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Enhancing Patient Safety: A Study on Adr Monitoring in Tertiary Care Hospitals

Jeril[1], Dipanwita Kamila[1], Bhargavi S.[1], Ruhana[2,*]

Abstract

Background: *Adverse drug reactions (ADRs) are a major concern in healthcare, causing patient morbidity and mortality. The objective of this study was to investigate the adverse drug reactions in a tertiary care hospital.* ***Methods:*** *From January to July 2024, an observational study was carried out at Bangalore's Akash Super Specialty Hospital. 51 individuals had their demographics, medications, and suspected adverse drug reactions (ADRs) gathered. The Naranjo scale was used to classify ADRs by drug class, organ system impact, and cause.* ***Result:*** *Results: A total of 51 ADRs were identified. Skin reactions (25.4%) were the most frequent, followed by central nervous system (CNS) effects (13.7%) and gastrointestinal (GI) disturbances (17.6%). Antibiotics (23.5%) and anticancer drugs (13.7%) were the most associated drug classes. Causality assessment revealed 17 (33%) definite ADRs, 25 (49%) probable ADRs, and 9 (18%) possible ADRs.* ***Conclusion:*** *This study highlights the prevalence of ADRs in a tertiary care setting. Vigilant monitoring and reporting of ADRs are crucial for patient safety and medication optimization. Additional research is needed to explore the mechanisms of ADRs and to implement strategies to prevent them.*

Keywords: Adverse drug reactions, drug safety, pharmacovigilance, patient safety, drug-induced issues

INTRODUCTION

The World Health Organization defines an adverse drug reaction as an unpleasant and unanticipated response to a drug that occurs at dosages typically used for disease prevention, diagnosis, or therapy, or to modify physiological function [1]. It is widely accepted that "No drug is absolutely free from side effects". It has been reported that approximately 5% of hospital admissions are attributed to drug-induced issues, while 10–20% of inpatients experience adverse drug reactions (ADRs). These reactions are estimated to rank between the fourth and sixth leading causes of mortality [2].

The classification of adverse drug reactions (ADRs) can be intricate, but the categorization into type A and type B reactions has been commonly employed for many years. Type A reactions are characterized by an amplified (augmented) pharmacological effect of the drug when administered within the recommended therapeutic dose. On the other hand, type B reactions are unpredictable, idiosyncratic, or unusual responses that cannot be anticipated based on the drug's known pharmacological profile [3].

Adverse drug reaction (ADR) reporting has historically served as an early warning system, significantly enhancing patient safety. The practice of pharmacovigilance and systematic ADR reporting was initiated following the thalidomide disaster in the mid-20th century. Thalidomide, a drug prescribed in several countries to manage morning sickness in pregnant women, was later found to be a teratogen, leading to congenital

***Author for Correspondence**
Ruhana
E-mail: ruhana@adityapharmacy.in

[1]PharmD Intern, Department of Pharmacy Practice, Aditya Bangalore Institute of Pharmacy Education and Research, Yelahanka, Bangalore, Karnataka, India
[2]Assistant Professor, Department of Pharmacy Practice, Aditya Bangalore Institute of Pharmacy Education and Research, Yelahanka, Bangalore, Karnataka, India

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disorders in newborns. In response to this tragedy, numerous countries established National Pharmacovigilance Centers to monitor and address medication safety more effectively [4].

REPORTING OF ADR

Over the previous half-century, spontaneous reporting systems, such as the yellow card scheme in the United Kingdom, managed by the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Commission on Human Medicines, have been the primary means of detecting potential adverse drug reactions.

In India, a reporter can send a completed ADR reporting form straight to the National Coordinating Center for Adverse Drug Reactions (NCC) or their nearest Adverse Drug Reaction Monitoring Center (AMC). These reports are confirmed by healthcare professionals, placed into big flow, and transmitted to NCC for further review. The reports are ultimately analyzed at the National Coordination Centre (NCC) and forwarded to the WHO Uppsala Monitoring Centre. The gathered data is entered into a drug safety database, where it is reviewed and assessed by experts to identify new safety signals [5].

