



# EVALUATION OF DETECTION, ASSESSMENT, MONITORING, PREVENTION AND AWARENESS OF ADVERSE DRUG REACTION'S IN A TERTIARY CARE HOSPITAL

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## Abstract

### Background:

Adverse Drug Reactions are the recognized hazards of drug therapy and they can occur with any class of drugs. The main aim of this study was to detect, assess, monitor and prevention of adverse drug reactions in inpatients of a tertiary care hospital.

### Methods and Material:

It was a prospective observational study on adverse drug reactions was carried out among inpatients who were between 18-85 years in the tertiary care hospital. A total of 200 prescriptions of patients were included in study. The collected data was sorted and analyzed on the basis of severity, age and gender.

### Results:

A total of 90 ADRs were reported during the study period with male predominance (52%) and geriatric age group. More number of ADRs was from General Medicine and Neurology departments in which the most affected organ system were the Skin (26%) and the GIT (25.5%). The severity assessment revealed that most of them were severe (51%) followed by moderate and mild reactions. Of the reported reactions 33% were definitely preventable and casualty assessment was done which showed that 56% were definite, probable (26%), possible (8%).

### Conclusion:

The study concluded that adverse drug reactions to drugs are common and some of them resulted in increased healthcare cost due to the need of some interventions and increased length of hospital stay. The health system should promote the spontaneous reporting of Adverse Drug Reactions to drugs, proper documentation and periodic reporting to regional pharmacovigilance centers to ensure drug safety.

**Index terms:** Adverse Drug Reactions, Prospective study, Spontaneous reporting, Pharmacovigilance.

## INTRODUCTION

The World Health Organization (WHO) defines an ADR as “any response to a drug that is noxious, unintended and occurs at doses normally used in man for prophylaxis, diagnosis, therapy of disease, or for modification of physiological function” It has the potential to minimize harm through promoting broader safety concerns for newly introduced as well as already established products. ADR'S increase not only morbidity and mortality but also add to the overall health care cost. An increase in the number of drugs on the market, an ageing, an upward trend in polypharmacy are contributing factors to the prevalence of ADRs worldwide. The most commonly used method is the spontaneous adverse drug reaction reporting scheme. The suspected adverse drug reaction reporting scheme is important in identifying previously undetected adverse reactions and has provided many early warnings of drug safety hazards to allow appropriate drug regulatory action to be taken. In 1997, India joined hands with the World Health Organization (WHO) Adverse Drug Reaction Monitoring Programmed based in Uppsala, Sweden. A National Pharmacovigilance Centre located in the Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi and two WHO special Centre's in Mumbai (KEM Hospital) and Aligarh (JLN Hospital, Aligarh Muslim University). These centers were to report ADRs to the drug regulatory authority of India. In many countries ADRs rank among the top 10

leading causes of mortality. So there is a need to study ADRs seriously to create awareness about ADRs among patients to motivate health care professionals in the hospital to report ADRs to minimize the risk. Early detection, evaluation and monitoring of ADR are essential to reduce harm to patients and thus improve public health.

**Importance of ADR Reporting In India:**

Adverse Drug Reactions are fourth to sixth leading cause of death among hospitalized patients and it occurs in 0.3 per cent to 7 per cent of all hospital admissions. The incidence of serious ADR's is 6.7 percent. There is a rapid increase in the number of new drugs entering the market from last few decades India being the second most populated country has over one billion potential drug consumers, and no amount of pre-clinical and clinical data is sufficient to conclude the complete safety of a drug, under this scenario it becomes necessary to report any untoward reaction of any pharmaceutical product to assess its safety and efficacy to ensure maximal patient health.

**SUBJECTS AND METHODS**

The study was hospital based prospective observational study. This study was carried out in In-patient departments (IPD) which include General Medicine, Orthopedics, Gastroenterology, Neurology, Nephrology, Pulmonology, Urology, Cardiology of Sunshine hospitals, Secunderabad during the period of 6 months from November 2018 to April 2019.

**STUDY DESIGN**

A protocol was prepared and submitted, which was approved by Institutional Ethics Committee of Sunshine hospitals, Secunderabad, which is a Multi-super specialty tertiary care hospital. In this study 300 patients were enrolled after obtaining the consent. The data collection form was prepared and used. This form mainly contains the demographic details of the patient, medication history, diagnosis and treatment of the patient. The study includes only inpatients and age greater than 18 years were included and who are willing to participate only enrolled in the study. Those who are below 18 years of age, not willing to participate, pregnant and lactating women, psychiatric patients were excluded from our study

**METHODOLOGY**

All the data collected during the study will be processed using SPSS software. All the data will be represented as average (±SEM) and percentages, Rates of ADR or ADRS occurrence during the hospital stay will be calculated as percentage of inpatient or outpatient population treated. Student's t-test was used to compare mean values.

