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ANALYSIS OF ADVERSE DRUG REACTIONS SPONTANEOUSLY REPORTED IN A TERTIARY CARE HOSPITAL AT HOSUR TAMIL NADU, USING WHO-UMC CAUSALITY ASSESSMENT SCALE: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT: Background: Adverse drug reactions (ADRs) are a global health concern, contributing to morbidity, prolonged hospital stays, and increased healthcare costs. In India, underreporting and inconsistent causality assessment hinder pharmacovigilance. WHO UMC scale standardizes ADR classification; semi urban hospital data remain limited. **Objective:** To systematically analyze ADRs reported in a semi urban tertiary hospital in Hosur, Tamil Nadu, using the WHO UMC causality assessment scale, and to evaluate their severity, preventability, and drug class distribution. **Methods:** A prospective observational study was conducted over one year at St. Peter's Medical College & Hospital. All spontaneously reported ADRs from inpatients and outpatients were included. Data were collected using Pharmacovigilance Programme of India (PvPI) forms and assessed with the WHO UMC causality scale, Hartwig and Siegel severity scale, and Schumock and Thornton preventability criteria. **Results:** A total of 36 ADRs were documented in patients aged 9 months to 80 years, with slight female predominance. Cephalosporins (42%) were leading, followed by contrast agents (22%) and NSAIDs (11%). Dermatological reactions were most frequent, systemic events linked to contrast agents and opioids. Severity: 50% mild, 33% moderate, 17% severe, several ICU admissions. Preventability: 67% preventable, 33% not. WHO UMC classified most "Probable," fewer "Possible," none "Certain." **Conclusion:** ADRs in this semi urban hospital were mostly mild and preventable, linked to antibiotics and contrast agents; severe ICU cases demand vigilance, stronger pharmacovigilance, allergy documentation, and clinician awareness.

INTRODUCTION: Pharmacovigilance is defined by the World Health Organization as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug related problems, including herbal medicines" [3].

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Adverse drug reactions (ADRs) are a major public health concern, contributing to prolonged hospitalization, increased healthcare costs, and mortality. Globally, ADRs account for approximately 10% of hospital admissions, and 5–20% of hospitalized patients experience a serious ADR [2].

Older adults are particularly vulnerable due to polypharmacy and comorbidities, with studies highlighting their heightened risk [1]. In India, pharmacovigilance has expanded through initiatives such as the Pharmacovigilance Programme of India (PvPI), yet underreporting

remains a critical challenge. The ADR reporting rate is estimated to be below 1%, compared to a global average of 5%, limiting the detection of rare and serious reactions [5, 8]. Strengthening structured monitoring and reporting systems is therefore essential to improve patient safety.

Causality assessment is central to pharmacovigilance, providing a systematic approach to evaluate the relationship between a drug and a suspected reaction. Several algorithms exist, including the Naranjo, Jones, and Yale scales; however, the WHO Uppsala Monitoring Centre (UMC) system remains widely adopted for its standardized global applicability [7, 11]. Severity is commonly assessed using the Hartwig–Siegel scale, which categorizes ADRs into mild, moderate, and severe levels [12], while preventability is evaluated using the Schumock–Thornton criteria [13–15].

Indian tertiary care hospital studies consistently identify antibiotics, particularly cephalosporins, and non steroidal anti inflammatory drugs (NSAIDs) as leading causes of ADRs. Krishna *et al.* [4] reported antibiotics as the most frequent culprits in a retrospective study, while Yadav *et al*. [6] emphasized preventability in a prospective study from Bangalore. Venkatasubbaiah *et al.* [10] highlighted systematic ADR reporting in teaching hospitals, and Xavier *et al.* [9] underscored the importance of structured causality assessment.

Despite these findings, regional disparities persist, with most published studies focusing on urban tertiary hospitals. Semi urban and rural regions remain underrepresented in national pharmacovigilance databases. This gap is particularly relevant in semi urban hospitals such as Hosur cater to diverse patient populations with high drug utilization rates. Addressing this evidence gap is crucial to strengthen localized pharmacovigilance and improve patient safety outcomes.

MATERIALS AND METHODS:

Study Design and Duration: This was a prospective observational study conducted over a period of one year at St. Peter's Medical College & Hospital, Hosur, Tamil Nadu. The study was designed to capture all spontaneously reported adverse drug reactions (ADRs) during the study period, without any intervention in prescribing practices. The prospective design ensured real-time documentation and minimized recall bias.

Study Setting: The study was carried out in a tertiary care teaching hospital that caters to both urban and semi-urban populations. The hospital has multiple clinical departments including General Medicine, Pediatrics, Orthopedics, ENT, Radiology, and Surgery, providing a diverse patient pool with varied drug utilization patterns. This setting was chosen to generate localized pharmacovigilance data from a semi-urban region, which is underrepresented in national ADR databases.

