RESEARCH PAPER

Pharmacovigilance of Adverse Drug Reactions in Patients with Respiratory Diseases: Insights from a Tertiary Care Teaching Hospital

Dr. Harsh Chauhan[1*], Dr. Harsh Chaudhary[2], Dr. Pratibha Rani[3], Dr. Mohd Riyaz[4], Dr. Sadhna Solanki[5], Dr. Ashutosh Pathak[6], Prof. Dr. Prithpal Singh Matreja[7]

[1*]Doctor of Pharmacy, Teerthankar Mahaveer College of Pharmacy, Teerthanker Mahaveer University, Moradabad, India, 244001, Email: hcrkd22@gmail.com

[2]Doctor of Pharmacy, Teerthankar Mahaveer College of Pharmacy, Teerthanker Mahaveer University, Moradabad, India, 244001, Email: Jattranaharsh30@gmail.com

[3]Doctor of Pharmacy, Teerthankar Mahaveer College of Pharmacy, Teerthanker Mahaveer University, Moradabad, India, 244001, Email: ak05011963@gmail.com 4

[4]Department of Pharmacy Practice, Guru Ram Dass college of Pharmacy, Punjab, 152107, Email ID: drmohdriyaz984@gmail.com

[5]Doctor of Pharmacy, Teerthankar Mahaveer College of Pharmacy, Teerthanker Mahaveer University, Moradabad, India, 244001, Email: Solankisadhna72@gmail.com 1

[6]Department of Pharmacy Practice, Teerthankar Mahaveer College of Pharmacy, Teerthanker Mahaveer University, Moradabad, India, 244001, Email ID: ashutos4088@gmail.com

[7]Department of Pharmacology, Teerthankar Mahaveer Medical college & Research center, Teerthanker Mahaveer University, Moradabad, India, 244001, Email:drpsmatreja@yahoo.co.in

Corresponding Author

Dr. Harsh Chauhan

Doctor of Pharmacy, Teerthankar Mahaveer College of Pharmacy, Teerthanker Mahaveer University, Moradabad, India, 244001, Email: hcrkd22@gmail.com

ABSTRACT

This pharmacovigilance study conducted over six months at a tertiary care teaching hospital evaluated the incidence, pattern, severity, and causality of adverse drug reactions (ADRs) in 239 patients with respiratory diseases. The cohort, aged 1 to 104 years with a mean age of 37.38 years, predominantly comprised males (54.8%) and patients from the respiratory department (62.3%). Common diagnoses included asthma (31.4%), pneumonia (19.7%), COPD (19.2%), tuberculosis (16.3%), and pulmonary fibrosis (13.4%). Polypharmacy was frequent, with most patients receiving four to six drugs, including widely prescribed bronchodilators, corticosteroids, and antibiotics. ADRs were identified in 23% of participants, with a significant association found between ADR occurrence and age, treatment department, and diagnosis, but not with the number of drugs prescribed. Bronchodilators (38.2%), antibiotics (20%), and corticosteroids (12.7%) were the most common drug classes implicated. Oral administration was the most frequent route for ADR-causing drugs (58.2%). The majority of ADRs were classified as probable (58.2%) and moderate in severity (58.2%) based on the Naranjo scale. Frequently reported symptoms included cough, nervousness, palpitations, tachycardia, and tremors. These findings underscore the critical need for vigilant monitoring and targeted interventions to improve medication safety and patient outcomes in respiratory care settings. The study advocates enhanced pharmacovigilance, especially in older patients and those receiving bronchodilators, antibiotics, and corticosteroids, to mitigate ADR risks and optimize therapeutic efficacy.

Keywords: : Adverse Drug Reactions (ADR), Respiratory Diseases , Pharmacovigilance ,Drug Safety

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INTRODUCTION

Pharmacovigilance studies systematically track, assess, and prevent adverse drug reactions (ADRs) after medications are authorized for general use1, ensuring ongoing safety in real-world populations[1]. These studies are crucial in pulmonary diseases, where medication regimens are often complex and patients may be at higher risk of ADRs due to disease characteristics, comorbidities, and polypharmacy[2].

Major Respiratory Diseases and Drug Safety Challenges

1. ASTHMA

A chronic inflammatory airway disease characterized by reversible airflow obstruction and airway hyperreactivity. Asthma involves bronchospasm, airway inflammation, and mucus secretion[3]. Hypersecretion, producing symptoms like wheezing, breathlessness, and chest tightness[4]. Treatment involves bronchodilators (e.g., SABAs, LABAs, anticholinergics) and anti-inflammatory drugs (e.g., inhaled corticosteroids, leukotriene modifiers, biologics)[5].

