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# A COMPARATIVE STUDY FOLLOWING SINGLE-DOSE VERSUS THREE-DOSE PERIOPERATIVE ANTIMICROBIAL PROPHYLAXIS IN CLEAN ELECTIVE SURGICAL CASES

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## ABSTRACT

**Background:** Appropriate antibiotic prophylaxis in surgery is directed towards the most likely pathogens encountered during the surgical procedure. The type of operative procedure is helpful in deciding the appropriate antibiotic spectrum.

**Aim & objective:** Evaluate and compare the outcomes following single-dose versus three-dose perioperative antimicrobial prophylaxis in clean elective surgical cases.

**Methodology:** 200 patients undergoing clean elective surgery were divided in two groups based on odd and even registration numbers. The studyGroup I received a single dose of injection cefotaxime (30 mg/kg/dose) half an hour prior to start of surgery. Group II received three doses of antimicrobial agent and the follow up was done till 1 month following surgery for Surgical Site Infection. Data were analyzed using Chi square test and Fischer exact test in SPSS version 20.

**Results:** Out of 100 patients included in the study in each group, 3 patients (3%) in single dose group and 4 patients (4%) in three dose group developed SSI within 30 days of surgery.

**Discussion:** Indiscriminate use of antibiotics is discouraged because it may lead to the emergence of antibiotic-resistant strains of organisms or serious hypersensitivity reactions.

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## INTRODUCTION

Appropriate antibiotic prophylaxis in surgery is directed towards the most likely pathogens encountered during the surgical procedure. The type of operative procedure is helpful in deciding the appropriate antibiotic spectrum and is considered before administering any preoperative medication. National Institute for Health and Clinical Excellence (NICE), 2008 recommends antibiotic prophylaxis to patients before clean surgery involving the placement of prosthesis or implants. The NICE guideline considers giving a single dose of antibiotic prophylaxis intravenously on starting anaesthesia and earlier for operations in which a tourniquet is used.<sup>[1]</sup>

The appropriate antibiotic is chosen before surgery and administered before the skin incision is made. <sup>[2]</sup> Perioperative antibiotic prophylaxis generally is not continued beyond the day of surgery in clean elective surgical cases.<sup>[3]</sup>

There are various protocols of antibiotic prophylaxis in literature with none of them extending beyond 24 to 48 hours of the incision time keeping the renal parameters of the patient in consideration.The decision to use prophylactic antibiotic therapy, however, must be based on balancing possible benefit against possible adverse effects. Indiscriminate use of antibiotics is discouraged because it may lead to the emergence of antibiotic-resistant strains of organisms or serious hypersensitivity reactions. In particular, prolonged use of prophylactic antibiotics may also mask the signs of established infections.<sup>[4]</sup>

Prophylactic antibiotic therapy is no substitute for careful surgical technique using established surgical principles, and indiscriminate or general use of prophylactic therapy is not in the best interest of the patient. Antibiotic agents can be used effectively only as adjuncts to adequate surgery. <sup>[5]</sup>

No evidence supports the practice of continuing prophylactic antibiotics until central lines, drains, and chest tubes are removed and most regimens of prophylaxis are completed within 24 hours of the time of incision. However, there is evidence of increase in the recovery of resistant bacteria by this practice.<sup>[6]</sup>

The differentiation between major and minor wound infection is important. There are scoring systems for the severity of wound infection like Southampton scoring system.<sup>[7]</sup>

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With the fear of developing wound infection after surgery many surgeons administer antibiotics for a period of 7-10 days even in clean uncontaminated surgeries. This practice is not only expensive to the patients but also can lead to hospital-acquired infections.<sup>[8]</sup>

The purpose of conducting this study is to know whether prophylactic administration of antibiotics can decrease postoperative morbidity, shorten hospitalization, reduce the overall cost attributable to infection and prevent unnecessary use of antibiotics for long periods. **AIM:** 

# The aim of this study was to compare the outcomes following single-dose versus three-dose perioperative antimicrobial prophylaxis.

