SHORT COMMUNICATION

Hospital-based trends in adverse drug reactions: A descriptive analysis

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Abstract

Background: Adverse Drug Reactions (ADRs) remain a significant contributor to morbidity and hospital admissions, especially in settings with high rates of polypharmacy and irrational drug use. In India, hospital-based pharmacovigilance systems provide vital insights into community prescribing patterns and medication safety. *Aim and Objectives:* To assess the frequency, severity, and characteristics of spontaneously reported ADRs at a tertiary care ADR Monitoring Centre (AMC) and to explore their implications for public and community health. *Material and Methods:* A retrospective observational study was conducted at the AMC under the Pharmacovigilance Programme of India (PvPI) at KMCH Institute of Health Sciences & Research, Coimbatore, from January 2021 to December 2024. All spontaneously reported ADRs were analysed using the WHO-UMC causality assessment scale and the Hartwig and Siegel severity scale. Data on demographics, drug class, route of administration, affected organ systems, and ADR characteristics were evaluated using SPSS version 27. Results: A total of 131 ADRs were reported. The majority were observed in adults aged 19–65 years (85%) and in females (66%). Intravenous administration accounted for the highest number of ADRs (55%). Antimicrobials were the leading drug class (60%), particularly cephalosporins, penicillins and quinolones. Cutaneous reactions were most frequent (64%), including itching (34%) and rashes (22%). Most ADRs were classified in severity as mild (53%) moderate (38%) and severe (9%) *Conclusion:* This study underscores the burden of antimicrobial-related ADRs and highlights the utility of hospital-based pharmacovigilance in promoting safe prescribing practices. Regular feedback, prescriber education, and an improved ADR reporting culture are critical for reducing drug-related morbidity and informing community-level health interventions.

Keywords: Adverse Drug Reactions, Pharmacovigilance, Hospital-Based Study, Causality Assessment, ADR Reporting

Introduction

An Adverse Drug Reaction (ADR) is defined by the World Health Organization (WHO) as an unpleasant and unexpected reaction that happens in patients after they take pharmaceuticals for the diagnosis, treatment, or prevention of a disease at dosages that are normally used. Since 2012, the phrase has broadened to include not only the authorized use of a medication in prescribed quantities but also reactions resulting from errors, misuse, or abuse, as well as suspected reactions to off-label or unlicensed medications. Although this shift may alter the reporting and surveillance practices of pharmaceutical regulators and manufacturers, it should not affect clinical practice in terms of managing ADRs [1]. ADRs are commonly observed in clinical settings, often resulting in unplanned hospital admissions, developing during hospital stays, and presenting symptoms after

discharge, according to significant studies carried out in the United States and the United Kingdom in the late 20th and early 21st centuries. Despite several preventative efforts, research shows that 5-10% of patients may have an ADR upon admission, during hospitalization, or after discharge. Over time, the frequency of ADRs has stayed quite constant [2].

A large variety of prescription and over-the-counter medications are readily available in the Indian pharmaceutical market, which frequently encourages polypharmacy and self-medication [3]. Communities are especially susceptible to drug-related issues because of factors including illiteracy, lack of information, and the impact of aggressive pharmaceutical marketing, which all contribute to irrational drug usage [4]. A strategic method for identifying, assessing, and reducing such medication-related hazards is hospital-based ADR monitoring. These establishments frequently act as sentinel surveillance facilities, providing vital information about medication safety profiles in practical settings [5].

Adverse drug reaction Monitoring Centers (AMCs) are a countrywide network. India's pharmacovigilance initiative, which was started in 2010 under the Pharmacovigilance Programme of India (PvPI), seeks to improve ADR reporting procedures [6]. Healthcare workers frequently lack the time, motivation, or training necessary to report suspected ADRs. Hence underreporting is still a major problem [7].

