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Original Article

Assessment of Adverse Drug Reactions of Antibiotics in General Surgical Patients of a Charitable Hospital

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ABSTRACT

Objective: To study the Adverse Drug Reactions (ADRs) related to antibiotics in surgical patients. **Materials and Methods:** A prospective observational study was conducted in the General Surgery Department for six months. All surgical patients receiving antibiotic therapy were enrolled in the study, and necessary demographics details, diagnosis, suspected ADRs, and suspected drug details were documented. The scales Naranjo and WHO were used to determine ADRs' causality, whereas severity and preventability were measured using Modified Hartwig and Siegel scale, Modified Schumock and Thornton scale, respectively. **Results:** There were 32 ADRs identified among 300 study subjects receiving antibiotic therapy, which had a male predominance of 68.75% and a higher occurrence in the age range of 40-49. Causality assessment based on the WHO-UMC criteria showed that 56.25% of ADRs were probable, whereas, by Naranjo's scale, 71.87% of ADRs were possible. Penicillins, Fluoroquinolones, and Cephalosporins were the most common antibiotics prescribed to induce ADRs (21.875%). The most frequently experienced ADRs were gastrointestinal reactions (65.625%) followed by skin reactions (28.125%). **Conclusion:** The occurrence of antibiotic-induced ADRs in the study is 10.66%. The study concluded that ADRs are indeed a major drug-related problem affecting health outcomes and an issue that needs to be addressed vastly. It also emphasizes the importance of a clinical pharmacist in monitoring and reviewing the subjects' treatment.

Key words: Adverse Drug Reaction, Antibiotics, Assessment, Drug Safety, Pharmacovigilance.

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INTRODUCTION

Drugs are primarily used to relieve symptoms, treat or reduce an illness's severity or medical condition. But they can also prove to be fatal; hence the saying "Drugs are Double-Edged Weapons".[1] Antimicrobials are medicines that kill or prevent the growth of pathological microorganisms in the body. Among all drug classes, antimicrobials are the most prescribed agents worldwide.[2] In usual surgical practice, antibiotics are administered as surgical prophylaxis, an adjunct to common surgeries and surgical procedures. In order to reduce the chances of developing surgical site infections, prophylactic antibiotics are given preoperatively. For conditions like cellulitis, or postoperative pneumonia, primary therapy of antibiotics are given, i.e., when the operation is not performed.[3] Antibiotics are one of the major drug classes responsible for adverse drug reactions.[4] Since antibiotics are one of the important drugs used in surgical patients, they are at an increased risk of developing Adverse Drug Reactions (ADRs) and Adverse Drug Events (ADEs). All these contribute to increased mortality and morbidity among them. The results of various studies conducted in different parts of the world suggest, on average, the occurrence of antibiotic-induced ADRs range between 0.15% and 30%. Although in one of the studies performed at a South Korean tertiary care hospital, 62.8% were proved to be antibiotic-related ADRs[5] whereas 40.9% occurrence was reported in an Indian tertiary care hospital.[6] Pharmacotherapy is crucial for surgery, which cannot be neglected. Health care professionals prescribe a wide range of drug classes in surgery, and antibiotics comprise most of them to prevent complications such as surgical site infections and postoperative sepsis. This has led to a significant increase in mortality rates, hospital readmissions, increased length of stay, and healthcare costs. As a result of drug therapy, many surgical patients experience severe dermatological reactions. It has been noted that these ADRs are unlikely to be reported or documented anywhere. Hence, pharmacovigilance is necessary to improve patient care and safety in medication usage. All medical and paramedical interventions like spontaneous reporting enhance public health and encourage the safe use of medicines. It also contributes to assessing the benefit, harm, effectiveness, and risk of drugs, enabling safe, rational, and more effective (including cost-effective) use. Thereby promoting understanding about pharmacovigilance services among the public.[7] With this background, the study aims to monitor and analyze ADRs related to antibiotics and analyze their incidence, causality, severity, and preventability in the General Surgery department patients.

