

## Utilization of Antimicrobial Agents Used For Surgical Prophylaxis in Consideration with Co-morbidities in Patients Undergoing Surgeries

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**Conflicts of Interest:** Nil.

### Abstract

**Objectives:** To see whether there is any difference in choice of antimicrobial agents used for surgical prophylaxis in consideration with co-morbidities in patients undergoing surgeries

**Methods:** A prospective, observational study was conducted in 600 surgical cases from General surgery, Obstetrics and Gynaecology and Orthopaedics departments in a tertiary care hospital. Data were collected from medical case sheets about AMA used for surgical prophylaxis with regards to dose, timing, frequency, duration and past history of patient with regards to co-morbid condition like diabetes mellitus, tuberculosis, HIV and chronic asthma.

**Results:** In General surgery and Obstetrics and Gynaecology department metronidazole was commonly used and in Orthopaedics department amikacin was commonly used for surgical prophylaxis either in combination with ceftriaxone or cefotaxime. In none of above patients there found any difference in choice of antimicrobial agents used for surgical prophylaxis with regards to associated co-morbidities when compared with the patients without any associated co-morbidities.

**Conclusion:** Metronidazole and amikacin were commonly used for surgical prophylaxis in combination with cephalosporins.

**Keywords:** Antimicrobial agents, surgical prophylaxis, utilization, co-morbidities

### Introduction

Surgical site infection (SSI) accounts for 15% of all nosocomial infections and among surgical patients, represents the most common nosocomial infection.<sup>1</sup> Approximately 1 million patients have surgical site infections each year in the United States, extending the average hospital stay by one week and increasing the cost of hospitalization by 20 percent. This translates to an additional \$1.5 billion in health care costs annually.<sup>2</sup>

The purpose of surgical prophylaxis is to reduce the incidence of SSI with minimum alteration of normal microbial flora of host.<sup>3</sup> Proper antibiotic prophylaxis has been shown to be effective in reducing the incidence of surgical site infections and the selection of an appropriate antimicrobial agent (AMA) depends on the pathogen most likely to cause an infection at surgical site.<sup>4</sup>

Approximately 30–50% of antibiotic use in hospital practice is now for surgical prophylaxis. However,

frequently, the antibiotic is either given at the wrong time or continued for too long.<sup>5</sup>

Consequences of SSIs increases the cost of treatment, longer duration of hospital stay and increase use of antimicrobials which can enhance the antimicrobial resistance among the pathogens likely to cause surgical wound infections.<sup>6,7</sup>

Inappropriate usage and prolonged postoperative doses do not provide any added benefit but may increase the incidence of antibiotic resistance.<sup>8</sup> These type of errors in the surgical prophylaxis for surgical patients are one of the most common types of medication errors in hospitals and there is a necessity to generate baseline data on the pattern of the use of prophylactic antimicrobials.<sup>9</sup>

So the monitoring of prescriptions and drug utilization studies could identify the related problems and provide feedback to prescribers. In a developing countries like India due to availability of limited funds for health care it becomes very important to prescribe drug rationally so that available funds can be optimally utilised.<sup>10</sup>

Hence this study was planned to evaluate the utilization pattern of antimicrobial agents used for surgical prophylaxis with respect to the associated co-morbidities in the patients.

## **Methodology**

### **Study design**

This was a prospective, observational, hospital based study to evaluate the utilization of antimicrobial agents used for surgical prophylaxis including treatment of post-operative infections. The study was conducted by the Department of Pharmacology, in collaboration with the Departments of General surgery, Orthopaedics and Obstetrics and Gynaecology in a tertiary care hospital.

### **Study population:**

Patients undergoing surgeries of clean or clean-contaminated type of surgical wound in the three surgical

departments namely General surgery, Orthopaedics and Obstetrics and gynaecology of tertiary care hospital, were screened for the study and subjects who satisfy the inclusion and exclusion criteria mentioned below were recruited for the study.

### **Inclusion criteria**

1. Patients undergoing surgeries in surgical department's namely General surgery, Orthopaedics and Obstetrics and Gynaecology.
2. Surgical operations classified as clean (Class I) or clean-contaminated (Class II) according to National Research Center (NRC) Classification.

### **Exclusion criteria**

1. Patients below the age of 18 years. (To exclude minor age group population)
2. Surgical operations classified as contaminated (Class III) or dirty (Class IV) according to NRC Classification.

