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An observational analysis of prevalence of adverse drug reaction in a tertiary care multispecialty hospital

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Abstract

Adverse drug reactions (ADRs) represent a major healthcare challenge requiring improved identification and management strategies. A three-month prospective observational study (January-April 2025) at a tertiary care hospital analysed ADRs using validated assessment tools for causality and severity. Over a three-month period, 15 ADRs (3% incidence) were documented among 500 admissions, a notable increase from previous reporting due to enhanced clinical vigilance. Most cases involved middle-aged males, with antibiotics being the most common cause and dermatological symptoms predominating. The majority of reactions were mild to moderate; with full recovery in 93.3% of patients .Enhanced patient safety requires comprehensive ADR monitoring and reporting systems, with clinical pharmacists playing a crucial role in identification, documentation, and risk mitigation.

Keywords: Adverse Drug Reaction(ADR), Pharmacovigilance, Drug safety, Patient Management

1. Introduction

Adverse drug reactions (ADRs) constitute unanticipated and harmful physiological responses occurring when medications are administered at recommended therapeutic dosages for prevention, diagnosis, treatment, or physiological modification. These reactions are defined by their unintended and potentially harmful impact on patient well-being[1]. Clinical data indicates that 10-20% of hospitalized patients experience at least one adverse drug reaction. In response to significant historical incidents such as the thalidomide crisis, the World Health Organization established global pharmacovigilance initiatives now spanning over 70 countries, designed to detect and minimize medication-related health risks proactively.[1,2]

The Indian healthcare system faces considerable challenges from ADRs. Research from a South Indian tertiary care center documented that ADRs represented 0.7% of total hospital admissions, with fatal reactions constituting 1.8% of all reported adverse events[3]. Despite these concerning statistics, India's ADR reporting frequency remains under 1%, significantly below the international average of 5%[4]. Further complicating this landscape is the widespread utilization of traditional and complementary medicine, including herbal preparations, which introduces additional complexity to pharmacological safety monitoring, especially when used alongside conventional pharmaceutical therapies[2,3].

2. Background

India's position as the world's fourth-largest pharmaceutical manufacturer creates distinctive challenges for adverse drug reaction monitoring[5,6]. The nation's expanding role as a clinical trial destination exposes increasingly diverse populations to novel therapeutic agents. This pharmaceutical growth, juxtaposed with economic limitations (reflected in a per capita income of approximately 3 lakh)[7], emphasizes the critical importance of early ADR identification and mitigation to ensure optimal patient outcomes while maintaining cost-effectiveness.

Pharmacovigilance infrastructure in India continues to evolve6. Addressing recognized deficiencies, the National Pharmacovigilance Program (NPP) was established in 2005 and subsequently revitalized in July 2010 under the Ministry of Health and Family Welfare's

direction8. This program, administered by the Central Drugs Standard Control Organization (CDSCO), was reconstituted as the Pharmacovigilance Program of India (PvPI)9. The initiative incorporated plans for nationwide ADR Monitoring Centers (AMCs) to strengthen medication safety surveillance systems10.

Systematic analysis of ADR underreporting has identified several significant barriers: insufficient knowledge among healthcare practitioners, limited professional engagement, inadequate access to reporting mechanisms, time constraints, and skepticism regarding the practical impact of submitted reports11

Physicians play a crucial role in the ADR reporting ecosystem. This research aims to investigate prevalence of ADR and for the awareness among healthcare professionals, who are essential to enhancing pharmacovigilance systems and improving patient safety outcomes.

3. Materials and Method

3.1 Study Design:

An observational study was carried over a period of 3 months from mid-January 2025 to mid April 2025 in Indus International Hospital at Derabassi Mohali district, Punjab, India.

3.2 Characteristics Of The Study Site:

A 200-bedded tertiary care private hospital providing inpatient services across all departments. The average daily inpatient consultancy is 60-80.

3.3 Ethical Consideration

This study was conducted after obtaining the ethical approval from the hospital of Ethics committee of Indus international Hospital.

The research encompassed a comprehensive patient population, including individuals across all genders who experienced adverse drug reactions during the study period. Specific exclusion criteria were applied to maintain research integrity, eliminating outpatients, cases involving intentional or accidental poisoning, instances of drug overdose, and patients presenting with drug abuse or intoxication scenarios. Through authorized hospital access, researchers methodically examined

prescription records within the targeted department, facilitating a structured review of medical documentation and treatment methodologies to ensure a rigorous and systematic investigation of adverse drug reactions.

