

## “A Clinical Study of Effectiveness of Single Dose of Prophylactic Antibiotic in Comparison with Multiple Doses of Prophylactic Antibiotic in Elective Lower Segment Caesarean Section”

Geetha Vani TM<sup>1</sup>, Lakshmi narayanamma V<sup>2</sup>, Indira Iruganti<sup>3</sup>

<sup>1</sup>Post Graduate, Department of OBG, SV Medical College, Tirupati

<sup>2</sup>Assistant Professor, Department of OBG, SV Medical College, Tirupati

<sup>3</sup>Associate Professor, Department of OBG, SV Medical College, Tirupati

Corresponding Author: Dr.T.M.Geetha Vani,

**Abstract:** Caesarean delivery is frequently complicated by surgical site infections (SSIs), endometritis and urinary tract infection..in view of prevailing concerns about antibiotic resistance, the present study aims to know if single dose antibiotic is as effective as multiple doses in prevention of post-operative infection in elective lower segment caesarean section.it is found that the incidence of post operative surgical site and other infections is similar in both groups.

**Material And Method:** The study population : women undergoing elective lower segment caesarean section at government maternity hospital ,Tirupati.All patients received inj Cefotaxime IV half hour before surgery. In addition the multiple dose group received antibiotics for five days post-operatively. Each patient in the study was observed till discharge for presence of any morbidity like endometritis, urinary tract infections, and wound infections.

**Results:** There was no statistically significance in the rate of infections in both the groups. The rate of febrile morbidity, endometritis, urinary tract infection and wound infections were statistically not significant. However the difference in cost of antibiotic in both the groups was significant.

**Conclusions:** Single dose antibiotics are effective as multiple doses in prevention of post-operative infections in caesarean sections. Careful periodic surveillance of antibiotic prophylaxis is necessary to detect the emergence of drug resistant strains of bacteria in our institution because it caters to the needs of local population.

**Keywords:** Antibiotic prophylaxis, caesarean section, infectious morbidity, multiple doses, single dose.

Date of Submission: 30-01-2020

Date of Acceptance: 15-02-2020

### I. Introduction

Over the past decades, caesarean section has become one of the most common major surgical procedures worldwide, given to its continuously rising rates both in developed and developing countries.<sup>1</sup> women undergoing caesarean delivery have a 5- to 20-fold greater risk of infectious complications when compared with those who deliver vaginally.<sup>2,3</sup> Fever, endometritis, wound infection and urinary tract infection compose the majority of the complications.<sup>4,5</sup> Given the worrisome trend of increasing caesarean section rates worldwide, measures aimed at reducing postpartum infectious morbidity are an important area of focus. Traditional principles of skin antisepsis, thorough surgical technique and antibiotic prophylaxis have been proven effective for the prevention of infectious complications associated with any surgery.<sup>6</sup> In caesarean sections, the potential of prophylactic antibiotics has been extensively studied both in high-risk and low-risk women, showing a clear benefit and reducing the incidence of postpartum infectious morbidity.<sup>7,8</sup>

There is no consensus regarding the number of doses of prophylactic antibiotic in caesarean section.WHO has recommended a simplest and shortest anti biotic regimen as prophylaxis for caesarean section, administered intravenously.the choice of the antibiotic was left to the individual hospitals who are supposed to develop their own protocol based on the local bacterial flora, availability and cost effectiveness of antibiotics and local resistance patterns.

It is common to use prophylactic usage of antibiotics for seven days in the post operative period. The purpose of this review is to examine infectious morbidity comparing single and multiple doses of the same antibiotic, to assess the optimal regimen for antibiotic prophylaxis in caesarean section. Careful periodic surveillance of antibiotic prophylaxis is necessary to detect the emergence of drug resistant strains of bacteria.

## **II. Aims And Objectives Of Study**

- 1.To compare if single dose of prophylactic antibiotic is as effective as multiple doses in prevention of post-operative infection in caesarean section.
- 2.To compare the two groups in terms of pain scale and need for analgesia.

## **III. Material And Methods**

STUDY POPULATION: Women undergoing elective caesarean section in government maternity hospital, Tirupati.

Study setting: post operative ward in government maternity hospital, Tirupati.

Study Period: From approval of Ethical Committee.

Sample size: convenient sample size of 50 in study and 50 in control group.

