

Comparison of Effectiveness of Single Dose Early Ceftriaxone for Elective Caesarean Section Before Skin Incision Versus Late Ceftriaxone After Cord Clamping in Prevention of Post-Operative Infectious Morbidity

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ABSTRACT

Introduction: The likelihood of infection is between five and twenty times greater for women undergoing caesarean sections compared to those delivering vaginally. The regular use of prophylactic antibiotics reduces the likelihood of post-caesarean infection by more than 50% compared to baseline rates. This study was conducted to compare effectiveness of ceftriaxone before skin incision versus ceftriaxone after cord clamping with respect to post-operative maternal or neonatal morbidity.

Materials and Method: 150 women scheduled for elective caesarean sections were randomized into two groups: EC and LC. Subjects in group EC received an early single iv dose of ceftriaxone, one gram, 30 to 60 minutes prior to skin incision. Subjects in group LC received late ceftriaxone at the same dosage via intravenous administration immediately following cord clamping. The comparison was made among two groups for “post-operative infectious morbidity”, including pyrexia and the incidence of surgical site infections, as well as new-born outcomes like neonatal sepsis as well as the necessity for resuscitation.

Results: Pyrexia was significantly more prevalent in Group LC, with 29.33% of patients affected compared to 9.33% in Group EC ($p = 0.003$). Other complications, such as superficial surgical site infections (SSI) with induration and erythema, purulent discharge, serosanguinous discharge, and deep incisional SSI, were less frequent in EC group but showed no statistically significant differences between the two groups, with p-values of 0.43, 0.08, 0.40, and 0.50, respectively.

Conclusion: The administration of ceftriaxone prior to skin incision has led to a modest reduction in infection morbidity following cesarean section compared to administering the antibiotic post-cord clamping.

Keywords: Antibiotic Prophylaxis, Caesarean section, Ceftriaxone, Neonatal outcomes, Surgical Site Infection.

INTRODUCTION

A caesarean section, commonly referred to as a C-section, is a surgical procedure undertaken to deliver a baby through incisions made in the mother's abdominal wall and uterus. It is a widely performed and critical surgical intervention conducted to safeguard the lives of both the woman

and her new-borns. An increasing number of infants are born through caesarean section annually. Evidently, this will also result in a rise in surgical complications. [1] Infectious comorbidities are an important contributing factor of complications and pose a high mortality risk following a caesarean operation. [2] The use of antibiotics to prevent postoperative infections is referred to as antibiotic prophylaxis. It may be classified as “primary, secondary (suppression), or tertiary (eradication).” [3] Three before research has shown that antibiotic use before to caesarean section can diminish the likelihood of postoperative infection complications. A variety of drugs are accessible and can markedly reduce the occurrence of surgical wound infections. [4] The likelihood of infection is between five and twenty times greater for women undergoing caesarean sections compared to those experiencing vaginal deliveries. [5] The regular use of prophylactic antibiotics reduces the likelihood of post-caesarean infectious morbidity by more than 50% from baseline rates, which range from 20% to 50%. Consequently, antimicrobial prophylaxis is recommended for all women preparing for caesarean sections. [5] Infections as well as fever worsen deliveries in a minimum 10% and up to 15% of patients, respectively, despite current guidelines for antibiotic treatment. [5] Infectious complications that may occur following a caesarean delivery include “fever, bacterial infection of the wound, endometritis, bacteraemia, and various severe infections such as pelvic abscess, septic shock, necrotizing fasciitis, septic pelvic vein thrombophlebitis, and urinary tract infection (UTI).” [6] The incorrect application of antimicrobial agents is the principal factor contributing to the emergence of antibiotic resistance. The unnecessary use of broad-spectrum regimens and incomplete rounds of antimicrobial treatment are contributing reasons. [7] Seven The majority of practitioners still prefer extended antibiotic therapy. Antimicrobial prophylaxis denotes

the use of antimicrobial agents to prevent the transmission of infection, while antibiotic therapy pertains to the utilization of antibiotics to address an existing infection. [8] The use of prophylactic antibiotics acts as an adjunct to diminish intraoperative microbial load to a level manageable by the host’s innate as well as adaptive immune systems, rather than to sterilize tissue. [9-12]

