SINGLE-DOSE CEFAZOLIN PROPHYLAXIS IN ELECTIVE LSCS- A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

BACKGROUND

Surgical site infections are the most common nosocomial infections. Postoperative complications, especially surgical site infections can double the length of time a patient stays in hospital and increase the cost of healthcare. Antibiotic prophylaxis before surgery has evolved over last twenty years and is definitely valuable to reduce postoperative wound infection. Obstetric surgeries are considered as clean contaminated wounds where antibiotic prophylaxis has proven beneficial in preventing postoperative complications, antibiotic resistance and economic burden. But, in countries like India, even a large group of obstetricians are reluctant to follow it. Hence, this study was conducted.

The aim of the study is to study the effectiveness of single-dose cefazolin prophylaxis in preventing postoperative complications in patients undergoing elective cesarean compared to postoperative antibiotics.

MATERIALS AND METHODS

This was a prospective observational study conducted in the Department of Obstetrics and Gynaecology, Medical College, Kottayam, from January 2014-December 2014. After obtaining permission from the hospital ethical committee for research, hundred patients undergoing elective cesarean in our hospital were selected for the study using strict inclusion and exclusion criteria of which fifty patients received injection cefazolin 2g intravenously one hour before surgery. Remaining fifty patients who were matched for age, parity and body mass index were given cefotaxime and metronidazole pre and postoperatively. All these patients were followed up postoperatively for complications, antibiotic change and duration of hospital stay. Statistical analysis done using suitable software.

RESULTS

Complications were comparable in those receiving prophylactic cefazolin and those receiving postoperative antibiotics. Both groups required antibiotic change for complications. Patients requiring prolonged hospital stay was comparable in both the groups. Surgical site infections was the commonest cause of prolonged hospital stay.

CONCLUSION

Antibiotic prophylaxis with cefazolin is as effective as postoperative antibiotics in preventing postoperative complications in a major referral centre in India. Hence, antibiotic prophylaxis should be preferred in uncomplicated surgeries as it reduces patient's morbidity, antibiotic resistance and workload of hospital staff.

KEYWORDS

Antibiotic Prophylaxis, Cefazolin, Single Dose, Surgical Site Infections, Hospital Stay, Antibiotic Resistance, Elective Caesarean.

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BACKGROUND

Surgical procedures especially caesarean sections have been consistently increasing over the last few decades. The increasing trend in caesarean sections have been due to the advances in foetal as well as maternal surveillance methods and also there is an increasing demand for caesarean section.

Major concern about the increasing caesarean section rates is that postoperative complications are also showing an increasing trend. Despite the advances made in asepsis, antimicrobial drugs, sterilisation and operative techniques, Surgical Site Infections (SSI) continue to be a major challenge in all branches of surgery in hospitals.[1] They have been responsible for the increasing cost, morbidity and mortality related to surgery and continue to be a major problem even in hospitals with the most modern facilities and standard protocols of preoperative preparations and antibiotic prophylaxis.

According to Centre for Disease Control (CDC), National Nosocomial Infection Surveillance System reports SSIs are

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the third most frequently reported nosocomial infection.[2] SSI can double the length of time a patient stays in a hospital and increase the costs of healthcare. Additional costs attributable to SSI of between $814 and $6626 have been reported depending on type of surgery and severity of infection.[3] Additional costs are related to reoperation, extra nursing care and intervention, and drug treatment costs. Indirect costs due to loss of productivity, patient dissatisfaction and litigation and reduced quality of life have been studied less extensively.

Obstetric surgeries belong to clean contaminated group and risk of infection with aerobic and anaerobic bacteria without prophylaxis is about 10-34% for caesarean section.[4]

The reason for increased infectious morbidity are-

1. Genitourinary system has normal bacterial flora that can turn pathogenic.
2. Skin incisions for LSCS (lower segment cesarean section) are placed 2.5-3 cm above public symphysis, which is less vascular.
3. Genital tract has open access through vagina by which ascending infections can occur early.[5]

The single most common reason for puerperal sepsis is caesarean section.[6]The common infections seen are urinary tract infection, endometritis, wound infection, perineal infection and sepsis. Numerous studies have investigated the use of prophylactic antibiotics to reduce these complications, but they vary in type of antibiotic, dosage schedule and route of administration. There is level 1 evidence to prove that a single preoperative dose of antibiotic is as effective as a full five-day course of antibiotic therapy and it should be administrated within one hour prior to incision.[7] Cefazolin provides adequate coverage for procedures, which do not involve gastrointestinal tract.[8]