Inclusion criteria:

1. Pregnant women who are undergoing elective caesarean section.

Exclusion criteria:

1. All women who are not willing for the study.
2. Pregnant women with known hypersensitivity to cefotaxime.
3. Diabetes, heart disease, BMI > 30kg/sqm
4. Patient undergoing Emergency LSCS.
5. Patient with fever at the time of caesarean section.

## **IV. Methodology**

- The Institute Ethics Committee clearance obtained and informed consent was taken from the recruited women.
- A detailed history taken which includes the epidemiological factors like age, education, occupation, marital status, socioeconomic status, residence and living conditions, personal history like diet, sleep, stress levels, smoking, alcohol intake, family history.
- Detailed general examination including general condition, height, weight, BMI, thyroid, breast, spine, and gait are recorded. Vitals are recorded and systemic examination of patient including Cardiovascular and respiratory system is done.
- Women in the study group were given injection CEFOTAXIME 1 g intravenously just before the administration of anesthesia.
- Women in the control group are given iv antibiotics for 48 hours twice daily followed by oral antibiotic TABLET Cefixime 200 mg twice daily from D3 to D7.
- Based on visual analogue pain scale paracetamol either oral or injectable was prescribed to patient. injectable paracetamol was given on 0 post operative day .pain scale was monitored from first post operative day until discharge on all days for all patients. average pain scale was calculated in both study group and control group.
- Both groups are followed every day from day of surgery until discharge from hospital .vital parameters like pulse rate, blood pressure, cardiovascular system and respiratory system of the patient examined once in 2 hours on day of surgery. and twice daily from first post operative day. thorough examination of wound, lochia, breast, involution of uterus and calf muscles are examined daily.
- The primary outcome measure was the incidence of 1. febrile morbidity, defined as an oral temperature of >38 C on two occasions at least four hours apart, excluding the first 24 hours. 2. wound infection. 3. microbiological evidence of infection at any site in the form of positive swabs.
- Once febrile morbidity was identified, women were examined thoroughly to localize the potential source of infection and relevant laboratory investigations were done.
- In case of discharge from the wound swabs taken and sent for culture sensitivity.
- In case of burning micturition urine sent for culture sensitivity.
- In case of offensive lochia high vaginal swab was taken and sent for culture sensitivity
- In case of cough x ray chest and if necessary sputum for culture sensitivity sent.
- Based on the culture report antibiotic was added in study group and changed in control group.
- After discharge patients in both groups were recalled at two weeks and again at six weeks and any signs of infection were noted..

**Statistical analysis**

The data collected was tabulated in Microsoft Excel Worksheet analysis was done by epiinfo version 7.results are expressed in terms of percentages and proportion.. For comparison of means, unpaired *t* - test. For comparison of proportions, Chi -square test was used.

**Ethical issues**

Before collection of data all the subjects are briefed about the purpose of study and written informed consent will be obtained All investigations will be done free of cost ,no financial burden will be imposed on the patient.

**V. Results**

**Table: 1 BASELINE CHARACTERISTICS OF STUDY GROUP AND CONTROL GROUP.**

S.NO	PARAMETERS	SINGLE DOSE OF ANTIBIOTIC	MULTIPLE DOSES OF ANTIBIOTIC
1	<b>AGE (YEARS)</b>		
	≤25	15	13
	26-34	25	27
	≥35	10	10
2	<b>PARITY</b>	Primi-11 Multi-39	Primi-15 Multi-35
3	<b>BMI</b>	Normal-46 >25 kg/sqm- 4	Normal-43 >25 kg/sqm- 7
4	<b>SOCIOECONOMIC STATUS</b>		
	Upper lower and lower	20	20
	Upper and lower middle	30	30
5	<b>EDUCATION</b>	Primary- 15 Secondary-25 Degree-10	Primary- 18 Secondary-26 Degree-6
6	<b>BOOKED /UNBOOKED</b>	Booked-40 Un booked-10	Booked-45 Un booked-5

Baseline characteristics of study and control group are similar.

**Table:2 Indications for LSCS**

INDICATION for LSCS	SINGLE DOSE OF ANTIBIOTIC	MULTIPLE DOSES OF ANTIBIOTIC
Primi with Breech	8	10
Post Caeserean Pregnancy	35	30
2 Prior Post Caeserean Pregnancy	4	6
Primi with CPD	2	4
Primi with twins	1	0

There is no statistical significance in between the two groups in terms of indications.

