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Original Research Article

Analysis of Adverse Drug Reactions in a Tertiary Care Hospital of Bihar

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Abstract:

Background: Adverse drug reactions (ADRs) pose a growing challenge to patient safety and healthcare systems, especially in complex therapeutic landscapes. Despite national efforts like the Pharmacovigilance Programme of India (PvPI), regional data—particularly from tertiary care centers remains limited. This gap is largely due to under-reporting, highlighting the need for strengthened ADR monitoring and reporting mechanisms. This study aims to generate regional ADR data to support improved monitoring and safer clinical practice.

Objective: To analyze the pattern, frequency, and outcomes of ADRs in a tertiary care hospital in Bihar, contributing real-world data to support regional pharmacovigilance efforts.

Materials & Method: This prospective observational study, conducted from January 2023 to December 2024, analyzed adverse drug reactions (ADRs) reported from both inpatient and outpatient departments of a tertiary care hospital. Patient demographics, drug details, and reaction characteristics were documented using standard ADR forms. ADRs were assessed for causality, severity, and preventability, and reported to the Indian Pharmacopoeia Commission via VigiFlow. The findings were systematically compiled and visualized, ensuring confidentiality and contributing to regional pharmacovigilance data.

Result: A total of 526 adverse drug reactions (ADRs) were analyzed during the study period, with adults comprising the majority of cases. Antibiotics were the most frequently implicated drug class, followed by anticancer and analgesic agents. Gastrointestinal, dermatological, and neurological systems were predominantly affected. Most ADRs were classified as possible or probable, moderate in severity, and largely preventable. Recovery outcomes were favorable, with over 77% of cases either resolving or in recovery, highlighting the importance of vigilant ADR monitoring and management.

Conclusion: This study presents a detailed analysis of adverse drug reaction patterns in a tertiary care hospital in Bihar, emphasizing the importance of a robust pharmacovigilance system. It highlights the role of timely detection, clinician engagement, and awareness initiatives in enhancing patient safety and optimizing therapeutic outcomes.

Keywords: Adverse drug reaction, Reporting, Pharmacovigilance, Causality, Drug Safety, Tertiary Care Hospital.

Introduction

Over the past few decades, advances in drug development have significantly improved patient outcomes, offering more targeted therapies, enhanced disease management, and prolonged life expectancy. However, this progress has been accompanied by a notable rise in the incidence of Adverse Drug Reactions (ADRs), which now represents a growing concern in clinical practice and public health. ADR as defined by World Health Organization (WHO) is 'a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function' [1].

As the pharmaceutical landscape becomes increasingly complex—with polypharmacy, biologics, and personalized medicine—patients are more vulnerable to unintended and sometimes severe drug-related effects, which have now become a critical concern in clinical practice and public health [2]. ADRs not only compromise patient safety but also contribute to increased hospital admissions, longer stays, and higher healthcare costs. Some studies have estimated that ADRs are responsible for approximately 6% of all hospital admissions and are

particularly prevalent among elderly populations, individuals with multiple comorbidities, and those undergoing chronic or high-risk treatments [3]. It is also estimated that ADRs are the fourth to the sixth leading cause of death worldwide [4]. Moreover, the variability in genetic makeup, metabolic profiles, and drug interactions plays a critical role in determining the likelihood and severity of ADRs. Overall, the impact of ADRs extends beyond individual patients, influencing prescribing behavior, regulatory decisions, and the overall trust in medical systems.

Given these implications, systematic ADR reporting is an essential pillar of drug safety surveillance. It enables healthcare professionals and regulatory authorities to monitor real-world drug performance, detect emerging safety signals, and implement timely risk mitigation strategies. Accurate and timely reporting also supports post-marketing surveillance, informs updates to clinical guidelines, and contributes to the continuous refinement of benefit-risk assessments [5].

Pharmacovigilance plays a pivotal role in this domain which aims at ensuring safe and effective use of medications by systematically collecting, analyzing, and interpreting high-quality data on drug-related adverse events. According to WHO, Pharmacovigilance is defined as 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem' [6].

