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Original Research Article

A Retrospective Study on the Incidence and Pattern of Adverse Drug Reactions

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Abstract:

Background: Adverse drug reactions (ADRs) are a major cause of morbidity and underreported in India despite expanding pharmacovigilance systems.

Aim: To evaluate the incidence and pattern of ADRs in a tertiary care hospital.

Methodology: A retrospective observational study was conducted over six months using 147 ADR reports from an ADR Monitoring Centre. Data were analyzed for demographics, drug classes, causality (Naranjo scale), and severity (Hartwig scale) using descriptive statistics.

Results: ADRs were more common in males (55.78%) and predominantly affected the 16–30 years age group (31.29%). Dermatology (30.61%) and General Medicine (20.41%) reported the highest cases. Antibiotics were the leading cause (40.82%), followed by anticancer drugs (13.61%) and NSAIDs (12.24%). Most ADRs were classified as possible (50.34%) or probable (44.22%). Severity assessment showed that 48.98% were mild, 40.82% moderate, and 10.2% severe.

Conclusion: ADRs were mainly mild to moderate, with antibiotics being the most implicated drugs. Strengthening pharmacovigilance and rational prescribing is essential to enhance drug safety.

Keywords: Adverse Drug Reactions, Pharmacovigilance, Retrospective Study, Antibiotics, Drug Safety, Causality Assessment.

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Introduction

India is an ethnically diverse nation with diverse patterns of disease and the co-existence of traditional and modern systems of medicine, from ancient to cutting-edge scientific medicine. This is further complicated by a high degree of socioeconomic inequalities that result in huge disparities in accessibility and affordability of health care among different population groups [1]. Despite these disparities, India is a leader in the pharmaceutical industry. The Indian pharmaceutical sector is one of the world's largest and is worth close to $18 billion and is growing at the rate of 12-14% annually. In fact, it provides almost 40% of the world's generic drugs [2]. In fact, it is the fourth-largest pharmaceutical industry in the world, and has over 6000 registered drugs, which is increasing day by day [3].

Yet, along with the increase in drug production and use, there is a huge scope for improvement in the reporting of adverse drug reactions (ADRs) [5] In India, ADR reporting is as low as 1% in contrast to 5% globally [4]. This low rate of reporting indicates the need to improve pharmacovigilance (PV) systems in the country. Pharmacovigilance is the science and practice of detecting, assessing, understanding and preventing adverse effects or any other drug-related problems [5]. It is an important public health activity that helps in assuring the safe and effective use of medicines in the market in different physiological and pathological states.

ADR reporting in India is not a new phenomenon. ADR monitoring and reporting has been in place for around 30 years, with the first reports being made in 1986, when doctors from medical institutions started reporting systems to identify potential adverse outcomes of prescription medicines and promote rational prescribing practices [6] This prompted the development of the first ADR monitoring program with 12 regional centres covering a population of

around 50 million each. However, the program lost its momentum and was inactive for more than a decade.

Later, India became a member of the World Health Organization (WHO) ADR Monitoring Programme located in Uppsala, Sweden, in 1997. Drug monitoring was initiated in three medical colleges in New Delhi, Mumbai and Aligarh. But this also didn't prove successful. In 2005, the World Health Organisation (WHO) sponsored and World Bank-funded National Pharmacovigilance Program (NPVP) for India was launched on January 1. This was the official start of India's involvement in the WHO Programme for International Drug Monitoring (PIDM) that is coordinated by the Uppsala Monitoring Centre (UMC), Sweden. The NPVP was replaced by a more formalised nationwide program, the Pharmacovigilance Programme of India (PvPI) in July 2010, under the Ministry of Health and Family Welfare. The National Coordination Centre (NCC) was initially based at AIIMS in New Delhi but was moved to the Indian Pharmacopoeia Commission (IPC) in Ghaziabad in April 2011.

PvPI has set up a network of over 150 ADR Monitoring Centres (AMCs) in Indian medical colleges, covering the country. These facilities receive ADR reports from clinicians from hospitals and other health care institutions, enter into a web-based database for ADR reporting (vigiflow) and follow up as per the standard operating procedures [7]. This systematic approach has greatly enhanced ADR reporting and monitoring in India but there are still gaps.

An adverse drug reaction is any harmful or unintended response to a medicinal product used at normal doses for diagnosis, treatment or prevention of disease or for modification of physiological function [9]. They may result in the alteration of therapy, dose, or the withdrawal of the drug. ADRs can be broadly grouped into six categories: Type A (dose-related), Type B (non-dose-related), Type C (dose- and time-related), Type D (time-related), Type E (withdrawal), and Type F (failure of therapy) [8]. ADRs are a major cause of morbidity and mortality, resulting in increased duration of hospital stay, healthcare costs, and reduced quality of life. Indeed, ADRs are often listed as one of the top ten causes of morbidity and death in many countries, among both outpatients and inpatients [9].

