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A drug utilization study of Prospective analysis of prescribing pattern of antimicrobials used in surgical procedures in tertiary care hospital

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Abstract: *Introduction:* Antimicrobials are the most commonly prescribed group of drugs today, but the problem of its overuse or inappropriate use is a global phenomenon. Majority of the antimicrobial use is preoperative during surgical procedures. *Methodology:* The prescribing trends of antimicrobials used during surgical procedures were assessed in 500 patients and were compared among different types of surgeries. The surgical antimicrobial prophylaxis in clean and clean contaminated surgeries was compared with the published guidelines for prophylaxis. *Results:* The prescribing pattern shows that average three antimicrobials were prescribed in patients, with cephalosporins being the most commonly prescribed antimicrobial group. About 42% percent of the total antimicrobials were prescribed from outside hospital source and as many as 90.4% of the patients were prescribed one or more antimicrobial from outside the hospital source. *Conclusion:* There is a considerable scope for improving prescribing pattern of drugs to achieve rational and cost effective antimicrobial use.

Keywords: Drug Utilization Study, Antimicrobials, Surgery, Prophylaxis, Prescription.

Introduction

Antimicrobials are the most commonly prescribed group of drugs today, but the problem of its overuse or inappropriate use is a global phenomenon. Irrational drug prescribing is considered a common occurrence. Drug Utilization Study is a process by which quality of drug prescribing is measured with respect to criteria. It is a pharmacoepidemiological tool that aims at monitoring, evaluating and making necessary alterations in prescribing patterns with an ultimate goal of achieving rational and cost effective medical care [1-2].

Majority of the antimicrobial use is for prophylaxis to prevent infection following surgical procedures, to reduce the morbidity and mortality associated with perioperative infections [3]. The principles of antimicrobial prophylaxis in surgery are clearly established and several guidelines have been published [4-14]. The present study was undertaken to analyze the current prescribing trends of perioperative antimicrobial use in surgical wards of a tertiary care hospital and to do a quantitative analysis of overall antimicrobials used, their source and the cost. This prescribing pattern was compared with some of the published guidelines for the use of antimicrobials for surgical prophylaxis [4, 6, 11].

Material and Methods

This is a prospective single centered observational study conducted on patients admitted in general surgical wards who were receiving peri operative antimicrobials in a tertiary care hospital. Institutional Ethics Committee approval was obtained prior to

commencement of the study. The data was collected after obtaining written informed consent from the patient. The study consisted of 2 parts;

Part 1: Drug utilization review of the prescribing of antimicrobials agents. For this, case records of total 500 patients were reviewed and enrolled in the study as per the following inclusion/ exclusion criteria.

Inclusion Criteria:

- Patients above 12 yr
- Patient's admitted in general surgical wards who had undergone surgical procedure
- Patients receiving peri-operative antimicrobial therapy

Exclusion Criteria:

- Patients not willing to give consent
- Patients who are receiving antimicrobials for conservative management

Data was obtained from the case papers of the patients and by taking history from the patients and was recorded in Case Record Form (CRF) .The collection of data for every patient was obtained from first day of admission, during pre-operative and post operative period. Patients were followed up until all the antimicrobials were discontinued or till the patient is discharged. Antimicrobial therapy given to the patient at discharge was not included. The following parameters were noted:

1. Patients Demographic Data: Name, Age , Sex, Address, Occupation
2. Date of admission ,Date of Surgery, Date of Discharge
3. Diagnosis and the surgical procedures done.
4. Type of the Surgery done according to the National Research Council Criteria into Clean (Class I), Clean – Contaminated(Class II), Contaminated(Class III) and Dirty(Class IV)
5. Details of each antimicrobials prescribed
   a. Drug Name(Generic/Brand)
   b. Dose
   c. Route of administration
   d. Frequency of administration
6. Time of change of route of administration from intravenous to oral therapy
7. Duration of all the antimicrobials prescribed.