A 2014 Cochrane research demonstrated that antibiotic prophylaxis significantly decreased the frequency of endometritis, wound infections after surgery, as well as severe infectious complications by between 60 and 70% compared to no prophylaxis. [13] In obstetrics, antimicrobial agents are administered post-cord clamping due to concerns that administering them to the foetus may obscure signs of infection in the new-borns. [14] Consequently, prophylactic antibiotics have often been deferred until following surgical delivery and the clamping of the neonate’s umbilical chord. “A 1999 recommendation from the Centres for Disease Control and Prevention in Atlanta (USA)” advised antibiotic usage solely in high-risk caesarean deliveries. [15]

To mitigate the danger of maternal infections post-surgery, prophylactic antibiotics have been advised in multiple guidelines and assessments since 2008, to be taken before to cord clamping. [16-18]

At now, there is insufficient robust evidence to endorse the right time of prophylactic antibiotics in caesarean sections. This study aimed to assess post-operative infection morbidity and new-borns outcomes in women administered ceftriaxone prior to skin incision versus after cord clamping.

MATERIALS & METHODS

This was an observational and prospective study carried out in the Department of Obstetrics and Gynaecology from December 2023 to January 2024 on use of preoperative i.v. antibiotic on maternal and foetal outcome in LSCS in tertiary care hospital of eastern India. The research was conducted in accordance with “the principles of good

clinical practice and the Declaration of Helsinki.” The registered study participants received an information sheet, which was clarified to them, followed by the acquisition of their informed consent in writing.

Inclusion Criteria:

- Women of age between 25 and 35 years
- Women of gestational age between 34 to 40 weeks
- Women scheduled for “elective lower segment caesarean section” during the research period.

Exclusion criteria:

- Women with history of diabetes mellitus.
- Obesity
- Immunocompromised status
- History of antibiotic consumption within 14 days of CS

Sample size: With 18% incidence of pyrexia or SSI in EC group and 40% in LC group as reported in study of Baranwal P et al. (2023),^[19] minimum sample size to achieve 85% power with 0.05 alpha value was found to be 150 with 75 patients in each group.

Women in group EC received a single iv dose of ceftriaxone 1 gram 30 to 60 minutes prior to skin incision. Women in group LC received an identical dose of ceftriaxone intravenously immediately following cord clamping.

The parameters that were investigated included age, parity, duration of pregnancy, indications for elective CS, as well as infectious morbidity after surgery such as "endometritis, pyrexia, surgical site infection, urinary tract infection, and other severe infectious morbidities including

bacteraemia, septic shock, septic thrombophlebitis, necrotizing fasciitis, and infection-related mortality." Endometritis was diagnosed when uterine pain, malodorous lochia, tachycardia, leukocytosis, and a maternal fever exceeding 100.4°F were observed on two separate occasions. Purulent exudate, erythema, and induration at the surgical site indicated the presence of SSI. Maternal fever, flank pain, and urine culture results revealing over 105 colonies of gram-negative urinary bacteria have been used to diagnose UTI.

The assessed new-born outcomes comprised neonatal sepsis indicated by positive blood cultures, the necessity for neonatal resuscitation, NICU hospitalization, and the immediate adverse effects of antibiotic on the infant, including severe diarrhoea and rashes.

STATISTICAL ANALYSIS

Data obtained from the subjects were displayed in tabular format utilizing Microsoft Excel 2016 and subsequently transferred to GraphPad Prism ver 8.4.3. Data were presented as mean±SD (standard deviation) for all continuous variables, including age, gestational age, as well as length of surgery, while frequency and percentage were utilized for categorical data, like incidence of infectious morbidity. The unpaired t-test and Fisher's exact test were employed to assess the statistical significance of differences between EC and LC group for continuous and categorical variables, respectively. The two-tailed p-value of less than 0.05 was considered a criterion for statistical significance.