The World Health Organization initiated its programme for International Drug Monitoring in 1968, marking a pivotal step toward global drug safety surveillance. To strengthen this initiative, the Uppsala Monitoring Centre (UMC) was established in 1978 in Sweden as a WHO Collaborating Centre. UMC continues to serve as the global hub for collecting, analyzing, and sharing adverse drug reaction data from member countries, fostering international collaboration and signal detection. In India, the Pharmacovigilance Programme of India (PvPI) was formally launched in 2010 by the Central Drugs Standard Control Organization (CDSCO), operating under the Directorate General of Health Services, Ministry of Health and Family Welfare (MoHFW). The program aims to ensure patient safety by monitoring ADRs and promoting the rational use of medicines. Since April 2011, the Indian Pharmacopoeia Commission (IPC), located in Ghaziabad, has been designated as the National Coordination Centre (NCC) for PvPI. IPC oversees the nationwide network of Adverse Drug Reaction Monitoring Centres (AMCs), which serve as the backbone of India's pharmacovigilance infrastructure. As of now, over 1050 AMCs have been established across medical colleges, tertiary care hospitals, and corporate healthcare institutions. These centers are responsible for collecting, assessing, and forwarding ADR reports to IPC, which in turn contributes to the global database maintained by UMC [7].

There is a need to understand and strengthen the pharmacovigilance system to control and reduce the impact of adverse drug reactions on public health. Encouraging a culture of vigilance among healthcare providers, educating patients about potential side effects, and simplifying reporting procedures are vital steps toward strengthening this system. Ultimately, robust ADR monitoring safeguards public health and ensures that therapeutic advances translate into safer, rational and more effective care [8]. Although the Pharmacovigilance Program of India (PvPI) encourages the reporting and monitoring of adverse drug reactions, the regional data especially from tertiary care centers, is still scarce to understand the full picture of ADRs for directing interventions where they have the greatest impact. The limited availability of ADR data is largely due to widespread under-reporting, with rates as low as 1% in India compared to approximately 5% in other countries [9]. This highlights an urgent need to raise awareness among both healthcare professionals and the general public about the critical role of monitoring drug outcomes in ensuring patient safety and improving pharmacovigilance.

Studies across various regions of India have examined the prevalence and characteristics of adverse drug reactions, underscoring the importance of continuous pharmacovigilance. Given Bihar's dense population and evolving healthcare landscape, there is a pressing need for more in-depth research on ADRs to strengthen patient safety and enhance the region's healthcare infrastructure.

With these considerations, this research was carried out with the objective of mapping out and thoroughly examining adverse drug reactions pattern in a tertiary care hospital of Bihar. Understanding that collecting real-world information is essential, this study was done to fill in the gaps within regional pharmacovigilance through proposed observational research. This research is expected to provide valuable information to the healthcare providers, policy makers, and regulatory authorities for improving safety measures and optimizing drug therapy.

Materials and Methods

This study was initiated after getting permission from the Institutional Ethics Committee (1615/IEC). This study was an observational and prospective in design and was conducted from January 2023 to December 2024. Within the specified study timeframe, all the patients from both outpatient and inpatient departments who experienced ADR were enrolled. All patients included in the survey were

provided with appropriate instructions. Moreover, family members and formal caregivers of these patients were guided to report any ADRs directly to adverse drug reaction monitoring center (AMC) of this Institute or to the concerned healthcare professionals. Relevant patient and reaction particulars were gathered for every suspected ADR case using standard reporting forms [10]. The data comprised of patient's first name initials, gender and age which was categorized as pediatric with age ranging from 0-12 years, adolescent with 13–17-year, adult with age between 18-65 years, or geriatric with over 65 ages. In addition, their weight and relevant clinical background like co-morbidities, previous drug allergies any known history of adverse drug reactions, and pertinent medical history was recorded in the patient's case sheets alongside the evaluation from their previous consultations during admission.

Drug information was noted, which forms a part of clinical record, including the name(s) of the medications, dosage forms, frequency, administration route, indication, therapy duration, start date, last date, dosing, and other medications including self-medications and herbal therapies during that time span. As any new symptom(s) occurring in the patient which were considered to be drug induced, and not due to the disease itself or its complications, were regarded as suspected drugs causing ADRs. The available information was consulted with respective health care professionals where necessary to provisionally confirm these suspected drugs causing ADRs. In addition, within a patient's hospital stay (in-patients) or a course of therapy (out-patients), observed symptoms or signs were continuously analyzed to determine their association with the administration of pharmacotherapy.