Part 2: To compare the antimicrobial prophylaxis to the preexisting guidelines reference for clean (class I) and clean contaminated (class II) surgeries. Contaminated and Dirty Classes will not be included to avoid differences in discriminating prolonged prophylaxis from post-operative therapy. For analysis of appropriateness of prophylaxis each of the following parameter in each patient was compared with the guidelines;

- Timing of first dose administration: It was considered as compliant if given within 60 minutes before surgery or just before incision and as non compliant if the first dose was given after the initiation of surgery
- Duration of Injectable antimicrobials: It was considered as compliant if the parenteral administration was discontinued within 24 hrs after the first dose and non compliant if the time of administration exceeded 24 hrs.
- No. of Antimicrobials used per patient: The therapy was considered compliant if the total no of antimicrobials used were in accordance with the guidelines for that particular type of surgery reference and non compliant if the no of antimicrobials exceeded those mentioned in guidelines.
- Choice of Antimicrobial: The therapy was considered compliant if the antimicrobial prescribed was according to guidelines for that particular type of surgery and non compliant the antimicrobial used was not according to the guidelines for that particular type of surgery.

Plan of Statistical Analysis of Data: Descriptive statistical terms such as mean, standard deviation, median, interquartile range (IQR), percentage etc were used to describe the data which was collected. The patients were grouped in 4 NRC classes according to type of surgery and following drug indicators were determined for each group.

- Percentage of various groups of antimicrobials prescribed
- Average number of antimicrobials used for each patient

- Duration of parenteral therapy and the total duration of antimicrobials prescribed
- Percentage of drugs prescribed from outside hospital schedule among three socioeconomic classes was compared using chi square test.
- P value less than 5% was considered statistically significant
- Microsoft Excel and Graph pad instat version 3 was used for the statistical analysis.

Results

Total of 500 patients undergoing surgical procedures were enrolled during the study period of 1 year and they received a total no. of 1539 antimicrobials during their hospital stay.

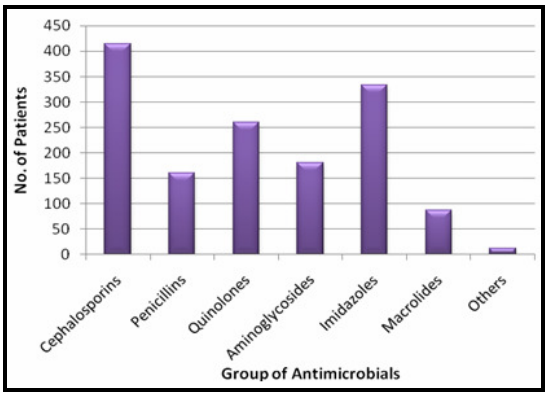
Table-1: Number of patients according to type of surgery according to NRC criteria

Type of Surgery	N (%)
Clean (Class I): e.g. Hernia repair, breast surgeries, hydrocele, varicose vein, radical neck dissection, lump excision etc	236 (47.2%)
Clean Contaminated (Class II): All elective surgeries e.g. Cholesystectomy, Appendicectomy, Colorectal surgeries, small intestinal surgeries, oropharyngeal surgery	105 (21%)
Contaminated (Class III): Same as Class II but these are emergency surgery without bowel preparation	114 (22.8%)
Dirty (Class IV): e.g. Incision and drainage of abcess, debridement, exploratory laparatomy for intestinal perforation	45 (9%)

Table 1 shows the distribution of patients according to the type of surgery. Maximum Percentage of patients (47.2%) undergone surgeries which were classified as Clean (Class I), while 22.8% and 21% patients belonged to Contaminated and Clean Contaminated respectively,9% patients underwent dirty surgeries.

Part I: *Analysis of drug utilization pattern of antimicrobials:* The prescribing frequency of various groups of antimicrobials in patients is shown in Figure 1. The figure 1 shows the group wise distribution of antimicrobials. Cephalosporin's was the most commonly prescribed antimicrobial. It was given 415 (83%) patients, second most common were Imidazoles in 334(66.8%) patients, and Quinolones were third most common, given in 260(52%) patients. Aminoglycoside were given in 180(36%), Penicillin group of antimicrobial in 160(32%) patients and Macrolides in 87(17.4%).

Fig-1: Graph showing prescribing frequency of different antimicrobial groups



Total 1539 antimicrobials were prescribed with an average of 3.08 ± 1.04 (mean ± SD).

