Role of Antibiotic Prophylaxis in Clean and Clean Contaminated Elective Surgery

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Antibiotic prophylaxis is a recognized concept in surgery. We studied the need for prophylaxis in clean and clean contaminated surgery in the setting of third world tertiary care center. A randomized single blind study was conducted with three arms. 278 patients of ASA and 2 were included in this study. They were randomized to prophylaxis with Cefuroxime, triple regime and placebo. The placebo wing was terminated prematurely due to unacceptable infection rate and Cefuroxime was found to be equal or better than triple regime in our study.
Keywords: Antibiotic, clean wound, contamination wound

The principle of administering antibiotics pre-operatively as prophylaxis was established in the early sixties by Burke[1] and Polk[2]. It was shown that prophylactic antibiotics reduce the incidence of postoperative infections provided they were administered jut before surgery. In subsequent years there were many studies, which varied widely and often produced controversial conclusion[11,12]. The results obtained from the better-designed trials, has established the role of antibiotic prophylaxis for various surgical procedure[6,13,14].

Numerous surveys of antibiotic use in hospitals in the UK and elsewhere show that between 25% and 50% of all antibiotics prescribed are for the prevention, rather than for the treatment of infection.

Postoperative wound sepsis has been established as the most common nosocomial infection in patients undergoing surgery[4]. It is an important cause of morbidity resulting in a prolongation of hospital stay, an increase in the cost of medical care and an inconvenience to patients and their families

Aims and objectives:

1. Assessment of advantages or otherwise of surgical prophylaxis in clean elective surgical procedures commonly performed by the general surgeon
2. Comparison of two methods of surgical prophylaxis:
   Monotherapy: single dose
   Combination therapy: single dose

Patients and methods:

The randomized single blind study was carried out at Mayo Hospital, Lahore from January 1999 to June 2001 comprising 278 subjects. The patients belonged to one general surgical unit.

The inclusion criteria were:

1. All clean or clean contaminated surgical procedures.
2. Patients with Asa (American Society of Anaesthesiologists) Grade 1 or 2.
3. Non diabetic patients or patients without any immunocompromise

Exclusion criteria were:

1. All emergency surgical procedures.
2. Patients suffering from malignancy.
3. All procedures which had a significant spill/cobntamination of gastrointestinal contents or other contaminated material.
4. All patients with major intraoperative breaks in sterility.
5. All redo surgeries .

Surgical procedures were classified according to the chance of the wound becoming contaminated and by inference to the size of the bacterial inoculum entering the wound[5].

Table 1: Classification of operation

Class	Definition
Clean	Operations in which no inflammation is encountered and the respiratory alimentary or genitourinary tracts are not entered. There is no break in aseptic operating theatre technique.
Clean contamination	Operations in which the respiratory, alimentary or genitourinary tracts are entered but without significant spillage.
Contaminated	Operations where acute inflammation (without pus) is encountered or where there is visible contamination of the wound. Examples include gross spillage from a hollow viscus during the operation or compound/open injuries operated on within four hours.
Dirty	Operations in the presence of pus, where there is a previously perforated hollow viscus, or compound/open injuries more than four hours old.

The patients were divided into three groups. Group A received a single shot of Inj. Cefuroxime 750mg iv just before induction. Group B received Inj. Cephradine 500mg iv in clean cases and with an addition of Inj. Gentamicin 80mg iv plus Inj. Metronidazole 500mg iv in clean contaminated cases. Group C was also initially included in this study which comprised a placebo group. This division was randomized by drawing of lots. Data was also collected regarding the demographic features of the

patients as well as their history comorbid factors like H/O diabetes, systemic steroid intake or other indicators of immunocompromise.

Wound infection was classified as superficial and deep and were both included in the infected subgroups. Daily inspection of the wounds was done while the patient was admitted and routinely on first and second follow-up visits to OPD usually on 7th and 15th postoperative day. A patient presenting history of increased pain and/or fever was also checked for wound infection. Statistical analysis of the results using both direct and inferential statistics was done.

Results:

The results showed some surprising trends. To start with the patient characteristics are given in Table 2.

Table 2: Patient characteristics

Mean age	37 years
Age range	15-63 years
Males	161(58%)
Females	117(42%)
Comorbidity	102(37%)

Group C was initially enrolled by equally with other groups but an in-house analysis during the study showed an infection rate of 18% and it was deemed unethical to continue this wing in the face to such overwhelming wound infection. Hence it was discontinued.

The actual number of patients enrolled were henceforth 243. Out of which 120 received Cefuroxime and 123 received the combination regimen. The most frequent procedure done was inguinal hernia repair followed by cholecystectomy, paraumbilical hernia repair, incisional hernia, vascular surgery (arterial and venous) and misc. (Table 3)

Table 3: Distribution of cases

	Clean cases	Clean contaminated
Group A (120)	84(70%)	36(30%)
Group B (123)	78(63%)	45 (36.9%)

Infection rates among the two groups were follows (Table 4)

	Clean cases	Clean contaminated	Over all rate
GroupA (120)	2.1%	7.7%	3.8%
Group B (123)	2.3%	7.2%	4.1%

The difference in overall infection rates was found to be significant in favour of group B, but broken down this was also true in clean contaminated cases but not in clean cases. Patients above 55 years had significantly increased infection rates in both the groups and in both clean and clean contaminated cases categories.

Discussion:

A wound infection develops as a result of a complex interaction between the bacteria inoculated into the wound during surgery and the local and systemic resistance of the host to infection. The size of the bacterial inoculum is directly correlated with the risk of a postoperative wound infection. The primary benefit of antibiotics is reduction of the inoculum of viable bacteria in the wound. 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.

But the disadvantage of widespread use of antibiotics is the emergence of colonization with pathogens of increased virulence and resistance. Hence the need to limit the antibiotic use.

This question was raised in our study that should prophylactic antibiotics be used at all in a setting like Mayo Hospital, The inordinately high infection rated in this group led to the termination of that wing of the study., thus proving conclusively the need for antibiotic prophylaxis. This is also the general consensus for clean contaminated surgery among the current literature[6,7,8]. For clean surgery[9] we need to take into conxideration the facilities for infection control available in the setting of study and as per the findings of Group C, prophylactic antibiotic use is strongly recommended. In some studies routine prophylaxis is recommended[10].

As an arise, we eliminated the bias for infection produced due to variation in general host defenses by excluding malnourished and immunocompromised patients and also those with malignancy.

Comparing the two group of antibiotic use we found that a single shot of a second generation cephalosporin (Cefuroxime) seems to be more effective compared to a combination regimen including metronidazole for preventing wound infection in clean contaminated surgery and as an overall trend in both clean and clean contaminated groups. This is more convenient and cost effective and hence is recommended by our study.

Conclusion:

Antibiotic prophylaxis is recommended for operations with a high risk of postoperative wound infection or with a low risk of infection but significant consequences if infection occurs. These operations include clean-contamianted procedures and most clean procedures in a setting like ours. A single dose at induction of Cefurozime seems to work at least as well and in a significant proportion of cases better that a combination of Cephradine, Gentamicin and Metronidazole and is the recommended prophylaxis.

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