

PHARMACOVIGILANCE IN PRACTICE: ASSESSING ADVERSE DRUG REACTIONS IN TERTIARY CARE HOSPITAL CENTRAL INDIA

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ABSTRACT

Objective: Our study aimed to evaluate the frequency, severity, and causality of ADRs reported at the ADR Monitoring Centre, Department of Pharmacology, MGM Medical College, Indore, to improve drug safety practices.

Methods: A retrospective study at the ADR Monitoring Centre in Indore analyzed suspected ADR Reporting Forms from the past six months. The analysis focused on ADR frequency, severity, and causality, categorized using the World Health Organization (WHO) causality assessment scale.

Results: Over six months, 502 ADR forms were reported at Maharaja Yashwant Rao Hospital, Indore, with males (25-55 years) accounting for 50% of the cases. The psychiatry department reported the most ADRs (57.5%), followed by pediatrics (12.1%) and gynecology (9.7%). Commonly implicated drug classes were antipsychotics, antibiotics, and anticonvulsants. Valproate (14%), ceftriaxone (8%), and olanzapine (6%) were frequently involved drugs. About 52.6% of ADRs were certain, and 25% were probable in causality analysis.

Conclusion: Monitoring and reporting ADRs are crucial in healthcare. Raising awareness about ADR reporting among doctors and patients can promote safer drug use, reduce associated ADR-related morbidity, ease the treatment burden on patients, and enhance their quality of life.

Keywords: Adverse drug reaction monitoring, Healthcare awareness, Drug safety, Causality, Pharmacovigilance

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INTRODUCTION

Pharmacovigilance is a cornerstone of modern healthcare, focusing on identifying, evaluating, understanding, and mitigating Adverse Drug Reactions (ADRs) to safeguard public health and ensure the safe use of medications [1-4]. Over the past 170 y, pharmacovigilance has evolved significantly, with key milestones such as the Thalidomide disaster of 1961, which spurred the development of global drug monitoring systems, including the WHO's Uppsala Monitoring Centre in 1978 [5-8].

The spontaneous reporting system, despite challenges such as under-reporting, remains a widely adopted method for signal detection. Modern pharmacovigilance has transitioned from reactive to proactive, risk-based strategies that are integrated throughout the lifecycle of pharmaceuticals [9-14]. Real-world data evaluation has further emphasized the importance of ADR monitoring and reporting as a vital component of pharmacovigilance.

In India, ADR monitoring is conducted under the Pharmacovigilance Programme of India (PvPI) [15-21]. However, ADR reporting rates remain under 1%, significantly lower than the global rate of 6-10%, due to limited awareness, knowledge gaps, and insufficient infrastructure [22-26]. This under-reporting underscores the need for enhanced pharmacovigilance practices to ensure patient safety.

Causality assessment is crucial in pharmacovigilance to determine the likelihood of a drug causing an ADR. Various tools, including the WHO-Uppsala Monitoring Centre system, Naranjo's algorithm, and the Liverpool algorithm, are used for this purpose, each with varying levels of agreement [27-30].

This study aims to bridge this gap by analyzing spontaneous ADR reports from Maharaja Yashwantrao Hospital (MYH) and MGM Medical College, Indore. Using the WHO-UMC causality assessment scale, we evaluate the severity and causality of reported ADRs to quantify medication-associated risks in a tertiary care setting.

MATERIALS AND METHODS

Study design

An observational, retrospective, record-based study was conducted at the ADR Monitoring Centre in Indore.

Inclusion criteria

All suspected ADR reported from tertiary care hospitals and health facilities from September 2022 to September 2023 were included in the study.

Exclusion criteria

ADR forms with incorrect or insufficient data were excluded from the analysis. Additionally, cases involving drug poisoning, medication errors, doubtful causality, or ADR forms lacking sufficient information were excluded.

Data collection and processing

Spontaneous ADR forms were analyzed. Cases involving drug poisoning, medication errors, doubtful causality, and ADR forms lacking sufficient information were excluded.