OBSERVATIONS & RESULTS

Table 1: Comparison of baseline demographic and clinical parameters between EC (before skin incision) and LC Group (after cord clamping)

Parameters	Group EC (n = 75)	Group LC (n = 75)	P-Value
Age in years (Mean ± SD)	29.64 ± 4.60	28.76 ± 4.73	0.25*
Number of primigravida, n (%)	35 (46.67)	33 (44.00)	0.87**
Gestation age in years (Mean ± SD)	38.52 ± 1.26	38.75 ± 1.21	0.26*
Haemoglobin in g/dl (Mean ± SD)	10.56 ± 2.67	10.83 ± 2.86	0.55*
Duration of surgery in minutes (Mean ± SD)	63.86 ± 12.63	66.79 ± 13.22	0.17*

*Unpaired t-test **Fisher's exact test

Most of the patients in either EC or LC group belonged to 28-32 years of age groups and 37-39 weeks of gestational age. There was no significant difference between

EC and LC group with respect to age, parity, gestational age and duration of surgery ($p > 0.05$).

Table 2: Comparison of infectious morbidity between EC (before skin incision) and LC Group (after cord clamping)

Parameters	Number of Patients (%)		P-Value (Fisher's exact test)
	Group EC (n = 75)	Group LC (n = 75)	
Pyrexia	7 (9.33)	22 (29.33)	0.003
Superficial SSI with induration and erythema	6 (8)	10 (13.33)	0.43
Purulent discharge	8 (10.67)	17 (22.67)	0.08
Serosanguinous discharge	5 (6.67)	9 (12)	0.40
Deep incisional SSI	0 (0)	2 (2.67)	0.50
Endometritis	0 (0)	1 (1.33)	>0.999
Urinary Tract Infection	7 (9.33)	15 (20)	0.10
SSI: Surgical Site Infection			

Notably, pyrexia was significantly more prevalent in Group LC, with 29.33% of patients affected compared to 9.33% in Group EC ($p = 0.003$). Other complications, such as superficial surgical site infections (SSI) with induration and erythema,

purulent discharge, serosanguinous discharge, and deep incisional SSI, were less frequent in EC group but showed no statistically significant differences between the two groups, with p-values of 0.43, 0.08, 0.40, and 0.50, respectively.

