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A Prospective Study on Adverse Drug Reaction- Monitoring, Reporting, Patient Counselling on Safe Medication Practice in A Tertiary Care Hospital

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Abstract:

- ***Background:***

Adverse Drug Reactions (ADRs) remain a critical challenge in clinical therapeutics, significantly impacting global morbidity, mortality, and healthcare costs. In the Indian context, the Pharmacovigilance Programme of India (PvPI) serves as the primary regulatory framework for identifying and mitigating these risks.

- ***Objective:***

This study aimed to evaluate the incidence, clinical patterns, and severity of suspected ADRs, perform rigorous causality assessments, and implement a structured pharmaceutical counseling framework to enhance medication safety in a tertiary care setting.

- ***Methodology:***

A prospective, non-interventional observational study was conducted across the Inpatient Departments (IPD) of Orthopedics and General Surgery at Arunai Medical College and Hospital (October 2025–February 2026). Out of 728 screened patient records, suspected ADRs were documented using the CDSCO reporting tool. Causality was validated via the WHO-UMC scale and Naranjo's Probability Scale, while severity was stratified using the Modified Hartwig and Siegel Scale.

- ***Results:***

A total of 80 ADRs were identified, representing an incidence rate of 10.98%. Demographic analysis revealed a male predominance (63.75%) and a higher susceptibility within the geriatric and middle-aged cohorts (mean age: 53.6 \pm 21.1 years). Antimicrobials (23.75%) and Analgesics (15%) were identified as the primary pharmacotherapeutic triggers. The most frequent clinical manifestations were gastrointestinal (39.2%), with constipation being the predominant symptom. Severity assessment categorized 56.25% of reactions as "Mild" and 43.75% as "Moderate." Causality analysis classified the majority of cases (66.25%) as "Probable."

- ***Conclusion:***

The study underscores a notable ADR burden in surgical and orthopedic settings, frequently exacerbated by polypharmacy. These findings advocate for an integrated pharmacovigilance approach—led by clinical pharmacists—emphasizing active surveillance and patient education to pre-emptively manage medication-related risks and optimize therapeutic outcomes.

Keywords: *Adverse Drug Reaction, Pharmacovigilance, Patient Counseling, PvPI, Suspected Drug.*

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I. INTRODUCTION

➢ *Adverse Drug Reaction (ADR):*

Adverse Drug Reactions (ADRs) are unintended, harmful responses to medicines occurring at normal doses used for prevention, diagnosis, or therapy. Unlike side effects, ADRs may be severe, unpredictable, and sometimes life-threatening. Globally, ADRs contribute significantly to hospital admissions, prolonged hospital stays, increased treatment cost, and morbidity.

An ADR is nuanced and varies slightly between different scientific authorities. According to the WHO (2005), an ADR is any 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 physiologic function.

➢ *Pharmacovigilance*

According to the World Health Organization (WHO), Pharmacovigilance is the science and activities concerned with the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. Pharmacovigilance has been adopted globally to encompass the entire lifecycle of a medicinal product, from its initial pre-clinical development through to its widespread use in the general population.

- *Scope and Objective of Pharmacovigilance:*

✓ To create a nation-wide system for patient safety reporting.
✓ To identify and analyses new signal from the reported cases.
✓ To analyse the benefit - risk ratio of marketed medications.
✓ To generate evidence-based information on safety of medicines.
✓ To support regulatory agencies in the decision-making process on use of medications

- *The Role of Pharmacovigilance and Institutional Reporting:*

✓ *Signal Detection:*

Spontaneous reporting in hospitals is the primary source of safety signals for new drugs.

✓ *Detection of Rare Events:*

Reactions occurring at rates of 1 in 10,000 or 1 in 50,000 can only be identified once the drug is used in the "real world" population.

✓ *Vulnerable Populations:*

Tertiary hospitals provide data on safety in children, the elderly, and pregnant women—groups often excluded from pre-marketing trials.

✓ *Economic Impact:*

Identifying ADRs early in a hospital setting can prevent extended stays and reduce the institutional financial burden.

➢ *Methods of Monitoring ADR*

Pharmacovigilance employs various methods to monitor, detect, and assess adverse drug reactions (ADRs) to ensure the safety and efficacy of medications. These methods can be broadly categorized into passive and active surveillance, targeted spontaneous reporting, comparative observational studies, and clinical trials.

➢ *ADR Reporting Systems:*

Adverse Drug Reaction (ADR) reporting systems are critical components of pharmacovigilance, facilitating the collection, assessment, and monitoring of suspected adverse effects associated with medications. These systems serve as vital mechanisms for healthcare professionals, patients, and other stakeholders to report ADRs to regulatory authorities and pharmaceutical companies.

➢ *Components of ADR Reports:*

Adverse Drug Reaction (ADR) reports are crucial documents in pharmacovigilance, containing essential information to facilitate the assessment and management of suspected adverse effects associated with medications. These reports are typically submitted by healthcare professionals, patients, or consumers to regulatory authorities or pharmaceutical companies.