Challenges include monitoring for ADRs such as paradoxical bronchospasm and medication errors, especially inhaler technique problems[6].

2. CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

A progressive disease causing irreversible airflow limitation mainly caused by smoking and environmental exposuresVV. Management includes bronchodilators (LABAs, LAMAs), inhaled corticosteroids in select cases, pulmonary rehabilitation, oxygen therapy, and sometimes surgery or transplantation[7]. COPD patients face risks of exacerbations, respiratory failure, infections, and drug-related adverse events that complicate therapy and pharmacovigilance[8].

3. PULMONARY FIBROSIS

Characterized by progressive scarring of lung tissue resulting in stiffness and impaired gas exchange. Idiopathic Pulmonary Fibrosis (IPF) is the most common form with no known cause, while other fibrosis types relate to autoimmune diseases, exposures, drugs, or radiation[9]. Treatment focuses on symptom control and slowing progression with antifibrotics (nintedanib, pirfenidone), oxygen, rehabilitation, and lung transplantation in severe cases[10]. Pharmacovigilance addresses antifibrotic side effects, the impact of supportive therapies, and complications like pulmonary hypertension and respiratory failure[11].

4. TUBERCULOSIS (TB)

An infectious disease mainly caused by Mycobacterium tuberculosis, spread by airborne droplets[12]. It presents as latent infection (non-contagious) or active disease (contagious). Diagnosis involves sputum smear and culture, PCR-based NAAT, and imaging[13].

Treatment requires prolonged multidrug regimens with issues around compliance, drug resistance (MDR-TB/XDR-TB), and ADRs related to antibiotics. Pharmacovigilance monitors safety, resistance patterns, and consequences of poor adherence[14].

5. PNEUMONIA

Inflammation of lung tissue due to infections (bacterial, viral, fungal) or non-infectious causes (aspiration, chemical irritants)[15]. Treatment is pathogen-specific, often antibiotics for bacterial cases, antivirals for viruses like influenza or COVID-19, antifungals for fungal pneumonia, plus supportive care such as oxygen and hydration[16]. Pharmacovigilance monitors ADRs, treatment complications, and medication errors including antibiotic misuse[17].

Pharmacovigilance in respiratory medicine is essential due to the high prevalence of polypharmacy, comorbidities, and vulnerable populations such as the elderly and children, which increase risks of drug interactions and adverse drug reactions (ADRs)[18]. Lung diseases alter drug pharmacokinetics and pharmacodynamics, making careful monitoring crucial[19]. Key strategies include ADR detection using reports and electronic health records, prevention through dose adjustments, adherence and inhaler education, and fostering a strong reporting culture. Elderly patients require simplified regimens and close monitoring for atypical ADRs, while pediatric patients need weight-based dosing and enhanced post-marketing surveillance[20]. In outpatients, self-management demands education and virtual monitoring, while hospitalized patients need active surveillance, decision support tools, and pharmacist involvement. Interdisciplinary collaboration and technology integration, such as smart inhalers, telemedicine, and electronic prescribing, help optimize safety. Overall, pharmacovigilance minimizes morbidity, enhances therapy outcomes, and supports safer use of bronchodilators and corticosteroids, the most frequent culprits in respiratory ADRs[21].

LITERATURE REVIEW

1. **Yavordios & Beltramo (2025)** – French Pharmacovigilance Database Study on DrugInduced Diffuse Lung Disease (DI-ILD)This expansive retrospective analysis of 7,234 adult cases over 37 years (1985–2022) examined drug-induced diffuse lung diseases reported to the French Pharmacovigilance Database (FPVD). The study included 13,059 suspected drugs covering 1,112 unique compounds. The majority of cases were serious (96.7%), with a notable mortality of 13.3%. Males comprised 54.4%, and median age was 69 years. The most frequent adverse drug reactions (ADRs) were interstitial lung disease (51%), pulmonary edema (15.6%), and pulmonary fibrosis (10.5%). Amiodarone was the most commonly implicated drug (10%), followed by methotrexate (3.1%). Anti-cancer (31.2%) and cardiovascular (29.1%) drugs were the leading therapeutic classes involved. This represents the largest known pharmacoepidemiological study on DI-ILD, highlighting the severity of these conditions and the critical need for prompt diagnosis and withdrawal of the offending drugs to reduce mortality and morbidity[15].

