

COMPREHENSIVE PHARMACOVIGILANCE STUDY IN PATIENTS WITH ASTHMA AT A TERTIARY CARE TEACHING HOSPITAL

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Abstract

Background: Asthma is a chronic inflammatory airway disorder requiring long-term pharmacotherapy, often involving multiple drug classes. This increases the risk of adverse drug reactions (ADRs), making pharmacovigilance essential for ensuring patient safety and optimizing therapeutic outcomes.

Objective: To evaluate the incidence, pattern, causality, and severity of ADRs associated with asthma therapy in a tertiary care teaching hospital.

Methods: A prospective observational study was conducted at Teerthanker Mahaveer tertiary care hospital in Moradabad, Uttar Pradesh, India, involving 238 patients diagnosed with asthma. Data on patient demographics, drug therapy, and ADRs were collected using the Pharmacovigilance Programme of India (PvPI) reporting format. ADRs were assessed for causality using Naranjo's scale, severity using the Hartwig scale, and preventability using the Schumock and Thornton criteria. Descriptive statistics were applied using MS Excel/SPSS. Ethical approval was obtained, and informed consent was secured from all participants.

Results: A total of 55 ADRs were reported, indicating a notable occurrence among the study population. The mean age of patients was 37.53 ± 1.27 years, with a male predominance (55%). ADRs were more common in younger age groups (≤ 30 years), accounting for approximately 58% of total reactions. Polypharmacy was associated with a higher ADR incidence (24.81%) compared to non-polypharmacy (20.95%). Most ADRs were classified as "probable" (58.18%) according to Naranjo's scale, followed by "possible" (29.09%). Severity assessment revealed that the majority were moderate (58.18%), while 32.72% were mild and 9.09% were severe. Bronchodilators were the most frequently implicated drug class (38.2%), followed by antibiotics (20%) and corticosteroids. Among individual drugs, salbutamol, amoxicillin, and prednisolone were commonly associated with ADRs.

Conclusion: ADRs are relatively common in asthma pharmacotherapy, particularly among patients receiving polypharmacy and bronchodilator-based regimens. Most reactions are moderate and probable, suggesting that they are predictable and potentially preventable. Strengthening pharmacovigilance systems, promoting rational drug use, and enhancing clinician awareness can significantly improve patient safety and therapeutic outcomes in asthma management.

Keywords: Asthma, Adverse Drug Reactions, Pharmacovigilance, Polypharmacy, Bronchodilators, Naranjo Scale.

1. INTRODUCTION

Asthma is a chronic inflammatory airway disease characterized by variable airflow limitation, bronchial hyperresponsiveness, and recurrent respiratory symptoms such as wheezing, dyspnea, chest tightness, and cough. It affects more than 230 million individuals worldwide and represents a substantial burden on healthcare systems due to its chronicity and episodic exacerbations.¹ The cornerstone of asthma management involves long-term pharmacotherapy aimed at achieving symptom control, preventing exacerbations, and maintaining optimal pulmonary function. Standard therapeutic regimens include short- and long-acting bronchodilators, inhaled and systemic

corticosteroids, leukotriene receptor antagonists, methylxanthines, and adjunctive agents depending on disease severity and comorbid conditions.²

While these pharmacological agents are effective in improving clinical outcomes, their long-term and often combined use increases the risk of adverse drug reactions (ADRs). ADRs are a significant cause of morbidity and healthcare utilization, accounting for approximately 6.5% of hospital admissions and affecting up to 14.7% of hospitalized patients.³ In asthma therapy, commonly reported ADRs include tachycardia, tremors, hypokalemia, adrenal suppression, osteoporosis, behavioral changes, and gastrointestinal disturbances, depending on the drug class involved.⁴ For instance, β_2 -agonists such as salbutamol are associated with a high incidence of adverse effects, with pooled estimates indicating that up to 34% of patients may experience some form of adverse event, most commonly palpitations and tachycardia.⁵ Similarly, long-acting bronchodilators have been linked with increased cardiovascular adverse events, particularly those leading to treatment discontinuation.⁶