- *A Well-Documented Report Includes Several Key Components:*

✓ *Patient Information:*

Patient information forms the foundation of an ADR report, providing demographic details such as age, gender, and relevant medical history. This includes information on underlying conditions, previous drug allergies, and current therapies. Patient identifiers are often anonymized to protect confidentiality while ensuring that sufficient clinical context is provided to understand the reported adverse event.

✓ *Description of the Adverse Reaction:*

A comprehensive description of the adverse reaction is crucial for assessing its severity, clinical manifestations, and impact on the patient's health.

- Symptoms and Signs**:** Detailed description of the adverse event, including onset, duration, and progression.
- Severity: Assessment of the adverse reaction's severity using standardized scales or clinical judgment.
- Outcome**:** Information on the outcome of the adverse event, such as recovery, hospitalization, or long-term consequences.

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✓ *Information on Suspected Drug(s):*

Clear identification of the suspected drug(s) associatedwith the adverse reaction is essential for determining causality and assessing the drug's safety profile. This includes:

- Name of the Drug: Exact name, formulation, strength, and route of administration.
- Dose and Duration: Details of drug dosage, frequency of administration, and duration of therapy at the time of the adverse event.
- Temporal Relationship: Timeline linking drug administration to the onset of the adverse reaction.

➢ *Who Can Report?*

All healthcare professionals, including doctors, dentists, pharmacists, nurses and other healthcare professionals are requested to report all suspected adverse reactions to medicines (including vaccines, complementary medicines) particularly serious ADRs and those related to new medicines. Consumers should be encouraged to report all suspected adverse drug reactions to their healthcare provider.

➢ *What to Report?*

ADRs resulting from prescription medicines, (OTC) medicines, complementary medicines and vaccines should be reported. Ideally serious, undocumented and unexpected ADRs are to be reported. If there is any doubt about whether or not an ADR has occurred and should be reported, it is always best practice to submit a report as causality does not need to have been established.

➢ *When to Report an ADR?*

Healthcare professionals are encouraged to report suspected ADRs even when they do not have all the facts or are uncertain that the medicine is definitely responsible for causing the reaction. However, healthcare professionals should note that even if all the facts are not available at the time of reporting, the minimum information required for a valid case (i.e. information about the patient, suspected medicine, the reaction and information about the reporter) should always be included in the report.

➢ *Why to Report?*

As a healthcare professional, it is a moral and ethical responsibility to report suspected adverse reactions associated with pharmaceutical products to safeguard public health.

➢ *Where to Report?*

CDSCO offers a multiple user-friendly way to submit a report:

- Reporting through ADR nearest ADR Monitoring Centers (AMCs) of PvPI using appropriate ADR Reporting Form such as 'Medicines Side Effect Reporting Form for Consumers' & 'Suspected Adverse Drug Reaction Reporting Form for Healthcare Professionals'. Serious Adverse Event following immunization can also be reported in Serious AEFI case Notification For available on http://www.ipc.gov.in
- Reporting through Online portal through the PvPI website
- Reporting through Mobile application using ADR PvPI App
- Reporting through Toll-Free Helpline number (call: 1800-180-3024)

➢ *Objective*

- To assess the type, severity of the reported Adverse Drug Reaction (ADRs).
- To document and report Adverse Drug Reaction (ADR) to the AMC (Adverse drug Monitoring Centre) using suspected adverse drug reaction reporting forms.
- To counsel patients regarding their medications, possible Adverse Drug Reaction (ADR).
- To promote awareness about Adverse Drug Reaction (ADR) reporting among healthcare professionals and patients.
- To provide patient counseling and improve safety: Empowering patients through education to recognize and report ADRs
- To create a nation-wide system for patient safety reporting.
- To identify and analyses new signal from the reported cases
- To analyses the benefit - risk ratio of marketed medications.
- To generate evidence-based information on safety of medicines
- To support regulatory agencies in the decision-making process on use of medications
- To communicate the safety information on use of medicines to various stakeholders to minimize the risk
- To improve the Quality of patient life.
- To promote rational use of medicine.

➢ *Need For Adverse Drug Reaction Reporting:*

Adverse Drug Reaction (ADR) reporting is an essential part of patient safety and clinical practice, especially in tertiary care hospitals, where a large number of complex cases are treated using multiple medications. These hospitals play a central role in detecting, assessing, and reporting ADRs to strengthen the national pharmacovigilance system such as High patient load and polypharmacy, Early detection of serious and rare reactions, Enhance Patient Safety, Provides valuable clinical data, Educational and training role, Supports pharmacovigilance system and Strengthens hospital pharmacovigilance Unit.

II. METHODOLOGY

The primary objective of this study is to monitor, identify, and document Adverse Drug Reactions (ADRs) through a passive surveillance approach while enhancing patient safety through structured counseling. As a prospective, non-interventional study, it observes patients in real-time under standard care conditions without any experimental deviation from the physician's prescribed treatment.