Numerous clinical trials have demonstrated a reduction in risk of wound infection or endometritis by as much as 70% in patient undergoing caesarean section. These studies differ in their timing of drug administration that is before surgical incisions or after cord clamping. They also have not demonstrated a superior result with broad-spectrum antibiotics when compared with cefazolin. Therefore, cefazolin is the recommended agent.[9]

Despite, several studies showing the efficacy of antibiotic prophylaxis, most surgeons are reluctant to depend on single-dose antibiotic prophylaxis alone. The usual practice is to start antibiotics in low dose preoperatively and to continue postoperatively for 5-7 days. This maybe due to overcrowding in wards, malnutrition, poor hygiene of our patients, as well as suboptimal sterilisation techniques, theatre facilities, surgical techniques and skills.

If single-dose antibiotic prophylactically is better than postoperative antibiotics (cefotaxime and metronidazole) in reducing postoperative infections, it should be advocated as-

1. It will reduce hospital stay and hence morbidity of patient.
2. It is more economical and has implications in policy making.
3. It reduces workload for hospital staff.
4. It reduces development of antibiotic resistance.

Many studies have been conducted abroad comparing cefazolin with other drugs as antibiotic prophylaxis, but none has compared antibiotic prophylaxis with postoperative antibiotics. Moreover, studies are lacking in India. Hence, this study aims to compare the outcome in patient undergoing elective LSCS after receiving antibiotic prophylaxis as opposed to those receiving antibiotics postoperatively for 5-7 days in a Tertiary Care Government Institution in Kottayam District of Kerala State, India.

Objectives- To study the effectiveness of single-dose cefazolin as antibiotic prophylaxis in elective cesarean compared to postoperative antibiotics. Outcomes analysed were postoperative complications, need for change of antibiotics and duration of hospital stay.

MATERIALS AND METHODS

- Study design -Prospective observational study.
- Study period - 1 year.
- Study procedure.

Prior to study approval obtained from institutional ethics committee, informed written consent obtained from study participants before data collection and assurance given to maintain anonymity. Hence, no ethical issues in this study. Patients undergoing elective LSCS for indications like previous LSCS, prime breech, twins with 1st non-vertex were selected for the study using the following inclusion and exclusion criteria.

Inclusion Criteria

Patient posted for elective LSCS in the Department of Obstetrics and Gynaecology without any comorbidities that is other systematic illness like diabetes, anaemia, bronchial asthma, COPD and heart disease.

Exclusion Criteria

- Complicated pregnancies - preeclampsia; diabetes mellitus with pregnancy.
- Systemic disease like chronic liver disease, renal disease, heart disease.
- Body mass index >30 vertical incisions needed for LSCS.

Study Tools

- Proforma for data collection.
- Clinical examination.
- Case record.

Procedure

The study group will be divided into 2 groups.

- Group 1 - Patient receiving single prophylactic dose of IV cefazolin 2g 1 hour before surgery.

- Group 2 - Age and BMI matched patient who received intravenous cefotaxime and metronidazole pre and postoperatively for 5-7 days.

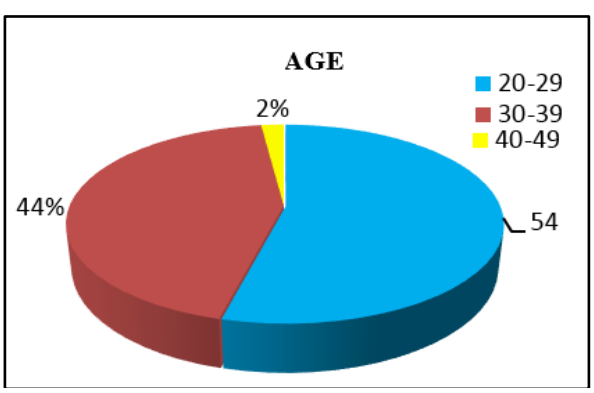
Each patient is followed up till discharge. On postoperative follow up, the outcomes analysed are-

1. Postoperative fever/febrile morbidity defined as temperature of >100.4°F recorded on at least two occasions 6 hours apart excluding first 24 hours after surgery.
2. Surgical site infection- In the first postoperative week diagnosed using following criteria-
   a) Purulent discharge (culture not required).
   b) Organism isolated from fluid/tissue of superficial incision.
   c) At least one sign of inflammation (induration, erythema, local rise of temperature).
   d) Wound deliberately opened by surgeon for drainage.
   e) Treating surgeon declares the wound is infected.
3. Urinary tract infection when patient complains of dysuria and there is presence of pus cells in urine routine examination.
4. Respiratory tract infection- patient has productive cough and confirmation by sputum culture not needed.
5. Addition of a new antibiotic for treating fever, respiratory infection, urinary tract infection or SSI.
6. Prolongation of hospital stay- either due to infection or for the completion of antibiotic course added due to postoperative infection.

