

# Effect of Single-Dose Antibiotic Prophylaxis versus Conventional Antibiotic Therapy in Surgery: A Randomized Controlled Trial in a Public Teaching Hospital

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## Abstract

**Introduction:** Antibiotic uses in surgical procedures are varied depending on the nature of surgical procedures, environmental hygiene, and availability of drugs, especially in public hospitals. Various studies postulate prophylactic antibiotic use is cost effective than post-operative use of antibiotics.

**Materials and Methods:** A randomized controlled trial was done in our surgical unit in Kanyakumari Government Medical College, and the results were compared with the control group from the other surgical unit where conventional antibiotic are used for 7-10 days. All patients in study group undergoing surgeries were given 1 g cefotaxime after test dose 60 min prior to surgery. In the control group, the patients were given 3 days intravenous injection ciprofloxacin 200 mg intravenous (IV) twice a day, injection metronidazole 500 mg thrice a day, and injection amikacin 500 mg twice a day and the next 4 days the same antibiotics were given in oral route. Total 60 patients are randomized to 30 each group. The outcome of the surgery in term of duration of surgery, Surgical Site Infection, Cost and Antibiotic side effects were compared in both groups.

**Results:** It is observed both the duration of hospitals stay cost and side effects are significantly increased for the control group patient than the study group. Antibiotic side effects are ( $P < 0.05$ ) for control group and cost ( $P < 0.001$ ) were high for control group. The infection rate is similar in both groups. Grade 2 infection in 2 cases out of 30 in each group and there is no significant differences.

**Conclusion:** Prophylactic single-dose antibiotic is more useful and cost-effective in our public hospitals which can reduce the expenditure for drugs in country like India.

**Key words:** Antibiotics, Antibiotic resistance, Conventional therapy, Cost effective, Prophylaxis, Resistant bacteria

## INTRODUCTION

Antimicrobial agents were considered as magic bullets and effective tools to combat infections in various therapeutic settings. However, the non-judicious usage

of these antibiotics has become a subject of controversy. Rational antibiotic use is promulgated with much vigor as the resultant effect of injudicious antibiotic usage had propelled the emergence of antibiotic resistance and spiraled the cost escalation in therapeutic care.<sup>1</sup>

Antibiotic resistance has become a global menace, and WHO in 2012 had given a clear call to reduce the antibiotic use and prevent resistance to antibiotics.<sup>2</sup>

Antibiotic prophylaxis is a therapeutic method in which antimicrobial agents are used prophylactically to prevent the infectious complications in a therapeutic procedure.

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In conventional antibiotic use, antimicrobials are used for a predetermined period after therapeutic procedure to combat the infection.<sup>3</sup>

Various techniques of antibiotic prophylaxis, the quantities and nature of drug use, timing of the use of the drug were studied by various cross-sectional studies and based on the data the standard protocol of antibiotic prophylaxis for each procedure were randomized and published.<sup>4</sup>

In this era of antibiotics, the cornerstones of infection control, such as meticulous surgical skill, respectful tissues handling, inbuilt environmental sanitation, adequate preoperative preparation, congenial theater environment, and adequate wound care, are given less priority.<sup>5</sup>

As per various studies cited and Cochrane data reviewed the conventional use of antibiotic for much longer period are not justified.

Most often in public hospitals where the environmental hygiene is not adequately maintained and over load of surgical patients with the fear of development of surgical site infections even for clean and clean-contaminated surgeries antibiotics are given for 7-10 days. The traditional approach for this multi dose usage often leads to huge expenditure to the hospital and enhance emerging of resistance to the particular drug and the group to which it belong.

Hence, this study is intended to study the effect of single-dose antibiotic prophylaxis given 60 min prior to surgery with the standard chosen antibiotic versus the conventional use of same antibiotics for 7 days or until the patient is discharged from the hospital.

## **MATERIALS AND METHODS**

This study was conducted as a randomized case-control prospective study in the Department of Surgery in Kanyakumari Government Medical College Hospital from 2014 July to 2015 July. Totally 60 patients admitted for clean surgery in our hospital without any co-morbid conditions were included in this study.

The patients were randomized into study group in one surgical unit getting admission on Wednesday and patient getting admitted to Thursday unit is included as a control.

All the surgeries were carried out in the same theater environment, and same preoperative safety protocol, and post-operative care is followed for all patients.

