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### **Original Research Article**

# To study the effectiveness of prophylactic use of ceftriaxone (single dose) in caesarean section in low risk patients in a tertiary care center, Moradabad, India

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#### **ABSTRACT**

**Background:** There is increasing incidence of caesarean section throughout the world. As caesarean section is associated with infectious complications which increase the rate of morbidity and mortality of mothers. For prevention of infectious complications antibiotics are used but careless use of antibiotics increasing incidence of antibiotic resistance. Many guidelines and studies recommend single dose antibiotic prophylaxis for women undergoing elective or non-elective caesarean section. The aim of this study was to assess the effectiveness of Ceftriaxone as prophylactic antibiotic (single dose) in caesarean section in low risk patients.

**Methods:** A Prospective single blind study was carried out in the department of obstetrics and gynaecology, TMMC and RC Moradabad, a tertiary care center, in all low risk patients underwent for Elective and Emergency Lower segment caesarean section for 1 year from 1<sup>st</sup> June 2015 to May 2016 on 110 patients. Data was collected and analyzed by percentage and proportion.

**Results:** Prevalence of caesarean section was maximum in women of 26-35years age group (52.72%), about 67.27% was emergency LSCS, most common indication of caesarean section was Fetal distress (29.09%), refusal for vaginal delivery after caesarean section (10.90%) was one of the cause for increasing rate of repeat caesarean section, 41.81% women in labour, 72.27% cases were with intact membrane, in 9.09% cases, antibiotic had to change in post-operative period due to urinary tract infection and surgical site infection, most common post-operative complication was superficial surgical site infection with purulent discharge (2.72%). No major life-threatening complication occurred. **Conclusions:** Single dose of Ceftriaxone is effective for prevention of post-caesarean infectious complication.

**Keywords:** Caesarean section, Endometritis, Infectious complications, Preventive antibiotic, Surgical site infection, Urinary tract infection

#### INTRODUCTION

The single most important risk factor for postpartum maternal infection is caesarean section. Caesarean section rate average >20% in developed world and have similar percentage of hospital deliveries in developing countries. Infectious complications following caesarean section

include fever, wound infection, endometritis, bacteraemia, other serious infection (including pelvic abscess, septic shock, necrotizing fasciitis and septic pelvic vein thrombophlebitis) and urinary tract infection. Infectious complications following Caesarian Section are an important and substantial cause of maternal morbidity and are associated with a significant increase in hospital

stay.<sup>1</sup> So post-caesarean section infections cause a significant burden in terms of patient morbidity and cost to health services around the world. Now a day the major public health issue is antibiotic resistance because it leads to infections by multidrug resistant bacteria that causes increase morbidity and increase cost of therapy.

Antibiotic resistance development results mainly from the inappropriate use of antibiotics. Incomplete courses of antibiotic therapies and the unnecessary use of broader spectrum regimens play a role.<sup>2</sup>

Extended antibiotic coverage is still preferred by most of practitioners. Prophylactic antibiotic means to use antibiotics to prevent development of infection and antibiotic treatment means to use antibiotic to resolve the established infection.<sup>3</sup>

The administration of prophylactic antibiotics is not intended to sterilize tissue, but to act as an adjunct to decrease the intra-operative microbial load to a level which can be managed by the host innate and adaptive immune responses. <sup>4-6</sup> The goal of antibiotic therapy is to achieve sufficient tissue levels at the time of microbial contamination.<sup>3</sup>

Ideally, a drug regimen (for prophylaxis) should be:

- Proven effective in well-designed prospective, randomized, double-blind clinical trials,
- Active against the majority of pathogens likely to be involved,
- Attain adequate serum and tissue levels throughout the procedure,
- Not associated with the development of antimicrobial resistance,
- Inexpensive and
- Well-tolerated.

In many respects, penicillin's and cephalosporins meet these criteria.<sup>7</sup>

Currently, the Cochrane database of systemic reviews; ACOG and CDG recommend narrow range 1st generation cephalosporine or ampicillin single dose prophylaxis. As these are equally effective in clean contaminates surgical procedure.<sup>1,8</sup>

The aims and objective of the study was to assess the effectiveness of Ceftriaxone-3<sup>rd</sup> generation cephalosporine (single dose) as prophylactic antibiotic in caesarean section (both elective and Emergency) in low risk patients for prevention of post-operative infections.

We used Ceftriaxone for our study for prophylactic antibiotic as local resistant pattern was resistant to multiple antibiotics including Ampicillin and Azithromycin but showing sensitivity to ceftriaxone, having long half-life, cost effective, safe and effective

against microorganisms likely to be encountered in procedure.<sup>6,7</sup>

#### **METHODS**

The prospective single blind study was conducted in department of Obstetrics and Gynaecology in Teerthankar Mahaveer University and Research Center, Moradabad for a period of 1 year after permission from ethical committee of the institute.

#### Criteria for inclusion

All low risk patients undergoing for Elective or Emergency Lower segment caesarean section.

