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Effectiveness of Surgical Prophylaxis And Expenditure on Antimicrobial Agents Used For Treatment of Post-Operative Infections

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Abstract:
Background: *Surgical site infection (SSI) accounts for 15% of all nosocomial infections and represents the most common nosocomial infection.*
Objectives: *to access effectiveness of surgical prophylaxis in prevention of post-operative infections and expenditure on antimicrobial agents used for treatment of post-operative infections.*
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 antimicrobial agents (AMA) used for surgical prophylaxis and for post-operative infection.*
Results: *No post-operative infections occurred in 80.5%, 94.5% and 87% patients of General surgery, Orthopaedics and Obstetrics and Gynaecology respectively. 34%, 14% and 47% of total expenditure was because of AMA used for treatment of post-operative infections respectively.*
Conclusion: *Surgical prophylaxis was found effective in preventing occurrence of post-operative infections in patients undergoing surgeries. Consequences of post-operative infections increases the cost of treatment*
Keywords: *Surgical prophylaxis, expenditure, effectiveness, post-operative infections*

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I. Introduction

Surgical site infection (SSI) accounts for 15% of all nosocomial infections and among surgical patients, represents the most common nosocomial infection. (1) 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. (2)

The incidence of SSIs in India has not been systematically studied, hence there are neither global SSI rates nor SSI rates stratified by surgical procedure according to the 9th edition of the International Classification of Diseases (ICD-9) criteria.(3) The purpose of surgical prophylaxis is to reduce the incidence of SSI with minimum alteration of normal microbial flora of host. (4) The concept of preoperative use of antimicrobials to prevent postoperative infection in surgical patients was introduced before the modern era of antibiotics. (5) 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. (6) The studies carried out in India shows an overall infection rate of 4.04% to 30% for clean surgeries and 10.06% to 45% for clean-contaminated surgeries and also reported Staphylococcus aureus as the commonest isolate from the post-operative wound infection. (7) Hence, the necessity of this study was to access effectiveness of surgical prophylaxis in prevention of post-operative infections and to calculate the cost expenditure on antimicrobial agents used for treatment of post-operative infections occurred in studied population.

II. 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.
- Record of post-operative infection if occurs in study patients on the basis of criteria for diagnosis of post-operative infection (surgical site infection) such as signs of inflammation at the operative wound, serous/non-purulent/pus discharge from operative wound along with AMA used for post-operative infection .

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

Data assessment:

The effectiveness of surgical prophylaxis was assessed by calculating number of patients without any post-operative infection during the hospital stay who received the antimicrobial agents for surgical prophylaxis purpose. Total expenditure on antimicrobial agents used for surgical antibiotic prophylaxis and for post-operative infections if occurred in study patients were calculated on the basis of cost of each antimicrobial agent given in government rate contract (RC) book of in drug store of hospital to high-lighten the direct cost burden on health care system due to post-operative infections.

Statistical analysis:

For the statistical analysis average, mean and standard deviation (SD) were calculated by using Microsoft Excel 2013 and Fisher's Exact test was used for comparing multiple variables by calculating p-value using GraphPad QuickCalcs software online.

III. 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.

Effectiveness of surgical prophylaxis:

Table 2: Effectiveness of surgical prophylaxis in prevention of post-operative infections in study groups

Department	Surgical prophylaxis received n (%)	Surgical prophylaxis not received n (%)	No post-operative infections occurred n (%)	Post-operative infections occurred n (%)	p-value
General surgery (n=200)	197 (98.5%)	3 (1.5%)	161 (80.5%)	39 (19.5%)	**<0.0001***
Orthopaedics (n=200)	200 (100%)	0 (0%)	189 (94.5%)	11 (5.5%)	**<0.0008***
Obstetrics and Gynaecology (n=200)	198 (99%)	2 (1%)	174 (87%)	26 (13%)	**<0.0001***
Total (n=600)	595 (99.17%)	5 (0.83%)	524(87.33%)	26 (4.33%)	

Fisher's exact test,* p-value <0.05 as significant.

Table 2 shows in General surgery department, surgical antimicrobial prophylaxis was received in 197 (98.5%) of patients and in 161 (80.5%) patients, no post-operative infections occurred. In Orthopaedics, surgical antimicrobial prophylaxis was received in 200 (100%) of patients and no post-operative infections were occurred in 189 (94.5%) patients. In Obstetrics and Gynaecology, surgical antimicrobial prophylaxis was received in 198 (99%) patients and no post-operative infections were occurred in 174 (87%) patients.

