



## EVALUATION OF UTILIZATION PATTERN OF ANTIMICROBIAL DRUGS IN POSTOPERATIVE PATIENT IN DEPARTMENT OF OTORHINOLOGY AT GOVERNMENT HOSPITAL: A PROSPECTIVE CROSS-SECTIONAL STUDY

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**ABSTRACT** **Introduction:** Surgical site infection (SSI) is the most common post-operative complication and represents a significant burden in terms of patient morbidity and mortality. Antimicrobial drugs (AMAs) are the primary therapeutic modes for treatment of infection and have been demonstrated to control SSI.

**Objective:** The objective of this study was to evaluate drug utilization pattern of AMAs in postoperative patients at government hospital.

**Material and Methods:** This was prospective, Cross-sectional, observational study done on 150 patients of either gender at Government Medical College, Saharanpur.

**Results:** Our study revealed male predominance over female. Patient with age group of 21-30 (29%) were more in numbers going for surgery. Tonsillectomy 28 (18.66%) was most common type of surgery. Nausea & Vomiting were most commonly observed ADRs. Total 81.26% of drugs were prescribed with generic name. cephalosporins was most commonly prescribed AMAs for postoperative. Average no of AMAs/prescription was 2.38.

**Conclusion:** Drug utilization studies help to analyze ongoing health care practices, so that lacunae in the system can be identified help to guide hospitals and doctors to develop antibiotic policy that helps to decrease chance of antimicrobial resistance and motivate cost effective utilization of antimicrobial agents.

**KEYWORDS :** Antimicrobial drugs, Drug utilization study, Postoperative, Infection.

### INTRODUCTION

Surgical site infection (SSI) is the most common post-operative complication and represents a significant burden in terms of patient morbidity and mortality, and cost to health services around the world. They are the second commonest nosocomial infection accounting for approximately one quarter of 2 million hospital acquired infections in USA annually.<sup>1</sup> Between 1.9% and 2.7% of all surgical patients, more than 500,000 per year, are diagnosed with SSI leading to an estimate of 8000 annual deaths.<sup>2,3</sup>

The routine life of children and adults are disturbed by diseases of ear, nose and throat (ENT) and also cause significant morbidity.<sup>4</sup> Infections remain the major cause of ENT diseases because of increase in the population.

Antimicrobial agents (AMAs) consumption in humans is increasing globally. The greatest increase between 2000 and 2010 was in low- and middle-income countries, but in general, high-income countries still use more antibiotics per capita. Growing economic prosperity and rising incomes, as well as expanding insurance coverage, have increased antibiotic consumption. Inappropriate use of broad spectrum antimicrobials leads to decrease in sensitivity of antimicrobials against microorganisms. With increasing multidrug resistance and limited availability of newer agents, there is urgent need for vigilant surveillance, stringent infection control practices, as well as rational antibiotic prescription as rational use of AMAs helps in reducing significant morbidity and mortality.

In India, there are National Treatment guidelines for Antimicrobial use in infectious diseases given by National Centre for disease Control (NCDC), Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India (2016)<sup>5</sup> and Treatment Guidelines for Antimicrobial Use in Common Syndromes given by Indian Council of Medical Research (ICMR), Department of Health Research, New Delhi, 2017.<sup>6</sup>

Antibiotic prophylaxis can protect the patients from post-operative infections by abating the bacterial load present within the surgical site at the time of operation.<sup>7</sup> Hence, antibiotics should be administered prophylactically before giving an incision to any intra-operative patient and as well as postoperatively.

Judicious use of AMAs has been shown to be effective in reducing the incidence of surgical site infections as studies suggest that 40- 60% of these infections are preventable.<sup>8</sup> Also it results in good hospital

functioning, which leads to increase in patient's satisfaction, maintains high reputation for the hospital, fewer hospitalizations.