2. **Ben-Noun (2000**) – Overview of Drug-Related Respiratory Disorders (ARDs)This review described various drugs causing adverse respiratory problems. Calcium antagonists, dipyridamole, and beta-blockers can provoke asthma; ACE inhibitors frequently cause cough. Interstitial pneumonitis (IP) may be induced by amiodarone, tocainide, flecainide, gold, and penicillamine, sometimes linked to autoimmune conditions like Goodpasture's disease and systemic lupus erythematosus. Hydrochlorothiazide has been associated with IP and pulmonary edema. Antiasthmatics may cause paradoxical bronchospasm; leukotriene antagonists have connections to Churg-Strauss syndrome. NSAIDs, including aspirin, may exacerbate asthma. Cytotoxic drugs commonly cause persistent pneumonitis and fibrosis. Some psychiatric medications can induce noncardiogenic pulmonary edema. Hormone therapies and oral contraceptives can increase asthma risk or worsen symptoms. Because these druginduced respiratory disorders are variable and sometimes unpredictable, rapid discontinuation of the causative agent is vital for preventing serious complications [22].

3. Inácio et al. (2017) – Systematic Review of Patient Reporting in Pharmacovigilance This systematic review synthesized 34 studies to assess the role and impact of patient reports of adverse drug reactions (ADRs) within pharmacovigilance systems. Patient reporting provides unique, complementary information to healthcare professional (HCP) reports by detailing the severity and impact of ADRs on daily life. Although patient reporting rates remain relatively low globally, these reports enhance understanding of medication safety and inform regulatory decision-making. Despite clear benefits, knowledge gaps remain about patient reporting processes, including barriers, reliability, and integration with professional reports. Enhancing patient involvement can improve ADR detection and enrich pharmacovigilance data quality[23].

4. Fonseca et al. (2021) – Portuguese Pharmacovigilance Study on Inhaled Medications This study analyzed 230 spontaneous reports (SRs) related to inhaled medications used in asthma, COPD, and asthma-COPD overlap submitted to the Portuguese Pharmacovigilance System from 2007 to 2017. There were 599 suspected ADRs reported. The highest frequency of reports involved inhaled corticosteroid/long-acting beta-2 agonist combinations (32.2% of SRs and 32.7% of ADRs). Men made up 51.3% of cases; the most affected age group was non-elderly adults (39.1%). Most reports (70.4%) were serious. Dyspnea was the most common symptom (4.8%), and respiratory disorders accounted for 19.5% of the ADRs. Many events were anticipated and associated with controller medications; some were linked to overuse or misuse of reliever inhalers, underscoring the significance of pharmacovigilance in optimizing inhaler safety and adherence[24].

5. Monica Zolezzi (2005) – Spontaneous Reporting of Respiratory ADRs in New Zealand This earlier study from the Spontaneous Adverse Drug Reaction Centre (SANZ) found that respiratory organ disorders comprised about 4% of 4,415 ADRs reported between 1981 and 1990. Commonly implicated were ACE inhibitors causing cough, NSAIDs and beta-blockers triggering asthma attacks, amiodarone and sulfonamides causing interstitial pneumopathy, and benzodiazepines leading to respiratory depression. The study highlighted the limitation of spontaneous reporting as primarily signalgenerating, emphasizing that precise diagnosis relies on clinical correlation including timing of drug exposure and reaction occurrence, alongside thorough literature review. This indicated the importance of combining pharmacovigilance data with clinical expertise to assess respiratory ADRs accurately[25] .

METHODOLOGY

Study Design

A single-center prospective observational study was conducted from January to June 2025 at Teerthanker Mahaveer Hospital and Research Centre, Moradabad, India. After ethics committee approval, 239 patients diagnosed with respiratory diseases were enrolled regardless of age or gender, with data collected via tailored forms capturing demography, medical/drug history, ADR events, severity, and class.

Data Collection and Analysis

ADRs were adjudicated using the Naranjo scale, which applies a structured scoring system to assess causality between drug and observed event. Statistical analysis utilized SPSS v29, employing chi-square and likelihood-ratio testing to evaluate associations with demographic and clinical variables ($p < 0.05$ considered significant).

