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Study On Drug Utilization Patterns And Adverse Drug Reactions (Adrs) Severity Associated With Antiasthmatic Therapy

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ABSTRACT

Background

Asthma is a chronic airway disorder causing recurrent wheezing, breathlessness, chest tightness, and cough, often requiring long-term pharmacotherapy. Antiasthmatic agents such as bronchodilators, corticosteroids, leukotriene receptor antagonists, and biologics are prescribed alone or in combination based on disease severity. While rational prescribing ensures better control, inappropriate patterns may lead to poor outcomes and higher healthcare burden.

Despite their effectiveness, antiasthmatic drugs can cause adverse drug reactions (ADRs) ranging from mild effects like tremors and oral thrush to severe complications including cardiovascular events and corticosteroid toxicity. Monitoring ADRs and their severity is vital for patient safety and adherence.

Drug utilization studies, when combined with pharmacovigilance provide insights into prescription trends, rationality, and ADR severity, thereby supporting safer therapeutic decisions. The present study evaluates prescribing patterns of antiasthmatic agents and assesses the severity of associated ADRs to promote rational drug use and improved patient care.

Aim

To evaluate the prescribing patterns of antiasthmatic agents and assess the severity of adverse drug reactions (ADRs) associated with their use.

Objectives

1. To evaluate the prescribing patterns of antiasthmatic agents in asthma management.

2. To assess and categorize the severity of adverse drug reactions (ADRs) associated with antiasthmatic therapy.

Material and Methods

150 patients were enrolled for evaluating adverse effects with antiasthmatic drugs. All patients were followed up by medical history, history of drugs, and any severity of ADR. The study was assessing the distribution, prescribing pattern the management of ADRs. Also, the study determined the severity of ADRs with antiasthmatic agents in pulmonary medicine departments in tertiary care teaching hospitals.

Results and observations

In 150 patients (mean age 47.6 years), β2-agonists were most prescribed (44.6%), followed by methylxanthines (20.6%), corticosteroids (18%), and anticholinergics (9.3%).

ADRs were most frequent with β2-agonists, including tremors (27.2%), sleepiness (36.3%), and headache (36.3%). Corticosteroids caused mouth ulcers (14.2%), epigastric pain, vomiting, and acne (21.4% each). Anticholinergics produced dry mouth (25%) and constipation (75%), while methylxanthines were associated with insomnia (33.3%), headache

(66.6%), and nausea (22.2%).

Conclusion

The study highlights that β2-agonists were the most frequently prescribed antiasthmatic agents and also accounted for the majority of adverse drug reactions, followed by methylxanthines, corticosteroids, and anticholinergics. While most ADRs were mild to moderate in nature, their occurrence emphasizes the need for careful monitoring and rational prescribing. Regular assessment of prescription patterns and ADR severity can improve patient safety, optimize therapeutic outcomes, and promote rational use of antiasthmatic drugs in clinical practice.

Keywords: *Antiasthmatic drugs, Prescription pattern, Adverse Drug Reactions, Severity*

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1. INTRODUCTION

Asthma is a chronic inflammatory disorder of the airways characterized by recurrent episodes of wheezing, breathlessness, chest tightness, and coughing, which significantly impairs quality of life and increases healthcare burden worldwide. According to the Global Initiative for Asthma (GINA) 2024 report, approximately 300 million individuals are affected globally, with a rising prevalence in developing countries due to urbanization and environmental changes[1]. In India, asthma affects an estimated 2–3% of the population, contributing substantially to morbidity and economic burden[2].

The management of asthma involves long-term pharmacotherapy with antiasthmatic agents such as inhaled β2-agonists, corticosteroids, methylxanthines, leukotriene receptor antagonists, and newer biologics[3]. These drugs are used either alone or in combination depending on disease severity and patient response. Rational prescribing of antiasthmatic therapy plays a crucial role in disease control, whereas irrational use may result in suboptimal outcomes, polypharmacy, unnecessary costs, and increased risk of adverse events[4].

Adverse drug reactions (ADRs) are an important concern in asthma management. Though antiasthmatic drugs are effective in symptom relief and disease control, they are associated with adverse effects ranging from mild symptoms like tremors, headache, and dry mouth to more severe complications such as systemic corticosteroid toxicity and cardiovascular effects[5]. Monitoring ADRs is essential for ensuring patient safety, improving adherence, and achieving therapeutic success.

Drug utilization studies (DUS) combined with pharmacovigilance approaches are valuable tools to assess prescribing trends, rationality of therapy, and drug safety in real-world clinical practice[6]. Such studies not only identify inappropriate prescribing but also provide insights into the frequency and severity of ADRs, thereby guiding safer therapeutic strategies[7]. In this context, the present study was undertaken to evaluate the prescribing patterns of antiasthmatic agents and to assess the severity of ADRs among patients attending the Pulmonary Medicine Department of a tertiary care teaching hospital. This work aims to provide evidence for rational drug use and improved patient safety in asthma management

2. MATERIALS AND METHODS

Study Site
The study was conducted in Medicine and Pulmonary Medicine OPD in J K and tertiary care Hospitals, Bhopal.