Methods of measurement

Spontaneous ADR reports were analyzed. Specific responses were categorized by departments, drug classes, and affected organ systems. Reactions were classified into six categories: certain, probable, possible, unassessable/unclassifiable, unlikely, and conditional/unclassified, using the WHO-UMC causality assessment scale [31]. Outcomes and management of ADRs were also analyzed.

Study site

The study was conducted at Maharaja Yashwant Rao Hospital and the Department of Pharmacology, Mahatma Gandhi Memorial Medical College, Indore Madhya Pradesh, India.

Study duration

Reports were collected from September 2022 to September 2023.

Study population

The study population included ADR reports from patients across all clinical departments of Maharaja Yashwantrao Hospital. This included both in-patient and out-patient cases. Consent was obtained while filling out the ADR forms. After consultation with the institutional ethics committee, the study was deemed eligible for exemption from further ethical review.

Sample size

The study incorporated 502 ADR forms, which were submitted through the Suspected ADR form. Patients, Doctors, and all health care professionals were informed about the significance of ADR reporting through counseling sessions.

Sampling method

All reported forms from September 2022 to 2023 were included.

Tools utilized for data collection and analysis

ADR Form and WHO-UMC Causality Assessment Scale.

Data analysis

Descriptive statistics were applied to identify common trends and patterns in the adverse drug reactions. Frequencies and percentages of different categorized values were calculated. Additionally, mean, range, and standard deviation (SD) were also calculated. The χ^2 test was used for comparing categorical values, with significance set at p-values < 0.001.

RESULTS

A total of 502 cases were evaluated. Adverse drug reactions (ADRs) were more prevalent among male patients, comprising 60.36% (303 cases), compared to females. The age distribution was diverse. Young adults (20-29 y) represented a significant portion at 24.10%, highlighting their substantial presence in reported ADR incidents. Middle-aged adults (40-49 y) comprised the majority at 32.27%, followed by children (3-12 y) at 12.35%. This varied distribution underscores the importance of considering different age groups in understanding ADR patterns. The mean age of the patients was 43.32±9.58 y.

Table 1: Demographic details of suspected Adverse drug reaction N=502

Parameter	Number of patients with ADR, n (%)	P value
Age group (y)		
Children (3-12 y)	62 (12.35%)	1.0000 (NS)
Adolescents (13-19 y)	37 (7.37%)	
Young adults (20-29 y)	121 (24.10%)	
Adults (30-39 y)	50 (9.96%)	
Middle-aged adults (40-49 y)	162 (32.27%)	
Older adults (50-59 y)	39 (7.77%)	
Seniors (60 y and above)	31 (6.17%)	
Sex		
Male	303 (60.34%)	0.9174 (NS)
Female	199 (39.64%)	
Route of administration		
Oral	340 (67.73%)	1.0000 (NS)
Parenteral	147 (29.28%)	
Topical	15 (2.99%)	

In our study, we analyzed the routes of administration for adverse drug reactions (ADRs). The majority of ADRs occurred through oral administration, constituting 67.73% of cases followed by parenteral (29.28%) and topical (2.99%) (table 1).

Adverse drug reactions, as reported by different departments varied considerably. Of all the departments, psychiatry registered

the highest number with 30.26% of cases. The Pediatrics department documented 14.14% while Obstetrics and Gynecology department reported 12.95%. The Medicine department accounted for 11.55% of ADRs. The Oncology and Dermatology departments closely followed with 8.76% and 8.17% of ADRs, respectively (fig. 1).

