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Study Comparing Two Step Vs Single Step Preoperative Antibiotic Prophylaxis for Prevention of Surgical Site Infection

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Running Title: Pre-operative Intra-incisional Antibiotic Infiltration

ABSTRACT:
Introduction and objectives: Wound infection is one of the major causes for increased post-operative morbidity. This study was aimed at evaluation of pre-operative intra-incisional antibiotic infiltration in prevention of surgical site infection and its comparative efficacy with pre-operative intravenous antibiotic therapy. **Material and methods:** A prospective comparative study on 150 subjects randomized into three groups of 50 patients: GROUP A: Prophylaxis by pre-operative intra-incisional infiltration of the third generation cephalosporin (Cefotaxime). GROUP B: Prophylaxis by intravenous antibiotics. GROUP C: Both intravenous and intra-incisional infiltration. The patients were followed on daily basis till the date of discharge and grading of wound condition done according to Southampton Wound Grading System and data analyzed statistically. **Results :** The range of age in study was 18 to 60 years. The no. of male and female patients was almost similar. The overall rate of SSI in this study was 12%. The Rate of SSI was maximum in Group B (20%) and least in Group C (4%). **Conclusion:** The overall rate of SSI reduced significantly in patients receiving both intra incisional and intravenous antibiotics as compared to others. The higher concentration achieved at the incision site by the intra-incisional route, making it a better mode of administering prophylactic antibiotics.

Keywords: Intra-incisional antibiotics, surgical site infection,preoperative prophylaxis.

I. INTRODUCTION

Wound infection is one of the major causes for increased post-operative morbidity. A recent prevalence study found that SSIs were the most common healthcare-associated infection, accounting for 31% of all HAIs among hospitalized patients.[1] The CDC healthcare-associated infection (HAI) prevalence survey found that there were an estimated 157,500 surgical site infections associated with inpatient surgeries in 2011.[2] NHSN data included 16,147 SSIs following 849,659 operative procedures in all groups reported, for an overall SSI rate of 1.9%.[3]Among many methods, the discovery of Penicillin antibiotic by Alexander Fleming is one of the major landmarks in this regard. Initially the antibiotics were administered post-operatively for a prolonged periods, subsequently it was discovered that antibiotics need to administered preoperatively for prophylaxis of wound infection. The effects of preoperative systemic antibiotics are limited due to various factors responsible for wound infection like age, operative procedure, coexisting illnesses etc. along with certain drawbacks associated with the use of systemic antibiotics like fibrin forming impervious layer around the incision site and systemic distribution and toxicity with antibiotics.

The search for alternative modes of administration of prophylactic antibiotics for the decrease in rate of wound infection is continuously going on. One amongst such methods is the intra-incisional infiltration of prophylactic antibiotics along the incision site. This method ensures a high concentration of the antibiotic at the incision site and it has also been proven to provide systemic cover by the absorption of the antibiotic from the infiltration site. The antibiotics were initially infiltrated along the incision site just before suturing the skin incision at the end of the procedure. Even though this resulted in good results in terms of reduction of wound infection but the infiltration of the prophylactic antibiotic preoperatively has yielded much better results.

Even though intra-incisional antibiotics have been proved to be effective their exact role in terms antibiotic prophylaxis is yet to be well defined. This study was undertaken to study the role of intra-incisional antibiotics when used alone or in combination with a systemic antibiotic in decreasing surgical site infection.

II. AIMS AND OBJECTIVES:

1. To evaluate intra-incisional antibiotic (Cefotaxime) infiltration in prevention of surgical site infection and its comparative efficacy with pre-operative intravenous antibiotic (Cefotaxime) therapy.
2. To assess the advantage of intra-incisional antibiotic (Cefotaxime) therapy over intravenous therapy with regards to its clinical application.

III. MATERIAL AND METHODS:

A prospective comparative study on 150 subjects randomized into three groups of 50 patients each was conducted in Department of Surgery of Guru Nanak Dev Hospital, attached to Government Medical College, Amritsar Patients selected were prospectively randomized into following three groups:-

GROUP A: Prophylaxis by pre-operative intra-incisional infiltration of the third generation cephalosporin i.e. inj. Cefotaxime 1gm diluted in 10ml of distilled water, in 1 cm circumference of the proposed incision in the skin, subcutaneous tissue and muscle, with 23G needle.

