

Comparison of Single Dose of Cefotaxime Versus Multiple Doses of Cefotaxime and Metrogl as Antibiotic Prophylaxis in Elective Caesarian Section

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Abstract

Background: Post operative wound infection was a common complication seen in women who undergo caesarean sections. Keeping the expectant mother in antibiotic coverage prior commencement of caesarean section might have an advantageous situation for the treating obstetrician to prevent postpartum infections. However, it is to be ascertained that administration of single dose antibiotic preoperatively is effective in comparison to administration of multiple doses of antibiotic both pre and postoperatively to prevent postpartum infectious morbidity and wound infections. This study was conducted to compare the efficacy of single dose of 1 gm intravenous Cefotaxime given half an hour prior surgery to multiple doses of Cefotaxime and Metrogl given preoperatively and postoperatively as per hospital antibiotic protocol in prevention of postpartum morbidity.

Methods: The study was a quasi experimental study conducted by the Department of Obstetrics and Gynecology, GSL Medical College, Rajahmundry from Jan 2018 – Jan 2020. The participants were divided into two groups, Group A (test group) and Group B (control group) and both groups were administered a single dose of 1gm Cefotaxime intravenously half an hour prior to skin incision of caesarean section. In addition the control group received multiple doses of Inj Cefotaxime 1gm intravenously BD and Inj Metrogl 500 mg TID pre and post operatively for 48 hrs, followed by oral administration of Tab Cefexime 200 mg BD and Tab Metrogl 500 mg TID for next five days including seven days antibiotic coverage

as per hospital antibiotic protocol. Both groups are followed up for the incidence of post-operative complications such as Surgical Site Infection (SSI), fever, endometritis and Urinary Tract Infection (UTI).

Results: The Study included a total of 140 women (70 in each group) with various gravida. A total of five women (3.57%) had serous discharge, three women (2.14%) had wound gapping, two (1.42%) had wound in duration. Only one woman (0.71%) each had puerperal pyrexia and endometritis. Majority of women amounting to 91.4% had nil complications. Statistical analysis was undertaken using Pearson-Chi square test.

Conclusion: The single dose of one antibiotic efficacy is as good as multiple doses of two antibiotic regimens as prophylaxis in reducing the incidence of postpartum infectious morbidity in women delivered by undergoing elective caesarean section.

Keywords: Single dose antibiotic; Prophylaxis; Surgical Site Infection; Urinary Tract Infection; Endometritis; Postpartum infectious morbidity.

Introduction

The Lower Segment Caesarean Section (LSCS) over the past couple of decades is the most commonly performed major surgical procedure in Obstetrics worldwide, given to its continuously rising rates both in developed and developing countries.^{1,2} According to the data received over 150 countries,

18.6% of all births occurred by caesarean section, ranging from 6% to 27.2% in least and most developed regions respectively. Based on data received from 121 countries, the trend analysis showed that between 1990 – 2014, the global average rate of caesarean section had risen to 12.4%. In Asia the average annual rise in caesarean section rate is 6.4%.³ According to the data collected by the Union Ministry of Health and Family Welfare under the HIMIS (Health Information Management System), over 14% of total births are by caesarean section at public facilities and 33.8% at private facilities in 2018–19. Women who undergo caesarean section have 5–20 fold greater risk of infectious complications comparing to those who deliver vaginally.^{4,5} The common complications, that occur following caesarean section are SSI (Surgical Site Infection), fever, UTI (Urinary Tract Infection), Endometritis.^{6,7} Because of increased incidence of caesarean section rate, the aim should be at reducing postpartum infection morbidity. Thorough aseptic precautions, good surgical techniques, optimum intra operative period and antibiotic prophylaxis have been proved to be effective in prevention of infectious complications associated with surgery.⁸

Many studies have shown that, inspite of reduction in the total amount of antibiotics administered, there is no statistical significance in postpartum complications after caesarean section. Prophylactic antibiotics reduce the incidence of SSIs^{9,10} and evidence based guidelines recommend their use prior to incision rather than during or after procedure.^{9,10,11,12} Hence the aim of present study is to compare the efficacy of single dose of 1gm intravenous Cefotaxime given half an hour prior surgery to multiple doses of Cefotaxime and Metrogyl given preoperatively and postoperatively as per hospital antibiotic protocol in prevention of postpartum morbidity.

Material and Methods

The study was a prospective quasi experimental study done in the Department of Obstetrics and Gynecology, GSL Medical College, Rajahmundry for duration of two years from Jan 2018 – Jan 2020. Ethical clearance for the study was obtained by the ethical committee of research at GSL Medical College, Rajahmundry.

