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Decoding adverse drug reactions in respiratory care: a prospective predictive and severity-based analysis at a tertiary care hospital in India

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Abstract

Adverse drug reactions (ADRs) are a major concern in healthcare, including morbidity, longer hospitalization, and increased healthcare expenses. Despite the necessity of ADR monitoring, reporting is poor, particularly in developing countries such as India. This study assessed the severity, predictability, and causality of ADRs in a tertiary care hospital's respiratory department. A prospective observational study was conducted at KLE's Dr. Prabhakar Kore Hospital, Belagavi, Karnataka, from September 2023 to January 2025. Patients aged 45 years and above with chronic respiratory conditions were included. ADRs were assessed using validated scales, including the World Health Organization-Uppsala Monitoring Center Scale, the Modified Hartwig and Siegel Scale, and the Predictability Assessment. Descriptive statistics were applied to analyze ADR patterns. Among the 107 patients enrolled, 63.5% were elderly and 59.8% were female. Mild ADRs accounted for 60.7% of cases, while serious responses were reported in 3.7%. Predictability analysis revealed that 77.5% of ADRs were foreseeable. Causality assessment revealed ADRs as probable (51.4%), possible (37.3%), and certain (10.2%). Drug withdrawal was the most popular intervention (55.1%). The most commonly reported ADRs were gastrointestinal disorders (33.6%), followed by respiratory (18.6%) and cardiovascular disorders (16.8%). The study highlighted the need for improved pharmacovigilance programs to reduce ADR-related hazards in respiratory patients. Improving ADR reporting methods and predictive assessments can enhance patient safety and maximize therapeutic outcomes.

Key words: adverse drug reactions, respiratory disorders, pharmacovigilance, predictability, severity, causality assessment.

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Introduction

Adverse drug reactions (ADRs) represent a significant challenge in healthcare, contributing to increased morbidity, mortality, and healthcare costs [1]. An ADR is defined by the World Health Organization (WHO) as a toxic, unanticipated reaction to a medication that happens at dosages typically used in humans for disease prevention, diagnosis, or treatment, or for altering physiological function. ADRs can take many different forms, from minor symptoms that go away on their own to serious, life-threatening illnesses [2].

Understanding the traits, risk factors, and management of ADRs is essential for maintaining patient safety and improving therapeutic results because of the potentially dire implications [1]. According to research, the prevalence of ADRs among hospitalized patients ranges from 10% to 20%. Due to high rates of unreported and negligent drug use, the incidence of ADRs in India places a significant strain on the healthcare system. Early diagnosis, prevention, and management of drug-related morbidity and mortality depend on efficient ADR monitoring.

ADR reporting is still in its infancy in India, nevertheless, and is beset by issues like inadequate feedback systems, uncertainty regarding reporting protocols, and a lack of knowledge among medical practitioners [2].

Monitoring ADRs requires pharmacovigilance, which the WHO defines as a collection of procedures for recognizing, comprehending, and evaluating drug-related hazards. In order to provide information about successful drug usage in a variety of patient populations, including the elderly, children, and patients with illnesses, good pharmacovigilance programs are crucial. Numerous cases of medications being taken off the market or prohibited because of reported side effects highlight the importance of pharmacovigilance. Pharmacovigilance includes identifying, monitoring, evaluating, and recording drug-related problems as well as comprehending the causes of side effects. The negative effects of medicinal drugs can be reduced by efficiently monitoring ADRs through pharmacovigilance, protecting patient health, and encouraging better prescription habits [1].

The purpose of this study was to evaluate the severity, predictability, and causality of ADRs in a tertiary care hospital in India. This study aimed to offer important insights into the ADR landscape in the Indian healthcare context by assessing these important factors. The results aided in the creation of focused plans for boosting patient safety, encouraging responsible drug use, and increasing ADR monitoring in India.

Objectives

This study was conducted to monitor ADRs in the respiratory department of a tertiary care hospital in Belagavi, Karnataka, and analyze the predictability, severity and causality assessment of ADRs.

Materials and Methods

A prospective observational study was carried out at the respiratory department of a tertiary care hospital in Belagavi, North Karnataka, at KLEs Dr. Prabhakar Kore Hospital, Belagavi, India, from September 2023 to January 2025. We recruited participants aged 45 years and older with chronic obstructive respiratory disease who had cognitive impairment. Convenience sampling was used to calculate the sample size, taking into account the availability of eligible patients during the study period.