CAUSALITY ASSESSMENT

Causality assessment is essential for determining or evaluating the relationship between adverse drug reactions (ADRs) or adverse events (AEs) and medications. This process plays a vital role in reducing the occurrence of such events and limiting patients' exposure to potential medication-related risks. By analyzing and interpreting case reports, causality assessment provides a systematic approach that depends on a thorough evaluation of the clinical-pharmacological details of the patient's history and the quality of observational data. Its objectives are achieved using four key criteria: temporal eligibility, de-challenge and its outcome, re-challenge, and its outcome, and the identification of confounding factors. Table 1 lists some tools or scales that are used for causality assessment [6].

Table 1. Example of some of the different tools/scales used for causality assessment.

Expert Judgment or Global Introspection Tools	Algorithmic Tools	Probabilistic Tools
WHO-UMC Causality Assessment Criteria	Naranjo Scale.	Bayesian adverse reaction diagnostic instrument (BARDI).
Swedish method by Wilholm et al.	Roussel Uclaf causality assessment method (RUCAM).	Australian method.
	Dangaumou's French method.	

This study plays a vital role in enhancing patient safety through the systematic evaluation of adverse drug reactions (ADRs). Currently, understanding the link between specific medications and negative side effects may be limited. This study aims to bridge that gap by using the Naranjo scale to determine the likelihood of a drug causing an ADR. Additionally, the study will document the affected organ system and categorize the drug class involved. By creating a clearer picture of ADRs, this study can inform better medication choices and ultimately reduce the risk of harm to patients.

MATERIALS AND METHODS

This observational study was conducted at the inpatient ward of Akash Super Specialty Hospital, Bangalore, from January to July 2024. The study included a total of 51 patients, both male and female, aged 18 years and above.

Data was collected from patient case sheets, including demographics (age, sex, weight), medical history, co-morbidities, past and current medications, recently diagnosed diseases, drug treatment plans, and laboratory results. ADRs were classified into three categories: definitely preventable, probably preventable, and not preventable.

Follow-up was conducted until discharge. Discovered ADRs were reported to the nearest Pharmacovigilance center using the Indian Pharmacopoeia Commission (IPC version 1.2)

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documentation form. Data was entered into Microsoft Excel and analyzed descriptively, with results presented as percentages and frequencies.

RESULTS

A total of 51 adverse drug reactions (ADRs) were collected in this observational study. The gender distribution of the patients was as follows: 32 (62.74%) were male and 19 (37.25%) were female (Table 2).

Table 2. Distribution of patients according to gender.

S.N.	Gender	No. of Patients	Percentage %
1.	Male	32	62.74%
2.	Female	19	37.25%
	Total	51	100%

The age distribution of the patients showed that 1 (1.9%) were in the 0–20 years age group, 17 (33.3%) were in the 20-40 years age group, 17 (33.3%) were in the 40–60 years age group, and 16 (31.3%) were 60 years and older (Table 3) (Figure 1).

Table 3. Distribution of patients based on age.

S.N.	Age	No. of Patients	Percentage
1.	0–20	1	1.9%
2.	20–40	17	33.3%
3.	40–60	17	33.3%
4.	Above 60	16	31.3%
	Total	51	100%

