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Original Research Article

Effectiveness of single versus multiple doses of antibiotics in elective cesarean section for prevention of post operative morbidity

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ABSTRACT

Background: Caesarean section is one of the commonest major abdominal surgeries worldwide given to its increasing rate. The most common post-operative complication following caesarean section is considered as the infective morbidity. Many studies have shown a clear advantage of antibiotic prophylaxis in the reduction of postoperative infective morbidity. However, indiscriminate use of antibiotics is still being continued in many centres. This study was aimed at comparing the efficacy of single versus multiple doses of antibiotics in preventing postoperative morbidity following Elective caesarean section.
Methods: This was a prospective comparative study that included 200 patients undergoing elective caesarean section at SNR District Hospital, Kolar, during the study period. These patients were divided into two groups, group 1 received single dose of Inj ceftriaxone 2gm I/V and group 2 received a single dose of Inj ceftriaxone 1 gm I/V within 30-60 mins of commencement of surgery followed by Inj ceftriaxone 1gm I/V BID for 5 days post-operatively. Patients were followed up prospectively for the development of infective morbidity in the form of surgical site infections.
Results: Mean age, mean haemoglobin levels, and duration of surgery were comparable in patients with SSI in both groups. The incidence of surgical site infection was found to be 10% in the patients who received single dose antibiotic prophylaxis which was comparable with 9.5% in multiple dose group.
Conclusions: Single-dose antibiotic prophylaxis is as effective as multiple-dose antibiotic prophylaxis in elective caesarean section in preventing post operative infective morbidity.

Keywords: Antibiotic prophylaxis, Caesarean section, Ceftriaxone

INTRODUCTION

Caesarean section has classically been defined as an operative procedure performed for the delivery of the fetus with placenta and membranes through a surgical incision made on the abdominal wall and an intact uterine wall after the period of viability.[1] The rates of caesarean section vary widely because of differing perceptions by healthcare providers as well as by pregnant women of its benefits and risks.[2]

Complications following caesarean section include post-operative fever, endometritis, wound infection (surgical site infection), mastitis, urinary tract infection and also major complications in the form of haemorrhage, injury to adjacent organs, pelvic abscess, septic shock, thrombosis/embolism, disseminated intravascular coagulation, need for blood transfusion and thrombophlebitis which compose majority of the complications of which surgical site infection (SSI) is the commonest complication in developing countries.[3]

Caesarean section is a major risk factor for postpartum infection, with a possible 5-20 fold increase in infection rates compared to a vaginal delivery.[4] The incidence of post-caesarean infection varies widely worldwide-ranging from 2.5-20.5%.[5]

Infectious complications that occur after caesarean delivery are an important cause of maternal morbidity and mortality, especially in low-resource settings. Known risk factors for post-caesarean infection include anemia, obesity, immunocompromised states, emergency delivery, low socio-economic status, prolonged labor and ruptured membranes, obstructed labor, inadequate skills or technique of the surgeon, prolonged surgery and excessive blood loss.[6] With the increase in caesarean deliveries worldwide, reduction in postpartum infectious morbidity can be achieved by use of prophylactic antibiotics.

International evidence-based guidelines recommend the pre-operative administration of prophylactic antibiotics 30-60 minutes prior to incision for all women undergoing caesarean section.[7] Single-dose therapy reduces the costs, potential toxicity, and the risk of colonization with resistant organisms and also the unwanted exposure of the new-born to excessive dose of antbiotics.[2]

While the global estimates of surgical site infection have varied from 0.5% to 15%, studies in India have consistently shown higher rates ranging from 23% to 38%.[6] This study will help us to know the effectiveness of single dose over multiple dose antibiotics in prevention of post-operative infections thereby reducing the post-operative morbidity in women undergoing caesarean section and also help us in postulating antibiotic protocols for prevention of post caesarean infections.

METHODS

This was a prospective comparative study conducted on women undergoing elective caesarean section at the SNR District Hospital, Kolar between July 2022 to June 2023 who fulfilled the following inclusion and exclusion criteria. Total sample size was 200 subjects.

Inclusion criteria

All pregnant women between the age group 19 -39 years, having completed 37 weeks of gestation posted for elective caesarean section were included in the study

Exclusion criteria

Women with known or suspected hypersensitivity to cephalosporins and patients with current evidence of infection in the form of fever, foul smelling discharge per vaginal discharge, raised total leucocyte count >10000/cumm or any evidence of chorioamnionitis were excluded. Also patients with immunocompromised status and those with medical illness such as diabetes mellitus, severe anemia (Hb<7g/dl) and morbid obesity (BMI >35) or women with PROM > 6 hrs or in labour for >6 hrs and those undergoing emergency caesarean section, with multiple gestation and previous LSCS were excluded from the study.