### **The Use of Antibiotics are Predetermined as Follows**

#### **Study group**

One dose of 1 g injection cefotaxim IV after test dose 60 min prior to surgery and no more antibiotics are prescribed.

#### **Control Group**

No pre-operative antibiotic given. In the post-operative ward for the first 3 days IV antibiotics are given as follows:

- Injection ciprofloxacin 200 mg IV bd
- Injection metronidazole 500 mg IV tds
- Injection amikacin 500 mg IV bd.

Next 4 days:

- Tablet ciprofloxacin 200 mg oral bd
- Tablet metronidazole 400 mg oral tds.

#### **Ethical Aspect**

The study proposed was approved by the Ethical Committee of our institution. All participants were provided and obtained informed consent after explaining all the features of studies.

#### **Inclusion Criteria for the Surgical Patients**

Patients with the age group 20-60 both male and female with no co-morbid conditions and posted for following surgeries are included in the study.

1. Inguinal hernia all type undergoing lichen stein mesh repair
2. Hydrocoel for eversion of sac
3. Varicose vein for trendlenberg operation
4. Umbilical hernia for mesh repair
5. Epigastric hernia for mesh repair
6. Benign thyroid condition for hemi/subtotal thyroidectomy.

#### **Exclusion Criteria**

- History of hypersensitivity to cephalosporin group of antibiotics
- Patient with co-morbid renal, cardiac, hepatic damages
- Patient on steroid or having immune deficiency
- Non-willing patients
- Patients on long-term medication for diabetes, hypertension, or psychiatry problems.

#### **Demographic Variable**

The age, sex, height, weight, and socio-economic status were studied.

#### **Variables Measured**

- Duration of surgery
- Development of infection based on Southampton grade
- Cost of antibiotics
- Complications due to the side effects of antibiotics.

**Pre-operative Preparation and Care**

All the patients posted for these elective surgeries were admitted on the day prior to surgery. All necessary investigation are done and anesthetic fitness obtained. The operative site was cleaned/shaved with aseptic precaution. All patients were asked to take body bath with soap on the day of surgery and the operative site covered with a sterile dressing.

**Aseptic Precautions in the Operation Theater**

Theater asepsis is maintained, and checklists were verified. All the instruments were counter checked for sterility from CSSD Department. Standard surgical scrub for 5-10 min mandatorily followed by the surgical team.

**Operation Techniques**

After anesthesia, the operative site is prepared with povidine iodine and spirit. The principles of surgery, especially minimal tissue handling, adequate hemostasis, less use of cautery, appropriate use of drains were followed. Wound closed without tension, and a sterile dressing applied.

**Post-operative Care**

The patient were kept in the post-operative ward for 3 days and shifted to general ward after 3 days. Temperature and vitals are monitored periodically, and the charts are maintained. Wound inspection was done on 3<sup>rd</sup>, 5<sup>th</sup>, and 7<sup>th</sup> day. Dedicated staff followed up with the drugs to be administered and ensured the antibiotics are given at appropriate time as per the protocol.