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➢ *Study Design and Setting:*

Non interventional Prospective observational study conducted as part of Pharmacovigilance Programme of India (PvPI)

➢ *Study Site*

The study will be conducted in the inpatient Department of Orthopaedics and Department of Surgery of, (Arunai Medical College of Hospital, Velu nagar, Thenmathur, Tiruvannamalai-606 603.) which provides a diverse patient demographic and a wide range of pharmacological interventions.

➢ *Study Duration*

The data collection phase will span 4 months, from November 2025- February 2026

➢ *Study Population*

The study population for this research comprises patients admitted to the Inpatient Departments (IPD) of Orthopedics and General Surgery at(Arunai Medical College of Hospital, Velu nagar, Thenmathur, Tiruvannamalai-606 603.). These departments were specifically selected due to the high clinical relevance of drug monitoring in surgical settings.

- *Patients in These Wards Typically Undergo Intensive Pharmacological Management Involving:*

✓ *Multiple Drug Classes:*

Extensive use of NSAIDs, opioids, broad-spectrum antibiotics, and prophylactic anticoagulants.

✓ *Complex Procedures:*

Physiological stress from surgical interventions which may alter drug metabolism and increase susceptibility to adverse events.

✓ *Extended Monitoring:*

The inpatient nature of these departments allows for a rigorous, prospective observation of drug effects from the point of admission through the postoperative recovery phase.

➢ *Inclusion Criteria and Exclusion Criteria:*

To maintain the integrity of the data, the following criteria define the study participants:

- *Inclusion Criteria*

✓ All patients (irrespective of age and gender) admitted to the Orthopedics and Surgery IPDs during the study period.
✓ Patients prescribed at least one medication for their surgical or orthopedic condition.
✓ Patients with pre-existing conditions that mimic ADRs:
✓ Patient or caregivers who are willing to provide informed consent.

- *Exclusion Criteria*

✓ Patients admitted for less than 24 hours (short-stay or day-care procedures).
✓ Patients with pre-existing organ failure (conditions that mimics ADRs) where symptoms might overlap with ADRs, making causality assessment difficult.
✓ Patients who are unconscious or unable to communicate and lack a caregiver participation.
✓ Patients with incomplete medical records.

➢ *Sample Size*

A total of 728 patient records were reviewed during the study period, of which 80 cases were identified with suspected adverse drug reactions.

- The overall incidence of ADRs in the study population was 10.98% (n=80).

➢ *Materials and Tools:*

The following validated tools and material are utilized for the data collection and causality assessment process:

- Tools: Used the standard ‘Suspected ADR Reporting form’ recommended by the Central Drugs Standard Control Organization (CDSCO) for recording the reaction details.
- Reporting Sources: Spontaneous reports from healthcare professionals (HCPs), patients, and patients' relatives.
- Confidentiality: Personal identifiers were masked, and analyses were conducted at a group level to maintain full anonymity.
- Consent: Individual patient consent was exempted as it was a non-interventional study with no personal information disclosed
- Patient Information Leaflets (PILs): Customized materials used during the counseling sessions

➢ *Analysis & Assessment Scales:*

Causality Assessment: Relationship between drugs and reactions was determined using:

- WHO-UMC Scale: For standardized global causality assessment
- Naranjo’s Algorithm: To determine the probability of the drug causing the ADR.

✓ Process: Data were recorded and computerized in Microsoft Excel following PvPI protocols.
✓ Severity Assessment: Categorized into seven levels (mild, moderate, or severe) based on the Hartwig Scale.
✓ Statistical Analysis: Data were analyzed using Microsoft Excel

➢ *Study Procedure*

The workflow of the study is divided into three critical phases:

- *Phase1:*

Detection and Reporting: In this passive surveillance model, ADRs are identified through spontaneous reports from healthcare professionals, Patients or from their guardians during daily ward rounds. No clinical intervention or change in therapy is suggested by investigator.

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- *Phase 2:*

Documentation and assessment: Once a suspected ADRs is identified, the patient history, medication records, and laboratory data are collected. Each ADR is then analyzed on basis of Causality, Severity.

- *Phase 3:*

Patient counseling: Patients suspected with ADRs were provided counseling regarding the safe use of medications and the importance of reporting adverse drug reactions. The counseling includes basic information about prescribed drug such as indication, dose, duration, possible side effects, precautions, and measure to be taken in case of adverse events.

➢ *Ethical Considerations*

The study is conducted in accordance with approval from the Institutional Research Council (IRC) of ARUNAI MEDICAL COLLEGE & HOSPITAL, Velu nagar, Thenmathur, Tiruvannamalai – 606 603

III. RESULT

Spontaneous ADR reports were collected and analyzed during 4 months at the AMC.

