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Comparative study of antibiotic prophylaxis for elective caesarean section at a tertiary care hospital in Northern Karnataka, India

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Abstract
Background: Women undergoing caesarean section have an increased risk of postoperative infection and infectious morbidity compared with women giving birth vaginally. Infectious morbidity for the mother, consisting primarily of endomyometritis and wound infection remains a leading cause of post-operative complications. Prophylactic antibiotics are expected to work in conjunction with the antiseptic measures taken before and during surgery. Present comparative study was conducted between injection Ceftriaxone single dose versus routine 5 day course of ampicillin and metronidazole in elective caesarean delivery patients at a tertiary care center.
Material and Methods: This comparative, prospective, hospital based study was conducted in the department of Gynaecology and Obstetrics, in patients posted for elective LSCS, BMI < 30, willing to participate in study & follow up for 3 months. Patients were randomly divided in 2 groups each consisted of 100 patients as Group A patients received injection Ceftriaxone 1gm. intravenous stat at the time of induction of anesthesia &Group B - patients received intravenous ampicillin and metronidazole for 1 day followed by oral for next 4 days.
Results: Mean age was 23.9±3.8 years in group A & 23.1±3.4 years in group B. BMI at the time of admission was 28.5±6.7 kg/m² & 29.1±5.9 kg/m² in group A & B respectively. Mean duration of surgery was 44.1±7.1 min in group A & 45.2±5.7 in group B. Average blood loss in both groups was comparable. Mean days of hospitalisation was 4.3±3.7 days & 5.1±2.9 days in group A & B respectively. History of previous laparotomy like LSCS, ectopic surgery, etc. was present in 37 & 31 patients from group A & B respectively. Fever was most common morbidity noted (Group A–5 & Group B-4) followed by urinary tract infection (Group A – 3 & Group B -4), wound infection, endometritis & early neonatal sepsis. Statistical difference between group A & B was non-significant for all morbidities. One patient from each group required resuturing. No mortality was noted in present study.
Conclusion: This study shows single dose antibiotic prophylaxis is as effective as conventional multi dose antibiotic therapy. It is cost effective, antibiotic resistance of microorganisms can be prevented, reduces patient side effects, nursing staff work.

Keywords: prophylactic antibiotic, caesarian delivery, ceftriaxone, ampicillin and metronidazole

Introduction
Over the last few decades a consistent increase has been observed in the rate of ceasarean deliveries is noted worldwide & India. It is often argued that obstetricians also increasingly prefer for surgical birth than a normal birth due to multiple reasons as women not opting for vaginal delivery, medicolegal issues, precious pregnancies, etc.
Women undergoing caesarean section have an increased risk of postoperative infection and infectious morbidity compared with women giving birth vaginally [1]. Caesarean sections have been shown to have nearly five times the risk of postpartum infection as vaginal births (and this is with a policy of antibiotics at caesarean section) and just over 75% occur after hospital discharge [2]. Infectious morbidity for the mother, consisting primarily of endomyometritis and wound infection remains a leading cause of post-operative complications [3].
Prophylactic antibiotic treatment is use of antibiotics before, during, or after a diagnostic, therapeutic, or surgical procedure to prevent infectious complications. A Cochrane review from 2014 compared antibiotic prophylaxis with no prophylaxis and concluded that antibiotic prophylaxis decreased the risk for postpartal wound infection, endometritis and severe infectious

complications by 60–70%. Prophylactic antibiotics are expected to work in conjunction with the antiseptic measures taken before and during surgery.

Around 40%–60% of SSIs can be prevented with the use of proper antibiotic prophylaxis. The most commonly used types of antibiotics are penicillins, cephalosporins, fluoroquinolones, tetracyclines and macrolides, with each class including many drugs [6]. Present comparative study was conducted between injection Ceftriaxone single dose versus routine 5 day course of ampicillin and metronidazole in elective caesarean delivery patients at a tertiary care center.

Material and Methods

This comparative, prospective, hospital based study was conducted in BLDE Universitys Shri B M Patil Medical College and research center Vijayapur, North Karnataka, India., in the department of Gynaecology and Obstetrics from January 2020 to April 2020. Local institutional ethical committee approval was taken.