Study Design
Prospective observational study conducted in OPD patients (150) with bronchial asthma. Data were collected through patient follow up, including medical history, drug history and details of ADR. The study was assessing the distribution, prescribing pattern the management of ADRs. Institutional Ethics Committee approval was taken. Written informed consent in the local vernacular language was obtained from every patient at the time of enrolment.

Study Population
Data collected from 150 OPD persons who have suffering from bronchial asthma and taking antiasthmatic drugs. All bronchial asthma patients who had been taking antiasthmatic medications for at least one month were included in the study. Patients with other comorbidities such as hypertension, diabetes mellitus, arthritis, respiratory infections (including COPD, bronchitis, and other lung diseases), immunocompromised states, and pregnancy were excluded from the study.

Study Procedure

Patients diagnosed with bronchial asthma attending the Pulmonary Medicine Department were enrolled in the study. Each patient was followed up weekly for a period of three months. Demographic details, medication history, and relevant laboratory investigations were recorded.

Prescriptions of the enrolled patients were collected and analyzed to study the prescribing patterns of antiasthmatic drugs. Data collected included the name of the drug or drug combination, dosage form, daily dosage, frequency of administration, whether prescribed by generic or brand name, and co-prescribed medications.

All patients were monitored for the occurrence of adverse drug reactions (ADRs). Information regarding ADRs was obtained through patient interviews, clinical examination, and medical records. ADRs were documented in terms of type, onset, and distribution, and their severity was assessed using standard pharmacovigilance criteria. The management of ADRs and the extent of recovery were also recorded during follow-up.

Thus, the study evaluated prescription trends of antiasthmatic therapy, identified the severity of associated ADRs, and assessed patient recovery following appropriate management.

3. RESULTS AND OBSERVATIONS

Prospective evaluation of prescriptions of 150 patients on antiasthmatic drugs, attending the OPD in department of Pulmonary Medicine in J. K. Hospital has done.

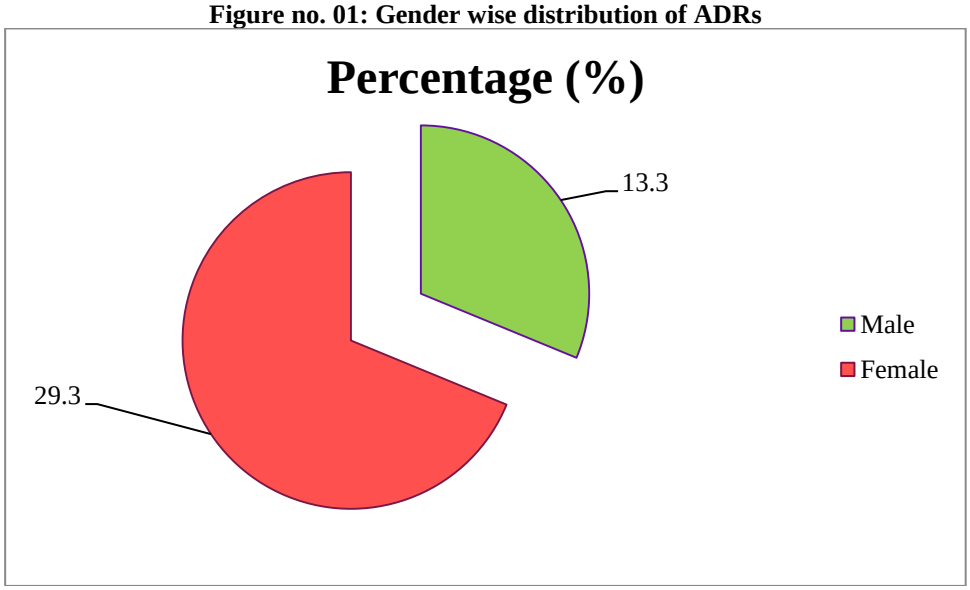
Gender Distribution of ADR Cases:

Table no.01: Gender wise distribution of ADRs

Gender	Number of Patients	Percentage (%)
Male	**20(out of 150)**	**13.3**
Female	**44(out of 150)**	**29.3**
Total	**64**	**42.6**

This table no.1 shows the gender-wise distribution of adverse drug reaction (ADR) cases among patients receiving antiasthmatic therapy. Out of the total 150 patients observed, 64 experienced ADRs, accounting for 42.6% of the study population. Among them, females reported a higher proportion of ADRs (29.3%) compared to males (13.3%).

Figure no. 01: Gender wise distribution of ADRs



As shown in this graph, females (29.3%) experienced a higher incidence of adverse drug reactions (ADRs) than males (13.3%), indicating greater susceptibility among women to ADRs from antiasthmatic therapy.

