THE STUDY OF RATIONALITY AND ADR OF ANTIBIOTICS WITH ACCORDANCE TO WHO INDICATORS IN SURGICAL DEPARTMENT IN TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

INTRODUCTION: Antibiotics are used to prevent infections before, during and after the surgery. Surgical antibiotic prophylaxis (SAP) is one of the pillars of SSI prevention and is defined as the prevention of infectious complications by administering an effective anti-microbial agent prior to exposure to contamination during surgery. There are potential adverse effects of the administration of antimicrobials both in the individual and the population. Antimicrobial prophylaxis should, therefore, only be offered to patients where there is evidence or, in the absence of evidence, expert consensus that the potential benefits of prophylaxis outweigh the risks.

AIM: To study the prescribing pattern of antibiotics in Surgical department.

METHODOLOGY: A prospective, observational study was carried for a period of six months where patient of all gender and age group who received antibiotics with surgical history were chosen for the study.

RESULTS: ADRs are unwanted drug effects that can lead to hospital admission, prolongation of hospital stay and emergency department visits. The WHO/INRUD developed core prescribing indicators to measure the performance of health-care providers in key dimensions related to the appropriate use of drugs. In my study, average number of drugs per encounter was 10.97, generic names were only 7.11%, and percentage of encounters with antibiotics prescribed was 23.66%. Out of 2413 injections prescribed in 350 patients, 604 antibiotics were antibiotic prescribed as parenteral.

CONCLUSION: The study enrolled 350 patients from the Inpatient wards of St. Philomena's hospital and found that 13 patients were encountered with ADRs, with Metronidazole induced vomiting being the common ADR. The WHO and Naranjo causality assessment was probable, and the antibiotic prescribing pattern was in moderate compliance with the WHO core prescribing indicators.

INTRODUCTION:

Surgery is a field of medicine that uses operating methods to treat damage, disease, or to enhance body functions. Surgery is a crucial component in treating a variety of medical diseases. Surgical site infections (SSIs), where pathogenic microorganisms contaminate a surgical wound, grow, and harm tissue, are known as SSIs. Antibiotics are drugs that either stop or slow the growth of microorganisms. These antibiotics are taken before, during, and after surgery to avoid infections. Since microbiological culture and susceptibility results typically need 24 h for the identification of infections and antibiotic susceptibility patterns, the antibiotics are initially administered as empirical therapy. The pathogens implicated and risk factors for major resistance patterns, the severity of the clinical patient, and the source of infection all play a significant role in determining the empiric antibiotic regimen.

When surgery is initiated, a single dose regimen based on the most prevalent organism guarantees that the MIC is reached during skin incision, lowering the risk of surgical site infection. Antimicrobial prophylaxis is utilized in certain surgical procedures depending on the risk of infection involved and the effectiveness of the medication. Antimicrobial prophylaxis is not necessary for all surgical operations.The bacteriology of the surgical site should be taken into account more than anything else when selecting an antibiotic prophylactic. Exogenous (from outside the body), or endogenous (from the patient's own natural flora) are the two ways that organisms involved in an SSI are acquired (from contamination during the surgical procedure). Resident flora can be predicted, allowing for the selection of the best antibiotics, based on the procedure's kind, anatomic location, and NRC categorization. The indicators are facility-based measurements designed to reflect procedures in a sample of medical institutions that is intended to be representative.

The fundamental goal of indicators is to specify a small number of objective metrics that can be used to explain the drug usage situation in a nation, region, or specific medical facility. Researchers will be able to compare situations in various locations or at various times using these metrics or indicators. Regardless of who measures them or when they are taken, the drug use indicators mentioned are meant to measure particular features of healthcare practitioners' behavior in healthcare facilities in a reproducible manner.

STUDY MATERIAL AND METHOD:

Study site: Tertiary care Hospital, Bangalore.

Study period: The study was conducted for a period of six months.

Study design: This was a hospital based prospective Observational study.

Inclusion criteria: Both gender of all age groups who received antibiotics for surgery.

Exclusion criteria: Patients who were not willing to participate in the study.

Source of data:

1. Patient case sheets
2. Interview with patient/attender
3. Interview with consultant/resident

Method of study: The research student participated in ward rounds on daily basis and reviewed the surgical case sheets. Relevant information from the case sheets were recorded in the data collection form. The pooled data was analysed and expressed using descriptive statistics. Ethical Approval: Ethical committee clearance was obtained from the Institutional Ethics Committee of St. Philomena's Hospital, Bengaluru.