Although ADR monitoring is known to be important, India's proportional contribution to ADR reporting is low. While more than one lakh Individual Case Safety Reports (ICSRs) have been sent to the World Health Organisation's (WHO) global database of ADRs (Vigibase), this is only around 1.8% of the total number of ADR reports, despite India's share of the world population exceeding 15% [7]. This highlights the need for better reporting systems and more awareness among healthcare practitioners. The current ADR reporting rate of 1% in India, compared to the global average of 5%, also highlights this [10]. As a result, voluntary and consumer-based reporting are now increasingly encouraged to improve data collection and drug safety.

Underreporting of ADRs in India is due to a number of factors. As reported in studies like that by Tandon et al., they include complacency, fear of legal action, guilt, career-building, lack of awareness and training, lethargy and lack of time of healthcare providers [11]. These factors have a negative impact on the pharmacovigilance culture of health institutions. As a result, improving institutional pharmacovigilance systems and promoting the engagement of clinicians is crucial in the production of epidemiological data on ADRs.

Drugs can be thought of as a "two-edged sword" as they are both beneficial and potentially harmful [12]. Pharmacovigilance's primary goal is to ensure benefits outweigh risk ratios of medications. Here, retrospective studies on the incidence and patterns of ADRs are essential to determine risk factors, frequently involved drugs and target organs.

Moreover, geographical data from these studies can help policymakers and healthcare managers to develop strategies, implement drug safety measures and enhance institutional and state-level pharmacovigilance systems. Therefore, the present study was undertaken to evaluate and analyze the incidence and patterns of adverse drug reactions in a hospital setting in Bihar, India, with the aim of enhancing ADR reporting practices and contributing to safer and more effective healthcare delivery.

Methodology

Study Design: This study was designed as an observational, retrospective, record-based study aimed at evaluating the incidence and pattern of adverse drug reactions (ADRs). The study involved systematic review and analysis of previously recorded ADR reports without any direct intervention or patient interaction.

Study Area: The study was conducted in the Department of Pharmacology at Bhagwan Mahavir Institute of Medical Sciences, Pawapuri, Nalanda, Bihar, India.

Study Duration: The study was carried out over a period of six months from May 2025 October 2025.

Sample Size: A total of 147 ADR reports were included in the study. These reports met the predefined inclusion criteria and were considered adequate for analysis.

Study Population: The study population consisted of all patients whose ADRs were reported and documented at the ADR monitoring centre during the study period. Patients belonging to all age groups and both genders were included to ensure a

comprehensive evaluation of ADR patterns across different demographic categories.

Data Collection: Data were collected from spontaneously reported ADR forms available at the ADR monitoring centre. Relevant clinical and demographic details were extracted from these records, and additional information was obtained from patient case sheets whenever required. In cases of incomplete data, the reporting physician was contacted for clarification. The collected data were evaluated based on patient characteristics such as age and sex, reaction characteristics based on the affected organ system, and drug characteristics including drug class and route of administration. Causality assessment was performed using the Naranjo Probability Scale, severity assessment was done using Hartwig's Severity Assessment Scale, and outcomes were categorized as fully recovered, recovering, unknown, or fatal. Management strategies for ADRs were also documented.

Inclusion Criteria

- All spontaneously reported ADR forms available during the study period
- ADR reports with complete and adequate information
- ADRs reported in patients of all age groups and both genders

Exclusion Criteria

- Cases of drug poisoning
- Medication errors
- ADR reports with doubtful causality
- ADR forms with incomplete or insufficient data

Study Procedure: All eligible ADR forms were carefully reviewed and screened based on inclusion and exclusion criteria. The data were systematically extracted and categorized according to predefined variables. Each ADR was assessed for causality, severity, and outcome using standard assessment scales. The compiled data were then organized for further statistical analysis.

Statistical Analysis: The collected data were entered into Microsoft Excel and analyzed using appropriate statistical methods. Descriptive statistics were applied to summarize the data, and the results were expressed in terms of frequencies and percentages. The findings were presented using tables and charts to facilitate clear interpretation of ADR patterns."

Result

Table 1 shows the gender distribution of patients with adverse drug reactions (ADRs) (N=147). Males accounted for a higher proportion, with 82 cases (55.78%), while females contributed 65 cases (44.22%). Overall, ADRs were more commonly observed in males compared to females in the study population.