Inclusion Criteria

The following criteria were considered as inclusion criteria:-

- (a) The women in the study group were either Primi or Multigravida.

- (b) Non-labouring with unruptured membranes.
- (c) Term gestation with haemoglobin > 9gm%.
- (d) Electively posted for LSCS.
- (e) Intra-operative period i.e skin incision to skin closure was kept approximately 1 hour.

Exclusion Criteria

The following were considered as exclusion criteria:-

- (a) Hypersensitive to Cefotaxime.
- (b) Premature rupture of membranes.
- (c) History of medical disorders associated with pregnancy like heart disease, diabetes, renal disease, liver disorder, anaemia with Hb<9gm%, Ante partum haemorrhage and h/o fever within seven days prior to LSCS, BMI > 30 kg/m².
- (d) Postpartum Haemorrhage (PPH) during intra operative or immediate postpartum period (within 24 hrs of surgery).

Study tools – proforma for data collection, clinical examination and case record.

Methodology

The patients were divided into Group A (test group) and Group B (control group). The patients of Group A received Inj Cefotaxime 1gm intravenously half an hour prior to skin incision. For Group B the patients received Inj Cefotaxime 1gm intravenously BD and Inj Metrogyl 500mg TID pre and post operatively for 48 hrs, followed by oral administration of Tab Cefexime 200 mg BD and Tab Metrogyl 500 mg TID for next five days including seven days antibiotic coverage as per hospital antibiotic protocol. The wound dressing was changed on day 3 of surgery i.e after 48 hrs of surgery and suture removal was carried out on day 7 after surgery. If there were no complications, then the Patient was discharged on day 7 of surgery. In both groups, bladder catheter was removed after 24 hours. Surgical Site Infection assessment was undertaken on post operative day 3, day 7 and day 30. SSI was indicated by presence of fever, signs and symptoms of abdominal wound infection or endometritis. Febrile morbidity was defined by temperature above 100.4°F or 38°C at least four hours apart and on two or more occasions excluding the first twenty four hours after delivery. Abdominal wound infection was defined by presence of serous or purulent discharge from the wound with induration, local rise of temp and tenderness with partial or total dehiscence of wound. Endometritis was defined as presence

of fever associated with uterine tenderness and foul smelling lochia. Urinary tract infection when patient complains of dysuria, increased frequency of urination, and presence of pus cells in urine routine examination.

Analysis- after completion of data collection, it was coded and entered into Microsoft excel and transferred to SPSS 21 software. Association between variables tested with chi-square test. Level of significance taken as P value less than 0.05 and highly significant when p is less than 0.01.

Results

140 antenatal women who underwent Lower Segment Caesarean Section with or without sterilisation were considered for the study, (Fig. 3 and Table 1), of which 70 women were administered single dose Cefotaxime 1gm intravenous preoperatively as prophylaxis. And the remaining 70 women whose age and BMI matched were administered with Cefotaxime and Metrogl as per the hospital antibiotic protocol. Out of 140 women included in the study 74.2% women belonged to age category of 18-25 years (Fig. 1). The BMI in 76.2% was less than 25 kg/m² at the time of delivery (Fig. 2), as most of the women belonged to low socio economic background. The most common indication for caesarean section in both groups was previous caesarean section with term gestation and planned parenthood for which they underwent elective LSCS and tubal ligation.