Drug Utilization Research (DUR) was defined by the WHO in 1977 as "The marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social and economic implications".<sup>9</sup> The increased interest in DUR has resulted due to recognition of the virtual explosion in the marketing of Antimicrobial drugs, the wide variations in the patterns of drug prescribing and consumption, and the increasing concern about the cost of drugs.<sup>10</sup> A prescription-based survey is considered to be one of the most effective and best methods to assess and evaluate the prescribing attitude of physicians. Hence, with an aim to promote rational use of drugs the study has been planned out to evaluate the drug utilization pattern of Antimicrobial drugs in postoperative patients at government hospital.

### AIMS AND OBJECTIVE

The main objectives of the study were

1. To evaluate the demographic in the enrolled patients.
2. To observe the pattern of Antimicrobial use in postoperative patients.
3. To identify the occurrence of ADRs & report the same to ADR Monitoring centre (AMC).
4. To observe for the practice of prescribing the medicine by their generic name and brand name.

### MATERIAL AND METHODS

This was prospective, Cross-sectional study observational study done at Government Medical college, Saharanpur, India following approval from Institutional Ethics Committee. The duration of the study was 12 months from August 2019 to January 2020. A total of 150 patients were enrolled for the study after straining them through inclusion and exclusion criteria.

### INCLUSION CRITERIA

- i. All postoperative patients of either gender in the age group of 21 and above were included.
- ii. All those Patients who were willing to give signed written informed consent form were included.

### EXCLUSION CRITERIA

- I. Patients who were not willing to sign the informed consent were excluded.
- ii. All postoperative of either gender in the age group of less than 21

were excluded.

iii. Pregnant women and Lactating mother.

**Study Procedure**

A patient information Sheet was prepared to inform the patient or the Patients attendants about the purpose and necessity of the study and written consent was obtained from either Patients or Patients attendants. A specially designed data entry format was used to enter all the information pertaining to the patient and drug therapy given were recorded in a **Case Record Form (CRF)**, the information of which were obtained from Patient case files. During the course of the study the enrolled Patients were followed for occurrence of ADR and the same were reported to ADRs Monitoring centre. The data was collected during regular visit to In Patients Departments (IPD) in the Department of Otorhinology, Government Medical college, Saharanpur. Standard data entry format were used to enter all the patient details collected during visit to IPD at the study site. The prescriptions were individually screened to assess the prescribing pattern of Antimicrobial drugs. All the Patients were followed up till their admission in IPD following their enrollment. Based on the history and Pill count all the Participants were observed for the compliance of the therapy. After completion of the study, collected data were analyzed using appropriate statistical tests student's t test and chi-square test and checked for the significant if any.

**RESULTS AND OBSERVATIONS**

Following result was obtained during the study period.

- During the study Period, a total of 150 Patients undergoing treatment with different kinds of Antimicrobial agents were enrolled at Hospital out of 150 Patients it was observed that 86 (57.33%) were Male whereas 64 (42.66%) Patients were female. Similarly, out of 150 Patients, it was observed that at majority of Patients were in the Age group of 21-30 (29%) followed by Age group of 31-40 (26%) while Patients with age group of <21 was minimum (12.33%). as represented in Table no 1. In our study at government hospital  $\chi^2$  was 2.61, d.f was 3 and p value was 0.4477, which indicates that there was no association between age group and gender.

**Table 1: Gender wise Age group distribution of Patients with different surgery (n=150)**

GOVERNMENT HOSPITAL			
Age group (years)	Patients		Total (%)
	Male (%) (n=86)	Female (%) (n=64)	
<21	11 (12.79)	8 (11.71)	19 (12.33)
21-30	26 (30.23)	17 (27.34)	43 (29.00)
31-40	20 (23.25)	19 (29.68)	39 (26.00)
41-50	15 (6.86)	12 (19.53)	27 (18.00)
>51	14 (16.86)	08 (11.71)	22 (14.66)
Total	86 (100)	64 (100)	150 (100)
Grand Total (%)	<b>57.33</b>	<b>42.66</b>	<b>100</b>

$\chi^2$  2.61 d.f=3 p=0.4477

- During the study Period on analyzing different types of Surgery Gender wise it was observed that out of 150 Patients, most commonly performed surgery was Tonsillectomy 28 (18.66%) followed by Adenoidectomy and Mastoidectomy 21 (14.00%) each while least performed surgery was Parotidectomy 6 (4.00%) as depicted in Table no 2. In our study at government hospital  $\chi^2$  was 3.130, d.f was 3 and p value was 0.5201 which indicates that there was no association between age group and gender.