### **Detailed research plan**

#### **Data collection**

A prospective, observational study was conducted for a period of six months from July to December 2015 in 600 patients admitted for various surgeries in three surgical departments namely General surgery, Orthopaedics and Obstetrics and gynaecology, after taking official permission from above mentioned departments and after approval from Institutional Ethical committee.

The data were collected from medical case sheet (I.P.D. file) and operation notes while the patients were still in the hospital.

The data were collected on a case record form designed for study, includes:

- Demographic details of patients
- Diagnosis, name of surgery done, type of surgery
- Details of Antimicrobial agents (AMA) used for surgical prophylaxis with regards to dose, route, timing of first

dose, frequency of administration and total duration of surgical prophylaxis.

Data retrieved from case record forms were entered in Microsoft Excel sheet and assessed for various parameters to find out study objectives.

**Data assessment**

Data were assessed for comparing choice of antimicrobial agents used for surgical prophylaxis in patients with and without associated co-morbidities like diabetes mellitus, HIV, tuberculosis which increases risk of surgical site infections.

**Statistical analysis**

For the statistical analysis average, mean and standard deviation (SD) were calculated by using Microsoft Excel 2013

**Results**

Data of total 600 surgical cases, 200 cases from each of the three surgical department's namely General surgery, Orthopaedics and Obstetrics and Gynaecology departments were analysed.

**Demographic details:**

Table I: Age, gender and types of surgery included in study from different departments:

Department	Age ± S.D.	Gender		Types of surgery	
		Males	Females	Class I	Class II
General surgery	44.85 ± 14.37	138 (69%)	62 (31%)	134 (67%)	66 (38%)
Orthopaedics	44.24 ± 18.00	133 (66%)	66 (33%)	182 (91%)	18 (9%)
Obstetrics & Gynaecology	29.40 ± 18.00	0 (0%)	100 (100%)	9 (4.5%)	191 (95.5%)

Table I shows that mean age of patients was 44.85 ± 14.37, 44.24 ± 18.00 and 29.40 ± 18.00 in General surgery, Orthopaedics and Obstetrics & Gynaecology departments respectively.

With respect to gender there were 138 (69%) and 133 (66%) males in General surgery and Orthopaedics departments respectively. Also 62 (31%) and 66 (33%) were females in General surgery and Orthopaedics departments respectively.

Naturally all were females in Obstetrics & Gynaecology department.

134 (67%), 182 (91%) and 9 (4.5%) were class I type of surgeries in in General surgery, Orthopaedics and Obstetrics & Gynaecology departments respectively.

66 (38%), 18 (9%) and 191 (95.5%) were class II type of surgeries in in General surgery, Orthopaedics and Obstetrics & Gynaecology departments respectively.

**Pattern of antimicrobial agents use for surgical prophylaxis:**

Table II: Antimicrobial agents (AMA) used for surgical prophylaxis in different departments:

Name of drug	General surgery n (%)	Orthopaedics n (%)	Obstetrics and Gynaecology n (%)	Total n (%)
Ceftriaxone	105 (53.30%)	151 (75.50%)	10 (5.05%)	266 (44.33%)
Metronidazole	<b>134 (68.02%)</b>	112 (56%)	<b>198 (100%)</b>	444 (74%)
Amikacin	80 (40.61%)	<b>174 (87%)</b>	6 (3.03%)	260 (43.33%)
Cefotaxime	67 (34.01%)	49 (24.50%)	142 (71.71%)	258 (43%)
Gentamicin	0 (0%)	28 (14%)	94 (47.47%)	122 (20.33%)

Table II shows antimicrobial agents used for surgical prophylaxis.

Metronidazole was commonly used for surgical prophylaxis in 134 (68.02%) cases of General surgery

either in combination with ceftriaxone or cefotaxime but not as a single prophylactic agent.

Amikacin was commonly used for surgical prophylaxis in Orthopaedics department i.e. in 174 (87%) cases either in combination with ceftriaxone or cefotaxime but not as a single prophylactic agent.

Metronidazole was commonly used for surgical prophylaxis in Obstetrics and Gynaecology department i.e. in 198 (100%) cases either in combination with ceftriaxone or cefotaxime but not as a single prophylactic agent.

