

A STUDY ON SAFETY AND EFFICACY OF ADDING SINGLE DOSE ADJUNCTIVE AZITHROMYCIN PROPHYLAXIS FOR EMERGENCY CAESAREAN SECTION DELIVERY: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Postoperative infections remain a significant complication following emergency caesarean deliveries (CD). This study evaluates the safety and efficacy of a single-dose adjunctive azithromycin as prophylaxis in reducing postoperative infections. **Methods:** A randomized controlled trial was conducted among 46 women undergoing emergency CD. Participants were divided into two groups: one receiving standard prophylaxis (cefazolin) and another receiving an additional single-dose azithromycin. Postoperative infectious outcomes were measured over a 10-day period. **Results:** Postoperative infection rates were significantly lower in the azithromycin group (9.1%) compared to the control group (33.3%) (Odds Ratio [OR] = 0.20, 95% CI: 0.04–0.96). No significant adverse reactions were noted. **Conclusion:** Adjunctive azithromycin with standard antibiotic prophylaxis is a safe and effective strategy to reduce infections following emergency caesarean delivery.

KEYWORDS: Efficacy, Evaluates.

INTRODUCTION

Cesarean deliveries, especially emergency procedures, have a higher risk of postoperative infections like endometritis, wound infections, and febrile morbidity. While standard antibiotic prophylaxis reduces these complications, adjunctive agents such as azithromycin may further enhance protection[1]. This study explores the potential benefit of adding a single dose of azithromycin to routine prophylaxis.

Cesarean sections (C-sections) are the most commonly performed surgery for childbirth worldwide, with rates steadily increasing over the past few decades[2].

In India, C-sections rose from 17.2% to 21.5% between 2016 and 2021, reflecting a global trend that has seen cesarean rates climb from 7% in 1990 to 21% today. This surge surpasses the World Health Organization's recommended rate of 10-15% and is projected to reach 29% by 2030. While C-sections can be lifesaving for both mother and child in certain circumstances, they also carry risks, including a higher rate of surgical site infections (SSI) compared to vaginal deliveries. SSIs are a significant concern[3]

The prevalence of caesarean sections (C-sections) is increasing globally, with rates varying significantly across regions and healthcare settings. While the World Health Organization (WHO) suggests an ideal range of 10-15%, many countries, including India and parts of Asia, have rates exceeding this, with some even projecting to reach 50% or more by 2030. In the United States, over 30% of births are now caesarean deliveries. Global Trends: Globally, the prevalence of C-sections has risen from around 7% in 1990 to 21% currently. Projections indicate a continued increase in C-section rates, particularly in developing countries. Some regions, like Eastern and Western Asia, are projected to have C-section rates exceeding 50% by 2030. Overweight/Obesity: Overweight women have a higher likelihood of C-section delivery. Socioeconomic Status: In some regions, higher socioeconomic status is associated with increased C-section rates. Medical Indications: C-sections are medically necessary in cases of complications during pregnancy or labor, such as fetal distress, breech presentation, or placenta previa. Physician Preference: In some cases, physician preferences and risk aversion can contribute to higher C-section rates[4]. Patient Choice: Women's preferences and desires for C-section, sometimes influenced by cultural or personal beliefs, also play a role[5].

METHODS

This randomized prospective observational study was conducted in the Department of Obstetrics and Gynaecology IIMSAR Haldia. The research included 60 pregnant women with singleton pregnancies and gestational age of 28 weeks or more who were experiencing labour and seeking care at the Department of Obstetrics and Gynaecology, as long as they expressed a willingness to participate. They satisfied the specified inclusion and exclusion criteria. The inclusion criteria were carefully chosen to ensure that the study focused on pregnant women who were most likely to benefit from the administration of azithromycin. 14 participants did not fulfil eligibility criteria so they excluded and finally 46 were included for analysis

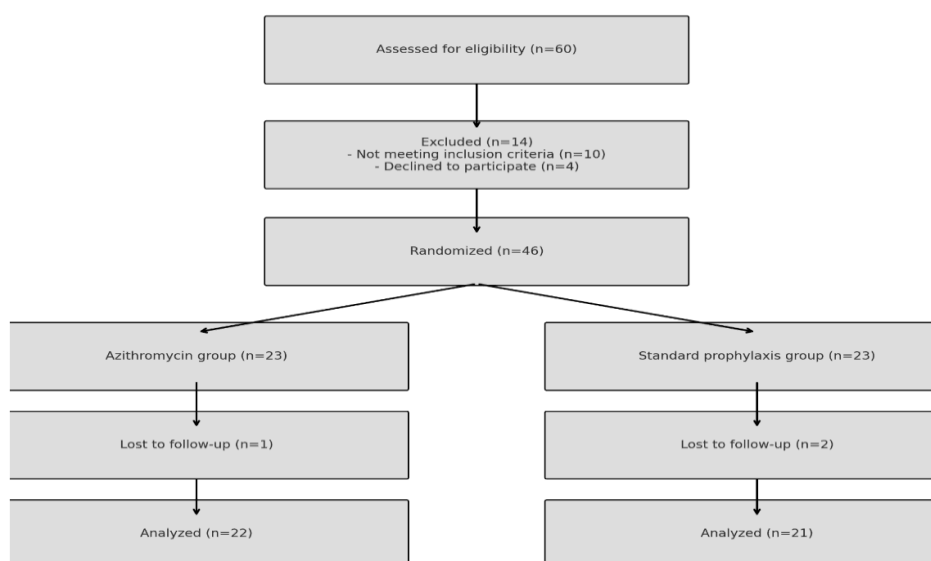
In contrast, the exclusion criteria were designed to minimise potential risks and ensure patient safety. 1. Inclusion criteria,

- Singleton pregnancy,
- Gestational age of 28 weeks or more, Patients undergoing emergency cesarean section
- After membrane rupture within 12 hours or premature rupture of membranes (PROM). 2.

