

Efficacy of Extended-Spectrum Antibiotic as Prophylaxis for Emergency Caesarean Delivery

Nayana Shivalingappa¹, Radhika Chetan², Monika Bhaskar³, Sharadini Ghattargi⁴, Srinivas K⁵

¹Junior Resident, Department of OBG, Bangalore Medical College and Research Institute, Bangalore, Karnataka, India, ²Associate Professor, Department of OBG, Bangalore Medical College and Research Institute, Bangalore, Karnataka, India, ³Senior Resident, Department of OBG, Bangalore Medical College and Research Institute, Bangalore, Karnataka, India, ⁴Assistant Professor, Department of OBG, Bangalore Medical College and Research Institute, Bangalore, Karnataka, India, ⁵Professor, Department of OBG, Bangalore Medical College and Research Institute, Bangalore, Karnataka, India

Abstract

Background: Caesarean delivery (CD) is the most commonly performed surgery with associated infectious morbidity. Many trials have given conflicting evidence on the use of extended-spectrum antibiotics in reducing Surgical site infections (SSIs) and endometritis following CD. This study aimed to compare the efficacy of pre-incision extended-spectrum antibiotic prophylaxis compared with narrow-spectrum antibiotic prophylaxis in women undergoing emergency LSCS. Outcome indicators include post-operative SSIs, endometritis, urinary tract infections, and duration of hospital stay. **Material and Methods:** This is a randomised case-control study conducted at a single centre, in which 598 women undergoing emergency CD were randomly assigned to two groups. Group 1 included 296 women receiving standard antibiotic prophylaxis, and Group 2 included 302 women receiving an additional single dose of azithromycin along with standard antibiotic prophylaxis. They were followed up during the hospital stay and up to 6 weeks to determine the SSI and endometritis rates. **Results:** All women underwent emergency or non-elective CD for various indications. Overall, the SSI rate in the study group is 4.6%. There was a significant reduction in endometritis among Group 2 women, who received extended-spectrum antibiotic prophylaxis, 1.65% Vs 3.7% in Group 1 (P value 0.009). However, the reduction in SSI rates was not statistically significant (P=0.329). **Conclusion:** The addition of a single dose of Azithromycin to the standard antibiotic prophylaxis reduced the risk of endometritis following emergency CD without a significant effect on SSI rates. More epidemiological data on the microbiological patterns of SSI and the impact of antibiotics on these microbes are required before implementing extended-spectrum antibiotics for routine prophylaxis in CD.

Keywords: Surgical site infections, Endometritis, Extended antibiotic, Azithromycin, Emergency caesarean delivery.

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INTRODUCTION

Caesarean delivery (CD), a common surgical procedure performed worldwide, is associated with the risk of sepsis and endometritis. Infection complications and sepsis-related maternal deaths are more common after CD than vaginal delivery.^[1,2] Administration of prophylactic antibiotics reduces the risk of surgical site infections (SSI), endometritis, and serious infectious complications by 60-70%.^[1,3] Despite administration of prophylactic antibiotics, infectious complications such as endometritis, SSI, pelvic abscess, and UTI are seen in the postpartum period after CD. These breakthrough infections are reported to be about 10-30% based on the type of antibiotic used, the timing of antibiotic administration, patient-clinician factors, the period of follow-up, and data accuracy.^[4-7] Breakthrough infections are generally polymicrobial, including *E. coli*, beta-haemolytic streptococci, *Ureaplasma*, and mycoplasma infections.^[7-10] Extended-spectrum antibiotics or adjunctive prophylaxis, like Azithromycin or Clarithromycin, when added to the traditional spectrum of antibiotics (cephalosporins), have significantly reduced the risk of endometritis and surgical site infections.^[7,11-16] However, in health centres with low baseline SSI rates, the reduction in

SSI or endometritis risk was not significant, with the use of azithromycin as extended prophylactic antibiotic.^[14,17,18] Global CD rates were 7% in 1990 and 21% in 2021.^[19] With ever-increasing CD rates, prevention of infectious complications gains importance, without negative impacts such as drug resistance or adverse events on mother and baby. This study was undertaken with the hypothesis that the use of extended-spectrum antibiotics may reduce endometritis and SSI rates after non-elective CD at a high-volume, tertiary care centre in a developing country like India. We added a single 500mg oral dose of azithromycin to the routine prophylaxis for emergency CD, where infection morbidity is expected to be higher than in elective CD. Azithromycin is a category B drug, which is safely used in pregnancy. There are no reports of adverse events in the offspring

Address for correspondence: Dr. Radhika Chetan,
Department of OBG, Bangalore Medical College and Research Institute, Bangalore,
Karnataka, India
E-mail: radhikaobg@gmail.com

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when it was used as extended spectrum prophylaxis for SSI after CD.^[20]

MATERIALS AND METHODS

Setting: Study conducted at the tertiary care centre, Vanivilas Hospital, attached to Bangalore Medical College and Research Institute, from March 2019 to July 2021. Permission taken from the institutional ethical committee (No. BMCRI/PG/352/2019-20). This referral hospital has an average delivery rate of 1300 per month, out of which 30-34% are caesarean sections. 5-7% was the baseline SSI rate in the year 2018-2019.