**RESULTS**

FIGURE-1: GENDER WISE DISTRIBUTION:

GENDER	NO. OF PATIENTS	PERCENTAGE
MALE	47	52
FEMALE	43	48

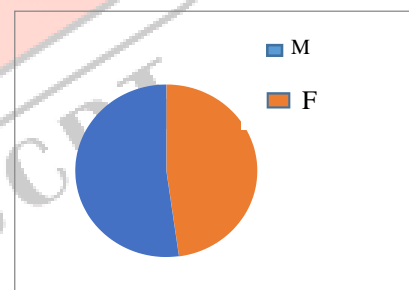


FIGURE-2: AGE WISE DISTRIBUTION:

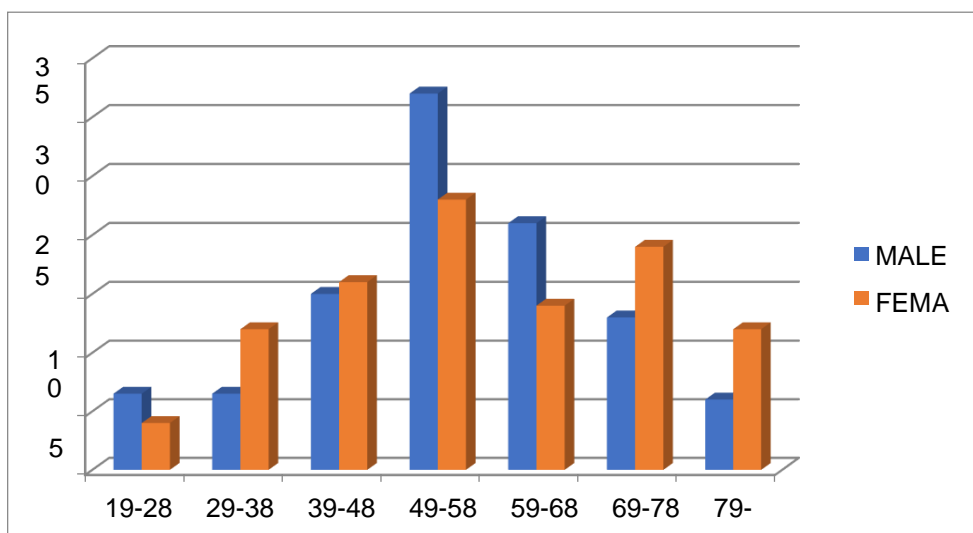


FIGURE-3: DEPARTMENT WISE EFFECT:

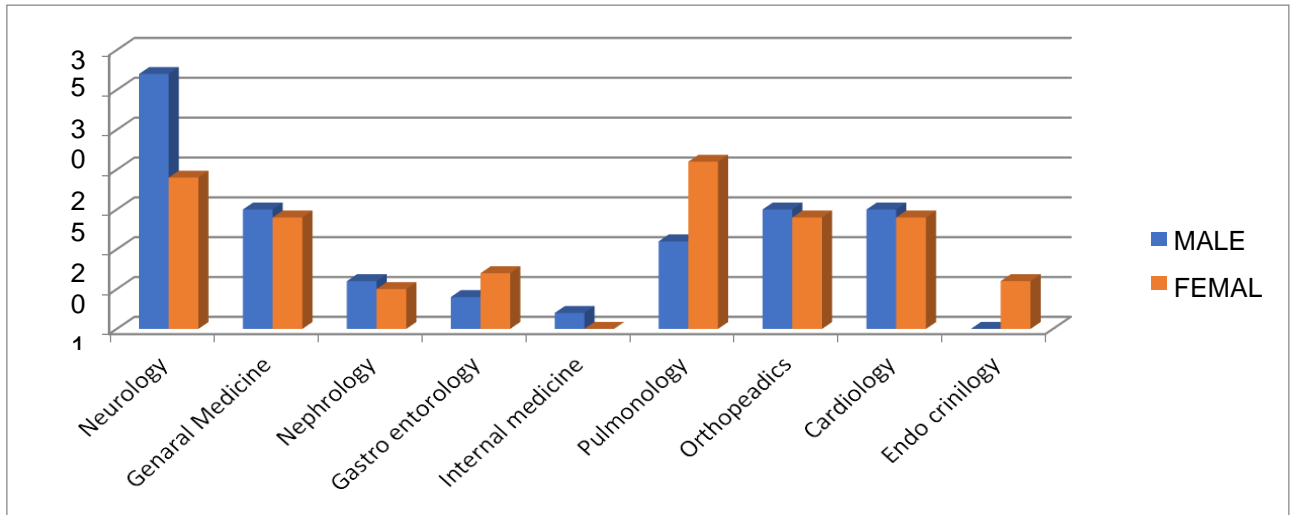


FIGURE-4: ORGAN SYSTEM AFFECTED:

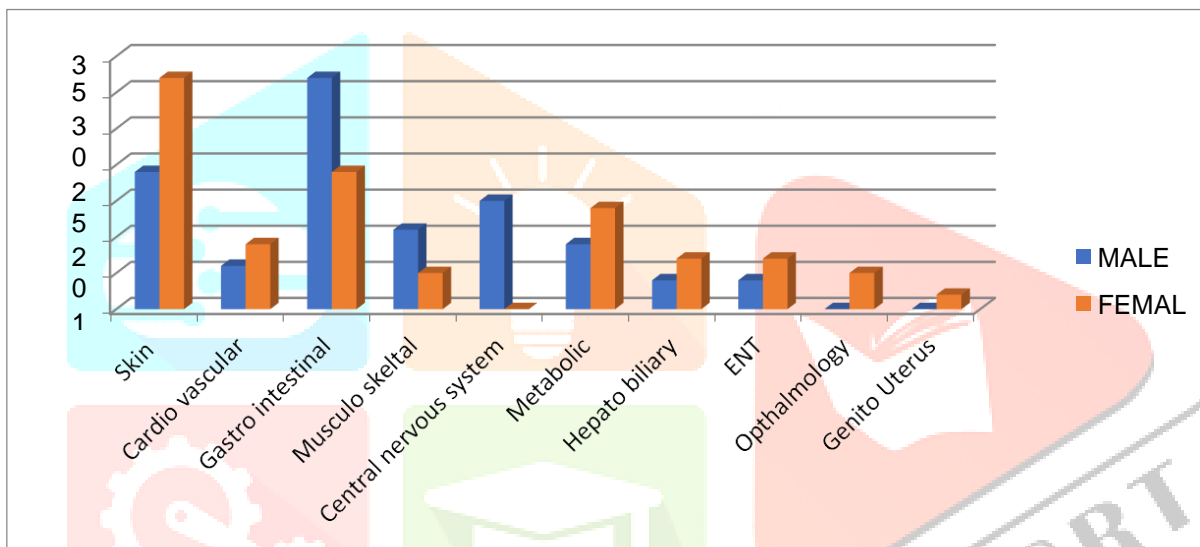


FIGURE-5: PRESENTING COMPLAINTS:

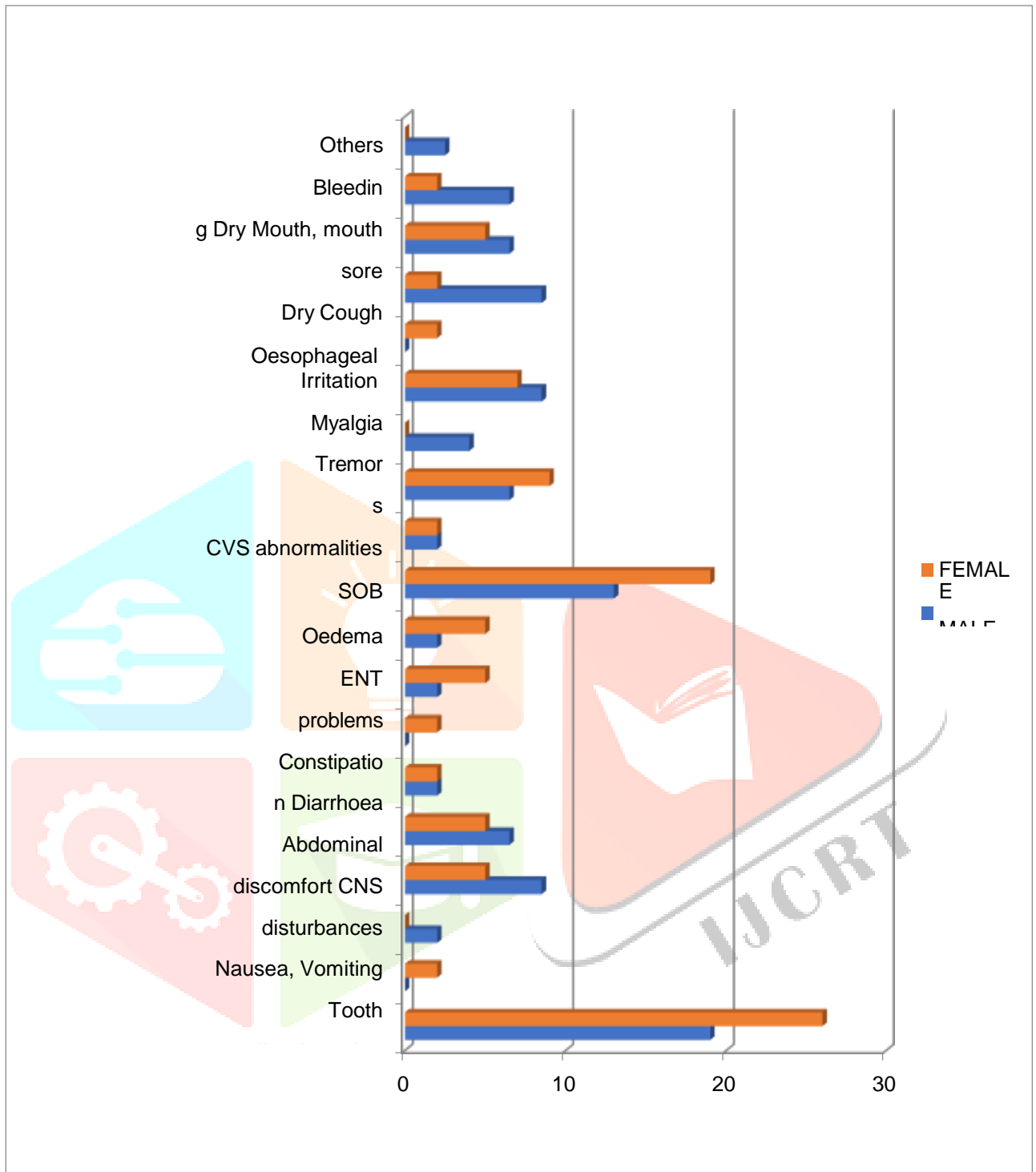


FIGURE- 6: SUSPECTED THERAPEUTIC CLASS OF DRUGS:

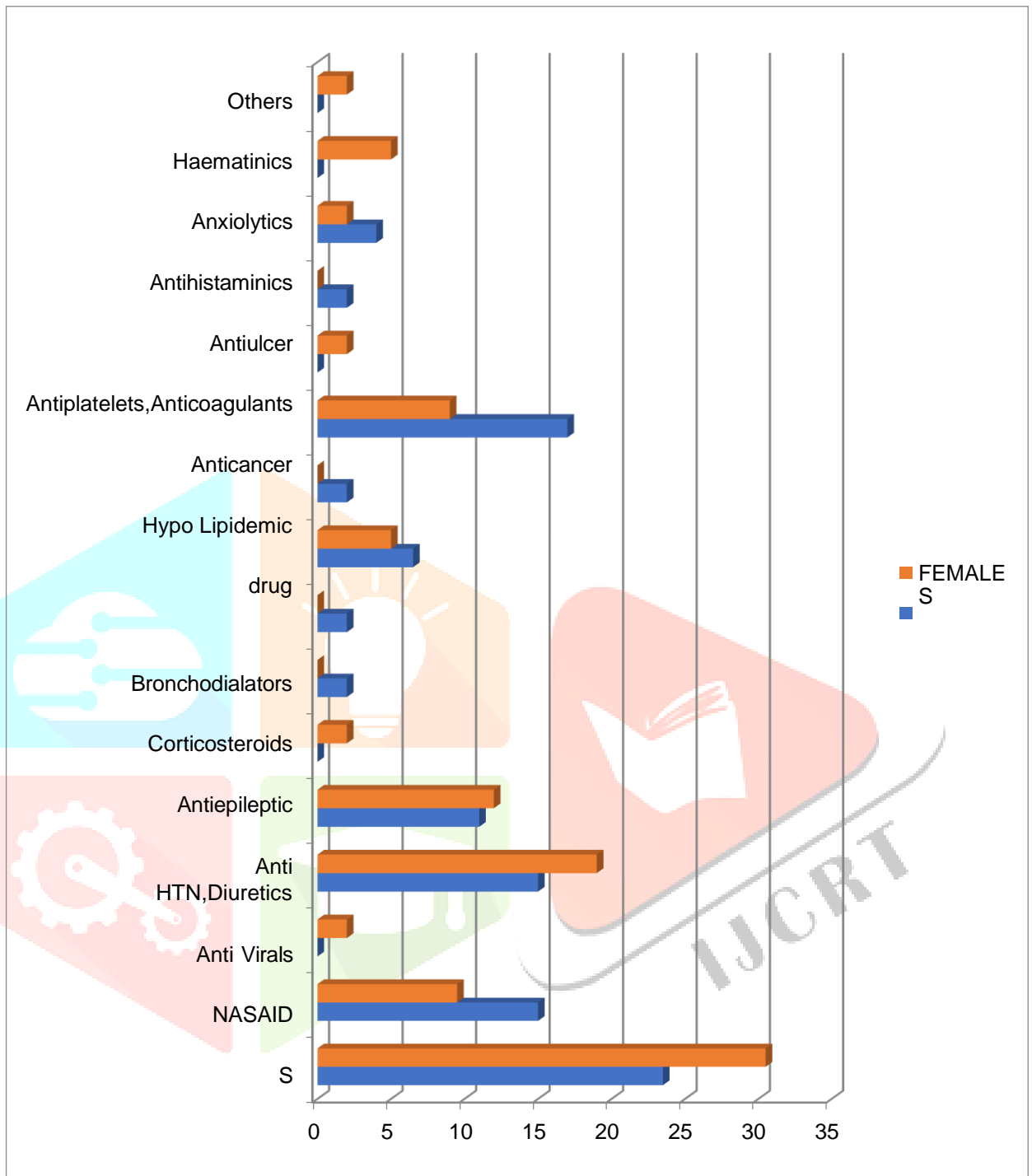


FIGURE-7: ANTIMICROBIAL AGENTS:

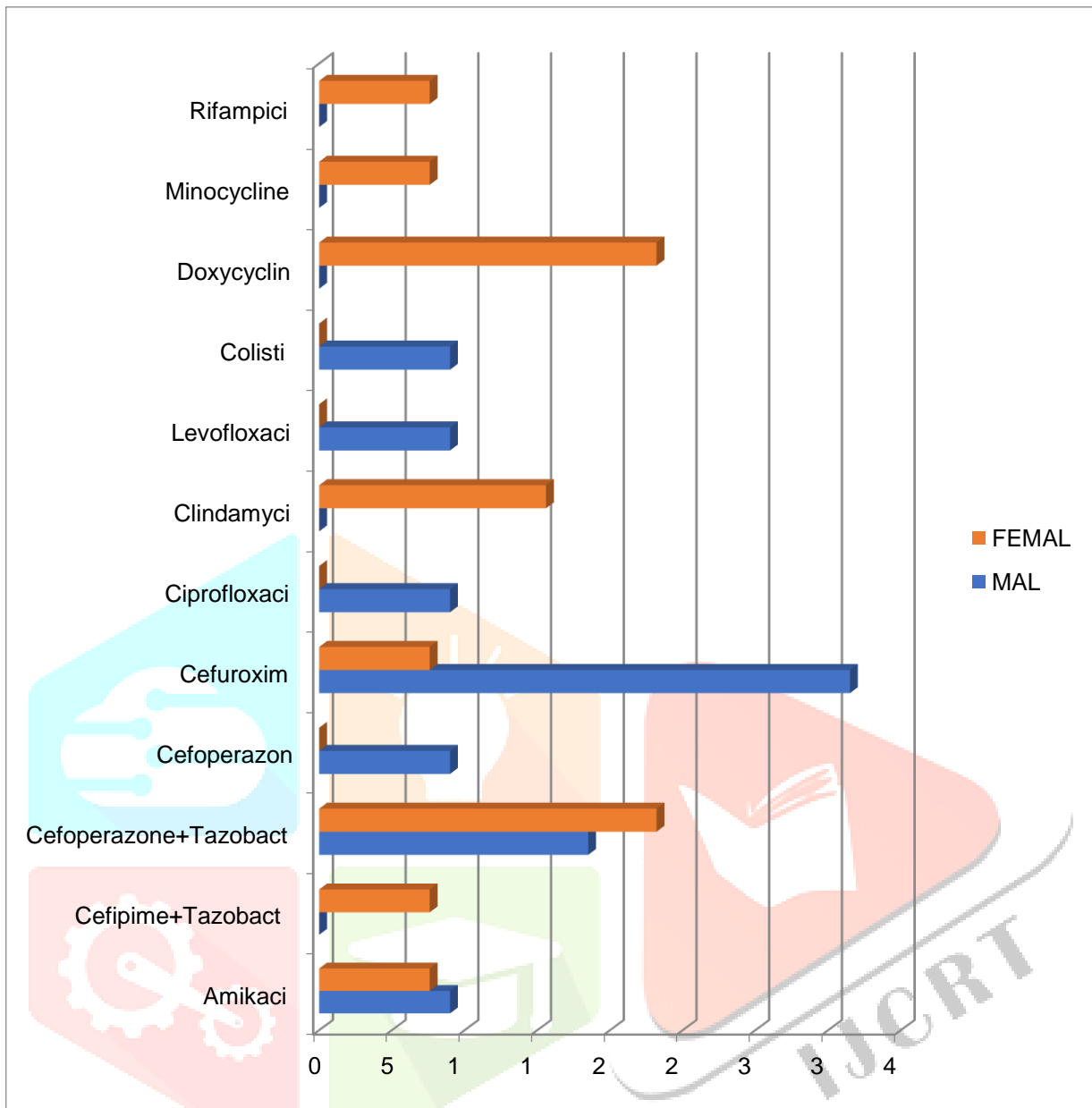


FIGURE-8: WHO CAUSALITY ASSESSMENT:

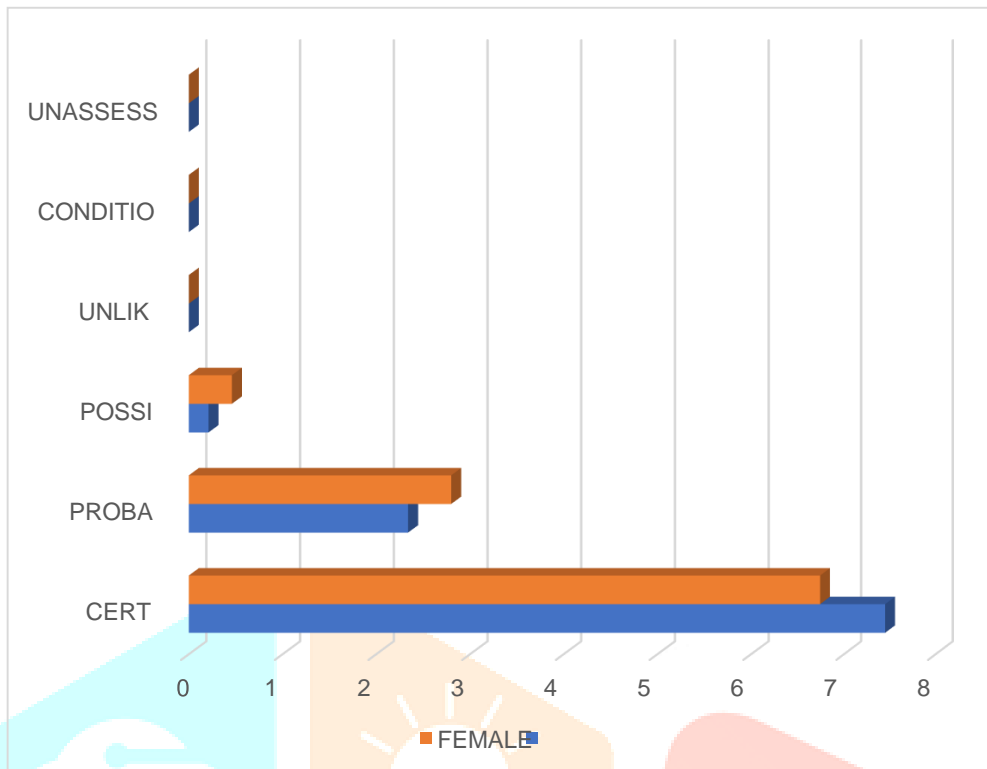


FIGURE-9: NARANJO'S CAUSALITY ASSESSMENT:

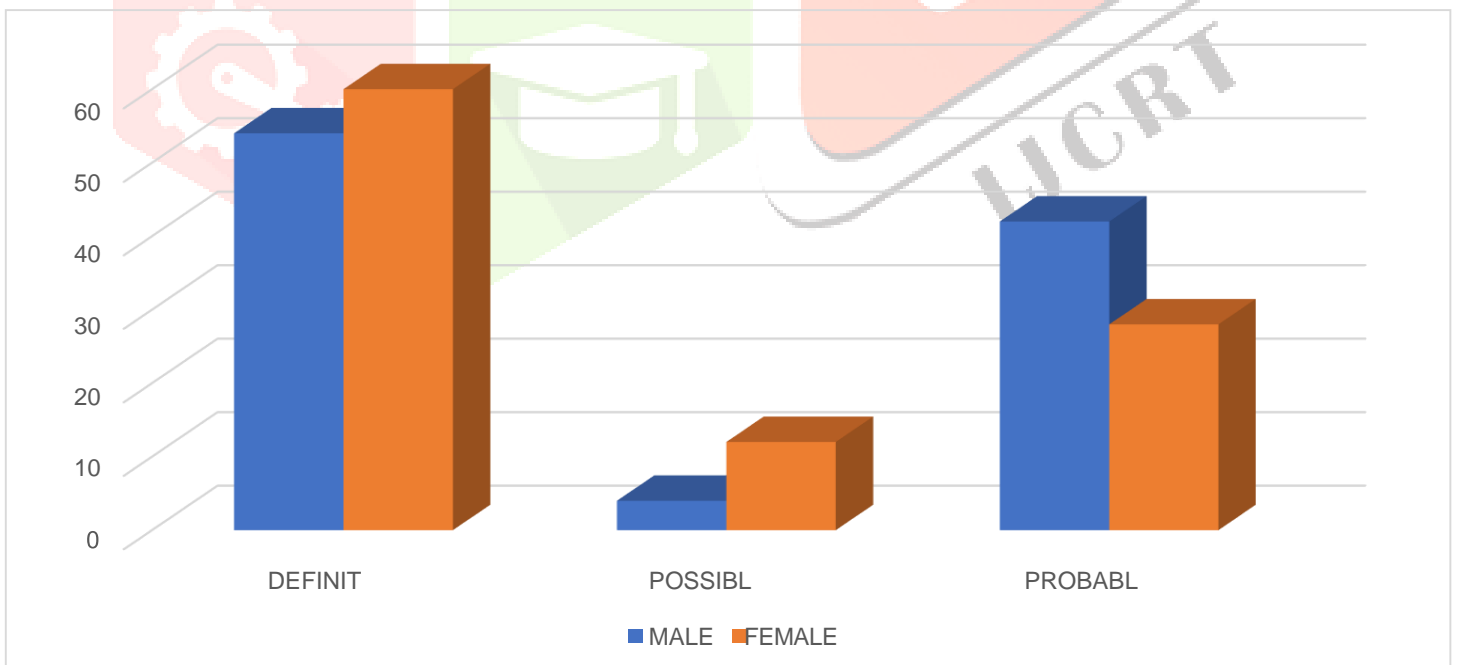


FIGURE-10: MODIFIED HARTWIG SCALE

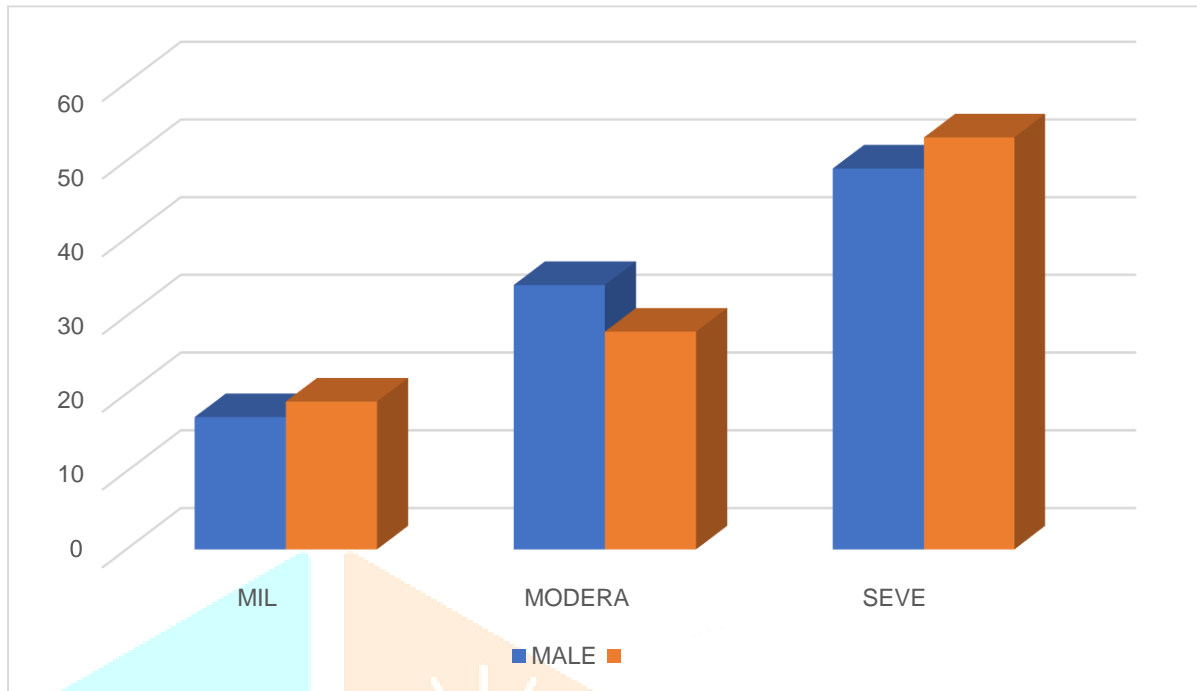


FIGURE-11: MODIFIED SHAMROCK AND THORNTON SCALE