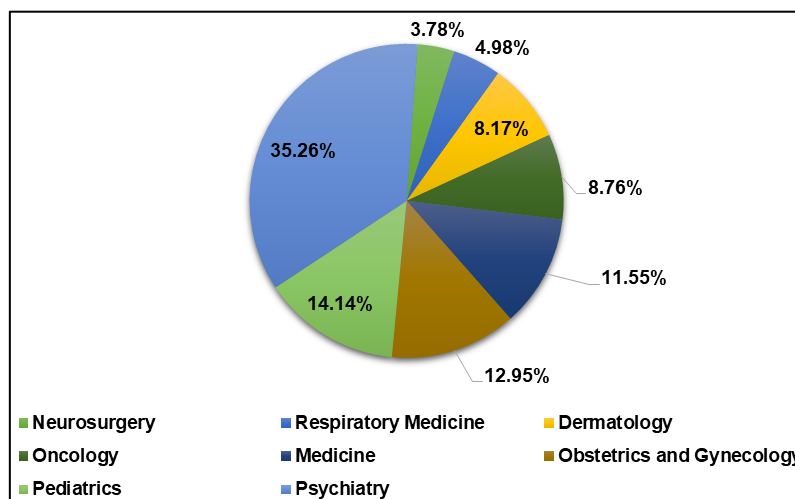


Fig. 1: Distribution of ADR forms received by different departments; out of all the adverse effects caused by drugs, CNS problems were 40.35% of the cases. Skin-related issues were 22.80% of ADRs. Gastrointestinal-related issues were observed in 18.29%, and 10.02% exhibited general symptoms, Hematological issues were 9.25% of cases (fig. 2)

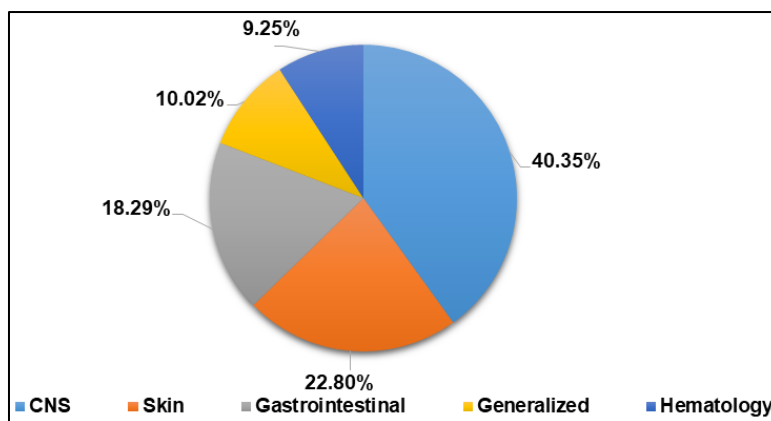


Fig. 2: Organ affected due to adverse drug reactions, varying rates of occurrence were observed among the different drug classes collected from ADR forms. The highest rate was reported for antipsychotics at 30.75%, followed by antibiotics at 12.28% and anticonvulsants at 9.27%. Minimal rates, ranging from 5.26% to 6.76%, were observed in chemotherapy agents, hormones, and antiemetics. Miscellaneous drugs had a rate of 4.51%, while analgesics were reported at 5.51%. Other drug classes, including PPIs, antivirals, blood transfusions, and anti-TB drugs, showed rates below 5.01% (fig. 3)

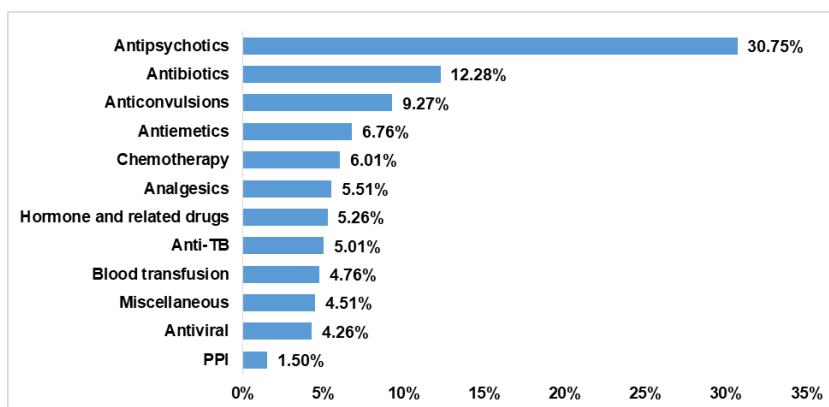


Fig. 3: Distribution of suspected drugs according to their classes; among the 502 ADR forms, we identified and analyzed a total of 510 suspected drugs. Valproate (14.14%) and Risperidone (10.76%) were the most prevalent, followed by Ceftriaxone (8.76%), Olanzapine (6.7%), and Ranitidine (5.7%) (table 2). Less common drugs, such as Fluvoxamine, Quetiapine, and Amoxiclav, each accounted for less than 5% of the cases, along with several others