After obtaining informed consent from the selected patients, the patients were divided randomly into 2 groups.

Group 1 (SD): 100 women received single dose of Inj. ceftriaxone 2 gm IV within 60 mins before skin incision, no further IV or oral antibiotics were given.

Group 2 (MD): 100 women received Inj. ceftriaxone 1 gm IV within 60 mins before skin incision followed by antibiotics as per the regular practice of our hospital- Inj. ceftriaxone 1 gm IV BD 12th hourly for 5 days postoperatively.

These patients underwent regular pre operative evaluation, along with antenatal fetal surveillance. The patients were followed up postoperatively with regular monitoring of vitals and signs of infection such as fever, rise in total leucocyte count, wound discharge and wound dehiscence. Wound inspection carried out on post operative day 3, 5 and 7. Suture removal done on day 7. As SSI is considered as the commonest cause of infective morbidity in post caesarean cases, in our study we have included SSI as the major infective morbidity. In case the patient reported back to the hospital within 30 days of post operative period with complaints of any discharge from the surgical site or gaping of the wound, it was considered as SSI and treated accordingly. The patients who developed SSI were treated accordingly with appropriate antibiotics after culture and sensitivity, with daily dressings, and when needed re suturing was carried on.

Statistical analysis

Data obtained was coded and entered into the Microsoft Excel Spreadsheet. The data was analyzed using statistical software SPSS v21.0. The categorical data was expressed in terms of frequencies and percentages while continuous data was expressed as mean ± standard deviation (SD). The two groups were compared using chi-square test for categorical data and independent sample t ‘test was used to compare the means of continuous parameters. A 'p' value of less than or equal to 0.05 was considered to be statistically significant.

RESULTS

A total of 200 subjects were counselled and included in this prospective study to study know the effectiveness of single versus multiple dose antibiotic prophylaxis in patients undergoing elective caesarean section at SNR District Hospital, Kolar where group 1(n=100) received single dose of Inj. ceftriaxone (SD) and group 2(n=100) received multiple dose (MD) of Inj. ceftriaxone as per regular protocol of the hospital.

Age

Out of 100 patients in group SD, 25% patients belonged to 19-22 years, 44% patients belonged to 23-26 years, 23% patients belonged to 27-30 years and 8% patients belonged

to 31-36 years, respectively. Whereas in group MD (100 patients), 28% patients belonged to the age group of 19-22 years and 32% patients belonged to 23-26 years, 26% belonged to 27-30 years and 14% patients belonged to 31-36 years. Mean age of subjects in the study was 25.38±4.04 years (Table 1).

Table 1: Age wise distribution of the study subjects.

Age group (in years)	Single dose (%)	Multiple dose (%)	Total	Percentage
19-22	25	28	53	26.5
23-26	44	32	76	38.0
27-30	23	26	49	24.5
31-36	8	14	22	11.0
Total	100 (100)	100 (100)	200	100

Socio-economic status

With regard to socioeconomic status, in the SD group, majority (81%) belonged to the lower middle class, 12% belonged to lower class and 6% belonged to upper lower class and only 1% to upper middle class. Among the MD group, majority (81%) belonged to lower middle class followed by lower class which comprised of 13%, upper lower class of 3% and upper middle class comprised of 3% respectively (Table 2).

Table 2: Socio economic status of study subjects (SES).

SES	Single dose (%)	Multiple dose (%)	Total	Percentage
Upper middle class	1	3	4	2
Lower middle class	81	81	162	81
Upper lower class	6	3	9	4.5
Lower class	12	13	25	12.5
Total	100 (100)	100 (100)	200	100

Obstetric score

It is observed in the study that, in SD group majority (62%) of patients were primigravida, 26% were second gravidas, 11% were third gravidas and only 1% were fourth gravidas. In the MD group, majority (59%) of patients were primigravida, 28% were second gravidas, 11% were third gravidas and 2% fourth gravida.

Body mass index

In the study, it was noted that majority 117 (58.5%) of the patients were in the category of normal body mass index. In the SD group, 57% belonged to normal BMI, 36% were of overweight category and only 7% belonged to the obese BMI group of Indian BMI classification. Among the MD group, 60% belonged to the normal weight group, 37% to overweight category and only 3% belonged to the obese BMI group.