**Table 2: Distribution of types of Surgery Gender wise (n=150)**

GOVERNMENT HOSPITAL				
S.No	Type of Surgery	Patients		Total (%) (n=150)
		Male (%) (n=86)	Female (%) (n=54)	
1.	<b>Tonsillectomy</b>	17 (19.76)	08 (14.81)	28 (18.66)
2.	<b>Adenoidectomy</b>	10 (11.62)	10 (18.51)	21 (14.00)
3.	<b>Tympanoplasty</b>	07 (8.13)	06 (11.11)	13 (8.66)
4.	<b>Mastoidectomy</b>	13 (15.11)	06 (11.11)	21 (14.00)
5.	<b>Hemithyroidectomy</b>	05 (5.81)	02 (3.70)	07 (4.66)
6.	<b>Parotidectomy</b>	03 (3.48)	03 (5.55)	6 (4.00)
8.	<b>Excision of Mass</b>	11 (12.79)	05 (9.25)	17 (11.33)
9.	<b>FESS</b>	09 (10.46)	08 (14.81)	19 (12.66)

10.	<b>Dacryocystorhinostomy</b>	11 (12.79)	06 (11.11)	18 (12.00)
Grand Total (%)		86(100)	54 (100)	150 (100)
		$\chi^2$ 3.130	d.f=3	p=0.5201

- In our study on analyzing co morbidities of study population in Government, it was noted that in Maximum patients i.e. 16 (10.66%) were affected with Hypertension followed by Diabetes Mellitus 12(8.00%), Gastritis 09 (6.00%) while least cases observed were Tuberculosis 01 (0.66%) as depicted in Table no 3. In our study at government hospital t value was 1.85 and p value was 0.396 which indicates that there was no association between age group and gender.

**Table 3: Co- Morbid conditions in Patients (n=150)**

GOVERNMENT HOSPITAL			
Co-Morbid Conditions	Patients		Total (%) (n=64)
	Male (%) (n=33)	Female (%) (n=31)	
Hypertension (HTN)	07 (16.66)	09 (14.66)	16 (10.66)
Epilepsy	01 (15.78)	01 (9.33)	02 (3.33)
Thyroid	01 (7.01)	03 (14.66)	04 (2.66)
Diabetes Mellitus (DM)	09 (13.15)	03 (5.33)	12 (8.00)
Tuberculosis	1 (8.77)	00 (10.66)	01 (0.66)
Gastritis	04 (8.77)	05 (8.00)	09 (6.00)
Ischemic Heart Disease (IHD)	02 (3.50)	06 (9.33)	08 (5.33)
Others	08 (14.03)	04 (9.33)	12 (8.00)
Total (%)	33 (100)	31 (100)	64 (100)
Grand Total (%)	<b>51.56</b>	<b>48.43</b>	<b>100</b>

t value =2.05, p value=0.312

- In our study out of 150 patients with different types of surgery at Government hospital the study reports revealed that Overall Utilization of AMAs were 357 (67.87%) which were prescribed for treating surgical wound infection. Amongst 357 AMAs, Cephalosporin was most commonly prescribed drug which appeared to be prescribed in 95(26.61%) encounters followed by Penicillin 82(22.96%), Macrolides 38(10.64%), Fluoroquinolones 35(9.80%) encounters while the least prescribed drugs were Antifungal in 11(3.08%) encounters as depicted in Table no 4.