RESULT AND DISCUSSION:

Table 1: Distribution of Patients with respect to Gender

SL.NO	GENDER	NO. OF PATIENTS	PERCENTAGE
1	Female	220	62.86%
2	Male	130	37.14%
	TOTAL	350	100.00%

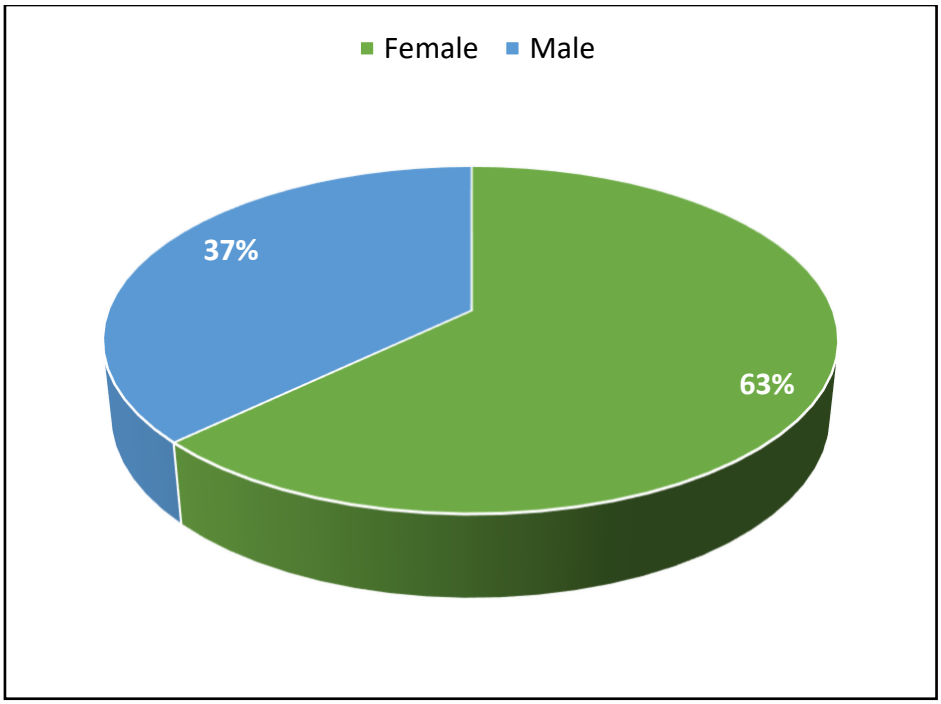

Figure 1: Distribution of Patients with respect to Gender

The research included a total of 350 patients who underwent surgery in the inpatient wards of St. Philomena's Hospital. Out of 350 cases, 220 (62.86%) were female and 130 (37.14%) were male.

Table 2: Distribution of Patients with respect to Age

SL.NO	AGE (YEARS)	NO. OF PATIENTS	PERCENTAGE
1	<1	1	0.29%
2	1-10	6	1.71%
3	10-20	10	2.86%
4	20-30	66	18.86%
5	30-40	49	14.00%
6	40-50	71	20.29%
7	50-60	48	13.71%
8	60-70	56	16.00%
9	70-80	28	8.00%
10	80-90	15	4.29%
	TOTAL	**350**	**100.00%**