3.4 ADR Reporting:

Healthcare professionals across various specialties and service types were invited to submit adverse drug reaction (ADR) reports without the burden of establishing a definitive causal relationship. The reporting process was designed to be accessible and flexible, offering multiple channels for notification.

These channels included standardized ADR reporting forms, telephone reporting, direct communication, patient referrals, and in-person consultations. The primary goal was to create a low-barrier system that encouraged comprehensive reporting of potential adverse drug events[1].

The ADR reporting enhancement strategy centered primarily on the principal investigator's active participation in daily hospital rounds, directly engaging healthcare staff to identify potential adverse drug reactions. This was complemented by targeted patient interviews during rounds, which helped uncover medication reactions that clinical staff might have overlooked. These direct engagement approaches significantly improved reporting rates.

Upon receiving a suspected ADR report, a comprehensive investigation was initiated. This involved carefully reviewing patients' medical records and conducting targeted interviews with both patients and healthcare providers to gather comprehensive and relevant information about the reported adverse event.

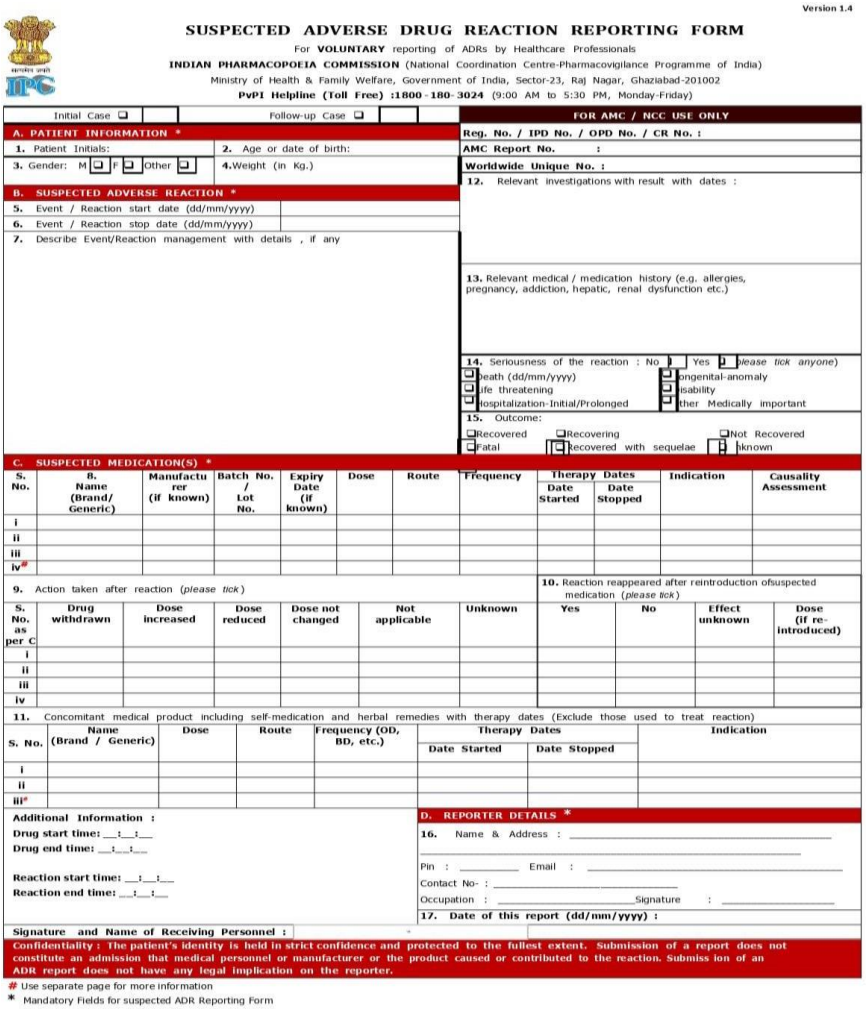
The data collection process was thorough and systematic, capturing critical details about the incident. This included a detailed description of the adverse event, specific medications involved, presenting symptoms, comprehensive medical history, allergic history, time of drug given, time of suspected adverse reaction, action taken after reaction and any concomitant medical product exposure.

