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A Prospective Observational Study on Adverse Drug Reactions in A Tertiary Care Hospital

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Abstract:

Background: Adverse drug reactions (ADRs) represent a significant burden on healthcare systems, contributing to increased morbidity, mortality, prolonged hospitalization, and escalating healthcare costs. Active pharmacovigilance is essential to identify, assess, and prevent ADRs in clinical settings. This study was undertaken to systematically evaluate ADRs in a tertiary care hospital with respect to causality, severity, preventability, implicated drug classes, and organ systems affected.

Methods: A prospective observational study was conducted over six months at Nimra Hospital, Andhra Pradesh, India. A total of 76 patients from inpatient departments who experienced ADRs following the commencement of treatment were included. Data were collected using CDSCO-ADR reporting forms. Causality was assessed using the Naranjo Algorithm; severity was graded using the modified Hartwig and Siegel Scale; and preventability was evaluated using the Schumock and Thornton Scale. ADRs were classified using the A–F type classification system. Pregnant and lactating women and patients admitted for intentional or accidental poisoning were excluded.

Results: Among 76 ADR cases, 53.94% occurred in females and 46.05% in males. The highest incidence was in the 41–60 year age group (34.21%). Antibiotics were the most frequently implicated drug class (25%), followed by anticancer agents (17.10%), and cardiovascular drugs, NSAIDs, and corticosteroids (11.84% each). Gastrointestinal reactions were the most common (27.63%), followed by cutaneous (17.10%) and neurological (9.21%) manifestations. Causality assessment revealed 60.52% probable, 38.15% possible, and 1.31% definite reactions. Severity was moderate in 64.4%, mild in 34.2%, and severe in 1.3% of cases. Preventability analysis showed 82.89% of ADRs were definitely preventable. Type A (augmented) reactions predominated at 65.7%. ADRs constitute a significant public health concern in the tertiary care setting. The majority of identified ADRs were preventable and dose-related, underscoring the need for continuous pharmacovigilance, rational prescribing, and an active role of clinical pharmacists in ADR monitoring and reporting.

Keywords — Adverse drug reactions, pharmacovigilance, Naranjo algorithm, causality assessment, Hartwig severity scale, Schumock and Thornton, tertiary care hospital, antibiotics

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I. INTRODUCTION

An adverse drug reaction (ADR) is defined by the World Health Organization (1972) as 'a response to a drug that 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.' ADRs are distinct from adverse events in that they carry an implied causal relationship between the drug and the untoward outcome.

ADRs represent a major global health problem. They are a leading cause of hospital admissions, prolonged inpatient stays, and avoidable mortality. Epidemiological data consistently show that ADRs account for 5–10% of all hospital admissions, with

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incidence rising sharply among elderly and polymedicated patients. In India, reporting and systematic monitoring of ADRs have historically been inadequate, despite the establishment of the Pharmacovigilance Programme of India (PvPI) in 2010 and the subsequent expansion of Adverse Drug Reaction Monitoring Centres (AMCs) across the country.

Risk factors predisposing patients to ADRs include polypharmacy, extremes of age, compromised renal or hepatic function, genetic polymorphisms in drug-metabolizing enzymes, comorbidities, and characteristics of the drug itself. ADRs may be classified by mechanism (Type A–F and Type U) or by severity (mild, moderate, severe, lethal). Type A reactions — which are dose-related, predictable extensions of the drug's pharmacological action — account for the majority of ADRs and are, in principle, preventable through careful prescribing, dose adjustment, and therapeutic drug monitoring.

Although numerous studies on ADRs have been conducted in tertiary care settings in India, regional heterogeneity in prescribing patterns, disease burden, and patient demographics necessitates institution-specific surveillance. This prospective observational study was therefore undertaken at Nimra Hospital, Andhra Pradesh, to characterize ADRs across inpatient departments, assess their causality, severity, preventability, and type, identify the most commonly implicated drug classes and organ systems, and to strengthen local pharmacovigilance practice.

2. MATERIALS AND METHODS

2.1 Study Design and Setting

A prospective observational study was conducted over six months at Nimra Hospital, Andhra Pradesh, India — a tertiary care teaching hospital affiliated with Nimra College of Pharmacy. The study was approved by the Institutional Review Board (IRB) of Nimra College of Pharmacy, Jupudi, Andhra Pradesh.

