op day.

Surgical site infections	Present		Absent		Total		P value
	No.	%	No.	%	No.	%	
Single dose	8	2.7	292	97.3	17	2.8	
Multiple dose	9	3	291	97.0	583	97.2	0.99
Total	17	5.7	583	100.0	600	100.0	

Table 7: Type of surgical site infections in study subjects at day 3.

Type of surgical site infections	Sero-sanguinous discharge		Purulent discharge		Induration		P value
	No.	%	No.	%	No.	%	
Single dose	5	1.7	3	1	0	0.0	
Multiple dose	5	1.7	1	0.3	3	1	0.23
Total	10	1.7	6	1	3	0.5	

The list of indication of elective caesarean section in women receiving single or multiple doses of prophylactic antibiotics is shown in (Table 3). These two groups were almost similar in indication for CD. The commonest indications for elective caesarean section in both groups were previous caesarean sections, cephalopelvic disproportion (CPD) and caesarean delivery on maternal request (CDMR).

Incidence of fever was 1.3% (n=4) in the single dose group and 0.6% (n=2) in multi-dose group; this difference was not statistically significant (Table 4).

Urine routine monitoring was done for all patients on 3rd post-operative day. In single dose group 2.3% (n=7) patients and in multi-dose group 2.0% (n=6) patients had >5 pus cells. All these patients who had >5 pus cells in urine routine monitoring, were subjected to urine culture screening. Four (1.40%) patients in single dose group had positive culture (*E. coli* was detected in three patients and *Klebsiella pneumonae* in one patient) and three (1.0%) patients, in multi dose group, (all the three patients had *E. coli* in growth). These results were statistically not significant (Table 5). Eight (2.7%) patients in single dose group and nine (3.00%) patients in multi-dose group had

surgical site infection (SSI), however, this difference was not statistically significant (Table 6).

On third post-operative day, equal number of patients had serosanguinous discharge in both groups (5 in each group) (1.7% in each) while three (1.0%) patients had purulent discharge in single dose group and one (0.3%) in multi-dose group, however the difference was not statistically significant (Table 7).

All discharges were cultured but no organisms were isolated. After 3rd day wound were examined on 7th post-op day, three (1.0%) patients had induration in single dose group and five (1.7%) patients in multi-dose group. Patients came for follow-up after 4 weeks, all wound healed well in both the groups.

DISCUSSION

Incidence of fever was 1.3% in the single dose group and 0.6% in multi-dose group; this difference was not statistically significant. We compared our results with the following studies. In a study by Nagarashi et al, incidence of febrile morbidity was 4.1% in single dose group versus 3.5% in multi dose group, which was not statistically significant.[8] In a study by Prathima et al, among elective caesarean delivery, one patient in single dose group and no patient in multi-dose group developed fever.[9] Again among emergency caesarean deliveries 3 and 4 patients developed fever in single and multi-dose group respectively, and neither result was statistically significant (p=0.45 and 0.83). However, in our study, we did not take any emergency caesarean cases.

It was apparent in our study, that the number of patients having febrile illness may appear to be less in multi-dose group but there was no statistically significant difference between the two groups.

The overall incidence of fever was very low in our study due to good sterility being maintained in the operation theatres, great emphasis being given to part-preparation and strict adherence to aseptic precaution.

Though SSIs are not life threatening in most cases, they tend to prolong the length of hospital stay, increase hospital cost and in some cases, re-admission for women trying to cope with both the postoperative period and new baby.[10] The global estimate of SSI was 0.5-15%.[11] In the current study eight (2.7%) patients in single dose group and nine (3.00%) patients in multi-dose group had surgical site infection (SSI), however, this difference was not statistically significant. In a study by Babeeta et al, incidence of SSI was 8% in single dose group and 10% in multi-dose group (p value of >0.05), the difference was not statistically significant.[12] In another study conducted by Ansari et al on post-operative evaluation of wound infection, the incidence of wound infection was 2% in single dose group and 3% in multi-dose group.[13] Another similar study conducted by Shah et al, concluded that there was no statistically significance in the rate of infections in both the groups.[14] Lyimo et al, conducted a similar study which showed the incidence of surgical site infection (12/250) 4.8% in single dose when compared to 16 /250 (6.4%) in multiple doses group.[15] In a study by Westen et al, in the single dose group (n-89) six women (6.7%) developed a wound infection compared with nine (10.3%) in multi-dose (n-87), which was non-significant.[16] In contrast to our study, a study conducted by Abro et al showed 17/208 (8.2%) patients had SSIs. Ten patients (9.6%) were in the single dose group and seven (6.7%) were in multi-dose group (p=0.004).[17] This difference was statistically significant. They concluded that multiple doses of prophylactic antibiotics over 24 hours should be used instead of single dose in surgical prophylaxis in clean-contaminated and contaminated procedures. Similar to this study, Roex et al conducted a study which showed 3/66 (4.5%) in single dose and 0/77 (0.00 %) in multi dose group developed wound infection. The multi-dose group showed fewer post-operative infections. The difference was statistically significant (p<0.05).[18]

Similar to our study, most of the studies say that there is no statistically significant difference in wound infection in both the groups, but contrast to this, few studies say multi-dose is better than single dose.