The complexity of asthma pharmacotherapy is further compounded in tertiary care settings, where patients frequently present with severe disease, multiple comorbidities, and exposure to polypharmacy. Polypharmacy significantly increases the likelihood of drug–drug interactions, cumulative toxicity, and inappropriate prescribing, thereby elevating ADR risk.⁷ Additionally, factors such as age, gender, genetic predisposition, environmental exposures, and adherence variability contribute to inter-individual differences in ADR occurrence and severity.⁸ Pharmacogenomic studies have demonstrated that genetic polymorphisms can influence both drug efficacy and susceptibility to ADRs, highlighting the need for individualized therapy.⁹

Pharmacovigilance, defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, plays a critical role in ensuring drug safety.¹⁰ Effective pharmacovigilance systems facilitate early detection of ADRs, enable causality assessment, and support risk minimization strategies. Tools such as Naranjo’s causality scale and standardized severity assessment methods are widely used to evaluate ADRs in clinical practice.¹¹ Moreover, hospital-based pharmacovigilance programs have demonstrated their utility in identifying drug-related problems, reducing preventable harm, and improving therapeutic outcomes.¹²

Despite the recognized importance of pharmacovigilance, there remains a paucity of comprehensive, real-world data on ADR patterns in asthma therapy, particularly in tertiary care teaching hospitals in developing countries. Existing studies suggest that bronchodilators contribute significantly to ADR burden, accounting for nearly 18.5% of reported reactions in hospitalized patients.¹³ However, systematic evaluation of ADR incidence, causality, severity, and associated risk factors such as polypharmacy is still limited.

Therefore, the present study was undertaken to comprehensively evaluate the incidence, pattern, causality, and severity of ADRs associated with asthma therapy in a tertiary care teaching hospital. By identifying high-risk drug classes and patient-related factors, this study aims to strengthen pharmacovigilance practices and enhance the safety and effectiveness of asthma management.

2.2 Study Site

Teerthankar Mahaveer hospital and Research center, Moradabad Uttar Pradesh, India

2.4 Study Population

Patients diagnosed with asthma and receiving treatment

2.5 Inclusion Criteria

- Patients of all age groups
- Diagnosed cases of asthma
- Patients willing to provide informed consent

2.6 Exclusion Criteria

- Patients with incomplete data
- Patients with other severe comorbid respiratory conditions (e.g., COPD)

2.7 Data Collection

- Patient demographics
- Drug therapy details
- ADR occurrence and description
- Laboratory findings (if applicable)

2.8 Tools Used

- ADR Reporting Form (PvPI format)
- WHO-UMC causality assessment scale
- Hartwig severity assessment scale
- Schumock and Thornton preventability scale

2.9 Statistical Analysis

- Descriptive statistics (frequency, percentage)
- Data analyzed using MS Excel/SPSS

2.10 Ethical Considerations:

The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Prior approval was obtained from the Institutional Ethics Committee (TMU/IEC/2024-25/PG/144) and written informed consent was obtained from all participants before enrollment. Patient confidentiality was maintained throughout the study.

3. Results

Table1: Baseline Demographic and Clinical Characteristics of the Study Population (n = 238)

Variables	Value
Age (mean ± SD)	37.53±1.27
Age Group n (%)	
≤20	44 (18.5)
21-30	45 (18.9)
31-40	52 (21.8)
41-50	42 (17.6)
51-60	21 (8.8)
61-70	23 (9.7)
>70	11 (4.6)
Gender n (%)	
Male	131 (55)
Female	107 (45)
Weight(mean ± SD)	65.23±1.38
Department n (%)	
Respiratory	149 (62.5)
Gynaecology	13 (5.5)
Paediatrics	31 (13.0)
General Medicine	45 (18.9)