Design and Population: A study was designed for a randomised case-control study. Women undergoing emergency caesarean deliveries (non-elective) after 32 weeks of gestational age are selected. Women undergoing emergency CD for non-progress of labour, foetal distress, failed induction after 24 hours of starting induction, and women with rupture of membranes for at least 4 hours with or without labour were included in the study after taking written consent. Women undergoing elective CD, receiving antibiotics other than cefotaxime before planned CD, and women with known cardiac disease or azithromycin/cefotaxime drug allergy were excluded. They were allocated to two groups by simple randomisation using a random number generator.

Sample size calculated using the formula shown in [Figure 1].

$$n = \frac{(Z_{\alpha/2} + Z_{1-\beta})^2 2PQ}{d^2}$$

Figure 1: Formula for sample size calculation

The sample size calculated to compare the effect of extended-spectrum antibiotics along with standard antibiotics on the rate of infection in the mother, with 90% power, at 5% level of significance, based on a study done by Jyothi MS et al,^[16] and Tita et al,^[7] with a 10% loss to follow-up (attrition). The sample size for estimation is 438, and the corrected prevalence sample size is 635.

Intervention and Allocation concealment: Group one received routine prophylactic antibiotic: Intravenous (IV) Injection of Cefotaxime, 1 gram, 30 minutes to 1 hour before skin incision, and Tab. B-complex (placebo) in a sip of water orally, 30 minutes to 1 hour before skin incision.

Group two consisted of women receiving an extended-spectrum antibiotic. Tab. Azithromycin 500 mg, single dose, orally, in a sip of water, given along with IV injection of cefotaxime 1 gram, 30 min -1 hour before skin incision.

Women received the drug in serially numbered envelopes as selected by the principal investigator. The patient and treating clinician were blinded to the drug allocation.

A total of 635 women were recruited in the study, 318 in group 1 and 317 in group 2. Women were followed up till the duration of hospital stay (minimum 5days) and asked to follow up at 6 weeks when they come for postnatal follow-up (contraception or neonatal immunisation). If women did

not come in person, a telephonic discussion was held to determine the outcome. 296 women in group 1 and 302 women from group 2 were followed up till 6 weeks. 37 were lost to follow-up as they could not be contacted by telephone due to the wrong phone number.

Hence, the final results were summarised for 598 women [Figure 2].

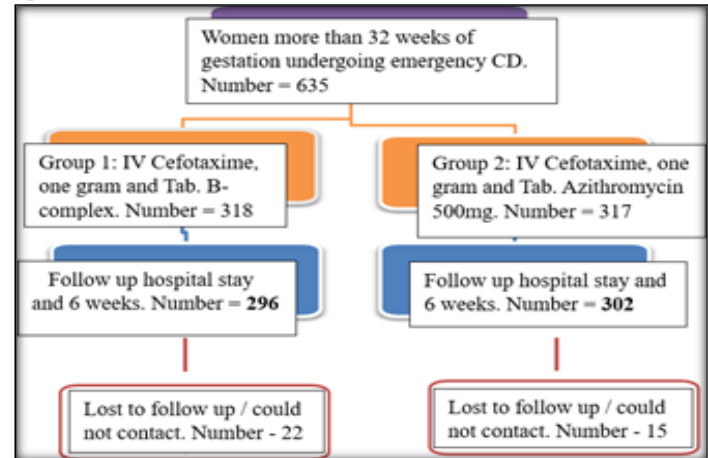


Figure 2: Study Design and population

Data Analysis: collected data, entered into Microsoft Excel spreadsheets, and EpiData software. Analysis was performed using SPSS 16. Mean and standard deviation were calculated for normally distributed data. Appropriate significance tests –Chi-square test, Levene's Test for Equality of Variances, and t-test for Equality of Means were performed.

Outcome indicators: Risk of Surgical site infections and endometritis among recruited women up to 6 weeks after CD. SSI and endometritis were defined as per CDC criteria.^[21]

Superficial SSI – Involving the skin and subcutaneous fat without rectus fascia or muscle involvement. Associated with either redness, pain, or tenderness, or Purulent discharge with positive or negative laboratory confirmation of microorganism. Diagnosis by the treating clinician was also included in the outcome.