The KLE COP Ethics Committee in Belagavi granted approval for the study protocol (Reference number- KLECOPBGMEC/D005-2023). The severity, recovery status, drug details, and results of ADRs were among the information gathered and assessed from the ADR reports. Using the proper scales, the gathered data was assessed for causality, predictability, seriousness, and severity. Descriptive statistics were used for the study analysis.

Inclusion criteria

- ADRs from the respiratory departments of both the outpatient department and inpatient department of a tertiary care teaching hospital, Belagavi, Karnataka, India.
- Patients aged above 45 years of both genders.
- Patients with adequate auditory, fine motor, and visual skills.

Exclusion criteria

- ADRs resulting from the use of blood or blood products.
- ADRs associated with alternative medicine systems such as homeopathy, siddha, ayurveda and unani.
- Previous head injury or brain tumor, cognitive decline, epileptic condition
- Patient diagnosed with kidney and liver dysfunction, due to altered drug metabolism and increased toxicity, which could confound the assessment of ADR severity and causality.

Results

The demographic distribution of ADRs (Table 1) underscores the diverse vulnerability among adults and the elderly. The elderly accounted for 63.5% of the reported ADR cases, with adults making up 36. 4%. The gender distribution of ADRs indicated that females were predominant, with 59.8% of the documented ADR cases, whereas males accounted for 40.2% of the overall total.

The evaluation of severity was performed using a modified Hartwig and Siegel Scale, which shows that the majority of the ADRs were classified as mild, representing 60.7% of instances. ADRs of moderate severity made up 34.5% of the overall total, whereas severe ADRs were observed less often at 3.7% (Table 2).

The predictability of ADRs classified according to the types of reactions indicated that a considerable proportion of ADRs were predictable, making up 77.5% of cases. On the other hand, non-predictable ADRs represented 22.4% of occurrences. The distribution implies that a significant majority of ADRs can be foreseen based on established drug effects or patient characteristics, highlighting the significance of risk evaluation and oversight in clinical practice (Table 2).

According to the WHO-Uppsala Monitoring Center Scale

Table 1. Details of demographic data of adverse drug reactions.

	Demographic variables	Number of patients (n=107), n (%)
Age group	Elderly	68 (63.5)
	Adult	39 (36.4)
Gender	Female	64 (59.8)
	Male	43 (40.2)

Table 2. Severity predictability, seriousness and causality assessment of adverse drug reactions.

Scales	Types	Number of ADRs, n (%)
Severity assessment by Modified Hartwig and Siegel Scale	Mild	65 (60.7)
	Moderate	37 (34.5)
	Severe	4 (3.7)
Predictability as per types of ADRs	Non-Predictable	24 (22.4)
	Predictable	83 (77.5)
Seriousness as per WHO-UMC scale	Serious	20 (18.6)
	Non-Serious	87 (81.3)
Causality Assessment as per WHO-UMC scale	Certain	11 (10.2)
	Probable	55 (51.4)
	Possible	40 (37.3)
	Unlikely	1 (0.93)

ADRs, adverse drug reactions; WHO-UMC, World Health Organization-Uppsala Monitoring Center Scale.

(WHO-UMC), ADRs were classified by their severity, showing a significant percentage of serious cases at 18.6%. In contrast, non-serious ADRs made up the majority, accounting for 81.3% of the overall total (Table 2).

The evaluation of causality for ADRs using the WHO-UMC scale uncovers a range of causal links. Most ADRs were identified as probable, making up 51.4% of the instances, followed by possible ADRs at 37.3%. A smaller percentage was considered certain (10.2%), whereas merely a trivial amount was classified as unlikely (0.93%) (Table 2).

Patient safety and management depended heavily on the steps taken after ADRs occurred. According to the data, the most frequent course of action (55.1% of cases) was to withdraw the medications. In contrast, in 15.8% of cases, the drug's dosage was reduced, and in 22.4% of cases, it remained unchanged. Furthermore, in 6.54% of cases, no particular action was taken. The importance of customized interventions based on the severity and type of adverse event is highlighted by these percentages, which showed the variety of approaches used by medical professionals in response to ADRs (Table 3).