Figure I: Number of antimicrobial agents (AMA) used for surgical prophylaxis per patient in different departments:

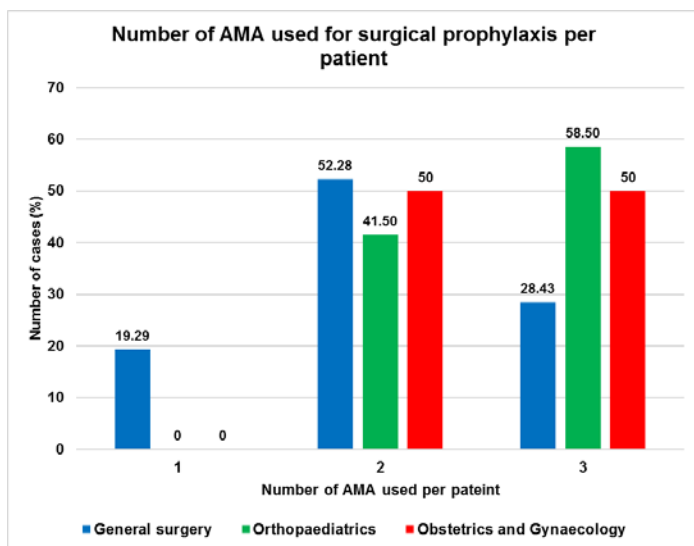


Figure I shows a single antimicrobial agent per case was used in 19.29% patients of General surgery whereas in all cases of Obstetrics and Gynaecology and Orthopaedics more than one antimicrobial agents were used for surgical prophylaxis per patient.

Combination of two antimicrobial agents per case were used in 52.28%, 41.50% and 50% patients of General surgery, Orthopaedics and Obstetrics and Gynaecology departments respectively.

Combination of three antimicrobial agents per case were used in 28.43%, 58.50% and 50% patients of General

surgery, Orthopaedics and Obstetrics and Gynaecology departments respectively.

**Difference in choice of antimicrobial agents used for surgical prophylaxis in patients with and without associated co-morbidities in study departments:**

Figure II: Number of patients with and without co-morbidities:

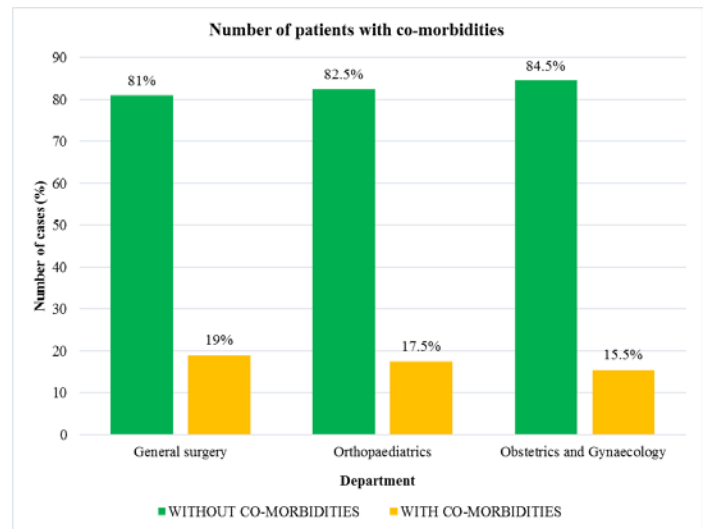


Figure II shows among the study departments' patients with associated co-morbidities like diabetes mellitus, tuberculosis, HIV which increases risk of surgical site infections.

19%, 17.5% and 15.5% patients had associated with above mentioned co-morbidities in General surgery, Orthopaedics and Obstetrics and Gynaecology departments respectively.

Table III: Number of cases with co-morbidities which increases risk of surgical site infections

Co-morbidities	General surgery n (%)	Orthopaedics n (%)	Obstetrics and gynaecology n (%)
Diabetes mellitus	19 (9.5%)	16 (8%)	12 (6%)

<b>HIV</b>	5 (2.5%)	3 (1.5%)	6 (3%)
<b>Tuberculosis</b>	10 (5%)	9 (4.5%)	8 (4%)
<b>Chronic asthma</b>	4 (2%)	7 (3.5%)	5 (2.5%)
<b>Total</b>	<b>38 (19%)</b>	<b>35(17.5%)</b>	<b>31 (15.5%)</b>

In General surgery department 19 (9.5%), 5 (2.5%), 10 (5%) and 4 (2%) patients were suffering from co-morbidities like diabetes mellitus, HIV, tuberculosis and chronic asthma respectively.