**Table: 3 PAIN SCALE (VISUAL ANALOG SCALE)**

	STUDY GROUP	CONTROL GROUP
<b>PAIN-SCALE9(Average)</b>	48 hours	48 hours
<b>NEED FOR ANALGESIA (average)</b>	48 hours	72 hours

**There is no statistical significance in terms of pain scale and need for analgesia in both study group and control group.**

**Table:4 POSTOPERATIVE COMPLICATIONS IN THE STUDY**

S.NO	SYMPTOMS	SINGLE DOSE OF ANTIBIOTIC	MULTIPLE DOSES OF ANTIBIOTIC
1	Unexplained fever	2	5
2	Secondary Haemorrhage	0	0
3	Endometritis	0	0
4	Urinary tract infection	3	2
5	Mastitis	0	0
6	Wound infection	2	5
7	Deep Vein thrombosis	0	0
8	Upper respiratory tract infection	4	3

**There is no statistical significance but there is clinical significance in terms of wound infection between study group and control group.**

## VI. Discussion

Present study aims to compare single dose of prophylactic antibiotic is as effective as multiple doses of prophylactic antibiotic in elective lower segment caesarean section. In present study baseline characteristics are similar in terms of demographic factors like age, parity, BMI, socioeconomic status and education when compared with other studies.

In this study most common indication for lower segment caesarean section was post caesarean pregnancy followed by primigravida with breech presentation. Indications are similar in both groups. No significant difference seen in terms of indication in both groups.

All patients in the study received antibiotics half an hour before surgery and those in multiple doses received additional doses post operatively. Classen et al have shown that the timing of antibiotic administration was critical in preventing post-operative wound infections.<sup>9</sup> For most surgical procedure it is desirable to administer prophylactic antibiotic pre operatively before tissue injury and bacterial contamination. Subsequently, a retrospective cohort study of 1316 term, singleton caesarean delivery reported on a policy change in timing of antibiotic prophylaxis from post clamping to pre incision which resulted in a reduction of 60% in rate of SSI's and a 50% reduction in the rate of endometritis and 80% decrease in cellulitis.<sup>10</sup> Since there is overwhelming evidence for the need and effectiveness of prophylactic antibiotics to prevent infections following caesarean delivery, the current debate focuses on the choice and timing of administration. In our study the incidence of febrile morbidity in the single dose group was 4% and in the multiple dose group was 10%. Though the incidence is lower in the multiple dose group the association is not significant. In another randomized trial comparing single versus three doses of the same drug as on this study, cefotaxime showed the incidence of febrile morbidity to be 14% in the single dose group and 20% in the three dose group.<sup>11</sup> Hawrylyshyn et al found incidence to be 8.3% in single dose and 12.3% in multiple dose regimen.<sup>12</sup> There is no incidence of endometritis in this study of the single group and the multiple dose group. In a prospective study of 122 patients studied two doses of amoxicillin-clavulanic acid versus three doses of the same had 0% incidence of endometritis in the two dose and 1.6% in the three dose group.<sup>18</sup> In the study by Noyes et al 293 patients received single dose of one of the three drugs cefazoline, ampicillin-sulbactam or cefotaxime.<sup>13</sup> The incidence of endometritis with cefazoline regimen was 14.3%, with ampicillin-sulbactam was 7.4% and cefotaxime was 11.1%. The result was that single dose prophylaxis is equally effective as the multiple doses for controlling febrile morbidity. The incidence of urinary tract infections (UTI) was found to be 6% in the single dose group while in the multiple dose group it was 4%. In a study by J Shetty et al the incidence of UTI in two dose group was 2% and 1% in the triple dose group.<sup>14</sup> In our study 16 patients in the single dose group (5.6%) and 14 patients in the multiple dose group (4.6%) had wound infections. In the multicentric trials evaluated by Hopkins L, Smaill F in the Cochrane review compared various trials that compared different antimicrobial agents, comparison between the routes and the number of doses of drugs given.<sup>15</sup>

The results indicated that multiple dose does not offer any added benefit when compared with single dose regimen. The incidence of other infections like upper respiratory tract infections in the single dose group was 6% and in the multiple dose group was 8%. Clarke et al reported post-operative complications added 8.1 days to the duration of hospitalization. In our study also patients with post-operative complications were hospitalized for 12-16 days as compared to those without complications. In a report describing emergence of resistance to antibiotics; it was found that resistance developed in patients who were continued antibiotics for four days postoperatively compared to patients who received three perioperative doses.<sup>21</sup> This showed that shorter course of antibiotic administration reduced the emergence of resistance. Use and misuse of antibiotics not only affects individual patient also hospital and community environment. The prophylactic use of antibiotics in surgery may be limited to 1-2 doses of a suitable agent perioperatively and never more than 24

hours. If we can predict and administer additional antibiotic prophylaxis only to those population at high risk majority of the patients would be spared from unnecessary drug administration.