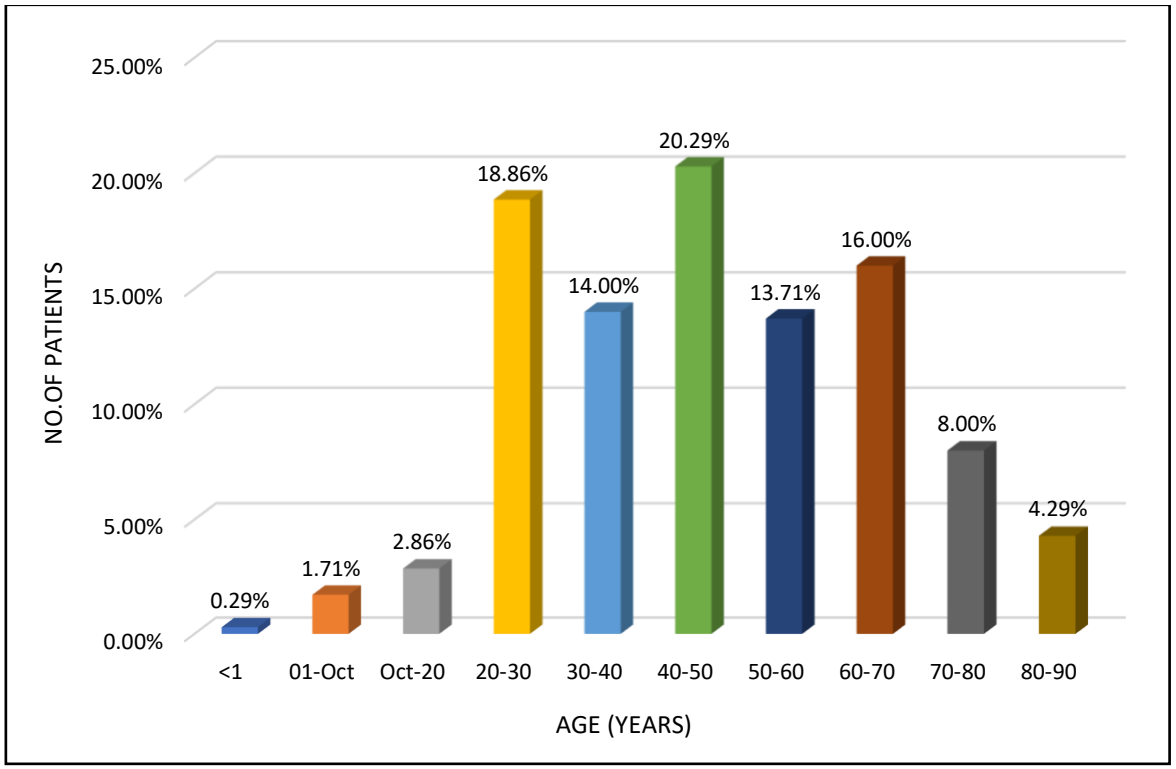

Figure 2: Distribution of Patients with respect to Age

Among 350 patients included, 71 patients (20.29%) were found to be in the age group of 40- 50 years followed by 66 patients (18.86%) between the age group of 20-30 years, 56 patients (16.0%) between the age group 60-70 years, 49 patients (14.0%) were in age group of 30-40 years, 48 patients (13.71%) were in the age group of 50-60 years, 28 patients (8.0%) were in age group of 70-80 years, 15 patients (4.29%) were in the age group of 80-90 years, 10 patients (2.86%) were in age group of 10-20 years, 6 patients(1.71%) were in the age group of 1-10 years, 1 patient was found to be below 1 year.

