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Case studies

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### Research on case studies of patients admitted in hospital: A basic necessity to overcome adverse drug events

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#### ABSTRACT

The study of ADRs is the concern of the field known as pharmacovigilance. An adverse drug event refers to any injury caused by the drug and any harm associated with the use of the drug (e.g. discontinuation of drug therapy). ADRs are a special type of adverse drug events Adverse drug events are defined as unwanted response to a therapeutic drug. This is a research study which infers the statistical collection of data from approximately 293 cases which are collected from private medical college hospital at mahabubnagar. Complications arising from drug treatment are the most common cause of adverse events in hospital inpatients.

**Keywords:** Adverse drug reaction, inappropriate administration, drug-drug interactions, dosage errors.

#### INTRODUCTION

Adverse drug reactions are those unintended reactions caused by drugs when used at normal doses. WHO defines an adverse drug reaction as “Any response to a drug which is noxious and unintended and which occurs at doses normally used in human being for prophylaxis, diagnosis, or for the modification of physiological function”.<sup>[1]</sup>

An adverse drug reaction describes harm associated with the use of given medications at a normal dosage during normal use. ADRs may occur following a single dose or prolonged administration of a drug. The meaning of this expression differs from the meaning of "side effect", as this last expression might also imply that the effects can be beneficial.<sup>[2]</sup>

#### OBJECTIVES

To collect and evaluate the statistical data of most prevailing diseases causing increased hospitalization and to increase the knowledge regarding the common avoidable adverse drug reactions.

To provides guideline updates for Pharma co-epidemiological studies and to support clinical pharmacy and Pharmacovigilance studies.

It is our effort through this research to decrease the prevalence of ADR's and improve therapeutic efficacy.

#### METHODOLOGY

A Retrospective study was performed for a period of 3 years and spontaneous data was recorded.

Epidemiological data like age, adverse drug reactions and disease conditions in hospitalised patients during these 3 years of duration was collected from various departments of hospital and made into tabular and graphical representation for easy evaluation.

Data on the reported ADRs was evaluated to understand the pattern of the ADRs with respect to patient demographic disease, Nature of the reactions, characteristics of the drugs involved, and outcome of the reactions.

ADR identified by physicians was considered and was included in the study.

ADR were categorised into definite,probable,possible and unlikely by using Naranjo`s causality assessment

scale.This data was useful to minimise the ADR occurrence further.

**Inclusion criteria**

- Patient’s name, age, gender.
- Drugs prescribed.
- Dosage of drugs prescribed & dosage form manufacturer.
- Route of Administration.

**Exclusion criteria**

- Incomplete information regarding patient.

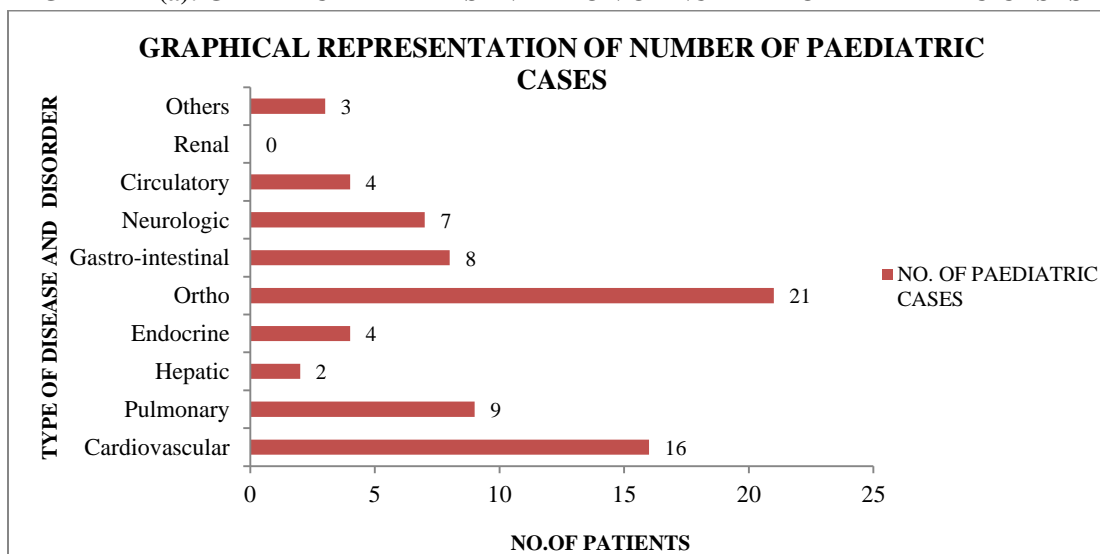
**RESULTS**

**Table 1: Age-Wise Distribution Of Number Of Cases**

S. No	Diseases and Disorders	No. of paediatric cases(a)	No. of adult cases(b)	No. of geriatric cases(c)
1	Cardiovascular	16	18	18
2	Pulmonary	9	6	10
3	Hepatic	2	7	3
4	Endocrine	4	20	13
5	Ortho	21	16	9
6	Gastro-intestinal	8	22	10
7	Neurologic	7	10	19
8	Circulatory	4	5	2
9	Renal	0	5	3
10	Others	3	11	12

The above table shows cases enrolled based on age.

