

## Study of Adverse Drug Reactions in a Tertiary Care Hospital

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Conflict of interest: Nil

### Abstract

ADR is defined as “a response to a drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function. Adverse drug reaction(ADR) is the fourth leading cause of morbidity and mortality.

### Material & Method:

**Aim:** To study the ADRs reported in a tertiary care hospital.

### Analysis of ADRs:

1. Causality according to Naranjo’s ADR probability scale.
2. Preventability using the criteria described by Schumock & Thornton Scale.
3. Severity of ADR was analyzed according to criteria’s developed by Hartweig *et al.*

**Results:** A total of 133 ADRs forms with 145 reactions were collected from the indoor patients during the study duration. Most of ADR from Gastrointestinal system. Drug class implicated in Most of ADR was antineoplastic drugs.

**Conclusion:** This study strongly suggest that hospital based reporting ADR is very necessary Measures to improve detection & reporting ADR must done by all health care professionals. It will also improve patient’s safety.

**Keywords:** Adverse Drug Reactions, Antineoplastic Drugs.

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### Introduction

ADR is defined as “a response to a drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function” [1] Adverse drug effects are divided into: 1. Predictable (Type A or Augmented) reactions, 2. Unpredictable (Type B or Bizarre) reactions.[2]. Pharmacovigilance is defined by WHO as “the science and activities relating to the detection, understanding, and prevention of

adverse effects or any other drug related problems” [3]. Adverse drug reaction(ADR) is the fourth leading cause of morbidity and mortality [4]. Around 6% of Hospital admissions are estimated to be due to ADR’s and about 6-15% of hospitalized patients experience a serious ADR.[5]

### Material & Methods

**Aim:** To study the ADRs reported in a tertiary care hospital

CDSCO prescribed ADR forms were filled up and collected from various wards in Hospital

**Duration of study:**6 month

Only the ADRs documented by the Doctor – in – charge were taken for the purpose of study. Data was evaluated according to :

1. Patient demography
2. Nature of the reaction

3. Characteristics of drugs involved

**Analysis of ADRs**

1. Causality according to Naranjo’s ADR probability scale.
2. Preventability using the criteria described by Schumock & Thornton Scale.
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**Results**

A total of 133 ADRs forms with 145 reactions were collected from the indoor patients during the study duration.



