ABSTRACT

1. Title: A Randomised, double blinded, controlled trial to compare the efficacy of extended spectrum antibiotic with narrow spectrum antibiotics as prophylaxis in Cesarian delivery in preventing post Cesarian endometritis and surgical site infections.


3. Degree and Subject: M.S, Obstetrics and Gynaecology

4. Word Count: 436

Background: Cesarian delivery (CD) is the most commonly performed surgical procedure worldwide. Infection related complications of CD are common and is potentially life threatening. Administration of prophylactic antibiotic prior to skin incision decreased the post CD infectious morbidity. Despite the prophylactic antibiotic there is a chance of 10-20% of postpartum infections due to different strains of micro-organisms and development of antibiotic resistant bacteria. To overcome this situation, adding the extended spectrum antibiotic along with standard antibiotic would further decrease the incidence of endometritis, wound infection, and therefore, length of hospital stay. There is need for more randomized controlled trials to compare the efficacy of preoperative administration of extended spectrum antibiotic with standard narrow spectrum antibiotic in preventing post CD infectious morbidity.
5. **Objective:** To compare the efficacy of a combination of antibiotics with standard care (intravenous Cefazolin and intravenous Azithromycin vs intravenous Cefazolin and intravenous placebo) administered as prophylaxis for CD in the prevention of infectious morbidity following Cesarian delivery.

6. **Setting:** Tertiary care Hospital in South India.

7. **Methods:** This was a randomised, double blinded, controlled trial, where mothers were randomised to the study protocol once they the decision was made for CD. Each of the randomised woman received two injections prior to skin incision (Inj. cefazolin along with study drug or Inj. Cefazolin with a placebo) according to the randomisation code. After CD, these women were monitored in the ward for evidence of infection or any adverse event the drug might have caused. They were followed up till 42 days post delivery for any infectious morbidity (surgical site infections, urinary tract infection and readmission).

8. **Results:** The total number of women recruited into the study were 635. Of these, 37 women had to be excluded due to following reasons. Three women who delivered vaginally after randomization, 3 women whose drug bottles was broken, and 1 women who was probably allergic to the study drug were excluded from the analysis. In addition, 25 women were lost to follow up and in 5, hospital numbers were not noted and could not be entered into the study. The mean and SD for hospital stay for the mothers were 4.14 in the study group. Women who received extended spectrum antibiotic along with standard narrow spectrum antibiotic prior to
skin incision had significantly less post CD endometritis, when compared with mothers who received standard narrow spectrum antibiotics alone (p >0.009)

5. **Conclusions**: Extended spectrum antibiotic, when used as prophylaxis at CD resulted in significant reduction in postoperative endometritis whereas reduction in surgical site infections, UTI and hospital stay was not statistically significant when compared to narrow spectrum antibiotics.