A total of 80 ADR reports were generated from 728 patients. The occurrence of ADRs dominated among male 63.75% (51) than female patients 36.25% (29) (table 1). Maximum number of ADRs were reported from the breadwinner group i.e., patients aged between 32 and 75 years, and the overall mean age of the patients was 53.6 ± 21.1years. A peak of ADR reports was attained in December with 37 reports, which decreased to 17 in January. (Figure 1)

Table 1 Demographic Parameter Among the Patients Developing ADRs

Parameters	**Number of patients with ADRs, n (%)**
Total ADRs	80
Age Group:	
0-32	14(17.5%)
32-75	50(62.5%)
>75	16(20%)
Sex:	
Male	51(63.75%)
Female	29(36.25%)

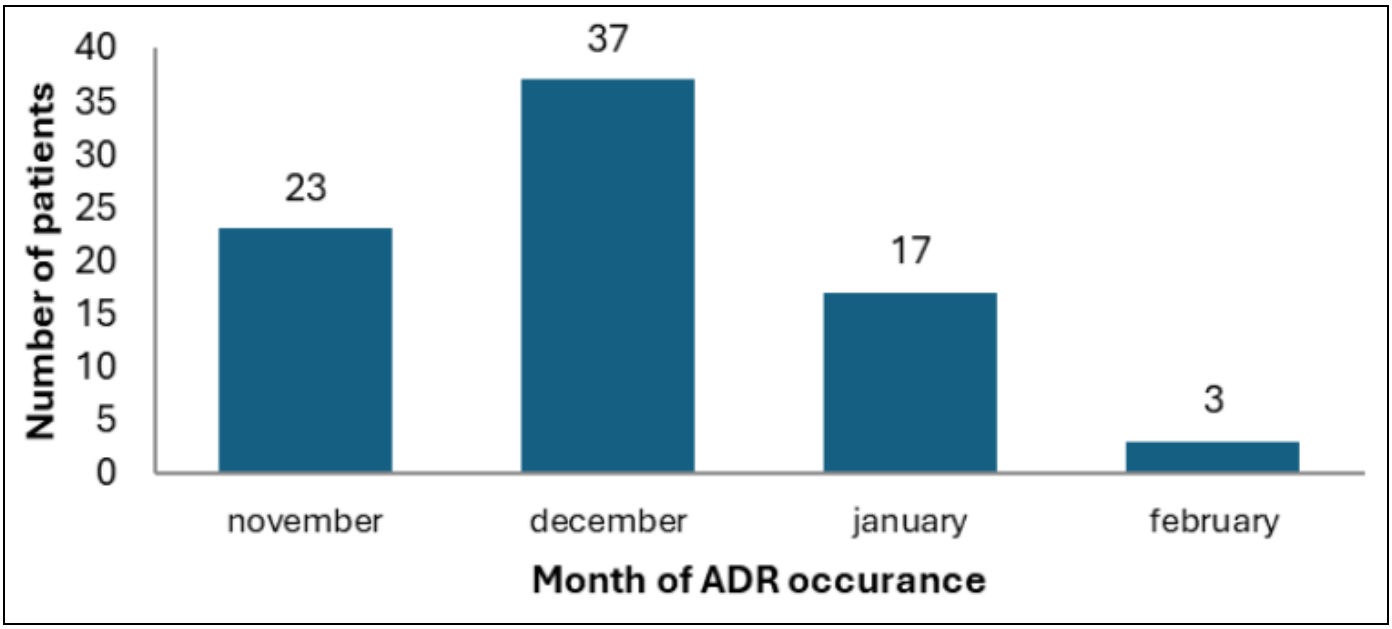

Fig 1 Frequency of Type of ADRs Reported Per Month.

The reported adverse drug reactions were associated with various pharmacological drug classes, including antibiotics, analgesics, NSAIDs, antihypertensives, antidiabetics, antiepileptics, and other central nervous system drugs. Antibiotics are commonly used to treat infections and are frequently implicated in ADRs due to their widespread use.

In total, 80 drugs were implicated in causing the ADRs, and Antibiotic were associated with the maximum number of the ADRs (23.75%) followed by the drugs of Analgesic (15%) and NSAIDs (%10). (Figure 2)