Table 3: Distribution of Patients based on Surgery

SL. NO	TYPE OF SURGERY	NO. OF PATIENTS	PERCENTAGE
1	MAJOR	295	84.29%
2	MINOR	55	15.71%
	TOTAL	**350**	**100.0%**

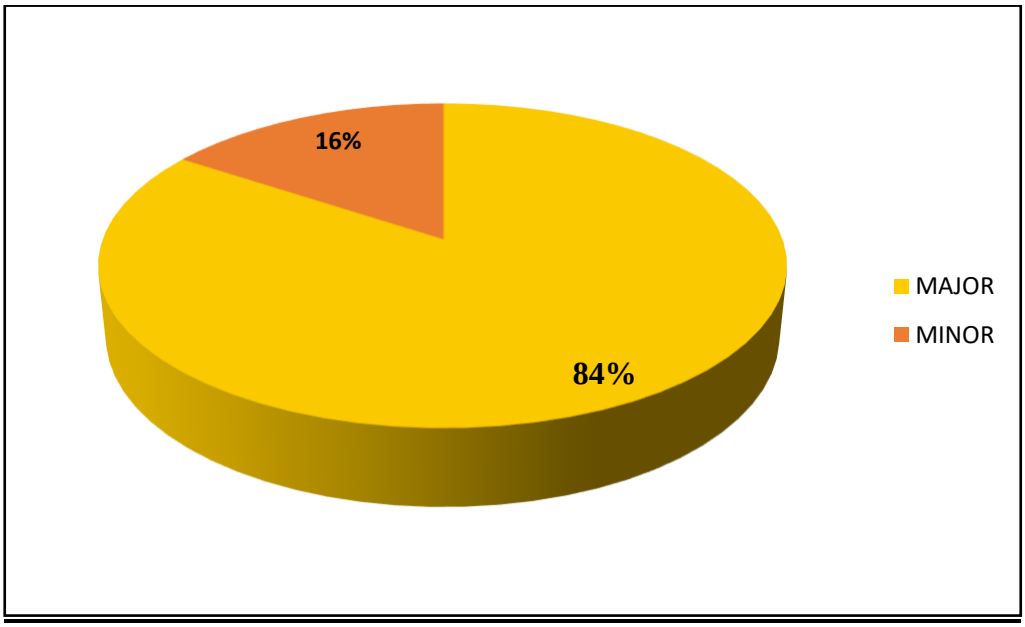

Figure 3: Distribution of Patients based on Surgery

The terms ‘Major’ and ‘Minor’ surgery are widely used to describe procedures. The phrases are commonly used to explain procedures to patients. Out of 350 patients, 295 patients (84.29%) had undergone Major surgery and 55 patients (15.71%) had undergone Minor surgery.

Table 4: Distribution of Patients based on Post-Operative Complication

SL. NO	POST OPERERATIVE COMPLICATION	NO. OF PATIENTS	PERCENTAGE
1	NO	276	78.857%
2	YES	71	20.29%
	TOTAL	**350**	**100.00%**

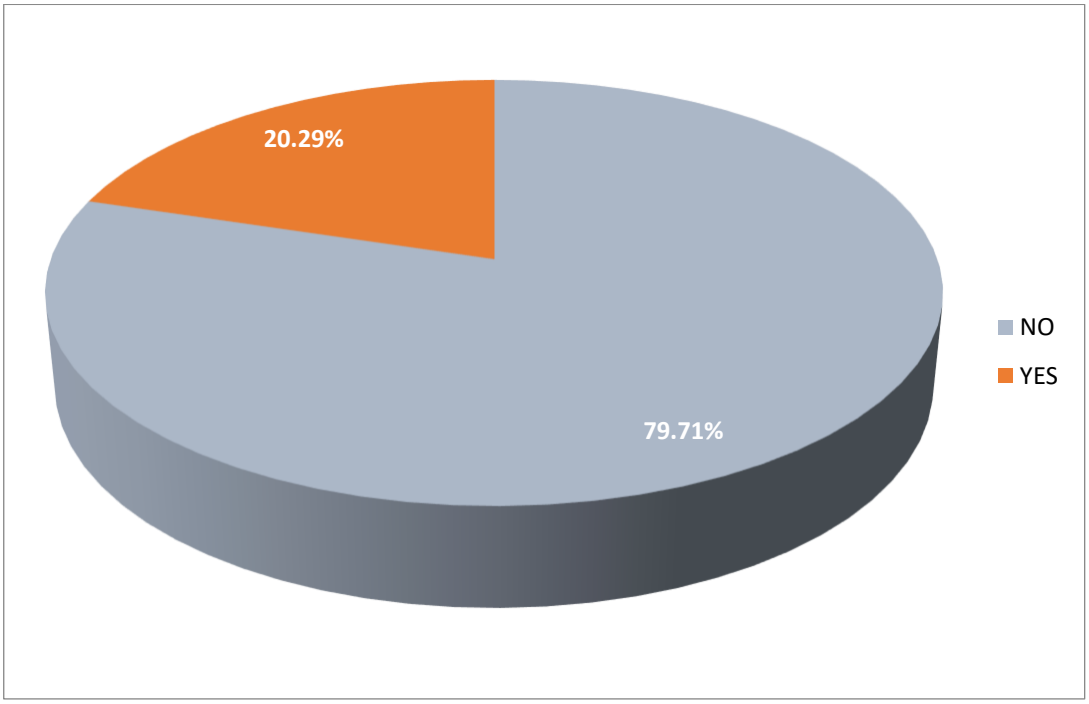

Figure 4: Distribution of Patients based on Post-Operative Complication

Postoperative Complications increase patient morbidity and mortality and are a target for quality improvement programs.Among 350 patients included in the study, 71 patients (20.29%) developed Post-operative Complications.