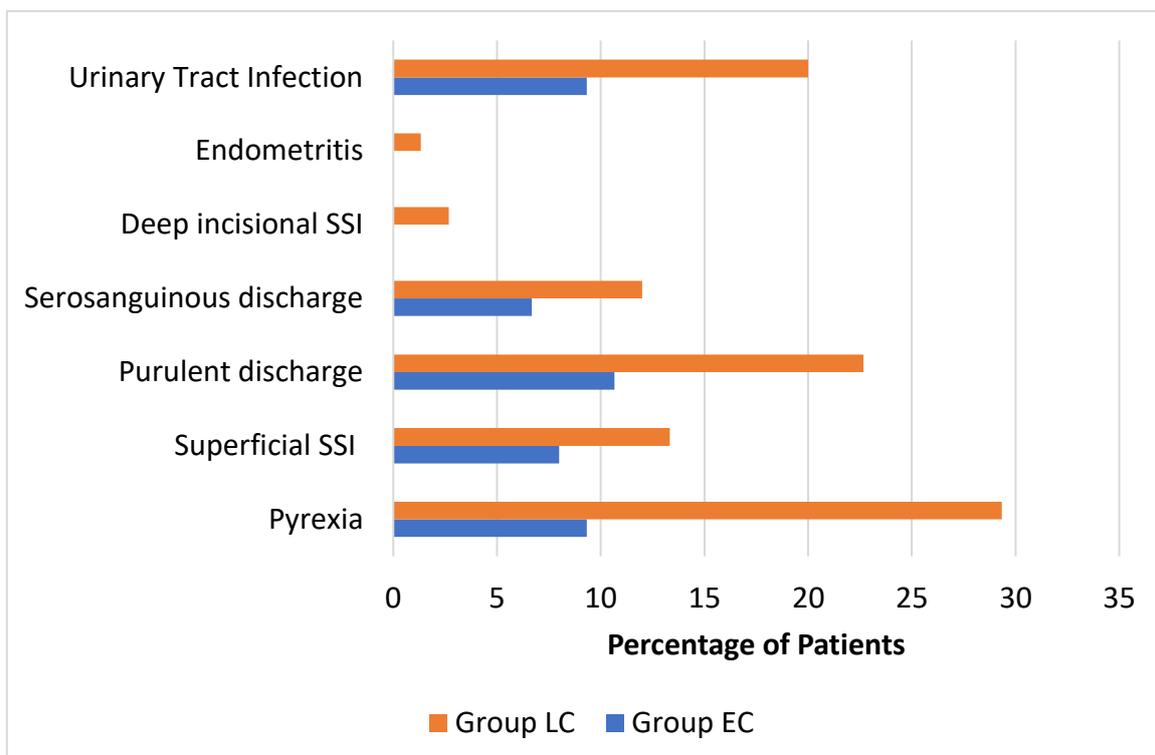


Figure 1: Comparison of Infectious Morbidity

Table 2: Comparison of neonatal outcome between EC (before skin incision) and LC Group (after cord clamping)

Parameters	Number of Patients (%)		P-Value (Fisher's exact test)
	Group EC (n = 75)	Group LC (n = 75)	
Requirement of resuscitation	8 (10.67)	6 (8)	0.74
NICU admission	12 (16)	15 (20)	0.67
Respiratory distress	7 (9.33)	10 (13.33)	0.61
Neonatal sepsis	2 (2.67)	4 (5.33)	0.68
Anomaly	0 (0)	0 (0)	NA

The requirement for resuscitation occurred in 10.67% of Group EC patients and 8% of Group LC patients. In terms of NICU admissions, 16% of Group EC patients and 20% of Group LC patients were admitted. Respiratory distress was reported in 9.33%

of Group EC and 13.33% of Group LC patients. Instances of neonatal sepsis were noted in 2.67% of Group EC and 5.33% of Group LC. However, the difference between EC and LC group was not significant with respect to neonatal outcome ($P > 0.05$).

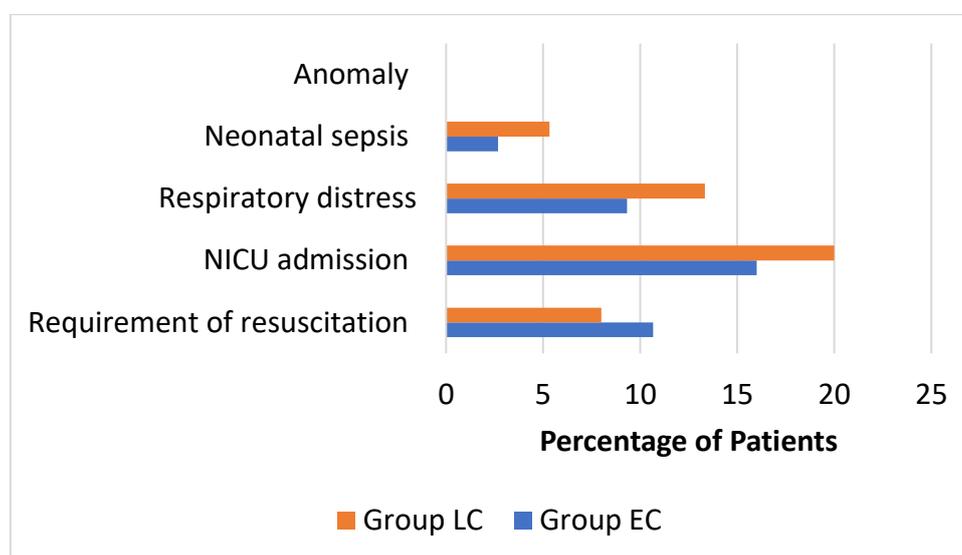


Figure 2: Comparison of Neonatal Outcomes between Two Groups

DISCUSSION

A caesarean section has become one of among the most prevalent medical operations globally. The predominant post-operative complications are infection morbidities, such as endometritis or SSI. Prophylactic use of antibiotics has demonstrated a reduction in infection morbidity among both high-risk as well as low-risk women undergoing elective caesarean sections. Our study exclusively recruited low-risk women devoid of diseases such as severe anaemia, obesity, and diabetes mellitus. To eliminate the influence of several factors associated with urgent deliveries, only elective caesarean sections were considered. An elective CS is