GROUP B: Prophylaxis by systemic antibiotics. A single dose of the 1gm inj. Cefotaxime will be administered intravenously approximately 20 minutes before the surgical incision to be given.

GROUP C: Both intravenous administration of 1gm Cefotaxime 20 minutes before incision and intra-incisional infiltration of 1gm cefotaxime diluted in 10ml of distilled water.

Wound was covered with occlusive dressing for 48 hours and first inspection of wound was done after 48 hours.

The patients were followed on daily basis till the date of discharge and grading of wound condition done according to Southampton Wound Grading System and data analysed statistically.

Observation and results:

The mean age of Group A was 36.20±11.91, Group B was 41.72±12.44 and in Group C, it was 42.26±13.01 (in years). The overall mean age was 40.66±12.71. Total no. of male patients was 74 and total no. of female patients was 76.

Table 1. OVERALL RATE OF SSI

Group	A	B	C	TOTAL
No. of Cases	50	50	50	150
No. of SSI	6	10	2	18

In our study Table 1 showing overall rate of SSI in this study was 12%. The Rate of SSI was 12% in Group A, 20% in group B and 4% in Group C.

Table 2. NO. OF SSI

Group	SSI					
	Clean		Clean contaminated		Dirty	
	No.	SSI	No.	SSI	No.	SSI
Group A	10	0	32	3	8	3
Group B	25	3	23	7	2	0
Group C	14	0	31	1	5	1
Total	49	3	86	11	15	4

Table 2 showing Rate of SSI in Clean cases was 8%, 11% in Clean-contaminated cases and 26% in Dirty cases. Overall, the rate of SSI was lowest in clean cases and highest in dirty cases.

Table 3. SSI IN RELATION TO DURATION OF SURGERY

GROUP	DURATION OF SURGERY (Hours)		
	<1 (52 Cases)	1-2 (94 Cases)	2-3 (4 cases)
	No. of SSI	No. of SSI	No. of SSI
GROUP A	3	1	2
GROUP B	4	5	1
GROUP C	0	2	0
TOTAL	7	8	3

The rate of SSI also depended upon duration of surgery. It was maximum in cases that lasted 2-3 hours. (3 out of 4) But, the incidence of SSI reduced in surgeries that lasted for 2-3 hours in group C, as compared to Group A and Group B. It was significant on statistical analysis. (P value A/C = 0.018, B/C = 0.027).

Total no. of patients with duration of post-operative stay <3 days was 16, 3-7 days was 124, and those with stay >7 days were 10. The minimum length of post-operative hospital was 1 day and maximum was 14 days. None of the patient with <3 day duration of stay had SSI. 13 out of 124 patients had SSI, when it was 3-7 days. And 5 out of 10 patients showed signs of SSI, in stay longer than 7 days. Considering the patients who had post-operative stay >7 days, group C had reduced incidence of SSI as compared to Group A. But it was not statistically significant. (P value > 0.05).

All the patients were graded according to Southampton Wound Grading System. Maximum no. of cases were in Grade 0 (48%) and Minimum cases were found in Grade 4. (3.33%). (fig. 1)

Out of the total 18 cases of SSI, 11 cases had discharge from wound site. Out of 5 swab samples sent from group A, only 1 had growth of organisms and that was E. Coli. Out of 6 swab samples sent from group B, 4 showed growth of organisms. Out of which, 2 were E. Coli and 2 were Staph. The most common pathogen found in study was E. Coli.

IV. DISCUSSION

Surgical site infection (SSI) is one of the commonest complications following surgery. The rate of SSI has been brought down considerably by the various aseptic measures and the use of prophylactic systemic antibiotics. However the rate has been static over the past few decades. This has introduced newer modes of administering prophylactic antibiotics, one of which is the intra-incisional infiltration of the antibiotic. This ensures a higher concentration of the antibiotic at the incision site and also a better compliance in terms of administration of the antibiotic as compared to systemic antibiotics.