#### Criteria for exclusion

Patient with

- PROM >6 hour,
- Referred patient from outside,
- Handled by DAI (Quack),
- Severe anemia (<7g/d),
- Prone to infection (Diabetics, Cardiac disease, any infective focus, Immuno-compromise patient,
- Intrauterine manipulation: manual removal of placenta,
- Rupture uterus,
- Prior antibiotics within 2 weeks,
- Allergy to cephalosporin,
- Duration of surgery prolonged >1 hour,
- Blood loss >1 Lt.

A detail history, general examination, obstetrics examination and laboratory investigations like hemogram, urine examination, blood sugar and serology (HIV, HBs AG, HCV) of each patient was done. Consent for participation in study was taken from patients.

Patients in inclusion group received-single dose, 1gm of Inj. Ceftriaxone, 30-minute prior the incision on skin in the surgery after skin sensitivity test, placenta was taken out with control cord traction, uterus was closed in single layer if haemostasis achieved otherwise in two layers, skin closed by Subcuticular non-absorbable suture or mattress suture depending upon subcutaneous fat.

All patients were monitored for vital signs. Temperature charting, per abdominal examination and perineal examination done (for any foul smelling vaginal discharge-Lochia) during hospital stay per day. For surgical wound checkup, dressing was done on 3<sup>rd</sup> post-operative day. Post-operative hemogram and urineroutine and microscopy were done on 3<sup>rd</sup> post-operative day.

#### Patients were followed

 Up to 8days of operation in the hospital. Most of the patient discharged on 4<sup>th</sup> post-operative day if everything was fine and asked to come on 8<sup>th</sup> postoperative day for stitch removal,

- 1week after discharge from hospital,
- After 6weeks of operation.

All patients were informed that having fever, discharge or pain at surgical wound site, foul smelling discharge from vagina, pain in lower abdomen or burning urination visit to hospital and inform concerning doctors.

All patients record form was filled for proper documentation. The outcomes were studied in the form of

- Fever.
- Surgical site/Wound infection,
- Endometritis,
- Urinary tract infection,
- Serious infectious complications (such as bacteremia, septic shock, septic thrombophlebitis, necrotizing fasciitis or death due to infection),
- Any adverse event of treatment
  - -Allergic reaction
  - -Antibiotic associated diarrhea.

#### **RESULTS**

Table 1 showing maternal characteristics in which more than half (n-58), 52.72% women were in 26-35 years age group and most of them, n-44 (40%) were multigravida.

Table 1: Maternal characteristics (n=110).

Age in years	Number	%
18-25	44	40
26-35	58	52.72
36-45	8	7.27
Parity		
$G_1$	34	31
$G_2$	32	29.09
$G_3$	44	40

As shown in Table 2, out of 110 patients, 74 patients (67.27%) underwent emergency LSCS and rest were planned/elective LSCS.

Table 2: Type of lower segment caesarean section (LSCS), (n-110).

Type of LSCS	Number	%
Elective LSCS	36	32.72
Emergency LSCS	74	67.27

Most of LSCS was done for Fetal Distress, n-32 (29.09%), followed by repeat caesarean section with scar tenderness (10.90%) and refusal of VBAC/TOLAC (Vaginal delivery after caesarean section/trial of labour after caesarean section (10.90%), last indication pointing out one of the cause of increasing rate of repeat caesarean section e.g.-refusal of VBAC/TOLAC (Table 3).

Table 3: Indications for LSCS, (n=110).

Indications	Number	%
Previous 2LSCS + Scar tenderness at 36 weeks POG	12	10.90
Refusing for VBAC/TOLAC	12	10.90
Contracted pelvis	4	3.63
Failed induction of labour (post-dated pregnancy)	8	7.27
Fetal distress	32	29.09
Abnormal presentation in labour (transverse lie, breech)	8	7.27
Elderly primigravida at 37 weeks POG with h/o myomectomy	2	1.81
Previous LSC		
With scar tenderness	6	5.45
With twin pregnancy	2	1.81
With trans. Lie	2	1.81
With breech	4	3.63
Cephalo pelvic disproportion (CPD)	8	7.27
Oligohydraamnios + dearrange colour doppler at 38weeks of POG in primigravida with h/o infertility	4	3.63
Previous LSCS with short IP (inter pregnancy) interval	6	5.45

As shown in Table 4, out of 110 patients, 46 (41.81%) were in active labour, in 80 patients (72.27%) membrane was intact. In about 9.09% (n-10) cases antibiotic was changed mainly due to Surgical site infection (SSI) and urinary tract infection confirmed by culture and sensitivity test of Pus/discharge and urine respectively.

Most common post-operative complication was surgical site infection and urinary tract infection. Febrile morbidity seen in 1.81% patients. No major life-threatening complications occurred, there was no any case showed side effect of antibiotics, all well tolerated (Table 5).

Table 4: Conditions of patients in inclusion group, (n-110) pt.-patient.

Conditions of patients	Number	%
PT in active labour	46	41.81
Status of membrane (n-110)		
Intact	80	72.27
Rupture	30	27.27
No. of point in which antibiotic changed	10	9.09
Reason for change of antibiotics		
UTI	5	4.54
SSI	5	4.54

Table 5: Outcomes of the study in inclusion group, (n=110).