Details of the reaction was analyzed which included describing the adverse reaction or problem, organ system affected, issues with the reaction date such as the onset date, duration, clinical symptoms presented, what was done regarding therapy including whether the drug was stopped, dose decreased, or not changed at all, de-challenge and re-challenge information pertaining to ADR management. [11]. Further, the suspected ADRs were categorize using the WHO-UMC Causality Assessment Scale, as Certain, Probable/Likely, Possible, Unlikely, Conditional/Unclassified, and Unassessable/Unclassifiable [12]. ADRs were also categorized on the basis of severity and preventability using modified Hartwig and Siegel severity scale [13]. Each ADR was assessed in terms of its outcome such as recovered/resolved, recovering/resolving, not recovered/not resolved/ongoing and others. The gathered information was assessed for their quality based on the important details listed and their reliability. This information was then organized and condensed in a systematic manner and were checked for completeness as well as credibility and correctness. The suspected ADRs which were eligible under PvPI guidelines were documented and reported to Indian Pharmacopoeia Commission, Ghaziabad via the VigiFlow software to generate Individual Case Safety Reports (ICSRs). Following the reporting process, the study findings were compiled and presented using tables, pie charts, and bar diagrams, reflecting appropriate proportions and percentages. Strict confidentiality was maintained throughout, regarding particulars of involved patients.

Results

During the study period, we observed and analyzed a total of 526 adverse drug reactions. The distribution of ADRs considering the demographic details of patient, is shown in Table 01. From a total of 526 cases, males comprised slightly over half with 260 (49.4%) and females constituted 266 (50.6%). The cohort between 18-65 years (adult) had the greatest share of ADRs at 75.3%, with geriatrics contributing next at 13.7%. Children aged 0 to 12 years (pediatrics) comprised 6.7% of the adverse drug reactions, and adolescents aged between 13 and 17 years contributed an additional 2.7%.

Table 1: Distribution based on demographics.

Category	Number of ADRs (n = 526)	Percentage (%)
Gender		
Male	260	49.4%
Female	266	50.6%
Age group		
Pediatrics	35	6.7%
Adolescents	14	2.7%
Adults	396	75.3%
Geriatrics	81	15.3%

On analyzing the suspected drugs, antibiotics were the prominent class causing ADRs followed by anti-cancer drugs, miscellaneous drugs, analgesics, hormones & related drugs and other classes

summarized in Table 02 with corresponding counts and percentages.

Table 2: Suspected drugs causing ADRs

Antibiotics (n=114)	Amoxicillin+Clavulanic acid, Levofloxacin, Ceftriaxone, Azithromycin, Cefixime, Cefpodoxime, Cefuroxime, Cefoperazone+Sulbactam, Ofloxacin, Piperacillin+Tazobactam, Clarithromycin, Ciprofloxacin, Amikacin, Rifaximin, Doxycycline, Tetracycline, Clindamycin, Linezolid, Faropenam
Anticancer drugs (n=66)	Cisplatin, Rituximab, Gemcitabine, Vincristine, Methotrexate
Miscellaneous drugs (n=61)	Pregabalin+Nortriptylline, Naproxem+Domperidone, Chlordiazepoxide+Clidinium, Calcium citrate, Benfotiamine, Pantoprazole+Flunarizine, Ferrous fumarate, Methylcobalamin
Analgesics (n=53)	Paracetamol, Tramadol, Dicyclomine+Mephenamic acid, Diclofenac, Aceclofenac, Etoricoxib
Hormones & related drugs (n=47)	Prednisolone, Hydrocortisone, Deflazacort, Teneligliptin, Dexamethasone, Metformin, Glibenclamide, Glimepiride
Antidepressants (n=39)	Escitalopram, Amitriptyline, Sertraline, Mirtazapine, Paroxetine, Duloxetine
Antihypertensives (n=31)	Amlodipine, Telmisartan, Cilnidipine, Olmesartan, Losartan
Antipsychotics (n=25)	Olanzapine, Aripiprazole, Quetiapine, Palperidone, Clozapine
Diuretics (n=23)	Spironolactone+Torasemide, Furosemide, Furosemide+Lasilactone
Anticonvulsants (n=18)	Levetiracetam, Phenytoin, Lacosamide, Carbamazepine, Valproic acid, Topiramate
Antitubercular drugs (n=13)	Bedaquiline, Rifampicin, Pyrazinamide
Beta blockers (n=11)	Metoprolol, Labetalol, Timolol, Propranolol
Proton pump inhibitors (n=08)	Esomeprazole, Rabeprazole
Antihistaminics (n=06)	Levocetrizine, Fexofenadine, Montelukast, Cetrizine
Antiemetics (n=04)	Ondansetron, Domperidone
Antianxiety (n=04)	Clonazepam, Etizolam, Lorazepam
Hypolipidaemics (n=03)	Rozuvastatin, Atorvastatin