ADR results, as shown in the table, showed different states after an ADR occurs. The majority of ADR cases [46 (42.9%)] were categorized as "recovering", indicating continuous progress. Furthermore, a significant percentage of cases [40 (37.3%)] were "recovered" from the ADRs. On the other hand, only 15 (14.01%) of the population remained "not recovered". Additionally, only 5 cases (4.6%) were classified as "unknown". Additionally, 1 case (0.93%) resulted in the patient's death (Table 4).

Systemic classes are used to categorize ADRs s, which offer important insights into the various physiological systems impacted by drug use. The most commonly reported ADRs, accounting for 33.6% of all reports, were gastrointestinal disorders, highlighting the prevalence of gastrointestinal symptoms such as xerostomia, constipation, and unusual tongue taste. At 18.6% of the reports, respiratory diseases come in second, suggesting a high prevalence of respiratory reactions such as cough, bronchitis, sinusitis, nasal mucosal dryness, and bronchospasm. Disorders of the cardiovascular system, including hypertension, irregular ECG readings, and arrhythmias, accounted for 16.8%. Skin and subcutaneous reactions, such as rashes, hives, and itching, accounted for 12.1%. The rates for neurological conditions, such as headaches, tremors, and giddiness, as well as musculoskeletal conditions, including joint pain, muscle weakness, and a decline in bone density, were 7.47% and 5.6%, respectively. Hypokalaemia, hyponatremia and anemia were seen among the 5.83% of ADRs linked to a decline in laboratory values (Table 5).

Table 3. Actions taken in response to adverse drug reactions.

Action taken	ADRs
Drug withdrawn	59
Dose of the drug not changed	24
Dose of the drug reduced	17
Not applicable	7

ADRs, adverse drug reactions.

Table 4. Outcomes of adverse drug reactions.

Category	Number of ADRs, n (%)
Recovered	40 (37.3)
Not recovered	15 (14.01)
Recovering	46 (42.9)
Unknown	5 (4.6)
Death	1 (0.93)

ADRs, adverse drug reactions.

Table 5. Classification of adverse drug reactions.

Types of adverse drug reactions	Number of reports
Gastrointestinal disorders	36
Respiratory disorders	20
Cardiovascular disorders	18
Dermatological disorders	13
Neurological disorders	8
Musculoskeletal disorders	6
Biochemistry abnormalities	6

ADRs, adverse drug reactions.

Discussion

Important patterns regarding ADR causation assessments were found in the present study and the study conducted by Khan *et al*. A strong link between medication administration and observed reactions was seen in the present study conducted at Belagavi respiratory department study, where the WHO-UMC categorized the majority of ADRs as probable (51.4%), followed by possible (37.3%), certain (10.2%), and unlikely (0.93%). Similar drug classes, especially antibiotics and anti-tubercular drugs, were linked to respiratory ADRs in the current research, as well as the study conducted by Khan *et al*. While causality assessment techniques are uniform across Indian tertiary care settings, the comparative data indicate the adoption of improved pharmacovigilance practices, as evidenced in the study by Khan *et al*.

These results highlight the importance of methodical causality assessment in respiratory medicine for creating preventive measures and enhancing patient safety results. There were significant methodological similarities between the two studies, which examined ADR monitoring in tertiary care hospitals. These included prospective observational designs and causality assessment frameworks. However, significant variations in their findings and scope were found. The current study most likely concentrated exclusively on respiratory patients and medications, even though Khan *et al*. looked at ADRs in internal medicine patients and found that antibiotics (40.62%) were the main culprits with primarily dermatological manifestations (68.75%). Khan *et al*. used a thorough "stimulated spontaneous reporting" system, using the Hartwig-Seigel scale for severity assessment and Naranjo's scale for causality. They found that older patients (aged 61-80 years) and females (54.05%) had a higher prevalence of ADRs. These opposing methods draw attention to complementary viewpoints: Specialty-related ADR patterns are captured by department-specific monitoring, while more extensive implementations create systematic hospital-wide pharmacovigilance. A notable contrast emerges when examining the demographic distribution of ADRs across the two datasets of the present study and the research by Gershnabel Milk *et al*.

In the present study, it was determined that the elderly constitute a substantial proportion (63.5%) of reported ADR cases, with adults accounting for the remainder (36.4%). Furthermore, females represent a majority (59.8%) of the documented ADR cases.