All collected information was meticulously reviewed and systematically documented using a specially designed ADR documentation form. This approach ensured accurate and complete record-keeping, facilitating a robust system for tracking and analyzing potential adverse drug reactions[1].

3.5 Designing of ADR Reporting system:

ADR Documentation Form

The research team created a comprehensive ADR documentation form following Indian Pharmacopoeia Commission guidelines. This form systematically captured patient demographics, detailed event descriptions, complete medication histories with dosing regimens, and relevant medical context including comorbidities and allergies. This structured approach enabled rigorous documentation and multi- dimensional analysis of each reported incident[1].



Version 1.4

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For **VOLUNTARY** reporting of ADRs by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India)

Ministry of Health & Family Welfare, Government of India, Sector-23, Raj Nagar, Ghaziabad-201002

PvPI Helpline (Toll Free) :1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

Initial Case ❑ Follow-up Case ❑

FOR AMC / NCC USE ONLY

A. PATIENT INFORMATION *

1. Patient Initials:
2. Age or date of birth:
3. Gender: M ❑ F ❑ Other ❑
4. Weight (in Kg.)

Reg. No. / IPD No. / OPD No. / CR No. :
AMC Report No. :
Worldwide Unique No. :

B. SUSPECTED ADVERSE REACTION *

5. Event / Reaction start date (dd/mm/yyyy)
6. Event / Reaction stop date (dd/mm/yyyy)
7. Describe Event/Reaction management with details , if any
12. Relevant investigations with result with dates :
13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.)
14. Seriousness of the reaction : No ❑ Yes ❑ *(please tick anyone)*
❑ Death (dd/mm/yyyy) ❑ Congenital-anomaly
❑ Life threatening ❑ Disability
❑ Hospitalization-Initial/Prolonged ❑ Other Medically important
15. Outcome:
❑ Recovered ❑ Recovering ❑ Not Recovered
❑ Fatal ❑ Recovered with sequelae ❑ Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/ Generic)	Manufacturer (if known)	Batch No. / Lot No.	Expiry Date (if known)	Dose	Route	Frequency	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication	Causality Assessment
i											
ii											
iii											
iv#											

9. Action taken after reaction *(please tick)*

10. Reaction reappeared after reintroduction ofsuspected medication *(please tick)*

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if re-introduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication
i							
ii							
iii*							

Additional Information :
Drug start time: __:__:__
Drug end time: __:__:__
Reaction start time: __:__:__
Reaction end time: __:__:__

D. REPORTER DETAILS *

16. Name & Address :
Pin : Email :
Contact No- :
Occupation : Signature :
17. Date of this report (dd/mm/yyyy) :

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submiss ion of an ADR report does not have any legal implication on the reporter.

Use separate page for more information
* Mandatory Fields for suspected ADR Reporting Form

Figure 1: ADR Reporting Template

Criteria for Reportable ADR

The study applied the WHO definition of ADRs as unintended and potentially harmful responses occurring at standard medical dosages. This inclusive definition covers reactions from prophylactic treatments, diagnostics, therapeutic interventions, and physiological function-modifying medications, providing healthcare professionals with a comprehensive framework for recognizing, reporting, and investigating medication-related adverse events[1].

Assessment of ADR Reports

The assessment of reported adverse events followed a systematic methodology to investigate the potential causal relationship between suspected medications and observed adverse reactions. The process involved collecting comprehensive data from appropriate sources and obtaining expert opinions from clinicians and the hospital's Causality Assessment Committee (CAC).

Following initial causality assessment, each reported reaction underwent detailed analysis and evaluating severity. This approach ensured an unbiased, thorough investigation of adverse drug reactions, ultimately enhancing patient safety and supporting evidence-based medical practice.

Causality Assessment

The study used the Naranjo's assessment scale to systematically evaluate the causal relationship between suspected medications and reported adverse reactions. These validated tools enabled precise categorization of drug-reaction connections, supporting evidence-based pharmacovigilance analysis.

Naranjo's Assessment Scale[12]: Definite, probable, possible and doubtful.

Assessment of Severity

The severity of reported reactions was assessed by using CTCAE Grading [version5.0] and was categorized into mild, moderate, severe, life threatening consequences and death.