The System Organ Classes (SOCs) most commonly affected by ADRs were the gastrointestinal tract (28.71%), skin (26.42%), and central nervous system (20.34%). These three systems accounted for the majority of organ involvement, indicating their particular susceptibility to adverse drug effects in the studied population (Figure 01).

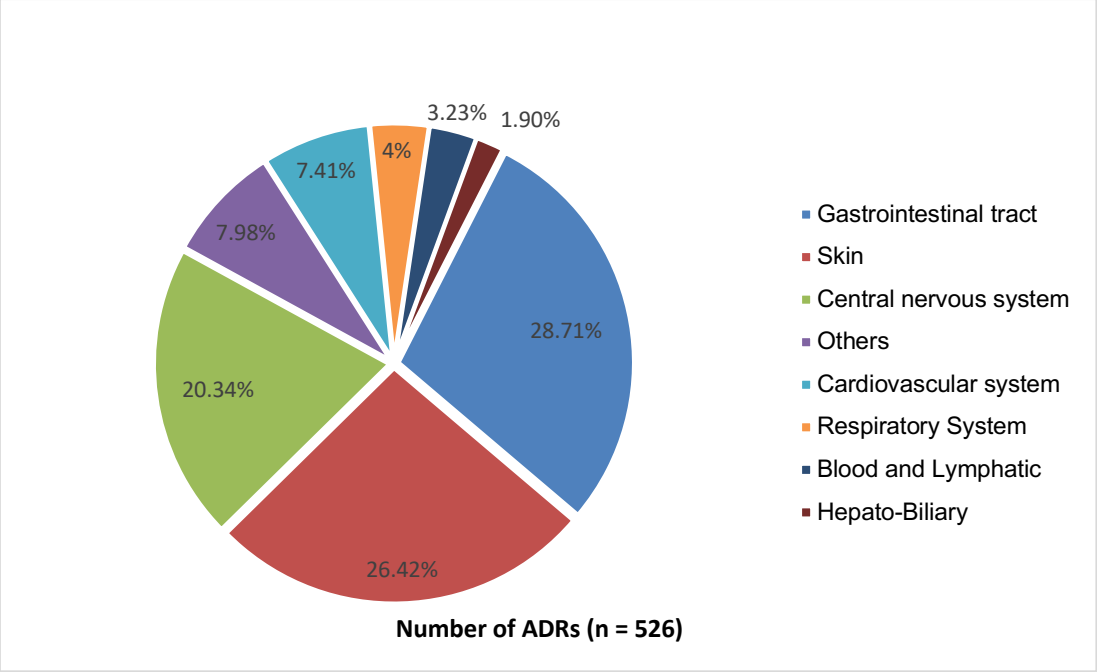

Figure 1: System Organ system involvement in adverse drug reactions

Causality assessment showed that most adverse drug reactions were classified as Possible (48.29%) or Probable/Likely (41.26%), with only 4.75% deemed Certain. The remaining cases fell into other categories (Figure 02). In terms of severity, 57.83% of ADRs were moderate, followed by mild cases at 41.83%. Preventability analysis revealed that 60.84% of ADRs were probably preventable, 38.78% were definitely preventable, and only 0.38% were not preventable, as shown in Figure 03 and 04 respectively.

