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A revisit to practice of antibiotic prophylaxis in caesarean section

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Abstract
Background: Women undergoing cesarean delivery are 5-20 fold greater risk of infection than women undergoing vaginal delivery. Infectious complications after cesarean delivery are an important cause of maternal morbidity, increase in hospital stay and cost of treatment. The use of antibiotic prophylaxis for cesarean section can reduce the incidence of postoperative infectious morbidity.
Material and Methods: This was a prospective case control study involving 140 women undergoing cesarean delivery for various indications, who were divided into two groups, Group A and B with 70 patients in each which was conducted at Maharajah's Institute Of Medical sciences, vizianagaram, Andhra Pradesh for duration of 1 year. Group A received antibiotic prophylaxis of ceftriaxone 1gm IV 30 minutes before skin incision and another dose at 24 hours, Group B received Ceftriaxone 1gm IV 30 minutes before cesarean section, followed by Ceftriaxone 1gm+ Metronidazole 100ml IV 8th hourly for 48 hours followed by oral cefixime till suture removal. Postoperatively, both groups of patients were followed up for febrile and infectious morbidity and neonatal outcome was followed during hospital stay for infectious morbidity.
Results: Total of 140 patients were analysed in both groups of 70 patients in each. Baseline characteristics like age, parity, gestational age, socioeconomic status, were similar in both groups. Postoperative morbidities like Febrile morbidity and surgical site infection (p=0.8) did not differ significantly. The neonatal infectious morbidity in both groups (p=0.66) and recovery was uneventful.
Conclusion: Double dose of single antibiotic regimen was equally effective as compared to multiple doses of multiple drugs and extended antibiotic therapy. We can cut down on antibiotic misuse among parturients which has implications in global emergence of antibiotic resistant bacteria and epigenetic and allergic diseases in the offspring.

Keywords: Antibiotic prophylaxis, cesarean delivery, infectious morbidity, neonatal outcome, antibiotic resistance

1. Introduction
Individual choice and self-directed practice of antibiotic use makes it difficult to choose what to follow. Unscrupulous use of them has emerged as a brain storming on Global and National level Action Plan on Anti-Microbial Resistance, (GAP-AMR and NAP-AMR).
Cesarean delivery poses at 5-20 fold greater risk of infection than vaginal delivery [1]. Infections in obstetrics account for 11% of maternal mortality, and also the morbidity adds to hospital stay and cost of treatment [2]. Preoperative prophylactic antibiotics are intended to reduce the size of the bacterial inoculum and to change the characteristics at the operative site during the brief time that host defenses are impaired by the trauma of surgery [3].
The infectious complications range from mild to severe and could sometimes be fatal, which include fever, surgical site infection (SSI), UTI, pneumonia, endometritis, pelvic abscess, septic pelvic vein thrombosis, sepsis and septic shock [4]. Commonly, the infections are of polymicrobial origin, which includes E Coli, Staphylococcus aureus, Coagulase negative Staphylococci, Group B Streptococcus, other gram negative aerobic rods, Enterococcus faecalis, Gardnerellavaginalis, anaerobes and genital mycoplasma [5, 6].
Standard guidelines including those by WHO, ACOG, ICMR and NICE, recommend single dose pre-incision antibiotic prophylaxis in uncomplicated caesarean deliveries, most also recommend cephalosporin's as the preferred choice [7, 8, 9, 10]. The efficacy of single dose of single antibiotic prophylaxis is as effective as prolonged use of combination of antibiotics [11, 12].
We aimed to determine the efficacy & safety of double-dose compared with multiple-dose antibiotic prophylaxis to prevent post-caesarean section maternal and neonatal morbidity.

2. Materials and Methods

This was a prospective case control study involving 140 women undergoing cesarean delivery for various indications, who were divided into two groups, Group A (cases) and Group B (controls) with 70 patients in each which was conducted at Maharajah's Institute Of Medical sciences, vizianagaram, AP, over a duration of 1 year.

Group A received antibiotic prophylaxis of ceftriaxone 1gm IV 30 minutes before skin incision and another dose at 24 hours

Group B received Ceftriaxone 1gm IV 30 minutes before cesarean section, followed by Ceftriaxone 1gm+ Metronidazole 100ml IV 8th hourly for 48 hours followed by oral cefixime till suture removal.