Feedback to Reporters:

After carefully analyzing the reported adverse drug reactions, individualized feedback was communicated to all reporting healthcare professionals. This acknowledgment was extended through the issuance of personalized "thank you" notes, recognizing their contribution to medication safety monitoring.

4. Results

Our analysis identified 15 documented ADRs among 500 General Medicine admissions (3% incidence) over the three-month study period. This represents a substantial improvement from historical reporting levels, which averaged only 4 ADRs annually over the preceding six years (2019-2024). This five-fold increase in detection rate stems from enhanced clinical vigilance and systematic daily monitoring procedures implemented during the study period. The principal investigator's active presence during clinical rounds facilitated immediate recognition and documentation of adverse reactions that might otherwise have gone unreported. Additionally, the introduction of increased engagement of healthcare professionals in the pharmacovigilance process further strengthened the ADR identification and reporting system.

Demographic analysis revealed a predominance of male patients (73%) compared to females (27%) [Figure 2]. Age distribution showed 60% of reactions occurring in patients aged 30-59 years, with the remaining 40% in those 60 years and above. Notably, no ADRs were documented in the 18-29 age group. All affected patients had no prior history of medication allergies or adverse reactions.

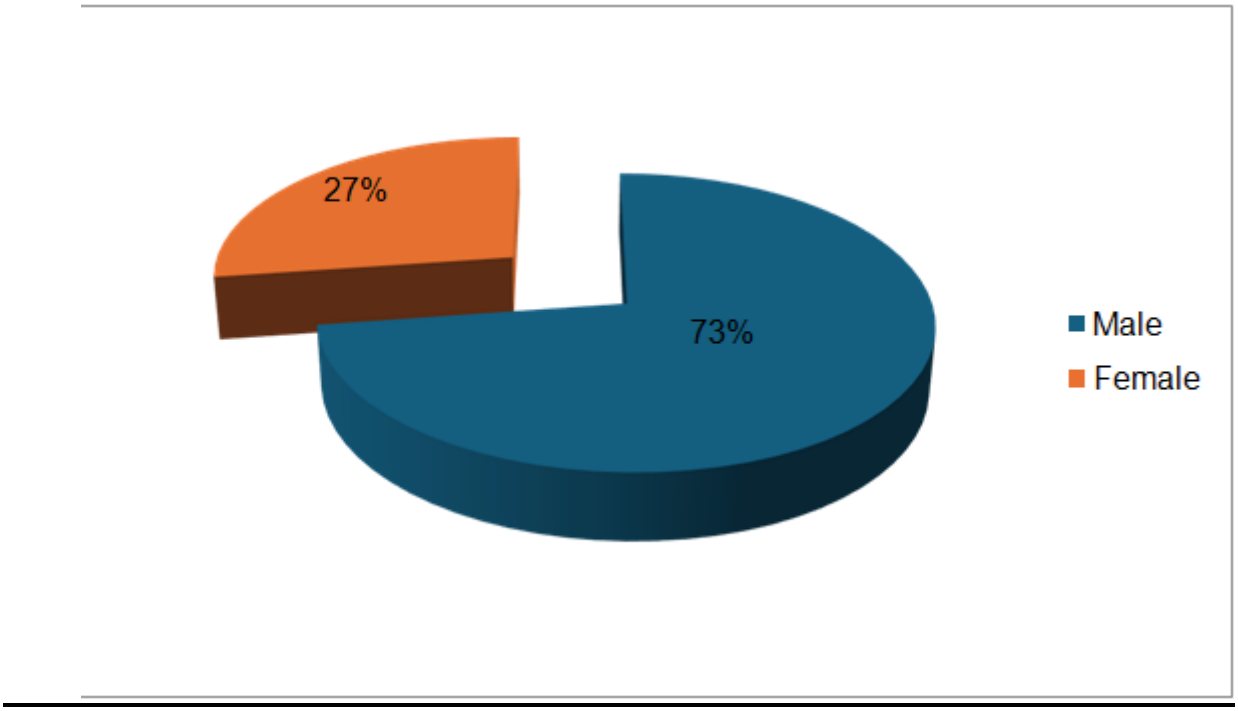


Figure 2

Medication classification revealed antibiotics as the primary culprits (40%, n=6), followed by equal distribution among nutritional supplements (13.3%, n=2), blood transfusions (13.3%, n=2), and NSAIDs (13.3%, n=2), with miscellaneous medications accounting for the remaining cases (20%, n=3). [Figure 3]

