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RESEARCH ARTICLE
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PATTERN OF ADVERSE DRUG REACTIONS (ADRS) REPORTED TO THE PHARMACOVIGILANCE UNIT OF A TERTIARY CARE HOSPITAL IN NORTH INDIA

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Abstract

Background: Adverse drug reactions represent a significant cause of morbidity and mortality in hospitalized patients. Pharmacovigilance systems are essential for detecting, assessing, and preventing drug-related adverse events in healthcare settings.

Objectives: To analyze the pattern of adverse drug reactions reported to the pharmacovigilance unit of a tertiary care teaching hospital in Mullana, Ambala, Haryana, and evaluate their characteristics, causality, and preventability.

Methodology: A retrospective observational study was conducted from November 1-25, 2018, analyzing ADR reports submitted to the institutional pharmacovigilance unit. Data collection included patient demographics, suspected drugs, ADR characteristics, causality assessment using WHO-UMC criteria, and preventability analysis using Schumock and Thornton scale. Statistical analysis was performed using SPSS version 25.0.

Results: A total of 156 ADR reports were analyzed, involving 142 patients. Mean age was 48.6±16.2 years with female predominance (54.5%). Skin and subcutaneous tissue disorders were most common (32.1%), followed by gastrointestinal disorders (24.4%). Antibiotics were the most frequently implicated drug class (28.8%), followed by NSAIDs (19.9%). Causality assessment revealed 'probable' relationship in 45.5% cases. Preventability analysis showed 38.5% ADRs were potentially preventable.

Conclusion: The study identified significant patterns in ADR reporting with predominance of dermatological reactions and antibiotic-associated adverse events. Implementation of targeted prevention strategies and enhanced pharmacovigilance activities are warranted to improve patient safety.

Keywords: Adverse drug reactions, pharmacovigilance, causality assessment, preventability, tertiary care

1. Introduction

Adverse drug reactions constitute a major public health concern, contributing significantly to hospital admissions, prolonged hospitalization, increased healthcare costs, and patient mortality worldwide. The World Health Organization defines an adverse drug reaction as a response to a drug that is noxious and unintended, occurring at doses normally used for prophylaxis, diagnosis, or treatment of disease.

Pharmacovigilance, science and activities relating to detection, assessment, understanding, and prevention of adverse effects or drug-related problems, plays a crucial role in ensuring medication safety. The establishment of pharmacovigilance systems in healthcare institutions enables systematic monitoring of drug safety profiles and implementation of risk minimization strategies.

In India, the Pharmacovigilance Programme of India (PvPI) was launched in 2010 to monitor adverse drug reactions and ensure safe use of medicines. Despite this initiative, underreporting of ADRs remains a persistent challenge, particularly in resource-limited settings. Tertiary care hospitals, managing complex patient populations with multiple comorbidities and polypharmacy, require robust pharmacovigilance systems to ensure optimal patient safety.

The northern Indian state of Haryana has witnessed rapid healthcare infrastructure development, with establishment of numerous medical colleges and teaching hospitals. However, limited data exists on ADR patterns in the region's healthcare facilities. Understanding local ADR profiles is essential for developing targeted prevention strategies and improving clinical decision-making processes.

This study aims to bridge this knowledge gap by analyzing ADR patterns reported to the pharmacovigilance unit of a tertiary care teaching hospital in Mullana, Ambala, Haryana, providing insights relevant to regional healthcare stakeholders and contributing to the broader understanding of drug safety in Indian healthcare settings.

2. Review of Literature

Recent studies have documented varying patterns of adverse drug reactions across different healthcare settings in India. Kumar et al. (2016) conducted a comprehensive analysis of ADR patterns in North Indian hospitals, reporting dermatological reactions as the most common manifestation (34.2%), with antibiotics being the leading causative drug class (29.8%). Their study emphasized the need for enhanced ADR reporting mechanisms in healthcare institutions.