Deep SSI – Infection involving fascia or muscle with either fever, pain, purulent discharge, or abscess, or diagnosis by the treating clinician.

Endometritis is a febrile condition associated with uterine tenderness, foul-smelling vaginal discharge (lochia) or purulent lochia, and leucocytosis without other infection.

UTI (Urinary tract infection) - is an infection of the urinary tract involving the bladder, urethra, or upper urinary tract, suggested by symptoms with laboratory evidence of significant bacteriuria.

Readmission - Readmission in view of wound infection, superficial or deep, or for any other reason within the six weeks following CD.

RESULTS

A total of 598 women were included in the final analysis, as 37 women could not be followed up for 6 weeks after CD. The study's attrition rate is 6.35%. These women who dropped out of the study did not develop the SSI, endometritis, or UTI during the hospital stay (4-6 days).

Group 1 included 296 women who received standard antibiotic

protocol along with a placebo. Group 2 included 302 women who received azithromycin in addition to the standard antibiotic protocol. Both groups were comparable in terms of age, gestational age, BMI (Body Mass Index), antenatal risk

factors including anaemia, HDP (Hypertensive disorders of pregnancy), PROM (Premature rupture of membranes), duration of surgery, and blood loss during surgery [Table 1].

Table 1: Demographic features and characteristics of study population.

Variables	Group 1	Group 2	P value	
Number of women	296	302	Total 598	
Mean age	27.26 ± 4.63	27.49 ± 4.36	0.373	
Mean Gestational age	38.74 ± 1.13	38.71 ± 1.06	0.721	
Number of pregnancies	1. First pregnancy	128	117	0.561
	2. Previous live birth	168	185	
BMI	1. <18	4	6	0.549
	2. 18-22.9	227	236	
	3. 23-25	65	60	
Risk factors	1. HDP	28	32	0.176
	2. Anaemia	52	56	
	3. Hyperglycaemia	39	41	
	4. Hypothyroidism	15	12	
Duration of PROM (in hours)	Sample	110 patients	105 patients	0.944
	< 6	28	29	
	6-12	61	58	
	13-18	49	47	
Indication for CD	1. Foetal distress	98	99	0.912
	2. Nonprogress of labour	102	102	
	3. Failed induction	48	50	
	4. Breech presentation	16	18	
	5. CPD in labour	08	09	
	6. APH	22	22	

Indications were similar in both groups, non-progress of labour and foetal distress being the most common indication in both groups. APH (Antepartum haemorrhage) included both placenta previa and abruption in labour, taken as emergency cases. Other indications included transverse lie in

labour, oligo-hydramnios, and women who were not willing to continue induction.

A total of 27 women developed SSI, giving 4.6% incidence [Table 2].

Table 2: Primary outcome measures

Outcome	Group 1 (296 women)	Group 2 (302 women)	Total (598 women)	P value
SSI	1. Superficial	08	06	0.329
	2. Deep	08	05	
	Total	16	11	
Endometritis	17	05	22 (3.7%)	0.009
UTI	02	05	07 (1.13%)	0.265
Re-admission rates	3	4	07 (1.13%)	1.000

In the SSI group, 16 vs 11 belonged to groups 1 and 2, respectively, though this difference was not statistically significant. Endometritis was more common in Group 1, which received the standard antibiotic protocol (17 women vs 5 women in Group 2; P value 0.009). Risk of UTI and readmission rates were not significant between the groups. All primary outcomes occurred during the hospital stay (4-7 days). Readmission in both groups occurred due to a fever unrelated to the primary outcome.

Of 49 culture swabs, 20 showed bacterial growth (Table 3) and were sensitive to various antibiotics (Table 4). SSI cases

were managed with wound debridement and regular dressing. Superficial SSI required oral antibiotic preparation (Amoxicillin and clavulanic acid). Deep wound infections (13 cases) required systemic antibiotics as per the culture report. Endometritis cases were treated as per the culture reports. Culture-sterile patients were treated with Piperacillin and Tazobactam. All endometritis cases responded to antibiotics and were symptom-free by 2-3 days. Diagnosis of neonatal sepsis was made in 11 babies in group 1 and 9 babies in group 2 (not statistically significant). There were no neonatal deaths due to sepsis in either group.