## VII. Conclusion:

Pre-operative antibiotic prophylaxis ensures the therapeutic concentration of antibiotic in serum, tissues and wound during contamination. The antibiotic chosen should be active against the bacteria that will be encountered during the surgery. The drug should be administered for the shortest period to minimize the development of resistance. The drug should be safe and economical to the patient. Careful periodic surveillance of antibiotic prophylaxis is necessary to detect the emergence of drug resistant strains of bacteria in our institution because it caters to the needs of local population.

In this study single dose of prophylactic antibiotic is as effective as multiple doses of prophylactic antibiotic.

But as the sample size is small, larger studies are needed to validate this finding.

## References:

- [1]. Richards WR. An evaluation of the local use of sulphonamides in certain gynaecological operations. *Am J Obstet Gynecol* 1945; 46: 541-545.
- [2]. Declercq E, Barger M, Cabral HJ, Evans SR, Kotelchuck M, Simon C, et al. Maternal outcomes associated with planned primary cesarean births compared with planned vaginal births. *Obstet Gynecol* 2007;109:669–77.
- [3]. Gibbs RS. Clinical risk factors for puerperal infection. *Obstet Gynecol* 1980;55(5 Suppl):178s–84s.
- [4]. Leigh DA, Emmanuel FX, Sedgwick J, Dean R. Post-operative urinary tract infection and wound infection in women undergoing caesarean section: a comparison of two study periods in 1985 and 1987. *J Hosp Infect* 1990;15:107–16.
- [5]. MacLean AB. *Clinical Infection in Obstetrics and Gynaecology*. Oxford: Blackwell Scientific, 1990.
- [6]. Owen J, Andrews WW. Wound complications after cesarean sections. *Clin Obstet Gynecol* 1994;37:842–55.
- [7]. Chelmow D, Ruehli MS, Huang E. Prophylactic use of antibiotics for nonlaboring patients undergoing cesarean delivery with intact membranes: a meta-analysis. *Am J Obstet Gynecol* 2001;184:656– 61.
- [8]. Smaill FM, Grivell RM. Antibiotic prophylaxis versus no prophylaxis for preventing infection after cesarean section. *Cochrane Database Syst Rev* 2014;(10):CD007482.
- [9]. Thigpen BD, Hood WA, Chauhan S et al. Timing of prophylactic antibiotic administration in the uninfected labouring gravid: a randomized clinical trial. *Am J Obstet Gynecol* . 2005;192:186471.
- [10]. Andrews WW, Hauth JC, Cliver SP, Savage K, Goldenberg RL. Randomized clinical trial of extended spectrum antibiotics prophylaxis with coverage for ureaplasma urealyticum to reduce post cesarean delivery endometritis. *Obstet Gynecol*. 2003; 101(6):1183-1189.
- [11]. Bernard Gonik. Single versus three dose cefotaxime prophylaxis for caesarean section. 1985 volume65, nos 2:189-193.
- [12]. Hawrylyshn PA, Bernstein P, Papsin FR. Short term antibiotics prophylaxis in high risk patients following caesarean section. *Am J Obstet Gynecol* 1983; 145: 285-289.
- [13]. Clarke SKR. Sepsis in surgical wounds with particular reference to staphylococcal aureus. *Br J Surg* 1957; 44:592-596.
- [14]. Bratzler DW, Houch PM. Antimicrobial prophylaxis for surgery: An advisory statement from the national surgical infection prevention project. *Clin Infect Dis* 2004; 38:1706-1714.
- [15]. David C, Classen R, Evans S et al. The timing of prophylactic administration of antibiotics and the risk of surgical wound infection. *N Engl J Med* 1992;326:281-286.

Dr.T.M.Geetha Vani, etal. “A Clinical Study of Effectiveness of Single Dose of Prophylactic Antibiotic in Comparison with Multiple Doses of Prophylactic Antibiotic in Elective Lower Segment Caesarean Section”. *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*, 19(2), 2020, pp. 20-24.