3. Daily dressing with saline
4. Suture removed on the 5-6<sup>th</sup> day.

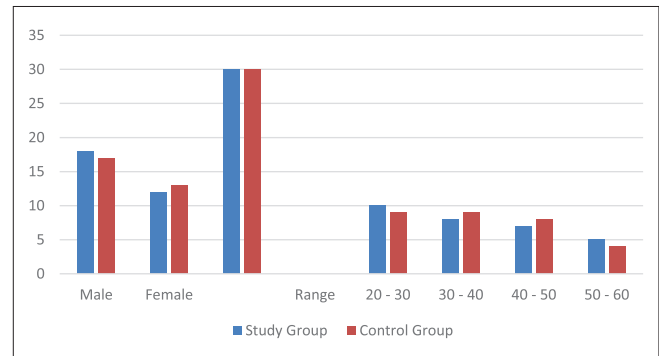


Figure 1: Demographic profile

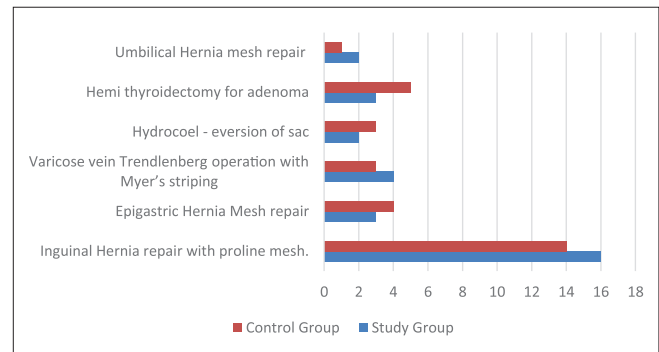


Figure 2: Nature of surgery in each group

**OBSERVATION AND RESULTS**

Total 60 patients undergoing surgical procedures were taken into two groups. Patients in the control group undergoing surgical procedures were given, 7 days of antibiotics and discharged on the 8<sup>th</sup> day after removal of suture materials. 30 patients were grouped into study group, who got only one dose of prophylactic antibiotic 1 h before surgery. The Demographic profile of all patients in both the group were studied and tabulated in Table 1 and Figure 1.

**Demographic Profile**

The patients in the both group have undergone following surgeries and number of patients for each surgery in each group were tabulated in Table 2 and Figure 2.

The mean weight, hemoglobin level, type of anesthesia, and duration of surgery for each group of patients in different surgeries were measured and tabulated in Table 3.

**Antibiotic Profile**

**Study group**

1. Injection cefotaxim 1 g IV 1 h prior to surgery
2. 3<sup>rd</sup> day dressing changed and checked for infection

**Table 1: Demographic profile of the study and control group**

Average cost	Study group	Control group
Sex		
Male	18	17
Female	12	13
Total	30	30
Mean age		
Range		
20-30	10	9
30-40	8	9
40-50	7	8
50-60	5	4

**Table 2: Nature of surgery in each group**

Nature of surgery	Study group	Control group	Total
Inguinal hernia repair with proline mesh	16	14	30
Epigastric hernia mesh repair	3	4	7
Varicose vein trendlenberg operation with Myer's striping	4	3	7
Hydrocoel - eversion of sac	2	3	5
Hemithyroidectomy for adenoma	3	5	8
Umbilical hernia mesh repair	2	1	3
Total	30	30	60

**Table 3: Mean Hb status, weight, duration of surgery and type of anesthesia**

Type of surgery	Study group				Control group			
	Weight	Hb	Type of anesthesia	Duration of surgery (min)	Weight	Hb	Type of anesthesia	Duration of surgery (min)
Inguinal hernia	52	9.6	Spinal	45	53	9.8	Spinal	48
Epigastric hernia	70	9.8	Spinal	45	69	9.6	Spinal	56
Varicose vein	54	9.4	Spinal	50	52	9.3	Spinal	53
Hydrocele	53	9.6	Spinal	30	51	9.5	Spinal	35
Hemi thyroidectomy	48	9	GA	60	47	9.1	GA	45
Umbilical hernia	51	9.4	Spinal	45	52	9.3	Spinal	50

Hb: Hemoglobin, GA: General anesthesia

### Control Group

- First 3 days
  - Injection metronidazole 500 mg IV tds
  - Injection ciprofloxacin 200 mg IV bd
  - Injection amikacin 500mg IV bd
- Next 4 days
  - Tablet ciprofloxacin 500 mg oral bd
  - Tablet metronidazole 400 mg oral tds
- 3<sup>rd</sup> day dressing changed and checked for infection
- Daily dressing with betadine solution
- Suture removal on the 6<sup>th</sup> and 7<sup>th</sup> day.

### Infection Grading in the Ward

Based on the Southampton scoring system on the 3<sup>rd</sup>, 5<sup>th</sup>, and 7<sup>th</sup> post-operative period the wounds were inspected and the infection grades are noted.

### Southampton Scoring System

Grade:

- 0 = Normal healing
- 1 = Bruising and mild erythema
- 2 = Erythema and signs of inflammation
- 3 = Clear (or) serous discharge
- 4 = Pus formation
- 5 = Deep, severe wound infection.

Out of the 60 patients' only 4 patients, 2 in each group shown infection in the post-operative period. 2 had grade 1 infection, and another 2 had grade 3 infection. No change in the protocol done. On dressing and saline wash infections controlled and all patient were discharged with the good general condition. No statistically significant difference with infection prolife noted in both the group. The results are tabulated in Table 4.

