

A Profile of Adverse Drug Reactions in a Tertiary Care Teaching Hospital and Associated Factors

TY Sree Sudha^{1*}, Yakaiah Vangoori² and Anjaly Mary Varghese²

¹Department of Pharmacology, AIIMS-Raipur, Chhattisgarh - 492099, India.

²Department of Pharmacology, Santhiram Medical College & General Hospital, Nandyal, A.P, India,

*Corresponding Author E-mail: yakaiahpharma143@gmail.com

<https://dx.doi.org/10.13005/bpj/2135>

(Received: 03 October 2020; accepted: 24 February 2021)

The present study was conducted to identify, analyze the causality, and severity of adverse drug reactions and to find out the factors associated with ADR related factors. Adverse effects of drugs are identified as one of the main reason for increasing in-patient number in the hospital. This has become financial burden and also rise in mortality rate in society. The main purpose of the pharmacovigilance program is to identify the risks linked with the use of drugs. This study may be useful to identify and prevent adverse effects caused by drugs to increase the quality of life and ability of doctors to treat consequences of ADRs more effectively. The main aim of the present study was to explore and identify adverse effects caused by drugs and to improve patient safety with pharmacovigilance activities. An observational study was conducted as part of Pharmacovigilance program for 14 months (January 2018 - Feb 2019). ADRs reported from hospital were filled into Suspected ADR forms - CDSCO forms. Causality assessment was done based on WHO- UMC causality scale and severity was assessed using Hartwig-Siegel scale. By taking history of the patient, and by regular monitoring of the inpatients, the causative factors for ADR related hospital admissions were evaluated. Total 145 ADR reports were analyzed. Most of the ADRs were observed in females (60%). Majority of ADRs were caused by NSAIDs (32.4%), followed by antimicrobials (20%). Most common organ systems involved was skin (38%). Causality assessment showed 85.5% ADRs as probable. 18.6% of ADRs were of severe type and 51% moderate. ADR related hospital admissions were found in 53 cases (36.5%) and 92 cases of ADRs occurred during hospitalization (63.4%). The study generated a data of ADRs that is useful to the clinicians for optimum and safe use of drugs in day to day practice and help in creating 'P' drug list. The major reasons for ADR related hospital admissions are OTC and non-compliance. Hence a constructive Pharmacovigilance to minimize ADR related hospitalization, treatment cost, morbidity and mortalities are the need of the hour.

Keywords: Pharmacovigilance, NSAIDs, OTC, Adverse Effects.

According to world health organization (WHO), the definition of adverse drug reaction is "any noxious, unintended, or undesired effect of a drug that occurs at doses used in human for prophylaxis, diagnosis, or therapy¹. An adverse effects of drugs are main causes for patient illness and has increased health care costs². Adverse

effects related death rate is in between fourth and sixth leading causes of death in the USA³. In India also, many scientific studies have revealed that adverse effects of drugs leads to 1.8% of death rate out of 0.7% of total admissions⁴. According to WHO, Pharmacovigilance program was defines as "the science and activities relating to the detection,

assessment, understanding, and prevention of adverse drug reactions or any other drug-related problems²⁵. Many research studies were proved that patients admitted with adverse effects of drugs ranges from 2.0 to 21.4% and 1.7 and 25.1% of inpatients were reported ADR during their stay in hospital⁶⁻⁹. Various factors can influence the susceptibility of adverse effects of drugs are multiple drug therapy, disease severity, age, and the type and number of drugs prescribed¹⁰⁻¹⁵. In developing and developed nations, the frequency and type of adverse drug reactions are due to disease prevalence, access to medicines, drug use patterns, and drug management systems¹⁶. Reporting of adverse reactions of drugs have become mandatory in hospitals to evaluate causes for adverse effects¹⁷. This may be useful to detect reasons and to set preventable measures for better patient safety and it gives more knowledge to doctors to minimize the problems^{18, 19}.

The present study was undertaken to

- Identify, analyze the causality, and severity pattern of ADRs reported from various departments.
- Identify the factors/reasons associated with ADR related hospital admissions
- Evaluate ADRs that occurred during inpatient stay at the Hospital
- Facilitate the development of a pharmacovigilance service in a tertiary care hospital.