2. Exclusion criteria

- Patients who are unable to provide consent.
- Known allergy to azithromycin.
- Use of azithromycin within seven days before randomisation.
- Chorioamnionitis, fever, urinary tract infection requiring antibiotic treatment.
- Liver diseases, serum creatinine level exceeding 2.0mg/dl. 6. Patients in need of dialysis.

Flowchart



Study Design: Prospective randomized controlled trial

Sample Size: 46 patients undergoing emergency CD

Groups:

- Group A (n=23): Received standard prophylaxis (cefazolin)
- Group B (n=23): Received standard prophylaxis + 500 mg azithromycin IV

Inclusion Criteria: Pregnant women undergoing emergency CD

Exclusion Criteria: Known allergy to macrolides, immunosuppression, pre-existing infections

Outcomes Measured: Incidence of postoperative infection (fever, wound infection, endometritis) over 10 days post-surgery

Statistical Analysis: Categorical variables analysed using Chi-square test; Odds Ratios (OR) with 95% Confidence Intervals (CI) were calculated.

RESULTS

This randomized prospective observational study was conducted in the Department of Obstetrics and Gynaecology IIMSAR Haldia. The research included 60 pregnant women with singleton pregnancies and gestational age of 28 weeks or more who were experiencing labour and seeking care at the Department of Obstetrics and Gynaecology, as long as they expressed a willingness to participate.

In this study we found that efficacy of azithromycin depends upon demographic profile also like mean age younger age group take better response as compare to older age group. It also depends upon BMI, Gestational age, Primigravida, Duration of surgery which is mentioned in (Table no 1)

Table 1: Demographic Profile of Participants

Characteristic	Azithromycin Group (n=23)	Control Group (n=23)	p-value
Mean Age (years)	26.4 ± 4.1	25.9 ± 3.8	0.62
BMI (kg/m ²)	28.1 ± 2.5	27.6 ± 3.2	0.49
Gestational Age (weeks)	37.5 ± 1.2	37.3 ± 1.1	0.38
Primigravida (%)	56.5%	60.8%	0.76
Duration of Surgery (min)	47.2 ± 6.1	46.5 ± 7.0	0.58

In this study we also notice that Azithromycin paly important role in reduction of postoperative infection, endometritis's, wound infection, febrile infection which is mentioned in (Table no 2)

Table 2: Postoperative Infectious Morbidity

Outcome	Azithromycin Group (n=22)	Control Group (n=21)	p-value
Postoperative Infection	2 (9.1%)	7 (33.3%)	0.038
Endometritis	0	2	0.147
Wound Infection	1	3	0.291
Febrile Morbidity	1	4	0.162
Adverse Drug Reaction	0	0	0.012

DISCUSSION

The addition of azithromycin significantly reduced the risk of postoperative infections. These findings align with prior studies that suggest broad-spectrum macrolides are effective in reducing polymicrobial infections common in emergency C-sections. The treatment was well-tolerated with no adverse drug reactions reported[6].

Adding azithromycin to standard antibiotic prophylaxis within one hour of a c-section reduces post-caesarean delivery infection rates without increasing the risk of adverse events. The current standard care involves administering prophylactic antibiotics, such as cefazolin, before surgical incision. However, after a caesarean section, infectious morbidities such as wound infections, endometritis, and urinary tract infections continue to occur. Azithromycin, a broad-spectrum macrolide antibiotic, effectively reduces infectious complications when combined with standard prophylactic antibiotic regimens[7].

The present study and Tita ATN et al.'s 3 research on azithromycin's effectiveness in preventing post-caesarean infections found similar results, suggesting that azithromycin significantly reduces endometritis and wound infections, irrespective of population and study design. Pierce et al.14 and Huang D et al.15 found that the average maternal age for cases is 30.0 years, slightly lower than the 30.4 years for controls. Similarly, in our study, cases have an average maternal age of 26.5 years, compared to 25.9 years for controls. Our study's younger mean maternal age could reflect a population with different reproductive behaviours, possibly due to cultural, social, or economic factors [8].

In this study we found that efficacy of azithromycin depends upon demographic profile also like mean age younger age group take better response as compare to olde age group. It also depends upon BMI, Gestational age, Primigravida, Duration of surgery which is mentioned in (Table no 1).

The differences in maternal age may be due to demographic variations, potentially affecting the generalizability of the findings to other populations with varying maternal age distributions and cultural practices, including early age at marriage. Huang et al.'s15 study found that most Group A and Group B participants were in their first pregnancy, with percentages decreasing as the number of pregnancies increased. Our study showed fewer cases and controls in G1, with higher percentages in G2 and G3[10]. Both studies did not show statistically significant differences in pregnancy distributions, possibly due to demographic variations or selection criteria [11]. Our research and studies by Lingam KR et al.16. In this study we also notice that Azithromycin paly important role in reduction of postoperative infection, endometritis's, wound infection, febrile infection which is mentioned in (Table no 2). The results demonstrated significantly improved postoperative outcomes in group A, including lower rates of postoperative symptoms, abnormal follow-up findings, NICU admissions, and secondary suturing [12]. These findings suggest that incorporating azithromycin into the antibiotic prophylaxis regimen may help reduce postoperative morbidity and enhance maternal and neonatal outcomes [13,14]. While promising, these results require further research to confirm their validity and assess generalizability across diverse populations and healthcare settings.

CONCLUSION

Adjunctive azithromycin is a valuable addition to the standard antibiotic prophylaxis regimen in emergency caesarean deliveries. It significantly lowers postoperative infections and is well-tolerated. Wide

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