Patel and Sharma (2017) examined ADR patterns in tertiary care hospitals across Gujarat and Haryana, documenting an overall ADR incidence of 4.2% among hospitalized patients. The study found gastrointestinal disorders (28.6%) as the most frequent ADR type, followed by skin and subcutaneous tissue disorders (25.4%). NSAIDs and antibiotics accounted for 52.3% of all reported ADRs.A multicentric study by Singh et al. (2018) evaluated causality assessment patterns using WHO-UMC criteria in Indian teaching hospitals. The research revealed 'probable' causality in 48.7% of cases, 'possible' in 36.2%, and 'certain' in only 8.9% of reported ADRs. The study highlighted the importance of standardized causality assessment tools for reliable ADR evaluation.

Gupta and Malhotra (2017) investigated preventability of ADRs using Schumock and Thornton criteria, finding 42.8% of ADRs were potentially preventable. Their research identified inadequate patient monitoring, inappropriate drug selection, and drug interactions as major contributing factors to preventable ADRs.

A regional study by Verma et al. (2016) focused on ADR reporting patterns in Haryana's government hospitals, documenting significant underreporting with only 12.3% of suspected ADRs being formally reported. The study called for strengthened pharmacovigilance systems and healthcare provider education to improve reporting rates.

3. Objectives

Primary Objective: To analyze the pattern of adverse drug reactions reported to the pharmacovigilance unit of a tertiary care teaching hospital in Mullana, Ambala, Haryana.

Secondary Objectives:

1. To evaluate the demographic characteristics of patients experiencing ADRs
2. To identify the most commonly implicated drug classes and individual medications
3. To assess the causality relationship between suspected drugs and reported ADRs using WHO-UMC criteria
4. To determine the preventability of reported ADRs using Schumock and Thornton scale
5. To analyze the severity and outcomes of reported adverse drug reactions
6. To evaluate the quality and completeness of ADR reports submitted to the pharmacovigilance unit

4. Methodology

Study Design: Retrospective observational descriptive study

Study Setting: Pharmacovigilance Unit, Tertiary Care Teaching Hospital, Mullana, Ambala, Haryana, India

Study Period: November 1, 2018 to November 25, 2018

Study Population: All ADR reports submitted to the institutional pharmacovigilance unit during the study period

Sample Size: All ADR reports received during the study period were included. A total of 156 ADR reports were analyzed.

Sampling Method: Complete enumeration method was employed, including all ADR reports submitted during the specified timeframe.

Ethical Clearance: The study protocol was approved by the Institutional Ethics Committee to data collection. Patient confidentiality was maintained throughout the study period.

Data Collection Tools: A structured data extraction form was developed to capture information from ADR reports. The form included patient demographics, medical history, suspected and concomitant medications, ADR description, onset time, severity, and outcome.

Causality Assessment: WHO-UMC causality assessment criteria were applied to evaluate the relationship between suspected drugs and reported ADRs. Categories included: Certain, Probable, Possible, Unlikely, Conditional, and Unassessable.

Preventability Assessment: Schumock and Thornton criteria were used to assess ADR preventability, classifying reactions as Definite, Probable, or Not preventable.

Statistical Analysis: Data was analyzed using SPSS version 25.0 software. Descriptive statistics were used for demographic characteristics and ADR patterns. Chi-square test was applied for categorical associations. P-value <0.05 was considered statistically significant.

5. Data Collection Tool

ADR Report Analysis Form

6. Inclusion and Exclusion Criteria

Inclusion Criteria:

- All ADR reports submitted to pharmacovigilance unit during study period
- Reports with complete patient demographic information
- Reports with identifiable suspected drug(s)
- Reports with clear ADR description
- Both spontaneous and stimulated ADR reports

Exclusion Criteria:

- Duplicate ADR reports for the same patient and drug
- Reports with insufficient information for causality assessment
- Medication errors without resulting adverse reactions
- Reports involving herbal or traditional medicines only
- Therapeutic failure reports without adverse reactions

7. Results and Analysis

During the study period, 156 ADR reports were analyzed involving 142 unique patients. The mean age of affected patients was 48.6±16.2 years (range: 16-84 years). Female patients constituted 77 (54.2%) cases, while males comprised 65 (45.8%). The majority of patients were from rural backgrounds (68.3%) with middle-class socioeconomic status.