Figure 2 shows the total number of antimicrobials prescribed. Prescriptions containing single antimicrobial were 17(3.4%), in 160 (32%) two antimicrobials were prescribed. Three antimicrobials were given in 139 (27.8%) and four antimicrobials were prescribed in 143 (28.6%), Five antimicrobials were given in 33 (6.6%) were as 8 (1.6%) patients had more than six antimicrobials prescribed. The most frequently prescribed two antimicrobials were cephalosporin with imidazoles. Most frequently prescribed three antimicrobial combinations consisted of cephalosporin with an aminoglycoside and imidazoles.

Fig-2: Graph showing frequency distribution of number of antimicrobials used per patient

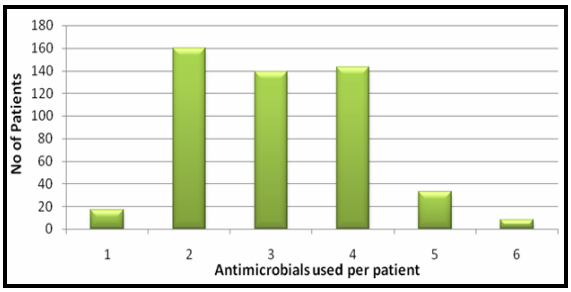


Table-2: Comparison of number of antimicrobials used per patient between different surgical classes				
	Class I Clean N=236	**Class II Clean-Contaminated N=105**	**Class III Contaminated N=114**	**Class IV Dirty N=45**
Median	2	4***	4***	3***@
IQR	2-3	3-4	3-4	2-5
Mean ± SD	2.44 ± 0.84	3.69 ± 0.68	3.75 ± 0.71	3.29 ± 1.41
Range	1 – 5	2 -6	2 -6	1 -6

The p value for the comparison among all 4 groups was < 0.0001 by Kruskal Wallis test (Non parametric ANOVA) followed by Dunn's posthoc test for multiple comparisons. (*** p<0.001 as compared to class I. @ p<0.05 Comparison of Class IV with that of Class II & Class III). The number of antibiotics prescribed per patient was significantly less (p<0.001) in Class I as compared to Class II, Class III, Class IV surgeries., also it was significantly less (p<0.05) in Class IV as compared to Class II and Class III (Table-2).

Table-3: Comparison of duration (in days) of injectable antimicrobials between different types of surgeries					
	Class I Clean N=236	**Class II Clean-Contaminated N=105**	**Class III Contaminated N=114**	**Class IV Dirty N=45**	**All surgical classes N=500**
Median	1	3***	3***	4***	2
IQR	1-2	3-5	3-5	1-6	2-6
Mean ± SD	1.45 ± 0.90	3.98 ± 1.57	3.66 ± 1.57	3.98 ± 2.64	2.75±1.88
Range	1-7	1-7	1-9	1-10	1-10

The p value for the comparison among all 4 groups was < 0.0001 by Kruskal Wallis test (Non parametric ANOVA) followed by Dunn's posthoc test for multiple comparisons (*** p<0.001 as compared to Class I). Total duration of administration of injectable antimicrobials was significantly longer (p<0.001) in Class II, Class III, Class IV as compared to Class I (Table-3 & 4).

Table-4: Comparison of total duration (in days) of antimicrobials between different types of surgeries.					
	Class I Clean N=236	**Class II Clean-Contaminated N=105**	**Class III Contaminated N=114**	**Class IV Dirty N=45**	**All surgical patients N=500**
Median	2	6***	5***	5***	4
IQR	2-3	5-8	4-7	3-8	1-4
Mean ± SD	2.82 ± 1.34	6.27 ± 2.32	5.55 ± 2.27	5.76 ± 3.45	4.43±2.56
Range	1-10	2-11	1-14	1-14	1-14

Part II: *Comparison of antimicrobial prophylaxis in clean and clean contaminated surgery with the published guidelines.*

Table-5: Comparison of recommended prophylactic regimen vs most commonly used regimens in the present study.

