CHEMOPROPHYLAXIS IN SURGICAL SITE INFECTION: IS IT REALLY NECESSARY

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ABSTRACT

Objective: To determine the need of using chemoprophylaxis for surgical site infection (SSI) in clean and clean contaminated general surgical procedures and to compare the efficacy of monotherapy using Cefuroxime and combination therapy using Triple Regime.

Methodology: This prospective randomized single blinded study included 534 patients. We included all ASA Grade 1 or 2, immunocompetent patients undergoing clean or clean contaminated surgery. Group A received placebo. Group B received single dose Cefuroxime 750mg iv preoperatively and Group C received triple regime. Any SSI was recorded which occurred up to 30 days post operatively.

Results: The three groups were well matched demographically. (p value < 0.05). Group A (43 patients) was terminated early due to unacceptably high rate of wound infection. Amongst the remaining 491 patients, 247 were randomized to Group B and 244 to Group C. Among the clean cases Group C showed a lower rate of infection (2.6% vs 2.8%; p=0.17). However, Group B had significantly lower infection among the clean contaminated procedures (6.9% vs 7.7%; p=0.03) and overall (4.1% vs 4.9%; p=0.04).

Conclusion: The high rate of infection demonstrated in patients receiving placebo indicates a need for routine chemoprophylaxis for SSI. A single dose of Cefuroxime at induction seems to work at least as well or better than triple regime and is the recommended prophylaxis.

Key Words: Chemoprophylaxis, Surgical site infection (SSI), Cefuroxime.

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INTRODUCTION

Surgical site infection (SSI) is defined as an infection occurring within 30 days after a surgical operation and can be confined to skin or deeper structures. The principle of administering antibiotics pre-operatively as prophylaxis was established in the early sixties by Burke¹ and Polk². It was shown that prophylactic antibiotics reduce the incidence of post-operative infections. Subsequently, numerous studies were done on this issue which varied widely in their results and conclusions^{3,4}. However, better-designed trials have

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Date Received: September 14, 2011 Date Revised: May 31, 2012 Date Accepted: June 14, 2012 established the role of antibiotic prophylaxis for SSI's⁵⁻⁷.

Numerous international surveys of antibiotic use in hospitals conclude that between 25% and 50% of all antibiotics prescribed are for prevention, rather than treatment.³ SSI's account for 14 to 25% of all nosocomial infection.⁸ A study of the patients who had SSI and expired demonstrated that in 70% of those patients, the SSI was causally linked to the death⁸.

Postoperative wound sepsis has been established as the most common nosocomial infection in patients undergoing surgery⁹. It is an important cause of illness, resulting in a prolongation of hospital stay, increase in the cost of medical care and inconvenience to patients and their families^{10,11}.

This series aims to ascertain the need of using chemoprophylaxis in clean and clean contaminated surgical procedures and to compare the efficacy of Cefuroxime monotherapy and triple regime combination therapy in preventing SSI.

METHODOLOGY

This prospective randomized single

blinded study was carried out at a tertiary care hospital, from June 2004 to December 2006. 534 patients were enrolled in the study. Informed consent was obtained from all the patients. We included all patients undergoing clean or clean contaminated surgery who were classified as ASA (American Society of Anesthesiologists) Grade 1 or 2 and did not have any co-morbidities predisposing to infection like diabetes or steroid use. Patients undergoing emergency or malignancy surgery, with significant preoperative contamination and those who refused consent were excluded. Surgical procedures were classified into four categories: clean, clean-contaminated, contaminated and dirty^{5,12,13}. The last two categories were excluded since they were outside the scope of the present study.

The patients were randomly divided into three cohorts by drawing lots. Group A was the placebo group which did not receive any antibiotics. Group B received a single dose of IV Cefuroxime 750mg at induction. Group C received Cephradine 500mg IV in clean cases, with additional Gentamycin 80mg IV & Metronidazole 500 mg IV in clean contaminated cases. Wounds were inspected daily to look for any evidence of infection while the patient was admitted and upto 30th post operative day on visits to the clinic. Both the superficial and deep wound infections were recorded as infectious complications. Patients presenting with unusual pain \pm fever were investigated for infection by sending blood counts and requesting ultrasound.

Statistical analysis of the results was done using SPSS 11.0.

RESULTS

We included 534 patients in the study randomly divided into three cohorts, which were well matched regarding their ASA status, age, sex and comorbidity (p < 0.05) (Table 1).

