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Role of Prophylactic Antibiotic (Cefotaxime) In Elective Surgical Procedures

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Abstract

Introduction: The role of prophylactic antibiotics in elective surgical procedures in preventing surgical site infections has been well documented, however, their need continues to be ambiguous.

Aim: To evaluate the role of prophylactic cefotaxime therapy in the prevention of surgical site infection in elective surgery and its side effects

Materials and Methods: 100 patients undergoing elective surgery were enrolled in the study after taking informed consent. They were divided into two groups of 50 each. Group A patients (control group) did not receive any preoperative, intraoperative or postoperative antibiotics whatsoever, and Group B patients (study group) received a single dose of intravenous cefotaxime half and hour prior to the induction of anaesthesia. The severity of wound infection was graded according to Robertson's Classification into grades 0-IV. Culture and sensitivity was done for the presence of pus.

Results: Of the 100 patients in the study, 7% patients developed surgical site infection. However with the administration of prophylactic antibiotics the rate of post-operative infection fell from 7(14%) to 0% (p<0.001). The duration of hospital stay was prolonged in patients that did not receive prophylactic antibiotics.

Conclusion: The use of cefotaxime as a prophylactic antibiotic is a cost effective method in preventing wound infection following clean, elective surgical procedures.

INTRODUCTION

Surgical site infections (SSIs), defined objectively by the Centers for Disease Control (CDC) as infections occurring after surgery in the part of the body where the surgery took place, still represent a major factor of patients' mortality and morbidity.[1] Furthermore, health care costs are doubled by SSIs and the length of hospital stay increased by an average of 7 days. For these reasons, the importance of perioperative antimicrobial prophylaxis has been well established. Antimicrobial prophylaxis (AP) plays an important role in reducing SSIs, especially if patient-related risk factors such as comorbidities (i.e., poor nutritional status, diabetes, immunosuppression), coexistent remote body-site infections, length of preoperative hospitalization, and microbial colonization are present.[2,3]

There are 3 basic factors which act singly or in combination for the development of post-operative wound infection They are a) bacterium inoculum of sufficient numbers as well as necessary virulence, b) a local substrate upon which contaminating microbes can live, c) some impairment, be it local or systemic in host resistance.[4,5] Various measures to control the post-operative infection are directed at these 3 factors.[6-9] Low infection rates are best obtained by observing strict asepsis in the wards and operation theatres and by strict adherence to the principles of good surgical technique involving gentle handling of tissues that curbs the amount of clot and cellular necrosis that may serve as nutrition to any bacterial inoculum.

The role of prophylactic antibiotics is to increase local tissue resistance against the majority, if not all, of invading pathogens.[10-12] The merits and demerits of prophylactic antibiotics in surgery have been hotly debated for the last four decades. Well controlled prospective blind studies have outlined many of the areas in which antibiotic prophylaxis is of real benefit as well as those clinical situations in which risk of antibiotic prophylaxis outweigh their expected usefulness due to their potential harmful effects.

Cefotaxime, a third generation cephalosporin is a potent, broad spectrum antibacterial agent. It is highly effective against a broad range of organisms including gram negative bacteria. It is an ideal peri-operative prophylactic antibiotic with minimal side effects.[11] Cefotaxime's broad spectrum and high bactericidal activity against gram negative anaerobes plus the activity of its metabolite, desacetylcefotaxime (which is active against gram-negative anaerobes in general and Bacteroides fragilis in particular) make cefotaxime ideally suited for use in prophylaxis in the area of surgical intervention.[51] Cefotaxime is rapidly and more completely absorbed after intramuscular or intravenous administration and produces maximum serum level within 0.5-1 hour. Serum half-life of cefotaxime is approximately 1-2 hrs.[11]

This study would aim at evaluating the efficacy of Cefotaxime as a prophylactic pre-operative antibiotic.