**Table no 4: Overall Utilization of AMAs in Postoperative Patients at Government hospital**

GOVERNMENT HOSPITAL					
S. No	Class of AMAs	Drugs Used	Patients		Total Encounters
			Male (%)	Female (%)	
1.	<b>Penicillins</b>	Amoxycillin	07 (3.51)	04 (2.53)	11 (3.08)
		Amoxycillin + Clavulanic acid	31 (15.57)	27 (17.08)	58 (16.24)
		Ampicillin + Cloxacillin	08 (4.02)	05 (3.16)	13 (3.64)
2.	<b>Fluoroquinolones</b>	Ciprofloxacin	06 (3.01)	03 (1.89)	09 (2.52)
		Norfloxacin	01 (0.50)	02 (1.26)	03 (0.84)
		Levofloxacin	13 (6.53)	11 (6.96)	24 (6.72)
3.	<b>Nitroimidazoles</b>	Metronidazole	12 (6.03)	08 (5.06)	20 (5.60)
		Ornidazole	05 (2.51)	03 (1.89)	08 (2.24)
4.	<b>Tetracyclines</b>	Doxycycline	10 (5.02)	09 (5.69)	19 (5.32)
5.	<b>Macrolides</b>	Azithromicin	14 (7.03)	06 (3.79)	20 (5.60)
		Erythromycin	07 (3.51)	11 (6.96)	18 (5.04)
6.	<b>Cephalosporins</b>	Cefaclor	09 (4.52)	05 (3.16)	14 (3.92)
		Cefixime	19 (9.54)	15 (9.49)	34 (9.52)
		Cefotaxime	10 (5.02)	08 (5.06)	18 (5.04)
		Cefadroxil	04 (2.01)	03 (1.89)	07 (1.96)
		Cefuroxime	02 (1.00)	01 (0.63)	03 (0.84)
7.	<b>Aminoglycosides</b>	Ceftriaxone	10 (5.02)	09 (5.69)	19 (5.32)
		Gentamicin	03 (1.50)	02 (1.26)	05 (1.40)
		Neomicin	02 (1.00)	00 (0.00)	02 (0.56)
8.	<b>Antifungals</b>	Amikacin	05 (2.51)	04 (2.53)	09 (2.52)
		Clotrimazole	06 (3.01)	05 (3.16)	11 (3.08)
9.	<b>Others</b>	Chloramphenicol	15 (7.53)	17 (10.75)	32 (8.96)
Total (%)			<b>199 (100)</b>	<b>158 (100)</b>	<b>357 (100)</b>

- In our study out of 150 patients with different types of surgery at Government hospital the study reports revealed that overall utilization of drugs used for Co-morbidity in Postoperative Patients were 169 (32.13%) which were prescribed for treating Co-morbidity. Amongst 169 drugs prescribed, Antihypertensives was most commonly prescribed drug which appeared to be prescribed in 45(26.62%) encounters followed by others group 32(18.93%), Hematinics & Vitamins 22 (13.01%), Oral Hypoglycemics 21(12.42%) encounters while the least prescribed drugs were Anti –Anginal in 08(4.73%) encounters as depicted in Table no 5.

**Table no 5: Utilization of Drugs Used for Co-morbidity in Postoperative Patients at Government hospital**

GOVERNMENT HOSPITAL					
S. No	Class of Drugs	Other concomitantly Drugs Used	Patients		Total Encounters
			Male (%)	Female (%)	
1.	Oral Hypoglycemics	Metformin	07 (8.75)	04 (4.49)	11 (5.64)
2.		Glicazide	07 (8.75)	03 (3.37)	10 (4.76)
3.	Anti-Hypertensives	Hydrochlorthiazide	09 (11.25)	05 (5.61)	14 (8.03)
4.		Amlodipine	04 (5.00)	10 (11.23)	14 (7.14)
5.		Enalapril	04 (5.00)	05 (5.61)	09 (3.86)
6.		Losartan	02 (2.50)	06 (6.74)	08 (5.35)
7.	Antiepileptics	Levetiracetam	02 (2.50)	08 (8.98)	10 (5.95)
8.		Carbamazepine	06 (7.50)	02 (2.24)	08 (2.38)
9.	Anti-Thyroid	Levothyroxine	03 (3.75)	06 (6.74)	09 (5.325)
10.	Hematinics & Vitamins	Folic acid	05 (6.25)	05 (5.61)	10 (5.91)
11.		Vit. B6	05 (6.25)	07 (7.86)	12 (5.35)
12.	NSAIDs	Paracetamol	04 (5.00)	02 (2.24)	06 (3.55)
13.		Diclofenac	03 (3.75)	05 (5.61)	08 (1.78)
14.	Anti –Anginal	GTN	03 (3.75)	03 (3.37)	06 (3.55)
15.		Isosorbide Mononitrate	01 (1.25)	01 (1.12)	02 (1.18)
16.	Others	Sumatriptan	02 (2.50)	02 (2.24)	04 (2.36)
		Omeprazole	01 (1.25)	05 (5.61)	06 (3.55)
		Pantoprazole	04 (5.00)	07 (7.86)	11 (6.50)
		Antitubercular	08 (10.00)	03 (3.37)	11 (6.50)
<b>Total (%)</b>			<b>80 (100)</b>	<b>89 (100)</b>	<b>169 (100)</b>