In contrast, the study by Gershnabel Milk *et al.*, which focuses on eosinophilic adverse reactions related to specific biologics (dupilumab, omalizumab, and mepolizumab), presents a different

picture. While the age distribution among dupilumab-treated patients mirrors the adult age range (18-64 years), data regarding omalizumab and mepolizumab groups reveal a female predominance, although age distribution is challenging to ascertain due to missing data. The variance in demographic representation may stem from the specific patient populations receiving these biologic treatments and the nature of the adverse events being tracked. As such, a "one-size-fits-all" approach may not be effective in mitigating ADRs, and tailored strategies may be necessary for distinct populations [3].

The assessment of ADR severity also reveals interesting contrasts. The current study, employing a modified Hartwig and Siegel Scale, classifies the majority of ADRs as mild (60.7%), with moderate and severe reactions occurring less frequently (34.5% and 3.7%, respectively). Conversely, the research by Gershnabel Milk *et al*. categorizes biologically associated eosinophilic granulomatosis with polyangiitis (EGPA), eosinophilic respiratory, and hyper eosinophilic syndrome (HES) reactions as "serious". In this cohort, a significant proportion of patients with these reactions required hospitalization: 34%, 45%, and 58%, respectively, in the dupilumab group, with one death reported in the HES group. Similarly, among omalizumab-treated patients, 50%, 40%, and 79% of those with EGPA, eosinophilic respiratory complications, and HES, respectively, required hospitalization, with 9 deaths occurring in the EGPA group. The disparate severity profiles likely reflect the nature of the drugs and the specific adverse reactions under scrutiny. While common medications may elicit primarily mild to moderate reactions, biologic therapies can, in certain instances, trigger severe, life-threatening eosinophilic conditions.

The evaluation of causality, performed using the WHO-UMC scale, offers additional insights into the nature of ADRs across the two datasets. In the current research, most ADRs were classified as probable (51.4%) or possible (37.3%), with only a smaller percentage considered certain (10.2%). Comparatively, the study by Gershnabel Milk *et al.* does not provide a specific causality assessment using the WHO-UMC scale but focuses on identifying associations between specific biologics and eosinophilic adverse reactions. The emphasis on probable and possible causal links in the first dataset underscores the inherent challenges in definitively attributing ADRs to specific medications, particularly in complex clinical scenarios.

There are also some parallels and discrepancies between patient safety and management procedures after ADRs. The study by Gershnabel Milk *et al.* emphasizes the sizeable percentage of patients who need hospitalization and, in certain situations, have fatal outcomes, but it offers little information on particular management techniques. The current study's emphasis on medication withdrawal emphasizes how crucial it is to act quickly to reduce ADRs and stop additional harm.

A comparison of the ADR dataset from the current study and the research by Gershnabel Milk *et al.* shows both significant differences and parallels in terms of management strategies, causality, severity evaluations, and demographic distributions. In certain cases, biologic therapies can cause severe, life-threatening eosinophilic conditions that frequently require hospitalization, whereas common medications may primarily cause mild to moderate reactions in a larger patient population. While the widespread practice of medication withdrawal emphasizes the significance of timely intervention following ADRs, the differences in demographic representation highlight the need for customized pharmacovigilance strategies. In the future, improving patient safety and treatment results will require combining these various data sources and implementing sophisticated, data-driven strategies. hand, failed to emphasize predictability and rather focused on comparative incidence rates. The research by Zou *et al*. and the current study both emphasize ADRs in respiratory medicine, highlighting the necessity of systematic assessment techniques and pharmacovigilance. While Zou *et al.* carried out a retrospective Food and Drug Administration Adverse Event Reporting System based analysis, particularly on anti-interleukin-5 monoclonal antibodies, the current study is a prospective observational examination of ADRs across a variety of respiratory medications in an Indian tertiary care setting. The WHO-UMC and Modified Hartwig and Siegel Scales were employed in this investigation, whereas disproportionality analysis was used by Zou *et al*. [4-6].

The demographic distribution of ADRs is a critical area of focus, underscoring the varied susceptibility across different patient segments. As both datasets reveal, age and gender appear to be key determinants in ADR occurrences. The present study indicates that the elderly constitute a substantial portion (63.5%) of reported ADR cases, with adults accounting for the remaining 36.4%. This trend aligns with the understanding that physiological changes associated with aging can influence drug metabolism and excretion, thereby increasing the risk of adverse events. Moreover, that study notes females make up 59.8% of documented ADR cases, while males account for 40.2%. However, "clinical studies have discussed that women are 1.5 to 1.7 times more at risk of ADRs than males", suggesting there may be other factors, such as hormonal differences, that increase ADRs. Such variations underscore the importance of considering individual patient characteristics when assessing ADR risk. "Both age and gender serve as the main risk factors regarding ADR occurrences", but understanding the underlying factors and contradictory reports is the first step in improving predictability.