Severity of ADRs by Gender:

Table no.02: Severity of ADRs by Gender

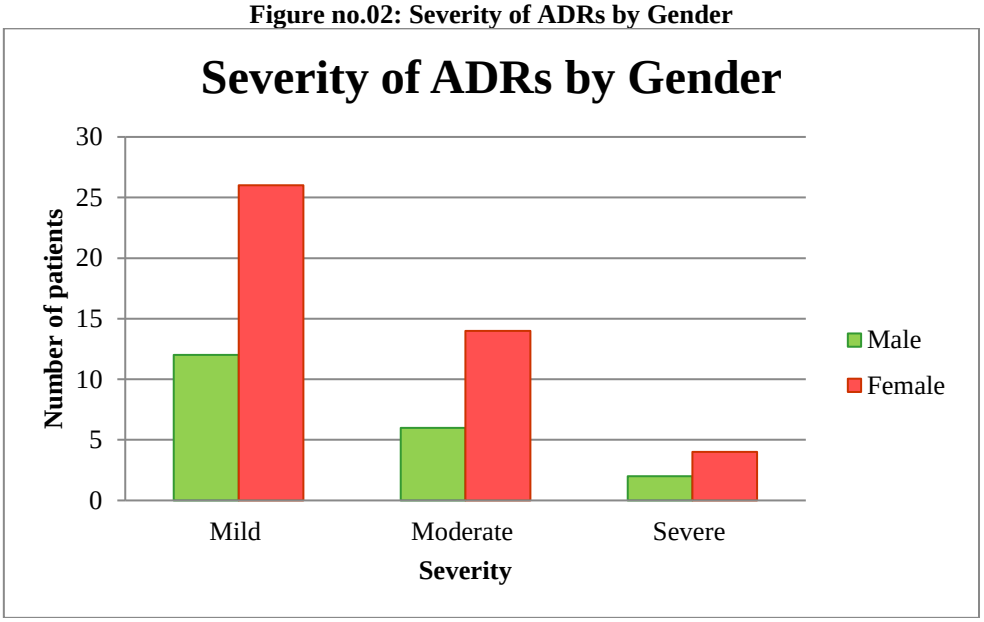
Gender	Mild ADRs (n=number)	Moderate ADRs (n=number)	Severe ADRs (n=number)	Total cases (%)
Male	12	6	2	20(13.3%)
Female	26	14	4	44(29.3%)
Total	38	20	6	64(42.6%)

As per the Table no. 02, the gender-wise distribution of adverse drug reactions (ADRs) according to their severity among patients receiving antiasthmatic therapy. Out of the total 64 ADR cases observed, the majority were mild in nature (38 cases, 59.3%), followed by moderate (20 cases, 31.2%) and severe reactions (6 cases, 9.3%). This indicates that most ADRs were not life-threatening and could be managed symptomatically, whereas severe cases were relatively uncommon.

When stratified by gender, females reported a higher number of ADRs (44 cases, 29.3% of the study population) compared to males (20 cases, 13.3%). Among males, mild ADRs accounted for 12 cases, with fewer moderate (6) and severe (2) events. In contrast, females experienced a greater proportion of ADRs across all categories, with 26 mild, 14 moderate, and 4 severe cases. This suggests that female patients were more frequently affected and also experienced a broader spectrum of ADR severity compared to males.

Severity of ADRs by Gender:

Figure no.02: Severity of ADRs by Gender



The bar graph illustrates the severity of adverse drug reactions (ADRs) caused by antiasthmatic drugs in relation to gender, categorized into mild, moderate, and severe cases. It is evident that females experienced a higher number of ADRs across all severity levels compared to males. In the mild category, which is the most common, around 27 females were affected as compared to about 15 males, indicating a clear predominance among female patients. For moderate ADRs, the gender gap persists, with approximately 15 females experiencing reactions versus around 8 males. Severe ADRs, although least reported, were also slightly more frequent in females (about 4 cases) than in males (around 2 cases). Overall, the graph highlights that antiasthmatic drug therapy is associated with a greater burden of ADRs in females, not only in terms of total cases but also across every severity category, suggesting possible gender-based differences in susceptibility or reporting of adverse effects to antiasthmatic medications.

Causality Analysis of Reported Adverse Drug Reactions (Naranjo Scale)