MATERIAL AND METHODS

- This was a prospective observational study conducted at ADR monitoring center of Santhiram Medical College & Hospital, Nandyal.
- The study was conducted as part of pharmacovigilance program over 14 months (Jan 2018 - Feb 2019).
- A total of 145 cases reported over a period of 14 months were included in the study.
- The suspected adverse drug reactions reported to the pharmacovigilance center were filled into CDSCO reporting forms.
- Temporal relationship between drug and event was assessed using WHO - UMC causality assessment scale.
- The Severity of reactions was assessed using Hartwig and Siegel scale.
- By taking thorough history of the patient, identified the **causative factors** for ADR related

hospital admissions.

- By regular monitoring of the inpatient and by using several parameters like data evaluation, drug and reaction characteristics, and treatment of reaction and its outcomes, evaluated **ADRs that occur in hospitalized patients**.

- The data were analyzed and shown as number of cases and percentages in each table.

RESULTS

A total of 145 ADRs were reported over 14 months. Of these, 40% were in males and 60% were in females (Figure: 1).

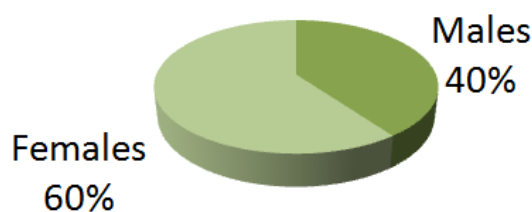


Fig. 1.

- Gender – Wise distribution of ADRs
- AGE wise Distribution of ADRs

Highest number of ADRs reported in the age group of 21- 40 years of age followed by >60 years of age group (Figure: 2).

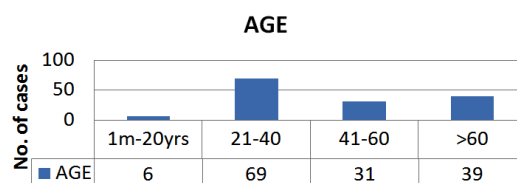


Fig. 2.

Department wise distribution of ADRs

Maximum number of cases were reported from the department of medicine (41.8%) followed by Dermatology (22%) and department of surgery (12.4%). (Figure: 3).

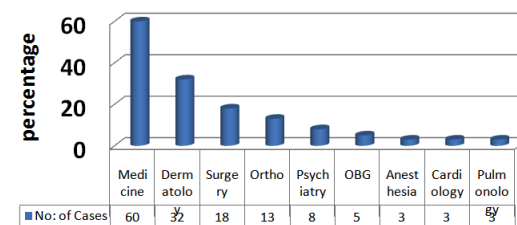


Fig. 3.

ADRs in various drug classes

Among the suspected drugs causing ADRs, highest percentage 32.4% accounted for NSAIDs, antimicrobial agents (AMAs) accounted for 20% of the total cases followed by other drugs accounted for 30.3% (Figure 4).

- NSAIDs
- Antimicrobials
- Antipsychotics
- Antiepileptics
- Antiseptics
- Skel musc relaxants
- Corticosteroids
- Nutrition supplements
- Others

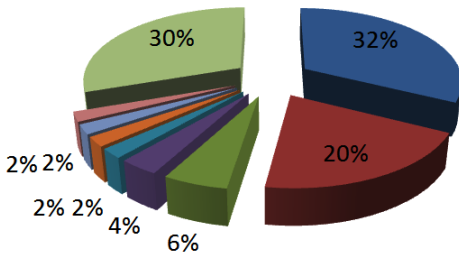


Fig. 4.

Organ systems involved in ADRs

The most common adverse drug reactions involved skin and appendages (37.9%) and CNS (23.5%) (Figure 5).

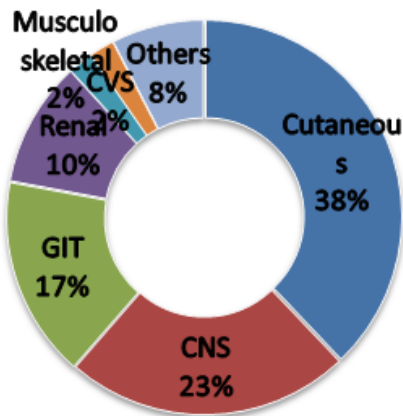
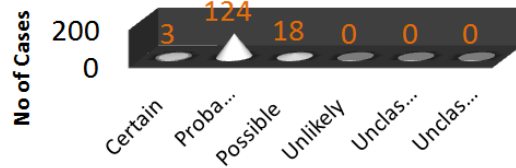


Fig. 5.