Table2: Age- and Gender-wise Distribution of Adverse Drug Reactions (ADRs) in Asthma Patients (n = 55)

AGE GROUP	MALE n(%)	FEMALE n(%)	TOTAL n(%)
≤20	9 (16.3)	7 (12.72)	16 (29.09)
21-30	4 (7.2)	12 (21.8)	16 (29.09)
31-40	3 (5.4)	1 (1.8)	4 (7.2)
41-50	3 (5.4)	3 (5.4)	6 (10.9)
51-60	3 (5.4)	2 (3.6)	5 (9.09)
61-70	4 (7.2)	2 (3.6)	6 (10.09)
>70	2 (3.6)	0 (0)	2 (3.6)
Total	28 (50.9)	27 (49.09)	55 (100)

Table3: Numbers of ADRs in patients receiving Poly-Pharmacy VS not receiving Poly-Pharmacy.

Therapy	Number of patients	Numbers of ADRs	%
Poly-pharmacy	133	33	24.81
Non Poly-Pharmacy	105	22	20.95

Table4: Naranjo's classification of ADRs

Assessment score	Number of ADRs	% of ADRs
POSSIBLE	16	29.09
PROBABLE	32	58.18
HIGH	5	9.09
DOUBTFUL	2	3.63

Total	55	100
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Table5: Severity Assessment of ADRs

Assessment	Number of ADRs	% of ADRs
MILD	18	32.72
MODERATE	32	58.18
SEVERE	5	9.09
Total	55	100

Table5: Distribution of Adverse Drug Reactions (ADRs) According to Drug Class in Asthma Therapy (n = 55)

Class of Drug	Number of ADRs	% of ADRs
BRONCHODILATORS	21	38.2
CORTICOSTEROIDS	7	12.7
SYSTEMIC CORTICOSTEROIDS	6	10.9
LEUKOTRINE MODIFIERS	4	7.3
ANTIBIOTICS	11	20.0
PHOSPHODIESTERASE 5 INHIBITORS	6	10.9
Total	55	100.0

Table5: Drug-wise Distribution of Adverse Drug Reactions (ADRs) in Asthma Patients (n = 55)

Drug	Number of ADRs	% of ADRs
SALBUTAMOL (I)	7	12.7
TERBUTALINE	2	3.6
SALMETERAL	2	3.6
FORMATERAL	2	3.6
IPRATROPIUM BR	4	7.3
THEOPHYLINE	4	7.3
BECLOMETHASONE	2	3.6
FLUTICASONE	2	3.6
BUDESONIDE	1	1.8
MOLTELUKAST	2	3.6
ZAFIRLUKAST	2	3.6
AMOXICILLIN	5	9.1
BUDESONIDE	2	3.6
PREDNISOLONE	5	9.1
METHYLPREDNISOLONE	1	1.8
CEPHALEXIN	3	5.5
AZITHROMYCIN	2	3.6
RIFAMPICIN	1	1.8
SIDENAFIL	3	5.5
TADALAFIL	3	5.5
Total	55	100.0

Statistically significance.

A statistically significant association was observed between age and ADR occurrence, with higher incidence in patients aged ≤ 30 years compared to older patients ($\chi^2 = 10.84$, $p = 0.001$; OR = 3.08, 95% CI: 1.67–5.68). However, no significant association was found between gender and ADR occurrence ($\chi^2 = 0.32$, $p = 0.57$). Similarly, although ADRs were more frequent in patients receiving polypharmacy, the difference was not statistically significant ($\chi^2 = 0.52$, $p = 0.47$).

4. Discussion

The present prospective observational study provides a comprehensive evaluation of adverse drug reactions (ADRs) associated with asthma pharmacotherapy in a tertiary care teaching hospital. The overall incidence of ADRs (55 events

among 238 patients) highlights that ADRs remain a clinically relevant concern in asthma management, particularly in settings characterized by complex therapeutic regimens and polypharmacy.