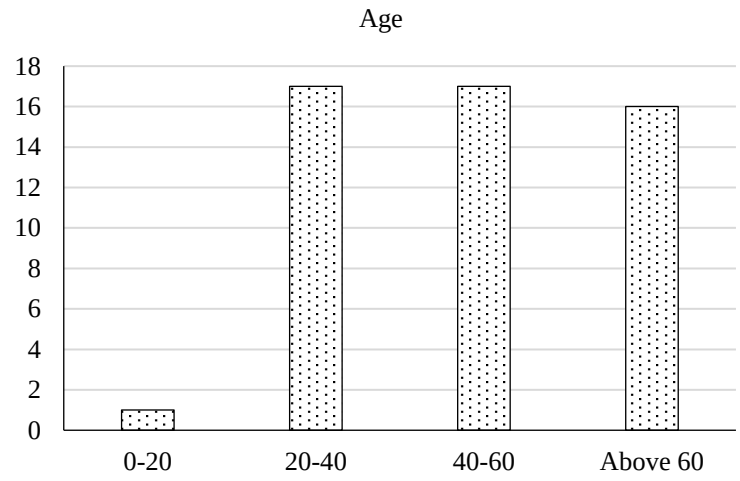

Figure 1. Distribution of patients based on age.

The organs or organ systems affected by ADRs were as follows: skin (13, 25.4%), central nervous system (CNS, 7, 13.7%), liver (2, 3.9%), gastrointestinal (GI, 9, 17.6%), cardiovascular (CVS, 10, 19.6%), eye (1, 1.9%), respiratory (6, 11.7%), and excretory (3, 5.8%), as shown in Table 4 (Figure 2).

Table 5 shows the classes of drugs involved in ADRs, including antibiotics (12, 23.5%), anticancer (7, 13.7%), analgesics (6, 11.7%), antihypertensives (3, 5.8%), antidiabetics (3, 5.8%), antipsychotics (3, 5.8%), anti-tuberculosis (ATT, 2, 3.9%), antihistamines (1, 1.9%), antithyroid (1, 1.9%), antifungals (1, 1.9%), steroids (1, 1.9%), antiepileptics (1, 1.9%), anticoagulants (1, 1.9%), and others (9, 17.6%).

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Table 4. Distribution of organ/system affected by ADR.

S.N.	Organ System	No. of Patients	Percentage
1.	Skin	13	25.4%
2.	CNS	7	13.7%
3.	Liver	2	3.9%
4.	GI	9	17.6%
5.	CVS	10	19.6%
6.	Eye	1	1.9%
7.	Respiratory	6	11.7%
8.	Excretory	3	5.8%
	Total	51	100%

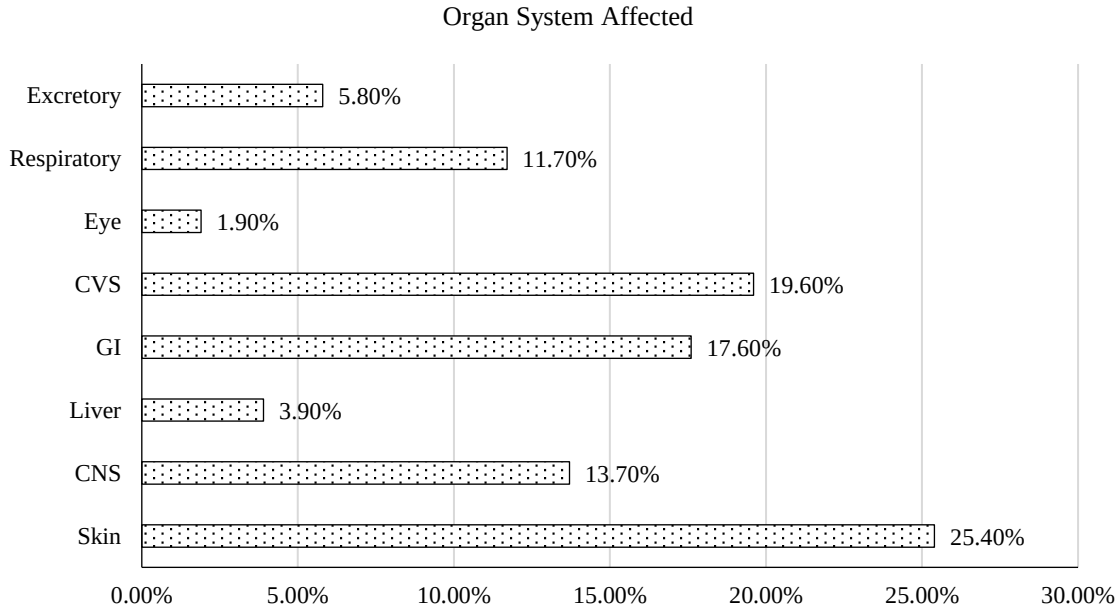

Figure 2. Distribution of organ /system affected by ADR.