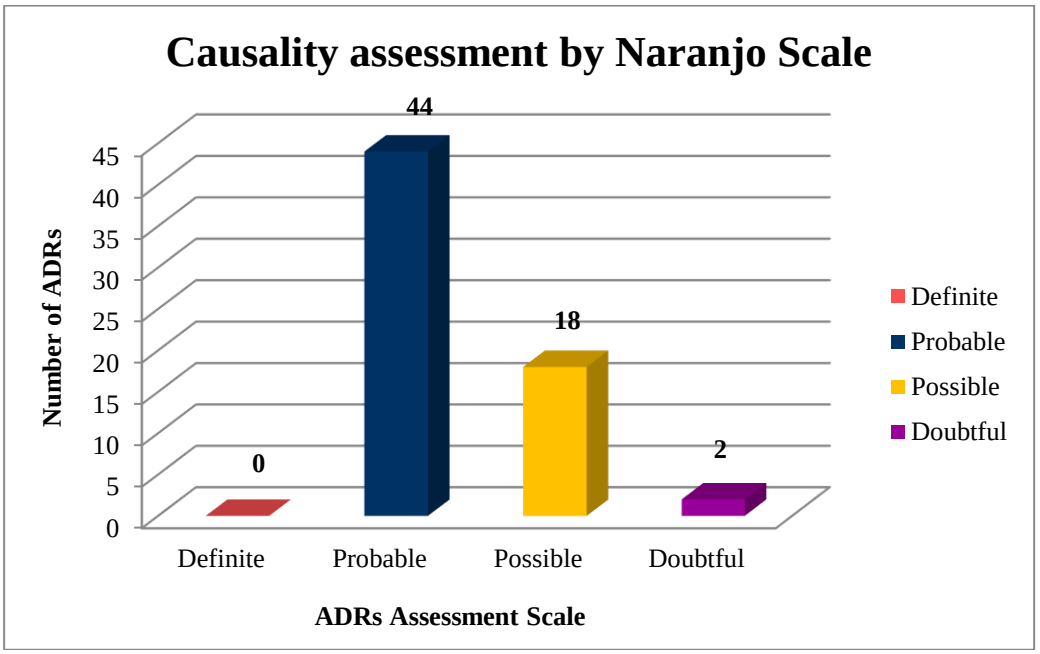


Figure no.03 : Causality Analysis of Reported Adverse Drug Reactions (Naranjo Scale)

The above graph presents the distribution of adverse drug reactions (ADRs) associated with anti-asthmatic drugs based on the Naranjo causality assessment scale.

Out of the total ADRs reported, the majority **44 cases(68.8%)** were classified as **"Probable",** indicating a strong likelihood that the anti-asthmatic drug caused the reaction. **18 cases(28.1%)** were assessed as **"Possible",** suggesting a moderate connection between the drug and the ADRs, where other factors could also be involved. Only **2 cases(3.1%)** were categorized as **"Doubtful",** meaning a weak or unclear association. Notably, there were **no ADRs** assessed as **"Definite",** implying no reactions had conclusive evidence directly linking them to the medication.

Table no.03 Recovery Outcome Report of ADR Cases (n = 64)

Outcome	Number of Cases	Percentage (%)
Recovered	46	71.9
Recovering	14	21.9
Not recovering	4	6.2
Fatal	0	0

The recovery outcome report of 64 adverse drug reaction (ADR) cases associated with antiasthmatic drugs demonstrates that the majority of patients experienced favorable outcomes. Out of the total cases, 46 patients (71.9%) recovered completely, indicating that most ADRs were manageable and resolved after appropriate intervention or withdrawal of the suspected drug. Additionally, 14 cases (21.9%) were in the process of recovery, suggesting partial improvement at the time of assessment. However, a smaller proportion, 4 patients (6.2%), did not show recovery, highlighting the persistence of adverse effects in some individuals. Importantly, no fatal outcomes (0%) were reported, signifying that none of the ADRs led to mortality. Overall, these findings indicate that while ADRs with antiasthmatic drugs are relatively common, the majority are non-fatal and show a high tendency toward recovery with proper management.

Figure no.04 Recovery Outcome Report of ADR Cases (n = 64)

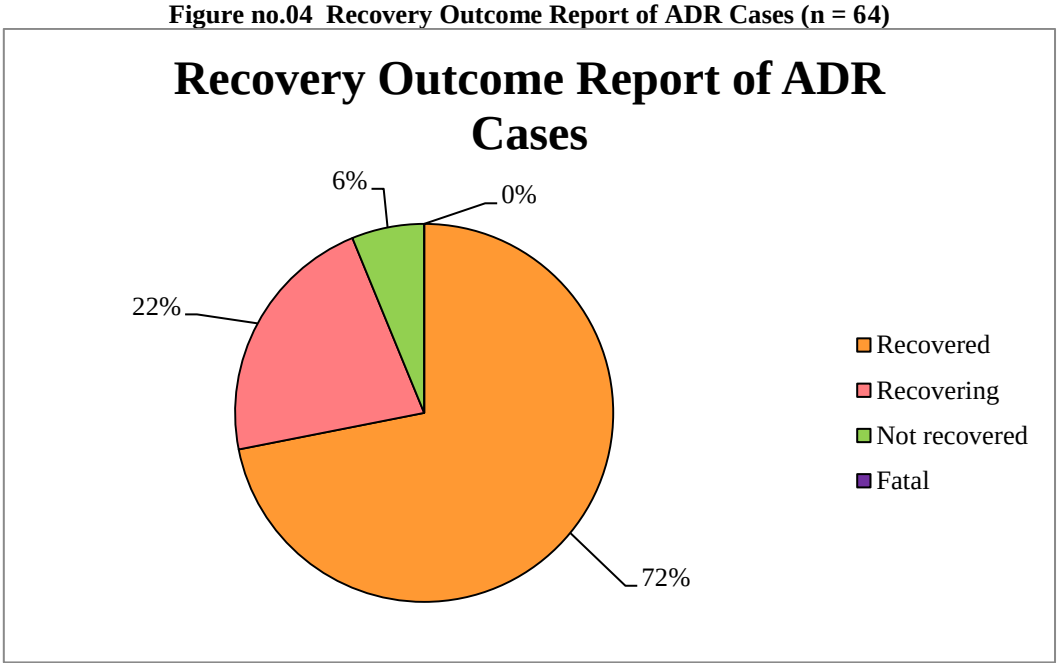
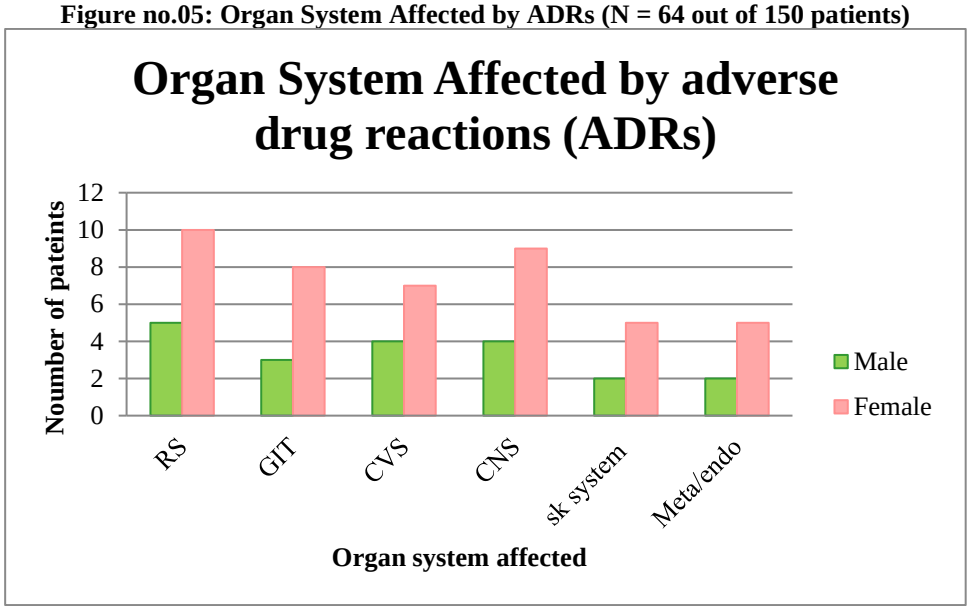