2.2 Study Population

All patients admitted to the inpatient departments (IPD) across all clinical departments who experienced one or more adverse drug reactions following commencement of treatment were enrolled. Data were collected from 180 patients screened during daily ward rounds; 76 confirmed ADR cases were included in the final analysis.

Inclusion criteria: All inpatients who developed ADR(s) after initiation of treatment during the study period.

Exclusion criteria: Patients admitted for accidental or intentional drug poisoning; pregnant and lactating women.

2.3 Data Collection

Daily ward rounds were conducted in all inpatient departments in collaboration with junior and senior physicians. Patient demographic data (age, sex), medical history, comorbidities, complete drug treatment records (including OTC drugs and supplements), co-medications, route and dosage of administration, and clinical notes were recorded in a structured data entry format. The CDSCO Suspected ADR Reporting Form was used as the primary data collection instrument. Drug information was cross-referenced using validated online databases including Drugs.com, Up To Date, and Medscape.

2.4 Assessment Tools

Causality: Assessed using the Naranjo Algorithm. Scores: >9 = definite; 5–8 = probable; 1–4 = possible; 0 = doubtful.

Severity: Graded using the modified Hartwig and Siegel Severity Scale (7 levels: Levels 1–2 = mild; 3–4 = moderate; 5–7 = severe).

Preventability: Evaluated using the Schumock and Thornton Scale (definitely preventable, probably preventable, not preventable).

Type Classification: ADRs classified as Type A (augmented), B (bizarre), C (chronic), D (delayed), E (end of use), F (failure), or U (unclassified).

2.5 Statistical Analysis

Descriptive statistics were used throughout. Data were expressed as frequencies and percentages. Results were tabulated and compared with findings from previous published studies.

Table 1: Drug Classes Implicated in ADRs

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3. RESULTS

3.1 Drug Classes Implicated in ADRs

Table 1 presents the distribution of ADRs by drug class and gender. Antibiotics were the most frequently implicated class overall (25%), with a higher proportion in females (26.82%) than males (22.85%). Anticancer agents were the second most common class (17.10%), predominantly in males (28.57%). Cardiovascular drugs, NSAIDs, and corticosteroids each accounted for 11.84% of ADRs.

3.2 Gender Distribution

Of the 76 patients with ADRs, 41 (53.94%) were female and 35 (46.05%) were male (Table 2), indicating a female preponderance. This may be attributable to differences in pharmacokinetics, immune response, and tolerability patterns in female patients.

Table 2: Distribution of ADRs by Gender

S.No	Gender	Total ADRs (n=76) / %
1	Male	35 (46.05%)
2	Female	41 (53.94%)

3.3 Age Distribution

Patients in the 41–60 years age group had the highest incidence of ADRs (34.21%), followed by 19–40 years and 61–80 years (26.31% each), 0–18 years (11.84%), and >81 years (1.73%) (Table 3). ADRs in adults predominated over geriatric patients

Table 3: Distribution of ADRs by Age Group

S.No	Age Group	No. of Patients	Percentage (%)
1	0–18 years	9	11.84
2	19–40 years	20	26.31
3	41–60 years	26	34.21
4	61–80 years	20	26.31
5	>81 years	1	1.73

3.4 Organ Systems Affected

The gastrointestinal system was the most frequently affected organ system (27.63%), followed by other organ systems (21.05%), cutaneous reactions (17.10%), neurological (9.21%), cardiotoxicity, haematological, and ENT (6.57% each), and hepatotoxicity and musculoskeletal (2.63% each)

S.No	Class of Drugs	Male (n)	Male %	Female (n)	Female %	Total %
1	Antibiotics	8	22.85	11	26.82	25.00
2	Anticancer	10	28.57	3	7.31	17.10
3	CVS Drugs	5	14.28	4	9.75	11.84
4	NSAIDs	4	11.42	5	12.19	11.84
5	Corticosteroids	4	11.42	5	12.19	11.84
6	Hypoglycemic Agents	1	2.85	4	9.75	6.57
7	Anti-tubercular	1	2.85	1	2.43	2.63
8	CNS Drugs	0	0	2	4.87	2.63
9	Others / Infusion	2/0	5.71/0	3/2	7.31/4.87	6.57/2.63