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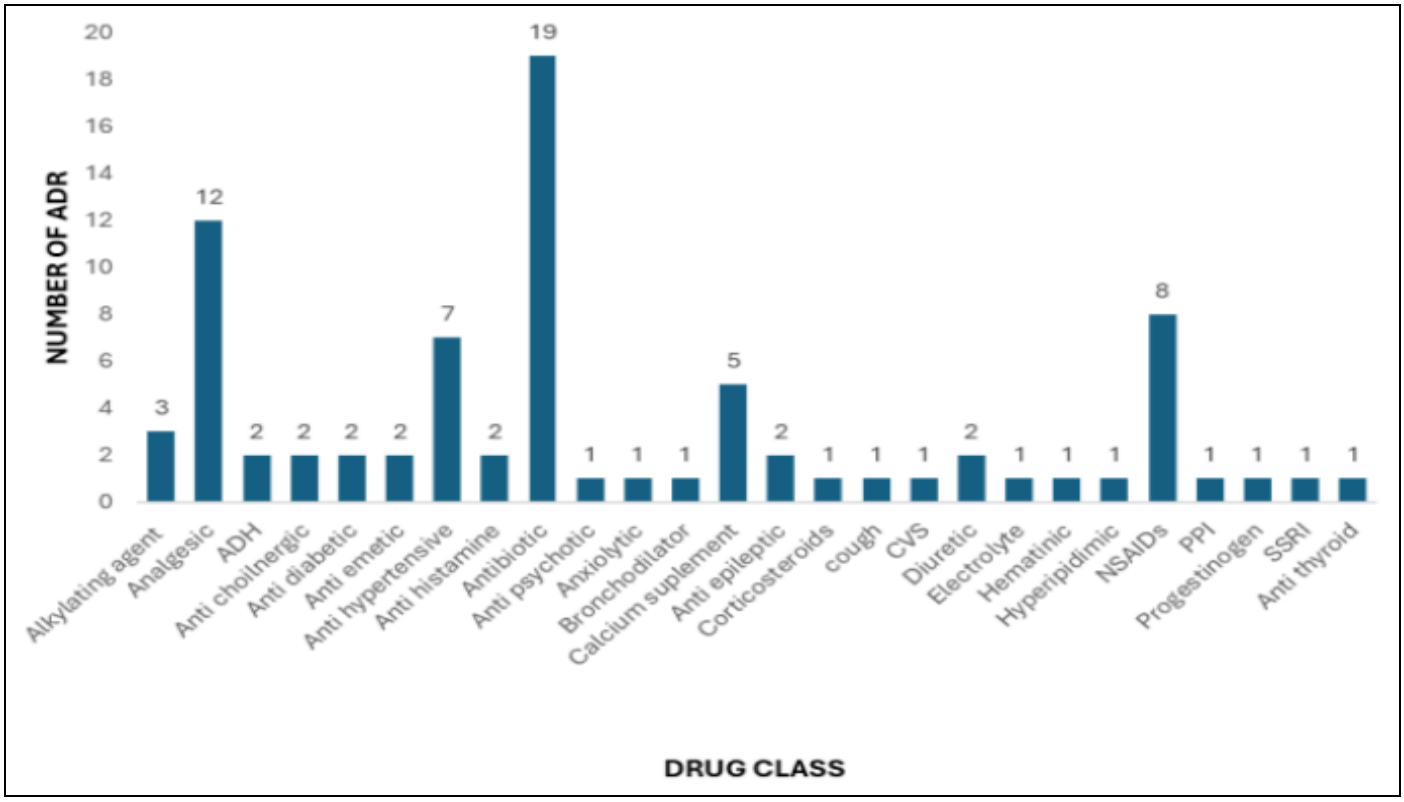

Fig 2 Occurrence of ADRs Related to the Pharmacological Drug Classes

Organ-system–based classification and frequency analysis of adverse drug reactions are essential to identify the most commonly affected systems and detect safety patterns. This approach helps in understanding the safety profile of the drug, supports clinical monitoring, and improves patient counseling.

(Table 2) presents the types of ADRs reported in various system organ classes (SOCs). The ADRs of Gastrointestinal Disorder were most common among all SOCs followed by Nervous system Disorder.

Table 2 Frequency of ADR Symptoms Based on the Involvement of Organ System

System Organ Class	ADR symptoms n (%)	Most Common ADRs (n)
Gastrointestinal disorders	31 (39.2%)	Constipation (12), Gastritis/GI irritation (6), Nausea & vomiting (4), Diarrhea (9)
Nervous system disorders	14 (17.7%)	Drowsiness (5), Headache ± dizziness (3), Agitation/Irritability (2), Restlessness (4)
Renal and urinary disorders	12 (15%)	Polyuria (2), Hematuria (2), Creatinine spike (2), Oliguria (1), Proteinuria (4), Hyperuricemia (1)
Metabolic & electrolyte disorder	9 (11.4%)	Dehydration (3), Dry mouth (2), Hypokalemia (1), Hypoglycemia (1)
Cardiovascular disorders	5 (6.3%)	Hypertension (3), Tachycardia (1), QT prolongation (1)
Respiratory disorders	7 (8.9%)	Dry cough (3), Throat irritation/dryness (3) Persistent cough (1)
Hepatobiliary disorders	3 (3.8%)	Hepatotoxicity (1), Elevated ALP (1), Elevated ALT (1)
Musculoskeletal disorders	3 (3.8%)	Leg edema with tenderness (2), Shoulder/hip pain (1)
Peripheral vascular disorder	3 (3.75%)	Pedal edema (1), Leg edema (2)
General disorders	3 (3.8%)	Loss of appetite (2), Fatigue-like symptoms (1)
Endocrine/breast disorders	1 (1.3%)	Breast tenderness (1)
Injury/procedural complication	1(1.3%)	Injection site pain (1)

The list of drugs most frequently associated with the reported adverse drug reactions (ADRs) showed that tramadol was the most commonly suspected drug, particularly associated with constipation, anxiety, drowsiness, dehydration and hypoglycemia.

Constipation was the most frequently observed ADR, with tramadol and its injectable formulation contributing to the majority of cases, followed by Ultracet and Shelcal. Dehydration was mainly associated with tramadol and the combination analgesic zerodol-P. Diarrhea was commonly reported with ceftriaxone injection, chymoral forte and

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ferrisone, while dry cough and throat irritation were predominantly linked to nebicard and montelukast. Rare but clinically significant ADRs such as QT prolongation and rhabdomyolysis were suspected with cefuroxime and rosuvastatin, respectively.