Table 1: Gender distribution of patients with ADR (N = 147)

Gender	Number of ADRs	Percentage (%)
Male	82	55.78
Female	65	44.22
Total	**147**	**100**

Table 2 shows the age-wise distribution of adverse drug reactions (ADRs) among the study population (N=147). The highest proportion of ADRs was observed in the 16–30 years age group, accounting for 46 cases (31.29%), followed by 31–45 years with 38 cases (25.85%). The 46–60 years group contributed 27 cases (18.37%), while both the youngest (0–15 years) and oldest (>60 years) age groups had equal numbers of ADRs, with 18 cases each (12.24%). Overall, ADRs were more common in younger and middle-aged adults, particularly in the 16–45 years age range.

Table 2: Age-wise distribution of ADRs (N = 147)

Age Group (years)	Number of ADRs	Percentage (%)
0–15	18	12.24
16–30	46	31.29
31–45	38	25.85
46–60	27	18.37
>60	18	12.24
Total	**147**	**100**

Table 3 shows the department-wise distribution of adverse drug reactions (ADRs) among the study population (N=147). The highest number of ADRs were reported from the Dermatology department, accounting for 45 cases (30.61%), followed by General Medicine with 30 cases (20.41%). Oncology contributed 22 ADRs (14.97%), while Pediatrics and Surgery reported 15 (10.2%) and 12 (8.16%) cases respectively. Other departments together accounted for 23 ADRs (15.65%). Overall, Dermatology and General Medicine were the major contributors to ADR reporting.

Table 3: Department-wise distribution of ADRs (N = 147)		
Department	**Number of ADRs**	**Percentage (%)**
Dermatology	45	30.61
General Medicine	30	20.41
Oncology	22	14.97
Pediatrics	15	10.2
Surgery	12	8.16
Others	23	15.65
Total	**147**	**100**

Table 4 shows the distribution of drug classes implicated in adverse drug reactions (ADRs) among the study population (N=147). Antibiotics were the most common contributors, accounting for 60 ADRs (40.82%), followed by anticancer drugs in 20 cases (13.61%) and NSAIDs in 18 cases (12.24%). Antiepileptics were responsible for 12 ADRs (8.16%), while cardiovascular drugs accounted for 10 cases (6.8%). Other drug classes contributed to 27 ADRs (18.37%). Overall, antibiotics were the leading cause of ADRs, with other classes contributing to a lesser extent.

Table 4: Drug class implicated in ADRs (N = 147)		
Drug Class	**Number of ADRs**	**Percentage (%)**
Antibiotics	60	40.82
Anticancer drugs	20	13.61
NSAIDs	18	12.24
Antiepileptics	12	8.16
Cardiovascular	10	6.8
Others	27	18.37
Total	**147**	**100**

Table 5 presents the causality assessment of adverse drug reactions (ADRs) among the study population (N=147). The majority of ADRs were categorized as possible, accounting for 74 cases (50.34%), followed by probable reactions in 65 cases (44.22%). Only a small proportion, 8 cases (5.44%), were classified as definite. Overall, most ADRs had a reasonable but not confirmed association with the suspected drugs, with relatively few having a definite causal relationship.

Table 5: Causality assessment of ADRs (N = 147)		
Causality Category	**Number of ADRs**	**Percentage (%)**
Definite	8	5.44
Probable	65	44.22
Possible	74	50.34
Total	**147**	**100**

Table 6 shows the severity assessment of adverse drug reactions (ADRs) among the study population (N=147). Nearly half of the ADRs were mild, accounting for 72 cases (48.98%), followed by moderate reactions in 60 cases (40.82%). Severe ADRs were relatively less common, observed in 15 cases (10.2%). Overall, the majority of ADRs were mild to moderate in severity, with a smaller proportion being severe.

Table 6: Severity assessment of ADRs (N = 147)		
Severity Level	**Number of ADRs**	**Percentage (%)**
Mild	72	48.98
Moderate	60	40.82
Severe	15	10.2
Total	**147**	**100**

Discussion

In the current retrospective study on adverse drug reactions (ADRs), there is a slightly greater proportion of ADRs in males (55.78%) than in females (44.22%) indicating a slight male predominance. This is in line with the findings of Sharma et al. [13] who also observed a higher incidence of ADRs in males in a tertiary care hospital. But this is in contrast to several previous studies that regarded

females to be an important risk factor for ADRs because of physiological and pharmacokinetic variations [8]. The differences in gender distribution in various studies could be explained by variations in prescription patterns, health care seeking behaviour, and population demographic. Hence, while our findings are in agreement with some Indian hospital-based studies, they also raise questions on the variability in gender susceptibility to ADRs."