Nature of Surgery	Two Most common surgeries	Recommended Antimicrobial	Most commonly used antimicrobials in the present study
Clean Surgeries	Hernia repair, N=128	No prophylaxis recommended	Cefazolin(n=67), Cefotaxime(n=56)
	Hydrocoele, N=50	No prophylaxis recommended	Cefazolin(n=31), Cefotaxime(n=19)
Clean Contaminated surgeries	Biliary surgeries N=53	Cefazolin	Cefotaxime(n=28), cefazolin(n=13) plus Amikacin(n=31) and Metronidazole(n=22)
	Appendicectomy N=21	Cefoxitin/ Cefotetan+ Metronidazole	Cefotaxime(n=13), Ceftriaxone(n=5) plus Amikacin(n=16) and Metronidazole(n=19)

Table-6: Comparison of antimicrobial prophylaxis with guidelines in class I and class II surgeries

Parameter	Compliance with guidelines	Class I Clean N=236	Class II Clean Contaminated N=105
Timing of First dose	Compliant	233 (98.72%)	103 (98.10%)
	Non Compliant	5 (21.18%)	2 (11.9%)
Duration of Injectable Prophylaxis	Compliant	174 (73.72%)	4 (3.81%)
	Non Compliant	62 (26.27%)	101 (96.19%)
No of Antimicrobial per patients	Compliant	8 (3.38%)	3 (2.86%)
	Non Compliant	228 (96.62%)	102 (97.14%)
Choice of Antibiotics	Compliant	4 (3.8 %)	14 (13.34%)
	Non Compliant	232 (96.2%)	91 (86.66%)

Right timing of first dose was followed in 98.72% patients in class I surgeries and in 98.10% in class II surgeries.

Compliance for duration of injectable prophylaxis was seen in 73.72% of cases in class I surgeries but the compliance was low in class II surgeries (3.81%). The duration of injectable prophylaxis was more than 24 hours in 26.27% of patients in class I and 96.19 % of patients in class II surgeries. Number of antimicrobials used per patient was in excess of those recommended in as many as 96.2% patients class I and 97.14% patients in class II surgeries. Only 3.8% patients in class I and 13.34 % patients in class II showed compliance for the proper choice of antimicrobials according to the guidelines.

Discussion

The present study was undertaken to review the prescribing trends of antimicrobial agents used perioperatively during surgical procedures and to compare the current pattern of prophylaxis with the published guidelines in clean and clean contaminated surgeries. Data was collected from 500 indoor patients of general surgery wards that were undergoing surgical procedures and were receiving perioperative antimicrobials for the purpose of prophylaxis or for treatment.

The total number of antimicrobials prescribed in 500 patients was 1539 [table no.1]. The average number of antimicrobials prescribed

per prescription was 3.08±1.04 with a maximum of six antimicrobials per prescription. In most of the patients (32%) two antimicrobials were used followed by use of four antimicrobials in 28.6% patients and three antimicrobials in 27.8% patients, showing a trend towards polypharmacy. Use of single antimicrobial agent was seen in only 3.4% patients (Table 2, Figure 2).

Most of the published guidelines do not recommend any prophylactic antimicrobials for clean surgeries like hernia; however in our study median of two antimicrobials were used in clean surgeries (Table no. 2 & 5). In clean contaminated surgeries, guidelines recommend use of single first generation cephalosporin in biliary surgeries, whereas use of second generation cephalosporin plus an additional agent for anaerobic infections is recommended in intestinal and colorectal surgeries. However in our study median of four antimicrobials were used in clean contaminated surgeries (Table no. 2). This might be because of insufficient knowledge about antimicrobials and the surgeons' emphasis on use of multiple antimicrobials to be on safer side to eliminate the risk of surgical site infections.

Usage of more than required number of antimicrobials per patient will increase the cost of therapy, the risk of adverse events, drug interactions, emergence of resistance, super infections and may also contribute to non compliance by patients. Therefore it is preferable to keep the number of drugs as low as possible to minimize the risk of drug interactions, development of resistance and also to minimize the cost of therapy.

The injectable antimicrobials were discontinued within 24 hours in most (73.72%) of the cases of clean surgery. However the median duration of injectable antimicrobial prophylaxis was three days in case of clean contaminated surgeries (Table 3). This appears to be inappropriate as most of the published guidelines recommend use of prophylactic injectable antimicrobials lasting only until 24 hours. In clean contaminated surgeries like appendicectomy and colorectal surgeries, the peristalsis does not return to normal within 24 hours and hence oral route of feeding is delayed, thus the surgeons must have been compelled to use the parenteral route of administration of antimicrobials beyond 24 hours.