Table 2: Suspected drugs in ADR forms (N=502)

Suspected drugs	N (%)
Valproate	72 (14.14%)
Risperidone	55 (10.76%)
Ceftriaxone	45 (8.76%)
Olanzapine	35 (6.7%)
Ranitidine	29 (5.7%)
Fluvoxamine	29 (5.7%)
Fluoxetine	27 (5.3%)
Risperidone with THP	27 (5.38%)
Quetiapine	25 (4.7%)
Amoxiclav	25 (4.7%)
Diclofenac	18 (3.3%)
Clonazepam	13 (2.3%)
Isoniazid	13 (2.3%)
Cefoperazone	13 (2.3%)
Iron sucrose	13 (2.3%)
Metronidazole	10 (1.9%)
Momentasone	7 (1.3%)
IV Fluids (RL)	7 (1.3%)
Capecitabine	5 (1%)
Clobetasol	5 (1%)
Betamethasone valerate	5 (1%)
Carbamazepine	5 (1%)
Acyclovir	5 (1%)
Blood Transfusion	5 (1%)
IV Fluids (NS)	5 (1%)

The outcomes of adverse drug reactions varied as follows: 3.98% were classified as "unknown", 12.75% were categorized as "recovering/resolving", and a significant majority, 83.27% were "recovered/resolved" (fig. 4).

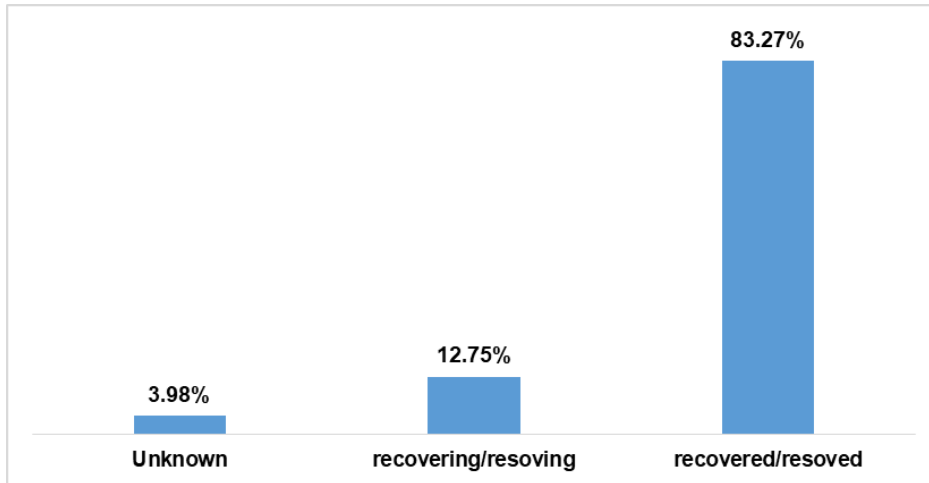


Fig. 4: Outcome of ADRs from suspected ADR reports, the causality assessment revealed that 52.79% were categorized as "certain", 25.5% as "probable or likely", 20.72% as "unlikely", and only 0.99% as "conditional" (fig. 5)