MATERIALS AND METHODS

A prospective study was conducted in in the General Surgery Department of a Charitable Hospital, Mangaluru after obtaining approval from the institutional ethics committee (Ref. No: NGSMIPS/IEC/15/2019-20). Patients of age 18 years receiving antibiotics were included in the study. Relevant demographics data, including age, gender, complaints on admission, relevant past medical and medication history, drug therapy details, previous allergies, duration of antibiotic therapy (parenteral and oral), were obtained. The prescriptions of all subjects were scrutinized for assessment of ADRs. Identification of ADRs was made after a thorough analysis of the subjective and objective findings, based on the subjects' regular follow-up. Demographics of the subjects were studied

to analyse the pattern of ADRs, their clinical types, and causative drugs. Also, subjects administered with test doses of antibiotics were observed for ADRs.

Analysis of Antibiotic induced ADRs was done using the causality assessment scale-Naranjo's scale and WHO causality scale, severity assessment scale-Modified Hartwig and Siegel scale, preventability assessment scale - Modified Schumock and Thornton scale.

***Causality*:** For assessing whether a drug has caused the reaction, a causality assessment was performed using Naranjo's scale that classifies ADRs induced by antibiotics as definite, probable, or possible and WHO causality scale as possible, likely, or certain.[8]

***Severity*:** Based on the severity of the reactions, ADRs of antibiotics were graded into mild, moderate, severe using the criteria developed by Hartwig and Siegel scale for severity assessment.[9]

***Preventability*:** The Schumock and Thornton scale categorized antibiotic induced ADRs into definitely preventable, probably preventable and not preventable.[10]

***Predictability*:** Furthermore, the ADRs were identified as predictable (Type A reactions) and unpredictable (Type B reactions) using Rawlins and Thompson classification.[11] Statistical analysis included qualitative characteristics documentation using frequency/percentage like age, gender, social habits, route of administration, antibiotic class, and frequency of ADRs. The p value <0.05 was considered as statistically significant. Data obtained was entered into an excel spreadsheet and analysed by using SPSS.

RESULTS

Out of 300 patients were enrolled during the study, 32 patients were developed ADRs. The percentage occurrence of ADRs in the study was 10.66%.

Demographic Characteristics

Most of the ADRs developed were observed among 40-49 years (17.74%). Among the ADRs developed, male predominance 22(68.75%) was observed. The occurrence of ADRs in female patients was found to be 10(31.25%). The study showed that 18(56.25%) patients with ADRs had no history of social habits, and 14(43.75%) had a history of smoking, alcohol consumption, or both. Higher ADRs were observed in our study subjects who received both parenteral and oral antibiotics than with either parenteral or only oral antibiotics. Antibiotic-specific polypharmacy was observed in patients during the study. Polypharmacy with ADRs was observed as 3.33%, and polypharmacy without ADRs was 6%. Odds Ratio for polypharmacy is found to be 7.969 [Confidence Interval (95%) = 3.297-19.262]. Diabetes mellitus 10 (31.25%) followed by Hypertension 8(25%), Stroke 3(9.375%), Chronic Kidney Disease 1(3.125%), and Ischemic Heart Disease 1(3.12%) was observed in patients who were enrolled along with other co-morbidities. The demographic characteristics of patients are depicted in Table 1.

Antibiotic Class Responsible for ADRs

The antibiotic classes commonly responsible for the development of ADRs were Penicillins (21.87%), Fluoroquinolones (21.87%), and Cephalosporins (21.87%). Table 2 depicts the antibiotic class responsible for ADRs. The most common antibiotics inducing ADRs were found to be Amoxicillin Clavulanate 5(15.62%), Ceftriaxone 5(15.62%), and Clindamycin 4 (12.5%) Ciprofloxacin 4(12.5%), followed by Piperacillin and Tazobactam 2(6.25%), Ofloxacin 2(6.25%), metronidazole 2(6.25%) and other antibiotics are summarized in the Table 2.

Types of ADRs Caused by Antibiotics

Gastrointestinal reactions (65.62%) accounted for most of the ADRs, followed by skin reactions (28.12%) and others (6.25%). The different types of ADRs caused by antibiotics are depicted in Figure 1.

Analysis of ADRs

The causality assessment of suspected ADRs was analysed using the WHO-UMC and Naranjo's scales. According to Naranjo's scale, the ADRs were mainly possible 23(71.87%) followed by probable 9(28.12%). By WHO-UMC causality assessment, most of the ADRs were probable 18(56.25%) and possible 14(43.75%). The Modified Hartwig and Seigel Scale was used to conduct a severity assessment of ADRs. Out of 32 ADRs, the majority were mild 20(62.5%) followed by moderate 11(34.37%) and severe 1(3.12%). Using the Modified Schumock and Thornton scale, the preventability assessment of ADRs was done. It was observed that all 32(100%) ADRs were probably preventable. According to the Predictability Assessment scale, most of the ADRs were predictable (57.60%) than unpredictable ADRs (42.40%). The analysis of ADRs is depicted in Table 3.

