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Original Research Article

Evaluation of Adverse Drug Reaction Patterns in a Tertiary Care Hospital: A Cross Sectional Study

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Abstract

Background: Adverse drug reaction (ADR) is an appreciably harmful reaction from an intervention related to the use of the medicinal product, which predicts hazard from future administration and specific treatment, or alteration of the dosage regimen, or withdrawal of the product. Aim of this study to evaluate which group of drug is causing maximum number of adverse reactions and to evaluate which gender/age group of patient is most vulnerable to adverse reactions.

Methods: This cross sectional retrospective study was conducted at Department of Pharmacology, JLNMC, Bhagalpur, Bihar. This study included ADRs reported various department of hospital to pharmacology department of Jawaharlal Nehru Medical College and Hospital, Bhagalpur, Bihar from July 2025 to September 2025. A total of 100 ADRs were included. The details of ADRs were collected and data was analyzed using IBM SPSS 23 software. The results are expressed in percentages.

Results: A total of 100 ADRs were evaluated. Nearly 81% of ADRs were due to antimicrobials, which is highest among all other groups of drugs. Parenteral drugs contributed highest ADRs (72%) followed by oral formulations (28%). A maximum number of ADRs were observed in 31–60 years of age group (48%). Both the genders contributed almost equal proportions of ADRs, with female being affected in 52% of cases. Most of the reactions were non-serious (80%) i.e maculopapular rash and itching followed by angioedema while serious reactions were only 20%. Based on causality assessment, the probable cases had a higher incidence (93%), followed by possible (4%) and remaining were certain (3%).

Conclusion: From the study, we conclude that most of the ADRs of type-A of mild severity and preventable, and GIT is the most common system affected. Careful attention is needed in monitoring and reporting of ADR"s.

Keywords: ADR, OPD, IPD, Pharmacovigilance.

Introduction

Adverse drug reaction (ADR) contributes to drug-related morbidity and mortality and increases the economic burden of the country. ADR is defined by WHO as "Any untoward response of a drug which is noxious unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or modification of physiological function or pathological state for the benefit of recipient".[1] It is important to monitor the effects of drugs, both intended and unwanted, to get an evidence-based assessment of the risk-benefit ratio.

ADRs are seen frequently in hospitals due to a combination of factors such as the complexity of diseases, drug interactions, polypharmacy, and possible negligence. Inadequate information or incompleteness in the reported ADR form hinders the analysis of ADR. Knowledge of the adverse effects of drugs is important for effective treatment. Communicating the potential harm of drug use to patients is a matter of high priority and should be carried out by every prescriber.[2] Children are especially vulnerable to adverse drug reactions (ADRs) and their incidence rates range from 0.6% to 16.8% of children exposed to a drug during a hospital stay.[3] These susceptibilities are explained in part by physiological changes during growth, influencing drug bioavailability and disposition. The lack of information from clinical trials increases the uncertainties about the benefit-risk profile of commonly used medicines in pediatrics.[4,5]

ADR monitoring in the hospital setting is vital because it helps to understand the nature and type of ADRs and to identify high-risk patients for developing ADRs. Pharmacovigilance (PV) is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects or any other drug-related problem.[6] PV in India is still in its infancy and ADR reporting rates are below 1% and require more data.[7] This might be due to a lack of ADR reporting due to guilt, lack of awareness, motivation, ignorance, training, and time limitations among healthcare personnel.

The significance of this study is to emphasize the awareness of the healthcare providers on vigilant monitoring of ADRs and promptly reporting to prevent the occurrence in populations. However, the present study has some limitations as it is an analytical study for a very short duration and involves a small study population. This study would give an insight into the patterns in tertiary health care centers and may help to increase awareness for further Pharmacovigilance studies.

Materials and Methods

This cross sectional retrospective study was conducted at Department of Pharmacology, JLNMC, Bhagalpur, Bihar. This study included ADRs reported various department of hospital to pharmacology department of Jawaharlal Nehru Medical College and Hospital, Bhagalpur, Bihar from July 2025 to September 2025. The details of ADRs like age, gender, suspected drug, type of ADR and causality assessment were noted and data is entered in excel sheet and subjected for statistical analysis. While collecting data, patient identity was kept anonymous.

The data analysis was done using IBM SPSS 23 software. Descriptive statistics was applied and results were expressed in percentages.

Results

A total of 100 ADRs were evaluated. Out of 100 ADRs, 52% contributed from women and rest 48 % collected from men (Table 1).

Table 1 : Gender wise division of ADRs

Gender	Number of ADRs	Percentage
Male	48	48%
Female	52	52%
Total	100	100%

A maximum number of ADRs (48%) were observed in the patients of 31–60 years of age followed by 26%, 17% and 9% which were observed in 0-18 years, 18-30 years and > 60 years of patients respectively (Table 2).

Table 2: Division of ADRs based on age groups

Age Group (Yrs.)	Number of ADRs	Percentage
0-18	26	26%
18-30	17	17%
31-60	48	48%
>60	9	9%

Nearly 78% of ADRs were due to antimicrobial agents, which was highest among all other groups of drugs (Table 3).