(Table 4 – Organ Systems)

Table 4: ADRs by Organ System and Gender

Organ System	M (n)	M %	F (n)	F %	Total %
Gastrointestinal	11	30.55	10	25.00	27.63
Other Organ Systems	5	13.88	11	27.50	21.05
Cutaneous	6	16.66	7	17.50	17.10
Neurological	3	8.33	4	10.00	9.21
Cardiotoxicity	4	11.11	1	2.50	6.57
Haematological	2	5.55	3	7.50	6.57
ENT	2	5.55	3	7.50	6.57
Hepatotoxicity	2	5.55	0	0.00	2.63
Musculoskeletal	1	2.77	1	2.50	2.63

3.5 Most Frequently Reported ADRs

Tramadol-induced vomiting was the most common single-drug ADR (7.89%), followed by dexamethasone-induced hyperglycemia (5.26%), doxycycline-induced glossitis (3.94%), rituximab-induced dyspnoea (3.94%), and human actrapid-induced hypoglycaemia (2.63%). Infusion-related reactions included rash/pruritus with single-donor platelets (SDP) and bilateral pedal oedema with Dextrose-NS.

3.6 Causality Assessment (Naranjo Algorithm)

Using the Naranjo Algorithm, 46 ADRs (60.52%) were classified as probable, 29 (38.15%) as

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possible, and 1 (1.31%) as definite. No ADR was classified as doubtful (Table 5).

Table 5: Causality Assessment by Naranjo Algorithm

Category	n	Percentage (%)	Naranjo Score
Definite	1	1.31	>9
Probable	46	60.52	5–8
Possible	29	38.15	1–4
Unlikely	0	0.00	0

3.7 Severity Assessment (Hartwig and Siegel Scale)

The majority of ADRs were moderate in severity (64.4%), followed by mild (34.2%) and severe (1.3%). No lethal ADR was recorded (Table 6).

Table 6: Severity Assessment using the Hartwig and Siegel Scale

Severity	Female (n)	Female %	Male (n)	Total %
Mild	12	31.5%	14	34.2%
Moderate	25	65.7%	24	64.4%
Severe	1	2.6%	0	1.3%

3.8 Preventability Analysis (Schumock and Thornton Scale)

Of 76 ADRs, 63 (82.89%) were definitely preventable, 11 (14.47%) probably preventable, and only 2 (2.63%) were not preventable (Table 7). Among definitely preventable ADRs, adults accounted for the largest share (57.14%), followed by geriatric patients (25.39%) and children (17.46%).

Table 7: Preventability Analysis by Age Group

Category	Total (n)	Total %	Children	Adults	Geriatrics
Definitely Preventable	63	82.89%	11 (17.46%)	36 (57.14%)	16 (25.39%)
Probably Preventable	11	14.47%	0	8 (72.72%)	3 (27.27%)
Not Preventable	2	2.63%	0	0	2 (100%)

3.9 ADR Type Classification

Type A (augmented, dose-related) reactions were the most prevalent (65.7%), followed by Type B (bizarre/idiosyncratic, 19.7%), Type U (unclassified, 10.5%), and Types C and D (1.31% each). No Type E or Type F reactions were recorded (Table 8).

Table 8: Classification of ADRs by Type

Type	Description	n	Percentage (%)
Type A	Augmented / Dose-related	50	65.7
Type B	Bizarre / Idiosyncratic	15	19.7
Type C	Chronic / Long-term	1	1.31
Type D	Delayed	1	1.31
Type E	End of Use	0	0
Type F	Failure of Therapy	0	0
Type U	Unclassified	8	10.5

3.10 Fate of Suspected Drugs and Outcomes

The suspected drug was withdrawn in 52 cases (68%), the dose was altered in 3 cases (4%), and no change was made in 21 cases (28%). Dechallenge was performed in 45 cases (61.84%), rechallenge in 9 cases (11.84%), and drug status was unknown in 20 cases (26.31%). Regarding outcomes, 59 patients recovered (77.36%), 9 were continuing treatment (11.84%), and outcomes were unknown in 8 cases (10.52%). There were no fatalities.