### **OBJECTIVES:**

- 1. To evaluate and compare the outcomes following single-dose versus three-dose perioperative antimicrobial prophylaxis in clean elective surgical cases with or without an implant being used in surgery.
- 2. To correlate surgical wound outcome and rate of infection with the nature of surgery and use of prosthesis if any

## **MATERIALS AND METHODS:**

This study consists of cases who were patients admitted to general surgical ward for undergoing clean elective surgery- laparoscopic and conventional surgery at a tertiary care Medical college from July 2012 to June 2014. The study was a prospective comparative study of 100 patients in each arm with total 200 cases. Ethical clearance was taken from the Medical college ethical committee prior to the study.Patients admitted to general surgical ward undergoing clean elective surgery- laparoscopic or conventional surgery at a tertiary care medical college were selected for the

All patients operated in emergency settings; patient with uncontrolled diabetes, collagen vascular disease, chronic liver and chronic renal disease were excluded.Consent was taken with all patients about the treatment. Cases were divided into two groups on the basis of OPD book registration number. Patients with odd registration number were placed in group one and patients with even registration number were placed in group two. First hundred cases meeting inclusion criteria were taken up for study in each group and the cases having any of the exclusion criteria were excluded from the studyGroup I received a single dose of injection cefotaxime (30 mg/kg/dose) half an hour prior to start of surgery. Starting time of surgery was the time of first incision and repeat dose of antibiotic was not given as duration of all surgeries was less than 3 hours.

Group II received three doses of antimicrobial agent, first dose half hour prior to start of surgery, second dose 12 hours after the first dose and third dose 12 hours after the second dose.

Follow up was done on the 3<sup>rd</sup> post-operative day, the 7<sup>th</sup> post-operative day and after 1 month following surgery. All cases were evaluated on the basis of types of surgery performed and prophylaxis undertaken. Wound swab cultures were taken and patients were started on broad spectrum antimicrobial agent which was modified as per antimicrobial sensitivity pattern later. **STATISTICAL ANALYSIS:**  All data were analyzed using Chi square test and Fischer exact test in SPSS version 20. **RESULTS:** 

This was a prospective comparative study involving 200 cases from July 2012 to June 2014. 200 patients undergoing clean elective surgery at tertiary care hospital were included in the study. Patients with odd registration number were placed in group one and patients with even registration number were placed in group two. These patients were followed up for 30 days postoperatively and findings were recorded. Of these, none of the patients were lost to follow up.



### a) <u>Age wise incidence of SSI:</u>

The patients included were of various ages ranging from 02 years to 82 years. The incidence of SSI was highest in the patient >50 age group in both the antibiotic group (Fig 7).

Table 7: Age wise incidence of SSI



# Figure 7: Age wise incidence of SSI

## b) <u>Sex wise incidence of SSI:</u>

In the single dose group,2 males out of 68 had SSI and 1 out of 32 female had SSI. However in three dose group, 4 males out of 73 had SSI and there was no SSI among 27 female. This study found an increased incidence of SSI in males compared to females in both the groups which was however, not significant by the Fischer exact test [P = 0.676]

## c) <u>Surgical wound outcome and rate of infection:</u>

Out of 100 patients included in the study in each group, 3 patients (3%) in single dose group and 4 patients (4%) in three dose group developed SSI within 30 days of surgery. In the single dose group, out of 56 patients with

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implants, 3 patients had SSI and out of 44 patients without implants, none had SSI. Similarly, in the three dose group, out of 59 patients with implants, 1 patient had SSI and out of 41 patients without implants, three patients had SSI (table 4, figure 4).