Outcome	Number	%
Pyrexia	2	1.81
Superficial Incisinal SSI with		
Induration + erythema	0	0
Purulent discharge	3	2.72
Serosangunous discharge	2	1.81
Deep incisinal SSI	0	0
Organ/space SSI	0	0
Endometritis	0	0
Urinary tract infection	5	4.54
Serious infectious complication		
(such as bacteraemia, septic shock, septic thrombophlebitis, necrotizing fasciitis or death due to infection)	0	0
Any adverse event of treatment		
Allergic reaction	0	0
Antibiotic associated diarrhoea		

#### **DISCUSSION**

There is increasing incidence of Caesarean section in both developed and developing countries. There are 5-20% greater risks for infection in women undergoing caesarean section (C.S.) than vaginal delivery.<sup>1</sup>

Risk factors associated with increased risk of infections among women having C.S.-Em.LSCS, Labour and its duration, ruptured membrane and its duration of rupture, the socio economic conditions of the women, no. of prenatal visits, method and no. of vaginal examination during labour and internal fetal monitoring, UTI, Anemia, blood loss during delivery, obesity, diabetes ,general anaesthesia, the skill of the operator and operative technique.<sup>1</sup>

Many studies recommend prophylactic antibiotics for C.S. to prevent post-operative complications. According to ACOG guidelines-a narrow spectrum 1<sup>st</sup> generation cephalosporin (Cefazolin) over Ampicillin as the regimen of choice because increasing microbial resistance to the latter generally after cord clamping.<sup>9</sup> In Cochrane guideline both Ampicillin and 1<sup>st</sup> generation

cephalosporin is good for prophylactic antibiotics, SOGC guideline recommendations are-1.<sup>7,10</sup> All women undergoing elective or emergency Caesarean section should receive antibiotic prophylaxis (I-A) 2.

The choice of antibiotic for Caesarean section should be a single dose of a first-generation cephalosporin. If the patient has a penicillin allergy, clindamycin or erythromycin can be used (I-A) 3. The timing of prophylactic antibiotics for Caesarean section should be 15-60minutes prior to skin incision. No additional doses are recommended (I-A) 4. If an open abdominal procedure is lengthy (>3hours) or estimated blood loss is greater than 1500ml, an additional dose of the prophylactic antibiotic may be given 3-4hours after the initial dose (III-L).

Extended spectrum regimens (e.g.-a regimen involving the use of both the standard narrow spectrum antibiotics in addition to a second antibiotic of a different class e.g. azithromycin, gentamycin, metronidazole) are significantly more effective in reducing post caesarean infections (by 30-60%) and shortening of hospital stay (and cost) than narrow spectrum agent along. 11-14

A recent cohort study confirmed a corresponding drop in rates of post caesarean endometritis with increasing use of azithromycin based Extended spectrum prophylaxis.<sup>15</sup> However, antibiotic to be chosen depends on antimicrobial susceptibility patterns in the local hospitals, in our hospital, microbes are multidrug resistant including Ampicillin and Azythromycine.<sup>16</sup>

Following antibiotic prophylaxis febrile morbidity in our study was 1.81% without infection. However, in Bagratee found prevalence of febrile morbidity 8% in his randomized controlled trial of prophylactic antibiotic in elective C.S. Sadique et al found febrile morbidity 30% without infection. 17,18 Mudholkar AS et al found febrile morbidity in 0.3% without infection or wound erythema in their study. 19 A study for evaluation of prophylactic antibiotic in Caesarean section by Ansari N et al found fever episode in 4% of cases, Endometritis and wound infection in 2% cases. 20 In the study of short term antibiotic prophylaxis by Shetty J et al found 1% incidence of wound infection and endometritis. 16

Mudholkar AS not found any case of endometritis however wound infection episode was 0.93% and case failure was 7%.<sup>19</sup> In present study superficial incisional surgical site infection (SSI) was found in (4.54%). No deep Incisional SSI and organ/space SSI found, and no cases of endometritis found, in 9.09% cases antibiotic had to change. Incidence of UTI was 4.54% in present study, Ansari with al found 3% cases with UTI in their study.<sup>21</sup> No cases of pelvic cellulitis, bacteraemia, Septic shock, septic thrombophlebitis, necrotizing fasciitis or death due to infection found. The success of prophylactic antibiotic during C.S. not only depends on antibiotics but also must

strictly follow the guideline for prevention of surgical site infection by CDC. <sup>22</sup>

#### **CONCLUSION**

As there was no significant infectious morbidity in our study, we found that Ceftriaxone (single dose) is effective in prevention of post Caesarean infectious complications. Being single dose, it is cost effective as various study of comparison between single Vs multiple dose of Ceftrixone for prophylaxis of post caesarean section infection found no statistical significant different in efficacy of single dose. Due to single dose less side effect, less chance of bacterial resistance, well tolerable, it is decided in our department as a policy that Ceftriaxone should use as prophylactic antibiotic in patients undergoing for lower segment caesarean section (in low risk cases).

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Institutional Ethics Committee

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