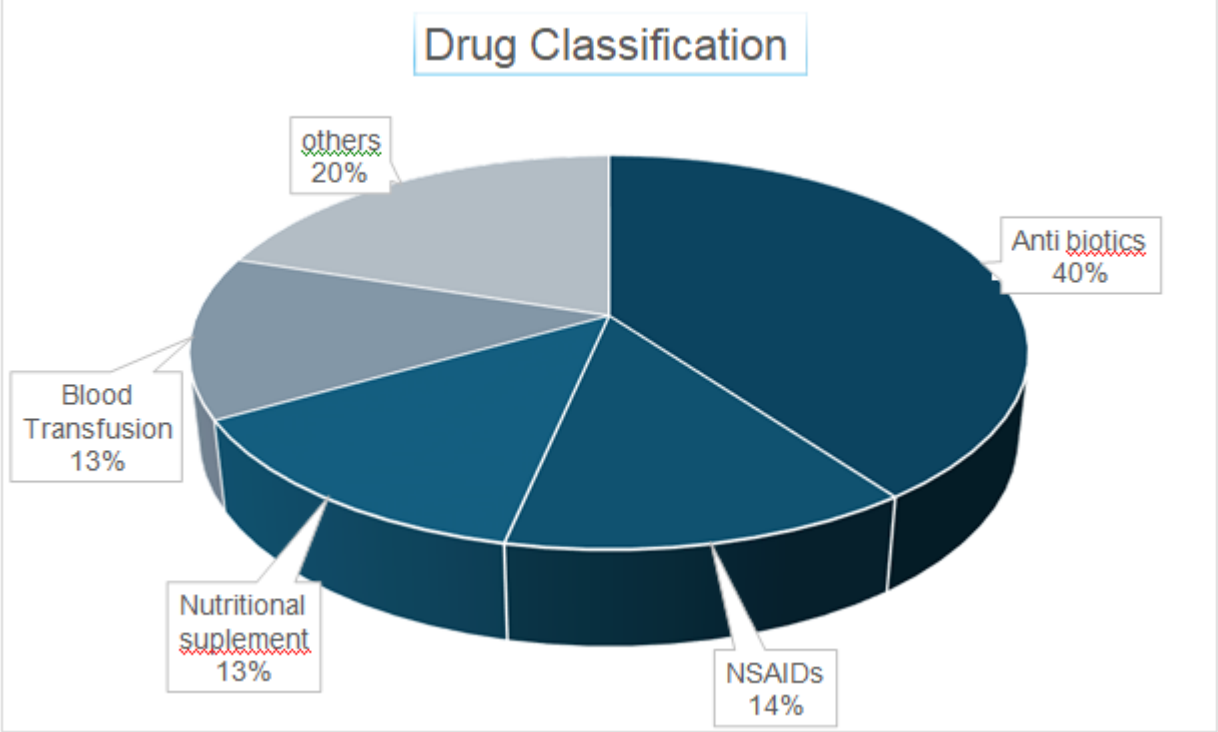


Figure 3 Medication classification of Suspected Drugs for adverse reaction.

The clinical manifestations varied considerably, with dermatological reactions predominating (35%), followed by cardiovascular effects (20%), and equal proportions of musculoskeletal and gastrointestinal disturbances (15% each). Respiratory complications constituted 10% of cases, while 5% presented as systemic reactions. [Figure 4]