Management, Treatment Approach, and outcomes after the management of ADRs

A total of 10(31.25%) ADRs were managed by withdrawing the suspected drugs, whereas 22(68.75%) had no drug withdrawal or dose alteration. 26(81.25%) of the patients who developed ADRs received specific treatment, whereas 5(15.62%) of the patients received symptomatic treatment and 1(3.12%) received neither. Following the management of ADRs based on their nature, patient outcomes were analysed. 31 (96.87%) of the ADRs detected were completely resolved.

ADRs of Antibiotic Test Doses

The data of only 52 patients receiving antibiotic test doses were accessible, out of which 3 (5.76%) developed ADRs. Rashes 2(6.06%) followed by itchy blisters 1(3.03%) were developed when patients were administered a test dose of antibiotics. The suspected antibiotics responsible for developing ADRs, when administered with a test dose, are Amoxicillin-clavulanate, cefotaxime, and ciprofloxacin.

DISCUSSION

In our study, the occurrence of antibiotic-induced ADRs in the general surgery department was 10.66%. The occurrence of ADRs reported by a study conducted by Vijaishri *et al.*,[12] was 12.56% which is quite similar to our study result and another study conducted by Shamna *et al.*,[1] which showed an occurrence of 0.3% which is contradictory to our study result.

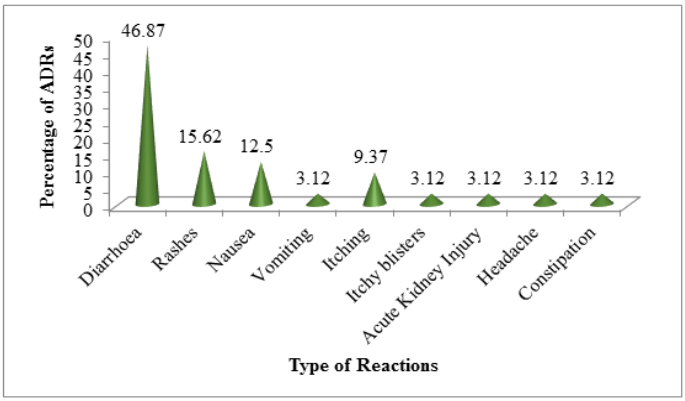

Figure 1: Types of ADRs caused by antibiotics.

Table 1: Demographic Characteristics of Patients.

Demographic characteristics		Number of patients with ADRs (*n*=32)	Number of patients without ADRs (*n*=268)	Total number of patients (*n*=300)
Age group	18-29 Years	5 (15.62%)	34 (9.23%)	39 (13%)
	30-39 Years	1 (3.12%)	38 (14.17%)	39 (13%)
	40-49 Years	11 (34.37%)	51 (19.02%)	62 (20.66%)
	50-59 Years	5 (15.62%)	65 (24.25%)	70 (23.33%)
	60-69 Years	7 (21.87%)	51 (19.02%)	58 (19.33%)
	70 Years and above	3 (9.37%)	29 (10.82%)	32 (10.66%)
Gender	Male	22 (68.75%)	172 (64.17%)	194 (64.66%)
	Female	10 (31.25%)	96 (35.88%)	106 (35.33%)
Smoking	Yes	4 (12.5%)	10 (3.73%)	14 (4.66%)
	No	28 (87.5%)	258 (96.26%)	286 (95.33%)
Alcohol consumption	Yes	4 (12.5%)	12 (4.47%)	16 (5.33%)
	No	28 (81.25%)	256 (95.52%)	284 (94.66%)
Both smoking and alcohol consumption	Yes	6 (18.75%)	41 (15.29%)	47 (15.66%)
	No	26 (81.25%)	227 (84.7%)	253 (84.33%)
Route of administration	Oral	2 (5.55%)	34 (94.44%)	36 (12%)
	Parenteral	13 (7.69%)	156 (92.30%)	169 (56.33%)
	Both oral and parenteral	12 (12.63%)	78 (82.10%)	95 (31.66%)
		5 (5.26%)		
Disease pattern	Diabetes mellitus	10 (31.25%)	71 (26.49%)	81 (27%)
	Hypertension	8 (25%)	60 (22.38%)	68 (22.66%)
	CKD	1 (3.125%)	2 (0.74%)	3 (1%)
	IHD	1 (3.125%)	9 (3.35%)	10 (3.33%)
	Stroke	3 (9.375%)	3 (1.11%)	6 (2%)