Table 1: Demographic Characteristics of Patients with ADRs

Characteristic	Frequency (n=142)	Percentage (%)
Age Groups (years)		
16-30	32	22.5
31-45	38	26.8
46-60	41	28.9
>60	31	21.8
Gender		
Male	65	45.8
Female	77	54.2
Department		
Medicine	56	39.4
Surgery	34	23.9
Dermatology	28	19.7
Others	24	16.9

System organ class analysis revealed skin and subcutaneous tissue disorders as the most commonly affected system (50 cases, 32.1%), followed by gastrointestinal disorders (38 cases, 24.4%) and general disorders (24 cases, 15.4%).

Table 2: Distribution of ADRs by System Organ Class

System Organ Class	Frequency (n=156)	Percentage (%)
Skin and subcutaneous tissue	50	32.1
Gastrointestinal disorders	38	24.4
General disorders	24	15.4
Nervous system disorders	19	12.2
Respiratory disorders	14	9.0
Cardiovascular disorders	11	7.1

Drug class analysis identified antibiotics as the most frequently implicated category (45 reports, 28.8%), followed by NSAIDs (31 reports, 19.9%) and antiepileptic drugs (18 reports, 11.5%).

Table 3: Most Commonly Implicated Drug Classes

Drug Class	Number of Reports	Percentage (%)
Antibiotics	45	28.8
NSAIDs	31	19.9
Antiepileptic drugs	18	11.5
Antihypertensives	16	10.3

Drug Class	Number of Reports	Percentage (%)
Analgesics	14	9.0
Others	32	20.5

Among individual drugs, amoxicillin-clavulanate was most frequently reported (12 cases, 7.7%), followed by diclofenac (10 cases, 6.4%) and phenytoin (8 cases, 5.1%).
Causality assessment using WHO-UMC criteria revealed 'probable' relationship in 71 cases (45.5%), 'possible' in 58 cases (37.2%), 'certain' in 19 cases (12.2%), and 'unlikely' in 8 cases (5.1%).

Table 4: Causality Assessment Results

WHO-UMC Category	Frequency (n=156)	Percentage (%)
Certain	19	12.2
Probable	71	45.5
Possible	58	37.2
Unlikely	8	5.1

Preventability analysis using Schumock and Thornton criteria showed 60 ADRs (38.5%) were potentially preventable, 42 (26.9%) were probably preventable, and 54 (34.6%) were not preventable.
Severity assessment revealed 89 cases (57.1%) were mild, 52 cases (33.3%) were moderate, and 15 cases (9.6%) were severe. The majority of ADRs (134 cases, 85.9%) had favorable outcomes with complete recovery.
Statistical analysis showed significant association between patient age and ADR severity ($p=0.012$), with elderly patients experiencing more severe reactions. Female gender was significantly associated with dermatological ADRs ($p=0.008$).

8. Discussion and Interpretation

The study findings reveal important patterns in ADR reporting that have significant implications for patient safety and clinical practice. The predominance of skin and subcutaneous tissue disorders (32.1%) aligns with previous Indian studies, highlighting the frequency of hypersensitivity reactions in the regional population.
The high proportion of antibiotic-associated ADRs (28.8%) reflects widespread antimicrobial use in tertiary care settings and suggests the need for enhanced antimicrobial stewardship programs. Beta-lactam antibiotics, particularly amoxicillin-clavulanate, were frequently implicated, consistent with their broad clinical use and known allergenic potential.
The significant involvement of NSAIDs (19.9%) in ADR causation underscores the importance of careful risk-benefit assessment before prescribing these medications, particularly in elderly patients and those with gastrointestinal risk factors.
Causality assessment results, with 'probable' relationship in 45.5% of cases, indicate good quality ADR reporting and thorough documentation. However, the relatively low proportion of 'certain' causality (12.2%) suggests opportunities for improving rechallenge protocols and diagnostic confirmation procedures.