The median total duration of antimicrobials for all surgical cases was four days, with a range of one to fourteen (Table 4). The median total duration of antimicrobial use for clean-contaminated surgeries was six days in our study (Table no.4). This suggests that there is overuse of antimicrobials for prolonged duration in this class of surgeries. In the present study, local hospital guidelines for surgical antimicrobial prophylaxis were not available. Therefore compliance of antimicrobial prophylaxis for clean and clean contaminated surgeries was compared with some standard published guidelines for surgical antimicrobial prophylaxis [5-14].

Evaluation of the time of administration of first dose revealed that 98.72% patients in clean surgical class and 98.10 % patients in clean contaminated class received their first dose at induction or within 60 minutes prior to the induction of anesthesia (Table 6). The guidelines recommend that the first dose of antimicrobial agent used for prophylaxis should be started at the induction of anesthesia or at least 60 minutes prior to the induction of anesthesia. Thus time of administration of first dose was satisfactory in most of the patients. This high compliance rate could be attributed to the routine of initiation of prophylactic antimicrobials by anesthetists /surgeons at the time of induction of anesthesia.

In our study the choice of antimicrobial according to the type of surgery was in accordance with the guidelines only in 3.8% in clean surgeries and 13.34 % in clean contaminated surgeries (Table 5). In our study cefazolin or cefotaxime were administered although not recommended in many patients of clean surgeries such as hernia repair. In patients with clean-contaminated surgeries such as biliary surgeries and appendicectomy, the use of 3rd generation cephalosporin cefotaxime was preferred (Table 5).

The results show that there was a preference for third generation of cephalosporins in our study which was inappropriate as per the

guidelines. Cefotaxime was very commonly used both in clean and clean contaminated surgeries. For surgical prophylaxis it is important to select an antimicrobial agent with narrowest spectrum of activity to reduce the emergence of resistance and also because broad spectrum antibiotics may be required later if patient develop serious surgical site infections. Therefore published guidelines recommend that the use of third generation cephalosporin should be avoided for the purpose of surgical prophylaxis.

Similar to this study many studies have analyzed the adherence to surgical antimicrobial prophylaxis. Lipika Parulekar et al [16] studied the compliance of surgical antimicrobial prophylaxis in 100 consecutive surgical procedures in a tertiary care hospital in India. Out of these 90 patients had received prophylaxis. They found that choice of antimicrobial was appropriate in 68% patients, and it was administered at appropriate time in 89%, whereas the antimicrobial was discontinued within 24 hours in 63% patients.

R.A Kulkarni et al [17] conducted a study on prescribing pattern of surgeons for surgical procedures. This was a questionnaire study in which data from 650 surgeons all over India was analyzed. They compared the choice of antimicrobials in preoperative prophylaxis with guidelines which showed that only 8% and 6% surgeons prescribes according to the guidelines in clean and clean contaminated surgeries respectively. Surgeons preferred 3rd and 4th generation cephalosporin or a combination of 2nd, 3rd or 4th generation cephalosporins with an aminoglycoside plus an agent for anaerobic infections in all types of surgeries. Out of all the surgeons only 6% and 1% discontinued the antimicrobials within 24 hours in clean and clean contaminated surgeries respectively. Results of our study regarding compliance to guidelines are comparable to those reported in this questionnaire type of study.

Overall compliance to guidelines in various studies has varied from as low as 0 to 53%, usually is in the range of 20-30%. Many studies have revealed a high frequency of prescriptions of antimicrobials when not needed, inappropriate choice and use of multiple antimicrobials and prolonged duration of antimicrobials [15-19].

The timing of administration of antimicrobials in most studies was more satisfactory than other criteria for adherence to guidelines (commensurate with what is seen in our study). The major limitation of our study was that the rate of surgical site infection in different types of surgery was not evaluated. The incidence of surgical site infection ranges from 2 to 10% in clean and clean contaminated surgeries [7]. Further studies can be carried out to assess the incidence of surgical site infections. Our study did not include the antimicrobials prescribed at discharge so the actual total duration of antimicrobial use will be more than what is reported in our study.

Conclusion

There is a considerable scope for improving prescribing pattern of drugs to achieve rational and cost effective antimicrobial use. Various interventional strategies like formulation of local hospital guidelines for antimicrobial prophylaxis, regulations on prescribing drugs outside hospital source and control by regulatory authorities can be implemented.

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