Table no.04: Organ System Affected by ADRs (N = 64 out of 150 patients)

Organ System Affected	Common ADRs Observed	Drugs Involved	Male (n=20)	Female (n=44)	Total (n=64, 42.6%)
Respiratory system	Cough, throat irritation, paradoxical bronchospasm	β2-agonists, inhaled corticosteroids	5	10	15
Gastrointestinal system	Nausea, vomiting, dyspepsia	Leukotriene antagonists, corticosteroids	3	8	11
Cardiovascular system	Palpitations, tachycardia, hypertension	β2-agonists, systemic corticosteroids	4	7	11
Central nervous system (CNS)	Headache, dizziness, tremors, insomnia	β2-agonists, leukotriene antagonists	4	9	13
Musculoskeletal system	Myopathy, osteoporosis, muscle cramps Myopathy, osteoporosis, muscle cramps	Corticosteroids, β2-agonists (high dose)	2	5	7
Metabolic/Endocrine	Hyperglycemia, weight gain, menstrual irregularities	Corticosteroids	2	5	7

As shown in table no. 04,among the 150 patients receiving antiasthmatic drugs such as β2-agonists, corticosteroids, and leukotriene antagonists, a total of 64 patients (42.6%) developed adverse drug reactions (ADRs). Out of these, males accounted for 20 cases, whereas females accounted for 44 cases, indicating a higher susceptibility among female patients. The most commonly affected organ systems were the respiratory system (23.4%), presenting mainly as cough, throat irritation, or paradoxical bronchospasm, and the central nervous system (20.3%), with symptoms such as headache, tremors, dizziness, and insomnia. Cardiovascular manifestations (17.2%), including palpitations and tachycardia, were also notable, particularly among those receiving β2-agonists and systemic corticosteroids. Gastrointestinal ADRs (17.2%) like nausea and dyspepsia were primarily linked to leukotriene antagonists and steroids. Musculoskeletal complications (10.9%), such as myopathy and osteoporosis, and metabolic/endocrine effects (10.9%), including hyperglycemia and weight gain, were mainly attributed to prolonged corticosteroid use. Overall, the analysis demonstrates that females experienced a higher frequency of ADRs across nearly all organ systems, highlighting possible gender differences in drug metabolism and response to antiasthmatic medications.

Figure no.05: Organ System Affected by ADRs (N = 64 out of 150 patients)



