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Case controlled Clinical study of Prophylaxis with a single dose of cefepime for caesarean section.

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Abstract :

Background : The incidence of caesarean section is on the rise world wide. Post caesarean infection is a very serious morbity and calls for considerable manpower ,time and financial burden on the society. Again with the inadvartment use of antibiotics many drug resistant microbial have emerged.This is of very serious concern while managing a post caesarean wound infection. Attempts have been made to bring down such infections by taking all aseptic precautios and use of minimal possible yet effective dose of prophylactic antibiotics in sch circumstances. with this background current study was conducted.

Objectives : To Evaluate the effectiveness of single dose of cefepime prophylaxis in caesarean section to that of ampicillin, gentamicin and metronidazole for 5 days post-operatively with regard to post-operative morbidity, cost of the treatment, hospital stay and side effects.

Material & Methods: Two hundred cases were selected among the pregnant women who underwent emergency caesarean section or elective caesarean section at OBG Department at Bapuji Hospital, Chigateri General Hospital and Women and Children Hospital, Davangere during the study period August 2011 to June 2013.

This is a cross sectional study comparing the drug efficacy of prophylactic single dose injection of cefepime given intravenously immediately after clamping the umbilical cord during caesarean section with the control group of injection Ampicillin, + Gentamicin, Metronidazole given routinely for 5 days post operatively in prevention of post-operative infection.

Injection cefepime was given IV immediately after clamping the umbilical cord during caesarean section to prevent the masking of neonatal sepsis.

Result : The majority of cases were Emergency sections, the major indication being foetal distress followed by previous section with CPD. The post operative morbidty in study group with prophylaxis was statistically low (12%) when compared to control group (32%). The majority wound complications observed were purulent discharge and wound gaping.

Conclusion : Single dose cefepime prophylaxis was cost effective, easy to prepare and administer, has significantly reduced post-operative morbidity, reduced the hospital stay of the patients ,has no major side effects and can be widely applied in routine practice.

Keywords : Prophylaxis, caesarean section, cefepime, fourth generation cephalosporin

Introduction :

The greatest effort of modern antibiotic therapy is its influence on evolution of modern surgery[1] Caesarean section is one of the commonest forms of surgery performed in modern days; though there is decline in perinatal morbidity and mortality; maternal morbidity is on the rise due to bacterial infection.[1] The commonest complication associated with surgery being post-operative wound infection, hence the concept of prophylactic antibiotics has gained wide acceptance.[1,2]

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In addition to patient discomfort and morbidity associated with wound sepsis; there are consequences involving nursing time and increased costs that are more easily quantified.[3]

Therefore antibiotics should be present at the site of possible contamination at the time bacteria are introduced so as to prevent infection.[1] Thus prophylactic antibiotics defined as short term "use of antibiotics for the prevention of infection in the absence of clinical signs and symptoms of infection" came into consideration.[4,5]

Various analysis have shown decreased wound infection and improved physical and psychological well being given appropriate prophylactic antibiotics compared with that of untreated or placebo groups.[2]

The concept of antimicrobial prophylaxis for caesarean section has now gained wide acceptance.[2,6] Most clinical trials have shown the efficacy of antimicrobials not only in preventing endometritis but also in reducing wound infection.[7]

The choice of prophylactic antibiotics involves several criteria; including the spectra of activity, the likelihood of encountering virulent bacteria at surgery; the population incidence of post-operative infections, complications without prophylaxis; cost and potential toxicities.[3]

Morbidity due to urinary tract infections, febrile episodes and respiratory tract infections were also noted in the post-operative period.[4,8]

Hence attempts have been made to bring down such infections by taking all aseptic precautios and use of minimal possible yet effective dose of prophylactic antibiotics in such circumstances.with this background current study was conducted.

In this study the effectiveness of single dose of cefepime prophylaxis in caesarean section has been studied and compared to that of ampicillin, gentamicin and metronidazole for 5 days post-operatively with regard to post-operative morbidity, cost of the treatment, hospital stay and side effects.

Materials and methods .

Two hundred cases were selected among the pregnant women who underwent emergency caesarean section or elective caesarean section at hospitals attached to J J M Medical college, Davangere during the study period August 2011 to June 2013. Out of that hundred cases were taken as study group and hundred were taken as control group, by simple random sampling.

Inclusion criteria :

All the women who underwent cesarean section :

1) Primigravida and Multigravida
2) With term gestation
3) With membranes intact
4) With membranes ruptured with in 6 hours.
5) Afebrile
6) Not on any antibiotics
7) Elective / emergency caesarean section.