Antibiotics have been shown to decrease the rate of SSI in all types of surgical cases even when given prophylactically. Also intra-incisional antibiotics were as effective as systemic antibiotics in the prophylaxis of SSI. In a study, the effect of intravenous and intra-incisional Cephaloridine was compared and they were found to be equally efficacious.[4] The rates of SSI were not significantly different between the two groups—major wound sepsis (3.5% and 2.1%) and minor wound sepsis (12.4% and 15.5%). On the other hand, a study done with Cephamandole, have shown that the intra- incisional infiltration to be more efficacious than intravenous administration.[5] In yet another study done to see the efficacy of intra-incisional antibiotics 624 patients undergoing abdominal operations received a single preoperative dose of Amoxycillin/clavulanic acid combination for the prophylaixs of SSI.[6] They were randomized to have the antibiotic injected intravenously at the time of induction of anaesthesia or infiltrated subcutaneously along the line of the proposed incision. The incidence of SSI was considerably lower in the group given the antibiotic in the abdominal wall. However in none of these studies was the combination of both systemic and intra-incisional antibiotics tried. This study has been done to evaluate the effect of antibiotics when given both I/V and intra-incisionally.

The overall rate of SSI in this study was 12%. It was comparable to a study done over patients of cholecystectomy in which the rate of SSI was 11.25%.[7]The overall rate of SSI in this study was 8% in the clean and 11% in clean-contaminated group and 26% in the contaminated and dirty group. In this study, the incidence of SSI in Group A, B and C was 12%, 20% and 4%. The difference in rates of SSI was statistically significant. The rates are comparable to reports from a study, where the rate of SSI was 10%, 18% and 2.5% in various groups respectively.[8] The rate of SSI reduced in Group C as compared to Group A as well as to Group B and it was statistically significant.(P value < 0.02).

The difference in the rates of SSI between the Indian study groups and the study groups in the developed countries could probably be due to - poorer nutritional status, increased incidence of infective diseases and the operating environment.

It is reported that prophylactic antibiotics do not play a significant role in clean and clean-contaminated cases especially when the rate of SSI <5%. The policy of not administering prophylactic antibiotics for clean and clean-contaminated cases cannot be advocated because of the operative environment.

The rate of SSI in contaminated cases is also high. This could be because of the high degree of contamination from the endogenous sources (eg, perforated viscus). As this factor cannot be modified, the prophylactic antibiotics particularly the intra-incisional infiltration may play a significant role in the prophylaxis of SSI. This was evident from the decreased incidence of SSI in group C in the contaminated cases, but it was not statistically significant.

In the present study Diabetes mellitus was taken as an exclusion criteria and no specific association was noted between SSI and any pre-existing illness (hypertension, CAD etc). The post-operative incision site swab could be a good predictor of the postoperative SSI. A study showed that during cholecystectomy the number and species of bacteria cultured from the bile were predictive of wound contamination.[9] Data from the National Nosocomial Infections Surveillance System reveals that the most common SSI pathogens are

Staphylococcus aureus, Enterococcus, coagulase negative Staphylococcus, Enterobacteriaceae, Pseudomonas species.[10] Studies in India have shown 79.33% of the isolates to be gram negative bacteria; Pseudomonas being the most common followed by staphylococcus.[11]In this study, only 45% of swab samples sent for culture and sensitivity showed any growth of organisms. Escherichia coli was the most common pathogen found. No growth of organisms was seen in group C.

V. CONCLUSION

The SSI was 12% in the group receiving prophylactic antibiotics (intra- incisional), 20% in group receiving I/V antibiotic and 4% in group receiving both (systemic and intra-incisional). The overall rate of SSI reduced significantly in patients receiving both intra incisional and intravenous antibiotics as compared to others. There is advantage of administering both systemic and intra-incisional antibiotics over either given alone for SSI prophylaxis in Dirty Cases and surgeries lasting between two to three hours. There is definite correlation between the duration of surgery and rate of SSI.The higher concentration achieved at the incision site by the intra-incisional route, making it a better mode of administering prophylactic antibiotics.

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