Table 5: Distribution based on Post-Operative Complication reaction

SL. NO	POST SURGERY COMPLICATIONS	NO. OF PATIENTS	PERCENTAGE
1	NAUSEA	11	15.49%
2	BREATHLESSNESS	2	2.82%
3	VOMITING	7	9.86%
4	TACHYCARDIA	2	2.82%
5	LOOSE STOOLS	2	2.82%
6	INCREASE IN WBC COUNT	1	1.41%
7	HEADACHE	4	5.63%
8	GIDDINESS	1	1.41%
9	DROWSY	1	1.41%
10	FEVER	15	21.13%
11	COUGH	3	4.23%
12	CONSTIPATION	1	1.41%
13	COUGH+GIDDINESS	1	1.41%
14	COUGH+TACHYCARDIA	1	1.41%
15	CSF LEAKAGE POSITIVE	1	1.41%
16	FEVER+HEADACHE	1	1.41%
17	FEVER+INCREASE IN WBC	2	2.82%
18	FEVER+LOOSE STOOLS	2	2.82%
19	FEVER+NAUSEA+INCREASE IN WBC+TACHYCARDIA+	1	1.41%
20	FEVER+TACHYCARDIA+BLEEDING+ HYPOTENSION+MALENA+NAUSEA+ GIDDINESS	1	1.41%
21	FEVER+TACHYCARDIA+HYPOTENSIVE+ LEUCOCYTOSIS+DARK BROWN RYLE'S TUBE OUTPUT	1	1.41%
22	FEVER+VOMITING	1	1.41%

23	FEVER SPIKE+SEIZURE LIKE EPISODE+LOOSE STOOLS	1	1.41%
24	FEVER+INCREASE IN WBC+TACHYCARDIA	1	1.41%
25	NAUSEA+FEVER	1	1.41%
26	NAUSEA+LOOSE STOOLS+TACHYCARDIA	1	1.41%
27	NAUSEA+VOMITING+ITCHING	1	1.41%
28	THROAT PAIN/ IRRITATION	3	4.23%
29	VOMITING+LOOSE STOOLS	1	1.41%
	TOTAL	**71**	**100%**

Table 6: Distribution of Patient based on PONV Encountered

SL. NO	POST-OPERATIVE NAUSEA AND VOMITING	NO. OF PATIENTS	PERCENTAGE
1	NAUSEA	11	44.00%
2	VOMITING	7	28.00%
3	FEVER+NAUSEA+INCREASE IN WBC+TACHYCARDIA+	1	4.00%
4	FEVER+TACHYCARDIA+BLEEDING+ HYPOTENSION+MALENA+NAUSEA+ GIDDINESS	1	4.00%
5	FEVER+VOMITING	1	4.00%
6	NAUSEA+FEVER	1	4.00%
7	NAUSEA+LOOSE STOOLS+ TACHYCARDIA	1	4.00%
8	NAUSEA+VOMITING+ITCHING	1	4.00%
9	VOMITING+LOOSE STOOLS	1	**4.00%**
	TOTAL	**25**	**100.00%**

