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Original Research Article

A randomised controlled trial comparing the efficacy of single dose prophylactic ceftriaxone versus post-operative ciprofloxacin and metronidazole combination in reducing post-operative wound infection after clean surgeries

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ABSTRACT

Background: Surgical site infections were considered to be the major contributor to increased morbidity and mortality in clean surgeries. Many studies prove that single dose prophylaxis is more effective than multiple dosing. No data currently exist about comparative efficacy of single dose prophylactic ceftriaxone with postoperative ciprofloxacin and metronidazole combination in reducing postoperative wound infection after clean surgeries. Hence the present study was done to compare their efficacy in terms rate of incidence of wound infection and side effects.
Methods: This prospective study was done on 120 patients who were selected for clean surgeries at Sapthagiri Institute of Medical Science and Research Centre, Bengaluru during the period from April 2015 and March 2016. 60 patients received single dose of ceftriaxone prophylactically and considered as study group and other 60 patients received combination of ciprofloxacin and metronidazole postoperatively for 5-7 days and considered as control group. The efficacy of drugs was estimated in terms of reducing the incidence of wound infection.
Results: The wound infection rate was 13.33% in the study group and 28.33% in control. Staphylococcus aureus was the most common organism isolated from wound discharge. However, gram negative organism accounted for majority of infections. There were no major side effects encountered in either of the groups.
Conclusions: The study concludes that single dose ceftriaxone can be widely applied in the routine practice in clean surgeries. The single dose ceftriaxone showed many advantages over the control group in terms of Reduced the incidence of postoperative wound infection with no major side effects.

Keywords: Clean surgeries, Multiple dose ciprofloxacin and metronidazole, Single dose ceftriaxone, Wound infections

INTRODUCTION

Infection continues to be the most important cause of the failure of surgical operations despite the development of more and more powerful antimicrobial drugs. The prophylactic use of antibiotics for surgical procedures has become a standard practice. Surgeons throughout the world recognize the advantages, in virtually all types of procedures, of having a microbiologically active drug available during the critical interval in which bacterial

contamination can occur. To achieve this aim, a great variety of antibiotics are currently administered before or during the operation.[1]

Single dose prophylaxis is as effective as multiple dosing and is preferable because it is less likely to alter antibiotic resistance patterns of bacteria in a hospital.[2] An ideal prophylactic antibacterial regimen should be selected for surgeries and to be administered intravenously in the operating room just before induction of anaesthesia, rather than earlier. This will avoid the possibility of premature administration of the antibacterial regimen if the surgical procedure is delayed.[3] No single antibiotic agent or combination should be relied on for effective prophylaxis in all operations. The agent or agents should be chosen primarily based on their efficacy against the exogenous and endogenous microorganisms usually known to cause infectious complications in each clinical setting as well as their safety profile and cost.[4]

Effective antibiotic prophylaxis can reduce the incidence of postoperative infection and be highly cost effective. Worldwide the cephalosporins are the most widely used antibiotics for surgical prophylaxis. The spectrum of antibacterial activity of ceftriaxone which covers major gram positive, gram negative, aerobic and anaerobic pathogens makes it ideally suitable for surgical prophylaxis.[5] The purpose of the study was to compare the efficacy of single dose of ceftriaxone given preoperatively with routinely used antibiotics like Ciprofloxacin and Metronidazole combinations given for 5-7 days postoperatively in clean surgery with regard to postoperative wound infection.

METHODS

This was a prospective study conducted on 120 patients who were undergoing clean surgeries at Sapthagiri Institute of Medical Science and Research Centre, Bengaluru during the period from April 2015 and March 2016.

Patients aged under 12 years and over 70 years, patients with preoperative fever, contaminated and dirty surgeries, patients with history of cough pre-operatively, patients who were on antibiotics within 7 days pre-operatively, patients with previous history of heart diseases, patients with diabetes, patients on steroid therapy, and immune compromised patients were excluded from the study. After getting approval from Institutional ethics committee and informed consent from the patients, all the 120 patients were divided into two groups consisting of 60 in each. Patients who were receiving 1 gram of Ceftriaxone one hour prior to induction of anaesthesia on the table were considered as study group. Patients who were given with Ciprofloxacin and Metronidazole for 5-7 days postoperatively were considered as control group.

Postoperatively the patients were examined for febrile episodes, any evidence of infections by clinical examination, and investigated if necessary. The wound was left exposed from the 2nd postoperative day onwards; the wound was inspected regularly for signs of wound infection. Any discharge form the wound was sent for culture and sensitivity, in other cases of suspected wound infection culture swab was taken from the depth of the wound after cleaning the surrounding skin with spirit.

Postoperatively all the patients were looked for temperature of 100.4-degree F or more in 24 hours after surgery on two occasions 6 hours apart and for signs of wound infection like redness, collection or discharge, pain or tenderness. Statistical analysis was performed using Fisher's exact test, Chi square or Mann-Whitney test where indicated. $P<0.05$ was considered statistically significant.

RESULTS

Of the total 120 patients, 60 patients were given with 1 g of Ceftriaxone one hour prior to induction of anaesthesia on the table and considered as study group.

Table 1: Distribution of patients according to type of surgery and incidence of infection.