Indication for caesarean section

Among the SD group, most common indication for caesarean section was cephalopelvic disproportion which was around 45%, followed by oligohydramnios 16%, malpresentations 6%, meconium-stained amniotic fluid 8%, caesarean delivery on maternal request 8%, pre-eclampsia 7%, short stature 4% and macrosomia 3%.

In the MD group, common indication was cephalopelvic disproportion which constituted 41%, oligoamnios were around 19%, macrosomia 8%, malpresentations 8%, meconium-stained amniotic fluid around 11%, caesarean delivery on maternal request were 5%, bad obstetric history was 4%.

Pre-operative haemoglobin

In group SD, 85 patients had Hb between 10-12 gm % and 15 patients had Hb >12 gm%. Among MD group, 80 patients had Hb between 10-12 gm% and 20 patients had Hb >12 gm%. Mean haemoglobin in group SD was 11.139±1.040 gm% whereas mean haemoglobin in group MD was 11.025±1.07 gm%. Difference in mean haemoglobin between the 2 groups was not statistically significant.

Gestational age

In the SD group, 81% were between 38-40 weeks of gestation, 12% belonged to the >40 weeks, and 7% to the 37 weeks group. In the MD group, 82% were between 38-40 weeks, 14% belonged to >40 weeks gestational age.

In the study group, total of 9.5% (19) subjects of the study group developed SSI. 10% of the patients from SD group and 9% of the patients from MD group developed SSI. However, this difference between the two groups was not statistically significant (p value =0.5).

Table 3: Comparison of surgical site infections among the two groups.

SSI	Single dose (%)	Multiple dose (%)	Total	Total in percentage (%)	
Present	10	9	19	9.5	χ^2 value=0.058 P value =0.5
Absent	90	91	181	90.5	
Total	100 (100)	100 (100)	200	100	

Table 4: Organisms isolated from patients with SSI.

Organisms	Single dose (%)	Multiple dose (%)	Total	Total in percentage(%)
K. pneumoniae	1	2	3	1.5
E. coli	3	3	6	3
S. aureus	2	1	3	1.5
Methicillin susceptible *staphylococcus aureus*	2	2	4	2
No growth	92	92	184	92
Total	100 (100)	100 (100)	200	100

Among 10 patients with SSI in SD group, on culture sensitivity *E. coli* was isolated in three patients, *K. pneumoniae* in one patient, *S. aureus* in 2 patients, MSSA in 2 patients. No growth was seen in 2 patients of SD group with SSI.

Among 9 patients with SSI in the MD group, *E. coli* in 3 patients, MSSA was isolated in 2 patients, *K. pneumoniae* in 2 patients and *S. aureus* was isolated in 1 patient. No growth was seen in 1 patient of MD group with SSI (Table 4).

Table 5: Antibiotics used in the treatment of SSI in our study.

Antibiotics	Single dose (%)	Multiple dose (%)	Total	Percentage
Inj. amikacin	1	0	1	0.5
Inj. ceftriaxone	4	0	4	2
Tab. amoxicillin + clavulanic acid	1	2	3	1.5
Inj.piperacillin + tazobactum	1	8	9	4.5
Inj. Ceftriaxone + T.linezolid	1	0	1	0.5
T. Norfloxacin	1	0	1	0.5
Inj Ceftriaxone +Inj.amikacin	4	0	4	2
Inj.Ceftriaxone + T.amoxicillin + clavulanic acid	3	0	3	1.5
Inj.piperacillin + tazobactum+ Inj. amikacin	1	0	1	0.5
Inj.piperacillin + tazobactum + amoxicillin + clavulanic acid	0	1	1	0.5
Inj.piperacillin+T.amoxicillin + clavulanic acid	0	2	2	1
Nil	83	87	170	85
Total	100 (100)	100 (100)	200	100

Among 10 patients of the single dose group with SSI, 1 patient received a combination of Inj. piperacillin and tazobactum, 4 patients of the single dose group were treated with a combination of inj ceftriaxone and inj amikacin and 4 patients received only Inj ceftriaxone and 1 received Inj. ceftriaxone with tablet amoxicillin with clavulanic acid.

Among 9 patients of the multiple dose group with SSI, 8 patients received a combination of Inj.piperacillin and tazobactum, 1 patient received tablet amoxicillin with clavulanic acid. These antibiotics were also used for other infections like fever and UTI other than SSIs in both the groups (Table 5).

In the single dose group, 7 patients had at least one episode of fever, of which 5 had only one episode and 2 had recurrent episodes which subsided on using antibiotics. Among the multiple dose group, 5% (5) patients developed at least 1 episode of fever, of which 4 had only one episode and 1 patient had recurrent episodes which was evaluated and treated accordingly. However, this difference was not statistically significant (p value =0.384) (Table 6).