Overall, analgesics, antibiotics and cardiovascular drugs constituted the major classes of drugs implicated in ADR occurrence in the study population. (Table 3)

Table 3 Most Frequently Associated Drugs with ADR Symptoms at an AMC

ADR symptom (n)	Name of suspected drug for the ADR (n)
Constipation (13)	Tramadol (5), Inj. Tramadol (3), Ultracet (2), Shelcal (2), Alprax (1)
Dehydration (3)	Tramadol (2), Zerodol-P (1)
Diarrhea (3)	Inj. Ceftriaxone (1), Chymoral forte (1), Ferrisone (1)
Drowsiness / Sedation (3)	Tramadol (1), Clonazepam (1), Haloperidol (1)
Dry cough / Throat irritation (3)	Nebicard (2), Montelukast (1)
Headache / Dizziness (3)	Mannitol (2), Metronidazole (1)
Hypertension (2)	Zerodol (2)
Hypokalemia (2)	Inj. HAI (1), Inj. HM (1)
Vomiting (2)	Chymoral forte (1), Labetalol (1)
Anxiety (2)	Tramadol (2)
Gastritis / GI irritation (2)	NSAIDs (1), Ciprofloxacin + Alprax (1)
Creatinine spike (2)	Shelcal (1), Cefuroxime (1)
Dry mouth (2)	Shelcal (1), Paciano (1)
Polyuria (2)	Tolvaptan (1), Inj. Mannitol (1)
Peripheral edema / swelling (2)	Nebicard (1), Amlong (1)
Sleep disturbance / Insomnia (2)	Montelukast (1), Gentamycin + Metronidazol (1)
Injection site pain (2)	Meropenem (1), Diclofenac (1)
Leg edema / pain (2)	Glimepiride 5 mg (1), Ciprofloxacin (1)
Hepatotoxicity (1)	Paracetamol (1)
QT prolongation (1)	Cefuroxime (1)
Rhabdomyolysis (1)	Rosuvastatin (1)
Hypoglycemia (1)	Tramadol (1)

Hardwig Scale shows the severity assessment of ADR reported at the Adverse Drug Reaction Monitoring Centre (AMC) shows that the majority of reactions were mild. A total of 26 mild ADRs were reported in males and 19 in females. Moderate ADRs were the next most common with 25 cases reported among males and 10 cases among females. No severe ADRs were reported in both male and female during this study period. Higher number of ADRs was observed in male patients compared to females in both mild and moderate categories. Figure 3.

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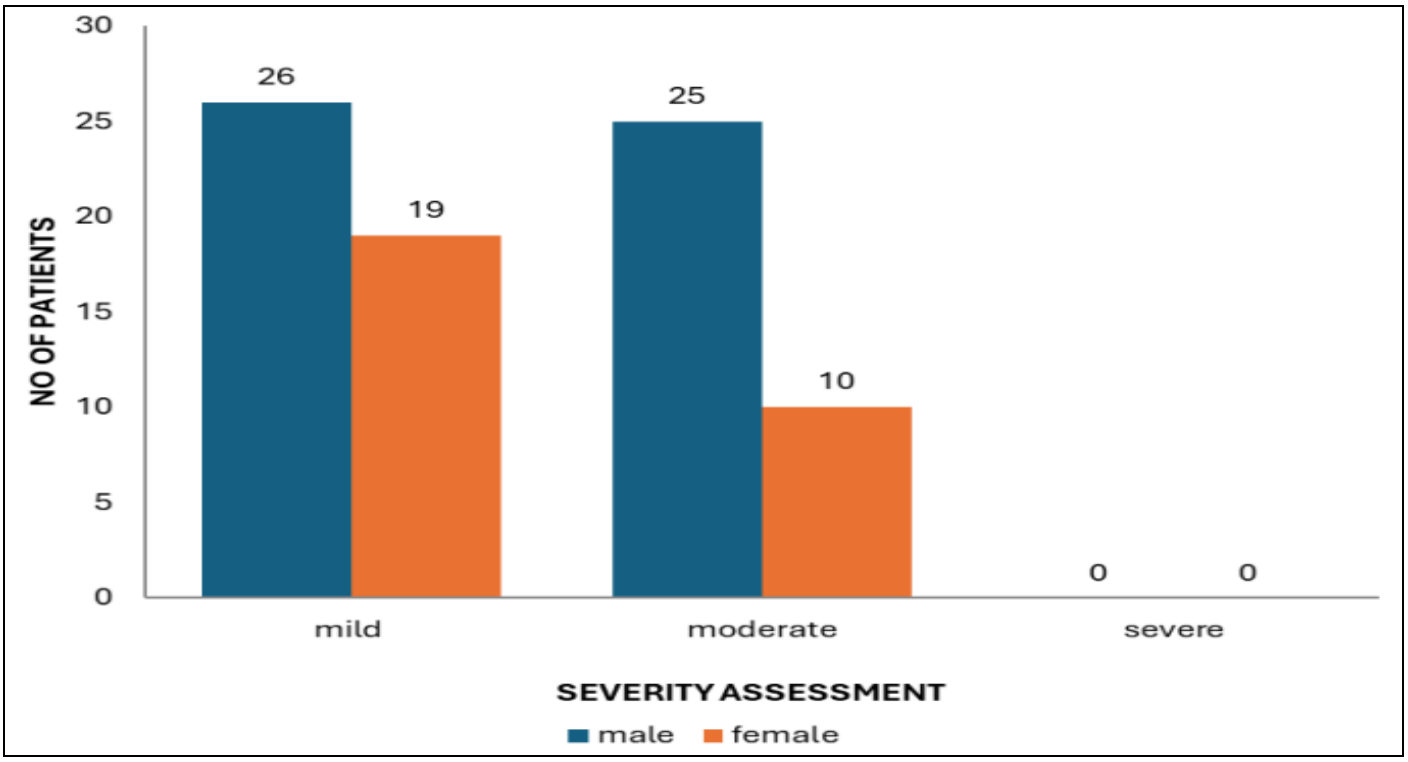