Notwithstanding these difficulties, ADR data from hospitals could be used as a stand-in for patient behavior and community-level prescribing practices, especially in rural and resource-constrained areas. Furthermore, identifying high-risk medication classes, vulnerable patient groups, and frequently impacted organ systems is made possible by tracking ADR trends over time [8]. In addition to helping hospitals make the best clinical decisions possible, this data also informs public health initiatives, laws, and educational initiatives meant to raise community knowledge of drug safety [9]. Single-center studies provide valuable insights into institution-specific prescribing patterns and drug safety issues influenced by local patient demographics and clinical practices. Accordingly, this study evaluates the trends, occurrence, and severity of spontaneous ADRs reported to the AMC at KMCH Institute of Health Sciences & Research, Coimbatore, with the aim of identifying locally relevant safety patterns and potential community health implications.

Material and Methods

Study design and type: This was a retrospective observational study conducted to evaluate the occurrence and severity of spontaneously reported ADRs.

Study setting: The study was carried out in the Department of Pharmacology, which functions as an AMC under the PvPI, at KMCH Institute of Health Sciences & Research, Coimbatore.

Inclusion and exclusion criteria: All spontaneously reported ADRs received at the AMC from January 2021 to December 2024 were included in the study. Reports with incomplete data or those lacking essential information for assessment were excluded.

Ethical approval: The study was approved by the Institutional Human Ethics Committee (IHEC Approval No. 03/IHEC/2024). Patient confidentiality was strictly maintained, and data was anonymized prior to analysis. As the study involved retrospective review of existing data, informed consent was not applicable.

Strategy for data collection: ADRs reported during the study period were recorded using a standardized data collection form. Information on patient demographics, drug details (name, class, route of administration), ADR characteristics (clinical presentation, affected organ system), and temporal relationship with drug intake was collected.

Causality assessment was done using the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) Causality Assessment Scale. Severity of ADRs was graded using the Hartwig and Siegel Severity Assessment Scale [10, 11].

Statistical analysis: Data was entered in Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) version 27. Descriptive statistics were applied, and results were presented as frequencies and percentages.

Results

A total of 131 spontaneous ADRs were reported at the AMC from January 2021 to December 2024. ADRs were reported in individuals ranging from 3.5 months to 79 years of age, and was predominant in the age group of 19-65 years of age (85%). ADRs were more frequently observed in female patients (66%) in comparison to male patients (34%). Drugs given via Intravenous route (IV) (55%) showed most ADRs, followed by oral route (27%) (Table 1).

Antimicrobials were responsible for 60% of the ADRs, with cephalosporins accounting for the majority (30%), followed by penicillins (23%) and

Table 1: Demographic parameter and route of drug administration among the patients developing ADRs

Parameter	Patients with ADR n (%)
Adverse drug reactions	131
Age group (years)	
0-18	8 (6)
19- 65	111 (85)
>65	12 (9)
Sex	
Female	87 (66)
Male	44 (34)
Route of drug administration	
Intravenous	72 (55)
Oral	36 (27)
Intradermal	12 (9)
Intramuscular	5 (4)
Topical	6 (5)

quinolones (19%). The most commonly reported drugs in these antimicrobial categories were ceftriaxone (third-generation cephalosporins), piperacillin (penicillins), and ciprofloxacin (quinolones). Followed by antimicrobials, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (5%) and anticonvulsants (4%) caused substantial ADRs shown in figure 1. Among all organ system classes, skin and subcutaneous tissue disorders were the most prevalent ADRs (64%), followed by immune system related disorders (13%) and gastrointestinal tract effects (6%). Most frequently reported ADRs are itching (34%), rashes (22%) and allergic reactions (5%). In accordance with the WHO causality assessment scale, 93% of the ADRs were probable and 5% were certain. With reference to the Hartwig scale for severity assessment, most of the reported ADRs were mild (53%), (38%) were moderate and (9%) were severe. No serious adverse events had been reported.