Study Population:

Inclusion Criteria: All inpatients and outpatients of any age and either sex who developed suspected ADRs after initiation of treatment were eligible for inclusion. ADRs were identified through spontaneous reporting by clinicians, nurses, and pharmacists. However Only 36 ADRs were documented over one year, reflecting spontaneous reporting rather than true incidence; without denominator data (total patients / total Prescription) , frequency or incidence will not be estimated, highlighting underreporting as a key limitation of the study.

Exclusion Criteria:

- Duplicate ADR reports, repeat reactions in the same patient, incomplete forms, medication errors, overdose-related events, and vaccine-related reactions were excluded
- Patients with ADRs due to drug poisoning (accidental or intentional).
- Patients with ADRs attributed to alternative medical systems such as Ayurveda, Unani, Homeopathy, or Naturopathy. These exclusions ensured that only ADRs related to allopathic medications were analyzed.

Data Collection: Data were collected using the standardized suspected ADR reporting forms recommended by the Pharmacovigilance Programme of India (PvPI).

Each form captured department/ward, patient status, drug details, onset, management, dechallenge, seriousness, and final outcome. However the study focused only on documenting ADRs for implicated drugs; denominator data were not collected, so incidence or prevalence was not estimated.

ADR Reporting Process: ADR identification and reporting were performed by treating clinicians and nursing staff across inpatient wards and outpatient departments, using standardized PvPI forms. Reports were documented by trained pharmacology faculty and subsequently reviewed and validated by the institutional pharmacovigilance committee before inclusion in the dataset.

No active surveillance was conducted; reporting was voluntary, with no legal implications for healthcare professionals. Clinicians received periodic sensitization sessions on ADR recognition and documentation, and patient confidentiality was strictly maintained throughout.

Assessment Tools:

Causality Assessment:

- The WHO-UMC causality assessment scale was applied to classify ADRs into categories: Certain, Probable, Possible, Unlikely, Conditional/Unclassified, and Unassessable.
- This ensured standardized evaluation of the drug-event relationship.

Severity Assessment:

- The Modified Hartwig and Siegel scale was used to grade ADRs into mild, moderate, and severe categories.
- Severe ADRs were defined as those requiring ICU care, prolonging hospital stay, or causing life-threatening events.

Preventability Assessment:

- The Schumock and Thornton criteria were applied to classify ADRs as Preventable, Probably Preventable, or Not Preventable.
- This helped identify gaps in clinical practice where ADRs could have been avoided.

Data Analysis: All data were entered into Microsoft Excel for analysis. Results were expressed in numbers and percentages.

- Descriptive statistics were used to summarize demographic variables, drug classes, organ systems affected, severity, preventability, and causality categories.
- Frequency distributions were tabulated for drug classes and ADR types, and results were presented in tables with percentage values
- No inferential statistics or p-values were applied, as the analysis was limited to descriptive methods.

Ethical Considerations: The study protocol was reviewed and approved by the Ethics Committee of St. Peter's Medical College & Hospital. As the study involved voluntary ADR reporting without patient identifiers, formal informed consent was not required. Confidentiality of patient information was strictly maintained in accordance with PvPI guidelines.

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RESULTS:

Demographic Profile: During the one-year study period, 36 ADR cases were documented across all age groups (9 months–80 years). Adults (19–60 years) accounted for the majority, while elderly patients (>60 years) contributed significantly, highlighting their vulnerability. Pediatric cases formed a small proportion. Of the total, 20 females (55.6%) and 16 males (44.4%) were affected, consistent with reports suggesting women may be more prone to ADRs due to pharmacokinetic, hormonal, and immunological factors. ADRs were reported across multiple departments including General Medicine, Radiology, ENT, Orthopedics,

Pediatrics, and Surgery, underscoring their occurrence across diverse clinical settings.

TABLE 1: SOCIODEMOGRAPHIC PARAMETERS

Variable	Total
Age (years)	N (%)
0–18	3(8.3)
19–40	15(41.7)
41–60	10(27.8)
>60	8(22.2)
Total	36 (100)

Drug Classes Involved: Of the 36 ADR cases, cephalosporins were most frequent (15 Cases, 42%; Ceftriaxone, Cefoperazone+Sulbactam), followed by radiocontrast agents (8 Cases, 22%; Iohexol, CECT dye) often linked to systemic reactions. NSAIDs (4 Cases, 11%; Indomethacin, Naproxen) caused allergic manifestations, while penicillin + β-lactamase inhibitors (4 Cases, 11%; Piperacillin/Tazobactam) produced papular rashes and hypersensitivity.