Exclusion criteria :

1) Hypersensitivity to any cephalosporin or penicillin group of drugs.
2) Antibiotic treatment within two weeks prior to surgery
3) Presence of chorioamnionitis which is defined as presence of documented rupture of membranes with fever.
4) Temperature > 100.4^0F.
5) Uterine tenderness or maternal tachycardia>100 beats/ min.
6) Foul smelling amniotic fluid.
7) Leaking per vaginum for more than 6 hours
8) Prolonged labour more than 24 hours
9) Any other infection if present

Dosage schedule :

- Study group **:** Injection cefepime 1 gm IV as a single dose immediately after clamping the umbilical cord during caesarean section.
- Control group : Injection Ampicillin – 500 mg IV 8^{th} hourly + Injection Gentamicin – 80 mg IV/IM 12^{th} hourly +Injection Metronidazole 500 mg IV 8^{th} hourly

For 48 hours post operatively and switched over to oral Ampicillin and Metronidazole with injection Gentamicin for next 3 days.

We have looked for following parameters during post operative period.

1) Temperature of 100.4^0 F or more 24 hours after surgery.
2) Wound infection.
3) Foul smelling lochia.
4) Urinary tract infection.
5) Respiratory tract infection.

In clinical examination, patient's general condition, pulse rate, temperature, blood pressure, cardio-vascular system, respiratory system, foul smelling lochia were studied. Follow up of patients was done according to the following criteria.

- Oral temperature record was maintained 6 hourly.
- Post-operative routine investigations - urine culture was sent on the morning following removal of catheter.
- Blood culture was to be sent if fever in any patient lasted for >96 hours (4days), in case of wound infection, culture swabs were taken and sent to laboratory.
- Vaginal swab was sent for culture in suspected cases of endometritis, in cases of febrile morbidity total count, differential count and ESR was done.
- Wound was inspected as per wound infection score on 3^{rd} and 4^{th} post operative day and after removal of sutures on 5^{th} day.
- The patient was discharged on 6^{th} post-operative day if no infection was present.
- Comparison between study and control group regarding all the above criteria was done by chi-square test where frequency variables were involved and student 't' test where continous variables were involved.

Statistical analysis :

- Results are expressed as Mean SD Range and number and percentages.
- Student's t-test was used for comparing means of two groups. Chisquare test was used for analyzing categorical data.

Results and Discussion

Table 1 Showing Type of LSCS done

Types of LSCS	Study (n = 100)	Control (n = 100)
Elective	18(18%)	20(20%)
Emergency	82(82%)	80(80%)

It was observed that majority of caesarean section done were emergency both in study and control group

Table 2 Showing Indications for caesarean section

Indication	Study group (n = 100)	Control group (n = 100)
1. Foetal distress	46 (46%)	45(45%)
2. Previous LSCS with CPD	10	8
Not willing for VBAC	2	2
Gestational hypertension	1	-
Oblique lie	1	-
Breech presentation	1	1
Threatened scar rupture	1	2
3. Previous 2 LSCS	4	4
4. Mid pelvic contraction	1	-
5. Major degree CPD	5	2
6. PE with CPD	1	-
7. Brow presentation	3	2
8. Primi with breech presentation	6	5
9. Oblique lie	1	-
10. Face presentation	1	2
11. Transverse lie	1	4
12. Placenta praevia	3	2
13. Abruptio placente	3	2
14. Imminent eclampsia	2	3
15. Oligohydramnios	3	4
16. Precious pregnancy	1	-
17. Failed induction	2	3
18. PPROM with unfavourable cervix	1	1
19. PROM	-	1
20. Twins	1	-
21. Deep transverse arrest	1	1
22. Failure to progress	-	4
23. Cord prolapse	-	2

The numbers also show the percent as the total number taken were 100 both in study and control group.

It is evident by the table that majority of the cases had indication of foetal distress, study group (46%) and control group(45%) followed by

Previous lscs with cpd,study group(10%) control group(8%).

Form the table 3 it is clear that purulent exudate and wound separation were found in > 80% of the cases of wound infection.

From the table 4 it can be seen that the morbity was more in emergency caesarean section group, study group with 12.2% and control group with 20%, highlighting the advantage of use Prophylactic antibiotic.

The table 5 shows clearly shows that lesser wound score was seen in both study group (96%) and controlgroup(87%), however the control group had more number of subjects (8%) in the higher score range of 4-12, and the sudy group did not show that trend.

From the table 6 it is clear that post operative morbidity was more in control group 32 (32%), as compared to only 12(12%) in study group.

Also it is clear that wound infection was the commonest morbidity in control group (40%).

From the table 7 it can be seen that more number of subjects (25%) in the control grouop required additional antibiotics to manage post operative morbidity.

Disscussion :

Puerpereal infection remains the common problem of any surgery in pregnancy. Prevention of infection is far more practical than treatment when they are established.