Discussion

The four-year hospital-based examination of ADRs offers important information about pres-cribing patterns, drug safety, and the implications of community-level pharmacovigilance. This study highlights the wider community health issues brought on by drug-related morbidity in addition to identifying frequent patterns of ADRs in a tertiary care context. One important finding of this study was that adults aged 19–65 years accounted for 85% of all ADRs. This is in line with research by Patel *et al*., (2016) which found that 80% of ADRs occurred in this age group[12].This is likely due to their higher exposure to pharmaceutical agents as a result of the burden of chronic diseases and their higher healthcare utilization. Previous studies have found lower ADR incidence in geriatric (9%) and pediatric (6%) populations, which may be related to underreporting or more cautious prescribing in these populations [13]. According to the gender-based distribution, ADRs were more common in

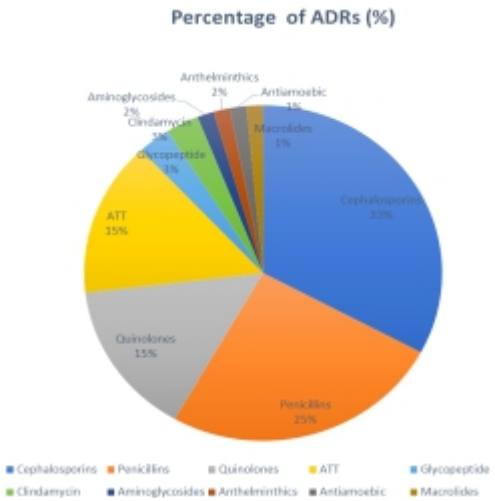

Figure 1: ADRs related to antimicrobials

ADR - Adverse drug reaction; ATT - Anti-tubercular drugs

women (66%) than in men (34%). This conclusion supports earlier findings by Ramesh *et al*., and who ascribe this trend to changes in drug metabolism, physiological and hormonal differences, and immunological responses in females [14].

IV route was linked to a considerable percentage of ADRs (55%), which is consistent with results from other institutional studies. Although IV delivery guarantees quick medication action, it also puts patients at risk for severe systemic reactions, such as anaphylaxis and hypersensitivity. Despite being safer, 27% of ADRs occurred via the oral route, highlighting the fact that even widely used formulations carry some risk. Healthcare providers must also be vigilant due to the incidence of ADRs through less often utilized routes, such as intradermal (9%) and intramuscular (4%) notably during allergy testing or injectable therapy. The predominance of antimicrobials (60%) as causative agents, particularly cephalosporins (30%), penicillins (23%), and quinolones (19%), underscores the prevailing antibiotic prescribing trends in both hospital and community settings [15, 16]. This pattern mirrors the high burden of infectious diseases and the potential for overprescription or empirical antibiotic use, which can lead to both ADRs and Antimicrobial Resistance (AMR). Ceftriaxone, piperacillin, and ciprofloxacin were frequently implicated-drugs commonly used for moderate to severe infections, reflecting their widespread utility and risk potential.

NSAIDs (5%) and anticonvulsants (4%) were also notable contributors, consistent with global pharmacovigilance data that highlight these drug classes as common culprits due to their narrow therapeutic indices and immunologic reaction potential [17]. These findings suggest the need for more robust prescribing oversight and patient education in both inpatient and outpatient settings. The most often impacted organ systems were the skin and subcutaneous tissue (64%), followed by the gastrointestinal (6%) and immunological (13%) systems. This pattern highlights the frequency of cutaneous ADRs and is consistent with worldwide pharmacovigilance data from the Uppsala Monitoring Centre and Indian investigations [18, 19]. Mohan *et al*., demonstrated that fixed-dose antituberculous combinations can cause significant cutaneous ADRs. This highlights the need for vigilant pharmacovigilance monitoring and prompt reporting to improve drug safety in tuberculosis therapy [20]. Ghodge *et al*., (2017) identified antimicrobials and antiepileptics as common causes of adverse cutaneous drug reactions, pre-dominantly presenting as maculopapular rashes. This underscores the need for prompt pharmacovigilance reporting to enable early signal detection and improve patient safety [21]. In line with research by Sumith Kumar *et al*., the most common symptoms, itching (34%) and rashes (22%), were mainly associated with beta-lactams and NSAIDs [22]. According to a study by Ahmed NJ, metronidazole and macrolides were commonly related with gastrointestinal Adverse Drug Reactions (ADRs), such as vomiting and diarrhea, and antibiotic-associated diarrhea was identified as a common hospital-based ADR [23]. According to the study by Paulmann *et al*., (2019) global research of severe cutaneous adverse reactions, anticonvulsants were the main cause of severe ADRs such as Stevens - Johnson syndrome (SJS) and drug reaction with eosinophilia and systemic symptoms (DRESS) [24]. Using the WHO-UMC criteria, the majority of