Table 5. Classes of drugs involved in ADR.

S.N.	Class of Drug	No. of Patients	Percentage
1.	Antibiotics	12	23.5%
2.	Anticancer	7	13.7%
3.	Analgesics	6	11.7%
4.	Antihypertensive	3	5.8%
5.	Antidiabetics	3	5.8%
6.	Antipsychotic	3	5.8%
7.	ATT	2	3.9%
8.	Antihistamine	1	1.9%
9.	Antithyroid	1	1.9%
10.	Antifungal	1	1, 9%
11.	Steroids	1	1.9%
12.	Antiepileptics	1	1.9%
13.	Anticoagulants	1	1.9%
14	Others	9	17.6%
	Total	51	100%

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Table 6 shows the classification based on causality assessment of ADRs: definite ADRs (17, 33%), probable ADRs (25, 49%), and possible ADRs (9, 18%). The ADRs were assessed by using WHO probability scale (Figure 3).

Table 6. Causality assessment based on the Naranjo scale.

S.N.	Causality Assessment	No. of Patients	Percentage
1.	Definite ADR >9	17	33%
2.	Probable 5–8	25	49%
3.	Possible 1–4	9	18%
	Total	51	100%

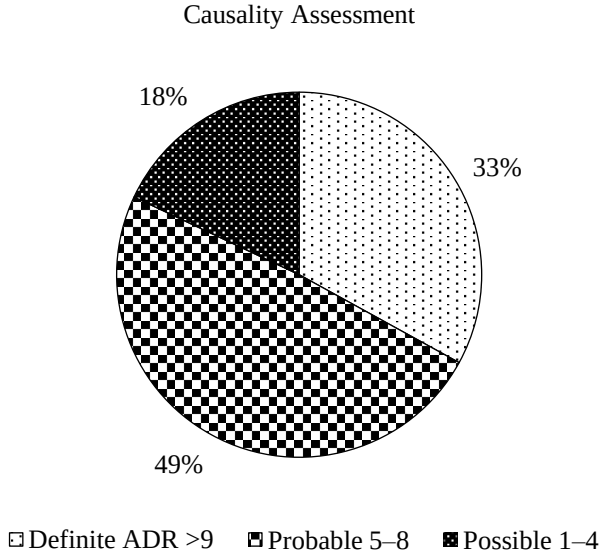

Figure 3. Causality assessment based on the Naranjo scale.

Table 7 shows the classification of the types of reactions observed from reported ADRs, including diarrhea, itching, allergic symptoms (sneezing, running nose, etc.), generalized weakness, facial puffiness, hypoglycemia, headache, nausea and vomiting, anemia, thrombocytopenia, increased liver enzymes, cough, insomnia, tardive syndrome, hyperpigmented plaques, constipation, delirium, hyperkalemia and hyponatremia, and hypertension.

DISCUSSION

The gender distribution of the patients showed that there were 32 males (62.74%) and 19 females (37.25%), indicating a higher incidence of suspected ADRs in males. This finding is like a study conducted by Daulat MP. et al., which showed that there were 72 (55.38%) male and 58 (44.62%) female patients, indicating a male preponderance [7].

In our present study, the age distribution of the patients showed that 1 (1.9%) were in the 0-20 years age group, 17 (33.3%) were in the 20–40 years age group, 17 (33.3%) were in the 40–60 years age group, and 16 (31.3%) were 60 years and older. Most patients (33.33%) were in the 20–60 years age group, which is similar to the study conducted by Rajan A. et al., which showed that the majority (62.2%) belonged to the 18–60 years age group [8].