MATERIAL AND METHODS

Hundred cases were picked up at random from surgical wards of Rajindra Hospital, Patiala undergoing routine, elective surgery. The patients were divided into A and B.

Group A was comprised of 50 cases. No antibiotics were given to these patients during pre-operative, intra-operative, and post-operative period. These cases formed the control group.

Group B also included 50 cases. In each case one pre-operative dose of cefotaxime 2 gms was administered intravenously half an hour before induction of anaesthesia. These patients formed the study group.

A detailed history, clinical examination and investigations was carried out in all the cases.

To assure standardization of valid sampling following criteria were established for exclusion from study groups.

(a) Concomitant infectious process related or unrelated to surgical procedure contemplated.
(b) Gross contamination of operation site at the time of surgery.
(c) Diabetes, steroid therapy and other factors predisposing to infections.
(d) Administration of systemic antibiotics within a week prior to surgery.
(e) Any known sensitivity to cephalosporins.

Only those cases were included in whom operative wounds produced were clean as classified by National Academy of Sciences (1964), excluding emergency procedures.

Pre-operative preparation

The operative site was shaved on the evening before operation. All the patients were asked to take bath the same evening

Operation theature

The first dose of antibiotic was given ½ hour prior to induction of anaesthesia by intravenous bolus. The site of operation was prepared by painting with 10% povidine iodine (Betadine) solution which was allowed to dry up. Sterilized sheets draped. During operation full asptic measures were taken in all cases. The duration of operation was noted. After the operation, the wound was immediately covered with sterile gauge and sealed.

Post-operative care

No other antibiotic was given in the post-operative period. The wound were first inspected on the third post-operative day after which the wounds were kept exposed and inspected daily till removal of stitches. The Severity of wound infection was graded according to Robertson's Classification (1958) into the following grades:

Grade 0: No infection.

Grade I: Minimal infection-redness about a stitch.

Grade II: Pustule about a stitch or minor infection of wound edges without separation and with no systemic reaction.

Grade III: Frank infection of a relatively small portion of wound with purulent discharge and some systemic reaction

Grade IV: Frank infection usually with systemic reaction or dehiscence of wound.

For statistical purposes we did not include Grade I and Grade II infections as antibiotic is not required in Grade I and II infections.

Culture and sensitivity was done only in the presence of pus i.e. for infection of grade 2, 3 and 4.

Details of records were kept as per proforma attached with the plan.

SAMPLE SIZE: 97

Sample size calculation: Formula for calculating sample size**:**

N = N*X / (X + N – 1),

where**,**

$X = Z_{A/2}^2 * P * (1-P) / MOE^2$,

And $Z_{A/2}$ is the critical value of the normal distribution at A/2 (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), MOE is the margin of error, P is the sample proportion, and N is the population size.

N=2890

P=7%

MOE=5%

SO, N= 97

To reduce the margin of error sample size is taken as 100 (50 each in both groups).

STATISTICAL ANALYSIS:

Data collected will be entered into MS-Excel 2013 spreadsheet. The collected data will be analyzed using IBM Statistical Package for Social Sciences (IBM SPSS) Version 22 software will be reported in terms of frequency tables, mean, percentage, bar diagram and pie chart. Chi-square test (fisher's exact test wherever applicable) will be applied to find the association between variables and p-value less than 0.05 will be considered statistically significant.

RESULTS

Out of a total 100 cases, 17 patients developed wound infection post-operatively, giving an infection rate of 17%. In 5 cases, as the severity of infection was Grade I and in 5 cases Grade II infection was seen, and were excluded, hence the infection rate can be considered to be 7%. In Group A, 12 out of 50 patients developed wound infection (24%). In Group B, 5 out of 50 patients developed wound infection (10%). Total incidence of surgical site infection is found to be statistically insignificant (p=0.062) on comparing both the groups. [Table 1]