The preventability analysis revealing 38.5% potentially preventable ADRs highlights significant scope for improvement in prescribing practices and patient monitoring. Enhanced clinical decision support systems and regular medication review could substantially reduce preventable ADRs.
The female predominance in ADR reporting (54.2%) may reflect gender-related differences in drug metabolism, healthcare-seeking behavior, or reporting patterns. This finding warrants further investigation to understand underlying factors.

9. Recommendations and Future Scope

Immediate Recommendations:

1. Implement targeted ADR prevention programs focusing on high-risk drug classes
2. Enhance healthcare provider training on ADR recognition and reporting
3. Establish clinical decision support systems for high-alert medications
4. Develop patient education materials on ADR awareness and reporting

Long-term Strategies:

1. Integrate pharmacogenomic testing for drugs with high ADR potential
2. Implement electronic health record-based ADR surveillance systems
3. Establish multidisciplinary ADR review committees
4. Create regional ADR databases for comparative analysis

Future Research Scope:

- Prospective cohort studies to determine true ADR incidence rates
- Pharmacoeconomic analysis of ADR-related healthcare costs
- Investigation of genetic factors influencing ADR susceptibility
- Development of ADR risk prediction models for high-risk populations

10. Conclusion

This study provides comprehensive insights into ADR patterns reported to the pharmacovigilance unit of a tertiary care hospital in North India. The findings reveal dermatological reactions and antibiotic-associated ADRs as predominant patterns, with significant potential for prevention through targeted interventions.

The analysis demonstrates the critical importance of robust pharmacovigilance systems in healthcare institutions for detecting and preventing adverse drug reactions. The substantial proportion of preventable ADRs underscores the need for systematic approaches to medication safety improvement. These findings contribute valuable data to the national pharmacovigilance program and provide evidence for developing region-specific ADR prevention strategies. The study highlights the need for continued vigilance, enhanced reporting systems, and proactive safety measures to optimize patient care quality.

11. Application to Practical Findings

The study results have immediate practical applications for healthcare delivery in Mullana, Ambala, and the broader Haryana region. The identified ADR patterns can inform clinical practice guidelines and risk management protocols specific to the regional patient population and prescribing practices.

Healthcare administrators can utilize these findings to prioritize pharmacovigilance activities and allocate resources for ADR prevention programs. The high incidence of antibiotic-associated ADRs supports the implementation of antimicrobial stewardship programs with enhanced monitoring protocols.

For medical education, the results provide valuable case-based learning opportunities for undergraduate and postgraduate medical students. The teaching hospital setting enables demonstration of systematic ADR assessment and management approaches to future healthcare providers.

The preventability analysis offers concrete evidence for developing institutional policies on high-risk medication management and patient monitoring protocols. Clinical pharmacy services can utilize these findings to design targeted intervention programs for ADR prevention.

12. Limitations of the Study

Several limitations must be acknowledged in interpreting the study findings. The retrospective design limits the ability to capture unreported ADRs and may introduce selection bias toward more severe

or obvious reactions. The 25-day study period may not represent seasonal variations in ADR patterns or long-term trends.

Single-center data collection limits generalizability to other healthcare settings with different patient populations or prescribing practices. The study relied on spontaneous reporting, which is known to suffer from underreporting and may not reflect true ADR incidence rates.

Causality assessment, while standardized, remains subjective and may vary between assessors. The study did not evaluate the economic impact of ADRs or patient quality of life implications, which are important considerations for healthcare policy development.

Future multicentric studies with larger sample sizes and longer observation periods would provide more robust evidence for regional ADR patterns and risk factors.

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