The demographic profile of the study population revealed a mean age of 37.53 ± 1.27 years with a slight male predominance (55%). Interestingly, a higher proportion of ADRs was observed in younger age groups (≤ 30 years), accounting for nearly 58% of total ADRs. This finding contrasts with several studies that report increased ADR susceptibility in elderly populations due to altered pharmacokinetics and pharmacodynamics. However, in the present study, increased ADR reporting in younger individuals may be attributed to higher healthcare-seeking behavior, better symptom recognition, or greater exposure to bronchodilator therapy during acute exacerbations.

Polypharmacy emerged as an important determinant of ADR occurrence, with a higher incidence observed in patients receiving multiple drugs (24.81%) compared to those on fewer medications (20.95%). This aligns with established evidence that polypharmacy increases the risk of drug–drug interactions, cumulative toxicity, and prescribing errors. In asthma management, the concurrent use of bronchodilators, corticosteroids, antibiotics, and adjunctive therapies is common, particularly in moderate-to-severe cases, thereby increasing ADR susceptibility.

Causality assessment using Naranjo's scale indicated that the majority of ADRs were classified as "probable" (58.18%), followed by "possible" (29.09%), suggesting a strong temporal association between drug exposure and adverse events. Only a small proportion of ADRs were categorized as "definite" or "doubtful," which reflects the inherent challenges in establishing definitive causality in real-world clinical settings where rechallenge is often not feasible due to ethical concerns.

Severity assessment demonstrated that most ADRs were moderate in nature (58.18%), with fewer mild (32.72%) and severe (9.09%) reactions. The predominance of moderate ADRs suggests that while most reactions required therapeutic intervention or dose modification, they were not life-threatening. However, the presence of severe ADRs underscores the need for vigilant monitoring, especially in high-risk populations.

Drug class-wise analysis revealed that bronchodilators were the most frequently implicated agents (38.2%), followed by antibiotics (20%) and corticosteroids. Among bronchodilators, agents such as salbutamol and ipratropium bromide accounted for a significant proportion of ADRs. These findings are consistent with the pharmacological profile of β_2 -agonists and anticholinergics, which are known to cause cardiovascular and neurological adverse effects such as tachycardia, tremors, and palpitations. Antibiotic-associated ADRs may reflect their frequent use in managing respiratory infections or exacerbations, although their use in asthma should ideally be limited to confirmed bacterial infections. Corticosteroids, both inhaled and systemic, were also associated with ADRs, albeit at a lower frequency. Their adverse effects, including metabolic disturbances and immunosuppression, are well documented, particularly with long-term use. Leukotriene modifiers contributed to a smaller proportion of ADRs, indicating a relatively favorable safety profile.

5. Conclusion

The present study demonstrates that adverse drug reactions (ADRs) are a significant and clinically relevant concern in the pharmacological management of asthma in a tertiary care teaching hospital. With an overall occurrence of 55 ADRs among 238 patients, the findings indicate that ADRs are relatively common, particularly among younger patients and those receiving polypharmacy. Bronchodilators emerged as the most frequently implicated drug class, followed by antibiotics and corticosteroids, highlighting the need for cautious and rational use of these agents. The higher incidence of ADRs in patients on polypharmacy further reinforces the role of drug–drug interactions and cumulative drug exposure as key contributing factors. Causality assessment revealed that the majority of ADRs were "probable," while severity evaluation showed that most reactions were moderate in nature, requiring clinical attention but rarely leading to life-threatening outcomes. These findings emphasize that many ADRs associated with asthma therapy are predictable and potentially preventable. Strengthening pharmacovigilance practices through systematic monitoring, early detection, and appropriate intervention can significantly reduce ADR burden. Additionally, promoting rational prescribing, minimizing unnecessary polypharmacy, and increasing awareness among healthcare professionals and patients are essential strategies to enhance medication safety.

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