7 patients developed severe infection (Grade IV) All the patients belonged to group A. Significant SSI (Grades III and IV) was compared and the result was statistically significant (p=0.012), meaning that prophylactic antibiotics reduced the incidence of significant SSI in our series. Antibiotic prophylaxis also reduced the severity of SSIs. (p=0.0003) [Table 2]

There were 40 males and 60 females included in the study. In group A, out of 21 males, 3 got infected, giving the SSI rate of 14.29% and out of 29 females, 9 got infected, giving the SSI rate of 31.03 percent. In group B, 1 out of 19 males got infected, giving the rate of 5.26% and 4 out of 31 females got infected, giving the SSI rate of 12.90%. Antibiotic prophylaxis has no effect on the relation of sex with SSI in both groups (p=0.67) [Table 3]

The age range for the patients varied between 10-75 years. Majority of the patients were in the age group of 30-49 years. The incidence of wound infection rises consistently as the age advances. There were 4 cases above the age of 61 years and 2 out of these got wound infection (50%). We found that that the incidence of SSI increases with age in both groups, regardless of antibiotic prophylaxis (p=0.1) [Table 4]

The maximum surgical site infection rate was seen following MRM (33.3%) followed by laparoscopic cholecystectomy (26.4%) followed by thyroidectomy (25%) and hernia (18.75%). The infection rate in interval appendicectomy was 28%. The results were statistically insignificant (p=0.272), meaning that the distribution of SSIs in both the groups in relation to the type of surgery was similar. [Table 5]

When the operation time is more than 60 minutes, the infection rate rises steeply as compared to when the operation was completed in less than 60 minutes. Thus, infection rate rises in direct proportion to the duration of the operation, in both groups. (p=0.337) [Table 6]

The infection rate was increased when the wound was drained. In Group A the infection rate was 12% when the wound was not drained as compared to 36% when the wound was drained. In Group B the infection was 0% when the wound was not drained as compared to 21.74% when the wound was drained. SSI rate increased when the wound was drained in both the groups. (p=0.515) [Table 7]

47 patients were found obese as per height-weight-frame standard. Infection rate amongst the obese was 27.27% and 4% in groups A and B respectively, thus, being significantly higher in the obese. On comparing both groups the result was significant (p=0.025), showing that antibiotic prophylaxis reduced the incidence of SSIs. [Table 8]

In majority of the patients the pre-operative stay was less than 2 days. It has been found that the infection rate doubles if the pre-operative hospital stay is prolonged. The incidence of SSI in relation to preoperative stay was similar in both the groups. (p=0.113) [Table 9]

Out of 100 patients, 77 were discharged before 10 days of their post-operative stay. Few patients had to be detained because of wound complications. 13 cases had to be kept for more than 10 days because of their wound infection. Post-operative stay increased with the incidence of SSIs in both the groups. (p=0.518) [Table 10]

The commonest organisms were E coli. Patients who developed deep seated wound infection belonged to group A. Out of the 7 severely infected, one case had burst abdomen on the 7th postoperative day. In this case no growth of organisms was obtained. [Table 11]

TABLE 1: TOTAL INCIDENCE OF SURGICAL SITE INFECTIONS

Group	**No of patients**	**No. of Patients with SSI's**	**%age**
Group A	50	12	24
Group B	50	5	10
P value	0.062		

Table 2: **SEVERITY OF SURGICAL SITE INFECTION**

Grade of Infection	**Group-A**		**Group-B**	
	No. of Patients	**%age**	**No. of Patients**	**%age**
0	38	76.00	45	90.00
I	4	8.00	1	2.00
II	1	2.00	4	8.00

III	0	0.00	0	0.00
IV	7	14.00	0	0.00
Total	50	100	50	100
p value	0.0003			

Table 3: **RELATION OF SEX OF THE PATIENT WITH SURGICAL SITE INFECTION**

Gender	Group-A			Group-B		
	Total No. of Patients	**No. of Patients with SSI's**	**%age**	**Total No. of Patients**	**No. of Patients with SSI's**	**%age**
Male	21	3	14.29	19	1	5.26
Female	29	9	31.03	31	4	12.90
P vlaue	0.670					