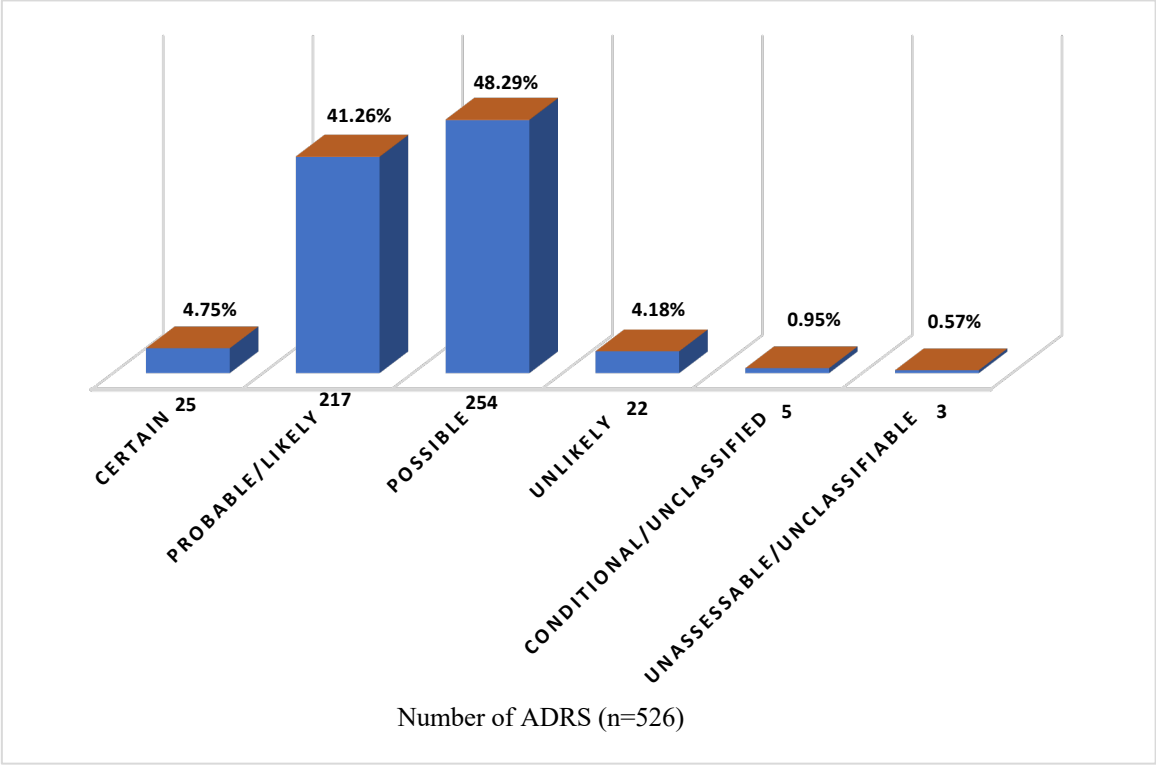

Figure 2: Causality of reported ADRs

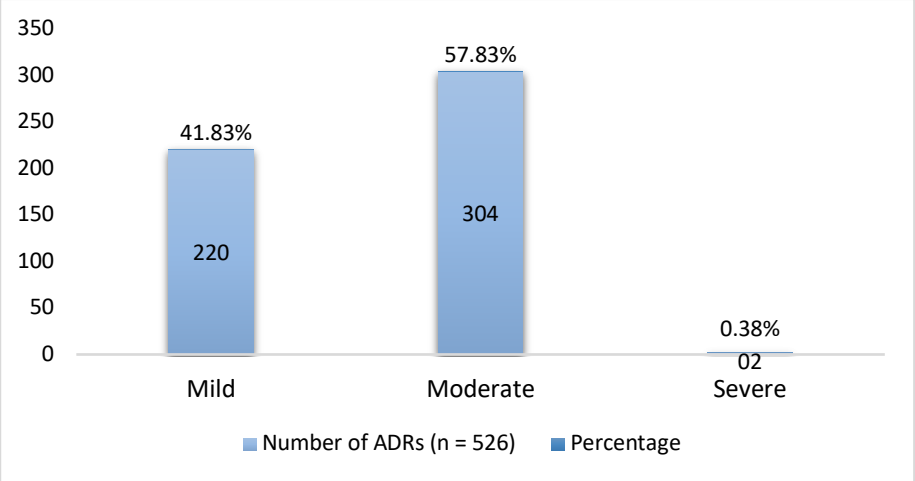

Figure 3: Severity assessment of ADRs

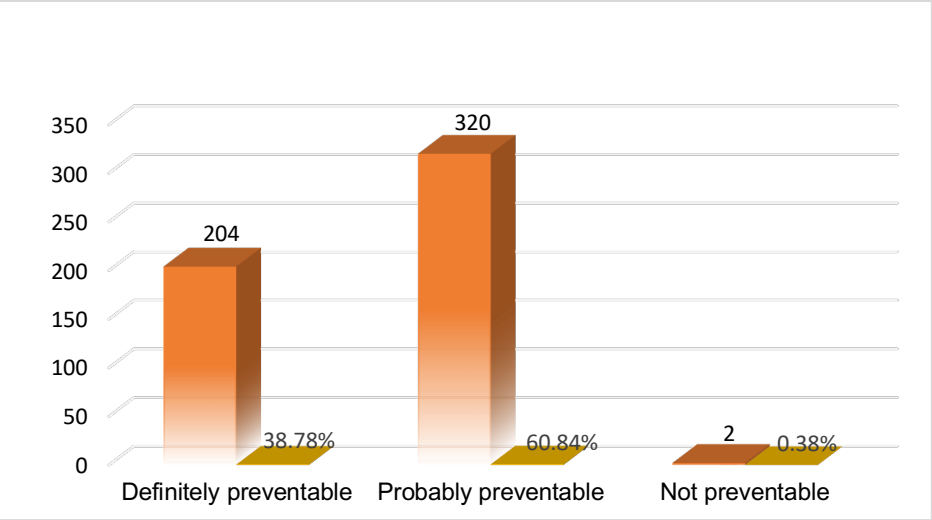

Figure 4: Preventability assessment of ADRs

Concerning the management of ADRs, not changing the drug dose was the most common approach taken with a prevalence of 52.85%. In 44.11% of instances, the believed medication was discontinued. Other measures