Figure 1: Patient characteristics

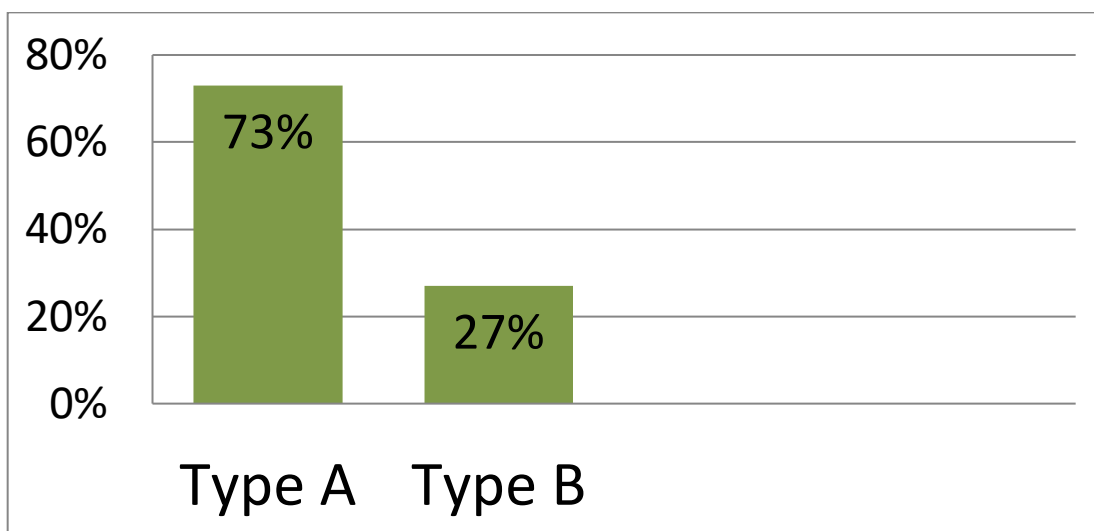


Figure 2: Type of the reported ADRs

**Table 1: Classification of ADRs**

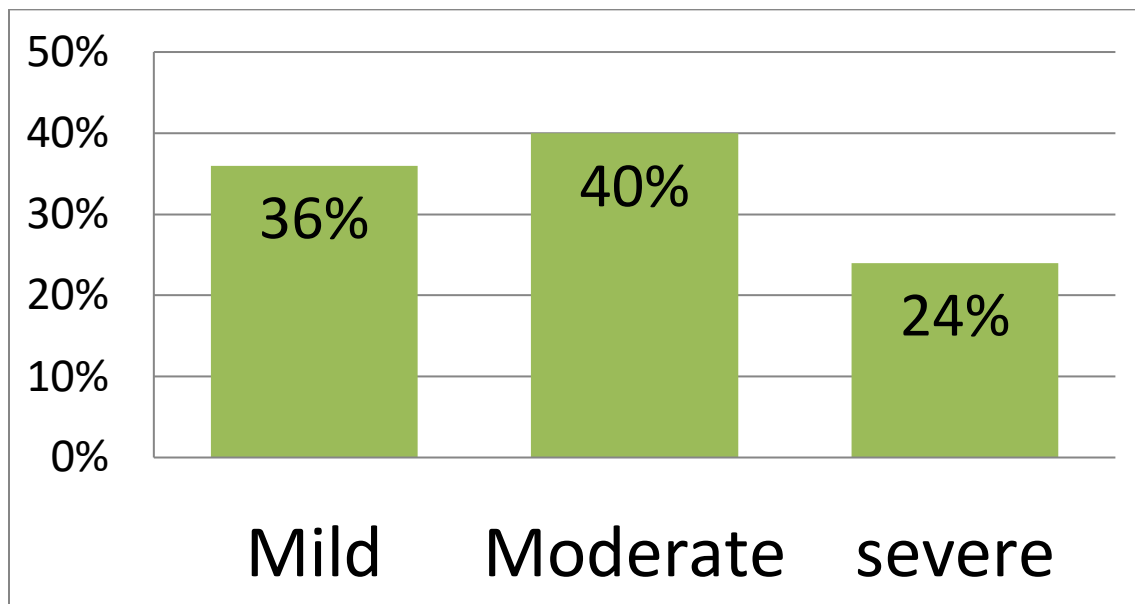
SOC	No. of ADR reports (%), n = 145	Preferred Term (PT)	Percentage (%)
Gastrointestinal disorders	56(42.1%)	Vomiting Diarrhea Nausea	23(17%) 8(6%) 6(4%)
Skin & Subcutaneous Disorders	45(33.8%)	Alopecia Rash Maculopapular Urticaria	14(10%) 9(6.7%) 6(4%)
Blood and Lymphatic System disorders	21(15.7%)	Bone marrow failure	19(14.2%)
Central Nervous System	17(12.7%)	Ataxia	4(3%)

**Table 2: Drug Class most commonly associated with ADRs**

Class of drug	Percentage
Antineoplastic	50
Antibiotics	21
Antimalarials	11.51
Antimycobacterials	4.70

**Table 3: Causality analysis of ADR**

Causality	Number of ADR(%)
Definite	18(13.5)
Probable	106(79.6)
Possible	9(6)

**Figure 4: Analysis of ADR for severity**

**Table 4: Analysis of ADRs for Preventability**

Preventability	No of ADR(%)
Preventable	7(5.2%)
Not Preventable	126(94.7%)

## Discussion

Incidence of ADR in 6 month interim analysis was 0.5% (Lazarou *et al*, in a metaanalysis have reported incidence of up to 15% in indoor patients) [6]. In our study Type A reaction was most common(73%). Most common drug class was Antineoplastic agents(50%) followed by antimicrobials(38%). Most common System Organ Class was gastro-intestinal system (42%). The scale of most of ADR was Probable[7] Most of the reactions were “MILD” and “MODERATE” on severity assessment scale.[8] Only 5.2% of the reported ADRs were preventable according to the scale used by us.[9]

## Conclusion

This study strongly suggest that hospital based reporting ADR is very necessary Measures to improve detection & reporting ADR must done by all health care professionals. It will also improve patient's safety.

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