**GRAPH-1(a): GRAPHICAL REPRESENTATION OF NUMBER OF PEDIATRIC CASES**



**Figure: 1(a) GRAPH-1(b): GRAPHICAL REPRESENTATION OF NUMBER OF ADULT CASES**

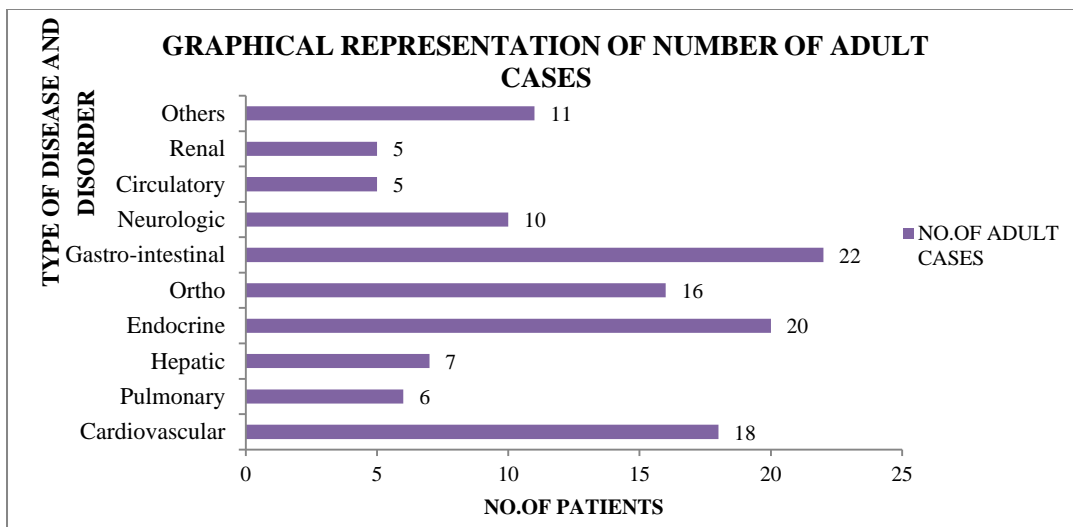


Figure: 1(b) GRAPH -1(c): GRAPHICAL REPRESENTATION OF NUMBER OF GERIATRIC CASES

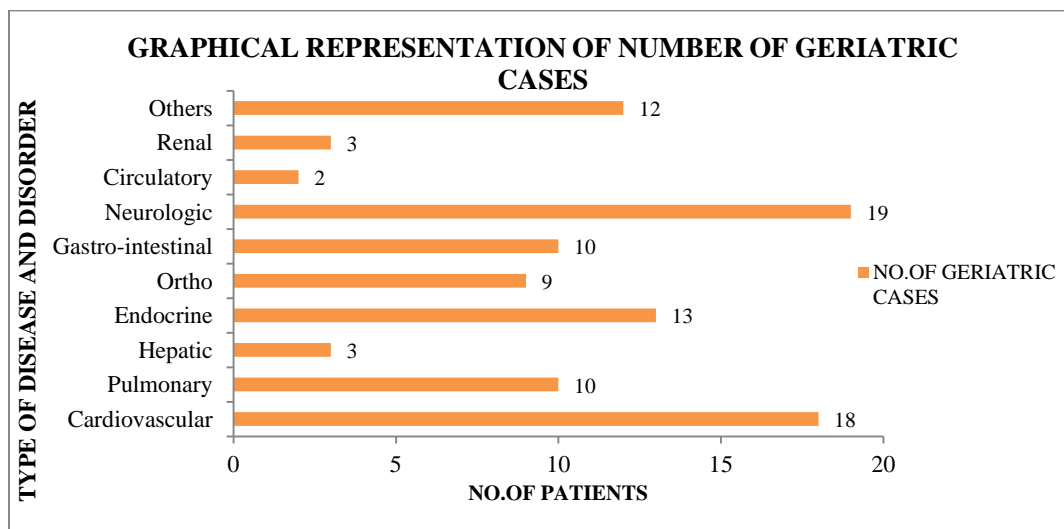


Figure: 1(c) Based upon age total number of cases in each department are found to be cardio-vascular(52), pulmonary(25) hepatic(12), endocrine(37), orthopedic(46), gastro-intestinal tract(40), neurological(36), circulatory(11), renal(8) and others(26).