Advances in surgery and sophisticated life-saving procedures make it essential to pay particular attention to the prevention of infection. Previously, the use of prophylactic antibiotics in surgery was controversial for some time. But various studies have clearly proved that there is a definitive role of prophylactic antibiotics in surgery (like Parulekar et al, Chelmow et al)[1,2]. The primary aim of perioperative antibiotic is to reduce the infection and thereby reduce morbidity and mortality.

Study by Parulekar et al (2001)[1] had included both elective and emergency caesarean section in their studies, whereas studies by Chelmow et al (2004)[7], Ahmed et al (2004)[7] and Baqratu et al (2002)14 included only elective caesarean section in their studies.

Faro et al (1990)[15], Eliot et al (1986)[16], Kristensen et al (1990)[17] and Mansue et al (1989)[18] had included only

Table 3 Showing the Wound infection score used in the study

Wound characteristics	Proportion of wound infected (%)					
	0	**< 20**	**20-39**	**40-59**	**60-79**	**> 80**
Serous exudates	0	1	2	3	4	5
Erythema (>5mm from the edge of the incision)	0	1	2	3	4	5
Purulent exudates	0	2	4	6	8	10
Separation of deep tissue	0	2	4	6	8	10

emergency caesarean section in their studies.

In our study, both emergency and elective caesarean sections have been included.

All the studies including the present study showed single dose to be more efficacious in prevention of febrile morbidity, except in the study by Saltzman (1986) which showed better results with multiple doses antibiotic therapy compared to the single dose prophylaxis.The percentage of urinary tract infections was calculated and compared with other studies.[13]

The rate of post partum endometritis in study group when compared to control group in different studies showed significant difference in most of the studies. This present study also showed statistically significant difference of incidence of endometritis ($p < 0.05$) between two groups.

Incidence of wound infection in both study and control groups have been studied and compared with other available studies. In the present study wound infection was significantly low (Chi-square test=5.21, p value<0.05) in the study group.

In the present study, the difference of overall morbidity between the two groups is statistically significant (p value is<0.05); whereas in Von Mandach study there was no statistically significant difference.[12]

The cost effectiveness of the treatment in both groups was compared. Single dose antibiotic has been found to be more economic. In an economic review by Chelmow (2004) revealed a significant reduction in overall cost of treatment (30$) in the study group7.

Prophylactic single dose Cefepime has better postoperative outcome as compared to routine antibiotic therapy probably due to its administration in the per-operative period and its broader spectrum of action.

Febrile morbidity, urinary tract infection, endometritis, wound infection as also overall postoperative morbidity showed promising results.

It also reduces the hospital stay and thus reducing the financial burden on health care system.

Injection Cefepime did not produce any significant side effects in this study group.

This study failed to identify side effects of this drug probably due to small sample size.

This study should be continued, as large sample size will help to give a statistically significant difference between two groups in respect to overall postoperative morbidity and side effects of the drug. The post operative infections in both study and control groups required administration of other antibiotics by oral or intravenous route namely Ciprofloxacin, Norfloxacin, 2nd dose of Cefepime, injection Amikacin

These additional drugs were given in 10% of cases in the study group and 25% of cases in the control group. ($P < 0.01$) which is statistically significant.

Second dose of cefepime had to the repeated in two cases in the study group.

Table 4 : showing Morbidity patterns in study and control groups

Type of LSCS	Study group (n = 12) (%)	Control group (n = 32) (%)
Elective	2 (11.1 %)	7 (35 %)
Emergency	10 (12.2 %)	25 (20 %)

Table 5 : Wound infection score

Wound infection score	Study group (n=100)	Control group (n=100)
0	96(96%)	87(87%)
2	2(2%)	3(3%)
4 – 12	-	8(8%)
20	2(2%)	2(2%)

Conclusion

Single dose cefepime prophylaxis has shown many advantages over the control group as follows;

Cefepime significantly reduced post-operative morbidity. Cefepime prophylaxis was more cost effective. Cefepime reduced the hospital stay of the patients.

Cefepime has no major side effects. It was easy to prepare and administer than multiple doses of antibiotics. Thus it is concluded that the single dose cefepime prophylaxis in caesarean section can be widely applied in routine practice.

Table 6 : showing the Comparison of morbidity indices in both groups

Morbidity	Study Group (n = 12)		Control Group (n = 32)	
	No. of cases	Percent -age	No. of cases	Percent age
1) Urinary tract infection	4	4(30%)	6	6(18.7%)
2) Wound infection	4	4(30%)	13	13(40%)
3) Foul smelling lochia(endometritis)	-	-	4	4(12%)
4) RTI	4	4(30%)	6	6(18.7%)
5) Only fever	-	-	3	3(9.37%)

Table 7 : Showing Additional drugs given

Groups given	No. of cases additional drugs
Study	10%
Control	25%

$(X^2 = 7.79, P < 0.01)$,

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