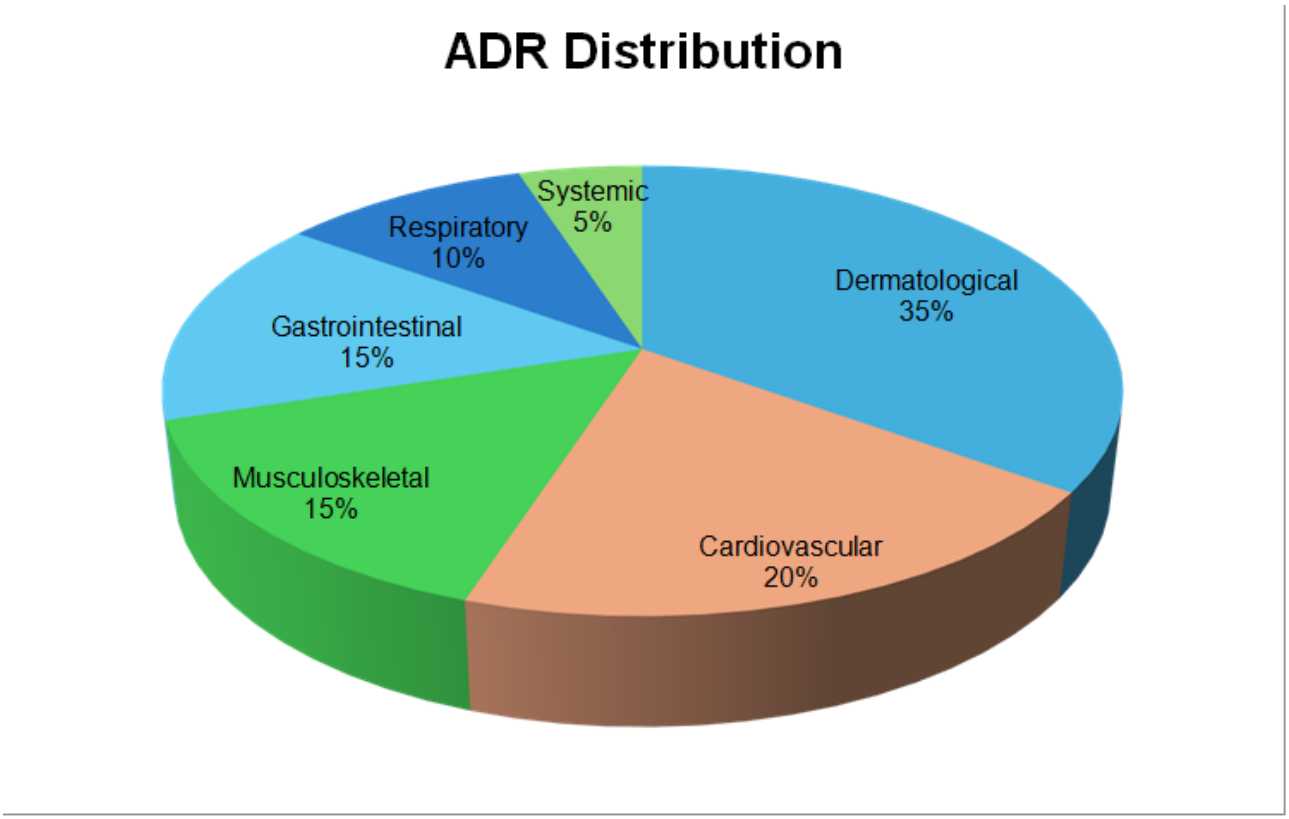


Figure 4 Distribution of symptoms of adverse drug reaction.

Causality assessment using Naranjo's algorithm classified 26% of reactions as definite, 40% as probable, 27% as possible, and 7% as doubtful. [Figure 5]

Severity evaluation using CTCAE grading demonstrated that most reactions were mild (53.3%) or moderate (33.3%), with fewer severe cases (13.3%). [Figure 6]

Regarding management strategies, medication withdrawal was implemented in 80% of cases initially. Among the 20% where dosing remained unchanged, 7% eventually required drug discontinuation due to persistent or worsening symptoms, while 13% continued therapy without further complications.