Table 2: Representation Of Percentage Of Type Of Observed Adr`S

S.NO	TYPES OF ADR OBSERVED	PERCENTAGE OF ADR`s
1.	Cardiovascular	10.56%
2.	Dermatological	6.56%
3.	Gastrointestinal	5.32%
4.	Pulmonary	1.29%
5.	Others	0.3%

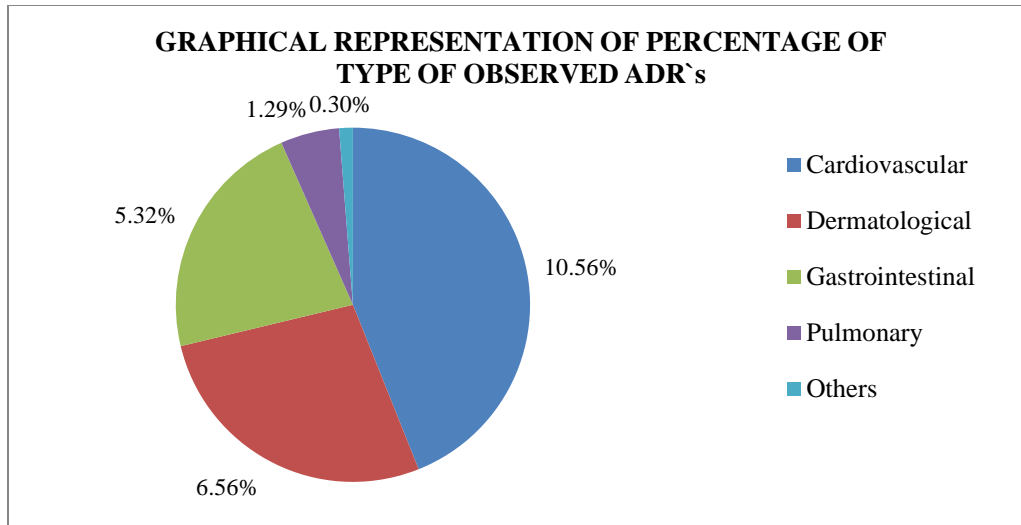


Figure: 2

Table-3: Representation Of Percentage Of Probability Of ADR(%) Based On Naranjo`S Causality Assessment Scale

S.no	Causality assessment scale	Percentage of adr(%)
1.	Probable	49.32%
2.	Possible	42.81%
3.	Unlikely	6.31%
4.	Definite	1.56%

The above table shows percentage of adverse drug reactions assessed according to the Naranjo`s causality assessment scale.

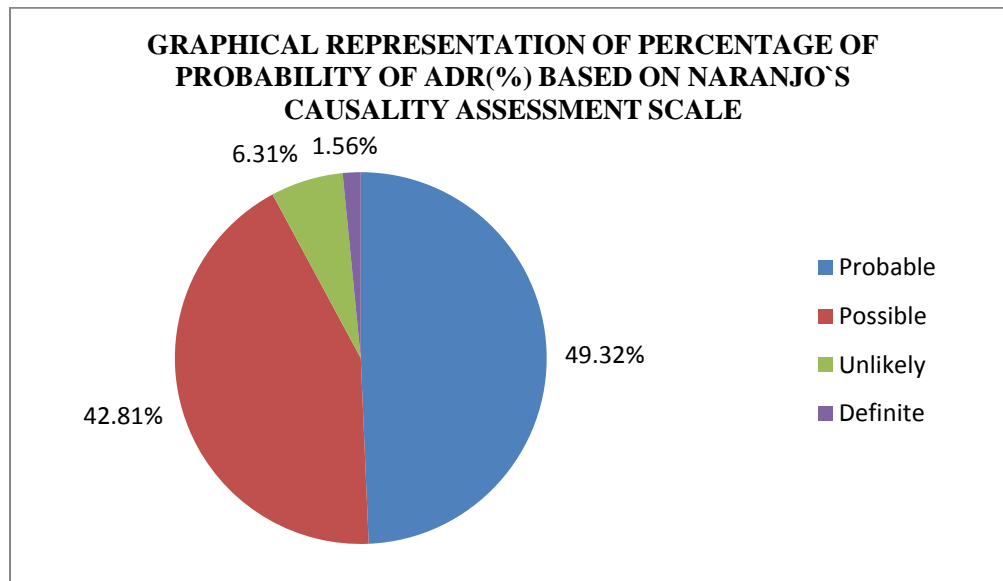


Figure: 3

## DISCUSSIONS

The database collection of 293 cases were reported in which males (53.92%) were found to exceed females

