Section: Miscellaneous

Original Research Article

SOCIODEMOGRAPHIC AND DRUG-CLASS WISE PATTERNS OF ADVERSE DRUG REACTIONS IN A TERTIARY CARE HOSPITAL IN WESTERN ODISHA

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ABSTRACT

Background: Adverse Drug Reactions (ADRs) are a significant cause of morbidity and healthcare burden. Understanding the demographic and pharmacological patterns of ADRs can help formulate targeted strategies for prevention and intervention. **Objective:** To analyze the sociodemographic characteristics and drug-class-wise distribution of ADRs among patients at a tertiary care hospital in Western Odisha.

Materials and Methods: A prospective observational study was conducted over 24 months (Nov 2018 to Oct 2020) at VIMSAR, Burla. Data were collected through active and passive surveillance from inpatients and outpatients. Demographic profiles, drug classes, systems affected, and routes of drug administration were analyzed using descriptive statistics.

Results: Out of 303 ADRs recorded, 69.7% occurred in females and 30.3% in males. The age group 19-60 years was most affected (84.5%). Most ADRs were reported in patients from rural areas (67.6%), lower-middle socioeconomic class (31.3%), and unemployed individuals (39.2%). Gastrointestinal system (47.5%) was the most affected, followed by dermatological (20.5%). Anti-cancer drugs were the predominant class causing ADRs (50.8%), followed by anti-tubercular (17.2%) and antimicrobials (10.2%). Parenteral administration accounted for 65.7% of ADRs.

Conclusion: ADRs were more common among females, rural residents, and those using parenteral medications. Anti-cancer and anti-tubercular drugs were leading contributors. Sociodemographic profiling can guide improved monitoring and preventive strategies in pharmacovigilance.

Keywords: Adverse Drug Reaction, Pharmacovigilance, Demographics, Drug Classes, Parenteral, Odisha.

INTRODUCTION

Adverse Drug Reactions (ADRs) are an important public health concern, leading to significant morbidity, mortality, and healthcare expenditures worldwide.[1,2] ADRs are defined as any harmful or unintended response to a medication that occurs at normal doses used for prophylaxis, diagnosis, or treatment.[3] Globally, ADRs account for approximately 5% of all hospital admissions and affect 10–20% of hospitalized patients.[4,5] In India, the burden is amplified due to widespread use of polypharmacy, self-medication, and limited awareness of drug safety monitoring systems.[3,6]

Pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of ADRs, plays a crucial role in ensuring drug safety.[3,4] The World Health Organization (WHO) emphasizes spontaneous reporting of ADRs through national programs such as the Pharmacovigilance Programme of India (PvPI).[4,7] Despite the structured network of Adverse Drug Reaction Monitoring Centers (AMCs) in India, under-reporting remains a significant challenge.[8,9]

Odisha, with its diverse population including tribal and rural communities, presents unique challenges

for pharmacovigilance. Sociocultural factors, access to healthcare, literacy levels, and local prescribing practices influence ADR occurrence and reporting.[7,10] The current study was conducted at Veer Surendra Sai Institute of Medical Sciences and Research (VIMSAR), Burla, a tertiary care hospital serving a wide geographic catchment. The goal was to document the sociodemographic and therapeutic patterns of ADRs to identify high-risk populations and inform better pharmacovigilance practices.[9,10]
This manuscript focuses on identifying which populations are most vulnerable to ADRs and which drug classes are most commonly implicated. By assessing the role of age, gender, education, occupation, and socioeconomic status alongside drug categories and administration routes, this study aims to support the rational and safe use of medications in clinical settings.

MATERIALS AND METHODS

This study was a prospective observational analysis conducted over a 24-month period from November 2018 to October 2020 at Veer Surendra Sai Institute of Medical Sciences and Research (VIMSAR), Burla, a tertiary care teaching hospital in Western Odisha.
The study population included both outpatients and inpatients from various clinical departments of the hospital. Suspected ADRs were captured via two mechanisms:
Active Surveillance: Through regular, ward visits by the pharmacovigilance team.
Passive Surveillance: Through spontaneous reports by physicians, pharmacists, and nursing staff.
Inclusion Criteria: Patients of any age and gender who experienced suspected ADRs after receiving one or more medications. ADRs caused by newer drugs (introduced within the last 4 years) and Serious ADRs caused by older drugs.
Exclusion Criteria: ADRs due to intentional or accidental drug overdose along with Poisoning cases or reactions due to non-pharmaceutical substances.
ADR details were recorded using standardized PvPI (Pharmacovigilance Programme of India) reporting forms. Each report included patient demographics, clinical details of the reaction, name and type of drug(s) suspected, dose, route, latency, outcome, and management. All reports were reviewed and validated by the hospital's ADR monitoring committee, which included pharmacologists, clinicians, and PvPI-trained personnel.

Descriptive statistics (frequencies and percentages) were used to categorize data based on age, sex, socioeconomic status, drug class, organ systems affected, and route of administration. Charts and tables were prepared using Ms Office(Excel) 2013v.

RESULTS

Total 303 study participants were enrolled in the study during the study period. Table 1 presents the age and gender distribution of 303 reported ADR cases. The majority (84.5%) occurred in individuals aged 19–60 years, indicating that the working-age population is most commonly affected. Children and adolescents (0–18 years) accounted for only 3.9% of cases, while older adults (>60 years) comprised 11.6%. A notable gender disparity was observed, with females comprising 69.7% of the cases, suggesting a higher susceptibility or reporting rate among women.