- During the study period, out of 150 patients at Government hospital the study reports revealed that a total of 51 patients observed ADRs who were treated with AMAs where adverse drug reactions (ADR) were found to be more prone among females constituting about 30 patients and about 21 in male patients. Among the ADRs observed at Government Hospital majority of Patients 19(37.25%) had Nausea & Vomiting followed by Others 9 (17.64%), Rash & Urticaria 6(11.76%), GIT disturbances in 05 (9.80) patients while least observed ADRs appeared to be Thrombocytopenia & Gum Hyperplasia in 1(1.96%) each patients as depicted in Table no 6. In our study at government hospital  $\chi^2$  was 7.396, d.f was 3 and p value was 0.0051 which indicates that there was association between ADRs and gender.

**Table 6: ADRs observed with AMAs (n=150)**

GOVERNMENT HOSPITAL			
ADRs observed	Patients		Total (%) (n=51)
	Male (%) (n=21)	Female (%) (n=30)	

Nausea & Vomiting	09(42.85)	10 (33.33)	19 (37.25)
Headache	01 (4.76)	02 (6.66)	03 (5.88)
GIT disturbances	02 (9.52)	03 (10.00)	05 (9.80)
Rash,Urticaria	03 (14.28)	03 (10.00)	06 (11.76)
Anemia	01 (4.76)	02 (6.66)	03 (5.88)
Thrombocytopenia	01 (4.76)	00 (7.31)	01 (1.96)
Gum Hyperplasia	00 (0.00)	01 (3.33)	01 (1.96)
Osteomalacia	01 (4.76)	03 (10.00)	04 (7.84)
Others	03 (14.28)	06 (20.00)	09 (17.64)
<b>Grand Total (%)</b>	<b>41.17 (100)</b>	<b>58.82 (100)</b>	<b>100</b>
$\chi^2= 7.396$		d.f =3	p =0.0051*
*P<0.05 is considered as significant			

- Our study report revealed that Average number of drugs/prescription was 3.51 where as average number of AMAs/prescription was 2.38. Percentage of AMAs used by generic name and brand name per prescription was 81.26 and 18.74 respectively.

**Table 7: WHO prescribing parameters**

GOVERNMENT HOSPITAL	
Parameters	Numbers
Total drugs prescribed	526
Percentage of AMAs used by generic name/prescription	81.26
Percentage of AMAs used by brand name/prescription	18.74
Average number of drugs/prescription	3.51
Average number of AMAs/prescription	2.38
Percentage of AMAs prescribed for Intravenous route	91.08%
Percentage of AMAs prescribed from Essential medicine list (EML)	94.13%
Percentage of AMAs prescribed from National list of essential medicine (NLEM)	88.79%
Average duration of ICU stay	1.1
Average duration of hospital stay	6.12

**AMA –Antimicrobials**

**DISCUSSION**

The Antimicrobial prescription by the surgeon reveals important data regarding rational drug usage. In general practice, the therapeutic approach for postoperative patients for ENT infections is nearly empirical and the main aim of surgeon is to treat as specifically as possible, while covering the most likely pathogens. The present study indicates general prescribing trends of antibiotics in postoperative patients of ENT department.