Results

Demographics

Age of the participants ranged from 1 to 104 years with mean: 37.38 + 19.78 years; and the weight ranged from 8 to 98 Kg with mean: 65.09 + 21.40 Kg.

Age according to gender

Among males, the age group reveal: 20 to 39 years (32.1%), 40 to 59 years (32.1%), greater than 60 years (16%), 1 to 5 years (7.6%), 12 to 18 years (5.3%), 6 to 11 years (4.6%), and 19 to 20 years (2.3%). Among females; the majority were in the age group: 20 to 39 years (45.4%), 40 to 59 years (22.2%), greater than 60 years (14.8%), 12 to 18 years (5.6%), 6 to 11 years (6.1%), 1 to 5 years (4.6%), and 19 to 20 years (1.9%).

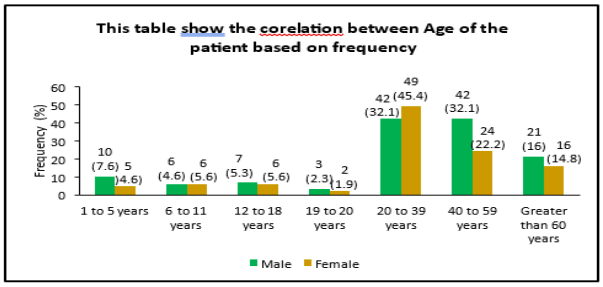


Figure 1 Age according to gender

Association between gender and ADR The Chi square test was used to find the association between gender and ADR. There was no association ($p > 0.05$) between gender and ADR. [Table -11]

Table 1: Association between gender and ADR

	ADR				Chi square	p value
	ADR		No-ADR			
	n	%	n	%		
Gender	Male	28	50.9	103	56.0	0.44	0.507
	Female	27	49.1	81	44.0		

Confirmed drug that caused ADR

The confirmed drug that caused ADR were AMOX (9.1%), SAL (9.1%), PRED (7.3%), THEO (7.3%), ALBU (5.5%), BUDE (5.5%), CEPH (5.5%), SILD (5.5%), TADA (5.5%), AZIT (3.6%), FLUT (3.6%), FOR (3.6%), IPRA (3.6%), MONT (3.6%), TIO (3.6%), BECL (1.8%), BECLO (1.8%), METH (1.8%), PDS (1.8%), RIFA (1.8%), SALM (1.8%), SLIND (1.8%), TERB (1.8%), ZAFI (1.8%), and ZAR (1.8%).

CODE OF DRUGS

The provided codes map each respiratory, antibiotic, cardiovascular, and adjunct drug to a unique abbreviation used in the pharmacovigilance study for efficient data recording and analysis of adverse drug reactions (ADRs).

Common bronchodilators and inhaled corticosteroids include Salbutamol (ALBU), Tiotropium Bromide (TIO), Terbutaline (TER), Salmeterol (SAL), Formoterol (FOR), Ipratropium Bromide (IPRA), Theophylline (THEO),
Beclomethasone (BECLO), Fluticasone (FLUT), Mometasone (MOME), Budesonide
(BUDE); leukotriene modifiers: Montelukast (MON), Zafirlukast (ZAR); mast cell stabilizers: Cromolyn Sodium (CRO), Nedocromil Sodium Cromolyn Sodium (NENA). Antibacterial and antifungal agents are Amoxicillin (AMOX), Cephalexin (CEP), Azithromycin (AZIT), Levofloxacin (LEVO), Fluconazole (FLU), Voriconazole (VOR), with TB drugs such as Isoniazid (ISO), Rifampicin (RIFA), Pyrazinamide (PYRA), and Ethambutol (ETHAM). Other notable drugs are PDE-5 inhibitors Sildenafil (SLIND), Tadalafil (TADA), pulmonary hypertension agents Bosentan (BOSE), Ambrisentan (AMBRI), and Epoprostenol (EPO). Systemic and oral steroids include Prednisolone (PDS) and Methylprednisolone (MPDS). The table also encodes analgesics like Codeine (CODE), Dextromethorphan (DEXT), NSAIDs Ibuprofen (IBU), Naproxen (NAPRO), cardiovascular drugs Lisinopril (LISIN), Enalapril (ENAL), and opioids Morphine (MORP), Fentanyl (FENT), ensuring consistent reporting and ease of cross-referencing drug-related ADRs within the dataset.