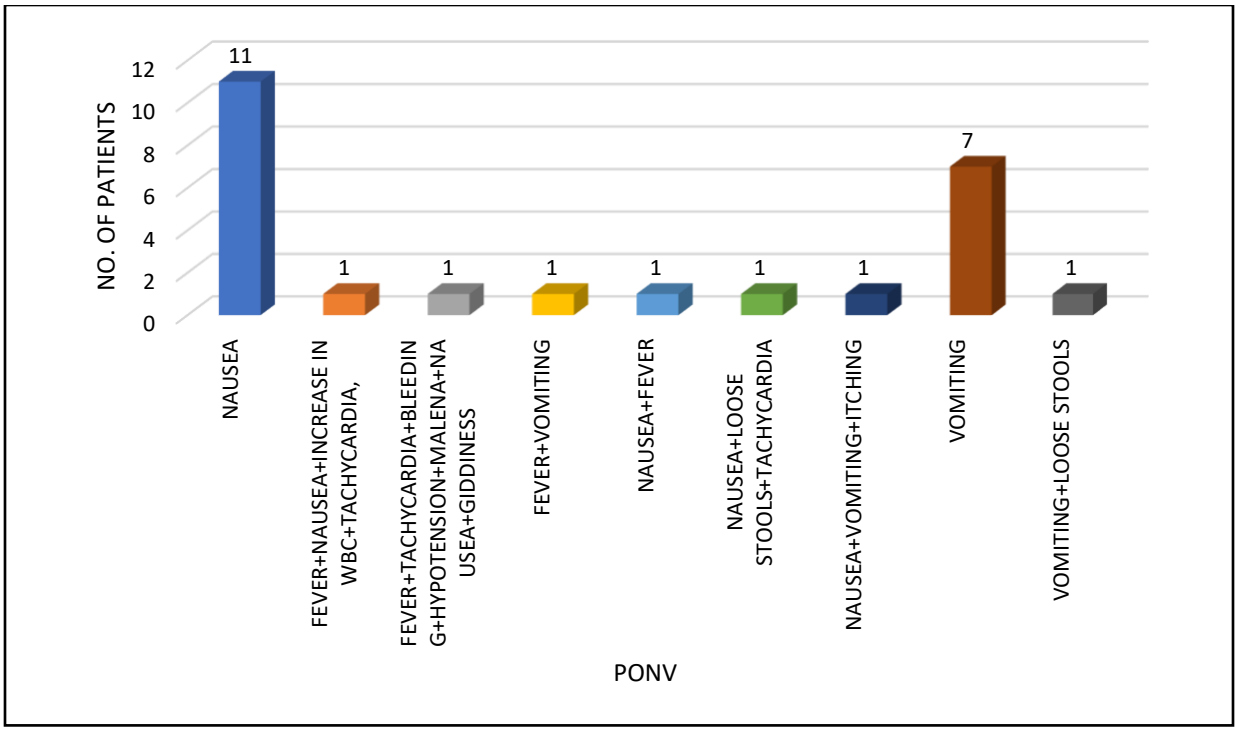

Figure 5: Distribution of Patient based on PONV Encountered

It was observed that out of 71 patients, 15 patients (21.13%) developed Fever, 11 patients (15.49%) developed Nausea and 7 patients (9.86%) developed Vomiting followed by less common reactions including Headache, Cough, Breathlessness, Giddiness and Tachycardia. The result was different from the study carried out by **Dencker et al.**[39]

Postoperative nausea and vomiting (PONV) remains a significant clinical issue that can detract from patient's quality of life in hospital/treatment facility, as well as increases the chance of readmission.[40]

Among 71 patients who developed Post-Operative Complications, 25 patients had Post-operative Nausea and Vomiting where 11 patients (44.0%) had Nausea followed by 7 patients (28.0%) had Vomiting and remaining were Nausea/Vomiting with other complications.

Table 7: Distribution based on ADR Encountered

SL.NO	ADR ENCOUNTERED	NO.OF PATIENTS ENCOUNTERED WITH ADR	PERCENTAGE
1	NO	337	96.29%
2	YES	13	3.71%
TOTAL		**350**	**100.00%**

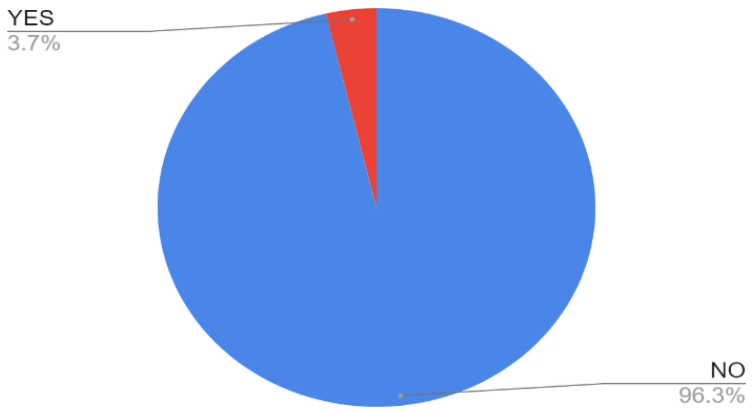

Figure 6: Distribution based on ADR Encountered

Adverse drug reactions (ADRs) are unwanted drug effects that have considerable economic as well as clinical costs as they often lead to hospital admission, prolongation of hospital stay and emergency department visits.

Out of 350 patients, 13 patients (3.71%) developed adverse drug reactions.

Table 8: Distribution Based On ADR Reaction

SL. NO	DRUG	ADVERSE REACTIONS	FATE OF THE DRUG	NO. OF ADR	PERCENT
1	3% NACL	FEVER SPIKE	STOPPED	1	7.69%
2	CHEMOTHERAPY (PALCITAXEL+ CARBOPLATIN)	VOMITING	STOPPED	1	7.69%
3	INJ. AMOXICILLIN/ CLAVULANIC ACID	LOOSE STOOLS	STOPPED	1	7.69%
4	INJ.AUGMENTIN	VOMITING	STOPPED	1	7.69%
5	INJ.CEFTRIAXONE	LOOSE STOOLS	STOPPED	1	7.69%
6	INJ.CLEXANE	HEMATURIA	STOPPED	1	7.69%
7	INJ.DEXONA	HYPOGLYCEMIA	STOPPED	1	7.69%
8	INJ.METRONIDAZOLE	FEVER SPIKE	STOPPED	1	7.69%
9	INJ.METRONIDAZOLE	NAUSEA	STOPPED	1	7.69%
10	INJ.METRONIDAZOLE	VOMITING	STOPPED	2	15.38%
11	IV ANTIBIOTICS	VOMITING AND LOOSE STOOLS	STOPPED	1	7.69%
12	TAB.IVABRID	BRADYCARDIA	WITHHOLD	1	7.69%
	TOTAL			**13**	**100.00%**