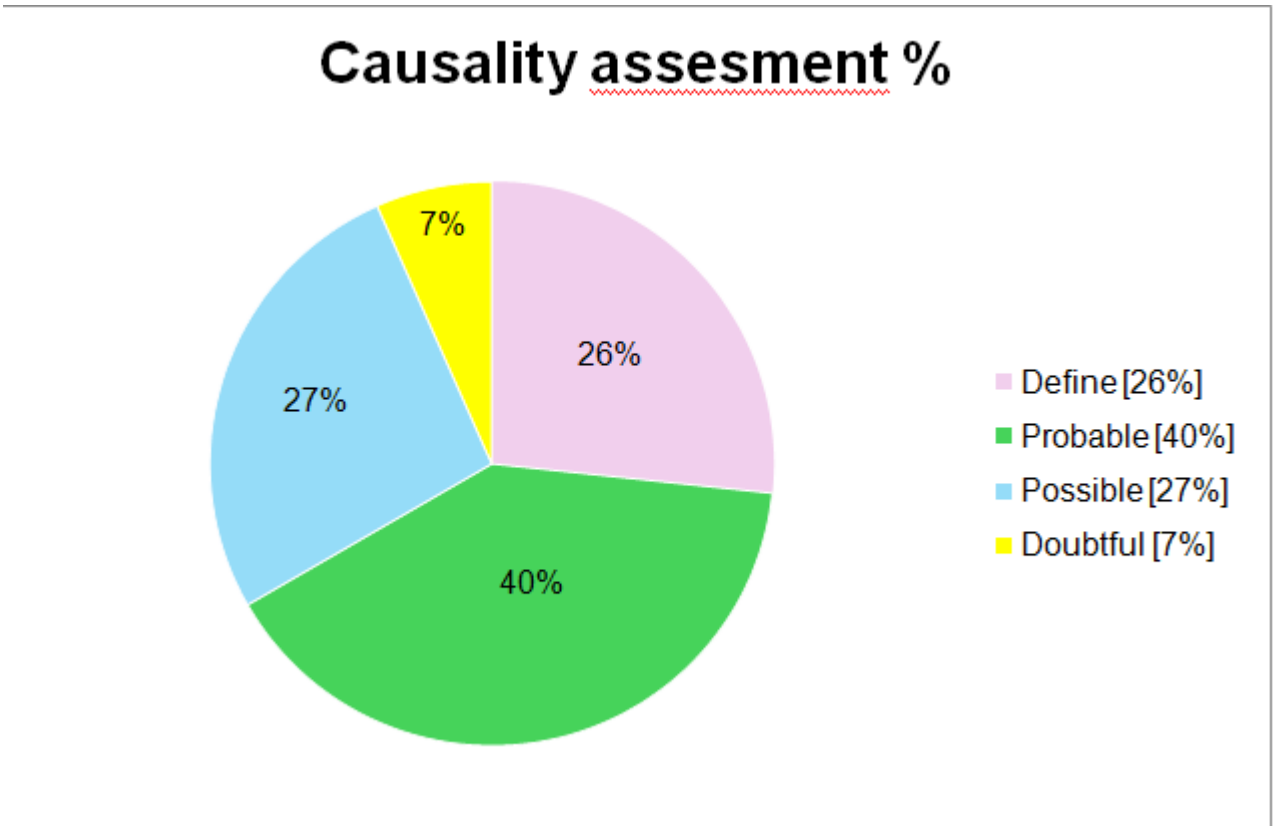


Figure 5- Causality assessment of suspected ADRs using Naranjo's scale

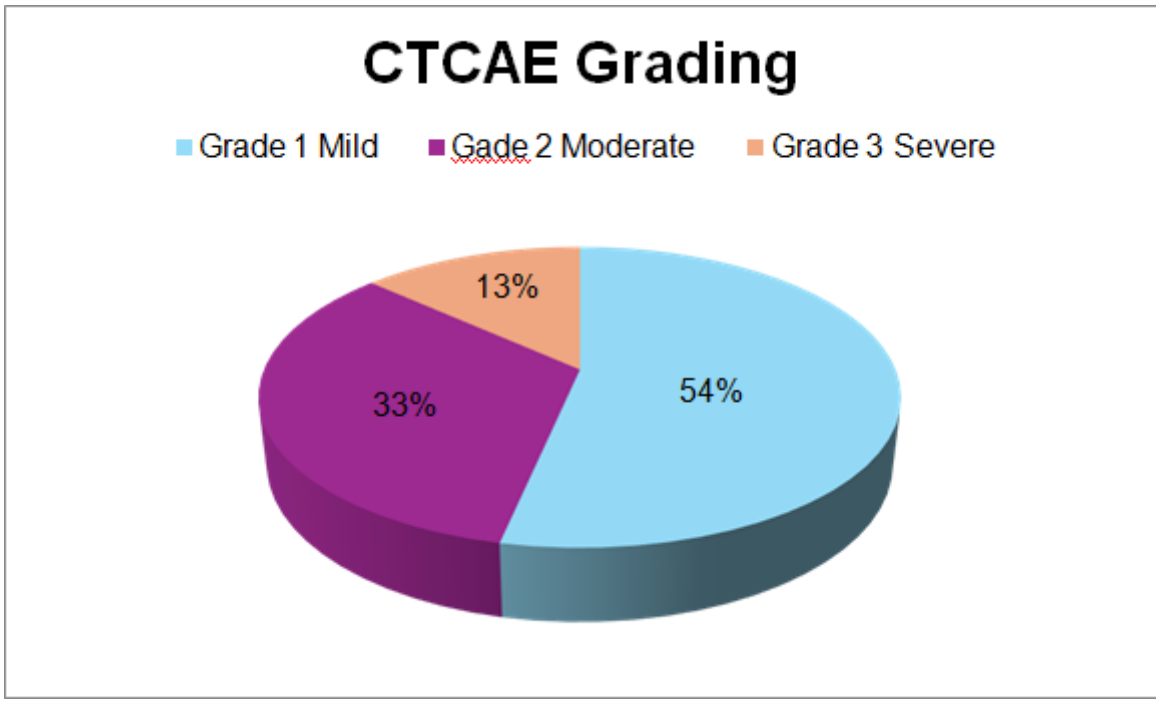


Figure 6- Severity Grading (using CTCAE grading)

5. Discussion

The incidence of suspected ADRs was found to be 3% and is comparable with the study done by Rao et al,[13] which evaluated the reports of ADRs in the inpatients at a south Indian hospital for their incidence and pattern and found that the incidence of ADRs was 2.8% in hospitalized patients.

According to the present findings the ADRs in the hospital patients were more documented in males which is consistent with the earlier report by Gupta et al[14]. Sex ratio in admitted patients might be an intervening factor but does not seem to be a major determinant.

Our causality assessment using Naranjo's scale revealed that 26% of ADRs were definite, 40% were probable, 27% were possible, and 7% were doubtful. These results contrast with Sriram's[15] study which found that 63% of ADRs were possibly drug-related whereas 37% were classified as probably or definitely related to the drug. Our findings demonstrate a higher percentage of ADRs classified as definite or probable (66% combined) compared to Sriram's study (37%), suggesting stronger causality relationships in our patient population.

Both the present study and Sriram's[15] study identified antibiotics as the leading cause of ADRs, highlighting their significant role in drug-related adverse events. However, the present study reported a higher incidence (40%) compared to Sriram's[15] findings (23%).

Under-reporting is a major problem even in western countries where the pharmacovigilance system is well established. In India the major problem is a lack of proper system of pharmacovigilance. Our ability to anticipate and prevent such ADRs can be facilitated by the establishment of standardized approaches and active reporting of suspected ADRs by all