Causality assessment

Assessment of ADRs using WHO-UMC causality assessment scale showed that 85.5% of ADRs were probable, 12.4% were classified as possible and 2.1% were certain to have occurred due to drug administration (Figure 6).



□ WHO UMC Scale

Fig. 6.

Severity assessment- Hartwig-siegel Scale

Reported ADRs were mainly mild to moderate in severity (Figure: 7).

SEVERITY ASSESSMENT- Hartwig-siegel Scale

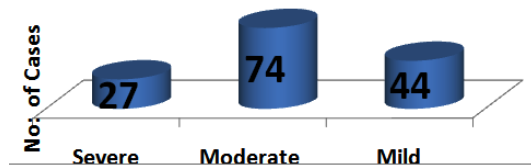


Fig. 7.

Frequency distribution of Hospital Admission due to ADR (Table : 1)

The patients got admitted due to adverse drug reactions is 53 out of 145 patients and high percentage was noted under severity i.e; 45.2%. All these 53 cases got admitted due to factors like self medication , over the counter use of drugs (OTC), non-compliance.

ADRs occurred in Hospitalized Patients (Table :2)

The adverse drug reactions occurred in Hospitalized Patients is 92 out of 145 and higher percentage seen in females . 59.7% were moderate reactions and all cases were recovered.

DISCUSSION

The fundamental role of Pharmacovigilance centers is to collect and process data regarding ADRs and to support hospitals in the identification of these reactions²⁰. The centers' actions serve to reduce risks related to medication usage, improve patients' quality of life, prevent iatrogenic diseases, and minimize health expenses. Pharmacovigilance

Table 1.

Age	No : of Cases	Gender		Mild	Severity		Outcome
		Male	Female		Moderate	Severe	
1 m-20 yrs	3	24 (45.2%)	29(54.7%)	11(20.7%)	18(33.9%)	24(45.2%)	Recovered-53(100%)
21-40	20						
41-60	10						
>60	20						
	Total:53 (36.5%)						

Table 2.

Age	No : of Cases	Gender		Mild	Severity		Outcome
		Male	Female		Moderate	Severe	
1m-20 yrs	3	37 (40.2%)	55(59.8%)	34(37%)	55(59.7%)	3 (3.2%)	Recovered 92(100%)
21-40	53						
41-60	18						
>60	18						
	Total – 92 (63.5%)						

program of India (PVPI) is monitoring peripheral ADR reporting centers to decrease drug induced complications, better patient compliance, quality of life and to reduce cost of health care. It was reported that many physiological systems were affected by drugs but highest affected system is skin that is about 38%. Its clinical symptoms appeared as multiple fluid filled lesions, skin rashes, flushing, and dried skin. In the present study, NSAIDs have shown highest prevalence of adverse effects among many drugs used in various conditions. Rechallenge was not done for ADRs because of ethical reasons which may affect the causality assessment. The treatment expenditure of ADRs was not assessed.

CONCLUSION

Study generated a data of ADRs, which will give information to the clinicians for optimum and safe use of drugs in day to day practices and helps in creating their own 'P' drug list. The major reasons for frequency distribution of HOSPITAL ADMISSIONS due to ADR are OTC and non-compliance. In our study out of 145 cases, 53 cases were accounted for hospital admissions

due to ADRs. out of 53 cases , 24 (45.2%) cases were severe .To reduce prolong hospitalization , treatment cost, morbidity and mortalities must need a constructive pharmacovigilance like Awareness and sensitization programmes among medical and non-health professionals and also must for people who are illiterate and no medical knowledge, whom using drugs over many years without knowing of their noxious effects. Pharmacovigilance is a continuous ongoing process which ensures the safety of the patients.

On the basis of our results we feel that NSAID use could be moderated by increased knowledge of their noxious effects on continuous use over many years because NSAIDs are available over the counter.

Funding

No funding sources

Conflict of interest

None declared.

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