Table 6: Association of postoperative fever with single/multiple dose of antibiotic group.

Fever	Single dose (%)	Multiple dose (%)	Total	Percentage	
Present	7	5	12	6	χ^2 value=0.355 P value =0.384
Absent	93	95	188	94	
Total	100 (100)	100 (100)	200	100	

Table 7: Association of duration of stay with single/multiple dose of antibiotic group.

Duration of stay	Single dose (%)	Multiple dose (%)	Total	Percentage	
</= 5 days	90	91	180	90.5	χ^2 value=1.418 P value =0.186
5-10 days	6	1	7	3.5	
> 10 days	4	8	12	6	
Total	100 (100)	100 (100)	200	100	

In the SD group maximum (90%) patients were discharged from hospital within 5th postoperative day, while 6% had to stay between 5-10 days, about 4% patients had to stay for >10 days. Among the MD group, maximum (91%) patients had a hospital stay of <5 days, 1% stayed between 5-10 days and around 8% had to stay for >10 days. It was observed that the mean length of hospital stay in the single dose group was 8.54±2.45 days and in multiple dose group was 9.10±3.02 days, respectively. The mean duration of hospital stay was not statistically different among the two groups (p = 0.186) (Table 7).

Table 8: Association of management of SSI with single/multiple dose of antibiotic group.

Treatment type	Single dose (%)	Multiple dose (%)	Total	Percentage	
Antibiotic + daily dressing	7 (70)	5 (55.5)	12	63.15	χ^2 value=1.527 P value =0.676
Antibiotic + daily dressing + re suturing	3 (30)	4 (44.5)	7	36.85	
Total	10 (100)	9 (100)	19	100	

In group SD, out of 10 patients with SSI, 7 patients required antibiotic with daily dressing and 3 patients required re-suturing due to wound dehiscence. Whereas in group MD, out of 9 patients with SSI, 5 patients required antibiotic with daily dressing, and only 4 patients required re-suturing. The requirement of daily dressing and re-suturing was not statistically significant between the two groups (p = 0.676) (Table 8).

NICU admissions

Among the single dose group 4% of babies required NICU admission. In the multiple dose group also 4% babies needed admission to NICU for various reasons, which was not statistically significant (p value =0.64).

Neonatal sepsis

It was observed that occurrence of a proven case of Neonatal sepsis was more in single dose group compared to multiple dose group. 0.5 % (1) of the babies born to the study patients had neonatal sepsis which belonged to the single dose group, while none of the babies born to mothers from the multiple dose group. However, this difference was not statistically significant (p value =0.5).

DISCUSSION

Multiple studies have proven the positive effect of prophylactic antibiotics in reducing infectious morbidity. The aim of prophylactic antibiotics is to reduce the post-partum infection and its complications thereby reducing the post-operative morbidity and mortality. Antibiotic prophylaxis for caesarean section is to be administered pre operatively, so as to ensure a high plasma concentration of antibiotic in the plasma during the surgery.[12] Various studies done in obstetric cases proved that there is a definite role of prophylactic antibiotics in caesarean section.[8-11,13]

The Mean age of patients in our study was 25.38±4.04 years. Mohan et al in their study showed that most of the patients in their study on post operative infections in cesarean section belonged to 21-30 years of age, which was comparable to our study.[8]

With regard to Socio economic status, in our study majority of the patients in single dose group(81%) and multiple dose group (81%) belonged to lower middle class. In the study conducted by Anuradha et al on postoperative infectious morbidity, majority (47.1%) of the patients

belonged to the lower middle class group, which has similarity with our study with respect to socioeconomic status.[14]

The most common indication for caesarean section in our study, in both the groups was cephalopelvic disproportion which was around 86 (43%). The study conducted by Mishra et al between 2017-20 found that the commonest indications for elective caesarean section in both single and multiple dose groups were previous caesarean sections, cephalopelvic disproportion (CPD) and caesarean delivery on maternal request (CDMR), these observations are comparable to our study findings.[15]

Surgical site infections (SSIs) are defined as healthcare associated infections in which a wound infection occurs after a surgical procedure within 30 days of postoperative period. They are common adverse events in hospitalized patients following caesarean section. Appropriate and timely antibiotic prophylaxis has been shown to be highly effective in reducing the incidence of SSI.[16]

Though SSIs are not life threatening in most cases, they tend to prolong the length of hospital stay, increase hospital cost and in some cases, re-admission may be required which has deleterious effect on women trying to cope with both the postoperative period and newborn baby.[17]