In Orthopaedics department 16 (8%), 3 (1.5%), 9 (4.5%) and 7 (3.5%) patients were suffering from co-morbidities like diabetes mellitus, HIV, tuberculosis and chronic asthma respectively.

In Obstetrics and gynaecology department 12 (6%), 6 (3%), 8 (4%), 5 (2.5%) patients were suffering from co-morbidities like diabetes mellitus, HIV, tuberculosis and chronic asthma respectively.

Table IV: Difference in choice of antimicrobial agents (AMAs) used for surgical prophylaxis in cases with co-morbidities with respect to cases without any associated co-morbidities:

Category Department	Cases with co-morbidities n (%)	Cases with co-morbidities where different AMAs used for surgical prophylaxis n (%)
General surgery	38 (19%)	0 (0%)
Orthopaedics	35 (17.5%)	0 (0%)
Obstetrics and gynaecology	31 (15.5%)	0 (0%)

Table IV shows in General surgery, Orthopaedics and Obstetrics and Gynaecology departments 38 (19%), 35 (17.5%) and 31 (15.5%) patients had associated co-morbidities like diabetes mellitus, tuberculosis, HIV and chronic asthma which increases risk of surgical site infections, but in none of above patients there found any difference in choice of antimicrobial agents used for surgical antibiotic prophylaxis with regards to associated co-morbidities when compared with surgical antibiotic prophylaxis given to the patients without any associated co-morbidities like diabetes mellitus, tuberculosis, HIV and chronic asthma.

### Discussion

This was a prospective, observational and hospital based study conducted in surgical departments namely Generals surgery, Orthopaedics and Obstetrics and Gynaecology of tertiary care hospital with aim to evaluate the utilization and pharmaco-economics of antimicrobial agents used for surgical prophylaxis.

In this study patients above 18 years undergoing clean and clean-contaminated types of surgeries in three surgical departments namely Generals surgery, Obstetrics and Gynaecology and Orthopaedics were included.

In General surgery department maximum number of cases included in study were belonged to age group of 48-57 i.e. 52 (26%) cases with mean age of  $44.85 \pm 14.33$ (SD) years.

In Orthopaedics department maximum number of cases included belong to age group of 28-37 i.e. 42 (21%) with mean age of  $44.24 \pm 17.50$ (SD) years.

In Obstetrics and Gynaecology department maximum number of cases included belong to age group of 18-27 i.e. 120 (60%) with mean age of  $29.40 \pm 10.26$ (SD) years.

A study on surgical prophylaxis pattern in India by Kaur R et al <sup>14</sup>, mean age was  $40.22 \pm 15.22$ (SD) and  $31.40 \pm$

12.98(SD) for General surgery and Obstetrics and Gynaecology cases included in study.

In this study male patients were more admitted as compared to female patients in total as well as separately in General surgery and Orthopaedics departments. The reason for more male admissions in this study may be attributed to more male to female ratio in Maharashtra and in the Indian scenario it is noticed that female populations are reluctant to utilize health care facilities even if they are critically ill.

In all 600 cases enrolled in study from General surgery, Orthopaedics and Obstetrics and Gynaecology departments, 325(54.16%) were clean surgeries and 275(45.83%) were clean-contaminated surgeries.

In a study by Ramesh A. et al <sup>15</sup>, 60 % were clean surgeries and 40% were clean-contaminated surgeries.

In General surgery and Obstetrics and Gynaecology departments, metronidazole was most commonly used antimicrobial agent for surgical prophylaxis. Metronidazole was used in combination with 3rd generation cephalosporins i.e. either with ceftriaxone in 37.57% cases from General surgery and in 9.09% cases from Obstetrics and Gynaecology departments or with cefotaxime in 24.43% cases from General surgery and 71.26% cases from Obstetrics and Gynaecology departments. But metronidazole was not used as a single drug for surgical prophylaxis in either of above departments.

The prophylactic regimen in patients undergoing surgery should include an agent effective against the most likely infecting organisms, but need not eradicate every potential pathogen. <sup>(13)</sup>

In a review by Reichman DE et al <sup>(14)</sup> common pathogens encountered during the surgical procedures in General surgery and Obstetrics and Gynaecology, were found to be gram negative bacilli and anaerobes.