Expenditure on antimicrobial agents (AMA) used for surgical prophylaxis and for post-operative infections:

Table 3: 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	**134 (68.02%)**	112 (56%)	**198 (100%)**	444 (74%)
Amikacin	80 (40.61%)	**174 (87%)**	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 3 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.

Table 4: Antimicrobial agents (AMA) used for the treatment of post-operative infections occurred:

Name of drug	**General surgery n (%)**	**Orthopaedics n (%)**	**Obstetrics and Gynaecology n (%)**
Amikacin	**35 (89.74%)**	5 (45.45%)	8 (30.80%)
Metronidazole	23 (58.97%)	**6 (54.55%)**	**21 (80.80%)**
Cefotaxime	13 (33.33%)	1 (9.09%)	6 (23.08%)
Piperacillin+Tazobactum	11 (28.21%)	0 (0%)	0 (0%)
Ceftriaxone	10 (25.64%)	5 (45.45%)	4 (15.38%)
Linezolid	0 (0%)	5 (45.45%)	0 (0%)
Co-trimoxazole	0 (0%)	5 (45.45%)	0 (0%)
Imipenem	0 (0%)	0 (0%)	8 (30.80%)
Meropenem	0 (0%)	0 (0%)	4 (15.38%)
Ciprofloxacin	0 (0%)	0 (0%)	3 (11.54%)
Levofloxacin	0 (0%)	0 (0%)	2 (7.69%)

Table 4 shows Antimicrobial agents (AMA) used for the treatment of post-operative infections occurred: For the treatment of post-operative infections occurred in General surgery department, Amikacin was used in 35 (89.74%) patients and metronidazole in 23 (58.97%) both of each either in combination with ceftriaxone or cefotaxime but not as monotherapy for treatment of post-operative infections.

For the treatment of post-operative infections occurred in Orthopaediatrics department, Metronidazole was used in 6 (54.55%) patients and amikacin in 5 (45.45%) both of each either in combination with ceftriaxone or cefotaxime but not as monotherapy for treatment of post-operative infections. For the treatment of post-operative infections occurred in Obstetrics and Gynaecology department, Metronidazole was used in 21 (80.80%) patients and amikacin in 8 (30.80%) both of each either in combination with ceftriaxone or cefotaxime but not as monotherapy for treatment of post-operative infections

Table 5: Total expenditure on antimicrobial agents used for surgical prophylaxis and for treatment of post-operative infections in different departments

Department	**Expenditure on AMA used for surgical prophylaxis (Rs)**	**Expenditure on AMA used for treatment of post-operative infections (Rs)**	**Total expenditure on AMA (Rs)**
General surgery	45,199.15	24,124.17	69,323.22
Orthopaedics	80,777.8	13,295.9	94,073.7
Obstetrics and Gynaecology	47,526.42	42,590.4	90,116.82
Total	**1,73,503.37**	**80,010.47**	**2,53,513.74**

Table 5 shows total expenditure on antimicrobial agents used for surgical prophylaxis and for treatment of post-operative infections in different departments. For General surgery department, total expenditure on AMA was Rs. 69,323.22 among which Rs. 45,199.15 was total expenditure because of AMA used for surgical prophylaxis and Rs. 24,124.17 was because of AMA used for treatment of post-operative infections. For Orthopaedics department, total expenditure on AMA was Rs. 94,073.7 among which Rs. 80,777.8 was total expenditure because of AMA used for surgical prophylaxis and Rs. 13,295.9 was because of AMA used for treatment of post-operative infections.

For Obstetrics and Gynaecology department, total expenditure on AMA was Rs. 90,116.82 among which Rs. 47,526.42 was total expenditure because of AMA used for surgical prophylaxis and Rs. 42,590.4 was because of AMA used for treatment of post-operative infections.

IV. 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 ± 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 ± 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 ± 10.26(SD) years.