Age-wise analysis in our study found young adults (16-30 years) were the most affected with ADRs (31.29%) followed by 31-45 years (25.85%). This finding contrasts with traditional reports like Kulkarni [6], in which the elderly were more susceptible to ADRs, attributed to polypharmacy and physiological changes with age. Likewise, Edwards and Aronson [8] highlighted the vulnerability of the elderly. In our study, the increased risk for young adults may be due to increased access to health care, increased exposure to medications, and a greater propensity for reporting ADRs. But underreporting in the young and elderly may conceal the true incidence in these populations. Therefore, our results indicate a possible trend in ADRs, perhaps due to changing health-care patterns.

When we compared the numbers of ADRs across different departments, it was found that the maximum number of ADRs (30.61%) occurred in the Department of Dermatology, followed by General Medicine (20.41%) and Oncology (14.97%). This finding is consistent with Khobragade et al. [12], who also found a higher proportion of dermatology-related ADRs, largely because of easily recognized skin signs and symptoms. In contrast, few ADRs were reported from departments like ophthalmology and ENT in previous studies [12], which could be explained by low systemic drug exposure or underreporting. Our study also highlights the significant role of Oncology (14.97%) in contributing to the ADRs, highlighting the toxicity of the drugs used in this speciality, as reported in other pharmacovigilance studies [3]. So, it seems that the distribution of ADRs across departments is influenced by both medications use and the prominence of the ADRs.

Regarding drug classes, antibiotics were the most frequent drug class in our study (40.82%), followed by anticancer drugs (13.61%), NSAIDs (12.24%) and antiepileptics (8.16%). Our results are in agreement with other studies, such as those by Arulmani et al. [14] and Shamna et al. [3], where antibiotics were found to be the most common cause of ADRs. The prominence of antibiotics is likely due to their common use and potential for allergic reactions. Likewise, the gastrointestinal and hypersensitivity ADRs of NSAIDs have been reported in previous studies [6]. The consistent representation of drug classes in several studies highlights the need for careful use and monitoring, particularly in vulnerable populations.

In terms of causality, most ADRs reported in our study were assessed as "possible" (50.34%), "probable" (44.22%) and "definite" (5.44%). This is slightly different from Khobragade et al. [12], where more ADRs were "possible" or "probable". The high number of "possible" ADRs in our study may be due to several limitations of retrospective studies, including lack of information (that is, documentation) and lack of rechallenge. Although, the use of validated algorithms such as the Naranjo algorithm [15] helps to standardize causality, uncertainty remains a common issue in pharmacovigilance. Therefore, our study suggests a need to enhance documentation and surveillance to improve causal inference.

The severity assessment showed that the majority of ADRs were mild (48.98%) to moderate (40.82%) and only 10.2% were severe. This finding is in line with Arulmani et al. [14], where reactions were mostly non-serious and reversible. In line with this, Hartwig et al. [16] highlighted the fact that the majority of ADRs are mild to moderate and do not require extensive care. The low percentage of severe ADRs in our study supports the notion that although ADRs are common, they are not often severe. But the existence of a small number of severe reactions highlights the need for early identification and treatment of ADRs.

Our study also shows similar patterns in recovery and management strategies compared to previous research. Earlier studies have demonstrated the common practice of drug withdrawal in the management of ADRs [13]. While our study does not explicitly report recovery rates, the high proportion of mild to moderate ADRs indicates that most cases were likely to have a good outcome. Also, the ongoing use of essential drugs like anticancer drugs after ADRs have subsided, as observed in previous studies, illustrates the dilemma of weighing the benefits and risks of drug use.

In general, findings from our study are in agreement with previously published data, especially with regards to drug classes, severity and departmental distribution of ADRs. But variations in age and gender distributions highlight the impact of local factors and medical practices on ADR profiles. The analysis highlights the need for ongoing pharmacovigilance and local data to enhance drug safety and patient outcomes.

Conclusion

This retrospective study underscores that adverse drug reactions (ADRs) were more prevalent in males than females, and the highest rates occurred in young adults and middle-aged adults. Analysis by department demonstrated a high percentage of ADRs observed in dermatology and general medicine departments, suggesting a greater impact in these specialties. In terms of ADR-inducing drug classes, antibiotics were the most frequent followed

by anticancer drugs and nonsteroidal anti-inflammatory drugs, warranting particular monitoring of these widely used drugs. Causality evaluation revealed that the majority of ADRs were assessed as possible or probable (signifying a plausible causal relationship with the suspected drugs), with few definite ADRs. Regarding the severity, most ADRs were classified as mild to moderate, while the number of severe reactions was relatively low. In conclusion, the results highlight the need for ongoing pharmacovigilance, early recognition and rational drug prescribing to reduce the burden of ADRs in clinical practice.

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