Our study revealed that out of 150 prescriptions the demographic data showed that the number of male patients suffering from ENT disease and hence operative procedure was more than the number of female patients which was similar to the findings of Pradhan et al<sup>11</sup> & Shankar PR et al<sup>12</sup> and contradictory to the findings of Arora R et al.<sup>13</sup> The most common age group of patients was 21-30 accounting 43 (29%) followed by 31-40 accounting 39 (26%). These finding support the study done by Arora R et al<sup>13</sup> who also reported most common ENT infections in these age group. One of the most obvious reason could be because this is productive age group where people are in their professional stage thereby getting exposed to the dust, smoke and different environments.

In our study most common type of surgery was tonsillectomy comprising of 28 (18.66%) cases followed by Adenoidectomy & Mastoidectomy comprising of 21(14.00%) cases while the least cases was of Hemithyroidectomy 07 (4.66%) & Parotidectomy 6 (4.00%). A study done by Dr Vidisha Vivek Parulekar et al<sup>14</sup> reported a total of 79 surgery in otorhinology out of 386 surgery amongst different types of surgery. Not much of the study with different types of surgery in otorhinology was found in literature. Similarly, Our study revealed that out of 150 patients going for different types of surgery a total of 64 patients was suffering from different types of co-morbidities with majority of cases being of Hypertension accounting 16 (10.66%) cases followed by Diabetes Mellitus 12 (8.00%) while the least no of co-morbidities was of Tuberculosis accounting a total of 01 (0.66%) cases. These findings were in contradiction to the findings of Arora R et al<sup>13</sup> who reported Diabetes Mellitus as most common type of co-morbidity followed by hypertension in their study done on different types of ENT manifestations. However it was in accordance to the findings of Sathiya SB et al<sup>15</sup> accounting hypertension as most commonest type of co-morbidity.

Our study reports revealed that overall utilization of AMAs were 357 (67.87%) for treating surgical wound infection & amongst 357 AMAs, Cephalosporin was most commonly prescribed drug which appeared to be prescribed in 95(26.61%) encounters followed by Penicillin 82(22.96%), Macrolides 38(10.64%), Fluroquinolones 35(9.80%) encounters while the least prescribed drugs were Antifungal in 11(3.08%) which was contradictory to the findings of Arora R et al<sup>13</sup> & Kishore Kumar Y et al<sup>16</sup> who reported penicillin as most common type of prescribed drug. Similarly, most common type of drugs for management of co-morbidities was Antihypertensives followed by Antidiabetics which was contradictory to the findings of Arora R et al.<sup>13</sup> In our study most common type of ADRs with different types of prescribed drugs was Nausea & Vomiting 19 (37.25%) followed by Rash & Urticaria 06 (11.76%) while least common type of ADRs was Thrombocytopenia & Gum Hyperplasia accounting a total of 01 (1.96%) cases. The study report revealed 81.26% of drugs being prescribed with generic name while percentage of AMAs prescribed was 2.38%. Similarly 94.13% of AMAs were prescribed with Essential medicine list while 88.79% of AMAs were prescribed from National list of essential medicine which was almost similar to the findings of Dr Vidisha Vivek Parulekar et al.<sup>14</sup>

## CONCLUSION

Cephalosporins and Penicillin were the two most frequently prescribed antimicrobial agents which are included in essential drug list. The use of the generic names was found to be satisfactory, but the average number of drug per prescription was high while average number of AMAs per prescription was satisfactory. Drug utilization studies help to analyze ongoing health care practices, so that lacunae in the system can be identified and proper strategies can be planned to rectify them. This outcome is an important tool to guide hospitals and doctors to develop antibiotic policy that helps to decrease chance of antimicrobial resistance and motivate cost effective utilization of antimicrobial agents. The findings of the present study will be helpful in making guidelines for postoperative management. Further such studies with large sample size would guide clinician toward rational drug prescribing which is an ultimate aim of drug utilization studies.

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