ADRs were categorized as probable (93%), with a lesser percentage being certain (5%). This is consistent with research by Naranjo *et al*., (1981) which found that "probable" ratings were more common because of limited follow-up data and ethical restrictions in the rechallenge [25, 26]. According to the Hartwig severity scale, the majority of ADRs were classified as mild (53%), moderate (38%), and severe (9%). These results were consistent with those of Shinde *et al*., who also observed a similar distribution [27]. Findings of our study on the prevalence of cutaneous manifestations and ADRs due to antibiotics are consistent with pharmacovigilance data from Thailand and other Southeast Asian nations. According to one study, skin reactions including urticaria and rashes are the most common clinical presentations, and antibiotics, especially beta-lactams, are the main cause of ADRs [28]. Similar ADR patterns to those observed in India are observed in Southeast Asia due to the region's extensive empirical use of antibiotics, easy availability to over-the-counter medications, and low public knowledge of responsible drug use.

These similarities highlight the need for community-level drug safety education, standardized ADR monitoring systems, and improved antimicrobial stewardship in the region. The broader public health relevance of these findings lies in their utility for strengthening pharmaco-vigilance mechanisms and antibiotic stewardship. Systematic ADR documentation can generate early warning signals and guide drug safety communications. Reports linked to anti-microbial use, in particular, are vital in curbing the irrational use of antibiotics and combating antimicrobial resistance through informed prescribing policies.

This study emphasizes the critical role of hospital-based pharmacovigilance in understanding and responding to community health challenges. By identifying trends in age, gender, drug class, and organ system involvement, healthcare institutions can design targeted interventions to reduce the incidence and severity of ADRs.

In the community context, such data are invaluable in advocating for better regulation of over-the-counter drug use, enhanced public awareness, and improved integration of ADR reporting systems across primary care settings. By identifying high-risk medications and influencing evidence-based clinical guidelines, labeling and reporting novel ADRs might help change prescribing patterns. It has been demonstrated that providing prescribers with feedback on ADR trends increases reporting rates and decreases needless prescriptions.

In addition, effective communication and ongoing training for Healthcare Professionals (HCPs) regarding medication safety and the significance of reporting ADRs can improve patient care and guarantee safer therapeutic results in the community. When reporting ADRs, it is crucial to make sure that HCPs receive objective, fact-based information and are shielded from potential legal action.

Enhancing healthcare organizations' open and non-punitive reporting cultures can promote a more proactive pharmacovigilance environment, which will ultimately improve public health outcomes.

Conclusion

This study highlights the burden and patterns of ADRs in a hospital setting, with antimicrobials, adult patients, and females being most affected. Cutaneous reactions were predominant, and most ADRs were mild to moderate in severity. The findings underscore the importance of hospital-based pharmacovigilance

in guiding safer prescribing practices, enhancing ADR reporting, and informing community-level drug safety policies. Strengthening surveillance and promoting a non-punitive reporting culture are key to reduc-ing drug-related morbidity and improving public health outcomes.

Limitations of the study

Despite its strengths, the study is limited by its reliance on spontaneous reporting, which is inherently subject to underreporting and selection bias. Additionally, lack of follow-up data may have led to an underestimation of long-term ADR outcomes. Nevertheless, the insights provided form a foundation for strengthening pharmacovigilance training, particularly among undergraduate health professionals, and support the need for active surveillance systems at the community level.

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