Table 3: Bacterial culture in SSI and endometritis

Bacteria isolated	Group 1	Group 2
1. Culture positive	13	07
Enterobacter group, E coli	03	02
Staphylococcal (Aureus, epidermidis)	04	03
Acinetobacter baumannii	02	00
Pseudomonas aeruginosa	03	01

Klebsiella	01	01
2. Contaminants	03	04
3. Sterile	17	11

Table 4: Anti-Microbial Agent (AMA) sensitivity pattern

AMA	Group 1	Group 2
Amoxicillin-clavulanic acid	03	02
Linezolid	01	01
Piperacillin-Tazobactam	04	02
Tigecycline	01	00
Gentamycin	01	01
Amikacin	01	00
Levofloxacin	02	01
Total	13	07

DISCUSSION

SSI is a vital parameter to assess the quality of care and reflects the standards of service provision. It is influenced by multiple parameters: a pre-procedure, intra-procedure, and post-procedure bundle of care, as recommended by WHO.^[22,23] CD being a common procedure done worldwide, SSI associated with it carries the risk of maternal sepsis and serious consequences. Clinical trials have shown reduced risk of SSI and endometritis in developed,^[7,14,15] and developing countries,^[13,16] using add on therapy of azithromycin to traditional 1st or second-generation cephalosporin. A systematic review reported decreased rates of SSI with Azithromycin as an add-on therapy,^[20] and reduced endometritis, as Mycoplasma and Ureaplasma are covered by this agent.^[7,8] Hence, a study was undertaken at a public care hospital with a high obstetric load. Emergency CDs were chosen as they carry a high risk of SSI. Groups could be homogenised, as the study centre has an average of 300 women undergoing CD each month. 598 women could be recruited to the study, matched for age, gestational age, BMI, and other obstetric risk factors, including PROM, in both groups.

There is a significant reduction in endometritis risk in the azithromycin group (1.65%) vs 3.7% in group 1 (P value 0.009) in the current study among women undergoing emergency CD. Though there was a numerical decrease in SSI in the azithromycin group (5.4% vs 3.6% in group 1), it was not statistically significant. and a single-centre clinical trial by Jyothi M S et al using intravenous (IV) Azithromycin along with cefazolin for both elective and emergency CD revealed reduced endometritis and SSI risk among 200 women.^[16] Endometritis in the study group was 2% vs 8% in the control group; SSI rate was 3% vs 15% in the control group, with a statistically significant reduction in febrile morbidity in the postoperative period. Tita et al. conducted a multicenter trial with IV Azithromycin, including 2013 women undergoing non-elective CD.^[24] He reported a significant reduction in endometritis, 3.8% Vs 6.1% in the control group. SSI rates also dropped to 2.4% Vs 6.6% in the control group. Corrine Jabs et al. reported no difference in SSI rates with adjunctive azithromycin for CD in centres with low SSI rates.^[18] This study was conducted in two phases, pre- and post-introduction of adjunctive azithromycin prophylaxis for CD involving 2145 women undergoing elective and emergency CD. SSI rate was 3.5% in the pre-

intervention phase Vs 2.9% after the introduction of IV azithromycin, which was not statistically significant. Similarly, additional azithromycin did not show clinical benefit in the study reported by Stephanie Pierce et al in women undergoing all types of CD.^[14] The outcome, including endometritis, SSI, and maternal infection risk, was 4.7% in the pre-implementation phase Vs 5.3% in the post-implementation phase.

In the current study, micro-organisms commonly grown in culture included Staphylococcus and the Enterobacteria group. However, Mycoplasma or Ureaplasma species were not cultured from SSI swabs or vaginal swabs. E. coli and Klebsiella were the most common organisms responsible for SSI, as reported by Jyothi M S et al.^[16] As Azithromycin primarily prevents Ureaplasma infections that lead to postpartum sepsis, it is important to obtain baseline microbiological data on maternal infections following deliveries. It is essential to discuss with the microbiologist whenever there are increased rates of SSI or endometritis cases in maternity centres. Use of additional antibiotic regimes should be based on baseline microbiological data and antibiogram in respective hospital centres, as there is a risk of emergence of antibiotic resistance. Though we had baseline SSI rates, there was a lack of data on endometritis rates and on swab culture analysis. The hospital infection control board should disseminate knowledge on hospital-acquired infections, microbiological cultures, and antibiograms among all healthcare providers, which will reduce maternal sepsis rates.

CONCLUSION

Use of a single dose of oral azithromycin as an extended-spectrum antibiotic for emergency CD reduces the risk of endometritis without a significant reduction in SSI. Large epidemiological datasets with microbiological data are required to understand better the benefits and risks of extended-spectrum antibiotic therapy combined with conventional prophylaxis for CD.

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Conflicts of interest

There are no conflicts of interest.

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