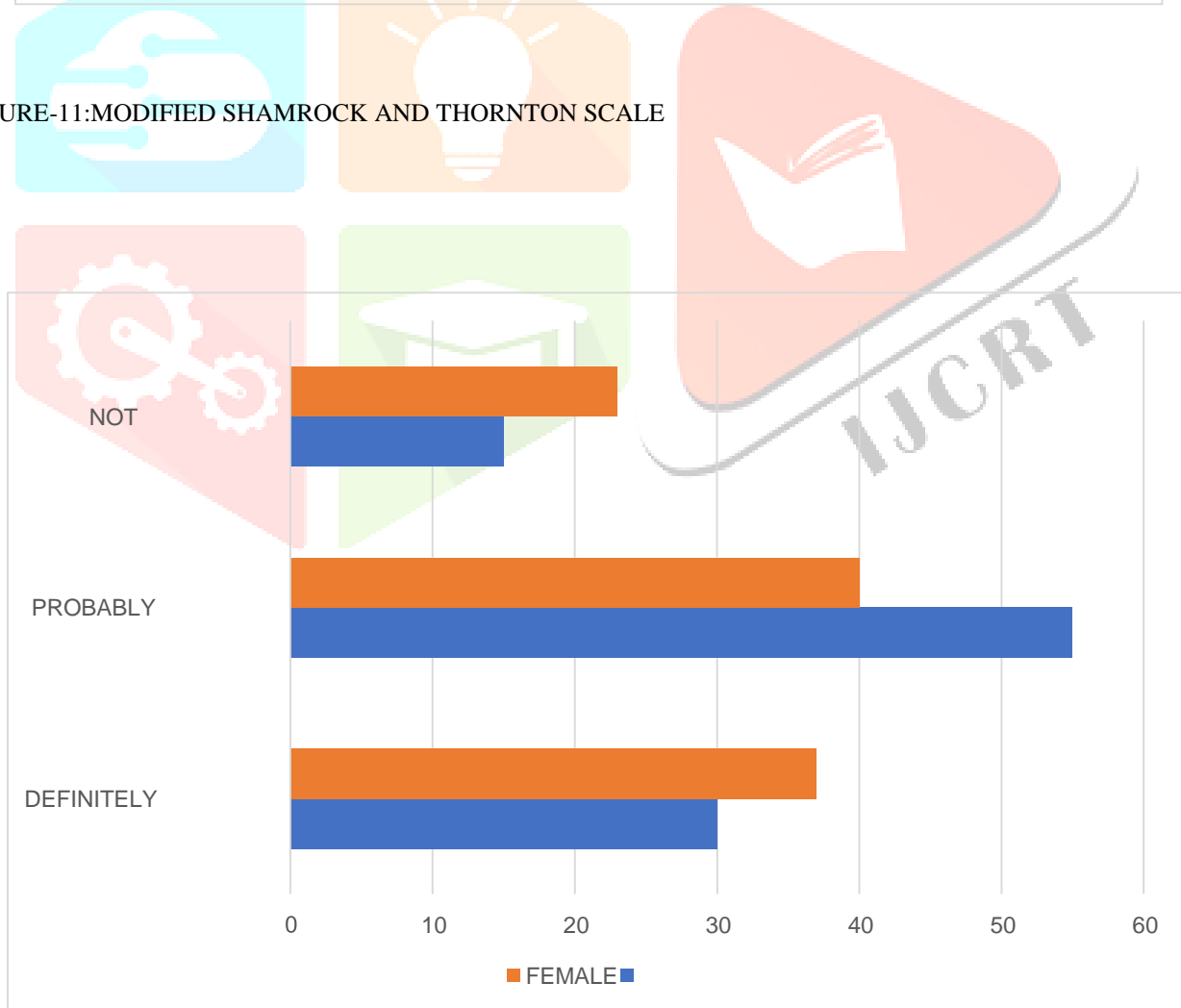




FIGURE-12: COMPARISON OF INCIDENCE BETWEEN HCP AND PSR

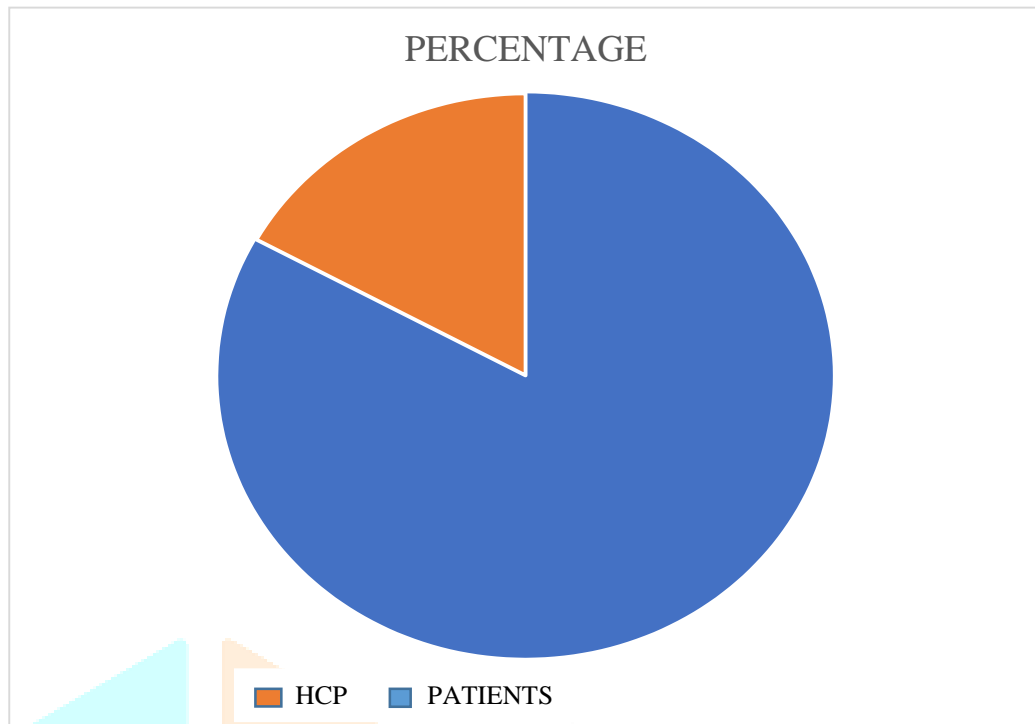
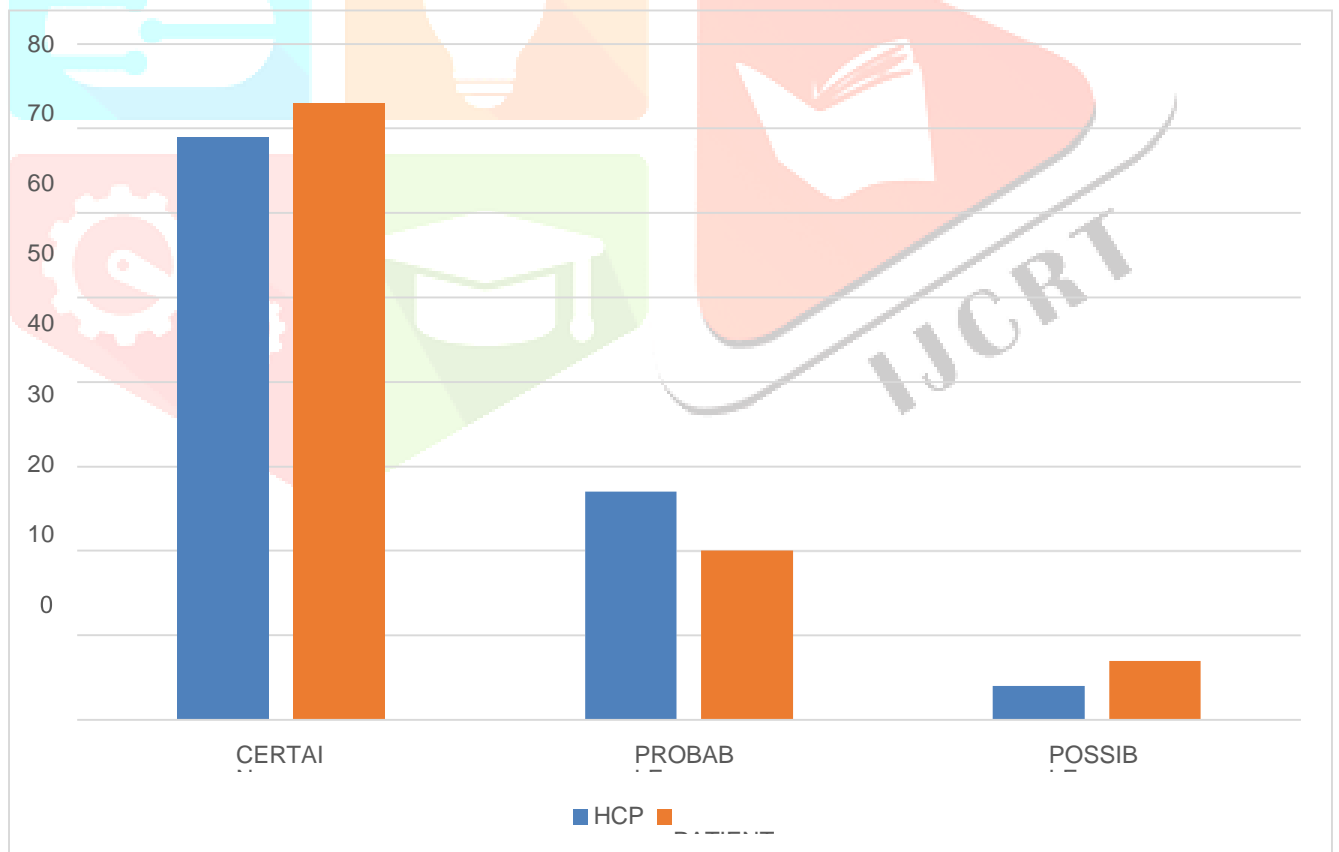