Table 1: Age and Gender distribution (N = 303)

Age Group (Years)	Number of Cases	Percentage (%)
0–18	12	3.90
19–60	256	84.50
>60	35	11.60

Table 2 outlines the socio-demographic characteristics of the patients. A significant proportion (67.6%) resided in rural areas, reflecting possible disparities in healthcare access or medication practices. The most common occupational group was unemployed individuals (39.2%), and a large share of patients had completed high school education (41.0%). Lower-middle-class individuals formed the largest socioeconomic group (31.3%), highlighting a potential correlation between economic status and ADR incidence.

Table 2: Socio-demographic characteristics

Variable	Most common category	Percentage (%)
Residence	Rural	67.6
Occupation	Unemployed	39.2
Education Level	High School	41.0
Socioeconomic Status	Lower-middle class	31.3

Table 3 identifies the organ systems affected by ADRs. The gastrointestinal (GI) system was the most commonly impacted, involved in 47.5% of cases. Dermatological reactions were the next most frequent (20.5%), followed by the central nervous system (9.2%) and musculoskeletal system (8.1%). These findings suggest a need for focused monitoring of GI and skin-related symptoms in patients undergoing pharmacological treatment.

Table 3: Organ system affected

Organ System	Number of Cases	Percentage (%)
Gastrointestinal	144	47.5
Dermatological	62	20.5
Central Nervous System (CNS)	28	9.2
Musculoskeletal	25	8.1

Table 4 shows the drug classes responsible for ADRs. Anti-cancer drugs accounted for over half of the cases (50.8%), making them the leading contributor. Anti-tubercular drugs (17.2%) and antimicrobials (10.2%) followed. Anti-retrovirals and NSAIDs were implicated in a smaller proportion of cases, at 5.0% and 4.0%, respectively. These results underline the importance of pharmacovigilance in high-risk drug categories, especially anti-cancer medications.

Table 4: Drug Class Involved

Drug Class	Number of Cases	Percentage (%)
Anti-cancer	154	50.8
Anti-tubercular	52	17.2
Antimicrobials	31	10.2
Anti-retrovirals	15	5.0
NSAIDs	12	4.0

Table 5 describes the route of drug administration and the onset time of ADRs. Parenteral administration was the most common route (65.7%), followed by oral intake (34.0%), while inhalational use was rare (0.3%). The majority of ADRs (88.8%) developed within 1–7 days of drug initiation, indicating a short latency period and emphasizing the need for early monitoring post-administration.

Table 5: Route of Administration and Onset Time

Route/Onset	Number of Cases	Percentage (%)
Parenteral	199	65.7
Oral	103	34.0
Inhalational	1	0.3
Onset (1–7 days)	269	88.8

DISCUSSION

This study offers significant insights into the demographic and pharmacological trends of ADRs in a tertiary healthcare setting in Odisha.

The predominance of ADRs among women aligns with other global and Indian studies, which attribute gender differences in ADRs to variations in pharmacokinetics, pharmacodynamics, hormonal influences, and drug metabolism pathways.[10-13] Additionally, women tend to seek more healthcare services and may be more likely to report symptoms, potentially increasing ADR detection.

The age group most commonly affected was between 19 and 60 years, representing the working population. This age range has higher exposure to medications due to lifestyle-associated conditions and more frequent healthcare engagement.[11,12]

The overrepresentation of unemployed and semiskilled individuals underscores how lower socioeconomic status is linked to higher ADR risk—likely due to reduced health literacy, delayed care-seeking, and polypharmacy from over-the-counter or traditional remedies.[14]

The finding that rural residents comprised nearly 68% of ADR cases may reflect the healthcare-seeking patterns in rural Odisha, where tertiary care facilities such as VIMSAR serve as referral hubs. Also, rural populations often face challenges in accessing quality healthcare, leading to inappropriate or excessive medication use.[15,16]

Gastrointestinal and dermatologic manifestations of ADRs were most prevalent, consistent with the known side-effect profiles of commonly used drugs like NSAIDs, antimicrobials, and chemotherapeutic agents.[14-17] Anti-cancer medications, being cytotoxic and immunosuppressive, were most commonly implicated, which agrees with national reports indicating frequent ADRs in oncology departments.[15-18]

Interestingly, parenteral drugs were more frequently associated with ADRs than oral ones, likely due to the acute care setting where injectable therapies are standard. This raises concerns regarding aseptic administration practices and monitoring for immediate hypersensitivity or systemic reactions.[16-19]

Our study also confirms that most ADRs occur within the first week of initiating a drug, underscoring the need for early vigilance in therapy.[3,15] Education and counselling at the point of prescribing, especially for high-risk drugs and populations, could mitigate many of these early-onset events.

Overall, the findings reinforce the value of hospital-based pharmacovigilance and ADR monitoring programs in capturing critical data to inform clinical practices and public health policies. Empowering healthcare workers with continuous training and promoting community awareness can significantly enhance ADR reporting and management.[1,5,19]

CONCLUSION

This study highlights that ADRs are influenced by both pharmacological factors and patient socio-demographics. Enhancing ADR reporting and monitoring among high-risk groups, particularly rural populations and users of high-risk drugs like chemotherapy agents, should be a priority. Future studies should focus on interventions to reduce preventable ADRs.

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