Suspected drugs causing ADR

The suspected drugs causing ADR were Salbutamol (Albuterol) (12.7%), Amoxicillin (9.1%), Prednisolone (9.1%), Theophylline (7.3%), Budesonide (5.5%), Cephalexin (5.5%), Sildenafil
(5.5%), Tadalafil (5.5%), Azithromycin (3.6%), Beclomethasone (3.6%), Fluticasone (3.6%),
Formoterol (3.6%), Ipratropium Bromide (3.6%), Montelukast (3.6%), Salmeterol (3.6%), Terbutaline (3.6%), Tiotropium Bromide (3.6%), Zafirlukast (3.6%), Methylprednisolone (1.8%), and Rifampicin (1.8%). [Table – 16]

Table 2: Suspected drugs causing ADR

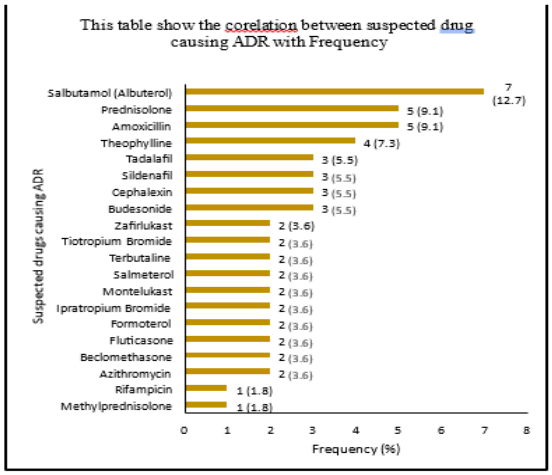


Figure 2 Suspected drugs causing ADR

Class of ADR drugs
The class of ADR drugs identified were Bronchodilators (38.2%), Antibiotics (20%), Corticosteroids (12.7%), Pulmonary Hypertension Meds (10.9%), and Systemic Corticosteroids (10.9%). [Table – 17]

Table 3: Class of ADR drugs

Class of drug	Frequency	%
Antibiotics	11	20.0
Bronchodilators	21	38.2
Corticosteroids	7	12.7
Leukotriene Modifiers	4	7.3
Pulmonary Hypertension Meds	6	10.9
Systemic Corticosteroids	6	10.9

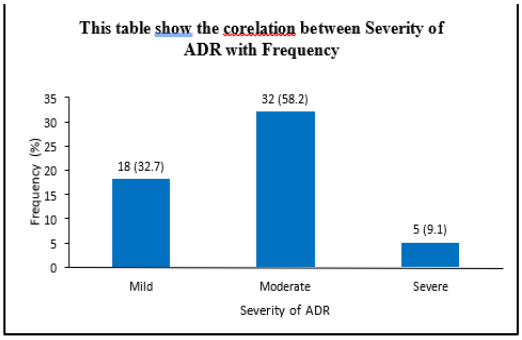
Naranjo scale

The Naranjo scale ranged from 0 to 9 with mean: 5.40 + 2.05. The severity of Naranjo scale revel: doubtful (3.6%), possible (29.1%), probable (58.2%), and highl (9.1%).

Table 4: Naranjo scale

Severity (Naranjo Scale)	Frequency	%
Doubtful (0)	2	3.6
Possible (1-4)	16	29.1
Probable(5-8)	32	58.2
Highly (9+)	5	9.1

Figure 3: Severity of ADR



Symptoms
The symptoms identified were cough (16.4%), nervousness (16.4%), palpitations (16.4%), tachycardia (16.4%), tremors (16.4%), headache (12.7%), hoarseness (12.7%), nausea (12.7%), oral thrush (12.7%), vomiting (12.7%), rash (10.9%), seizures (10.9%), anaphylaxis (9.1%), diarrhoea (9.1%), hives (9.1%), increased appetite (9.1%), irritability (9.1%), weight gain (9.1%), dry mouth (7.3%), urinary retention (7.3%), flushing (5.5%), nasal congestion (5.5%), peripheral Edema (5.5%), vision changes (5.5%), abdominal pain (3.6%), hyperactivity (3.6%), wheezing (3.6%), euphoria (1.8%), gastrointestinal upset (1.8%), osteoporosis (1.8%), photosensitivity (1.8%), and sleep disturbances (1.8%). [Table – 22]