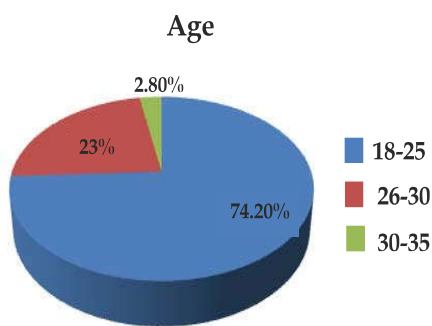


Fig. 1: Distribution According to Age

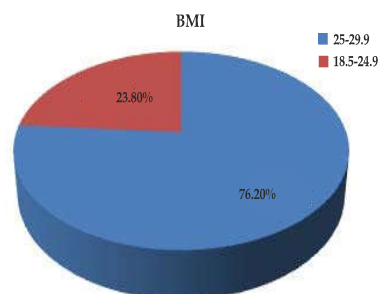


Fig. 2: Distribution According to BMI

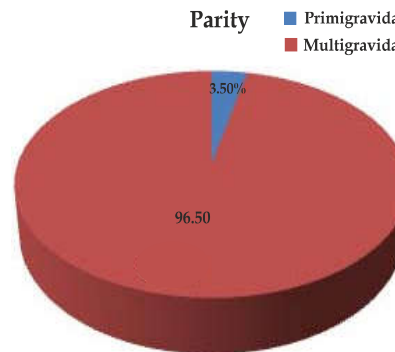


Fig. 3: Distribution According to Parity

Table 1: Indications for LSCS

S. No	Categories	Group 1 (n=70)	Group 2 (n=70)
1	Post LSCS + planned parenthood	58	46
2	Severe Oligohydramnios	02	07
3	Severe Oligohydramnios + PIH	00	02
4	Post LSCS	01	01
5	Infertility conceived (IUI)	01	02
6	Primi with Psychiatric illness	01	00
7	Previous pregnancy + PIH	02	01
8	Breech	01	03
9	Uterine malformation	00	04
10	Macrosomia	00	02
11	Failed induction	00	02
12	IUGR	02	00
13	Short stature + CPD	02	00
Total		70	70

Table 2: Outcomes of the study

S. No	Categories	Group 1 (n=70)	Group 2 (n=70)
1	Surgical Site Infections (SSIs)		
	(a) Serous discharge from wound	04	01
	(b) Wound gapping	02	01
	(c) Wound induration	01	01
2	UTI	01	00
3	Peurperal pyrexia	00	01
4	Endometritis	00	00
5	Serious infectious complications eg. septicemia, thromboplebtis, necrotisig fasciitis, burst abdomen	00	00
6	Any adverse event of Rx eg. Allergic reaction, Antibiotic associated diarrhoea	00	00
7	Nil complications	62	66
Total		70	70

It is observed from the above (Table 2) that a total of 12 (08 + 04) women in both groups developed complications. To ascertain whether single dose

prophylaxis or two drugs multiple dose prophylaxis is better in preventing complications, Pearson Chi square test has been carried out and the chi-square value obtained is 8.925 and the 'p' value obtained is 0.258, which is insignificant.

It is evident from above that, antibiotic change required in both groups, consisting of eight women (11.5%) in group 1 and four women (5.7%) in group 2 (Fig. 4). On Statistical analysis, the chi-square value is 3.398 and 'p' value is 0.183 indicating there is no statistical significance.

Discussions

Any antibiotic is effective in clean and uncontaminated cases and choice should therefore depend on other factors such as cost¹³ and affordability. Many studies have reported that there is no added benefit of using multiple doses over single dose of antibiotic for prophylaxis of caesarean section.^{14,15} Single dose prophylaxis has not been accepted and multiple dose regimen are still used in many centres.^{16,17,18,19} In fact single dose therapy reduces medicinal cost and staff workload. Prophylactic antibiotic must cover the contaminating organisms most likely present in the tissues at the time of incision is made and therapeutic concentrations should be maintained throughout the procedure. Therefore, prophylactic antibiotic is not meant to cover every possible pathogen that may cause infection but by reducing the number of organisms present, it enables the patient's immunological defences to work

adequately.²⁰ Inappropriate use of broad spectrum antibiotics beyond the recommended time use will lead to emergence of drug resistant organisms.

Therefore the study desired to determine whether a single prophylactic antibiotic dose of third generation Cephalosporin i.e Cefotaxime is as effective as multiple doses of Cefotaxime and Metrogyl regimen. In this study, the test group i.e single dose antibiotic group has not been administered with Metrogyl and only Cefotaxime, the third generation cephalosporin has been administered which is widely active against gram positive and gram negative bacteria and also possess some coverage against anaerobic bacteria. Also, all the cases in test group were low risk, non labouring and with no premature rupture of membranes. It is found in the study that there was not even a single case of endometritis in both groups. One case from control group had fever of 102°F. On post operative day 6, antibiotics were changed and anti malarials were added to the treatment empirically as the patient hails from endemic zone. Fever completely subsided on after two days of initiating anti malarial treatment.