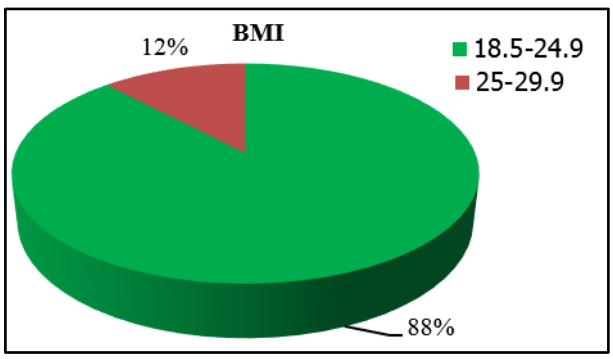
Analysis- After completion of data collection, it was coded and entered into Microsoft Excel and transferred to SPSS 16 software. Association between variables tested with 'Chi-square test' and 'Fischer's test.' Level of significance taken as 'p' value <0.05 and highly significant of p<0.01.

RESULTS

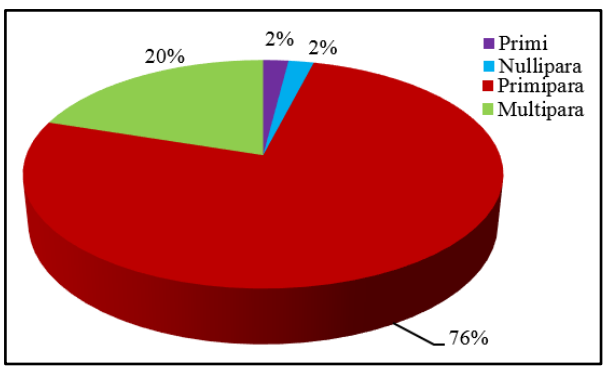
Hundred pregnant ladies who underwent Lower Segment Caesarean Section (LSCS) with/without sterilisation were taken for the study, out of which, 50 patients received cefazolin prophylaxis and the next 50 patients who are age and BMI matched were given cefotaxim postoperatively.



Graph 1. Distribution According to Age



Graph 2. Distribution According to BMI



Graph 3. Distribution According to Parity

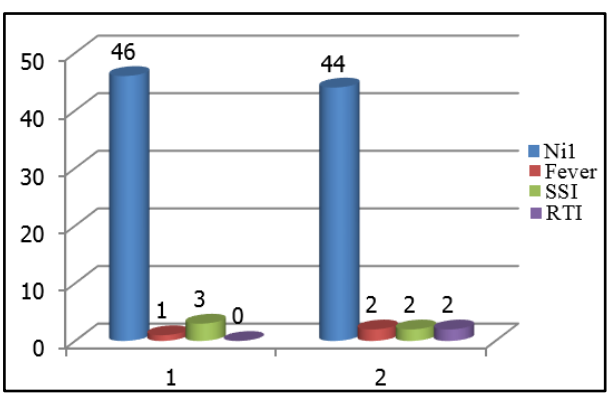
Complication	Frequency
Nil	90
Fever	3
SSI	5
RTI	2
Total	**100**

Table 1. Postoperative Complications

Ten patients among the hundred, developed complications, as seen in the above table.

Coming to the analysis, whether cefazolin prophylaxis or cefotaxime postoperatively is better in preventing postop complications, see Table 2.

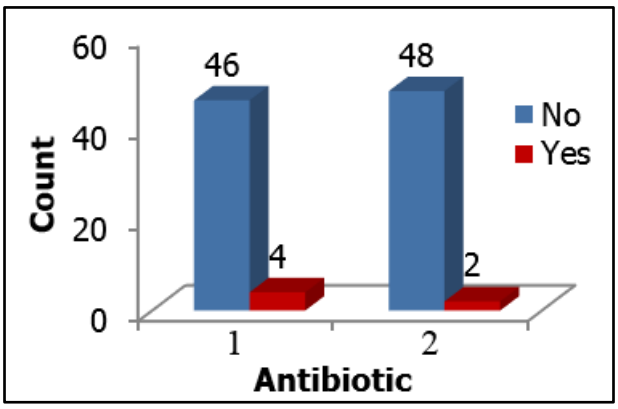
92% of patients who received cefazolin had no complications. 2% developed fever and 6% SSI. Among the cefotaxime group, 88% had no complications, but 4% each developed fever, SSI and RTI. Statistically, this is insignificant as the Chi-square is 2.578 and 'p' value is 0.461.