A study on surgical prophylaxis pattern in India by Kaur R et al [(8)], mean age was 40.22 ± 15.22(SD) and 31.40 ± 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 [(9)], 60 % were clean surgeries and 40% were clean-contaminated surgeries. Surgical antimicrobial prophylaxis is one of the measures used to prevent the development of surgical site infections (SSI). Prophylactic antimicrobial agents by providing an adequate level of antimicrobial agent in the tissues before surgery can reduce the incidence of SSI. [(10)] Surgical antibiotic prophylaxis (SAP) is not only intended to establish bactericidal tissue and serum levels at the time of skin incision, but also to reduce the microbial burden of intraoperative contamination to a level that cannot overcome host defenses. [(11)]

In this study the effectiveness of surgical prophylaxis was assessed by measuring prevention form surgical site infections in patients who received surgical prophylaxis. In this study surgical prophylaxis was received to 98.5 %, 100% and 99% of cases undergone various surgeries in General surgery, Orthopaedics and Obstetrics and Gynaecology departments respectively. No surgical site infections were occurred in 80.5%, 94.5% and 87.0% cases in surgeries in General surgery, Orthopaedics and Obstetrics and Gynaecology departments respectively. p-values calculated by using Fisher's exact test were less than 0.05 and the association between surgical prophylaxis received and protection from surgical site infections is considered to be statistically significant, proving effectiveness of surgical prophylaxis in prevention of surgical site infections.
In General surgery three corn excision surgeries and in Obstetrics and Gynaecology two dilatation and evacuation surgeries were not given any prophylactic AMA but as theses were small, OPD-base and clean type of surgeries, no post-operative infection occurred in them.

A report published by Swedish Council in August 2010 on Antibiotic Prophylaxis for Surgical Procedures-A Systematic Review [(12)] states that there is strong scientific evidence that without surgical antimicrobial prophylaxis, surgical site infections would occur in 30-40% cases of large intestinal and rectum surgeries and surgical prophylaxis can decrease frequency of surgical site infections from 35-40% to 5-10% and also in vascular surgeries. In meta-analyses of heterogeneous studies, perioperative antibiotic prophylaxis with ceftriaxone showed a decrease in the relative risk of SSI of 30% compared to other cephalosporins [(13)] and a 22% reduction compared to a range of antibiotics. [(14)]

Effectiveness of surgical prophylaxis in prevention of surgical site infections is well established, despite this, surveys have shown that optimal practice of surgical prophylaxis isn't achieved in many hospitals. [(15)] 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. [(16)]

In a review by Reichman DE et al [(17)] 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 3rd 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 [(18)] 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. [(18)]

So combination of 3rd 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. Cost of each AMA used for surgical prophylaxis and for treatment of post-operative infections per department were calculated on the basis of prices given in rate contract (RC) book of drug store of the study institution. Out of total expenditure on AMAs, 63%, 85% and 52% of expenditure was because of AMAs used for surgical prophylaxis in General surgery, Orthopaedics and Obstetrics and Gynaecology departments respectively, indicating that for more than half of total expenditure, AMAs used for surgical prophylaxis were the stakeholders.

Such a high contribution by antimicrobial agents used for surgical prophylaxis was because almost 99% of cases in study groups received AMAs for surgical prophylaxis and more than one AMA i.e. combination of two or three antimicrobial agents in most of cases for more than 24 hours of duration after surgery was used as discussed above. Remaining 34%, 14% and 47%of total expenditure was because of use of antimicrobial agents for treatment of post-operative infections occurred in General surgery, Orthopaedics departments and Obstetrics and Gynaecology respectively. Though post-operative infections occurred in 19.5% and 13% cases of General surgery and Obstetrics and Gynaecology, costly antimicrobial agents on the basis of culture-sensitivity reports like Imipenem, meropenem and levofloxacin were used. In Orthopaedics department post-operative infections occurred in only 5.5% of cases, use of costly antimicrobial agent on the basis of culture-sensitivity reports like linezolid for the treatment of post-operative infections contributed to the expenditure. For treatment of post-operative infection selection of antimicrobial agent on the basis of culture-sensitivity was justified by hospital antibiotic policy. Consequences of post-operative infections 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. [(19) (20)]

V. Conclusion

So though surgical prophylaxis was found effective in preventing occurrence of post-operative infections in patients undergoing surgeries there is need of for continued surveillance of surgical prophylaxis practices and measures to promote rational surgical antibiotic prophylaxis.

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