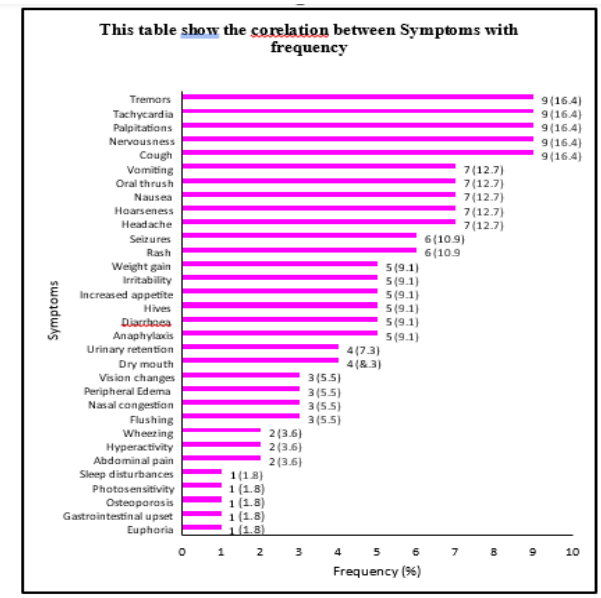
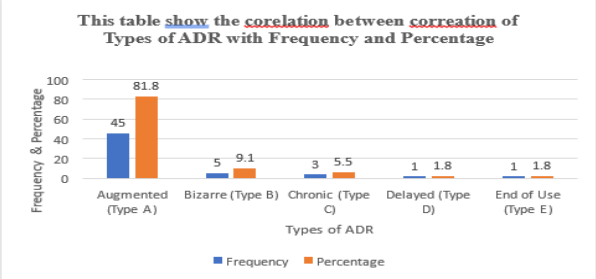


Figure 4 Symptoms

Types of ADR

The data shows the distribution of different types of adverse drug reactions (ADRs) categorized by their characteristics. The majority, 81.8%, are Type A or Augmented reactions, which are predictable and dose-dependent effects related to the drug's known pharmacology. About 9.1% are Type B or Bizarre reactions, which are unpredictable, idiosyncratic, and not dose-related. Chronic reactions (Type C), which develop after prolonged use, account for 5.5%. Delayed reactions (Type D) that appear some time after treatment and withdrawal reactions occurring after stopping a drug (Type E) each represent 1.8%. This distribution highlights that most ADRs are predictable and dose-related (Type A), while the less common types are often more complex or time-dependent, underscoring the importance of careful dosing and monitoring to prevent most ADRs.

Figure 5 Types of ADR



This table show the corelation between correation of Types of ADR with Frequency and Percentage

Statistical analysis:

The pharmacovigilance study conducted at a tertiary care teaching hospital included 239 participants aged 1 to 104 years (mean age 37.38 years). Most participants were male (54.8%) and primarily from the respiratory department (62.3%). Common diagnoses were asthma (31.4%), pneumonia (19.7%), COPD (19.2%), tuberculosis (16.3%), and pulmonary fibrosis (13.4%). The majority received four drugs (49.8%), with frequently prescribed medications including Budesonide, Salbutamol, Amoxicillin, Azithromycin, and Prednisolone. ADRs were identified in 23% of participants. Significant associations were found between age, department, diagnosis, and ADR occurrence, but not with gender or the number of drugs prescribed. The most common drugs causing ADRs were Amoxicillin, Salbutamol, Prednisolone, and Theophylline, mainly bronchodilators and antibiotics. Oral administration was predominant among ADR-causing drugs. Causality assessment showed most ADRs were probable (58.2%), with moderate severity being most frequent (58.2%). Symptomatically, cough, nervousness, palpitations, tachycardia, and tremors occurred commonly. The study highlights the importance of monitoring ADRs across demographics and clinical variables with statistical rigor using software

like SPSS for data analysis.The study involved 239 participants aged 1 to 104 years (mean 37.38±19.78), mostly males (54.8%) and primarily from the respiratory department (62.3%). Common diagnoses included asthma, pneumonia, COPD, tuberculosis, and pulmonary fibrosis. Most patients received four drugs, with Budesonide, Salbutamol, Amoxicillin, Azithromycin, and Prednisolone frequently prescribed. Adverse drug reactions (ADRs) occurred in 23% of participants. Significant associations were found between ADR occurrence and age, treatment department, and diagnosis, but not gender or number of drugs prescribed. Bronchodilators and antibiotics were the main drug classes linked to ADRs, mostly administered orally. Causality assessment classified most ADRs as probable, with moderate severity predominating. Common ADR symptoms included cough, nervousness, palpitations, tachycardia, and tremors. Data analysis used descriptive statistics and chi-square tests with SPSS, considering $p<0.05$ significant.