Inclusion criteria:

Pregnant women undergoing c section for medical, obstetric and at maternal request were included.

Exclusion criteria:

- Prolonged PROM (> 12hrs).
- Presence of chorioamniotis.
- Intrauterine fetal death.

Outcome measures

The primary outcome of the study was to evaluate maternal and neonatal morbidity between the groups.

All women with an indication for cesarean section were assessed for eligibility and were included after informed consent. The following demographics were obtained and assessed: age, parity, gestational age, BMI, preoperative hemoglobin, indication for cesarean section. Both the groups were followed up for maternal complications like febrile morbidity, infections like SSI, urinary, respiratory and endometritis.

Febrile morbidity was defined as temperature above 38ºC at least 4 hours apart on two or more occasions, excluding the first 24hrs after delivery.

Surgical site infection (SSI) classification as per Centre for Disease Control (CDC) was used in the study [13]

Superficial incisional SSI- skin and subcutaneous tissue is involved, treated by antibiotic and dressing.

Deep incisional SSI- Deep soft tissue (fascial and muscle layers) involved or occurrence of wound dehiscence managed by secondary suturing.

Organ/space SSI-any part of anatomy (organs or spaces) other than the incision, managed by exploration and closing.

Urinary tract infection - 5 pus cells /HPF or positive urine culture ± dysuria and fever.

Endometritis: Marked uterine tenderness and/or malodorous vaginal discharge with fever.

The neonatal outcome was followed during hospital stay for infectious morbidity, neonatal jaundice, duration of NICU stay, Phototherapy and antibiotic course.

Neonatal sepsis: Neonates who were symptomatic underwent sepsis screen and subsquently managed.

With all aseptic conditions, mothers were prepared preoperatively. Spinal anesthesia was preferred. On 2nd postoperative day, maternal total leukocyte count& hemoglobin level were checked and 3rd postoperatively, dressing was changed for group A mothers and Evidence of any postoperative complications were looked for, investigated and were compared between the groups.

Statistical analysis

Data in the two groups were compared, Statistical analysis was done using SPSS Version 22. Descriptive statistics were represented with percentages, mean and standard deviation. Chi square test was used for significance where $p = < 0.05$ was considered statistically significant along with odds ratio and 95% confidence intervals.

3. Results

A total of 140 cases of cesarean delivery were recruited for the study.

There was no statistical difference in baseline demographic data like age, parity, socioeconomic status, preoperative hemoglobin between the two groups.

The mean body mass index for group A and group B were 25.96±4.05 and 23.9±4.14 respectively and there was statistical significance ($p < 0.05$) as shown in table 1.

Maternal comorbidities were compared between both groups and was found to be similar.

The mean maternal hospital stay for group A and group B were 5.56±0.73 and 8.43±1.55 and respectively and there was statistical significance ($p < 0.05$) as shown in table 1.

Elective and emergency cesarean sections were compared in two groups and found to be similar as shown in table 2.

The most common indication of elective CS was previous CS in group A and B which was 63.3% and 54% respectively and of emergency section was fetal distress which was 32.4% in group A and 33.3% in group B as shown in table 3.

Table 1: Shows comparison of demographic data in group A and B.

S. No	Characteristics	Group A Mean (N = 70)	Group B Mean (N = 70)	T Test	P Value (< 0.05)
1.	Age	24.9±4.15	25.3±3.90	0.591188	0.27
2.	Parity	1.72±0.78	1.86±0.88	0.996229	0.16
3.	Hemoglobin	11.83±1.55	11.86±1.73	0.109076	0.45
4.	BMI	25.96±4.05	23.92±4.14	-3.023928	0.0014
5.	Gestational Age AT CS	38.2±1.67	38.07±1.53	-0.479262	0.316
6.	Mother Hospital Stay	5.56±0.73	8.43±1.55	14.0151	0

Table 2: Shows type of CS in both the groups

Type of CS	Group A = 70	Group B = 70	P Value
Elective	33(47.1%)	37(52.8%)	1.00
Emergency	37(52.8%)	33(47.1%)	