(46.07%) with higher percentage of cardiovascular cases (17.74%) which mainly constitutes of coronary artery disease, myocardial infarction and arrhythmias

which is then followed by ortho cases which constitute 15.69%. In both of them males outnumbered the females. The next disease and disorder is seen in females which occupies 9.5% in which uterine prolapse, polycystic ovarian syndrome, cervicitis, urinary tract infection range from 23.7%, 38.3%, 24.2%, and 13.8% respectively. In paediatric population seizures, pneumonia, gastritis are seen more constituting about 7.5% in 293 cases. The next high reported cases are of diabetes mellitus (7%) and alcoholic liver disease (6%) with high percentage in males than in females. The remaining other cases relate to hypertension (3.6%), hernia (2.8%), appendicitis (2.7%), intestinal obstruction (2.0%), cellulitis(1.9%), meningitis(1.7%) and nephrotic syndrome (1.4%) show high prevalence in males than in females except in anemia in which females outnumber males population.

Of all the enrolled cases 24.03% of patients were reported with ADR's, out of which highest number of ADR's were related to cardiovascular diseases (10.56%) followed by dermatological ADR's (6.56%), Gastrointestinal ADR's(5.32%) pulmonary ADR's (1.29%) and (0.3%) of ADR's were others. The ADR's related to cardiovascular departments were mostly hypersensitivity skin reaction, bradycardia, headache. The adverse drug reactions which were most commonly reported from the dermatology department were rashes, dermatitis, urticaria, Steven Johnson syndrome, oral candidiasis etc with a percentage of incidence of (6.56%) of all the enrolled cases. The gastrointestinal ADR included gastric erosions, dyspepsia, pancreatitis etc. 41.9% of the total ADRs were associated with polypharmacy wherein 3 or more drugs were prescribed.

Among all cases the common avoidable ADR's are seen in pulmonary, Gastrointestinal, anaphylaxis, hepatic and others (Hypertension, skin rashes, urticaria).

## REFERENCES

- [1] Brennan TA, Leape LL, Laird NM .et al. Incidence of adverse drug events and negligence in hospitalised patients, *N Engl J Med.*1991; 324; 370-376.
- [2] Leap LL, Bates DW, Cullen DJ. et al. Systems analysis of adverse drug events *JAMA.*1995; 274: 35-43.
- [3] Kohn LT, Corrigan GM, Donaldson MS, To err is human ; building a safer health system. Institute of medicines, Washington DC: National Academy Press; 1991.

Causality assessment was undertaken based on Naranjo's criteria in our study. It was seen that out of the total 24.03% ADRs reported, 49.32% were found to be Probable, 42.81% were considered as Possible, 6.31% were unlikely and 1.56% were classified as definite. Similar results were observed in the study conducted by Sharminder Kaur, Vinod Kapoor,<sup>1</sup> Rajiv Mahajan,<sup>1</sup> Mohan Lal,<sup>2</sup> and Seema Gupta on Monitoring of incidence, severity, and causality of adverse drug reactions in hospitalized patients with cardiovascular disease majority of ADRs (118 of 208, 56.7%) were rated as probable followed by possible (90 of 208, 43.3%) when analyzed on Naranjo ADR probability scale. In the study conducted by Shalini Chawla, Bhupinder Singh Kalra, Pinky Dharmshaktu, and Pooja Sahni on the topic Adverse drug reaction monitoring in a tertiary care teaching hospital the results showed that of all the ADR's reported maximum were possible(47.8%) followed by probable (47.3%) but they used WHO causality assessment scales.

## CONCLUSION

The therapeutic errors have been noted due to inappropriate administration, drug-drug interactions, dosage errors, drugs not stopped despite of onset of adverse reactions etc.

Our collected data show that the profile and seriousness of ADR vary according to the user's intake of medication.

This collected data is used for the improvement of reporting of serious or unrecognized ADR which increase our knowledge on risk/benefit ratio and optimize their occurrence.

This retrospective study is helpful in gaining better knowledge on patient medical history of ADR's, thus it is easy to decrease the risk of ADR to minimum extent which helps in improving the quality of life and in promotion of effective and safe drug therapy.