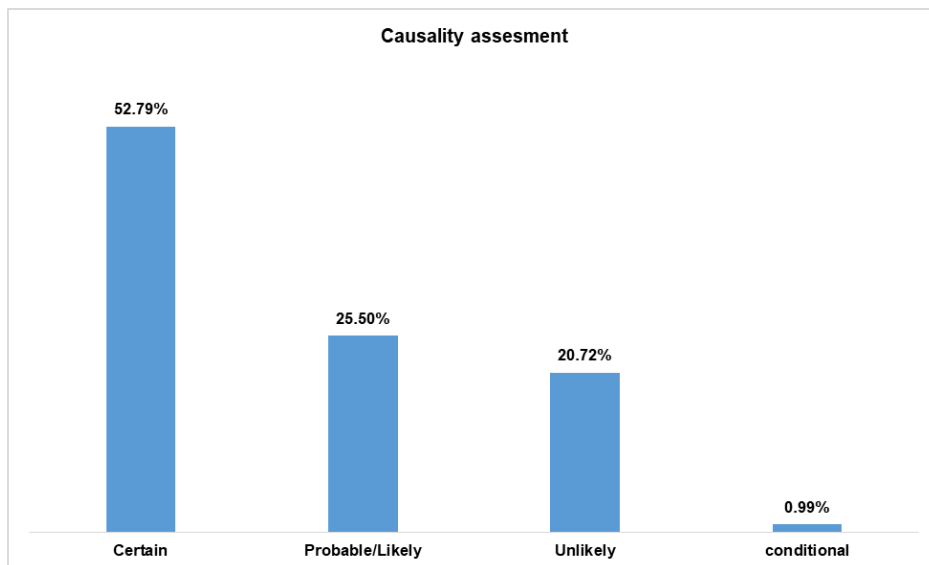


Fig. 5: Causality Assessment of Suspected ADRs according to the WHO-UMC scale, regarding the severity of the cases, 86% of the cases were classified as mild, 11% as moderate, and 2% as severe (fig. 6)

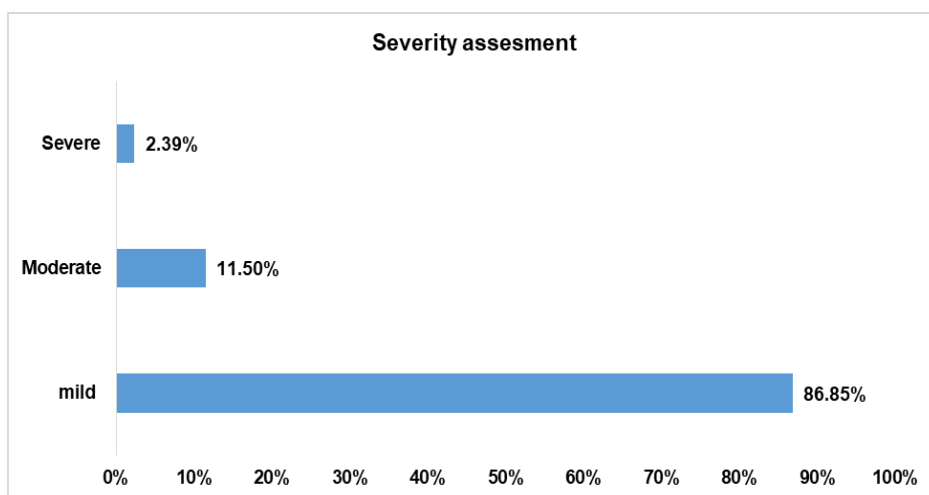


Fig. 6: Severity assessment of suspected ADR forms; after assessing adverse drug reactions, it was noted that the drug was withdrawn in 59.96% of cases, the dose remained unchanged in 23.31% of cases, and a dose reduction was implemented in 16.53% of cases (fig. 7)

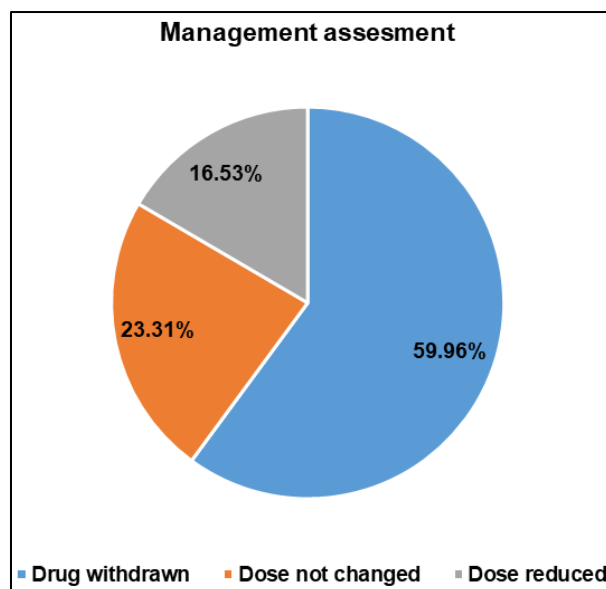


Fig. 7: Assessment of management during the occurrence of adverse reaction, the causality of ADRs was categorized using the WHO causality assessment scale to assess the relationship between a drug and the occurrence of an ADR