like substitution or dose reduction made up for the rest of the percentage (Figure 05).

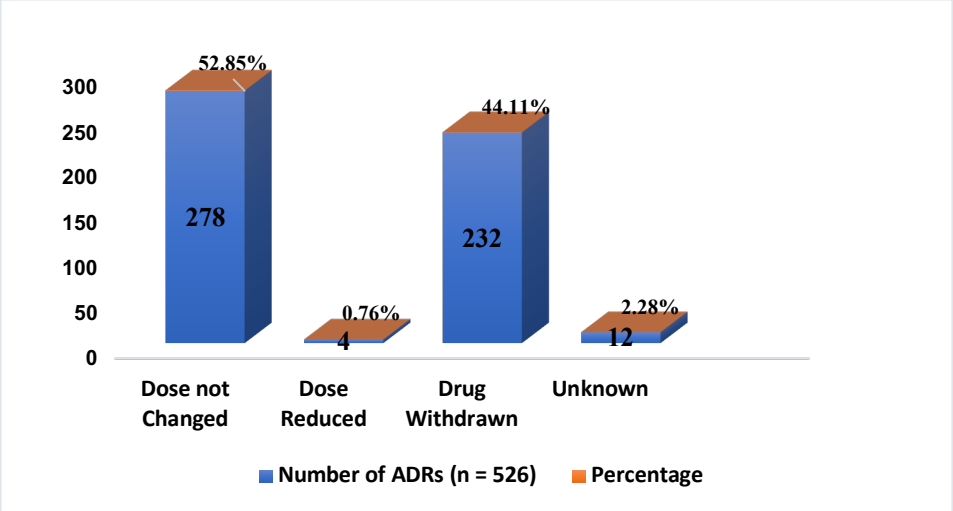

Figure 5: Action taken with suspected drugs

The results associated with adverse drug reactions indicated a high resolution or recovery rate. A considerable number of ADRs were documented as Recovering/Resolving (56.50%) and 20.72% had Recovered/Resolved completely along with other categories as detailed in Table 03.