Among 13 patients, 2 patients (15.38%) developed Metronidazole Induced Vomiting, 1 patient (7.69%) developed Chemotherapy Induced Vomiting, 1 patient (7.69%) developed 3% NaCl Induced Fever, 1 patient (7.69%) developed Amoxicillin-Clavulanic acid Induced Vomiting, 1 patient (7.69%) developed Amoxicillin-Clavulanic acid Induced Loose Stools, 1 patient (7.69%) developed Ceftriaxone Induced Loose Stools, 1 patient (7.69%) developed Clexane Induced Hematuria, 1 patient (7.69%) developed Dexamethasone Induced Hypoglycemia, 1 patient (7.69%) developed Metronidazole Induced Fever, 1 patient (7.69%) developed Antibiotic Induced Vomiting + Loose Stools, 1 patient (7.69%) developed Metronidazole Induced Nausea

and 1 patient (7.69%) developed Ivabradine Induced Bradycardia respectively where none of the ADR were postoperative complication.

Table 9: Distribution based on the Causality Assessment Scale of ADR using WHO Scale

SL. NO	CAUSALITY ASSESSMENT OF ADR (WHO SCALE)	NO.OF ADVERSE REACTIONS ENCOUNTERED	PERCENTAGE
1	CERTAIN	0	0%
2	PROBABLE	13	3.71%
3	POSSIBLE	0	0%
4	UNLIKELY	0	0%
5	CONDITIONAL / UNCLASSIFIED	0	0%
6	UNASSESSABLE / UNCLASSIFIABLE	0	0%
	TOTAL	**13**	**100.00%**

Table 10: Distribution based on the causality assessment Using NARANJO Scale

SL.NO	CAUSALITY ASSESSMENT OF ADR(NARANJO SCALE)	NO.OF ADVERSE REACTIONS ENCOUNTERED	PERCENTAGE
1	DEFINITE(>8)	0	0%
2	PROBABLE(5-8)	13	3.71%

3	POSSIBLE(1-4)	0	0%
4	DOUBTFUL(<1)	0	0%
	TOTAL	**13**	**100.00%**

All the 13 ADRs were found be “Probable: as per causality assessment using Naranjo and WHO scale.

PRESCRIBING INDICATOR

- **Indicator 1- Measure Degree of Polypharmacy**

Table 12: Average number of Drugs per Encounter

TOTAL NO. OF DRUG PRODUCTS PRESCRIBED	NO. OF CLINICAL ENCOUNTER	AVERAGE
3842	350	10.97

- **Indicator 2-Measure of the Tendency to Prescribe by Generic Name**

Table 13: Percentage of Drugs Prescribed In Generic Name

NO. OF DRUGS PRESCRIBED IN GENERIC NAME	TOTAL NO. OF DRUG PRODUCT PRESCRIBED	PERCENTAGE
273	3842	7.11%

- **Indicator 3- Measure the use of Antibiotics Prescribed**

Table 14: Percentage of Encounters with an Antibiotics Prescribed

NO. OF ANTIBIOTICS PRESCRIBED	TOTAL NO. OF ENCOUNTER SURVEYED	PERCENTAGE
350	1479	23.66%

- **Indicator 4- Measure the use of Injections Prescribed**

Table 15: Percentage of Encounters with an Injections Prescribed

NO. OF PATIENT ENCOUNTER DURING WHICH AN INJECTIONS ARE PRESCRIBED	TOTAL NO. OF ENCOUNTER SURVEYED	PERCENTAGE
350	1479	23.66%

Table 16: Distribution of Patient based on Drugs Prescribed According to Formulary

SL.NO	NUMBER OF DRUGS PRESCRIBED FROM FORMULARY	NO. OF PATIENTS	PERCENTAGE
1	DID NOT FOLLOW	273	78%
2	FOLLOW	77	22%
	TOTAL	**350**	**100.00%**