Table 4: **PERCENTAGE OF INFECTED CASES WITH RESPECT TO AGE IN BOTH THE GROUPS**

Age Groups (in years)	Group-A			Group-B		
	Total No. of Patients	**No. of Patients with SSI's**	**%age**	**Total No. of Patients**	**No. of Patients with SSI's**	**%age**
10-29	9	0	0.00	9	0	0.00
30-49	25	4	16.00	22	0	0.00
50-69	15	7	46.66	16	3	23.07
>69	1	1	100.00	3	2	66.66
p value	0.100					

Table 5: **INCIDENCE OF SURGICAL SITE INFECTION RELATED TO THE TYPE OF SURGERY**

DISTRIBUTION OF OPERATION

Procedure	Group-A			Group-B		
	Total No. of Patients	No. of Patients with SSI's	%age	Total No. of Patients	No. of Patients with SSI's	%age
Appendectomy	6	2	33.3	6	0	0.00
Fibroadenoma and lipoma excision	8	0	0.00	8	0	0.00
High Ligation	2	0	0.00	2	0	0.00
Laparoscopic Cholecystectomy	17	4	23.5	17	5	29.41
Lord's Plication	2	0	0.00	2	0	0.00
MRM	3	2	66.67	3	0	0.00
Hernia repair	8	3	37.5	8	0	0.00
Striping and ligations	2	0	0.00	2	0	0.00
Thyroidectomy	2	1	50.0	2	0	0.00
p value	0.272					

Table 6: **RELATION OF DURATION OF OPERATION AND SURGICAL SITE INFECTIONS**

Duration (in mins)	Group-A			Group-B		
	Total No. of Patients	No. of Patients with SSI's	%age	Total No. of Patients	No. of Patients with SSI's	%age
25-49	19	0	0.00	29	0	0
50-74	25	7	28.00	13	2	15.38
75-99	4	3	75.00	8	3	37.50
>99	2	2	100.00	0	0	0.00

p value	0.337

Table 7: **RELATION OF THE ABDOMINAL DRAIN WITH SURGICAL SITE INFECTION**

Drain Used	**Group-A**			**Group-B**		
	Total No. of Patients	**No. of Patients with SSI's**	**%age**	**Total No. of Patients**	**No. of Patients with SSI's**	**%age**
Yes	25	9	36.00	23	5	21.74
No	25	3	12.00	27	0	0.00
p value	0.515					

Table 8: **RELATION OF OBESITY WITH SURGICAL SITE INFECTION**

	Group-A (n=50)			**Group-B (n=50)**		
	Total No. of Patients	**No. of Patients with SSI's**	**%age**	**Total No. of Patients**	**No. of Patients with SSI's**	**%age**
Obesity	22	6	27.27	25	1	4.00
P value	0.025					

Table 9: **RELATION OF PRE-OPERATIVE STAY AND SURGICAL SITE INFECTION**

Preoperative Stay (in days)	**Group-A**			**Group-B**		
	Total No. of Patients	**No. of Patients with SSI's**	**%age**	**Total No. of Patients**	**No. of Patients with SSI's**	**%age**
1	29	2	6.90	37	0	0.00
2	12	4	33.33	12	5	41.67
3	8	5	62.50	1	0	0.00

4	1	1	100.00	0	0	0.00
p value	0.113					

Table 10: **POSTOPERATIVE DELAY IN DISCHARGING THE PATIENT**

Postoperative Stay (in days)	**Group-A**			**Group-B**		
	Total No. of Patients	**No. of Patients with SSI's**	**%age**	**Total No. of Patients**	**No. of Patients with SSI's**	**%age**
4-5	3	0	0.00	2	0	0.00
6-7	16	0	0.00	22	0	0.00
8-9	21	3	14.29	13	1	7.69
10-11	2	1	50.00	10	2	20.00
12-13	2	2	100.00	2	1	50.00
>13	6	6	100.00	1	1	100.00
p value	0.518					