Table 8: Rates of febrile morbidity in various studies.

Authors (years of study)	Single dose n/N (%)	Multiple dose n/N (%)	Significance yes/no
Rajashree et al (2014)[20]	4.1%	3.5%	P-1.451, no
Prathima et al (2016)[9]	2.8%	0%	P-0.457, no
Mugisa et al (2016)[24]	None	None	No
Shah et al (2011-2013)[14]	3.6%	1.3%	P-0.1139, no
Bhattachan et al (2011)[22]	4%	2%	P-1.00, no
Siddig et al (2001)[23]	3%	2%	No

Patients were discharged on 3rd post-op day; and reviewed on 7th day. Three (1.0%) patients had induration in single dose group and five (1.7%) patients in multi-dose group.

We followed CDC Guidelines for SSI (2017) and according to guideline, follow up was done till 30th day post-caesarean. At the end of 30 days, all wounds had

healed well.[19] In a study by Nagarashi et al, all the patients were reviewed after 24 hours and their catheter was removed. They were assessed for SSI on day 3, 7, and 30 post-operatively. The incidence of SSI was 6.7% in single dose group and 7.2% in multi-dose group.[8,20] In another study conducted by Borade et al, patients were followed up for 30 days post op, they also did not find any induration and discharge on the 30th day post-op.[21]

Table 9: Comparison of wound infections in other studies.

Authors	Single dose	Multiple dose	P value
Babeeta et al (2013-2014)[12]	8%	10%	p>0.05
Ansari et al (2014)[13]	2%	3%	p-0.50
Shah et al (2011-2013)[14]	5.6%	4.6%	p-0.857
Lyimoet et at (2011-2012)[15]	4.8%	6.4%	p>0.05
Westnet et al (2008-2009)[16]	6.7%	10.3%	p-0.40
Abro et at (2011-2012)[17]	9.6%	6.7%	p-0.004
Roex et al (1984-85)[18]	4.5%	0%	p<0.05
Present study	2.7%	3.0%	p=0.99

CONCLUSION

Therapeutic concentration of antibiotic in serum, tissues and wound during cesarean is assured by antibiotic prophylaxis. Choice of antibiotic should be such that it should cover the common bacteria that may be encountered during surgery. The drug administration should be done for the shortest period to minimize the development of resistance and the adverse effect of the drug. Single dose antibiotic prophylaxis was found to be comparable to multi-dose antibiotics in our study. Since the single dose antibiotic is as efficacious as multi-dose regimen, it is advocated that single dose prophylactic antibiotic can be given in elective cesarean section as it is cost effective and efficient as multi-dose regimen, ensures complete compliance, minimize side effects and cut-down nursing work-load. Many other studies were found to collaborate, our findings. It is a well-known fact that multi-drug resistance is the result of injudicious use of antibiotics; however, in-spite of the medical fraternity being well aware of this fact indiscriminate use of antibiotics is prevalent in our practice. We need to drive home the fact that a blunderbuss antibiotic therapy is not necessary for all routine cases, especially, where good sterility can be maintained. This study was done to set practical example to curtail over-judicious use of antibiotics in our own institution and we were glad to note that it indeed brought down the use of multiple antibiotics in planed surgeries.

Recommendations

Over-judicious use of multi-dose antibiotics should be discouraged to decrease and prevention of drug resistance. In institutions with good sterility conditions single dose antibiotic policy should be in place for planned clean surgeries. Hesitation to adopt this policy is prevalent in many institutions hence small studies of the nature of our study can be undertaken in various institutions to instil confidence amongst practicing surgeons to adopt single dose antibiotic prophylaxis in planned surgeries. Institutions should have a clear drug policy for various type of surgeries. Quality control department in the institutions should ensure adherence to the institutional drug-control policy.

ACKNOWLEDGMENTS

The authors are grateful to all the participants for their support and contribution.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Mishra V. Comparison of single dose versus multiple doses of antibiotic prophylaxis in elective caesarean section. Int J Reprod Contracept Obstet Gynecol 2022;11:3332-9.