The remaining 5 Cases (14%) involved corticosteroids, antihistamines, carbapenems, opioids, and nutritional supplements, each associated with isolated but clinically relevant ADRs.

TABLE 2: DISTRIBUTION OF SUSPECTED DRUGS AND ASSOCIATED ADRS (N = 36)

Class of drugs / drug	N (%)	Type of ADR
Cephalosporins (Ceftriaxone, Cefoperazone+Sulbactam)	15 (42)	Rash (6), itching (4), swelling (3), systemic reaction (2)
Radiocontrast agents (Iohexol, CECT dye)	8 (22)	Chills/rigors (4), tachycardia (2), hypotension (2)
NSAIDs (Indomethacin, Naproxen)	4 (11)	Rash (2), itching (1), bronchospasm (1)
Penicillin + β-lactamase inhibitors (Piperacillin/Tazobactam)	4 (11)	Papular rash (2), hypersensitivity (2)
Other drugs (corticosteroids, antihistamines, carbapenems, opioids, nutritional supplements)	5 (14)	Wheeze (1), headache (1), giddiness (1), breathlessness (1), isolated rash (1)
Total	36 (100)	

Clinical Characteristics of ADRs: The majority of ADRs were dermatological, presenting as itching, rash, and swelling, particularly with cephalosporins and NSAIDs. Systemic reactions such as chills, rigors, tachycardia, and hypotension were primarily associated with contrast agents and opioids. Respiratory manifestations, including wheeze and breathlessness, were observed with corticosteroids and vitamin injections. Neurological symptoms such as headache and giddiness were reported with vancomycin and certain antibiotics. Notably, several ADRs required ICU admission, including cases linked to Tramadol, Cefoperazone + Sulbactam, and Iohexol, highlighting the potential severity of drug reactions even in routine clinical practice.

Severity Assessment (Hartwig Scale): Severity analysis using the Hartwig and Siegel scale revealed that:

- Mild ADRs (Level 1–2) accounted for 50%, typically involving simple allergic reactions that resolved with drug withdrawal or symptomatic treatment.
- Moderate ADRs (Level 3–4) comprised 33%, requiring hospitalization or antidote administration.
- Severe ADRs (Level 5) represented 17%, necessitating intensive medical care or ICU admission.
- No ADRs reached Level 6–7, indicating that there were no cases of permanent harm or death during the study period.

TABLE 3: SEVERITY OF ADRS (HARTWIG–SIEGEL SCALE)

Severity level	N (%)	Examples
Mild (Level 1–2)	18 (50)	Simple allergic reactions resolved with withdrawal/symptomatic care
Moderate (Level 3–4)	12 (33)	Hospitalization, antidote administration
Severe (Level 5)	6 (17)	ICU admission (Tramadol, Cefoperazone+Sulbactam, Iohexol)
Very severe (Level 6–7)	0 (0)	None observed

Severe ADRs (n = 6): Six ADRs were classified as severe (Level 5) and required ICU admission. One case involved Tramadol, presenting with generalized seizures and recovering after 3 days of ICU care with anticonvulsants and supportive management.

Two cases were linked to Iohexol contrast, manifesting as acute systemic reactions (chills, hypotension, dyspnea, bronchospasm); both required 1–2 days of ICU stay, managed with oxygen, IV fluids, bronchodilators, and steroids, with full recovery.

The remaining cases were associated with Cefoperazone + Sulbactam, presenting as anaphylaxis with hypotension and severe urticaria with bronchospasm; patients received adrenaline, IV fluids, corticosteroids, and antihistamines, required 2–4 days of ICU admission, and were discharged stable. Hence all Severe ADR Cases were treated accordingly and all patients recovered well and discharged.

Preventability Assessment (Schumock Criteria): Application of the Schumock and Thornton criteria showed that 67% of ADRs were preventable or probably preventable, often related to predictable allergic reactions or inadequate test-dose monitoring, 33% were not preventable, particularly those associated with contrast agents and unpredictable infusion reactions.

This highlights the importance of allergy documentation, careful monitoring during test doses, and clinician awareness to reduce preventable ADRs.

TABLE 4: PREVENTABILITY OF ADRS (SCHUMOCK–THORNTON CRITERIA)

Category	N (%)	Examples
Preventable	12 (33)	Predictable allergic reactions
Probably preventable	12 (33)	Inadequate test dose monitoring
Not preventable	12 (33)	Contrast agent infusion reactions
Total	36 (100)	

Causality Assessment (WHO-UMC): Based on the WHO-UMC scale, most ADRs were classified as Probable (24, 67%), reflecting a clear temporal relationship with drug intake and improvement after withdrawal. Possible ADRs (12, 33%) were mainly linked to contrast agents, where alternative explanations could not be excluded. No cases were deemed certain, as rechallenge was not ethically feasible, and none were categorized as Unlikely or Unassessable.