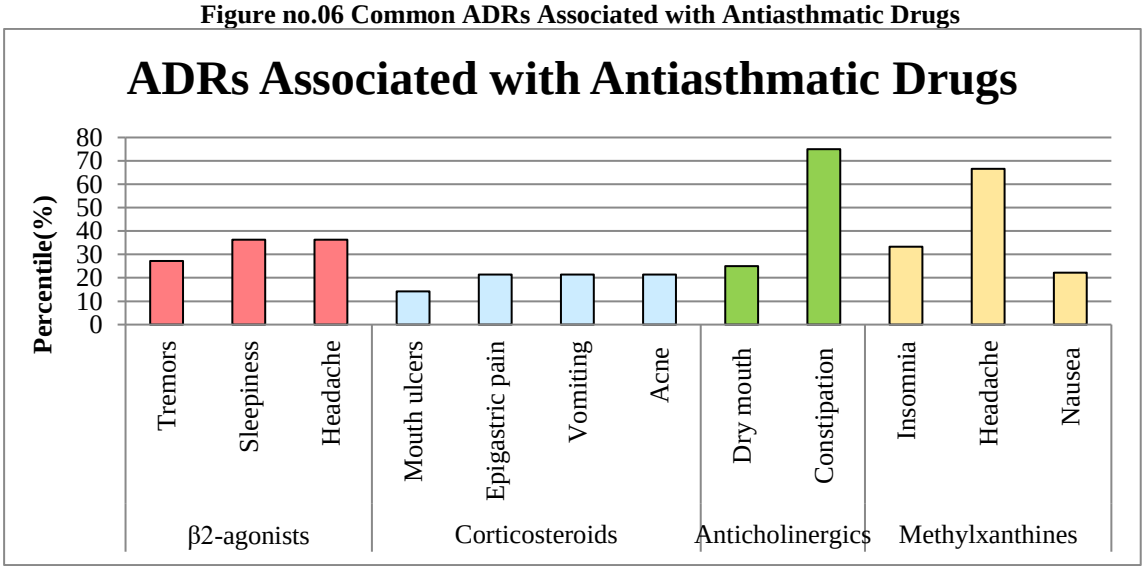
The graph presents the distribution of adverse drug reactions (ADRs) caused by antiasthmatic drugs across different organ systems in 64 patients out of 150, with a gender-wise comparison. It clearly shows that females experienced a higher number of ADRs across all organ systems compared to males. The respiratory system (RS) and central nervous system (CNS) were the most commonly affected, followed by the gastrointestinal (GIT) and cardiovascular (CVS) systems. Musculoskeletal and metabolic/endocrine (sk system and Meta/endo) effects were less frequent but still more pronounced in females. Overall, the data highlights a greater susceptibility among females to ADRs across multiple organ systems.

Table no.05 Common ADRs Associated with Antiasthmatic Drugs

Drug Class	Reported ADRs	Percentage (%)
β2-agonists	Tremors	27.2
	Sleepiness	36.3
	Headache	36.3
Corticosteroids	Mouth ulcers	14.2
	Epigastric pain	21.4
	Vomiting	21.4
	Acne	21.4
Anticholinergics	Dry mouth	25.0
	Constipation	75.0
Methylxanthines	Insomnia	33.3
	Headache	66.6
	Nausea	22.2

According to above mention table , The analysis of Common ADRs associated with antiasthmatic drugs showed that β2-agonists most commonly caused tremors (27.2%), sleepiness (36.3%), and headache (36.3%). Corticosteroids were linked to mouth ulcers (14.2%), epigastric pain, vomiting, and acne (21.4% each). Anticholinergics primarily produced dry mouth (25%) and constipation (75%), while methylxanthines were associated with insomnia (33.3%), headache (66.6%), and nausea (22.2%).

Figure no.06 Common ADRs Associated with Antiasthmatic Drugs



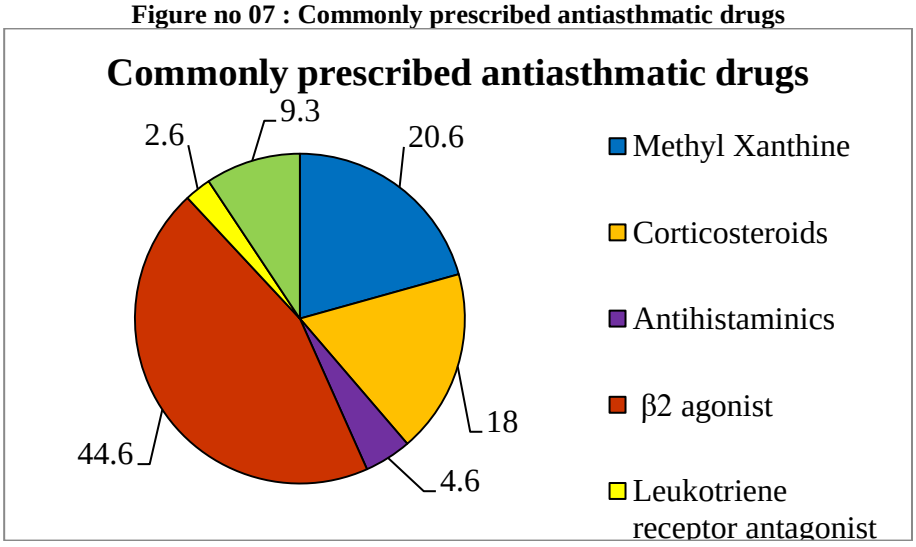
According to above mentioned figure, ADRs associated with antiasthmatic drugs across different classes. Among β2-agonists, sleepiness and headache (36.3% each) were most frequent, followed by tremors (27.2%). Corticosteroids commonly caused epigastric pain, vomiting, and acne (21.4% each), with mouth ulcers at 14.2%. Anticholinergics showed a marked predominance of constipation (75%) compared to dry mouth (25%). For methylxanthines, headache (66.6%) was the leading ADR, followed by insomnia (33.3%) and nausea (22.2%).