Inclusion criteria - Patients posted for elective LSCS, BMI < 30, willing to participate in study & follow up for 3 months. The caesarean was considered elective when the procedure was performed in the absence of labor and before rupture of membrane.

Exclusion criteria

- Women who had known or suspected hypersensitivity to cephalosporins
- Any co-existing diseases like diabetes mellitus, hypertension or cardiac problem that will require multi dose antibiotics
- Surgical procedure exceeding more than 90 minutes and if blood loss was more than 1500ml.

Patients received information about objective of present study prior to surgery and a written informed consent was obtained. Baseline assessment including vital signs, general physical, systemic and obstetric examination were performed. Routine blood (CBC, RBS, RFT) and urine analysis & if required urine culture and sensitivity, high vaginal swab culture and sensitivity were carried out.

Patients were randomly divided on alternate number basis, in 2 groups (Group A and Group B) each consisted of 100 patients.

Group A - patients received injection Ceftriaxone 1gm. intravenous stat at the time of induction of anesthesia.

Group B - patients received intravenous ampicillin and metronidazole for 1 day followed by oral for next 4 days.

Temperature monitoring, vital signs, abdominal, perineal examinations was performed daily till 7days. If body temperature was more than 101^0 F on 2 occasions 4 hours or more apart, excluding the night of surgery, it was considered as febrile morbidity and appropriate investigations were performed including urine culture, blood culture, high vaginal swab culture before starting appropriate multi dose antibiotics. Wound was inspected for superficial or deep infection, any pus discharge, surgical site abscess formation, wound dehiscence, vault haematoma and pelvic abscess. At discharge, patients were instructed to contact if they have any signs and symptoms of infection. All patients were followed up to 3 months at monthly intervals. Incidence of postoperative morbidity (febrile morbidity and infectious morbidity such as wound infection, chest infection, UTI, pelvic abscess and dehiscence of scar) was primary outcome. Data was collected in pre-designed proforma & entered in SPSS for descriptive and analytical study. A p value of <0.05 was considered significant.

Results

Patients were randomly divided on alternate number basis, in 2 groups (Group A Ceftriaxone 1gm iv stat and Group B ampicillin and metronidazole for 5 days) each consisted of 100 patients. Mean age was 23.9±3.8 years in group A & 23.1±3.4 years in group B. BMI at the time of admission was 28.5±6.7 kg/m² & 29.1± 5.9 kg/m² in group A & B respectively. Mean duration of surgery was 44.1±7.1 min in group A & 45.2±5.7 in group B. Average blood loss in both groups was comparable. Mean days of hospitalisation was 4.3±3.7 days & 5.1±2.9 days in group A & B respectively. History of previous laparotomy like LSCS, ectopic surgery, etc. was present in 37 & 31 patients from group A & B respectively.

Fever was most common morbidity noted (Group A – 5 & Group B -4) followed by urinary tract infection (Group A – 3 & Group B -4), wound infection, endometritis & early neonatal sepsis. Statistical difference between group A & B was non-significant for all morbidities. One patient from each group required resuturing. No mortality was noted in present study.

Discussion

Most of the estimated 75,000 maternal deaths occurring worldwide yearly as a result of infections are recorded in low-income countries. Although the reported incidence in high-income countries is relatively low (between 0.1 and 0.6 per 1000 births), it is nonetheless an important direct cause of maternal mortality [7, 8].

Post-caesarean section infection is associated with obesity, diabetes, immunosuppressive disorders, chorioamnionitis, rupture of membranes > 18 hours, corticosteroid therapy, staple suture wound closure, fewer prenatal care visits, repeat caesarean section, emergency caesarean section, length of surgery > 60 minutes, a prolonged labour, excessive blood loss during labour, delivery, or surgery, and failure to follow proper steps for wound care after leaving the hospital.