Table 11: **BACTERIAL GROWTH PATTERNS IN WOUND CULTURE**

Culture of Pus	**Total No. of Cases**	**%age**	**Group-A**		**Group-B**	
			No. of Patients with SSI's	**%age**	**No. of Patients with SSI's**	**%age**
Esch. Coli.	2	11.77	2	4.00	0	0.00
Staph Aureous	1	5.88	1	4.00	0	0.00
Kleb. Pneumonie	1	5.88	1	2.00	0	0.00
No Growth	7	41.18	3	6.00	4	8.00
Culture Not Done	6	35.29	5	10.00	1	2.00

DISCUSSION

There is still dispute over the use of the prophylactic antibiotics in surgery though these are prescribed routinely in the surgical wards. Antibiotics are not used in many clean surgical operations, due to improved sterilization techniques. From the use of post-operative antibiotics, the trend nowadays is shifting more and more towards prophylactic antibiotics. Hence, only pre-operative prophylactic antibiotics are given and post-operative antibiotics are omitted altogether.

The infection rates as reported by different workers all over the world differ considerably. The variation in infection rate is due to different criteria for selection of the patients, grading of infection and antibiotics chosen.

Antimicrobial Prophylaxis (AP) In Different Clinical Settings

- Breast Surgery – The incidence of SSIs ranges from 1% to 30% with a prevalence of gram negative bacteria (40- 50%).[13,14] A higher incidence is reported in mastectomies,[15-17] in early reconstruction after mastectomy, chemotherapy, and/or local radiotherapy, in presence of implants, expanders or drainage and in reoperations. A lower incidence is reported in needle biopsies.[18] The most recent American report of NHSN[19] showed SSI rates ranging from 0.9% to 6.4%; European reports showed rates from 0.5-% and 4%. In 2007, antibiotic prophylaxis was reported from European studies[20] in 60-80% of mammoplasties and in 30% of mastectomies and more frequently in reports from the USA especially in case of prosthesis and drainage (90%)[20]
- Cholecystectomy – AP has been always recommended by the available guidelines in open cholecystectomy, whilst in laparoscopic cholecystectomy is still controversial because of the lower incidence of SSI.[21-24] Before the introduction of AP the incidence of SSI was 10-20%.[25] Data from recent US and European studies reported rates ranging from 0.2% to 1.7% and 0.4% to 6.8%, respectively.[19,26,27]
- Urological Surgery – No antimicrobial agent has proven to be superior for urologic procedures and various regimens have been evaluated including cephalosporins, fluoroquinolones, aminoglycosides, nitrofurantoin and trimethoprim-sulfamethaxozole.[28-30]
- Hernia – Inguinal hernia repair is classified as clean surgery and AP is not recommended since SSI following hernia repair are usually superficial and they successfully treated with drainage. Since the 90s, with the introduction of prosthetic materials, some authors supported AP and experimental studies prophylaxis showed a reduction of infection after placement of propylene mesh.[31-33] So far, there is no data showing an higher incidence of SSIs in hernioplasty compared to herniorrhaphy (repair without prosthetic material).[34] The incidence of SSI in this procedure is <2%.[35,36] But several studies reported an average incidence ranging from 4-10%.[37-39] The most recent US and European studies showed incidence between 0.7%-5.2% and from 0.3%-5.3% respectively.[26,27] A lower incidence of SSIs is described for laparoscopic hernia repair.[40] However recent studies confirmed a protective effect of AP in preventing SSI: a surveillance study conducted in Italy and Spain showed that 50% of surgeons used AP in hernia repair,[41] while in UK, AP was used by 90% of surgeons.[42]

Conclusion: The use of cefotaxime as a prophylactic antibiotic is a cost effective method in preventing wound infection following clean, elective surgical procedures.

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