DISCUSSION

This pharmacovigilance study involving 239 participants aged 1 to 104 years provides important insights into drug safety within a tertiary care hospital. The participant demographics showed a majority of younger adults (20-39 years) and middle-aged individuals (40-59 years), with more males overall but females dominating the 20-39 age group. Most patients came from the respiratory department, reflecting pulmonary focus, with common diagnoses like asthma, pneumonia, COPD, and tuberculosis.

Polypharmacy was common, with four drugs typically prescribed, mainly inhaled corticosteroids (Budesonide) and bronchodilators (Salbutamol), alongside antibiotics such as Amoxicillin. Adverse drug reactions (ADRs) occurred in 23% of patients, highlighting ongoing risks even in controlled settings. Statistically, ADRs were significantly associated with patient age, treatment department, and diagnosis, but not with gender or the number of drugs prescribed, suggesting that drug type rather than count influenced ADR risk.

The majority of ADRs were deemed probable in causality and moderate in severity. Bronchodilators were most often implicated, consistent with their systemic side effects, followed by antibiotics and corticosteroids. Oral drug administration predominated among ADRs, with inhaled and intravenous routes less frequent but still notable.

Common ADR symptoms—cough, nervousness, palpitations, tachycardia, tremors—closely matched bronchodilator effects, while other symptoms like nausea and oral thrush reflected broader drug classes. The study emphasizes the need for vigilant monitoring, especially in older adults, and suggests that educational efforts to raise awareness of pulmonary medication ADRs could enhance patient safety. Furthermore, the unexpected lack of ADR association with polypharmacy calls for future research to better understand drug-related risk factors and improve prescribing practices in pulmonary care.

This observational study rigorously used descriptive statistics and chi-square tests via SPSS software for data analysis, underscoring the value of pharmacovigilance in tertiary care hospitals for detecting, understanding, and mitigating ADRs to improve clinical outcomes.

CONCLUSION

This pharmacovigilance study, conducted in a tertiary care teaching hospital, provides a comprehensive overview of adverse drug reactions (ADRs) in a diverse patient population, with a particular focus on those with pulmonary conditions. The findings underscore the significant prevalence of ADRs (23% of participants), emphasizing the ongoing need for robust drug safety surveillance.

The study confirms that age is a statistically significant factor in ADR occurrence, highlighting the increased vulnerability of older patients. While polypharmacy was common, with four or six drugs being frequently prescribed, its direct association with ADRs was not statistically significant in this cohort, suggesting that other factors, such as specific drug classes or individual patient characteristics, might play a more dominant role in predicting adverse events.

Bronchodilators, antibiotics, and corticosteroids were the most implicated drug classes, with oral administration being the most common route for ADR-causing drugs. The majority of these ADRs were classified as probable by the Naranjo scale and were predominantly of moderate severity, often presenting as symptoms like nervousness, palpitations, and tremors, commonly associated with bronchodilators, or gastrointestinal issues linked to antibiotics.

These results provide valuable insights for clinicians and policymakers. They advocate for heightened vigilance in prescribing and monitoring pulmonary medications, especially in older patients. Furthermore, the findings call for targeted educational interventions focusing on highrisk drug classes and their common ADRs. Ultimately, continuous pharmacovigilance efforts, informed by such real-world data, are essential to enhancing patient safety and optimizing therapeutic outcomes in pulmonary care.

LIMITATION

Being a single- center study, generalizability is limited. The observational design can identify associations but not causality, and underreporting may persist despite active surveillance. Lack of a control group and limited detail on some drug associations further constrain interpretability.

RECOMMENDATIONS

1. Enhanced monitoring of high-risk drugs (bronchodilators, antibiotics, corticosteroids) and patient subgroups (elderly, cardiac comorbidity) is essential.
2. Develop prescribing guidelines tailored to drug class risks and age-specific vulnerabilities.
3. Target education in the safe use of inhaled medications and recognition of ADR symptoms.

4. Cultivate a culture of prompt, comprehensive ADR reporting and analysis to inform practice and policy, addressing gaps in current pharmacovigilance systems.

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