Table 3: Outcomes of ADRs

Parameter	Number of ADRs (n = 526)	Percentage
Outcome		
Recovered / Resolved	109	20.72%
Recovering / Resolving	297	56.50%
Not Recovered / Not Resolved / Ongoing	58	11.02%
Recovered/Resolved with sequelae	41	7.80%
Fatal	00	00%
Unknown	21	3.99%

Discussion

Adverse drug reactions remain one of the most pressing challenges in the medical sector, contributing to increased treatment costs, clinical complications, and affecting healthcare efficiency. In India, the Pharmacovigilance Programme of India (PvPI) plays a pivotal role in addressing this issue by collecting and analyzing ADR data, facilitating risk communication, and implementing corrective measures to enhance patient safety. As part of a national initiative, our tertiary care hospital in Bihar reported 526 ADRs to PvPI through its Adverse Drug Reaction Monitoring Centre (AMC) in the duration of two years, employing a criteria-based reporting approach. This proactive engagement highlights the shared responsibility of healthcare professionals in advancing PvPI's mission of promoting safe and effective medication use across the country.

As per the collected details, there was no significant difference in ADR occurrence among males (49.4%) and females who were slightly higher (50.6%). This suggests that there was almost even exposure across both genders for our study population. As with some Indian studies, [14] and [15] from Northeast and South India, respectively, noted a slightly higher prevalence—around 8% more—in females. This change may be caused by differences in population demographics, region-specific prescribing habits, or healthcare-seeking behavior unique to the area.

According to several pharmacovigilance studies, the highest prevalence of adverse drug reactions was seen in the adult population. This is due to their higher rates of attending hospitals and greater healthcare utilization compared to children, teenagers, and older patients. The results derived from the study had parallels with some of earlier works [16-18] and were opposed in another study [15] which argued that geriatrics were more exposed.

Analysis of the suspected drugs revealed that antibiotics were the leading contributors to adverse drug reactions in our study. This trend aligns with findings reported by Shakur et al., in an earlier study from the same institution, where antibiotics were similarly identified as a prominent class associated with ADRs [19]. Supporting this trend, there are some more studies, including a study done in a South Korean teaching hospital also found that each of those drug classes was maximally of all antibiotic-related ADRs [20,21]. In this study, following antibiotics other drug categories such as anti-cancer drugs, miscellaneous drugs, analgesics, hormones and related drugs, and other classes contributed to the overall ADR burden. These distributions, highlights the need for heightened pharmacovigilance across these key drug groups—particularly antibiotics, given their widespread use and potential for adverse reactions. The significance of ADR reporting from all departments and units for system-wide assessment and tracking of adverse drug reactions is illustrated by this study. This also supports more investigation into creating workable solutions to lessen the effects of ADRs. Throughout the period, the patients were routinely followed-up and the therapy results were discussed with the attending physicians to obtain comprehensive information on the suspected drugs causing adverse reactions.

On analyzing the system organ system, we found that gastrointestinal tract (GIT) was the most commonly affected system, aligning with findings from several other studies [22,23]. However, this contrasts with the observations of Fredy et al., who reported skin manifestations as the most prevalent [24]. In our study, skin-related ADRs ranked second, which is consistent with the findings of M. Venkatasubbaiah et al [23].

The WHO-UMC causality assessment scale was used to conduct causality assessment, one of the most important aspects of pharmacovigilance. Our study suggests that the "possible" category encompassed the majority of ADRs. This finding aligns with observations from other studies conducted in tertiary care teaching hospitals, where most reported ADRs were similarly classified as "possible" using the same assessment tool. [14,18,20,25]. This substantiates the persistent difficulties encountered in attempting to make a

definitive connection between a medication and an adverse drug reaction in practice settings where polypharmacy, other medical conditions, and the natural course of disease progression can all complicate causal relationships. Assessing the severity of adverse drug reactions is essential for determining the need for clinical intervention, treatment modification, or enhanced monitoring. In our analysis, 57.83% of ADRs were classified as moderate in severity, indicating that these reactions may require therapeutic adjustments or supportive care but are not immediately life-threatening. Mild ADRs accounted for 41.83%, typically involving transient symptoms that resolve without significant medical intervention. These severity patterns are consistent with findings from other observational studies. [26,27]. Assessment of preventability helps improve drug use and patient safety. In this study out of the 526 averagely recorded cases of ADRs, most were categorized under probably preventable, which were 60.84%. This was followed by definitely preventable cases which were 38.78%. Only a very small percentage (0.38%) were deemed not preventable. Similar patterns have been documented in other observational studies [20,28].