healthcare professionals including physicians, dentists, nurses and pharmacists. This could be further improved by pharmacist involvement for encouraging them through conducting educational programs on pharmacovigilance, lectures, newsletters, personalized letters, etc to aid and increase reporting of ADR.

5. Conclusion

This study underscores the urgent need to improve hospital-based adverse drug reaction reporting systems. By enhancing awareness and systematic reporting among healthcare professionals, patient safety can be significantly strengthened. We recommend implementing comprehensive medication management approaches that include detailed patient screening, thorough medical history reviews, and technology integration through electronic medical records, hospital intranet systems, and computerized reporting mechanisms. Clinical pharmacists play a pivotal role in this process, serving as essential facilitators in monitoring, reporting, and mitigating medication-related risks. Through collaborative networks and systematic surveillance approaches, healthcare institutions can create robust pharmacovigilance practices that ultimately enhance patient outcomes and contribute to safer medication use in clinical settings.

7. Conflict of Interests

Authors have no conflict of interests.

8. Authors' Contributions

PA developed and wrote the protocol, and was responsible for the data analysis, and interpretation of results. PA and HKS was responsible for data gathering, and detection and documentation of ADRs. DSL and PA was responsible for the assessment of severity and reporting of ADRs also for the assessment of causality assessment through standard scales. PKG had valuable suggestions for guideline preparations and prepared the manuscript and reviewed the data analysis and interpretation of results. All authors have read and approved the content of the manuscript.

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