The organs or organ systems affected by ADRs were as follows: skin (13, 25.4%), central nervous system (CNS, 7, 13.7%), liver (2, 3.9%), gastrointestinal (GI, 9, 17.6%), cardiovascular (CVS, 10, 19.6%), eye (1, 1.9%), respiratory (6, 11.7%), and excretory (3, 5.8%). In our study, most patients experienced skin reactions, consistent with the findings of Lithite RJ. et al. [9].

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Table 7. Classification of type of reaction observed from reported ADR.

S.N.	Type of Reaction	No. of ADRs (%)
1.	Diarrhea	6 (11.5%)
2.	Itching	5 (9.61%)
3.	Allergic symptoms (sneezing, running nose, etc.)	5 (9.61%)
4.	Generalized weakness	4 (7.69%)
5.	Facial puffiness	4 (7.69%)
6.	Hypoglycemia	3 (5.76%)
7.	Headache	3 (5.76%)
8.	Nausea and vomiting	3 (5.76%)
9.	Anemia	3 (5.76%)
10.	Thrombocytopenia	3 (5.76%)
11.	Increased liver enzymes	3 (5.76%)
12.	Cough	2 (3.84%)
13.	Insomnia	2 (3.84%)
14.	Tardive syndrome	1 (1.92%)
15.	Hyperpigmented plaques	1 (1.92%)
16.	Constipation	1 (1.92%)
17.	Delirium	1 (1.92%)
18.	Hyperkaliemia and hyponatremia	1 (1.92%)
19.	Hypertension	1 (1.92%)

In our study on ADRs, it was observed that antibiotics were the most associated drugs, accounting for 12 cases (23.5%). and anticancer drugs (7, 13.7%), while other drug classes were also associated, such as analgesics (6, 11.7%), antihypertensives (3, 5.8%), antidiabetics (3, 5.8%), antipsychotics (3, 5.8%), anti-tuberculosis (ATT, 2, 3.9%), antihistamines (1, 1.9%), antithyroid (1, 1.9%), antifungals (1, 1.9%), steroids (1, 1.9%), antiepileptics (1, 1.9%), anticoagulants (1, 1.9%), and others (9, 17.6%). Our study resembles the study conducted by Misra D. et al., where the most common drug class associated with ADRs was antimicrobial (36.1%) [10].

In our study, the classification based on causality assessment of ADRs revealed that 17 (33%) were definite, 25 (49%) were probable, and 9 (18%) were possible. Our findings differed from the study conducted by Hemavathy G. et al., which showed that 41.7% were probable and 58.3% were possible [11].

The classification of the types of reactions observed from reported ADRs included diarrhea, itching, allergic symptoms (sneezing, running nose, etc.), generalized weakness, facial puffiness, hypoglycemia, headache, nausea and vomiting, anemia, thrombocytopenia, increased liver enzymes, cough, insomnia, tardive syndrome, hyperpigmented plaques, constipation, delirium, hyperkalemia and hyponatremia, and hypertension. Our study differed from the findings of Palanisamy et al., where the majority of adverse reactions reported were skin-related [12].

The short duration of the study, a smaller number of ADRs, and limited patient follow-up were the drawbacks of this study.

The strength of our study is that the drug responsible for ADRs in our study is very commonly used. This proves that there is a need for a continuous ADR monitoring system in hospitals. Careful planning and monitoring of drug therapy should be done to prevent the majority of ADRs.

CONCLUSIONS

This observational study aimed to identify, evaluate, and document adverse drug reactions (ADRs) in patients admitted to a tertiary care teaching hospital. A total of 51 ADRs were reported, affecting

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various organ systems and associated with a wide range of medications. The most common ADRs were skin reactions, followed by central nervous system (CNS) effects and gastrointestinal (GI) disturbances.

Our findings emphasize the importance of vigilant ADR monitoring in tertiary care settings to ensure patient safety and optimize medication use. By identifying and addressing ADRs, healthcare providers can reduce adverse outcomes and improve patient quality of life. Further research is essential to investigate the underlying mechanisms of ADRs and to develop effective strategies for their prevention and management.

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