Graph 4. Antibiotic * Complication Cross Tabulation

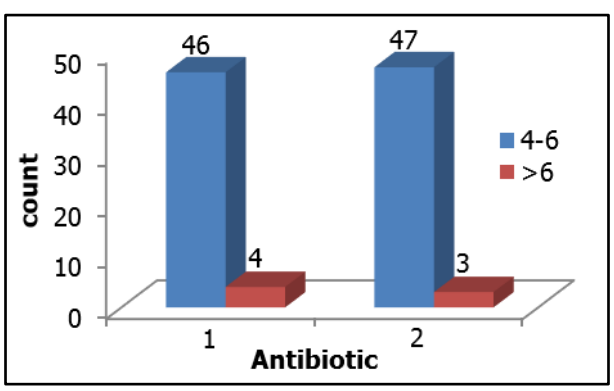
Antibiotic	Complication				Total
	Nil	Fever	SSI	RTI	
Group 1 cefazolin prophylaxis	46	1	3	0	50
Group 2 cefotaxime postoperative	44	2	2	2	50
Total	**90**	**3**	**5**	**2**	**100**

Table 2. Antibiotic- Complication Cross Tabulation



Graph 5. Antibiotic * Antibiotic Change

Four patients in the cefazolin group required antibiotic change, whereas only 2 patients in the cefotaxime group had antibiotic change, i.e. 8% and 4%, respectively. But, there is no significance statistically, Chi-square being 0.709 and 'p' value 0.40. The Fisher's exact test is 0.678.



Graph 6. Antibiotic * Discharged on POD

Seven patients had prolongation of hospital stay after the surgery due to the development of complications. Of this, 57.1% belonged to the cefazolin group and 42.9% to the cefotaxime group. Among the cefazolin group, 8% had prolongation of hospital stay, whereas the cefotaxime had only 6%. But, the Chi-square being 0.154 and 'p' value 0.695. The Fisher exact test is 1.0. There is no statistical significance in the prolongation of hospital stay and the antibiotic administered.

Complication	Discharged on POD		Total
	4-6	>6	
Nil	90	0	90
Fever	1	2	3
SSI	0	5	5
RTI	2	0	2
Total	**93**	**7**	**100**

Table 3. Complication *Discharged on POD

It is evident that none of the patients who developed no complications had prolongation of hospital stay, whereas all the 5 cases of SSI (100%) were discharged after the 7th postop day. Two patients out of the 3 who developed fever, i.e. 66.67% had prolongation of hospital stay. This is statistically very significant as 'p' value is 0.00 and Chi-square 89.759.

DISCUSSION

Choice of parenteral prophylactic antibiotics and route of administration have become standardised on the basis of well-planned prospective clinical studies.

The recommendation is to use a single dose of cephalosporin such as cefazolin intravenously half to one hour before incision for clean contaminated surgeries and elective clean procedures involving a foreign body. Additional doses are recommended when the operation lasts longer than 2-3 hours.[10]

There is great difference between prophylactic and empiric therapy. Prophylactic antibiotic must cover the most likely contaminating organisms and must be present in tissues when initial incision is made. Therapeutic concentrations should be maintained throughout the procedure. Empiric therapy is the continued use after the operative procedure based on intraoperative findings. Inappropriate prophylaxis involve unnecessary use of broad-spectrum agents and continuation of therapy beyond the recommended time period. These practices increase the risk of adverse effects and promote the emergence of resistant organisms.[11]

Cefazolin is a first generation cephalosporin and is a pregnancy category B drug. It provides good coverage of gram-positive and has modest gram-negative coverage. US Center for Disease Control recommend it at a dose of 1-2 g IV not more than thirty minutes before skin incision.[12]An additional dose if blood loss exceeds 1500 mL or at 4 hours, if procedure lasts more than four hours.[13]

A total of 100 patients who underwent elective caesarean were taken for the study. Half of the patients received cefazolin prophylaxis and other half received cefotaxime pre and postoperatively. The age group distribution was 54% between 20-29 years, 44% between 30-39 years and 2% between 40-49 years. The ladies in the 2nd and 3rd decades of life are coming with pregnancy and the proportion is comparable. In our study, shift towards older age group was noted. More and more women are career oriented in Kottayam, which is the first district in India to achieve 100% literacy and hence get married late. Also, ours being a tertiary care centre, more infertility treated patients are there who are in the third decade of life.