Table no 06 : Commonly prescribed antiasthmatic drugs

Antiasthmatic Drug Class	Number of prescriptions(150)	Percentage(%)
Methyl Xanthine	31	20.6
Corticosteroids	27	18
Antihistaminics	07	4.6
*β*2 agonist	67	44.6
Leukotriene receptor antagonist	04	2.6
Anticholinergics	14	9.3

The table presents the distribution of commonly prescribed antiasthmatic drugs among 150 prescriptions. Among the different drug classes, β2 agonists were the most frequently prescribed, accounting for 67 prescriptions (44.6%), followed by Methylxanthines with 31 prescriptions (20.6%) and Corticosteroids with 27 prescriptions (18%). Anticholinergics were used in 14 cases (9.3%), while Antihistaminics and Leukotriene receptor antagonists were less commonly prescribed, with 7 prescriptions (4.6%) and 4 prescriptions (2.6%) respectively. This indicates that β2 agonists form the mainstay of asthma management, while other classes are used as adjuncts depending on patient needs and therapeutic goals.

Figure no 07 : Commonly prescribed antiasthmatic drugs



According to pie diagram (figure no.04) the percentage distribution of commonly prescribed antiasthmatic drugs among 150 prescriptions. It shows that β2 agonists dominate the prescriptions with 44.6%, followed by methyl xanthines (20.6%) and corticosteroids (18%), indicating their significant role in asthma management. In contrast, anticholinergics (9.3%), antihistaminics (4.6%), and Leukotriene receptor antagonists (2.6%) were prescribed less frequently, highlighting their comparatively limited but supportive use in treatment.

Drug Utilization Pattern of Antiasthmatic Drugs (n=150)

1. Most Utilized Drug Class

β2 agonists were the most utilized, prescribed in 44.6% of cases (67/150).

This shows they are the mainstay therapy in asthma management, aligning with standard guidelines.

2. Moderately Utilized Drug Classes

Methyl Xanthines (20.6%) and Corticosteroids (18%) were prescribed frequently, reflecting their use as add-on or controller therapy.

Corticosteroids indicate a rational approach in preventing inflammation and reducing exacerbations.

3. Least Utilized Drug Classes

Anticholinergics (9.3%), Antihistaminics (4.6%), and Leukotriene receptor antagonists (2.6%) were used sparingly, suggesting their role is limited to specific indications or patient subsets.

4. Overall Utilization Trend

Reliever drugs (β2 agonists) dominate prescriptions, showing higher reliance on immediate symptom control.

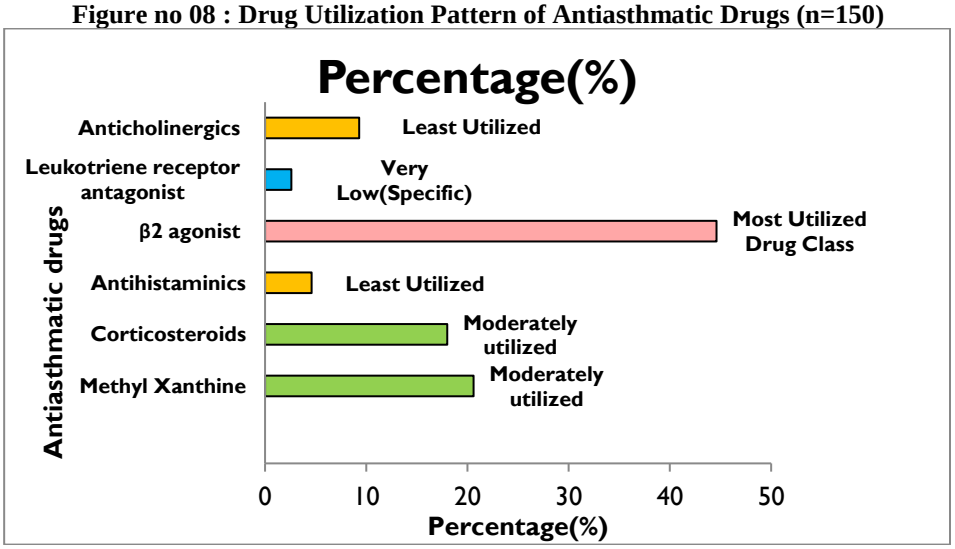
Controller drugs (corticosteroids, leukotriene antagonists) are less prescribed, which may indicate either milder asthma in the study population or a tendency toward symptomatic management rather than long-term prevention.