*CKD; Chronic Kidney Disease, IHD; Ischemic Heart Disease

In the current study, penicillins (21.87%), cephalosporins (21.87%), and fluoroquinolones (21.875%) were the main drug classes that contributed to antibiotic-induced ADRs. Comparable results were obtained from a study carried out by Dhar *et al.*,[13] maximum ADRs were reported with penicillins and cephalosporins (40.4%) followed by fluoroquinolones (15.8%).

In our study, 65.62% of the ADRs were gastrointestinal reactions followed by skin reactions (28.12%); these findings were parallel to a study performed by Vijaishri *et al.*,[12] where the gastrointestinal reactions were 46.15% followed by skin reactions (14.7%). A study conducted by Arulappen *et al.*,[14] has observed contradicting results to our study where gastrointestinal reactions were only 10.9%.

The occurrence of ADRs in patients with antibiotic polypharmacy was 3.33% in our study, which is in contrast to a study conducted by Ahmed *et al.*,[15] which show 10.5% of antibiotic polypharmacy.

As per the WHO-UMC causality assessment, most of the ADRs were probable (56.25%) and possible (43.75%), similar to a study carried out by Jayanthi *et al.*,[16] which revealed that 78% of the ADRs were probable and 22% were possible. Contradictory to this, a study conducted by Dhar *et al.*,[13] showed 61.9% of ADRs as possible and 25.3% probable and a study by Jung IY *et al.*,[5] observed 62.1% possible and 35.7% probable.

In this study, most ADRs were categorized into possible (71.87%) followed by probable (28.12%) using Naranjo's causality assessment scale. A study by Akalu *et al.*,[17] showed that 55% of the ADRs were possible and 38% were probable. In contradiction, a study carried out by Richa *et al.*,[18] classified 71.69% of ADRs as probable and 28.31% possible.

Severity assessment of ADRs was conducted in this study using the Modified Hartwig and Seigel Scale in which the majority of the ADRs were of mild (62.5%) severity followed by moderate (34.37%) and severe (3.125%). A similar study by Akalu *et al.*,[17] showed that 87% of the ADRs were mild, 13% was moderate (and none showed severe/lethal. Contradictory to our result, a study performed by Shamna *et al.*,[1] observed most of the ADRs to be moderate (63.26%) followed by mild (28.57%) and severe (8.16%) reactions.

In this study, the preventability assessment of ADRs was done using Modified Schumock and Thornton scale. It has been observed that all ADRs were probably preventable. A study by Vijaishri *et al.*,[12] revealed contradicting results where 98% of the ADRs were not preventable, 1% probably preventable, and 1% definitely preventable.

Using Rawlins and Thompson classification, 57.6% of the ADRs were identified as predictable (Type A) and the remaining as unpredictable (Type B). This is contradictory to a study by Jayanthi *et al.*,[16] which found 67% of ADRs to be unpredictable (Type B).

Table 2: Antibiotic class responsible for ADRs.