DISCUSSION

Adverse drug reactions (ADRs) are common in clinical practice but are frequently overlooked by clinicians. Even when recognized and reported by patients or healthcare providers, ADRs are often under-reported. Many physicians are unaware that clinically significant ADRs should be reported to ADR monitoring centers. In our study, we identified 502 ADRs over one year. Male patients experienced a higher prevalence of ADRs compared to females. Our findings highlighted a notable presence of young adults (ages 20–29), with the highest number of cases occurring among middle-aged adults (ages 40–49). Similarly, a study on ADRs found a higher incidence among male patients [32], and another comparable study observed significant occurrences of ADRs among young adults, especially those aged 20–29, with most reported cases among middle-aged adults [33].

In our study on adverse drug reactions (ADRs), most ADRs occurred through oral administration, which contrasts with the findings of Pathak *et al.*, who found that the intravenous route was a major contributor [34].

Our study found significant variation in ADRs across departments, with psychiatry reporting the highest incidence, followed by pediatrics and obstetrics/gynecology. In contrast, Modi *et al.* reported that dermatology recorded the highest number of ADRs [35].

Among the various adverse effects induced by drugs, central nervous system (CNS) problems emerged as the predominant effects, succeeded by skin-related concerns and gastrointestinal manifestations. In contrast to our investigation, studies conducted by Jindal *et al.* [36] and Jatana *et al.* [37] reported that the most prevalent adverse effects were related to the skin. Jindal *et al.* specifically identified skin rashes as the most common ADRs.

Diverse drug classes exhibited distinct occurrence rates in collected ADR forms. Antipsychotics had the highest reported rate, succeeded by anticonvulsants and antibiotics. In parallel, a study conducted by Kaur and Princy *et al.* found that antibiotics were most frequently linked with ADRs, followed by antipsychotics [38, 39].

In this study, causality assessment showed that over 50% of ADRs were categorized as 'certain,' with most cases resulting in complete recovery. Additionally, the majority of cases were classified as "mild" in terms of severity assessment, and a significant number of drugs were withdrawn. This contrasts with the findings of the study conducted by Patil *et al.*, where a majority of ADRs fell into the "probable" category according to the WHO causality assessment

scale. Only 9 (3%) ADRs were identified as severe, leading to changes in the administered drugs [40]. In a study by Giri K *et al.*, 64% of adverse effects were categorized as "possible" [41].

ADR data often rely on voluntary reporting, and there is a risk of under-reporting or selective reporting, which could skew the frequency and severity of reported adverse reactions. The study was conducted in a single-center setting, so the results may not fully capture the broader practice variability, thus limiting the applicability of findings to other healthcare settings.

CONCLUSION

Our institute acknowledges the challenges of polypharmacy, ADR diagnosis, and the heavy workloads of physicians while emphasizing the importance of ADR reporting. To overcome these challenges, we have initiated seminars and workshops for clinicians and staff, facilitated one-on-one interactions, and assigned a technical associate to gather ADR reports. Additionally, we offer a toll-free number for patients to report ADRs and provide training for future healthcare professionals to promote pharmacovigilance. We aim to raise awareness among both physicians and patients to strengthen the pharmacovigilance system in India. Future activities will focus on increasing ADR reporting awareness among consumers and non-health professionals to enhance the quality of life and reduce hospital stays. As we continue our efforts, we acknowledge that "Much has been done, but more is to be done."

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AUTHORS CONTRIBUTIONS

Conceptualization: Dr. Avina Kharat, Methodology: Dr. Pooja Mishra, Dr. Meghna Shinde, Dr. Avina Kharat, Formal analysis and data collection: Dr. Avina Kharat, Dr. Aneri Patel, Dr. Vignan N., Writing and original draft preparation: Dr. Avina Kharat, Dr. Aneri Patel, Dr. Vignan N., Final review: Dr. Pooja Mishra, Dr. Meghna Shinde, Dr. Avina Kharat, Dr. Vignan N.

CONFLICT OF INTERESTS

Declared none

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