Table no.07: Drug Utilization Pattern Analysis

Drug Class	Number of Prescriptions	Utilization Category	Clinical Significance
β2 agonist	67	High utilization	First line reliever therapy
Methyl Xanthine	31	Moderate utilization	Add on therapy ,bronchodilation
Corticosteroids	27	Moderate utilization	Controller therapy (anti-inflammatory)
Anticholinergics	14	Low utilization	Used in acute severe cases/COPD overlap
Antihistaminics	7	Low utilization	Limited role in asthma control
Leukotriene receptor antagonist	4	Very Low Utilization |	Specific cases, pediatric use

The prescribing pattern indicates a largely rational approach, with β2-agonists being the primary choice for immediate symptom relief, while methylxanthines and corticosteroids are employed for supportive and preventive management. The relatively lower prescription rates of leukotriene receptor antagonists, antihistaminics, and anticholinergics highlight their more specialized yet important roles in therapy. Notably, the comparatively reduced use of corticosteroids (18%) may suggest possible underutilization of preventive treatment, which deserves consideration in clinical practice to achieve sustained asthma control.

Figure no 08 : Drug Utilization Pattern of Antiasthmatic Drugs (n=150)



4. DISCUSSION

In this prospective study of 150 patients attending the outpatient department in the Pulmonary Medicine Department at J.K. Hospital, 42.6% (n = 64) experienced adverse drug reactions (ADRs) from antiasthmatic therapy. Females showed notably higher rates (29.3%) than males (13.3%), consistent with broader literature showing women have greater susceptibility to ADRs.

Study conducted by Paneerselvam K (2023) in tertiary care centre hospital Tamilnadu ,58.05% of the study population were males and 41.95% were females; however, these results do not align with the findings of the present study[8].

The present study's findings are consistent with the observations of Fuseini H et al. (2017), who reported a higher prevalence of asthma among adult female patients[9].

Similarly, population pharmacokinetic data underline that sex differences can predict ADRs specifically in women[10]. According to the severity analysis by Jamali AN et al. (2010)[11], the majority of ADRs were mild (86.7%), with 13.3% classified as moderate, and no cases reported as severe. In contrast, our present study revealed that most ADRs were mild (59.3%), followed by moderate (31.2%), and a smaller proportion were severe (9.3%). When compared with the findings of Jamali AN et al. (2010), the results were generally consistent for mild to moderate ADRs; however, a significant difference was observed regarding the occurrence of severe reactions, which were reported only in the current study Causality assessment by the Naranjo Scale classified 68.8% of ADRs as "Probable," 28.1% as "Possible," and 3.1% as "Doubtful," with no "Definite" cases. This distribution suggests that while many ADRs are strongly linked to antiasthmatic agents, definitive causation (where re-challenge or other strict criteria are met) remains elusive. Prior studies employing similar causality tools also find a majority of ADRs fall into "Probable" or "Possible" categories[12].

Outcomes were broadly favorable: 71.9% of patients fully recovered, 21.9% were recovering at time of observation, while 6.2% did not recover. No fatalities occurred. The high recovery rate indicates that although ADRs are common, most are manageable with appropriate intervention or drug cessation.

Organ system involvement showed respiratory system ADRs (23.4%) and central nervous system (20.3%) to be the most frequently involved, followed by gastrointestinal, cardiovascular, musculoskeletal, and metabolic/endocrine systems. These results are consistent with the established side-effect patterns of antiasthmatic drugs. β_2-agonists are frequently associated with tremors, palpitations, sleepiness, and respiratory irritation. Corticosteroids often lead to acne, vomiting or epigastric discomfort, mouth ulcers, as well as musculoskeletal and endocrine disturbances. Anticholinergics are typically linked to dry mouth and constipation, while methylxanthines are more commonly related to insomnia, headache, and other mild gastrointestinal or CNS effects[13].

A key observation in your drug utilization pattern shows that β_2-agonists were most prescribed (44.6%), followed by methylxanthines (20.6%) and corticosteroids (18%). Anticholinergics, antihistamines, and leukotriene receptor antagonists were less frequently used.

Salbutamol with ipratropium bromide was the most frequently prescribed inhaled bronchodilator (87%), followed by formoterol with budesonide (26%). This pattern was consistent with findings of present study, where salbutamol was also reported as the most commonly prescribed agent[14].

Another study of asthmatic prescriptions in a tertiary care centre found β2-agonists and corticosteroids were the most common combination drugs, followed by methylxanthines[15].

This difference might reflect local practices, perceived severity of asthma, patients' access to controller medications, or clinician preference. The lower utilization of corticosteroids (18%) in your cohort suggests possible underuse of preventive therapy, which is a concern given current asthma management guidelines (e.g., GINA) that emphasize early and sustained anti-inflammatory treatment to reduce exacerbations and improve long-term control. Under-utilization may contribute to higher symptom burden, increased frequency of ADRs (from over-use of reliever agents), and poorer quality of life.

5. LIMITATIONS

Include the observational nature of the study, potential under-reporting of mild ADRs, and lack of long-term follow-up. Also, exact doses, duration of therapy, and adherence levels were not deeply explored, which could influence ADR incidence.

6. CONCLUSION

In conclusion, this study highlights a fairly high incidence of ADRs among antiasthmatic drug users, particularly among females. The drug utilization pattern shows dominance of β_2-agonists for symptom relief, but relatively lower use of corticosteroids for prevention. This suggests an opportunity to align local prescription practices more closely with guideline recommendations, ensuring greater emphasis on preventive/ controller therapy to reduce ADRs and improve asthma outcomes.

CONFLICT OF INTEREST – NIL

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