Type of surgery	Study group		Control group	
	Total no. of patients undergoing surgery N (%)	No. of patients noted with infection N(%)	Total no. of patients undergoing surgery N (%)	No. of patients noted with infection N (%)
Herniorrhaphy/hernioplasty	32 (53.3)	5 (15.62)	38 (63.33)	11 (28.94)
Cholecystectomy	8 (13.3)	2 (25)	9 (15)	3 (33.33)
Hemithyroidectomy/subtotal thyroidectomy	4 (6.66)	-	2 (3.33)	-
Fibroadenoma enucleation/ simple mastectomy/modified radical mastectomy	13 (21.66)	1 (7.69)	8 (13.33)	3 (37.5)
Total no. of cases	60 (100)	8 (100)	60 (100)	17 (100)
Overall incidence of infection	13.33%		28.33%	

The other 60 patients received Ciprofloxacin and Metronidazole for 5-7 days postoperatively and considered as control group. The distribution of patients according to type of surgery and percentage of wound infection in

different type of surgeries was listed in Table 1. The prevalence wound infection was more in of patients undergoing hernioplasty and the incidence was higher in control group compared to study group. In patients who underwent with hemi or subtotal thyroidectomy no cases were noted with wound infection in both the groups. Overall incidence of infection was lesser in the study group (n=8, 13.33%) compared to the control group was (n=17, 28.33%). This difference was significant statistically (X2=4.093, p<0.05).

Table 2: Rate of infection by pathogenic organisms.

Organisms	Study group		Control group	
	Total no of cases (n=8)	% of infection	Total no of cases (n=17)	% of infection
S. aureus	3	37.5	7	41.17
E. coli	3	37.5	4	23.52
Pseudomonas	1	12.5	2	11.76
Klebsiella	1	12.5	-	-
Proteus	-	-	3	17.64
No growth	-	-	1	5.88

Rate of infection caused by specific pathogens was summarized in Table 2. *S. Staphylococcus aureus* was the commonest organism isolated from wound discharge in both the groups followed by *Escherichia coli.*

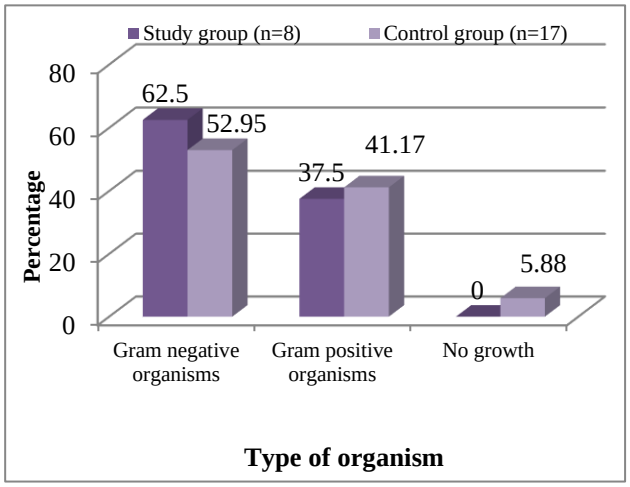

Figure 1: Overall percentage of infection by organisms.

No organism growth was found in one case of control group. However, gram negative organism accounted for majority of wound infection (Figure 1).

DISCUSSION

Postoperative wound infection has been the greatest obstacle to advancement of surgery down the centuries. Many factors are associated with the development of surgical site infections. Appropriate administration of prophylactic antibiotics reduces the incidence of these infections.[6] In developed countries, single dose antibiotic has proven to be effective prophylaxis for many types of surgeries.[7]

Prophylactic antibiotics should be given preoperatively and intravenously for preventing wound infections. Antibacterial agents administered as early as three hours after experimental contamination of wound, have no influence on the infection rate of the operative wounds. If the body already has adequate antibiotic concentration at the time of contamination, infection can be adequately prevented.[8]

Early trials of prophylactic antimicrobial agents often failed to show efficacy in preventing surgical wound infections because the antibiotics were given after surgery was completed. Using a guinea pig model of subcutaneous *S. aureus* infection, Burke demonstrated that administering antibiotics before or shortly after the inoculation of skin with *S. aureus* reduced the size of the ensuing skin lesion markedly and that with each delay of an hour in antibiotic administration, the resulting lesion became larger until the third hour. By the fourth hour, the lesion was the same size as in untreated control animal.[9]

These results were supported by a similar study done in LDS hospital on 2847 patients undergoing elective clean and clean contaminated surgical procedures it was proved that preoperative antibiotic administration was associated with lowest risk of surgical wound infection.[10] In the present study the percentage incidence of wound infection was lesser in group of patients who received ceftriaxone preoperatively (13.33%) than the patients who received combination of ciprofloxacin and metronidazole postoperatively for 5-7 days (28.33%). This was in accordance with the Lippert et al.[11]

In a systematic review done from cochrane database, it was found that the single dose prophylactic antibiotics significantly reduced the incidence of surgical site infection for patients undergoing breast cancer surgeries.[12] From all these it is clearly evident that preoperative prophylaxis is much better than the postoperative care in terms of minimising wound infections.

Frequently observed isolated pathogens from wound infections are found to be *S. aureus*, *E. coli*, *Enterococcus* and coagulase negative *Staphylococci*. Increased incidence of wound infections are caused by antimicrobial-resistant organisms such as methicillin-resistant *S. aureus* (MRSA).[13,14]

In the present study, S. aureus was the most common organism isolated from wound discharge in both the groups. This was in agreement with the findings of Ranjan et al.[15]

There were no major side effects in the study group or control group except for few minor side effects in both

groups. One patient in the study group developed skin rashes which subsided with injection chlorpheneramine maleate and three patients in the control group developed nausea and vomiting which subsided on injection ondansetron.

CONCLUSION

Surgical wound infections are very common in many cases. Although, they cannot be eliminated completely, a reduction in incidence of the infection rate to a minimal level could have significant benefits by reducing postoperative morbidity and mortality, and wastage of health-care resources. The findings of the study conclude that single dose prophylactic ceftriaxone was more effective in terms of fewer wound infections after clean surgeries and cost effective as well than receiving multiple doses of ciprofloxacin and metronidazole postoperatively.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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