The severity of ADRs is another critical dimension that requires careful consideration. The present study employs a modified Hartwig and Siegel Scale, revealing that the majority of ADRs are classified as mild (60.7%), with moderate reactions accounting for 34.5% and severe reactions occurring less frequently at 3.7%. This suggests that while most ADRs may not be life-threatening, a significant proportion can still lead to considerable discomfort and morbidity. These findings are further reinforced by another set of data from the research of Baniasadi *et al.*, where ADRs classified by the WHO-UMC showed that serious cases accounted for 18.6%, with non-serious ADRs making up the majority (81.3%). "The severity of ADRs is determined by the healthcare provider based on the patient's symptoms and clinical course", highlighting the subjective aspect of this area. This is further complicated as "ADRs are considered mild if they fall into levels 1 or 2, moderate if they are in levels 3 or 4, and severe if they are in levels 5 to 7". As the severity can impact a patient's everyday life, it is imperative to have appropriate documentation. The contrasting metrics that come from the classification further emphasize the need for clear evaluation [6-9].

Predictability and causality assessment are pivotal in understanding and managing ADRs. A predictability study indicated that a considerable proportion of ADRs (77.5%) are predictable, implying that they can be foreseen based on established drug effects or patient characteristics. This distribution highlighted the significance of risk evaluation and oversight in clinical practice. In contrast, 22.4% of ADRs were classified as non-predictable, underscoring the inherent challenges in anticipating all potential adverse events. It is worth noting that "the evaluation of causality for ADRs using the WHO UMC scale uncovered a range of causal links". Most ADRs were identified as probable (51.4%), followed by possible ADRs at 37.3%, while a smaller percentage was considered certain (10.2%), and a trivial amount was classified as unlikely (0.93%). Although algorithms can help with assessing the causality of ADRs, they cannot prove or disprove such an association [4].

In the study by Baniasadi *et al.*, patient safety and management depend heavily on the actions taken following ADR occurrences, with 55.1% of cases involving withdrawal of the medication. However, in 15.8% of cases, the drug's dosage was reduced, in 22.4% of cases, it remained unchanged, and in 6.54% of cases, no particular action was taken. These percentages highlight the variety

of approaches employed by medical professionals in response to ADRs and emphasize that customised interventions based on the severity and type of adverse event are most appropriate. Furthermore, the categorization of ADR cases in the present study is done as "recovering" (42.9%) and "recovered" (37.3%), indicating continuous progress and positive outcomes in a significant percentage of instances. However, there are still a number of cases where patients did not recover (14.01%) and a few cases where the result was "unknown" (4.6%), with rare but tragic outcomes of a patient's death (0.93%). When determining the long-term effects of ADRs, multi-morbidity, associated polypharmacy, female gender, and increased age are associated with an increased risk of ADRs and must be considered when planning management strategies [10]. These factors may lead to increased morbidity, increased hospital stays, and increased cost of treatment, resulting in compromised patient safety. Therefore, it remains a high priority to minimize risk while maximizing recovery [10].

This study was conducted at a single center with a relatively small sample size, potentially limiting the generalizability and statistical power of the findings. The focus on patients aged 45 years and above may exclude relevant data from younger populations. Future multicenter studies with larger sample sizes, broader patient populations, and extended follow-up are recommended.

Conclusions

The assessment of ADRs in healthcare settings, particularly in tertiary care hospitals in India, is essential for improving patient outcomes and minimizing drug-related harm. Accessibility of ADR reporting mechanisms, predictability of risk factors, and accurate severity assessment are critical components of effective pharmacovigilance programs. By conducting comprehensive studies and implementing targeted interventions, healthcare systems can enhance their ability to monitor, manage, and prevent ADRs, thereby promoting safer and more effective medication use. This research contributes to the growing body of knowledge on ADRs and provides a foundation for future studies aimed at optimizing drug safety in diverse healthcare contexts. Patient safety and treatment outcomes can be improved by strengthening pharmacovigilance programs and improving ADR surveillance processes in respiratory care. Clinical practice should incorporate the early detection and treatment of predictable ADRs.

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