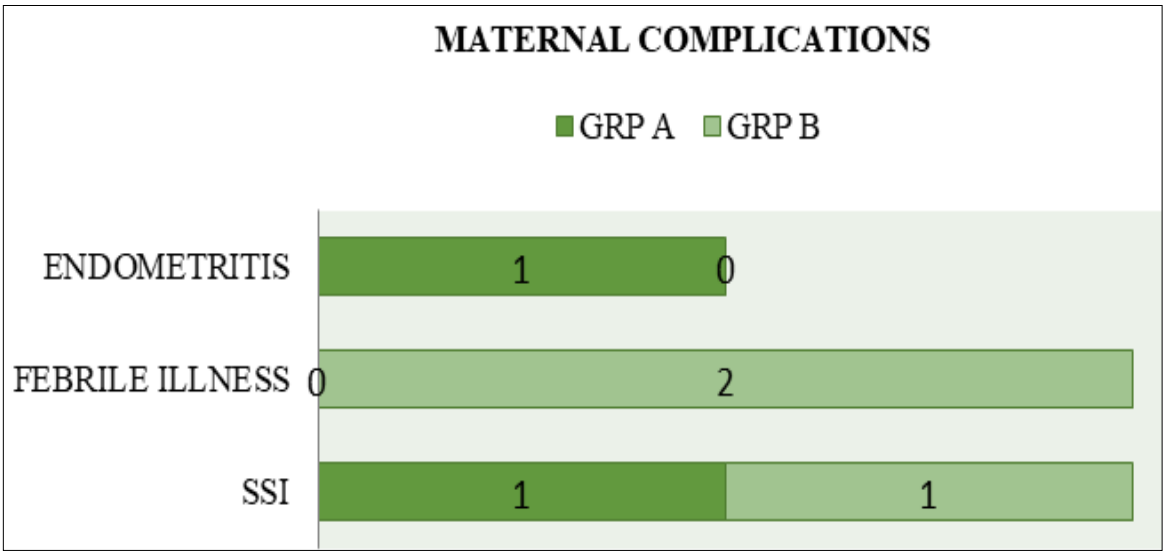
Table 3: Shows indications of LSCS in both the groups

Indication	Group A = 70		Group B = 70	
	Elective	Emergency	Elective	Emergency
Previous CS	21(63.3%)	6(16.2%)	20(54%)	9(27.2%)
Fetal Distress	4(12.1%)	12(32.4%)	0	11(33.3%)
Malpresentation	1(3%)	1(2.7%)	1(2.7%)	2(6%)
Twins	1(3%)	0	1(2.7%)	0
CPD	4(12.1%)	3(8.1%)	10(27%)	0
FGR	0	3(8.1%)	1(2.7%)	1(3%)
OLIGO	0	10(27%)	1(2.7%)	7(21.2%)
PIH	1(3%)	2(6.4%)	1(2.7%)	3(9%)
GDM	1(3%)	0	2(5.4%)	3(9%)

CS- cesarean section, CPD - Cephalo pelvic disproportion, FGR- Fetal growth restriction, Oligo-Oligohydramnios, PIH- Pregnancy induced hypertension, GDM- Gestational diabetes mellitus.

Maternal complications

The postoperative complications like surgical site infection (SSI) was seen in 1.4% (n=1) in group A and 1.4% (n=1) in group B (p=0.8).Febrile morbidity was seen in 2.8% (n=2) in group B and none in group A.One case in Group A had endometritis, she was TORCH IgG positive and developed malodorous lochia on day 5 and her recovery was uneventful. Overall, there was no statistical significance in postoperative complications in both the groups as shown in figure 1.



SSI: Surgical site infection.

Fig 1: Shows postoperative maternal complications in both groups.

Neonatal characteristics

The neonate course in the hospital was recorded like birth weight, any phototherapy days and NICU stay. There was a statistical significance in NICU stay between the group, where group A and group B had mean NICU stay of 0.55±0.79 and 1.22±1.92 respectively and showed p=0.0008 as shown in table 4.

Table 4: Shows neonatal characteristics between the groups

S. No	Characteristics	Group A Mean=71	Group B Mean=71	T Test	P Value (< 0.05)
1.	Birth Weight	3.22±2.66	2.8±0.47	-1.340120	0.09
2.	NICU Stay	0.55±0.79	1.22±1.92	2.394422	0.0008
3.	Phototherapy Days	0.77±0.77	0.76±1.07	2.512350	0.006

Neonatal complications

The neonatal infectious morbidity in group A patients was 2.8% compared to 4% in group B (p=0.66) With average duration of 6 days of NICU stay in group A and 10 days in group B recovery was uneventful. The antibiotic course in neonates in group A was 5 days and group B was 7 days which showed no statistical difference between them as shown in table 5.