### Cost Estimation

The cost involved for the each patient for the antibiotics and syringe usage are calculated for each patient in average. The study group antibiotic cost was only 30 rupees while for each patient in the control group it was more than 890 rupees. On statistical analysis, it shows gross significance with *P* factor < 0.001. The cost for each patient in average is tabulated in Table 5.

**Table 4: Grade of post-operative infections**

Grade of infection	Study group			Control group		
	3 <sup>rd</sup> day	5 <sup>th</sup> day	7 <sup>th</sup> day	3 <sup>rd</sup> day	5 <sup>th</sup> day	7 <sup>th</sup> day
Grade I	-	1	-	-	1	-
Grade II	-	-	-	-	-	-
Grade III	-	1	-	-	1	-
Grade IV	-	-	-	-	-	-
Grade V	-	-	-	-	-	-

**Table 5: Average cost of antibiotics**

Average cost	Study group	Control group	<i>P</i> factor
Cost of antibiotics	Rs. 30/patient	Rs. 890/patient	0.001

### Side Effects of Antibiotic Treatment

All patients were observed for the known side effects of the drugs used and also watched for adverse drug reactions. No patients had adverse drug reactions from both the groups.

None developed antibiotic side effects in the study group. In control group, four patients had severe metallic taste and one patient had urticarial rash following the antibiotic use.

## DISCUSSIONS

This randomized control study to assess the effectiveness of one dose of prophylactic antibiotic versus the traditional use of 7 days antibiotics has shown no significant difference in the wound infection rate in both the groups. However, there is a significant increase in the cost and side effects of antibiotics in the control group using conventional 7 days antibiotics.

The use of prophylactic antibiotic in all surgical cases are advocated ever since, the concept of use of antibiotic pre-operatively to curtain and prevent wound infection was postulated by Bernard and Cole in 1964.<sup>6</sup>

The overall experience from across the world has categorically recommended using the specific antibiotics in the pre-operative period than traditional use of 5-7 days of antibiotics in the post-operative period.

With much advancements in the asepsis of the environment and hygiene of the theaters, it was questioned in many surgical settings on the need of antibiotic at all for clean and clean-contaminated surgical cases. However, in high turnover hospitals in public setting, even while all the sterile precautions are adhered too, the surgical procedures can imbibe bacteria or other microbial agents in the blood and lead to bacteremia the use of long-acting antibiotic to cover the perioperative period is recommended.<sup>7</sup>

In 2001, Chambers in their study recommended that first generation cephalosporin antibiotic the cefazolin are drugs of choice for the use of prophylactic antibiotics for the general surgical prophylaxis than the second or third generation cephalosporin.<sup>8</sup>

Naz in a comparative study between a single-dose cephradine as the prophylactic antibiotics versus conventional dose of antibiotics in major gynecological procedures have stated prophylactic antibiotic use is adequate provided standard principles of operative surgery are adhered.<sup>9</sup>

Wideman and Matthijssen in his study conducted on the use of cefazolin versus cefotaxime as the prophylactic antibiotic in 118 hysterectomy patients in 1982 stated cefotaxime and cefazolin are equally beneficial on all aspect, and use depend on the cost and availability.<sup>10</sup>

Many studies have been conducted on the choice of antibiotic and timing of use of antibiotics. Most of the studies have recommended the first dose to be given 30-60 min prior to surgery, and long-acting antibiotic must be selected.<sup>11</sup>

Fernandez Arjona *et al.* had conducted a study to find out the economic advantages following use of prophylactic antibiotic rather than traditional 7 days antibiotics, using 5260 patients in a medical Centre in Southern Taiwan and stated that use of prophylactic antibiotic alone for the surgical patients had resulted in gain of 1.5 million dollars for the public.<sup>12</sup>

Our study also proves, there is a significant advantage of economic gain when only prophylactic antibiotic is used.

Antibiotic are magic bullets but inadvertent and over use can cause potential side effects and also leads to the

development of drug resistance bacteria. In our study, it is noted a significant number of the patient had developed side effects of antibiotic during this period.

More than the antibiotics clean surgical environment, hand washing, adequate preparation of patients and following universal precaution will improve the wound healing and prevent the infection in the patient.

## CONCLUSION

Our study concludes that even in public institutions where the turnover of the patients are the high judicious use of prophylactic antibiotic alone can prevent any wound infections which will lead to potential economic benefits and prevent the development of resistant strains of bacteria.

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