Assessing clinical workflows and the safety of the patients within the practice involves understanding the processes in place for managing adverse drug reactions. According to our findings, 52.85% of instances had the medication dosage left intact, indicating that a sizable percentage of adverse drug reactions experienced were either mild, resolved on their own, or controlled without the need for treatment modifications. On the other hand, for a noteworthy 44.11% of cases, the implicated drug was discontinued which shows an effort to address more serious or enduring reactions. A reduction in dosage was noted only in 0.76% of the cases, which may suggest that clinicians either found reduction less effective or chose complete withdrawal when an ADR was documented. Additionally, 'Unknown action' categories were noted in 2.28% of cases, suggesting a need for more thorough documentation. The majority of adverse drug reactions had good outcomes. Clearly, most patients experienced 'Recovering/Resolving' (56.50%) or 'Recovered/Resolved' (20.72%) reactions to the treatment. The hospital's ADR management strategies appeared to be positively impacting patient recovery, given the high rate of favorable outcomes. However, in some patients (11.02%) the reactions were found to be 'Not recovered/ongoing' with a minuscule fraction (7.80%) 'Recovered/resolved with sequelae', and in 3.99% of cases, the outcome was recorded as 'Unknown.' This once more indicates that additional thorough tracking and documentation along with active case management would bolster future assessments. Similar trend has been seen in other studies also with either recovered or recovering from the reactions [19,23].

The healthcare systems are placing greater emphasis on pharmacovigilance, risk minimization strategies, and post-marketing surveillance. However, despite these efforts underreporting remains a persistent challenge across healthcare settings in India. The reasons attributed to under-reporting includes insufficient time due to clinical workload, lack of information and knowledge about reporting system and the significance of spontaneous reporting, fear of legal repercussions, low perceived impact: A belief that individual reports do not contribute meaningfully to public health or regulatory action reduces motivation, all contribute to the issue at hand [14,29]. Resolving the problem of underreporting of adverse drug reactions requires special consideration since ignoring this problem puts patients at risk, in addition to compromising the effectiveness and safety of medications. To improve reporting rates, experts recommend targeted interventions such as continuous medical education (CME), simplified digital reporting platforms, and stronger institutional support through policy mandates and performance-linked incentives. In addition, streamlining the reporting workflows can aid in the improvement of pharmacovigilance systems because more developed nations have more advanced legal frameworks for reporting adverse drug reactions, more reports of adverse drug reactions are made. This indicates that a robust operational framework, coupled with ongoing training, can greatly enhances the effectiveness of these systems [14, 29,30].

Conclusion

This study makes a valuable contribution to the regional pharmacovigilance repository by presenting a comprehensive analysis of adverse drug reaction patterns observed in a tertiary care hospital in Bihar. It highlights the vital importance of a robust and responsive pharmacovigilance framework in protecting patient health. While ADRs continue to pose a significant clinical challenge, the findings demonstrate that timely detection, systematic documentation, and proactive management can effectively reduce harm and enhance therapeutic outcomes.

Since its recognition by the Indian Pharmacopoeia Commission (IPC) in December 2012, our Adverse Drug Reaction Monitoring Centre (AMC) has worked diligently to promote awareness and reporting. Through a series of sensitization initiatives—including seminars and workshops for healthcare professionals, as well as street shows targeting consumers and non-medical audiences—the AMC has fostered a culture of vigilance across the institution.

Although notable progress has been achieved, further strengthening of ADR monitoring systems is essential. Encouraging spontaneous and consistent reporting by clinicians through streamlined communication channels will be key to advancing patient safety and optimizing treatment protocols.

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