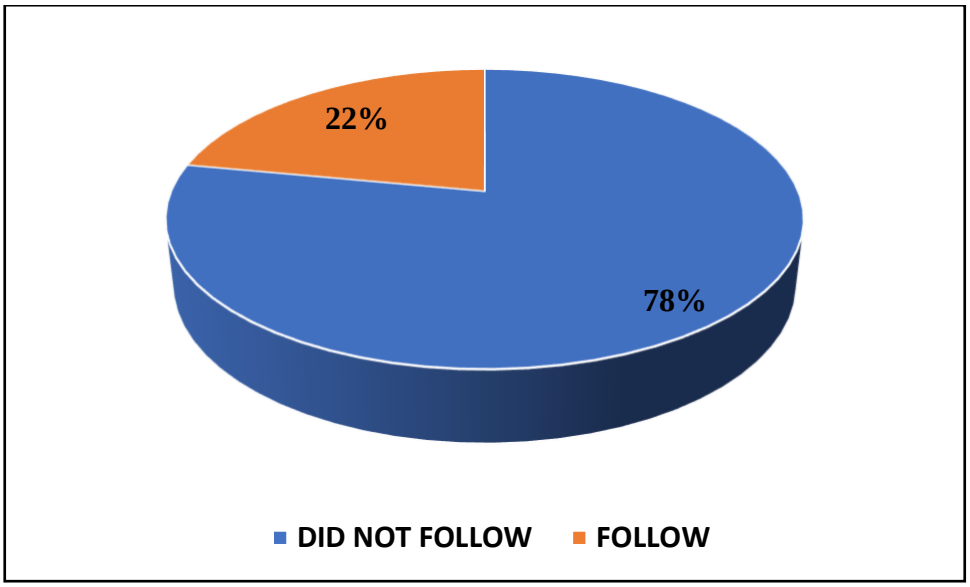

Figure 8: Distribution of Patients Based on Drug Prescribed According to Formulary

- **Indicator 5-Measure the Antibiotics use as per the Formulary**

Table 17: Percentage of Antibiotics Prescribed according to the Formulary

NO. OF ANTIBIOTICS PRESCRIBED WHICH LISTED ON FORMULARY	TOTAL NO. OF DRUGS PRESCRIBED	PERCENTAGE
77	3842	2.00%

Table 18: Distribution of Antibiotic Injections With respect to total number of Injections Prescribed in 350 Patients

TOTAL NUMBER OF ANTIBIOTICS INJECTIONS	TOTAL NUMBER OF INJECTIONS	PERCENTAGE
604	2413	25.03%

The WHO/INRUD developed core prescribing indicators for a routine monitoring of antibiotic use. The WHO core indicators of prescribing practices measure the performance of health-care providers in key dimensions related to the appropriate use of drugs.

In my study, average number of drugs per encounter was 10.97

Drugs prescribed by generic names were only 7.11% in my study, which is too low compared to the standard WHO ideal value of 100%.

The analysis of two common expensive mode of drug administration such as antibiotics and injections showed that percentage of encounters with antibiotics prescribed was 23.66%, which is within the standard range of 20-26.8% of the WHO prescribed values.

Percentage of encounters with injections in my study was 23.66 % which was clearly within the standard range of WHO ideal value (13.4-24.1%).

The percentage of drugs prescribed as per formulary in my study was 100%, which is equal to the ideal standard value of 100%.

Among 350 patients, only in 77 patients (22.0%) drugs were prescribed according to the antibiotic guideline of the hospital.

It was observed that out of 2413 injections prescribed in 350 patients, 604 antibiotics (25.03%) were antibiotic prescribed as parenteral.

CONCLUSION:

During the study period of six months a total number of 350 patients were enrolled into the study from the Inpatient wards of St. Philomena's hospital.

Majority of the patients included in the study underwent a major surgery.

It was observed that only 13 patients were encountered with ADRs during the study among which Metronidazole induced vomiting was the common ADR.

The WHO and Naranjo causality assessment for the ADRs were found to be probable.

There was moderate compliance with the WHO core prescribing indicators. With polypharmacy being common, prescribing of drugs by generic name was negligible, and all the drugs were prescribed from formulary, the prescription of antibiotics and injections was found to be within the normal limit.

I like to conclude the study by stating that the antibiotic prescribing pattern were in moderate compliance with the WHO core prescribing indicators.

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