conducted on a woman having intact membranes prior to the onset of labour. The present study selected ceftriaxone because to its remarkable stability versus "beta-lactamases, penicillinases, and cephalosporinases," as well as its efficacy against both "gram-negative and gram-positive bacteria." There is an absence of definitive and robust evidence concerning the time of antibiotic prophylaxis. The standard protocol has been to administer a single medication—usually a cephalosporin—after cord clamping to safeguard the foetus against exposure to medications that may obscure neonatal infection. Research indicates that administering antibiotics fifteen to thirty

minutes prior to a skin incision diminishes infection morbidity without affecting neonatal outcomes. [14, 20-22]

The current study revealed that women administered ceftriaxone before skin incision had approximately a 50% reduced likelihood of SSI compared to those who got it after cord clamping. However, statistically significant difference was not observed in this instance. The present study revealed no instances of endometritis. In a double-blinded randomized controlled trial conducted by Thigpen et al., with 302 female subjects, the LC group exhibited a greater incidence of endometritis (14.7%) compared to the EC group (7.8%). The infection rates for the surgical site had been 3.9% in the EC and 5.4% in the LC group. The data indicated no difference in post-infectious morbidity rates between the two groups. [23]

In the randomized controlled trial conducted by Witt et al., 1,112 women were allocated into three distinct groups. group 1 received 2 g of cefazolin before skin incision, group 2 received the same antibiotic after cord clamping, while group 3 received saline injection prior to skin incision. Around 2.4 percent of women in groups 1- and 2- developed surgical site infections, while around 0.3% had endometritis. [24]

No subjects in either of the groups in the research developed endometritis. Regular cervical swab culture was not carried out in our study. The hospital's policy mandates cervical swab cultures only in cases where fever is present alongside malodorous lochia and uterine pain.

In the present investigation, women administered ceftriaxone before skin incision possessed a reduced incidence of fever. Fever manifested in seven percent of subjects in Alekwe et al.'s study, that evaluated the efficacy of a single dosage of ceftriaxone against many doses of antibiotics in preventing post-caesarean infection complications. [25] Fever was observed in twenty participants (8.3%) in the study conducted by Bagratee et al., which investigated whether prophylactic

antibiotics administered during the elective caesarean section might reduce post-caesarean infection complications. [26]

Approximately 16% of newborns in both cohorts of the current study necessitated NICU admission, surpassing rates observed in previous investigations. [21, 23] Admission was necessitated by respiratory distress, early birth, and other factors. In the current study, neonatal sepsis with a positive blood culture occurred in approximately 2% of neonates born to women administered ceftriaxone prior to skin incision versus 1.8% of neonates born to women who received the drug post-cord clamping. The findings of Owens et al. are analogous to our outcome. [22] The use of antibiotics prior to skin incision had no impact on neonatal infections or NICU hospitalization.

The limitation of our study was that none of the participating women were at a higher risk for post-caesarean infection comorbidities. Consequently, late infestations were not evaluated. The lack of routine evaluation for asymptomatic bacteriuria in all pregnant women during the prenatal period may have resulted in an increased incidence of UTI resulting in positive cultures.

CONCLUSION

The use of ceftriaxone prior to skin incision has led to a modest reduction in infection morbidity following a caesarean delivery, in contrast to administering the antibiotic post-cord clamping. No significant differences in unfavourable neonatal outcomes were observed when the antibiotic was administered prior to skin incision; thus, our study indicates the need for further investigation into the potential risks of adverse neonatal outcomes linked to preoperative antibiotic administration. The accumulation of sufficient evidence about the use of antibiotics prior to the caesarean delivery would facilitate this intervention, leading to a decrease in post-operative maternal or infectious complications.

Declaration by Authors

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