BMI distribution of the study group shows 88% in the normal range 18.5-24.9 and only 2% in the pre-obese

range, i.e. 25-29.9. This is because women with BMI >30 have been excluded from the study. BMI will influence the outcome of surgery by increasing the rates of SSI.[14,15] When we take the parity distribution, 2% were primigravida, 2% nullipara, 76% primipara and 20% multipara. This was because majority of caesarean was done for previous caesarean. The primary cesarean rates of our institution are well below the WHO recommendations.

Postoperative complication rate in this group was 10% of which SSI contributed to 5%. This was much less than obtained in other studies.

Our Study	Yalcin N et al,[16] Turkey	Starling C E et al,[17] Brazil	Eltahawy AT et al,[18] Saudi Arabia
5%	0.3%	11.6%	18.3%

Table 4. Incidence of SSI in Various Studies

In a study in Lady Harding Medical College, Delhi, in India where post discharge surveillance was also included, infection rate was 24.2%.[19] Post discharge surveillance was beyond the scope of our study because our hospital is a tertiary referral care centre that caters to five districts of central Kerala and border districts of Tamil Nadu. Hence, post discharge surveillance requires more resources in the form of personnel and money.

In this study, complications that were followed up were postoperative fever, SSI, UTI and RTI. An incidental finding was the occurrence of thrombophlebitis in 2 patients who belonged to the cefotaxime group. This was due to detainment of cannula beyond first postoperative day. With appropriate surgical techniques and aseptic precautions, use of antibiotic prophylaxis can reduce morbidity of patients.

Though statistically not significant, cefazolin group contributed to 8% of total complications only and cefotaxime group to 12%. Of the total SSI developed in this group, 60% was in cefazolin group and 40% in cefotaxime group. Four patients in cefazolin group required antibiotic change, while only two patients in cefotaxime group had antibiotic change. This was not significant statistically, but it is to be noted that there was prompt addition of antibiotic in the cefazolin group, but in the cefotaxime group, it was done a day later.

Seven patients had prolongation of hospital stay after surgery due to the development of complications. Of this, 57.1% belonged to the cefazolin group and 42.9% to the cefotaxime group. There is no statistical significance in the prolongation of hospital stay and the antibiotic administered. But, it was seen that patients with no complications had a usual postoperative hospital stay. Five cases of SSI (100%) were discharged after the 7th postoperative day. Two out of the three who developed fever (66.67%) had prolonged hospital stay. This is statistically very significant. Similar findings are seen in many studies, which shows that development of postoperative complications have doubled hospital stay and increased expenditure.[20]

To summarise, rate of SSI in the study group was 5%, postoperative fever 3% and respiratory infections 2%. There is no statistically significant difference in the development of complications between the two study groups. Postoperative complications are an important cause for prolongation of hospital stay. Risk of thrombophlebitis is more in those receiving postoperative antibiotics.

In a busy tertiary care centre, antibiotic prophylaxis helps in reducing workload of hospital staff. Administration of cefazolin being cheaper has implications in policy making. Antibiotic prophylaxis helps in reducing the emergence of resistant microorganisms.

CONCLUSION

Antibiotic prophylaxis has long been established as effective in preventing postoperative complications, especially SSI. The reluctance to depend only on prophylaxis is due to limitation of sterilisation techniques, theatre facilities, aseptic precautions and surgical skill. This study proves that cefazolin prophylaxis is as effective as postoperative antibiotics in preventing postoperative complications. Postoperative antibiotics should not be an excuse for laxity in aseptic precautions and surgical techniques.

Recommendations

1. Antibiotic prophylaxis should be preferred in uncomplicated surgeries.
2. All hospitals should have a protocol regarding administration of antibiotic prophylaxis and antibiotic policy that should be strictly followed.
3. Postoperative antibiotics should be given if there are complications intra or postoperatively.
4. Preparation of incision site should be done on the day of surgery, preferably by clipping.
5. Patients should be advised to take bath preoperatively and postoperatively using soap-containing chlorhexidine.
6. Vaginal packs soaked in povidone-iodine can be kept prior to surgery at the time of catheterisation to prevent ascending infections from vagina.
7. Strict adherence to aseptic techniques and minimal tissue handling during surgery.

Limitations

1. Post discharge surveillance was not done in this study.
2. Matching patients with respect to operating surgeon could not be done.

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