FIGURE-13: WHO SCALE CASUALTY ASSESSMENT



**DISCUSSION**

In the present study, the pattern of ADRs reported in medicine department, with assessment of its causality, severity and preventability and the ADR reporting between patient and HCP were compared in terms of response rate, pattern, causality, severity, preventability factors. One year study revealed that male patients 47 (52%) predominated over females 43 (48%) in ADR occurrence depicted in Fig.1. Fig. 2 shows the age wise distribution of the total population and revealed that the geriatric patients were more accounted 47 (52.5 %), followed by adults 41(45.5%), and children 2(2%). Fig.3 showed that maximum number of ADRs were reported from the Neurology 23(26%), General medicine 13(14%), Pulmonology 14(16%), Cardiology

13(14%), Nephrology 5(6%), Orthopaedics 13(14%), Gastroenterology 5(6%). Fig.4 results revealed that the skin 20 (22%) was the most affected organ system by ADRs followed by the GIT 13(14%), CNS 6(7%), Lab abnormalities 14(16%), CVS 7(8%) and Others 30( 37%). Fig.8 WHO causality assessment scale revealed that ADRs were certain 51(57%), possible 32(35%), probable 7(8%). Fig. 9 shows the causality assessment of reported ADRs as per the Naranjo scale and revealed that 64(71%) were definite, 23(26%) were probable, 3(3%) were possible, and 0% were unlikely. By using modified Hartwig severity assessment Fig-10, 46(51%) reactions accounted for severe followed by moderate 28(31%) and mild reactions 16(18%). Preventability of reported ADRs was assessed using the modified Shamrock and Thornton method. Using this scale, Fig-11, results revealed that 30(33%) of the ADRs were definitely preventable, while 43 (48%) were probably preventable and 17(19%) were not preventable .

### CONCLUSION

ADRs are potentially avoidable causes for seeking medical attention. Majority of Adverse drug reactions and adverse drug events are predictable and preventable. Hence continuous monitoring and reporting of ADRs can have a positive impact on the medication-use, improving the quality of patient care and in reducing the occurrence of devastating ADRs and Adverse events. The awareness about adverse drug reaction to improve the quality of patient care ensure safe use of drug and also help health-care professionals for improved reporting of ADRs. ADR monitoring should be designed to determine rate of reactions by carefully recording drug usage and adverse reactions. If such studies are to be expanded to include greater number, all health care personnel will have to assume a major role in data collection. A pharmacist based ADRs system could be adapted to a wide variety of hospitals and even to community surveillance of adverse drug reactions and this system will be very effective for patient care and also development of drug safety in the country.

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