Table 3 : Division of ADRs based on Pharmacological classification of drugs

Pharmacological classes		Number of ADRs	Percentage
Antimicrobial Agents	Sulphonamides (4)	78	78%
	β-lactamantibiotics (35)		
	Tetracyclins (1)		
	Aminoglycosides (4)		
	Macrolides (1)		
	FQs (15)		
	Antifungal (3)		
	Antiviral (6)		
	Anticancerdrug (1)		
	Antiprotozoal/Anti- amoebic (2)		
	Others (6)		
Gastrointestinal tract	Drugs on pepticulcer (4)	4	4%
Autocoids	Histamine and Anti-Histaminics (2)	7	7%
	NSAIDs (5)		
Drug acting on CNS	Anti-epileptics (5)	5	5%
Hormones & Related drugs	Corticosteroids (1)	2	2%

	Anti-thyroiddrug (1)		
Drugs acting on blood Components	Haematinics (1)	1	1%
Miscellaneous drugs	Snake anti-venom (2)	3	3%
	Omnipaque (1)		

Parenteral drugs involved in 72% of total ADRs and remaining 28% by oral formulations (Table 4).

Table 4: Division of ADRs based on route of administration

Route of administration	Number of ADRs	Percentage
Parenteral	72	72%
Oral	28	28%
Topical	0	0

Based on causality assessment, the probable cases had a higher incidence (93%), followed by possible (4%) and 3 % of certain (Table 5).

Table 5: Division of ADRs based on Causality Assessment

Causality	Number of ADRs	Percentage
Probable	93	93%
Possible	4	4%
Certain	3	3%

Around 80% of ADRs were non-serious which includes maculopapular rash and itching followed by angioedema while serious reactions were only 20% (Table 6).

Table 6: Division of ADRs based on seriousness

Serious/Non-serious	Number of ADRs	Percentage
Serious ADRs	20	20%
Non-serious ADRs	80	80%

Table 7 shows characteristics of ADRs observed in patients. Most of patients (61%) presented with maculopapular rash or itching, followed by blisters (9%) and angioedema (6%).

Table 7: Division of ADRs based on type of reactions

Type of Reactions	Number of ADRs	Percentage
Maculopapular rash, itching	61	61%
Cushing syndrome	1	1%
Breathlessness	2	2%
Angioedema	6	6%
Nausea/Vomiting	3	3%
CNS (altered sensorium ataxia)	3	3%
Cytopenia	2	2%
Blister	9	9%
Fever, chills	8	8%
Anaphylaxis	3	3%
Lymphadenopathy	1	1%
Hypotension	1	1%

Discussion

Pharmacovigilance Programme of India (PvPI) is Government of India's flagship health-monitoring programme which collates and analyses drug related adverse events. In 2017-18 NCC-PvPI has received 90,198 Individual Case Safety Reports (ICSRs) through VigiFlow® from various ADR Monitoring Centres (AMCs) enrolled under the umbrella of PvPI. A mobile app "ADR PvPI" for the benefit of all healthcare stakeholders, including common man has been developed indigenously.[8]

The NCC-PvPI, housed at the Indian Pharmacopoeia Commission (IPC), continued its mission during 2023-2024 to safeguard public health by monitoring drug safety. Key activities included celebrating the National Pharmacovigilance Week and publishing important guidance documents and safety alerts.[9]

In our study, 61% of ADRs were due to involvement of skin and subcutaneous tissue. This finding is similar to the previous study done by Preeti et al and others where maculopapular rashes and itching were the most common reactions.[10] Previous study by R. Jhaj also showed that

maculopapular rash is the most common adverse effect.[11]

This type of reaction is mainly due to anti-microbial agents. The suspected drug was withdrawn in all the cases for the management of the ADRs. Faulty practices like the use of antibiotics in viral infections, too low doses or unnecessarily prolonged duration of treatment and prescribing antibiotics in all fever cases– considered as irrational which actually can do more harm than any benefit.

Moreover, in our study the ADRs were contributed almost equally by both men and women. This finding is similar to the study carried out by Jimmy Jose et al.

However, adverse drug reaction was maximum in age group between 30 to 60 which is different from our study findings.[12]

In a similar study conducted by Siraj Sundaran et al. it was found that the drugs most frequently associated with ADRs were antibiotics, antiepileptics and antihypertensives.[13]

When assessing the causality of a ADRs, the SOC level provides a logical starting point for data retrieval and analysis.[14] The SOC findings from the current study showed a substantial number of cases under blood and lymphatic system disorders, gastrointestinal disorders, metabolism and nutrition disorders, skin and subcutaneous tissue disorder. Prior studies corroborate the high incidence of ADRs categorized under the SOCs of gastrointestinal disorders, skin and subcutaneous tissue disorders.[15,16]

The main limitation of our study is small sample size. We could be able to collect only 100 ADRs from our Pharmacovigilance cell. However, effort would be made to include good number of ADRs in future.

Conclusion

Most of the patients recover from ADRs with appropriate and timely intervention, but it is important to understand the pattern and occurrence of ADRs for patient safety, and this is possible only with an effective and robust pharmacovigilance system.

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