Across the globe, SSIs are associated with increased morbidity and mortality; sequelae include revision surgeries, poor quality of life, prolonged antibiotic treatment and rehabilitation, and associated lost work and productivity. Moreover, SSIs are associated with a substantial economic burden to the healthcare system as a result of increased length of hospital stay and increased risk of readmission [9]. Current strategies aimed at preventing SSIs include improved hygiene, aseptic surgical techniques, carrier screening, decolonization, application of antibiotics to the surgical site prior to wound closure, and intravenous antibiotic prophylaxis [10].

At many institutes, prophylactic antibiotic was being administered after cord clamping, so that it did not reach the foetal circulation. Concerns of masking signs of sepsis in babies, developing resistance to antibiotics and masking organisms in blood culture because of the transplacental transfer of the drug was the main reason for administration of the drug after cord clamping. However, recent studies suggested that, giving the drug prior to skin incision would significantly decrease the incidence of maternal infection without causing harm to the baby [11, 12].

Single dose antibiotic prophylaxis is well-established for abdominal and vaginal hysterectomy and cumulative meta-analysis data indicate the same. Perioperative antimicrobial prophylaxis has been advocated in surgical procedures, but recent guidelines and publications showed that single dose

antibiotic prophylaxis is equally effective in clean, and clean contaminated surgical procedures [13]. Following elective surgery, wound infection in patients who receive perioperative antibiotics (within 3 hours following skin incision) occurs in 1.4% compared to 0.6% in those who receive antibiotics within the 2 hours before skin incision [14].

In present study, there was no significant difference between two groups, so single dose antibiotics is as effective as routine 5 days course. It reduces patient side effects, cost of treatment, staff work, etc. The administration of single dose antibiotic prophylaxis also reduces the load on the staff and decreased the costs, which is a good for low-resource settings and should be adopted if the cost has to be reduced [15].

A study for evaluation of prophylactic antibiotic in Caesarean section by Ansari N *et al*. [16] found fever episode in 4% of cases, Endometritis and wound infection in 2% cases. Mudholkar AS [17] not found any case of endometritis however wound infection episode was 0.93%. Similar findings were noted in present study. Pinto-Lopes R *et al*. [18] in 2017 in his review article included 16 studies, involving 2695 women and no significant difference was observed between single dose and multiple dose antibiotic prophylaxis in the incidence of postpartum infectious morbidity, endometritis, and wound infection. A trend towards lower risk of urinary tract infection was seen with multiple dosing.

Another randomized, non-blinding clinical trial of 500 eligible participants compared IV single dose of gentamicin (3 mg/kg) plus metronidazole (500 mg) 30-60 minutes prior to CS with same regimen prior to the operation but continued for 24 hours. Pre-operative single dose antibiotic prophylaxis for emergency caesarean showed a lower cumulative incidence of surgical-site infection, a reduced staff workload and a minimized medication cost compared to multiple doses till 24 hours [19]. While one meta-analysis, which was based solely on elective cesarean delivery, did not find a risk reduction for any maternal outcome in favor of preoperative in comparison with postoperative antibiotic prophylaxis [20].

With reference to the kind of antibiotic to be used for prophylaxis, systematic review of Cochrane database suggests that both cephalosporins and penicillins represent good choices for prophylaxis in women undergoing CS, although the bacterial resistance, impact on post-discharge maternal and infant infections are not known. More costly extended-spectrum penicillins, second or third generation cephalosporins and combination regimens have not been demonstrated to be more effective [21].

Table 1: Characteristics of patients in two surgical groups

	Group A	Group B
Mean age in years	23.9±3.8	23.1±3.4
BMI in kg/m²	28.5±6.7	29.1± 5.9
Mean duration of surgery (min)	44.1±7.1	45.2±5.7
Mean blood loss (ml.)	635±60	660±70
Mean days of catheterisation	1	1
Mean days of hospitalisation (days)	4.3±3.7	5.1±2.9
History of previous laparotomy	37	31

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Conclusion

This study shows single dose antibiotic prophylaxis is as effective as conventional multi dose antibiotic therapy. It is cost effective, antibiotic resistance of microorganisms can be prevented, reduces patient side effects, nursing staff work. Further knowledge of antibiotic susceptibility and resistant strains is to be considered while choosing antibiotic.

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