The absence of clinical endometritis in this study is comparable to other studies by Shakya & Sharma¹⁴ 2010 and Gideon Alex Mugisa & Paul Kiondo²¹ 2018 and Mohan et al²² where no cases of endometritis were reported in both the single dose and multiple dose groups among mothers delivered by elective caesarean section. The incidence of urinary tract infection in this study was 1.4% in test group and febrile morbidity was 1.4% in control group

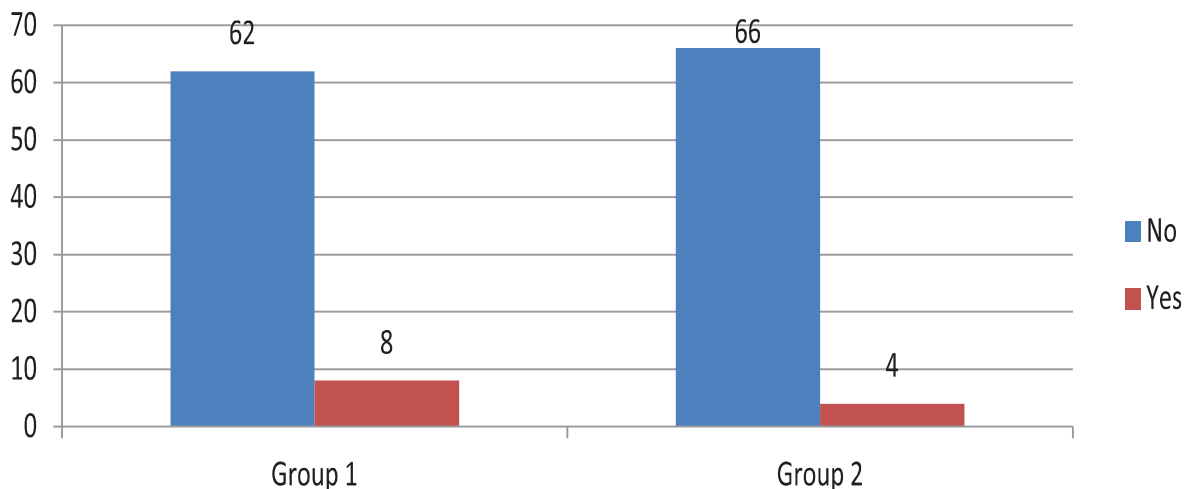


Fig. 4: Antibiotic change

Table 3: Comparison with other studies

S. No	Symptoms	Shakya & Sharma et al ¹⁴		Mohan et al ²²		Gideon Alex Mugisa & Paul Kiondo et al ²¹		Chandrika et al	
		Test	Control	Test	Control	Test	Control	Test	Control
1	Fever	4%	6%	5.81%	-	nil	nil	nil	1.4%
2	UTI	4%	nil	nil	-	nil	nil	1.4%	nil
3	Endometritis	nil	nil	nil	-	nil	nil	nil	nil
4	RTI	-	-	nil	-	-	-	nil	nil
5	W o u n d Infection	nil	nil	2.33%	-	1.3%	2.4%	10%	4.3%

(Table 3) comparable with other studies mentioned above. The patient with UTI complained of increased frequency and burning micturition but had no fever and on routine urine examination showed 6-8 pus cells. The patient was kept on Tab Nitrofurantoin 100mg BD orally for seven days. The prevalence of wound site infection was 10% in test group in comparison to 4.5% in control group i.e multiple dose antibiotic group.

The test group had reported four cases and control group had reported with one case that had clear serous discharge from the wound but there was no wound gapping. The discharge was sent for culture and sensitivity. However, no organism could be isolated. All the five cases were put on empirical treatment with Cap Augmentin 625 mg BD orally for five days. The serous discharge reduced by the 3-4th day of antibiotic therapy. There were two cases of wound induration, one in each group for which empirical treatment with Cap Augmentin 625 mg BD and Tab Chymoral forte (Trypsin-Chymotrypsin) 1mg BD orally for five days were administered. These patients are discharged on seventh day after suture removal. The difference was not statistically significant, which is comparable to the other studies. However, in cases of skin dehiscence in surgical site infection patients intravenous antibiotics were given for total seven days depending on culture and sensitivity report and secondary suturing of skin was done after five days of i.v antibiotics and wound dressing. The limitation of the study is, it was done on small number of patients and on elective non labouring patients with no premature rupture of membranes.

Conclusion

This study has established that the single dose

of one antibiotic efficacy is as good as multiple doses of two antibiotic regimens as prophylaxis in reducing the incidence of postpartum infectious morbidity in women delivered by undergoing elective caesarean section. Considering the number of women examined in the study is minimal, it would be prudent in recommending that single dose antibiotic prophylaxis should be continued in lieu of multiple dose antibiotic prophylaxis in low risk elective caesarean section, to ensure strict adherence to the principles of Microbiology and Pharmacology in order to prevent occurrence of multidrug resistant organisms. However, the choice of using single or multi drug antibiotics may be decided on case to case basis by the treating gynaecologist taking into the consideration of the antibiotic policy of the hospital/institute.

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