<b>Table 4: Surgica</b>	wound outcome and rate of infection following sin	le-dose versus three-dose p	erioperative antimicrobia	al prophylaxis
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	Single dose			Three dose			Fischer exact 2 tailed
	With implants	Without	%	With implants	Without	%	P-value
		implants			implants		
SSI	3	0	3	1	3	4	1
NO SSI	53	44	97	58	38	96	-
TOTAL	100		100	100		100	-

# Figure 4: Surgical wound outcome and rate of infection following single-dose versus three-dose perioperative antimicrobial prophylaxis



d) Smoking wise incidence of SSI:

In the single dose antibiotic group, incidence of SSI in non-smoker was 1 in 90 patients whereas in smoker 2 out of 10 patients. However, in three dose antibiotic group incidence of SSI in non-smoker group was 3 out of 91 patients whereas in smoker group 1 out of 9 patients. The incidence of SSI was higher among smoker in both the antibiotic group.

- e) Incidence of SSI with timing of surgery:
- f) In our study all surgeries were performed in less than three hours in both the antibiotic group. The operating time ranged between a minimum of 25 minutes to maximum of two hours and 30 minutes. Incidence of SSI with timing of surgery couldn't be compared as none of the surgeries were of duration more than 3 hours.

## DISCUSSION

In spite of the use of prophylactic antibiotics, SSIs are still a risk of surgery and represent a substantial burden of disease for both patients and healthcare services in terms of morbidity, mortality and economic cost.

The incidence of SSIs have been estimated to be less than 5% for clean surgery to more than 20% for dirty surgery. In this study, we found an incidence rate of 3% in single dose antibiotic group and 4% in three dose antibiotic group in clean surgeries which is similar to other studies conducted in India. <sup>[9, 10]</sup> Hence, single dose antibiotic treatment in clean surgeries is not inferior to three dose antibiotic treatment.

In the study there was no SSI in patients receiving single-dose antimicrobial prophylaxis whereas three SSIs were seen in patients receiving three-dose antimicrobial prophylaxis in surgeries without implants. Similarly, there was three SSI in three-dose antimicrobial group and one SSI in single-doseantimicrobial groupof patients who underwent surgeries with implant. Study done by Rachel L Berger et al states patient who underwent hernia repair with mesh had more surgical site infections (19.8% versus 7.9%).  $^{[11,\,12]}$ 

Our study revealed a higher incidence of SSI in males compared to females in accordance with other global studies.<sup>[13]</sup>Another Study conducted in India by Kamat showed an SSI rate of 33.8% in males against 28 % in females.This difference may be explained by the existence of increased risk factors in males like alcohol, smoking, hypertension, etc. <sup>[14]</sup>

In this study, the rate of SSI was more in obese patients (BMI >30kg/m<sup>2</sup>) in both the antimicrobial group. Different studies showed that obesity is an independent risk factor for development of SSI. <sup>[15]</sup>

Our study also revealed a higher incidence of SSI among smokers in both the antibiotic group.<sup>[16]</sup> This may be because of local systemic vasoconstriction causing tissue hypoxia, which delays primary wound healing.

Multiple studies across the world have revealed an increased incidence of SSI with longer operating time of more than three hours. <sup>[17, 18]</sup> In our study all surgeries were performed in less than three hours in both the antimicrobial group. Incidence of SSI with timing of surgery couldn't be compared as none of the surgeries were of duration more than 3 hours.

Our study shows an increase incidence of SSI with staphylococcus aureus which is similar to other studies.<sup>[12]</sup>

## CONCLUSION

Though this approach is recommended by NICE guidelines (2008), the optimum duration of antibiotic prophylaxis and the regimes are still in controversy as many surgeons preferred to use multiple dose antibiotics to prevent SSI in health care settings like ours where there is high risk of acquiring infections. However for implementing the single dose antibiotic recommendation, the extra caution and care should be taken focusing on various outcome variables like age, sex, body mass index, smoking history, nature of surgery, use of implants, drains and prosthesis, etc. The decision to use prophylactic antibiotic therapy, however, must be based on balancing possible benefit against possible adverse effects. Indiscriminate use of antibiotics is discouraged because it may lead to the emergence of antibiotic-resistant strains of organisms or serious hypersensitivity reactions.

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