The global estimate of SSI ranges from 0.5-15%.[18] In our study, it was seen that Surgical Site Infections prevalence in SD group was 10% and in MD group it was 9%. 9.5% (19) of the total study patients had SSI. However, this difference was not statistically significant (P value =0.5). In a study by Babeeta et al conducted on antibiotic prophylaxis in cesarean section, incidence of SSI was 8% in single dose group and 10% in multi-dose group (p value of >0.05).[19] A study conducted by Shah et al, concluded that there was no statistical significance in the rate of infections in both single and multiple dose antibiotic groups.[20] In another study conducted by Ansari et al on post-operative evaluation of wound infection, the incidence of wound infection was 2% in single dose group and 3% in multi-dose group.[21] When compared to this study, the prevalence of SSI in our study was high. These small differences in the prevalence of SSI in different studies may be because of variation in selection criteria, environmental factors and varied infection control protocols with regard to personal hygiene and nutrition.

The most common organism causing SSI in our study was *E. coli* (38%) in both the groups followed by methicillin susceptible *Staphylococcus aureus* (25%), *K. pneumoniae* (18.7%) and *S. aureus* (18.7%) in decreasing order. The probable reasons for the low culture of the anaerobic organism in our study could be the wide prevalent use of metronidazole as a prophylactic antibiotic in our centre for the postoperative patients. In a study conducted by 41 Njoku et al on microbiological pattern of surgical site infection following caesarean section revealed that gram-negative organisms were more prevalent (62.7%) than gram-positive bacteria (37.3%).[22] The isolated bacteria were *S. aureus* (37.3%), *Klebsiella. pneumoniae* (27.1%), *E. coli* (22.0%), *Pseudomonas aeruginosa* 3 (5.1%), *Klebsiella oxytoca* (5.1%) and *Bacteroides* (3.4%) in their study.

A study conducted by Sundari et al on surgical site infections post cesarean section, the most common pathogenic organisms causing SSI was found to be *S. aureus* 35% followed by gram negative rods of which *Klebsiella* species was 24%, *E. coli* in 18%.[23] The differences in the prevalence of various organisms in our study and other studies was not statistically significant.

In our study, the occurrence of febrile episodes was more in single dose group compared to multiple dose group. 6% (12) of the study patients developed fever of which 7 were from the SD group and 5 from the MD group. Gerald et al in his study mentioned that the overall incidence of postoperative febrile morbidity, defined as temperature >38°C measured twice at least 4 h apart on two occasions excluding the first 24 h post caesarean section, was 11.5%, with no difference between the single and multiple dose groups.[24] This incidence is high when compared to our study. Factors that have been proposed to potentially affect infectious morbidity are shaving of surgical site, uterine exteriorization and suturing of subcutaneous tissue.

Febrile morbidity in the study by Bhattachan et al was 2% and 6% in single versus multiple doses respectively.[25] Pooja et al in their study conducted at a tertiary care centre had findings comparable to our study which had infective rates of 1.9% and 4.9% respectively in group SD and in group MD.[26]

Pinto-Lopes et al in their study on single dose versus multiple dose of antibiotic prophylaxis in caesarean section concluded that there was no sufficient data to conclude whether there is a difference between single and multiple dose regimens in reducing the incidence of infectious morbidity after caesarean section.[4] Shaheen et al compared one day of antibiotic prophylaxis with seven days of antibiotic prophylaxis in elective caesarean sections in Pakistan and found no statistically significant differences in wound infections.[27]

A study by Mohan et al on using cefotaxime 1g IV 30mins before surgery also showed that single dose was equally effective compared to conventional multiple dose antibiotic therapy in preventing wound infection.[8] The study added to the findings of various studies that, it is effective to prevent postoperative complications with a single dose of prophylactic cefotaxime. The findings of this study demonstrated that standard multi-dose antibiotic therapy and single- dose antibiotic prophylaxis are equally effective. When compared to the multi-dose regimen, single dose is more affordable and can be used to reduce the development of microbial resistance.

Limitations of this study could be attributed to small sample size and also the financial limitations faced at a district hospital. Also the results could vary in our study compared to other similar studies due to the difference in study population with respect to personal hygiene, nutrition, variation in the steps of the surgery and the definition of post operative morbidity.

CONCLUSION

This study proves that single dose antibiotic is equally efficacious when compared to multiple dose antibiotic prophylaxis in preventing surgical site infections and other postoperative infective morbidities in patients undergoing elective caesarean section. The use of single dose antibiotic prophylaxis is cost-effective and may help in overcoming the development of antibiotic resistance, and hence its use needs to be encouraged.

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