4. DISCUSSION

This six-month prospective observational study identified 76 ADRs from a screened cohort of 180 inpatients across all clinical departments of a tertiary care hospital. The findings are broadly consistent with published literature, while also highlighting institution-specific patterns relevant to local prescribing practice.

The female predominance in ADR occurrence (53.94%) observed in the present study corroborates findings by Biyabani et al. (2018), who reported a

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female predominance of 72%, and by Akhtar et al. (2018), who similarly found higher ADR incidence among female patients. Differences in body composition, hormonal milieu, and immune reactivity are thought to underlie this sex-based disparity in ADR susceptibility.

Adults aged 41–60 years had the highest ADR incidence (34.21%), consistent with the results of Shareefuddin et al. (2017) who observed adult predominance at 36%. Although geriatric patients are considered a high-risk group due to polypharmacy and reduced drug clearance, the relatively lower geriatric ADR proportion in this study (26.31% for 61–80 years) may reflect the demographics of the study institution's catchment population.

Antibiotics were the leading implicated drug class (25%), a finding consistent with studies by Sujatha Sowmyanarayan and Swati Banerjee (2018), Abdul Aslam et al. (2018), Jerin James and Jamuna Rani (2020), and Palanisamy et al. (2013). The high ADR burden from antibiotics underscores the critical need for antimicrobial stewardship programmes in tertiary care settings. The second largest contributor was anticancer drugs (17.10%), reflecting the significant oncology patient load at the study site and consistent with findings reported by Pooja et al. (2016) and Saini et al. (2015).

Gastrointestinal reactions were the predominant manifestation (27.63%), followed by cutaneous (17.10%) and neurological (9.21%) reactions. This pattern aligns with studies by Deepti Chopra et al. (2016), who identified the gastrointestinal system as the most affected, and Sharma et al. (2015), who reported skin and gastrointestinal systems as the most frequently involved. The high proportion of GI ADRs is attributed to the extensive use of NSAIDs, antibiotics, analgesics, and anticancer agents — all of which have well-established gastrointestinal toxicity profiles.

Causality assessment using the Naranjo Algorithm revealed that 60.52% of ADRs were probable, which is comparable to findings by Singh et al. (2017), who reported a majority of probable reactions by WHO-UMC criteria, and Shareefuddin et al. (2017), who found 78.45% probable reactions. The low proportion of definite ADRs (1.31%) reflects the inherent difficulty of rechallenge in routine clinical practice.

Severity assessment using the modified Hartwig and Siegel Scale showed that 64.4% of ADRs were of moderate severity. This is consistent with findings of Shareefuddin et al. (2017) (72.92% moderate) and Khandelwal et al. (2021), who reported most ADRs as mild and resolving upon drug withdrawal. The absence of any fatal outcome in this study is an encouraging finding.

Preventability analysis revealed that 82.89% of ADRs were definitely preventable — a rate considerably higher than the 34% reported by Thiesen et al. (2013) but reflective of patterns seen in institutions where polypharmacy and incomplete medication review contribute substantially to ADR occurrence. Polypharmacy was the leading identified predisposing factor (19.73%), followed by intercurrent disease (15.78%) and drug characteristics (13.15%), consistent with results by Asawari et al. (2012).

The predominance of Type A reactions (65.7%) reinforces the preventable and dose-related nature of most ADRs observed. Type A reactions are by definition predictable from a drug's pharmacological profile and responsive to dose reduction or drug withdrawal. Their high prevalence suggests systematic opportunities for prevention through improved prescribing habits, dose optimization, therapeutic drug monitoring, and active pharmacist involvement in medication review.

5. CONCLUSION

This prospective observational study demonstrates that ADRs are a prevalent and significant clinical problem in the tertiary care setting, with the majority being preventable (82.89%), dose-related (Type A, 65.7%), and of moderate severity (64.4%). Antibiotics were the most commonly implicated drug class, and the gastrointestinal system was the most frequently affected. Polypharmacy and intercurrent disease were the dominant predisposing factors.

These findings underscore the critical importance of structured pharmacovigilance programmes, rational antimicrobial and analgesic prescribing, regular

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medication review, and the active participation of clinical pharmacists in ADR identification, documentation, and reporting. Continuous and systematic ADR monitoring studies in tertiary care hospitals are recommended to capture evolving reaction patterns and support evidence-based pharmacovigilance in India.

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