So combination of 3<sup>rd</sup> generation cephalosporin with metronidazole provide adequate coverage to gram negative bacilli as well as anaerobes encountered during the surgical procedures in General surgery and Obstetrics and Gynaecology for surgical prophylaxis.

A study by Mangram AJ et al <sup>(15)</sup> also state that metronidazole in combination with cephalosporins provide good anaerobic cover and hence recommended for surgical prophylaxis.

In Orthopaedics department, amikacin was most commonly used antimicrobial agent for surgical prophylaxis. Amikacin was used in combination with 3rd generation cephalosporins i.e. either with ceftriaxone in 70% cases or with cefotaxime in 17% cases but was not used as a single drug for surgical prophylaxis in Orthopaedics surgical procedures.

In combination with amikacin, ceftriaxone was used more commonly than cefotaxime. It might be because former has longer duration of action compared to cefotaxime and Orthopaedics surgeries last for longer duration and hence required a steady plasma and tissue concentration of prophylactic antimicrobial agent for whole duration of surgery.

The common pathogens encountered during Orthopaedics surgical procedures were found to be staphylococcus aureus and gram negative bacilli. <sup>(15)</sup>

So combination of 3<sup>rd</sup> generation cephalosporins with amikacin both having the spectrum of activity against gram negative bacteria provide a good coverage against gram negative bacilli encountered during Orthopaedics surgical procedures but without any additive role as both of them having same spectrum of activity with regards to gram negative bacteria.

Also a study on patterns of antimicrobial use by surgeons in India by Kulkarni R et al <sup>(16)</sup> states that amikacin with 3<sup>rd</sup> generation of cephalosporins which having broad-

spectrum gram negative coverage has been shown to provide no additional benefits.

Average number of antimicrobial agents used per surgical case for providing surgical prophylaxis were  $2.09 \pm 0.68$  (SD),  $2.58 \pm 0.49$ (SD) and  $2.50 \pm 0.50$ (SD) in General surgery, Orthopaedics and Obstetrics and Gynaecology departments

In a study on Surgical site infection and Antibiotics use pattern in a tertiary care hospital by Giri BR et al<sup>(17)</sup>, average number of antimicrobial agents use for surgical prophylaxis per case were  $2.1 \pm 1.36$ (SD).

In this study there were patients undergoing surgeries with co-morbidities like diabetes mellitus, human immune deficiency virus (HIV) infection, tuberculosis (TB) and chronic asthma.

These co-morbidities are considered as a risk factors for development of surgical site infection (SSI).<sup>(18)(19)</sup>

So study planned to see whether there is any difference in choice of antimicrobial agents used for surgical prophylaxis for surgical procedure in patients with co-morbidities and without co-morbidities.

In this study in General surgery, Orthopaedics and Obstetrics and Gynaecology departments, 38 (19%), 30 (15%), 31 (15.5%), patients had associated co-morbidities which were considered as risks factors for surgical site infections (SSI).

But the study found that there were no any difference in choice of antimicrobial agents used for surgical prophylaxis in patients with co-morbidities and patients without co-morbidities undergoing same surgical procedures in all of three surgical departments.

Hence the study findings shows that the surgical prophylaxis was given in accordance with the surgical procedures and irrespective of patient's co-morbid conditions.

A study by Timothy Tan et al<sup>(20)</sup> on should preoperative antibiotics be tailored according to patient's co-morbidities? reveals that co-morbidities do not significantly alter organism profile at surgical sites and results of this study support current guidelines, which provide a universal recommendation rather than protocol that is tailored to patients pre-existing co-morbidities.

Standard guideline for surgical prophylaxis i.e. ASHP<sup>(21)</sup> has mentioned co-morbidities like diabetes mellitus, HIV, TB and chronic asthma as risk factors for surgical site infections but not mentioned need of change in surgical antimicrobial prophylaxis with respect to pre-existing co-morbidities in patients.

Co-morbidities were consistently found to be associated with SSI incidence. The most frequently considered co-morbidity was diabetes and control of perioperative hyperglycemia can help in minimizing risk of surgical site infections.<sup>(22)(23)</sup>

So these pre-existing co-morbidities which are the patients related risk factors for surgical site infections should be managed peri-operatively so as to reduce risk of post-operative infections and plan of surgical antimicrobial prophylaxis remains universal with respect to surgical procedures.<sup>(24)</sup>

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