Table 5: Shows outcome in sick neonates

Neonatal Outcome	Group A (N=2)	Group B (N=3)	Overall Percentage	P Value	ODDS Ratio	CI (95%)
Neonatal Sepsis	2(2.8%)	3(4%)	5(3.5%)	0.6511	1.5221	0.2465-9.3968
Days of antibiotic use	5	7	-	-	-	-
NICU Stay	6	10	-	-	-	-

4. Discussion

This study involved 140 women with 70 in each group of mothers and 142 neonates, 71 neonates in each group.

Demographic data

Both groups were similar in terms of demographics and operative characteristics which was similar to studies by Igwemadu *et al*. [14], Bhattachan *et al*.` [15] and Pooja *et al*. [16]
Though Group A mothers had high BMI compared to group B mothers, there was better wound healing in group A mothers.
Maternal comorbidities like anemia, hypo/hyperthyroidism were similar in both the groups and didn't have much impact on complications.

C Section

The majority of CS performed during our study period in group A was emergency c section (52.8%) and group B was elective (52.8%). Similar results were obtained by Igwemadu *et al.* [14] where most were elective CS -59.2% for single dose arm and 53.7% for multiple dose arm. Bhattachan *et al.* [15] found elective CS and emergency CS were 37% and 63% respectively.
Elective CS was done in cases with an indication as they have sterile operating field. The most common indication for CS was previous cesarean section.

Maternal complications

SSI

The incidence of wound infection following cesarean delivery ranges from 3% to 15% with an average of 6% [17], it prolongs the hospital stay, increases cost, and work load. In our study only one case (1.4%) in each group A and group B had wound infection. This finding is comparable to Bhattachan *et al.* [15] and Pooja *et al*. [16] where 1% and 0%, 1.9% and 2.5% in single and multiple doses respectively.

Febrile morbidity

In our study, two cases (2.8%) of group B developed postoperative febrile illness. None of the cases had any signs and symptoms of underlying focal or systemic illness. These findings were comparable to the study of Bhattachan *et al.* [15] and Pooja *et al*. [16] which 2% and 6%, 1.9% and 4.9% in single and multiple doses respectively.

Duration of hospital stay

The mean maternal hospital stay for group A and group B were 5.56.±0.73 and 8.43±1.55 and respectively and there was statistical significance ($p < 0.05$).
As most of them were from low SES and poor environment, they opted to stay in the hospital.

Neonatal complications

The neonatal infectious morbidity in group A patients was 2.8% compared to 4% in group B ($p = 0.66$) With average duration of 6 days of NICU stay in group A and 10 days in group B recovery was uneventful. Mean NICU stay was 0.55±0.79 and 1.22±1.92 in group A and group B respectively which was statistically significant ($p < 0.05$). The antibiotic course in neonates in group A was 5 days and group B was 7 days which showed no statistical difference between them.
It has been suggested that exposure to antibiotics during fetal/neonatal life affects the development of allergic diseases via their adverse and possible long term effect on gut micro biota of both mother and child as well as the vaginal micro biota of the mother. Antibiotic use may delay and interfere with the early colonization of the child's gut micro biota.

Treatment cost

The cost related to antibiotic treatment in single antibiotic double dose regimen with ancillary medications is INR 300 and that in multiple antibiotic regimen is INR 800. Apart from this tangible saving on expenditure, the intangible gain on man hour from nursing care for repeated drug administration and patient satisfaction on early discharge are the areas to consider. This similar result was found in study by Pooja P *et al*. [16] where cost related to single antibiotic, single dose regimen is INR 70 and that in multiple dose regimen is INR 1100.

5. Conclusion

Demographically matched cases and controls were compared with short and long antibiotic prophylaxis and found to have similar outcomes with fivefold cost benefit, shortened hospital stay with lesser health care attention among the single antibiotic regimen group. We can cut down on antibiotic misuse among the parturient which has implications in global emergence of antibiotic resistant bacteria and epigenetic and allergic diseases in the offspring.

6. Conflict Of Interest: None to declare.

7. Ethical Issues: None

8. Source of funding: None

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