Fig 3 Assessment of severity of ADRs reported

The causality assessment of the reported ADRs classified as Certain, Probable/Likely, Possible, Unlikely using WHO-UMC Scale and Naranjo's Algorithm, shows that the majority of cases probable/likely were reported as (53cases) ADRs, more than possible which is reported as (22cases) ADRs. A smaller number of ADRs (5 cases) were assessed as certain. No cases were categorized as unlikely.

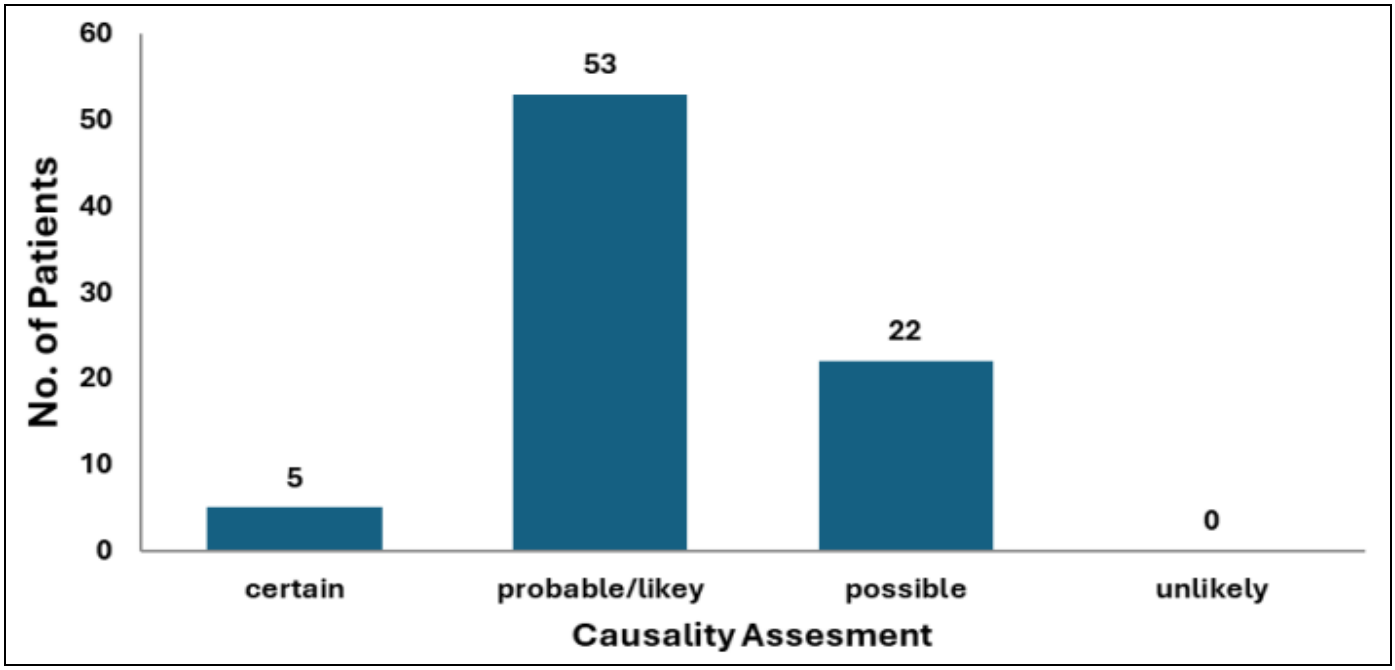

Fig 4 Assessment of Causality of ADRs Reported

IV. DISCUSSION

This prospective observational study was carried out over a period of 5 months. The 1st month was committed to preparatory activities, including finalization of the study protocol, obtaining institutional approval, preparation of data collection forms, and sensitization of healthcare professionals regarding ADR reporting. The subsequent 4months were utilized for systematic data collection and continuous monitoring of hospitalized patients for suspected ADRs.