Drug class	Drug name	ATC code	Type of ADR	Occurrence of ADRs (*n*=32)	Frequency of ADRs (*n*=32)	Occurrence of ADRs in antibiotic class (*n*=32)
Penicillins [n=133 (44.33%)]	Amoxicillin clavulanate (n=109)	J01CR02	Diarrhea	2(6.25%)	5 (15.625%)	7(5.25%)
			Rashes	2(6.25%)		
			Itching	1 (3.125%)		
	Piperacillin tazobactam (*n*=32)	J01CR05	Diarrhea	2(6.25%)	2 (6.25%)	
Cephalosporins [n=158 (52.66%)]	Cefotaxime (15)	J01DD01	Rashes	1 (3.125%)	1 (3.125%)	
	Ceftriaxone (79)	J01DD04	Nausea	1 (3.125%)	5 (15.625%)	7 (4.42%)
			Diarrhea	3 (9.37%)		
			Itching	1 (3.125%)		
	Cefoperazone salbactam (*n*=55)	J01DD62	Diarrhea	1 (3.125%)	1 (3.125%)	
Carbapenem [n=16 (5.33%)]	Meropenem (*n*=6)	J01DH02	Vomiting	1 (3.125%)	1 (3.125%)	1 (6.25%)
Aminoglycoside [n=11 (3.66%)]	Amikacin (*n*=10)	J01GB06	AKI	1 (3.125%)	1 (3.125%)	1 (9.09%)
Fluoroquinolones [n=44 (14.66%)]	Ciprofloxacin (*n*=32)	J01MA02	Diarrhea	1 (3.125%)	4 (12.5%)	7 (15.9%)
			Rashes	1 (3.125%)		
			Itching	1 (3.125%)		
			Itchy blisters	1 (3.125%)		
	Ofloxacin (*n*=4)	J01MA01	Constipation	1 (3.125%)	2 (6.25%)	
			Diarrhea	1 (3.125%)		
	Ciprofloxacin Ornidazole (*n*=2)	J01RA02	Rashes	1 (3.125%)	1 (3.125%)	
Nitroimidazole [n=104 (34.66%)]	Metronidazole (*n*=78)	J01XD01	Headache	1 (3.125%)	2 (6.25%)	3 (2.88%)
			Nausea	1 (3.125%)		
	Ornidazole (*n*=28)	J01XD03	Nausea	1 (3.125%)	1 (3.125%)	
Macrolide [n=4 (1.33%)]	Azithromycin (*n*=2)	J01FA10	Nausea	1 (3.125%)	1 (3.125%)	1 (25%)
Lincosamide [n=37 (12.33%)]	Clindamycin (*n*=6)	J01FF01	Diarrhea	4 (12.5%)	4 (12.5%)	4 (10.81%)
Oxazolidinone 14 (4.66%)	Linezolid (*n*=14)	J01XX08	Diarrhea	1 (3.125%)	1 (3.125%)	1 (7.14%)

*AKI- Acute Kidney Injury, ATC; Anatomical Therapeutic Chemical

Following management, 96.875% of the patients recovered from the developed ADRs. This is similar to the studies conducted by Shamna *et al.,*[1] and Jayanthi *et al.,*[16] where 89.79% and 79% of the patients recovered, respectively. In contradiction, in a study conducted by Vijaishri *et al.,*[12] 92.3% were recovering.

In patients who underwent test doses of antibiotics, 5.76% developed ADRs, which mainly included rashes (6.06%) and itchy blisters (3.03%). This is similar to a study conducted by Iammatteo *et al.,*[19] where 11% of the patients who underwent test doses developed ADRs.

Limitations

The study's limitations included study duration, comparatively lower number of subjects enrolled than similar studies conducted by other investigators, Lack of knowledge on ADRs and adverse drug reporting

Table 3: Analysis of ADRs.

Category	Frequency (%)
Causality Assessment Scale	
WHO- UMC Scale	
Probable	18 (56.25%)
Possible	14 (43.75%)
Naranjo Scale	
Probable	9 (28.12%)
Possible	23 (71.87%)
Severity Assessment Scale	
Mild- Level 2	20 (62.5%)
Moderate - Level 3	11 (34.37%)
Severe - Level 5	1 (3.125%)
Preventability Assessment Scale	
Probably preventable	32 (100%)
Predictability Assessment scale	
Predictable	18 (57.60%)
Unpredictable	14 (42.40%)

or underreporting among healthcare professionals, and restricted access to documents of subjects admitted in intensive care units.

CONCLUSION

The occurrence of antibiotic-induced ADRs in our study is 10.66%. It observed a trend of male predominance in the ADRs occurred and was seen mostly in the middle age group of 40-49 years. The Causality Assessment showed that most of the ADRs were in the category of probable and possible. The majority of the subjects were observed to have gastrointestinal and dermatological reactions. The antibiotic drug classes contributing to the occurrence of ADRs were mainly Penicillins, Cephalosporins, and Fluoroquinolones. The present study concluded that ADRs are indeed a major drug-related problem affecting health outcomes and an issue that needs to be addressed vastly.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

ADE: Adverse Drug Event; **ADR:** Adverse Drug Reaction; **WHO:** World Health Organization; **PV**: Pharmacovigilance; **WHO-UMC:** World Health Organization - Uppsala Monitoring Centre.

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