TABLE 5: CAUSALITY ASSESSMENT (WHO-UMC SCALE)

Category	N (%)
Certain	0 (0)
Probable	24 (67)
Possible	12 (33)
Unlikely / Un Assessable	0 (0)
Total	36 (100)

All causality (WHO-UMC), severity (Hartwig and Siegel), and preventability (Schumock and Thornton) assessments were independently performed by two trained pharmacology faculty members. In cases of disagreement, consensus was reached through discussion. When consensus could not be achieved, the matter was referred to the departmental pharmacovigilance (PV) unit for expert review.

DISCUSSION: This prospective observational study conducted at a semi-urban tertiary care hospital in Hosur, Tamil Nadu, provides important insights into the epidemiology, severity, preventability, and causality of adverse drug reactions (ADRs) in routine clinical practice. By documenting ADRs across diverse age groups and specialties, our findings reinforce existing evidence from urban tertiary hospitals while addressing regional gaps in pharmacovigilance reporting.

Cephalosporins were the most frequently implicated drug class (42%), consistent with previous Indian studies where antibiotics were the leading cause of ADRs [6, 9]. Yadav *et al.* [6] reported antibiotics as the predominant culprits in a prospective study from Bangalore, while Xavier *et al.* [9] highlighted similar trends in Karnataka. The second most common group in our study was contrast agents (22%), often associated with systemic manifestations such as chills, tachycardia, and hypotension.

These findings parallel those of Arya *et al.* [11], who documented frequent contrast-induced ADRs in intensive care settings, and Zazzara *et al.* [1], who emphasized systemic risks in older adults undergoing diagnostic procedures. The predominance of cephalosporins and contrast agents underscores the need for cautious prescribing, allergy screening, and pre-procedural risk assessment.

Severity grading using the Hartwig–Siegel scale revealed that 17% of ADRs were severe, necessitating intensive care unit (ICU) admission. Acharya *et al.* [7] similarly reported ICU-level ADRs linked to cephalosporins and contrast agents in a tertiary care teaching hospital. The occurrence of life-threatening ADRs in a semi-urban setting highlights the importance of rapid response protocols, staff training, and resource allocation for ADR management.

A notable finding was that 67% of ADRs were preventable or probably preventable, often involving predictable allergic reactions or inadequate test-dose monitoring. This observation supports the conclusions of Tandon *et al.* [5], who identified underreporting and lack of awareness as major barriers to effective pharmacovigilance in India. Strengthening allergy documentation, routine use of test doses, and proactive monitoring could substantially reduce the burden of preventable ADRs. The remaining 33% of ADRs were not preventable, primarily those associated with contrast agents and unpredictable infusion reactions, reflecting the limitations of current screening tools and the need for improved predictive models.

Application of the WHO-UMC causality scale classified most ADRs as "Probable," with a smaller proportion as "Possible." No ADRs were categorized as "Certain," consistent with the ethical and clinical challenges of rechallenge protocols in routine practice. Acharya *et al.* [7] and Arya *et al.* [11] similarly reported low rates of "Certain" classification, reinforcing the utility of WHO-UMC in real-world pharmacovigilance. Our findings demonstrate that systematic application of WHO-UMC enhances the consistency and reliability of ADR classification, even in resource-constrained environments. Most published ADR studies in India have focused on urban tertiary hospitals [4, 6, 10], leaving semi-urban and rural regions underrepresented in national pharmacovigilance databases. As noted by Sahu and Das [8], regional disparities in ADR reporting hinder comprehensive drug safety surveillance. By documenting ADRs in a semi-urban hospital, our study contributes localized evidence to national pharmacovigilance efforts. Furthermore, the inclusion of pediatric and geriatric patients reflects the broad applicability of ADR monitoring across age groups. Zazzara *et al.* [1] emphasized the vulnerability of older adults to ADRs due to polypharmacy, a trend corroborated in our elderly cohort.

CONCLUSION: This prospective observational study conducted at St. Peter's Medical College, Hosur, demonstrates that adverse drug reactions are a significant clinical concern across all age groups, with a predominance in adults and elderly patients. Cephalosporins emerged as the leading drug class associated with ADRs, followed by contrast agents, NSAIDs, and penicillin combinations. Dermatological manifestations were the most common, while systemic and respiratory reactions accounted for the more serious cases, some requiring ICU admission. Severity analysis revealed that while half of the ADRs were mild, nearly one-fifth were severe, underscoring the importance of vigilance in routine prescribing and monitoring practices.

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CONFLICT OF INTEREST: The authors declare no conflict of interest.

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