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Adverse drug reactions (ADRs) continue to represent a significant challenge to patient safety, particularly in tertiary care hospitals where polypharmacy and complex disease conditions are common. This study conducted at AMC, A total of 80 ADRs were identified from 728 hospitalized patients in four months duration, highlighting the ongoing burden of ADRs in routine clinical practice.

In difference to some previously published studies that report a female predominance, the present study observed a higher incidence of ADRs among male patients (63.75%). This finding may be attributed to the greater number of male admissions in the selected departments and higher exposure to analgesics and antibiotics in surgical and orthopaedic department. The majority of ADRs were reported among patients aged 32–75 years, with a mean age of 53.6 ± 21.1 years, indicating that middle-aged and elderly populations are more susceptible, possibly due to comorbidities, altered pharmacokinetics and increased drug exposure.

The number of ADRs was highest in general surgery followed by orthopaedic departments. This is due to the wide use of antibiotics in these departments for the treatment of various infections ADR reporting peaked in December and then gradually decreased in the months that followed. Increased clinical workload, seasonal variations in hospital admissions, or better awareness and reporting in the study's early stages could all be contributing factors to this trend. Other hospital-based pharmacovigilance studies have documented similar temporal variations. Antibiotics were the most commonly implicated group (23.75%), followed by analgesics (15%) and NSAIDs (10%), according to a study of drug classes.

System organ class (SOC) analysis showed that gastrointestinal disorders were the most commonly affected (39.2%), followed by nervous system disorders (17.7%) and renal and urinary disorders (15%). Constipation was the single most frequently reported ADR, largely associated with opioid analgesics, particularly tramadol.

However, several other studies have observed gastrointestinal symptoms such as vomiting and diarrhoea as the most common manifestation of ADR. The majority of the patients recovered completely from the effects of ADR since most of the reactions were mild (56.25%) according to the Hartwig’s criteria.

About 43.75% of the cases were moderate ADR requiring interventions. The causality assessment of the reported ADRs according to the Naranjo scale revealed that no reactions were certain and most of them were probably with a lesser number of possible ADRs. No reactions were unlikely.

Hence, from the above discussion, we can conclude that there is a similar pattern in the occurrence of ADRs from the drugs implicated to the manifestations that occur.

Continuous education, sensitization of healthcare professionals, and strengthening institutional reporting mechanisms are essential to improve the quality and quantity of ADR reports submitted to the Pharmacovigilance Programme of India (PvPI).

V. LIMITATIONS OF THE STUDY

- *Spontaneous Reporting Bias (Passive Surveillance):*

Since this study relied largely on voluntary or spontaneous reporting, it is subject to inherent under-reporting. Many mild or well-known adverse reactions (ADRs) may have gone unnoticed or unreported by busy healthcare staff, which is a common challenge where reporting rates are estimated at only 1% compared to a global average of 5%.

- *Detection of Rare Events:*

While a sample of 728 patients is significant for a single-center study, it is likely inadequate for detecting "very rare" ADRs that occur at frequencies of 1 in 10,000 or 1 in 50,000. Such rare events typically require much larger populations or multi-center active surveillance to be identified.

- *Surgical "Masking" Effect:*

In surgical and orthopedic settings, identifying ADRs is particularly complex because clinical signs (such as rashes, swelling, or hypotension) can be obscured by surgical drapes or the effects of anesthesia. Furthermore, it is often difficult to distinguish whether a symptom, like post-operative nausea or pain, is a reaction to a drug or a result of the surgical trauma itself.

- *Absence of Post-Discharge Follow-up:*

The monitoring was limited to the inpatient duration. This means "Delayed" (Type D) reactions that manifest days or weeks after exposure, or reactions occurring after the patient returned home, were likely not captured.

- *Single-Center Generalizability:*

As the study was conducted at a single medical college and hospital over five months, the findings may not be fully representative of the diverse patient populations and prescribing patterns found across all of India.

VI. CONCLUSION

This study aims to emphasize the awareness of the health-care providers and patients on vigilant monitoring of ADRs and to encourage prompt reporting of the same to prevent the occurrence of ADRs. In Tertiary care hospital ADRs are common in middle-aged and elderly patients showing multiple medications. Antibiotics, analgesics, and NSAIDs were the major drug classes concerned, with gastrointestinal and nervous system disorders being the most commonly affected organ systems. The majority of ADRs were mild to moderate and showed a probable causal relationship with the suspected drugs.

Early detection, systematic documentation, and causality assessment of ADRs play a vital role in minimizing patient harm and improving therapeutic outcomes. The

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incorporation of patient counselling significantly contributes to medication safety by allowing patients to recognize and report adverse reactions on time.

This study gives the importance of active participation by healthcare professionals, especially pharmacists, in pharmacovigilance activities. The national pharmacovigilance system can be strengthened through consistent training initiatives, public awareness campaigns, and institutional support for ADR reporting. Even though limited by its short duration and single-centre design, the study provides valuable insight into ADR patterns in surgical and orthopaedic inpatient surroundings and the present study had some limitations in the observational study of short duration; still, this would give an insight into the current situation and of trends in ADRs in tertiary health-care centres and will help to increase awareness for further pharmacovigilance activities.

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