Group A, the placebo group, initially enrolled 43 patients but early analysis during the study demonstrated an infection rate of 19% and it was deemed unethical to continue this cohort due to the high infection rate.

The number of patients from that point on was 491, out of which 247 received cefuroxime (Group B) and 244 received triple regime (Group C). The most frequent procedure performed was hernia repairs with inguinal hernia being the most frequent hernia repaired, followed by cholecystectomy, breast lumpectomy, thyroidectomy and vascular surgery. Clean and clean contaminated procedures shows similar distribution in both groups (Table 2).

The infection rates in clean contaminated cases and in all the patients combined together were significantly lower in Group B. Patients above 50 years had significantly increased infection rates in both the groups (Table 3).

| Mean Age | 33 years | |
|-------------|-------------|--|
| Age Range | 16-58 years | |
| Males | 331(62%) | |
| Females | 203(38%) | |
| Comorbidity | 166(31%) | |

Table 1: Patient Characteristics

| Table 2: | Distribution | of Cases |
|----------|--------------|----------|
|----------|--------------|----------|

| | Clean Cases Clean Contaminated | |
|---------------|--------------------------------|----------|
| Group B (247) | 175 (71%) | 72 (29%) |
| Group C (244) | 154 (63%) | 90 (37%) |

Table 3: Infection Rates

| | Clean Cases | Clean Contaminated | Overall Rate |
|--------------|-------------|---------------------------|---------------------|
| Group B(247) | 2.8% | 6.9% | 4.1% |
| Group C(244) | 2.6% | 7.7% | 4.9% |
| p-value | 0.1 | 0.02 | 0.03 |

DISCUSSION

There is almost universal agreement that contaminated and dirty wounds require antibiotics¹⁴. However, the need for chemoprophylaxis in clean and clean contaminated surgery is still a hotly debated issue with both opponents and proponents. An SSI develops as a result of an interaction between the peroperative pathogen inoculum and the host resistance to infection¹⁵. The size of the inoculum relates directly to likelihood of SSI. Antibiotics reduce the number of viable pathogens in the wound¹⁶. Prophylactic antibiotic use in surgery is for operations in which the risk of postoperative wound infection is high or in which the rate of wound infection is relatively low but the consequences of infection are significant. Conversely, the major disadvantage of injudicious use of antibiotics seems to be the emergence of pathogens of increased virulence and resistance¹⁷. Hence antibiotics need to be used only when absolutely necessary¹⁸.

The first question raised in this study was that should prophylactic antibiotics be used at all in a setting like ours. The inordinately high infection rate in the placebo wing conclusively proved the need for antibiotic prophylaxis. This also seems to have become a generally accepted consensus in literature^{5,19,20}. Large scale studies of patient undergoing clean surgery have shown reduction of infection ranging from 39% to 75%²²⁻ ²⁴. A Cochrane Review appraising antibiotic usage in a clean procedure has concluded further placebo controlled randomized trials of the effectiveness of antibiotic prophylaxis in such surgeries are unlikely to be justified⁵. For clean surgery the inoculum is expected to be minimal²¹. However, the infection control protocols and their strict enforcement needs to be implemented and monitored. But in the developing world these facilities may still be in planning and evolution phase. Hence, taking in view the findings of Group A, prophylactic antibiotic use may be a necessary precaution. D'Amico et al have found that a single dose of antibiotic at induction of anesthesia may be prudent and does not have any impact on antibiotic resistance²⁵. Other workers have also advocated routine use of chemoprophylaxis²⁷.

Some studies, comparing multi-antibiotic regime use to monotherapy have found latter to be superior in terms of ease and economy of usage as well as patient acceptance^{26,27}. Others propound monotherapy with a broad spectrum second generation cephalosporin to be equally effective or superior to a gentamycin based combination, but preferable on account of lower toxicity²⁸. The reported SSI rate was significantly lower in

monotherapy arm as compared to multi-therapy²⁶⁻²⁸. The present study shows similar results where the cohort given monotherapy has had lower infection rates and this has reached statistical significance.

CONCLUSION

Antibiotic prophylaxis for SSI is recommended for clean and clean contaminated procedures especially in a setting like ours. The high rate of infection demonstrated in patients receiving placebo indicates a need for routine chemoprophylaxis. A single dose of Cefuroxime at induction seems to work at least as well or better than triple regime and is the recommended prophylaxis.

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